Medoc
advanced medical systems

Q Sense

Small Fiber Test

Technical Reference Manual

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This device complies with 93/42/EEC MDD

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1 Safety Guidelines and Regulations

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. The manual and software are available in English.

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

1.3 Target Population and Contraindications

The Q-Sense can be used on both healthy subjects and patients suffering from wide range of neuropathic, CNS and pain conditions. Minimum age reported in the literature is 6.

The only known contraindication is related to the skin on which the thermode is applied – it must be used in contact with intact skin only. The thermode also intended to be applied on the skin only, not on the eyes and the mouth.

1.4 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 Q-SENSE system complies with safety requirements for medical electrical systems (based on the IEC 60601-1 standard).
- The Q-SENSE system complies with electromagnetic emission levels (based on table 201 in the IEC 60601-1-2 standard).
- The Q-SENSE 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 recommended to keep a distance of 3 meters between portable and mobile RF communications equipment and the Q-SENSE (based on table 206 in the IEC 60601-1-2 standard).

1.5 Safety Requirements

The Q-SENSE 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 Q-SENSE system. Connecting or replacing external Q-SENSE accessories is allowed.

No modification of this equipment is allowed.

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

Keep all liquids away from the Q-SENSE system.
Unplug the Q-SENSE system if it is not to be used for a long period of time.
Do not block airflow anywhere around the Q-SENSE system.

1.5.1 Warnings

- Only personnel properly trained to operate the Q-SENSE system should use this system.
- Do not turn on system power until all cables have been properly connected and verified.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth
- Do not use any power supply which not supplied by Medoc (Medoc's power supply Cat.# DT 00017).
- Do not use any electrode paste, gel, or other materials on the contact point between the Thermode plate and the skin of the tested subject.
- To reduce the risk of injury, place the Thermode on the subject only before starting the test and while the test screen is visible. After the test is complete, remove the Thermode from the subject's skin while the test screen is still visible.
- Connect the Thermode to the patient's skin ONLY during the test; not during system Self-Test, programming or maintenance.
- The computer that is used to operate the Q-SENSE 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 Q-SENSE system is not allowed.
- Using a Thermode without the appropriate calibration table may result in potential harm or injury.
- Using the Q-SENSE system not according to instructions may result in potential harm or injury.

- Adverse Reaction: Skin irritation (in addition to pain sensation) beneath the probe has been reported with the use of a stimulator, which was based on similar technology as the Q-Sense device.
- Be aware of potential risk of skin damage caused by wrong parameter combination.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment
-

1.5.2 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.
- 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 Q-SENSE system must not be connected to a network while it is used for running tests.
- The Q-SENSE system does not require special precautions regarding EMC, and needs to be installed and put into service according to this manual.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use caution when using the Q-SENSE Thermode on patients with suspected neuropathies as they may be more susceptible to soft tissue or nerve damage at extreme temperatures. Also, patients with neuropathies may not be able to properly discontinue use of the device during prolonged hot or cold stimulation.

1.5.3 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.

1.6 System Protection

1.6.1 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.

1.6.2 Temperature Safety Mechanisms

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

Software protection mechanisms include:

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

Hardware protection mechanisms include:

- If the Thermode temperature reaches 57°C an analog circuit overrides the system and lowers the temperature gradually.

1.6.3 Thermode Detection

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

1.7 Equipment Labels, Symbols, Warning Statements and Abbreviations

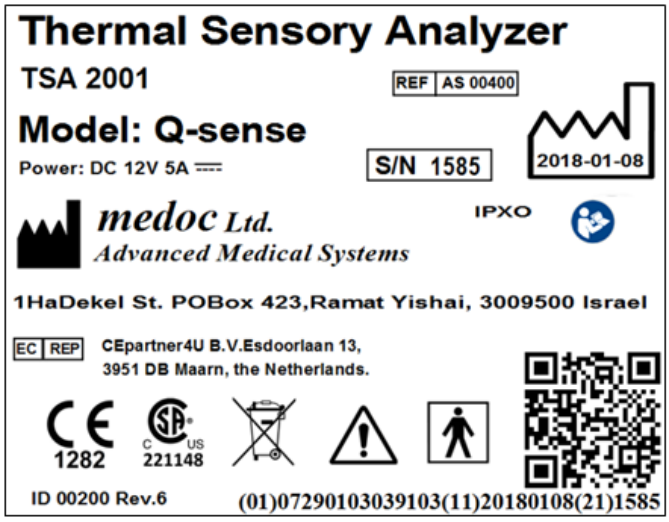


Figure 1: Q-Sense Label

Table 1: Equipment Labels

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

Manual edition refers to current version of manufactured system

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

1.8 Electromagnetic immunity

The Q-Sense is intended for use in the electromagnetic environment specified below. The customer or the user of the Q-Sense 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	<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	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 Q-sense may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.

	(>95 % dip in UT) for 5s	(>95 % dip in UT) for 5s	
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
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the Q-sense, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3V/m	3V/m	
	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	
	10V/m from 80MHz to 2.7GHz	10V/m from 80MHz to 2.7GHz	

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.
* 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 Q-Sense is used exceeds the applicable RF compliance level above, the Q-Sense should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Q-Sense. ** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group1 Class A	The Q-sense uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The Q-sense is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Q-sense or shielding the location.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

1.9 Recommended Separation Distance between Portable and Mobile RF Communications Equipment and Q-Sense

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

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

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

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

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

1.10 Technical Data

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

The table below describes the technical specifications and capabilities of the Q-Sense system.

Table 2: Q-SENSE Specifications

Parameter	Specification
Thermode Active Area	30x30 mm
Thermode temperature Range	20 – 50 °C
Heating Rate	0 – 2 °C/Sec ± 10%
Cooling Rate	0 - 1 °C/Sec ± 10%
Stimulation Methods	Limits, Levels & TSL Ramp & Hold (optional)
Set-Point Resolution	0.1 °C
Display Resolution	0.1 °C
Repeatability	± 0.3 °C
Absolute Accuracy	±0.3 °C
Operating Mode	Intervals* *(Short pause between patients may be required)
Minimum Inter Stimuli Interval (ISI)	2 sec
Maximum Consecutive Stimuli	10
Baseline Thermode Temperature Range	28 – 40 °C
Programmable Parameters	Method, Adaptation Temperature, Heating Rate, Cooling Rate, Number of Stimuli, ISI, Sound Option, Randomize Option
Communication with PC	USB
Communication with Printer	Via PC
Standards	IEC 60601-1; IEC 60601-1-2
Approvals	CE, FDA
Operating Voltage	12 VDC, 5A
Power Supply	100 – 240 VAC, 4 – 2 A, 50/60 Hz
Power Consumption	Approx. 60W
Dimensions	31cm X 28 cm X 16cm (table or wall mount) Shipping: 53cm X 34cm X 22cm
Weight	Approx. 4.5 Kg Shipping: Approx. 10 Kg
Software	Propriety Software Application (Included)
Computer Requirements (PC not included)	Notebook PC (Atom CPU not supported) At least 2 GB RAM, 6 GB Free disc space. Windows 7/8 (32 & 64 bit), Windows XP (32bit) sp. 3 and above.

Parameter	Specification
Screen Resolution	1366X768 and higher
Patient Response Unit	2 buttons (Yes / No) Response Unit
Product life time	10 years
Thermode life time	1 year

2 Overview

The Q-Sense Thermal Sensory Analyzer is a QST (Quantitative Sensory Testing) device including advanced software package designed for clinical use and research in the field of Pain Management.

2.1 Training

Users of Q-Sense shall have received adequate training on its safe and effective use before attempting to work with it. Training requirements may vary from country to country. The User shall make sure that training is received in accordance with local laws or regulations that have the force of law. Information on training is available from your local Medoc representative.

2.2 System Description

The Q-Sense is a TSA 2001 model, which enables the user to perform various thermal test paradigms including the method of Limits, Levels, and TSL. These test paradigms can be utilized for a wide range of thermal QST pain measures such as thermal pain threshold and tolerance.

Intended use: The Q-Sense is a pain management and pain research intended to be used for the quantitative assessment of small nerve fiber dysfunctions. It measures sensory thresholds such as the cold and warm sensation, and heat-induced pain.

2.3 Q-SENSE Thermode

The Thermode is the active component of the system which delivers the actual stimulus. The main components of the Q-Sense Thermode include:

- Active Thermal Element – The active Thermal element is a Thermoelectric Cooler (TEC), a peltier element, which generates a temperature gradient according to the direction and amplitude of power (electrical current) it is given.
- Temperature Sensors (Thermistors) - The Thermistors are resistors which change their resistance with temperature. Two thermistors are used to sense the slightest change in temperature and deliver feedback to the temperature control unit. The temperature control unit adjusts the power output to this feedback.
- Contact Plate – Contact plate is the external area of the Thermode which comes in contact with the skin of the tested subject. The plate is aluminum coated for heat dispersion.
- Cooling Elements – The cooling elements disperse heat from the TEC

For more detailed specifications of the Q-Sense please refer to the Technical Specifications in section 1.10, page 25

2.4 Terminology

The following terms are used throughout this manual:

Table 3: Terminology

Term	Description
Thermode	The probe which is used to apply the thermal stimulation on the subject's skin.
TEC	Thermo Electric Cooler (TEC), a Peltier element used as the active heat generator in the Thermode.
Rest Temperature	The initial/rest temperature of the Thermode, after system initialization and in between tests. Also referred to as Adaptation Temperature.

Term	Description
Baseline Temperature	The initial temperature the stimulus starts from
Destination Temperature	The final temperature the stimulus ends with.
Duration Time	Indicates the time the probe will remain at the destination
Trial	Represents one stimulus
Sequence	A set of trials with the same specifications
Test	A set of sequences.
Event	A specific occurrence during a test such as the onset of a stimulus, reaching a specific temperature and etc.
LUT	A Look Up Table (LUT) maps one set of values to another. A LUT is used to map between the readings from the temperature sensors to the actual temperature it represents.
Firmware	The program embedded on the internal processor of the system

2.5 System Status

- **Online:** This is the Q-SENSE system full operating mode and indicates full communication between MEDOC Main Station and Q-Sense System. While on-line the Q-Sense 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 Q-SENSE system. All tests performed while working in this mode are simulated. No actual thermal stimulation is performed and there is no access to the Q-SENSE 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 Q-SENSE 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 Q-SENSE active states are as follows:

- **Rest Mode**: The Q-SENSE system is active and ready to perform a test. The temperature is maintained at the specified Rest Mode temperature. In this mode, patient, program and result management are possible.
- **Test Run**: The Q-SENSE system is running a (predefined) test. The Thermode is active, and the temperature varies according to the active program.
- **Safe Mode**: No test can be performed and safety mechanisms are activated. The system must perform a Self-Test before resuming normal operation.
- **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 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 Thermode is functioning according to system requirements.

- **Black Box**: The system has detected an error and is currently logging data in the internal memory. The log file can be exported later for service use.

2.7 Application Methods

Method is the type of the test program. Q-SENSE supports the following 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.
- **Levels**: A set of stimuli is emitted, and for each stimulus, the subject is required to respond. The following stimulus is calculated according to the subject's response. For more details, refer to section 2.7.2.
- **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.
- **Ramp & Hold** (optional, available with specific license): The temperature of the stimulus is maintained for a predetermined duration.
- **VAS Search** (optional, available with specific license): A set of Ramp & Hold stimuli is emitted, and for each stimulus, the subject is required to report the perceived level of pain. The following stimulus is calculated according to the subject's response.

Before using each of these methods, make sure you have read section 6, Page 49, Test Procedure and Management, which addresses the following topics: Tested subject selection, Program selection, and Stimuli administration.

2.7.1 Limits Method

This reaction time inclusive method consists of stimuli of continuously changing intensity. With each stimulus, when the subject perceives a predefined sensation, he/she manually stops the stimulus.

The Limits method is the most widely used method for threshold determination, because it requires the shortest test procedure of all methods, and it can measure not only pain thresholds, but also non-painful thermal thresholds.

For detailed information refer to section 7.6.1, page 62.

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.

For detailed information refer to section 7.6.2, page 66.

2.7.3 Thermal Sensory Limen (TSL)

The TSL is another reaction time dependent method is the detection of **Thermal Sensory Limen (T.S.L.)**. In this algorithm, once started, the stimulus temperature does not stop at adaptation, rather, it continues directly from the warm threshold to the cold threshold and vice versa. After several oscillations between warm and cold sensory thresholds, the 'Limen' of no

thermal sensation is calculated as the difference between means of cold-sensation and warm-sensation. Using the TSL method, allows the Limen or 'no thermal sensation' area to be calculated.

For detailed information refer to section 7.6.3, page 70.

2.7.4 Ramp & Hold Method

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

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

"Return to Baseline" option

The diagram below shows a general view of the sequence and predefined parameters. For the definition of each parameter, see 7.6.4, page 73.

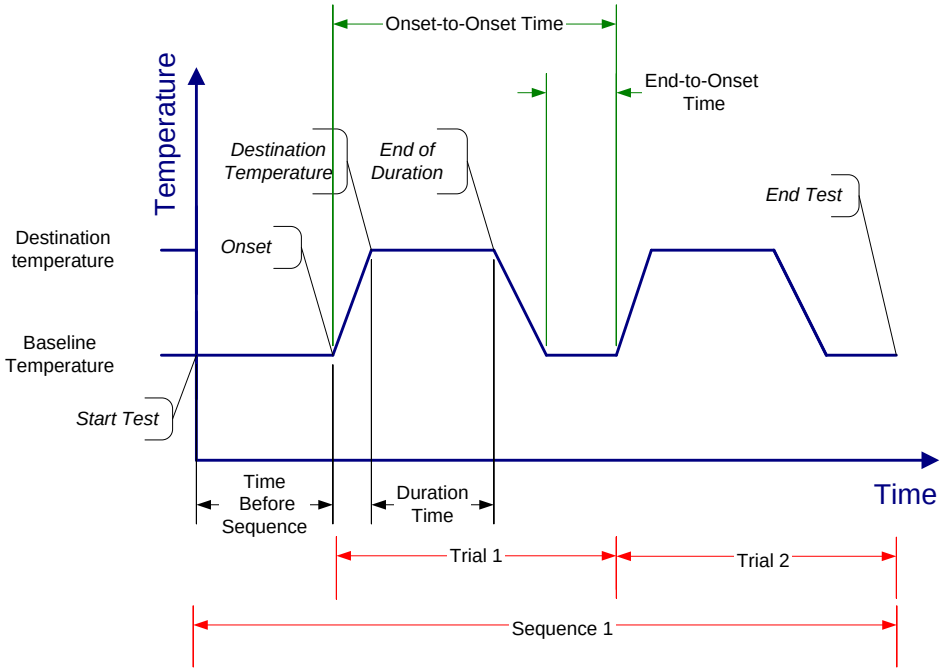


Figure 2: Ramp &Hold Sequence – Return to Baseline

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

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

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

"Return to the Next Destination" option

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

This is available only for sequences consisting of one trial.

See definition of each parameter in section 7.6.4, page 73.

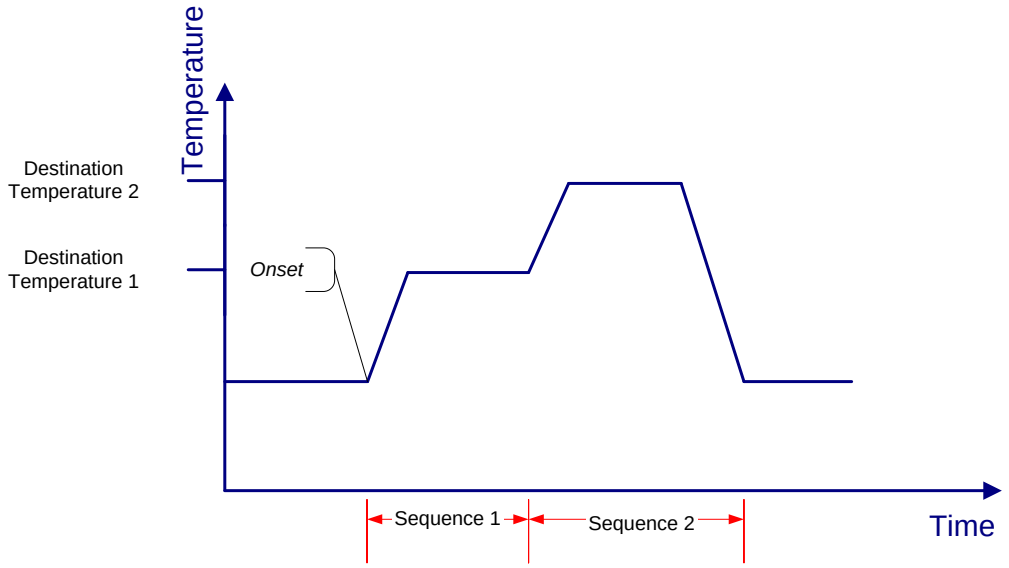


Figure 3: Ramp & Hold Sequence – Return to Next Destination

2.7.5 VAS Search Method

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

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

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

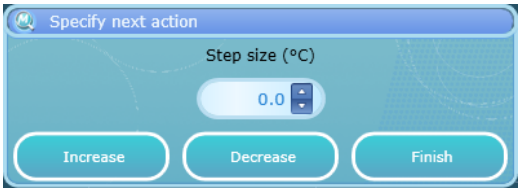


Figure 4: VAS Search – Manual Mode

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

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

See section 7.6.5, page 75 for full description of program details and parameters.

2.7.6 Chain Option

The chain option enables to chain any of the above methods, any number of times, in any order.

For detailed information refer to section 7.6.6, page 77.

3 System Components

Q-SENSE components contain the following receptacles and controls:

Table 4: Q-SENSE Connectors side Panel receptacles

#	Description	Mate with
1	Q-sense Thermode Main receptacle Blue – power connector Green – Sensor connector	
2	Response Unit receptacle Use for recording patient response during test	

Table 5: Connectors to power side panel

1	Power Supply Power supply is used to connect electricity port and to the power port in the Q-sense system.	
2	Communication USB Cable This cable is used to connect the Q-sense com port with a computer.	

3.1 Power side Panel

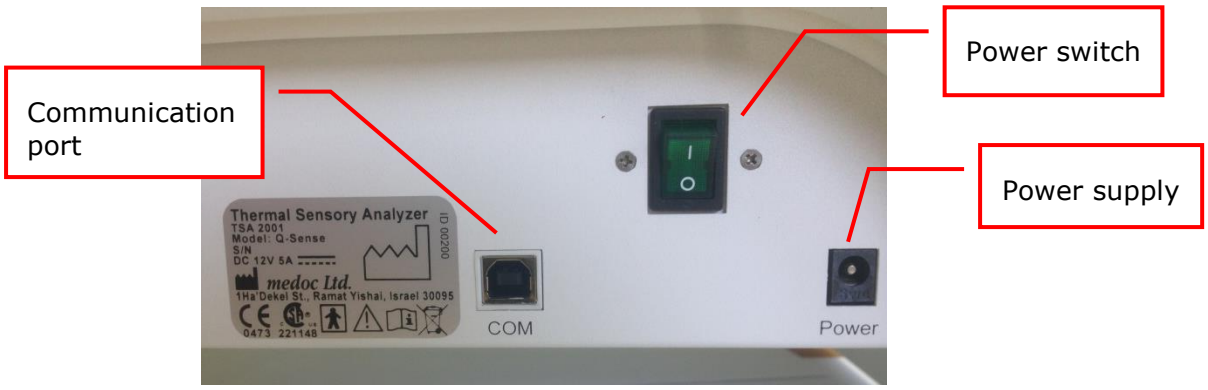


Figure 5: Power side panel

3.2 Connectors side panel

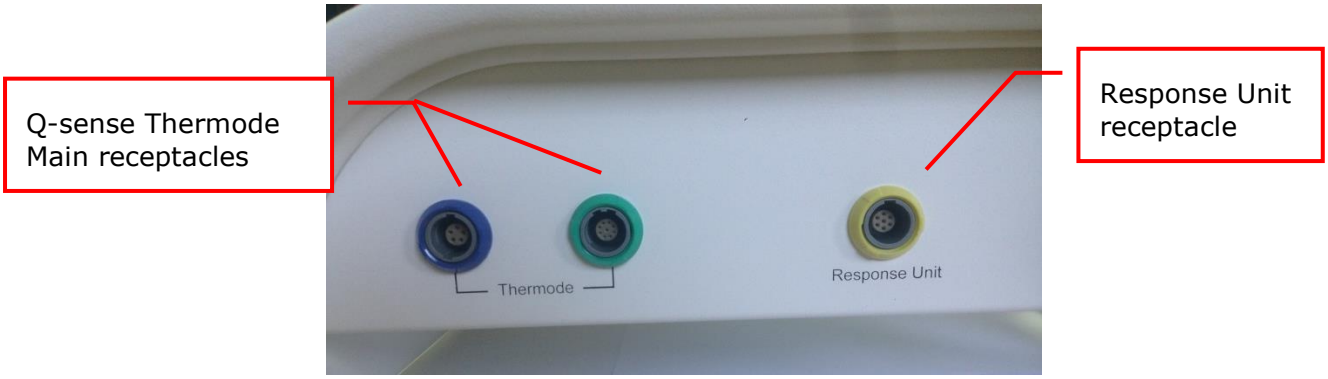


Figure 6: Connectors side panel

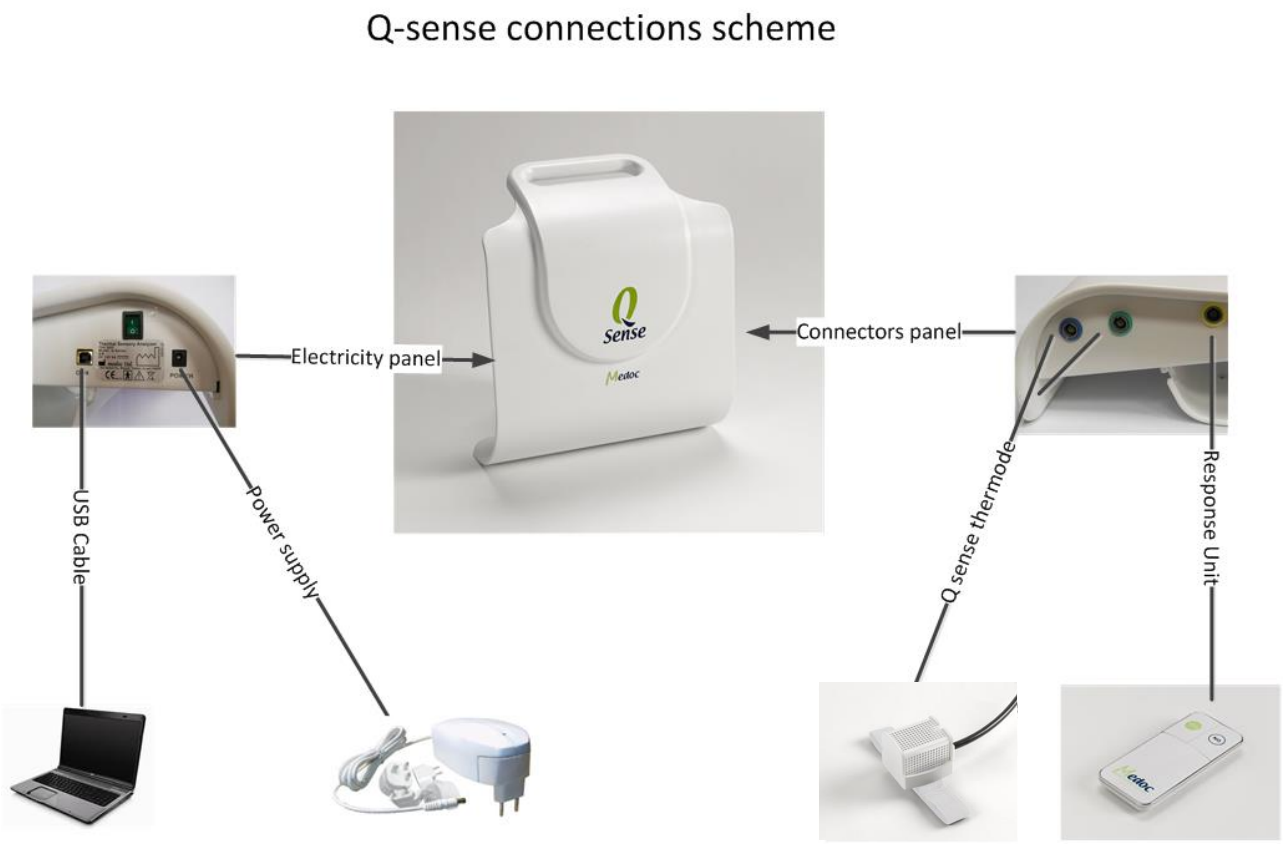


Figure 7: Q-SENSE System Wiring Schema

4 Setup and Installation

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

Complete and verify the entire Q-Sense setup and installation process before the using the system

4.1 Computer Requirements

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

Safety	Computer must comply with IEC 950 – EN 60950 – UL 60950
Processor	Intel Core i3 4xxx or better (avoid low power processors such as Atom, Pentium or Celeron)
Memory	4 GB RAM
Storage	128 GB
USB slots	2 free USB slots (3 for AlgoMed and Q-Sense CPM)
Monitor/Display	13'' (15'' recommended)
Screen Resolution	1366 x 768 pixels, 96 DPI (max. 1920x1080)
Operating System	Windows 7, 8, 10 32/64 bit (Not recommended: Windows XP service pack 3. Please see note below)
Other	Microsoft Office 2007 or above (required for viewing results in excel)

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

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

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

4.2 Installation USB Content

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

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

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

4.3 Setup and Installation Main Steps

The assembly procedure consists of the following steps:

1. Selecting a location for the system. See section 4.4, page 37.
2. Connecting the Thermode and any additional accessories to the system. See section 4.5, page 38.
3. Connecting the laptop and installing the MEDOC Main Station software. See section 04.6, page 39.
4. Configuring the system.

See Q-Sense Technical Reference Service Manual for further details on the system components.

4.4 Selecting a Location

An appropriate location for the Q-SENSE system should meet the following criteria:

1. The room temperature should be kept between 18°C and 24°C.
2. The Q-Sense 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.
5. It is possible to hang the Q-Sense system using Medoc Wall Hanger. To hang the system: Connect Medoc Wall Hanger to the specific site on the wall.
   5.1. Mark the screw's holes on the wall, and take the hanger off the wall.
   5.2. Use a 6 mm drill bit to create holes on the wall in the points you marked in b section.
   5.3. Insert masonry anchors to the drilled holes.
   5.4. Connect the hanger by screwing the attached screws to the masonry anchors.

Different type of walls requires different masonry anchors.

Figure 8: Connecting Wall hanger to the wall

4.5 Device Connections

1. Ensure that the laptop meets the requirements set by Medoc (See section 4.1, page 36).
2. Make sure that your Laptop, Q-SENSE unit and printer (optional) are all **OFF**.
3. Connect the system, Thermodes and accessories. See Figure 9

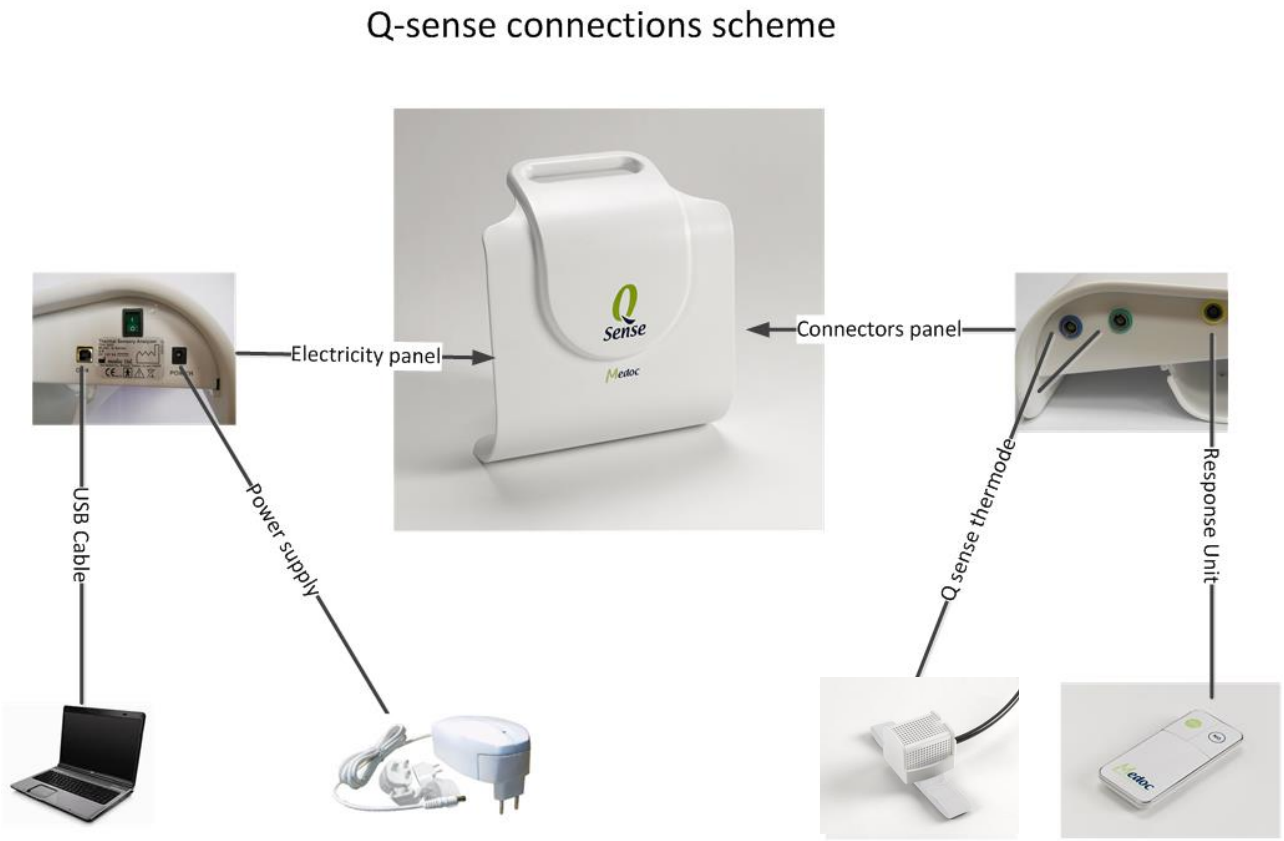


Figure 9: Q-SENSE System Wiring Schema

Do NOT connect the USB cable to the Q-SENSE system before complete installation of the MEDOC Main Station software.

Thermode and Response Unit connectors are color coded.
The Response Unit plug should be connected to yellow receptacle.
The Thermode green and blue plugs should be connected to the green and blue receptacles respectively.

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 Q-SENSE system that has not been specifically authorized and approved by Medoc.

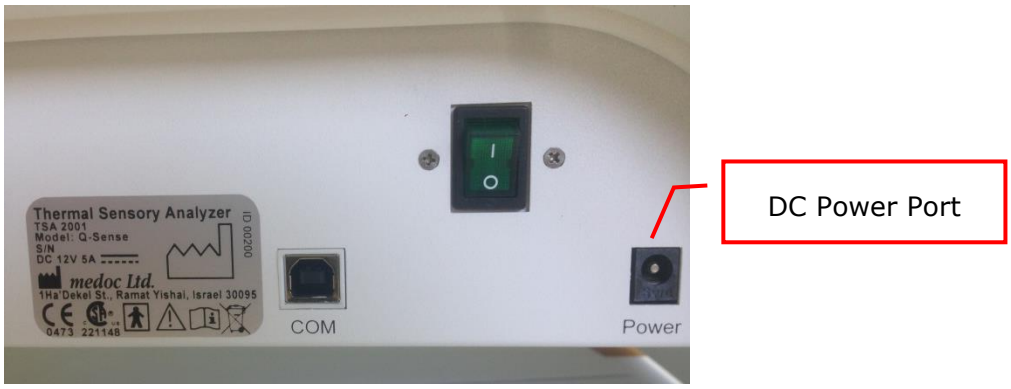


Figure 10: DC power port

4. Connect the Q-SENSE power supply to an AC outlet and the cable to the DC power port.

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 in section 23, page 156.

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.

The following instructions will guide you through the installation procedure:

1. Insert the **USB drive** into an available USB port on the computer
2. Open the folder to view files.

3. Double-click **Setup.exe** to start software installation
4. Click **Next** to continue the installation.
5. Select the file location where Medoc Main Station should be installed. You can use the location recommended by the installation. Click **Next** to continue.
6. Select the location of the Medoc Main Station shortcuts in the start menu. You can use the location recommended by the installation. Click **Next** to continue.
7. Installing normative data – please read the agreement carefully. If you agree to the term please choose to install normative data. Click **Next** to continue.
8. Privacy – please read the terms carefully. If you agree please choose to allow data collection. You may cancel this option any time later if you choose to.
9. The installation is now in progress. Depending on your computer configuration it may take up to several minutes.
10. After installation has completed, click **Finish** to close the wizard.
11. **Restart** your Computer.
12. Medoc Main Station software is now ready to be used.

4.7 Unit Protection

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

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

4.8 Product Activation

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

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

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

To complete the activation process, simply start Medoc Main Station software and follow the instructions given in the activation wizard. If the activation wizard is not displayed when you start Medoc Main station Software, go to the Home screen, select Options and then select Product Registration. See Figure 11.

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

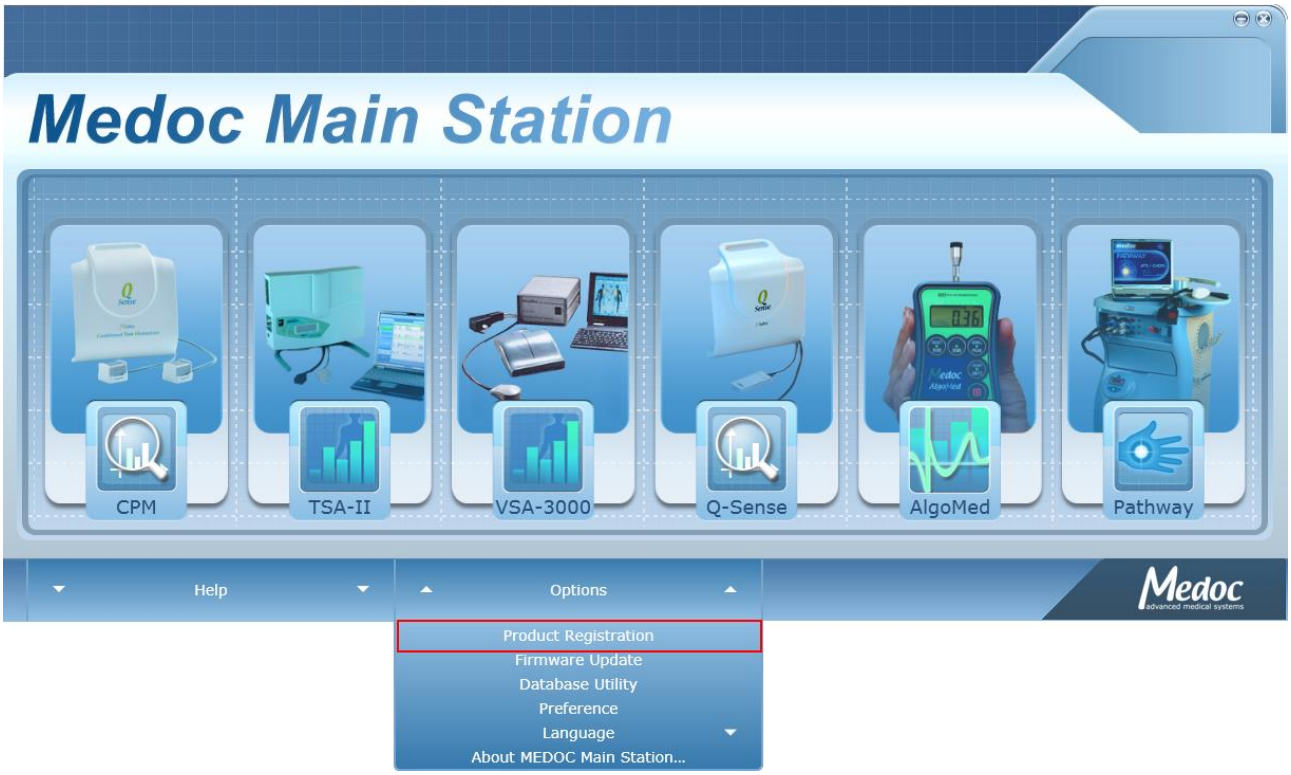


Figure 11: Home screen product registration link

5 Operation

The purpose of the following chapters is to specify the Q-SENSE applications and to bring in-detail step-by-step instructions for conducting thermal stimuli.

This chapter specifies Q-SENSE behavior at start up and MEDOC Main Station basic components.

5.1 Power up Q-SENSE System

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

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

1. **Connect** your PC using USB cable to the **COM** connection, communication port, at the side of the Q-SENSE system.

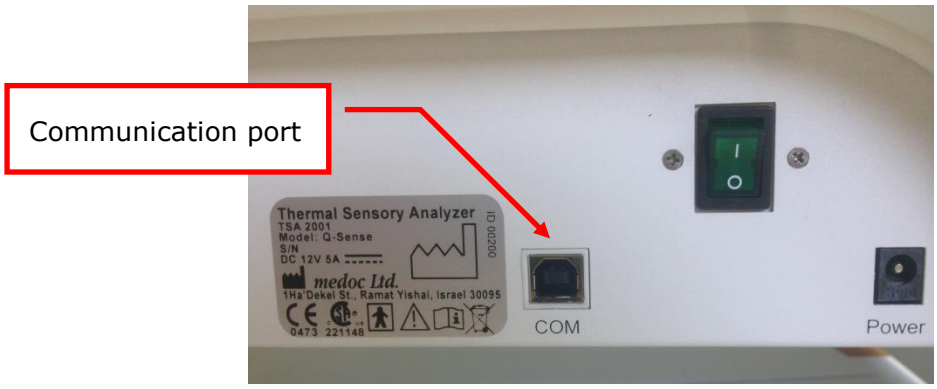


Figure 12: Q-sense COM port

2. Power up the Q-SENSE system by using the main switch on the side of the Q-SENSE.

5.2 Starting Q-SENSE

Before initializing the Q-SENSE system, ensure that the Thermode is connected correctly.

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.

1. Turn **ON** the Q-SENSE unit, by using the main power switch
2. Turn **ON** the laptop
3. Start Medoc Main Station software by double-clicking the icon
4. The Home screen is displayed showing the available devices (license dependent).

Figure 13: Home Screen

5. To select Q-Sense, click on the Q-Sense image.
6. When the login screen is displayed, enter your user name and password and select "**Q-SENSE**" in the "**connect to**" field.

Initial login Username and Password are both *admin*.

For more information on user management please refer to section 10.1.5

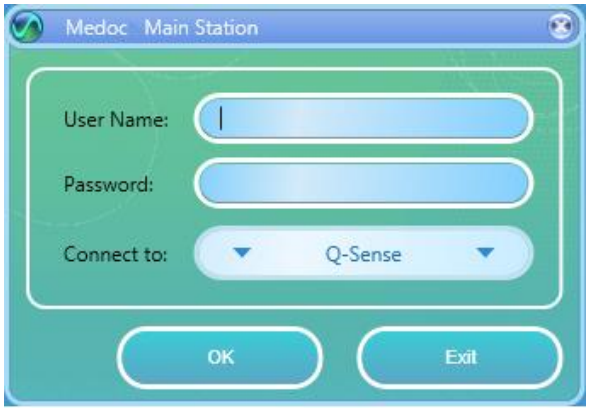


Figure 14: Login Screen

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

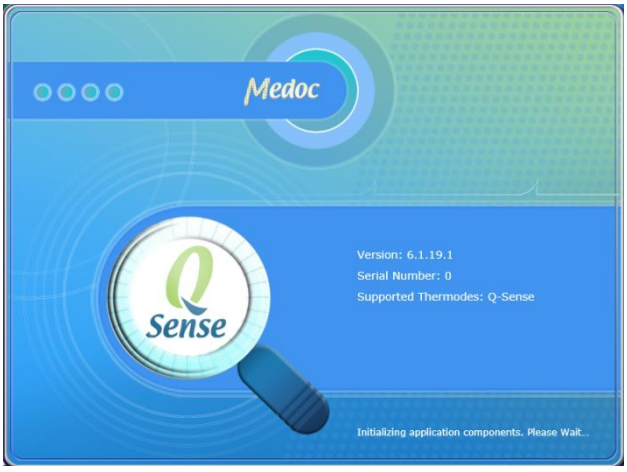


Figure 15: Q-Sense Splash Screen

8. When communication is established, the system will enter SAFE MODE and remain in this state until completing the system Self-Test, see section 5.3 below. Make sure the Thermode is not attached to the Subject and click on OK on the following message:

5.3 System Self-Test

Upon system start up, Q-SENSE will automatically enter SAFE MODE state. 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.

System self-test must be completed successfully before Q-SENSE can be used. The following message prompting for system self-test is displayed. Make sure the Thermode is not attached to a patient and click **OK**.

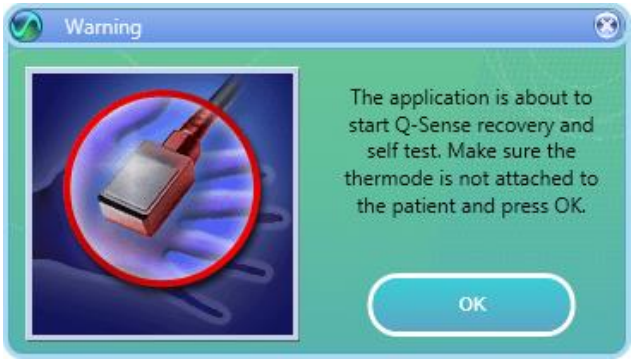


Figure 16: Self-Test Prompt

The system will perform a complete self-test of all enabled Thermodes according to your system settings.

After self-test has completed successfully, Q-SENSE State will change to **Rest Mode**.

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

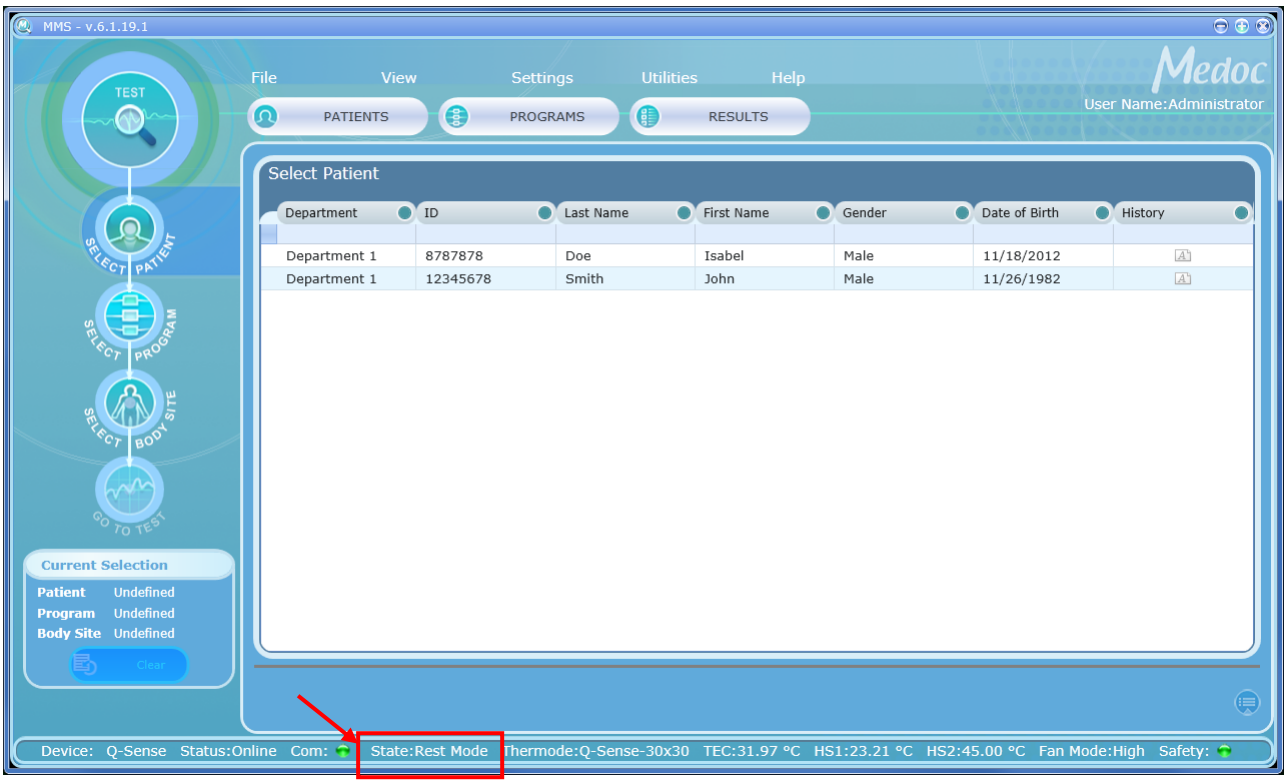


Figure 17: Q-Sense in Rest Mode

5.4 Basic Operation

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

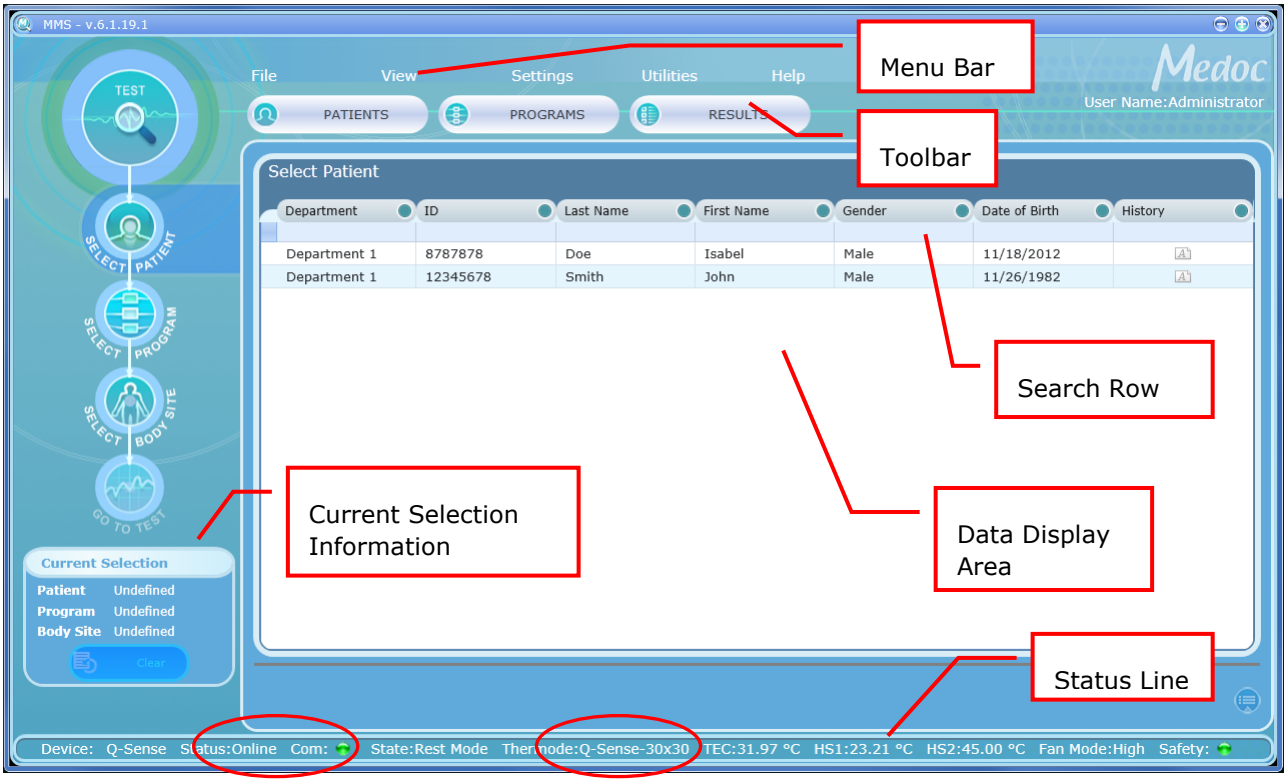


Figure 18: Test Navigator – Main Menu

Note that the status line also indicates the type and model of the Thermode, you are currently applying to (see red circle, 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
- Data Display Area – View list of patients, programs or body sites
- Status Line – Continues real-time display of Q-SENSE status and Thermode temperature.

  The components are detailed in the following sections.

5.4.1 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 Q-SENSE.
	Switch Device	Return to Home Screen and select another device or change preferences.
	Exit	Exit MEDOC Main Station.
View	Test	Switch to Test Editor 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	Q-SENSE system and Thermode hardware configuration and management.
	Test settings	Test configuration and display preferences
	Status	Status configuration- On line\Demo.
Utilities	Department	Add/Remove Departments for patient list management.
	ICD 9	Add/Remove ICD 9 codes.
	Normative Data	Normative Data database and Editor.
	Black box	System hardware and software logs
	Device recovery	Initiate Q-SENSE system self-test in case safety was triggered.
	Log Files	View software log files
	Probe Files	Import or export the termode calibration details.
Help	Operating Manual	Link to the Q-SENSE Technical Reference Manual
	Service Manual	Link to the Q-SENSE Technical Reference Service Manual
	About …	System and software information
	Service Call	Submit a Service Call via Medoc web site*.
	FAQ	FAQ on Medoc web site*.
*internet connection required		

5.4.2 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

5.4.3 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.

5.4.4 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 Thermode.

5.4.5 Data Display Area

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

5.4.6 Q-Sense 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 PATHWAY 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.
Thermode	Indicates the type and model of the Thermode currently connected to the system: Q-sense 30x30mm.
TEC	Temperature of the Thermode.
HS1/HS2	Temperature of heat-sink (cooling element)
Fan Mode	Indicates the Fan mode.
Safety	Safety status. A green indicator is displayed for OK and a red indicator for Safe Mode activation – Thermode is disconnected from input. 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

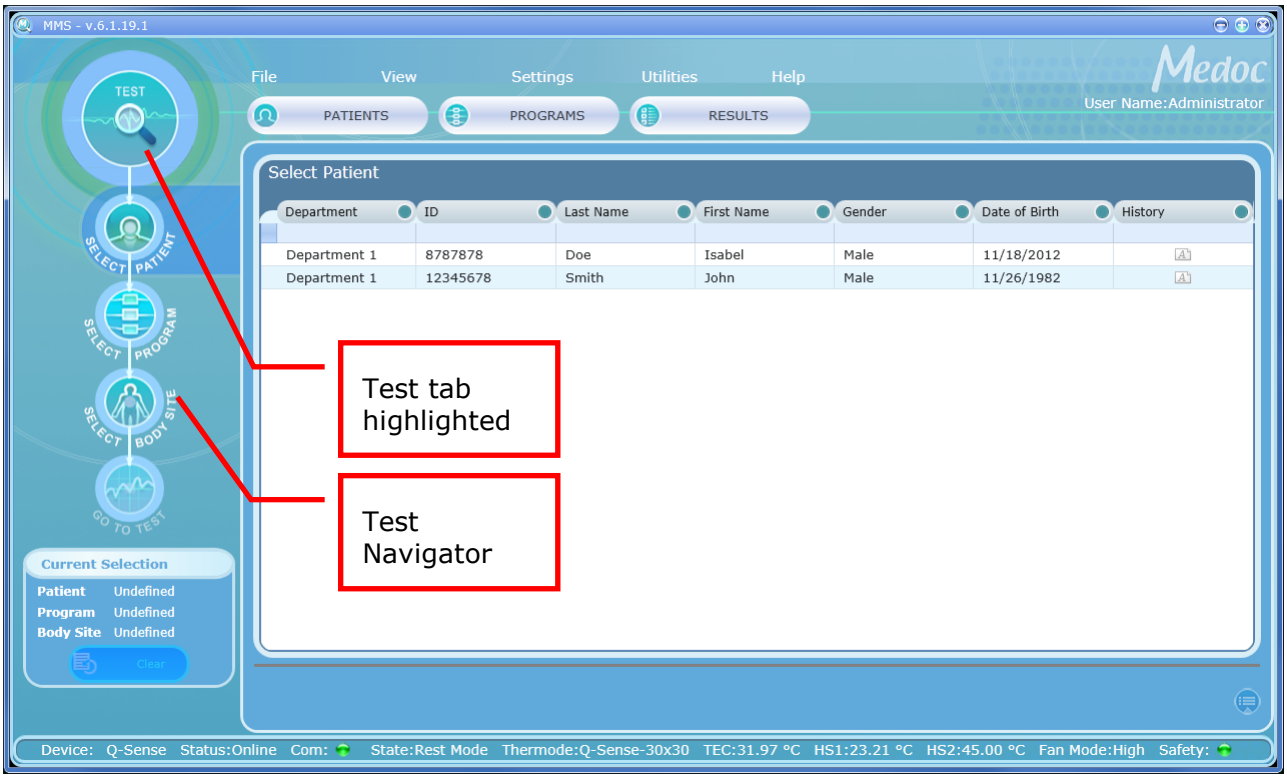


Figure 19: Test Management Main Screen

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 that will be used for the test.
- **Select Body Site** – Select the body site and its details for the current test. This step is optional.
- **Go to Test** and **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 on the Test Navigator
2. Use the Search Row (see section 5.4.3 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.

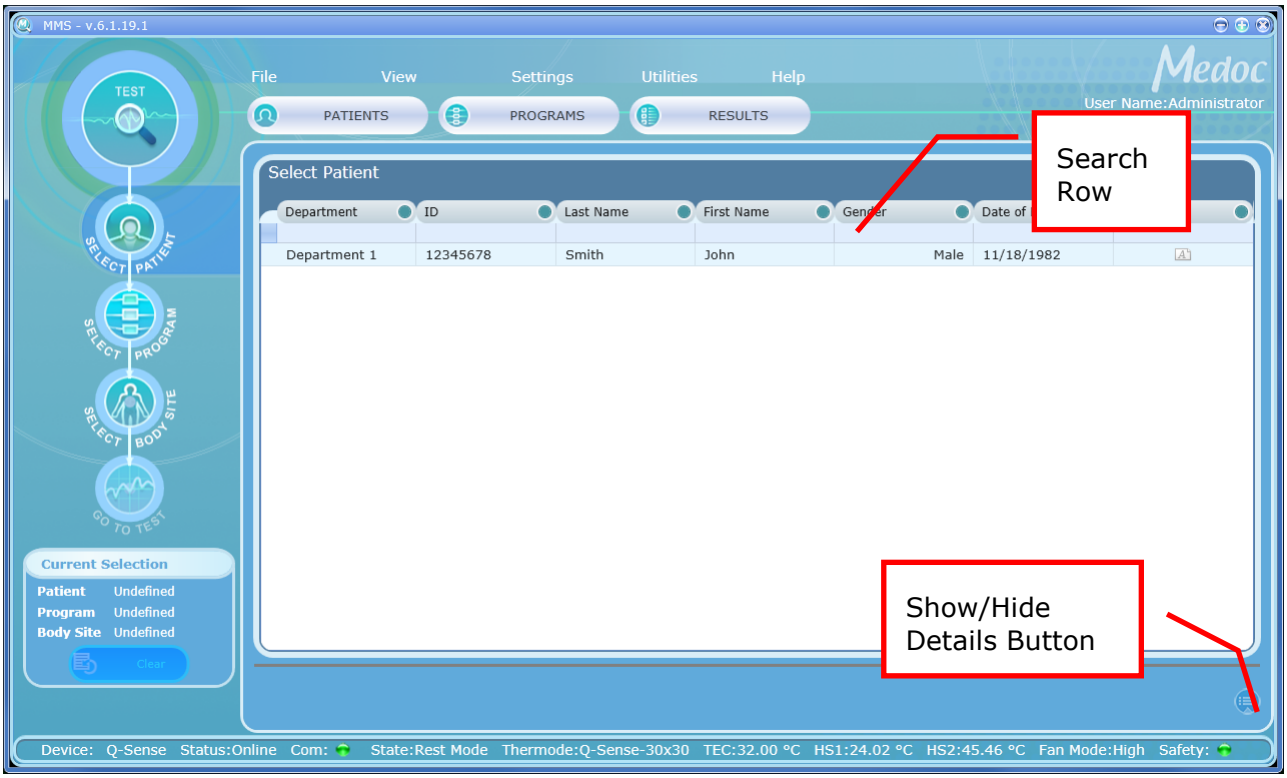


Figure 20: Patient Selection Menu

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 on the **Show Details** button.
5. 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 83).

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

It is not possible to run a test before you select the tested 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 the **Select Program** button on the Test Navigator
2. Use the Search Row (see section 5.4.3 above) to filter and sort list in order to find the relevant patient entry.

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

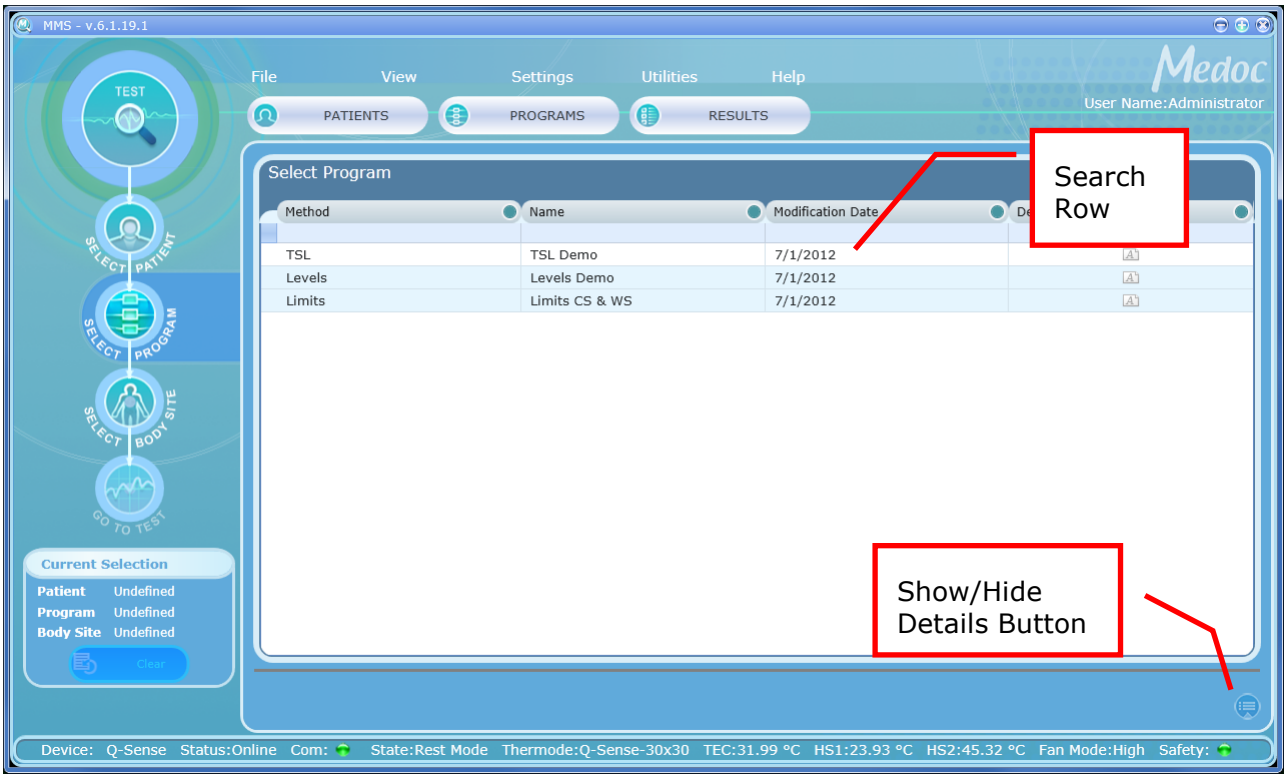


Figure 21: Program Selection Menu

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 patient details, click on the **Show Details** button.
5. The following options are available in the program details view:

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

Program details can only be viewed from the Test screen. For editing, refer to Program Management section (section 7, page 58).

6. Click 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 **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 tested 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 tested body site is optional. A test can be initiated without selecting a body site.

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

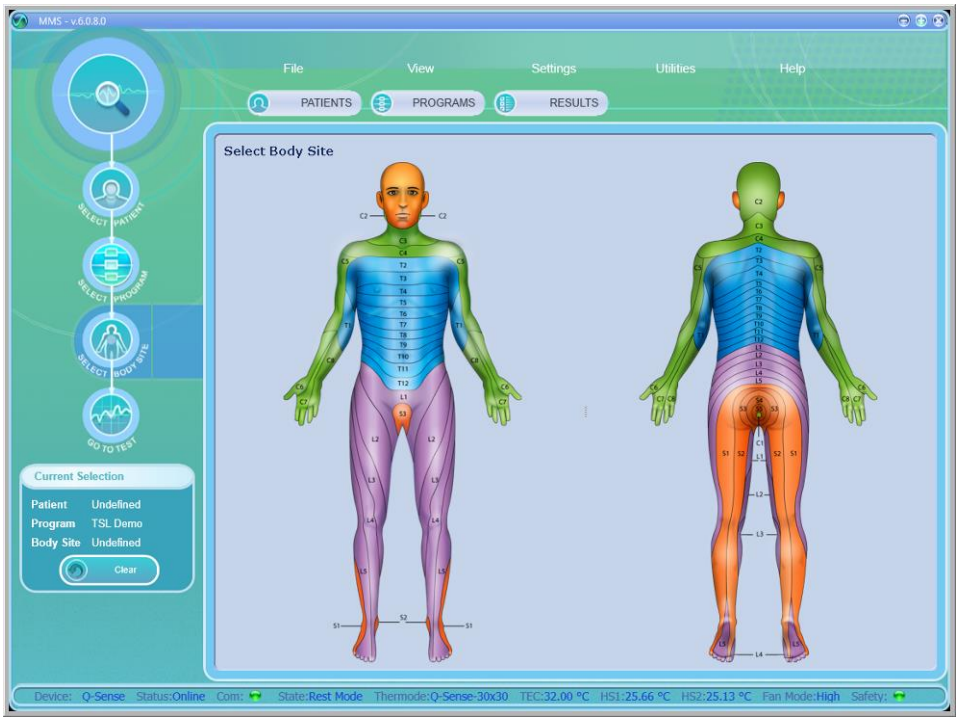


Figure 22: Select Body Site screen

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

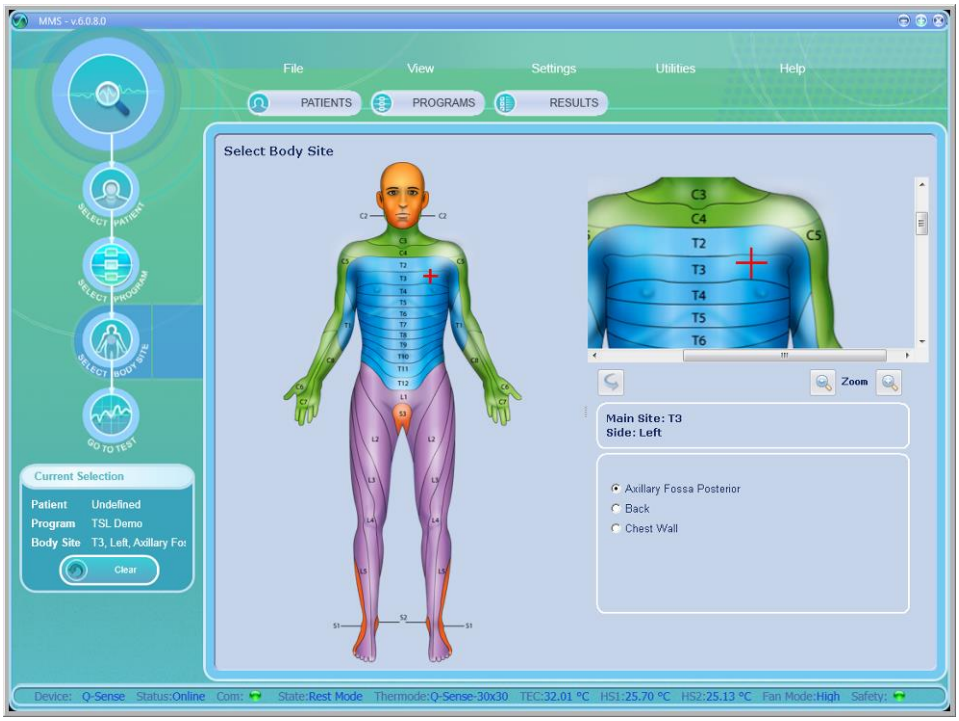


Figure 23: Select Body Site – Specific site selection

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 Patient and a Program before you try to proceed with an actual test.

1. Click the **Go to Test** button 

The following screen is displayed:

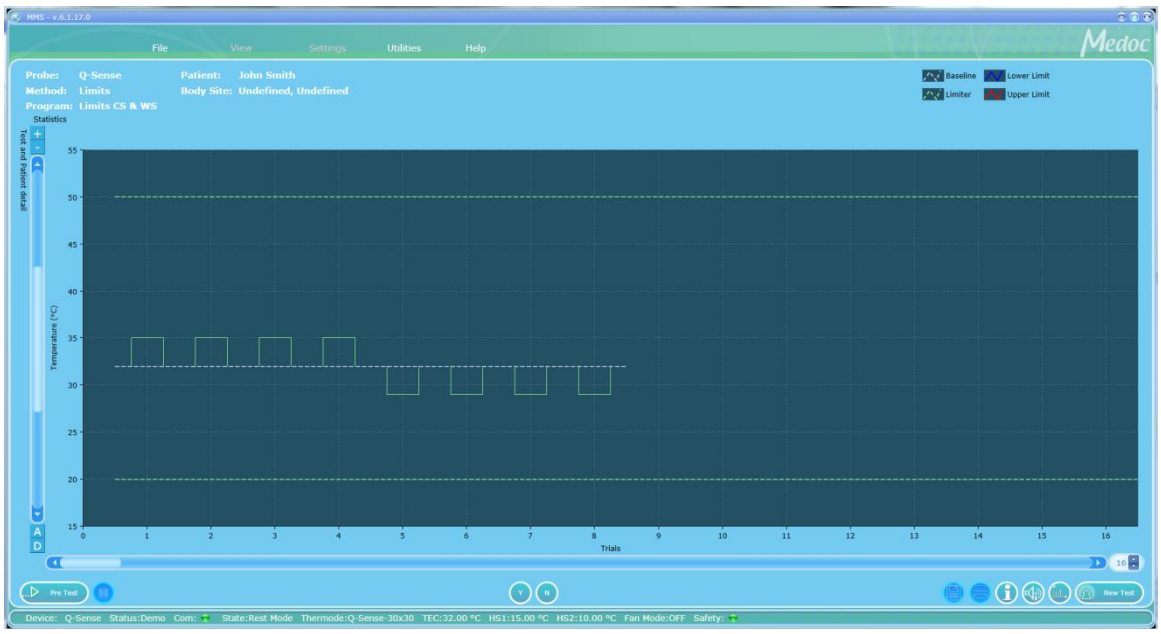


Figure 24: Pre-Test Screen

2. Click 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, jell or other material on the contact point between the Thermode and the tested subject's skin.

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.

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 the **Start** button ( ).

5. To pause the stimulation, click the **pause** button ( ).

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

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

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

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

After concluding a stimulation session, always clean the Thermode contact plate. For further details, refer to section 18, page 151.

Do NOT immerse the Thermode in any kind of liquid.

6.4.1 *Test and Post-Test Options*

Table 8: Test Run options

	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
	Play audio test instructions for the subject. To assign an audio file with default instructions, refer to section 10.3.2.2.
	Automatic zoom along the temperature axis. The temperature axis scale expands according to the highest and lowest temperatures displayed on screen. Button is located at the bottom left of the graph. Alternatively, change zoom manually by using the **+/-** buttons.
	Reset zoom to the original (default) scale. Button is located at the bottom left of the graph.
	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.
	Return back to the test screen to start a new test with or without clearing certain test details such subject and program. Last test results are not saved automatically.
	Indicate positive subject response in Limits, Levels, and TSL protocols.
	Indicates negative subject response in Limits, Levels, and TSL 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.

6.4.2 Temperature Graph Display

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

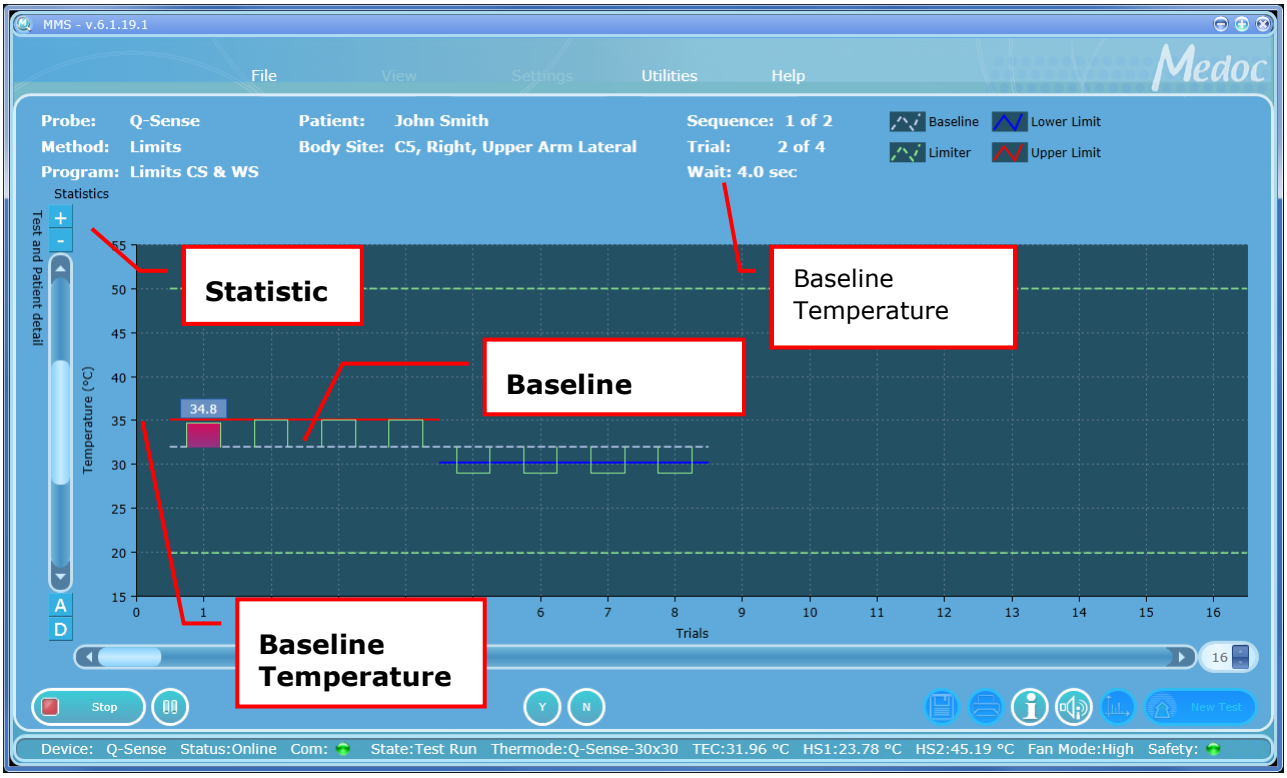


Figure 25: Real-Time Test

The+ following information is displayed:

9. Stimuli display (including CoVAS and events where applicable)
10. Current probe and program details.
11. Current sequence and trial data
12. Legend
13. Axes labels: Temperature axis on the left and CoVAS on the right (where applicable)
14. 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.
15. 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. The table below describes the available options.

Table 9: Hot Keys

Button	Key	Action
	**S**	Can be used instead of the **Stop** button to finalize; then stop the test.

Button	Key	Action
	**Spacebar**	Can be used instead of the following buttons in sequence: **pre-test** / **run test** / **pause** / **resume test**.
	**Y**	Can be used instead of the **YES** button. Not available in Search method.
	**N**	Can be used instead of the **NO** button. Not available in Search method.
	**T**	Can be use instead of the **Trigger** button.
	Tab	Wrong Sensation option. Available in Levels and TSL only.
	Delete	To **Delete** / **Undelete** a trail from statistics of a **Limits** test. Available only after test is complete and before it is saved. Delete trail is colored in Yellow.

7 Program Management

This chapter describes how to manage your stimulation programs. Programs can be created, duplicated or removed from the database. Following are the detailed individual parameters for program.

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 at the toolbar. The following screen is displayed:

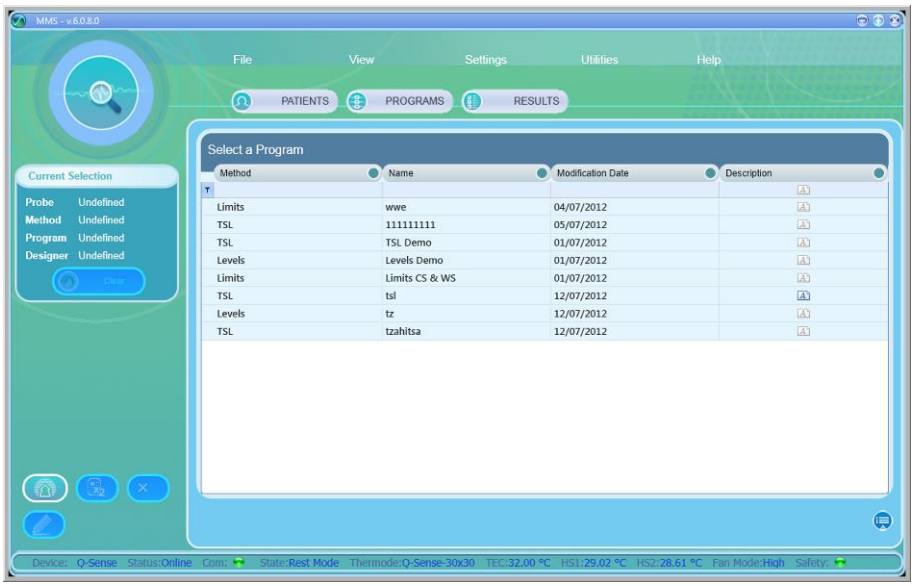


Figure 26: Program Management screen

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.

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

The following options are available in the Program Management screen:

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

 or 	Show or Hide program preview

- Current Selection control - displays the selected program information.
- Current Thermode control - displays the Thermode that is used for the selected program.

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

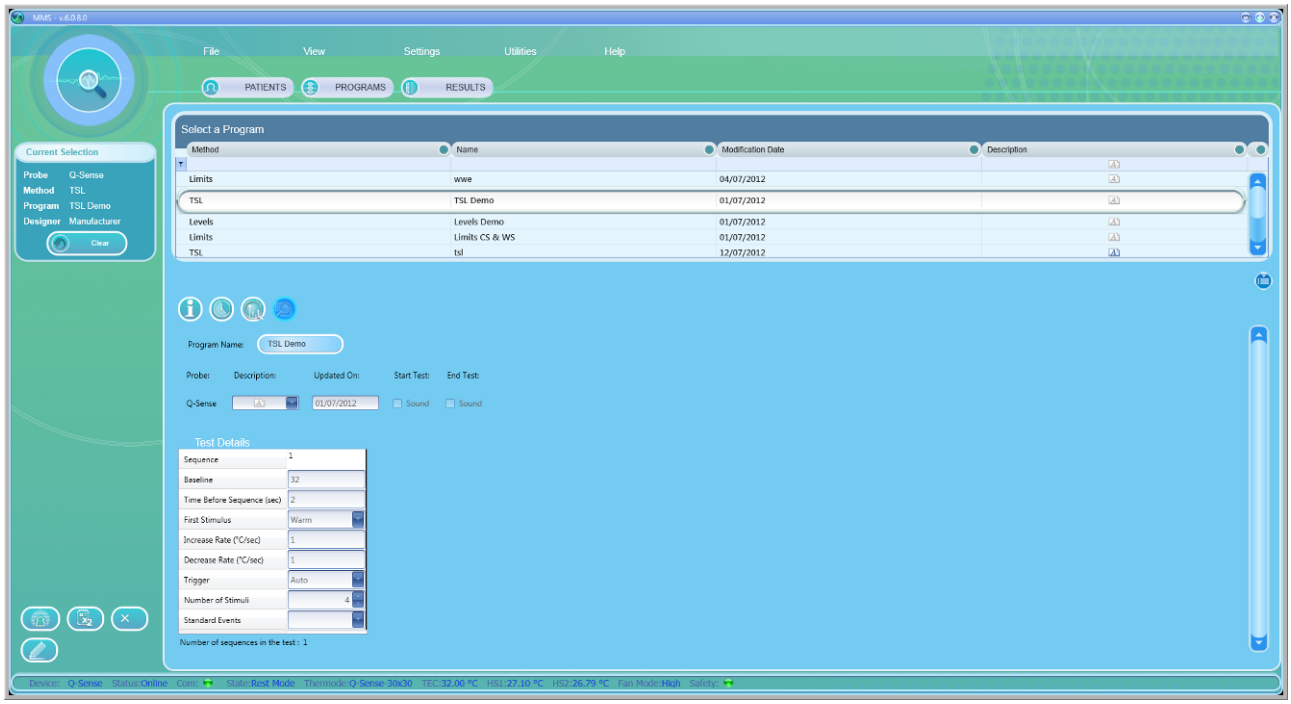


Figure 27: Program Management – Program Preview

The following options are available in the Program Preview:

	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 preview screen.

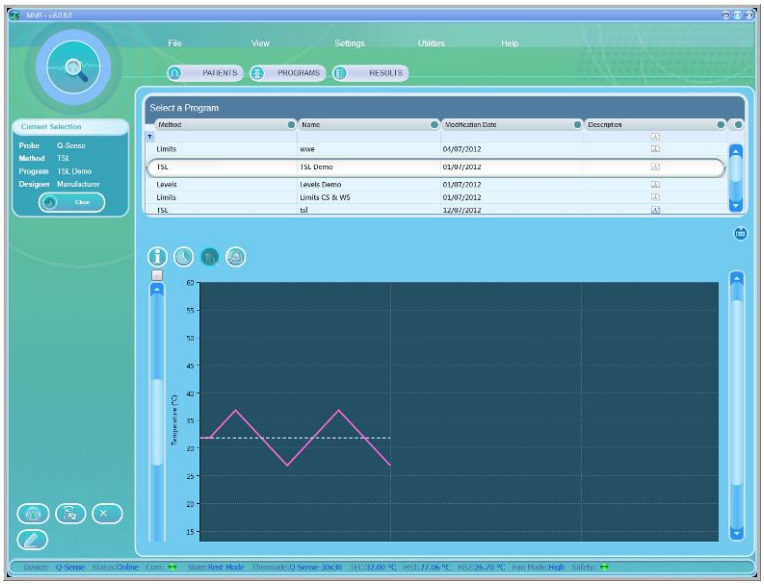


Figure 28: Program graph preview

7.2 Creating a New Program

To create a new program, perform the following procedure:

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

Figure 29: New Program Screen

2. In the **Probe Type** drop-down list, select the Q-sense probe. The following options are available (in accordance with your licensing agreement):

Table 10: Probe Type options

Parameter	Description
Q-sense	Can operate with one of the following methods: Levels, Limits, TSL, Ramp & Hold (optional, license is needed), Chain.

3. From the **Method** drop-down list, select the required stimulation method (Limits, Levels TSL or Chain).
4. Type the program name.
   For faster identification, it is advisable to type a meaningful name.

5. Click **OK**.
   The **Program Details** screen is displayed (see below).

7.3 Removing a Program

To remove a program from the program list:

9. Click the **Remove** icon ().
10. Click **Yes** to the prompt.
    The selected program is deleted.

7.4 Duplicate A Program

To duplicate a program from the program list:

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

7.5 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.

7.6 Program Details

The following screens enable the formation of program protocols. There are two test types:

Programmed – the Thermode temperature varies according to the program parameters.

Manual – the Thermode temperature varies according to selected accessory.

Following are sampled menus:

- Limits
- Levels
- TSL
- Ramp and Hold (optional)
- VAS Search (optional)
- Chain

The following functions are available in the program menus:

-  Displays a list of the program revision history by version date and username.

-  Displays the Test Instructions Editor for editing test instructions. Refer to section 7.8, page 80.
-  Returns to the previous menu.
-  Copies the selected record (sequence).
  Not available in Levels, TSL and Chaining programs.
-  Pastes the copied record to the right of the selected record.
  Not available in Levels, TSL and Chaining programs.
-  Adds a new record to the end of the current program.
  Not available in Levels, TSL and Chaining programs.
-  Adds a new record to the left of the selected record.
  Not available in Levels, TSL and Chaining programs.
-  Previews the program graph.
-  Checks program validity, and marks missing or incorrect parameters.
-  Saves the information displayed.

7.6.1 Limits

In this method, the system generates a number of stimuli of continuously changing intensity. With each stimulus, when the subject perceives a predefined sensation, he/she manually stops the stimulus. For method explanation, refer to section 2.7.1, page 29.

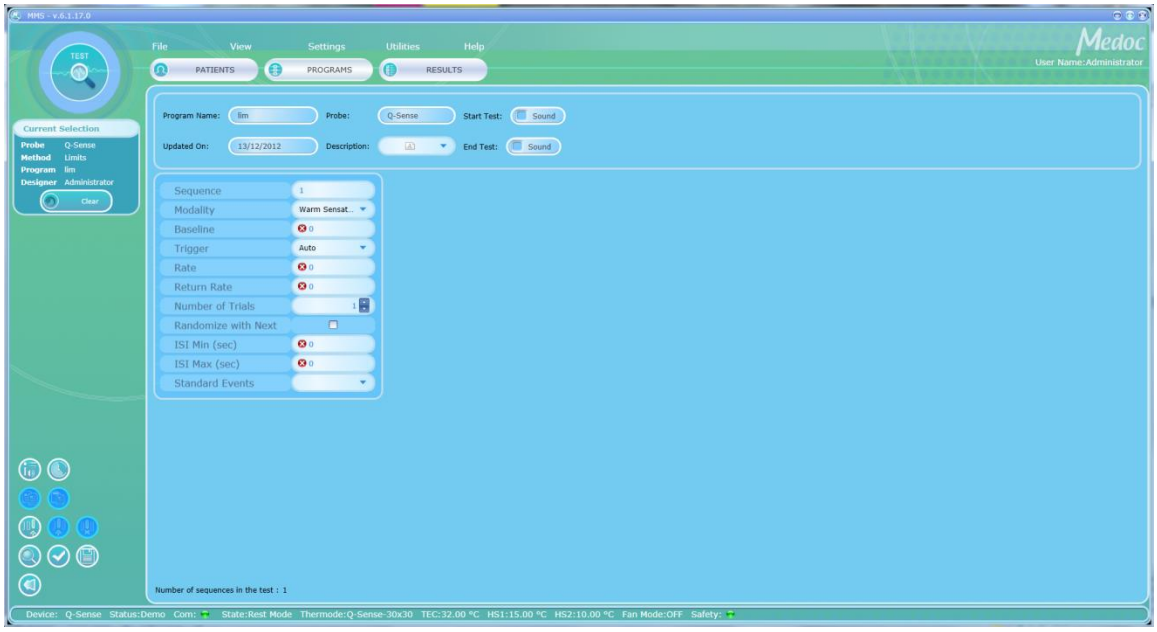


Figure 30: Program Menu – Limits

When adding or editing programs, follow these rules:

Enter meaningful information in the Program Description section of the screen.

Define all the parameters of a sequence for that sequence to be valid.

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.

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 11: Program Details

Parameter	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 ( ).

Parameter	Description
Update on	The date on which the latest changes were made and saved.
Start test/End test	Defines if these events are indicated by sound.

Table 12: Program Parameters

Parameter	Description
Modality	Four different types of sensation can be delivered to the subject: Warm sensation; Cold sensation; Hot pain.
Baseline (°C)	Temperature from which each new stimulation sequence begins – between 28°C to 40°C for Q-sense thermode.
Rate (°C/sec)	Defines the temperature rate of increase per second, from the baseline until the subject's response. Type an acceptable value: 0.1 to 2°C/Sec for Q-sense thermode
Return Rate (°C/sec)	Defines the temperature rate of decrease per second, from the temperature at which the subject responded, down to the baseline. Type an acceptable value: ..0.1-1°C/sec for Q-sense thermode.
Number of Trials	The number of trials in the sequence – between 1 to 100.
Randomize with next	Randomizes the next trial or sequence.
ISI Min (sec) / ISI Max (sec)	Variable time between trials. Type acceptable value: 2-100.
Standard Events	Enables the system to alert you when stimulation procedure arrives at some standard events.

The following screen shows a test consisting of 2 sequences, each comprising of 4 trials:

Figure 31: A Limits Method Test

Test statistics are hidden by default.

The bottom of the screen displays the total records (sequences) in the current program.

To view the statistics details, place the cursor at the bottom end of the statistics tab and drag it down.

Click the **Tack** icon at the upper right of the screen to lock or unlock the statistics display (indicated by the circle in Figure 31).

Following are the statistic details:

Figure 32: Statistical analysis of results

The following information is displayed:

- Sequence index.

- Modality – WS (warm sensation); CS (cold sensation); HP (hot pain).
- Number of recorded trials.
- Averaged temperature – In each of the sequence trials, the subject stops the temperature change once perceiving a predefined sensation. The temperatures at which the subject stopped the stimulations are averaged to yield the value of the threshold.
- Variance and STD (Standard Deviation) – Statistical measures of the variation in the distribution of the temperatures that are averaged to give the threshold. Variance and STD are calculated for a finite sample.

It is possible to remove a Limits Trail using the Delete button on the PC key board. Refer to section 6.4.3, page 56 for details.

7.6.2 Levels

In this method, the system generates a number of stimuli of changing intensity according to the subject response. With each stimulus, the subject receives a stimulation of varying intensity which is determined according to his previous response. Test is terminated after predefined temperature step size and number of alternations is achieved. For a method explanation, refer to section 2.7.2, page 29.

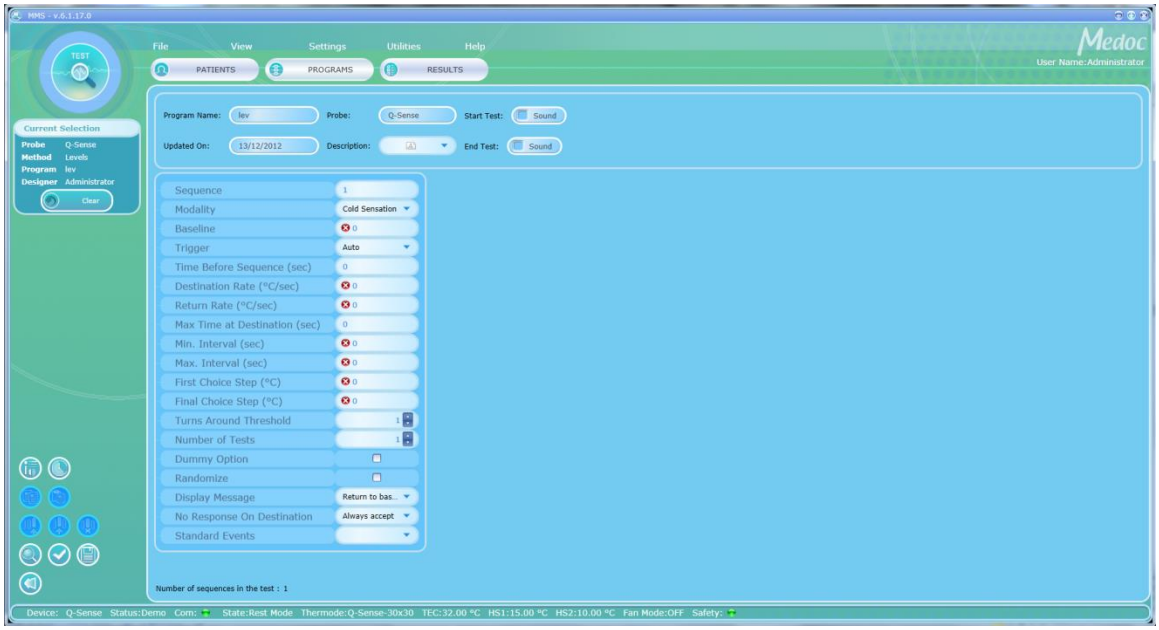


Figure 33: Program Menu – Levels

When adding or editing programs, follow these rules:

Enter meaningful information in the Program Description section of the screen.

Define all the parameters of a sequence for that sequence to be valid.

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.

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

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

Table 13: Program Details

Parameter	Description
Program Name	Displays the name of the program (editable).
Probe	Displays the probe that is used in 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.
Start test/End test	Defines if these events are indicated by Sound.

Table 14: Program Parameters

Parameter	Description
Modality	Two different types of sensation can be delivered to the subject: Warm sensation; Cold sensation.
Baseline (°C)	Temperature from which each new stimulation sequence begins – between 28°C to 40°C for Q-sense thermode.
Trigger	Defines the trigger type: Auto or Manual.
Time Before Sequence (sec)	The time interval before the first trial of the current sequence between 0 to 600 seconds.
Destination Rate (°C/sec)	Defines the temperature rate of increase or decrease per second, from the baseline until the current destination temperature. Type an acceptable value: ..... 0.1 to 2°C/Sec for Q-sense thermode Increasing temperature or 0.1 to 1°C/Sec for Q-sense thermode Decreasing temperature

Return Rate (°C/sec)	Defines the temperature rate of increase or decrease per second, from the destination temperature, down to the baseline. Type an acceptable value: ..... 0.1 to 2°C/Sec for Q-sense thermode Increasing temperature or 0.1 to 1°C/Sec for Q-sense thermode Decreasing temperature
Max. Time at Destination (sec)	Defines the maximum duration in seconds, between the time that the temperature reached the destination and the time it returned to the baseline. In case a YES response was detected, the maximum time will not complete, and the temperature will return to the baseline and continue to the next trial. Acceptable value: 0 to 600, and according to safety temperature – time limitations.
Min. Interval (sec) / Max. Interval (sec)	Variable time between trials. Actual time is set randomly in between the min. and max. values.
First Choice Step (°C)	The initial step size that is used until the first YES response is detected. Acceptable value: 0.2 – 5 °C
Final Choice Step (°C)	The fixed step size that is used in the final Turns Around Threshold. Acceptable value: 0.1 – 2 °C
Turns Around Threshold	The number of turns (YES to NO or NO to YES) at the Final Choice Step which is required to complete the test.
Number of Tests	The number of tests in a sequence – between 1 to 5.
Standard Events	Enables the system to alert you when stimulation procedure arrives at specific standard events.
Dummy Option	Enables dummy stimulus to increase test reliability. Dummy frequency is randomized, and it has average of 10%.
Randomize	Randomizes number of tests in order to increase sequence reliability.
Display Message	Determine when message to test subject is displayed on screen. Available options: **Destination** – Display message upon reaching trail destination temperature **Return to Baseline** – Display message upon trail return to baseline temperature
No Response on Destination	Define program behavior if subject responds after the **Maximum Time at Destination** is over. Relevant only if **Maximum Time at Destination** is larger than 0 and **Display Message** is set to Destination. **Always Accept** – Accept subject's response and continue the test ..... **Always Repeat** – Ignore subject's response and repeat the same trial again **Manually Select** – Manually select whether the response should be accepted (press 'A') or ignored (press 'I').

The following screen shows a sequence of Levels Method Test:

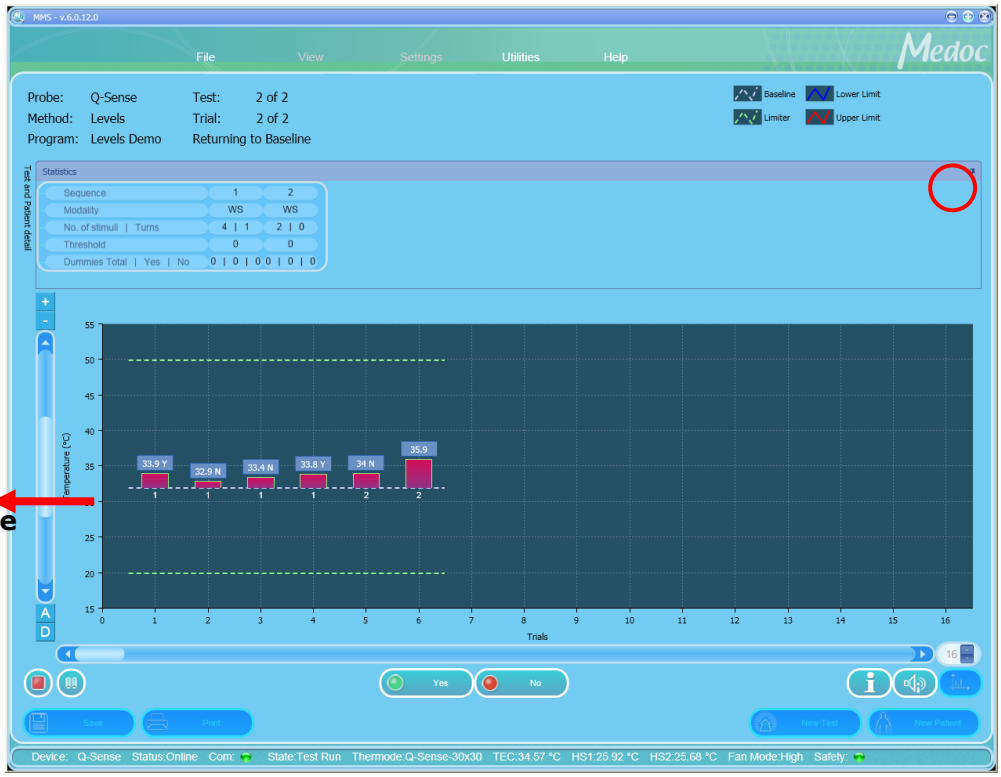


Figure 34: A Levels Method Test

Test statistics are hidden by default.

The bottom of the screen displays the total records (sequences) in the current program.

To view the statistics details, place the cursor at the bottom end of the statistics tab and drag it down.

Click the **Tack** icon at the upper right of the screen to lock or unlock the statistics display (indicated by the circle in Figure 31).

Following are the statistic details:

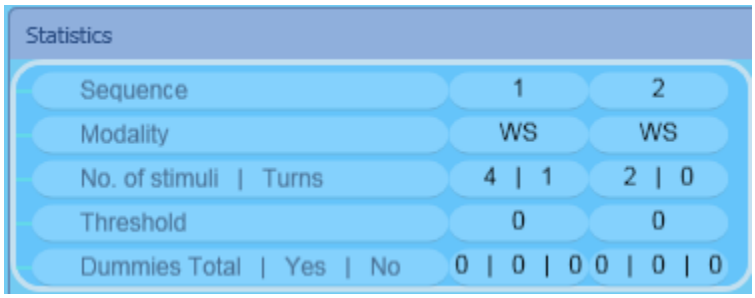


Figure 35: Statistical Analysis of the Results

The following information is displayed:

- Sequence index.
- Used modality – WS (warm sensation); CS (cold sensation).
- Number of recorded stimuli and number of turns.
- Threshold – In test trial, the subject response is recorded. The threshold is calculated as the average response of the last two trials.
- Dummies – The total number of dummy stimuli and their response type (Yes or No).

7.6.3 Thermal Sensory Limen (TSL)

In this method, the system generates warm sensation and cold sensation stimuli, alternating according to the subject response. The stimuli direction changes after each subject response. For a method explanation, refer to section 2.7.3, page 29.

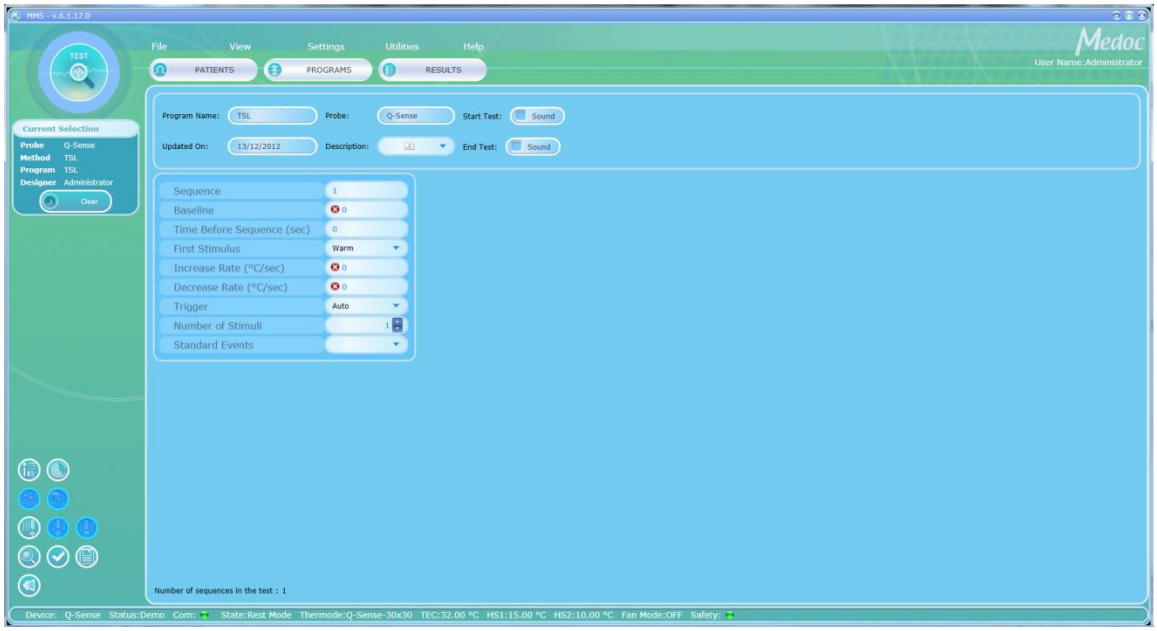


Figure 36: Program Menu – TSL

When adding or editing programs, follow these rules:

Enter meaningful information in the Program Description section of the screen.

Define all the parameters of a sequence for that sequence to be valid.

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.

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

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

Table 15: Program Details

Parameter	Description
Program Name	Displays the name of the program (editable).
Probe	Displays the probe that is used in 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.
Start test/End test	Defines if these events are indicated by Sound.

Table 16: Program Parameters

Parameter	Description
Baseline Temperature (°C)	Temperature from which each new stimulation sequence begins – between 28°C to 40°C for Q-sense thermode.
Time Before Sequence (sec)	The time interval before the first trial of the current sequence. Ranges between 0 to 600 seconds.
First stimulus	Determines whether the TSL test will start with warm or cold stimulus.

Increase Rate (°C/sec)	Defines the temperature rate of increase per second, from the destination temperature down to the baseline. Type an acceptable value: .0.1- 2°C/sec for Q-sense thermode.
Decrease Rate (°C/sec)	Defines the temperature rate of decrease per second, from the baseline until a response is recognized. Type an acceptable value: .. 0.1-1°C/Sec for Q-sense thermode
Number of stimuli	The number of required subject responses until test termination.
Standard Events	Enables the system to alert you when stimulation procedure arrives at specific standard events.

The following screen shows a sequence consisting of TSL Method Test:

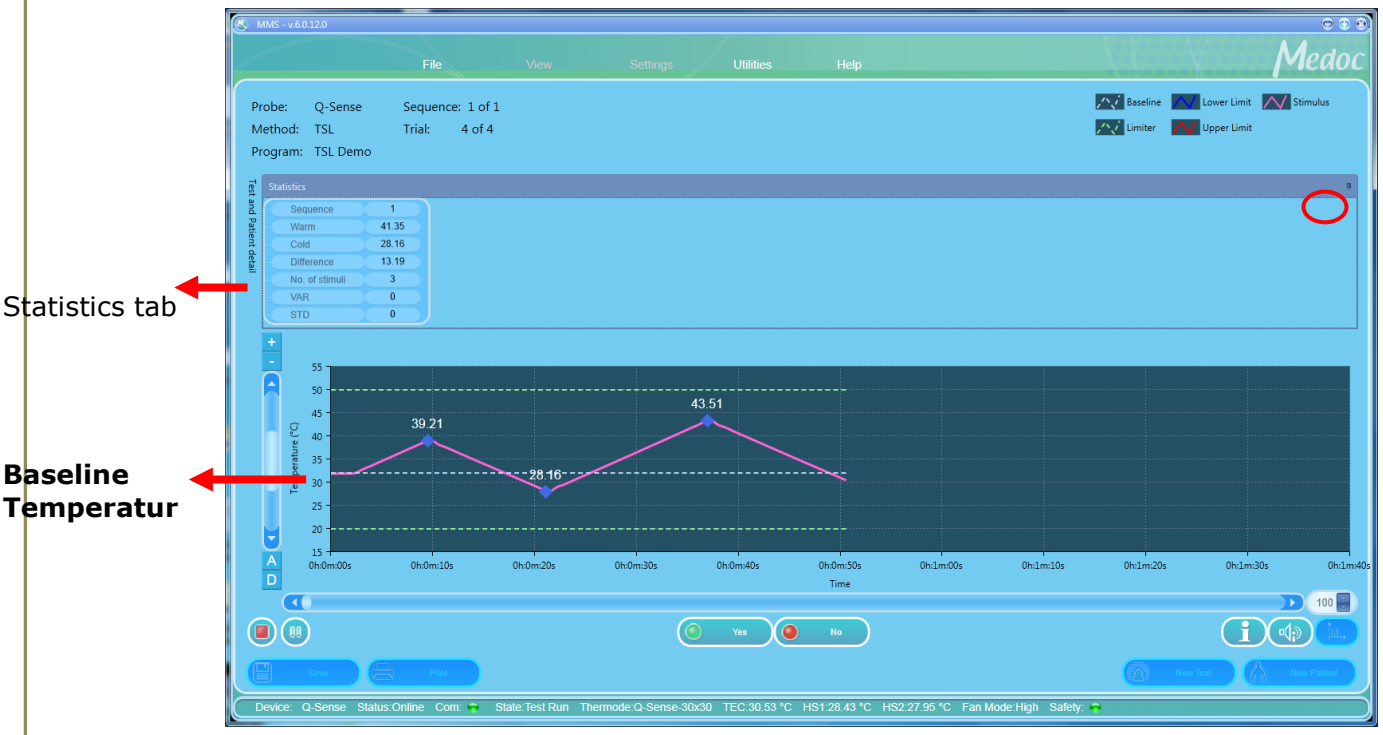


Figure 37: A TSL Method Test

Test statistics are hidden by default.

The bottom of the screen displays the total records (sequences) in the current program.

To view the statistics details, place the cursor at the bottom end of the statistics tab and drag it down.

Click the **Tack** icon at the upper right of the screen to lock or unlock the statistics display (indicated by the circle in Figure 37).

Following are the statistic details:

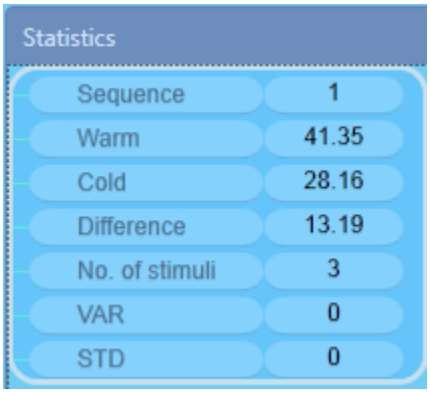


Figure 38: Statistical Analysis of the Results

The following information is displayed:

- Sequence index.
- WS (warm sensation) – Threshold
- CS (cold sensation) – Threshold
- D – the absolute difference between WS and CS
- Number of recorded stimuli.
- Variance and STD (Standard Deviation) – Statistical measures of the variation in the distribution of the temperatures that are averaged to give the threshold.

7.6.4 Ramp and Hold

In this method, the temperature rises (or falls) to a predetermined destination, at a predetermined rate, remains there for a predetermined duration, and proceeds to the next destination. For an example graph and an explanation of the method, refer to section 2.7.4, page 30.

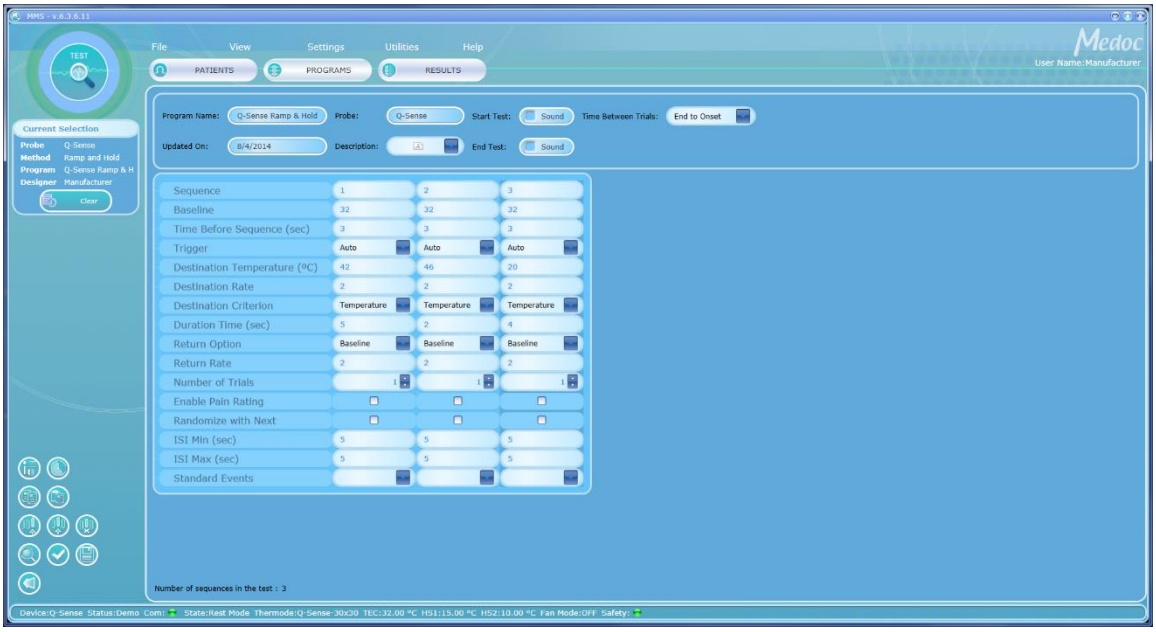


Figure 39: Program Menu – Ramp and Hold

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

Table 17: Program Parameters

Parameter	Description
Baseline (°C)	Temperature from which each new stimulation sequence begins. – Between 28°C to 40°C for Q-sense thermode.
Time before sequence (sec)	The time interval before the first trial. Valid range: 0 to 600 (sec).
Trigger	Trigger mode: • Automatic – the stimulus will start automatically after the defined Inter Stimulus Interval (ISI). • Manual – The operator must initiate the onset of the stimulus after the defined ISI
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.
Destination rate (°C/Sec)	Defines the temperature change rate from the baseline to destination temperature. 0.1 to 1°C/Sec for Q-sense thermode.
Destination criterion	Temperature: The system recognizes that it has reached the target temperature, by monitoring the temperature. Time: The system recognizes that it has reached the target temperature, by referring to the theoretical time that is required to reach the destination temperature according to the selected rate.
Duration time (sec)	Defines the duration for Thermode temperature to remain at destination temperature before returning to baseline. Valid range: 0 to 600 (sec)
Return option	Defines whether the temperature returns to the baseline or proceeds to the destination temperature of the next sequence. Select the relevant option from the drop-down menu. Note that when the "next destination" option is selected certain fields become inactive, because they are no longer relevant (for example, the **Number of Trials** turns to '**1**').
Return Rate (°C/Sec)	Defines the temperature change rate from the destination temperature back to baseline. 0.1 to 1°C/Sec for Q-Sense thermode
Number of Trials	The number of trials per sequence. Valid range: 1 to 100
Enable Pain Rating	Enables pain rating patient response at the end of the duration time of each trial Advanced options are available for configuration with specific license. See section 25.4 page 180
Randomize with next	Randomize trials with next sequence
ISI Min (sec)	Minimum Inter-Stimulus-Interval (ISI). Valid range: 0 to 600 (sec)

Parameter	Description
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	Enables the system to alert you when stimulation procedure arrives at specific standard events.

Note that this program is available only with special license and not a part of basic Q-Sense configuration

7.6.5 VAS Search

In this method, the temperature of the first stimulus rises (or falls) to a predetermined destination, at a predetermined rate, remains there for a predetermined duration, and returns to baseline. Patient estimation of perceived magnitude of sensation is recorded for the first stimulus. The intensity of the next stimulus is determined by patient response being higher or lower than the desired pain rating. For a method explanation, refer to section 2.7.5 page 31.

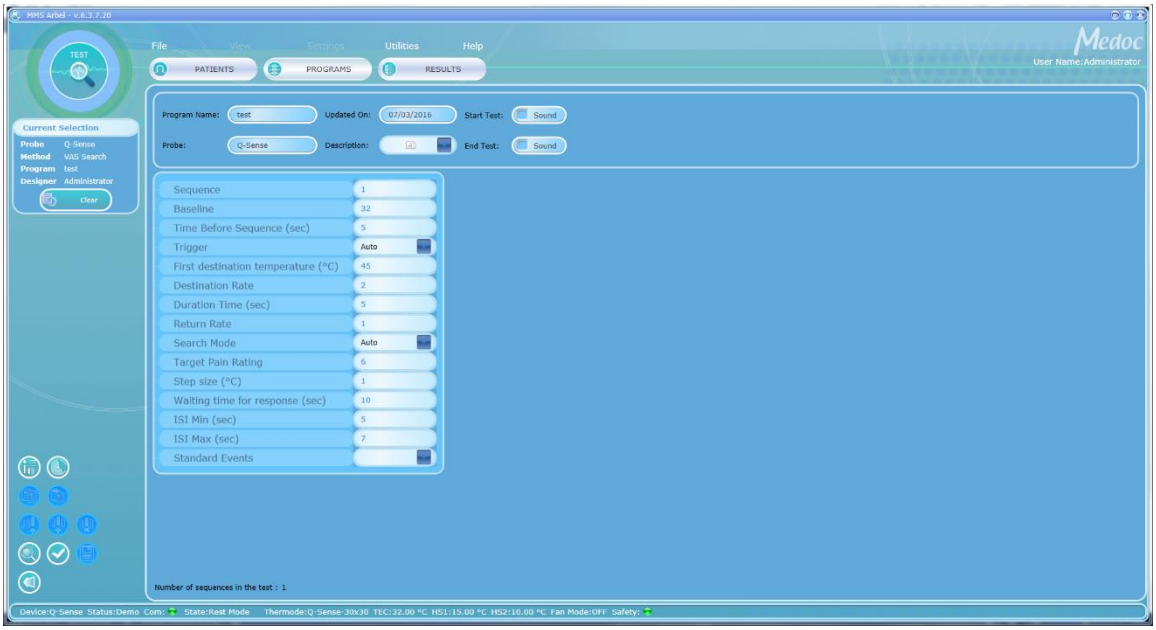


Figure 40: Program Editor – VAS Search

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

Table 18: Program Parameters

Parameter	Description
Baseline (°C)	Temperature from which each new stimulation sequence begins. Valid range: 28°C to 40°C
Trigger	Trigger mode: • Automatic – the stimulus will start automatically after the defined Inter Stimulus Interval (ISI).

	• Manual – The operator will initiate the onset of the stimulus after the defined ISI.
First destination temperature (°C)	Defines the destination temperature for the first trial. Valid range is limited by safety limitations and depends on the duration time.
Destination Rate (°C/sec)	Defines the temperature change rate from the baseline to destination temperature. Valid range: 0.1 to 2°C/Sec
Duration Time (sec)	Defines the duration for Thermode temperature to remain at destination temperature before returning to baseline. Valid range: 0 to 600 (sec)
Return Rate	Defines the temperature change rate from the destination to baseline temperature. Valid range: 0.1 to 1°C/Sec
Search Mode	Search mode: • Automatic – starting from the second trial, the stimulus parameters will be defined automatically by the predetermined target pain rating and step size. • Manual – At the end of each trial the user will define the destination temperature of the next trial, until the desired pain rating is reached. The user also decides when to finish the program (i.e. when the desired pain rating is achieved). In manual mode the 'Target Pain Rating' and 'Step size' parameters become dimmed.
Target Pain Rating	Relevant for Automatic search mode only. Defines the pain rating that needs to be reached. If the actual pain rating of the current trial is lower than 'Target Pain Rating' value, the temperature of the next trial will increase by the Step Size (see below) and vice versa. Valid range: 1 - 100
Step Size (°C)	Relevant for Automatic search mode only. Determines the step size by which the temperature will increase/ decrease in every new trial. The direction of the temperature change will depend on the difference between the target and the actual pain ratings (see above in 'Target Pain Rating' description) Valid range: 0.1 – 10 (°C)
Waiting time for response (sec)	Time for which the pain rating dialog will remain on the screen waiting for user to respond.
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 7.6.7

Note that this program is available only with special license and not a part of basic Q-Sense configuration

7.6.6 Chaining Programs

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.

For a method explanation, refer to section 2.7.6, Page 32.

As can be viewed in Figure 41, 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 19: 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.

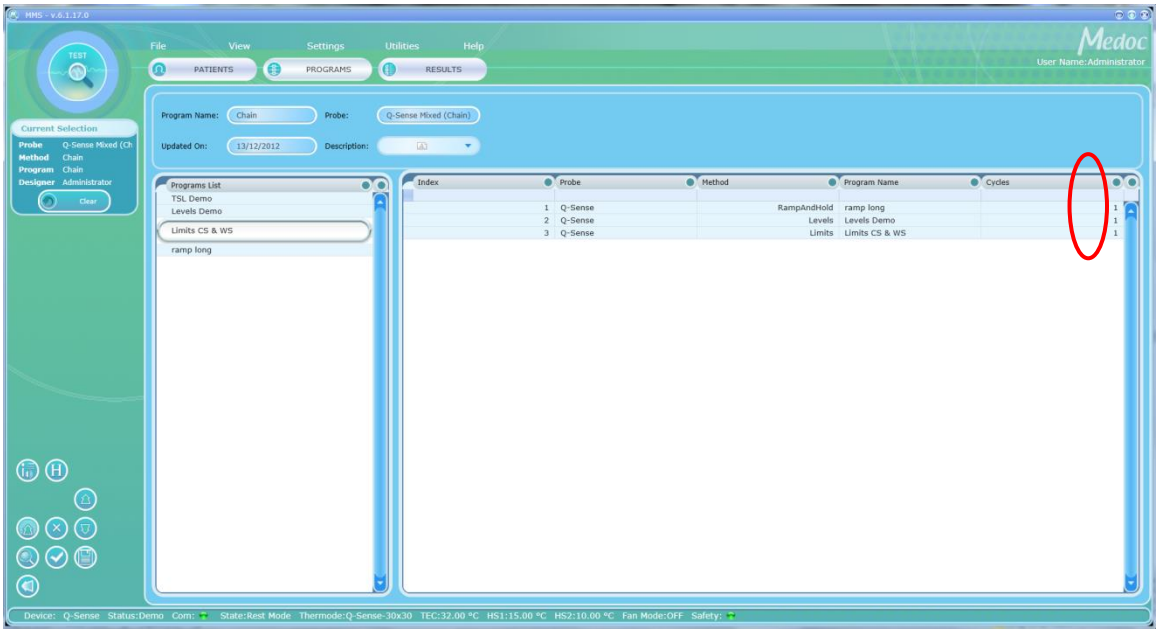


Figure 41: Program Chain Editor

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 20: Program Details

Column	Description
Program name	The program name (editable).

Column	Description
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 21: 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).

7.6.7 Next Sequence Definition

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

Figure 42: Program Editor Next Sequence Definition

Two checkboxes are available and unchecked by default:

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

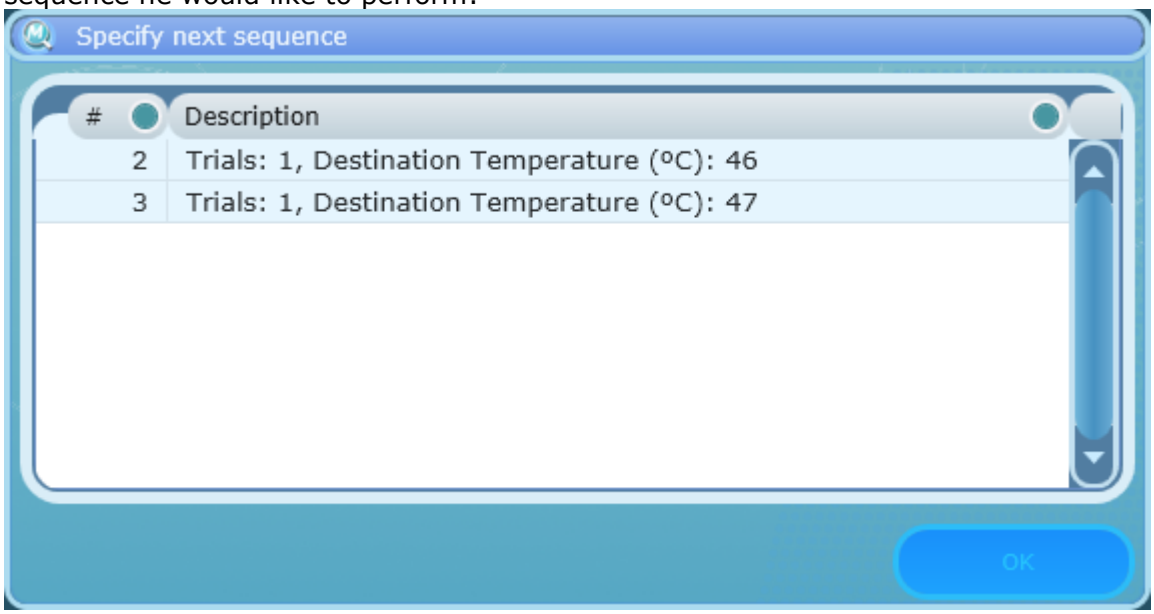


Figure 43: Manual Next Sequence definition

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

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

7.7 Standard Events

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

Every event is also marked on the screen during the test by an asterisk (*).

7.7.1 Standard Event Configuration

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

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

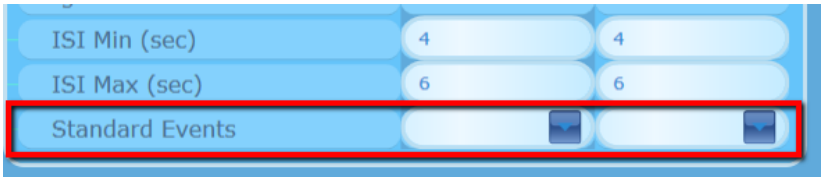


Figure 44: Standard Events in Program Editor

3. Click the arrow on the left to open the standard event editor.
   For each event that you want to configure mark the Sound column to activate.
4. Click anywhere on the screen to close the Standard Events dialog.
5. The available standard events vary according to the test method. For a list of the available standard events according to the program type continue to the following section.

7.7.2 List of Standard Events according to Program Type

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

Table 22: List of standard events according to program type

Program Method	Standard Events	Description
Limits	**Onset**	The start of each trial in the sequence
Levels	**Onset**	The start of each trial in the sequence
TSL	**Destination**	Subject response was detected
Ramp and Hold (optional)	**Onset**	The start of each trial in the sequence *Note: In current release that is the only Standard Event available for Ramp and Hold.*
	Destination	Thermode temperature reached target temperature *Note: Will be available in next release*
	End of duration	End of duration at target temperature *Note: Will be available in next release*

7.8 Test Instructions

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

To enter test instructions, perform to the following procedure. All other (standard) tests will be assigned the standard instructions, as entered in section 10.3.2, page 129.

11. 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.

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

Figure 45: Test Instructions Editor

13. To edit the text instructions,

    13.1. Deselect the relevant **Use default instruction** checkbox.
    The **Edit** button becomes enabled.

    13.2. Click the **Edit** button.
    The text editor is displayed, displaying the standard instructions.

    13.3. Edit the instructions as required, as described in section10.3.2.1, page129.

14. To replace the audio instructions,

    14.1. Deselect the relevant **Use default instruction** checkbox.
    The **Play** button becomes an enabled **Browse** button.

    14.2. Click the **Browse** button.
    The Audio instruction screen is displayed.

    14.3. Replace the instructions file, as described in section 10.3.2.2, page 130 .

7.9 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 ats.

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 Q-SENSE programs follow the procedure below:

1. Open the program list in the **Programs** screen.

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

In order to import Q-SENSE 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:

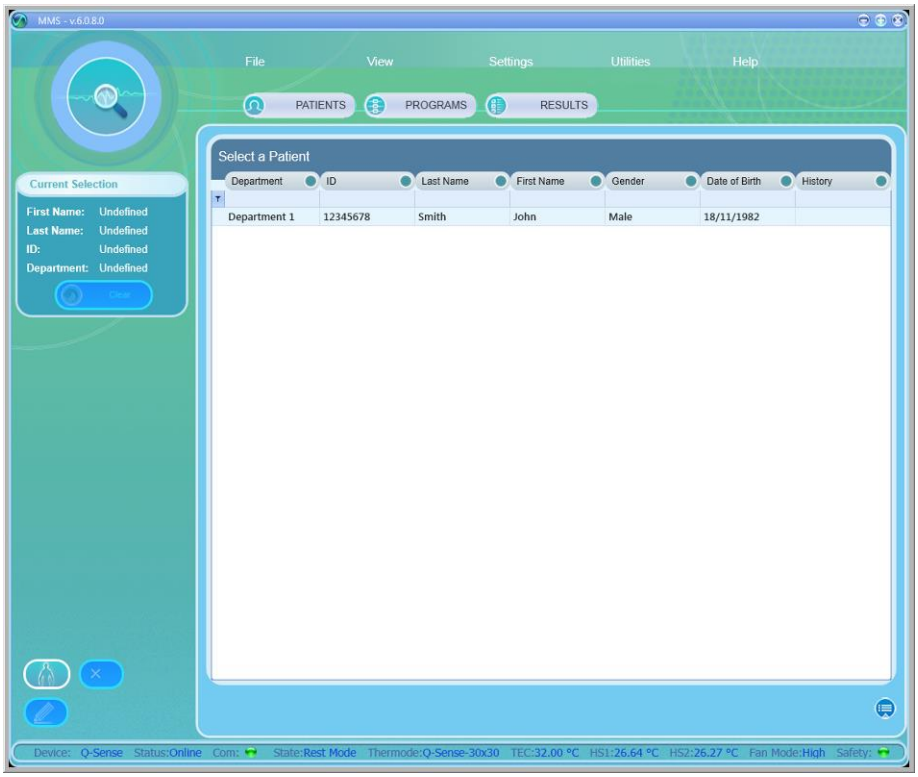


Figure 46: Patients List

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 section10.1.2, page 106.

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:

	New Patient
	Delete Patient
	Edit Patient details
 or 	Show or Hide Patient preview

- Current Selection control - displays the selected program information.

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

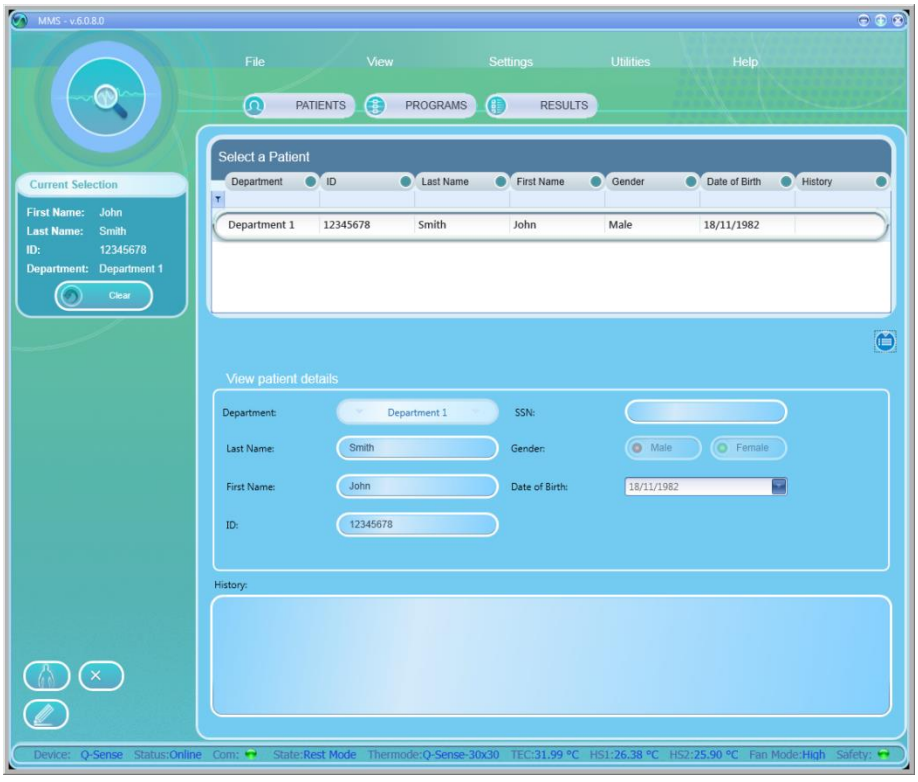


Figure 47: Patient Management – Patient details preview

Patient details cannot be edited from the preview control screen

8.2 Add New Patient

To add a patient to the patients list:

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

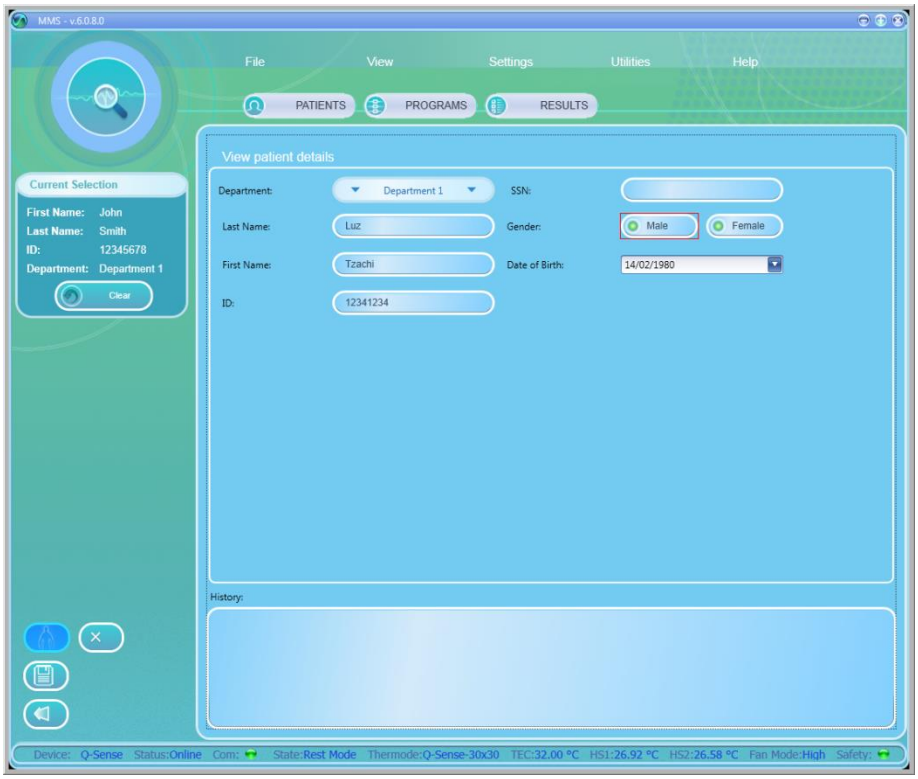


Figure 48: Patients Editor Screen

16. 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.

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

18. 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 86.

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 106.

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 mange (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 116.

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

Figure 49: Edit Department Menu

2. To define a new department, click the **New** button; then, type the department name.
3. To rename a department, select the required department; then click the **Rename** button. (Available only for System Administrators and Medical Supervisors)
4. 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)
5. To close the dialog, click the **Close** button.

8.6 ICD 9 Management

MEDOC Main Station enables you to mange (Add, Edit, Remove) your ICD 9 code.

ICD 9 management is enabled according to the authorization level of the current user. For further information, refer to section 10.1.5, Page 116.

1. From the **Utilities** menu at the top of the screen, select the **ICD 9** option.
   The *Edit departments* menu is displayed:

Figure 50: Edit ICD Menu

2. To define a new ICD 9 code, click the **New** button; then, type the ICD 9 code and description, and click OK.
3. To edit an ICD 9 code, select the required code; then click the **Edit** button.
   (Available only for System Administrators and Medical Supervisors). A code and description window is opened. Edit the relevant fields and click OK.
4. To remove a code, select the required department; then click the **Remove** button. At the prompt click the **OK** button.
   (Available only for System Administrators and Medical Supervisors)

   To close the dialog, click the **Close** button.

8.7 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 ats.

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 Q-SENSE 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 Q-SENSE 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:

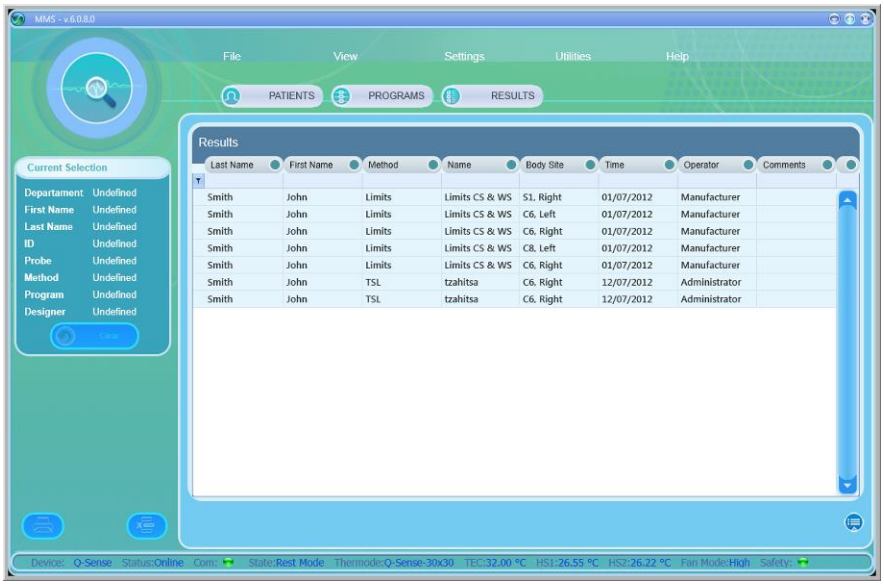


Figure 51: Results List

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 110.

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:

 or 	Show or Hide Results preview
	Print Selected Results file / files
	Delete selected Results file from Q-SENSE Data Base

- Current Selection control - displays the selected program information.

When you open the Results preview bar, the following screen is displayed:

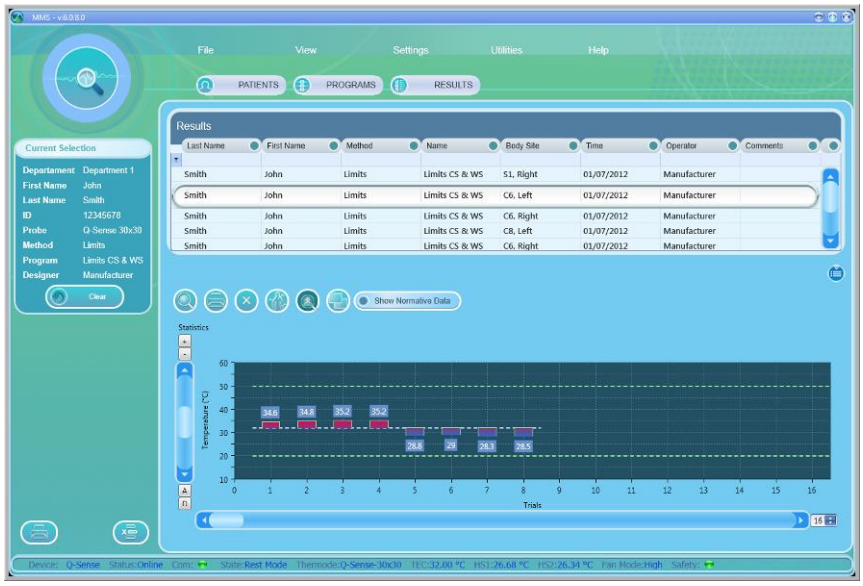


Figure 52: Result preview display

The following options are available:

	View Patient 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 Graph
Check box	Show / Hide Normative Data display.

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 ats. 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 Q-SENSE 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 Q-SENSE 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**	Q-Sense
5	**Model**	30x30
6	**Method**	Limits
7	**Program**	Q-sense limits test
8	**Start time**	18/06/2012 11:25
9	**End time**	18/06/2012 11:30
10	**Patient Details**	
11	**Department**	Department 1
12	**ID**	12345678
13	**Last Name**	Smith
14	**First Name**	John
15	**Gender**	Male
16	**Date of Birth**	18/11/1982
17	**History**	
18	**Program Details**	
19	**Program Name**	Q-sense limits test
20	**Probe**	Q-Sense
21	**Description**	
22	**Updated on**	18/06/2012 11:24
23	**Body Site**	
24	**Body Site Main**	Undefined
25	**Body Site Side**	Undefined
26		

Figure 53: Export Result File Opened In Excel – Description Tab Sample

Data: containing the detailed information of the test:

	A	B	C	D	E	F	G	H	I	J
1	Timestamp [msec]	Heater [C]	Tec [C]	Water [C]	PCB [C]	COVAS	Baseline [C]	LimiterMax [C]	LimiterMin [C]	Events
2	15		31.99			0				
3	30		31.99	0		0	32	50	20	
4	35		31.99	0		0	32	50	20	
5	55		31.99	0		0	32	50	20	
6	75		31.99	0		0	32	50	20	
7	80		31.99	0		0	32	50	20	
8	95		31.99	0		0	32	50	20	
9	115		31.99	0		0	32	50	20	
10	135		31.99	0		0	32	50	20	
11	155		31.99	0		0	32	50	20	
12	175		31.99	0		0	32	50	20	
13	190		31.99	0		0	32	50	20	
14	195		31.99	0		0	32	50	20	
15	215		31.99	0		0	32	50	20	
16	235		31.99	0		0	32	50	20	
17	245		31.99	0		0	32	50	20	
18	255		31.99	0		0	32	50	20	
19	275		31.99	0		0	32	50	20	
20	295		31.99	0		0	32	50	20	
21	300		31.99	0		0	32	50	20	
22	315		31.99	0		0	32	50	20	
23	335		31.99	0		0	32	50	20	
24	355		31.99	0		0	32	50	20	
25	375		31.99	0		0	32	50	20	
26	395		31.99	0		0	32	50	20	
27	410		31.99	0		0	32	50	20	
28	415		31.99	0		0	32	50	20	
29	435		31.99	0		0	32	50	20	
30	455		31.99	0		0	32	50	20	
31	465		31.99	0		0	32	50	20	
32	475		31.99	0		0	32	50	20	

Figure 54: Export Result File Opened In Excel – Data Tab Sample

In order to import Q-SENSE 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 55: 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.

   5.1. Print with Preview
   Print Preview is displayed according to the active template and test method. Refer to **10.1.3**, page **110** for details regarding Printing Options.
   Press the **Print** icon or select one of the export options.

   5.2. 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 Q-SENSE user to generate Reports of Q-SENSE tests.

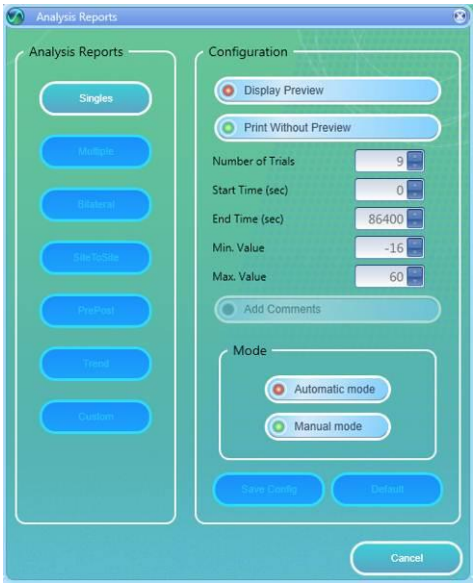


Figure 56: Analysis Report

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 section 10.1.3, page 110 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.	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.	1. Test Method: TSL, Levels, Limits 2. Selection of 2 result files 3. Identical Test Subject 4. Identical Test Program 5. Identical Main and Specific body site 6. Opposite body site sides

Report Type	Description	Restrictions
Site to Site	Compare test statistics of same test subject in two different Body Sites.	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
Pre / Post	Compare test statistics of same test subject and site, performed in different date and time	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.	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.	Vary according to report analysis • Contact Medoc Service for Details.

Reports Examples:

Print Date: 21/06/2012 11:25; Test Date: 18/06/2012 11:51
User: Administrator

Q-SENSE 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:

Program Details
Probe: Q-Sense - 30x30 Method: Levels Designer: Administrator
Program Name: Q-sense Levels
Description:

Body Site
Main Site: Undefined Side: Undefined Specific Site:

Test Results

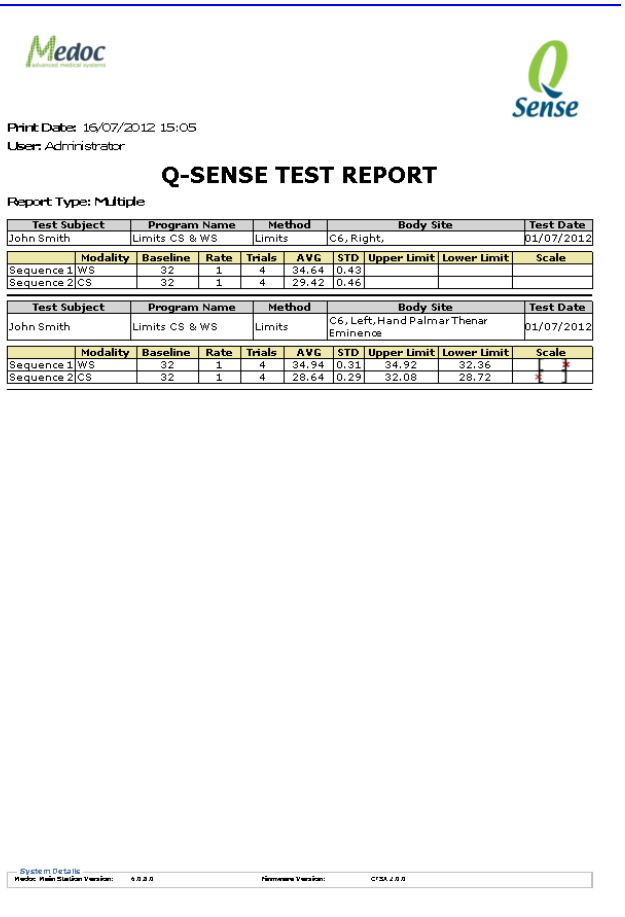
	Modality	Baseline	Rate	Turns	AVG
Test # 1	CS	32	1	2	27.16

Test Graph

Comments

System Details

Figure 57: Single Results Report



Print Date: 16/07/2012 15:05
User: Administrator

Q-SENSE TEST REPORT

Report Type: Multiple

Test Subject	Program Name	Method	Body Site	Test Date
John Smith	Limits CS & WS	Limits	C6, Right,	01/07/2012

	Modality	Baseline	Rate	Trials	AVG	STD	Upper Limit	Lower Limit	Scale
Sequence 1	WS	32	1	4	34.64	0.43			
Sequence 2	CS	32	1	4	29.42	0.46			

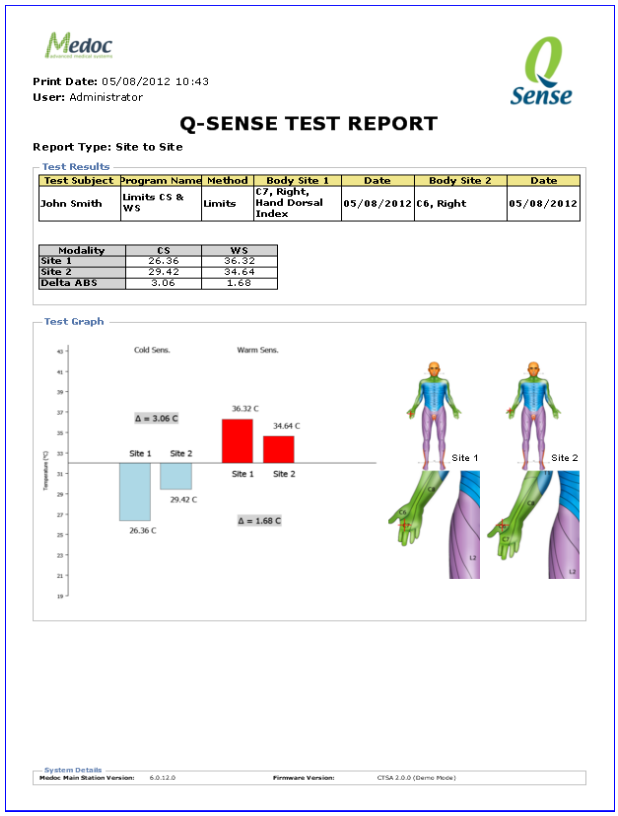
Test Subject	Program Name	Method	Body Site	Test Date
John Smith	Limits CS & WS	Limits	C6, Left, Hand Palmar Thenar Eminence	01/07/2012

	Modality	Baseline	Rate	Trials	AVG	STD	Upper Limit	Lower Limit	Scale
Sequence 1	WS	32	1	4	34.94	0.31	34.92	32.36	
Sequence 2	CS	32	1	4	28.64	0.29	32.08	28.72	

System Details

Figure 58: Multiple Results Report

Analysis Report Examples:



Medoc

Print Date: 05/08/2012 10:43
User: Administrator

Q Sense

Q-SENSE TEST REPORT

Report Type: Site to Site

Test Results

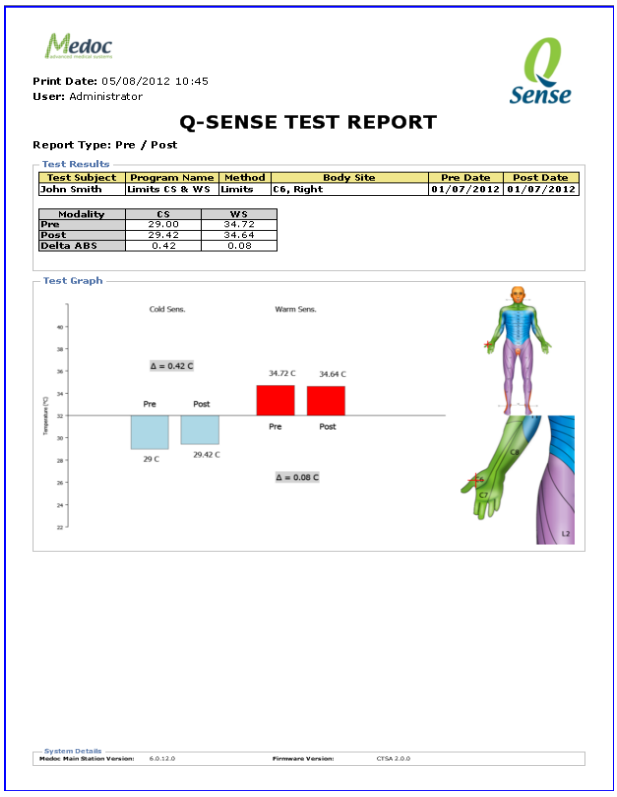
Test Subject	Program Name	Method	Body Site 1	Date	Body Site 2	Date
John Smith	Limits CS & WS	Limits	C7, Right, Hand Dorsal Index	05/08/2012	C6, Right	05/08/2012

Modality	CS	WS
Site 1	26.36	36.32
Site 2	29.42	34.64
Delta ABS	3.06	1.68

Test Graph

System Details
Medoc Main Station Version: 6.0.12.0
Firmware Version: CTSA 2.0.0 (Demo Mode)

Figure 59: Site to Site Results Report



Medoc

Print Date: 05/08/2012 10:45
User: Administrator

Q Sense

Q-SENSE TEST REPORT

Report Type: Pre / Post

Test Results

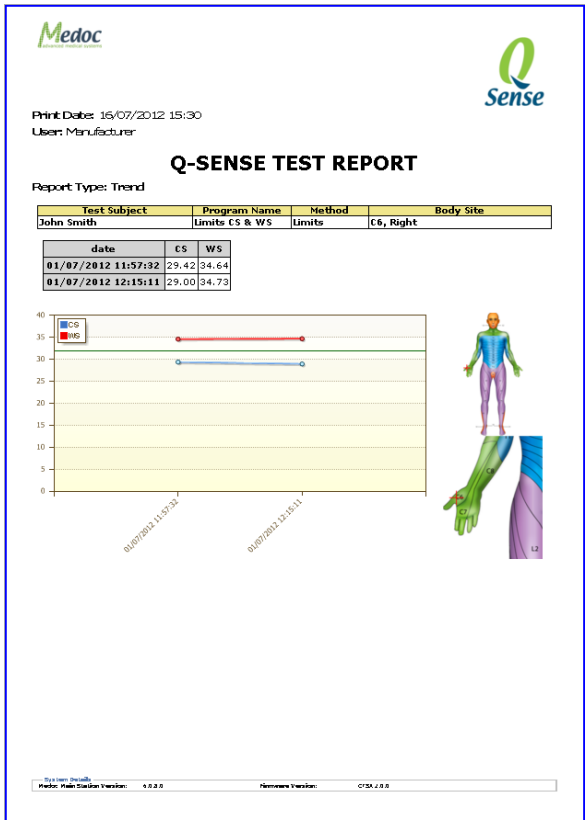
Test Subject	Program Name	Method	Body Site	Pre Date	Post Date
John Smith	Limits CS & WS	Limits	C6, Right	01/07/2012	01/07/2012

Modality	CS	WS
Pre	29.00	34.72
Post	29.42	34.64
Delta ABS	0.42	0.08

Test Graph

System Details
Medoc Main Station Version: 6.0.12.0
Firmware Version: CTSA 2.0.0

Figure 60: Pre / Post Results Report



Medoc

Print Date: 16/07/2012 15:30
User: Manufacturer

Q Sense

Q-SENSE TEST REPORT

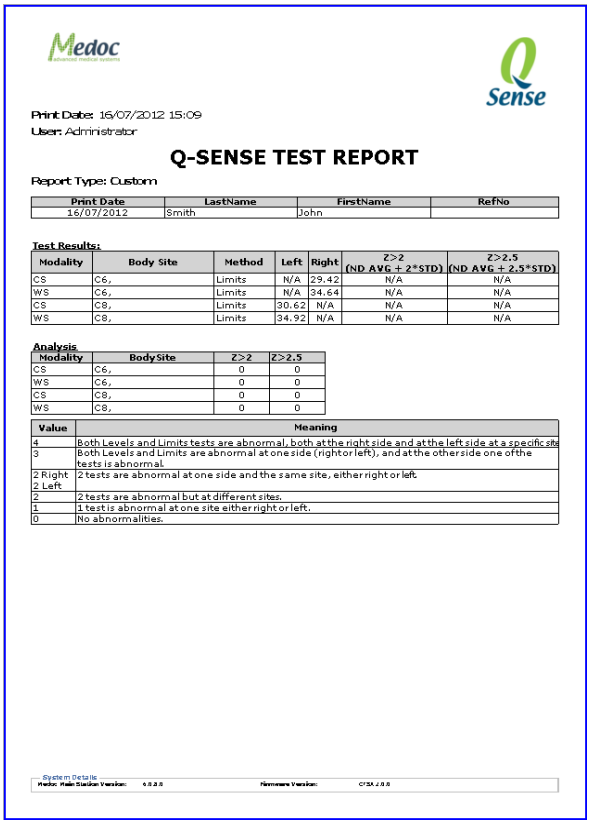
Report Type: Trend

Test Subject	Program Name	Method	Body Site
John Smith	Limits CS & WS	Limits	C6, Right

date	CS	WS
01/07/2012 11:57:32	29.42	34.64
01/07/2012 12:15:11	29.00	34.73

System Details
Medoc Main Station Version: 6.0.0.0
Firmware Version: CTSA 2.0.0

Figure 61: Trend Results Report



Medoc

Print Date: 16/07/2012 15:09
User: Administrator

Q Sense

Q-SENSE TEST REPORT

Report Type: Custom

Print Date	LastName	FirstName	RefNo
16/07/2012	Smith	John	

Test Results:

Modality	Body Site	Method	Left	Right	Z>2 (ND AVG + 2*STD)	Z>2.5 (ND AVG + 2.5*STD)
CS	C6,	Limits	N/A	29.42	N/A	N/A
WS	C6,	Limits	N/A	34.64	N/A	N/A
CS	C8,	Limits	30.62	N/A	N/A	N/A
WS	C8,	Limits	34.92	N/A	N/A	N/A

Analysis

Modality	Body Site	Z>2	Z>2.5
CS	C6,	0	0
WS	C6,	0	0
CS	C8,	0	0
WS	C8,	0	0

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

System Details
Medoc Main Station Version: 6.0.0.0
Firmware Version: CTSA 2.0.0

Figure 62: Custom Report Results

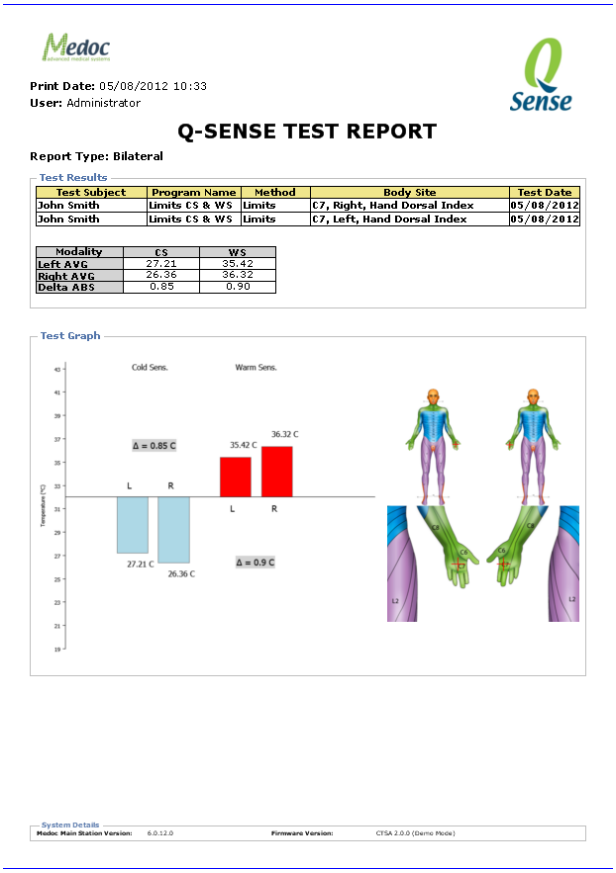


Figure 63: Bilateral Results Report

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 TSL.

End Time (Manual Mode)	Determine the display of test graph end time for time based tests. Available for TSL.
Min. Value. (Manual Mode)	Determine display of the test graph minimum temperature. Available for TSL.
Max. Value. (Manual Mode)	Determine display of the test graph maximum temperature. Available for TSL.
Add Comments	Allow adding comments for the generated report. Available for all report type beside Singles.

9.3.1.3 Custom Reports Configuration

1. Save the custom report you would like to use
2. Go to Settings --> Software Settings --> Report Options tab
3. Select the required template from the left column and click Copy Template

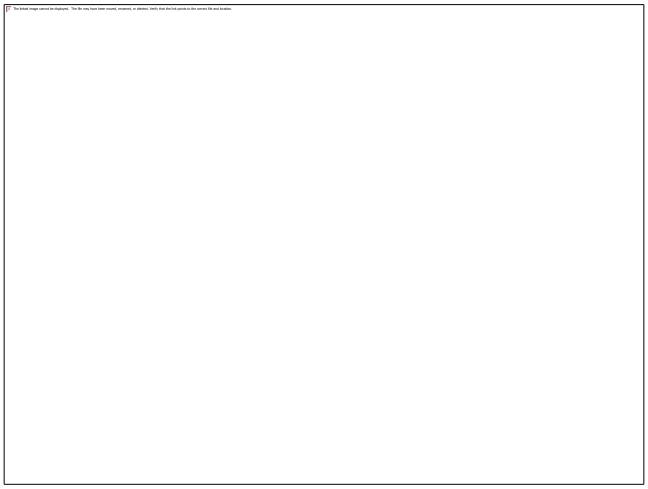


Figure 64: Custom Report Configuration

4. A copy of the Multiple template will be added to the list (can be renamed).
5. Select the copy and click Edit Template.

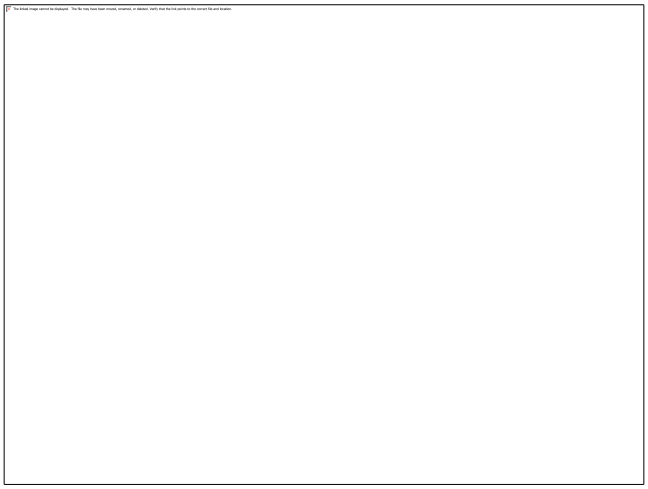


Figure 65: Custom Report Configuration

6. The report designer window will open. Go to the file menu and select "open report". Select the report template saved in step 1.
7. After the report template opens, close the report designer window with the X on the right corner. There is no need to save.
8. Back in the report options window, select the copy again and click the >> button (move right).

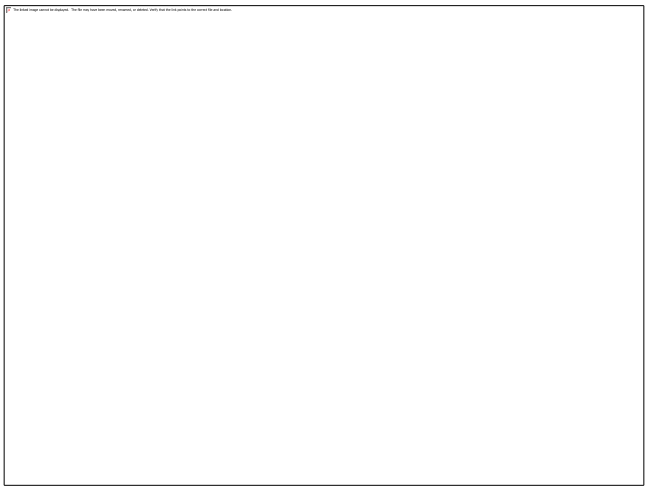


Figure 66: Custom Report Configuration

9. Click Apply and close the report options. This report will now replace the existing report of the selected type

10 System Configuration

Q-SENSE system configuration is performed via three different setting menus:

1. Software Settings see section **10.1**, Page **105.**
2. Hardware Settings see section **10.2**, Page **123.**
3. Test Settings see section **10.3**, Page **125.**

The available system configuration options depend on user authorization level. Refer to section 10.1.5.2, page 115.

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 67: Software Settings Dialog

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

- Q-Sense
- Authorization
- Report Options
- Results Field
- Patient's Fields

10.1.1 Communication

The General Software Settings screen enables you to configure general software, database and communication settings (see Figure 67 above). Configuration options are described in the table below.

Table 25: Software Settings - General

Parameter	Description
Q-Sense COM Port	Set the COM port to which the Q-SENSE system is connected to the computer: **Auto Detect** – Automatically scan all available ports. **Simulator** – Work in Demo Mode (MEDOC Main Station will not connect to Q-SENSE system. **COM X** – Set the specific port the Q-SENSE is connected to. Click **Connect** to establish communication.
Calibration COM Port	Set the COM port to which the Thermometer is connected to. This is only required during the Automatic Calibration Procedure. Click the **Check** button to test communication between the computer and YSI thermometer. Green light indicates "pass", and Red indicates "fail". For further details refer to Automatic Calibration section in the Service Manual.

10.1.2 Patient Fields

Configure the available fields for entering patient details and determine which fields will be displayed in the patient list. The configuration of patient fields affect all users (see section 10.1.5, page 116), however every user can determine what fields to see when viewing the patient list.

To access Patient Field settings: from the top menu bar, select **Settings** and then **Software Settings**.

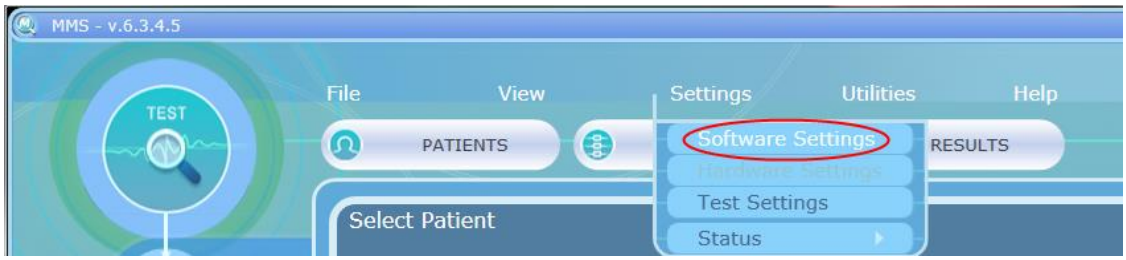


Figure 68: Open Software Settings

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

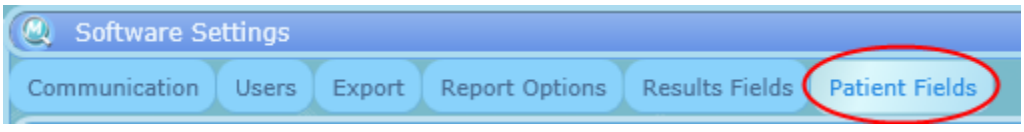


Figure 69: Software Settings - Patient Fields tab selection

The following window is displayed:

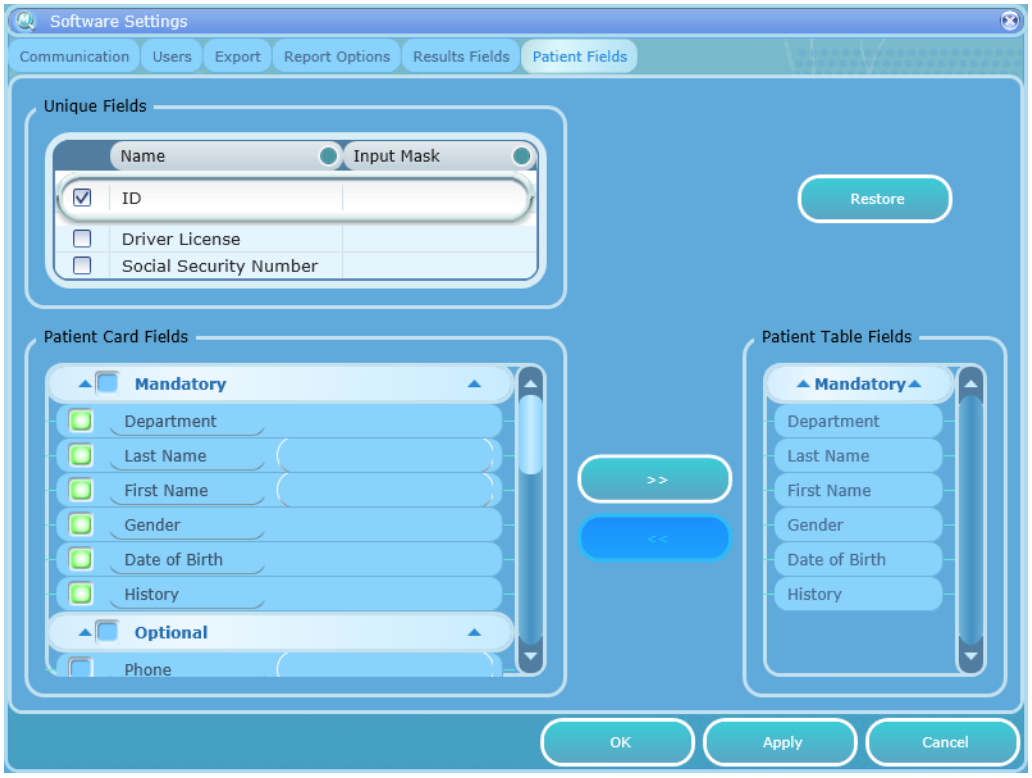


Figure 70: Software Settings - Patient Fields

Patient Fields consist of the following types:

Unique Fields – The selected 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 – the selected fields will be available when entering patient details.

1. **Mandatory fields** – these fields will be mandatory when creating a new patient card and entering the patient details. It will not be possible to save the patient card if one of the mandatory fields is not filled.
2. **Optional fields** – built in commonly used fields that can be added / removed from the patient card.
3. **User Defined fields** – similar to the optional fields, these customizable fields can be added or removed from the patient card. Rename the fields as needed.

Patient Table Fields – these are the fields will show in the patient list.

10.1.2.1 Add/Remove Patient Field

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.

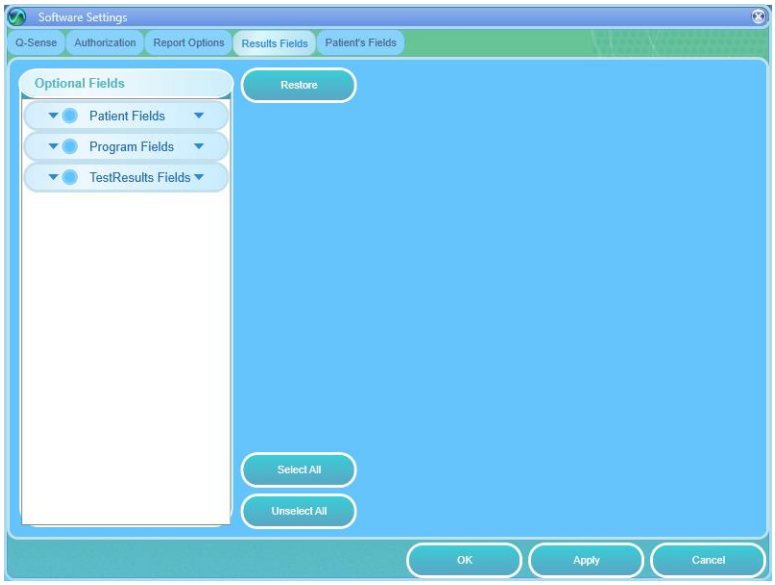


Figure 71: Results Fields Configuration Screen

Table 26: 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 **Ofptional 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 72: Report Options tab

Available Options:

Table 27: Report Options

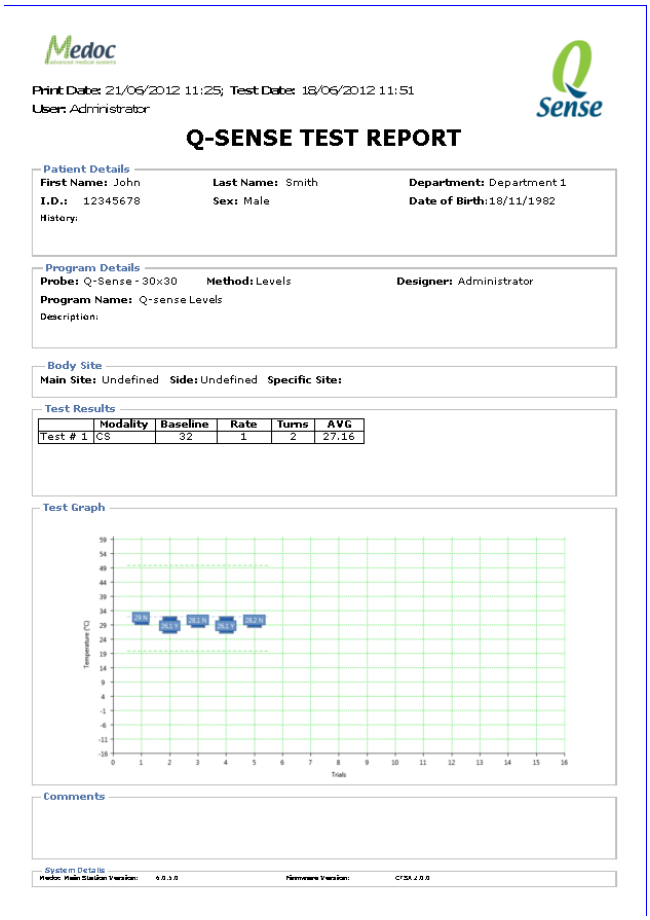
Parameter	Description
User Logo	Enables and configure display of customized user Logo to the report printouts
Report Templates Options*	Enables editing Detailed Report templates: 1. Manage Report templates data base 2. Edit custom made reports 3. Manage Active Templates list * Available Only when Detailed Report Option is selected

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 Q-SENSE 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.

Q-SENSE 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: 21/06/2012 11:25; Test Date: 18/06/2012 11:51
User: Administrator

Q-SENSE 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:

Program Details

Probe: Q-Sense - 30x30 Method: Levels Designer: Administrator
Program Name: Q-sense Levels
Description:

Body Site

Main Site: Undefined Side: Undefined Specific Site:

Test Results

	Modality	Baseline	Rate	Turns	AVG
Test # 1	CS	32	1	2	27.16

Test Graph

Comments

System Details

Figure 73: Detailed Report example

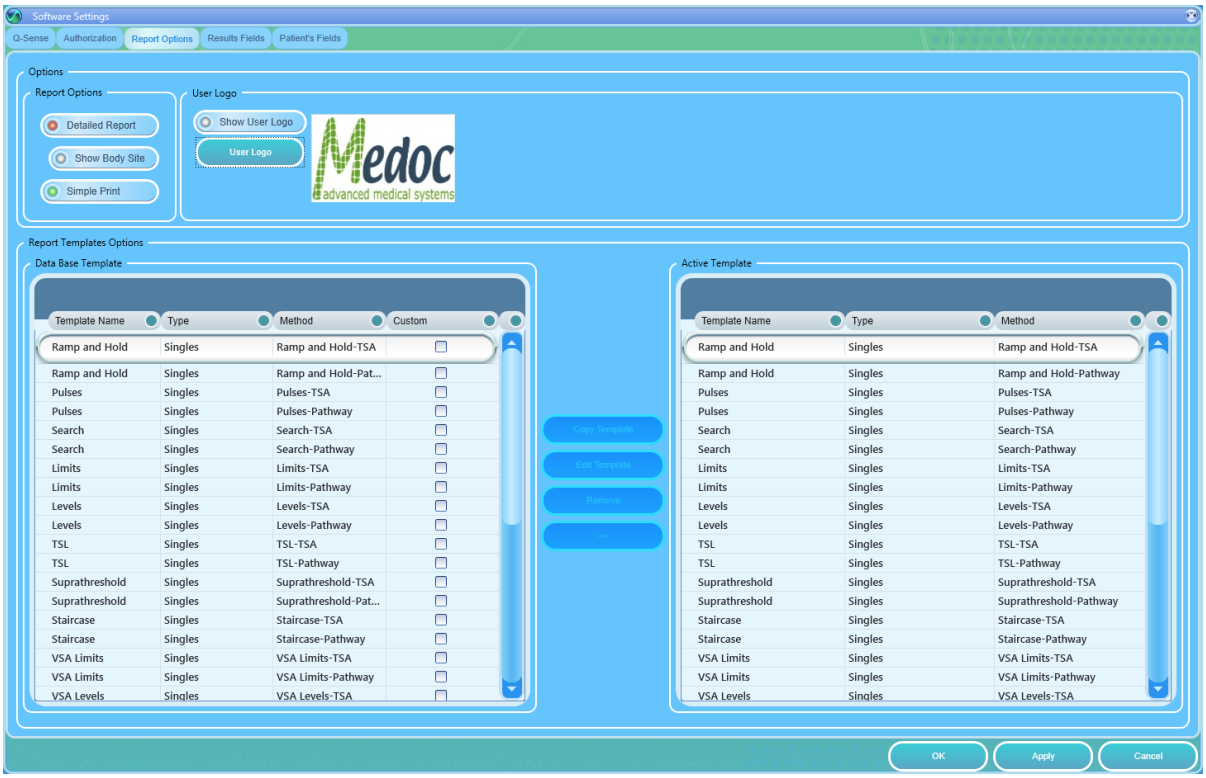


Figure 74: Detailed Report Options

The following actions are available in the Detailed Report:

Table 28: 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 Q-SENSE reports. Logo preview will appear on the right side when custom logo is in use. • 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.

10.1.4.1.1Data Base Templates

The data base templates option displays the available templates from the Q-SENSE 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 Q-SENSE data base contains a template for each of the Q-SENSE 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.

Q-SENSE 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 75: 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:

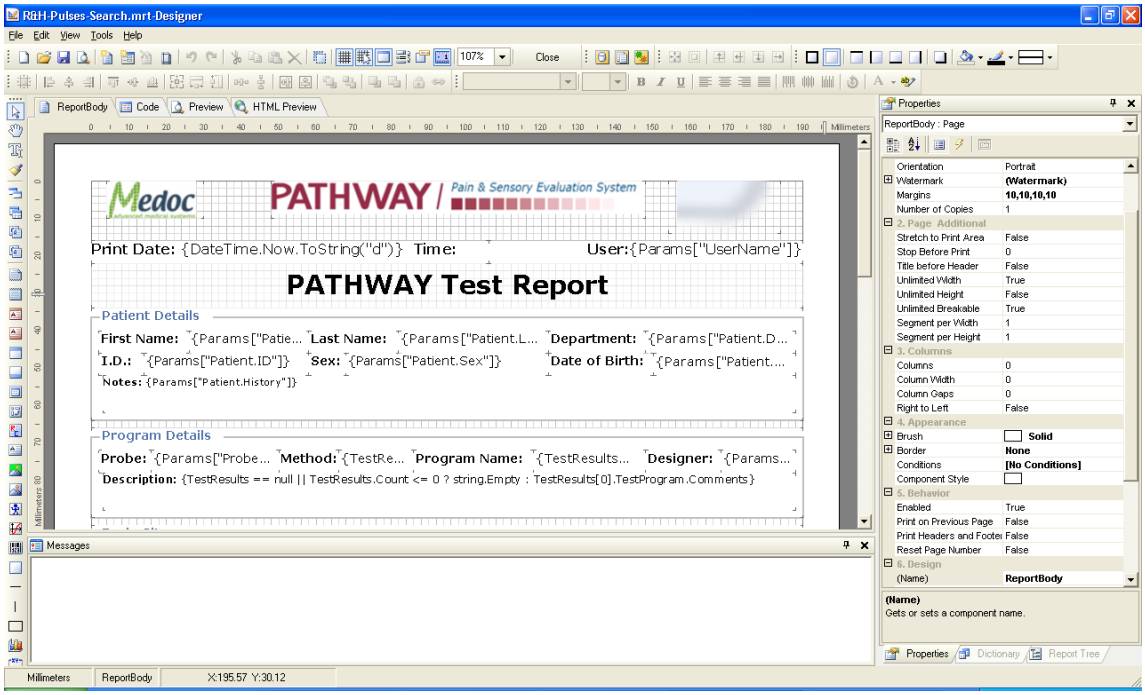


Figure 76: Report Editor Screen

7. Edit Report template according to your needs.

   7.1. All report parameters may be edited.

   7.2. All existing data may be accessed through the Q-SENSE 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 Q-SENSE data base (only custom templates can be deleted).

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

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.

10.1.5 User Management

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

There are four available authorization levels: Software Administrator, Biomedical Engineer, Medical Supervisor and Operator. Refer to Table 29 for a list of allowed and restricted actions according to user authorization level.

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

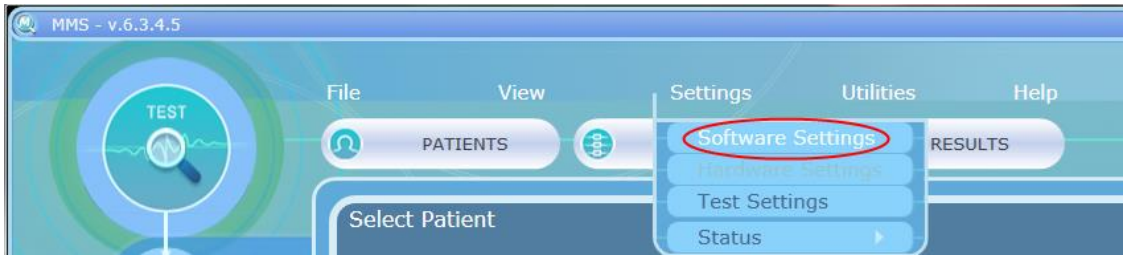


Figure 77: Open Software Settings

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

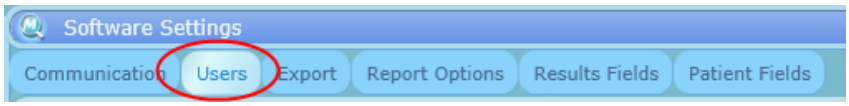


Figure 78: Software settings users tab selection

The following window will be displayed:

Figure 79: Software Settings Users Tab

10.1.5.1 Add\Remove Users

1. Click the "add user button" at the bottom of the user list 

Figure 80: Software Settings Add New User

2. Enter the following information:
   2.1. User Name – this will the name the user will use when logging in to Medoc Main Station.
   2.2. Last Name and First Name – these will be used for display and to identify actions performed by this user
   2.3. Role – Select a role or authorization level for this user. Note that a user can only create users with roles equal or lower than his/hers own authorization level. Refer to Table 29 for a list of roles and their allowed and restricted actions.
   2.4. Password – choose a password for this user which will be required when logging in to Medoc Main Station.
3. Click Apply to confirm
4. Continue to add users as needed by clicking the "add new user" button and entering the relevant information (repeat steps 1-3).
5. Click OK to end and close the user management panel.

Medoc Recommendations:

1. **Create Operator level users for each site**
2. **Create a Biomedical Engineer user for basic troubleshooting and calibration at the sites if needed.**
3. **Change the password to the default admin user**

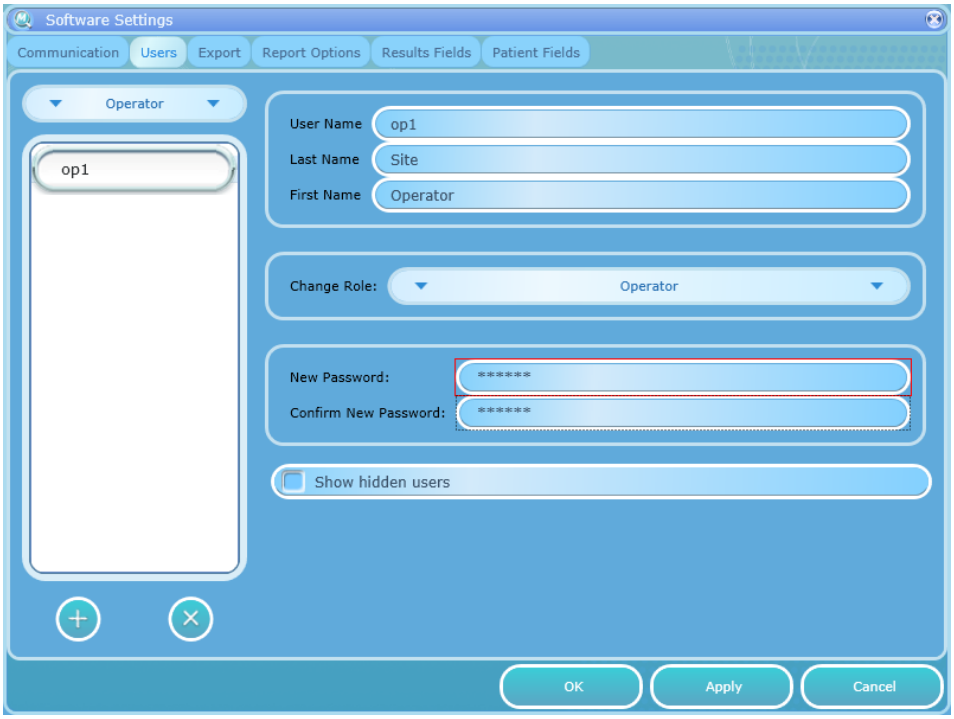


Figure 81: Software settings filled

To remove a user from the list, select the user and click the "delete selected user" button 

10.1.5.2 Authorization Levels

Users must be assigned to one of the following Authorization Levels or Roles, which will determine which actions are permitted and which actions are restricted.

1. Administrator – can perform all actions. Administrators have full control over the patients, programs and results, as well as software and hardware configuration (within the capabilities of Medoc Main Station).
2. Biomedical Engineer – intended for a user who may handle the technical operations such as Thermode calibration and certain hardware and software configurations. Biomedical Engineers cannot delete patients or results.
3. Medical Supervisor – intended for a user who may handle the medical or clinical operations such as program design. A medical supervisor will have limited access to hardware configurations.
4. Operators – intended for user who will only be operating the system, performing common tasks such as adding patients to the list and performing a tests. Operators cannot make any changes to software and hardware configurations and have limited access to patient, programs and results.

Table 29 below lists the main allowed and restricted actions for each role or Authorization Level.

Table 29: Authorization Levels (main actions)

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
Patient	Add Patient	√	√	√	√
	Edit Patient	√	√	√	√
	Delete patient	√	X	√	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
	Print	√	√	√	√
Test	View Patient Details	√	√	√	√
	View Program Details	√	√	√	√
	Clear	√	√	√	√
	Go to Test…	√	√	√	√
Tool bar - File	Export	√	√	√	√
	Import	√	√	√	√
	Export to Excel	√	√	√	√
	Print	√	√	√	√
	Log Off	√	√	√	√
	Exit	√	√	√	√
	Switch device	√	√	√	√
Tool bar - View	Test	√	√	√	√
	Patient	√	√	√	√

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
	Programs	√	√	√	√
	Results	√	√	√	√
Tool bar - Settings	**Software Settings**				
	Q-Sense				
	View	√	√	√	√
	Edit	√	√	√	√
	Patient's fields				
	View	√	√	√	√
	Edit	√	√	√	X
	Results fields				
	View	√	√	√	√
	Edit	√	√	√	X
	Report options				
	View	√	√	√	√
	Edit	√	√	√	X
	Authorization				
	View	√	√	√	√
	Add	√	√	√	X
	Edit	√	√	√	X
	Delete	√	√	√	X
	Hardware Settings				
	General				
	View	√	√	√	√
	Enable thermode	√	√	√	X
	Rest Mode temp.	√	√	√	X
	% duration …	√	√	√	X

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
	Safety				
	View	√	√	√	√
	Edit	✗	✗	✗	✗
	Thermode				
	View	√	√	√	√
	Edit	√	√	√	✗
	General	√	√	√	✗
	Edit LUT tables	✗	✗	✗	✗
	Manual calibration	√	√	√	✗
	Automatic calibration	√	√	√	✗
	Add new Thermode	√	√	√	✗
	Test settings				
	Instruction Configuration				
	View	√	√	√	√
	Edit	√	√	√	✗
	Body sites				
	View	√	√	√	√
	Edit	√	√	√	✗
	status				
	Demo	√	√	√	√
	On-line	√	√	√	√
	Department				
	Add Department	√	√	√	√
	Delete Department	√	✗	√	✗

Screen	Function	Software Administrator	Biomedical Engineer	Medical Supervisor	Operator
	Rename Department	√	X	√	X
	Normative data				
	View	√	√	√	√
	Edit	√	√	√	X
	Delete	√	√	√	X
	Import/Export	√	√	√	X
	Black Box				
	Software				
	View	√	√	√	√
	Export	√	√	√	√
	Q-SENSE 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, pulse duration and polarity; timeout limitations; detection delay, etc.

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

Figure 82: Hardware settings – General tab

The following options are available:

Table 30: Hardware Settings Tab Sheets

Parameter	Description
General	For setting default hardware parameters.
Safety	For displaying safety parameters.
Thermodes	For setting thermode parameters and calibration.

10.2.1 General

The following options are available in the General tab:

Table 31: Hardware Settings – General tab options

Parameter	Description
Reset temperature (ºC)	Sets the temperature in which the system remains, when it is on but not in use.

Parameter	Description
Ramp timeout (% of duration)	If Ramp temperature continues to be detected beyond this setting, an error message is displayed. The test is not aborted.
Thermode enabled	If the use of probe type is not possible (for example, because it is broken) its usage can be disabled by deselecting the checkbox.

10.2.2 Safety

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

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

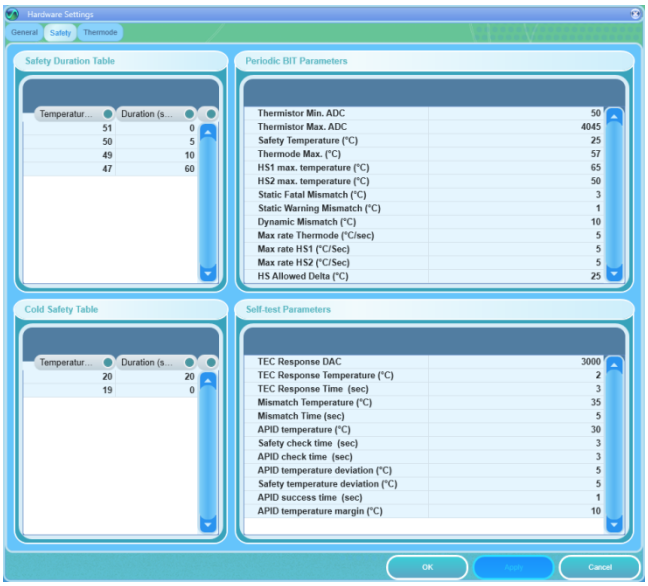


Figure 83: Hardware settings – Safety tab

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.

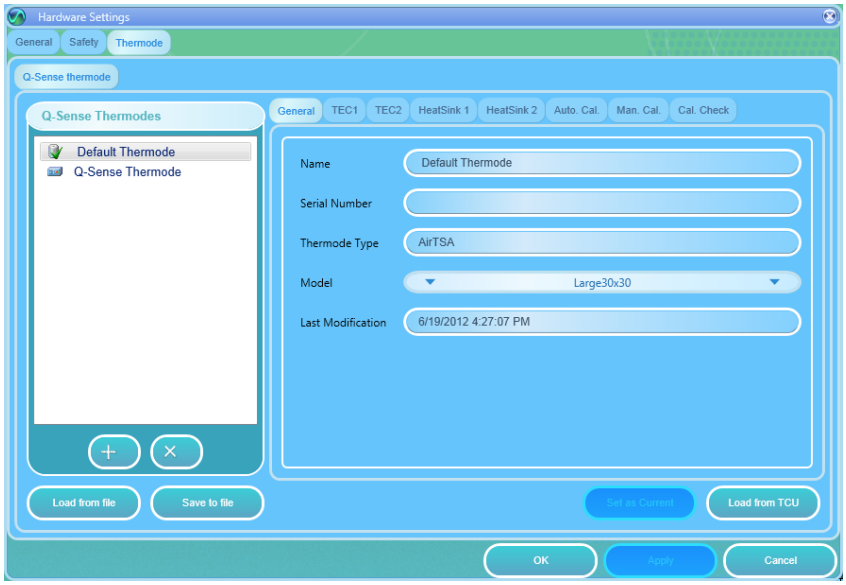


Figure 84: Hardware settings – Thermode tab

10.3 Test Settings

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

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

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

Test configuration– change how the test is performed and displayed

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

Body Sites – customize list of body sites.

10.3.1 Test Configuration

Control test behavior and appearance.

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

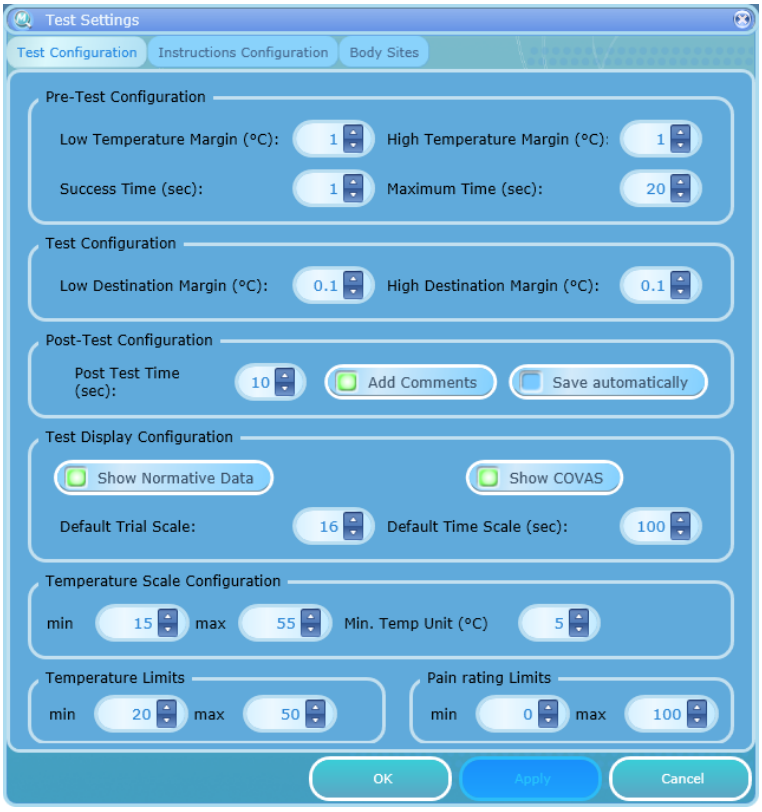


Figure 85: Test Configuration Settings

The following options are available:

10.3.1.1 Pre-test settings

Table 32: Pre-test parameters

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

10.3.1.2 Test Configuration

Table 33: 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 Configuration

Table 34: Post-test parameters

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

10.3.1.4 Test Display Configuration

Table 35: Test Display configuration

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

10.3.1.5 Temperature Scale Configuration

Table 36: Temperature Scale Configuration

Parameter	Description
Temperature Scale Range	Sets the default limits for the test graph.
Minimum Temp Unit	Sets the minimum resolution of the grid

10.3.1.6 Temperature Limits

Table 37: Temperature Limits

Parameter	Description
Temperature Limits	Sets the minimum and maximum temperature that is allowed during a tes. This parameter does not replace the safety limitation of the Q-Sense; it allows limiting the stimulus temperature to a specific range, according to unique requirements. In case the temperature violates the temperature limits, the following actions are taken by the Q-Sense system: Limits Protocol: stimulus is terminated and temperature returns to baseline temperature, and then continues to the next trial. The terminated trial is marked with an asterisk. The terminated trial will be taken into consideration when calculating test statistics. TSL Protocol: the temperature does not exceed the allowed range, according to the temperature limiter. If the temperature reaches the limiter the direction of the stimulus is changed automatically and the temperature is marked on the screen. The terminated trial will be taken into consideration when calculating test statistics. Ramp & Hold Protocol: upon verifying a program the test parameters are checked according to the current temperature limiter. In case a temperature limit of a test parameter is violated, an error message indicating the violated parameter is displayed.

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.

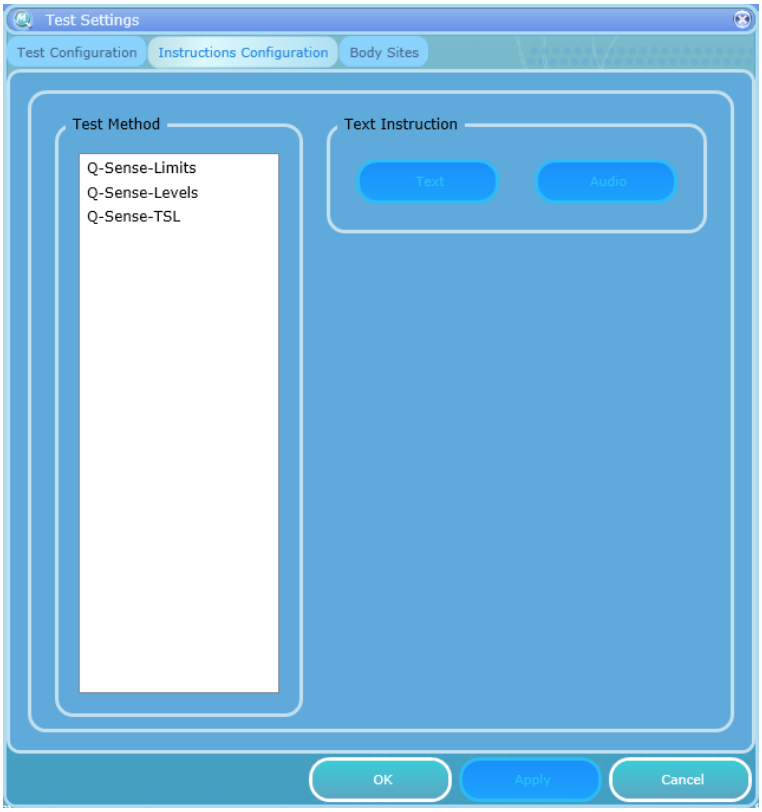


Figure 86: Instructions Configuration

Two formats are available:

- Text – a text (written) description.
- Audio – a vocal description, in wav, wma or mp3 format.

10.3.2.1 Text

To create text instructions for a test method:

20. Choose the desired test type –Limits test.
21. Click the **Text** button.
    The following screen is displayed:

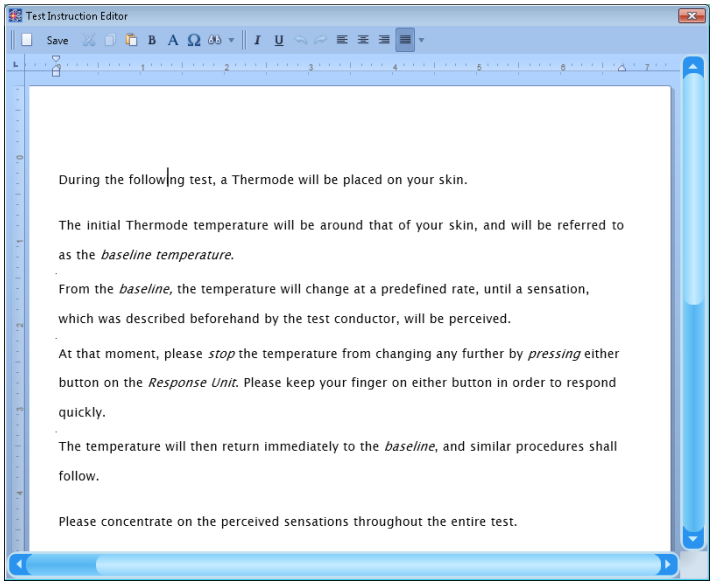


Figure 87: Test Instructions Editor

22. Enter the required text.
23. Click the **Save** button.
24. Close the window.

For editing Text instructions use the text editor.

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

Figure 88: 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 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

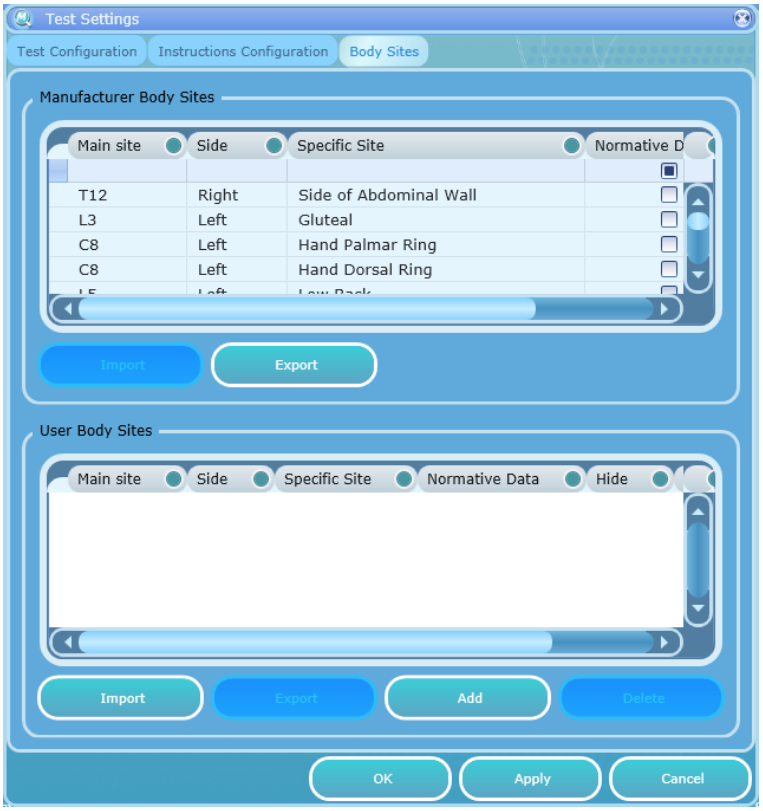


Figure 89: Body Sites Editor

10.3.3.1 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 Dermatomic 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.

- 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.

10.3.3.2 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 Dermatomic 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.

- 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 (Q-SENSE) version.
- Q-SENSE serial number.
- Supported Thermodes (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:

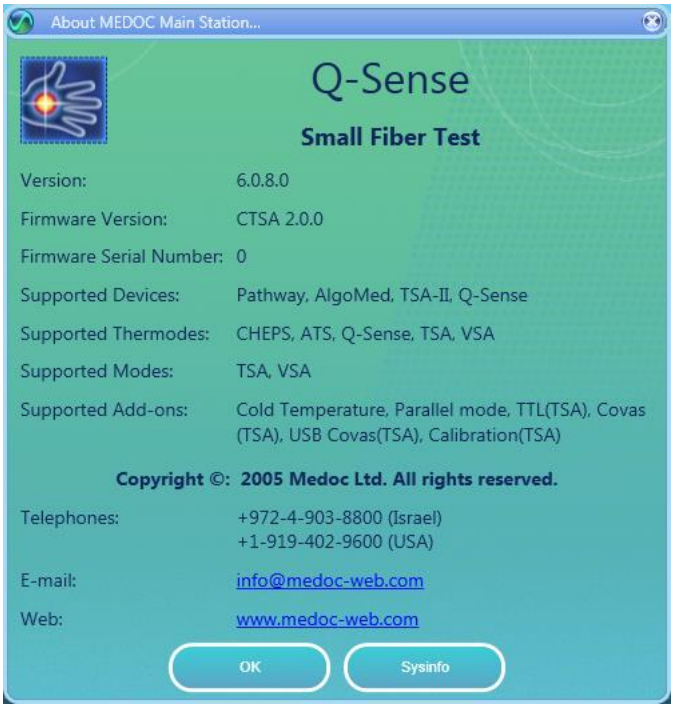


Figure 90: System Information

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:

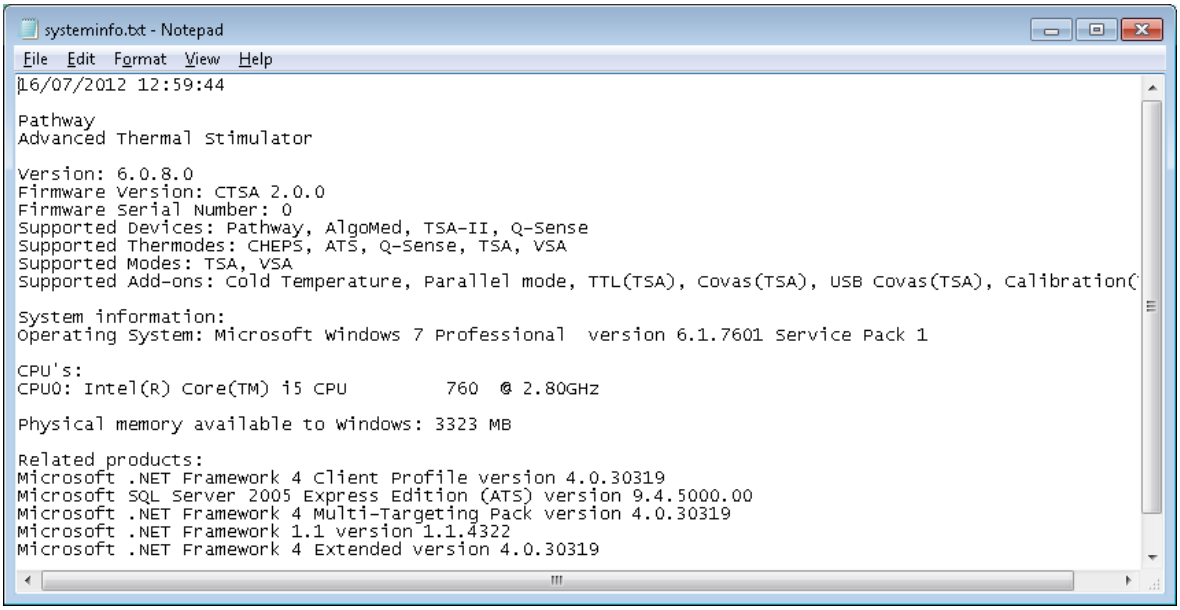


Figure 91: Sysinfo File Sample

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

12 The Black box (Logger)

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:

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

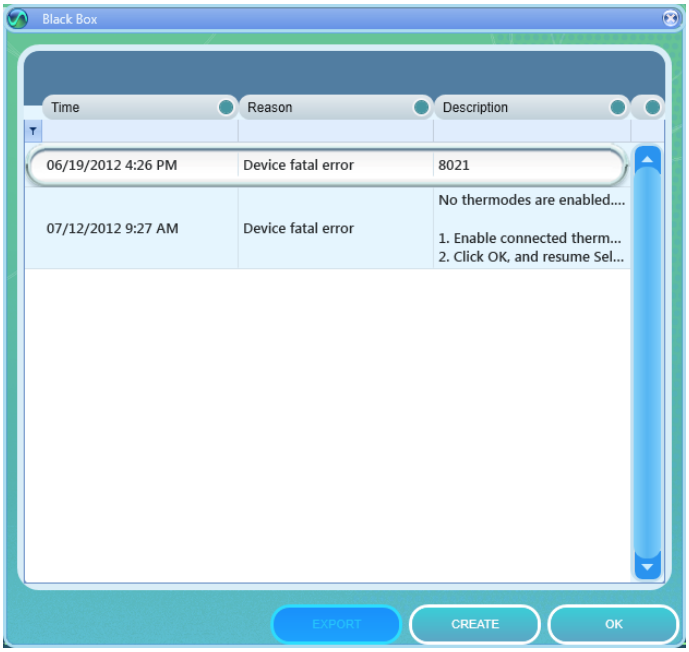


Figure 92: Black Box – Software

26. Select the entry to export and click **Export** button.
27. The **Save As** window is displayed.
28. 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.
29. After Export is completed, click **OK**.
30. To close the **Black Box** window, click the **OK** button.

13 Appendix A – Normative Data

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

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

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

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

13.1 Normative Data License Agreement

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

PEASE READ THIS AGREEMENT CAREFULLY.

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

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

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

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

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

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

1. Medoc is not responsible or liable for, and does not guarantee or underwrite, the accuracy, completeness or applicability of the information contained in the Normative Data.

2. Medoc is not responsible or liable for the use you make of the ND Feature, nor is it liable for your conclusions from such use.

3. Medoc is not responsible or liable for any clinical diagnostics reached or treatment given based on the Normative Data.

4. Any use of the ND Feature and the information contained therein is at the user's sole responsibility and liability.

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

13.2 Enable Normative Data

Normative Data is automatically enabled if you agreed to the terms and conditions during Medoc Main Station installation (see section 4.6). However, even if you decided not to enable Normative Data during installation, you can always enable later.

To enable normative data follow the instructions given below:

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

Figure 93: Normative Data Editor - Enable Normative Data

2. If normative data was not enabled during MMS installation, the tables will be blank. To enable Normative Data, click on **Enable normative data** (circled above). The following screen is displayed:

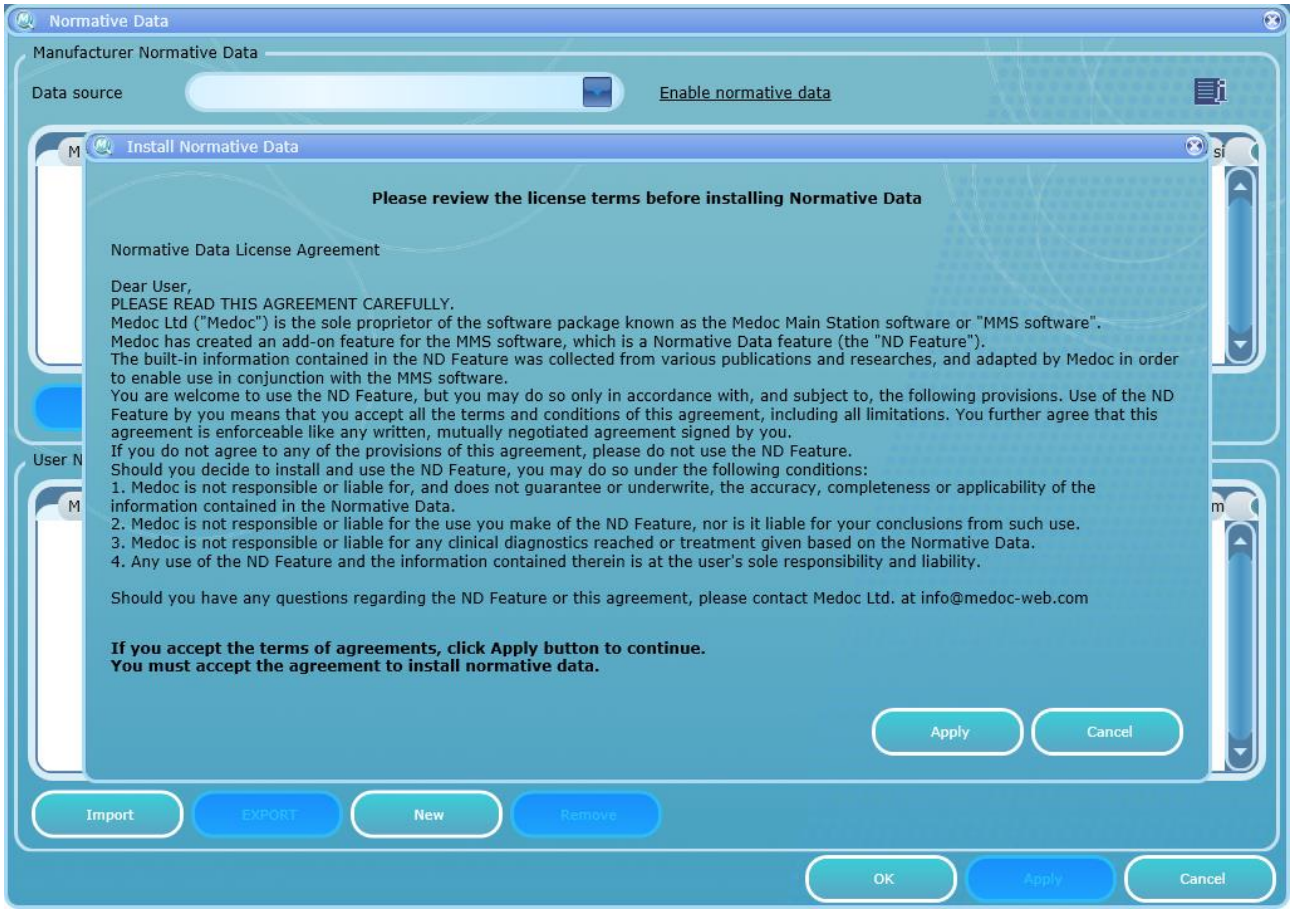


Figure 94: Normative Data License Agreement

3. Read the license agreement and click **Apply** to accept.
4. Normative Data is now enabled.

13.3

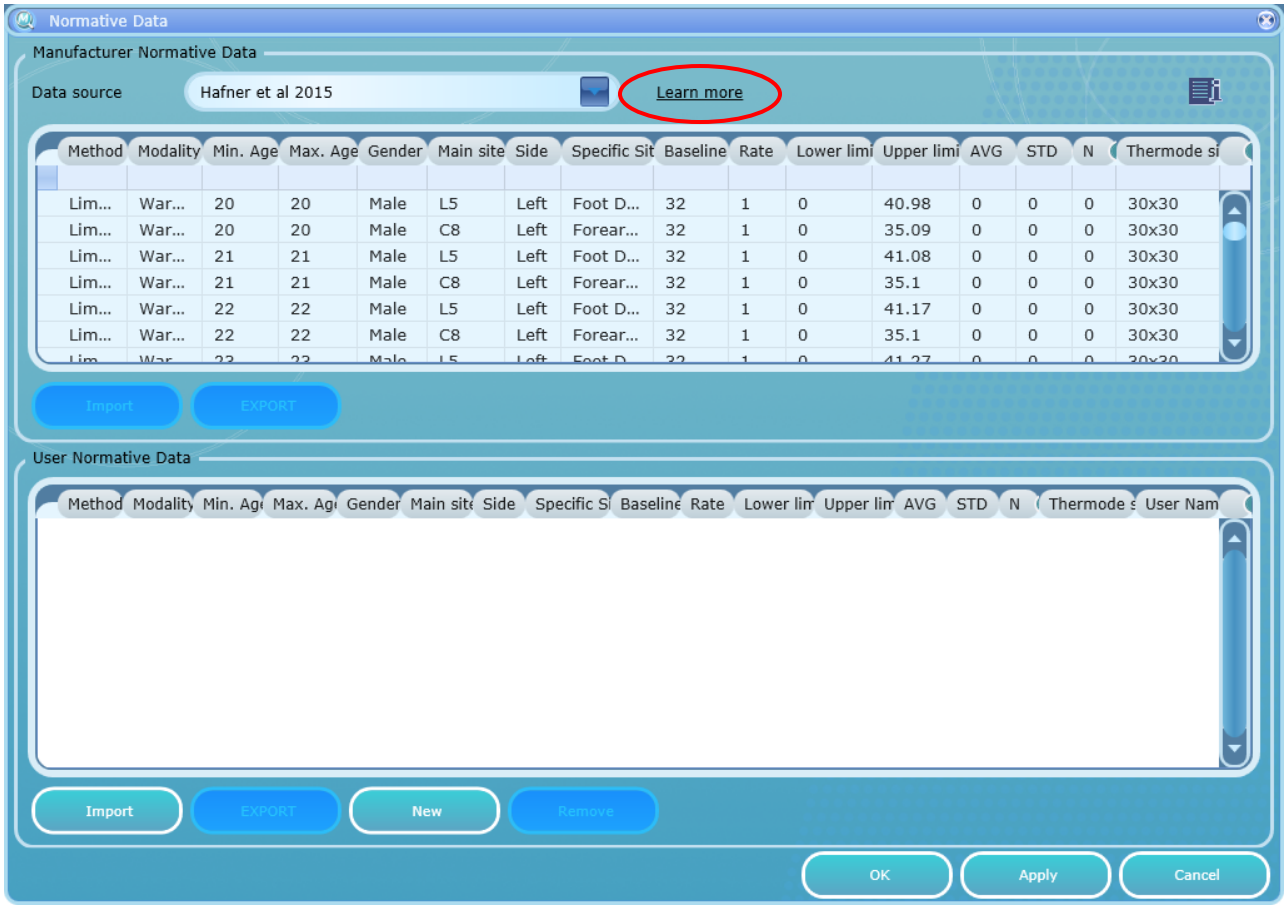


Figure 95: Normative Data Editor - Learn More

13.4 Normative Data Editor

The Normative Data editor allows you to change the Normative Data source, view and export the available built-in normative data, to import, add or modify your own normative data.

13.4.1 Selecting the Normative Data Source (Built-In Tables)

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

To select Normative Data source table following the instructions below:

1. Open the Normative Data editor: select **Utilities** from the top menu bar, and then select **Normative Data**.
2. Click the arrow to right of the data source name. A list will open displaying the list of available sources. See Figure 96.

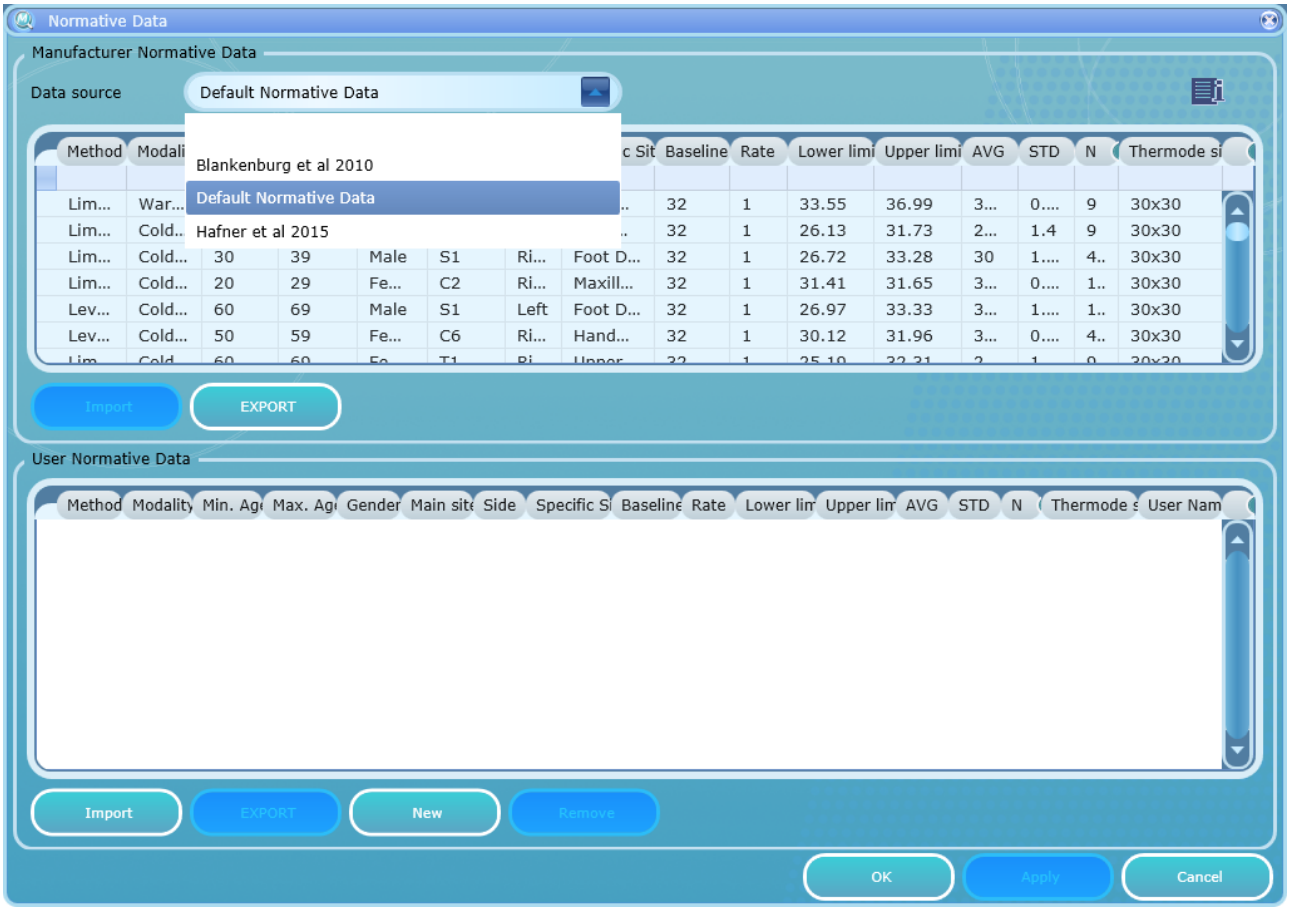


Figure 96: Normative Data screen select source

3. Click on one of the sources in list to select. Note that changing the normative data source will affect the display of normative data in results and in the reports. Confirm your selection.
4. To learn more about the selected normative data source click on the "learn more" link. Please note this link may not be available for all sources. See Figure 95.

Changing the normative data source affects the display of normative data in saved test results and in generated reports.

13.4.2 Normative Data Tables

The Normative Data editor includes two separate tables:

1. Manufacturer Normative Data
2. User Normative Data

The Manufacturer Normative Data table is a 'read-only' table. The data cannot be edited or modified. If needed, you can export the data, modify it and import it again as User Normative Data or add new Normative Data to a blank table.

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

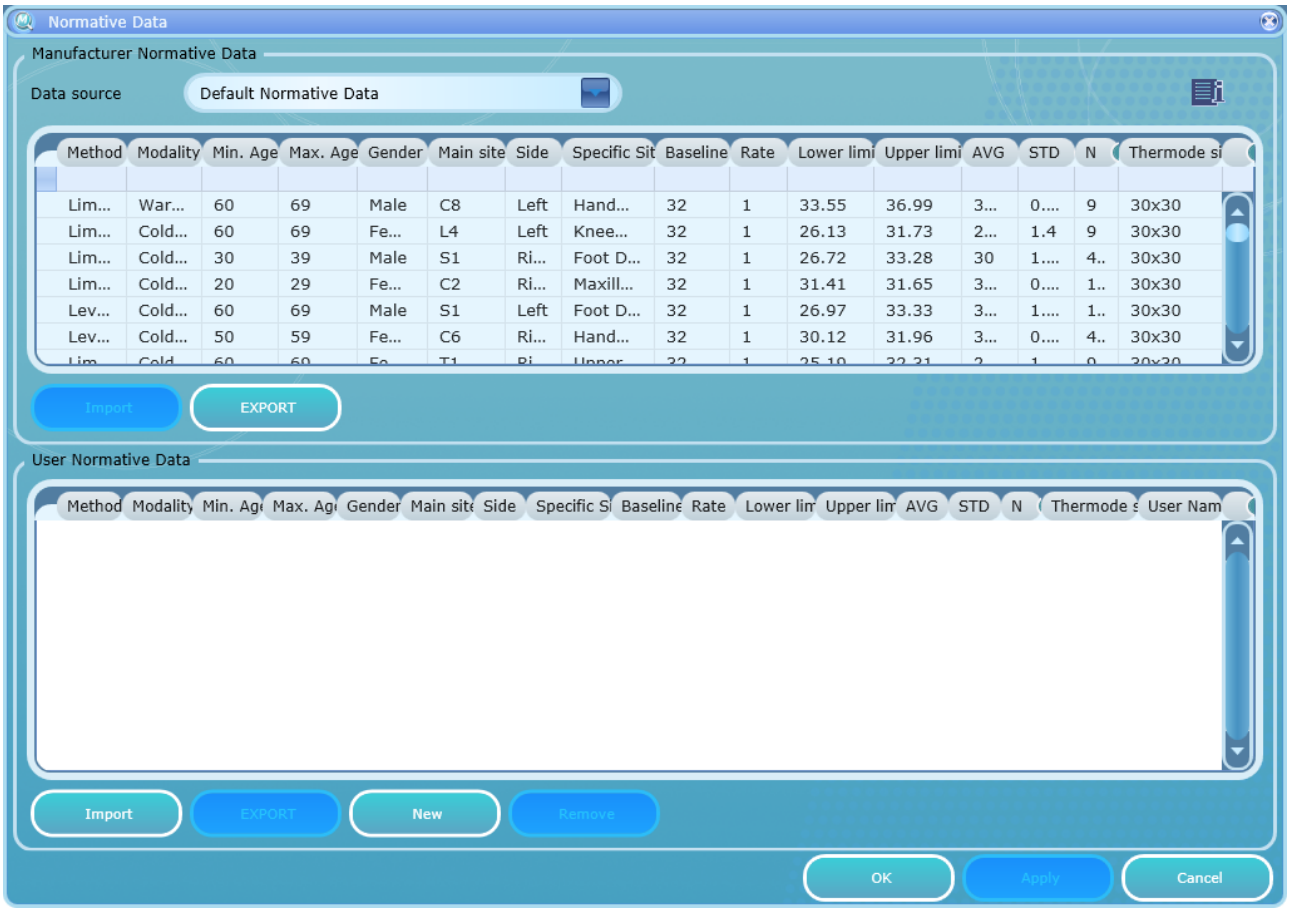


Figure 97: Normative Data Editor

Normative data tables include the following parameters:

Table 38: Normative Data Fields

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

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

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

The following operations are available:

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

To add new normative data to the list:

1. Click the **New** button to add a new row to the User Normative Data table
2. Enter the details for the normative data (for information about the specific parameters see Table 38 above)
3. Click the **New** button to add more rows or **Apply** to save and apply the new data.
4. To modify existing data in the User Normative Data table, just change the values you want to modify and click **Apply** to confirm changes.

To import normative data from a file:

5. Normative data can be imported only into the User Normative Data table. The data must be arranged in a formatted table and saves as an excel file.
6. To see the correct format, export one or more records from the Manufacturer Normative Data. To do so, select one or more records in the Manufacturer Normative Data table and click the **Export** button.

7. Open the exported file, delete the existing data except for the column headers and add your own data in exactly the same format. Save the file as .xlsx or .xls.
8. To import the file into the User Normative Data table, click the **Import** button below the User Normative Data table and select the file you want to import.

13.5 Display of Normative Data in Tests, Results and Reports

The Normative Data can be displayed during the test, overlaid on saved test results and in the reports. 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.

- 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 B – Backing Up and Restoring the Database

The Data Base Utility enables Back-up and restore system date base.

During installation of MEDOC Main Station, a default data base is created. It is called: "Computer name/**ATS**". This data base allows backup and reconstruction of the data base.

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

It is highly recommended to define database accessibility via Windows (not SQL).

To backup or restore the Q-SENSE system database, perform the following procedure:

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

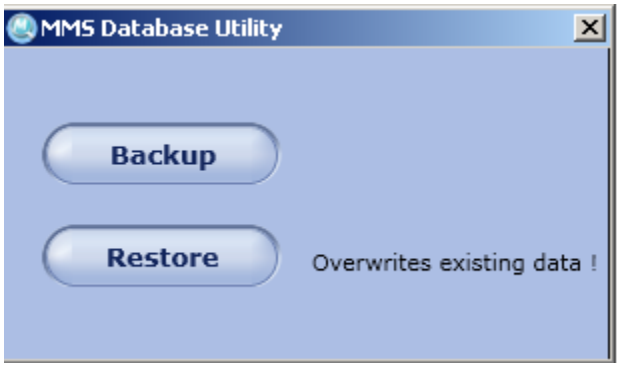


Figure 98: Database Utility – Backup/Restore Menu

2. To backup the data base, click the **Backup** button.
   A **Saving** dialog box is displayed. Use a meaningful name for better identification.

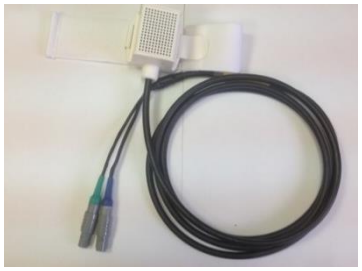
Due to Windows security, Database backup files can be saved only under: "*C:\MEDOC\DataBaseBackup*".

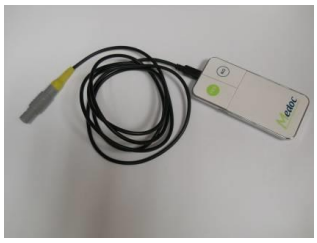
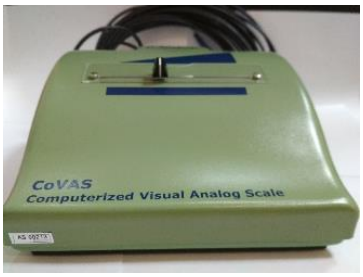
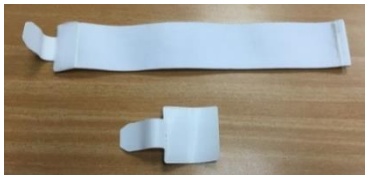
3. To restore a database, click the **Restore** buttonAt the prompt, click the **OK** button.
   A dialog box that allows choosing the data base source will open and allow choosing the data base you'd like to use.
4. Choose the desired data base and click the **Open** button.

15 Appendix C - 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 39: Accessories

Description	Cat. No.	
Standard Q-sense 30x30mm Thermode This is the standard thermal probe, which is capable of heating the skin. Used on large body sites.	AS 00402	 
Temperature Calibration Kit This kit is used for checking and calibrating the temperature calibration of the *Q-sense themodeII* unit, which can be a requirement of certain grant-funded research/study protocols. See the service manual for operation details.	AS 00406	 

Description	Cat. No.	
Response Unit This unit enables the tested subject to respond to the stimuli by pressing one of two buttons. Depending on the selected test, the tested subject feedback signal terminates any process or causes the test to continue following a Yes/No response.	AS 00403	 
USB CoVAS – Computerized Visual Analog Scale While the Q-sense 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.	AS 00213	 
Thermode Strap	AS 00404	

Description	Cat. No.	
		
Wall Mount Used to hang the system on a wall.	MP 00501	 
Power Supply Power supply is used to connect electricity port and to the power port in the Q-sense system.	DT 00017	 
USB Cable This cable is used to connect the Q-sense com port with a computer.	WA 00278	 

16 Appendix D – System and Module Description

16.1 System Description

The Q-SENSE modular design makes it easy to troubleshoot and replace parts.

The system consists of main module:

- Q-SENSE Accessories

For a detailed description of the accessories, refer to section 15

  - Thermode (to be attached to the tested subject's skin).
  - Response Unit.
- Q-SENSE Utilities
  - Laptop.
  - Printer.

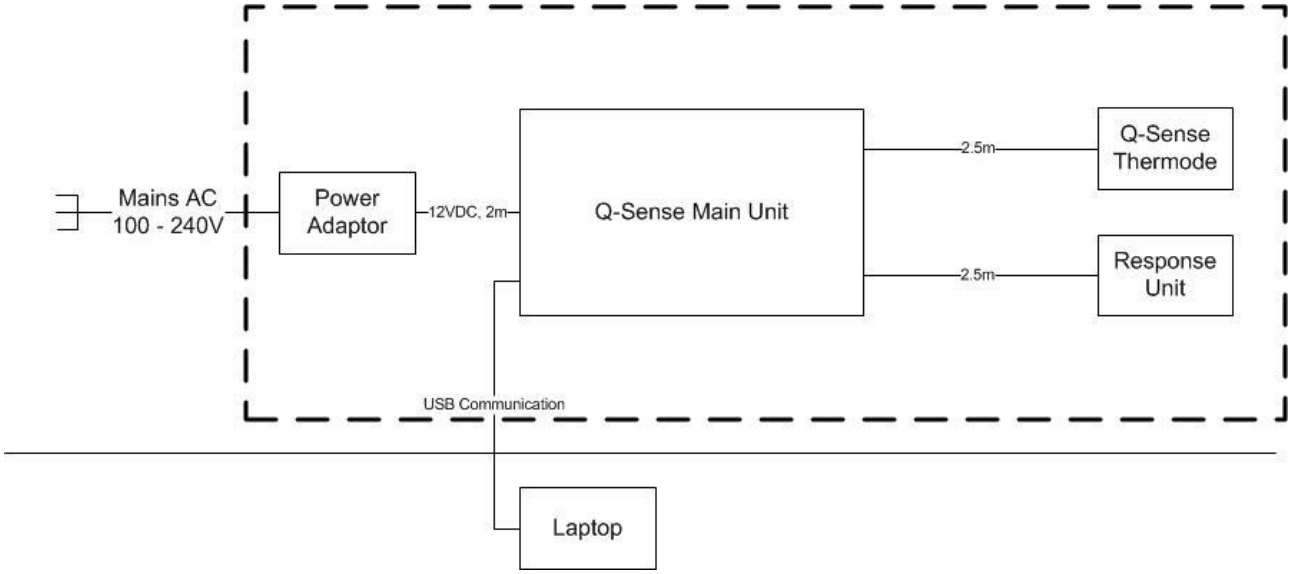


Figure 99: System Diagram

17 Appendix E – Preventive and Periodical Maintenance

This chapter describes periodic maintenance procedures.

17.1 Periodical System Run and Visual Check

A periodical system run and visual examination are necessary for maintaining performance of Q-SENSE system. The periodical run keeps all Q-SENSE accessories and subunits in operational condition at all times. Periodical system run is required, if the system or the supplied Thermode is 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.
    1. Check that accessories connector is intact.
    2. Check that accessories body is intact.
    3. Check that there is no visible damage to the Thermode heads.
2. Install all available Thermode types (Q-sense type), according to your license type, to the Q-SENSE system.
3. Connect all available Q-Sense accessories (Response Unit) to the Q-SENSE system.
4. Connect the communication cable from the Q-Sense system to the computer running MEDOC Main Station.
5. Power ON the Q-SENSE system.
6. Start MEDOC Main Station and ensure that communication is established.
7. Run the system for about 10 minutes; check for any visible malfunctions.
8. Run a few different test protocols such as Limits.
9. Repeat steps 8 and 9 with all the Thermodes supplied with the system.

Switch Thermodes only when the Q-Sense system is turned OFF!

Remember to change calibration tables prior switching to different Q-sense Thermode type (30x30mm).

10. If the system is not planned for use for three weeks or more, perform the following instructions:
    a. Turn OFF the Q-SENSE system through the main switch.
    b. Disconnect all accessories from the Q-SENSE system, and store them in a dry place.
    c. Disconnect all Thermodes from the Q-SENSE system, cover the Thermode heads with soft cloth and store in dark dry place.

Changes, additions or maintenance to the equipment carried out by persons without appropriate qualifications and training and /or using un approved spare parts may lead to serious risk of injury and damage to the equipment as well as making the warranty void.

17.2 Periodical Thermode Calibration

A periodical Thermode Calibration is necessary for the Q-SENSE system performance.

Perform Thermode Calibration every six months, according to the Thermode calibration service manual.

17.3 Periodical Thermode Maintenance

1. Inspect Thermode to confirm mechanical integrity and no visual damage before use on patient.
2. Replacing Thermode once a year is needed to keep System integrity. Please contact Medoc representative in your Area for more information on Thermode replacement and warranty extended plan.

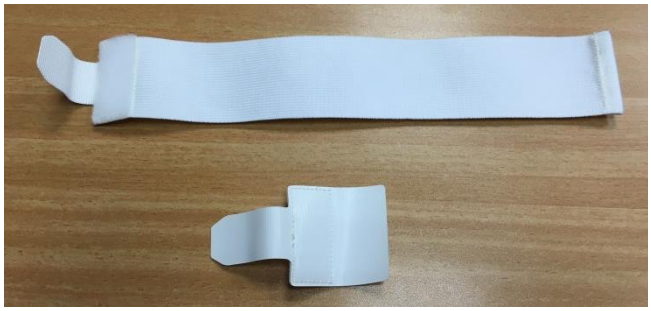
18 Appendix F – Cleaning and Disinfecting

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. Make sure the Thermode Head Case Perforated is clean of dust.
4. Store the Thermode in a clean, dry area.

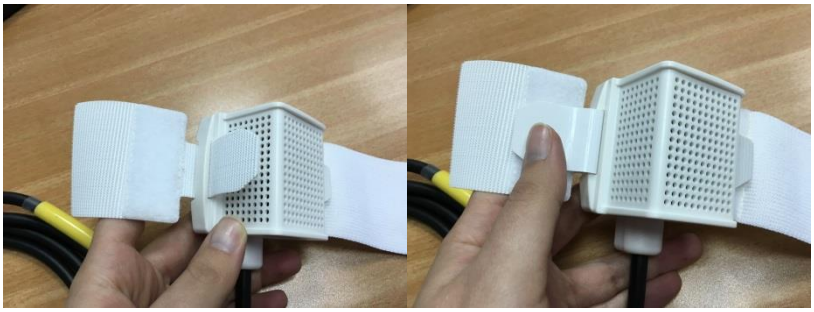
19 Appendix G - Thermode straps assembly instructions

1. The Q-sense Thermode strap is made out of two part – short and long

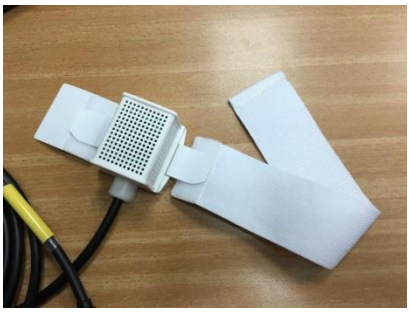


2. Insert the round end of the long strap into the slot on the Thermode side (when the hook side is facing to you) and fold it on the loop side.

3. Insert the round end of the short strap into the slot on the other side of the Thermode (when the hook side is facing to you) and fold it on the small loop square.



4. The Thermode is ready to use



20 Appendix H – List of Accompanying Documents

Table 40: Q-sense Accompanying Documents

- Quick installation guide.
- Release Notes.
- Acceptance Test Procedure (doc)
- Packing list
- Q-sense drilling model for assembly holder
- Q-Sense Operating Manual

21 Appendix I – Transportation and Storage conditions

The environment conditions for Q-SENSE 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 J – Environmental Conditions

The environment conditions for Q-SENSE system during standard use are as follows:

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

23 Appendix K – Upgrading procedure

This section regards installation for users having older version of Medoc Main Station.

1. Users having previous version of Medoc Main Station on the laptop will have the following screen displayed:

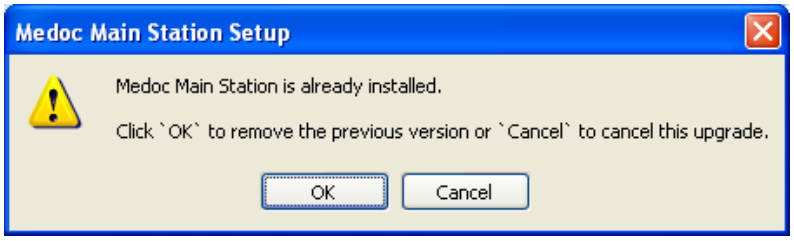


Figure 100: Previous version message

2. To upgrade version, continue with installation and click OK. The following screen will be displayed:

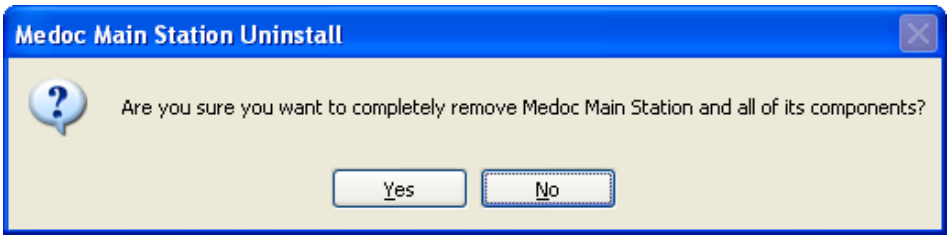


Figure 101: Removing previos version screen

3. In order to remove older versions of MMS Click YES. The following screen will be displayed:

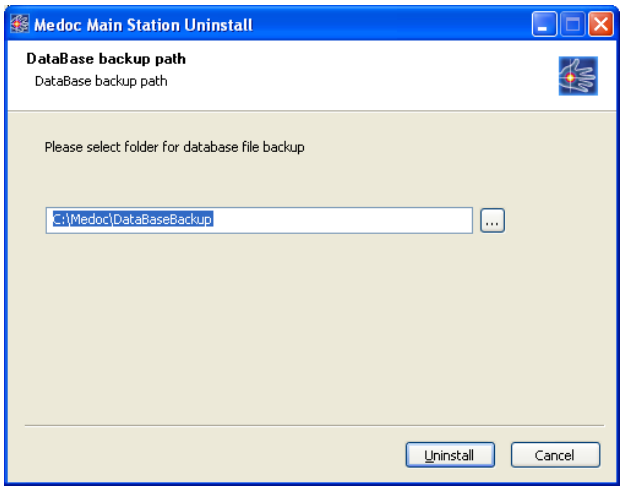


Figure 102: Data Backup Path

4. Choose folder for database file backup and click Uninstall. The following screen will be displayed:

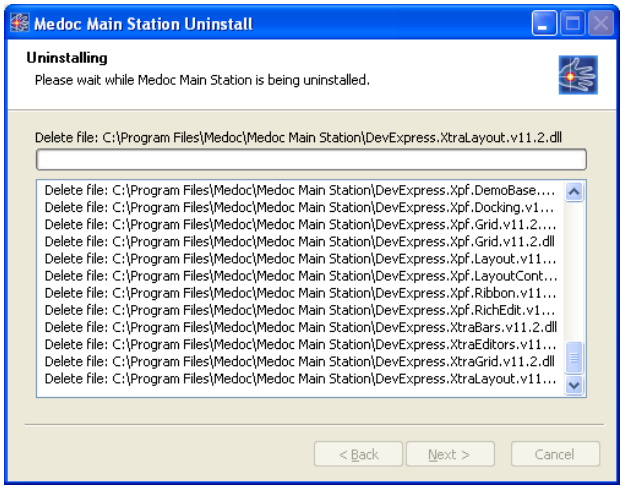


Figure 103: MMS Uninstall

5. When uninstall is complete the following screen will be displayed:

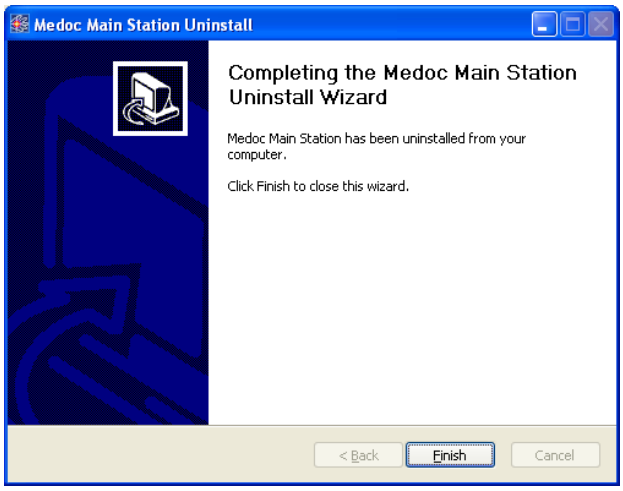


Figure 104: Uninstall Completed

6. Click finish. The following screen will be displayed:

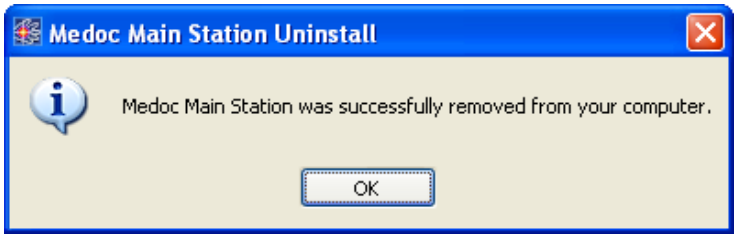


Figure 105: MMS successfully removed

7. **Click OK. To continue installation refer to Section 4.6, Page 39.**

24 Appendix L – Troubleshooting – Operator Level

The troubleshooting section describes some of the Q-SENSE 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 24.1.1, page 158.

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

24.1 Numbered Software Error and Warning Messages

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

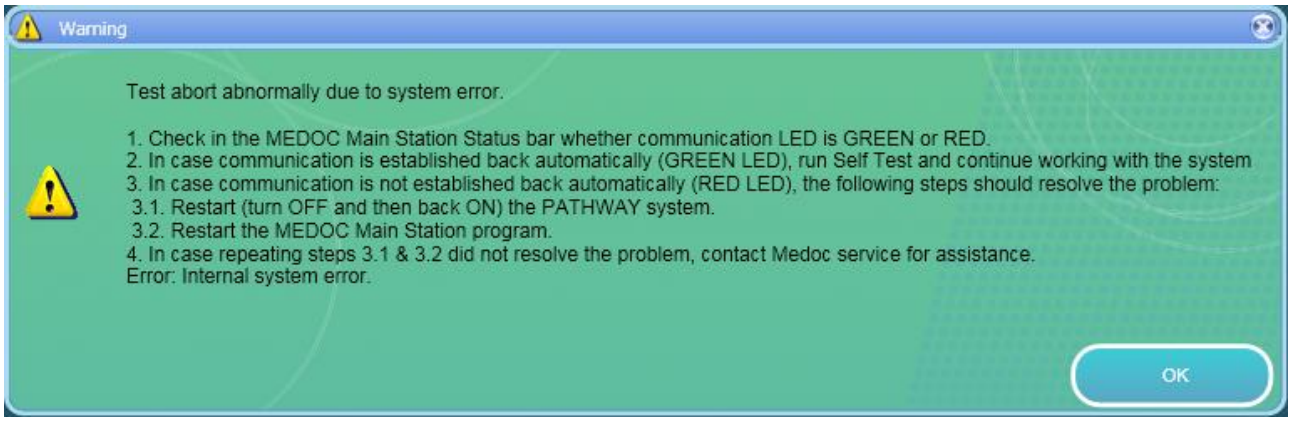


Figure 106: Error and Warning Messages Sample

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

24.1.1 Frequent Warning Messages

Table 41: Warnings

№	Warning	Explanation
1.	The application is about to start Q-SENSE 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. 1. Remove Thermode from subject. 2. Click the **OK** button to start performing a Self Test.

№	Warning	Explanation
2.	Q-SENSE 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 Q-SENSE system is in Safe Mode and must perform Self Test before it continues with normal operation. 1. Click **YES** if you wish to resume the Self Test. 2. Click **NO** if you do not want to resume the Self Test.
3.	Do you want to retry Q-SENSE recovery?	The Q-SENSE is ready to retry performing Self Test. 1. Click **YES** to start the Self Test. 2. Click **NO** to continue working in Safe Mode.
4.	A conflict occurred while importing a user-defined field. Please resolve the conflict by performing one of the next actions: 1. Choose the local definition for this field. 2. Choose the imported definition for this field.	There is a conflict between the existing user-defined entry in the data base and the one you have imported. 1. Select the entry you wish to keep: local definition, or imported definition.
5.	A conflict occurred while importing a user. Please resolve the conflict by performing one of the next actions: 1. Choose one of the local users. 2. Edit the conflicting fields in the imported user.	There is a conflict between the existing Q-SENSE user entry in the data base and the one you have imported. 1. Select the entry you wish to keep: local user, or imported user, or modify the conflicting fields in the imported user.
6.	A conflict occurred in department name. Please resolve this conflict by performing one of the next actions: 1. Choose the local department. 2. Edit the imported department name.	There is a conflict between the existing department name in the data base and the one you have imported. 1. Select the entry you wish to keep: local department, or imported department, or modify the imported department name.
7.	A conflict occurred while importing a patient. Please resolve the conflict by performing one of the next actions: 1. Choose one of the local patients. 2. Edit the conflicting fields in the imported patient.	There is a conflict between the existing patient in the data base and the one you have imported. 1. Select the entry you wish to keep, local patient, or imported patient, or modify the imported department name
8.	Configuration data was changed. Press YES to save the configuration data. Press No to discard changes. Press Cancel to continue editing.	The Q-SENSE configuration data has been changed. Select one of the presented options and continue.

№	Warning	Explanation
9.	Program violates safety limitations, and cannot be saved. Modify program settings, and retry saving. Violations: Sequence: ##, Temperature: ##, Actual time (sec): ##, Allowed time (sec): ##	The program you have designed violates the Q-SENSE safety limitations and therefore can not be saved to the data base. You have to modify the program parameters that are stated as violation according to the Q-SENSE safety table before saving this program.
10.	Deleting current Thermode is not allowed. Please set other Thermode as current and then delete this Thermode.	You can not delete a Thermode you are currently using from the data base. 1. Set another Thermode as the current (active) Thermode. 2. Delete the Thermode you wish to remove from data base
11.	Are you sure you want to save this Thermode in the local database and then set it as current? 1. Click YES to proceed. 2. Click NO to abort.	You are about to save the selected Thermode parameters to the Q-SENSE data base and set it as the current (active) Thermode of the Q-SENSE system. Select one of the presented options and continue.
12.	Are you sure you want to replace the selected Thermode tables with the current Q-SENSE tables? 1. Click YES to proceed. 2. Click NO to abort.	You are about to replace the selected data base Thermode parameters with the current (active) Q-SENSE Thermode parameters. Select one of the presented options and continue.
13.	Some of the program parameters are invalid. Press YES to continue editing. Press NO to discard all changes.	One or more of the program parameters is not valid and must be modified. Select one of the presented options and continue.
14.	The default instruction is not defined for this program.	No test instructions are defined for the selected method. You can add instructions through **Settings → Test Settings → Instructions Configuration**
15.	Thermode calibration data was changed but not saved. Press Ok to exit calibration and discard the new calibration data. Press Cancel to continue calibration.	The Thermode calibration data was not saved. Select one of the presented options and continue.

№	Warning	Explanation
16.	The configuration of the Thermode was changed. Selecting another Thermode will discard current changes. Press YES to select another Thermode and discard the changes Press NO to continue editing previous Thermode.	You have changed Thermode configuration but have not saved it. Select one of the presented options and continue.
17.	The imported Thermode has the same serial number as existing "Thermode Name" Thermode (serial number: #####). Press Yes to override the existing Thermode. Press No to create a new Thermode (serial number will be omitted).	The Thermode file you try to import to the data base has same serial number as existing data base Thermode. Select one of the presented options and continue.
18.	Sensor <Sensor Name>*: missing calibration table entries in range 10 - 48. *<sensor name>= TEC\HS1\HS2	The sensor LUT can not be complete, because there are missing entries. Complete the missing entries and continue.
19.	Sensor "Sensor Name": The number of defined calibration table entries is less than the required 10.	In order to complete calibration there must be at least 10 entries in the calibration table. Complete missing entries and continue.
20.	The number of defined calibration table entries is more than the required 10, but less than the recommended 20. 1. Click YES if you want Q-SENSE to perform interpolation and fill out the missing values. 2. Click NO to enable return to the Hardware Settings and fill in missing values.	When performing manual calibration, at least 10 entries are required, although 20 are recommended by Medoc. This message states that you have calibrated less than the recommended number of points. You can choose to complete 20 entries or let the program interpolate the missing values.
21.	You cannot change Q-SENSE (firmware) Thermode values directly	Q-SENSE Thermode firmware can only be viewed. Only Thermode data bases can be edited, and then set as current Q-SENSE Thermode firmware.
22.	Destination temperature is lower than the baseline. The interval between baseline and destination must be less than 15°C. Sequence 1 - The interval is 36 - 20 = 16°C	When performing Cold EP tests there are restrictions that must be followed: The interval between the baseline temperature and destination temperature must be less than 15°C. Make sure that your program complies with these restrictions; then continue.

№	Warning	Explanation
23.	Destination rate is out of range: Sequence 1 - For a destination temperature of 23°C, the range must be [0.1…1].	When performing a Cold EP test there are restrictions that must be followed: • Temperature change rate must be within the specified range. Make sure that your program complies with these restrictions and continue.
24.	Destination temperature is lower than the baseline. Sequence 2 - Return rate must be in the range [0.1…2]	When performing a Cold EP test there are restrictions that must be followed: • The temperature return rate must be within the specified range. Make sure that your program complies with these restrictions and continue.

24.1.2 Frequent Error Messages

Table 42: Errors

№	Error Message	Solution
1.		The appearance of this icon, beside a configurable field or parameter, states that the parameter value is illegal. 1. Move the cursor over the sign for further information.

№	Error Message	Solution
2.	**Communication with Q-Sense was lost .** 1. Click OK to check if communication can be re-established automatically, run self-test and continue working with the system 2. In case communication is not re-established automatically: 1.1 Close Medoc Main Station and switch OFF the device 1.2 Verify that the device communication cable is connected firmly to device and computer. 1.3 Turn ON the device and start Medoc Main Station. 2. If steps 1 & 2 fail, contact Medoc support for further assistance.	Communication between Q-SENSE system and PC was lost. Follow the message instructions to solve the error. 1. Click OK to check if communication can be re-established automatically, run self-test and continue working with the system 2. In case communication is not re-established automatically: 2.1 Close Medoc Main Station and switch OFF the device 2.2 Verify that the device communication cable is connected firmly to device and computer. 2.3 Turn ON the device and start Medoc Main Station. 3. If steps 1 & 2 fail, contact Medoc support for further assistance.
3.	No Thermodes are enabled. Error Code: 800D 1. Enable connected Thermode via Hardware Settings, General tab. 2. Click OK, and resume Self Test when prompted.	The Q-SENSE does not have any enabled Thermodes. You must enable the connected Thermodes via **Hardware Settings** and then perform **Self Test**, before continuing working with the system.
4.	Failed to recovery from Safe Mode, Q-SENSE returns Acknowledge Code = ##.	The Q-SENSE system was unable to complete Self Test recovery due to an error. The Q-SENSE system is reporting the acknowledge code that was generated. 1. Write the Acknowledge Code number or name. 2. Restart the Q-SENSE system and program. 3. Continue working. If the problem persists, contact Medoc service and state the Acknowledge Code number or name you experienced.

№	Error Message	Solution
5.	Failed to recovery from Safe Mode, no response from Q-SENSE during timeout period.	The Q-SENSE system was unable to complete the Self Test recovery, because the program could not connect to the system. 1. Restart the Q-SENSE system and program. 2. Continue working. If the problem persists, contact Medoc service.
6.	MEDOC Main Station can't locate Q-sense device. Please check the following: 1. Verify that the correct port is selected. Refer to the computer device manager which port Q-Sense is connected. 2. Make sure Q-Sense device is connected and turned ON.	MEDOC Main Station failed to connect to the Q-Sense system. 1. Verify that the correct port is selected. Refer to the computer device manager which port Q-Sense is connected. 2. Make sure Q-Sense device is connected and turned ON.If the problem persists, contact Medoc service.
7.	Unsupported TCU firmware version. Firmware version: ###	MEDOC Main Station has detected that the firmware version installed on the Q-Sense system is not compatible with the software. 1. Make sure the HASP is well connected. 2. Restart Q-SENSE system and software and try to log in In case Restart did not solve the problem: 1. Load the firmware, .hex file. Use the installation CD, from which you installed the program; or the update folder in the Medoc FTP site, from which you downloaded from, see Service Manual for further information.
8.	User Name or Password are incorrect.	The username or password you have entered is not the right ones. 1. Verify that you have typed the correct user name and password. 2. Try to log in. If the problem persists, try the *admin* user name and password.

№	Error Message	Solution
9.	Command: ### failed ###. No response from Q-SENSE.	The command failed, because no response from the Q-SENSE was detected. 1. Write the command name or number. 2. Restart the Q-SENSE system and program. 3. Continue working. If the problem persists, contact Medoc service and state the Acknowledge Code number or name.
10.	Command: ### failed ###. Q-SENSE returns Acknowledge Code = ###.	The command failed as a result of the displayed acknowledges code. 1. Write the command name or number and the acknowledge code. 2. Restart the Q-SENSE system and program. 3. Continue working. If the problem persists, contact Medoc service and state the Acknowledge Code number or name you experienced.
11.	The Thermode cannot be saved because its verification failed.	One or more of the Thermode parameters are illegal and therefore can not be saved. Verify that all Thermode parameters are legal and modify the illegal ones; then save the Thermode parameters.
12.	The following safety limitation has been violated. Temperature: 51 °C; Allowed time: 0 (sec). Error Code: 8002	The Q-SENSE system detected that a safety limitation was violated during a test run, and switched automatically to safe mode in order to prevent any damage. The violated temperature and the time of the event are displayed, together with the error code. 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 Q-SENSE system is enabled to continue work. If the problem persists, stop using the Q-SENSE system and contact Medoc service.

№	Error Message	Solution
13.	Static sensor mismatch. Error Code: 8003	The Q-SENSE system has detected a mismatch between its sensors, and therefore switched to Safe Mode in order to prevent any damage. 1. Check that the Thermodes are intact and undamaged. 2. Run the Self Test to verify that the Q-SENSE system is enabled to continue work. 3. Run Thermode calibration. If the problem persists, stop using the Q-SENSE system and contact Medoc service.
14.	Static sensor mismatch. Mismatch (difference) temperature 4 (°C). Error Code: 8003	The Q-SENSE system has detected a mismatch between its sensors during static temperature measurement, and therefore switched to Safe Mode in order to prevent any damage. The mismatched temperature that was measured is as reported in the message. 1. Check that the Thermode is intact and undamaged. 2. Run Self Test to verify that the Q-SENSE system is enabled to continue work. If the problem persists, stop using the Q-SENSE system and contact Medoc service.
15.	Dynamic sensor mismatch. Mismatch (difference) temperature: 10 (°C). Error Code: 8004	The Q-SENSE 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. The mismatched temperature that was measured is as reported in the message. 1. Check that the Thermode is intact and undamaged. 2. Run the Self Test to verify that the Q-SENSE system is enabled to continue work. If the problem persists, stop using the Q-SENSE system and contact Medoc service.

№	Error Message	Solution
16.	Thermode TEC did not respond to temperature changes. Error Code: 8007 Make sure that the blue connector is connected properly	The Thermode has failed to pass TEC (part of the Thermode) test during the Self Test, and therefore the Q-SENSE has switched to Safe Mode in order to prevent any damage. 1. Check that the Thermode is intact and undamaged. 2. Make sure that the blue connector is connected properly 3. Run Self Test to verify that the Q-SENSE system is enabled to continue work. 4. If self Test fails, Restart system and software and retry. If the problem persists, stop using the Q-SENSE system and contact Medoc service.
17.	TEC sensor is shorted or disconnected. Error Code: 800A	The Q-SENSE 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. 1. Check that the Thermode is intact and undamaged. 2. Run Self Test to verify that the Q-SENSE system is enabled to continue work. If the problem persists, stop using the Q-SENSE system and contact Medoc service.
18.	Empty command buffer. Error Code: 400C	An error has occurred in the Q-SENSE processor during run time. 1. Click OK and continue working as usual. If the problem persists, send the corresponding error code to the Medoc service team.

№	Error Message	Solution
19.	Time mark missed. Error Code: 400D	An error has occurred in the Q-SENSE processor during run time. 1. Click OK and continue working as usual. 2. Restart the Q-SENSE system and software. If the problem persists, send the corresponding error code to the Medoc service team.
20.	Sample buffer full. Error Code: 2001	An error occurred in the Q-SENSE processor during run time. 1. Click OK and continue working as usual. If the problem persists, send the corresponding error code to the Medoc service team.
21.	Finite ramp by temperature timeout. Thermode temperature: 35 (°C). Error Code: 2002	The Q-SENSE system was unable to complete the requested command in the allowed time, and has therefore switched to Safe Mode in order to prevent any damage. 1. Check that the Fan mode is according to requirement. 2. Run Self Test to verify that the Q-SENSE system is enabled to continue work. If the problem persists, stop using the Q-SENSE system and contact Medoc service.
22.	Safety cold duration limit violation. Temperature level: 20 (°C), Time entry: 10(sec). Error Code: 800E	The Q-SENSE system has detected that the safety limitation was violated, and therefore switched to Safe Mode in order to prevent any damage. 1. Make sure that the program you are trying to run complies with the safety limitations. 2. Run Self Test to verify that the Q-SENSE system is enabled to continue work.
23.	System could not establish communication! Retry: The system will retry to establish communication. Cancel: Continue working without connecting to device.	The program was unable to establish communication with the Q-SENSE system. Select one of the presented options and continue.

№	Error Message	Solution
24.	The thermometer does not respond. 1. Check that the thermometer is turned on. 2. Check that the thermometer is connected to the correct COM (see setting > software setting > calibration COM port).	Automatic calibration had failed, because the program could not communicate with the thermometer. Follow the displayed instructions, and retry.
25.	The measured temperature 51(˚C) is out of permitted range [20…50].	During automatic calibration the measured temperature exceeded the allowed range. 1. Reduce calibration range (increase minimum and decrease maximum) through Automatic calibration properties. 2. Retry calibrating. If calibration is still out of range, calibrate the Thermode manually to bring it back into range.
26.	Have not been able to read temperatures from the Thermometer for 60 seconds. 1. Verify that the thermometer communication cables are connected properly. 2. Verify that the thermometer is turned on. 3. Restart the automatic calibration procedure.	The program was unable to communicate with the thermometer. Follow the displayed instructions, and retry.
27.	1. Check that the thermode is properly placed in the jig and connected to the Q-Sense. 2. During automatic calibration software safety protection is lowered; therefore, it is not allowed to place Thermode on human subjects Click YES to continue calibrating. Click NO to discontinue calibration	Warning notification before automatic calibration. Follow the displayed instructions, and continue.
28.	Can not open thermometer serial communication port, because it is used by Medoc Main Station	The selected calibration COM port is in use by the Q-SENSE system. 1. Select the appropriate calibration COM port through Settings→Software Settings→General. 2. Retry calibration.

№	Error Message	Solution
29.	Q-sense Thermode was not detected by Q-SENSE. The Thermode has been disabled. 1. Make sure that the Thermode is properly connected to the Q-Sense system. 2. Enable the Thermode through the Hardware Settings, General menu. 3. Click Yes to try again. Or 4. Click No to continue working.	The Q-SENSE system could not detect one of the enabled Thermodes, and therefore disabled it in order to prevent any damage. Follow the displayed instructions to continue working.
30.	Some of the Safety parameters (Temp Vs. Time) are violating the Q-SENSE safety limitations. 1. Click OK to continue working with current non-approved safety parameters. 2. Click Restore to restore safety parameters to the Q-SENSE definition.	The Q-SENSE 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!
31.	Communication between Q-SENSE and PC lost while in Test Run mode. Error Code: 800C	Communication between the Q-SENSE system and the PC has been lost. 1. Restart the Q-SENSE system and program. 2. Run Self Test. 3. Continue working with the system. If the problem persists, contact Medoc service.

№	Error Message	Solution
32.	 **Error start with:** System.NullRefeenceException: Object reference not set to an instance of an object. at Medoc.SysInfoHelper.GetSeriaPortNanes()	SQL server could not find COM port or Virtual COM port and cannot start SQL services. 1. Press OK. 2. Copy the file **Add SERIALCOM to registry.reg** from Q-SENSE installation CD to your computer. The file located in **Medoc Manufacture Remote Assistance Tools** folder. 3. Run the **Add SERIALCOM to registry.reg** file by double click on it. 4. Connect the computer to Q-SENSE communication port using USB cable. Make sure that the driver is installed properly according to Q-SENSE installation instructions. 5. Turn ON the Q-SENSE system. 6. Start MEDOC Main Station. If the problem persists, contact Medoc service.

24.2 Faulty System Responses

Table 43: Faulty System Responses

Malfunction	Solution
Thermode does not heat	The Thermode does not heat up, and remains at room temperature or cold. The Q-SENSE Temperature status, displayed on status bar, indicates a temperature other than the current Rest Mode temperature. The malfunction may be caused by the Thermode, or by the voltage supplied from the power supply. 1. Verify that the Q-SENSE system is in Online mode. 2. Power OFF the Q-SENSE unit, and replace the Thermode. 3. Power ON the Q-SENSE unit and check if the Thermode heats up. 4. Verify that the Q-SENSE system is not in Safe Mode (Safety indicator, in status bar, is GREEN)

Malfunction	Solution
Power Failure	Perform power supply and cable check. 1. Check that the power cable you are using is not damaged. Make sure that the cable and its connectors are undamaged. a. Check that the power cable that you are using is connected properly to Q-Sense Power COM. Perform power-switch check. 2. Turn ON the main power switch of the Q-SENSE system. A green LED indicates it is ON. * If the problem persists, contact Medoc service for support.
Constant Communication problems	1. Perform COM port check. a. 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. b. Check that the communication cable is connected properly. c. One end must be connected to the back of the Q-SENSE COM port; the other end to your laptop. 4. Turn ON the Q-SENSE system. 5. Disconnect and then reconnect the communication cable from the COM port of the Q-Sense System, while the Q-Sense system (software and hardware) is running. 6. Restart the Q-Sense system.
Automatic Calibration Failure	1. Verify you selected proper COM port for Thermometer in Software Settings menu. 2. Make sure that the operating system decimal symbol is set to dot. To change decimal symbol go to Control Panel→Regional and Languages Options→Regional Options→Decimal Symbol.
Display Settings	5. Make sure that the font setting on your laptop is set for 96dpi. 6. Make sure that your screen resolution is set according to instructions in section 36**4.1**, Page **36.**
No TEC Response	1. Power and communication Check. a. Check that the system is ON.

Malfunction	Solution
	b. Check that communication can be established. 2. Thermode connection check. a. Make sure that the enabled Thermode is connected properly to the Q-Sense system. 3. Restart MEDOC Main Station and Q-Sense system. 4. TEC temperatures refresh check. a. Check that the TEC temperature in the software status bar is not freezing i.e., see that the temperature value changes; there should be a fluctuation of about 0.1˚C. 5. TEC response check for Q-sense Thermode only: a. Start the Q-Sense system and software. b. Go to Settings→Hardware Settings→Thermode. c. Select the Q-sense Thermode then press the calibration tab. d. Change the Thermode temperature using the temperature spin box. e. Check if the temperature in the status line has changed according to the set temperature. 6. Consult Medoc service for further instructions.

25 Appendix M – Licensed Options

25.1 FTP Support

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

25.1.1 Export Configuration

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

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

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

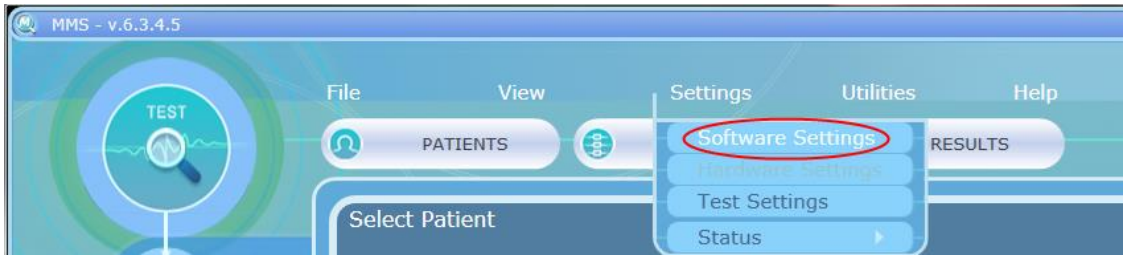


Figure 107: Open Software Settings

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

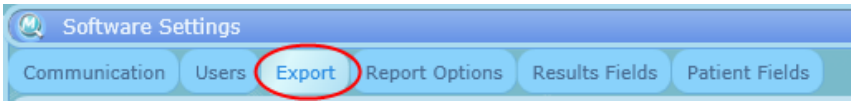


Figure 108: Software settings export tab selection

The following window will be displayed:

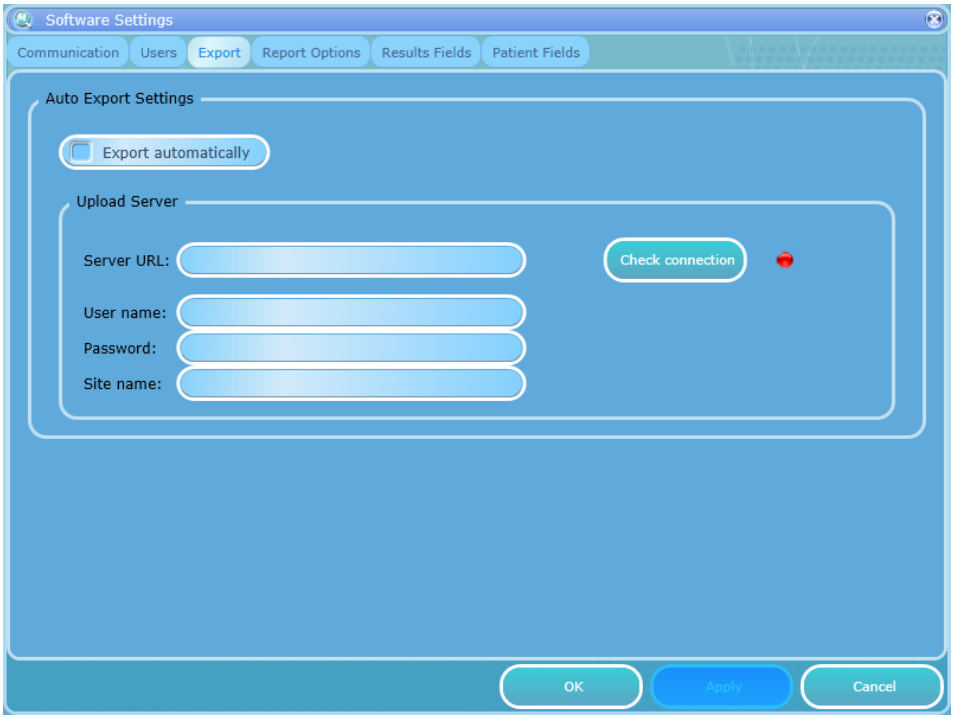


Figure 109: Software Settings Export Tab

25.1.1.1 Configure the FTP Upload Server

To configure the server enter the following details:

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

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

25.1.1.2 Automatic Export

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

To enable automatic export:

1. Make sure the FTP server details are entered correctly and check the connection.
2. Mark the "Export automatically" checkbox.
3. Make sure auto-save option is enabled (see 10.3.1).

25.2 CoVAS

Enables continues pain rating using the USB CoVAS device.

25.2.1 CoVAS Calibration

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

The CoVAS should be calibrated when:

- It is used for the first time
- Software or firmware are re-installed

To Calibrate the CoVAS:

1. Connect the CoVAS to the Computer (USB connection).
2. In the Hardware Settings windows, select the USB CoVAS tab.

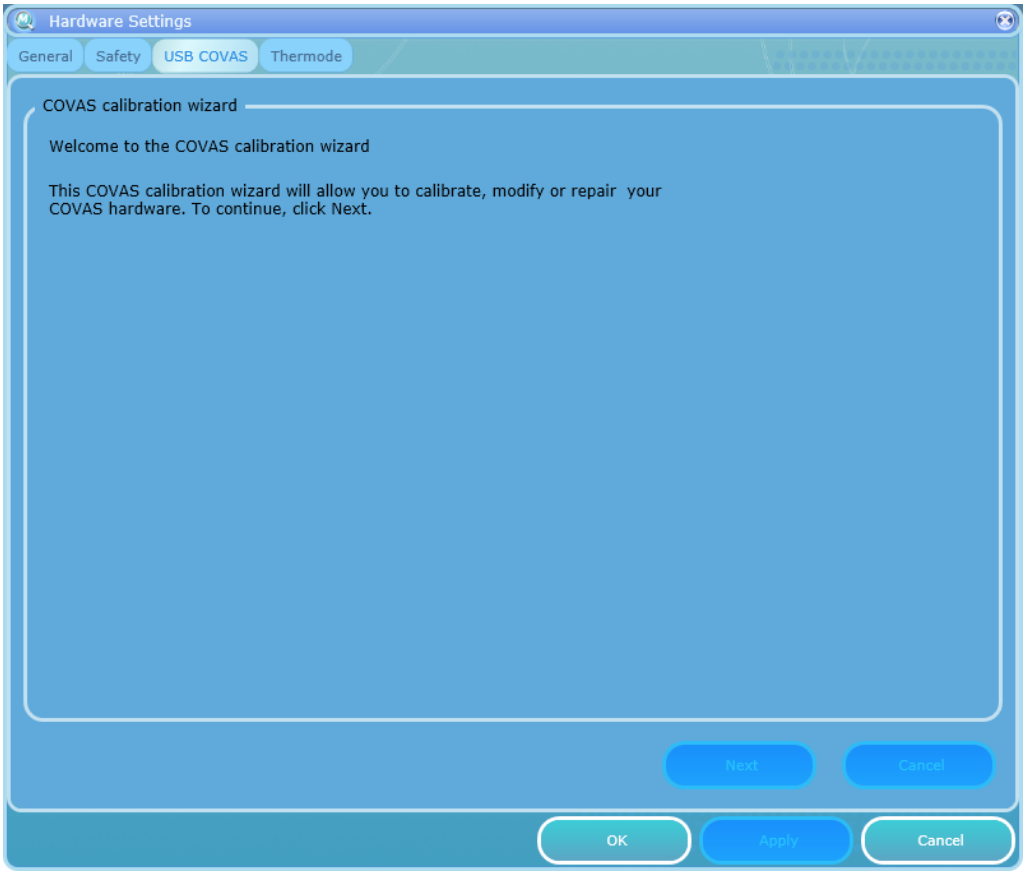


Figure 110: CoVAS Calibration Tab

3. Click the Next button and follow the instructions shown on screen (a short version is given here)
4. Move the CoVAS slider all the way to the left and click the Next button.
5. Move the CoVAS slider all the way to the right and click the Next button.
6. Click Next to save the calibration results.

7. Click the Finish button to complete the calibrating process; then click OK.

25.3 Patient Record Control

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

25.3.1 Control Patient Field Entry Format with Input Masks

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

Input Masks

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

The **Regular Characters** represent the alphabetic or numeric characters that must or may be used to enter data in the field. Refer to Table 44 for a list of Regular Characters and their definitions.

The **Special Characters** represent the case and various delimiters and symbols. Refer to Table 45 for a list of Special Characters and their definitions.

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

Table 44: Regular Characters

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

Table 45: Special Characters

Character	Definition
>	All the characters that follow are converted to upper case
<	All the characters that follow are converted to lower case
<>	No case checking is performed

/	Used to separate months, days and years in dates. The character used depends on the regional settings of the computer
:	Used to separate hours, minutes and seconds in time values. The character used depends on the regional settings of the computer
$	Currency symbol. The symbol used depends on the regional settings of the computer

Examples

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

25.3.2 Add/Remove Patient Fields

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

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

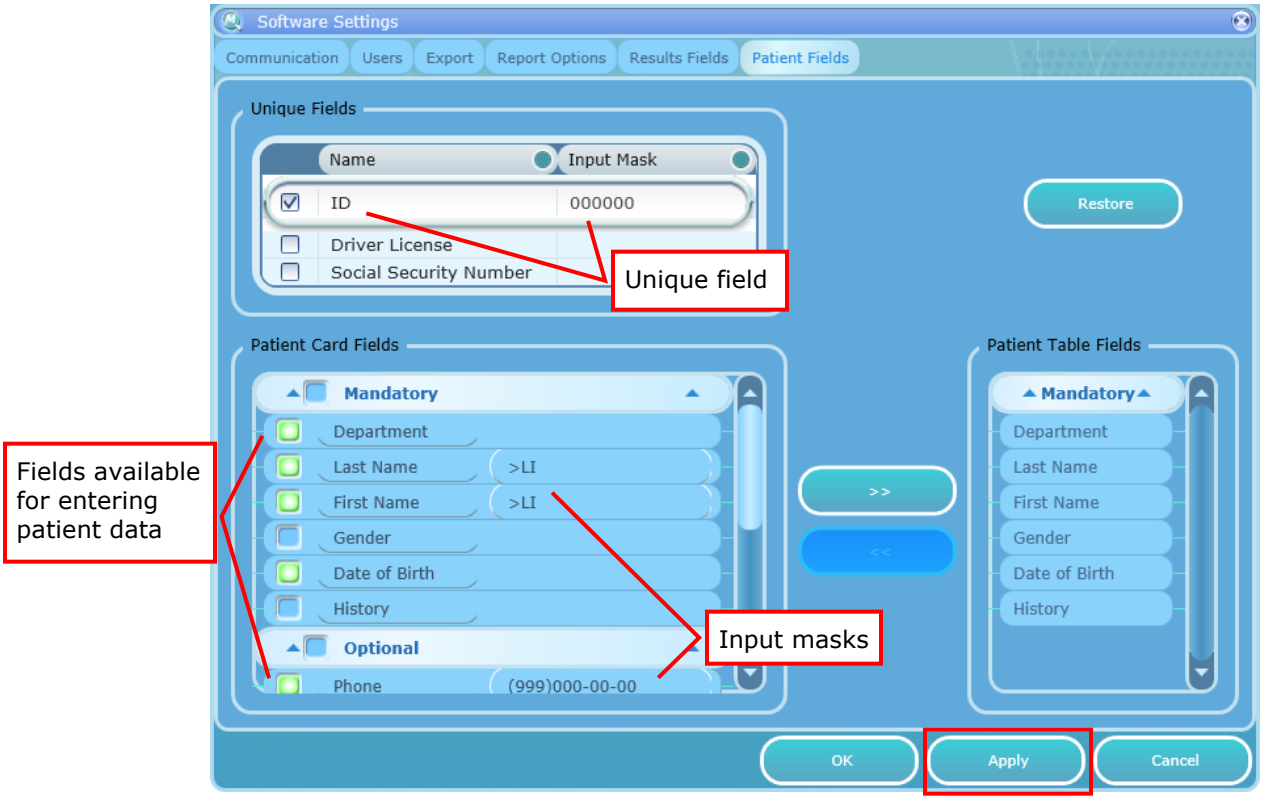


Figure 111: Patient Fields with Input Masks

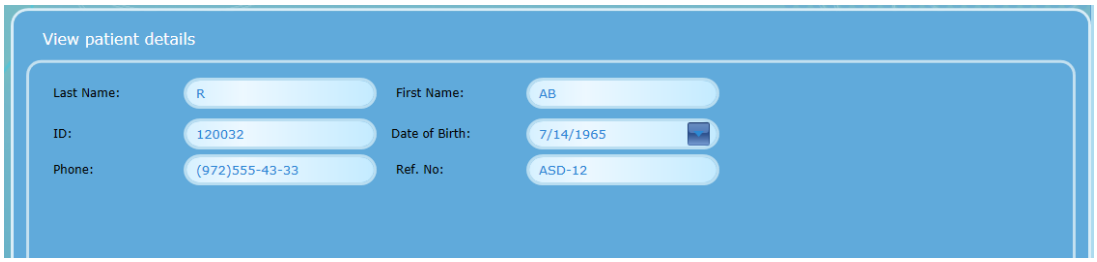


Figure 112: Patient Card with Selected Patient Fields

<u>To add Patient Fields to the Patient Table</u>:

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

<u>To remove Patient Fields from Patient Table:</u>

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

<u>To restore the default Patient Fields</u>:

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

25.4 Pain Rating

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

25.4.1 Pain Rating Parameters Configuration

Pain rating is available only for Ramp & Hold program.

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

The following options can be configured:

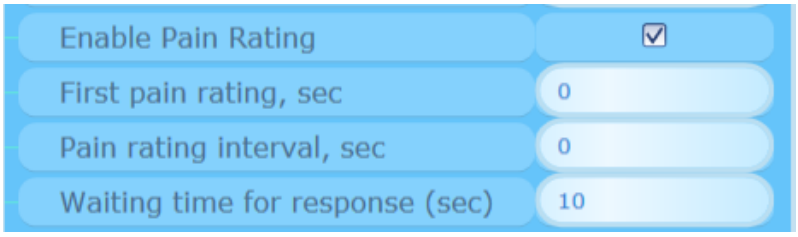


Figure 113: Pain Rating Parameters

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

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

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

Pain rating interval – determines the interval between pain ratings.

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

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

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

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

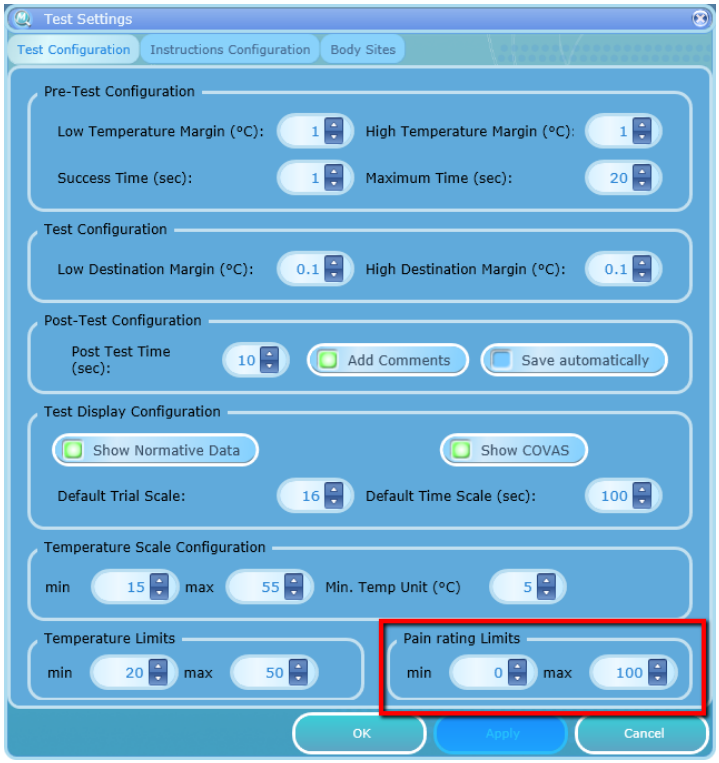


Figure 114: Pain Rating Limits

26 Appendix N – fMRI functionality

26.1 fMRI Thermode

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

Q-sense 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 harm to the test subject.

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

The fMRI Q-sense system was tested in the following MR environments:
Field Strength: 3T and 7T; Max. Spatial gradient: 72 mT/m
Max. dB/dt: 346 T/m/s; RF Fields: max. power 35KW pep;
TX bandwidth: 800kHz; RX bandwidth: 500Hz-1MHz; maximal RF field strength: 24,7 µT CP
SAR: whole body 4 W/kg, head 3.2 W/Kg

The fMRI Q-sense system was tested in the following MR Sequences:
1. **Echo Planer Imaging (EPI) bold (fMRI)**
2. **rf_noise and rf_noise spectrum electromagnetic noise interference (Siemens protocol)**

26.1.1 Q-sense system configuration in fMRI mode:

The fMRI Q-sense system includes the following components:

- 

Control room thermode cable
- 

Q-Sense fMRI Thermode

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

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

The filters are to be connected via appropriate 9-pin D-type cutouts in the penetration panel, with the thermode air tube to be passed through a waveguide of appropriate dimensions (according to the MRI scanner manufacturer design).

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

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

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

26.1.2 Installation –MR Filter

1. Complete the setup and installation procedure as described for a regular Q-sense system, according to the System Block diagram below.
2. Connect the system devices according to the following stages:

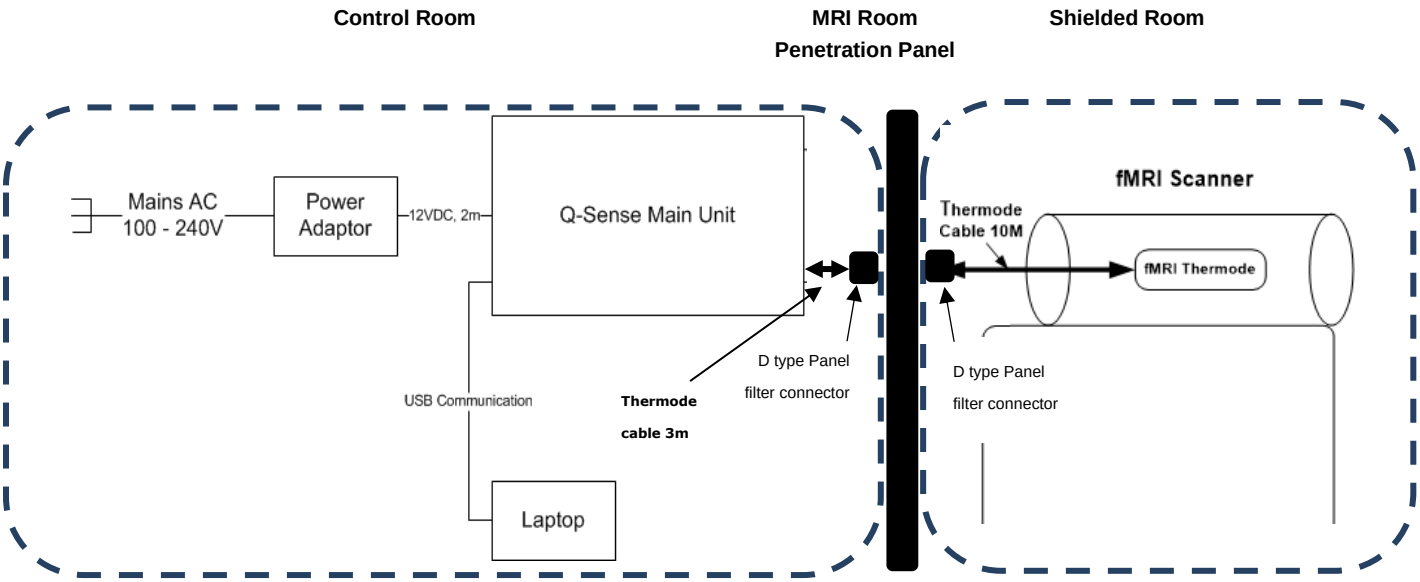


Figure 115- fMRI room setup

2.1. Connect the Q-sense 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:

2.2. Make sure your PC, Q-sense fMRI unit are all OFF.

2.3. Install the fMRI thermode Control Room part (see Figure 116) according to the following instructions:

2.3.1. Connect the D type panel filter connector on your MRI room penetration panel.

2.3.2. Connect Q-sense fMRI Connectors to the Q-sense fMRI unit

Figure 116: Q-sense fMRI Thermode Control Room part WA 00281

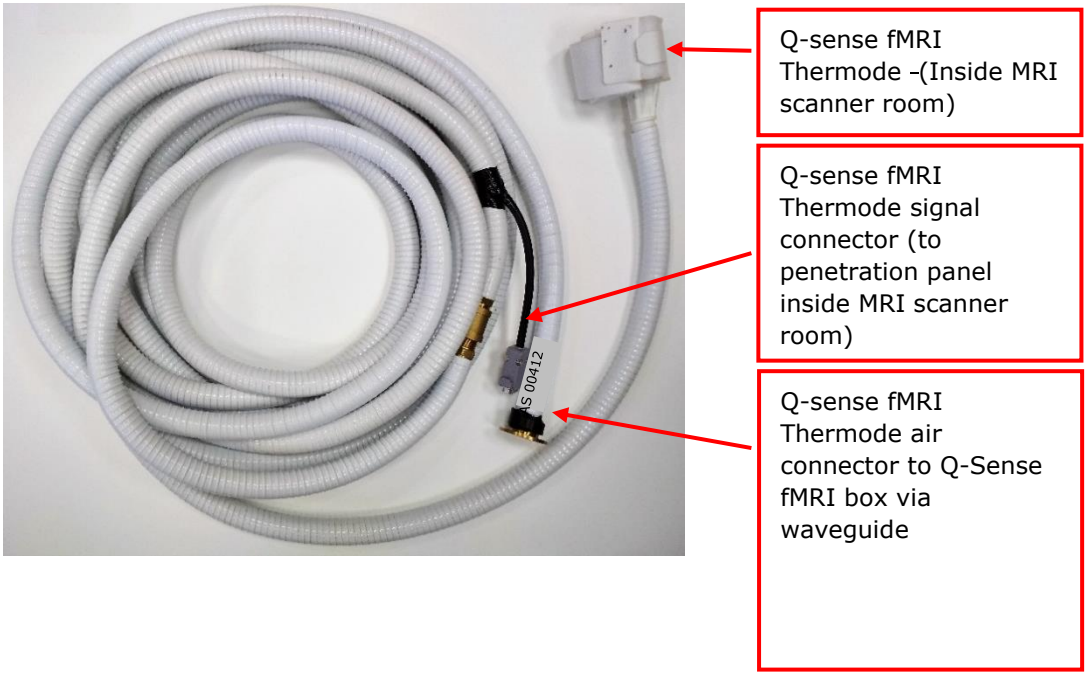


Figure 117: Q-sense fMRI Thermode Shielded room part AS 00412

2.4. See Figure 117, for description of the fMRI Thermode- Shielded room part components:

2.4.1. Q-sense fMRI Thermode

2.4.2. Q-sense fMRI Thermode connector

2.4.3. Connection to MRI

2.5. Connect the main power cord to the Q-sense system.

3. The fMRI Thermode- Shielded room part - should be placed inside the fMRI room. All the other devices' connectors should be placed outside of the fMRI room.
4. Connect the required devices and accessories, as described in Figure 115
5. Conduct three phantom tests:
   5.1. Conduct the test, when the Q-sense is OFF,
   5.2. Conduct the test, when the Q-sense is ON and software is OFF,
   5.3. Conduct the test, when the Q-sense 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.

26.2 TTL functionality

Q-sense systems with FMRI thermode functionality support TTL functionality which can be used for synchronization with external systems.

26.2.1 Q-sense fMRI side panel

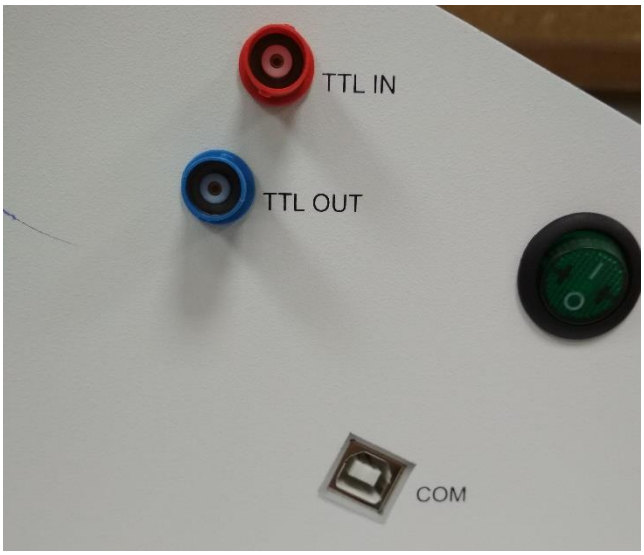


Figure 118: Q-sense fMRI side panel

26.2.2 TTL set up

Q-sense can send 1-bit TTL from the side panel TTL OUT BNC connector (see Figure 118)

Figure 119: HW settings for Q-sense fMRI

The polarity of the TTL can be configured in Q-sense hardware settings. See figure 119

1. **TTL Polarity:**
   - **1.1. TTL OUT:** Configure the Polarity of TTL OUT pulse: 5V or (-)5V. For 5V: The TTL is 0V when Idle and 5V when triggered. For (-)5V: The TTL is 5V when Idle and 0V when triggered.
   - **1.2. TTL IN:** The polarity of the TTL IN does not need to be configured. Q-sense will automatically detect if it is 5V or (-)5V.
2. **TTL Pulse out Duration:**
   - **2.1.** Configure the duration of the TTL OUT. The allowed range is: 50 – 1000 msec.

26.2.3 Standard Event Configuration

TTL trigger shall be sent only if the standard event is configured in the program

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

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

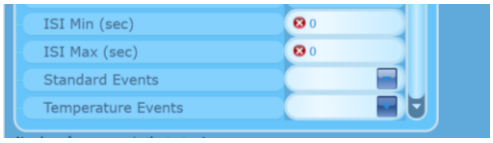


Figure 120: Standard Events in Program Editor

3. Click the blue arrow on the right to open the standard event editor.

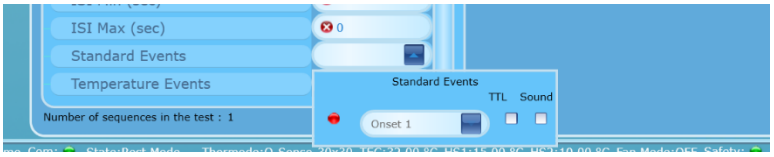


Figure 121: Standard Event Editor

4. Mark TTL option to activate TTL OUT signal output for various standard events (Onset, Temperature UP/DOWN, End of duration, End of test).

26.2.4 TTL specifications

Parameter	Description
Synchronization options TTL Input	Externally trigger the onset of stimulus Voltage: ± 5V Current: 10 – 15 mA Minimum Duration: 10 msec.
Synchronization options TTL Output	Can indicate various events during stimuli (depending on protocol used) Voltage: ± 5V Current: 2 mA Duration: 50 – 1000 msec

26.3 Blower control

Regular thermode 30x30 is cooled by an internal fan in the thermode enclose. fMRI 30x30 thermode is cooled via the air tube by a blower inside the main unit.

It is possible to turn off the blower for work in an office environment.

In order to do that there is a need to defined two types of thermodes in the HW settings. Thermode type "30x30" and thermode type "fMRI 30x30". By setting thermode type 30x30 as current you will disable the blower and activate the regular thermode fan. Setting thermode type as fMRI 30x30 will activate the blower and disable the regular thermode fan.

For additional info please refer to section 10.2.3

Use of a thermode without appropriate cooling may result in the thermode providing inaccurate temperatures, and may result in the test being stopped due to safety mechanisms being activated, especially in prolonged cold detection threshold protocols.

Ensure that the correct thermode type is selected in HW settings.