CE

QST.Lab

THERMAL CUTANEOUS STIMULATOR

TCS II.1 & TCS II.1.b

User's manual

Software version 14.33.12 © and later

CONTENT

THERMAL SKIN STIMULATOR TCS II.1

USER'S MANUAL

1. Presentation of the TCS II.1

The TCS II.1 is a thermal-contact stimulator for the skin. The TCS II.1 is intended for scientific research on the human and animal thermoception system. The TCS II.1 is equipped with all the necessary accessories for efficient operation. The operation of the TCS II.1 is simple and clear and does not require any special training (except reading the User's Manual).

The operating principle of the TCS II.1 consists of placing the surface of the probe, which includes the Peltier elements, on the skin of the subject (human or animal) and triggering a thermal stimulation of predetermined duration and intensity.

1.1. Symbols

⚠ Indicates important additional information, advice, or recommendations.

⚠ Warns against misuse of the SDC II.1. The device may be damaged if it is not used correctly.

⚠ Warns of a potentially dangerous situation (risk of injury)!

2. Safety and operating instructions

To maintain the highest level of personal safety during the various tests and measurements, QST.Lab recommends preventing damage to the TCS II.1 and maintaining it in optimum operating condition. To this end, the following warnings should be taken into account:

- If the test equipment is used in a manner not in accordance with the manual, the protection provided is no longer guaranteed.
- For your own safety, read the manual; otherwise, you may suffer personal injury or damage the TCS II.1.
- Do not use the TCS II.1 or any accessories if damage is visible.
- Take usual precautions to avoid risk of electric shock when working on devices connected to the TCS II.1 (e.g., EEG systems).
- Do not disassemble or attempt to repair the TCS II.1 in the event of a breakdown or malfunction.
- Do not attempt to use the TCS II.1 if an error message prompts you to contact QST.Lab.
- Do not use the unit outdoors.
- Do not pour liquid on the TCS II.1.

2.1. Protection against the risk of first-degree burns

2.1.1. Self-test at startup

When the TCS II.1 is switched on, it performs a self-test of the five stimulation zones. If one or more zones are defective, the TCS II.1 will sound five beeps and display a message in the main interface menu warning that one or more stimulation zones are defective. Before contacting QST.Lab, check that the stimulation probe is correctly connected. If the probe is connected properly and the problem persists, please contact QST.Lab.

2.1.2. Temperature/Duration of safety function

The TCS II.1 uses a temperature/stimulation duration function that sets a maximum stimulation duration depending on the selected stimulation temperature. For example, the TCS II.1 does not allow more than 2 seconds for stimulation at 60°C or 12 seconds for stimulation at 50°C.

This function integrates four parameters: the setpoint temperature, the dwell time at the setpoint temperature, the ramp to reach the setpoint temperature, and the return ramp. The TCS II.1 automatically adjusts one or more of these parameters to ensure that the total energy received by the skin does not cause burns.

⚠️The limitation of the Time/Temperature software protects against first-degree burns only for a single stimulation on the same area of the skin. The user must never stimulate the same area of skin consecutively when the stimulation temperature is above 42°C.

2.1.3. Real-time testing

During a stimulation, the TCS II.1 checks every millisecond whether the temperature measured by the sensors of the stimulation elements conforms to its theoretical temperature, which depends on the stimulation parameters. If a sensor is removed during a stimulation, the TCS II.1 will detect an inconsistency, emit five alarm beeps and stop the stimulation.

⚠️ This security feature can generate false failure alarms depending on certain stimulation configurations (temperature, duration, ramp, return ramp). If this problem occurs, you can contact QST.Lab for an adjustment.

2.2. Protection against electric shock

2.2.1. Battery management

The battery consists of 14 SAMSUNG ICR18650-26F cells assembled in a configuration of two parallel banks of seven batteries connected in series."7 in series and 2 in parallel". The battery has a voltage of 21 V when empty, 29.4 V when fully charged, and a nominal voltage of 25.2 V. Its capacity is 5200 mAh, 131 Wh.

The battery manufacturer has subjected these cells to stringent safety tests, and the cells were found to satisfy the UN 38.3 standard for the safe transport of lithium batteries. In addition, a battery management system automatically shuts down the stimulator if the voltage drops below 21 V to ensure long battery life. The device does not contain any overvoltage devices, so voltages cannot exceed the battery voltage.

2.2.2. Automatic switch-off

An external charger, connected to the mains, ensures full charging by controlling the charging current and voltage. The device switches off automatically when the charger is connected to the stimulator, thereby preventing the device from working if it is plugged into an electrical outlet.

2.2.3. Galvanic insulation

All external parts of the sensor are electrically insulated from the rest of the device:
- The aluminum heatsink is not electrically connected to the appliance.
- The stimulation surface (gold part) is electrically insulated with ceramic.
- The temperature sensors (thermocouples) are electrically insulated from the rest of the device by electronic insulators that provide electrical isolation at voltages greater than 2500 VDC.

- The rest of the surface in contact with the skin consists of an electrical insulator (FR4 epoxy laminate) coated with an insulating varnish (polyurethane).
- The probe tip is molded out of a special, non-conductive black epoxy resin insulation

2.3. Recommendations for cleaning/disinfecting the stimulator and its accessories

The user of the TCS II.1 and its accessories (probe, charger, response buttons) is responsible for their decontamination if hazardous products have been spilt on any of its external or internal parts.

2.3.1. Recommended cleaning / disinfection products

Alcohol wipes are preferable for cleaning and/or disinfecting the control unit, the probe, and the charger. Wipes moistened with water may also be suitable for simple cleaning without disinfection.

2.3.2. Prohibited products for cleaning/disinfecting the stimulator and its accessories

When cleaning and/or disinfecting the TCS II.1 and its accessories, the glycol and polyol families of solvents for plastics are absolutely prohibited.

The user is responsible for ensuring that these solvents do not contact the TCS II.1 or its accessories.

⚠ **The user must contact QST.Lab if there is any doubt about the compatibility of cleaning products with the TCS II.1 and its accessories.**

2.4. Standards applied

The TCS II.1 is manufactured and tested in accordance with the following regulations:

- Electromagnetic compatibility (EMC):

  IN 61326-1; EN61326-2-6; EN55011

  "Electrical equipment for measurement, control and laboratory use - Part 1: General requirements."

- Electrical safety compliance:

  EN 61010-1/A1

  "Safety requirements for electronic equipment for measurement, control and laboratory use - Part 1: General requirements"

  EN 61010-2-010

  "Specific requirements for electronic equipment used for the heating of materials"

⚠ The TCS II.1 is intended for scientific research only (RUO, Research Use Only) on the human and animal thermoception system. The TCS II.1 is not a medical device (MD) and must not be used for diagnostic purposes.

3. Description

Figure 1

1: Stimulation surface
2: Heat exchanger by ambient air
3: Stimulation probe protection
4: ON/OFF switch
5: Response button connector
6: Connector for input triggers (On devices manufactured before 09/2021, this connector is labelled 'STIM'.)
7: DB9 connector for output to external devices (e.g., EEG triggers for evoked potentials), 0–5 V TTL output
8: USB connectors for data logging and software updates
9: AC/DC power connector
10: Thermal probe connector
11: USB connector for computer control of the TCS and firmware updates (only TCSII.1)
12: Subject response button, to be connected to connector 5
13: Serial-to-BNC adapter for trigger output, to be connected to connector 7

3.1. Thermodes

- Thermoelectric system cooled by natural convection with ambient air
- Materials in contact with the skin: epoxy resin and polished varnish (non-active areas), ceramics with a pure gold deposit (active areas), tin–bismuth alloy (temperature sensor)
- Temperature sensors: thermocouples
- Temperature range: 0 to 60°C (limited by software)
- Hot or cold stimulation rate: adjustable from 0 to 300°C/s
- Five independent stimulation surfaces

⚠ The stimulation elements (1, Figure 1) are extremely fragile. They must be handled with extreme care. They must never be placed on a hard surface (table, support, etc.). They must only contact the subject's skin. Do not clean the stimulation head with a detergent or damp cloth. If necessary, clean the stimulation elements very gently with an alcohol wipe.

3.2. Temperature regulation system

- System control using serial commands sent via USB connection (virtual serial port at 115,200 baud)
- 8-bit trigger output (0–5 V)
- Relative temperature resolution: ±0.1°C
- Absolute temperature resolution: ±0.5°C
- Autonomous battery operation (approximately 15 hours, depending on the frequency of stimulation)

3.3. Dimensions

- Part of the thermode in contact with the skin: depends on the type of thermode (see website for details)
- Overall diameter of the thermode: depends on the type of thermode (see website for details)
- Total length of the thermode: depends on the type of thermode (see website for details)
- Weight of the thermode: 0.4 kg
- Length of thermode cable-control unit: 200 cm
- Dimensions of the control unit: 35 × 30 × 12 cm^3
- Weight of the control unit: 3 kg

3.4. Limits of use

- Ambient temperature: 17 to 40°C

⚠ The ambient temperature limits for using the TCS II.1 are controlled by the device; if the TCS II.1 is in a thermal environment outside this range, it will automatically switch off.

- Humidity: 30% to 80%, non-condensing

3.5. Trigger connection

The trigger output connector (7) uses a 74HC595 shift register with its own 5 V power supply isolated from the TCS II.1 stimulator. By default, all trigger outputs are at 0 V.

The activated trigger outputs switch to 5 V for 300 ms at the beginning of the stimulation. The activated trigger lines correspond in binary to the trigger number entered as a parameter. For example:
- 001" activates trigger output 0
- 002" activates trigger output 1
- 004" activates trigger output 2

...
- 255" activates all trigger outputs from 0 to 7 simultaneously.

3.6. Battery

The battery consists of 14 SAMSUNG branded cells in 18650 format. The battery has a voltage of 21 V at idle, 29.4 V at full charge, and a nominal voltage of 25.2 V. Its minimum capacity is 5200 mAh, which enables more than 10 hours of autonomous device operation. To ensure long battery life, a battery management system automatically shuts down the stimulator if the voltage drops below 21 V.

3.7. Charging the battery

1) Connect the specific charger supplied (29.4 V, 1.2 A) to the stimulator (connector 9, Figure 1). The charge indicator on the charger will light red during charging and will turn green when charging is complete. A full charge takes approximately 5 hours (90% charge in 4 hours).

⚠ The *ON/OFF* button must be in the OFF position during loading. The charger charge indicator will remain green if the *ON/OFF* button is in the ON position.

2) At the end of the charging process, the battery voltage will be 29.4 V. The TCS II.1 switches off automatically when the battery voltage drops below 21 V. The TCS II.1 cannot be restarted until the battery has been at least partially recharged.

- The battery charge level is displayed on the touch screen of the TCS II.1 when it is used in screen mode (i.e., not connected to a computer via the USB/serial port).

⚠ Only use the charger supplied with the TCS II.1.

⚠ The TCS II.1 switches off automatically if the charger is connected.

⚠ The stimulator cannot be used during charging.

4. Getting started

4.1. *ON/OFF* button

To turn on the TCS II.1, set the *ON/OFF* button to the ON position (4, Figure A). To switch off the TCS II.1, set the *ON/OFF* button to the OFF position.

4.2. Stimulations

The stimulation parameters and the launching of stimulations can be managed directly from the touch screen or by commands sent via the USB/serial link.

The touch panel and the USB/serial link cannot be used simultaneously: Connecting the USB/serial link automatically disconnects the touch panel.

The touch screen allows access to manual stimulations or standard protocols offered by the interface. The interface also allows the user to create simple personalized protocols.

5. Controlling the TCS II.1 via USB/serial link

5.1. USB/serial connection

Connect the stimulator with the USB cable (type A/B) to the control computer (connector 11, Figure A).

5.1.1. Serial communication parameters

- 115,200 baud
- 8 data bits
- No parity
- 1 stop bit
- No flow control

5.1.2. Configuration of the serial port and the communication terminal under Windows

1) In the "Coolterm"© application supplied with the TCS II.1, in the Option> Serial Port menu, select the serial port and com number proposed by the application. The communication speed should be 115,200 baud (Figure 2).
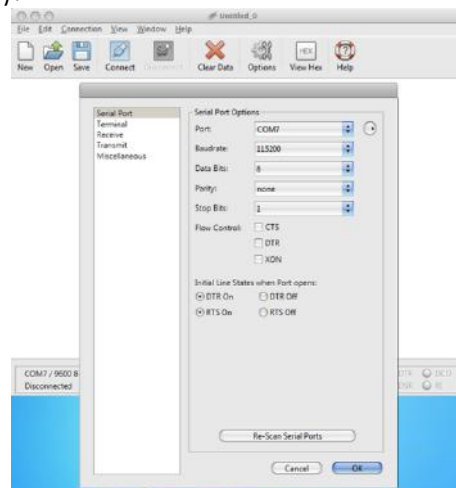
Figure 2

2) Click OK and then click Connect. Enter the letters "Oa" (capital o) on the keyboard. The stimulator will return the current temperatures of the five zones and the neutral temperature. The last two values on each line are control parameters for diagnosis in the event of device failure (Figure 3).
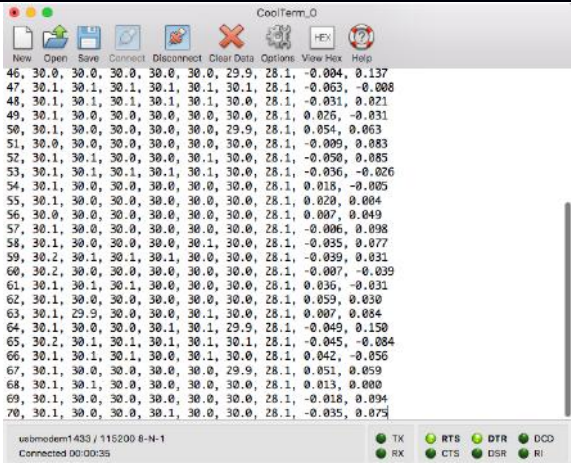
Figure 3

5.1.3. Configuration of the serial port and communication terminal on the operating system

1) The setup procedure is the same as that in section 5.1.2. The serial port to be selected is the "usbmodem 1441" port (Figure 4).
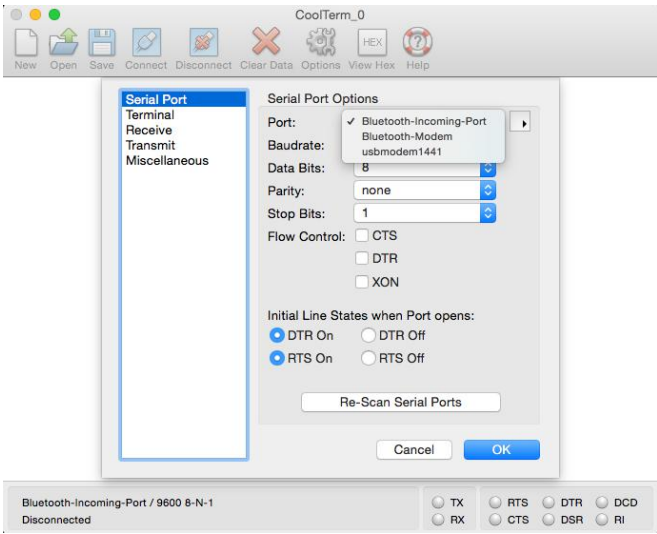
Figure 4

5.2. The TCS II.1 commands

To control the TCS II.1, the user must transfer commands via the serial port, which can be carried out two ways:

1) Enter commands from the keyboard via a "serial terminal" program such as the Coolterm © program supplied with the TCS II.1 (a solution suitable for a test phase or simple protocol).

2) Automatically use a computer program (solution adapted to more complex protocols).

A "serial terminal" program is a window in which the characters you enter on the keyboard are automatically sent to the serial device (here, the TCS II.1 connected to the computer). The characters returned from the device (TCS II.1) are automatically displayed in this same window. Free "serial terminal" software (Coolterm®) is provided on the USB key supplied with the device.

5.3. Stimulation settings via USB/serial port

⚠ When the TCS II.1 is connected to a computer via a USB/serial port, the touch panel will turn off automatically.

Action	Order	Parameters for x	Unit	Default value for x
Setting the baseline temperature	**Nxxx**	200–450	0.1°C	300
Surface selection	**Sxxxxx**	0 or 1 per surface		00000
Setting the target temperature	**Csxxx***	000–600	0.1°C	100
Adjusting the stimulation rate	**Vsxxxx***	0001–9999	0.1°C/s	Depends on the type of sensor
Setting the return speed	**Rsxxxx***	0001–9999	0.1°C/s	Depends on the type of sensor
Setting the stimulation duration	**Dsxxxxx***	00010 –99999	ms	00100
Trigger number and its duration	**Txxxxxx**	001–255 / 010–999	Trig #/ms	255300

* The letter **S** indicates the zone on which the control is located (1, 2, 3, 4, and/or 5). If the control is to apply to all surfaces, **S** is set to 0. The default value for the **S** control is 00000. Therefore, all zones are disabled when the TCS II.1 is switched on. To perform Serial Com stimulation tests, activate at least one zone.

⚠ You must enter as many characters as the control parameters require.

> For example:
> To obtain a stimulation rate of 50°C/s on surface 1:
> Correct input: V10500
> Incorrect entry: V1500 or V1050

- It is not necessary to confirm the order with the "Enter" key.

⚠ It is important to allow at least 1 ms between each character of the instruction. The unit scans the serial port every millisecond. Characters may be unreadable if this delay is not implemented.

⚠ Duration of stimulus measures

Stimulus duration includes the duration of the ramp and the time the stimulus is maintained at its set temperature, as shown in Figure 5.

Figure 5

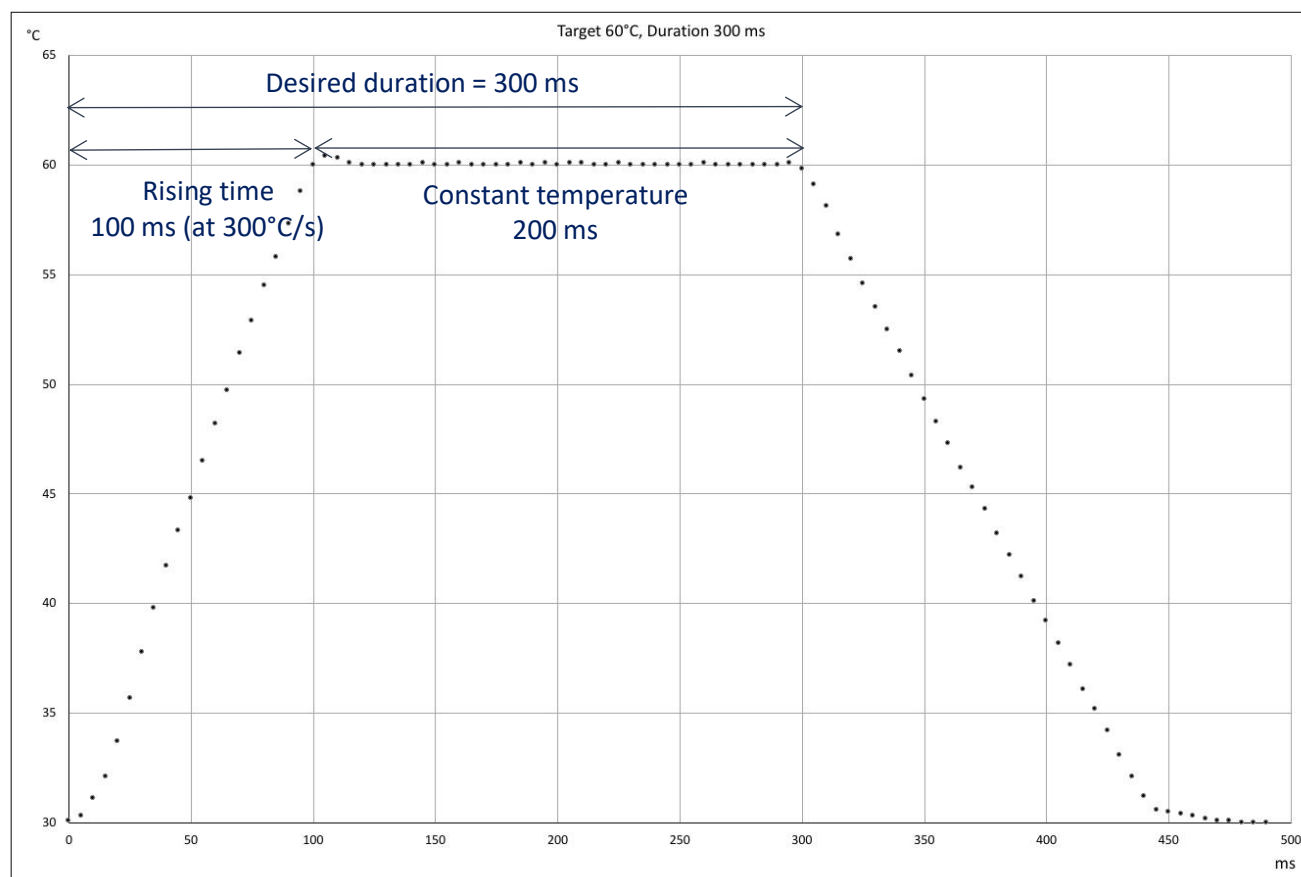Example of the time distribution of a temperature curve. For example, when a duration of 300 ms is required, the TCS II.1 incorporates the time to reach the desired temperature (here, 60°C with a speed of 300°C/s) and the necessary holding time required at the desired temperature so that the total duration of the stimulation is 300 ms.

5.4. Functional controls

Action	Order	Information
Display TCS commands	**H**	
Display current temperatures	**E**	Neutral temperature then each surface
Display the current values of the stimulator parameters	**P**	
Display the status of the button	**K**	01 if pressurized; 0 otherwise
Display voltage and % battery charge	**B**	
Automatic calibration of the reference temperature	**G**	Displays Nxxx with neutral t° in case of success
Trigger stimulation with the current settings	**L**	
Force a halt to the current stimulation	**A**	
Display time (in milliseconds) after stimulation with the L-control	**Yxxxx**	One line every 10 ms If "0000", then the default stimulation duration is "0000".
Deactivate the display of current temperatures	**F**	
Return the status of buttons *1* and *2*	**K**	CR+00 both released; CR+11 both pressed; CR+10 button *1* pressed; CR+ 01 button *2* pressed
Return error codes for probe diagnosis	**Q**	Returns "xxxxx" for each zone and the basic temperature; x = 0 : OK / x > 1 : ERROR
Allow regular display of current temperatures	**Oa**	1 Hz
Allow the display of temperatures during stimulation	**Ob**	100 Hz
Reset the TCS (same action as switching OFF and ON again)	**Oc**	
Define a maximum stimulation temperature	**Omxxx**	xxx' 1/10 °C
Define the speed in 1/100°C	**Ovsxxxxx**	xxxxx'='00001' to '99999'
Define the temperature in 1/100°C	**Otsxxxx**	xxxx'='0001' to '6000'
	Oe	
Send a trigger as an output	**Oo**	
User-defined temperature profile defined by segments of variable duration	**Uwxxxxxxnnnnnddttttd ddttt...**	xxxxx": defined zones ("11111" all zones, "10000" only zone 1, ...), "nnn": number of segments ("000" to "999") dddttt: list of the segment duration in tens ms ('001' to '999') and the temperature at the end of the segment ('000' to '600').
Activate/deactivate the temperature profile for each zone	**Uexxxxx**	(x = '1' = on or '0' = off = default)
Display the temperature profile for each zone	**Ur**	
Read the time and date of the clock	**Xr**	Return hhmmssddmmyy
Buzzer	**Zdddfff**	ddd: duration in 10× ms, fff: frequency in 10× Hz

6. TCS II.1 control via touch screen

6.1. Main menu

From the main menu, the user can access the different modes of using the stimulator.

1) Touch the *Subject* button to access the interface for entering information on the subject.

2) Touch the *History* button to access data graphs generated by the stimulator.

3) Touch the *Settings* button to read and set the general settings of the TCS II (date/time, software version).

4) Touch the *Stimulation settings* button to access the stimulation interface.

5) Touch the *Threshold and Standard protocols* button to access the threshold estimation interface.

6) Touch the *Custom protocols* button to access the interface for programming or executing a stimulation protocol.

6.2. Subjects menu

The Subject interface allows the user to enter information about the subject.

NB: The information entered is used to name the subject's results file.

1) *Ident* field. To enter an anonymous code for the test subject, use this field. The result files will be named according to this code.

2) *Last name* and *First name* fields: If a code has not been entered in the *Ident* field, the name of the resulting file will begin with the initials of the subject's first name and surname.

3) *Age* field: Touch this field to enter the age of the subject. The age of the subject will also be added to the name of the result file.

4) *Gender* button: Touch the *F* (female) or *M* (male) button to specify the gender of the subject. The letter *F* or *M* will also be part of the result file name.

5) Touch the *Exit* arrow to return to the main menu when all the fields are filled in. If all the fields have not been filled in, the result file will be named as the date and time at which the test is performed.

6.3. History menu

6.3.1. Types of files

1) **Results files from threshold measurements**

Two types of files are recorded when a threshold is measured: (a) an image file in .png format, corresponding to the curves drawn during the test and (b) a data file in .csv format, containing the stimulation temperatures, the subject's response (button pressed or not), and the subject's reaction time. Only the .png file can be viewed on the TCS II.1 screen using the *Open* button. The .csv data file is only accessible after the file has been exported to a USB memory stick for reading on a computer.

2) **Stimuli stored in the "Stimulation Settings" menu**

When stimuli, as configured in the "Stimulation Settings" menu, are saved, they can be retrieved from the *History* menu and exported to a USB memory stick. The exported formats are a .png image file and a .csv raw-data file.

6.3.2. Exporting files

To export the files stored in the memory of the TCS II.1, (1) press the *Image* button on the TCS II.1 at the bottom of the screen (a list of files present appears), (2) insert a USB memory stick in the reader, (3) select the desired file(s), and (4) press the arrow indicating export from the TCS II.1 to the USB memory stick.

6.3.3. Deleting files

To delete files from the TCS II.1, select the desired files and press the *Delete* button.

⚠ **Any deletion will be final.**

6.4. Stimulation Settings menu

6.4.1. Interface description

The interface consists of (i) a graph showing the time/temperature function according to the selected parameters, (ii) the current temperatures of the five stimulation zones, and (iii) the control buttons.

1) **<u>Buttons *1* to *5*</u>**

   When buttons *1* to *5* appear in blue, the corresponding stimulation zones on the thermal probe are active and will reach the set temperatures. To deactivate the stimulation zones, press the corresponding buttons (these will appear in gray).

   The colored lines around the buttons correspond to the colors of the curves displayed in the graph. To display the curves individually for each stimulation zone, simply deactivate the corresponding button.

   The stimulation parameters can be set independently for each stimulation zone. To do this, select the zone to be set and deselect the other zones. Then press the *Set parameters* button.

2) **<u>*Set* button</u>**

   Method
   Press this button to set the method for setting up the stimulation. The stimulation settings can be set in two ways. The active setting method is the one highlighted on the *Method* line:

   A) The *Set temp./speed* method
      With this method, a forward and a reverse ramp speed, a temperature, and a stimulation duration can be set.

      Baseline
      The *Baseline* button is used to set the baseline temperature of the sensor. The stimulation zones will return to this base temperature after each stimulation.

      Adj. to skin
      Press this button while holding the probe for several seconds on the subject's skin to match the baseline temperature to the skin temperature. Once the sensor reaches the skin temperature, the temperature will be displayed in the *Baseline* field.

      Offset
      This option allows the user to set a delay for the temperature ramp start. In particular, this option allows the creation of a time offset between the different stimulation zones.

   B) The *Point-to-point curve* method
      This method allows the user to define temperature targets at a specific point in time over the stimulation time interval.

      Add point
      Press this button to add a target temperature at a given time to the stimulation time interval. For example, if the stimulation duration is 1 second, a stimulation point can be added at any time between 0 and 1 second (0.1 s, 0.2 s, etc.).

Delete point
To delete created points, press this button. The buttons will turn red and simply touch the point to be deleted on the graph.

Edit point (coming soon)
This button is used to edit a point to change its temperature or position on the time scale.

Reset curve
This command erases all the stimulation points created.

OK
Press this button to confirm the stimulation settings.

ESC
Press this button to abandon the stimulation setting. No changes entered will be saved.

3) <u>*Reset* button</u>

This button resets all the stimulation parameters with a time window of 1 second and a stimulation temperature of 30°C (i.e., the baseline temperature).

4) <u>*Load* button</u>

This button allows a stimulus created and saved beforehand or a stimulus imported from a USB key to be loaded.

The stimulus menu displays either the stimulus files in the TCS II memory (*TCS* button at the bottom of the active screen), or stimulus files on a USB memory stick (*USB* button at the bottom of the active screen), which will need to be imported into the TCS before use.

5) <u>*Save* button</u>

This option allows the stimulation parameters to be saved to a file for later use (e.g., in programming a protocol).

Create a file:
1) Enter a file name by touching the *File Name* field.
2) Press the *Save* button. The stimulation file will be saved in the TCS memory.

Exporting a stimulation file:
1) The image button *TCS* is activated in green.
2) Select a stimulus file from the file-list window.
3) Insert a USB memory stick into the TCS.
4) Press the arrow pointing from the *TCS* button to the *USB* button.

Importing a stimulation file:
1) Insert the USB memory stick with the stored stimulation file into the TCS.
2) Activate the *USB* button by pressing it.
3) Select the stimulus file to import.
4) Press the arrow pointing from the *USB* button to the *TCS* button.
5) Press the *TCS* button. The imported stimulus file is now in the file list.

6) *Stimulate* button

This button activates the stimulation with the saved settings. The temperature curve is displayed for each stimulation zone of the probe.

⚠ **Because of the manufacturing tolerances of the Peltier elements that make up each stimulation zone, the temperature curves may show slight time differences of a few milliseconds to a few tens of milliseconds between them. These differences do not imply that the stimulation probe is damaged.**

7) *E.T.R. (estimated temperature at receptors)* button

The TCS II.1 incorporates a skin thermal diffusivity model based on the biological heat transfer equation (BHTE) (Pennes, 1948). The temperatures at the thermal receptors estimated by this model have been validated physiologically (Chen et al., 1980) and by psychophysical methods in humans (Dufour et al., 2020).

The user can view the curve of estimated temperatures at different skin depths (0 to 300 μm) by pressing the *E.T.R.* button after pressing the *Stimulate* button.

6.5. Threshold and Standard protocols menu

Three methods for measuring thresholds are available in this menu of the TCS II.1. Depending on the chosen method, different parameters must be specified.

6.5.1. Method of Limits

The method of Limits consists of slowly increasing/decreasing the temperature (usually 1 to 2°C/sec) starting from a baseline temperature and asking the subject to press the response button as soon as he or she feels a change in temperature. The subject pressing the button stops the temperature progression, and the last temperature read will be set as the subject's detection threshold.

1) Select the type of threshold (cold or warm) to be measured by pressing the *Cold* or *Warm* button. This information will appear in the name of the result file.
2) Press the *Area* field to select the skin area to be stimulated. This information will appear in the name of the result file.
3) Specify the speed of the stimulation ramp by pressing the *Ramp* field.
4) Specify the speed of return to baseline temperature by pressing the *Return* field.
5) Specify the baseline temperature by pressing the *Baseline* field. If the user desires the baseline temperature to be the temperature of the skin area to be stimulated, place the probe on the subject's skin and press *Adj. to skin*.
6) Press the *Nb Stimuli* field to set the number of stimuli you wish to include in the average threshold.
7) Press the *Inter Stimulus Interval* field to set the waiting time between trials.
8) Enable or disable the *Beep* button if you want a sound to be emitted or not at each stimulation.

1) *Save* button

Pressing the *Save* button will save the entered threshold measurement parameters to a file.

1) Assign the threshold settings a name by pressing the *File name* field and then press *Save*.

2) Exporting threshold parameters
To export a threshold file to a USB memory stick, select the file to be exported and then press the arrow button pointing from the *TCS* button to the *USB* button.

3) Importing threshold parameters
To import a threshold file from a USB memory stick, (a) insert the USB memory stick into the TCS II, (b) press the *USB* button, (c) select the threshold file to be imported, and (d) press the button of the arrow pointing from the *USB* button to the *TCS* button. Finally, press the *TCS* button to view and select the threshold file to be opened.

2) *Load* button

To load threshold parameters stored in a threshold file, press the *Load* button. Press either the *TCS* button if the file to be loaded is in the memory of the TCS II.1 or the *USB* button if the file to be loaded is on a USB memory stick already inserted into the TCS II.1. For a threshold file to be loaded from a USB memory stick, it must first be imported into the TCS II.1 by selecting it on the USB memory stick and then pressing the arrow pointing from the *USB* button to the *TCS* button. Press *Open* to load the selected file.

3) *Start* button

The *Start* button activates the stimulation/response interface. This interface recalls in title the defined parameters. The graphic window shows a horizontal black line corresponding to the baseline temperature defined in the parameters.

- To start, press the *Start* button.
- The program starts a stimulation after a countdown, visible at the top of the screen.
- The temperature is increased/decreased, depending on the type of threshold (warm, cold), at the rate set in the parameters.
- As soon as the subject senses a change in temperature, he or she should press the response button connected to the TCS II.1 via the *Resp* connector.
- The temperature of the stimulation surface at the time the button is pressed is shown on the graph.
- The program constructs two curves: (1) a curve that corresponds to the threshold temperature in each trial and (2) a curve that corresponds to the average temperature of all the trials.
- The user can stop the program by pressing *Pause*.
- The user can then either resume the threshold measurements if additional more trials are desired for estimating the average threshold or stop the measurements by pressing *Save*.
- Press the back arrow at the bottom left of the screen to exit the program.
- The threshold calculated by the program is expressed as an absolute value or as a delta relative to the baseline temperature. This threshold corresponds to the average temperature of all the trials.

Nb: To save the threshold measurements, press the *Save* button before exiting the program. The results can be consulted in the "History" menu and can be exported to a USB memory stick in two formats: (1) an image corresponding to the graphs drawn during the test and (2) raw data in .csv file format.

6.5.2. Method of Levels

The method of levels differs from the limit method in two respects:

1) The instruction given to the subject:
   The subject must indicate whether or not, by pressing the answer button or not, he or she felt a thermal stimulation. With this method, some stimulations will be presented at an infra-liminar intensity that the subject will not feel, and some will be presented at a supra-liminar intensity that the subject will feel.

2) The characteristics of the stimuli:
   Stimulations should be brief (a few milliseconds) so that the subject does not feel a temperature ramp. The intensity of the stimulation is defined by the program according to the subject's response to the intensity of the previous response, according to the algorithm detailed below.

   Unlike the method of Limits, the response time of the subject does not influence the threshold because the probe can reach the target temperature within a few milliseconds.

Adaptive Staircase algorithm:

The stimuli are presented with an initial step of 1°C. (i) At each response reversal, the size of the thermal intensity step is halved; (ii) when the minimum is reached (i.e., 0.1°C), the intensity step is constant; (iii) when there is no response reversal, the first two steps maintain the same intensity and the intensity steps are doubled from the third step onwards; (iv) if a response reversal follows a doubling of the step size, the third intensity step remains the same. The threshold is defined as the average of the last 10 inversions when the step size is at least 0.1°C.

- The steps for setting the threshold are the same as those described for the Limits method in section 6.5.1. Only the duration of the stimulation is to be entered in combination with the adaptive staircase method. The faster the probe, the shorter the stimulation duration can be. (e.g., 500 ms for a T03- or T04-type probe with a speed of 300°C/s).

  Response Timeout: This field allows the user to set the maximum amount of time the subject is allowed to press the response button.

- *Sham %*: Specify the rate of sham stimulations you want to introduce in the threshold measurement. If you specify a non-zero rate, it is important to activate the Beep button so that the subject is warned when to detect a stimulation or not.

- *Threshold accuracy*: The threshold estimation algorithm will stop after 10 inversions of responses for the smallest step (see description of the algorithm above). The amplitude of the smallest step can be defined here in °C. The smaller the step, the more accurate the threshold will be, but the more stimulations and time will be needed to estimate the threshold.

- The threshold program, started by pressing the *Start* button, operates as described in section 6.5.1.

- The graph reports the subject's responses for the different stimulation temperatures defined according to the algorithm described above. A circle is plotted when the subject presses the button and a cross is plotted when the subject does not press the button after a stimulation.

- The program waits for a response from the subject (after stimulation) for a period of time defined in the *Response timeout* field. If the subject does not press the response button, the program proceeds to the next stimulation.

- The program stops when it has determined the threshold according to the previously described algorithm.

6.5.3. Constant method

The Constant method should be used with short-duration stimuli, similar to the stimuli in the Adaptive Staircase method. It is to be used when the user wishes to establish a psychometric function allowing the calculation of different parameters (e.g., sensitivity vs decision criteria).

- This method requires a rapid threshold estimate to be established beforehand using the Limits method or the Adaptive Staircase method. This threshold must be entered in the *Estimation* field.

- The program will define 10 levels of thermal intensity.

- The step between the intensities is 0.1°C for a cold threshold and 0.5°C for a warm threshold.

- The program will present each intensity level 20 times in random order, i.e., 200 stimulations in total (10 intensities × 20 trials).

- At each trial, the subject has 2 s to press the button before the next trial is started.

- The program traces the psychometric function (number of detections vs intensity) as the trials progress.

- The program can be interrupted by pressing the *Pause* button. The *Resume* button resumes the program.

  ⚠ **It is imperative to save the test at the end before exiting the program by the exit arrow at the bottom left; otherwise, the data will be lost.**

6.5.4. Thermal Sensory Limen

In this algorithm, once started, the stimulus temperature does not stop at Baseline but 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 for the Limen or 'no thermal sensation' area to be calculated.

1) Select the type of threshold (cold or warm) to be measured first by pressing the *Cold* or *Warm* button.

2) Press the *Area* field to select the skin area to be stimulated. This information will appear in the name of the result file.

3) Specify the speed of the stimulation ramp by pressing the *Ramp* field.

4) Specify the baseline temperature by pressing the *Baseline* field. If the user desires the baseline temperature to be the temperature of the skin area to be stimulated, place the probe on the subject's skin and press *Adj. to skin*.

5) By pressing the *Duration* field, you can specify how long the threshold temperature should be held after the subject's response before starting the next threshold measurement. Note

that in the standard protocol this duration is 0, as the temperature changes immediately after the subject's response.

6) Press the *Nb Stimuli* field to set the number of stimuli you wish to run.

7) Enable or disable the *Beep* button if you want a sound to be emitted or not at each stimulation.

8) To reduce the total stimulation area, it is possible to deactivate one or more of the 5 zones of the probe by clicking on the zone numbers.

6.5.5. Temporal Summation

In this test, the perceived intensity of a single stimulus is compared with that of a series of n repetitive stimuli of the same physical intensity (usually 1/s) applied within the same area. The subject is asked to give a pain rating representing the single stimulus, and the estimated mean over the whole series of n stimuli using a '0–100' numerical or Visual to Analog rating scale. The whole procedure can be repeated N times. Wind-up ratio (WUR) is calculated as the ratio: mean rating of the N series divided by the mean rating of the N single stimuli.

1) Press the *Set single stim.* button to enter the single stimulus parameters: Temperature, stimulation duration, ramp, return ramp and the time to wait after the pain/temperature rating.

2) Press the *Set stim. series* button to enter the parameters of the stimulus series: Temperature, stimulation duration, ramp, ramp back, the time to wait after the pain/temperature rating, the interval between stimuli in the series and the number of stimuli in the series.

3) Press the *Area* field to select the skin area to be stimulated. This information will appear in the name of the result file.

4) Specify the baseline temperature by pressing the *Baseline* field. If the user desires the baseline temperature to be the temperature of the skin area to be stimulated, place the probe on the subject's skin and press *Adj. to skin*.

5) Select the judgement mode by pressing the *VAS* or *Num* field. The VAS field is only active if an eVAS is connected to the TCS beforehand.

6) If the *Num* field is selected, a number pad will be displayed after the single stimulus and the series of stimuli. The experimenter can enter the rating given by the subject. The values will be saved in the result file in csv format (see History Menu).
If the *VAS* field is selected, the program will wait for the subject to validate their judgement by visual analogy after pressing one of the eVAS response buttons.

7) Press the *Nb Blocs* field to set the number of Single/Series blocs you wish to run.

8) Enable or disable the *Beep* button if you want a sound to be emitted or not at each stimulation.

9) To reduce the total stimulation area, it is possible to deactivate one or more of the 5 zones of the probe by clicking on the zone numbers.

6.6. Protocol menu

This menu allows the user to create, export, and import experimental protocols (i.e., sequences of instructions that the TCS II.1 will execute automatically).

6.6.1. Protocol management

1) <u>**Locked** button</u>

To avoid operating errors, all new protocols are locked by default, as indicated by the button in the top-right corner, which appears in red with the inscription *Locked*. Changes cannot be made to the protocol until it has been unlocked. To unlock a protocol, simply press the *Locked* button and confirm the unlocking. The button will turn green, and it becomes possible to add or modify events.

2) <u>**New button**</u>
Press this button to create a new protocol.

3) <u>**Load button**</u>
Press this button to load a previously created and saved protocol. The protocol can either be loaded from the internal memory of the TCS II or from a USB memory stick. To load a protocol stored on a USB memory stick, it must first be copied to the memory of the TCS II.1. To copy a protocol, press the arrow pointing from the *USB* memory stick button to the *TCS II* button.

4) <u>**Save button**</u>

Press this button to save the created protocol. The protocol can either be saved in the internal memory of the TCS II.1 or to a USB memory stick.

6.6.2. Steps management

1) <u>**Add** button</u>

Press this button to add a step after the selected step (highlighted) or to add a first step if the protocol is empty.

1.1 <u>*Stimulation* button</u>
Pressing this button brings up the stimulation settings interface (*Stimulation Settings* menu). The user can either enter all of the stimulation parameters if they are not yet saved in the TCS II.1 memory or load previously saved stimulation parameters. Press the exit arrow at the bottom left of the screen to return to the *Protocol* menu.

1.2 <u>*Threshold* button</u>
Pressing this button takes the user directly to the *Thresholds* measurement programs (*Thresholds* menu). The user can either enter all the parameters of the threshold measurement program or load previously saved parameters.

When the protocol arrives at this step, it will execute the set threshold measurement program.

1.3 <u>*Wait* button</u>
This option puts the protocol on hold for an event that can be
a) A time interval defined in the field to the right of the *Duration* button
b) A time interval of random duration defined in the left and right of the *Random Delay* command
c) Trigger(s) input from a peripheral device connected to the TCS II.1 via the *Stim* connector (e.g., MRI scanner trigger); the number of triggers that the program must wait for before moving on to the next step can be set

d) A press of the response button connected to the TCS II.1 via the *Resp* connector; the waiting time can be set in the *Timeout* field

e) A rating on a numerical scale which will be done on a numerical pad appearing on the screen.

1.4 *Trigger out* button

This command sends triggers to the *Trigger Out* output. If the device to receive the triggers allows it, different values can be encoded in binary (1, 2, 4, 8 ... 255, for this option, a special adaptor will be needed). The "Output trigger" cable provided with the TCS II.1 sends a single pulse (0–5 V TTL). When using this cable for TTL outputs, set the trigger number to 1 or 255.

1.5 *Beep* button

This command introduces a sound that can be set in frequency and duration (default 1800 Hz, 500 ms).

1.6 *Repeat* button

The steps before this command can be repeated a specified number of times. Specify the step at which the repetition should start and the number of times the steps should be repeated.

1.7 *Baseline* button

Set the baseline temperature. If the desired base temperature is that of the skin area to be stimulated, press the *Adj. to skin* button while holding the probe on the subject's skin until the skin temperature is measured by the probe and reported in the *base temperature* field.

1.8 *VAS* button

This button launches the management program of the analogue visual scale electronic system available from QST.Lab (see http://www.qst-lab.eu/accessories).

1.9 *Set Const. Temp.* button

This function allows you to impose a constant temperature on the probe. The probe will remain at this temperature until a new set point is reached with the same option or until the protocol is completed. Only then will the probe return to the base temperature.

- To set the same temperature for all zones, press the 'Temperature' button.
- To set the same ramp speed for all zones, press the 'Speed' button.
- To set different temperatures and/or speeds to different zones, press the temperature and speed fields for each zone.
- To specify how long the temperature should be maintained for all zones, press the *Hold* button.
- To specify different temperature duration for different zones press the *Hold* field for each zone.
- To activate/deactivate a zone, press the zone number. The deactivated zones will be at the base temperature.

⚠ Warning! When you set a temperature with this option, the probe will remain at that temperature until you set a new temperature or until the protocol is terminated. For temperatures above 42°C it is therefore very important to ensure that the stimulation duration does not cause first degree burns. The temperature/duration safety function is no longer active in this mode.

1.10 *Cancel* button

If you do not wish to add the current step, press the *Cancel* button.

2) _Edit_ button

To change a step, press this button after selecting the step. The selected step should appear in blue.

3) _Delete_ button

To delete a step, press this button after selecting the step. The selected step should appear in blue.

6.6.3. Execution of the protocol

1) _Execute_ button

- All the steps programmed in the protocol are executed automatically when the _Execute_ button is pressed.

- When the program reaches a step that can be paused, such as a waiting time programmed with the _Wait_ command, the _Execute_ button will display the word "Pause". The program can then be paused. The program can be resumed by pressing the same button, which indicates _Resume_.

- The program can be stopped by pressing the _Cancel_ button.

- The time elapsed since the start of the protocol is shown in the field to the left of the _Cancel_ button.

- To exit from the Protocol Menu, press the exit arrow key at the bottom left of the screen.

6.6.4. Data recording

By activating the 'Rec. Temp' button, the TCS II will record the information listed in the table below at a frequency of 10 Hz. The file format is CSV. The file can be exported to a USB key from the 'History' menu.

Elapse Time (Sec)	Step Number	Step Name	Temp. Zone 1 °C	Temp. Zone 1 °C	Temp. Zone 1 °C	Temp. Zone 1 °C	Temp. Zone 1 °C	eVAS* Finger Position	eVAS* Response Button
* Refer to eVAS user manual									

6.7. Settings menu

6.7.1. General information

This menu shows the following information:

- The version of the interface software
- The serial number of your TCS II.1
- The serial number of the probe currently connected to the TCS II.1
- The address of the QST.Lab website

6.7.2. Time and date setting

The user must access this menu to change the date and time of the TCS II.1. It is important to set the date and time of the TCS II as all results, protocols and settings files will be dated to facilitate their organization.

6.7.3. Minimum and Maximum Temperature Limitation

It is possible to limit the temperature range in which you want the TCS II to operate. By default, this range is set between 5 and 50°C but it can be extended to 0 to 60°C, for example for very brief stimulations for evoked potential studies.

6.7.4. MRI Filter strength

For MRI compatible machines and probes, it is possible to set the intensity of the digital filter. Indeed, some types of MRI scans such as arterial perfusion scans generate more important electromagnetic disturbances which require to increase the strength of the digital filters. If you notice large variations in the temperature display, you should adjust the filter strength.

⚠   *Note that the higher the filter strength, the lower the speed of the probe.*

6.7.5. MRI Extension cables

For optimal operation, the temperature of the connectors on both sides of the penetration panel between the scanner room and the control room must be the same with a tolerance of about 0.5°C.

At start-up, if the probe and the control unit are connected via the extension cables, the TCS II.1 checks the temperatures of the connectors of both extension cables. If it detects a difference, it adjusts the temperature control system accordingly.

We recommend leaving the extension cables connected for at least 20 minutes before turning on the TCS II.1 to allow the connector temperatures to stabilize.

You can check the temperature of the connectors at any time and force the system to adjust by pressing the Calibrate button.

7. Firmware and interface software update

The firmware and interface software can be modified according to user requests and to implement future improvements.

7.1. Update for TCS II.1 version

7.1.1. Firmware update

The update must be performed from a computer running Windows 7 or later.

1) Switch on the TCS II.1.

2) Connect the TCS II.1 to the computer (connector 11, Figure 1) using the USB A/B cable supplied with the TCS II.1.

3) Run the "UpdateFirmware.exe" application using the USB memory stick supplied with the TCS II.1. The application will ask for the binary firmware.

4) Select the binary file downloaded from the download area of our website.

7.1.2. Updating the interface software

When a new update of the touch screen interface is released, you can download it from the website www.qst-lab.eu (download section) and copy it to a USB memory stick.

The key must then be inserted into the TCS II.1, which must be switched off. The TCS II.1 must then be switched on and will be updated automatically at startup.

⚠   *The USB stick must be formatted in FAT32 format (Windows).*

7.2. Update for TCS II.1.b version

When a new firmware or touch-panel interface update is released, you can download it from the website www.qst-lab.eu (section Download/TCS II.1.b) and copy the file "TCSUpdate_V14.zip" to a USB memory stick.

⚠   *Do not uncompress the zip file.*

The key must then be inserted into the TCS II.1.b, which must be switched OFF. Switch ON the TCS II.1.b. The firmware and software update will be performed automatically at startup.