QST Lab device review

Core technology, temperature rates and range

The technology is based on the use of micropeltier elements, which allow fast rates and passive cooling through a heat sink. Passive cooling through a heat sink may have the consequence of less stability in temperature at low rates and the inability to keep a long stable ramp and hold. The heat sink is part of the head of the thermode, it is not protected for touching, and may become very warm to the touch during extensive use.

Thus far, there have been no scientific reports or studies in which lower rates than 2 °C/sec have been used or where any ramp and hold has been conducted longer than 300 msec.

QST Lab has conducted a study in which they compared the “Limits method” for cold detection to show that the “Limits method” is not as precise as a very fast ramp-and-hold “Levels method”. In this study it is apparent that even their method works best if their ramp-and-hold plateau is longer rather than shorter (best results are in their longest plateau which is 300ms, possibly, if they could hold a longer plateau, results would be even better). Secondly, it is compared to the Limits method for cold detection at 2 and 4 °C/sec. This is not a relevant comparison since this does not fall within the scientific consensus of limits at 1 °C /sec or less, and because their measurement would reflect by this reaction time, rather than sensation threshold, as most people detect cold within 1-2 °C difference. The use of 2 and 4 °C /sec rates for Limits might be due to the instability of the stimulation in 1 °C /sec rate suggested above.

Assumption: their QST thermode (980mm) which has a maximum rate of 20 °C /sec. might work like the Q-Sense.

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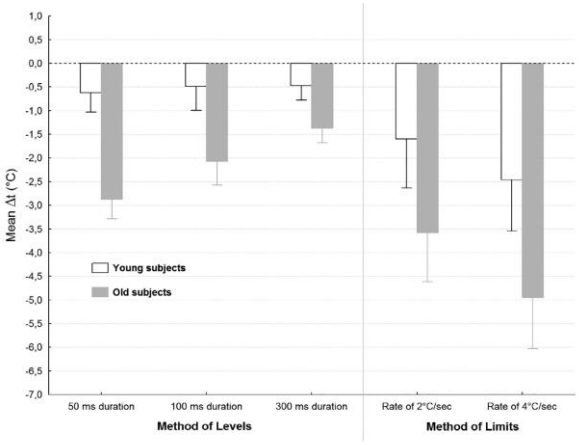


FIGURE 1. Mean cool perception thresholds (Δt, °C) for the method of levels (MLe) and the method of limits (MLi) during both sessions in younger and older patients. Three stimulation durations were used with the MLe (300, 100 and 50 ms), and 2 rates of temperature change were used with the MLi (2°C/s and 4°C/s).

Available probes

Probe size	Best suited for (according to QST Lab)	Maximum rate	fMRI version speed	Total dimensions (mm2)	Of which stimulation surface (mm2)	Continuous stimulation surface?	Strap-able?	Publication using this probe:
T08	fMRI & QST	170 °C /sec	100 °C /sec	2436	420	no - 5 zones devided over 15 micropeltiers of 7*12mm	yes	NA
T06	High Sensitive QST	20 °C /sec	20 °C /sec	3420	980	almost - 5 zones divided over 10 micropeltiers	yes	NA
T04	Cold-Heat Eps and thermal grill	300 °C /sec	100 °C /sec	2320	158.4	no - 5 zones of 3.2*9.9mm	yes	NA
T03	Cold-Heat Eps	300 °C /sec	100 °C /sec	1520.5	120	no - 15 micropeltiers devided into 5 zones	no	Lithfous 2019, Lenoir 2018
T01	Small Area Stimulations	300 °C /sec	100 °C /sec	262.5	38.4	almost - 5 zones divided over 5 micropeltiers	no	NA

Safety

QST lab by their own declaration have undergone very basic safety testing according to ISO/IEC 17050-12010. This is not nearly the type of scrutiny medical grade devices like Medoc go through when getting a CE Medical device class II certification under the watchful eye of a notified body, or the requirements of the FDA for clearance.

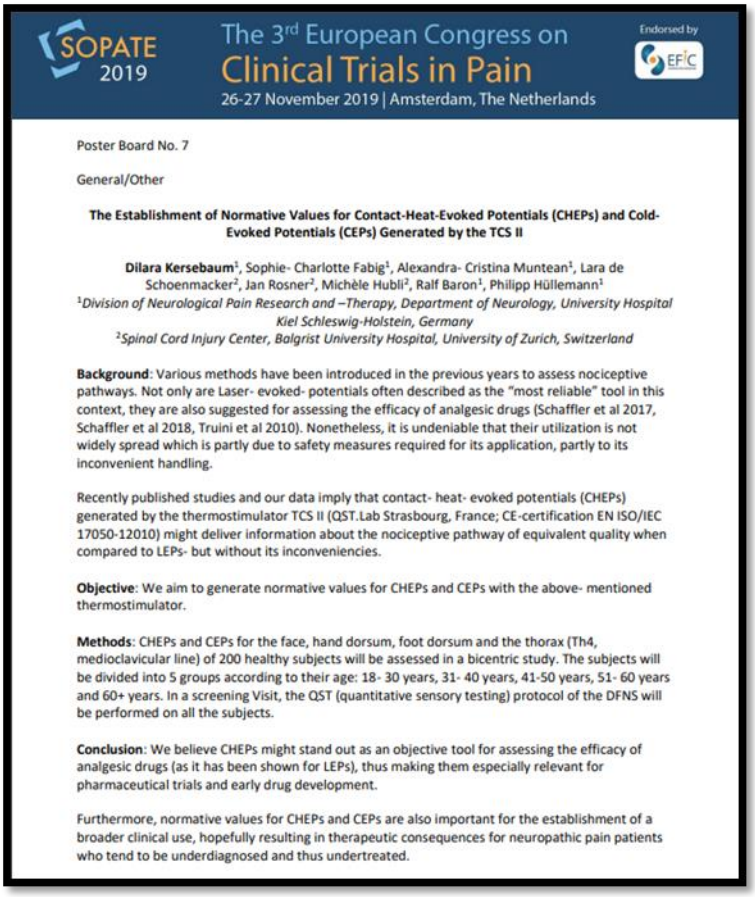
Their devices supposedly go from 0 °C up to 60 °C at a speed of 300 °C /sec. It is unknown what safety mechanisms are in place to stop the thermode from going over 60 °C , to limit the duration of a stimulus at >50 °C and other issues that pertain to safeguarding from injury.

Normative data

Thus far, most of the published articles using QST lab, have used their prototype thermode of 16 micropeltiers that doesn't exist on their website anymore. Currently no normative data exist for their device/thermodes.

It is known that QST Lab is working together with the Ralf Baron lab in Kiel, Germany, and the Armin Curt group at the Spinal Cord Injury Center in Zurich, Switzerland, to get normative data for the Contact Heat Evoked Potentials and Cold Evoked Potentials. It is not clear why they are aiming to use this for clinical trials, as the use of their device in a clinical trial would require more extensive medical device certification and audits.

It is currently not known whether they also work to get accepted by the DFNS to have their 980mm QST thermode included in the DFNS accepted devices. This is a major, and threatening possibility.



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General/Other

The Establishment of Normative Values for Contact-Heat-Evoked Potentials (CHEPs) and Cold-Evoked Potentials (CEPs) Generated by the TCS II

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Background: Various methods have been introduced in the previous years to assess nociceptive pathways. Not only are Laser- evoked- potentials often described as the "most reliable" tool in this context, they are also suggested for assessing the efficacy of analgesic drugs (Schaffler et al 2017, Schaffler et al 2018, Truini et al 2010). Nonetheless, it is undeniable that their utilization is not widely spread which is partly due to safety measures required for its application, partly to its inconvenient handling.

Recently published studies and our data imply that contact- heat- evoked potentials (CHEPs) generated by the thermostimulator TCS II (QST.Lab Strasbourg, France; CE-certification EN ISO/IEC 17050-12010) might deliver information about the nociceptive pathway of equivalent quality when compared to LEPs- but without its inconveniencies.

Objective: We aim to generate normative values for CHEPs and CEPs with the above- mentioned thermostimulator.

Methods: CHEPs and CEPs for the face, hand dorsum, foot dorsum and the thorax (Th4, medioclavicular line) of 200 healthy subjects will be assessed in a bicentric study. The subjects will be divided into 5 groups according to their age: 18- 30 years, 31- 40 years, 41-50 years, 51- 60 years and 60+ years. In a screening Visit, the QST (quantitative sensory testing) protocol of the DFNS will be performed on all the subjects.

Conclusion: We believe CHEPs might stand out as an objective tool for assessing the efficacy of analgesic drugs (as it has been shown for LEPs), thus making them especially relevant for pharmaceutical trials and early drug development.

Furthermore, normative values for CHEPs and CEPs are also important for the establishment of a broader clinical use, hopefully resulting in therapeutic consequences for neuropathic pain patients who tend to be underdiagnosed and thus undertreated.

Calibration

There is no information available regarding calibration of their devices. External calibration, using contact thermometers, would require for the thermode to keep a stable temperature for a long while, which is doubtful that QST-Lab's device is able to do. Additionally, each of the micropeltiers would need to be tested separately, imagine doing that on 15 different small surfaces.

In the past QST Lab claimed to calibrate one TEC vs. the other, which resulted in deviation of several degrees at the extreme temperatures. We are not certain, but the chances are high that this is still the case.

fMRI use

QST Lab declare that all of their thermodes can be manufactured in fMRI compatible versions. It is not known whether they have been tested in such an environment already, whether there is a use of a filter or sound wave, whether there are artifacts etc.. The QST Lab device has TTL out, it is not known whether they have TTL in (probably don't), and they don't have external control.

The price of the device with fMRI compatible probe is higher than the regular, currently it is 10,000 € (for probe alone).

Battery operated

Battery life is not known. It is not apparent how much of charging is needed for the device to work.

One of the US QST Lab users had a technical problem related to the battery.

In QST Lab's largest probe with intended use of QST, the use of battery is limiting the speeds (up to 20 °C/sec), due to limited power output pulse of the battery.

Product life time

QST Lab claim there is no maintenance to the device. It is apparent that they don't work with local distributer. It is unsure whether the device can be opened, or that parts can be exchanged outside of a lab setting. Because the device is very young, it is currently hard to know what its weak points are, whether their thermodes keep calibration (because nobody checks it), and how fragile/reliable it is. It is unknown whether there is a comprehensive warranty policy in place for the device and its parts.

Pricing

Device with a 'regular' probe – 18,000 €

Device with fMRI compatible probe – 20,000 €

Regular probe – 6,000 €

fMRI probe – 10,000 €

Open Questions

Pricing:

How the device is priced, i.e. different probes. What is the service and warranty policy?

Regulatory status:

Are they aspiring to get FDA or CE certification for Medical device? How can they sell to hospitals/universities where patients undergo experiments without it?

fMRI compatibility:

Have their devices been tested in an fMRI environment, if so where? Are there artifacts? What about safety in the scanner?

Customer base:

It is known that QST Lab devices are present in Switzerland, Germany, Holland, Belgium, France, Italy, USA. We know for a fact that the Dutch device is a paid device, about the others it may be partially paid or not at all. Are any of our current customers involved in them? How can they be deterred?

Performance:

Can the device work at slow rates stably? Can it be used in Ramp&Hold mode? For how long can a temperature me maintained, especially for cold temperatures?

Comparison – Medoc vs QST Lab

1. Application: Evoked potentials

1.1 Parameters comparison

Comparison parameter	**TSA 2 CHEPS**	**QST LAB CHEPS**
Rates	Up to 70 °C /sec for heat EPs Up to 50 °C /sec for cold EPs Same for fMRI	300 °C /sec for both heat and cold EPs fMRI probes have slower rates (100 °C /sec max.)
Temperature range	0-55 °C	0-60 °C
Portability	Portable	Portable and battery operated (~4Kg)
Price	~ 22K $ ex-works, ~ 33K $ end user (for standard) ~24.5K $ ex-works, ~37K $ end user (for fMRI)	~19.5 K $ end user (for standard) ~ 22K $ end user (for fMRI)
FMRI	fMRI configuration available	fMRI configuration available
Surface	572mm^2	160 mm^2 (rectangular probe) – probe with 300 C/sec 420 mm^2 – probe with 170 C/sec
Validation	Over 200 papers published for evoked potentials Over 400 in general with PW CHEPS	6 papers published so far
Normative data	Available	Not Available, in the works
Thermode	Strap-able	3 out of 5 thermodes are stap-able
Software	Flexible, with many options and possibilities External control available TTL In and Out available	*Simple with built-in protocols* (unknown) No external control available TTL out available

Regulation status	CE and FDA approved	Not FDA approved CE: no medical grade CE certification, as attested to by QST Lab's own label

1.2 Medoc pros and cons - CHEPS

Medoc Strengths:

- Validation: hundreds of papers published with Pathway CHEPS (~400) vs 6 with QST Labs device. Of those 6, only one possibly conducted with a thermode now available on the market
- Normative data: available for various populations and body sites with Medoc, QST Lab normative data will now started to be collected
- Surface: 572 mm^2 (PW CHEPS) vs 160 (max) mm^2 (QST Labs)

  PATHWAY CHEPS large surface allows to achieve higher stimulus intensity and robust evoked potentials at lower temperatures and shorter durations.
- Regulation: Medoc CHEPS: FDA and CE approved device, QST Labs: none.
- Service – Medoc is represented by experienced and professional local distributors all over the world. QST Lab has no representation in countries other than France, where the headquarters are located.

Medoc Weaknesses:

- Rates: maximum 300 ℃ /sec with QST Labs device (but only 100 ℃ /sec in the scanner), vs 70 ℃ /sec with TSA2 CHEPS
- Portability and price: QST Lab is relatively small and portable (4kg), battery operated and cheaper (~EURO 18,000)

2. Application: QST

1.1 Parameters comparison

	Medoc's QST devices	**QST LAB QST**
Rates	Up to 13 °C /sec (for TSA2)	Up to 170 °C /sec for 420 mm^2 surface probe Up to 20 °C /sec for the 980 mm^2 probe
Temperature range	0-53 °C /sec	0-60 °C /sec (Safety?)
Portability	Portable: Q-Sense (6kg) / TSA2 (10 kg)	Portable: ~4Kg
Price	Q-Sense - ~12-15K $ end user price, depending on the region TSA2 - ~30K $ end user price	~20K $ end user price
FMRI	fMRI configuration available	fMRI configuration available
Surface	30x30 – standard	Up to 980 mm2 probe of 10 micropeltiers
Validation	Over 2000 papers published with Medoc devices Standard protocols available for various modalities	2 relevant papers: in 1 heat pain thresholds, in 1 cold detection thresholds No standard/ validated protocols for any modality
Normative data	Available	Not Available, might be in the works
Thermode	Various sizes and shapes to fit specific body parts Option for dual-thermode	2 available probes "for QST" – 980 mm^2 and 420 mm^2 surface. Probe for animal testing is available
Software	Flexible, with many options and possibilities	Unknown
Regulation status	CE and FDA approved	Not FDA approved CE: no medical grade CE certification, as attested to by their own label

2.2 Medoc pros and cons

Medoc Strengths:

- Surface: Medoc - probe surface (30x30) is aligned with recommended standard protocols; a large surface promises robust and intensive stimulation

  QST Labs – QST probe of 980 mm2 made from 10 micropeltiers, it is not clear whether this probe is able to be stable in slow rates like 1 °C /sec or less.
- Validation: Over 2000 papers published with Medoc devices, with more than 250 in 2018-19 vs 1 QST paper with QST Lab.
- Normative data: Many DFNS and others normative data publications with Medoc devices (TSA) for various modalities and body sites vs. none with QST Lab.
- Regulation: Medoc QST devices are FDA and CE approved devices, while QST Lab isn't.
- Configurations: Medoc has various thermode sizes and shapes for specific body parts; option for dual thermode configuration
- Service – Medoc is represented by experienced and professional local distributors all over the world. QST Lab has no representation in countries other than France, where the headquarters are located.

Medoc Weaknesses:

- Portability: QST Lab device is small and portable (4kg)
- Price: QST Lab's device is cheaper (~EURO 18,000 for QST Lab)
- Flexibility of stimulation surface: Five Independent stimulation zones (each can be set at a different temperature). Might be a nice thing to "play" with for researchers