



PinPrick Stimulator Set

Tactile stimulators for
quantitative sensoric testing
(QST)



User manual

1. Intended use

The “PinPrick” or punctate needle stimulators enable the application of reproducible tactile/mechanical stimuli on the human skin. They are manually applied on different areas of the body. The stimulation is solely based on the force of freely movable weights inside the guiding tubes. The different weights result in different stimulus intensities. One set includes seven PinPrick stimulators with logarithmically staggered weights. The tips of the PinPrick stimulators have a uniform geometry.

In addition, three different stimulators for light and stroking tactile stimuli are provided.

By means of the different standardized stimulators a quantitative sensoric testing (QST) of the individual tactile/mechanical sensitivity of pain gets possible. The uniform needle geometry and the defined weights guarantee the comparability of test results with different persons and by different operators.

This user manual describes the parts and the application of the PinPrick stimulators and the accessories.

2. Safety instructions



- The main risk of the PinPrick stimulator application is the unintended penetration of the needle through the patient's or subject's skin. The stimulators are designed in that way, that a penetration of the skin should not occur even with the biggest weight if the instructions in this manual are considered especially with respect to handling and cleaning.
- Do not touch any injured or morbid skin with the stimulators.
- Do not use more than 256 mN if you apply the PinPrick stimulators in the face. Do not use more than 128 mN during wind-up measurements in the face.
- Do not push the PinPrick stimulators onto the skin. Instead let them act by means of the weight alone. Otherwise you could unintentionally penetrate the skin, especially if you apply the biggest weight. Please take care not to touch the skin with the guiding tubes.

3. Set components

- 7 different PinPrick stimulators for different standardized stimuli
- set for light tactile stimuli:
 - brush: SenseLab™ Brush-05
 - cotton bud: Böttger 09.143.9105
 - piece of cotton wool (Q-tip) attached to an elastic plastic strip
- metronome used as a clock during wind-up measurements: Korg MA-1
- box
- user manual with test certificate



Figure 1: Complete PinPrick stimulator set

4. Instructions for use

4.1. Before the first use

Before you use the PinPrick stimulators for the first time you should familiarize yourself with their behaviour. For this purpose carefully take the „64 mN“ stimulator out of the box by handling it approximately in the middle of the guiding tube. First keep it in a preferably horizontal position.

Then move it slowly into the vertical and experience how the needle slowly slides out of the guiding tube by means of the weight. In the maximum position the needle protrudes about 25 mm out of the tube before it is blocked by an internal stop.

By swaying the stimulator between the vertical and the horizontal orientation you can slide the needle in and out of the tube.

Repeat this procedure with all PinPrick stimulators first to experience the sliding characteristics of each stimulator, second to check if all needles are moving smoothly.



The needles of the PinPrick stimulators are delicate mechanical components that can be easily deformed by incorrect handling and/or tilted application of a force. Please do not press them transversely onto hard objects. Please do not let them fall down. If a needle is anyhow deformed, please contact the manufacturer before your next application.

4.2. Correct application of the PinPrick stimulators

The significance of the pain threshold determination with PinPrick stimulators critically depends on their reproducible application. The following aspects are of special importance in this context:

1. a comparable contact area between tip and skin
2. a consistent effective weight
3. a comparable movement of the needle onto the skin

The first two aspects are intuitively clear, since they have a direct influence on the person's sensitivity. The reproducibility is achieved by the uniform tip geometry and the calibrated weights. However, in order to actually apply the identical tip geometry and the correct weight you have to apply the stimulators in upright orientation and orthogonal direction to the skin.

The third aspect shall be further explained by figures 2 and 3. The figures show the forces which have been measured by a force sensor when the PinPrick stimulators have been applied with different velocities and in differently swinging movements. It gets obvious that the effective force strongly varies with the movement characteristics. Therefore, please take care for a smooth and uninterrupted movement of the stimulators onto the skin.

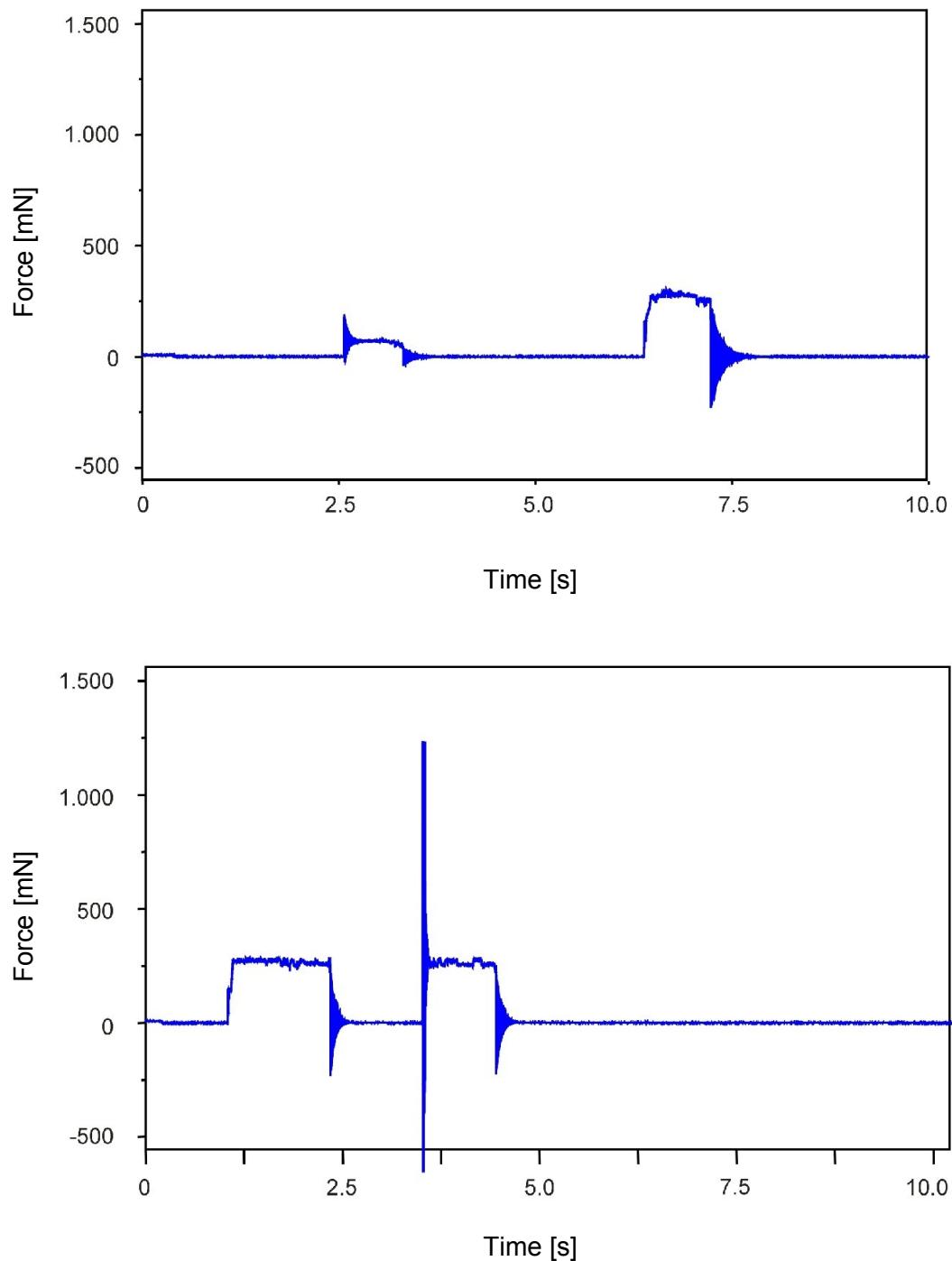


Figure 2: Diagram of forces resulting from different movement velocities of the PinPrick stimulators (single stimulus application). In the upper recording the stimulators of 64 mN and 256 mN have been applied correctly. In the lower recording the 256 mN stimulator generated an unintended impulse since it was applied with too much power.

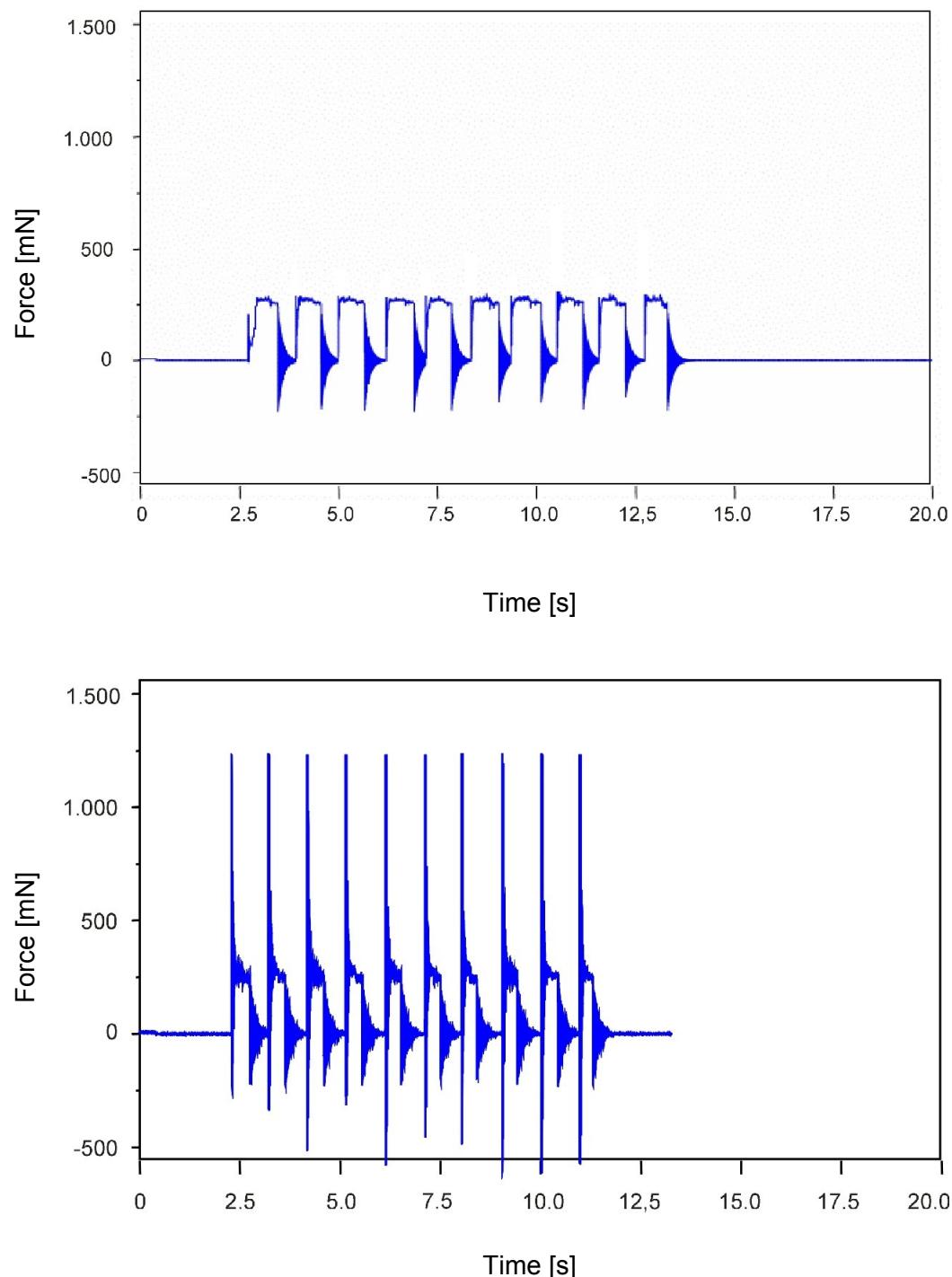


Figure 3: Diagram of wind-up measurements with correct (top) and too swinging (bottom) power.



- The needle should already be in the outward position before the PinPrick stimulators are applied onto the skin. Therefore, move the PinPrick stimulators in the upright position before the application. Move them in your hand so that the weight slides up and down in order to release any resistance. Otherwise, if the needle slides out of the guiding tube in an uncontrolled manner you can cause lesions of the patient or subject, a deformation of the needle, and/or damage of the needle's tip.
- Always place the needle onto the skin in upright orientation. Otherwise you will apply another effective weight or another tip geometry as desired. In that case, the comparability of the measurements will be affected.
- Place the PinPrick stimulators in a smooth movement onto the respective area of the skin. Swinging placement can affect the effective force impact.

4.3 QST applications

The stimulators are used for different quantitative sensoric testing (QST) procedures, as recommended by e.g. the German Research Network on Neuropathic Pain (DFNS) or other European collaborations.

a) Determination of the mechanical pain threshold

The standardized PinPrick needles enable the determination of the mechanical pain threshold by means of a modified method of limits. For this purpose the geometrical average of the mechanical pain threshold is calculated from usually five series of ascending and descending stimulus intensities.

Literature:

- [1] Chan et al., 1992
- [2] Greenspan and McGillis, 1994
- [3] Hampf et al., 1990
- [4] Ziegler et al., 1999

b) Determination of the mechanical pain sensitivity of the skin and the mechanical allodynia with moving stimuli

Here, the stimuli are applied in a balanced series. After determination of the stimulus/response function you can find out whether or not there is a hyperalgesia or a hypoalgesia or a mechanical allodynia.

The stimulators for light tactile stimuli are moved in a single stroking movement over the skin (1-2 cm in length). Please apply the cotton wool in that way that the plastic strip is slightly bent. The elastic force of the plastic strip was designed in that way that the resulting pressure will then be in a range of 100 mN. The Böttger cotton tab was selected to enable a smooth force of about 3 mN in stroking application. The stimulation intensity of the Brush-05 is in the range of 200-400 mN.

The patients or subjects shall verbally rate the stimulus intensity with a number (0 – 100). Here, „0“ stands for „no pain“, which is not the same as „not noticed“. If a stimulus is not recognized at all it should be marked as „-“. „100“ corresponds to the maximum pain which can be imagined by the

person.d as „-“. „100“ corresponds to the maximum pain which can be imagined by the person.

Literature:

[1] LaMotte et al., 1991

[2] Ziegler et al., 1999

c) Wind-up

In this test a single stimulus is applied by means of the 256 mN PinPrick stimulator. Then - after a period of 10 seconds – a series of ten identical punctate stimuli with a frequency of 1 Hz is applied in the same skin area. The size of this area should be about 1 cm². Immediately after the single stimulus and again after the subsequent series of stimuli a summarizing rating is performed by means of a numerical scale. From the recorded rating of the stimulus intensity the ratio between the rating for the single stimulus and the series of stimuli is calculated. This is usually done in five repetitions. The geometrical average of all ratios is the “wind-up” value.

Literature:

[1] Price et al., 1977

[2] Magerl et al., 1998

More information about QST applications can be found on the website www.neuro.med.tu-muenchen.de/dfns/patienten/QST.html.

5. Disinfection and maintenance instructions

5.1 Disinfection, sterilisation

The application of the PinPrick stimulators is a non-invasive procedure. We have already indicated in the safety instructions that there is an improbable residual risk of penetration through the skin.

Therefore, as an additional safety measure for minimizing the risk of infection, you should clean the needles before each application. Please use an appropriate disinfection spray.



- The PinPrick stimulators should be disinfected before each application.
- The needles of the PinPrick stimulators are delicate mechanical components that can be easily deformed by incorrect handling and/or tilted application of a force. Please do not press them transversely onto hard objects. Please do not let them fall down. If a needle is anyhow deformed, please contact the manufacturer before your next application.

For sterilisation we recommend to use chemical sterilisation.

Tests have shown that it is also possible to use heat sterilisation in the autoclave. However, in this case the last step of the process has to be a drying step. Otherwise the sliding characteristics of the PinPrick stimulators can be affected.



- Steam sterilisation can change the sliding characteristics of the mechanical parts and therefore the effective weight. The friction force can even increase in that extent that the weights do not move freely anymore. Please consider the notes regarding disinfection and sterilisation in this user manual. Therefore please check the sliding characteristics of the stimulators after each sterilisation before you apply them to the skin.

5.2 Maintenance

Please take care for a generally clean status of the stimulators. Keep them in the box included in delivery. Contaminated stimulators should be cleaned with a dry cloth. Please pay attention that

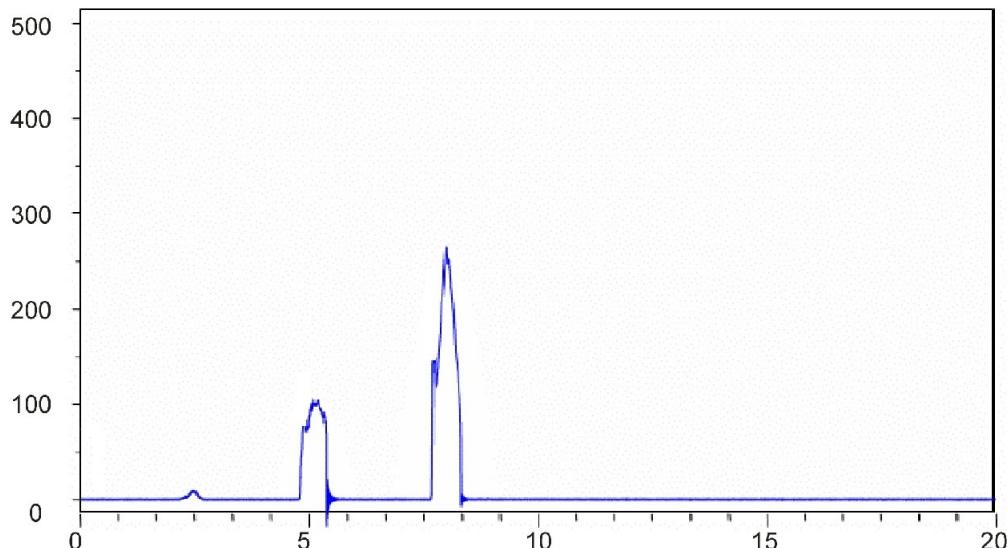
- 1) no liquid is entering into the guiding tubes, since this can affect the sliding characteristics
- 2) the needles are not deformed



- If you observe any resistance or unusual noise during the application of the PinPrick stimulators the sliding surface of the weight inside the guiding tube could be contaminated or damaged. In that case another effective weight as desired will act on the skin. Therefore, you should once again check the respective stimulator. If you can not restore the original behaviour by repeated reciprocating the stimulator you should contact the manufacturer.

6. Technical data

stimulus intensity	PinPrick stimulators: brush: SenseLab™ Brush-05: cotton bud Böttger 09.143.9105: cotton wool (Q-Tip) on plastic strip: All weights have been checked before delivery by means of force sensors.	8, 16, 32, 64, 128, 256, 512 mN ~ 200-400 mN ~ 3 mN ~ 100 mN
needle / tip geometry	flat contact area (diameter 0.25 mm) radius of curvature: 5 (+0, -5) µm length of needle: 19.5 mm material: stainless steel, support: PEEK	
guiding tube:	diameter: 10 mm material: stainless steel	
weight:	set with 7 PinPrick stimulators: 960 g	
metronome:	Korg MA-1, see the user manual in the metronome packing	



*Figure 4: Recording of forces from left to right:
cotton bud Böttger 09.143.9105, Q-Tip on plastic strip, and
SenseLab™ Brush-05*

7. Safety

The PinPrick stimulator set has left our firm in a faultless state. In order to maintain this state you should always store the stimulators in the delivered box in dry environments.



The product is a class-1 product in terms of the medical device directive (MDD). It has been tested according to the requirements of our certified quality management in compliance with the standard EN ISO 13485.

7.1. Marking

Each PinPrick stimulator is marked with the lettering „The PIN PRICK“, the characterizing weight, a serial number, and the CE mark. The marking is engraved into the guiding tube.



Figure 5: Marking of a PinPrick stimulator

7.2 Service

The sliding characteristics of the internal weights can change due to changes of the surface quality, mechanical distortion, or dirt. Therefore we recommend to check the PinPrick stimulators in periodic intervals of at least two years, better one year.

Please contact the manufacturer who can perform these calibration measurements. We have appropriate measurement devices available and can issue a test certificate.

8. Contact

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Germany
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Fax: +49-6221-13803-01
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9. Summary of Warning Notes



- The PinPrick stimulators should be disinfected before each application.
- Do not touch any injured or morbid skin with the stimulators.
- The needles of the PinPrick stimulators are delicate mechanical components that can be easily deformed by incorrect handling and/or tilted application of a force. Please do not press them transversely onto hard objects. Please do not let them fall down. If a needle is anyhow deformed, please contact the manufacturer before your next application.
- The needle should already be in the outward position before the PinPrick stimulators are applied onto the skin. Therefore, move the PinPrick stimulators in the upright position before the application. Move them in your hand so that the weight slides up and down in order to release any resistance. Otherwise, if the needle slides out of the guiding tube in an uncontrolled manner you can cause lesions of the patient or subject, a deformation of the needle, and/or damage of the needle's tip.
- Always place the needle onto the skin in upright orientation. Otherwise you will apply another effective weight or another tip geometry as desired. In that case, the comparability of the measurements will be affected.
- Place the PinPrick stimulators in a smooth movement onto the respective area of the skin. Swinging placement can affect the effective force impact.
- Do not use more than 256 mN if you apply the PinPrick stimulators in the face. Do not use more than 128 mN during wind-up measurements in the face.
- Do not push the PinPrick stimulators onto the skin. Instead let them act by means of the weight alone. Otherwise you could unintentionally penetrate the skin, especially if you apply the biggest weight. Please take care not to touch the skin with the guiding tubes.
- If you observe any resistance or unusual noise during the application of the PinPrick stimulators the sliding surface of the weight inside the guiding tube could be contaminated or damaged. In that case another effective weight as desired will act on the skin. Therefore, you should once again check the respective stimulator. If you can not restore the original behaviour by repeated reciprocating the stimulator you should contact the manufacturer.
- Steam sterilisation can change the sliding characteristics of the mechanical parts and therefore the effective weight. The friction force can even increase in that extent that the weights do not move freely anymore. Please consider the notes regarding disinfection and sterilisation in this user manual. Therefore please check the sliding characteristics of the stimulators after each sterilisation before you apply them to the skin.
- In any case, please consider the notes and instructions in this user manual.