



Qualia Labs

A QUALIA Company

Softening Brain Probes

IC-3-16E | BP-5-16E

User Guide

www.qualia-labs.com

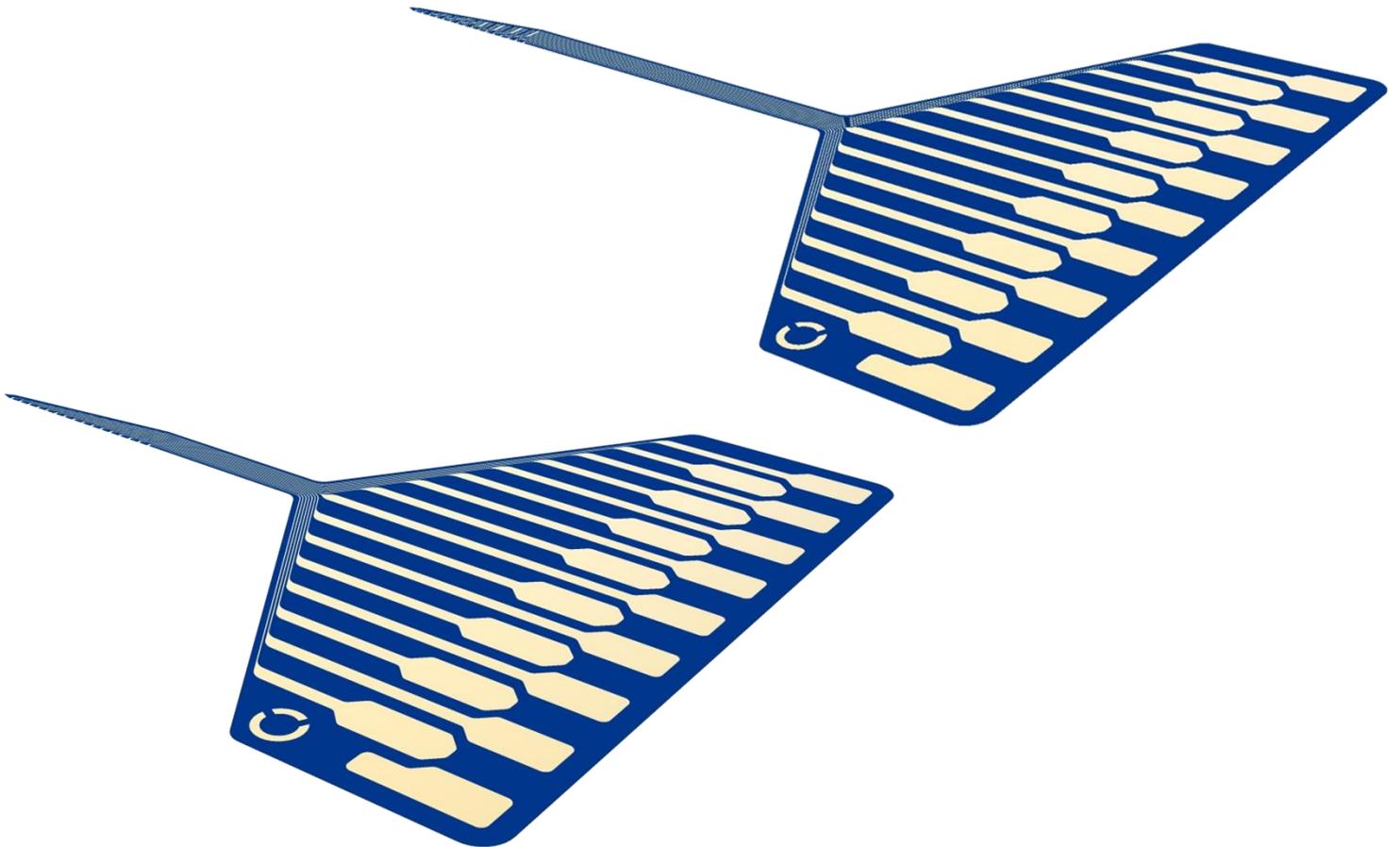




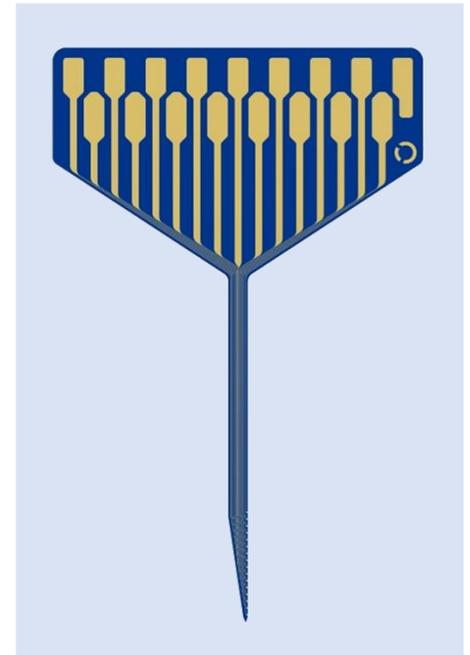
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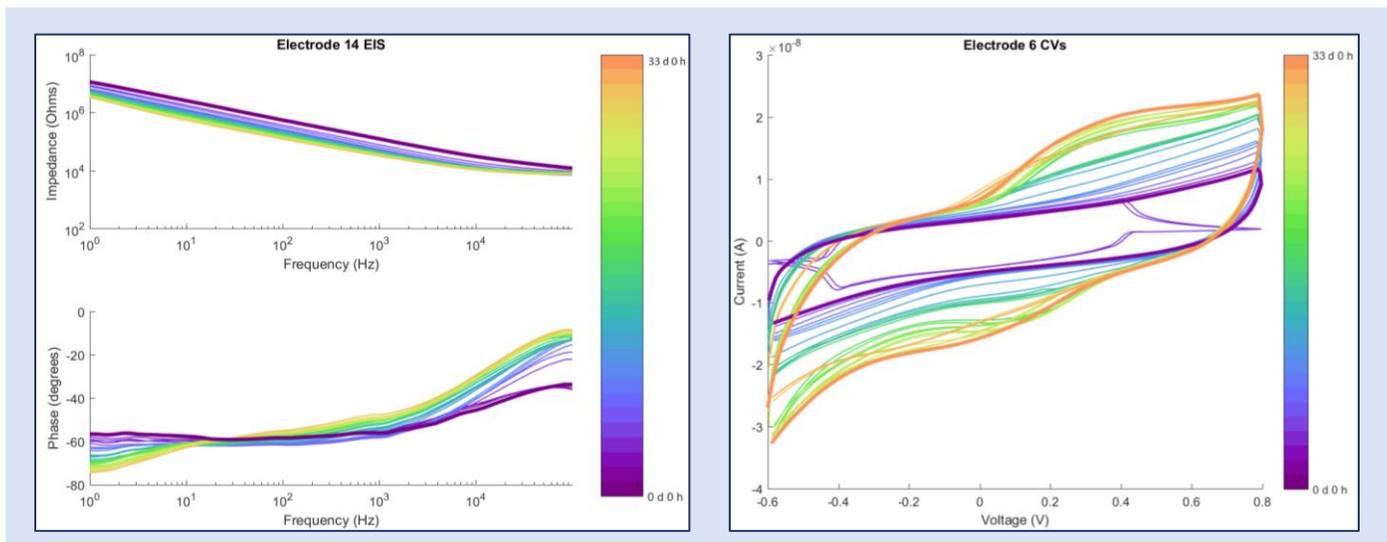
Introduction

Our softening brain probes are fabricated on thiol-ene acrylate shape memory polymer (SMP) substrates that are stiff at room temperature for surgical manipulation and insertion, but decrease in elastic modulus by orders of magnitude at body temperature. This limits the foreign body response by significantly reducing the mechanical mismatch between the implant and brain tissue.



Pre-Testing

Qualia Labs electrochemically evaluates the impedance of every probe shipped to ensure device functionality and proper electrical characteristics. Electrical impedance spectroscopy is run at multiple frequencies in the 10 Hz to 100 kHz range for each device in addition to cyclic voltammetry testing. Accelerated aging tests are performed on select devices from each production wafer to ensure proper quality control.



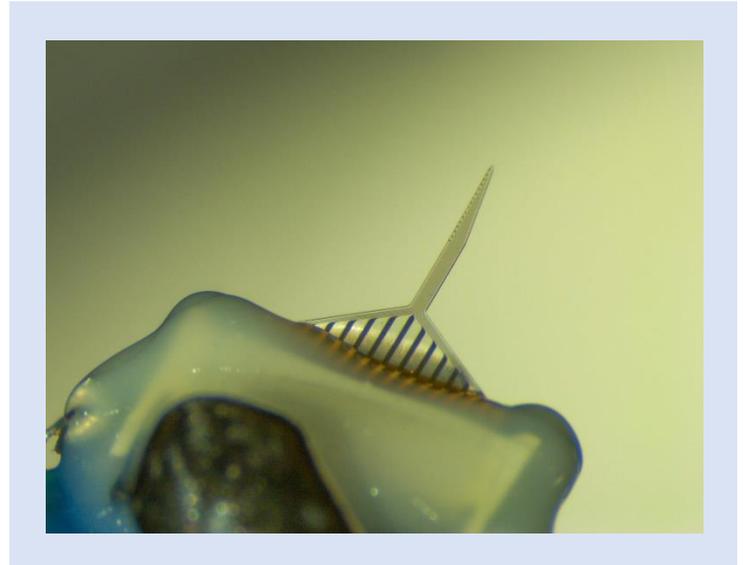


Device Handling

Each softening implant device is packaged individually in a plastic box and held in place with soft foam surrounding the connector. The counter and reference wires are wrapped alongside the connector. The shank itself is free floating and does not touch the foam material.

Although the shape memory polymer (SMP) substrate is not brittle like silicon-based devices, it can still be damaged by rough handling, mainly by tearing. Care must be taken not to touch or interact with the shank at any time.

Once removed from its packaging, we advise against soaking the device in liquid for long periods before implantation. Exposure to temperatures above 45°C should also be avoided. These actions may prematurely trigger the probe's softening properties and lead to physical deformation that will increase the difficulty of implanting the device when using conventional stereotaxic frames and micromanipulators.





Sterilization

Qualia Labs recommends that ethylene oxide (EtO) gas sterilization be used with our devices.

Autoclave and UV sterilization will decrease the softening capabilities of the device and should not be used¹. Devices can be sterilized within their boxes with the lid closed to limit direct air flow.

Additionally, boxes should be oriented within sterilization pouches such that the SKU label is facing up when the pouch is placed in the sterilization chamber. Ensure that the probe is pointed downward, which limits probe mobility and allows gravity to prevent probe deformation during the higher temperature stages of the EtO process.

The sterilization cycle should last at least 24 hours, followed by outgassing for at least 72 hours at 37°C in a vacuum oven. Qualia Labs is not responsible for device damage due to sterilization using other methods or procedures. Upon request, cuffs can also be shipped pre-sterilized and degassed.





Implantation Tips

- Devices are shipped with wires wrapped around the foam to provide stability during transport. Please carefully unwrap these wires before removing the device from the foam.
- Mounting of devices into the stereotaxic frame will vary based on the specific system used. We have found that the NeuroNexus Insertion Tool (IST-CM) allows the user the freedom to connect around the Omnetics connector, thereby leaving the shank in full view to assist in placement during implantation.
- Qualia Labs probes are fabricated on planar substrates but may develop a slight curl across devices with longer shanks during assembly, testing, and shipping. This bending in the probe shaft can lead to buckling during implantation. If you encounter this slight bend in the implant, the tip of the probe can be lowered onto the surface of the brain just until it catches on the surface to anchor the shaft. The micromanipulator can then be moved to straighten the shaft before attempting to implant the probe further.
- It is advised that before implantation, both the counter and reference electrodes should be wrapped around skull screws, which are in contact with cerebral spinal fluid. As before, care must be exercised to avoid breaking the delicate wires and to ensure that they do not come in contact with the device shank.
- The Qualia Labs softening brain probe is designed to have a 2 GPa modulus at ambient room temperature, which will facilitate the insertion of the device into cortical structures. However, this modulus is not sufficient to pierce the dura; therefore, it must be reflected before insertion. We have found the optimal insertion speed with minimal buckling to be around 1 mm/s.



Implantation (continued)

- Once inside the cortex, the SMP starts to soften and become more compliant. Further insertion of the probe during this time period will become increasingly difficult due to the softening. The device can be in contact with PBS briefly during positioning without softening. However, subsequent removal and re-insertion is not advised.
- If probe capture histology is planned, it is highly recommended that use of silicone-based dura sealants (e.g. Kwik-Cast Sealant) is avoided as the epoxy will firmly attach to the surface of the device and resist attempts to separate the two materials.
- If device capture is desired, we recommend the following procedure:
 1. The reflected dura can be sealed using a collagen matrix cut into small strips and placed around the device.
 2. The edges need to overlap the craniotomy. We have used a cyanoacrylate tissue adhesive, which has been formulated to cure in the presence of physiological fluids to create a protective seal over the collagen matrix and the soft tissues beneath. It will also aid in protecting the soft neural tissues from the harsh epoxy used to make a headcap.
- Dental epoxy (Stoelting Co., IL) has been used effectively to seal the craniotomy, attach the intracortical implant to the skull without adversely affecting the SMP implant's functionality, and provide the foundation to allow chronic insertion of recording equipment into the device.



Additional Resources

1. M. Ecker et al. *Macromol. Mater. Eng.* 2017, 302, 1600331.
2. A.J. Woolley et al. *J Neurosci. Methods.* 2011, 201, 67.

Return Policy

Upon arrival, please inspect device packaging. If devices appear to have been damaged in shipment, please email us at sales@qualia-labs.com within 7 days of receipt to request a replacement.

All sales are final, no exceptions. Unused items may be exchanged with permission from Qualia Labs within 30 days of delivery. Custom-designed orders may not be exchanged.

If you have any other concerns regarding your order, please feel free to reach out to us at sales@qualia-labs.com.

Contact Information

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