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Electrode Characterization and Long-term *In Vitro* Testing

Neural Stimulation and Recording Electrodes Properties Measurement and Long-term Testing

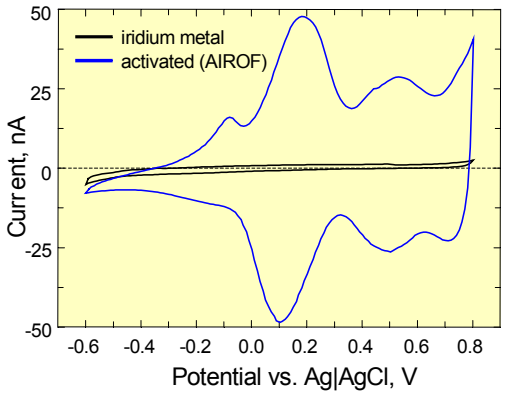
Electrode Characterization

Extensive *in vitro* electrochemical and physical properties characterization of electrodes and electrode coatings for neural stimulation, recording, and pacing applications are available from EIC Biomedical. Testing is provided for electrodes fabricated by EIC Biomedical or for sponsor-supplied electrodes. A more detailed discussion of the tests methods is found in references 1-3.

Electrochemical Measurements

Typical electrochemical measurements include:

Cyclic Voltammetry (CV). To assess the near-equilibrium properties of the electrode including: determining the maximum available charge for stimulation pulsing (charge-storage-capacity), identifying the presence of electro-active impurities and contaminates, estimating electrochemical and geometric surface areas, identifying the presence electrolyte leakage under insulation at electrode sites, and assessing long-term stability.



Cyclic voltammetry of an iridium microelectrode before and after activation to AIROF

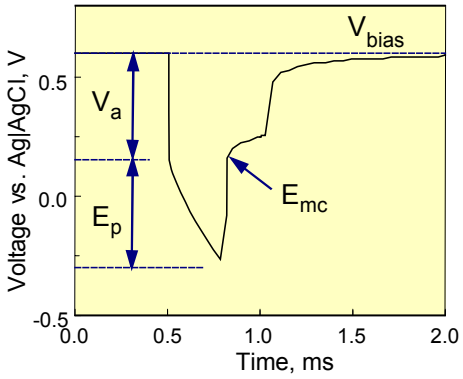
Electrochemical Impedance Spectroscopy (EIS). EIS estimates relative charge-injection capacities for stimulation and thermal noise contributions during neural recording; impedance changes in specific frequency ranges can differentiate between changes in electrolyte environment or degradation of electrode coatings; consistency in EIS response is useful in assessing electrode stability during long-term testing.

Voltage and Current Transients. Voltage and current transients are measured in response to either a current or voltage stimulus. Voltage transients are used to determine the charge-injection capacity of an electrode, power consumption, driving voltage, and maximum positive and negative electrochemical potential excursions. The consistency of voltage transients during long-term pulsing is a strong indicator of electrode stability.

Other available electrochemical techniques include:

- Potentiodynamic polarization – for corrosion studies
- Chronoamperometry – for biosensor measurements
- Potentiostatic polarization – for corrosion studies

A variety of other electrochemical measurements are available as required for more specialized applications.

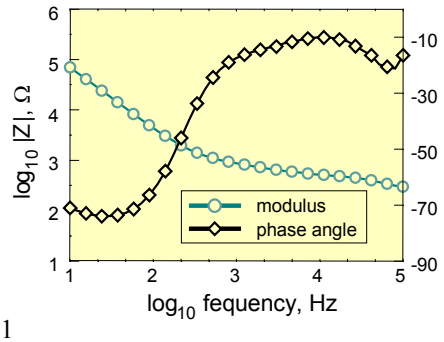


Analyzing voltage transients during current pulsing

Analytical Measurements

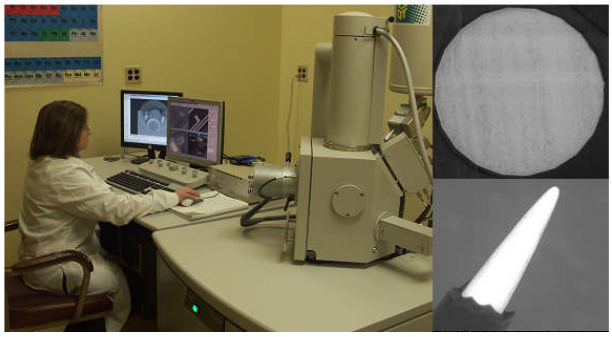
Analytical techniques at EIC Biomedical for characterization of electrodes and electrode encapsulation include:

- Scanning Electron Microscopy (SEM) with high and low vacuum and environmental operating modes,



EIS can be measured from 0.01-10^5 Hz as a function of bias and temperature

- Chemical analysis and surface mapping by energy dispersive x-ray spectroscopy in the SEM
- Infrared and UV-VIS spectroscopy
- Differential scanning calorimetry and thermogravimetric analysis
- Metal dissolution rates by analysis of test electrolytes using ICP-AA.
- Leakage current measurements to assess the stability of encapsulating materials.

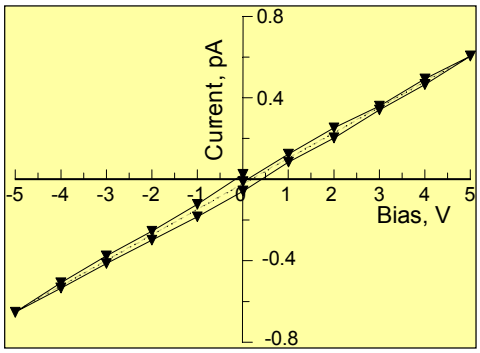


SEM Laboratory at EIC Biomedical

Long-term Testing

Extended long-term testing of electrodes is conducted to assess stability under conditions that closely match the physiological environment. Electrodes are maintained at 37°C in buffered physiological saline with a composition that closely matches the inorganic constituents of interstitial or cerebrospinal fluid [1]. Often stimulation studies are conducted with the implantable pulse generator (IPG) that will be used clinically. Electrodes are characterized periodically during long-term pulsing studies by CV, EIS, and voltage transient measurements. Electrode corrosion or dissolution is characterized by SEM and by analysis of the test electrolyte for dissolved metals. Recording electrodes are characterized by CV and EIS measurements.

Long-term electrode testing at 37°C using CO_2 for pH control



Sub-picoAmp leakage currents assess dielectric encapsulation at 37°C under continuous voltage bias

Electrode Testing at EIC Biomedical

EIC Biomedical works with sponsors to develop a focused test plan. Written test specifications with objectives, methods, evaluation criteria, and schedule are developed and approved by EIC Biomedical and the sponsor. Formal written reports are provided at the end of the study. EIC personnel conducting the studies are highly trained and approved for such testing under the EIC Biomedical quality assurance plan.

For more information about electrode testing, please contact us at:

eicbiomedical@eiclabs.com

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1. Cogan SF, Neural Stimulation and Recording Electrodes. Annu Rev Biomed Eng. 10:275-309, 2008.
2. Cogan SF, Troyk PR, Ehrlich J, Plante TD. *In vitro* comparison of the charge-injection limits of activated iridium oxide (AIROF) and platinum-iridium microelectrodes. IEEE Trans Biomed Eng. 52:1612-4, 2005.
3. Winter JO, Cogan SF, Rizzo JF Neurotrophin-eluting hydrogel coatings for neural stimulating electrodes, J Biomed Mater Res B Appl Biomater. 81(2): 551-63, 2007.
4. Cogan SF, Troyk PR, Ehrlich J, Gasbarro CM, Plante TD. The influence of electrolyte composition on the in vitro charge-injection limits of activated iridium oxide (AIROF) stimulation electrodes. J Neural Eng. 4:79-86, 2007.

Limitations

Test results provided by EIC Biomedical will not establish the suitability or safety of test articles for medical or other applications. The use of test results and test articles for any intended application is the responsibility of the end-user. The end-user is cautioned that the results of *in vitro* testing do not establish *in vivo* safety. The performance of electrodes and electrode encapsulation will depend on the manner of their use, fabrication and post-fabrication history, and other factors that may not be readily predicted.

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