BACHELOR THESIS

Neurotechnology – Design of a semi-dry Electroencephalography electrode

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Biomedical Engineering Degree

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ABSTRACT

In the research of the brain, the most complex organ of the human body, its function can be studied through the analysis of Evoked Potentials (EP). This evoked activity can be reproduced in a diverse way and recorded with an Electroencephalogram (EEG). To register the different types of brainwaves, the electrodes have a very important role. The first part of the thesis presents an extended literature review of the different types of EEG electrodes available on the market, out-standing publications and patents. A semi-dry porous ceramic electrode prototype was proposed to register EEG signals. The sensor model was developed with the aim of improving the accuracy of the actual sensors, checking many current designs, and improving artefact attenuation. It was not possible to test this design for lack of time and resources. Additionally, an EEG headset was also studied and developed to place the in-built-reservoir sensors according to the 10-20 placement system. Moreover, on the second part of this project, a skin-electrode contact impedance protocol was presented and tested with four different dry electrode materials in a diverse frequency range. The protocol used, which is a combination of some techniques already employed, has differentiated and separated the potential external hazards that can provoke an impact on bioimpedance measurements. The results obtained allow to determine the degree of utility of an electrode and how much time was required and recommended to place the electrodes before its optimal impedance acquisition.

Keywords: *Electroencephalography (EEG), semi-dry electrode, impedance, EEG headset.*

INDEX

List of Figures

List of Tables

1 Introduction

1.1 Motivation

Due to my curricular internship in a hospital during the first bachelor semester, I was especially motivated to work on a project that was related with Neurotechnology.

In my opinion, learn how to work in a research team in a foreign country, learn to differentiate articles according to their results with expert senior researchers and have the opportunity to do it all abroad, were some of my principal incentives in order to be able to do this project at the *Institut National des Sciences Apliquées* of Lyon.

1.2 Problem statement

The Electroencephalography (EEG) is well-known as a basic and efficient technique to record the brain activity and it has been extended in clinical diagnosis of neurological diseases, since it enables accurate and continuous monitoring of physiological conditions and dysfunctions of the human brain. Thanks to emergent technologies, as wearable technology, big data and mobile health, the actual improvements made on this sector are directly related to real-world applications.

One of the objectives on this project is to find an optimum EEG electrode design, which permits brain signal recording. However, this sensor prototype does not have to have long-previous placement processes, like some actual designs, that can cause discomfort situations to patients or subjects as: cutting all the existent hair on the head, applying high pressures to the electrode and the skin provoking skin damage, using abrasive gels or pastes, etc. Obviously, there exist different electrode types that have good results acquiring brain signals, but their use is not compatible with the hindrances mentioned.

In addition, after designing the sensor prototype, it is necessary to create a headset or cap design to place the electrodes for the EEG signal measurement. To design this cap it would be interesting to create a wireless headset. Also, the number of electrodes placed that needed to be used, will be studied.

1.3 Objectives

Main Objective:

- To create an EEG electrode design that acquires brain signals and can be used in patients with short/medium hair. Its application cannot provoke skin-contact damage.

Specific Objectives:

- To understand the electrode performance and the electronic principles of this medical device;
- To do a review of the existing electrodes and their properties (companies, patents, papers, documents);
- To find a method to prove the quality of its performance, if it is usable or not; and
- To compare the existing materials used in these devices.

1.4 Significance of the study

Nowadays, the Biomedicine is expanding and more funds are allocated to research and develop new investigation lines in Neurotechnology. This project is a useful tool to see the different EEG electrode types that exist in the world. The most interesting ideas are used to create an optimum sensor design that one day may be used in the current EEG market. Therefore, the results presented of this project can be discussed and used in other studies in the future.

2 Physiological background

2.1 EEG signals

The Electroencephalography (EEG) is a noninvasive technique used to monitor and diagnose brain related diseases, as mentioned before. This technique is based in recording electrical activity of scalp potentials over multiple areas of the brain, which have very low peak-to-peak amplitudes. The recorded waveforms from the scalp reflect in the test the patient's cortical electrical activity by placing sensor devices on subject's scalp. This procedure normally is completely painless.

The brain cells communication takes place through these electrical impulses, Evoked Potentials (EP). The cortical nerve cell inhibitory and excitatory postsynaptic potentials, generate the EEG signals. These postsynaptic potentials are summated in the cortex and are extended to the scalp surface, where they are recorded as an Electroencephalogram. A typical brain signal, measured from the scalp, can have an amplitude of about 0.5 µV to 100 µV, which is about 100 times lower than electrocardiography (ECG) signals, and a frequency in the range of 0.5 Hz to about 100 Hz [1].

Brain patterns form wave shapes that are commonly sinusoidal, Fig. 1, and there exist different types.

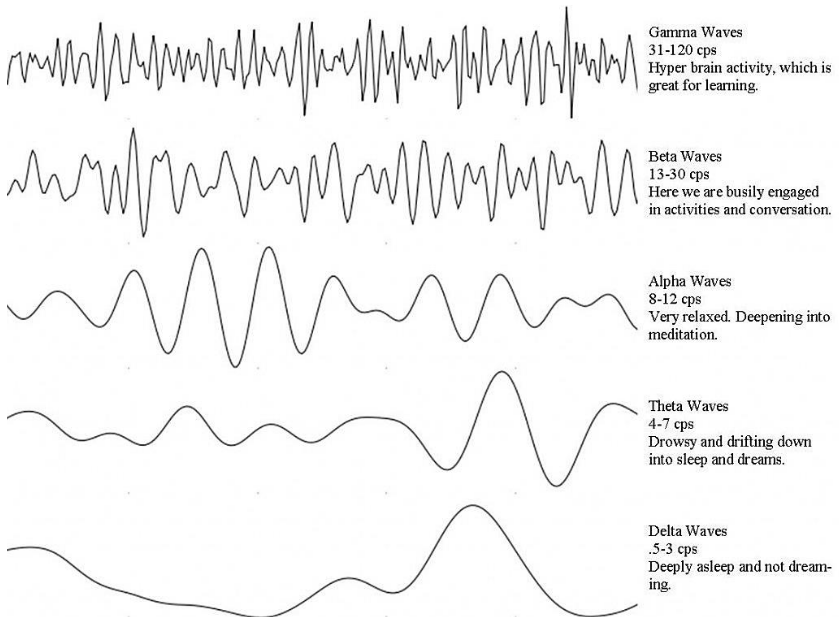


Fig. 1. *Brainwaves types* [2].

- Infra-Low (<0.5Hz)

These type of signals, also known as Slow Cortical Potentials, are thought to be the basic cortical rhythms that underlie our higher brain functions. They appear to take a major role in brain timing and network function.

- Delta waves (0.5 to 3.5 Hz)

Delta signals are slow but loud brainwaves (low frequency and deeply penetrating, like a drum beat) and they are generated in dreamless sleep. During this period waves, the body is undergoing a process of healing and regeneration from the previous day's activities.

- Theta waves (4 to 7 Hz)

Theta is our gateway to learning, memory and intuition. These waves are associated with light meditation and sleep, and with a wide range of cognitive processing such as memory encoding and retrieval. These signals commonly appear on young children and normal adults during light sleep, the Rapid Eye Movement (REM) sleep. Clinically, they are typical of space occupying foreign bodies or tumors in brain.

- Alpha waves (8 to 12 Hz)

Alpha waves exist mostly at range 8Hz to 12Hz. They dominate occipital scalp region when the eyes are closed and the patient is relaxed. Biofeedback training often uses alpha waves to monitor relaxation, imagination, visualization, learning, memory, and concentration. They are also linked to inhibition and attention.

- Beta waves (13 to 38 Hz)

Beta brainwaves dominate our normal waking state of consciousness when attention is directed towards cognitive tasks. Beta is a "fast" activity, presented when we are alert, attentive, and engaged in problem judgment, decision making or focused in mental activity.

Beta brainwaves are further divided into three bands: Lo-Beta (Beta 1, 12-15Hz) can be thought of as a "fast idle". Beta (Beta 2, 15-22Hz) is high engagement or actively figuring something out. Hi-Beta (Beta 3, 22-38Hz) is highly complex thought, integrating new experiences, high anxiety or excitement.

- Gamma waves (39 to 42 Hz)

Gamma brainwaves are the fastest brainwaves and are related to simultaneous processing of information from different brain areas, attention span and memory [3].

Otherwise, complex patterns of neural activity can be currently recorded occurring within fractions of a second after the administration of a stimulus. As mentioned, EEG can determine the relative strengths and positions of electrical activity in different brain regions. However, this technique provides less spatial resolution compared to Magnetic Resonance Imaging (MRI) and Positron Emission Tomography (PET). So in some cases, for better allocation within the brain, these EEG images are often combined with another clinical tests: MRI, scans etc. We can find different clinical EEG application examples in humans and animals:

- Monitor alertness, coma and brain death;
- Area location of damage following head injury, stroke, tumor, etc.;
- Test afferent pathways (by evoked potentials);
- Monitor cognitive engagement (alpha rhythm);
- Control anesthesia deepness (“servo anesthesia”);
- Investigate epilepsy and locate seizure origin;
- Test epilepsy drug effects;
- Assist in experimental cortical excision of epileptic focus;
- Monitor human and animal brain development;
- Test drugs for convulsive effects;
- Investigate sleep disorder and physiology; etc.

Furthermore, this clinical test is also used to diagnose some other diseases related with: brain infection, brain hemorrhage, Alzheimer's disease, degeneration of brain tissue, metabolic or hormonal conditions that affect brain tissue, etc.

Furthermore, EEGs are very popular in nonclinical neuroscience and cognitive research. In the context of brain-computer interfacing (BCI), EEG recently has become a tool to enhance human and machine interactions. This BCI system translates the brain activity patterns of a user into messages or commands for an interactive application, so the activity that is being measured can be processed by the system too [4]. Neurofeedback or brain function training, are two other research applications.

2.2 EEG Measurement

The Encephalography is a technique widely used due to its high temporal resolution, good portability, and relative low costs. Actual Encephalographic measurements, employ a recording system which consists of:

- Electrodes;
- Biopotential amplifiers;
- A/D converters; and
- Recording device/Data port.

1. <u>Electrodes</u>

The electrodes are an essential part of the EEG recording process, having the ability to perceive the electrical brain activity. These devices are used in EEG machines and can be divided into two big groups: noninvasive (surface devices) and invasive electrodes (penetrate the patients' scalp). The recording signal method is the same for both electrode groups.

In general, invasive electrodes, like needles, provide greater signal clarity because they penetrate directly into the body and the signal acquired does not have signal muffling caused by the hair or skin. However, their application can cause discomfort or pain to subjects or patients.

On the other hand, the noninvasive electrodes do not use to cause so many painful situations to the patients or subjects as the invasive electrodes. There exist models characterized for their electronic circuit, shape and gel application. In addition, these electrodes fabrication normally is more expensive, thus they need extensive regulatory processes. The materials used have to be biocompatible and some devices are reusable.

The recording signal method is the same for both electrode groups. The scalp allows measurement of potential changes in basic electric circuit conducting between a signal electrode, active or passive, and a reference electrode in the surface. The active electrodes are used to:

1. Solve the problems related to a wide impedance range of the sensor;
2. Solve capacitive coupling between the cable and sources of interference; and
3. Reduce the movement of cables and connectors

On the other hand, the passive electrodes record the EEG signal without pre-modifying it.

The signal and reference sensors convert ionic current into electric current. So, with two initial input signals we will have only one final output signal. A third electrode is also used in this record process and its use will be explained in the following section.

Moreover, the EEG electrodes do not just record brain signals, because they also register all kind of external electromagnetic pollution. The most important source of noise comes from power lines, which oscillations of electromagnetic signals are of 50 Hz or 60Hz, depending on the country. These two electrodes record the same noise, but measure different EEG signals, because they are placed at different points in the head.

2. Biopotential Amplifiers

After the first contact between the electrode and the patient's scalp, the biopotential amplifiers enable signal modeling. The differential amplifiers "change" the microvolt recorded waves into useful information. These signals that have been registered, will be processed until they can be accurately digitalized. Biopotential amplifiers are the most critical building blocks of an EEG readout circuit because they constitute the first processing step and determine if the signal acquired is usable or not. In addition, they are also responsible of preventing distortion of the measured signal.

As mentioned before, two principle electrodes (active/passive and reference) located in different head sites, detect the electrical signal from the brain. Then, the amplifier subtracts the two signals recorded between the pair of sensors, canceling out the existent noise. This means that the output from the machine is actually the difference in electrical activity picked up by the two electrodes. Therefore, the placement for each electrode is critical because the closer they are to each other, the less differences in the brainwaves that will be.

Additionally, the wires that are connected to active electrodes, transfer the signal to a first amplifier section, the buffer amplifier. Here the signal is electronically stabilized and amplified by a factor 5 to 10. A differential pre-amplifier is next in line and filters and amplifies the signal by a factor of 10 -100. These pre-amplifiers processes only take place in active electrodes, no passive electrodes. Sometimes, the primary amplifier section, which receives direct signals from the patient, can be found in the power and control circuits. Optical isolators can be used to prevent the unwanted feedback into the circuitry from the patient. The separation prevents the possibility of accidental electric shock.

Then, after going through this first stage, the signals are multiplied by hundreds or thousands of times and this is only possible if the noise measured by the two sensors is exactly the same [5]. Special parameters are studied and can be modified to acquire a better signal quality in routine settings:

- The amplifier gain is the ratio of the output signal to the input signal. In order to provide optimum signal quality and adequate voltage level for further signal processing, the amplifier has to provide a gain of 100–100000 (the highest need not to be the best, it combines different parameters) and has to maintain the best possible signal-to-noise ratio. However, gain is not considered a useful measure in clinical applications because the output voltage is not measured.
- In order to decrease an impact of the electrically noisy environment, the differential amplifiers must have high Common-Mode Rejection Ratios (CMRR), minimum 100 dB. Additionally, the amplifier input impedance should be at least 1000 MΩ at 60 Hz to prevent source impedance mismatch from decreasing the overall CMRR of the amplifier. The EEG amplifiers need to have a high input impedance to verify the connection between the electrodes and the scalp remains negligible, and warn us if the electrode does not have any contact at all. This high input impedance is important because it depends on the signal-noise between the electrodes and the scalp. We do not have to confuse the amplifier high input impedance and the skin-electrode contact impedance (Z contact). In general, we can say that the smaller the contact impedance, the lower the noise signal is. This allows us to check the quality of the established contact of the electrodes. Normally, to acquire these low impedance levels, the process can require a thorough cleaning of the scalp and/or a use of a gel (wet electrodes). The use of dry electrodes comes with large and variable skin-electrode impedance, as well as large electrode polarization voltages. To minimize signal attenuation, the amplifiers can have very high input impedances. In conclusion, the impedance between electrode and tissue

should decrease to have very good results, compared with the input impedance of the amplifier, which have to be very high.

- Electrode polarization voltage develops across the electrolyte-electrode interface due to an uneven distribution of anions and cations. This offset voltage can be as large as a few hundreds of mV and may saturate the instrumentation amplifiers. As a result, these amplifiers should be able to tolerate at least 300mV DC offset while amplifying the EEG signals.
- Signal to Noise Ratio (SNR) is another parameter to be taken into consideration when biopotential amplifier is been designed. High SNR requires very low noise amplifiers and filter limitation. Current technology offers differential amplifiers with voltage noise of less than 10 nV/√Hz and current noise less than 1p A/√Hz [6].
- The sensitivity for a routine recording is normally set at 7 microvolts/mm [7].

3. A/D converters

After amplifying the signal, the A/D converter changes the brainwave from analog to digital form. The amplifiers are AC-coupled with low-frequency cut-off filters below 1 Hz and a bandwidth extending to somewhere between 50 and 100 Hz, depending on the device. In addition, for attenuating AC noise when the low-pass cut-off is above 50 Hz, many EEG amplifiers can employ a 50 or 60 Hz notch specific filter for those. Analog low-pass filters prevent distortion of the signal by interference effects with sampling rate, called aliasing, which would occur if frequencies greater than one half of the sampling rate survive without diminishing.

The A/D converters are interfaced to a computer system and each sample registered can be saved in the device memory. In fact, it is necessary a minimally 12 bit A/D converter with accuracy lower than overall noise (0.3-2 µ Vpp.), and the sampling frequency is usually between 128–1024 Hz.

4. Recording device

After de A/D converters, the signal goes to personal computer stores and displays to obtain the data on screen (data port). Different types of recording instruments provide a temporary or permanent record of the EEG. During such recordings, an oscilloscope can be used to allow visual signal portions of interest that have been previously recorded. Computers can also be used as recording/signal processing devices once the signals have been digitized. Since the brain produces different signals at different points on the skull, multiple electrodes are used. The number of channels that an EEG machine has is related to the number of electrodes used. The multi-channel configurations can comprise up to 128 or 256 active electrodes [6]. But it depends on the electrode type, the recording purpose and the study.

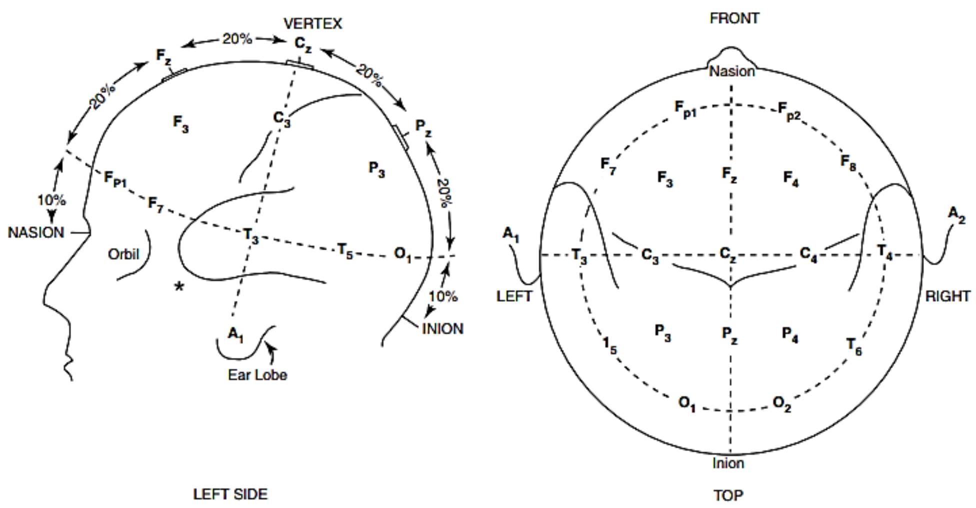
2.2.1 Standardized Electrode Placement

<u>10 – 20 Electrode placement:</u>

The first human EEG recording system was invented in 1924. Then, in 1958 the International Federation in Electroencephalography and Clinical Neurophysiology, adopted a standardization method for electrode placement called 10 – 20 electrode placement system. It is the most widely used system to describe the location relation between the scalp electrodes and the cortical areas. The standard set of electrodes in adults consists of 21 recording sensors, and an extra ground electrode, Fig. 2a,b.

To understand how this system works, the head is divided into proportional distances from prominent skull landmarks to provide adequate coverage of all regions of the brain. Each head site has a letter that identifies the lobe and a number or another letters, to identify the location of hemisphere. The odd numbers are referred to the left-sided electrodes and even numbers to the right side parts of the head.

a)



b)

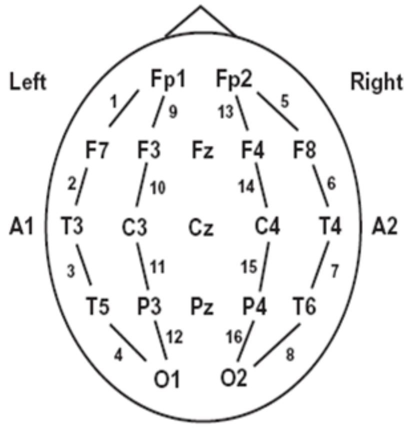


Fig. 2. *10-20 placement system (a) and its sensor placement order (b) [6].*

The letters used in Fig. 2 are: "F" for Frontal lobe, "T" for Temporal lobe, "C" for Central lobe, "P" for Parietal lobe and "O" for Occipital lobe. The letter "z" is referred to an electrode placed on the midline of the head. The smaller is the number, the closer is the position of electrode to the midline. "Fp" stands for Front polar. As we can see in Fig. 21, Nasion is the point between the forehead and nose and Inion is the bump at the back of the skull. It is used the letter “A” for Auricular or earlobe and they are measured along a transverse line between Cz – T3, T4, C3 and C4 are marked at 20% intervals of the above measured line.

As seen in the Fig. 2a, the Fpz is marked at 10% of the measured Inion and Nasion. Fz, Cz, Pz and O are marked at 20% intervals along the midline. Some electrodes are located doing the half distance between other two electrodes: C4 (Cz and T4). In other cases, we can mark 5% of the half to the left and right of OZ to have the true marks of O1 and O2 respectively. To mark F7 and F8 we measure a 10% interval starting in Fp1 and Fp2. Then to measure F3, we will measure Fp1 to C3 and mark midpoint and measure Fz to F7 and mark midpoint. Each electrode location is carefully studied in this system and needs an extensive previous calibration process.

Furthermore, the reference electrode forms an essential part in the EEG acquisition system, as mentioned before. The reference electrode is commonly placed half way between Cz and Pz or half way between Cz and Fz. Another method to acquire a reference sensor is to use two electrodes at positions A1 and A2 and linked them together. The principle used in their placement is the same, try to use a location that is as electrically silent as possible.

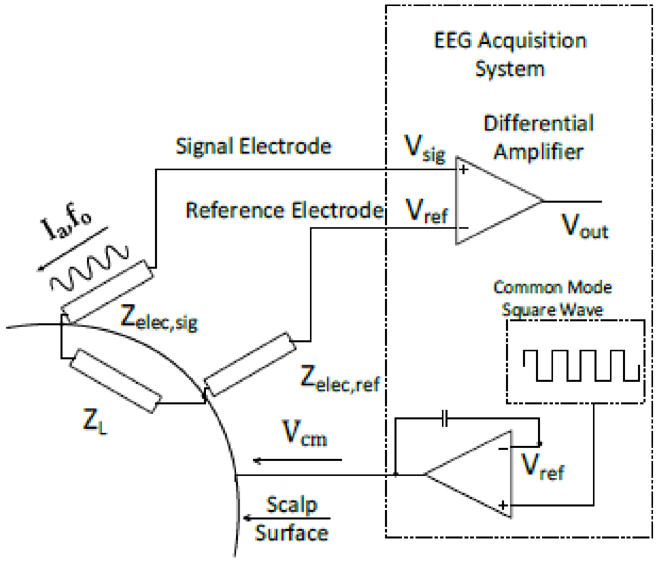
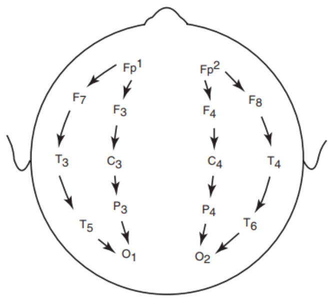


Fig. 3. *Scalp impedance circuit with signal and reference electrodes* [8].

Moreover, the other third electrode, Fig. 3, called neutral or ground electrode, keeps the body's DC voltage level in-line with the readout circuits to properly amplify the EEG signal. Without the ground electrode connected to the body, the electrode potentials will saturate the amplifiers' input. It is important as it is used by the system to reduce the effect of external interferences [9].

We can find also, different EEG surface montages that indicate the distribution of potentials on the head:

<table>
<tr><th>Montage Type and explanation</th><th>Montage scheme</th></tr>
<tr><td><u>Longitudinal Bipolar Montage:</u>
• Inputs 1 and 2 of an amplifier record in anterior-posterior. In this method, the input 2 of one amplifier is also at the input of the next amplifier.
• Best for analyzing low- to medium-amplitude waveforms that are highly localized.</td><td>
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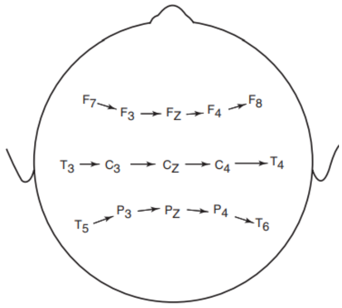
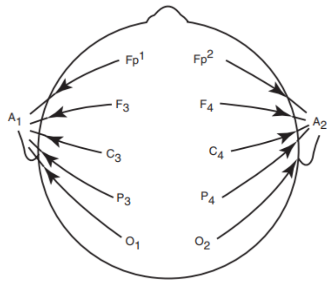
Transverse bipolar Montage

- It is similar to longitudinal bipolar, but electrode derivations are arranged around transverse lines from left to right.
- They sharply distinguish potential changes in neighboring electrodes and localize potentials more precisely.



Referential ear Montage

- Connects inputs 1 of a group of amplifiers to electrodes placed on various parts of the head and inputs 2 of these amplifiers to a common electrode, the reference electrode.
- Referential montage produces a higher-amplitude waveform due to longer inter-electrode distance.



Laplacian Montage

- For analysis of spatial sampling of EEG. It uses weighted average of the nearest neighboring electrodes surrounding input 1 of an electrode.
- Extremely helpful in detecting focal abnormality on EEG and electrographic seizure topography.

Tab. 1. *Different EEG montages to record brain signals* [7].

Modified 10 – 20 electrode placement (MNC):

The MNC is a sensor placement system where additional electrodes are placed for increase spatial resolution according to the American Clinical Neurophysiology Society guidelines. This MCN (Modified Combinatorial Nomenclature) system, Fig. 4, uses 1, 3, 5, 7 and 9 for the left hemisphere which represents 10%, 20%, 30%, 40%, and 50% of the Inion-to-Nasion distance respectively. The introduction of extra letters allows the naming of extra electrode sites [6].

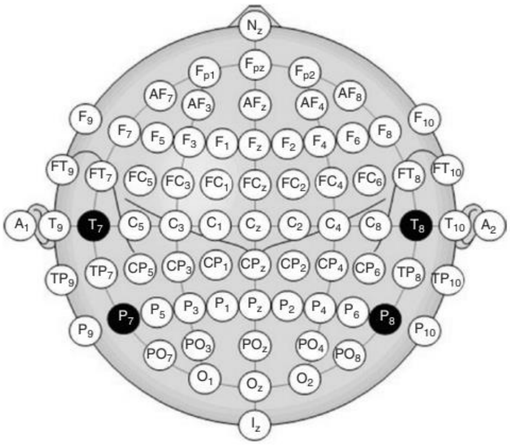


Fig. 4. *MCN system* [9].

Otherwise, there exist two issues that can limit the use of these systems:

1. They can consume a lot of energy to record EEG signals; and
2. They need an exhaustive previous calibration.

In consequence of a poor electrode placement, the system can: be an ECG artifact, have high contact impedance, have electrode popping and sweat influence [10].

2.3 EEG noninvasive electrode review

According to the amount of electrolytes presented at the electrode-skin interface, noninvasive EEG electrodes have been divided into three different categories: wet electrodes, semi-dry/ quasi-dry electrodes and dry electrodes. These devices are used to make connection between the conducting fluid of the tissue, in which the electrical activity is generated, and the input circuit of the amplifier, as it has been explained in the previous sections.

2.3.1 Wet electrodes

Wet electrodes are the most commonly used sensors in the EEG history. These sensors, during signal registration processes, use electrolytic gels or pastes that contain Cl− anions. The Cl- anions in these different gels or pastes used with wet electrode, play an important role in establishing a non-polarized electrode-electrolyte interface and a stable electrode skin interface. In conclusion, the gels facilitate the transduction of the ionic currents. These sensors can have different shapes as disks, Fig. 5, pellets or wires, and can have a diverse range of diameter measures. In addition, the long flexible leads that are in contact with the sensor part, can be plugged into a pre-amplifier section, depending on the electrode type.

Fig. 5. *Wet electrode disks (Ag/AgCl)* [11].

Silver chloride (AgCl) is preferred for common neurophysiologic applications. Thanks to Ag properties of solubility in salt, AgCl quickly saturates and comes to equilibrium. The reversible oxidation-reduction reactions occurring at the metal-electrolyte interface in these type of electrodes are [12] (1):

(1)
$$Ag \longleftrightarrow Ag^{+} + e^{-}$$
$$Ag^{+} + Cl^{-} \longleftrightarrow AgCl$$

In conclusion, Ag is a good metal used in metallic skin-surface electrodes [13]. Moreover, wet electrodes can be made from other materials. We can also find, tin (Sn) electrodes, gold (Au) and platinum (Pt) electrodes as well. The general wet electrodes contact impedance (Z contact) uses to be below 5000 Ω and should be measured to guarantee a correct EEG signal.

The wet electrode-tissue contact corresponds to an equivalent circuit model, Fig. 6.

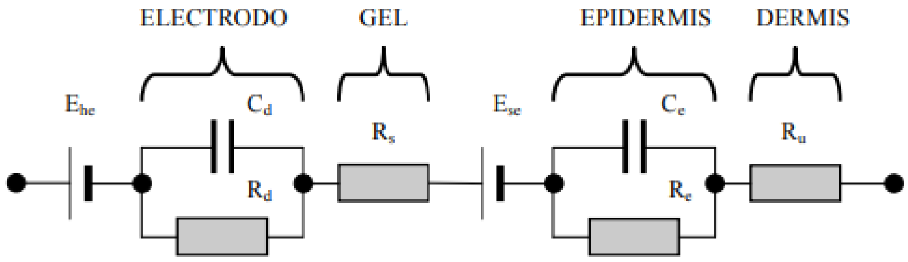


Fig. 6. *Equivalent electrode circuit – wet electrode* [14].

The generators E_{he} and E_{se} represent, respectively, the cell potential and the skin-contact potential difference. The equivalent circuit model for wet electrodes consists of a parallel RC circuit that models the impedance associated between electrode and the contact electrolyte. The R_s resistance is the conductive gel/paste and electrode leads. Finally the parallel R_e-C_e circuit corresponds to epidermis impedance and R_u to the resistive impedance presented by the dermis.

The Capacity Cd is basically formed by a double barrier of charges at the interface between electrode and electrolyte. If the electrode moves, the load distribution is modified. This can produce a change in the potential difference of the cell until the equilibrium is reached again. Similarly, when we are using two electrodes and one of them do not make a good skin-contact while the other remains in equilibrium, a variation of the potential difference between them, can appear. These variations can be a signal noise origin [14].

However, these electrodes suffer from severe limitations such as tedious and time-consuming preparation processes. Then, once an acceptable electrode impedance has been achieved, a countdown begins until the gel dries causing the disappearance of transductive properties. Wet electrodes are not suitable for long-term measures. In addition, the abrasive pastes and the electrolyte gel, despite being minimally invasive and barely harmful, can be sticky products that make the patients' hair and scalp dirty [15] or cause allergic reactions.

2.3.2 Semi-dry electrodes

The semi-dry or quasi-dry electrodes are an alternative option to wet sensors. This type of electrode has the same electrical equivalent circuit as the wet electrode [16]. The absence of the application of the conductive gel directly to the electrode, always leads to a relative high contact impedance (several hundreds of kΩ or higher), due to the less effective ionic conduction. However in quasi-dry electrodes, the conductive gels of wet electrodes are replaced for a small amount of electrolyte liquid stored in a reservoir inside the electrode structure. This solution can flow through porous structures (solid hydrogels, etc.) with capillary action by applying pressure to the electrode or the main reservoir. This “tank” concept seems to be a promising solution for EEG real-world applications.

The electrode prototype illustrated in Fig. 7 can be an example of a semi-dry electrode. The results obtained of skin-electrode contact impedance and high signal quality, can be comparable with wet sensor ones. The latest generation of semi-dry electrodes, which does not need manual change of the liquid, can use in-situ polymerized alginate hydrogel instead of conductive gels. Also, there exist headset structures with a common insertion hole, which allows the distribution of the electrolyte solution to the reservoirs or tanks of all the electrodes at the same time. Therefore, semi-dry electrodes can avoid most of wet sensors drawbacks and maintain their technical superiorities.

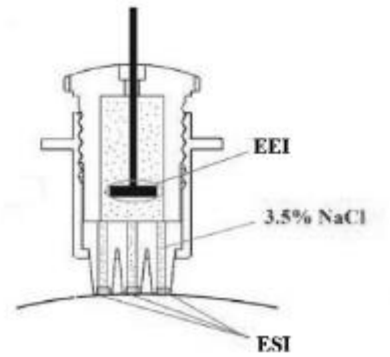


Fig. 7. *Semi-dry electrode sketch* [17].

However, there exist different problems associated with these type of electrodes. Firstly, some sensors can need additional pressure to enable a continuously releasing of the electrolyte solution. Secondly, some electrodes can show deterioration and shape deformation related to that pressure applied. This can cause electrode coating failure whether these situations last long periods of time. Moreover, it is very difficult to achieve uniform pressure to a sensor to have a good quality EEG signal. The non-uniform pressure will bring uncontrolled, unexpected moistener release, thus leading to signal instability [17].

Some of the most interesting and recently created devices are commented below.

1. Novel passive ceramic based Semi-dry electrode

One of the most interesting electrode design consists in a reservoir construction that has a direct contact with a number of porous columns. In Fig. 8 is designed a semi-dry electrode that includes five porous ceramic pillars made of Al_2O_3 (Fig 8.B.a,b) (Aluminum oxide) considering it for its mechanical properties (wearability, resistance to compression and hydrophilic characteristics) and a built-in reservoir (Fig. 8.B.c) containing 500 µL 3.5% saline solution (Fig 8.B.d) with an inner sintered Ag/AgCl electrode (Fig. 8.B.e). This sensor can be used in individuals with short hair and does not need pre-cleaning skin processes. The physical dimensions of the porous ceramic pillars are 1.20 mm × 7.00 mm with a few micrometer pores structure. Using the capillary force of the porous ceramics, the semi-dry electrode enables continuous release of saline solution from the built-in reservoir.

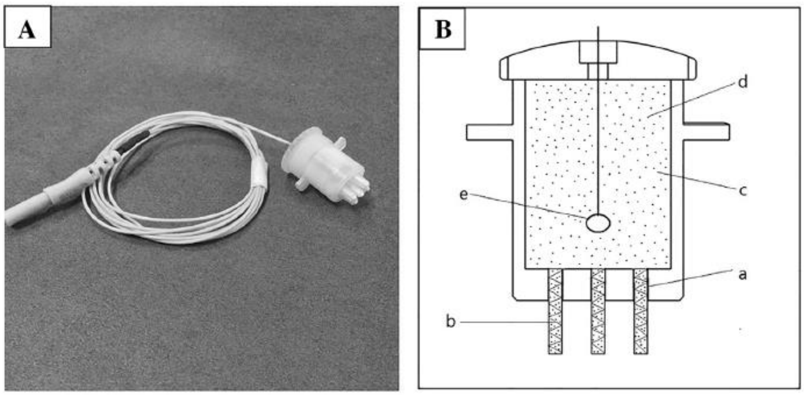


Fig. 8. *Semi-dry electrode (A) and a schematic diagram of the semi-dry electrode prototype, including porous ceramic pillars and its different parts (B)* [16].

EEG signals were simultaneously recorded using a 9-channel gel-based electrode and semi-dry electrode arrays setup on ten subjects. The semi-dry electrodes polarization voltage was stable and equivalent to that of the gel electrodes. The EEG signal tests have shown that the semi-dry electrode was able to acquire reliable EEG signals similar to those of the commercial gel-based Ag/AgCl electrodes, Fig. 9 [16].

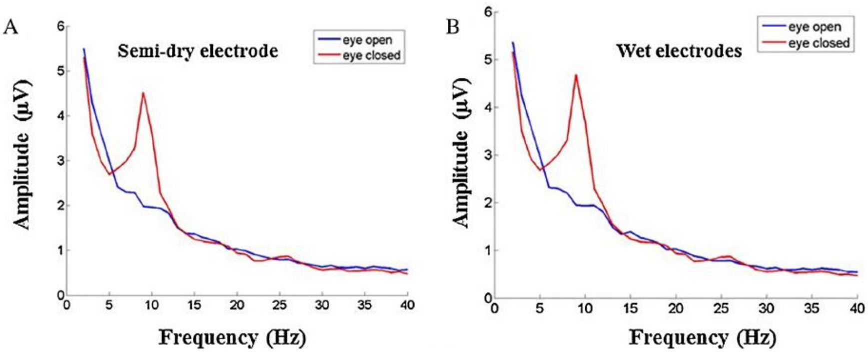


Fig. 9. *Results of EEG recording in eye open/closed paradigm and SSVEPs paradigms: Spectrum of semi-dry (A) and wet (B) electrode Pz from a representative subject (#5) in eye open/closed paradigm* [16].

2. <u>No pins - Novel polymer-based electrode prototype (patented)</u>

Polymer materials are also good material choice in some sensors' design. This other electrode prototype shares the reservoir principle of the previous electrode, but it does not have porous pillars. In this case, the scalp surface of interest will be locally hydrated upon the application of a small adduction pressure to the electrode body, so the sensor shape tends to change, as we can see in Fig. 10. This design principle is commonly used for its simplicity. In this case, the liquid, which can locally hydrate the scalp, is a small solution amount (1-2mL) located in a PU reservoir with silver coating, to ensure good operation, in direct contact with the electrode. It is another possible solution:

1. To avoid dirty processes or damaging the hair; and
2. Gel running among electrodes if it is used external gel application.

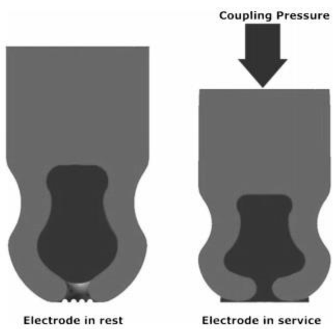


Fig. 10. *Scheme of the quasi-dry electrode concept. In dark is represented the volume of the reservoir* [17].

The in vivo experiments also used to achieve the sensor full potential, a special cap that was able to apply a constant pressure to electrode structures. For this reason these type of designs will probably induce scalp discomfort for the patient or subject. Anyway, the in vivo tests showed that the quasi-dry electrode was able to reliably acquire EEG signals similar to those of the commercial Ag/AgCl reference electrodes [18].

3. Polymer soft legs electrode- Cognionics

Another existent type of semi-dry electrode available on the market, is a sensor with "soft" legs due to external electrolyte contact process designed by Cognionics, Fig. 11. This quasi-dry electrode is an ionically conductive polymer device with 5 soft pins and it is used on irregular skin surfaces and hairy heads to improve EEG signal quality. This sensor does not have a constant reservoir or tank humidification. Thanks to its material properties, it is flexible and reusable.

To obtain these soft legs, first of all they are submerged in clean water during 10-20 seconds and then they air dry for a few minutes. It is necessary to prove that the legs are soft after the water application. Secondly, the Cognionics team applies with a brush a glycol-based solution without leaving any dry parts. This can be done while the sensors are located into the EEG cap and have contact with the subjects' scalp, but this process it is not as comfortable as the reservoir idea. These type of devices need a constant supervision to verify that they are not dry [19].

Fig. 11. *HydroFlex sensor (Patent Pending)* [19].

2.3.3 Dry electrodes

Nowadays, many research groups are dedicated to develop dry EEG electrodes that can solve the different issues caused by wet electrodes on patients. There exist diverse dry electrode prototypes, but all of them have a common performance method: to transfer the bioelectrical signal between electrode and the scalp by direct resistive "attachment" without any extra added electrolyte solution (liquids, gels etc.). In fact, a dry electrode is not absolute dry, as the word can indicate, because a tiny amount of sweat and moisture is always present on the skin and it influences in the measurement.

As expected, dry electrodes have shown many advantages such as rapid setup as well as user convenience and comfort due to elimination of patients' skin preparation, post-cleaning processes and conductive gel applications. However, electrode-scalp impedance of dry electrodes normally results in several MΩ due to the lack of electrolytes on the contact surface. This impedance can be used to compare effectiveness of different electrode types. As mentioned before, a lower electrode-scalp contact impedance provides a better SNR ratio and shows more accurate and quality measurements of EEGs [17].

Nowadays, there exist two approaches to resolve the issue of electrode-skin contact impedance for low-noise biopotential sensing. The traditional solution has been to simply abrade the skin to obtain a very low contact resistance (5–10 kΩ). At the other extreme, one common practice is based on using an amplifier with such high input impedance that the skin-electrode impedance becomes negligible. For wet electrodes, neither extreme is necessary, but the problem of contact impedance becomes a much more pressing problem for dry and noncontact sensors, for which maximizing input impedance is the only viable alternative.

The equivalent electrical circuit of a dry electrode is showed in Fig. 12. Z_{ES} indicates the electrode scalp impedance due to the pins-scalp contact (in the scheme case). Z_S denotes the impedance of the epidermis layer, whereas Z_D is the impedance of the inner dermis layer. The overall impedance faced by the electrode is given by the sum of the three elements [8].

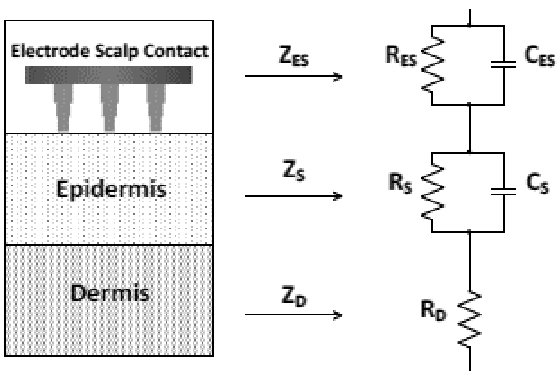


Fig. 12. *Equivalent electrode circuit – dry electrode* [8].

In addition, the dry electrodes sometimes do not make a good contact to scalp due to the diverse situations (movement, irregular surfaces, etc.). So dry electrodes can be susceptible to environmental noise and can produce noisier EEG signals. Therefore, active dry electrodes have been proposed by in-site pre-amplification or shielding, aiming to minimize the environmental noise due to eye-blink, high frequency activity, leads deterioration etc. [20], [21], as mentioned before. Anyway, now there are already several existing brain computer interfaces (BCI) based on alpha rhythms, steady-state visually evoked potentials (SSVEP) or P300, that use dry electrodes [22], [23].

In the literature, noninvasive dry electrodes will be classified in the following categories according to the type of skin contact:

Skin Contact

1. Disk, pellet contact

In 1994, Babak A. Taheri, Robert T. Knight and Rosemary L. Smith published the design of an active dry electrode. The device sensing element was a 3 mm stainless steel disk which had a 200 nm thick Si_3N_4 (nitride) coating deposited onto one side. The back side of the disk was attached to an impedance converting amplifier. The prototype electrode was mounted on a copper plate attached by a Velcro strap that held the electrode and associated electronics in place on the scalp.

The performance of that prototype dry electrode was compared to commercially available gel-based electrodes in three different areas: spontaneous EEG, sensory evoked potentials, and cognitive evoked potentials. The results suggest that the dry electrode performs comparably to conventional electrodes for the recorded types of EEG signal analysis [24].

2. Spiky contact

- Resistant Tips:

These type of electrodes make electrical contact to the scalp via a set of “pins” or “tips”. In the current electrode market, different pin-shaped electrodes can be fabricated by different nonflexible materials and companies. The QUASAR hybrid electrode is a good example of a dry biosensor. This device uses a combination of high impedance resistive and capacitive contact to the scalp that can be as high as 10MΩ. The electrode has an inner circular section with 19 pins and in the external concentric section 12 pins more are located, Figure 13. In total, this sensor has 32 pins. In order to reduce the contact impedance, undesired effect, the electrode is directly connected, back-to-back to an amplifier with ultra-high input impedance. The signal acquired with this electrode was compared to wet-electrode signals, showing similar results when the subject had the eyes closed. This comparison was performed on EEG envelopes of 50 µV peak-to-peak, because other low signals were not showed. Moreover, an EEG harness was used to fix the electrodes in hairy locations [25].

Fig. 13. *QUASAR Hybrid electrode – US 5cent coin to compare dimensions* [15].

Many similar sensors are currently marketed. The g.SAHARA electrode produced by *g.TEC* can be highlighted. This active dry-electrode consists in an eight-pin device made of a special golden alloy. These pins can have the sufficient length to go through the patients' hair to the scalp, depending on the different size chosen [26]. Secondly, *Neuroelectrics*, also have an electrode model called Drytrode. It does not need gel application and it is formed by Ag/AgCl with 10-point contact surface. Its lifecycle is 100 uses [27]. The *Cognionics* team has too a dry-electrode design called Flex Sensor. The electrode body is fabricated by a conductive elastomer but at the end of its 8 probes, small Ag/AgCl spheres can be found. The pins are not in direct contact with the patient's skin and do not produce uncomfortable contact. The sensor has a skin-contact impedance of 100-2000kΩ with unprepared skin and it can be used 200-400 times [28]. Also we can find electrodes fabricated with other materials like titanium or Polyurethane (PU) [29]. *Neurospec* has also fabricated another sensor called EL120. This electrode has contact posts designed to improve contact through fur or hair. Its 12 pins create a 10 mm contact area and have 2mm deep to push to provide good contact with the skin surface. It is reusable, but according to its manufacturer, it can be used with or without gel [30]. Some electrodes can also be 3D printed, for example Alexandre Barachant fabricated a 3D printed sensor with Graphene filled PLA filament and coated with silver ink.

In [31], the sensor was designed to contact the scalp surface with 17 spring contact tips, made of gold, inserted into a thin Cu plate that served as a flexible substrate to the sensor. Its design keeps high geometric conformity between the sensor and the irregular scalp surface, thus maintaining low electrode impedance. Additionally, the flexible substrate in which the spring probes are inserted permit the attachment of the sensor to the scalp without pain when force can be applied. This sensor was compared with wet electrodes, achieving similar results in terms of signal quality recordings and electrode impedance with a better temporal derive, thus enabling long-term EEG records. In conclusion, there exist many other tip designs nowadays that can be found on different sites, but they share the same basic principle.

- Flexible Tips:

Since rigid materials are used to fabricate pin-shaped electrodes, they have a high probability of causing injuries and sense of pain with their design. More recently, in other studies, another type of dry electrode with pins flexible pins have been created. At Shanghai Jiao Tong University, Department of Micro/Nano-electronics, in 2018 they presented a novel soft pin-shaped dry electrode. In this study, they proposed a passive dry EEG electrode design made from carbon fiber with high flexibility and conductibility. The soft conductive polymer properties can reduce discomfort that rigid materials can cause. The several micro bristles at the top of soft pins were shaped by carbon fiber and polyurethane (PU)/carbon nanotube (CNT), Fig. 14a. Thanks to its bristle structure, the electrode enabled the direct contact with scalp increasing the wearing comfort without any treatment, Fig. 14b. The surfaces of carbon fibers were electroplated with Au to reduce the contact impedance between scalp and electrode, which was measured with the mean valve of 133 kΩ. To reduce this contact impedance, a high pressure should be employed. To understand how the recording device works, a single carbon fiber monofilament was used as a signal recording and was first coated with polymer insulating layer. Then, a large number of carbon monofilament fibers were integrated into an electrode array. The top of the array was hardened to needle like by annealing treatment. Finally, the insulating layer on the top of the carbon fiber needle was removed by burning and the conductive carbon fibers were exposed. After the electrode fabrication, a 3D printed headgear was used to fix the dry electrode on scalp. The dry electrodes were placed based on international 10/20 system and pressed on scalp by springs in the 3D printed electrode holder, Fig. 14c.

Finally, the published results showed the influences of dry electrode on skin. Alpha rhythms from auditory evoked potential (AEP) and steady-state visual evoked potential (SSVEP) were respectively measured to evaluate the electrode performance for EEG recording and they have been compared with an Ag/AgCl electrode results. The coherence between dry electrodes and Ag/AgCl gel electrode was more than 0.9 at most of the frequencies, which was very similar to the coherence between two Ag/AgCl wet electrodes [32].

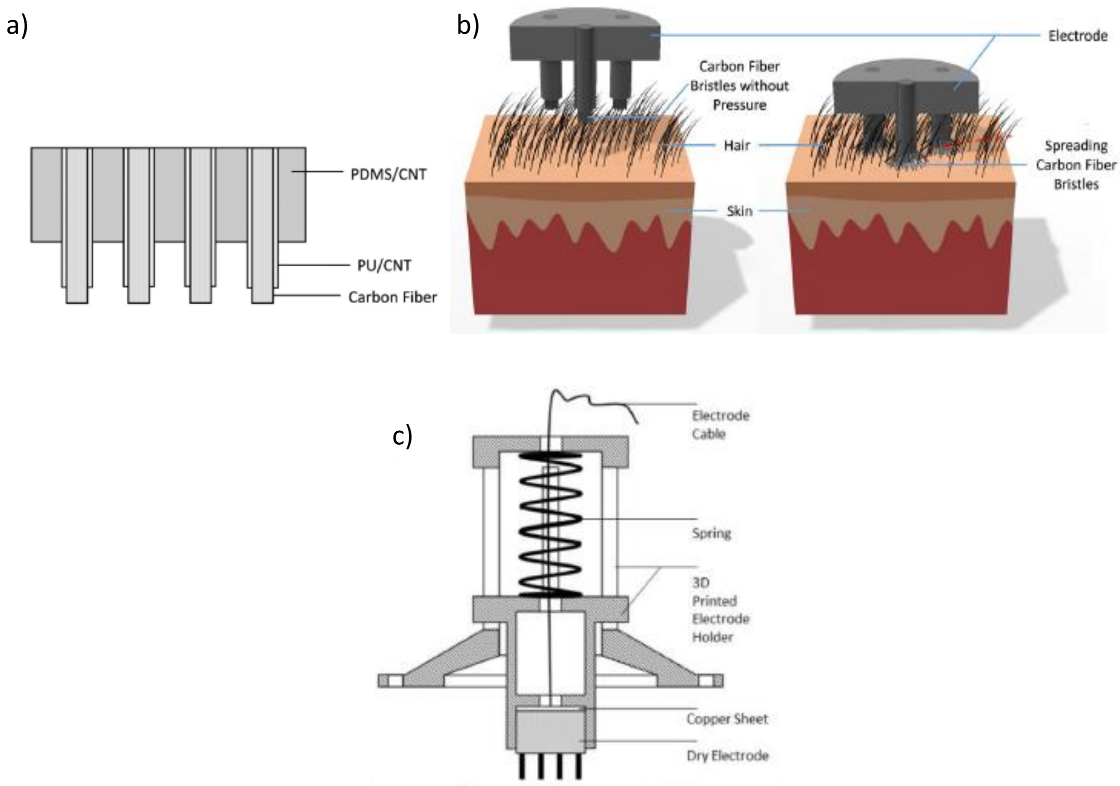


Fig. 14. *Dry electrode structure (a), Schematic diagram of pin-shaped electrode and bristles made of carbon fibers on the tip of pins, without pressure and under pressure (b), Prototype of single electrode holder (c) [32].*

Other flexible designs can be found in other articles. For example in [33] (Fig. 15), the authors presented a passive low-cost dry electrode for EEG that was made of flexible metal-coated polymeric bristles to reduce the reported discomfort by distributing the pressure on the skin uniformly and flexibly. The bristles looked like little brushes. The coating was accomplished by painting the bristles with a silver-based conductive ink. Although the coating was resistant to flexing the bristles, it tended to wear out after multiple uses; this is a clear device weakness. In addition, they examined various standard EEG paradigms to validate the performance of the novel electrodes in terms of signal quality in comparison with an Ag/AgCl wet electrode.

The electrode-skin impedance with freshly coated electrodes was typically 80 kΩ for low-to-medium, unobtrusive pressure on the scalp through hair. However, after 10 months of use, their impedance was 150-200 kΩ. In the final results, the bristle-sensors produced a signal that could be compared with gel-based electrodes recorded brainwaves, between 7 and 44 Hz. Furthermore they provide high redundancy acting towards maintaining mechanical and electrical contact, while providing better comfort to some of the subjects than both the gel-based electrodes and the array-of-pins electrodes, creating thus the opportunity for longer term use in BCI applications. However, these types of electrodes presented a possible hazard related to some paints or inks sued, because they can be toxic for skin.

Fig. 15. *Silver coated bristle dry electrode* [34].

Some metallic electrodes fabricated in the past cause irritation in some patients' skin. In 2014 an alternative design was presented to avoid Fe or Cu materials. This flexible electrode was manufactured with silicone including silver based and SiO_2 materials. The contact area was optimized to provide the proper skin-contact impedance. This device is an eleven pin-shaped dry electrode and the results obtained showed that it was applicable for EEG signals measures [34]. Some other soft materials can be used to avoid allergic reactions.

3. <u>Heterogeneous/Textile</u>

Other devices that do not use pins or bristles have been also tried. For example, in 2011, a low-cost dry electrode was fabricated with electrically conductive polymer foam covered by a conductive fabric. This sensor was proposed for long-term EEG measurements and for hairy sites. Its dimensions were 14.00 x 8.00 x 8.00 mm. Due to material properties, the sensor was able to adapt to irregular scalp surface and even the hairy sites, thus keeping low skin–electrode interface impedance (2 kΩ/h after 5h recording). Also, they reported that dry foam electrode exhibited both polarization and conductivity due to the use of conductive fabric, which provided partly polarizable electric characteristics. The impedance recorded was compared with wet electrodes with and without previous skin preparation at F10 and POz (Forehead and hairy locations). The results showed were better for the foam based electrode and the analysis of motion artifacts was also in favor of it [35]. The polymer foam covered with a thin metal layer or conductive textile demonstrated to work for recording EEG signals. If the foam electrode was covered with textile materials, it could have been integrated into a textile cap in a single process, making it a robust construction [36].

In conclusion this heterogeneous sensor is another possible option to be used in EEG measurements. Textile electrodes made from fabric, can be produced by weaving, knitting or embroidering conductive yarn to the structure. This yarn is made by interlacing different metal filaments coated with aluminum, copper, silver and nickel. The coating techniques used are diverse: metal foil and laminates, conductive paints and lacquers, sputter coating, vacuum deposition, flame and arc sprying, and electroless plating. In [37], they have created a Polyethylene terephthalate (PET), used as a substrate, coated by copper plating including Stannous Chloride and other materials. The deposited copper was characterized by SEM and XRD. In addition, a layer of a foam was placed between the folded layers of the conductive fabric to ensure pressure to an electrode side and to record better quality signals. Finally, a cotton (nonconductive fabric) with a 2cm hole was placed above the conductive fabric, Fig. 16. The acquired signals were compared with commercial available electrodes. The final results showed that the soft material could be used for high quality recordings of EEG signals with subjects with very thick hair (for example neonatal patients).

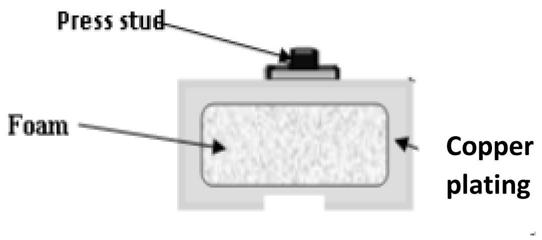


Fig. 16. *Textile electrode* [37].

Noncontact/capacitive

Another type of gel-less electrode are the capacitive electrodes. The noncontact electrode, can sense signals with an explicit gap between the sensor and body. This enables the sensor to operate without a special dielectric layer and through insulation like hair, clothing or air. Noncontact electrodes have been typically described simply as coupling signals through a small capacitance (10's pF). In addition, there is always a significant resistive element in these devices (>100MΩ), designing an amplifier to acquire signals from such a high source impedance is quite challenging. Typical design problems related to these sensors include achieving a high enough input impedance and a stable network that does introduce excessive noise [38]. However, there are some major drawbacks for the use of capacitive electrodes. Firstly, the amplitude levels are so low that they are probably not suitable for recording spontaneous EEG signals and are susceptible to motion. For this reason, I will not look into different capacitive devices types [15].

3 Laboratory report

On 21 May, I had the pleasure to visit one of the Inserm departments in Lyon. This organization is the only public research corporation in France totally dedicated to human health. Its objective is to promote the health of all French people by advancing knowledge about different diseases, treatment innovations, and public health research. The department visit in the Lyon Neuroscience Research Center (CRNL) was guided by Emmanuel Maby, research engineer specialized in real-time neuroimaging, BCI and neurofeedback.

First of all, we started solving doubts, talking a little bit about the project and the different EEG devices that exist actually on the market. In his office he had different EEG headsets that he utilizes in some real projects and presentations. Then, we talked about the projects that he is coming up with. As mentioned, Brain Computer Interface is a communication method that depends on the neural activity generated by the brain regardless of peripheral nerves and muscles. There are many BCI applications that can be implemented, such as applications for disabled people to interact with computational devices, applications for gamers to play games with their thoughts, social applications to capture feelings and emotions, applications for human brain activities, etc. [39]. Currently, he was working with TDAH children to analyze their signal brain response to some studied stimulus. In this study, only the frontal and occipital brainwaves were recorded. To better understand this project, he explained me a real game that the kids had to do when they were experiment subjects.

First, the children were in front of a PC with the EEG cap/headset working and connected via USB to the computer. Then, in the screen they were appearing a couple of cards covered and some uncovered. The objective was to find the same pair of cards uncovering the ones that were covered, which were located in the center of the screen. When the activity began, some random flashes appeared above the covered cards every few seconds. A photodiode registered the flash apparition and the computer recorded the EEG signal simultaneously. Finally, with a calculation program and signal processing they could know which brainwaves were the interesting ones in the study, because they only had to place a 100-200 points window on the EEG signal after the photodiode response. This is an efficient way to focus only on the important measured information related to the capacity of concentration of the participants comparing the EEG signals and the flashes, as seen in Fig. 17. In addition, it is a practical way to work without fear for lag registration signal.

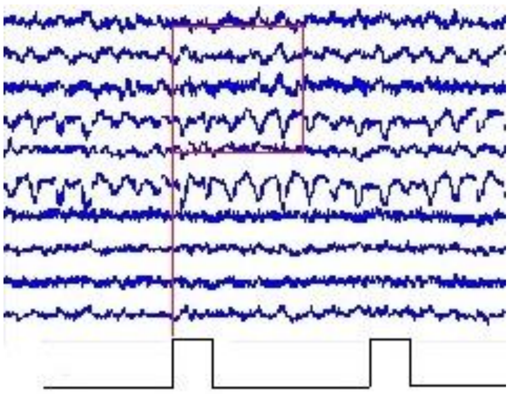


Fig. 17. *Scheme of a patient's EEG signal, the photodiode response at a flash and a window of 100-200 points, which relates the two signals - Author's own.*

Moreover, we talked about the importance of electrode and headset ergonomics, because if the children are distracted by some huge and uncomfortable device that will have contact for two hours with their head, the experiment results would be null. So in this research application, they try to work with caps, which have the electrodes placed inside. This is another way to minimize external risk situations for the study.

The number of electrodes minimally necessary on BCI are 8 electrodes. The location of them depends on the study application and the brain region that is more interesting on the experiment. Generally in the studies that they perform in CRNL, they use active electrodes to acquire better results. Mr. Maby showed me some active dry electrodes used on some patients depending on their hair length, Fig. 18. The pins that are used are covers of different sizes.

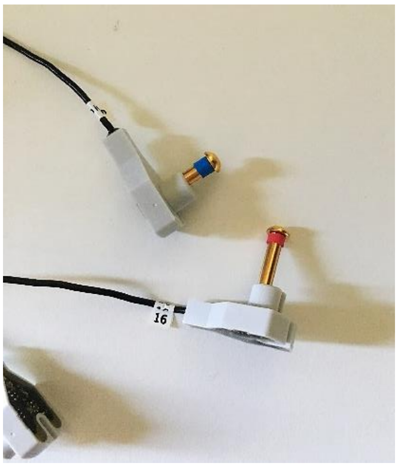


Fig. 18. *Active dry electrodes – CRNL - Author's own.*

In conclusion, this visit helped me to have more vision of real scenarios and applications that exist in investigation centers. Also, to touch and see some headsets and electrodes and to analyze their strengths and weaknesses brought me more knowledge about these medical devices. All the existent doubts related to the design part of the project were resolved.

On 28 May, my electrode and headset design ideas were presented to Dr. Jérémie Mattout and his team at the Inserm building. They contributed with some interesting suggestions and improvements for the electrode design.

4 Design overview

4.1 Introduction

As it has seen before, conventional wet (gel) and dry electrodes are widely employed for biopotential measurements such ECG and EEG, despite their disadvantages, such as long preparation time, discomfort, pain and skin irritation. As mentioned, the objective of this new electrode is to improve the recording method of brain signals and adapt the design to modern and challenging nonhospital and/or mobile monitoring applications.

To achieve it, this thesis first has conducted an EEG literature review focusing on how the signals can be measured, the different existing placement systems, and the different type of electrodes commonly used. This review was extensive and it served to emphasis on the technical aspect of the project, such as the design to be used, suitability of components and the technical information to be employed in the development of the sensor. All of the studied and mentioned devices improvements, have been combined to highlight the most “rising aspects” of EEG electrode systems.

4.2 Description of the background art

Before doing the electrode design, we have to be aware of the actual patent designs that are in the current market. This patent research provides information of some quasi-dry sensors patents:

- WO. Pat. No. 2012/140,629 is a novel PU electrode prototype with a reservoir that has been commented in the last chapter. It is a quasi-dry electrode patent and can be found in [40].

- Moreover, in 2001, D. Marro, T. Washburn and D. LaBombard wanted to determine the different levels of consciousness after anesthesia processes in patients, recording brain signals with electrodes fitted with large gel reservoirs. U.S. Pat. No. 6,301,493 is a braille-tip electrode prototype with perforations that permits the conductive gel transmission through the hair onto the skin. These “tanks” used are semi-spherical polyethylene reservoirs and supposedly allow a low impedance acquisition without any previous skin preparation processes. In this patented sensor, they also used open cell PU sponges [41].

- CN. Pat. No. 103,767,704 presents a porous metal electrode with a PDMS reservoir to moisturize patients’ skin, thus permits low impedance EEGs measures in comparison with dry electrodes. This porous titanium sensor is fixed with a wire to an Ag/AgCl electrode [42].

- Another design proposed is based in a hair-grasping EEG electrode with a locking fixation placement. U.S. Patent Publication Number 2008/0154112. U.S. Pat. No. 6,853,576 creates a pin-electrode and a fixation tool that dispenses electrolyte gel directly to an integrated sensor reservoir providing a faster humidify method, and a rapid process for placing sensors [43].

- U.S. Pat. No. 6,574,513 is a wrap electrode construction wherein the material provides sufficient volumetric capacity to absorb and held saline solution. The wrap, with a fibrous structure, surrounds the electrode in an inner cavity and allows direct sensor-contact with the scalp [44].

- In 2017, U.S. Pat. No. 9,820,670 proposes a pressed carrier electrode system with an assembly, which carries a reservoir containing a conductive gel through distal openings of tubular members [45]. Another interesting pillar construction is U.S. Pat. No. 6,381,481, where flexible resilient fingers are in direct contact with a conductive gel adjacent to the conductive plastic (silicone containing carbon) pillars. If the initial position of the tips is not altered, this can provide a seal protection to the liquid. But if they are under pressure, the liquid can have contact with the scalp [46].

- The flexible semi-dry multi-layer patented device, CN. Pat. No. 108,652,620, is a two-reservoir device with a one-way liquid check valve. This device is formed by four principle layers: a flexible electrode body layer, foam, reservoir and the circuit [47]. Another quasi-dry electrode that can be highlighted is CN. Pat. No. 106,963,376. This sensor is formed by two-cushioning units, two reservoirs and an electrode contact columns below the tanks. The lower cushioning unit is placed into the first reservoir units and the springs are mounted in a coaxial mode. The second reservoir, and a first sump, provides the automatic liquid supplies through the cylinder columns, made by sintered porous metal. This design allows low impedance results to ensure stable long EEG acquisition [48].

- A semi-dry conductive comb designed is also studied in 2018. CN. Pat. No. 207,693,566 is a quasi-dry electrode formed by a conductive core aquogel and conductive bristles. A sensor top cover is moved under pressure and allows the liquid movement through the electrode legs [49].

All the figures of the patents are found in Appendix A.

4.3 Prototype

As mentioned, some researchers and companies have adopted quasi-dry electrodes designs to acquire good EEG signals measurements. One of the most promising ideas is based in some electrode form with an in-built gel reservoir which slowly and continuously hydrates the remote skin site via capillary action. Some studies proof that electrode structures with penetrating electrolyte can give quality and stable signal performance [50]. The other external hydration techniques are not easy to access or comfortable as the reservoir idea. These reservoir electrode structures have been shown to overcome, to a significant degree, the inherent disadvantages of dry electrode structures (high impedances, contact issues etc.) as in [16].

However, many investigation studies have considered during the past years flexible or rigid dry-electrodes brush designs [32], [33] as principle design ideas. When these bristles or tips are in contact with the skin, they ensure a larger contact surface and lower skin impedances in comparison with other dry electrode constructions.

In conclusion, for semi-dry electrodes and dry-electrodes the most promising ideas shown in the last chapters can be classified in two principles: flexibles or rigid porous tips used with reservoirs.

This project is based in the design and development of a novel passive horizontal quasi-dry EEG electrode with a reservoir and external permeable ceramic rigid-bristles. An Ag/AgCl electrode inside the reservoir will record EEG signals.

In order to guarantee the success of this prototype and to revise the initial criteria, the next reference points are essential to design the new electrode:

- The electrode has to record EEG signals (frequency rang should be 4-30 Hz);
- No physical or chemical damage to human tissue;
- High mechanical strength and easy to be fixed;
- Small impedance between dry electrode and skin;
- Has to be used in some real applications; and
- Needs an ergonomic headset/cap construction.

4.3.1 Dimensions and materials

Dimensions

The existing and commented semi-dry electrodes with reservoir, are fabricated as big “vertical” sensor structures. In this project, is proposed a lateral construction for a semi-dry electrode with a 3.00 cm diameter. This idea, which has been applied in other sensors, avoids “massive” headset or cap constructions with giant electrodes or two-reservoir models, and also opens up to other exciting design possibilities. This electrode will have 7 legs, one in the middle and the other 6 will be separated 60º and will be distributed along the circumference. All the legs will have direct contact with the reservoir. In addition, each leg will be divided into two different parts: the pillar part and the “bristle” part, both will be fabricated with the same materials. The pillar part will measure 3.00 ϕ mm x 5.00 mm and the set of rigid bristles can have a total diameter of 10.00 mm each one x 4.00 mm, Figure 19. A single bristle can have a diameter of 0.50 mm. Flexible tips were not chosen because I wanted to be reduced to the maximum the noise recorded by the electrode.

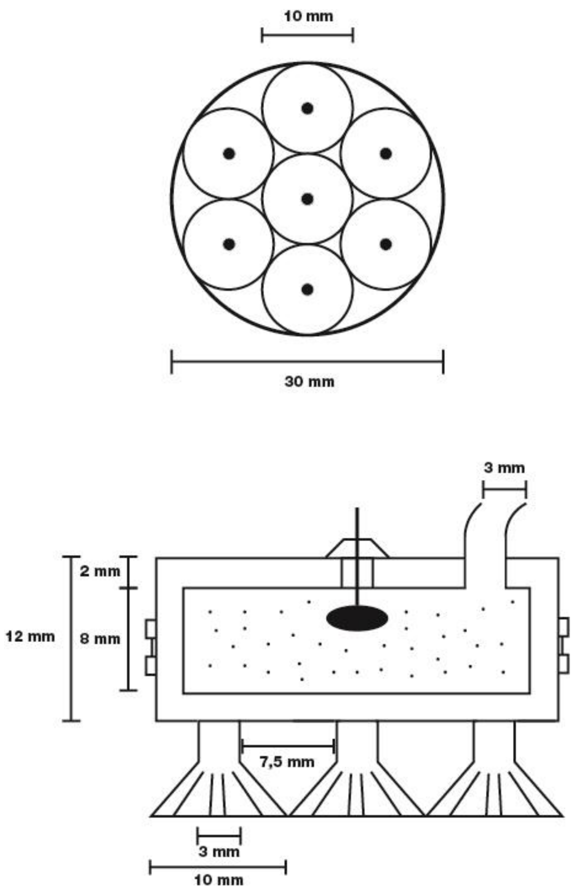


Fig. 19. *Passive noninvasive semidry electrode – Illustrator program - Author’s own.*

Using (2) to calculate the volume of the cylindrical reservoir, being the ratio 14 mm and height 8.00 mm, this tank will have a total capacity of 4.92 mL, ≈ 5mL. The solution will be supplied by a tub located on the electrode top, facilitating the constant solution inlet into the tank without using external liquid manual change and avoiding pressure application to its performance.

(2)

$$V = \pi \cdot r^2 \cdot h$$

The biopotential sintered Ag/AgCl electrode that will be used is chosen for its non-polarized nature and less noise properties in low frequencies (12.5 mm diameter x 1.00 thick mm. Warner instruments, USA). In addition, if we can imagine a situation where the electrode is located on the top of the head, the Ag/AgCl sensor will record the activity of the leg that is in the middle and also from a little parts of the external legs, which will work also as support pillars. Otherwise, if the electrode is located in a lateral region, the electrode could move and its registration focus could change some millimeters in long-term measurements. In that case, the external legs will register the brain signals, Fig. 20.

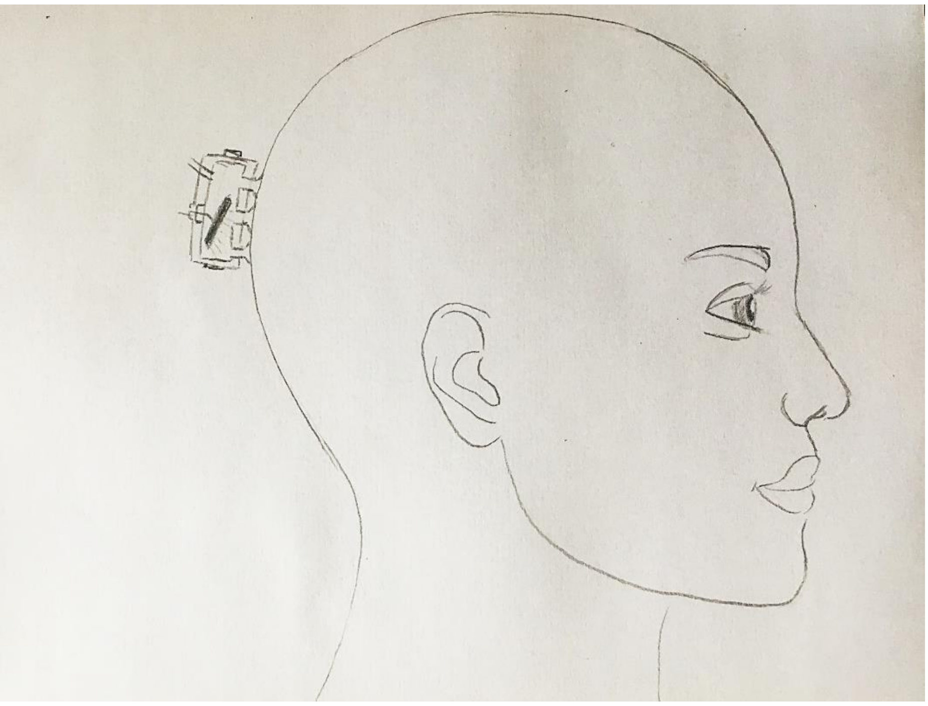


Fig. 20*. EEG signal measurement if the electrode was located in a lateral region of the head – Author's own.*

Thanks to capillary force of the ceramic porous, the semi-dry electrode enables the continuous release of a saline solution from the built-in reservoir. This electrode will be in contact with a 3M KCl solution (LabChem), the most used on these type of sensors. KCl has the ability to form a crusty layer of solid KCl if the solution is constantly exposed to the atmosphere in long-term measurements, but in this case the solution will not have contact with the atmosphere because it will remain in the reservoir.

Materials

First of all, the quasi-dry electrodes can be subject to pressures (axial or/and lateral) to record high-quality EEG signals, so the different materials that have to be chosen should have certain mechanical properties to adapt themselves to these conditions. Some devices with a high biocompatibility level of their materials, could empower numerous clinically relevant applications including electrode device interfaces, which serve as a key foundation by providing a high "fidelity channel" for electronic communication between medical devices and soft tissues. There have been substantial advances creating new electrode materials, including the use of biocompatible low impedance materials (iridium oxide, carbon nanotubes, conducting polymers, etc.). All the existent biomaterials comparing their mechanical compliance (Pa) and Electrical Conductivity (S-cm^{-1}) used in electrode devices are showed in Fig. 21 [51].

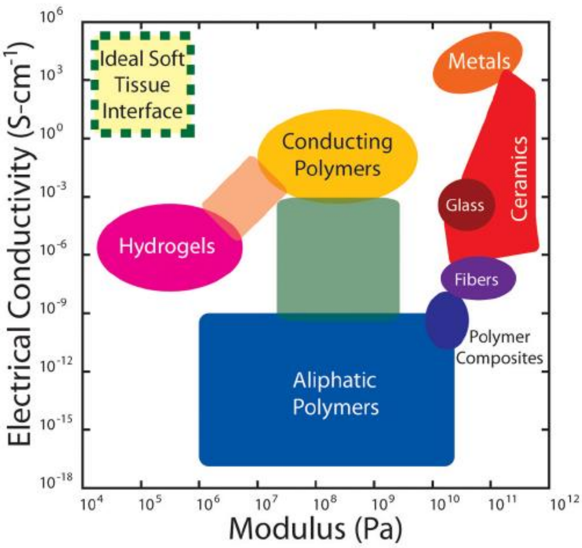


Fig. 21. Diagram to identify ideal materials for electrically-active tissue-device interfaces for use in vitro or in vivo [51].

Two different materials are proposed for the electrode body construction. Both materials have to be light and impermeable to fluids because they will be in contact with the reservoir saline solution and the liquid have to remain inside the tank. The first material option is a non-plastic and firm material, which is not susceptible to deformations caused by applied stresses. If the external body is rigid, the Ag/AgCl electrode will not record the sensor deformation noise and record it with the EEG signal. Actually, Polypropylene is used in medical applications for being inert and hydrophobic [52], and it is biocompatible. Also is used in suture processes (resistant properties), oxygenator membranes and in containers. Its tensile strength and surface hardness, Tab. 2 [53], shows that is an ideal option for a rigid structure. This material will also recover the pillar part of the legs of the electrode to assure good fixation.

Polymer	Tensile strength (MPa)	Flexural modulus/ (modulus of elasticity) (GPa)	Elongation at break (%)	Strain at yield (%)	Notched Izod impact strength (kJ/m)	Surface hardness
Carbon/hydrogen-containing polymers						
Low-density polyethylene (LDPE)	10	0.25	400	19	1.064	SD 48
High-density polyethylene (HDPE)	32	1.25	150	15	0.15	SD 68
Crosslinked polyethylene (PE)	18	0.5	350	N/Y	1.064	SD 58
Polypropylene (PP)	26	2	80	N/Y	0.05	RR 85

Tab. 2. Mechanical properties of Carbon/hydrogen-containing polymers [53].

On the other hand, it is known that the head does not have a regular surface. If the electrode body has some elastic properties, this will assure a total electrode-skin contact surface, Fig. 22. In 2014, [54], they created a based-EPDM rubber electrode containing various additives for optimum conductivity, flexibility and ease of fabrication. So, the other option proposed is an EPDM body electrode to assure a total contact with the patients' scalp.

The two proposals have to be fabricated to record the EEG signals and the skin-electrode contact impedance to compare the results and chose the best option.

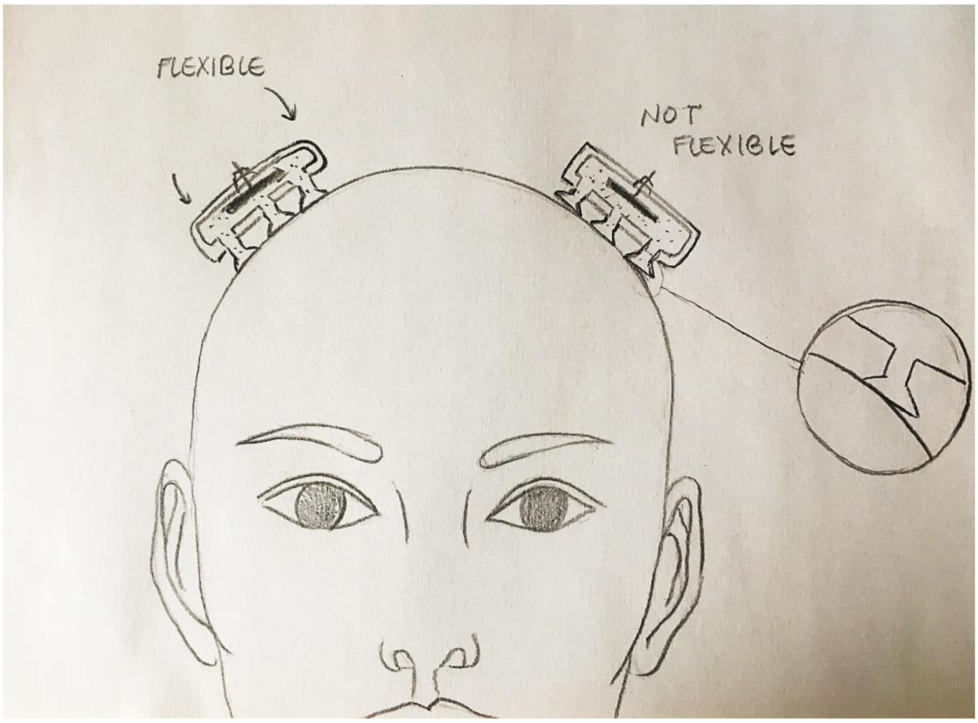


***Fig. 22**. Sketch of a flexible EPDM electrode and a rigid PP electrode - Author's own.*

Moreover, Polyvinyl Chloride (PVC) can be chosen for the tub used to fill the reservoir due to its tensile strength, surface hardness (flexible) and water resistance, Tab. 3. It is a biocompatible material and it is actually used in biomedical applications, such as tubes, blood containers, dialysis solutions, packaging [55] etc. The inner tube diameter will be 2.0 mmm, UK supplier.

Polymer	Tensile strength (MPa)	Flexural modulus/ (modulus of elasticity) (GPa)	Elongation at break (%)	Strain at yield (%)	Notched Izod impact strength (kJ/m)	Surface hardness
Chlorine-containing polymers						
Chlorinated poly(vinyl chloride) PVC	58	3.1	30	5	0.06	SA 70
Unplasticised PVC (UPVC)	51	3	60	3.5	0.08	RR 110
Plasticised PVC	14-20	0.007-0.03	280-95	N/Y	1.05+	SA 85

Tab. 3. Mechanical properties of Chlorine-containing polymers [53].

To fabricate the pillars and the bristles, the materials that have the better response applying high-pressures without having plastic behaviors, are the metals, ceramics, fibers or some polymer composites. The metal group seem to be the best mechanical materials option and there exist porous metals in bio-sensing. However, they are hard materials that can produce discomfort in the area of the scalp, because the lower part of the prototype pillars is formed by very slim rigid bristles. If the pillars were fabricated by metals (Titanium, silver etc.) and a high pressure was applied, the bristles could penetrate the scalps' patients as little needles. Instead, there exist some ceramics that can be permeable and can have a certain interesting degree of porosity [56]. Moreover, this biomaterial group has a high electrical conductivity level and good mechanical properties. For this design prototype, an existent porosity degree is essential necessary to form electrolyte-skin-contact. According to ceramic Modulus of Elasticity (GPa), Tab. 4, Al_2O_3 (alumina) seems to be the best option, in conjunction with Zirconia. This is not the first model of a quasi-dry electrode that uses porous alumina to register EEG signals. U.S. Pat. No. 3,989,036 is an electrode formed by a water-permeable alumina insulating member (when it is in direct contact with the patient's scalp), and its shape was adapted to be impregnated with a conductive liquid [57]. In conclusion, the alumina is chosen for its mechanical properties and for being used in previous constructions of other semi-dry sensors.

Material	Young's Modulus (GPa)	Compressive Strength (MPa)	Bond strength (GPa)	Hardness	Density g/cm^3	KIc (MPam$^{1/2}$)
Inert Al_2O_3	380	4000	300-400	2000-3000 (HV)	>3.9	5.0-6.0
ZrO_2(PS)	150-200	2000	200-500	1000-3000 (HV)	≈ 6.0	4.0-12.0
Graphite (LTI)	20-25	138	NA	NA	1.5-1.9	NA
Pyrolitic Carbon	17-28	900	270-500	NA	1.7-2.2	NA
Vitreous Carbon	24-31	172	70-207	150-200 (DPH)	1.4-1.6	NA
Bioactive HAP	73-117	600	120	350	3.1	<1
Bioglass	≈ 75	1000	50	NA	2.5	0.7
AW Glass Ceramic	118	1080	215	680	2.8	≈ 2
Bone	3-30	130-180	60-160	NA	NA	NA

Tab. 4. Characteristics of Bioceramics [58].

To determine the ideal alumina degree of porosity a high porosity level has to be considered. However, the pore size should be small enough to ensure the liquid retention inside the structure. The liquid tightness also depends on the properties of the electrolyte fluid that will be used (density and viscosity). Generally, 5-50 µm are the parameters used in porous polymers for bristle electrodes [59]. In published studies, a porous alumina with a pore size of 10–40 µm is allowed to use the material for macro and microfiltration processes. These results revealed that the materials have a high degree of macrostructure homogeneity, and is efficient in water filtering [60]. Likewise, this may be a big pore size to retain the liquid inside its structure, because it will go easily through the 40 µm foramen. In [16] they used porous Al_2O_3 with a size pore of 3-6 µm to retain a saline solution. This range of values is closer to the polymer studies and results. In this prototype, a 5 µm size pores alumina will be used.

Moreover, G. Li et al., also studied the electrode/scalp impedance of a ¡n alumina porous electrode. The test was based fixing a 9-channel headset of semi-dry alumina electrodes. The electrode located in Cz was used as the electrode reference. They did not use methods to clean the skin before the test. All impedances presented in the study were measured by an impedance/gain-phase analyzer (Solartron 1260, UK) using 50 mV AC sinusoid signal at a frequency range from 100 kHz to 1 Hz. The influence of the semi-dry electrode structure on semi-dry electrode/scalp impedance at 100 kHz and 10 Hz was also investigated.

The published results pointed out from a pair of semi-dry electrodes at 10 Hz an impedance of 42.1 ± 16.4 kΩ (electrode 1) ∽ 51.4 ± 21.8 kΩ (electrode 2) was measured. So the impedance in this case of a single electrode can be half approximately.

The average impedance of a pair of electrodes of the ten subjects was 44.4 ± 16.9 kΩ, ranging from 21.87 ± 2.9 kΩ (subject 8, male, with short, thin and rare hair) to 69.59 ± 5.02 kΩ (subject 10, female, with long, thick and dense hair). The lowest contact impedance of a dry electrode reported is 80 kΩ [33]. In conclusion, Al_2O_3 can have good impedance properties at those frequencies, and can be a good possible material choice. The obvious individual variations of the impedance can be mainly explained by different skin conditions of the participants, including size of sweat glands and pores, the thickness of skin, density of hair, gender etc. However, this results have to be checked in a laboratory with another impedance test and protocol.

4.3.2 Production

First of all, one leg (pillar and its bristles) will form a single manufactured piece. The cylindrical base of the electrode with seven holes will be another independent fragment. The seven legs will be introduced into the holes by the pillar parts. This can be the assembly (1).

The Ag/AgCl disk electrode and its wire can be located into the remaining part of the cylinder made of polypropylene or EPDM. This can be the assembly (2).

Then, the cylinder with the electrode (assembly 2) and the base and legs (assembly 1), can join closing the cylinder structure. Finally, the PVC tub will be introduced into its hole and the other external accessories will be located to finish the production process.

4.3.3 Cleaning methods

As sterilization methods, polypropylene can be repeatedly autoclaved at 121 ºC and 15 psi (heat sterilization) [61], PVC can also be sterilized by Gamma Radiation or EtO [62]. Finally, Al_2O_3 can be sterilized by heat methods, accomplished through exposition of the medical device to high temperatures [63].

However, sterilization processes will not be necessary applied because this sensor is a noninvasive device.

Polypropylene and EPDM have a waterproof surfaces that resist aggressions, they are easy to clean. But in this case, they are in direct contact with a porous material. Using water and distilled water would be enough to clean the materials. In addition, the alumina part will be cleaned by spray water and alcohol can be used on PVC.

5 Skin-electrode contact Impedance

5.1 Introduction

The skin-electrode contact impedance (Z contact) is an important noise-determining signal parameter, as it has been explained in the EEG measurement section. To prove that any design electrode is a promising propose, register this impedance with the main materials and electrode designs (materials and shape) is required to prove its effectiveness. There exist three different processes to measure the skin-contact impedance of an EEG electrode. The first method is a two-electrode construction, Fig 23a. Current is injected to el. 1 trough el. 2, the voltage between the two sensors is measured, and the Z contact impedance of el. 1 is registered. Then, in Fig. 23b, we find the second possible construction which uses four electrodes. The voltage is measured between the two electrodes placed in the center, el. 2 and el. 3, and the impedance measured is from el. 1. Finally, in Fig. 23c, three electrodes are used to register Z contact. The current is injected to el. 1 and goes to el. 3. The voltage variation is measured between the el. 1 and another electrode, el. 2, which is placed very close to the first one, and the Z contact measured is from el. 1.This el. 2 can be a wet electrode, or another type of electrode, and works as a reference electrode.

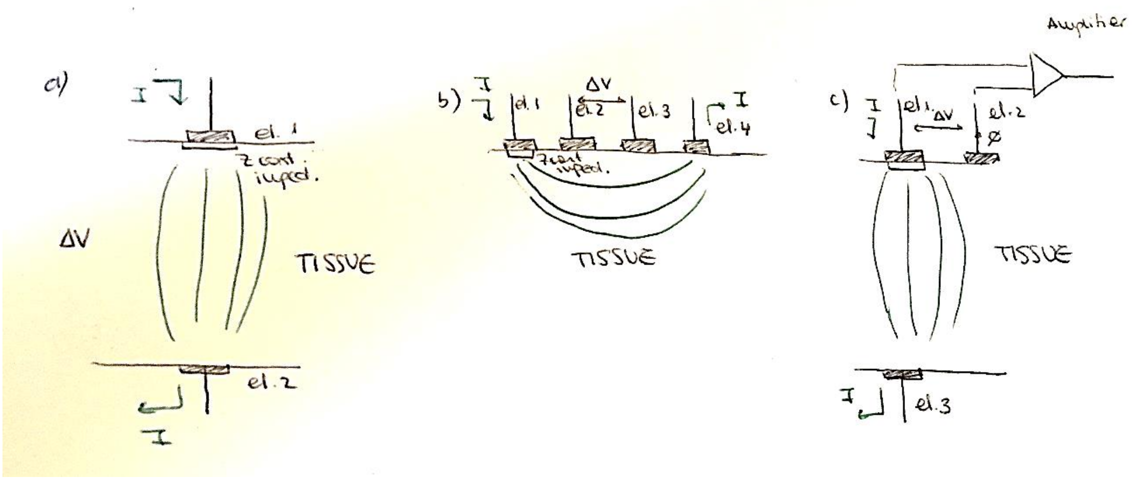


Fig. 23. Electrode skin-impedance measurement with: two electrodes (a), four electrodes (b) and three electrodes (c) - Author's own.

The protocol used to register skin-electrode contact impedance in different electrode types, can depend on different factors:

1. Skin measurement site: It is not the same to register the Z contact in a subject's wrist, hand or forearm. So, to solve this situation, a group of electrodes will be placed near together in a "large" surface to have the same skin conditions, example: thigh or back. Additionally, the experiments can be repeated changing the electrodes position to have more accurate results.

2. Time and psychophysiological answer: Gel increases the actual contact area between skin and electrodes, which results in a reduced contact impedance and stable results. After placing a sensor, the subject or patient can start sweating due to a stressful response to a situation. This amount of sweat can produce variations in the recorded numbers. It is proposed to do series of simultaneous measurements to reduce the likelihood of ambiguous results.

3. Temperature: If the subject's temperature increase, the Z contact is reduced. Series of simultaneous measurements can show more similar results.

4. Pressure: If a certain pressure is applied to an electrode or material sample the contact area will increase, and in consequence the impedance measured will decrease. The protocol used to measure Z contact, has to assure the same pressure conditions for each type of electrode to allow comparison with the other sensors.

5. Measurement artifact: There exist different artifacts (movable, non-movable) that measure Z contact that can work at different frequency range. Depending on the study and application, it has to be chosen one or another depending on its work properties and the study characteristics.

6. Subject: The subject sex, age or skin color influence in impedance measurements. Subjects with dark skin will have the highest Z contact registers in comparison with subjects with pale skin, even though they have the same age and sex.

7. Area of the electrodes used: All the electrodes that will be compared, have to have the same contact surface in order to compare the results obtained.

8. Previous preparations: Skin preparation includes skin abrasion and cleansing to remove dead cells from the epidermis top layer, causing a decrease in the skin-electrode contact impedance. If it is necessary a previous preparation, must be included in the protocol.

The protocol used in every study or investigation is a basic pillar to know if the results published are veridical.

5.2 Laboratory measurements

5.2.1 Protocol

The protocol used in this project to register electrode-contact impedance of four different **dry** electrodes, is explained below:

- The three-electrode construction, el.1, el.2 and el.3, in Fig. 23c., is chosen for its fast application and the ability to compare different sensor types.

- First of all, ensure that the contact area of the electrodes that are compared located in el.1 position are exactly the same. Cut the materials **in the exact same shapes** (we will not compare square electrodes with circle electrodes). In addition, a piece of the materials have to be exposed to be able to put a crocodile clip in contact with them. This clip will be connected to two different wires: one to inject the current to the circuit and the other one to measure the voltage variation. This is a multi-frequency record.

- Chose a large skin area to make the measurement with the same surface shape: thigh or back, depending on the subject.

- Place electrode el.2 and el.3 on both sides of the area tissue. These sensors used, can be gelled electrode because their material are not relevant for the measurement. We will just focus on the materials of el.1.

- Then, the first electrode (sample 1) will be placed and tied with one elastic bandage that **cannot cover the exposed** part of the material. Scotch can be used to ensure that it does not move. The sample has to be as close as possible to el.2, Fig. 24. The crocodile clip will be placed to the exposed part, and the multi-frequency measurements will start. The record will lasts 2-3 minutes.

- When the process is finished the crocodile clip is “disconnected” from sample 1. The sample 1 remains at its location.

- Then, the sample 2 is located, as shown in Fig. 24, and tied with an elastic bandage **without going over the sample 1.** Its exposed part will have contact with the clip. Then, the measurement will start: 2-3 minutes more. This process will follow these steps until sample 4 is located and tied.

- After the first measurements round, the samples are all placed correctly. Then, the process starts over again with the sample 1 and the crocodile clip (2-3mn measurement). Then, sample 2 with the clip, 2-3mn, sample 3, 2-3mn more, and finally sample 4 with 2-3mn measurement. We will **only change the clip location** following the order. Six records will be registered at least for each sample.

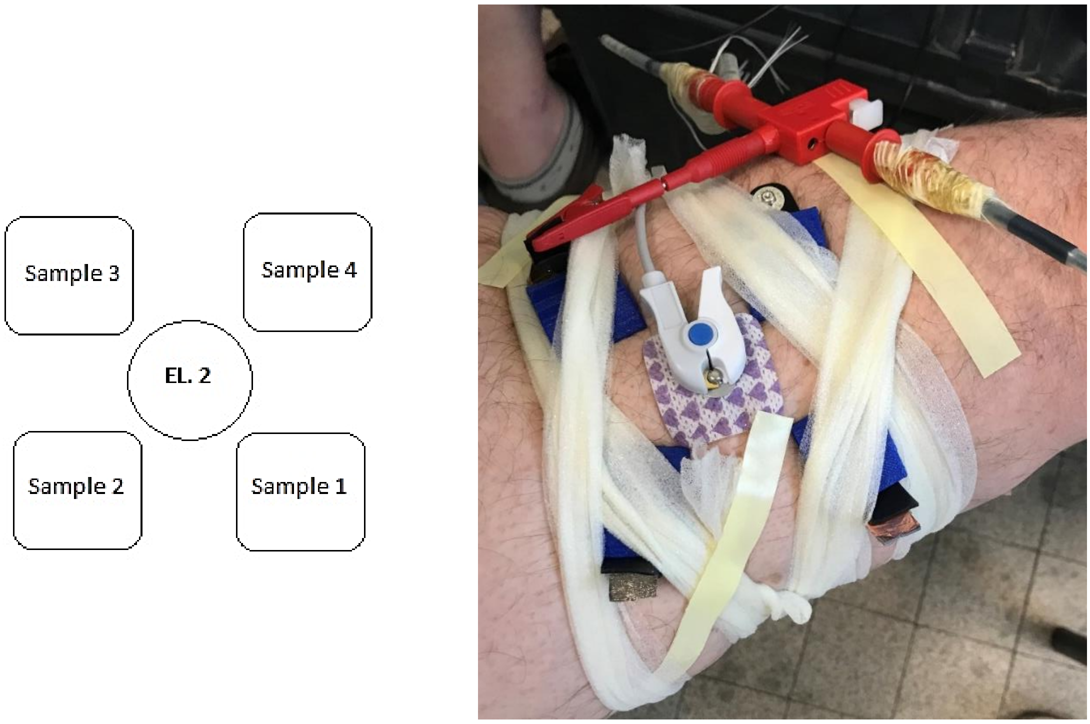


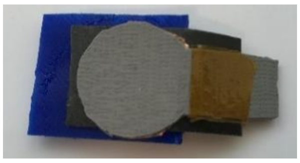
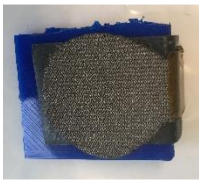
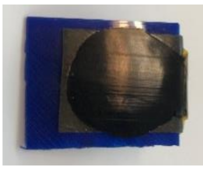
Fig. 24. Samples placement order - Author's own.

This protocol is a fast way to measure the Z contact of a material without having to invest a lot of money and resources.

5.2.2 Materials and process

In the protocol test, the frequency range oscillated between 1M Hz and 10 Hz. The software used was *Smart* and we used four dry electrode materials. These materials were glued to a polymeric resistant base with a piece of double-sided scotch, Tab. 5, to provide the same surface conditions. Each sample had 2.00 cm ϕ.

The impedance interference, the frequency response analyzer and the impedance test module used were from *solartron*. No any skin preparations, such as cleaning by some skin prep gels or alcohols, were made on the skin subject.

Sample	Material	Electrode
1	Stainless steel electrode.	
2	Polymer with unidirectional conductive threats in the middle.	
3	Shieldex Med-tex P180 (Ag) (is only elastic in one direction) – Appendix B.	
4	Conductive silicone.	

Tab. 5. *Samples used and their materials - Author's own.*

In appendix C there are some pictures taken during the measurement and some devices that we used.

5.3 Signal Modeling

All the data acquired in the six different moments for each sample was registered in Zscan and opened with excel, Appendix D. Impedance comparison graphs were made to analyze their trend for each electrode type. In addition, the module and phase (Theta) were calculated for sample 1, 3 and 4. Sample 2 module and phase were excluded by the unusual values of their results. The results obtained for each sample are shown in graphic representations, Appendix E. To obtain these representations, the mathematical formulas used were (3):

(3)

$$M = R + jX$$

$$|M| = \sqrt{R^2 + X^2}$$

$$\varphi(^{\circ}) = \frac{Arctan(\frac{X}{R})}{\pi}$$

Where R is the Real impedance and jX the imaginary impedance.

In addition, to model the signals and to obtain some numerical answers, all the data acquired was copied and pasted in Zview. The fitting model circuit, Fig. 25, for the dry materials was used to measure Rs, Rp, and Pseudo-C values (Capacity and alpha) in each case and each sample. The Pseudo-C is a Constant Phase Element #2, and it was used according to the Dr. Bernard Boukamp equation format. The program used allowed you to use sliders to fit only a part of the data to obtain a better graphic representation.

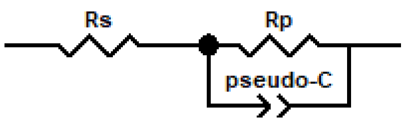


***Fig. 25**. Fitting circuit model in ZView.*

The final results obtained will be presented and discussed in the results section.

6 Headset

6.1 Introduction

Over the years, EEG hardware technology has been evolving to more convenient, wireless and comfortable designs, leaving behind the traditional and complicated affair of patches and cables. Additionally, some currently headsets and headbands are combining the brainwaves acquisition with heart rate measures, breathing, Electrooculography (EOG), head movements, impedance measurements at a single frequency, and skin temperature for emotion detection and eye tracking [64].

The actual wireless systems in charge to acquire EEG signals, aesthetically are very diverse. However, all have to be ergonomic to not cause damage or discomfort to a patient or subject. The basic principle of their performance is similar for all the headset/headbands models and it is based on: a group of electrodes, one central control unit and a data port. The central control unit amplifies the signal that is received by the electrodes, and generally is formed by a microcontroller, an amplifier, a communication circuit (Bluetooth, Wi-Fi, etc.) and a battery. The data port system could be a PC, smartphone, monitor, etc.

The devices that are constantly sending the recorded information should have long-lasting batteries. In addition, all the registered signals in a long period of time can be processed with mathematical modulus to obtain activity summaries.

In some occasions, depending on the application, the signals recorded have to be specifically post-processed and modeled to obtain the particular and relevant information. These processes are usually used in research studies and investigations.

6.1.1 Signal processing

When the first EEGs were measured, it was only possible to write the raw signal on a paper thanks to a galvanometer chart recorder. The digitalization of these brainwaves enabled many other ways of visualizing the signals. This process, opened the doors to the signal processing, which appeared to be a very useful tool for knowing more information about the EEGs.

As mentioned in the first sections, the analog signals are converted to discrete signals (A/D converters), which can be saved in data files for further processing. The frequency at which samples are recorded is defined by the sampling frequency, and its value is not fixed because it depends on the study. Some principle processing concepts will be explained down below.

- Nyquist–Shannon sampling theorem

This theorem defines a condition for which it is possible to determine a limit sampling frequency. The discrete signal, result of the A/D conversion, can save all the information of the continuous signal with a specific bandwidth. The mathematic relation is showed in the next formula [65].

(4) $$fNyquist = \frac{fs}{2}$$

Where fs is the update frequency of the Digital to Analog conversion.

- Fourier transform

The Fourier transform is an operation which decomposes a time domain signal in its frequency content. It is a powerful tool to analyze the amount of a specific frequency in a signal. The resulting signal from the transformation expressing in the frequency domain is named spectrum. In the EEG domain, the sampling frequency must be greater than 200 Hz and must be chosen according to the study.

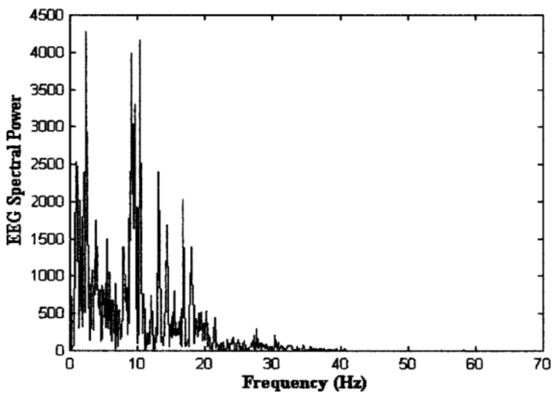


Fig. 26. *Example of an EEG spectrum obtained via Fourier Transform. The sampling frequency used is 128 Hz* [66].

- Frequency filters

Depending on its range

By defining the cutoff frequencies, it is possible to determine which specific range of frequencies is desired to be removed or maintained in the EEG system application: Lowpass filter, Highpass filter, Bandpass filter or Bandstop filter, which aims to remove a punctual frequency.

It is important to highlight that the cutoff frequency does not define a perfect exact limit from which the change is applied, there is a transition range.

Depending on its response

The impulse response of a filter enables us to classify them into two groups. Finite Impulse Response filter (FIR): As its name indicates, the impulse response of a FIR filter has a finite duration in time. It can be said that it has a finite settling time. The other filter is the Infinite Impulse Response filter (IIR): Oppositely, its impulse response has infinite duration.

All the filters have their advantages and drawbacks, being a good or a bad choice in different cases.

Finally, some softwares are commonly used to analyze these signals: MATLAB, which has some toolboxes that are used for different applications like EEGLAB [67], TMSEEG [68] and others, R Language [69], Python [70], LabVIEW [71] or other neurofeedback packages.

6.2 Review

First of all, as it has been mentioned before, the external structure of a wireless headset depends on the purpose of its use. The number of channels, if it is a stationary or portable device, the predefined metrics offered, the type of electrodes chosen etc. are selected in relation to its commitment. This section will make an actual review of some caps designs and their applications:

- EMOTIV EPOC + a 14 channel EEG, is designed for human brain research applications, Fig. 27a. The electrodes used are wet sensors, so it is necessary a previous process to humidify them. It is a wireless device (Bluetooth or USB option) with an autonomy of 6 hours using Bluetooth. It has an internal Lithium Polymer battery of 640mAh. However, thanks to its electrode placement, is not a good option if the study wants to record and pay specifically attention to the frontal region of the brain and it does not adapt very well to all types of heads. It has a totally weight of 1.19 Kg. Moreover, EMOTIV also has a 5 channel EEG device designed for BCI applications that uses polymer semi-dry electrodes. This other device can detect facial expressions, performance metrics and mental commands, Fig. 27b. These two devices have the central control unit within the structure. This brand also provides a flexible cap, EPOC Flex, made of fabric with 8, 16 or 32 available channels to record EEG signals while the subject can be in movement. It is available in different head sizes and weighs between 80-160 gr, Fig. 27c [72].

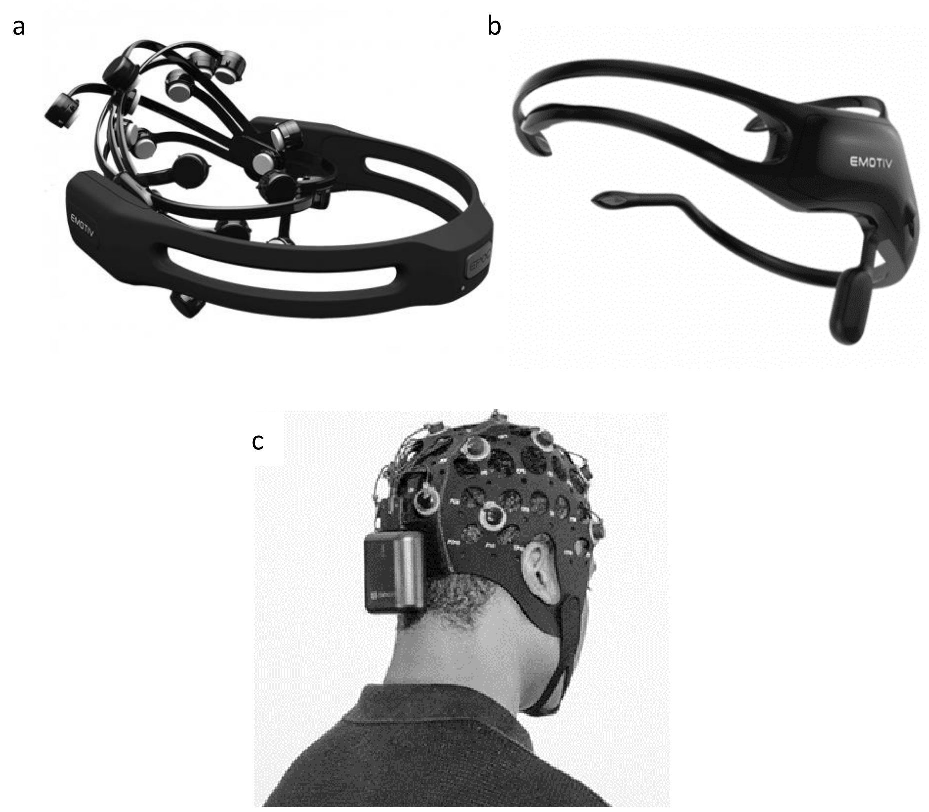


Fig. 27. EMOTIV EEG devices: Epoc + (a), Insight (b) and Epoc Flex (c) [72].

- Otherwise, OpenBCI has created a 3D-printeable EEG headset. This device is not fabricated to send any kind of signals, it is only capable of receiving them and sampling up to 16 channels of EEG from up to 35 different 10-20 locations. Otherwise, they sell too a 21-channel flexible cap with coated or sintered Ag/Cl electrodes similar to the EMOTIV ones [73].

- Wearable sensing has proposed diverse EEG headsets and caps for dry and wet electrodes. The DSI 24 can be highlighted in research applications and continuous impedance monitoring. This headset is designed for 21 dry sensors located according to the 10-20 system. It is a bluetooth wireless device with an autonomy of 8 hours, thanks to a Li-ion battery, and with frequency sampling at 300 Hz [74], Fig. 28a. As shown in the figure, the central control unit is found on the top. Otherwise, this company also sells another headset called DSI-Hybrid-EEG+fNIR. This wireless headset is used for neuroscience research applications. It can register EEG signals, hemodynamic subject's response or bloody-oxygen-levels. Each sensor has 4 pairs of fNIR and a pin-shaped electrode, Fig. 28b [75].

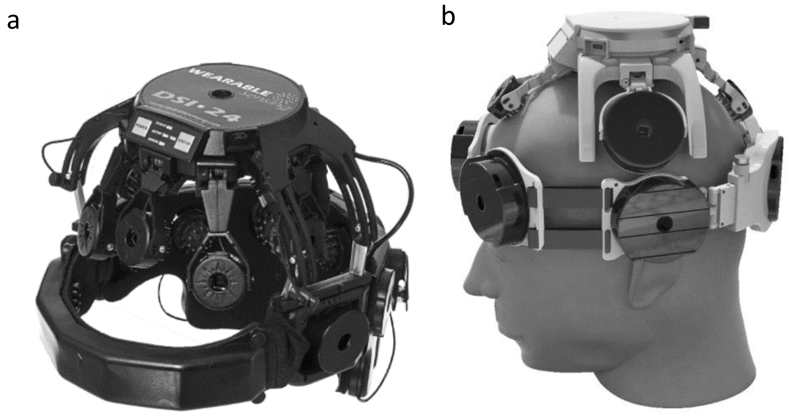


Fig. 28. Wearable sensing DSI 24 (a) and DSI-Hybrid-EEG+fNIR (b) [74].

- Neuroelectrics, mentioned before for its electrode designs, has developed different headsets and caps for EEG. This brand sells a hardware system that does not cover the chin subject, but surrounds the subject's ears. It is another option to hold the reference electrodes in a simpler way. The Starstim R20 system allows multiple electrode montages that can be arranged to specific brain networks with multi-focal targets, and it is used in research studies. For EEG measurements it can have up to 20 channels and the data transmission is via Wi-Fi. It has a SD card for off-line measurements and the central control unit it is found in the nape part. All the detailted device information (SNR, resolution, bandwith etc.) can be found in their website [76]. They also dispose more EEG caps aesthetically similar to Epoc Flex.

- Advanced Brain monitoring presents the B-Alert X24 system, a 20-channel device for non-clinical applications. It can work 6 hours in Bluetooth mode and is formed by transparent elastic strips, not causing discomfort as other big hardware structures. However, its placement lasts 20 minutes, Fig. 29 [77], there are available different headset sizes depending on the subject's head.

Fig. 29. B-Alert X24 [77].

- Otherwise, Cognionics has presented a wireless EEG headset system with real-time measures available with 8, 20 or 30 channels. This device supports the 10-20 array, and use active electrodes. The recorded activity is send via Bluetooth (or microSD card) and the central control unit is placed on top. Additionally, the device is not as heavy as the EPOC +, it only weighs 450 grams, Fig. 30 [78].

Fig. 30. Cognionics wireless EEG headset, 8 channels [78].

- Other companies have launched to the market some EPOC Flex alike-caps to record EEG signals: ANT Neuro, G.tec, BioSemi, mBrainTrain, Brain products LiveAmp/ArtiChamp etc. The flexible fabric structure has been used a lot thanks to its comfort, good fit and easy implementation. However, these headsets use dry electrodes with small diameters in comparison with the semi-dry sensor design proposal in this project.

Patents:

- U.S. Pat. No. 61/602,292 is a flexible EEG headset. It is fabricated with strips, which have electrode ports. The electrodes position complies with the 10-20 standard for EEG electrode placement. It also has adhesives that secure the EEG headset. The electrodes used have a dual-layer foam reservoir, and an inner layer is in contact with the electrode, receiving gel from that part [79].

- W.O. Pat. No. 2012/036,639 is a tension-adjustable headset apparatus for securing an EEG headset assembly. The tension-control mechanism allowed the length of tension belts to be adjustable to acquire the optimal headset for each patient [80].

These patent figures can be found in Appendix F.

6.3 Proposal

In order to create the design of the headset/cap according with the established semi-dry electrode measures and the 10-20 system placement, it is necessary to know the device application and during how long it will work. As a passive electrode, in BCI applications, according to the meeting with Manu Maby, eight electrodes with similar characteristics as the design proposal in this project, would be enough to start the measurement. Then, depending on the application and the interest areas, the number could be reduced.

The eight electrodes would be united by adjustable elastic strips, which would be attached to the electrodes as a harness, Fig. 31. The union method between an electrode and a strip is based in a lane principle, Fig. 32. The material used to fabricate these pieces can be polypropylene, thanks to its rigid, good mechanical properties, density and weigh.

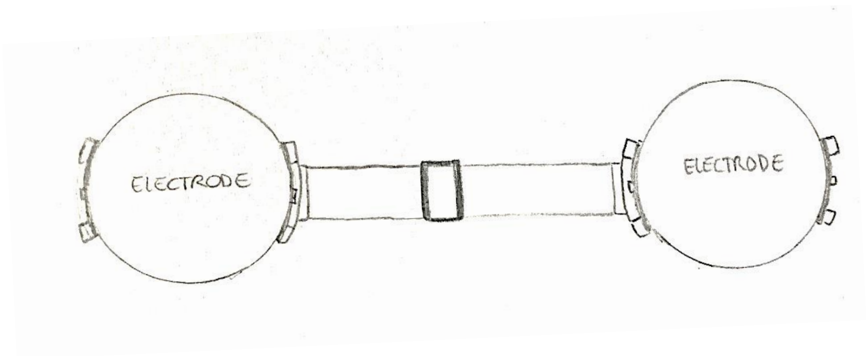


Fig. 31. Sketch of two electrodes and an elastic strip – Author's own.

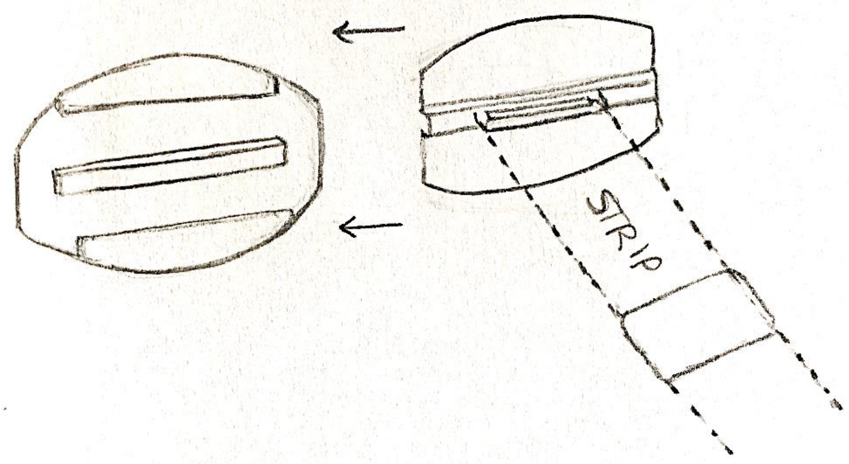


Fig. 32. Sketch of the union method between an electrode and a strip – Author's own.

All the wires of the electrodes used would be connected to a central control unit located in the back of the head as a headband, and the ground electrode located near the ears used would be dry Ag/AgCl electrode disks. The semi-dry electrodes designed in this project can be too big to locate them near the ear or in the subject's face. The technical characteristics of the central control unit (battery, wireless connection (Bluetooth, Wi-Fi), amplifiers type, etc.) would be chosen in function of the measurement application.

Additionally, all the PVC tubs connected to the electrode reservoirs would be united among them. A common PVC tub would be introduced into the control unit case and the KCl solution can be supplied externally for all the sensors at the same time.

7 Safety

During the design and development of a medical device, it is essential to conduct a risk assessment to ensure the safe of the device, reduce adverse events and avoid causing any harm to the patients or users. According to the European Medical Device Regulations (MDR) document, Annex IX. Classification rules. Chapter 3: Part 1. Rule 1.1., a passive semi-dry electrode is a Class I device because is a noninvasive device that is in direct contact only with external intact skin. Directive 93/42 EEC regulates these type of devices [81]. To ensure and guarantee the design safety, a risk analysis was undertaken, according to the general safety and performance requirements from the Annex I of the Medical Device Regulation (MDR). The International standard ISO 13485 has key points for design and production of the medical devices: Managing the work environment, managing risks associated with medical devices, control the traceability of the manufactured medical devices and verification of compliance with customer requirements.

The risk assessment was managed by ISO 13485 Clause 7. Product realization: planning for the product realization and the risk management (ISO 14971). The risk analysis can be found in Appendix G, while the possible risks found are in Tab. 6.

Electrode/headset design hazard	Chemical Hazard	Construction/patient hazard
• **Too much noise from external sources.** • **Too much electrode movement/deflection.** • **Electrode assembly causes discomfort.** • **Electrode/headset cost too high.**	• Use of KCl - conductive solution.	• The headset proposal is not ergonomic, not very good electrode-scalp contact.

Tab. 6. Possible risks and failures - Author's own.

To detect and prevent the potential hazards presented in Tab. 10, the following procedures should be employed:

1. The construction of the electrode has to be tested before. Material checks are required to ensure their mechanical properties and skin-electrode contact impedance through laboratory experiments. The economic costs will be evaluated according to the results obtained by the different materials.

2. Test the skin-electrode contact response after long-term measurements on leather and observe if the ceramic bristles are deformed after the record. Test the ergonomic

headset on subjects to adjust the design.

3. This EEG design has a chemical risk since there are necessary chemicals or conductive solutions to record the EEG signal. Provide to the subject all the data sheet information about de 3M KCl solution, Appendix H. After the skin-contact wash the skin with water. If the subject has irritation after exposure, wash all exposed skin area with mild soap and water, followed by warm water rinse.

4. The most important aspect of device safety is to maintain an electrical isolation barrier between users connected to an EEG device, and the device (typically a computer) to which the EEG device is connected. Before human trials, a test to nullify the existence of exposed wires will be undertaken. In addition, the headset design has a wireless communication, so it will be no physical connection to any external electrical devices.

8 Results and discussion

As described previously, we were interested in finding an innovative electrode prototype. To know and to understand if the chosen design is promising, a validation method for electrode proposals was created. This method was based in Skin-Contact electrode impedance measures. All the results obtained in the Impedance acquisition were compared with the Cole-Cole plot, Fig. 33. The stretch between x=0 and R_∞ is Rs, and the stretch between R_∞ and R_0 is Rp.

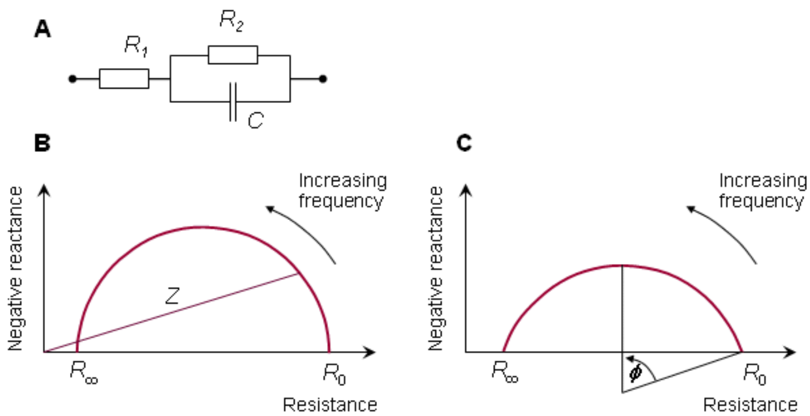


Fig. 33. Three element model of tissue impedance (A), Cole-Cole plot for impedance at a single time constant (B), and the depressed Cole-Cole plot (C) [82].

ZScan – Graphic results

The data obtained for the different dry electrode materials in ZScan, was first compared to observe the initial and final response of the samples over the time, Fig. 34 and Fig. 35. In these graphic representations, Z imaginary, values in inverse order, and Z real are shown. The second sample was excluded because its values did not allow to note the trend of the other electrodes values in a same graphic representation. The metallic points in the surface of the material were too far between them to register uniform values in the sample that we had created, maybe with a sample with a bigger diameter would have had more stable results.

The curves formed by all the points do not make a total semicircle because the software and measuring equipment used in this project do not have the ability to perform at those frequencies. If we have used another type of measuring equipment, we could have seen the entire Cole-Cole plot.

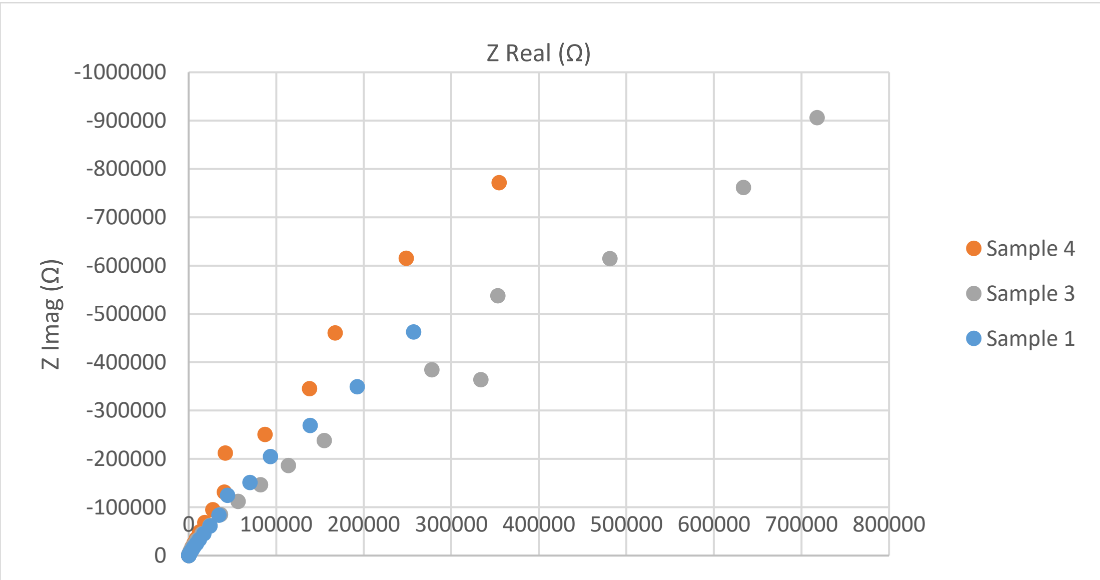


Fig. 34. Graphic representation of the impedance materials in the first measure.

As we know, with dry electrodes in an initial moment the skin is not treated with any gel or process and the impedance measures acquired can be higher because there is not sweat or electrolytic solution in direct contact with the materials. As we can see in Fig. 34, the Sample 4 was the material with the highest Z contact when the experiment started, and the sample 3 seemed to have the best impedance results.

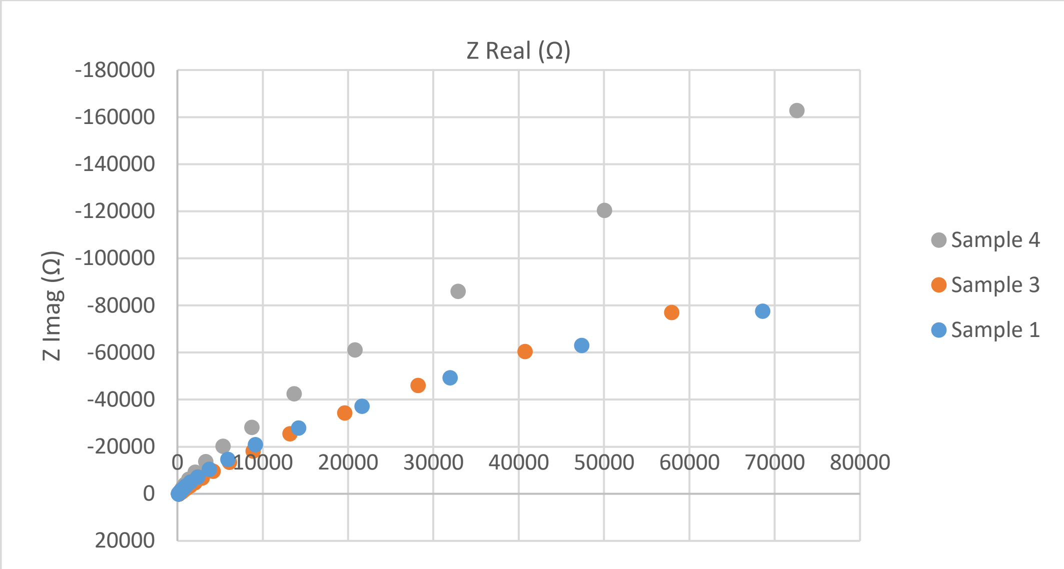


Fig. 35. Graphic representation of the impedance materials in the last measure.

However, after six measures, the materials were more inclined to be in contact with subject's sweat and the results obtained were more real. So in that final moment, the Sample 4 was still the electrode with the worst impedance results in comparison with Sample 3 and Sample 1. But, Sample 1 was the material that tended to have the smallest curve and the better impedance-time results.

ZView – Numerical results

The impedance, module and phase graphic representation of all the measurements obtained for the samples in ZView are in Appendix I. The Rs, Rp, Cp and Alpha were written down to compare and observe the variation of the results in a numerical form, Tab. 7, 8, 9 and 10. The product of Rp and Cp, a constant of time, is another way to observe the curves trend.

El. 1	Time (h)	Rs (Ω)	Rp (Ω)	Ps-C-Q (nF)	Ps-C-Apha	Rp*Cp
1.1	14:06	107,4	2,45E+06	2,29E-10	0,74861	5,62E-04
1.2	14:21	141,8	324680	5,16E-09	0,81963	1,67E-03
1.3	14:34	139,1	232690	6,97E-09	0,82573	1,62E-03
1.4	14:45	140,7	203220	8,11E-09	0,82854	1,65E-03

1.5	14:56	141,2	199770	8,49E-09	0,82876	1,70E-03
1.6	15:07	142,5	195150	8,87E-09	0,82925	1,73E-03

Tab. 7. *ZView results for Sample 1.*

EL 2	Rs (Ω)	Rp (Ω)	Ps-C-Q (nF)	Ps-C-Alpha
2.1	686,9	1,32E+07	2,47E-11	0,94378

Tab. 8. *ZView results for Sample 2.1.*

El.3	Time (h)	Rs (Ω)	Rp (Ω)	Ps-C-Q (nF)	Ps-C-Alpha	Rp*Cp
3.1	14:16	123,8	812340	1,78E-10	0,8374	1,45E-04
3.2	14:28	116,2	973570	1,64E-10	0,7048	1,60E-04
3.3	14:40	146,3	708180	6,08E-10	0,71546	4,31E-04
3.4	14:51	142	509760	1,20E-09	0,7275	6,10E-04
3.5	15:02	153,2	401560	1,91E-09	0,7389	7,68E-04
3.6	15:13	161,8	319020	3,12E-09	0,75596	9,95E-04

Tab. 9. *ZView results for Sample 3.*

El. 4	Time (h)	Rs (Ω)	Rp (Ω)	Ps-C-Q (nF)	Ps-C-Alpha	Rp*Cp
4.1	14:19	162,5	3,91E+06	4,86E-10	0,82676	1,90E-03
4.2	14:31	185,4	1,07E+06	5,96E-09	0,86136	6,39E-03
4.3	14:43	182,2	735650	9,25E-09	0,87096	6,80E-03
4.4	14:54	179,5	654450	1,07E-08	0,87357	6,98E-03
4.5	15:04	190,9	624260	1,23E-08	0,87981	7,71E-03
4.6	15:15	188,1	594970	1,27E-08	0,87761	7,55E-03

Tab. 10. *ZView results for sample 4.*

The visual representation between the numerical results obtained in the tables for each material with ZView, and the measurement time are shown in Appendix J. Four overlapping graphs were made to observe the time variation for Sample 1, Sample 3 and Sample 4 with the numerical results, Fig. 36, 37, 38 and 39. Sample 2 was excluded because the results obtained were unusable.

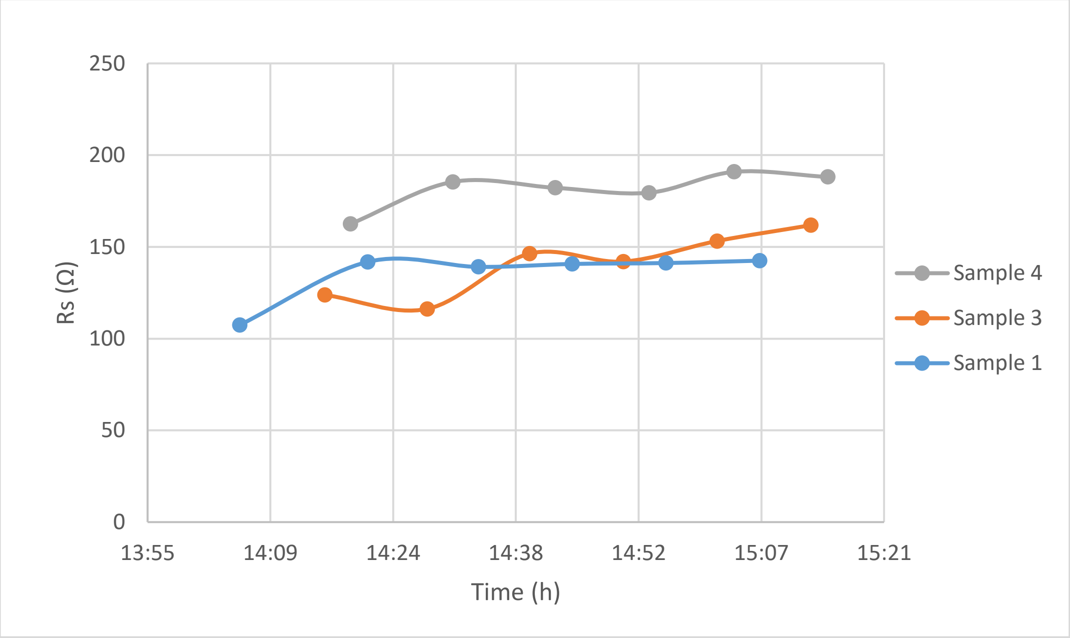


Fig. 36. Graphic representation between time and Rs for different electrode materials.

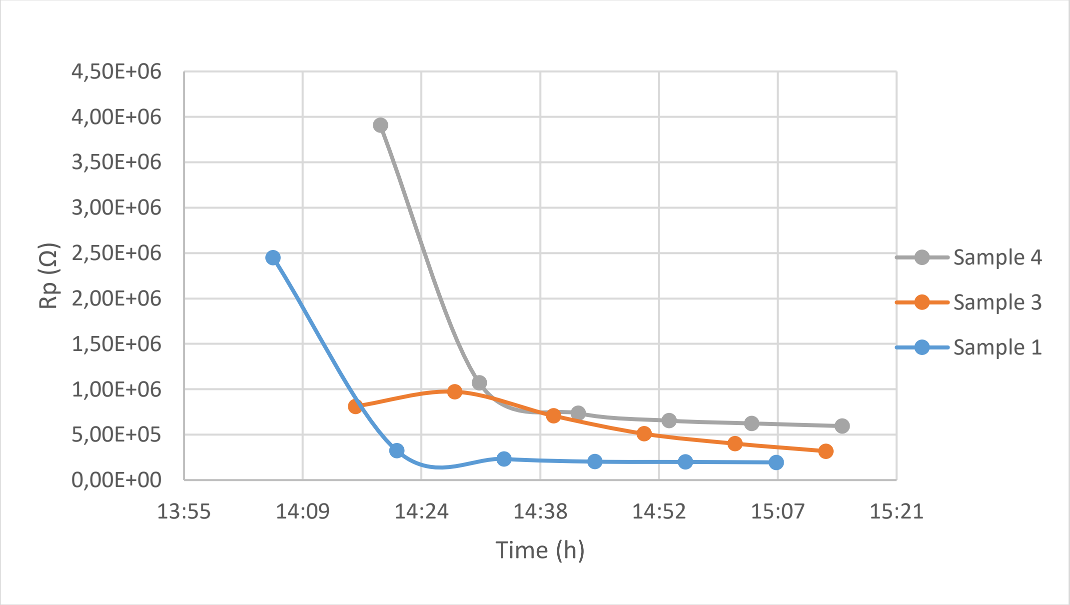


Fig. 37. Graphic representation between time and Rp for different electrode materials.

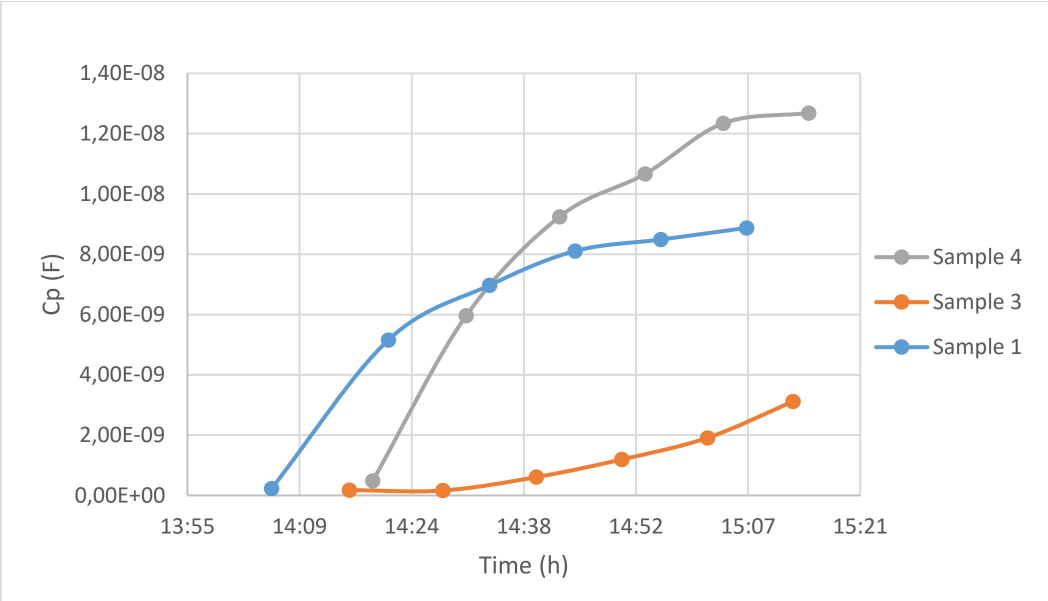


Fig. 38. Graphic representation between time and Cp for different electrode materials.

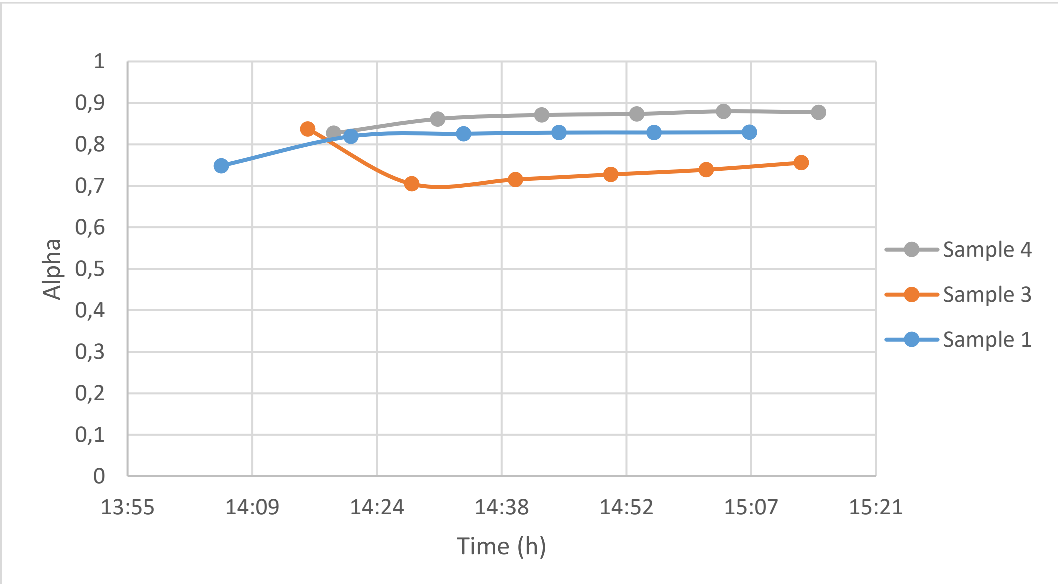


Fig. 39. Graphic representation between time and Alpha for different electrode materials.

First of all, as we can see in the last four graphs, the Sample 1 had the most stable and interesting results during time in comparison with Sample 3 or Sample 4. All the materials tended to stabilize at a certain point, but none of them had an almost straight line from the second measurement as Sample 1 in Rs and Rp. In the Rp graph, we can see that the values of all the materials decreased during time. The lowest impedance contact value (Rp) registered was 1.9 kΩ and belonged to Sample 1, so it had the best impedance results.

Secondly, the pseudo-capacitor values increased very rapidly for Sample 4 and 1, instead for Sample 3. The values in the graph were totally related with the alpha ones: if the material had a very high pseudo-capacitor value, its alpha value would be high too.

The alpha values are in a range between 0 and 1 and do not have units. If the result tends to 1, this means that there's more moisture in the region that is in contact with that material. As we can see, Sample 4 had the best alpha results, but as we have seen in the other representations, it was not the best material choice according to its resistance results. All the materials used, had different surface textures and they were influenced differently by the moisture. Some of them were more absorbents than others and could show different responses to a same situation.

After having studied the behavior of these materials it was possible to determine how much time was required and recommended to place the electrodes before its optimal impedance acquisition according to their graphic representation, Tab. 11.

Sample	Time (minutes)
Sample 1 – Stainless steel	15
Sample 3 - Shieldex Med-tex P180	24
Sample 4 - Conductive silicone	17

Tab. 11. *Time required to start any measurement according to the sample materials.*

In conclusion, the stainless steel electrode was the material with the better results in the study. The conductive silicone had also an interesting behavior because it stabilized so quickly, although its impedance results were high. Finally, the Shieldex Med-Tex P180 presented good impedance results but it was an unstable material in comparison with the others.

We only did six measures for each sample during twenty minutes, if we had done more measures the results obtained will be more accurate.

9 Conclusions

EEG is the measure of the brain's electrical activity. This non-invasive technique can help to associate some brain disorders and it fulfills an important role on brain investigations. This bachelor thesis presented an extended literature of some electrode designs found in different search engines, which has helped me to understand the electronical and physiological principles related with sensors and to understand them operation.

In addition, a semi-dry electrode design and a support method for the sensor prototype were proposed in this project. The sensor prototype did not need external axial pressure applied for its functioning. Nevertheless, all the technical aspects of the headset design will depend on the study application that would be carried out.

The main construction of the semi-dry electrode presented could not be built for lack of the required porous materials and time. However, a protocol has been created for skin-electrode impedance measurements and would be used when the sensor prototype will be fabricated. With the analysis of the results obtained with this protocol, we may have reached a way to determine the level of utility of an electrode and the time needed to place it before it can start working.

This Z contact multi-frequency measurement technique may help in the future to achieve better reliability results for different electrode designs. As a continuation of the project I would recommend to test this protocol in another environments and with different type of electrodes, since I cannot affirm that our conclusions of this thesis would be able to be applied in all the possible impedance tests.

As an engineer, I have learned how to make an extensive study and to have criteria to choose the most interesting and relevant information used in the project. I have managed to work individually and know how to arrive at optimal solutions for every situation taking into account the contributions provided by the people asked for help.

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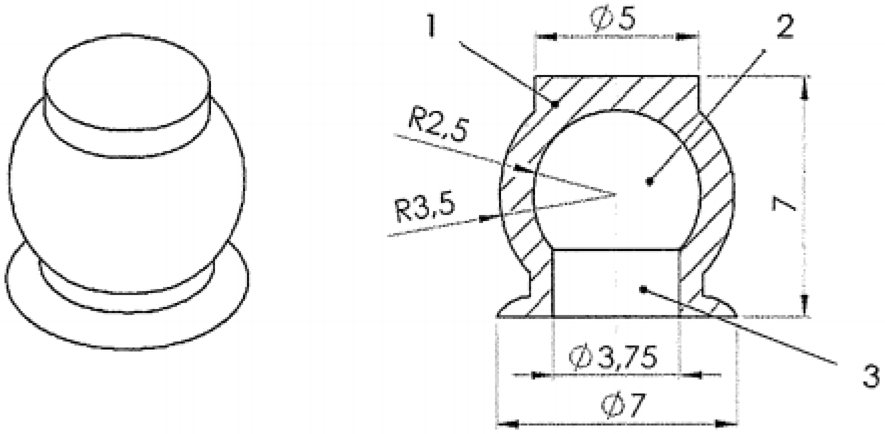
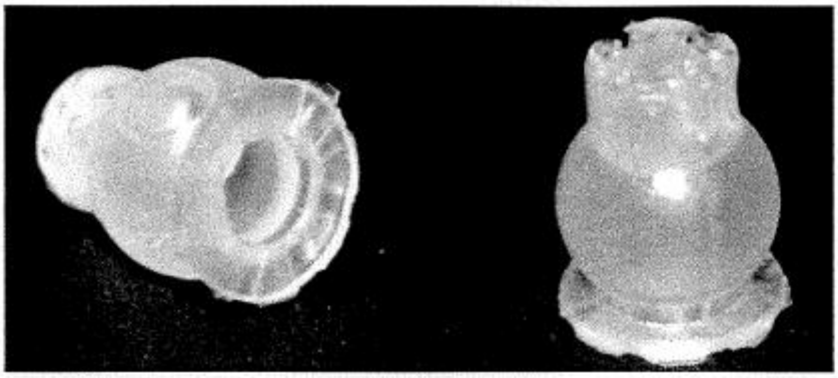
11 Annexes

11.1 Appendix A: Patent figures

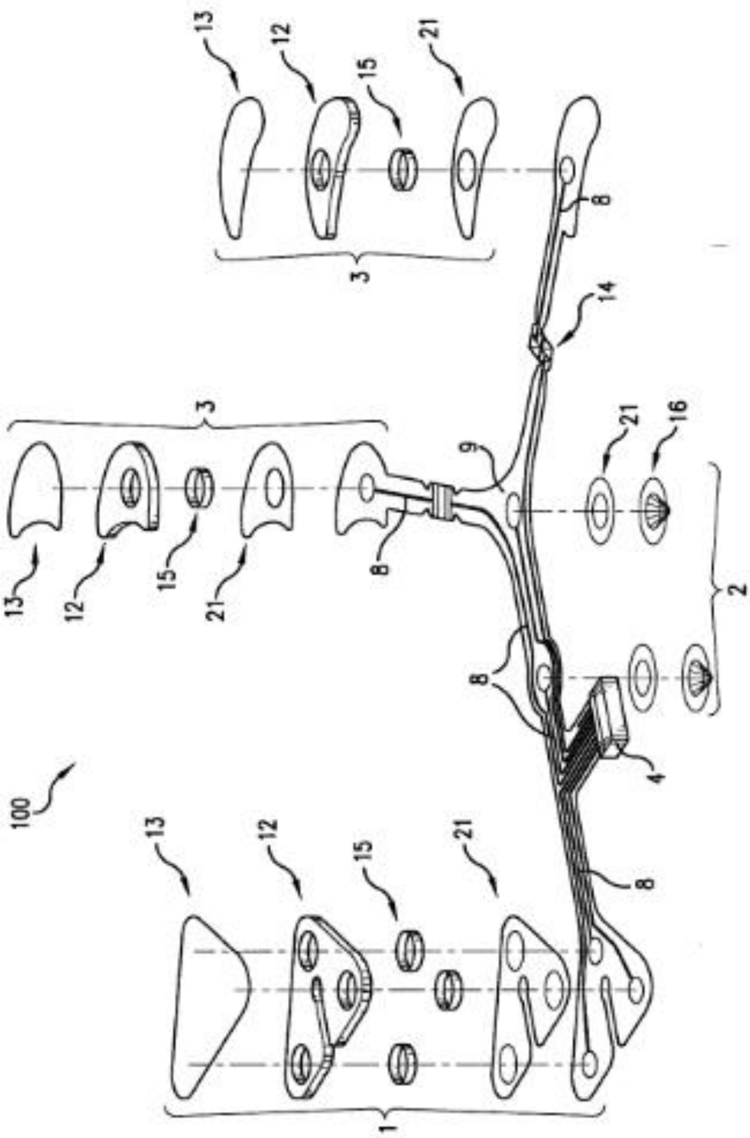
A.1. WO. Pat. No. 2,012,140,629



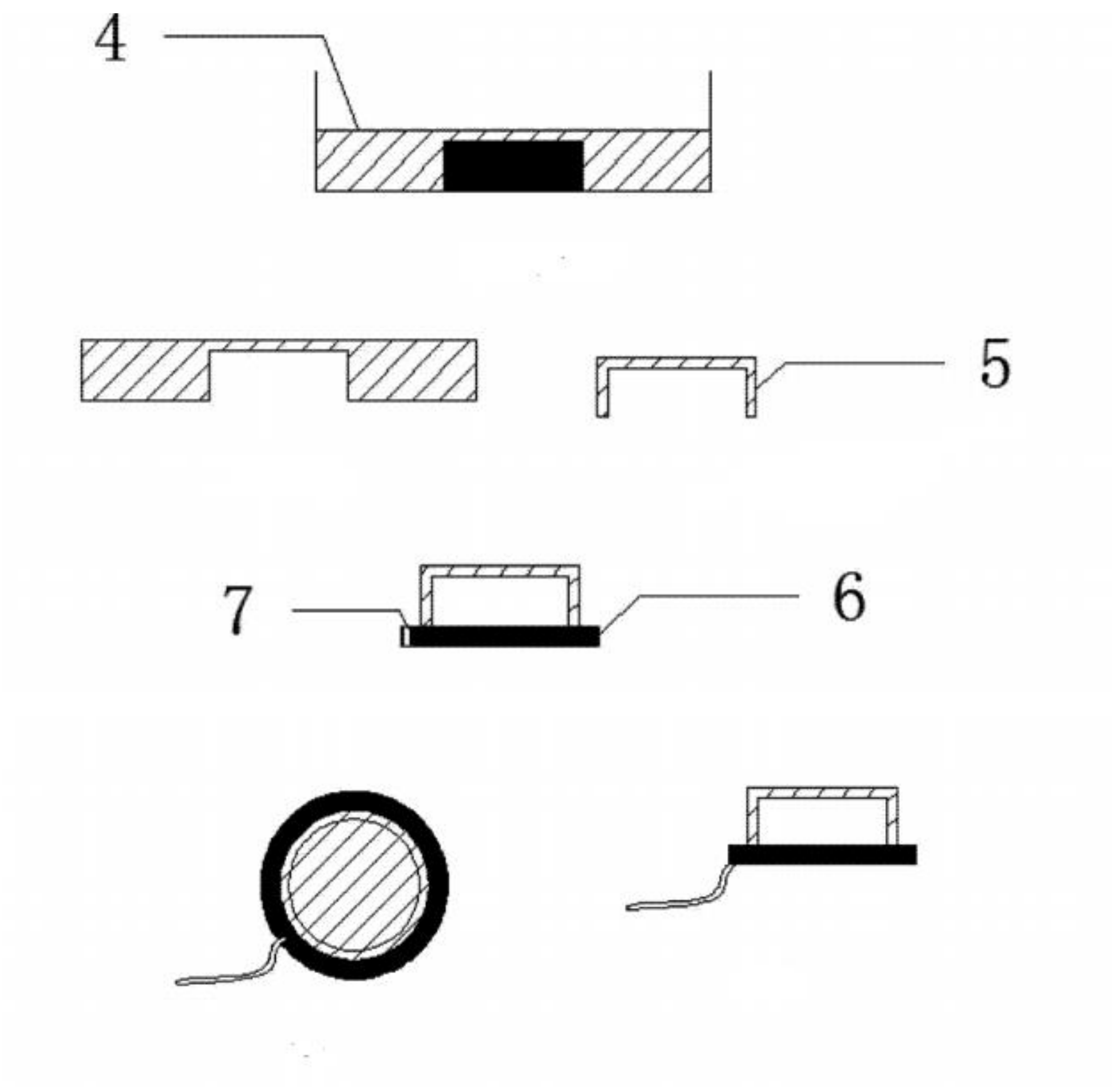


A.2. U.S. Pat. No. 6,301,493

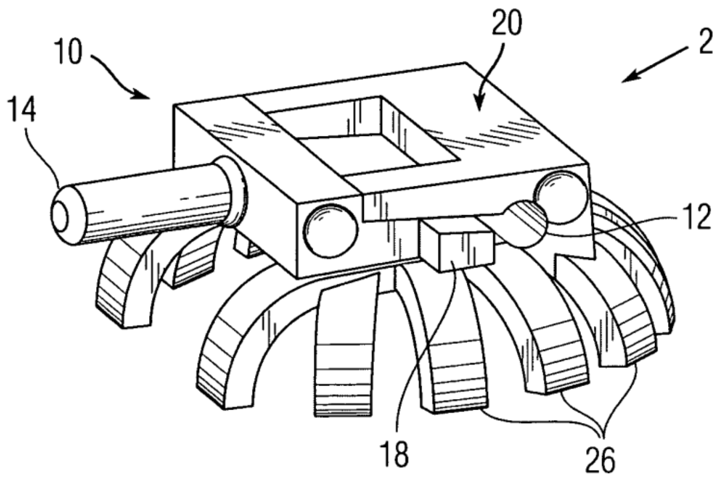
U.S. Patent Oct. 9, 2001 US 6,301,493 B1



A.3. CN. Pat. No. 103,767,704



A.4. U.S. Patent Publication Number 2008/0154112



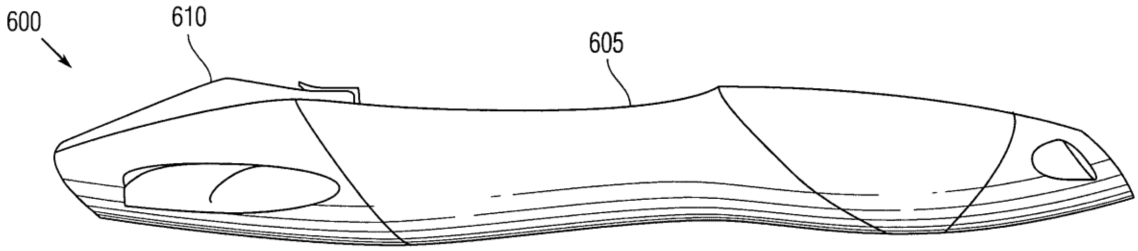


Fig. 16

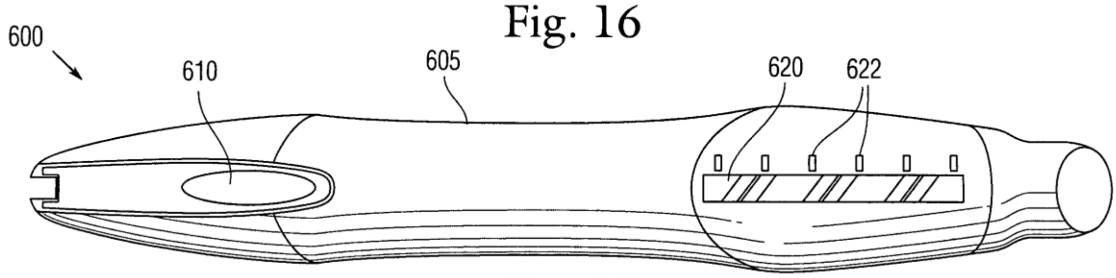


Fig. 17

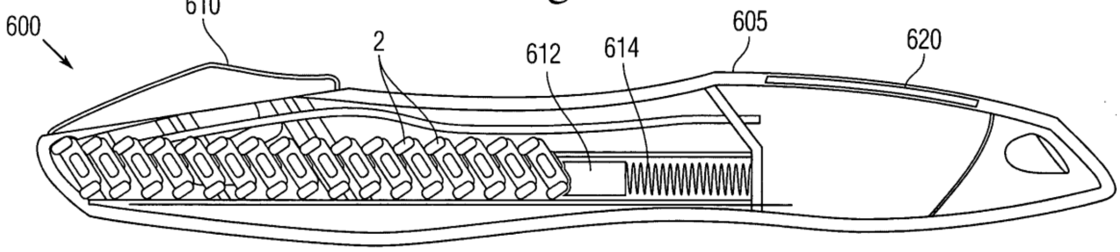


Fig. 18

A.5. U.S. Pat. No. 6,574,513

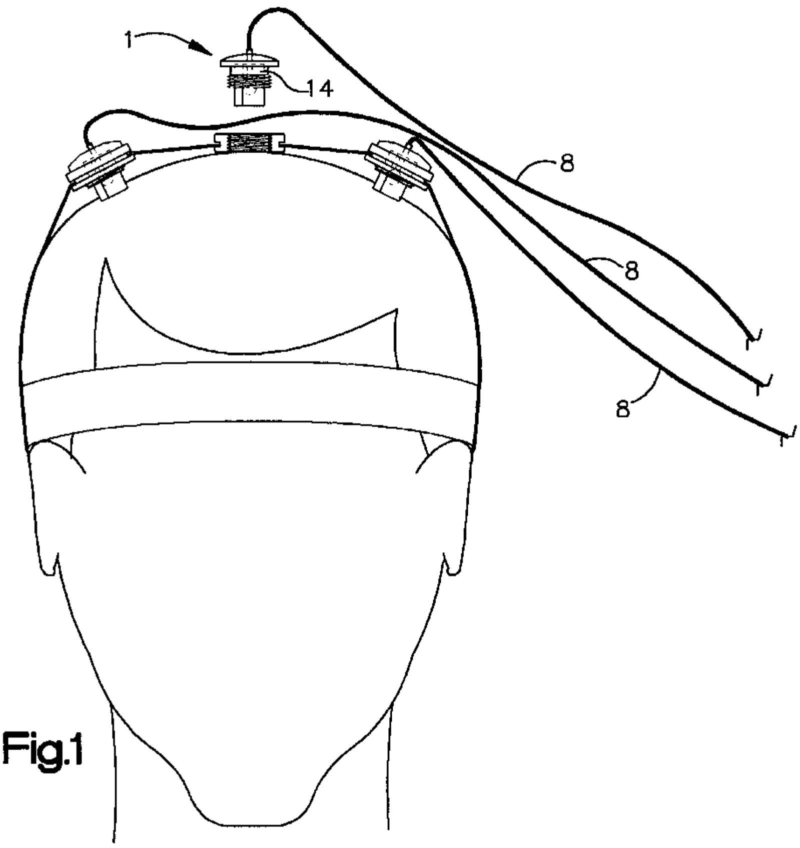


Fig.1

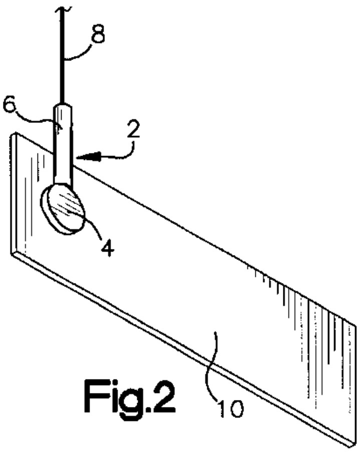


Fig.2

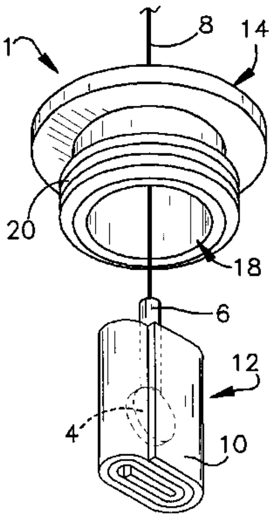


Fig.3A

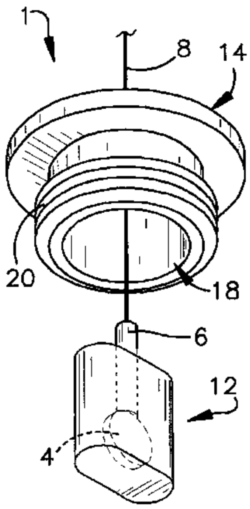
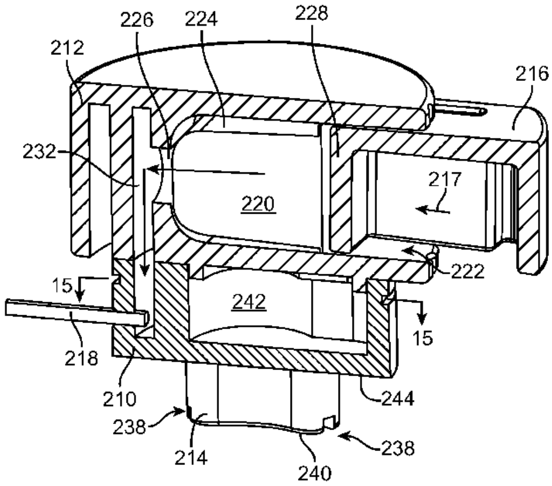


Fig.3B

A.6. U.S. Pat. No. 9,820,670



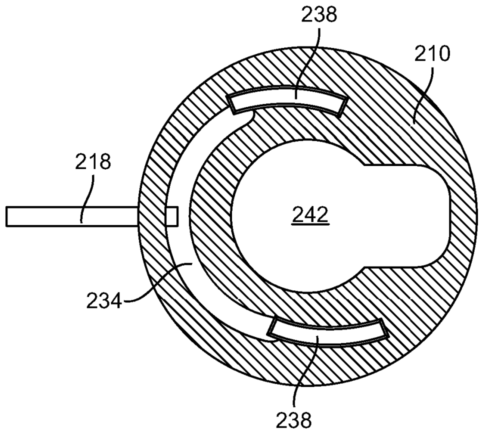
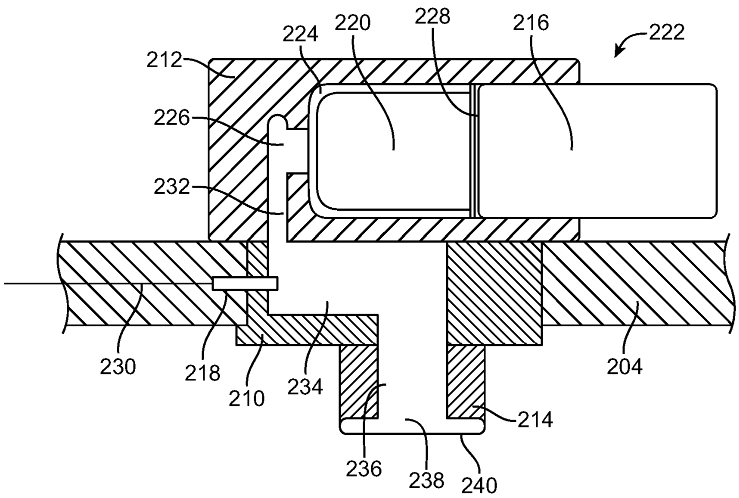


FIG. 15



A.7. U.S. Pat. No. 6,381,481

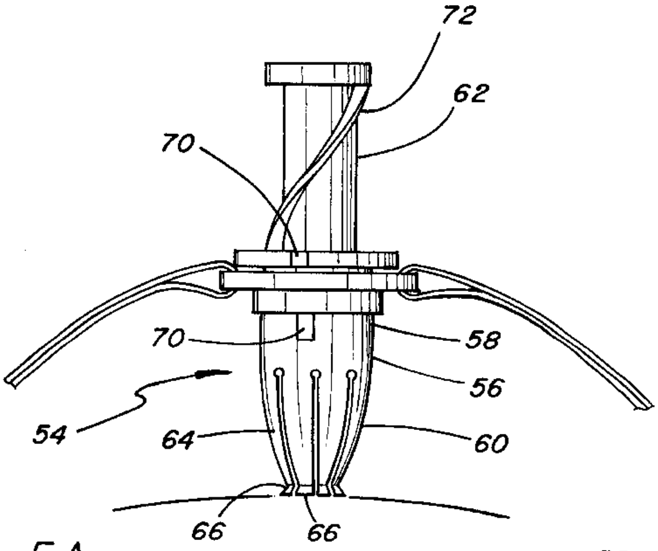


FIG. 5A

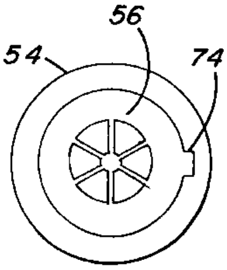


FIG. 5B

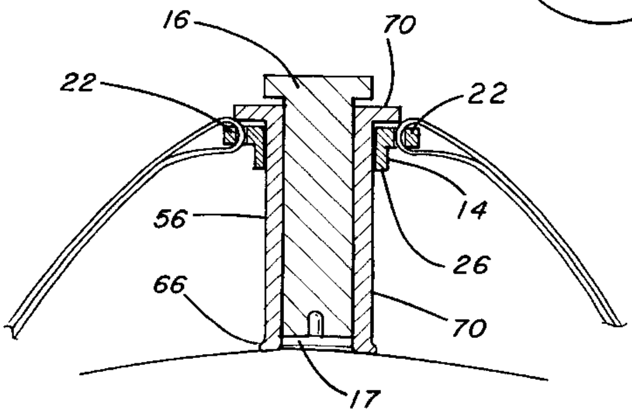


FIG. 6

A.8. CN. Pat. No. 108,652,620

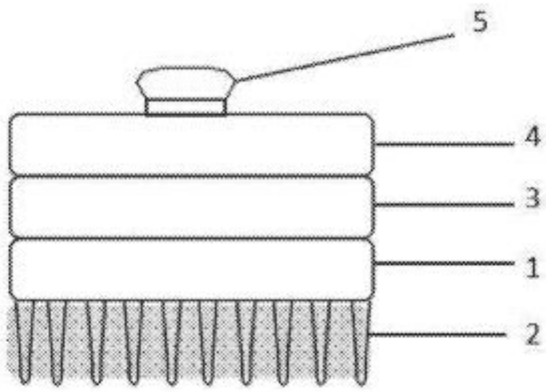
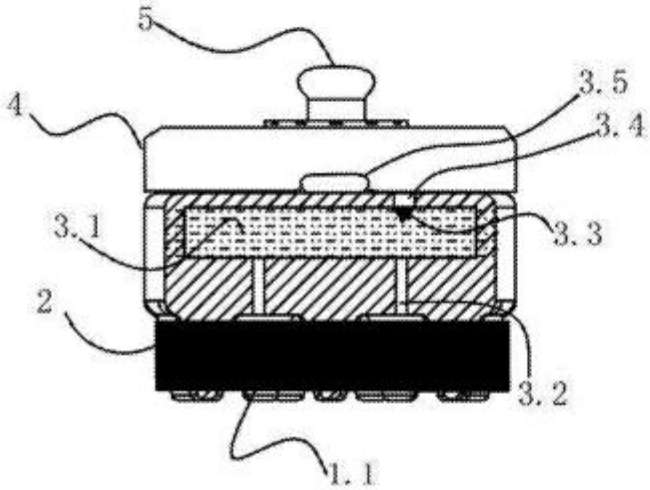
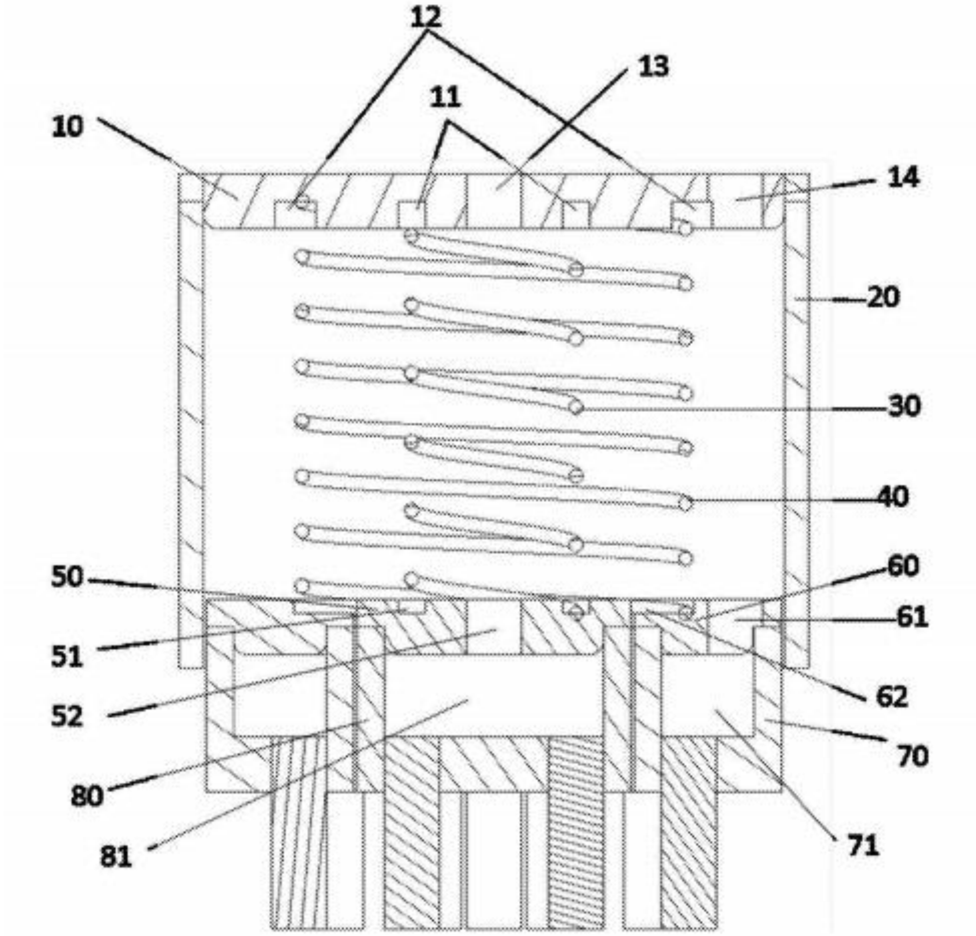


图1



A.9. CN. Pat. No. 106,963,376



A.10. CN. Pat. No. 207,693,566

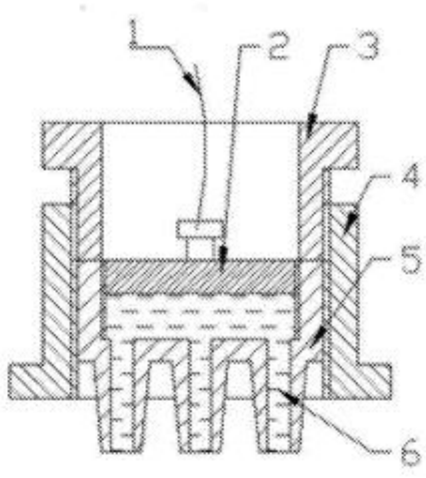
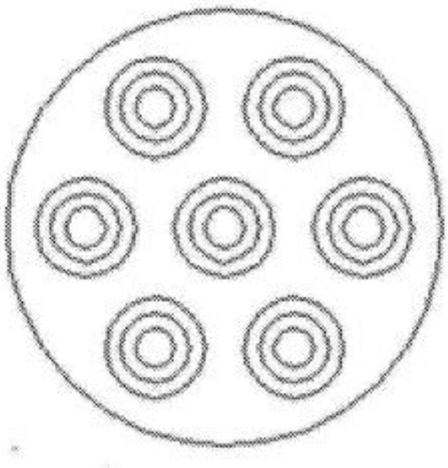


图1



11.2 Appendix B: Sample 3 Materials

visit: www.statex.de — contact: info@statex.de

Technical Data Sheet

Ag Ni Sn Cu

Shieldex® produced by statex

Shieldex® Med-tex P180

No.: 1101301180

Purpose	Antibacterial fabric for general use Base material for fungicidal products Base material for mattress/pillow covers for allergen protection Medical clothes, Compression wrap, Base material for wound dressing
Description	Silver plated knitted fabric
Raw material	94% Polyamide + 6% Dorlastan
Plating	99% pure Silver
Stretch	095 / 020% OS (one stretch direction-warp)
Temperature Range	-30˚C to 90°C / -22°F to 194°F
Total Thickness	0.55mm ± 10%
Weight	210g/m² ± 10%
Roll Width	135cm ± 5cm
Roll Length	Average 30m

Compliance and Certification

RoHS
REACH
Öko-Tex®

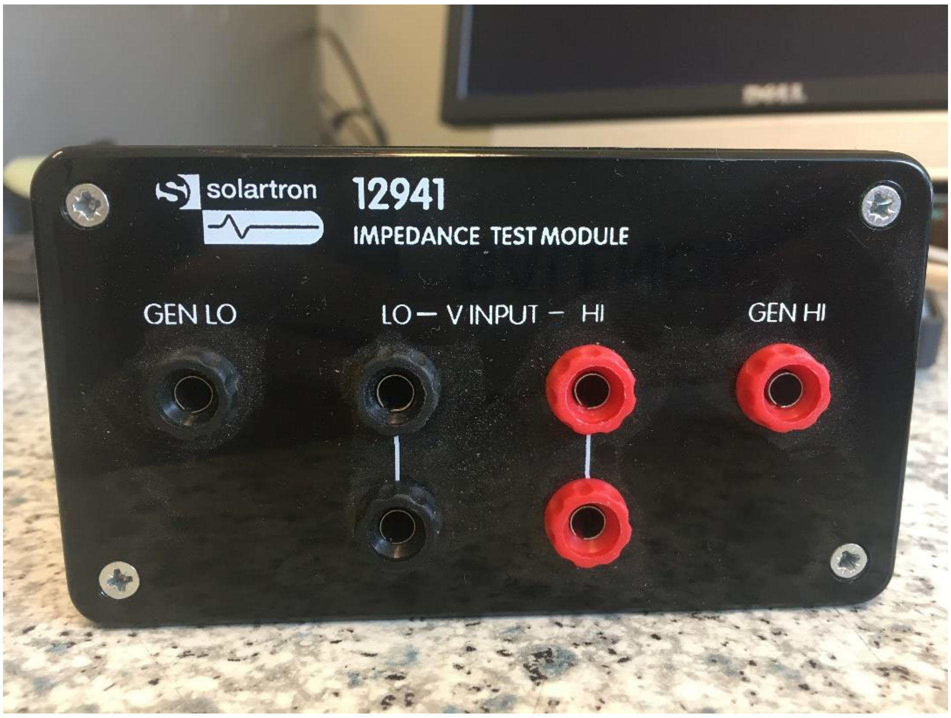
Alterations Reserved
02.07.13/06

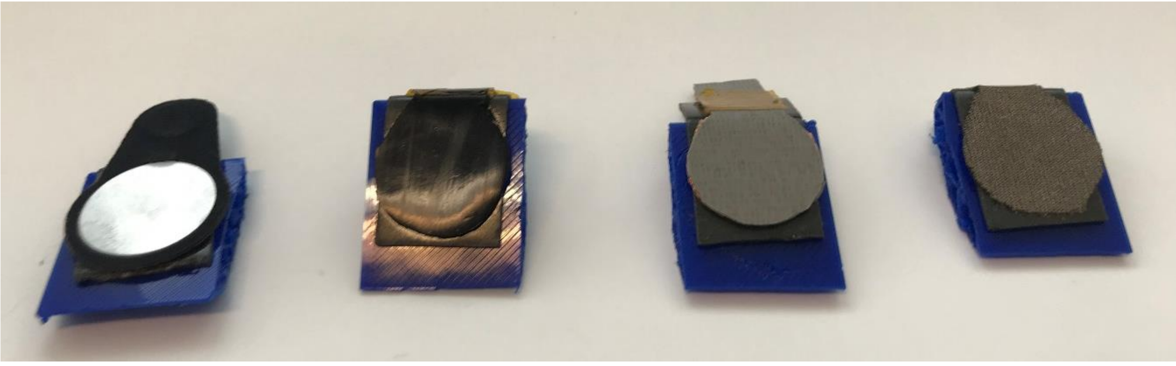
statex®

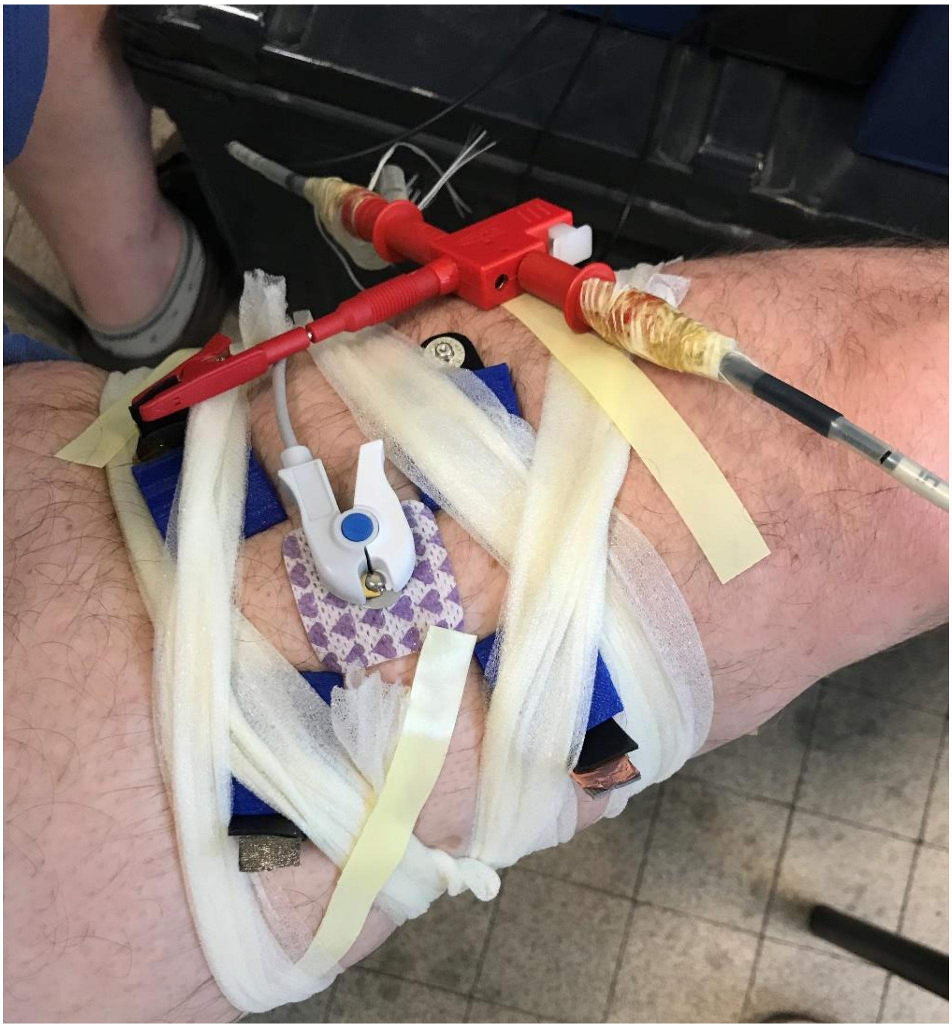
PRODUKTIONS + VERTRIEBS GMBH

Kleiner Ort 11 - 28357 Bremen / Germany
Tel: +49 421 27 50 47 - Fax: +49 421 27 36 43
info@statex.de - www.statex.de

11.3 Appendix C: Skin-electrode impedance contact measurements







11.4 Appendix D: ZScan data

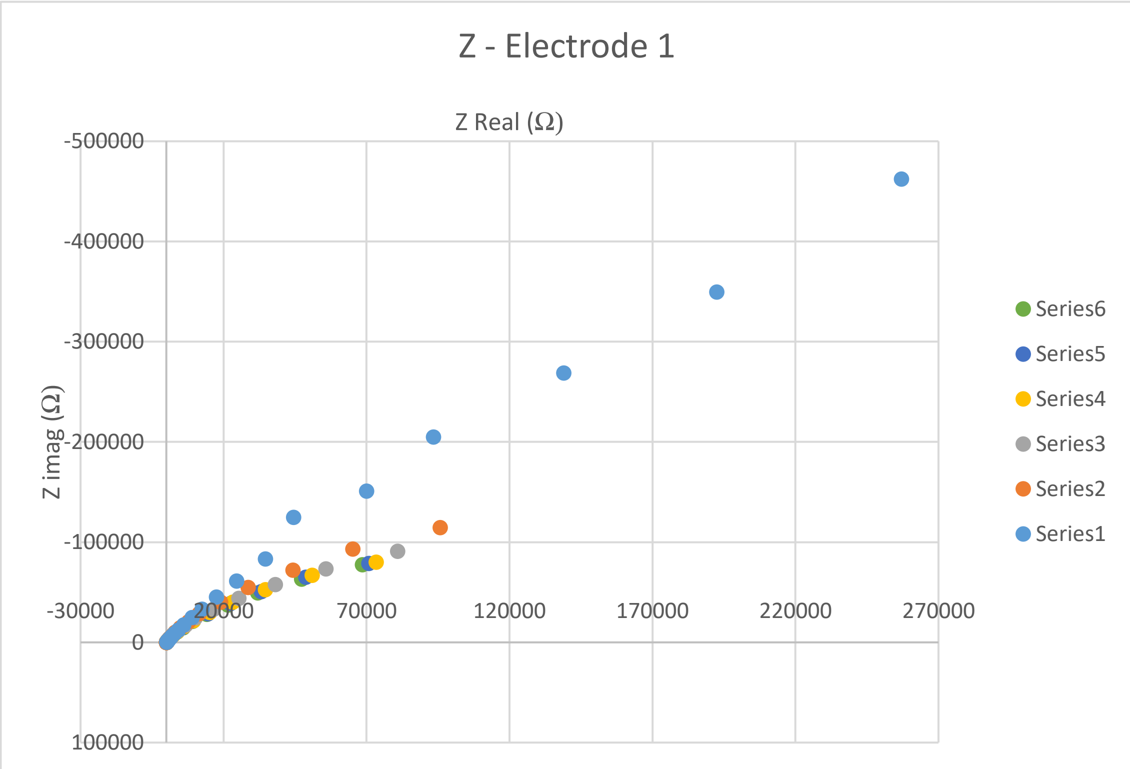
FREQ	El. 1.1		El. 1.2		El. 1.3		El. 1.4		El. 1.5		El. 1.6	
	Real	Imag	Real	Imag	Real	Imag	Real	Imag	Real	Imag	Real	Imag
1000000	182,431	-97,62077	148,4888	1,332989	144,2219	3,790843	146,0293	8,555598	146,6138	3,639345	147,2191	4,173697
630957,3	186,9502	-151,6545	145,9669	-14,20305	141,2195	-11,55229	142,4201	-6,34867	142,5506	-9,271191	144,5414	-8,272611
398107,2	201,5439	-230,6461	148,3438	-30,98994	143,7246	-25,04527	144,1295	-20,42589	144,6555	-21,62058	146,416	-20,59945
251188,6	227,3737	-342,5403	154,1391	-50,3275	148,7865	-40,84451	149,5257	-35,04951	149,2956	-35,08014	151,1143	-33,64707
158489,3	268,2418	-502,4763	162,5984	-75,25183	155,9111	-60,70586	155,2664	-53,34428	155,3338	-51,78242	157,659	-49,95877
100000	329,6945	-731,079	174,5295	-109,238	165,7054	-87,56056	163,5127	-77,56149	163,5782	-74,50491	164,4149	-72,06335
63095,73	418,3181	-1037,933	190,8945	-157,1384	178,7398	-125,7571	175,2998	-112,0642	176,3021	-107,2116	174,556	-103,6391
39810,72	551,8475	-1496,36	213,4019	-225,7121	195,9419	-180,9352	190,4776	-161,888	191,1842	-154,6454	189,982	-149,5478
25118,86	747,7126	-2151,815	244,244	-324,8788	219,4471	-261,336	211,3268	-234,6494	209,3643	-224,228	208,0687	-217,3124
15848,93	1036,42	-3081,694	286,5543	-469,427	251,0095	-379,7841	238,7796	-342,346	234,1948	-327,5977	229,013	-317,7938
10000	1446,674	-4327,065	345,2224	-681,9644	294,8488	-555,6781	277,3531	-502,8429	270,6718	-482,0994	263,5436	-465,5605
6309,573	2062,411	-6167,194	426,94	-996,4471	357,5061	-818,2916	333,3257	-743,1488	324,1917	-713,849	312,4864	-692,7614
3981,072	2954,616	-8772,229	546,4409	-1462,693	451,0907	-1210,464	415,818	-1102,788	403,9448	-1061,074	390,3846	-1031,135
2511,886	4265,545	-12423,93	722,5682	-2155,104	593,7617	-1794,81	544,459	-1639,435	528,3217	-1579,323	510,9558	-1535,258
1584,893	6204,08	-17579,73	990,4786	-3171,573	819,1664	-2661,822	750,8904	-2436,188	727,8139	-2347,539	705,0065	-2283,367
1000	9042,815	-24716,87	1416,072	-4669,057	1177,353	-3933,149	1086,365	-3598,136	1048,874	-3470,645	1024,032	-3371,445
630,9573	12501,46	-33214,79	2091,534	-6860,946	1773,013	-5776,669	1635,212	-5291,195	1586,953	-5099,76	1546,349	-4955,504
398,1072	17531,71	-45198,9	3177,855	-10017,35	2742,362	-8421,428	2533,392	-7707,292	2459,234	-7421,801	2397,331	-7210,862
251,1886	24616,76	-61176,88	4951,203	-14515,62	4311,355	-12136	3993,944	-11094,91	3862,379	-10674,55	3765,596	-10364,47
158,4893	34697,93	-83175,34	7792,614	-20724,14	6819,142	-17254,09	6291,969	-15738,41	6084,407	-15134,05	5923,937	-14662,2
100	44579,56	-124626,3	11497,21	-28619,13	10155,94	-24415,82	9565,138	-21548,07	9486,904	-21586,47	9136,57	-20942,4
63,09574	70115,95	-151053,7	19066,6	-40239,69	16619,75	-32973,47	15265,58	-29984,6	14698,91	-28766,9	14212,35	-27941,98
39,81071	93472,5	-204779	28691,84	-54941,22	25464,79	-44100,32	23240,28	-40210,6	22470,59	-38921,06	21649,51	-37271,41
25,11886	138993,4	-268852	44383,43	-72066,91	38130,53	-57648,63	34700,11	-52425,63	33214,11	-50751,51	31991,74	-49273,01
15,84893	192556,3	-349475,1	65214,37	-93158,44	55857,67	-73310,2	51053,74	-67000,37	48762,46	-65141,98	47385,91	-62979,34
10	257058,3	-462447,4	95825,53	-114403,1	80888,54	-90989,15	73470,02	-80193,2	70882,76	-78658,02	68592,82	-77631,74

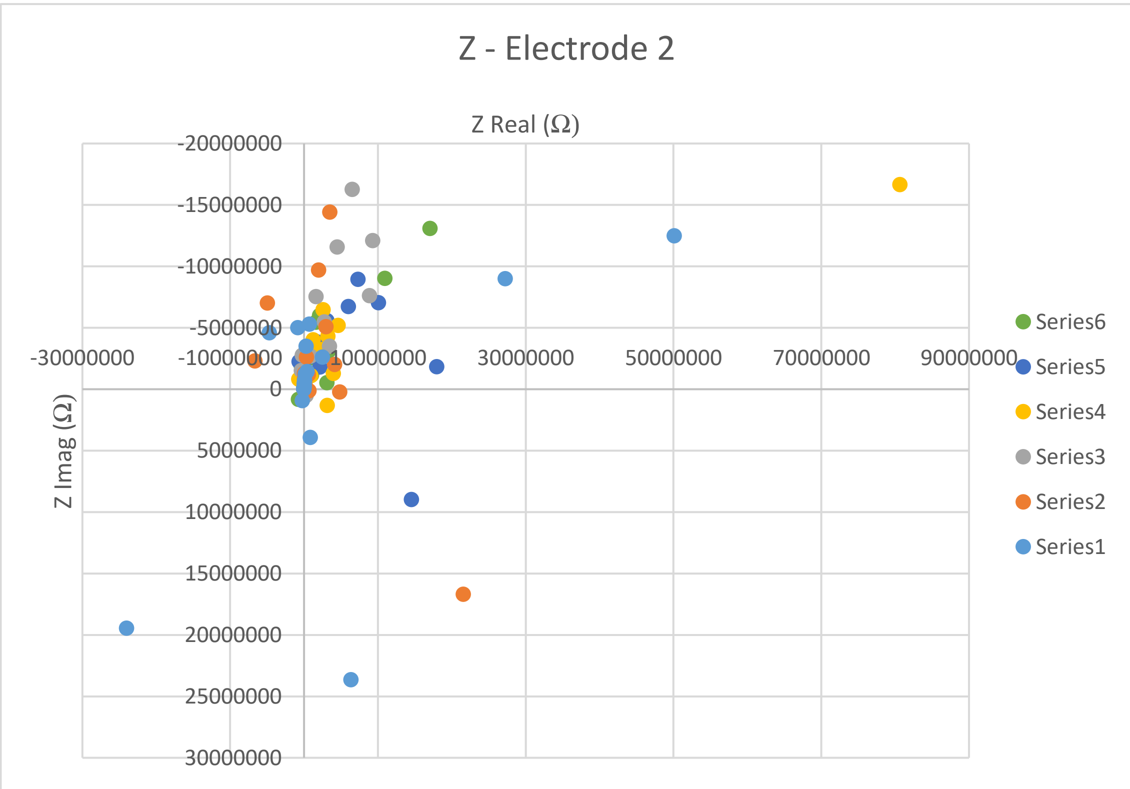
	El. 2.1		El. 2.2		El. 2.3		El. 2.4		El. 2.5		El. 2.6	
FREQ	Real	Imag	Real	Imag	Real	Imag	Real	Imag	Real	Imag	Real	Imag
1000000	1114,912	-4175,371	1131,557	-3470,53	945,0592	-3589,532	1076,362	-3665,949	826,3246	-3549,077	980,1069	-3624,903
630957,3	1203,08	-6181,776	1285,065	-5027,958	1092,025	-5249,287	1271,112	-5370,583	1003,175	-5226,379	1105,768	-5334,205
398107,2	1479,285	-9337,938	1521,762	-7555,16	1385,191	-7931,494	1538,15	-8139,459	1254,769	-7834,302	1374,781	-8038,482
251188,6	1900,467	-14468,61	2014,032	-11756,06	1789,234	-12130,14	1915,724	-12507,2	1693,459	-12082,7	1675,733	-12441,55
158489,3	1960,658	-22730,88	2662,21	-18119,04	2348,553	-18593,75	2429,623	-18999,82	2067,035	-18610,85	1969,291	-19566,94
100000	2473,284	-33988,86	3844,317	-28296,36	3202,52	-28497,28	3085,456	-30481,94	3292,983	-28860,95	2947,959	-29525,13
63095,73	3814,449	-53953,88	6263,051	-42137,82	5559,172	-44060,17	4790,224	-45991,84	4218,6	-44924,81	3391,577	-46864,02
39810,72	12131,04	-82013,51	7121,575	-63994,43	9608,808	-68949,18	7330,203	-72414,46	8277,965	-68625,98	7530,015	-69644,05
25118,86	12864,24	-124691,3	10748,2	-98921,84	14176,93	-103001,4	8297,122	-109868,9	11122,88	-104449	15232,72	-111116,4
15848,93	14290,31	-189251,7	17678,29	-155104,7	22542,98	-165473,8	24209,59	-168292,1	16100,92	-171598	25598,18	-174181,3
10000	21176,11	-299191,1	27376,7	-232057,5	34265,97	-238843,2	32093,68	-253621,5	34969,8	-247378,2	35846,5	-249579,2
6309,573	36746,9	-459146	57524,11	-373514,6	42058,34	-382653,9	66074,28	-388178,6	68561,7	-379934,6	75419,91	-421506
3981,072	82636,93	-723325,1	88955,1	-516667,8	114934,1	-578788,6	185576,7	-536814,2	142692	-607472,3	90497,04	-576766
2511,886	164807,7	-1223352	59557,7	-864019,8	183923,9	-831397,8	279119,1	-895751,2	273592,8	-795571,3	266651,7	-912049,3
1584,893	409289	-1431957	96872,14	-1276419	316915,3	-1272742	407345,9	-1407276	79508,59	-1301549	479750,9	-1280635
1000	-810802,1	-4994136	583443,6	-1163428	-338021,8	-1521060	960052,4	-1104898	-677464,2	-2251110	1040758	-1140610
630,9573	291292,5	-3504486	344122,8	-2606845	847130,9	-2688311	1267865	-4025513	715673,3	-2644154	937901,7	-2549697
398,1072	713741,7	-5289019	2971569	-5071952	3444311	-3491776	2558343	-3228587	2156176	-1788478	1335593	-3300157
251,1886	2487336	-2618657	4138731	-2019514	-235258,6	-2753129	2577663	-6465020	1709297	-3862063	3338582	-3101946
158,4893	5,01E+07	-1,25E+07	-4965508	-7006990	2758550	-5467446	3244214	-4302412	3132176	-5582437	1659907	-5433904
100	-209481	941234,8	681330,4	137356,1	311062,3	531436,4	-703680,7	-799743,3	219881,2	-946837,8	-747813	840959,6
63,09574	2,72E+07	-9000809	1970513	-9705095	8867272	-7621233	4642781	-5191143	7300610	-8924524	2111525	-5986216
39,81071	-4685280	-4597506	4846133	246511,5	9318732	-1,21E+07	916163,3	-3571464	1,01E+07	-7046681	3102089	-518618,9
25,11886	6340409	2,36E+07	3520180	-1,44E+07	6543483	-1,62E+07	8,07E+07	-1,67E+07	6016989	-6721958	1,71E+07	-1,31E+07
15,84893	-2,40E+07	1,95E+07	2,16E+07	1,67E+07	4477997	-1,16E+07	3965759	-1288787	1,80E+07	-1836879	1,09E+07	-9004471
10	876628,8	3935813	-6627263	-2284630	1623581	-7520743	3145808	1337460	1,46E+07	8997714	-355828,4	-1866205

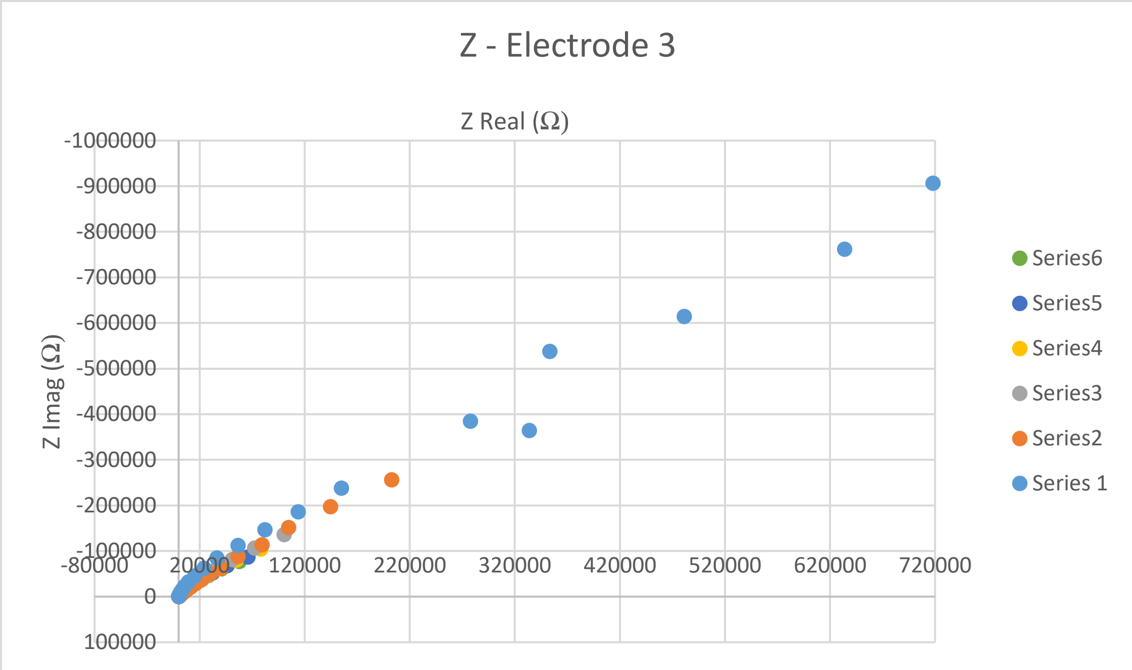
	El. 3.1		El. 3.2		El. 3.3		El. 3.4		El. 3.5		El. 3.6	
FREQ	Real	Imag	Real	Imag	Real	Imag	Real	Imag	Real	Imag	Real	Imag
1000000	228,4508	-253,4927	191,6819	-76,74466	176,982	-26,99105	159,6254	-15,69065	166,3159	-7,304574	174,1976	10,69882
630957,3	237,6131	-384,7621	196,6165	-125,1656	177,8613	-53,95672	159,9591	-35,87341	165,0855	-25,44344	168,4385	-9,147544
398107,2	262,2911	-588,4279	213,1244	-192,012	187,0292	-86,88228	166,8096	-59,30855	169,7078	-45,1946	170,1616	-29,31509
251188,6	304,0825	-893,0151	242,5637	-283,8597	202,1302	-128,944	178,5917	-88,20078	178,89	-68,59066	176,9869	-50,66281
158489,3	374,3643	-1352,616	288,7677	-412,8555	226,5995	-184,5106	196,1394	-125,8307	192,813	-98,23357	187,7108	-76,17798
100000	485,0684	-2042,104	357,7952	-592,5297	262,3745	-259,4656	220,6246	-176,3758	212,3591	-137,8048	203,0228	-108,9326
63095,73	668,9378	-3046,897	460,5891	-838,9133	310,6055	-360,8233	254,2499	-244,9243	237,6636	-191,6773	223,6603	-153,1926
39810,72	961,135	-4545,389	609,5471	-1183,364	379,1717	-500,9423	300,878	-339,5563	273,6182	-265,7971	251,8274	-213,9465
25118,86	1436,984	-6825,629	826,9714	-1660,397	474,2303	-692,7439	364,0685	-469,9552	322,0881	-368,7609	290,0246	-298,2001
15848,93	2235,194	-10155,28	1138,917	-2315,498	605,293	-957,1672	450,5854	-651,0479	387,5042	-512,1095	341,7863	-416,464
10000	3560,514	-15032,84	1583,409	-3195,313	783,6769	-1323,261	568,5278	-903,9054	477,4753	-713,6818	411,4262	-584,0671
6309,573	5828,939	-22049,17	2206,603	-4414,879	1029,859	-1831,293	729,4149	-1258,379	600,957	-998,6962	507,5593	-822,9506
3981,072	9504,812	-31972,92	3087,685	-6073,228	1366,764	-2537,992	952,8613	-1756,915	770,275	-1402,445	640,7972	-1165,221
2511,886	15474,82	-45009,18	4312,134	-8322,077	1828,246	-3514,017	1264,02	-2460,243	1009,045	-1977,269	829,2411	-1655,204
1584,893	24401,64	-62340,96	6021,187	-11380,21	2481,442	-4881,744	1698,071	-3440,736	1344,54	-2784,455	1099,378	-2355,785
1000	36578,55	-84684,79	8447,909	-15443,17	3398,081	-6794,791	2325,424	-4824,055	1832,338	-3933,839	1487,905	-3347,44
630,9573	56571,05	-111733,1	11658,75	-20898,91	4697,25	-9417,018	3215,422	-6753,967	2535,577	-5546,756	2066,887	-4758,349
398,1072	82253,02	-146251,5	16158,69	-28228,95	6545,964	-13055,11	4506,186	-9446,473	3568,693	-7808,903	2924,071	-6749,05
251,1886	114061,5	-186033,8	22128,84	-37714,23	9192,145	-18037,64	6385,573	-13155,85	5087,659	-10951,47	4209,484	-9540,67
158,4893	155180,5	-237924,5	30352,38	-50296,39	13010,75	-24800,37	9106,958	-18223,31	7322,747	-15257,57	6132,844	-13358,33
100	334005,4	-363880,2	40406,75	-62148,4	19511,75	-33908,45	13813,05	-25028,56	10486,04	-20630,92	8882,196	-18152,09
63,09574	277872,2	-384314,3	56574,74	-88452,34	26035,64	-45629,81	18772,65	-34088,91	15426,66	-28825,07	13194,67	-25460,49
39,81071	353266,8	-537764,2	79616,6	-113732,5	36670,53	-61049	27173,31	-45824,79	22314,1	-38944,56	19612,16	-34401,93
25,11886	481293,6	-614247,9	104907,4	-151256,8	51099,91	-81016,52	38364,4	-60687,93	32369,42	-51746,51	28237,66	-46097,29
15,84893	633927,8	-761690	144660,1	-196842,8	72600,05	-106447,1	54735,64	-79844,03	46225,44	-67859,97	40773,33	-60408,71
10	718019,9	-906363,3	202756,2	-255673,5	100663	-135710	78236,14	-104263,2	66162,02	-86738,54	57942,07	-77102,41

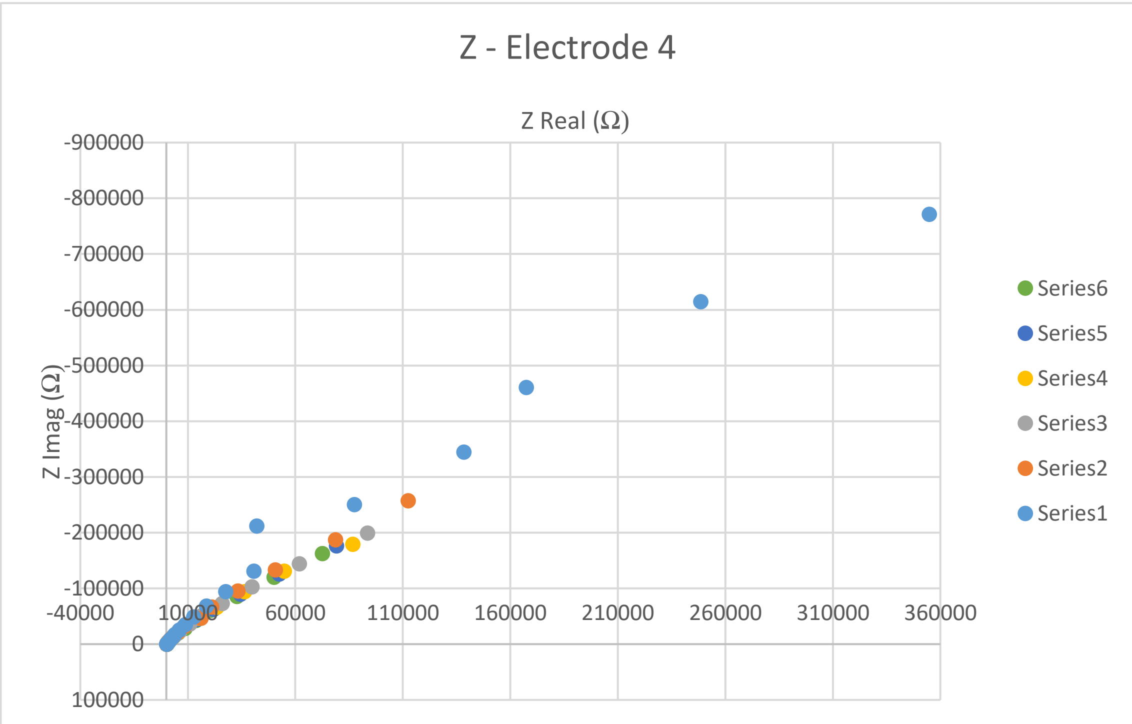
	El. 4.1		El. 4.2		El. 4.3		El. 4.4		El. 4.5		El. 4.6	
FREQ	Real	Imag	Real	Imag	Real	Imag	Real	Imag	Real	Imag	Real	Imag
1000000	214,3764	-103,7147	198,4792	14,08546	189,7237	9,737099	186,5917	7,328798	211,9537	40,9388	203,1279	32,85348
630957,3	215,889	-161,3464	188,9795	-10,01752	184,2897	-6,41666	181,6156	-6,483174	194,8751	15,19351	190,0569	9,377873
398107,2	226,7681	-247,1991	189,2849	-31,27803	185,3368	-21,2337	182,4849	-19,75021	191,4895	-4,602488	187,8996	-8,695876
251188,6	247,4935	-372,0198	194,1262	-52,9977	189,1573	-37,49926	185,9507	-34,01149	192,7594	-22,58336	190,9919	-23,26835
158489,3	280,058	-554,6411	201,6485	-81,6725	194,7267	-57,66726	190,9198	-51,79632	196,5599	-42,26528	194,7672	-42,11945
100000	329,031	-821,9886	211,7195	-121,9185	201,8332	-85,97305	197,2141	-76,58641	201,8684	-67,4894	200,1495	-65,0357
63095,73	399,7678	-1192,222	225,6422	-179,3842	210,9637	-127,2002	205,0591	-113,2076	204,4438	-105,3683	207,6587	-97,97755
39810,72	508,279	-1762,124	244,9339	-264,5224	223,3538	-188,7691	215,4438	-168,3018	213,4597	-156,6367	216,0313	-147,5829
25118,86	668,4366	-2598,07	271,7475	-391,0998	240,4816	-281,664	230,0594	-251,4068	225,2858	-235,2176	228,5846	-222,4723
15848,93	908,5111	-3761,957	309,544	-580,5682	264,6639	-421,792	250,6788	-378,0052	244,4553	-354,1534	245,858	-336,1374
10000	1281,509	-5533,532	363,4979	-865,2219	300,525	-634,3629	281,3959	-570,2949	273,2184	-535,7054	271,5488	-509,246
6309,573	1834,699	-8127,004	442,2695	-1294,144	353,9109	-956,9804	327,2455	-862,6869	315,7316	-811,9668	311,2391	-772,7236
3981,072	2700,101	-11896,77	561,1243	-1941,514	435,9691	-1446,01	399,1925	-1307,197	382,3918	-1232,361	373,791	-1174,215
2511,886	3980,249	-17408,89	742,0924	-2915,4	564,9067	-2185,84	513,0479	-1980,588	488,1307	-1869,211	474,4858	-1783,28
1584,893	6007,846	-25375,4	1024,945	-4367,544	770,6336	-3294,597	697,9354	-2991,822	660,1045	-2827,466	637,4308	-2705,38
1000	8941,02	-35346,71	1470,867	-6556,313	1106,644	-4962,948	998,5251	-4512,846	944,2001	-4273,453	904,1229	-4082,391
630,9573	12793,64	-49020,24	2213,116	-9796,183	1661,637	-7450,14	1501,623	-6788,079	1418,608	-6426,639	1359,112	-6141,836
398,1072	18677,72	-68367,27	3406,046	-14600,28	2571,825	-11126,46	2326,13	-10153,85	2200,828	-9616,954	2109,71	-9193,446
251,1886	27587,23	-94615,22	5342,054	-21613,32	4067,639	-16528,08	3692,7	-15087,02	3488,01	-14282,53	3329,668	-13675,35
158,4893	40784,35	-131174,6	8486,164	-31738,32	6488,701	-24315,48	5942,497	-22205,28	5612,069	-21075,23	5376,411	-20149,54
100	42015,7	-211965,9	16232,04	-46450,41	10886,21	-36308,66	8581,355	-33064,73	8029,786	-30905,24	8745,382	-28181,98
63,09574	87435,48	-250645,2	21113,24	-66595,44	16505,63	-51136,66	15117,97	-46730,79	14279,89	-44336,23	13711,46	-42490,34
39,81071	138364	-345001	33339,32	-95311,88	25991,78	-72921,61	23468,08	-66202,02	22008,67	-62693,73	20843,18	-61132,11
25,11886	167460	-460873,4	50640,13	-133467,8	39772,32	-103105,8	36456	-94500,61	34490,77	-89686,1	32896,62	-85959,63
15,84893	248493,3	-614799,9	78675,72	-187174,6	61883,8	-144198,1	54810,47	-131419,1	52509,39	-125738,9	50080,3	-120466,2
10	354794,9	-771497,6	112418,9	-257286,2	93519,57	-199690,5	86768,8	-179663,2	79095,05	-176408,6	72627,56	-162784,5

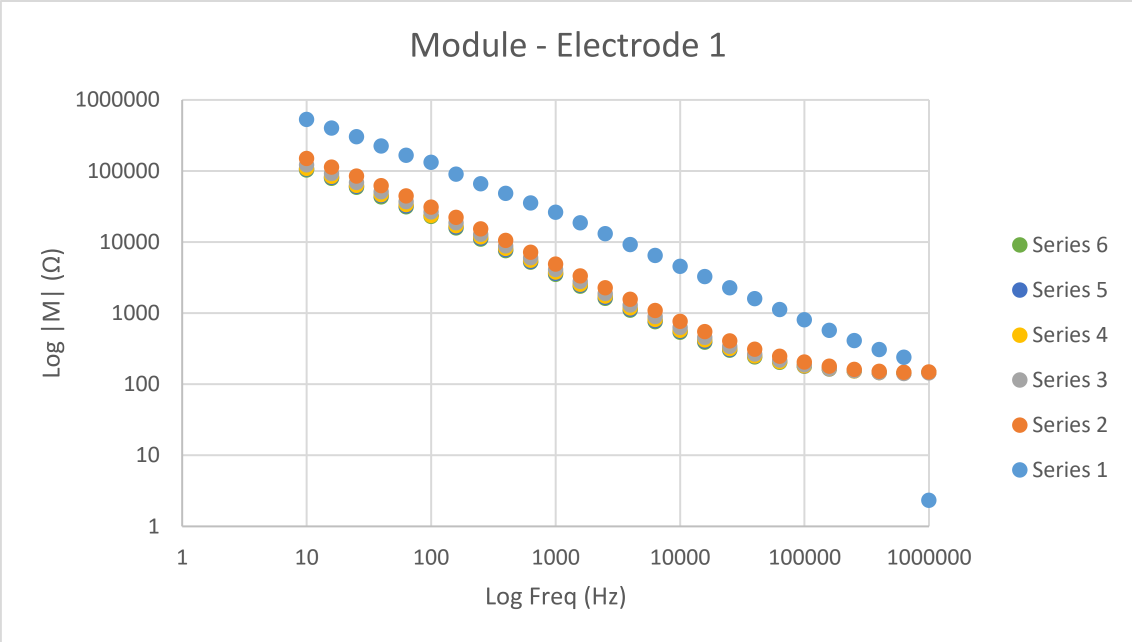
11.5 Appendix E: Impedance, module and phase – Graphic Representations

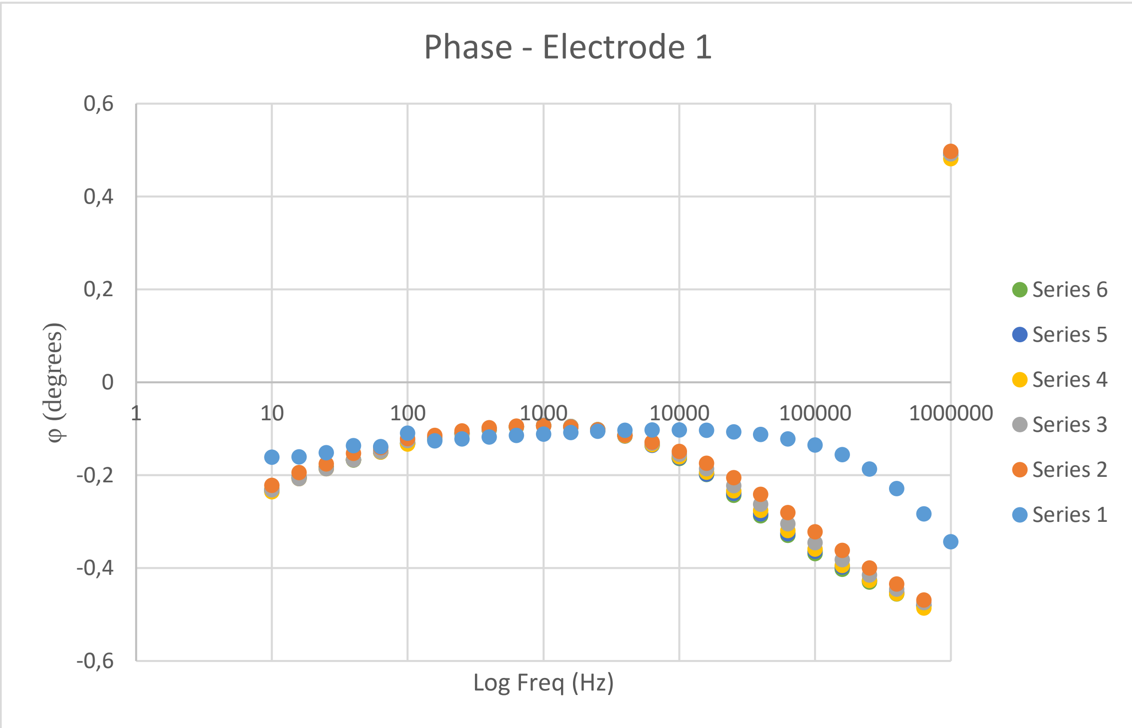


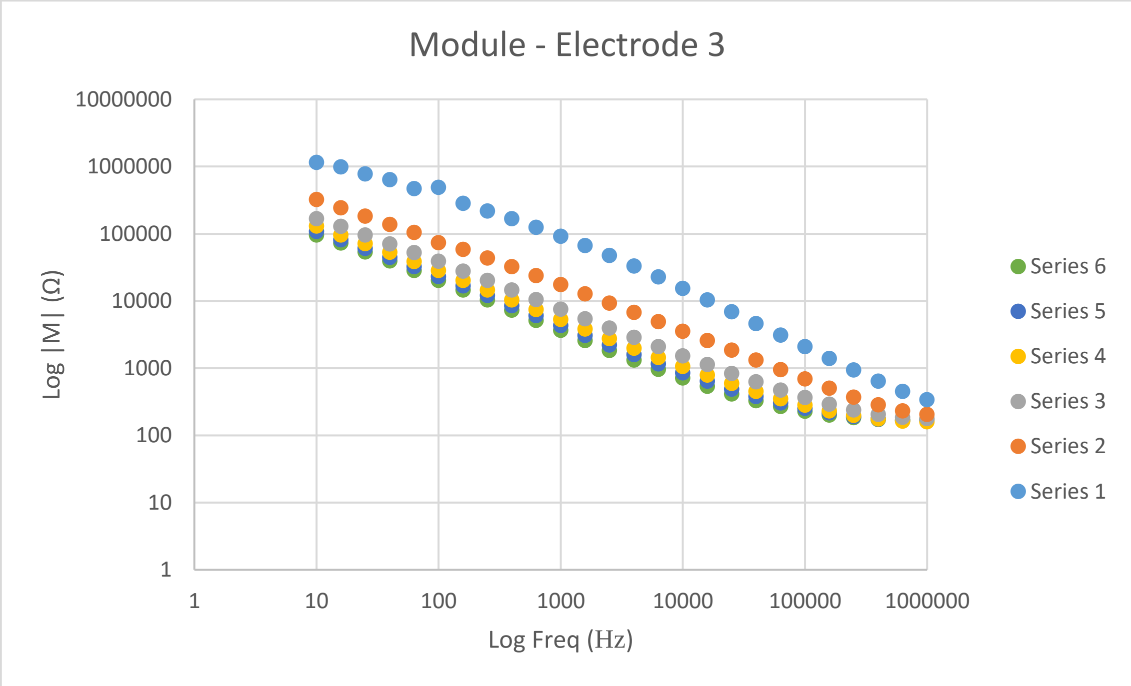



Z - Electrode 3
Z Real (Ω)
Z Imag (Ω)
-1000000
-900000
-800000
-700000
-600000
-500000
-400000
-300000
-200000
-100000
0
100000
-80000
20000
120000
220000
320000
420000
520000
620000
720000
Series6
Series5
Series4
Series3
Series2
Series 1

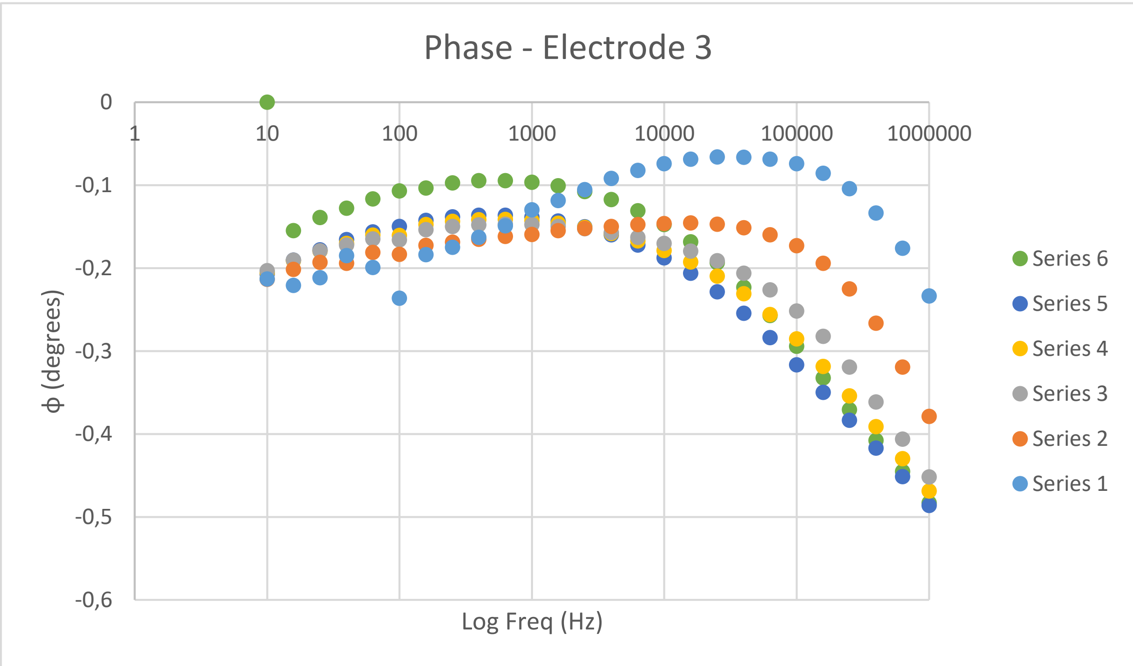

Z - Electrode 4
Z Real (Ω)
Z Imag (Ω)
-900000
-800000
-700000
-600000
-500000
-400000
-300000
-200000
-100000
0
100000
-40000
10000
60000
110000
160000
210000
260000
310000
360000
Series6
Series5
Series4
Series3
Series2
Series1


Module - Electrode 1
1000000
100000
10000
1000
100
10
1
Log |M| (Ω)
1
10
100
1000
10000
100000
1000000
Log Freq (Hz)
Series 6
Series 5
Series 4
Series 3
Series 2
Series 1

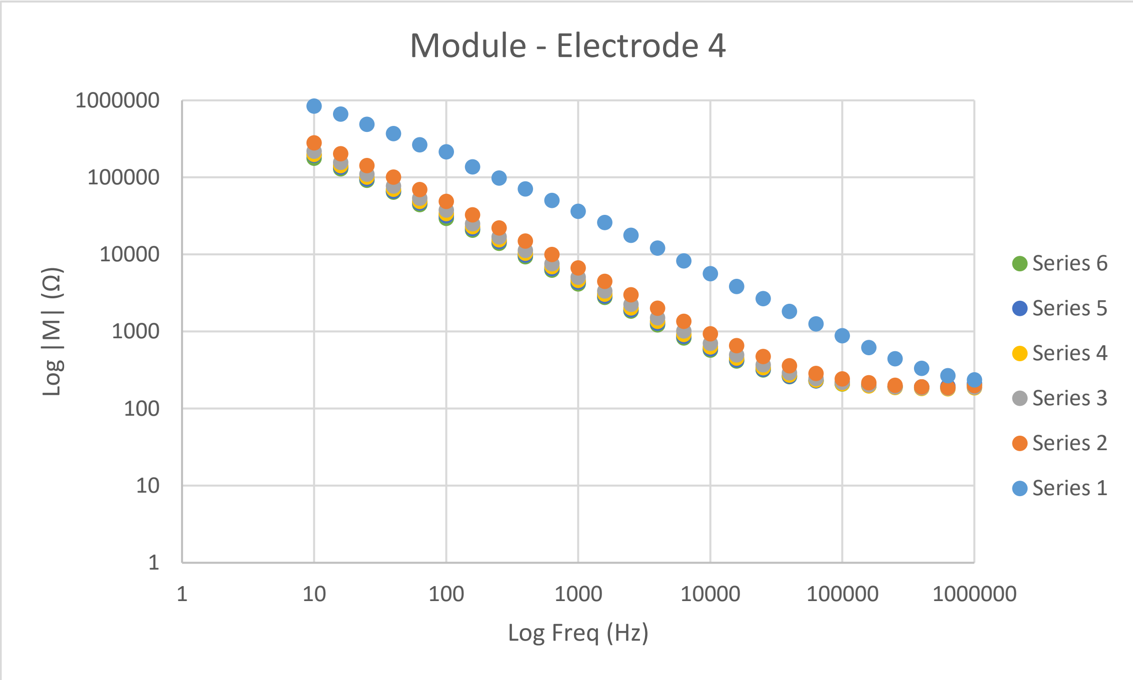

Phase - Electrode 1
0,6
0,4
0,2
0
-0,2
-0,4
-0,6
φ (degrees)
1
10
100
1000
10000
100000
1000000
Log Freq (Hz)
Series 6
Series 5
Series 4
Series 3
Series 2
Series 1

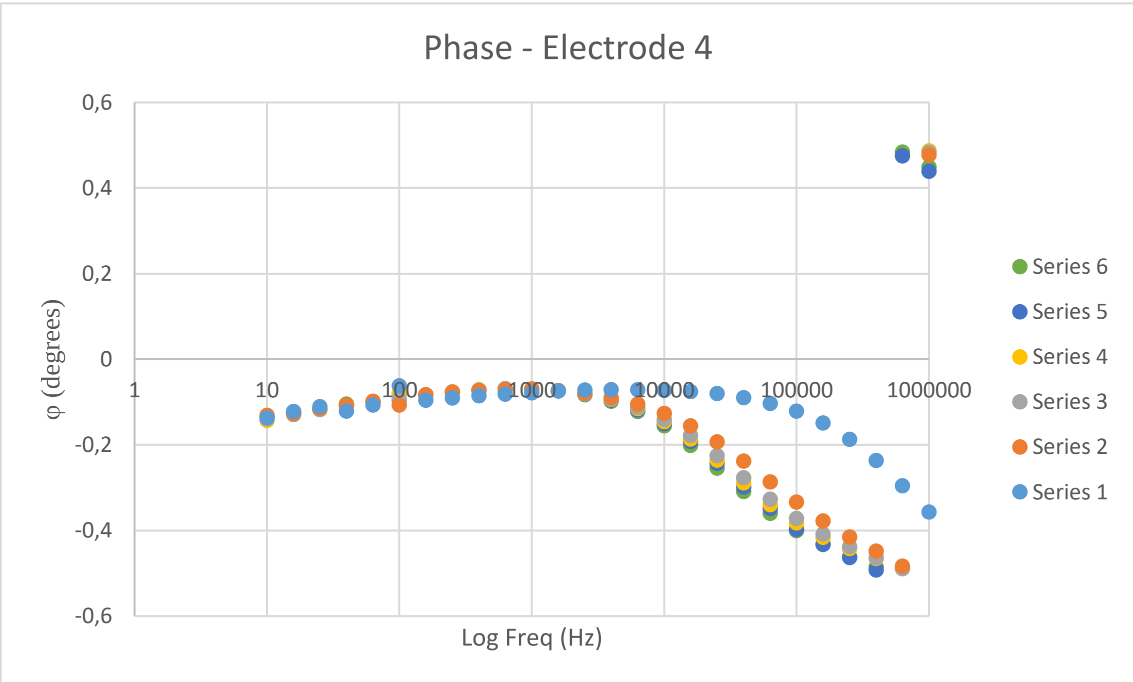


Module - Electrode 3
Log |M| (Ω)
10000000
1000000
100000
10000
1000
100
10
1
1
10
100
1000
10000
100000
1000000
Log Freq (Hz)
Series 6
Series 5
Series 4
Series 3
Series 2
Series 1



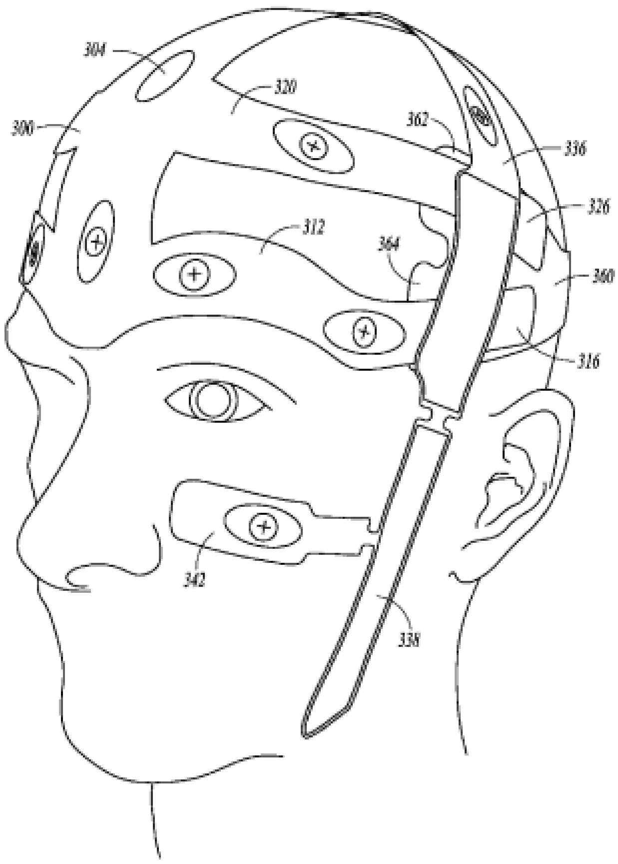
Phase - Electrode 3
ϕ (degrees)
0
-0,1
-0,2
-0,3
-0,4
-0,5
-0,6
1
10
100
1000
10000
100000
1000000
Log Freq (Hz)
Series 6
Series 5
Series 4
Series 3
Series 2
Series 1

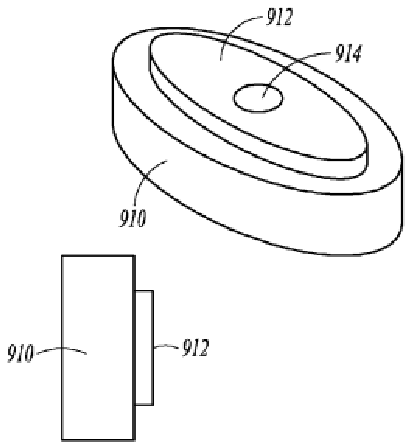

Module - Electrode 4
Log |M| (Ω)
1000000
100000
10000
1000
100
10
1
1
10
100
1000
10000
100000
1000000
Log Freq (Hz)
Series 6
Series 5
Series 4
Series 3
Series 2
Series 1


Phase - Electrode 4
φ (degrees)
0,6
0,4
0,2
0
-0,2
-0,4
-0,6
1
10
100
1000
10000
100000
1000000
Log Freq (Hz)
Series 6
Series 5
Series 4
Series 3
Series 2
Series 1

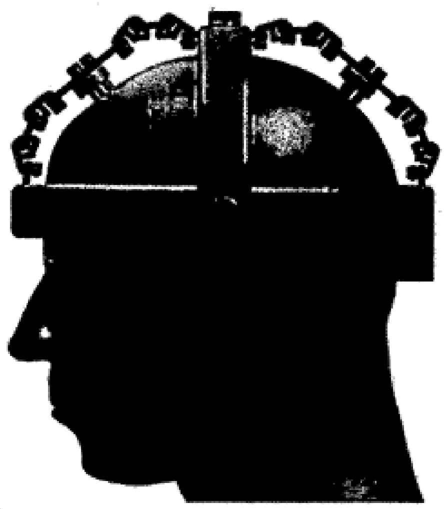
11.6 Appendix F: Headset patents

F.1. U.S. Pat. No. 61/602,292





F.2. W.O. Pat. No. 2012/036,639



11.7 Appendix G: Risk Analysis

Item	Function	Failure			Current design controls	Index			NPR	Code
		Potential failure mode	Potential effect of the failure	Potential causes Mechanisms of failure		G	O	D		
Semi-dry Noninvasive electrode	Record EEG signals (brain waves)	Too much noise from external sources	Reliable data acquisition not possible	Noise considera-tion not properly addressed	Error proofing, material check, test in vivo	9	1	1	9	R1
		Too much electrode movement /deflection	Reliable data acquisition not possible	Incorrect headset design	Test on patients, instructions of installation and use, error proofing	8	1	2	16	R2
		Electrode cost too high	Final device cannot be built	Inadequate planning prototype	Check the design choice, test plans, Material check	8	1	1	8	R3
		Electrode assembly causes discomfort	Uncomfortable situations in long-measure-ments for the patient	Mechanical design not well-suited for application	Check the design choice, test plans, test in vivo, correct instructions	7	2	1	14	R4
		Wrong headset size	Slow measure-ment processes, non-valid results	Device is insufficient , incorrect fabrication	Check the design in vivo tests, instructions of installation and use	9	1	2	18	R5
		KCl solution	May cause eye, skin, or respiratory system irritation	Direct contact with the skin	Wash skin with soap and plenty of water after its application.	6	1	1	6	R6

Severity, occurrence and detection; NPR

Gravedad

Criterio	Clasificación
Irrazonable esperar que el fallo produjese un efecto perceptible en el rendimiento del producto o servicio. Probablemente, el cliente no podrá detectar el fallo.	1
Baja gravedad debido a la escasa importancia de las consecuencias del fallo, que causarían en el cliente un ligero descontento.	2 3
Moderada gravedad del fallo que causaría al cliente cierto descontento. Puede ocasionar retrabajos.	4 5 6
Alta clasificación de gravedad debido a la naturaleza del fallo que causa en el cliente un alto grado de insatisfacción sin llegar a incumplir la normativa sobre seguridad o quebrando de leyes. Requiere retrabajos mayores.	7 8
Muy alta clasificación de gravedad que origina total insatisfacción del cliente, o puede llegar a suponer un riesgo para la seguridad o incumplimiento de la normativa.	9 10

Ocurrencia

Criterio	Clasificación	Probabilidad
Remota probabilidad de ocurrencia. Sería irrazonable esperar que se produjera el fallo.	1	1/10.000
Baja probabilidad de ocurrencia. Ocasionalmente podría producirse un número relativo bajo de fallos.	2 3	1/5.000 1/2.000
Moderada probabilidad de ocurrencia. Asociado a situaciones similares que hayan tenido fallos esporádicos, pero no en grandes proporciones.	4 5 6	1/1.000 1/500 1/200
Alta probabilidad de ocurrencia. Los fallos se presentan con frecuencia.	7 8	1/100 1/50
Muy alta probabilidad de ocurrencia. Se producirá el fallo casi con total seguridad.	9 10	1/20 1/10

Detección

Criterio	Clasificación	Probabilidad
Remota probabilidad de que el defecto llegue al cliente. Casi completa fiabilidad de los controles.	1	1/10.000
Baja probabilidad de que el defecto llegue al cliente ya que, de producirse, sería detectado por los controles o en fases posteriores del proceso.	2 3	1/5.000 1/2.000
Moderada probabilidad de que el producto o servicio defectuoso llegue al cliente.	4 5 6	1/1.000 1/500 1/200
Alta probabilidad de que el producto o servicio defectuoso llegue al cliente debido a la baja fiabilidad de los controles existentes.	7 8	1/100 1/50
Muy alta probabilidad de que el producto o servicio defectuoso llegue al cliente. Este está latente y no se manifestaría en la fase de fabricación del producto.	9 10	1/20 1/10

NPR = G x O x D

Failure rates

1	Very unlikely	Once per 1000 years or more seldom
2	Remote	Once per 100 years
3	Occasional	Once per 10 years
4	Probable	Once per year
5	Frequent	Once per month or more often

Risk matrix

Risk	Negligible			Marginal			Critical			Catastrophic
Highly frequent										
Frequent										
Probable										
Occasional										
Remote			R6	R3			R3	R2	R5	
Highly unlikely									R1	

11.8 Appendix H: KCl safety sheet

LabChem performance through chemistry

Potassium Chloride, 3.0M (3.0N)

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 12/10/2013 Revision date: 02/20/2017 Supersedes: 12/10/2013 Version: 1.1

SECTION 1: Identification

1.1. Identification

Product form	:	Mixtures
Product name	:	Potassium Chloride, 3.0M (3.0N)
Product code	:	LC18795

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture	:	For laboratory and manufacturing use only.
Recommended use	:	Laboratory chemicals
Restrictions on use	:	Not for food, drug or household use

1.3. Details of the supplier of the safety data sheet

LabChem Inc
Jackson's Pointe Commerce Park Building 1000, 1010 Jackson's Pointe Court
Zelienople, PA 16063 - USA
T 412-826-5230 - F 724-473-0647
info@labchem.com - www.labchem.com

1.4. Emergency telephone number

Emergency number	:	CHEMTREC: 1-800-424-9300 or 011-703-527-3887

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Not classified

2.2. Label elements

Not classified as a hazardous chemical.

2.3. Other hazards

Other hazards not contributing to the classification	:	None.

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS-US classification
Water	(CAS No) 7732-18-5	80	Not classified
Potassium Chloride	(CAS No) 7447-40-7	20	Not classified

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	:	Allow victim to breathe fresh air. Allow the victim to rest.
First-aid measures after skin contact	:	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	:	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	:	Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries	:	Not expected to present a significant hazard under anticipated conditions of normal use.

02/20/2017 EN (English US) Page 1

Potassium Chloride, 3.0M (3.0N)
Safety Data Sheet
according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

4.3. Indication of any immediate medical attention and special treatment needed
Obtain medical assistance.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: Not applicable.
Reactivity	: None.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment	: Safety glasses. Gloves.
Emergency procedures	: Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions
Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections
See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep container closed when not in use.
Incompatible products	: Strong oxidizers. Strong acids. silver nitrate.
Incompatible materials	: incompatible materials.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Potassium Chloride (7447-40-7)
Not applicable

Water (7732-18-5)
Not applicable

8.2. Exposure controls

Appropriate engineering controls	: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Personal protective equipment	: Safety glasses.

Hand protection	: Wear protective gloves.
Eye protection	: Chemical goggles or safety glasses.
Respiratory protection	: Wear appropriate mask.
Other information	: Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear, colorless liquid.
Color	: Colorless
Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Non flammable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Specific gravity / density	: 1.13
Solubility	: Soluble in water.
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: 0.893 cSt
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: Not applicable.
Oxidizing properties	: None.

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

None.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong oxidizers. silver nitrate.

Potassium Chloride, 3.0M (3.0N)

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

10.6. Hazardous decomposition products

Hydrogen chloride. Potassium oxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Likely routes of exposure : Skin and eye contact

Acute toxicity : Not classified

Potassium Chloride (7447-40-7)	
LD50 oral rat	2600 mg/kg
ATE US (oral)	2600.000 mg/kg body weight
Water (7732-18-5)	
LD50 oral rat	≥ 90000 mg/kg
ATE US (oral)	90000.000 mg/kg body weight

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Reproductive toxicity : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity – single exposure : Not classified

Specific target organ toxicity – repeated exposure : Not classified

Potential Adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Potassium Chloride (7447-40-7)	
EC50 Daphnia 1	825 mg/l

12.2. Persistence and degradability

Potassium Chloride, 3.0M (3.0N)	
Persistence and degradability	Not established.
Potassium Chloride (7447-40-7)	
Persistence and degradability	Not established.
Water (7732-18-5)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Potassium Chloride, 3.0M (3.0N)	
Bioaccumulative potential	Not established.
Potassium Chloride (7447-40-7)	
Bioaccumulative potential	Not established.
Water (7732-18-5)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

Potassium Chloride, 3.0M (3.0N)

Safety Data Sheet

12.5. Other adverse effects

Effect on the global warming : No known effects from this product.
GWPmix comment : No known effects from this product.

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

This product or mixture does not contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

Potassium Chloride, 3.0M (3.0N)	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria
Potassium Chloride (7447-40-7)	
Listed on the Canadian DSL (Domestic Substances List)	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria
Water (7732-18-5)	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria

EU-Regulations

No additional information available

National regulations

Potassium Chloride (7447-40-7)
Not listed on the Canadian IDL (Ingredient Disclosure List)

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

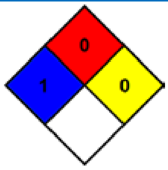
Revision date : 02/20/2017
Other information : None.

Potassium Chloride, 3.0M (3.0N)

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

NFPA health hazard	: 1 - Materials that, under emergency conditions, can cause significant irritation.
NFPA fire hazard	: 0 - Materials that will not burn under typical dire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.
NFPA reactivity	: 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating	
Health	: 1 Slight Hazard - Irritation or minor reversible injury possible
Flammability	: 0 Minimal Hazard - Materials that will not burn
Physical	: 0 Minimal Hazard - Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosives.
Personal protection	: A A - Safety glasses

SDS US LabChem

Information in this SDS is from available published sources and is believed to be accurate. No warranty, express or implied, is made and LabChem Inc assumes no liability resulting from the use of this SDS. The user must determine suitability of this information for his application.

11.9 Appendix I: Rs, Rp, Pseudo-C – Mathematic Model – Z View

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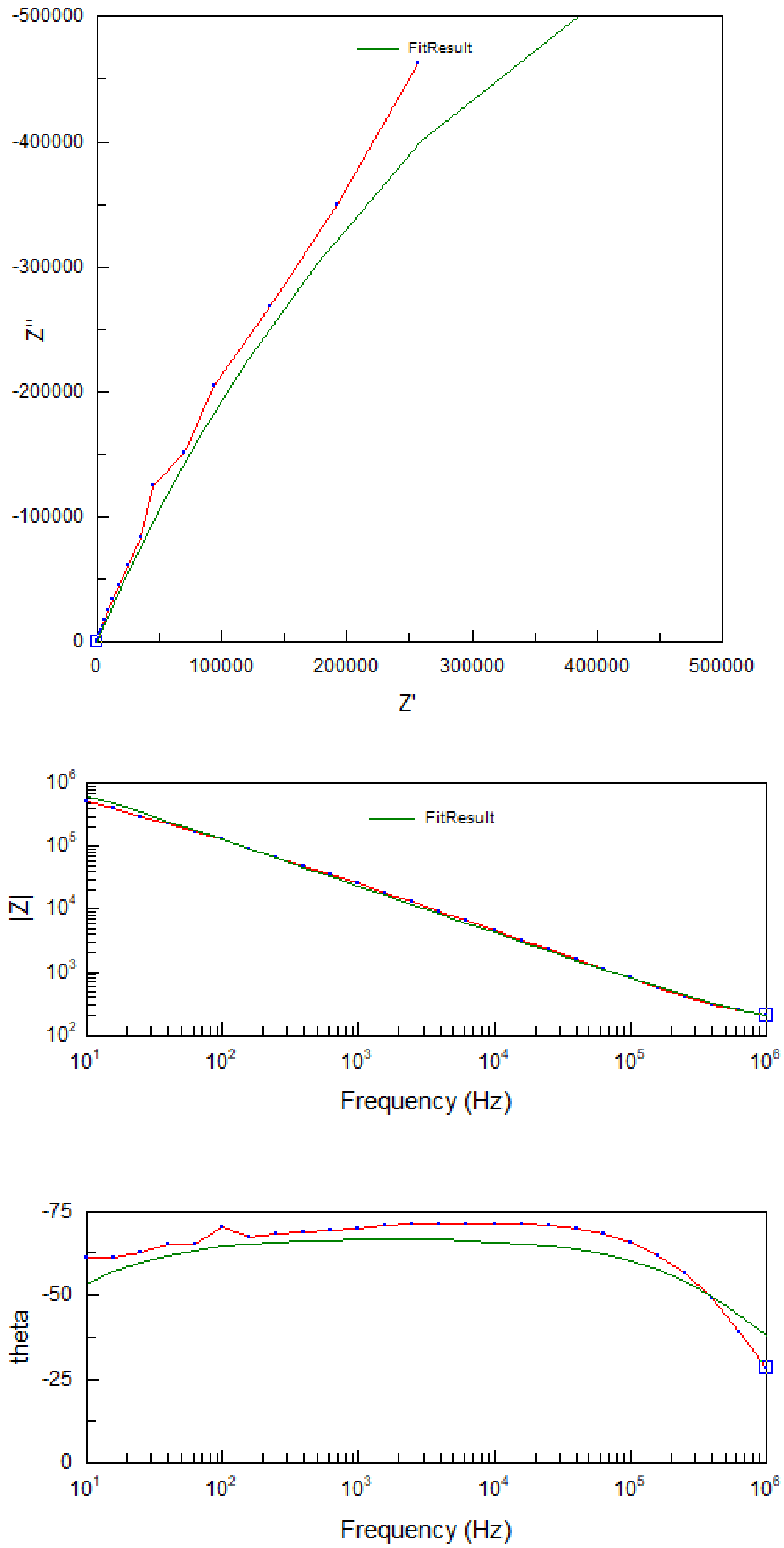

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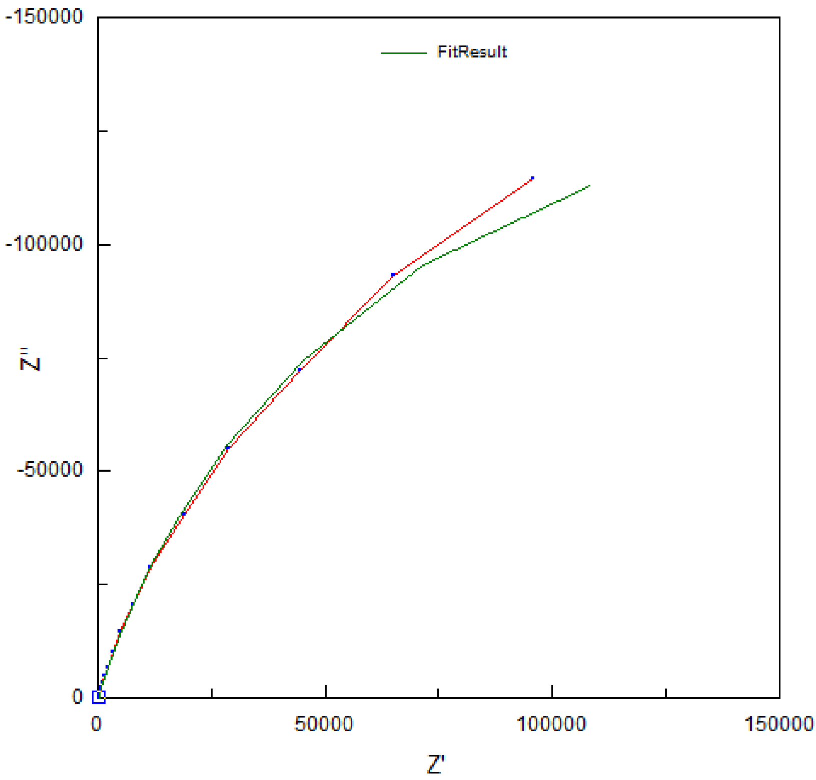
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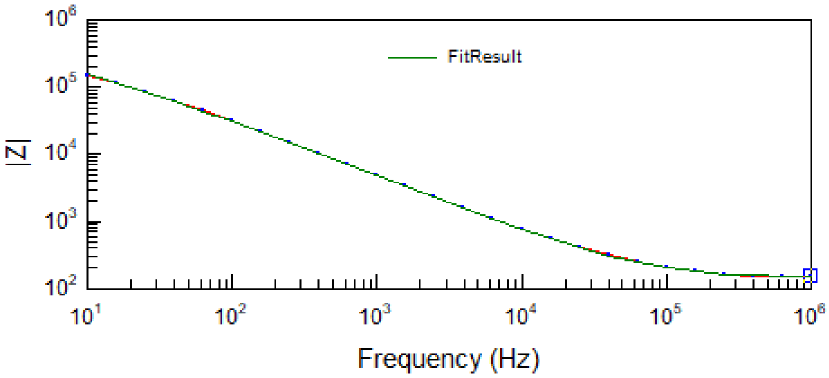
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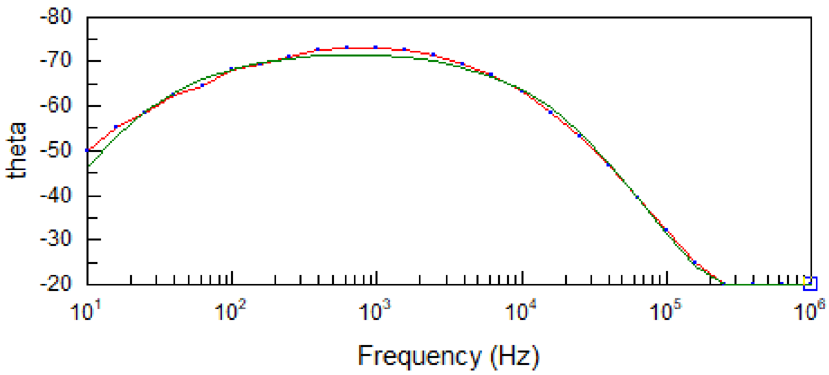
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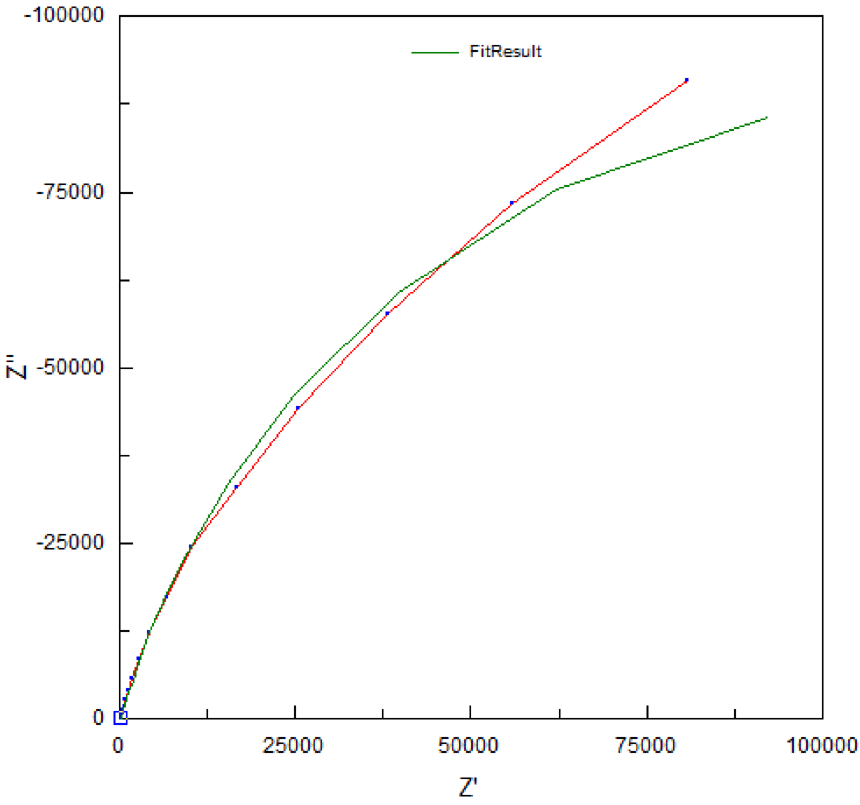
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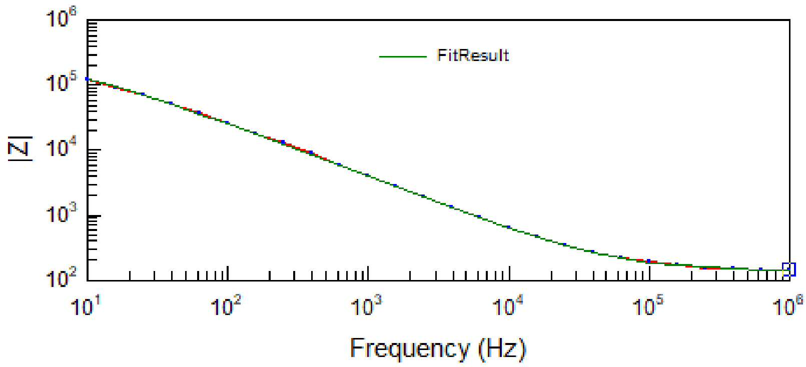
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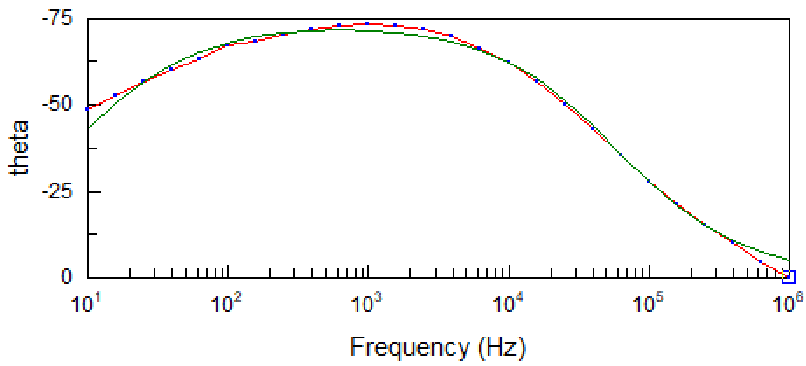
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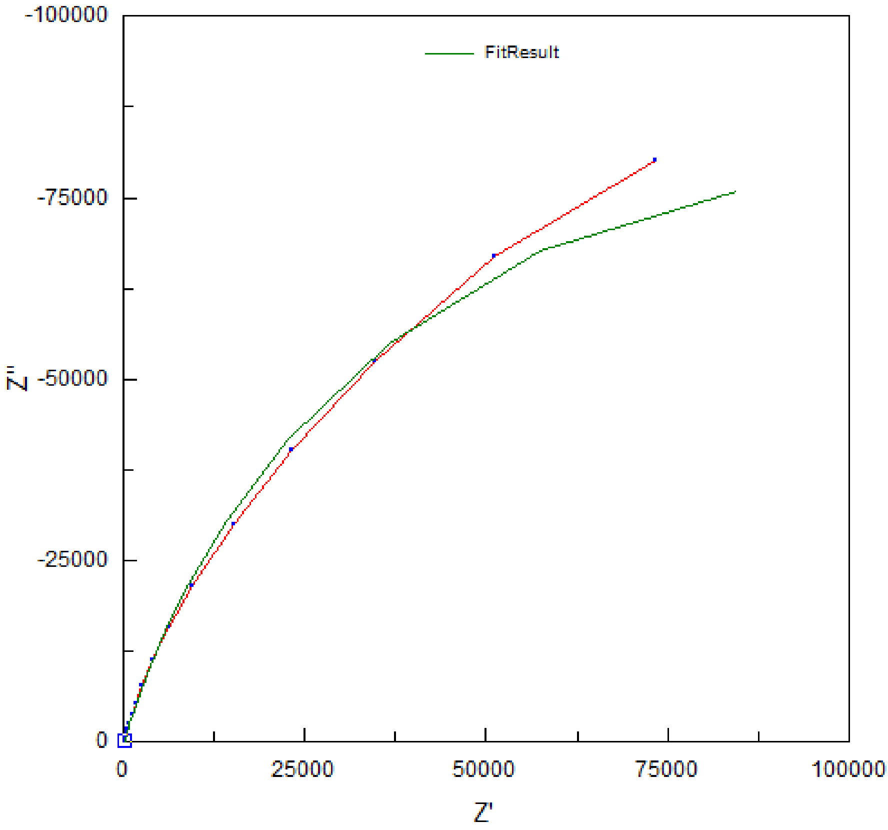
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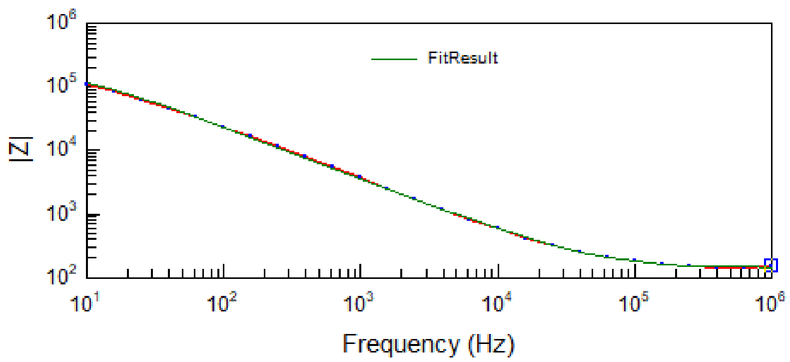
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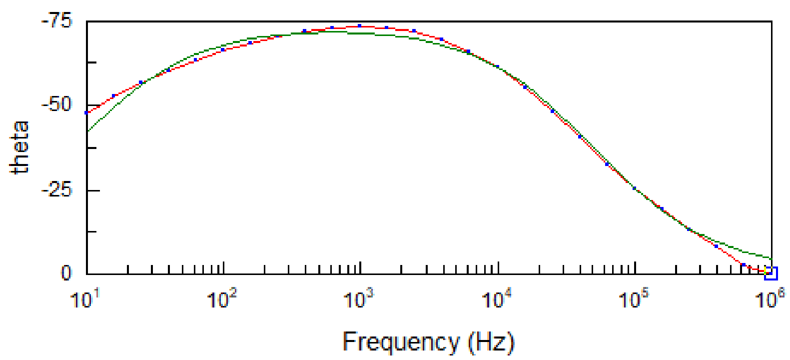
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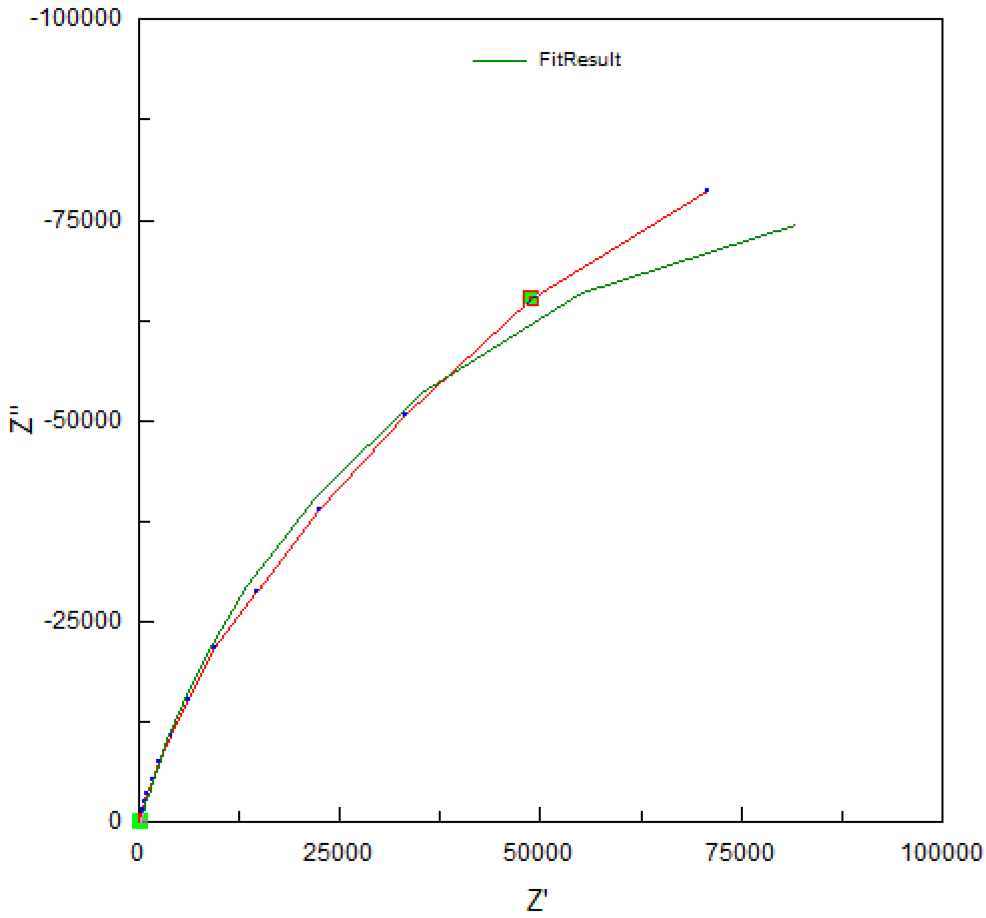
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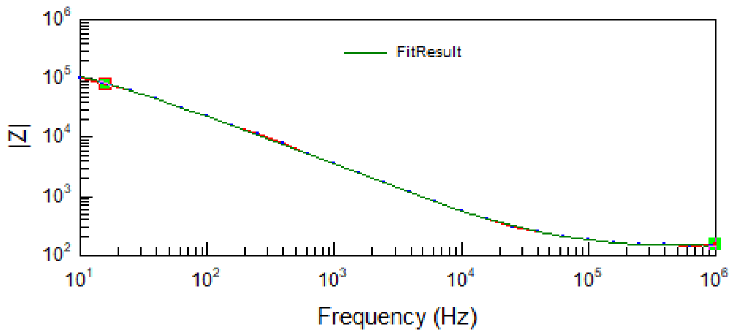
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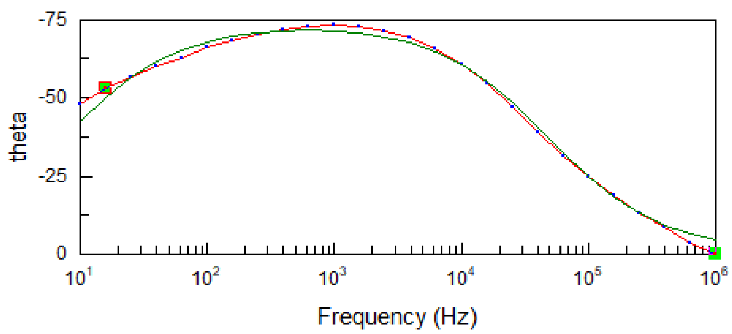
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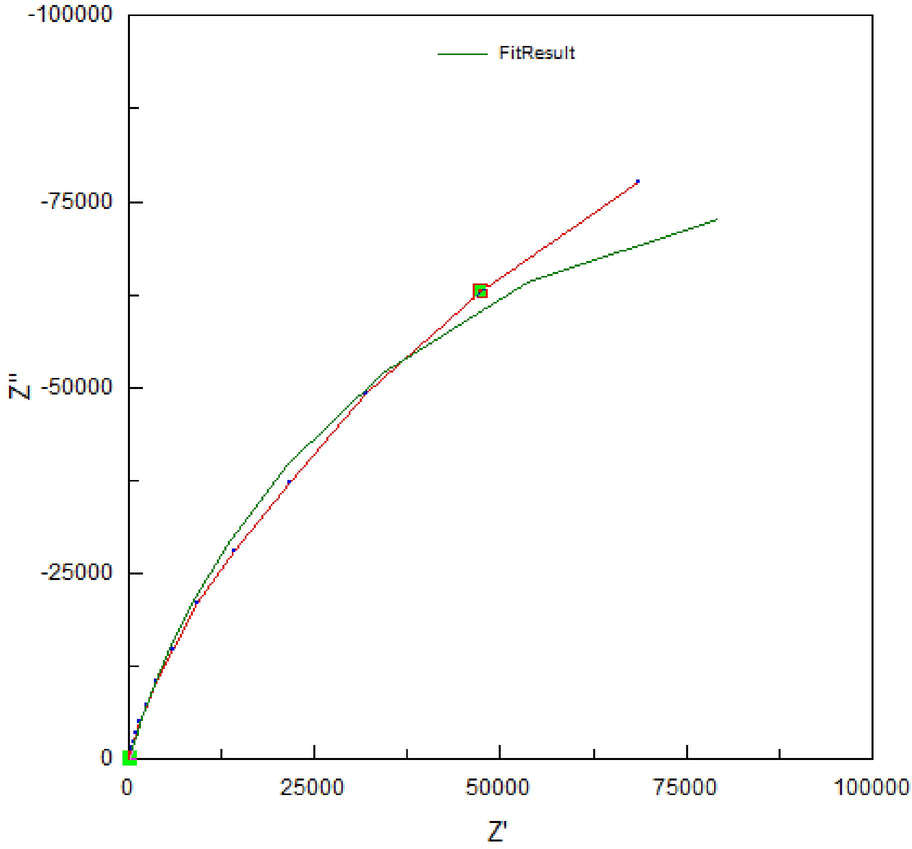
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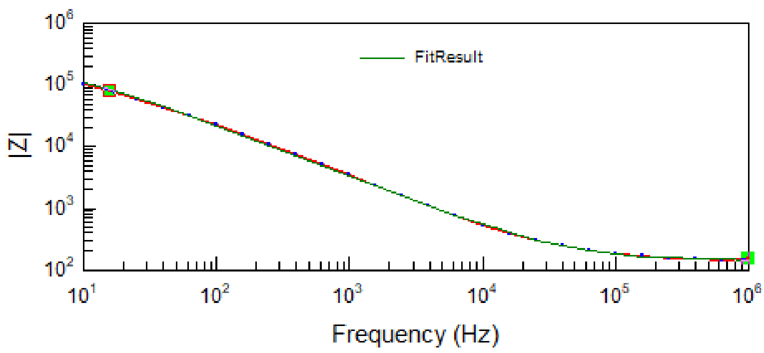
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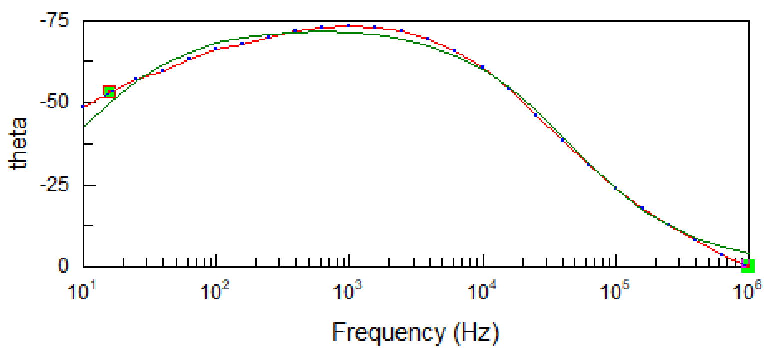
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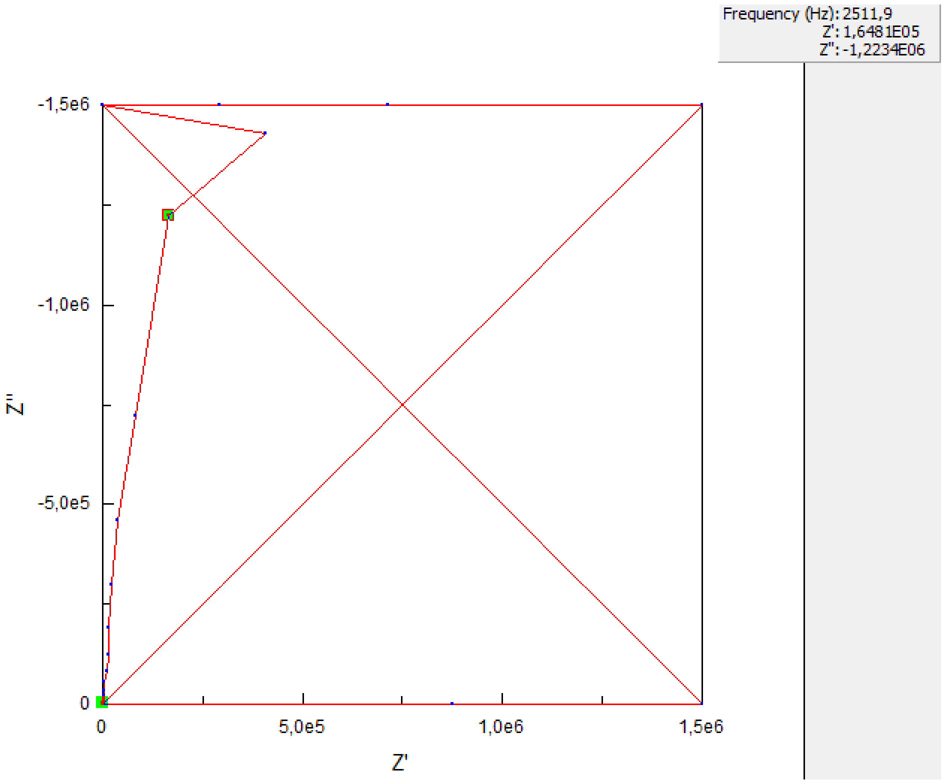
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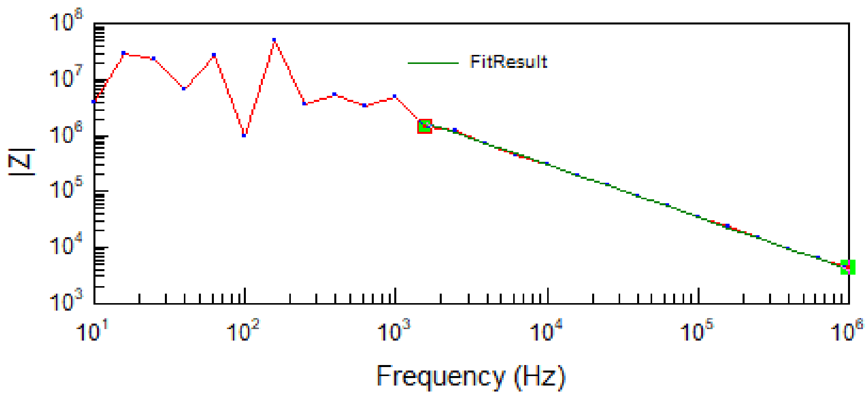
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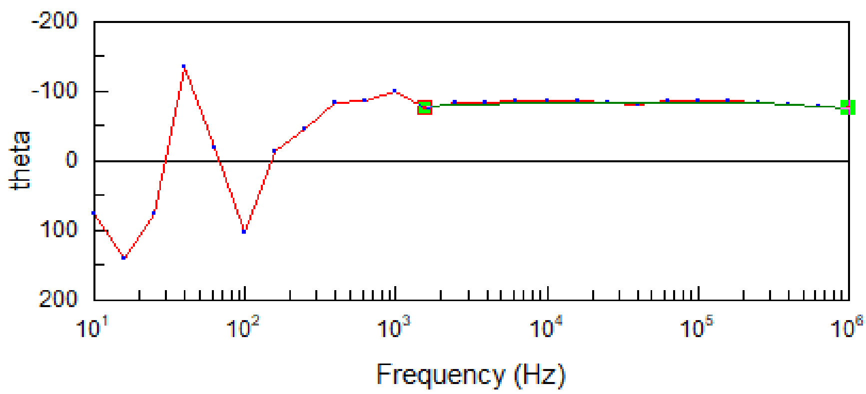
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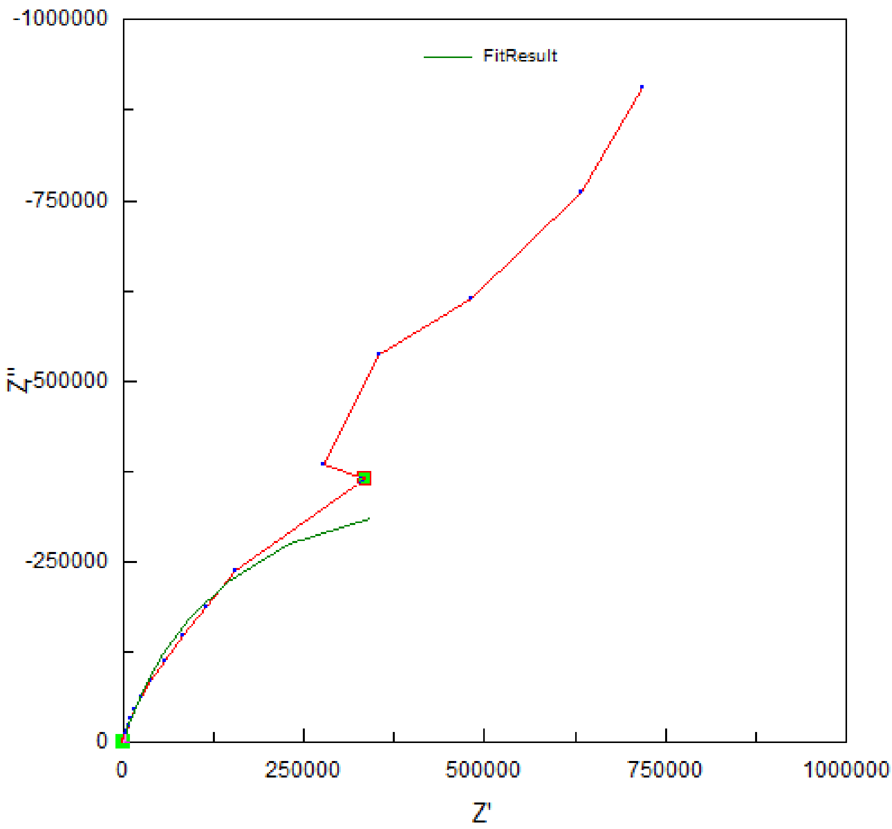
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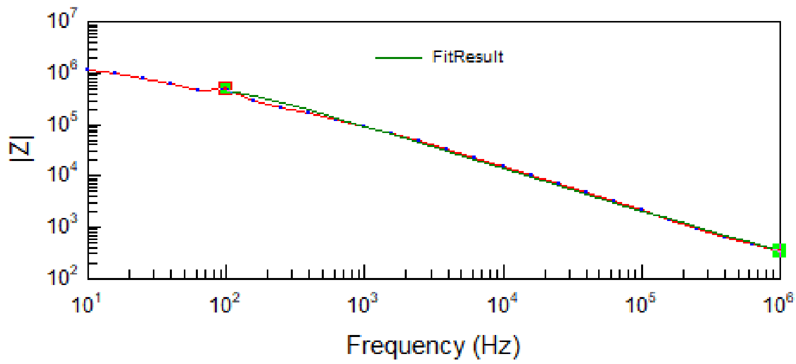
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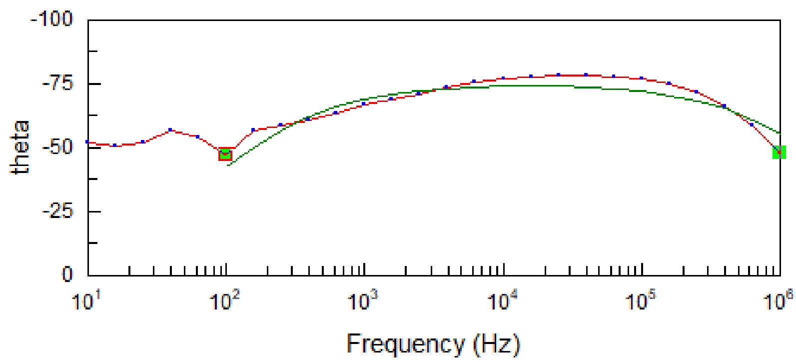
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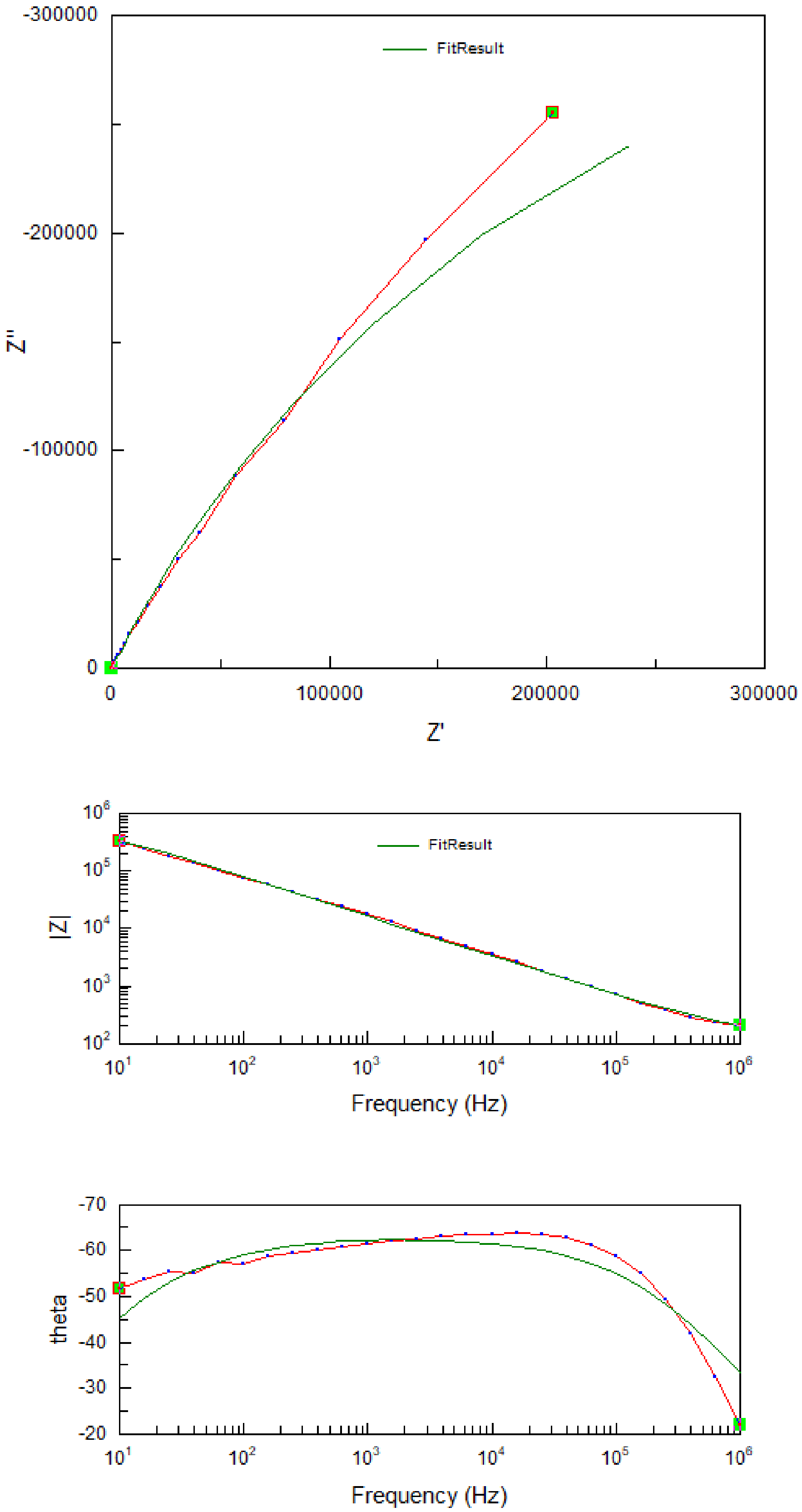
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Frequency (Hz)

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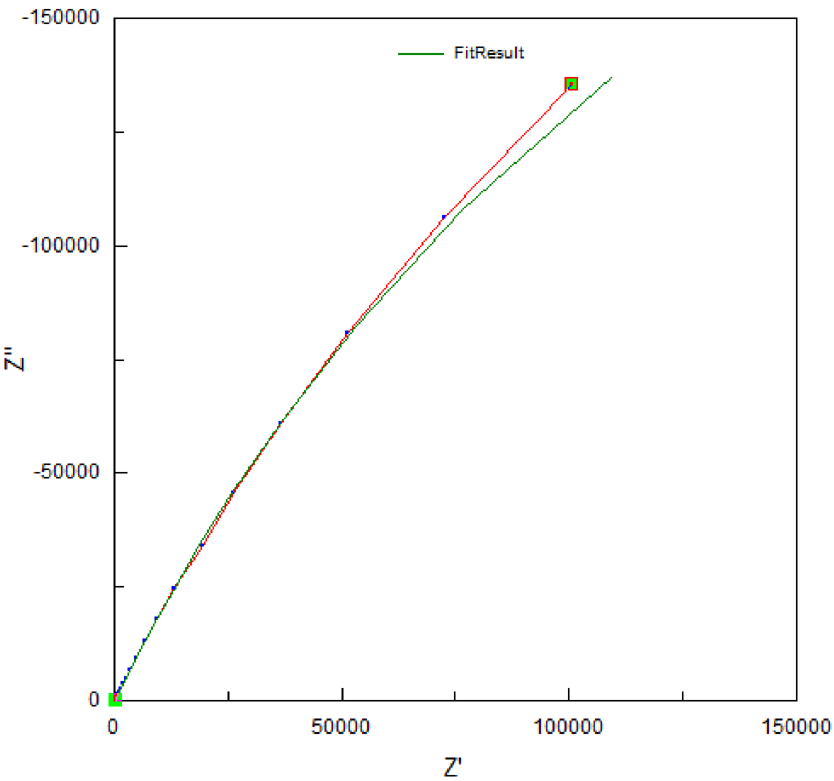
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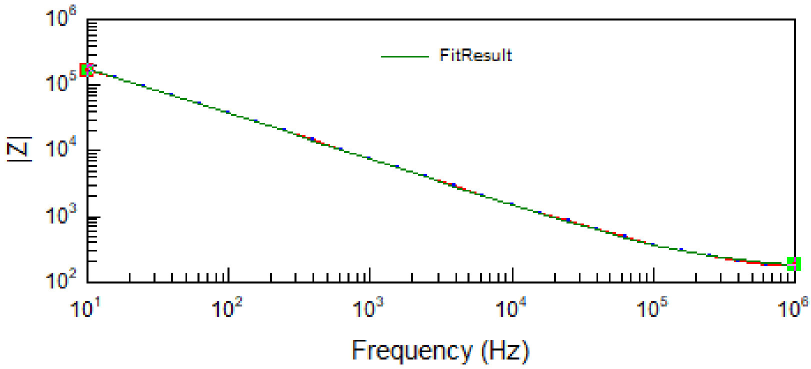
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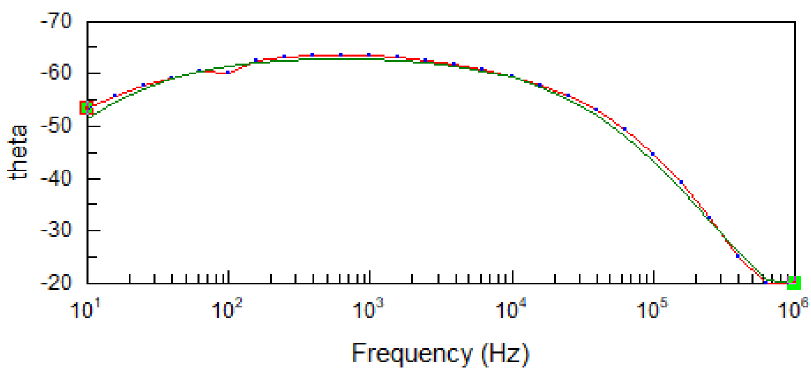
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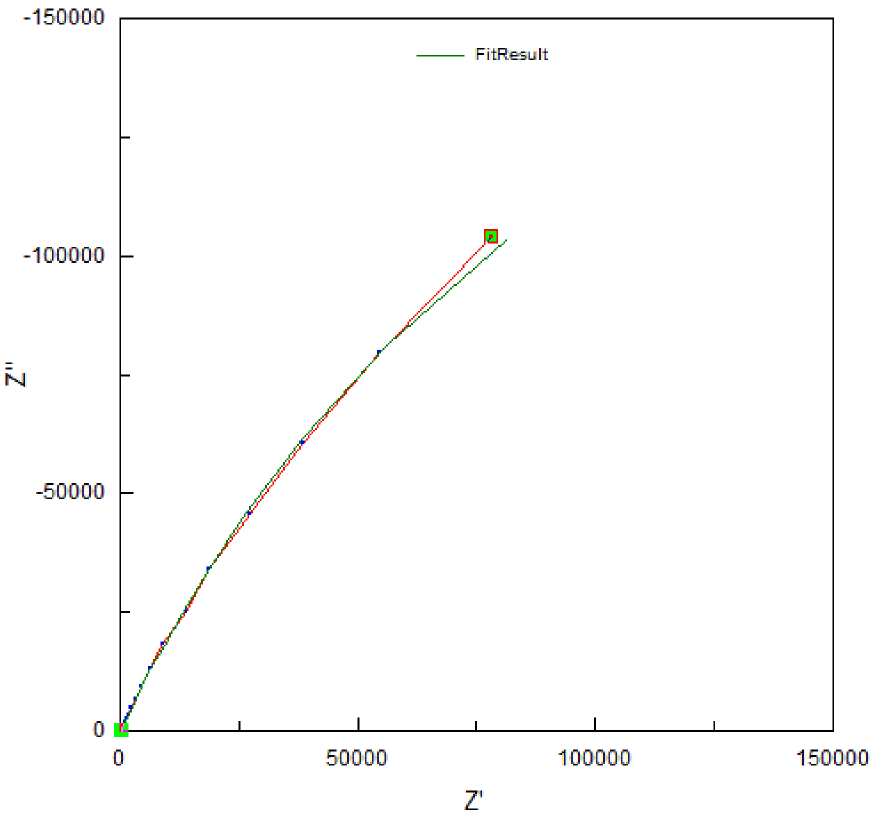
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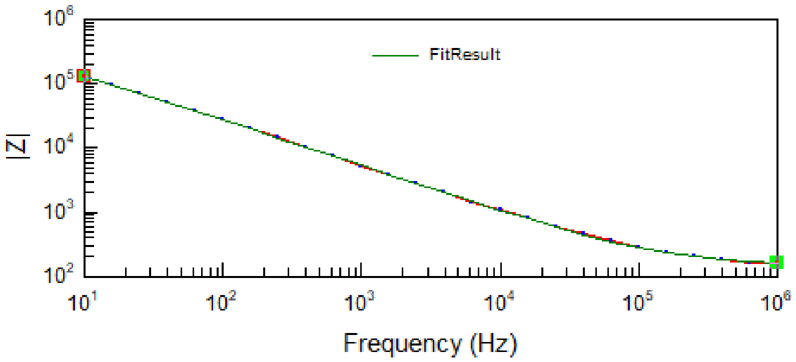
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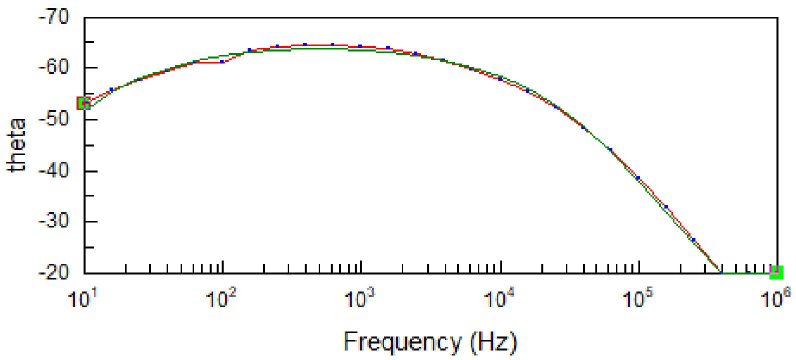
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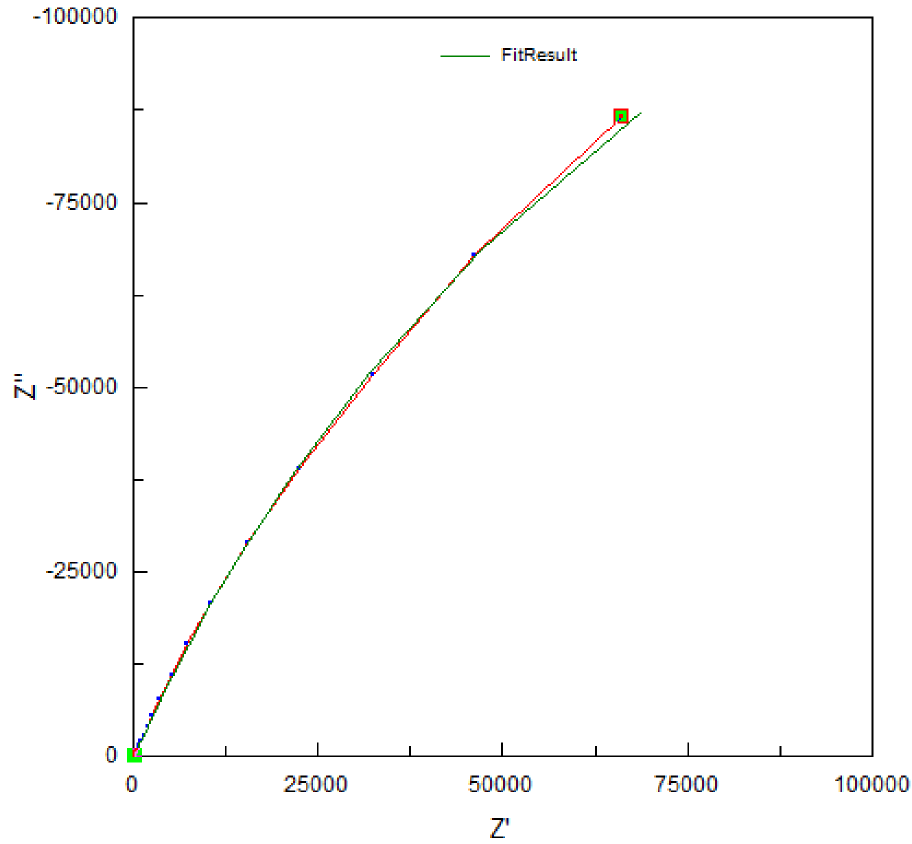
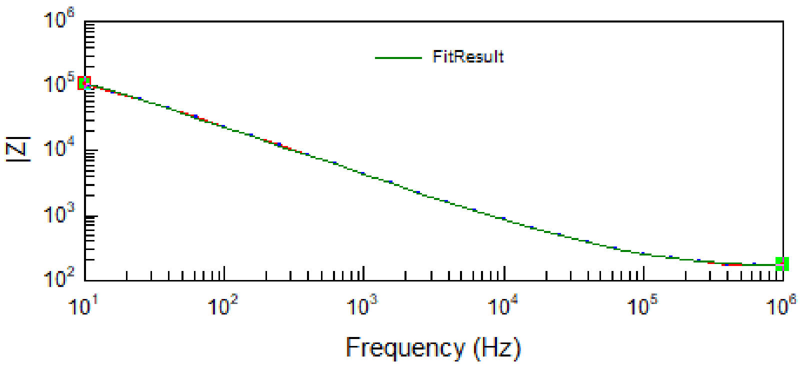
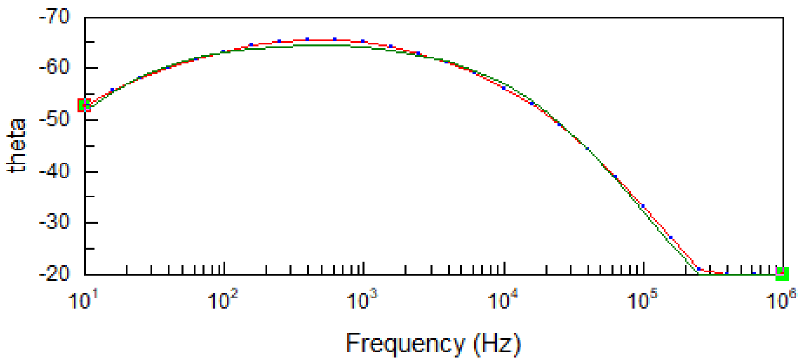
10^2
10^3
10^4
10^5
10^6
Frequency (Hz)

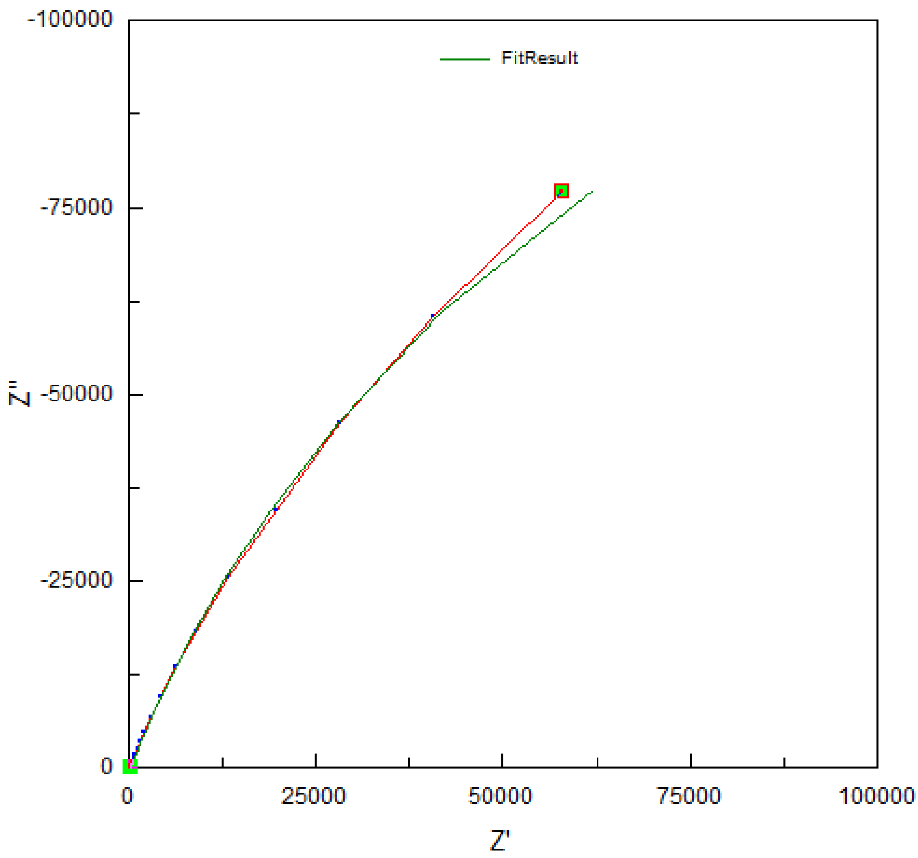
I.12. El. 3.5

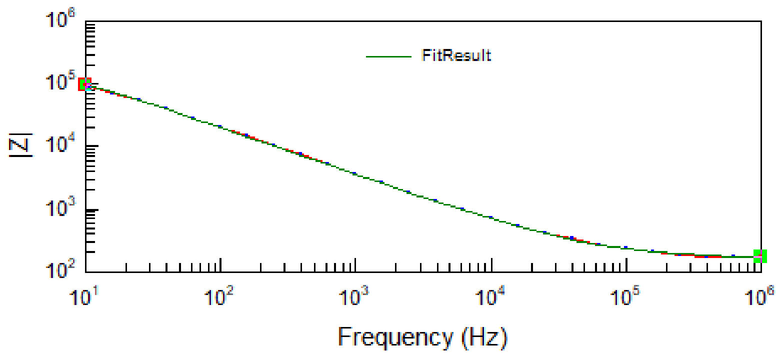

FitResult
-100000
-75000
-50000
-25000
0
Z''
0
25000
50000
75000
100000
Z'

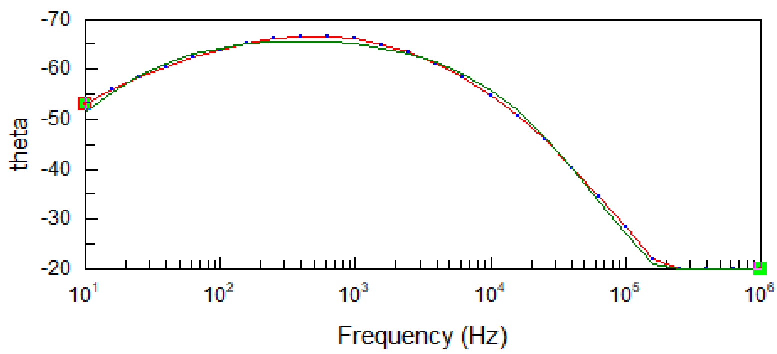

FitResult
|Z|
Frequency (Hz)


-70
-60
-50
-40
-30
-20
theta
Frequency (Hz)

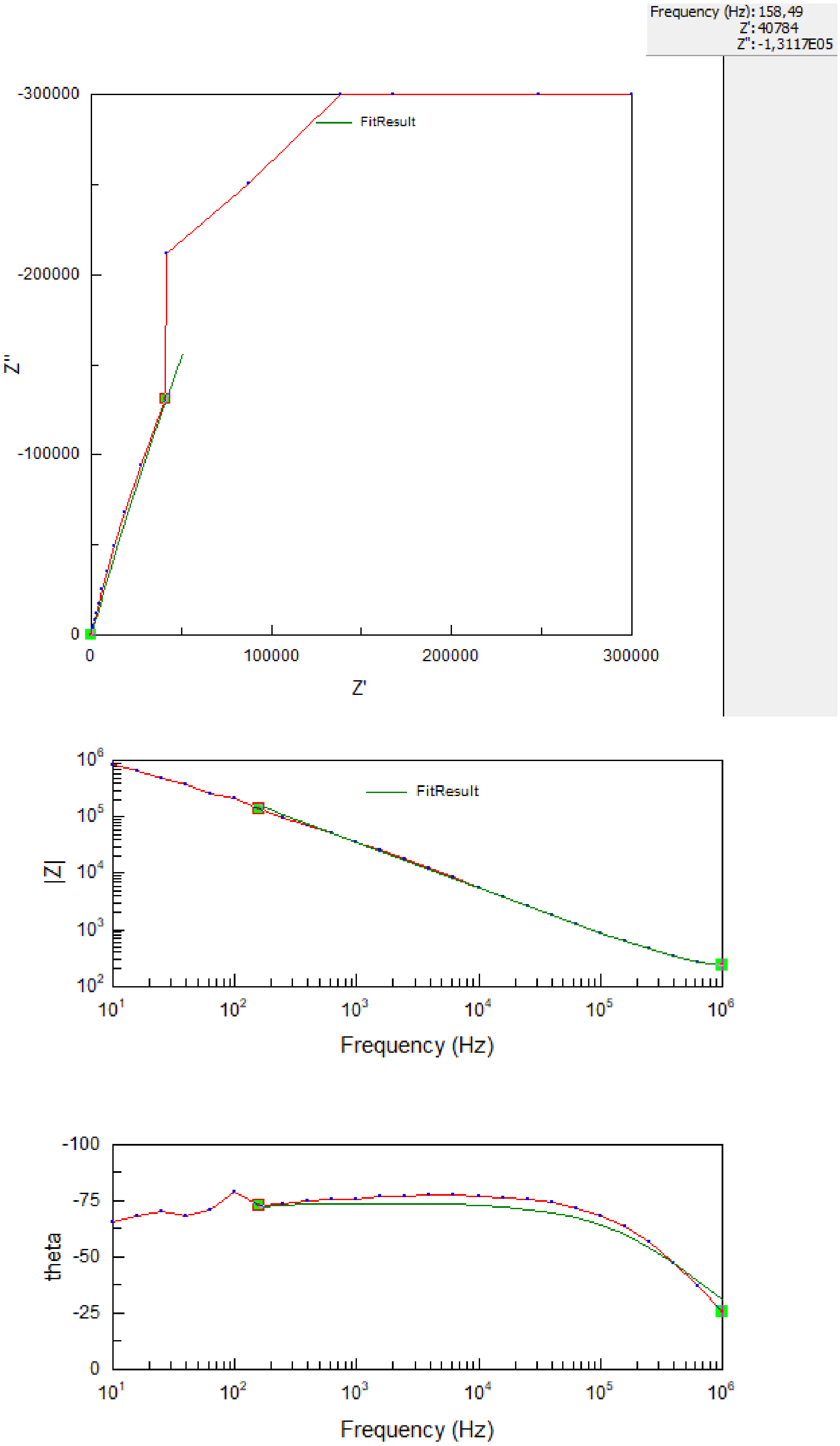
I.13. El. 3.6


-100000
-75000
-50000
-25000
0
Z''
FitResult
0
25000
50000
75000
100000
Z'

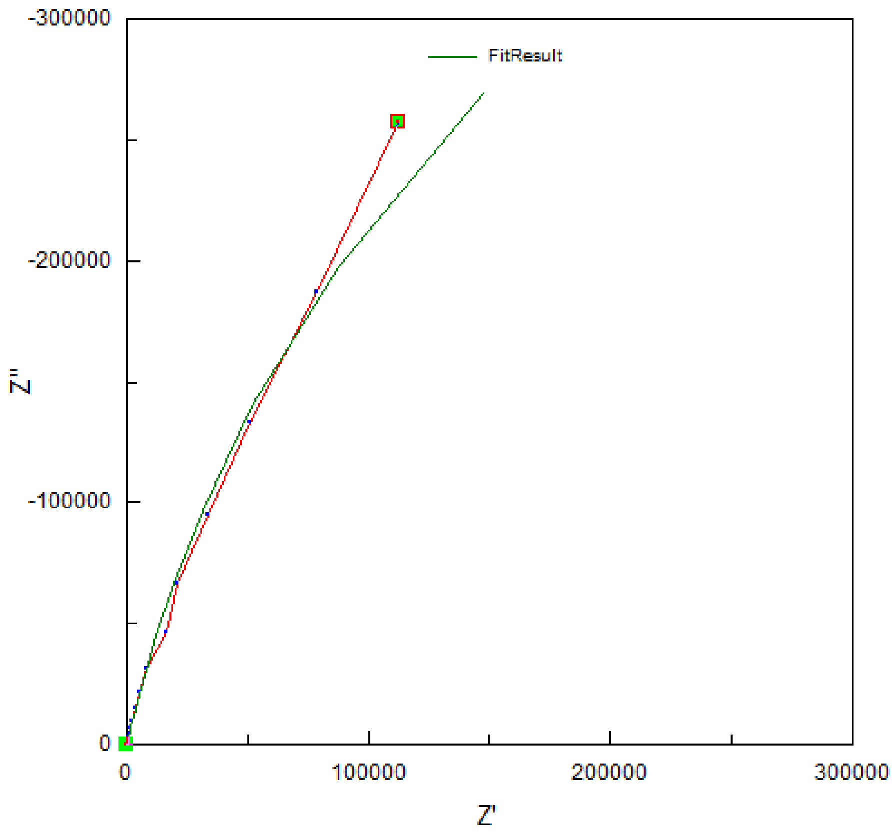

10^6
10^5
10^4
10^3
10^2
|Z|
FitResult
10^1
10^2
10^3
10^4
10^5
10^6
Frequency (Hz)

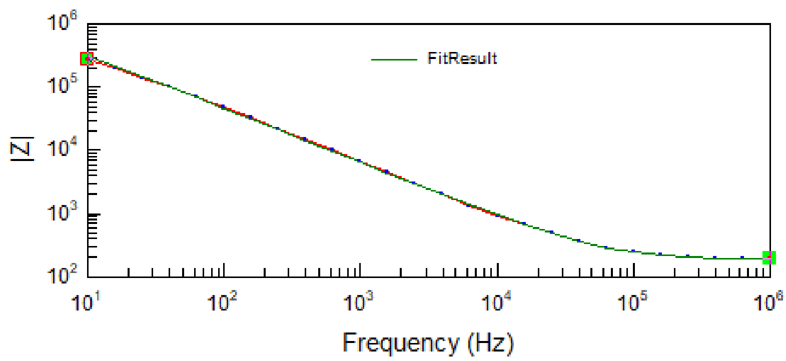

-70
-60
-50
-40
-30
-20
theta
10^1
10^2
10^3
10^4
10^5
10^6
Frequency (Hz)

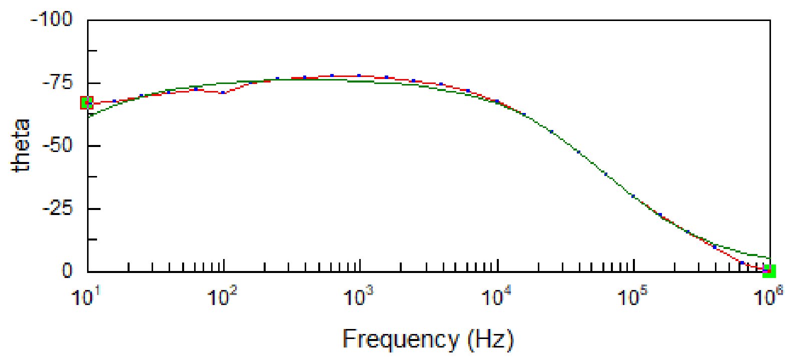
I.14. El. 4.1


Frequency (Hz): 158,49
Z': 40784
Z'': -1,3117E05
-300000
-200000
-100000
0
Z''
0
100000
200000
300000
Z'
FitResult
|Z|
Frequency (Hz)
FitResult
theta
-100
-75
-50
-25
0
Frequency (Hz)

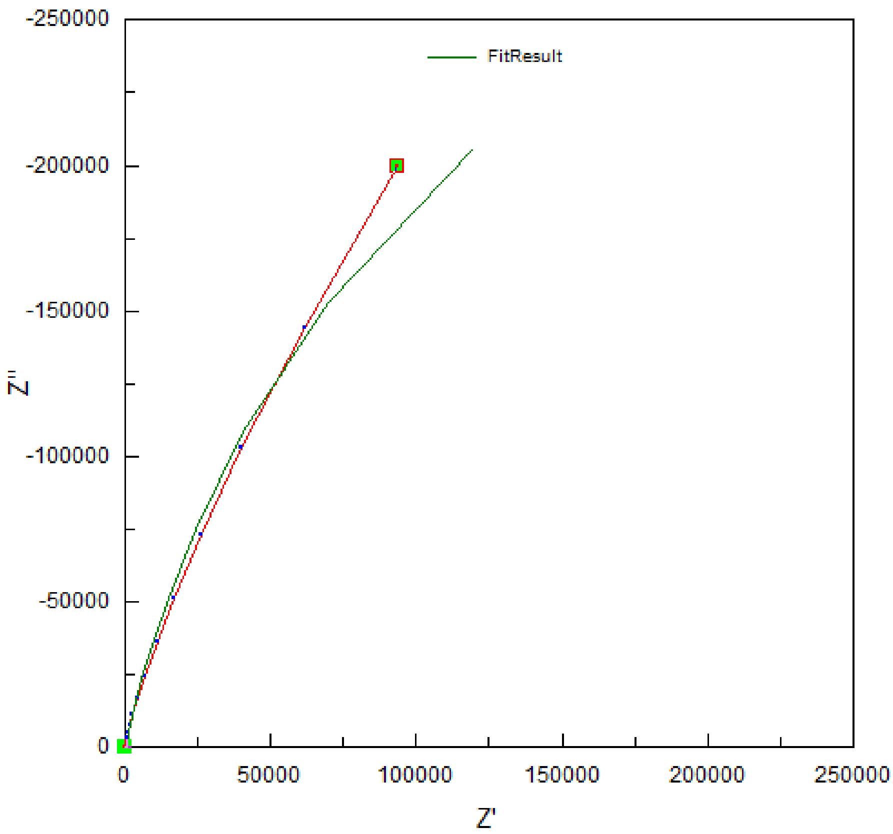
I.15. El. 4.2

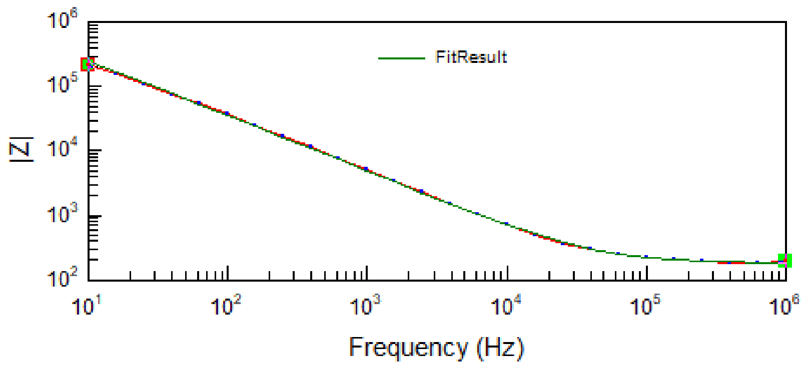

FitResult
-300000
-200000
-100000
0
Z''
0
100000
200000
300000
Z'

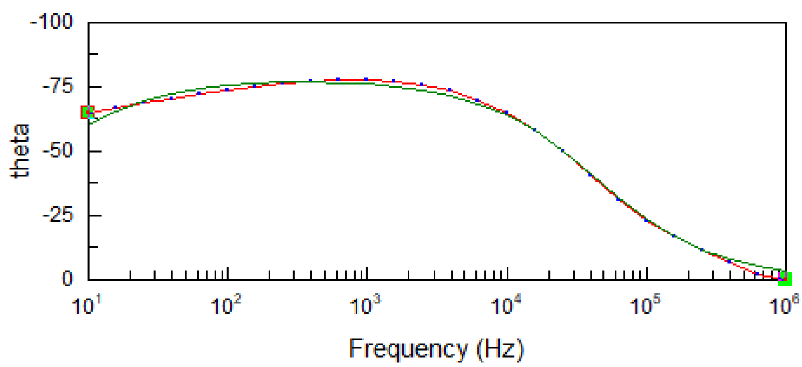

FitResult
10^6
10^5
10^4
10^3
10^2
|Z|
10^1
10^2
10^3
10^4
10^5
10^6
Frequency (Hz)


-100
-75
-50
-25
0
theta
10^1
10^2
10^3
10^4
10^5
10^6
Frequency (Hz)

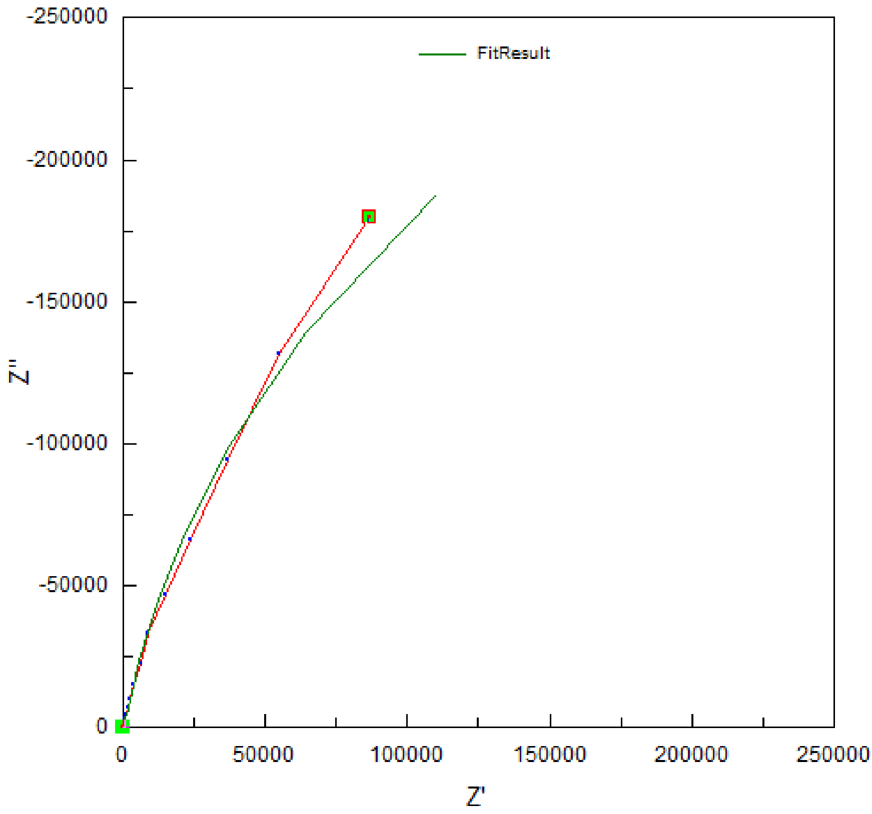
I.16. El. 4.3

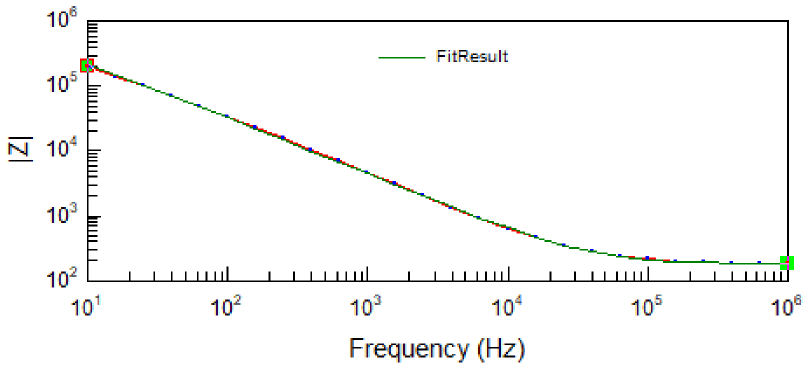

FitResult
-250000
-200000
-150000
-100000
-50000
0
Z''
0
50000
100000
150000
200000
250000
Z'

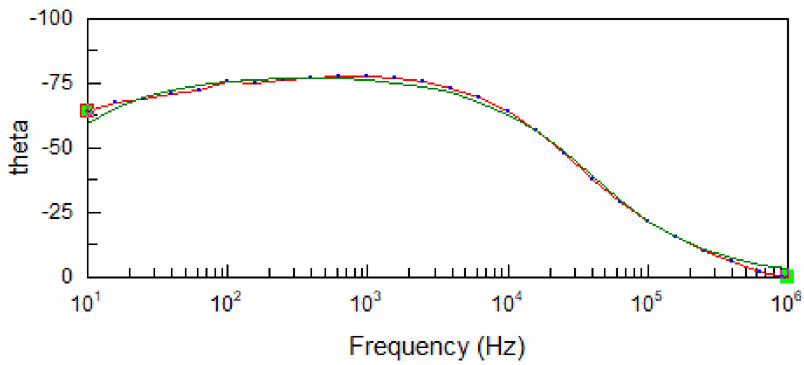

FitResult
|Z|
Frequency (Hz)


-100
-75
-50
-25
0
theta
Frequency (Hz)

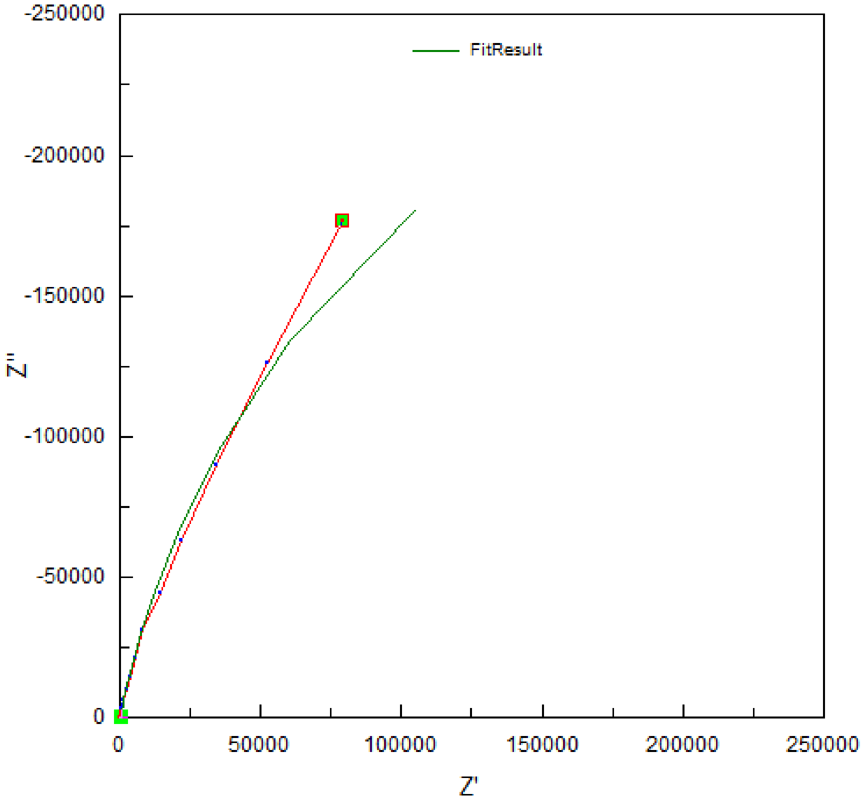
I.17. El. 4.4

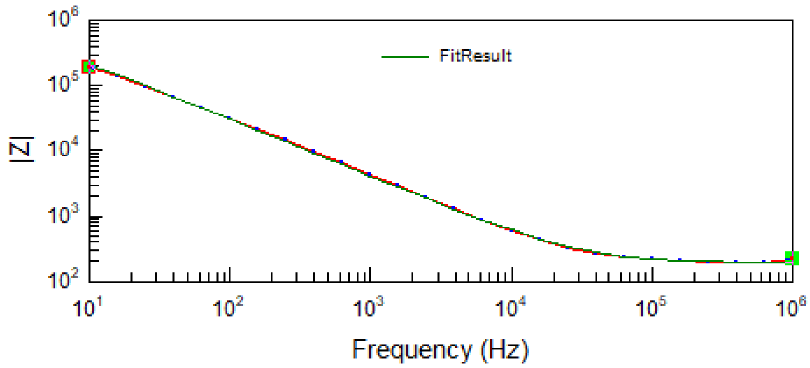

FitResult
-250000
-200000
-150000
-100000
-50000
0
Z''
0
50000
100000
150000
200000
250000
Z'

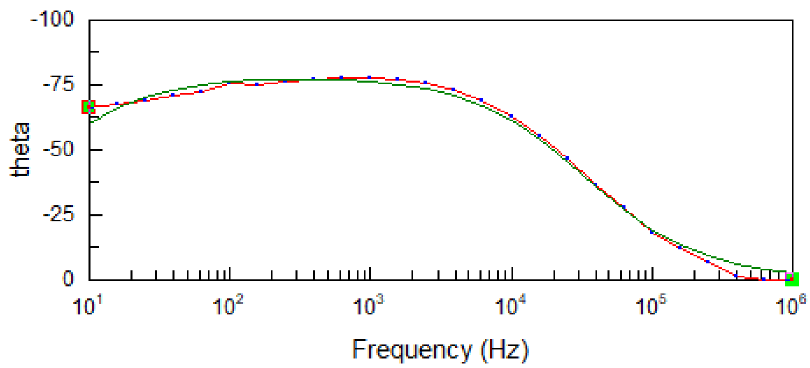

FitResult
|Z|
Frequency (Hz)


-100
-75
-50
-25
0
theta
Frequency (Hz)

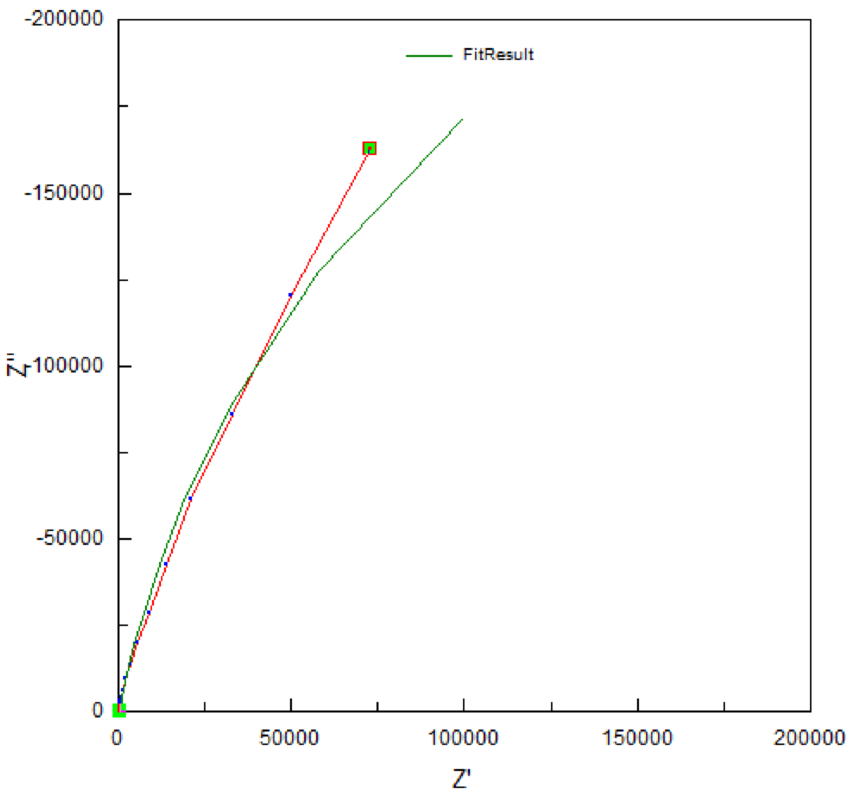
I.18. El. 4.5

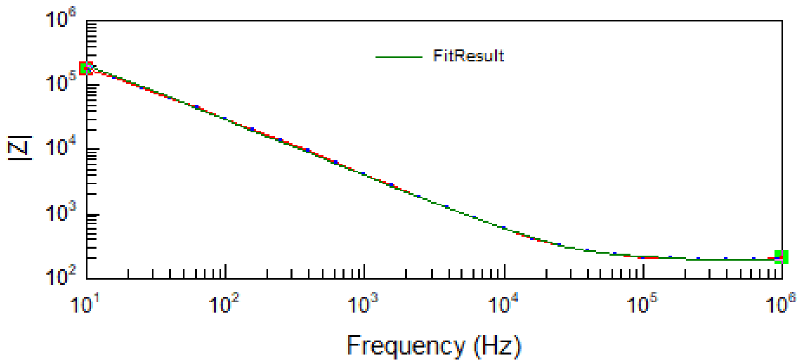

FitResult
-250000
-200000
-150000
-100000
-50000
0
Z''
0
50000
100000
150000
200000
250000
Z'

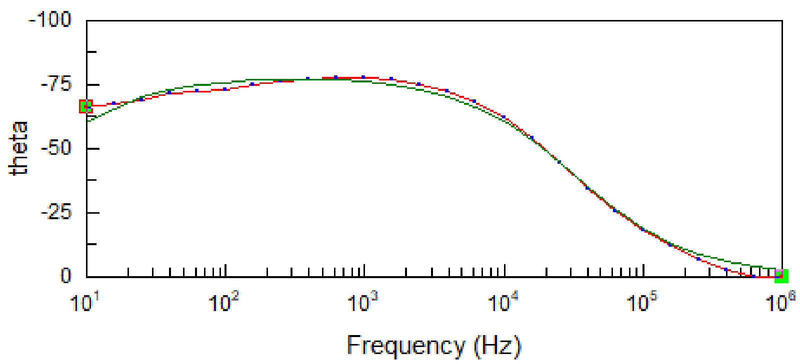

FitResult
|Z|
10^6
10^5
10^4
10^3
10^2
10^1
10^2
10^3
10^4
10^5
10^6
Frequency (Hz)


theta
-100
-75
-50
-25
0
10^1
10^2
10^3
10^4
10^5
10^6
Frequency (Hz)

I.19 El. 4.6

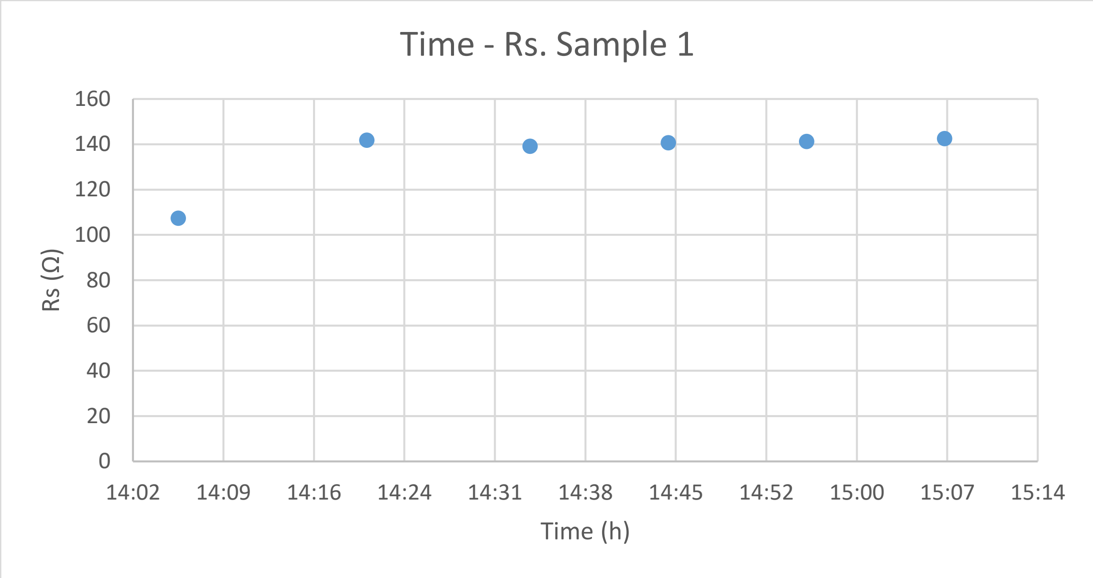

FitResult
-200000
-150000
-100000
-50000
0
Z''
0
50000
100000
150000
200000
Z'

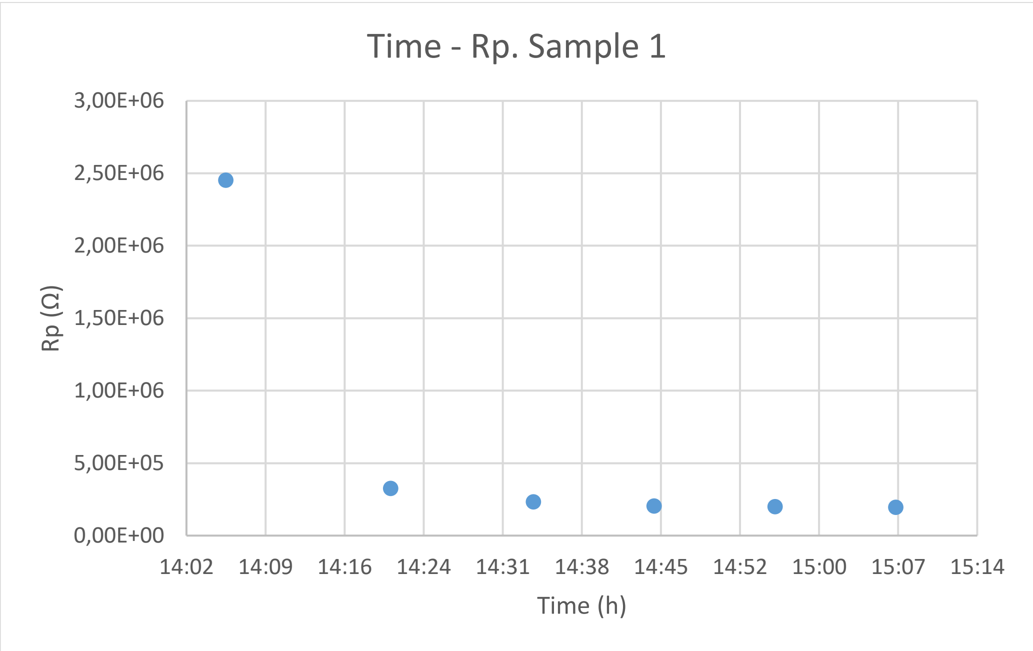

FitResult
|Z|
Frequency (Hz)

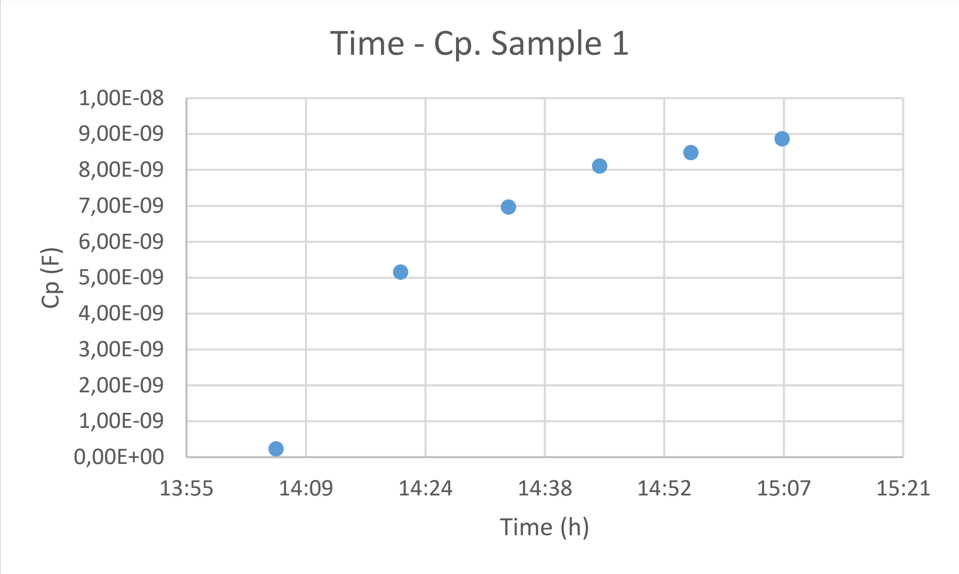

-100
-75
-50
-25
0
theta
Frequency (Hz)

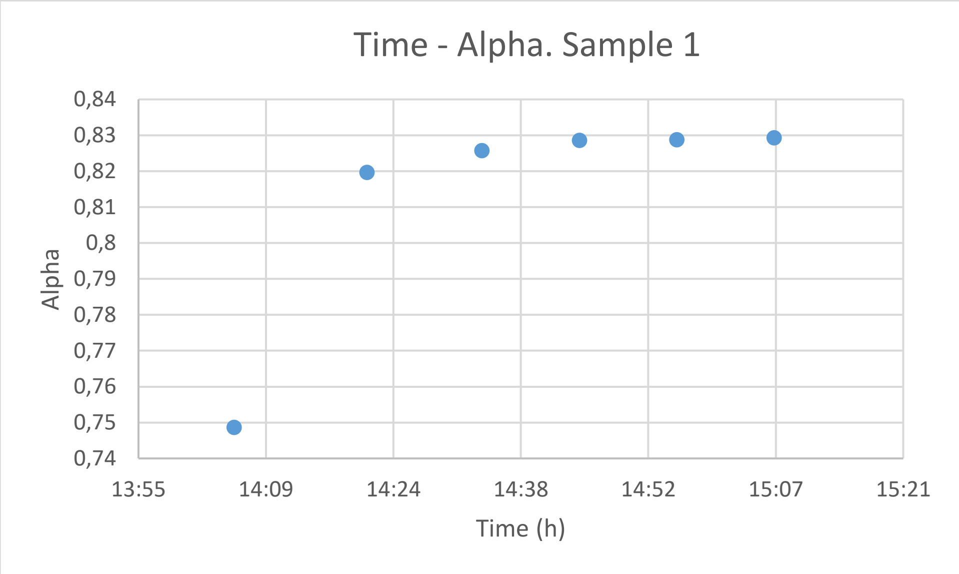
11.10 Appendix J: Time vs. results obtained with ZView – Graphic representations

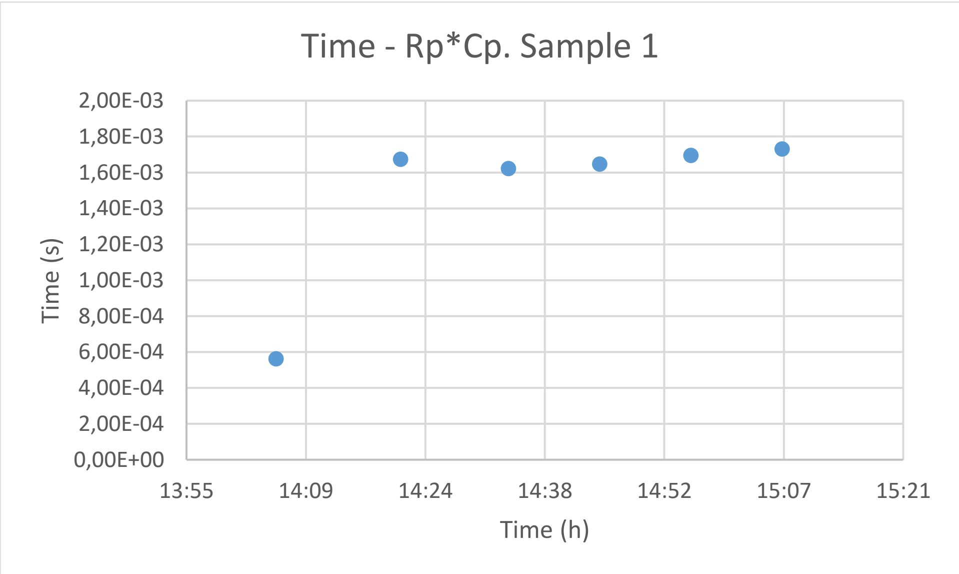
J.1. Sample 1



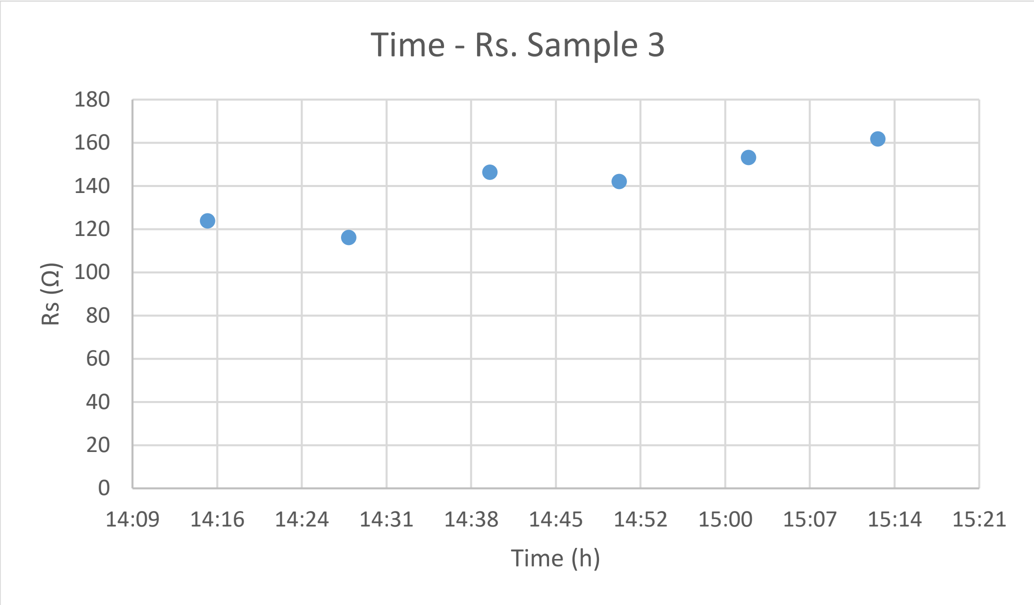


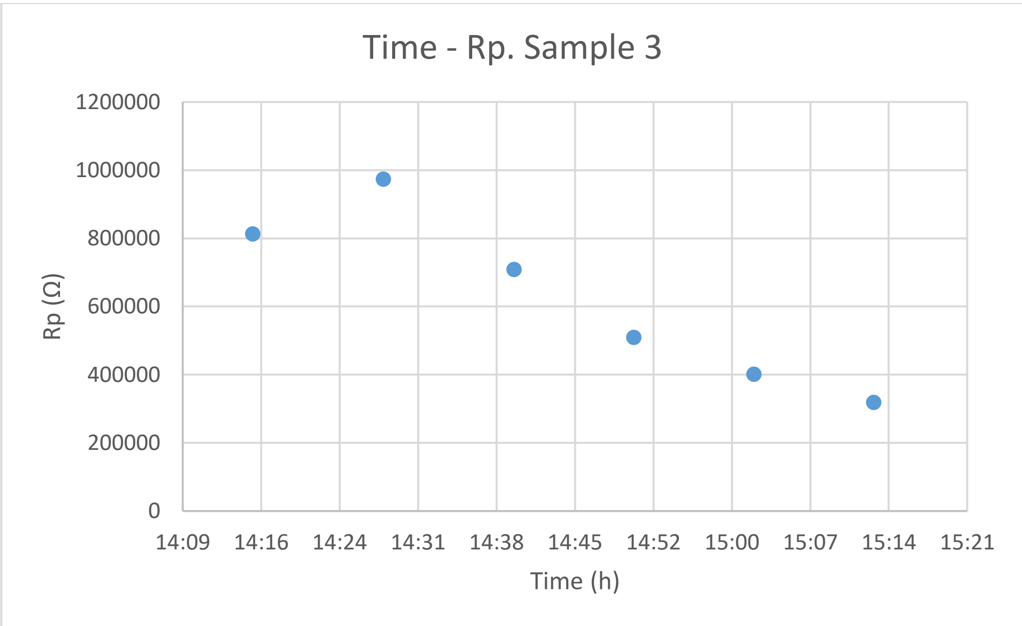

Time - Cp. Sample 1
Cp (F)
1,00E-08
9,00E-09
8,00E-09
7,00E-09
6,00E-09
5,00E-09
4,00E-09
3,00E-09
2,00E-09
1,00E-09
0,00E+00
13:55
14:09
14:24
14:38
14:52
15:07
15:21
Time (h)

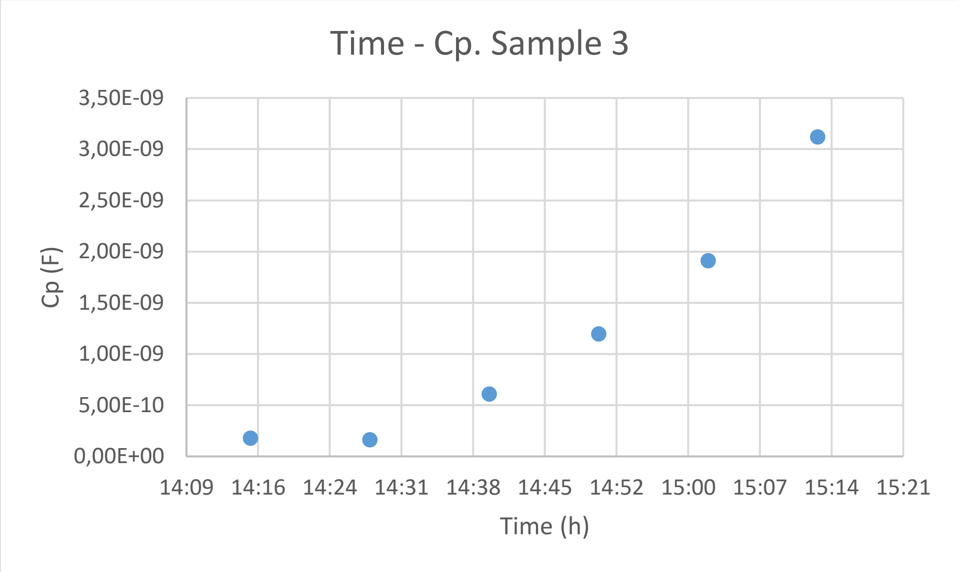

Time - Alpha. Sample 1
Alpha
0,84
0,83
0,82
0,81
0,8
0,79
0,78
0,77
0,76
0,75
0,74
13:55
14:09
14:24
14:38
14:52
15:07
15:21
Time (h)


Time - Rp*Cp. Sample 1
Time (s)
2,00E-03
1,80E-03
1,60E-03
1,40E-03
1,20E-03
1,00E-03
8,00E-04
6,00E-04
4,00E-04
2,00E-04
0,00E+00
13:55
14:09
14:24
14:38
14:52
15:07
15:21
Time (h)

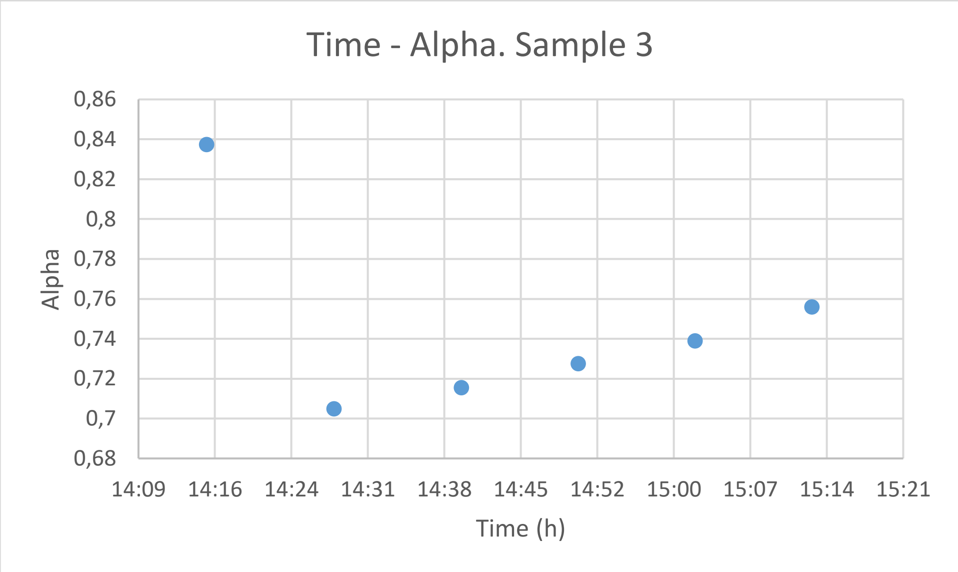
J.2. Sample 3


Time - Rs. Sample 3
180
160
140
120
100
80
60
40
20
0
Rs (Ω)
14:09
14:16
14:24
14:31
14:38
14:45
14:52
15:00
15:07
15:14
15:21
Time (h)

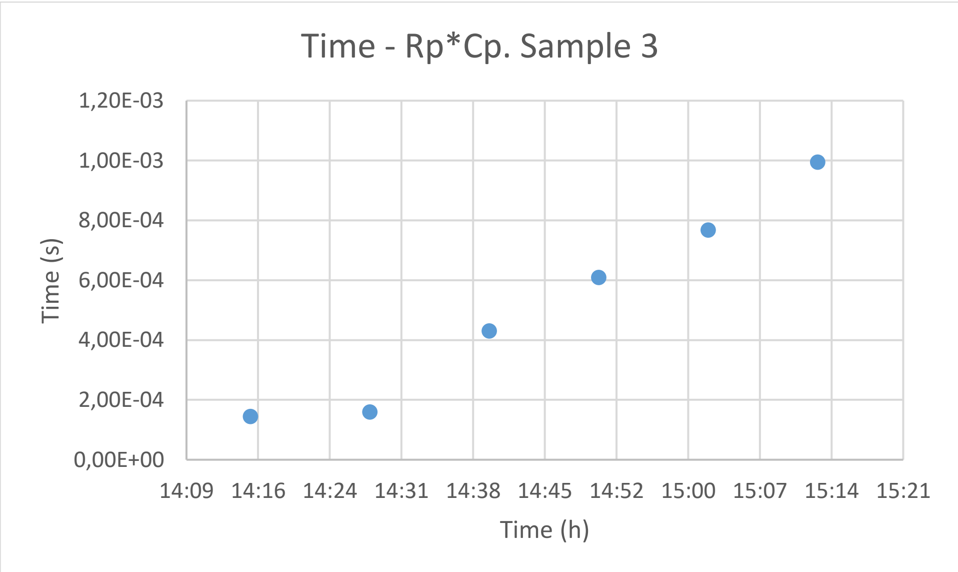

Time - Rp. Sample 3
1200000
1000000
800000
600000
400000
200000
0
Rp (Ω)
14:09
14:16
14:24
14:31
14:38
14:45
14:52
15:00
15:07
15:14
15:21
Time (h)



Time - Cp. Sample 3
Cp (F)
3,50E-09
3,00E-09
2,50E-09
2,00E-09
1,50E-09
1,00E-09
5,00E-10
0,00E+00
14:09 14:16 14:24 14:31 14:38 14:45 14:52 15:00 15:07 15:14 15:21
Time (h)

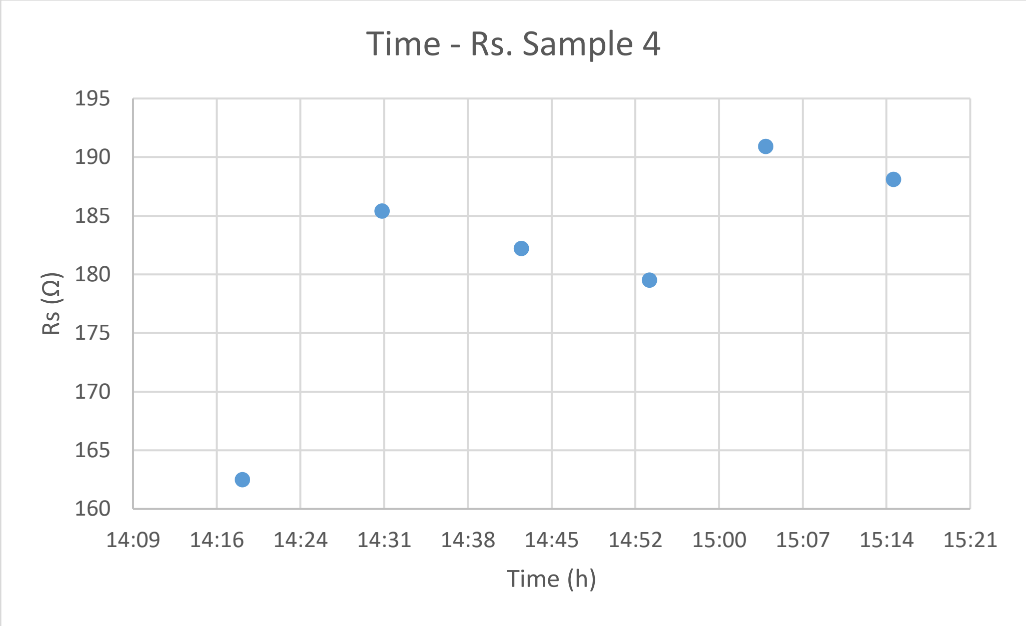


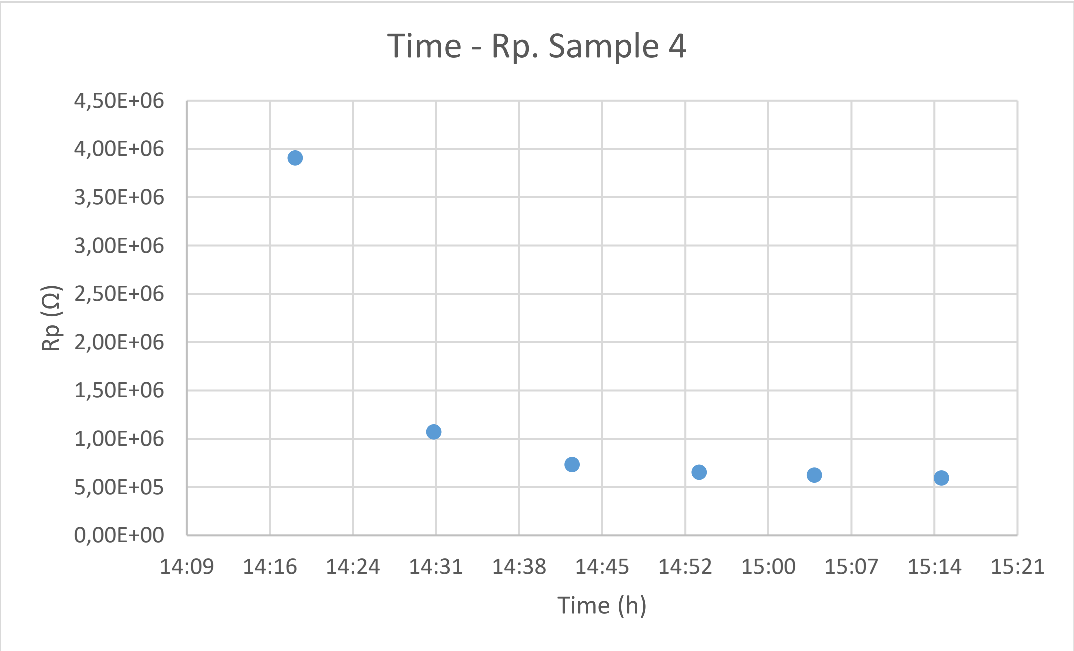
Time - Alpha. Sample 3
Alpha
0,86
0,84
0,82
0,8
0,78
0,76
0,74
0,72
0,7
0,68
14:09 14:16 14:24 14:31 14:38 14:45 14:52 15:00 15:07 15:14 15:21
Time (h)

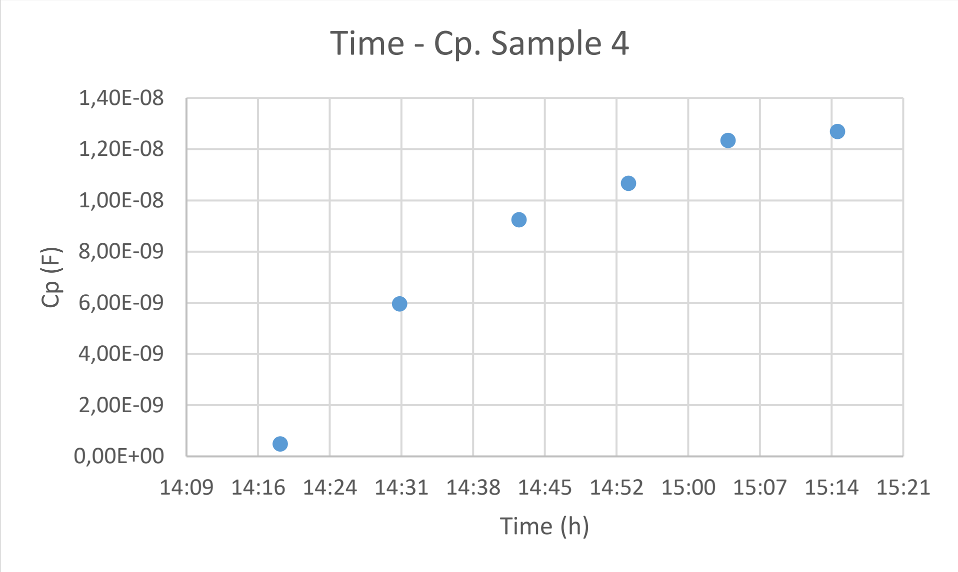


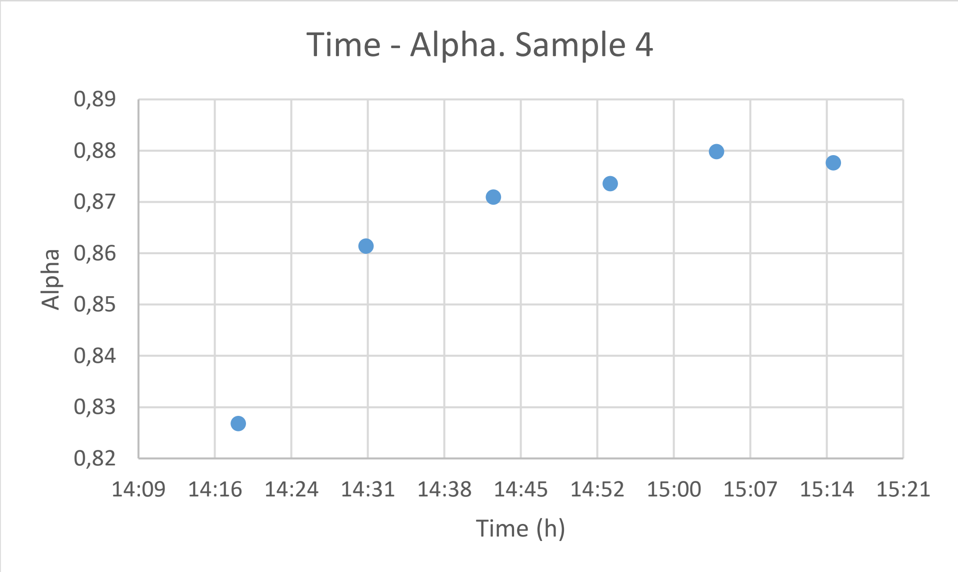
Time - Rp*Cp. Sample 3
Time (s)
1,20E-03
1,00E-03
8,00E-04
6,00E-04
4,00E-04
2,00E-04
0,00E+00
14:09 14:16 14:24 14:31 14:38 14:45 14:52 15:00 15:07 15:14 15:21
Time (h)

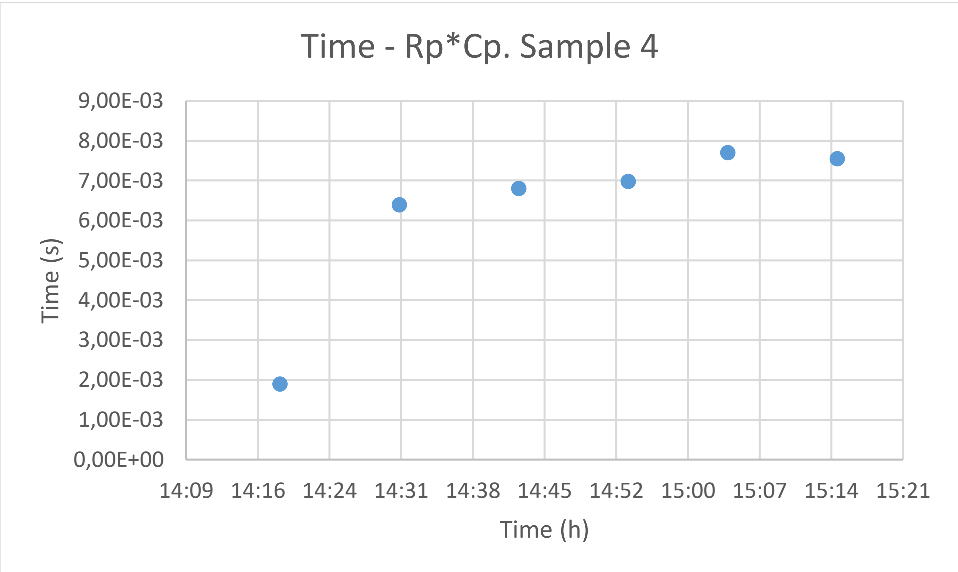
J.3. Sample 4


Time - Rs. Sample 4
Rs (Ω)
195
190
185
180
175
170
165
160
14:09
14:16
14:24
14:31
14:38
14:45
14:52
15:00
15:07
15:14
15:21
Time (h)


Time - Rp. Sample 4
Rp (Ω)
4,50E+06
4,00E+06
3,50E+06
3,00E+06
2,50E+06
2,00E+06
1,50E+06
1,00E+06
5,00E+05
0,00E+00
14:09
14:16
14:24
14:31
14:38
14:45
14:52
15:00
15:07
15:14
15:21
Time (h)


Time - Cp. Sample 4
1,40E-08
1,20E-08
1,00E-08
8,00E-09
6,00E-09
4,00E-09
2,00E-09
0,00E+00
Cp (F)
14:09 14:16 14:24 14:31 14:38 14:45 14:52 15:00 15:07 15:14 15:21
Time (h)


Time - Alpha. Sample 4
0,89
0,88
0,87
0,86
0,85
0,84
0,83
0,82
Alpha
14:09 14:16 14:24 14:31 14:38 14:45 14:52 15:00 15:07 15:14 15:21
Time (h)


Time - Rp*Cp. Sample 4
9,00E-03
8,00E-03
7,00E-03
6,00E-03
5,00E-03
4,00E-03
3,00E-03
2,00E-03
1,00E-03
0,00E+00
Time (s)
14:09 14:16 14:24 14:31 14:38 14:45 14:52 15:00 15:07 15:14 15:21
Time (h)