Spring 5-5-2016

Next Generation Electrode

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The Next Generation Electrode

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1. Introduction

1.1 Problem Definition

An electroencephalogram (EEG) is a common tool used to measure and record electrical activity in the brain. This test is helpful for diagnosing and treating disorders such as epilepsy, brain tumors, head injury, encephalopathy and encephalitis. The number of tests given each year is approximately 10-25 million with a majority used to diagnose epilepsy. The EEG records voltages over time between electrode sensors that pick up the electric potential generated by millions of neurons. The signal is produced by action and post-synaptic potentials of neurons that ultimately change transmembrane potential. This change provides a recording from the surface of the scalp that is generated by the many biopotentials in the brain. Sensors, referred to as electrodes, on the patient's scalp detect these potentials.[1] Before an EEG test begins, the site of application is prepared by lightly abrading the skin to void it of any dead tissue and reduce impedance. A specialized nurse or technologist attaches 16-21 electrodes on the scalp using an electrically conductive paste in a process that can take up to 45 minutes.[2] Usually there are 19 recording electrodes plus a ground and reference electrode to give a total of 21, as seen below in Figure 1. Additional electrodes can also be added to increase spatial resolution for a particular area of the brain.

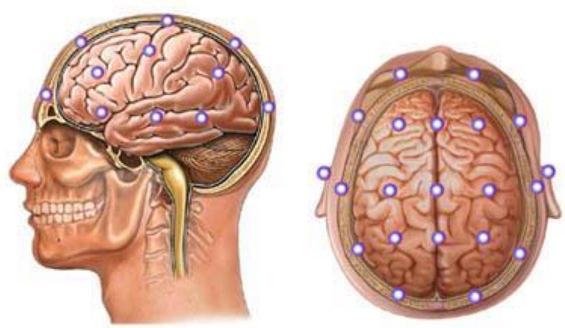

Figure 1. Placement of sensors for and EEG. According to the International 10-20 System, placement of electrodes should follow the figure above. Additional sensors may be used in specialized cases.[2]

In most cases an EEG is performed as one test in a series of neurological evaluations. Seldom does an EEG make the sole basis for a diagnosis. Often an EEG is used in conjunction with Computerized Tomography (CT) scans to diagnose such disorders as epilepsy, tumors, head injury, encephalopathy, and encephalitis. A CT scan can reveal abnormalities such as tumors and bleeding cysts that may lead to epileptic seizures. It uses a rotating X-ray and detector frame to capture cross sectional images of the body. Conventional EEG cup electrodes have a bulky metal crimp that reflects the photons of the X-ray. As a result, conventional EEG electrodes containing the crimps produce a starburst artifact on the CT image.[4] Artifacts can compromise the image, cause it to become unclear, and even unreadable. If a physician wishes to record EEG data before and after performing a CT scan, they would have to remove all of the electrodes and replace them after the scan. This task not only increases cost to the facility, but also affects quality of patient care. Every time the electrodes are removed, vital brain information is not being recorded. If a trained technician is not available to place the electrodes back on, even more time goes by in which signals are not being recorded. The patient is also at an increased risk for skin irritation and breakdown due to the multiple rounds of skin abrasions and reapplication of the conductive gel. The risk for skin irritation and breakdown may prevent the electrodes from being placed on the same portion of the skin, which may cause inconsistencies in the signal readings.[5]

Because Rhythmlink noticed the source of most electrode starburst artifacts in a CT image came from the crimping of the lead wire of the pin, they developed the Invisa-Electrode.[4,6] This new electrode uses a biocompatible, conductive adhesive to join the electrode to the lead wire. The only source of magnetic properties found in the electrode is un-tinned copper wire found in the lead wire that is inserted into the hollowed pin. However, the magnetic properties of this metal composition are so minimal that they generally do not cause artifacts.[8] The downside of the Invisa-Electrode can be attributed to the manufacturing process. Making the electrodes is cumbersome, costly, and time consuming due to the conductive adhesive and a heat shrink placed over the connection.[4,6] Because this design relies on the conductive properties of the adhesive in order to transfer the signal from the electrode cup to the lead wire, the adhesive must be applied accurately to the connection between the cup and wire. To address these issues, it was necessary to create a new adhesion technique that would encompass the same characteristics of the current Invisa-Electrode while simplifying the manufacturing process. This resulted in the solution pathway known as the hollowed pin approach.

The hollowed pin approach prototype was made without using the conductive adhesive and the heat shrink, both of which are issues in the manufacturing process. The electrode design was altered to create a hollowed pin geometry that would allow the electrode lead wire to be inserted into the pin. Heat staking, a type of heat welding, was then used to secure the wire within the pin. Additionally, the plastic used to produce the cup electrode was altered to a 40% carbon loaded conductive polymer that allowed the signal to be carried through the electrode directly to the lead wire.

There are currently very few CT compatible EEG electrodes on the market. Ives EEG Solutions, a competitor to Rhythmlink, has a product on the market which has been FDA approved to be CT compatible. Their electrodes are made of conductive Ag/AgCl impregnated plastic. In order to record an EEG with the quality of metal electrodes, a thin layer of conductive silver epoxy is added. Pictures of the final product indicate that the Ives Imaging Friendly EEG Electrode System still used metal crimping and a heat shrink. If this is the case, then the electrodes are not completely artifact free by the standards set out by Rhythmlink. Additionally their electrodes are not considered disposable. This may result in poor recordings if the electrodes are not cleaned properly. Cleaning chemicals such as acetone will dissolve the plastic and other materials may scratch the silver epoxy coating. Additionally, no patents on the individual electrodes have been found.[7]

1.2 Goals & Objectives

1. The first goal of this project was to obtain the most optimal connection technique. This technique was easier to manufacture than the current ABS plastic electrodes, but retained key

properties such as continuity and artifact free CT imaging. This goal was completed by adhering to the following objectives:

- Create a prototype without the heat shrink and conductive adhesive
- Produce a connection tensile strength of 15 Newton's
- Minimize starburst artifacts in CT scan
- Maintain signal quality and noise production

2. The second goal of this project was to increase manufacturability and decrease cost to Rhythmlink. This would make the new electrode marketable, and should be completed by adhering to the following objectives:
    - Decrease production time by 10%
    - Decrease production cost by 10%

1.3 Alternative Solutions

In the beginning stages of the project, multiple solutions were considered. The first option was the use of a plastic crimp in place of the metal crimp Rhythmlink currently uses. This solution was discarded due to the complexity of developing a new crimping system. Overmolding was also considered. In this scenario, the company that currently extrudes Rhythmlink's conductive plastic electrodes would place the stripped end of a lead wire into the current electrode mold. A powdered conductive plastic would then be placed into the mold, heated and melted directly over the wire in order to create a connection. Due to the amount of outsourcing, this was not an ideal solution. Another alternative solution considered using a conductive heat shrink to secure the lead wire to the electrode pin. The conductive heat shrink would be placed over the wire to pin connection and heated until the heat shrink decreased in size, creating a tight connection around the wire and electrode. This solution could help in manufacturing by eliminating the conductive adhesive

2. Design

In order to decrease the manufacturing time and cost of Rhythmlink's EEG electrode production, the number of components currently used in the design were reduced. Most importantly, the conductive adhesive was removed because it causes difficulties and time delays during EEG electrode production. These objectives were achieved through the development of a hollowed pin design.

2.1 Hollowed Pin Approach

The current EEG electrode used by Rhythmlink has a solid cylindrical pin extending from the electrode cup. The lead wire was then placed on top as seen in Figure (A), followed by the addition of conductive adhesive and a shrink wrap. Rhythmlink has perfected the cup geometry to be optimal for testing in a clinical setting. Because of this, the current cup design used by RhythmLink was not altered. The pin design was changed, however, to a hollowed cylinder extending up to the electrode cup wall as seen in Figure (B). The hollowed pin allowed for the lead wire to be inserted into the hollow cavity. The pin was then welded around the wire using a heat stake. Hollowing out the EEG electrode cup pin, removed the heat shrink and conductive adhesive from the current Invisa-Electrode design used by RhythmLink.

2.1.1 Use of Conductive Plastic

The material used to mold the EEG electrode cups was changed from a simple thermoplastic, acrylonitrile butadiene styrene (ABS), to a 40% carbon loaded ABS conductive polymer. The 40% carbon loaded ABS conductive polymer was used rather than the ABS non-conductive polymer because it can propagate a signal from the scalp through the cup and into the lead wire without the use of conductive adhesive. The conductive plastic allows for the removal of the Ag/AgCl coating, but removal of the coating could increase resistance and decrease signal quality.

2.1.2 Pin Design Geometry

The pin was hollowed out slightly larger than the 0.75 mm diameter un-tinned copper lead wire. The internal diameter of the pin was made as close as possible to the diameter of the lead wire in order to enhance the amount of contact points between the internal wall of the pin and the lead wire, while also allowing for easy insertion of the wire into the hollow pin.

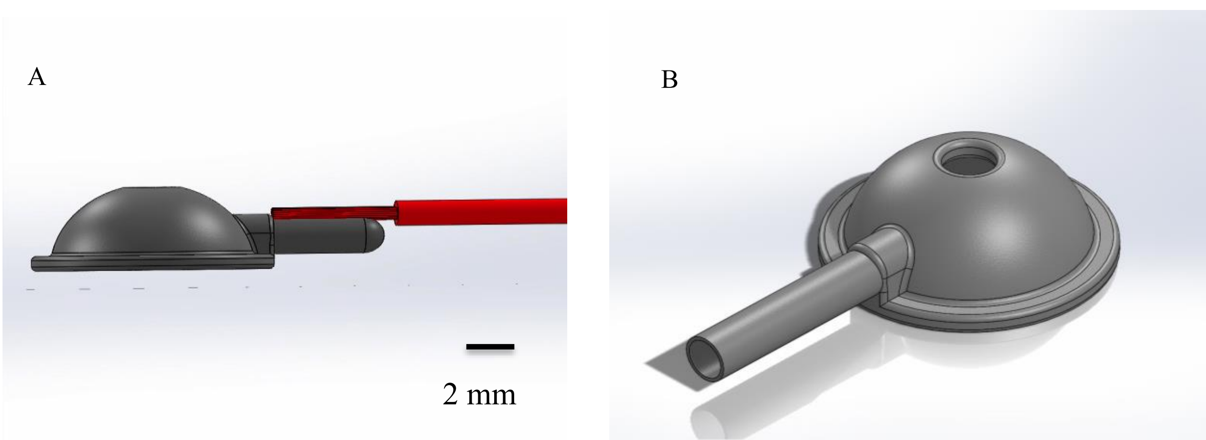

Figure 2. (A) Rhythmlink's current EEG cup electrode. This electrode cup design is used in Rhythmlink's conventional EEG electrodes along with the current Invisa-Electrode. In the scenario of the Invisa-Electrode the lead wire is adhered to the top of the pin using conductive adhesive. Next, a heat shrink is shrunk over the connection joint. **(B) New hollowed out design.** This figure shows the hollowed out pin design created in SolidWorks.

The designs were then 3D printed using an ABS-like clear plastic as seen in Figure 3. The ABS-like plastic material was chosen because it had similar properties to the conductive ABS plastic and was cheap in price. The pin length was 8.5 mm from the center of the cup to the end of the pin, the pin diameter was 1.2 mm, and the inside hollow diameter of the pin is shown to be 0.75 mm, leaving a pin wall thickness of 0.225 mm.

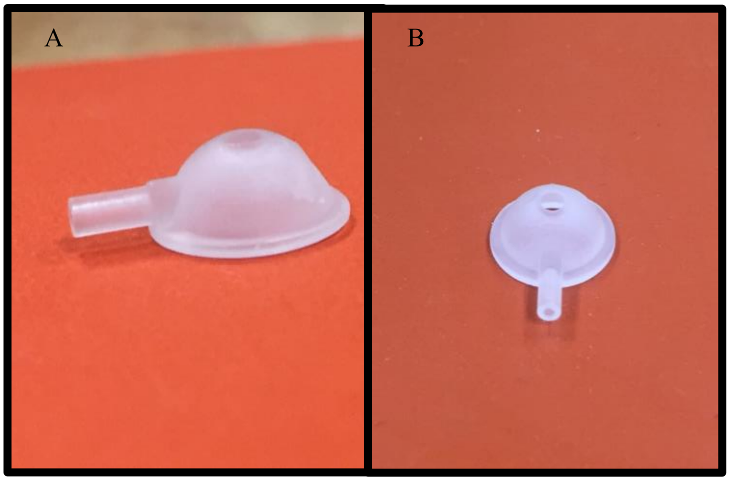

Figure 3. Multiple views of 3D printed prototype. From The hollowed out pin can be seen in Figure B.

2.1.3 Lead Wire

An un-tinned copper lead wire was used because it is CT compatible and further enhances in optimizing the solution. The un-tinned wire is also much thinner than tinned wire with a diameter of .75 mm and a total diameter including the PVC coating of 1 mm. The small size allows the lead wire to be easily inserted into the hollow pin. This insertion can be seen in Figure 4.

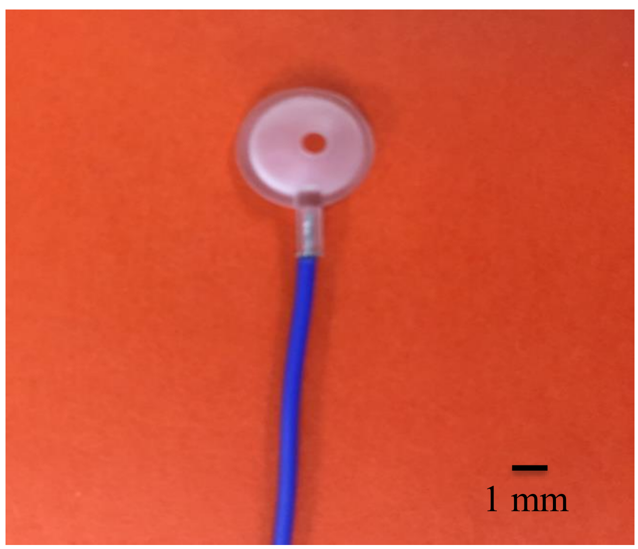

Figure 4. Lead wire and pin connection. This image shows the un-tinned copper lead wire fitting securely inside the ABS-like plastic hollowed pin prototype. The internal diameter of the hollowed pin is 0.75 mm and the diameter of the un-tinned lead wire is just under 0.75 mm in diameter.

2.1.4 Heat Staking Form

To enhance the method of heat staking, a form was designed in PTC Creo as seen in Figure 5. The form held the cups and wire in place so that they would not move upon applying pressure from the heat stake. The area being heat staked was so small that a solid base, free of movement, was needed for the design.

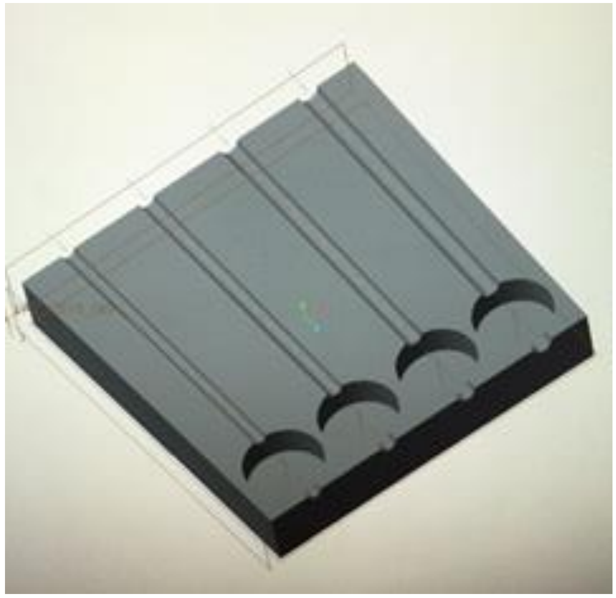

Figure 5. Heat staking form. This device allows the electrode and wire to be held tightly in place during heat staking.

2.1.5 40% Carbon Loaded Conductive Plastic Electrodes with Hollowed Pins

The final aspect of the design was a prototype of the 40% carbon loaded conductive plastic electrode with a hollowed out pin, and is shown in Figure 6. The pins were hollowed by a drill press with a 0.78 mm diameter drill bit to allow for a tight fit around the 0.75 mm diameter un-tinned copper wire. A 1.1 mm diameter drill bit was then used to widen the opening to fit the 1 mm lead wire with PVC. This was critical in the design to further enhance the mechanical strength of the electrode joint connection, as including the PVC inside of the pin while heat staking established a stronger connection than only including the lead wire.

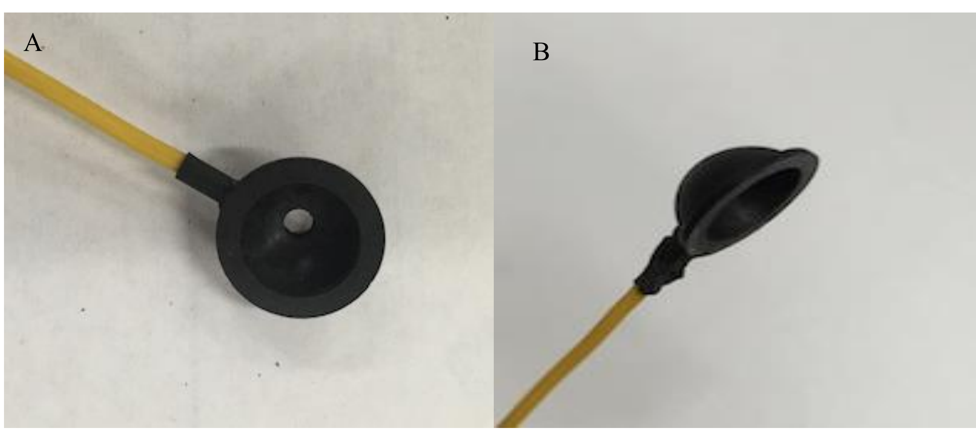

Figure 6. 40% Carbon Loaded Conductive Plastic Electrode with Hollowed Pin. (A) The lead wire with PVC is inserted into the hollow pin, but not yet heat staked. (B) Prototype after heat staking over the wire with PVC and hollow pin connection.

3. Methodology

3.1 Creating a New Pin Design in SolidWorks

The geometry of the electrode pin was altered by hollowing it out in order for the lead wire to be inserted. It was determined that the geometry of the cup should not be changed because the current geometry used by the Invisa-Electrode established a good signal, and was considered to be effective by Rhythmlink. The changes to the pin were made in SolidWorks. As a result, nine different geometries were created by changing pin length, pin thickness, and the diameter of the hollowed out portion. The specifics on these dimensions can be seen in Table 1A of the appendix. The geometries were then narrowed down to three of the most ideal dimensions in order to save money in 3D printing.

3.2 3D Printing the New Design

The 3D printed models desired for testing were outsourced to a company called Protolabs, who said printing the various iterations of the hollowed pin geometry would not be feasible. This was due to the inability of the 3D printers used by Protolabs to create such minimal alterations in the wall thickness of the pin. The geometry with the thickest pin wall was printed, and dimensions are referenced in Figure 3 of Design. Twenty electrodes were ordered and printed out of an ABS-like plastic, as it would mimic the properties of the ABS plastic currently used by Rhythmlink.

3.3 Testing the Design with the Heat Stake

A crucial aspect of the hollowed pin design was whether the plastic of the pin would melt and reform into a stable bond with the lead wire. To test this, samples of the lead wire were stripped of the PVC at the tip and inserted in the hollow pin of the 3D printed prototype. The heat stake was then heated to 800 °F and pressed onto the pin to melt and form the plastic by applying heat and pressure.

3.4 Designing and Printing a Form to Hold the Cups During Heat Staking

To accurately and safely use a heat stake, it was necessary to have a form that holds the object being heat staked in place. Rhythmlink did not have a form that fit the electrode cup, making it difficult to properly heat stake. Using the dimensions of the electrode, a form was designed in PTC Creo for 3D printing. The design could hold four electrodes and can be seen in Figure 5 of Design.

3.5 Creating a 40% Carbon Loaded Conductive Polymer Electrode Prototype

Rhythmlink had previously received some sample 40% carbon loaded conductive plastic electrodes. A .78 mm drill bit was used to drill a hole into ten of the conductive electrode cups. The hole was widened at the opening with a 1.1 mm drill bit to allow for the PVC coating to fit in. The electrode and lead wire were placed into the heat stake form and secured with tape. Once the PVC and wire were inserted into the hollowed pin, the heat stake was heated to 800 °F. The point of the heat stake was pressed along multiple points of the pin to ensure proper melting of the conductive plastic and the PVC. The electrode was then flipped and heat staked again. The time taken to place the wire in the pin and heat stake was recorded for each electrode.

3.6 Testing Resistance and Continuity of Electrodes

In order to prove that the 40% carbon loaded electrode cups performed just as well as the ABS plastic EEG electrodes used by Rhythmlink, resistivity and continuity were measured with a multimeter and compared. These tests were performed on the ABS plastic EEG electrodes twice, the 40% carbon loaded electrode cups uncoated with solid pins, 40% carbon loaded electrode cups coated in Ag/AgCl with solid pins, and 40% carbon loaded electrode cups uncoated with hollow pins.

3.7 Nicolet EEG and Impedance Testing

For the EEG testing, a control was determined through testing of two sets of the electrode cups that Rhythmlink currently uses, as these give a baseline for comparison. In preparation for the EEG testing with the Nicolet Biomedical software, Nuprep was applied to the area of the scalp on which the electrode would be placed. This solution lightly abrades the skin to decrease any impedance that would be a result of dead skin. The electrodes were placed in 8 areas of the scalp: Fz, Cz, F8, F7, O1, O2, A1, and A2, as seen in Figure 7. The electrodes were applied with Ten20 paste. This paste allows the signal to be conducted from the skin to the electrode while also acting as a glue to keep the electrode on the skin. As the electrodes were placed, their impedances were recorded. The ideal impedance for the electrodes is under 10 kΩ and the values should all be within 3 kΩ of each other. If the impedances were too high or too spread out, the electrode was reapplied until acceptable values were reached.

Once all electrodes were in place, the test subject was instructed to relax for 40 seconds, blink, and clench their jaw. These three tests were performed on the two sets of ABS plastic EEG electrodes, the 40% carbon loaded conductive plastic electrodes with solid pins, the 40% carbon loaded conductive plastic electrodes coated in Ag/AgCl with solid pins, and the 40% carbon loaded conductive plastic electrodes uncoated with hollow pins. Care was taken to place the electrodes in relatively the same area in each test to maintain consistency.

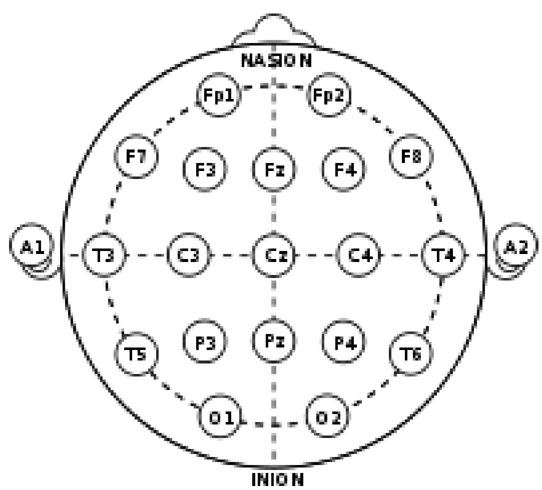

Figure 7. Labeled placement of EEG electrodes. For testing, Electrodes were placed at the Fz, Cz, F8, F7, O1, O2, A1, and A2 points on the scalp of the test subject. The Fz location was used as the ground electrode.[8]

3.8 Uniaxial Tensile Testing on Crimped Electrodes and Prototype

Once a connection was established between the conductive plastic hollow pins and the lead wires, Rhythmlink's Instron uniaxial tensile testing equipment was used to test the tensile strength of the connection. Protocol for an electrode manufactured by Rhythmlink is 15N, so the connection required at least 15N strength. The tensile strength of ten standard crimped ABS plastic electrodes was also measured for comparison.

3.9 Decrease Production Time and Cost by 10%

The solution allowed for removal of the conductive adhesive and the heat shrink, and cost and time analyses were performed on the new design. The cost analysis took into account the price of each component of the design, including the electrode cup, lead wire, conductive adhesive, and heat shrink. It also included the price of ordering a new custom mold as well as labor for each component. The time analysis took into account the time required to apply each component of the Invisa-Electrode, involving the lead wire, heat shrink, conductive adhesive, and heat staking.

3.10 Budget

Rhythmlink provided all materials needed for the project. The budget was kept at $1500, and many of the materials needed were already owned by Rhythmlink, so there was not much financial burden placed on the company.

Table 1. Budget of materials used in designing the Next Generation Electrode. The electrode deep cups, copper lead wire with PVC jacket, heat stake, SolidWorks software, and conductive plastic electrodes were already available at Rhythmlink, and their average prices are listed. 3D printing makes up the greatest cost towards the project, as it costs $100-$200 to 3D print a prototype. Rhythmlink also ordered the conductive heat shrinks, making them the sole funding source for the project, with a total budget of $1500.

Material	Cost	Funded by
Electrode Cups	**$100**	**Rhythmlink**
Copper Lead Wire with PVC Jacket	**$100**	**Rhythmlink**
Heat Stake	**$400**	**Rhythmlink**
SolidWorks Software	**$100**	**Rhythmlink**
Conductive Plastic Resin	**$100**	**Rhythmlink**
3D Printing	**$600**	**Rhythmlink**
ER08 Collets	**$50**	**Rhythmlink**
Conductive Heat Shrinks	**$50**	**Rhythmlink**
Total Projected Budged	**$1500**	**Rhythmlink**

3.11 Guidelines and Compliance

This project has been done in compliance with FDA, ISO 13485, and MDD standards. The design control follows the FDA 21 CFR 820.30 guidelines, also known as EP001, which can be seen in Figure A1 of the Appendix. At the end of the project, the EP001F35.00 - Feasibility Stage Gate Signoff will be followed in order to get feasibility authorization to move on to the Business Case stage.

4. Results

4.1 3D-Printed Prototypes

The heat stake was used in an attempt to melt the pin of the 3D printed prototype in Figure 3 to the wire. When the heat stake was used to melt the pins to the pins, they cracked and crumbled rather than melting, as seen in Figure 8. The crumbling could be attributed to two sources: the different melting properties of the ABS-like plastic used in the 3D printed prototypes and the way the 3D prototypes were printed. The difference in the melting properties of the ABS-like plastic as compared to the ABS plastic Rhythmlink used resulted in the plastic not melting as evenly and becoming as malleable as necessary. Also, the 3D prints were made through a method called layered blowing, which essentially created the 3D print through melting several layers of the plastic into each other. This is different from creating a mold of the design that is a continuous solid, which likely led to the crumbling reaction of the plastic to the heat.

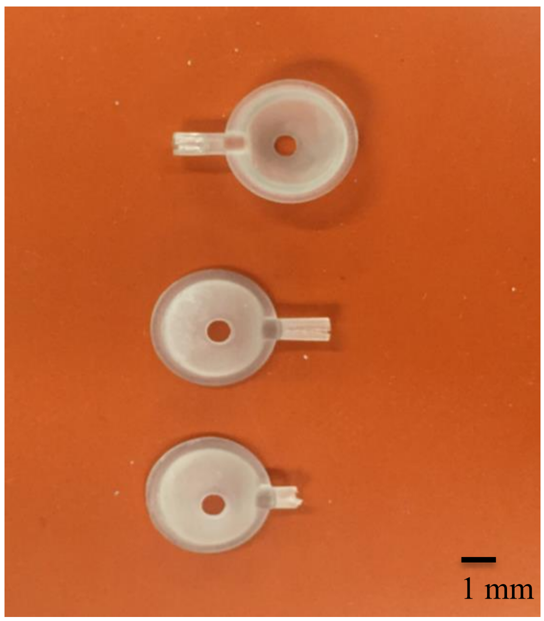

Figure 8. Crumbling and cracking of the ABS-like prototype. When the prototype was heat staked with a wire inside, the pin did not melt but rather cracked and crumbled.

4.2 Resistivity Testing

Resistance and continuity testing were measured through the wire and cup connection of the different designs. Testing was completed with trials of the currently used ABS plastic electrodes, the 40% carbon loaded conductive plastic cups with solid pins, 40% carbon loaded conductive plastic cups with solid pins coated in Ag/AgCl, and 40% carbon loaded conductive plastic cups uncoated with hollow pins. The average resistance of the trials can be seen in Table 2 below. Rhythmlink's manufacturing benchmark is below 2 Ω and the signal must be continuous. The average resistance of the ABS plastic and conductive plastic coated in Ag/AgCl was close to 2 Ω, while the conductive plastic electrodes that were not coated had a resistance much larger than 2 Ω. The signal was continuous for every electrode connection tested.

A multimeter was used to record the measurements, and continuity was signaled as a long beep from the multimeter.

Table 2. Average resistance of the wire to cup connection in each of the different trials. The averages were taken from 10 different electrodes. A resistance above 2 Ω would not pass the benchmark test.

Electrode	Average Wire and Cup Resistance (Ω)
ABS Plastic Electrodes	1.78
ABS Plastic Electrodes Trial 2	1.82
40% Carbon Loaded ABS (Conductive)	33.67
Coated 40% Carbon Loaded ABS in Ag/AgCl	2.09
40% Carbon Loaded ABS with hollowed pins	20.5

4.3 EEG Testing of the Currently Used ABS Plastic

The 40% carbon loaded conductive plastic electrodes were tested against the ABS plastic EEG electrodes Rhythmlink uses. Two trials for the ABS plastic electrodes were conducted to serve as a control. Eight of the 12 electrodes were placed on a subject's head and a Nicolet machine was used to measure impedance at each electrode, along with EEG signals between the electrodes. The results of the two EEG tests have similar responses for relaxing with eyes closed, blinking, and clenching teeth. When relaxing, the signal did not alter much from its baseline. When blinking, the signal would dip up or down with each blink. When clenching the teeth, the signal would increase and decrease rapidly while clenched. Both controls expressed similar results, providing an example of an acceptable signal. The blinking data is shown in Figure 9 below.

Figure 9. EEG electrode signals of the subject blinking slowly for the two control trials. Each dip in the signal represents a blink. Size and frequency of the dips may change due to the duration and speed of the blinks. (A) Control A. (B) Control B.

4.4 EEG Testing of the 40% Carbon Loaded Conductive Plastic Electrodes

The next trial was conducted on the 40% carbon loaded conductive plastic cups with solid pins. The results of the EEG test had a similar response when compared to the controls for relaxing with eyes closed, blinking, and clenching teeth. The blinking data comparing the conductive plastic cups to the control is shown below in Figure 10.

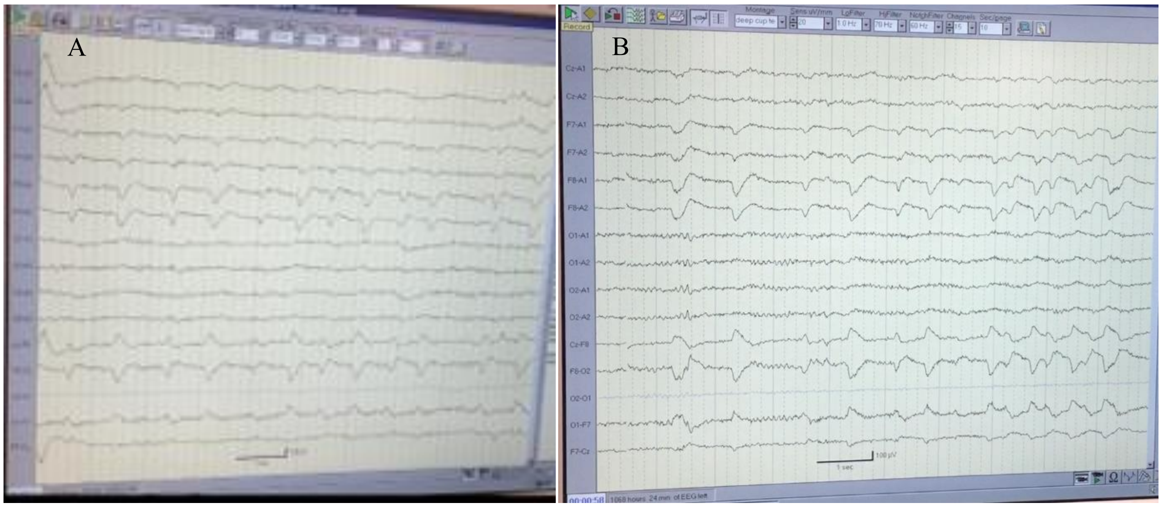

Figure 10: EEG electrode signals of the subject blinking slowly comparing the conductive plastic cups to the control. Each dip in the signal represents a blink. Again, size and frequency of the dips may change due to the duration and speed of the blinks. (A) Conductive plastic cups. (B) Control.

4.5 EEG Testing of the 40% Carbon Loaded Conductive Plastic Electrodes Coated in Ag/AgCl

The next trial was conducted on the 40% carbon loaded conductive plastic cups with solid pins coated in Ag/AgCl. Once again, the results of the EEG test had a similar response when compared to the controls for relaxing with eyes closed, blinking, and clenching teeth. The blinking data comparing the conductive plastic cups to the control can be seen below in Figure 11.

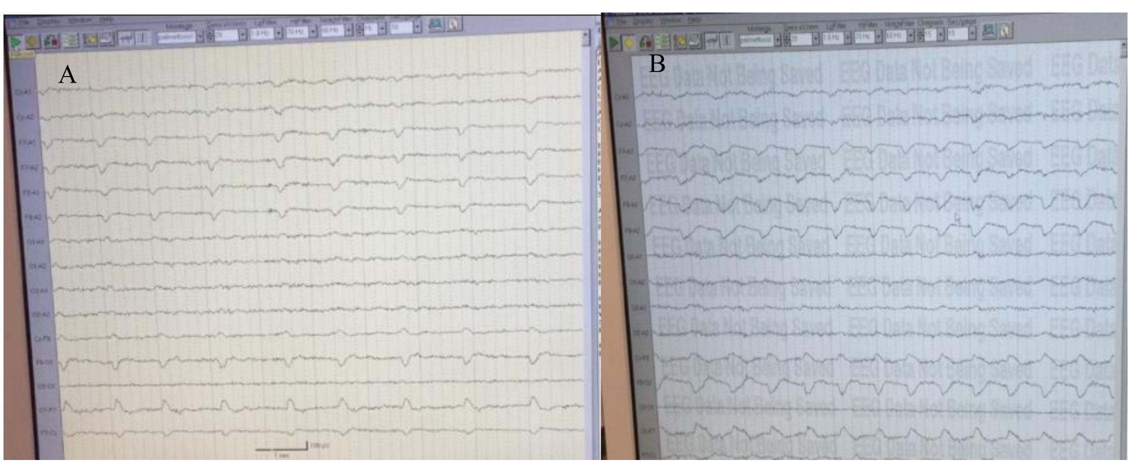

Figure 11. EEG electrode signals of the subject blinking slowly comparing the conductive plastic cups coated in Ag/AgCl to the control. Each dip in the signal represents a blink. (A) Conductive plastic cups coated in Ag/AgCl. (B) Control.

4.6 EEG and Resistivity Testing of 40% Carbon Loaded Conductive Plastic Electrodes with Hollow Pins

The final trial was conducted on the 40% carbon loaded uncoated conductive plastic cups with hollow pins. Electrodes near the bottom half of the data showed some artifacts, but the overall trend of a dip per blink can still be seen. Artifacts could have arisen from the electrodes not being placed on the head in enough contact to the skin, as one hair between the electrode and the skin could lead to an off signal. The blinking data comparing the conductive plastic cups to the control is shown below in Figure 12.

Figure 12. EEG electrode signals of the subject blinking slowly comparing the conductive plastic cups uncoated with hollow pins to the control. Each dip in the signal represents a blink. (A) Conductive plastic cups with hollow pins. (B) Control.

4.7 Impedance Results from EEG Testing

The desired impedance for each electrode is under 10 kΩ, and it is also desired to have all impedances within a 3 kΩ range. The ABS plastic electrodes met these requirements, but the conductive plastic electrodes had impedances greater than 10 kΩ and were not within 3 kΩ of each other. When the conductive electrodes were coated in Ag/AgCl, however, their impedance was 5, close to that of the two trials of ABS plastic, similar to the resistance measurements. Positions A1, A2, O1, and Com-ground did not show for the conductive plastic electrodes, but sometimes would flash at 19 kΩ. Since the highest the scale the Nicolet machine would read is 20 kΩ, it could be determined that these other electrodes were around 20-25 kΩ of impedance. Table 3 shows average impedance data for the different trials.

Table 3. Average impedance results from Nicolet testing for each trial. In each trial 8 electrodes were tested. It is highly suggested that impedance be under 10 kΩ, but benchmark is flexible depending on signal quality.

Electrode	Average (kΩ)
ABS Plastic	3.25
ABS Plastic Trial 2	5.5
40% Carbon Loaded ABS	12.8
40% Carbon Loaded ABS Coated in Ag/AgCl	5
40% Carbon Loaded ABS with Hollow Pins	17.67

4.8 Uniaxial Tensile Testing

Uniaxial tensile testing was performed on the conductive plastic electrodes with hollow pins and one set of the ABS plastic EEG electrodes. The average tensile strength of the conductive plastic electrodes with hollow pins was 9.27 N, and the average tensile strength of the ABS plastic electrodes was 32.86 N. The tensile strength of four of the hollow pins, however, was over 10 N, and was 19.36 N for one. The protocol Rhythmlink follows says that the product must have over 15 N tensile strength in order to be used, and some of the electrodes made using the hollow pin design and heat staking were close to that value, as seen below in Figure 13. Some of the pins designed had a thinner wall of the pin than others, as the hollow portion was widened out by hand. Once a custom mold is created that has a wall thickness just big enough to fit the wire and PVC, a more uniform wall thickness will be in place and should establish a stronger connection between the pin and the wire.

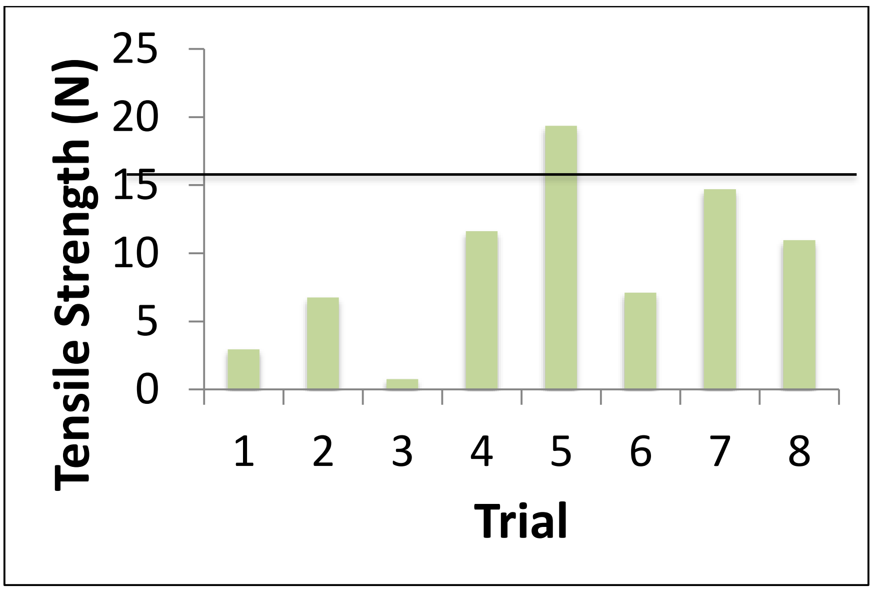

Figure 13. Uniaxial tensile testing of conductive plastic cups with hollow pins. The line at 15 N represents the manufacturing minimum limit followed by Rhythmlink.

4.9 Cost Analysis

To perform the cost analysis the cost of each part used in the hollowed pin design was compared to the parts used on the Invisa-Electrode. The cost of the ABS plastic cup was \$.03, the conductive adhesive was \$.48, and the heat shrink was \$.03. The labor for applying the conductive adhesive was \$.04 and applying the heat shrink was \$.01 per electrode. Therefore the combined cost of using the conductive adhesive is \$.52 and using the heat shrink was \$.04 per electrode, so if both components were eliminated using the hollow pin design, then \$.56 was saved per electrode. The one time price of a custom mold for the hollowed pin design is around \$7900. The cost of using 40% carbon loaded conductive plastic in place of the ABS plastic was also added, but is only about \$.002 per electrode.

4.10 Time Analysis

The time it currently takes to assemble the Invisa-Electrode was compared to the hollow pin design. The time it takes to apply the conductive adhesive is 27 seconds per electrode, and it takes 9 seconds to apply the heat shrink. In the hollowed pin design, the time it takes to heat stake was added to the production time. In making the ten conductive electrodes with hollow pins, the time taken to insert the wire into the pin and heat stake the connection was recorded for each electrode, and the average time for the process was 94.3 seconds. The method was repeated, and the average time for the process was then 64.9 seconds, as seen in Table 4. Trial 5 also took only 50 seconds, showing that with practice and more training, the production time could potentially decrease. If the time to heat stake is less than 27 seconds, which it should be with a trained technician and 3D printed conductive plastic electrodes with hollow portions better fitting to the wire, then using the hollow pin geometry without needing the conductive adhesive should save time.

Table 4. Time required to place the wire with PVC coating into the hollow pin and heat stake. This time includes inserting the wire into the pin, placing the components into the heat staking form and securing it with tape. The heat stake was then pressed down several times along the pin. The assembly is flipped, re-secured in the heat stake form and heat staked on the backside.

Trial	Time (s)
1	63
2	55
3	71
4	55
5	50
6	58
7	53
8	55
9	63
10	51
Average	**64.9**

5. Conclusion

The success of this project involved providing a promising proof of concept, in which the proposed solution resulted in accurate EEG readings and met the other goals and objectives outlined in this report. This implied that a marketable product for sale by Rhythmlink was not the final outcome of this project, but rather the designs and data necessary to produce the promise of such a product. In analyzing the goals and objectives, a proposed solution to the first goal of creating an optimal connection technique between the lead wire and the cup electrode was produced. This solution included the production of a prototype of a hollowed pin geometry for 40% carbon loaded polymer electrode cups for future production by Rhythmlink.

The other main goal of the project was to produce a product that was more time and cost efficient to produce. The goal was to reduce the time to produce each electrode by 10% and the cost by 10% as well. Upon comparing the cost of production for the Invisa-Electrode with that of the hollowed pin approach, it was estimated that $0.56 was eliminated from the cost of producing each electrode. This savings greatly exceeded 10% as desired in the goal of the project. The time, however, was not definitively reduced do to the lack of a finished manufacturing process. However, there was enough evidence of the potential for at least matching the production time of the Invisa-Electrode that Rhythmlink was convinced this was not a concern.

There were certain problems that arose within this project, with some becoming limiting factors. For example, the inability of Protolabs to provide the 3D prototypes needed to test multiple versions of the product limited the testing of multiple dimensions for the pin geometry. This was addressed simply by creating a prototype through other means and no longer utilizing the 3D printing option. Another limiting factor was the impedance of the 40% carbon loaded conductive plastic being used in the designs. The impedance levels tested in the Nicolet machine were higher than the impedance in the ABS plastic EEG electrodes, and were greater than 10 kΩ, which was not ideal. But, further testing showed that the coating of the cups in Ag/AgCl reduced the impedance values below the 10 kΩ threshold. The results of the Nicolet testing were also positive, as the signal showed distinct change during blinking and clenching of the teeth and was similar to the signals received with conventional ABS plastic electrodes, as confirmed by a sales representative at Rhythmlink who was familiar with the signals. Additionally, Rhythmlink said that one of their current electrodes, the PressOn, did not have impedances within the required range and was still marketable because of its good signaling results. Another problem was the large range of resistivity values from electrode to electrode, which may have been due to the quality of the manufacturing. Rhythmlink acknowledged this issue and proposed the quality differences from electrode to electrode may have been due to the cup electrodes that were tested being samples obtained from the vendor and not mass-produced.

Overall, this project was a success due to the completion of a proof of concept. This conclusion was validated through testing that showed quality results when compared to the signal quality, resistivity values, continuity of signal, and impedance values of the Invisa-Electrode. As the project progressed, adjustments were made to improve results and a prototype was created that showed high quality EEG signals while being a much simpler and efficient design for production.

6. Future Plans

Upon proof of concept, there are several more steps Rhythmlink will need to pursue in order to produce a functioning, marketable product. In order to actually produce the hollowed pin design, a custom mold must be purchased. This will allow Rhythmlink the ability to mass produce the cups, which will enable the company to explore more expansive testing and eventually large quantities of the cups for sale. While the mold will be costly, the proof of concept has adequately shown the potential of the design to be successful and the mold will be essential for the continuation of the project.

Another purchase that will greatly increase the efficiency of production and will improve the quality of each cup electrode that is made through heat staking is the acquisition of a clamshell heat stake attachment. Using this attachment will allow for 360 degrees of simultaneous contact when heat staking, improving both the welding technique as well as the time efficiency. This part works using two half circles that clamp on both sides of the pin, to distribute the heat and pressure evenly. Utilizing this attachment will help to maximize the points of contact between the lead wire and electrode cup, which will produce a stronger and more consistent weld around the joint.

As was the case throughout the proof of concept, testing will be a critical aspect of the future direction associated with this project. The tensile strength of the connection between cup and wire will be of particular interest, as it was the one of the few parameters the design has yet to definitively meet. Prior to spending a significant amount of money on an expensive custom mold, Rhythmlink should pursue ways to improve the consistency of the bond strength through experimenting with different wall thicknesses in order to best determine the necessary dimensions for the electrode cup pin. This will insure that the cups produced through the new mold will be able to provide an optimum connection with the wire when heat staked. If the required uniaxial tensile strength of 15 N is difficult to reach, a heat shrink may need to be placed over the joint for increased stability.

Further testing should also be conducted on the necessity of the Ag/AgCl coating that will be included in the hollowed pin design. The results of previous tests showed that the coating is beneficial in producing lower resistance and impedance values, but it has yet to be tested with the hollowed pin design. From the cost analysis, this coating has a negligible impact on the cost of production of each cup, so it is included in the current design. However, more testing should be done on the effect of the coating in conjunction with the hollowed pin to confirm the necessity of this extra component.

A requirement from the FDA for any product that is declared CT compatible is actual testing of the product in a CT scan. This should not be an issue for the hollowed pin design, as the materials were specifically chosen to eliminate any components that would cause artifacts in the CT scans. The removal of the metal crimping as the technique for connecting the wire and the cup electrode will be the crucial aspect of eliminating starburst artifacts in the CT scans, as the density of the metal in these crimps is believed to be the primary cause of the starburst artifacts. Additionally, the use of un-tinned wire aids in the reduction of the artifacts because of its non-magnetic properties. The copper wire used in these lead wires as opposed to the tinned wire is considered non-magnetic because the magnetic properties of copper are so small they are typically deemed negligible.[9]

As the manufacturing process is refined by training personnel, ordering the mold, and using the new clamshell heat stake attachment, a new cost and time analysis will have to be completed. The mold would allow for the more cost and time efficient mass production of the CT compatible electrode cup design. Training personnel and a new heat stake attachment will decrease the amount of time spent making each electrode. As a result the cost of labor will decrease. Further automation and mass production will conclude the Next Generation Electrode project.

8. References

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9. Appendix

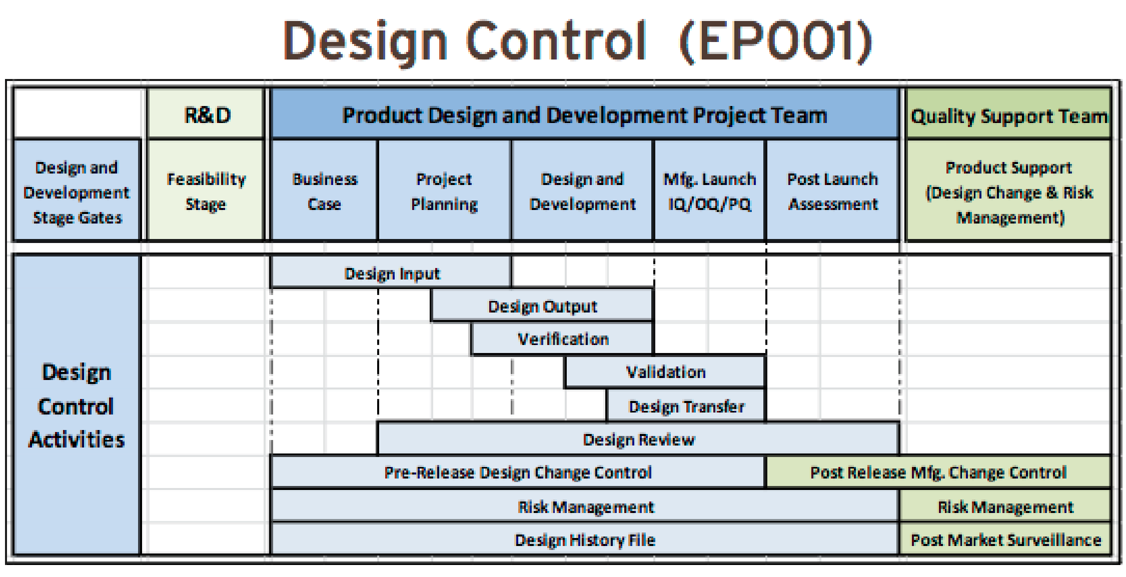

Figure A1: FDA EP001 Design Control Stage Gates. This is a visual of the many design gates included in the EP001 guidelines. Palmetto Solutions is strictly focused on the feasibility stage

Table 1A. New pin geometry dimensions. Nine prototypes were designed in SolidWorks with the following dimensions.

Pin Length (mm)	Radius of Hollowd Extrusion (mm)	Extrusion Length (mm)
9.5	.55	5.5
10	.6	6.0
10.5	.65	6.5
9.5	.6	5.5
9.5	.65	5.5
10	.55	6.0
10	.65	6.0
10.5	.55	6.5
10.5	.60	6.5

Figure A2: ABS Plastic Electrodes – Clenching Teeth. (A) EEG signal of control A of the ABS Plastic electrode and (B) control B of the ABS Plastic electrode while the subject was instructed to clench their jaw.

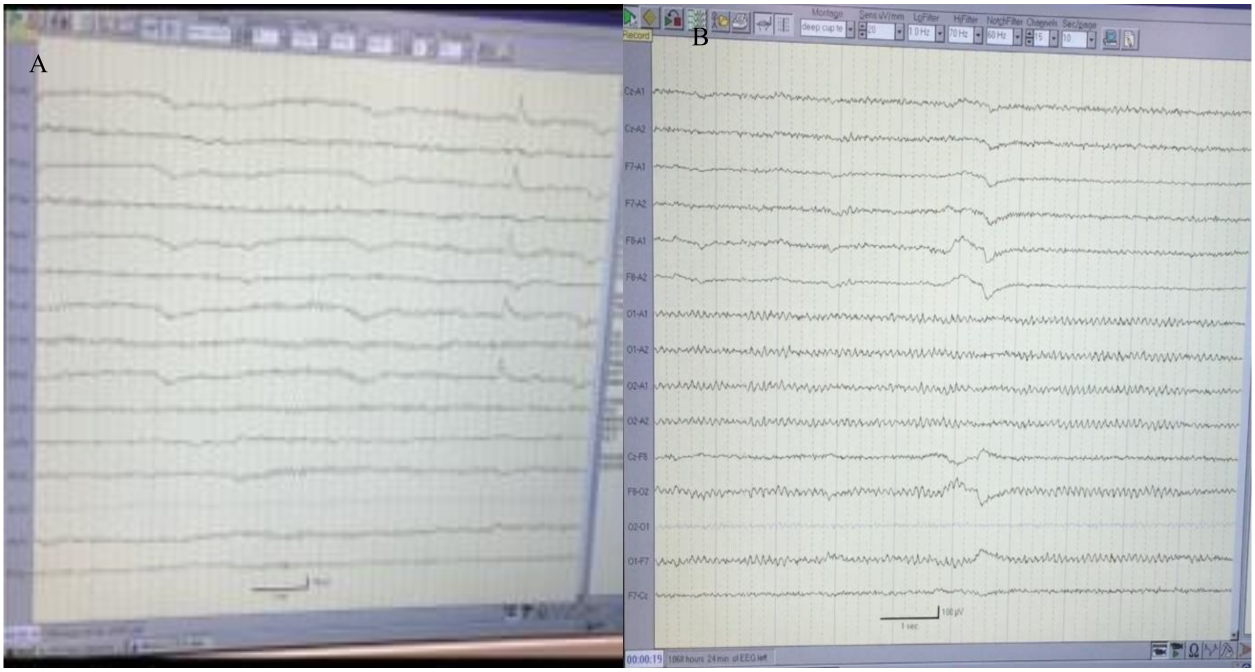

Figure A3: 40% Carbon Loaded ABS Plastic Electrodes – Relaxing. (A) EEG signal of control A of the 40% Carbon Loaded ABS Plastic electrode and (B) control B of the 40% Carbon Loaded ABS Plastic electrode while the subject was instructed to relax with their eyes closed.

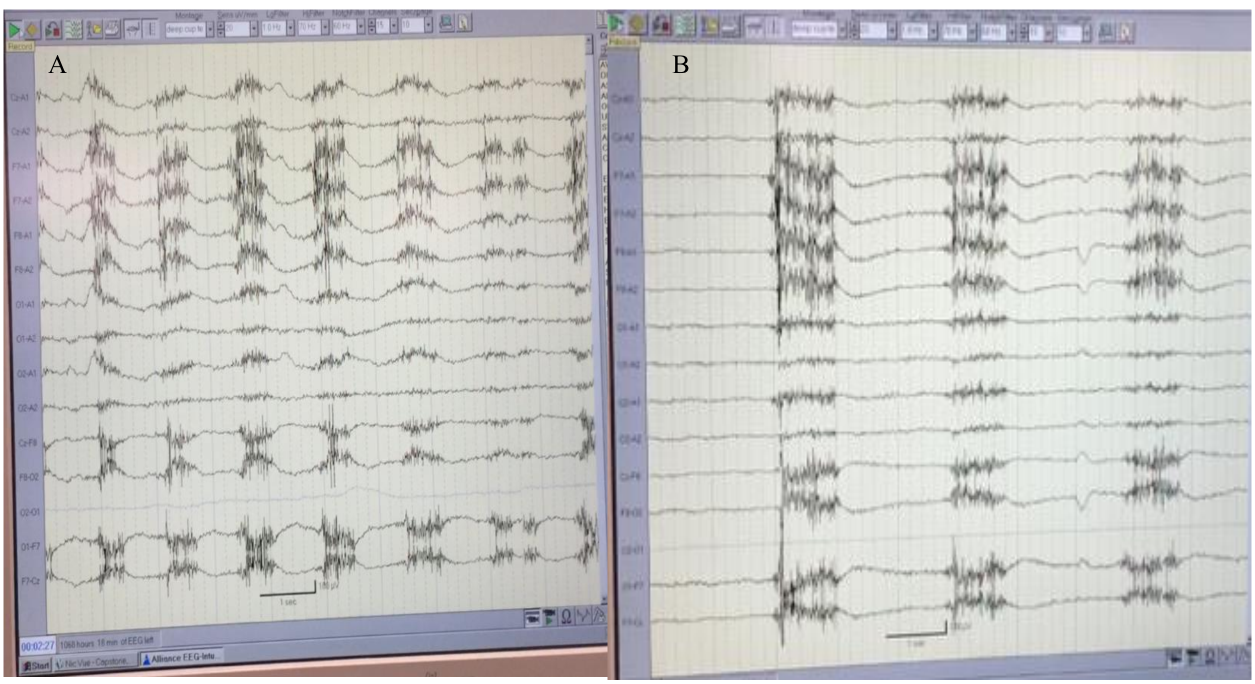

Figure A4: 40% Carbon Loaded ABS Plastic Electrodes – Clenching Teeth. (A) EEG signal of control A of the 40% Carbon Loaded ABS Plastic electrode and (B) control B of the 40% Carbon Loaded ABS Plastic electrode while the subject was instructed to clench their jaw.

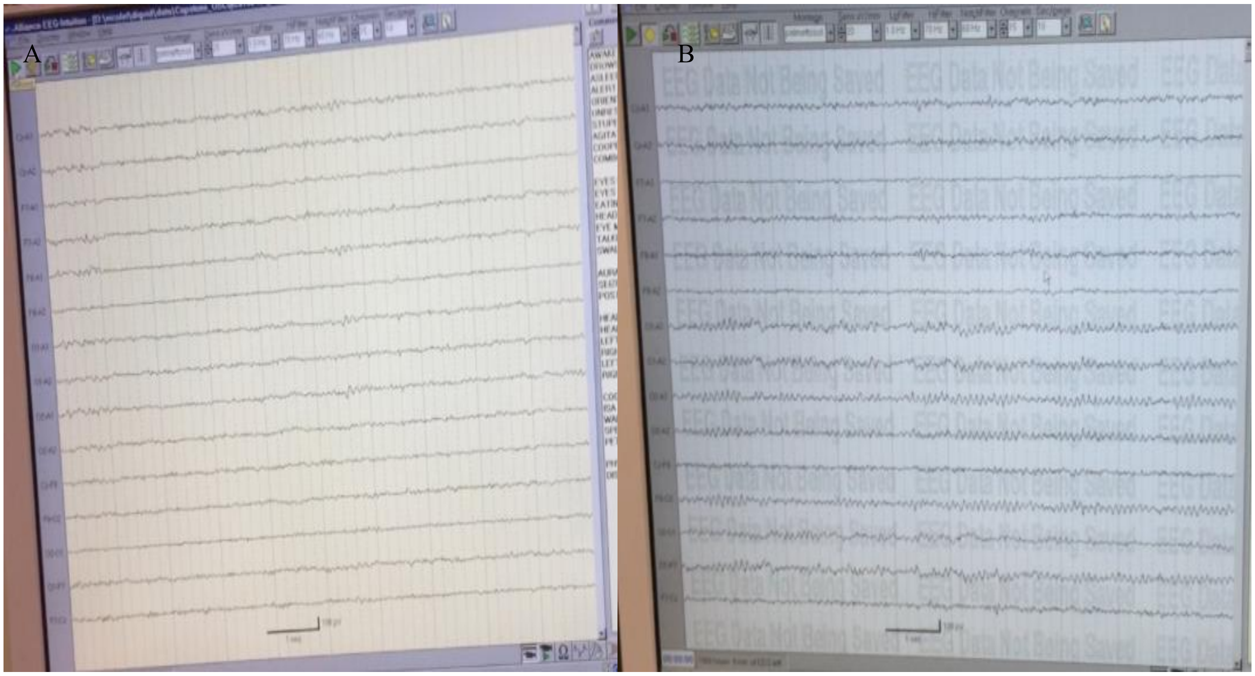

Figure A5: 40% Carbon Loaded ABS Plastic Electrodes Coated in Ag/AgCl – Relaxing. (A) EEG signal of control A of the 40% Carbon Loaded ABS Plastic electrode and (B) control B of the 40% Carbon Loaded ABS Plastic electrode while the subject was instructed to relax with their eyes closed.

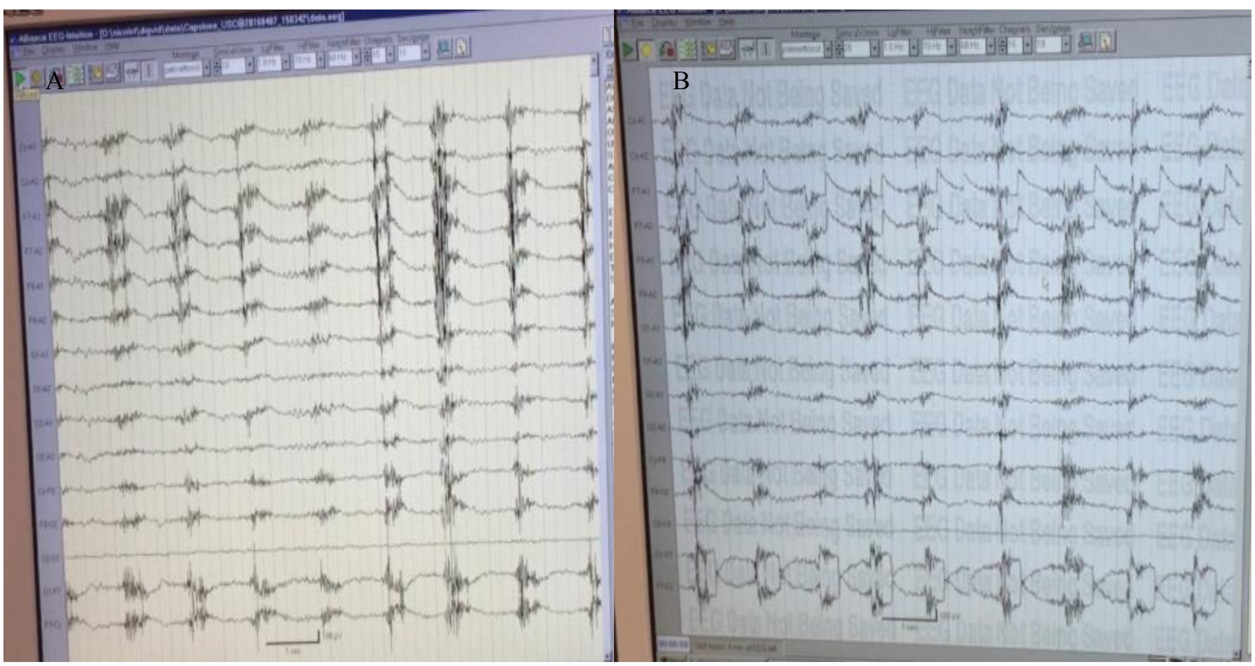

Figure A6: 40% Carbon Loaded ABS Plastic Electrodes Coated in Ag/AgCl – Clenching Teeth. (A) EEG signal of control A of the 40% Carbon Loaded ABS Plastic electrode and (B) control B of the 40% Carbon Loaded ABS Plastic electrode while the subject was instructed to clench their jaw.

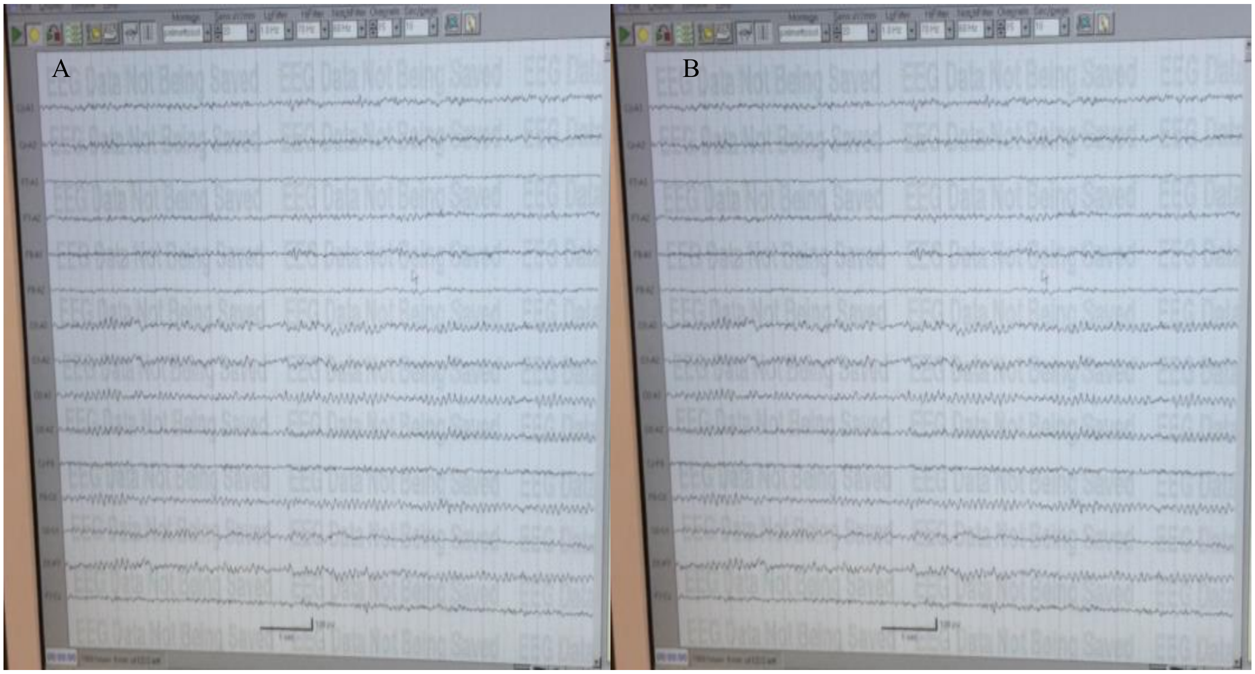

Figure A7: Hollow 40% Carbon Loaded ABS Plastic Electrodes – Relaxing. (A) EEG signal of control A of the 40% Carbon Loaded ABS Plastic electrode and (B) control B of the 40% Carbon Loaded ABS Plastic electrode while the subject was instructed to close their eyes and relax.

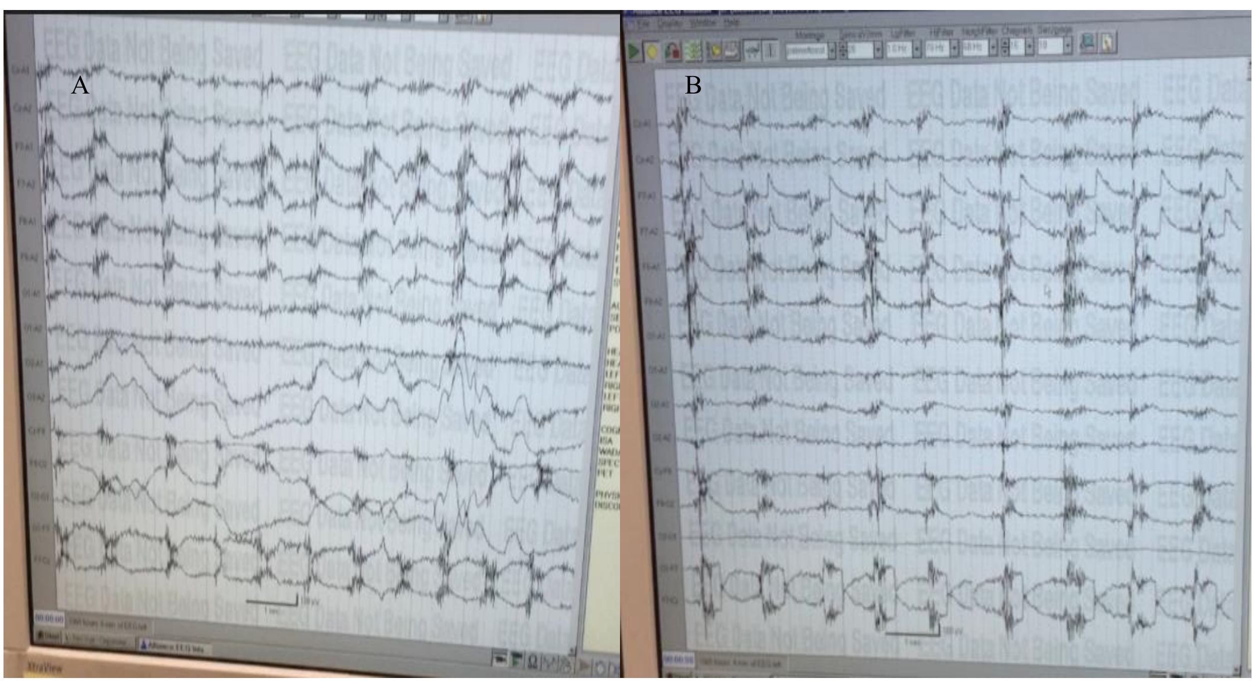

Figure A8: Hollow 40% Carbon Loaded ABS Plastic Electrodes – Clenching Teeth. (A) EEG signal of control A of the 40% Carbon Loaded ABS Plastic electrode and (B) control B of the 40% Carbon Loaded ABS Plastic electrode while the subject was instructed to clench their jaw.