MECH 437-001
BIOMEDICAL DEVICE DESIGN

FINAL REPORT & PORTFOLIO

EEG Helmet

Prepared for:
Professor Carl Nelson
University of Nebraska - Lincoln

BY:
River Kramer, Adam Johnson, Ana Figueroa, & Nestor Franco-Baltazar

Signature:__________River J Kramer______________

Signature:_________Adam Johnson______________

Signature:___________Ana Figueroa______________

Signature:_____Nestor Franco-Baltazar__________

Date Due:_______05/09/22________

Date Received:_______05/09/22__________

Review of Existing products

Electroencephalography (EEG) was discovered in 1929, and it is a method of "seeing inside" the human brain. The complex brain signals used by the human brain work as electrical signals in a way; by hooking these to the surface of the human skull, these signals produced by neurons can be read and mapped using these electrodes. These mapped signals can be very effective in mapping brain activity to help diagnose medical phenomena such as seizures. But, in order to take a look at these signals, electrodes have to be placed onto the surface of the scalp to obtain the data from brain waves. It was quickly realized that there needed to be a more efficient way of placing the electrodes which led to the creation of EEG Helmets/Caps.

Existing EEG Caps are shaped similar to motorcycle helmets. These caps come in different sizes that adapt to the size of the skull of the user and are typically attached using a strap around the chin to hold it steady. They also have the electrode placement predetermined based on the locations correlating to the brain. The most recent advancement of the EEG cap is the utilization of dry electrodes in the commercial use setting. This created two subgroups of EEG caps, dry- and wet-EEG caps. A dry-EEG cap makes direct contact with the scalp without the need for a conductivity substance. A wet-EEG cap requires the use of saline, electrolytic gels, or even tap water humidity to be on the scalp to improve conductivity. Though these dry electrodes prove a better overall experience, the wet electrodes still provide an overall better accuracy of data collected.

Other groups of EEG caps include Bluetooth or wired. A Bluetooth EEG cap was designed to remove the necessity of being "tied down" while wearing an EEG cap to bed. Since a lot of neurological studies are conducted while the patient is asleep, a Bluetooth connection also prevents a choking hazard when having to be plugged in and exposed to wires and cords on the bed. These types of EEG caps typically have large batteries which add to the overall weight of the cap that can hold charge for longer periods of time. While non-bluetooth caps require a plug in and have the advantage of being lighter, the Bluetooth EEG cap has the advantage of being independent.

Existing EEG Technology Gap

Currently, the EEG helmet that is commonly used can be a very useful and accurate device in diagnosing many brain function issues faced throughout human kind. The biggest technology gap involving the EEG helmets is the comfortability between the helmet itself and the user. Through much research it is seen that a majority of these helmets use a strap system to secure them, as well as the gel to keep the electrodes fastened to the head. Through interviews with frequent users of EEG caps, the following three key features that have a gap include:

1. The gel used to fasten the electrodes to the head is often very uncomfortable, messy, and difficult to get out of the patients hair after the EEG scan is complete.
2. The electrode's inside of the helmet are very poorly padded and are uncomfortable for the patient to lay on as they are required to fall asleep during the seizure activity scans.
3. The chin strap used to fasten the EEG helmet can apply the pressure onto the patient's head in a very uncomfortable manner several times in the installation and scan process.

Functional decomposition of the task

Functional Requirements:

1. Sustain Impact (3)
2. Feel Comfortable (2)

3. Form to Scalp/Head (2)
4. Allow Replacement (3)
5. Envelope Entire Brain Area (1)
6. Display Brain Signals (1)
7. Analyze Brain Function **(1)**
8. Remain Fixed to Head **(2)**
9. Survive Many Cycles of Use **(3)**

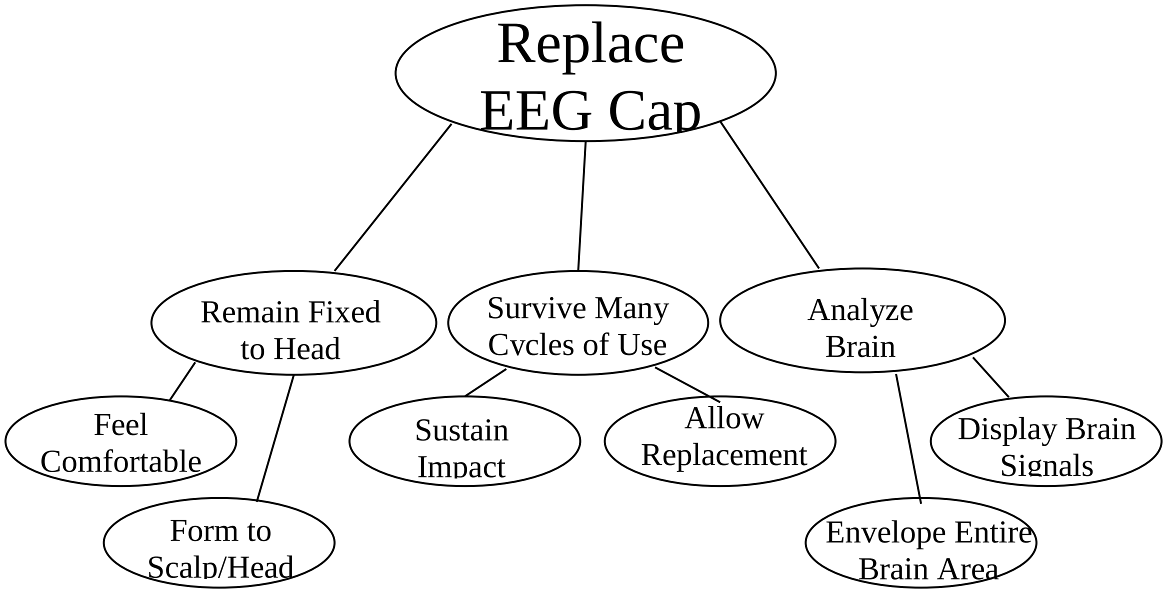


Figure 1: Functional decomposition for EEG cap

Morphological chart

Table 1: Morphological chart for EEG cap

Functions	**1**	**2**	**3**
Feel Comfortable	Cushion	Room Temp Adhesive	Symmetric Shape
Form to Scalp/Head	Formable Gel/Pad	Soft Framework	Large Surface Area
Sustain Impact	Sturdy Padding	Tear Resistant Framework	Polished/Dull Attachments
Allow Replacement	Simple Single Diode Attachments	Symmetric Parts	Individual Attachments
Envelope Entire Brain Area	Large Surface Area	Symmetric Shape	Adjustable Size
Display Brain Signals	Symmetric Design	Metallic/Conductive Parts	Wired Framework

Identification of product specifications (e.g., forces or displacements required)

Based on the gap in the technology of modern EEG helmets as well as the existing product standards that exist, these are some product specifications that need to be followed in the redesign:

1. The helmet needs to consist of >32 channels or electrodes and fit/cover the standard human head size (cranial circumference of 42 cm - 64 cm) [1].
2. The electrodes need to be capable of working at sampling rates up to 1000 Hz at 24 bits in order to accurately read neuron activity [2].
3. The amplifiers need to be capable of 70 Hz AC bandwidth.
4. Bluetooth 2.1 is ideal to ensure the measurements remain accurate with the fewest attachments to the helmet.
5. Battery life of the Bluetooth 2.1 helmets needs to be able to perform for >8 hrs to ensure a full sleep/brain study can be performed.
6. Weight needs to be minimal to make patient comfort high, preferably <450g
7. The helmet must be capable of an input range and noise capabilities within the specifications of the following:

$$\pm 100\ mV, < 1\ \mu VRMS(0.5 - 30\ Hz)\ @\ 256Hz\ \ \pm 400\ mV, < 4\ \mu VRMS(0.5 - 30\ Hz)\ @\ 256Hz\ (biopolar\ EG)$$

8. The helmet and electrodes must be able to withstand the standard weight of a human head resting on them during the scans (>5000 g mass of typical human head)

Evaluation of concepts (Pugh Decision Matrix)

Concept 1:

Cushion, formable gel/pad, sturdy padding, simple single diode attachment, large surface area, symmetric design.

Concept 2:

Room temp adhesive, soft framework, tear resistant framework, symmetric parts, symmetric shape, metallic/conductive parts.

Concept 3:

Symmetric shape, large surface area, polished/dull attachments, individual attachments, adjustable size, wired framework.

The Pugh Decision Matrices for EEG Improvement can be found in **Appendix I**

QFD of your selected concept compared to state of the art

The QFD for EEG Improvement can be found in **Appendix II**

Modeling of parts

A diagram of the EEG cap can be found in **Appendix III.**

Material selection

Wired Mesh Covering (not necessary but would benefit the user and longevity of device):

Two possible materials that can be used to provide a covering for the wired mesh framework are Silicone or Latex. A pros and cons analysis can be found in **Appendix IV.** After this analysis, it can be determined that **Silicone** is a better material to choose for the wired framework covering.

Wired Framework:

There are two standard wires that can be used in the wired framework Copper or Aluminum. A pros and cons analysis can be found in **Appendix IV.** After this analysis, it can be determined that **Copper** is a better material to choose for the wired framework.

Electrodes:

The electrode placement will be throughout the entire cap and some may be close to the battery. If the battery fails, it can overheat and damage nearby electrodes. To ensure that the electrodes will not be damaged if the battery overheats, they will be made from the most efficient thermal shock resistant metal that also has the best conductivity. To maximize thermal shock resistance, the material index needs to maximize $\sigma f/E\alpha$ (σf = failure strength, E = Young's modulus, and α = thermal expansion coeff.) [5]. Since conductivity is more important than maximum thermal shock, it had a heavier weight in the analysis. The data [6] can be found in **Appendix IV** and it was concluded that Copper is the best material for the electrodes.

Battery:

The purpose of the battery is to be common and rechargeable in case they need to be replaced, last long periods of time and have a quick recharge time. These three factors are taken into consideration when choosing the battery and a table with values can be found in **Appendix IV**. It was concluded that Lithium Ion is the best type of battery for the EEG cap.

Chin Strap:

The chin strap is a basic component of the EEG cap. Therefore the strap should be a woven material and a pros and cons analysis can be found in **Appendix IV.** After this analysis, all materials remain very similar, but **Polypropylene** is a better material to choose for chin strap because it is tear resistant and durable.

DFM/DFA and sensitivity analysis

DFM rules followed:

- Cost effective, made of accessible materials.
- Simple design to minimize number of parts.
- Standardize components for repairability.
- Fabrication will not require secondary operations.
- Avoided any tight tolerances.

DFA can be found in **Appendix V**.

From the DFA chart it can be deduced that the best mode of assembly is as follows: <Wire mesh, Fastener, Battery, Electrodes> since it goes from lowest assembly index to highest.

FMEA

The FMEA chart can be found in **Appendix VI**.

<u>Appendices</u>

Appendix I: Pugh Decision Matrices for EEG Improvement

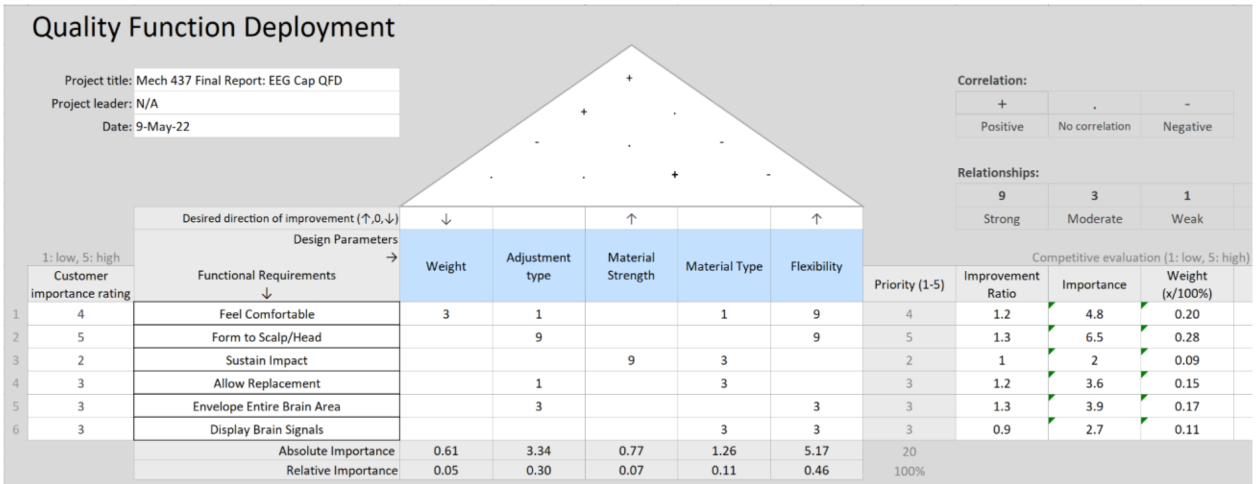
Iteration 1:

FRs	Concept 1	Concept 2	Concept 3
Feel Comfortable	+	DATUM	+
Form to Scalp/Head	+	DATUM	0
Sustain Impact	0	DATUM	+
Allow Replacement	+	DATUM	+
Envelope Entire Brain Area	+	DATUM	+
Display Brain Signals	-	DATUM	0
Total Score:	3	0	4

Iteration 2:

FRs	Concept 1	Concept 2	Concept 3
Feel Comfortable	+	-	DATUM
Form to Scalp/Head	+	0	DATUM
Sustain Impact	+	-	DATUM
Allow Replacement	+	-	DATUM
Envelope Entire Brain Area	0	-	DATUM
Display Brain Signals	-	0	DATUM
Total Score:	3	-4	0

Appendix II: QFD Matrix for EEG Design Candidates



Quality Function Deployment

Project title: Mech 437 Final Report: EEG Cap QFD
Project leader: N/A
Date: 9-May-22

Correlation: + Positive; . No correlation; - Negative

Relationships: 9 Strong; 3 Moderate; 1 Weak

	Customer importance rating (1: low, 5: high)	Functional Requirements ↓ / Design Parameters →	Weight	Adjustment type	Material Strength	Material Type	Flexibility	Priority (1-5)	Improvement Ratio	Importance	Weight (x/100%)
		Desired direction of improvement (↑,0,↓)	↓		↑		↑				
1	4	Feel Comfortable	3	1		1	9	4	1.2	4.8	0.20
2	5	Form to Scalp/Head		9			9	5	1.3	6.5	0.28
3	2	Sustain Impact			9	3		2	1	2	0.09
4	3	Allow Replacement		1		3		3	1.2	3.6	0.15
5	3	Envelope Entire Brain Area		3			3	3	1.3	3.9	0.17
6	3	Display Brain Signals				3	3	3	0.9	2.7	0.11
		Absolute Importance	0.61	3.34	0.77	1.26	5.17	20			
		Relative Importance	0.05	0.30	0.07	0.11	0.46	100%			

Competitive evaluation (1: low, 5: high)

Appendix III: Simple model of EEG cap

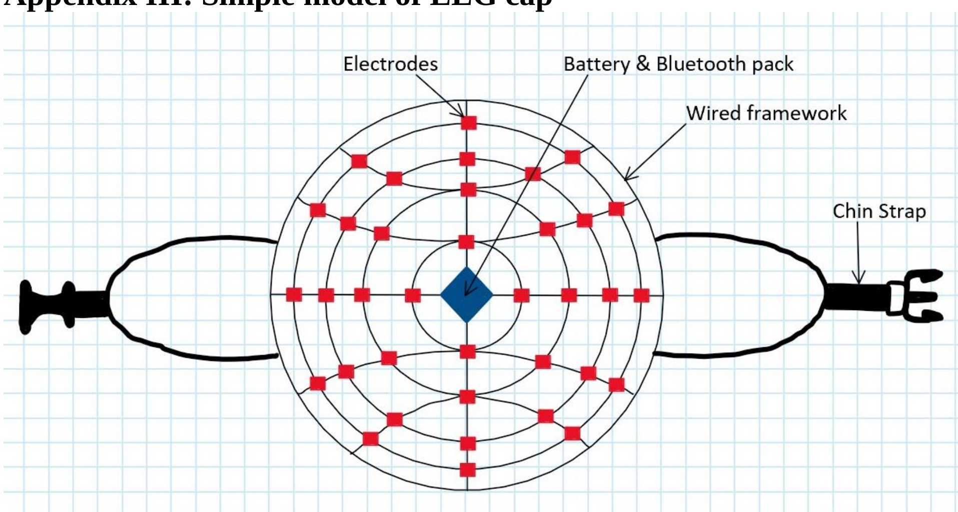


Figure 2: Model of EEG Cap when flattened out

Appendix IV: Material Selection Analysis

Table 2:Pros and Cons list for the materials for the elastic mesh portion of the cap

Material	Pros	Cons
Latex	• Provide a snug fit • Easily Stretch	• Some might be allergic • Breaks easily
Silicone	• Soft and comfortable • Flexible without tearing • Allergy free • Last long periods of time	• More expensive

Table 3:Pros and Cons list for the materials for the metal framework portion of the cap

Material	**Pros**	**Cons**
Copper	● Stable ● Durable ● Conductivity is higher (.6 megamho/cm) [5]	● Spark if installed incorrectly ● More expensive
Aluminum	● Lighter ● More malleable ● Less expensive	● Conductivity is lower (.4 megamho/cm) [5]

Table 4: Metal selection for Electrodes using the material index for maximize thermal shock resistance and conductivity

Metal for Electrode	***σf* = failure strength (MPa)**	***E* = Young's modulus (GPa)**	***α* = thermal expansion coeff. (μm/mK)**	**Material Index *(σf/Eα)* (μm/mK)**	**Conductivity (W/mK)**
Silver	110	83	18.9	7.012 * 10^-5	430 W/mK
Nickle	345	200	13.4	1.287 * 10^-4	90.7 W/mK
Copper	210	120	16.5	1.061 * 10^-4	401 W/mK
Gold	220	79	14.2	1.961 * 10^-4	320 W/mK
Stainless Steel (304L)	485	193	17.3	1.453* 10^-4	20 W/mK
Titanium Alloy (Grade 5 ti-6Al-4V)	1170	116	9.2	1.096 * 10^-3	6.7 W/mK

Table 5: Battery selection analysis for the EEG cap [7]

Small, Common Rechargeable Battery Types	**Dry Cell**	**Lifespan before needing to be recharged when used at a high capacity (driving an RC car)**	**Recharge Time (Avg.)**
NiMH (Nickel-Metal Hydride)	AAA	17 hours	4.5 hours
Li-ion (Lithium Ion)	AAA	16 hours	2.5 hours

Table 6:Pros and Cons list for the materials for the chin strap portion of the cap [8]

Material	**Pros**	**Cons**
Nylon	● Stretchy ● Lightweight ● Dries Quickly ● Easy to clean ● Retains Color	● Non-durable ● Tears quickly
Polypropylene	● Moisture absorbent ● Chemical resistant ● Tear resistant ● Durable	● Difficult to dye or paint ● Highly flammable
Polyester	● Can blend with natural fibers ● Stain resistant ● Low production Cost ● Pet-friendly	● Dries slowly ● Not breathable ● Hard to clean ● Not environmentally friendly

Appendix V: DFA, DFM and Sensitivity Analysis

Part	Retrieve			Handle			Insert						# Parts	Assembly Index	Part Required
							AL = alignment difficult NTD = not top down HIP = hold in place			OB = obstructed RES = resistance					
	Small <12mm (+1) <2mm (+2)	Tangled (+2)	Flexible (+2)	No end symm (+2)	No insert symm (+2) (+1) if clear	Heavy or tools needed (+2)	AL (+2)	OB (+2)	NTD (+2)	RES (+2)	HIP (+2)	FASTEN Twist (+1) Screw (+3)			
WIRE MESH			2										1	2	YES
FASTENER			2								2		1	4	YES
ELECTRODES	1						2				2	1	36	6	YES
BATTERY										2	2		1	4	YES
												Total	23	16	

Appendix VI: FMEA

function	failure mode	failure effect	severity	cause	occurrence	preventative action	detection action	detection	RPN	recommended action
Feel Comfortable	Fits too tight	Headache	4	not adjusted correctly	5	adjust correctly	User feedback	3	60	Check adjustment
	Fits too loose	Slide off head	7	not adjusted correctly	3	adjust correctly	User feedback	4	84	Check adjustment
Form to scalp/head	unable to form to scalp	Incorrect electrode placement	7	Material selection	4	Choose different material	Observation	2	56	Discard/Choose different material
Sustain Impact	Damaged	Device inoperable	9	Dropped device	7	Handle with care	Handling	1	63	Handle with care
	Broken device	Device inoperable	9	Dropped device	7	Handle with care	Handling	1	63	Handle with care
Allow Replacement	Nonrepairable	Unable to repair device	7	Made device non reusable	2	Design device to be repairable	Observation	3	42	Design device to be repairable
	Parts not compatible	Unable to repair device	7	Repair parts not standardized	3	Design to standards	Observation	2	42	Standardize device
Envelope entire brain area	Too small for area	Incorrect brain signal detection	6	Incorrect fitting	3	Ensure correct fitment on user	User feedback	6	108	Custom sizing
	Too big for area	Incorrect brain signal detection	6	Incorrect fitting	3	Ensure correct fitment on user	User feedback	6	108	Custom sizing
Display brain signals	Incorrect display	Incorrect diagnosis	9	Unaccurate electrode placements	6	Ensure correct placement	Observation	6	324	Check electrode placements and connections.
	Incorrect display	Incorrect diagnosis	9	Electrodes not connected correctly	7	Check connections.	Inaccurate reading	4	252	Check electrode placements and connections.

References

[1] "The Neuron." *A Brief Introduction to the Brain:Neuron2*, http://www.ifc.unam.mx/Brain/neuron2.htm#:~:text=The%20aaction%20potential%20is,stereotyped%20all%20or%20none%20signal.

[2] Neudorfer, Clemens, Clement T. Chow, Alexandre Boutet, Aaron Loh, Jürgen Germann, Gavin JB Elias, William D. Hutchison, and Andres M. Lozano. "Kilohertz-Frequency Stimulation of the Nervous System: A Review of Underlying Mechanisms." *Brain Stimulation* 14, no. 3 (2021): 513–30. https://doi.org/10.1016/j.brs.2021.03.008.

[3]"EEG CAP: Standard 64ch-ACTICAP-Slim with Built-in Electrodes." *DigitalOne*, Brain Support, https://www.brainlatam.com/manufacturers/eeg-electrode-caps/eeg-cap- standard-64ch-acticap-slim-with-built-in-electrodes-205.

[4]*Material Indices - VUB*. http://mech.vub.ac.be/teaching/info/Ontwerpmethodologie/Appendix%20les%203%20Materiaal%20Indices.pdf.

[5]Patton, Don. "Aluminum vs. Copper Conductivity." *Sciencing*, 2 Mar. 2019, https://sciencing.com/aluminum-vs-copper-conductivity-5829267.html.

[6]"Website about Elements and Materials." *Material Properties*, 27 Feb. 2021, https://material-properties.org/.

[7]"The Best Rechargeable AA and AAA Batteries." *The New York Times*, The New York Times, 29 Jan. 2013, https://www.nytimes.com/wirecutter/reviews/best-rechargeable-batteries/.

[8]Kledger@qualitylogoproducts.com, and 866-312-5646 x 325. "A Guide to Polyester, Nylon, & Polypropylene Fabric." *Https://Www.qualitylogoproducts.com/*, https://www.qualitylogoproducts.com/promo-university/guide-to-materials.htm.