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## Introduction

#### About The Brain

- The brain is comprised of a complex network of nerve cells also known as neurons [1].
- The neurons in the brain communicate to each other using tiny electrical, and chemical impulses called synapses[1].
- Neurons can be stimulated by an electrical current to facilitate the depolarization or hyperpolarization due to increase of membrane potential.

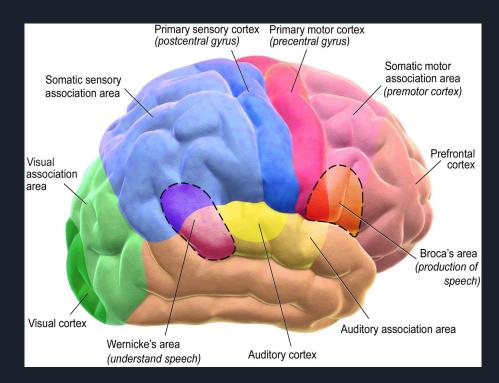


Figure 1: the Brain "Brain - Google Search." *Google.com.* N. p., 2018. Web. 15 Oct. 2018.

#### What is tDCS

- Transcranial direct current stimulation (tDCS) is a form of neurostimulation where low levels of constant current is applied to a target areas of the brain.
- The tDCS works by sending a directional positive and negative current through electrodes attached to the scalp [1].
- The placement of the electrodes can change the direction of the current and which area of the brain it affects.
- The low current can alter a neuron's activity in a desired direction, that is tDCS can strengthen or weaken the signals between neurons also known as synaptic plasticity [1].

[1] Reinhart, Robert MG, et al. "Using transcranial direct-current stimulation (tDCS) to understand cognitive processing." Attention, Perception, & Psychophysics 79.1 (2017): 3-23.

#### Who uses tDCS

- tDCS is a tool that can be used in a variety of settings, today it is primarily used for research in everything from learning [2] to drug addiction [1], enhance a person's attention span, coordination, memory, and problem-solving ability [6]
- Recent studies shows tDCS helps in relaxation, and certain profession involved in stressful work environment use it. For example: surgeons, soldiers, pilot and sport personnel[3][4][5].
- Studies also have shown that tDCS has very high potential to treat depression, anxiety, PTSD, and chronic pain [6]



https://www.scientificamerican.com/article/amping-up-brain-function/

<sup>[1]</sup> Shahbabaie A, Hatami J, Farhoudian A, Ekhtiari H, Khatibi A, Nitsche MA. Optimizing Electrode Montages of Transcranial Direct Current Stimulation for Attentional Bias Modification in Early Abstinent Methamphetamine Users. Frontiers in Pharmacology. 2018;9:907. doi:10.3389/fphar.2018.00907.

<sup>[2]</sup> Bachtiar V, Johnstone A, Berrington A, et al. Modulating Regional Motor Cortical Excitability with Noninvasive Brain Stimulation Results in Neurochemical Changes in Bilateral Motor Cortices. *The Journal of Neuroscience*. 2018;38(33):7327-7336. doi:10.1523/JNEUROSCI.2853-17.2018.

<sup>[3]</sup> Ciechanski, P., et al. "Effects of transcranial direct-current stimulation on laparoscopic surgical skill acquisition." BJS Open 2.2 (2018): 70-78.

<sup>[4]</sup> Choe, Jaehoon, et al. "Transcranial direct current stimulation modulates neuronal activity and learning in pilot training." Frontiers in human neuroscience 10 (2016): 34.

<sup>[5]</sup> Sample, Ian. "US Military Successfully Tests Electrical Brain Stimulation To Enhance Staff Skills." the Guardian. N. p., 2016. Web.15 Oct. 2018.

<sup>[6] &</sup>quot;What Is TDCS - Learn About Neurostimulation." The Brain Stimulator TDCS Devices. Retrieved Oct. 20. 2018, from thebrainstimulator.net/what-is-tdcs/

# People Affected by tDCS Treatable Conditions

- Estimated 40 million adults in U.S. have an anxiety disorder. [1]
- Estimated 16.1 million adults in U.S have major depressive disorder. [2]
- Estimated 23.4 million adults in U.S. experience chronic pain [3]
- About 80 million adults can be treated by tDCS

<sup>[1] &</sup>quot;Facts & Statistics." Anxiety and Depression Association of America, ADAA. Retrieved Oct. 21. 2018, from adaa.org/about-adaa/press-room/facts-statistics.

<sup>[2] &</sup>quot;Depression." Anxiety and Depression Association of America, ADAA. Retrieved Oct. 20. 2018, from adaa.org/understanding-anxiety/depression.

<sup>[3] &</sup>quot;NIH Analysis Shows Americans Are In Pain." National Center for Complementary and Integrative Health, U.S. Department of Health and Human Services, 11 Aug. 2015, nccih.nih.gov/news/press/08112015.

#### tDCS Montages

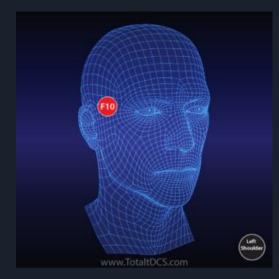
- Montages are the position of electrodes
- Different montages for desired treatments



Reduces chronic pain



Treating depression and anxiety



Accelerated learning

# Problem and Need Statement

### Current Problem

- Most devices in the market are expensive (\$30 - \$200)
  - Extra cost for more features
- Requires prior set up and is hard to use
  - Incorrect electrode placement can cause adverse effects
- Bulky and not disposable



https://caputron.com/products/apex-type-a-tdcs-device?variant=542710 0024894

### Need Statement

To find a way to make a low cost, easy to use, and disposable tDCS device that can be disposed after a single dose (20~40 minutes).

# Prior Art

#### Types of Electrodes - Adhesive Electrode

- Cheapest type
- Easy to prepare
- The conductive material could be carbon.
- This type of electrode is designed for direct skin contact for montages including the forehead, or for bald individuals.



The Brain Stimulator tDCS Devices. Choosing The Right Electrodes for tDCS. Retrieved Oct. 22. 2018, from https://thebrainstimulator.net/choosing-electrodes/

#### Types of Electrodes - Carbon Electrode

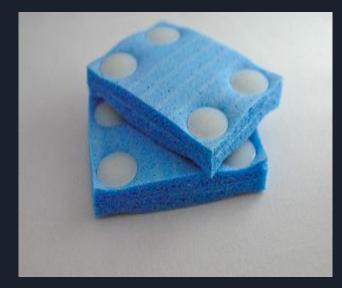
- A little more expensive than adhesive type
- Harder to prepare
  - gel application
  - strap to hold the position
- The conductive material is carbon.



The Brain Stimulator tDCS Devices. Choosing The Right Electrodes for tDCS. Retrieved Oct. 22. 2018, from https://thebrainstimulator.net/choosing-electrodes/

### Types of Electrodes - Sponge Electrode

- Sponge material to conduct electric current.
- Allows current flow on the hair.
- Requires a conductive rubber insert that is connected to the device



http://soterixmedical.com/research/1x1/accessories/1x1-easypad

#### Iontophoresis

- Notably Iontophoresis devices like the IontoPatch® present a noteworthy solution to the problem of applying electric current to human skin.
- This device uses a small battery to provide a unregulated but relatively constant voltage on the skin to deliver drugs transdermally.
- Others examples are- Body med, Active tek and I-Bresis patch.



http://www.iontopatch.com/device.html?fbclid=lwAR06i6e6Ab VL3-DXtS2AmJJ1UWTT3mbXqUSO0zvm7ziTf7nfbctlovuJ38

#### EEG Electrode Locator Headgear

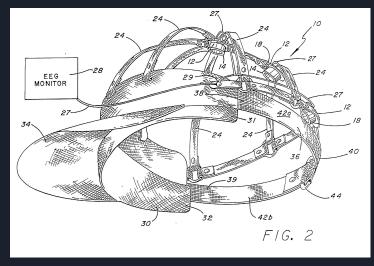
- Portable EEG Electrode Locator Headgear, includes an elastic stretchable cap that is connected to EEG electrode locators on the inside [1].
- The EEG electrode locators are connected to straps that can be repositioned depending on the areas that are targeted.
- The device also comes with an optional plunger assembly that can be used to part the hair for preparation for electrode placement.



https://bio-medical.com/accessories/eeg-caps.html

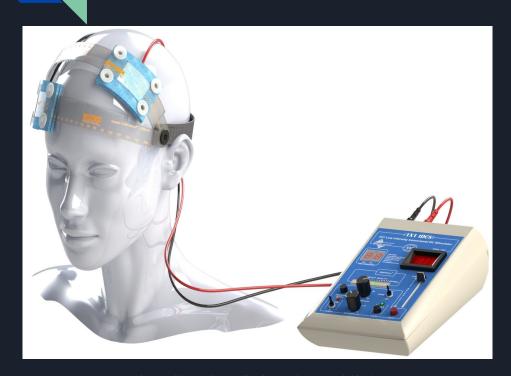
### EEG Electrode Locator Headgear Patent

- Headgear has adjustable straps to correctly place electrodes
  - Cons: if the device has too many adjustable options it is less convenient to use and setup
- Headgear is collapsible and portable, it can be made of sterilizable plastics [1]
- A thin flexible plastic with plastic fasteners could be cheap and disposable



https://patents.google.com/patent/US20020029005A1/en?q=(headgear)&q=(electrodes)&status=APPLICATION&oq=(headgear)+(electrodes)+status:APPLICATION

#### Soterix Medical 1x1 system



https://soterixmedical.com/research/1x1

- This is a complete and modular system for conducting a variety of tDCS montages using the headgear. The circuit it comes with is also fully featured.
- Our Project will may try to adopt the simple design of the headgear, but reduce the number of options available for headgear positioning. The circuit that will be used will also be less fully featured.

#### White Market tDCS devices



- These devices are similar in formfactor and design as the Soterix system.
- Some notable differences are in cost (typically around 30 dollars) and the fact that there are much fewer features.
- These devices are made in china, the quality control is probably not trustworthy and they are not sold under a specific company.

#### The Brain Stimulator v3.0:

- The Brain Stimulator v3.0 is an example of a portable tDCS.
- The device features a push buttons which allow the user to increase and decrease the current flow, as well as shut off the device at any time.
- The precision components and streamlined circuitry allows the device to operate at the highest 2 milliamp setting for over 90 hours.
- It has a replaceable battery and has a 30-minute "set & forget" session timer.



Figure 7: The Brain Stimulator v3.0

#### Thync Device

- Thync Device is one of the self-usable portable brain stimulation devices in market currently.
- Thync doesn't directly target the brain.
- The triangular module applies pulsed electrical currents to the electrodes attached to it, targeting nerves on the face.
- Thync claims to have two effects or "vibes", calming or energizing

#### **Electric Feel**

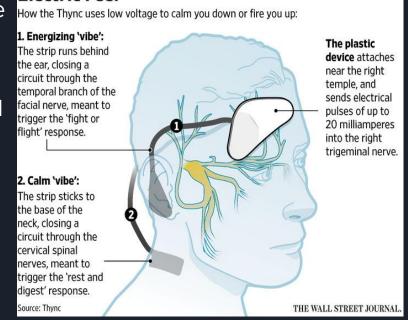


Figure 6: Thync Device

# Project Specifications

### Limitations

Device	Limitations
EEG Electrode Locator Headgear	The device needs a little more work for people with hair. Requires the application of saline before use.
Iontophoresis	Uncertainty of constant voltage and output current. Also requires application of saline before use.
Soterix Medical 1x1 device	The device is expensive and not disposable.
Thync Device	The device is expensive and not disposable.
White Market tDCS devices	They are not disposable, not a lot of features quality is not trustworthy.
The Brain Stimulator v3.0	Even though the device is relatively cheap, it requires a bit expertise to set up which is prone to mistake by an individual.

Table 1: limitations of prior art

### Chart of Requirements

Parameter	Value
Electrode size	25.46 A/m <sup>2</sup> current density must be maintained. So electrode pads should be larger than 2.546 cm <sup>2</sup> for 1 milliamp current [1]
Current	Avoid above 2 mA (safety threshold) [2]
Voltage requirement	less than or equal to 9 V [9] This is partially due to the availability of a low cost power supply above 9 volts.
Duration	5 - 30 minutes [2]
Dosage	Single dose
Headgear circumference	Around 57.2 cm [3] (elastic material)
Weight	Less than 1 lb
Length (packaged)	Less than 6 in
Width (packaged)	Less than 6 in
Height (packaged)	Less than 6 in (preferably packs flat in bag)

#### Table 2: Product Design specification

- 1. Bikson M, Datta A, Elwassif M. Establishing safety limits for transcranial direct current stimulation. Clinical neurophysiology: official journal of the International Federation of Clinical Neurophysiology. 2009;120(6):1033-1034. doi:10.1016/j.clinph.2009.03.018.
  - Thair H, Holloway AL, Newport R and Smith AD (2017) Transcranial Direct Current Stimulation (tDCS): A Beginner's Guide for Design and Implementation. Front. Neurosci. 11:641. doi: 10.3389/fnins.2017.00641
  - Neyzi O, Bundak R, Gökçay G, et al. Reference Values for Weight, Height, Head Circumference, and Body Mass Index in Turkish Children. Journal of Clinical Research in Pediatric Endocrinology. 2015;7(4):280-293. doi:10.4274/jcrpe.2183.

### Intellectual Property Claims

- Device will be disposable
- Device will be extremely easy to use
  - a. Patient should be able to self administer the medication
- Device will come in easy to open packaging
  - a. It will be ready to use and pre assembled inside packaging unlike existing products
- Headgear should easy to put on
- Device should output a steady current of 2 mA or less depending on the type of device used
- The device should be usable for only single 5-30 minute dose, then safely deactivated

#### References

- 1. Churchland, Patricia Smith. Neurophilosophy: Toward a unified science of the mind-brain. MIT press, 1989.
- 2. Reinhart, Robert MG, et al. "Using transcranial direct-current stimulation (tDCS) to understand cognitive processing." Attention, Perception, & Psychophysics 79.1 (2017): 3-23.
- 3. Mondino, Marine, et al. "Transcranial direct current stimulation for the treatment of refractory symptoms of schizophrenia. Current evidence and future directions." Current pharmaceutical design 21.23 (2015): 3373-3383.
- 4. Shahbabaie A, Hatami J, Farhoudian A, Ekhtiari H, Khatibi A, Nitsche MA. Optimizing Electrode Montages of Transcranial Direct Current Stimulation for Attentional Bias Modification in Early Abstinent Methamphetamine Users. *Frontiers in Pharmacology*. 2018;9:907. doi:10.3389/fphar.2018.00907.
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- 9. Manders, Eric. Handboek neurologische communicatiestoornissen. Maklu, 2016.