Sponsor: Dr. Bikson
Carim-sanni Sobur
Donghyun Seo
Eric Luu
Radhanath Purakait
Shalih Miah

The main goal of this project is to create a easily disposable tDCS device that comes in a ready to use package without requiring any prior setup. The reason for this device is to provide an alternative treatment for various mental disorders (specifically depression and anxiety) and to optimize normal behaviors such as attention span and learning. The device aims to assist professionals when performing tasks and also provide aid for patients certain mental disorders.

Background

Transcranial direct current stimulation (tDCS) is a form of neurostimulation where low levels of constant current is applied to certain areas of the brain. The brain is comprised of a complex network of nerve cells also known as neurons. Neurons are responsible for processing and transmitting signals throughout the brain and react to everything that happens in our bodies. Neurons communicate by sending small electrical, and chemical impulses called synapses through the cell body with the help of neurotransmitters. Electrical synapses, unlike chemical synapses, conduct nerve impulses faster (approximately 10 times faster), causing information to pass from neuron to neuron more quickly [5]. The process of polarization and depolarization of the cell bodies and the synaptic connections can be modulated with direct current. A anodal stimulation (negative voltage) will tend to produce more frequent neuronal firing and increase plasticity due to hyperpolarization of neurons, cathodal stimulation will similarly create the opposite physiological effect [19]. However, it is not clear how this physiological response relates to changes in mood and behavior as the full link has not been established [19].

The tDCS works by sending a one directional current through electrodes attached to the scalp. The placement of the electrodes can change the direction of the current and which area of the brain it affects, so where to put the electrodes is very important. The low current can alter a neuron's activity in a desired direction. This means that tDCS can strengthen or weaken the signals between neurons also known as synaptic plasticity [20]. Synaptic plasticity is linked to memory and the ability to learn, therefore, enhancing synaptic plasticity can enhance coordination, attention span, problem solving, etc.

The tDCS was mainly developed to help patients that have experienced brain injuries. However, studies have shown that tDCS can also be used on healthy people to stimuli parts of their brain to increase their cognitive performance. Depending on what area of the brain is being stimulated studies have shown that tDCS has the capability to enhance a person’s attention span, coordination, memory, and problem-solving ability. People with occupations such as military personnels, pilots, policemen, watchmen, or anyone with job the requires focus can benefit from tDCS. Furthermore, studies also have shown that tDCS has very high potential to treat depression, anxiety, PTSD, and chronic pain [5].

The reason tDCS can be considered a relevant device is because most common disorders in the world that many people suffer from is depression and anxiety. Even the most healthiest person is subject to fall under depression and anxiety. It's been estimated that around 264 million people worldwide have an anxiety disorder [6] and 322 million people worldwide live with depression [7]. In the U.S alone 18.1% of the population or 40 million adults around the age of

18 and older are affected by Anxiety disorders every year, yet only 36.9% are receiving treatment [12]. Additionally, a study was done in 2015 where it showed that 6.7% of U.S population (~16.1 million adults around the age of 18 and older) were affected by major depressive episode at least once in a year. Depression is considered a leading cause of disability in the United States [12].

As effective as tDCS seems, it has a controversial view in the scientific community. A study performed to analyze researchers' perspective on tDCS, found that a high percentage of researchers claimed tDCS to be ineffective in terms of enhancing normal functions [11]. The study also found a disparity among the effectiveness ratings across different domains. Researchers that had tDCS as an integral part of their studies rated the effectiveness of tDCS higher than those that did not. Ethical concerns also arise because the long term effects of tDCS are unknown. Studies done using tDCS are often associated with short term simulations thus, there are a lack of studies that analyzes the long term adverse effects of tDCS.

Principles of operation

A tDCS device consists of an electrical circuit, a pair or more electrodes, and potentially some headgear to place electrodes properly. In order to apply DC to the brain the current must be generated at the circuit. This circuit provides a flow of electrons from the negatively charged electrode to the positively charged electrode. Sometimes manufactures may include additionally waveforms. It includes a battery and potentially some safety and regulative circuitry. Regulatory circuitry may modulate the voltage applied to the skin to maintain safe current limits. Critically there must be some measure of dosage that the circuit maintains. Dosage is understood as the current (Amperes) level and time of treatment (seconds).

The next hurdle is the actual contact point where the current meets the patient's forehead. Electrodes of different shapes and sizes (3X5,5x5,5x7 and 5x10 depending on the montage) are used to make safe and effective contact with the human skin. The idea is that the electrode has low contact resistance to reduce the heat produced as current flows. Heat can develop due to poor conductivity and due to low contact area of the electrode [4]. Even if the electrodes are effective in passing current, they must also be positioned correctly. Positioning of the electrodes are known as montages and there are different montages for different desired treatments and mental effects [3]. For example in figure 2 (left), the anode is connected to F3 and the cathode is connected FP2, this treats depression and anxiety [25]. In figure 2 (middle), only the anode is connected to F10, and this aids in accelerated learning. In figure 2 (left), the anode is connected the F4 and the cathode is connected to F3, this reduces addictive tendencies.

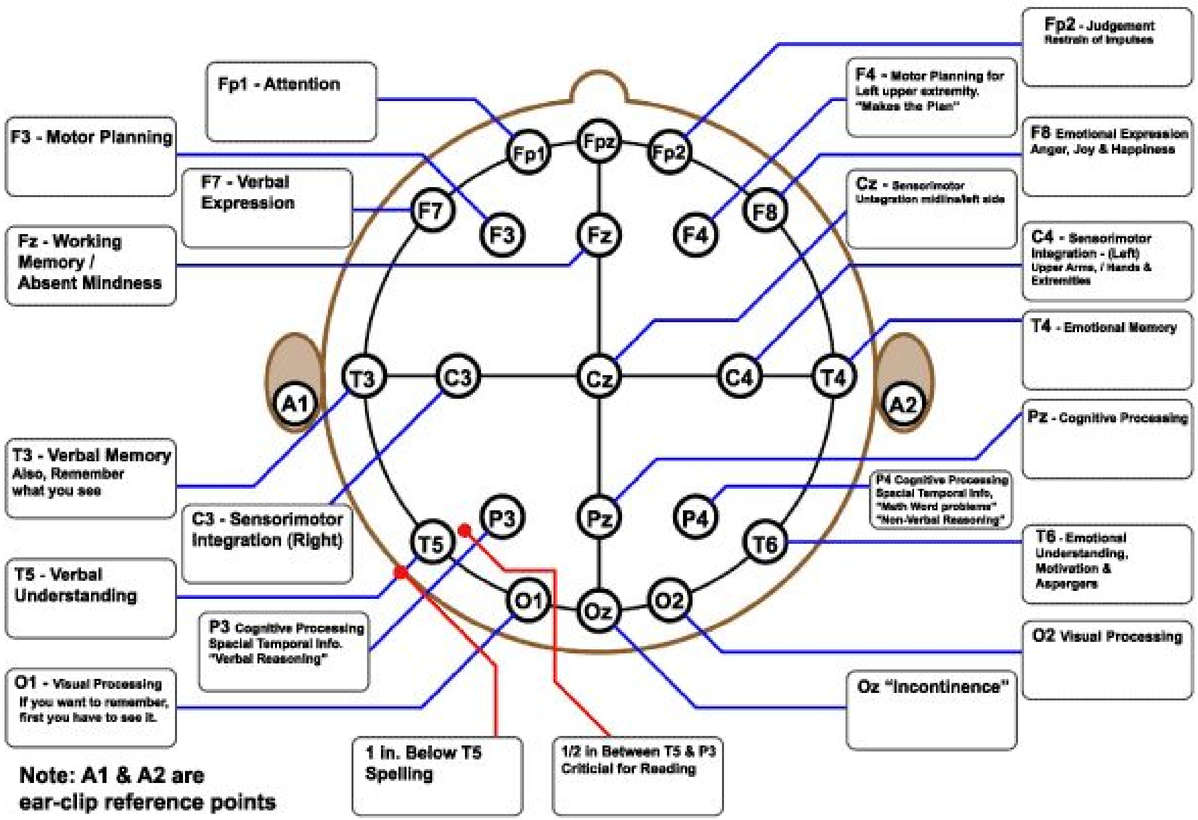

Figure 1: Montage positions [28]

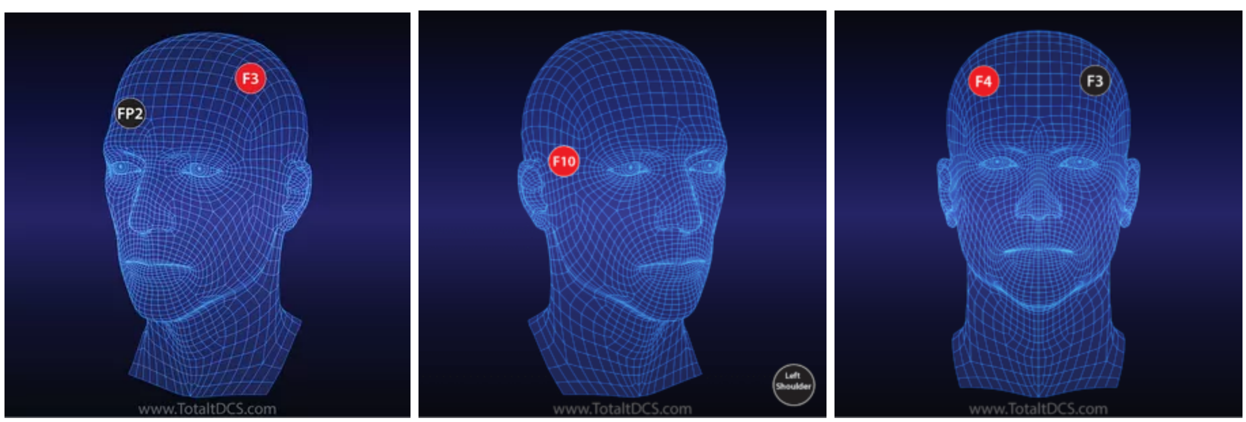

Figure 2: Different types of montages for providing aid in learning and treatment for depression, anxiety and addiction [25]

Who uses Transcranial Direct Current stimulation?

tDCS is a tool that can be used in a variety of settings. Today, it is primarily used for research in any subject regarding learning , drug addiction and improving focus [2],[1].

Generally the devices are actually somewhat difficult to use, they require special training to place electrodes on the head and scalp, they procedure also needs to be supervised as the circuits often do not have enough fail safe measures for layman users. This is why tDCS has mostly stayed in the clinical setting.

There have been efforts to move tDCS outside the practitioner patient relationship, currently one can even buy tdcs devices on common online retailers . However the problem of usability is a common motif throughout the different use cases. Combined with issues of misuse and safety it is evident that strides in innovation are necessary.

Need Statement: There is a need to develop a low cost ready-to-use tDCS device that can be disposed after a single use (20~40 minutes).

Sponsor Specifications

There are numerous tDCS devices in the market currently, but most devices are bulky and tedious to use. Considering the tDCS devices in market currently most are not pre-packed device ready to use package without requiring any prior setup and are not easily disposable. The implementation of a disposable and single use device that is "straight out of the bag use" for professionals (military personnel, police officers, guards) or for a sessions on the go was proposed. Our sponsor has identified certain criteria that has not been meet in current tDCS devices in the market. The three major feature our sponsor is specific about is: Disposability, simplicity and single use.

I. **Disposable**: tDCS devices are used in various profession as mentioned above, for example surgeons, soldiers, pilots and other profession. In the case of a surgeons for example after surgery they dispose everything used. Our focus is to target this professionals and deliver tDCS in the environment and ways they are used to. Disposability does not mean it has to be cheap to dispose, but disposable and affordable like other essential tool for such professionals.

II. **Single use**: Most professionals mentioned above usually have pre-packaged components needed for their job. Usually most components are single use, they are usually only used during their job. Compared to an individual that uses tDCS daily and needs a long time use device, someone like a drone pilot would prefer a straight out of the box, single use device for their shift[24].

III. **Simplicity and compact design**: Simplicity of this new tDCS device is a key. Most of the professionals we are targeting are not used to reading long steps to use most of the tools they use. Secondly the device should not be hindering their way that is it needs to be compact. Setting up such devices in a intensive care unit for example should not require additional scientist to oversee the mounting[22].

There are many tDCS devices with various designs and cheap prices out there. Our target is to meet the needs of professionals and certain individuals that are used to a certain lifestyle. Those who are used to the act of "straight out of the box", "single use" and "dispose"[22][23][24].

Prior art

Many tDCS devices on the market today are quite expensive (>$30). Worde, none of the devices we found are disposable. However, the key feature of user operability. This section describes complete devices available in the market at the moment, while demonstrates individual aspects of the device we are going to design, none simultaneously have the simplicity in design and usability needed and no tDCS device has approached the design of disposable stimulator, so we will have to borrow inspiration from tDCS devices and disposable medical devices.

Existing tDCS-Portable

Thync Device

Thync Device is one of the self-usable portable brain stimulation devices in market currently. Unlike its competitors, which use cranial electrotherapy or transcranial direct current stimulation (tDCS), 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. It modulates some of the hormones underlying fight to fight response by ramping these hormones up or down. Thync claims to have two effects – or "vibes", calming or energizing [15].

Disadvantages: The device is expensive, not disposable and its montages are restricted to the forehead + Neck and forehead + back of the ear.

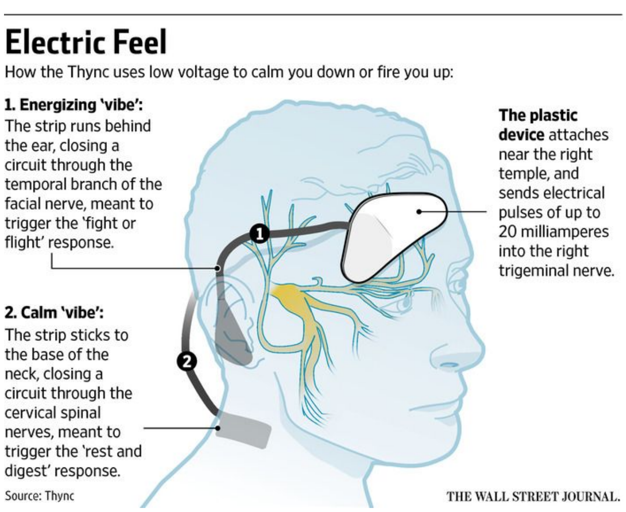

Figure 3: Thync device [17]

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. It has a Smart Current Ramping that creates smooth current transitions, providing comfortable tDCS sessions. 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.

Disadvantages: The device even though relatively cheap requires a bit expertise to set up. Electrode positioning also is prone to mistake by patient input.

Figure 4: The Brain Stimulator v3.0 [18]

Advantages:

The portability and simplicity of the thync device and Brain Stimulator v3.0 could be employed in our design. Although we are proposing a design without the need of a expert and fixed electrode to avoid patient mistake. The thync device is the closest to our approach but it is expensive. Limited to one montage and not disposable.

Soterix Medical 1x1

Soterix Medical 1x1 system is a suite of modular components for direct current stimulation, it consists of a simple plastic headgear, snap-on sponge electrodes, and a versatile electrical circuit. This system is notable for its simple and clean design, the headgear is lightweight, flexible and versatile for most montages. It is similar to the brain stimulator V3 however it has more current dosing options and has headgear that allows one to precisely place electrodes for montages.

From this design we should take the strap design and possibly the useful markings on it. Although our design should aim to have the user do as little calibration as possible. One problem about this device is that the circuit is very expensive and has too many options. A disposable device doesn't need to be this complex, and it's feature set should be limited so that the circuit is also physically small.

Figure 5: The complete soterrix platform can be read more about on: https://soterixmedical.com/research/1x1, our sponsor's website.

White market devices

There exist a grey area of devices that are cheap, but are of questionable quality, mostly because they are not actually associated with any particular company. These devices are typically used by do it yourselfers. Some are just constant current power supplies with off the shelf electrode leads to the device [26]. Some are a bit more questionable in design with high current outputs, or manual voltage control [27]. That said this niche is important to look at because these devices achieve a very low cost at the detriment of features and sometimes safety. Our device should approach the low price point of these devices as much as possible by leveraging disposability to sink costs lower.

Figure 6: Go flow pro [26]

Is much like the brain simulator V3, however it is even more compact and portable. This device has a unique design in that it fits straight on a 9v battery and has simple controls for current and dose time. The advantage of this device is that it is very portable and convenient. One of the main disadvantages of the device is the high cost.

Figure 7: Focus Go flow pro [26]

Headgear

Headgear application can vary in terms of design and electrode attachment. A suitable headgear would require minimal to no setup and comes ready to use. An example is the Portable EEG Electrode Locator Headgear, which includes an elastic stretchable cap that is connected to EEG electrode locators on the inside [15]. 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. If we can potentially combine the plunger with the cap containing the electrode locators so that no assembly would be required then the headgear for this device could be used as a guide for designing our device. This headgear design is useful for its portability

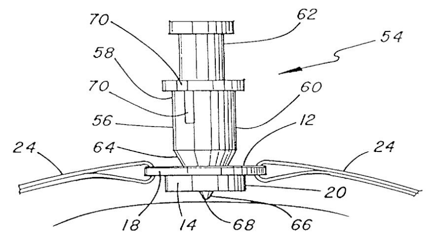

FIG. 3

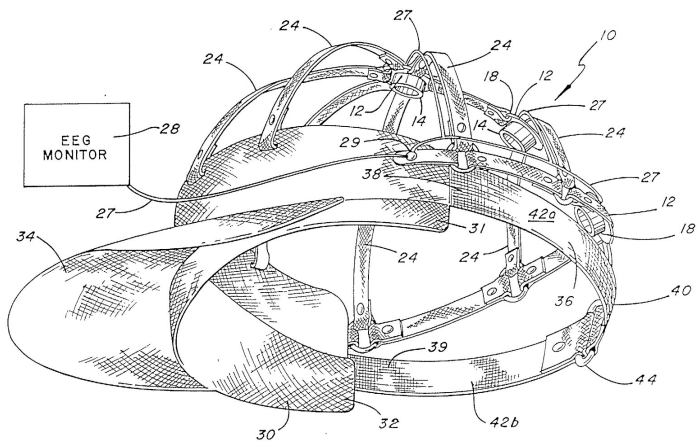

FIG. 2

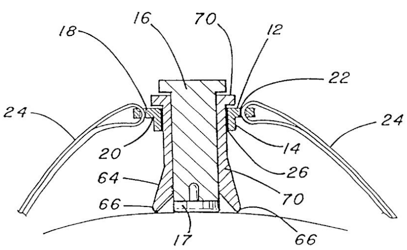

FIG. 4

Figure 8: The EEG Electrode Locator Headgear that shows the straps that can be repositioned (left) and the plunger assembly (right) [15].(Patent: US6381481B1)

Electrode Approaches

Electrode design is important to the function of our device. The job of the electrode is to conduct electrical current from the circuit to the scalp without generating contact resistance and therefore heat. This is done through the use of an electrolyte to conduct electric current evenly and safely without a metal on skin interface that can be hazardous to the epithelium. In tDCS current must be applied through the scalp which is typically covered in hair. For hairy areas a sponge electrode is favorable because adhesive electrodes cannot make contact with the skin.

Electrodes are placed on the montages to allow electric currents to flow safely from the device to the desired part of the brain. There are generally 3 types of electrodes that can be used for tDCS [21]. An example of them is adhesive electrode. This is the cheapest type among the three. It conducts current on the bare skin by easily just place it on the desired montage, but its current flow through hair could be disrupted. Another example is rubber carbon electrode. It is a bit more expensive than the adhesive electrode, and harder to prepare it because it requires gel application on the targeted area and needs a strap to prevent sliding from the position. Last example is the most prefered type for tDCS, the sponge electrode. It is the most expensive type among the three but it can conduct current through the hair by salinating the target area. This also needs a strap to hold it on the target area.

https://thebrainstimulator.net/choosing-electrodes/

Figure 9: Electrode sponges [21],[14]

<u>Simple Circuit</u>

Iontophoresis

There are no single use or disposable tDCS devices on the market today. Most devices are actually costly and aren’t designed from a single use or usability standpoint. There however direct current medical devices on the market that do hit the intersection between disposability and effectiveness. Notably Iontophoresis devices like the IontoPatch® line [13] 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. The takeaway is that we should similarly use a small battery in an easy to use clean packaging that can be used with minimal instruction. There are however two critical problems for such a cheap and minimal circuit. One is that the power supply may provide a relatively constant voltage, but there is no real way to tell if the output current is correct or consistent between uses. Additionally there is a problem of how there is no dosing mechanism in terms of timing the dose. We can use this design as inspiration for how we can implement tDCS in a similar product

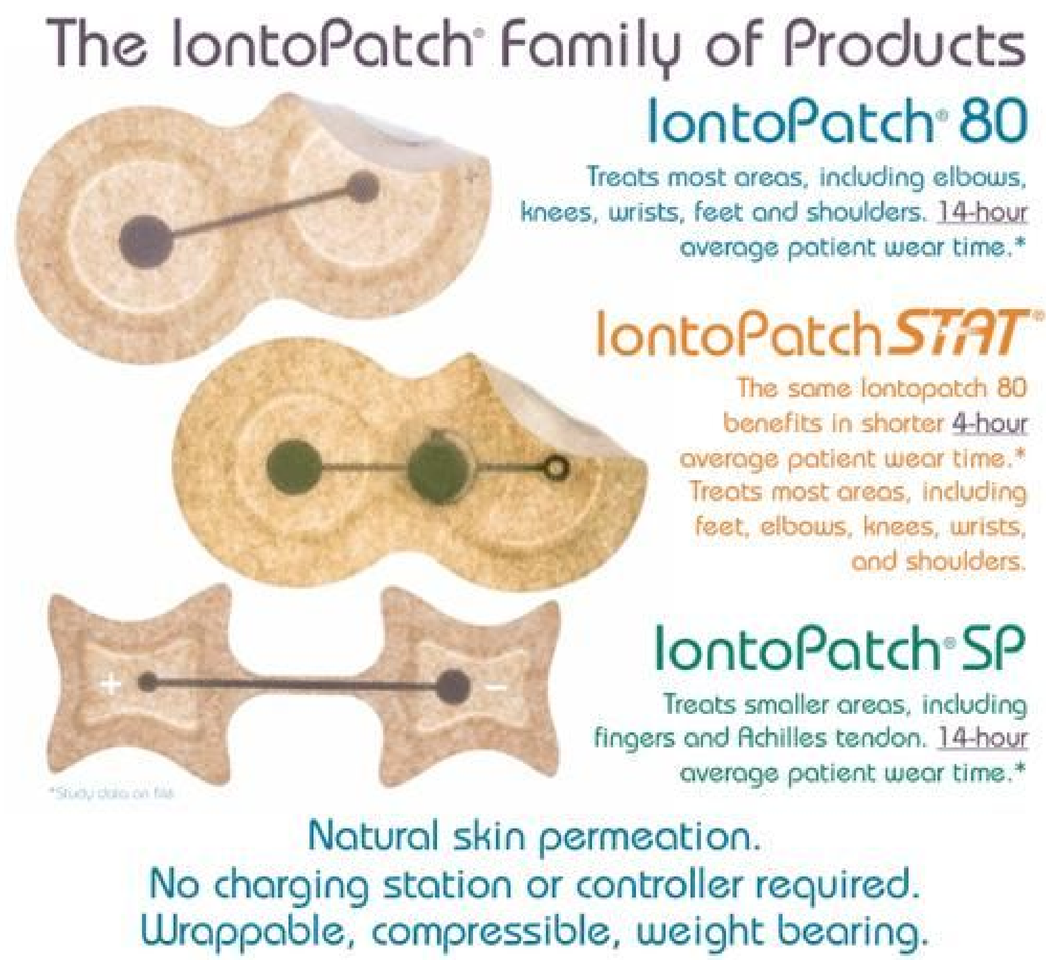

Figure 10: Iontophoresis patches (http://www.iontopatch.com/device.html?fbclid=IwAR06i6e6AbVL3-DXtS2AmJJ1UWTT3mbXqUSO0zvm7ziTf7nfbctIovuJ38I).

Product Design Specification

Parameter	**Value**
Electrode size	25.46 A/m^2 current density must be maintained. So electrode pads of about 16 cm^2 must be used above 1 milliamp current [8]
Maximum Current	2 mA [9]
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.
Headgear circumference	57.2 cm (elastic material) [10]
Weight	Less than 16 oz
Length (packaged)	Less than 6 in
Width (packaged)	Less than 6 in
Height (packaged)	Less than 6 in (preferably packs flat in bag)
Dosage	Less than 30 minutes

1. Electrical Safety
    a. Current amplitude
        i. The current needs to below a certain limit to prevent skin and neural damage, up to 2 mA (milliamperes) DC.
        ii. Current would be specified on the headgear with a label.
    b. Electrode interactions
        i. Electrodes must use an electrolyte, and the current must not pass through metal or rubber materials as this can cause undesirable chemical

interactions.
(https://www.sciencedirect.com/science/article/pii/S1388245715010883)

ii. Electrode size matters, high current (1mA) requires larger electrodes (larger than 4 cm × 4 cm).

iii. Long term exposure and excessive current can cause itching and redness and skin damage, electrical safety mechanism to automatically stop current should be implemented.

c. Component selection/consistency

i. Components selected should have correct tolerances to be safe within physiological current and voltage limits.

ii. Devices should be reliable between each other to provide consistent current output.

d. Dosage

i. Dosage should not exceed 30 minutes (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2754807/)

e. Safety precautions

i. The device should come with simple and clear instructions on the device itself to prevent misuse. However, actual use of the device should be intuitive.

f. Battery safety

i. A shelf stable alkaline battery should be used to power the device, it doesn't need to be reusable or high capacity.

g. Contact quality and material: electrodes connected to the sponge. Use fasteners to tight it if needed.

h. Ramp up and down current

   i. gradually increasing current for safety. Increases by 0.05 mA before reaching actual current.

   ii. Few minutes before the session end the stimulation, it will slowly lower the current until it eventually powers down. (One use).

i. Voltage protection: the device has a voltage limit and would not exit reasonable voltage (9 V suggested).

2. Low cost and environmental safety

   a. This is a very cheap and easy to make device, as it only should costs 15 dollars or less.

   b. The materials that should be used range from resistors, potentiometer, batteries, wires, pcb board, nfc chip. All are low cost.

   c. The circuit should be enclosed with fabric, plastic, or special paper to be safe to handle.

   d. Circuit should be protected from moisture of electrodes in individual package

3. Ergonomics:

   a. One person should be able to operate the device.

   b. Device has an option for powering on/off.

   c. The wires connecting to the electrodes are long enough so that the user can place the device in his/her pocket.

        i. Preferably the headgear is already attached to the circuit with no need to connect wires.
        ii. The PCB can be flexible to fit on the head.
    d. Device should be ready to go once opening.
    e. User should not have to think about pad placement and voltage. It should be hands free operation.
    f. Electrodes and cheap headgear needs to be designed for this device
        i. Headgear should accommodate different head sizes.
4. Size and Weight Restrictions:
    a. Weight should not exceed 1 lbs.
    b. Length should not exceed 6 in.
    c. Width should not exceed 6 in.
    d. Height should not exceed 6 in.
    e. Should be able to be packaged in a simple plastic bag with electrode safely.
5. User Interface Design
    a. Buttons/controls: Power/Start button, buttons for each duration/power (current).
        i. Sponsor has indicated that the duration and amperage for individual devices may not need to be changeable by user but by manufacturer.
    b. Packages should be clearly labeled with current rating.
    c. The user should be able to pull the device out of the bag without safety precautions and be able to use it immediately.
    d. Device should be for specific application.

e. Montage specification

    i. Different montage headgear should be sold with devices rated for specific currents.

    ii. Device specifications should be easy to modify at factory.

    iii. Packages are designed for individual use cases.

6. “Stretch“ goals

    a. User changeable current

        i. Our device should at least be able to have settings that can let the user choose current within safe range.

        ii. Universal application depending on the complexity.

    b. Give user ability to change waveform.

    c. One important feature is sterilizability, if possible it should make the product stand out for uses in sterile environments like operation rooms (mentioned by sponsor).

Intellectual property claims

1. Device will be disposable
2. Device will be extremely easy to use
    a. Patient should be able to self administer the medication
3. Device will be sterilizable*
4. Device will come in easy to open packaging

a. It will be ready to use and pre assembled inside packaging unlike existing products

5. Device should output a steady current of 2 mA or less depending on the type of device used
6. The device should be usable for only one 15-30 minute dose and then safely deactivate
7. Headgear is easy to put on and use properly

* This aspect of the device may not be fulfilled in final design, however it is a goal

References

1. 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.
2. 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.
3. Nasseri P, Nitsche MA, Ekhtiari H. A framework for categorizing electrode montages in transcranial direct current stimulation. *Frontiers in Human Neuroscience*. 2015;9:54. doi:10.3389/fnhum.2015.00054.
4. Thair H, Holloway AL, Newport R, Smith AD. Transcranial Direct Current Stimulation (tDCS): A Beginner's Guide for Design and Implementation. *Frontiers in Neuroscience*. 2017;11:641. doi:10.3389/fnins.2017.00641.
5. "What Is TDCS - Learn About Neurostimulation." The Brain Stimulator TDCS Devices. Retrieved Oct. 20. 2018, from thebrainstimulator.net/what-is-tdcs/.
6. "Managing Stress and Anxiety." Anxiety and Depression Association of America, ADAA. Retrieved Oct. 20. 2018, from adaa.org/living-with-anxiety/managing-anxiety.
7. "Depression." Anxiety and Depression Association of America, ADAA. Retrieved Oct. 20. 2018, from adaa.org/understanding-anxiety/depression.
8. 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.
9. Matsumoto H, Ugawa Y. Adverse events of tDCS and tACS: A review. Clin Neurophysiol Pract. 2017;2:19-25.
10. 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.
11. Riggall, K., et al. "Researchers' Perspectives on Scientific and Ethical Issues with Transcranial Direct Current Stimulation: An International Survey." *Brain Stimulation*, vol. 8, no. 2, 2015, p. 360., doi:10.1016/j.brs.2015.01.160.
12. "Facts & Statistics." Anxiety and Depression Association of America, ADAA. Retrieved Oct. 21. 2018, from adaa.org/about-adaa/press-room/facts-statistics.
13. Yanaki, Jamal S. "Active transdermal medication patch and circuit board for same." U.S. Patent No. 8,862,223. 14 Oct. 2014.
14. Soterix Medical. Research/1x1/Accessories/1x1-easypad. Retrieved Oct. 21. 2018, from http://soterixmedical.com/research/1x1/accessories/1x1-easypad.

15. Levendowski, Daniel, et al. *Portable EEG Electrode Locator Headgear*. Patent No. US20020029005A1. 7 Mar. 2002.
16. Tyler, William J., et al. "Transdermal neuromodulation of noradrenergic activity suppresses psychophysiological and biochemical stress responses in humans." Scientific reports 5 (2015): 13865.
17. "Thync Device - Google Search." *Google.com*. N. p., 2018. Web. 11 Oct. 2018.
18. "The Brain Stimulator - Cranial Stimulation Devices." *The Brain Stimulator tDCS Devices*. N. p., 2018. Web. 16 Oct. 2018.
19. Mohammadi* A. Induction of Neuroplasticity by Transcranial Direct Current Stimulation . *Journal of Biomedical Physics & Engineering*. 2016;6(4):205-208.
20. "What Is Transcranial Direct-Current Stimulation (TDCS)?" *NEUROMODEC*, neuromodec.com/what-is-transcranial-direct-current-stimulation-tdcs/.
21. The Brain Stimulator tDCS Devices. Choosing The Right Electrodes for tDCS. Retrieved Oct. 22. 2018, from https://thebrainstimulator.net/choosing-electrodes/
22. Ciechanski, P., et al. "Effects of transcranial direct‐current stimulation on laparoscopic surgical skill acquisition." BJS Open 2.2 (2018): 70-78.
23. Choe, Jaehoon, et al. "Transcranial direct current stimulation modulates neuronal activity and learning in pilot training." Frontiers in human neuroscience 10 (2016): 34.
24. Sample, Ian. "US Military Successfully Tests Electrical Brain Stimulation To Enhance Staff Skills." the Guardian. N. p., 2016. Web.15 Oct. 2018.
25. "TDCS Electrode Placement Montage Guide - Total TDCS." *Total TDCS Electrode Placement Montage Guide*, totaltdcs.com.
26. https://www.ebay.com/itm/4mA-Transcranial-Direct-Current-Stimulation-TDCS-DIY-ELECTRODES-HEADBAND/292758679611?hash=item4429c6f03b:g:CaEAAOSwa3BZ~2h1:rk:9:pf:0
27. https://www.ebay.com/itm/Transcranial-Direct-Current-Stimulation-TDCS-DIY-from-0-2-to-2mA/292751912473?_trkparms=aid%3D888007%26algo%3DDISC.MBE%26ao%3D1%26asc%3D20131227121020%26meid%3De1863033c909414289f9c2b049f358e7%26pid%3D100009%26rk%3D1%26rkt%3D1%26sd%3D292758679611%26itm%3D292751912473&_trksid=p2047675.c100009.m1982
28. DIY | DIY Tdcs | Page 2." Diytdcs.com. N. p., 2015. Web. 15 Oct. 2018.