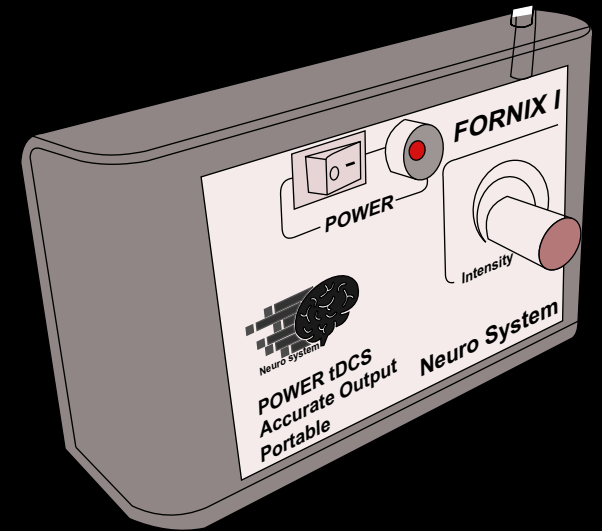


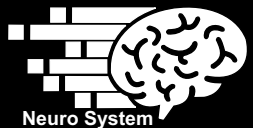


 **ULTRA [ARRAY]
PROCESSING SINA**



Investigational Product

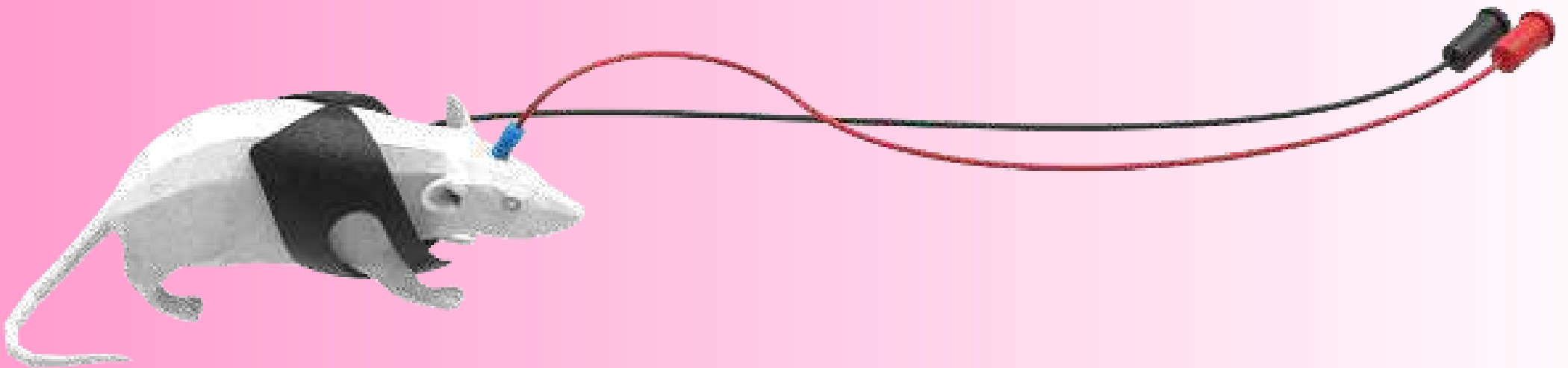
FORNIX
tDCS Device



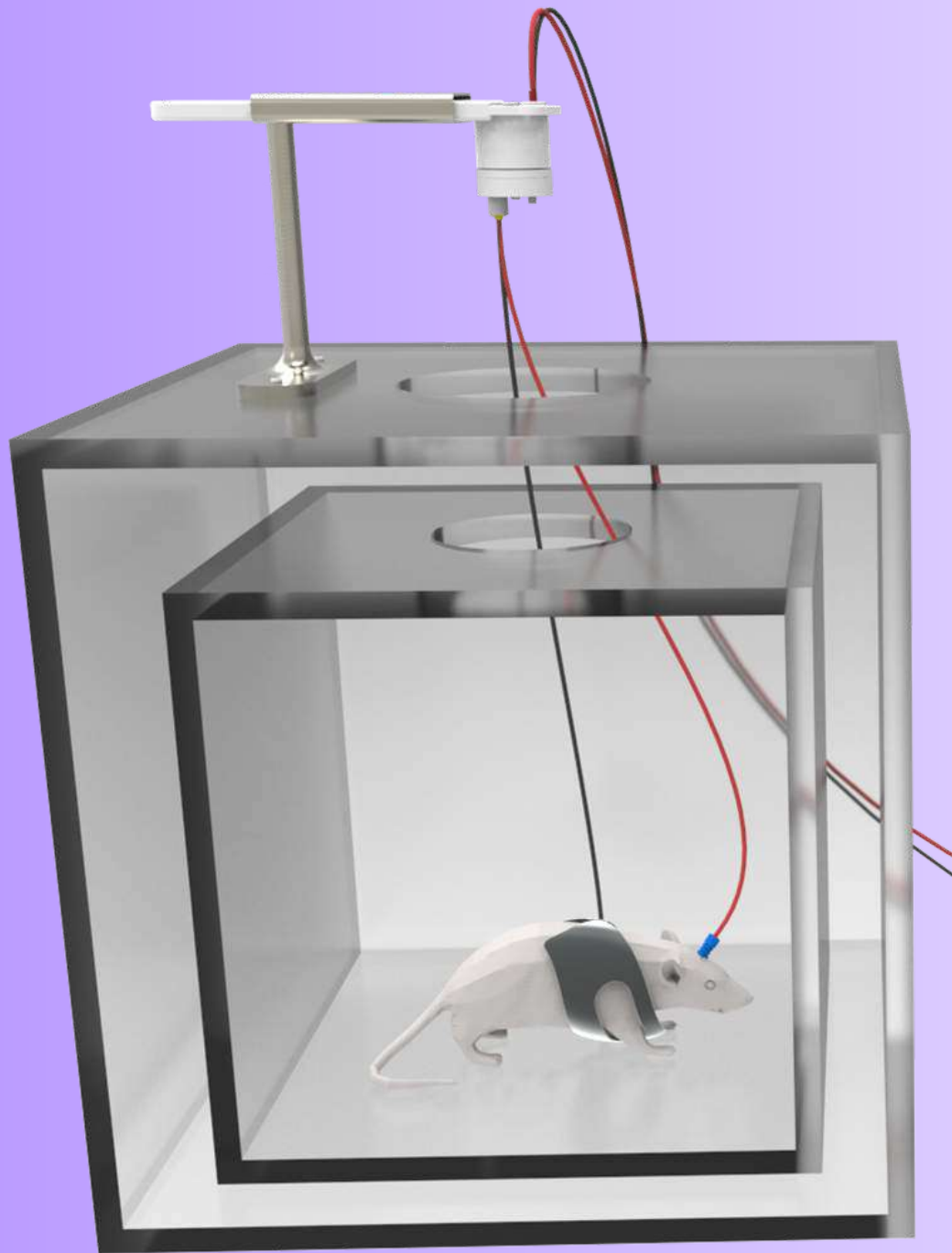
Animal DCS Stimulator

Industry Standard Animal Direct Current Stimulation System

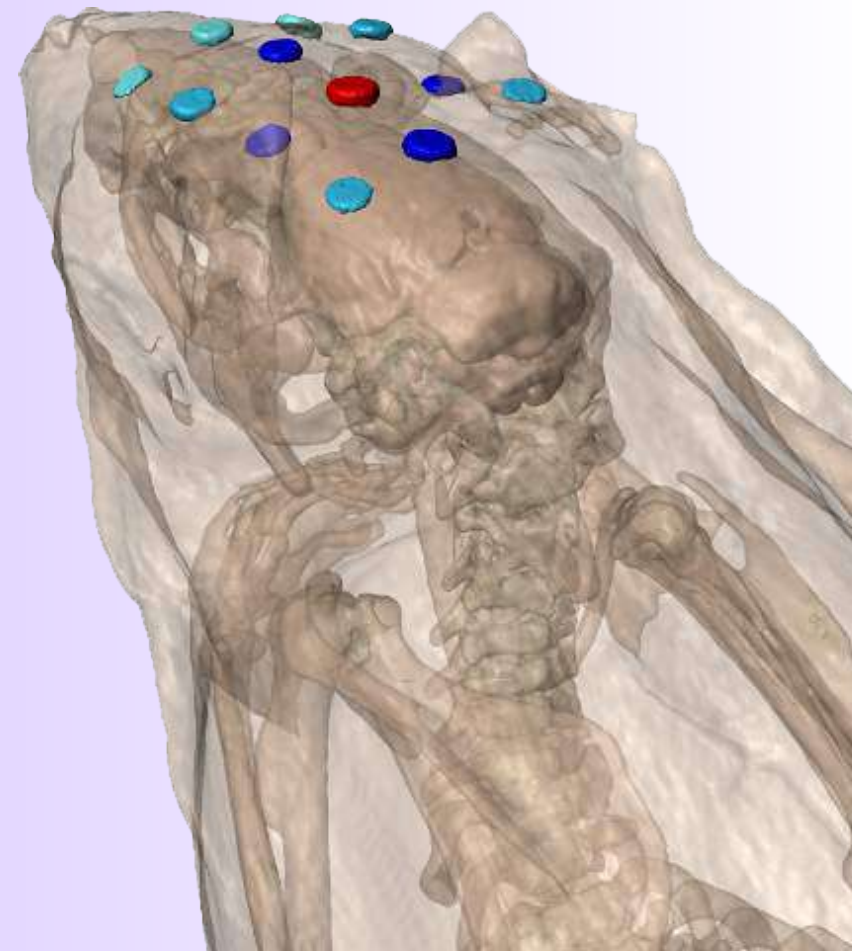
The Neuro System Animal tDCS device provides reproduction of all tDCS protocols used in animal experiments and can be used for DCS in tissue systems such as brain slice and culture. The device provides a resolution of 10 μA spanning 20 μA to 1000 μA , allowing researchers ultimate flexibility in setting intensity dose. Experimental systems can provide a very wide range of potential loads, and the Animal tDCS is the only system engineered to ensure reliable stimulation, even under unexpected conditions. The device provides a resolution of 1 min spanning 5 min to 60 min allowing researchers ultimate flexibility in setting duration dose. For any dose, simply engaging the sham switch enables a matched sham dose. In addition to initiating stimulation from device front panel, the device can be triggered to start by a trigger pulse.



The Complete System for Animal tDCS



Our hardware, software, and material scientists have applied same engineering rigor to the design of our pre-clinical stimulation systems including the Animal tDCS system. The stimulator and associated accessories is the only stimulation platform specially designed for rodent experiments based on years of experience and testing. The Animal tDCS stimulator is the only system designed for consistent and controlled current delivery, even at very low currents in the μA range.



A small and lightweight device, designed for routine clinical treatment of depression

Introduction

Here at Neuro System we don't believe in standing still. We strive for innovation, pushing ourselves to make the best equipment and offer the most adaptable software in the industry.

Flexibility, reliability, and accuracy

Our systems are designed to meet the stringent requirements of the working professional while giving you the best tools for neurofeedback. Precision Current Sources, tDCS, tACS , tECS and HD-tECS means you have access to the most capable neurofeedback system possible.

With a constantly expanding protocol database and a powerful community of minds, we provide access to the latest neurofeedback protocols and treatment methods. Whether you are a clinician, a patient, or just interested in learning more about what we can offer, take a look and...

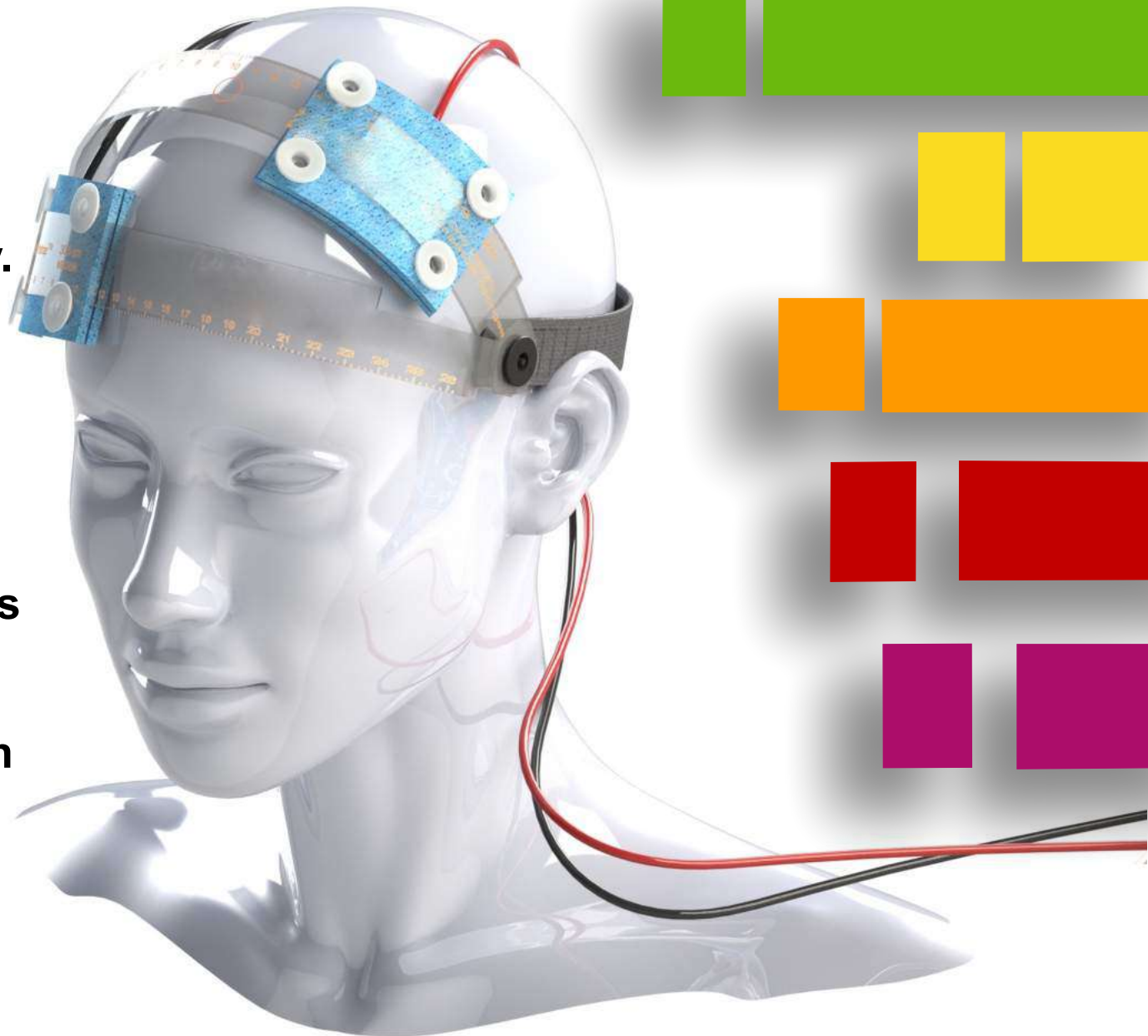
Step into the Future.

 **ULTRA [ARRAY]**
PROCESSING SINA



FORNIX I **tDCS**TM

- **Effective: additive effects to medication and psychotherapy. A viable monotherapy option even for those who do not benefit from medication**
- **Free from serious side effects: an alternative for patients who cannot tolerate antidepressants**
- **Easy to use: an automated procedure with only one button to press**
- **Affordable**



Specifications

DC Mode Output Range: 0~2 mA

Channel Number: one

Current Control: Analog

Current Limit: No

Impedance Check: No

True Current Show: No

Rechargeable Battery: Yes

Battery Life Time: 3~4 hour

Adjustable Current Limit: No

Abort Button: No

Battery indicator: Yes

Dimensions: tDCS/tACS size: 2.2"x4.5"x5.3"

Power Source: 2 cell li-ion

Garranty: Limited 1 year



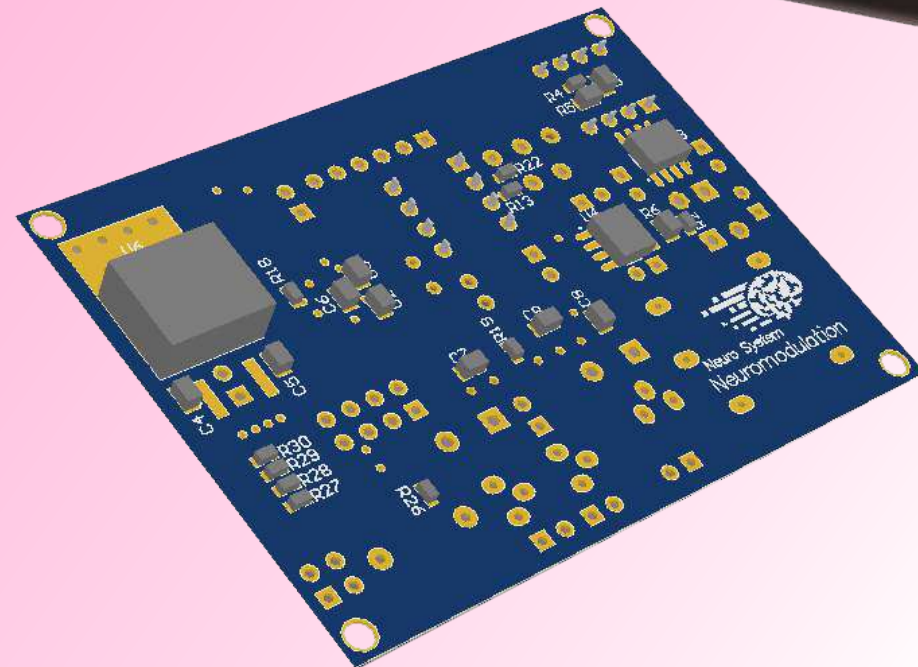
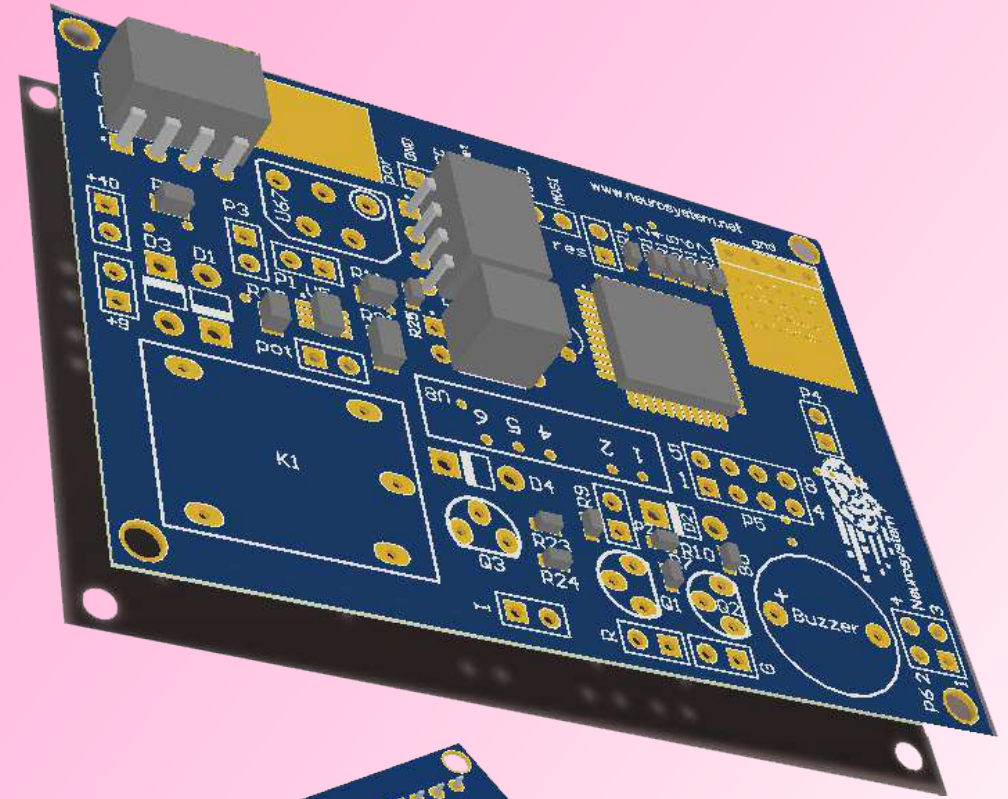
The Method

FORNIX Depression Treatment applies a weak electric current using two electrodes placed over the scalp. The current modulates activity in the left dorsolateral prefrontal cortex (DLPFC).

In patients with major depression, the DLPFC is the cortical area where brain function is known to be changed.

The goal of FORNIX Depression Treatment is to increase the excitability of the left DLPFC, and consequently relieve the symptoms of major depression.

Electrodes are inserted into single-use sponge pouches soaked with saline. neuroCap is used to correctly position the electrodes on the patient's scalp and to help ensure optimal electrode contact



Clinical Impact

Efficacy

In a study by Brunoni et al (1), the use of tDCS alone led to a remission rate of 40%, whereas the remission rate for tDCS and sertraline combined was 47%. Shiozawa's (2) meta-analysis of tDCS studies concluded that the results of active tDCS treatment in depression are clinically relevant.

Duration of effects

In a study by Martin et al (3), with weekly maintenance 84% of patients avoided relapse for three months after the acute treatment stage. In Boggio et al's (4) study, patients were found to be free from relapse without active maintenance for one month after completion of a treatment period.

Safety and Tolerability

tDCS is well tolerated and is not associated with serious side-effects or withdrawal effects (5). Itching or tingling of the skin under the electrodes and a mild headache are relatively common but harmless symptoms of tDCS treatment.

(1)-Brunoni AR, Valiengo L, Baccaro A, Zanão TA, de Oliveira JF, Goulart A, Boggio PS, Lotufo PA, Benseñor IM, Fregni F. The sertraline vs. electrical current therapy for treating depression clinical study: results from a factorial, randomized, controlled trial. *JAMA Psychiatry*. 2013 Apr; 70(4):383-91.

(2)-Shiozawa P, Fregni F, Benseñor IM, Lotufo PA, Berlim MT, Daskalakis JZ, Cordeiro Q, Brunoni AR. Transcranial direct current stimulation for major depression: an updated systematic review and meta-analysis. *Int J Neuropsychopharmacol*. 2014 Sep; 17(9):1443-52.

(3)- Martin DM, Alonzo A, Ho KA, Player M, Mitchell PB, Sachdev P, Loo CK. Continuation transcranial direct current stimulation for the prevention of relapse in major depression. *J Affect Disord*. 2013 Jan 25; 144(3):274-8.

(4)- Boggio PS, Rigonatti SP, Ribeiro RB, Myczkowski ML, Nitsche MA, Pascual-Leone A, Fregni F. A randomized, double-blind clinical trial on the efficacy of cortical direct current stimulation for the treatment of major depression. *Int J Neuropsychopharmacol*. 2008 Mar; 11(2):249-54.

(5)- National Institute for Health and Care Excellence (NICE) guidance 2015: Transcranial direct current stimulation (tDCS) for depression. Available from www.nice.org.uk/IPG530

(6)- Brunoni AR, Amadera J, Berbel B, Volz MS, Rizzerio BG, Fregni F. A systematic review on reporting and assessment of adverse effects associated with transcranial direct current stimulation. *Int J Neuropsychopharmacol*. 2011 Sep; 14(8): 1133-45



FORNIX

Depression Treatment

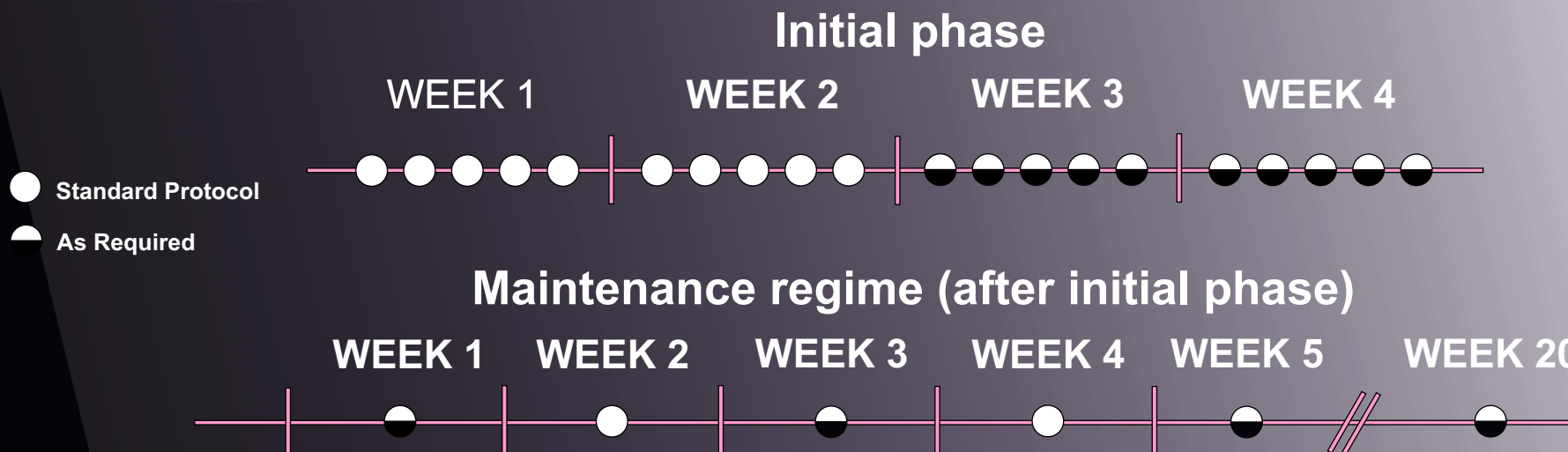
Standard protocol

The standard treatment protocol for acute major depression consists of ten daily sessions, excluding weekends. Once all the daily sessions have been completed, there is a maintenance phase of one session every other week, delivered twice. During each session FORNIX delivers a constant current of 2 mA for 30 minutes.

Modifications to the standard protocol

Under the supervision of the attending psychiatrist, the standard protocol may be adjusted for an individual patient's special needs. Such adjustment may include adding one or two extra weeks of daily stimulation to the initial phase or extending the duration of the maintenance phase. Note that other treatment parameter modifications – either to the placement of electrodes, the duration of the sessions or the stimulation current employed – may require research permission from your institution's ethics committee.

For research cooperation, please contact Neuro System.



Suitable for most patients

FORNIX Depression Treatment is a potential option for most adult patients with major depression. Stimulation can be used as a monotherapy and has been found to have additive effects to both medication and psychotherapy.

Special care should be taken with patients with diagnosed bipolar disorder as there have been reports in the literature of manic episodes after tDCS treatment.

Contraindications for the use of FORNIX Depression Treatment: implanted active or non-active devices in the head area (excluding dental implants), cardiac pacemaker implantation or acute eczema in the skin under the electrode pouches.

Easy to use anywhere

Starting a treatment session is straightforward. The FORNIX tDCS device has a single control button. There is no possibility to modify the function of the device by accident. The device has embedded features to ensure that it delivers a constant 2mA current. Unless the session is combined with simultaneous psychotherapy, presence of a medical professional is not required during the 30 minute stimulation period.



Improve Mathematical Abilities

The 'three Rs' of reading, writing and arithmetic could become four. Random electrical stimulation, a technique that applies a gentle current through the skull, leads to a long-lasting boost in the speed of mental calculations, a small laboratory study of university students has found.

If unobtrusive brain stimulation proves safe and effective in larger classroom trials, the technology could augment traditional forms of study, says Roi Cohen Kadosh, a cognitive neuroscientist at the University of Oxford, UK, who led the study. "Some people will say that those who are bad at mathematics will stay bad. That might not be the case."

Cohen Kadosh's team made headlines in 2010, when it showed that a different form of electrical jolt - transcranial direct current stimulation (tDCS) - helped volunteers to learn and remember a number system made up of unfamiliar symbols.

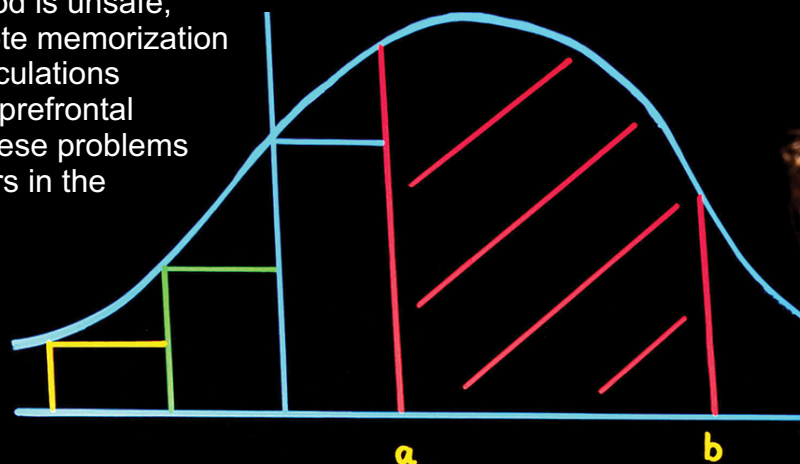
In tDCS, electrical current flows continuously between electrodes placed on different parts of the scalp, activating neurons in one area and quieting them in another. It feels like a baby tugging gently on your hair. By contrast, with transcranial random-noise stimulation (tRNS), "people ask 'are you sure it's on?'" says Cohen Kadosh. As the name implies, the technique involves electrical currents flowing through electrodes in random pulses, activating neurons in multiple brain areas. There is no evidence to suggest that either method is unsafe, he says. In the latest study, his team tasked 25 Oxford students with rote memorization of mathematical facts (such as $2 \times 17 = 34$) and more complicated calculations (for example, $32 - 17 + 5$). Thirteen volunteers received tRNS to their prefrontal cortices, a part of the brain involved in higher cognition, while doing these problems for five days in a row. They became faster at both tasks than volunteers in the control group, who were electrically stimulated only briefly.

Surprise test

The volunteers (and their experimenters) thought that the study would end there. But six months later, Cohen Kadosh's team got 12 of them back in the lab and tested how quickly and accurately they answered similar maths problems - this time without electrical stimulation.

The six returning volunteers who had previously received stimulation were on average 28%, or more than a second, faster than the control group at correctly answering the problems involving calculation.

When Cohen Kadosh's team tested them for rote learning, they found no difference between the two groups. The results are published today in *Current Biology*.



$$P(a < Z < b) = \Phi(b) - \Phi(a)$$

$$Z = \frac{X - \mu}{\sigma}, \mu = E(X), \sigma^2 = \text{Var}(X)$$

$$P(A|B) = \frac{P(A \cap B)}{P(B)}$$

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Improving Interference Control in ADHD Patients with tDCS

The use of transcranial direct current stimulation (tDCS) in patients with attention deficit hyperactivity disorder (ADHD) has been suggested as a promising alternative to psychopharmacological treatment approaches due to its local and network effects on brain activation. In the current study, we investigated the impact of tDCS over the right inferior frontal gyrus (rIFG) on interference control in 21 male adolescents with ADHD and 21 age matched healthy controls aged 13–17 years, who underwent three separate sessions of tDCS (anodal, cathodal, and sham) while completing a Flanker task. Even though anodal stimulation appeared to diminish commission errors in the ADHD group, the overall analysis revealed no significant effect of tDCS. Since participants showed a considerable learning effect from the first to the second session, performance in the first session was separately analyzed. ADHD patients receiving sham stimulation in the first session showed impaired interference control compared to healthy control participants whereas ADHD patients who were exposed to anodal stimulation, showed comparable performance levels (commission errors, reaction time variability) to the control group. These results suggest that anodal tDCS of the right inferior frontal gyrus could improve interference control in patients with ADHD.



Enhancement of selective attention by tDCS

Transcranial Direct Current Stimulation (tDCS) enhances performance on working memory tasks. However, such effects may be dependent on modulation of specific aspects of working memory. We therefore tested the hypothesis that tDCS improves selective attention in the context of a Sternberg task. Subjects had to maintain a memory set while responding to distracter stimuli. Probes consisted of one item from the memory set, and one item that could have been presented as a distracter. TDCS was found to improve reaction time significantly only when the incorrect choice had been a distracter stimulus. The results thus support the notion that tDCS effects on working memory might be mediated by a specific effect on selective attention. Enhancement of selective attention by tDCS: Interaction with interference in a Sternberg task.



Brain stimulation for the treatment of brain diseases with tDCS (other diseases)

Epilepsy

Active tDCS treatment was associated with significant reductions in epileptic discharge frequency immediately and 24 and 48 h after tDCS. Moreover, 4 weeks after treatment, a small (clinically negligible but statistically significant) decrease in seizure frequency was detected. All patients tolerated tDCS well.(1)

Autism spectrum disorder (ASD)

Schneider and Hopp (2011) conducted an open tDCS study in children with autism. The purpose was to improve language acquisition in patients with minimal verbal language. In this study the authors selected 10 ASD participants (age range 16–21). Post-anodal tDCS of the Broca area, mean vocabulary scores were significantly higher than the pre-anodal tDCS scores.(2)

Schizophrenia

Childhood-onset schizophrenia is a rare and severe form of the disorder (Nicolson and Rapoport, 1999), that is neurobiologically and physiologically continuous with adult onset schizophrenia. Hallucinations are, probably, the most dramatic clinical symptom that causes significant problems for the life of patients with schizophrenia. For tDCS, one study was recently published with regard to childhood-onset schizophrenia (Mattai et al., 2011). This study aimed to investigate the tolerability of tDCS in this patient group. Twelve participants (12 children, age range 10–17) were assigned to one of two groups: bilateral anodal DLPFC stimulation (n = 8) or bilateral cathodal superior temporal gyrus (STG) stimulation (n = 5). The stimulation protocol consisted of 20 min per day, per 2 weeks. No subjects reported significant discomfort at the electrode sites. However, four individuals had transient redness of the skin under the electrodes that resolved within about an hour after treatment. Although no significant clinical improvement has been reported, this study is the first to demonstrate that tDCS with the applied parameters is well tolerated in adolescents. Complaints of fatigue reported by some patients could be related to unspecific effects, such as medication regimens that frequently include the atypical antipsychotic clozapine.(3)

Reference:

- (1)-<https://www.ncbi.nlm.nih.gov/pubmed/23415937>
- (2)-<https://www.ncbi.nlm.nih.gov/pubmed/21631313>
- (3)-<https://www.ncbi.nlm.nih.gov/pubmed/10578456>
- (4)-<https://www.ncbi.nlm.nih.gov/pubmed/22032743>



Neuro System assumes no responsibility for the use or reliability of its products in any manner other than what is explicitly indicated at Neuro System website:
www.neurosystem.ir under TERMS AND CONDITIONS.

Note :
This Device is Investigational !

THE FORNIX IS NOT MEDICAL DEVICE, IT HAS NOT BEEN APPROVED BY THE FDA AS A MEDICAL DEVICE TO TREAT OR CURE ANY MEDICAL CONDITIONS.

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