BrainPatch Headset Device User Manual

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I. Device description and package contents

Device description

BrainPatch has developed and patented a new Neuro Technology solution for all businesses and households implemented in the headphone headset powered by mobile application. Electrical Stimulator inbuilt into the headphones pairs low-intensity electrical stimulation with the music of your choice. Our device is an implementation of Non-invasive Galvanic Vestibular Stimulation. It allows everyone to achieve a meditation-like state of mind, calmness and stress relief within seconds at a push of a button anywhere in the world. The device benefits from

- Convenient compact design, which allows you to use the device whenever and wherever.
- A range of different stimulation protocols to suit different needs (relaxation, concentration)
- An easy-to-use mobile application with a user-friendly interface
- Quick and simple set-up with Bluetooth-powered smartphones

Technical specifications

(hardware v1.2.5)

Power supply	3.4-4.2V Lithium-Polymer Battery, 800 mAh
Charging	USB-C: 5V, 100 mA
Typical current consumption during stimulation	100-300 mA
Current consumption during audio playback	20-40 mA
Current consumption in “off” state	<1 mA
Maximum achievable stimulation current	+/- 1.8-2.2 mA
Stimulation voltage range	+/- 42 V
Stimulation waveform and frequency	Controlled via an app, tACS frequency 0.01-5000 Hz at 100 points per cycle
Controls on the headset	On/Off button, Volume Control
Connectivity	Bluetooth Classic (Audio+microphone), Bluetooth Low Energy (Electrical stimulation)
CE/UKCA-marking	None

Features

- Quick and easy application - just put on the headset and the earpads will be touching the right locations behind the ears on the mastoids. The electrode application location is similar to that of other Galvanic Vestibular Stimulation (GVS) devices.
- Wireless control of the stimulation via the BrainPatch iOS and Android Applications (Python interface and cross-platform GUI sold separately)
- A range of pre-set protocols combined with music for: e-meditation, instant relaxation, demonstration of vestibular stimulation and a stimulation experience that makes one feel light-headed as if one had a few drinks
- Backed by scientific studies (see www.brainpatch.ai/science for more details)
- Real-time measurement and streaming of actual current and voltage on the electrodes during stimulation
- Contact quality (impedance) measurement protocol prior to stimulation
- Range of available bipolar stimulation waveforms including tDCS (with and without ramp), tACS (slow wave to very high frequency), pulse stimulation with controlled pulse width, which can be combined in any sequence and precisely timed. More waveforms to be added on demand.
- Silicone ear pads comfortable for long stimulation protocols
- Reusable highly absorbent saline-soaked foam pads for low impedance contact. Re-use recommended for up to 4 weeks, not recommended to be swapped between individuals.

- Randomization and blinding mode (available separately)
- Instruments to view usage statistics within the test group and set up pre- and post-stimulation questionnaires in the BrainPatch app
- Can also be used as standard wireless headphones for music or conversation

Package contents

BrainPatch headset (battery included)

Charging cable (5V plug not included)

Storage case for the headset

Several pairs of conductive foam (dry) sealed in plastic bags

100 ml bottle with stimulation solution (if the bottle was shipped empty, instructions on making the solution can be found below)

Plugs for the headset to preserve the solution from evaporation

II. Intended use

Technique

Non-invasive electrical stimulation of mastoid regions.

Technique description

The e-meditation device relies on a technique called Transcutaneous Electrical Stimulation of Mastoid Regions, and this involves application of small values of currents directly to the skin behind the ears. A variation of this stimulation already exists in consumer products (Modius Health/Sleep, Use Your Head, Zing, Alphastim) targeting weight loss, sleep, anxiety, energy levels, etc. Other variations of the stimulation have been performed in the past and in scientific/medical studies they were reported to be effective in alleviation of migraines and were trialled for stroke recovery. In the course of the research conducted by our team, we developed a protocol that combines music with the electrical stimulation and can be used to enhance relaxation. We also gathered preliminary data that shows that this stimulation can enhance performance (on numerical calculations) and we believe it will have a positive effect on your productivity and mental well-being.

Expected benefits

Relieving stress in any possible way helps avoid its negative consequences, which include loss of productivity, trouble sleeping, feeling depressed or feeling agitated as well as more

severe health implications. While it is possible to reduce levels of stress by meditation, going on a holiday or simply taking time off work, these are not always readily available.

The benefit of slow-wave mastoid stimulation combined with music is that the relaxing effects and the feeling of a clear mind are achieved within minutes. It is important for the maximal performance of the individual. Through purchasing and using the BrainPatch device for the e-meditation experience you will not only feel a pleasant sensation, but also feel more relaxed at the end of it which is believed to provide an effective solution to stress. If you provide feedback, this would be most welcome and could help bring the benefits of e-meditation experience to a larger audience, but at the same time develop ways of tailoring the stimulation to you, hence significantly contributing to the improvement of quality of your life and life of others worldwide.

III. Contraindications and risks

Contraindications:

The device and the e-meditation experience can be used by anyone regardless of gender, ethnicity, age (as long as you're over 18) or beliefs. Note, however, that women are more sensitive to the stimulation than men and may feel more comfortable with a lower setting.

The device cannot be used if:

- You have a skin condition i.e. eczema or psoriasis.
- You have an open wound at the site of the stimulation.
- You suffer from a neurological disease or condition like epilepsy, schizophrenia, stroke, concussion etc.
- You have metal implants in your head or piercings under the stimulation site.
- You have a heart condition including hypertension, coronary heart disease etc.
- You have a problem linked to the vestibular system i.e. vestibular balance disorders, or a history of hydrocephaly.
- You have been diagnosed with depression or anxiety.
- You are under 18 years old at the time of signing this form.
- You are a regular smoker and suffer from hypertension
- You are driving, walking or in motion
- You are planning to drive or operate heavy machinery in the course of the next few hours following the stimulation or in the process of the stimulation.

Please note, that this list is not exhaustive and if at any point during the course of the stimulation you feel uncomfortable, please terminate the session immediately and contact BrainPatch customer support.

Risks

Electrical stimulation is a technique that has been utilized in research, in clinics and in consumer settings for decades. There are many different subclasses of it, depending on the application site, stimulation protocol, etc. Our device uses the standard practice for using a salt solution for interfacing with the skin to minimize the risk of skin burn and it uses

multiple barriers at the level of hardware and software to control the level of current passing through.

However, in some cases, participants report itching or light burning sensation due to the irritation of the skin, in some circumstances the skin may appear red. This is, however, harmless and will go away as soon as the stimulation stops. Should you experience it, please terminate the stimulation by pressing the stop button or lifting up the headset and inform the member of our team.

Participants who were exposed to prolonged stimulation at too high a setting, reported feeling of dizziness and disorientation. This is also harmless and normally disappears within 1-2 hours, during which driving or operating heavy machinery should be avoided. Should you experience it, please inform the a member of our team.

The researchers have not reported any adverse health effects of mastoid electrical stimulation as of January 2023. Nevertheless, it should be noted that this is a novel technique and unpredicted risks might be possible. Our device has been used by more than 500 people and no severe or long-term health effects were reported.

The device must not be worn or be in contact with a person when it is connected to the electric mains supply in any way, as doing this connects the body to the mains supply and in case of charger failure to block overvoltage may have serious or even lethal consequences.

IV. Disclaimer

Your purchase and use of this e-meditation device and experience is entirely voluntary. It is your choice whether to use it or not. You can withdraw from using at any moment of the experience and you can return the device for a full refund within 30 days of receiving it.

EXCEPT FOR MATTERS INVOLVING OUR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR OTHER MATTERS WHICH CANNOT BE LEGALLY EXCLUDED, IN NO EVENT SHALL BRAINPATCH BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL DAMAGES OR LOSSES OF ANY KIND ARISING OUT OF OR RELATED TO THE USE OR MISUSE OF OUR PRODUCT AND/OR E-MEDITATION EXPERIENCE EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES IN ADVANCE AND REGARDLESS OF THE FORM OF ACTION.

NOTE THAT WHILE THE DEVICE WAS DESIGNED WITH ALL THE APPROPRIATE SAFETY FEATURES IN MIND AND EVERY DEVICE WAS TESTED DURING ASSEMBLY, NEITHER THE DEVICE NOR ANY OF THE WAVEFORMS IT IS CAPABLE OF DELIVERING HAVE A CE/UKCA OR A SIMILAR CERTIFICATION IN PLACE. BY USING THE DEVICE YOU ACCEPT THAT YOU ARE USING AN UNCERTIFIED PRODUCT.

V. Downloading the App

Android phone users

Please download the app using the link below:

https://brainpatch.ai/android

When installing the app, accept the messages about third party installations.

When launching the app, for wireless connectivity to function you need to accept warnings about enabling Bluetooth connection and location sharing (no location data is being collected/shared, but it is simply required for the functioning of Bluetooth Low Energy).

You also need to enable local storage for usage logging and also for uploading custom tracks.

Apple iPhone users

Please download and install TestFlight from the AppStore.

Then you can download the BrainPatch app using the link below, it will also appear in your TestFlight app:

https://testflight.apple.com/join/u3JyQ8Vd

When installing the app, accept the messages about third party installations.

When launching the app, for wireless connectivity to function you need to accept warnings about enabling Bluetooth connection and location sharing (no location data is being collected/shared, but it is simply required for the functioning of Bluetooth Low Energy).

You also need to enable local storage for usage logging and also for uploading custom tracks (the latter currently not available for iOS devices).

VI. Connecting the headset

Connecting Audio

1. Switch on the headset by pushing the power button for 1-2 seconds (sliding the “Vol+” switch in v1.2.3 design), you will see the LED blinking and hear an audio tone when the device is on.
2. Open Bluetooth settings on your iPhone or Android, connect to the BrainPatch device. If you see multiple BrainPatch devices available on an Android phone, connect to the one with the “headset” icon.

3. Once successfully connected and paired, you will hear an audio tone. It will connect and pair with your phone automatically next time you switch it on.

Connecting stimulator

1. With the device switched on open the BrainPatch application
2. Login or register a new account
3. On the main screen you will find the Settings icon that looks like a cog, enter settings
4. The App will start looking for BrainPatch devices automatically and it will show the available device
5. Touch the device to connect
6. After successful connection the “Device is not connected” message will disappear, a green “Device is connected” message will appear briefly. It will connect with your phone automatically next time you launch the BrainPatch App.

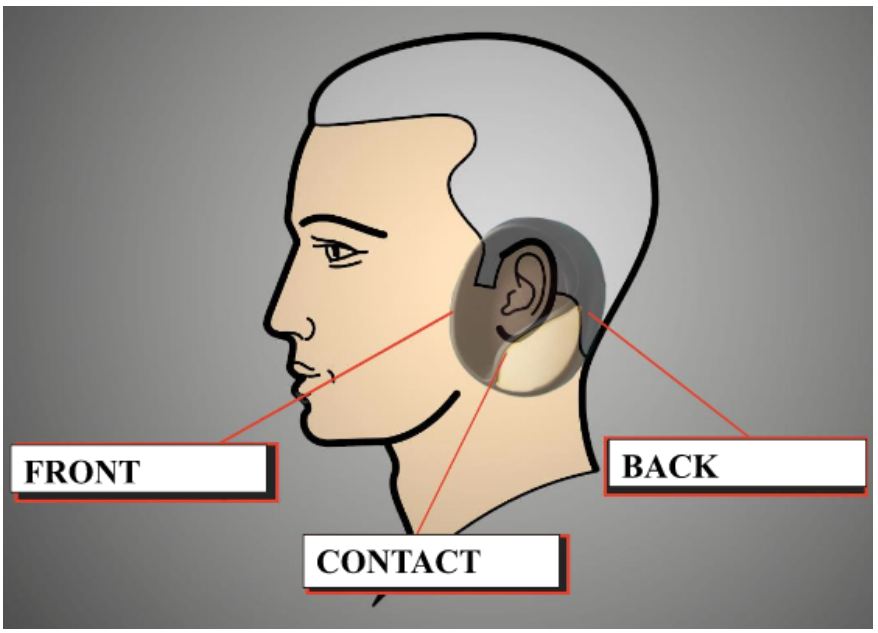
Charging

1. To charge the headset you need to connect the provided charging cable to a 5V outlet and the USB-C slot on the device.
2. DO NOT USE THE DEVICE FOR ANY PURPOSE WHEN IT IS PLUGGED IN
3. If the charging has started you should see a red (green light in older versions) light appear at the bottom. Also if you have the BrainPatch App open you would see the battery charging icon when the device is connected.
4. If the red (green) light does not come on, try switching on the device. When you switch off the device, the green light will persist, full charging should normally take approximately 4-10 hours.
5. After the charging is completed, the red light will disappear. If the red light is blinking - this indicates a charging error. Please disconnect the charging cable and try reconnecting again.

VII. Procedures and recommendations for the use of the device

1. Ensure the device is fully charged
2. To prepare the stimulant solution (if it was not supplied, if you ran out of the liquid or if the liquid does not appear clear) dissolve a teaspoon of salt in a cup of boiled water. Let it cool and store in a supplied bottle.
3. To prepare the pads, soak them thoroughly from both sides in the stimulant solution, or simply pour the solution inside the plastic bags approximately filling ⅓-¼ and squeeze to make sure the solution is evenly soaked up.
4. Insert the pads into the slots in the earpads with the protruding side facing outwards as shown on this photo.

5. Before each use, squeeze the foam and slide your finger along the foam to ensure the liquid is evenly distributed and add more solution if you don't see any coming out. After use attach the cover to minimise evaporation, or place the pads back inside the plastic bag.
6. Before starting the session you should be seated comfortably on the chair or on a mat ideally with something supporting your head as you lean back.
7. Switch on the device, launch the BrainPatch App on your iPhone or Android and connect to the device via the App and also through your Bluetooth settings (for Audio).
8. Before the stimulation session the app may ask you a question or a series of questions about your state.
9. You will need to mount the headset on your head such that the electrode foam pads are placed behind your ears such that the foam is in direct and firm contact with the skin on the mastoid bone and there is nothing (no earring, piercings and as much hair moved out of the way as possible) between the headset and the skin.



10. After you have selected the desired protocol, in order to check the connectivity between the skin and the electrodes the headset produces a small non-perceptible constant current for 3-6 seconds.
11. After the connectivity has been ensured, the session starts. Based on multiple previous recordings we recommend: 3 min of stimulation with the maximum current of 0.3 mA (LOW), 0.6 mA (MEDIUM) or 1.2 mA (HIGH) depending on your comfort level. We recommend starting with LOW, but in the course of the stimulation you will receive control over the current, so you will be able to adjust it to a level that is more comfortable for you.
12. In the meditation applications the electrical stimulation waves are combined with relaxing music to enhance the experience and the effects of the stimulation.
13. These can be perceived as a sensation of light-headedness, relaxation, vestibular illusion, this is normal.
14. If you feel an unpleasantly strong tingling sensation, please stop the session, try to wet the foam more and if the sensation occurs, please change the stimulation pads or try again at a different time of the day. While as far as we are aware, this sensation carries no negative consequence, we also know that it will not deliver the desired relaxing sensation.
15. If you feel at any time discomfort or nausea, you can stop the application by pressing the "ABORT" button or simply by lifting up the headset. You may feel a sudden stop as you do this or see a flash of light – these effects are temporary and are a normal reaction. As far as we are aware, they carry no negative consequence.
16. After the stimulation session you may be asked to fill in the small questionnaire about your experiences.

VIII. Maintenance and storage

This device must be stored in a place where the temperature is between 5-30 degrees Celsius (40 – 80 degrees Fahrenheit).

The foam pads should be stored away from light.

The device should be regularly charged after use.

IX. Troubleshooting and repair information

Fault description	Solution
The device does not turn on	Ensure that the device is fully charged
The device does not turn on and I cannot charge it	Try performing a hard reset by holding the power button (middle slider button in hardware v1.2.3) for 10-20s. After reset, try powering on the device. If it doesn't power on, please contact the BrainPatch representative.
The device turns on, but I cannot hear any beeps on one or both earpads	This suggests that the speaker/driver connection is broken. Contact BrainPatch representative for support, to order a new device or get a replacement.
The device turns on, I hear the beeps, but the music comes out of my phone, not the headset.	Ensure that the Bluetooth on your phone is on and that the audio is connected as in the instructions above. Try increasing the volume on your phone.
I cannot see the headset in the audio settings of my phone	Check that the headset is not already connected to another device. If it is not connected to another device, turn the device on and wait for ~60 seconds until the blue LED starts blinking slowly. The headset should now appear in your phone's Bluetooth settings
The blue light is continuously on	You have accidentally entered the firmware upload mode. Switch off the device and turn it on normally, the LED should start blinking normally.
I cannot connect to the device in the BrainPatch App	Ensure your Bluetooth is on. Go into settings in your BrainPatch App and press "Find devices". If you're in an environment with a lot of other Bluetooth Low Energy devices, the device may only appear after pressing "Find devices" multiple times.

I have launched the stimulation, but I do not feel anything at all	1. Ensure that the foam is thoroughly wet, fully saturated with the stimulation solution and properly inserted into its slots. If you press the foam, you should see liquid coming out. 2. Ensure that the foam and the liquid is in good contact with the skin (you should feel the liquid). 3. Press down on the earpads to make better contact 4. Try gradually increasing your stimulation setting
The foam is contact with the skin, but I still don't feel any stimulation, nor tingling at any strength setting	Go into settings on the BrainPatch App, enable "Developer mode". Enter any protocol and the impedance check mode turns on. So, you should see the peak current and voltage levels displayed. You should see current displayed
I feel a mild tingling/needles during stimulation	This is normal. If it is unpleasant, try applying a very thin layer of any moisturising cream and repeating the process.
The tingling/needles is too strong and painful	Stop the stimulation. Try applying a very thin layer of any moisturising cream and repeating the process. If it is still painful, please contact BrainPatch representative to arrange a return of the device.
I feel nauseated or sick during the stimulation.	Stop the stimulation immediately and do not use the device the same day. On a different day, make sure you have eaten properly and start with a lower setting to build up your vestibular system's familiarity with the process. If you still feel sick, please contact BrainPatch representative to arrange a return of the device.
The device body is damaged (or something inside is rattling)	Please do not turn, use or charge the device. Contact BrainPatch representative for support, to order a new device or get a replacement.
The foam pads have dried out	If you're using the device once a week or less - consider storing the pads in sealable plastic bags rather than covered with the

	plugs. If the pads do not appear discoloured, you can rinse them under running water, squeeze all of it out, allow to dry and then add more stimulation solution as in the instructions

X. Reorder and consumables information

The stimulation solution can be prepared at home as mentioned above

The pads are re-usable multiple times on the same person if stored away from the UV light. If you notice severe discoloration, or any spots on the pads, please dispose of them and use a fresh pair.

Do not share pads to avoid cross-transmission, label the plastic bag if there is more than one user of the same device.

We do not recommend washing the foam pads, but if you need to wash them for sterilisation purposes - do not use a sterilising or sanitizer solution. Instead, use hand soap and after thoroughly washing, make sure that the soap is completely rinsed out and squeeze out any water remaining before soaking up the stimulation solution again.

To order more replacement pads, or if you would like to order more devices, or any contents of the packaging, please contact us on sales@brainpatch.ai.

XI. Revision history

v0.4. (current) 17 Oct 2023

Updated button designations as in version 1.2.4

Updated light designations as in version 1.2.5

Added a statement to forbid use while charging.

Updated team members.

v0.3. 5 July 2023

Added features

Added information on frequency to the tech specs

v0.2. 19 May 2023.

Added manufacturer information

Version numbers

Description with picture of the headset, technical specifications, package contents

Added charger as electrical stimulation risks,

Added troubleshooting and repair info,

Added info on re-ordering and consumables,

Added photos and drawings in the protocol

Added information about storage

Corrected and added minor details to the protocol

v0.1. 4 May 2023 created the document

Original document contained information on intended use, contraindications, risks, connection to the App and procedure for stimulation.

XII. Manufacturer information and contact details

BrainPatch Ltd. is the manufacturer of the Headset Device.

Registered company number in the UK: 11271285

Address in the UK:

BrainPatch Ltd.,

Central Research Laboratory, The Shipping Building, The Old Vinyl Factory,

252 Blyth Road,

Hayes, UB3 1HA

United Kingdom

Registered company number in Ireland: 678405

Mailing address in Ireland:

BrainPatch Ltd.,

Inniscarra,

Main Street, Rathcoole Co Dublin,

Rathcoole,

Dublin, D24E029,

Ireland

Point of contact for sales:

sales@brainpatch.ai

For any customer support in Kazakhstan:

Yaroslav Gaschenko

yar@brainpatch.ai

For all other enquiries:

Dr. Nickolai Vysokov, CEO

nickolai@brainpatch.ai