PlatoScience

Instructions for Use
PlatoWork 2.0 tDCS Neurostimulator

Table of Content

Name of the device

PlatoWork 2.0 tDCS Neurostimulator

Manufacturer

PlatoScience ApS
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Version and compatibility instructions

Date of issue: 2024-06-26
Version of instructions: 4
Software: PlatoApp v6.0.0+, Firmware v31
Hardware: PCB v3.0
Common specifications applied: 32022R2346 (22/06/2023)

Intended purpose

The PlatoWork 2.0 Neurostimulator headset is a plug and play device controlled by an app (Android/iOS), designed to provide neurostimulation in a safe and effective way to optimise brain activity.

The PlatoWork 2.0 headset is optimising the natural brain activity for improving cognitive functions. It increases natural electric activity in specific neuronal networks, strengthening neuronal processes in the regions of the brain that are responsible for higher cognitive functions.

What's in the box

- 1 x PlatoWork 2.0 headset
- 1 x Get started guide
- 1 x Micro USB cable (70 cm)
- 1 x Hardshell case
- 1 x Bottle for Saltwater
- 9 x Electrode Sponges (Accessory)

Description of the PlatoWork headset

The neurostimulation technology used in PlatoWork is called tDCS, short for transcranial direct current stimulation. tDCS works by sending a low-intensity current between two electrodes. In the region of the brain where the current enters, brain activity increases. In the region of the brain where the current exits, the activity in the brain decreases. An increase in activity means that tDCS enhances the natural activity processes that occur in the brain. The PlatoWork headset cannot induce activity that is not there already, but it can enhance the natural plasticity, and thereby your brain's ability to develop new neural connections. The device applies electrical direct current to electrodes placed over 10-20 areas F3, F4 and Pz and the underlying brain areas. The currents also target the brain areas in between electrodes.

Intended user

There are no gender or age restrictions for tDCS, but it is considered advisable to defer the use of this technique until maturity. Therefore the headset must not be used by anyone under the age of 18.

Prerequisites

For the headset to function as intended, a smartphone or other device running either iOS 12+ or Android 9+ is necessary to run PlatoApp.

Specification of the benefits to be expected

PlatoWork 2.0 is not approved as a standalone treatment for any medical condition, and PlatoScience does not provide, sell or recommend tDCS as a treatment in itself. PlatoWork 2.0 provides tDCS as a tool to increase neuroplasticity (the brain's ability to form and reorganise synaptic connections) especially in response to learning or adaptation. Patients should not expect medical benefits from use of the product, as the benefits below are dependent on training paradigms used in conjunction with the device, and thus a medical clinician/professional should be consulted if needed.

Benefits for the patient:
Increasing neuroplasticity; the brain's ability to form and reorganise synaptic connections, especially in response to learning or adaption. PlatoScience does not make any claims or give any recommendations about the medical or clinical benefits of PlatoWork 2.0.

Exclusions

The following categories of users shall be excluded, and must thus not use the device:
(a) persons with a history of epilepsy;
(b) persons undergoing pharmaceutical treatment for conditions related to the central nervous system;
(c) persons undergoing therapeutic treatment which change the excitability of the central nervous system;
(d) users of illicit substances or other substances that modify a person's natural perception regardless of whether those are commonly understood as therapeutic drugs;
(e) persons who have a tumour in the central nervous system;
(f) persons who have vascular, traumatic, infectious or metabolic lesions or diseases of the brain;
(g) persons who suffer from sleep disorders, drug dependency or alcoholism;
(h) persons who are less than 18 years old;
(i) pregnant women.

Reference: Common specifications (EU) 2022/2346 (22/06/2023)

Contraindications

The PlatoWork headset is intended to be fully operated by the patient. There are no requirements for any previous education, knowledge or experience to do so except the ability to read and follow the content of these instructions.

However, the PlatoWork headset **cannot** be used:

- in patients with cranial or intracranial implants (e.g. plates, screws, deep brain stimulator, etc.), metallic implants such as electrodes, stents, clips, pins, plates, screws, braces, or other metallic objects such as shrapnel or jewellery.
- in users with metallic passive implanted medical devices and other metallic objects present on or inside the body, as well as users with active implantable medical devices (for example pacemakers, implanted cardioverter-defibrillators, cochlear implants and neural implants) and active body-worn medical devices (for example neural stimulation devices and medication infusion devices).
- in patients with any defects in the neurocranium (e.g. after skull trepanation)
- in patients with epilepsy
- in patients with large vessel occlusions (e.g. complete blockage of an internal carotid artery) and possible changes in brain perfusion (stroke)
- in patients with skin diseases of the scalp
- in combination with other brain stimulation device
- by people younger than 18

Side effects

Neuromodulation with tDCS is generally well tolerated with few side effects. It is common to experience skin sensations (itching, tingling or light burning) under the electrodes during stimulation which tends to decrease as the skin habituates to the sensation. It is also very common to experience reddening of the skin beneath the electrodes, headaches, and mild fatigue.

It is uncommon but some people have been reported to experience nausea and on very rare occasions insomnia, or burns underneath the electrodes have been reported. To avoid the risk of burns it is important to abort stimulation if a strong burning sensation appears under the electrodes.

Any serious incident that has occurred in relation to the device should immediately be reported to PlatoScience and the local competent authority.

Precautions

Stimulation with tDCS can sometimes be uncomfortable, but it should never be painful. If you experience any pain or unexpected effects, not described here or by your provider, during stimulation, immediately stop the session and contact your healthcare practitioner and PlatoScience.

- Only use as instructed by your provider.
- Maximal use is 30 minutes per day (1 full session up to 2 milliampere current strength). Excessive use, or use beyond this limit, increases the likeliness of the risks listed under side effects above.
- If you have any medical condition seek medical advice before use.
- If any redness or irritation persists, consult a physician.
- Consult your doctor if you have any concerns about your health.
- Check integrity and functionality of the product before use.
- Always read the entire instructions before use.
- If you experience any pain or discomfort STOP and contact a medical professional immediately.

Warnings

- Do not charge the PlatoWork headset with any other micro USB cable then the one supplied with the headset.
- Do not use a charging brick or USB power supply with the USB cable that exceeds the power specifications given by these instructions (5 V D.C, 3W).
- Only use sponges with the PlatoWork headset that have been supplied by PlatoScience.
- Do not use any third party cables or accessories with the device as this could negatively affect the electromagnetic compatibility and performance of the device.
- Keep the headset out of the reach of children and animals.
- Do not use the headset if you are allergic to cotton or rubber silicone.

- Do not use the PlatoWork headset in environments with strong magnetic fields (e.g. close to an MRI) as it could result in improper operation of the device.
- Do not use the PlatoWork headset adjacent (closer than 30 cm) or stacked with other equipment e.g. portable radio frequency communications equipment including peripherals such as antenna cables and external antennas.
- Do not use the PlatoWork headset close to high frequency surgical equipment as it could result in improper operation.
- The lithium polymer ion battery is only intended to be replaced by trained service personnel as incorrect replacement could result in hazards such as excessive temperatures, fire or explosion.
- No modification or service of this equipment is allowed by the patient or by service personnel that is not affiliated with PlatoScience.
- Prolonged use of the device may result in chafing or irritation of the skin at the points of contact.
- Keep the device dry, clean and out of sunlight.
- Do not use the device if it is damaged.
- Only use the headset on areas of the scalp where the skin is intact.
- Do not attempt to use the device while the device is charging.
- Do not just take the PlatoWork headset off during stimulation. Instead use the stop button in the app and let the headset ramp down the current to 0 milli ampere (mA) before removing it.

Environments suited for use

The PlatoWork headset is intended to be used in the home healthcare environment or a professional healthcare facility environment e.g. at home, in the workplace, the office of a psychologist or a hospital. We do however not recommend using the device outdoors, close to any strong magnetic fields or close to active high frequency surgical equipment as this could cause improper operation of the device.

Degradation of performance

The PlatoWork headset can deliver up to 2 mA and 22V during normal operation. However, should the performance of the device for any reason degrade e.g. due to electromagnetic disturbances to the point where the output exceeds 4 mA or 40V it would be considered an unacceptable risk and all use of the headset must immediately be stopped.

As a user, any degradation of performance will be experienced as an increase in the discomfort/pain from using the headset. If there is a change in the level of discomfort, this can indicate a degradation of performance, and usage of the device should immediately be discontinued.

Data security

IT security measures, including protection against unauthorised access, are secured in accordance with GDPR regulations.

Getting started

To get started with your first neuromodulation you will need around 5-10 minutes to prepare and get everything ready. The headset is ready for use immediately after it is turned on, and the delay before use is only dependent on the time it takes to finish the necessary setup as described below.

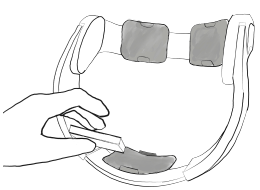
1. **Download** PlatoApp onto your smartphone (www.platoscience.com/app)

2. **Sign in** by creating an account and filling in the necessary details within the app, or use account details from your provider if you have been provided with such.

3. **Fill the saltwater bottle.** Fill the bottle with drinkable water, add ¼ teaspoon of regular kitchen salt, screw the lid back on and mix well.

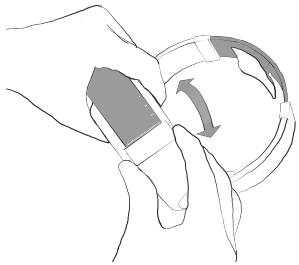
4. **Turn on** the headset by simply unfolding it. The LED on the left side should start to blink blue to indicate that the headset is powered up.

5. **Get the sponges ready.** Fill the case used to store the sponges with saltwater and dip a dry sponge in it. Repeat with the remaining two dry sponges. Place a sponge in each of the three electrodes.



6. **Put the headset on.** Make sure that the two textured silicone pads are placed right above the ears. Use four fingers to measure the distance between the centre of your eyebrows and the bottom of the two front sponges to ensure that the headset is correctly placed.

7. **Ensure headset fit.** For the headset to work, it has to sit tightly on your head so all three sponges must be firmly pressed against your scalp. If the headset feels too loose, adjust the sliders on all four sides to obtain a tighter fit between the sponges and your scalp. The sliders are each marked with I, II, III and IIIIIII to indicate from smallest to largest head size.



8. **Select mode.** Open PlatoApp and select the simulation mode you would like to use or has been suggested by your provider.

9. **Connect.** After selection of stimulation mode the headset will automatically connect with your phone (make sure your phone's Bluetooth is turned on). The logo on the headset will turn from blinking blue to solid blue once it is connected. When starting the session, the app will first test that the headset has sufficient contact with your head. When the test is successful, you can change the current setting to your liking (0.8-1.6 mA), put your phone away and begin your task.

10. **Shutdown.** The app will count down to zero and inform you when the current has been ramped down to zero milli ampere (mA) and the headset can be safely removed. If you would like to stop your session before the time has run out please use the pause or exit button and wait until the app shows that the current has been fully ramped down and it is safe to remove the headset.

Videos with instructions

Videos with instructions on how to safely use the device are available on the internet, by visiting www.platoscience.com/videos

Colours of indicator lights and their meaning

Colour	Meaning
Red	Error device needs to be restarted
Green (solid)	Normal operation
Green (pulse)	Stimulation in session
Blue (solid)	Connected via Bluetooth to phone
Blue (pulse)	Bluetooth active but not connected to phone

Troubleshooting

The two most common challenges you might experience when you are new to neurostimulation with PlatoWork are:

Establishing good contact. At the beginning of every session the contact between the headset and the scalp is tested and displayed as a percentage. This is a safety feature to ensure that the stimulation is as comfortable as possible. If the app will not let you past the contact test please try the following:

1. Readjust the sizing of the headset and ensure that the electrodes fit tightly to your scalp.
2. Readjust the headset so the entire surface of the sponge is touching the scalp.
3. Make sure the sponges are fully moist with saltwater.
4. Make sure that there is not too much dry hair directly underneath the electrodes e.g. if you have thick or curly hair under the electrodes try applying a small amount of salt water directly to the hair.
5. Clean the electrodes on a regular basis as a build up of dried salt, dirt, etc. can increase the resistance and thus make it harder to establish good contact.
6. Replace sponges when they are worn out after approximately 90 sessions.

Trouble connecting via Bluetooth to the headset. The Bluetooth communication between the headset and the app is all handled by the app. This means that the headset cannot be paired via settings in your phone. If the app cannot find the headset please try the following steps:

1. Ensure that your phone's Bluetooth is on
2. Ensure that the headset is turned on by checking that the LED on the side is blinking blue
3. Go to the Play/App store and download the newest version of PlatoApp.
4. Open the app and try again.

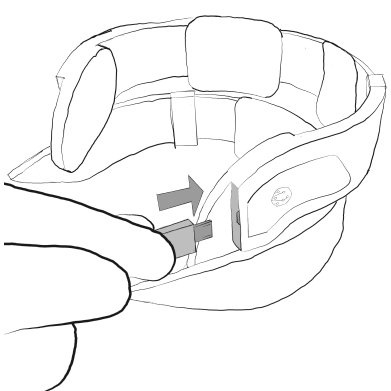
Storage and maintenance

Storage

The headset should be stored in a location that is not in direct sunlight with a temperature range of 5°C to 35 °C at a humidity level of 15% to 90% at an air pressure of 700-1060 hPa. At these temperatures there is no need to wait for the PlatoWork headset to warm up or cool down before use.

Charging

Use the provided micro USB cable to charge the internal lithium ion polymer battery when the battery status shown in the app starts to get low. Should there be insufficient charge on the battery to start and run a full session the app will inform you and you will not be able to start a session before charging the battery.
In order to charge the battery, collapse the headset, and insert the micro-USB into the headset port on the left side. The other end of the cable is a regular USB and must use a USB port that provides 5 V D.C. at 3W.



Cleaning

It is recommended to clean the headset and especially the electrodes after each use with normal wet wipes. If the cleaning is skipped it is possible that salt and dirt will accumulate on the electrodes over

time making it harder to establish a good connection between the user and the headset. If this already has happened it is instead recommended to use alcoholic wet wipes to clean the headset.

If the headset is transferred to another patient or used simultaneously by multiple users/patients It is recommended to clean the headset with alcoholic wet wipes between uses and to not share sponges.

Sponges

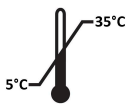
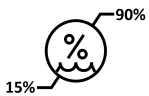
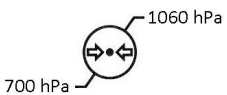
After each use, take out the sponges from the headset and rinse them under lukewarm tap water. Ideally, let them air dry first before placing them back into the protective plastic case. Doing this will help maintain the sponges for approximately 90 sessions. Should the sponges wear out (get too thin, stop retaining water, get dirty, etc.) a new set can be ordered from www.platoscience.com/replacement-sponges

Performance characteristics

Compatible head sizes	55-60cm
Dimensions	17x19x21cm
Weight	≈187g
Electrode size	4x5cm (20cm^2)
Electrode location	F3, F4 and Pz (10-20 system)
Operating time per charge	≈ 7.5h (15 sessions)
Mode of operation	Continuous
Maximal current output	2.05 mA
Maximal voltage output	22V (firmware), 24V (hardware)
Battery	LiPo, 3.7V, 500mAh, rechargeable (≈90 discharge cycles corresponding ≈1350 sessions, non-replaceable).
Classification	Internally powered medical equipment.
Charging	5V D.C, 3W
Bluetooth operating range	1-5m
Water ingress protection	IP22
Expected service life time	Headset: 5 years Micro USB cable: 5 years Sponges: 90 sessions
Expected shelf life	Headset: 12 months
Temperature	Use/Storage/Transport: 5°C to 35°C
Humidity	Use/Storage/Transport: 15% to 90%, non-condensing
Atmospheric pressure (Altitude)	Use/Storage/Transport: 700 hPa to 1060 hPa (-382m to 3000m)

Explanation of markings

Symbol	Description
	Indicates the medical device manufacturer
	Indicates the date and country of manufacture.
SN	Indicates the serial number so that a specific medical device can be identified
REF	Indicates the catalogue number so that the medical device can be identified
LOT	Indicates the batch code so that the batch or lot can be identified
	Indicates the need for the user to consult the instructions for use
	Type BF applied part. Indicates that the PlatoWork headset is electrical connected to the user (the three conductive electrodes) but not directly connected to the heart of the user.
MD	Indicates that the item is a medical device.
IP22	Ingress Protection. Protected against solid objects over 12mm, e.g. fingers and direct sprays of water up to 15 degrees from a vertical position.
CE	CE Mark

	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
	General warning sign
	Indicates the temperature limits to which the medical device can be safely exposed
	Indicates the range of humidity to which the medical device can be safely exposed
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed

Product disposal

The sponges are made of cellulose and can be disposed of as household waste.
The PlatoWork headset and charger cable should be disposed of as electronic waste according to local rules. Should these rules not be clear to you please contact local authorities to determine the proper method of disposal.

Contact us

Please do not hesitate to contact our customer care service (hi@platoscience.com) if you have any questions or require assistance with your PlatoWork headset.

Electromagnetic compliance (EMC)

The PlatoWork headset intentionally receives and transmits RF electromagnetic energy for the purpose of its operation (Bluetooth Low Energy) at a frequency of 2.4 GHz (2402-2480 MHz) using Gaussian Frequency Shift Keying (GFSK) modulation with a maximal effective isotropic radiated power (EIRP) of 4 dBm.

The headset is compliant with the following emission and immunity standards:

Emission Limits & Measurements				
Phenomenon	**Standard**	**Method**	**Level**	**Result**
Radiated RF	EN 60601-1-2	CISPR 11 Group 1, Class B EN 301 489-1 EN 301 489-17	30 MHz - 230 mHz: 40 dBuV/m (QP), 230 MHz - 1000 MHz: 47 dBuV/m (QP). 1 GHz - 3 GHz: 70 dBuV/m (Peaks), 50 dBuV/m (Average), 3 GHz - 6 GHz: 74 dBuV/m (Peaks), 54 dBuV/m (Average).	Pass

Immunity Limits & Measurements				
Phenomenon	**Standard**	**Method**	**Level**	**Result**
Electrostatic Discharge (ESD)	EN 60601-1-2	EN 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air discharge	Pass
Radiated Immunity	EN 60601-1-2	EN 61000-4-3	10 V/m 80 MHz– 2.7 GHz 80% AM at 1 kHz	Pass
Rated Power Frequency Magnetic Fields	EN 60601-1-2	EN 61000-4-8	30 A/m	Pass

To help ensure the safe performance of the device in regards to EMC throughout the expected service life PlatoScience recommends that users adhere to all warnings contained in these instructions, only use the device in suited environments and use the correct environmental conditions to store the device.

List of applied standards

1. Device
PlatoWork 2.0 tDCS Neurostimulator

2. Legislation and Quality	
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
Common specifications 02022R2346 (22.06.2023)	Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to MDR (C/2022/8626)

3. Risk Management	
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971

4. CE Marking and Labeling	
2011/65/EU 2015/863 2017/2102	Directive 2011/65/EU of the European Parliament and of the council of 8 June 2011 on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices

5. Technical Evaluation	
EN 60601-1:2006/A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-11:2015/A1:2021	General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
EN 62133-2:2017/A1:2021	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
EN 60529:1991/A2:2013	Degrees of protection provided by enclosures (IP Code)
EN 62304:2006/A1:2015	Medical device software – Software life cycle processes
EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices - Amendment 1

6. Biological Evaluation	
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

7. Clinical Investigation	
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practise

8. Post-Market Surveillance	
ISO/TR 20416:2020	Medical devices - Post-market surveillance for manufacturers in this record.

9. Applicable Directives	
2012/19/EU	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on Waste Electrical and Electronic Equipment (WEEE)

10. Guidelines	
MDCG 2021-24	Guidance on classification of medical devices
MDCG 2020-08	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies
MDCG 2020-07	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
MDCG 2020-06	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and notified bodies
MDCG 2020-05	Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies
MEDDEV 2.12/2 Rev. 2	Post-market clinical follow-up studies a guide for manufactures and notified bodies
MEDDEV 2.12/1 Rev. 8	Guidelines on a Medical Devices Vigilance System
MEDDEV 2.12/1 Rev. 8	Additional guidance regarding the Vigilance System as outlined in MEDDEV 2.12/1 Rev. 8 from July 2019