



platoscience
neurostimulation

PlatoWork Manual

PlatoWork 2.0 tDCS Neurostimulator

Instructions for use

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Name of the device








PlatoWork 2.0 tDCS Neurostimulator






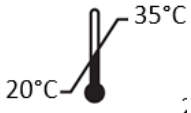
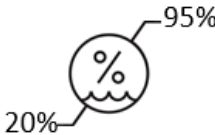
Manufacturer

PlatoScience Aps, Republikken, Vesterbrogade 26, 1620 Copenhagen V, Denmark.

Product labels

Symbol Explanation

Symbol	Name	Standard / Note
	Medical device manufacturer Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	EN ISO 15223-1
	Company logo	None
	Serial number Indicates the manufacturer's serial number so that a specific medical device can be identified.	EN ISO 15223-1
	Catalogue number	EN ISO 15223-1
	Date of manufacture Indicates the date when the medical device was manufactured.	EN ISO 15223-1
	Type BF applied part (Body Floating)	IEC 60417-5333
	Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified.	EN ISO 15223-1
IP10	Ingress protection rating 10. 1. Protected from touch by hands greater than 50 millimeters.	IEC 60529

	2. Not protected from liquids.	
	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	EN ISO 15223-1
	CE marked product	Medical Device Directive 93/42/EEC, as amended with 2007/47/EEC
	WEEE symbol indicating separate collection of WEEE - Waste electrical and electronic equipment.	WEEE Directive 11(2)
	Symbol related to restriction of the use of certain hazardous substances in electrical and electronic equipment.	Directive 2011/65/EU, COMMISSION DELEGATED DIRECTIVE (EU) 2015/863, Directive (EU) 2017/2102
	Follow instructions for use	EN IEC 60601-1
	Temperature limit	EN ISO 15223-1
	Humidity limitation	EN ISO 15223-1

Intended use

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

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

Condition(s) or disease(s) to be screened, monitored or diagnosed

Conditions which imply heightened mental strain.

Patient population

There is no gender or age restriction, but it is considered advisable to defer the use of this technique until maturity.

Intended user (education, knowledge, experience)

There are no specific requirements for users.

Environment for use

The PlatoWork headset is intended for personal use at home, working place etc. It is intended for Indoor use, but can also be used outside as long as it is protected from rain etc.

Specification of the clinical 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. We offer tDCS as a tool to support and increase the efficacy of existing treatment protocols. Patients should not expect medical benefits from unsupervised use of the product. The medical benefits are dependent on treatment paradigms in conjunction with the device and thus a medical clinician/professional should be advised.

Medical benefits for the patient:

Increasing neuroplasticity; the brain's ability to form and reorganize synaptic connections, especially in response to learning or adaption.

The performance characteristics of the device

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	≈ 7.5h (15 sessions)
Maximal current output	2.0mA
Maximal voltage output	22V (firmware), 24V (hardware)
Battery	Rechargeable LiPo 3.7V, 500mAh
Charging	5V D.C, 0.5A (1C)
Bluetooth operating range	1-3m
Water ingress protection	IP10

Prerequisites

To operate the headset, it is required to download and use a smartphone app provided by PlatoScience (Android and iOS). The most recent app is always available from platoscience.com/app. As for accessories, only the sponges provided together with the headset must be used. Using other sponges than the ones provided by PlatoScience may compromise the safe use of the device

If you have been provided with this device by your healthcare practitioner, always follow the instructions from the healthcare practitioner. If you experience any unexpected effects, or effects not described by your healthcare practitioner, immediately stop using the device and inform your healthcare practitioner. The tDCS stimulation can sometimes be uncomfortable, but it should never be painful. If you experience any pain during stimulation, immediately stop the session and contact your healthcare practitioner.

Risks and side effects

Frequency of use (how often product is intended to be used):

The recommended use time is no more than 30 minutes per day or one full session.

Function related to risk:

The physical adverse effects are restricted to the site of stimulation. It is common to experience a tingling sensation in the skin at the beginning of the stimulation, as well as a reddening of the skin after the electrodes/headset are removed ('erythema'). In very rare cases skin lesions under the electrodes may occur.

The users should be confirmed to have no metallic implants in the skin or brain, nor any skin disease. The skin should be clean prior to using the device.

Precautions

- Do not use if the device is damaged
- Only use as instructed by your healthcare provider.
- Max use per day (5 days * 30min)

Preparing and handling the device

Before use, make sure to follow all the instructions for preparation as provided in the smartphone app, including expanding the sponges and mixing salt water.

Appropriate use of device

The installation of the device is controlled by the app, and the app will inform you if there are any challenges with the installation or setup.

The sponges last ~90 sessions. If sponges get dirty, worn out, hold less water, or in other ways don't function properly, they need to be replaced. Use the replacement sponges provided together with the device.

Date of issue of the instructions for use

18.04.2022

In the event of any serious incident

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

Product disposal

Sponges are made of cellulose and can be disposed of as household waste.

The headset and charger cable should be disposed of as electronic waste according to local rules.

Necessary software and data security

For the device to function as intended, a smartphone or other device running either iOS 10+ or Android 5+ is necessary. IT security measures, including protection against unauthorized access, are secured in accordance with GDPR regulations.

PlatoWork Extended Instructions

Contraindications

tDCS is a well-tolerated method with few side effects. Individual patients reported redness underneath the electrodes worn on the scalp, mild stinging sensations under the electrodes and mild headaches that pass after 30 minutes.

The following are contraindications for the use of PlatoWork. It should therefore not be used

- in combination with other brain stimulation devices
- in patients with cranial or intracranial implants (e.g. plates, screws, etc.)
- in patients 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 or open wound on skin underneath the electrodes worn on the scalp

Warnings

PlatoWork headset should be prepared for use according to instructions defined in this document.

Product cannot be used in other purposes than described in this document.

- Keep out of reach of children.
- If you have any medical condition seek medical advice before use.
- If any redness or irritation persists, consult a physician.
- Cease use if the product causes any discomfort.
- Consult your doctor if you have any concerns about your health.
- Check integrity and functionality of the product before use.
- Clean product before use.
- Always read the instructions before use.
- If you experience any pain or discomfort STOP and contact a medical professional immediately.

Limitations

There will be individual differences in the effect of neurostimulation. Therefore, as some groups show effects of tDCS on e.g. cognition and motor skills, others report negative results.

The most effects of tDCS is seen in a learning situation, where the brain is modulated e.g. by synaptic plasticity.

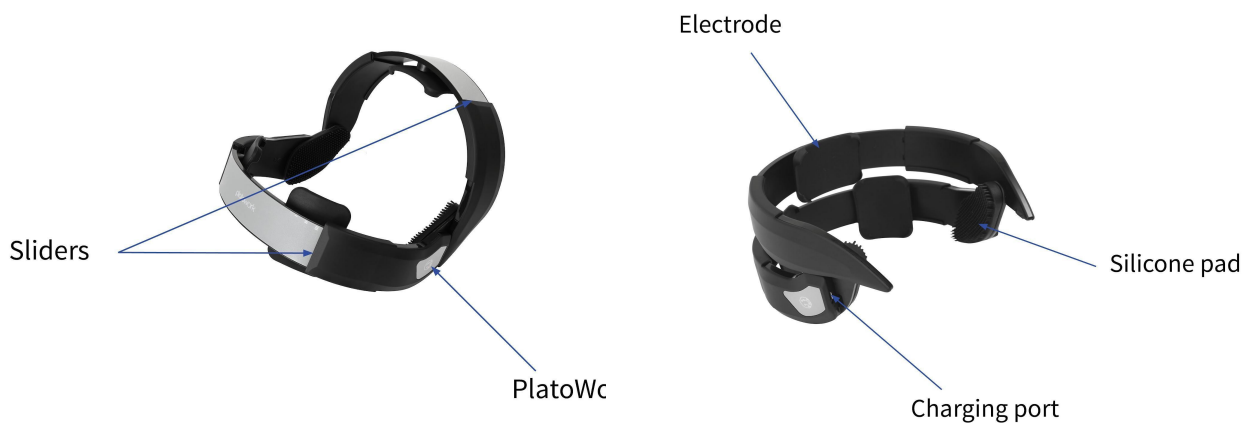
- The Platowork headset is not intended for use when users can't follow instructions, due to excess movement, inability to read or hear instructions.

- Prolonged use of the device may result in chafing or irritation of the skin at the points of contact.

Getting started

Download PlatoApp here: platoscience.com/app

Your PlatoWork



Turning on PlatoWork

To turn on your PlatoWork, simply unfold the headset. To turn it off, collapse the headset again. You will know the headset is fully open and operational when you hear the “CLICK” sound and the PlatoWork logo on the side of the headset starts blinking blue.

Once PlatoWork is turned on and PlatoApp is open, the app will automatically connect to your headset. There is no need to go into your phone settings for Bluetooth pairing.

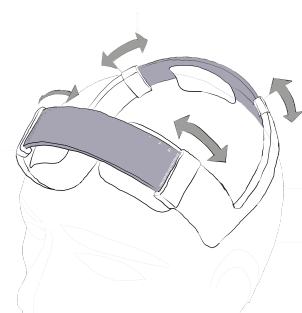


Sleep mode

After 20 minutes of not using PlatoWork, the headset will go into sleep mode and will turn off to save energy. To turn it on again, simply close and reopen PlatoWork.

Sliders

The grey areas of PlatoWork have four adjustable sliders, which can be adjusted to fit your head size. The sliders are each marked with I, II, III and IIIIII to indicate from smallest to largest head size.



Prepare the Essentials

Saltwater

Ensure the bottle provided is filled with saltwater, used to soak the electrode sponges. Prepare the saltwater by filling the bottle with drinkable water. Add 1/4 teaspoon of regular kitchen salt into the water, replace the lid and shake the mixture.

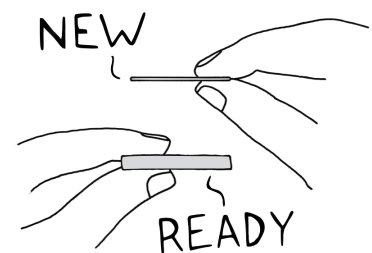
(more info about the saltwater in the section [‘When you are out of saltwater’](#))



Sponges

The sponges provided are compressed and need to be soaked in saltwater before use. Moisten 3 dry sponges (1 mm thickness) with the saltwater until they are fully expanded (5mm thickness).

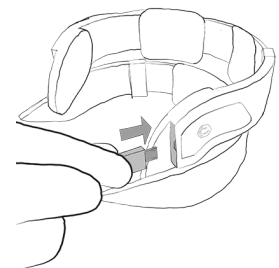
Tip: Fill the sponge case with saltwater and dip a dry sponge in it. Repeat with the remaining two dry sponges.



Charging the headset

When you receive PlatoWork, the built-in battery is already charged. The app will indicate when your headset needs charging. You can find the charging port on the side, which is only accessible when you collapse the headset. Connect the cable that is present in the box and the other end to any USB port.

A small green light next to the charging port will indicate that the battery is recharging. The light will turn off when the battery is fully charged. Recharging a flat battery will take approximately 1 hour.



Start a neurostimulation session

Now that you are familiar with PlatoWork and you have prepared the essentials, you are ready to start a neurostimulation session.

As is with most new devices, it might take some attempts to find the right fit and get the first session going. Setup will become easier, as you become more familiar with your PlatoWork headset.

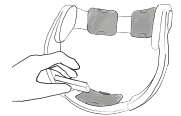
We recommend starting with the “Learn” mode on your app, for your first session. Our users have found that this mode gives the best first-time experience.

PlatoWork setup

1. **Activate** the headset by simply unfolding it (it will make a 'click' sound when it's fully opened). When the headset is turned on, the logo on the left side of the headset will blink blue.



2. **Place the sponges.** Make sure that the sponges are fully moist with saltwater, but not dripping wet. Place a sponge in each of the three black electrodes



3. **Put the headset on.** Make sure that the two textured silicone pads are placed right above the ears, and that you have two sponges in the front and one in the back. Use four fingers to measure the distance between the center of your eyebrows and the bottom of the two front sponges to ensure that the headset is correctly placed.



4. **Ensure headset fit.** For the headset to work, it has to sit tightly on your head so all three sponges are firmly pressed against your scalp. If the headset feels too loose, adjust the sliders to obtain a tight fit between the sponges and your head.



5. **Select mode.** Open PlatoApp and select your stimulation mode.



6. **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 put your phone away and begin your task.

Using the PlatoWork headset

Important

Never take the headset off or adjust it during an active session, as this could lead to a short but uncomfortable 'sting' under the active electrodes ([more info below](#)).

Keep the usage to a maximum of one full session, or 30 minutes total, per day per user ([more info below](#)).

Ensuring good contact

For neurostimulation to work, the electrodes need to have good contact with the head. Good contact is ensured by a combination of 1. Sponges (pre-soaked in saltwater), 2. Pressure, and 3. Sponge surface touching the head. When starting a session, the headset will test if the relevant electrodes have sufficient contact, and ask you to improve contact if they don't. If asked to improve the contact by adjusting the headset, please make sure that:

1. The sponges are moist.
2. The headset is fitted tightly to your head.
3. The angle of the electrodes is aligned with your head so the whole surface of the sponge is touching the head.
4. There is not too much hair directly underneath the electrodes.

Tip: If you are having trouble, look at the instructions in the [Getting Started](#) section and try adjusting the headset again.

Bluetooth range

Like all Bluetooth devices, the PlatoWork headset has a certain working Bluetooth range. This working range is between 2 and 3 meters from your phone. To avoid Bluetooth connection issues we recommend keeping your phone at close range during stimulation. The working range depends on many factors such as surroundings, radio performances and antennas which all vary from phone to phone.

Select mode

In the app you need to choose between six modes: Learn, Create, Concentrate, Rethink, Calm and Clarity. When selecting a mode, decide if you need to focus on a task at hand or create new ideas. We suggest you try out each mode with different tasks to figure out what works best for you.

Saltwater

The saltwater is a crucial component in maintaining the required conductivity when using the headset. The salt ensures that the electrical contact between the headset and your head stays consistent throughout your session. Too little salt will result in a low contact between the electrodes and the skin, too much salt can cause irritations on the skin.

We recommend starting with 1/4 teaspoon of salt for the bottle provided with the headset, following the refill instructions ([When you are out of saltwater](#)). If you experience irritation or discomfort under the electrodes, and the app confirms that your headset contact is correct, review your saltwater ratio.

For the saltwater to have an effect, it needs to be +0.6% NaCl - meaning at least 6 gram per 1 litre of water. This equals as little salt as 0.6g in the bottle provided with the headset. To achieve this, either mix 1 teaspoon to 1 litre of water (and then use this saltwater), or use an exact measure to add 0.6 gram of salt to the saltwater bottle.

Purchasing saline water

If you prefer, you can purchase premixed saltwater ('saline', or 'saline solution') at most pharmacies/drug stores. Standard, or normal, saline contains 0.9% salt (0.9g per litre, NaCl 0.9%), which is a bit higher salinity than strictly necessary. The only potential negative effect of this increased salinity is potential discomfort under the electrodes, as described above. If you buy pre-mixed saltwater/saline, make sure it only contains water and NaCl (salt).

Adjusting the intensity slider

During stimulation, the app offers a slider to adjust the intensity of the stimulation. The slider is there to enable users to adjust the sensation on the skin under the electrodes to their liking, as the same current might be experienced differently from user to user. The relationship between the intensity slider and the effect of the stimulation is not linear, so feel free to adjust up or down as you prefer.

If the current feels too intense on the skin, in the beginning, reduce the intensity down gradually to find a comfortable level. Normally the sensitivity of the skin is reduced during a session, so after 5-7 minutes you can try to turn the intensity back up and see how it feels.

Headset light indicators

- Blue-blinking: Awaiting connection with Bluetooth
- Blue: Connected via Bluetooth
- Green-blinking: Testing electrode contact
- Green-slowly pulsating: Ongoing session
- No light: Closed headset or sleep mode

Sleep mode

If the headset is open (and thus turned on) but not in use for 20 minutes, it will enter sleep mode to save battery. To wake it up from sleep mode, simply close and reopen the headset.

PlatoAcademy

We operate a Facebook group called [PlatoAcademy](#). PlatoAcademy enacts as a closed user forum for all PlatoWork users, where we can all share our experiences and discuss topics related to

neurostimulation.

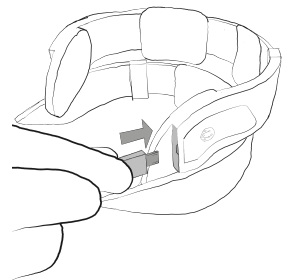
Maintaining the headset

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 plastic case. Doing this will help maintain the sponges.

Charging the headset

After around 15 sessions, the headset will require charging. The app will inform you when the battery is getting low. Charge the headset with the provided USB cable only.



When sponges get worn out

Your sponges can last for many sessions (~90) if treated correctly. But if they begin to get worn out and are discoloured, you can order new sponges at cost price from platoscience.com/replacement-sponges.

When you are out of saltwater

Follow these steps to refill:

1. Remove the screw cap, and fill the bottle with drinkable water.
2. Add 1/4 teaspoon of regular kitchen salt to the water.
3. Screw the lid back on, and shake the mixture.

Note: as little as 1/10 of a spoon, or two pinches, is sufficient, equivalent to 1 teaspoon per liter. See more details in the section '[Saltwater](#)'.

Troubleshooting

I cannot turn on the PlatoWork headset

Gently fold PlatoWork and reopen it. PlatoWork turns ON automatically once you open it and hear the “click” sound.

The headset goes into sleep mode if it is not used for more than 5 minutes. Make sure your phone’s Bluetooth is on or try to recharge the headset for 1 minute.

I cannot get the PlatoWork headset to connect to my phone

Try the following steps:

1. Open the app and initiate a stimulation session. If there is no connection, the app will show an error message.
2. Ensure that your phone’s Bluetooth is turned on.
3. Go to the App Store and download the newest version of PlatoApp.

I cannot get past the electrode test

This problem is caused by insufficient contact between the headset electrodes and your skin. Refer to the [Getting Started](#) instructions again to ensure proper contact.

Things you can do:

1. Readjust the headset so it is fitted tightly to your head.
2. The angle of the electrodes are aligned with your head so the whole surface of the sponge is touching the head.
3. Make sure the sponges are sufficiently moist.
4. Check your Bluetooth is on.
5. There is not too much dry hair directly underneath the electrodes.

If you still cannot pass the electrode test, empty your saltwater bottle and prepare a new mixture following the method in section “[When you are out of saltwater](#)”.

Additionally, apply pressure on the front of the headset by gently pressing inwards against your forehead. Please do not hesitate to contact us (hi@platoscience.com) if you require more help, we would be happy to walk you through the process.

Red marks under the electrodes

Some users experience temporary red marks under the electrodes after stimulation; this is normal and always disappears quickly after the session. The marks are caused by a combination of heat, current, and the saltwater used to moisten the sponges. If you discover marks after your session, try reducing the amount of salt in the water (see the section about “[Saltwater](#)”). You should also ensure to regularly rinse the sponges under running tap water to avoid salt build-up.

My skin itches when using the PlatoWork headset

This feeling is quite normal and caused by personal levels of skin sensitivity. If you experience an itching sensation while running a session, try to lower the intensity or add more water to the sponges. You can also experiment with lower saltiness/salinity in the saltwater, as described under '[Saltwater](#)'. Please note that your skin will most likely adjust to this sensation the more you use the headset, and most users don't even notice this after getting familiar with the headset.

I wear glasses - can I use PlatoWork?

PlatoWork is fixed just above the ears and can be worn with most types of glasses.

What if I have thick hair?

Thick or coarse hair can be a challenge but is not impossible to maintain sufficient conductivity. The problem is often biggest for the electrode at the back of the headset. Usually, the problem can be solved by adding additional saltwater to the sponges and parting the hair to allow the sponge to have maximum contact with the scalp. If problems persist, try dampening the hair underneath the electrode, to ensure contact between the sponge and the scalp.

What's in the box

Sponges

In the provided plastic case, there are nine paper-thin sponges. The purpose of the sponges is to ensure good contact between the headset and the skin.

- **Detach:** Store the sponges in the plastic casing. We recommend allowing them air dry before placing them in the plastic case.
- **Rinse:** After every session, rinse the sponges under running lukewarm tap water. Before the next usage, they need to be moistened with saltwater from the bottle.
- **Replace:** If the sponges wear out (get too thin, stop retaining water, get dirty, etc.) a new set can be ordered from platoscience.com/replacement-sponges

Bottle for saltwater

The bottle is used for containing the saltwater, which is used to soak the white electrode sponges for ensuring a good electric conductivity between the electrodes and the scalp. More information about saltwater and refill can be found under '[Saltwater](#)'.

USB cable to charge the battery

The USB-cable provided is used for charging the headset which runs on an internal lithium-ion battery. This battery can last up to 15 sessions with a normal headset connection. On the mode screen of the app, you can see the battery status, and whether it has enough charge to start a session. If it gets too low, you can charge the device using the cable provided by collapsing the headset, and inserting the micro-USB into the headset port on the left side. The other end of the cable is a regular USB and will fit any USB port. There is a green light indicator next to the USB when the device is charging, and the indicator will turn off when the battery is fully charged.

The case

PlatoWork is housed in a black hardshell case to protect and store the headset and its accessories together. The casing should be sufficient for normal use.

Additional information

General tips for neurostimulation

When you get to know your PlatoWork, you will learn how the various modes work for you. All brains are different, so it is impossible to predict the exact effects for each user. We encourage you to try the modes for different tasks and see what works for you.

Some modes can give a mild effect, while others can give a quite strong cognitive sensation. In general, try to avoid focusing too much on the fact that you're being stimulated, and rather find a relevant task to work on during the stimulation.

Feel free to combine all four modes, but from our experience, we have found that a creative mode quickly followed by a focus mode (or vice versa) will neutralise the effects.

The effect

While tDCS is a well-proven technology, the experience varies from person to person and depends on the state of mind you are in while using it.

A stimulation session lasts for 30 minutes and the effect will appear slowly after 3-5 minutes. After the session ends, the effect will last for approximately 1 hour, but this is very individual. In the app, you can send us feedback about your experience with the stimulation. Please use this opportunity to inform us of your neurostimulation experience.

Why should I not take the headset off during use?

Never take the headset off or adjust it during an active session, as this could lead to a small but uncomfortable 'sting' under the active electrodes. The explanation is simple: A rapid change in current can be uncomfortable to the skin, and taking the headset off, moving it, lifting and putting it back on will potentially cause an immediate change in the current reaching the skin. This is not dangerous but can be a bit painful, and/or give the sensation of a sting and sometimes a small visual flash.

Why maximum 30 minutes per day?

For safety reasons, we ask all users to keep the usage to a maximum of one full session, or 30 minutes total, per day per user. There are no reports of negative effects caused by longer usage, but there are also no rigorous longitudinal studies of potential negative effects of 30+ minutes stimulation.

Disclaimer of responsibility

To the fullest extent permitted by law, PlatoScience shall not be liable to any person for any loss or damage which may arise from the use or misuse of the product(s), including death or personal injury resulting from negligence, fraud or deceit, beyond defective parts or flaws that occur due to problems in the manufacture.

This disclaimer of liability for damages will not be affected if any remedy provided shall fail of its essential purpose. In any case, the total compensation liabilities of PlatoScience shall not exceed the price paid for the product(s) by the purchaser.

In addition to the damages which may occur due to the use of the product(s), PlatoScience will not be liable for damages of the product(s) which occur due to the following events:

- In addition to the damages which may occur due to the use of the product(s), PlatoScience will not be liable for damages of the product(s) which occur due to the following events:
- In the event that the product(s) is misused or used for purposes other than its intended purposes.
- In the event that the product(s) is damaged because the user does not follow this product manual.
- In the event that the product(s) is damaged because the user has disassembled, repaired, or modified it in such a way as is not explained in this product manual.
- In the event that the product(s) is damaged by a third party.
- In the event that the product(s) is damaged due to a force majeure event, including but not limited to fire, flood, earthquake, storm, hurricane or other natural disasters.
- In the event that the surface of the product(s) is damaged by use.

