# Data Sheet (EPTEV01V02) Home tDCS


The Home tDCS device (EPTEV01V02) consists of a single-phase current source designed to generate a galvanic current, which is used for transcranial direct current stimulation (tDCS). This technique targets the central nervous system to treat conditions related to the musculoskeletal and central nervous systems. The device is intended for home use by patients following a medical prescription.

## INDICATIONS FOR USE OF THE HOME DEVICE

The areas of application of the Home tDCS are:

- Chronic neuropathic pain.
- Chronic pain.
- Fibromyalgia.
- Stroke.
- Major depressive disorder (MDD).
- Auditory hallucinations in schizophrenia.

# OPTIONS

## BASIC

- 1 Unit Signal generator device (EPTEV01V02).
- 1 Portable flash memory for the installation of the Ionclinics Home tDCS Software to the PC, for the correct configuration of the device in home mode (USBEP2V01).
- 1 Unit Ionclinics Home tDCS Software.
- 1 Unit Communication cable from the PC to the device (CSWEP2V01).
- 1 Unit Therapy output cable from the device to the electrodes (CEV03).
- 1 Unit Positioning cap (GTDCSV01).
- 1 Electrolytic Gel Unit (GELCON250EP2V01).
- 1 Unit Mini crosshead screwdriver.
- 1 Unit Carrying case for transporting the device, with space to hold all the components of the device and to keep it protected and clean.
- Set. Silicon surface electrodes (ELFEPB4V01).
- Set. Sponges for circular electrodes (ESP67V01).
- Set. Electrode fixation system (FIELECEP2V01).
- Set. Fixing tool (HEFIEP2V01).
- Set of AA batteries (BATV01).

# OPTIONS

## Individual tDCS KIT per patient

- 1 Unit Therapy output cable from the device to the electrodes (CEV03).
- 1 Unit Positioning cap (GTDCSV01).
- 1 Electrolytic Gel Unit (GELCON250EP2V01).
- Set. Silicone surface electrodes (ELFEPB4VO1)
- Set. Sponges for circular electrodes (ESP67V01).
- Set. Electrode fixation system (FIELECEP2V01).
- Set of AA batteries (BATV01).

## GENERAL

| | |
|---|---|
| **Dimensions** | 220x140x46 mm |
| **Container** | High impact resistant ABS case |
| **Weight** | 350 g (without batteries) |
| **Internal power supply** | 3 non-rechargeable 1.5 V alkaline batteries AA type |
| **Device classification** | Class IIa according to regulation 09 of Annex VIII of Regulation (EU) 2017/745 on medical devices. |
| **Design standards** | Designed and manufactured in accordance with the essential requirements set out in Regulation (EU) 2017/745 on medical devices. |

# TRANSCRANIAL DIRECT CURRENT THERAPY (tDCS)

| | |
|---|---|
| Polarity | Continuous monopolar |
| Maximum output voltage | 40 V |
| Maximum power | 200 mW |
| Minimum output current | 100 µA |
| Maximum output current | 5000 µA |
| Minimum resistance | 0 Ω |
| Maximum resistance | 7000 Ω @ Imax |
| Minimum current resolution | 50 µA (I ≤ 1000 µA)<br>100 µA (I > 1000 µA) |
| Minimum treatment time | 1 s |
| Maximum treatment time | 3600 s |
| Minimum treatment time resolution | 01 s (t ≤ 10)<br>02 s (10 < t ≤ 60)<br>10 s (t > 60) |
| Minimum ramp time In | 1s |
| Maximum ramp time In | 300s |
| Minimum ramp time resolution In | 01 s (t ≤ 10)<br>05 s (10 < t ≤ 60)<br>10 s (t > 60) |
| Minimum ramp time Out | 1s |
| Maximum ramp time Out | 60s |
| Minimum time resolution Ramp Out | 01 s (t ≤ 10)<br>05 s (t >10) |
| Minimum contact electrode surface | 1 cm² |
| Maximum contact electrode surface | 100 cm² |
| Minimum surface resolution | 0,5 cm² (S ≤ 10)<br>01 cm² (S > 10) |

**The electrode fixation system and polarity are configured according to the protocol, preventing patients from altering them at home. Patent pending.**

Thanks to this unique system, patented by Ionclinics, the device can be safely used at home without the need for remote monitoring by professionals. This enhances the productivity of clinical centers and reduces the overall cost of applying the technique.

- The electrodes are secured to the cap using a patented system designed to ensure that patients cannot alter or manipulate their positioning.
- This same system also prevents any changes to the polarity of the cables once they are connected.
- If a patient attempts to modify them, the mechanism will break, stopping the therapy from continuing.

**Reusable circular electrodes:**

- Conductive silicone designed for reuse across multiple sessions with the same patient.
- They are compatible with the fastening systems specifically created for the home device.

**Reusable circular sponges:**

- Reusable across multiple sessions with the same patient, these components are made from soft, skin-friendly materials to ensure effectiveness and safety.
- They are conductive and designed to be moistened for improved conductivity.
- They allow the use of conductive gel (GELCON250EP2V01).

**Software for configuring the Home tDCS device, offering the following features:**

- Patient registration and protocol assignment.
- Define the total number of sessions and daily multi-sessions to accelerate treatment results.
- Set application times with the option to extend a time window, facilitating patient adherence to the treatment.
- Create protocols with scheduled de-escalation and maintenance phases.
- Define and modify all parameters that configure the signal.
- Create, save, and customize new protocols.
- Download session data from the home device to monitor the entire application process.
- Print or export a PDF schedule of sessions and treatment times to provide detailed information to the patient.

**Specific caps with a 10/20 system designed for individual patient use::**

- They facilitate the precise placement of electrodes according to treatment protocols, while also allowing for positional adjustments as needed.
- The caps are adjustable and made from elastic, breathable, and biocompatible materials.