Programmable Direct Current Stimulator

DC-STIMULATOR

User manual

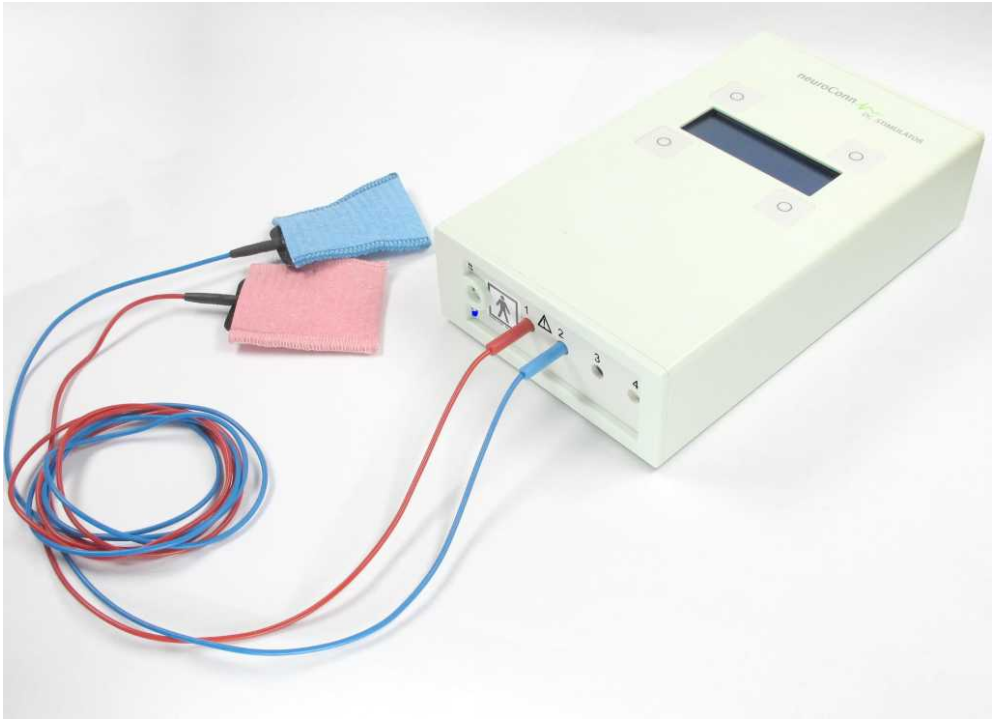


Table of contents

1 Preface

Thank you for buying a product of neuroConn GmbH.

The DC-**STIMULATOR** allows you to perform a transcranial direct current stimulation (tDCS) as part of a non-invasive Interventional Neurophysiology. Weak electrical currents (max 2 mA) at a duration of 15..30 minutes are applied at different positions on the head. The electrical charge and current density applied during tDCS are far below the threshold for releasing a stimulus and take modular effect to existing neuronal elements.

Depending on duration, used current, current density and frequency the stimulation is effective on inhibiting or activating cortical activity.
If established treatments fail a supporting therapeutic effect on depression and neuropathic pain in the lower limbs is probable and during rehabilitation of speech and motor skills after stroke and on auditory hallucinations in schizophrenia possible.

Users of the DC-**STIMULATOR** are physicians and psychologists with knowledge about the effects of non-invasive brain stimulation and experience in brain stimulation.

The essential performance of the DC-**STIMULATOR** during cranial electrotherapy is to ensure that:

- a maximum output current of 2 mA will not be exceeded (max. tolerance 5 %)
- a predefined stimulation time will not be exceeded (max. tolerance (1%)

This manual shows you how to operate the DC-**STIMULATOR**.

The devices of the neuroConn GmbH are delivered with user manuals in English or German language (Germany, Austria and Switzerland) depending on the destination country.

The manual contains all the information required by Directive 93/42/EEC Annex I Section 13. Also the standards EN1041:2008 (Providing of information by the manufacturer of medical devices) and EN980:2008 (Symbols for the labeling of medical products) as well as EN60601:2006 (Medical electrical equipment; part 1: general requirements for safety) including the essential performance characteristics: table D.1 – Common symbols & table D.2 safety marks are applied.

Note

The following signs bring important information to your attention:

This informs the user that failure to follow these instructions may cause harm to the user and others or may damage the DC-**STIMULATOR** or other equipment.

This is a general hint or useful advice for better use of the DC-**STIMULATOR**.

2 Safety

The DC-**STIMULATOR** has been certified as an active medical device class IIa.

CAUTION FOR UNITED STATES OWNERS AND OPERATORS: Investigational Device. Federal (or US) law limits this device to investigational use.

The construction of the DC-**STIMULATOR** conforms to the regulations set out in the Medical Device Directive 93/42/EEC (Date of issue 14th June 1993), which was put into German law. The requirements of the following standard(s) or normative document(s) are fulfilled:

- EN 60601-1:2006 Medical electrical equipment Part 1: General requirements for safety
- EN 60601-1-2:2007 Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 62304:2006 Medical device software - Software life-cycle process
- EN 62366:2008 Medical devices - Application of usability engineering to medical devices
- EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
- EN ISO 14971:2012 Medical devices - Application of risk management to medical devices

Important Notes

Stimulation currents of greater than 2,000 µA or stimulation durations of longer than 20 min are for research purposes only. The manufacturer assumes no liability for any injury in these cases.

DC currents can harm body tissue. Ensure that limitations for current density are adhered to. The German authority ”Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)“ recommends a current density limit of 0.1 mA/cm². The manufacturer assumes no responsibility for any injury caused by a too high current density.

Modifications and repair of the DC-**STIMULATOR** must be carried out only by the manufacturer or a company authorized by the manufacturer.

The DC-**STIMULATOR** must never be opened. The manufacturer assumes no responsibility for any damage caused by such a practice. If any technical problems are experienced, always inform the dealer or manufacturer.

Medical electrical devices such as the DC-**STIMULATOR** are subject to particular precautions regarding EMC and must be installed and operated according to established practice.

Portable and mobile HF communication equipment can influence electrical devices such as the DC-**STIMULATOR**.

The DC-**STIMULATOR** is not protected against liquid spills (IEC 60529: IP20). The operator should avoid handling liquids when using the device as there is a risk of electric shock. Should liquid spill onto the device, please unplug the device and inform the dealer or manufacturer immediately.

The device must not get in contact with liquid spills because liquid spills can damage the device and can be a risk for the patient, the operator or third persons.

The DC-**STIMULATOR** must not be used in combination with a defibrillator as it has no appropriate protection. The manufacturer accepts no responsibility for any injury caused by such use.

The DC-**STIMULATOR** must not be used on patients with a pacemaker or brain stimulator as such use can interfere or damage these devices. The manufacturer accepts no responsibility for any injury caused by such use.

The DC-**STIMULATOR** must not be used on patients with implanted intracranial metals such as clippings, coilings, ventriculo-peritoneal shunts, endoprosthesis etc.. The manufacturer accepts no responsibility for any injury caused by such use.

For safety reasons, never use bipolar stimulation on any other part of the body apart from the head. Bipolar stimulation setups can harm the heart should the electrodes be misplaced. The manufacturer accepts no responsibility for any injury caused by such use.

There is the possibility of an electrostatic discharge by touching the patient (for example the patient's head) or the DC-**STIMULATOR**. Having an electrostatic discharge while electrodes are attached to a subject may cause a discharge current to flow through the electrodes leading to a shock sensation similar to that experienced in everyday life. Such currents are not dangerous but they are unpleasant. Please avoid touching the patient during stimulation.

The patient must not touch the contacts at the rear side of the device.

NB: the human body reacts differently to direct current (DC) stimulation.

The output circuit of the constant current source of the DC-**STIMULATOR** is equipped with an electrical fuse which limits the current to 5 mA. Therefore, in any faulty condition and during normal operation, the fuse will become open circuit if the current exceeds 5 mA by a significant amount. The higher the current exceeds 5 mA that faster it will become open circuit.

Do not disconnect the electrodes if current is flowing as this will cause a strong stimulus to be delivered.

The DC-**STIMULATOR** must not be positioned or run close to flammable mixtures of anesthetic gas because it has no appropriate protection.

The DC-**STIMULATOR** must not be positioned or run in an oxygen rich environment because it has no protection against a risk of fire.

You must not connect any devices / components / cables, that are not described in this manual or that are not part of the delivery, to the inputs or outputs of the system.

During the use of the DC-**STIMULATOR** on patients interventions on the device must not be performed.

A damaged DC-**STIMULATOR** must not be connected to the patient.

Damaged devices or accessory components must not be connected to the DC-**STIMULATOR**.

With opened skull or after trepanation a stimulation with the DC-**STIMULATOR** must not be performed.

Safety aspects of transcranial Direct Current Stimulation (tDCS)

Attention! - In following situations the patient might be injured!

Only place the electrodes on healthy skin. If there are known allergies you should consult a general practitioner or dermatologist first. Never use it with injured skin areas. Stimulation of injured skin areas might result in redness of the skin (erythema) and skin burns. The manufacturer accepts no responsibility for any injury caused by such use.

Never use tap water to wet the sponges or the skin before or during the stimulation. **This might result in skin burns!** Always use **0,9 % NaCl solution!** The manufacturer accepts no responsibility for any injury caused by such use.

If you attach the electrodes with electrode paste only use the electrode paste supplied by the manufacturer. The use of other electrode pastes and gels might result in in redness of the skin (erythema) and skin burns. The manufacturer accepts no responsibility for any injury caused by such use.

Thermal limit for current density

To avoid burning the patient, the German authority (Bundesanstalt für Arzneimittel und Medizinprodukte) gives a limit of 0.1 mA/cm² for DC current applications. Observations of tDCS stimulated patients show, that even current densities as low as 0.028 mA/cm² can sometimes be painful.

> E.g.: Using electrodes with a surface area of 35 cm² with a current of 1 mA applies a current density of 0.02857 mA/cm².

Histological limit for current density

To avoid permanent injury of tissue, current density should not be higher than 25 mA/cm². This limit is far above the limit for thermal effects of the current density.

Histological limit for the duration of DC current applications

To avoid permanent injury of tissue, duration of DC current applications should be temporary. The charge per surface area should not exceed a value of 216 C/cm².

> E.g.: Using electrodes with a surface area of 35 cm² with a current of 1 mA over a period of 15 min applies a charge of 0.025 C/cm².

To calculate the charge per surface area for intermittent DC current, the current density must be included as well as the number of pulses and its duration.

Safe stop mode

At high currents, aborting the stimulation causes an unpleasant, sometimes even painful “current leap” for the patient. The “safe stop mode” can prevent this by reducing the current slowly and continuously (1 mA per second) down to 0 µA.

The “safe stop mode” is active in any stimulation mode and works during either manual and automatic abortion since it exceeds thresholds of impedance, current or voltage, as well as during the turning on and off the device.

The output current is continuously monitored by the microcontroller program, but it needs a finite time to discover high impedances and start the “safe stop mode” procedure. If there is a very short lasting interruption of the current path that lasts in the order of 200-500 ms or less the stimulator will not detect it. Short interruption of the current path has to be avoided during direct current stimulation.

Do not disconnect the electrodes if current is flowing for this will cause a strong stimulus to be delivered.

3 Getting Started

General conditions

Before using the DC-**STIMULATOR**, please read the following advice to make sure a proper environment is provided:

- The room temperature should be between 10 and 40 °C (50 and 104 °F) and the air humidity should be between 20 and 93 % (non condensing). The air pressure must be between 690 and 1080 hPa (3000 m).

- Keep the system away from direct sunlight, heat sources, liquids or corrosive chemicals.

- Keep the system away from magnetic objects. It can be damaged by too strong magnetic fields.

- Keep the system away from strong electric or electromagnetic fields.

If the device has been exposed to low temperatures or to drastic temperature fluctuation (e.g. during transport), the resulting condensation might damage the device. For safety reasons, wait until the DC-**STIMULATOR** has reached room temperature (at least 1 hour) before using the device. The manufacturer accepts no responsibility for any injury caused by insufficient acclimatization of the device.

The DC-**STIMULATOR** is suitable for mobile use and can be carried carefully around within the range of its attached cables, even whilst in operation.

Components

The following instructions refer to the DC-**STIMULATOR** equipped with all options. Depending on the specification of your DC-**STIMULATOR** some of the sockets / components might not be available on the system.

You must not connect any devices / components / cables, that are not described in this manual or that are not part of the delivery, to the inputs or outputs of the system.

DC-STIMULATOR

DC-**STIMULATOR** *upside*

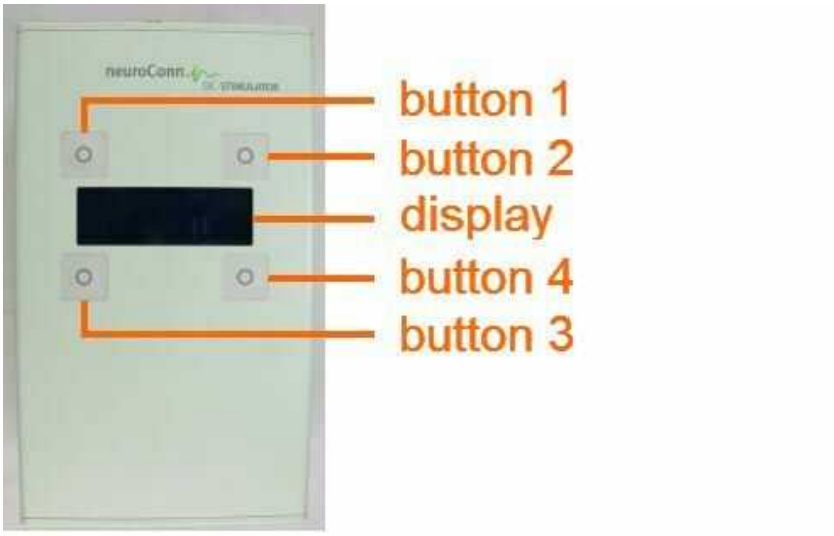


Figure 1: Upside of DC-STIMULATOR

DC-**STIMULATOR** *bottom side*

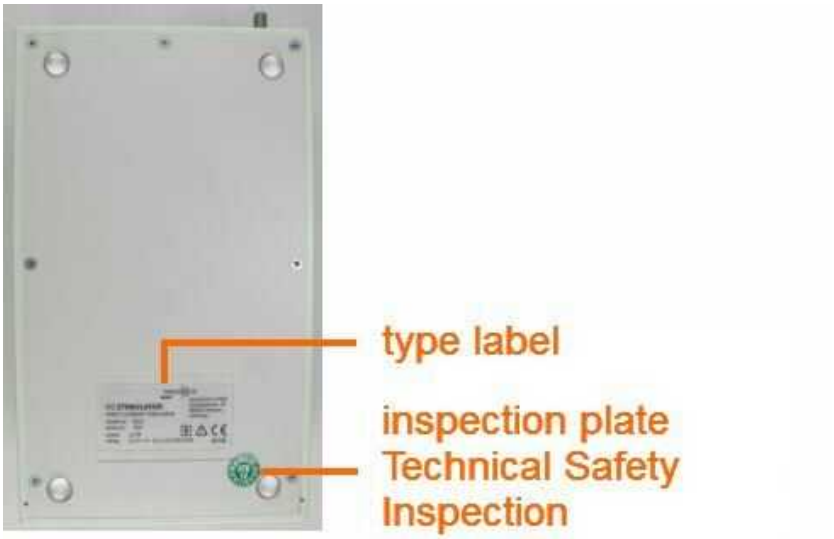


Figure 2: Bottom side of the DC-STIMULATOR

DC-**STIMULATOR** *front side*

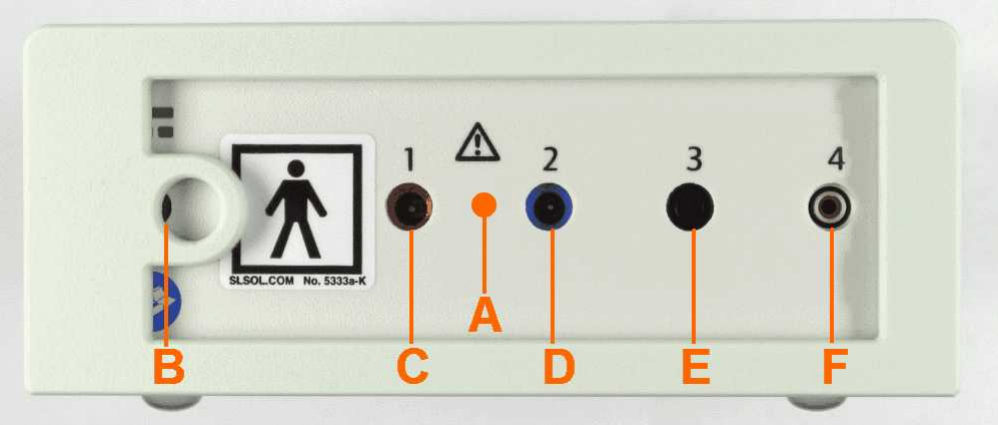


Figure 3: Front side of the DC-STIMULATOR

	Label/ icon	Specifications
		Pay attention! It is necessary to note the manual's instructions for this socket!
		applied part BF
		refer to instruction manual (ISO 7010-M0002)
A		moveable front plate
B		socket for charger
C	**1**	socket "1" (anode - positive) for touch-proofed safety connectors according to DIN 42802-2 (ø 1.5 mm)
D	**2**	socket "2" (cathode - negative) for touch-proofed safety connectors according to DIN 42802-2 (ø 1.5 mm)

E	**3**	socket "3" (ground) for touch-proofed safety connectors ø 2 mm to connect the adapter box TRIGGER IN
F	**4**	socket "4" (signal) for touch-proofed safety connectors ø 2 mm to connect the adapter box TRIGGER IN

DC-**STIMULATOR** *rear side*

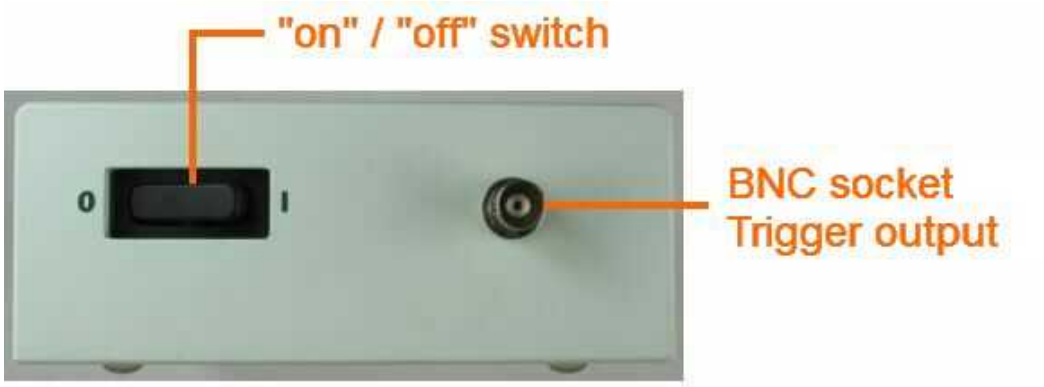


Figure 4: Rear side of the DC-STIMULATOR

The patient must not touch the contacts at the rear side of the device.

Equipment

Adapter box TRIGGER IN

This adapter box is a module for connecting external trigger sources to the DC-**STIMULATOR**. It consists of the following components:

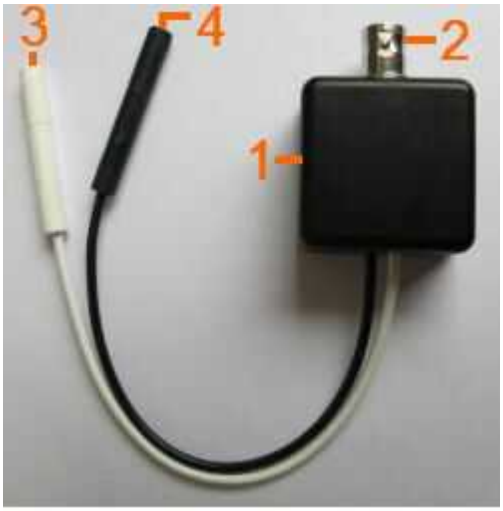


Figure 5: Adapter box TRIGGER IN

1 adapter box

2 BNC socket

3 touch-protected connecting cable ø 2 mm to plug in into socket 4 (signal) of the DC-**STIMULATOR**

4 touch-protected connecting cable ø 2 mm to plug in into socket 3 (ground) of the DC-**STIMULATOR**

Consumables

Starter set

The rubber electrodes und sponge pads of the starter set are available in different sizes. The standard starter set contains rubber electrodes 5 x 7 cm (35 cm^2) and the appendant sponge pads.

Figure 6: Starter set of the DC-STIMULATOR

1 rubber electrodes, 1 pair

2 sponge pads for the rubber electrodes, 1 pair, red-blue

3 rubber strap combination for fixing the rubber electrodes on the head, 1 set

4 connection cables, approx. 150 cm, 1 pair, red-blue

Only use rubber electrodes and sponge pads (class I equipment) supplied by the neuroConn GmbH.

Type label

The type label of the DC-**STIMULATOR** consists of the elements shown in Figure 7.

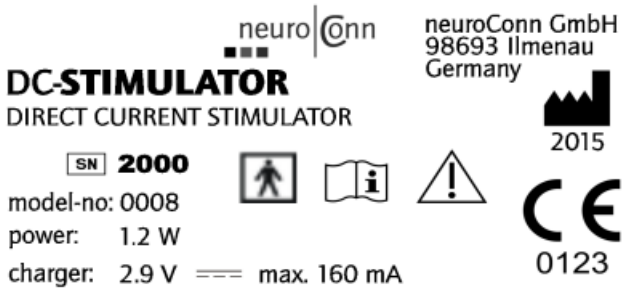


Figure 7: Type label of the DC-STIMULATOR

	manufacturer, address and production year
	serial number
	applied part BF
	Mind the manual!
	Attention!
	certified by the European Union Notified Body CE 0123, CE sign
	Direct Current

model-no	model number
power	power input
charger	charging device

Additional pictogram on equipment/consumables:

item number

certified, CE sign

Further labeling:

On the side of the type label a sticker with ISO 7010-M0002 is added (Refer to instruction manual).

On the edge of the type label the STK sticker (inspection plate Technical Safety Inspection) for the next safety check up will be added. The next check up is determined by neuroConn's STK policy (24 months, MTK 12 months) and added by a hole using a ticket punch.

Power supply

The DC-**STIMULATOR** is equipped with built-in rechargeable and non-spillable batteries. This type of battery has several advantages for the user:

- They do not have a “memory effect” like NiCd batteries. Charging from any charge state of the batteries is possible without risking loss of capacity.

- After 500 charge cycles approx. half of the nominal capacity is still available. The end of the batteries’ life is reached after approx. 1000 charge cycles.

These batteries are not fully precharged and must therefore be fully charged before regular

use of the device. To charge, connect the external charger to it (see Manual: External charger for details).
With fully charged batteries, the DC-**STIMULATOR** runs continuously for approx. 4-8 hours depending on the equipment. Daily charging is recommended if the DC-**STIMULATOR** is used regularly.
Charging of the completely discharged DC-**STIMULATOR** batteries will take approx. 8 hours. It is therefore recommended that the batteries are completely discharged only when there is time enough for charging.

For safety reasons, charging the batteries is possible only when no electrodes are connected. The front plate of the DC-**STIMULATOR** can be moved so that either the electrodes or the external charger may be connected. Never try to plug in both at the same time.

Only use the supplied processor controlled charger “Mascot 2116” for charging the DC-**STIMULATOR**. It is optimized for the used type of battery and continuously monitors battery state to prevent overcharging or overdischarging.

Use of other battery chargers, power supplies or energy sources for charging or discharging can cause fire or explosion and can damage the DC-**STIMULATOR**. The manufacturer assumes no responsibility for any damage caused by such a practice.

NiMH batteries will discharge slowly when not used for a longer period of time. After 1 month of disuse approx. 30 % of accumulated energy will be lost. It is therefore recommended system is recharged after a long period of disuse.

When the batteries reach the end of their life, please contact the dealer or manufacturer. The DC-**STIMULATOR** must not be opened to change the batteries. The manufacturer accepts no responsibility for any injury caused by this.

For environmental reasons, do not throw away the DC-**STIMULATOR** because of the batteries it contains. Please return it to the manufacturer.

Activating the DC-STIMULATOR

Turn on the switch at the rear side of the DC-**STIMULATOR** (see Figure 8).

Some warnings and additional information will be displayed at start up. Please read these messages carefully. This process cannot be skipped. Following this process the DC-**STIMULATOR** is ready to use.

Figure 8: Activating the DC-STIMULATOR

Mode standby

If the DC-**STIMULATOR** is not used over a longer period of time, it switches automatically to standby mode in order to save energy.
After 30 seconds of inactivity the display turns dark. Additionally, an acoustic warning signal (beep) reminds you every 60 seconds of inactivity that the device is still switched on.
Press an arbitrary button to end standby mode.

Turning off the DC-STIMULATOR

Turn off the switch at the rear side of the DC-**STIMULATOR** (see Figure 9).

NB: It is very easy to forget to switch off the DC-**STIMULATOR** after use. Therefore, always check the switch setting carefully to avoid total discharge of the DC-**STIMULATOR** batteries (charging will take approx. 8 hours should this happen).

Figure 9: Turning off the DC-STIMULATOR

4 Operating Basics

External charger

The DC-**STIMULATOR** front plate can be moved because of the necessary change between the two operating modes “Charge” and “Stimulation” (see Figure 10 and Figure 11).

Figure 10: Front plate in "Charge" position

Figure 11: Pushing into "Stimulation" position

For safety reasons, never use electrodes and charger at the same time. Take care of the operative front plate to avoid such a circumstance. Never remove the front plate. The manufacturer accepts no responsibility for injury caused by this.

Whilst the front plate is in the “Stimulation” position, the electrodes and the external trigger (optional - see Manual: Trigger input) can be put into the sockets. Hold the connector, not the cable, whilst plugging it into the sockets (see Figure 12 and Figure 13).

Figure 12: Plug the electrode into the socket

Figure 13: Connected electrodes

External charger

While the front plate is in the “Charge” position, the DC-**STIMULATOR** can be charged according to the following instructions:

- Plug the charger into the appropriate DC-**STIMULATOR** socket (see Figure 14 and Figure 15).

The DC-**STIMULATOR** is deactivated automatically following insertion of the charger's plug until it is removed again.

Figure 14: Charger connector and socket of the DC-STIMULATOR

Figure 15: Connected charger

- Connect the external charger (Figure 16) to a live outlet. The LED of the charger lights orange during the charging process and lights green when the charging process is finished.

Figure 16: External charger Mascot 2116

Mind the manual of the external charger!

- When charging is finished (LED lights green) take the external charger out of the DC-**STIMULATOR** and the live outlet.

You can leave the charger plugged in even if the DC-**STIMULATOR** is fully charged. There is no risk of damaging the DC-**STIMULATOR**.

If the LED on the charger flashes between red and green, please make sure the plug is connected properly or ask the manufacturer for a new charger.

Only use the charger supplied with the device, the “Mascot 2116”, for charging. It is optimized for the type of battery used and continuously monitors battery state to prevent overcharging or overdischarging.

The use of other battery chargers, power supplies or energy sources for charging or discharging may cause fire or explosion and may damage the DC-**STIMULATOR**. The manufacturer accepts no responsibility for any injury caused by such use.

Electrodes

During a stimulation procedure, the electrodes are connected to socket "1" (anode - positive) and socket "2" (cathode - negative). By changing the electrode wires an easy change of anodal and cathodal stimulation mode is possible.

Electrodes may only be inserted into the sockets whilst the front plate is in the “Stimulation” position (see Manual: Operating Basics).

Hold the connector, not the cable, when plugging the electrodes into the sockets (see Figure 12 and Figure 13). The electrodes will need touch-proofed safety connectors according to DIN 42802-2 (ø 1.5 mm) for use with your DC-**STIMULATOR**.

DC currents can harm body tissue. Ensure that limitations for current density are kept. The German authority ”Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)“ recommends a limit value for current density of 0.1 mA/cm². The manufacturer accepts no responsibility for any injury caused by a too high current density.

The electrodes therefore need to provide the following conditions to keep the current density low:

- sufficient surface area,

- low impedance, i.e. appropriate material and good skin contact.

Furthermore, the electrode material must be resistant to electrochemical processes that occur during long term DC currents, especially for metal-to-body reactions at the transition from skin to electrode. Non-metallic electrodes must be used, e.g. conductive rubber electrodes inside a sponge soaked with physiological salt solution.

Dampening of the sponges has to be done in an adequate distance of the DC-**STIMULATOR** (more than 1 m). The device must not get in contact with liquid spills, it might get damaged.

If you use sponges you must not insert the rubber electrodes in a dry sponge. If so the rubber electrode can be damaged. The manufacturer assumes no liability for damages in this case. Always use a damp sponge when insert the electrode.

Never use tap water to wet the sponges or the skin before or during the stimulation. **This might result in skin burns!** Always use **0,9 % NaCl solution!** The manufacturer accepts no responsibility for any injury caused by such use.

Before each stimulation look and functionality of the sponge pads have to be checked!

Cleaning and storing

Cleaning and storing the rubber electrodes

The rubber electrodes are less susceptible to mechanical stress and chemical substances. However, they should not be overstressed mechanically or thermally.
When required clean the rubber electrodes using clear water.

In general, disinfection of the electrodes beyond normal cleaning is only necessary if people from high-risk groups (e.g. drug users) are in contact with it. In this case, the careful use of a common disinfection product (mind the instructions of use) or 90 % alcohol is

recommended to ensure user protection.

The storing occurs expediently in wall holders. If the electrodes will not be used for a longer period of time, please separate cable and rubber electrode.

Cleaning and storing the sponges

After each use the sponges should be cleaned by careful hand wash only employing an appropriate detergent.
In general, disinfection of the sponges beyond normal cleaning is only necessary if people from high-risk groups (e.g. drug users) are in contact with it. In this case, the careful use of a common disinfection detergent (mind the instructions of use) is recommended to ensure user protection.

The storing occurs at a dry and dust-free place.

Damp sponges must not be stored in closed packages (e.g. foil bag).

If the sponges are not used for a longer period of the, please store the sponges in physiologic salt solution ca. 5 minutes before the new measurement.

Impedance control

Before beginning stimulation, the DC-**STIMULATOR** will detect the impedance levels. A DC current of 120 µA is used for several milliseconds. If impedance is above the adjusted level, e.g. if there is no load connected to the device or if electrodes are unsuitable, a message will be displayed. Stimulation cannot be started in this case. Keep the electrode impedance below the adjusted limitation. This limit can be increased if necessary (see Software Reference Manual: Impedance limit for details).

During stimulation permanent monitoring of all parameters occurs. The results will be shown in the last line of the display. If there is any fault condition, e.g. electrodes slipping off or impedance increases above the adjusted limit, stimulation will be stopped automatically and a message will be displayed. Try to keep electrode impedance below the adjusted limitation. You can increase this limit if necessary (see Software Reference Manual: Impedance limit for details).

Please also note the relationship between electrode impedance and maximum stimulation current, shown in Figure 17.

NB: Impedance warnings also appear if voltage limitation of 22 V is reached or exceeded. For example, a current of 2 mA at 10 kOhm impedance produces a voltage drop of 20 V. An impedance of 20 kOhm produces a voltage drop of 40 V, which is above the limit.

Impedance control is designed for measurements with “real” electrodes. A comparison with ohmic resistances could lead to divergent values - especially in all noise modes and with currents < 150 mA at the time of measurement.

Ensure, therefore, that appropriate impedance limits are used. Try to decrease impedance as much as possible before you raise impedance limit.

A manual check of the electrode impedance can be started by pressing button 2 and 3 simultaneously.

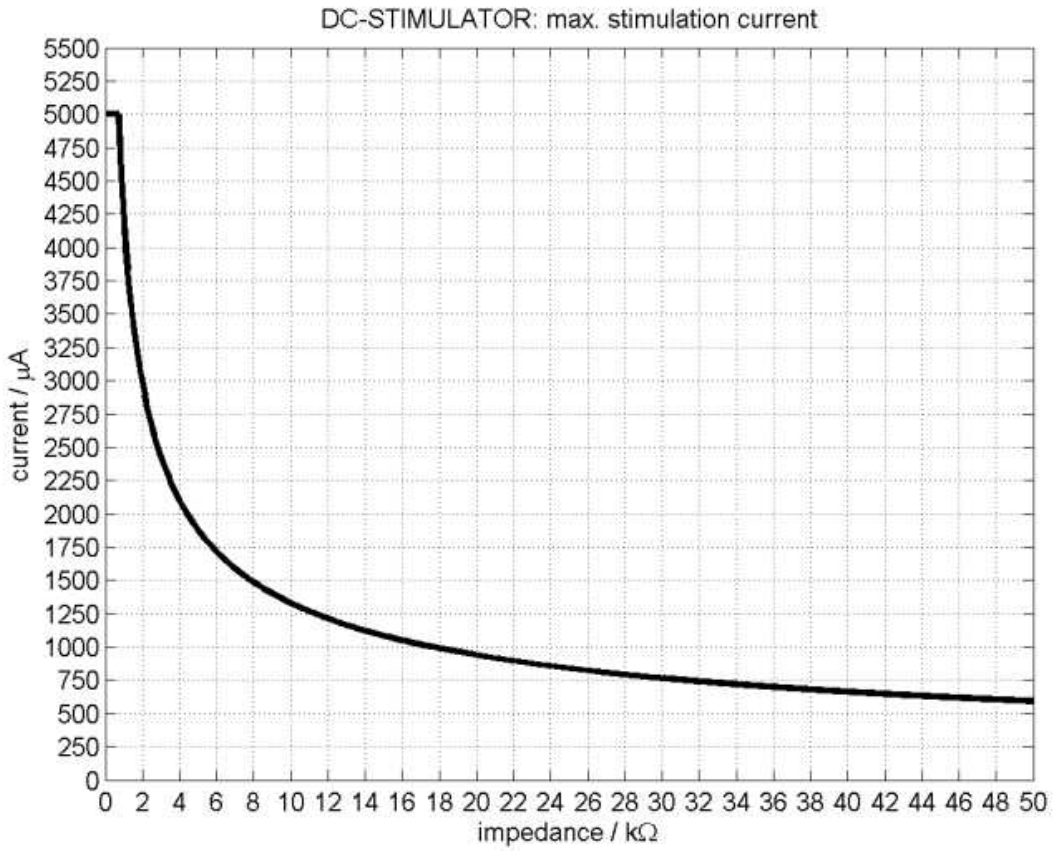


Figure 17: Relationship betw een electrode impedance and maximum stimulation current

If the stimulation current is below 150 µA the impedance check does not work correctly because of technical reasons. A long fade in value leads to a current below 150 µA for several seconds and most time stimulation is canceled. Experienced data show that current changes of 0.5 mA per second do not provoke pain for the patient.

Additional hardware

The DC-**STIMULATOR** can be extended by the additional components described below. For more details, please ask your dealer or the manufacturer.

Trigger input

To start stimulation remotely or via other devices, the DC-**STIMULATOR** can be used with an external trigger. The trigger mode can be adjusted by the software (see Software Reference Manual: Trigger input).
The external trigger must be connected to socket “3” (ground) and socket “4” (signal) of the DC-**STIMULATOR**. An adapter for the use of BNC cables is enclosed (see Figure 18).

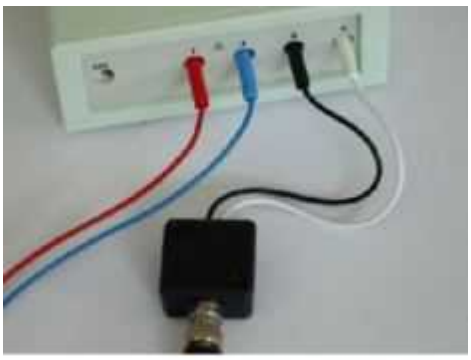


Figure 18: DC-STIMULATOR with connected TRIGGER MODULE

The trigger input is galvanically isolated from the DC-**STIMULATOR** for reasons of safety.

External trigger source requirements

The external trigger source must use TTL levels:

low level	0-0.4 V
high level	2.4-5.25 V
min. current of trigger source	3 mA

The DC-**STIMULATOR** works:

- with **level detection** (not edge detection)
- with **"active high"**, i.e. stimulations are started by high levels

The trigger level must last for a minimum of **1 ms**.

Cleaning the device

Clean the DC-**STIMULATOR** using a cloth slightly dampened with water. For the display a standard commercial TFT display cleaner should be used. Spray some cleaner on a soft and clean cloth before wiping the display gently.

Never spray cleaner directly onto your DC-**STIMULATOR** and never let liquid run into the device. Never use harsh or caustic chemicals to clean the DC-**STIMULATOR**. The manufacturer accepts no responsibility for any damage caused by such use.

In general, disinfection of the system beyond normal cleaning is only necessary if people from high-risk groups (e.g. drug users) are in contact with it. In this case, the careful use of a common disinfection product is recommended to ensure user protection. Wipe the surface of the DC-**STIMULATOR** and the electrode cables / supply cables with your disinfection product (e.g. 90 % alcohol).

Moving the device

Switch off the DC-**STIMULATOR** and disconnect all connecting cables. Usually, the DC-**STIMULATOR** comes in a plastic shipping case cushioned with foam, thus ensuring safe and reliable shipment. Room temperature should be between 10 and 40 °C (50 and 104 °F) and the air humidity should be between 20 to 93 % (non condensing). The air pressure must be between 690 to 1080 hPa (3000 m).

If the device has been exposed to low temperatures or to drastic temperature fluctuation (e.g. during transport), any resulting condensation could damage the device. For safety reasons, do not operate the DC-**STIMULATOR** until is has reached room temperature (at least 1 hour). The manufacturer accepts no responsibility for any injury caused by insufficient acclimatization of the device.

Pay attention on the correct positions of the single components and make sure that the optical fiber cable of the AMPLIFIER never gets folded.

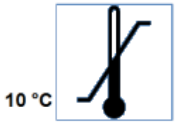
Additionally used pictogram's and warning signs to the packaging:

This side up

Fragile

Handle with care

Keep dry



Room temperature between 10°C and 40°C

Relative humidity between 20% and 95%

Air pressure between 660 hPa and 1080 hPa

Storing the device

If the DC-**STIMULATOR** is not used for a while, it is recommended that it is stored in a safe, dry and dust-free place. The temperature must be between 10 and 40 °C (50 and 104 °F) and the air humidity must be between 20 and 93 % (non condensing). The air pressure must be between 690 and 1080 hPa (3000 m).

5 Software Reference Manual

The following chapter refers to software version 4.3.00.17 and higher. The software version of your system is shown directly after activating the device.

Display, button, menu

The DC-**STIMULATOR** is operated by using the 4 buttons near the display's corner (see Figure 19).

In the whole Software Reference Manual the numbering of the buttons shown in Figure 19 is used.

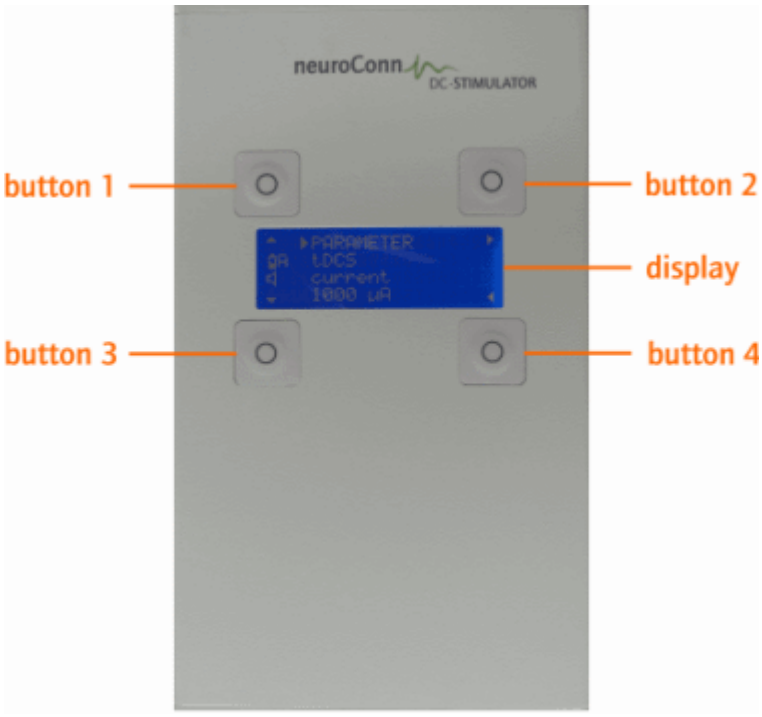


Figure 19: Numbering of the buttons of the DC-STIMULATOR

The display of the DC-**STIMULATOR** consists of 4 lines, in which settings, functionalities and modifiable parameters are shown (Figure 20).

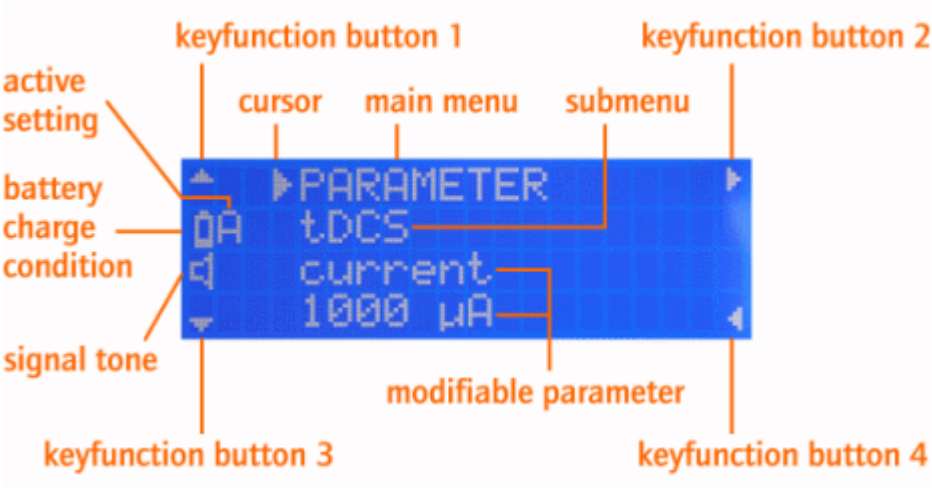


Figure 20: Description of the display of the DC-STIMULATOR

The button's functionality depends on displayed menu and is symbolized through an icon near the display's corner. If there is no icon then the corresponding button has no function in this menu.
Use buttons 1 and 3 on the left for moving the cursor up and down in order to reach different menus or values. Use buttons 2 and 4 on the right for changing menus or values at the cursor position.

At the display's left side the battery charge condition is displayed. A white filled battery symbolizes full charged battery. If the battery symbol is blinking, the batteries need to be charged before the DC-**STIMULATOR** is used further (see Manual: External charger for details).

A blank loudspeaker symbol indicates that the signal tone of the DC-**STIMULATOR** (for warnings and notices) is not active. After activating the signal tone (see Software Reference Manual: Signal tone) the symbol is filled white.

The user can save parameters into 4 different configurations, the so called settings A-D. The active setting is shown in the display beside the battery symbol. It's parameter will be recalled as initial settings at the next start up. For details on loading and saving settings see Software Reference Manual: Load setting.

The following chapters of this manual are arranged according to the main menus (PARAMETER, STIMULATION and SYSTEM) and the corresponding submenus.
To open a main menu the cursor has to be in the first line of the display. Push button 2 or 4 until you achieve the desired main menu.

PARAMETER

This menu offers the selection of stimulation waveform modes and the associated parameters like current, duration etc..
The chosen parameters can be saved into configurations (setting A - D) by pushing button 1 and 3 simultaneously. Stimulation parameters, which are not saved in a configuration, can not be recalled on the next start-up.

To modify the stimulation waveform mode please follow these instructions:

- Press button 2 or 4 to select main menu PARAMETER.

- Move the cursor to line 2 on the display by pressing button 3.

- Switch to desired stimulation waveform mode by pressing button 2 or 4 several times.

To modify the parameters current, duration etc. please follow these instructions:

- After you have switched to the desired stimulation waveform mode move the cursor to line 3 by pressing button 3.

- Press button 2 or 4 to select the desired parameter.

- Move the cursor to line 4 by pressing button 3.

- Pressing button 2 und 4 you can set the parameter. Press button 1 to confirm and save the value.

tDCS

Using the stimulation waveform mode tDCS a transcranial direct current stimulation can be applied.

A current of value *[current]* µA will last for *[duration]* seconds.
To avoid painful current steps the user can define controlled rising and falling of the DC by adjusting *[fade in]* and *[fade out]* values (Figure 21). These fade in and fade out periods are both additional to the stimulation's *[duration]*. The total stimulation time will therefore be calculated as follows:

total stimulation time = fade in + duration + fade out

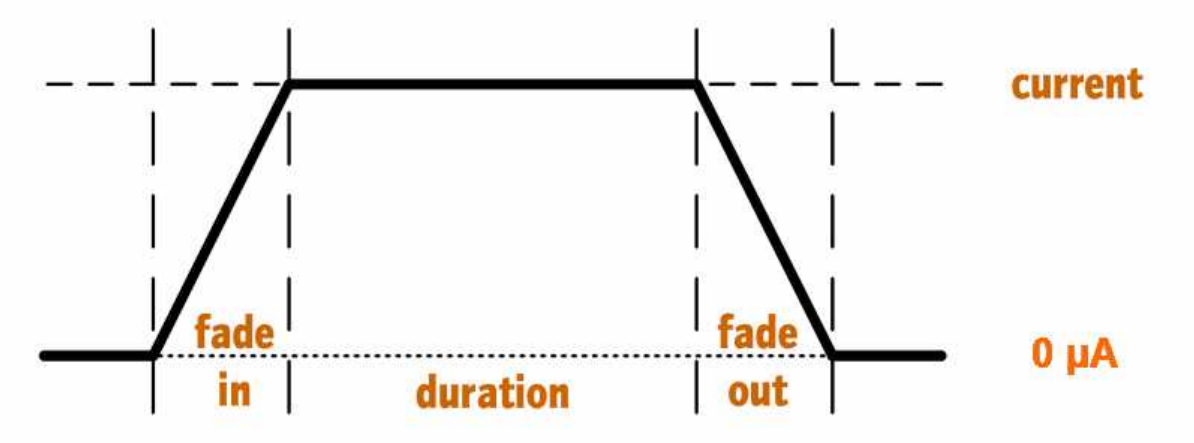


Figure 21: Timing chart of current during tDCS

The following table summarizes the available parameters for stimulation waveform mode tDCS:

	minimum value	increment	maximum value	unit
current	250	250	2000	µA
duration	30	30	1800	s
fade in	0	1	120	s
fade out	0	1	120	s

If the stimulation current is below 150 µA the impedance check does not work correctly because of technical reasons. A long fade in value leads to a current below 150 µA for several seconds and most time stimulation is canceled. Experienced data show that current changes of 0.5 mA per second do not provoke pain for the patient.

STIMULATION

This menu is used to start the stimulation.
The stimulation parameters have to be set in the main menu PARAMETER or fixed in the active setting.

In the main menu STIMULATION the display show following items (Figure 22):

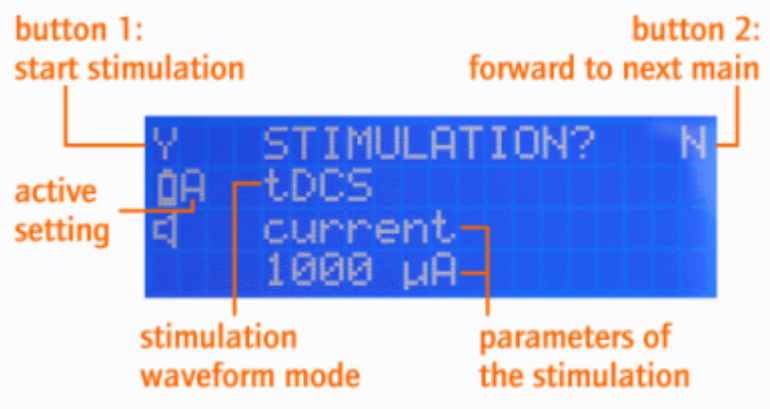


Figure 22: Main menu STIMULATION

Line 3 of the display shows all stimulation parameters set by the user. Press button 1 to start the stimulation. Then the system performs an impedance check (Figure 23), measuring the electrode impedance between electrode and skin.

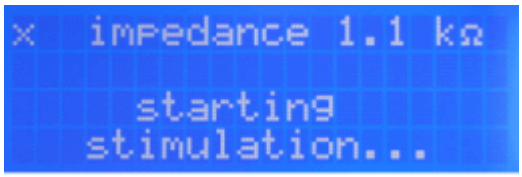


Figure 23: Impedance check after start of stimulation

If the impedance is below the preset impedance limit (see Software Reference Manual: Impedance limit) the stimulation starts.

In case impedance exceeds the predefined limit, e. g. due to insufficient electrode contact or an unfixed electrode, the display reads: “Impedance above … kΩ”. Press button 1 (x) to go back to the main menu PARAMETER.

During the stimulation the display indicates the selected type of stimulation, the remaining time of the stimulation as well as the present values of the current, the voltage and the electrode impedance (see Figure 24).

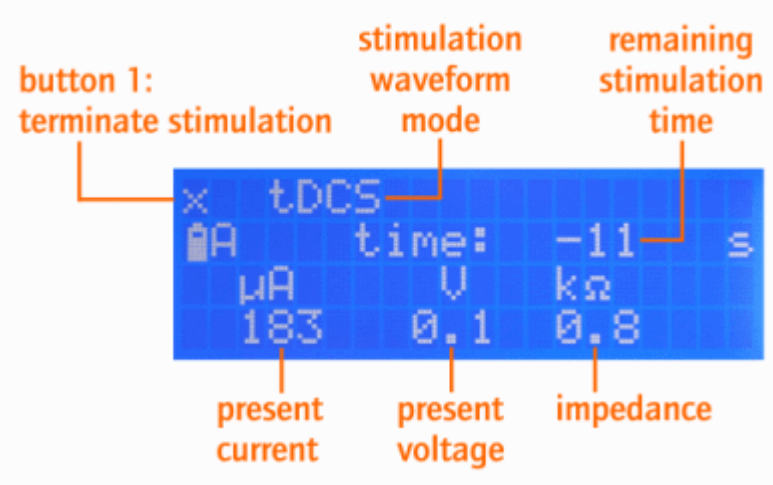


Figure 24: Display during stimulation

Terminating the stimulation

The ongoing stimulation can be terminated by the user at any time by pressing button 1 (x). The display indicates: “Stimulation terminated by user!”. The menu then returns to the main menu PARAMETER.

Impedance control

The device permanently measures the electrode impedance during stimulation. If the predefined impedance limit is exceeded during stimulation an error warning occurs and the stimulation will pause immediately. Press button 1 to go back to the main menu PARAMETER.

Completing the stimulation

The stimulation stops automatically after the predefined time is over. The menu returns to the main menu PARAMETER.

SYSTEM

In the Software Reference Manual the chapter Trigger input only describe software settings. For technical details please see Manual: Operation Basics.

Trigger input (optional)

To start stimulation remotely or via other devices, the DC-**STIMULATOR** can be used with an external trigger. For technical details please see Manual Operation Basics: Trigger input.

Trigger input can be:

disabled (Standard)
Trigger input is disabled.
The stimulation can be started manually in STIMULATION menu (see Software Reference Manual: STIMULATION). One stimulation only will be performed.

single
Trigger input is enabled for one stimulation.
After pressing "Y" in STIMULATION menu (see Software Reference Manual: STIMULATION), the DC-**STIMULATOR** will wait for the trigger event to start the stimulation. One stimulation will be performed after the trigger event.

repetitive
Trigger input is enabled for repetitive triggering.
After pressing "Y" in STIMULATION menu (see Software Reference Manual: STIMULATION), the DC-**STIMULATOR** will wait for the trigger event to start the stimulation. One stimulation will be performed after the trigger event.
After this stimulation the DC-**STIMULATOR** will wait for the next trigger event. This repetitive procedure can be stopped by pressing the button 1 (X).

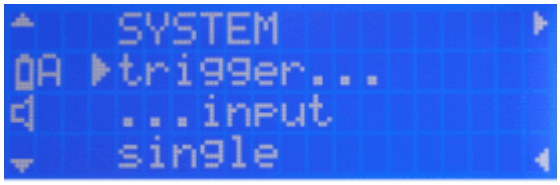


Figure 25: Main menu SYSTEM, submenu trigger input

To enable / disable the trigger input please follow these instructions (see Figure 25):

- Press button 2 or 4 to select main menu SYSTEM. Move the cursor to line 2 on the display by pressing button 3.

- Switch to submenu trigger input by pressing button 2 or 4 several times. Move the cursor to line 4 on the display by pressing button 3 (Figure 25).

- Press button 2 or 4 to enable / disable the trigger input.

- Press button 1 several times to move the cursor back to line 1 (the main menu).

The trigger input is disabled automatically when you turn your DC-**STIMULATOR** off. However, you can save the set of trigger input in the setting.

Impedance limit

In this submenu you can adjust the impedance value from a minimum of 5 kOhm in steps of 5 kOhm to a maximum of 90 kOhm.

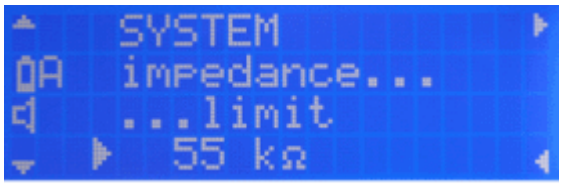


Figure 26: Main menu SYSTEM, submenu impedance limit

To change the settings of the impedance limit please follow these instructions (Figure 26):

- Press button 2 or 4 to select main menu SYSTEM. Move the cursor to line 2 on the display by pressing button 3.

- Switch to submenu impedance limit by pressing button 2 or 4 several times. Move the cursor to line 4 on the display by pressing button 3 (Figure 26).

- Press button 2 or 4 to set the impedance limit (increment 5 kOhm).

- Press button 1 several times to move the cursor back to line 1 (the main menu).

NB: Suitable electrodes will be necessary for useful impedance conditions (see Manual Operation Basics: Electrodes for details).

Operating in every main menu except during stimulation you can start a manual impedance check by pressing button 2 and 3 simultaneously.

Load setting

In the so-called settings you can predefine sets of parameters (e. g. type of current, voltage, duration etc.). 4 settings (A, B, C, D) can be saved. The settings are used in study mode (see Software Reference Manual: Study mode).

First you need to load one of the 4 settings. Then you can change and save the stimulation parameters in the loaded setting. To load a setting follow these instructions (Figure 27):

- Press button 2 or 4 to select main menu SYSTEM. Move the cursor to line 2 on the display by pressing button 3.

- Switch to submenu load setting by pressing button 2 or 4 several times. Move the cursor to line 4 on the display by pressing button 3.

- Select the setting (A, B, C, D) by pressing button 2 or 4.

- If you now use button 1 to move the cursor upwards, the display shows “load setting...” and returns automatically to the main menu PARAMETER. There you define the stimulation parameters (see Software Reference Manual: PARAMETER).

- Press buttons 1 and 3 simultaneously to save the changes in the setting. For a few seconds the display shows "save setting A" (depending on choice B, C or D).

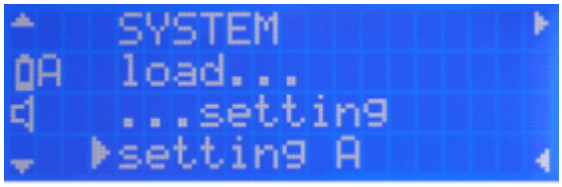


Figure 27: Main menu SYSTEM, submenau load setting

The stimulation parameters defined in the settings still remain active after rebooting the DC-**STIMULATOR**. Switching on the DC-**STIMULATOR** always setting A (in study mode setting B) is the active setting.

Study mode (optional)

The study mode was designed to facilitate the performance of double-blind comparative studies on the effectiveness of transcranial electric stimulation. 200 5-digit codes are available in the manual which are used to switch between “normal” and “sham” stimulation in double-blind conditions.

In study mode the user can select the settings (B, C or D) but he cannot make any modifications to the parameters of the settings in order to prevent accidental changes of the parameters in the course of a study.

At the beginning of a clinical trial the supervisor can save setting B, C and D according to his needs (in normal operation mode). Furthermore a code list consisting of some codes for normal and pseudo stimulation must be prepared. The code list can be executed by staff. Only the supervisor has information on which code belongs to normal or pseudo stimulation.

We recommend to keep a record each code used, the patient data, time of stimulation, result of stimulation etc. This facilitates the analysis of the data.

Codes for sham stimulation

18739	25829	32965	47315	20067	07350	29051	30589	00961	43519
47452	18457	17158	46430	51370	64628	31020	59167	29560	52724
54320	10896	25815	34128	47062	37302	30199	29183	05750	29064
24005	19826	55826	49773	62243	36565	00932	39071	53490	64034
14542	46116	34213	61138	46750	14944	29467	11285	63492	23312
03214	49501	58642	18753	16462	61127	08584	61657	45996	55553
13714	29824	05313	55779	36834	20925	24569	56871	24390	04829
13096	03243	37139	07990	34217	07671	50457	24579	53961	03056
39184	62203	18926	58250	06657	04280	15355	61151	04137	17315
65505	13892	32663	19037	44089	62782	50236	43655	08581	06252

Codes for normal stimulation

23613	35947	17155	39147	03229	37424	45931	63064	49185	48496
28303	41567	52627	05497	61961	60027	39451	16617	57242	33646
48014	27671	63004	04722	36268	19135	56227	22004	44577	03502
23373	32656	28471	36861	40410	07427	58867	49450	51847	53408
43909	13164	17897	41040	35183	03899	05830	17780	26808	31066
59571	39075	21558	31338	39136	10580	54360	62660	39029	01884
53222	39984	45973	06042	27845	24613	10889	54601	54961	29596
62691	09643	57011	50425	29108	40672	62369	41943	16208	23114
12311	32154	26822	30377	40038	04664	20596	39871	11470	40699
16119	38493	33164	30459	35482	61756	22397	26332	20164	26972

“Sham” stimulation means that the chosen stimulation mode will be displayed, but that no stimulation will occur. Only a small current pulse will occur every 550 ms (110 µA over 15 ms) instead of the stimulation current. The peak current lasts for 3 ms. This current pulse enables an impedance control which reliably detects bad electrode contact or electrode disconnection. Average current over time is not more than 2 µA, which has no therapeutic effect.

The user will not see any difference between sham and normal stimulation since the device displays no information about this. The patients may feel a difference, depending on stimulation current in normal mode.

Timing chart of current - normal stimulation

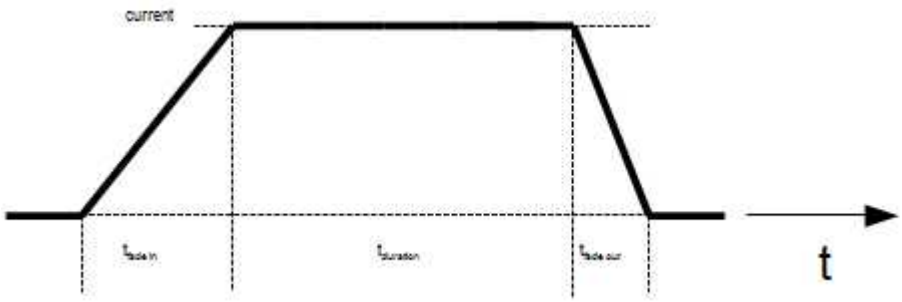


Figure 28: Timing chart of current during tDCS

In order to compare the normal with the “sham” stimulation a time chart of current in tDCS mode is shown in Figure 28.

Timing chart of current - sham stimulation

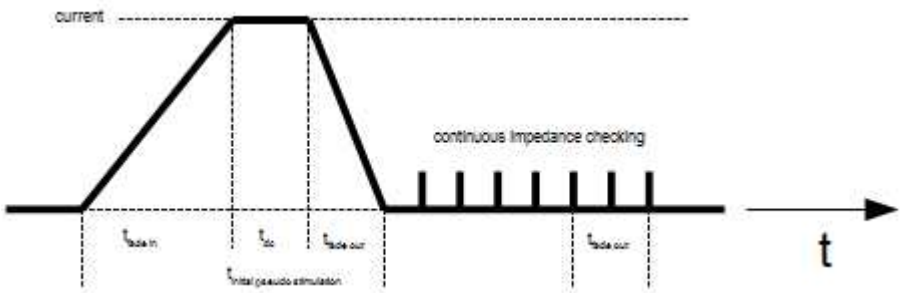


Figure 29: Timing chart of current during sham stimulation (tDCS)

$t_{dc} = t_{duration}/30$

Example: $t_{fade\ in} = 8$ s; $t_{fade\ out} = 5$ s; $t_{duration} = 900$ s

Stimulation starts with 8 s fade in followed by 30 s direct current followed by 5 s fade out followed by 870 s without any stimulation (just impedance control).

Explanation: The “sham” stimulation is initiated by a short normal-like stimulation in order to give the patient the same kind of skin sensations that he feels with a normal stimulation. After that initial sequence only continuous impedance control is performed in order to detect electrodes slipping off and to show real values at the display.

Procedure

Preparation

- Load setting B as described in the Software Reference Manual: SYSTEM Load setting.
- Set form and parameters of current (duration, amplitude etc.). Press buttons 1 and 3 simultaneously to save the parameters in setting B.
- Repeat these steps for settings C and D if necessary.
- Compile the code lists for normal and sham stimulations.

Enabling study mode

- Press button 2 or 4 to go to the main menu SYSTEM. Press button 3 to move the cursor to line 2 on the display.

- Now keep pressing buttons 2 or 4 until you get to the submenu study mode. Press button 3 to move the cursor to line 4 on the display.

- Press button 2 or 4 to enable / disable the study mode. The display shows “save, please wait”.

- Press button 1 several times to move the cursor back to line 1 (the main menu).

After enabling the study mode you have to reboot the DC-**STIMULATOR** (switch off and switch on the device). Without reboot the study mode will not work correctly.

Procedure of a study

After rebooting the system in active study mode the display indicates only the limited selection of the settings (Figure 30).

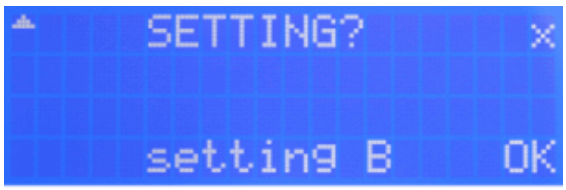


Figure 30: Display in active study mode, limited selection of settings

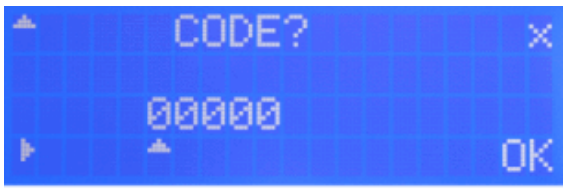


Figure 31: Display for entry of code for normal or sham stimulation.

Use button 1 to switch between settings B, C and D. Press button 4 (OK) to confirm your selection.

The system now requests a code for normal or sham stimulation (Figure 31).
Press button 1 repeatedly to insert the correct number. Move the cursor to the next digit by pressing button 3. Insert the right number as described above.
Button 2 leads you back to the settings selection.

Now confirm the entered code with button 4 (OK). You will get to the main menu STIMULATION and then can start/cancel the normal/sham stimulation as usual.

Completing the study

To finish the study switch the DC-**STIMULATOR** on. The display will immediately switch to limited selection of settings (Figure 30). Press button 2 and enter the mastercode as described in Software Reference Manual: MASTERCODE.
Confirm with button 4 (OK). You will no get back to main menu PARAMETER. To disable the study mode proceed as described in Software Reference Manual: Enabling study mode.
After next reboot the DC-**STIMULATOR** will start in the standard operating mode.

After disabling the study mode you have to reboot the DC-**STIMULATOR** (switch off and switch on the device). Without reboot the standard operation mode will not work correctly.

Language set

You can operate the DC-**STIMULATOR** in German or English language. The language can be adjusted in this submenu.

To change the language settings please follow these instructions:

- Press button 2 or 4 to select main menu SYSTEM. Move the cursor to line 2 on the display by pressing button 3.
- Switch to submenu language set by pressing button 2 or 4 several times. Move the cursor to line 4 on the display by pressing button 3 (Figure 32).
- Press button 2 or 4 to confirm "change". Thereafter you can choose between "deutsch" and "english" by pressing button 2 (Figure 33).
- Press button 4 (OK) to activate the language setting.
- Press button 1 several times to move the cursor back to line 1 (the main menu).

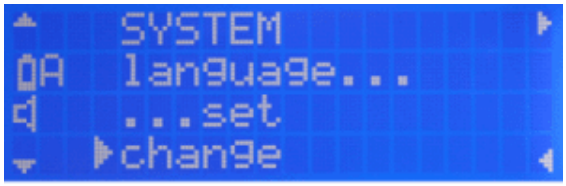


Figure 32: Main menu SYSTEM, submenu language set

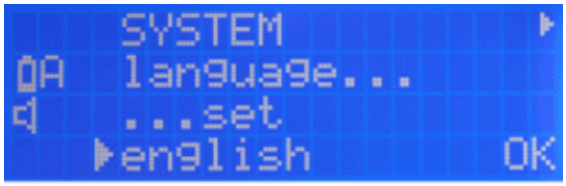
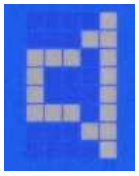


Figure 33: Main menu SYSTEM submenu language set: english

Signal tone

The DC-**STIMULATOR** can give out an acoustic warning signal in case of the following events:

- when you switch the device on
- when you set implausible stimulation parameters
- when you enable / disable the study mode
- when the DC-**STIMULATOR** is switched on and not used for more than one minute



The speaker symbol in the third line informs you about the current status of the signal tone. If the speaker symbol is filled, the signal tone is enabled. If the speaker is unfilled, the signal tone is disabled.

To change the settings of the signal tone please follow these instructions:

- Press button 2 or 4 to select main menu SYSTEM. Move the cursor to line 2 on the display by pressing button 3.
- Switch to submenu signal tone by pressing button 2 or 4 several times. Move the cursor to line 4 on the display by pressing button 3.
- Press button 2 or 4 to enable / disable the signal tone.
- Press button 1 several times to move the cursor back to line 1 (the main menu).

Backlight brightness

Backlight brightness can be adjusted in the submenu "backlight brightness".

To change the settings of the backlight brightness please follow these instructions:

- Press button 2 or 4 to select main menu SYSTEM. Move the cursor to line 2 on the display by pressing button 3.

- Switch to backlight brightness by pressing button 2 or 4 several times. Move the cursor to line 4 on the display by pressing button 3 (Figure 34).

- Press button 2 or 4 to adjust the backligth brightness. Minimum value is 5 %, maximum value 100 %, increment 5 %.

- Press button 1 several times to move the cursor back to line 1 (the main menu).

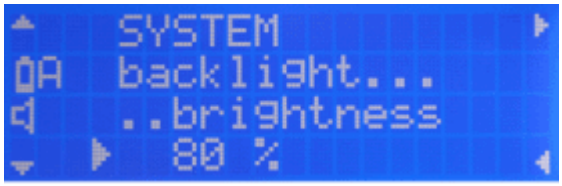


Figure 34: Main menu SYSTEM, submenu backlight brightness

NB: Backlight brightness is an important factor of the DC-**STIMULATOR** operating time, since backlight needs, at maximum, 30 % of the power consumption.

MASTERCODE (optional)

The MASTERCODE is only available for devices that are delivered with the optional study mode.

The MASTERCODE is a “password” that allows the user to access and modify all main and submenus in active study mode.
The MASTERCODE is printed on a sticker that is attached to the surface of the device upon delivery. The sticker should be removed and put into the corresponding field at the last page of the user manual.

Figure 35: Mastercode entry

To enter the MASTERCODE press button 2 in the settings selection in active study mode. Then follow these instructions:

- The cursor is located in the first digit (see Figure 35). Press button 1 to increase the value by 1 per press. After 9 comes 0.

- Now press button 3 to move the cursor to the next digit. Select the corresponding number by pressing button 1 several times.

- Repeat until all digits are correct.

- Press button 4 (OK) to confirm the MASTERCODE and to return to the main menu PARAMETER.

You can stop entering the MASTERCODE at any time by pressing button 2. Then you return to the settings selection.

6 Troubleshooting

If any further assistance is required, or if any problems are experienced during DC-**STIMULATOR** use, please contact your dealer or the manufacturer.

Hotline:

- Tel. +49 (0) 3677 68 979 0
- Fax. +49 (0) 3677 68 979 15
- info@neuroconn.de

7 Technical Specifications

Essential performance

- a maximum output current of 2 mA (tDCS) will not be exceeded (max. tolerance 5%)
- a predefined stimulation time will not be exceeded (max. tolerance (1%)

General

- 135 mm x 225 mm x 55 mm (W x D x H), weight 0.8 kg
- power consumption approx. 0.2-1.5 W (depending on backlight brightness and applied current)
- power supply via built-in rechargeable and non-spillable batteries
- external battery charger “Mascot 2116”
- touch-protected connecting (electrode) sockets ø 1,5 mm (DIN 42802)
- alphanumerical display, 4 buttons
- not protected against the spilling of liquids (DIN EN 60529 IP 20)

Stimulation

- DC current 250 - 2000 µA, increment of 250 µA
- inaccuracy of DC current max. 1 %
- internal DAC resolution of signal generation 16 bit
- quartz time base error max. 0.001 %
- internal time resolution of signal generation 0.49 ms

- voltage limit max. ±22 V

The device's DC offset is between +/-10 µA without stimulation after an operating time of 5 min at the time of delivery. This offset can increase up to +/-20 µA during normal operation. It is recommended to request a check of this offset during normal safety inspection.

Trigger input (optional)

- "active high“

- TTL levels, amplitude: 2.4 to 5.25 V

- pulse width: min. 1 ms

- current of ext. trigger source min. 3 mA

8 Electromagnetic compatibility

To ensure the safe operation of your device or system, be sure to observe the operating manual for your device or system, the information in the chapter "Safety" and the following additional guidelines and safety precautions.

The device or system complies with the EMC requirements of the international standard IEC 60601-1-2:2001 and is suitable for use in an environment with a medical application.

Information for ensuring electromagnetic compatibility

- All data and signal cables must have sufficient shielding. Use of unshielded oder badly shielded cables may lead to increased emission of interference and/or reduced fault-tolerance of the device.

- All casing covers must be properly secured.

- Portable and mobile wireless communication devices such as mobile phones may influence medical electrical devices. It is imperative that you observe the safety distances given below.

- Protect the contacts of all sockets and plugs of the device or system against static electricity. Avoid touching contacts. Should touching be unavoidable, take the following safety measures:
  Touch an earthed object before touching the contacts. This discharges static charges.
  or
  Wear an earthing strap.

- Use only the cables supplied when connecting peripheral devices.

- Each peripheral device you want to connect must comply with the requirements for use in an environment with a medical application.

- Install only system expansions that satisfy the requirements and rules governing safety and electromagnetic compatibility. If you install other expansions, you may damage the device or system or violate the safety regulations and regulations governing RFI suppression.

The effects of static electricity, fast transients or strong electromagnetic fields on the device or system can cause malfunctions.

Guidance and manufacturer's declaration - electromagnetic emissions

The device or system is intended for use in the electromagnetic environment specified below. The customer or the user of the device or system should assure that it is used in such an environment.

Emission test	**Compliance**	**Electromagnetic environment - guidances**
RF emissions IEC CISPR 11	Class B	The device or system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	not applicable	The device or system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	not applicable	The device or system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity

The device or system is intended for use in the electromagnetic environment specified below. The customer or the user of the device or system should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge IEC 61000-4-2	±6 kV (contact) ±8 kV (air)	passed, B	Floors should be wood concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30 %.
Electric fast transient/ burst IEC 61000-4-4	2 kV (peak) for power supply lines	not applicable line length smaller than 3 m, use of battery during therapy	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	not applicable line length smaller than 3 m, use of battery during therapy	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	> 95 % reduction for 1 cycle 30 % reduction for 25 cycles 60 % reduction for 5 cycles > 95 % reduction for 250 cycles	not applicable use of battery during therapy	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	50 Hz 3 A/m (rms)	passed	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	0.15-80 MHz 3 V (unmodulated) 80 % AM (1 kHz)	not applicable line length smaller than 3 m, use of battery during therapy	
			Portable and mobile RF communications equipment should be used no closer to any part of the device or system, including cables, than the recommended separation distance

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	0.08-1; 1.4-2; 2-2.7 GHz 3.3;1 V/m (unmodulated, rms) 80 % AM (1 kHz)	passed, A	calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=[3.5/E_1]\sqrt{P}$ 80 to 800 MHz $d=[7/E_1]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[a] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1:
At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2:
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be

predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location with the device or system is used exceeds the applicable RF compliance level above, the device or system should be observed to verify normal operation. If abnormal performance is obsered, additional measures may be necessary, such as reorienting or relocating the device or system.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Performance Criteria

A All functions of a device/system perform as designed during and after exposure to disturbance.

B One or more functions of a device/system do not perform as designed during exposure but return automatically to normal operation after exposure is removed.

C One or more functions of a device/system do not perform as designed during exposure and do not return to normal operation until exposure is removed and the device/system is reset by simple "operator/use" action.

This means for the user of the neuroConn system: if voltage dips, short interruptions and voltage variations on power supply input lines occured the user has to turn off and turn on the device. After this restart the system provides all functionalities as usual.

D One or more functions of a device/system do not perform as designed during and after exposure and cannot be returned to proper operation without repairing or replacing the device/system.

Recommended separation distances between portable and mobile RF communication equipment and the device or system

The device or system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device or system can help prevent electromagnetic inference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device or system as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz d=[3.5/3]sqrt(P)	80 MHz to 800 MHz d=[3.5/3]sqrt(P)	800 MHz to 2.5 GHz d=[7/3]sqrt(P)
0.01	not applicable	0.2	0.4
0.1	not applicable	0.4	0.8
1	not applicable	1.2	2.4
10	not applicable	3.7	7.4
100	not applicable	11.7	23.4

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1:
At 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2:
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9 Service

Warranty

The DC-**STIMULATOR** is covered by a 12 month warranty worldwide and a 24 month warranty within the European Union.

Maintenance

The DC-**STIMULATOR** should be maintained every 12 months.
According to the german medical products law a technical safety inspection has to be done every 24 month (only in Germany). Please read also the service manual and/or the "Medizinproduktebuch" (Germany).
Inspections or maintenance activities don't have to be carried out preventively.

Return

For environmental reasons please send the DC-**STIMULATOR** at the end of its lifetime (not earlier than five years after delivery) back to the manufacturer or a company authorized by the manufacturer.

Safety inspection

More detailed inspection protocols are available from the manufacturer.

Content of the safety inspection (every 24 months):

1. visual examination
- check for mechanical integrity
- completeness of the product
- labels (note the enclosed documents)

2. functional tests
- turning on and off the switch
- check of the different operation modes
- simulation of electrodes slipping off of by changing the resistance
-

3. metrological test
- measuring the output current of the DC-**STIMULATOR**
- check whether the accuracy limits are complied

4. safety control
- according to the appropriate content of the EN 62353:2008

5. final acceptance test (FAT) as specified by the neuroConn GmbH

Please contact the manufacturer for detailed information to carry out the final acceptance test.

The metrological control (every 12 months) includes the steps 1 - 3.

10 Distributors

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E-Mail: info@rogue-resolutions.com
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We have additional or exclusive distributors in the countries listed below:

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VIC 3175 Dandenong, Australia

Tel.: (+44) 2920 660198

E-Mail: info@symbioticdevices.com.au
Web: www.symbioticdevices.com.au

Benelux (Belgium / The Netherlands / Luxembourg)

MedCaT B.V.
Doorndistel 1
NL-7891 WV KLAZIENAVEEN, The Netherlands

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11 Intended use and therapeutic application

Since the beginning of the 19th century efforts have been made to achieve therapeutic effects with the help of electricity, but the level of knowledge was not high enough. The growing knowledge in the field of neurophysiology during the last two decades enabled huge development steps of this type of therapy.
Newly the Interventional Neruophysiology combines all therapeutic procedures, which are based on applying electrical current to parts of the nervous system [1, 2].

[1] Claaßen, J., Schnitzler, A.: Interventionelle Neurophysiologie - Grundlagen und therapeutische Anwendungen, Georg Thieme Verlag, Stuttgart - New York, 2013

[2] Wassermann, E.; Epstein, Ch., Ziemann, U., Walsh, V., Paus T., Lisanby, S.: Oxford Handbook of Transcranial Stimulation, Oxford Library of Psychology, 2008

The transcranial direct current stimulation (tDCS) as a part of the non-invasive Interventional Neurophysiology applies weak electrical currents (up to 2 mA) at a duration of 15..30 minutes at different positions on the head.
The electrical charge and current density applied during tDCS are far below the threshold for releasing a stimulus and take modular effect to existing neuronal elements.

Intended use

Depending on duration, used current, current density and frequency the stimulation is effective on inhibiting or activating cortical activity.
If established treatments fail a supporting therapeutic effect on depression and neuropathic pain in the lower limbs is probable and during rehabilitation of speech and motor skills after stroke and on auditory hallucinations in schizophrenia possible.

Essential performance (also see Preface):

- the device specific maximum output current will not be exceeded
- a predefined stimulation time will not be exceeded (max. tolerance (1%)

Patient population

age group:	18 - 99 years
weight:	45 - 120 kg
nationality:	global
patient state:	conscious adult patients
disabilities:	not relevant
excluded patient types:	patients with opened skull, after trepanation or with heart resp. brain pacemaker patients with any skin damage
further criteria:	none

Intended user profile

The responsiblity to inform about the current state of research and clinical application and to further their education rests with the operators.

2. physicians / psychologists

education:	university degree
knowledge:	effects of non-invasive brain stimulation on the brain
language knowledge:	german and / or english

experience:	• experience in brain stimulation • knowledge of the current state of technology and of the textbook "Interventionelle Neurophysiologie", mainly the therapy chapters (see [1])
permitted disabilities:	none

Intended conditions of use

Use in clinics, practicing doctors and psychologists

Indications

The transcranial direct current stimulation can be used in the treatment of the following diseases if established treatments failed:

- depression
- neuropathic pain in the lower limbs
- problems with speech and motor skills after stroke
- auditory hallucinations in schizophrenia

Contraindications

Under the following conditions a transcranial electrical stimulation must not be performed:

- in combination with a defibrillator for it has no appropriate protection
- with a pacemaker or brain stimulator for it can interfere or damage these devices
- on patients with implanted intracranial metals such as clippings, coilings, ventriculo-peritoneal shunts, endoprosthesis etc.
- on patients with opened skull or after trepanation

Adverse reactions

The following adverse reactions occurred in trials:

- itching, tingling, headache, burning sensation, discomfort

In a clinical trial treating patients suffering from depression:

- rare cases of euphoria, hypomania, nausea, disorientation, anxiety, and insomnia

No specific risks due to the treatment are known.
Burns can occur if other liquids than saline solution are used to wet the electrodes.

Overview of the therapeutic recommendations for tDCS for adults [3]

Neuropathic pain in the lower limbs	Probable analgesic effect of anodal tDCS of M1 of the left hemisphere or contralateral to pain side • tDCS • anodal • duration: 20 minutes • current: 1..2 mA • electrode size: 5x7 cm • treatment schedule: 5-20 daily sessions	Level B
Motor stroke	possible effect of combined cathodal tDCS of contralesional M1 + anodal tDCS of ipsilesional M1 in the chronic phase of stroke recovery. • tDCS • anodal and cathodal • duration: 30 minutes • current: 1..2 mA • electrode size: 5x7 cm • treatment schedule: 1-5 sessions followed by training	Level C
Broca's aphasia	possible efficacy of anodal tDCS applied to Broca's area on the left hemisphere • tDCS • anodal • duration: 20 minutes • current: 2 mA • electrode size: 5x7 cm • treatment schedule: 10-15 daily sessions followed by training	Level C

Depression	probable antidepressant effects of anodal tDCS of the left DLPFC with right orbiotofrontal cathode in depressed patients without treatment resistance (support of the therapy). • tDCS • anodal • duration: 30 minutes • current: 2 mA • electrode size: 5x7 cm • treatment schedule: 10-15 daily sessions	Level B
Auditory hallucinations (schizophrenia)	recommendation for anodal tDCS of the left DLPFC with the cathode over the left temporo-parietal junction or the right DLPFC. • tDCS • anodal • duration: 20 minutes • current: 2 mA • electrode size: 5x7 cm • treatment schedule: 10 daily sessions	Level C

Level A	definitive efficacy
Level B	probable efficacy
Level C	possible efficacy

No recommendation can be given to date for [3]

No recommendation means the absence of sufficient evidence to date, but not the evidence for an absence of effect.

Fibromyalgia	No recommendation for anodal tDCS of the left M1
Migraine	No recommendation for anodal tDCS of the left M1 or cathodal tDCS of V1
Postoperative pain	No recommendation for anodal tDCS of the left DLPFC
Parkinson's disease	No recommendation for anodal tDCS of M1

Motor stroke	No recommendation for cathodal tDCS of contralesional M1 or anodal tDCS of ipsilesional M1.
Depression	No recommendation for cathode location over the right DLPFC. No recommendation for associated cognitive symptoms.
Multiple sclerosis	No recommendation for anodal tDCS of M1 or the left DLPFC for motor or sensory disorders, including pain
Epilepsy	No recommendation for cathodal tDCS of epileptic focus
Disorders of consciousness	No recommendation for anodal tDCS of the DLPFC
Alzheimer's disease	No recommendation for anodal tDCS of the temporo-parietal cortex or the left DLPFC
Tinnitus	No recommendation for anodal tDCS of the left temporal cortex or the right DLPFC
Addiction and craving	No recommendation for anodal tDCS of the left DLPFC

[3] Jean-Pascal Lefaucheur et al.: Evidence-based guidelines on the therapeutic use of transcranial direct current stimulation (tDCS), in press 2015

[4] Paulus, W. Transcranial brain stimulation: potential and limitations, e-Neuroforum; September 2014, Volume 5, Issue 2, pp. 29-36

12 Disclaimer

This manual has been validated and reviewed for accuracy. The manual is accurate for the DC-**STIMULATOR** at the time of this manual's production.
Changes to the DC-**STIMULATOR** are possible at any time according to the latest research and development in science and technology.

The DC-**STIMULATOR** and manual are subject to change without notice. The manufacturer accepts no responsibility for damages incurred directly or indirectly from errors, omissions or discrepancies between the DC-**STIMULATOR** and the manual.

Validity

This manual is valid from serial number 2000.

Version

- version number: 4.0.3

- created: October 14, 2015

13 Notes

14 Manuals Equipment

The following pages show manuals of some equipment and consumables of the DC-**STIMULATOR**. These manuals refer to the DC-**STIMULATOR** equipped with all options and consumables. Depending on the specification of your DC-**STIMULATOR** some of the equipment/consumables might not be available.

Rubber electrodes and sponge pads

neuroConn GmbH Rubber electrodes ENG
REF 305050 – 305057, 305059, 305090

- DESCRIPTION -
Rubber electrodes are admixed with an electrically conductive material (graphite or carbon); spezific volume conductance 2,8 Ω/cm², resistance 50..100 Ω.

- USAGE -
Rubber electrodes are regarded by neuroConn GmbH as a component of the "original medical product" DC-STIMULATOR and its versions (DC-STIMULATOR /PLUS/MR/MC/MOBILE) so that in combination the medical product can be applied according to its intended purpose (cranial electrotherapy).

- APPLICATION -
To attach the rubber electrodes to the desired place on the head with a rubber band or VeloStrip combination please insert them in a neuroConn GmbH sponge pad soaked with 0.9% NaCl solution or use Ten20 electrode paste (minimum thickness 0.5 cm) and connect the electrode cables.
After the cranial electrotherapy remove the rubber electrode from the sponge pad/electrode paste, disconnect the electrode cable and clean the rubber electrodes using clear water.
If necessary disinfect the rubber electrodes using your common disinfection product.

- CAUTION -
Ensure adequate electrode size so that limitations for current density are kept. You must not insert the rubber electrode in a dry sponge pad. This might damage sponge pad and electrode. Always use 0.9% NaCl solution or electrode paste Ten20 (minimum thickness 0.5 cm); other media might result in skin burns and bleeding into the skin during cranial electrotherapy.
Rubber electrodes are qualified for MR investigations.

- SAFETY AND HANDLING -
The chemical composition of the rubber electrodes is quite safe, biological reactions with the skin are not to be expected.
Rubber electrodes can be used many times but cannot be sterilized. The rubber electrodes should be stored at a dry and dust-free place at room temperature without connected cables.
They should not be overstressed mechanically or thermally.
Rubber electrodes may be disposed without special handling.

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Sátori Gyula
Kálmán u. 31
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Hungary CE

Supplied by
neuroConn GmbH
Albert-Einstein-Str. 3
98693 Ilmenau
Germany

neuroConn GmbH Sponge pads red/blue ENG
REF 305060 – 305068, 305090

- DESCRIPTION -
Sponge pads consist of 70% regenerated cellulose and 30% cotton as well as a portion dyestuffs.

- USAGE -
Sponge pads are classified by neuroConn GmbH as a component of the "original medical product" DC-STIMULATOR and its versions (DC-STIMULATOR /PLUS/MR/MC/MOBILE) so that in combination the medical product can be applied according to its intended purpose (cranial electrotherapy).

- APPLICATION -
If the sponge pads are used along with neuroConn GmbH rubber electrodes please wet the sponge pads with 0.9% NaCl solution before each use. The electrodes are inserted in the wet (not dropping) sponge pad and attached to the desired place on the head with a rubber band or VeloStrip combination.
After the cranial electrotherapy remove the rubber electrode from the sponge pad and clean the sponge pad carefully by handwash only employing an appropriate detergent. If necessary disinfect the sponges using a common disinfection detergent.

- CAUTION -
NEVER USE TAP WATER to wet the sponge pads before or during cranial electrotherapy. This might result in skin burns and bleeding into the skin. Always use 0.9% NaCl solution.
You must not insert the rubber electrode in a dry sponge pad. This might damage sponge pad and electrode. Always use a damp sponge pad when inserting the rubber electrode.
Sponge pads are not qualified for MR investigations.

- SAFETY AND HANDLING -
The chemical composition of the sponge pads is quite safe, biological reactions with the skin are not to be expected.
The sponge pads can be used many times but cannot be sterilized.
The sponge pads should be stored at a dry and dust-free place at room temperature. Damp sponge pads must not be stored in closed packages, this might destroy them.
The sponge pads may be disposed without special handling.

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CE

Electrode paste Ten20

Ten20® Conductive Paste A0009 Rev 11 ENG

REF: 10-20-4 4oz (114 g) Jar; 10-20-8 8oz (228 g) Jar; 10-20-4T 4oz Tube (114 g)

Ten20 Conductive formulation contains: Polyoxyethylene 20 Cetyl Ether, Water, Glycerin, Calcium Carbonate, 1,2 Propanediol, Potassium Chloride, Gelwhite, Sodium Chloride, Polyoxyethylene 20 Sorbitol, Methylparaben, Propylparaben.

— USAGE —

For use in neuromonitoring procedures in conjunction with non-gelled neurodiagnostic electrodes, e.g.: EEG exams, evoked potential procedures, PSG, and MSLT procedures.

— APPLICATION —

Do not dispense paste directly onto the electrode or on the head. Place the amount of paste needed on a surface such as a strip of surgical tape.

Do not use too much paste. The size of the area of the paste becomes the effective size of the electrode. This can reduce inter-electrode distances, potential differences measured and compromise the exam.

Ten20 Conductive Tube: Press the tube from below to push paste to the top of the tube. Press with the thumb at the top of the tube to dispense the paste.

Ten20 Conductive Jar: Use a tongue blade to remove the paste.

— PASTE WITH GAUZE OR TAPE —

The adhesive quality of **Ten20 Conductive** is usually sufficient to adhere the electrodes to the skin and provide conductivity for the neurodiagnostic exam.

First, gently abrade the skin with an abrasive product such as **Nuprep.** Use a bell shaped cup electrode with the hole in the center Apply just enough paste inside of the EEG electrode to very slightly overfill the cup.

Place the electrode onto the electrode site and press with medium pressure. A small amount of paste may come out of the hole. Pressing too hard will cause all of the paste to come out and the electrode will not adhere well. Use either tape or a postage stamp size piece of gauze to fix the electrode in place.

If the electrode site has hair around it, use a cut up piece of gauze the size of a postage stamp and press onto the electrode. The paste that came out of the hole when it was pressed into place will hold the gauze square. If no paste comes out of the hole, place a small amount of Ten20 Conductive on the gauze and press the gauze onto the electrode using the paste to make it stick.

If the electrode site does not have hair around it, use surgical tape such as 1" Micropore tape to secure the electrodes. Use the same technique as above pressing the electrode into place. Use 3 or 4 cm of tape (1 1/4") to cover the electrode and the lead hub.

This is effective at Fp1, Fp2 and the ground electrode. Do this on any other sites not surrounded by hair if the patient is balding.

— A_1 and A_2 —

Attach A_1 and A_2 on the earlobe using the amount of paste as described above. Point the hub of the electrode up and slightly forward. Allow the lead to come over the top of the ear and then direct it to the back of the head. Use a longer piece of tape than normal so that you cover the hub of the lead, the electrode, then loop the tape to the back of the earlobe.

— CAUTIONS —

Avoid eye contact. If product is introduced in the eye, rinse with warm water for 10 to 15 minutes. Avoid rubbing the eyes.

Use topically on intact skin only. Do not use on or near open wounds, bruised or weakened skin due to injury or the medical condition of the patient.

Do not use on patients with a history of skin allergies or sensitivity to cosmetics and lotions. If rash, redness, itch, swelling, or abnormality appears on skin, wash off immediately.

Instruct patients to communicate any persistent redness, soreness or swelling at the electrode site. Topical infections can leave permanent scars if left untreated.

Patients' tolerance for topical applications to the skin varies widely. Some patients poorly tolerate adhesives, abrasives, conductive media, and salts. Respond to any complaint that may signal product intolerance.

Long term electrode sites must be checked for irritation and redness at least daily by removing the electrode and evaluating the skin condition under the electrode.

Ten20 Conductive Paste contains insoluble materials that may shadow, or interfere with Magnetic Resonance Imaging (MRI) examination. Prior to an MRI exam, ensure all materials used in the neurodiagnositc examination are cleaned from the electrode sites.

Do not use with current-inducing electrodes.

— SAFETY AND HANDLING —

- Collodion Remover, a Mavidon product, can be used to remove product from hair, if necessary.
- Excessive exposure may cause fingers to become dry and chapped. Wash from hands after applying to the patient. If dry hands persist, use gloves when applying the product.
- Ten20 is non-toxic if accidentally ingested.
- Ten20 may be disposed of without special handling. Keep containers tightly closed and store at room temperature. Avoid prolonged cold temperature or freezing.

Expiration date on tube seal and bottom of jar. Information also available at: **www.doweaver.com**

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Index

- T -

- U -

- V -

- W -

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