neuroConn

Programmable Direct Current Stimulator

DC-STIMULATOR

(PLUS version)

User's manual

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1 Preface

Thank you for buying a product of neuroConn GmbH.

The DC-**STIMULATOR** PLUS is a stimulator for cranial electrotherapy which provides a stimulation using weak direct or alternating current (transcranial Electrical Stimulation tES) within non-invasive Interventional Neurophysiology.

The electrical charge and current density applied during tES 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 and thus provides changing of neuronal plasticity in numerous neuropsychiatric diseases so that pathological conditions are corrected (treatment of major depression), clinical symptoms are improved (pain management) or conditions for a complementary therapeutic intervention are optimized (rehabilitation after stroke).

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

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 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** PLUS or other equipment.

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

2 Safety

The DC-**STIMULATOR** PLUS 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** PLUS 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** PLUS must be carried out only by the manufacturer or a company authorized by the manufacturer.

The DC-**STIMULATOR** PLUS 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** PLUS 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 medical electrical devices such as the DC-**STIMULATOR** PLUS.

The DC-**STIMULATOR** PLUS 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 DC-**STIMULATOR** PLUS 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** PLUS 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** PLUS 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** PLUS. 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.

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

The output circuit of the constant current source of the DC-**STIMULATOR** PLUS 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.

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 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 as this will cause a strong stimulus to be delivered.

3 Getting Started

General conditions

Before using the DC-**STIMULATOR** PLUS, 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 95 % (non condensing). The air pressure must be between 660 and 1080 hPa (3500 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** PLUS 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** PLUS 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** PLUS equipped with all options. Depending on the specification of your DC-**STIMULATOR** PLUS some of the sockets / components might not be available on the system.

*DC-**STIMULATOR** PLUS upside*

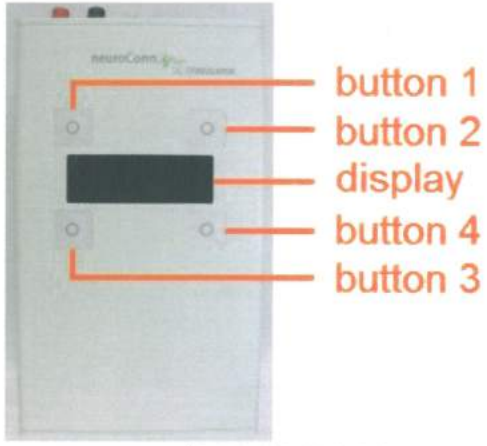


Illustration 1: Upside of DC-STIMULATOR PLUS

*DC-**STIMULATOR** PLUS bottom side*

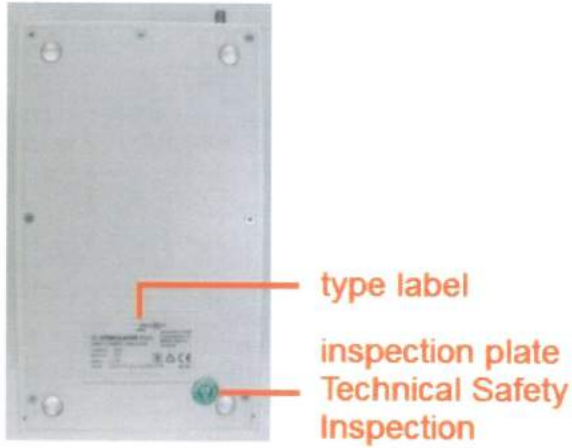


Illustration 2: Bottom side of the DC-STIMULATOR PLUS

*DC-**STIMULATOR** PLUS front side*

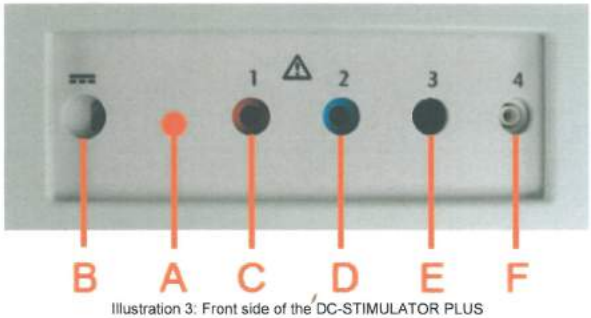


Illustration 3: Front side of the DC-STIMULATOR PLUS

	Label/ icon	Specifications
	⚠	Pay attention! It is necessary to note the manual's instructions for this socket!
A		moveable front plate
B	⎓	socket for charger "Ansmann ACS110 Traveller"
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 PLUS rear side

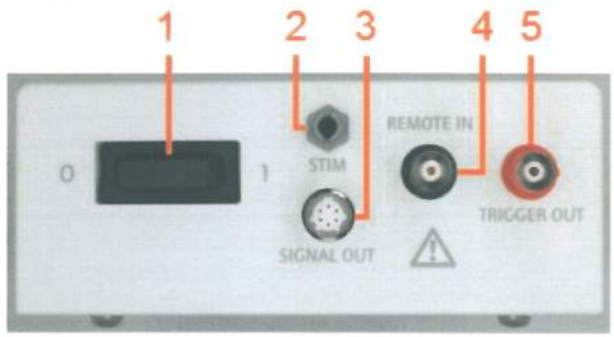


Illustration 4: Rear side of the DC-STIMULATOR PLUS

	Label/ icon	Specifications
	⚠	Pay attention! It is necessary to note the manual's instructions for this socket!
1	**0 / I**	"on"/"off" switch of the DC-**STIMULATOR** PLUS
2	**STIM**	HFBR socket to plug in the optical cable of the adapter box SIGNAL OUT tACS-EEG NP
3	**SIGNAL OUT**	socket to plug in the SIGNAL OUT cable of the adapter box SIGNAL OUT
4	**REMOTE IN**	socket to connect the BNC cable for REMOTE
5	**TRIGGER OUT**	socket to connect the BNC cable for TRIGGER OUTPUT

Equipment (optional)

Adapter box TRIGGER IN

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

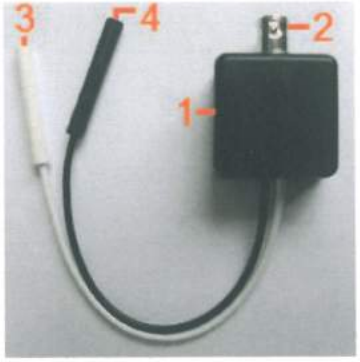


Illustration 5: Adapter box TRIGGER IN

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** PLUS

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

Adapter box SIGNAL OUT

The adapter box SIGNAL OUT is used to provide the stimulation cycle as an separate output signal at the DC-**STIMULATOR** PLUS. The available versions of the adapter box are: MONITOR, tACS-EEG and tACS-EEG NP.

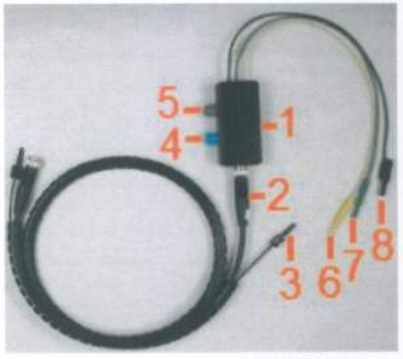


Illustration 6: Adapter box SIGNAL OUT

		Monitor	tACS-EEG	tACS-EEG NP
1	adapter box SIGNAL OUT	x	x	x
2	SIGNAL OUT cable to plug in into the SIGNAL OUT socket of the adapter box and the DC-**STIMULATOR** PLUS	x	x	x
3	optical cable to plug in into the HFBR socket "STIM" of the DC-**STIMULATOR** PLUS and the appendant optical input of the NEURO **PRAX®** TMS/tDCS amplifier			x
4	BNC socket, provided signal: "Voltage signal (oscilloscope)"	x	x	x
5	BNC socket, provided signal: "Electric trigger"	x	x	x
6	touch-protected connecting cable ø 1.5 mm (DIN 42802) to connect it to EEG amplifiers, provided signal: Signal-		x	x
7	touch-protected connecting cable ø 1.5 mm (DIN 42802) to connect it to EEG amplifiers, provided signal: Signal+		x	x
8	touch-protected connecting cable ø 1.5 mm (DIN 42802) to connect it to EEG amplifiers, provided signal: GND		x	x

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.

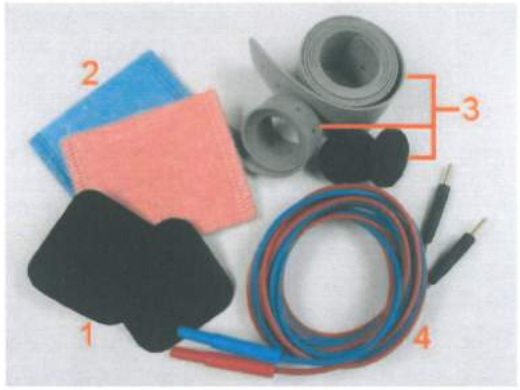


Illustration 7: Starter set of the DC-STIMULATOR PLUS

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

Type label

The type label of the DC-**STIMULATOR** PLUS consists of the elements shown in Illustration 8.

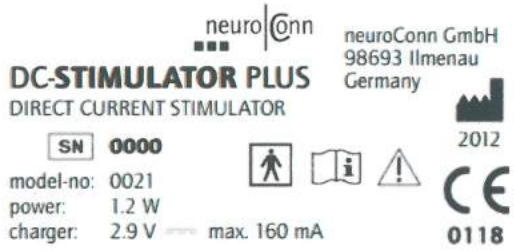


Illustration 8: Type label of the DC-STIMULATOR PLUS

	manufacturer, address and production year
SN	serial number
	applied part BF
	Mind the manual!
	Attention!
CE 0118	certified by the European Union Notified Body CE 0118, CE sign
⎓	Direct Current
model-no	model number
power	power input
charger	charging device

Additional pictogram on equipment/consumables:

REF	item number
CE	certified, CE sign

Power supply

The DC-**STIMULATOR** PLUS is equipped with built-in rechargeable batteries. These batteries are not fully precharged and must therefore be fully charged before regular use the device. To charge, connect the external charger to it (see Manual: External charger for details).

⚠ For safety reasons, charging the batteries is possible only when no electrodes are connected. The front plate of the DC-**STIMULATOR** PLUS 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 "Ansmann ACS110" for charging the DC-**STIMULATOR** PLUS. 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** PLUS. The manufacturer assumes no responsibility for any damage caused by such a practice.

Activating the DC-STIMULATOR PLUS

1. Turn on the switch at the rear of the DC-**STIMULATOR** PLUS (see Illustration 9).

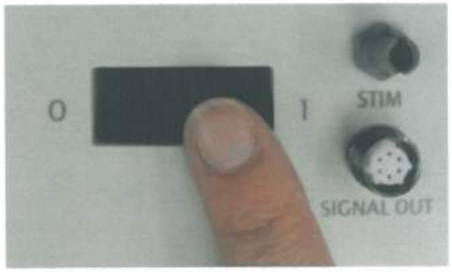


Illustration 9: Activating the DC-STIMULATOR PLUS

2. Some warnings and additional information will be displayed at start up (Illustration 10 - Illustration 13). Please read these messages carefully. This process cannot be skipped. Following this process the DC-**STIMULATOR** PLUS is ready to use.

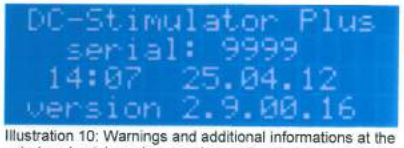


Illustration 10: Warnings and additional informations at the start up (serial number, version, optional: date and time)

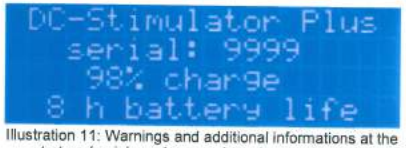


Illustration 11: Warnings and additional informations at the start up (serial number, version, charge of battery)

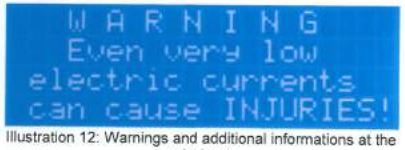


Illustration 12: Warnings and additional informations at the start up

Illustration 13: Warnings and additional informations at the start up (configuration of the sockets at front of the device)

Mode standby

If the DC-**STIMULATOR** PLUS 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 PLUS

Turn off the switch at the rear of the DC-**STIMULATOR** PLUS (see Illustration 14).

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

Illustration 14: Turning off the DC-STIMULATOR PLUS

4 Operating Basics

DC-STIMULATOR PLUS and external charger

The DC-**STIMULATOR** PLUS front plate can be moved because of the necessary change between the two operating modes "Charge" and "Stimulation" (see Illustration 15 and Illustration 16).

Illustration 15: Front plate in "Charge" position

Illustration 16: 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 Illustration 17 and Illustration 18).

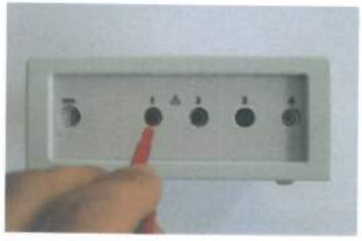


Illustration 17: Plug the electrode into the socket

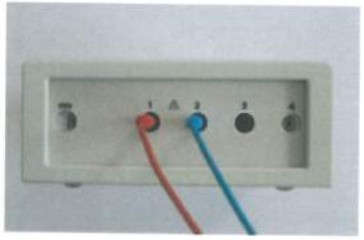


Illustration 18: Connected electrodes

Energy source

The DC-**STIMULATOR** PLUS is equipped with high capacity nickel metal hydride (NiMH) 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.

With fully charged batteries, the DC-**STIMULATOR** PLUS runs continuously for approx. 4-8 hours depending on the equipment. Daily charging is recommended if the DC-**STIMULATOR** PLUS is used regularly.

Charging of the completely discharged DC-**STIMULATOR** PLUS batteries will take approx. 8 hours. It is therefore recommended that the batteries are completely discharged only when there is time enough for charging.

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** PLUS 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** PLUS because of the batteries it contains. Please return it to the manufacturer.

External charger

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

- Plug the charger into the appropriate DC-**STIMULATOR** PLUS socket (see Illustration 19 and Illustration 20).

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

Illustration 19: Charger connector and socket of the DC-STIMULATOR PLUS

Illustration 20: Connected charger

- Plug in the charger into a live outlet. The "Power" and "Charge" LEDs will turn red (see Illustration 21). NB: The "Ready" LED will blink for a short initialization time. When charging is complete, the "Ready" LED will turn green.

Illustration 21: External charger

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

When purchased, the DC-**STIMULATOR** PLUS batteries are not fully precharged. Full capacity will only be obtained after 5 complete charge cycles. The external charger supplied, the "Ansmann ACS110", can support such discharge/charge cycles by pressing the yellow button for longer than 5 seconds after connecting the external charger to the DC-**STIMULATOR** PLUS. The LED "Discharge" will turn yellow (see Illustration 21). See the "Ansmann ACS110" user manual for details.

It is recommended that at least 1 complete discharge/charge cycle is completed before regular use of the DC-**STIMULATOR** PLUS. This procedure will take up to 16 hours.

Only use the processor controlled charger supplied with the device, the "Ansmann ACS110", 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** PLUS. 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 Illustration 17 and Illustration 18). The electrodes will need touch-proofed safety connectors according to DIN 42802-2 (ø 1.5 mm) for use with your DC-**STIMULATOR** PLUS.

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.

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.

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** PLUS 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 Illustration 22.

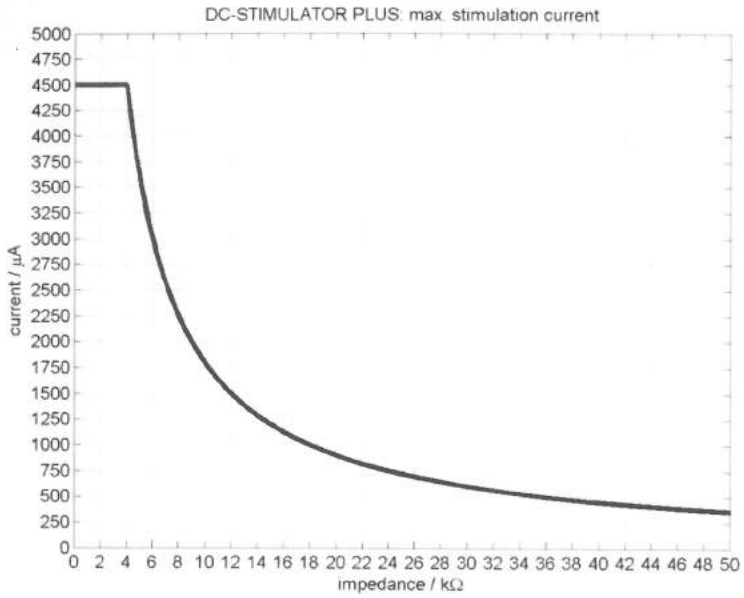


Illustration 22: Relationship between electrode impedance and maximum stimulation current

NB: Impedance warnings also appear if voltage limitation of 22 V is reached or exceeded. For example, a current of 2 mA @ 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.

There is no reliable detection of slow increases of impedance during stimulation with the modes "noise HF" and "sinus" (high frequency). Impedance can be clearly above the settled limit without a resulting deactivation. Only an electrodes slipping off will be surely detected. This has technical reasons with changing currents less than 150 µA.

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.

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.

Cleaning the device

Clean the DC-**STIMULATOR** PLUS 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** PLUS and never let liquid run into the device. Never use harsh or caustic chemicals to clean the DC-**STIMULATOR** PLUS. 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** PLUS and the electrode cables / supply cables with your disinfection product (e.g. 90 % alcohol).

Moving the device

Switch off the DC-**STIMULATOR** PLUS and disconnect all connecting cables. Usually, the DC-**STIMULATOR** PLUS 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 95 % (non condensing). The air pressure must be between 660 to 1080 hPa (3500 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** PLUS 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.

Storing the device

If the DC-**STIMULATOR** PLUS 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 95 % (non condensing). The air pressure must be between 660 and 1080 hPa (3500 m).

Please recharge the batteries completely before you store the DC-**STIMULATOR** PLUS.

Additional hardware

The DC-**STIMULATOR** PLUS 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** PLUS 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** PLUS. An adapter for the use of BNC cables is enclosed (see Illustration 23).

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

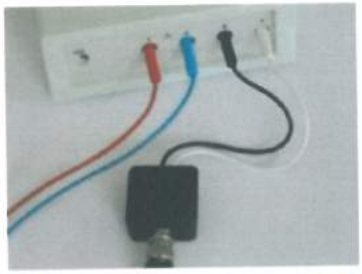


Illustration 23: DC-STIMULATOR PLUS with connected TRIGGER MODULE

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** PLUS 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**.

Trigger output

An additional BNC socket is provided at the rear side of the DC-**STIMULATOR** PLUS. This allows a trigger signal to be sent out during "SINUS" and "PULSE" mode only at a defined position of the signal curve. The trigger output can be enabled by the software (see Software Reference Manual: Trigger output for details).

The trigger output is the BNC socket. The trigger is galvanically isolated from the DC-**STIMULATOR** PLUS for reason of patient safety.

The trigger is energized with an internal battery. The battery must be changed if its capacity is exhausted. To do this the DC-**STIMULATOR** PLUS must be sent back to the manufacturer.

⚠ Only the manufacturer can undertake a trigger battery change. The manufacturer accepts no responsibility for any damage caused by change of battery by the user.

Trigger signal specifications

The trigger uses CMOS levels:

- pulse-shaped trigger with voltage of **3 V**
- **"active high"**, i.e. trigger impulse is carried out as high level
- pulse width: 0.45 ms ± 10 %
- raising edge marks the moment of the trigger event
- occurring delay of maximum 1 ms
- maximum load: 10 mA (affecting battery life-span)

REMOTE

The REMOTE mode enables you to operate the DC-**STIMULATOR** PLUS externally controlled by a voltage supply source. The generated current follows proportionally to the applied voltage. Hereby - voltage source and the output of the constant current source are galvanically isolated.

The REMOTE mode is for investigational use only. The manufacturer assumes no liability for any injury in this case.

While REMOTE mode is active, no safety monitoring of the current occurs by the DC-**STIMULATOR** PLUS. The system only measures the electrode voltage. An acoustic signal and a warning notice on display appear if the voltage limit of the device is reached. There is no automatic interruption of the stimulation. The operator has to start an appropriate intervention (e.g. stop stimulation, reduce applied voltage) on his own.

Using the REMOTE mode the internal safe stop mode of the the DC-**STIMULATOR** PLUS is not active. The operator has to avoid "current pulses". The manufacturer assumes no liability in this case.

Functional principle

Using an external voltage supply source voltages between U_{in}=-2...+2 V will be applied to the DC-**STIMULATOR** PLUS (see Illustration 24). Out of this the DC-**STIMULATOR** PLUS will generate a proportional current I_{out}=-4...+4 mA according to the transfer function: I_{out} [mA]=2*U_{in} [V]

A linear transfer characteristic is only guaranteed within this working range.

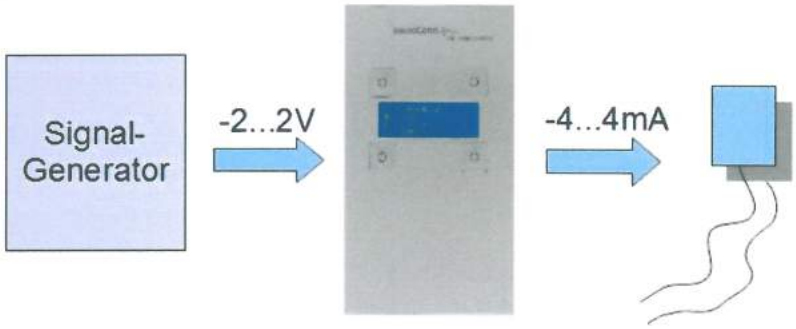


Illustration 24: Functional principle of REMOTE mode of the DC-STIMULATOR PLUS

In REMOTE mode, direct and alternating voltage as well as arbitrary voltage signal can be processed. The proportionality of the current amplitude relative to the externally supplied voltage can be guaranteed up to a frequency of 300 Hz. At frequencies higher than 300 Hz the current follows the characteristic shown in Illustration 25.

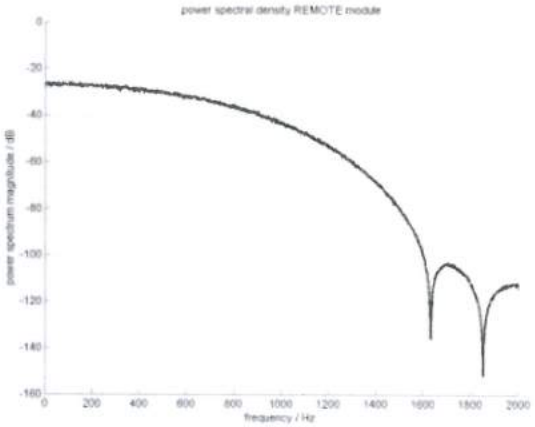


Illustration 25: Power spectral density as a function of the frequency of the applied voltage

Connecting an external voltage supply source

Connect the external voltage supply source to socket „REMOTE IN" at the rear side of the DC-**STIMULATOR** PLUS via the BNC cable supplied by the manufacturer, see Illustration 26.

Illustration 26: Connecting BNC cable of external voltage supply to socket „REMOTE IN"

The input „REMOTE IN" is galvanically isolated from the current source of the DC-**STIMULATOR** PLUS by reason of patient safety. All components comply with the standard EN 60601-1.

SIGNAL OUT

The additional hardware modul SIGNAL OUT, which is placed at the back side of the device, extends the DC-**STIMULATOR** PLUS by referential output signals. This galvanically isolated interface enables the user to record and display:

- analogues signals, that are proportional and shape-preserved to the applied current,
- a digital signal, which indicates the stimulation period.

Possible applications of this extension are:

- recording and online correction of stimulation current induced artifacts in the EEG signals using the software NEURO **PRAX**® TMS/tDCS,

- recording of these signals by other medical devices (e.g. external EEG amplifiers) for user specific post-processing,
- signal monitoring with non medical devices (e.g. oscilloscops)
- synchronization of stimulation periods with other devices.

Illustration 27: Extension SIGNAL OUT at the rear side of DC-STIMULATOR PLUS

Safety

The safety notes as given in chapter 2 (Safety) are mandatory. Additionally, the following safety instructions are specific to the hardware extension module and must be observed by the user:

The use of hardware extension SIGNAL OUT is limited to the applications described below. The manufacturer does not assume liability for any other applications.

The SIGNAL OUT is galvanically isolated from the power supply of the DC-**STIMULATOR** PLUS. This guarantees patient safety when a line-operated device is connected to the DC-**STIMULATOR** PLUS. All components used in the device comply with the Norm EN 60601-1.

Connecting the adapter box SIGNAL OUT

To connect the adapter boxes SIGNAL OUT to the DC-**STIMULATOR** PLUS, plug in the SIGNAL OUT cable provided by the manufacturer (see Illustration 29) and - if neccessary -

the optical cable (Illustration 28) into the sockets SIGNAL OUT and STIM at the rear side of the device.

Illustration 28: Connecting the optical cable with the socket STIM (top) of the SIGNAL OUT extension

Illustration 29: Connecting the SIGNAL OUT cable with the socket SIGNAL OUT (bottom)

Use only the cables and adapters provided by the manufacturer. The manufacturer assumes no liability in case other cables and adapters are used.

Output signals:

The SIGNAL OUT adapters can provide the following output signals:

Signal+	A voltage (+2.5 mV @ 1 mA) that is proportional to the stimulation signal is added on the offset of 25 mV.
Signal-	A voltage (-2.5 mV @ 1 mA) that is proportional to the stimulation signal is added on the offset of 25 mV. Signal+ and Signal- are inverted.
GND	Referential potential for Signal+, Signal-, Electric trigger and Voltage signal (oscilloscope)
Electric trigger	It provides an electric trigger signal for the complete duration of the stimulation, "active high", 5 V.
Voltage signal (oscilloscope)	A voltage signal of 2.25 V @ 4.5 mA, that is proportional to the stimulation current.

The HFBR socket (STIM) provides an optical trigger signal for complete duration of stimulation. (analog Electric trigger).

Adapter boxes and their functions

SIGNAL OUT MONITOR

The adapter box SIGNAL OUT MONITOR (Illustration 30) is used to connect the DC-**STIMULATOR** PLUS to non-medical devices, e.g. an oscilloscope, to monitor the stimulation signal online as well as to trigger external devices. The adapter box has two BNC sockets. The white BNC socket provides the signal "Electric trigger", as described above. The blue BNC socket provides the "Voltage signal (oscilloscope)".

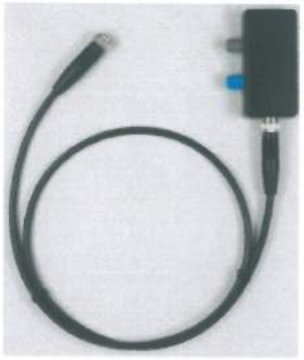


Illustration 30: Adapter box SIGNAL OUT MONITOR

SIGNAL OUT tACS-EEG

In order to record and analyze the stimulation signal with external medical amplifier, the adapter box SIGNAL OUT tACS-EEG (Illustration 31) is required. This adapter box contains two BNC sockets: white for "Electric trigger" and blue for "Voltage signal (oscilloscope)".

Additionally, this adapter box comes with three touch-protected connecting cables ø 1,5 mm (DIN 42802) to connect it to EEG amplifiers as follows:

green cable:	Signal+
yellow cable:	Signal-
black cable:	GND

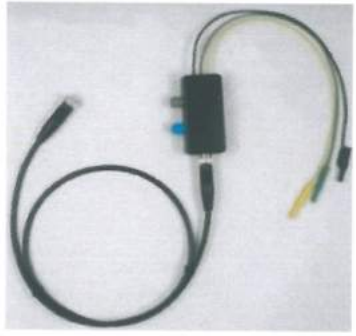


Illustration 31: Adapter box SIGNAL OUT

The manufacturer does not deliver hard- and software for visualization of the signals provided by the SIGNAL OUT.

SIGNAL OUT tACS-EEG NP

The adapter box SIGNAL OUT tACS-EEG NP (Illustration 32) is exclusively used to operate the DC-**STIMULATOR** PLUS together with the NEURO **PRAX®** TMS/tDCS. Using the correspondent software the stimulation-induced artifacts can be recorded and corrected online in the EEG.

To perform the online correction of the stimulation-induced artifacts in the EEG the NEURO **PRAX®** TMS/tDCS amplifier and the correction software are required.

This adapter box includes one BNC socket ("Voltage signal (oscilloscope)"), one HFBR socket ("Optical trigger") and three touch-protected ø 1,5 mm cables (DIN 42802) to connect the NEURO **PRAX®** amplifier to the adapter box.

green cable:	Signal+
yellow cable:	Signal-
black cable:	GND

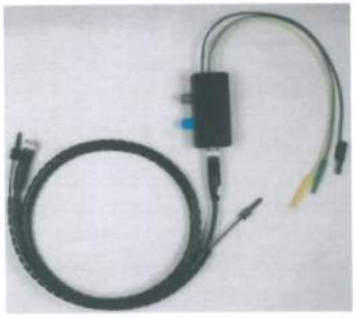


Illustration 32: Adapter box SIGNAL OUT tACS-EEG NP

5 Software Reference Manual

The following chapter refers to software version 3.2.xx.17

Display, button, menu

The DC-**STIMULATOR** PLUS is operated by using the 4 buttons near the display's corner (see Illustration 33).

In the whole Software Reference Manual the numbering of the buttons shown in Illustration 33 is used.

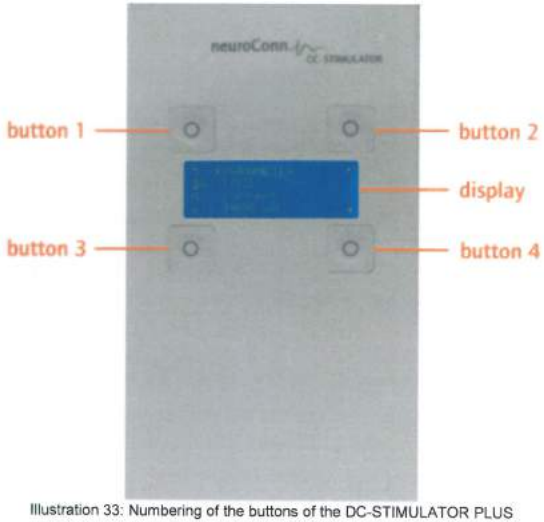


Illustration 33: Numbering of the buttons of the DC-STIMULATOR PLUS

The display of the DC-**STIMULATOR** PLUS consists of 4 lines, in which settings, functionalities and modifiable parameters are shown (Illustration 34).

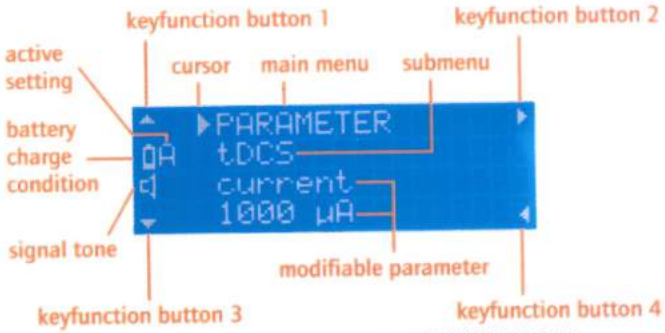


Illustration 34: Description of the display of the DC-STIMULATOR PLUS

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** PLUS is used further (see Manual: External charger for details).

A blank loudspeaker symbol indicates that the signal tone of the DC-**STIMULATOR** PLUS (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, SCHEDULE, REMOTE 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.

The DC-**STIMULATOR** PLUS is already equipped with preset stimulation modes. For special demands it can be equipped individually with customer specific stimulation modes. For details please contact the manufacturer.

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 (Illustration 35). 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

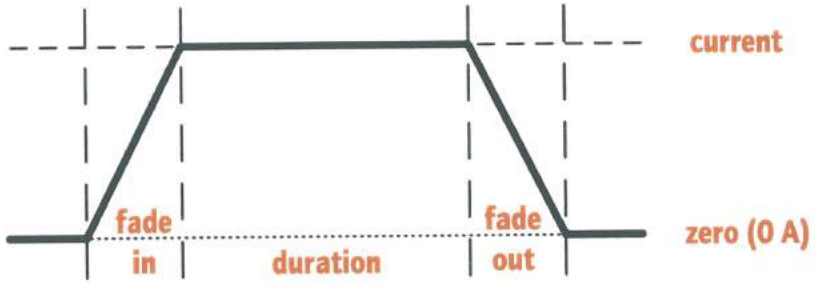


Illustration 35: Timing chart of current during tDCS

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

	minimum value	increment	maximum value	unit
current	-4500	25	4500	µA
duration	15	15	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.

pulse mode

Stimulation waveform pulse mode generates a "rectangular pulse waveform".
The current raises abruptly from 0 µA to *[current]* µA, remains stable for *[pulse width]* ms and jumps back tu zero again (see Illustration 36). Next pulse follows after *[ISI-pulse width]* ms (ISI = Interstimulus interval).
This cycle will be repeated for *[cycles]* times.

The total stimulation time will be calculated as follows:

total stimulation time = cycles * ISI

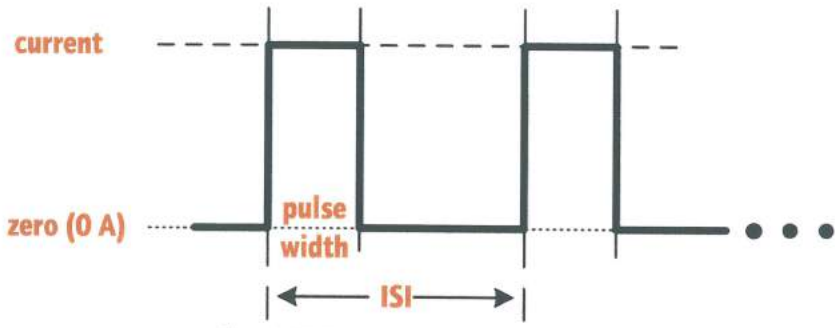


Illustration 36: Timing chart of current during pulse mode

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

	minimum value	increment	maximum value	unit
current	-1500	25	1500	µA
pulse width	50	50	ISI-50	ms
ISI	pulse width + 50	50	2000	ms
cycles	1	1	500	-

sinus (hw)

Stimulation waveform mode sinus (hw) generates a half wave sinus.
Current peak magnitude is *[current]* µA and the waveform returns to zero after *[duration]* s (Illustration 37).

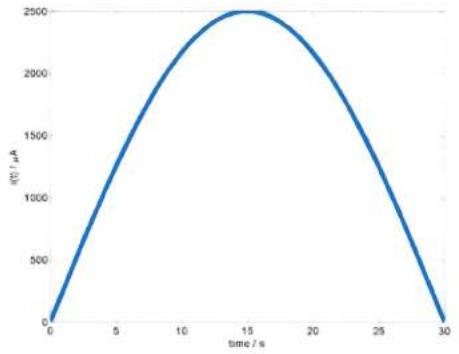


Illustration 37: Timing chart of current during mode sinus (hw), magnitude 2500 µA, duration 30 s

The following table summarizes the available parameters for stimulation waveform mode sinus (hw):

	minimum value	increment	maximum value	unit
current	-1500	25	1500	µA
duration	5	5	1800	s

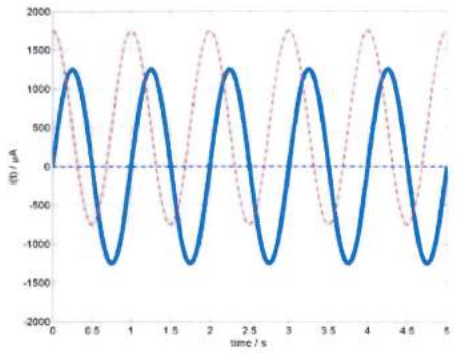
sinus (tACS)

Stimulation waveform mode sinus generates sinusoidal waveforms, optional having an offset mean value (Illustration 38).

Peak to peak magnitude is *[current]* µA, mean value is *[offset]* µA. Adjust the frequency to *[frequency]* Hz, the phase shift to *[phase]* degrees. A number of *[cycles]* sinus periods will be generated.

To avoid painful current steps the user can define controlled rising and falling of the sinus wave by adjusting *[fade in/out]* values.

Optional: If trigger out is enabled, every *[trig. cycles]* period(s) an output trigger pulse occurs.



The current profile is calculated as follows:

i = (current/2 * sin(2*pi*t/T – pi/2)) + offset

with T = (1/frequency)
and t = 0:0.01:(T*cycles)

The total stimulation time will be calculated as follows:

((2 x fade in/out) / frequency) + (cycles / frequency).

Illustration 38: Timing chart of current during sinus, current 2500 µA
blue: offset 0 µA, phase 0 degree
red: offset 500 µA, phase 90 degrees

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

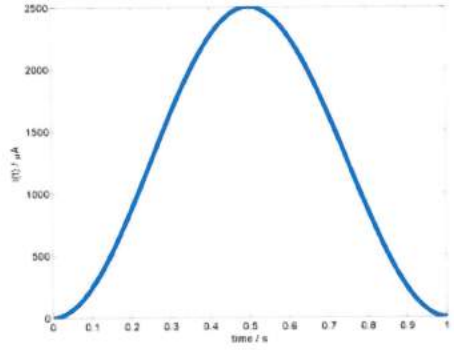
	minimum value	increment	maximum value	unit
current	25	25*	3000	µA
offset	-1000	10	1000	µA
frequency	0.01	0.01*	250**	Hz
phase	0	5	360	°
cycles	1	1*	350000**	2π
trig. cycles (optional)	1	1*	9999	2π
fade in/out	0	1*	100	2π

* dynamic increment, depending on duration of keypress

** You can adjust frequency in conjunction with cycles only within the range, that the total stimulation time does not exceed 8 hours.

sinus (w)

Stimulation waveform mode sinus (w) generates a single sinusoidal current pulse which is phase and offset shifted (Illustration 39).
Peak amplitude is *[current]* µA and the waveform duration is determined by *[frequency]* in Hz.



The current profile starts at 0 µA and ist calculated as follows:

i = (current/2 * sin(2*pi*t/T – pi/2)) + current/2

true for:

T = (1/frequency)

t = 0:0.01:(1/frequency)

Illustration 39: Timing chart of current during sinus (w), current 2500 µA, duration 1 s

This mode is useful to generate single "softened" current pulses.

The following table summarizes the available parameters for stimulation waveform mode sinus (w):

	minimum value	increment	maximum value	unit
current	-1500	25*	1500	µA
frequency	0.01	0.01*	100	Hz

* dynamic increment, depending on duration of keypress

noise (tRNS)

For this mode on each sample (sample rate 1280 sps) a random current level is generated. Statistically the random numbers are normally distributed over time, the probability density follows a Gaussian bell curve.

A waveform will be applied with 99 % of the values located between [-current/2] and [+current/2] µA. Only 1% of the current level will not be in this interval but within the range of ± [current/2 + current/10] µA .

One can shift the whole signal by varying *[offset]*. Signal last for *[duration]* seconds.
To avoid painful current steps the user can define controlled rising and falling of the signal by adjusting *[fade in/out]* values.
Stimulation waveform mode noise generates a wide band noise signal (0 to 250 Hz).

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

	minimum value	increment	maximum value	unit
current	0	25	3000	µA
offset	-500	50	1000	µA
duration	5	5	1800	s
fade in/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.

noise HF

Current level of stimulation mode "noise HF" is generated similar to stimulation mode "noise". Additionally a digital high-pass filter is used to highly damp frequencies below 100 Hz ("colored noise"). The signal contains fractions between 100 Hz to 640 Hz only.

For the mode "noise HF" the signal is scaled after filtering in order to achieve analog amplitudes to signals created with "noise".

The following table summarizes the available parameters for stimulation waveform mode noise (HF):

	minimum value	increment	maximum value	unit
current	0	25	3000	µA
offset	-500	50	1000	µA
duration	5	5	1800	s
fade in/out	0	1	120	s

noise LF

Current level of stimulation mode "noise LF" is generated similar to stimulation mode „noise". Additionally a digital low-pass filter is used to highly damp frequencies above 100 Hz ("colored noise"). The signal contains fractions up to100 Hz only.

For the mode "noise LF" the signal is scaled after filtering in order to achieve analog amplitudes to signals created with "noise".

The following table summarizes the available parameters for stimulation waveform mode noise (LF):

	minimum value	increment	maximum value	unit
current	0	25	3000	µA
offset	-500	50	1000	µA
duration	5	5	1800	s
fade in/out	0	1	120	s

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 (Illustration 40):

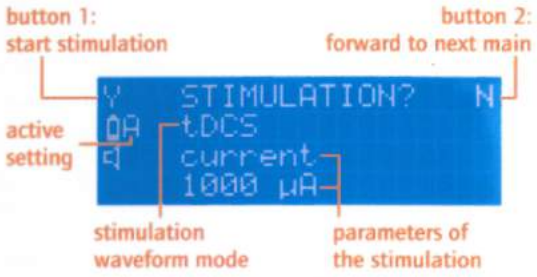


Illustration 40: Main menu STIMULATION

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 (Illustration 41), measuring the electrode impedance between electrode and skin.

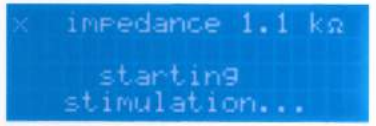


Illustration 41: Impedance check after start of stimulation

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 (Y) again to discard the stimulation. Alternatively press button 4 (N) to continue the stimulation after reducing the impedance.

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 impedance above the electrodes (see Illustration 42).

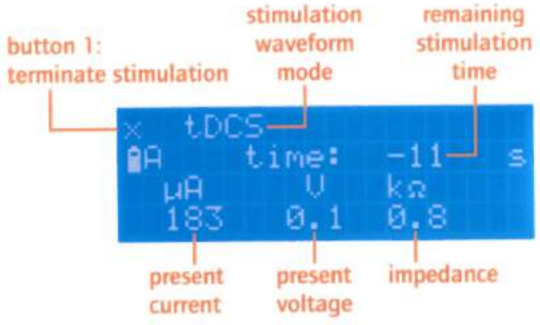


Illustration 42: Display during stimulation

Advice for stimulation waveform mode "sinus":

When stimulation waveform mode is "sinus" the 4th line of the display indicates the absolute values of the current and the voltage.

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 (Y) to discard the stimulation.
Alternatively press button 4 (N) to continue the stimulation after reducing the impedance.

Completing the stimulation

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

SCHEDULE (optional)

The SCHEDULE mode allows to operate the DC-**STIMULATOR** PLUS outside a hospital or doctor's surgery. The patient can only carry out a predefined treatment plan which has to be customized and programmed by the doctor. Only the doctor and or instructed staff can modify the plan using the mastercode.

So the doctor is able to set the parameters and numbers of the individual stimulations within the treatment plan, the exact starting time as well as the interval between the stimulations. The internal logfile records each single treatment session carried out out by the patient and allows the doctor to readout the complete series afterwards.

Treatment routine

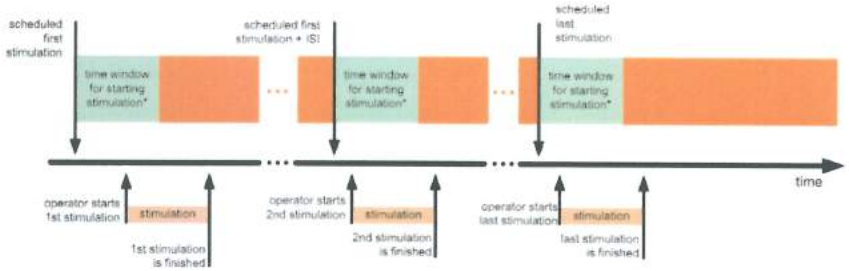


Illustration 43: Treatment routine

The following example illustrates a typical treatment routine:
Mr X is to receive stimulation of 20 minutes starting 1 April, 2012 trough 21 April, 2012, once a day at 11:15 am. He can perform the stimulation on his own at home with the DC-**STIMULATOR** PLUS. The doctor in charge programs the device as follows (see Illustration 43):
The first stimulation starts on 1 April, 2012 at 11:15 am.
The interstimulus interval (ISI) is set to 24 hours, since stimulation has to start at the same time every day.
Since the treatment involves 21 stimulations, the doctor sets the last stimulation for 21 April, 2012.
The time window for starting a stimulation is 1/20 of the interstimulus interval, but at least 15 min. With an ISI of 24 hours the start time window is 72 minutes.
This gives Mr X 72 minutes beginning at 11:15 am to initiate the stimulation.

If Mr X switches the stimulator on before 11:15 am or after 12:27 am, he cannot start a stimulation (see Illustration 44).
The doctor defines the so-called stimulation setting, which includes all stimulation parameters such as type and intensity of current, duration etc. He can program up to 4 different settings (A-D). Mr X can only switch between these settings but he cannot change any parameters (see Illustration 45)
After the treatment the doctor can check in the logfile if Mr X has carried out the required stimulations.

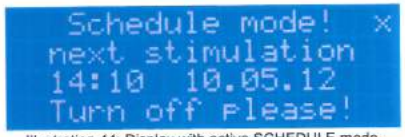


Illustration 44: Display with active SCHEDULE mode, when the DC-STIMULATOR PLUS was switched on outside the start time window for starting a stimulaion

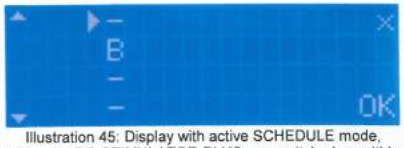


Illustration 45: Display with active SCHEDULE mode, when the DC-STIMULATOR PLUS was switched on within the start time window. There is only setting B available.

Sometimes problems occur during a stimulation, e.g. due to detached or dry electrodes. To get the chance to complete an interrupt stimulation the user can fix problems and continue stimulation within a time slot of [3 x stimulation duration] (at least 15 minutes). Multiple interrupting is possible. All these events will be logged.

Discarding an interrupt stimulation is possible, too. But notice: in SCHEDULE mode, there is no possibility to restart the complete stimulation. The next stimulation will not be start until the next start time window is valid.

Please read below, how to set the parameters for treatment schedule:

Before entering or activating a new treatment the DC-**STIMULATOR** PLUS checks the logfile for entries from previous sessions. If so, it is not possible to program a new schedule. Therefore you should always check the logfile first. Decide if the data in the logfile is still required, read them out and delete all logfile entries (see Software Reference Manual: Logfile).

Global time

Before you can program the first treatment schedule in your DC-**STIMULATOR** PLUS, you need to set the internal time and date. Once set, the internal time remains active and precise for months, even if the device is switched off. The preset time is GMT + 1.

Illustration 46: Main menu SCHEDULE, submenu global

Illustration 47: Setting date and time of the DC-STIMULATOR PLUS

To modify the global time please follow these instructions (see Illustration 46):

- Press button 2 or 4 to select main menu SCHEDULE.
- Move the cursor to line 2 on the display by pressing button 3.
- Switch to submenu global time by pressing button 2 or 4 several times.
- Move the cursor to line 4 on the display by pressing button 3 (Illustration 46). If you press button 2 you will get to the settings as shown in Illustration 47 (h - hour, m - minute, D - day, M - month, Y - year).
- Pressing button 2 moves the cursor left or right. Once the cursor is in the right position you can press button 1 or 3 to increase or decrease the digit.
- Press button 4 (OK) to confirm time and date.
- Press button 1 several times to move the cursor back to line 1 (the main menu).

First stimulation

In the submenu "first stimulation" you can set the starting time and date of the first treatment.

Illustration 48: Main menu SCHEDULE, submenu first stimulation

To modify the time and date of the first stimulation please follow these instructions (see Illustration 48):

- Press button 2 or 4 to select main menu SCHEDULE.
- Move the cursor to line 2 on the display by pressing button 3.
- Switch to submenu first stim by pressing button 2 or 4 several times.
- Move the cursor to line 4 on the display by pressing button 3 (Illustration 48). If you press button 2 you will get to the settings as shown in Illustration 47 (h - hour, m - minute, D - day, M - month, Y - year).
- Pressing button 2 moves the cursor left or right. Once the cursor is in the right position you can press button 1 or 3 to increase or decrease the digit.
- Press button 4 (OK) to confirm time and date of the first stimulation.
- Press button 1 several times to move the cursor back to line 1 (the main menu).

Interstimulus interval

The interstimulus interval (ISI) describes the "break" between two subsequent stimulations. It may vary from 1 to 96 hours.

Illustration 49: Main menu SCHEDULE, submenu interstimulus interval

To modify the interstimulus interval please follow these instructions (see Illustration 49):

- Press button 2 or 4 to select main menu SCHEDULE.
- Move the cursor to line 2 on the display by pressing button 3.
- Switch to submenu interstim interval by pressing button 2 or 4 several times.
- Move the cursor to line 4 on the display by pressing button 3 (Illustration 49).
- Pressing button 2 increases the ISI by 1 hour, button 4 reduces the ISI by 1 hour.
- Press button 1 to confirm and save the ISI.
- Press button 1 several times to move the cursor back to line 1 (the main menu).

In case you set ISI = 0 ("logging"), the start time window for stimulation will not be checked, but nevertheless, all stimulations will be recorded in the logfile.

Last stimulation

In the submenu "Last stimulation" you can set the date and time of the last stimulation of the treatment schedule by entering a total number of single stimulation sessions.

Illustration 50: Main menu SCHEDULE, submenu last stimulation

To modify the time and date of the last stimulation please follow these instructions:

- Press button 2 or 4 to select main menu SCHEDULE.
- Move the cursor to line 2 on the display by pressing button 3.
- Switch to submenu last stim by pressing button 2 or 4 several times.
- Move the cursor to line 4 on the display by pressing button 3. If you press button 2 you will get to the settings as shown in Illustration 50.
- Press button 1 to increase the number of stimulations, the duration of one interstimulus interval will be added on the indicated time and date.
  Or press button 3 to reduce the number of stimulations. In this case the duration of one interstimulus interval will be subtracted from the indicated time and date
- Press button 4 to confirm and safe.
- Press button 1 several times to move the cursor back to line 1 (the main menu).

Scheduling

In the submenu" Scheduling" the SCHEDULE mode can be enabled or disabled. If the mode is disabled the DC-**STIMULATOR** PLUS can be used for any kind of stimulation at any time. The logfile is also disabled.

Illustration 51: Main menu SCHEDULE, submenu scheduling enabled/disabled

To modify the scheduling mode please follow these instructions (see Illustration 51):

- Press button 2 or 4 to select main menu SCHEDULE. Move the cursor to line 2 on the display by pressing button 3.
- Switch to submenu scheduling by pressing button 2 or 4 several times. Move the cursor to line 4 on the display by pressing button 3.
- Button 2 or 4 enables/disables the SCHEDULE mode. On the display you will read "preparing schedule, setting up system, please wait".
- Press button 1 several times to move the cursor back to line 1 (the main menu).

You need to reboot the DC-**STIMULATOR** PLUS to activate the modifications to this setting.

The active SCHEDULE mode is indicated by a star (*) to the right of the speaker symbol.

To activate the mode "only logging" you need to activate the SCHEDULE mode an set ISI = 0.

Restricted mode

In this submenu you can enable or disable the restricted mode. The restricted mode provides a simplified user interface for the application of the device without medicinal staff around (e. g. at the patient's home). The restricted functions prevent operating errors and injuries caused by incorrect use. With the restricted mode being active the user can only select one of max. 4 settings. He cannot make any modifications to the stimulation parameters.

The restricted mode is always combined with scheduling to avoid harmful excessive stimulation during home use.

To modify the restricted mode please follow these instructions:

- Press button 2 or 4 to select main menu SCHEDULE. Move the cursor to line 2 on the display by pressing button 3.
- Switch to submenu restricted mode by pressing button 2 or 4 several times. Move the cursor to line 4 on the display by pressing button 3.
- Button 2 or 4 enables/disables the restricted mode. On the display you will read "save, please wait".
- Press button 1 several times to move the cursor back to line 1 (the main menu).

You need to reboot the DC-**STIMULATOR** PLUS to activate the modifications to this setting.

Restricted setting

In the submenu restricted setting you can specify which of the 4 predesigned stimulation settings are selectable by the patient during restricted mode operation. Furthermore, you can switch between active and sham stimulation.
In Illustration 52 setting A and C are active (B and D are disabled). Setting A is an active stimulation while setting C is a sham stimulation.

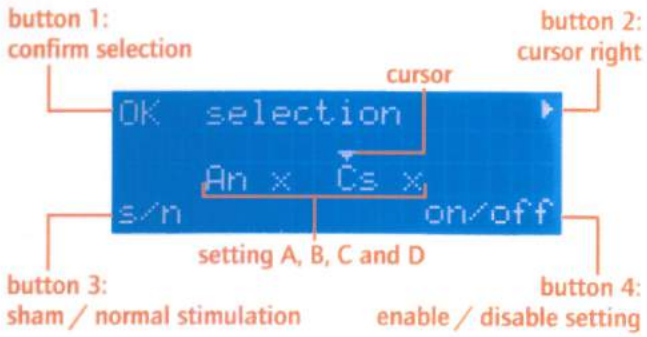


Illustration 52: Main menu SCHEDULE, submenu restricted setting - change settings

To modify the restricted setting mode please follow these instructions:

- Press button 2 or 4 to select main menu SCHEDULE. Move the cursor to line 2 on the display by pressing button 3.
- Switch to submenu restricted setting mode 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 open "selection" (Illustration 52).
- The cursor is now positioned in the second line over setting A. Press button 4 to enable / disable setting A. If setting A is enabled press button 3 to change between active and sham stimulation
- Move the cursor to setting B by pressing button 2 and act likewise. Repeat these steps for settings C and D.
- Press button 1 (OK) to confirm. Now press button 4 to save the entries. To cancel the saving process press button 3.
- Press button 1 several times to move the cursor back to line 1 (the main menu).

Logfile

The internal logfile contains the treatment schedule and records all applied stimulations. In this submenu you can read and clear the logfile.

Illustration 53: Main menu SCHEDULE, submenu logfile (read/clear)

To work with the logfile please follow these instructions (see Illustration 53):

- Press button 2 or 4 to select main menu SCHEDULE.
- Move the cursor to line 2 on the display by pressing button 3.
- Switch to submenu logfile by pressing button 2 or 4 several times.
- Move the cursor to line 4 on the display by pressing button 3.
- You can switch between "read" and "clear" by pressing button 2. Confirm your entries with button 4 (OK).
- When select "clear" all logfile entries will be deleted and a new treatment schedule can be setup.
  With "read" all logfile entries are displayed one after another (see Illustration 54).

When clearing the logfile data ALL entries are deleted. It is not possible to delete single logfile entries.

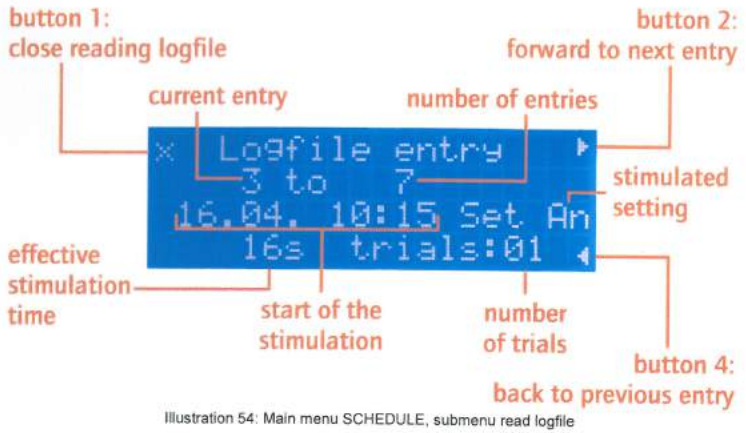


Illustration 54: Main menu SCHEDULE, submenu read logfile

You can switch between single logfile entries by pressing buttons 2 and 4.

The starting time indicates the predefined starting time, but not the time of the actual start of the stimulation. This is only indicated with the "logging" mode (ISI = 0) being active.
The effective stimulation time shows if the patient finished or discarded the stimulation.
If the number of trials is bigger than 1, the stimulation was interrupted due to some problems (e. g. electrode slipped off), but continued after wards.
The stimulated setting indicates, which of the predefined settings (A, B, C or D) was selected by the patient and if the stimulation was normal (n) or sham (s).

REMOTE (optional)

The REMOTE mode enables you to operate the DC-**STIMULATOR** PLUS externally controlled by a voltage supply source. The generated current follows proportionally to the applied voltage. Hereby - voltage source and the output of the constant current source are galvanically isolated.

The REMOTE mode is for investigational use only. The manufacturer assumes no liability for any injury in this case.

Menu navigation

To activate REMOTE mode switch to main menu REMOTE using button 1 or 2 (Illustration 55).

Whilst REMOTE mode is active the electrode impedance will not be controlled. The manufacturer recommend to control impedance manually (pressing button 2 and 3 simultaneously) while attaching the electrodes before starting the REMOTE mode to ensure a good connection between patient and electrodes.

Illustration 55: Main menu REMOTE

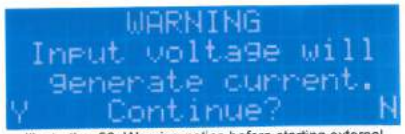


Illustration 56: Warning notice before starting external voltage control

Pressing button 3 "Y" (Illustration 55) a warning notice occurs at the display (Illustration 56). Confirming this warning by pressing button 3 "Y" the external voltage control will start after a few seconds. Otherwise you can get back to main menu REMOTE by pressing button 4 "N" (Illustration 56)

During the stimulation, at the bottom right corner of the display you can see the present electrode voltage (Illustration 57).

Illustration 57: Display during stimulation in REMOTE mode

Press button 1 "x" (Illustration 57) to finish external voltage control.

SYSTEM

In the Software Reference Manual the chapters Trigger input, Trigger output and Signal out 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** PLUS 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** PLUS 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** PLUS 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** PLUS will wait for the next trigger event. This repetitive procedure can be stopped by pressing the button 1 (X).

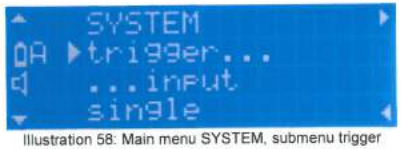


Illustration 58: Main menu SYSTEM, submenu trigger

To enable / disable the trigger input please follow these instructions (see Illustration 58):

- 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 (Illustration 58).
- 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** PLUS 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.

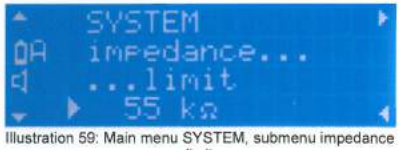


Illustration 59: Main menu SYSTEM, submenu impedance limit

To change the settings of the impedance limit please follow these instructions (Illustration 59):

- 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 (Illustration 59).
- 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.

Trigger output (optional)

An additional BNC socket is provided at the rear side of the DC-**STIMULATOR** PLUS. This allows a trigger signal to be sent out during stimulation waveform mode "sinus" and "pulse mode" only at a defined position of the signal curve. For technical details please see

Manual Operation Basics: Trigger output.

Trigger output can be:

disabled (Standard)

Trigger output is disabled.

enabled

Trigger output is enabled.

To enable / disable the trigger output please follow these instructions (analog Trigger input):

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

Hint for stimulation mode „sinus"

A defined phase shift of the trigger impulses toward the sinus signal can be achieved by using the "phase" setting (initial phase shift of the sinus signal in degrees).
An iteration of the trigger impulse every t sinus periods (t×2π) can be achieved by using the "trig.cycle" setting - counted from the beginning and ignoring the phase shift.
No plausibility check of the trigger events will be carried out. So, for example, no trigger impulse will be released if the "trig.cycle" >> "cycles".

The trigger output module ist disabled automatically when you turn your DC-**STIMULATOR** PLUS off. However, you can save the set of trigger output in the setting.

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 can be used in schedule mode and in restricted mode (see Software Reference Manual: SCHEDULE).

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 (Illustration 60):

- 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).

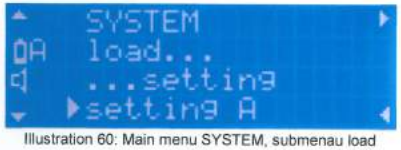


Illustration 60: Main menu SYSTEM, submenau load setting

The stimulation parameters defined in the settings still remain active after rebooting the DC-**STIMULATOR** PLUS. The parameters loaded before system shutdown are the standard parameters after reboot.

SIGNAL OUT (optional)

The SIGNAL OUT allows you to track, analyze and process the voltage waveform the DC-**STIMULATOR** PLUS sends out to external devices (e. g. Oscilloscope, measuring amplifier, PC). For technical details on SIGNAL OUT please see Manual Operating Basics: SIGNAL OUT.

SIGNAL OUT can be:

disabled (Standard)

The SIGNAL OUT is inactive.

enabled

The SIGNAL OUT is active.

To enable / disable the SIGNAL OUT 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 OUT 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 OUT.
- Press button 1 several times to move the cursor back to line 1 (the main menu).

The SIGNAL OUT ist disabled automatically when you turn your DC-**STIMULATOR** PLUS off.

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

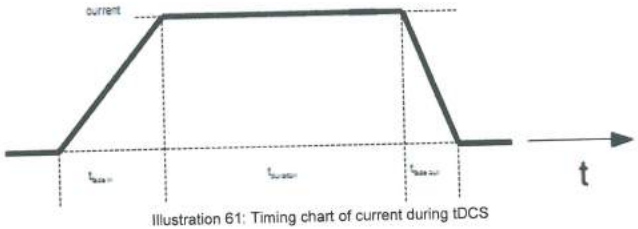


Illustration 61: Timing chart of current during tDCS

In order to compare the normal with the "sham" stimulation a time chart of current in tDCS mode is shown in Illustration 61.

Timing chart of current - sham stimulation

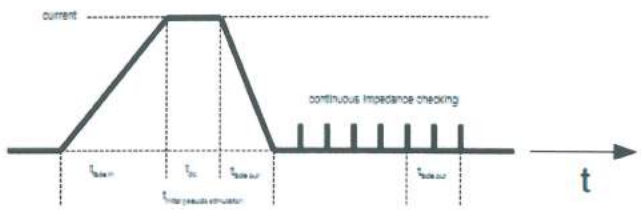


Illustration 62: Timing chart of current during sham stimulation (tDCS)

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

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.

Study mode and SCHEDULE cannot be active at the same time. If study mode is active, you can only use the mode "Logging" (ISI = 0).

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** PLUS (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 (Illustration 63).

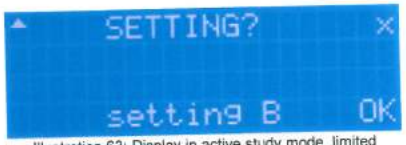


Illustration 63: Display in active study mode, limited selection of settings

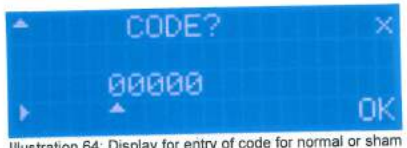


Illustration 64: Display for entry of code for normal or sham stimulation.

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 (Illustration 64).
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** PLUS on. The display will immediately switch to limited selection of settings (Illustration 63). 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** PLUS will start in the standard operating mode.

After disabling the study mode you have to reboot the DC-**STIMULATOR** PLUS (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** PLUS 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 (Illustration 65).
- Press button 2 or 4 to confirm "change". Thereafter you can choose between "deutsch" and "english" by pressing button 2 (Illustration 66).
- 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).

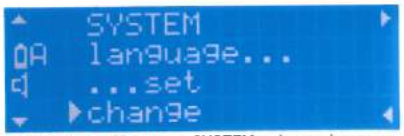


Illustration 65: Main menu SYSTEM, submenu language set

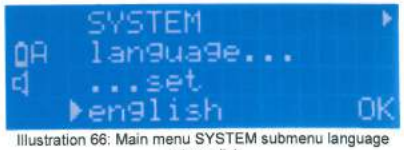


Illustration 66: Main menu SYSTEM submenu language set: english

Signal tone

The DC-**STIMULATOR** PLUS 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 SCHEDULE mode
- when the DC-**STIMULATOR** PLUS is switched on and not used for more than one minute

In the optional mode REMOTE the signal tone is always active, independent from any settings made.

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 (Illustration 67).
- 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).

Illustration 67: Main menu SYSTEM, submenu backlight brightness

NB: Backlight brightness is an important factor of the DC-**STIMULATOR** PLUS 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 either the SCHEDULE or the study mode.

The mastercode is a "password" that allows the user to access and modify all main and submenus in active SCHEDULE or 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.

Illustration 68: Mastercode entry

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

- The cursor is located in the first digit (see Illustration 68). 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** PLUS use, please contact your dealer or the manufacturer.

Hotline:

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7 Technical Specifications

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 the equipment)
- power supply via built-in rechargeable batteries
- external battery charger "Ansmann ACS110 Traveller"
- run continuously for approx. 6 h (depending on the equipment)
- touch-protected connecting (electrode) sockets ø 1,5 mm (DIN 42802)
- alphanumerical display, 4 buttons

Stimulation

- DC current -4500...+4500 µA, increment 25 µA
- inaccuracy of DC current max. 1 %
- hardware offset ±10 µA
- internal DAC resolution of signal generation 16 bit
- quartz time base error max. 0.001 %
- internal time resolution < 1 ms (sampling rate 2048 sps)
- voltage limit max. ±20 V
- stimulation waveform modes: tDCS, pulse mode, sinus, noise, noise HF, noise LF

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: 2.0 to 5.25 V
- pulse width: min. 1 ms

Trigger output (optional)

- "active high"
- CMOS TTL level: min. 3.0 V
- pulse width: 0.45 ms ±10 %

REMOTE (optional)

- input voltage: -2...+2 V, galvanically isolated
- output current: -4...+4 mA
- 3 dB cut-off frequency 300 Hz

SIGNAL OUT (optional)

- Signal+: 25 mV offset + 2.5 mV @ 1 mA
- Signal-: 25 mV offset - 2.5 mV @ 1 mA

- Voltage signal oscilloscope: 2.25 V @ 4.5 mA
- electric trigger: "active high", 5 V
- optical trigger: HFBR socket

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 60601-1-2:2007 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.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions IEC CISPR 11	Class B	The device or system is use 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) 5/50 ns (T_r/T_h) 5 kHz repetition rate	passed, B	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode 1.2/50 (8/20) µs (T_r/T_h)	passed, B	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	> 95 % reduction for 0.5 cycle 60 % reduction for 5 cycles 30 % reduction for 25 cycles > 95 % reduction for 250 cycles	passed, B/C	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device or system requires continued operation during power mains interruptions, it is recommended that the device or system is powered by an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	50 Hz 3 A/m	passed, A	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 (2 kHz)	passed, A	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 calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=[3.5/V_1]\sqrt{P}$

Radiated RF IEC 61000-4-3	0.08-1; 1-2; 2-2.5 GHz 3 V/m (unmodulated, rms) 80 % AM (2 kHz)	passed, A	$d=[3.5/E_1]\sqrt{P}$ 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	0.2	0.2	0.4
0.1	0.4	0.4	0.8
1	1.2	1.2	2.4
10	3.7	3.7	7.4
100	11.7	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** PLUS is covered by a 12 month warranty worldwide and a 24 month warranty within the European Union.

Maintenance

The DC-**STIMULATOR** PLUS should be maintained every 12 months.

Return

From the fifth year after delivery, the DC-**STIMULATOR** PLUS can be taken back by the manufacturer or a company authorized by the manufacturer.

10 Distributors

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We have additional or exclusive distributors in the countries listed below:

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11 Literature

Some useful publications on tDCS applications and safety have been assembled (in reverse chronological order). This is not a comprehensive list.

2011

Modulating a desired region of interest?
Optimized multi-electrode stimulation increases focality and intensity at target.
Dmochowski JP, Datta A, Bikson M, Su Y, Parra LC.
J Neural Eng. 2011 Jun 10;8(4)
PMID: 21659696 [PubMed - as supplied by publisher]

From a point of simulating the region of interest?
Gyri-precise head model of transcranial DC stimulation: Improved spatial focality using a ring electrode versus conventional rectangular pad.
Datta A, Bansal V, Diaz J, Patel J, Reato D, Bikson M.
The City College of the City University of New York, New York, NY.

2008

Noninvasive brain stimulation for Parkinson's disease and dystonia.
Wu AD, Fregni F, Simon DK, Deblieck C, Pascual-Leone A.
Neurotherapeutics. 2008 Apr;5(2):345-61. Review

Noninvasive brain stimulation with transcranial magnetic or direct current stimulation (TMS/tDCS)-From insights into human memory to therapy of its dysfunction.
Sparing R, Mottaghy FM.
Methods. 2008 Apr;44(4):329-37. Review

2007

The use of tDCS and CVS as methods of non-invasive brain stimulation.
Been G, Ngo TT, Miller SM, Fitzgerald PB.
Brain Res Rev. 2007 Dec;56(2):346-61. Epub 2007 Aug 28. Review

Technology insight: noninvasive brain stimulation in neurology-perspectives on the therapeutic potential of rTMS and tDCS.
Fregni F, Pascual-Leone A.
Nat Clin Pract Neurol. 2007 Jul;3(7):383-93. Review

Noninvasive Human Brain Stimulation.
Wagner T, Valero-Cabre A, Pascual-Leone A.
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12 Disclaimer

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

The DC-**STIMULATOR** PLUS 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** PLUS and the manual.

Validity

This manual is valid for serial numbers 1000 to 1999.

Version

- version number: 2.4.0
- created: September 10, 2014

13 Notes

14 Additional hardware extension DC-STIMULATOR MR

The DC-**STIMULATOR** MR is an additional option for the DC-**STIMULATOR** PLUS. In addition to the fields of application of the DC-**STIMULATOR** PLUS using the DC-**STIMULATOR** MR transcranial electrical stimulation (tES) can be applied even during functional magnetic resonance imaging to precise locate cortical activity.

Important notes

The DC-**STIMULATOR** MR system is designed for transcranial stimulation during fMRI. Only those components and accessories which are indicated for use inside the MR scanner room like the INNER BOX, the connection cable, the MR capable electrodes shall be moved into the MR scanner room.

Never place the DC-STIMULATOR PLUS and the OUTER BOX inside the scanner. They are magnetic. INNER BOX and OUTER BOX must not be interchanged. Please note the different labeling on the boxes.

During MR measurement, high energy is sent out from the High Frequency (HF) coil of the MR scanner. This HF or RF (radio frequency) field induces a current in every electrical conductor. This could be the main cause for a potential temperature rise during investigation. The DC-**STIMULATOR** MR and the attached accessories have several safety precautions included in their design to avoid temperature rise or heating on electrodes or wires as well the spreading of sheath waves.

It is up to the user of the equipment to follow carefully the instructions within the manual and during aural introduction to keep your patient healthy and to avoid damage of the equipment. Before you start stimulation, inform your patient on those physical phenomena.

AVOID ANY LOOP OF ANY WIRE during stimulation. The manufacturer does not assume any liability for any damage in this case.

The DC-**STIMULATOR** MR must not be used with non attached or short circuited electrodes. Especially, no load and short circuit can cause sheath waves. The wires are not protected against sheath waves.

NEVER start a MR sequence if:

- the patient is connected to the DC-**STIMULATOR** MR but the **STIMULATOR** is turned off,

- ELECTRODE CABLE or INNER BOX are non attached or short circuited in the scanner room.

In these cases the ELECTRODE CABLES might be destroyed! The manufacturer does not assume any liability for any damage in this case.

Use only accessories which are supplied by the manufacturer. Do not use other electrodes for recording, which were not supplied by the manufacturer. The manufacturer does not assume any liability for any damage in this case.

Modifications and repair of the DC-**STIMULATOR** MR will be done exclusively by the manufacturer or a company authorized by the manufacturer.

You must not open the DC-**STIMULATOR** MR components in any case. The manufacturer assumes no liability for any damage in this case. If you have technical problems with your system, always inform your dealer or the manufacturer.

Medical electrical devices like the DC-**STIMULATOR** MR are subject to particular precautions regarding the Electro Magnetic Compatibility (EMC) and has to be installed and operated according to the EMC advices that are included within the accompanying documents.

The DC-**STIMULATOR** MR system is not protected against liquid spills (IEC 60529 IP20). You should therefore avoid handling liquid substances as there is a risk of electric shock. In case of liquid spills onto the device, you should unplug the machine. Immediately inform your dealer or the manufacturer.

The DC-**STIMULATOR** MR must not be used in conjunction with defibrillator and during application of high frequency surgery, since it has no appropriate protection. The manufacturer assumes no liability for any damage in this case.

Do not use the DC-**STIMULATOR** MR during fMRI on neonates and children.

After stimulation remove the INNER BOX and all relevant cables and electrodes out of the MR scanner room to avoid aging of the components.

Avoid automatic movements of patient's table inside the scanner. Uncontrolled table movements can cause damage on patient or DC-**STIMULATOR** MR equipment. The manufacturer does not assume any liability for any damage in this case.

Components

The DC-**STIMULATOR** MR consists of 7 components (see Illustration 69):

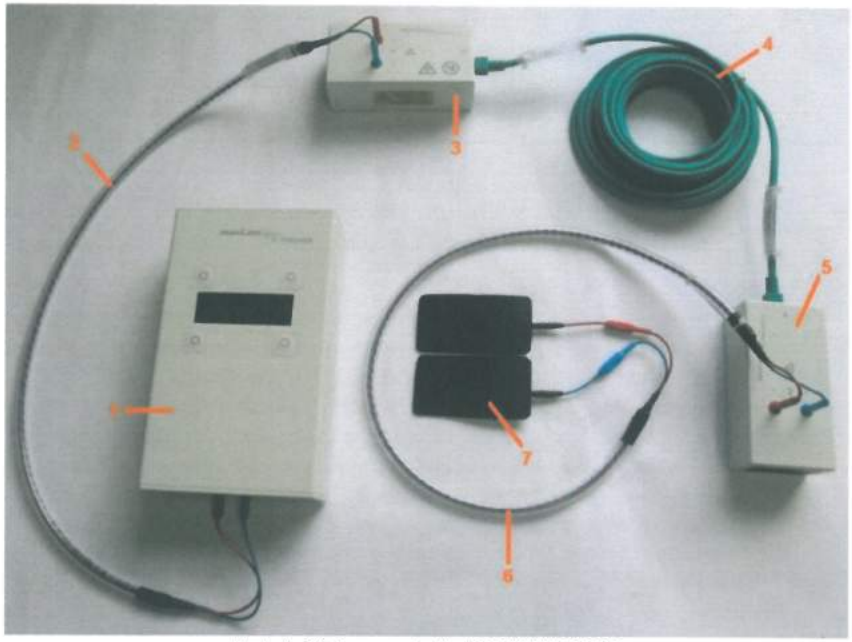

Illustration 69: Components of the DC-STIMULATOR MR
(1 - DC-STIMULATOR MR, 2 - STIMULATOR CABLE, 3 - OUTER BOX,
4 - BOX CABLE, 5 - INNER BOX, 6 - ELEKTRODE CABLE, 7 - MR-compatible electrodes)

1. The stimulator - DC-**STIMULATOR** PLUS

   Please note, only the DC-**STIMULATOR** PLUS (see Illustration 70) can be used for carrying out transcranial stimulation during functional MRI. Any other stimulator may introduce noise into the scanner. The functioning and settings of the DC-**STIMULATOR** PLUS are described in detail in the manual.

Illustration 70: DC-STIMULATOR PLUS

2. STIMULATOR CABLE

   The STIMULATOR CABLE (see Illustration 71) connects the DC-**STIMULATOR** PLUS with the OUTER BOX. Please take care, that the colors on the plugs and socket do match. STIMULATOR CABLE and ELECTRODE CABLE are not interchangeable.

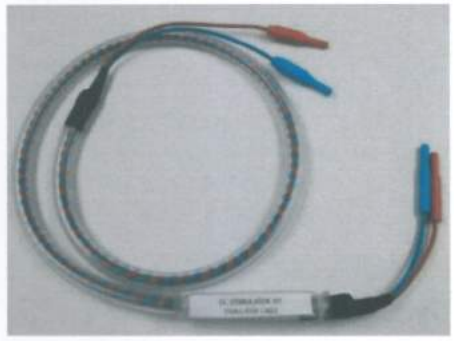

Illustration 71: STIMULATOR CABLE

3. OUTER BOX

   The OUTER BOX (see Illustrations 72 to 74) is a filter box which absorbs RF noise mostly between 50 to 140 MHz, at those frequency ranges where 1.5 T and 3.0 T scanners have their resonance frequency. Please place the OUTER BOX before connecting the BOX CABLE as close as possible to the cable exchange pipe in the wall of the scanner room to avoid any interference from outside the scanner room via the BOX CABLE into the scanner.

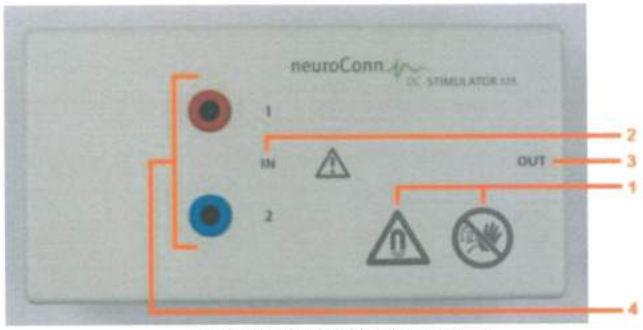

Illustration 72: OUTER BOX, view from above

Illustration 73: OUTER BOX, front view with MR warning sign

Illustration 74: OUTER BOX, side view with socket for the BOX CABLE

	Label/ icon	Specifications
		Pay attention! It is necessary to note the manual's instructions for this socket!
1		Warning signs: Never place the OUTER BOX inside the scanner. It is magnetic.
2	**IN**	Input (Connection to STIMULATOR CABLE)
3	**OUT**	Output (Connection to BOX CABLE)
4	**1 and 2**	Sockets for electrode channels (red: Anode / blue: Cathode)
	1	Channel 1
	2	Channel 2

4. BOX CABLE

The BOX CABLE (see Illustration 75) is used to connect OUTER BOX and INNER BOX. Please make sure that no loop will be introduced within scanner room. Herewith much higher voltages can be induced. Also the manufacturer recommends to tape the wire and keep it away as long as possible from the coil within the scanner.

Illustration 75: BOX CABLE

5. INNER BOX

The INNER BOX (see Illustrations 76 und 77) provides the connectors for the ELECTRODE CABLE inside the scanner room. Please take care, that the colors on the plugs and socket do match. Therefore an MR-compatible ELECTRODE CABLE is not interchangeable with a normal one.

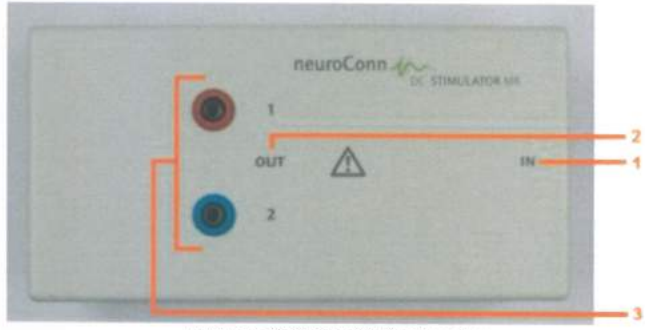

Illustration 76: INNER BOX, view from above

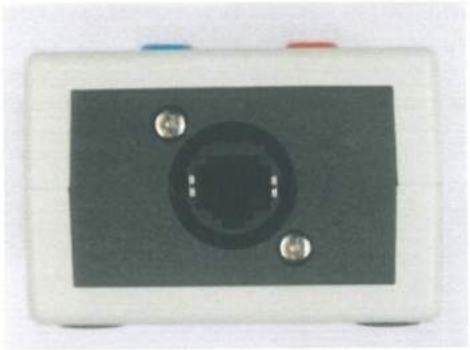

Illustration 77: INNER BOX, side view with socket for the BOX CABLE

	Label/ icon	Specifications
	⚠	Pay attention! It is necessary to note the manual's instructions for this socket!
1	**IN**	Input (Connection to BOX CABLE)
2	**OUT**	Output (Connection to ELECTRODE CABLE)
3	**1 and 2**	Sockets for electrode channels (red: Anode / blue: Cathode)
	1	Channel 1
	2	Channel 2

6. ELECTRODE CABLE

The ELECTRODE CABLE (see Illustration 78) for use during functional MR-imaging is a different one as during normal transcranial stimulation. A 5 kΩ resistor is included in each wire to reduce induction voltage due to high RF impulses.

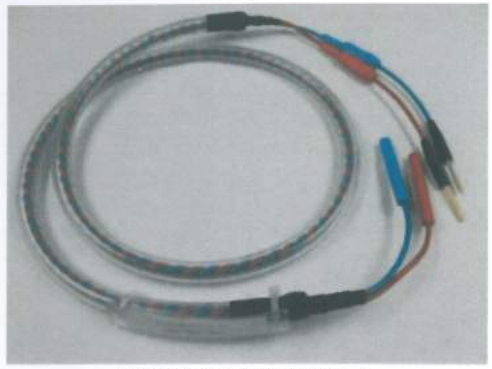

Illustration 78: ELEKTRODE CABLE

7. MR-compatible electrodes

The electrodes (see Illustration 79) for use during functional MR-imaging are of a different type as during normal transcranial stimulation in order to get the best image quality.

Illustration 79: MR-compatible electrodes)

Stimulation setup

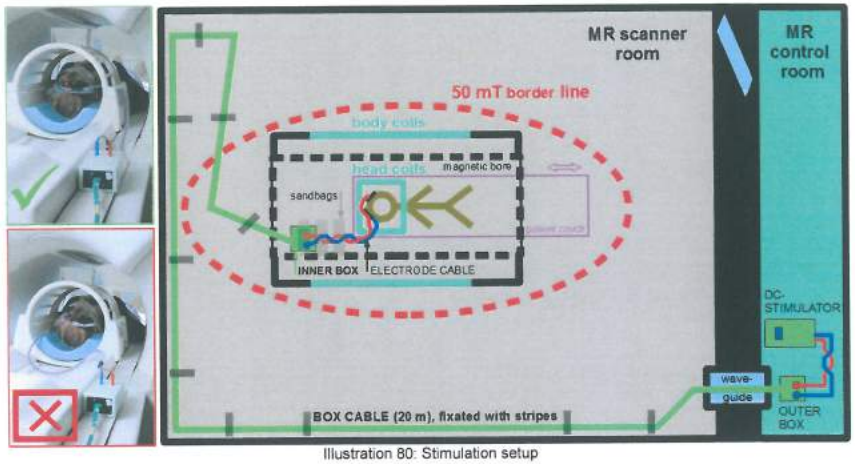

Illustration 80: Stimulation setup

Illustration 80 shows the correct stimulation setup of DC-**STIMULATOR** MR. Please note that the DC-**STIMULATOR** MR and the OUTER BOX are kept outside the MR scanner room. The used STIMULATOR CABLE and ELECTRODE CABLE are not interchangeable among each other due to different kind of sockets and plugs.

NEVER start a MR sequence if:

- the patient is connected to the DC-**STIMULATOR** MR but the **STIMULATOR** is turned off.
- ELECTRODE CABLE or INNER BOX are non attached or short circuited in the scanner room.

In these cases the ELECTRODE CABLES might be destroyed! The manufacturer does not assume any liability for any damage in this case.

Attach the electrodes with TEN20 electrode paste closely to the scalp. You may use some alcohol to reduce the impedance before stimulating. You will achieve the best results if the connectors of the attached electrodes are orientated to the left or the right of the head (see cond3 in Illustration 81).

Only use the Ten20 electrode paste supplied by the manufacturer. Usage of other electrode pastes or gels may induce skin irritations and burning of the skin. The manufacturer does not assume any liability for any damage in this case.

For successful stimulation the current circuit must be closed. Between electrode impedance and maximum stimulation current is a relationship as shown in Illustration 82. The value of electrode impedance must be below the readable value in Illustration 82. Otherwise the DC-**STIMULATOR** MR stops operation after fading in.
It is recommended to test the impedance before entering the MR scanner room.

cond1: water phantom

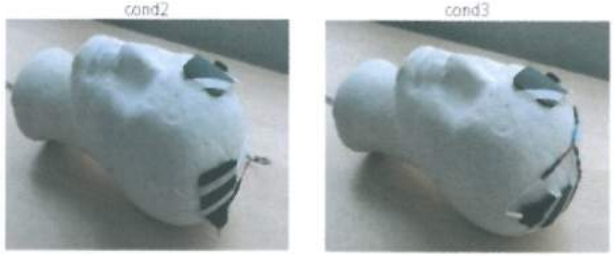

Illustration 81: top: simulation of perturbation cond1-cond3
cond2: electrode connection anode point to occiput, electrode connection cathode point to the right side
cond3: electrode connection anode point to the left side, electrode connection cathode point to the right side

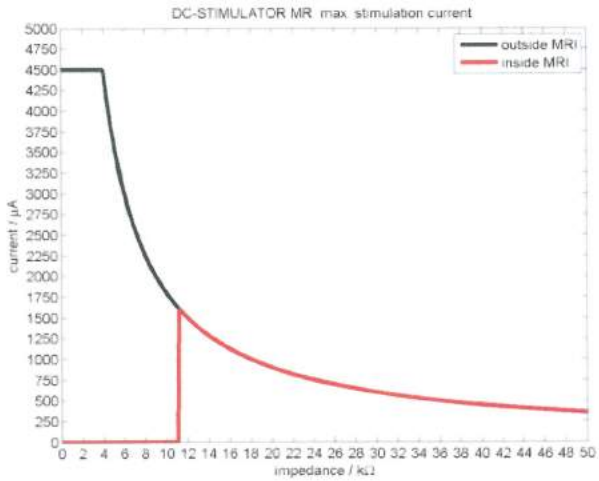

Illustration 82: Relationship between electrode impedance and maximum stimulation current

Noise on MRI

During development cycle of the DC-**STIMULATOR** MR the noise emitted by the equipment was monitored by many measurements taken within 1.5 T and 3.0 T SIEMENS scanners at the universities of Jena and Goettingen, Germany. If the OUTER BOX is placed closely to cable exchange pipe in the wall between scanner and scanner control room, the noise can be reduced. However, we recommend to test the equipment on your scanner and to measure the signal-to-noise ratio within your setup.

Literature

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15 Manuals Equipment

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

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 neurodiagnosite 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.dowaver.com**

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CE

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 VelcoStrip 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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Hungary CE
2014

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 VelcoStrip 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.

CE
2014

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External charger ACS110 Traveller

ANSMANN energy

ACS 110 Traveller

Battery pack charger

GB Operating Instructions

Use of the charger
Charger/discharger for nickel cadmium (NiCd) and nickel metal hydride (NiMH) battery packs of 1-10 cells (1.2-12.0 V) with a capacity of 800-7,200 mAh

Features
- For worldwide use thanks to a switch mode power supply (100-240 V AC) and exchangeable primary plug set
- Microprocessor controlled charging
Testing cycle at the beginning of the charging in order to identify the number of cells and to identify and report defective battery packs
- Short circuit detection and electronic protection against reversed polarity
- Battery pack charge status at the beginning of the charging is not important
- Microprocessor controlled charge status monitoring during the whole charging time
- Includes safety features such as voltage gradient supervision and -delta V switch off, plus a safety timer
- Optional discharging of the battery pack before use by pressing the discharge button. Automatic switching over to fast charging after discharge
- LED status indication
- Automatic switching over to trickle charge once fully charged

Indicators
LED red „Power" (1): Steady light shows that the charger is ready for use. It lights once the charger is plugged in.
LED red „Charge" (2): Steady light indicates the fast charging process after connecting the battery pack.
LED green „Ready" (3): Steady light indicates the battery pack is fully charged. After approx 2 minutes it switches to flashing, which indicates trickle charging.
Once the battery pack is connected, the testing cycle is initiated and the green LED flashes for around 1 minute.
If it carries on flashing and the red LED "Charge" does not light, it indicates that the battery pack is not connected properly and maybe has an incorrect polarity.
LED yellow „Discharge" (4): Steady light indicates the discharging process after pressing the yellow button. The LED „Ready" flashes for around 1 minute indicating the testing cycle.

Controls and Accessories
Discharge button (5): Press this button for about two seconds to start the optional discharging process of the battery pack.

Attention
Charge only nickel/cadmium (NiCd) or nickel/metalhydride (NiMH) battery packs. Danger of explosion if other types of batteries are inserted.

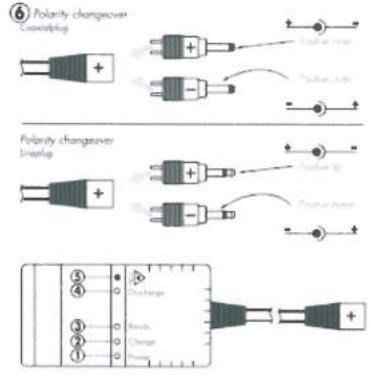
Safety Instructions
Do not attempt to open the charger.

Keep the charger in a dry place (indoor use only).
In order to avoid the risk of fire and/or electric shock, the charger must be protected against high humidity and water.
Do not plug in the charger if there are any signs of damage to the housing, mains pins, cables or connectors. In case of a defect please return to an authorised service centre.
Keep the charger out of reach of children.
If the safety instructions are not followed, this may lead to damage to the charger or batteries or even to serious injury to the user.

Operation
Connect the charger to the mains. With the exchangeable primary plug set and the electronic power supply (100-240 V AC) the charger can be used worldwide. To change the primary plug, unlock the mechanism on the back of the unit towards the arrow. Attach the right primary plug to the unit until it is clicks in place. Once the charger is connected to the mains, the power indicator lights and the charger is ready for use.
Connect the battery pack to the charger. Usually the battery pack is brought into contact via the output plugs which are enclosed. When connecting the plug to the secondary cable, pay attention to the correct polarity (see figure 6). The red LED „Charge" lights and indicates the charging process. During the testing cycle the green LED „Ready" flashes also but goes out after around 1 minute when the test phase is over. After termination of the fast charge the charger switches automatically to trickle charge. The red LED „Charge" is off and the green LED „Ready" is constantly on for approx. 2 minutes. After around 2 min. the indicator changes to green flashing. The battery pack can be removed at this time or left connected to keep topped up until use.
If the green LED „Ready" flashes immediately after connecting the battery pack and the red LED „Charge" lights up sporadically, this means that the polarity (+/–) at the charging cable is not set correctly. Please reverse the polarity (see figure 6). If both LEDs are still flashing after changing the polarity and the steady light „Ready" does not light permanently, the battery pack is defective and cannot be recharged at all. In this case the pack has to be replaced.
The optional discharging procedure can be started by pressing the button for discharging (5) for about 2 seconds. The yellow LED „Discharge" (4) lights and indicates the discharging procedure. During the first minute the green LED „Ready" (3) flashes but should turn off after the test phase. After discharging, which can in some cases last for several hours, the charger automatically switches over to fast charging.

Environment
Rechargeable batteries are not to be disposed in domestic waste. Return used batteries to your dealer or to a battery recycling collection point.

Specification
Prim.: 100-240 V AC, 50-60 Hz, 17VA
Sec.: 1.45-4.5 V DC, max. 800 mA, 9.6 VA



MASTERCODE

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