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 labelling 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.
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 62304:2006 Medical device software - Software life-cycle process
- EN 62366:2008 Medical devices - Application of usability engineering to medical devices
- 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, ventriculoperitoneal 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 the 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 redness of the skin (erythema) and skin burns. The manufacturer accepts no responsibility for any injury caused by such use.

**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 0.625 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 650 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 front side**

**Illustration 3: Front side of the DC-STIMULATOR PLUS**

**Label/Icon** | **Specifications**
--- | ---
A | ![Warning Icon] Pay attention! It is necessary to note the manual's instructions for this socket!
B | moveable front plate
C | socket for charger “Ansmann ACS110 Traveller”
D | socket “1” (anode - positive) for touch-proofed safety connectors according to DIN 42602-2 (ø 1.5 mm)
E | socket “2” (cathode - negative) for touch-proofed safety connectors according to DIN 42602-2 (ø 1.5 mm)
F | socket “3” (ground) 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**
--- | ---
1 | ![Warning Icon] Pay attention! It is necessary to note the manual's instructions for this socket!
2 | 0/1 "on"/"off" switch of the DC-STIMULATOR PLUS
3 | STIM HFBR socket to plug in the optical cable of the adapter box SIGNAL OUT (ACS-EEG NP)
4 | SIGNAL OUT socket to plug in the SIGNAL OUT cable of the adapter box SIGNAL OUT
5 | REMOTE IN socket to connect the BNC cable for REMOTE
6 | 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:

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, IACS-EEG and IACS-EEG NP.

<table>
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<th>Monitor</th>
<th>IACS-EEG</th>
<th>IACS-EEG NP</th>
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<td>adapter box SIGNAL OUT</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>2 SIGNAL OUT cable to plug in into the SIGNAL OUT socket of the adapter box and the DC-STIMULATOR PLUS</td>
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<tr>
<td>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/DCS amplifier</td>
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<tr>
<td>4 BNC socket, provided signal: “Voltage signal (oscilloscope)”</td>
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<td>x</td>
<td>x</td>
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<tr>
<td>5 BNC socket, provided signal: “Electric trigger”</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>6 touch-protected connecting cable ø 1.5 mm (DIN 42802) to connect it to EEG amplifiers, provided signal: Signal-</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>7 touch-protected connecting cable ø 1.5 mm (DIN 42802) to connect it to EEG amplifiers, provided signal: Signal+</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>8 touch-protected connecting cable ø 1.5 mm (DIN 42802) to connect it to EEG amplifiers, provided signal: GND</td>
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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 cm²) and the appendant sponge pads.
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 7: Starter set of the DC-STIMULATOR PLUS

Illustration 8: Type label of the DC-STIMULATOR PLUS

manufacturer, address and production year
serial number
applied part BF
Mind the manual!
Attention!
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:
item number
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 of 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).

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).

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).
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 time, 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.

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 it 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.

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 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 $U_{in}=-2...+2\ \text{V}$ will be applied to the DC-STIMULATOR PLUS (see Illustration 24). Out of this the DC-STIMULATOR PLUS will generate a proportional current $I_{out}=-4...+4\ \text{mA}$ according to the transfer function: $I_{out} [\text{mA}] = 2 \cdot U_{in} [\text{V}]$

⚠️ 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 module 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/IDCS,
- 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. oscilloscopes)
- 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 26) and - if necessary -
the optical cable (Illustration 28) into the sockets SIGNAL OUT and STIM at the rear side of the device.

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 HFRB 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)".

**SIGNAL OUT IACS-EEG**

In order to record and analyze the stimulation signal with external medical amplifier, the adapter box SIGNAL OUT IACS-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
The manufacturer does not deliver hardware and software for visualization of the signals provided by the SIGNAL OUT.

**SIGNAL OUT tAAS-EEG NP**

The adapter box SIGNAL OUT tAAS-EEG NP (Illustration 32) is exclusively used to operate the DC-STIMULATOR PLUS together with the NEURO PRAX® TMS/IDCS. Using the corresponding 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/IDCS 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 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

**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.

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

\[
\text{total stimulation time} = \text{fade in} + \text{duration} + \text{fade out}
\]

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum Value</th>
<th>Increment</th>
<th>Maximum Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>current</td>
<td>-4500</td>
<td>25</td>
<td>4500</td>
<td>µA</td>
</tr>
<tr>
<td>duration</td>
<td>15</td>
<td>15</td>
<td>1800</td>
<td>s</td>
</tr>
<tr>
<td>fade in</td>
<td>0</td>
<td>1</td>
<td>120</td>
<td>s</td>
</tr>
<tr>
<td>fade out</td>
<td>0</td>
<td>1</td>
<td>120</td>
<td>s</td>
</tr>
</tbody>
</table>

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.

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum Value</th>
<th>Increment</th>
<th>Maximum Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>current</td>
<td>-1500</td>
<td>25</td>
<td>1500</td>
<td>µA</td>
</tr>
<tr>
<td>pulse width</td>
<td>50</td>
<td>50</td>
<td>2000</td>
<td>ms</td>
</tr>
<tr>
<td>ISI</td>
<td>pulse width + 50</td>
<td>50</td>
<td>1500</td>
<td>ms</td>
</tr>
<tr>
<td>cycles</td>
<td>1</td>
<td>1</td>
<td>2000</td>
<td>ms</td>
</tr>
</tbody>
</table>
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).

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum Value</th>
<th>Increment</th>
<th>Maximum Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>current</td>
<td>-1500</td>
<td>25</td>
<td>1500</td>
<td>μA</td>
</tr>
<tr>
<td>duration</td>
<td>5</td>
<td>5</td>
<td>1800</td>
<td>s</td>
</tr>
</tbody>
</table>

sinus (tACS)

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

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.

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

The current profile is calculated as follows:

\[ i = \text{current} \times \sin(2\pi \times f(T - \pi/2)) + \text{offset} \]

with:

- \( f = \text{frequency} \)
- \( T = 0.001 \times \text{cycles} \)

The total stimulation time will be calculated as follows:

\[ (2 \times \text{fade in/out}) / \text{frequency} = \text{cycles} / \text{frequency} \]

Illustration 38: Timing chart of current during sinus, current 2500 μA blue, offset 9 μA, phase 0 degree red, offset 500 μA, phase 50 degrees

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum Value</th>
<th>Increment</th>
<th>Maximum Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>current</td>
<td>25</td>
<td>25*</td>
<td>3000</td>
<td>μA</td>
</tr>
<tr>
<td>offset</td>
<td>-1000</td>
<td>10</td>
<td>1000</td>
<td>μA</td>
</tr>
<tr>
<td>frequency</td>
<td>0.01</td>
<td>0.01*</td>
<td>250**</td>
<td>Hz</td>
</tr>
<tr>
<td>phase</td>
<td>0</td>
<td>5</td>
<td>360</td>
<td>°</td>
</tr>
<tr>
<td>cycles</td>
<td>1</td>
<td>1*</td>
<td>350000**</td>
<td>2π</td>
</tr>
<tr>
<td>trig. cycles (optional)</td>
<td>1</td>
<td>1*</td>
<td>9999</td>
<td>2π</td>
</tr>
<tr>
<td>fade in/out</td>
<td>0</td>
<td>1*</td>
<td>100</td>
<td>2π</td>
</tr>
</tbody>
</table>

* 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 is calculated as follows:

\[ i = \frac{\text{current}}{2} \times \sin(\pi \times \text{frequency} \times t - \pi) + \text{current}/2 \]

true for:

\[ T = \frac{1}{\text{frequency}} \]

\[ t = 0.001 \times \frac{1}{\text{frequency}} \]

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):

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum Value</th>
<th>Increment</th>
<th>Maximum Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>-1500 µA</td>
<td>25* µA</td>
<td>1900 µA</td>
<td>µA</td>
</tr>
<tr>
<td>Frequency</td>
<td>0.01 Hz</td>
<td>0.01* Hz</td>
<td>100 Hz</td>
<td>Hz</td>
</tr>
</tbody>
</table>

* dynamic increment, depending on duration of keypress

noise (tRNS)

For this mode on each sample (sample rate 1280 spa) 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:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum Value</th>
<th>Increment</th>
<th>Maximum Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>0 µA</td>
<td>25 µA</td>
<td>3000 µA</td>
<td>µA</td>
</tr>
<tr>
<td>Offset</td>
<td>-500 µA</td>
<td>50 µA</td>
<td>1000 µA</td>
<td>µA</td>
</tr>
<tr>
<td>Duration</td>
<td>5 s</td>
<td>5 s</td>
<td>1800 s</td>
<td>s</td>
</tr>
<tr>
<td>Fade in/out</td>
<td>0 s</td>
<td>1 s</td>
<td>120 s</td>
<td>s</td>
</tr>
</tbody>
</table>

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):

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum Value</th>
<th>Increment</th>
<th>Maximum Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>0</td>
<td>25</td>
<td>3000</td>
<td>µA</td>
</tr>
<tr>
<td>Offset</td>
<td>-500</td>
<td>50</td>
<td>1000</td>
<td>µA</td>
</tr>
<tr>
<td>Duration</td>
<td>5</td>
<td>5</td>
<td>1800</td>
<td>s</td>
</tr>
<tr>
<td>Fade in/out</td>
<td>0</td>
<td>1</td>
<td>120</td>
<td>s</td>
</tr>
</tbody>
</table>

**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 to 100 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):

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum Value</th>
<th>Increment</th>
<th>Maximum Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>0</td>
<td>25</td>
<td>3000</td>
<td>µA</td>
</tr>
<tr>
<td>Offset</td>
<td>-500</td>
<td>50</td>
<td>1000</td>
<td>µA</td>
</tr>
<tr>
<td>Duration</td>
<td>5</td>
<td>5</td>
<td>1800</td>
<td>s</td>
</tr>
<tr>
<td>Fade in/out</td>
<td>0</td>
<td>1</td>
<td>120</td>
<td>s</td>
</tr>
</tbody>
</table>

**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 shows following items (Illustration 40):

![Illustration 40: Main menu STIMULATION](image)

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](image)

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]

**Terminating the stimulation**
The ongoing stimulation can be terminated by the user at any time by pressing button 1 (K). 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 by the patient and allows the doctor to readout the complete series afterwards.

![Illustration 43: Treatment routine]

**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.

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

Illustration 47: Display with active SCHEDULE mode, when the DC-STIMULATOR PLUS was switched on within the start time window. There is only setting B available.

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.

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.

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.

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 save.
- 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.

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 and 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 predefined 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.

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.

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.

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 afterwards.
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.

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).

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).

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.

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

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).

Load setting

In the so-called settings you can redefine 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, submenu 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 is 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

<table>
<thead>
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<th>Code</th>
<th>Description</th>
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<td>07390</td>
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<td>06252</td>
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</table>
Codes for normal stimulation

23613  35947  17155  39147  03229  37424  45931  63064  49185  48486
28303  41567  52627  61961  60027  39451  16817  57242  33646
46014  27871  63004  04722  32268  19135  56227  22004  44577  03502
23373  32566  28471  36861  40410  07427  58667  49450  51847  53408
43909  13164  17897  41040  35183  03999  05830  17799  26908  31066
59275  39075  21558  31338  39136  10980  54360  62960  30929  01884
53223  35864  45673  06942  27645  24813  10889  54001  54981  29596
62891  09643  57011  50425  29108  40672  62369  41943  16208  23114
12311  32154  26822  30377  40038  04664  20956  39871  11470  40699
16119  33493  31614  30459  35482  61756  22397  26332  20164  28972

"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

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

Timing chart of current - sham stimulation

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

\[ t_{dc} = \frac{t_{duration}}{30} \]

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

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](image)

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/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).
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.

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 backlight 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).

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.

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

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Class B</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>not applicable</td>
<td>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.</td>
</tr>
<tr>
<td>Voltage fluctuations/</td>
<td>not applicable</td>
<td>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.</td>
</tr>
<tr>
<td>flicker emissions</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge</td>
<td>18 kV (contact)</td>
<td>passed, B</td>
<td>Floors should be wood concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>18 kV (air)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electric fast transient/burst</td>
<td>2 kV (peak)</td>
<td>passed, B</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>5/50 ns (T1/T0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 kHz repetition</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>≥1 kV differential</td>
<td>passed, B</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>mode</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥2 kV common mode</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.2/50 (6/20) µs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(T1/T0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and</td>
<td>&gt; 95 % reduction</td>
<td>passed, B/C</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>voltage variations on power supply</td>
<td>for 0.6 cycle</td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>input lines</td>
<td>60 % reduction</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>for 5 cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>30 % reduction</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>for 25 cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; 95 % reduction</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>for 250 cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency</td>
<td>50 Hz</td>
<td>passed, A</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>magnetic field</td>
<td>3 A/m</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(50/60 Hz)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conducted RF</td>
<td>0.15-50 MHz</td>
<td>passed, A</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>3 V (unmodulated)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>80 % AM (2 kHz)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>d=[p/3.5V]²r²(P)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## 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 occurred 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 interference 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.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter [W]</th>
<th>Separation distance according to frequency of transmitter [m]</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>( d = \frac{(3.5/E_i)^{1/2} \text{sq} \sqrt{P} )</td>
<td>( d = \frac{(7/E_i)^{1/2} \text{sq} \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.2</td>
</tr>
<tr>
<td>0.1</td>
<td>0.4</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.7</td>
</tr>
<tr>
<td>100</td>
<td>11.7</td>
</tr>
</tbody>
</table>

### Notes:

- **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.

- **Field strength 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 accurately with an electromagnetic site survey should be considered.**

- **Field strength in the location with the device or system is used increases the applicable RF compliance level above, the device or system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device or system.**

- **Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.**
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 60 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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Cardiff CF11 9LJ
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Tel.: (+44) 2920 660198
E-Mail: info@rogue-resolutions.com
Web: www.rogue-resolutions.com

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

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

Benelux (Belgium / The Netherlands / Luxembourg)

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Fax: (+90) 212 221 67 76
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Web: www.binasmedikal.com

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E-Mail: inquiries@jalimedical.com
Web: www.jalimedical.com
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, Farra LC.
PMID: 21659696 [PubMed - as supplied by publisher]

From a point of stimulating 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, Debiec O, 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.

2007

The use of tDCS and CVS as methods of non-invasive brain stimulation.
Been G, Ngo TT, Miller SM, Fitzgerald PB.

Technology insight: noninvasive brain stimulation in neurology-perspectives on the therapeutic potential of rTMS and tDCS.
Fregni F, Pascual-Leone A.

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

Transcranial and deep brain stimulation approaches as treatment for depression.
Rau A, Grossheinrich N, Palm U, Pogarell O, Pachberg F.

Recent advances in the treatment of chronic pain with non-invasive brain stimulation techniques.
Fregni F, Freedman S, Pascual-Leone A.
Lancet Neurol. 2007 Feb;6(2):188-91. Review

Safety aspects of transcranial direct current stimulation concerning healthy subjects and patients.
Porilez C, Boros K, Antal A, Paulus W.

2006

Transcranial direct current stimulation of the primary motor cortex affects cortical drive to human musculature as assessed by intermuscular coherence.
Power HA, Norton JA, Porter CL, Doyle Z, Hui I, Chan KM.
J Physiol. 2006 Oct 6; [Epub ahead of print]

Contribution of noninvasive cortical stimulation to the study of memory functions.
Fisz A, Cohen LG.
Brain Res Brain Res Rev. 2006 Oct 3; [Epub ahead of print]
Transcranial direct current stimulation applied over the somatosensory cortex - Differential effect on low and high frequency SEPs.
Dieckhofer A, Waberzinski TD, Nitsche M, Paulus W, Buchner H, Gobbele R.

Transient tinnitus suppression induced by repetitive transcranial magnetic stimulation and transcranial direct current stimulation.
Fregni F, Marcondes R, Boggio PS, Marcolin MA, Rigonatti SP, Sanchez TG, Nitsche MA, Pascual-Leone A.
Eur J Neurol. 2006 Sep;13(9):996-1001.

Enhancement of non-dominant hand motor function by anodal transcranial direct current stimulation.
Boggio PS, Castro LO, Savagim EA, Braithe R, Cruz VC, Rocheo RR, Rigonatti SP, Silva MT, Fregni F.

Non-invasive brain stimulation: a new strategy to improve neurorehabilitation after stroke?
Hummel FC, Cohen LG.

Anticonvulsant effects of transcranial direct-current stimulation (tDCS) in the rat cortical ramp model of focal epilepsy.

Cognitive effects of repeated sessions of transcranial direct current stimulation in patients with depression.
Fregni F, Boggio PS, Nitsche MA, Rigonatti SP, Pascual-Leone A.
Depress Anxiety. 2006 Jul 14; [Epub ahead of print]

Effects of transcranial direct current stimulation on working memory in patients with Parkinson's disease.
Boggio PS, Ferrucci R, Rigonatti SP, Covre P, Nitsche M, Pascual-Leone A, Fregni F.
J Neurol Sci. 2006 Jul 13; [Epub ahead of print]

Testing for causality with transcranial direct current stimulation: pitch memory and the left supramarginal gyrus.
Vines BW, Schneider NM, Schlaug G.

Modeling the current distribution during transcranial direct current stimulation.
Miranda PC, Lomarev M, Hallock M.

Noninvasive cortical stimulation with transcranial direct current stimulation in Parkinson's disease.
Fregni F, Boggio PS, Santos MC, Lima M, Vieira AI, Rigonatti SP, Silva MT, Barbosa ER, Nitsche MA, Pascual-Leone A.
Mov Disord. 2006 Jun 30; [Epub ahead of print]

A sham-controlled, phase II trial of transcranial direct current stimulation for the treatment of central pain in traumatic spinal cord injury.
Pain. 2006 May;122(1-2):197-209.

After-effects of transcranial direct current stimulation (tDCS) on cortical spreading depression.
Lieberetz D, Fregni F, Monte-Silva KK, Oliveira MB, Amancio-dos-Santos A, Nitsche MA, Guedes RC.

Contralateral and ipsilateral motor effects after transcranial direct current stimulation.
Vines BW, Nair DG, Schlaug G.

Transcranial DC stimulation (tDCS): A tool for double-blind sham-controlled clinical studies in brain stimulation.
Gandiga PC, Hummel FC, Cohen LG.

Treatment of major depression with transcranial direct current stimulation.
Fregni F, Boggio PS, Nitsche MA, Marcolin MA, Rigonatti SP, Pascual-Leone A.

Dopaminergic modulation of long-lasting direct current-induced cortical excitability changes in the human motor cortex.

Transcranial direct current stimulation and the visual cortex.
Antal A, Nitsche MA, Paulus W.
2005

Drivers of brain plasticity.
Hummel FC, Cohen LG.

Recharging cognition with DC brain polarization.
Wassermann EM, Grafman J.

Non-synaptic mechanisms underlie the after-effects of cathodal transcutaneous direct current stimulation of the human brain.
Ardivolo G, Bossi B, Barbieri S, Priori A.

Modulating parameters of excitability during and after transcranial direct current stimulation of the human motor cortex.

Anodal transcranial direct current stimulation of prefrontal cortex enhances working memory.

Transcranial direct current stimulation of the unaffected hemisphere in stroke patients.
Neuroreport. 2005 Sep 28;16(14):1551-5.

Noisy vestibular stimulation improves autonomic and motor responsiveness in central neurodegenerative disorders.
Yanamoto Y, Shuzuki ZR, Soma R, Ohashi K, Kwak S.

How does transcranial DC stimulation of the primary motor cortex alter regional neuronal activity in the human brain?

2004

Facilitation of probabilistic classification learning by transcranial direct current stimulation of the prefrontal cortex in the human.
Kincea T, Antal A, Nitsche MA, Bartfai O, Paulus W.

Outlasting excitability shifts induced by direct current stimulation of the human brain.
Paulus W.

Direct current stimulation over MT+V5 modulates motion aftereffect in humans.

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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
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 precisely 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):

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.

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.

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.
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.

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 77: INNER BOX; side view with socket for the BOX CABLE.

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<td>2  OUT</td>
<td>Output (Connection to ELECTRODE CABLE)</td>
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<td>2</td>
<td>Channel 2</td>
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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.

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 78: ELECTRODE CABLE

Illustration 79: MR-compatible electrodes
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.
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 8x4 (114 g)    Jan 16-20-8 8x8 (236 g)  Jan 16-20-87
4x4 Tube (114 g)

Ten20 Conductive formulation contains: Polyethylene Glycol 350
 Celol Ether, Water, Glycerin, Calcium Carbonate, 1,2 Propylene
 glycol, Potassium Chloride, Gheeine, Sodium Chloride, Polysorbate
 20 Sorbitol, Methylparaben, Propylparaben.

USAGE

Use in neuro-monitoring procedures in conjunction with non-polarized
 neurodiagnostic electrodes, e.g. EEG exams, avoided potential
 problems with the PEG, and MSG, 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 ring 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 compromises
 the exam.

Ten20 Conductive Paste: 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 ball shaped cup electrode with the hole in the center
 Apply just enough paste inside the EEG electrode to very slightly
 moisten the cup.

Place the electrode onto the electrode paste 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 and the electrode
 will not adhere well. Use either tape or a postage stamp size piece of
 gauze to stick to the electrode in place.

If the electrode site has hair around it, use a cut up piece of gauze
 to wrap around the post to aspirate and press onto the electrode.

The paste that came out of the hole when it was pressed into place will
 harden in the gauze. 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 "3M" to secure the electrodes. Use the same technique as above
 pressing the electrode into the paste. Use 3 or 4 cm of tape (1 1/4"
) to cover the electrode and the headhold.

This is effective for F1, F2 and the ground electrode. Do this on
 any other sites not surrounded by hair if the patient is balding.

A1 and A2

Attach A1 and A2 on the patient using the amount of paste as
described above. Point the hub of the electrode up and slightly
 forward. Allow the paste to come over the top of the ear and then
 direct it to the back of the head. Use a larger 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 wall.

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, broken or excoriated skin due to injury or the medical
 condition of the patient. Do not use on patients with a history of skin
 allergies or sensitivities to cosmetics and lotions. If rash, redness,
 itch, swelling, or abnormal appearance occurs, wash off immediately.

Restrict patients to communicate any persistent redness, swelling or
 sweating at the electrode site. Topical electrodes can leave permanent
 scars if not cleaned.

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

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

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

Do not use with current inducing electrodes.

SAFETY AND HANDLING

Collection Remove any electrode product, including tape, glue
 or gauze, after application. Wash from hands after applying the
 product. If dry hands period, 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 keep at room temperature. Avoid prolonged
 cold temperature or freezing.

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 estimate the equipment on your scanner and to measure the signal-to-noise ratio within your setup.

Literature


Rubber electrodes and sponge pads

neuroCon GmbH  
Rubber electrodes  
REF 360550 - 360555  
360560 - 360565  

- DESCRIPTION -  
Rubber electrodes are delivered with an electrode-conductive material (granular or carbon), specific volume conductor 0.2 cm³/nH, resistance 50 - 100 Ohms.

- IMAGE -  
The rubber electrodes are regarded by neuroCon GmbH as a component of the original medical product DC-STIMULATOR and its versions (DC-STIMULATOR PLUS/RECHARGEABLE) so that in combination the medical product can be supplied according to its intended purpose (clinical electrophysiology).

- APPLICATION -  
To attach the rubber electrodes to the desired place on the head with a rubber band or Vaseline combination, please insert them in a neuroCon GmbH sponge pad and screw with 0.5 Nm or less force. If necessary, the rubber electrodes may be used without the sponge pads.

NOTE -  
Ensure adequate electrode contacts if the tension for current density is too low. You must not insert the rubber electrodes into a dry sponge pad. This might damage the sponge pad and electrode. Always use a 0.9% NaCl solution or electrode paste (neuroCon GmbH) for better contact.

- SAFETY AND HANDLING -  
The chemical composition of the rubber electrodes is quite safe, biologically compatible with the skin and 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 left stored mechanicially or thermally.

neuroCon GmbH  
Sponge pads red/blue  
REF 360560 - 360565  

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

- IMAGE -  
Sponge pads are classified by neuroCon GmbH as a component of the original medical product DC-STIMULATOR and its versions (DC-STIMULATOR PLUS/RECHARGEABLE) so that in combination the medical product can be supplied according to its intended purpose (clinical electrophysiology).

- APPLICATION -  
If the sponge pads are used along with neuroCon GmbH rubber electrodes, please wet the sponge pads with a 0.9% NaCl solution before use. The electrodes are inserted in the wet (damp) sponge pad and fixed with a rubber band or Vaseline combination.

After the cranial electrode combination, the rubber electrodes are taken from the sponge pads and clean the sponge pads and electrodes by hand. Only applying an appropriate dampness is necessary to disinfect the sponge pads using a common disinfection gel.

CAUTION -  
NEVER USE TAP WATER to wet the sponge pads before or during cranial electrode combination. This might burn and bleed into the skin. Always use a 0.9% NaCl solution.

External charger ACS110 Traveller

- GB Operating Instructions -  
Use of the charger  
Battery plate:  
V: 12 ± 0.5  
AC 230V  
DC 12V  
Input  
Output  
Features -  
- Automatic charging
- Automatic charging
- Vandal-proof
- Protection against overvoltage
- Overload protection
- Short circuit protection
- Battery charger changes at the beginning of the charging and not immediately
- Microprocessor-controlled battery charger monitoring during the whole charging process
- The charger automatically switches to trickle-charge after the charger becomes idle
- Possible exchange of the battery pack before or while charging the battery pack
- Automatic switching over to trickle-charge after discharge
- 6 safety lines

Indicators  
- Red line + Power:  
- LED light shows whether the charger is ready to use.
- Green line + Power:  
- LED light shows whether the battery pack is ready to use.
- Yellow line:  
- LED light indicates whether the battery pack is damaged and cannot be used.
- LED light shows whether the battery pack is charged.
- LED light shows whether the battery pack is not connected properly and may cause damage.

Controls and Accessories  
- 6 safety lines
- Automatic switching over to trickle-charge after discharge
- 6 safety lines

Safety Instructions  
Do not attempt to open the charger.
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