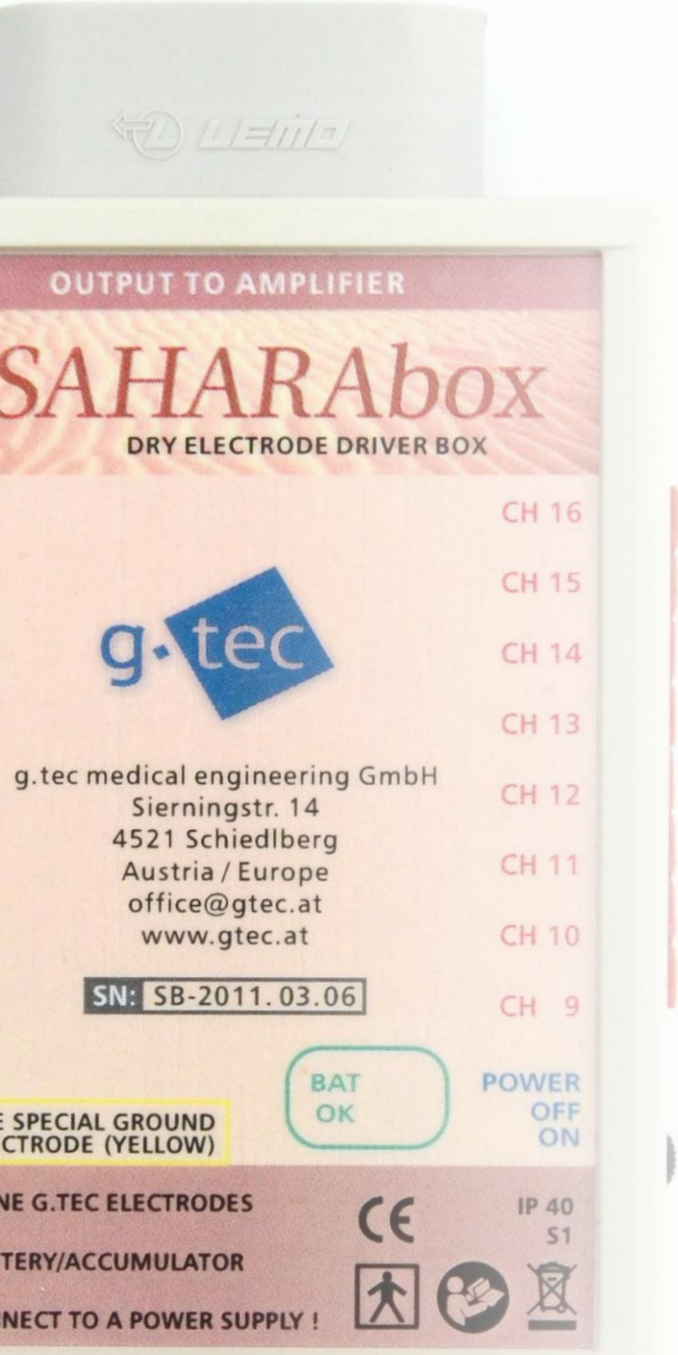
g.tec medical engineering GmbH
4521 Schiedlberg, Sierningstrasse 14, Austria
Tel.: (43)-7251-22240-0
Fax: (43)-7251-22240-39
office@gtec.at, http://www.gtec.at



g.tec GUGER TECHNOLOGIES

g.SAHARAsys
ACTIVE DRY ELECTRODE SYSTEM

Instructions for use V1.14.01

How to contact g.tec:

☎	++43-7251-22240-0	**Phone**
	++43-7251-22240-39	**Fax**
	g.tec medical engineering GmbH Sierningstrasse 14, 4521 Schiedlberg, Austria	**Mail**
	http://www.gtec.at	**Web**
@	office@gtec.at	**E-mail**

Content

1 Disclaimer

g.SAHARAsys is not a medical product.

2 Important Notes

Attention

- conductible parts of all electrodes must **not** have contact to earth or other conductible parts
- the device is **not** protected against the effect of cardiac defibrillator discharge
- the device must **not** be used in humans with pace-makers or electrical stimulators
- it is not allowed to use other power supply units than a 9V battery block
- pay attention to the precautions regarding electromagnetic compatibility (see Chapter Electromagnetic compatibility)
- the operator has to be familiar with the operation of g.SAHARAsys and must operate the device according to the instruction for use manual.
- pay attention to avoid electrostatic discharge impulses when connecting electrode to the safety sockets of the device (see Chapter Save operation of g.SAHARAbox)

Warning and safety notice

g.SAHARAsys must only be connected to the applied part of type BF of an electroencephalograph classified medical device UMDNS code 11-467 e.g. g.USBamp or g.BSamp (g.tec medical engineering GmbH). Furthermore the following leakage currents have to be checked

- Ground leakage current
- Enclosure leakage current
- Patient leakage current

Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

Inspection

The manufacturer is responsible for safety, performance and reliability of the device under the condition as supplied to the customer at the time of delivery and

a) if changes are performed by the manufacturer only and service and repair is performed by corresponding qualified personnel only.
b) the device is used according to the instruction for use.

According to (EN 62353:2008) the device and its accessories have to be checked in intervals of two years.

The intended function of the equipment

Measuring, recording and analysis of electrical activity of the brain (EEG) and/or through the attachment of multiple electrodes at various locations.

The device **must not** be used for patient monitoring. The device **must not** be used for the determination of brain death. Additional examinations are needed for diagnosis and no diagnosis may be done only based on using this device.

The intended environment of use

The device **must not** be used in dangerous conditions such as wet rooms or explosive environments. The relative humidity must be between 25 % and 95 %. The device **must not** be used in combination with any other medical high-frequency device. The usage of a high frequency device together with g.SAHARAsys can result in burnings under the electrodes and could damage the biosignal amplifier.

Electrodes

Only electrodes of type g.SAHARAelectrodes from g.tec medical engineering GmbH must be used for the device.

3 Introduction to g.SAHARAsys

g.SAHARAsys is g.tec's latest high-end and high-performance dry active electrode system for non-invasive electrophysiological derivations. The system allows the acquisition of 16 biosignal channels for EEG (Electroencephalogram) using g.tec's genuine active dry electrodes. The system is designed for use with biosignal amplifiers with monopolar (unipolar) or bipolar (differential) inputs.
The system avoids or reduces artifacts and signal noise resulting from high impedance between the electrode(s) and the skin (e.g. 50/60 Hz coupling).
No modifications are required for the biosignal amplifier so that it can be used with or without the active electrode system. However, using active electrodes and standard (passive) electrodes at the same time requires independent (isolated) ground and reference potentials such as provided by the g.USBamp from g.tec medical engineering GmbH.

g.SAHARAbox with active electrodes

Highlights

- capture the whole EEG frequency spectrum from 0.1-40 Hz
- perform EEG recordings without gel
- measure EEG including cap and electrodes montage in about one minute or below
- washing hair is no longer required
- pick up frequency spectra for P300, motor imagery and SSVEP based BCIs
- 16 single and easily replaceable input electrodes per unit
- system connectors for user specific cables
- connects directly to g.tec's amplifiers
- electrodes fit to the g.GAMMAcap² system

4 g.SAHARAsys basic components

g.SAHARAsys consists of the following items:

1

g.SAHARAbox

active dry electrode driver box

8-16

g.SAHARAelectrode for g.GAMMAcap
dry gold coated active multi-pin electrode (standard/long-pin version)
Color: orange

8-16

g.SAHARAclip for **g.SAHARA electrode**
active clip connector to use g.SAHARA electrodes
Color: orange

1

g.SAHARAclipREF
active clip connector to use with disposable mastoid electrodes as reference
Color: blue

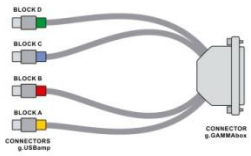
1

g.SAHARAclipGND
passive clip connector to use with disposable mastoid electrodes as ground
Color: yellow

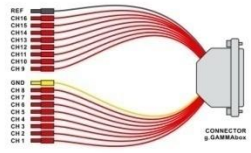
1

Instructions for use

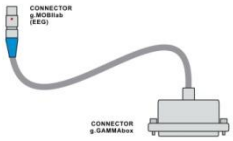
5 g.SAHARAsys specific components



g.USBampSAHARAconnector
adapter cable to connect g.SAHARAbox to g.USBamp, 16 channels, GND and REF



g.BSampSAHARAconnector
adapter cable to connect g.SAHARAbox to g.BSamp (or to other amplifiers), 16 channels, GND and REF, with 1.5 mm touch proof safety connectors



g.MOBIlab+SAHARAconnector
adapter cable to connect g.SAHARAbox to g.MOBIlab+, 8 channels, GND and REF

Disposable Ag/AgCl mastoid electrodes
for reference and ground, to be used with g.SAHARAclipREF and g.SAHARAclipGND

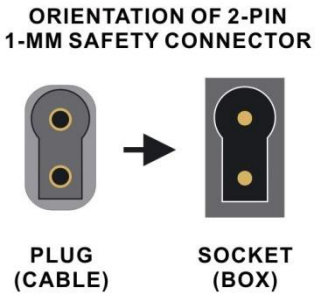
g.GAMMAcap²
flexible EEG cap, 160 pre-cut positions, available sizes: S, M, L, with chin strap or optional chest belt

6 g.SAHARAbox explanation of switches, connectors and LEDs

Sockets, connectors and switch

g.SAHARAbox has 16 x 2-pin touch proof safety input sockets for the active electrodes, one 2-pin touch proof safety input socket for the reference electrode and one 2-pin touch proof safety input socket for the ground electrode.
g.SAHARAbox has 1 output connector for an adapter cable to connect to a biosignal amplifier.

g.SAHARAbox, top view



Orientation of 2-pin safety connectors: g.SAHARAbox has 18 male input sockets for the active, reference and ground electrodes

Marking on top side and LED

GND	GROUND, input connector for ground electrode
REF	REFERENCE, input connector for active reference electrode
CH1 – CH8	CONNECTORS FOR DRY ELECTRODES CH1 - CH8, input 2-pin sockets for active electrodes
OUTPUT TO AMPLIFIER	CONNECTOR FOR ADAPTER CABLE TO BIOSIGNAL AMPLIFIER
POWER (0/I)	POWER OFF/ON, for switching ON/OFF the device
CH9 – CH16	CONNECTORS FOR DRY ELECTRODES CH9 - CH16, input 2-pin sockets for active electrodes
BAT OK	Indicates that battery power is OK, replace battery if green LED remains off when switching the device on
CE	CE mark
	Do not dispose the device with domestic waste. Dispose it via the separate collection system for electrical and electronic equipment.
	applied part of type BF
	follow instructions for use

g.tec - medical engineering GmbH Sierningstrasse 14 A - 4521 Schiedlberg Austria / Europe office@gtec.at www.gtec.at	manufacturer address
IP 40	IP 40: Protection rating is IP 40
S1	Permanent operation
SN SH-20xx.xx.xx	Device serial number in the format SH-20year.month.number

Connection to amplifiers

g.SAHARAbox can be connected to g.USBamp, g.MOBIlab+, g.BSamp or any amplifier meeting the safety conditions as listed in section 1 and having 1.5 mm safety input sockets.

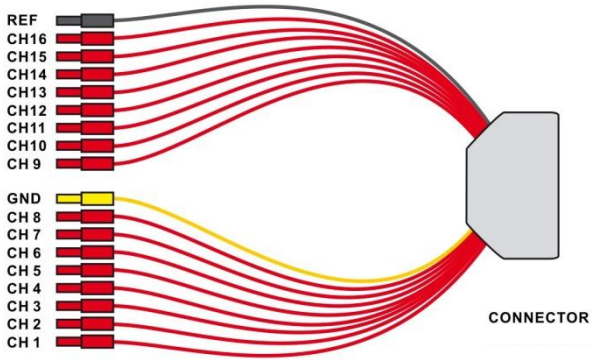
g.USBampSAHARAconnector

g.USBampSAHARAconnector is connecting the output of g.SAHARAbox to the system input sockets (Blocks A, B, C and D) of g.USBamp.

Connector for g.USBamp

g.BSampSAHARAconnector

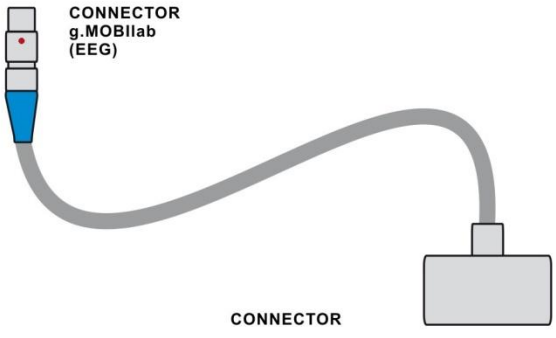
This universal connector connects the output of g.SAHARAbox to g.BSamp or any electroencephalography amplifier equipped with 1.5mm safety input sockets.



Universal connector for g.BSamp

g.MOBIlab+SAHARAconnector

g.MOBIlab+SAHARAconnector is connecting the output of g.SAHARAbox to the system input socket of g.MOBIlab+ (8-channel EEG version).



Connector for g.MOBIlab+

7 Safe operation of g.SAHARAbox

Setting up g.SAHARAbox

Avoiding electrostatic discharge impulses to the safety input sockets:
Electrostatic discharge (ESD) events can harm electronic components inside your device. Under certain conditions, ESD may build up on your body or an object and then discharge into another object, such as the device. To prevent ESD damage, you should discharge static electricity from your body before you interact with any of your devices.

You can protect against ESD and discharge of static electricity from your body by touching a metal grounded object (such as the potential equalization). When connecting the electrodes to the device you should always ground yourself to remove any static charge your body may have accumulated.

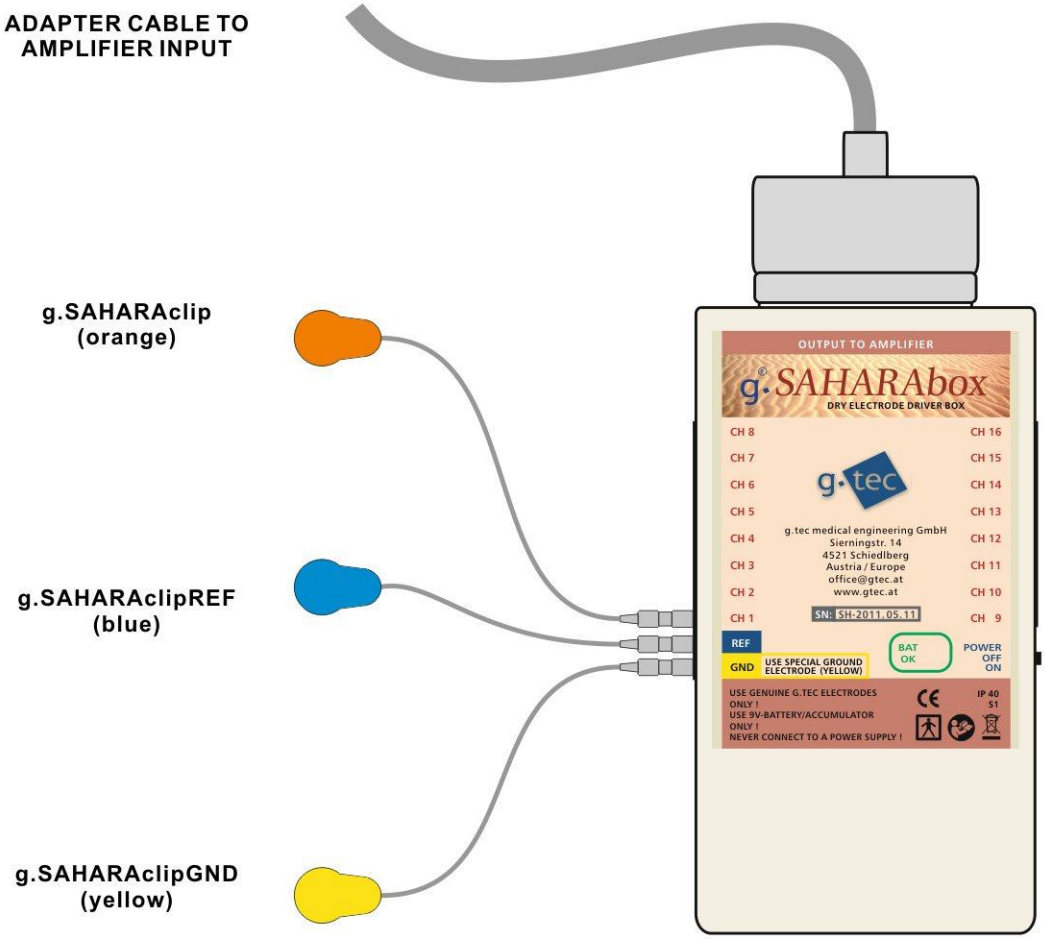
To operate g.SAHARAsys perform the following steps:
g.SAHARAsys enables high quality signal recording even for very high impedance at recording electrodes. For the ground, reference and recording electrodes a reliable connection to the skin is required but skin preparation is not needed.

Step 1: Disconnect any electrode cables before opening the battery unit with a corresponding screw-driver. Insert the 9V battery block or a corresponding accumulator into the battery unit of g.SAHARAbox. Close the battery compartment and tighten the screw appropriately.

Step 2: Place the g.SAHARAelectrodes in the cap (see g.GAMMAcap², Instructions for use) from the inner side and attach the g.SAHARAclips from the outer side. Make sure that the cap fabric keeps out of the clip contacts. Connect the 2-pin plugs of the electrode cables to the sockets CH1 – CH16 on the g.SAHARAbox.

Step 3: Attach disposable adhesive mastoid electrodes to the right and left mastoid (bone behind the ear) and attach g.SAHARAclipGND (yellow) for ground and g.SAHARAclipREF (blue) for reference to the electrodes. Connect the corresponding plugs to the REF (blue) and GND (yellow) sockets on g.SAHARAbox.

Note: Check the correct orientation of the plug and the socket for every dry electrode and for the GND and REF electrode.



g.SAHARAbox connection scheme

Step 4: Put on the cap (see g.GAMMAcap^2, Instructions for use) and ensure comfortable fixation of the cap either by using the chest or the chin belt. Make sure that each electrode is placed correctly with all pins on the skin. For short and normal hair use the standard version of g.SAHARAelectrode, for long and dense hair use the long-pin version. Use a cap size (S,M or L) which assures a gentle pressure of all electrodes to the skin without causing pain to the subject. Turn each electrode back and forth for a few times by an angle of 10° – 20° to remove hair between the electrodes and the skin and to ensure a proper galvanic contact between the electrode pins and the skin.

Step 5: Connect the output adapter cable attached to g.SAHARAbox at the “OUTPUT TO AMPLIFIER” socket to the input socket(s) of your amplifier.

Step 6: Switch on g.SAHARAbox with the switch on the right side (switch position POWER ON).

The correct operation of g.SAHARAbox is indicated by a green LED on the top side (BAT OK). If the LED is not on please check the 9V battery supply. When the “BAT OK” LED turns off during a recording session you may continue the session. The remaining operation time is 30 – 60 min. Replace the battery after ending the session.

Step 7: Start the data viewer of the recording software and wait for 1 – 3 minutes for the galvanic junctions between the skin and the electrodes to stabilize.

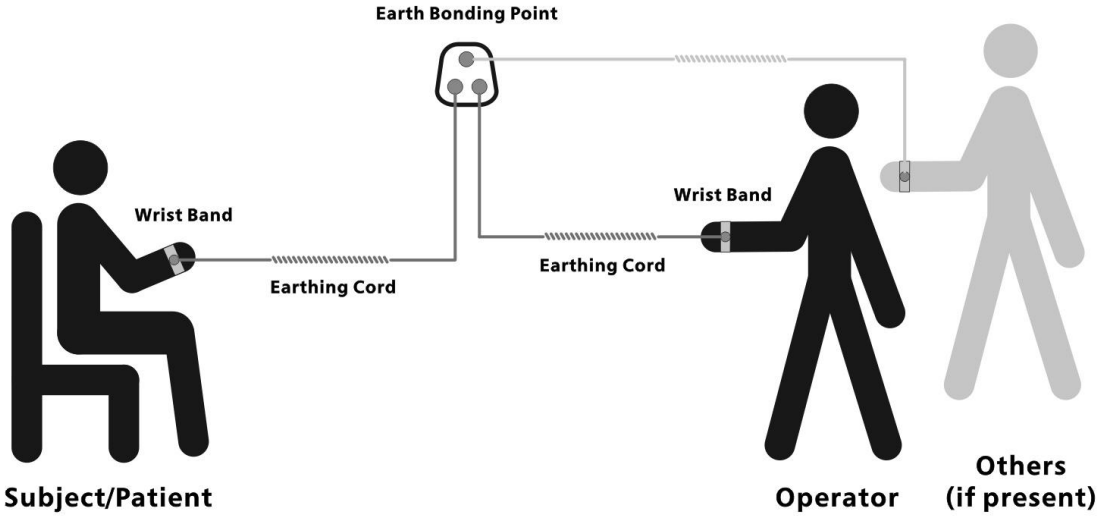
Recommended hardware settings:		
Highpass filter:	Lowpass filter:	Notch Filter:
(0.1 Hz) 0.5 Hz – 5 Hz	30 Hz – 40 Hz	50/60 Hz on

After 4-5 minutes at the latest, all signals should be visible and show a stable baseline. In case of high drifts or noisy signals on a certain channel the corresponding electrode needs to be checked for perfect contact to the skin. Put gentle pressure onto the electrode and move it a little bit on the skin, then wait again for 1 minute and check the signal again.

Special requirements for high quality EEG recording with dry electrodes

EEG recordings in general are quite sensitive to a number of disturbing influences such as movements of the subject, the cables and the electrodes or coupling of electromagnetic and electrostatic fields in the closer environment of recording. For dry electrodes especially movements of the electrodes and electrostatic charges can cause significant artifacts in the signals. Consider the following actions to avoid artifacts:

- Avoiding electrode and cable movements
  - Assure a comfortable and relaxed position of the subject during recording
  - Instruct the subject to stay in a relaxed position and to avoid movements
  - Place electrode wires in a way avoiding tension and direct contact to moving parts of the body
  - If the subject needs to speak during the recordings use the chest belt rather than the chin strap to fixate the cap
- Avoiding electrostatic charges
  - Choose an antistatic environment/lab for high quality recordings
  - Use a room with antistatic carpet or floor covering or wooden/stone floor instead of normal carpets or artificial parquet floors
  - Furniture made of wood, metal and leather is preferable to any plastic materials and synthetic textiles
  - Cotton clothing is preferred to wool and synthetics
  - Avoid shoes with synthetic sole
- Grounding
  - Grounding of equipment (potential equalization conductor) and metal-made furniture to a central earth/ground contact (lab ground) is recommended
  - The subject as well as the operator(s) may be grounded to avoid electrostatic charges (e.g. using an antistatic wrist band connected to the lab ground)



Example of recommended connection via antistatic wrist bands of the subject and the operator(s) to one common earth bonding point.

Switching off and storage of g.SAHARAbox

Please perform the following steps to switch off and store g.SAHARAbox correctly:

Step 1: Switch off the device with the switch on the side (switch position POWER OFF). The green LED is off.

Step 2: Disconnect all electrodes.

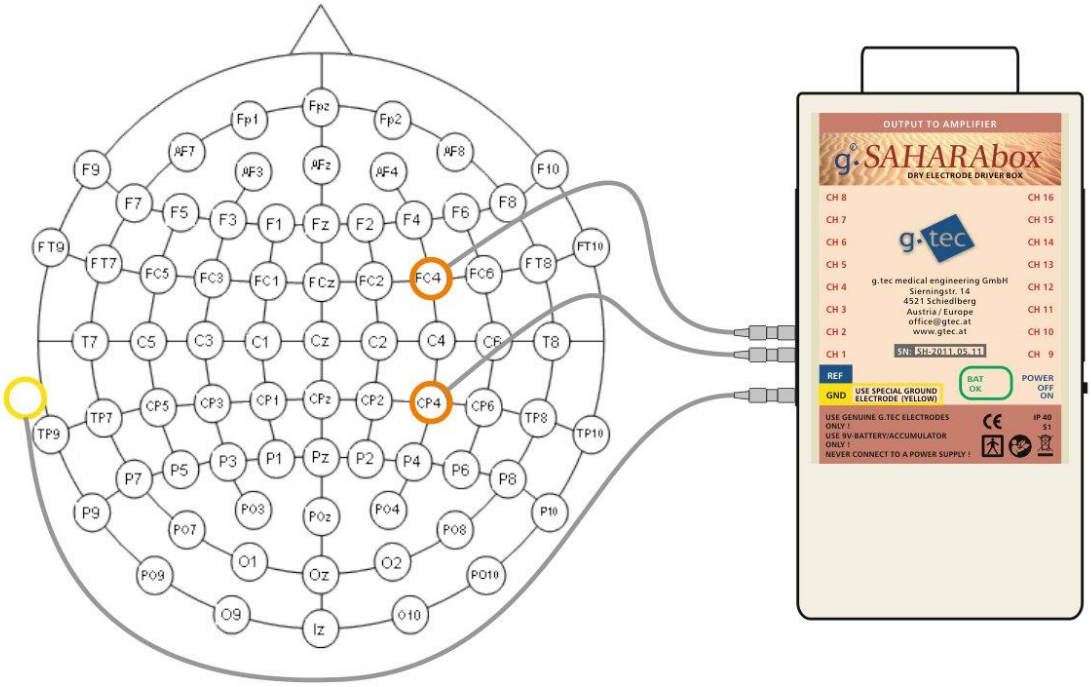
Step 3: Disconnect the g.SAHARAbox from the amplifier

Step 4: Remove the battery if you do not plan to use the device within the next couple of weeks.

Step 5: Cleaning of dry electrodes: Clean and disinfect the electrodes with a smooth cotton cloth and alcohol (70%). Treat electrodes carefully and avoid any damage of the gold-coated pins. Store electrodes in a dry and clean place. For instructions on cleaning the cap please see g.GAMMAcap[2] Instructions for use.

8 Bipolar (differential) derivation

When g.SAHARAsys is used for bipolar (differential) recordings with an amplifier with bipolar inputs the reference electrode is not needed. Assure a good contact of the ground electrode and use e.g. channel 1 for the electrode of the non-inverted input and channel 2 for the electrode of the inverted input. Make sure that the output (adapter) cable of g.SAHARAbox is connected accordingly to the used setup.



Example of a bipolar (differential) EEG recording with g.SAHARAsys: Ch1 (pos. CP4) is used as the non-inverted (+) input and channel 2 (pos. FC4) is used as the inverted (-)input. In this case the output channel 1 of g.SAHARAbox has to be connected to the (+) input of the amplifier and channel 2 to the (-) input of the amplifier.

When using g.SAHARAbox for bipolar recordings with g.USBamp all channels have to be recorded monopolar (with a reference electrode) and bipolar recordings are computed with g.USBamp (see g.USBamp setup, Instructions for use).

9 General notes

Transportation and storage conditions

The device can be stored at temperatures between –20 to +60 degrees Celsius. The relative humidity must be between 25 % and 95 %. Wait before usage of the device till condensed water disappeared (wait at least 1h in a heated room).

Location details

Do not use the device near a heating system or directly in the sun. The maximal temperature of the environment must not be above 40 ° Celsius.

Waste disposal details

Bring the device to a recycling center or sent it back to the manufacturer.

Cleaning

You can clean the g.SAHARAbox carefully with a damp cloth or medical rubbing alcohol (max 70%). Liquid must not enter the g.SAHARAbox.

10 Declaration of conformity

Product name

Product: g.SAHARAbox

Manufacturer
g.tec medical engineering GmbH, Sierningstrasse 14, 4521 Schiedlberg, Austria

Classification

Safety class	internally powered
Type of applied part	BF
Protection against mechanical distortion and liquids	IP40
Operation mode	S1 (permanent operation)

CE mark

CE

g.SAHARAbox is not a certified medical device. The product is NOT intended to be used as a medical device. The manufacturer declares in sole responsibility that g.SAHARAbox is in conformity with the general requirements for safety (low voltage directive) 73/23/EWG and 89/336/EWG (electromagnetic compatibility).

Dr. Christoph Guger
Chief Executive Officer

Dr. Günter Edlinger
Chief Executive Officer

Schiedlberg, 2011

11 Technical specifications

Model	g.SAHARAbox
Type	Active electrode driver/supply unit
Rated power consumption	180 mW
Rated DC voltage	9V DC
Rated current of fuse	
Rated voltage of fuse	
Produced	2011
Producer	g.tec medical engineering GmbH Sierningstrasse 14 4521 Schiedlberg Austria http://www.gtec.at

Maximum voltages at the following sockets

OUTPUT TO BIOSIGNAL AMPLIFIER	+/- 2.5 V

Maximum current at the following sockets

CH1 – CH16	100 µA
REF	100 µA

System Settings

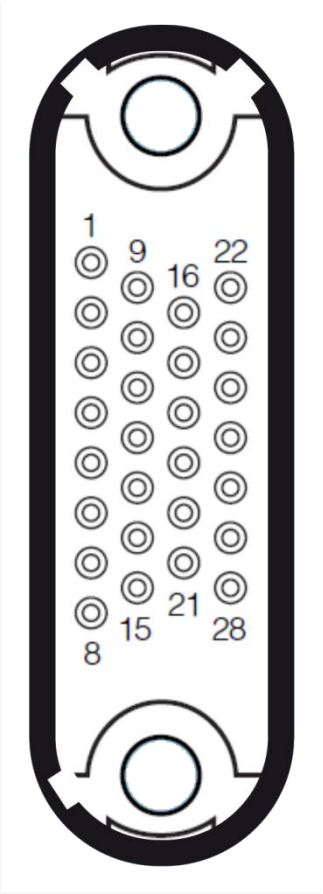
Channels 1 to 16

Sensitivity:	$\pm$ 1 V
Highpass:	0.1 Hz
Lowpass:	40 Hz
Input Impedance:	~10^8 Ω

12 PIN assignment g.SAHARAbox

Pin-assignment for the 28 pin socket OUTPUT TO AMPLIFIER
(recent version)

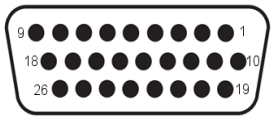
28pin LEMO	function
1	GND
2	GND
3	GND
4	GND
5	REF
6	REF
7	REF
8	REF
9	Ch 1
10	Ch 2
11	Ch 3
12	Ch 4
13	Ch 5
14	Ch 6
15	Ch 7
16	Ch 8
17	Ch 9
18	Ch 10
19	Ch 11
20	Ch 12
21	Ch 13
22	Ch 14
23	Ch 15
24	Ch 16
25	n.c.
26	n.c.
27	n.c.
28	n.c.



Pin-assignment for the 26 pin plug OUTPUT

TO AMPLIFIER (old version)

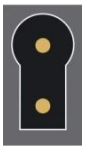
26pin Sub-D	function
1	CH 15
2	CH 13
3	CH 11
4	CH 09
5	REF
6	CH 02
7	CH 04
8	CH 06
9	CH 08
10	CH 16
11	CH 14
12	CH 12
13	CH 10
14	GND
15	CH 01
16	CH 03
17	CH 05
18	CH 07
19	GND
20	GND
21	GND
22	GND
23	REF
24	REF
25	REF
26	REF



13 PIN assignment electrode sockets

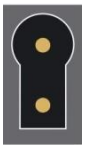
All active electrodes and active reference electrode sockets for g.SAHARAbox:

2pin connector	function
1	supply +
2	supply -



All ground electrode sockets for g.SAHARAbox

2pin connector	function
1	GND
2	NC



14 Electromagnetic compatibility

Please keep in mind the respective precautions in this Instructions for use manual before installing and operating g.SAHARAbox. Pay attention to the fact that mobile HF-communication devices (e.g. mobile phones) may interfere with electric devices. g.SAHARAbox must not be used nearby or stockpiled with other devices. Only the original components for g.SAHARAbox (see Chapter “g.SAHARAbox basic components”) from g.tec medical engineering GmbH are to be used for this device. Using third party manufacturer accessories may result in increased emission or decreased functional immunity of g.SAHARAbox. As electric and magnetic fields may interfere with the functional reliability of the device, avoid using g.SAHARAbox close to devices emitting powerful magnetic fields.


g.tec
GUGER
TECHNOLOGIES
contact information
g.tec medical engineering GmbH
Sierningstrasse 14
4521 Schiedlberg
Austria
tel. +43 7251 22240
fax. +43 7251 22240 39
web: www.gtec.at
e-mail: office@gtec.at