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64-channel active electrode driver box for g.Hlamp

Instructions for use V1.14.03

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Instructions for use

Disclaimer

The 64-channel active electrode driver box for g.Hlamp is not a medical device. The product is not intended to be used as a medical device. Additional examinations are needed for any medical diagnosis, and no diagnosis must be done based on this device. However, the product is manufactured according to the IEC 60601-1 standard as this is a more rigorous standard compared to other applicable standards.

Attention

- conductible parts of all electrodes must **not** have contact to earth or other conductive materials
- the device is **not** protected against the effect of cardiac defibrillator discharge
- the device must **not** be used with people with pace-makers or electrical stimulators
- do not use any power supply units other than the internal safety supply of g.Hlamp
- pay attention to the precautions regarding electromagnetic compatibility (see chapter electromagnetic compatibility)
- the operator has to be familiar with the operation of the 64-channel active electrode driver box for g.Hlamp and must operate the device according to the instructions for use
- use genuine active electrodes provided by g.tec only

Warning and safety notice

Accessory equipment connected to the device must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). 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 for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If you have any questions, consult the technical service department or your local representative or g.tec medical engineering GmbH, Austria.

Inspection

For safety, performance and reliability of the device, the manufacturer will be responsible if:

- a) service, repair and changes are performed by the manufacturer only
- b) the device is used according to the Instructions for use

The device and its accessories have to be checked at least once every two years (in Austria according to ÖVE-E 8751-1/2000 + A1/2003).

The intended function of the equipment

Measuring, recording and analysis of electrical activity of the brain (EEG), muscles (EMG), eyes (EOG) and heart (ECG) and/or through the attachment of multiple electrodes at various locations to aid data acquisition in research.

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 any medical diagnosis, and no diagnosis must be done based on 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 this device could damage the device and cause burning under the electrodes.

Recommended electrodes

Only active electrodes provided by g.tec medical engineering GmbH must be used with the device.

The device **must not** be used directly on the heart.

1 Introduction to the 64-channel active electrode driver box for g.Hlamp

The system allows the acquisition of 64 (128, 192 or 256) biosignal channels such as EEG (Electroencephalogram), EOG (Electrooculogram), EMG (Electromyogram) and ECG (Electrocardiogram) using g.tec's genuine active electrodes. The system is designed for use with g.Hlamp. **The system is specially engineered to avoid or reduce artifacts and signal noise resulting from high impedance between the electrode(s) and the skin (e.g. 50/60 Hz coupling, artifacts caused by electrode or cable movements, distorted signals or background noise).** The biosignal amplifier (g.Hlamp) is ready for use with an active or passive electrode system without further accessories or modifications.



64-channel active electrode driver box for g.Hlamp

Highlights

- EEG, ECG, EMG and EOG recording without cable/movement artifacts
- Minimal 50/60 Hz power line interference
- No preparation of skin necessary
- No need for abrasive gels
- 64 single and easily replaceable input electrodes per unit
- One connector for 64 signals
- Connects directly to g.Hlamp
- Electrodes fit to gtec's g.GAMMAcap² system

2 Basic components

64-channel active electrode driver box for g.Hlamp



Multi-pole cable to input of g.Hlamp



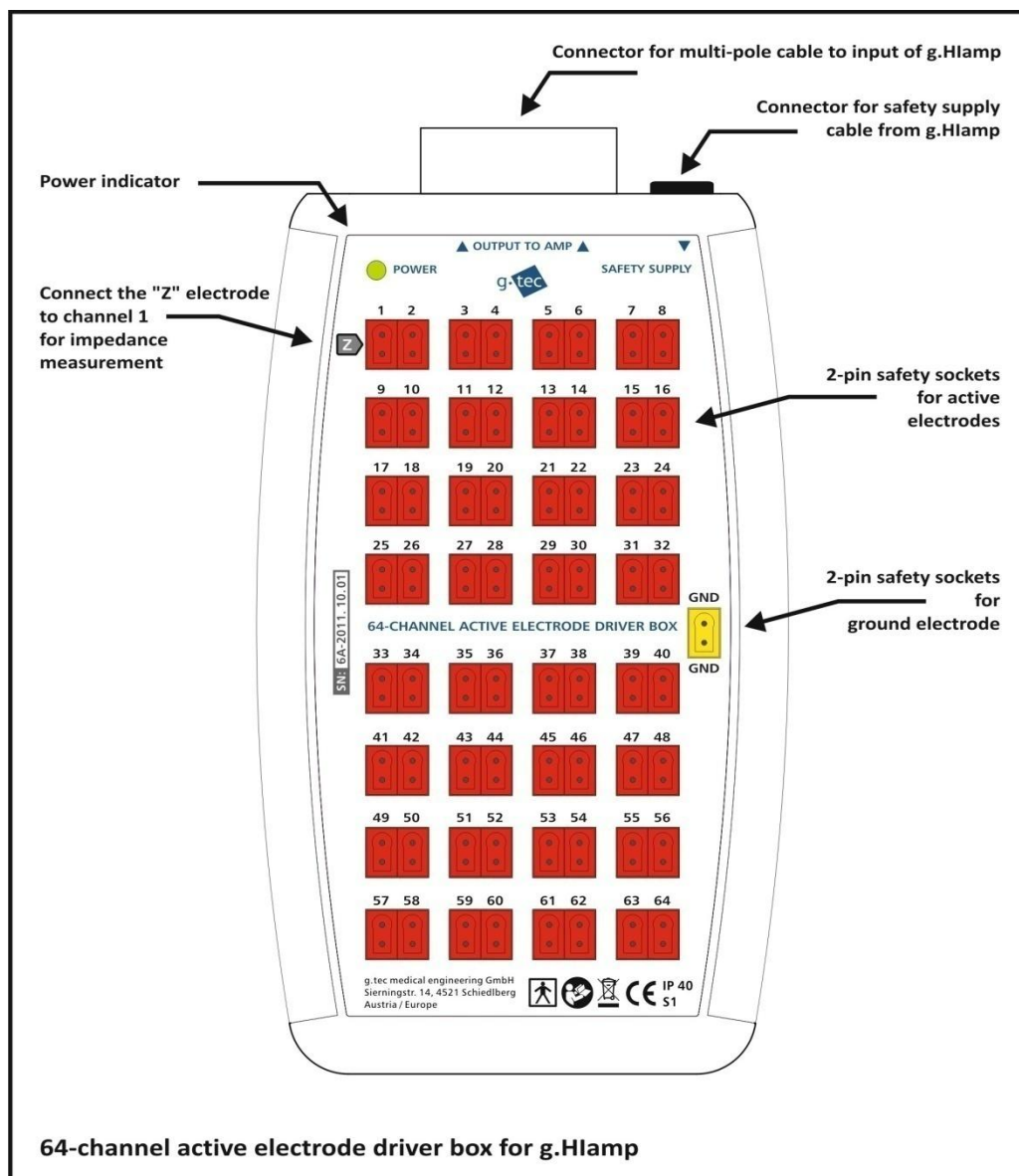
Safety-supply cable from g.Hlamp



3 Explanation of connectors and LED

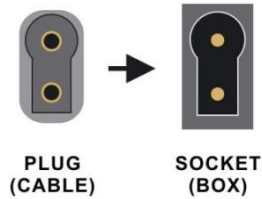
Sockets, connectors

The 64-channel active electrode driver box for g.Hlamp has 64 2-pin touch proof safety input sockets for the active electrodes (red), one 2-pin touch proof safety input socket for the ground electrode (yellow), one output connector for the multi-pole connector cable to the biosignal amplifier (g.Hlamp) and one connector for the safety supply cable.



The 64-channel active electrode driver box for g.Hlamp, top view

ORIENTATION OF 2-PIN 1-MM SAFETY CONNECTOR



Orientation of 2-pin safety connectors: *The 64-channel active electrode driver box for g.Hlamp has 65 male input sockets for the active and ground electrodes*

Marking on top side and LED

GND	GROUND, input connector for ground electrode
CH1 – CH64	CONNECTORS FOR ACTIVE ELECTRODES CH1– CH64, input 2-pin sockets for active electrodes
OUTPUT TO AMPLIFIER	CONNECTOR FOR MULTI-POLE CABLE TO g.Hlamp
POWER (green LED)	POWER: The green LED indicates that the box is supplied with power and ready to use
“Z”	A special Z-electrode (black) needs to be used for channel 1 if the impedance measurement option is used via g.Hlamp.



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



attention to instructions for use

g.tec medical engineering GmbH
Sierningstr. 14, 4521 Schiedlberg
Austria/Europe

manufacturer address

IP 40
S1
SN: 6A-2011.10.01

IP 40: Protection rating is IP 40
permanent operation
serial number in the format Year.Month.Number

4 Active electrodes

g.tec provides the following types of active electrodes to be used with the 64-channel active electrode driver box for g.Hlamp:



g.LADYbird
active sintered Ag/AgCl electrode
Color: red



g.LADYbird 'Z'
active sintered Ag/AgCl electrode
Color: black
(to be used on channel 1 to enable impedance measurement with g.Hlamp)



g.LADYbirdGROUND
passive sintered Ag/AgCl electrode
Color: yellow



g.GAMMAearclip Ag/AgCl
active sintered Ag/AgCl earlobe reference electrode
Color: blue



g.SCARABEO
active sintered Ag/AgCl electrode
Color: grey, connector color: grey



g.SCARABEO Z
active sintered Ag/AgCl electrode
Color: grey, connector color: black
(to be used on channel 1 to enable impedance measurement with g.Hlamp)



g.SCARABEO GND

passive ground sintered Ag/AgCl electrode
Color: grey, connector color yellow

5 Safe operation of the 64-channel active electrode driver box for g.HIamp

Setting up the 64-channel active electrode driver box for g.HIamp

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 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 the 64-channel active electrode driver box for g.HIamp, perform the following steps:

The system enables high quality signal recording even with suboptimal impedance at recording electrodes. However, to achieve best results, the ground electrode should have a perfect connection with low impedance. Clean the skin and eventually use abrasive gel to prepare the location where the ground electrode is applied. For all other recording electrodes, a reliable connection to the skin is required, but skin preparation is not necessarily needed. g.GAMMAgel or g.GAMMAcream has to be used for all electrodes. For EEG derivation from the hairy scalp, the gel can be applied with a syringe (with a blunt cannula) to assure reliable contact with the skin.

Step 1: Connect the 64-channel active electrode driver box for g.HIamp to the black safety supply cable and connect the cable to the black safety supply socket on g.HIamp (located under the multi-pole input connectors A – D). Assure the correct orientation of the plug (Arrow pointing towards the socket on top)!

Step 2: Connect the 64-channel active electrode driver box for g.HIamp to the blue multi-pole cable and connect the cable to the input socket on the g.HIamp (A – D). Assure the correct orientation of the plug (see red markings on the plugs and sockets)!

Step 3: Connect the active electrodes (color coded red) to the red sockets 1 – 64 (or less). Connect the ground electrode (color coded yellow) to the GND input socket. If the internal impedance measurement should be used, a special 'Z'-electrode (color coded black) needs to be connected to channel 1 instead of the standard red electrode. The 'Z'-electrode provides a normal signal on channel 1, just like the other electrodes do. It just has an internal modification needed to provide synchronous impedance measurement of all other channels. Impedance measurements can be performed for all input channels except for channel 1.

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

Step 4: Switch on g.Hlamp and check the green LED on the 64-channel active electrode driver box for g.Hlamp (indicating power in the box).

Step 5: Assure a correct montage of all electrodes and a proper application of the electrode gel (Please see instructions for use g.GAMMAcap²). Start an appropriate program and perform the impedance measurement (Please see the corresponding instructions for use for the software g.Recorder or g.HIGHspeed online processing for SIMULINK). For best signal quality, the impedance of all electrodes should be below 30 kOhm (green range) or below 50 kOhm (orange range). If the impedance is above 50 kOhm but below 100 kOhm (blue range) the signals should still be OK, but may be affected by noise and electromagnetic interference. Above 100 kOhm (red range) signals may be very noisy or lost. In this case, please check the electrode to ensure it is properly filled with gel and is in contact with the skin! An area of about 1 cm² of skin should have persistent contact with the gel.

Note: g.Hlamp does not have a fixed common reference input channel. The reference channel can be defined via the recording software. E.g. one can define channel 64 as the reference and connect the active earlobe reference electrode to this channel (please see the instructions for use of the corresponding software).

Attention: Be careful when unplugging electrodes from the 64-channel active electrode driver box for g.Hlamp! Never tear at the electrode cables as this will break the wire and destroy the entire electrode! The electrodes should remain connected to the box for cleaning. Just disconnect the box from the amplifier and protect it from liquids while cleaning the electrodes.

Note: All types of Ag/AgCl electrodes have a limited life time and need to be replaced from time to time. Careful treatment and cleaning will keep the electrodes working longer!

6 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 %. Before using the device, wait until any condensed water disappears. (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 temperature of the environment must not be above 40° Celsius or below +5° Celsius.

Waste disposal details

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

Cleaning

You can clean the device carefully with a damp cloth or medical rubbing alcohol (max 70%). Liquid must not enter the 64-channel active electrode driver box for g.Hlamp.

7 Declaration of conformity

Product name

Product: 64-channel active electrode driver box for g.Hlamp

Manufacturer

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

Classification

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

CE mark



The manufacturer declares in sole responsibility that the 64-channel active electrode driver box for g.Hlamp is in conformity with the general requirements for safety (low voltage directive) 73/23/EWG and 89/336/EWG (electromagnetic compatibility).

The 64-channel active electrode driver box for g.Hlamp is not a certified medical device. The product is NOT intended to be used as a medical device. However, the product is manufactured according to the IEC 60601-1 standard as it is a more rigorous standard than other standards.

A handwritten signature in blue ink, appearing to read 'Guger Ch.'.

Dr. Christoph Guger
Chief Executive Officer

A handwritten signature in blue ink, appearing to read 'Günter Edlinger'.

Dr. Günter Edlinger
Chief Executive Officer

Schiedlberg, 2014

8 Technical specifications

64-channel active electrode driver box for g.Hlamp

Model	64-channel active electrode driver box for g.Hlamp
Type	Active electrode driver/supply unit
Rated power consumption	75 mW
Rated DC voltage	5V DC
Produced	see serial number of the device
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 2.5V

Maximum current at the following sockets

CH1 – CH64 100 μ A

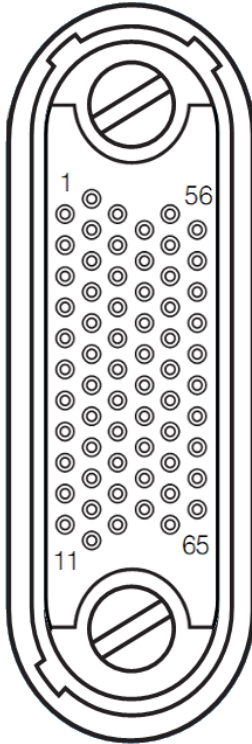
Settings

Channels 1 to 64

Sensitivity:	± 1 V
Highpass:	0 Hz
Lowpass:	10 kHz
Input Impedance:	$>10^{10}\Omega$

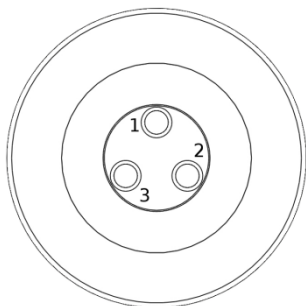
9 PIN assignment: Multi-pole connector

Channels 1-64



Pin	Direction	Function
1		Channel 1
2		Channel 2
3		Channel 3
.		.
.		.
.		.
63		Channel 63
64		Channel 64
65	Pas	Signal GND

10 PIN assignment: Safety supply cable



Pin	Direction	Function
1	Supply	Analog GND (0V AP)
2	DNC	Internal use – do not connect
3	Supply	Auxiliary supply (+5V AP)

11 PIN assignment: Electrode connectors

All active electrodes

2 pin connector	function
1	supply +
2	supply -



All ground electrodes

2 pin connector	function
1	GND
2	NC



12 Electromagnetic compatibility

Please keep in mind the respective precautions in this Instructions for use manual before installing and operating the 64-channel active electrode driver box for g.Hlamp. Pay attention to the fact that mobile HF-communication devices (e.g. mobile phones) may interfere with electric devices. The 64-channel active electrode driver box for g.Hlamp must not be used near, or stockpiled with, other devices. Using third party manufacturer accessories may result in increased emission or decreased functional immunity of the device. As electric and magnetic fields may interfere with the functional reliability of the device, avoid using the 64-channel active electrode driver box for g.Hlamp close to devices emitting powerful magnetic fields.



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