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g.HIamp

UDI label

GlobTek power supply	SN:	RoHS
64 channel electrode connector box	SN:	6P-

Instruction for use V2.16.01

printed July 2017

The product with the above serial number is a prescription device for use in the USA

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 Important Notes

Attention

- conductible parts of all electrodes must **not** have contact with the 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
- you must not use other power supply units than the GlobTek GTM21097-3005 which is delivered with g.HIamp
- pay attention to the precautions regarding electromagnetic compatibility (see Chapter Electromagnetic compatibility)
- the operator has to be familiar with the operation of g.HIamp 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.HIamp)
- every time before using g.HIamp check the device and its accessories for possible damages of connectors, sockets and cables. Cables, connectors, accessories, or other parts of the equipment must be replaced immediately when damaged or not working correctly.

Warning and safety notice

If g.HIamp is connected to other devices (except the power supply supplied with g.HIamp) like a PC the following leakage currents have to be checked.

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

The leakage currents must be checked if several g.HIamps are interconnected according to IEC 60601-2-49. Accessory equipment connected to the analog and digital interfaces 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 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.

Visual inspection of the inside of g.HIamp might influence its electromagnetic shielding and operation. The manufacturer does not recommend disassembly of g.HIamp, including visual inspection of the inside of the device, without first contacting the manufacturer.

Inspection

The manufacturer is responsible for the safety, performance and reliability of the device 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 must be checked once every two years (minimum).

Interference

g.HIamp and its components have been tested and comply with the electromagnetic compliance limits (IEC 60601-1-2:2007 Class A). See Chapter Electromagnetic compatibility. The equipment, if not installed and used in accordance with the instructions, may cause interference to other devices in the vicinity. If this equipment does interfere with other devices, which can be determined by turning the equipment off and on, try to correct the interference by one or more of the following measures:

- reorient or relocate the receiving device.
- increase the separation between the equipment.
- connect the equipment to an outlet on a different circuit than the one used by the other devices.
- consult g.tec Technical Support (see page 2, How to contact g.tec)

The intended use of the equipment

The g.HIamp amplifier is intended to be used to acquire biopotentials and transmit them to a computer via the USB port connection. These biopotentials include for example the electroencephalogram (EEG), electromyogram (EMG), electrooculogram (EOG), and electrocardiogram (ECG).

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.HIamp can result in burnings under the electrodes and could damage the biosignal amplifier.

Recommended electrodes

The manufacturer recommends golden re-useable cup EEG electrodes (model C32-634) from Technomed, Co (K072016) with 1.5 m cable and electrode gel (model: E9) from Electro-cap Intl., Inc. (K111717).
The electrode diameter should be between 2 and 10 mm. The electrode impedance should be below 5 kOhm. The electrodes must have a 1.5 mm safety connector.

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

Properties of PC or notebook

g.HIamp requires a PC compatible desktop, notebook workstation or embedded computer running a Microsoft Windows operating system (Windows 7 or Windows 10 (Threshold 2), 64bit, Professional English).

The table below lists optimal settings:

Hardware	**Properties**
CPU	Processor working at 2000 MHz
Harddisk	20-30 gigabyte
RAM	2 - 4 gigabyte
USB 2.0 port (EHCI – enhanced Host controller interface)	one free USB port for each g.HIamp

Prescription device

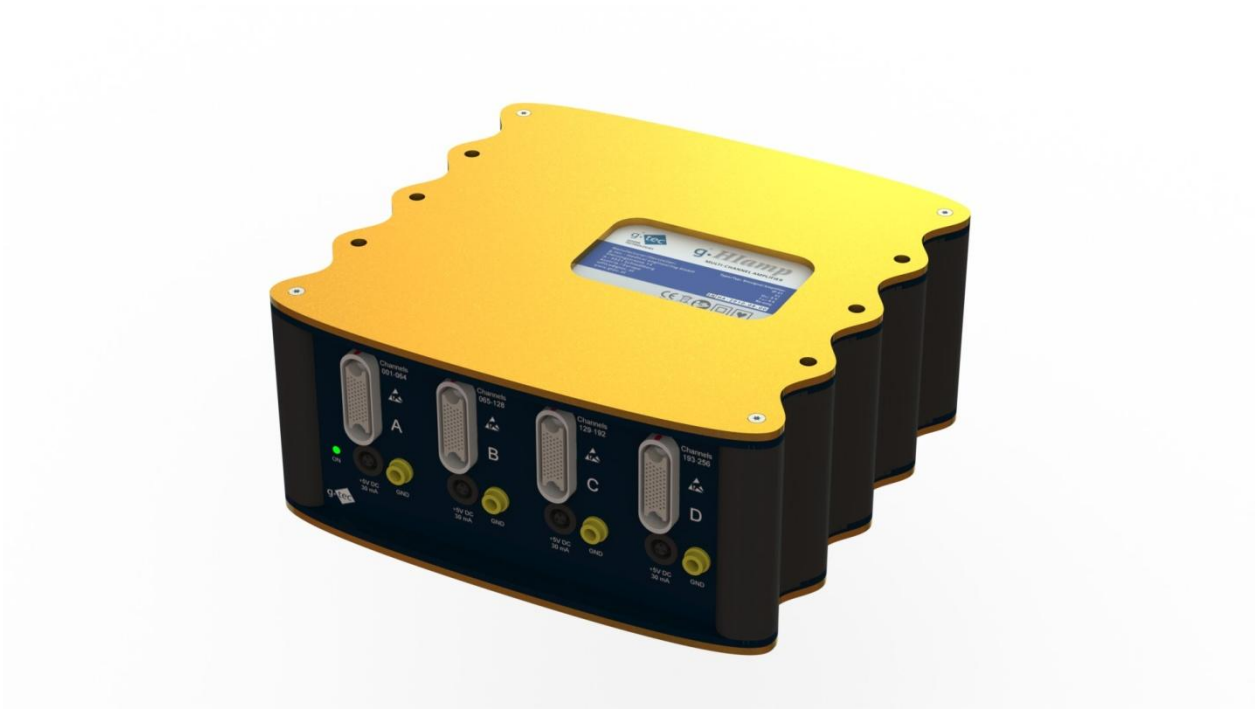
Caution: US federal law restricts the herein described devices to sale by or on the order of a physician.

2 Introduction to g.HIamp

g.®HIamp is g.tec's multi-channel high-end biosignal amplifier with USB technology. The device allows the acquisition of up to 256 biosignal channels such as EEG (Electroencephalogram) with 24 bit. The sampling frequency can be set up to 38400 Hz.

The USB amplifier can be connected directly to a PC or notebook with an USB connector without any additional data acquisition device needed. Each channel is equipped with a synchronized analog to digital converter to perform the simultaneous sampling. Each analog to digital converter is operating with 614.4 kHz and performs a 16 times oversampling. This results in a sampling rate of 38400 Hz for each channel. A powerful floating point DSP performs an additional decimation and the real-time filtering of the biosignal data. The sampling frequency can be adjusted between 256 Hz and 38400 Hz. Therefore, a sampling frequency of 256 Hz yields to an over-sampling rate of 2400 with a very high signal to noise ratio.

Furthermore, the device has an internal impedance check unit. Standard electrodes with safety connectors can be connected to g.HIamp via optionally available electrode connector boxes. The device is controlled with a C language Application Programming Interface (C API).



g.HIamp 256-Channel Amplifier

Highlights

- biosignal recording via USB
- up to 256 analog inputs with 24 Bit
- up to 38400 Hz sampling frequency per channel

sampling frequency [Hz]	max. no. of channels*)
256	256
512	256
600	256
1200	256
2400	256
4800	256
9600	144
19200	80
38400	40

*) the number of available channels depends on the purchased type of amplifier

- digital filtering of all biosignal data via g.HIamp for sampling frequencies up to 4800 Hz
- over-sampling to achieve a high signal to noise ratio
- can be connected to a PC or notebook
- simultaneous sample and hold of all available channels
- connection of electrodes with standard safety connector via electrode connector boxes
- system connectors for user specific patient cables

3 g.HIamp basic components

g.HIamp consists of the following items:

1 g.HIamp USB biosignal amplifier
depending on your selected type it has either
256 analog input channels for the 256-Channel Amplifier or
144 analog input channels for the 144-Channel Amplifier or
80 analog input channels for the 80-Channel Amplifier

1 64 channel electrode connector box

1 connection cable from 64 channel electrode connector box to g.HIamp

1 GlobTek GTM21097-3005 – medical power supply unit

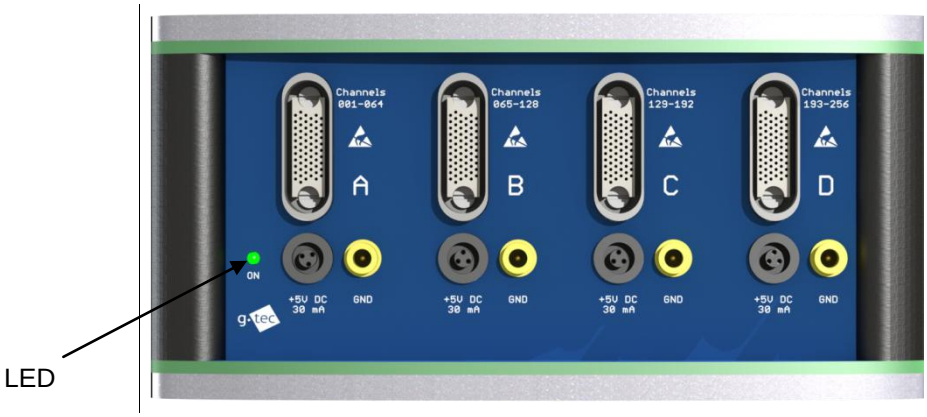
1 Power line cord

1 USB cable

1 Instruction for use

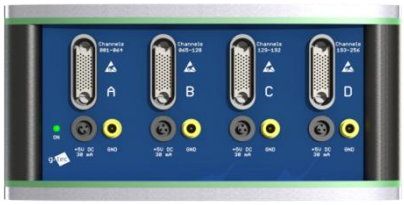
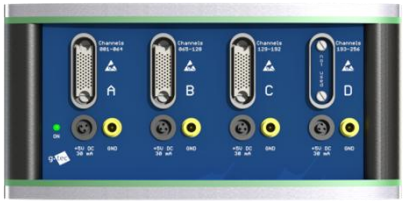
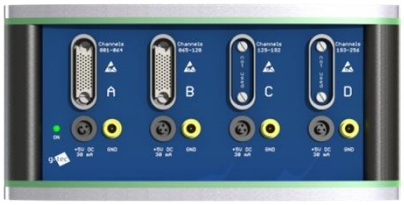
4 Explanation of switches, connectors and LEDs

Sockets, connectors and LEDs on the front side



Example: g.HIamp 256-Channel Amplifier front side

g.HIamp has up to 4 mono-polar amplification groups with one ground socket each. The analog input channels for EEG are connected via push-pull connectors.

g.HIamp Amplifier Type	**Group A** Channels	**Group B** Channels	**Group C** Channels	**Group D** Channels
256-Channel Amplifier 	**001-064**	**065-128**	**129-192**	**193-256**
144-Channel Amplifier 	**001-064**	**065-128**	**129-144** Not used 145-192	Not used
80-Channel Amplifier 	**001-064**	**065-080** Not used 081-128	Not used	Not used

GND:	Each group has one ground socket GND and all 4 ground sockets are interconnected.
+5V DC 30 mA:	A total of four +5 V DC sockets providing a +5 Volt auxiliary power supply is available. On each socket the maximum DC output current is limited to 30 mA. The intended function of the +5 V DC power supply is to power other appropriate applied parts of type CF only as specified by g.tec medical engineering GmbH.
LED:	The green LED on the left side (ON) indicates power on.
	The electrostatic discharge warning symbol: electrostatic discharge impulses must be avoided when connecting electrodes to any of the safety sockets or push pull connectors. Follow the steps in chapter “Save operation of g.HIamp” to avoid electrostatic discharge impulses.

Sockets, connectors and switch on the rear side

g.HIamp rear view

POWER

POWER	switch for switching ON/OFF the device
POWER SUPPLY	socket for the connection of the external power supply unit
FUSE	4A / 250V fuse, type 20 mm, quick-acting
DIGITAL IN 1	socket for digital inputs
DIGITAL IN 2	socket for digital inputs
HOLD	socket to enable keeping the input signal on the same signal level
USB	USB socket for the connection with the PC or notebook

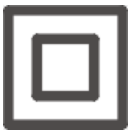
5 Marking on the top side

g.HIamp 256-Channel Amplifier	
g.HIamp 144-Channel Amplifier	
g.HIamp 80-Channel Amplifier	

do not dispose g.HIamp with domestic waste. Dispose it via the separate collection system for electrical and electronic equipment

applied part of type CF

follow instruction for use



safety class II

manufacturer address

Type/Typ: 256-Channel Amplifier

device type for 256-Channel Amplifier

or

Type/Typ: 144-Channel Amplifier

device type for 144-Channel Amplifier

or

Type/Typ: 80-Channel Amplifier

device type for 80-Channel Amplifier

IP 41
S1

IP 41: Protected against particulate matter of degree 4 (wire with diameter of 1 mm). Protection against ingress of water of degree 1 (protection against vertical falling water drops).
S1: Permanent operation.

Unique Device Identification (UDI)

SN HA-2017.02.02

Serial number in the format HA-Year_of_production.Month.Number

REF 7002US

g.tec product number/code in the format xxxxxx

+EBCI7002US0/$$+7HA-2017.92.027

Human readable form of UDI

Machine readable form of UDI

Rx only

Prescription device in the USA

rated DC voltage

rated DC current

The figures below show the packaging of the device and the labelling of the box.

medical & electrical engineering

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phone: +43 7251 22240 fax: +43 7251 22240 39
http://www.gtec.at - office@gtec.at

UDI label:

g.Hlamp
256-Channel Amplifier
REF 7002US
SN HA-2017.02.02
+EBCI7002US0/$$+7HA-2017.92.027

6 Medical power supply GlobTek GTM21097-3005

Medical power supply

Part of the medical equipment g.HIamp is the GlobTek GTM21097-3005. It is a 5 V DC medical power supply unit. If the medical power supply is connected to power line the green LED shows the correct operation of the device.

Labels and LEDs on the power supply:

Power Supply	power supply connector to g.HIamp
LED	the green light indicates power on
GlobTek Inc.	manufacturer name
Power Supply for Medical Use	device type
Model: GTM21097-3005	model name
Input: 100-240V, ~1.6A max, 50-60 Hz	input voltage range, maximum current, frequency range
Output: +5V DC 6.0A	output voltage, direct current, maximum current
CAUTION: for indoor use only!	environmental usage
CE	CE mark
EN60601-1, IEC60601-1	medical normative
S/N: RoHS102746129/11	serial number in the format RoHSxxxxxxxxx/xx

7 USB cable

Part of the medical equipment g.HIamp is the USB cable. It is a 4 pin cable used for the connection of g.HIamp with a PC. One side has a standard USB connector (PC USB) the other side a Mini-Snap 8-pin connector (USB).

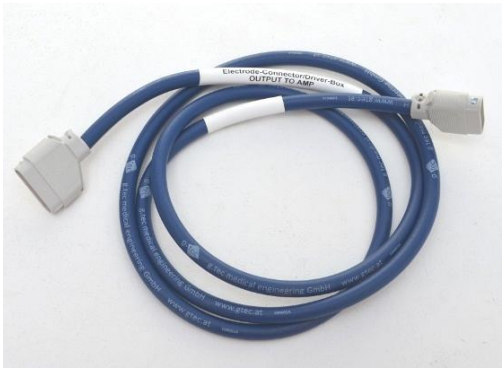
USB cable

Labels on the USB cable:

PC USB	USB connector to PC
USB	USB connector to g.HIamp

8 64 channel electrode connector box and multi lead connection cable

Part of the medical equipment is the g.tec 64 channel electrode connector box and the corresponding connection cable. One 64 channel electrode connector box enables the connection of 64 electrodes and 1 ground electrode with 1.5mm standard safety plugs to g.HIamp via the multi lead connection cable.



64 channel electrode connector box and multi pin connection cable

Labels on the electrode connector box:

CE mark

do not dispose with domestic waste. Dispose it via the separate collection system for electrical and electronic equipment

follow instruction for use

6P-year.mm.nr	serial number in the format 6P-Year.Month.Number
Output to g.HIamp	socket for connector cable to g.HIamp
1-64	channels 1-64
GND	ground socket
IP40	IP 40: Protected against particulate matter of degree 4 (wire with diameter of 1 mm). No protection against ingress of water.

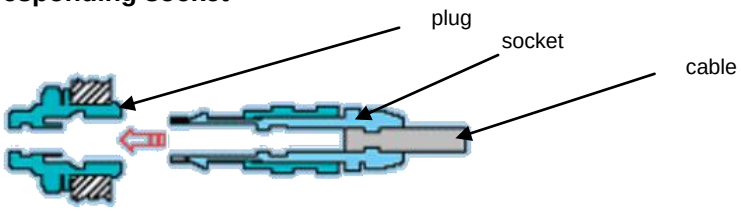
Labels on the multi pin connector cable:

Electrode-Connector/Driver-Box OUTPUT to AMP	Connect this side to the electrode connector box
g.HIamp A/B/C/D	Connect this side to the g.HIamp

9 Push-Pull Connectors

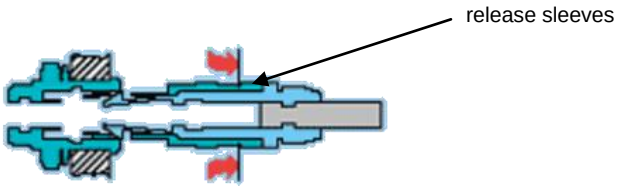
g.HIamp connections on the rear side rely on highly reliable self-latching connectors based on the push-pull principle.

Connecting a plug to the corresponding socket



For connecting the self latching plug to the socket push the plug axially into the socket.

Disconnecting a plug from a socket



For disconnecting the plug from the socket pull on the outer release sleeves only.

Attention: It is not necessary to use any tool for disconnecting the plug from the socket.

10 Safe operation of g.HIamp

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

To start g.HIamp for recording perform the following steps:

Step 1: Connect the medical power supply unit GTM21097-3005 with the POWER SUPPLY connector to the POWER SUPPLY socket of g.HIamp.

Step 2: Connect the USB cable connector USB to the USB socket of g.HIamp and the PC USB connector of the cable to a USB connector of the PC.

Step 3: Connect the medical power supply unit to power line with the power line cord.

Step 4: For EEG recordings place the electrodes with conductive gel to the subject's head according to the international 10-20 electrode system[1]. The electrode impedance should be below 5 kOhm.

Step 5: Connect the electrodes to the sockets 1 – 64 and ground socket of the 64 channel electrode connector box and connect the box via the connection cable to the corresponding input socket of block A (channels 001-064) on g.HIamp.

Step 6: Switch on g.HIamp with the switch on the rear side (switch position ON).

The green LED of the medical power supply unit must be on. Please contact the manufacturer if the medical power supply unit is not working correctly.

The correct operation of g.HIamp is indicated by a green LED on the front side. If the LED is not on please control the power supply connection and the fuse of g.HIamp.

[1] Webster, J.G.,(ed.): Medical Instrumentation: Application and Design, p.194-216. Houghton Mifflin: Boston 1992.

Measuring biosignal data

In measuring mode, all input channels are amplified and each channel is sampled with a 24 bit analog to digital converter. In default mode the sampling rate is 256 Hz. The DSP performs the bandpass filtering of each channel between 0.5 and 100 Hz. Additionally a corresponding mains frequency notch filter (50/60 Hz) can be applied. Then the signal is transmitted via USB to the PC.

Calibrating g.HIamp

In calibration mode all input sockets must be shorted and the internally generated square wave of amplitude ±7.5 mV and 10 Hz is applied to the input amplifiers.

Impedance measurement

In impedance measurement mode all electrodes are connected to the amplifier and to the subject's body. The internally generated square wave (+/- 7.5 mV) is supplied on the signal ground connector. The signal transmission can be evaluated to calculate the electrode impedance at 10 Hz.

HOLD of inputs

A TTL high impulse on the HOLD (signal constant) input socket can be used to hold the current signal on a constant level as long as the TTL impulse is set to high.

Switching off and storage of g.HIamp

To switch off g.HIamp and to store the device correctly, please perform the following steps:

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

Step 2: Disconnect all electrode connector boxes and electrodes.

Step 3: Disconnect the power supply cable.

Step 4: Disconnect the USB cable.

Step 5: Disconnect the power cord from the medical power supply.

11 General notes

Classification

Safety class	II
Type of applied part	CF
Protection against mechanical distortion and liquids	IP41
Operation mode	S1 (permanent operation)

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 and 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 medical rubbing alcohol. Liquid must not enter the g.HIamp.

12 Declaration of conformity

Product name

Product: g.HIamp 256-Channel Amplifier, g.HIamp 144-Channel Amplifier, g.HIamp 80-Channel Amplifier

Manufacturer

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

Classification

Safety class	II
Type of applied part	CF
Protection against mechanical distortion and liquids	IP41
Operation mode	S1 (permanent operation)

The manufacturer declares in sole responsibility that the physiological signal amplifier g.HIamp 256-/144-/80-Channel Amplifier is in conformity with the following standards:

EN standards:
EN 60601-1: 1996 (+A1 +A2 +A12 +A13),
EN 60601-2-26: 2004,
EN 60601-1-2: 2007,
EN 60601-2-25+A1: 2001,
EN 60601-2-40: 1998.

and IEC standards:
IEC 60601-1: 1996 (+A1 +A2 +A12 +A13),
IEC 60601-2-26: 2004,
IEC 60601-1-2: 2007,
IEC 60601-2-25+A1: 2001,
IEC 60601-2-40: 1998.

Dr. Christoph Guger
Chief Executive Officer

Dr. Günter Edlinger
Chief Executive Officer

Schiedlberg, July 2017

13 Technical specifications

g.HIamp

Model	g.HIamp
Type	256-Channel Amplifier or 144-Channel Amplifier or 80-Channel Amplifier
Rated power consumption	20 VA
Rated DC voltage	5 V
Rated current of fuse	4A, quick acting fuse, type 20 mm
Rated voltage of fuse	250 V≈
Produced	see serial number of g.HIamp
Producer	g.tec medical engineering GmbH Sierningstrasse 14 4521 Schiedlberg Austria http://www.gtec.at

Maximum voltages at the following sockets

USB	5 V DC
HOLD	5 V DC
DIGITAL IN	5 V DC
POWER SUPPLY	5 V DC

Amplifier Settings for all channels of the corresponding type

Sensitivity	± 250 mV
Highpass	0 Hz
Lowpass	19.2 kHz
Input Impedance	>100MΩ

Analog-digital converter (ADC)

ADC resolution	24 Bit
Sampling frequency	38400 Hz per channel
Number of ADCs	
Type 256-Channel Amplifier	256
Type 144-Channel Amplifier	144
Type 80-Channel Amplifier	80

Analog signal processing time and digital inputs

sampling frequency [Hz]	ASD_{ADC} AI/DI* for amplifier Version < 1.0.9 [samples]	ASD_{ADC} AI/DI* for amplifier Version >=1.0.9 [samples]**
256	1	2
512	2	3
600	2	3
1200	2	4
2400	3	6
4800	6	11
9600	11	21
19200	21	40
38400	NA	40

*) **A**nalog **S**ignal line **D**elay due to the **A**nalog **D**igital **C**onverter between **A**nalog **I**nput and **D**igital **I**nput lines. Due to the intrinsic filtering and down sampling of the ADC for analog channels, there is a delay between the analog biosignal input and digital trigger input lines.

**) increased ASD_{ADC} from Version 1.0.9 onward is due to an improved anti-aliasing filter

Digital inputs at HOLD

TTL input Sensitivity 0 - 5 V

Digital inputs at DIGITAL IN1

Digital inputs 1-8 Sensitivity 0 - 5 V

Digital inputs at DIGITAL IN2

Digital inputs 9-16 Sensitivity 0 - 5 V

Medical power supply

Isolated medical power supply

Rated power consumption 30 VA

Rated AC voltage (input) 100-240 V

Rated frequency 50-60 Hz

Rated DC voltage (output) 5 V

Rated DC current 6 A

Maximum voltage on Power Supply connector 5 V DC

Producer GlobTek, Inc.

186 Veterans Drive, Northvale, NJ, 07647, USA

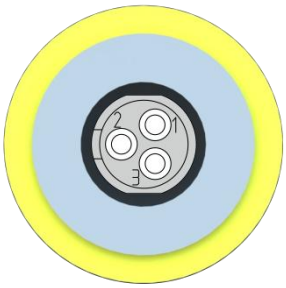
Reseller	GlobTek, Inc. Germany
	Hafenweg 26a, 48155 Münster, Germany
Model number	GTM21097-3005

14 Pin assignment of g.HIamp rear side connectors (coding not shown)

USB

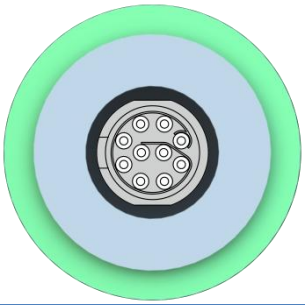
Pin	Direction	Function
1	I	USB Vbus
2	IO	USB Data -
3	IO	USB Data +
4	I	USB ID
5	Pas	Digital GND
6	Pas	Shield
7	NC	No internal connection
8	NC	No internal connection

HOLD



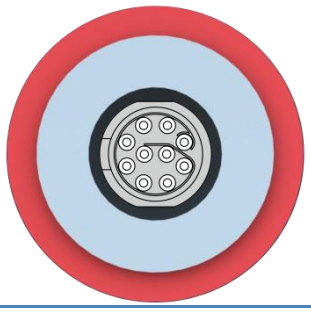
Pin	Direction	Function
1	O	Vcc (3.3 V)
2	I	Short cut analog inputs
3	Pas	Digital GND

DIGITAL IN 1



Pin	Direction	Function
1	I	Digital In 1
2	I	Digital In 2
3	I	Digital In 3
4	I	Digital In 4
5	I	Digital In 5
6	I	Digital In 6
7	I	Digital In 7
8	I	Digital In 8
9	Pas	Digital GND
10	O	Vcc (3.3V)

DIGTAL IN 2



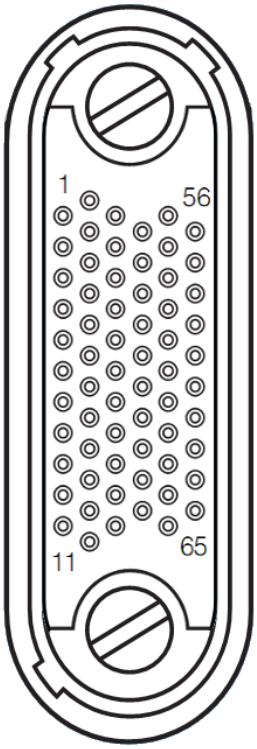
Pin	Direction	Function
1	I	Digital In 9
2	I	Digital In 10
3	I	Digital In 11
4	I	Digital In 12
5	I	Digital In 13
6	I	Digital In 14
7	I	Digital In 15
8	I	Digital In 16
9	Pas	Digital GND
10	O	Vcc (3.3V)

POWER SUPPLY

Pin	Direction	Function
1	Supply	V+ (5V)
2	Supply	V- (0V)

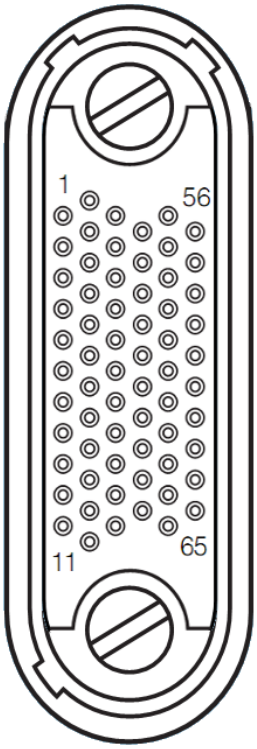
15 Pin assignment of g.HIamp front side connectors

Channels 001-064 (A)



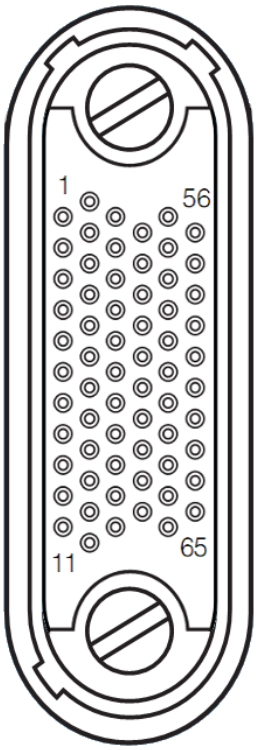
Pin	Direction	Function
1	I	Channel 1
2	I	Channel 2
3	I	Channel 3
.	I	.
.	I	.
.	I	.
63	I	Channel 63
64	I	Channel 64
65	Pas	Signal GND

Channels 065-128 (B)



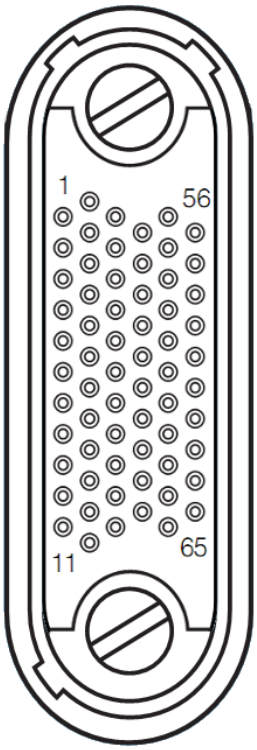
Pin	Direction	Function
1	I	Channel 65
2	I	Channel 66
3	I	Channel 67
.	I	.
.	I	.
.	I	.
63	I	Channel 127
64	I	Channel 128
65	Pas	Signal GND

Channels 129-192 (C)



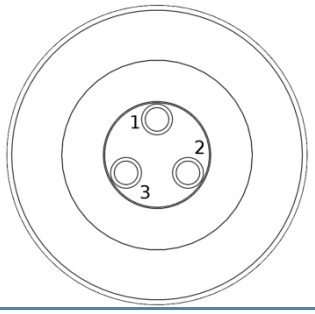
Pin	Direction	Function
1	I	Channel 129
2	I	Channel 130
3	I	Channel 131
.	I	.
.	I	.
.	I	.
63	I	Channel 191
64	I	Channel 192
65	Pas	Signal GND

Channels 193-256 (D)



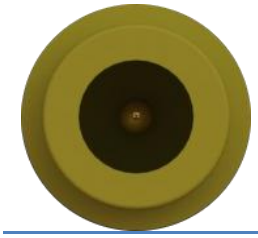
Pin	Direction	Function
1	I	Channel 193
2	I	Channel 194
3	I	Channel 195
.	I	.
.	I	.
.	I	.
63	I	Channel 255
64	I	Channel 256
65	Pas	Signal GND

+5V DC - 30 mA



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

GND



Pin	Direction	Function
1	Pas	Signal GND

List of abbreviations

I	input
O	output
IO	input/output
Pas	passive connection
DNC	do not connect

16 Electromagnetic compatibility

Medical devices have to comply with special safety regulations regarding electromagnetic compatibility (EMC). Please keep in mind the respective precautions in this instruction for use manual before installing and operating g.HIamp. Pay attention to the fact that mobile HF-communication devices (e.g. mobile phones) may interfere with medical electric devices. g.HIamp must not be used nearby or stockpiled with other devices. Only the original components for g.HIamp (see Chapter “g.HIamp 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.HIamp. As electric and magnetic fields may interfere with the functional reliability of the device, avoid using g.HIamp close to devices emitting powerful magnetic fields, e.g. magnetic resonance machines, x-ray equipment.

Following values are below the values given by IEC 60601-1-2 for electromagnetic immunity testing:

Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	1 → $V1$ in V
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	1 → $E1$ in V/m
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 500 V for power supply lines all other < 3 m

The lower compliance levels are allowed (according to normative IEC60601-1-2, top 36.202.1 A) as g.HIamp must be able to accurately measure biosignals having very low amplitudes. Using electromagnetic interference suppression would yield to an inappropriate too low signal to noise ratio for g.HIamp.

Guidance and manufacturer´s declaration – electromagnetic emission

g.HIamp is intended for use in the electromagnetic environment specified below. The customer or the user of the g.HIamp should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The g.HIamp uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The g.HIamp is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 500 V for power supply lines all other < 3 m	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the use of the g.HI amprequires continued operation during power mains interrupts, it is recommended that the g.HI ampbe powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

The g.HIamp is intended for use in the electromagnetic environment specified below.

The customer or the user of the g.HIamp should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the g.HI amp, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter: **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	1 → $V1$ in V	$d = \left(\frac{3.5}{V1}\right) * \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	1 → $E1$ in V/m	$d = \left(\frac{3.5}{E1}\right) * \sqrt{P}$ 80 MHz to 800 MHz
			$d = \left(\frac{7}{E1}\right) * \sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the g.HIamp is used exceeds the applicable RF compliance level above, the g.HIamp should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation the g.HIamp.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the g.HIamp

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left(\frac{3.5}{V1}\right) * \sqrt{P}$	80 MHz to 800 MHz $d = \left(\frac{3.5}{E1}\right) * \sqrt{P}$	800 MHz to 2.5 GHz $d = \left(\frac{7}{E1}\right) * \sqrt{P}$
0.01	0.35	0.35	0.70
0.1	1.11	1.11	2.21
1	3.50	3.50	7.00
10	11.07	11.07	22.14
100	35.00	35.00	70.00

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

NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.