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

g.USBamp
USB BIOSIGNAL AMPLIFIER

UDI label

GlobTek power supply SN: RoHS

Instruction for use V2.16.09

printed Sept. 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 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
- the potential equalization conductor should be connected to a potential equalization conductor of the room where g.USBamp is used
- it is not allowed to use other power supply units than the original medical technical power supply which is delivered with g.USBamp
- pay attention to the precautions regarding electromagnetic compatibility (see Chapter Electromagnetic compatibility)
- the operator has to be familiar with the operation of g.USBamp 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.USBamp)
- every time before using g.USBamp 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.USBamp is connected to other devices (except the power supply supplied with g.USBamp) 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.USBamps are interconnected according to IEC 60601-2-49. The interconnection of several g.USBamp or the connection to other devices can decrease the degree of protection from cardiac float (CF) to body float (BF).

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.

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.

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

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 to aid in monitoring and diagnosis as routinely found in clinical settings for the EEG.

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

Recommended electrodes

The manufacturer recommends EEG electrodes and gel from Grass Instruments, Co (E5GH electrodes, EC-2 electrode cream, in the USA the electrodes must be FDA cleared).

The electrode diameter should be between 2 and 10 mm. The electrode impedance should be below 5 kOhm.

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

Properties of PC or notebook

g.USBamp requires a PC compatible desktop, notebook workstation or embedded computer running a Microsoft Windows operating system (Microsoft Windows 10 Pro (Threshold 2), English, 64-Bit).

The table below lists optimal settings:

Hardware	**Properties**
CPU	2 GHz or faster processor
Harddisk	20-30 GByte
RAM	2-4 GByte
USB 2.0 port (EHCI – enhanced Host controller interface)	one free USB port for each g.USBamp

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.USBamp

g.®USBamp is a high-end biosignal amplifier with USB 2.0 technology from g.tec. The device allows the acquisition of 16 biosignal channels such as EEG (Electroencephalogram) with 24 bit and a sampling frequency of 38.400 Hz per channel. The amplifier has 4 potential separated groups with 4 input channels each. This allows to simultaneously record EEG using independent ground electrodes without interference. The 4 groups can be interconnected to record e.g. 16 EEG channels with the same ground and reference potentials.

The USB amplifier can be connected directly to a PC or notebook with an USB connector without any additional data acquisition device needed. 16 analog to digital converters perform the simultaneous sampling. Each analog to digital converter is operating with 2.4576 MHz and performs a 64 times oversampling. This results in a sampling rate of 38.400 Hz for each channel. A powerful floating point DSP performs an additional oversampling and the real-time filtering of the biosignal data. The sampling frequency can be adjusted between 64 Hz and 38.400 Hz. Therefore, a sampling frequency of 128 Hz yields to an over-sampling rate of 19.200 with a very high signal to noise ratio.

Furthermore, the device has an internal calibration unit and impedance check. A driven right leg (DRL) signal for the suppression of power line interference can be generated. Standard electrodes with safety connectors can be directly connected to g.USBamp. The device is controlled with a C language Application Programming Interface (C API).

g.USBamp

Highlights

- EEG recording via USB
- 16 analog inputs with 24 Bit and 38.400 Hz sampling frequency per channel
- digital filtering of the biosignal data
- over-sampling to achieve a high signal to noise ratio
- can be connected to a PC or notebook
- simultaneous sample and hold of 16 channels
- direct connection of electrodes with standard safety connector
- system connectors for user specific patient cables

3 g.USBamp basic components

g.USBamp consists of the following items:

1 g.USBamp – USB biosignal amplifier

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 LED on the front side

g.USBamp has 4 mono-polar amplification groups with separated ground and reference potentials:

Group A:

Safety sockets 1 - 4: 4 analog input channels for EEG
Push-pull connector A is connected to safety sockets 1 - 4

Group B:

Safety sockets 5 - 8: 4 analog input channels for EEG
Push-pull connector B is connected to safety sockets 5 - 8

Group C:

Safety sockets 9 - 12: 4 analog input channels for EEG
Push-pull connector C is connected to safety sockets 9 - 12

Group D:

Safety sockets 13 - 16: 4 analog input channels for EEG
Push-pull connector D is connected to safety sockets 13 - 16

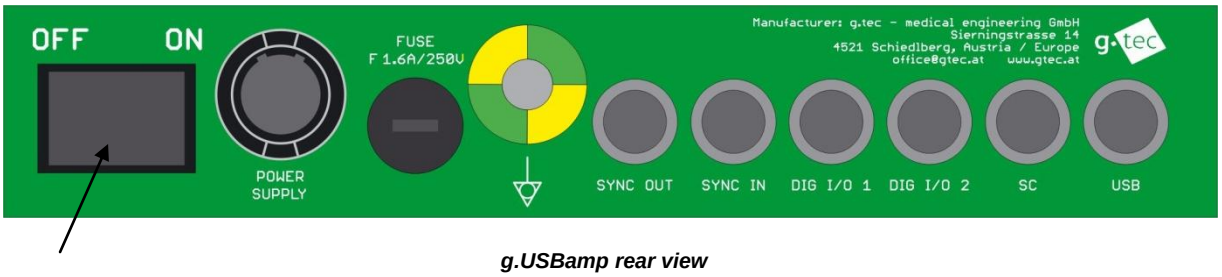
Each group has its own reference socket R and ground socket G. The 4 ground sockets and reference sockets can be connected. The calibration signals are also available on the push-pull connector on group D. The DRL socket is for internal testing usage only.

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.USBamp” to avoid electrostatic discharge impulses.

g.USBamp front side sockets, connectors and LED

Sockets, connectors and switch on the rear side

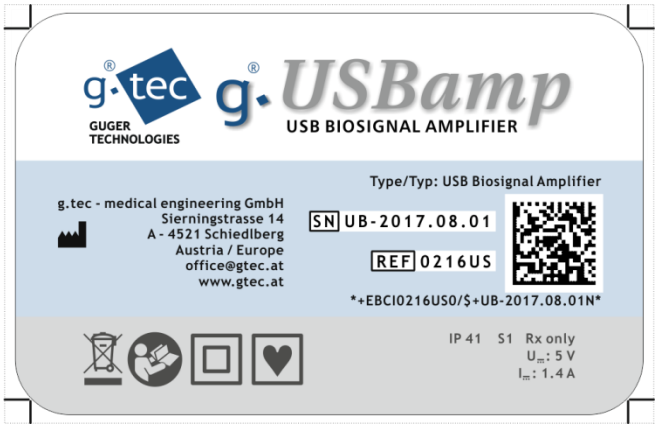


g.USBamp rear view

POWER

POWER	switch for switching ON/OFF the device
POWER SUPPLY	socket for the connection of the external power supply unit
FUSE	1.6A / 250V fuse, type 20 mm, quick-acting
	potential equalization conductor
SYNC OUT	socket for the synchronization with another g.USBamp
SYNC IN	socket for the synchronization with another g.USBamp
DIG I/O 1	socket for digital inputs and outputs
DIG I/O 2	socket for digital inputs and outputs
SC	socket to disconnect the input electrodes from the amplification units. The amplifier unit inputs are connected to ground potential.
USB	USB socket for the connection with the PC or notebook

5 Marking on the top side



do not dispose g.USBamp 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: USB Biosignal Amplifier

device type

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).

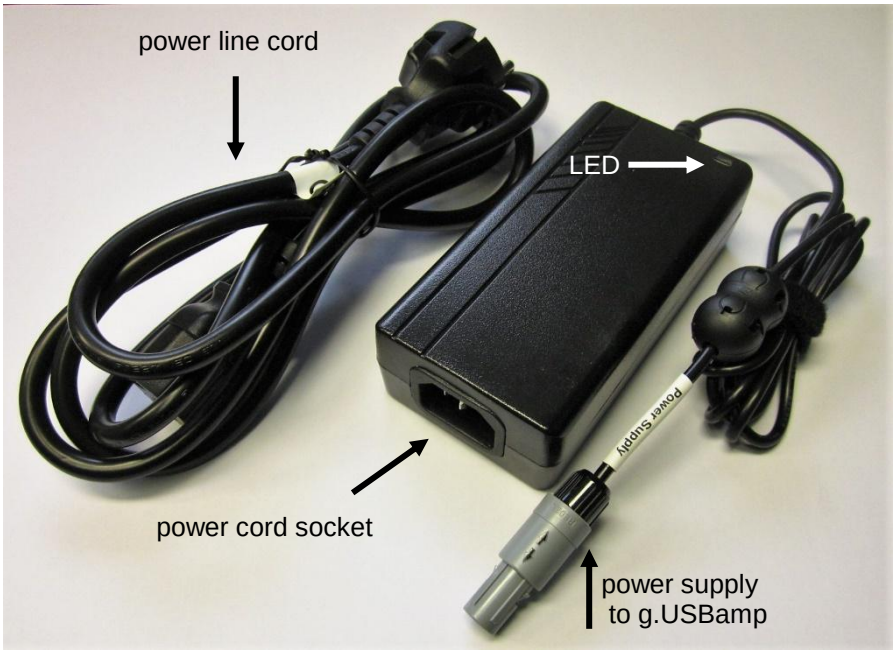
S1: Permanent operation.

SN UB-2017.0.01	Serial number in the format UB-Year_of_Production.Month.Number
REF 0216US	g.tec product number/code in the format xxxxxx
+EBCI7002US0/$+UB-2017.08.01N	Human readable form of UDI
	Machine readable form of UDI
Rx only	Prescription device in the USA
$U_{\text{⎓}}$: 5 V $I_{\text{⎓}}$: 1.4 A	rated DC voltage rated DC current

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

UDI label:

6 Medical power supply GlobTek GTM21097-3005



Medical power supply

Part of the medical equipment g.USBamp is the GlobeTek 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.

7 USB cable

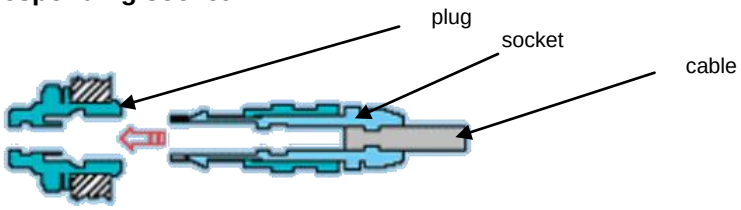
Part of the medical equipment g.USBamp is the USB cable. It is a 4 pin cable used for the connection of g.USBamp with a PC. One side has a standard USB connector (PC USB) the other side a Mini-Snap 4-pin connector (USB).

USB cable

8 Push-Pull Connectors

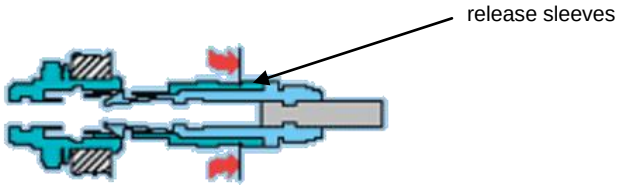
g.USBamp connections on the rear side rely on highly reliable self-latching connectors based on the push-pull principle.

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.

9 Safe operation of g.USBamp

Setting up g.USBamp

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 (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 start g.USBamp for recording perform the following steps:

Step 1: Connect the medical power supply unit GTM21097-3005-5 with the POWER SUPPLY connector to the POWER SUPPLY socket of g.USBamp.

Step 2: Connect the USB cable connector USB to the USB socket of g.USBamp 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.

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.

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 – 16, to the reference and ground sockets of g.USBamp.

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

The correct operation of g.USBamp 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.USBamp.

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 128 Hz. The DSP performs the bandpass filtering of each channel between 1 and 30 Hz. Additionally a 50 Hz notch filter is applied. Then the signal is transmitted via USB to the PC.

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

Calibrating g.USBamp

In calibration mode, all electrode input sockets are disconnected from the input amplifiers. Additionally an internally generated sine wave with amplitude of ±10 mV and 10 Hz is connected to the input amplifiers.

Impedance measurement

In impedance measurement mode, sequentially to each electrode an internally generated sine wave with ±10 mV and 20 Hz is applied. The voltage loss is measured and transmitted via USB to the PC.
NOTE: The ground electrode must be connected to group D if the impedance is measured for all groups.

Shortcut of inputs

A TTL high impulse on the SC input socket can be used to disconnect all electrode input sockets from the input amplifiers and to connect the inputs to ground potential.

Synchronization of multiple g.USBamps

On socket SYNC OUT the digital converter clock rate can be measured. On SYNC IN it is possible to apply the clock signal for the digital converters.

Switching off and storage of g.USBamp

To switch off g.USBamp 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 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.

10 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 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 medical rubbing alcohol. Liquid must not enter the g.USBamp.

11 Declaration of conformity

Product name

Product: g.USBamp

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 electroencephalograph g.USBamp is in conformity the following standards:

IEC 60601-1: 1996 (+A1 +A2 +A12 +A13),
IEC 60601-2-26: 2004,
IEC 60601-1-2: 2003,
IEC 60601-2-25+A1: 2001,
IEC 60601-2-40: 1998.

Dr. Christoph Guger
Chief Executive Officer

Dr. Günter Edlinger
Chief Executive Officer

Schiedlberg, Sept. 2017

12 Technical specifications

g.USBamp

Model	g.USBamp
Type	USB biosignal amplifier
Rated power consumption	7 VA
Rated DC voltage	5 V
Rated current of fuse	1.6 A, quick acting fuse, type 20 mm
Rated voltage of fuse	250 V≈
Produced	see serial number of g.USBamp
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
SC	5 V DC
DIGITAL I/O	5 V DC
SYNC IN	5 V DC
SYNC OUT	5 V DC
POWER SUPPLY	5 V DC
8 pin socket D (DRL, calibration)	± 250 mV AC

Amplifier Settings

Channels 1 to 16

Sensitivity:	± 250 mV
Highpass:	0 Hz
Lowpass:	6.6 kHz
Input Impedance:	$>10^{10}\ \Omega$

Analog-digital converter (ADC)

ADC resolution	24 Bit
Sampling frequency	38.400 Hz per channel
Number of ADCs	16

Analog signal processing time and digital inputs

sampling frequency [Hz]	ASD_{ADC} AI/DI* [samples]
32	2
64	2
256	1
512	1
600	2
1200	2
2400	2
4800	2
9600	3
19200	4
38400	7

*) **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.

DRL and calibration output

Digital-analog Converter (DAC)

DAC resolution	12 Bit
Sampling frequency	600 Hz per channel
Number of DACs	2 (DRL, calibration)
Output voltage calibration	± 250 mV
Output voltage DRL	± 5 mV, for internal testing usage only

Digital inputs at SC

TTL input	Sensitivity:	0 - 5 V

Digital inputs and outputs at DIGITAL I/O 1

Digital inputs 0, 1, 2, 3	Sensitivity:	0 - 5 V
Digital outputs 1 and 2	Sensitivity:	0 – 3.3 V

Digital inputs and outputs at DIGITAL I/O 2

Digital inputs 4, 5, 6, 7	Sensitivity:	0 - 5 V
Digital outputs 3 and 4	Sensitivity:	0 – 3.3 V

Digital inputs at SYNC IN

ADC sclock extern -	Sensitivity:	0 - 5 V
ADC sclock extern +	Sensitivity:	0 - 5 V

ADC clock extern -	Sensitivity:	0 - 5 V
ADC clock extern +	Sensitivity:	0 - 5 V

Digital outputs at SYNC OUT

ADC sclock extern -	Sensitivity:	0 – 3.3 V
ADC sclock extern +	Sensitivity:	0 – 3.3 V
ADC clock out -	Sensitivity:	0 – 3.3 V
ADC clock out +	Sensitivity:	0 – 3.3 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

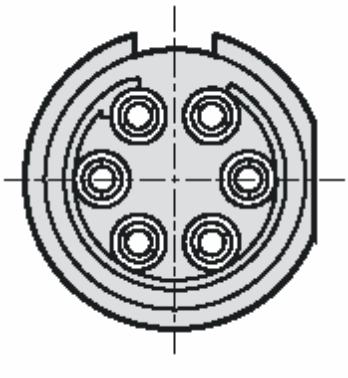
13 PIN assignment

Pin 1 is marked with a special surrounding in the pictures. Then the numbering follows the indicated line.

g.USBamp

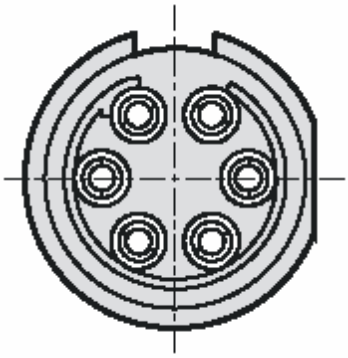
Pin-assignment for the 6 pin socket A

Pin 1 analog input 3
Pin 2 analog input 2
Pin 3 analog input 4
Pin 4 reference analog group A
Pin 5 ground group A
Pin 6 analog input 1



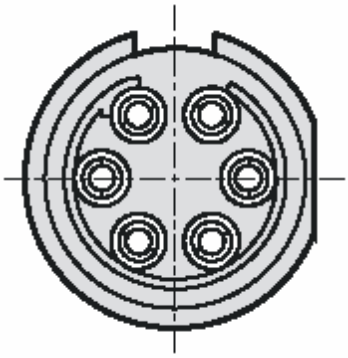
Pin-assignment for the 6 pin socket B

Pin 1 analog input 7
Pin 2 analog input 6
Pin 3 analog input 8
Pin 4 reference analog group B
Pin 5 ground group B
Pin 6 analog input 5



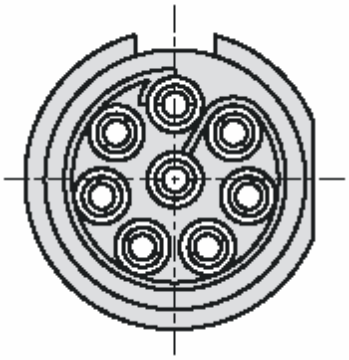
Pin-assignment for the 6 pin socket C

Pin 1 analog input 11
Pin 2 analog input 10
Pin 3 analog input 12
Pin 4 reference analog group C
Pin 5 ground group C
Pin 6 analog input 9

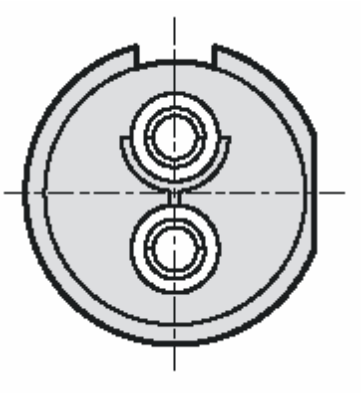


Pin-assignment for the 8 pin socket D

Pin 1 analog input 15
Pin 2 analog input 14
Pin 3 analog input 16
Pin 4 reference analog group D
Pin 5 ground group D
Pin 6 DRL
Pin 7 analog input 13
Pin 8 calibration



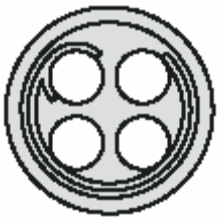
Pin-assignment for the 2 pin socket POWER SUPPLY



Pin 1 +5 V

Pin 2 ground

Pin-assignment for the 4 pin socket SC



Pin 1 ground digital

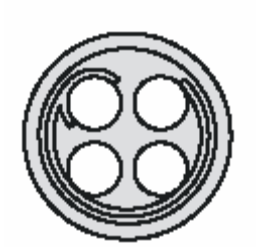
Pin 2 for internal use only, do not connect

Pin 3 for internal use only, do not connect

Pin 4 TTL input

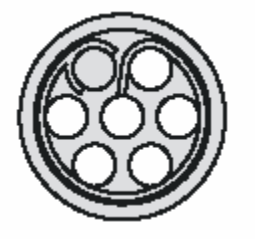
Pin-assignment for the 4 pin socket USB

Pin 1 D -
Pin 2 +Vbus
Pin 3 ground digital
Pin 4 D +



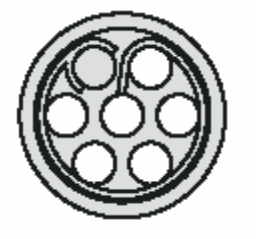
Pin-assignment for the 7 pin socket DIGITAL I/O 1

Pin 1 digital input 0
Pin 2 digital input 1
Pin 3 digital input 2
Pin 4 digital input 3
Pin 5 digital output 0
Pin 6 digital output 1
Pin 7 ground digital



Pin-assignment for the 7 pin socket DIGITAL I/O 2

Pin 1 digital input 4
Pin 2 digital input 5
Pin 3 digital input 6
Pin 4 digital input 7
Pin 5 digital output 2
Pin 6 digital output 3
Pin 7 ground digital



Pin-assignment for the 5 pin socket SYNC OUT

Pin 1 ADC sclock out -
Pin 2 ADC sclock out +
Pin 3 ground digital
Pin 4 ADC clock out -
Pin 5 ADC clock out +

Pin-assignment for the 5 pin socket SYNC IN

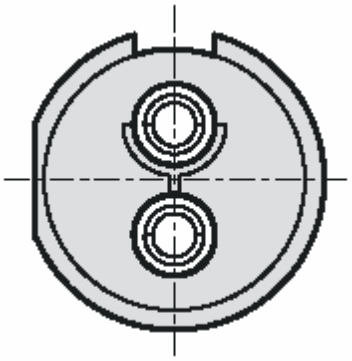
Pin 1 ADC sclock extern -
Pin 2 ADC sclock extern +
Pin 3 ground digital
Pin 4 ADC clock extern -
Pin 5 ADC clock extern +

Power supply unit cable

Pin-assignment for the 2 pin connector POWER SUPPLY

Pin 1 +5 V

Pin 2 ground



USB cable

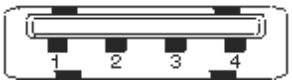
Pin-assignment for the 4 pin connector PC USB

Pin 1 +Vbus

Pin 2 D-

Pin 3 D+

Pin 4 ground digital



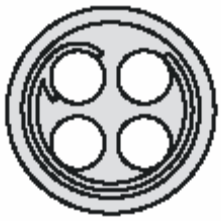
Pin-assignment for the 4 pin connector USB (Mini-Snap)

Pin 1 D –

Pin 2 +Vbus

Pin 3 ground digital

Pin 4 D +



14 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.USBamp. Pay attention to the fact that mobile HF-communication devices (e.g. mobile phones) may interfere with medical electric devices. g.USBamp must not be used nearby or stockpiled with other devices. Only the original components for g.USBamp (see Chapter "g.USBamp 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.USBamp. As electric and magnetic fields may interfere with the functional reliability of the device, avoid using g.USBamp 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

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

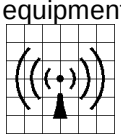
Guidance and manufacturer´s declaration – electromagnetic emission

The g.USBamp is intended for use in the electromagnetic environment specified below. The customer or the user of the g.USBamp should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The g.USBamp 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 B	The g.USBamp 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer´s declaration – electromagnetic immunity

The g.USBamp is intended for use in the electromagnetic environment specified below. The customer or the user of the g.USBamp 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	± 2 kV 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.USBamp requires continued operation during power mains interrupts, it is recommended that the g.USBamp be 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.USBamp is intended for use in the electromagnetic enviroment specified below.
The customer or the user of the g.USBamp 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.USBamp , 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.USBamp is used exceeds the applicable RF compliance level above, the g.USBamp should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation the g.USBamp .

[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.USBamp

The g.USBamp is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the g.USBamp can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the g.USBamp 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.