

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>



GUGER
TECHNOLOGIES

g. GAMMAsys
ACTIVE ELECTRODE SYSTEM

Instructions for use V2.14.01

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Instruction for use

Disclaimer

g.GAMMAsys is not a medical device. The product is not intended to be used as a medical device. Additional examinations are needed for diagnosis and no diagnosis must be done based on using 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 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 or corresponding accumulator
- pay attention to the precautions regarding electromagnetic compatibility (see Chapter Electromagnetic compatibility)
- the operator has to be familiar with the operation of g.GAMMAsys and must operate the device accordingly to the Instructions for use
- never connect g.GAMMAsys to a charging device.
- use genuine electrodes or sensors provided by g.tec only
- for use with g.USBamp: Do not connect electrodes (e.g. for EEG, EOG, EMG, ECG, ...) to the input sockets (red, blue and yellow 1.5 mm-DIN-safety sockets) of blocks (A, B, C and/or D) which are used for g.GAMMAsys (connected via genuine adapter cable)
- you must only use active electrodes and standard (passive) electrodes at the same time if your amplifier has independent (isolated) ground potentials such as provided by g.USBamp

Warning and safety notice

If g.GAMMAbox is connected to 3rd-party devices the following leakage currents have to be checked.

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

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. In doubt, 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 in intervals of 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 diagnosis and no diagnosis may be done only based on the use of 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 device can result in burnings under the electrodes and could damage it.

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 g.GAMMAsys

g.GAMMAsys is g.tec's high-end and high-performance active electrode system for non-invasive electrophysiological derivations. The system allows the acquisition of 16 (32, 48 or 64) 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 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, artifacts caused by electrode or cable movements, distorted signals or background noise).

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 potentials such as provided by g.USBamp.



g.GAMMAbox with active electrodes

Highlights

- EEG, ECG, EMG and EOG recording without cable/movement artifacts
- Minimal 50/60 Hz power line interference
- No preparation of skin necessary
- Avoids the use of abrasive gels
- 16 single and easily replaceable input electrodes per unit
- system connectors for user specific cables
- connects directly to g.USBamp, g.MOBllab+ and g.BSamp
- electrodes fit to existing g.EEGcap system or to g.GAMMAcap system

2. g.GAMMAsys basic components

g.GAMMAsys consists of the following items:

1	g.GAMMAbox	Active electrode driver box
8 or 16	Active electrodes	Active sintered Ag/AgCl or Au electrodes, 1 mm / 2 pin touch proof connector
1	Reference electrode	Active reference sintered Ag/AgCl or Au earlobe electrode
1	Ground electrode	Sintered Ag/AgCl or Au ground electrode
1	Electrode gel	
1	Instructions for use	

3. g.GAMMAsys optional components

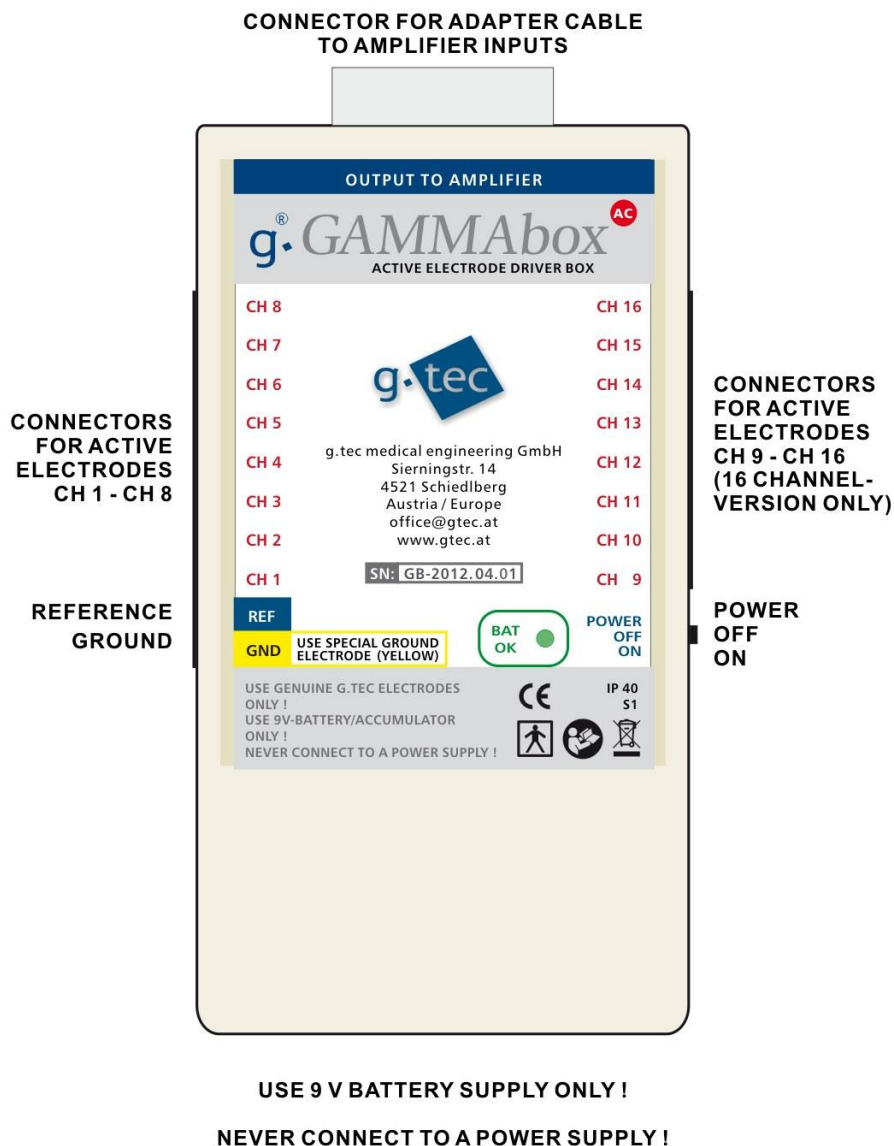
g.USBampGAMMAConnector	16 + 2 channel system connector for g.USBamp
g.MOBllabGAMMAconnector	8 + 2 channel system connector for g.MOBllab+ 8 channel version
Universal g.GAMMAbox connector	16 +2 channel connector with 1.5 mm safety connectors for g.BSamp or other amplifiers

4. g.GAMMAbox explanation of switches, connectors and LEDs

Sockets, connectors and switch

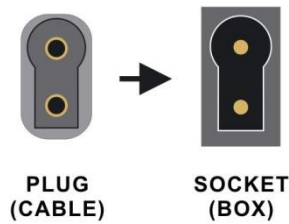
g.GAMMAbox has 16 2-pin touch proof safety input sockets for the active electrodes, one 2-pin touch proof safety input socket for the reference electrode and one 2-pin touch proof safety input socket for the ground electrode.

g.GAMMAbox has 1 output connector for an adapter cable to a biosignal amplifier.







g.GAMMAbox, top view

ORIENTATION OF 2-PIN 1-MM SAFETY CONNECTOR



Orientation of 2-pin safety connectors: g.GAMMAbox 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 ACTIVE ELECTRODES CH1 - CH8, input 2-pin sockets for active electrodes
OUTPUT TO AMPLIFIER	CONNECTOR FOR ADAPTER CABLE TO BIOSSIGNAL AMPLIFIER
POWER (0/I)	POWER OFF/ON, for switching ON/OFF the device
CH9 – CH16	CONNECTORS FOR ACTIVE ELECTRODES CH9 - CH16, input 2-pin sockets for active electrodes
BAT OK	Indicates that battery power is ok
	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
<div style="background-color: #e6f2ff; padding: 5px;"> g.tec - medical engineering GmbH Sierningstrasse 14 A - 4521 Schiedlberg Austria / Europe office@gtec.at www.gtec.at </div>	
	manufacturer address

IP 40

S1

IP 40: Protection rating is IP 40

Permanent operation




5. Active electrodes

g.tec provides the following types of active electrodes to be used with g.GAMMAsys:

	<p>g.ACTIVE electrode for g.EEGcap active sintered Ag/AgCl electrode Color: red</p>
	<p>g.LADYbird electrode for g.GAMMAcap² active sintered Ag/AgCl electrode Color: red</p>
	<p>g.BUTTERfly electrode for g.GAMMAcap² active high purity gold (Au) electrode Color: red</p>
	<p>g.GAMMAclip active electrode connector active clip connector to use disposable electrodes as active electrodes Color: red</p>
	<p>g.SCARABEO active electrode active sintered Ag/AgCl electrode Color: grey</p>

6. Reference electrodes

g.tec provides the following types of active reference electrodes to be used with g.GAMMAsys:

	g.GAMMAearclip Ag/AgCl active sintered Ag/AgCl earlobe reference electrode Color: blue
	g.GAMMAearclip Au active high purity gold (Au) earlobe reference electrode Color: blue
	g.GAMMAclipREF active reference clip connector to use disposable electrodes as active reference electrodes Color: blue
	If needed any type of active electrode (see 5) can be used as a reference electrode as well.

7. Ground electrodes

g.tec provides the following types of ground electrodes to be used with g.GAMMAsys:

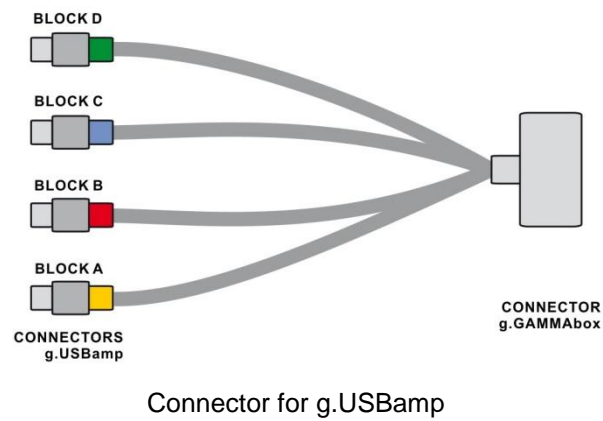
	<p>g.ACTIVEground Ag/AgCl sintered Ag/AgCl ground electrode to be used with g.EEGcap Color: white</p>
	<p>g.LADYbirdGND electrode for g.GAMMAcap² sintered Ag/AgCl ground electrode Color: yellow</p>
	<p>g.BUTTERflyGND electrode for g.GAMMAcap² high-purity gold (Au) ground electrode Color: yellow</p>
	<p>g.GAMMAclipGND clip connector to use disposal electrodes as ground Color: yellow</p>
	<p>g.SCARABEO GND sintered Ag/AgCl ground electrode Color: grey, cable/connector: yellow</p>

8. Optional components

g.GAMMAbox can be connected to g.USBamp, g.MOBllab+, g.BSamp or any amplifier having 1.5 mm safety input sockets.

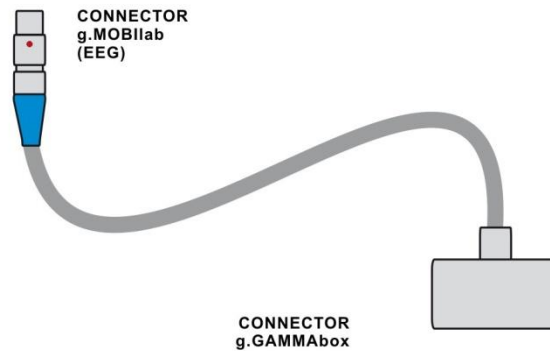
g.USBampGAMMAconnector

g.USBampGAMMAconnector is a LEMO connector connecting the output of g.GAMMAbox to the system input sockets (Blocks A, B, C and D) of g.USBamp.



g.MOBllabGAMMAconnector

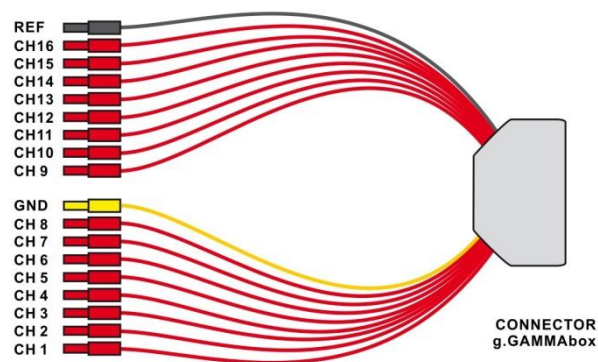
g.MOBllabGAMMAconnector is a LEMO connector connecting the output of g.GAMMAbox to the 8-channel EEG input socket of g.MOBllab+.



Connector for g.MOBllab+

g.BSamp (universal) connector

The universal connector is a LEMO connector connecting the output of g.GAMMAbox to g.BSamp or any amplifier equipped with 1.5mm safety input sockets.



Universal connector for g.BSamp

9. Safe operation of g.GAMMAsys

Setting up g.GAMMAsys

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 g.GAMMAsys perform the following steps:

g.GAMMAsys enables high quality signal recording even for suboptimal impedance at recording electrodes. However, to achieve best results the ground electrode should have perfect connection with low impedance. Clean the skin and use abrasive gel to prepare the location where the ground electrode is applied. For the reference electrode and recording electrodes a reliable connection to the skin is required but skin preparation is not necessarily needed. g.GAMMAgel has to be used for all electrodes (except for pre-gelled electrodes). For EEG derivation from the hairy scalp the gel can be injected with the doser tip of g.GAMMAgel (original container) or with a syringe (without needle) to assure the contact to the skin.

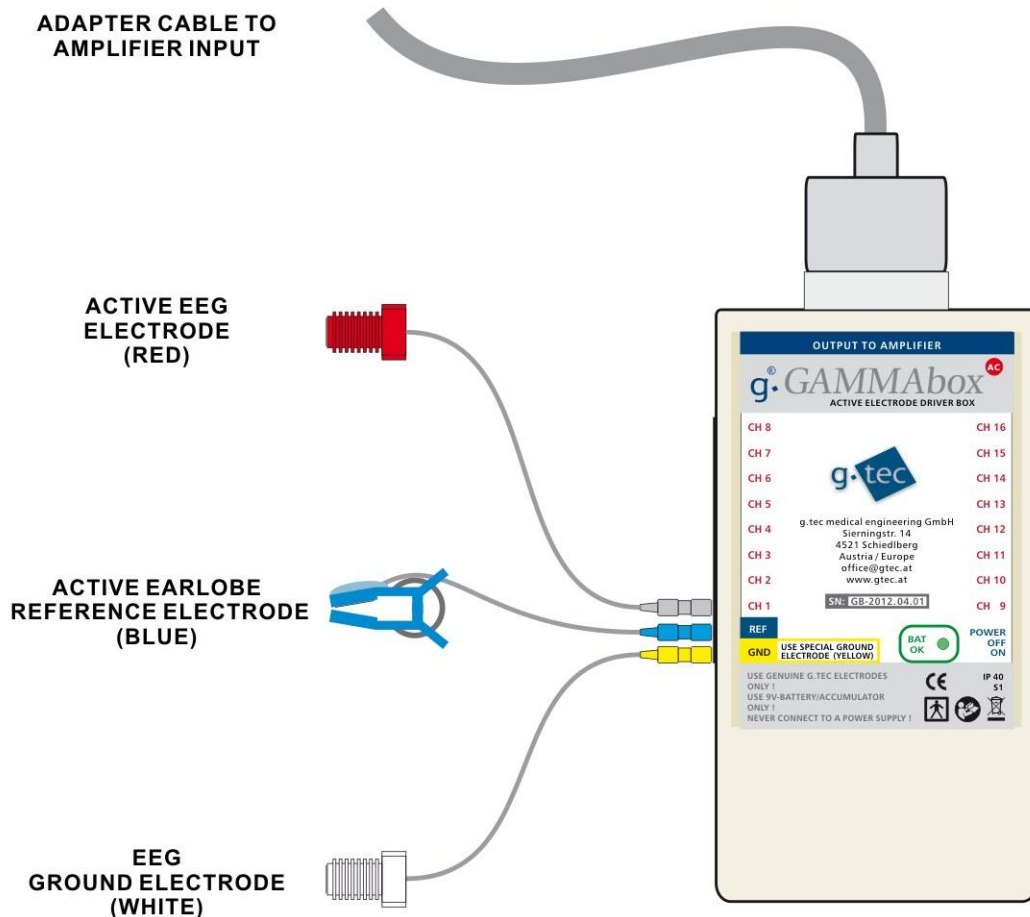
Step 1: Insert the 9V battery block or a corresponding accumulator into the battery unit of g.GAMMAbox.

Step 2: For EEG recordings place the electrodes with conductive gel to the subject's head according to the international 10-20 electrode system ¹.

Step 3: Connect the active (color coded red or grey) electrodes to the sockets 1 – 16 (or 1 – 8). Connect the active earlobe reference electrode (color coded blue) to the REF input socket and connect the ground electrode (color coded white or yellow) to the GND input socket.

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

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



g.GAMMAbox connection scheme

Step 4: Connect the output cable attached to g.GAMMAbox at the “OUTPUT TO AMPLIFIER” socket to the input socket(s) of your amplifier.

Step 5: Switch on g.GAMMAbox with the switch on the right side (switch position POWER I).

The correct operation of g.GAMMAbox 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.

Switching off and storage of g.GAMMAsys

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

Step 1: Switch off the device with the switch on the side (switch position POWER 0). The green LED is off.

Step 2: Disconnect all electrodes.

Step 3: Disconnect the g.GAMMAbox from the amplifier

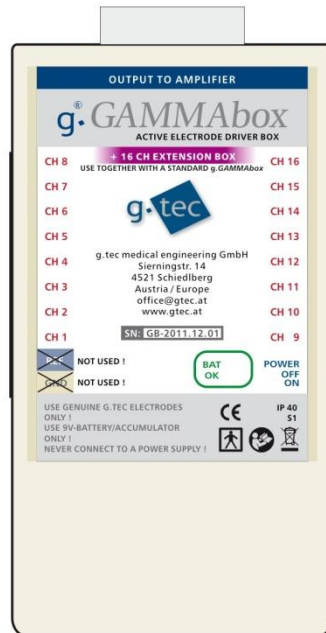
Step 4: Remove the battery if you do not plan to use the device within the next couple of weeks.

Step 5: Clean EEG electrodes immediately after use. Clean the electrodes only with warm water. Do not soak electrodes for more than 2 minutes. Avoid any rough treatment of the electrode surface. If required a smooth toothbrush or a waterpick (oral irrigator) can be used for cleaning

Note: All types of Ag/AgCl electrodes have limited life time and need to be replaced from time to time. Careful treatment prolongs lifetime of electrodes!

10. Using multiple g.GAMMAboxes for 32-, 48- or 64-channel recordings

To perform recordings with more than 16 channels with active electrodes multiple units of g.GAMMAbox can be used. For this purpose one standard g.GAMMAbox has to be used to connect the ground and reference electrode. For all additional channels one or more g.GAMMAbox “extension boxes” have to be used. The extension box is similar to the standard box but ground and reference connectors are not used.

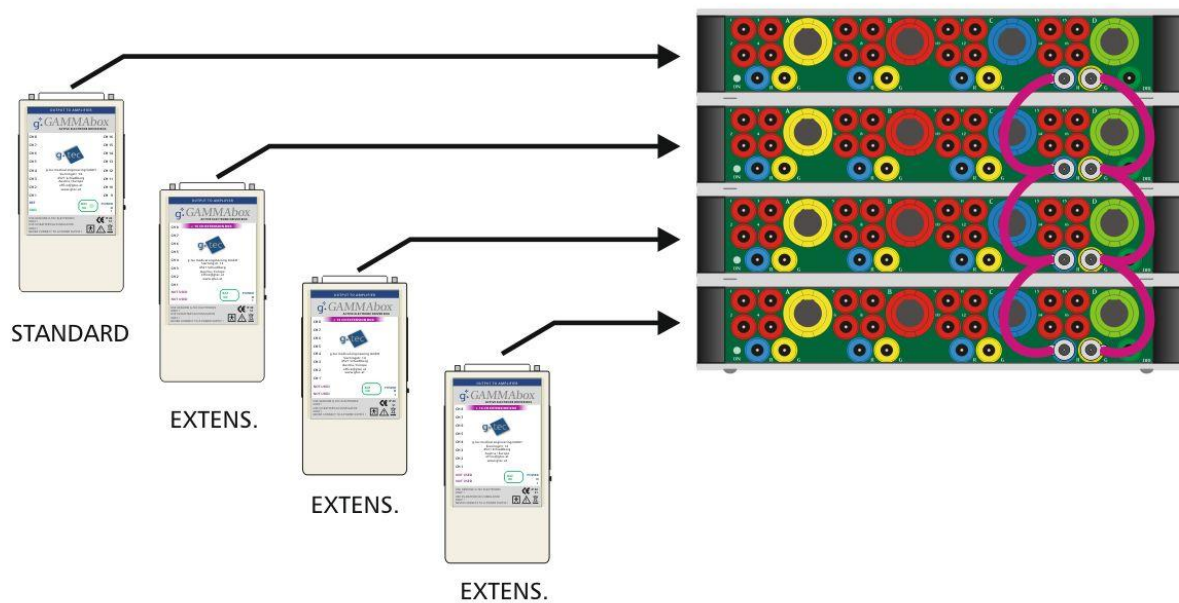


g.GAMMAbox “+16 CH EXTENSION BOX”

Note: Extension boxes can only be used in combination with one standard g.GAMMAbox as reference and ground electrodes cannot be used in extension boxes!

Important: Do not use multiple standard g.GAMMAboxes together in one system! An extension box must not be replaced by a standard g.GAMMAbox!

channels of the amplifier have to use a common reference and a common ground. When using multiple g.USBamp units ground sockets have to be interconnected with shortcut cables as well as reference sockets:



Use of one standard g.GAMMAbox and 3 extension boxes for a 64 channel recording system. Interconnect common reference sockets as well as common ground sockets.

11. Bipolar (differential) derivation

The diagram illustrates a 10x10 electrode grid for EEG/MEG recording. The electrodes are arranged in a circular pattern, with labels for each electrode. The grid is divided into four quadrants by a vertical line (Fz, Cz, Pz, Oz) and a horizontal line (Fp, Cp, Pp, Op). The electrodes are labeled as follows:

- Top Row (Fp):** Fp1, Fp2, Fp3, Fp4, Fp5, Fp6, Fp7, Fp8, Fp9, Fp10
- Row 2 (F):** F1, F2, F3, F4, F5, F6, F7, F8, F9, F10
- Row 3 (FC):** FC1, FC2, FC3, FC4, FC5, FC6, FC7, FC8, FC9, FC10
- Row 4 (C):** C1, C2, C3, C4, C5, C6, C7, C8, C9, C10
- Row 5 (CP):** CP1, CP2, CP3, CP4, CP5, CP6, CP7, CP8, CP9, CP10
- Row 6 (P):** P1, P2, P3, P4, P5, P6, P7, P8, P9, P10
- Row 7 (PO):** PO1, PO2, PO3, PO4, PO5, PO6, PO7, PO8, PO9, PO10
- Bottom Row (Oz):** Oz

The diagram shows the connections between the electrodes and the GAMMAbox amplifier. The connections are as follows:

- Channel 8 (CH 8):** Connected to Fp2 (yellow electrode).
- Channel 4 (CH 4):** Connected to FC4 (red electrode).
- Channel 2 (CH 2):** Connected to CP4 (red electrode).
- Channel 1 (CH 1):** Connected to GND (yellow electrode).

The GAMMAbox amplifier is shown on the right, with a list of channels and their corresponding electrode connections. The amplifier is labeled "OUTPUT TO AMPLIFIER" and "ACTIVE ELECTRODE DRIVER BOX". It features a "REF" section with "GND" and "USE SPECIAL GROUND ELECTRODE (YELLOW)". It also has a "POWER OFF ON" switch and a "BAT OK" indicator. The amplifier is connected to the electrodes via a cable with multiple channels.

When using g.GAMMASys for bipolar recordings with g.USBamp all channels have to be recorded mono polar (with a reference electrode) and bipolar recordings are computed with g.USBamp (see g.USBamp setup, instructions for use).

12. General notes

Classification

Safety class	internally powered
Type of applied part	BF
Protection against mechanical distortion and liquids	IP40
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.

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 g.GAMMAbox.

13. Declaration of conformity

Product name

Product: g.GAMMAsys

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

g.GAMMAsys 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.GAMMAsys is in conformity with the general requirements for safety (low voltage directive) 73/23/EWG and 89/336/EWG (electromagnetic compatibility).

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

Dr. Christoph Guger
Chief Executive Officer

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

Dr. Günter Edlinger
Chief Executive Officer

Schiedlberg, 2012

14. Technical specifications

g.GAMMAbox

Model	g.GAMMAbox
Type	Active electrode driver/supply unit
Rated power consumption	180 mW
Rated DC voltage	9V DC
Produced	2012
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 μ A

REF 100 μ A

Amplifier Settings

Channels 1 to 16

Sensitivity:	± 1 V
Highpass:	0 Hz (0.1 Hz for "AC"-Box)
Lowpass:	10 kHz
Input Impedance:	$>10^{10} \Omega$

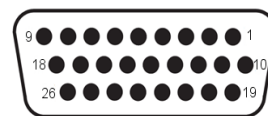
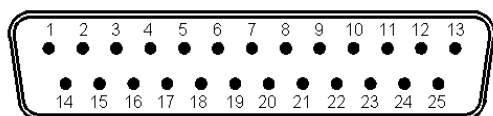
15. PIN assignment g.GAMMAbox

Pin-assignment for the 25 and 26 pin plug OUTPUT TO AMPLIFIER (old versions)

Note: For a g.GAMMAbox with serial number > GB-2009.09.xx the OUTPUT TO AMPLIFIER socket is a 26 pin sub-D26 socket; otherwise the output socket is a 25 pin sub-D25 socket.

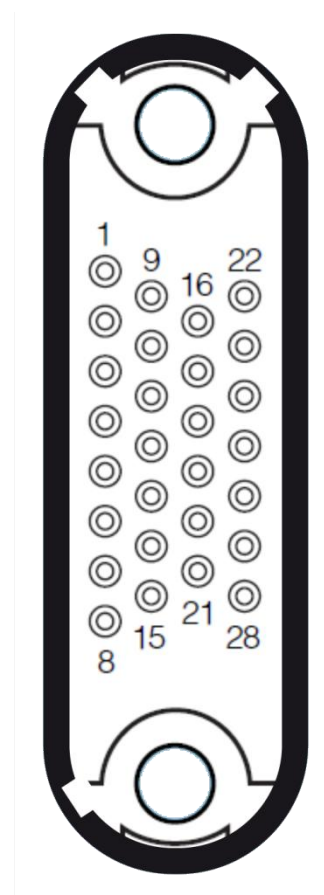
25pin Sub-D	function
1	CH 16
2	CH 14
3	CH 12
4	CH 10
5	n. c.
6	REF
7	REF
8	REF
9	REF
10	CH 02
11	CH 04
12	CH 06
13	CH 08
14	CH 15
15	CH 13
16	CH 11
17	CH 09
18	GND
19	GND
20	GND
21	GND
22	CH 01
23	CH 03
24	CH 05
25	CH 07

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



**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.



16. PIN assignment electrodes

All active electrodes and active reference electrodes for g.GAMMAsys:

2pin connector	function
1	supply +
2	supply -



All ground electrodes for g.GAMMAsys

2pin connector	function
1	GND
2	NC



Electromagnetic compatibility

Please keep in mind the respective precautions in this Instructions for use manual before installing and operating g.GAMMAsys. Pay attention to the fact that mobile HF-communication devices (e.g. mobile phones) may interfere with electric devices. g.GAMMAsys must not be used nearby or stockpiled with other devices. Only the original components for g.GAMMAsys (see Chapter “g.GAMMAsys 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.GAMMAsys. As electric and magnetic fields may interfere with the functional reliability of the device, avoid using g.GAMMAsys close to devices emitting powerful magnetic fields.

Electrode life-time and replacement

g.tec uses special lightweighted, thin and highly flexible cables for active electrodes to provide high comfort and easy laying, especially for multi-channel recording. Such cables are sensitive and need to be treated with special care. Following some basic guidelines will lead to a prolonged life-time of electrodes and cables:

- never pull on electrodes cables
- avoid knots in cables
- avoid heavy bending of electrode cables
- do not soak cables and electrodes for more than 5 minutes
- avoid exposition to direct sunlight or chemical agents
- do not autoclave electrodes
- make sure that no gel remains on electrodes or cables after cleaning
- protect connectors from contamination with gel, water or disinfectant
- always make sure that electrodes, cables and caps are completely dry before storing

Warranty/replacement of electrodes:

Electrode life-time highly depends on proper usage, careful treatment and cleaning, and appropriate storage. g.tec will provide warranty replacement of electrodes only if there is no visible physical damage of the parts such as damaged, broken or squeezed cables or isolation, eroded contact pellets or damaged housings or connectors.



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