

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





Instructions for use V2.14.00

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Instruction for use

Disclaimer

g.GAMMAcap² is not a medical product. The product is not intended to be used as a medical product.

Intended function

The intended function of the equipment is to measure EEG signals in humans for research purposes from the intact surface of the body.

Attention

Use genuine electrodes or sensors provided by g.tec only

Inspection

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

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

The product **must not** be used for patient monitoring. The product **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 product.

The intended environment of use

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

Recommended electrodes

Only genuine electrodes from g.tec medical engineering GmbH shall be used with the device.

1 Introduction to g.GAMMAcap²

g.GAMMAcap² is the second version of g.tec's high-end electrode cap for non-invasive Electroencephalogram derivations. The cap allows the derivation of 160 biosignal EEG (Electroencephalogram) channels from predefined positions using g.tec's genuine active or passive electrodes. The system is designed for use either with g.GAMMAsys for active electrodes, active electrode connector boxes for g.Hlamp, g.SAHARAsys for dry electrodes or with passive ring electrodes. The cap is available in 3 adult sizes (small, medium and large) that come with 160 pre-cut holes. A total of 74 electrode positions are labeled on g.GAMMAcap² according to the extended international 10/20 system (10/10 system) and in addition electrodes can be mounted on 86 intermediate electrode positions. For kids another 3 sizes (mini, midi and maxi) are available without pre-cut intermediate positions. Electrodes are inserted at the desired electrode positions via small holes in the cap and additional positions can be added by the user.



g.GAMMAcap² with active g.LADYbird electrodes

Important: g.GAMMAcap² allows replacing or changing electrodes if required, but the cap is not designed for frequent changing of electrodes. Usually electrodes remain in the cap also for cleaning!

Highlights

- easy positioning of EEG electrodes via indicated electrode positions directly on the cap according to the extended international 10/10 system
- saves time for cleaning as electrodes remain inserted in the cap
- · easy to do individual repositioning of electrodes
- usage of NEW active g.SAHARA, g.LADYbird, g.SCARABEO and g.BUTTERfly electrodes from g.tec
- usage of passive g.LADYbird Ag/AgCl electrodes
- gold plated electrodes and Ag/AgCl (for DC recordings) electrodes are available
- active electrodes connect via g.GAMMAbox to g.USBamp, g.MOBIlab+ and g.BSamp or via an active electrode connector box to g.Hlamp
- dry electrodes connect via g.SAHARAbox to g.USBamp, g.MOBllab+ and g.BSamp
- passive electrodes connect directly to g.USBamp, g.MOBIlab+ and g.BSamp or via a passive electrode connector box to g.Hlamp
- active/dry electrodes can connect via g.GAMMAbox/g.SAHARAbox to 3rd party amplifiers with
 1.5 mm safety input sockets

2 g.GAMMAcap² basic components

g.GAMMAcap² and related items:

1 g.GAMMAcap²



Electrode cap sizes of either S, M or L with chin-strap. small (green seam): 50 - 54 cm (head circumference) medium (red seam): 54 - 58 cm (head circumference) large (blue seam): 58 - 62 cm (head circumference) The electrode positions according to the extended international 10/10 system are indicated on the cap.

A total of 160 electrode positions according to the international 10/10 system are pre-cut. For kids sizes (mini: 32-36 cm, midi: 37-43 cm and maxi: 44-48 cm) only 74 positions are pre-cut.

2 g.GAMMAcap²BELT



Chest belt set consisting of one adjustable chest belt with Velcro strap (90 – 150 cm) and 2 adjustable straps for g.GAMMAcap², a measuring tape and a syringe for gel.

3 g.GAMMAgel and g.GAMMAcream



Special highly conductive high-viscosity electrode gel or cream for g.GAMMAsys active electrodes, water-soluble, non-abrasive, non-greasy, non-irritant, non-corrosive, CE class 1 product, in doser can, 200 g, easy insertion through electrode holes

4 Electrodes

The following electrode types can be used with g.GAMMAcap²:

- g.SAHARAelectrodes (dry)
- g.LADYbird (active)
- g.LADYbird (passive)
- g.BUTTERfly (active)
- g.GAMMAearclip Au (active)
- g.GAMMAearclip Ag/AgCl (active)
- g.SCARABEO electrodes with holder rings

3 Electrode assembly/disassembly and initial cap setup

Select a cap with the appropriate size for your intended application. For recordings in adults the medium sized cap will fit for almost all of the subjects. In case you need different cap sizes we highly recommend to use separate electrodes instead of changing electrodes between different caps as g.GAMMAcap² is not designed for frequent removal of the electrodes.

Insertion of g.SAHARAelectrodes

Step 1

Position the g.SAHARAelectrode at the desired electrode position on the inner side of the cap.

Step 2

Assure that the press-stud socket is not covered by the fabric

Step 3

Attach the g.SAHARAclip to the electrodes

Step 4

The electrode can now be turned to have the wire outlet in the desired direction







Step 3



Step 4

To remove an electrode from the cap, detach the clip from corresponding press-stud socket.

Insertion of g.BUTTERfly electrodes

Place the electrode in the desired orientation over the dedicated hole

Step 1: Insert the left "wing" of the electrode into the hole and stretch the textile to the right side of the electrode

Step 2: Insert the right "wing" into the hole and leave the rest of the electrode outside

Step 3: Assure a similar tension of the textile on both sides of the electrode for optimal fitting









Step 1 Step 2

To remove an electrode from the cap, just stretch the textile carefully and tilt the electrode for removal.

Insertion of g.LADYbird electrodes (active and passive) and g.SCARABEO holder rings

Place the electrode or holder ring over the dedicated hole

Step 1

Insert the rim of the textile into the notch of the black plastic housing at one side of the electrode

Step 2

Retain the inserted textile with a finger and carefully stretch it along the notch. Insert the textile into the notch from the inner side of the cap

Step 3

Assure that the hole in the textile is fully seated in the notch of the electrode housing

Step 4

The electrode can now be turned to have the wire outlet in the desired direction









Step 1 Step 2 Step 3

To remove an electrode or holder ring from the cap, just stretch the textile carefully and tilt the electrode for removal.

Tip: Especially for multi-channel setups it is often helpful to use small cable ties to attach electrode wires to each other and also to the cap (e.g. to the strap fixation rings). Make sure that electrode wires are never strained when the cap is placed correctly on the subject's head. Keep in mind that the cap can be stretched up to 20% depending on head size and shape. Electrode wires can also be attached to the cap with a textile tagging gun using short tagging cords. Make sure that wires are laid in loops to allow for stretching of the fabric.



Small cable ties fixate electrode cables



Short tagging cords attach wires to the cap

Adding additional positions

To add an additional electrode position, a small cut has to be made in the textile with a sharp knife. For g.LADYbird and g.BUTTERfly electrodes a 7-mm long cut along the fiber direction will be suitable. For g.SAHARAelectrodes and g.SCARABEO holder rings a 3 or 4-mm long cut will be suitable.



Wrong!

Do not cut against the fiber direction



Correct!
Cut along the fiber direction



Be careful not to cut more than a slot of a length of 7 mm



You have to cut 7 cross-fibers

Alternatively, a 4-mm hollow punch (3-mm for g.SHAHARA electrodes or g.SCARABEO holder rings) can be used as well for adding additional holes for electrodes. The insertion of electrodes always works as described above.







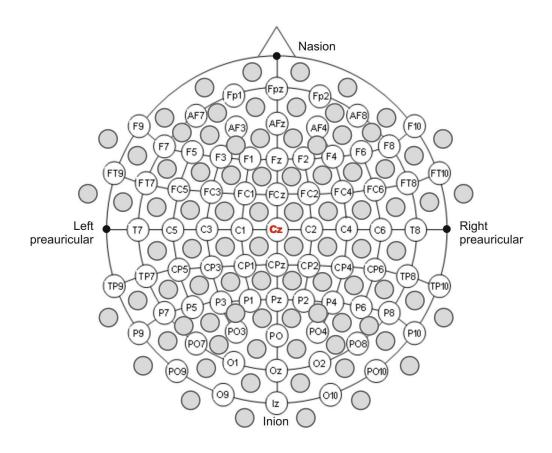


4 Safe Operation of g.GAMMAcap²

The "10-10" system or "International 10-10" system is an internationally recognized method to describe the location of scalp electrodes for EEG recordings. The naming convention of the electrode positions is related to the underlying brain area. The "10" and "10" refer to the fact that the actual distances between adjacent electrodes are 10% of the total front-back or right-left distance of the skull. The human brain is divided into the left and right hemisphere and different brain lobes. Hence the naming convention of the electrodes resembles this anatomical finding. Each electrode site has a letter to identify the lobe and a number to identify the hemisphere location. The letters F, T, C, P and O stand for Frontal, Temporal, Central, Parietal and Occipital lobes, respectively. However, there exists no central lobe. The "C" letter is only used for identification purposes only. A lower case "z" (zero) refers to an electrode placed on the midline. Odd numbers refer to electrode positions on the left hemisphere and even numbers refer to those on the right hemisphere.

The distances between two anatomical landmarks (the Nasion and the Inion) are the basis for the positioning of the EEG electrodes. The Nasion is the point between the forehead and the nose. The Inion is the lowest point of the skull from the back of the head and is normally indicated by a prominent bump. The bump is more pronounced in males compared to females.

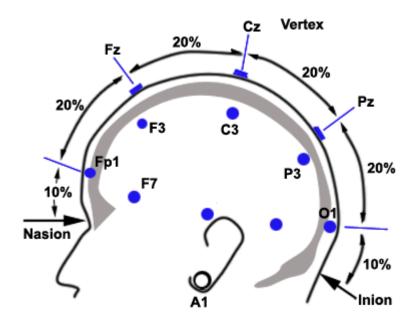
Layout of extended 10-10 system with 74 labeled and further 86 intermediate non-labeled electrode positions



Mounting the electrode cap

In order to properly mount the g.GAMMAcap² measure the distance between the Nasion and Inion and the distance between the left and right preauricular points of the subject. The position at the half of both distances is the vertex position Cz. Put on g.GAMMAcap² and align this measured position with the position Cz of the electrode cap. Now the electrode cap is in the correct position.

Note: Any kind of electrode cap with predefined positions might cause some difference between the "true" 10-20 positions and the positions indicated on the cap. The amount of the deviation depends on cap size, head size and head shape. Always use the electrode position "Cz" to position the cap on the subject's head as a possible deviation keeps lowest in this way.



Nasion - Inion distance

Fix the cap with the chest belt and the adjustable straps to avoid the cap getting out of place. Alternatively you can use the chin strap to fixate the cap.



Fixating the g.GAMMAcap 2 with the chin strap

Skin preparation and application of electrode gel

Attention:

On occasion, the gel/paste used to mount the electrodes to the scalp may irritate the skin.

Dry electrodes

g.SAHARAelectrodes do not need any skin preparation or gel.

Passive electrodes

For passive electrodes (g.LADYbird, passive) preparation of the skin is required to obtain low impedance between the electrode and the skin. Use g.tec's abrasive electrode gel for this purpose. Put a small amount of abrasive gel on the tip of a cotton bud and insert it through the hole in the electrode. Then rub the skin by moving the cotton bud to the left and to the right with slight pressure against the skin for about 10 seconds. This procedure may cause an unpleasing feeling to the subject but should never cause pain! The amplitude of the movement should be between 5 and 10 mm. Avoid rotary movements. Make sure that the gel has contacted an area of about 1 cm² of the skin.





Then insert g.GAMMAgel or abrasive gel with a syringe (without needle) or with the doser can into the electrode. Make sure that the entire electrode is filled with gel.





Check the impedances of all electrodes against the ground electrode using g.Zcheck or use the integrated impedance check when using g.USBamp or g.Hlamp. Assure perfect skin preparation for the ground electrode to obtain reliable impedance values. The impedances should be below 5 kOhm. If the impedance of an electrode is above 10 kOhm, please repeat the abrasive skin preparation.

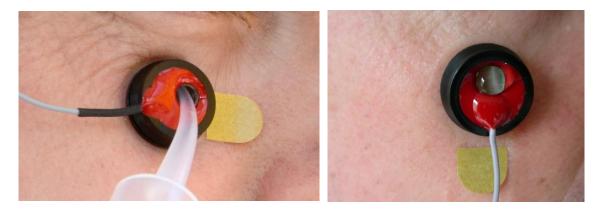
Tip: If g.LADYbird electrodes are used with adhesive washers directly on the skin (e.g. for EOG derivation or as mastoid electrode) the best procedure is as follows: First attach the adhesive washer at the appropriate position but leave the outside protection film on. Prepare the skin with abrasive gel and then remove the protection film to attach the electrode. Now fill the electrode as described above.

Active electrodes

When using g.LADYbird active, g.SCARABEO or g.BUTTERfly electrodes, skin preparation with abrasive gel is not required. However, a perfect contact between the gel and an area of $0.5-1~cm^2$ of skin has to be assured for proper signal quality. g.GAMMAgel is best to be applied with the genuine doser can or with a syringe (for g.SCARABEO use a syringe with a 2-mm blunt cannula). Insert the tip of the doser or syringe into the ready-mounted electrode and make sure to reach the skin. Press the can (or syringe) and move around a bit with the tip on the skin with slight pressure to make sure that gel is distributed on the skin. Then carefully fill the electrode with gel. It is essential that gel fills for sure the gap between the skin and the electrode surface! However, using too much gel may cause shortcuts between electrodes.



g.LADYbird active electrodes can be used with adhesive washers directly on the skin as well (e.g. for EOG or mastoid reference derivation. In this case just mount the electrode and fill it as described above.



g.GAMMAearclip electrodes are attached with g.GAMMAgel as well. Just put a small amount of gel onto the electrode surface (Au or Ag/AgCl disk) and put the earclip to the earlobe with the electrode

outside.



Note: Impedance checking is not required with active electrodes! As soon as the electrodes are correctly filled with gel, the impedance of the signal transmission to the amplifier is at a level of a few hundred Ohms. When using g.Hlamp with active electrodes an internal impedance check can be performed to assure the proper filling of all electrodes.

In case a signal shows high noise, drift or other disturbance check the proper filling of the electrode ring and assure that the gel reaches the skin. Be aware of the fact that the ground electrode is a passive electrode and therefore it is the only electrode that needs to be mounted with special care. A very high impedance at the ground electrode may reduce the signal quality. One can use abrasive gel to prepare the skin at the ground electrode if necessary.

Removal of the electrode cap and cleaning

Note: g.GAMMAcap² is designed to be cleaned and washed with the electrodes remaining in the cap!

After using g.GAMMAcap², carefully disconnect the fixation straps from the cap and put it off. Wash the straps only if necessary as they may lose tension from frequent washing. Clean g.GAMMAcap² together with the electrodes immediately after use. Follow the instructions accurately to avoid damage of electrodes and connectors:

- Soak the cap with electrodes in warm water for 3 5 minutes only in case the gel got dry from long-term use. You may use some liquid soap or shampoo for washing the cap.
- Never put the safety connectors into the water and avoid any contamination with gel!
- Clean the electrodes with a smooth toothbrush under running warm water. Avoid heavy
 mechanical treatment of the electrode surface, especially for sintered Ag/AgCl electrodes. For
 g.SCARABEO electrodes use the special cleaning brush to clean the inside of the electrodes.

- A water pick (oral irrigator) may be used at low pressure for gentle cleaning of g.LADYbird and g.SCARABEO electrodes.
- In the last step rinse the electrodes with clean water. Put one towel inside the cap and one outside to remove the water. Then put the cap to an appropriate place for drying. Avoid stretching the textile during the process of drying.

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

Note: 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 contanination with gel, water or desinfectant
- 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.

Important:

Do not use any detergents!

Do not machine-wash!

Do not use a laundry dryer!

Do not put into ultrasonic bath!

Do not autoclave!

For disinfection (if required) use 'Sekusept plus' disinfection solution or disinfection alcohol (70%, 5 minutes) only. Do not exceed the treatment time indicated in the Sekusept manuals. 'Sekusept plus' is a product of ECOLAB (www.ecolab.com) and is available from most local healthcare providers.



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