MEDICAL
COMPUTER
SYSTEMS

MCScap

EEG electrode caps

USER MANUAL

PRODUCT OFFICIAL INFORMATION

Product name: *MCScap*

Description:

MCScap is system of the EEG-recording cap with removable passive Ag/AgCl electrodes and accessories.

MCScap is intended for use with encephalographs and amplifiers of medical signals, e.g. FirstAmp, NVX and other similar devices.

MCScap can be used in clinical practice, neurology and functional diagnostics, and also to scientific researches.

GMDN code: *63131, Electroencephalographic electrode cap, reusable*

Product code by 93/42/EEC: *MD 0100 General non-active, non-implantable medical devices*

Classification: *class I as per Appendix IX of Directive 93/42/EEC, rule 1.*

Declared for compliance with: *European Directives 93/42/EEC (MDD), 2011/65/EU (RoHS 2), 2002/96/EC (WEEE)*

Manufacturer: *Medical Computer Systems Ltd.*

ADDRESS: Passage 4922, bldg.4-2, Zelenograd, Moscow, 124460, Russia.

PHONE/FAX: +7 495 913 31 94 / +7 495 913 31 95.

E-mail: mks@mks.ru Internet: www.mks.ru Internet-shop: www.mcscap.com

Authorized representative in EU: *GVB-geliMED GmbH.*

ADDRESS: Ginsterweg 4a 23795 Bad Segeberg, Germany.

PHONE/FAX: 0 45 51 - 95 67 30 / 0 45 51 - 95 67 33.

E-mail: export@gvb-gelimed.de Internet: www.gvb-gelimed.de

Customer service: *For questions about this product please contact at:*

WARNING

⚠ *Do not use the EEG cap with removable passive Ag/AgCl electrodes and accessories (hereafter - product) for other purposes than it is intended.*

⚠ *Use IEC 60601-1 standard to combine the product with other devices such as encephalograph. The operator bears the responsibility for use of any devices together with a product. Use of a product with other devices should not lead to failure and-or increase of a risk level of the operator and the patient. Using electrodes of the same type.*

⚠ *Do not operate the product within powerful radio interference producing sources such as arc welders, radio thermal treatment equipment, x-ray machines or any other equipment that produces electrical sparks. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the product, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.*

⚠ *Do not use in magnetic resonance imaging.*

⚠ *Always observe the safety requirements of this manual for operation and maintenance. If any problems don't open the product, do not unauthorized repairs, any doubts please contact your local supplier.*

⚠ *Take care of the product's components. Avoid the cables' breaks, kinks, tension, excessive stretching of the EEG cap and other mechanical efforts. Take care of arranging cables/wires to avoid the risk of entanglement or strangulation.*

⚠ *Electrode sensors are fragile and require careful and caring treatment. Always put electrodes on a soft surface, such as a napkin or a towel.*

⚠ *Reapply of a product present a potential risk of cross-infection especially when are used on abraded skin, unless they are restricted to a single patient or disinfection between patients.*

⚠ *Use the special EEG electroconductive gel/paste for the EEG acquisition.*

⚠ *Don't break the conditions of transportation, storage and operating of the product. Do not expose the product to direct sunlight.*

Warranty

The manufacturer hereby guarantees that the product will be free from any defects in materials and workmanship (except for consumables) for the period of **one year** from the date of delivery. This warranty does not apply to any damages caused by wrong use, modification, and non-fulfillment of operation requirements. If this product requires repair under our warranty, a customer shall notify the supplier or manufacturer about the defects and send the product thoroughly packed in a shipping container to the supplier or manufacturer for the purpose of inspection and service.

Please, look thoroughly through this manual before its use. The manual contains detailed information and guidelines required for proper and safe operation of this product. Failure to follow these requirements may result in wrong results, damage or injury. The manufacturer disclaims its responsibility for any injuries or losses caused by product misuse. The manufacturer reserves its right to make changes and amendments in this manual without notice, which improve the performance of this product. If any misprints occur in this document, they will be corrected in further publications.

Symbols on labels

	Refer to instruction manual		Caution.
	Mild process. Maximum washing temperature 30° C		Hand wash only
	Do not tumble dry		Do not wring
	Do not dry clean		Do not iron
	Drip dry in the shade		Catalog number
	Waste Electrical and Electronic Equipment. Separate collection with electrical and electronic equipments for recycling.		Date of manufacturing.
	This device conforms to Directive 93/42/EEC.		Serial number.

Common description

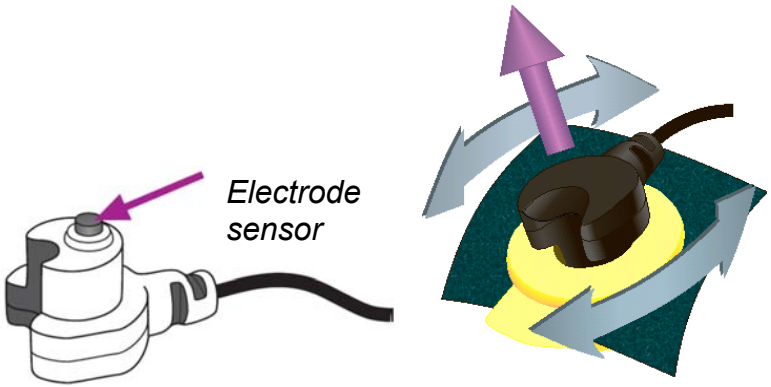
EEG-caps are made of elastic material that provides the most comfortable fit of the electrodes without additional adjustment. Numerous holes are intended for ventilation and electrode alignment to head according to modified combinatorial electrode nomenclature[1].

Many sizes of cap cover the head sizes from 24 cm to 66 cm head circumference. EEG-cap fixed to the head using chin belt or chest belt.

Reusable EEG electrodes have a channel for gel and the recording surface is silver/silver chloride (Ag/AgCl). Sintered technology of sensors guaranties minimal polarization and long-term stability. Electrode contact with the skin is provided through EEG gel.

EEG electrodes fixed to the EEG-cap using special fixing ring or the electrode hole on the cap. EEG electrodes are connected to an electroencephalograph through single or united connectors.

Point EEG electrodes MCScap-E sensor for installation in a fixing ring



Cup EEG electrodes MCScap-NT sensor for installation on the textile base of the EEG-cap (similarly for other electrodes MCScap-C, MCScap-T, MCScap-NTC, MCScap-NTH)

[1] *Oostenveld, R. & Praamstra, P. The five percent electrode system for high-resolution EEG and ERP measurements. Clinical Neurophysiology 2001; 112: 713-719*

INSTRUCTIONS FOR USE

STEP 1. Measure the circumference of the patient's head.

Head size measure around the fullest part of the head just above the ears using a flexible tape measure. Taking the measurement at the forehead. Circumference of the head should be measured at a point approximately one inch above the eyebrows or at whatever point gives the largest possible measurement. After the measuring choose the proper cap size.

STEP 2. Put the cap on the patient.

Beginning from the front of head, where the subject may hold the edge of cap, pulling the cap over of the head. Next, adjust the electrode position **Cz** halfway between Nasion and Inion. The frontopolar and occipital electrode positions should now be placed correctly. Otherwise choose another cap size. When measured correctly, the frontopolar electrodes (e.g. **Fp1/Fp2**) should lie directly above the eye brows.

Make sure, that **Cz** is right-left-centered as well, and that lateral electrode positions are symmetrical.

Affix the cap with the chin belt. Pay attention to the correct location of its. The wide part of a belt should fit a chin and shouldn't slump on the neck. The belt tension should provide reliable fixing of cap.

Don't pull in tight chin belt. The subject should feel comfortable even during long-term research.

Attach the cap on the head is possible with use the chest belt. This type of attachment is effective in cases where during the test pressure of the chin strap hinders the patient's actions, for example, if the patient should talk.

The chest belt is attached directly to the patient's chest. Chest belt is arranged in V-shape or X-shape, which contributes to a secure fit of the cap. Tension is regulated by the length of the straps.

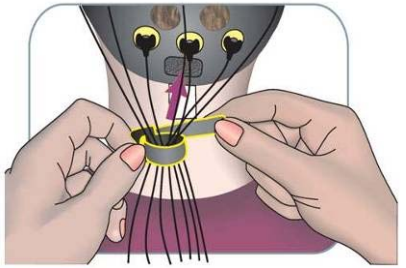
STEP 3. Insert the electrodes in the cap accordance with the research scheme.

Point EEG electrodes insert into fixing ring until it stops.

Cup EEG electrodes insert into electrode hole.

Pay attention that electrode cables are not confused and not bended.

To avoid confusion of wires, use coupler for wires. Insert a coupler tip through the hole at the other end, strongly tighten and then fix a tip with velcro.



STEP 4. Connect the electrodes to the skin through EEG gel.

Fill the syringe with gel. *Gel should not be too fluid nor too viscous.* Set supplied the nozzle-dispenser. The nozzle-dispenser should sit tightly on the syringe and should not hang or subside. Use only supplied the nozzle-dispenser with blunt needle. Spiky needle can damage patient skin.

Slide the hair directly under the EEG electrodes with use the nozzle-dispenser needle. It will help to reduce the impedance and increase the quality of researches.

STEP 5. Fast connection.

In cases where it is necessary to promptly fast disconnect or connect the electrodes mounted on the patient, for example, when registering somnogrammy, can be used passive adapter. It can also be used when it is necessary to increase the distance from the patient to the amplifier.

Minimizing impedances

Recommended to use electroencephalograph in mode of impedance measurement. Insert a syringe needle of the nozzle-dispenser into a hole of electrode and squeeze out a few gel. Then take out a needle from hole and remove remaining gel. If it has not given results repeat procedure. If after that the impedance remains too high, check the electrode.

Maintenance

Electrodes and cap after use should be immediately cleared of gel while it has not dried up!

Recommended a thorough cleaning after each recording. For cleaning a product make sure it is not connected to an electroencephalograph any more. Don't wet the connectors! The connectors must be max far from the any liquids!

For the cap with preinstalled electrodes: Don't take electrodes from the cap with preinstalled electrodes for cleaning after recording. Carefully clean the cap with electrodes together.

For the cap with removable electrodes and TouchProof connectors: Carefully take the electrodes from the cap:
- for a point EEG electrode with rotational motions remove it from the fixing ring;
- for a thin (cup) EEG electrodes pull site of cap portion near the hole of the electrode with another hand and remove the electrode from the hole. Do not pull the electrode!

Under most circumstances cleaning of caps and electrodes is carried out in a detergent. Be attentive: dish-detergents often leave a film. A children's shampoo will be a good choice. *Improper maintenance can lead to product damage. Do not use abrasive materials, strong disinfectant solutions, for example, on acetone basis to product clearing.*

For disinfection use 70% ethanol solution. Never soak a product in the solution but wipe it with soft gauze moistened with ethanol. Before disinfection carefully wash out a product from the gel rests. Also, gas sterilization with ethylene oxide is acceptable.

Warning

- do not soak electrodes in saline solution or chloride because salt is generally aggressive to the electrodes' surface and corrosion of connections will result;
- do not use autoclave or other hot sterilization methods because the wire insulation can be damaged.

Afterwards rinse the cap with warm water and the electrodes with distilled water. Finally dry them thoroughly with a soft cotton cloth. The rest can be dried in the air.

The electrodes and caps should be stored in a dark and dry place. When assembling a product follow the research scheme. In case of damage contact your supplier.

See video *How to clean MCScap products?* at our website www.mcscap.com/video/

Malfunctions and their correction

Malfunction	Possible cause	Corrective actions
Torn cap.	Excessive stretching and other mechanical efforts of the EEG cap.	Replace the EEG cap.
Electrode positions on the head are no correctly.	Larger or smaller of the cap.	Use another cap size.
	Erroneous placement of electrodes.	Insert the electrodes in the cap accordance with the research scheme.
Electrode connectors can not be connected to the cap	Electrode connectors do not comply with the cap.	Replace the electrode or the cap.
Electrode connectors can not be connected to the electroencephalograph.	Electrode connectors do not comply with the electroencephalograph.	Replace the electrode.
No signal.	Electrodes are not connected to the electroencephalograph.	Connect the electrodes to the electroencephalograph.
	No contact between an electrodes and patient's skin.	Minimizing impedances.
	Electrodes are faulty.	Replace the electrode.
	Wet cap.	Dry cap.
One or several EEG leads have high level of noise.	Poor contact between an electrode and patient's skin	Minimizing impedances.
	System are located near to the power line sources that generate disturbances	Bring system as far apart as possible from electric wiring, outlets, transformers or other electric power equipment.

If you fail to remedy a trouble, contact the local supplier or manufacturer.

Technical data

Parameter	**Value**			
SET	**CLINIC**	**SLEEP**	**PROFESSIONAL**	**ELECTRODE SET**
Image				
Recommended application area	routine EEG	routine EEG, sleep EEG, high resolution EEG, TMS-EEG	scientific research, high resolution EEG, *MR-compatible EEG available by order*	routine EEG, scientific research
Electrode type	MCScap-C	MCScap-T	MCScap-NTC *MCScap-NT available by order*	MCScap-E *MCScap-T, MCScap-NT, MCScap-NTH available by order*
Material of electrode sensor	Ag/AgCl	Ag/AgCl sintered	Ag/AgCl sintered	Ag/AgCl sintered
Number of electrodes (channels)	20 (19)	20 (19) *from 11 up to 129 available by order*	20 (19) *from 11 up to 129 available by order*	25 (24) *from 11 up to 129 available by order*
Electrode polarization	≤ 50 mV	≤ 50 mV	≤ 50 mV	≤ 50 mV
Resistance of electrodes insulation	≥ 1000 MΩ	≥ 1000 MΩ	≥ 1000 MΩ	≥ 1000 MΩ

Parameter	**Value**			
SET	**CLINIC**	**SLEEP**	**PROFESSIONAL**	**ELECTRODE SET**
Dielectric strength of electrodes insulation	1500 V	1500 V	1500 V	1500 V
Diameter of a conductive surface	6(+1/-1) mm	3(+1/-1) mm	6(+1/-1) mm	depending on the type of electrode
Square of a conductive surface	26(+1/-1) mm^2	7(+1/-1) mm^2	≥ 30 mm^2	depending on the type of electrode
The impedance of the electrode	≤ 5 kΩ	≤ 5 kΩ	≤ 5 kΩ	≤ 5 kΩ
Spare electrode	no	no	1	1
Channels in Standard caps	Fp1, Fp2, F3, F4, C3, C4, P3, P4, O1, O2, F7, F8, T3, T4, T5, T6, Cz, Fz, Pz, GND	Fp1, Fp2, F3, F4, C3, C4, P3, P4, O1, O2, F7, F8, T3, T4, T5, T6, Cz, Fz, Pz, GND	Fp1, Fp2, F3, F4, C3, C4, P3, P4, O1, O2, F7, F8, T3, T4, T5, T6, Cz, Fz, Pz, GND	According to system 10-20, 10-10, 10-5
Ear electrodes	no	no, *can be included by order*	no *can be included by order*	yes
Marking of the electrodes	yes	yes	yes	no (labels for marking are Included)
Additional wire protection	no	no	yes	no
Exit of electrode cable from the cap	back of the head	top of the head	back of the head	no
Connector type	D-sub DB25 Male	D-sub DB25 Male	D-sub DB25 Male	TouchProof 1.5 mm (DIN 42 802-ST)

Parameter	Value			
SET	**CLINIC**	**SLEEP**	**PROFESSIONAL**	**ELECTRODE SET**
Length of the electrode cable	1.2 m	1.5 m	1.5 m	1.2 m
Standard set	EEG cap CLINIC, EEG starter kit (gel, syringe, needle, brush), User manual	EEG cap SLEEP, additional fixator (elastic bandage), EEG starter kit (gel, syringe, needle, brush), User manual	EEG cap PROFESSIONAL, 1 spare electrode with TP connector, EEG starter kit (gel, syringe, needle, brush), bag, User manual	2 textile caps MCScap 10-20 with fixing rings, 26 EEG electrodes MCScap-E, ear electrode fixators, 2 sets of labels for marking electrodes, EEG starter kit (gel, syringe, needle, brush), bag, User manual
Available sizes	*XL (60-66 см), XL/L (57-63 см), L (54-60 см), L/M (51-57 см), M (48-54 см), M/S (45-51 см), S (42-48 см), S/XS (39-45 см)*	*XL (60-66 см), XL/L (57-63 см), L (54-60 см), L/M (51-57 см), M (48-54 см), M/S (45-51 см), S (42-48 см), S/XS (39-45 см) XS (36-42 см), Inf I (32-36 см), Inf II (28-32см), Inf III (24-28см)*	*XL (60-66 см), XL/L (57-63 см), L (54-60 см), L/M (51-57 см), M (48-54 см), M/S (45-51 см), S (42-48 см), S/XS (39-45 см)*	*XL (60-66 см), XL/L (57-63 см), L (54-60 см), L/M (51-57 см), M (48-54 см), M/S (45-51 см), S (42-48 см), S/XS (39-45 см)*
Size by color	by color of the textile cap	by color of the seam	by color of the seam	by color of the seam

Parameter	**Value**			
SET	**CLINIC**	**SLEEP**	**PROFESSIONAL**	**ELECTRODE SET**
Weight	less 1 kg	less 1 kg	less 1 kg	less 2 kg
Mean time to failure (MTTF)	150 cycle	300 cycle	300 cycle	300 cycle
Warranty	12 months	12 months	12 months	12 months
Mechanical resistance	according IEC 60601-1:2005 (ed3.1)			
Operating conditions	+10 ... +45°C, relative humidity of 40 to 80%			
Storage conditions	+5 ... +45°C, relative humidity up to 80%			
Transportation conditions	-50 ... +50°C, relative humidity up to 97% without condensation			

Note:

1. The default settings are highlighted **in bold font**.

2. Cycle refers a use, disassembly, washing and disinfection of the helmet, cleaning and disinfection of the electrodes.

Compliance Restriction of Hazardous Substances

The object is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2).

Utilization

This device is subject to disposal upon expiration of its service life, providing that its performance is fully used up.

This device must be disposed according to regulations of local legislation. If the EU countries, electronic equipment is subject to the European Directive 2012/19/EU (WEEE). Do not dispose this device with normal household waste.

Electrode nomenclature according to: *Oostenveld, R. & Praamstra, P. The five percent electrode system for high-resolution EEG and ERP measurements. Clinical Neurophysiology 2001; 112: 713-719.*

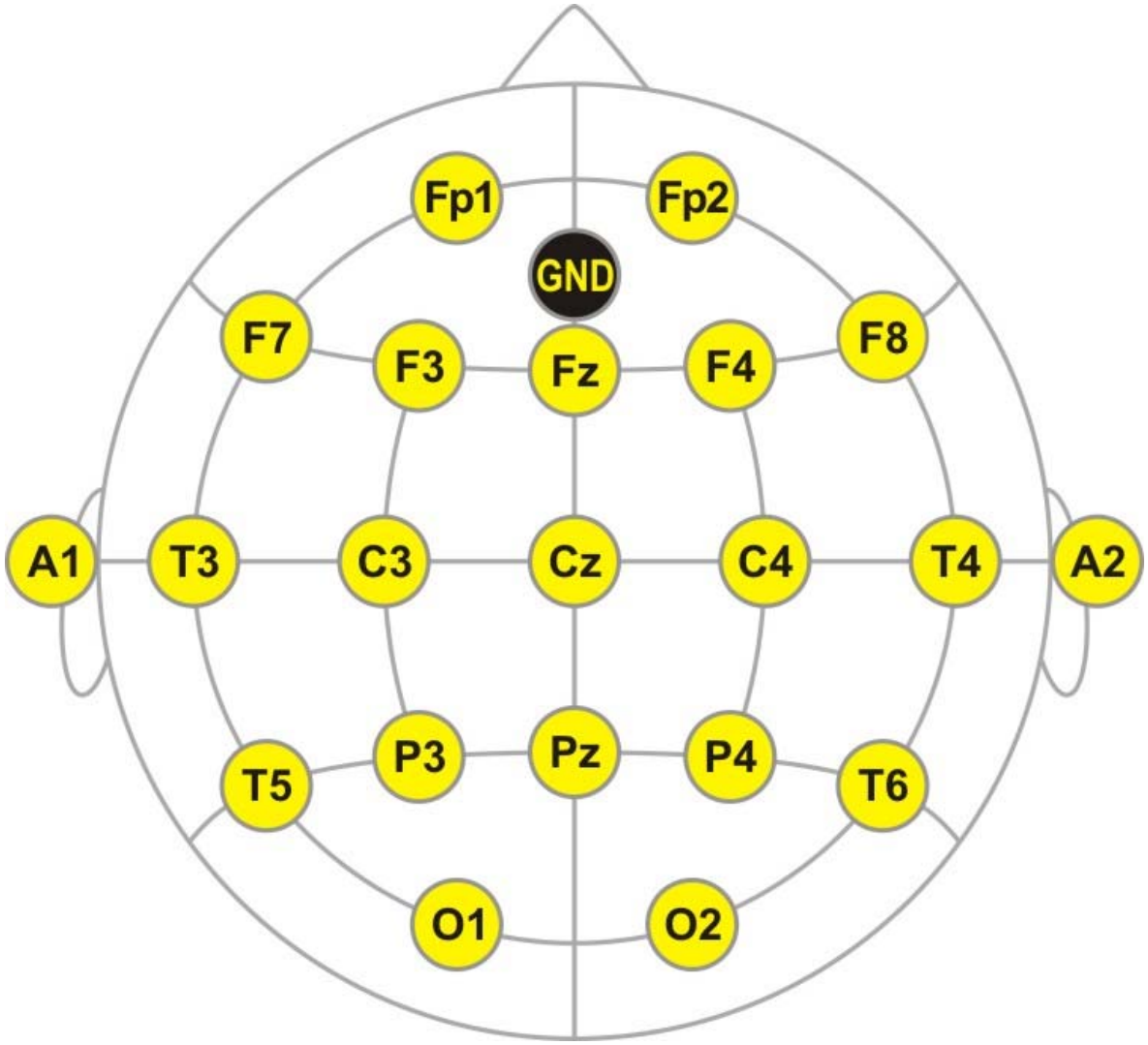
10-20 system

Electrode positions and labels:

- *yellow circles indicate positions of the 10-20 system (**T3, T4, T5 and T6 corresponds to T7, T8, P7 and P8** of the 10-20 system)*

- black circles indicate positions of the *"ground" **GND** (AFz of the original 10-20 system**)** EEG electrode*.

*NOTE: **A1** and **A2** electrodes are placed on the left and right ear lobes.*

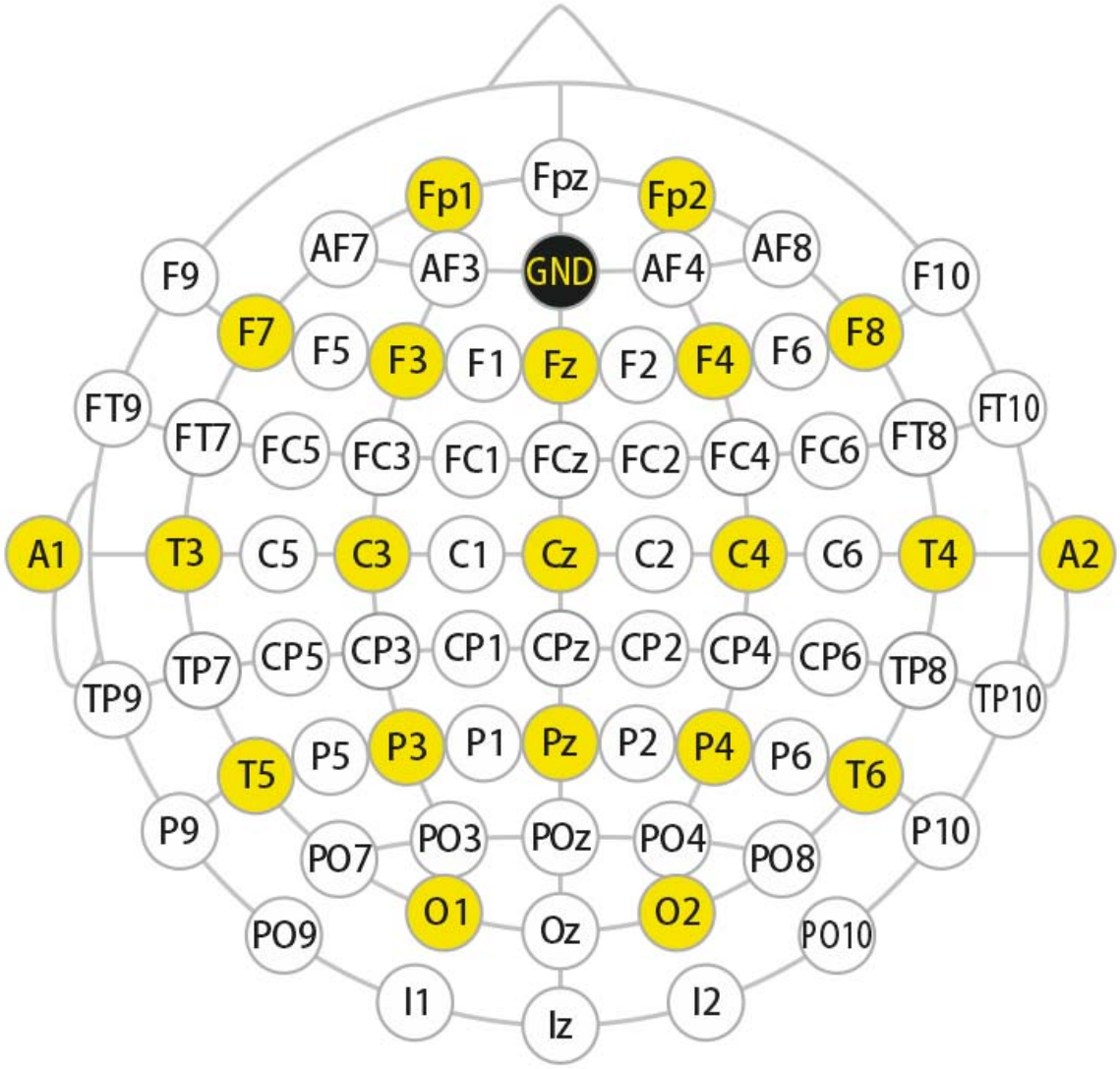


10-10 system

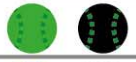
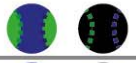
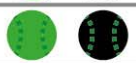
Electrode positions and labels:

- yellow circles indicate positions of the original 10-20 system,
- white circles indicate additional positions introduced in the 10-10 extension,
- black circles indicate positions of the *"ground"* ***GND*** *(AFz of the original 10-20 system**)** EEG electrode*.

*NOTE: **A1** and **A2** electrodes are placed on the left and right ear lobes.*



MCScap size table

Size	Head circumference	Color of cap/ seams	Intended for
XL	60-66 cm	green 	adults
XL/L	57-63 cm	green and blue 	adults
L	54-60 cm	blue 	adults (most)
L/M	51-57 cm	blue and red 	adults
M	48-54 cm	red 	children, women
M/S	45-51 cm	red and yellow 	children
S	42-48 cm	yellow 	babies
S/XS	39-45 cm	yellow and green 	babies (up to 1 year)
XS	36-42 cm	green 	infants (up to 3 months)
Inf I	32-36 cm	blue 	newborn infants
Inf II	28-32 cm	red 	newborn infants, preemies
Inf III	24-28 cm	yellow 	newborn infants, preemies

Correct size is important for quality EEG acquisition and patient comfort.
Check the head circumference of patient before EEG examination.