

COMBY EEG CAP INSTRUCTION FOR USE

Name of the medical device:

COMBY EEG CAP with 21 electrodes connected to D-Sub 25 pin connector

Intended use: For EEG and QEEG recordings

Specifications:

1. Molded foam elastic rubber 5mm in diameter, which is made of rubber network connected by plastic connectors. Spaces are set according to the International 10-20 system. The Caps are made in six different sizes depending on the circumference of the head.
2. Electrodes (gold-plated or sintered silver-silver chloride) 8 mm in diameter.
3. Contact wires are connected to the electrode by soldering. Soldering point is isolated. Sealed in a plastic housing, so there is no possibility of contact with the conductive contact gel. The electrodes are positioned on the rubber network. Since the electrode wires are pulled through a hole in the plastic housing of other electrodes, in the plastic tube. At the end of the plastic tube the wires are connected to the 25 pin D-SUB connector.



Packing:

- 1 Comby EEG cap
- 1 instruction for use and maintenance with a technical data
- 1 packet with 5 extensions for the gel application
- 2 sticks with cotton wool
- 1 tape measurement for selection of the caps according to head circumference

LABELING

On the label on the product is a unique serial number and catalogue number.

CECXYYZZZ

CEC- COMBY EEG CAP

X- MATERIAL MARK, 1 – for sintered Ag/AgCl electrodes, 2 - for gold plated electrodes

YY- number of electrodes built into the Cap ZZZZ- CAPS SIZE, example: 4752 means a size 47-52

Article no.	DESCRIPTION	
CEC1215762	Comby EEG cap with 21 electr. green, Ag/AgCl sint.	size 57-62 cm
CEC1215257	Comby EEG cap with 21 electr. red Ag/AgCl sint.	size 52-57 cm
CEC1214752	Comby EEG cap with 21 electr. yellow, Ag/AgCl sint.	size 47-52 cm
CEC1214247	Comby EEG cap with 21 electr. green, Ag/AgCl sint.	size 42-47 cm
CEC1213742	Comby EEG cap with 21 electr. red, Ag/AgCl sint.	size 37-42 cm
CEC1213237	Comby EEG cap with 21 electr. yellow, Ag/AgCl sint.	size 32-37 cm
CEC1112732	Comby EEG cap with 11 electr. yellow, Ag/AgCl sint.	size 27-32 cm

Article no.	DESCRIPTION	
CEC2215762	Comby EEG cap with 21 electr. green, goldplated	size 57-62 cm
CEC2215257	Comby EEG cap with 21 electr. red, goldplated	size 52-57 cm
CEC2214752	Comby EEG cap with 21 electr. yellow, goldplated	size 47-52 cm
CEC22134247	Comby EEG cap with 21 electr. green, goldplated	size 42-47 cm
CEC2213742	Comby EEG cap with 21 electr. red, goldplated	size 37-42 cm
CEC2213237	Comby EEG cap with 21 electr. yellow, goldplated	size 32-37 cm
CEC2112732	Comby EEG cap with 11 electr. yellow, goldplated	size 27-32 cm



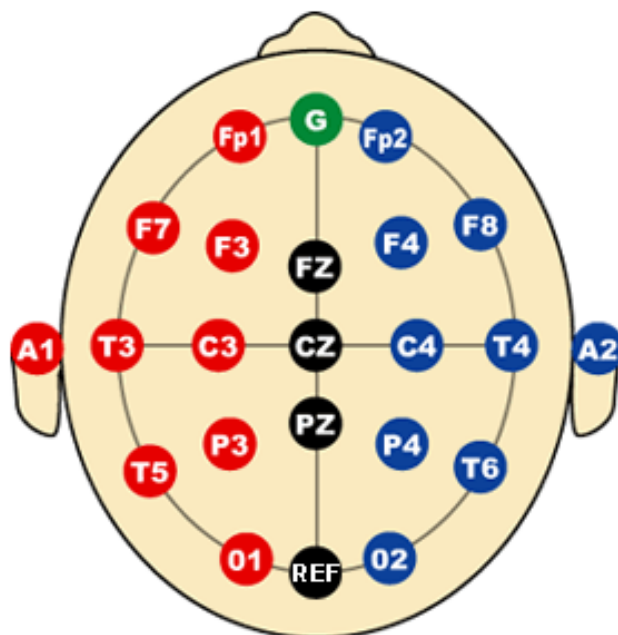
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Figure of the International 10-20 system



Standard pin-out + (Ref)

Pin on Sub-D connector	Electrode	Position on the head	Pin on Sub-D connector	Electrode	Position on the head
1	Fp1	L	14	Fp2	R
2	F3	L	15	F4	R
3	C3	L	16	C4	R
4	P3	L	17	P4	R
5	O1	L	18	O2	R
6	F7	L	19	F8	R
7	T3	L	20	T4	R
8	T5	L	21	T6	R
9	Gnd	C	22	Cz	C
10	Fz	C	23	Pz	C
11	Ref		24		
12			25		
13	Ref				

L-left side of the head
R-right side of the head
C-central part of the head



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INSTRUCTIONS FOR USE COMBY EEG CAPS

Comby EEG cap is different from the other caps, because are based on its ease use, availability of electrodes, the possibility of moving the electrodes if necessary: if there is a defect or a bone defekt, nevus, fresh wounds. They have very good ventilation and sweating artifacts are mostly avoided. Application of a contact gel is with plastic blunt tip. No options to cause bleeding as it is the case in other EEG caps where the gel is applied with a metal needle. Electrodes are placed with accordance to International 10-20 system, but must meet the proper selection of Cap with regard to the head circumference. If the electrodes must be moved, it is necessary to emphasize in the recording description. After recording electrode is necessary to return to its original place.

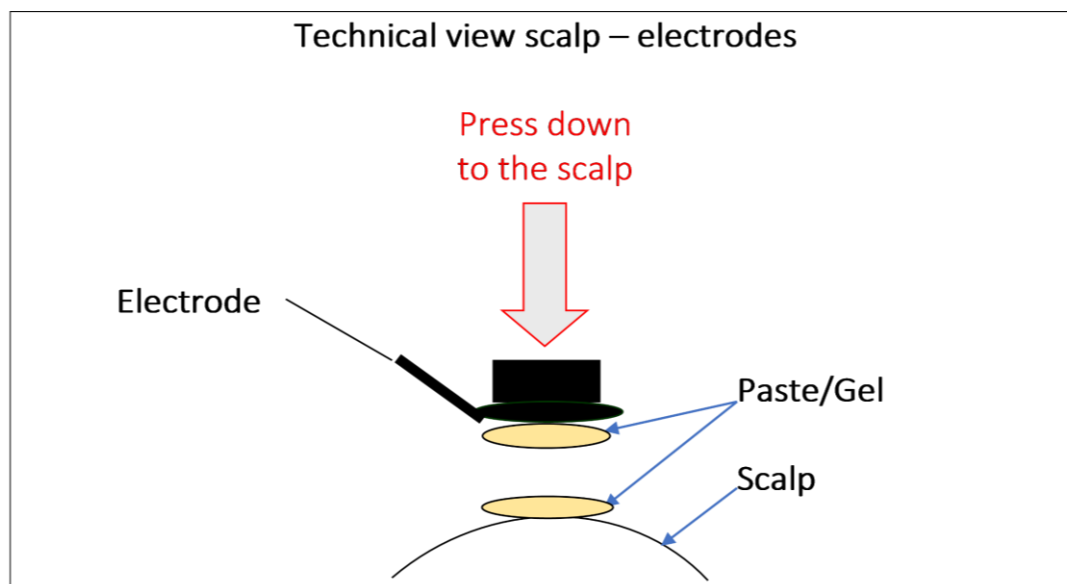
The gel is applied in a way to lift the electrode left or right side gently from the scalp, parted hair using gel applicator, gently abrasion with applicator, if needed clean the skin with NUPREP, and then put the contact gel under the electrode.

As standard, the Comby EEG caps can be ordered with 20-23 electrodes, which include additional electrodes, such as Ref, A1 and A2. We also produce caps on the client request and the type of recording we are producing the Caps made in accordance to the partial I10-10 System up to 42 electrodes.

Comby caps can be connected to the EEG device directly if your EEG device has a 25-pin connector or via adapter cable.

Instruction for the patient for EEG recording

1. Wash the hair with shampoo.
2. Do not use hair preparation: gel, hair spray, hair oil, foam...
3. Do not come to EEG with wet hair
4. Do eat before EEG (possibility of hypoglycemia)



For the technically optimum recording quality is necessary to meet the following requirements:

1. Choose the correct size by measuring the circumference of the head cap with attached measuring tape
2. Before the first recording or after a long break, the electrodes clean with cotton wool soaked in

physiologic saline

3. Ensure that all electrodes are tight-fitting to the head
4. Tighten the Cap under the chin or on the chest belt
- 5 spaced hairs with a plastic gel applicator and at the same time slightly abrasion a skin by moving the applicator left right
6. If necessary, use an abrasive paste (Nuprep)
7. Apply a sufficient amount of gel, just below the electrode (not in the around to avoid a short circuit between adjacent electrodes)
8. Recommended to achieve impedance about 5 kohms
9. If the impedance is too high check contract electrode-skin, or accuracy of contact wire (option of the brake: faulty wiring, connector)



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10. It is not allowed to record with different types of electrodes (e.g., a cap with gold-plated electrodes, and the ear, or the reference electrode of the tin)

11. If the gel dries on contact electrodes it creates an insulating layer and prevents recording because it creates a high resistance. Gel should be cleaned from the electrodes after each or daily recording with distilled water

CLEANING, MAINTENANCE AND DISINFECTION OF COMBY EEG CAPS

COMBY EEG CAP is supplied non-sterile, and is intended for reuse. After completing daily or as needed recording, a Cap wash in warm water with a light solution of liquid disinfectant detergent (such as Ivory or similar, or disinfectant hand detergent). With a cotton stick sodden in the distilled water, clean any residual layer of gel on each electrode. Rinse and dry the Caps with the towel (cotton or paper) and leave to dry for the next day.

Pay attention to the residual layer of gel which could dry in the same of electrodes, because it creates high resistance layer that prevents the recording.

In the procedure of disinfection please use solutions like MetriCide or similar. Disinfection process should be carried out according to disinfectant's manufacturer instructions.

Exclusively with cotton stick soaked in distilled water clean any residual layer of gel on each electrode.

WARNING

It is not allowed to use abrasive or sharp objects to clean the electrodes as this may result in permanent destruction of the electrodes!

Usage of strong disinfectant significantly shortens the Cap's lifetime!

Contact gel should be applied with attached plastic applicator!

DISPOSAL OF COMBY EEG CAP

Comby EEG Cap is a medical device and needs to be disinfected before disposal. Parts of COMBY EEG CAP are electronic equipment and need to be disposed according to local regulation for electronic waste.

IMPORTANT:

This is a medical device. Please consult this instruction for usage before starting to work.

The device is to be used only by authorized and EEG trained medical personnel.

Please also consult our videos

<https://bit.ly/combyeegcapPREZ>

<https://bit.ly/combyeegcapINSTR>

EUDAMED INFORMATION

BASIC UDI:

385889415COMBYEEGCAPPP

SRN Single Registration Number :

Not available yet in Croatia

CE marked from 2000
In compliance with ISO 13485:2016
QMS per EN ISO 9001:2015



ISO 13485
LL-C (Certification)



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