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# USER MANUAL

## Disposable EEG Electrodes

### 1. Product model

Flex-cap

### 2. Indication for use

Disposable EEG Electrodes (models: FLEX-CAP) is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.

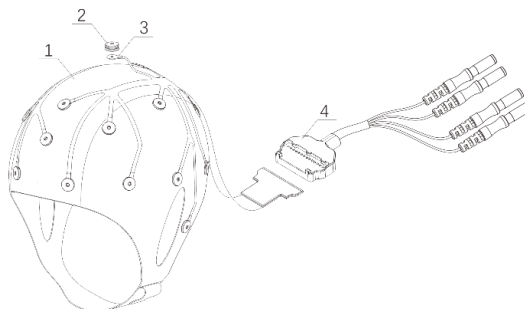
### 3. Warnings

- 1) Do not use for electrical stimulation.
- 2) The size, shape, and type of electrodes may affect the safety and effectiveness of recording.
- 3) The electrical performance characteristics of electrodes may affect the safety and effectiveness of recording.
- 4) You should contact the manufacturer of the recording device if you do not know if the electrode can be used with the recording device.
- 5) Disposable EEG electrodes is non-sterile and single use only.
- 6) Do not place the electrodes on a wound or inflamed skin.
- 7) Check for any adverse skin reactions. If some adverse reactions occurred at the scalp (skin), the cap should be taken off from the head immediately.

### 4. Precautions

- 1) The long-term effects of cutaneous electrodes for recording are unknown.
- 2) Keep electrodes out of the reach of children.
- 3) Use caution if electrodes are applied over areas of skin that lack normal sensation.

### 5. Product Structure and composition

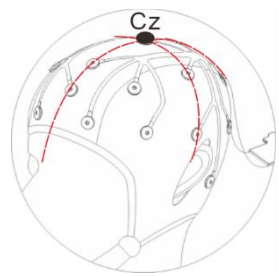
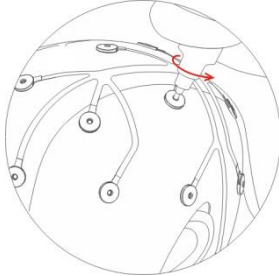


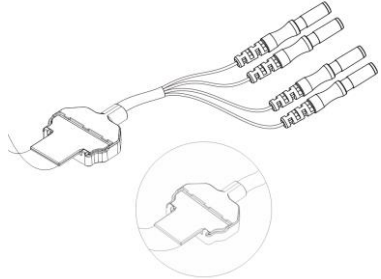
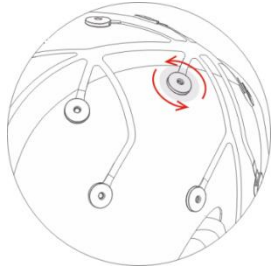
| No | Name   | Qty   |
|----|--|-------|
| 1  | Elastic fabric cap   | 1     |
| 2  | Electrode base   | 2-128 |
| 3  | Printed Electrodes   | 2-128 |
| 4  | M-Quick connector cable with touch-proof safety sockets DIN42-802 ( $\Phi=1.5\text{mm}$ ) (non-disposable) |       |

## 6. Technical Specifications

- (1) The electrode resistance:  $<100\ \Omega$
- (2) AC impedance:  $< 2\text{k}\Omega$  (at 10 Hz)
- (3) DC offset voltage:  $<100\ \text{mV}$
- (4) Combined offset instability and internal noise: after a 1 min stabilization period, a pair of electrodes connected gel-to-gel shall not generate a voltage greater than  $150\ \mu\text{V}$  p-p in the passband (first-order frequency response) of 0.15 to 100 Hz, for a period of 5 min following the stabilization period.
- (5) Bias current tolerance:  $\leq 100\ \text{mV}$
- (6) Type of Connectors: touch-proof safety socket DIN 42 802 ( $\Phi=1.5\text{mm}$ )

## 7. Instruction for use

|   |   |
|---|---|
| Step 1: Select the appropriate size of Disposable Electrodes according to patient's head size.  |   |
| Step 2: Take out the disposable EEG electrodes cap from a package bag. Align Cz on its position, then put on the cap on patient and fix the chin strip.                                 |  |
| Step 3: Inject conductive gel into scalp under the electrodes by a syringe with a blunt needle, and then rotate the syringe gently assisting the conductive gel penetration into scalp. |  |

|  |   |
|--|---|
| <p>Step 4: Connect the electrodes to M-Quick connector cable with touch-proof safety sockets DIN42-802 (<math>\Phi=1.5\text{mm}</math>), then to EEG equipment via touch-proof safety socket DIN 42 802 (<math>\Phi=1.5\text{mm}</math>) connector at the end of the cable.</p>  |  |
| <p>Step 5: Press or tap each electrode slightly towards to scalp and assist conductive gel reaching the scalp. If the impedance of an electrodes is high and affects the reading, user should rotate the electrode gently until the impedance values reach the requirements. The key point is to make sure that the contact is established between electrodes and scalp, via conductive gel or paste.</p>  |  |
| <p>Step 6: After completing the record, remove the cap from patients' head.</p>  |   |
| <p>Step 7: After remove the cap, use a soft tissue or towel to clean the residue conductive gel gently and/or wash head using warm water, applying shampoo is recommended.</p>   |   |
| <p>Note: The using time of the caps to recording EEG signals depends on the kind of electroconductive media which is used. The maximum duration of use is recommended no more than 24 hours. If more than 24 hours recording process is needed, pay attention to user comfort and skin allergic reactions. If the impedance of the electrodes is too high during long-time recording, adding additional electroconductive media during the recording process into the electrodes is feasible.</p>  |   |
| <p><b>Tips:</b> Scalp preparation before using Disposable electrodes. Whether processing the skin preparation depends on your needs, there are several methods can be considered as follows.</p> <p>(1) When low impedance is needed in EEG measurement, the skin preparation is recommended by using a cotton swab with abrasive gel or with medical ethanol to rub onto skin where will mount electrodes.</p> <p>(2) Press or rotate the electrodes at the mount sites lightly with 4 or 5 small circular motions is an effective way to reduce electrode impedance.</p> |   |
| <p>Handling instructions: This product is disposable, the product after use should be disposed in accordance with local regulations</p>  |   |

## 8. Troubleshooting

| Problem   | Suggested Solution  |
|---|---|
| EEG machine indicates that certain electrodes have high impedance | Slightly press or rotate the electrode.   |
| All electrodes have mains-type (50Hz) noise                       | Ensure that the REF & GND electrodes have been in good contact to scalp with enough conducting gel, which ensures the reference electrode and the earth electrode are in good working order. If they are floating off the scalp, the noise on all electrodes will appear. |
| All electrodes exhibit motion artefact when someone passes by.    | Improve the scalp contact of the REF & GND electrodes. Make sure the REF & GND electrodes are not pulled off by the weight of the ribbon cable.   |











## 9. Storage

Store in a dry place and keep away from sunlight.

## 10. Shelf life

2 years.

## 11. Reference of symbol

|   |  |   |                     |
|---|--|---|---------------------|
|  | Batch number   |  | Date of Manufacture |
|  | Please read the instruction Book carefully before using                                      |  | Validity            |
|  | Warning , please refer to the instructions in the annex                                      |  | Manufacturer        |
|  | Keep away from sunlight  |  | Keep dry            |
|  | European union authorized representative   |   |                     |
|  | The product meets the basic requirements of European medical devices directive 93 / 42 / EEC |   |                     |



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## 12. Manufacturer & EU Representative Information



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