

720 01 K

Disposable Neurology Surface Electrode 720-15-K Wet Gel with 150 cm lead wire and K connector



Recommended Applications:	Surface EMG Evoked Potentials (EP) Polysomnography (PSG) Intra Operative Monitoring (IOM)
Features:	Pre-gelled and self adhesive Instant Electrical Contact and an instant signal Strong Adhesive
Directions:	Prepare the skin using paste or abrasive. Degrease using alcohol swab. Peel electrode from its protective backing and apply. Press on the edge to ensure maximum adhesion. DO NOT press over the sensor area.
Storage:	Electrodes should be stored between 10°C and 25°C (50°F and 77°F)
Shelf Life:	In unopened pouches: 12 months. In opened pouches: 1 month We recommend to close the pouch tightly with a clip.
Packing:	10 electrodes in a pouch 50 pouches in a box (500 electrodes) Pouch = Laminated foil bag
Precautions:	Single patient use only. For monitoring and recording bio potential from the site on the skin. Not for stimulation. US: Federal law restrict this product to be used only by or by order of a physician.
Electrode Size:	22x30 mm
Measuring Area:	Measuring area 95 mm ² Sensor area 7 mm ² . Sponge area Ø11 mm.
Sensor material:	Silver/Silverchloride (Ag/AgCl)
Connector type:	K - male 1.6 mm
Conductive Media:	Pre-gelled conductivity wet gel
Adhesive:	Medical Acrylic Adhesive
Backing Cap Material:	Foam PVC
Duration Time:	Up till 24 hours
Typical Electrical Properties:	
DC offset:	0.5 mV
Impedance:	800 ohm
Slope:	0.3 mV/sec
Manufacturer:	Medicotest A/S

QUALITY SPECIFICATION FOR MEDICOTEST DISPOSABLE ELECTRODES

Between 5% and 10% of all electrodes produced are inspected in the Quality Control Department. All measurements are in accordance with the specifications in the AAMI Standard, "Standard for Pregelled Disposable Electrodes".

1 Electrical Specification

- 1.1 AC Impedance: 10Hz impedance with a level of impressed current not exceeding $100\mu\text{A}$. Test generated on electrode pair connected gel-to-gel.

medicotest electrodes: Average 0.5K ohm (AAMI standard less than 2.0K ohm).

- 1.2 DC Offset Voltage: Polarization potential generated by an electrode pair connected gel-to-gel.

medicotest electrodes: Average 0.3mV (AAMI standard less than 100mV).

- 1.3 Defibrillation Overload Recovery: Value of polarization potential across the electrode pair and rate of change of the recovery of the slope after a simulated defibrillation.

medicotest electrodes: After 5 seconds $< 13\text{mV}$ slope maximum $0.3\text{mV}/\text{sec}$, average $0.1\text{mV}/\text{sec}$ (AAMI standard $< 100\text{mV}$, slope maximum $1.0\text{mV}/\text{sec}$).

2 Electrolyte Gel

The main ingredients of the gel are sodium chloride, polyvinylpyrrolidone, hydroxyethylcellulose and preservatives.

The composition of the gel and the concentration of salts are carefully monitored and controlled. The pH of the gel is maintained at $\text{pH } 7.0 \pm 0.2$.

The amount of gel dosed onto the electrodes is carefully controlled varying less than 5% from the target weight.

3 Raw Materials

All raw material used undergoes daily Quality Control to ensure consistency of quality.

4 Traceability

A system of "Batch Numbers" ensures that for each batch of electrodes, time and date of production, operator, machine and raw material used are registered.

5 Other Measurements

To ensure product quality other quality control checks include:

Distribution of paste
Viscosity of paste
Stress test, on bond between press-stud and electrode
Stress test, on lead
Stress test, on finished electrode.

6 Shelf Life

To ensure that all electrodes have a shelf life of at least 2 years unopened and 3 months opened both long term monitoring and accelerated tests are used.

7 Manufacturing

Quality Control inspectors make planned and spot checks on equipment and manufacturing procedures.

8 Final Inspection

Between 5% and 10% of all electrodes are sent for quality control prior to movement to stock.

9 Electrode Design

Electrode design is the key parameter in the production of a quality electrode.

The construction of an electrode with a decentred press-stud minimizes the amount of artefact caused by movement of the skin or electrode even when the lead is pulled.

The use of wet gel offers a large contact area to the skin and so reduces the skin impedance.