

EEG PREWIRED HEADCAPS



BIONEN S.A.S.

Via P. Petrocchi, 42/1
50127 Firenze – Italia
www.bionen.it

BIONEN
medical devices

GENERAL INFORMATION

Intended use: Electroencephalogram (EEG) on integral skin

Instructions for use: Using a meter, measure the patient to determine the appropriate measure headphones to the actual size of the head and measure the distance nasion-inion directly along the median axis of the scalp. Locate the position of the two front electrodes (Fp1 and Fp2) on the patient's forehead above the nasion to 10% of the distance nasion-inion (eg. If the distance is nasion-inion 36 cm, Placing the electrodes in 3,6 cm above the nasion) and mark this position with a pencil. Fit the headset by placing the two front electrodes in the points identified, all other electrodes will automatically be positioned, if the measurement of the headset is adequate.

Attach the headset using the preferred mounting methods:

- Connect the chest strap a few centimeters above the mamillary line and fix the two shoulder straps of the headphone crossing them to adhere better to the headset on the head.
- Connect the chin to the two fastening rings side of the headset.

Clean the skin carefully through the holes of the electrode by means of degreasing with abrasive creams or solutions. Use a cotton swab to models with cylindrical electrodes, a needle bevel for all other models. To promote contact between skin and electrode, fill the wells of electroconductive cream electrodes by means of a syringe with needle bevel or directly using the cream of the tube (in models with cylindrical electrodes).

After inserting the connector into the registrant machine, measuring the interelectrode impedances. If some electrodes with impedances are too high, re-apply the electroconductive cream and use August chamfer / cotton swab so as to scarify the underlying skin.

The application of the cap and of the electrodes is painless and does not cause discomfort to the patient.

Cleaning instructions: After use, at the end of shift, the headset must be washed, both for hygienic reasons and because all the cream must be removed from the headset, to avoid that the fabric loses elasticity.

Use detergents for delicate clothing. Other detergents or soaps, especially those commonly used in hospitals, they leave a residual film on the electrode. After a few washes the film will isolate the electrode

and artifacts will occur. Before washing the headset remove metal clips. Remove mechanically or by means of a jet of water residues electroconductive cream.

Immerse the headset in cold water with detergent for delicate garments for 4 hours, avoiding to insert the connector into the water. taking care not to wet the connector Rinse in running water and dry at room temperature. Hang the headphones in such a way that the connector is higher, otherwise the water may corrode the terminals. When dry, reapply the clips.

Do not use electric dryers as too high a temperature will weaken the elastic material and the duration of life of the headset will be extremely reduced.

Sterilization: Device NOT. Do not autoclave.

Lifetime: reusable device. If used properly the headset can be reused up to 500 times before the deterioration of the electrical parts. Also the elasticity of the fabric determines the life of the headset. If the headset loses elasticity must be replaced because they no longer guarantees the exact positioning of the electrodes. Do not use after 5 years of placing on the market.

Storage: No special precautions for handling and storage but it is good practice to store the headset in its case after washing, always dry well.

Packaging: minigrip resealable bag / box.

Contraindications and interactions: none.

Declared toxicity: none. LATEX FREE

Transport and Waste disposal: there are no particular mode of transport and disposal. Treat as medical waste in accordance with current regulations.

CND code: N010102

Regulation: Class I device.

Comply with the MDD 93/42/CEE (D.L. 46/97) and manufactured according to the procedures of BIONEN Quality System certified ISO 13485.

EEG PREWIRED HEADCAPS

- High-quality signal with low impedance for reliable recording even in long-term tests
- UNIVERSAL OR DEDICATED connection compatible with popular systems for EEG
- Elastic fabric with coding to 7 colors for a simplified use
- Available in 7 sizes (1 neonatal, pediatric 2, 4 adults):
- 3 versions available: flat electrode, cylindrical spool electrode in Ag/AgCl
- Accessory Kit consists of: syringe, blunted needle, chest strap and elastic laces, chin strap.



UNIVERSAL HEADCAPS:

Universal Headcaps used with the adapter cable (ref. 0015,011 or 0016.011) can be used on EEG instruments from various manufacturers

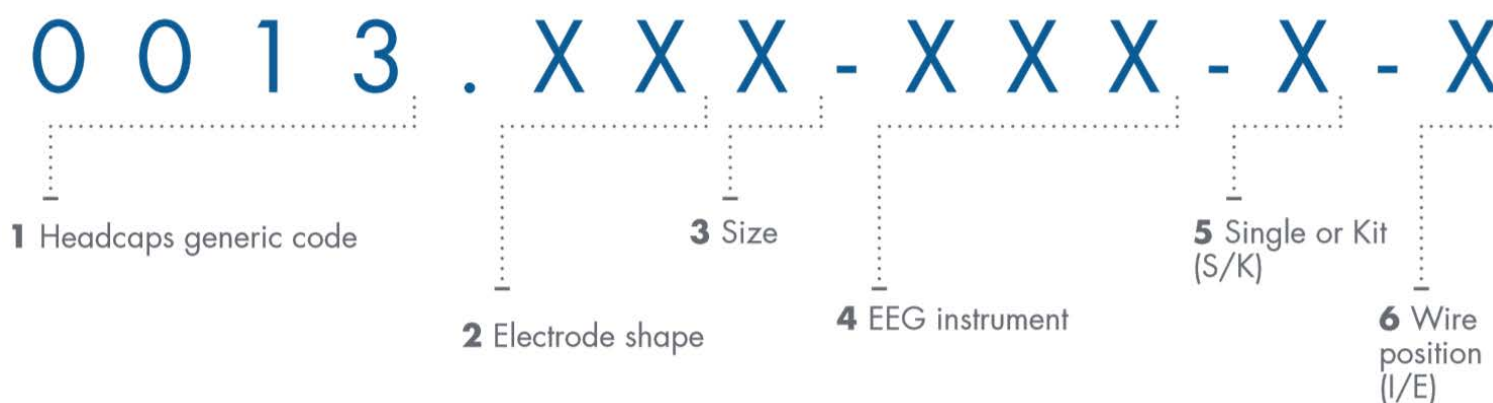
AVAILABLE CONFIGURATIONS:

REF.	USE	MODEL	N° ELECTRODES	ELECTRODE TYPE	SIZE	COLOR	
0013.C00	EEG	-	10	CILINDRIC AG/AGCL	0	NEWBORN	-
0013.C01	EEG	-	10	CILINDRIC AG/AGCL	1	NEWBORN	BOWN
0013.C02	EEG	-	10	CILINDRIC AG/AGCL	2	PEDIATRIC	PINK
0013.C03	EEG	-	10	CILINDRIC AG/AGCL	3	PEDIATRIC	LIGHT BLUE
0013.C04	EEG	-	21	CILINDRIC AG/AGCL	4	ADULT	GREEN
0013.C05	EEG	-	21	CILINDRIC AG/AGCL	5	ADULT	YELLOW
0013.C06	EEG	-	21	CILINDRIC AG/AGCL	6	ADULT	RED
0013.C07	EEG	-	21	CILINDRIC AG/AGCL	7	ADULT	BLUE
0013.F00	EEG	-	10	FLAT AG/AGCL	0	NEWBORN	-
0013.F01	EEG	-	10	FLAT AG/AGCL	1	NEWBORN	BOWN
0013.F02	EEG	-	10	FLAT AG/AGCL	2	PEDIATRIC	PINK
0013.F03	EEG	-	10	FLAT AG/AGCL	3	PEDIATRIC	LIGHT BLUE
0013.F04	EEG	-	21	FLAT AG/AGCL	4	ADULT	GREEN
0013.F05	EEG	-	21	FLAT AG/AGCL	5	ADULT	YELLOW
0013.F06	EEG	-	21	FLAT AG/AGCL	6	ADULT	RED
0013.F07	EEG	-	21	FLAT AG/AGCL	7	ADULT	BLUE
0013.L00	EEG	-	10	SPOOL AG/AGCL	1	NEWBORN	-
0013.L01	EEG	-	10	SPOOL AG/AGCL	1	NEWBORN	BOWN
0013.L02	EEG	-	10	SPOOL AG/AGCL	2	PEDIATRIC	PINK
0013.L03	EEG	-	10	SPOOL AG/AGCL	3	PEDIATRIC	LIGHT BLUE
0013.L04	EEG	-	21	SPOOL AG/AGCL	4	ADULT	GREEN
0013.L05	EEG	-	21	SPOOL AG/AGCL	5	ADULT	YELLOW
0013.L06	EEG	-	21	SPOOL AG/AGCL	6	ADULT	RED
0013.L07	EEG	-	21	SPOOL AG/AGCL	7	ADULT	BLUE

FAST CONNECTION HEADCAPS

The fast connection headcaps have a specific connector for each EEG system and allow an immediate connection of the head.

Codification system:



2 – **Electrode shape:** FOX = Flat electrode - COX = Cylindric electrode - LOX = Spool electrode

3 – **Size:** 1 to 7: 1 = newborn; 2 = small pediatric; 3 = pediatric, 4 = small adults; 5 = medium adult; 6 = large adults; 7 = extra large adult

REF.		SIZE	CIRCUMFERENCE	COLOR
0013.XX 1	1	NEWBORN	30 ± 2CM	BROWN
0013.XX 2	2	SMALL PEDIATRIC	35 ± 2CM	PINK
0013.XX 3	3	PEDIATRIC	40 ± 2CM	LIGHT BLUE
0013.XX 4	4	SMALL ADULT	45 ± 2CM	GREEN
0013.XX 5	5	MEDIUM ADULT	50 ± 2CM	YELLOW
0013.XX 6	6	LARGE ADULT	55 ± 2CM	RED
0013.XX 7	7	EXTRA LARGE ADULT	60 ± 2CM	BLUE



4 – EEG Instruments: DEDICATED headcaps for direct connection on the EEG instrument must specify the model used, the code follows the following code system:

BRAND	MODEL SYSTEM EEG	CODE SYSTEM
BIONEN	BluNet EEG	BLU
EBN (ATES Medica Device)	NEUROTRAVEL	NTL
EBN (ATES Medica Device)	NEUROTRAVEL SMART	NTS
EBNeuro	SAFETY – SIRIO	SIR
EBNeuro	VEGA	VEG
EBNeuro	HALLEY 32	H32
EBNeuro	MIZAR – BE	MBE
EBNeuro	BE MICRO	BEM
EBNeuro	BE LIGHT	BEL
EBNeuro	BE LIGHT 36	B36
EBNeuro	BE PLUS	BEP
EBNeuro	NEMUS 2	NEM
Micromed	BRAIN QUICK	BQK
Nihon Kohden	NEUROFAX	NKH
-	UNIVERSALE	UNI
-	SINGOLI TOUCH PROOF	TPR

5 – Single / Kit: Headcaps can be ordered complete with accessories kit (K) or single (S)

6 – Cables Position: Headcaps can have internal cables (I) or external (E)

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ADAPTERS AND ACCESSORIES:

REF.	DESCRIPTION	USE	CND
0014.001	ELECTRODE FOR EMERGENCY (MCH CONNECTOR 2MM)	EEG	N010199
0014.002	ELECTRODE FOR EMERGENCY (FMM CONNECTOR 1.5MM)	EEG	N010199
0014.003	EMERGENCY CABLE L = 1M (FMM CONNECTOR 1.5MM)	EEG	N010199
0014.004	REPLACEMENT ELECTRODE	EEG	N010199
0014.005	ELECTRODE FOR EMERGENCY (FMM CONNECTOR 1.5MM)	EEG	N010199
0014.006	REPLACEMENT ELECTRODE	EEG	N010199
0015.011	CONNECTING CABLE FOR HEADCAPS WITH 10 PREWIRED ELECTRODES - CONNECTOR D = 1.5 MM (UNIVERSAL)	EEG	Z129080
0016.011	CONNECTING CABLE FOR HEADCAPS WITH 21 PREWIRED ELECTRODES - CONNECTOR D = 1.5 MM (UNIVERSAL)	EEG	Z129080
0052.003	CASE FOR HEADCAPS	EEG	-
0063.001	CHEST BELT AND ELASTIC LACES L = 130 ADULTS	EEG	-
0063.002	CHEST BELT AND ELASTIC LACES L = 100 PEDIATRIC	EEG	-
2011.001	RIBLENE CHIN	EEG	-
2011.003	CHIN WITH WHITE VELCRO (INFANT)	EEG	-
2011.004	LEATHER CHIN WITH VELCRO (ADULT)	EEG	-
2011.005	NEOPRENE CHIN (ADULT)	EEG	-
2011.011	RIBLENE CHIN WITH TIES (ADULT / PEDIATRIC)	EEG	-
2011.014	LEATHER CHIN WITH VELCRO (PEDIATRIC)	EEG	-
2011.015	NEOPRENE CHIN (Pediatric)	EEG	-
2011.024	LEATHER CHIN WITH VELCRO (INFANT)	EEG	-
4020.00X	LINEN REPLACEMENT HEADSET X SIZE =	EEG	-
0049.001	August CANT STEEL FOR INJECTION CREAM Lessee - STERILIZABLE	EEG	N010199
0049.002	STEEL BLUNDED NEEDLE FOR CREAM CONDUCTIVE INJECTION - DISPOSABLE NONSTERILE - CONF. 100 PCS.	EEG	N010199
0049.003	STEEL BLUNDED NEEDLE FOR CREAM CONDUCTIVE INJECTION - DISPOSABLE NONSTERILE - CONF. SINGLE	EEG	N010199
0049.004	PLASTIC BLUNDED NEEDLE FOR CREAM CONDUCTIVE INJECTION - DISPOSABLE NONSTERILE - CONF. 100 PCS.	EEG	N010199
2072.001	SYRINGE NONSTERILE	EEG	-

