

BIONEN

medical devices



ACCESSORIES FOR
NEUROPHYSIOLOGY



*Electrodes are the first element
in the bioelectric analogical data
acquisition chain.
A low quality electrode
produces low quality registrations.*

Carlo Nencioni
BIONEN FOUNDER

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QUALITY
IS NOT A DETAIL,
DETAILS MAKE
QUALITY.

PACKAGING

BIONEN has always been committed to the well-being of patients and the community, with a strong connection to the local territory. This commitment extends to product development and manufacturing processes aimed at minimizing BIONEN's environmental footprint and **reducing resource usage** throughout the production cycle.

For years, BIONEN has been reducing its reliance on fossil resources for energy consumption in its facilities. Since 2024, all of BIONEN's energy comes from **100% renewable** non-fossil sources. Process upgrades have also led to a reduction in water consumption and manufacturing waste.

A significant step in this commitment has been the revamp of BIONEN's product packaging. This initiative has enabled the **removal of 99% of plastic** from our packaging, representing a significant stride toward a lighter ecological footprint and a more sustainable future for our planet.

With our environmental dedication, we strive to play our part in reducing plastic pollution and promoting material circularity. The new packaging is entirely **biodegradable and easily recyclable**, thereby reducing our environmental impact.

Furthermore, we've designed a new layout to simplify product use and storage.

At BIONEN, we are continuously dedicated to innovation and improvement to make our products better for our customers and the environment.



COMPANY

BIONEN stands out for its dedication to research, design, and production of top-quality electrodes and accessories for recording biological signals since 1989.

Our range includes a variety of needle and surface electrodes designed to accurately capture and measure brain (EEG) and neuro-muscular (EMG/ENG) activity.

With over 30 years of experience, BIONEN has earned a solid reputation as a leader in the production of accessories and consumables for quality diagnostic investigations, with a particular focus on neuroscience.

QUALITY

Our Company Quality System complies with the European Standard ISO 13485 which specifies the guidelines for R&D, design, manufacturing, installation, and service of medical devices.

Our products are CE certified according to the MDR (UE) 2017/745, MDD 93/42/ECC and its revised version, and according to the FDA Quality Systems Regulation 21 CFR.820.

INFORMATION FOR U.S. CUSTOMERS

Certain devices and references made herein to specific indications of use may have not received clearance or approval by the United States Food and Drug Administration. Practitioners in the United States should first consult with their local BIONEN representative (or BIONEN staff directly) in order to ascertain product availability and specific labeling claims.

Federal (USA) law restricts certain devices referenced herein to sale, distribution, and use by, or on the order of a physician licensed by the law of the State in which she/he practices to use or order the use of the device.

BIONEN



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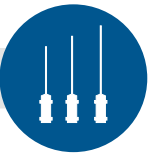
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QUALITY FOR...



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EMG NEEDLE ELECTRODES

In clinical practice, two types of EMG are widely utilized: needle EMG (intramuscular) and surface EMG. During intramuscular EMG, a needle electrode is inserted through the skin into the muscle tissue. This insertion process yields valuable insights into the muscle's condition and the function of its innervating nerve. Normal resting muscles emit specific, customary electrical signals upon needle insertion, which are then analysed. Abnormal spontaneous activity may signal nerve and/or muscle damage.

The patient is instructed to contract the muscle smoothly, allowing assessment of the shape, size, and frequency of resulting motor unit potentials. However, each electrode track provides only a localized view of the muscle's activity. Given the varied internal structure of skeletal muscles, electrodes must be placed in different locations for accurate diagnosis.

BIONEN Needle Electrodes are meticulously designed and manufactured to ensure both high reliability during electromyography (EMG) and minimized discomfort during needle insertion.

EMG CONCENTRIC NEEDLE ELECTRODES

BIONEN Needle Electrodes are designed and built to ensure high reliability during electromyographic (EMG) examinations.

The cannula, made of stainless steel AISI 304, is characterized by high strength and flexibility, essential features for optimal electrode use. The sensor is made of different materials for STANDARD and PREMIUM needles. BIONEN PREMIUM needles feature a sensor made of higher-quality material, ensuring better signal quality.

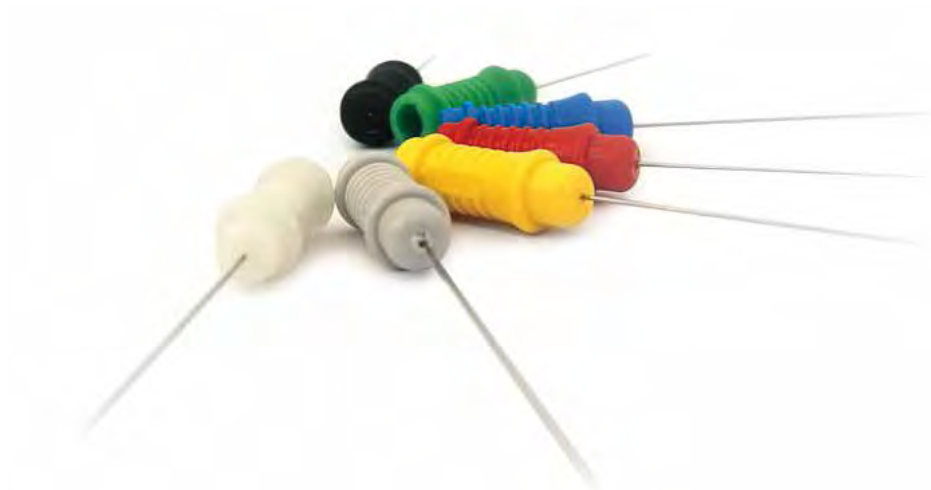
The tip is designed for excellent penetration and reduced discomfort for the patient, even with multiple insertions.

The connector includes a marker to allow the physician to orient the needle tip. Additionally, the connector is color-coded to facilitate recognition of the needle size.

BIONEN EMG needles are constantly monitored and controlled with regard to the electrical functionality, dimensional characteristics, penetration and friction force. Stability and low variability are guaranteed in every needle's batch.

INTENDED USE: **EMG**

- Sensor in different material for STANDARD and PREMIUM needles
- Sharp three-edged tip for quick and painless insertion
- Ergonomic hub for a secure grip by the operator
- Bevel indicator: Easy identification on hub of the bevel recording area
- Coaxial hub to easy connect the needles into the BIONEN needle holder without orientation
- Packaging: Single Pouch
- Sale Packaging: 25 electrodes
- Sterilization: Gamma Rays
- Shelf Life: 60 months (5 years) from sterilization





EMG CONCENTRIC NEEDLE ELECTRODE - STANDARD

REF MDR	REF	L	Ø	QTY	COLORS
0280-4625-000	0028.012	25 mm	0,46 mm (26G)	25/box	●
0280-4630-000	0028.013	30 mm	0,46 mm (26G)	25/box	●
0280-4637-000	0028.014	37 mm	0,46 mm (26G)	25/box	●
0280-4645-000	0028.016	45 mm	0,46 mm (26G)	25/box	●
0280-4665-000	0028.017	65 mm	0,46 mm (26G)	25/box	●
0280-4650-000	0028.018	50 mm	0,46 mm (26G)	25/box	●
0280-4675-000	0028.019	75 mm	0,46 mm (26G)	25/box	●
0280-3025-000	0028.111	25 mm	0,30 mm (30G)	25/box	●
0280-3525-000	0028.112	25 mm	0,35 mm (28G)	25/box	●
0280-3530-000	0028.113	30 mm	0,35 mm (28G)	25/box	●

EMG CONCENTRIC NEEDLE ELECTRODE - PREMIUM

REF MDR	REF	L	Ø	QTY	COLORS
0281-4625-000	0028.612	25 mm	0,46 mm (26G)	25/box	●
0281-4637-000	0028.614	37 mm	0,46 mm (26G)	25/box	●
0281-4650-000	0028.618	50 mm	0,46 mm (26G)	25/box	●



NEEDLE HOLDER FOR CONCENTRIC NEEDLES

REF	L CABLE	INSTRUMENT SIDE
0030.011-S	100 cm	5 pole DIN
0030.011-S150	150 cm	5 pole DIN
0030.011-S200	200 cm	5 pole DIN



EMG COATED MONOPOLAR NEEDLE ELECTRODES

- Optimized tip grinding process for an easy and painless skin penetration
- Color-coded hub for an easy determination of the right code
- Ergonomic hub for a secure grip by the operator
- Packaging: Single Pouch
- Sale Packaging: 25 electrodes
- Sterilization: Gamma Rays
- Shelf Life: 60 months (5 years) from sterilization



INTENDED USE: **EMG**

EMG COATED MONOPOLAR NEEDLE ELECTRODES

REF MDR	REF	Ø NEEDLE	L NEEDLE	QTY	COLORS
0247-3525-000	0024.071	0,35 mm (28G)	25 mm	25/box	●
0247-3535-000	0024.072	0,35 mm (28G)	35 mm	25/box	●
0247-3545-000	0024.073	0,35 mm (28G)	45 mm	25/box	●
0247-4525-000	0024.074	0,45 mm (26G)	25 mm	25/box	●
0247-4537-000	0024.075	0,45 mm (26G)	37 mm	25/box	●
0247-4550-000	0024.076	0,45 mm (26G)	50 mm	25/box	●
0247-4575-000	0024.077	0,45 mm (26G)	75 mm	25/box	●

NEEDLE HOLDER FOR CMNE

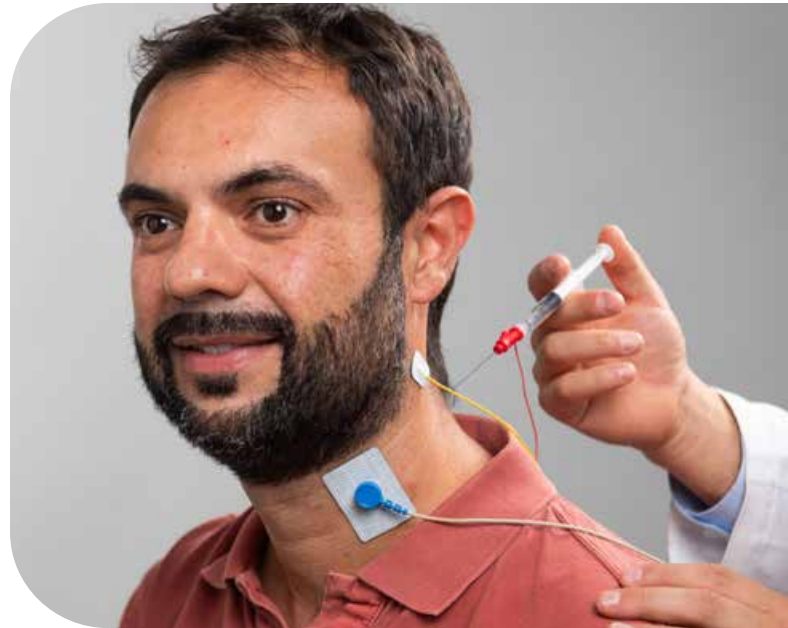
REF	L CABLE	INSTRUMENT SIDE
0025.201	100 cm	female D=1,5 mm





HYPODERMIC NEEDLE ELECTRODES FOR BOTULINUM TOXIN INJECTION

The BIONEN Botulinum Toxin Injection Needle is an innovative solution that combines the precision of recording spontaneous EMG activity with the effectiveness of intramuscular injection of the toxin. The incredibly sharp tip of the needle guarantees almost painless skin penetration for the patient. Equipped with luer-lock connection for easy application with the syringe.



- Sterile hypodermic needle for single use (ISO 7864)
- Material: AISI 304 stainless steel, electrically insulated coating.
- Recording surface limited to the area of the exposed bevels and inner cannula face.
- Needle hub with a secure Luer-Lock fitting to which the injection syringe is connected.
- Wire with touch-proof connector which provides for electrical connection to a stimulating or recording device.
- Packaging: Single Pouch
- Sale Packaging: 12 electrodes
- Sterilization: Gamma Rays
- Shelf Life: 60 months (5 years) from sterilization



INTENDED USE: **EMG**

HYPODERMIC NEEDLE ELECTRODES FOR BOTULINUM TOXIN INJECTION

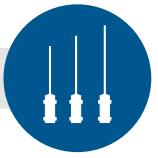
Instrument side connector: female D=1,5 mm (DIN 42802)

REF MDR	REF.	L NEEDLE	Ø NEEDLE	L CABLE	QTY	COLORS
0270-4625-000	0028.521	25 mm	0,46 mm (26G)	100 cm	12/box	●
0270-4637-000	0028.524	37 mm	0,46 mm (26G)	100 cm	12/box	●
0270-4650-000	0028.525	50 mm	0,46 mm (26G)	100 cm	12/box	●

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SUBDERMAL NEEDLE ELECTRODES

Subdermal Needle Electrodes are a widely used type of electrode for acquiring neurophysiological signals, particularly in critical environments such as ICU/NICU and operating rooms.

These electrodes are employed for the acquisition of signals from both the central and peripheral nervous systems and are available in various configurations, ensuring maximum flexibility of use for physicians and technicians. The electrodes can feature straight or twisted needles, single, twisted or flat configurations, and come with cables of various lengths.

BIONEN places great importance on the materials and production of these electrodes, ensuring ease of use and excellent product quality.

SUBDERMAL NEEDLE ELECTRODES

BIONEN Subdermal Needle Electrodes guarantee solidity, strength and flexibility. Each electrode is made of stainless steel AISI 304 and is used for placement directly in the scalp. Needle tip grinding is optimized to guarantee a simple and painless skin penetration. Subdermal Needles feature low noise and impedance level for a clear and reliable signal.

- Material: Stainless Steel AISI 304
- Ultra-sharp lancet tip for easy and gentle skin penetration
- Packaging: Single Pouch to reduce the risk of cross-contamination
- Box with multicolour cables
- Sterilization: Gamma Rays
- Shelf Life: 60 months
- Custom cable lengths are available on request

INTENDED USE: **NCS EEG IONM**

SUBDERMAL NEEDLE ELECTRODES

Instrument side connector:

female D=1,5 mm (DIN 42802)

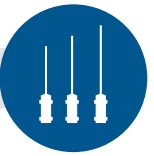
SIZE CODE EXAMPLE:

0021.021-**XXX**



REF	L	Ø	L CABLE (XXX)	QTY
0021.021-XXX	10 mm	0,35 mm	100/150/200/250 cm	40/box
0021.022-XXX	15 mm	0,35 mm	100/150/200/250 cm	40/box
0021.023-XXX	25 mm	0,35 mm	100/150/200/250 cm	40/box
0021.026-XXX	hook	0,35 mm	100/150/200/250 cm	40/box





REMOVABLE SUBDERMAL NEEDLE ELECTRODES

REF	L	Ø	PLUG	POUCH	QTY
0024.001	10 mm	0,35 mm	male D=1 mm	5 pcs.	40pouch/box
0024.002	15 mm	0,35 mm	male D=1 mm	5 pcs.	40pouch/box
0024.003	25 mm	0,35 mm	male D=1 mm	5 pcs.	40pouch/box
0024.004	hook	0,35 mm	male D=1 mm	5 pcs.	40pouch/box



REMOVABLE SUBDERMAL NEEDLE ELECTRODES WITH CABLE

REF	L	Ø	PLUG	L CABLE	POUCH	QTY
0024.005	12 mm	0,35 mm	male D=1 mm	6 cm	5 pcs.	40pouch/box
0024.006	10 mm	0,35 mm	male D=1 mm	6 cm	5 pcs.	40pouch/box
0024.007	15 mm	0,35 mm	male D=1 mm	6 cm	5 pcs.	40pouch/box
0024.008	25 mm	0,35 mm	male D=1 mm	6 cm	5 pcs.	40pouch/box
0024.009	hook	0,35 mm	male D=1 mm	6 cm	5 pcs.	40pouch/box



NEEDLE HOLDER

REF	L	INSTRUMENT SIDE	PATIENT SIDE
0025.005	100 cm	female D=1,5 mm	female D=1 mm
0025.131	150 cm - shielded	5 pole DIN	2 x female D=1 mm
0025.135	150 cm - shielded	5 pole DIN	3 x female D=1 mm



SUBDERMAL NEEDLE ELECTRODES

REF	L	Ø	QTY
0026.011	10 mm	0,35 mm	25/box
0026.012	15 mm	0,35 mm	25/box
0026.013	20 mm	0,35 mm	25/box



NEEDLE HOLDER

REF	L CABLE	INSTRUMENT SIDE
0030.011-S	100 cm	5 pole DIN
0030.011-S150	150 cm	5 pole DIN



TWISTED SUBDERMAL NEEDLE ELECTRODES

Instrument side connector:
female D=1,5 mm (DIN 42802)

SIZE CODE EXAMPLE:
0021.050-XXX



AVAILABLE COLORS



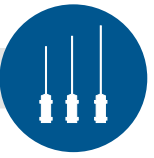
REF.	L	Ø	L CABLE (XXX)	QTY
0021.050-XXX	12 mm	0,35 mm	100/150/200/250 cm	16/box
0021.051-XXX	18 mm	0,35 mm	100/150/200/250 cm	16/box
0021.055-XXX	15 mm	0,35 mm	100/150/200/250 cm	16/box
0021.056-XXX	hook	0,35 mm	100/150/200/250 cm	16/box
0021.057-XXX	23 mm	0,35 mm	100/150/200/250 cm	16/box
0021.058-XXX	25 mm	0,35 mm	100/150/200/250 cm	16/box
0021.059-XXX	6 mm	0,35 mm	100/150/200/250 cm	16/box

COLOR 



COLOR 



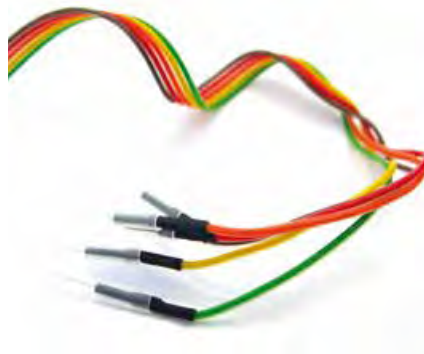


SUBDERMAL NEEDLE ELECTRODES WITH FLAT CABLE

Instrument side connector: female D=1,5 mm (DIN 42802)

SIZE CODE EXAMPLE: 0021.201

REF	L	Ø	L CABLE (XXX)	QTY
0021.201	L=10 mm	0,35 mm	5 poles L=150 cm	10/box
0021.202	L=15 mm	0,35 mm	5 poles L=150 cm	10/box
0021.206	hook	0,35 mm	5 poles L=150 cm	10/box



CORK-SCREW SUBDERMAL NEEDLE ELECTRODES

Instrument side connector: female D=1,5 mm (DIN 42802)

SIZE CODE EXAMPLE: 0021.030-XXX

REF	L CABLE (XXX)	QTY
0021.030-XXX	100/150/200 cm	20/box
0021.030-250	250 cm	12/box

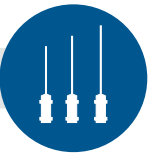


IONM KITS

Neurological monitoring during surgical procedures is now considered a standard medical practice, increasingly recognized for its significance. This monitoring offers valuable insights into the nervous system's condition to surgical teams, assisting them in decision-making and minimizing the risk of neurological harm. BIONEN, a leader in neurophysiology accessories production, prioritizes the

support its accessories offer to physicians and neurophysiology technicians. Following guidance from key opinion leaders (KOLs), BIONEN has developed specialized kits for intraoperative neurophysiological monitoring (IONM). These kits aim to streamline patient preparation and ensure optimal electrode usage, thereby enhancing surgical outcomes.





● IONM KITS

● 0021.1K1 - KIT FOR ENCEPHALIC DEATH ASSESSMENT

REF	QTY	KIT CONTENTS
0021.201	2/box	Subdermal needle electrode L=15mm – flat cable 5 poles L=150 cm
0021.022 - 150	2/box	Subdermal needle electrode L=15mm – cable L=150 cm



0021.201



0021.022-150

● 0021.0K8 - KIT FOR EMG/EP DURING VERTEBRAL STABILIZATION (VS1)

REF	QTY	KIT CONTENTS
0021.050 - 200	16/box	Subdermal needle electrode L=18mm – twisted cable L=200 cm
0021.030 - 150	6/box	Cork-screw subdermal needle – cable L=150 cm
0021.021 - 150	2/box	Subdermal needle electrode L=10mm – cable L=150 cm
0065.043 - 200	6/box	Adhesive electrode 15x20mm Ag/AgCl – cable L=200 cm
0047.006	1/box	Adhesive electrode 35x45mm Ag/AgCl – cable L=150 cm



0021.050-200



0021.030-150



0021.021-150



0047.006



0065.043-200

KIT FOR IOM



0021.051-200



0021.022-200



0021.032-250

0021.0K1 - KIT FOR EMG/EP DURING SPINE SURGERIES (SP1)

REF	QTY	KIT CONTENTS
0021.051-200	8/box	Subdermal needle electrodes L=18 mm - twisted cable L=200 cm
0021.022-200	2/box	Subdermal needle electrodes L=15 mm - cable L=200 cm
0021.032-250	2/box	Cork-screw Subdermal needle electrode - twisted cable L=250 cm

0021.0K2 - KIT FOR EMG/EP DURING SPINE SURGERIES FOR 5 LEVELS (SP2)

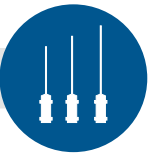
REF	QTY	KIT CONTENTS
0021.051-200	16/box	Subdermal needle electrodes L=18 mm - twisted cable L=200 cm
0021.022-200	6/box	Subdermal needle electrodes L=15 mm - cable L=200 cm
0021.032-250	6/box	Cork-screw Subdermal needle electrode - twisted cable L=250 cm

0021.0K3 - KIT FOR EEG/EP DURING BRAIN SURGERIES (BR1)

REF	QTY	KIT CONTENTS
0021.051-200	8/box	Subdermal needle electrodes L=18 mm - twisted cable L=200 cm
0021.022-200	4/box	Subdermal needle electrodes L=15 mm - cable L=200 cm
0021.032-250	2/box	Cork-screw Subdermal needle electrode - twisted cable L=250 cm

0021.0K4 - KIT FOR EEG/EP FOR UPPER AND LOWER CRANIAL NERVES (BR2)

REF	QTY	KIT CONTENTS
0021.051-200	6/box	Subdermal needle electrodes L=18 mm - twisted cable L=200 cm
0021.022-200	4/box	Subdermal needle electrodes L=15 mm - cable L=200 cm
0021.032-250	2/box	Cork-screw Subdermal needle electrode - twisted cable L=250 cm



● **0021.0K5** - KIT FOR BAEP (BRAINSTEM AUDITORY EVOKED POTENTIALS) (BAEP1)

REF	QTY	KIT CONTENTS
0021.051-200	1/box	Subdermal needle electrodes L=18 mm - twisted cable L=200 cm
0021.022-200	4/box	Subdermal needle electrodes L=15 mm - cable L=200 cm
0021.032-250	1/box	Cork-screw Subdermal needle electrode - twisted cable L=250 cm

● **0021.0K6** - KIT FOR VEP (VISUAL EVOKED POTENTIAL) (VEP1)

REF	QTY	KIT CONTENTS
0021.051-200	2/box	Subdermal needle electrodes L=18 mm - twisted cable L=200 cm
0021.022-200	2/box	Subdermal needle electrodes L=15 mm - cable L=200 cm
0021.032-250	2/box	Cork-screw Subdermal needle electrode - twisted cable L=250 cm



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EEG ELECTRODES

Electroencephalography (EEG) is the recording of electrical activity along the scalp. In clinical contexts, EEG refers to the recording of the brain's spontaneous electrical activity over a short period of time, (20–40 minutes), as recorded from multiple electrodes placed on the scalp.

Electrodes are placed with a conductive gel or paste, after preparing the scalp area by light abrasion to reduce impedance due to dead skin cells.

Many systems typically use electrodes attached to an individual wire, some systems use caps or nets into which electrodes are embedded.

Electrode locations and names are specified by the 10–20 International System to ensure that the naming of electrodes is consistent across laboratories.

An EEG can determine changes in brain activity that may be useful in diagnosing brain disorders, especially epilepsy. An EEG may be helpful for diagnosing or treating a variety of physical disorders:

- Epilepsy or other seizure disorders
- Brain tumor
- Head injury
- Brain dysfunction (i.e. encephalopathy)
- Inflammation of the brain (encephalitis)
- Stroke
- Sleep disorders
- Dementia

An EEG may also be used to confirm brain death in someone in a persistent coma. A continuous EEG is used to help find the right level of anesthesia for someone in a medically induced coma.

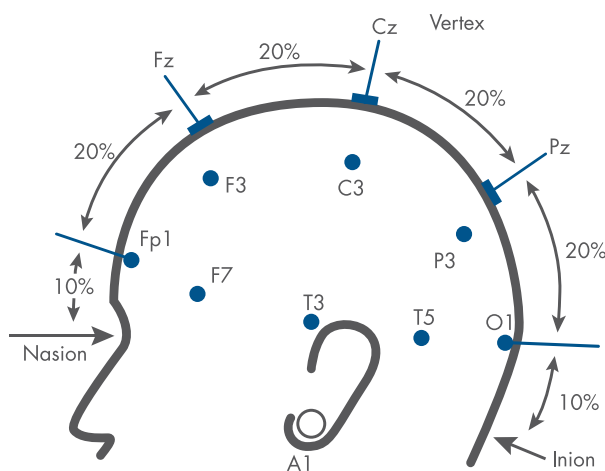
EEGs are safe and painless. Sometimes seizures are intentionally triggered in people with epilepsy during the test, but appropriate medical care is provided if needed.

10-20 INTERNATIONAL SYSTEM (EEG)

EEG electrodes are placed on the scalp according a recognized method to correctly localize the electrode positioning. This method was developed to ensure standardized reproducibility so that a subject's studies could be compared over time and subjects could be compared to each other.

The 10–20 International System is based on the relationship between the location of an electrode and the underlying area of cerebral cortex. The “10” and “20” refer to the fact that the actual distances between adjacent electrodes are either 10% or 20% of the total front–back or right–left distance of the skull. Each site has a letter to identify the lobe and a number to identify the hemisphere location.

ELECTRODE	LOBE
F	Frontal
T	Temporal
C	Central
P	Parietal
O	Occipital



There exists no central lobe; the “C” letter is used only for identification purposes.

A “z” (zero) refers to an electrode placed on the midline.

Even numbers (2,4,6,8) refer to electrode positions on the right hemisphere, whereas odd numbers (1,3,5,7) refer to those on the left hemisphere.

In addition, the letter codes A, Pg and Fp identify the earlobes, nasopharyngeal and frontal polar sites respectively.

Four anatomical landmarks are used for the essential positioning of the EEG electrodes: first, the nasion which is the distinctly depressed area between the eyes, just above the bridge of the nose; second, the inion, which is the lowest point of the skull from the back of the head and is normally indicated by a prominent bump. Then the pre auricular points anterior to the ear.

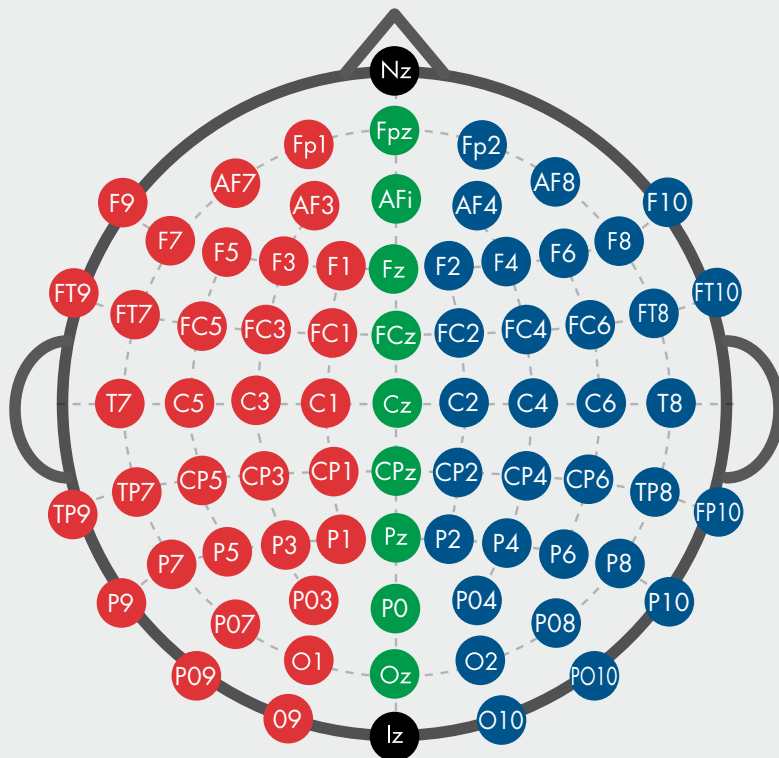
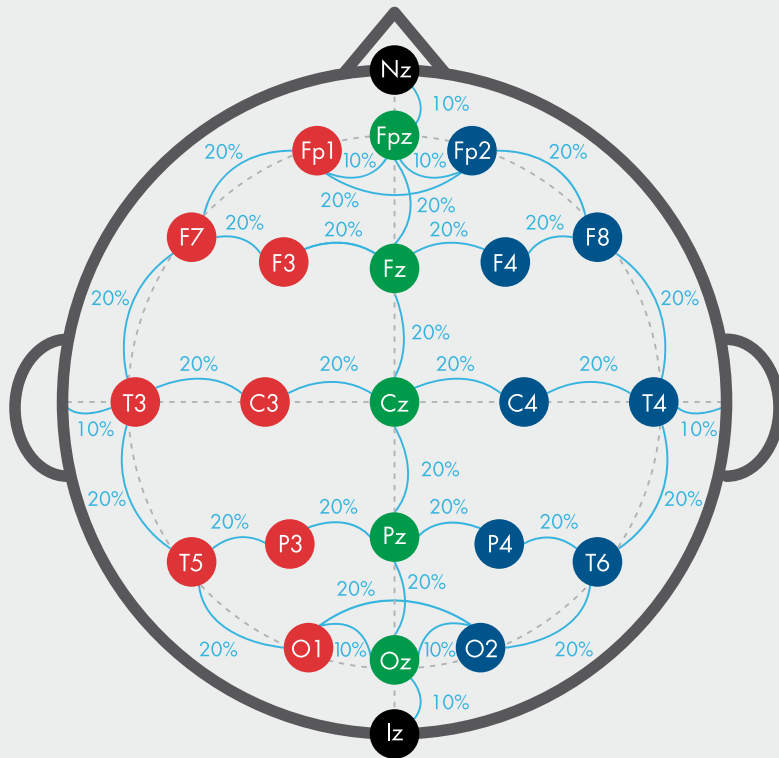
With the advent of multi-channel EEG hardware systems and the concurrent development of topographic and tomographic signal source localization methods, the international 10/20 system was extended to higher density electrode settings such as 10/10 and 10/5 systems, allowing more than 300 electrode positions.

In most clinical applications, 19 recording electrodes (plus ground and system reference) are used.

A smaller number of electrodes are typically used when recording EEG from neonates (usually 10). Additional electrodes can be added to the standard set-up when a clinical or research application demands increased spatial resolution for a particular area of the brain.

High-density arrays can contain up to 256 electrodes spaced around the scalp.

BIONEN can develop custom headcaps for your specific requirements.



PREWIRED HEADCAPS

Electrodes are positioned according to the 10-20 International System embedded on an elastic cap perfectly fitting on the head.

Headcap is simple and fast to place and guarantees the stability of the electrodes.

This system guarantees a drastic reduction of exam's preparation time and costs.

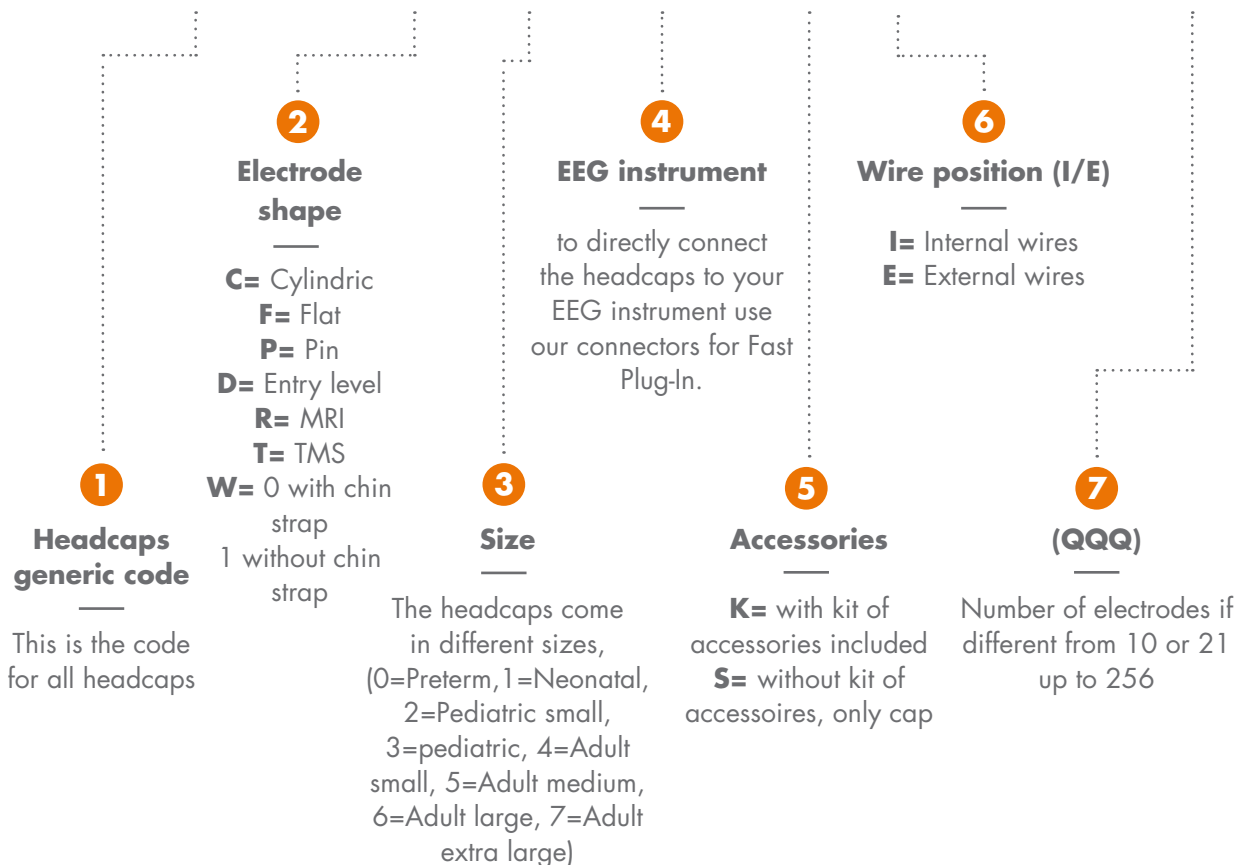
Our headcaps can be customized for electrodes' number and montages (10-20, 10-10, 10-5).

- Simple and fast to prepare
- Stable and correct placement of the electrodes
- Conductive paste insertion is simplified by the electrode's support hole
- Suitable for children and patients who need to reduce the preparation time
- Accessories' kit: thoracic belt, chin strap, elastic belts, syringe, blunted needle

INTENDED USE: **EEG**

BIONEN headcaps' range is wide and complete, to meet all customers' needs we have developed different solutions that are explained by the code itself:

0013.XWY-ZZZ-J-K-(QQQ)





SIZES & NUMBER OF ELECTRODES

8 color-coded sizes (2 neonatal, 2 pediatrics, 4 adults) are available for every model.

SIZE CODE EXAMPLE: 0013. XX **X** - XXX - X - X

REF	SIZE	PATIENT	HEAD CIRCUMFERENCE	AVAILABLE ELECTRODES #					
				10	21	32	64	128	256
0013.XX0	0	preterm	25 ± 2 cm	●	●				
0013.XX1	1	neonatal	30 ± 2 cm	●	●				
0013.XX2	2	pediatric small	35 ± 2 cm	●	●				
0013.XX3	3	pediatric	40 ± 2 cm	●	●	●			
0013.XX4	4	adult small	45 ± 2 cm	●	●	●	●		
0013.XX5	5	adult medium	50 ± 2 cm	●	●	●	●	●	●
0013.XX6	6	adult large	55 ± 2 cm	●	●	●	●	●	●
0013.XX7	7	adult extra large	60 ± 2 cm	●	●	●	●	●	●



FABRIC PERFORMANCES

Breathable, extremely light, the unique ultra-thin fabric with 27% LYCRA® and soft microfiber with unique performances. More comfortable fabric for the patient and easier maintenance for the operator.



Extra comfort

Offers great wearability and perfect shape even after repeated washing.



Breathability

Provides perfect breathability and greater freshness. These qualities make it cooler and more hygienic.



Extra resistant

more durable and resistant to the corrosive action of chlorine and protect it from the salt and corrosive agents in creams.



Quick drying

Dries twice as fast than other fabrics, quick and easy to maintain.



Extra fine

Supports with less bulk and superior softness.



Sensitivecosystem®

Commitment to Eco sustainability and the environment.

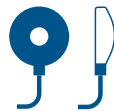
AVAILABLE ELECTRODES

All versions of BIONEN headcaps have Silver (Ag/AgCl) electrodes to guarantee reliable recording. Wires can be positioned outside or inside the fabric. Available electrodes' shapes are the following with different features:



CYLINDRIC ELECTRODES

0013.**CXx**



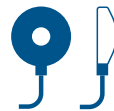
FLAT ELECTRODES

0013.**FXx**



PIN ELECTRODES

0013.**PXx**



ENTRY LEVEL ELECTRODES

0013.**DXx**



MRI ELECTRODES

0013.**RXx**

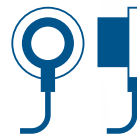


TMS ELECTRODES

0013.**TXx**

CYLINDRIC

CODE EXAMPLE 0013. **CXx** - XXX - X - X



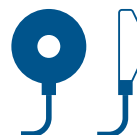
- Soft electrode holder to guarantee more patient comfort.
- Wider holes make paste insertion easier.
- Impedance reduction using a comfortable cotton swab.
- Simple maintenance and replacement of broken and emergency electrodes.



0013.**CXx** - XXX - X - **E**

FLAT

CODE EXAMPLE 0013. **FXx** - XXX - X - X



- Molded connection between electrode and wire avoid oxidation and increase the product life.
- Emergency electrodes available.



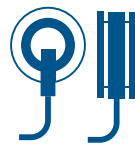
0013.**FXx** - XXX - X - **E**



PIN

CODE EXAMPLE 0013.**PXX-XXX-X - X**

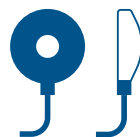
- Suggested for Long Term Monitoring (LTM) recordings, uncooperative patients
- Exclusive ultrathin electrode
- Internal wires, not in contact with the scalp



ENTRY LEVEL

CODE EXAMPLE 0013.**DXX-XXX-X - X**

- Suggested for a not intense use of prewired headcap in EEG recording
- Electrodes studied for a good impedance



EEG HEADCAPS FOR SPECIAL APPLICATIONS

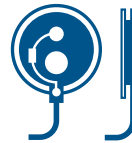


MRI

CODE EXAMPLE 0013.**ROX** - XXX - X - X

EEG-fMRI is a multimodal neuroimaging technique that allows to acquire EEG and fMRI data simultaneously. This technique is used to study brain activity in normal conditions and in presence of pathologies.

The EEG recorded on the surface of the head reflects the cerebral electrical activity, more specifically generated by post-synaptic potentials in the cerebral cortex.



Functional MRI detects hemodynamic changes throughout the brain. The EEG-fMRI therefore allows the direct correlation of these two important measures of brain activity.

The BIONEN MRI headcaps:

- are built with non-magnetic materials
- guarantee the safety of the subject by preserving the quality of functional and structural MR images.

TMS

CODE EXAMPLE 0013.**TOX** - XXX - X - X

TMS is a non-invasive technique for brain stimulation. The combination of stimulation techniques with electrophysiological recording methods in order to better understand human brain functioning is of great interest.

The co-registration of the EEG during magnetic stimulation offers real-time information on both the state of cortical activity and its functional connectivity.



From a technical point of view, EEG headcap during TMS must have a high dynamic range of acquisition in order not to saturate the signal and a reduced thickness of the EEG electrodes in order not to negatively influence the depth of action of the magnetic stimulus and not to be an obstacle to the positioning of the magnetic stimulation probe.



STAND-UP

CODE EXAMPLE

0013.**C1**X - XXX - X - X

0013.**F1**X - XXX - X - X

The Stand-Up headcap, the result of an innovative design that allows for excellent electrode adhesion without the need for a cumbersome chin strap, comfortable for all patients and ideal where patients require intubation or unobstructed airways.



AVAILABLE CONNECTORS FOR UNIVERSAL HEADCAPS

CODE EXAMPLE 0013. XXX - **UNI** - X - X

Universal headcaps models allow to use the same cap with EEG instruments produced by different manufacturers.

They are adaptable and compatible with most EEG instruments through the use of the adapter cable.

REF.	PATIENT SIDE	INSTRUMENT SIDE
0015.011	D -SUB 25 POLI MCH	10 x FMM 1,5 mm TP
0016.011	D -SUB 25 POLI MCH	21 x FMM 1,5 mm TP

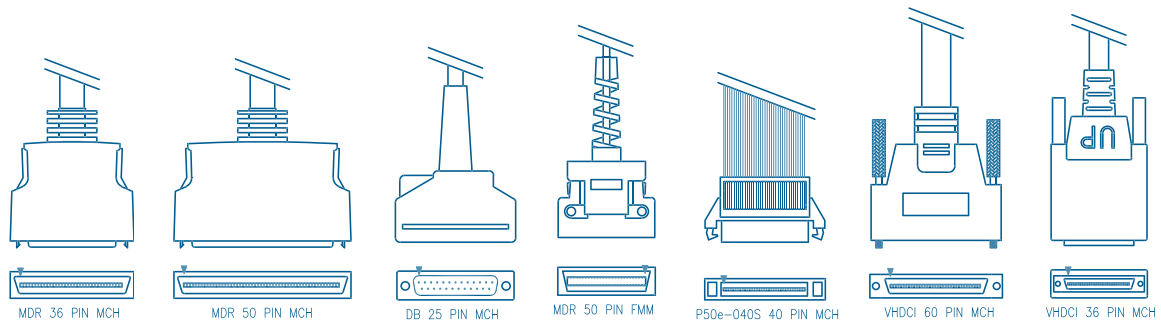


AVAILABLE CONNECTORS FOR FAST PLUG-IN HEADCAPS

CODE EXAMPLE 0013. XXX - **XXX** - X - X

BIONEN manufactures EEG headcaps with direct connection with main EEG instruments, further reducing the exam's preparation time and costs. No need of adapter cables.

The following configuration are included in our standard production, if the EEG system you need is not in the list, contact us.



MANUFACTURER	EEG INSTRUMENT MODEL	INSTRUMENT CODE	CONNECTOR TYPE
EBNeuro (ATES)	NEUROTRAVEL SMART	NTS	MDR 50 PIN MCH
EBNeuro	MIZAR - BE	MBE	MDR 50 PIN MCH
EBNeuro	BE MICRO	BEM	VHDCI 36 PIN MCH - BLACK
EBNeuro	BE LIGHT	BEL	MDR 36 PIN MCH
EBNeuro	BE LIGHT 36	B36	MDR 50 PIN MCH
EBNeuro	BE PLUS PRO/LTM	BPP	VHDCI 68 PIN MCH
EBNeuro	NEMUS 2	NEM	VHDCI 36 PIN MCH - GREY
Micromed	BRAIN QUICK	BQK	DB 25 PIN MCH
Nihon Kohden	NEUROFAX	NKH	MDR 50 PIN FMM
Deymed	TRUESCAN EEG	DEY	DB 25 PIN MCH
DX-SYSTEM	BRAINTEST PLUS	DXS	MDR 50 PIN MCH
Cadwell	ESSENTIA	CWL	MDR 36 PIN MCH
ALL	ALL	TPR	DIN 42802 (FEMALE 1,5 mm)



ACCESSORIES

BIONEN Headcaps can be delivered with or without accessories. To facilitate order use the following codification:

CODE EXAMPLE 0013. XXX - XXX - **X** - X

S= SINGLE CAP with chin strap

K= CAP with KIT of accessories

The complete Kit includes the following accessories in adult or pediatric version according to the cap's size:

REF	ACCESSORIES FOR PREWIRED HEADCAPS	ADULT KIT 0013 K01	PEDIATRIC KIT 0013 K02
2011.005	Chin strap adult	1	
2011.015	Chin strap pediatric		1
0063.001	Thoracic belt adult	1	
0063.002	Thoracic belt pediatric		1
2072.003	No sterile syringe 20 ml	1	
0049.002	Blunted needle		1

S= SINGLE CAP with chin strap



K= with KIT of accessories



CUP ELECTRODES



BIONEN Cup Electrodes for EEG are designed and manufactured to ensure high-quality signals and minimize noise.

Available in Ag, Ag/AgCl, and Ag/Au, the geometry of the electrodes ensures excellent adhesion to the patient for every type of application, from routine EEG to long-term monitoring (LTM) and sleep studies (PSG). The connection between the electrode, the cable, and the connector is designed to ensure maximum durability.

- Packaging: 10 cups/box with different colors
- Pure Ag/AgCl sensor ensures uniform high signal quality
- Pre-attached tangle-free lead wires
- Color coded lead wires for easy handling

INTENDED USE: **EEG EP PSG**



REUSABLE CUP ELECTRODES

AVAILABLE COLORS ● ● ● ● ● ● ● ● ● ●

REF	MATERIAL	Ø CUP	L CABLE	QTY
0012.005	Silver Chloride (Ag/AgCl)	10 mm	150 cm	10 pcs.
0012.006	Golden Silver (Ag/Au)	10 mm	150 cm	10 pcs.
0012.007	Silver (Ag)	10 mm	150 cm	10 pcs.



REUSABLE CUP ELECTRODES (LTM)

AVAILABLE COLORS ● ● ● ● ● ● ● ● ● ●

REF	MATERIAL	Ø CUP	L CABLE	QTY
0012.015	Silver Chloride (Ag/AgCl)	10 mm	150 cm	10 pcs.
0012.016	Golden Silver (Ag/Au)	10 mm	150 cm	10 pcs.
0012.017	Silver (Ag)	10 mm	150 cm	10 pcs.



DISPOSABLE CUP ELECTRODES

AVAILABLE COLORS



REF	MATERIAL	Ø CUP	L CABLE	QTY
0012.612	Ag/AgCl	10 mm	100 cm	10 pcs.



REUSABLE CUP ELECTRODES - RM COMPATIBLE

Instrument side connector: female D=1,5 mm (DIN 42802)

REF	MATERIAL	Ø CUP	L CABLE	QTY
0012.035	Silver Chloride (Ag/AgCl)	10 mm	150 cm	5 pcs.
0012.036	Golden Silver (Ag/Au)	10 mm	150 cm	5 pcs.
0012.037	Silver (Ag)	10 mm	150 cm	5 pcs.
0012.632	Silver Chloride (Ag/AgCl)	10 mm	150 cm	9 pcs.



CUP ELECTRODES PATIENT CABLE FOR EEG/LTM

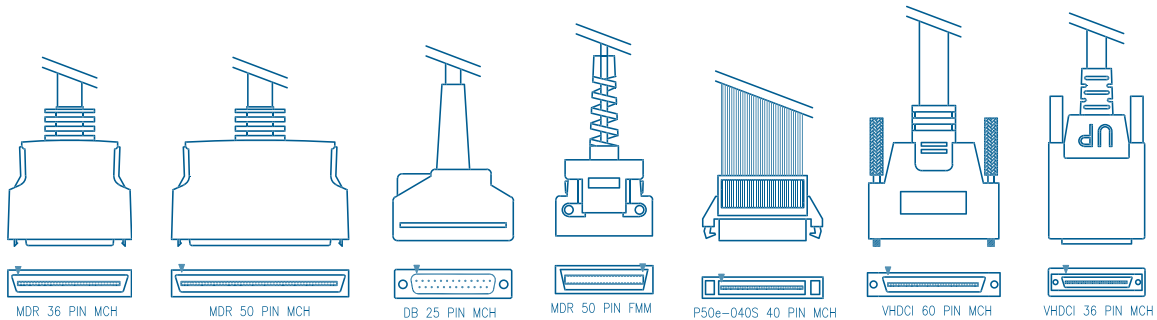
CODE EXAMPLE 0012.01X - YYY - ZZ

YYY= EEG instrument

to directly connect the headcaps to your EEG instrument use our connectors for Fast Plug-In.

ZZ= # ELECTRODES: 10/21

REF	MATERIAL (X)	Ø CUP	L CABLE
0012.015-YYY-ZZ	Silver Chloride (Ag/AgCl)	10 mm	150 cm
0012.016-YYY-ZZ	Golden Silver (Ag/Au)	10 mm	150 cm
0012.017-YYY-ZZ	Silver (Ag)	10 mm	150 cm



MANUFACTURER	EEG INSTRUMENT MODEL	INSTRUMENT CODE	CONNECTOR TYPE
EBNeuro (ATES)	NEUROTRAVEL SMART	NTS	MDR 50 PIN MCH
EBNeuro	MIZAR - BE	MBE	MDR 50 PIN MCH
EBNeuro	BE MICRO	BEM	VHDCI 36 PIN MCH - BLACK
EBNeuro	BE LIGHT	BEL	MDR 36 PIN MCH
EBNeuro	BE LIGHT 36	B36	MDR 50 PIN MCH
EBNeuro	BE PLUS PRO/LTM	BPP	VHDCI 68 PIN MCH
EBNeuro	NEMUS 2	NEM	VHDCI 36 PIN MCH - GREY
Micromed	BRAIN QUICK	BQK	DB 25 PIN MCH
Nihon Kohden	NEUROFAX	NKH	MDR 50 PIN FMM
Deymed	TRUESCAN EEG	DEY	DB 25 PIN MCH
DX-SYSTEM	BRAINTEST PLUS	DXS	MDR 50 PIN MCH
Cadwell	ESSENTIA	CWL	MDR 36 PIN MCH
ALL	ALL	TPR	DIN 42802 (FEMALE 1,5 mm)

BRIDGE ELECTRODES

BIONEN Bridge Electrodes are made of pure silver with an Ag/AgCl or sintered Ag/AgCl (silver/silver chloride) contact area.

Electrodes can be used with or without cotton cover.

If used with cotton cover, they are dampen in a saline solution, otherwise a conductive gel must be used.

Then they are positioned on the scalp using a silicone net in which electrodes are embedded.

It is common when high-density arrays of electrodes are needed.

INTENDED USE: EEG

BRIDGE ELECTRODES

REF.	MATERIAL	ELECTRODE SIDE	SIZE
0001.001	Ag/AgCl sintered	female D=1,5 mm	adult
0001.002	Ag/AgCl sintered	female D=1,5 mm	pediatric
0001.005	Ag/AgCl sintered screw	female D=1,5 mm	adult
0002.001	Ag/AgCl	female D=1,5 mm	adult
0002.002	Ag/AgCl	female D=1,5 mm	pediatric
0002.003	Ag/AgCl	male D=2 mm	adult



CABLE FOR BRIDGE ELECTRODES

REF	L	PATIENT SIDE	INSTRUMENT SIDE
0004.009	100 cm	alligator	female D=1,5 mm
0004.011	100 cm	spring D=2 mm	female D=1,5 mm





SILICONE NET

REF	N. BANDS	CHIN STRAP	SIZE
0005.000	6x4	plastic	adult
0005.001	6x2	plastic	adult
0005.002	4x2	plastic	pedatric
0005.003	6x2	velcro/neoprene	adult
0005.004	4x2	velcro/neoprene	pediatric
0005.005	4x2	velcro/neoprene	neonatal
0005.006	6x4	velcro/neoprene	adult

KIT FOR BRIDGE ELECTRODES

REF.	N°	TYPE	SIZE
0003.001	25+50	O'Ring - Cover	adult
0003.002	25+50	O'Ring - Cover	pediatric
0003.011	25	O'Ring	adult D=0,9 mm
0003.021	50	O'Ring	adult - pediatric

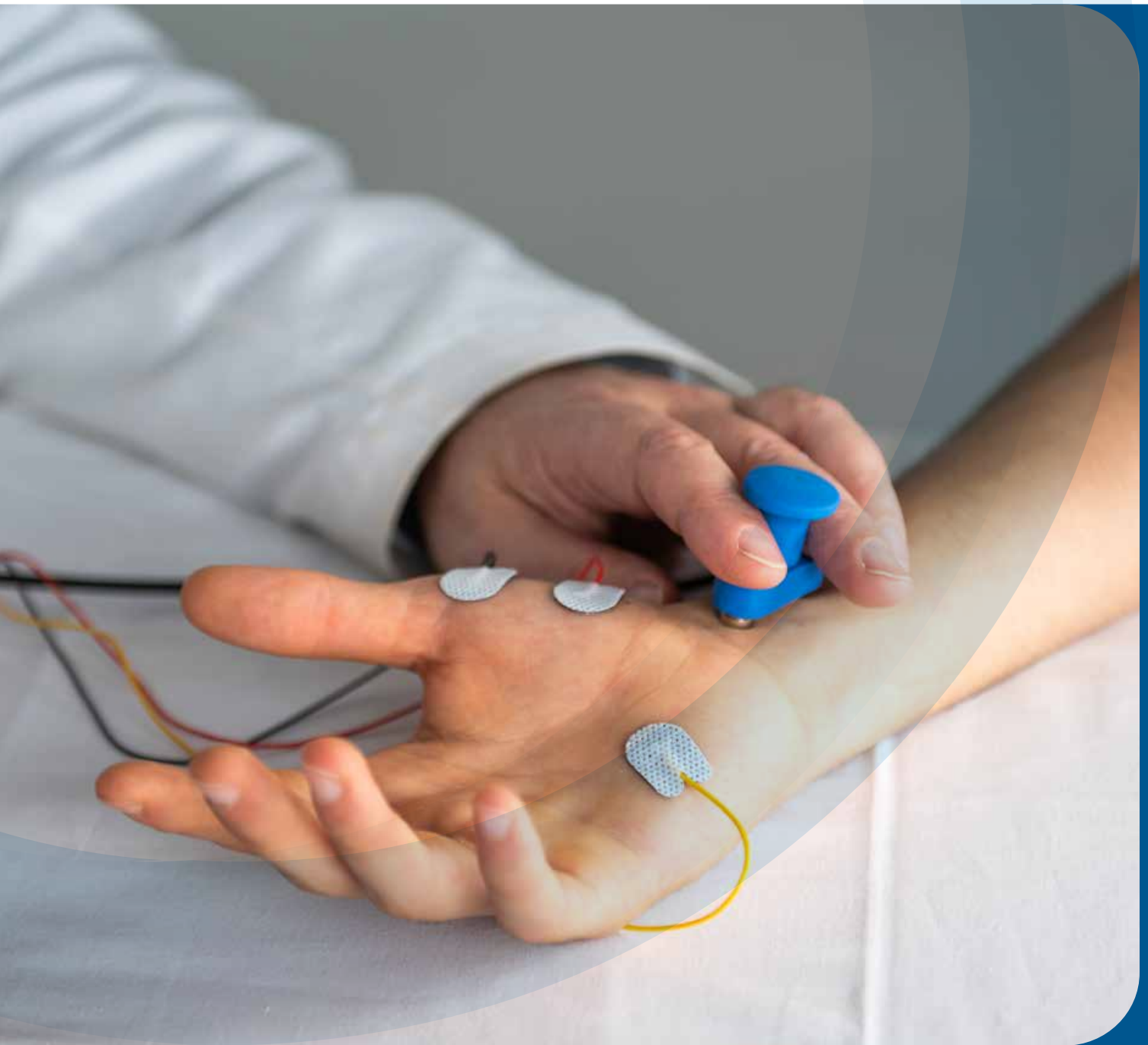


EAR ELECTRODES

REF	ELECTRODE	TYPE	CABLE L	INSTRUMENT SIDE
0006.001	Ag/AgCl sintered		100 cm	female D=1,5 mm
0007.002	Ag/AgCl		100 cm	female D=1,5 mm



QUALITY FOR...



BIONEN
medical devices



STIMULATING & RECORDING ELECTRODES

The study of the electrical conduction of major motor and sensory nerves under stimulation is carried out during Electroneurography examinations. In these tests, specific points of the body's nerves are electrically stimulated, and the resulting electrical potentials generated by muscle fiber contraction are analyzed. Often, the study of Somatosensory Evoked Potentials is associated with these exams, where bioelectrical potentials evoked by the stimulation of peripheral nerves in the upper and lower limbs through low-intensity electrical impulses are recorded via electrodes placed along the spine and on the head.

For these exams, it is important to use bipolar electrodes for both stimulation and recording of electrical potentials.

BIONEN offers a wide range of electrodes suitable for this purpose, designed to ensure ease of use and patient comfort during the examination. Additionally, these electrodes are compatible with all EMG/ENG and EP systems available on the market.



μPATTERN ELECTRODES

For selective stimulation of intraepidermal nociceptive fibres. Patent n. 1425199 (WO/2015/186087)

This surface electrode is designed for selective stimulation of the intraepidermal nociceptive fibres. It is completely noninvasive, selective, entirely safe, easy to tolerate. High number of stimuli can be delivered, allowing analysis of the evoked response so far unattainable.

INTENDED USE: **EP**

SIMPLE AND EFFECTIVE

- Disposable, no cross-contamination effect
- Application on the skin without any electroconductive paste
- Stimulation of a high amount of A δ fibers (wide stimulus surface)
- Low Depth of Electric Field: selective stimulus
- Maximum stimulus synchronization: minimal dispersion
- Vertex Cognitive Evoked Potentials

μPATTERN SURFACE ELECTRODES

REF	USE	SIZE	IDE	CABLE
0039.311	Single Use	15x15 mm	150 μm	twisted L=150 cm
0039.312	Reusable	15x15 mm	150 μm	twisted L=150 cm
0039.313	Reusable	10x10 mm	150 μm	twisted L=150 cm





STIMULATING AND RECORDING ELECTRODES

INTENDED USE: **EP - NCS**

BIPOLAR STIMULATORS

REF	L CABLE	INSTRUMENT SIDE	SIZE	INTERELECTRODIC DISTANCE
0038.002	150 cm	female D=1,5 mm	adult	25 mm
0038.003	150 cm	5 pole DIN	adult	25 mm
0038.010	150 cm	5 pole DIN	pediatric	15 mm
0038.013	150 cm	female D=1,5 mm	pediatric	15 mm



BAR STIMULATORS WITH FELTS

REF	L CABLE	INSTRUMENT SIDE	SIZE	INTERELECTRODIC DISTANCE
0038.022	150 cm	5 pole DIN	adult	40 mm
0038.023	150 cm	female D=1,5 mm	adult	40 mm
0038.032	150 cm	5 pole DIN	pediatric	20 mm
0038.033	150 cm	female D=1,5 mm	pediatric	20 mm



DISPOSABLE DTL ELECTRODES

INTENDED USE: **PERG**

REF	INSTRUMENT SIDE
0034.004	female D=1,5mm



ROUND FELT PADS

REF	DESCRIPTION	SIZE	CF.
4141.002	Round felts	Ø=8 mm	100 pcs.



RECTANGULAR FELT PADS

REF	DESCRIPTION	SIZE	CF.
4141.001	Rectangular felts	22X7 mm	100 pcs.



BELT FOR STIMULATORS

REF	MATERIAL	L	H
0062.031	Velcro	40 cm	2 cm
0062.026	Velcro Wraparound	50 cm	3 cm
0062.027	Velcro Wraparound	30 cm	3 cm





INTENDED USE: **NCS**

RING ELECTRODES

REF	L CABLE	INSTRUMENT SIDE	RING	Ø
0036.002	150 cm	2 x female D=1,5mm	elastic	2,5 mm
0036.101	150 cm	5 pole DIN	elastic	2,5 mm
0036.201	150 cm	5 pole DIN	not elastic	1 mm
0036.203	150 cm	2 x female D=1,5mm	not elastic	1 mm



PAIR OF SURFACE ELECTRODES

REF	MATERIAL	Ø	INSTRUMENT SIDE	L CABLE
0035.001	Ag/AgCl	8 mm	5 pole DIN	150 cm
0035.005	Ag/AgCl	8 mm	2 x female D=1,5 mm	150 cm



HAND-HELD BIPOLAR STIMULATING PROBES

REF	L CABLE	INSTRUMENT SIDE	SIZE
0039.000	150 cm	5 pole DIN	adult
0039.001	150 cm	3 pole DIN	adult
0039.002	150 cm	female D=1,5 mm	adult



HAND-HELD MONOPOLAR STIMULATING PROBES

REF	Ø TIP	INSTRUMENT SIDE
0039.201	5 mm	female D=1,5 mm
0039.202	2 mm	female D=1,5 mm
0039.212	5 mm	female D=2 mm



QUALITY FOR...



BIONEN
medical devices



GROUND & ADHESIVE ELECTRODES

For the acquisition of biological signals, adhesive electrodes are often used because they offer ease of use and low risk of cross-contamination, as they are single-patient use.

BIONEN Adhesive Electrodes are highly adhesive and ensure high signal quality; moreover, they are hypoallergenic and tested on delicate skin.

BIONEN also offers a wide range of cables for connecting these electrodes to EEG, EMG/ENG, EP, IONM, and PSG systems on the market, providing maximum flexibility of use, in addition to high signal quality, thanks to excellently shielded cables.

GROUND ELECTRODES

REUSABLE GROUND ELECTRODE

REF	MATERIAL	L BELT	L CABLE	INSTRUMENT SIDE
0008.041	Stainless Steel	50 cm	150 cm	female D=1,5 mm



REUSABLE GROUND BELTS

REF	MATERIAL	L BELT	CONNECTOR
0009.041	Conductive fabric	30 cm	SNAP
0009.042	Conductive fabric	50 cm	SNAP
0009.K41	Conductive fabric and cable	30 cm	SNAP - female D=1,5 mm
0009.K42	Conductive fabric and cable	50 cm	SNAP - female D=1,5 mm



ADHESIVE ELECTRODES

DISPOSABLE ROUND ADHESIVE ELECTRODES

REF	SIZE	MATERIAL	QTY
PG10C	Ø=26 mm	Ag/AgCl	30 pcs.



TAB ADHESIVE ELECTRODES

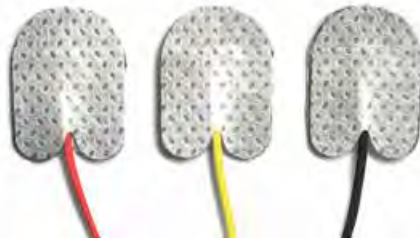
REF	SIZE	MATERIAL	QTY
0065.000	23X34 mm	Ag/AgCl	100 pcs.
0065.009	13X34 mm	Ag/AgCl	40 pcs.
0065.010	11X155 mm	Ag/AgCl	12 pcs.





DISPOSABLE ADHESIVE ELECTRODES WITH CABLE

REF	SIZE	MATERIAL	L CABLE	INSTRUMENT SIDE	QTY
0065.043	20X15 mm	Ag/AgCl	100 cm	female D=1,5 mm	12 pcs.
0065.043-150	20X15 mm	Ag/AgCl	150 cm	female D=1,5 mm	6 pcs.
0065.043-200	20X15 mm	Ag/AgCl	200 cm	female D=1,5 mm	6 pcs.
0065.053	20X15 mm	Ag/AgCl	15 cm	male D=0,7 mm	12 pcs.



REF	SIZE	MATERIAL	L CABLE	INSTRUMENT SIDE	QTY
0065.062	22X22 mm	Ag/AgCl	65 cm	female D=1,5 mm	3 pcs.



DISPOSABLE ADHESIVE GROUND ELECTRODES

REF	SIZE	MATERIAL	L CABLE	CONNECTOR	QTY
0047.001	35x45 mm	Ag/AgCl		SNAP	4 pcs.
0047.003	35x45 mm	Ag/AgCl	10 cm	female D=2 mm	4 pcs.
0047.006	40x40 mm	Ag/AgCl	150 cm	female D=1,5 mm	4 pcs.
0065.043-150	20x15 mm	Ag/AgCl	150 cm	female D=1,5 mm	6 pcs.
0065.043-200	20x15 mm	Ag/AgCl	200 cm	female D=1,5 mm	6 pcs.



CABLES

ADAPTER CABLE

REF	L	PLUG
0010.002	jumper	female 1,5 mm TP - male 1,5 mm TP

REF	L CABLE	INSTRUMENT SIDE	PATIENT SIDE
0004.016	100 cm	female D=1,5 mm	male D=1,5 mm

EMG PROXY

REF	L CABLE	INSTRUMENT SIDE
0057.203	100 cm	5 pole DIN
0057.204	150 cm	5 pole DIN

SNAP CABLES

REF	L CABLE	INSTRUMENT SIDE	COLOR X				
			1	2	3	4	5
0044.00x	120 cm	female D=1,5 mm	●	●	●	●	●
0044.07x	150 cm	female D=1,5 mm	●	●	●	●	●
0044.10x	200 cm	female D=1,5 mm	●	●	●	●	●

PATIENT CABLES

PATIENT SHIELDED CABLES

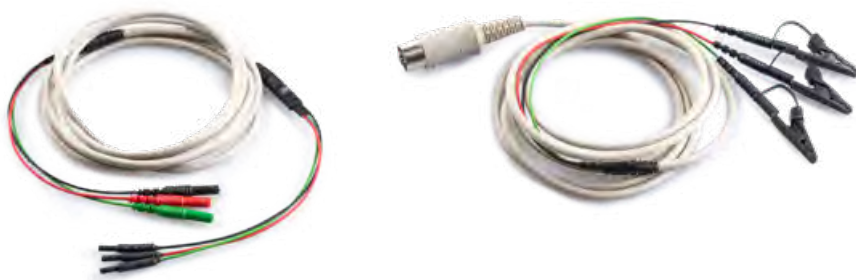
REF	L CABLE	INSTRUMENT SIDE	PATIENT SIDE
0025.130	150 cm - shielded	3 x female D=1,5 mm	3 x female D=0,7 mm
0025.133	150 cm - shielded	5 pole DIN	3 x female D=0,7 mm
0025.138	150 cm - shielded	5 pole DIN	2 x female D=0,7 mm
0025.137	150 cm - shielded	2 x female D=1,5 mm	2 x female D=0,7 mm





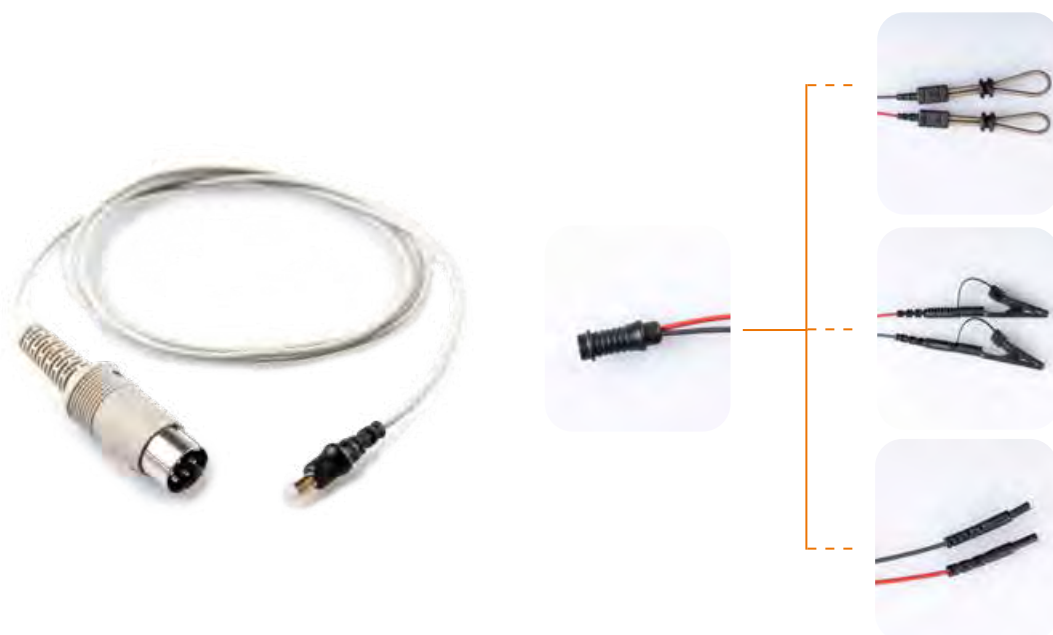
PATIENT SHIELDED CABLES

REF	L CABLE	INSTRUMENT SIDE	PATIENT SIDE
0057.003	150 cm	3 x 1,5 mm female TP	3 x alligator
0057.012	150 cm	5 pole DIN	2 x alligator
0057.103	150 cm	5 pole DIN	3 x alligator
0057.104	150 cm	5 pole DIN	3 x alligator P1
0057.107	150 cm	3 x female D= 1,5 mm	3 x alligator P1



EMG KIT

REF	L CABLE	PATIENT SIDE
0036.111	20 cm	Stimulating and recording elastic ring electrode D=2,5 mm
0025.141	20 cm	Shielded Cable with 2 Female D=0,7 mm
0025.142	20 cm	Shielded Cable with 2 TP MCH D=1,5 mm
0057.013	20 cm	Shielded Cable with 2 alligator clips
0035.006	20 cm	Pair of surface electrodes



QUALITY FOR..



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SLEEP SENSORS

Sleep studies are tests that record the body activity during sleep. They are helpful in identification of sleep disorders. A sleep disorder is a medical disorder of the sleep patterns of a person. Some sleep disorders are serious enough to interfere with normal physical, mental, social and emotional functioning.

Polysomnography (PSG), also known as a sleep study, is a multi-parametric test used in the study of sleep and as a diagnostic tool in sleep medicine.

Polysomnography is a comprehensive recording of the biophysiological changes that occur during sleep.

The PSG monitors many body functions including brain (EEG), eye movements (EOG), muscle activity or skeletal muscle activation (EMG) and heart rhythm (ECG) during sleep. Moreover, the breathing functions respiratory airflow, respiratory effort indicators and peripheral pulse oximetry.

BREATH SENSORS

BREATH TRANSDUCERS WITH THERMISTORE & CONNECTION CABLE (SLP)

1469	Airflow Thermistor – 1,5 mm female TP
1450S	Thermistor Flow Sensor – ADULT - key connector
1450-kit	Thermistor Flow Sensor + interface box – 1,5 mm female TP

These sensors provide the strongest and most accurate respiration airflow signal. They are especially robust and easy to use and clean. Powered by the interface box or your system.



THERMOCOUPLE SENSORS (SLP)

1401P	Thermocouple Flow Sensor – 1,5 mm female TP (3 ways) PEDIATRIC
1401	Thermocouple Flow Sensor – 1,5 mm female TP (3 ways) ADULT
1400	Thermocouple Flow Sensor – 1,5 mm female TP (3 ways) NEWBORN

These sensors do not need an interface box, and due to their low internal resistance they produce minimal noise.



CANNULAS

TRCM04-NS	Adult Pressure Canula
15814	Pediatric ThermoCan
0018.100	Interface ThermoCan cable - 1,5 mm female
15807-2A	Adult ThermoCan





THORACIC SENSORS

- More comfortable for the patient
- Ease to use
- High quality signal

BREATH TRANSDUCER WITHOUT BELTS

0018.060

Piezo Transducer



BREATH TRANSDUCER WITH BELTS

0018.061

1,5 mm female TP – ADULT

0018.071

1,5 mm female TP – PEDIATRIC



TREMOR SENSORS

TREMOR TRANSDUCERS

0018.103

1,5 mm female TP



BODY POSITION SENSORS

All sensors are also available separately from the kit

AC/DC OR SWITCH SENSORS (SLP)

1564V2-kit	DC body position sensor – 1,5 mm female TP + 1 band
1561-kit	AC body position sensor – 1,5 mm female TP + 1 band



MOVEMENT SENSORS

PIEZO FILM SENSORS (SLP)

1770-kit	Limb movement sensor kit (one limb) – 1,5 mm female TP + 2 bands
1772-kit	Limb movement sensor kit (two limbs) – 1,5 mm female TP + 2 bands
1730	Pair of Elastic ankle bands



MICRO MOVEMENT SENSORS (SLP)

1620-kit	Flex sensor kit (1 cable/10 disposable sensors)
1620	Flex sensors interface cable – 1,5 mm female TP
1601	Flex disposable sensors (10 pack)





EFFORT SENSORS

Piezo Crystal Sensors provide the strongest and most accurate signal replicating respiration movement.

They are especially robust, easy to use and clean. Available in 3 body attachments systems.

PIEZO CRYSTAL SENSORS (SLP)

1388-kit	Piezo Crystal Effort Sensor, Velcro tab – 1,5 mm female TP + 2 bands
1370-kit	Piezo Crystal Effort Sensor, double buckle – 1,5 mm female TP + 1 band
1387-kit	Piezo Crystal Effort Sensor, double loop – 1,5 mm female TP + 2 bands



Piezo Film Sensors are a lower cost alternative for effort sensing. These sensors feature an

encapsulated and isolated sensor element with a smooth, slim design.

PIEZO FILM SENSORS (SLP)

1389-kit	Piezo Film Effort Sensor, double loop – 1,5 mm female TP + 2 bands
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MICRO EFFORT SENSORS (SLP)

1390	Beltless miniature infant Effort Sensor – 1,5 mm female TP
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INDUCTIVE BANDS

INDUCTIVE BAND - REUSABLE

0018.R20_L150	Inductive Band torax/abdomen - reusable adult XX-Large
0018.R20_L120	Inductive Band torax/abdomen - reusable adult X-Large
0018.R20_L90	Inductive Band torax/abdomen - reusable adult Large
0018.R20_L60	Inductive Band torax/abdomen - reusable adult Medium
0018.R20_L40	Inductive Band torax/abdomen - reusable adult Small



INDUCTIVE BAND - DISPOSABLE

0018.R23	Inductive Band torax/abdomen (20m) - disposable
0018.R24_L40	Inductive Band torax/abdomen - disposable L=40 cm - Small
0018.R24_L60	Inductive Band torax/abdomen - disposable L=60 cm - Medium
0018.R24_L90	Inductive Band torax/abdomen - disposable L=90 cm - Large
0018.R24_L120	Inductive Band torax/abdomen - disposable L=120 cm - X Large
0018.R24_L150	Inductive Band torax/abdomen - disposable L=150 cm - XX Large



PIEZO REPLACEMENT CABLE (SLP)

9101	Inductive interface cable, abdomen – 1,5 mm female TP
9102	Inductive interface cable, thorax – 1,5 mm female TP





SNORING SENSORS

SNORE TRANSDUCERS

0043.001	1,5 mm female TP
0043.002	2 mm male TP



SNORE SENSORS (SLP)

1250	Piezo Snore Sensor – 1,5 mm female TP
1200	Dynamic Snore Sensor – 1,5 mm female TP



Piezo Sensors provide a signal proportional to the vibrations of the skin and are immune to ambient noise. They are especially robust, easy to use and clean.

Dynamic Sensors provide a signal proportional to sound intensity and have a wide frequency response. They are especially suited for monitoring respiratory sounds in addition to snoring.

CABLES

REF	L	INSTRUMENT SIDE	PATIENT SIDE
0044.030	50 cm	Key connector	2 x SNAP connector
0044.031	120 cm	Key connector	2 x SNAP connector
0044.033-G	250 cm	Key connector - Yellow	2 x SNAP connector
0044.033-B	250 cm	Key connector - Blue	2 x SNAP connector



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GEL & PASTES

BIONEN offers a wide range of products designed for skin preparation and treatment, electrode adhesion, and ensuring electrical conduction, tailored to the various needs of users. These products are of high quality and completely hypoallergenic.

ADHESIVE AND CONDUCTIVE PASTE & GEL

REF	NAME	DESCRIPTION	GR.	QTY
0069.000/00T	TEN 20	Adhesive and conductive paste	114 gr.	3 pcs.
0069.001	TEN 20	Adhesive and conductive paste	228 gr.	3 pcs.
0069.022	TEN 20 SINGLE USE	Adhesive and conductive paste	15 gr.	24 pcs.
0069.006	TENSIVE	Adhesive and conductive gel	50 gr.	1 pc.
0069.017	GURO'	Adhesive and conductive gel	50 gr.	1 pc.
0069.019	TN paste	Adhesive and conductive paste	250 gr.	1 pc.
0069.015	OneStep	Adhesive and conductive paste	100 gr.	1 pc.
0069.027	lic2	Adhesive and conductive paste	100 gr.	1 pc.
0069.028	ACP	Adhesive and conductive paste	100 gr.	1 pc.





ABRASIVE GEL

REF	NAME	DESCRIPTION	GR.	QTY
0069.005	NUPREP	Abrasive gel	114 gr.	3 pcs.
0069.025	NUPREP SINGLE USE	Abrasive gel	9 gr.	24 pcs.
0069.013	OneStep AbrasivPlus	Abrasive gel	120 gr.	1 pc.
0069.010	OneStep EEG gel	Abrasive and conductive gel	120 gr.	1 pc.
0069.018	SKRUB SKIN	Abrasive	250 gr.	1 pc.



CONDUCTIVE PASTE & GEL

REF	NAME	DESCRIPTION	GR.	QTY
0069.011	OneStep Cleargel	Conductive gel	500 gr.	1 pc.
0069.012	OneStep Cleargel	Conductive gel	120 gr.	1 pc.
0069.016	EEG CREAM	Conductive paste	250 gr.	1 pc.
0069.002	EEG GEL	Conductive gel	250 gr.	1 pc.
0069.026	LITHIUM GEL	Conductive gel	250 gr.	1 pc.



GENERAL SALES CONDITION

1. General Provisions

- a) The following definitions are used hereafter in this document.
- "Seller": refers to Bionen S.r.l. - Via Policarpo Petrocchi 42/1 50120 Firenze, Italy;
 - "Buyer": refers to the person or company the purchase order is received from.
- b) The Seller reserves the right to change, integrate or vary the General Terms and Conditions of Sale, by including such variations in the quotations or in any other written correspondence sent to the Buyer.

2. Offers and Orders

- a) Quotations and offers will keep in force from the date of issue to the end of the current year, unless differently stated by the Seller in writing.
- b) Orders placed by the Buyer shall not be regarded as accepted before these have been confirmed by the Seller in writing. The Seller has the right to reject any order with a total amount lower than 100.00€. If the Seller should fail to confirm an agreement in writing which it has entered into verbally, the Seller's invoice or the execution of the order by the Seller shall be regarded as confirmation.
- c) The order confirmed by the Seller is irrevocable by the Buyer exceeded five (5) working days from the issuance of order confirmation.

3. Samples

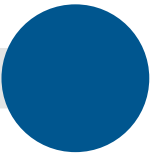
- a) The Buyer can require samples for quantities of 5 items per reference.
- b) Samples can be sent for free if the value of goods is within € 50.00 on base of price list.
- c) For samples with value more than € 50.00 seller accords an additional discount of 20% on the offer price.

4. Prices and Terms of Payment

- a) The prices of the Products shall exclude any statutory VAT which shall be payable at the date of payment or pursuant specific provisions included in the invoice. Unless otherwise stated all prices quoted in any document or correspondence issued by the Seller do not include packaging and transport costs, Taxes, stamps, custom duties and any other supplementary cost are not included in the prices. Unless an exception is made, those costs and expenses will be paid by the Buyer and, in case they are paid by the Seller, their amount will be invoiced to the Buyer as well as with the quoted prices.
- b) The payment of the Net Invoice Price shall be paid in advance with wire transfer.
- c) In addition to other remedies permitted under the applicable law and these General Terms and Conditions of Sale, the Seller reserves the right to recover default interest on delayed payments starting from the due date D.L. 192/2012 (EU No. 7/2011).
- d) If the Buyer fails to issue payments in the time and manner specified by the Seller or the Buyer business shall be operated beyond the ordinary course of business which shall include, without limitation, when seizure or protest has been made, payments shall be delayed or insolvency proceedings shall have been petitioned or opened, the Seller shall have the right to suspend or cancel, at its sole discretion, further delivery and to declare all its claims arising from the business relationship as immediately payable.

5. Delivery Terms

- a) Unless otherwise agreed, the delivery of the products shall be EXW (Incoterms 2020) from the Seller plant.
- b) Unless otherwise expressly agreed in writing any indicated time of delivery shall be non-binding for the Seller. Unless different agreement between the parties, the approximate term for the delivery is the one specified in the order confirmation.
- c) The delivery terms will be automatically considered as extended in the following case:
- if the Buyer do not communicate the data that are necessary for the supply within the due time
 - if the Buyer have outstanding payments;
- d) any liability to supply as a result of force majeure or other unforeseen incidents outside the Seller responsibility including, without limitation, strike, lock out, acts of public authorities, subsequent cease



of export or import opportunities shall, for their duration and in accordance with their impact, relieve the Seller from the obligation to comply with any agreed time for delivery.

6. Duty to Inspection and Acceptance of Products

Upon taking possession of the Products, the Buyer shall immediately conduct a conformity check on the Products compared to the data indicated in the order confirmation and record any objections

7. Terms of Warranty

a) Seller warrants the PRODUCTS to be free from defects in workmanship and materials and undertakes to replace and/or repair, free of charge, PRODUCTS or parts thereof which are found out to be defective during the period of 12 (twelve) months from the date of the invoice. Buyer shall notify Seller in writing of such defects as soon as they are found and, at Seller 's request, shall return the defective PRODUCTS to Seller 's Italian facilities at Buyer 's expense. The costs arising out of the shipment to Buyer of replaced or repaired PRODUCTS or parts thereof shall be borne by Seller. Any evident defect or damage of the manufacturing process or of the packaging must be notified in writing within 21 days from the date of the invoice. Disposable products are not under warranty.

b) The warranty shall not, in any event, apply to malfunctions of the PRODUCTS caused by misuse, abuse, accident, transportation damages, alteration, tampering with and unusual physical or electrical stress nor shall it apply if the PRODUCTS' batch number or other means of identification shall have been removed, erased or altered so as to render unidentifiable the PRODUCTS, their manufacturing date or their shipping date to Buyer.

8. Limitation of Liability

a) The Seller shall do its best endeavour to deliver the Products within the time agreed (if any), but it shall not be liable for any loss or damage of any kind whatsoever caused directly or indirectly by any delay in the completion of the contract or delivery of the Products.

b) Seller disclaims any liability for personal injuries, death, or property damages due to manipulations of the PRODUCTS, to their improper use by anyone or otherwise attributable to Buyer 's negligent acts or omissions.

c) The Seller will be entitled to make changes to the product at any moment, due to production needs, provided those changes do not alter the product performance and/or specifications in a substantial way.

9. Retention of Title.

The Product supplied shall remain in the property of the Seller until the date of the full payment by the Buyer of the entire price of the Products and of all amounts due to the Seller.

10. Brands.

Any identification brand and/or any other identification form positioned on the products which are sold by the Seller will not be removed.

11. Data Protection Law.

The personal data of the Buyer shall be processed in accordance with the Italian data protection law (Legislative Decree 196/2003). The Seller informs the Buyer that the Seller is the data controller and that the Buyer's personal data shall be collected and processed for the only purpose of the performance of this agreement. Pursuant article 7 of the Italian Legislative Decree 196/2003, the Buyer has the right to ask to the Seller the updating, amendment, integration, writing off and transformation in anonymous form of its data.

12. Applicable Law.

The present General Terms and Conditions of Sale and all the agreements executed between the Seller and the Buyer shall be governed by Italian laws.

Finito di stampare nel mese di Giugno 2024

BIONEN

medical devices

BIONEN S.r.l.
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50127 Florence, Italy
Phone: +39 (0)55 4265945
Fax: +39 (0)55 412188

info@bionen.it • www.bionen.it



www.imq.it

CERTIFICATO N.
CERTIFICATE N. **9124.BIO2**

CISQ is a member of



The International Certification Network
www.iqnet-certification.com

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

BIONEN SRL

VIA P. PETROCCHI 42/1 - 50127 FIRENZE (FI) Italy

UNITA' OPERATIVE / OPERATIVE UNITS

VIA P. PETROCCHI 42/1 - 50127 FIRENZE (FI) Italy

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Progettazione e produzione di elettrodi ed accessori per
apparecchiature elettromedicali per la rilevazione di segnali biologici
*Design and manufacturing of electrodes and accessories
for electromedical devices for detection of biological signs*

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO
PER LA CERTIFICAZIONE DEI SISTEMI QUALITA' E DI GESTIONE DELLE AZIENDE
*THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS
OF THE RULES FOR THE CERTIFICATION OF COMPANY QUALITY AND MANAGEMENT SYSTEMS*

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	29-06-1998	22-10-2024	13-11-2027

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



MS N° 0005MS

Membro degli Accordi di Mutuo
Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo
del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment
of the entire management System within three years



www.cisq.com

CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale. CISQ
is the Italian Federation of management system
Certification Bodies.



CERTIFICATO UE DI SISTEMA DI GESTIONE DELLA QUALITA'

Certificato n. 137/MDR

Visto l'esito delle verifiche condotte in conformità all'Allegato IX capi I e III del Regolamento (UE) 2017/745, si dichiara che il sistema completo di gestione della qualità istituito, documentato e implementato:

dal Fabbricante:

BIONEN SRL

50127 FIRENZE (FI) - VIA P. PETROCCHI 42/1 (ITA) - Italy

SRN: IT-MF-000018461

per i seguenti dispositivi:

Agoelettrodi per elettromiografia

Cavo ECG sterile monouso

è conforme e assicura la conformità di tali dispositivi ai requisiti applicabili del Regolamento UE suddetto ed è sottoposto alla sorveglianza prevista alla sezione 3 del medesimo Allegato.

Ulteriori informazioni sono presenti nell'Allegato tecnico che costituisce parte integrante e sostanziale del presente certificato.

Questo Certificato UE è rilasciato da IMQ S.p.A. quale Organismo Notificato n. 0051 per il Regolamento (UE) 2017/745 relativo ai dispositivi medici.

Gli esami ed i test effettuati (inclusi i riferimenti alle Specifiche comuni e/o alle norme applicate) sono documentati nel pertinente Rapporto di valutazione della conformità redatto da IMQ, tracciabile attraverso la Pratica IMQ (indicata nella sezione "Storico delle revisioni" che segue) e disponibile su richiesta.

Data di prima emissione: 2023-12-20

Data di emissione precedente: 2023-12-20

Data di emissione corrente: 2024-06-04

Data di scadenza: 2028-12-19



IMQ



EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 137/MDR

On the basis of the assessment carried out according to the Annex IX chapters I and III of the Regulation (EU) 2017/745, we hereby certify that the full quality management system established, documented and implemented:

by the Manufacturer:

BIONEN SRL

50127 FIRENZE (FI) - VIA P. PETROCCHI 42/1 (ITA) - Italy

SRN: IT-MF-000018461

for the following devices:

Electromyography needle electrodes

Disposable sterile ECG cable

complies and ensures the compliance of such devices with the applicable requirements of the aforementioned EU Regulation and it is subject to surveillance as required by the same Annex, section 3.

Further details are indicated in the Technical Attachment which is integral and substantial part of this certificate.

This EU Certificate is issued by IMQ S.p.A. as Notified Body no. 0051 for the Regulation (EU) 2017/745 related to medical devices.

Examinations and tests performed (references to applied common specifications and/or standard included) are documented in the relevant IMQ's conformity assessment Report, traceable through the IMQ's Project (indicated in the section "Revision history" below) and available on request.

First issue date:	2023-12-20
Previous issue date:	2023-12-20
Current issue date:	2024-06-04
Expiry Date:	2028-12-19

IMQ

Scheda tecnica n. 1

Technical sheet no. 1

Categoria di dispositivo: **Agoelettrodi per elettromiografia**
Device category: *Electromyography needle electrodes*

Classe di rischio: **Ila**
Risk class: *Ila*

Sito/i del Fabbricante / **- 50127 FIRENZE (FI) - VIA P. PETROCCHI 42/1 (ITA) - Italy**
Manufacturer's site(s):

Riferimenti ad altri certificati necessari per l'immissione sul mercato dei dispositivi in questione: **Non applicabile**
Reference to other certificates required for the placing on the market of the covered devices: *Not applicable*

Condizioni o limitazioni di validità: **Nessuna**
Conditions for or limitations to the validity: *None*

Altre informazioni rilevanti: **Nessuna**
Other relevant data: *None*

Dati dei dispositivi: **I dati dei dispositivi sono elencati nel documento 'Elenco dei dispositivi oggetto del Certificato UE n. 137/MDR' rev. 2 del 2024/06/04 allegato al presente certificato. Tale documento costituisce parte integrante e sostanziale del presente certificato.**

Device data: *Data of the devices are listed in the document 'List of the devices covered by the EU Certificate no. 137/MDR' rev. 2 dated 2024/06/04 attached to this certificate. This document is integral and substantial part of this certificate.*

Scheda tecnica n. 2

Technical sheet no. 2

Categoria di dispositivo: **Cavo ECG sterile monouso**
Device category: *Disposable sterile ECG cable*

Classe di rischio: **Ila**
Risk class: *Ila*

Sito/i del Fabbricante / **- 50127 FIRENZE (FI) - VIA P. PETROCCHI 42/1 (ITA) - Italy**
Manufacturer's site(s):

Riferimenti ad altri certificati necessari per l'immissione sul mercato dei dispositivi in questione: **Non applicabile**
Reference to other certificates required for the placing on the market of the covered devices: *Not applicable*

Condizioni o limitazioni di validità: **Nessuna**
Conditions for or limitations to the validity: *None*

Altre informazioni rilevanti: **Nessuna**
Other relevant data: *None*

Dati dei dispositivi: **I dati dei dispositivi sono elencati nel documento 'Elenco dei dispositivi oggetto del Certificato UE n. 137/MDR' rev. 2 del 2024/06/04 allegato al presente certificato. Tale documento costituisce parte integrante e sostanziale del presente certificato.**

Device data: *Data of the devices are listed in the document 'List of the devices covered by the EU Certificate no. 137/MDR' rev. 2 dated 2024/06/04 attached to this certificate. This document is integral and substantial part of this certificate.*

Storico delle revisioni

Revision history

N. No.	Data Date	Riferimento Pratica IMQ Reference to IMQ Project	Descrizione Description
1	2023-12-20	DM23-0076563-01	Prima emissione <i>First Issue</i>
2	2024-06-04	DM24-0101717-01	Estensione per inserimento nuova categoria di dispositivo ("Cavo ECG sterile monouso"); aggiornamento per correzione di refuso nell'identificazione di una marca di "Agoelettrodi per elettromiografia" <i>Extension for additional new device category ("Disposable sterile ECG cable"); updating for correction of typo in the identification of a trade mark of "Electromyography needle electrodes"</i>

Elenco dei dispositivi oggetto del Certificato UE n. 137/MDR

List of the devices covered by the EU Certificate no. 137/MDR

rev. 2 del of 2024/06/04

Categoria di dispositivo: Agolettrodi per elettromiografia Device category: Electromyography needle electrodes	
Modello/i Model(s): ./. Numero/i di catalogo (REF) / 028W-XXYY-ZZZ Catalogue number(s) (REF): Dove: W indica il tipo di sensore: 0 = Standard - 1 = Premium XX indica il Diametro dell'ago (da 0,30 a 0,55 mm) YY indica la Lunghezza dell'ago (da 15 a 75 mm) ZZZ indica il tipo di confezionamento secondario (da 5 a 100 pz)	Nome/i commerciale/i Trade name(s): ./. Marca/Marche Trade mark(s): BIONEN
Modello/i Model(s): ./. Numero/i di catalogo (REF) / 029W-XXYY-ZZZ Catalogue number(s) (REF): Dove: W indica il tipo di sensore: 0 = Standard - 1 = Premium XX indica il Diametro dell'ago (da 0,30 a 0,55 mm) YY indica la Lunghezza dell'ago (da 15 a 75 mm) ZZZ indica il tipo di confezionamento secondario (da 5 a 100 pz)	Nome/i commerciale/i Trade name(s): ./. Marca/Marche Trade mark(s): BIONEN
Modello/i Model(s): ./. Numero/i di catalogo (REF) / 0247-XXYY-ZZZ Catalogue number(s) (REF): Dove: XX indica il Diametro dell'ago (da 0,30 a 0,55 mm) YY indica la Lunghezza dell'ago (da 15 a 75 mm) ZZZ indica il tipo di confezionamento secondario (da 5 a 100 pz)	Nome/i commerciale/i Trade name(s): ./. Marca/Marche Trade mark(s): BIONEN
Modello/i Model(s): ./. Numero/i di catalogo (REF) / 027W-XXYY-ZZZ Catalogue number(s) (REF): Dove: W indica la Tipologia di punta (0 = ipodermica, 1 = tonda, 2 = tonda marcata) XX indica il Diametro dell'ago (da 0,30 a 0,90 mm) YY indica la Lunghezza dell'ago (da 15 a 75 mm) ZZZ indica il tipo di confezionamento secondario (da 5 a 100 pz)	Nome/i commerciale/i Trade name(s): ./. Marca/Marche Trade mark(s): BIONEN

Elenco dei dispositivi oggetto del Certificato UE n. 137/MDR

List of the devices covered by the EU Certificate no. 137/MDR

rev. 2 del of 2024/06/04

Categoria di dispositivo: Agolettrodi per elettromiografia
Device category: Electromyography needle electrodes

Modello/i Model(s): ./.

Numero/i di catalogo (REF) / NKD-NMYYZZ(P)

Catalogue number(s) (REF): Dove:

NKD-NM valore fisso che identifica la marca NIHON KHODEN

YY indica il Diametro dell'ago (da 0,30 a 0,55 mm)

ZZ indica la Lunghezza dell'ago (da 15 a 75 mm)

P indica il tipo di sensore

- "assente" = Standard
- P = Premium

Nome/i commerciale/i Trade name(s): ./.

Marca/Marche Trade mark(s): **NIHON KHODEN**



Elenco dei dispositivi oggetto del Certificato UE n. 137/MDR

List of the devices covered by the EU Certificate no. 137/MDR

rev. 2 del of 2024/06/04

Categoria di dispositivo: Cavo ECG sterile monouso
Device category: Disposable sterile ECG cable

Modello/i Model(s): ./.

Numero/i di catalogo (REF) / 0210.XXX

Catalogue number(s) (REF): Dove:

XXX indica la Lunghezza del cavo (da 100 a 250 cm)

Nome/i commerciale/i Trade name(s): **FasTip**

Marca/Marche Trade mark(s): **BIONEN**