waveguard™ net

User Guide

Rx Only. Caution: US Federal Law restricts this device to sale by or on the order of a physician.

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The **wave**guard EEG cap is a medical device of CE class I according to the Regulation (EU) 2017/745 (MDR).

In the USA, **wave**guard net EEG cap is a class II device according to the CFR, FDA 510(k) clearance No. K240575 (product codes NA-xxx).

In Canada, certain cap types are licensed as medical device class II according to the MDR under MDL number 88779.

For product registrations in other countries send your inquiry to sales@eemagine.com.

Important Notice

Every care has been taken to ensure the accuracy of the information in this document. However, we assume no responsibility for errors, inaccuracies, or omissions that may appear in this document.

We reserve the right to change the product without further notice to improve reliability, function or design. This document is provided without warranty of any kind, implied or expressed, including fitness for a particular purpose.

Please read this manual carefully before using a **wave**guard net.

The cleaning and disinfecting procedures as described aim at a most careful net maintenance. However, eemagine GmbH cannot control whether these procedures are properly followed, nor can we assess the quality of third-party cleaning products. As a consequence, eemagine GmbH does not assume any liability for the cleanliness of the nets and the fitness of net for EEG recordings after cleaning. In particular, eemagine GmbH does not assume any liability for infections that may be caused by using EEG nets previously washed and/or disinfected by the user.

In addition to this information, please always follow the regulations that apply locally in your country and hospital or institute. Contact your distributor if you are in doubt about what regulations apply and how to meet them.

Please contact your distributor in case of a defective net or other required support. Do not try to repair nets yourself if there is still warranty on the net. If you do so, the warranty will be void. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of your country.

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Document ID: UDO-SM-0297_EN	Approval (eemagine): DRN-13907

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1 Safety information

1.1 Intended purpose / Indications for use

waveguard EEG net caps are intended for recording electroencephalographic (EEG) signals, including event-related potentials (ERP) and evoked potentials (EP) on subjects or patients with intact scalps in combination with medical-grade EEG recording equipment (CE class IIa certified inside the European Union; class II device according to FDA regulations for USA).

The application of nets/caps on subjects or patients should only be carried out by medically trained personnel (EEG technicians). The technician must remain present during the entire recording session to prevent patient risks such as strangulation. Special infection control requirements may apply.

waveguard EEG net caps are intended to be used for patients from infant up to any age.

Regulatory information for users in the USA:

This is an EEG electrode set intended for routine clinical settings where rapid placement of a large number of EEG electrodes is desired.

The **wave**guard family are considered Medical Devices, denoted with the MD symbol in the device label.

1.2 Contra-indications

The nets should not be used on patients with skin injuries or problems such as blisters, burns, wounds from operation or other superficial wounds or transmissible diseases, such as – but not limited to – hepatitis, human immunodeficiency virus (HIV) or Creutzfeldt-Jacob disease.

Do not use the nets in a Magnetic Resonance Imaging (MRI) scanner or any other high-intensity electromagnetic field radiation environment.

In the event of defibrillation, disconnect the net and/or electrodes from the EEG recording equipment first.

1.3 Side effects

For the net application, there are no side effects known. Please apply the correct size of the net. Keep in mind that a too small net may cause a headache. Slight red marks on the exposed skin due to contact pressure are a regular effect of wearing the net and disappear within a short time (e.g., on the forehead).

For the saline solution, we recommend using 2 tsp of reagent-grade KCl (potassium chloride) per litre of water. KCl is generally recognized as safe as it is mostly used in food items and skin products. Do not use excess amounts of KCl than recommended as it can irritate the skin at very high concentrations.

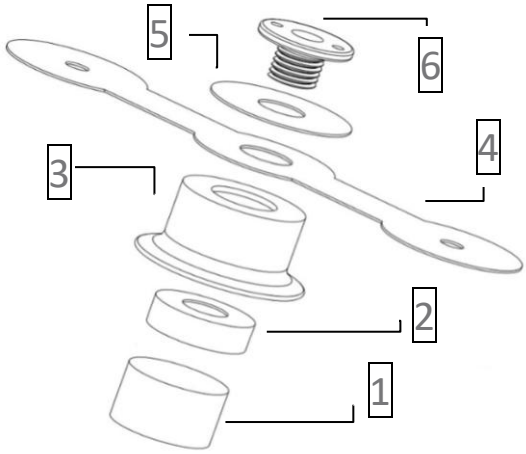
2 Important Warnings

- **Before the first use, make sure that the net is clean and properly disinfected.**
- Do not use incompatible electrode materials like platinum or stainless steel in one recording.
- Do not use brushes or any other hard materials (in particular, no metal tools such as screwdrivers) to clean the net.
- Always apply the correct net size (based on head circumference).
- Do not clean the net using an ultrasonic cleaning device.
- Do not keep the net submerged in water for prolonged periods (maximum one to two hours).
- Do not expose the net to hot environments over 50° Celsius (or short rinsing at 60° Celsius). The net wiring does not withstand higher temperatures. Hot-air drying may significantly reduce the lifetime of the net.
- Do not try to wring or squeeze the net! We recommend placing the net on a towel or drying rack for drying.
- Do not use any autoclaving procedure on the net.
- Make sure that the net connectors always remain dry.
- Please dry the net turned inside-out and in an upside-down position, with the cable being placed higher than the wet net, to prevent the adapter and tubing from being contaminated with water.
- Always disconnect the net holding the connector housing. Do not drag at the cable, as doing so will cause damage that is not covered by the warranty.

3 NET design

3.1 Net components

A short description of the individual components is provided below to help you identify parts and communicate problems when using the net.



Schematical representation of electrode assembly, PU electrode substrate [2], *and sponge insert* [1]

1 - High-quality Sponge material

2 - Electrode substrate with coated Ag/AgCl

3 - Special silicone ring to mechanically "hold" the saline-soaked sponge

4 - Elastomeric net structure in "waveguard grey"

6 - Top Screw to fixate the electrode

5 - Labels to quickly identify electrode positions

7 - Connector: depending on the net model, it is compatible with the eego EE-2xx and EE-5xx range of amplifiers or with many clinical EEG systems.

3.2 Compatibility

3.2.1 NET caps with shielded wires

The shielded **wave**guard nets are designed for use with ANT **eego** EEG amplifiers. The compatibility of each **wave**guard net model is described in the dedicated product datasheets.

Hardware related	The hardware supports the acquisition and processing of EEG data and includes an amplifier, a data acquisition computer and a monitor. Different models of **wave**guard net can either connect to EE-2xx and EE-5xx **eego** amplifiers. We do not recommend replacing a defective electrode using the FastFix electrode. For more information see 6.2.
Software related	The **wave**guard nets are compatible with the **eego**™ software. From the **eego** 1.10 version upwards, the net related hardware setups are preconfigured. For previous versions, they can be manually created using the datasheet. The *UDO-SM-0010 **eego** system User Manual* provides comprehensive descriptions of all Acquisition features and functions.

3.2.2 NET caps with Unshielded wires

Unshielded **wave**guard net models are equipped with Sub-D connectors and are designed for use with any clinical EEG system. Caps with Sub-D connectors (one per set of 32 channels) can usually be directly plugged into the EEG amplifier. If Touch-Proof single inputs (DIN 42802) are to be used, an adapter from Sub-D to single Touch-Proof leads can be provided.

3.3 Net features

Feature	***Description***
Special electrodes	**wave**guard net electrodes are passive sensors measuring the small changes in the electrical potential on the scalp. The **wave**guard net uses special electrodes, replacing the existing **wave**guard electrode bodies.
Electrode components	Each electrode consists of a substrate, plated with well-adhering Ag. A special silicone ring mechanically holds the electrolyte-soaked sponges in place. The use of sponges makes the electrodes soft and well-adaptable to different pressure forces.
Elastomeric structure	The stretchable and breathable silicone net structure provides a good compromise between elasticity and stability. It is soft enough to provide comfortable wearability for the subject, while also

	exerting enough force on the electrodes/sponges to ensure continuous contact with the scalp.
Cable protection	All the electrodes are mechanically fixated on the net structure. Cable guide tabs, integrated into the net structure, guide the shielded electrode cables.
Optimal pressure distribution	Given the correct size selection, the elastic silicone net ensures the best contact of the electrode sponges with the scalp and applies homogenous pressure across all channels.
Two different layouts	Current models are in equidistant and 10/20 layout. Refer to the datasheet for the electrode count and layout of each model.

*For further information about specific **wave**guard net models, please refer to the related product datasheet.*

4 Net application

✓ Always apply the correct size of the net (based on head circumference).

✓ Make sure that the net is completely dry before use.

4.1 Preparing the saline solution

WARNING: Improper cleaning and/or saline solution concentration can result in poor signal quality.

- Use a plastic bucket to prepare the saline solution.
- Add 1 litre of warm water (no warmer than 37 °C).
- Add 2 teaspoons of granular or powdered potassium chloride (KCl) into the saline solution bucket.
- Add 1 teaspoon of baby shampoo.
- Stir well until the KCl is completely dissolved.
- Remove the chin strap and dip the electrode end of the net into the saline solution bucket; be careful to prevent the connector of the net from coming into contact with the saline solution.
- Soak the net in the saline solution for at least 5-10 minutes to ensure adequate wetting of the sponges. Gentle agitation of the net facilitates the process.

× Do not reuse saline solution between subjects or sessions.

× Do not put the connectors into or close to the bucket.

4.2 Subject preparation

4.2.1 The subject's hair should be clean

Make sure the subject has properly washed the hair, best in the morning before the experiment. This removes the major layer of oil and dead skin residues.

Make sure that the subject did not use any hair conditioner. Conditioners may establish a protective layer on the scalp which could increase the electrical impedance of the electrodes.

✓ It is advisable to wash the subject's hair on the same day and before measurements are taken

✓ Brush the hair before the placement of the net

✓ Ask the subject to remove earrings, glasses, and hair ties. Glasses can be placed after the net application if needed

× Subjects should be reminded to not use hair conditioner after washing their hair before taking measurements

4.2.2 Comb or brush the hair of the subject

It is advantageous to brush or comb the hair of the subject using a relatively hard hairbrush before applying the net. Please be sure to use a brush or comb that avoids static charge. You can either assist the subject with the brushing or have the person do this him/herself. Brushing removes some dead skin particles/ dandruff, resulting in lower electrode impedances.

Try to establish a homogenous distribution of hair density on the subject's head. Untie the hair if necessary. Brush the hair of the subject and direct it into a symmetric shape.

4.3 Head measurement

4.3.1 Measure the head circumference

Measure the head circumference of the subject with a tape measure. Head circumference is measured over the most prominent part on the back of the head (occiput) and just above the eyebrows (supra-orbital ridges). Prepare the correct net size (according to the size table) for application.

Using the correct size of the net (refer to the head circumference table) is important for achieving a good accuracy of electrode positions. Applying a net that is too small may cause excessive wear. A net that is too big may cause loose electrode contacts and bad channels.

✓ Always apply the correct size of the net (related to head circumference).

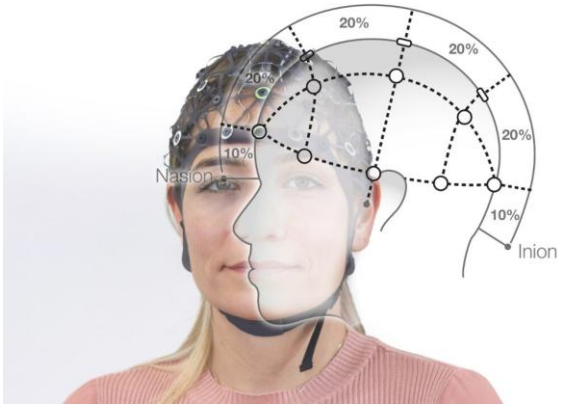
✓ Make sure that there is no electrolyte dripping before applying.

× Make sure that no external pressure is placed on the electrode, for instance by resting the head on a surface.

× Make sure that the hair of the subject(s) is completely dry before applying the net.

4.3.2 Measure the reference point

Find the reference point half the distance of Nasion to Inion and half the distance between the two pre-auricular points. Mark the position with an eyeliner or other skin-friendly marker.



4.4 Net placement and adjustments

4.4.1 Prepare

- Place a towel over the subject's shoulders to catch the excess saline solution drips.
- Lift the net vertically out of the saline solution bucket, waiting a moment for the net to drip excess electrolyte back into the bucket.
- Visually check the mesh for any tangling.

✓ Protect the connector end of the net from contact with liquid throughout the application process

✗ Do not squeeze or press the sponges to remove excess saline, as the sponges may become depleted of the saline.

4.4.2 Position the net

- Identify the front of the net with the GND electrode and the backside with the cable split.
- Position the frontal electrodes and ask the subject to gently hold them steady.
- Position the central electrode (see table below) on the reference point explained in 4.3. Note, this is a rough (!) estimate, absolute differences/distances between the respective positions differ depending on net size and head shape.

0/20 layout	64 ch equidistant	128 ch equidistant	256 ch equidistant
Cz	**5Z**	**Z7**	**Z12Z**

For the detailed layout chart and all positions/ naming, please refer to the specific product datasheet of each model.

4.4.3 Stretch the net over the head

- Gently pull the net over the subject's head, starting at the upper central area. Place the net from the top of the head, starting with the vertex electrodes and then work your way to the downward electrodes.

4.4.4 Adjust electrodes

- Visually check the structure for any tangling and make sure that the net is applied symmetrically.
- Check the positioning of the net and adjust it by grabbing large sections and shifting them uniformly.

4.4.5 Tighten the net fit

- Each electrode should have an upright stance on the scalp. Gently move the electrodes to position them correctly.
- Pull the earpieces of the net downwards to tighten the net fit to the scalp. Buckle the chin strap to fix the final position of the net.

4.5 Connecting the cap with the EEG recording system

For the shielded waveguard net, there's a connector for every set of 32 or fewer electrodes. Connect the net to the **eego** amplifier plugging the connectors.

✓ Always disconnect the caps holding the connector housing.

× Do not use incompatible electrode materials like platinum or stainless steel in one recording.

× Never drag at the cable! Note that dragged-out cables are not covered by the cap warranty.

For the unshielded waveguard nets, there's one connector for 21 electrodes.

Always make sure that properly matching connectors are used. Cable outlets at the cap side are numbered if more than one connector is present. When using more than 32 channels, double-check that the numbering is in accordance with the channel inputs at the EEG recording hardware (or adapters, if used).

When disconnecting a cap, take special care not to drag at the cables but hold the connector housing tightly to remove the plug.

4.6 Optimization of electrode contact

1. Check the impedance

   If you are using the net in combination with the **eego** amplifier and **eego** software, use the impedance measurement tool of the **eego** software to assess the connectivity of the electrodes. Maintain the impedances below 50 kOhm after application. For the GND and REF electrodes, maintain the impedance as low as possible, preferably below 20 kOhm.

2. Optimize electrode contact

   For channels above this impedance, you can adjust the specific electrode position by gently wiggling the electrode. If a wide range of electrodes are not properly positioned, then you can try to wiggle the whole net or apply light pressure with the palm of your hand. Be careful not to shift the complete positioning of the net.

   Sometimes it is difficult to create a good connection through the hair layers of the subject. In this case, wiggle the electrode while applying pressure to the electrode to push the hair aside.

✓ Wait at least 5 seconds after applying the net to read the correct impedance values.

× Do not push the electrode against the subject without a swipe movement or with high pressure.

5 Net Maintenance

5.1 Cleaning

Make sure that the net is properly cleaned after each measurement. We strongly recommend rinsing the net with lukewarm water immediately after use.

You can do this in a regular sink. Hold the net inside-out with one hand and rinse it, especially in between electrode pins. You can also clean the net in a bucket of water. Important note: cleaning does not disinfect the net. Please refer to the next chapter for disinfection procedures.

Using water to clean the net:

1. Completely submerge the net in a bucket of lukewarm tap water. Be careful not to wet the connectors.
2. Pull out and re-submerge the net. Repeat this procedure at least 5 times.
3. Remove the net from the bucket and let it dry.

Keep the cable and connectors away from the water when cleaning the net. Avoid any moisture near the connectors to completely prevent possible short circuits or corrosion. In case you need to clean the connectors, use a cotton swab slightly soaked with alcohol (do *not* use this on the electrodes).

✓ Make sure that the net connectors always remain dry.

× Do not rinse under the tap or shower head to avoid the sponges coming off the electrode's rings.

× Do not squeeze or wring the net!

× Avoid spilling any of the water on the connectors. Keep them distant from water sources.

5.2 Disinfection

Make sure that the net is adequately cleaned before disinfecting.

Examples of disinfectant solutions that are known to work satisfactorily are Cidex OPA (by Advanced Sterilization Products) or Metricide, Cavicide (by Metrex), Pursept AF (by Schülke & Mayr), Sekusept activ (by Ecolab) or Korsolex Extra (by BODE Chemie).

You must follow the disinfectant's instructions for use and take care to rinse the net properly. Plastic parts such as labels, flex-rings and the silicone mesh, may bleach slightly. This is normal and does not interfere with the normal usage of the net. However, the extensive use of disinfectants may reduce the lifetime of the nets.

! The use of disinfectant may reduce the lifetime of the nets.
! Alcohol is not an adequate solution for disinfecting electrodes.
! Hydrogen peroxide solutions should not be used.
! **Please make sure that local and hospital regulations for cleaning are always followed!**

General guidelines for disinfection are available through the following links:

- CDC (USA) - www.cdc.gov/infectioncontrol/guidelines/disinfection/
- Robert Koch Institute - doi.org/10.1007/s00103-017-2634-6
- World Health Organisation - www.who.int/infection-prevention/publications/decontamination/

Please remember that the use of unapproved disinfectants will void the warranty.

Disinfection solution

all quantities are stated for Korsolex Extra only. For other providers, please refer to their guidelines.

1. Mix 4% of the disinfectant liquid with 96% distilled water in a bucket.
2. Wear protective gloves.
3. Completely submerge the net in the liquid. Be careful to not wet the connectors.
4. Pull out the net and submerge it again in the solution. Repeat this procedure at least 5 times.
5. Leave the net submerged in the disinfectant for about 15 minutes.
6. Remove the net from the bucket and rinse the net with distilled water.

Neutral soap

1. Mix 10% of the neutral, non-perfumed soap with 90% distilled water in a bucket.
2. Completely dip the net in the liquid. Be careful not to wet the connectors.
3. Pull out the net and submerge it again in the solution. Repeat this procedure at least 5 times.
4. Leave the net submerged in the soap solution for about 15 minutes.
5. Remove the net from the bucket and rinse the net with distilled water.

✓ Make sure the net is adequately cleaned before disinfecting

× Do not use any kind of alcohol for disinfection of the **wave**guard net.

× Do not keep the net submerged in any disinfection liquid for prolonged periods.

5.3 Drying

A solution to shorten the drying time is to use a cooling (table) fan. In the cool air stream, drying is quick and safe, within approximately 30 minutes. Place the net at a distance of ca. 50 cm from the fan.

Ensure that no remaining water or other liquid may enter the connector during drying.

Avoid the connectors or other metals being in direct contact with the sponges/electrodes.

✓ Please dry the net ideally in an upside-down position, or on a head model, while the cable is placed higher than the wet net, to prevent the adapter and tubing from being contaminated with water.

✓ Pull the net inside out for drying.

× Do not try to wring or squeeze the net!

× Do not expose the net to hot environments over 50° Celsius.

× Do not use a hot hair dryer to dry the net.

5.4 Net sponge replacement

Before using the net, please be sure to check that the sponges are clean and intact.

- Moisten the sponges to remove with tap water. Avoid the connectors in contact with water and wet surfaces.

(The depicted and actual colour of the sponge may vary)

- The sponge can be easily removed when wet.
- Moisten the new sponge with tap water. Insert a moistened sponge into each silicone ring, as deep as possible.

- The surface of the sponge must lie flat, entirely against the surface of the electrode and be completely enclosed by the silicone ring. Approximately 1-2 mm of the sponge protrudes from the silicone ring.

- Avoid the connectors or other metals being in direct contact with the electrodes.

Warning: Sponges are small parts, do not swallow

5.5 Storage

Avoid long-term exposure of the net to sunlight or UV light. Store the net in a dark and dry place (best in a suitcase or plastic bag).

Caution: Avoid the connectors or other metals being in direct contact with the electrodes.

5.6 Transportation

Avoid long-time exposure of the net to sunlight or UV light during transportation. The net should always be transported with the sponges facing inside.

5.7 Usage & Environmental conditions

Parameter	Description	Unit	nom	min	max
Period of use	Routine EEG recording	h	1	NA	3
Operating temperature		°C	25	5	35
Cleaning temperature (defined procedure)		°C	25	20	40
Storage temperature		°C	NA	5	40
Transport temperature		°C	NA	0	40
Humidity		%	NA	15	70
Atmospheric pressure	(altitude <2000m)	kPa	NA	80	106
Max. Pollution degree	a micro-environment where only non-conductive pollution occurs except that occasionally a temporary conductivity caused by condensation is to be expected.	NA	NA	NA	NA

Note: The application is intended for a maximum of 3 hours consecutive use. The cap may then be prepared again by saline solution soaking and reapplied but it should never be used for prolonged periods in one patient (accumulated period below 20 hours).

6 Other important information

Carefully Inspect the net for visible damage at regular intervals, preferably before every use. Check, for example, the fixation of the wires and the cable protection, the cable bundles that extend from the net and the connector(s) for defects of the plastic housing, broken or corroded electrodes.

6.1 Waste disposal

Nets must be disposed of as electronic waste in accordance with local legal regulations.

WARNING: Before you dispose of any item, you must ensure that all materials that have been in contact with the patient are not contaminated. You may have to thoroughly clean and sterilize before disposal.

6.2 Warranty and Support

The **wave**guard net is made of high-quality materials:

electrode elements	Coated Ag/AgCl on Polyurethane (PU) *
Net structure	Silicone
electrode housing	Polyurethane (PU)

All nets are carefully inspected before they leave the factory. A waveguard net is delivered with a limited warranty that depends on the model. The **shielded** waveguard nets have a warranty period of **15 months**, and the **unshielded** models of 12 **months** after delivery, based on the condition that it was handled according to the indications for use described in this user guide. In summary, the limited warranty provides that each product, when delivered will conform to its specification and will be free from defects in material and workmanship, including:

- Missing sponges
- Broken silicone structure
- Breaking of electrode elements, if not caused by inadequate cleaning/handling
- Broken wires inside the net, defective cable extending from net to connector
- Defects inside the net connector

For repair claims please contact your distributor to get detailed information or instructions for warranty and self-repair services. Warranty is excluded for damage caused by misuse of the net for example:

- Defects in the chinstrap/chin-band
- Normal wear-and-tear of the electrode labels or other labels attached to the net
- Wear-and-tear of the silicon mesh and/or the wires due to inappropriate handling, e.g. contact with sharp objects.

Note: final judgment is taken by *eemagine GmbH* after having received the net in question.

IMPORTANT: Nets returned to the manufacturer for repair – warranty or not – are sent back to the customer's account without inspection/repair if they are not thoroughly cleaned.

6.3 Available sizes

Note: The size 'Baby' below is not an indication of the patient age. The waveguard nets are intended for infants (29 days from birth to 2 years) up to any age.

6.3.1 Shielded nets

24 Channels 10/20 extended layout	32 channel 10/20 extended layout	64 channel 10/20 extended layout	64 Channels equidistant layout	128 Channels equidistant layout	256 Channels equidistant layout	Sizes	Head circumference (cm) Min.	Max.	Size label color scheme	
NA-245.11	NA-255.11	NA-265.11	NA-261.11	NA-271.11	NA-281.11	**L** Large	56	61	●	●
NA-245.10	NA-255.10	NA-265.10	NA-261.10	NA-271.10	NA-281.10	**M** Medium	51	56	●	●
NA-245.09	NA-255.09	NA-265.09	NA-261.09	NA-271.09	NA-281.09	**S** Small	47	51	●	●
NA-245.08	NA-255.08	NA-265.08	NA-261.08	NA-271.08	--	**C** Child	43	47	●	●
NA-245.07	NA-255.07	NA-265.07	NA-261.07	--	--	**I** Infant	39	43	●	●
NA-245.06	NA-255.06	NA-265.06	NA-261.06	--	--	**B** Baby	36	39	●	●

(Size indication serves as a guideline only – optimal fit depends on head shape and hairstyle)

6.3.2 Unshielded nets

21 Channels 10/20 extended layout	21 channel 10/20 extended layout	Sizes	Head circumference (cm) Min.	Max.	Size label color scheme	
NA-301.11	NA-314.11	**L** Large	56	61	●	●
NA-301.10	NA-314.10	**M** Medium	51	56	●	●
NA-301.09	NA-314.09	**S** Small	47	51	●	●
NA-301.08	NA-314.08	**C** Child	43	47	●	●
NA-301.07	NA-314.07	**I** Infant	39	43	●	●
NA-301.06	NA-314.06	**B** Baby	36	39	●	●

(Size indication serves as a guideline only – optimal fit depends on head shape and hairstyle)

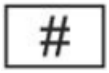
6.4 Product Lifetime

How long a net can be used with all electrodes intact and without compromising signal quality depends upon many factors. Careful handling and thorough cleaning are most important. The electrode sensors, the silicone mesh along with all other parts and materials have been selected and designed such that more than 250 cycles of recording and cleaning are expected to be reached.

In case you observe the signs of wear, tears or cracking in the silicone mesh or electrode connections or deformations of the general cap structure, it is indication that the net may have reached its end of life. Careful handling and thorough cleaning will help extend the life of the device.

Please do not hesitate to contact us in case you have suggestions on how the quality of the nets as well as this user manual can be further improved.

Appendix A: Explanation of Symbols

	Manufacturer symbol: indicated with name, address
	Catalogue number, product code
	Serial Number (SN)
	Product Variant
	Year of manufacture
	Conformité Europeenne, CE mark
	United Kingdom Conformity Assessed
	Follow the instructions for use (i.e., this user manual)
	Warning sign: warnings apply
	Special waste disposal regulations apply (EU)
	Medical Device
Rx only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
	QR code for traceability, including product code of the cap and its SN (UDI: Unique Device Identification)
	MR unsafe

Appendix B: EU Declaration of Conformity

Hereby we declare in exclusive responsibility that below identified products fully comply with the regulations of the Medical Device Regulation (EU) 2017/745 (MDR) on medical devices, as well as the relevant statutory requirements of the United Kingdom.
To the best of our knowledge given the information provided by our suppliers, products are also in conformity with the Council Directive 2011/65/EU (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as amended by Directive (EU) 2015/863. Products are not made with natural rubber latex, and do not contain BPA.

waveguard™ EEG cap and accessories

Electrode caps, adapters and leads for recording of EEG signals

The product family consists of devices that are classified according to MDR Annex VIII, rule 1, as **CE class I**, and meets the applicable *General Safety and Performance Requirements* of the MDR Annex I. This corresponds to the same classification and relevant statutory requirements of the United Kingdom.

We apply the conformity assessment procedure in accordance with MDR Annex IX and issue this declaration of conformity as manufacturer.

Products are marked with CE

The applicable sections of the following standards have been used as a basis for the conformity:

- <IEC 60601-1:2005/A1:2012>
- <EN ISO 14971:2019>
- <EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-18:2009>
- <IEC 62366-1:2015>
- <EN ISO 15223:2021>

This declaration DOC-QA-0001 is valid for product codes REF as stated in the appended product list.

The corresponding *Global Medical Device Nomenclature* (GMDN) code is: 63131.

We are registered with HIBCC, with *Labeler Identification Code* (LIC): B195.

EUDAMED assigned our *Single Registration Number* (SRN): DE-MF-000005560.

The *notified body* involved in the assessment of our quality management system is:
<notified body name, address>.
Current certificate EN ISO 13485:2016 <registration information>.

Dated at Berlin, Germany, on the _____ day of _____ <202x>.

<CEO>
eemagine Medical Imaging Solutions GmbH

For the exact <information> in the above text, see the official, signed declaration DOC-QA-0001. The contents of similar conformity statements may be different in countries outside the European Union.