

waveguard™ connect

EEG cap & accessories



User Guide

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

User Guide for the **waveguard™** connect EEG cap

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The **waveguard** EEG cap is a medical device of CE class I according to EU regulation 93/42/EEC (MDD), and also according to 2011/65/EU (RoHS).



In the USA, **waveguard** EEG cap is a class II device according to the CFR, FDA 510(k) No. K110223.

In Canada, certain cap types are registered 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 **waveguard** cap.

The cleaning and disinfecting procedures as described aim at a most careful cap 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 caps and the fitness of caps for EEG recordings after cleaning. In particular, eemagine GmbH does not assume any liability for infections that may be caused by using EEG caps 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 cap or other required support. Do not try yourself to repair caps yourself if there is still warranty on the cap. If you do so, the warranty will be void.

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Contents

1	SAFETY INFORMATION	4
1.1	Intended use	4
1.2	Contra-indications	4
1.3	Side effects	4
2	IMPORTANT TECHNICAL NOTES	5
3	WAVEGUARD CAPS	6
3.1	Description of the cap	6
3.2	Cap accessories	6
3.2.1	Adapters	6
4	APPLICATION OF THE WAVEGUARD CAP	7
4.1	Preparations and cap positioning	7
4.2	Fixation of the cap	7
4.3	Connecting the cap with the EEG recording system	8
4.4	Gel usage	9
5	CLEANING AND HANDLING OF CAPS	10
5.1	DOs and DON'Ts for Washing	10
5.2	Drying	11
5.3	Disinfecting caps	11
5.4	Maintenance of Tin (Sn) electrodes	12
6	OTHER IMPORTANT INFORMATION	12
6.1	Waste disposal	12
6.2	Warranty and Support	12
6.3	Available cap sizes	13
6.4	Lifetime of caps	13

1 Safety information

1.1 Intended use

waveguard EEG caps are intended for recording of electroencephalographic (EEG) signals, including event-related potentials (ERP) and evoked potentials (EP) on subjects or patients with intact scalp 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 cap must be dry and clean when used. The application of caps on subjects or patients should only be carried out by medically trained personnel (EEG technician). The technician must remain present during the entire recording session to prevent patient risks such as strangulation. Special infection control requirements may apply.

Regulatory information for users in the USA:

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

FDA 510(k) No. K110223

Some special type caps: e.g., neonatal, MEG-, MRI-compatible **waveguard** caps, are for research only in USA, and may need special washing procedures and/or precautionary measures to make sure that the cap is not magnetically contaminated.

1.2 Contra-indications

The caps 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 cap in a Magnetic Resonance Imaging (MRI) scanner or in any other high-intensity electromagnetic field radiation environment unless the type of the cap expressly states the compatibility with such a device.

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

1.3 Side effects

No side effects are known if properly applied. Please apply the correct size of the cap. Keep in mind that a too small cap may cause headache. Slight red marks on the exposed skin (e.g. at the forehead) due to contact pressure are a regular effect of wearing the cap and disappear within short time.

2 Important technical notes

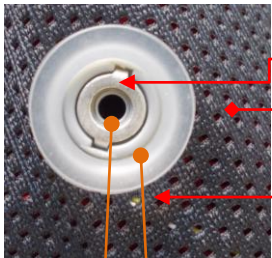

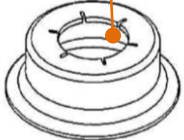


- Do not use incompatible electrode materials like platinum or stainless steel in one recording.
- Do not use hard brushes or any other hard materials (in particular no metal tools such as screw drivers) to clean electrodes.
- Apply always the correct size of cap (related to head circumference).
- Make sure that the cap is completely dry before use.
- Do not clean the cap using an ultrasonic cleaning device.
- Do not keep the cap submerged in water for prolonged periods of time (maximum one to two hours).
- Do not expose the cap to hot environments over 50° Celsius (or short rinsing at 60° Celsius). The cap fabrics as well as the wiring do not withstand higher temperatures. Hot-air drying may significantly reduce the lifetime of the cap.
- Do not try to wring or squeeze the cap! We recommend to gently dab the cap fabric using a towel, or to hold the cap between two towels for drying.
- Do not use any autoclaving procedure on the cap.
- Make sure that the cap connectors always remain dry.
- Please dry the cap ideally in an upside-down position, with the cable being placed higher than the wet cap, in order to prevent adapter and tubing to be contaminated with water.
- Always disconnect caps holding the connector housing. Never drag at the cable! Note that dragged-out cables are not covered by the cap warranty.



3 Waveguard caps

3.1 Description of the cap

We provide a short description of the individual parts here, which helps in communicating on details or identifying problems when using the cap.

	<p><i>Electrode element as seen from inside of cap</i></p> <p>“Electrode ring” Pure tin electrode material</p> <p>Inside “Lining” fabric (same material as outside fabric)</p> <p>“Wiring” (hidden between outside fabric and lining)</p>
	<p>“Electrode-housing” with electrode element and cable</p>
	<p>“Flex-ring” holds the gel and provides contact with skin</p>
	<p>“Top screw” with gel insertion hole</p>
	<p>“Label” (between outside fabric and top screw)</p>

3.2 Cap accessories

3.2.1 Adapters

The unshielded **waveguard connect** EEG caps come with Sub-D connectors. 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.

4 Application of the waveguard cap

- ✓ Apply always the correct size of cap (related to head circumference).
- ✓ Make sure that the cap is completely dry before use.

4.1 Preparations and cap positioning

Gently pull the cap over the patient's head, starting at the forehead. Pull on towards the back of the head while carefully placing the cap symmetrically.

To position the electrodes correctly, find the reference point halfway the distance of Nasion to Inion and halfway the distance between the two pre-auricular points. This is where electrode **Cz** is located. The frontal electrodes **Fp1**, **Fpz** and **Fp2** should be positioned at 10% of the Nasion-Inion distance, which is a few centimetres above the eyebrows. Likewise, positions **O1**, **Oz** and **O2** should be 10% above the Inion.

Using the correct size of cap (related to head circumference) is important for achieving a good positioning accuracy. Stretching a cap over a head that is too big for it may cause excessive wear of the fabric and also places the electrodes superior to their actual locations. Please refer to the size table and chart in this user guide. Head circumference is measured over the most prominent part on the back of the head (occiput) and just above the eyebrows (supra-orbital ridges).

Try to position the cap correctly in one go, without further shifting the cap. This may prevent slow drifts in the EEG because displaced hair tends to shift back. You may ask the patient to hold the frontal electrodes in place while putting on the cap.

It is advantageous to comb the hair using a relatively hard hairbrush before applying the cap. You can either assist the patient with the brushing, or have the person do this him/herself. The brushing removes some dead skin particles/dandruff, resulting in lower electrode impedances.



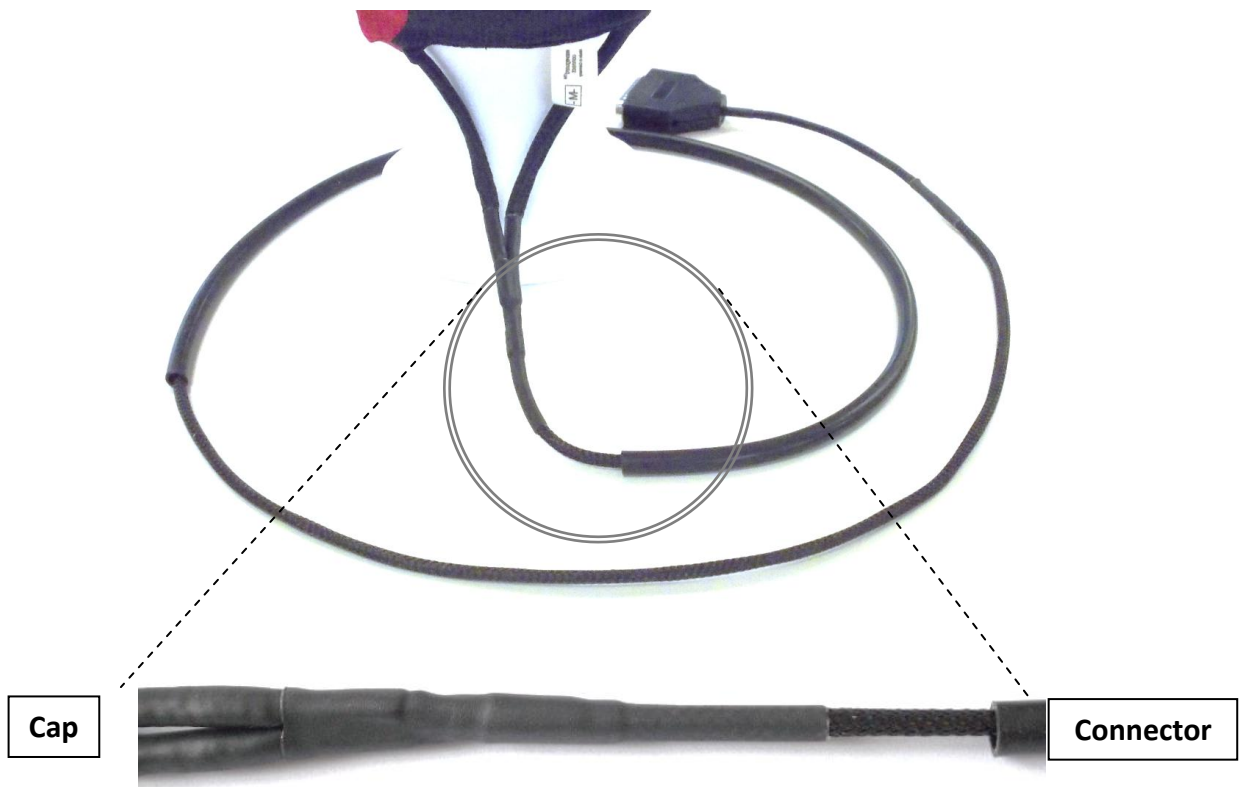
4.2 Fixation of the cap



The standard fixation of the cap is achieved with a chin band clipped to the left and right side below the ears. An alternative solution is provided as chin strap that is stretched over the chin and fixated with Velcro underneath the flaps of fabric that hold the fixation clips.

For users having problems with chin fixation, we provide a chest belt, which is clipped to the left and right side below the ears.

If your cap comes with a silicone protection tube, it is designed to protect the cap cable from contaminations with blood, dirt, sweat or other fluids when executing measurement. The recommended position during a measurement is to fix the tube close to the patient and cap. You can fix the silicone tube by pulling the end over the thicker part of the cable (see picture).



Silicone protection tube loosened



Silicone protection tube fixed

Before washing and/or drying you can gently slide down - away from the cap - the silicone protection tube if necessary for cleaning or to allow any moist inside the cable to evaporate.

4.3 Connecting the cap with the EEG recording system

- ✘ 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.
- ✓ Always disconnect caps holding the connector housing.

The cap comes with a connector for every set of 32 or less electrodes. 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.

4.4 Gel usage

We recommend using *OneStep* conductive gel. *You should use only conductive gel that is CE certified (Europe) or FDA approved (USA) for medical use.*

Apply the gel using dedicated syringes with blunt needles for easier insertion through the hole of the electrodes. Do not use too much gel, practice on how much to inject.

First bring in the blunt needle down through the hole and touch the scalp. Put some pressure on the syringe and inject gel while slowly taking out the syringe to form a gel bridge between scalp and electrode. Typically you need ca. 10 ml of gel for 32 electrodes. Be careful not to damage the skin with the needle, especially on the temples and on the mastoids: often the skin is more delicate at these positions.

You should never scratch the skin but may use the needle to move away some hair (gently move in circles) before inserting gel if necessary.



When using the cap for long time, i.e. more than 4 hours, you may have to apply additional gel to some contacts. Be careful when you remove the cap after long-time use since gel remnants may firmly attach the electrode flex-rings to the skin, and may cause flex-rings to come loose from the electrode-housing. To facilitate removing the cap, apply lukewarm water to the electrodes or to the cap and let the gel soak up the water for a minute.

5 Cleaning and handling of caps

5.1 DOs and DON'Ts for Washing

- ✘ Do not clean the cap using an ultrasonic cleaning device.
- ✘ Do not keep the cap submerged in water for prolonged periods of time (maximum one to two hours).
- ✘ Do not use any hard mechanical tool for cleaning of the electrodes. The electrode elements may break with force.
- ✘ Do not use any autoclaving procedure on the cap.
- ✓ Make sure that the cap connectors always remain dry.

We strongly recommend rinsing the cap with lukewarm water immediately after use.

You can do this at a regular sink; best is to use a **showerhead** attached to the faucet. Hold the cap inside-out with one hand, and rinse the gel out of the electrode cups with a firm spray of water.



The best way to clean the electrodes is to use an **oral douche** (or water-pik) machine such as available for dental cleaning. The focused water spray is perfect for getting out the gel and cleans the electrode elements completely. A regular shower head can be used to rinse off remaining gel.

You should also rinse clean the cap fabric!

Your next patient will appreciate a clean cap! It is not needed to wash the cap with soap each time, but if you do, please use a non-detergent, non-perfumed, soft soap.



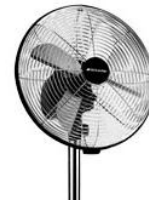
Keep the cable and connectors away from the water when cleaning the cap. Avoid any moisture near the connectors in order to completely prevent possible short-circuits or corrosion. In the event that you need to clean the connectors, use a cotton stick slightly damp with alcohol (do *not* use this on the electrodes).



5.2 Drying

- ✘ Do not expose the cap to hot environments over 50° Celsius (or short rinsing at 60° Celsius). The cap fabrics as well as the wiring do not withstand higher temperatures. Hot-air drying may significantly reduce the lifetime of the cap.
- ✘ Do not try to wring or squeeze the cap! We recommend to gently dab the cap fabric using a towel, or to hold the cap between two towels for drying.
- ✓ Please dry the cap ideally in an upside down position, with the cable being placed higher than the wet cap, in order to prevent adapter and tubing to be contaminated with water.

The cap must be completely dry before next use. Do not use a hot hair dryer to dry the cap. A solution to shorter drying time is to use a cooling (table) fan. In the cool air stream, drying is quick and safe, within approximately 20 minutes.



5.3 Disinfecting caps



Make sure that the cap is adequately cleaned prior to disinfecting.

Examples of disinfectant solutions that are known to work satisfactory are Cidex OPA (by Advanced Sterilization Products) or Metricide, Cavicide (by Metrex), or Korsolex Extra (by BODE Chemie).

You must follow the disinfectant's instructions for use and especially rinse the cap properly. Plastic parts, such as labels, flex-rings and the fabric, may bleach slightly. This is normal and does not interfere with the normal usage of the cap.

- ! The use of disinfectant may reduce lifetime of the caps.
- ! Alcohol is not an adequate solution for disinfecting electrodes.
- ! Please make sure that local and hospital regulations for cleaning are always followed!

5.4 Maintenance of Tin (Sn) electrodes

You must not use any chemical or electrolyte methods to remove oxidation. Those methods may cause irreversible damages resulting in degraded functionality of the electrodes and bad signal quality during your measurement.

In order to remove an oxidation layer, please clean the electrode surface with a wooden stick or by using the end of a cotton swap. Please handle with care to prevent damage to the electrode.



Electrode with layer of oxide;

after cleaning with wooden stick

If removal of the oxide layer is not possible or when the electrode-ring is damaged, please ask your distributor for repair/replacement. If many electrodes are affected, we recommend replacing the cap.

6 Other important information

Inspect the cap carefully in regular intervals, preferably prior to every use, for gel remnants in the electrodes, visible damage to fabric (outside and inner lining) and the cable protection, and the cable bundles that extend from the cap, and check the connector(s) for defects of the plastic housing, broken or corroded electrodes.

6.1 Waste disposal

Caps 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 waveguard cap is made of high-quality materials:

electrode elements	Pure Sn (tin) material
cap fabric	83% Polyester, 17% Elastan (spandex)
electrode housing	Polyurethane (PUE)
flexible ring (inside of cap)	Medical grade silicone (withstands acid, oil, solvents)

User Guide for the waveguard™ connect EEG cap

All caps are carefully inspected before they leave the factory. A **waveguard** connect cap is delivered with a limited warranty for the period of **4 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 will conform to its specification and will be free from defects in material and workmanship, including:

- Loose seams, holes in the cap fabric, e.g. caused by defects in the sewing process
- Breaking of electrode elements, if not caused by inadequate cleaning/handling
- Broken wires inside the cap, defective cable extending from cap to connector
- Defects inside the cap 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 cap and the examples:

- Broken/missing connector latches (high-density connectors only)
- Defects in the chin-strap/chin-band
- Broken/missing flex-rings
- Normal wear-and-tear of the electrode labels or other labels attached to the cap

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

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

6.3 Available cap sizes

Order code	Sizes	Head circumference		Head circumference		Fabric color scheme		
		Min. (cm)	Max. (cm)	Min. (in)	Max. (in)			
CS-3XX.11	L Large	56	61	22	24	●	●	●
CS-3XX.10	M Medium	51	56	20	22	●	●	●
CS-3XX.09	S Small	47	51	18.5	20	●	●	●
CS-3XX.08	C Child	43	47	16.9	18.5	●	●	●
CS-3XX.07	I Infant	39	43	15.4	16.9	●	●	●
CS-3XX.06	B Baby	36	39	14.2	15.4	●	●	●

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

6.4 Lifetime of caps

How long a cap 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 fabric along with all other parts and materials have been selected and designed such that more than 500 cycles of recording and cleaning can be reached.

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