eego™ amplifier EE-511

User Manual

eego amplifier EE-511 version 1.0

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IMPORTANT NOTICES

Following the MDR (EU) 2017/745 Annex VIII, **eego amplifier** is a CE class IIa medical device.

CE 0124

This User Manual only covers the EE-5xx eego amplifier. Refer to dedicated User Manual for other variants.

For US customers only:
Rx only
Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DISCLAIMER

We have attempted to write this document as accurately as possible. However, mistakes are bound to occur, and we reserve the right to make changes to the products, which may render parts of this document invalid.

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1 GENERAL INFORMATION

1.1 ABOUT THIS DOCUMENT

With this document, we provide you with all information required to set up and start working with the **eego** amplifier. It may be put to use as part of the **eego** system, which comes with a separate user manual, dedicated to the use of the eego software as installed with the system. Additional training materials are available on academy.ant-neuro.com.

If you encounter problems with the device that cannot be resolved using this document, please contact us directly via **support@eemagine.com** for further help (please make sure to state the product ID and serial number of your amplifier in the Subject section of your email).

We will coordinate communication with your dealer in case you purchased the device locally.

This document is provided on a USB storage device with each amplifier and also in printed form in the package.

1.2 INTENDED PURPOSE

The eego amplifier is intended for acquisition of EEG signals and to transmit them digitally to a computer, and is to be used by, or under the supervision of, a qualified medical practitioner or investigator who has knowledge about the principles of EEG, physiology and potential side effects.
The device is intended for use on humans.
The device is intended for use in a clinical environment (e.g., hospital, physician's office, etc).
The device is not intended for use in life support systems.

1.2.1 INDICATIONS FOR USE

The eego amplifier is used with compatible recording software and accessories for the acquisition of EEG signals and to transmit them digitally to a computer.
A patient will only be prescribed to undergo an EEG examination by a doctor in neurology or neuropsychiatry.

In addition, EEG is used in a broad range of neuroscience applications and fundamental research, e.g., neuropsychology, neuropsychiatry, to study brain function

1.2.2 CONTRA-INDICATIONS

For the eego amplifier, no contra-indications are given.

The system in which it is used may have contraindications for its intended purpose. For example, in the use of the eego system contra-indications for recording are related to the patient's health and general head condition. Do not use the system on persons that have/are:

- open wound on the scalp or skin problem
- not able to tolerate preparation procedures
- not able to tolerate EEG cap/electrodes

1.2.3 CLINICAL CLAIMS

Following the intended purpose as stated above, no clinical claims are made for the eego amplifier.

1.2.4 CLINICAL BENEFITS

An EEG amplifier is a critical part of the equipment used in electroencephalography (EEG) system. It plays a vital role in amplifying the tiny electrical signals produced by the brain, making them detectable and measurable. Here are some key benefits of an EEG amplifier:

1. Enables Brain Activity Recording:

The primary function of an EEG amplifier is to amplify the weak electrical signals generated by the brain's neurons. These signals, measured in microvolts, are too faint to be directly recorded without amplification. The amplifier boosts the signal strength, allowing for accurate recording and analysis.

2. Supports Research and Development:

EEG amplifiers are widely used in neuroscience to support research into various aspects of brain function, such as memory, perception, language, and decision-making. They also play a vital role in developing new treatments for neurological disorders.

Overall, EEG amplifiers are invaluable tools for studying and understanding brain function. They have revolutionized the field of neuroscience and continue to offer significant benefits for diagnosing, monitoring, and treating various neurological conditions.

1.2.5 USER PROFILE

The main user must be a physician with expertise in EEG that might train technical knowledgeable other users to operate the amplifier in combination with a compatible medically certified software and its settings under his supervision and review of all acquired data.

No special training material beyond the scope of this document is needed for the amplifier itself as the operation is simply achieved by plugging the amplifier into a computers USB port to start the device and unplugging to stop. Accessories and connectors are also covered without further special training needs.

The software will come with its own training material as needed and is than to be used.

In case training is still required please contact eemagine support for related arrangements. In case training is still required please contact eemagine support for related arrangements. Also, refer section 1.1 for further online materials.

1.2.6 INTENDED PATIENT POPULATION

All patients, of age pre-term (23 weeks gestational age) to old-age (no limit), without skin problems, no (potentially) transmissible diseases, all nationalities, and typically awake during a recording session.

1.3 TECHNICAL DATA AND FEATURES OVERVIEW

The eego amplifier has been designed as a mobile recording device for EEG signals.

It provides access to recorded data over a USB connection to external software over its signal driver interface. The eego amplifier EE-5xx is powered via the USB connection and does not require any additional power source.

This ultimate solution for mobile EEG recording provides 24 channels of referential EEG. The eego amplifier is best used in combination with a dedicated recording program (eg. eego system and neo monitor), CE class IIa software compliant with the eego amplifier and a waveguard EEG headcap (CA-505). The eego amplifier has two 1bit trigger input channels and one 1bit trigger output channel accessible through three separate micro coax connectors. Impedance values can be measured for all referential electrodes as well as the reference and patient ground electrode. An SDK is available for direct amplifier communication.

The implemented active shielding technology protects the EEG inputs from interference noise. Sampling rate and gain can be set through the user interface of the control software.

Detailed technical specifications, environmental conditions, the available product variants and PC requirements are given in the APPENDIX C: Datasheet for **eego** amplifier.

Note: eego amplifier does not interact with internet.

1.4 SAFETY WARNINGS

The following warnings and cautions apply to the **eego** amplifier:

- Proper use of the **eego** amplifier depends on careful reading of all instructions and labels that come with or on the device inaccurate measurements may be caused by incorrect use of the device.
- Non-compliance with warnings and safety regulations may result in severe personal injury!

If you are uncertain or have any questions about operational safety or about any of the warnings and cautions, then do not hesitate to call or email:

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Phone: +49 30 29048404
E-Mail: support@eemagine.com
http://www.eemagine.com

For warnings and safety regulations concerning **wave**guard EEG caps, please refer to the corresponding manual.

1.4.1 IMPORTANT INFORMATION

- There are no known side effects from the use of this equipment.
- ONLY APPLICABLE TO THE USA: Under federal law this apparatus may only be sold by or on the order of a physician or licensed practitioner. The apparatus may only be used under the constant supervision of or on the instructions of a physician or other authorized medical professional.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of your country (for USA, see 1.11).

1.4.2 SAFETY MEASURES

- The only external power supply that may be used in combination with the amplifier is a computer device in compliance with the specifications as in APPENDIX C: Datasheet.
- Make sure to use the device only with ISO 60950 or 60601-1 compatible devices for powering and trigger connection.
- Inspect the power cord of connected computers on a regular basis for damages. Do not operate the device with a damaged power cord.
- Do not connect active sensors or electrodes to any of the inputs of the amplifier.
- Do not use the device with adapters, EEG caps or other devices not explicitly listed to be compatible with the device.
- Take care when arranging sensor cap and other cables to avoid risks of entanglement or strangulation. Do not firmly fixate the device nor attached accessories to any immobile part to further reduce risk of asphyxiation. Never put cables in a loop around your neck.
- Reusable electrodes present a potential risk of cross-contamination. Please refer to the documentation that came with your electrodes for instructions on how to prevent this.
- Do not connect the device to a patient undergoing MRI, electro-surgery or defibrillation.
- Do not modify the equipment. Never attempt to unscrew any parts of the amplifier.

- ELECTRICAL SHOCK HAZARD: Do not connect electrode inputs to earth ground. Connecting an earth ground might result in electrocution.
- Conductive parts of ELECTRODES and associated connectors for APPLIED PARTS, including the NEUTRAL/GROUND/REFERENCE ELECTRODE, should not contact other conductive parts including earth.
- ELECTRICAL SHOCK HAZARD: Servicing of the equipment is to be done by approved technicians only.

1.4.3 PRECAUTIONARY MEASURES

- When the amplifier is not in use, please make sure to switch it off (disconnect USB cable).
- The amplifier needs special precautions regarding EMC; the use of accessories other than specified may result in increased emissions or decreased immunity of the **eego** amplifier EE-5xx and result in improper operation.
- The **eego** amplifier should not be used adjacent to or stacked with other equipment; if this is still necessary, verify normal operation in the configuration in which it will be used. Do also not stack multiple **eego** amplifiers directly on top of each other. Allow for some spacing of several cm in between.

- The use of portable and mobile RF communications equipment can adversely affect the recording; do not use an operating cellular phone within 30 cm (12 inches) of the amplifier, the cables and the electrodes to avoid excessive noise on the signals.
- Avoid the presence of nearby Radiofrequency identification (RFID) sources when operating the amplifier.
- During EMC testing the essential performance was monitored based on the input noise voltage (peak to peak) under short circuit load condition and on the accuracy of the reproduction of a triangular input signal (f = 6Hz, Amplitude = 1$mV_{pp,}$ DC offset = 300mV). The pass/fail criteria were a noise voltage level below 6μV_{pp} (50Hz low pass filtered) and correctness of the waveform within +/-20%. There is no special servicing procedure required to guarantee EMC over the lifetime of the device.
- Disposable electrodes which are used for electrophysiological measurements may pose a biohazard. Handle, and when applicable, dispose of these materials in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.
- The device neither needs a extended time to warm up before use nor to cool down after use. Essentially you can plug it in and start using it immediately via the control software (refer to the dedicated user manual of the control software before use). You can also plug it out immediately when the control software is no longer acquiring data.

1.4.4 WARNINGS

- Safety and performance of the device are not guaranteed when it is used together with accessories that were not explicitly listed as compatible.
- The device is not defibrillator-proof.
- The device is not suitable for use in an inflammable mixture of anesthetics and air, oxygen or nitrous oxide.
- No chemical agents are to be used with the device. Also, not for cleaning purposes.
- The device is not to be immersed in any liquid. Liquids must also not spill on it. Cleaning must be done with a dry cloth.
- If any liquids or moisture penetrate the device or a part thereof, turn the device off, have the device checked by the manufacturer.
- Do not expose the device to direct sunlight, heat from a source of thermal radiation, excessive amount of dust, moisture, vibration, or mechanical shock.
- Do not wind the cables in a loop smaller than 5 cm or bend them sharply, as this may damage the cables.
- During operation with an active connection via USB to a compatible computer, do not connect other USB devices, and do not make changes to any connections.
- If the **eego** amplifier is upgraded or replaced for any reason, make sure to have the control software and interfacing computer checked for compliance by eemagine support before continuing to work with the device. Similarly have the **eego** amplifier checked for compliance when the control software or computer is upgraded or replaced.
- During operation place the device in such a way that connectors and cables are easily accessible.
- Do not bring the device in touch with sharp objects such as pencil-points or pen-tips, as this may cause damage.

- Do not apply high pressure on the housing and contact the manufacturer when it appears deformed in any way.
- Do not use the device whenever parts of it are damaged.
- Do not perform measurements with reusable caps on patients with skin problems on the scalp or presumably transmissible diseases.

1.4.5 TROUBLE SHOOT

In case the device seems to behave unusual or does not show the LED states as described in Table 2-1 refer to the control software user guide for restarting or resetting an EEG recording. Should that not provide a solution to the problem than close the software, unplug the USB connector from the computer running the software. Afterwards reconnect the amplifier and restart the software. Try another recording. If that does not solve the issue contact support (contact information 1.8) for further guidance.

The device has no alarm states as such. It serves no life supporting critical functions. A compatible software might have related functions. Refer to the user guide of the software.

1.5 MAINTENANCE AND CLEANING

We would like to give a few general recommendations that may help to keep your equipment in good shape and ensure high quality of recordings.

The amplifier is mechanically robust – within limits. Try to protect the device as much as possible from falling and heavy mechanical shocks. Please take special care that the USB cable and the connectors on either side are not under mechanical stress. A broken USB connection may lead to expensive and time-consuming repair of the amplifier.

The EEG head-cap may be attached to the amplifier with the available screws on the connector in case of expected movement of the patient/subject. The screws do not need to be extremely tight but just hold the connectors in place, so please tighten the screws gently.

The expected lifetime of the device is 5 years.

There is no need for periodic testing of the device and accessories during the lifetime. After this, we recommend to test every year.

Do not attempt to repair a device yourself. Neither before nor after the lifetime. Contact eemagine under the contact given above and we'll provide service personnel with any required additional information as needed (technical diagrams, service equipment, part lists).

WARNING: If the amplifier requires cleaning, please use a dry cloth to remove dirt (e.g., gel remainders). Do not use alcohol or cleaning chemicals.

1.6 DISPOSING OF WASTE EQUIPMENT

The **eego** amplifier device bear the symbol for special waste disposal regulations (EU). The symbol means that the products must not be disposed of with regular waste. Instead, it is the user's responsibility to dispose of waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service, or the manufacturer.

1.7 SYSTEM AND DATA PROTECTION

All amplifiers interact without exception via a wired USB connections with the IT infrastructure (point to point isochronous transfer). There are no other communication interfaces accessible. The USB based API to the amplifier is proprietary and identification with product code and serial number is mandatory for the enumaration and detection of devices. This prevents wrong or unintended connections. Correct, uncompromised transfer of the data is further checked via a control channel transmitted with the EEG channel time series. Data loss or data modification during transport is thus identified and leads to exceptions in the controlling software for handling it further. The amplifier is not storing any patient information or recorded patient data at all. It only transmits recorded data.

Automated firmware updates via USB in the field are not possible but only possible at the manufacturers site in a manual controlled update process by technical experts.

The amplifiers have no connection to an IT infrastructure or only indirectly via a computer that by definition of the compatible accessories of an eego amplifier must run a medical CE approved software. With the protection of the firmware and lower communication controlled via the restricted proprietary USB protocol the IT security is fully governed by the the software and computer controlling the amplifiers that by requirements for medical equipment will cover all higher level Ethernet and related cyber/IT security risks.

1.8 PRODUCT VARIANTS

See the APPENDIX C: Datasheet..

1.9 PC REQUIREMENTS

See the APPENDIX C: Datasheet.

1.10 CONTACT INFORMATION

For more information and for reporting problems with **eego** amplifier, please contact eemagine at:

eemagine Medical Imaging Solutions GmbH
Gubener Str. 47, D-10243 Berlin, Germany
Phone: + 49 30 29048404, E-Mail: support@eemagine.com
www.eemagine.com

1.11 FDA MEDWATCH PROGRAM (USA ONLY)

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

1.11.1 SUBMITTING ADVERSE EVENT REPORTS TO FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

1) Report Online at www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

2) Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

3) Call FDA at 1-800-FDA-1088 to report by telephone

a) Reporting Form FDA 3500 commonly used by health professionals. The form is available at

https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting

2 THE EEGO AMPLIFIER EE-5XX, HARDWARE SETUP DESCRIPTION

2.1 THE EEGO AMPLIFIER EE-5XX

The **eego** amplifier device has been designed for mobile applications recording EEG and related electrophysiological signals. The compact electronic device is USB-powered and gives access to 24 referential input channels via a 68-pin high density connector (EEG IN) as shown in Figure 2-1. The **wave**guard cap CA-505 is designed for connecting directly with this input port.

The connection diagram of the amplifier the EEG cap and a computer is shown in Figure 2-4.

WARNING: Make sure to use the USB cable delivered with the device.

At the front (Figure 2-1) the USB cable with micro USB C plug powers the device, provides access to data communication and hardware control. Also two micro coax connectors provide 2 independent single bit trigger input lines (TR IN 1, TR IN 2). Trigger input signals can be acquired from devices that deliver TTL output. Additionally, one trigger (TR OUT) output signal can be acquired through the micro coax connector on the same side.

The trigger lines are electrically isolated from the patient leads of the amplifier. The trigger adapter XS-432 allows to connect the **eego** amplifier trigger input ports via a DB25 connector. The adapter connects to both ports. For details refer to the dedicated datasheet.

At the rear (Figure 2-2) a high-density 68-pin connector (EEG IN) provides access to 24 shielded referential and 4 bipolar channels, and reference and ground as well. Four through holes in the amplifier housing allow securing the amplifier, e.g., on a table.

Figure 2-1. Front view of the eego amplifier EE-5xx with USB cable and mini coax trigger input (TR IN1 & TR IN2) and output (TR OUT).

Figure 2-2. Rear view of the eego amplifier EE-5xx with 68-pin high density connector (EEG IN)

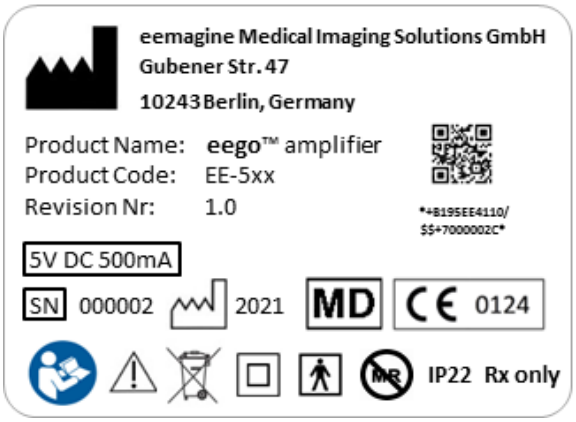


Figure 2-3. The product label at the bottom of the amplifier device shows manufacturer information, product name, code and revision, and serial number, year of production and CE marking. The symbols in the bottom row points are explained in Appendix B.

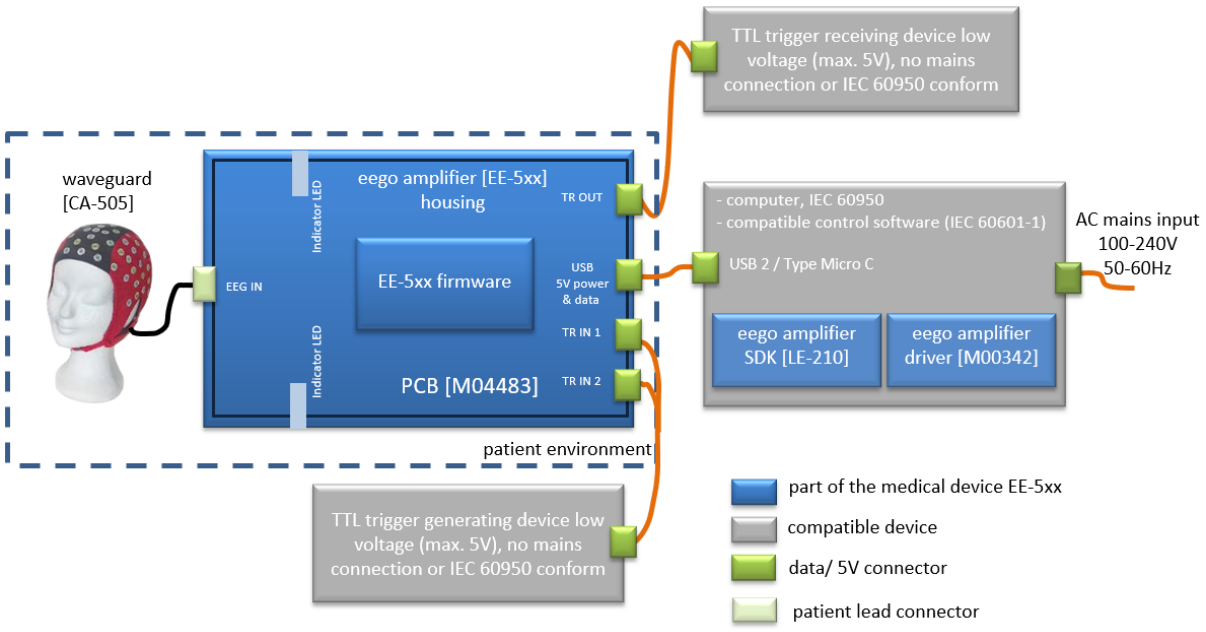


Figure 2-4: Connection diagram.

2.2 BIOSIGNAL AND IMPEDANCE MEASUREMENTS

Measurements of physiological parameters such as EEG require highest quality and fidelity of the electronic equipment and sensors used with it. The **eego** amplifier EE-5xx has been developed on the basis of latest state of the art core electronic components (integrated circuits). The modern chip-set allowed miniaturizing hardware without compromises in signal quality and keeping the power consumption low. The device weights less than 100 grams and has a small form factor.

The input stage of the 24 referential and 4 bipolar input channels to the amplifier has been optimized for EEG recordings with a **wave**guard head cap. The preamplifier component implements active shielding, which greatly suppresses external noise effects that typically contaminate EEG signal. Active shielding works such that the buffered input signal (no amplification of signal amplitude but impedance transformation) is put on the coaxial shield of an electrode lead inside the **wave**guard cap. This way, electrical transmission of external noise through the coaxial shield into the signal wire is minimized due to the zero-voltage difference between the signal wire and its shield.

The referential input stage of the amplifier registers incoming signals against a common dedicated reference electrode. The measured voltages strongly depend upon the quality of the reference signal and it is highly recommended to pay attention to good preparation of the reference electrode. For the **wave**guard cap model CA-505 the electrode Cz is defined as the REF electrode.

In order to measure physiological signals with high sensitivity, the human body acting as a source of voltage differences and the amplifier ground (the electrical zero-point from which the operating range is determined) have to be connected. This can be - for convenience - an electrode lead in the **wave**guard cap: the model CA-505 defines AFz to be the ground (GND) position. Nonetheless, any other accessible body part can be used to make the GND connection – with no effect on the measured signal amplitudes. See also the cap datasheet and its user guide for more information.

The GND connection actually implements a driven ground, that provides a reference for the measured voltages relative to the human body. Electrical currents are kept well below limits defined for patient safety in medical devices. The driven ground allows measuring signal amplitudes of the voltage of the driven ground without saturation effects, regardless of the polarity of the signal. The actual signal range is determined by the amplification factor of the input stage, which is programmable in steps.

With the **eego** amplifier you can also record bipolar signals. In this case the REF channel is not used but each of 4 bipolar channels are measuring the difference between its positive and negative input port.

Regardless of referential or bipolar recordings the amplified data stream of input signals is converted from analog (continuous in amplitude and time) to digital (discrete in amplitude and time). Both dimensions – voltage and time – are digitized in a way that the analog waveforms can be approximated without loss of quality in further review and analysis steps. The resolution is in the order of a few nV (nano Volts) depending on the selected signal. Each signal has its own converter, so that no multiplexing effects occur.

The digital data stream is converted into a protocol suitable for computer communication (USB). Communication between computer and amplifier works in two ways: control commands sent by the application software set the amplifier state and parameters (e.g., sampling rate and signal range), and

the amplifier sends EEG data, trigger and status information according to the respective operation mode.

The application software sets up communication via the USB 2.0 interface and provides the user interface to display and record the EEG waveforms.

The amplifier is simply switched on and off by connecting or disconnecting it from a USB 2.0 port of a compatible computer (refer to Appendix C for compatibility reference).

2.2.1 ADAPTER FOR EEG ACCESSORIES

The adapter XC-425 enables the use of referential EE-411/EE-430/EE-511 accessories on the EE-511 eego amplifier, for example to connect an EEG cap (CA-4xx models) or EEG touchproof adapter (XC-810).

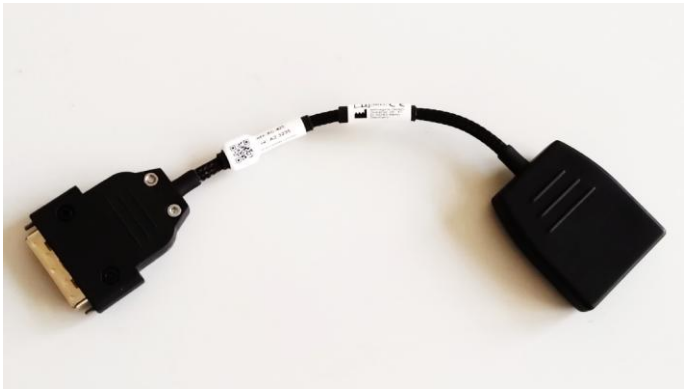


Figure 2-5. The XC-425 adapter for use on the eego amplifier EE-5xx, 68-pin high density connector EEG IN (Figure 2-2)

For more information, refer to the XC-425 datasheet, or contact our sales / support team (see 1.10).

2.3 RECORDING TRIGGER INPUT

In case you want to record event-related activity, you must have a trigger generating device available (maximum 5V), that is able to deliver TTL trigger pulses to a DB25 connector with the pinning defined in the datasheet for the XS-432 adapter.

WARNING: The trigger generating device must be IEC 60950 compatible. Do not connect any other devices to TR IN1 or TR IN2 and always use the adapter XS-432. The same holds for the trigger output port (TR OUT).

WARNING: To run an ERP experiment, please insert the trigger adapter XS-432 into the micro coax trigger input of the amplifier (TR IN 1 or TR IN 2). The adapter is than connected to the DB25 port of the trigger generating device. The adapter connects to both TR IN ports and carries the identifiers “1” and “2” on the top. Make sure the “1” is mating with TR IN 1 and the “2” with TR IN 2.

For more information, refer to the XS-432 datasheet, or contact our sales / support team (see 1.10).

The 2-bit trigger information is encoded in a decimal trigger code (from 1 to 3) in the recording software.

Figure 2-6. The XS-432 trigger adapter for use on the eego amplifier EE-5xx, front inputs TR IN1, TR IN2 (see Figure 2-1)

Please be aware that only rising flanks are detected as triggers and as high trigger bits! A trigger pulse should have a length of at least 2-3 times the reciprocal of the sampling rate. In between triggers the Low level must also be hold for 2-3 times the reciprocal of the sampling rate.

2.4 MOUNTING OPTIONS FOR THE EEGO AMPLIFIER

The **eego** amplifier EE-5xx can be used as a stationary device or as a mobile device.

When using **eego** amplifier as a stationary device, please make absolutely sure that the amplifier cannot drop from the table, e.g., when the patient is connected with the cap and tries to walk away or when the USB cable is dragged over the table sides. You can for example put a string through the mounting holes to fixate the amplifier housing.

WARNING: Do not touch the device for longer periods but only when moving it during setup or after operation. Do not press the device for longer time periods against the skin of the Subject or the Operator. As measured during safety inspection in a controlled test environment, the device surface may reach a temperature up to 57.9°C.
Keep contact duration to skin below 10s.

2.5 LED STATUS INDICATOR LIGHTS FOR THE EEGO AMPLIFIER EE-5XX

The LED lights are the both side edges of the eego amplifier EE-5xx and indicate power and data status. The LED indicators can have the following states:

LED 1	LED 2	Status
OFF	OFF	Device is OFF (USB not connected)
GREEN	OFF	Device is ON (powered via USB), no data is acquired
GREEN	GREEN	Data is acquired (streamed)
GREEN	YELLOW	Impedance measurement is active

Table 2-1 Status indicated by the LEDs.

APPENDIX A: CONNECTORS AND PINNING TABLES

EEG CONNECTOR

The eego amplifier EE-5xx has one EEG input connector labeled “EEG IN”. The 68-pin high density, high quality connector give access to the 24 shielded referential, 4 bipolar inputs, the reference electrode and the patient ground. The table below provides the mapping between connector pins and channel numbers.

Pin No	Channel	Pin No	Channel
1	REF (signal)	35	REF (shield)
2	Bipolar 4 NEG	36	not defined
3	Bipolar 4 POS	37	not defined
4	Bipolar 3 NEG	38	not defined
5	Bipolar 3 POS	39	not defined
6	Bipolar 2 NEG	40	not defined
7	Bipolar 2 POS	41	not defined
8	Bipolar 1 NEG	42	not defined
9	Bipolar 1 POS	43	not defined
10	24 (signal)	44	24 (shield)
11	23 (signal)	45	23 (shield)
12	22 (signal)	46	22 (shield)
13	21 (signal)	47	21 (shield)
14	20 (signal)	48	20 (shield)
15	19 (signal)	49	19 (shield)
16	18 (signal)	50	18 (shield)
17	17 (signal)	51	17 (shield)
18	16 (signal)	52	16 (shield)
19	15 (signal)	53	15 (shield)
20	14 (signal)	54	14 (shield)
21	13 (signal)	55	13 (shield)
22	12 (signal)	56	12 (shield)
23	11(signal)	57	11 (shield)
24	10 (signal)	58	10 (shield)
25	9 (signal)	59	9 (shield)
26	8 (signal)	60	8 (shield)
27	7 (signal)	61	7 (shield)
28	6 (signal)	62	6 (shield)
29	5 (signal)	63	5 (shield)
30	4 (signal)	64	4 (shield)
31	3 (signal)	65	3(shield)
32	2 (signal)	66	2 (shield)
33	1 (signal)	67	1 (shield)
34	V_PGND	68	AGND

TRIGGER CONNECTORS

The eego amplifier EE-5xx has two micro coax trigger input ports and one micro-coax trigger output port. (Figure 2-1)

TR IN 1: inner conductor is the positive TTL input terminal, outer conductor is trigger ground. The maximum input voltage is 5V.

TR IN 2: inner conductor is the positive TTL input terminal, outer conductor is trigger ground. The maximum input voltage is 5V.

TR IN 1 corresponds to the least significant trigger bit. TR IN 2 refers to the second trigger bit.

TR OUT inner conductor is the positive TTL output terminal, outer conductor is trigger ground. The maximum output voltage is 5V.

POWER AND DATA TRANSMISSION VIA USB CONNECTOR

The micro–USB C connector of the eego amplifier must be connected with a USB 2.0 compatible port of a compatible computer (refer to APPENDIX C: Datasheet).

Do not attach the eego amplifier USB interface to other devices.

Use only the USB cable provided with the eego amplifier for connecting to the computer. Please inspect the settings for the USB ports available at your computer, and make sure ‘power saving’ options are turned off for the USB ports.

APPENDIX B: EXPLANATION OF SYMBOLS

	Manufacturer symbol: indicated with name, address
	Serial number
	Year of manufacture
	Conformité Europeenne, CE mark, with number of Notified Body involved in the conformity assessment
	Follow the instructions for use (i.e., this user manual)
	Warning sign: warnings apply
	Special waste disposal regulations apply (EU)
	Safety according to class II electrical equipment (IEC 60601-1)
	Applied parts: type BF (IEC 60601-1)
	MR Unsafe (ASTM F2503-13)
IP22	IP Code (International/Ingress Protection Rating) as defined in international standard IEC 60529. (IP22: protection against fingers or objects < 12.5mm, vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle of 15° from its normal position)
	Medical Device
Rx only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
	QR code for the UDI encoding (human readable text is next to this) (UDI: Unique Device Identification)

APPENDIX C: DATASHEET

Manufacturer: eemagine Medical Imaging Solutions GmbH
Gubener Straße 47
10243 Berlin
Germany

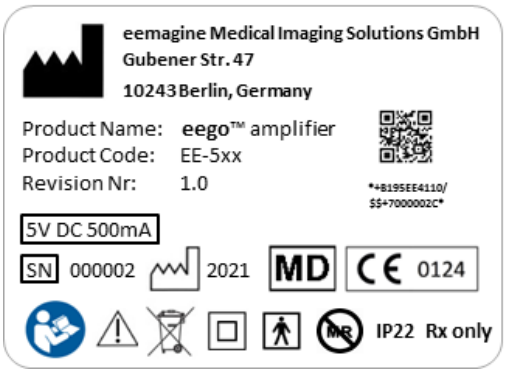
Product Name: eego amplifier

REF : EE-511 / version 1.0

Classification: CE class IIa according to the MDR (EU) 2017/745 Annex VIII

Description: The **eego** amplifier has been designed as a mobile recording device for EEG signals.

Figure 7 Example amplifier label.



It provides access to recorded data over a USB connection to external software over its signal driver interface. The **eego** amplifier EE-5xx is powered via the USB connection and does not require any additional power source.

The device provides 24 channels of referential and 4 channels of bipolar EEG. The **eego** amplifier is used in combination with a dedicated recording program, CE class IIa software compliant with the **eego** amplifier and a **wave**guard EEG headcap (e.g., CA-505). The **eego** amplifier has two 1-bit trigger input channels accessible through two micro coax connectors and one 1-bit trigger output through one micro coax connector. Impedance values can be measured for all referential electrodes as well as the reference and patient ground electrode. An SDK is available for direct amplifier communication.

The implemented active shielding technology protects the EEG inputs from interference noise. Sampling rate and gain can be set through the user interface of the control software.

Specifications:

Dimensions (width * depth * height)	115 * 90* 20 mm
Weight	<100 g
Resolution and input stage	24-bit, true DC input for all channels, one A/D converter per channel
Number of referential and bipolar channels	24 actively shielded referential and 4 bipolar inputs. Separate reference and patient ground
Input noise (referential)	< 1.0 μV_{RMS} (lowest sampling rate and signal range)
Input impedance (referential)	>1 GΩ
Input signal range	150 – 1000 mV_{PP} (programmable gain)
Common-mode rejection ratio (referential)	>100 dB
Maximum sampling rate	4096 Hz
Trigger input	2-bit TTL, electrically separated from amplifier
Trigger output	1-bit TTL, electrically separated from amplifier
USB output interface	USB 2.0, electrically separated from amplifier
Operating temperature	10°C to 40°C
Storage temperature	10°C to 40°C
Transport temperature	0°C to 50°C
Humidity	15% to 93%
Atmospheric pressure	70 kPa to 106 kPa
IP class	The enclosure protection class is IP22 according EN 60529 (IP22: protection against fingers or objects < 12.5mm, vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle of 15° from its normal position)
Electrical Safety Classification	Class II, type BF applied parts
OS requirements and control software	MS Windows 10 64bit Debian 8.x with g++ 4.9 compiler (32bit & 64bit OS and applications) 2GB RAM working memory USB 2.0 connection for amplifier The control software must be a medical certified software that is compatible, designed, and verified/validated for the **eego** amplifier and EEG recording. It must provide digital filter implementation for the EEG bands.
PC Compliance	EN 60950, EMC Directive 2014/30/EU, the Low Voltage Directive 2014/35/EU, the RoHS Directive 2011/65/EU, the Ecodesign Directive 2009/125/EC, and the Radio Equipment Directive 2014/53/EU where applicable

Warning:

Proper use of the **eego** amplifier depends on careful reading of all instructions and labels that come with or are present on the device. Incorrect use of the device may cause inaccurate measurements. Non-compliance with warnings and safety regulations may result in severe personal injury and total loss of equipment.

Disclaimer: We have attempted to write this document as accurately as possible. However, mistakes are bound to occur, and we reserve the right to make changes to the products, which may render parts of this document invalid. No part of this document may be copied or reproduced without the explicit permission of the authors.

APPENDIX D: DECLARATION OF CONFORMITY

Hereby we declare in exclusive responsibility that below identified product fully complies with the regulations of the **Medical Device Directive 93/42/EEC and Article 120 of** Regulation (EU) 2017/745 (MDR).
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.

eego amplifier

EEG DATA ACQUISITION

PRODUCT CODES:
EE-222, EE-223, EE-224, EE-225, VERSION 1.2
EE-410, EE-411, EE-430, EE-511, VERSION 1.0

The product is classified according to the MDR Annex VIII, rule 10, as **CE class IIa** device, and meets the applicable *General Safety and Performance Requirements* of the MDR Annex I.
We apply the conformity assessment procedure in accordance with MDR Annex IX and issue this declaration of conformity as manufacturer.

The product is marked with CE 0124

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

- <ISO 14971:2019>
- <IEC 60601-1:2005/A1:2012>
- <IEC 60601-1-2:2014>
- <IEC 80601-2-26:2019>
- <IEC 62366-1:2015/A1:2020>
- <IEC 62304:2006/A1:2015>
- <ISO 15223:2021>
- <ISO 20417:2021>

No Common Specifications are applicable

This declaration DOC-QA-0002 is valid for product codes REF as stated in the appended product list.

The corresponding *Global Medical Device Nomenclature* (GMDN) code is: 36740,
and the corresponding *European Medical Device Nomenclature* (EMDN) code is: Z12100302.

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, address and NB number>.
Current EC certificate registration no. <> is valid until <YYYY-MM-DD>.
The notified body involved in the assessment of our quality management system is:
<Notified Body, address and NB number>.
Current certificate EN ISO 13485:2016 registration no. <number>, is valid until <YYYY-MM-DD>.

Dated at Berlin, Germany, on the __##th__ day of ____Month____ 202x.

Frank Zanow, CEO
eemagine Medical Imaging Solutions GmbH
Gubener Straße 47, D-10243 Berlin, Germany

For the exact <information> in the above text, see the official, signed declaration DOC-QA-0002. The contents of similar conformity statements may be different in countries outside the European Union.