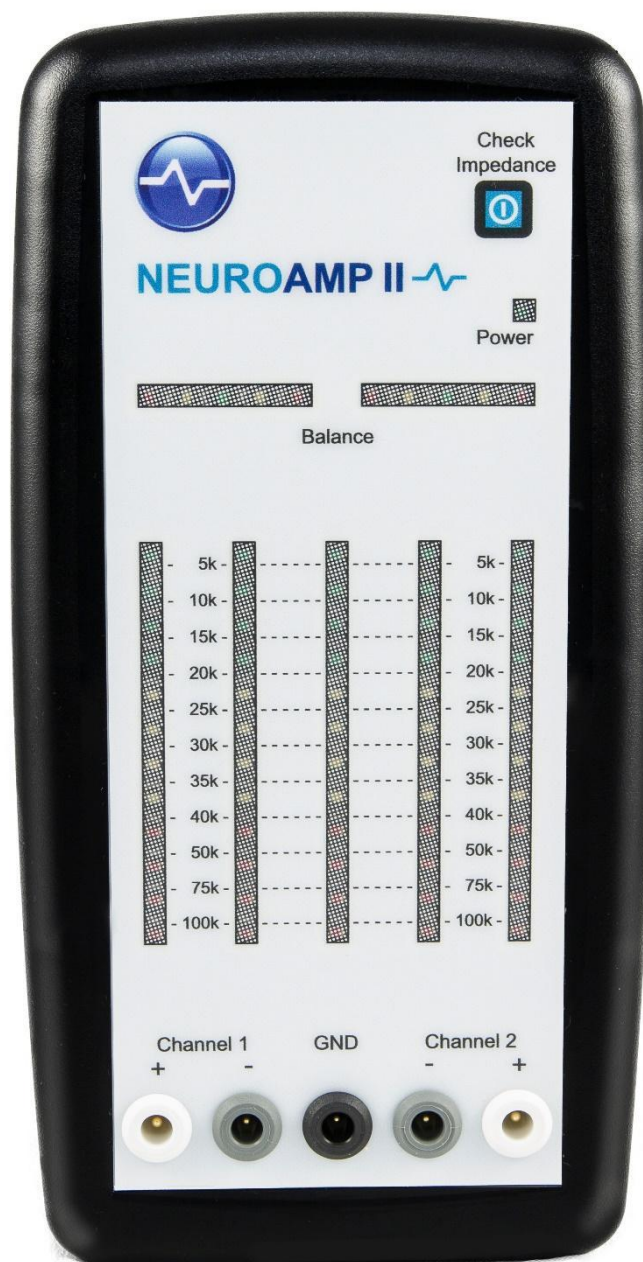


NEUROAMP II



Manual

Article no. A001001 and A001000

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Product Name:

NeuroAmp II

Basic-UDI:

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L005088 – Version 1.0

January 2025

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Note: In the following the device name EEG NeuroAmp II is representative for both models, NeuroAmp II (A00100 black housing) and NeuroAmp II.5s (A001001, grey housing), if not stated otherwise.

Overview

This four-in-one device applies high technology to ensure that your EEG signals will be more reliable. The EEG NeuroAmp II contains:

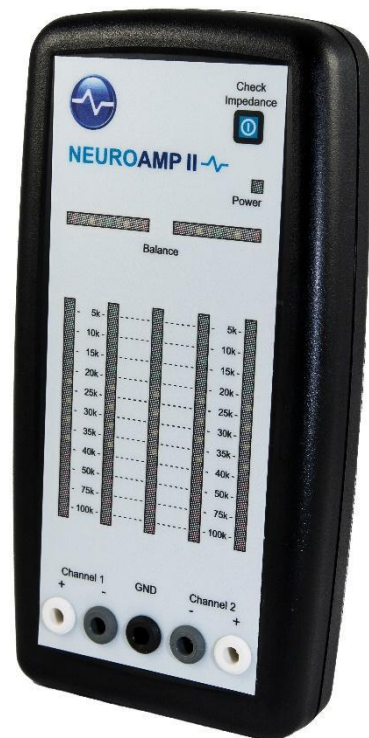
- Two-channel EEG Amp, EEG NeuroAmp II.5s expandable to 23- or 39 channels
- Impedance meter
- Eight peripheral channels
- Eight outputs for audio/visual/tactile feedback

The EEG amplifiers use carefully matched filters and high-resolution A/D converters to make sure that the EEG signal you see is actually an EEG signal.

The built-in impedance meter helps to achieve optimum electrode contacts. It even warns if the electrodes are worn out such that they start to produce extra noise.

Eight additional channels allow to measure peripheral biofeedback signals such as GSR, temperature or HEG.

Eight signal outputs directly control tactile or audio-visual feedback devices. It is easy to program and can also be used to control other hardware devices.



General Features

- Easy to use
- High-performance design to ensure reliable EEG readings
- Conforms to applicable standards with regard to professional medical devices

Power Supply

- Powered from USB – no batteries needed

Impedance Meter

- wide impedance range (<5k...100k)
- cancellation of electrode galvanic voltages
- cancellation of power line pick-up (notch filters)
- Bright, easy-to-read LED bar display
- Balance display for optimum EEG signal noise reduction
- Bad electrode warning

EEG Amplifier

- Two channels, EEG NeuroAmp II.5s expandable to 23- or 39 channels
- 100% remote-controlled by the therapist software
- Ultra low-noise amplifiers, DC coupled 32bit resolution
- Equivalent input noise: $< 0.01 \mu V / \sqrt{Hz}$
- High-performance filters for optimum anti-aliasing

Peripheral Sensor Interface

- three input jacks
- supply of power for active sensors
- high-performance filters for optimum noise suppression

Audio/Visual/Tactile Feedback Output

- eight programmable analog outputs
- DC -2.5 to +2.5V
- AC 1...250 Hz, max 5Vp-p

1 Purpose

The EEG NeuroAmp II is a biofeedback device intended for training the central nervous system to improve its capacity for self-regulation. To perform its intended function it can record and store the electrical activity of a patient's brain obtained from one or more channels by placing electrodes on the head. It must be used in combination with appropriate software and computer.

For purposes of this training task, information for feedback may be derived from one or more channels of EEG and from one or more peripheral physiology measures such as are conventionally used in biofeedback.

The EEG NeuroAmp II is intended to be used only by trained professionals who can ensure sound handling practices.

The device does not draw any diagnostic conclusion. Recorded data of Event-Related Potentials (ERP) or electroencephalogram (EEG) signals need to be interpreted by a clinical expert. The results of such interpretation have to be considered only in conjunction with other clinical findings.

The device can be used for indications caused by a poor self-regulation ability of the brain, such as attention problems, sleep disorders, anxiety disorders, mood disorders, trauma, migraine and others.

2 Safety Notices

2.1 Guidelines for Use

Please take the time to read this manual carefully before using the EEG NeuroAmp II for the first time in order to familiarize yourself with its operation. This manual is part of the product and must be available anytime. Use the device only for the intended purpose see chapter 1. The EEG NeuroAmp II may only be used for neurofeedback by a professional who can ensure sound handling practices and who was trained by BEE Medic or a training institute authorized by BEE Medic.

The following table explains the warning symbols used in this manual:



WARNING

Denotes a probably dangerous situation that may lead to severe injury or death



CAUTION

Denotes a probably dangerous situation that may lead to injury

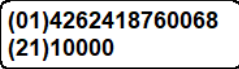
CAUTION

Denotes a situation that could lead to damage of the product

NOTICE

Warning symbol for situations that do not lead to death, injury or damage of property

Meaning of the symbols on the back label of the EEG NeuroAmp II:

	Conformity symbol
	Type BF equipment
	Do not dump in trash can
	Manufacturer/ Production year
	Read instruction manual / Warning, Attention
	QR Code
GS1-DataMatrix 	Serial number, in second row, here10000
	Medical device

2.2 Intended Purpose

The NeuroAmp II is a galvanically insulated multi-channel analog-to-digital and digital-to-analog converter interface for biosignal processing applications. It contains two EEG channels with integrated impedance measurement and display, as well as eight universal inputs and eight outputs for peripheral biosensor and feedback accessories.

2.2.1 Medical Conditions and Medical Indications

The device digitizes biosignals such as the EEG. It does not draw any diagnostic conclusions. There are no restrictions concerning medical conditions or medical indications for the application of the NeuroAmp II.

Contraindications

There are no known contraindications for the NeuroAmp II.

2.2.2 Intended Use

The NeuroAmp II is used to digitize biosignals from electrodes or peripheral sensors and transmit the data in real-time to a PC computer. It must be used in combination with appropriate software and computers.

The device does not draw any diagnostic conclusion. Recorded data need to be interpreted by a clinical expert or separate medical software devices. The measurements may be used to provide neurofeedback to patients with appropriate medical software devices.

2.2.2.1 Intended User Group and User Profile

The EEG NeuroAmp II is intended to be used only by trained professionals who can ensure sound handling practices.

2.2.2.2 Intended Patient Population

The device can be used on adult and pediatric patients. There are no limitations regarding age, weight and state of health as long as the usual indications and contraindications are observed.

2.2.2.3 Medical Context of Use

Intended place of operation

The device is intended for use in clinical settings, including hospitals, clinics, and specialized medical facilities. It is also intended to be used in home care environments.

Intended use environment

The device is intended to be used indoors only. The EEG NeuroAmp II may not be used at a patient undergoing a treatment that involves strong electromagnetic fields or electrical signals such as defibrillation, pacemakers, HF-surgery or MRI. The EEG NeuroAmp II is not defibrillator-proof.

Intended body site of application

The device is intended to be used with electrodes placed on the head.

Intended duration and intended frequency of use

A typical session of neurofeedback, biofeedback or EEG measurement takes about 30-45 minutes. In neurofeedback and biofeedback treatments usually 1-2 sessions per week are performed.

2.2.2.4 Non-medical Context of Use

Cleaning, disinfection and sterilization

As the device is not in direct contact with patients, no disinfecting is required. The NeuroAmp II can be cleaned with a clean cloth, dry or moist or with a small amount of alcohol or isopropyl.

Compatibilities

NeuroAmp II shall be used in combination with electrodes for measuring EEG signals on the scalp. It is designed to be used in combination with the BEE Software Suite but may also be used with other compatible medical software devices.

Storage and transport

The storage and transport conditions are ambient temperature between -30°C and +60°C, humidity between 25% and 95% without condensation and air pressure between 50 and 106 kPa.

2.2.3 Claims

Performance claims

The EEG NeuroAmp II is used for recording of electrical activities obtained from the patient's brain obtained from one or more channels by placing electrodes on the head of the patient. The device does not draw any diagnostic conclusion.

Usability and ergonomics claims

The usability of the NeuroAmp II with plugs for electrodes in different colors on the top, a “Check impedance” button on the top and plugs for various external bio sensors and feedback accessories in the front, which all ensure a good handling of the device.

The device requires no maintenance. No batteries need to be charged or replaced, the connection is made via the USB port. An impedance measurement can be triggered via a single button to easily check the electrode contact quality

Patient-benefits

The possibility to measure high quality data with the device has the benefit for the patient to receive high quality neurofeedback trainings when it comes to Neurofeedback applications, but also when speaking about QEEG and ERP measurements for supporting diagnostics, good data is of high importance to be able to see differences in the activity of the brain.

2.2.4 Risks

All risks are covered in the Risk Analysis, there are no residual risks that patients or users need to be informed about.

2.2.5 Side-effects

There are no side and adverse effects, complications and known clinical risks.

2.2.6 Principles of Operation

The NeuroAmp II is completely remote-controlled from a medical software device. No user interaction at the device is needed other than impedance checking. The impedance meter functionality is intended to be used during the electrode set-up process or for re-checking the electrode contacts. The impedance meter of the NeuroAmp II needs to be turned off during the EEG session, because its measurement signals would distort the EEG measurement. When turned off, the impedance meter electronics are completely disconnected from the electrodes and the EEG equipment.

2.2.6.1 Description of Inputs

The EEG NeuroAmp II is a device to record EEG using electrodes placed on the scalp of the patient. It can be used for one EEG channel operation (three electrodes: Ground, Active, Reference) or two EEG channel operations (five electrodes: Active1, Reference1, Ground, Active2, Reference2). The EEG amplifiers are DC coupled ultra-low-noise types without any 1/f noise. The EEG signals are then sampled with 1 mega-samples per second, filtered and downsampled to 500 or 250 samples per second and 32bit resolution for further signal processing in the medical software device.

Eight additional analog input channels allow the measurement of up to eight biometric signals such as temperature, or GSR.

2.2.6.2 Description of Outputs

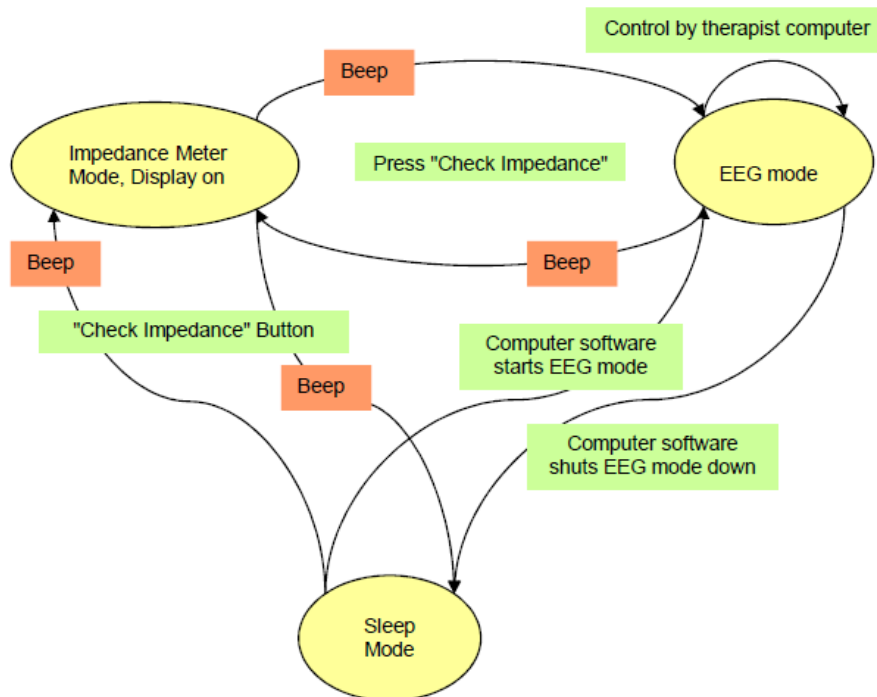
There are eight signal outputs for the primary purpose of audio- visual- and tactile feedback. These connect directly to devices such as a tactile feedback and can also be used to control other hardware devices. Warning: the tactile feedback output is galvanically connected to the other patient signal inputs. If the output shall be used to control devices other than ones connected to the patient, especially line operated devices, an appropriate insulation device must be applied.

2.2.6.3 Description of Functional Units

The EEG NeuroAmp II contains four function blocks:

1. EEG amplifier, two channels
2. Impedance meter for five electrodes
3. Peripheral sensor amplifiers, eight channels
4. Eight outputs for audio/visual/tactile feedback

The below figure shows the three operation modes of the EEG amplifier.



All functions are controlled by the medical software device, except the impedance meter that can also be turned-on by user interaction (button). The impedance meter helps achieve good EEG electrode contacts. It displays the impedances of up to five electrodes independently and in real time. The impedance meter functionality is intended for use during the electrode placement or re-checking process only; during the EEG measurement / neurofeedback training phase it will be turned off and disconnected from the amplifier circuitry.

All electrical connections are completely isolated from line (110 or 220VAC) power due to sophisticated internal galvanic isolation measures. Note that the computer(s) running the medical software device are required to either comply with the standards for electrical safety of medical equipment or to be placed more than ten feet or three meters away from the patient.

The NeuroAmp II can be used for one EEG channel operation (three electrodes: Ground, Active, Reference) or two EEG channel operation (five electrodes: Active1, Reference1, Ground, Active2, Reference2). The EEG amplifiers are DC coupled ultra-low-noise types without any 1/f noise. The EEG signals are then sampled with 1 mega-samples per second, filtered and downsampled to 500 or 250 samples per second and 32bit resolution for further signal processing in the biofeedback software.

During the electrode placement process, the impedance meter can be turned on by pressing the 'Check Impedance' button. It shows the actual electrode-scalp impedances by means of one LED display bar per electrode. In addition, one balance bar per channel shows the balance between the impedances of the respective active and reference electrode. Optimum balancing of the impedances within one channel maximizes noise canceling by the EEG amplifier. During the EEG measurement / neurofeedback training phase it must be turned off, because its measurement signals would disturb the EEG measurement. When turned off, the impedance meter circuitry is disconnected from the electrodes.

EEG electrodes produce galvanic voltages; they act like little batteries. These voltages depend on the electrode material, skin properties and the conducting gel used. In addition, old, worn-out electrodes (e.g. gold plating damaged) tend to show higher voltages and high differences between the electrodes. It has been shown that such voltages add a considerable amount of noise that cannot be distinguished from the EEG signal. For that, the impedance meter has a built-in galvanic voltage warning feature. If the voltage in one channel exceeds a certain level, the display starts blinking. If the voltage is so high that even the amplifier won't accept it anymore, the unit starts beeping.

There are two power management features: One-channel operation for the impedance meter and auto-power-off. If only one EEG channel is used (three electrodes), the impedance meter LED display for the channel not in use is turned off. If the impedance meter function is not turned off manually it will turn itself off after five minutes.

2.2.6.4 Description of Materials

The housing of the device is made of the biocompatible polymers Polycarbonate and Acrylonitrile Butadiene Styrene.

2.2.6.5 Description of Configuration/Variants

Predecessor to the EEG NeuroAmp II was the EEG NeuroAmp I. The EEG NeuroAmp I was built until 2012. The main changes with the EEG NeuroAmp II were that the analog-digital converter resolution was increased, the data acquisition rate was increased and the bandwidth was extended. There are two different versions of the NeuroAmp II:

- NeuroAmp II
- NeuroAmp II.5s: Same as NeuroAmp II, but in addition with plugs for x23 or x39 EEG amplifier for optimized for 23 or 39 channel EEG, ERP and QEEG measurements

2.2.6.6 Description of Accessories and Consumables

Accessoires

NeuroAmp x23	23-channel amplifier
NeuroAmp x39	39-channel amplifier
ERP Sync	Device for ERP measurement
pIRx3	Infrared temperature sensor for the forehead
Combisensor	measurement of heart rate, galvanic skin response and skin temperature
Brummi	Tactile feedback device
BEE Suite Software	Software for Neurofeedback, EEG measurement and advanced Neurofeedback applications

Consumables

Sintered Ag/AgCl electrodes	for EEG measurements
Jumper	for bypassing an electrode signal to several different input channels
Nuprep paste	abrasive paste for skin preparation to improve conductivity and lower skin impedance for better EEG measurements
Ten20 paste	conductive gel to safely secure EEG electrodes on the scalp

2.2.6.7 How the Device Fulfills its Purpose

The device uses electrical signals measured with electrodes on the surface of the scalp of a patient to measure EEG, ERP and QEEG. EEG electrodes produce galvanic voltages; they act like little batteries. These voltages depend on the electrode material, skin properties and the conducting gel used. In addition, old, worn-out electrodes e.g. gold plating damaged) tend to show higher voltages and high differences between the electrodes. It has been shown that such voltages add a considerable amount of noise that cannot be distinguished from the EEG signal. For that, the impedance meter has a built-in

galvanic voltage warning feature. If the voltage in one channel exceeds a certain level, the display starts blinking. If the voltage is so high that even the amplifier won't accept it anymore, the unit starts beeping.

2.2.6.8 Innovative Features of the Device and Innovative Medical Procedures

The product does not show any innovative features and medical procedures compared to devices that are on the market. The device has been on the market since 2006 already.

2.3 Basic Regulations

Make sure that you follow the national and local regulations with regard to biofeedback and neurofeedback.

2.4 Personnel and Qualification

- The therapist is responsible for the safety of use of the entire biofeedback or EEG biofeedback system consisting of the EEG NeuroAmp II in conjunction with electrodes, sensors, biofeedback software, tactile feedback systems, games, etc. He or she has to make sure that the computer running the data acquisition software is capable of handling the data volume transmitted from the EEG NeuroAmp II and of running all applied software properly.
- The therapist is responsible for proper and safe biofeedback or EEG biofeedback treatment methods. He is also responsible for any adverse effects occurring during or after the biofeedback treatment.
- Intended user: The EEG NeuroAmp II may only be used by a professional who was trained by BEE Medic or a training institute authorized by BEE Medic and can ensure sound handling practices.
- The client must be supervised at all times during the neurofeedback session and must never be unattended.
- The impedance meter function of the EEG NeuroAmp II is intended to help achieve good electrode contacts. The EEG amplifier is a low-noise high performance amplifier. However, no claims are made regarding the quality of the EEG signal. It is the responsibility of the practitioner to decide if the EEG signal is suited for the intended purpose.

2.5 Personal Safety Information

Adverse Effects

No adverse effects are known for the device itself. However, in case biofeedback therapy is performed by inexperienced or careless practitioners, it may cause unwanted effects, such as those associated with inappropriate activation, including tiredness, drowsiness, restlessness, and sleep dysregulation. Another unwanted effect that can occur is headaches. Such adverse effects should subside promptly unless inappropriate training is continued. When employed with persons diagnosed with certain conditions such as migraine, seizure disorder, or bipolar disorder, inappropriate application may provoke rather than suppress symptom expression on a transient basis.

The therapist is responsible for applying appropriate therapy methods. Therefore, EEG NeuroAmp II may be used only by a professional who can ensure sound handling practices.

The manufacturer of the EEG NeuroAmp II does not assume liability for any adverse effects whatsoever caused by biofeedback therapy.

Notice

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

ESSENTIAL PERFORMANCE

The essential performance of the EEG NeuroAmp II is a signal reproduction with an error of $\leq \pm 20\%$ at 1mVpp, 2Hz Δ .

In the neurofeedback application EEG training thresholds are constantly being adjusted so that the accuracy of signal reproduction has no impact on the training results.

In the EEG/ERP-measurement application EEG signals are processed and analyzed after the recording takes place. Signal quality is mainly impacted by a changing electrode contact over a recording session which might change the noise level on the signals.

Filters are usually designed in such way that disturbing artefacts, DC offsets and everything out of EEG bands are cancelled out. Results are always checked by a medical expert who can distinguish between proper EEG signals and any induced artefacts. A severe change in signal reproduction would be noticed by the medical expert during the EEG recording.



WARNING

Entanglement or strangulation by EEG electrode cables

- Take care in arranging client and sensor cables to avoid risk of client entanglement or strangulation
-

2.6 Device-related Safety Information

WARNING



The client must be supervised at all times during the neurofeedback session and must never be unattended. The system is not intended for home use where no qualified therapist is available.

WARNING



- The EEG NeuroAmp II may not be used at a client undergoing a treatment that involves strong electromagnetic fields or electrical signals such as defibrillation, pacemakers, HF-surgery or MRI. The EEG NeuroAmp II is not defibrillator-proof.
 - The EEG NeuroAmp II is not to be used either for critical client monitoring or for diagnostic purposes.
-

- Impedance meter readings may jump +/- one LED step due to electromagnetic interferences. If you suspect a problem in conjunction with interferences, contact the manufacturer for evaluation and remediation.
-

WARNING



Wrong EEG reading due to damaged electrodes or high galvanic voltages

Electrodes with damaged gold plating or other damages may reduce the EEG signal quality. The galvanic voltage warning signal indicates that the amplifier may be saturated

- Replace damaged electrodes
 - Replace electrodes if galvanic voltage warning signal (blinking display and/or periodic beep) occurs
-

WARNING



Electric shock from inappropriate accessories or unconnected electrodes

- Never connect a line operated device to any of the jacks of the EEG NeuroAmp II
 - As soon as at least one electrode or peripheral sensor is attached to a person, none of the other electrodes or peripheral sensors may come into contact with any conductive material that might provide a return path to ground.
-

- Use electrodes and peripheral sensors according to their safety instructions. As they are in direct contact with clients, they may present a potential risk of cross-infection and / or may become a biohazard after use.
 - Take care to use only approved biocompatible electrodes with the EEG NeuroAmp II
 - Apply electrodes to healthy skin only.
-

WARNING**Damage or electrical shock due to use of inappropriate accessories**

Accessories that are not intended for use with the EEG NeuroAmp II may damage the product, impair performance, breach the regulations or even cause electrical shocks. Inappropriate use may have dangerous consequences or at least damage the device and render the warranty invalid.

- Use only in conjunction with standard EEG electrodes and peripheral sensors that are intended for use with the EEG NeuroAmp II.
 - Do not plug equipment into the EEG NeuroAmp II unless it is meant to work with it, even if its plugs fit.
-

WARNING**Electrical shock due to use of inappropriate tactile feedback device**

The audio/visual/tactile feedback output is not galvanically isolated from the EEG part.

- Use approved feedback devices only. They must be galvanically isolated from line power or battery operated.
-

WARNING**Wrong EEG readings due to strong electromagnetic fields**

cellular phones, x-ray machines, radio thermal treatment equipment, etc. may disturb the EEG signal.

- Make sure that the recommended distances to radio wave emitters are met (see chapter 11 “Notes on EMC”).
 - The function of EEG NeuroAmp II could be degraded by exposure to electromagnetic disturbances exceeding the limits defined in chapter 11. This would be noticed by distorted EEG signals. In this case take care to eliminate the electromagnetic disturbances before continuing operation. This is only relevant when operating the EEG NeuroAmp II together with the x23 or x39 device.
-

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EEG NeuroAmp II, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION**Damage due to electrostatic discharge**

- Take anti-ESD measures such as anti-static mats or a humidifier to condition hot, dry air.
-

- The unit is not susceptible to electromagnetic disturbances below IEC 60601-1-2 immunity test levels, as long as the EEG electrode and USB connection cables are not longer than three meters.
 - Any effects caused by EM disturbances are free of risk to anybody.
-

CAUTION

Damage due to water or humidity

The EEG NeuroAmp II is not to be immersed in water or other liquids.

- Do not spill liquids on the EEG NeuroAmp II.
-

- Do not use or store the product in dusty, wet or dirty environments.
-



CAUTION

Injury of children or damage of product

- Store the unit out of reach of children to prevent them from injuring themselves or others and to avoid damage to the product.
 - Keep out of reach of small children, as some removable parts could be accidentally swallowed.
-

CAUTION

Damage by inappropriate handling or repair attempts

Inappropriate handling may damage the device and render the warranty invalid. Repair only by qualified personnel.

- Do not attempt to open the product and repair it yourself. The manufacturer accepts no liability for any damages thus incurred.
-

- Store in its original case at up to -40 ... 70°C, no condensation
 - Check the condition and the function of your EEG NeuroAmp II and the accessories in regular intervals.
-

WARNING



Possible Fire Hazard

EEG NeuroAmp II and its accessories are not to be used in oxygen-enriched environments. Use of electrical circuits in oxygen-enriched environment could result in a fire hazard.

WARNING



Use of the EEG NeuroAmp II adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

**WARNING**

Only original accessories supplied by the manufacturer may be used. All cables connecting the EEG NeuroAmp II with its accessories, such as the x23/x39, the ERP synch device, the combination sensor, the pIRx3, may not exceed 3 meter in length and must be shielded.

**WARNING**

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

NOTICE**Unauthorized access**

We recommend a password protection for your computer in order to prevent unauthorized access to the EEG NeuroAmp II while it is attached to the computer via USB connection.

3 Function

3.1 Description

This section describes the EEG NeuroAmp II in an EEG biofeedback setting, for details on the use of the EEG NeuroAmp II II.5s in an EEG- or ERP-acquisition setting, please refer to the manual of the NeuroAmp x23 or NeuroAmp x39 (A001007 or A001008).

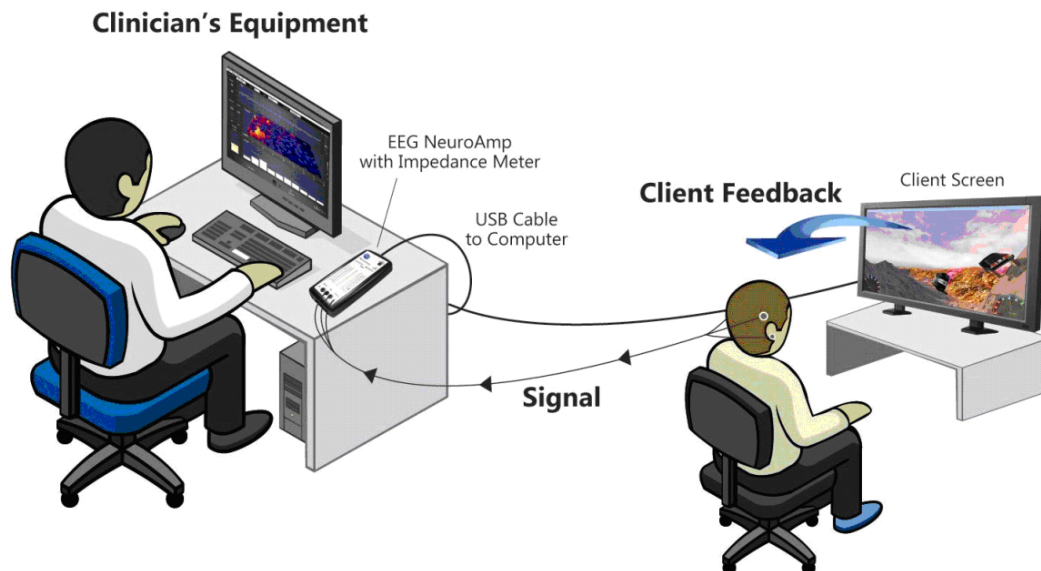


Figure 1: Use of the EEG NeuroAmp II in an EEG biofeedback setting

The EEG NeuroAmp II is a user-friendly high-performance interface between client and clinician computer for EEG biofeedback (neurofeedback) and/or peripheral biofeedback therapy.

The EEG NeuroAmp II contains four function blocks:

1. EEG amplifier, two channels
2. Impedance meter for five electrodes
3. Peripheral sensor amplifiers, eight channels
4. Eight outputs for audio/visual/tactile feedback

All functions are controlled by the PC software, except the impedance meter that can also be turned-on by user interaction (button). The impedance meter helps achieve good EEG electrode contacts. It displays the impedances of up to five electrodes independently and in real time. The impedance meter functionality is intended for use during the electrode placement or re-checking process only; during the EEG measurement / neurofeedback training phase it will be turned off and disconnected from the amplifier circuitry.

All electrical connections are completely isolated from line (110 or 220VAC) power due to sophisticated internal galvanic isolation measures. Note that the computer(s) running the therapist software and / or feedback software are required to either comply with the standards for electrical safety of medical equipment or to be placed more than ten feet or three meters away from the client. The system must comply with the standard for safety requirements for medical electrical systems, IEC 60601-1-1.

The EEG NeuroAmp II can be used for one EEG channel operation (three electrodes: Ground, Active, Reference) or two EEG channel operation (five electrodes: Active1, Reference1, Ground, Active2, Reference2). The EEG amplifiers are DC coupled ultra-low-noise types without any 1/f noise. The EEG signals are then sampled with 1 mega-samples per second, filtered and downsampled to 250 samples per second and 32bit resolution for further signal processing in the biofeedback software.

During the electrode placement process, the impedance meter can be turned on by pressing the 'Check Impedance' button. It shows the actual electrode-scalp impedances by means of one LED display bar per electrode. In addition, one balance bar per channel shows the balance between the impedances of the respective active and reference electrode. Optimum balancing of the impedances within one channel maximizes noise canceling by the EEG amplifier. During the EEG measurement / neurofeedback training phase it must be turned off, because its measurement signals would disturb the EEG measurement. When turned off, the impedance meter circuitry is disconnected from the electrodes.

EEG electrodes produce galvanic voltages; they act like little batteries. These voltages depend on the electrode material, skin properties and the conducting gel used. In addition, old, worn-out electrodes (e.g. gold plating damaged) tend to show higher voltages and high differences between the electrodes. It has been shown that such voltages add a considerable amount of noise that cannot be distinguished from the EEG signal. For that, the impedance meter has a built-in galvanic voltage warning feature. If the voltage in one channel exceeds a certain level, the display starts blinking. If the voltage is so high that even the amplifier won't accept it anymore, the unit starts beeping.

Eight additional analog input channels allow the measurement of up to eight biometric signals such as temperature, GSR, heart rate, etc.

There are eight signal outputs for the primary purpose of audio- visual- and tactile feedback. These connect directly to devices such as a tactile feedback and can also be used to control other hardware devices. Warning: the tactile feedback output is galvanically connected to the other client signal inputs. If the output shall be used to control devices other than ones connected to the client, especially line operated devices, an appropriate insulation device must be applied.

There are two power management features: One-channel operation for the impedance meter and auto-power-off. If only one EEG channel is used (three electrodes), the impedance meter LED display for the channel not in use is turned off. If the impedance meter function is not turned off manually it will turn itself off after five minutes.

Display and Buttons

(see Figure 5)

Check Impedance Button

The Check Impedance button is a push button covered by the front panel thus preventing it from being activated accidentally. This also allows easy cleaning and prevents dirt, grime and other contaminants from collecting around the button and entering the unit. Pushing the button toggles the impedance meter functionality on and off. If the unit is not turned off manually, it will do so automatically after five minutes. If the impedance meter functionality is turned on during EEG measurement, the EEG measurement and data transmission to the therapist computer is suspended as long as the unit remains in the impedance meter mode. If the impedance meter mode is not terminated manually, it will do so after five minutes and resume the EEG measurement.

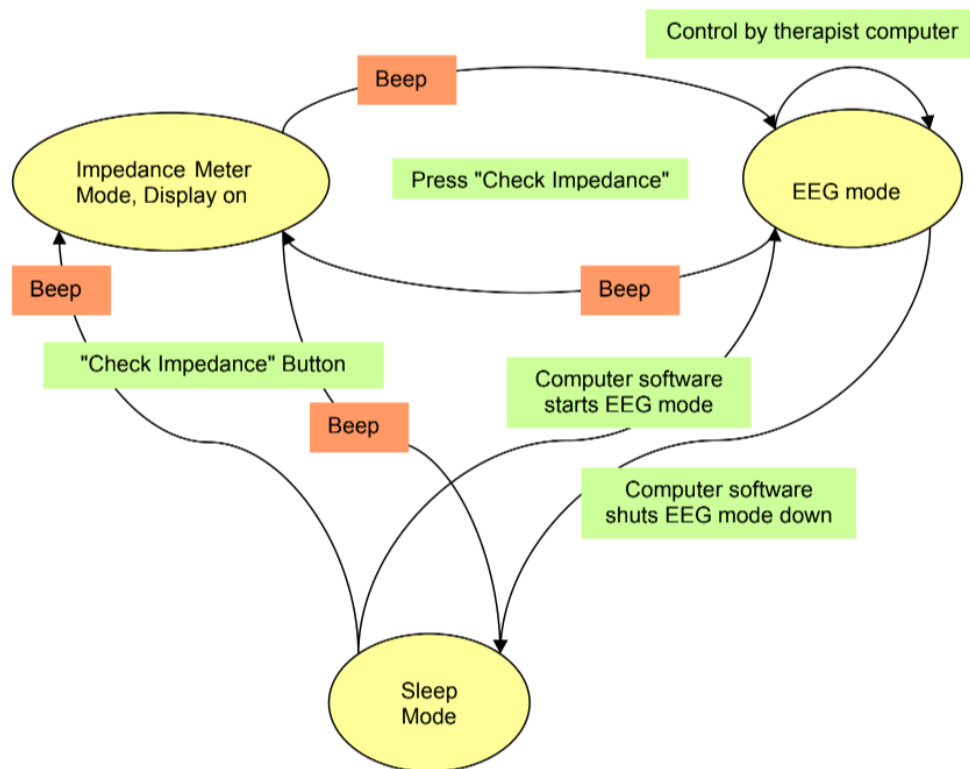


Figure 2: The three different modes of the EEG NeuroAmp II

Power indicator

The power indicator next to the Check Impedance button lights up when the EEG NeuroAmp II is turned on. That can be manual turn-on of the impedance meter function as well as automated turn-on by the therapist software.

Impedance Bars

The figure below shows the impedance ranges as well as the colors of the 12 LEDs that make up each impedance bar. The unit requires a minimum of three electrodes to be connected in order to perform a valid measurement. As long as there are less than three electrodes connected, only the lowest LED of the center bar will be lit indicating that the unit is turned on.

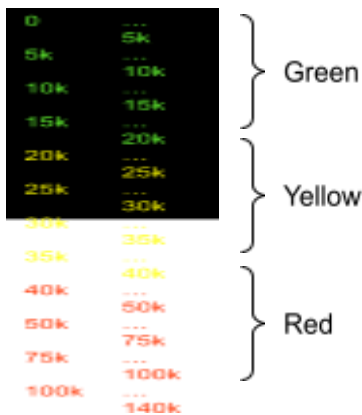


Figure 3: Impedance measurement ranges with their respective colors



CAUTION

Wrong EEG readings if electrode contacts are bad

The EEG signal may be noisy if the display shows red.

- Make sure that the electrode impedances are such that at least yellow readings are achieved

Balance Bars

The balance bars show how well the impedances of the two electrodes of an EEG channel are balanced (see figure below).



Figure 4: Impedance balance bars with their respective colors



CAUTION

Wrong EEG readings if electrode contacts are not balanced

The balance bar must not show red.

- Align electrodes such that display is yellow or green.
- In case of very good electrode contacts (green) a red in the balance bar may be tolerated. The user is responsible to decide if the signal quality is sufficient.

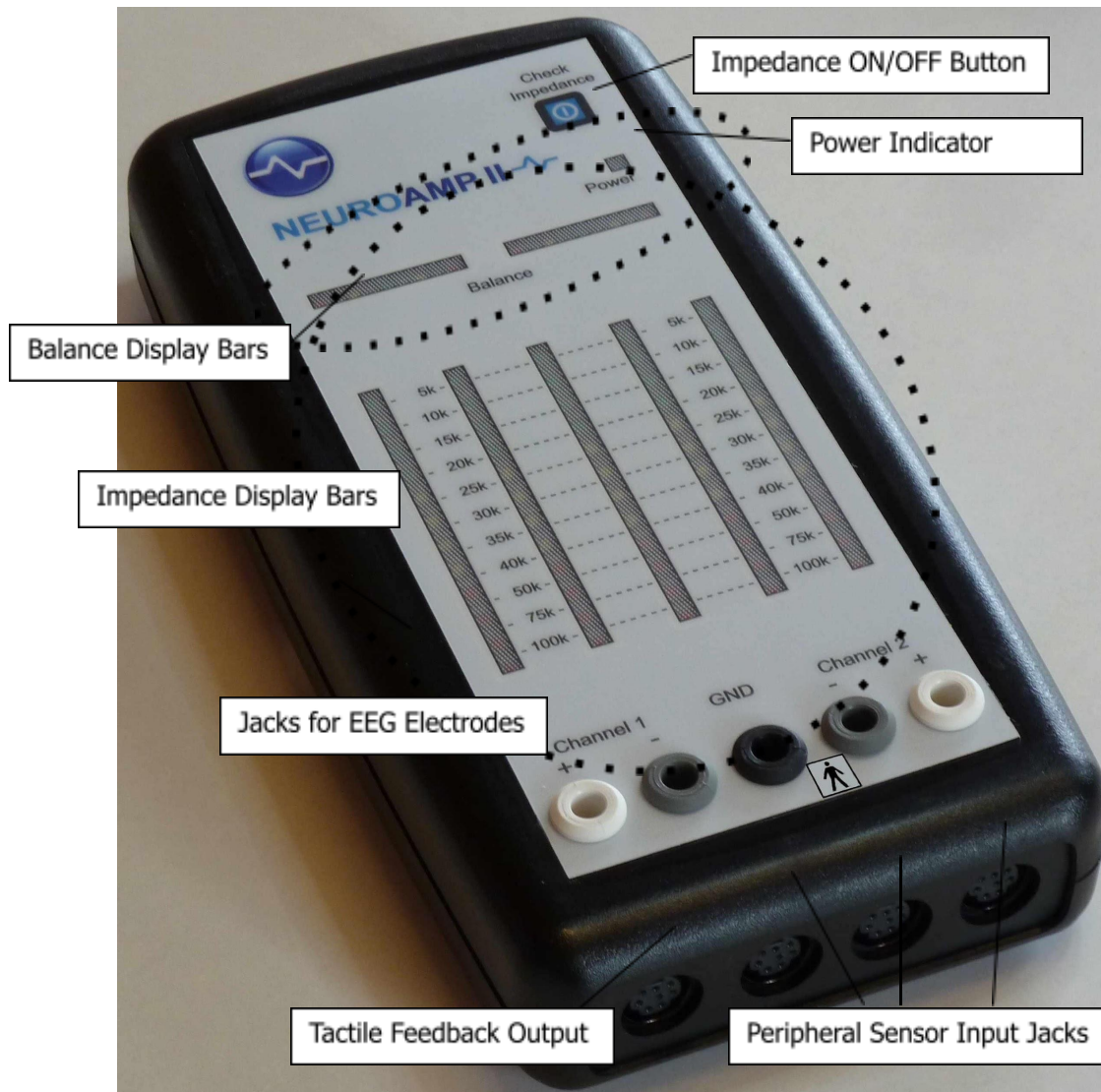


Figure 5: EEG NeuroAmp II outline



Figure 5a: USB connection between computer and EEG NeuroAmp II.5s and x23/x39-connection for accessories. Note: The x23-connection is available only for the model EEG NeuroAmp II.5s (A001001) device with a grey housing.

3.2 Electromagnetic Compliance

The EEG NeuroAmp II has been tested according to IEC 60601-1-2 and complies with:

- IEC / CISPR 11, Class B (RF emission)
- IEC 61 000-4-2 (Electrostatic Discharge - ESD)
- IEC 61 000-4-3 (RF susceptibility)
- IEC 61 000-4-6 (RF asymmetric)

No cable attached to the EEG NeuroAmp II shall be longer than three m / ten feet. The maximum length of the communications port cable with an extension cable must not exceed this limit.

4 Set-Up

4.1 Unpacking the EEG NeuroAmp II



WARNING

Death due to suffocation if packing material is swallowed

- Store packing material out of reach of children
-

Unpack your EEG NeuroAmp II.

Please check if the unit is damaged. If so, do not use it and return it for a replacement.

4.2 Set-Up in your EEG System



CAUTION

Incorrect EEG signals due to worn-out or damaged electrodes

Worn-out or damaged electrodes tend to produce high voltages that are very noisy. That noise cannot be distinguished from real EEG.

- Replace worn-out or damaged electrodes.
-



WARNING

Wrong EEG readings if galvanic voltage too high

A blinking LED display bar or beeps while in impedance meter mode indicate that the electrodes produce high galvanic voltages. See 4.2 for more details.

- Replace electrodes in case of galvanic voltage warning signal.
-

Now connect your electrodes and, if applicable, peripheral sensors and a tactile feedback device.

For your convenience, all five EEG connections are marked by different colors. Make sure that the black wire marked with 'GND' is connected to the ground electrode, which usually is an ear clip.

The two connectors to the left of the ground connector are for channel one and the two connectors on the right are for channel two of your EEG neurofeedback system. If you need only one channel, leave the second channel (labeled "Channel 2") disconnected (note: if you use an EEG extension cord, unplug the two plugs to the unused channel).

Place your EEG NeuroAmp II so that you can easily read the display during the electrode placement process.

Electrodes behave like little batteries. They produce a so-called galvanic voltage that depends on the electrode material, skin properties and the conductive gel used. It is important that the galvanic voltages at one channel are almost the same, i.e. the voltage difference is near zero. Because of that, use only electrodes of the same type per channel. Never mix e.g. silver and gold electrodes at one channel.

Examples for proper usage of various electrode types:

- All gold electrodes
- All silver electrodes
- Channel 1 gold, channel 2 silver. The ground clip may be any gold or silver

Example for bad electrode connection:

- Channel 1 plus = gold, channel 1 minus = silver

The impedance meter will warn you if your electrode galvanic voltages are too high. If you did not mix up different electrodes within one channel and still get the warning, replace the electrodes. Worn-out or damaged electrodes tend to produce high voltages that are very noisy. That noise looks like an EEG and cannot be distinguished from the real EEG.

The warning signal is a blinking LED bar display when in impedance meter mode. If the voltage is so high that the EEG amplifier is overloaded, a beeping sound is added to the warning.

Notice

We strongly recommend the use of sintered Silver-SilverChloride electrodes in order to take full advantage of the NeuroAmp's superior noise features at very low frequencies. Make sure to use electrodes that are approved as medical device and follow the care instructions in order to maintain their high quality.

For recording QEEGs or ERPS use caps from the company Electro-cap International, Inc (<http://www.electro-cap.com>) or similar caps (e.g. Pamel). The pin assignment must be compatible with the one specified in chapters 4.2 and 8 of x23-/x39-manual. Caps may have integrated ear electrodes or the ear electrodes can be separate. The ear electrodes must be compatible with the electrodes in the cap with respect to the electrode material.

5 Operation

5.1 General

The EEG NeuroAmp II is completely remote-controlled from your PC software. No user interaction at the device is needed other than impedance checking. The impedance meter functionality is intended to be used during the electrode set-up process or for re-checking the electrode contacts. The impedance meter of the EEG NeuroAmp II needs to be turned off during the EEG session, because its measurement signals would distort the EEG measurement. When turned off, the impedance meter electronics is completely galvanically disconnected from the electrodes and the EEG equipment.

See chapter 3.1 for a detailed description of the display.

5.2 Electrode Placement



WARNING

Entanglement or strangulation by cables

- Arrange client and sensor cables carefully
 - Observe client during the session
-



WARNING

Electric shock from inappropriate accessories or unconnected electrodes

- Never connect a line operated device to any of the jacks of the EEG NeuroAmp II
 - As soon as at least one electrode or peripheral sensor is attached to a person, none of the other electrodes or peripheral sensors may come into contact with any conductive material that might provide a return path to ground.
-



WARNING

Wrong EEG readings if galvanic voltage too high

A blinking LED display bar or beeps while in impedance meter mode indicate that the electrodes produce high galvanic voltages. See 4.2 for more details.

- Replace electrodes in case of galvanic voltage warning signal.
-

When you are about to start hooking up your client, turn on the impedance meter function of your EEG NeuroAmp II by pressing the "Check Impedance" button once. A short beep and a red light at the lower end of the center bar indicate that the unit is turned on.

The EEG NeuroAmp II requires at least three electrodes to be hooked-up for a valid measurement. After you place the first three electrodes for one EEG channel (i.e. the two active electrodes into the sockets labeled "Channel 1" and ground), the unit will start to show the three impedances independently, plus the balance bar showing how well the impedances of Active (+) and Reference (-) match. If you do not see any reading after placing the three electrodes, at least one of them is still not sufficiently connected with an impedance of more than 140 k Ω . Make sure that you clean the skin with alcohol or a small amount of abrasive gel before placing the electrode. Be sure to use a sufficient amount of conductive paste. Then, try to optimize the impedances by parting the hair, pressing on the electrodes or improving contact by re-cleaning the site and / or using more conductive paste.

The best results can be expected when all impedances are in the 'green range' (better than 20 k Ω) and the impedances matched (balance bar shows green). Note that for best performance of the amplifier, the electrode quality should never be 'red'.

As soon as you are happy with the results, turn off the impedance meter of the EEG NeuroAmp II by pressing the "Check Impedance" button. After a short beep the display will turn off indicating that the impedance meter part is disconnected from your EEG equipment.

5.3 Function check

Before starting the session with your patient check proper function of the EEG NeuroAmp II by pressing the "Check Impedance" button on your device. The device must then make a "beep" and the LEDs on the impedance meter must light up. Start your PC software and check if the data acquisition is running as expected. If you experience problems, please call support.

5.4 Re-Checking the Impedances during a Session

You may re-check the quality of the electrode connections at any time by turning the impedance meter mode of the EEG NeuroAmp II on. Note that during that phase no EEG measurement is possible, because the measurement signals distort the EEG signals.

After you pressed the "Check Impedance" button, your neurofeedback software stops the session and waits until you press the button again. After five minutes, the EEG NeuroAmp II will turn back into the previous mode by itself.

6 Cleaning, Maintenance and Disposal

This product has been developed and produced with great care and should also be handled with care. If you follow these recommendations you will prevent premature expiry of the warranty and enjoy the safe use of your product for years.

6.1 Cleaning

As the unit is not in direct contact with clients, no disinfecting is required. Clean your EEG NeuroAmp II with a clean cloth, dry or moist or with a small amount of alcohol or isopropyl.

6.2 Maintenance

Factory testing and calibration ensure equipment accuracy. The EEG NeuroAmp II does not require preventive inspections or calibration.

The EEG NeuroAmp II may only be opened by authorized, expert personnel. If it is opened without authorization, the guarantee entitlement expires.

The manufacturer is not liable for the function of the EEG NeuroAmp II if the owner or operator of the device does not properly maintain the device or when it is handled in a way inconsistent with proper use description in this user manual.

6.3 Disposal

Dispose of the unit as an electronic device in accordance with any applicable local, state and federal laws and regulations.

7 FAQ and Troubleshooting

7.1 Frequently Asked Questions

What does sampling rate and anti-aliasing mean?

The EEG NeuroAmp II amplifies the signals from your EEG electrodes and peripheral sensors. These signals are then converted to numbers that can be processed by the biofeedback software running on your PC. That conversion process involves very frequent measurements of the five sensor signals. The EEG NeuroAmp II measures a thousand times per second, i.e. the sampling rate is one kilohertz. The amplifiers not only amplify your bio signals, they also amplify all kinds of electromagnetic noise that is around you. Most frequency components of that noise are way beyond the EEG or peripheral sensor signal spectra, but they are measured anyway, if there are no counter measures built in to the device. In that case, much of that noise would appear in the EEG spectrum and look like a part of the EEG signal. That effect is called "aliasing".

The EEG NeuroAmp II contains two high-performance filters to avoid this aliasing effect to make sure that your EEG readings are not compromised.

Why do I need the impedance meter feature at all?

Successful neurofeedback builds on a good EEG signal. Using a distorted EEG signal is like trying to listen to a piece of music in the middle of a construction site. One important condition for a good EEG signal is good contacts of the EEG electrodes to the head. An impedance meter helps to achieve such good contacts. It is important that usage of the impedance meter is easy and fits in the process in a seamless way.

In addition, worn-out electrodes tend to produce high, noisy galvanic voltages that may reduce the quality of the EEG signal dramatically. Therefore, the impedance meter of the EEG NeuroAmp II has a built-in galvanic voltage measurement feature that warns in case of improper electrode configuration.

Do I need an impedance meter despite the high input impedance of the EEG Amp?

Modern EEG amplifiers do have such high input impedance that the impedance between electrodes and scalp is negligible with regard to the EEG signal. But not with regard to noise pick-up! EEG electrodes and the long cables pick up noise such as electromagnetic fields from the power lines, fields from thunderstorms, long-wave radio transmitters, etc. The most important noise source is pick-up from the power lines, which results in signals that are by a factor of up to a hundred thousand times larger than the EEG signal. To cope with that, most EEG amplifiers simply subtract the two signals gained from the 'Active' and the 'Reference' electrode thus canceling out the noise, which is supposed to be equal for both electrodes. We just need to make sure that the noise pick-up by both electrodes is exactly the same. In general, we can achieve that by two means: 1. arrange both EEG electrode wires so that they are as close as possible and 2. make sure that both electrode contacts are of equal quality. Because the input impedance of the EEG amplifier is very high, the absolute impedance values between electrodes and scalp almost do not matter. However, it is important that they are matched. That is why the EEG NeuroAmp II has a balance bar feature that helps to balance the two impedances of 'Active' and 'Reference' electrodes. If the electrode contact is good (impedance measurement green) a red balance display can be accepted.

Is the impedance measurement harmful?

No, not at all. Of course, the impedance meter uses a 'measurement signal' to determine the electrode - scalp impedances. This signal is so small that it cannot be felt by the body. The EEG NeuroAmp II conforms to the IEC 60601-1, which is the standard that defines the electrical safety of medical devices. Other equipment using similar measurement currents are e.g. body fat monitors or a scale with a body fat monitor.

Does the impedance meter in the EEG NeuroAmp II distort my EEG measurement?

No, because the impedance meter is completely galvanically disconnected from the electrodes and the EEG amplifier when it is turned off. So, turn the impedance meter function on while you are placing the electrodes and watch how you are doing. When you are done and want to start the neurofeedback session, turn it off. You can re-check the impedances at any time, but during that time, you will not measure EEG signals.

What is a DC offset, and why should I care?

Sometimes, EEG electrodes act like a little battery: They produce a DC voltage. Although this voltage can be much higher than a typical EEG signal, it does not influence our EEG measurement, because the EEG amplifiers do not amplify DC signals. However, there are two reasons to care about these galvanic voltages: First, they could saturate the highly sensitive input stage of the amplifier, and second, they add noise to the EEG signal. Especially old, worn-out or damaged electrodes may add huge amounts of noise. Therefore, the impedance meter feature of the EEG NeuroAmp II not only measures the impedances but also the galvanic voltages of the electrodes. If these voltages exceed certain thresholds, a warning shows you that you need to change your electrode configuration or to replace your electrodes.

How does the impedance meter of the EEG NeuroAmp II work?

The EEG NeuroAmp II uses a weak AC signal to determine the electrode - scalp impedances. The voltages used are smaller than $0.1V_{rms}$ and the currents are only a few micro Amps. Four to five times a second the unit applies a small current and then measures a voltage to determine the impedances using Ohm's law.

What can I do about line frequency pick-up?

Of course, good electrode contacts and good contact matching helps to reduce line frequency pick-up. Under certain circumstances, you might still see a line at 50 Hz or 60 Hz. In general, that is not a problem at all. Some recommend the use of a sharp low-pass filter or a notch filter. We, however, advise not to use such filters. First, they add phase distortions and delays. Second, you remove the easiest way to recognize that a contact went bad and needs to be re-adjusted.

One thing to note is that the line pick-up might add an offset to amplitude readings you might use on your screens. Neurofeedback training is mostly based on dynamically adapting thresholds so that an offset from line pick-up does not matter here. For a level reading (e.g. high-beta) you may use a sharp low-pass filter or notch filter because this reading does not need to be real-time.

7.2 Troubleshooting

Problem	Reason	Solution
Cannot turn impedance meter mode on.	EEG NeuroAmp II not connected to computer	Connect EEG NeuroAmp II to computer
	No USB power	Connect the EEG NeuroAmp II to a high-power USB port. Do not use USB hubs unless they have an own power supply
PC software cannot connect	EEG NeuroAmp II not connected to computer	Connect EEG NeuroAmp II to computer
	No USB power	Connect the EEG NeuroAmp II to a high-power USB port. Do not use USB hubs unless they have an own power supply
	Wrong COM port setting	Match the COM port setting of your PC software to the COM port number of the port the EEG NeuroAmp II is connected to (see chapter 4.2).
EEG channel does not measure a signal, although the electrodes are connected properly	Galvanic electrode voltage too high	Check in impedance meter mode if the galvanic voltage warning shows that the electrodes need to be replaced
I cannot measure EEG signals beyond 100Hz	100 Hz is the cut-off frequency of the anti-aliasing filter	This is normal and a no-fault condition
At the line frequency, the EEG shows a huge peak in its spectrum	Strong line noise pick-up	Re-check the impedances. In most cases, re-establishing good and balanced impedances solves the problem. In general it is advised to tie the electrode cables close together, e.g. by using a spiral cable tube, or by braiding the wires. Also, if you use one channel only, leave the input jacks of the non-used channel open
Even with three electrodes connected there is no impedance display other than the lower middle red light	One or more contacts have still more than 140k Ω	Improve contact quality by: • Skin preparation with alcohol or better abrasive gel • Application of sufficient amount of conductive gel If these measures do not help, at least one electrode is broken. Exchange the broken electrode with a new one.
Impedance meter display is fidgety	Measured value is at the border between two display LEDs	This is normal and a no-fault condition
LED bars run up and down randomly, or there are many artifacts in the EEG signal you cannot attribute to common causes	The unit is exposed to a strong electromagnetic field (e.g. long-wave radio transmitter)	The unit is not affected by levels lower than those according to IEC 60601-1-2. If, however, there is a larger electromagnetic field where you intend to operate the unit, we cannot guarantee proper operation. We recommend appropriate shielding of the room where the equipment is to be used.

Unit does not work, but connected to computer	Internal problem	Unplug USB connector and plug in again
---	------------------	--

8 Technical Data

EEG Amplifier	Number of channels	2
	Bandwidth (3dB)	DC ... 100Hz, at 250 sps, DC ... 160 Hz at 500 sps, no 1/f noise
	Data acquisition rate	1'024'000 samples per second (1Msps)
	Sampling rate	250 or 500 sps (sub-sampling after digital filter)
	Resolution	32bit, equivalent input noise: $< 0.01\mu\text{V}/\sqrt{\text{Hz}}$
	Input impedance	Typ. $10\text{E}12\text{ Ohm}$
	C-Mode	AC coupled, 0.08Hz, 13 bit
Peripheral Amplifier	Number of channels	8 (C-Mode: 3)
	Gain	1
	Frequency response	DC ... 65Hz at 250 sps, DC ... 130Hz at 500 sps
	Sampling rate	250 or 500 sps
	Resolution	24bit (C-Mode: 13 bit)
Audio/Visual/ Tactile Feedback Output	Number of channels	8
	Frequency range	DC ... 250Hz in 1Hz steps
	Amplitude range	-2.5V...+2.5V DC or 0 to 5Vp-p AC
	Power supply	3 x 5V, 100mA (max total current $< 150\text{mA}$)
	Driving current per ch.	$\pm 40\text{mA typ}$
Impedance Measurement	Impedance range	0 ... $140\text{k}\Omega$, indicator for $> 140\text{k}\Omega$
	LED steps	red: $>100\text{k}$, $100\text{k}...75\text{k}$, $75\text{k}...50\text{k}$, $50\text{k}...40\text{k}$
		yellow: $40\text{k}...35\text{k}$, $35\text{k}...30\text{k}$, $30\text{k}...25\text{k}$, $25\text{k}...20\text{k}$
		green: $20\text{k}...15\text{k}$, $15\text{k}...10\text{k}$, $10\text{k}...5\text{k}$, $<5\text{k}$
	Balance bars	red: more than $\pm 20\%$
		yellow: $\pm 10\% \dots \pm 20\%$
		green: less than $\pm 10\%$
	Measurement frequency	Half cycle: 150ms, full cycle: 300ms
	Max. electrode voltage	0.1Vrms
Power	Operating voltage	4.5 5.5V (USB powered)
	Power management	Auto power off after 5 minutes
	Power consumption ON (USB 5V)	$< 500\text{mA}$
	Power consumption OFF (USB 5V)	$< 50\text{mA}$
Signals	Power indicator	On if device turned on
	Check Impedance beep	1.6kHz, 200ms

	Galvanic voltage too high	LED bar blinks, if differential voltage is critical Periodic beep, if differential voltage is too high
Product class according to 93/42/EWG		Ila
Classification according to IEC 60601-1		Class II, Type BF
Life time		5 years
EMC: Compliance with IEC 60601-1-2		IEC / CISPR 11, Class B (RF emission) IEC 61 000-4-2 (Electrostatic Discharge - ESD) IEC 61 000-4-3 (RF susceptibility) IEC 61 000-4-6 (RF asymmetric)
Mechanical	EEG jacks	Shrouded plugs 4mm / 1.2mm Colors: White, Grey, Black, Grey, White
	Peripheral sensor jacks	4 x Mini DIN 8 pins
	Peripheral device jacks (only version grey device)	2MHz bipolar SPI interface, HDMI-like connector
	Size (LxWxH)	183 x 93 x 30 mm
	Weight	Black device: 300 g, grey device: 470 g
Environment	Storage and Transport	Temperature: -30°C...+60°C Rel. humidity: 25...95% Air pressure: 500 ... 1060 hPa
	Operation	Temperature: 10°C...+40°C Rel. humidity: 25...70% Air pressure: 700 ... 1060 hPa Not oxygen-enriched (<25%)

9 Accessories - optional

Optional accessories for EEG NeuroAmp II (A001000) with black housing:

- pIRx3 temperature sensor
- Combination Sensor

Optional accessories for EEG NeuroAmp II.5s (A001001) with grey housing:

- pIRx3 temperature sensor
- Combination Sensor
- NeuroAmp x23 - 23-channel digital EEG recording front-end
- NeuroAmp x39 - 39-channel digital EEG recording front-end
- ERP Sync for ERP recording

Please see the manuals of the accessories for details.

10 Notes on EMC according to IEC 60601-1-2

Guidelines and Manufacturer's Statement – Electromagnetic Emissions		
The EEG NeuroAmp II is intended for use in the electromagnetic environment specified below. The customer or the user of the EEG NeuroAmp II should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker IEC 61000-3-3	Not applicable	

Guidelines and Manufacturer's Statement – Electromagnetic Immunity			
The EEG NeuroAmp II is intended for use in the electromagnetic environment specified below. The customer or the user of the EEG NeuroAmp II should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ±2 kV, ±4 kV, ±8 kV, ± 15 kV air discharge	± 8kV contact ±2 kV, ±4 kV, ±8 kV, ± 15 kV air discharge	
Radiated RF IEC 61000-4-3	3 V/m: 80 MHz to 2.7 GHz	3 V/m: 80 MHz to 2.7 GHz	
Electrical fast transient / disturbance variables / burst IEC 61000-4-4	Not applicable	Not applicable	
Surge IEC 61000-4-5	Not applicable	Not applicable	
Conducted disturbances IEC 61000-4-6	3 V: 0,15 MHz – 80 MHz 6 V: IMS Bands	3 V: 0,15 MHz – 80 MHz 6 V: IMS Bands	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	

IMMUNITY to proximity fields from RF wireless communications equipment						
Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Immunity Test & Compliance Level (V/m)
385	380 - 390	Tetra 400	Pulse modulation ^{b)} 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM ^{c)} ± 5kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0,3	28
870						
930						
1 720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
5 500						
5 785						
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
^{a)} For some services, only the uplink frequencies are included.						
^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal.						
^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

11 Warranty

- The manufacturer guarantees that the product, when used in accordance with requirements, will remain free from defects for a period of two years from the date of purchase. For products where the durability is clearly indicated as less than two years, the warranty expires on the expiration date indicated on the packaging or in the user manual.
- Claims against the warranty can be made only when accompanied by the sales receipt, which must indicate the salesperson and date of purchase.
- The manufacturer offers no warranty in the case of:
 - Disregard of operating instructions
 - Operating errors
 - Improper handling
 - Third-party intervention by non-authorized persons for the purpose of device repair
 - Acts of nature, e.g., lightning strikes, etc.
 - Transport damage as a result of improper packaging of returned items
 - Lack of maintenance
 - Operational and normal wear and tear, which includes, for example, the following components:
 - filter
 - batteries
 - disposable articles, etc.
- The manufacturer is not liable for consequential damage caused by a defect if it is not intentional or due to gross negligence. The manufacturer is also not liable for minor physical injuries resulting from negligence.
- The manufacturer reserves the right to decide whether to eliminate defects, to deliver a defect-free item or to reduce the purchase price by a reasonable amount.
- If the manufacturer rejects a claim against the warranty, it assumes no expense for transport between customer and manufacturer.
- Implied warranty claims remain unaffected by these changes.

We accept no liability for accidental damage or for consequential damages, including, for example lost profit, downtime, damage or replacement of devices or property from a breach of the warranty.

