


Technical Manual

Neuro-Audio

Digital System for Auditory EP, OAE
and Screening PTA



TM032.02.003.002
(30.06.2020)

Neurosoft © 2020

5, Voronin str., Ivanovo, 153032, Russia

P.O. Box 10, Ivanovo, 153000, Russia

Phone: +7 (4932) 95-99-99; + 7 (4932) 24-04-34 Fax: +7 (4932) 24-04-35

E-mail: info@neurosoft.com Internet: www.neurosoft.com

Contents

Introduction.....	4
Abbreviations.....	5
Intended Use	6
Contraindications	6
Side Effects	6
Safety Measures.....	7
1. Description.....	8
1.1. Product Description	8
1.2. Principle of Operation	9
1.3. Connectors and Indicators	10
1.4. Labeling.....	13
2. Preparing the Product for Use.....	15
2.1. Requirements to Personnel.....	15
2.2. System Placement.....	15
2.3. Reducing Electrical Noise	16
2.4. Unpacking and Checking Delivery Set.....	18
2.5. Assembly and Connection to Computer.....	19
3. Proper Use	21
3.1. Setting-Up Procedures.....	21
3.2. Performing Tests	22
3.3. Troubleshooting.....	23
3.4. Actions in Emergency	25
4. Maintenance.....	25
4.1. General Requirements.....	25
4.2. User Maintenance.....	26
4.3. Periodic Maintenance	26
4.3.1. Checking of OAE Channel with Test Cavity	26
4.3.2. Checking of OAE Probe	28
4.3.3. Calibration of Stimulus Intensity within Free Field.....	31
4.4. Disinfection	33
4.5. Lifetime.....	34
5. Current Repair	34
5.1. General Requirements.....	34
6. Disposal	35
7. Acceptance, Delivery Set and Package Data.....	35
8. Warranty.....	36
9. Reclamation	37
Annex 1. Main Specifications.....	38
Annex 2. Delivery Set.....	42
Annex 3. Electromagnetic Emission and Immunity.....	47
Annex 4. Trig In/Out.....	51

Introduction

This technical manual is a combined document describing the operation and servicing of *Neuro-Audio* digital system for auditory EP, OAE and screening PTA (hereinafter referred to as “the system”).

The document certifies the technical parameters of the system, which are guaranteed by the manufacturer.

Do not start working with the system before you have read this manual!

You can send your responses and recommendations at the following address:

P.O. Box 10, Ivanovo, 153000, Russia

or by e-mail:

help@neurosoft.com

You can find additional information on **Neurosoft** products on our website:

www.neurosoft.com

or contact us by phone:

+7 (4932) 59-21-12 (Service Center)

+7 (4932) 95-99-99

+7 (4932) 24-04-34

You can also contact **Neuromed** Company, Authorized European Representative of **Neurosoft** Company (to Mr. Benjamin Scholl) by the following address:

360 avenue du Clapier

ZAC du Couquiou

84320 Entraigues sur-la-Sorgue

France

Phone: +33 621-304-580

E-mail: **info@neurosoft-france.com**

Abbreviations

ADC — analog-to-digital converter

VEMP — vestibular evoked myogenic potential

AEP — long-latency evoked potential

TEOAE — transient evoked otoacoustic emission

ABR — auditory brainstem response

MC — microcontroller

OAE — otoacoustic emission

DPOAE — distortion product otoacoustic emission

PC — personal computer

DSP — digital signal processor

AEP — auditory evoked potential

SOAE — spontaneous otoacoustic emission

MLAEP — middle-latency auditory evoked potential

ASSR — auditory steady-state response

EcochG — electrocochleography/electrocochleogram

Intended Use

The *Neuro-Audio* system is intended for use in electrophysiological and audiologic evaluation of hearing and vestibular function as an aid in detecting hearing loss and diagnosing hearing and vestibular related disorders. It can be used for screening and diagnostic applications. It allows recording auditory brainstem response (ABR) and other auditory evoked potentials (AEP), otoacoustic emissions (OAE) and screening pure tone audiometry (PTA).

Neuro-Audio bone conduction amplifier unit is intended to record bone conduction VEMPs. The target population for *Neuro-Audio* includes all ages.

The *Neuro-Audio* system must be used by trained personnel only, such as audiologists, ENT surgeons, hearing healthcare professionals, trained technicians or personnel with a similar level of education in a hospital, clinic, healthcare facility or other appropriate professional healthcare setting. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.

Contraindications

The *Neuro-Audio* system must not be used:

- if patient suffers from external otitis;
- if the insertion of the ear probe (or application of any other transducer) in the ear canal makes patient feel pain.

The *Neuro-Audio* system can be used, but with care:

- if patient has allergic or infectious skin diseases at the electrode or transducer application sites.

Side Effects

There are no known undesirable side effects for the *Neuro-Audio* system.

Safety Measures

*To provide safety measures and exclude the possibility of electric trauma of medical staff or patients, the medical staff is **PROHIBITED** to:*

- use the system which mounting and setting was done improperly, without following this technical manual;
- connect the system and surgical HF equipment to the patient simultaneously (it can cause system damage or patient's flash-burns in places of electrode placement);
- plug in any products not included into the delivery set, to the electrode connectors;
- eliminate faults by opening of the components included into the delivery set;
- conduct tests when the electronic unit box, computer or other devices comprising the system are opened;
- connect patient electrodes to **protective ground** or other conducting surfaces.

1. Description

1.1. Product Description

The *Neuro-Audio* is a multifunctional screening and/or diagnostic system that interfaces with the *Neuro-Audio.NET* audiologic software on a PC. It is a device with built-in 2-channel amplifier for evoked potentials recording, built-in microphone amplifier for OAE recording and a built-in auditory stimulator. The software is used to control the device during testing, to analyze, save and retrieve the recorded test data, to print test reports.

Depending on the installed software modules and licenses, it supports the following tests:

- auditory evoked potentials (ABR, AABR, ECoChG, MLR, LLR);
- otoacoustic emission (TEOAE, DPOAE, SOAE);
- auditory steady-state response (ASSR, multi-ASSR);
- cognitive evoked potentials (P300, MMN);
- vestibular evoked myogenic potentials (VEMP: air and bone conduction);
- pure tone audiometry (PTA: air, bone conduction and free-field).

There are 4 customized delivery sets of the *Neuro-Audio* system:

1. Standard delivery set (intended for ABR, AABR, VEMP and otoacoustic emission tests: TEOAE, DPOAE, SOAE).
2. Neuro-Audio/ABR delivery set (intended only for ABR, AABR tests).
3. Neuro-Audio/OAE delivery set (intended only for otoacoustic emission tests: TEOAE, DPOAE, SOAE).
4. Neuro-Audio/PTA delivery set (intended only for screening pure tone audiometry).

1.2. Principle of Operation

The principle of operation is based on the recording and input of bio-potentials and other physiological signals to computer and their further processing and analysis.

The block diagram of the system is shown in Fig. 1.

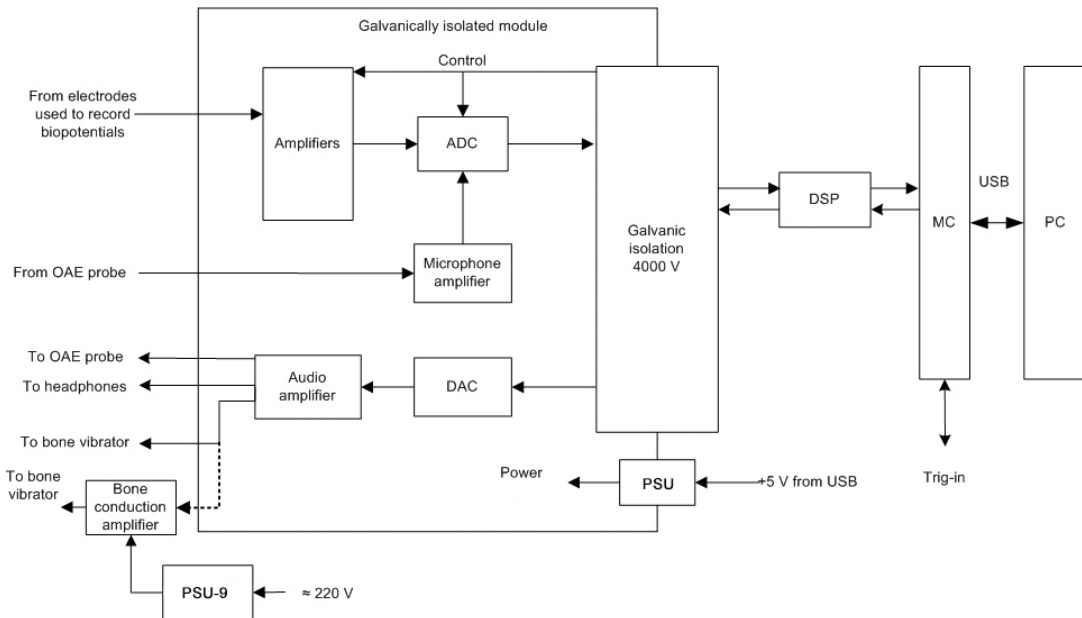


Fig. 1. The *Neuro-Audio* system

Biopotentials from the electrodes are transferred to the amplifiers, where they are amplified and then digitized by the analog-digital converter (ADC) delivered to the digital signal processor (DSP) via 4000 V galvanic isolation. The DSP controls the operation of the amplifiers and ADC via 4000 V galvanic isolation.

The unit microcontroller (MC) provides the connection between DSP of the module and the computer via USB. The DSP generates audio stimulator signal in a digital form which is converted to the analogous form by the digital-analogue converter (DAC). Then, the signal is amplified by the audio amplifier and delivered to the auditory stimulator. If there is a bone conduction amplifier, the signal is delivered from the audio amplifier output. Then, the amplified signal is delivered to the bone vibrator. Besides, the unit microcontroller receives trig-in signals and synchronizes them with the data flow from ADC.

The bone conduction amplifier is powered via mains-operated medical power supply unit (PSU-9) or built-in batteries.

The galvanically isolated part of the amplifier unit (the amplifier module) is powered via galvanically isolated DC converter of the power supply unit (PSU).

The digital system operates under control of PC (IBM PC type) with a mouse, keyboard, laser or jet printer and installed licensed Windows OS. Using PC,

the received signals are processed, displayed and presented in the different modes after mathematical analysis. The initial data is stored on the hard disk and the exam reports are generated and printed.

1.3. Connectors and Indicators

The front and side panels of the electronic unit are shown in Fig. 2, Fig. 3 and Fig. 4.

On the front panel of the electronic unit (Fig. 2) there are the touch-proof and DIN connectors to attach the electrodes, the impedance button to switch to the *Impedance measurement* mode and the LED indicator. The channels are marked with figures “1” and “2”. The on/off indicator glows yellow when the unit is connected to PC and it glows green during the signal recording.

The impedance indicators glow in the impedance measurement mode. You can switch to this mode using the *Neuro-Audio.NET* program settings (see user manual) or the *Impedance measurement* button. The colour of indicators means the quality of the electrode placement. The green colour means the quality is high, yellow colour – the quality is average and red colour – the quality is poor. The colours are specified in the software settings.

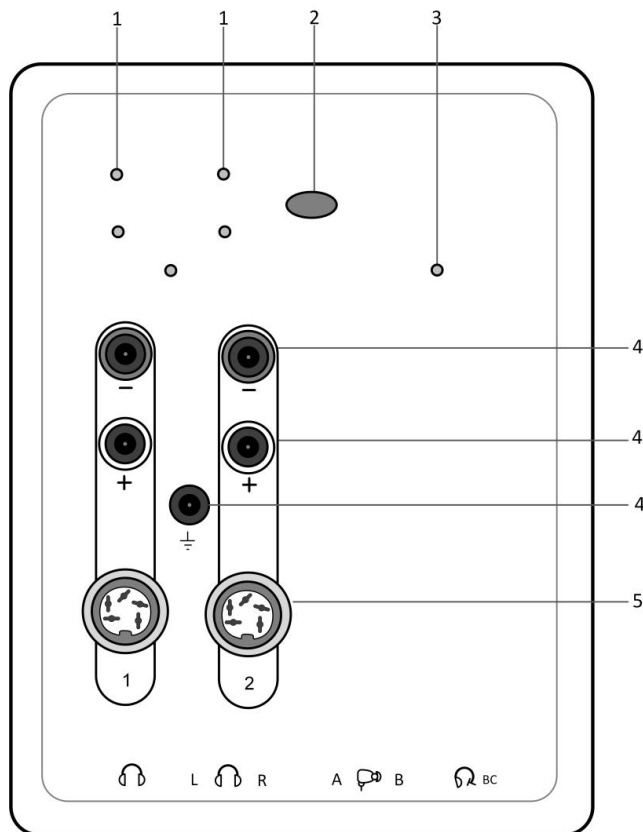


Fig. 2. Front panel

Designations shown in Fig. 2:

1 — impedance indicators;

2 — “Impedance” button;

3 — ON/OFF indicator;

4 — Touch-proof connectors;

5 — DIN connectors.

On the top side panel of the electronic unit (Fig. 3) there is a trigger socket (trig-in/trig-out) to attach stimulators of third-party manufacturers and the USB cable for connection to PC.

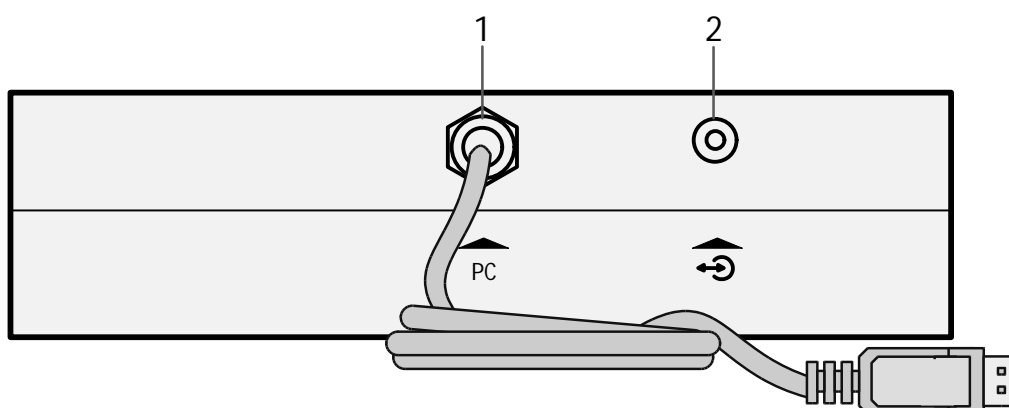


Fig. 3. Top panel

Designations shown in Fig. 3:

1 — USB cable.

2 — Trigger socket (trig in/trig out).

On the bottom side panel (Fig. 4) there are the connectors to attach the headphones, bone vibrator and OAE probe.

There are two types of connectors to attach the headphones: *3.5 stereo* and *6.3 mono*. Depending on the plug, they can be inserted in this or that connector. If you use the headphones with *6.3 mono* plug, pay attention to the order of connection. The left headphone must be plugged into the connector marked as “L”, the right one must be plugged into the connector marked as “R”.

Do not attach the headphones to the 3.5 stereo and 6.3 mono connectors simultaneously. It leads to incorrect stimulus volume in the headphones.

There are two types of connectors to attach OAE probe: *mini DIN 6* manufactured by Neurosoft (Russia) and *mini DIN 8* manufactured by Etymotic Research (USA).

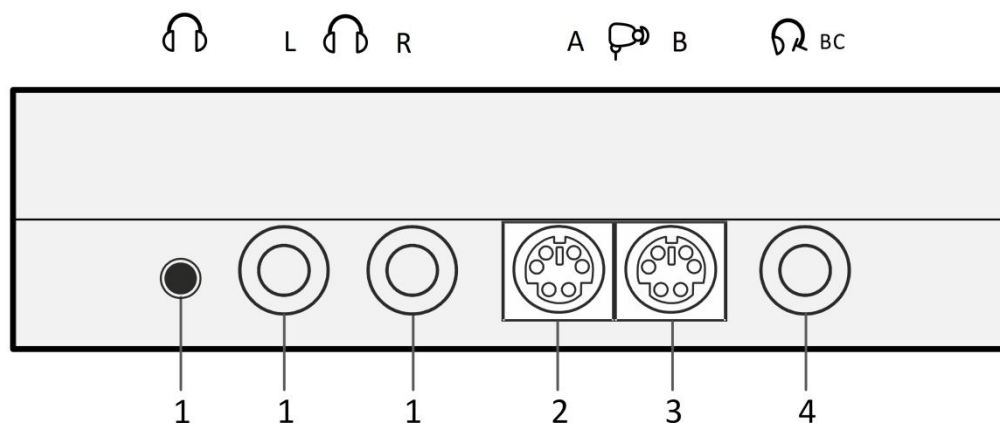


Fig. 4. Bottom panel

Designations shown in Fig. 4:

- 1 — connectors for headphones;
- 2 — connector for OAE probe (Neurosoft);
- 3 — connector for OAE probe (Etymotic Research);
- 4 — connector for bone vibrator.

The front and back panels of the bone conduction amplifier are shown in Fig. 5 and Fig. 6. The description of indicator colors is shown in Table 1.

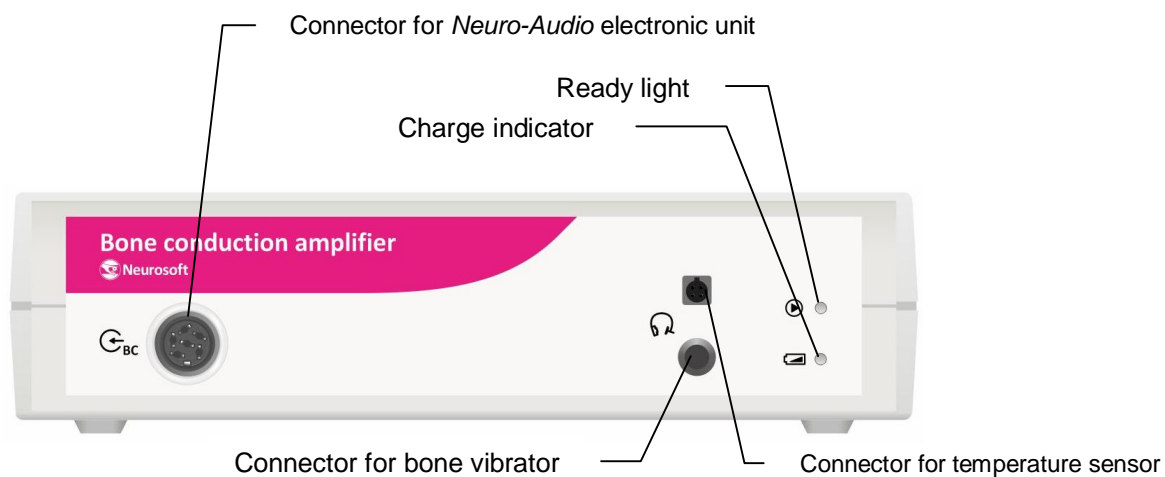


Fig. 5. Front panel of bone conduction amplifier

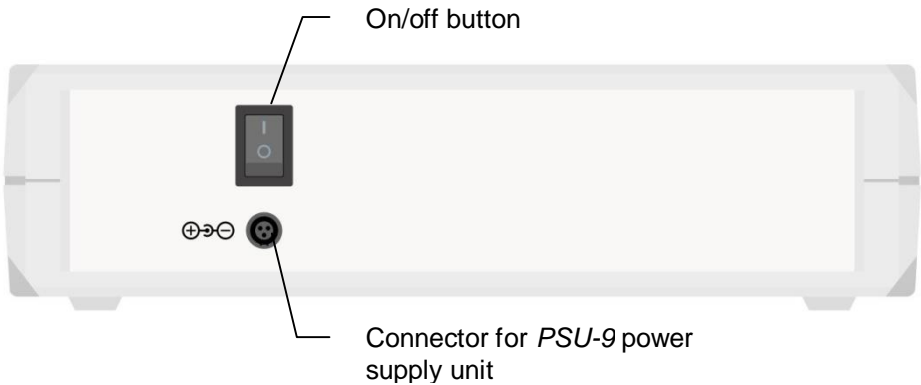


Fig. 6. Back panel of bone conduction amplifier

Table 1. The description of colors of bone conduction amplifier indicators

Color of indicator	Description
Ready indicator: green Charge indicator: green	The unit is on and ready for operation (stimulation).
Ready indicator: no illumination Charge indicator: green	Discharged battery. Charging from mains is required.
Charge indicator: yellow or orange	The built-in rechargeable battery is charging from mains (it usually takes 6-7 hours for complete charge).
Charge indicator: green (flashing)	Battery is fully charged.
Ready indicator: red	The bone vibrator overheat protection actuated.

1.4. Labeling

The example of the label for the system is shown in Fig. 7.

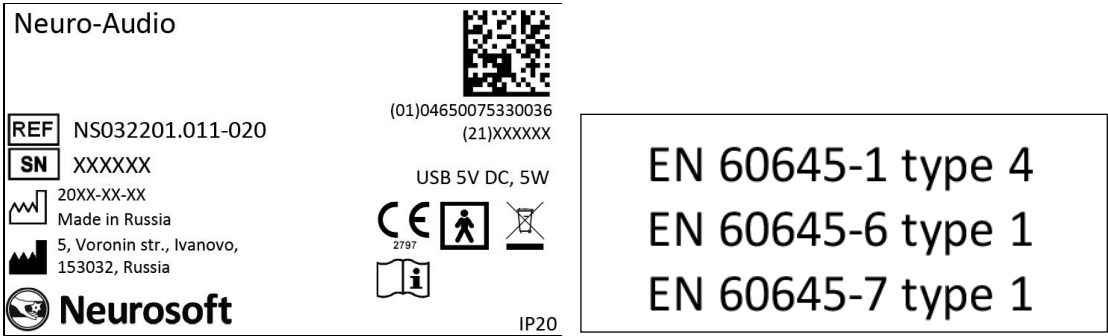





Fig. 7. The example of the label for the system

Interpretation of symbols on the label:

-  – attention: consult operational documentation.
-  – work parts of BF type according to EN 60601-1.
-  – mark of conformance to 93/42/EEC “Concerning Medical Devices” directive



– mark of conformance to 2012/19/EC “On waste electrical and electronic equipment (WEEE)” directive.



– number according to catalogue by ISO 15223-1.



– serial number by ISO 15223-1.



– date of manufacture by ISO 15223-1.



– manufacturer's name and address ISO 15223-1.



– ingress protection marking by EN 60529.

The equipment is identified with the GS1-128 barcode that includes the GTIN code and the serial number (Fig. 8).

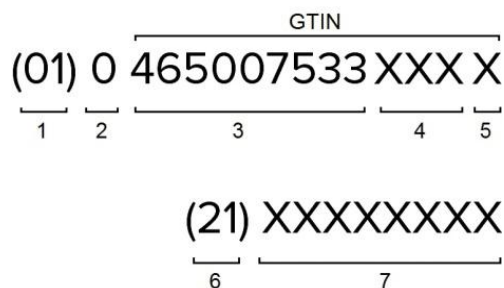


Fig. 8. The GS1-128 barcode

1 – identification key: GTIN,

2 – start digit,

3 – company number,

4 – article reference,

5 – check digit,

6 – serial number identifier,

7 – serial number.

GTIN – global trade item number can be used by a company to uniquely identify all of its trade items. GS1 defines trade items as products or services that are priced, ordered or invoiced at any point in the supply chain.

To ensure the automatic data reading the GS1-128 code is integrated to the barcode in DataMatrix format (Fig. 9).



Fig. 9. DataMatrix barcode

Data Matrix is a two-dimensional matrix barcode, consisting of black and white “cells” or modules of different brightness arranged in either a square or rectangular pattern. The DataMatrix barcode is described in ISO/IEC 16022:2006 standard.

To decode the data on device, DataMatrix barcode can be read quickly by a barcode reader or by the smartphone camera as a two-dimensional image.

2. Preparing the Product for Use

2.1. Requirements to Personnel

The mounting and setting of the system should be carried out by the person empowered by the manufacturer or technical personnel of the medical institution where the system is to be used. Remember, that accurate mounting of the system defines its safety and operation quality. Further, the important requirements for the mounting and setting of the system will be marked by ***bold and italic fonts***.

2.2. System Placement

Before mounting and setting the digital system, select a place for it taking into consideration the power wiring and protective ground in the room and follow the requirements and recommendations listed below.

Requirements concerning the room selection and placement of equipment:

- The recommended distance from the electronic unit to the short-wave or microwave therapeutic equipment is not less than 5 meters.
- ***The patient environment (within 1.5 meters) should contain only the electronic unit being the medical device with the required safety level. The fact is that the safety level of the computer equipment is insufficient for the use in the patient environment. Hence, a patient must not contact with the metal parts of computer equipment cases and the personnel must not touch simultaneously these parts and patient body. If the computer equipment used in the system corresponds to EN 60601-1 or is connected via the isolation transformer corresponding to EN 60601-1, and the isolation from the computer network is provided via the special isolation device corresponding to EN 60601-1, then it is not obligatory to fulfill this requirement.***

- Place the electronic unit on the maximum possible distance from power cables, switchboards, and different powerful electrical devices which can emit electromagnetic fields of mains frequency.

Requirements to mains:

- The system should be supplied from 230 V mains equipped with TN-S or TN-C-S ground system (according to IEC 60364-1).
- ***To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.***
- ***Before setting of the digital system, the quality of standard tripolar sockets and the integrity of protective ground circuit must be checked by the electrician. For more details see section 2.3 “Reducing Electrical Noise”.***
- ***In case the system components are connected to several tripolar sockets, make sure they are grounded to one and the same protective ground circuit. Otherwise, there is a danger of compensating current leakage (several tens of amperes) through the system connecting cables that leads to the equipment break-down.***

2.3. Reducing Electrical Noise

There are some factors that may impact ABR test results. They are the electrodes placement and its impedance, patient's condition, ambient noise. However, the electrical interference is the most important factor that can worsen the result greatly. The information concerning the electrical interference reduction is given in this section.

Grounding is crucial for the good ABR recording and safe operation.

The power cord contains a ground lead (typically indicated by yellow and green colours), but often the ground at the test site may not be sufficient.

In such cases follow these recommendations.

Ground the patient bed if it is made of metal.

Turn off all other electrical equipment not used in the room, especially the sources with neon lights.

In some cases, it may be necessary to find another room for testing if there is too much ambient or electrical noise.

You can also try to move a test site within the room as the patient might be near the power cord (or a kind of that) hidden in the wall close to the patient and electrodes.

Electrical interference may also appear through the ground lead if this is connected to many computers, autoclaves, instruments using high power etc. In this case a dedicated ground for the ABR recording site should be established.

Avoid any mixing of cables (for example, USB cables/power cord etc. mixed up with the electrodes cable used for the EP system).

Sometimes, the ground lead is found inside the wall outlet, but it is not connected to the ground.

If the ground is not connected or even missing, the ABR recordings will be distorted greatly.

The *Neuro-Audio* digital system is connected to the ground lead via a ground contact of tripolar outlet. If the ground lead is not connected, the digital system will pick up electrical noise/interference. On the screen it will be displayed as total harmonic distortion fully overlapping the ABR waveforms.

Some notebooks are not provided with the ground connection to the outlet ground. If you use such a notebook as a part of the digital system, take special measures to ensure the notebook ground contact to the outlet ground. To do this, use the power supply units with the required contact (a tripolar connector for mains lead attachment). To make sure that there is a connection between the notebook ground and outlet ground, measure the impedance between the protective ground pin of power supply unit outlet and ground connector pin attached to notebook. The impedance should not exceed 0.1 Ω .

Check the ground for proper and correct function of the digital system.

Due to high voltage, only experienced technicians or properly trained staff must change and check the ground.

To check the ground, follow these recommendations:

1. Use a dedicated ground tester.
2. Compare voltage/impedance from the wall outlet ground lead to a triangle of earth rods. The resistance must not exceed 8 Ω , and the peak-to-peak amplitude must not exceed 0.5 V.
3. More simple check is to use a voltage meter and measure the voltage directly in the wall outlet. Check the following:
 - 3.1. The voltage between the phase (hot) and zero (neutral) sockets must be stable (230 V for Europe /110 V for US (country specific)).

3.2. The voltage between the phase (hot) and ground sockets must be stable (230 V for Europe/110 V for US (country specific). It is the same voltage as in item 3.1 (see above) with a deviation of max 5 V.

If the measured voltage is much less than 230 V Europe/110 V US, the ground is not connected to true ground. Even though you can see the lead inside the wall outlet this lead is not connected to the true ground.

3.3. The voltage between zero (neutral) and ground it must be at about 0 V.

If the measured voltage differs much from 0 V, it means that the ground is not connected to the true ground. Even though you can see the lead inside the wall outlet this lead is not connected to the true ground.

The ABR equipment must be connected to a proper true ground to provide safe operation and obtain good ABR recording and correct test results.

To obtain the best ground, a separate ground dedicated to ABR recording site should be wired and connected directly to the true ground using at least three earth rods.

The best test site for ABR recordings is:

1. The electric magnetic shielded room (it is also soundproof as well).
2. Separate ground only for ABR recording.

Besides, follow these recommendations to exclude other factors except electrical noise:

1. Turn off the light and other electrical equipment not being used as the patient will be as antenna and pick up electrical interference.
2. Conduct testing in a soundproof room.
3. Do not let other patients/visitors come in the room as they may disturb the patient trying to relax.

2.4. Unpacking and Checking Delivery Set

If the box with the digital system was under the conditions of excessive moisture or low temperature which differs significantly from the working conditions, place it in the room with normal conditions and leave there for 24 hours.

Unpack the box and take out the components of the digital system. The delivery set should coincide with the packing list.

The computer equipment packed in separate boxes should be opened according to the user and technical manuals for these products.

Check the components of the digital system and make sure that there is no external damage.

2.5. Assembly and Connection to Computer

If you buy the digital system with the computer, the equipment is delivered with installed and configured software. If you buy the digital system separately, please, install the software from the flash drive included in the delivery set.

The software must be installed before the first connection of the digital system to PC. Read the corresponding section of the user manual before starting to work.

If the electronic media with the software is not available, please contact your local dealer. The list of authorized Neurosoft dealers can be found here: <https://neurosoft.com/en/pages/dealers>.

The digital system consists of the electronic unit and can be supplied with the patient button depending on the delivery set variant (Fig. 10). The electronic unit and patient button can be connected to PC either directly or using USB hub (not shown in Fig. 10). Remember, that the USB connector of the electronic unit (with a blue mark) and the patient button must be attached to the same USB controller of your PC. It can be done, if:

- the devices are attached to one and the same USB hub;
- the devices are attached to the alongside USB connectors (typically, the connectors of one controller are located nearby);
- the devices are attached to different USB hubs but connected to one and the same USB controller.

Do not use the system with the USB hubs not connected to the mains. The connection to USB connectors on the monitor or keyboard does not ensure the correct device operation.

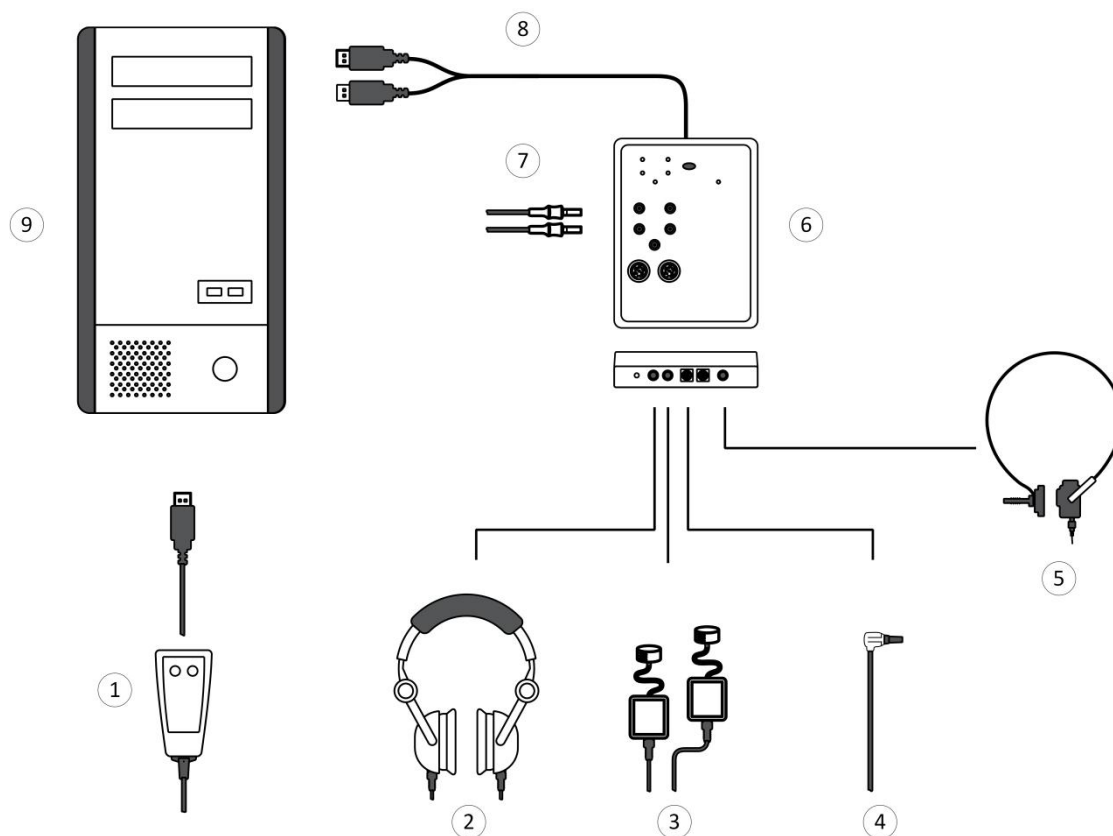


Fig. 10. Connection to PC

Designations shown in Fig. 10:

- 1 — patient button,
- 2 — auditory stimulator,
- 3 — insert earphones,
- 4 — OAE probe,
- 5 — bone vibrator,
- 6 — Neuro-Audio electronic unit,
- 7 — electrodes,
- 8 — to USB connector,
- 9 — PC system unit.

Place the holder to the testing site as near as possible and fix the *Neuro-Audio* electronic unit on it. Connect the required equipment (according to Fig. 10). The electrical units can be connected to PC when the power supply is on or off. The *Neuro-Audio* electronic unit is supplied with a cable with two USB connectors. To ensure the proper operation, attach both connectors to PC.

If the bone conduction amplifier (NS032201.012) is used, connect it to the *Neuro-Audio* electronic unit with a cable (NS032103.011). The bone vibrator should be connected to the corresponding connector of the bone conduction amplifier (Fig. 5 and Fig. 6). And the bone conduction amplifier itself should be connected to the PSU-9 power supply unit (NS057201.009) to operate from the mains or you can operate it from the built-in batteries.

When you install the program for the first time, the window shown in Fig. 11 will appear on the screen. Check the *Always trust software from "Neurosoft LLC"* checkbox and press *Install*.

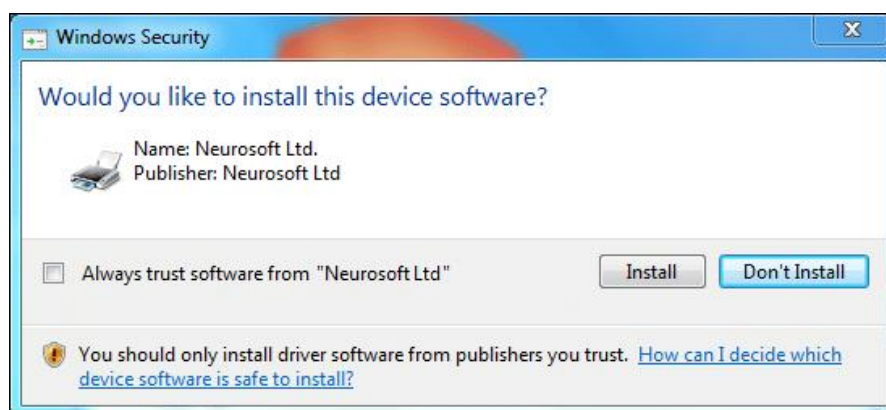


Fig. 11. Windows Security window

When the system is connected for the first time, the message box will appear in the right bottom corner of the taskbar (Fig. 12).

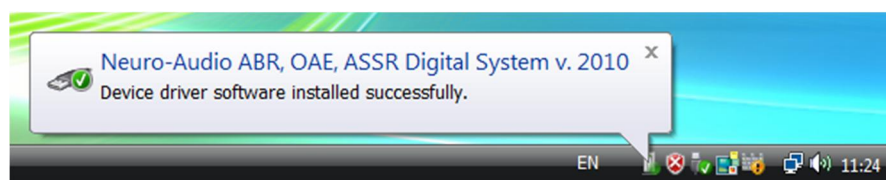


Fig. 12. Installation completed

3. Proper Use

3.1. Setting-Up Procedures

The operating limitations are given in Table 4 (see Operating conditions).

Before power supply is turned on, make sure the electronic unit and computer enclosures have no apparent mechanical failures that can be dangerous.

Switching On Power Supply and Testing Digital System

To switch on the power supply of the system, press *Power* on your PC. The electronic unit has no power supply switch and is constantly connected to PC. The power supply

is on, when the operating system has been loaded and the *Neuro-Audio.NET* software is started.

3.2. Performing Tests

Before testing, set up the digital system and other equipment following the recommendations in the user manual depending on a test type.

The test procedure includes the following stages:

- preparation (attaching electrodes, stimulators);
- signal recording;
- test analysis and printing the results.

Before placing the electrodes, degrease the patient skin with alcohol. When you attach EP electrodes, use the electrode abrasive paste. You can also connect and place the electrodes when the digital system is switched on. The more detailed information concerning electrodes is described in the user manual.

Do NOT use EP cable for the recording of cochlear microphone (CM) as it won't be detected because of stimulus artifact. Connect electrodes directly to the Neuro-Audio amplifier's touch-proof connectors.

When the surface electrodes have been placed, control the quality of their attachment using the impedance measurement. Switch on the impedance measurement mode (see the user manual).

The order of signal recording and further analysis is given in details in the user manual.

If the bone conduction amplifier (NS032201.012) is used, switch it on immediately before the recording. The on/off button is on the back panel of the amplifier unit (Fig. 6). Make sure that the ready light is green and start recording. The bone conduction amplifier (with the connected medical power supply unit) should be mains-powered but the battery operation is also possible. In this case, make sure the ready light is green. If it is off while the system is switched on, then the battery is discharged. Connect it to the mains for charging. If both ready light and charge indicator are green (the system is on), you can use the system. If the charge indicator is yellow, the charging from the mains is going on. When the recording is over, switch the amplifier off.

When the test is finished, the electrodes and transducers should be taken off the patient and disinfected (see section 4.4. "Disinfection").

If there are no more patients to be tested till the end of the working day, the digital system should be switched off. Exit the program and switch off the computer and printer.

3.3. Troubleshooting

If you have any problems with the digital system, first of all, check the connection of all units to PC, and if the units are connected through the USB hub, check the connection of the USB hub to PC and mains.

It is prohibited to use USB hubs not connected to mains.

The list of possible troubles and the ways of their removal is given in Table 2. If the trouble can't be eliminated by the user, the system is to be repaired.

Table 2. Troubleshooting

Trouble Symptom	Possible Cause	Way of Removal
Program message: "Program supported devices are not found".	Electronic unit of the <i>Neuro-Audio</i> digital system is not connected to PC.	Check whether the electronic unit is connected to PC. If there are no connection errors, disconnect the electronic unit from the computer and connect it again in several seconds. If it doesn't work, restart the computer.
Program message: "Link error: <i>Neuro-Audio</i> is not connected or defective".	Electronic unit of the <i>Neuro-Audio</i> digital system is not connected to PC.	Check whether the electronic unit is connected to PC. If there are no connection errors, disconnect the electronic unit from the computer and connect it again in several seconds. If it doesn't work, restart the computer.
Program message: " <i>Neuro-Audio</i> is already used by other program".	The other program using the <i>Neuro-Audio</i> digital system is running.	Close other programs using the <i>Neuro-Audio</i> system. If you can't find such a program, restart the computer.
Program message: " <i>Neuro-Audio</i> shutdown error. Close program, disconnect the system from PC and then connect it again".	Electronic unit shutdown fail	Close the operating program, disconnect the electronic unit from PC (USB hub) and connect it again. If it doesn't work, restart the computer.
Program message: "Timeout error. The device does not transfer data".	Equipment error	Restart the signal recording. If it fails, restart the computer.

Table 2(continued)

Trouble Symptom	Possible Cause	Way of Removal
Program message: "USB transfer error. Check the connection and restart the system".	The system was disconnected during the recording or failed when exchanging data through USB.	Check the connection of the <i>Neuro-Audio</i> digital system and restart the signal recording. If it fails, restart the computer.
Program message: "Install Service Pack 1 for operation under Windows XP".	The first version of Windows XP installed in your PC contains errors that result in the improper operation of USB devices.	Install Windows XP Service Pack 1, or later version of Windows (preferable).
There is high supply-line noise in the recorded signal (frequency – 50 (60) Hz or divisible to it – 100 (120) Hz, 150 (180) Hz, etc.).	The electrodes not used at the moment are connected to the amplifier (i.e. these electrodes are not applied on a patient and cause noise).	Disconnect the electrodes you do not use from the amplifier.
	The electrodes are placed on a patient improperly.	Start the impedance measurement and obtain the accepted values. If there are defects of electrodes (for example, their break), replace them.
	Bad grounding of the system.	Ground the computer safely. Ask the electrician to check the quality of tripolar sockets and the integrity of protective ground circuit.
	The presence of powerful noise sources (X-ray equipment, physiotherapeutic room, powerful refrigerating systems, electric motors, electric welding, etc.).	Try to switch off or move off these powerful devices farther away. If it is impossible, try to obtain better grounding parameters of the system.
Program message: "Processing error. The system is overloaded. Please, restart".	The processor was overloaded and failed to receive data from the system. If this message appears rarely (not more than 1-2 times a day), it is not considered as trouble.	Close all applications except the <i>Neuro-Audio.NET</i> program (if they are running) and restart the recording. If it doesn't work, restart the computer. If the trouble does not disappear, then, probably, the processing speed of your PC is not enough. The minimal requirements for PC are given in the user manual.
There is no stimulus when the recording is started.	The stimulation device (OAE probe, headphones, etc.) is not connected (or connected unreliably) to the stimulator unit.	Make sure that the stimulation device is connected to the stimulator unit in a proper way.
	The connection between stimulator and PC is broken.	Execute <i>Setup/Hardware reset</i> menu command and restart. If it fails, restart the computer.

Table 2 (continued)

Trouble	Possible cause	Way of Removal
The bone conduction amplifier has been left in the ON mode for more than 8 hours (the switch is on the back panel in position "1"). As a result, the ready light went off or became red and the amplifier stopped to operate. Or the ready indicator became red during the operation (stimulation).	The internal circuit of the power supply unit has switched off because of internal overheating due to long-term operation or battery discharge (in case the external AC power supply unit was not connected).	To restart the operation, set the switch to position "0" and connect the external AC power supply unit (if it was not connected). Wait for 10-15 minutes. Then, switch on the amplifier again (set the switch to position "1"). The problem should be corrected and the ready light will become green. Otherwise, the system has broken down and must be repaired.

3.4. Actions in Emergency

If the electrical insulation disturbance of any digital system component which causes the emergency (fire, mechanical failure, flood, medical staff evacuation) and occurrence of threat of electrical shock for patient or staff, or any changes in the performance of the device are observed, de-energize the digital system completely.

4. Maintenance

4.1. General Requirements

The safety measures during maintenance conform to the ones described in section 3 "Proper Use".

The requirements for medical staff are listed in section 2.1 "Requirements to Personnel".

The servicing of bought articles included in the system is performed according to user and technical manuals or standard rules.

If any problem is detected, use the information described in section 3.3 "Troubleshooting". If the troubles can't be eliminated using the control units or by restart, the system should be switched off and checked by the specialist.

The system should be serviced during operation and also maintained annually. The amount of maintenance is described in sections 4.2 "User Maintenance" and 4.3 "Periodic Maintenance".

The delivery set should match the packing list for the medical equipment.

4.2. User Maintenance

The user maintenance of the system includes the external examination, check of connectors and cables, cleaning and disinfection according to recommendations stated in section 4.4 “Disinfection”.

4.3. Periodic Maintenance

4.3.1. Checking of OAE Channel with Test Cavity

The checking of OAE channel with a test cavity should be performed in a quiet room. The checking is performed monthly or when it is required.

To check the functioning in the TEOAE mode, connect the OAE probe to the system, remove the ear tip and insert the OAE probe into the test cavity as far as it can go. Start TEOAE recording (see the user manual).

As the test cavity does not provide the normal functioning cochlea hair cells, the test result should be REFER. The sum and difference of A&B and A-B traces should be less than 0 (1000 averagings) (Fig. 13).

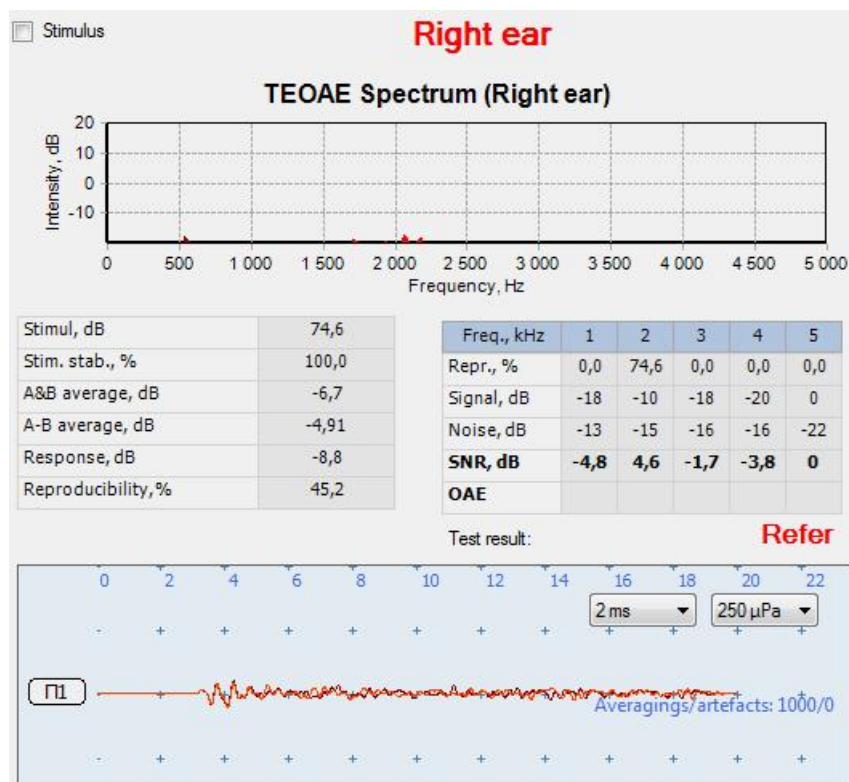


Fig. 13. Result of TEOAE check in a test cavity

If it is not so, make sure it is quiet in the room and the OAE probe sensitivity is specified correctly.

The functioning in the DPOAE mode is checked with the connected OAE probe inserted into the test cavity. Start the DPOAE test. During the frequency response

calibration (the *Seal control* mode) make sure that two similar traces of stimulus spectrum from the first and second telephones appear on the screen (Fig. 14).

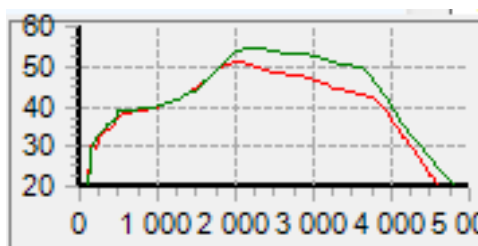


Fig. 14. Frequency response calibration

When the test is over, the result should be REFER. There must be no emission for all frequencies (Fig. 15).

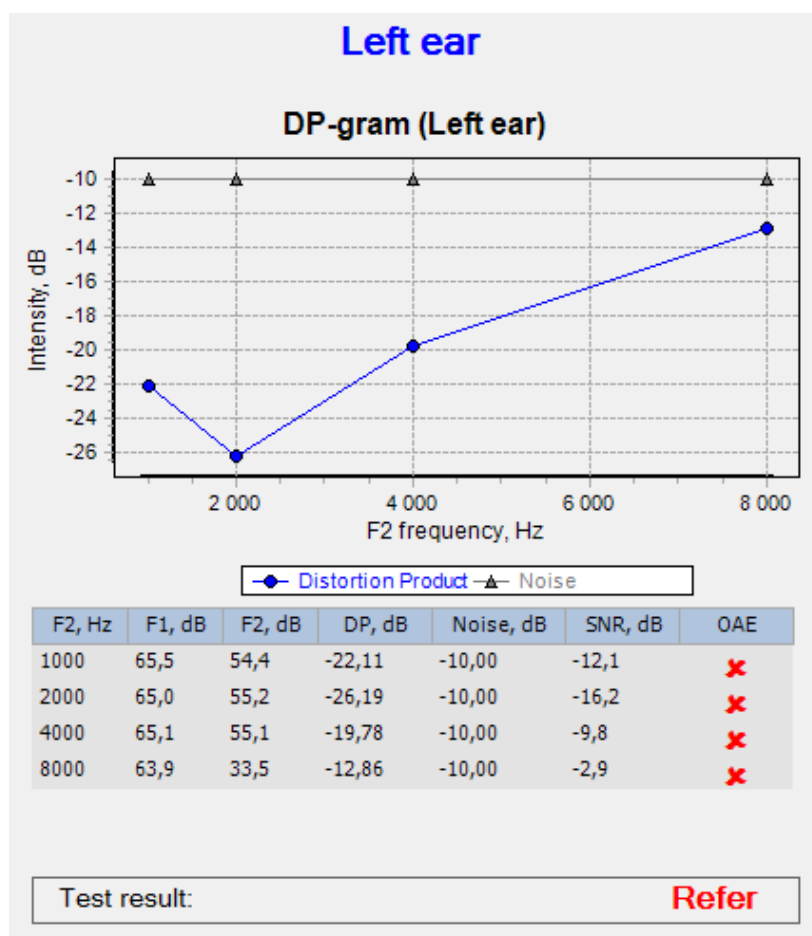


Fig. 15. Result of DPAOE check in a test cavity

When the test is over, close it using the *Exam/Close* menu command. When the *Save changes?* message box appears, press *No*.

4.3.2. Checking of OAE Probe

The probe check is performed monthly or when it is required.

To check the OAE probe, use the test cavity delivered with the system. Checking with the probe out of the test cavity leads to wrong results!

The check is performed in a special *OAE probe check* mode. In this mode the comparison of OAE probe responses with already set responses is carried out.

Start the *Neuro-Audio.NET* program, execute the *Setup/Change* menu command. Select the *Hardware* page and press *OAE Probe Check* (Fig. 16).

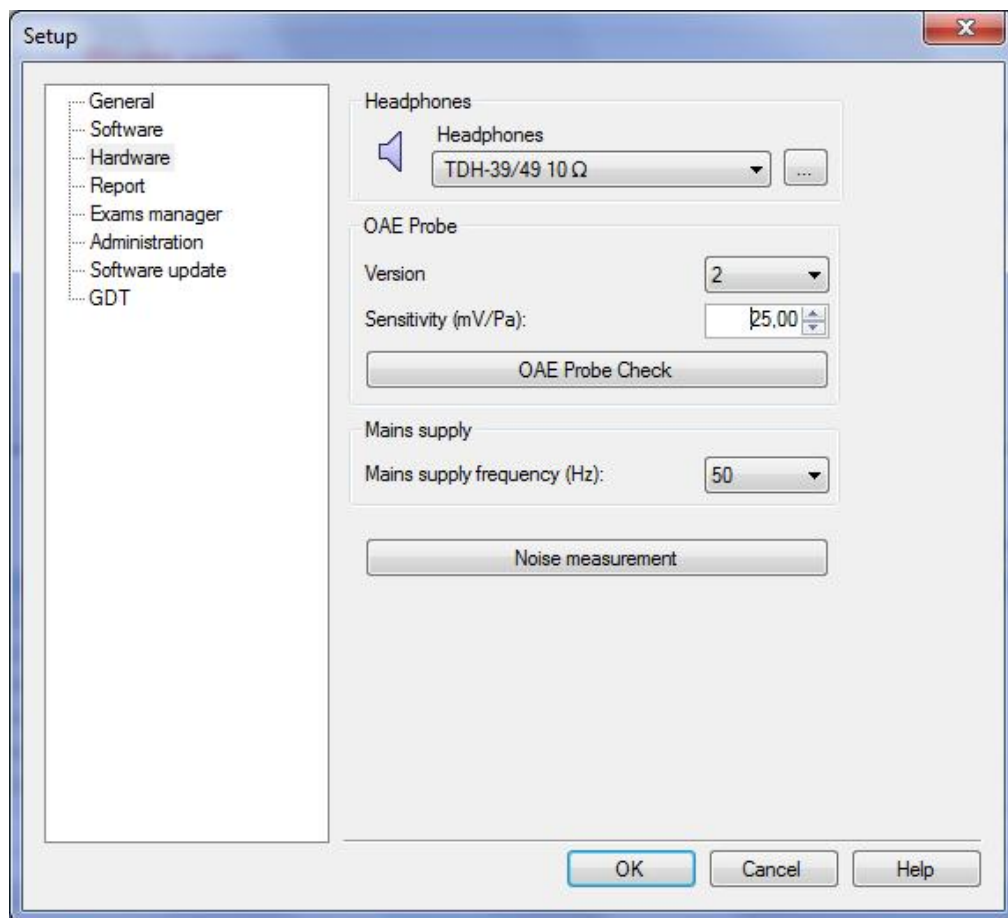


Fig. 16. Setup

The *OAE probe check* window appears (Fig. 17).

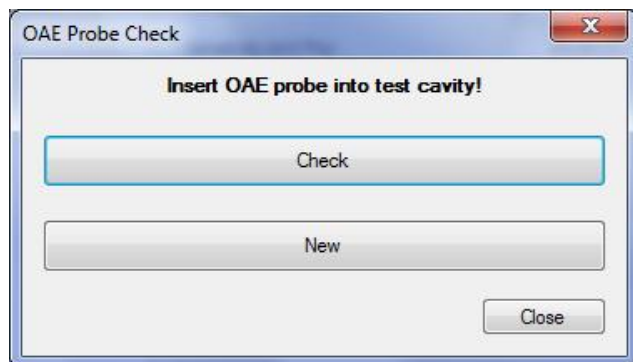


Fig. 17. The *OAE probe check* window

Connect the OAE probe to the system, take off the OAE probe tip and insert the OAE probe into the test cavity as far as it can go.

Press *Check* to start checking.

Do not press *New* as it can lead to the loss of data concerning OAE probe responses and you will not be able to check the probe. The *New* button is used only for the new probe as described below.

The results are displayed as several pairs of bars. The probe check is performed on several frequencies; each bar pair (for each probe loudspeaker) corresponds to one frequency. If the colour of bars is green, the OAE probe is operable. If even one bar in the pair is red, the probe is defective (Fig. 18).

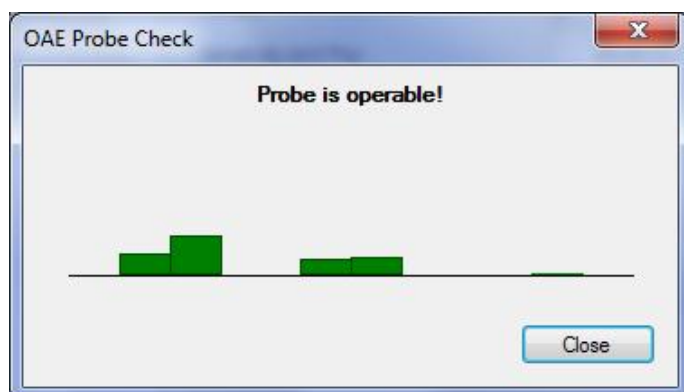


Fig. 18. Result of OAE probe check

If the OAE probe failed to pass the check even for one frequency and the message to replace the probe appears, perform the following:

- Try to extract the probe from the test cavity and insert it again. Then, run the check once again. If it is passed, the probe was inserted incorrectly.
- Try to clean the probe tip. If the OAE probe passes the repeated check, the OAE probe tip was clogged.

- If two first steps don't work, replace the OAE probe tip.
- If the tip replacement doesn't work, replace the OAE probe.

After the OAE probe replacement, save its specifications in the *OAE Probe Check* window (Fig. 17). Press *New* and wait until the progress bar reaches its end and the *Done* message appears (Fig. 19). The saving should be done in complete silence. Do not touch the OAE probe cable and try to avoid its casual vibrations.

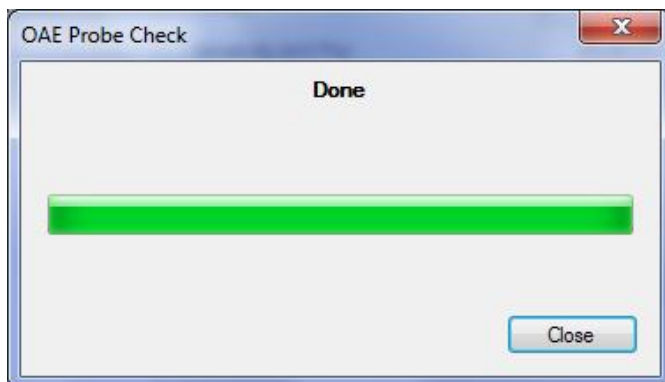


Fig. 19. Saving specifications of a new OAE probe

Then, press *Close*. The *Remember this probe as a new one?* message will appear (Fig. 20).

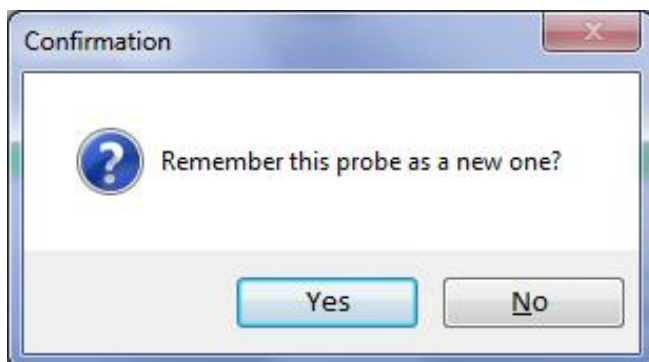


Fig. 20. Confirmation to save a new probe

If you pressed *New* in the *OAE Probe Check* window (Fig. 17) by chance or you are not sure in your actions, press *No*. To save the data of a new probe for further checking, press *Yes*.

The detailed instructions for the probe and probe tip replacement, cleaning and disinfection are described in the "OAE Probes OAE-02, OAE-03, OAE-04 and aScreen Probe" guidelines.

4.3.3. Calibration of Stimulus Intensity within Free Field

The placing of equipment for calibration of stimulus intensity within free field is shown in Fig. 21.

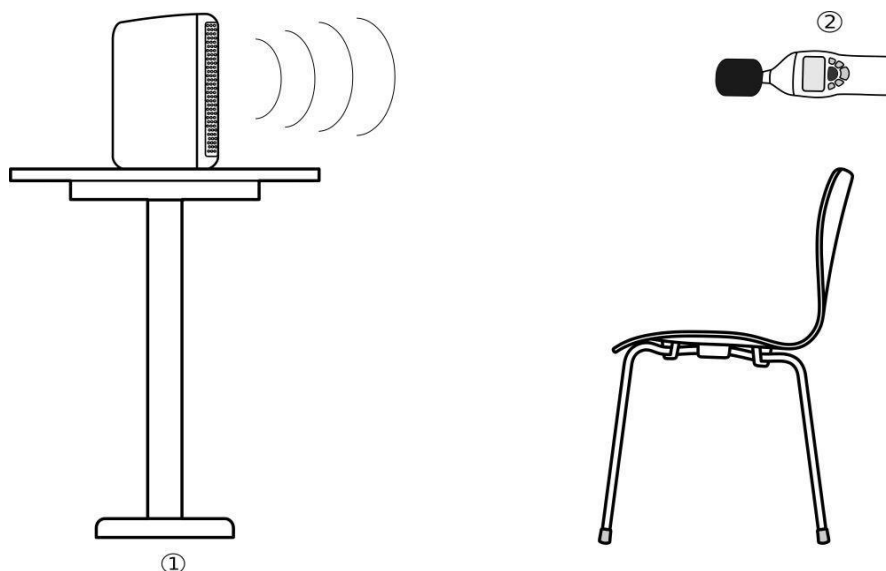


Fig. 21. Equipment placement during calibration

Designations shown in Fig. 21:

1 — acoustic system,

2 — sound level meter.

The calibration of stimulus intensity within free field is performed at the spot using a sound level meter. The acoustic system (stimulator) is placed within 1 meter from the estimated patient's head center on a special support located at the head level (with azimuth of 0°, i.e. straight before the patient). The sound level meter microphone is positioned at the proposed head center. The room acoustics should conform to the requirements for free field audiometry. The room and its interior should provide free wave transmission without any reflections. It should also be free from reflected and stationary waves.

During the operation the volume knob of the acoustic system should be set to maximum, and the bass/tone knobs should be at mid-position. The acoustic system is powered via isolation transformer.

During the calibration follow the steps below.

Run the *Neuro-Audio.NET* program. In the main menu select *Setup/Calibration mode...* Enter the password for the setting/calibration mode (see section 4.2 "Calibration mode in *Neuro-Audio.NET* software" of "Neuro-Audio" calibration guidelines).

Do not tell your password to anyone except those who will make calibration.

In the calibration mode create a new calibration file (press “+” in the bottom left corner of the calibration window).

Fill in the metadata of the calibration file:

1. Select *Loudspeaker* from the *Calibration File Name (Transducer)* dropdown list.
2. Select *Loudspeakers* from the *Transducer* dropdown list.
3. Fill in the serial number (from the loudspeaker label) in the *Transducer S/N (left)* field.

Go to the *Calibration* tab.

Select one of the following from the *Base DEMO file* dropdown list and press *Apply*:

1. **Loudspeaker (Binaural) 0° (DEMO)** – for binaural listening;
2. **Loudspeaker (Monaural) 0° (DEMO)** – for monaural listening (when one ear is tested in free field, the other must be occluded, for instance, with a special protection headphone or audiometric earphone with masking noise introduced to the non-tested ear).

Select *Pure tone* from the *Stimulus type* list. Sequentially select the tone frequency (from 250 Hz and up to 8000 Hz) from the *Frequency (Hz)* list. For each frequency do the following:

Measure sound pressure level with the sound level meter and enter the obtained data to the second row of Table 6. Use the C-scale of the sound level meter, if there is no C-scale, then use A-scale.

Table 3. Correction coefficient table

Frequency f, Hz	250	500	750	1000	1500	2000	3000	4000	6000	8000
Sound, dB SPL (or dBC or dBA)										
A-scale correction	8.6	3.2	1.0	0	-1.0	-1.2	-1.2	-1	0	1.1
C-scale correction	0	0	0	0	0	0.2	0.5	0.8	1.9	3.0
A intensity, dB										
SPL correction coefficient										

Then, calculate A-stimulus intensity (in dB) using the formula:

$$A = S_i + C_{\text{cor}},$$

where S_i is a measured sound pressure level (from the second row); C_{cor} is a correction coefficient. It is taken from the third row for A-scale and from the fourth row for C-scale (see Table 3).

Enter the results to the fifth row of Table 3 (A intensity, dB). Use the “+1 dB” and “-1 dB” buttons to obtain sound pressure level (recorded by the sound level meter and adjusted for A- or C-scale) equal to the specified *Target level* of (85 ± 2) dB SPL. Then, select the next frequency from the list (go on until you calibrate all frequencies).

To save the results in the calibration file press *Save changes* and then press *Close* to exit the calibration mode.

Finally, select *Setup|Assign calibration information...* in the main menu. In the *Assign calibration information* window select a newly created calibration file from the *Loudspeakers* dropdown list. The file should have the word “Loudspeaker” and serial number of loudspeaker in its name (in parentheses). Press *OK* and exit the *Neuro-Audio.NET* program.

After that, the newly created calibration file will be used by the program whenever *Loudspeakers* is selected as a transducer during the testing.

4.4. Disinfection

Clean the device only when it is switched off (USB cable or power supply is disconnected).

Clean the electrode cables only when they are detached from the Neuro-Audio electronic unit.

Do not use abrasive or solvent silicon-based cleaning agents, scrubbing pads or other abrasive applicators.

Never submerge the device or the cables in disinfectant or other liquids.

Be careful not to drip disinfectant directly into the input and output plugs and other openings in the cover. Otherwise, device could be damaged and patients and users could be in danger.

After the test is finished, please remove the electrodes and transducers from the patient and disinfect them following the instructions in this section.

Disposable surface electrodes (also, rubber or foam eartips and other disposable items) should be discarded after each use to avoid reusing them by mistake.

To clean and disinfect cup electrodes, follow the electrode manufacturer's instruction manual.

To clean and disinfect the OAE probe, refer to the "OAE Probes OAE-02, OAE-03, OAE-04 and aScreen Probe" guidelines, included in the delivery set.

The auditory transducer (headphones) is cleaned and disinfected according to the transducer manufacturer's instruction manual.

To clean and disinfect the *Neuro-Audio* electronic unit, electrode cables, bone vibrator, bone conduction amplifier unit and *PSU-9* power supply unit please follow the instructions below:

1. Switch off the device (disconnect USB cable or power supply) before cleaning.
2. For routine cleaning use a cloth gently wrung in Phenoles (Bacillotex® etc.) or 70% alcohol, 0,5% chlorohexidine.
3. If any dangerous viruses or skin diseases are suspected, use Aldehydes (Cidex® etc.) or chlorinates (Diversol BX®).
4. Remove disinfectant with a dry cloth.

4.5. Lifetime

The lifetime of the system is 5 years from the shipping date to a customer.

The manufacturer is obliged to provide technical support of the system during its whole lifetime.

5. Current Repair

5.1. General Requirements

The system repair requires special training of the technical staff, special equipment and service software which you can get from the manufacturer or the representative of the company. The repair connected with the opening of electronic units is prohibited. The repair of computer equipment must be performed by special services.

The current repair includes the repair of some component parts and cables. The repair of connected component parts is prohibited.

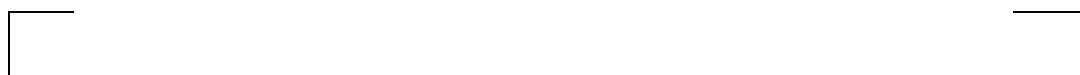
During the current repair all units must be switched off.

6. Disposal

The system and its accessories should not be disposed of in general waste. The system disposal should be performed according to your local regulations. The used Li-ion battery (in the bone conduction amplifier unit) must be disposed according to the local regulations. The battery contains the poisonous hydride of heavy metals and should be disposed in special places.

7. Acceptance, Delivery Set and Package Data

The *Neuro-Audio* digital system for auditory EP, OAE and screening PTA is collected and packed according to the requirements of design documentation.



Packed by _____
Signature

The detailed information on the delivery set is provided in the packing report which is the integral part of the manual and shall be kept with it.

8. Warranty

8.1. The manufacturer guarantees the system quality conformance to the requirements of design documentation if the rules of operation, storage, transportation, assembly and maintenance prescribed in the operational documentation are observed.

8.2. Warranty period is 24 months from the delivery date to the customer. The delivery date is the date of waybill or other shipment document for the system.

The warranty period for OAE probe is 12 months from the delivery date to the customer.

The warranty period for components exposed to wear (electrodes and cables) is 30 days.

The warranty does not cover consumables (gels and pastes).

The warranty period can be prolonged for the period from reclamation submission up to repair completion (see section 9 "Reclamation").

8.3. The warranty is voided in the following cases:

- if the rules of operation, storage, transportation and assembly prescribed in the operational documentation are not observed;
- when the warranty period is expired;
- if a user brakes the seal without permission of the manufacturer.

11.4. The manufacturer is obliged to repair the system in case of failure during the warranty period free of charge. The repair is carried out in Neurosoft service center (5, Voronin str., Ivanovo, 153032, Russia) in compliance with the procedure stated in section 9 "Reclamation".

You can also contact SAS Neuromed Company, Authorized European Representative of Neurosoft Company (Mr. Benjamin Scholl) by the following address:

360 avenue du Clapier

ZAC du Couquiou

84320 Entraigues sur-la-Sorgue

France

Phone: +33 621-304-580

E-mail: **info@neurosoft-france.com**

9. Reclamation

9.1. The written notification to Neurosoft in case of the system failure should include the following information:

- the customer's name and address,
- the serial number of the system (specified on the label and in section 7 "Acceptance, Delivery Set and Package Data"),
- the number and date of the invoice or other accompanying document,
- the detailed description of faults. If possible state the reasons and circumstances preceding fault detection (in addition it is recommended to attach test report, exam data, photos and other materials that allow solving the problem as soon as possible).

9.2. If the system is returned to the Service Center for repair, the following should be observed:

- the system should be decontaminated prior to sending. Please refer to section 4.4 "Disinfection".
- the system should be packed so to exclude the possibility of its damage during the transportation;
- the notification (see p. 9.1) and this technical manual must be included into the shipment with the system being returned.

Annex 1. Main Specifications

The main specifications of the system are given in Table 4.

Table 4. Main specifications

Parameter	Value
<i>EP channels</i>	
Number of channels	2
Input voltage range	20 μ V to 50 mV
The admissible error of voltage measurement should be within <ul style="list-style-type: none"> in the voltage range from 20 to 100 μV; in the voltage range from 0.1 to 50 mV. 	$\pm 15 \%$ $\pm 5 \%$
Voltage range of the obtained averaged evoked potentials	0.1 to 400 μ V
The admissible relative error of EP voltage measurement in the range from 1 to 400 μ V at not less than 2000 averagings	$\pm 10 \%$
Sampling rate	200 Hz – 80 kHz (1-2 channels), 160 kHz (1 channel)
Input impedance	not less than 90 M Ω
Input noise in 2–10000 Hz range (RMS)	not more than 0.5 μ V
High pass filter	0.01–5000 Hz
Low pass filter	10–10000 Hz
On/off notch filter 50 or 60 Hz (switchable)	not less than 40 dB
Common-mode rejection	not less than 100 dB
Gain	21-20832
<i>Auditory stimulator</i>	
Number of auditory channels	2
Bone vibrator calibration	B-71 (mastoid placement)
Bone vibrator headband static force	5.4N \pm 0.5N
TDH-39 headband static force	4.5N \pm 0.5N
Stimulation level (maximal for click)	100 dB nHL (TDH-39, ER-3C), 50 dB nHL (Bone vibrator)
Stimulation level (maximal for tone burst at 1 kHz)	110 dB nHL (TDH-39), 100 dB nHL (ER-3C), 60 dB nHL (Bone vibrator)
The sound pressure level at pure tone generation via the headphones: <ul style="list-style-type: none"> at tone frequency within 125 – 4000 Hz range at tone frequency within 4 – 8 kHz range 	with ± 3.0 dB accuracy with ± 5.0 dB accuracy
Stimulation level (minimal for pure tone)	-10 dB HL (or less)
Stimulus repetition rate	0.1–100 Hz with the admissible relative deviation of $\pm 0.1 \%$

Table 3 (continued)

Parameter	Value
Tone burst stimulation: <ul style="list-style-type: none"> • tone • stimulus duration 	20–10000 Hz 0.05–50 ms
Click stimulation: <ul style="list-style-type: none"> • stimulus duration 	50–5000 μ s with the admissible relative deviation of ± 2 %.
Continuous tone stimulation: <ul style="list-style-type: none"> • stimulus types 	pure tone; amplitude, frequency, amplitude and frequency modulation (MM=Mixed Modulation), exponential modulation (AM ²), stimulus with three carrier frequencies
<ul style="list-style-type: none"> • carrier frequency 	125–16000 Hz (HDA-200, ER-2) 125-8000 Hz (other earphones)
<ul style="list-style-type: none"> • modulation frequency 	within the following tolerance ± 2.5 % 20–200 Hz
Maximum total harmonic distortion should not exceed: <ul style="list-style-type: none"> • for air conduction • for bone conduction. 	2.5% 5.5%
Chirp stimulus (cochlear delay compensation): <ul style="list-style-type: none"> • wide-band • narrow-band 	250–10900 Hz 500 Hz, 1 kHz, 2 kHz, 4 kHz (bandwidth — $\pm 1/2$ octave)
Stimulus polarity	condensation, rarefaction, alternating
Frequency characteristics of masking noise	white noise (0.02–10000 Hz)
Noise masking intensity	0–127 dB SPL (stimulus relative)
Left/right/double-sided stimulation	yes
Number of bone vibrator channels	1
Stimulus intensity at bone vibrator output	-10 – 80 dB HL (at 3 kHz frequency)
Bone vibrator amplifier gain	(19.5 \pm 0.5) dB
<i>OAE channel</i>	
TEOAE stimulation	wide-band click (non-linear)
TEOAE stimulus intensity	30–90 dB SPL
Admissible relative deviation of TEOAE stimulus intensity	± 3 dB
Frequency range of TEOAE acquisition	0.5–5 kHz
Bandpass flatness: <ul style="list-style-type: none"> • in the band 0.5–2500 Hz • in the band 2500–4500 Hz 	not more than 6 dB not more than 15 dB
DPOAE stimulus intensity	0–70 dB SPL
The difference between indicated and actual sound pressure levels <ul style="list-style-type: none"> • for frequencies up to 4 kHz • for higher frequencies (up to 12 kHz) 	± 3 dB ± 5 dB
Frequency range of DPOAE acquisition (3 steps per octave)	0.5–12 kHz

Table 3 (continued)

Parameter	Value
f2/f1 DPOAE frequency ratio	1.1–1.3
Stimulus 3rd order intermodulation	-80 dB
<i>General parameters and specifications</i>	
Interface	USB
Supply voltage: <ul style="list-style-type: none"> • electronic units • desktop PC-based computer • notebook PC-based computer 	5 V DC 220/230 V AC (50 Hz) 220/230 V AC (50 Hz) / int. battery
Ingress protection	IP20 in compliance with EN 60529
Supply voltage of bone conduction amplifier unit: <ul style="list-style-type: none"> • battery • power supply unit <ul style="list-style-type: none"> ○ model ○ power voltage ○ output voltage 	Li-ion, 3.7 V PSU-9 100-240 V AC, 50/60 Hz 9 V DC
Dimensions: <ul style="list-style-type: none"> • <i>Neuro-Audio</i> electronic unit • bone conduction amplifier unit 	190×140×50 mm 235×63×166 mm
Weight: <ul style="list-style-type: none"> • <i>Neuro-Audio</i> electronic unit • bone conduction amplifier unit 	< 0.9 kg < 0.2 kg
<i>Climatic conditions</i>	
Operating conditions: <ul style="list-style-type: none"> • temperature • relative humidity • atmospheric pressure 	from +15°C to +35°C 30%–90°C, non condensing from 98 kPa to 104 kPa
Transportation conditions: <ul style="list-style-type: none"> • temperature • relative humidity • atmospheric pressure 	from - 25°C to +60°C 20%–95°C, non condensing from 70 kPa
Storage conditions: <ul style="list-style-type: none"> • temperature • relative humidity • atmospheric pressure 	from +5°C to +40°C 30%–85%, non condensing 70–106 kPa
Warm-up time	2 minutes
<i>Safety and electromagnetic compatibility</i>	
Safety standard	EN 60601-1:2006/A1:2013
Working with PC	Class I
Working with notebook (built-in rechargeable battery)	Internal power supply
Applied parts	BF type
Electromagnetic compatibility standard	EN 60601-1-2:2015

Table 3 (continued)

Parameter	Value
<i>Conformance to technical standards</i>	
Reference zero for calibration of audiometric equipment	EN ISO 389-1:2000 EN ISO 389-2:1996 EN ISO 389-3:2016 EN ISO 389-5:2006 EN ISO 389-6:2007 EN ISO 389-8:2004
Stimulus types	EN 60645-1:2015 EN 60645-3:2007
Tone audiometry (PTA)	EN 60645-1:2015 (Type 4)
Otoacoustic emission (OAE)	EN 60645-6:2010 (Type 1)
Auditory brain response (ABR)	EN 60645-7:2010 (Type 1)

Essential Performance Requirements

The essential performance requirements for the system are:

- stimulus generation and delivery via earphones (or other acoustic transducer); stimulus parameters must comply with EN 60645 standards, mentioned in Table 4;
- recording and storage of patient's response to stimulus.

The correct operation of the system means that the requirements are fulfilled.

Safety and Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is ensured by compliance with EN 60601-1-2:2015 requirements.

The system is intended for operation in the electromagnetic environment conditions which are specified in Annex 3 "Electromagnetic Emission and Immunity".

Do not use the system when other equipment is under or above it or when the system is in close proximity to other equipment. However, if it is required, the correct operation of the system should be verified.

Portable and mobile RF communication equipment can affect the system work. Do not use these devices less than 30 cm from any part of the system (including the cables) to avoid incorrect operation.

The use of the equipment not listed in Table 5 and Table 6 of this technical manual may result in increase of emission and reduce of immunity of the system.

As for safety, the system complies with EN 60601-1:2006/A1:2013 requirements. The electronic units are supplied by regulated power supply through USB interface, have double isolation and BF type applied parts according to EN 60601-1:2006/A1:2013.

Annex 2. Delivery Set

The delivery set includes the electronic amplifier unit, patient button and software that can be supplied to a customer both together and separately. The accessories and bought articles are also delivered. The delivery set is shown in Table 5 and Table 6 where 1 describes base delivery set, 2 – Neuro-Audio/ABR delivery set, 3 – Neuro-Audio/OAE delivery set, 4 – Neuro-Audio/PTA delivery set.

Table 5. Base delivery set

Name	Order code or main specification	Quantity, pcs.			
		1	2	3	4
Neuro-Audio electronic unit	NS032201.011-020	1	1	1	1
Holder H-1S	NS016201.038	1	1	1	–
Holder mount	NS006200.002	1	1	1	–
Patient button	NS028201.009-020	–	–	–	1
KM-7-2 USB hub1)	DS042.02.01.001.000	–	–	–	1
<i>Accessories for OAE Studies:</i>					
OAE probe OAE-02-2	NS006355.003-01	1	–	1	–
OAE probe tip	NS006221.001	1	–	1	–
Set of eartips (universal)	NS007998.002	1	–	1	–
Dental floss for probe tip cleaning Superfloss Regular	Oral-B, Ireland (50 pcs. in a pack)	1 pack	–	1 pack	–
Probe tip extractor	NS006206.016	1	–	1	–
Test cavity	NS006201.013	1	–	1	–
<i>Accessories for EP Studies:</i>					
Y-adapter	NS006103.019	1	1	–	–
Adapter for 2-channel EP recording	NS032103.006-05	1	1	–	–
Cup EP electrode with cable ²⁾ : <ul style="list-style-type: none"> • EEP (includes 5 pcs.) - NS990106.028-01.10, white, 1 m - NS990106.028-03.10, red, 1 m - NS990106.028-04.10, black, 1 m - NS990106.028-05.10, yellow, 1 m - NS990106.028-06.10, blue, 1 m - “Electrodes for EMG and EP Studies” technical manual 	NS990998.048-01	1 pack	1 pack	–	–

Table 5 (continued)

Name	Order code or main specification	Quantity, pcs.			
		1	2	3	4
• EEP	NS990106.072-01.10	5 pcs.	5 pcs.	–	–
• C1234	NS990106.049				
Cable for disposable electrode connection: <i>Alligator</i> clip — touch-proof, white (1 m)	NS990103.027-01.10	1	1	–	–
Cable for disposable electrode connection: <i>Alligator</i> clip — touch-proof, red (1 m)	NS990103.027-03.10	1	1	–	–
Cable for disposable electrode connection: <i>Alligator</i> clip — touch-proof, black (1 m)	NS990103.027-04.10	1	1	–	–
Cable for disposable electrode connection: <i>Alligator</i> clip — touch-proof, blue (1 m)	NS990103.027-06.10	1	1	–	–
Disposable surface electrode ²⁾	F 9049 (FIAB, Italy)	100	100	–	–
<i>Auditory stimulators and accessories:</i>					
Auditory stimulator (headphones):		1	1	–	1
• TDH-39 (with earcups)	NS032305.011				
• TDH-39	NS032305.009				
<i>Consumables:</i>					
Electrode adhesive paste ²⁾	TEN20, 114 g (USA)	1	1	–	–
Electrode abrasive paste for skin preparation ²⁾	Everi, 160 g (Italy)	1	1	–	–
Medical tape ²⁾	1527-2, Transpore (3M Company, 3M Health Care, USA)	1	1	1	–
<i>Software:</i>					
Neuro-Audio.NET software license with Neuro-Audio.NET/ABR module	NS001.221023	1	1	–	–
Neuro-Audio.NET software license with Neuro-Audio.NET/VEMP module	NS001.221643	1	–	–	–

Table 5 (continued)

Name	Order code or main specification	Quantity, pcs.			
		1	2	3	4
Neuro-Audio.NET software license with Neuro-Audio.NET/OAE module	NS001.219921	1	–	1	–
Neuro-Audio.NET software license with Neuro-Audio.NET/PTA module	NS001.219931	–	–	–	1
<i>Operational Documentation:</i>					
“Neuro-Audio” technical manual	TM032.02.003.002	1	1	1	1
“Neuro-Audio.NET” user manual	UM032.01.005.001	1	1	1	1
“Exam Manager” Annex to User Manual	AU999.01.003.000	1	1	1	1
“OAE Probes OAE-02, OAE-03, OAE-04 and aScreen Probe” guidelines	GL032.03.001.001	1	–	1	–
“EABR Test” guidelines	GL032.04.001.000	1	1	1	1
“VEMP: Vestibular Evoked Myogenic Potential” guidelines	GL032.05.001.000	1	1	1	1
“How to get quality ABR and ASSR recordings” guidelines	GL032.06.001.000	1	1	1	1
“Neuro-Audio” calibration guidelines	CG032.01.003.000	1	1	1	1
<i>Package:</i>					
Transportation bag	–	1	1	1	1

Notes:

¹⁾ The delivery with another USB hub complying with the requirements of EN 60601-1 is permitted.

²⁾ The accessories and consumables of analogous types can be used if their application is permitted in the country.

Table 6. Equipment and software included in base delivery set at customer's request

Name	Order code or main specification	Quantity, pcs.			
		1	2	3	4
Bone vibrator	NS032221.002	1	1	1	1
Bone vibrator	NS032998.001	1	1	1	1
Set of eartips (pediatric)	NS007998.001	1	–	–	1
SU-6 stand for electronic unit	NS016998.011	1	1	1	1
Disposable surface electrode ¹⁾	F3001NECG (FIAB, Italy)	1	1	1	1
Disposable electrode ¹⁾	PG10S (FIAB, Italy)	1	1	1	1
<i>Equipment for AEP Study:</i>					
Cup EP electrode with cable ²⁾ : • EEP (includes 5 pcs.) - NS990106.028-01.10, white, 1 m - NS990106.028-03.10, red, 1 m - NS990106.028-04.10, black, 1 m - NS990106.028-05.10, yellow, 1 m - NS990106.028-06.10, blue, 1 m - "Electrodes for EMG and EP Studies" technical manual • EEP • C1234	NS990998.048-01	–	–	1 pack	1 pack
	NS990106.072-01.10	–	–	5 pcs.	5 pcs.
	NS990106.049	–	–	5 pcs.	5 pcs.
Y-adapter	NS006103.019	–	–	1	1
Auditory stimulator (headphones): • TDH-39 (with earcups) • TDH-39	NS032305.011 NS032305.009	–	–	1	–
Insert earphones	ER-3C-10 (Etymotic Research Inc., USA)	1	1	1	1
Electrode abrasive paste for skin preparation ¹⁾	Everi, 160 g (Italy)	–	–	1	1
Electrode adhesive paste ¹⁾	TEN20, 114 g (USA)	–	–	1	1
Set of disposable eartips for insert earphones	ER3-14A (Etymotic Research Inc., USA)	1	1	1	1
Set of disposable eartips for insert earphones	ER3-14B (Etymotic Research Inc., USA)	1	1	1	1
Set of disposable eartips for insert earphones	ER3-14D2 (Etymotic Research Inc., USA)	1	1	1	1
Set of disposable eartips for insert earphones	ER3-14C (Etymotic Research Inc., USA)	1	1	1	1
Set of disposable eartips for insert earphones	ER3-14E2 (Etymotic Research Inc., USA)	1	1	1	1

Table 6 (continued)

Name	Order code or main specification	Quantity, pcs.			
		1	2	3	4
Bone conduction amplifier	NS032201.012-02	1	1	1	1
Bone conduction amplifier cable	NS032103.011	1	1	1	1
PSU-9 power supply unit	NS057201.009	1	1	1	1
<i>Equipment for OAE Study:</i>					
OAE probe OAE-02-02	NS006355.003-01	–	1	–	1
OAE probe tip	NS006221.001	–	1	–	1
Probe tip extractor	NS006206.016	–	1	–	1
Test cavity	NS006201.013	–	1	–	1
Set of eartips (universal)	NS007998.002	–	1	–	1
Dental floss for probe tip cleaning Superfloss Regular	Oral-B, Ireland (50 pcs. in a pack)	–	1 pack	–	1 pack
<i>Equipment for Cognitive EP Study Using P300 Technique:</i>					
Patient button	NS028201.009-02	1	1	1	–
KM-7-2 USB hub ²⁾	DS042.02.01.001.000	1	1	1	–
<i>Equipment for PTA Study:</i>					
Patient button	NS028201.009-02	1	1	1	–
KM-7-2 USB hub ²⁾	DS042.02.01.001.000	1	1	1	–
<i>Equipment for ECoG Study:</i>					
Electrode for electrocochleography	TED001 (SPES MEDICA S.R.L., Italy)	10	10	10	10
Insert earphones	ER-3C-10 (Etymotic Research Inc., USA)	1	1	1	1
Adapter for earphones	NS032103.004	1	1	1	1
<i>Accessories for EP Study:</i>					
Cable for disposable electrode connection: <i>Button</i> clip — touch- proof, black (1 m) ³⁾	NS990103.037-04.10 NS990103.026-04.10	1	1	1	1
Cable for disposable electrode connection: <i>Button</i> clip — touch- proof, red (1 m) ³⁾	NS990103.037-03.10 NS990103.026-03.10	1	1	1	1
Cable for disposable electrode connection: <i>Button</i> clip — touch- proof, white (1 m) ³⁾	NS990103.037-01.10 NS990103.026-01.10	1	1	1	1
Cable for disposable electrode connection: <i>Button</i> clip — touch- proof, blue (1 m) ³⁾	NS990103.037-06.10 NS990103.026-06.10	1	1	1	1
<i>Software:</i>					
Neuro-Audio.NET software license with Neuro-Audio.NET/ABR module	NS001.221023	–	–	1	1

Annex 3. Electromagnetic Emission and Immunity

Guidance and manufacturer's declaration – electromagnetic emissions

The digital system is intended for use in the electromagnetic environment specified below. The customer or the user of the digital system should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11:2009	Group 1	The digital system uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11:2009	Class B	The digital system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2:2005	Not applicable	
Voltage fluctuations' flicker emissions IEC 61000-3-3:2013	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The digital system is intended for use in the electromagnetic environment specified below. The customer or the user of the digital system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2:2008	±8 kV – contact	±8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±15 kV – air	±2 kV; ±4 kV; ±8 kV; ±15 kV	
Electrical fast transient/burst IEC 61000-4-4:2012	±2 kV – for power supply lines	±2kV ¹⁾	Mains power quality should be that of typical commercial or hospital environment.
	±1 kV – for input/output lines	Not applicable	
Surge IEC 61000-4-5:2004	±1 kV differential mode	±0.5kV; ±1 kV ²⁾	Mains power quality should be that of typical commercial or hospital environment.
	±2 kV common mode	±0.5kV; ±1 kV; ±2kV ²⁾	
Voltage dips IEC 61000-4-11:2004	0% U _T during 0.5 period at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	10 ms ³⁾	Mains power quality should be that of a typical commercial or hospital environment. If the user of the digital system requires continued operation during power mains interruptions, it is recommended that the digital system be powered from an uninterruptible power supply or a battery.
	0% U _T during 1 period	20 ms ³⁾	
	70% U _T during 25 periods. Monophase: at 0°	500 ms ³⁾	
Voltage interruptions IEC 61000-4-11:2004	0% U _T during 250 period	5000 ms ³⁾	
Power frequency magnetic field IEC 61000-4-8:2009	30 A/m at 50 or 60 Hz	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

¹⁾ Ensured by PC compliance with IEC 61000-4-4 requirements.



²⁾ Ensured by PC compliance with IEC 61000-4-5 requirements.

³⁾ Ensured by PC compliance with IEC 61000-4-11 requirements.

Note: U_T – is the a.c. mains voltage prior to application of the test level

Guidance and manufacturer's declaration – noise immunity

The system is intended for operation in electromagnetic conditions environment described below. The customer or user of the system should provide the system operation in the specified electromagnetic conditions environment.

Immunity test	IEC 60601 test level		Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6:2013	3 V in 0,15 MHz-80 MHz band; 6 V in ISM band between 0,15 MHz and 80 MHz; 80% AM at 1 kHz ¹⁾		3 V ³⁾	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. The recommended separation distance: $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3:2006	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz 3 V/m in 80 MHz-2.7 GHz band, 80% AM at 1 kHz		10 V/m	$d = 1.17\sqrt{P}$ (80 MHz to 800 MHz); $d = 2.33\sqrt{P}$ (800 MHz to 2.7 GHz), Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ¹⁾ , should be less than the compliance level in each frequency range ²⁾ . Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF wireless communication equipment IEC 61000-4-3:2006	Band (MHz)	Immunity level (V/m)		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 system, the cables and the electrodes to avoid excessive noise on the signals.
	380-390	27		
	430-470	28		
	704-787	9		
	80-960	28		
	1700-1990	28		
	2400-2470	28		
	5100-5800	9	9 V/m	

¹⁾ Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.

²⁾ Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

³⁾ Ensured by PC compliance with IEC 61000-4-6 requirements.

Notes:

1. At 80 MHz and 800 MHz, the higher frequency range is applied.

2. These guidelines are not applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**Recommended separation distances between portable and mobile
RF communications equipment and screening system**

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, P, W	Separation distance according to frequency of transmitter, d, m		
	$d = 1.17\sqrt{P}$ in the band from 150 kHz up to 80 MHz	$d = 1.17\sqrt{P}$ in the band from 80 up to 800 MHz	$d = 2.33\sqrt{P}$ in the band from 800 MHz up to 2.5 GHz
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

Notes:

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range is applied.
2. These guidelines are not applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
3. For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Annex 4. Trig In/Out

On the side panel of the digital system there is a trig in/out to attach stimulators of other manufacturers.

The connected devices must have protection class against electrical shock according to IEC 60601-1:2012.

The cables to connect the devices of other manufacturers are not included in the delivery set and must be produced according to the recommendations stated in this annex.

The trig in/out is a double-pin plug of 2.5 mm diameter. It is used as a trig-in to synchronize the program with the external stimulus and as a trig-out to deliver the pulse synchronously with the internal stimulators. The plug soldering and trig pulse parameters are given in Fig. 22.

If the trig in is used, then the negative polarity TTL pulse with not less than 5 μ s duration must be at the input. The pulse droop is considered as the beginning of synchronization. The synchronization signal is also generated when the input is connected to the common wire for not less than 5 μ s.

When the trig out is used, the negative polarity TTL pulse appears at the output of each stimulus and its fall corresponds to the beginning of the stimulus.

The trig out pulse duration is 100 μ s.

To connect the external devices, use the triple-pin plug of 2.5 mm diameter in a plastic case. The plug has both trig in and out. The pinout is shown in Fig. 22: 1 – trig in, 2 – trig out, 3 – common.

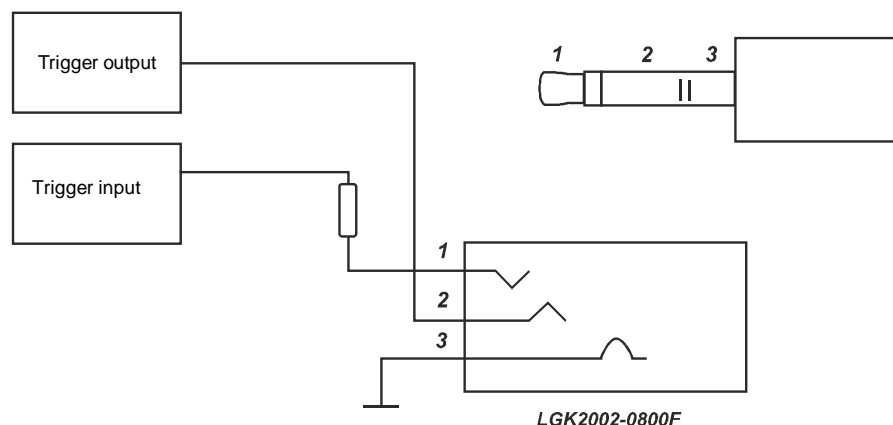


Fig. 22. The pinout

The external stimulators are connected to the trig in as follows:

1. Connect the external stimulator to the trig in with a cable.
2. Switch on the external stimulator power supply.
3. Run the program and check the *Third-party firm stimulator* checkbox on the *Hardware* tab (Fig. 23).

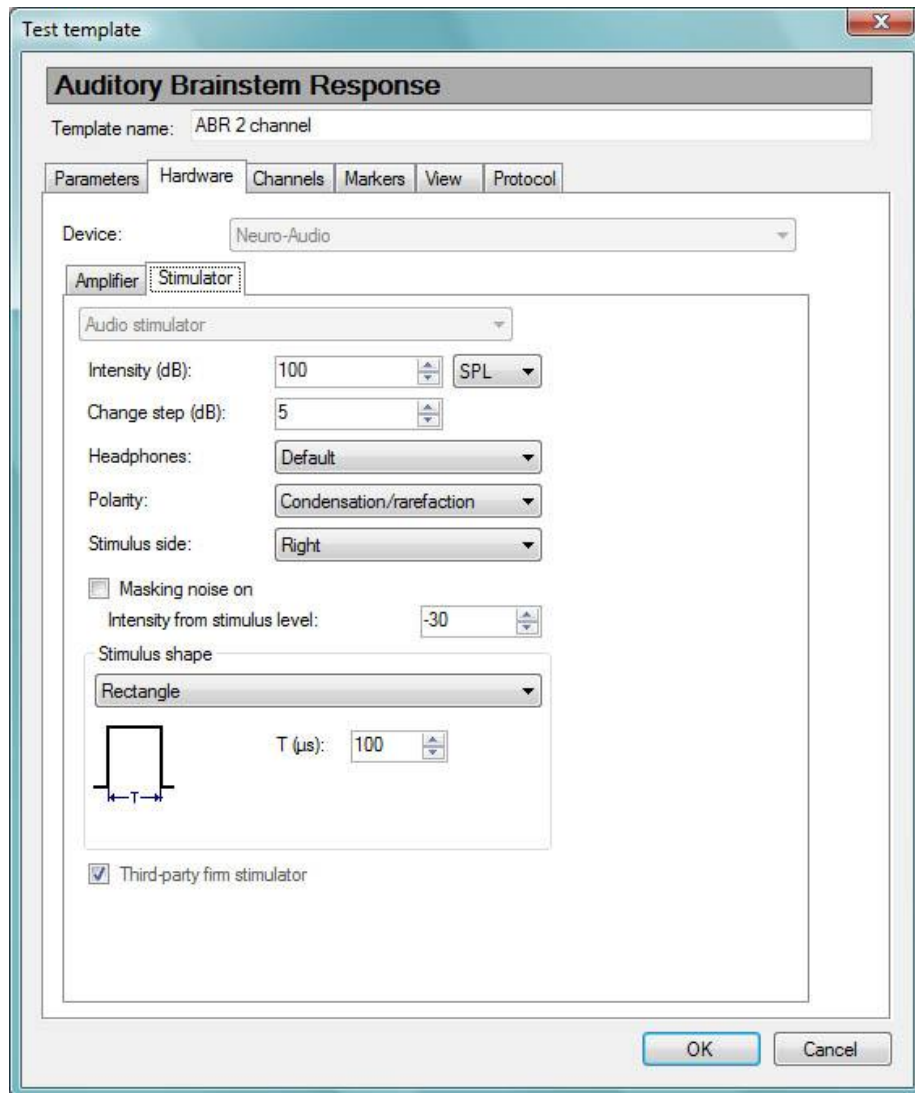


Fig. 23. The acquisition start from the external stimulator.

4. In the stimulation settings it is recommended to set those stimulus parameters which the external stimulator has as these particular values are saved together with the trace and taken into analysis.

In other aspects the signal acquisition does not differ from the one described in the corresponding chapters of the given manual.

The external stimulators connected to the trig out are used as follows:

1. Disconnect all standard stimulators from the device: headphones, OAE probe, bone vibrator.

2. Connect the external stimulator to the trig out with a cable.
3. Switch on the external stimulator power supply.
4. Run the program and uncheck the *Third-party firm stimulator* checkbox in the stimulation parameters settings.
5. In the stimulation settings it is recommended to set those stimulus parameters which the external stimulator has as these particular values are saved together with the trace and taken into analysis.

In other aspects the signal acquisition does not differ from the one described in the corresponding chapters of the given manual.