Technical Manual

Neuro-ERG/V

Veterinary Digital ERG System

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Contents

Introduction

This technical manual (hereinafter referred to as "the manual") is the combined document describing operation and maintenance of the *Neuro-ERG/V* veterinary digital ERG system (hereinafter referred to as "the system").

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

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

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

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

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Important Safety Instructions

Intended Use

The *Neuro-ERG/V* system is intended to perform electroretinography (ERG) tests and studies of flash visual evoked potentials (FVEPs).

The system can be used in veterinary hospitals and experimental laboratories of research institutions to study:

- functional state of animal brain;
- optic tract of animals.

General Description

The system is intended for veterinary use only!

The *Neuro-ERG/V* system is used to:

- evaluate the functions of retina in animals with cataracts and ocular media opacity;
- evaluate retinal function in animals with vision loss/visual impairment;
- evaluate retinal functions with altered, incomplete, missing pupil response to red light during normal response to blue light, and also if it is impossible to evaluate the response to light (atrophy of iris, miosis);
- diagnose specific retinal pathologies (cone degeneration, progressive retinal atrophy, etc.) in animals with typical disease history and ophthalmoscopic findings;
- make a differential diagnosis of neurological causes of vision loss from retinal pathology (the technique of visual evoked potentials is also used);
- detect the initial functional changes in retina that precede the clinical manifestations of the disease;
- control the progress of the pathological process and the effectiveness of treatment, determine the prognosis of the disease.

Features:

- 1-4 channel acquisition of signals in any unshielded room;
- Acquisition of flash visual evoked potentials;

- Electroretinography (ERG);
- Generation of examination report;
- Review, storage and printing of the recorded curves, results of their analysis and examination reports.

Contraindications

The electroretinography (ERG) is not recommended if the examined animal has:

- signs of acute inflammatory and/or allergic disease of cornea, conjunctiva, eyelid, or traumatic injury of eyeball;
- contraindications for sedation.

Possible Side Effects

Usually, the side effects are not observed. However, the following can occur very rarely:

- allergic reactions to the components of agents used for exam preparation or to the components of used electrodes;
- transient visual impairment during high-intensity long-term visual stimulation;
- small hemorrhages in the places where needle electrodes are applied.

1. Description

1.1. Main Specifications

Table 1. Main Specifications

Parameters	Values
Amplifier Channels	
Number of channels	4
Sampling rate	200 Hz – 40 (160) kHz
Voltage range	20 μV –50 mV
Ratio error of voltage measurement: • in the band from 20 up to 100 μV • in the band from 0.1 up to 50 mV	 ±15% ±5%
EP voltage range at averaging	0.1–400 μV
Ratio error of EP voltage measurement at averaging	±10%
Common-mode rejection	not less than 100 dB
Input noise level, rms	not more than 0.5 μV
Input impedance	not less than 200/1000 MΩ
Input capacitance of amplifiers	not more than 25/22 pF
Patient leakage current	not more than 0.1 μA
Bandpass flatness in the band: – from 0.02 up to 0.05 Hz and from 5 up to 10 kHz – from 0.05 Hz up to 5 kHz	 from –30 up to +5% from –10 up to +5%
High pass filter	0.02, 0.05, 0.1, 0.2, 0.3, 0.5, 1, 2, 3, 5, 10, 20, 30, 50, 100, 200, 300, 500, 1000, 2000, 3000 Hz
Low pass filter	10, 20, 35, 50, 75, 100, 150, 200, 300, 500 Hz; 1, 2, 3, 5, 10 kHz
Sensitivity	0.05, 0.075, 0.1, 0.15, 0.2, 0.25, 0.4, 0.5, 0.75, 1, 1.5, 2, 2.5, 4, 5, 7.5, 10, 15, 20, 25, 40, 50, 75, 100, 150, 200, 250, 400, 500, 750 μV/div.; 1, 1.5, 2, 2.5, 4, 5, 7.5, 10, 15, 20, 25, 40, 50 mV/div.
Relative error of sensitivity	±5%
Sweep speed	0.1, 0.15, 0.2, 0.25, 0.4, 0.5, 0.75, 1, 1.5, 2, 2.5, 4, 5, 7.5, 10, 15, 20, 25, 40, 50, 75, 100, 150, 200, 250, 400 ms/div; 0.5, 0.75, 1, 1.5, 2 s/div.
Relative error of sweep speed	±1%
Suppression ratio of power frequency by notch filter	not less than 40 dB

Table 1. Continued

Parameters	Values
Visual Stimulator	
Maximum brightness of: • LED goggles • mini-ganzfeld stimulator	 (1100 ± 110) cd/m^2 (1500 ± 150) cd/m^2
Maximum brightness power of: • white penlight • red penlight • blue penlight • green penlight	 (0.2 ± 0.05) cd (0.3 ± 0.075) cd (0.15 ± 0.0375) cd (0.2 ± 0.05) cd
Brightness control range	-3…0 log units
Stimulus duration	0.05–1500 ms
Relative deviation of stimulus duration	within ±10%
Stimulus frequency	0.01–100 Hz
Relative deviation of stimulus frequency	±1%
Left / right / two-sided stimulation when using LED goggles	available
General Parameters and Characteristics	
Interface	USB
Supply voltage: • electronic unit • desktop PC-based system • notebook PC-based system	 5 V DC 220/230 V AC (50 Hz) 110 V AC (60 Hz) 220/230 V AC (50 Hz) 110 V AC (60 Hz)/int. battery
Dimensions: • amplifier unit • auditory-visual stimulator unit	 190×140×50 mm 155×105×40 mm
Weight: • amplifier unit • auditory-visual stimulator unit	 not more than 1 kg not more than 0.5 kg
Safety	BF type
Transportation Conditions	
Temperature	-25 up to +60°C
Humidity	from 20 to 95% non-condensing
Atmospheric pressure	from 70 kPa
Storage Conditions	
Temperature	+5 up to +40°C
Humidity	from 30 to 85% non-condensing
Atmospheric pressure	70-106 kPa

Table 1. Continued

Parameters	Values
Operation Conditions	
Temperature	+10 up to +35°C
Humidity	from 30 to 85% non-condensing
Atmospheric pressure	70-106 kPa

Safety and Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is provided by conformance to IEC 60601-1-2-2014 (EN 60601-1-2:2015) requirements.

The system is intended for operation in electromagnetic environment, which special features are specified in Annex 2.

Portable and mobile RF communication equipment can affect the system operation.

The use of equipment not listed in Table 5 of this technical manual may result in increased emission and system decreased immunity.

As for safety, the system satisfies IEC 60601-1:2012 (AAMI/ANSI ES 60601-1:2005/(R2012) and A1:2012 and A2:2010/(R)2012, EN 60601-1:2006/A1:2013) and IEC 60601-2-40:2016 (EN 60601-2-40:2017). The electronic unit is supplied by regulated power supply through USB interface, it has double isolation and BF type applied parts according to IEC 60601-1:2012 (AAMI/ANSI ES 60601-1:2005/(R2012) and A1:2012 and A2:2010/(R)2012, EN 60601-1:2006/A1:2013).

1.2. Principle of Operation

The operation of the system is based on the recording and input of biopotentials to computer to perform the analysis of their electrical activity, including the response to stimulus.

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

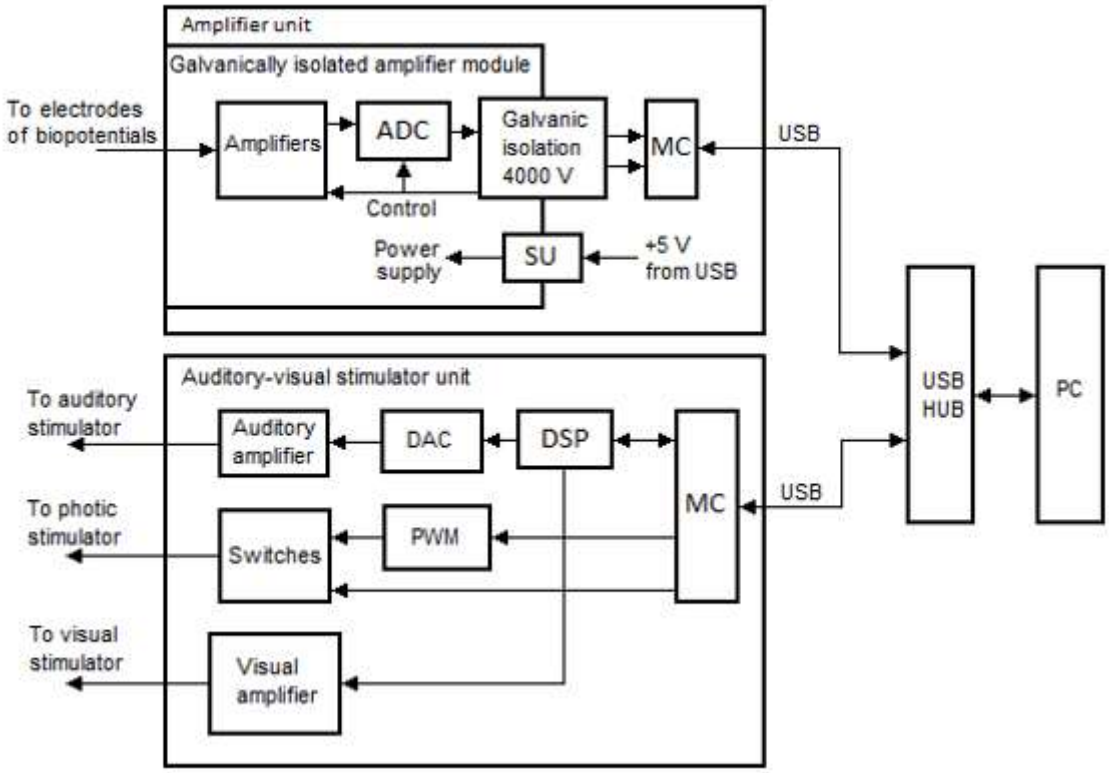

Fig. 1. Block diagram of system.

The function of amplification and recording of biopotentials is performed by the amplifier unit.

The biopotentials from the electrodes are delivered to the amplifiers of the amplifier unit where they are amplified, then quantized with the use of the analog-digital converter (ADC) and are transferred to the microcontroller (MC) via 4000 V galvanic isolation. The microcontroller provides the connection with the computer via USB and the transfer of the digitized data to the computer (PC). Besides, it controls the amplifiers and ADC operation via 4000 V galvanic isolation.

The power supply of the galvanically isolated part of the amplifier unit, i.e. the amplifier module is done via the galvanically isolated direct-voltage transducer of the supply unit (SU).

The microcontroller of the unit provides the connection between the digital signal processor (DSP) of the module and the computer via USB. Also, the MC generates the amplitude with the use of the pulse-wide modulator (PWM) and the pulse duration on the photic stimulator with the use of the switches. DSP generates the signal of the

sound stimulator in a discrete form, which is transformed by the digital-analog converter to the analog form, amplified by the sound amplifier and is supplied to the auditory stimulator. DSP also generates the visual signal which is transferred to the visual stimulator via the visual amplifier.

The photic stimulator is LED goggles with a set of super-power LEDs for the separate stimulation of the left and right eye.

All the units are attached to the computer via USB-hub.

The system operates under control of PC (IBM PC type) with the mouse, keyboard, laser or jet printer and installed licensed Windows 8/10 operational system.

Signal processing, displaying and presentation in different modes after mathematical analysis, then storing of the initial data on the hard disk, exam report generation and printing is done using PC.

1.3. Connectors and Indicators

The front and side panels of the amplifier unit are shown in Fig. 2 and Fig. 3.

On the front panel of the amplifier unit there are the touch-proof and DIN-connectors to attach the electrodes and operation indicator (Fig. 2). The channel numbers are marked with Arabic figures “1”, “2”, “3” and “4”. The operation indicator glows yellow if the unit is connected to the computer and it glows green at the signal recording during the program operation.

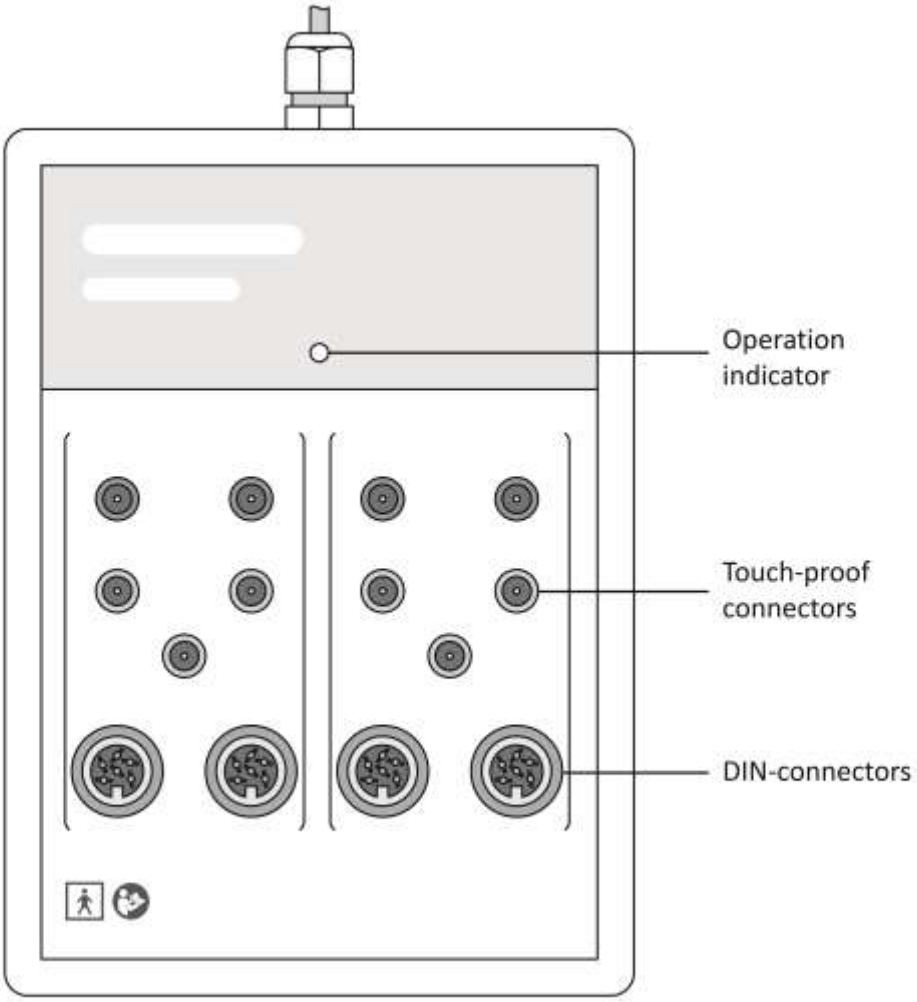

Fig. 2. Front panel of amplifier unit.

On the top side panel of the amplifier unit there are USB cable for connection to PC and the trigger input socket to connect the stimulators of third-party manufacturers (Fig. 3).

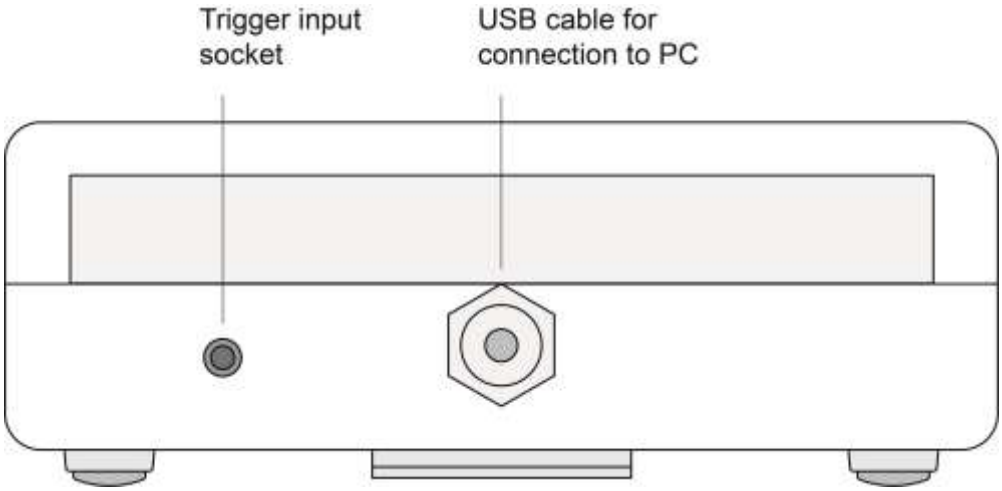

Fig. 3. Side panel of amplifier unit.

The front and rear panels of auditory-visual stimulator unit are shown in Fig. 4 and Fig. 5.

On the front panel of the auditory-visual stimulator unit there are the connectors for visual stimulator (LED goggles or mini-ganzfeld), multi-colored penlights and LED operation indicator (Fig. 4). The operation indicator glows yellow when the electronic unit is connected to PC and it glows green when the signal is recorded during the performance of visual or auditory stimulation.

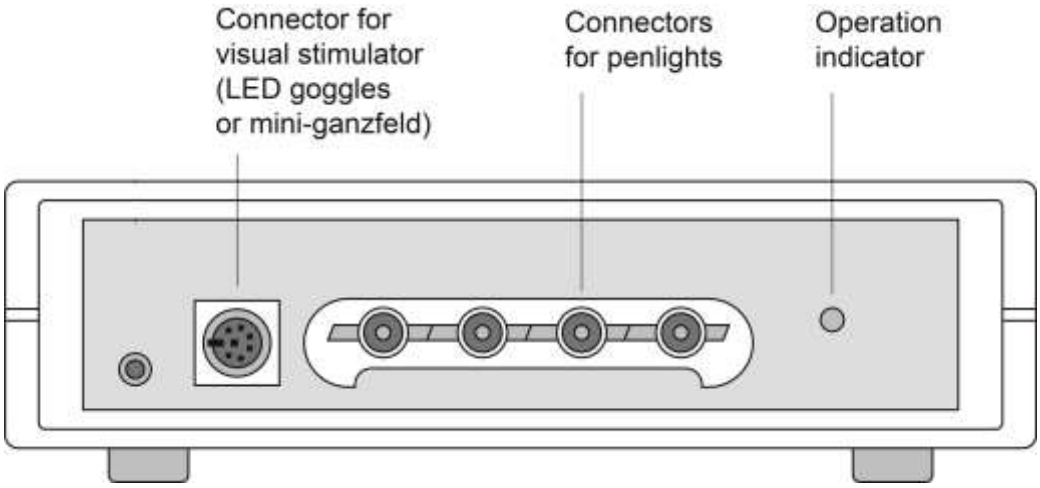

Fig. 4. Front panel of auditory-visual stimulator unit.

On the rear panel of the auditory-visual stimulator unit there are the connector for USB cable (for connection to PC), connector for reversal pattern monitor (not for veterinary use) and trigger output socket (Fig. 5).

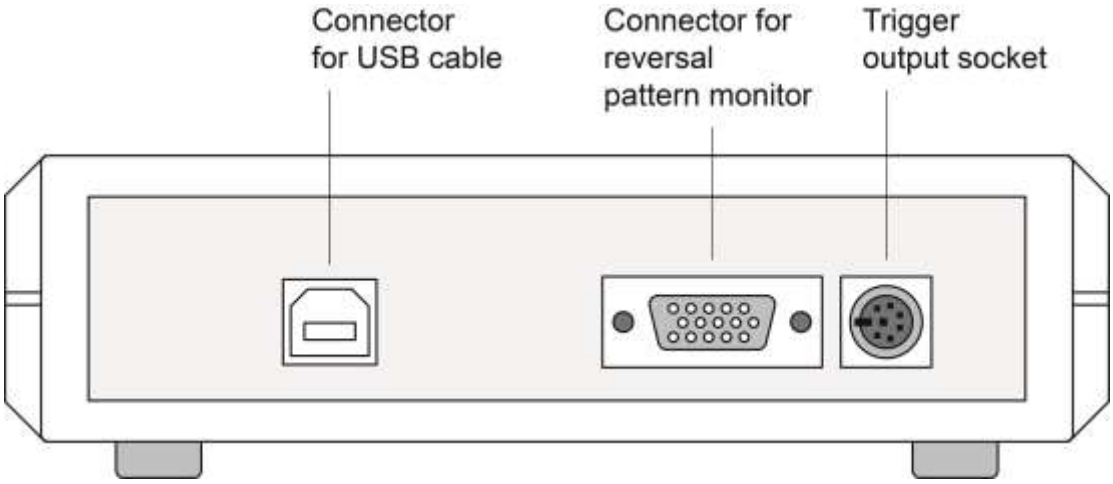

Fig. 5. The rear panel of the auditory-visual stimulator unit.

The USB hub KM-7-2 can also be included in the delivery set of the system. The information about the functions of the connectors and indicators of USB hub and also its operation is described in the corresponding technical manual.

1.4. Synchronization with Stimulators of Third-party Manufacturers

The trigger input socket is used for synchronization of the amplifier with other devices. It is located on the top side panel of the amplifier. The numbering of the socket pins is shown in Fig. 6 and the functions of these pins are described in Table 2.

The devices attached to the trigger socket must have the protection class against the electrical shock according to IEC 60601-1:2012 (AAMI/ANSI ES 60601-1:2005/(R2012) and A1:2012 and A2:2010/(R)2012, EN 60601-1:2006/A1:2013).

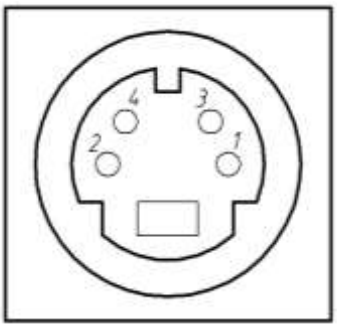

Fig. 6. Numbering of socket pins (view from the case outside).

Table 2. Functions of socket pins.

Pin number	Name	Function
3	+SYNC	Trigger signal input
4	0V	Common

For the synchronization, apply positive TTL pulse on the + SYNC output in relation to 0 V (Fig. 7). The synchronization will occur by the pulse front with ±25 μs accuracy.

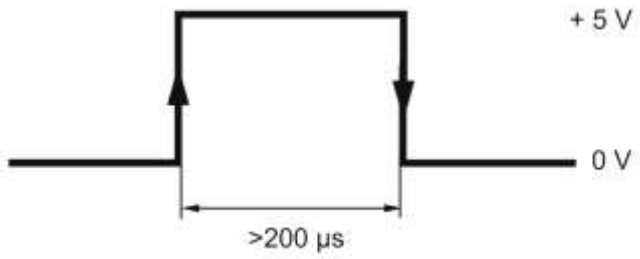

Fig. 7. Signal shape at +SYNC output in relation to 0 V.

To synchronize the auditory-visual stimulator with other devices, use the trigger output socket located on the side panel of the unit. The numbering of the socket pins is the same as on the amplifier.

When the trigger output is used with each stimulus generated by stimulators, negative polarity pulse appears at the connector which fall corresponds to the beginning of the stimulus.

The pulse duration at the trigger output is 2…5 μs.

1.5. Synchronization with *Neuro-MEP.NET* Software

The external stimulators connected to the trigger input must be used as follows:

1. Connect the external stimulator to the trigger input using a cable.

2. Switch on the external stimulator power supply.

3. Run the *Neuro-MEP.NET* software, execute the *Setup*|*Tests templates*|*Setup* menu command, select the required test template, press the *Change* button and select the *Third-party firm stimulator* check box on the *Hardware*|*Stimulator* page (Fig. 8). This step should be executed once for each template where the external stimulator is planned to be used. If you do not want to change the template, create the test and select the similar settings in it.

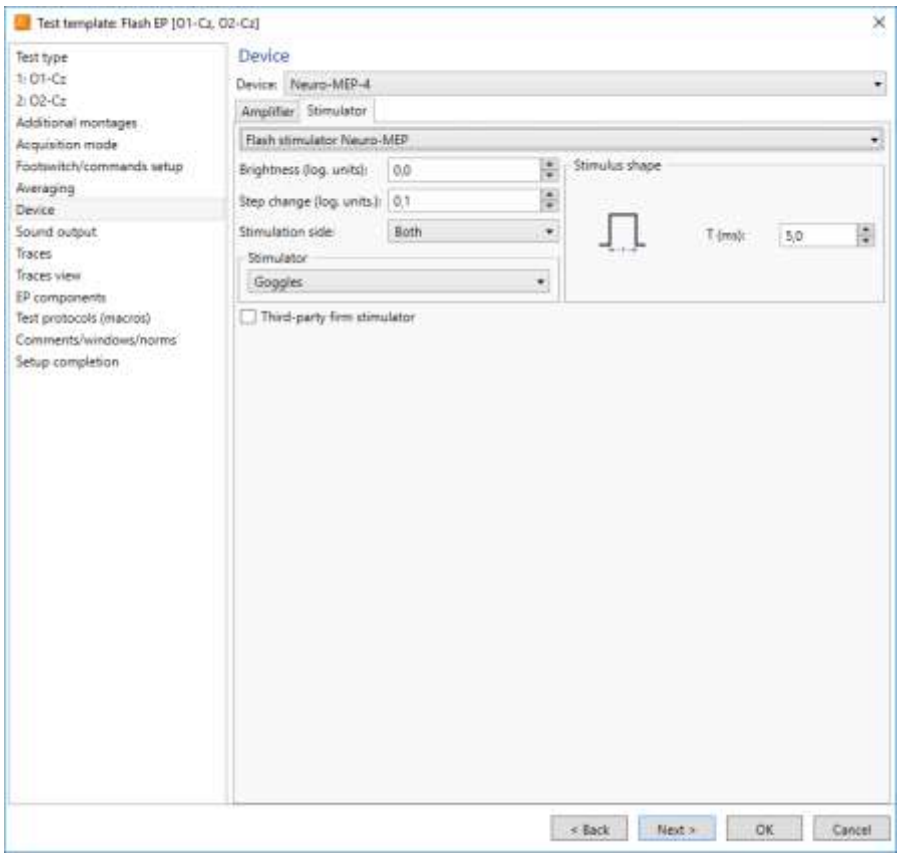

Fig. 8. The acquisition start window from external stimulator.

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.

5. Run the *Acquisition|Acquisition/stimulus* menu command. The device goes to the external stimulus standby mode. If this menu command is not executed, any stimuli from the external stimulator are ignored.

6. Start stimulation from the external stimulator.

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

The external stimulators connected to the trigger output must be used as follows:

1. Connect the external stimulator to the trigger output using a cable.

2. Switch on the external stimulator power supply.

3. Run *Neuro-MEP.NET* software.

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.

The *Third-party firm stimulator* check box (Fig. 8) is NOT checked!

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

1.6. Labeling

The example of labeling of electronic units is shown in Fig. 9.

Fig. 9. Labeling.

Interpretation of symbols on electronic units:

– mark of conformance to 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility.

– applied parts of BF type according to IEC 60601-1:2012 (AAMI/ANSI ES 60601-1:2005/(R2012) and A1:2012 and A2:2010/(R)2012, EN 60601-1:2006/A1:2013). ***This symbol is on the front panel of the amplifier and audio-video stimulator units.***

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

– attention: consult operational documentation. ***This symbol is on the front panel of the amplifier and audio-video stimulator units.***

REF – number according to catalogue by ISO 15223-1.

SN – serial number by ISO 15223-1.

– manufacturing date by ISO 15223-1.

– manufacturer’s name and address by ISO 15223-1.

IP20 – ingress protection according to IEC (EN) 60529.

The equipment is identified with the GS1-128 barcode integrated to the barcode in DataMatrix format (Fig. 10).

Fig. 10. 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. Assembly and Installation

2.1. Requirements to Personnel

The assembly and installation of the system should be carried out by a person who is empowered by the manufacturer or technical personnel of the medical institution which is going to use it. Remember, that the accuracy of system mounting defines the safety and quality of its operation. Further mounting and setting requirements which define the product safety will be marked by **bold font** in the text.

2.2. Room Selection and Placement

Before installation of the system, select the place for it taking into consideration the power wiring and protective ground in the room. Please, read the following requirements and recommendations:

Requirements concerning the room selection and equipment placement:

- The recommended distance from the electronic unit to the nearest electric mains is not less than 3 meters.

- The location of electronic unit in the immediate vicinity (less than 5 meters) with short-wave or microwave therapeutic equipment is not permitted (it can lead to its unstable operation).

- It is recommended to 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.

- ***The animal environment (within 1.5 meters) should contain only the electronic units being the medical device with the required safety level. As the computer equipment safety level is not sufficient for use in the animal environment, it is necessary to exclude the possibility of animal touching the metal parts of the computer equipment cases and the simultaneous contact of these parts and animal's body by the personnel. The computer equipment used in the system should correspond to IEC 60601-1:2012 (AAMI/ANSI ES 60601-1:2005/(R2012) and A1:2012 and A2:2010/(R)2012, EN 60601-1:2006/A1:2013 or be connected via the isolation transformer (specialized power supply unit – for notebook PC) corresponding to abovementioned requirements.***

Requirements to mains:

- ***Do not use electric mains where the neutral conductor and protective ground are combined. It is strongly prohibited.***

- ***The use of multi-socket electric mains extender without additional protective actions is prohibited. The fact is that the probable break of the circuit of the***

protective ground of the multi-socket electric mains extender can lead to summation of leakage current in all connected units on their metal parts to dangerous values.

- ***Before the system setting, the electrician must check the quality of standard tripolar sockets and the integrity of the protective ground circuit.***
- ***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 several tens of amperes compensating current leakage through the system connecting cables that leads to the equipment break-down.***

Requirements for PC connection to local area network (LAN):

To avoid the electrical shock, connect PC to local area network (LAN) according to 10/100/1000-BaseT-Ethernet standard only if LAN complies with safety requirements to ME equipment IEC 60601-1:2012 (AAMI/ANSI ES 60601-1:2005/(R2012) and A1:2012 and A2:2010/(R)2012, EN 60601-1:2006/A1:2013) or using the isolation transformer that conforms to the abovementioned requirements.

The variants of equipment placement when connected to the desktop or notebook PC are shown below (see Fig. 11, Fig. 12).

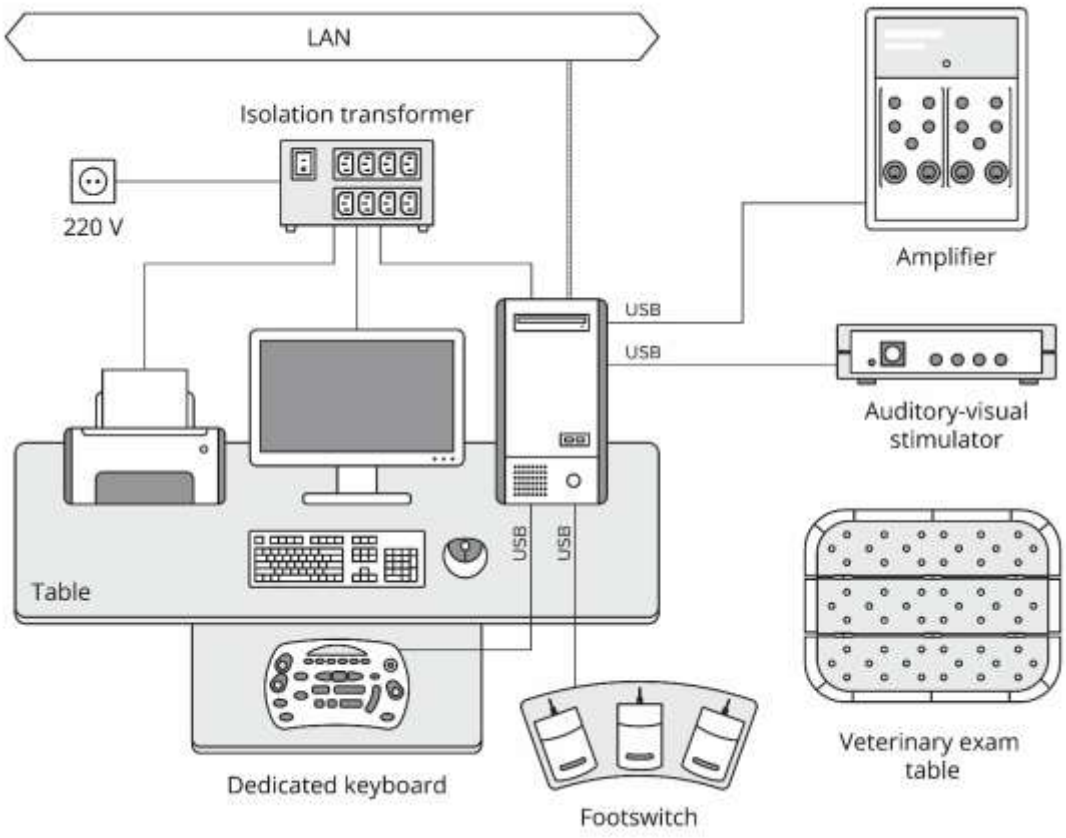

Fig. 11. Placement of equipment connected to desktop PC.

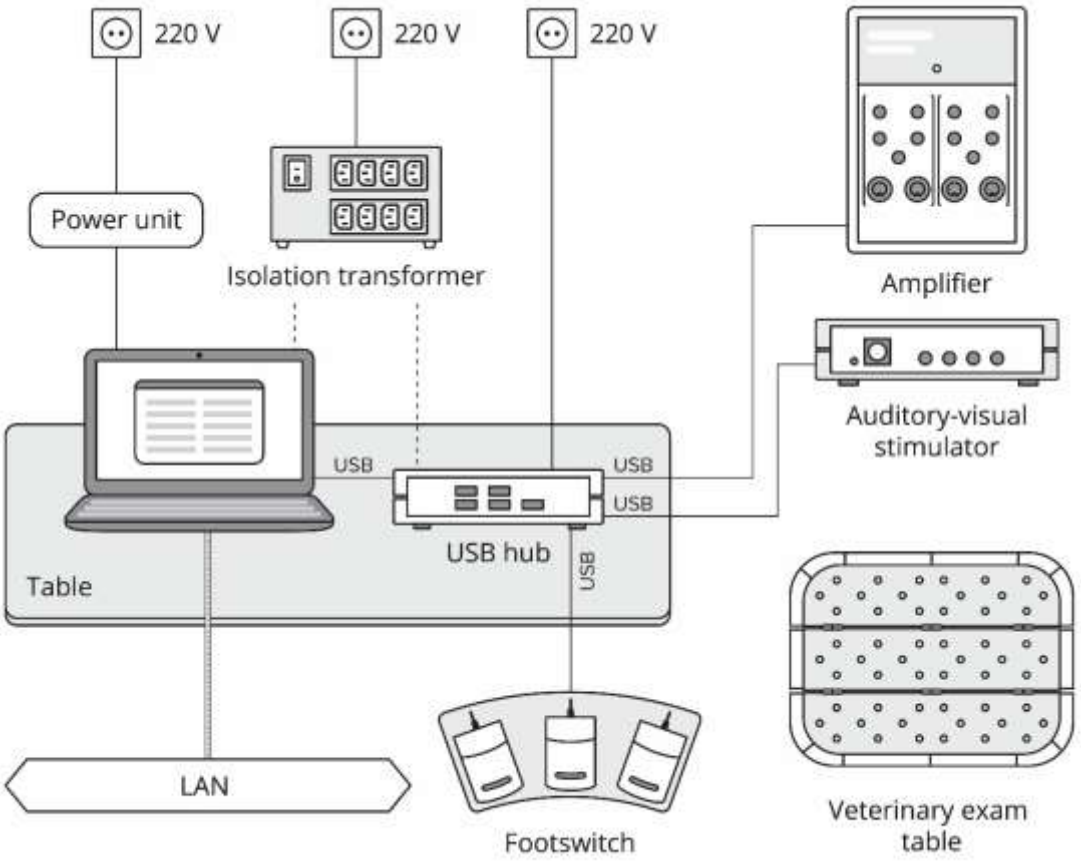

Fig. 12. Placement of equipment connected to notebook PC.

As a power unit, the notebook PC power unit corresponding to IEC 60601-1:2012 (AAMI/ANSI ES 60601-1:2005/(R2012) and A1:2012 and A2:2010/(R)2012, EN 60601-1:2006/A1:2013) is used. As for isolation transformer, the isolation transformer TM-630M or its analogue corresponding to IEC 60601-1:2012 (AAMI/ANSI ES 60601-1:2005/(R2012) and A1:2012 and A2:2010/(R)2012, EN 60601-1:2006/A1:2013) can be used.

It is allowed to connect the system components to PC using the external USB hub КМ-7 or its analogue that correspond to IEC 60601-1:2012 (AAMI/ANSI ES 60601-1:2005/(R2012) and A1:2012 and A2:2010/(R)2012, EN 60601-1:2006/A1:2013). The USB hub is connected to the network in accordance with Fig. 12.

2.3. Unpacking and Check of Delivery Set

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

Unpack the box and take the system components out. The delivery set should correspond to the packing report.

The computer equipment packed in the separate boxes should be opened according to user and technical manuals for these products. Check the system components and make sure that there is no external damage.

2.4. System Assembly and Connection

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

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

If the distributive is missing or the software update is required, address to your local dealer. The authorized Neurosoft dealers are listed on the website: https://neurosoft.com/en/pages/dealers.

The system consists of several units. Each of them is attached to USB connector of PC. The amplifier, auditory-visual stimulator, footswitch and a dedicated keyboard are shown in Fig. 14.

The devices can be connected either directly to the PC or via external USB hub KM-7-2 or its analogue. It is strongly prohibited to use passive USB hubs (not connected to the mains) as a part of the system. Remember that the amplifier and stimulator must be attached to one and the same USB controller, i.e. to one and the same USB-hub or to the alongside USB connectors or to several USB-hubs attached to the same USB controller. The footswitch and dedicated keyboard can be attached to any USB connectors or USB-hub. The connection to USB connectors on the PC monitor or keyboard does not ensure the correct device operation.

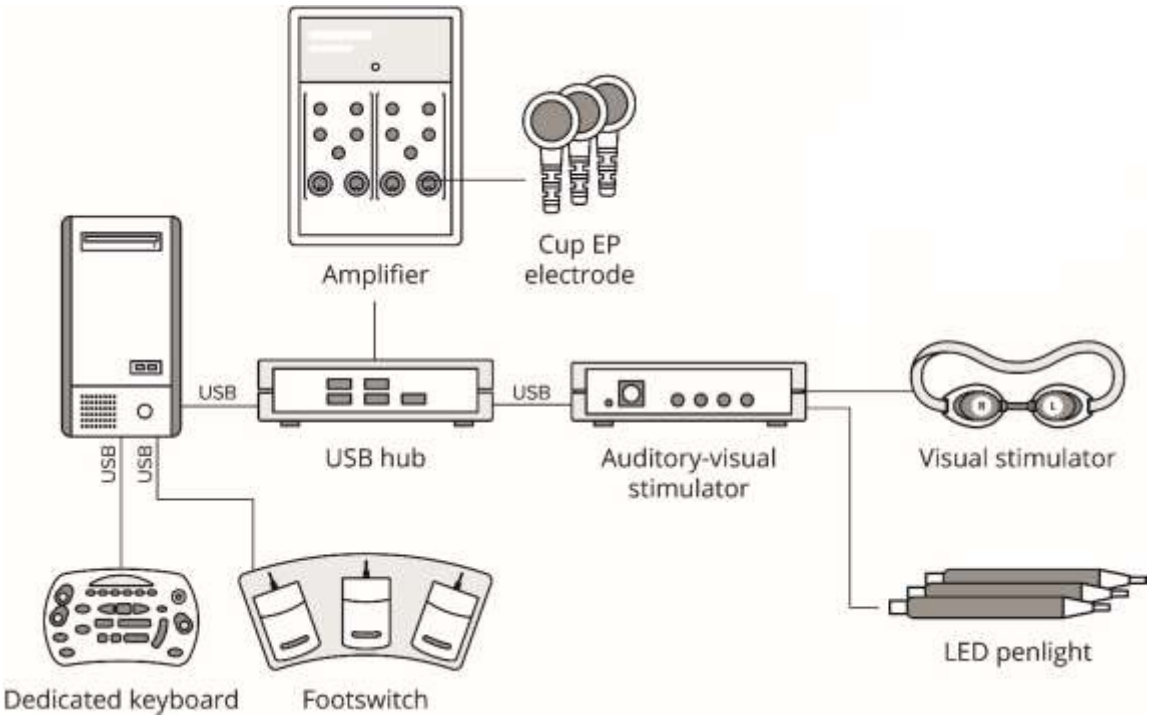

Fig. 13. Connection of system to computer.

If the mini-ganzfeld stimulator is included in the delivery set, it is connected to the auditory-visual stimulator via the connector used for the visual stimulator (LED goggles) (Fig. 14). The bracket assembly for mounting the mini-ganzfeld stimulator and LED penlights is shown in Fig. 14.

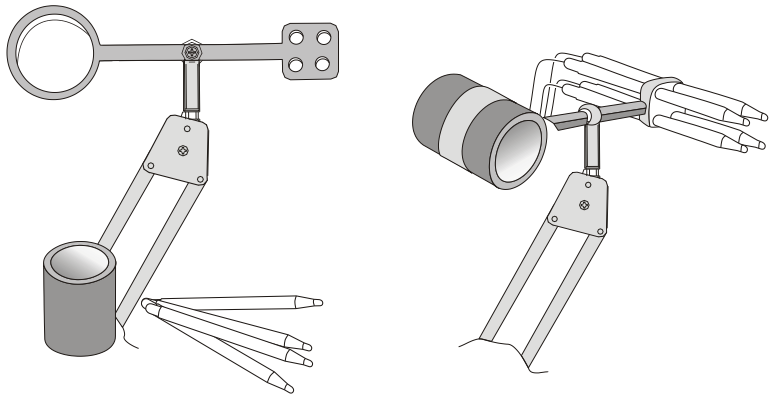

Fig. 14. Mini-ganzfeld stimulator and LED penlights.

Place the holder as near as possible to the place of exam carrying out and fix the amplifier unit on it. Connect all the necessary equipment. The electrical units can be connected to PC when the power supply is on or off.

Install the required software using the data storage device with the software distributive. Perform the same steps for all software modules included in the delivery set.

The mains plug must only be inserted in an appropriate mains socket outlet provided with a protective earth contact as it may impact the quality of recorded signals, especially low amplitude ones (evoked potentials).

3. Proper use

3.1. Safety Measures

To provide safety measures and exclude the possibility of electric trauma of medical staff or examined animal, it is PROHIBITED:

- to use the system which mounting and setting was done incorrectly without following the manual instructions;
- to connect the system and surgical HF equipment to the examined animal (it can lead to the damage of the system or cause flash-burns in the places of electrode placement);
- to connect any devices, not included in the system delivery set, to the electrode jacks;
- to eliminate faults by opening of the system components included in the delivery set;
- to perform tests when the electronic unit, computer or other devices of the system are opened;
- to connect electrodes placed on the examined animal to ***protective ground*** or other conducting surfaces.

3.2. Getting Ready

Operating Limitations:

- Ambient temperature is from +10 to +35°C.
- Relative humidity is from 30 to 85% (non-condensing).
- Atmospheric pressure is from 70 to 106 kPa.

Before the power supply is switched on, make sure that the electronic unit and computer equipment cases have no apparent mechanical failures which can represent danger.

Power Supply Switch on and System Test

The power supply of the system is switched on by pressing the *Power* button on the PC. The electronic unit has no power supply and it is connected to the PC all the time. The power supply is switched on when the operating system is loaded and the *Neuro-MEP.NET* program is started.

3.3. Troubleshooting

If you have any problems with the system, first of all, check the connection of all units to the PC. If the units are connected through the USB-hub, check the connection of the USB-hub to the PC and mains supply. It is prohibited to use passive USB-hubs (i.e., the USB-hubs that not connected to mains supply).

The list of some possible troubles and the ways of their removal is given in Table 3.

Table 3. Troubleshooting

Trouble	Cause	Way of Removal
The program message: “Neurosoft systems supported by the software can’t be found”.	The amplifier is not connected to the computer.	Check whether the amplifier is connected. If there are no connection errors, disconnect the amplifier from the computer and connect it again in several seconds. If it doesn’t work, reload the computer.
The program message: “Connection error: Neuro-MEP is not connected or faulty”.	The amplifier is not connected to the computer.	Check whether the amplifier is connected. If there are no connection errors, disconnect the amplifier from the computer and connect it again in several seconds. If it doesn’t work, restart the computer.
The program message: “Connection error: Neuro-MEP is already used by another program”.	The other program using the system is opened (for example, the second copy of Neuro-MEP.NET program).	Close the running program that is using the system. If you can’t find such a program, restart the computer.
The program message: “Neuro-ERG amplifier disconnection error”. Close the program, disconnect the amplifier from the computer and connect it again in several seconds”.	Amplifier disconnection error.	Close the running program, disconnect the amplifier from the computer (or USB-hub) and connect it again in several seconds. If it doesn’t work, restart the computer.
The program message: “The stimulators are not found. The signal registration is impossible”.	There are no stimulators connected to the computer.	Connect the stimulators to the computer. If the stimulators are connected, disconnect and connect them again in several seconds. If it doesn’t work, restart the computer.
The program message: “The connection error: Neuro-ERG auditory-visual stimulator is not connected or faulty”.	The auditory-visual stimulator is not connected to the computer.	Check whether the stimulator is connected. If there are no connection errors, disconnect the amplifier from the computer and connect it again in several seconds. If it doesn’t work, restart the computer.

Table 3. Continued

Trouble	Cause	Way of Removal
The program message: “Neuro-ERG auditory-visual stimulator is already used by the other program”.	The other program using the stimulator is opened (for example, the second copy of Neuro-MEP.NET program).	Close the running program that is using the stimulator. If you can’t find such a program, restart the computer.
The program message: “Neuro-ERG auditory-visual stimulator disconnection error”. Close the program, disconnect the stimulator from the computer and connect it again in several seconds”.	Stimulator disconnection error.	Close the running program, disconnect the stimulator from the computer (or USB-hub) and connect it again in several seconds. If it doesn’t work, restart the computer.
The program message: “Stimulator error”.	Device or computer error.	Execute the *Setup*|*Hardware reset* menu command. If it does not work, close the running program, disconnect the stimulator from the computer and connect it again in several seconds. If it doesn’t work, restart the computer.
The program message: “The synchronization of the amplifier and stimulator is impossible as the devices are connected to the different USB-controllers”.	The amplifier and stimulator are connected to the USB-connectors of the PC referring to different USB-controllers. Usually, such jacks are located far from each other on the computer case.	Connect the amplifier and stimulator to one USB-hub or USB jacks located next to each other.
The program message: “Data processing error because of the system congestion. Repeat the start”.	The processor was heavily loaded and did not have time to receive the next block of data from the system. If this message appears occasionally, it is not considered a trouble.	Close all the applications except *Neuro-MEP.NET* programs (if they are started) and start the acquisition again. If it fails, restart the computer. If the problem does not disappear, then, probably, the processing speed of your computer is not enough. The minimum requirements are described in the user manual for the software.
The program message: “Time-out error. The data from the device do not arrive”.	Equipment error.	Start the signal acquisition again. If it fails, restart the computer.
The program message: “USB transfer error. Check the hardware connection and try again”.	The system was disconnected during the acquisition or failed during the exchange via USB.	Check the connection of the system and start the acquisition again. If it fails, restart the computer.

Table 3. Continued

Trouble Symptom	Cause	Way of Removal
High electromagnetic interference in the recorded signal (frequency – 50 Hz or divisible to it – 100 Hz, 150 Hz, etc.).	The electrodes not used at the moment are connected to the amplifier (i.e. the electrodes are not applied on the examined animal but “hang in the air” and cause interference).	Disconnect the electrodes not used at the moment from the amplifier.
	Improper placement of electrodes.	Start the impedance measurement and obtain the accepted value. In case of electrode failure, replace them (for example, in the event of a break).
	Bad grounding of the system.	Ground the system properly.
	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 on the bigger distance. If it is impossible, try to obtain better parameters of the system grounding.
There is no stimulus during the acquisition with stimulation.	The stimulation device is not connected (or connected unsafe) to the stimulator unit.	Make sure that the stimulation device is connected to the stimulator unit safely.
	The connection between stimulator and computer is broken.	Execute the *Setup*|*Hardware reset* menu command and try the start again. If it fails, restart the computer.

3.4. Getting Started

Before you perform the exams using this system, set up the system and other equipment according to the user manual, depending on the type of examination.

The examination includes the following stages:

- placement of electrodes and sensors;
- signal recording;
- analysis and printing of the obtained results.

Before you place the electrodes on the examined animal, degrease its skin by alcohol in the places where the electrodes are applied. Use the adhesive paste for EP electrodes. Before you apply the needle electrodes, the reusable ones should be sterilized by autoclaving.

The electrodes can be applied and connected when the system is switched on. The working with electrodes is described in details in the manuals provided with them and in the user manual for the delivered software.

When the electrodes are applied, check the impedance to control the quality of their placement. First of all, the impedance measurement mode should be switched on (see the user manual).

The signal acquisition and analysis of the obtained results are described in details in the user manual.

When the examination is finished, remove the electrodes from the animal and disinfect them (see section 4.3 of this manual).

If the next exam is not planned till the end of the working day, the system should be switched off. For that exit the system software and then switch off the computer and printer. If the long-term dwell in operation is planned (several days or more), power supply plug of the isolation transformer is recommended to be disconnected to the power circuit.

3.5. Actions in Emergency

In case of electrical insulation disturbance of any system component which causes the emergency (fire, mechanical failure, flood, medical staff evacuation) and occurrence of threat of electrical shock for the examined animal or staff, de-energize the system completely.

4. Maintenance

4.1. General Requirements

The safety measures when servicing conforms to the ones described in chapter 3 “Proper Use”.

The qualification requirements to the staff are listed in section 2.1 “Requirements to Personnel”.

The maintenance of the bought articles included in the system is conducted according to user and technical manuals or typical rules.

When detecting the troubles, use the information given in section 3.3 “Troubleshooting”. If the troubles can’t be eliminated using the control tools of the system or by restart, it should be switched off and checked by the specialist.

The type, amount and intervals of maintenance, except the ones specified in this section, are not specifically established.

The check of delivery set is done by conformity to the packing report for the system.

4.2. User Maintenance

The system maintenance in the process of operation includes the external examination, check of connectors and cables, removal of contaminations from the surface of the cases using wet fabric, and also disinfection according to section 4.3.

4.3. Disinfection

Before cleaning the electronic unit, switch it off. As you clean, visually inspect the unit and its components for damage or wear. Contact *Neurosoft* if you notice damage to the exterior of the component.

For routine cleaning of the electronic unit, use a cloth gently wrung in phenoles (Bacillotex® etc.) or 70% alcohol, 0,5% chlorohexidine.

If dangerous virus contamination is suspected, use aldehydes (Cidex® etc.) or chlorinates (Diversol BX®).

Be careful not to drip disinfectant directly into the input and output plugs and other openings in the cover. Remove disinfectant with a dry cloth. Do not use abrasive or solvent silicon-based cleaning agent, scrubbing pads or other abrasive applicators.

Keep all cleaning fluids away from electrical connectors.

Visually inspect the interface cables and power cords that are used with components and accessories. If you notice unusual wear or breakage, disconnect the cable or cord immediately, and contact *Neurosoft* for replacement. Gently wipe them with a soft cloth moistened with disinfectant (for example, 1% chloramine solution or 3% hydro-

gen peroxide solution). The use of organic solvents and aromatic oils must be avoided. Never submerge the device or the cables in disinfectant or other liquids.

After testing the electrodes should be removed from the examined animal immediately. The disposable electrodes should be discarded after their use. The reusable electrodes should be disinfected in accordance with the accepted standards of veterinary practice.

5. Current Repair

5.1. General Requirements

The repair of the system requires special training of technical staff, special equipment and service software. The manufacturer and its representatives have everything necessary for this. The repair connected with the opening of electronic units is prohibited. The repair of computer equipment can be performed by companies specialized in computer equipment servicing.

The current repair of the system includes the repair of some component parts and cables. If the component parts are connected to the system, the repair is prohibited.

When performing the repair, all units must be switched off.

5.2. Cables and Adapters

The cables are examined externally, and the circuit is checked for short circuit or break. In case the cable is broken or short-circuited, replace it or cut it if the cable length is sufficient.

5.3. Computer Interface Cable (USB Cable)

The computer interface cable (Fig. 15) is examined externally, and the circuit is checked for short circuit or break. In case the cable is broken, replace it or cut it if the cable length is sufficient. Please, pay attention for the cable marking. The marking of wire size on the cable should be either 28AWG/2C+24AWG/2C, or 28AWG/2C+22AWG/2C, or 28AWG/2C+20AWG/2C.

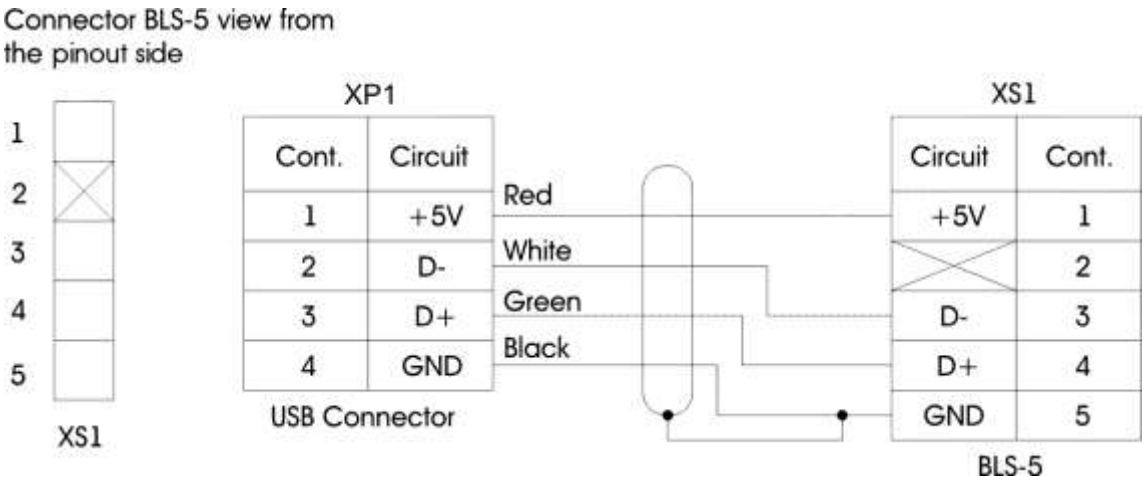

Fig. 15. Electrical schematic of computer interface cable.

5.4. LED Goggles

The LED goggles are examined for external signs of cable damage. The check of the circuits from the connector side is performed according to the schematic shown in Fig. 16. The check is done using the device designed to test the diodes. Disassemble the housing of the cable connector and inspect the montage. In case of cable damage see the instructions for USB cable repair (section 5.3 of this manual). If the failure is not detected, address the manufacturer.

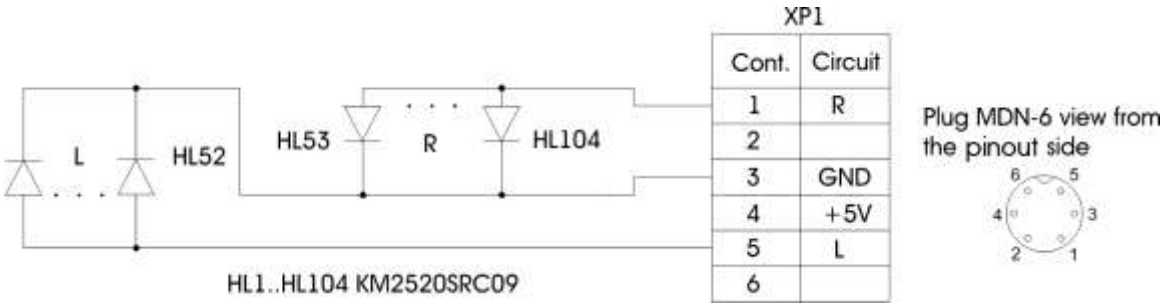

Fig. 16. Electrical schematic of LED goggles.

5.5. LED Penlights

The LED penlights are examined for external signs of cable damage. The check of the circuits from the connector side is performed according to the schematic shown in Fig. 17. The check is done using the device designed to test the diodes. Disassemble the housing of the cable connector and inspect the montage. If the failure is not detected, open the LED penlight case and make separate measurements of the resistance of each wire. In case of cable damage see the instructions for USB cable repair (section 5.3 of this manual). The detection and elimination of LEDs failure can be done only by the manufacturer.

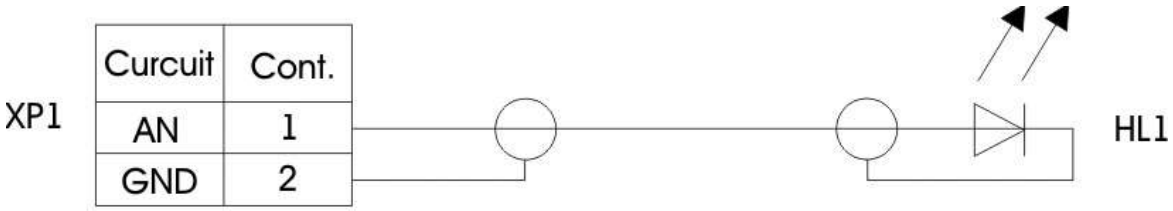

Fig. 17. Electrical schematic of LED penlights.

5.6. Mini-Ganzfeld Stimulator

The mini-ganzfeld stimulator is examined for external signs of cable damage. The check of the circuits from the connector side is performed according to the schematic shown in Fig. 18. The check is done using the device designed to test the diodes. Disassemble the housing of the cable connector and inspect the montage. In case of cable damage see the instructions for USB cable repair (section 5.3 of this manual). If the failure is not detected, address the manufacturer.

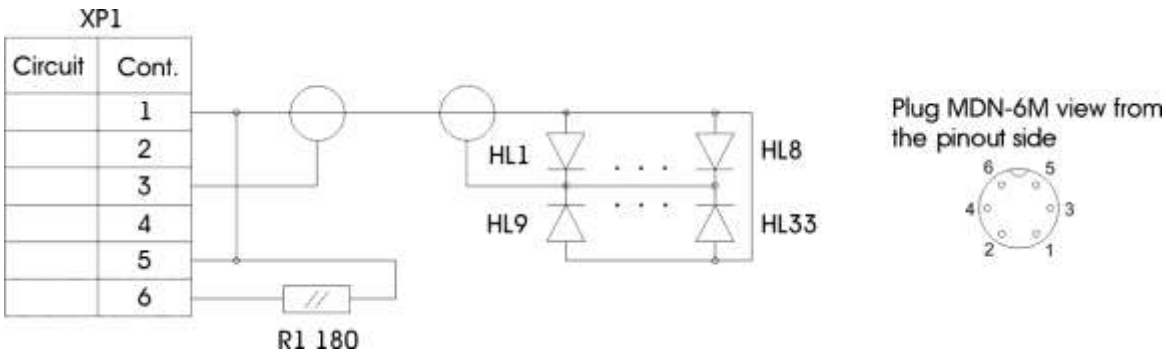

Fig. 18. Electrical schematic of mini-ganzfeld stimulator.

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.

7. Bullion Content Data

The bullion content data is presented in Table 4.

Table 4. Bullion content data.

Name	Silver content, g
Corneal hook electrode (NS006106.004)	0.21

8. Delivery Set and Package Data

The ***Neuro-ERG/V*** veterinary digital ERG system is collected and packed. The system is ready for operation.

Package report number _____

Package report date _____

The detailed information about the delivery set is described in the package report which is an integral part of this document and should be kept along with it.

9. Warranty

9.1. The manufacturer guarantees the system quality, if the rules of operation, storage, transportation, mounting and maintenance prescribed in the operational documentation are observed.

9.2. Warranty period for the system is 24 months from the delivery date to the customer.

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

There is no warranty for consumables (gels and pastes).

The warranty period can be prolonged for the period of repair (see chapter 10 “Reclamation”).

9.3. The guarantee is stopped if:

- the rules of operation, storage, transportation, mounting and technical servicing are not observed;
- the warranty period is expired;
- user breaks the seal without permission of the manufacturer.

9.4. The manufacturer is obliged to repair the system in case of its breakdown 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 chapter 10 “Reclamation”.

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

360 avenue du Clapier

ZAC du Couquiou

84320 Entraigues sur-la-Sorgue

France

Phone: +33 621-304-580

E-mail: info@neurosoft-france.com

In the **USA**, please, contact

Diagnus LLC

5 Larson Avenue, Smithtown, NY 11787 USA
+1 (800) 528-09-40
https://www.diagnus.us
E-mail: info@diagnus.us

10. Reclamation

10.1. In case of system breakdown or faultiness in the period of warranty and also product defect detected when primary acceptance, the consumer should send written notification to Neurosoft. This notification should contain the following information:

- customer's name and address;
- serial number of the system (it is written in the package report and on labels);
- number and date of the invoice or other accompanying document;
- detailed description of failures. If possible, please, indicate the reasons and circumstances preceding the fault detection (in addition it is recommended to add the test report, the test data, photos and other materials allowing solving the problem as soon as possible).

10.2. If the system is returned to the service center for repair or replacement, the following rules should be observed:

- the system should be decontaminated before sending to the service center. Read the rules of cleaning and disinfection described in section 4.3 "Disinfection").
- the system should be packed so to exclude the possibility of its damage during the transportation;
- the notice (see item 10.1 of this chapter) and this manual should be returned with the system.

Annex 1. Delivery Set

The amplifier, auditory-visual stimulator, footswitch, dedicated keyboard and software are included in the delivery set of the *Neuro-ERG/V* system. The mentioned components of the system as well as other components and bought articles can be delivered to the customer both jointly and separately. The delivery set for the system is described in Table 5.

Table 5. Base Delivery Set

Name	Order code or Main Specifications	Quantity, pcs.
Neuro-ERG amplifier	NS006201.018-023	1
Neuro-ERG auditory-visual stimulator	NS025201.014-023	1
Holder H-4S	NS016201.044	1
Holder mount for electronic unit	NS006200.002	1
Dedicated keyboard	NS035201.008-020	1
Bluetooth adapter	Interface: USB 2.0; Bluetooth standard: 2.0, 2.1, 4.0; Compatibility Bluetooth Universal Windows driver – available; Frequency: 2402-2480 MHz	1
USB cable (A→B)	NS007103.005-01	1
Technical manual for dedicated keyboard	TM035.02.001.000	1
Package	NS035901.001	1
Electrode holder	NS016221.023	1
Footswitch	NS028353.005	1
USB cable (A→B)	NS007103.005-01	1
Visual stimulator (LED goggles)	NS005302.006	1
LED photic stimulator on holder	NS012302.005	1
Electrodes and Accessories for EMG and EP Studies:		
Disposable subdermal single needle electrode with cable	NS990106.043-001 (S50716)	7
Y-adapter	NS006103.019	1
Corneal loop electrode	NS006106.005	25
Corneal hook electrode	NS006106.004	5
Adapter for corneal electrode	NS006103.011	2
Disposable ring electrode for electroretinography CareFusion 209 Inc, USA	NS231947	12
Set of penlights (red, blue, green, white)	NS006302.004	1
Holder for penlights and mini-ganzfeld stimulator	NS025201.012	1
Mini-ganzfeld stimulator	NS025302.005	1
Software:		
Neuro-MEP.NET software	with additional *Neuro-MEP.NET/ERG* software module	1
License for Neuro-MEP.NET software with additional *Neuro-MEP.NET/ERG* module	S002.104510	1

Table 5. Continued

Name	Order code or Main Specifications	Quantity, pcs.
Computer and Electronic Equipment:		
USB-hub KM-7-2 electronic unit	NS042201.013-020	1
USB cable, A-B type	NS007103.005-01	1
CEE 7/7 – IEC C13 power supply cable	220 V, 10 A, l = 1,8 m (3G×0,75 sq. mm)	1
Technical manual for KM-7, KM-7-2	TM042.01.004.000	1
Cardboard package		1
Isolation transformer TM-630[1)]	NS036201.004	1
Cable IEC C13 – IEC C14	220 V, 10 A, L=1,8 m, (3G×0,75 sq. mm)	1
Power cable IEC C14-Schuko type F socket	220/230 V, 10 A, L, not more than 1 m (3G×0,75 sq. mm)	1
Technical manual for TM-630	TM036.03.001.000	1
Package	NS036901.001	1
Operational Documentation:		
Neuro-ERG/V technical manual	TM006.04.001.000	1
Neuro-MEP.NET/V user manual	UM006.04.002.000	1
Package:		
Package	NS002901.001	1
Package	NS002901.002	1

Note:

[1)] The delivery of another transformer or USB hub certified according to IEC (EN) 60601-1, AAMI/ANSI ES 60601-1 is permissible.

Annex 2. Electromagnetic Emissions and Immunity

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The 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	Class B	The 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	Not applicable	
Voltage fluctuations' flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the 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% UT during 0.5 period at 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º.	10 ms[3)]	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
	0% UT during 1 period and 70% UT during 25 periods. Monophase: at 0º.	500 ms[3)]	
Voltage interruptions IEC 61000-4-11:2004	0% UT 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: UT – 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
				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:
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)]	$d = 1.17\sqrt{P}$
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	27 V/m	
	430-470	28	28 V/m	
	704-787	9	9 V/m	
	80-960	28	28 V/m	
	1700-1990	28	28 V/m	
	2400-2470	28	28 V/m	
	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 the 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 2.7 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.