Technical Manual

Neuron-Spectrum-1/V

Veterinary Digital EEG System

TM012.04.001.000
(08.07.2019)

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Contents

Introduction

This technical manual (hereinafter referred to as “the manual”) is the combined document describing the operation and servicing of the *Neuron-Spectrum-1/V* veterinary digital EEG 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:

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

or by e-mail:

help@neurosoft.com

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

www.neurosoft.com

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Important Safety Instructions

Intended Use

The *Neuron-Spectrum-1/V* veterinary digital EEG system is intended to perform clinical electroencephalography (EEG) and long-latency evoked potential (EP) testing in animals in any unshielded room.

General Description

The system is intended for veterinary use only!

The *Neuron-Spectrum-1/V* system is portable and records up to 8 EEG channels and 1 polygraphic channel (for ECG, EOG, etc.). The system can be used in veterinary for:

- assessment of brain functions;
- detection of epileptic paroxysmal abnormalities;
- localization of areas of pathologic activity in brain;
- long-term cerebral function monitoring in animals in veterinary hospitals.

Features:

- 8-channel EEG/EP recording in any unshielded room;
- photic stimulation;
- long-latency EP recording by EEG channels: flash visual evoked potentials;
- amplitude, spectral, periodometric, correlative and coherent EEG analysis, detection of seizures (spikes and sharp waves), generation of examination report, export and import of files in the standard EDF data format;
- review, storage and printing of recorded traces, results of analysis and exam reports.

Contraindications

Relative contraindications for system application are:

- signs of skin inflammation in the places where electrodes are applied;
- allergic reactions to the components used for skin preparation and application of electrodes (conductive gels and pastes, abrasive paste, medical patches);
- allergic reactions to silver compounds;
- contraindications for sedation (if sedation is used).

Possible Side Effects

The following side effects can occur rarely:

- skin irritation and allergic reactions to the components used for skin preparation and application of electrodes, allergic reactions to silver compounds.

Safety Measures

Do not use the system unless you read this manual and accompanying documents.

The system is to be used by trained personnel only. No person should attempt to use this system without necessary knowledge and training to understand its use and how the results should be interpreted. Before you start using the system read carefully this manual, the user manual for the *Neuron.Spectrum.NET* software and the technical manuals for devices included into the system delivery set.

To ensure safety 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.
- to clean the system by submersing into liquid, autoclaving, or steam cleaning as this may damage equipment or reduce its usable life. The disinfection of the system is described in section 4.3 “Disinfection”;
- to drop or damage the system. If the system has been dropped or damaged, the use of the device is permitted only after it is checked and repaired in the authorized service center;
- to operate the system by children.

1. Description

1.1. Main Specifications

Table 1. Main Specifications

Parameters	Values
EEG/EP Channels	
Number of channels	8
Sampling rate	100, 200, 500, 1000, 5000 Hz
A/D converter	16 bit
Voltage range	2–12000 μV
Ratio error of voltage measurement: • in the range from 10 to 50 μV • in the range from 51 to 450 μV	 ±25% ±7%
Sensitivity	1, 2, 5, 7, 10, 20, 50, 70, 100, 200, 500, 1000 μV/mm
Relative error of sensitivity	±5%
Sweep speed at EEG recording	3, 7, 15, 25, 30, 50, 60, 120, 240, 480, 960 mm/s
Sweep speed at EP recording	5, 10, 20, 50, 100, 200, 500 ms/div
Relative error of sweep speed	±2%
High pass filter	0.01, 0.05, 0.5, 0.7, 1.5, 2, 10 Hz
Low pass filter	15, 35, 75, 100, 150, 200, 250 Hz
Common-mode rejection	not less than 100 dB
Suppression ratio of power frequency by notch filter	not less than 40 dB
Input noise level (from peak to peak)	not more than 2 μV
Input impedance	mot less than 100 MΩ
Patient leakage current	not more than 50 nA
Photic Stimulator	
Number of channels	1
Stimulus duration	1–60 ms
Relative error of stimulus duration	±10%
Stimulation frequency	1–50 Hz
Relative error of stimulation frequency	±10%
Maximal brightness of LED stimulator	(16000±1600) cd/m^2
Left/right/two-sided stimulation	available
General Parameters and Specifications	
Interface	USB

Table 1. Continued

Parameters	Values
Supply voltage: • electronic units • desktop PC-based computer • notebook PC-based computer	 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
Electronic unit power consumption	not more than 0.25 V·A
Dimensions of electronic unit	95×130×25 mm
Weight of electronic unit	0.5 kg
Weight in package (without PC and printer)	not more than 4 kg
Safety	CF type
Transportation Conditions	
Temperature	from -25 to +60°C
Humidity	20 – 95% (non-condensing)
Atmospheric pressure	from 70 kPa
Storage Conditions	
Temperature	from +5 to +40°C
Humidity	30-85% (non-condensing)
Atmospheric pressure	70-106 kPa
Operation Conditions	
Temperature	from +10 to +35°C
Humidity	30-85% (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 3 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 60601-1-2-2014 (EN 60601-1-2:2015) and IEC 60601-2-26:2012 (EN 60601-2-26:2016).

The electronic unit is supplied by regulated power supply through USB interface, it has double isolation and CF 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 principle of operation is based on the acquisition and input of brain biopotentials and other physiological signals into PC for the analysis of brain electrical activity taking into account the impact of the other physiological signals.

The system includes the electronic unit that records EEG signals and other physiological signals by polygraphic channel, amplify them, convert into digital code and transmitting them to the PC.

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

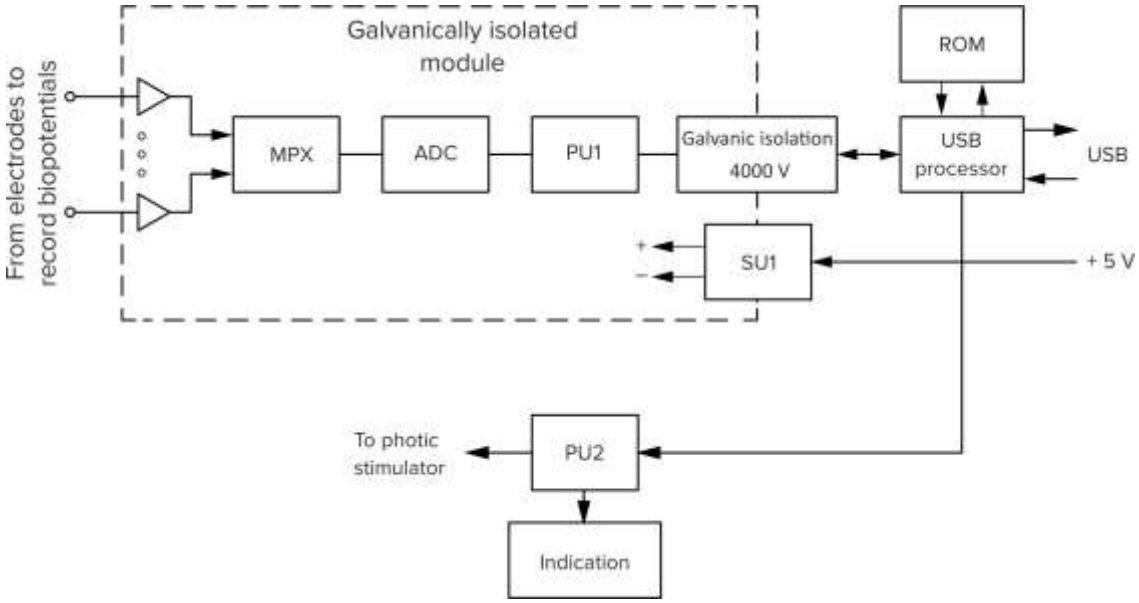

Fig. 1. The *Neuron-Spectrum-1/V* system.

Biopotentials from the electrodes are amplified and digitized by means of the analog-digital converter (ADC) and multiplexer (MPX) under the control of the processor PU1; then they are transmitted to the USB processor through the optrons of galvanic isolation.

The processor PU1 of the amplifier module controls the modes of measurement, calibration, impedance and internal diagnostics.

The power supply of the amplifier module is performed through the electrically isolated DC converter (SU1).

The processor PU2 controls the stimulus duration of photic stimulator and it also controls LEDs to indicate impedance.

All the processors receive commands and transmit data through the USB processor which forms the data packets to transmit them to the PC and deciphers data transmitted from the PC to control the modules.

The system operates under the control of PC (IBM PC type) with the mouse, keyboard, laser or jet printer and installed licensed Windows 8.1 (or later versions) 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 *Neuron-Spectrum-1/V* system are shown in Fig. 2 and Fig. 3.

The touch-proof connectors for electrode cables attachment, LED operation indicator and impedance indicators are located on the front panel (Fig. 2).

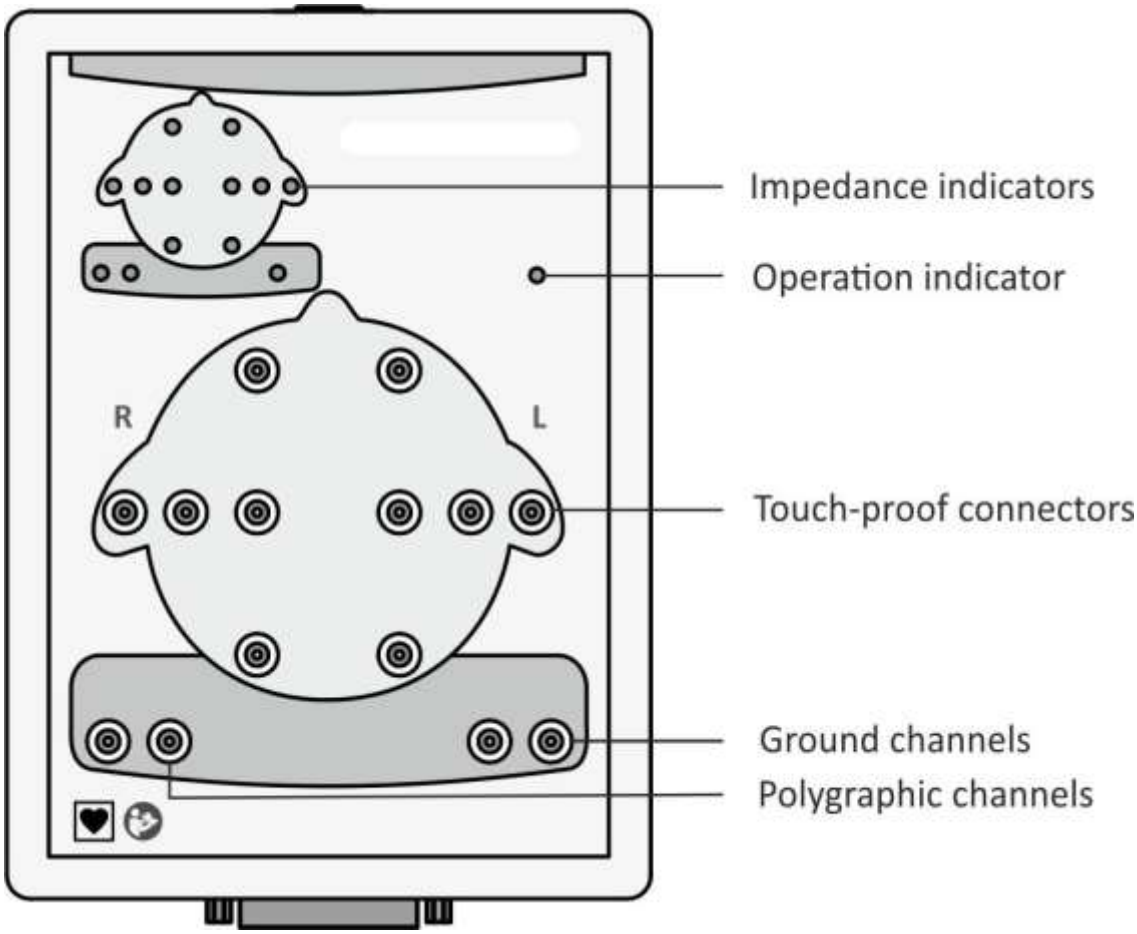

Fig. 2. Front panel of *Neuron-Spectrum-1/V*.

EEG channels are marked as “FP1…O2”, “A1”, “A2”, polygraphic channel is marked as “1”. The slot ⏚ is used to attach the ground electrode.

The operation indicator glows yellow when the electronic unit is connected to PC and it glows green when the signal is recorded during the program operation.

The color of impedance indicators means the quality of the electrode placement. The green color means the quality is high, yellow color – the quality is medium and red color – the quality is poor. The colors are specified in the software settings.

On the top side panel of the electronic unit (Fig. 3) there are the connector for photic stimulator, trigger socket (trig-in/trig-out) to attach stimulators of third-party manufacturers and connector to attach the system to the PC via USB cable. Other connectors are designed for other stimulators (not for veterinary use).

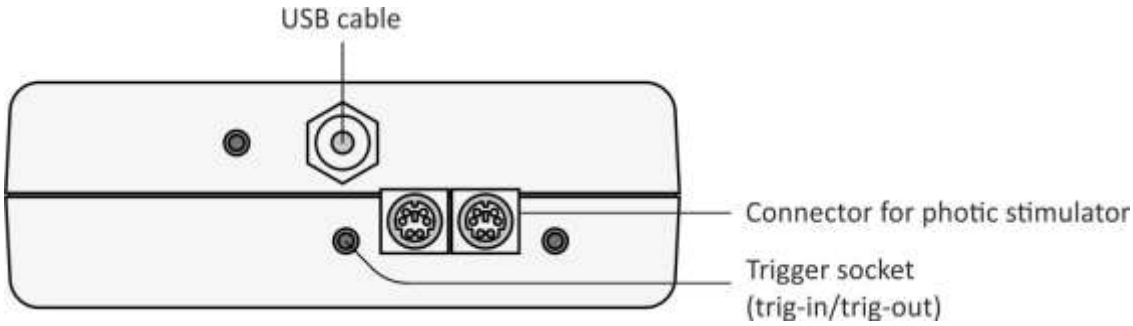

Fig. 3. Top side panel of *Neuron-Spectrum-1/V*.

1.4. Labeling

The example of labeling of the electronic unit is shown in Fig. 4.

Fig. 4. Labeling of electronic unit.

Interpretation of symbols on electronic units:

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

– 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.

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

– 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 by ISO 15223-1.

– applied parts of CF 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 electronic unit.***

– attention: consult operational documentation. ***This symbol is on the front panel of the electronic unit.***

The equipment is identified with the GS1-128 barcode integrated to the barcode in DataMatrix format (Fig. 5).

Fig. 5. 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.
- To prevent an electric shock, the system should only be connected to the mains power supply with protection grounding.

- 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.

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

Place the computer and electronic unit of the *Neuron-Spectrum-1/V* system according to your plan and connect the computer equipment according to the operational documentation for them.

The software installation and working with the *Neuron-Spectrum.NET* program is described in the user manual.

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 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.

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 connection of the *Neuron-Spectrum-1V* system to PC is shown in Fig. 6.

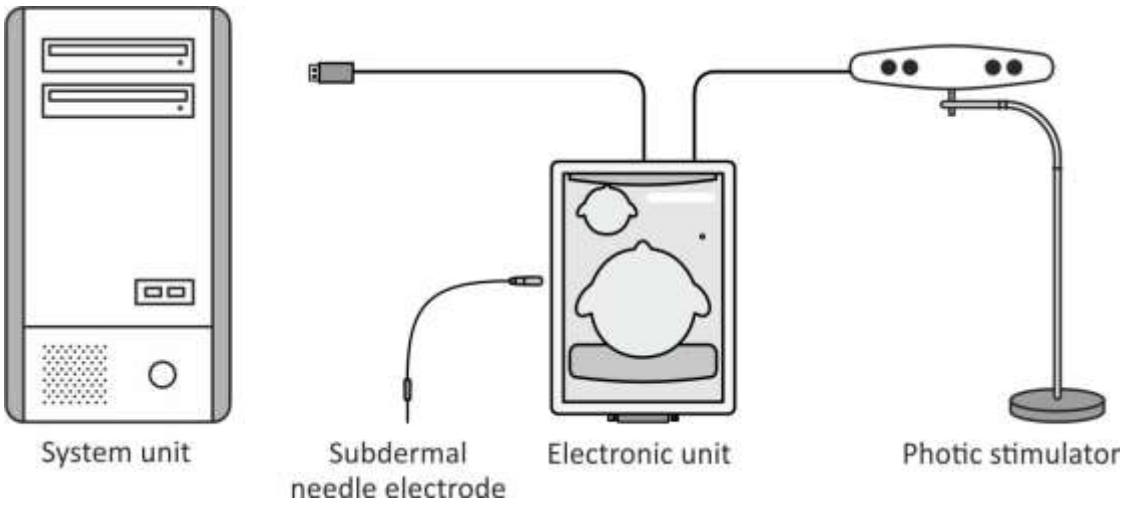

Fig. 6. Connection to PC.

Insert the USB cable connector into the USB socket of the computer system unit. The system must be connected to the USB port on the system unit or to USB hub powered from the mains. If the system is connected to the USB connectors on a computer monitor or keyboard, it may not work correctly. It is strongly prohibited to use passive USB hubs (not connected to the mains) as a part of the system.

Place and secure the assembled holder for the electronic unit on the table in the immediate vicinity of the veterinary exam table. Secure the holder mount on the assembled holder. Position the electronic unit on the holder mount.

Assemble the photic stimulator and secure it so that the LEDs can be placed in close proximity (10-30 cm) from the eyes of the examined animal. Connect the cable of the photic stimulator to the connector for photic stimulator on the top side panel of the electronic unit.

Connect the needle electrodes to the front panel of the electronic unit.

3. Proper use

3.1. 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 *Neuron-Spectrum.NET* program is started.

3.2. Getting Started

Before starting configure the system taking into consideration the exam type and recommendations of the user manual for this software.

The examination includes the following stages:

- preparation of animal for EEG recording and placement of electrodes;
- recording of ECG signals;
- analysis of the obtained results and their printing.

The electrodes can be applied and connected when the system is switched on. The needle electrodes are placed subcutaneously according to the fixed veterinary practice. The example of EEG recording is shown in Fig. 7. The skin is pre-treated with alcohol at the sites of electrode placement.

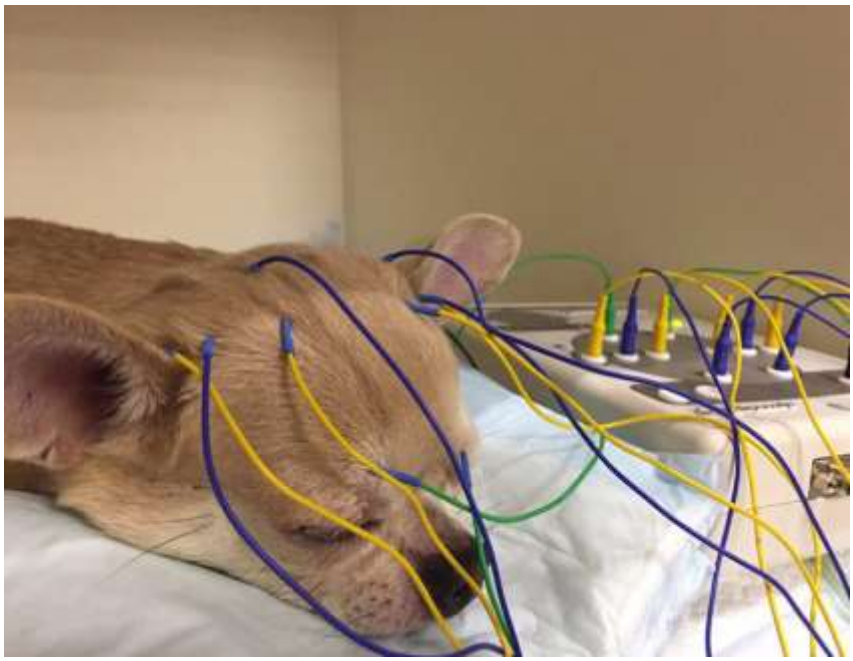

Fig. 7. EEG recording.

After recording, the electrodes must be removed from the animal and discarded.

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.

3.3. Troubleshooting

The list of some possible troubles and the ways of their removal is given in Table 2.

Table 2. Troubleshooting

Trouble	Cause	Way of Removal
When PC is switched on, the indicators on its front panel do not glow.	Incorrect connection of the PC to the mains.	Check the connection of the PC to the mains.
The loading of the operating system is not performed properly.	Fault of hardware or software.	Restart the PC. If the problem persists, contact the computer supplier.
The *Neuron-Spectrum* software doesn't start.	The software is not installed or it is installed incorrectly.	Check whether the software for the system is installed. Reinstall the software from the electronic media.
No EEG acquisition in the monitoring mode	The incorrect connection of the system.	1. Check the connection of the system to the PC. 2. Contact Neurosoft service center.

Table 2. Continued

Trouble	Cause	Way of Removal
When the starting program, the *Database connection error* message appears on the screen.	1. The database directory is not available. 2. The database directory has been renamed or replaced.	1. Check the PC connection to the local network. Make sure that the PC with the database directory is connected to the local network and switched on. 2. Restore the name and location of the database directory.
The exam report can't be generated or printed.	1. The printer is not set up. 2. The printer is not connected to the PC or it is out-of-order.	1. Set up the printer using the Windows control panel. 2. Check the printer connection and its working order.
The impedance is indicated as red color while the electrode is applied properly.	EEG cable is broken.	Replace the cable.
EEG traces recorded in one hemisphere channel are not displayed adequately.	1. Problems with referent electrode (ear electrode during monopolar recording with ear electrode referent). 2. Problems with electronic unit.	1. Check the quality of electrode placement by impedance measuring. 2. Change places of the referent electrodes cables (A1 and A2). If the problem is repeated in the other hemi-sphere that means the electrode is out of operation. Replace it. 3. If the problem persists, the electronic unit is out of operation. Consult Neurosoft company.
EEG traces recorded in one of the channels are not displayed adequately.	1. The derivation cable is out of order. 2. Problems with electronic unit.	1. Check the quality of electrode placement by impedance measuring. 2. Replace the electrode. 3. Consult Neurosoft company.

3.4. 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 “Important Safety Instructions. Safety Measures”.

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% hydrogen 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 needle electrodes should be discarded after use.

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. EEG Cables and Adapters

The cables are examined externally, and the circuit is checked for short circuit or break between the screen and the wire and between the wires. 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. 8) 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 labeling applied along its entire length. It is prohibited to use the cable with a different labeling.

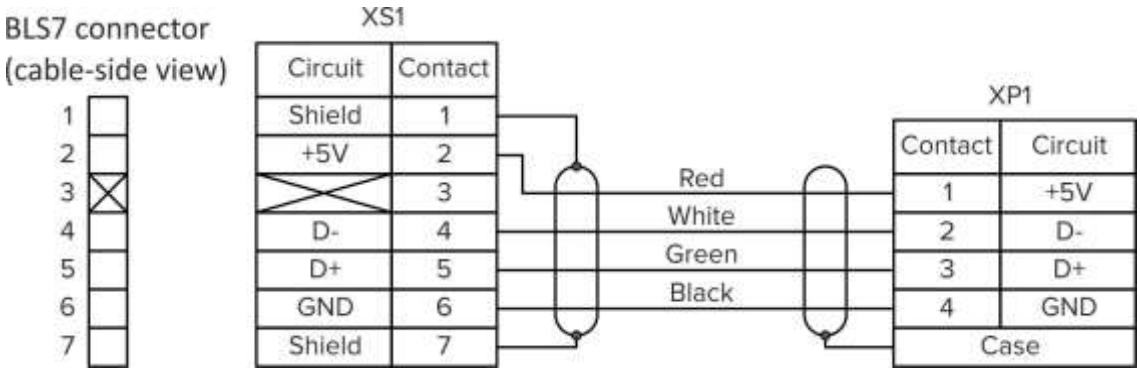

Fig. 8. Electrical schematic of USB cable.

5.4. Photic Stimulator

The photic stimulator is examined to detect the external signs of cable damage. The circuits from the connector side are controlled according to the schematic shown in Fig. 9 using the device for LED check. Open the cable connector case and check the montage. If damage is not detected, open the case of the photic stimulator and measure the resistance of each wire. If a damaged cable is found, further actions are similar to repairing the USB cable. The damage of LEDs can be eliminated only by the manufacturer.

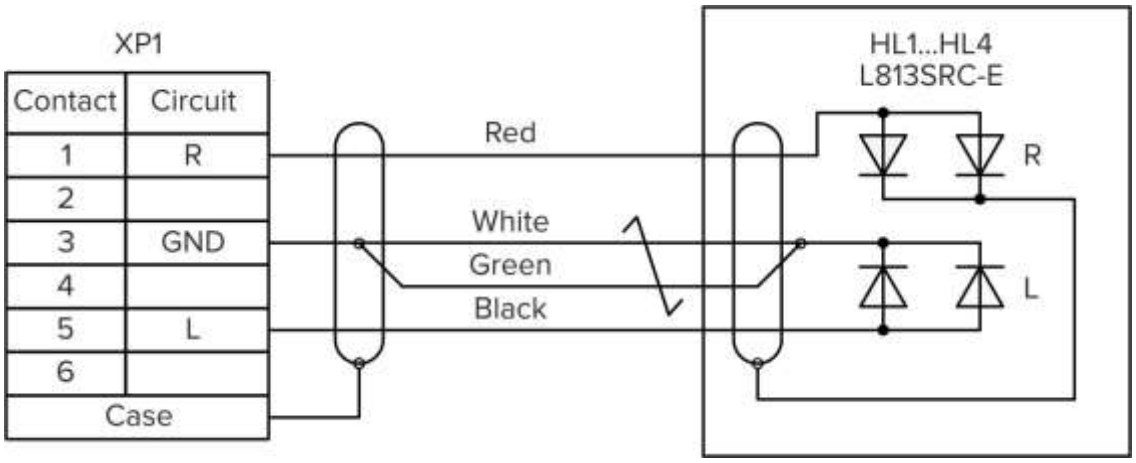

Fig. 9. Electrical schematic of photic stimulator.

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. Delivery Set and Package Data

The ***Neuron-Spectrum-1/V*** veterinary digital EEG 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.

8. Warranty

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

8.2. 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 9 “Reclamation”).

8.3. 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.

8.4. 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 9 “Reclamation”.

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

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84320 Entraigues sur-la-Sorgue

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E-mail: info@neurosoft-france.com

In the **USA**, please, contact

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5 Larson Avenue, Smithtown, NY 11787 USA
+1-(800)-528-0940
https://www.diagnus.us
E-mail: info@diagnus.us

9. Reclamation

9.1. 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).

9.2. 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 9.1 of this chapter) and this manual should be returned with the system.

Annex 1. Delivery Set

The base delivery set for the veterinary digital EEG system *Neuron-Spectrum-1/V* is given in Table 3.

Table 3. Base Delivery Set

Name	Order code or Main Specifications	Quantity, pcs[1)]
Neuron-Spectrum-1 electronic unit	NS015201.041-022	1
Assembled holder	NS016201.038	1
Holder mount	NS006200.002	1
LED photic stimulator on holder	NS012302.005	1
Disposable subdermal single needle electrode with cable	NS990106.043-001	15
Operational Documentation:		
Neuron-Spectrum-1/V technical manual	TM012.04.001.000	1
Neuron-Spectrum.NET user manual	UM015.04.003.000	1
Software:		
Neuron-Spectrum.NET software	without additional modules	1
Package:		
Package (set)	NS002901.001	1

Note:

[1)] The minimum sufficient quantities are specified.

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	$d = 2.23\sqrt{P}$ 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 applies.
[2)] These guidelines may not apply 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.