

Technical Manual

# **Poly-Spectrum-8/V**

Veterinary Digital ECG System



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# Introduction

This technical manual (hereinafter referred to as “the manual”) is the combined document describing the operation and servicing of the *Poly-Spectrum-8/V* veterinary digital ECG 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:

**Post Office 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**,

or ask questions by phone:

**+7 (4932) 59-21-12; +7 (4932) 24-04-37 (Service center),**

**+7 (4932) 24-04-34; +7 (4932) 95-99-99**

You can also contact our Authorized **European** Representative:

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# Important Safety Instructions

## Intended Use

The *Poly-Spectrum-8/V* veterinary digital ECG system is intended for recording of electrocardiogram (ECG) in animals.

The system can be used in in veterinary practices (including animal ambulatory services, animal hospitals, livestock farming, etc.) and research field.

## General Description

**The system is intended for veterinary use only!**

The *Poly-Spectrum-8/V* system is used to:

- estimate the electrical activity of the heart muscle and cardiac performance;
- detect the hidden pathology and potential cardiac disturbances;
- select the appropriate treatment and assess its effectiveness.

### Features:

- recording of electrocardiogram (ECG);
- real-time data transfer to PC and saving of ECG in the PC memory;
- displaying of ECG on the PC screen and/or printing it on the paper using a compatible device.

The *Poly-Spectrum-8/V* system is delivered with *Poly-Spectrum.NET* software that includes the *Poly-Spectrum.NET/Veterinary* additional module intended for ECG management and interpretation with automatic report generation.

## **Contraindications**

There are no contraindications for using the *Poly-Spectrum-8/V* system.

## **Possible Side Effects**

There are no side effects if the system is used properly.

The local allergic reactions to working surfaces of reusable ECG electrodes may occur.

## **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;
- 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”;
- drop the system from more than one meter height. 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.



# 1. Description

## 1.1. Main Specifications

Table 1. Main Specifications

Parameters	Values
<i>ECG Channels</i>	
Number of channels	8
Voltage range	0.03–5 mV
Ratio error of voltage measurement in the amplitude range: <ul style="list-style-type: none"> <li>• &lt; 500 <math>\mu</math>V</li> <li>• from 500 <math>\mu</math>V up to 5 mV</li> </ul>	within 25 $\mu$ V within 7%
Input noise level	not more than 20 $\mu$ V
Bandpass flatness: <ul style="list-style-type: none"> <li>• from 0.5 up to 60 Hz</li> <li>• from 60 up to 75 Hz</li> </ul>	from –10% up to +5% from –30% up to +5%
Relative error of interval measurement	within $\pm$ 7%
Relative error of calibration pulses recording	within $\pm$ 5%
Heart rate measurement range	30–240 beats per minute
Relative error of heart rate measurement	$\pm$ 1 beats per minute
Control of electrode placement quality	available
Control of electrode break during ECG recording	available
Defibrillation protection	available
Common-mode rejection ratio	not less than 100000
Input impedance	not less than 20 M $\Omega$
<i>General Parameters and Characteristics</i>	
Interface	USB

Table 1. Continued

Parameters	Values
Supply voltage: <ul style="list-style-type: none"> <li>• electronic unit</li> <li>• desktop PC-based system</li> <li>• notebook PC-based system</li> </ul>	5 V DC 220 V AC (50 Hz) 220 V AC (50 Hz) / int. battery
Dimensions: <ul style="list-style-type: none"> <li>• Electronic unit</li> <li>• Transportation bag</li> </ul>	(126×68×25) ± 5 mm (240×185×130) ±10mm
Cable length: <ul style="list-style-type: none"> <li>• PC connection cable</li> <li>• ECG cable (for limb leads)</li> <li>• ECG cable (for chest leads)</li> <li>• ECG cable NS017103.008</li> </ul>	(2.5 ± 0.2) m (2.0 ± 0.1) m (1.5 ± 0.1) m (1.45 ± 0.1) m
Weight: <ul style="list-style-type: none"> <li>• electronic unit</li> <li>• transportation bag</li> <li>• packed system (without computer)</li> </ul>	0.3 ± 0.05 kg 0.15 ± 0.05 kg not more than 1.5 kg
Applied parts	CF type with protection against defibrillator discharge
<i>Transportation Conditions</i>	
Temperature	from -25 to +60°C
Humidity	20 – 95% (non-condensing)
Atmospheric pressure	from 70 kPa
<i>Storage Conditions</i>	
Temperature	from +5 to +40°C
Humidity	30-85% (non-condensing)
Atmospheric pressure	70-106 kPa
<i>Operation Conditions</i>	
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 60601-2-25:2011 (EN 60601-2-25:2015).

The electronic unit is supplied by regulated power supply through USB interface, it has double isolation and CF type applied parts with protection against defibrillator discharge 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 electrical signals in the heart to computer to perform the analysis of cardiac function in animals.

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

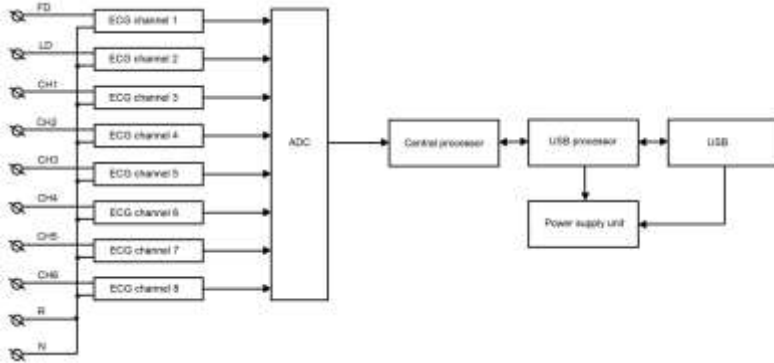


Fig. 1. The *Poly-Spectrum-8/V* system.

ECG signal is transferred to 8 channels of the amplifier via the electrodes. The amplified signal is delivered to the multi-channel analog-to-digital converter (ADC).

The central processor refers to the ADC from time-to-time, processes the received information and transfers it to the USB processor. The USB processor transfers data to the computer and controls the power supply unit.

The power supply unit provides all electronic components of the system with the required power supply from the USB bus in the mode of data reading to PC.

The PC is used to process the recorded physiological signals, display them on the monitor in various forms after the mathematical analysis, store the original signals on the hard disk, generate the examination reports and print them.

### 1.3. Connectors and Indicators

The panels of the *Poly-Spectrum-8/V* system are shown in Fig. 2 and Fig. 3.

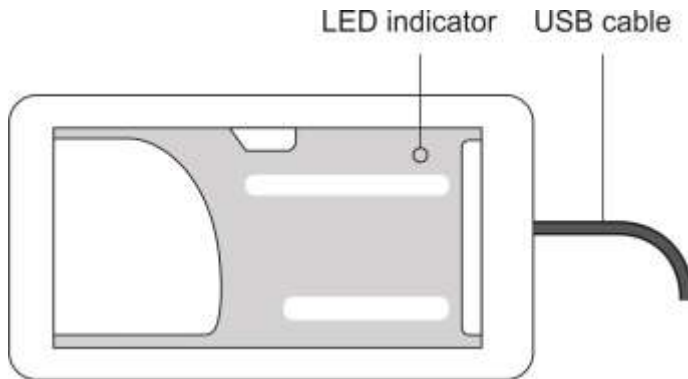


Fig. 2. Front panel of *Poly-Spectrum-8/V*.

If the LED indicator is orange, the device is connected to the computer and +5 V voltage is supplied to USB. The green color of the LED indicator means the device is in the operation mode.

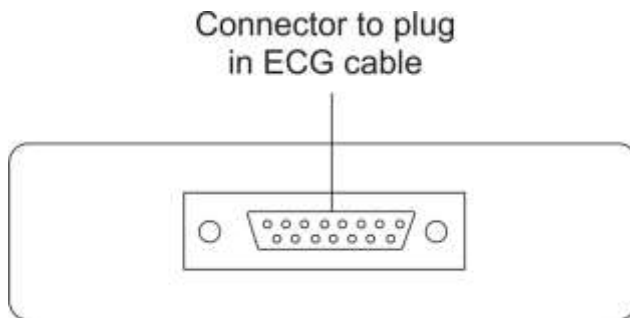


Fig. 3. Panel with the connector for ECG cable.







## 1.4. Labeling


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



Fig. 4. Labeling of electronic unit.

### Interpretation of symbols on electronic units:

-  – CF type applied parts with protection against defibrillator discharge 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) and IEC 60601-1-2-2014 (EN 60601-1-2:2015) and IEC 60601-2-25:2011 (EN 60601-2-25:2015).
-  – attention: consult operational documentation.
-  – number according to catalogue by ISO 15223-1.
-  – serial number by ISO 15223-1.
-  – manufacturer's name and address by ISO 15223-1.
-  – manufacturing date by ISO 15223-1.

 – 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.



- mark of compliance in the voluntary certification system in the Russian Federation.



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



– sign of the Member State of the Eurasian Economic Community and the Customs Union.

**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. 5).



Fig. 5. *DataMatrix* barcode.

DataMatrix code is a two-dimensional barcode, consisting of black and white "cells" or modules arranged in either a square or rectangular pattern. The DataMatrix code is described in ISO/IEC 16022:2006 standard.

To decode the information about the item DataMatrix code can be read by a scanner or a 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 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).
- **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.**



- 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.

**Requirements to mains:**

- Do not use electric mains where the neutral conductor and protective ground are combined. It is strongly prohibited.
- Before the system is installed, the quality of standard tripolar sockets and the integrity of protective ground circuit must be checked by electrician.
- The recommended distance from the electronic unit to the nearest electric mains is not less than 3 meters.

## **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 *Poly-Spectrum-8/V* system according to your plan and connect the computer equipment according to the operational documentation for them.

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. The installation and working with the program is described in the user manual.**

**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>.**

Insert the USB connector into the USB port of the PC system unit. The device drivers shall be installed automatically.

Plug the ECG cable in the ECG connector.

**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.**

The connection of two configurations of the *Poly-Spectrum-8/V* system is shown in Fig. 6 and Fig. 7.

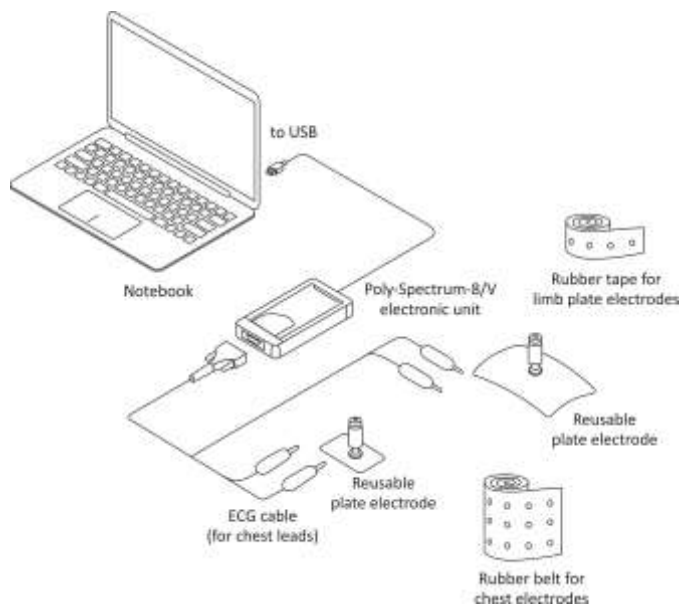


Fig. 6. Configuration 1.

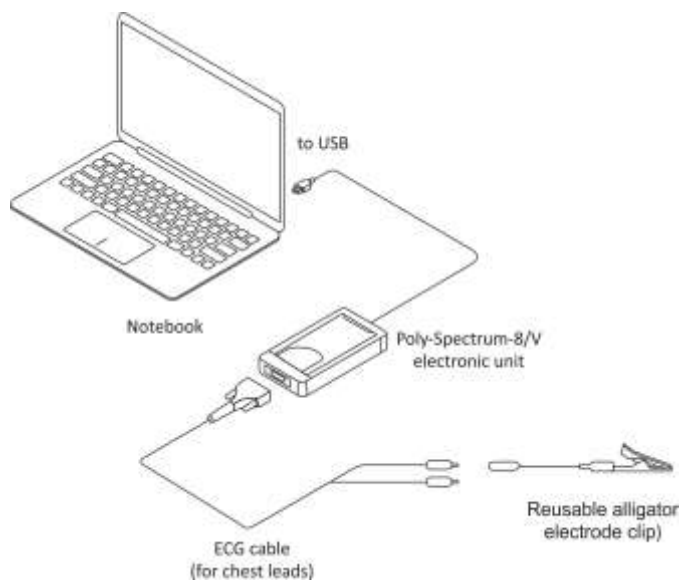


Fig. 7. Configuration 2.

## **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 *Poly-Spectrum.NET* program is started.

### **3.2. Getting Started**

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

The examination includes the following stages:

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

The detailed information of how to perform the examination is described in the user manual for the *Poly-Spectrum.NET* software with the *Poly-Spectrum.NET/Veterinary* additional module.

Depending on the examined animal, the position of its body during ECG recording is different. The placement of electrodes also differs significantly.

For horses, free standing posture is recommended; the limbs should be perpendicular to the body. It is desirable that the limbs are located parallel. The electrodes are applied in the area of metacarpus and metatarsus, directly on the skin pre-treated with alcohol and moistened with conductive fluid (electrode gel). It is not necessary to cut out the hair in the areas of electrode placement. There are three variants of electrode placement: standard (from limbs), X-Y lead and apex lead. In practice, the standard variant is used the most frequently; the other variants are special and used rarely.

The placement of electrodes for standard 6-lead ECG is shown in Fig. 8.

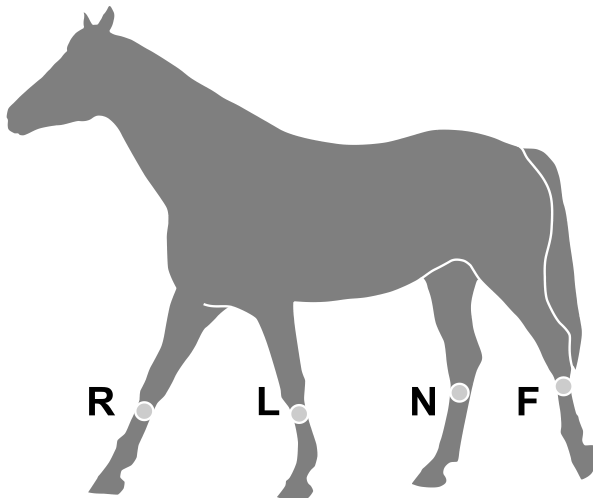


Fig. 8. Placement of electrodes for standard 6-lead ECG.

The placement of electrodes for X-Y lead is shown in Fig. 9.

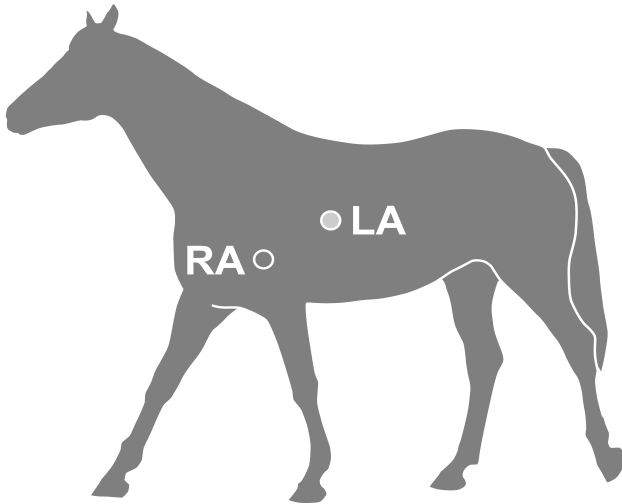


Fig. 9. Placement of electrodes for X-Y lead.

The placement of electrodes for apex lead is shown in Fig. 10.

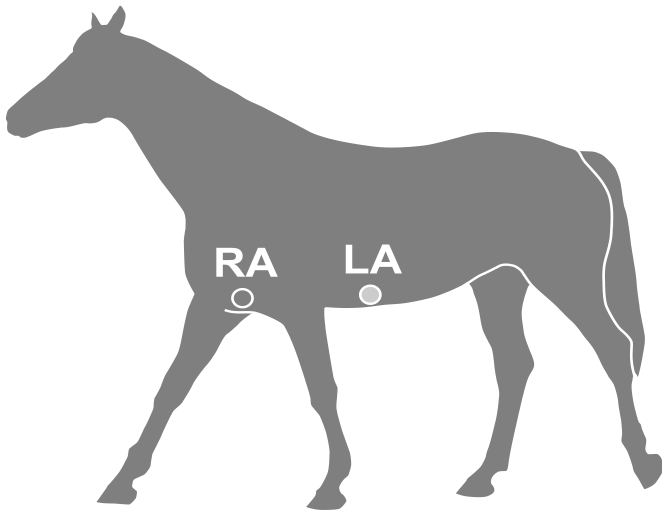


Fig. 10. Placement of electrodes for apex lead.

The ECG recording **in dogs and cats** is performed when the examined animal is in a forced lying position, on the right side, the forelimbs are extended perpendicular to the body and the back ones are at the angle of 45°. In dogs, 3 standard and 3 augmented leads are recorded, and also four chest leads (at the fifth or sixth intercostal space). In cats, only 3 standard and 3 augmented leads are recorded for the time being. The electrodes are applied directly on the skin pretreated with alcohol and moistened with conductive fluid (electrode gel). It is not necessary to cut out the wool in the areas of electrode placement except for long-term cardiac monitoring. In practice, it is also allowed to apply electrode gel on the already placed electrode. If the examined animal is very anxious during the placement of alligator electrode clips, put two-layer gauze moistened with saline under the clips. As it is difficult to fix the clips in small dogs and cats, ECG recording is allowed in a free sitting or standing position in these animals.

The placement of limb and chest electrodes on a dog is shown in Fig. 11.

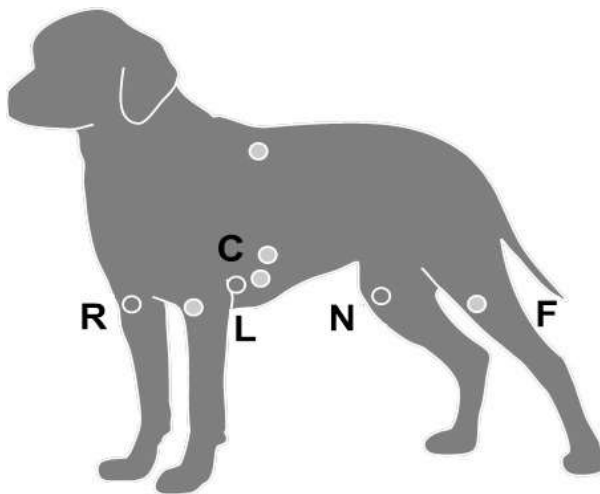


Fig. 11. Placement of limb and chest electrodes on a dog.

During ECG recording, the owner must be in sight, because the examined animal feels safe when the owner is nearby. The owner can gently stroke the animal or scratch it behind the ear. It is not allowed to use any sedatives or neuroleptics to calm the examined animal, because the unreliable results will be displayed on the ECG.

Before the ECG recording, it is recommended to perform the monitoring (for 2–3 minutes) and make sure that the heart rate returned to normal and there are no artifacts caused by emotions. Select the *Manual stop* option in the test settings to make the record long enough to select the cleanest parts of the ECG signal in the obtained record.

The analyzed part of the record should not be less than 1 minute. If arrhythmia or ectopic beats are detected, the recording should be increased to 20–30 minutes.

### 3.3. Troubleshooting

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

Table 2. Troubleshooting

<b>Trouble symptom</b>	<b>Cause</b>	<b>Way of removal</b>
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 <i>Poly-Spectrum</i> 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.



Table 2. Continued.

<b>Trouble symptom</b>	<b>Cause</b>	<b>Way of removal</b>
No ECG 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.
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.
When the starting program, the <i>Database connection error</i> 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.
Noisy signal or break is recorded while the electrode is applied properly.	ECG cable is broken.	Replace or repair the cable.

### 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 sections “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% chlorine 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 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. ECG Cables (NS003103.009, NS003103.010)

The electrical schematic of ECG cable is shown in Fig. 12.

The ECG cable is 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. To check or replace the resistors R1-R4 (TVO-0.5 10kΩ± 20%), disassemble the cable connectors.

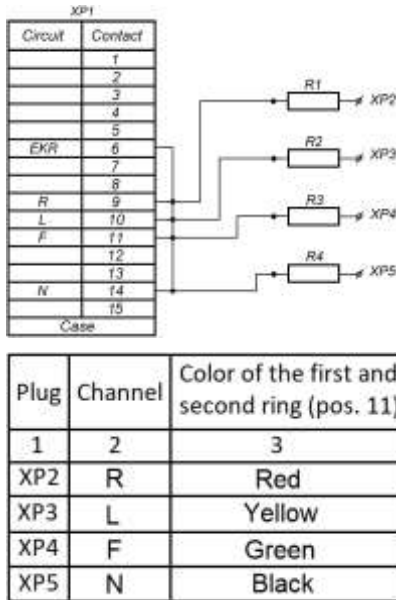


Fig. 12. Electrical schematic of ECG cable.

### 5.3. Computer Interface Cable (USB Cable)

The computer interface cable (Fig. 13) 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.

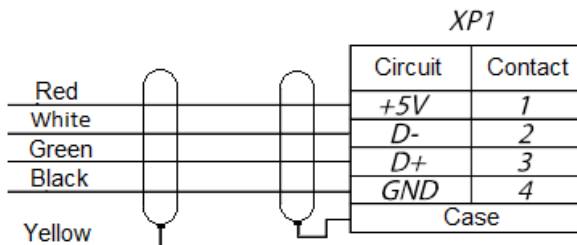


Fig. 13. Electrical schematic of USB cable.

## 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 **Poly-Spectrum-8/V** veterinary digital ECG 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):

360 avenue du Clapier

ZAC du Couquiou

84320 Entraigues sur-la-Sorgue

France

Phone: +33 621-304-580

E-mail: [info@neurosoft-france.com](mailto: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](mailto: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 ECG system *Poly-Spectrum-8/V* is given in Table 3.

Table 3. Base delivery set

Name	Order code or main specifications	Quantity, <sup>1)</sup> pcs
<i>Poly-Spectrum-8/V</i> electronic unit	NS003201.003-021	1
ECG cable (for limb leads)	NR6226 (LHi Technology, China) NS003103.010	1
ECG cable (for limb leads)	NR6227 (LHi Technology, China) NS003103.009	1
Veterinary ECG electrode clip	VV02 (Shenzhen Medke Technology Co, Ltd, China)	8
Reusable plate electrode (20x15) <sup>2)</sup>	F9024 (F9024/RU10P-SSC) (FIAB, Italy)	3-4 <sup>2)</sup>
Reusable plate electrode (30x20)	F9024 (F9024/RU10-SSC) (FIAB, Italy)	4
Rubber belt for plate electrodes	NS011211.007	2
Rubber tape fixator	NS004205.002	8
Rubber tape for ECG electrode fixation (300 mm)	NS011211.002	4
Electrode gel	TC 9398-005-76063983-2005 "Unimax", 250 ml	1
	TC 9398-004-76063983-2005 "Unigel", 250 ml	
Monopolar needle electrode (ECG)	NS990106.032	4
Reusable alligator electrode clip	NS007106.003	8

Table 3. Continued

Name	Order code or main specifications	Quantity, <sup>1)</sup> pcs
ECG cable (for limb leads and chest leads)	NS017103.008	1
<i>Software:</i>		
<i>Poly-Spectrum.NET</i> software	with <i>Poly-Spectrum.NET/Veterinary</i> additional module	1
<i>Operational Documentation:</i>		
<i>Poly-Spectrum-8/V</i> technical manual	TM003.04.001.000	1
<i>Poly-Spectrum.NET</i> user manual with <i>Poly-Spectrum.NET/Veterinary</i> additional module	UM004.03.001.000	1
<i>Package:</i>		
Transportation bag		1
Carton package (set)		1

*Notes:*

<sup>1)</sup> *The minimum sufficient quantities are specified.*

<sup>2)</sup> *3 - for large animals - 3, 4 - for small and medium-sized animals.*

## 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.

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
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	±2 kV <sup>1)</sup>	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	±0,5 kV; ±1 kV <sup>2)</sup>	Mains power quality should be that of typical commercial or hospital environment.
	±2 kV common mode	±0,5 kV; ±1 kV; ±2 kV <sup>2)</sup>	
Voltage dips IEC 61000-4-11:2004	0% UT during 0.5 period at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	10 ms <sup>3)</sup>	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 0°	500 ms <sup>3)</sup>	
Voltage interruptions IEC 61000-4-11:2004	0% UT during 250 period	5000 ms <sup>3)</sup>	
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.

<sup>1)</sup> Ensured by PC compliance with IEC 61000-4-4 requirements.


<sup>2)</sup> Ensured by PC compliance with IEC 61000-4-5 requirements.

<sup>3)</sup> 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 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
			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 <sup>1)</sup>	$3 V^{(3)}$	$d = 1.17\sqrt{P}$
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 <sup>1)</sup> , should be less than the compliance level in each frequency range <sup>2)</sup> . Interference may occur in the vicinity of equipment marked with the following symbol: 

**Guidance and manufacturer's declaration – noise 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
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	

<sup>1)</sup> 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.

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

<sup>3)</sup> 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)		
	$d = 1.17\sqrt{P}$ 150 kHz up to 80 MHz outside ISM bands	$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz	$d = 2.23\sqrt{P}$ 800 MHz to 2.5 GHz
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

Notes:

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range 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.