Technical Manual

Neuro-MEP
Neuro-ERG

Digital Neurophysiological Systems

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5, Voronin str., Ivanovo, 153032, Russia
P.O. Box 10, Ivanovo, 153000, Russia
Phone: +7 (4932) 24-04-34 Fax: +7 (4932) 24-04-35
E-mail: com@neurosoft.ru Internet: www.neurosoft.ru

Contents

Introduction

This technical manual (further "manual") is the combined document describing operation and servicing of multifunctional digital neurophysiological systems for EMG, EP, ERG and OAE **Neuro-MEP-4, Neuro-MEP-8** and **Neuro-ERG** digital systems (hereinafter referred to as "digital systems").

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

Do not start working with the digital 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.ru.

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

www.neurosoft.ru

or ask questions by phone:

+7 (4932) 24-04-37 (Service Department)

+7 (4932) 24-04-34

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

Chemin du tomple

84330 Le Barroux, France

Phone: +490-650-470, +622-748-384

Fax: +490-650-470

E-mail: **bscholl@orange.fr**

1. Description and Operation

1.1. Function

Digital system **Neuro-MEP-4** is intended for study of electrical activity of muscles and nerves and also somatosensory, visual, auditory evoked potentials (EP), magnetic EP, electroretinogram (ERG), otoacoustic emission (OAE) by 1-4 channels and **Neuro-MEP-8** is by 1-8 channels. It is done by biopotentials acquision and input into PC, and measurement, calculation and analysis of its parameters.

Digital system **Neuro-ERG** is based on **Neuro-MEP** digital system and intended for electroretinography, flash and reversal pattern visual evoked potentials (VEP) and EOG studies.

The digital systems can be used in the patient care institutions, diagnostics centers, neurosurgical hospitals and experimental laboratories of the research institutions for:

- brain functional state study;
- neuromuscular system study (**Neuro-MEP** digital system);
- study of auditory (**Neuro-MEP** digital system) and visual tracts.

The general properties, when carrying out the exams:

- 1-4/8 channel biopotentials recording in any unshielded room;
- Photic-, auditory (**Neuro-MEP** digital system), electrical stimulation (**Neuro-MEP** digital system) and stimulation carrying out with the use of checkerboard reversal pattern;
- Long-, middle-, short-latency flash and reversal pattern visual, auditory (**Neuro-MEP** digital system), cognitive (P300, MMN, CNV) (**Neuro-MEP** digital system), somatosensory (**Neuro-MEP** digital system) evoked potentials recording;
- Skin galvanic responses recording (**Neuro-MEP** digital system);
- Surface EMG recording (**Neuro-MEP** digital system);
- Stimulation EMG recording (**Neuro-MEP** digital system);
- Repetitive stimulation (**Neuro-MEP** digital system);
- Needle EMG recording (**Neuro-MEP** digital system);
- Electroretinogram study;
- Otoacoustic emission study (**Neuro-MEP** digital system);

- Exam report generation;
- Preview, storage and print of the recorded traces, results of their analysis and exam reports.

1.2. Specifications

Table 1. Main Specifications.

Parameters	Values
Biopotentials Acquisition Channels	
Number of channels	4/8*
Sampling rate – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	 200 Hz–40 kHz 200 Hz–40 (160) kHz
A/D converter	16 bit
Voltage range	20 μ–50 mV
Ratio error of voltage measurement: – in the range from 20 up to 100 μV – in the range from 0.1 up to 50 mV	 within ±15% within ±5%
EP voltage range at averaging	0.1–400 μV
Ratio error of EP voltage measurement at averaging	within ±10%
Common-mode rejection	not less than 100 dB
Noise level, rms	not more than 0.5 μV
Input impedance	not less than 200/1000** MΩ
Amplifiers input capacitance	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 – in the band 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 – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	 0,05; 0,1; 0,2; 0,5; 1; 2; 5; 10; 20; 50; 100; 200; 500 μV/div; 1; 2; 5; 10; 20; 50 mV/div. 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.
Ratio error of sensitivity	within ±5%

Table 1. Continued.

Parameters	Values
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.
Ratio error of sweep speed	within ±1%
Suppression ratio of power frequency by notch filter	not less than 40 dB
Electrical Stimulator	
Stimulus amplitude	0.1–100 mA
Absolute deviation of stimulus amplitude	±0.1 mA
Stimulus duration – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	 50 – 5000 µs 100 – 50000 µs
Absolute deviation of stimulus duration	±5 µs
Stimulus frequency at repetitive stimulation – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	 0.05–50 Hz 0,01–100 Hz
Relative deviation of stimulus frequency during repetitive stimulation	within ±1%
Interstimuli interval at paired stimulation – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	 10–5000 ms 10–100000 ms
Burst stimulation: – pulse frequency • if you use Neuro-MEP software • if you use Neuro-MEP.NET software – maximal burst duration • if you use Neuro-MEP software • if you use Neuro-MEP.NET software	 does not support 40–1000 Hz does not support 50 ms
Auditory Stimulator	
Number of channels	2 (right and left)
Stimulation level	0–127 dB SPL (TA-01) 0–130 dB SPL (TDH-39)
Stimulus frequency – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	 0.05–30 Hz 0.01–100 Hz
Relative deviation of stimulus frequency	within ±1%
Stimulus duration – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	 100–50000 µs 50–90000 µs
Relative deviation of stimulus duration	within ±15%
Left/right/double-sided stimulation	yes

Table 1. Continued.

Parameters	Values
Photic Stimulator	
Maximum brightness of: – LED goggles – mini-ganzfeld stimulator	(1100 ± 110) cd/m2 (1500 ± 150) cd/m2
Maximum luminescence power of: – white penlight – red penlight – blue penlingt – 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 – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	0.1–50 ms 0.05–1500 ms
Relative deviation of stimulus duration	within ±10%
Stimulus frequency – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	0.05–100 Hz 0.01–100 Hz
Relative deviation of stimulus frequency	within ±1%
Left/right/double-sided stimulation by LED goggles	yes
Pattern Stimulator	
Stimulation frequency – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	0.1–5 Hz 0.1–5 Hz
Relative deviation of stimulation frequency	within ±10%
Pattern resolution: – standard stimulator – high resolution stimulator	320×240 pixels, 15 colors 800×600 pixels, 16 millions of colors
OAE Probe	
Stimulus intensity – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	0–80 dB does not support
Absolute deviation of stimulus intensity	within ±3 dB
Stimulus duration – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	100–50000 μs does not support
Relative deviation of stimulus duration	within ±15%
Stimulus frequency – if you use **Neuro-MEP** software – if you use **Neuro-MEP.NET** software	0.05–50 Hz does not support
Relative deviation of stimulus frequency	within ±15%
Receiver bandpass flatness: – from 500 up to 2500 Hz – from 2500 up to 4500 Hz	not more than 10 dB not more than 20 dB

Table 1. Continued.

Parameters	Values
Microphone bandpass flatness: – in the band from 500 up to 4500 Hz	not more than 6 dB
General Parameters and Characteristics	
Interface	USB
Supply voltage: – Electronic units – 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 – Electrical stimulator control unit	 190×140×50 mm 155×105×40 mm 155×105×40 mm
Weight: – Amplifier unit – Auditory-visual stimulator unit – Electrical stimulator control unit	 not more than 1 kg not more than 0.5 kg not more than 0.5 kg
Safety	BF type

** if two 4-channel amplifier units are used (**Neuro-MEP-8** digital system).*
*** if amplifier unit with NSFT 006201.012 and higher is used.*

Safety and Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is provided by IEC 60601-1-2:2007 requirements fulfillment.

The digital system is intended for operation in electromagnetic environment, which special features are specified in Appendix 1.

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

The use of the equipment not listed in tables 2 and 3 of the present technical manual may result in increased emission and system decreased immunity.

As for safety, the digital system satisfies IEC 60601-1:1988 + A1:1991 + A2:1995, IEC 60601-1-1:2000 and IEC 60601-2-40:1998 requirements. The electronic unit is supplied by regulated power supply through USB interface, it has double isolation and BF type work parts according to IEC 60601-1.

Interpretation of Symbols on Electronic Units:

 – Attention: consult user and technical manuals.

 – Work parts of BF type according to IEC 60601-1.

– Mark of conformance to Russian standards requirements GOST R.

– Mark of measuring device with approved type.

0535 – Mark of conformance to 93/42/EEC “Concerning Medical Devices” directive.

– Mark of conformance to 2002/96/EC “On waste electrical and electronic equipment (WEEE)” directive.

1.3. Delivery Set

The delivery sets of **Neuro-MEP-4**, **Neuro-MEP-8**, **Neuro-ERG** digital systems include the electronic units of an amplifier, electrical stimulator and auditory-visual stimulator, patient button, footswitch, dedicated keyboard and software, which can be delivered to the customer both jointly and separately, and also components and bought articles. The delivery sets depending on the functional variant are represented in the Table 2 and Table 3.

The Table 2 and Table 3 include the following:

1. **Neuro-MEP-4** digital EMG and EP system;
2. **Neuro-MEP-8** digital EMG and EP system;
3. **Neuro-MEP-4** digital EMG and EP system (**Neuro-MEP-4/S** delivery set)
4. **Neuro-MEP-8** digital EMG and EP system (**Neuro-MEP-8/S** delivery set)
5. **Neuro-ERG** digital ERG system.
6. **Neuro-MEP-4** digital EMG and EP system (**Neuro-EMG** delivery set)
7. **Neuro-MEP-4** digital EMG and EP system (**Neuro-EP** delivery set)

Table 2. Base Delivery Set

Name	**Document code or main specifications**	**Number, pcs.**				
		1/2	**3/4**	**5**	**6**	**7**
Neuro-MEP amplifier unit	NSFT 006201.012	1/2	1/2	1	1	1
Neuro-MEP auditory-visual stimulator unit	NSFT 025201.010	1	1	1	-	1
Neuro-MEP electrical stimulator control unit	NSFT 024201.017	1	1	-	1	1
Holder	NSFT 016201.038 NSFT 016201.038-01	1	1	1	1	1
Cleat for 2 amplifier units fixation on holder	NSFT 006200.003	-/1	-/1	-	-	-
Holder fastener	NSFT 006200.002	-/1	-/1	1	1	1

Table 2. Continued.

Name	Document code or main specifications	Number, pcs.				
		1/2	**3/4**	**5**	**6**	**7**
Holder for dedicated keyboard	NSFT 035221.001	1	-	-	1	-
Electrode holder	NSFT 016221.023	1	1	1	1	-
Patient button	NSFT 028201.006	1	1	-	-	1
Footswitch	NSFT 028353.004 NSFT 028353.003	1	-	-	1	-
USB cable (A→B) reinforced	NSFT 007103.005-01	2	2	1	1	2
USB cable (A→B) standard	1.8 m	1	-	-	1	-
SVGA extension cable	3 m	1	1	1	-	1
Auditory stimulator for EP (headphones)	NSFT 032305.005 (TDH-39) NSFT 032305.001 (TDH-01)	1	1	-	-	1
Visual stimulator (LED goggles)	NSFT 005302.001	1	1	1	-	1
Loudspeaker	Edifier R18USB (2×1.2W, wood, wired remote control, USB)	2	2	-	2	-
Bluetooth adapter	Dongle 100 m Class 1, V2.1, CSR chipset	1	-	-	1	-
Electrode gel [1)]	TC 9398-005-76063983-2005, 250 g	1	1	-	1	1
Electrode adhesive paste [1)]	TEN20, 114 g	1	1	1	1	1
	TC 9398-007-76063983-2005, 120 g					
Abrasive paste for skin preparation [1)]	Everi (Italy)	1	1	1	1	1
Medical tape [1)]	Transpore (3M Company, 3M Health Care, USA)	1	1	1	1	1
Set of Electrodes and Accessories for EMG and EP Studies						
Stimulation bar electrode with replaceable steel and felt stimulation pads (adult) [1)]	TC 9442-990-13218158-2008 (NSFT 990998.009 (SBE-2)	1	1	-	1	1
Adjustable electro stimulating probe	NSFT 056998.001 (AESP-1)	1	-	-	1	-
Stimulation electrode with steel stimulation points (adult) [1)]	TC 9442-990-13218158-2008 (NSFT 990106.019-25 (SSE-2))	-	1	-	-	-
Cup EP electrode with cable [1)]	NSFT 990998.023 (set)	-	-	1	-	-
	NSFT 990998.023 (set)	1/2	1/2	-	1	1
	NSFT 990106.029-01.10 (EEP-2) NSFT 990106.072-01.10 (EEP-2)	8/16 pcs.	8/16 pcs.	5 pcs.	8 pcs.	8 pcs.

Table 2.Continued.

Name	Document code or main specifications	Number, pcs.				
		1/2	**3/4**	**5**	**6**	**7**
Ring electrode (wide) with cable [1)]	TC 9442-990-13218158-2008 (NSFT 990998.004 (RE-2))	1	1	-	1	-
Ground electrode with cable (pediatric) (250 mm) [1)]	TC 9442-990-13218158-2008 (NSFT 990998.007 (GE-1))	1	1	-	1	-
Ground electrode with cable (adult) (400 mm) [1)]	TC 9442-990-13218158-2008 (NSFT 990998.006 (GE-2))	1	1	-	1	-
Bar electrode (adult) [1)]	TC 9442-990-13218158-2008 (NSFT 990998.003 (BE-2))	2[2)]	2[2)]	-	2[2)]	-
Bar electrode (pediatric) [1)]	TC 9442-990-13218158-2008 (NSFT 990998.002 (BE-1))					
Surface electrode [1)]	TC 9442-990-13218158-2008 (NSFT 990998.001 (SE-1))	2	2	-	2	-
Reusable concentric needle electrode	Alpine Biomed Corp. (Denmark) 20, 30, 40 and 65 mm	2	2	-	2	-
Adapter for reusable needle electrode connection	NSFT 006103.009	1	1	-	1	-
Disposable concentric needle electrode	Alpine Biomed Corp. (Denmark) 25, 37, 50 and 75 mm	25	25	-	25	-
Adapter for disposable needle electrode connection	NSFT 006103.013	1	1	-	1	-
Disposable surface electrode	F 3001, FIAB (Italy)	1 pack	1 pack	-	1 pack	-
Adapter for disposable electrodes connection with Alligator clip (red, black)	NSFT 990103.027-03.02 NSFT 990103.022-03.02	2	2	-	2	-
	NSFT 990103.027-04.02 NSFT 990103.022-04.02	2	2	-	2	-
Pup-jack linker	NSFT 006103.019	2/5	2/5	1	2	1
Measuring reel	1 m	1	1	-	1	-
Marker	Red	1	1	-	1	-
Set of Accessories for ERG Studies Neuro-ERG						
Corneal “loop” electrode	NSFT 006106.005	-	-	25	-	-
Corneal “hook” electrode	NSFT 006106.004	-	-	5	-	-
Adapter for corneal electrode connection	NSFT 006103.011	-	-	2	-	-
Ear EEG electrode	TC 9442-016-13218158-2003 (NSFT 015106.015)	-	-	2	-	-
Cable for bridge or ear EEG electrode	NSFT 990103.036-01.10	-	-	2	-	-
Forehead and chin support assembly	NSFT 016998.004	-	-	1	-	-
Set of visual stimulators “penlights” (red, blue, green, white)	NSFT 006302.004	-	-	1	-	-
Mini-ganzfeld stimulator	NSFT 025302.001	-	-	1	-	-
Assembled holder for LED penlights and mini-ganzfeld stimulator	NSFT 025201.012	-	-	1	-	-
Ophthalmologic conductive gel [1)]	TC 9398-013-76063983-2006	-	-	1	-	-

Table 2. Continued

Name	**Document code or main specifications**	***Number, pcs.***				
		1/2	*3/4*	*5*	*6*	*7*
Software on CD						
Neuro-MEP.NET software	with Neuro-MEP.NET/ERG module	-	-	2	-	-
	with Neuro-MEP.NET/EP module	2	2	-	-	2
	with Neuro-MEP.NET/EMG module	2	2	-	2	-
Computer and Electronic Equipment						
Monitor (for pattern-stimulation)	LCD 19”	1	1	1	-	1
USB hub	NSFT 042999.002 **KM-7, KM-7-2**	1/2	1	1	1	1
Isolation transformer TM-630[3)]	TC 3413-004-13218158-2010 (NSFT 036999.001) TM-630M	1	-	1	1	-
Operational Documentation						
Neuro-MEP and **Neuro-ERG** technical manual	TM006.01.005.003	1	1	1	1	1
Neuro-MEP.NET (version 3) user manual	UM006.03.003.000	1	1	1	1	1
Workbook “EMG Studies Performing on Digital EMG and EP Systems Manufactured by Neurosoft Ltd.”	WB006.03.001.000	1	1	1	1	-
DK-01 technical manual	TM035.01.001.001	1	-	-	-	-
Exams Manager appendix to user manual	AU999.01.002.003	1	1	1	1	1
Package						
Transportation bag	-	1	1	1	1	1
Cardboard package (set)	-	1	1	1	1	1

Notes:
[1)] The accessories and consumables of analogous types can be used if their application is permitted in the country.
[2)] All the computer equipment must correspond to IEC 60950 and CISPR 22 for B class.
[3)] The supply with other isolation transformer or hub corresponding to IEC 60601-1 is allowed.

Table 3. Optional Equipment, Accessories and Software

Name	**Document code or main specifications**	**Number, pcs.**		
		1/2	**3/4**	**5**
Dedicated keyboard	NSFT 035201.005 (DK-01)	-	1	1
Holder for dedicated keyboard	NSFT 035221.001	-	1	1
Footswitch	NSFT 028353.004 NSFT 028353.003	-	1	-

Table 3. Continued.

Name	Document code or main specifications	Number, pcs.		
		1/2	3/4	5
Temperature sensor	NSFT 039351.003	1	1	-
Tendon hammer	NSFT 040356.001	1	1	-
Set of Accessories for High Resolution Pattern-Stimulator				
Adapter for high resolution pattern-stimulator connection	NSFT 033201.003	1	1	1
Video card	Nvidia PCI-E	1	1	1
Set of Electrodes and Accessories for EMG and EP Studies				
Stimulating bar electrode with replaceable steel and felt stimulation pads (pediatric) [1)]	TC 9442-990-13218158-2008 NSFT 990998.008 (SBE-1)	1	1	-
Stimulation electrode with steel stimulation points (pediatric) [1)]	TC 9442-990-13218158-2008 NSFT 990106.018-25 (SSE-1)	1	1	-
Ring electrode (narrow) with cable [1)]	TC 9442-990-13218158-2008 NSFT 990998.005 (RE-1)	1	1	-
Ground electrode (adult) with cable (700 mm) [1)]	TC 9442-990-13218158-2008 NSFT 990998.015 (GE-3)	1	1	-
Adapter for disposable electrodes connection with Alligator clip (green)	NSFT 990103.027-02.10 NSFT 990103.022-02.10	1	1	-
Adapter for EP recording	NSFT 990103.030-10	1	1	1
Adapter for earphones for audiometry	NSFT 032103.004	1	1	1
Set of Accessories for ERG Studies Neuro-ERG				
Corneal “loop” electrode	NSFT 006106.005	25	25	-
Corneal “hook” electrode	NSFT 006106.004	5	5	-
Adapter for corneal electrode connection	NSFT 006103.011	2	2	-
Ear EEG electrode	TC 9442-016-13218158-2003 (NSFT 015106.015)	2	2	-
Cable for bridge or ear EEG electrode	NSFT 990103.036-01.10	2	2	-
Forehead and chin support assembly	NSFT 016998.004	1	1	-
Set of visual stimulators “penlights” (red, blue, green, white)	NSFT 006302.004	1	1	-
Mini-ganzfeld stimulator	NSFT 025302.001	1	1	-
Assembled holder for LED penlights and mini-ganzfeld stimulator	NSFT 025201.012	1	1	-
Ophthalmologic conductive gel (7 g) [1)]	TC 9398-002-34616468-2002	1	1	-
Accessories for Poly-Spectrum-Rhythm/MEP:				
Tonometer [1)]	TC 9441-015-27418804-2007	1	1	-
Handgrip dynamometer [1)]	TC 64-1-3842-84	1	1	-

Table 3. Continued.

Name	Document code or main specifications	Number, pcs.		
		1/2	3/4	5
Manometer with attachment for Valsalva maneuver	NSFT 003359.001	1	1	-
Mouthpiece	NSFT 003204.002	1	1	-
Cable for one ECG channel (3 wires)	NSFT 007103.016	1	1	-
Reusable limb clamp ECG electrode [1)]	F 9024 SSC (FIAB, Italy)	1	1	-
Set of Accessories for OAE Studies Neuro-OAE				
OAE probe[2)]	NSFT 006355.003-02 (OAE-02-1)	1	1	-
	NSFT 006355.003-03 (OAE-02-1)			
OAE probe tip	ER10D-RPT	3	3	-
	NSFT 006221.001			
Adapter for OAE probe	NSFT 006103.024	1	1	-
Set of OAE probe tips	ER100 – RPT	1	1	-
Set of ear tips (universal)	NSFT 007998.002	1	1	-
Dental floss for probe tip cleaning (50 pcs.)	Oral-B (Ireland)	1	1	1
Probe tip extractor	NSFT 006206.016	1	1	-
Software on CD				
Neuro-MEP.NET software module	with Neuro-MEP.NET/ERG and Neuro-MEP.NET/HRV modules	1	1	-
Neuro-Audio.NET software	with Neuro-Audio.NET/OAE module	1	1	-
Poly-Spectrum.NET software	with Poly-Spectrum.NET/Rhythm module	1	1	-
Computer and Electronic Equipment [3)]				
System unit [4)]	TC 4013-003-13218158-2011 • Elegant • Elite	1	1	1
Monitor	LCD 19”	1	1	1
Printer	Laser or jet	1	1	1
Portable computer	Minimum requirements are in according with user manual for software used with the system	1	1	1
Notebook PC special power unit	DIN EN 60601-1:2000 – for EC countries	1	1	1
Built-in USB hub [5)]	3.5”, 5”	1	1	1

Table 3. Continued.

Name	Document code or main specifications	Number, pcs.		
		1/2	3/4	5
Operational Documentation				
Neuro-Audio.NET user manual	UM032.01.005.000	1	1	-
"**DK-01**" technical manual	TM035.01.001.001	-	1	1

Notes:

[1)] *The accessories and consumables of the analogous types can be used if their application is permitted in the country.*
2) OAE probe NSFT 006355.003-02 is supplied with the OAE probe tip NSFT 006221.001 and OAE probe NSFT 006355.003-03 is supplied with the OAE probe tip ER10D-RPT.
3) All the computer equipment must correspond to IEC 60950 and CISPR 22 for B class.
4) It is allowed to supply system with another PC which performances are not lower that stated in the user manual for software used with the system.
5) If the digital system is supplied together with the personal computer, the USB hub is mounted to the system unit.

1.4. Arrangement and Operation

The digital system principle of operation is based on the recording and input of biopotentials of muscles and also peripheral nervous and central nervous system to computer with the purpose of its electrical activity analysis, including the response to the stimulus.

The functional scheme of the digital system is represented on Fig. 1.

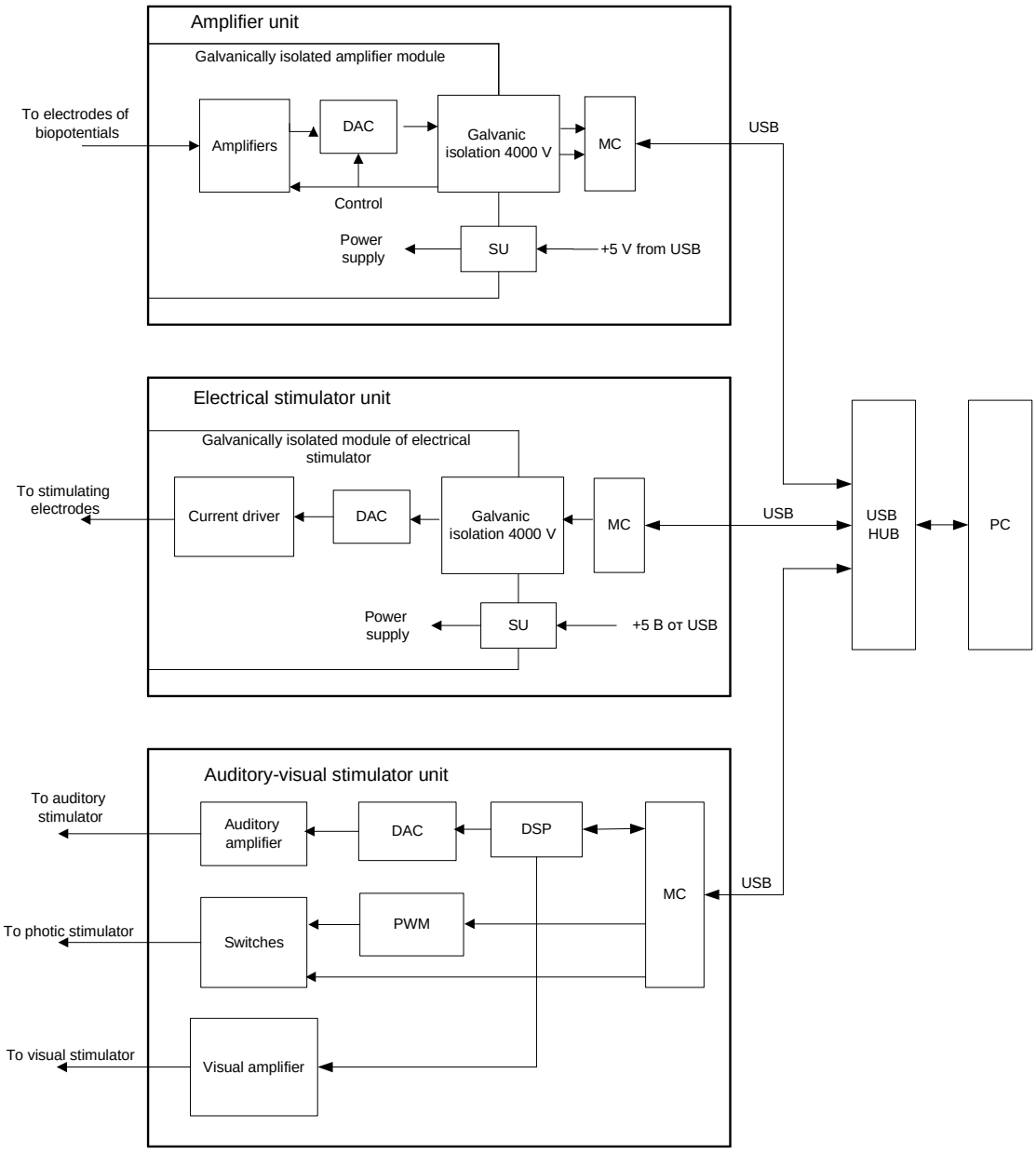

Fig. 1. The functional scheme of the digital system.

The function of the amplification and recording of the 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. amplifier module is done via the galvanically isolated direct-voltage transducer of the supply unit (SU).

The function of the electrical stimulation is performed by the electrical stimulator unit.

The microcontroller of the unit provides the connection with the computer via USB and generates the signal in the discrete form and supplies it to the digital-analog converter (DAC) via 4000 V galvanic isolation. The DAC transforms it to the analog form and the current driver generates the current pulse according to the specified form. The power supply of the galvanically isolated part of the electrical stimulator, i.e. electrical stimulator module is done via the galvanically isolated direct-voltage transducer of the supply unit (SU).

The functions of the auditory, photic and visual stimulation are performed by the electrical stimulator unit.

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 the set of the super-power LEDs for the separate stimulation of the left and right eye. The headphones can be used as an auditory stimulator and the video monitor as a visual stimulator.

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

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

1.5. Connectors and Indicators Function

The external views of the front and side panels of the amplifier unit are represented on the Fig. 2 and Fig. 3.

The front panel of the amplifier unit contains touchproof and DIN connectors to attach the electrodes and LED 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 glows green at the signal recording during the program operation.

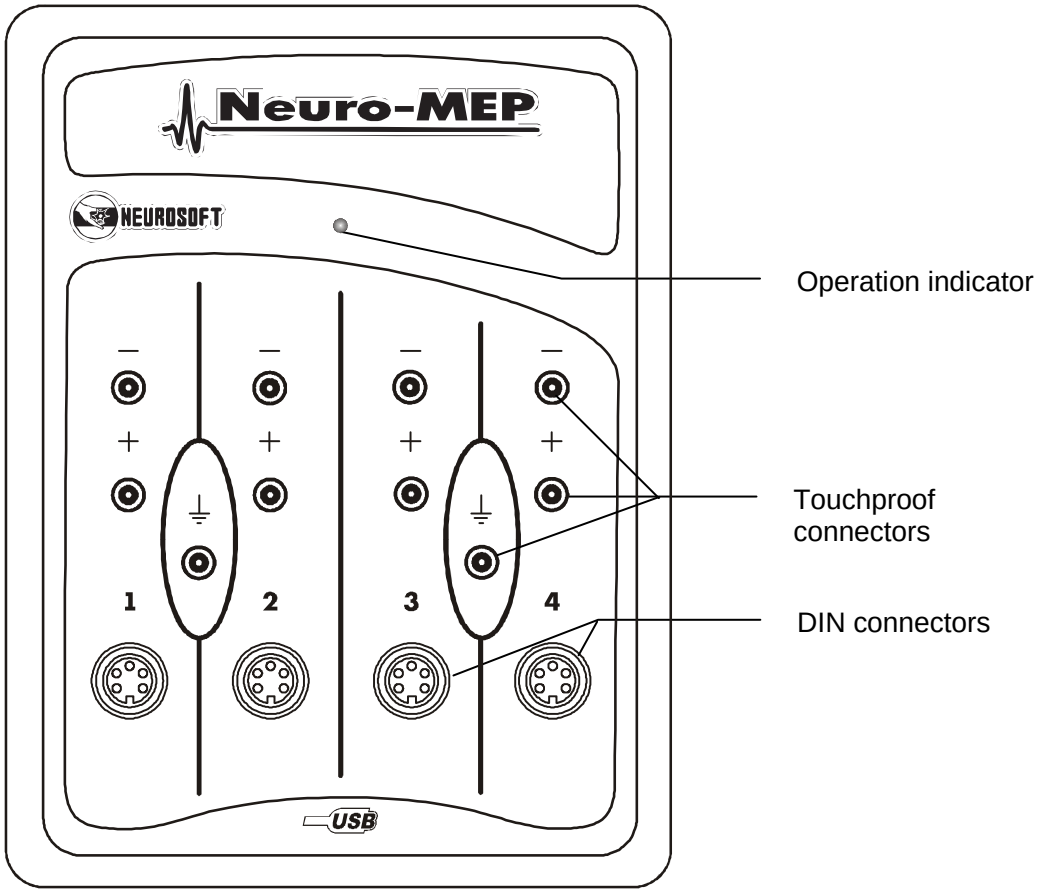

Fig. 2. The front panel of amplifier unit.

The top side panel of the amplifier unit contains USB cable to connect to computer PC and trigger input socket to connect the stimulators of third-party firms ⊖ (Fig. 3).

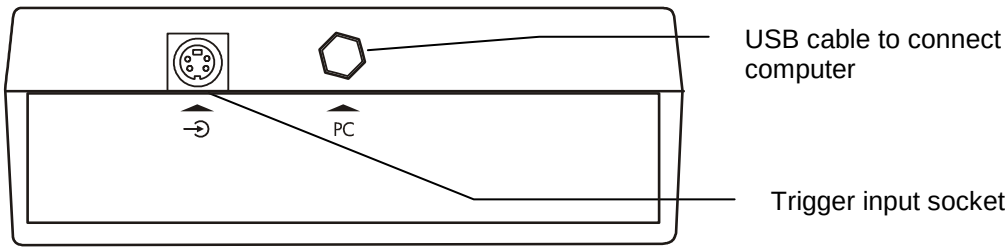

Fig. 3. The side panel of the amplifier unit.

The external views of the front and rear panels of the electrical stimulator are represented on the Fig. 4 and Fig. 5.

The front panel of the electrical stimulator unit contains the connector for the stimulating electrode attachment and LED operation indicator (Fig. 4). The operation indicator highlights yellow at the electronic unit connection to computer and highlights green at the signal recording during the program operation in the tests with the electrical stimulation.

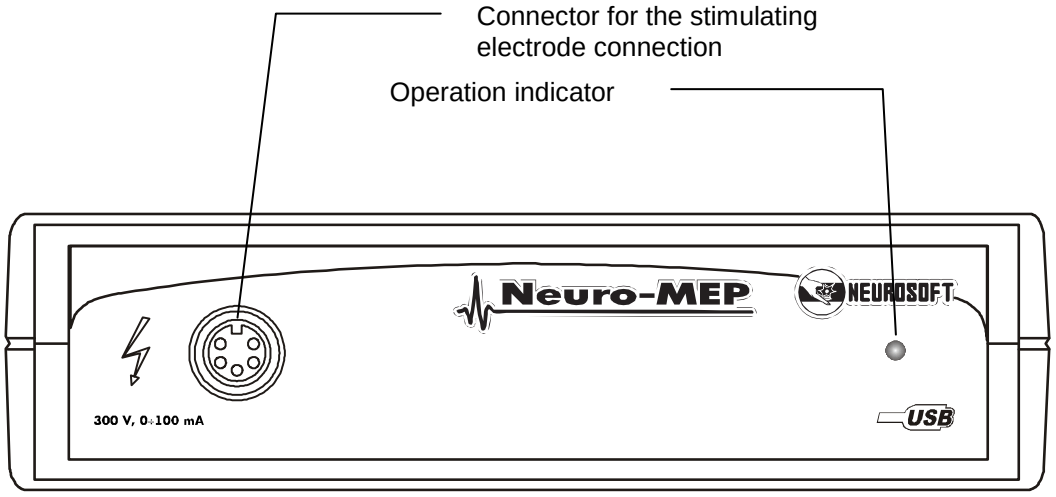

Fig. 4. The front panel of the electrical stimulator unit.

The rear panel of the electrical stimulator panel contains the USB cable connector (to attach to computer) and trigger output socket (Fig. 5).

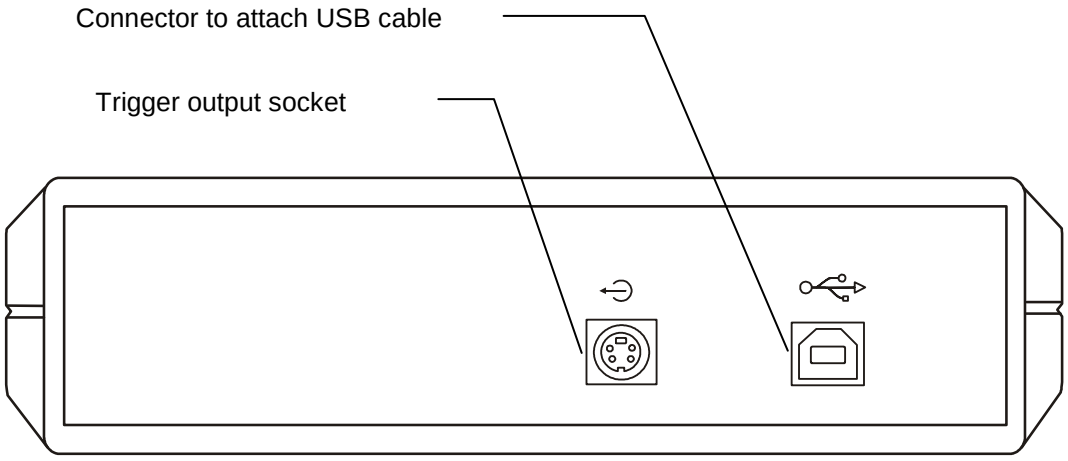

Fig. 5. The rear panel of the electrical stimulator unit.

The external views of the front and rear panels of auditory-visual stimulator unit are represented on the Fig. 6 and Fig. 7.

The front panel of the auditory-visual stimulator unit contains the connectors for the attachment of auditory stimulator (headphones) , visual stimulator (LED goggles or mini-ganzfeld) , multy-colored penlights and LED operation indicator (Fig. 6). The operation indicator highlights yellow at the electronic unit connection to computer and highlights green at the signal recording during the program operation in the tests with the visual or auditory stimulation.

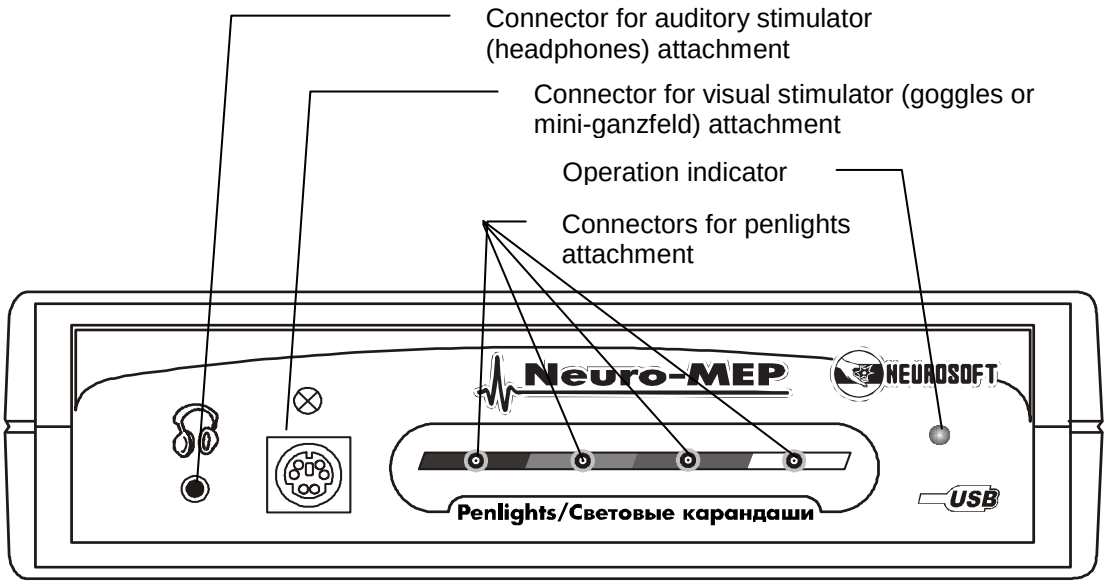

Fig. 6. The front panel of auditory-visual stimulator unit.

The rear panel of the auditory-visual stimulator unit contains the connector for USB cable attachment (to connect to computer) , the connector for reversal pattern monitor attachment and trigger output socket (Fig. 7).

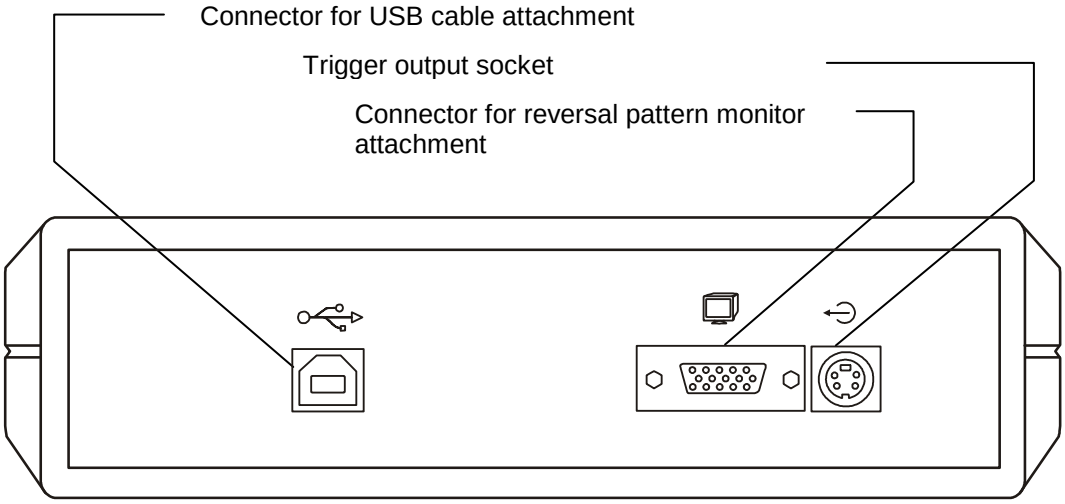

Fig. 7. The rear panel of the auditory-visual stimulator unit.

The digital system delivery set can include the USB hub KM-7. Read the information about the connectors and USB hub function and also operation with it in the corresponding technical manual.

1.6. Synchronization with Stimulators of Third-party Manufacturers

The trigger input socket is used for amplifier synchronization with other devices. It is located on the top side panel of the amplifier. The numeration of the socket pins is given on the Fig. 8, and the functions of these pins are described in the table (Table 4).

The devices attached to the trigger socket must have the protection class against the electrical shock according to GOST R 50267.0-92 (IEC 601-1-88).

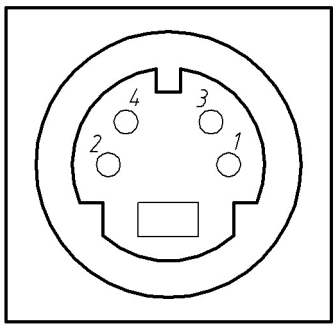

Fig. 8. The numeration of socket pins (view from the case outside).

Table 4. The Pin Functions

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

For the synchronization, it is required to supply the impulse of TTL level of the positive polarity (on the + SYNC output relative to 0V) (Fig. 9). The synchronization will occur by the pulse front with ±25 μs accuracy.

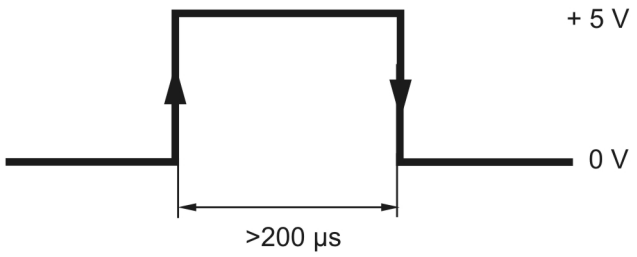

Fig. 9. The signal shape at the +SYNC output relative to 0V.

To synchronize the electrical stimulator and auditory-visual stimulator with other devices, the trigger output socket located on the side panels of these units, is used. The numeration of the socket pins is the same as on the amplifier.

When the trigger output is used, with each stimulus, generated by stimulators (electrical, auditory or visual one), 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.

1.7. Synchronization Use with Neuro-MEP.NET Software

The trigger output of external stimulators connected to the trigger input of an amplifier must be used in the following order:

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

2. Switch on the external stimulator power supply.

3. Run **Neuro-MEP.NET** software, execute **Setup|Tests templates|Setup** menu command, select the required test template, press “Change” button and check the “Third-party firm stimulator” check box on “Hardware|Stimulator” page (see Fig. 10). 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 perform the analogous settings in it.

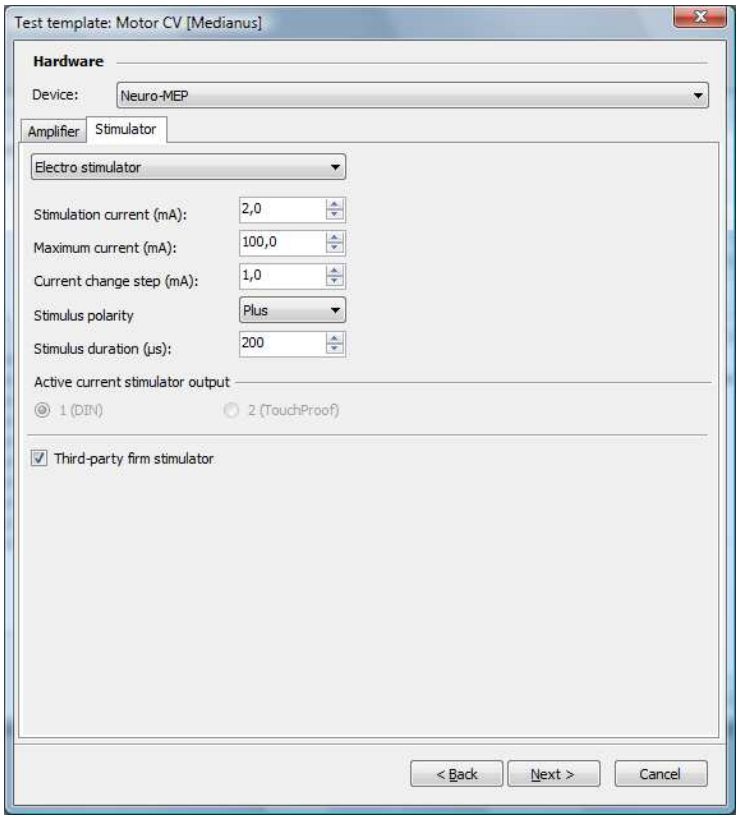

Fig. 10. The acquisition start window from external stimulator.

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. Use **Acquisition|Acquisition/stimulus** menu command. The device goes to 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 trigger input of external stimulators connected to the trigger output of **Neuro-MEP** stimulators must be used in the following order:

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** program.

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.

Keep in mind that the “Third-party firm stimulator” check box (Fig. 10) must not be checked!

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

2. Mounting and Setting

2.1. Personnel Requirements Conducting Mounting and Setting

The digital system mounting and setting should be carried out by the person who is empowered by the manufacturer or the technical personnel of the medical institution which is going to use it. It is necessary to remember that digital system mounting accuracy defines safety and quality of operation. Further mounting and setting requirements which define the product safety will be marked by bold and italic fonts in the text.

2.2. Room Selection and Placement

Before mounting and setting of digital system, it is necessary to select a place for it, taking into consideration power wiring and protective ground in the room. Please, read and respect the following requirements and recommendations:

Requirements concerning the room selection and equipment placement:

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

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

- ***The patient environment (within 1.5 meters) should contain only the electronic units being the medical device with the required safety level. The fact is that the safety level of the computer equipment is insufficient for the use in the patient environment. Hence, a patient must not contact with the metal parts of computer equipment cases and the personnel must not touch simultaneously these parts and patient body. The computer equipment used in the system should correspond to IEC 601-1-88 or be connected via the isolation transformer (specialized power supply unit – for notebook PC) corresponding to above-mentioned requirements.***

Requirements to mains:

- ***The use of electric mains in which the neutral conductor and protective ground are combined 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 digital system setting, the electrician must check the quality of standard tripolar sockets and the integrity of the protective ground circuit.***

- ***In case of digital system components connection to the several three-pole sockets, it is necessary to make sure that they are grounded on the one and the same ground loop. If this requirement is not followed, the leakage of electrical current equaling to several tens of milliamperes by the connection cables of the digital system can occur. It can lead to the equipment failure.***

The typical schematics of the equipment location when connecting to the desktop PC and notebook PC are given below (Fig. 11, Fig. 12).

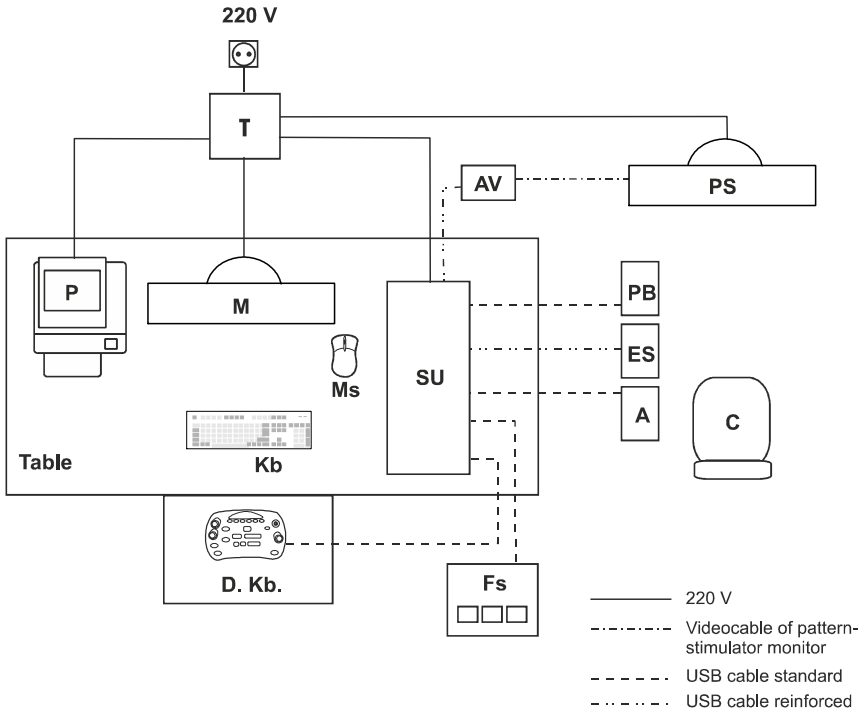

Fig. 11. Digital system placement sample when connecting to desktop PC (see explanation below).

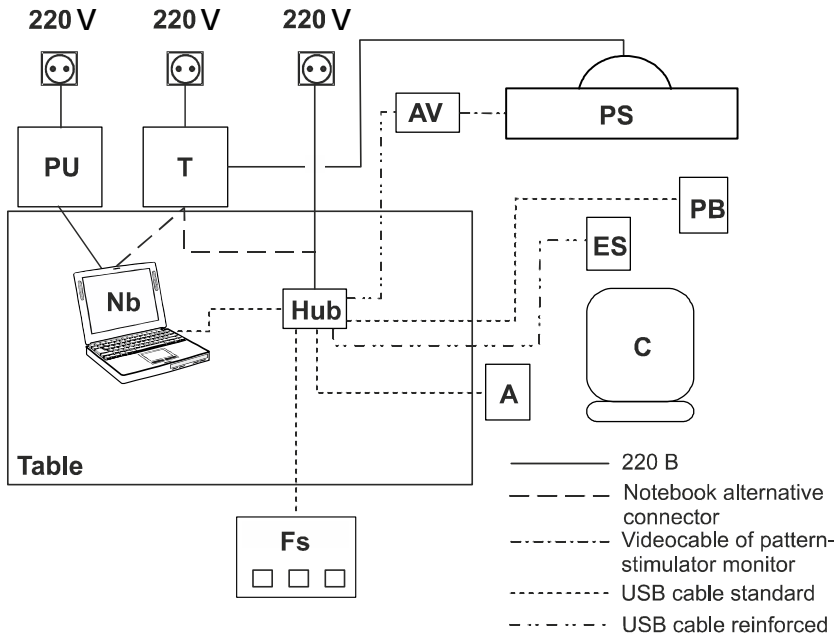

Fig. 12. Digital system placement sample when connecting to notebook PC (see explanation below).

The following abbreviations are used on the figures:

- A – amplifier;
- AV – auditory-visual stimulator;

- C – patient couch;
- D. Kb. – dedicated keyboard;
- ES – electrical stimulator;
- Fs – footswitch;
- Hub – KM-7 external USB hub or the analogous one according to GOST R 50267.0-92 (IEC601-1-88). The connection of the USB hub to the mains is performed according to the Fig. 12.
- Kb – keyboard;
- M – monitor;
- Ms – mouse;
- Nb – notebook PC;
- P – printer;
- PB – patient button;
- PS – pattern-stimulator monitor;
- PU – notebook PC power unit which corresponds to DIN EN 60601-1:2000 for EC countries;
- SU – system unit;
- T – isolation transformer which corresponds to DIN EN 60601-1:2000 for EC countries;

2.3. Unpacking and Check of Delivery Set

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

Unpack the box and take out the digital system components. Check the delivery set correspondence to the packing report for the medical equipment.

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

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

2.4. Mounting and Connection to Computer

If you purchase the digital system together with the computer (PC), the equipment is delivered with installed and configured software. If you purchase the digital system separately, please install the software from the compact disk (included in the delivery set) to computer. The software ***must*** be installed ***before*** the first connection of digital system to the computer. Study carefully the corresponding paragraph of the user manual before starting to work.

The digital system consists of several units; each of them has to be attached to USB connector of PC. An amplifier, an electrical stimulator, an auditory-visual stimulator, a patient button, footswitch and a dedicated keyboard are shown in Fig. 13. The devices can be connected either directly or using external USB-hub “KM-7” or analogous one. The use of passive USB-hubs that are not connected to the mains as a part of digital system is prohibited strongly. Remember that the amplifier, the stimulators (electrical, auditory-visual, magnetic, tendon hammer) and the patient button ***must*** be attached to the same USB controller, that is to the same USB-hub or to the alongside USB connectors or to several USB-hubs attached to the same USB controller. The footswitch and the dedicated keyboard can be attached to any USB connectors or USB-hub. The connection to USB connectors on the PC monitor and keyboard does not ensure the correct device operation.

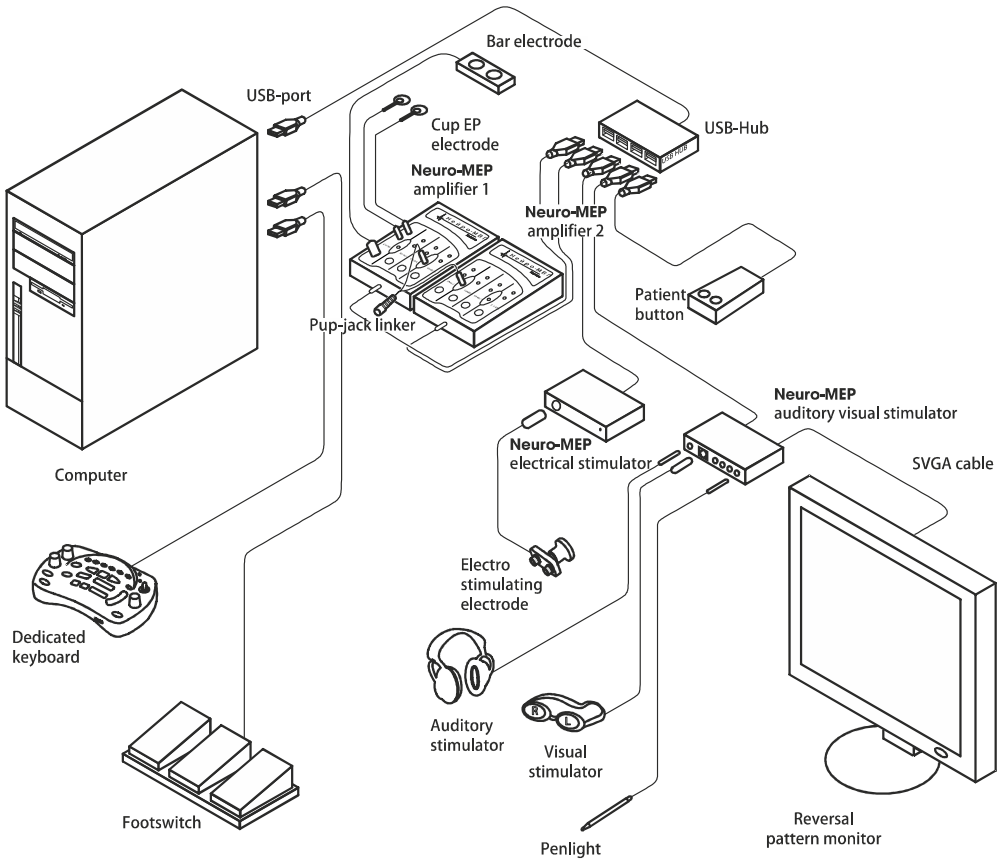

Fig. 13. The digital system connection to computer.

The delivery set depends on the delivery set variant. For example, the equipment variant, shown on the Fig. 14, consists only of an amplifier and an electrical stimulator and allows to carry out the EMG study and recorder somatosensory EP.

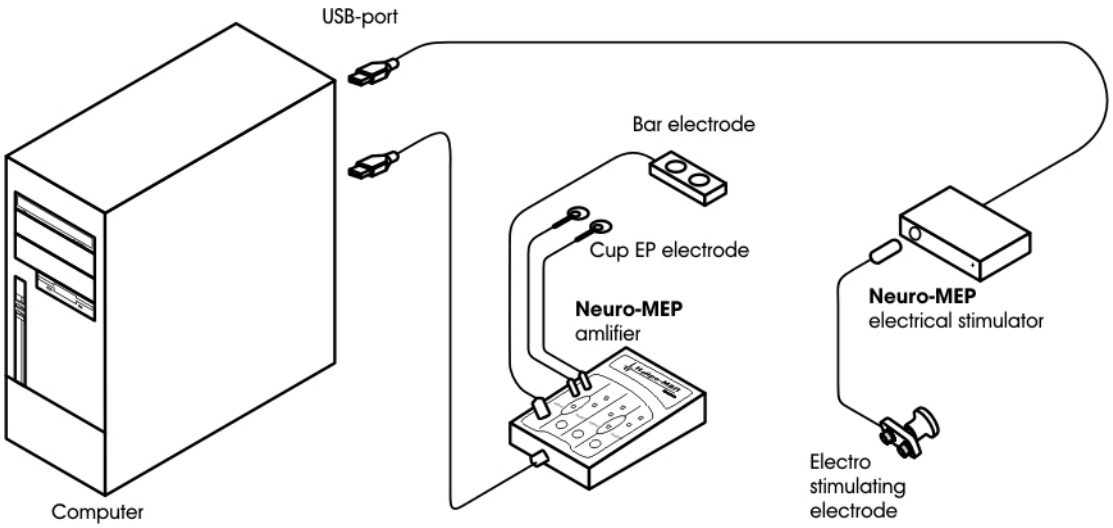

Fig. 14. The digital system connection to computer (variant).

An 8-channel version of the device is supplied with two 4-channel amplifiers. The program states that channels from 1 to 4 are in the amplifier with a lesser series number, channels from 5 to 8 – in the amplifier with greater series number. Both amplifiers should be connected to one USB-hub. When using 2 amplifiers, please, bear in mind that both connectors of ground electrodes are separated from each other and are to be connected by the pup-jack linker.

If the delivery set includes ganzfeld-stimulator, it can be connected to auditory-visual stimulator connector which is usually used for the visual stimulator connection (LED goggles) (Fig. 13).

The order of mounting of an arm for ganzfeld-stimulator and LED penlights fixation is given on the Fig. 15.

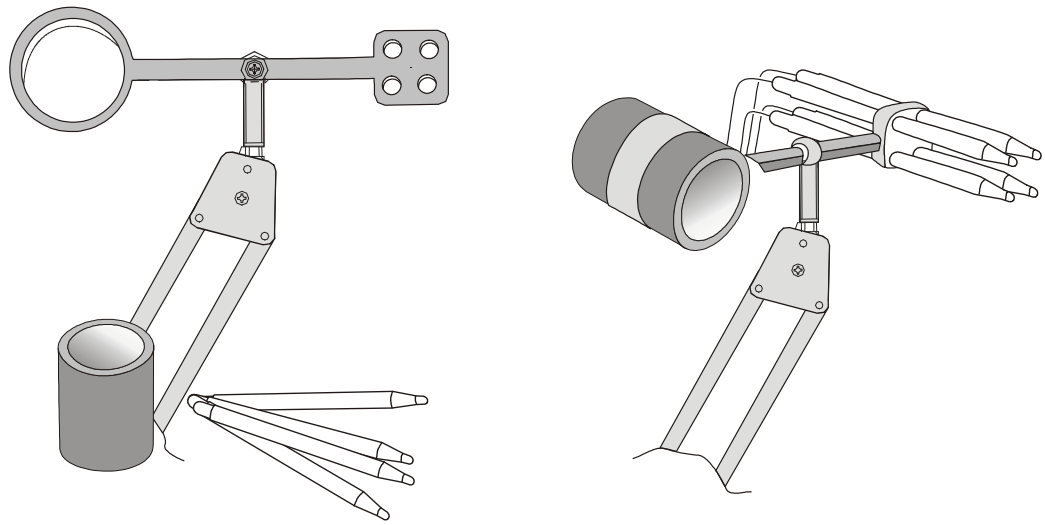

Fig. 15. Ganzfeld-stimulator and LED penlights.

If the temperature sensor is included in the delivery set, connect it to any available USB connector of PC.

Depending on the delivery set variant, the device may be supplied with high-resolution reversal pattern (800×600, 16 million of colors) instead of the standard reversal pattern (320×240, 2 of 15 colors). At that VGA card with VGA and DVI outputs is installed into the computer. The secondary monitor, connected through the special adapter (Fig. 16), is used as reversal pattern.

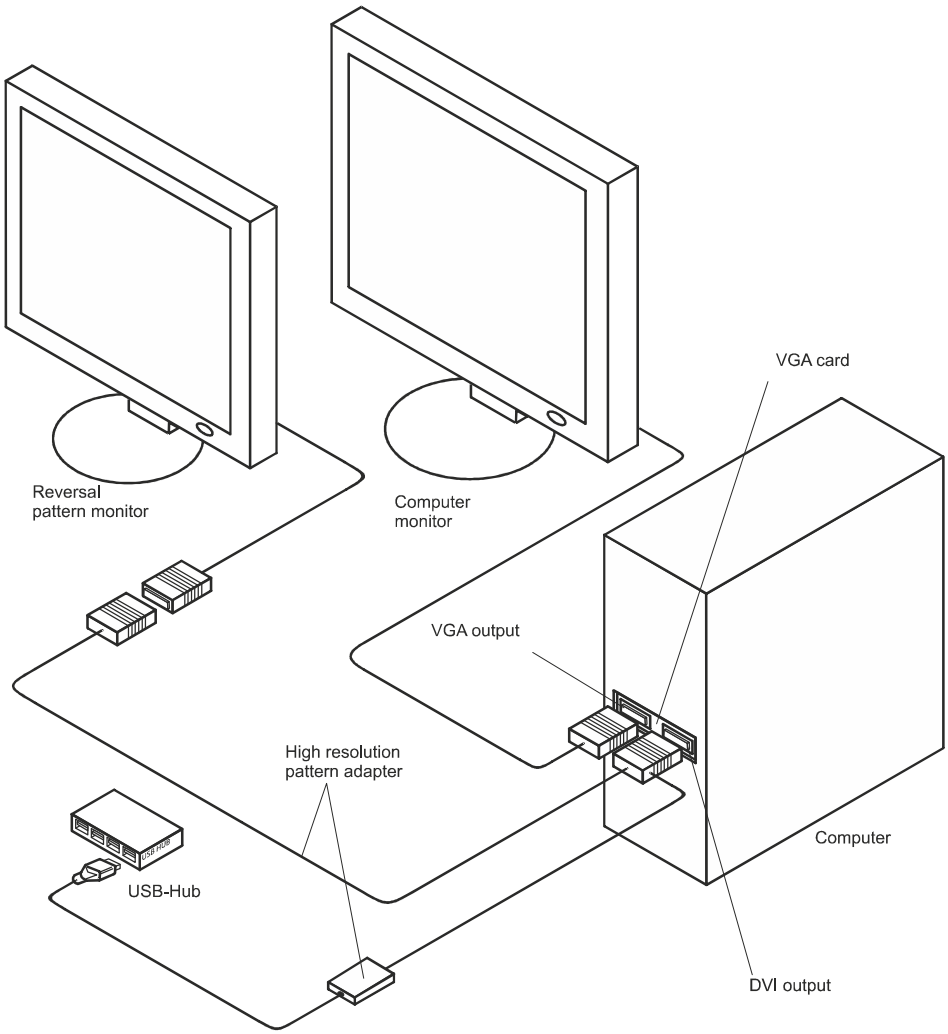

Fig. 16. High-resolution pattern adapter connection.

The high-resolution pattern adapter is to be connected to computer USB-port or USB hub (the digital system amplifier should be connected to the same USB-port or USB hub).

Windows desktop is to be extended to the second monitor. It is recommended to set 32-bit color rendition on both monitors. For the proper work of the reversal high-resolution pattern monitor it is necessary to install ***DirectX 9.0c***. Microsoft provides this software package free of charge.

Place the holder as near as possible to the place of checkup 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. If the window shown in the

Fig. 17 appeared after the digital system connection, press Next > button, ***without inserting the installation disk***.

Fig. 17. The window of new equipment wizard.

If the message such as “Device has not been tested on the Windows XP compatibility” appears, press the “Anyway continue” button.

The ground cable as a third cable should be connected to the mains to which the computer is connected. Please, remember that the quality of registered signals, especially with low amplitude (evoked potentials), depends on the ground safety.

3. Proper Use

3.1. Safety Measures When Using Digital System

To provide safety measures and exclude the possibility of medical staff' or patient' electric trauma, the medical staff is PROHIBITED:

- To use digital system, mounting and setting of which was done incorrectly, without following this manual instructions.
- To connect digital system and surgical HF equipment to the patient (it can cause patient's flash-burn in the places of electrode placement and digital system damage).
- To connect any products, which are not included in digital system delivery set, to the electrode jacks.
- To eliminate faults by opening of the components included in the delivery set.
- To provide exams when the electronic unit box, computer or other devices comprising digital system are opened.
- To connect patient electrodes to ***protective ground*** or other conducting surfaces.

When using digital system electrical stimulator, it is necessary to keep the following precautions:

- The patient with ***implanted electronic device*** (for example, cardio pacemaker) should not be influenced by the electrical stimulation.
- Trans-thoracic passing of stimulation current as a result of stimulating electrodes placement is forbidden.
- For elimination of patient's flash-burn in the places of stimulating electrode setting, it is necessary to provide the reliable "electrode – skin" contact by felt pads wetting.

3.2. Setting-Up Procedures

Operating Limitations:

- Ambient temperature is from +10 to +35°C.
- Relative humidity is to 80% at +25°C temperature.
- Atmospheric pressure is (760±30) mmHg.

Before power supply switching make sure that digital electronic unit and computer equipment cases have no apparent mechanical failures which can represent a danger.

Power Supply Switch on and Digital System Test

Digital system power supply switch on is done by pressing the “Power” key of your PC. The electronic unit has no power supply switch and is constantly connected to PC. Power supply switch on occurs after PC operational system loading and **Neuro-MEP.NET** program start.

3.3. Troubleshooting

If you have any problems with the digital system, first of all, check the PC connection, and if it is connected through USB hub, than the connection of USB hub to PC and mains supply. The use of passive USB hubs that is the USB hubs which are not connected to mains supply is prohibited.

The list of some possible troubles and the ways of their removal is given in Table 5.

Table 5. Possible Troubleshootings

Trouble Symptom	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 again in several seconds. If it doesn’t work, reload the computer.
The program message: *“Connection error: **Neuro-MEP-4** is not connected or in disrepair”.*	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 again in several seconds. If it doesn’t work, reload the computer.
The program message: *“Connection error: **Neuro-MEP-4** is already used by another program”.*	The other program using the digital system is opened (for example, second copy of **Neuro-MEP.NET** or **Neuro-MEP** program).	End other programs using the digital system. If you can’t find such a program, reload the computer.

Continuation of Table 5

Trouble Symptom	Cause	Way of Removal
The program message: *"**Neuro-MEP-4** amplifier disconnection error". End the program, disconnect the amplifier from the computer and connect again in several seconds".*	Amplifier disconnection error.	End the operating program, disconnect the amplifier from the computer (USB-hub) and connect again in several seconds. If it doesn't work, reload the computer.
The program message: *"The stimulators are not found. The signal registration is impossible".*	None of stimulators is connected to the computer.	Connect all the necessary stimulator to the computer. If the stimulators are connected, disconnect them and connect again in several seconds. If it doesn't work, reload the computer.
The program message: *"Connection error: **Neuro-MEP** electrical stimulator is not connected or in disrepair".*	Electrical stimulator is not connected to the computer.	Check whether the stimulator is connected. If there are no connection errors, disconnect the stimulator from the computer and connect again in several seconds. If it doesn't work, reload the computer.
The program message: *"Connection error: **Neuro-MEP** electrical stimulator is already used by the other program".*	The other program using the stimulator is opened (for example, second copy of **Neuro-MEP.NET** or **Neuro-MEP** program).	End other programs using the stimulator. If you can't find such a program, reload the computer.
The program message: *"**Neuro-MEP** electrical stimulator disconnection error". End the program, disconnect the stimulator from the computer and connect again in several seconds".*	Stimulator disconnection error.	End the operating program, disconnect the stimulator from the computer (USB-hub) and connect again in several seconds. If it doesn't work, reload the computer.

Continuation of Table 5

Trouble Symptom	Cause	Way of Removal
The program message: *"The connection error: auditory-visual stimulator **Neuro-MEP** is not connected or in disrepair".*	Auditory-visual stimulator **Neuro-MEP** is not connected to the computer.	Check whether the stimulator is connected. If there are no connection errors, disconnect the stimulator from the computer and connect again in several seconds. If it doesn't work, reload the computer.
The program message: *"Auditory-visual stimulator **Neuro-MEP** is already used by the other program".*	The other program using the stimulator is opened (for example, second copy of **Neuro-MEP.NET** or **Neuro-MEP** program).	End other programs using the stimulator. If you can't find such a program, reload the computer.
The program message: *"**Neuro-MEP** auditory-visual stimulator disconnection error". End the program, disconnect the stimulator from the computer and connect again in several seconds".*	Stimulator disconnection error.	End the operating program, disconnect the stimulator from the computer (USB-hub) and connect again in several seconds. If it doesn't work, reload the computer.
The program message: *"The connection error: magnetic stimulator **Neuro-MS** is not connected or in disrepair".*	Magnetic stimulator **Neuro-MS** is not connected to the computer.	Check whether the stimulator is connected. If there are no connection errors, disconnect the stimulator from the computer and connect again in several seconds. If it doesn't work, reload the computer.
The program message: *"Magnetic stimulator **Neuro-MS** is already used by the other program".*	The other program using the stimulator is opened (for example, second copy of **Neuro-MEP.NET** or **Neuro-MEP** program).	End other programs using the stimulator. If you can't find such a program, reload the computer.
The program message: "Magnetic stimulator coil is disconnected".	The magnetic stimulator coil is switched off (or connected incorrectly).	Connect the coil to the stimulator and make sure that the connection is reliable.

Continuation of Table 5

Trouble Symptom	Cause	Way of Removal
The program message: *"The button "Start" of the magnetic stimulator is pressed constantly".*	The coil position is wrong: for example, the "Start' button is pressed by the attachment.	Set free the "Start' button of the stimulator.
The program message: *"Circuit charge of the condenser is in disrepair".*	Magnetic stimulator power circuit is in disrepair.	Magnetic stimulator should be repaired.
The program message: *"Magnetic stimulator* ***Neuro-MS*** *switch off error". End the program, disconnect the stimulator from the computer and connect again in several seconds".*	Stimulator switching off error.	End the operating program, disconnect the stimulator from the computer (USB-hub) and connect again in several seconds. If it doesn't work, reload the computer.
The program message: *"Magnetic stimulator is overheated. Wait until it is cooled".*	Stimulator coil overheating.	Wait until the stimulator is cooled and continue the work or replace it with the other. The stimulator overheating indication is shown on the clipboard and described in the in the operational documentation.
The program message: "Second monitor initiation error".	The error when the program refers to the second monitor using the high resolution pattern.	Check the connection of the second monitor and high resolution pattern adapter to the computer and also the DirectX version installed on the computer (not less than DirectX 7.0).
The program message: *"Stimulator error".*	Devices or computer error.	Execute the command of the menu **Setup|Hardware reset.** If it does not work, end the operating program, disconnect the stimulator from the computer and connect again in several seconds. If no, reload the computer.

Continuation of Table 5

Trouble Symptom	Cause	Way of Removal
The program message: *"The synchronization of the amplifier and the stimulator is impossible as the devices are connected to the different USB-controllers".*	The amplifier (patient button) and one of the stimulator are connected to computer USB-connectors referring to different USB-controllers. Usually such jacks are located far from each other on the computer case.	Connect the amplifier, all the stimulators to one USB-Hub or USB jacks located not far from each other.
The program message: *"Data processing error because of the system congestion. Repeat the start".*	The computer processor was loaded and could not receive the next data block from the digital system. If this message appears seldom, it is not the trouble.	Close all the applications except **Neuro-MEP.NET** or **Neuro-MEP** program (if they are started) and start the signal registration again. If it fails, reload 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 registration of the signal again. If it fails, reload the computer.
The program message: *"Error of transferring by USB. Check the devices connection and repeat the start".*	The digital system was disconnected during the signal registration or failed when exchanging through USB.	Check the connection of the digital system and start the registration of the signal again. If it fails, reload the computer.
The program message: *"Service Pack 1 should be installed for operation of the equipment with Windows XP".*	The first version of Windows XP installed in your computer contains the errors resulting in the improper operation of USB devices.	Install Windows XP Service Pack 1, or the more late version of Windows (preferable), or, if it is not available, Windows ME.

Continuation of Table 5

Trouble Symptom	Cause	Way of Removal
High supply-line noise is in registered signal (frequency – 50 Hz or divisible to it – 100 Hz, 150 Hz, etc	Unusable at the moment electrodes are connected to the amplifier, the electrodes which are not set on the patient.	Disconnect the unusable at the moment electrodes from the amplifier.
	The electrodes are set bad.	Start the impedance measurement and obtain the accepted value. In case of electrodes fault (for example, break), replace them.
	Bad grounding of the digital system.	Ground the computer safely.
	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 digital system grounding.
	Shared connectors (ground) of two amplifiers are not connected in 8-channel digital system.	Connect shared connectors of two amplifiers by the separate cable.
When starting the signal registration in stimulus probes, the stimulus is absent.	The stimulation in the program is switched off.	Execute the command of the menu **Setup| Stimulator| Turn on stimulator** and make sure that this command is activated  .
	The stimulation device (goggles, headphones, etc.) 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 command of the menu **Setup|Hardware reset** and restart. If it fails, reload the computer.

3.4. Exams Performing Using Digital System

Before carrying out exams, it is necessary to set up the digital system and other equipment taking into consideration user manual recommendations.

Exam includes the following stages:

- electrodes and sensors set up;
- signal recording;
- analysis and printing of the results.

Before surface EMG electrode placement, it is necessary to degrease the skin by alcohol where the electrodes are set. The use of electrode gel for EMG electrodes and electrode abrasive paste for EP electrodes is preferable. Before the needle electrodes placement, they should be sterilized (autoclaving). Electrode connection and placement can be conducted when the digital system is switched on. The more detailed information about working with electrodes is described in the manuals provided with them and in the user manual for the used software.

After placement of surface electrodes it is necessary to control the electrode setting quality according to impedance measurement. First of all, the impedance measurement mode should be switched on (see the “User Manual”).

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

After finishing of the recording, the electrodes and sensors should be taken off the patient and disinfected (see the “User Manual”).

If the next patient is not planned till the end of the working day, the digital system should be switched off. For that exit the digital system software and then switch off the computer and the 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 the cases of electrical insulation disturbance of any digital system component which causes the emergency (fire, mechanical failure, flood, medical staff evacuation) and threat of patient or staff electrical shock, it is necessary to de-energize the digital system completely.

4. Servicing

4.1. General Requirements

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

Qualification requirements to the medical staff are listed in chapter 2.1 “Personnel Requirements Conducting Mounting and Setting”.

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

When detecting the troubles it is recommended to use the information given in 3.3 “Troubleshooting” chapter. If the troubles can’t be eliminated using EMG system control units or by restart, it should be switched off and checked by the specialist.

Type, volume and periodicity of the servicing except specified in this chapter, are not determined.

The delivery set check is done by conformity to the device packing report.

4.2. Digital System Servicing

Digital system servicing in the process of operation includes the external examination, check of jacks and cables, removal of contaminations from the units’ surface using wet fabric.

4.3. Conservation

The digital system components including accessories and operational documentation should be packed in separate plastic sachets and then placed in a manufacturer package.

5. Current Repair

5.1. General Requirements

Digital system repair requires special training of the technical staff and special equipment and service software which you can receive from the manufacturer or the representative of the firm. The repair connected with the electronic unit opening is prohibited. The repair of computer equipment and pattern-stimulator monitor can be conducted by dedicated establishments for computer equipment service.

The digital system current repair includes the component parts and cables repair. The component parts repair when connecting to digital system is prohibited.

When conducting current repair, all the units must be switched off.

5.2. Cables, Adapters and Linkers Repair

Cables are examined externally, and the circuit is checked for short circuit or break. In case of cable break, it is necessary to replace or cut it if the cable length is sufficient.

5.3. Amplifier Interface Cable Repair (USB Cable)

Amplifier interface cable is examined externally, and the circuit is checked for short circuit or break. In case of cable failure, it should be replaced or repaired by the length shortening. When replacing it is necessary to pay attention for cable marking. The marking of wire size on cable should be either 28AWG/2C+24AWG/2C, or 28AWG/2C+22AWG/2C, or 28AWG/2C+20AWG/2C.

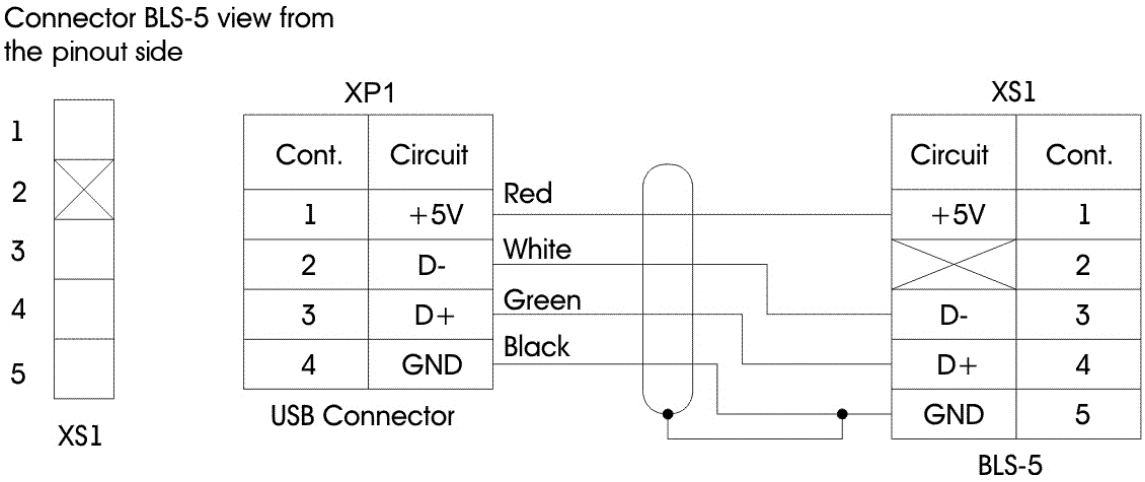

Fig. 18.Electrical schematic of amplifier interface cable.

5.4. Auditory Stimulator Repair

Auditory stimulator (headphones) is examined externally, and circuit resistance of dynamic head and cable are measured. The measured value should be within the range from 90 up to 110 Ω. When detecting the break or short circuit it is necessary to disassemble the cable connector case and check it. If the failure is not discovered, open the auditory stimulator unit and measure each cable and coil of dynamic head. If the cable break is detected, see the instruction on the USB cable repair. If the dynamic head failure is detected, address to manufacturer for the further repair.

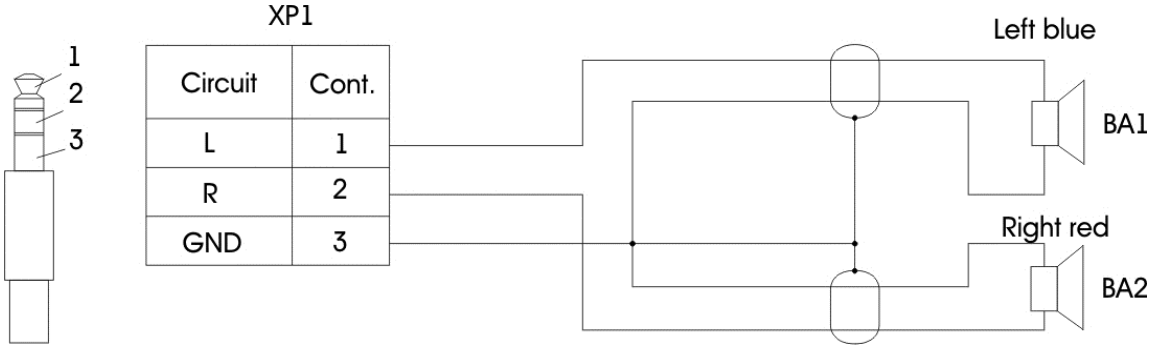

Fig. 19. Electrical schematic of auditory stimulator.

5.5. LED Goggles Repair

LED goggles are examined externally for the cable failure detection. Circuit control from the connector side is conducted according to Fig. 20 schematic by the device for LED check. It is necessary to open the cable connector case and check the montage. If the cable break is detected, see the instructions on USB cable repair. If the failure is not detected, address to the manufacturer.

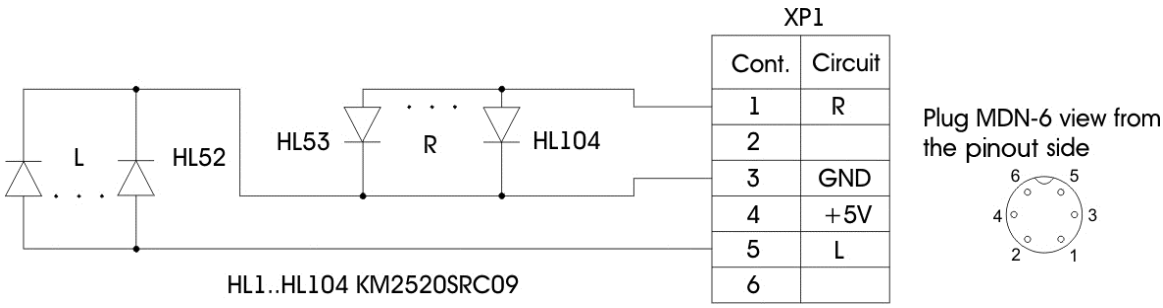

Fig. 20. Electrical schematic of LED goggles.

5.6. LED Penlights Repair

LED penlights are examined externally for the cable failure detection. Circuit control from the connector side is conducted according to Fig. 21 schematic by the device for LED check. It is necessary to open cable connector case and check the montage. If the failure is not detected, open the LED penlight case and measure the resistance of each cable. If the cable break is detected, see the instructions on USB cable repair. Detection and elimination of LEDs failure can be done only by manufacturer.

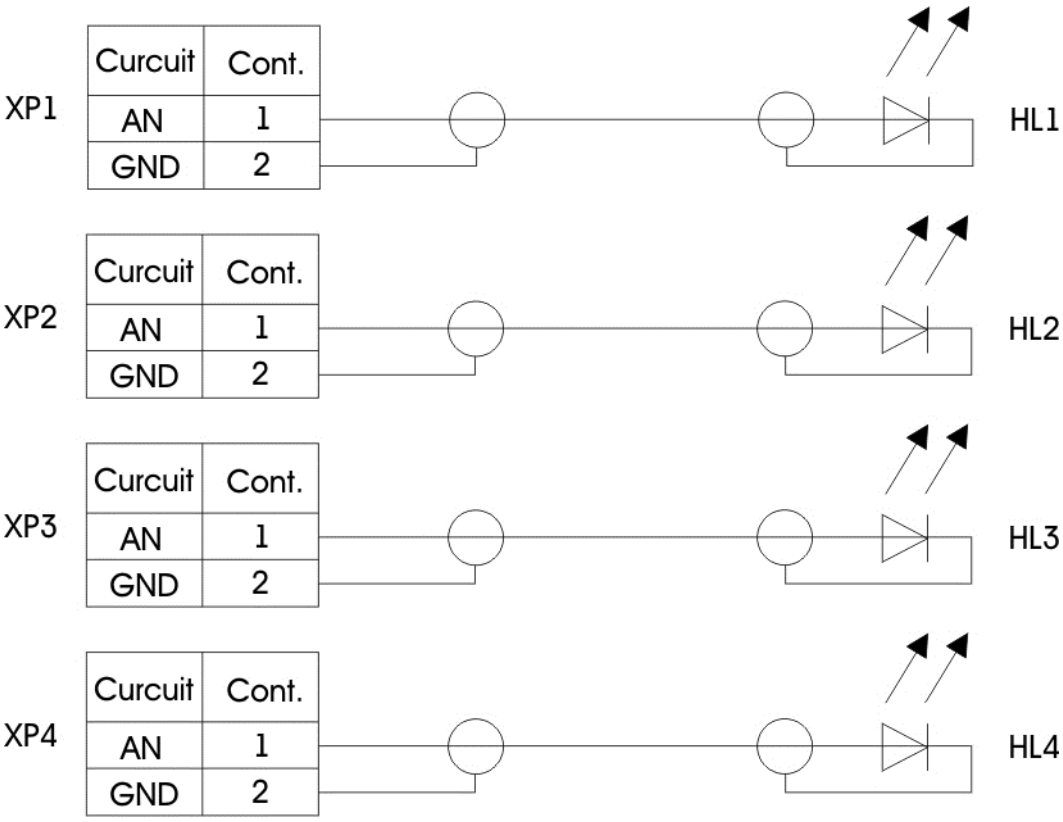

Fig. 21. Electrical schematic of LED penlights.

5.7. Ganzfeld Stimulator Repair

Ganzfeld stimulator is examined externally for the cable failure detection. Circuit control from the connector side is conducted according to Fig. 22 schematic by the device for LED check. It is necessary to open cable connector case and check the montage. If the cable break is detected, see the instructions on USB cable repair. If the failure is not detected, address to the manufacturer.

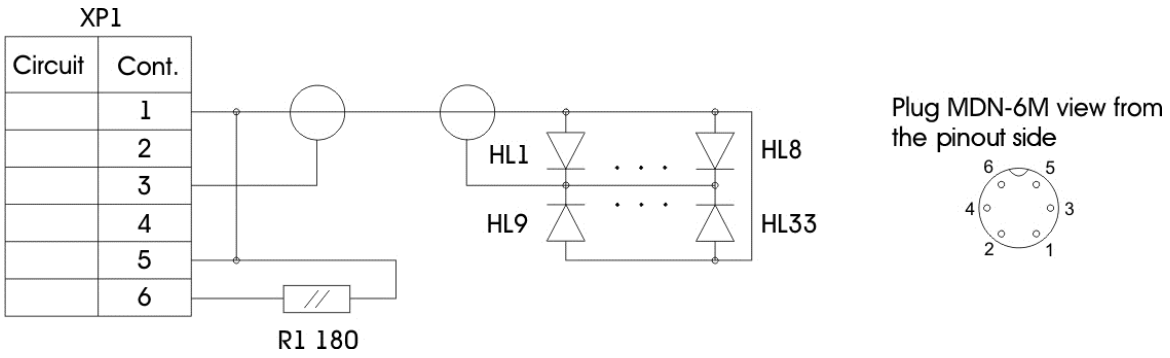

Fig. 22. Electrical schematic of ganzfeld stimulator.

5.8. Electro Stimulating Electrode Repair (Stimulus Probe)

Electro stimulating electrode is examined externally for the cable break and checked for the break and short circuit according to the schematic (Fig. 23). If the cable failure is detected, the further actions are analogous to the ones described above (see chapter 5.4 “Auditory Stimulator Repair”). The failure inside the electrode case can be detected only in manufacturer plant. This type of damage can not be repaired.

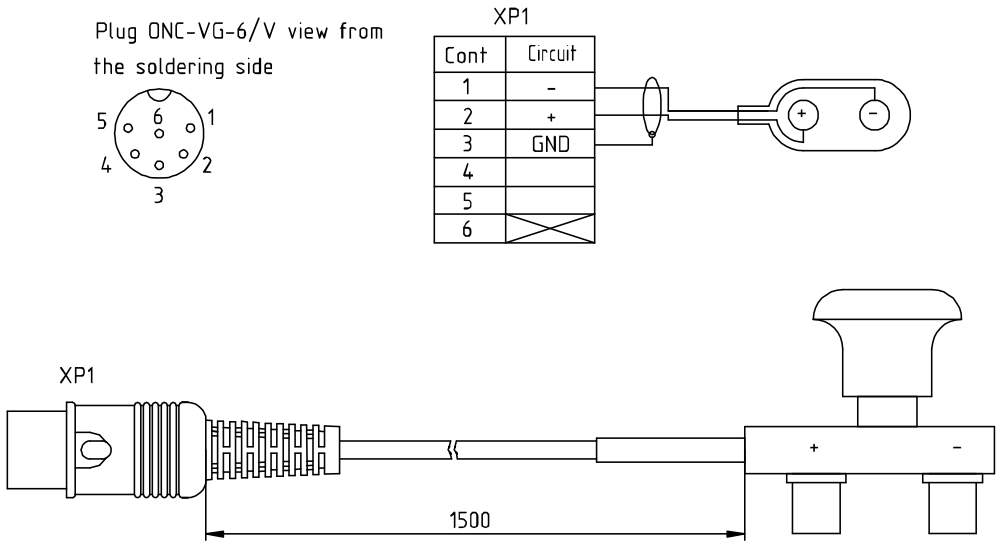

Fig. 23. Electrical schematic of electro stimulating electrode.

6. Packing and Transportation

The package should conform to the accepted one when manufacturing and delivering. In case the factory package is damaged, but the long-term system storage and transportation is expected, follow the given recommendations:

- The digital system with operational documentation should be packed in plastic sachets and cardboard boxes.
- The cardboard boxes should be covered by the paper tape or pressure sensitive adhesive.
- The digital systems can be transported by all kinds of covered carries (except non-heated airplane pods) according to rules of goods transportation for each mode of transport.

The digital system portage by sea transport should be done according to “Safety Regulations for Sea Transport of General Cargoes”.

The shipment type is by containers and part-load consignment.

7. Utilization

The device utilization is performed according to the current legislation of the area where the equipment is used. Special requirements to device utilization are not provided by the manufacturer.

8. Delivery Set and Package Data

☐ **Neuro-MEP-4** digital EMG and EP system,

☐ **Neuro-MEP-8** digital EMG and EP system,

☐ **Neuro-ERG** digital EMG and EP system,

is collected and packed according to TC 9441-006-13218158-2005 requirements.

The list of digital system units which have serial numbers is given in Table 6.

Table 6. The list of digital system units

№	Unit	Serial number
1	Amplifier unit №1	
2	Amplifier unit №2	
3	Auditory-visual stimulator unit	

4	Electrical stimulator unit	
5	Dedicated keyboard	
6	Patient button	
7	Footswitch	
8	Adapter for high resolution pattern-stimulator	
9	Tendon hammer	
10	Stimulation electrode with steel stimulation point	

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 the present document and should be kept along with it.

9. Acceptance Certificate

The digital system corresponds to TC 9441-006-13218158-2005 and is ready for operation.

DC representative _____
signature

10. Delivery Certificate

The system is delivered to a customer _____
Date

System was handed _____
Signature

System was accepted _____
Signature

11. Storage Data

The digital system should be stored in the manufacturer package in an enclosed space at +5-40°C and 80% maximal relative humidity (measured at temperature of 25°C). The air should be free from any admixtures which can cause the corrosion.

The digital systems should be put on the shelves not more than in four rows.

Information about the system storage before and in the process of operation is registered in Table 7.

Table 7. Storage Data.

Date of		Storage conditions	Position, name and signature of person responsible for storage
beginning of storage	**end of storage**		

12. Warranty

12.1. The manufacturer guarantees the system quality conformance to TC 9441-006-13218158-2005 requirements if the rules of operation, storage, transportation and mounting prescribed in the operational documentation are observed.

12.2. Warranty period is 24 months from the delivery date to the customer (chapter 10).

- The warranty period of components exposed to wear (cables) is 30 days.
- There is no warranty for consumables (gels and pastes).

- The warranty period can be prolonged for the period from reclamation submission up to repair completion (chapters 13, 14).

12.3. The operation of guarantee commitment is stopped if:

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

12.4. The manufacturer is obliged to repair the equipment in case of breakdown during the warranty period free of charge. The repair is carried out in the service center of Neurosoft Company (5, Voronin str., Ivanovo, 153032, Russia) only if this registration certificate is provided.

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

Chemin du tomple

84330 Le Barroux, France

Phone: +490-650-470, +622-748-384

Fax: +490-650-470

12.5. E-mail: **bscholl@orange.fr**

13. Reclamation Data

13.1. 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 Ltd., authorized European representative or nearest distributor. The actual list of Neurosoft Ltd. distributors is represented on the web site: http://www.neurosoft.ru/eng/useful/links.aspx. This notification should contain the following information:

- the consumer’s name and the address;
- the serial number of the system (see chapter 8 of the present manual or the system marking);
- the copy of chapter 10 of this manual or the number and the date of the invoice or other document confirming the system purchase.
- the detailed description of failures. If it is possible indicate the reasons and circumstances preceding the fault detection (in addition it is recommended to add the test report, the exam data, photos and other materials allowing to solve the problem as soon as possible).

13.2. In case of system return to the service center for the repair or the replacement, the following rules should be observed:

- it should be packed so to exclude the possibility of its damage during the transportation;
- the notice (see item 13.1) and the present manual must be added to the device being returned.

13.3. All the reclamations, its description and taken measures should be registered in Table 8.

Table 8. Reclamation Data.

The date of failure or trouble appearance	**Brief description of the trouble**	**The date of reclamation sending**	**Taken measures**	**Note**

14. Repair Data

Table 9. Repair Data.

Name and code of faulty unit	Degree of imperfec-tion	Date		Name of repair works	Position, name, signature of person	
		comple-tion of repair	arrival		Carried out the repair	Accepted the repair

Appendix 1. Electromagnetic Emissions and Immunity

Guidance and manufacturer's declaration – electromagnetic emissions

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

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

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV − contact	±6 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±8 kV − air	±8 kV	
Electrical fast transient/burst IEC 61000-4-4	±2 kV − for power supply lines	± 2 kV [1)]	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV − for input/output lines	Not applicable	
Surge IEC 61000-4-5	±1 kV differential mode	± 1 kV [2)]	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV common mode	± 2 kV [2)]	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 and 1cycle	20 ms [3)]	Mains power quality should be that of a typical commercial or hospital environment. If the user of the digital system requires continued operation during power mains interruptions, it is recommended that the digital system be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	100 ms [3)]	
	70% U_T (30% dip in U_T) for 25 cycles	500 ms [3)]	
	120% U_T (20% dip in U_T) for 25 cycles	500 ms [3)]	
	<5% U_T (>95% dip in U_T) for 5 s	5000 ms [3)]	
Power frequency magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

[1)] Ensured by PC compliance with IEC 61000-4-4 requirements.
[2)] Ensured by PC compliance with IEC 61000-4-5 requirements.
[3)] Ensured by PC compliance with IEC 61000-4-11 requirements.
Note: U_T – is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the digital system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands [1)]	3 V [3)]	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17\sqrt{P}$ (80 MHz to 800 MHz); $d = 2.33\sqrt{P}$ (800 MHz to 2.5 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: 

[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 digital system is used exceeds the applicable RF compliance level above, the digital 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 digital system.
[2)] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 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 applies.
2. These guidelines may not apply 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 digital system

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

Rated maximum output power of transmitter, W	Separation distance according to frequency of transmitter, m		
	150 kHz up to 80 MHz outside ISM bands $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
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.