ME01

Mitsar Co. Ltd.

ELECTROENCEPHALOGRAPHIC PC-CONTROLLED SYSTEM "MITSAR-EEG"

OPERATION MANUAL

Rev. 1.03 25-03-2010

Attention

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The information in this document is subject to change without notice.

Mitsar Co. Ltd. quality management system is certified to be in compliance with the European standard EN ISO 13485:2003.

In case of any troubles, problems or requests please do not hesitate to contact us:

in writing: Mitsar Co. Ltd.
Novorossiyskaya str., 21-2,
Saint Petersburg, 194021,
RUSSIA

via E-mail: support@mitsar.spb.ru

by phone
or FAX: +7 (812) 331-09-32, 297-90-13

CE 0537

For more information please visit: www.mitsar-medical.com

European Union representative:

MEDISAT Company
Bulgaria, Rousse 7000
”Han Asparuh”#31

Tel./fax: +359-82-839193
E-mail: office@medisat.org
Web site: www.medisat.org

Manufacturer warranty

Mitsar Co. Ltd warrants that each product we sell is free of manufacturing defects and conforms to its product specifications as defined in this manual.

If the product goes out of order during the warranty period, Mitsar Co. Ltd will correct all detected malfunctions by repair or partial replacement free of charge.

If in our judgment we are unable to do so, you may return it to us and we will refund your money.

Limit of warranty

This warranty is valid under proper usage and maintenance of the EEG system and doesn't cover damage caused by the following:

- improper usage;

- negligence, incompetence or intentional damage;

- unskilled maintenance;

- violation of operating conditions (abrupt deviations of temperature and humidity, power failures, etc.);

- violation of storage and transportation conditions;

- improper implementation of technical instructions.

Some components of the system may have separate warranty period specified in their documents. This warranty doesn't cover consumables.

We do not warrant uninterrupted or error-free operation of some parts of the EEG system. We provide non-Mitsar products "as is". Non-Mitsar manufacturers may provide their own warranties to these products. Separate software warranty is provided with software user documentation.

Customer responsibility

The EEG system will be reliable only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels and inserts. A defective system should not be used. Parts which may be broken or missing or those that are clearly worn or contaminated should be replaced immediately with new original replacement parts that have been manufactured by or available from Mitsar Co. Ltd.

The responsibility of Mitsar Co. Ltd for a non-functioning system is limited by the warranty set forth in this guide. If repair or replacement of this product becomes necessary after the expiration of the warranty, the customer should seek advice from Mitsar Co. Ltd prior to such repair or replacement. If this system needs repair, it should not be used until all repairs have been made and the system is functioning properly.

The owner of this system has the sole responsibility for any malfunction resulting from improper use or maintenance, or repair done by anyone other than a qualified Mitsar Co. Ltd representative and for any malfunctions caused by any parts that have been damaged or modified by anyone other than a qualified Mitsar Co. Ltd representative.

The owner of this system has the sole responsibility for connection this product to other systems not satisfying the electrical safety requirements class I, type BF, standards EN 60601-1, EN 60601-2-26, EN 60601-1-1, EN 60601-1-2 for medical devices.

Warranty and post-guarantee obligations

1. The manufacturer guarantees compliance of the system with technical specifications and operating requirements described below.
2. Warranty period is 24 months from the date of commissioning (date of signing the commissioning deed). If the delivery set includes a computer and/or other computer equipment, video camera, etc., warranties for such equipment shall be stipulated.
3. Warranty for electrodes and electrode fixing devices is 12 months if not stipulated otherwise by the electrode manufacturer.
4. During the warranty period Mitsar Co.Ltd will provide for the customer necessary consultation regarding operation of the system.
5. During the warranty period Mitsar Co.Ltd undertakes, against presentation of the filled guarantee coupon, to restore serviceability of the system by means of setting-up, repair or replacement of the entire device or its parts.
6. Mitsar Co. Ltd shall inform the customer during the warranty period on all new developments and modifications of the system, and shall suggest substitution of earlier software versions for upgraded ones free of charge (software upgrade).
7. Post-guarantee service for the system shall be carried out by Mitsar Co. Ltd or organization authorized by Mitsar under separate contract with the customer.
8. The warranty will be considered void:

- In a case of absence of guarantee coupon with date of commissioning, manufacturer signature and stamp;

- In a case of broken seals;

- In a case of mechanical damages caused during operation;

- If a liquid was poured over/into the bioelectric signal amplifier, including leakage of batteries of a type not recommended by Mitsar Co. Ltd;

- If batteries of not recommended type or voltage were used;

- In a case of attempts of unauthorized repair or changes in internal connections;

- If illegal copies of Mitsar software were used.

9. The present warranty does not include replacement of electrode sockets and batteries. This may be performed at the customer's request against separate charge.
10. The present warranty does not concern equipment not included into the delivery set (see section 1.1 below), if not otherwise stipulated by the delivery contract.
11. Guarantee coupons are enclosed.

Safety summary

Pay attention to all warnings, advices and notes provided in this manual. To avoid the possibility of injury to patient or user, damage to your system or data loss, always observe these safety precautions during the system operation.

Two signs are used to define potentially harmful or capable to cause damage conditions or procedures.

WARNING

WARNING sign indicates situation or procedures which may be dangerous for patient and/or user.

ATTENTION

ATTENTION sign indicates situation or procedures which may cause the equipment damage or its improper usage.

ATTENTION! Read section 2.4 Safety requirements.

Only trained personnel familiar with safety regulations is allowed to operate the system.

Only personnel properly trained to operate the Mitsar-EEG system should use it for patient examination.

Personal computer should be located outside the patient environment (see section 2.4 Safety requirements).
If it is necessary to locate a personal computer or other non-medical electrical equipment within the patient environment, read section: 1.75 Locating personal computer within the patient environment.

Do not turn on the system power until all cables have been properly connected and verified.

To provide patient safety, connect the patient electrodes only after the system is fully turned on.

To provide the patient safety, disconnect all recording and stimulating electrodes from patient before you turn off the system.

Connect patient electrodes only to corresponding inputs of bioelectric signal amplifier. Connection to any other devices or sockets may cause injuries.

Any devices connected to Mitsar-EEG system should be certified by Mitsar Co. Ltd to provide the conformity of system to requirements for leakage current in accordance with the standard EN 60601-1-1 for medical electrical systems.

Proper usage of this system depends on careful reading of all instructions and labels.

Turn off the system power before connecting or disconnecting any system component(s) or accessories. Otherwise, you can damage the system.

Do not disconnect or reconnect any system components or accessories with the system powered on. Otherwise, you can damage its components

A power interruption that occurs during EEG recording session may cause nonrecoverable data loss. If you experience frequent power interruptions, Mitsar Co.Ltd recommends usage of an Uninterruptible Power Supply (UPS).

Do not autoclave any parts of Mitsar-EEG system.

Do not use acetone or other solvents for cleaning the components of the system.

The mode of electrode resistance measurement can affect the function of the other equipment, e.g. causing interference.

Equipment marking

The following signs are used for marking of the Mitsar-EEG system:

Marking of BF type applied parts.

Marking of direct current.

Manufacturer name and address

Mark of conformity for obligatory certification (GOST R)

Mark of conformity to the requirements of Council Directive 93/42/EEC.

SN

Product serial number.

Contents

1. Description of Mitsar-EEG System

The electroencephalographic PC-controlled system "Mitsar-EEG" (hereinafter referred to as the EEG system) is intended for acquisition, storage at personal computer's HDD, processing, displaying at PC display, and printing out of electroencephalographic and electrocardiographic signals. The EEG system refers to medical measuring instruments class.

The EEG system is intended only for medical application and serves for recording and measuring of patient electrical brain activity.

The EEG system may be used for acquisition of electroencephalogram (EEG), video EEG and evoked potentials (EP) recording for diagnostics of brain diseases. The software package for Microsoft Windows XP/Vista allows performing an advanced computerized analysis of the EEG on a standard personal computer or notebook including digital filtering, montage reformatting, spectra and coherence analysis, topographic mapping, etc. Capabilities of EEG analysis depend on the type of software supplied.

The EEG system includes the biosignals converter (hereinafter referred to as the Amplifier) controlled by means of special software.

The Amplifier does not directly contact the patients. Accessories that contact patients, such as electrodes and fixing devices, should correspond to normative requirements and be adequately approved.

The EEG system is not sterile.

The system is intended for use in functional diagnostics wards and departments at out-patient clinics, hospitals and health research institutes, health centers, in medical exercises dispensaries and other medioprophylactic and educational medical institutions.

The personnel intended to work with the EEG system should be experienced enough in technique of clinical EEG observation. The user should be familiar with operation system Microsoft Windows XP/Vista.

The EEG system does not feature defibrillator protection!

1.1 Delivery set

Depending on the system purpose for different types of EEG investigation, the EEG system may contain different components.

Standard delivery set:

№	Component name	Q-ty
	Hardware*	
1	1-a Amplifier, version "Mitsar-EEG-03/35-201"	1 pcs.
	1-b Amplifier, version "Mitsar-EEG-05/70-201"	
	1-c Amplifier, version "Mitsar-EEG-10/70-201"	
	Accessories	
2	Amplifier-to-PC connection cable (MT-RSI 01, 5-7 meters)	1 pcs.
3	Photic stimulator with power supply and synchronization cable****	1 set
4	Phonostimulator with acoustic speakers and PC connection cable (USB A – USB B) ****	1 set
5	EEG electrodes and fixing devices**	1 set
6	Electro-Gel****	1 pcs.
7	EEG electrode connection cable****	1 pcs.
8	Set of batteries R6 (AA)****	4 pcs.
9	Rack for Amplifier and/or Photic stimulator****	2 pcs.
10	Dongle*****	1 pcs.
11	Portable cart****	1 set
12	Isolation transformer****	1 pcs.
13	Universal arm for the amplifier and/or Photic stimulator****	2 pcs.
	Software*	
14	14-a EEG Synapse software package	1 set
	14-b or WinEEG software package	
15	HBI normative database*****	1 set
	Operation documents	
16	Operation manual	1 pcs.
17	User's manual for software package (for corresponding software package)	1 pcs.

* Delivery version is stipulated in order.

** Possible replacement for electrodes with registration card. Possible delivery without electrodes. The electrodes should be CE marked for delivery to EC countries

*** Possible delivery without PC and/or printer as agreed with the customer. Configuration and PC resources are discussed with customer. PC being exported should comply with the requirements of destination country.

**** Possible delivery without this item as agreed with the customer.

***** Only for operation with WinEEG software.

Additional delivery set for video-EEG:

№	Component name	Q-ty
	Accessories*	
18	Video capture card	1 (2) pcs.
19	Video camera with rotating device and set of cables	1 set
20	Infrared video camera with built-in microphone and set of cables	1 set
21	Video camera remote control with set of cables	1 set
22	IR lamp	1 pcs.
23	Power supply for video cameras, microphone and IR light	1 set
24	Microphone and microphone amplifier (if necessary)	1 set
	Software	
25	WinEEG Video software package**	1 set
	Operation documents	
26	WinEEG software package user's manual	1 pcs.

* Delivery version is stipulated in order.
** WinEEG software with video-EEG option.

Additional equipment for EP investigation:

№	Component name	Q-ty
	Hardware	
27	PC for stimuli presentation*	1 set
	Accessories	
28	Patient response button	1 pcs.
29	PC-to-PC null-modem cable	1 pcs.
	Software	
30	PSYTASK software package**	1 set
	Operation documents	
31	PSYTASK software package user's manual	1 pcs.

* Possible delivery without PC as agreed with the customer. Configuration and PC resources are discussed with the customer. PC being exported should comply with the requirements of destination country.

** Delivered only with WinEEG.

Additional equipment for biofeedback:

№	Component name	Q-ty
	Hardware	
32	Adapter for video/audio biofeedback presentation "Jammer"	1 pcs.
	Accessories	
33	Jammer-to-PC connection cable	1 pcs.
34	Audio-video cable Jack 3.5 – 3RCA	2 pcs.
	Software	
35	BrainTuner software package	1 set
	Operation documents	
36	BrainTuner software package user's manual	1 pcs.

Typical EEG system connection diagrams depending on the purpose of EEG investigation are shown in section 1.7 of this manual.

1.2 Personal computer

PC is an important part of the EEG system. Personal computers and other peripheral devices (monitors, printers, etc.) used with the EEG system should comply with the requirements of standards EN 60950 or EN 60601-1 and should have conformance certificates.

Requirements to PC for routine investigations:

- Clock frequency at least 2.6 GHz;
- Ram at least 1 Gb;
- Hard disk at least 120 Gb;
- Video adapter (AGP or PCI-E) at least 128 Mb;
- DVD-RW;
- PC should have 1 free USB port for the amplifier and 1 for WinEEG security dongle;
- Operation system: Windows XP SP3; Windows Vista SP2.

Requirements to PC for ERP recording:

Primary PC	Slave (presentation) PC
- Clock frequency at least 2.6 GHz; - Ram at least 2 Gb; - Hard disk at least 160 Gb; - Video adapter (AGP or PCI-E) at least 128 Mb; - DVD-RW; - PC should have 1 free USB port for the amplifier and 1 for WinEEG security dongle - PC should have 1 free COM port for PC's synchronization with Null-modem cable or 1 extra USB port if USB-Serial adapter is used - Windows XP SP3.	- Clock frequency at least 2 GHz; - Ram at least 1 Gb; - Hard disk at least 40 Gb; - Video adapter (AGP or PCI-E) at least 128 Mb; - If the program is supplied on CD, a corresponding disk drive is required; - PC should have 1 free COM port for PC's synchronization with Null-modem cable or 1 extra USB port if USB-Serial adapter is used - Windows XP SP3; - CRT- or LCD-monitor with response time at most 8 ms.

Requirements to PC for video-EEG recording:

- Clock frequency at least 2.6 GHz;
- Ram at least 2 Gb;
- Hard disk at least 180 Gb;
- Video adapter (AGP or PCI-E) at least 256 Mb;
- If the program is supplied on CD, a corresponding disk drive is required;
- PC should have 1 free USB port for the amplifier and 1 for WinEEG security dongle
- PC should have 1 or 2 free PCI slots for video capture cards connection;
- Operation system: Windows XP SP3;
- DirectX 9.0c.

Most modern notebooks are suitable for operation with EEG system; however, we recommend consulting specialists of Mitsar Co.Ltd or our dealers when buying a notebook.

In case PC does not meet the above requirements, the system operability may be checked with a test, but Mitsar Co.Ltd does not guarantee complete operability.

Antivirus software is an importance element of data protection. However, its operation may cause failures during recording. Switch off active scanning during recording and planned scanning. If you experience any problem with antivirus software usage, consult Mitsar Co. Ltd.

1.3 Software

Software is an important element of the EEG system. Software controls hardware, collects and processes data, displays and prints it out, stores data on hard disk and provides user's interface.

The software includes the following modules:

1. EEG Synapse. The program includes basic function package for EEG recording and processing.

2. Basic version of WinEEG. The program includes advanced function package for EEG recording and processing.

3. The advanced version of WinEEG for investigation of event related potentials. This program also includes functions for ERP recording.

4. The advanced version of WinEEG for video-EEG. This program also includes functions for video-EEG recording.

5. PSYTASK. This program is intended for synchronous stimuli presentation during EEG recording for acquisition of brain event related potentials.

WinEEG program functions are protected with special electronic device (USB key) inserted into USB connector of PC or notebook. To open these functions, a USB key should be inserted and drivers for this device should be installed.

USB key is necessary for WinEEG program operation. Without this specially programmed electronic key most of program functions including data recording will be unavailable.

Available configurations of USB key are listed in the following table:

USB key type	EEG recording	ERP recording	Video-EEG recording	Comparison with normative database	Comparison with HBImed company normative database (7-89 years)
EEG-Base	+	-	-	-	-
EEG	+	+	-	-	-
EEG+Video	+	+	+	-	-
EEG+DB	+	+	-	+	-
EEG+DB+Video	+	+	+	+	-
HBI Database	+	+	-	-	+

1.4 Electrodes and sensors

Electrodes and fixing devices are important components of the EEG system delivered separately. All electrodes and fixing devices should comply with the normative requirements. Mitsar Co. Ltd recommends to use standard electrodes with touch proof connectors, and/or ElectroCap electrodes cap positioning system (Electro-Cap International Inc., USA) or any compatible electrode fixing system (CombyCap, ActiCap).

The electrodes may be delivered by Mitsar Co. Ltd, or user may purchase it separately.

The recommended standard EEG electrodes with Touch Proof connectors (DIN 42-802) are produced in various structural versions, e.g.: disk, bridge, needle, adhesive.

Disk and bridge electrodes are fitted with fixing devices, so called "mesh-caps" ("caps"). Adhesive electrodes are fixed on patient head with special adhesive paste (e.g. Ten20).

Recommendations for maintenance and disinfection of electrodes should be strictly followed. Needle electrodes require special attention.

For continuous EEG monitoring, e.g. in video-EEG monitoring rooms, Mitsar Co. Ltd recommends to use ElectroCap electrodes cap positioning system (Electro-Cap International Inc., USA) or any compatible electrode fixing system (CombyCap, ActiCap).

There are different popular versions of Electro-Cap systems delivery set:

SYS I set

Code number	Component name	Q-ty, pcs.
E1-M	Electrode cap, medium (54-58 cm)	1
E2	Electrode board adapter	1
E3-M	Body harness, medium	1
E4	Repair electrode	1
E5-9	Aural electrodes (1 pair)	1
E6	Disposable sponge disks (100 pcs in pack)	1
E7	Needle/Syringe Kit	1
E9	Electro-Gel (can 16 ounces = 473 ml)	1
E12	Measuring tape	1
E16	Ivory® Liquid for washing of caps	1
INS-1	User's manual	1
VID-1	Training video film	1

SYS II set

Code number	Component name	Q-ty, pcs.
E1-L	Electrode cap, large (58-62 cm)	1
E1-M	Electrode cap, medium (54-58 cm)	1
E2	Electrode board adapter	1
E3-M	Body harness, medium	1
E4	Repair electrode	2

E5-9	Aural electrodes (1 pair)	2
E6	Disposable sponge disks (100 pcs in pack)	1
E7	Needle/Syringe Kit	2
E9	Electro-Gel (can 16 ounces = 473 ml)	2
E12	Measuring tape	1
E16	Ivory® Liquid for washing of caps	1
INS-1	User's manual	1
VID-1	Training video film	1

SYS III set

Code number	Component name	Q-ty, pcs.
E1-L	Electrode cap, large (58-62 cm)	1
E1-M	Electrode cap, medium (54-58 cm)	1
E1-SM	Electrode cap, small (50-54 cm)	1
E1-XS	Electrode cap, ultra small (46-50 cm)	1
E2	Electrode board adapter	1
E3-M	Body harness, medium	1
E4	Repair electrode	4
E5-9	Aural electrodes (1 pair)	2
E6	Disposable sponge disks (100 pcs in pack)	2
E7	Needle/Syringe Kit	4
E9	Electro-Gel (can 16 ounces = 473 ml)	3
E12	Measuring tape	1
E16	Ivory® Liquid for washing of caps	1
INS-1	User's manual	1
VID-1	Training video film	1

Recommended set for perinatal wards

Code number	Component name	Q-ty, pcs.
I1-1	Perinatal electrode cap I (42-46 cm)	
I1-2	Perinatal electrode cap II (38-42 cm)	1
I1-3	Perinatal electrode cap III (34-38 cm)	1
E2	Electrode board adapter	1
I2	Perinatal body harness	1
E4	Repair electrode	5
E5-6	Aural electrodes 6 mm (1 pair)	2
E6	Disposable sponge disks (100 pcs in pack)	1
E7	Needle/Syringe Kit	1
E8B	Special blunt needle (100 pcs.)	1
E11	Electro-Gel (can 128 ounces = 3.8 l)	1
I3	Perinatal measuring tape	1

All electrodes used in EEG recording session should feature current-collecting surface of homogeneous material. Preferably to have electrodes of one manufacturer. Non-observance of these rules may cause high polarization voltage of electrodes and "suppression" of amplifies.

All electrodes used with the EEG system should be certified. Mitsar Co. Ltd does not guarantee the adequate quality of EEG recording, when using noncertified and defective electrodes.

Usage of noncertified electrodes may cause damage of the EEG system components.

The following sensors manufactured by S.L.P. Inc. were tested for poly signals recording:

Piezo Crystal Effort Sensor (Item #1387), Piezo Crystal Effort Sensor (Item #1388), Adult Nasal + Oral Pressure Monitoring Cannula Kit (Item #14802-FT-Kit), Body Position Sensor AC (Item #1561), Piezo Limb Movement Sensor (Item #1770), Piezo Snore Sensor (Item #1250).

1.5 System installation

Before the beginning of installation thoroughly read this manual.

ATTENTION! Read section 2.4 Safety requirements.

First turn-on and testing of EEG system is recommended to be performed by the manufacturer representative or by specialists specially trained at the manufacturer's.

The EEG system does not require special screened compartment if no sources of strong interference are present in the vicinity of the object (radio or TV transmitter, power transformer, radar station, X-ray unit, physiotherapy devices, etc.).

Check the presence of components and cables. Ensure that all components are not damaged.

Locate the system components on the working place observing safety requirements specified in this manual.

Open the battery section cover of the Amplifier box and insert the batteries into the cartridge. Pay attention to polarity of battery connection. Thus, the Amplifier is ready for operation.

Connect the Amplifier unit to the tripod (if any) and adjust the tripod height, locate the Amplifier in the place suitable for you. It is not recommended to install the Amplifier close to concrete walls, metal structures, near circuit voltage wires – this may cause additional interference induction 50/60 Hz.

Connect the system components in accordance with connection diagrams given in this manual below (see section 1.7).

Prior to system operation start, ensure that all cables are carefully laid and fixed with special means and can't be incidentally disconnected or trod on.

Connect the system with power supply unit 220 ± 22 V (50 Hz). Ensure that the system is connected to corresponding mains socket with reliable protective grounding.

Turn on the system by pressing the power button on the CPU unit.

There are no parts inside the EEG system which should be maintained by user except the batteries inside Mitsar-EEG Amplifier.

Do not open the EEG system cases if they are connected to power supply unit. Risk of electric shock.

1.6 System software installation

The corresponding drivers should be installed for any device plugged in to USB input, including those for the Amplifier. Driver installation for new devices being connected is a standard procedure performed by the operation system.

Detailed instruction on drivers and software installation can be found in the user's manual to the corresponding software.

1.7 Connection diagrams

The Mitsar-EEG Amplifier, EEG system accessories, computer, computer peripheral, and computer multimedia accessories can be connected in different way depending on the goals of EEG investigation. Typical system connection diagrams are shown below.

1.7.1 EEG recording

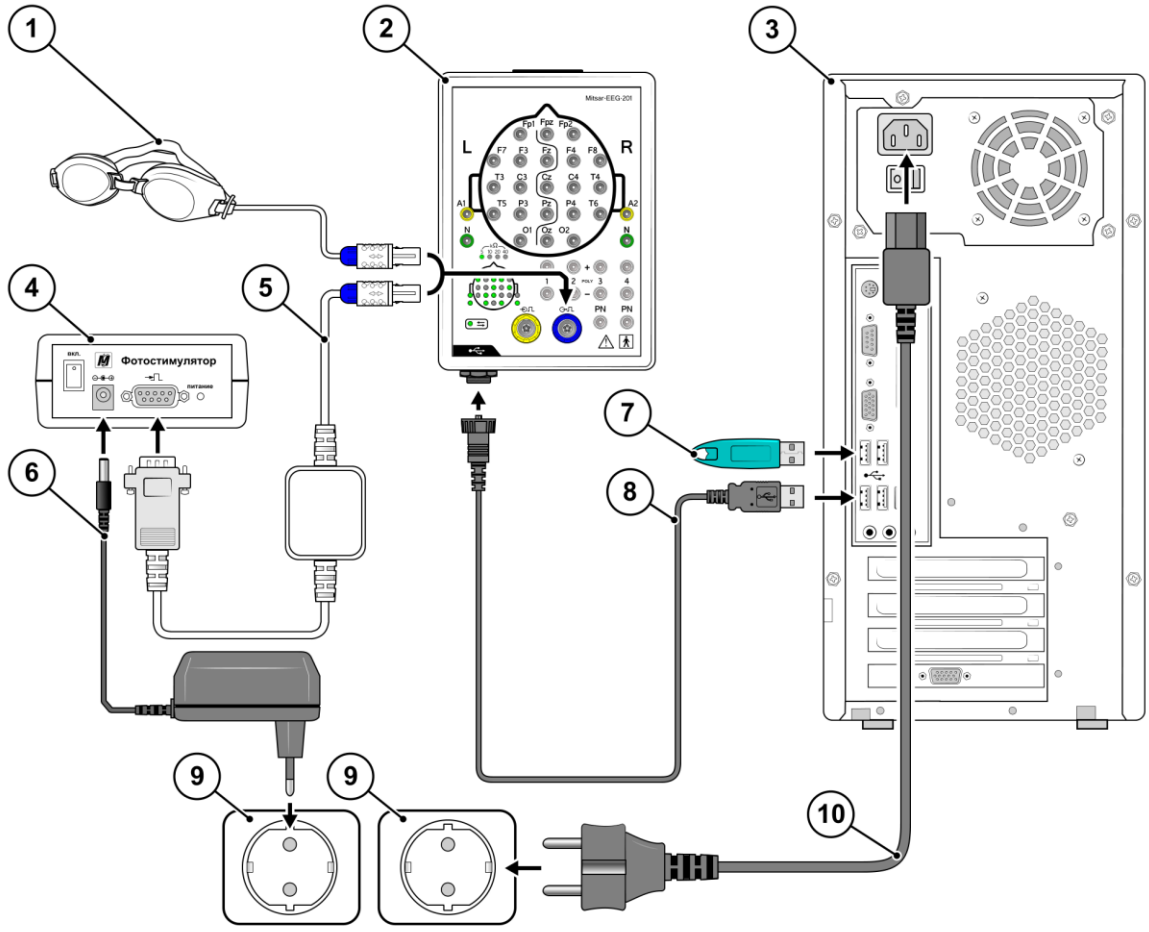

Figure 1. EEG system connection diagram

ATTENTION! Personal computer should be located outside the patient environment (see section 2.4 Safety requirements).

Figure 1 shows the following position numbers:

1. Photic stimulator (glasses);
2. Mitsar-EEG Amplifier box
3. CPU init;
4. Stationary photic stimulator;
5. Photic stimulator synchronization cable;
6. Photic stimulator power supply unit;
7. Dongle (only for WinEEG);
8. USB A cable– mini USB B;
9. Mains socket with grounding and isolation transformer;
10. PC power cable.

1.7.2 EP investigation

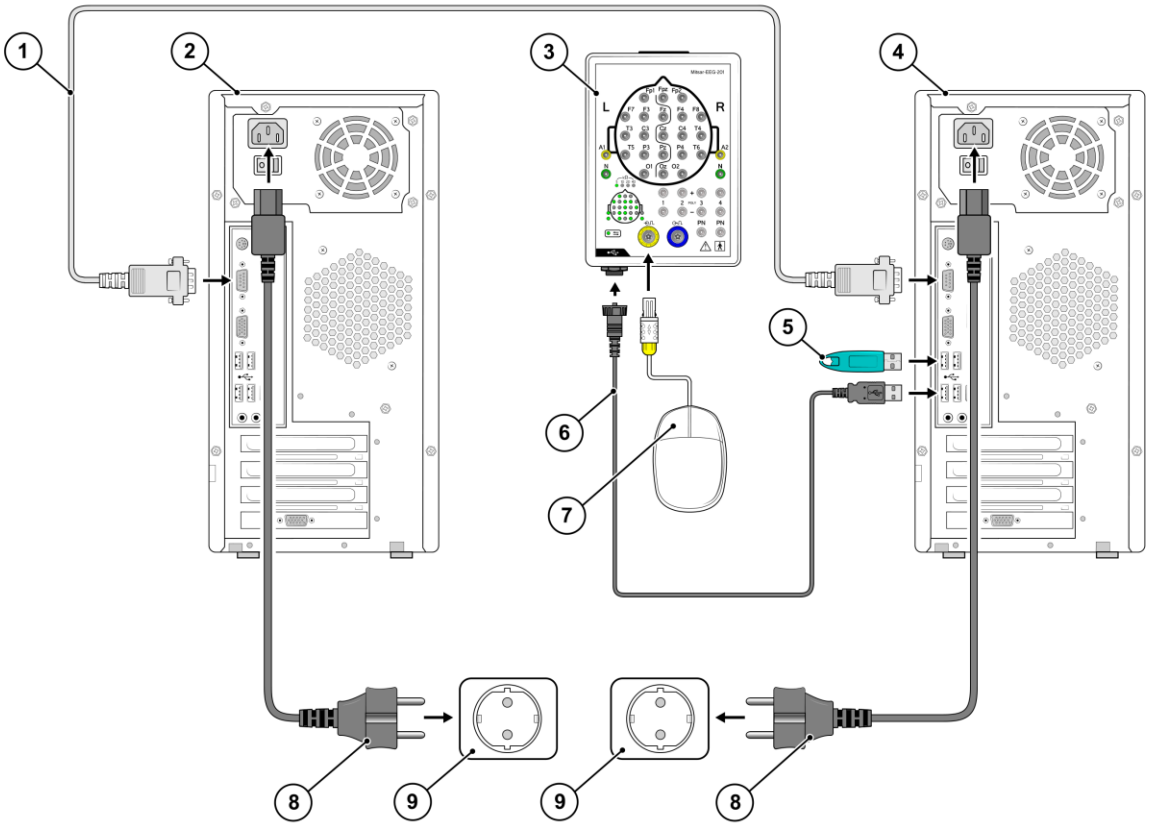

Figure 2. EEG system connection diagram for EP investigation

ATTENTION! Personal computer should be located outside the patient environment (see section 2.4 Safety requirements).

Figure 2 shows the following position numbers:

1. Synchronization (null-modem cable)
2. CPU unit with PSYTASK program;
3. Mitsar-EEG Amplifier box
4. CPU unit with WinEEG program;
5. Dongle
6. USB A cable– mini USB B;
7. Patient response button
8. PC power cable.
9. Mains socket with grounding and isolation transformer

1.7.3 Video-EEG recording

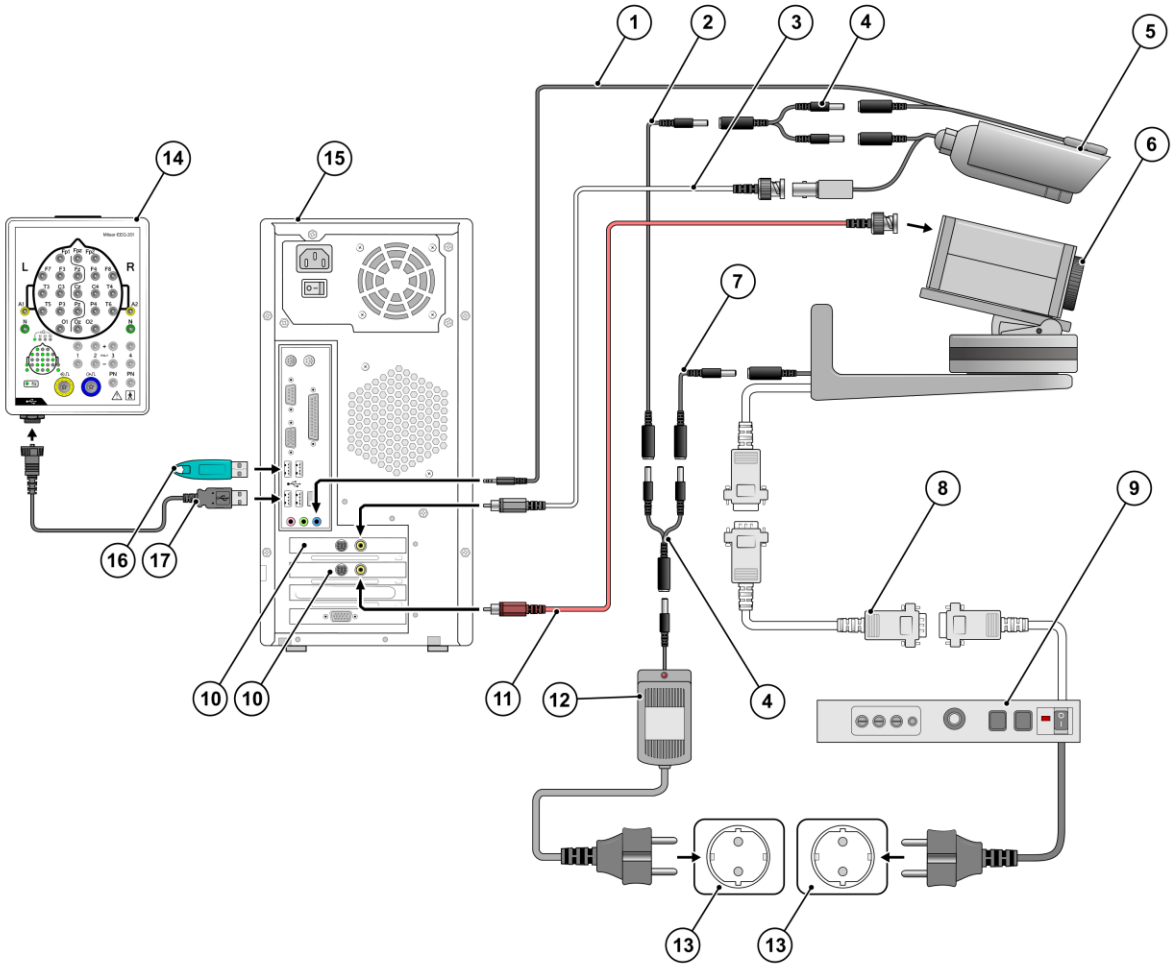

Figure 3. EEG system connection diagram for video EEG recording

ATTENTION! Personal computer and multimedia accessories should be located outside the patient environment (see section 2.4 Safety requirements).

Figure 3 shows the following position numbers:

1. Audio cable for microphone connection;
2. Camera power cable (5).
3. Video cable;
4. Power divider;
5. Infrared videocamera with built-in microphone and set of cables
6. Video camera with transfocator and rotating device;
7. Camera power cable (6).
8. Cable for connection control panel to rotating device;
9. Rotating device control panel;

10. Video capture cards;
11. Video cable;
12. Power supply unit;
13. Mains socket with grounding and isolation transformer;
14. Mitsar-EEG Amplifier box
15. CPU init;
16. USB key
17. USB A cable– mini USB B;

Different configurations of video EEG recording systems may be on the basis of electroencephalographic PC-controlled system “Mitsar-EEG”. Connections of multimedia accessories may differ from those in the diagram.

1.7.4 Investigation with phonostimulator

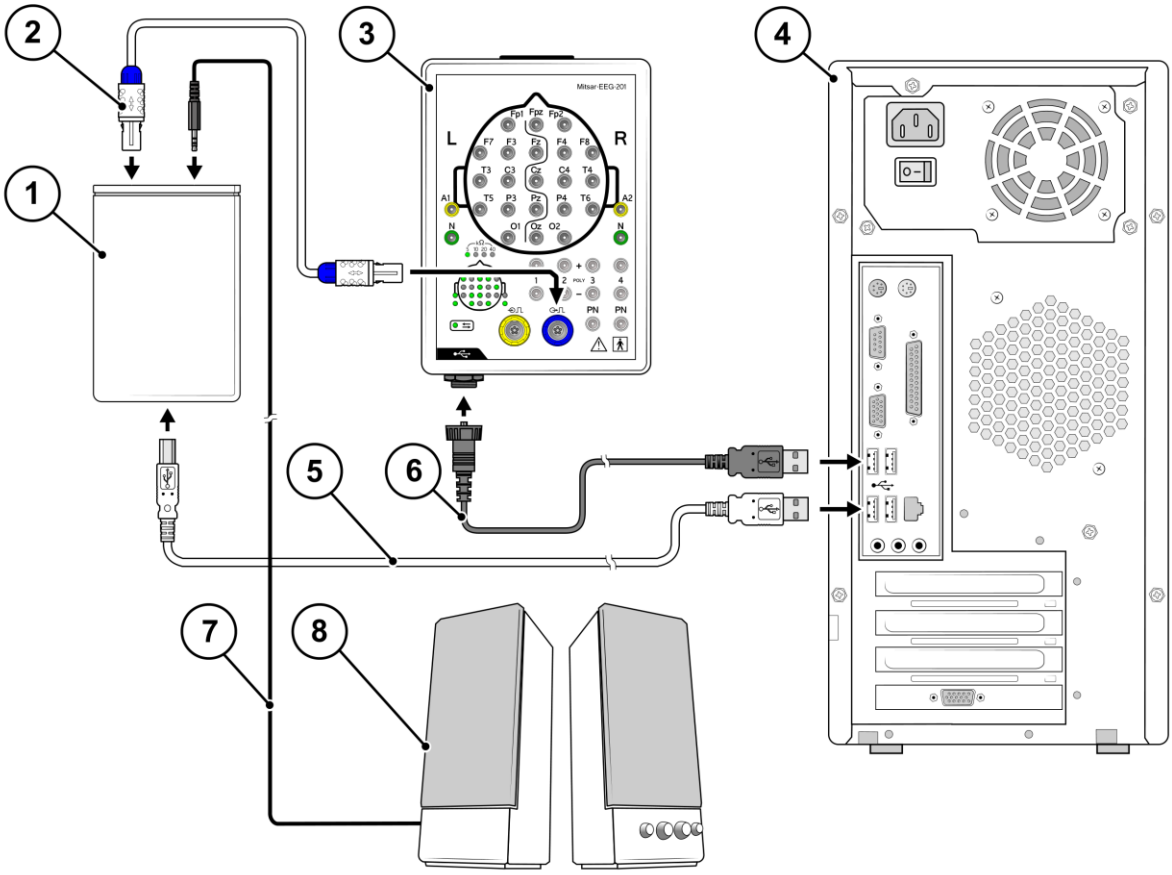

Figure. 4. Phonostimulator connection diagram.

ATTENTION! Personal computer should be located outside the patient environment (see section 2.4 Safety requirements).

Figure 4 shows the following position numbers:

1. Phonostimulator;
2. Phonostimulator synchronization cable;
3. Mitsar-EEG Amplifier box
4. CPU unit;
5. Cable USB A – USB B;
6. USB A cable– mini USB B;
7. Cable Stereo Jack 3.5 mm;
8. Audio columns.

1.7.5 Locating personal computer within the patient environment

Sometimes it is necessary to locate computers and other nonmedical parts of the system within the patient environment. This problem can be solved using mains isolation transformer corresponding the requirements of EN 60601-1 (IEC 60601-1).

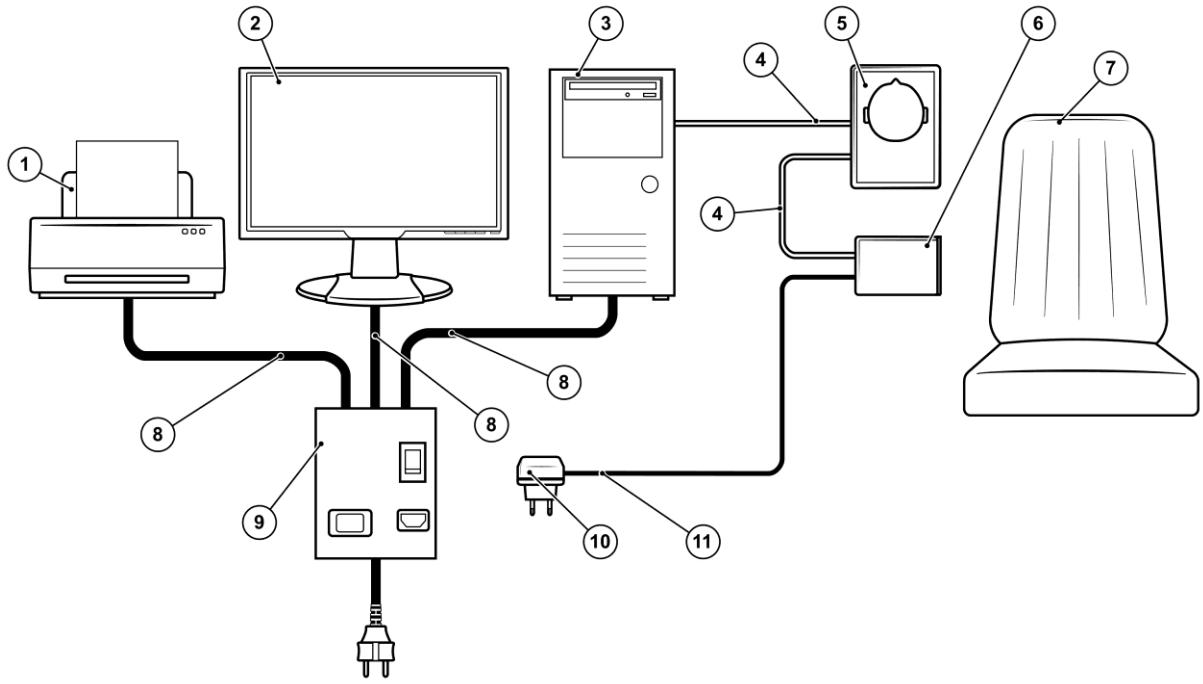

Figure 5. Connection of EEG system via isolation transformer.

Figure 5 shows the following position numbers:

1. Printer;
2. Monitor;
3. CPU unit;
4. Signal cables PC – Amplifier and Amplifier – photic stimulator
5. Mitsar-EEG Amplifier box
6. Photic stimulator;
7. Patient armchair;
8. Power cables;
9. Mains isolation transformer;
10. Photic stimulator power supply unit;
11. Photic stimulator power cable.

The connection diagram shown in Figure 6 is approximate and may differ depending on computer and other equipment involved.

The mains isolation transformer may be not included in the EEG system delivery set.

You can purchase transformer yourself or request the system supplier. For correct choice of transformer it is necessary to know the power and type of devices which it should be connected to. Consult Mitsar Co. Ltd for advice, if necessary.

ATTENTION! The choice of mains isolation transformer and connection of equipment to it should be performed by qualified specialist to follow all safety requirements.

The power of the mains isolation transformer should be sufficient to provide normal operation of all devices connected to it.

1.7.6 Mitsar-EEG portable workstation

Mitsar-EEG system combined with PC and isolation transformer could be installed on the portable cart together with universal arms for amplifier box and Photic stimulator. This solution allows you to be mobile and flexible inside your division and meets safety requirements.

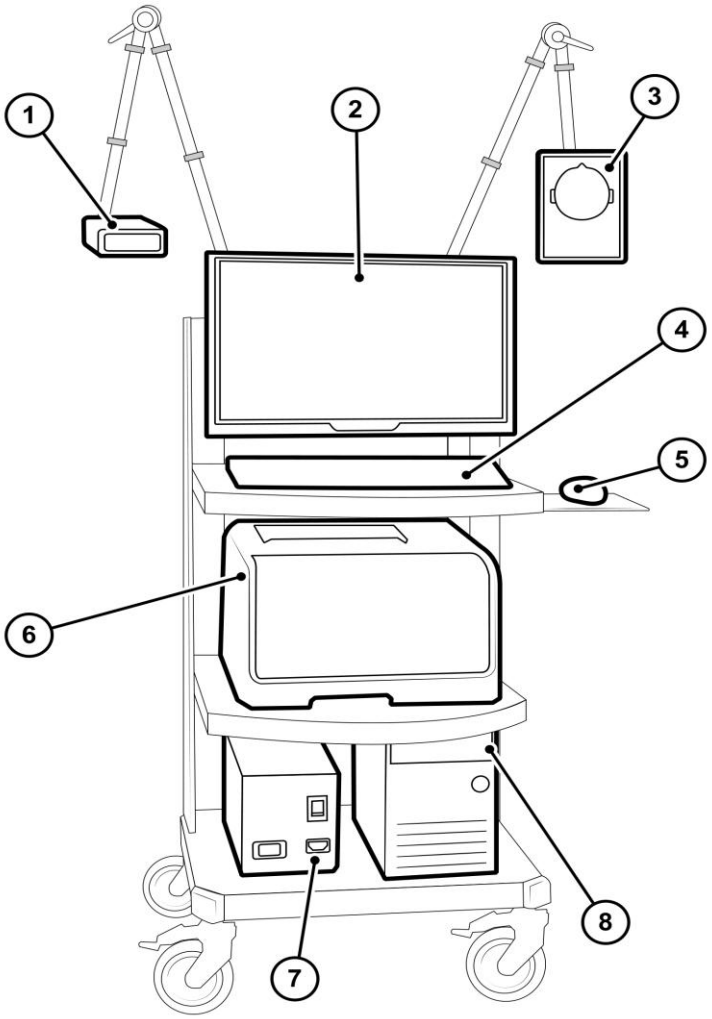

Figure 6.

Figure 6 shows the following position numbers:

1. Photic stimulator;
2. Monitor;
3. Mitsar-EEG Amplifier box;
4. Keyboard
5. Mouse
6. Printer;
7. Mains isolation transformer;
8. CPU unit.

2. Technical data

2.1 Biosignal Amplifier

The EEG system complies with the requirements of technical specifications TU 9441-001-52118320-2009.

The EEG system includes the biosignal amplifier (Amplifier), stationary or portable PC, and additional accessories. The Amplifier is controlled by special software.

The amplifier is delivered in the following versions: Mitsar-EEG-03/35-201 version (hereinafter: Version 03/35), Mitsar-EEG-05/70-201 (hereinafter: Version 05/70), Mitsar-EEG-10/70-201 (hereinafter: Version10/70).

The layout of Amplifier connectors and indicators is shown in Figure 7 by Version 10/70 example:

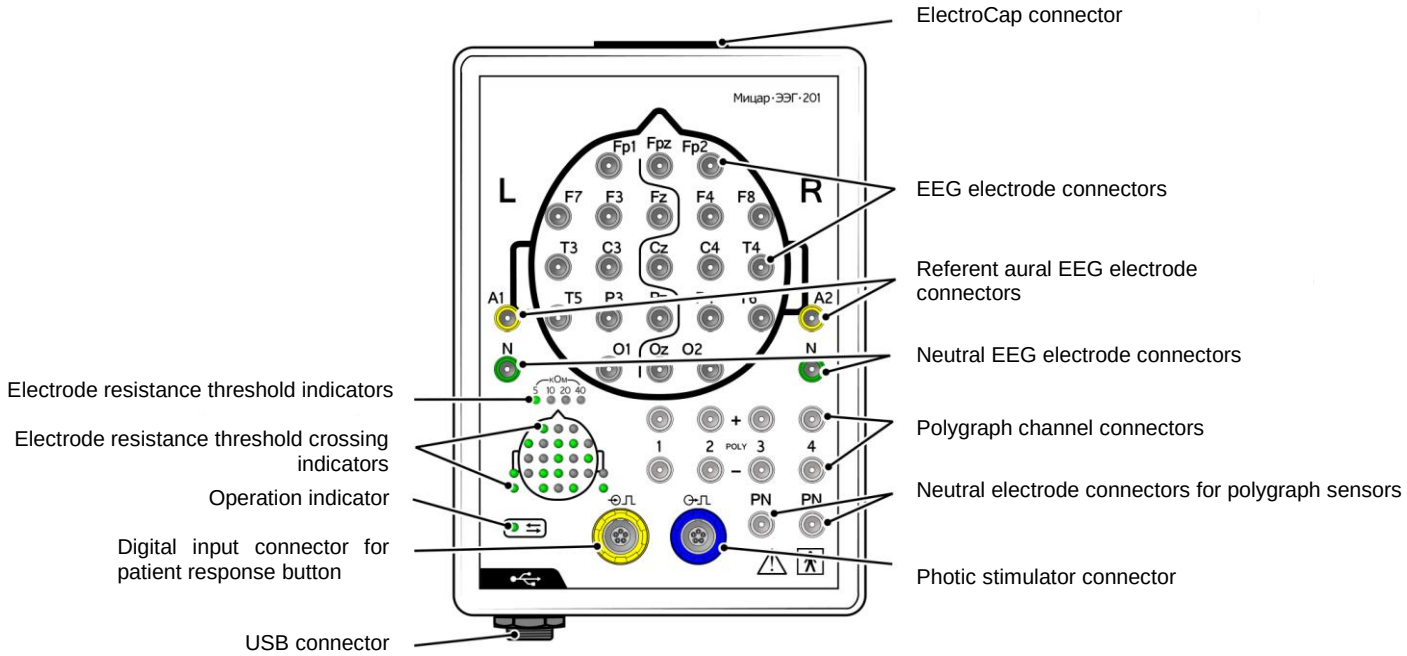

Figure 7. Mitsar-EEG-201 Amplifier box, layout of connectors and indicators layout for Version 10/70.

> ! For Version 03/35 no Fpz and Oz electrode connectors fitted.

> ! Versions 03/35 and 05/70 have only one pair of connectors for polygraph channels and one connector of neutral electrode for polygraph sensors**.**

No connector for ElectroCap electrode is fitted for Version 03/35.

2.2 Amplifier technical data

	Version		
	03/35	05/70	10/70
EEG channels			
Number of EEG channels	19	21	21
Bandwidth	0.53 – 35 Hz	0.16 – 70 Hz	0.16 – 70 Hz
Additional HF filters	1.6, 5.3 Hz	0.53, 1.6, 5.3 Hz	0.53, 1.6, 5.3 Hz
Additional LF filters	15, 30 Hz	15, 30 Hz	15, 30 Hz
Impedance check of electrodes	yes	yes	yes
Input voltage range	from 10 to 5000 μV		
Relative error, at most	within the range of 10 μV to 50 μV, ± 10 % within the range over 50 μV, ± 5 %		
Notch filter	-30 dB at 50 (60) Hz		
Sampling frequency	500 Hz per channel		
Input resistance	over 200 MΩ		
Internal noise voltage	at most 0.25 μV RMS		
Channel interaction ratio, at most	1 %		
Common-mode rejection	at least 100 dB at 10 Hz		
Amplifier capacity	16 bit		
Polygraph channels			
Number of polygraph channels	1	1	4
Bandwidth	0.16 – 70 Hz		
Additional HF filters	0.53, 1.6, 5.3 Hz		
Additional LF filters	15, 30 Hz		
Input voltage range	of 30 to 10000 μV		
Relative error, at most	± 10 %		
Input resistance	over 200 MΩ		
Other channels			
Number of digital inputs	2	2	2

External events inputs	yes	yes	yes
Photic stimulator (LED)	yes	yes	yes
Phonostimulator (download from PC)	yes	yes	yes
Connector for electrode cap	no	yes	yes

Other characteristics

Relative error of time intervals within the range of 0.2 to 10 s, at most	± 5 %
Amplifier electrical safety	BF type with internal power supply unit
System electrical safety	Class I, type BF
Amplifier power supply	of 3.6 to 6.5 V (4 batteries R6 type)
System power supply	220 ± 22 V (50 Hz)
Amplifier consumption current	at most 0.048 A at power voltage 6 V
Total operation time on one battery set	at least 50 h
Mean continuous time operation per day	at least 8 h
PC interface	via standard serial USB port
Amplifier mass	at most 1 kg
Amplifier overall dimensions (without tripod)	at most 200 x 140 x 55 mm

The polygraph channels may be used for input and displaying EEG signal. Due to the fact that these signals do not comply with the standard on EEG measuring channel, namely, due to small value of time constant there occurs distortion of QRS-complex, the EEG input signal can't be used for calculation of EEG parameters and making out a diagnosis by waveform. The input EEG signal may be used for position visual estimation and calculation of time delays between the R-wave position and some other signals.

2.3 Description of operation principle

EEG system is intended only for medical purposes. The system is used to measure and record the electrical activity of the patient's brain. Electroencephalographic and polygraph signals are obtained by placing electrodes (sensors) and enter the multichannel voltage amplifier (Amplifier).

The voltage amplifier (which functional diagram is shown in Figure 8) amplifies the electrical signals up to the level coordinated to the analog-digital convertor (ADC) range, and the signals come through analog filters (HF and LF first-order filters are used).

The amplified signals are reduced to common signal by means of the voltage switching unit. This signal is applied to ADC input which converts it to digital form sequentially for each channel. The ADC converts the signal to 16-bit digital code.

Synchronization of the voltage switching unit and the ADC, control of photic stimulator and data exchange with computer are effected by microcontroller-based control device. The data are transferred to computer via standard USB type serial interface through the decoupling device and the level converter providing conditioning levels of the decoupling device and serial interface. The decoupling device provides insulation strengthening.

The Amplifier is energized from electrochemical cells (internal power supply unit). Voltages necessary for device operation are generated by power supply unit which is initiated by program command and then maintained in turn-on condition by sending special commands. If program terminates command transmission to maintain device in turn-on condition or communication with computer is interrupted, the power supply unit automatically will be turned off in 2-5 seconds. Device turn-on condition is displayed with special operation indicator on the device front panel.

The system software provides creation of data files for input biosignal, primary digital filtration of the data, displaying of those as curves at a PC monitor, storing of the data on PC hard disk and their further processing.

EEG analysis features are described in the user's manual for the software.

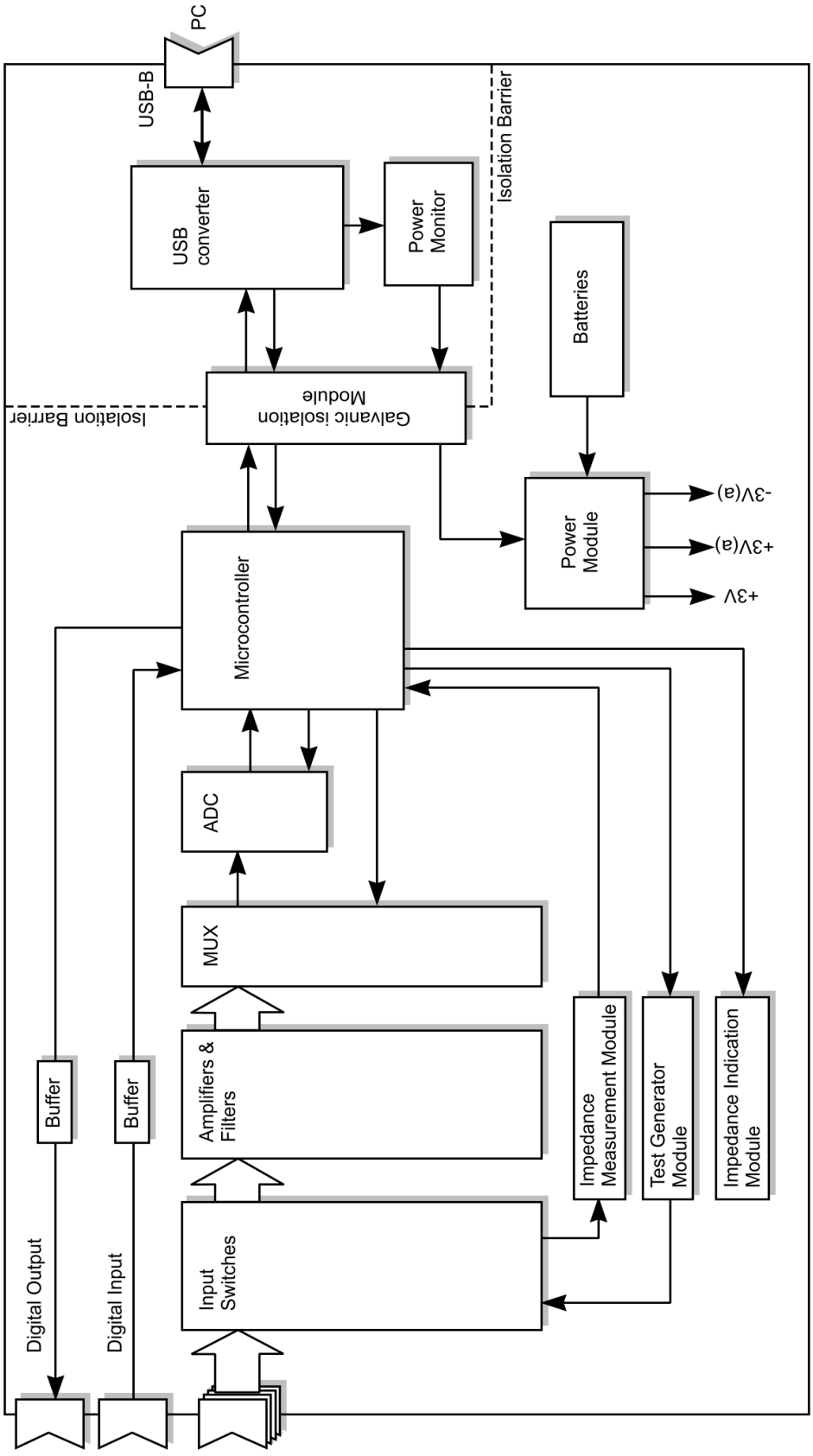

Figure8. Functional diagram of “Mitsar-EEG” Amplifier

2.4 Safety requirements.

The Amplifier complies with the usage safety requirements as per EN 60601-1, as a device with internal power supply unit of BF type. The EEG system conjointly with a line-supplied PC complies with the electrical safety requirements class I, type BF, standards EN 60601-1, EN 60601-2-26, EN 60601-1-1, EN 60601-1-2, EN 60601-1-4.

The Amplifier, as regards protection level against harmful water intrusion, refers to common devices (devices with housing without water intrusion protection IP 40) as per EN 60529.

2. General safety of the EEG system is provided by fulfillment of the requirements of standard EN 60601-1-1.

3. The Amplifier operates within the patient environment (see Figure 9).

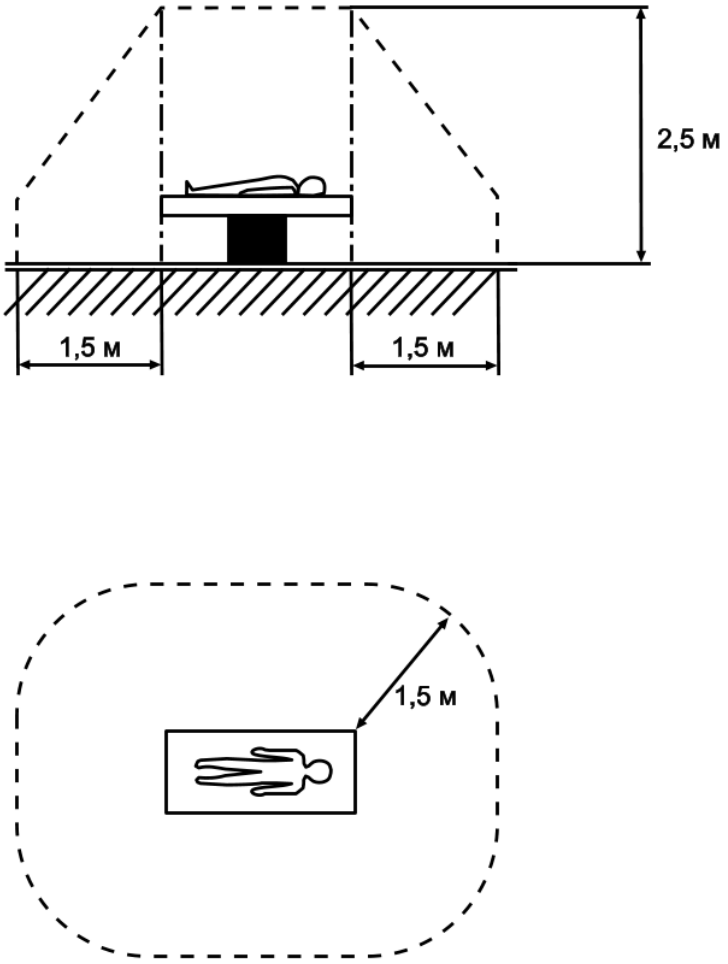

Figure 9. Example of patient environment.

4. The personal computer represents a subsystem of non-medical equipment and should be located outside the patient environment.

5. The decoupling device built-in the amplifier unit supports appropriate safety levels for the amplifier unit and PC after interconnection.

6. Electric strength of insulation between the applied parts and the PC connection cable (strengthened insulation) complies with the requirements of EN 60601-1.

7. The connection cable has the length of at least 3 m for removing the PC from the patient environment.

8. ATTENTION! PC and other non-medical electrical devices should be installed outside the patient environment.

If it is necessary to locate a personal computer or other non-medical electrical equipment within the patient environment, read section: 1.75 Locating personal computer within the patient environment.

9. ATTENTION! PC, monitor and printer should be connected to AC power supply line only via socket equipped with ground contact.

It is inadmissible to use multisocket extension cords without additional safety measures. A ground wire should be connected as the third wire of eurosocket. It is inadmissible to connect PCs via adapters isolating the third wire. Probable breakage of multisocket extension cord safety grounding will lead to summation of leakage currents up to dangerous values.

It is inadmissible to locate multisocket extension cords on the floor due to risk of liquid intrusion and their mechanical damages.

It is inadmissible to power PC via additional extension cord.

It is inadmissible to connect devices not referring to the EEG system to multisocket extension cord connected to the EEG system.

Multisocket extension cords and multiple socket-outlets should be connected via mains isolation transformer. Otherwise, the structure of multisocket extension cords and multiple socket-outlets should allow only tool assist connection (Figure 10). (Requirement of EN 60601-1-1, IEC 60601-1-1).

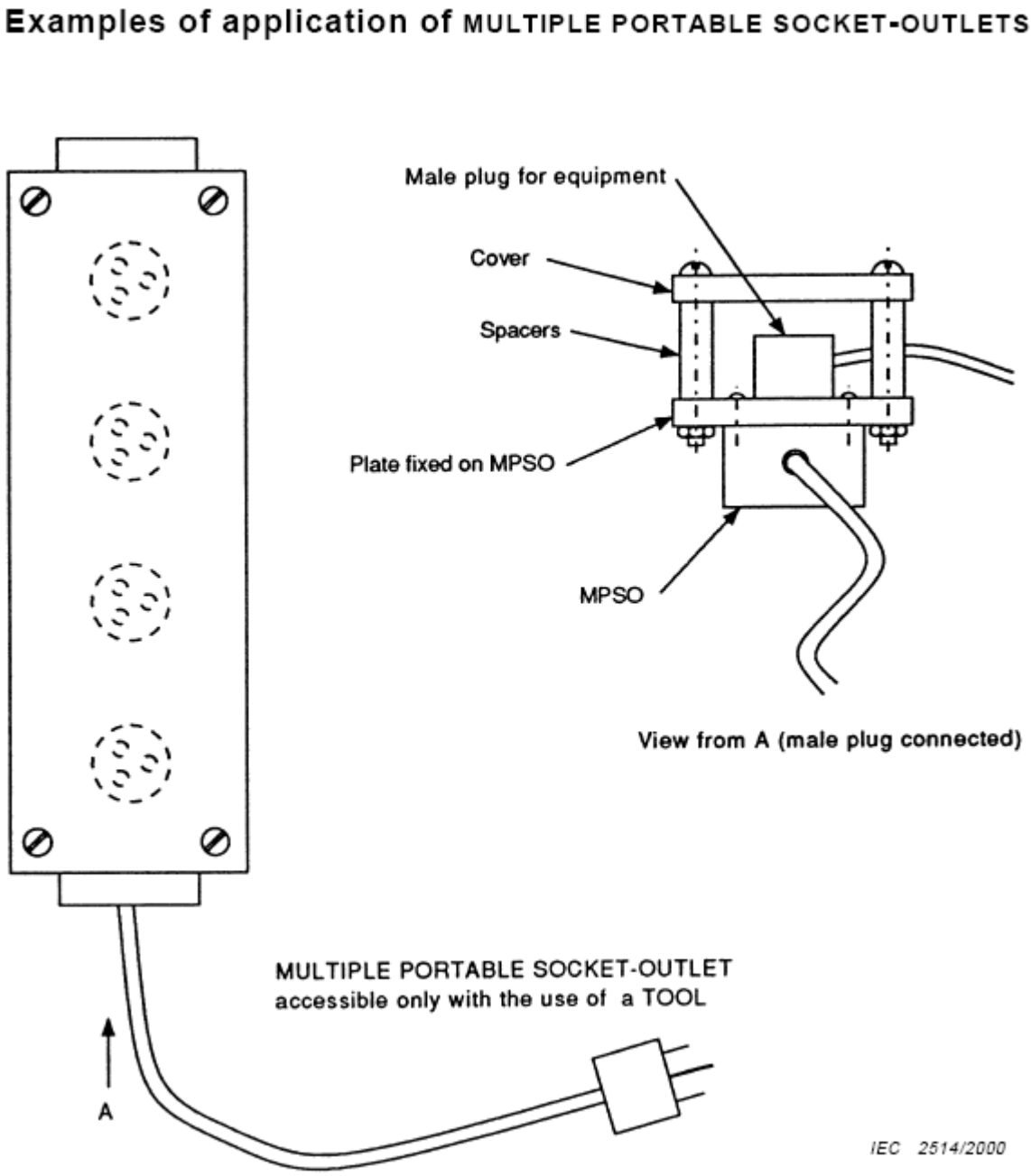

Figure 10. Example of multiple socket-outlets with tool assist connection.

10. PC should have electrical isolation for 1500 V.

11. The amplifier incorporates decoupling device for at least 4 kV voltage in circuit connections with PC.

12. The amplifier is energized from four R6 (AA) batteries 1.5 V and accumulators 1.2 V. It is recommended to use alkaline batteries (LR6 type), oxy-alkaline (Ni-Zn), ZR6 type batteries or nickel-metal-hydride (NiMH) accumulators (type R6, HR6).

It is inadmissible to use batteries of nonhermetic version.

It is inadmissible to use salt batteries (type R6), commonly designated: «Heavy Duty», or «Zinc Carbon», or «Zinc Chloride», or «ZnCl».

It is recommended to use batteries only of well-known manufacturers, e.g.: Duracell, Energizer, Toshiba, Philips, GP.

13. Only persons trained and instructed on safety precautions are admitted to operate the EEG system. A personnel training is a part of handing over procedure to the customer.

14. Prior to use the electrodes, thoroughly read this operation manual, provided by the manufacturer.

15. The requirements on computer equipment, operation system, its setting and other programs on the same PC, are given in section 1.2 and user's manuals on corresponding software supplied with device.

ATTENTION! The following residual risks occur when operating the EEG system:

1. Electric shock of patient or personnel due to mechanical damage of the Amplifier casing or casings of computer equipment.

Safety measures to avoid the risk:
The EEG system operation is prohibited in case of mechanical damage of the Amplifier casing or casings of computer equipment. The components with mechanical damage of casing should be immediately removed from operation and send for repair. The Amplifier is to be sent to manufacturer, and computer equipment to service center recommended by supplier of this equipment or to servicing organization.

2. Possibility to use materials contacting the patient body with insufficient sanitary, hygienic and toxicological parameters.

Safety measures to avoid the risk:
It is allowable to replace electrodes and/or their fixing devises, not delivered with the system, for the other only if the latter have corresponding certificates.

3. Bad record and/or incorrect interpretation of results is possible due to the following: inadequate personnel qualification; incorrect application of electrodes; interference; application of computer equipment, operation system and other software not recommended by the manufacturer.

Safety measures to avoid the risk:
The personnel operating the EEG system should be adequately qualified for correct application of electrodes, EEG recording and its interpretation.

3. Additional information

3.1 Other manuals

There are additional manuals with detailed information on the EEG system software.

1. User’s manual on EEG Synapse program.
2. User’s manual on WinEEG program.
3. User’s manual on PSYTASK program.
4. User’s manual on BrainTuner program.

3.2 Antivirus software

The EEG system software may conflict with antivirus software installed on PC. This may cause data loss when EEG recording. Therefore, active scanning of PC and virus cure during operation of our software is not recommended.

3.3 Turn-on

To provide patient safety, connect the patient electrodes only after the EEG system is fully turned on.

Turn off the system power before connecting or disconnecting any system component(s) or accessories. Otherwise, you may damage the system.

Turn-on the system by pressing the power button on the CPU unit.

3.4 Turn-off

To provide patient safety, disconnect all recording and stimulating electrodes from the patient before you turn off the system.

The amplifier automatically turns off at signal input stop, disconnection of interface cable and PC turn-off. No additional measures on the Amplifier turn-off are required.

Prior to the system turn-off, be certain to close an application program and exit Windows. Otherwise, it may cause data loss or problems may occur at the next system starting.

Turn-on the system by pressing the power button on the CPU unit.

3.5 Leakage current

The EEG system conjointly with PC complies with the electrical safety requirements class I, type BF, standards EN 60601-1, EN 60601-2-26, EN 60601-1-1.

The standard EN 60601-1 defines the permissible leakage currents for separate components. In case of connecting several systems to the patient, their leakage currents will sum. As a result, the total leakage current can exceed the allowable value and create a dangerous situation. If you want to connect equipment to the patient simultaneously with EEG recording, insure that the total leakage current do not exceed the allowable value.

It is inadmissible to use multisocket extension cords without additional safety measures. A ground wire should be connected as the third wire of eurosocket. It is inadmissible to connect PCs via adapters isolating the third wire. Probable breakage of multisocket extension cord safety grounding will lead to summation of leakage currents up to dangerous values.

When connecting other electric equipment, follow safety measures to avoid the system damage.

3.6 Relocation

Turn off the system before relocation.

When disconnecting cables, pull on connector, not cable.

3.7 Maintenance

Violation of storage and transportation conditions may cause its damage and malfunction. Under suspicion of equipment damage or malfunction, it should be turned off and protected against further operation.

It is recommended to examine daily cables for wear (e.g. breaks). If these symptoms present, disconnect cable for repair and replacement.

If the estimated service interruption of the Amplifier is over one month, it is recommended to take the batteries out of the battery compartment.

Exhausted batteries should be replaced by new ones when required. The symptom is a special warning message to replace battery, which appears when program running.

When using accumulators, follow the charging instructions provided by accumulator manufacturer. The Amplifier operation time from one accumulator set and the number of operation/charging cycles significantly depends on the type of charger. Consult the accumulator supplier or Mitsar Co. Ltd for advice to select a charger, if necessary.

It should be mentioned that the Amplifier operation time with one battery set is longer than that with a set of accumulators up to their discharge.

The Amplifier should be cleaned with standard means.

Do not autoclave any parts of the EEG system.

Do not use acetone for cleaning the components of the system.

The maintenance of the system components, being the standard computer equipment, should be performed in accordance with their operation manuals.

The electrodes after usage should be cleaned from electrolyte (contact gel, saline), rinsed and, if necessary, disinfected in accordance with instruction on corresponding type of electrode. More detailed information on special features of electrodes operation can be obtained from their manufacturers.

Do not apply agents containing ammonia for cleaning electrodes.

3.8 Service life

Mean service life of the Amplifier till discarding is at least 5 years.

The storage period shouldn’t exceed 1 year from the date of manufacture till commissioning.

The calibration period is 1 year.

3.9 Utilization.

Utilization of the equipment and batteries should be done in correspondence to the requirements of local organizations engaged in utilization of waste.

4. System operation

4.1 Application of electrodes

As a rule, the lead electrodes are applied on the patient in accordance with diagram 10-20 (see Figure 11), that allows with the help of different montages, containing of 16 to 24 leads, to record a sufficiently informative electroencephalogram.

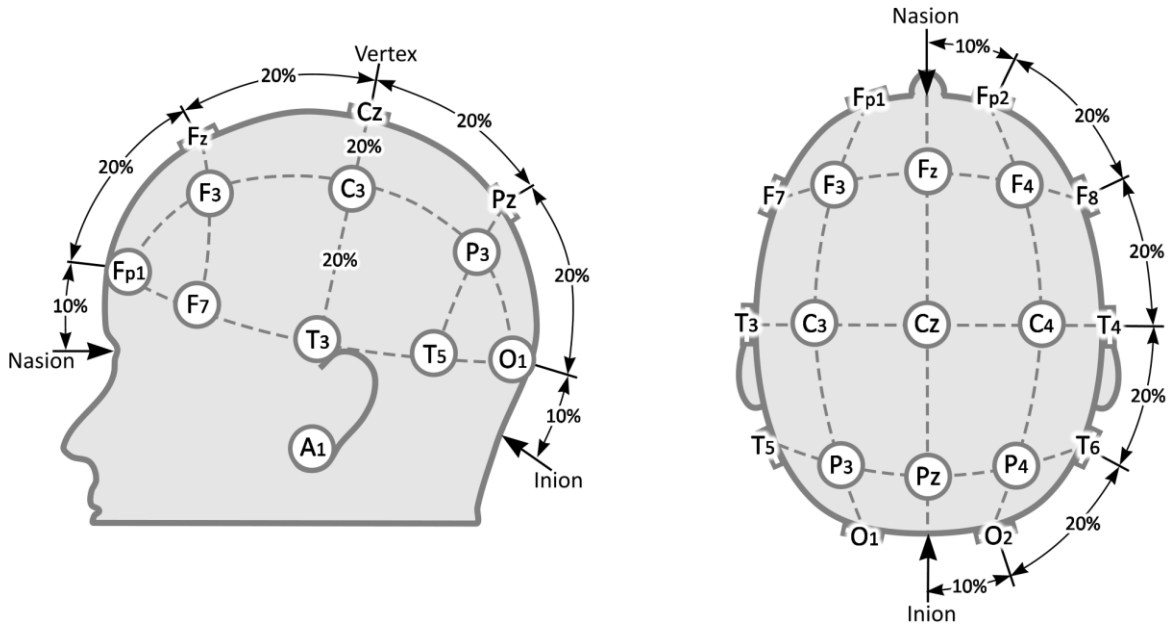

Figure 11. EEG electrodes application diagram in compliance with the International standard lead system 10-20 (as per H. Jasper, 1958).

High quality of EEG recording can be obtained only when using an electrolyte layer between the electrode surface and patient skin.

The following are used as such electrolyte:

– with bridge electrodes – cloth liner or cotton pellet moistened in saline;

– with disk electrodes – special contact high-conductivity gel, e.g. Unimaks, manufactured by Geltek-Medika Co, Ltd;

– with electrode caps manufactured by Electro-Cap we recommend to use only ECI Electro-Gel;

– with adhesive electrodes we recommend to use adhesive conductive paste, e.g. Ten20 manufactured by Weaver and Company.

For high-quality EEG recording the application of neutral and reference electrodes is obligatory.

The aural electrodes (sockets A1 and A2) serve as reference electrodes for EEG signals of corresponding hemisphere. Depending on the software settings (see corresponding software user’s manuals) the EEG is recorded either relative to A1, A2, or relative to (A1+A2)/2. In the second case sockets A1, A2 are electrically connected on software command.

Recording relative to independent reference lead

Available is recording relative to independent reference lead used instead of aural (parietal, frontal, etc.). For this recording it is necessary: a) to set option in software “to connect (to close) A1 and A2”, b) to connect reference electrode to one of sockets, A1 or A2.

In case the reference electrodes are not applied or defective, a noise-shaped signal will be recorded, not reflecting the actual brain activity.

The neutral electrodes (sockets N) serve to link biosignals to zero potential of patient body. These electrodes are usually applied either on cheekbones or forehead. Contact resistance of other electrodes in "Resistance check" mode is measured relative to neutral electrodes. In case the neutral electrode is not applied or defective, generally instead of EEG there may be observed: distorted low-frequency signal, 50 (60) Hz interference or saturation of amplifiers with spicular breakouts.

The Mitsar-EEG Amplifier also includes separate sockets (marked PN) for connection of neutral conductors of polygraph sensors (e.g. EEG).

The EEG system during recording initially applies monopolar montage; however, monopolar montage during and after recording may be converted to any other type suitable for user.

4.2 Measuring electrode resistance

The quality of electrode application (contact with skin) can be checked with mode “Resistance check” in program running with the EEG system. Herewith, the quality of electrodes application can be checked both in the program itself and on the device front panel.

In the program the chart with electrodes is displayed similarly to location of those in the device. The electrode color corresponds to resistance value designated on the scale.

Resistance can be checked from the front panel with the help of special resistance threshold crossing indicators of electrodes (see Figure 5). The current resistance threshold is also indicated on the front panel and may be changed with the help of program in the mode “Resistance check”. When applying electrodes, it is necessary to obtain that for the threshold set value all threshold crossing indicators go off.

The device provides high-quality EEG recording with the resistance value less 20 kΩ, it is recommended to obtain the resistance less 10 kΩ, and in the presence of strong radio interference, 5 kΩ.

In order to decrease the impedance, maximum attention should be paid to the quality of application of neutral and reference electrodes, as the signals from these electrodes will influence the record quality of all channels. If the impedance level is high at all leads, then at first instance the quality of neutral electrodes application should be checked. Unusable (not recording) electrodes should be disconnected from the switching box.

To improve recording quality and to decrease the transient resistance it is recommended to draw apart patient hair and to wipe the skin with alcohol in the place of electrode application.

4.3 Software operation

In the process of recording the signals from EEG and polygragh channels in digital form enter PC from the Amplifier unit and are displayed on the monitor screen as specific curves (graphs). Recording of EEG signals on PC hard disk can be initiated and stopped repeatedly for their storage (archiving) and the following analysis. The total record time is limited only by free space available on hard disk.

In parallel to EEG recording, it is possible to record patient video image (so called video-EEG).

After finishing recording of EEG signals, the saved data are available for visual analysis. Similar to recording, in visual analysis the EEG signals are displayed on the monitor screen in the form of oscillogram in the mode emulating the paper tape in the recorder. Additionally, the following is provided in the mode of visual analysis: possibility of manual measurement of signal parameters (intervals and amplitudes), measurement of horizontal and vertical scale (paper travel speed and sensitivity), marking of "interesting" parts of records, deleting artifact record parts, etc.

A detailed description of software operation is given in corresponding description enclosed with the system delivery set.

4.4 EEG recording operation features.

The main reason of unsatisfactory operation of the EEG system may be periodic line 50 (60) Hz or high frequency interference. Although, the EEG system complies with the requirements of standard EN 60601-1-2, due to small amplitude of EEG signals, there may occur signal distortions owing to external interference. This interference may be caused by various reasons:

1. Computer grounding is poor or absent.
2. The electrodes are contaminated. Follow maintenance instructions enclosed to electrodes.
3. Unsatisfactory application of EEG electrodes (indication for that is 50 (60) Hz pickup in one or more channels).
4. Unsatisfactory application of neutral or reference electrodes (indication for that is 50 (60) Hz pickup in one or more channels).
5. Damage of conductors or connectors for connection of electrodes.
6. Powerful electric equipment is present in the neighborhood of the EEG room which generates strong interference (e.g., X-ray installations, physiotherapy equipment, etc.).
7. TV or radio transmitter, radar or cellular station located within small distance from the building (distance depends on device capacity).

8. The Amplifier is located close to a wall with flush electric or cable wiring which screen is faulty or ungrounded
9. The amplifier is located near a large metallic surface (metal cabinet, box, safe, etc.) or close to a wall, behind which such object is located.
10. The cable connecting the Amplifier and PC is laid close to powerful device or interference source (CRT monitor, isolation transformer, laser printer, UPS, etc.
11. During investigation there is a sparkling electric switch, defective fluorescent lamp.
12. Domestic electric appliances (microwave oven, coffee grinder, etc.) are on at the time of investigation.
13. Cellular or radio telephone is used during investigation.

It is recommended to start search for unsatisfactory record quality reason from grounding connection and its quality, electrode applying quality and their operability and so on as per list. Eliminate the reason found. Some reasons may require relocation of the EEG system to another room or application of screened compartment.

Also pay attention to the fact that, although the EEG system complies with the requirements of electromagnetic compatibility, it may cause interference for operation of more sensitive equipment.

4.5 Troubleshooting

This section presents recommendations on troubleshooting during device operation.

All procedures listed below should be performed only by IT specialists, as an inexperienced user may cause complete computer failure.

If at an attempt to signal input, the operation indicator on the front panel does not go on, and no input is initiated, the following checks should be performed:

1. Check the USB cable connection. Connect the USB cable from the Amplifier to another USB socket of PC.
2. Batteries are incorrectly inserted or cartridge contact is faulty. Check the batteries polarity and cartridge contacts.
3. Batteries may be exhausted. Check batteries and replace them if necessary.

If after turning on the device, the input signal continues for 1-10 seconds (herewith, the operation indicator on the front panel is lighted), then it stops, and the device turns off, try to do the following:

1. Check batteries and their polarity in the Mitsar-EEG Amplifier. Replace batteries, if necessary.

2. May be hard disk of PC is full. Clear space on hard disk for the program operation. Check disk defragmentation.
3. Close all programs running in parallel, terminate antivirus automatic scanning, security programs, Ensure that nobody works with the data on your PC via local network. The processes running background may use much processor time.
4. Turn off all power saving options (Power Management), at least for the time of input: for monitor, hard disk, USB-port, etc., also it is desirable to disable screensaver.
5. Enable graphic acceleration in program settings.
6. In program use only oscilligraphy mode.
7. If your video card is slow, use 16-bit video modes, install DirectX, check correspondence of video card, drivers and the operation system in use, download and update video card drivers from the site of manufacturer or replace your video card with later versions.
8. If your PC is fitted only with integrated video card (except notebooks), try to install external video card.
9. Try to install the EEG system on another PC.

If none of recommendations listed above gives positive result, consult Mitsar Co. Ltd customer support or your dealer.

5. Manufacturer's declaration regarding electromagnetic compatibility

<table>
<tr><th colspan="3">ELECTROMAGNETIC EMISSION</th></tr>
<tr><td colspan="3">The Electroencephalographic PC-controlled System "Mitsar-EEG" 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.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The System uses HF energy only for its internal function. The HF emission is therefore very low, and it is improbable that nearby electronic devices might be disturbed.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The System is intended for use in all facilities, including residential areas and in any facilities connected directly to a public power supply providing electricity to Harmonic emissions buildings used for residential purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Interference 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	**EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast Transient / Burst EN 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	The quality of the line power supply should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of the line power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5 % UT (> 95 % dip of UT) for 0.5 cycles 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip of UT) for 5 seconds	< 5 % UT (> 95 % dip of UT) for 0.5 cycles 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip of UT) for 5 seconds	The quality of the line power supply 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 by an uninterruptible power supply or a battery.
Power frequency magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">RF immunity</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td>Immunity test</td><td>EN 60601-1-2 test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Conducted RF
EN 61000-4-6</td><td>3 Vrms from 150 kHz to 80 MHz</td><td>3 Vrms from 150 kHz to 80 MHz</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:
$d = [1,2]\sqrt{P}$</td></tr>
<tr><td>Radiated RF
EN 61000-4-3</td><td>3 Vrms from 80 MHz to 2.5 GHz</td><td>3 Vrms from 80 MHz to 2.5 GHz</td><td>$d = [1,2]\sqrt{P}$
from 80 MHz to 800 MHz

$d = [2,3]\sqrt{P}$
from 800 MHz to 2.5 GHz

Where "P" is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and "d" is the recommended separation distance in meters.

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:
  </td></tr>
<tr><td colspan="4">[1)] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the System.
[2)] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people.</td></tr>
</table>

Таблица 1

Recommended separation distances between portable and mobile RF communications equipment and the System

The System model is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user 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 (in watts)	**Separation distance according to frequency of transmitter (in meters)**		
	$d = 1{,}2\sqrt{P}$ From 150 kHz to 80 MHz	$d = 1{,}2\sqrt{P}$ From 80 MHz to 800 MHz	$d = 2{,}3\sqrt{P}$ From 800 MHz to 2,5 GHz
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance “d” in meters 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 according to the transmitter manufacturer.

Remarks:
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

(2) These guidelines may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

6. DEED OF COMMISSION

The Amplifier "Mitsar-EEG", serial # _____, found to be ready for operation.

Manufactured on _____

Mitsar Co.Ltd._____

(date, signature, seal)

7. DATA ON INSTALLATION AND ASSIGNMENT TO OPERATION

The electroencephalographic system "Mitsar-EEG" serial # _____, have been installed and commissioned.

Date of installaton: _____

	Signature	Position	Name
Commissioned by:	_____		
Assigned by:	_____		

«MITSAR» CO.LTD.

WARRANTY COUPON # 1

for repair / replacement within the warranty period

Medical equipment - electroencephalographic system "Mitsar-EEG",
serial # _____, manufacturing date _____,

Purshased _____
_____
_____
_____-
_____ (date, signature and the seller’s seal)

Commissioned _____
(date, signature and the seller’s seal)

Assigned for warranty service by _____
_____
_____
_____
_____
____

Head of the enterprise - signature and stamp:

The customer’s signature:

«MITSAR» CO.LTD.

WARRANTY COUPON # 2

for repair / replacement within the warranty period

Medical equipment - electroencephalographic system "Mitsar-EEG",
serial # _____, manufacturing date _____,

Purshased _____
_____
_____
_____-
_____ (date, signature and the seller’s seal)

Commissioned _____
(date, signature and the seller’s seal)

Assigned for warranty service by
_____
_____
_____
_____
_____
____

Head of the enterprise - signature and stamp:

The customer’s signature: _____

DECLARATION OF CONFORMITY

We

Mitsar Co. Ltd
Novorossiyskaya str. 21-2
194021, St. Petersburg, RUSSIA

Hereby declare under our sole responsibility that the product

Electroencephalographic PC-controlled system
MITSAR–EEG serial # _____

to which this declaration relates is in conformity with the provisions of Finnish Law 1505/94 and Act 1506/94 transposing Council Directive 93/42/EEC concerning medical devices.

……..St. Petersburg……
(place and date of issue)

…Peredreeva I.P…… Head of quality control department …
(name, position and signature of authorized person of the manufacturer)