



Mitsar Co.Ltd.



IM17

**ELECTROENCEPHALOGRAPHIC PC - CONTROLLED
SYSTEM "MITSAR - EEG"**

OPERATION MANUAL

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Mitsar Product Warranty

Mitsar warrants that each product we sell you is free from defects in labor and materials and shall conform to its product specifications as defined in the user documentation. If the product does not function as warranted during the warranty period, we will repair or replace it without charge. If in our judgment we are unable to do so, you may return it to us and we will refund your money.

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Misuse, accident, modification, unsuitable physical or operating environment, improper maintenance, or damage caused by a product for which we are not responsible may void the warranty. Certain components may have separate warranty periods as stated in the product user documentation. Consumables are not covered under warranty.

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This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels and inserts. A defective product should not be used. Parts which may be broken or missing or those that are clearly worn, distorted or contaminated should be replaced immediately with clean, genuine replacement parts that have been manufactured by or available from Mitsar.

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

The owner of this product has the sole responsibility for connection devices to the system not corresponded to the electrical safety requirements class I, type BF, standards IEC 60601-1:1988, IEC 60601-2-26:1994, IEC 60601-1-1:1992, IEC 60601-1-2:1993, IEC 60601-1-4:1996, CISPR 14 1 Ed. 3.0, Add 1, 2 : 1993-1998 for medical devices.

Mitsar Warranty and Post-Guarantee Obligations

1. The manufacturer guarantees compliance of the system with technical specifications subject to the customer's fulfillment of operating requirements described below.
2. Warranty period is 24 months beginning with the date of installation and commission (date of signing of the commission deed). If the BSC delivery set includes a computer and/or other computer equipment, video camera, etc., warranties for such equipment shall be stipulated separately.
3. Warranty for electrodes and electrode fixing devices is 12 months if not stipulated otherwise by the electrode manufacturer.
4. During warranty period the manufacturer will provide for the customer necessary consultation regarding operation of the system.
5. During warranty period the manufacturer 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. The manufacturer shall inform the customer during 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.
7. Post-guarantee service for the system shall be carried out by the manufacturer under separate contract with the customer.
8. The warranty will be considered void:
 - In a case of absence of guarantee coupon with date of commission, manufacturer's 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 device, including leakage of batteries of a type not recommended by the manufacturer;
 - If batteries of not recommended type and/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 battery cartridge, and replacement of batteries. Such defects may be eliminated at the customer's request against separate charge.
10. The present warranty does not concern equipment not included into the delivery set (see section 3.1 hereinabove), if not stipulated otherwise by the delivery contract.
11. Guarantee coupons are enclosed.

Safety Summary

Read and follow all WARNINGS, CAUTIONS and NOTES provided in this guide. To avoid the possibility of injury, damage to your system or data loss, always observe these safety precautions during system operation.



WARNINGS

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

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

The personal computer (as a part of Mitsar-EEG system) must not be situated closer than 1.5 m from a patient.

PC, monitor and printer (as a part of Mitsar-EEG system) must be connected to power supply line only via socket equipped with ground contact.

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

To reduce the risk of patient injury, turn on any system power before beginning of connection any patient electrodes.

To reduce the risk of patient injury, disconnect all recording and stimulating electrodes from the system before you turn off system power.

Connect patient electrodes to fully electrically isolated physiological devices only. Connection to any other devices or external electrical outlets may result in personal injury.

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 IEC 60601-1-1:1992 for medical electrical systems.



CAUTIONS

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

Turn OFF system power before connecting or disconnecting any system component(s) or accessories. You may damage the device(s).

Do not disconnect or reconnect any system components or accessories with the system powered on. You may damage the components.

A power interruption that occurs during a recording session may cause loss of data in that recording. If you experience frequent power interruptions, Mitsar recommends the usage of an Uninterruptible Power Supply (UPS) to help prevent power interruptions.

Do not autoclave any parts of Mitsar-EEG system.

Do not use acetone for cleaning the components of system.

Continuous impedance checking may need to be disabled if the impedance check signal interferes with other equipment.

Contents

| | | |
|--------|--|----|
| 1. | Mitsar-EEG System overview | 3 |
| 1.1. | Available additional manuals | 3 |
| 1.2. | Delivery set | 4 |
| 1.3. | USB KEY configurations | 5 |
| 2. | Mitsar-EEG Additional information | 6 |
| 2.1. | Software components | 6 |
| 2.2. | Electrodes | 6 |
| 2.3. | Antivirus software | 7 |
| 2.4. | System installation | 7 |
| 2.5. | Switching On | 7 |
| 2.6. | Switching Off | 8 |
| 2.7. | Leakage current | 8 |
| 2.8. | Transportation | 8 |
| 2.9. | Utilization | 8 |
| 3. | Mitsar-EEG Amplifiers technical data | 9 |
| 3.1. | Mitsar-EEG-201 amplifier | 9 |
| 3.1.1. | Basic technical data: | 10 |
| 3.1.2. | The Amplifiers functional diagrams | 14 |
| 3.1.3. | Principle of operation | 16 |
| 3.1.4. | Safety measures | 16 |
| 3.1.5. | Starting up | 17 |
| 3.1.6. | Operation procedures | 19 |
| 3.1.7. | Maintenance | 21 |
| 3.1.8. | Troubleshooting guide | 21 |
| 3.2. | Mitsar-EEG-202 amplifier | 23 |
| 3.2.1. | Basic technical data: | 24 |
| 3.2.2. | The Amplifiers functional diagram | 27 |
| 3.2.3. | Principle of operation | 28 |
| 3.2.4. | Safety measures | 28 |
| 3.2.5. | Starting up | 29 |
| 3.2.6. | Operation procedures | 30 |
| 3.2.7. | Maintenance | 33 |
| 3.2.8. | Troubleshooting guide | 33 |
| 4. | Mitsar-EEG connection diagrams | 34 |
| 4.1. | EEG recording with model 104xxxx and 105xxxx amplifiers | 34 |
| 4.2. | EEG recording with model 106xxxx and 107xxxx amplifiers | 35 |
| 4.3. | EEG recording with model 401xxxx and 403xxxx amplifiers | 36 |
| 4.4. | EEG recording with model 404xxxx and 406xxxx amplifiers | 37 |
| 4.5. | ERP recording with Mitsar-EEG amplifiers | 38 |
| 4.6. | Video EEG with Mitsar-EEG amplifiers | 39 |
| 4.7. | Two cameras with Video EEG with Mitsar-EEG amplifiers | 41 |
| 5. | Mitsar-EEG driver installation | 42 |
| 5.1. | Amplifier driver installation | 42 |
| 5.2. | USB KEY driver installation | 45 |
| 6. | Mitsar-EEG software installation | 47 |
| 6.1. | WinEEG program installation | 47 |
| 6.2. | WinEEG program initial setup and testing | 50 |
| 6.3. | WinEEG program initial setup of video EEG option | 52 |
| 6.4. | Initial equipment preparation for carrying out ERP studies | 53 |
| 7. | Mitsar-EEG software quick review | 56 |
| 7.1. | WinEEG program main functions | 56 |
| 7.2. | PSYTASK program introduction | 58 |

| | |
|---|----|
| 7.3. Quick EEG recording..... | 59 |
| 8. DEED OF COMMISSION..... | 61 |
| 9. DATA ON INSTALLATION AND ASSIGNMENT TO OPERATION | 62 |

1. Mitsar-EEG System overview

The electroencephalographic PC-controlled system “Mitsar-EEG” (hereinafter: the EEG system) is purposed for acquisition, storage at personal computer’s HDD, processing, displaying at PC’s display and printing out of electroencephalographic signals. The devices are intended for the clinical observation of electroencephalogram (EEG), video EEG and evoked (event related) potentials (ERP) recording for the diagnostics of brain diseases. The software package for MS Windows XP allow to perform an advanced computerized analysis of the EEG on the standard personal computer or Notebook including digital filtering, montage reformatting, spectra and coherence analysis, topographic mapping and etc.

The EEG-system includes the biosignals converter (hereinafter: the Amplifiers) The Amplifiers is controlled by means of the specially developed computer software.

Mitsar-EEG device is not sterile.

Device does not directly contact the patients. Accessories that contact patients, such as electrodes and caps, are the same as used with the legally marketed devices or are comprised of the same components materials as legally marketed accessories.

The system is intended for use in functional diagnostics wards and departments at out-patient’s clinics, hospitals, health research institutes, health centers and other medical institutions. Patient population includes adults, children and infants.

This document if intended for administrative personal of medical institute or clinic, medical doctors and medical nurses and other medical staff.

The personal 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 Windows XP also.

1.1. Available additional manuals

There are additional manuals in which the detailed information about software of system is included.

1. User manual for WinEEG program. The WinEEG program is intended for recording and processing EEG, Video EEG and event related potentials observation.
2. User manual for PSYTASK program. The PSYTASK program is intended for synchronous stimuli presentation during EEG recording for event related studies.

1.2. Delivery set

The delivery set can include the next components in dependence on customer order:

| No | Component | Quantity |
|-----|---|----------------------|
| 1. | The Amplifier Mitsar-EEG-201, Model 104xxxx ¹ with 4 batteries. | 1 piece ² |
| 2. | The Amplifier Mitsar-EEG-201, Model 105xxxx ¹ with 4 batteries. | 1 piece ² |
| 3. | The Amplifier Mitsar-EEG-201, Model 106xxxx ¹ with 4 batteries. | 1 piece ² |
| 4. | The Amplifier Mitsar-EEG-201, Model 107xxxx ¹ with 4 batteries. | 1 piece ² |
| 5. | The Amplifier Mitsar-EEG-202, Model 401xxxx ¹ with power adapter for medical device. | 1 piece ² |
| 6. | The Amplifier Mitsar-EEG-202, Model 403xxxx ¹ with power adapter for medical device. | 1 piece ² |
| 7. | The Amplifier Mitsar-EEG-202, Model 404xxxx ¹ with power adapter for medical device. | 1 piece ² |
| 8. | The Amplifier Mitsar-EEG-202, Model 406xxxx ¹ with power adapter for medical device. | 1 piece ² |
| 9. | Software with user manuals for EEG recording and processing | 1 set |
| 10. | Advanced software with user manuals for EEG and ERP recording and processing ³ | 1 set |
| 11. | Advanced software with user manuals for video EEG ³ | 1 set |
| 12. | EEG electrodes and caps ³ | 1 set |
| 13. | ECG electrodes connection cable | 1 piece |
| 14. | Operation manual | 1 piece |
| 15. | PC connection cable 5-7 meter | 1 piece |
| 16. | USB KEY | 1 piece |
| 17. | Tripod ³ | 1 piece |
| 18. | Photostimulator with cables and power adapter ³ | 1 piece |
| 19. | Patient warning button ³ | 1 piece |
| 20. | Null modem cable ³ | 1 piece |
| 21. | Desktop computer for data acquisition ^{3,4} | 1 piece |
| 22. | Laptop computer for data acquisition ^{3,4} | 1 piece |
| 23. | Desktop computer for stimuli presentation ^{3,4} | 1 piece |
| 24. | Printer ^{3,4} | 1 piece |
| 25. | Video capture card ³ | 1 piece |
| 26. | Video camera with set of cables ^{3,4} | 1 piece |
| 27. | Video camera remote control with set of cables ³ | 1 piece |
| 28. | IR light source ³ | 1 piece |
| 29. | Power supply for video camera, camera remote control and IR light source ³ | 1 piece |
| 30. | Microphone and microphone amplifier (if necessary) ³ | 1 piece |

¹ The description of this model is places below. Here “xxxx” is a serial number.

² The type of amplifiers depends of the customer’s order.

³ To be delivered at customer order.

⁴ The configuration or model should be discussed with customer.

The minimal configuration of Mitsar-EEG system includes:

1. One of amplifiers (Item 1.-8.)
2. Software with user manuals (Item 9.)
3. ECG electrodes connection cable (Item 13.)
4. Operation manual (Item 14.)
5. PC connection cable (Item 15.)
6. USB KEY (Item 16.)

1.3. USB KEY configurations.

A number of WinEEG functions are protected by special electronic device (USB KEY) connected to USB. To open their functionality it is necessary to connect USB KEY to USB and install driver for this device.

The possible configurations of USB KEY are enumerated in the following table.

| USB KEY label | EEG recording | ERP recording | Video EEG recording | Normative database comparison |
|---------------|---------------|---------------|---------------------|-------------------------------|
| EEG-Base | + | - | - | - |
| EEG | + | + | - | - |
| EEG+Video | + | + | + | - |
| EEG+DB | + | + | - | + |
| EEG+DB+Video | + | + | + | + |

2. Mitsar-EEG Additional information

2.1. Software components.

Most important component of system is the software. It controls the hardware components, acquires the data, processes the data, displays and prints out them, stores the data to hard disk and provides user interface. The software includes the next modules:

1. WinEEG base version. This is a program for recording and processing EEG.
2. WinEEG advanced version for ERP studies. This program includes also options intended for ERP and event related EEG changes studies.
3. WinEEG advanced version for video EEG. This program includes also option intended for video EEG.
4. PSYTASK. This is a program for synchronous presentation of visual and acoustic stimuli with EEG recording during ERP studies.

2.2. Electrodes.

Electrodes and electrodes caps are important component of EEG system but they are delivered separately. Mistar Co. Ltd recommends use the standard electrodes with touch proof connectors, ElectroCap electrode positioning system (Electro-Cap International Inc., USA) or any compatible electrodes cap . All electrodes used together with Mitsar-EEG system should be certified. Mitsar Co Ltd. does not provide the warranties of appropriate quality of EEG recording if not certified or damaged electrodes are used.



ATTENTION! The usage not certified electrodes can damage the system.

2.3. Antivirus software

The Mitsar-EEG system software can interfere with antivirus software. This can result in data loss during EEG recording. The active scanning is not recommended. Do not use the scanning during EEG recording.

2.4. System installation.

Before the beginning of installation read attentively this manual.

1. Start with installation from checking the components and cables. Be sure that these components have no damage.
2. Connect the components in accordance with connection diagrams presented in this manual below (see Chapter 4.).
3. Connect system to power source. The power supply requirement is present at next table.

| | |
|---|-----------|
| Power supply voltage | 100-240 B |
| Power supply frequency | 50-60 Hz |
| Power consumption (not including the computers) | 20 W |

4. Turn on the system.
5. Install the system specific drivers and software and test the EEG system in correspondents to instructions presented in this manual below (see Chapter 5 and 6).



ATTENTION! There are no parts inside the EEG system components which should be maintained by user except the batteries inside Mitsar-EEG-201 amplifiers.



ATTENTION! Do not open EEG system cases if the system is connected to power source.

2.5. Switching On



ATTENTION! Switch on the system before connection the electrodes to patient.



WARNING! Turn off the system before connection additional components and peripheral devices.

To switch on the system press “Power” button on PC.

2.6. Switching Off



ATTENTION! Disconnect the electrodes from the patient before switching off the system.

Close all application and turn off Windows before switching of the system.

Switch off the system before disconnecting it from power supply.

2.7 Leakage current.

The EEG system conjointly with a line-supplied PC complies with the electrical safety requirements class I, type BF, standards IEC 60601-1:1988, IEC 60601-2-26:1994, IEC 60601-1-1:1992, IEC 60601-1-2:1993, IEC 60601-1-4:1996, CISPR 14-1 Ed. 3.0, Add 1, 2 :1993-98.

The standard IEC 60601-1:1988 defines the permissible leakage current. The connection several systems to the patient the leakage current will sum that can result to not permissible value of total leakage current and running the risk of patient injury. Check the total value of leakage current of several systems before connection them to the patient.

2.8. Transportation.

Turn off the system before transportation.

2.9. Utilization.

The utilization of the system and the batteries should be done in correspondence to the domestic regulation.

3. Mitsar-EEG Amplifiers technical data

3.1 Mitsar-EEG-201 amplifier

The EEG system complies in accordance with the requirements of technical specifications TU 9441-001-25890578-99.

The EEG-system includes the multi-channel bio-signal amplifier, the personal computer in a desktop or portable (notebook-type) case and additional accessories. The Amplifier is controlled by means of the specially developed computer software.

The Amplifier is designed in four modifications: Model 104xxxx, Model 105xxxx, Model 106xxxx, Model 107xxxx. (where xxxx – serial number). The Amplifiers connector layout is presented on Figures 1 and 2.

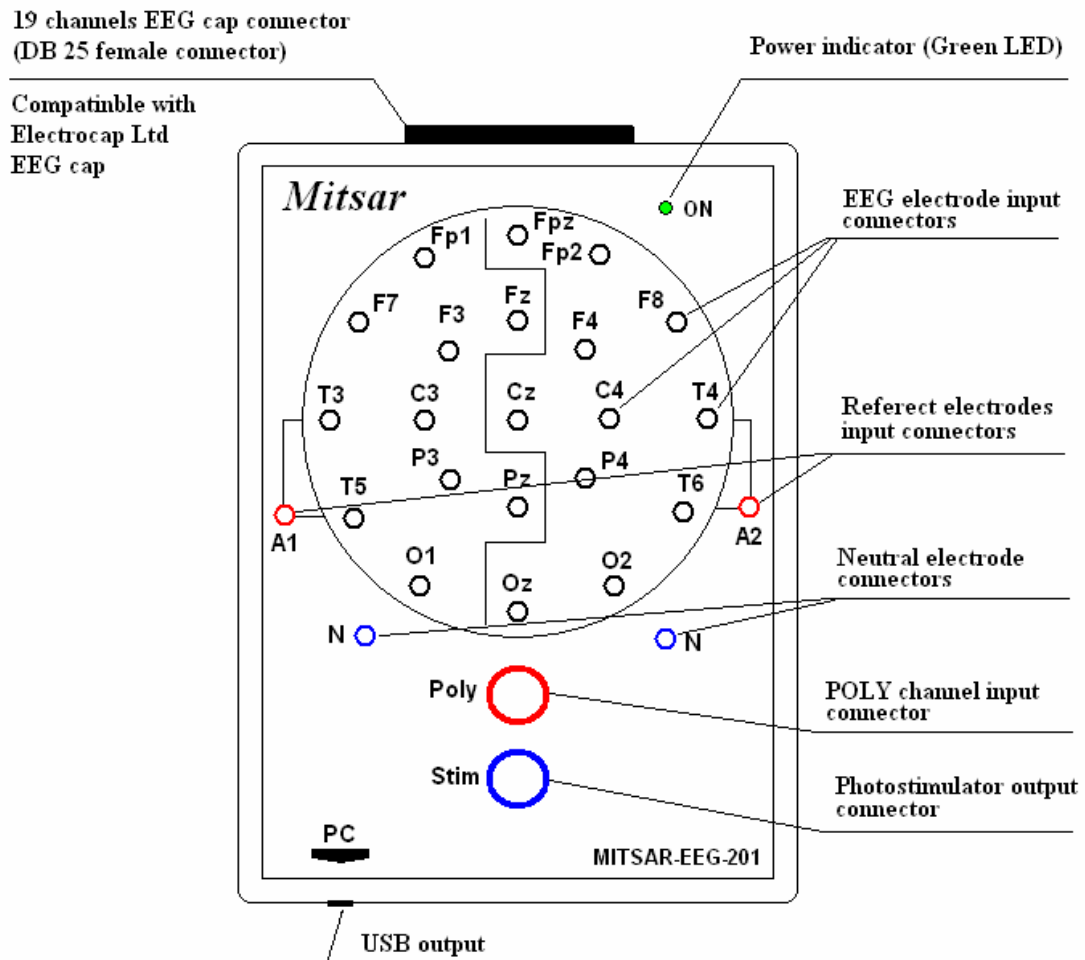


Figure 1. Mitsar-EEG-201 amplifier connectors layout for models 104xxxx and 105xxxx.

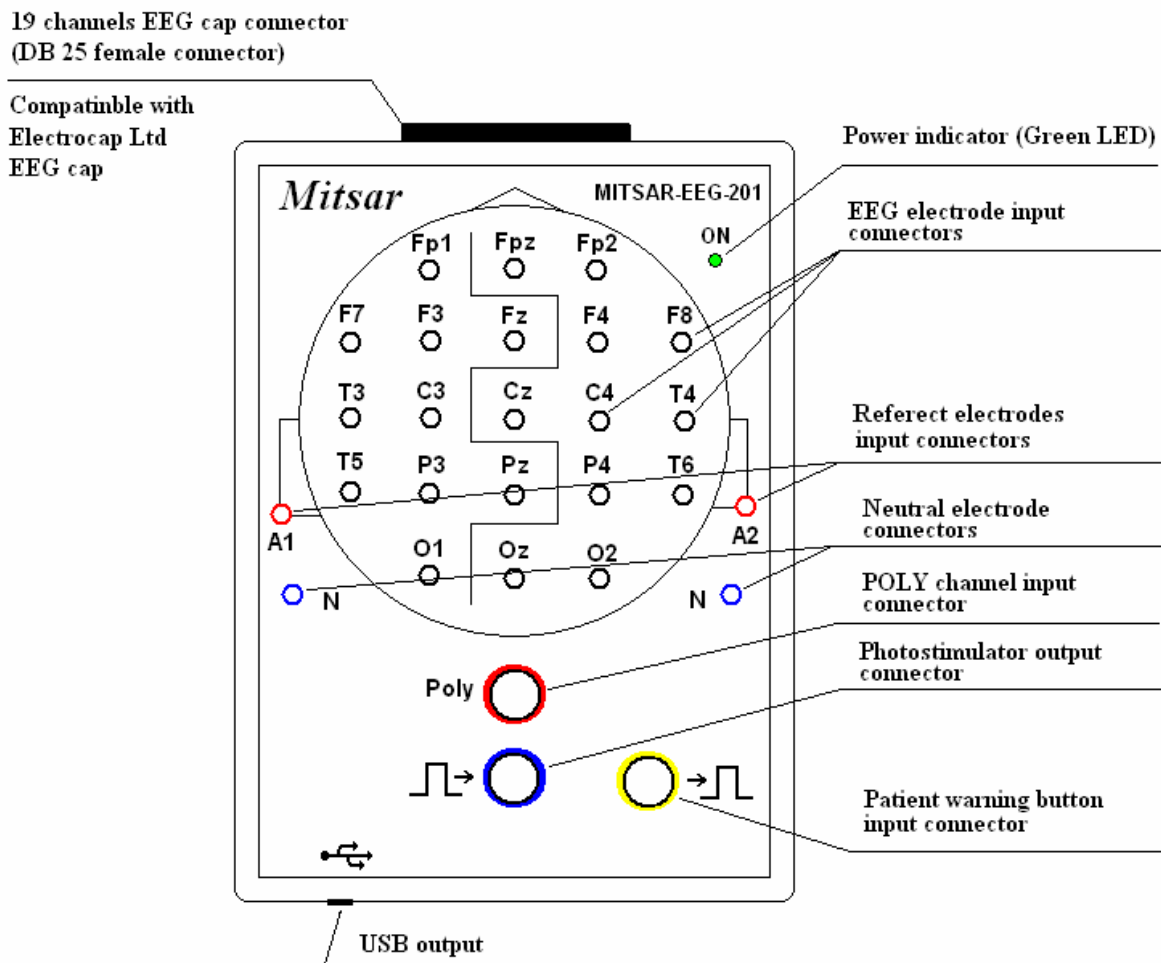


Figure 2. Mitsar-EEG-201 amplifier connectors layout for models 106xxxx and 107xxxx.



ATTENTION! The Fpz and Oz EEG input connectors absent in Model 104xxxx and Model106xxx.



ATTENTION! The 19 channels EEG cap connector is absent in Model 104xxxx and Model106xxx

3.1.1. Basic technical data:

1. Weight of the Amplifier: not more than 1 kg. Weight of the package without a computer and a printer: not more than 10 kg.
2. Dimensions of the Amplifier (without tripod): 185 x 135 x 45 mm.
3. The Amplifier operates by computer system.

4. Mitsar-EEG-201 is provided from internal power supply (four dry cells or storage batteries, type AA (R6), supply voltage: 3.0 to 6.5 V, 48 mA).
5. The Amplifier consumption current: not more than 0.048 A.
6. The Amplifier total operation time with one set of alkaline batteries: not less than 50 hours.
7. PC interface: USB.
8. Digital sampling rate per channel: 250 or 500 Hz.
9. Calibration signals: square-wave 0.5 Hz, 200 μ V.
10. Number of channels

| Model | EEG channels | Poly channels | TTL inputs |
|---------|--------------|---------------|------------|
| 104xxxx | 19 | 1 | 0 |
| 105xxxx | 21 | 1 | 0 |
| 106xxxx | 19 | 1 | 2 |
| 107xxxx | 21 | 1 | 2 |

10. EEG channel characteristics:

10.1. Input voltage range: 10 to 1000 μ V.

10.2. Permissible error for voltage measurements:

within the range of 10 μ V to 50 μ V: ± 10 %;

within the range of 50 μ V to 1000 μ V: ± 5 %.

10.3. Input resistance: not less than 200 M Ω .

10.4. Irregularity of the frequency amplitude response not more than 10 % within the designated frequency range:

| Model | |
|---------|---------------|
| 104xxxx | 1 to 17.5 Hz |
| 105xxxx | 0.65 to 35 Hz |
| 106xxxx | 1 to 17.5 Hz |
| 107xxxx | 0.65 to 35 Hz |

10.5. Lower threshold frequency of the Low Cut filter (High Pass filters) at level 0.7:

| Model | Hz | Hz (digital) | Hz (digital) |
|---------|-----------------|----------------|---------------|
| 104xxxx | 0.32 ± 0.06 | 1.6 ± 0.32 | 5.0 ± 1.0 |
| 105xxxx | 0.5 ± 0.1 | 1.6 ± 0.32 | 5.0 ± 1.0 |
| 106xxxx | 0.32 ± 0.06 | 1.6 ± 0.32 | 5.0 ± 1.0 |
| 107xxxx | 0.5 ± 0.1 | 1.6 ± 0.32 | 5.0 ± 1.0 |

10.6. Upper threshold frequency of the High Cut filter (Low Pass filter) at level 0.7:

| Model | Hz | Hz (digital) | Hz (digital) |
|---------|--------------|--------------|--------------|
| 104xxxx | 35 ± 3.5 | 30 ± 3 | 15 ± 1.5 |

| | | | |
|---------|--------------|------------|--------------|
| 105xxxx | 70 ± 7 | 30 ± 3 | 15 ± 1.5 |
| 106xxxx | 35 ± 3.5 | 30 ± 3 | 15 ± 1.5 |
| 107xxxx | 70 ± 7 | 30 ± 3 | 15 ± 1.5 |

- 10.7. Notch filter 50/60 Hz frequency: not less than 40 dB.
- 10.8. Internal noise voltage reduced to input within the range of 0.5 to 30 Hz: not more than 2 μ V (p-p).
- 10.9. Common mode rejection ratio: Typically 100dB at 50 or 60 Hz.
- 10.10. Channels interference factor: within ± 2 %.
- 10.11. Permissible ratio error limits for time domain within the range of 0.2 to 10 s: ± 5 %.
- 10.11. Input impedance: not less than 200 M Ω .

11. POLY channel characteristics.



ATTENTION! The POLY channel is intended for ECG signal input and representation. As the POLY channel does not comply the requirements of standard for measuring ECG channel especially due to low time constant that will result to distortion of the QRS complex, the incoming ECG signal may not be used for calculation of the ECG parameters and for diagnosing based on the curve shape. The incoming ECG signal can be used for visual estimation of the position and for calculation of time delays between the R-wave position and some other EEG waveforms.



ATTENTION! The POLY channels can be used for measurement patient response parameters using "Patient warning button" during Event-Related Potentials recording.

- 11.1. Input voltage range: 0.03 to 5 mV.
- 11.2. Voltage relative deviation from prescribed value within the range of 0.1 to 5 mV: not more than ± 15 %.
- 11.3. Irregularity of the frequency-amplitude response within the range of 1 to 17.5 Hz: not more than ± 15 %.
- 11.4. Common mode rejection ratio: not less than 80 dB.
- 11.5. Internal noise voltage reduced to input within the range of 0.5 to 15 Hz: not more than 10 μ V (p-p).
- 11.6. Permissible ratio error limits for time domain within the range of 0.2 to 10 s: ± 5 %.
- 11.7. Input impedance: not less than 100 M Ω .
12. Average operating time: not less than 8 hours per day.

13. Electrical safety of the Amplifiers complies with the requirements for instruments with internal power supply, type BF, standards IEC 60601-1:1988, IEC 60601-2-26:1994.
14. The EEG system complete with line-powered PC complies with the electrical safety requirements: class I, type BF, standards IEC 60601-1:1988, IEC 60601-2-26:1994 and IEC 60601-1-1:1992
15. Electromagnetic compatibility of the EEG system complies with requirements of standard IEC 60601-1-2:1993.
16. Working condition:
 - temperature range: +10 to +35°C;
 - moisture range: 25 to 95% (without condensation).

3.1.2. The Amplifiers functional diagrams.

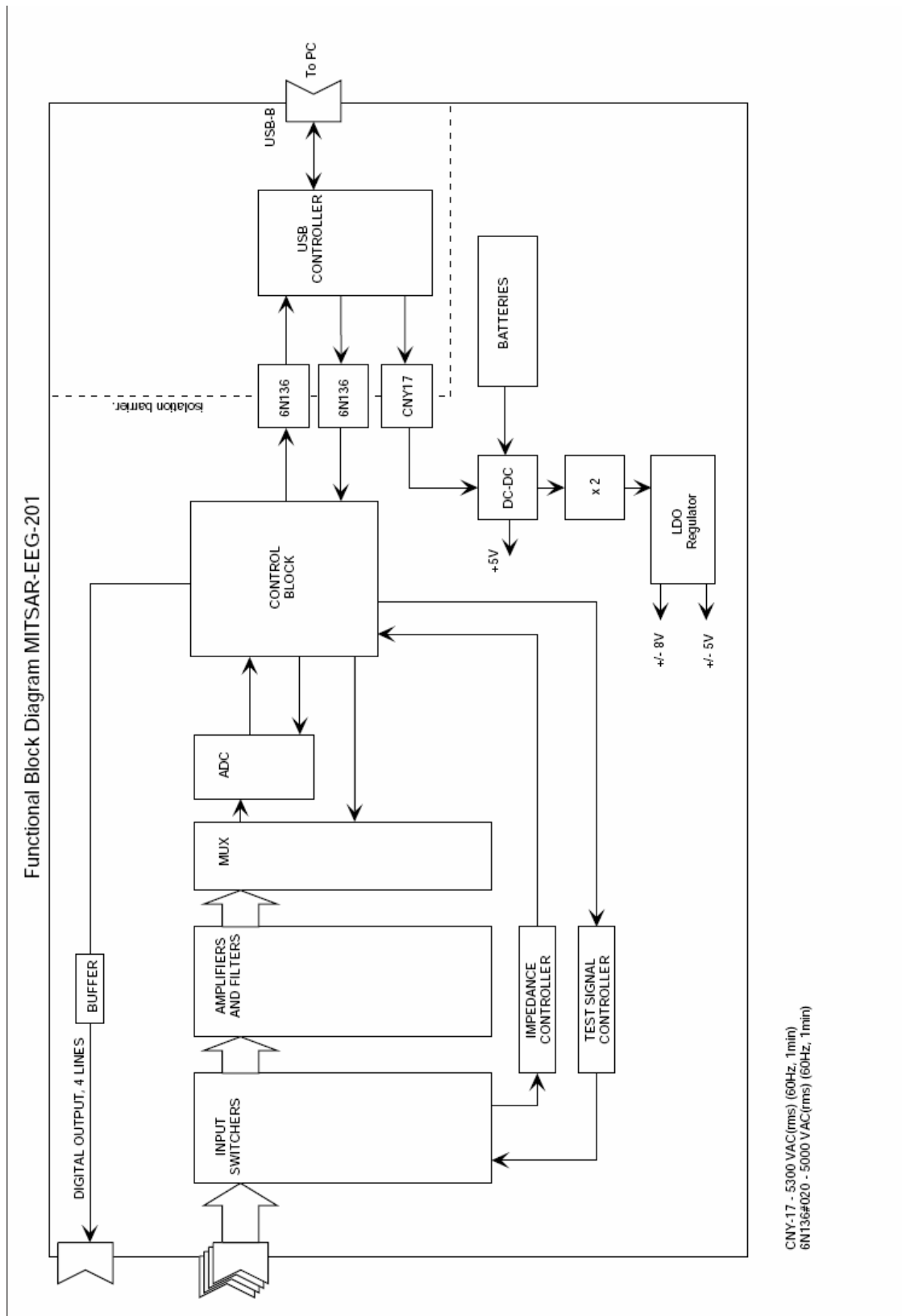


Figure 3. Functional diagram of Mitsar-EEG-201 amplifier for models 104xxxx and 105xxxx.

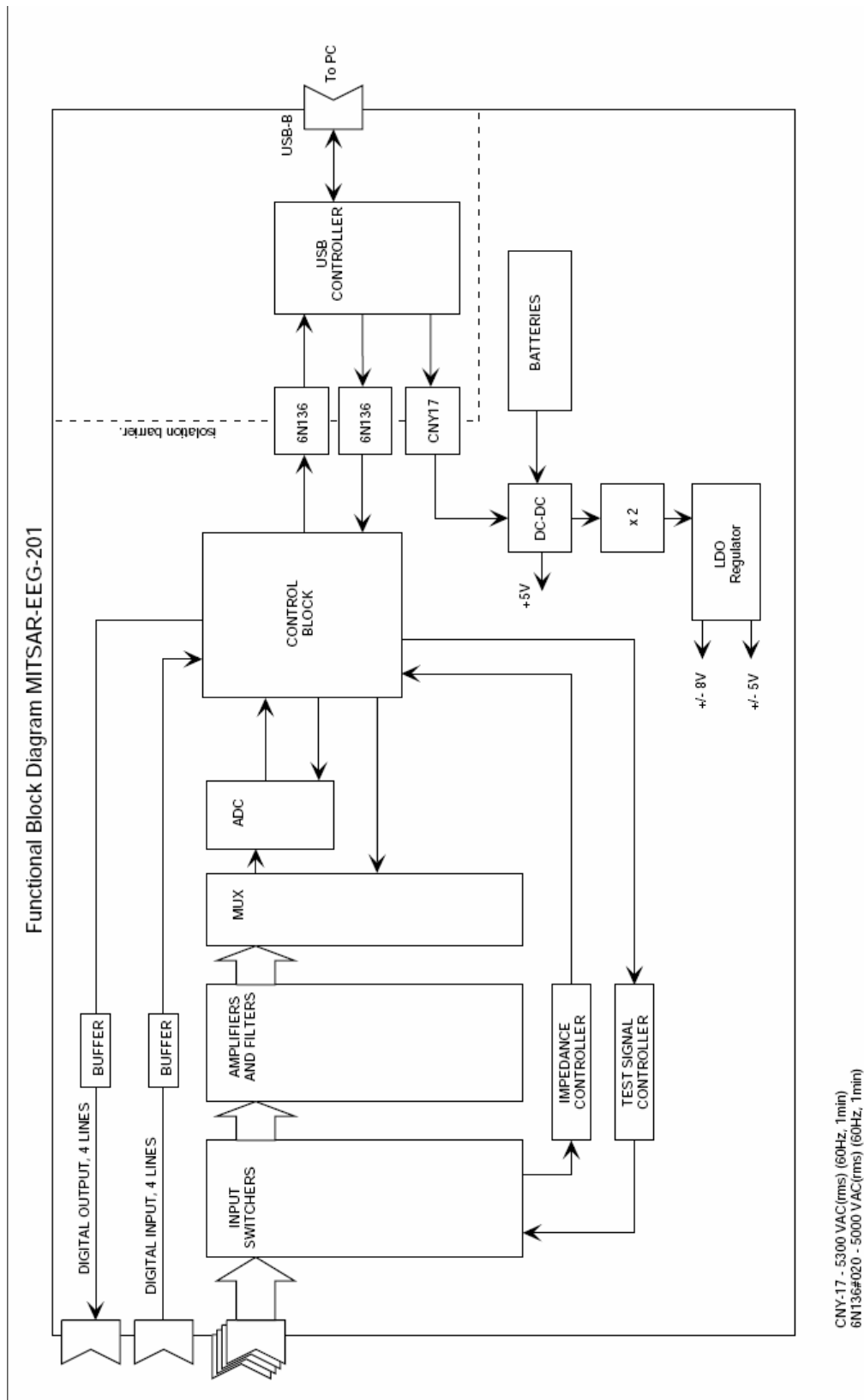


Figure 4. Functional diagram of Mitsar-EEG-201 amplifier for models 106xxxx and 107xxxx.

3.1.3. Principle of operation.

EEG system is intended only for medical purposes and it used to measure and to record the electrical activity of the patient brain. EEG and ECG signals are obtained by placing electrodes on the patient and enter the multichannel voltage amplifier.

The voltage amplifier amplifies the signals up to the level coordinated to the ADC's 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. The resulting signal enters the ADC input, and the ADC converts it into digital signal consequently for each channel. The ADC converts the signals into 16-bit digital code (65536 quantization levels).

Synchronization of operation for the voltage switching unit and the ADC, control for photostimulator and data communication with the PC, are provided by the microcontroller. The data are sent to the PC through a standard serial interface type *USB* via the decoupling device and the level converter. The decoupling device acts as a reinforced isolation and may withstand AC voltage of 4 kV for 1 minute.

The power supply of the Amplifiers is the batteries. Necessary internal voltages are generated by the internal power source (DC/DC converter) which is turned on by software command and is kept in ON state by special commands. The power source switch off automatically in 2 - 5 seconds after the program stops transmitting commands for keeping ON or after interruption of PC connection.

The system software provides creation of data files for input signal, digital filtration of the data, displaying of those as curves at a PC's monitor (memory oscilloscope mode), storing of the data on the PC's hard disk, and further processing and analysis of signals.

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

3.1.4. Safety measures

1. Regarding operation safety the Amplifiers complies with the requirements of standard IEC 60601-1-92 as a device with internal BF type power source. The EEG system conjointly with a line-supplied PC complies with the electrical safety requirements class I, type BF, standards IEC 60601-1:1988, IEC 60601-2-26:1994, IEC 60601-1-1:1992.

2. General safety of the EEG system is provided by fulfillment of the requirements of standard IEC 60601-1-1:1992.

3. The Amplifiers operates in a patient's environment.

4. The personal computer represents a subsystem of non-medical equipment and must be situated at distance from a patient providing impossibility of intended or accidental contact between a patient and the PC.

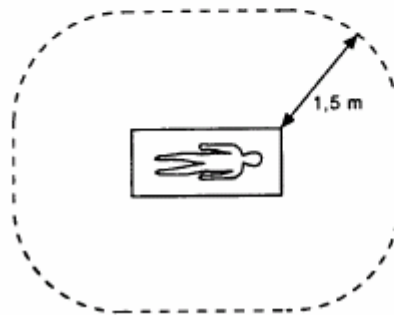
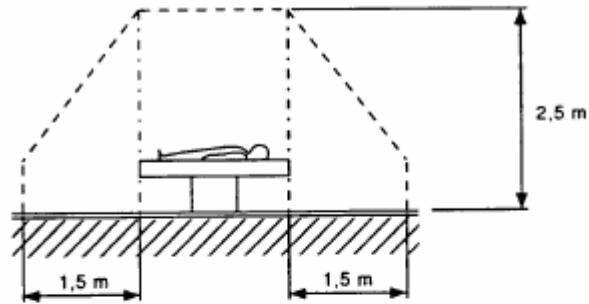
5. The integrated insulating decoupling device in the amplification module supports appropriate safety levels for the amplification module and for personal computer after interconnection.

6. Electric strength of the isolation between the operating parts and the PC connection cable (reinforced isolation) withstands AC voltage of 4 kV at operating temperature.

7. The connection cable has the length of 4 m at least for removing the PC from a patient’s environment.



8. ATTENTION! The PC must not be situated closer than 1.5 m from a patient.



IEC 2513/2000

Figure 5. An example of patient environment



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

10. Electric strength of the PC’s insulation against power line must be not less than 1500 V.

11. The Amplifiers has the decoupling device providing electric strength not less than 4 kV AC for computer connection circuits.

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

3.1.5. Starting up

1. First engaging and testing of the equipment should be carried out by the manufacturer’s representative(s) or by personnel specially trained by the manufacturer.

2. The system's operation site.

The EEG system “Mitsar-EEG” does not require a special screened camera subject to absence of closely situated interference source (radio or TV transmitter, power transformer, radar station, X-ray unit, physiotherapy equipment, etc.).

3. Place the EEG system's components at the site in accordance to safety measures described herein.

4. Open the battery compartment and insert batteries into the cartridge. Strictly observe the batteries' polarity. Now the unit is ready for operation.

5. Install the Amplifiers unit onto the tripod and install the Amplifiers in a proper place, adjusting the tripod height. It is not recommended to place the Amplifiers close to concrete or metal structures or close to power lines; that may cause additional 50/60 Hz stray pick-up.

6. Connecting the Amplifiers to the computer.

The Amplifiers is connected to the computer via serial port type *USB*. In order to connect them insert one connector of the cable into the PC's port and the other plug into the appropriate Amplifier connector.

The connector at the Amplifier's case is not used for another purpose. Direct the cable's connector properly, it should come into the socket without excessive force.

For correct choice of the PC's connector see the computer user's manual.

7. Methods of installation and use of the software are given in Chapter 6 of this manual.

After installation of the software carry out trial operation of the system in accordance to the instructions presented in Chapter 6 of this manual.

8. Recommendations on adjustment of computer.

The present section describes elimination of possible faults during the first starting-up or reinstallation of the software to a new computer. When similar fault appears during normal operation, the reason will likely be another.

All the activities described hereinafter should be executed by a qualified computer expert only. The actions of an inexperienced user may cause not repairable damage to the computer.

After switching the device on the signal comes to input for 1 to 10 seconds, after that the input disconnects and the device switches off.

In this case you have to carry out the following procedures (for PCs equipped with processors Celeron, Pentium III or higher):

a) Replace the batteries for new ones and start the device up again; if the situation repeats, then:

b) Enter program CMOS Setup while starting up the computer;

c) Enter the following settings (names may vary depending on a motherboard's type):

Virus Warning – Disabled

Power Management – disable Energy Saving function

3.1.6. Operation procedures

1. Operating the software.

Usage of the software is described in the user's manual included in the set of delivery of the system.

2. Reference input connectors.

Reference input connectors (A1 and A2) may be connected by the Amplifier's internal switch at the software command.

In case if input connectors A1 and A2 are connected it is possible to use as ear average referent: $(A1+A2)/2$ or as independent referent used instead of ear (parietal, frontal, etc.) position; in this case you may apply one or two reference electrodes.

In case if input connectors A1 and A2 are disconnected it is possible to use as referents: A1, A2 or $(A1+A2)/2$; in this case you should apply two reference electrodes.

3. Neutral ("ground") input connectors.

For successful EEG recording you must use one or two neutral electrodes. Connectors for these electrodes are marked "N".

If the neutral electrode is disconnected or defective, instead of EEG, you can observe, as usual, a distorted low frequency signal, 50(60) Hz interference or saturated amplifiers with pencil-beam pattern.

A special neutral ECG electrode is not provided. For ECG recording, the potential of appropriate EEG electrode is used.

4. EEG exploration features.

The main reason of unsatisfactory operation of the EEG system may lie in sporadic line 50(60) Hz interferences or high frequency interferences. These interferences may be caused by various reasons:

The electrodes are contaminated. Follow electrode maintenance instructions enclosed to electrodes.

Unsatisfactory applying of signal electrodes (additional indication for that is 50(60) Hz picked up in one or more channels).

Unsatisfactory applying of neutral or reference electrodes (additional indication for that is strong 50(60) Hz pickup in one or more channels).

The electrodes' wires or connectors are damaged.

Powerful electric equipment presents in the neighborhood of the EEG room which generates strong noise (X-ray installations, physiotherapy equipment, etc.).

Computer grounding is poor or absent.

The Amplifiers to computer connecting cable runs right against the computer's monitor.

There are some individual properties of the patient's skin or his/her mental state. In this case it is necessary to apply the electrodes more thoroughly, to set the patient at rest, to ask him/her to relax.

A list of reasons causing noises or disturbances during EEG taking is given hereunder:

| № | Reason | Permanent disturbance | Temporary disturbance |
|----|---|-----------------------|-----------------------|
| 1 | Computer is not grounded or it has a poor ground connection. | Yes | Yes |
| 2 | Pulsing photostimulator is not grounded or it has a poor ground connection* | Yes | Yes |
| 3 | The Amplifiers is installed too close to computer's monitor. | Yes | |
| 4 | The Amplifiers connecting cable runs right against the computer's monitor. | Yes | |
| 5 | There is powerful electric equipment in the neighborhood of the EEG room which generates strong noise (X-ray installations, physiotherapy equipment, etc.). | | Yes |
| 6 | There is radio or TV transmitter, radar station or cellular communication unit in the vicinity of the building (the distance depends on the unit's capacity). | Yes | Yes |
| 7 | The Amplifiers is placed right against the wall under which electric lines or cables are run | Yes | |
| 8 | The Amplifiers is placed too close to a wide metal surface (metal closet, box, safe, etc.) or to a wall behind which such object is placed. | Yes | Yes |
| 9 | There is a cable line with defective or ungrounded screen (TV, computer network, etc.) in the wall. | Yes | Yes |
| 10 | There is a sparking electric switch, defective fluorescent lamp(s) or such lamp(s) with a defective starter. | | Yes |
| 11 | There is a working engine source closely outside the building. | | Yes |
| 12 | Domestic electric appliances (microwave oven, coffee grinder, etc.) are on at the time of examination. | | Yes |
| 13 | Cellular or radio telephone is used at the time of exploration. | | Yes |

* Necessity of photostimulator grounding depends on the device type and means of connection to the Amplifiers (regular or optical cable).

The permanent disturbance means a disturbance (noise) which is always present at an EEG record. The temporary disturbance means a disturbance (noise) which appears at the record from time to time.

It is recommended to start search for unsatisfactory record quality reason from electrode applying quality and operating condition, and from grounding connection and its quality.

Use a possibility to check electrode operating impedance. The instrument provides high quality EEG recording if the resistance is less than 20 k Ω ; it is recommended to achieve resistance less than 10 k Ω , and in a case of strong radio interference – less than 5 k Ω .

Elimination of reasons 5 and 9 may require installation of the equipment in another room; elimination of reasons 5, 6 and 9 may require a screened room.

5. Switching off.

The Amplifiers switches off automatically after discontinuance of signals input, disconnection of connecting cable or switching the computer off. There are no other measures required for switch the Amplifiers off.

It is recommended to take the batteries out the compartment if service interruption exceeds one month presumably.

6. Power cells.

The Amplifiers is energized from four batteries or accumulators type AA (R6).

Non-hermetic batteries should not be used for power supply of the Amplifiers. It is recommended to use alkaline cells or *Ni-Mn* accumulators from well-known manufacturers.

3.1.7. Maintenance

1. It is recommended to take the batteries out the compartment if service interruption exceeds one month presumably.

2. Exhausted batteries should be replaced by new ones when required. The signs of batteries' exhaust are:

- Special warning message about necessity of battery change.
- More and more frequent warning “No response from ADC” or “No reply from the device” or “Channel faulty”.

3. The device should be cleaned by standard means.



ATTENTION! Do not autoclave any parts of Mitsar-EEG system.



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

4. The electrodes should be cleaned and sterilized by as described into their accompanying documentation.

3.1.8. Troubleshooting guide

Possible problems and methods of their elimination are given in the table below:

| Problem: symptoms | Reason | Method of elimination |
|---|---|------------------------------|
| After signal input attempt the power indicator remains dim. | Poor connection of the interface cable connector. | Check the connection. |

| | | |
|---|---|---|
| After signal input attempt the power indicator remains dim. | Batteries low. | Check the batteries. Replace if necessary. |
| After signal input attempt the power indicator remains dim. | Serial computer port faulty. | Check the computer port. |
| After attempt of signal input the power indicator remains dim, even after replacement of batteries. | Batteries are inserted in a wrong way or cartridge contact is faulty. | Check the batteries' polarity and cartridge contacts. |
| Power indicator glows. No signal from the instrument. | Poor connection in the interface cable connector. | Check the connecting cable. |
| Power indicator glows. No signal from the instrument. | Serial computer port faulty. | Check the computer serial port. |
| When the signals discontinue, the power indicator still glows. | Batteries exhausted. | Check the batteries. Replace if necessary. |

3.2 Mitsar-EEG-202 amplifier

The EEG system complies in accordance with the requirements of technical specifications TU 9441-004-52118320-2005.

The EEG-system includes the multi-channel bio-signal amplifier, the personal computer in a desktop or portable (notebook-type) case and additional accessories. The Amplifier is controlled by means of the specially developed computer software.

The Amplifier is designed in four modifications: Model 401xxxx, Model 403xxxx, Model 404xxxx, Model 406xxxx. (where xxxx – serial number). The Amplifiers connector layout is presented on Figures 5 and 6.

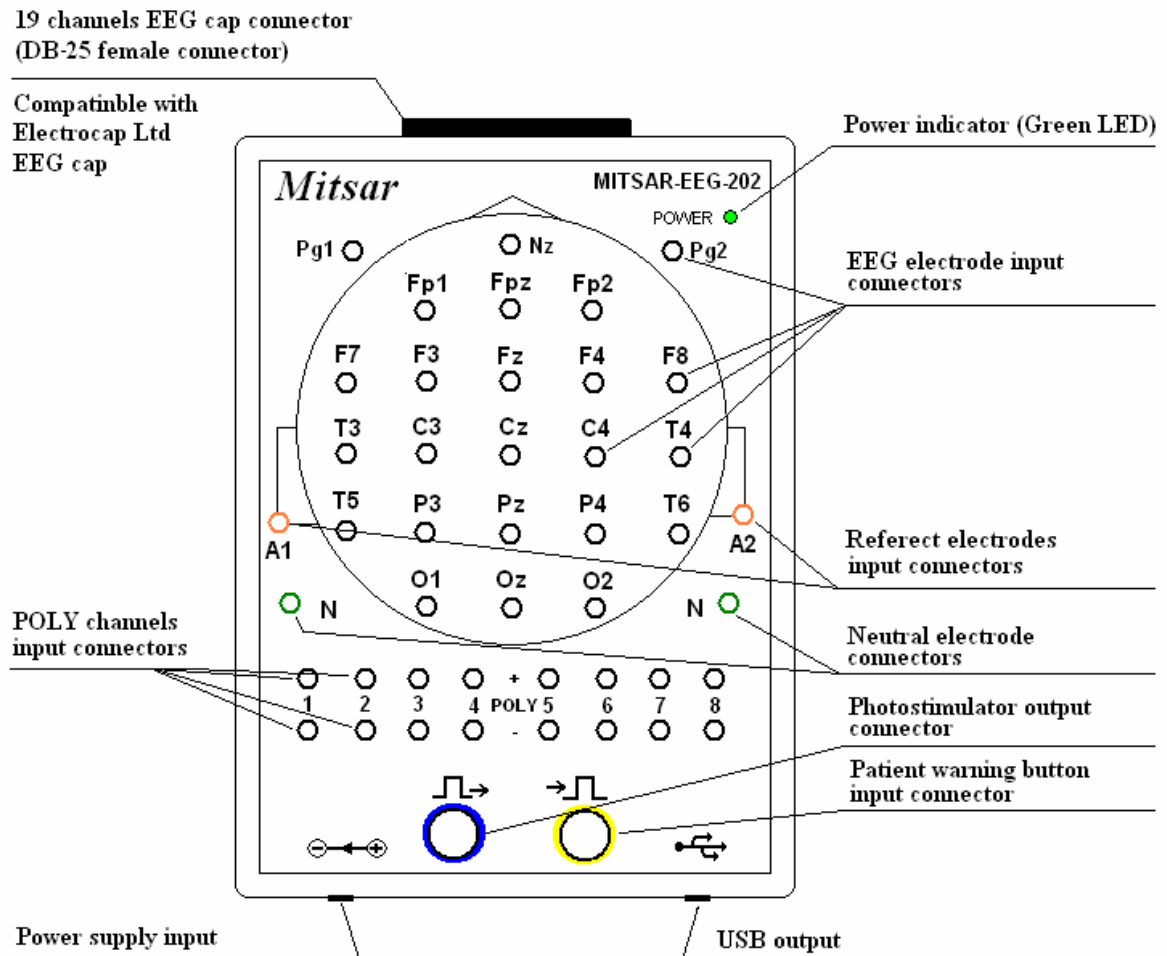


Figure 6. Mitsar-EEG-202 amplifier connectors layout for models 401xxxx and 403xxxx.

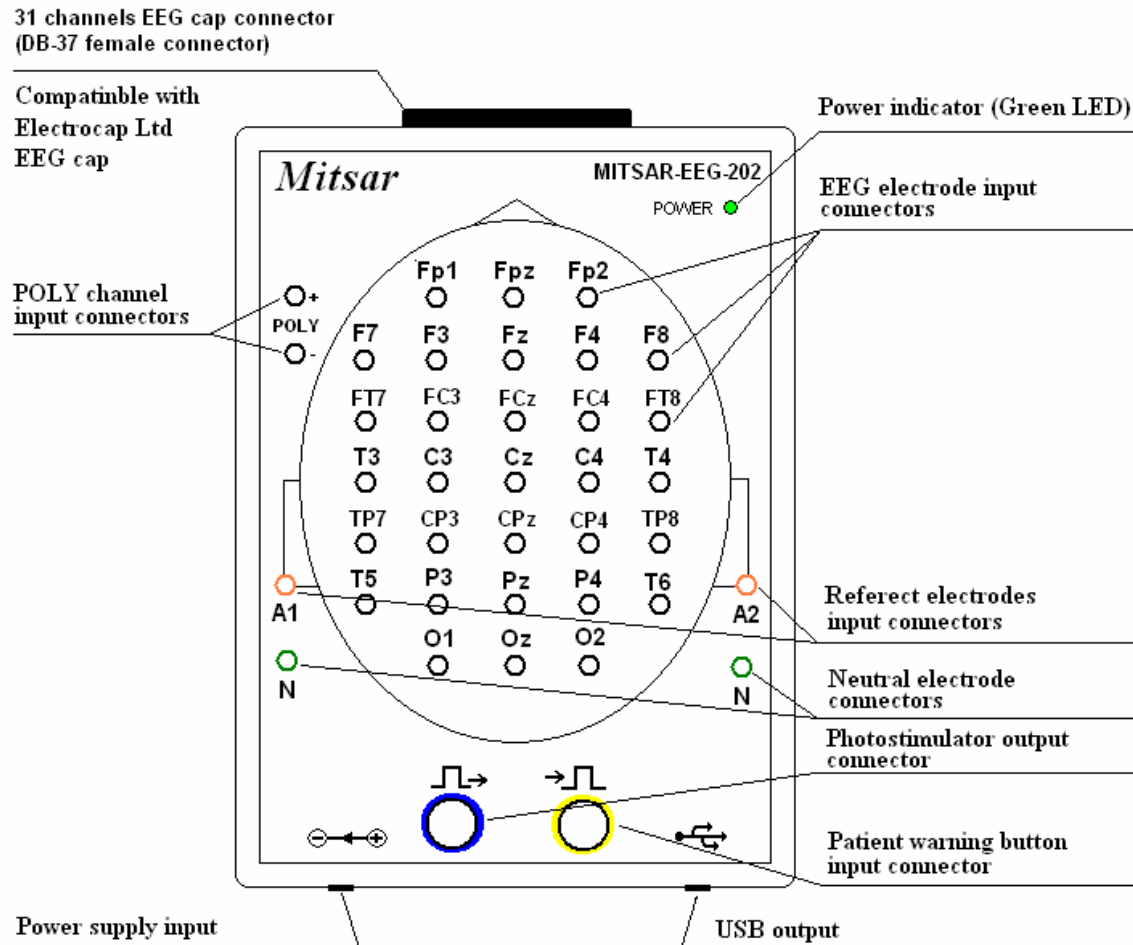


Figure 7. Mitsar-EEG-202 amplifier connectors layout for models 404xxxx and 406xxxx.

3.2.1. Basic technical data:

1. Weight of the Amplifier: not more than 2 kg. Weight of the package without a computer and a printer: not more than 10 kg.
2. Dimensions of the Amplifier (without tripod): 200 x 140 x 48 mm and power supply.
3. The Amplifier operates by computer system.
4. Power supply: 100-240 V, 50-60 Hz via 12V DC power adapter for medical devices.
4. The Amplifier consumption current: not more than 0.20 A (12V).
5. PC interface: USB.
6. Digital sampling rate per channel (internal): 2000 Hz.
7. Digital sampling rate per channel (to computer): 500 Hz.
8. Calibration signals: square-wave 0.5 Hz, 200 μ V.

9. Number of channels

| Model | EEG channels | Poly channels | TTL inputs |
|---------|--------------|---------------|------------|
| 401xxxx | 24 | 8 | 2 |
| 403xxxx | 24 | 8 | 2 |
| 404xxxx | 31 | 1 | 2 |
| 406xxxx | 31 | 1 | 2 |

10. EEG and Poly channels characteristics:

10.1. Input voltage range:

| Model | μV |
|---------|---------------|
| 401xxxx | 10-300000 |
| 403xxxx | 10-100000 |
| 404xxxx | 10-300000 |
| 406xxxx | 10-100000 |

10.2. Permissible error for voltage measurements:

within the range of 10 μV to 50 μV : $\pm 10\%$;

within the range of 50 μV to 100000 (300000) μV : $\pm 5\%$.

10.3. Input resistance: not less than 200 M Ω .

10.4. Irregularity of the frequency amplitude response not more than 10 % within the designated frequency range:

| Model | Hz |
|---------|-----------|
| 401xxxx | 0.35 - 75 |
| 403xxxx | 0.35 - 75 |
| 404xxxx | 0.35 - 75 |
| 406xxxx | 0.35 - 75 |

10.5. Lower threshold frequency of the Low Cut filter (High Pass filters) at level 0.7:

| 401xxxx | 403xxxx | 404xxxx | 406xxxx |
|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| DC | - | DC | - |
| 0.16 \pm 0.016 Hz (digital) | 0.16 \pm 0.016 Hz (digital) | 0.16 \pm 0.016 Hz (digital) | 0.16 \pm 0.016 Hz (digital) |
| 0.5 \pm 0.05 Hz (digital) | 0.5 \pm 0.05 Hz (digital) | 0.5 \pm 0.05 Hz (digital) | 0.5 \pm 0.05 Hz (digital) |
| 1.6 \pm 0.16 Hz (digital) | 1.6 \pm 0.16 Hz (digital) | 1.6 \pm 0.16 Hz (digital) | 1.6 \pm 0.16 Hz (digital) |
| 5.0 \pm 0.5 Hz (digital) | 5.0 \pm 0.5 Hz (digital) | 5.0 \pm 0.5 Hz (digital) | 5.0 \pm 0.5 Hz (digital) |

10.6. Upper threshold frequency of the High Cut filter (Low Pass filter) at level 0.7:

| Model | Hz | Hz (digital) | Hz (digital) | Hz (digital) |
|---------|----------|--------------|--------------|--------------|
| 401xxxx | 150 ± 15 | 70 ± 7 | 30 ± 3 | 15 ± 1.5 |
| 403xxxx | 150 ± 15 | 70 ± 7 | 30 ± 3 | 15 ± 1.5 |
| 404xxxx | 150 ± 15 | 70 ± 7 | 30 ± 3 | 15 ± 1.5 |
| 406xxxx | 150 ± 15 | 70 ± 7 | 30 ± 3 | 15 ± 1.5 |

- 10.7. Notch filter 50/60 Hz frequency: not less than 40 dB.
- 10.8. Internal noise voltage reduced to input within the range of 0.5 to 30 Hz: not more than 1.5 μ V (p-p).
- 10.9. Common mode rejection ratio: not less than 100 dB.
- 10.10. Channels interference factor: within ± 2 %.
- 10.11. Permissible ratio error limits for time domain within the range of 0.2 to 10 s: ± 5 %.
- 10.11. Input impedance: not less than 200 M Ω .
11. Average operating time: not less than 8 hours per day.
12. Electrical safety of the Amplifiers complies with the requirements for instruments with internal power supply, type BF, standards IEC 60601-1:1988, IEC 60601-2-26:1994.
13. The EEG system complete with line-powered PC complies with the electrical safety requirements: class I, type BF, standards IEC 60601-1:1988, IEC 60601-2-26:1994 and IEC 60601-1-1:1992.
14. Electromagnetic compatibility of the EEG system complies with requirements of standard IEC 60601-1-2:1993.
15. Working condition:
temperature range: +10 to +35°C;
moisture range: 25 to 95% (without condensation).

3.2.2. The Amplifiers functional diagram.

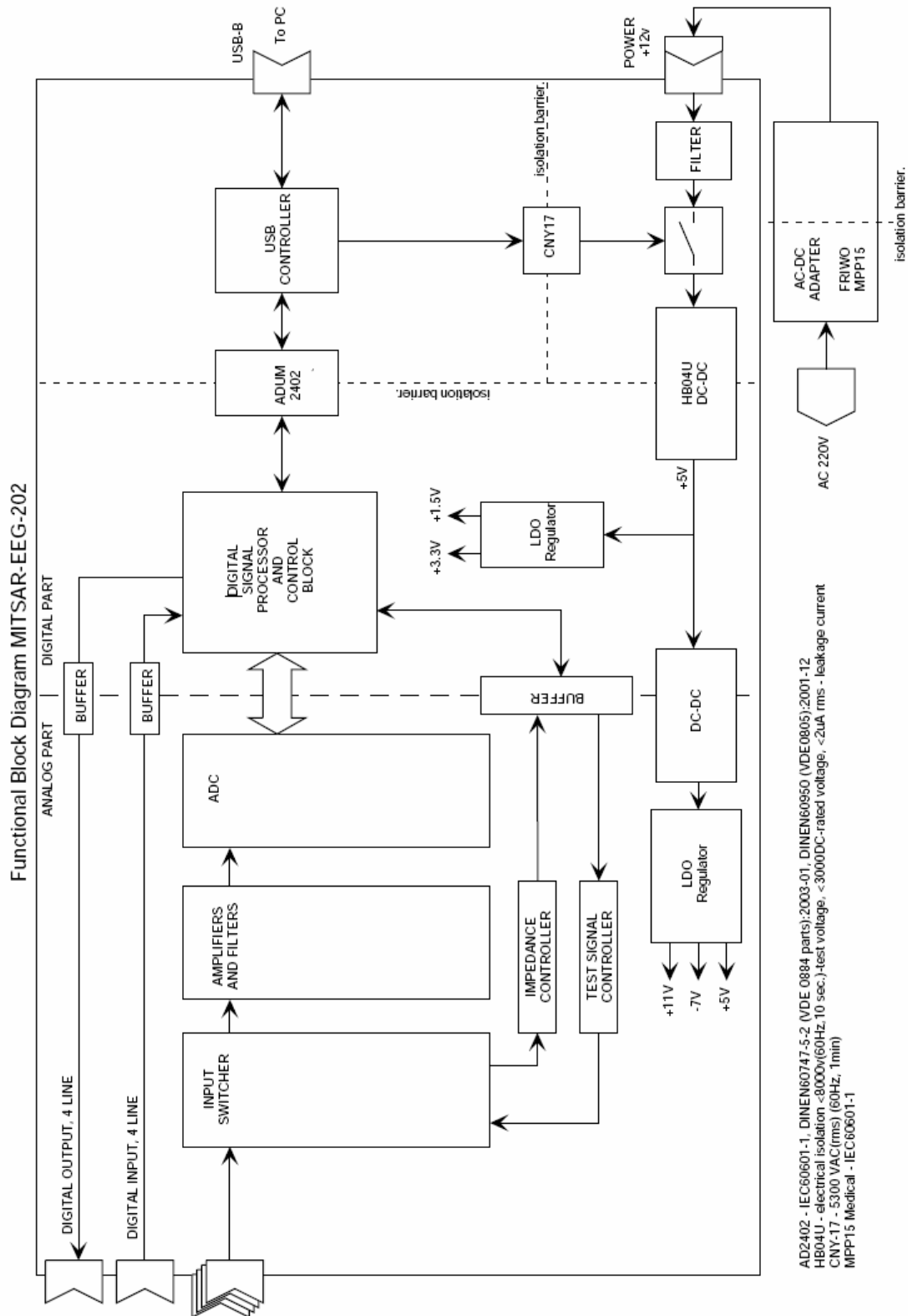


Figure 8. Functional diagram of Mitsar-EEG-202 amplifier for models 401xxxx, 403xxxx, 404xxxx and 406xxxx.

3.2.3. Principle of operation.

EEG and ECG signals are received by the electrodes and enter the multichannel voltage amplifier.

The voltage amplifier amplifies the signals up to the level coordinated to the ADC's 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. The resulting signal enters the ADC input, and the ADC converts it into digital signal consequently for each channel. The ADC converts the signals into 16-bit digital code (65536 quantization levels).

Synchronization of operation for the voltage switching unit and the ADC, control for photostimulator and data communication with the PC, are provided by the microcontroller. The data are sent to the PC through a standard serial interface type *USB* via the decoupling device and the level converter. The decoupling device acts as a reinforced isolation and may withstand AC voltage of 4 kV for 1 minute.

The power supply of the Amplifiers is a special power adapter designed for medical devices. Necessary internal voltages are generated by the internal power source (DC/DC converter) which is turned on by software command and is kept in ON state by special commands. The power source switch off automatically in 2 - 5 seconds after the program stops transmitting commands for keeping ON or after interruption of PC connection.

The system software provides creation of data files for input signal, digital filtration of the data, displaying of those as curves at a PC's monitor (memory oscilloscope mode), storing of the data on the PC's hard disk, and further processing and analysis of signals.

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

3.2.4. Safety measures

1. The EEG system conjointly with a line-supplied PC complies with the electrical safety requirements class I, type BF, standards IEC 60601-1:1988, IEC 60601-2-26:1994, IEC 60601-1-1:1992.

2. General safety of the EEG system is provided by fulfillment of the requirements of standard IEC 60601-1-1:1992.

3. The Amplifiers operates in a patient's environment.

4. The personal computer represents a subsystem of non-medical equipment and must be situated at distance from a patient providing impossibility of intended or accidental contact between a patient and the PC.

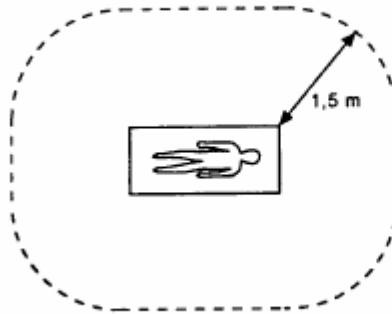
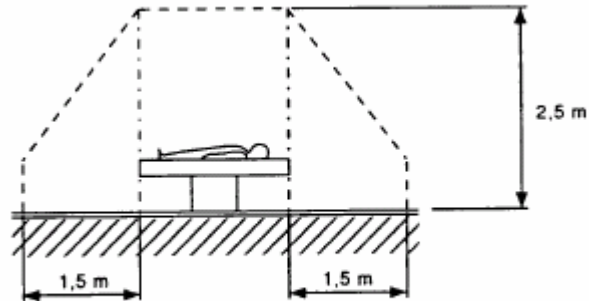
5. The integrated insulating decoupling device in the amplification module supports appropriate safety levels for the amplification module and for personal computer after interconnection.

6. Electric strength of the isolation between the operating parts and the PC connection cable (reinforced isolation) withstands AC voltage of 4 kV at operating temperature.

7. The connection cable has the length of 4 m at least for removing the PC from a patient's environment.



8. ATTENTION! The PC must not be situated closer than 1.5 m from a patient.



IEC 2513/2000

Figure 9. An example of patient environment



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

10. Electric strength of the PC's insulation against power line must be not less than 1500 V.

11. The Amplifiers has the decoupling device providing electric strength not less than 4 kV AC for computer connection circuits.

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

3.2.5. Starting up

1. First engaging and testing of the equipment should be carried out by the manufacturer's representative(s) or by personnel specially trained by the manufacturer.

2. The system's operation site.

The EEG system “Mitsar-EEG” does not require a special screened camera subject to absence of closely situated interference source (radio or TV transmitter, power transformer, radar station, X-ray unit, physiotherapy equipment, etc.).

3. Place the EEG system’s components at the site in accordance to safety measures described herein.

4. Install the Amplifiers unit onto the tripod and install the Amplifiers in a proper place, adjusting the tripod height. It is not recommended to place the Amplifiers close to concrete or metal structures or close to power lines; that may cause additional 50/60 Hz stray pick-up.

5. Connecting the Amplifiers to the computer.

The Amplifiers is connected to the computer via serial port type *USB*. In order to connect them insert one connector of the cable into the PC’s port and the other plug into the appropriate Amplifier connector.

The connector at the Amplifier’s case is not used for another purpose. Direct the cable’s connector properly, it should come into the socket without excessive force.

For correct choice of the PC’s connector see the computer user’s manual.

6. Connect power adapter to appropriate connector of Amplifier’s case and to power source.

7. Methods of installation and use of the software are given in Chapter 6 of this manual.

After installation of the software carry out trial operation of the system in accordance to the instructions presented in Chapter 6 of this manual.

8. Recommendations on adjustment of computer.

The present section describes elimination of possible faults during the first starting-up or reinstallation of the software to a new computer. When similar fault appears during normal operation, the reason will likely be another.

All the activities described hereinafter should be executed by a qualified computer expert only. The actions of an inexperienced user may cause not repairable damage to the computer.

After switching the device on the signal comes to input for 1 to 10 seconds, after that the input disconnects and the device switches off.

In this case you have to carry out the following procedures (for PCs equipped with processors Celeron, Pentium III or higher):

a) Enter program CMOS Setup while starting up the computer;

b) Enter the following settings (names may vary depending on a motherboard’s type):

Virus Warning – Disabled

Power Management – disable Energy Saving function

3.2.6. Operation procedures

1. Operating the software.

Usage of the software is described in the user manual included in the set of delivery of the system.

2. Reference input connectors.

Reference input connectors (A1 and A2) may be connected by the Amplifier's internal switch at the software command.

In case if input connectors A1 and A2 are connected it is possible to use as ear average referent: $(A1+A2)/2$ or as independent referent used instead of ear (parietal, frontal, etc.) position; in this case you may apply one or two reference electrodes.

In case if input connectors A1 and A2 are disconnected it is possible to use as referents: A1, A2 or $(A1+A2)/2$; in this case you should apply two reference electrodes.

3. Neutral (“ground”) input connectors.

For successful EEG recording you must use one or two neutral electrodes. Connectors for these electrodes are marked “N”.

If the neutral electrode is disconnected or defective, instead of EEG one can observe, as usual, a distorted low frequency signal, 50(60) Hz interference or saturated amplifiers with pencil-beam pattern.

4. EEG exploration features.

The main reason of unsatisfactory operation of the EEG system may lie in sporadic line 50(60) Hz interferences or high frequency interferences. These interferences may be caused by various reasons:

The electrodes are contaminated. Follow electrode maintenance instructions enclosed to electrodes.

Unsatisfactory applying of signal electrodes (additional indication for that is 50(60) Hz picked up in one or more channels).

Unsatisfactory applying of neutral or reference electrodes (additional indication for that is strong 50(60) Hz pickup in one or more channels).

The electrodes' wires or connectors are damaged.

Powerful electric equipment presents in the neighborhood of the EEG room which generates strong noise (X-ray installations, physiotherapy equipment, etc.).

Computer grounding is poor or absent.

The Amplifiers to computer connecting cable runs right against the computer's monitor.

There are some individual properties of the patient's skin or his/her mental state. In this case it is necessary to apply the electrodes more thoroughly, to set the patient at rest, to ask him/her to relax.

A list of reasons causing noises or disturbances during EEG taking is given hereunder:

| № | Reason | Permanent disturbance | Temporary disturbance |
|---|--|-----------------------|-----------------------|
| 1 | Computer is not grounded or it has a poor ground connection. | Yes | Yes |

| | | | |
|----|---|-----|-----|
| 2 | Pulsing photostimulator is not grounded or it has a poor ground connection* | Yes | Yes |
| 3 | The Amplifiers is installed too close to computer's monitor. | Yes | |
| 4 | The Amplifiers connecting cable runs right against the computer's monitor. | Yes | |
| 5 | There is powerful electric equipment in the neighborhood of the EEG room which generates strong noise (X-ray installations, physiotherapy equipment, etc.). | | Yes |
| 6 | There is radio or TV transmitter, radar station or cellular communication unit in the vicinity of the building (the distance depends on the unit's capacity). | Yes | Yes |
| 7 | The Amplifiers is placed right against the wall under which electric lines or cables are run | Yes | |
| 8 | The Amplifiers is placed too close to a wide metal surface (metal closet, box, safe, etc.) or to a wall behind which such object is placed. | Yes | Yes |
| 9 | There is a cable line with defective or ungrounded screen (TV, computer network, etc.) in the wall. | Yes | Yes |
| 10 | There is a sparking electric switch, defective fluorescent lamp(s) or such lamp(s) with a defective starter. | | Yes |
| 11 | There is a working engine source closely outside the building. | | Yes |
| 12 | Domestic electric appliances (microwave oven, coffee grinder, etc.) are on at the time of examination. | | Yes |
| 13 | Cellular or radio telephone is used at the time of exploration. | | Yes |

* Necessity of photostimulator grounding depends on the device type and means of connection to the Amplifiers (regular or optical cable).

The permanent disturbance means a disturbance (noise) which is always present at an EEG record. The temporary disturbance means a disturbance (noise) which appears at the record from time to time.

It is recommended to start search for unsatisfactory record quality reason from electrode applying quality and operating condition, and from grounding connection and its quality.

Use a possibility to check electrode operating impedance. The instrument provides high quality EEG recording if the resistance is less than 20 k Ω ; it is recommended to achieve resistance less than 10 k Ω , and in a case of strong radio interference – less than 5 k Ω .

Elimination of reasons 5 and 9 may require installation of the equipment in another room; elimination of reasons 5, 6 and 9 may require a screened room.

5. Switching off.

The Amplifiers switches off automatically after discontinuance of signals input, disconnection of connecting cable or switching the computer off. There are no other measures required for switch the Amplifiers off.

3.2.7. Maintenance

1. There is no special measure for maintenance of system.
2. The device should be cleaned by standard means.



ATTENTION! Do not autoclave any parts of Mitsar-EEG system.



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

3. The electrodes should be cleaned and sterilized by as described into their accompanying documentation.

3.2.8. Troubleshooting guide

Possible problems and methods of their elimination are given in the table hereunder:

| Problem: symptoms | Reason | Method of elimination |
|---|---|--|
| After signal input attempt the power indicator remains dim. | Poor connection of the interface cable connector. | Check the connection. |
| After signal input attempt the power indicator remains dim. | Poor connection of the power adapter. | Check the connection of the power adapter. |
| After signal input attempt the power indicator remains dim. | Serial computer port faulty. | Check the computer port. |
| Power indicator glows. No signal from the instrument. | Poor connection in the interface cable connector. | Check the connecting cable. |
| Power indicator glows. No signal from the instrument. | Serial computer port faulty. | Check the computer serial port. |

4. Mitsar-EEG connection diagrams

The Mitsar-EEG amplifiers, Mitsar-EEG system accessories, computers, computer peripheral and computer multimedia accessories can be connected at the different ways depending on the goals of EEG research. There are the connection diagrams for the typical Mitsar-EEG system configuration only.

4.1. EEG recording with model 104xxxx and 105xxxx amplifiers.

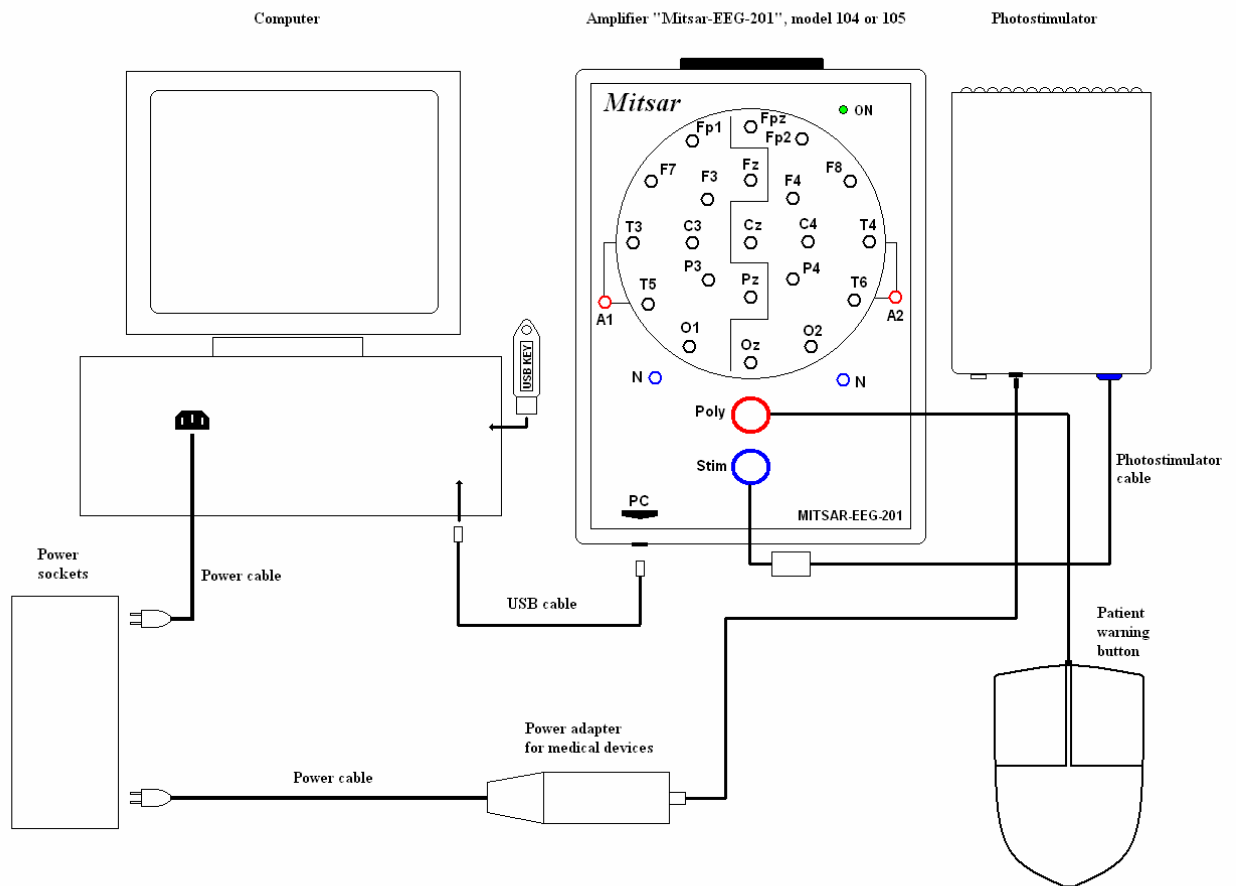


Figure 10. The connection diagram of Mitsar-EEG-201 amplifiers (Model 104xxxx and 105xxxx) with computer and Mitsar-EEG system accessories.



ATTENTION! The PC must not be situated closer than 1.5 m from a patient.

4.2. EEG recording with model 106xxxx and 107xxxx amplifiers.

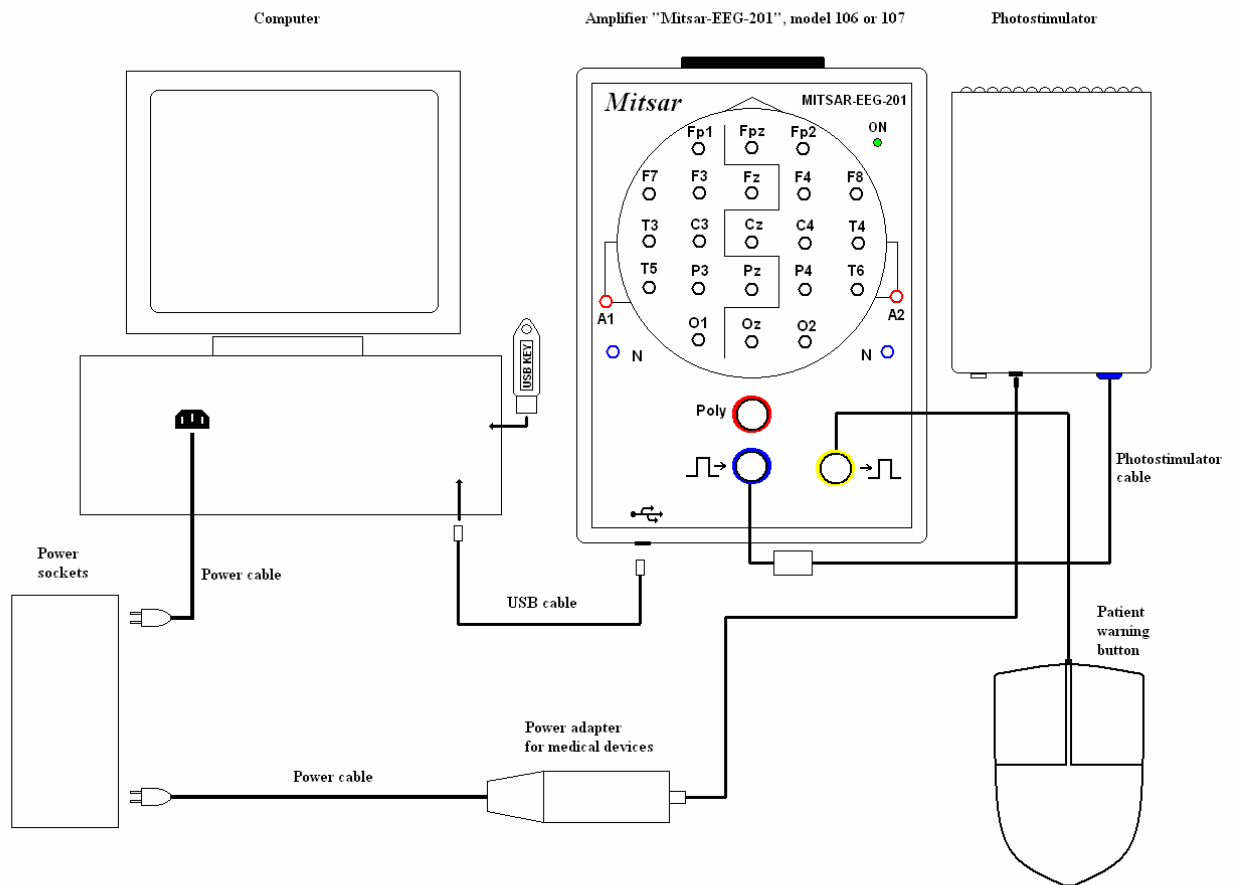


Figure 11. The connection diagram of Mitsar-EEG-201 amplifiers (Model 106xxxx and 106xxxx) with computer and Mitsar-EEG system accessories.



ATTENTION! The PC must not be situated closer than 1.5 m from a patient.

4.3. EEG recording with model 401xxxx and 403xxxx amplifiers.

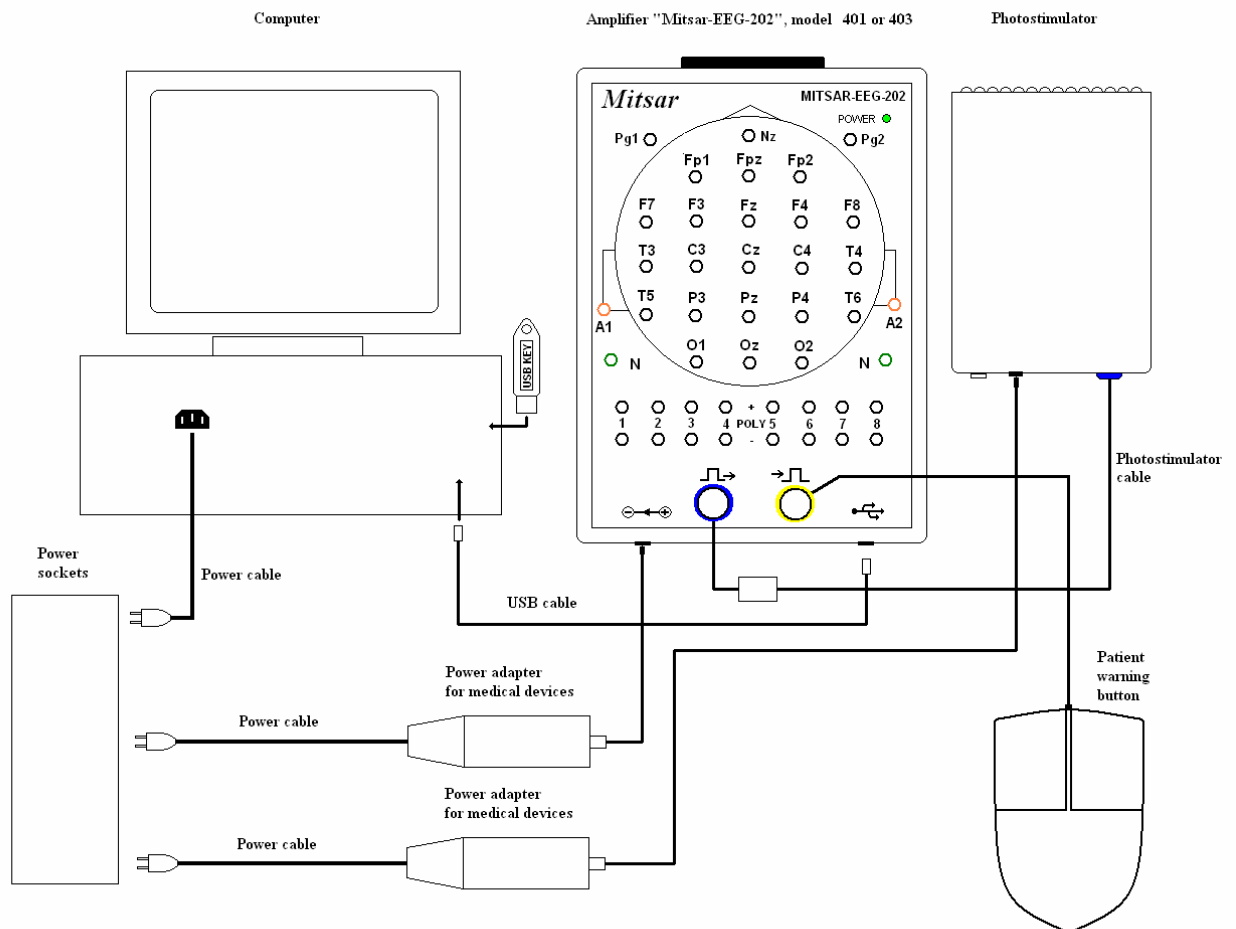


Figure 12. The connection diagram of Mitsar-EEG-202 amplifiers (Model 401xxxx and 403xxxx) with computer and Mitsar-EEG system accessories.



ATTENTION! The PC must not be situated closer than 1.5 m from a patient.

4.4. EEG recording with model 404xxxx and 406xxxx amplifiers.

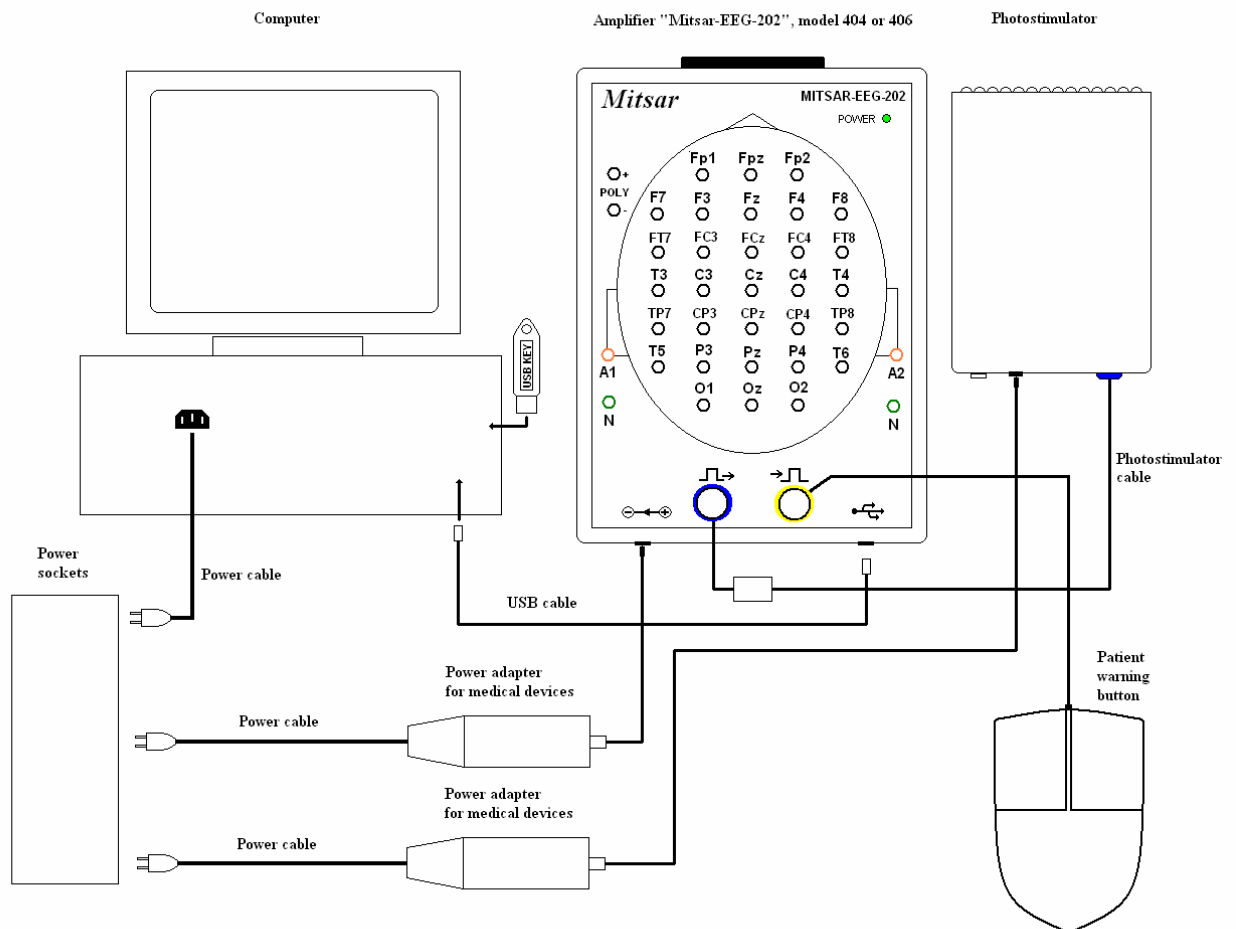


Figure 13. The connection diagram of Mitsar-EEG-202 amplifiers (Model 404xxxx and 406xxxx) with computer and Mitsar-EEG system accessories.



ATTENTION! The PC must not be situated closer than 1.5 m from a patient.

4.5. ERP recording with Mitsar-EEG amplifiers.

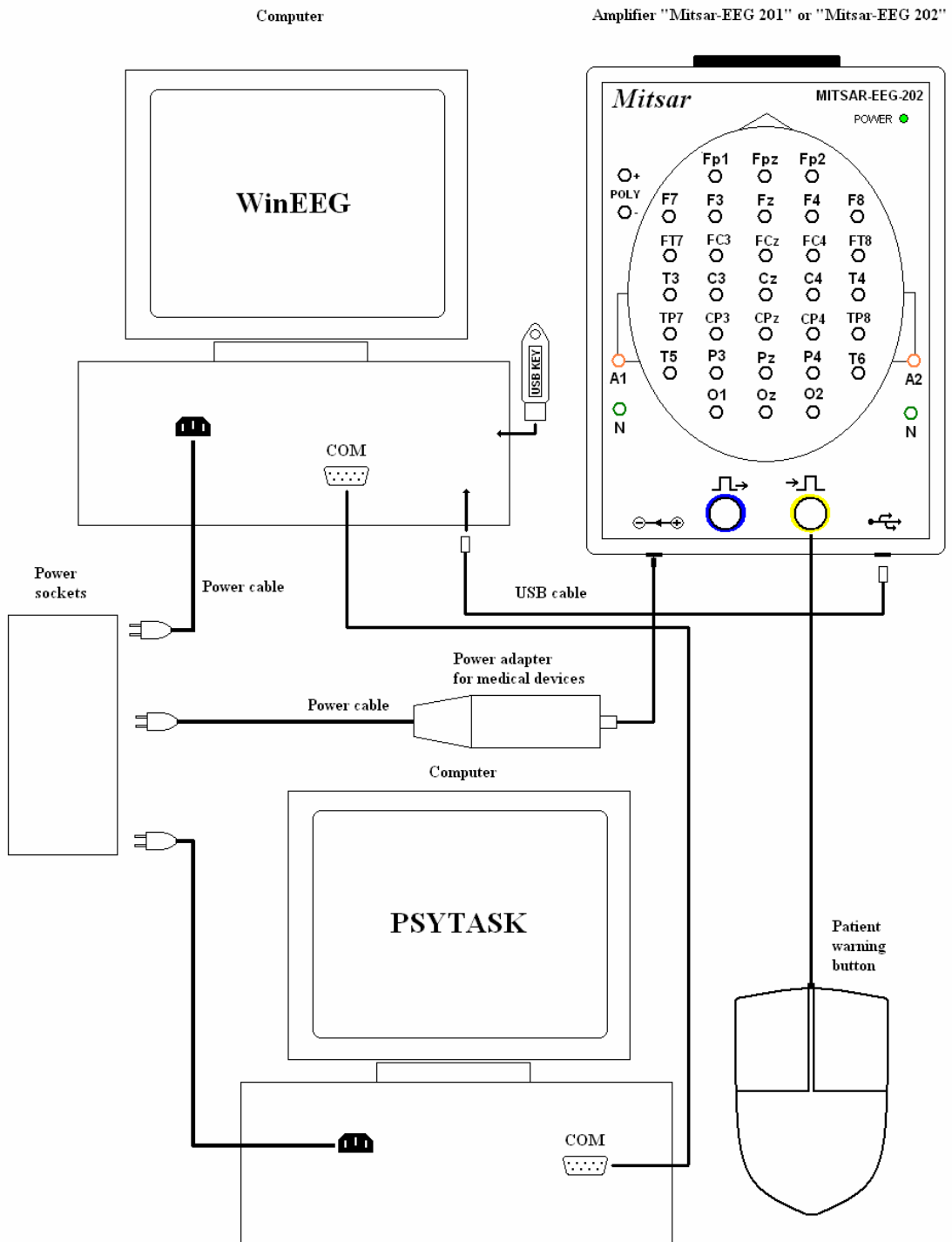


Figure 14. The connection diagram of Mitsar-EEG-201 amplifiers or Mitsar-EEG-202 amplifiers with computer and Mitsar-EEG system accessories for ERP studies.



ATTENTION! The PCs must not be situated closer than 1.5 m from a patient.

4.6. Video EEG with Mitsar-EEG amplifiers.

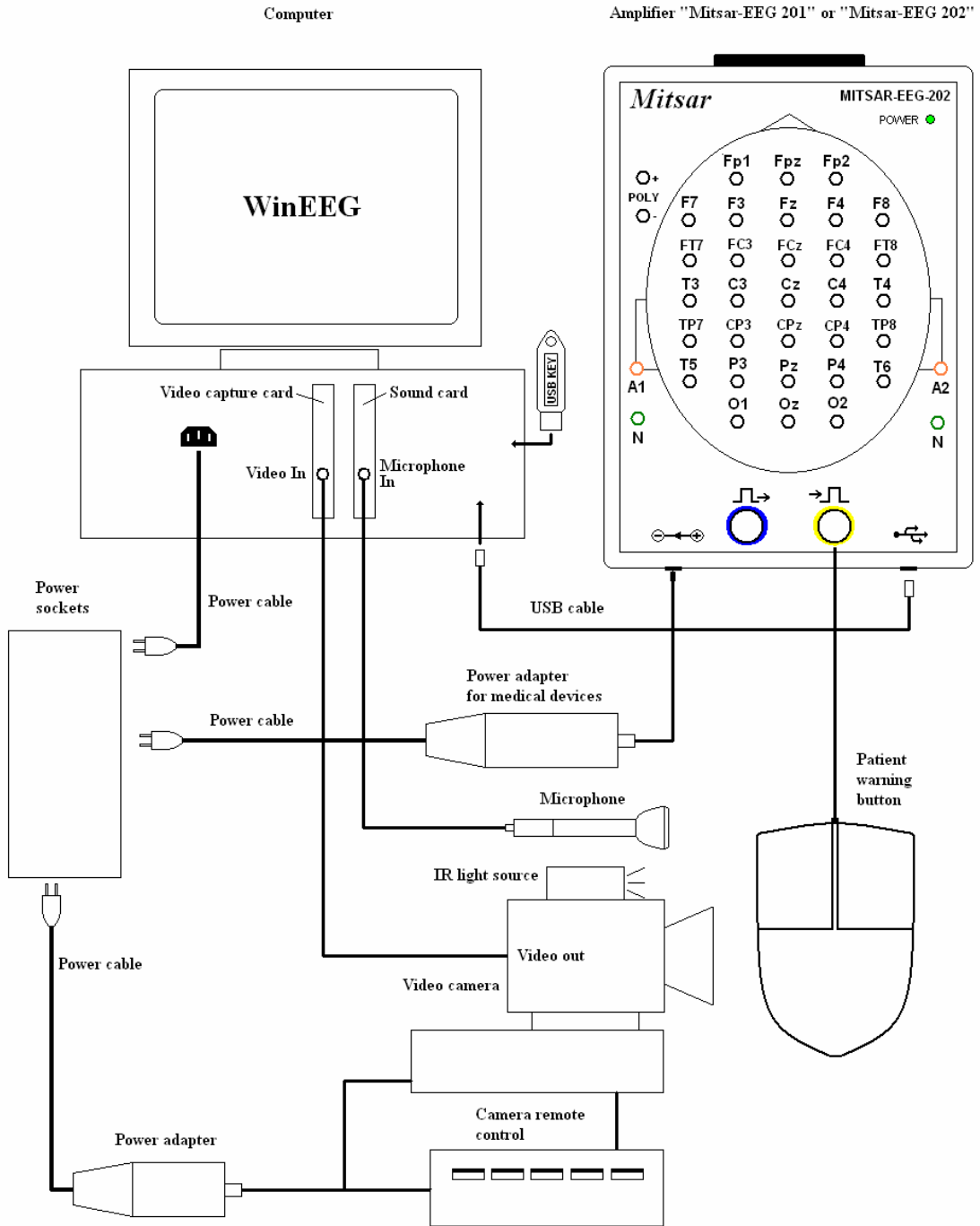


Figure 15. The connection diagram of Mitsar-EEG-201 amplifiers or Mitsar-EEG-202 amplifiers with computer and Mitsar-EEG system accessories for Video EEG.



ATTENTION! The PC must not be situated closer than 1.5 m from a patient.



ATTENTION! Different configuration of EEG system for Video EEG can be designed based on Mitsar-EEG amplifiers and accessories. The connection of multimedia devices can differ from this connection diagram.

4.7. Two cameras with Video EEG with Mitsar-EEG amplifiers.

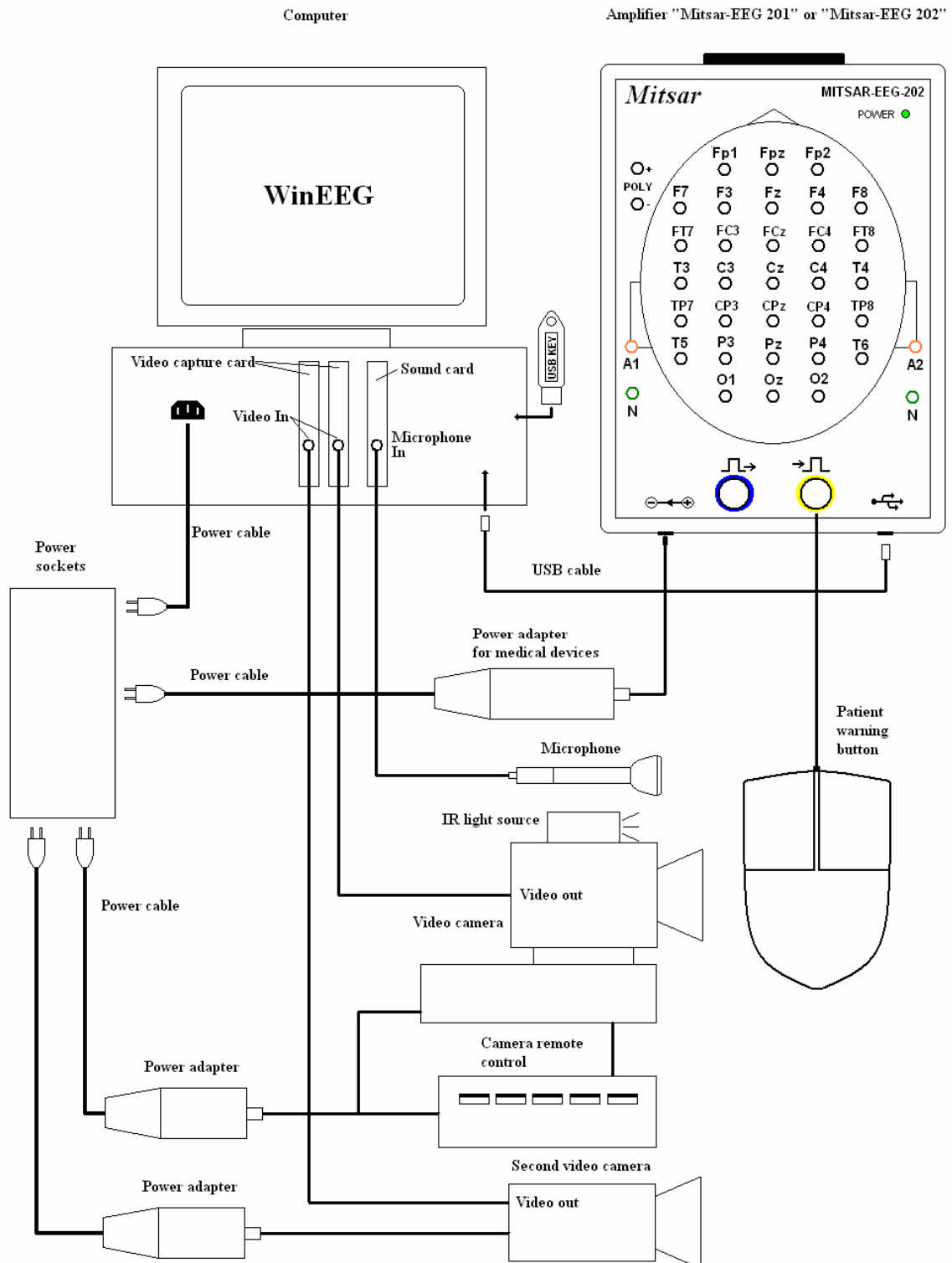


Figure 16. The connection diagram of Mitsar-EEG-201 amplifiers or Mitsar-EEG-202 amplifiers with computer and Mitsar-EEG system accessories for Video EEG.

ATTENTION! The PC must not be situated closer than 1.5 m from a patient.

5. Mitsar-EEG driver installation

5.1. Amplifier driver installation.

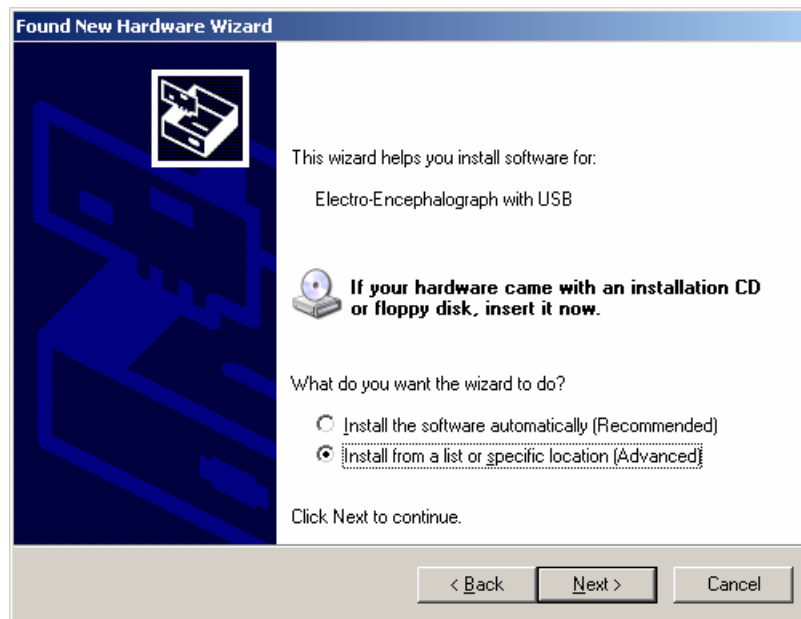
Corresponding driver should be installed for any device plugged in to USB input.

Driver installation is standard procedure performed by Windows XP. To install driver user should perform a number of standard steps listed below.

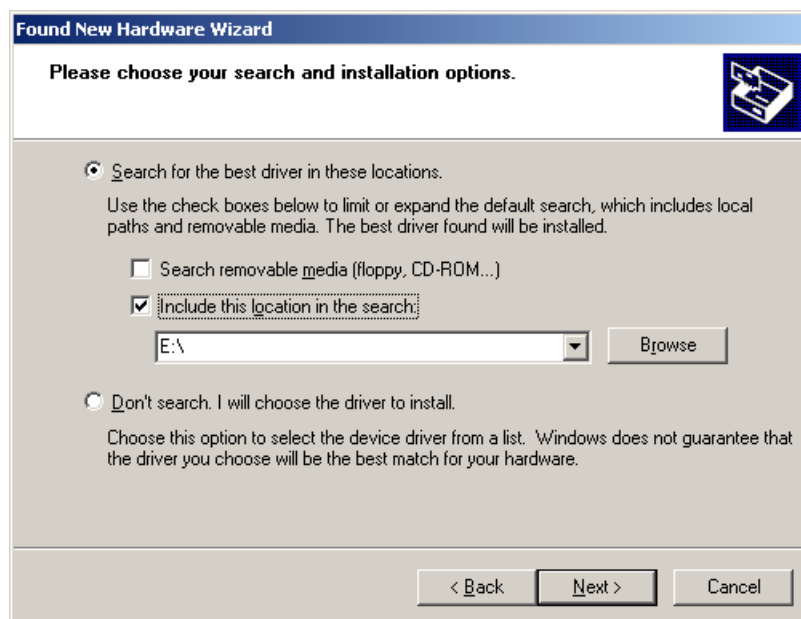
1. Insert the installation CD into your CD-ROM/DVD-ROM.
2. Connect your amplifiers USB cable to an available USB port on your computer. Windows automatically detects the device. **Found New Hardware Wizard** dialog box appears.



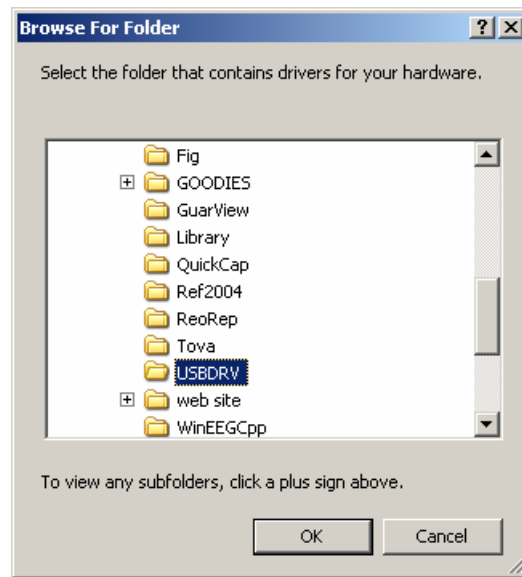
3. Select **No, not this time** and then click the **Next** button



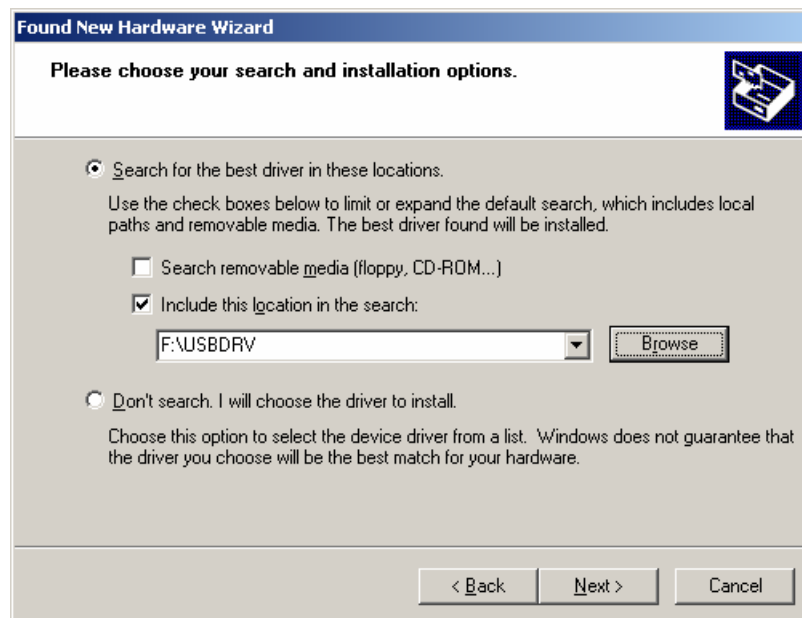
4. Select **Install from a list or specific location (Advanced)** and then click the **Next** button



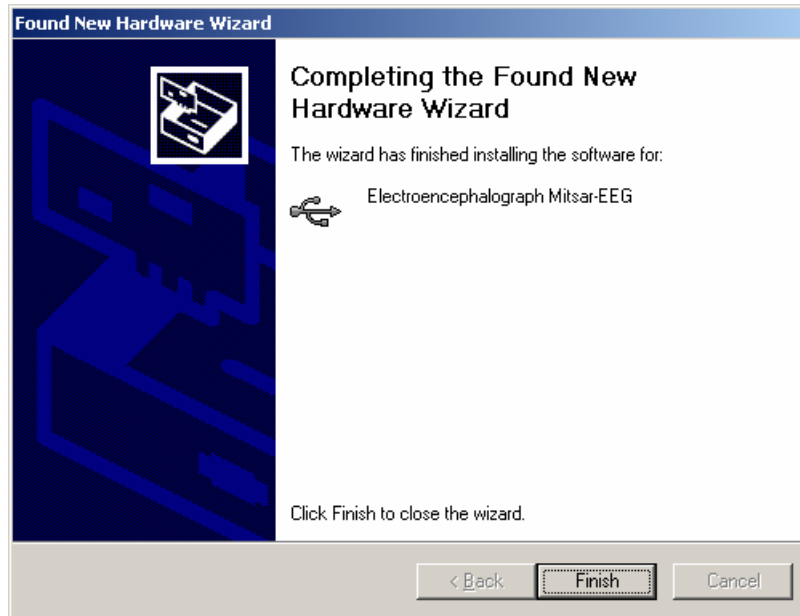
5. Select **Search the best driver in these locations**, uncheck **Search removable media (floppy, CD-ROM...)**, check **Include this location in the search**, and then click the **Browse** button



6. Find **USBDRV** folder on your installation CD and then click the **OK** button



7. Click the **Next** button. Windows will automatically install driver. Windows can ask you to specify corresponding **.inf** and **.sys** file. In this case select **usbisoch.inf** and **usbisoch.sys** – for **Mitsar-EEG-201**, models **104xxxx** and **105xxxx**, or **ftd2xx.inf** and **ftd2xx.sys** – for **Mitsar-EEG-201**, models **106xxxx** and **107xxxx**, and **Mitsar-EEG-202**, models **401xxxx**, **403xxxx**, **404xxxx** and **406xxxx** placed into **USBDRV** folder.



8. Click the **Finish** button to complete installation

5.2. USB KEY driver installation.

A number of WinEEG functions are protected by special electronic device (USB KEY) connected to USB. To open their functionality it is necessary to connect USB KEY to USB and install driver for this device.

1. Insert the CD to the corresponding drive
2. Open the “**ProtectionKey**” folder
3. Open “**Drivers**” subfolder
4. Run **INSTDRV.EXE**
5. Insert the USB KEY into the USB connector
6. Windows will detect a new hardware
7. Select Automatic search for the corresponding driver and allow Windows to install it (press button “**Next**”).
8. Sometimes you will need to reboot computer

If you haven't Security Key you can open protected functions by **Access Codes**. The **Access Codes** are distributed by Mitsar Ltd. Mitsar will give you these codes by requirement if you have purchased the corresponding hardware/software configuration.

The **Access Codes** are unique for each amplifier box and are active if this amplifier box is connected to computer only. To generate **Access Codes** it is necessary to know the information about amplifier box such as its version and its serial number. This information can be found using **Setup: Equipment parameters** command (For more information see **WinEEG User manual**). The following or similar string will be displayed in “**Amplifiers type**” field if the amplifier box is connected to the computer:

Mitsar 202 serial number 4010001 (37)

The access codes should be entered to corresponding fields:

“Main” to open EEG recording function.

“Video” to open video signal capture function.

“Database” to open comparison functions with normative database.



ATTENTION! The access code is 8-characters string with digits or capital English letters and without additional symbols such as space, point, comma and others.

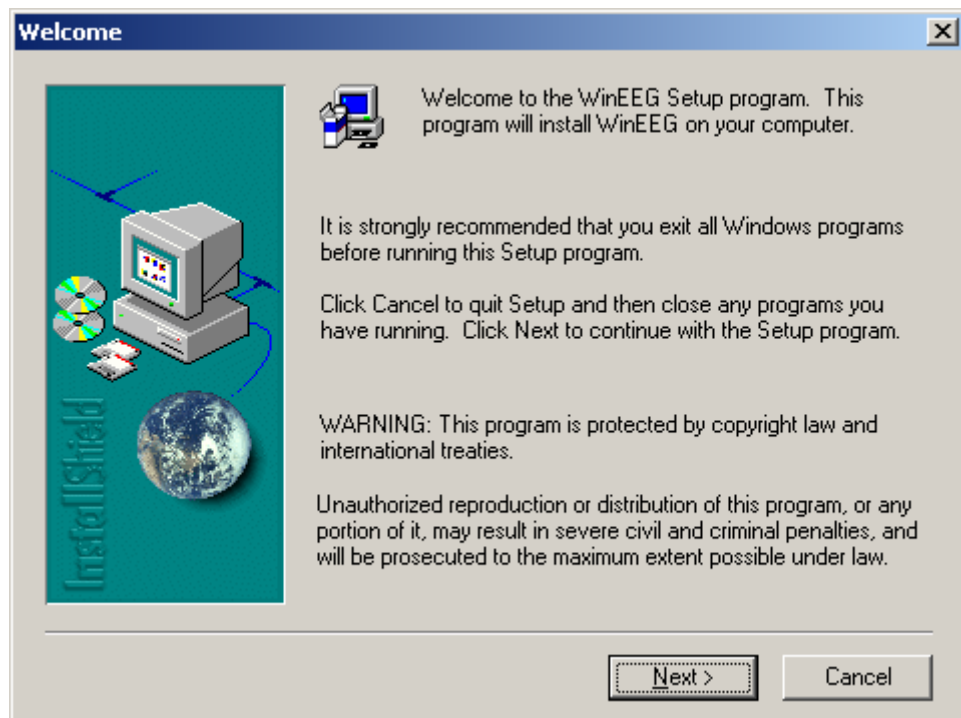
6. Mitsar-EEG software installation

6.1. WinEEG program installation.

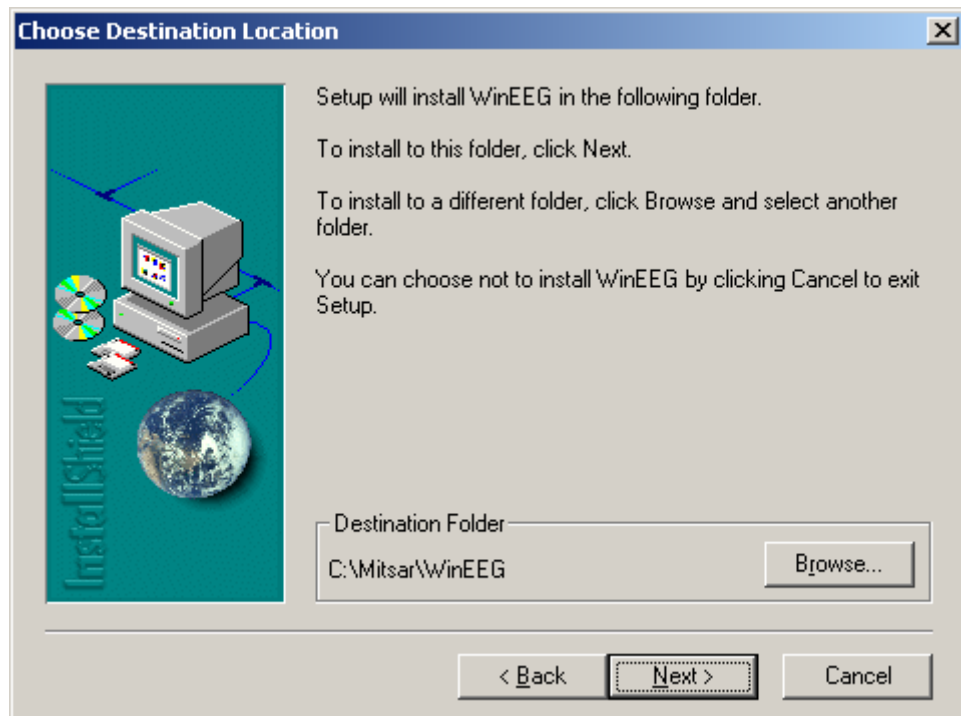
WinEEG is a program for EEG recording and processing.

WinEEG program should be installed on computer to which Mitsar-EEG amplifier is connected. To install WinEEG program:

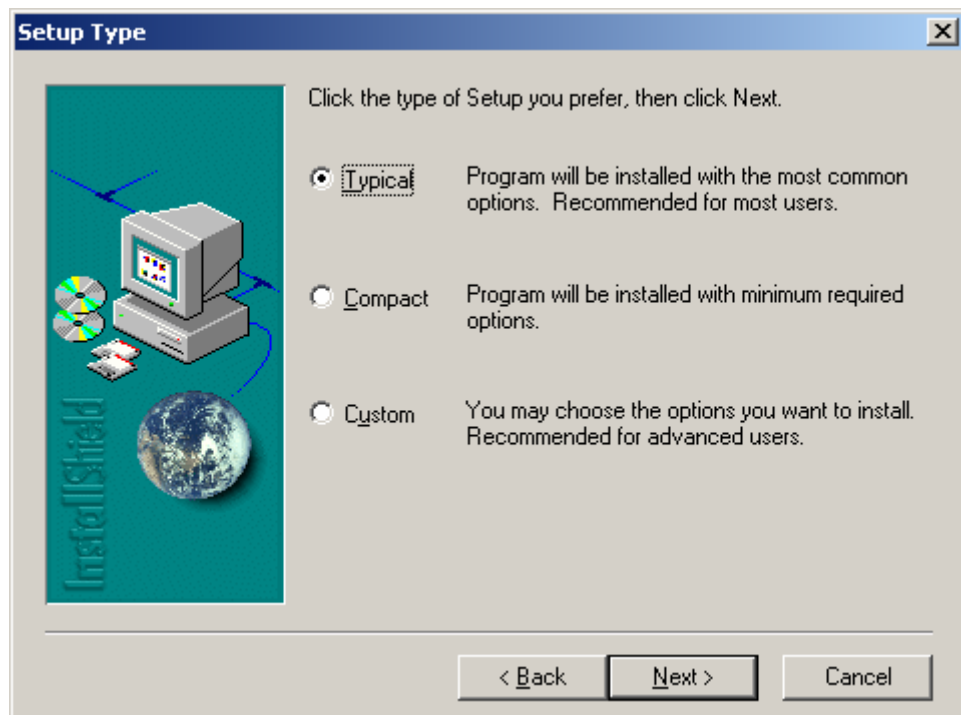
1. Insert the CD to the corresponding drive
2. Open folder with name “**WinEEG**”.
3. Run **SETUP.EXE** program.
4. Follow the instruction on the screen



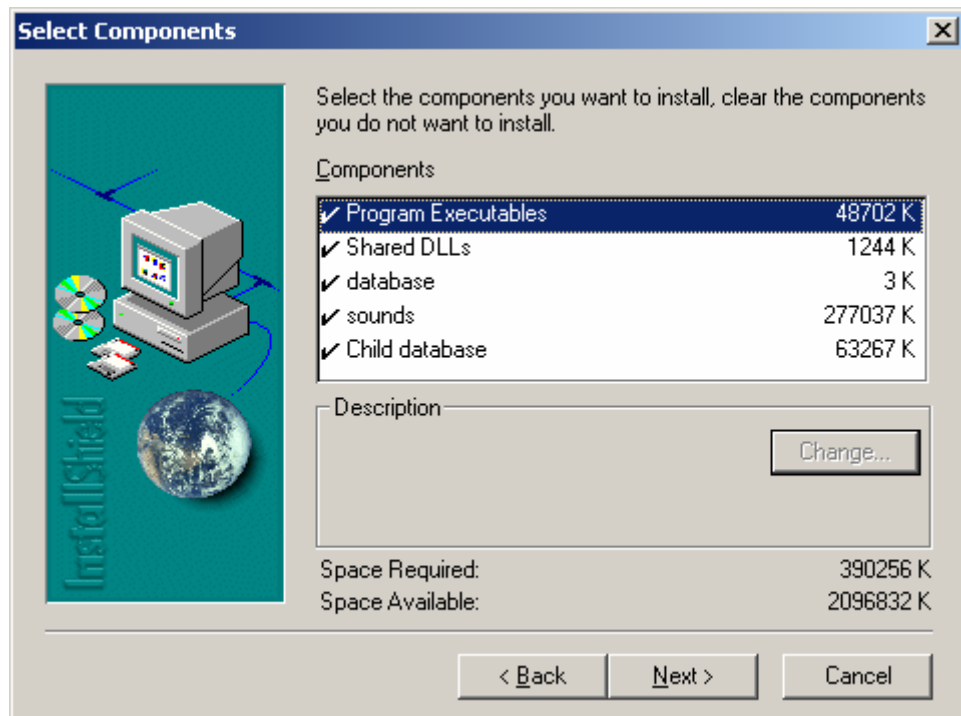
Press “**Next**” button to continue installation.



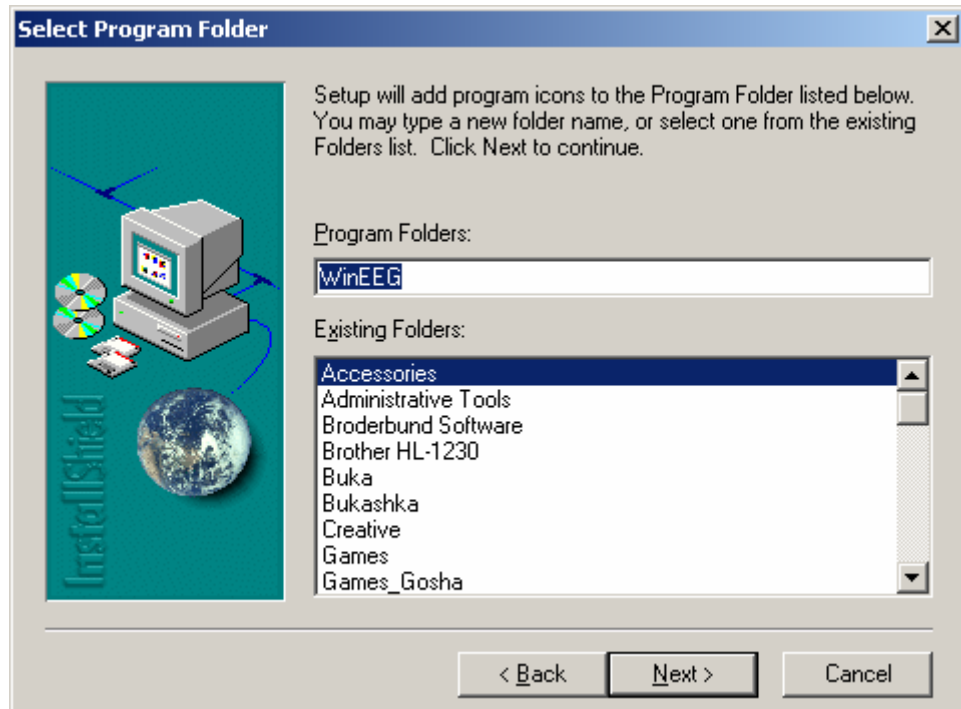
Press “**Browse...**” button if you like to change location of the WinEEG program. Press “**Next**” button to continue installation.



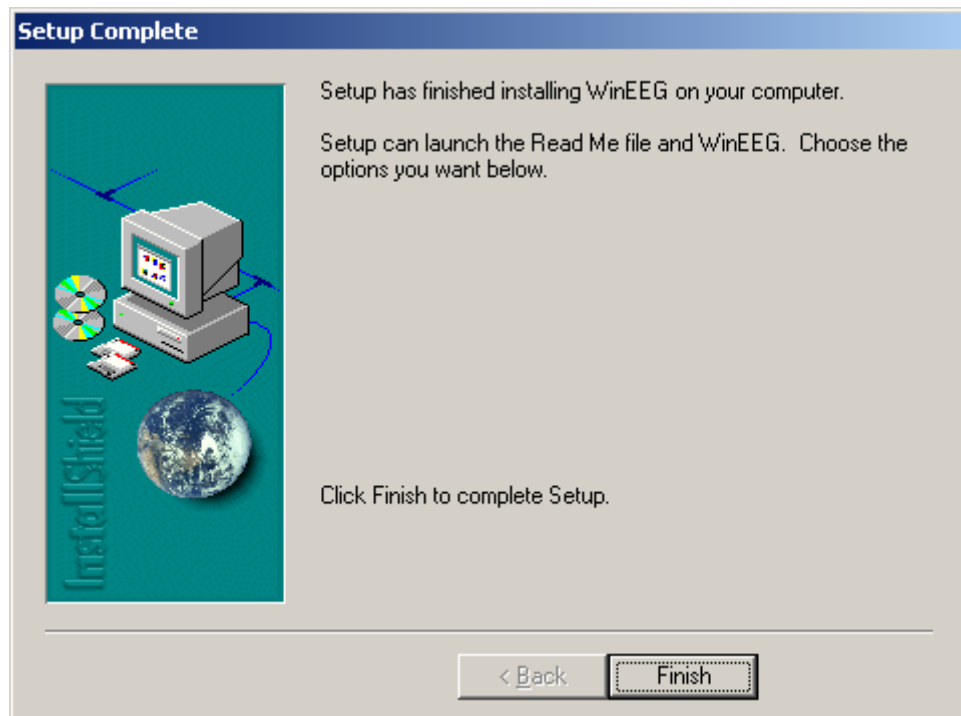
Select type of Setup you prefer. Press “**Next**” button to continue installation.



Select components you want to install. Don't install “**Sounds**” component if you don't plan to use auditory biofeedback. Don't install “**Child Database**” component if you will not use Normative Database including spectra and ERP. Press “**Next**” button to continue installation.



Type a new folder name if you want. Press “**Next**” button to continue installation.

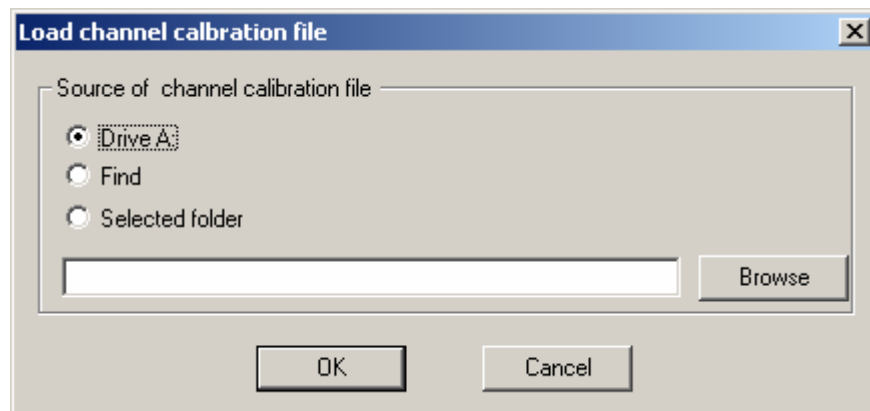


Press “**Finish**” button to complete Setup.

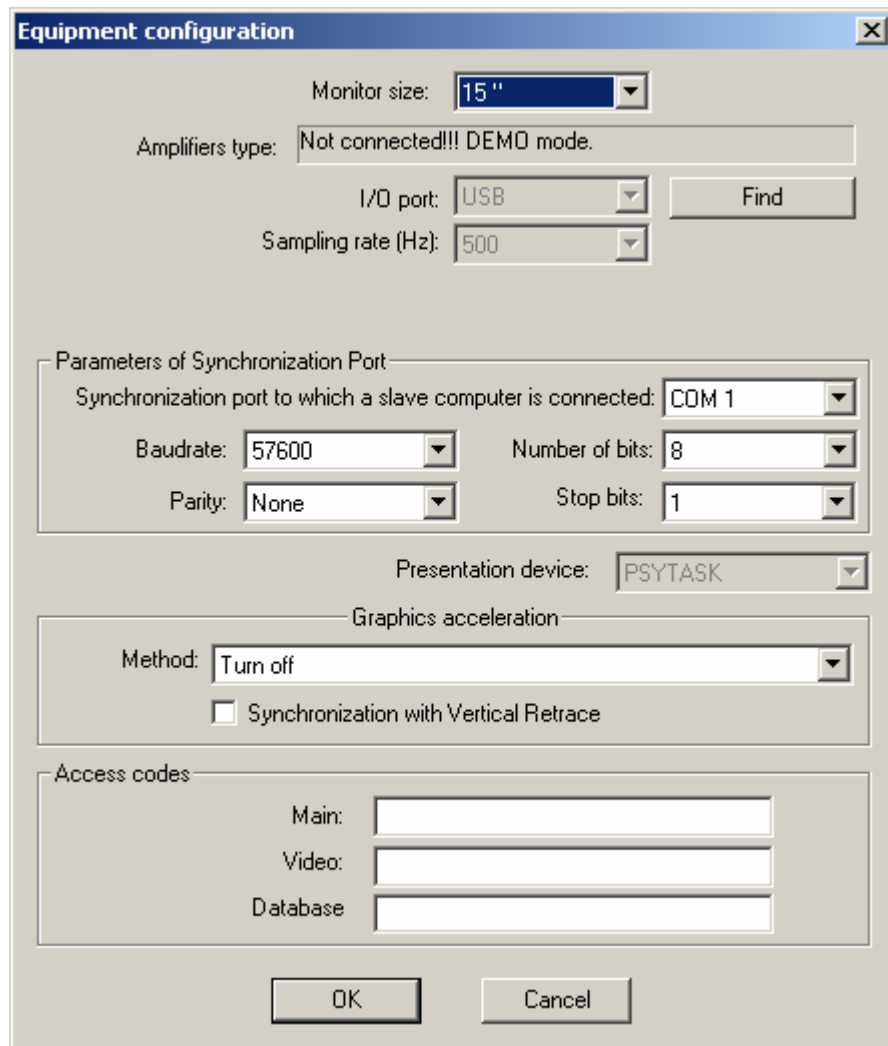
6.2. WinEEG program initial setup and testing.

The following steps should be done to complete installation of the WinEEG program.

1. Run WinEEG.EXE program.
2. WinEEG program will automatically ask the location of calibration file **EEG.CAL** distributed by Mitsar Co Ltd. together with Mitsar-EEG amplifiers.



3. Select the location of EEG.CAL file and press OK.
4. WinEEG will automatically copy EEG.CAL file to working folder of WinEEG program.
5. Run the **Setup: Equipment parameters** command. The next dialog window will be displayed at the screen.



6. Press button “**F**ind”.
7. WinEEG program will automatically search for connected to computer amplifier and displays it identification in **Amplifier type** field.
8. If WinEEG program is not able to find connected to computer amplifier it will display “**Not connected!!! DEMO mode**” string in **Amplifier type** field. In this case check the USB cable using to connect amplifiers to computer or reinstall amplifier driver.
9. If WinEEG program displays amplifier identification correctly perform the next steps is to check amplifier works properly.
10. Run the **File: New** command and press OK button.
11. Run the **Recording: Turn On (Off) Calibration** command.
12. Visually check the calibration signal on the screen. The calibration signal should be square waveforms with frequency – 0.5 Hz and amplitude – 200 uV. The calibration signal should be the same for all displayed channels.
13. Run the **Recording: Stop** command.
14. Close EEG window.

6.3. WinEEG program initial setup of video EEG option.

1. Run the **Setup: Video recordings** command. The next dialog window will displayed at the screen.

Video recoder parameters

Main Camera

Video Input Device: Pinnacle DV/AV Capture

Video Input: Video Composite

Video compressor: Microsoft MPEG-4 Video Codec V1

Frames per: 25 per second Resolution: 352 x 288 pixels

Video format Video Source

Audio Input Device: SoundMAX Digital Audio

Audio Source

Audio compressor: MPEG Layer-3

Would you like to capture audio?

Additional camera

Would you like to capture video from additional camera?

Video Input Device: AVerDVD EZMaker WDM Video Capture

Video Input: Video Composite

Video compressor: Microsoft MPEG-4 Video Codec V1

Frames per: 25 per second Resolution: 320 x 240 pixels

Video format Video Source

Video block length: 900

OK

2. Select **Video Input Device** for **Main camera** from the corresponding list.
3. Select **Video Input** from the corresponding list to which the camera is connected.

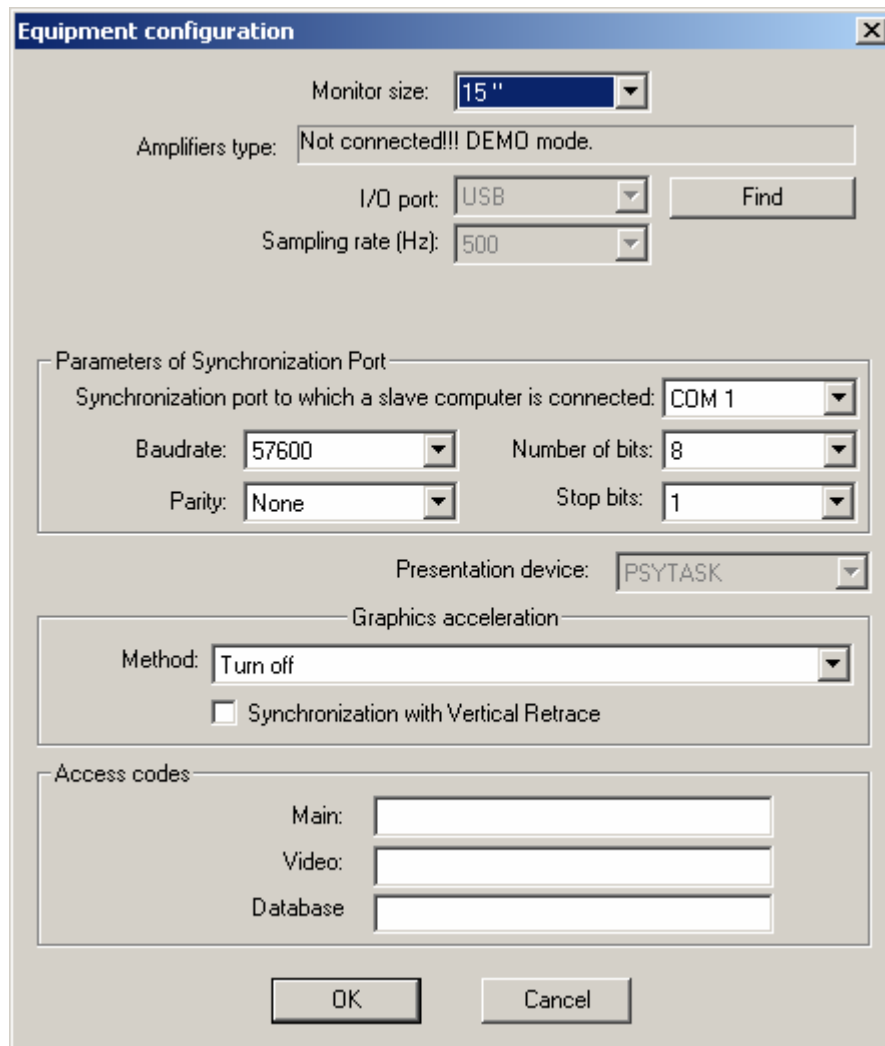
4. Select appropriate **Video compressor** for **Main Camera** that will be used for on line compression of video information. The compressors “**Microsoft MPEG-4 Video Codec V1**” or “**Microsoft MPEG-4 Video Codec V3**” will be the best for many system configurations. We don’t recommend you to use this option with rather slow computers. Use Source button to specify compression parameters if corresponding video capture card support on line compression.
5. Select frame rate if it is possible. We recommend use the sampling rate equals to 25 or 30 frames per second.
6. Press button **Video format** to specify parameters of video format. Usually these parameters include the resolution of video data. (Specific for video capturing device).
7. Press button **Video Source** to specify parameters of video capturing. (Specific for video camera)
8. Select **Audio input device** from the corresponding list.
9. Select appropriate **Audio compressor** that will be used for on line compression of audio information. The compressors “**MPEG Layer-3**” will be the best for many system configurations.
10. Turn of audio capturing checking the button “**Would you like to capture audio?**”
11. Specify minimal length of block of video data placed into one file using **Video block length** field. By another words the old video file will be closed and new file will be created every specified seconds.
12. Specify parameters for additional camera if it is connected and will be used. The parameters are specified at the same way as described above (see 2.-7.)

Attention! The video and audio compressors will be available if corresponding codecs have installed.

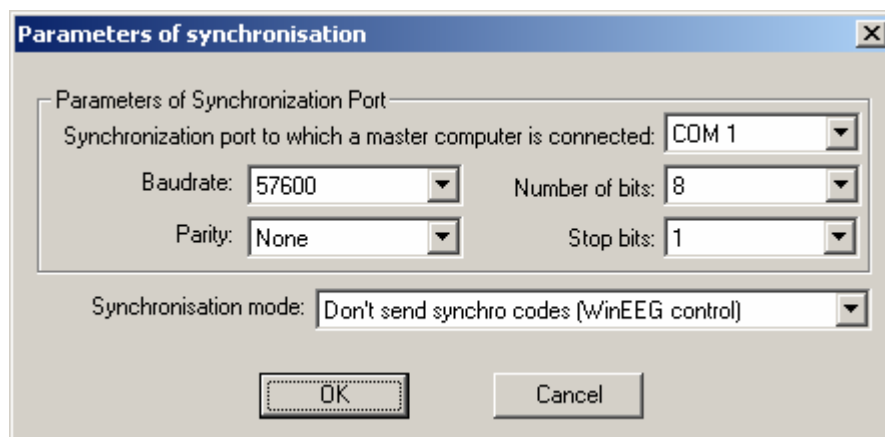
Attention! Please specify all parameters of Video format, Video source and Audio source carefully. The quality of recorded signal will depend on these parameters. Unfortunately corresponding dialog boxes are unique for each video capture and audio capture devices. Please look for information about them in corresponding operation manuals.

6.4. Initial equipment preparation for carrying out ERP studies

1. Turn off the computers.
2. Connect computers together by null modem cable.
3. Turn on the computers.
4. Install the PSYTASK program on computer that will be used for presentation of stimuli. The installation procedure is described in PSYTASK user manual.
5. Run the WinEEG program on computer to that the Amplifier is connected.
6. Run the PSYTASK program on computer that will be used for presentation of stimuli.
7. Run the **Setup: Equipment parameters** command of WinEEG program. The following dialog window will displayed at the screen.

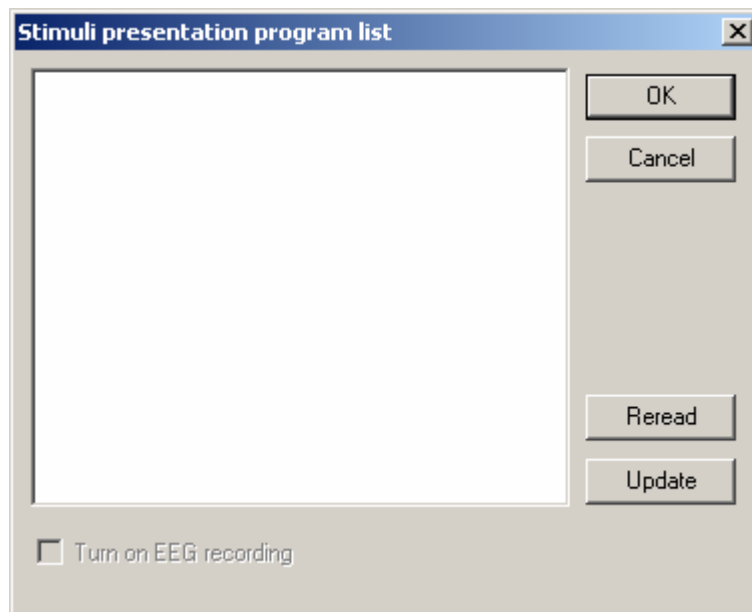


8. Run the **Modify synchronization parameters** command of PSYTASK program. The following dialog window will be displayed at the screen.



9. Check the all parameters of Synchronization ports. The parameters “Baudrate”, “Number of bits”, “Parity” and “Stop bits” should be identically defined in both programs.
10. Check parameter **“Presentation device”** of the WinEEG program. It should be specified as **“PSYTASK”**.

11. Check parameter “Synchronization mode” of the PSYTASK program it should be specified as “**Don’t send synchro code (WinEEG control)**”.
12. Select COM ports to that the null modem cable connected to each computer.
13. Press **OK** button to close the **Equipment configuration** dialog window of the WinEEG program.
14. Press **OK** button to close the **Parameters of synchronization** dialog window of the PSYTASK program.
15. Run the **Switch to Slave Mode** command of the PSYTASK program.
16. Run the Setup: **Stimuli presentation programs** command of WinEEG program. The following dialog window will displayed at the screen.



17. Click the **Update** button. If synchronization COM ports are defined correctly the progress bar will display a process of transferring of task protocols from the PSYTASK program to the WinEEG program. Otherwise the WinEEG program will report that the slave computer doesn't respond.
18. Change synchronization parameters if necessary and repeat steps 15.-17. In some cases it is necessary to find correct combination of COM ports step by step.

Attention!!! It is necessary to perform steps 15.-17 every time when the list of tasks or their parameters is changed in PSYTASK program.

Attention!!! PSYTASK program is able to send correct task protocols only. Please be attentive and check new task protocols before updating list of protocols for the WinEEG program if they were added.

Attention!!! The procedure of recording and analysis ERP is described in the WinEEG user manual.

7. Mitsar-EEG software quick review

This chapter includes quick review of Mitsar-EEG software: **WinEEG** and **PSYTASK** programs.

The **WinEEG** program is intended for the clinical observation of electroencephalogram (EEG), video EEG and evoked (event related) potentials recording for the diagnostic of brain diseases. The software is written for MS Windows XP is designed for recording and assessing EEG synchronously with video signals, as well as for recording and analyzing responses of the human brain induced by external stimuli or internal movements.

The **PSYTASK** program is intend for visual and auditory stimuli presentation synchronously with EEG recording. The stimuli are presented on the monitor of additional computer connected to the main computer (to witch Mitsar-EEG amplifier is connected). Two computers should be connected via COM ports.

7.1. WinEEG program main functions.

The main functions of WinEEG program is presented at following table.

| | |
|--------------------|--|
| Recording | <ul style="list-style-type: none"> - Continious, unlimited, - Moving paper emulation, - Synchronous with stimuli presentation for ERP and event related desynchronization (ERD) |
| Video EEG | <ul style="list-style-type: none"> - Synchronous on-line recording of EEG, video and audio signals (from one or two cameras and microphone). - On-line MPEG-4 compression of video signals and MPEG-3 compression of audio signal. - Off-line compression/recompression of video and audio signals. - Night video recording using video camera with infrared illuminant. - Manual marking of events during EEG and video recording. - Off-line synchronous playback of EEG, video and audio signals - Automatic positioning to video pictures corresponding to manually selected EEG sample or marker. - Editing of EEG and video signals to save meaningful fragments only. - Advanced service for preparation of CD copy of video EEG record. - Compact but powerful free video EEG viewer for displaying of CD copy of video EEG record provides next possibilities: off-line synchronous playback of EEG, video and audio signals, digital filtering of EEG data, montage reformatting, EEG mapping. |
| Artifacting | <ul style="list-style-type: none"> - OCG subtraction using regression method. - Spatial filtration on the basis of estimation of filter parameters using Principle Component Analysis (PCA) or Independent component analysis (ICA). - EEG epoch elimination on the basis of low and high frequency power values. - Manual EEG epoch elimination. |

| | |
|---|--|
| Remontaging | <ul style="list-style-type: none"> - Any monopolar. - Any bipolar. - Common average reference. - Weighted average references (Hjorth и Lemos). - Laplacian. - and some others |
| Digital filtering | <ul style="list-style-type: none"> - A set of IIR bandpass filters. - Notch filters at 50 or 60 Hz. (12-th order, more then 40 dB attenuation) - High order bandpass FIR filters. |
| Calculating | <ul style="list-style-type: none"> - Absolute and relative spectra, spectral ratios, spectral asymmetries, coherence, phase. - Cross correlations of EEG. - Spectral density arrays. - Event-related potentials (ERPs). - Event-related de/synchronization (ERD/ERS). - Event-related wavelet transforms (time-frequency decomposition of EEG responses and estimation event related bandpower). - Event-related wavelet coherence - Estimation a reaction time, omission and commission errors in behavioral paradigms. - Grand averaging of power spectra, coherence, event-related potentials, event-related de/synchronization, event-related wavelet bandpower, event-related wavelet coherence for selected subjects group and estimation of variance of computed parameters. |
| Mapping | <ul style="list-style-type: none"> - The above mentioned parameters into 2-D topograms using the Hot Metal, White-Grey, RGD, Blue-Red, Sokolow and some others mapping styles. - EEG spectra, ERPs into 3D Talarach atlas by means of LORETA time sequence displaying. - Dipole source localization for EEG and ERPs. |
| Automatic spike detection | <ul style="list-style-type: none"> - Automatic spike detection procedure based on amplitude-temporal parameters of waveforms. - Estimation and analysis of dipole sources parameters increase performance of procedure. - PCI of ICA decomposition of multi channel EEG before spike detection. - Manual editing of list of spikes. - Individual spikes averaging. - Calculation of synchronously to spikes averaged wavelet bandpower and wavelet coherence. - Manual copying spike waveforms and its parameters to clipboard. |
| Statistical comparison of power spectra, coherence, ERP, event-related de/synchronization. | <ul style="list-style-type: none"> - between different states (eyes opened, eyes closed) for one subject group by using t-score - between subject groups for one state by using t-score - between single subject and subjects group by using z-score. - between single subject and normative data base by using z-score. |
| Exporting | <ul style="list-style-type: none"> - Raw EEG to other applications by using European data format |

| | |
|----------------------------|--|
| | (EDF), ASCII format, or binary format, LEXICOR - Power spectra, coherence, event-related potentials, event-related de/synchronization wavelet bandpower and wavelet coherence for selected group of subjects for advanced statistical estimation by using ASCII format. |
| Importing | - Raw EEG from other EEG systems by using EDF, ASCII, LEXICOR, NeuroScan data formats. |
| Additional features | - Build-in database or Mitsar database MDB. - High quality printing of EEG signals. - Batch processing of EEG for selected set of EEG records. - Composing and color printing summary reports to include raw wave forms, time-frequency presentations, maps, LORETA images and text. - User defined list of final report templates. - EEG biofeedback. - Nonlinear analysis of EEG - D2 estimation (available by additional order) |

For more information please see the **WinEEG User manual**

7.2. PSYTASK program introduction

The PSYTASK is intended for preparation and carry out both psychophysics and psychophysiology investigations.

PSYTASK main features are:

1. Visual (on the monitor screen) and auditory (using sound card and speakers) stimuli presentation.
2. Reaction time measurement. To measure the reaction time keyboard and mouse can be used.
3. PSYTASK is working together with "Mitsar" digital EEG recorder (WinEEG software) and provides a synchronous stimuli presentation with EEG acquisition. In this case two computers connected via COM ports are used. PSYTASK program works on the first computer and WinEEG program works on the second computer. WinEEG program send synchronization codes to PSYTASK program to control its work and provides a synchronous stimuli presentation with EEG acquisition. The recorded data can be used to calculate and analyze event related potentials (ERP) and/or event related desynchronization (ERD).
4. PSYTASK program can send synchronization codes to another program via COM port. This feature provides a possibility to carry out ERP studies using another amplifiers and another program that is able to detect synchronization codes.
5. PSYTASK program have a users friendly interface that provide a possibility to design psychological tasks.
6. PSYTASK program measures the reaction time and task performance parameters (omission and commission errors) and save them to build-in database for the future analysis and final report preparation.

For more information how please see the PSYTASK User Manual.

7.3. Quick EEG recording.

The following steps describe briefly how to acquire an EEG and to create a final report:

1) Place the electrodes on the patient's head. For a normal investigation 19 electrodes are placed using the International 10-20 system. Also a "common point" electrode, a "N" electrode and reference electrodes must be placed.

Common point and reference electrodes are to be placed in any case, whether bipolar or monopolar montage is used. If EEG is assumed to be recorded in reference to ears two reference electrodes are placed on the ears. A reference electrode can be placed on the forehead and connected to A1 or A2 input (the appropriate electrode is provided in the set) and a corresponding montage is set in the program. EEG signal quality depends on paying special attention to the placement of common point and reference electrodes.

2) Connect the electrodes to their respective inputs on the front panel of the amplifier block.

3) Set the electrode impedance checking mode using **Recording: Impedance** command. If the impedance value is satisfactory (less than 5 KOhm), close the **Control of Electrode Impedance** dialog. Otherwise re-install those electrode(s) showing excessive impedance.

4) Run the **File: New** command. - Fill in the patient card, choose a montage and check it. When these actions are completed successfully, a new EEG window will be displayed on the screen.

5) Run the **Recording: EEG Monitoring** command. Visually check the quality of the live EEG displayed in the new window. If any channel is acquiring EEG poorly, re-install the corresponding electrode(s). Check EEG acquisition quality using a monopolar montage, without averaging.

6) Run the **Recording: EEG Recording** command to start recording signals to a file. To stop recording, run the **Recording: EEG Recording** command once more. One fragment of the EEG will be recorded. Record another fragment if necessary. If photostimulation is necessary turn the photostimulator on using the **Recording: Photostimulation (on/off)** command, wait for the time needed, change the photostimulation frequency or turn the photostimulator off, and so on. After finishing the photostimulation procedure, stop EEG recording.

7) Stop EEG acquisition using the **Recording: Stop** command.

8) Save the newly created EEG file into the database using the **File:Save** command.

9) Remove the electrodes and let the patient go.



ATTENTION! To avoid data loss, do not carry out Step 9 before Step 8.

10) Analyze the newly recorded EEG. (See **EEG window** chapter of the WinEEG user manual).

- 11) Open the **Final Report window** using the **Analysis: Final Report** command.
- 12) Compose the final report and save it to the database using the **File: Save** command.
- 13) Print the final report and illustrative fragments of the EEG using the **File: Print command**.
- 14) Close the WinEEG window using the **File: Exit** command.

The EEG recorded to the hard disk is the raw one, acquired using monopolar montage in relation to reference electrodes, with the widest bandwidth. But the EEG displayed on the screen is reformatted and filtered according to the montage parameters that have been set (see **Setup: Montage List** command). The raw EEG data may be reformatted into any montage, without limitation.

For more information how to do this please see the **WinEEG User manual** and the **PSYTASK User Manual**.

8. DEED OF COMMISSION

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

Modification (underline as required):

- Mitsar-EEG-104xxxx,
complied with technical specifications TU 9441-001-25890578-99
- Mitsar-EEG-105xxxx,
complies with technical specifications TU 9441-001-25890578-99
- Mitsar-EEG-106xxxx,
complies with technical specifications TU 9441-001-25890578-99
- Mitsar-EEG-107xxxx,
complies with technical specifications TU 9441-001-25890578-99
- Mitsar-EEG-401xxxx,
complies with technical specifications TU 9441-004-52118320-2005
- Mitsar-EEG-403xxxx,
complies with technical specifications TU 9441-004-52118320-2005
- Mitsar-EEG-404xxxx,
complies with technical specifications TU 9441-004-52118320-2005
- Mitsar-EEG-406xxxx,
complies with technical specifications TU 9441-004-52118320-2005

Manufactured on _____

Mitsar Co.Ltd. _____

(date, signature, seal)

9. 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 _____,

Purchased _____

(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 _____,

Purchased _____

(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-201 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)

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-202 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)