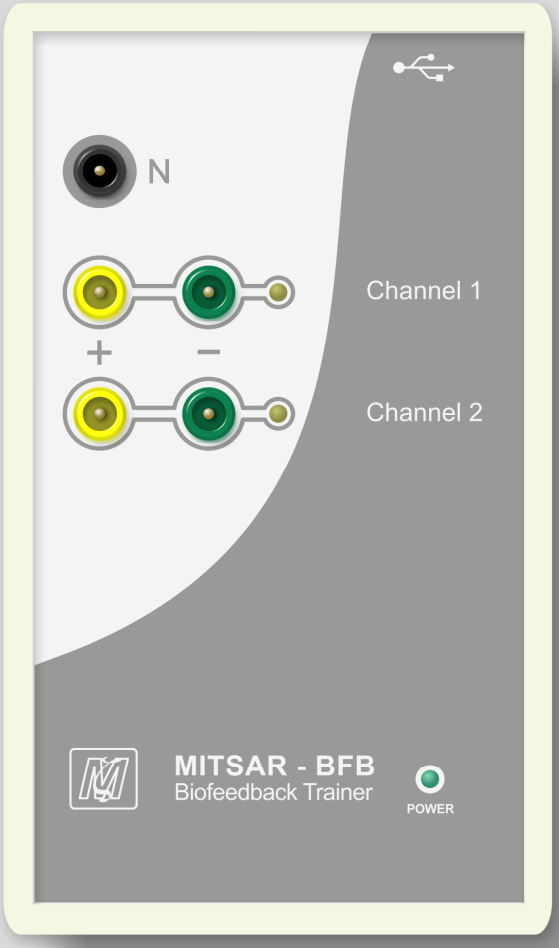
Mitsar Co.Ltd.

Biofeedback Trainer MITSAR-BFB

OPERATION MANUAL

MIRN.943119.005 RE



Saint-Petersburg 2007

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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.

Limit of Warranty

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.

Items Not Covered by Warranty

We do not warrant uninterrupted or error-free operation of a product. We provide certain non- Mitsar products on an “as is” basis. Non-Mitsar manufacturers or suppliers may provide their own warranties to you. Separate software warranty is provided with software user documentation.

Customer Responsibility

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.

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

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 60601-1-1:1992, 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

WARNING. Only trained personnel familiar with safety regulations is allowed to operate the Biofeedback Trainer.

WARNING. Only personnel properly trained to operate the Biofeedback Trainer should use it for patient testing.

WARNING. Do not make clinical decision base on Biofeedback Trainer measurement only. Biofeedback Trainer is auxiliary device that give the additional information about patient state. The diagnosis should be determined basing on totality of symptoms and measurements.

WARNING. The personal computer (as a part of Biofeedback Trainer) must not be situated closer than 1.5 m from a patient.

WARNING. PC, monitor, printer, TV set and video player (as a part of Biofeedback Trainer) must be connected to power supply line only via socket equipped with ground contact.

WARNING. Do not contact simultaneously to patient and any non medical part of Biofeedback Trainer such as PC, monitor, printer, TV set and video player.

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

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

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

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

WARNING. Any devices connected to Biofeedback Trainer 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.

WARNING. Any devices connected to Biofeedback Trainer including electrodes and electrodes positioning caps should be certified in compliance with domestic standards (Medical Device Directive (MDD) 93/42/EEC or FDA requirements).

WARNING. The personal computers are important parts of Biofeedback Trainer but they are delivered separately. All computers used with Biofeedback Trainer should be certified in compliance with domestic standards (for example IEC 60950 for Europe).

WARNING. Clean Biofeedback Trainer components with a soft cloth lightly moistened with mild detergent solution or 70% alcohol solution. The components should be disconnected from power supply during cleaning.

WARNING. Disinfect Biofeedback Trainer components with 10 % whiten solution based on chlorine.

WARNING. Follow the recommendation of companies producing electrodes and electrodes caps concerning cleaning and disinfection of them.

CAUTIONS

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

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

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

CAUTION. 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.

CAUTION. Mitsar amplifiers do not have build in protection from influence of defibrillator.

CAUTION. Do not use Biofeedback Trainer in moist condition. Otherwise you will increase the risk of electric shock, the device may work incorrectly and you may damage the device.

CAUTION. Do not spill any liquid on any part of Biofeedback Trainer including connectors, batteries compartment, cables and etc. This will increase the risk of electricity shock and may damage the device.

CAUTION. There are no parts inside the Biofeedback Trainer components which should be maintained by user except the batteries inside Mitsar-BFB Amplifier Box. Never attempt to repair, disassemble or reconstruct any unit. A serious electric shock could result if you ignore this precautionary measure.

CAUTION. Do not autoclave any parts of Biofeedback Trainer.

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

Equipment labeling

The next symbols are used for Biofeedback Trainer parts labeling.

This mark identifies TYPE BF APPLIED PART.

This mark identifies INTERNALLY POWERED EQUIPMENT.

This mark identifies manufacture date.

This mark identifies compliance with the Russian Federation safety standards (GOST)

This mark identifies compliance with the Medical Device Directive (MDD) 93/42/EEC.

SN

This mark identifies serial number.

1. Biofeedback Trainer overview

Biofeedback Psychophysiological Condition Trainer Mitsar-BFB (hereafter Biofeedback Trainer) is intended for brain training by its potentials registering while the examinee is executing specially programmed actions and perceiving brain activity changes as visual and acoustic images.

Application area: health centers, hospitals, medical research centers, psychological correction offices at schools. The trainer can be also used at home under the doctor's supervision.

The Biofeedback Trainer includes the bio-signals converter (hereinafter: the Amplifier Box). The Amplifier Box is controlled by means of the specially developed computer software.

The Biofeedback Trainer includes the video and audio signals converter (hereinafter: the Jammer). The Amplifier Box is controlled by means of the specially developed computer software.

Biofeedback Trainer 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.

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 Biofeedback Trainer should be experienced enough in technique of clinical neurofeedback 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 BrainTuner program.

1.2. Delivery set

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

Component	Document ID	Quantity
Mitsar-BFB biofeedback trainer consisting of	MIRN.943119.005	1
1.1 Mitsar-BFB Amplifier Box	MIRN.943119.005-01	1
1.2 Mitsar-BFB Jammer	MIRN.943119.031	1
1.3 EEG electrodes and fixation ware	PAMEL d.o.o. company	1 set
1.4 Batteries	R6 (AA)	4
1.5 USB “A-B” connection cable	SCUAB-7	2
1.6 Software CD	BrainTuner	1
Accessories		
2 Audio-video cable	Philips SWV3533	2
3 TV-set[1]	S a m s u n g	1
4 Video-player[1]	S a m s u n g	1
5 Personal Computer[1]	IBM	1
Instruction manuals		
6 Operation Manual	MIRN.943119.005РЭ	1
7 User’s Manual (for software pack)	MIRN.943119.005ПО	1

[1] is delivered separately on the client’s call

2. Biofeedback Trainer Additional information

2.1. Computer

The personal computer is important part of Biofeedback Trainer but it is delivered separately. All computers and other peripheral devices (as monitors, printers and etc.) used with Biofeedback Trainer should be certified in compliance with domestic standards (for example IEC 60950 for Europe).

2.2. 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. BrainTuner software.
2. Amplifier Box and Jammer device drivers for Windows.

2.3. Electrodes

Electrodes and electrodes caps are important component of Biofeedback Trainer but they are delivered separately. All electrodes and electrodes positioning caps should be certified in compliance with domestic standards. Mitsar Co. Ltd. recommends use the standard electrodes with touch proof connectors. All electrodes used together with Biofeedback Trainer 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.

WARNING. The usage not certified electrodes can damage the system.

2.4. Antivirus software

The Biofeedback Trainer software can interfere with antivirus software. This can result in data loss during EEG recording and BFB training. The active scanning is not recommended.

CAUTION. Do not use antivirus scanning during biofeedback training.

2.5. 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 В
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 Biofeedback Trainer in correspondents to instructions presented in this manual below (see Chapter 5 and 6).

WARNING. Do not open Biofeedback Trainer cases if the system is connected to power source.

CAUTION. There are no parts inside the Biofeedback Trainer components which should be maintained by user except the batteries inside Amplifier Box.

2.6. Switching On

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

CAUTION. Switch on the system before connection the electrodes to patient.

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

2.7. Switching Off

CAUTION. Disconnect the electrodes from the patient before switching off the system.

Switch off the system before disconnecting it from power supply.

2.8. Leakage current

The Biofeedback Trainer conjointly with a line-supplied PC complies with the electrical safety requirements class I, type BF, standards IEC 60601-1:1988,1994, 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 values of leakage current of several systems before connection them to the patient.

2.9. Transportation.

Turn off the system before transportation.

2.10. Operation life

The operation life is limited by five years after installation. The keeping period should not be longer that one year after production and before installation.

2.11. Utilization.

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

3. Biofeedback Trainer technical data

3.1. Mitsar-BFB Amplifier Box

The Mitsar-BFB Amplifier Box complies in accordance with the requirements of technical specifications TU 9441-005-52118320-2005.

The Amplifier Box connector layout is presented on Figures 1 and 2.

1. Neutral electrode connector.
2. Channel 1 electrode connectors (yellow – plus, green – minus).
3. Channel 2 electrode connectors (yellow – plus, green – minus).
4. USB connector.
5. Channel 1 bad quality indicator (yellow LED).
6. Channel 2 bad quality indicator (yellow LED).
7. Power and low battery indicator (green LED).

Figure 1. Mitsar-BFB Amplifier Box connectors and indicators layout (front view).

8. Label.
9. Battery compartment cover.

Figure 2. Mitsar-BFB Amplifier Box (rear view).

3.1.1. Amplifier Box basic technical data

1. Weight of the Amplifier Box: 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 Box: 160 x 95 x 35 mm.
3. The Amplifier Box operates by computer system.
4. Amplifier Box is provided from internal power supply (four dry cells or storage batteries, type AA (R6), supply voltage: 3.0 to 6.5 V).
5. The Amplifier Box consumption current: not more than 0.07 A.
6. The Amplifier Box 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 Hz.
9. Number of channels: 2.
10. Input voltage range: 10 to 200 μV.
11. Irregularity of the frequency amplitude response not more than 10 % within the

designated frequency range: 4 – 20 Hz.

12. Electrical safety of the Amplifier Box complies with the requirements for instruments with internal power supply, type BF, standards IEC 60601-1:1988.
13. The Biofeedback Trainer complete with line-powered PC complies with the electrical safety requirements: class I, type BF, standards IEC 60601-1:1988 and IEC 60601-1-1:1992
14. Electromagnetic compatibility of the Biofeedback Trainer complies with requirements of standard IEC 60601-1-2:1993.
15. Working condition:

    temperature range: +10 to +35℃;

    moisture range: 25 to 95% (without condensation).

3.1.2. Amplifier Box simplified functional diagram

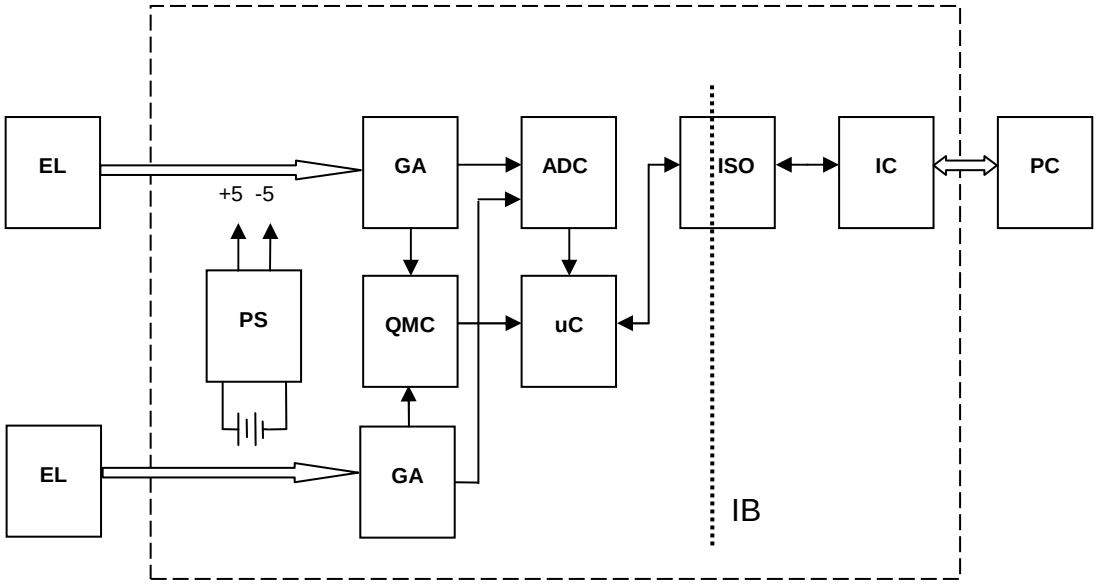


Figure 3. Amplifier Box simplified functional diagram

- (EL) – Electrodes
- (GA) – Gain Amplifier
- (QMC) – Quality Monitoring Circuit
- (ADC) – Analog-to-Digital Converter
- (ISO) – Electrical Isolation Circuit
- (uC) – Microcontroller
- (PS) – Power Supply
- (IC) – Interface Converter
- (IB) – Isolation Barrier
- (PC) – Personal Computer

3.1.3. Amplifier Box principle of operation

Electrodes avert the signal from the brain and direct it to the Gain Amplifier.

The signal in the Gain Amplifier increases up to the level concerted with the ADC measurement range and undergoes the analogue filtration.

Increased signal is moved to the ADC input which modifies the signal into the 12-digit code.

Quality Monitoring Circuit controls the gain amplifiers mode. It defines DC input and output levels and power-line noise, which indirectly characterize degree of quality of electrodes installation or their absence, and passes it to the controller.

ADC synchronization, data communication with the computer and quality of electrodes installation evaluation is provided by microprogram downloaded in microcontroller. Data are transferred to PC using standard USB-type interface through the electric isolation circuit and interface converter, which provides coordination of microcontroller and USB serial data link. ISO plays the part of isolation barrier and holds the voltage of 4 kV minimum.

Amplifier Box delivery is implemented by galvanic cells (internal power supply). Power Supply produces voltage necessary for the work of device.

Microprogram being executed in Amplifier Box microcontroller completes Amplifier Box switching on and off and reads the digital signal data. Also the microprogram reveals by using LEDs and notifies by sonic signals that electrodes were not installed correctly ore cells have low voltage level.

3.1.4. Safety measures

1. Regarding operation safety the Amplifier Box complies with the requirements of standard IEC 60601-1-92 as a device with internal BF type power source. The Biofeedback Trainer conjointly with a line-supplied PC complies with the electrical safety requirements class I, type BF, standards IEC 60601-1:1988, IEC 60601-1-1:1992.
2. General safety of the Biofeedback Trainer is provided by fulfillment of the requirements of standard IEC 60601-1-1:1992.
3. The Amplifier Box 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 Amplifier Box 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 5 m at least for removing the PC from a patient's environment.

WARNING. The personal computer (as a part of Biofeedback Trainer) must not be situated closer than 1.5 m from a patient.

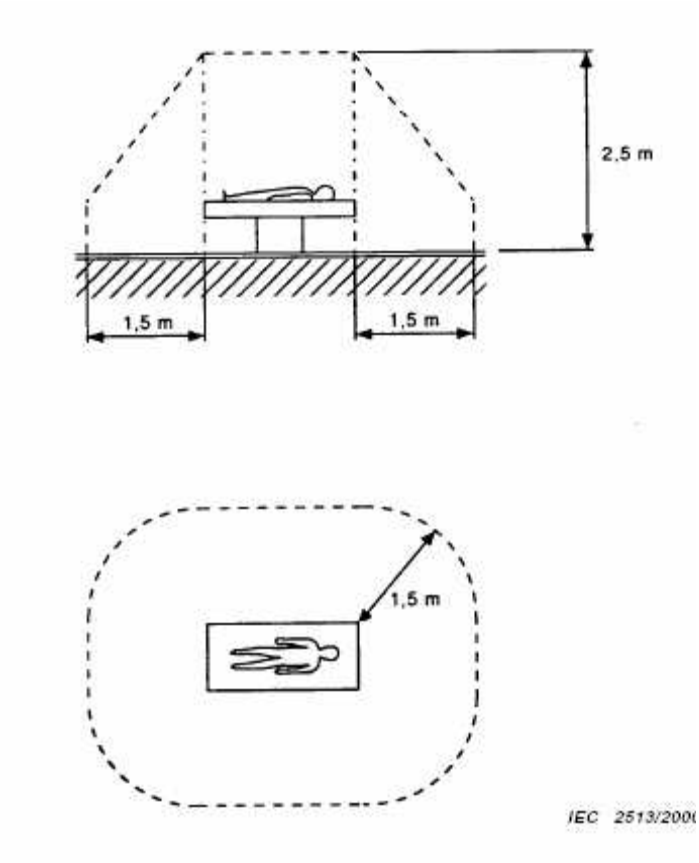


Figure 4. An example of patient environment

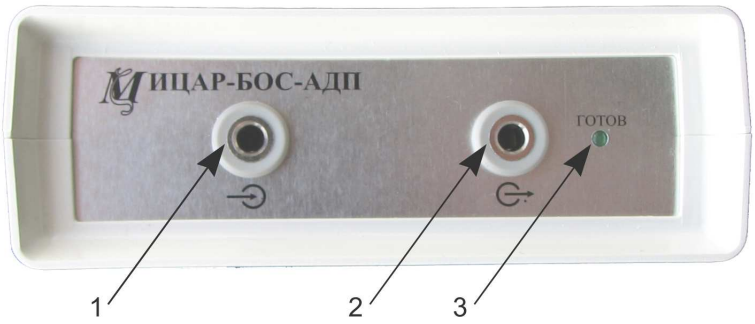
WARNING. PC, monitor, printer, TV set and video-player (as a part of Biofeedback Trainer) must be connected to power supply line only via socket equipped with ground contact.

8. Electric strength of the PC's insulation against power line must be not less than 1500 V.
9. The Amplifier Box has the decoupling device providing electric strength not less than 4 kV AC for computer connection circuits.
10. Only trained personnel familiar with safety regulations is allowed to operate the Biofeedback Trainer.

3.2. Mitsar-BFB Jammer

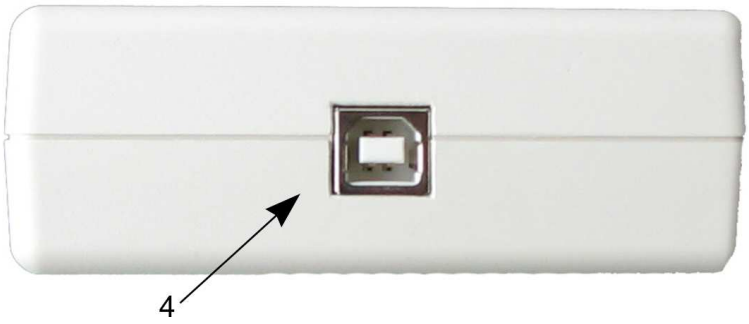
The Mitsar-BFB Jammer complies in accordance with the requirements of technical specifications TU 9441-005-52118320-2005.

The Jammer connector layout is presented on Figures 5 and 6.



1. Audio-Video input.
2. Audio-Video output.
3. Power indicator (green LED).

Figure 5. Mitsar-BFB Jammer connectors and indicators layout (front view).



4. USB connector

Figure 6. Mitsar-BFB Jammer connectors and indicators layout (rear view).

3.2.1. Jammer basic technical data

1. Weight of the Jammer: not more than 1 kg. Weight of the package without a computer and a printer: not more than 10 kg.
2. Dimensions of the Jammer: 160 x 95 x 35 mm
3. The Jammer operates by computer system.
4. The Jammer is provided from USB power supply (supply voltage: 5.0 V).
5. The Jammer consumption current: not more than 0.25 A.
6. Video channel technical data.

   field frequency: 50 Hz

   line length: 64 μs

   television system: PAL/SEKAM
7. Electrical safety of the Jammer complies with the requirements for instruments with

internal power supply, type BF, standards IEC 60601-1:1988.

8. The Biofeedback Trainer complete with line-powered PC complies with the electrical safety requirements: class I, type BF, standards IEC 60601-1:1988 and IEC 60601-1-1:1992
9. Electromagnetic compatibility of the Biofeedback Trainer complies with requirements of standard IEC 60601-1-2:1993.
10. Working condition:

    temperature range: +10 to +35℃;

    moisture range: 25 to 95% (without condensation).

3.2.2. Jammer simplified functional diagram

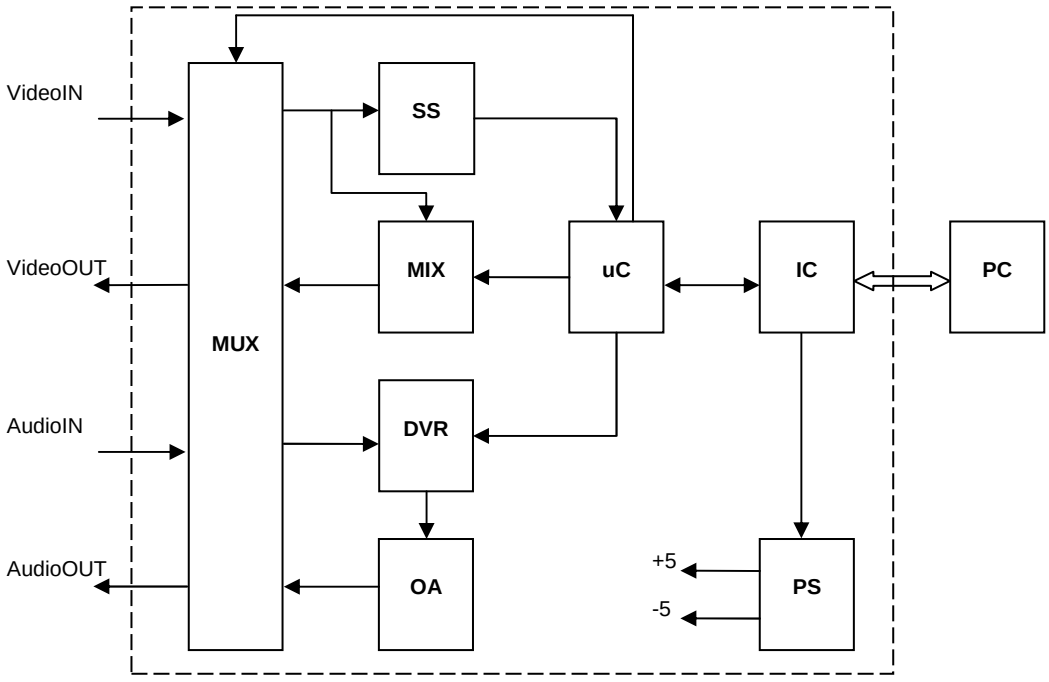


Figure 7. Jammer simplified functional diagram

- (MUX) – Multiplexer
- (SS) – Sync Selector
- (MIX) – Mixer
- (DVR) – Digital Volume Regulator
- (OA) – Output Amplifier
- (uC) – Microcontroller
- (IC) – Interface Converter
- (PS) – Power Supply.
- (PC) – Personal Computer

3.2.3 Jammer principle of operation

Video and audio signals enter the Multiplexer input which provides their through-passing to the output if the power supply voltage is off.

On Jammer duty video signal after the Multiplexer enters the Sync Selector which produces microcontroller-driving signals at the instants of field sync pulse and line sync pulse appearing.

Microcontroller generates disturbing signal similar to the input video signal. Video signal and disturbing signal relations depend on PC data came by serial interface.

Initial video signal and disturbing signal intermingle in the Mixer headed by the microcontroller and enter the Jammer output.

Audio signal after the Multiplexer enters the Digital Volume Regulator which lessens it depending on PC data came by serial interface. The regulator is headed by the microcontroller.

After the Digital Volume Regulator audio signal enters the Output Amplifier and hereafter the Output Connector.

Data are accepted from PC using the standard USB-type interface through the interface converter which provides coordination of microcontroller and USB serial data link.

Jammer delivery is implemented by DC Voltage 5V through the USB interface.

3.3. 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 Biofeedback Trainer system 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 Biofeedback Trainer'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. Place the Amplifiers Box on the table next to the examinee or on another appropriate surface. 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 Amplifier Box to the computer.

   The Amplifier Box 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 Box connector.

   The connector at the Amplifier Box'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. Switch on the computer and install the Amplifier Box driver. Methods of driver installation and use of the software are given in Chapter 6 of this manual.

8. Выключите компьютер.
9. Connecting the Jammer to the computer.

   The Jammer 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 Jammer connector.

   The connector at the Jammer'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

WARNING. The Mitsar-BFB Jammer must not be situated closer than 1.5 m from a patient.

10. Connecting the Jammer to the TV-set and video-player.

    The Jammer connected to the TV-set and video-player via special cables. Detailed instructions on connecting are contained in Chapter 4.

    The connector at the Jammer'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 TV's and video-player's connectors see theirs user's manual

11. Switch on the computer and install the Jammer driver. Methods of driver installation and use of the software are given in Chapter 6 of this manual.
12. 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.

3.4. 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. Neutral ("ground") input connectors.

For successful BFB training you must use neutral electrode. Connector for this electrode is 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.

3. BFB training features.

The main reason of unsatisfactory operation of the Biofeedback Trainer may lie in sporadic line 50(60) Hz interferences or high frequency interferences. In some cases when the electrodes were not installed appropriately the Amplifier Box generates noise-like sound using built-in speaker and indicates using yellow LEDs channels with inappropriate quality

of the electrodes installation. 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	The Amplifier Box is installed too close to computer's monitor.	Yes	
3	The Amplifier Box connecting cable runs right against the computer's monitor.	Yes	
4	There is powerful electric equipment in the neighborhood of the training room which generates strong noise (X-ray installations, physiotherapy equipment, etc.).		Yes
5	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
6	The Amplifier Box is placed right against the wall under which electric lines or cables are run	Yes	
7	The Amplifier Box 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
8	There is a cable line with defective or ungrounded screen (TV, computer network, etc.) in the wall.	Yes	Yes

9	There is a sparkling electric switch, defective fluorescent lamp(s) or such lamp(s) with a defective starter.		Yes
10	There is a working engine source closely outside the building.		Yes
11	Domestic electric appliances (microwave oven, coffee grinder, etc.) are on at the time of examination.		Yes
12	Cellular or radio telephone is used at the time of exploration.		Yes

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.

4. 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-MH accumulators from well-known manufacturers.

3.5. 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.

CAUTION. Do not autoclave any parts of Biofeedback Trainer.

CAUTION. 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.

3.6. Indicators

On the Amplifier Box faceplate three LED indicators are situated: two of the yellow color and one of the green.

Green LED (Fig. 1, pos. 7) flashes on when the Amplifier Box is being switched on. Even glow corresponds normal functioning. When cells de-energize and it is necessary to change them, the indicator starts blinking approximately a cycle per 4 seconds. It is attended with discontinuous sonic signal.

Yellow LEDs (Fig. 1, pos. 5, 6) flash on if the electrodes in the channel next to the appropriate indicator are not installed correctly for the normal functioning. Quality control is carried out only for the channels which were chosen for the current training in Brain Tuner (see documentation of this program). E.g., if we use for the training the first channel only, bad quality of electrodes installation in the second channel would not be controlled and indicated. The glow of the electrodes installation quality is attended by continuous noise-like sonic signal and additional indication in the Brain Tuner program (see documentation of this program).

NOTE. Neutral electrode relates to both channels. If it is installed inappropriately, the indicators of all channels chosen for training would flash on.

On the Jammer faceplate the green LED is situated (Fig. 2, pos. 3). Its glow marks that the Jammer is ready for work.

4. Biofeedback Trainer connection diagrams

There are the connection diagrams for the typical Biofeedback Trainer configuration.

4.1. BFB-training with computer

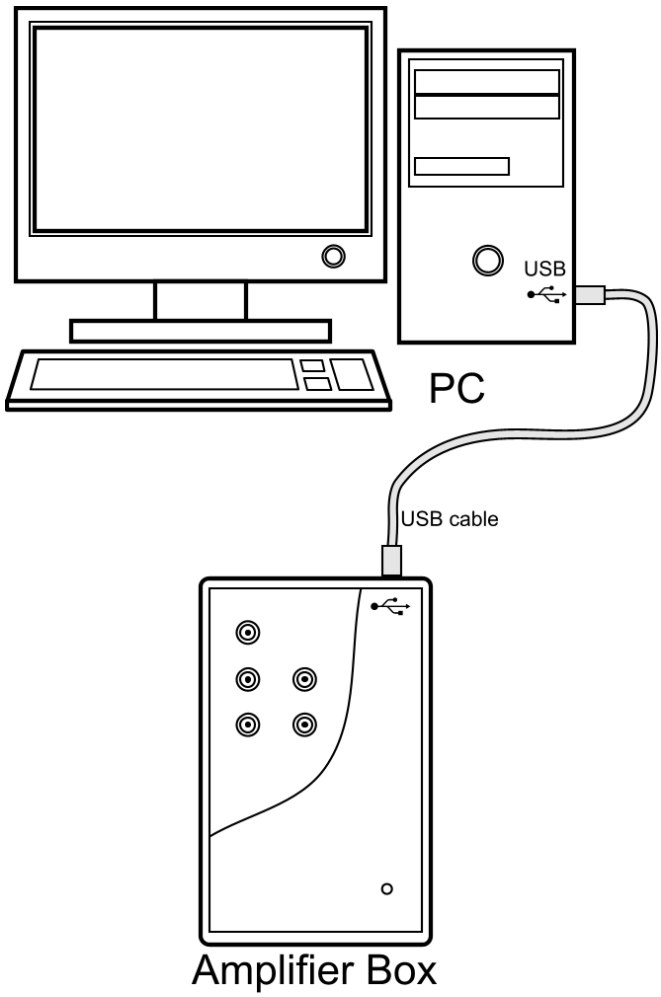


Figure 8. The connection diagram for BFB training with computer.

WARNING. The personal computer must not be situated closer than 1.5 m from a patient.

4.2. BFB-training with computer and Jammer

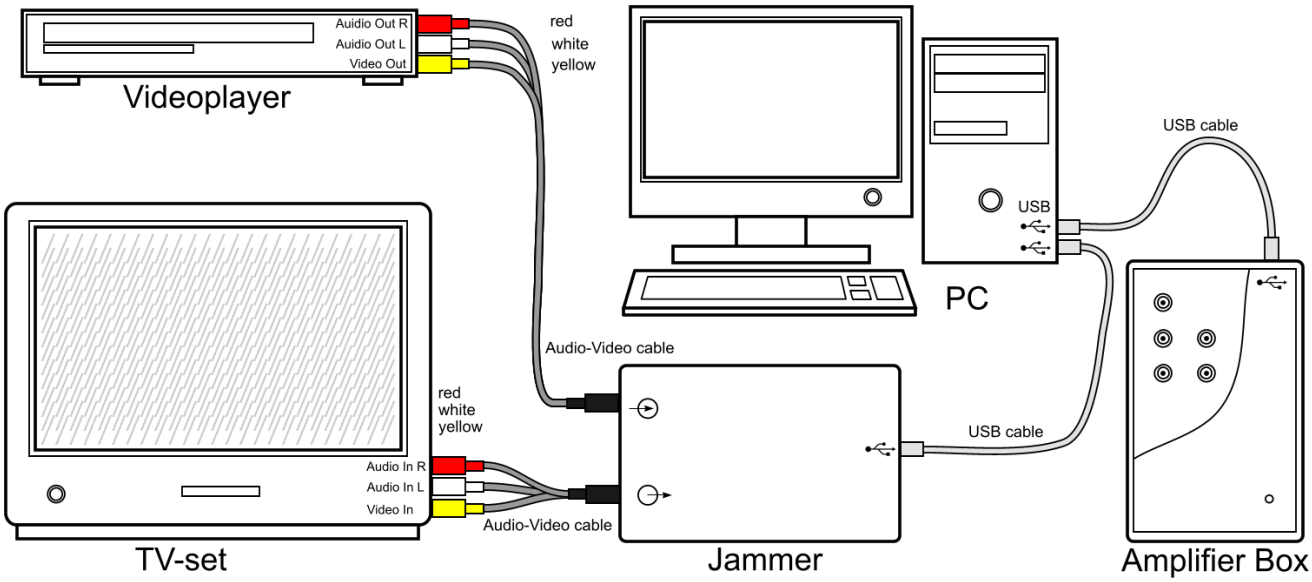


Figure 9. The connection diagram for BFB training with computer and Jammer.

WARNING. The personal computer, Jammer, TV-set and video-player must not be situated closer than 1.5 m from a patient.

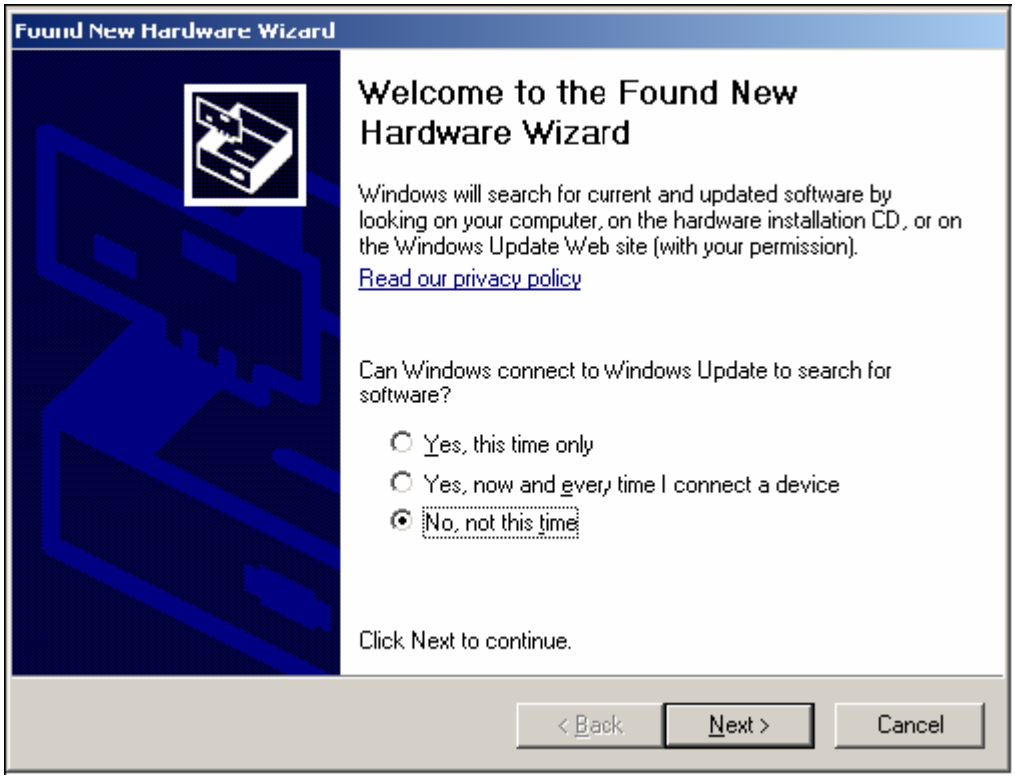
5. Biofeedback Trainer drivers installation

5.1. Amplifier Box driver installation

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

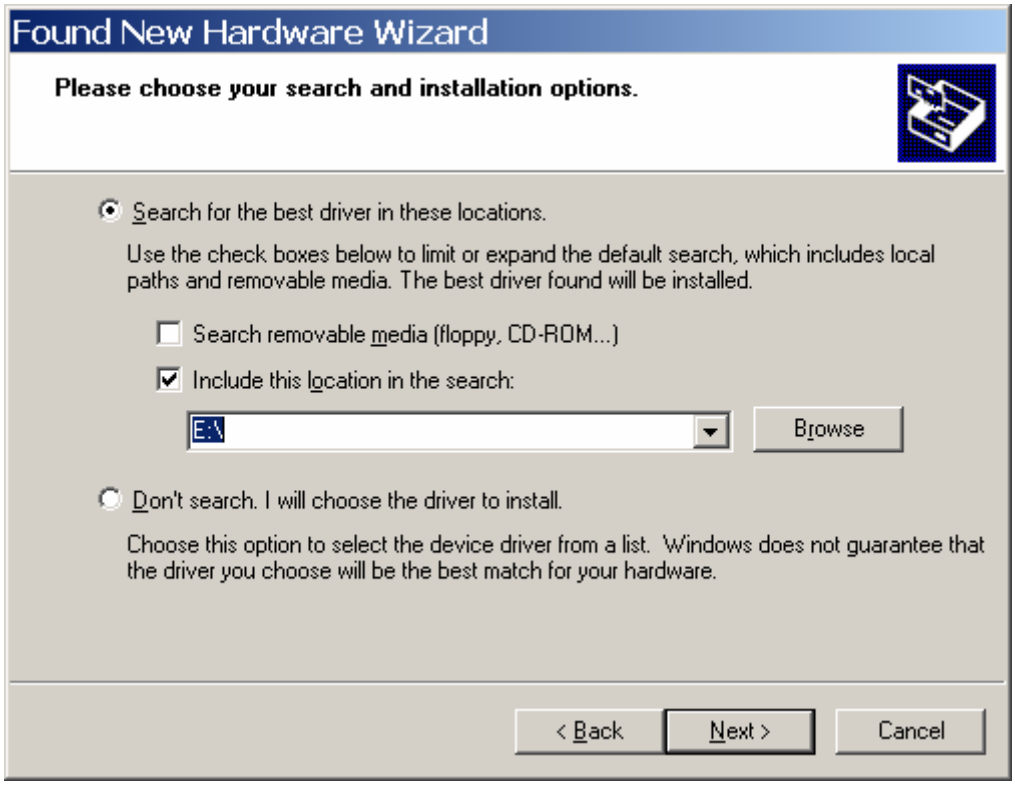
Driver installation is standard procedure performed by Windows XP. To install driver user should perform a number of standard steps listed below.

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.

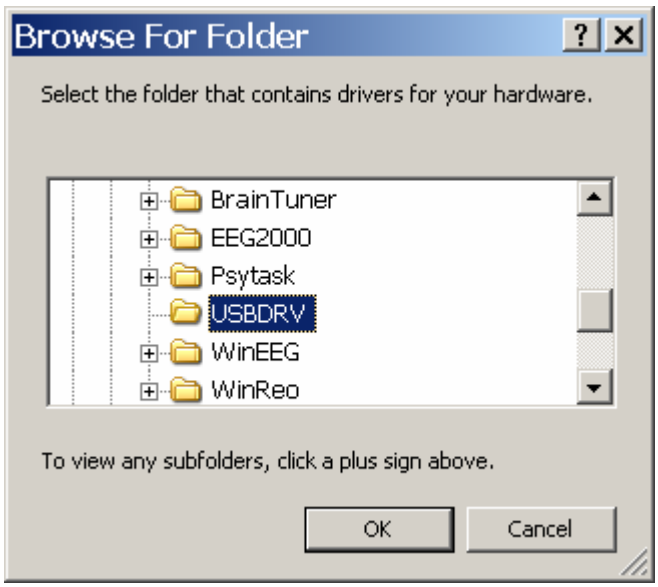


3. Select ***No, not this time*** and then click the ***Next*** button

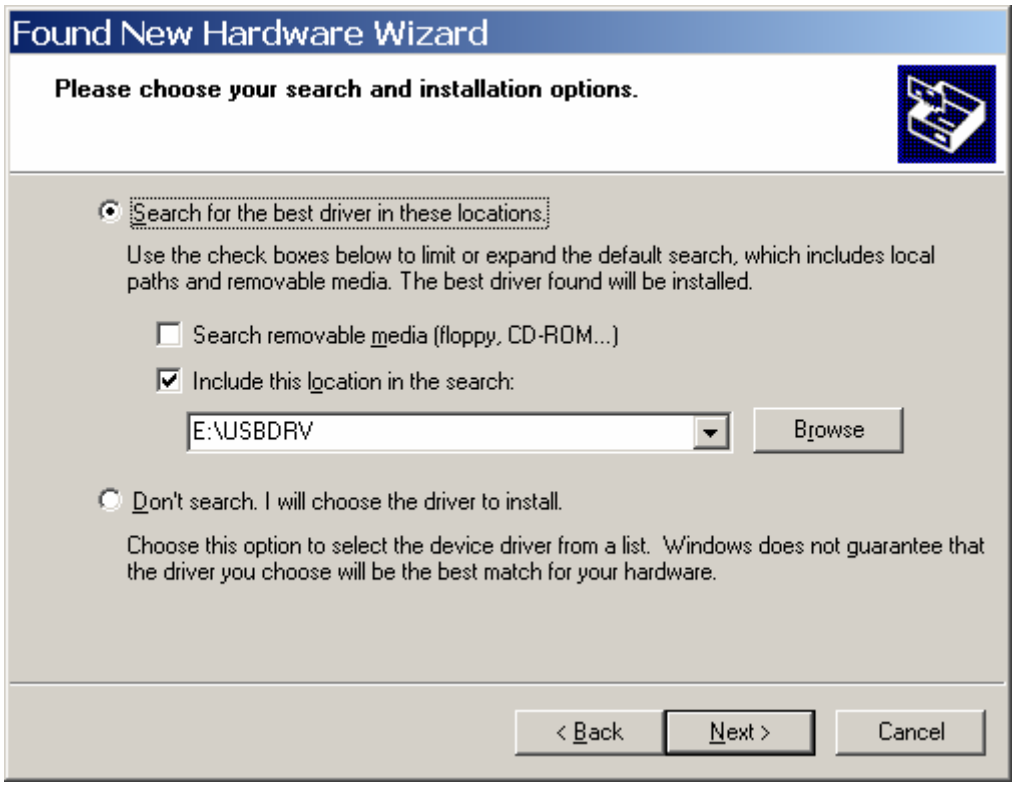
4. Select ***Install from a list or specific location (Advanced)*** and then click the ***Next*** button.



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.

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

5.2. Jammer driver installation

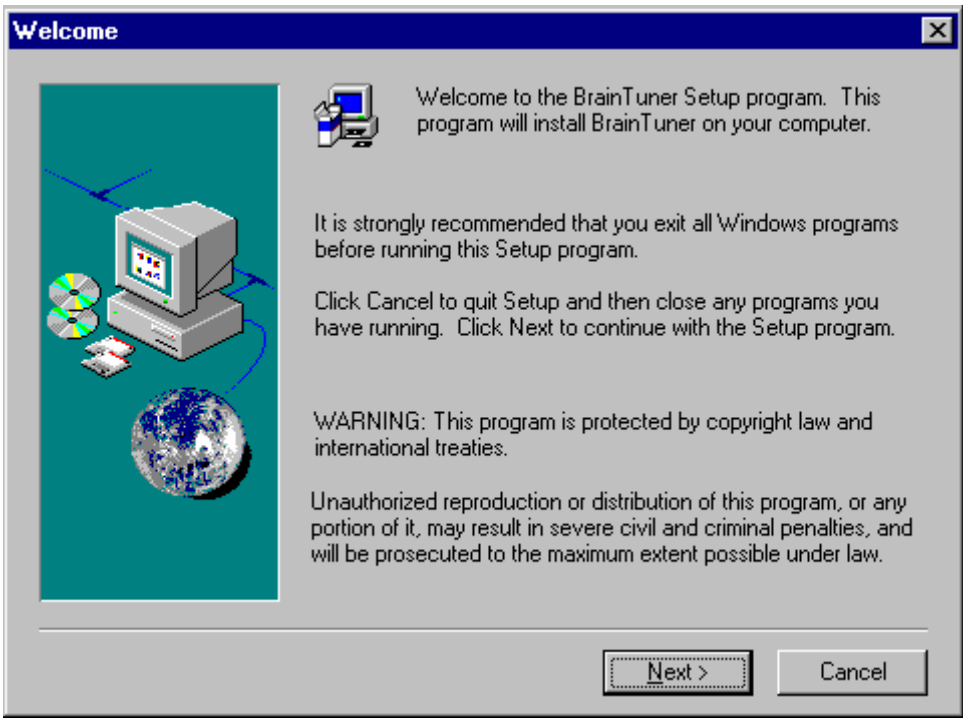
Jammer driver installation is executed in the same way.

CAUTION. Before the Jammer connecting and its drivers installing it is necessary to complete Amplifier Box connecting and its drivers installing.

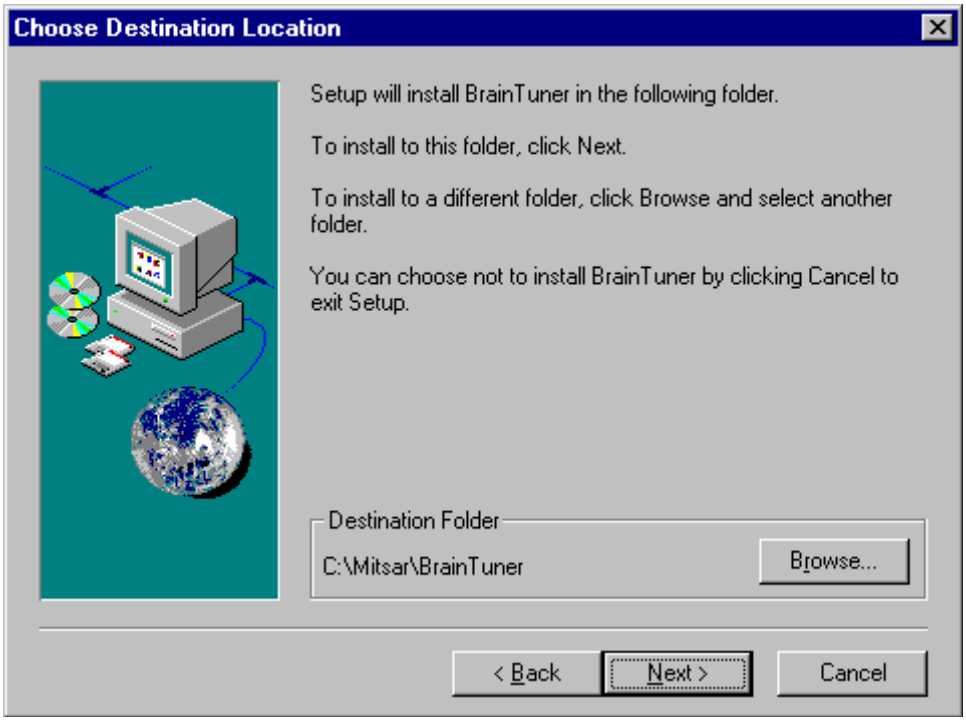
6. Brain Tuner software installation

To install BrainTuner program:

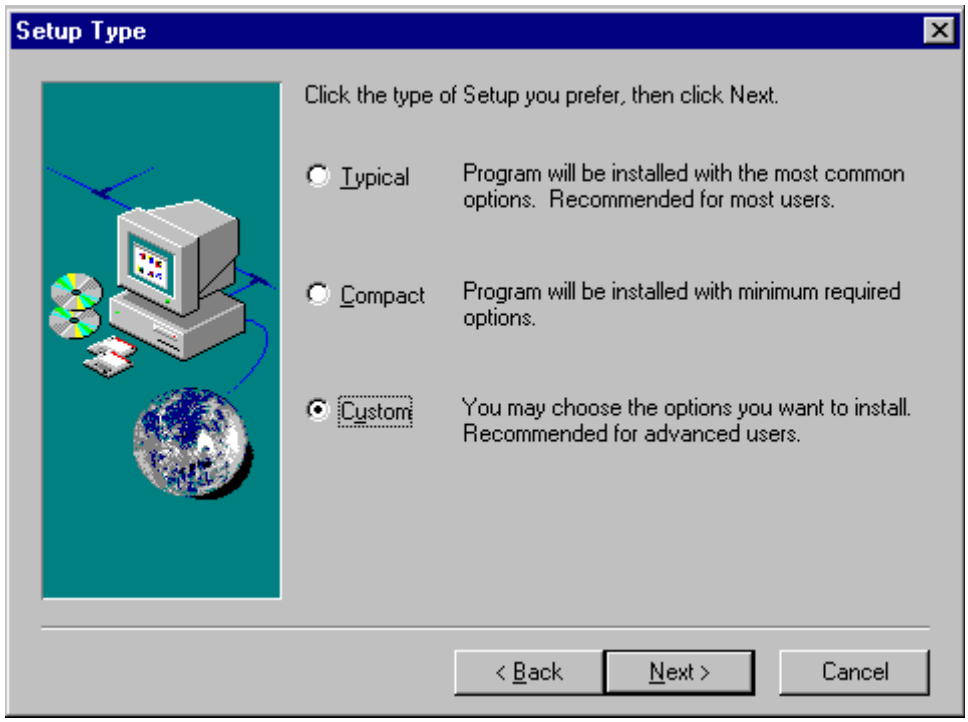
1. Insert the CD to the corresponding drive
2. Open folder with name “BrainTuner” (“BrainTunerE”).
3. Run SETUP.EXE program.
4. Follow the instruction on the screen



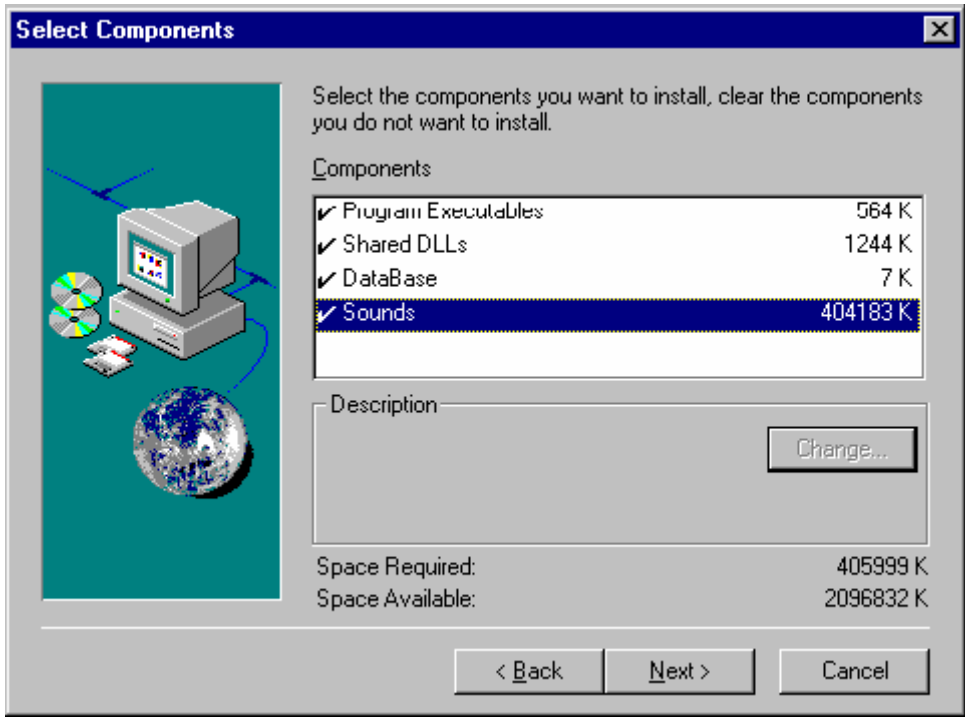
Press ***Next*** button to continue installation.



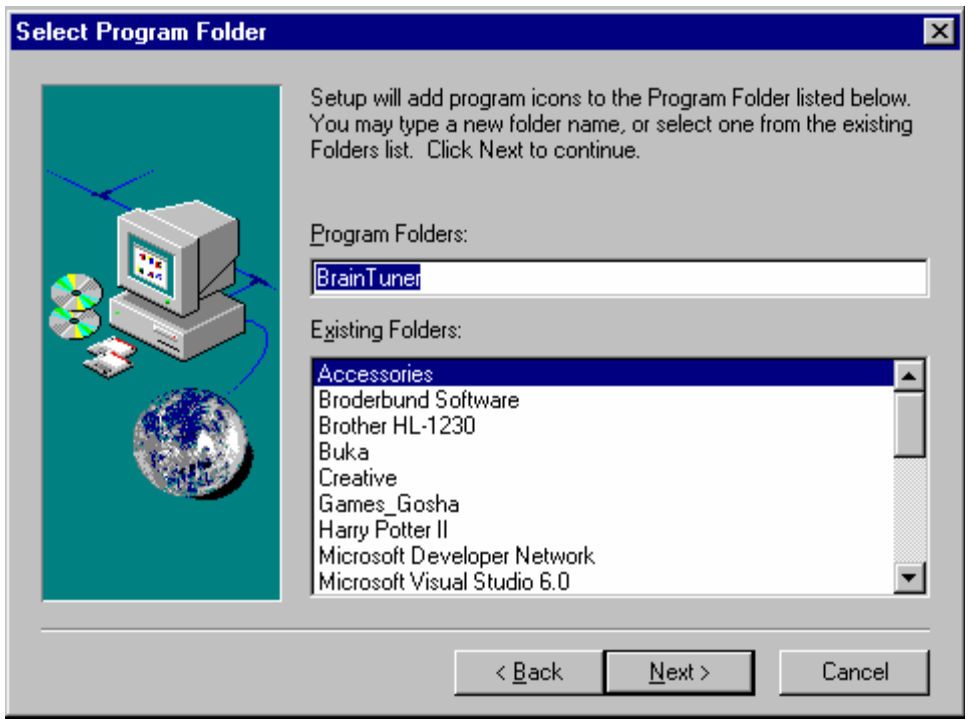
Press ***Browse…*** button if you would like to change location BrainTuner program. Press ***Next*** button to continue installation.



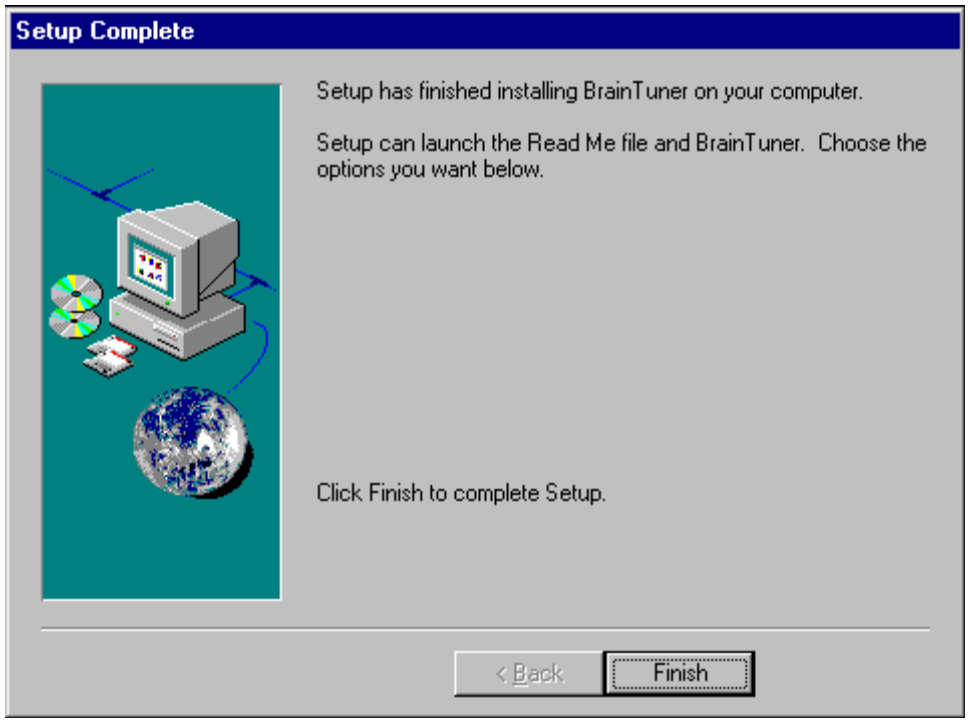
Select type of Setup you prefer. Press ***Next*** button to continue installation.



Select components you want to install. Don't install ***Sounds*** component if you don't plan to use auditory biofeedback. 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.

After finishing of Setup you need to run BrainTune program and set correctly the I/O ports using Setup: Equipment parameters command.

If you plan to use auditory biofeedback you need to set parameters of volume control using Setup: Biofeedback parameters command.

7. Deed of commission

Biofeedback trainer “Mitsar-BFB” including:

The Amplifier Box “Mitsar-BFB”, serial # _____, found to be ready for operation.

The Jammer “Mitsar-BFB”, serial # _____, found to be ready for operation.

Manufactured on _____

Mitsar Co.Ltd._____

(date, signature, seal)

8. Data on installation and assignment to operation

Biofeedback Trainer "Mitsar-BFB" serial # _____, have been installed and commissioned.

Date of installaton: _____

Signature Position Name

«MITSAR» CO.LTD.

WARRANTY COUPON # 1

for repair / replacement within the warranty period

Biofeedback trainer "Mitsar-BFB", 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

Biofeedback trainer "Mitsar-BFB", 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: