I. WORKING with the DEVICE to TREAT VARIOUS KINDS of VISUAL DISFUNCTIONS.

1. GENERAL PART

AMBLYOCOR is a variety of articles of equipment created on an entirely new approach which is intended to improve and stabilize various cases of visual acuity loss. A course of treatment may consist of 15-25 half–hour sessions.

AMBLYOTRON device. Common View

1.Indications for use:

- Restoration of visual acuity in all forms of ametropia: myopia, hypermetropia and astigmatism. The equipment is highly effective for severe cases of ametropia in children.
- Treatment of all forms of amblyopia: - disbinocular, anisometropical, refractive, and obscurational. Strabismus and nystagmus caused by, or linked with, Ambylopia (irrespective of age or severity of condition).
- Rehabilitation of patients suffering from organic forms of ophthalmic pathology, such as glaucoma or Retinal and Optic Nerve dystrophies. To maintain an optimum possible visual function with respect to any prevailing level of ophthalmic pathology.
- In treatment of Hypermetropia of the elderly, caused by Presbyopia, this new approach reduces the rate of visual acuity-loss due to aging, and keeps the prevailing function optimal.
- To stabilize and improve reduced visual function post Accommodation Spasm accompanied by headaches / migraines, aesthenopia, poor work concentration etc/.
- Prophylactic treatment for patients to avoid developing ophthalmic dysfunctions (in work that demand prolonged visual stress / effort such as long periods of Computer use) with short repeated courses of treatment.
- Post Refractive Surgery states where the results have been less successful and require lengthy post-operative Adaptation with imbalance between True (Potential) Visual Acuity and post-operational refraction, etc).

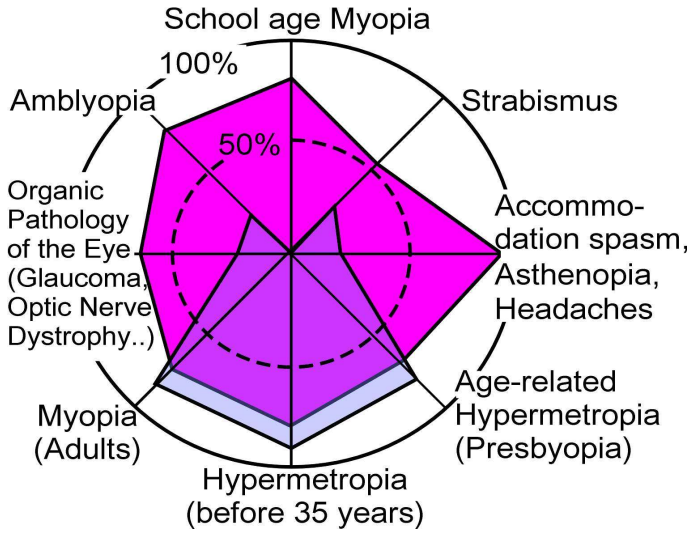


Fig. 28. The Diagram shows comparative effects of "Amblyocor" and Laser Surgery (PRK or Lasik) restoring visual acuity in different pathologies.
The effectiveness is expressed in % showing the amount of patients with improved eyesight.
"Amblyocor" Results are shown in red, Laser Surgery in blue.
Clearly, the new non-surgical approach is extremely advantageous for widespread pathologies, especially in children.

2. TYPICAL RESULTS

2.1. IN AMBLYOPIA: For refractive and anisometric forms a complete Reversal of Diagnosis in 92% of patients after one or two courses of treatment by a criterion of achieving an improvement of visual acuity in the amblyopic eye up to 20/80.

A 60% effect in treatment for disbinocular amblyopy. In 50% of patients the binocular vision is restored after 1-2 courses of treatment.

In other patients (peripheral fixation) the disease can be reduced to a considerably milder form. About 50% of patients suffering from obscurational amblyopy achieve a visual acuity of 20/80 – 20/30 without glasses.

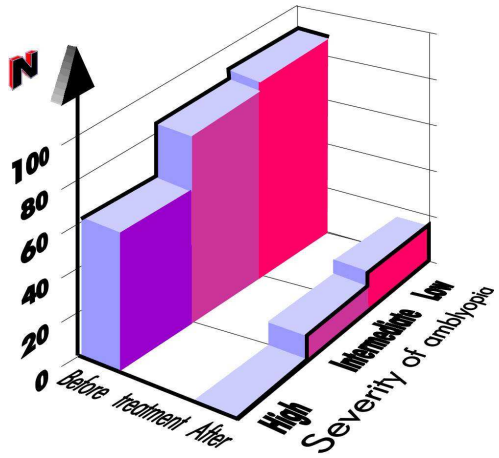
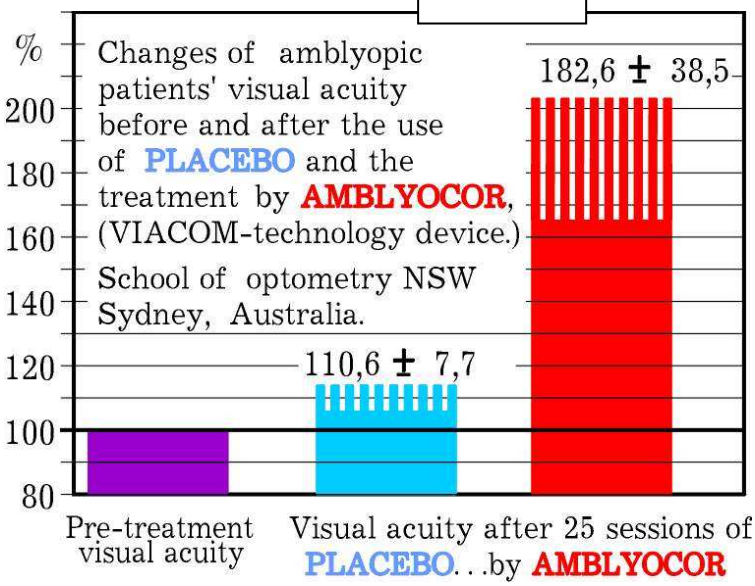


Fig. 29. After 2 – 3 courses of treatment the number of amblyopic patients is reduced by 92% (N=240).

Fig. 30.



80% of strabismus-affected patients can achieve either partial or full reduction of the squint angle or eliminate it altogether. Normally operations can be avoided in cases like these.

70% of nystagmus patients can enjoy suppression of symptoms after 1-2 courses of treatment. The treatment is especially efficient for spasmodic or mixed forms of the pathology.

2.2. **MYOPIA**

90% of myopic patients can improve their visual acuity by 2-4 gradations of the test table. Below is a table showing the results of the treatment by the device on 630 patients from Orenburg, Izhevsk, S.Petersburg and Vologda.

Low severity (N=315)		Medium severity (N=166)		High severity (N=149)	
VIS before	VIS after	VIS before	VIS after	VIS before	VIS after
20/110	**20/24**	**20/180**	**20/45**	**20/450**	**20/70**

The majority of the patients suffering from medium and low level myopia no longer need glasses. Severe cases achieve a far-sight optical correction by reducing it by 3-4 diopters.

2.3. 90% of the **FARSIGHTED** patients, as well as those with hypermetropic astigmatism, improve as the result of the treatment, especially at close distances.

The average improvement of visual acuity rises by 3-4 gradations of the test-table.

For age-caused farsightedness, in presbyopia, a patient should take yearly repetitions of the course to maintain the achieved level.

3. DESCRIPTION OF THE METHOD

A new approach implemented by “Amblyocor” and other devices of this type is called ‘**VISUAL ACUITY COGNITIVE MODULATION’**, (or “VIACOM” for short). It is based on a conditioned-reflex biofeedback procedure capable of restoring control over cortexl visual analytic processes.

To introduce the authors’ view of the physiological mechanisms involved in the method, it is necessary to consider the pathogenesis of visual acuity dysfunctions.

With amblyopia and strabismus[1] the neurons of the brain functionally and anatomically connected to the amblyopic eye are under considerable inhibitory neuron influence from the dominant eye. This pathogenetic mechanism evolves from the onthogenesis, at the time a child of 2-3 is forming his\her binocular function.

If one eye is to some degree different from the other (optical defect, bad angle between optical axes, retinal pathology, etc.) the binocular vision being formed is poorer than the one-eye vision. This is the factor that causes inhibitory neuronal suppression of the amblyopic (poorer) eye's visual perception.

In consequence, the brain loses control over the functions of the amblyopic eye leading to an even greater degradation of the visual function and progressive strabismus.

All the previous methods of treatment aim at the brain's ability to restore control over the amblyopic eye's visual functions. The most usual technique is patching the dominant eye. In this situation the brain is "forced" to provide visual identification using the open amblyopic eye.

If the patching treatment had started before the patient was 7-8 years old, this may help to about 50% of patients.

There is a group of methods though, which make use of various types of visual stimuli potentially capable of counteracting deep inhibition of neurons connected to the amblyopic eye (light therapy, laser stimulation). Clinical efficiency of these methods is, on the average, about 50-65%.

However, when the VIACOM-technology is applied, Ivan Pavlov's classical pattern of forming an instrumental conditioned reflex is at work.

Natural fluctuations of the brain's visual cortex neuronal excitability comprise a conditioned component manifested through the patient's mathematically analyzed EEG. These fluctuations of excitability are neither conscious nor neurophysiologically essential, being just a manifestation of endogenous neuronal processes of the visual cortex.

A motivation to watch an exciting movie or a denial of such, would definitely comprise a stimulus of this kind.

The VIACOM-technology makes possible an association between a conditioned element, the phase of higher excitability of neurons responsible for the amblyopic eye, and the unconditioned one, a positively stimulating component such as an opportunity of watching an attention holding film.

Conversely, a relatively unfavorable visual cortex neuron excitability level (in the phase of lowered excitability) is associated with an unconditioned negatively motivating stimulus, turning off the TV screen.

[1] One must distinguish between a congenital strabismus or a later acquired form through the disruption of the balance between the Oculomotor muscles (through infections, traumas, etc.) and the strabismus caused by the brain's loss of control over Oculomotor function, (Amblyopia).

As a result of this conditioned reflex biofeedback procedure these formerly neutral manifestations of the visual cortex neuronal activity, get connected to the motivational (meaningful) stimulus. This leads to the initiation of forming a new recurringly stable system of reflex connections ensuring a fuller reinforcement of the motivation.

The biofeedback procedure is performed with the dominant eye closed; hence the fluctuations of the visual cortex neuron excitability level, manifested through the EEG-analysis reflect the fluctuations of the afferent current\stream from the amblyopic eye. Consequently, the newly formed reflex mechanisms are, in the first place, directed towards the neuron activity directed to the amblyopic eye. Every spontaneous rise of the excitability level formerly unsupported due to its neutrality is now synchronized with a positive unconditioned stimulus during the biofeedback auto-training. A progressively amplifying conditioned-reflex mechanism results in higher-conditioned excitability phases (beyond any possible random excitability of visual cortex neurons) and these become dominant.

Gradually, with the VIACOM-technology achieving dominance, a growing part of the amblyopic eye afferentation overcomes the inhibition threshold, reaching the visual cortex and becoming a permanent component of its activity.

This leads to overcoming the inhibitory pathogenic pattern in amblyopia and to the patient's Remedial benefit and cure.

An important pathogenic factor in developing any form of ametropia is a fixed change in the parameters of the visual cortex neuron receptor fields, hence, a change in the mode of the interaction between them. This largely determines the quality of the visual perception (visual acuity, contrast, etc.).

For instance, in myopia, if one attempts to look into distance, the absence of focussing on the retina creates a constant excitement of the accommodation reflex chain. This gradually turns a normal reflex mechanism into a pathological factor. The spread of excitment inevitably leads to enlarging the summation-zone of the visual cortex neuron receptor fields.

It is for this reason that in progressive myopia the neuropathologic interaction involves not only the corresponding neuron groups but also those neurons which possess different projection and direction-orientative features.

This results in a greater deterioration of the visual function in addition to a pre-existing optical defect. This is why the VIACOM-technology (for myopic forms of ametropia) aims at reducing the excitability of the visual cortex neurons.

For hypermetropia a basic symptom is an insufficient degree of accommodation believed to be caused by the lack of activating influence of the brain's visual system on the cilliary (accommodation) mechanism.

That is why in hypermetropic cases the VIACOM-technology aims at raising the level of activating processes of the brain's visual system.

It has been mentioned above that amblyopy is accompanied by the enhancing of the inhibitory influence on the brain systems connected to the amblyopic eye. In this, a shrink of the receptive fields of the amblyopic eye neurons leading to a drastic reduction of their summation zone is observed. In consequence the fusion reflex is disturbed and, due to the lack of the feedback contour, also is the brain's ability to control eye movements.

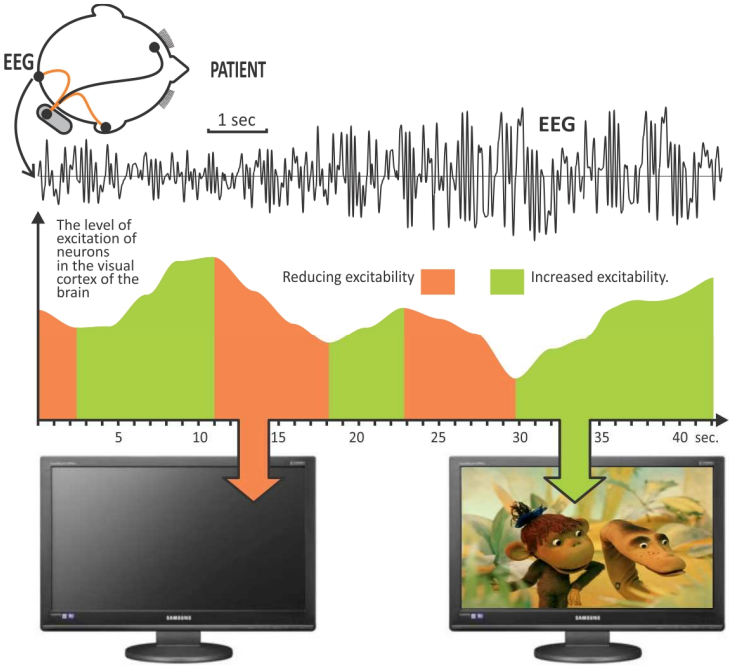
Strabismus is the result of these processes (disbinocular and refraction amblyopy). This is why to restore the visual function in amblyopia, the visual analysis neuron activity oriented towards the amblyopic eye is initiated.

A physiological basis of the therapeutic effect is a relative normalization of the receptive properties of the visual cortex neurons and the elimination of pathologic neurogenic factors left unattended to by ophtalmologists in their application of the conventional methods of treatment.

4. THE WAY THE EQUIPMENT WORKS

The method of treatment is a non-invasive one; it is a biofeedback procedure. A patient is placed in front of a TV set whose screen is showing a movie. The patient has his\her electroencephalogram (EEG) registered over the brain visual cortex projection. The EEG-amplifier signal is transmitted into a computer to analyze the brain bio-currents in real time. The computer is continuously calculating the value of the visual cortex neurons' summarized activity according to the EEG parameters and identifies the phases of their greater or lesser activity. Depending on the phase of the brain cortex neuron fluctuation activity the computer controls the turning of the TV screen on or off. Thus, a possibility of watching a movies or the absence of such a possibility wholly depends on the patient's brain visual cortex quality of work. In the course of daily repetitions of this procedure (usually it is 20 half-hour sessions) the patient's brain is gradually forming new reflex connections providing a higher level of visual functions owing to a stable increase (at hypermetropy) or decrease (at myopy) of the visual cortex neuron excitability and the optimization of their receptive field parameters.

The distinctive feature of "VIACOM"- technology is the achievement of a high and stable benefit in a comparatively short period of time. The patient is not required to perform great effort of self-motivation (will) since a conscious process does not bind the conditioned-reflex methods of influence; they generate positive/pleasurable emotions.



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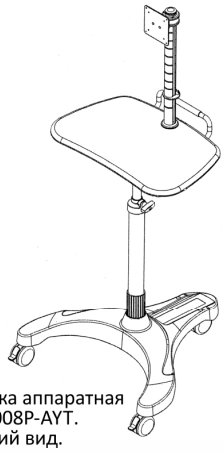
The electroencephalogram (EEG) registers via an occipital electrode attached to the patient.

The fluctuations of the brain visual cortex neurons are calculated during analysis of the EEG

The TV screen is live or blank depending on the fluctuations of the patient's visual cortex neuron excitability.

ПРИЛОЖЕНИЕ 2

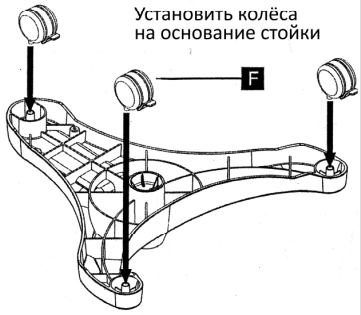
ИНСТРУКЦИЯ СБОРКИ СТОЙКИ АППАРАТНОЙ LPD008P-AYT



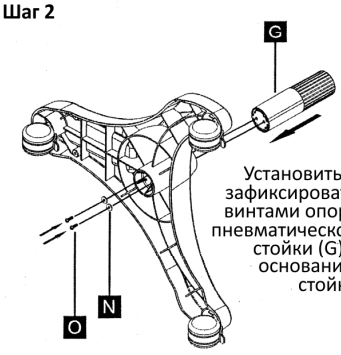
Стойка аппаратная LPD008P-AYT. Общий вид.

Шаг 1

Установить колёса на основание стойки

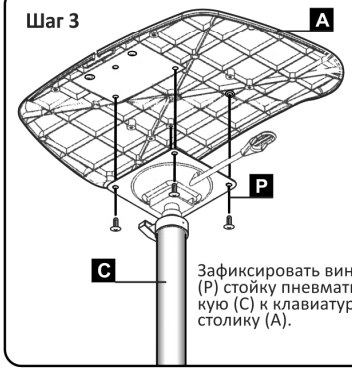


Шаг 2



Установить и зафиксировать винтами опору пневматической стойки (G) к основанию стойки

Шаг 3

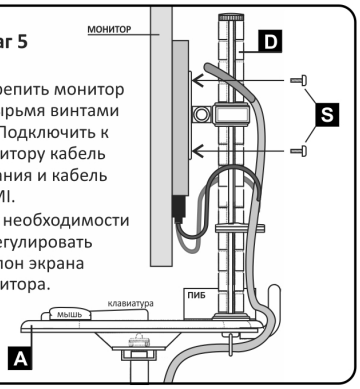


Зафиксировать винтами (P) стойку пневматическую (C) к клавиатурному столику (A).

Шаг 4

Продеть стойку монитора (D) в сборе с фиксатором монитора (M) через петлю кабеля, установить основанием на клавиатурный столик (A) и зафиксировать винтом (Q) в сборе с шайбой (J) и скобой (I) - показано стрелкой.

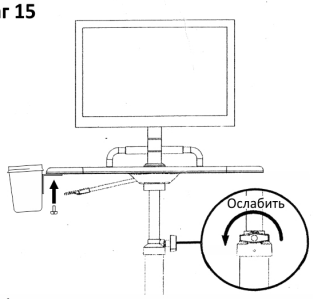
Шаг 5



Закрепить монитор четырьмя винтами (S). Подключить к монитору кабель питания и кабель HDMI.

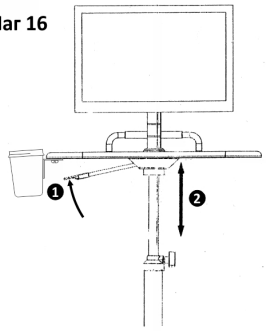
При необходимости отрегулировать наклон экрана монитора.

Шаг 15



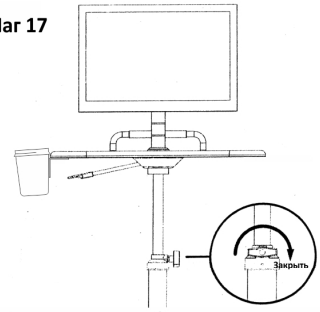
Зафиксировать корзину для принадлежностей одним винтом. Ослабить фиксатор пневматической стойки

Шаг 16



Нажав вверх и удерживая рычаг (1), отрегулировать высоту стойки (2)

Шаг 17



Зафиксировать выбранное положение стойки винтом, повернув его по часовой стрелки до упора

Вид сзади

Комплект кабелей «свернут» в кольцо, которое насаживают на стойку D, далее, его укладывают вдоль центральной опоры монтажной стойки и фиксируют с помощью прилагаемых пластиковых стяжек.

Гнездо для подключения наушников находится на боковой левой панели компьютерно-интерфейсного блока «Амблиотрон». При подключении наушников звук встроенных в монитор динамиков будет блокирован. Прибор комплектуется наушниками, фиксаторы которых устанавливаются на ушных раковинах. Это делает более удобным установку ушного (клипсы) ЭЭГ электрода.

Пред включением прибора в электрическую сеть:

1 Убедитесь в правильном и качественном подключении всех кабелей;

2. Убедитесь в наличии заземляющего контакта в сетевой розетке.

Прибор «Амблиотрон» приводится в рабочее состояние включением сетевых кнопок на сетевом фильтре и, далее, на верхней панели ПИБ и на мониторе. После их нажатия программа загружается в течение одной минуты и прибор «Амблиотрон» готов к работе.

Подключите кабель усилительного ЭЭГ-модуля к разъёму на передней стенке соединительного блока (под столиком). При этом должен включиться световой индикатор на усилителе.

Установка электродов на голове пациента описана на стр. 14-15.

III. WORKING with the PROGRAM "AMBLYOCOR"

Fig. 6

In contrast to the previous version of the software controlled by the DOS the new equipment and program are controlled by the operational system (OC) Windows9x/2000. Thus, to work effectively with the program one is supposed to possess some skills of operating the latter OC and of using the mouse as the basic device of controlling the program.

If the manufacturer supplies the device, the AMBLYOCOR program is launched automatically, simultaneously with the computer turned on. Its splash-screen on the monitor indicates that the program has been launched (Fig. 6).

1. INTRODUCTION OF THE INFORMATION ABOUT THE PATIENT INTO DATABASE.

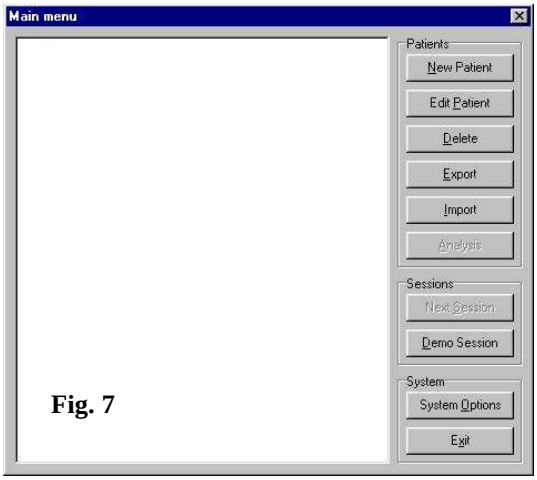


Fig. 7

Click the left button on the mouse to be followed by the Main Menu of the program (Fig.7).

Working starts with the introduction of the information about the patient. To do these click the button NEW PATIENT. A window to introduce the patient's name will appear (Fig.8). Introduce the patient's name (code) under the NAME from the keyboard. Under NOTES you can record additional information about the patient.

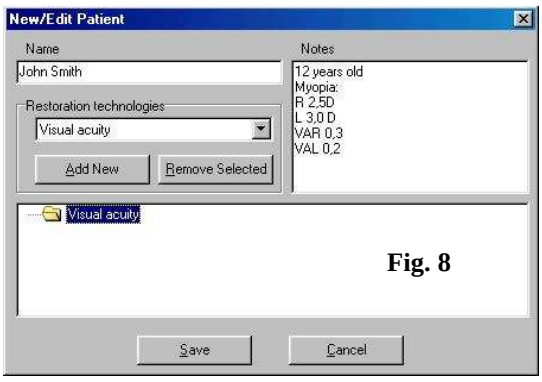


Fig. 8

To complete this phase of work press button Save**.**

It will bring the **MAIN MENU** with the picture of the file and the patient's name (Fig.9). Sign "+" before the patient's name means that the program has been set.

You can introduce some additional information into the "Notes" by using the option "Edit Patient".

Fig. 9

2. SETTING PARAMETERS IN THE ACTIVE WINDOW “VISUAL ACUITY”

To begin work one has to click the mouse on the patient’s name (or on “+“ sign). This will bring the name of the program «Visual Acuity» one is going to work with. Click the mouse on the program name (highlight it) and then press button «Next Session». This will open the program’s working window whose upper part is shown at Fig.10.

Fig. 10

Here follows the description of the functions of the buttons and of the menu.

2.1 The left part contains six buttons: Setup,Stop,Eye exam, Mode, Setup and Main Menu.

The window “Current Eye and Mode” shows information about an eye which is to watch the film (for the side and the mode of work, see below)

The window “T Work” shows the time of work. Below are two buttons with arrows to set up the time of work.

The window “Time Left” shows the time left until the end of the session.

The window “resistance” on the right shows the figures for electric resistance between the EEG-electrodes on the patient’s head. Below the window containing figures of resistance level there are two horizontal lines which are a graphical representation of the electric resistance values.

2.2 Button “Start” is intended to initiate the training procedure. Upon pressing it the session timing begins and the inscription on the button is changed to “Pause”. It means that repeated pressing the button leads to a temporary stop of the procedure. The next pressing the button resumes the session. This operation is possible only during work. During rest- time the “Start/Pause” button is blocked.

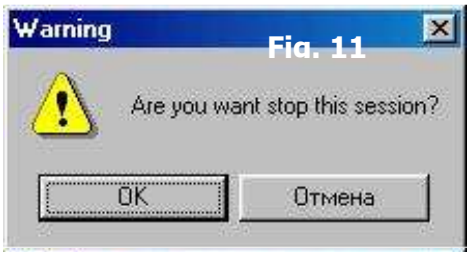
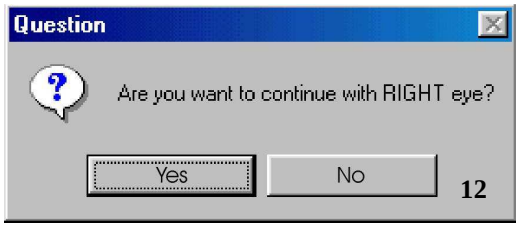


Fig. 11

2.3. The "Stop" button is active only during working period and is intended to stop a session. When pressed it brings a message (Fig. 11) asking to confirm one's decision to stop a session. If the "Cancel" button is pressed the session will continue. The result of pressing button "OK" depends on the phase a program is in. If it has been established that the work is to be performed by each eye in turn (which is, in fact, a most frequent mode of work) the program will suggest working with the second eye. (Fig.12). If this is not possible the program will bring the window to complete its work (Fig.13).



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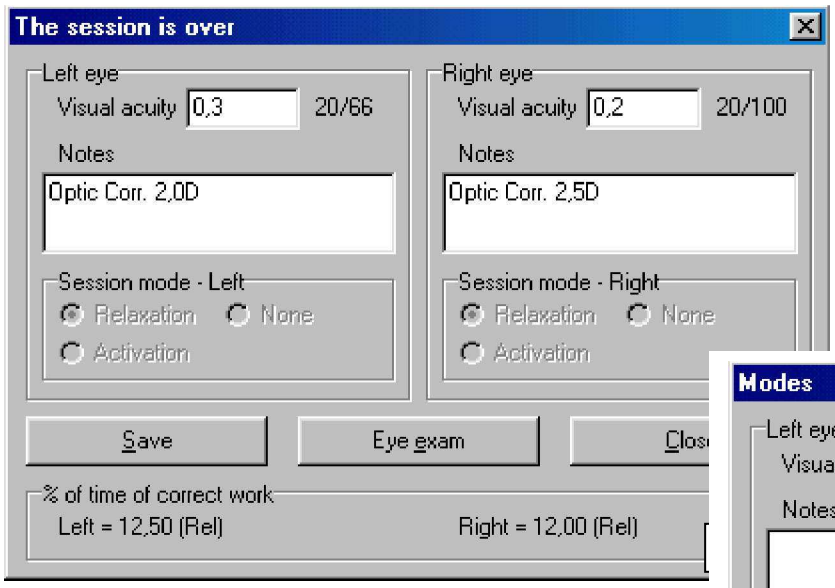
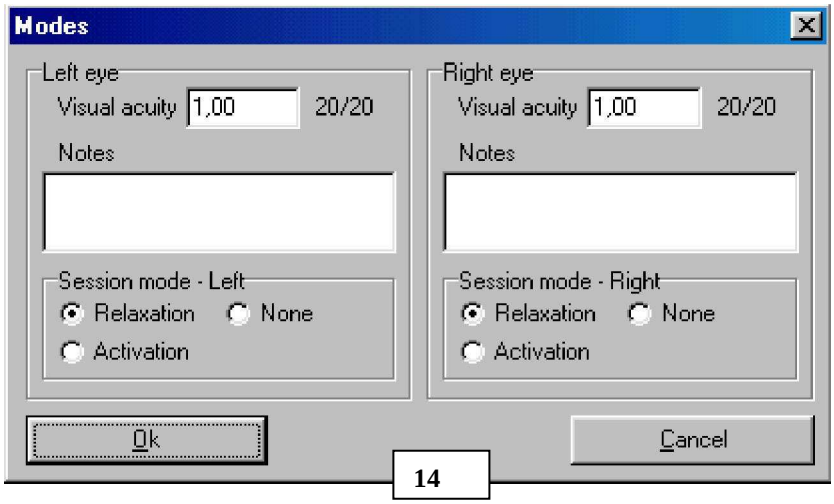


This window suggests to Save the result in the database, to make an examination of one's visual acuity with the help of an inbuilt visual acuity estimation program (Eye-exam, further) or to close the program without saving the result.

2.4. Pressing button "Mode" brings a window intended for setting a work mode. (Fig.14). This same window is automatically launched in the first session. The window is divided into two parts, to introduce information for the right and for the left eye, separately. The upper part has an indication of one's visual acuity in both American and European standards. These data can be introduced from the keyboard or set automatically upon visual acuity examination using the program "Eye exam" (see below).



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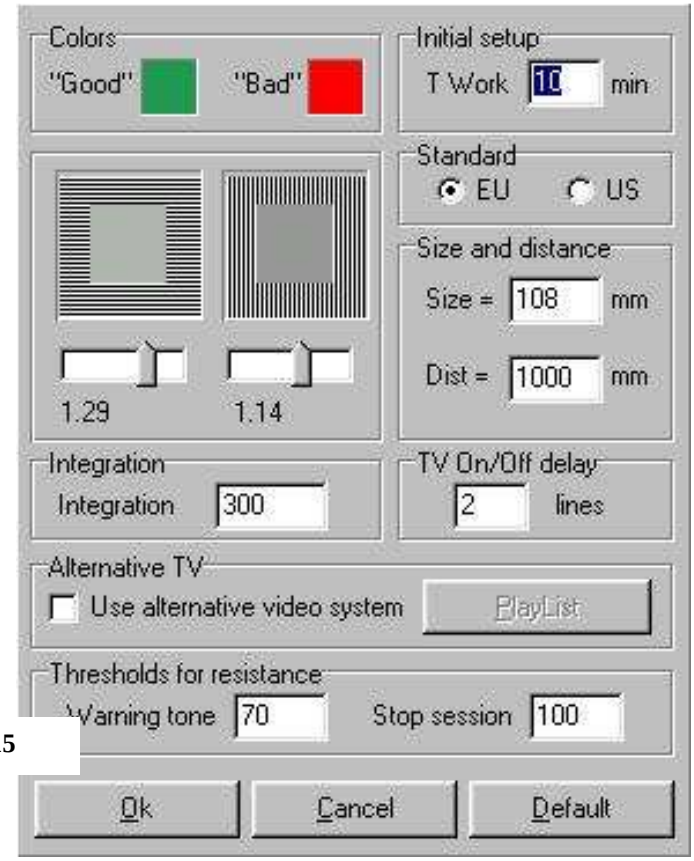
Any textual information about a patient can be saved in section "Notes".

In the bottom part of the window a variant of work modes for each eye is set – a relaxation mode, an activation mode , or it says that a particular eye is not to work (None).



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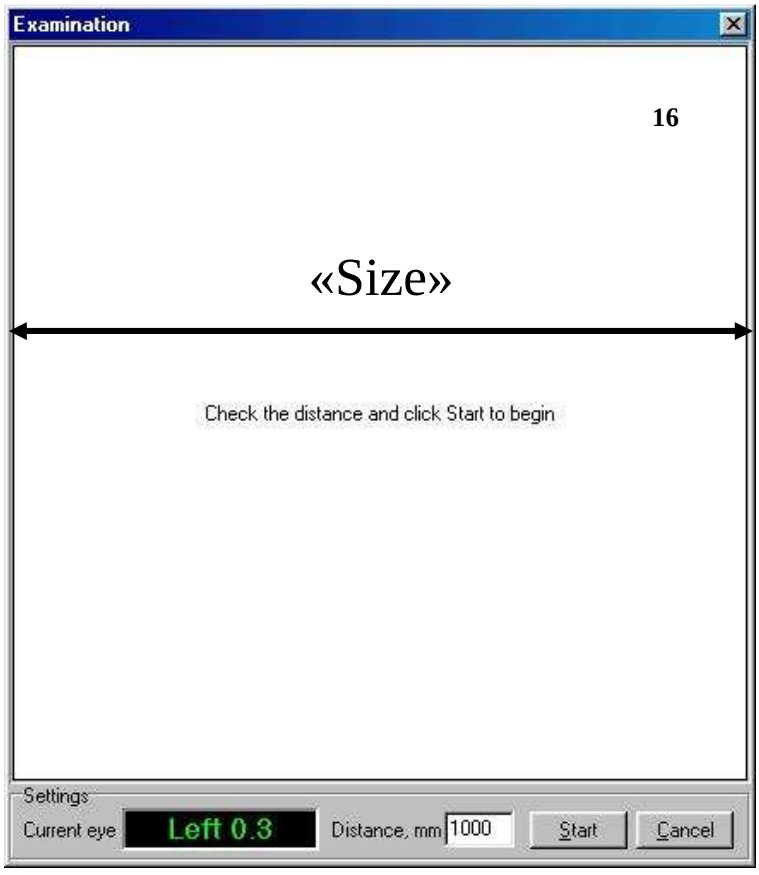
The choice is implemented by clicking the mouse in one of the circles next to the title of the work mode.

A black dot in the center of the circle means that this mode of work has been selected. The work mode can be be changed either before a start or during pause at any other moment of work. In the beginning of the following session all of prior settings are being kept if the preceeding session's result had been saved in the database. The purpose of each work mode as well as ways of working with a patient on the basis of his/her diagnosis are discussed below, in the third part of the Guide.

NB! SELECTING A WORK MODE IS THE MOST IMPORTANT PHASE in WORKING with a PATIENT. YOUR CORRECT CHOICE DETERMINES HOW EFFECTIVE the SIGH-TECH TECHNOLOGIES are GOING to BE.



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2.4. By pressing button **"Setup"** you open the setup window. (Fig.15).

2.4.1. Setting up the color of columns (section **"Colors"**). The colors for "Good" and "Bad" work performance are set up separately. The equipment supplier at the first installation of the program determines the colors of the graph. Should a user want to change pre-set colors he/she must make a double mouse click on the appropriate color square. Then a standard Windows color palette appears from which to choose the coloring.

2.4.2. Section "Initial Setup" sets up a typical work time period, i.e. 10 min., for each eye.

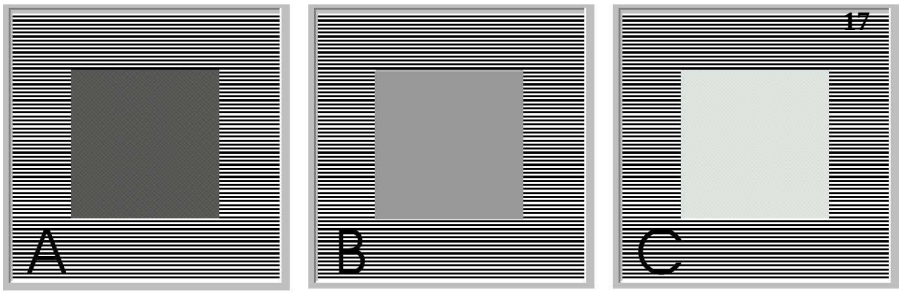
This figure will appear every time the program is launched in “T Work” window, thus making the setting period shorter.

2.4.3 In the “Standard” section either European or American style of presenting the results of the visual acuity examination is set, according to the user’s country.

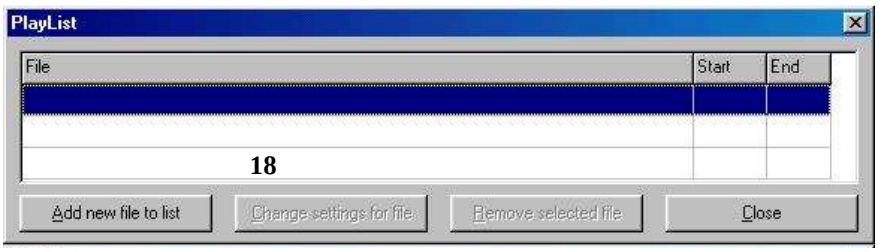
2.4.4. «Integration» is a quantitative measure of inertia in forming the graphic EEG picture. Ordinarily the constant value 300 is used. After the click on the appropriate window any other figures may be introduced from the keyboard.

2.4.5. Section “Size and Distance” contains some parameters for an optimal realization of the “Eye-exam” visual acuity examination computer test. “Size” is the real value for the “Examination” window span, which opens at pressing button “Eye-exam”. (Fig.16). With various monitor brands the actual size of the window varies. You should measure the width of the “Examination” window on your monitor with the help of a ruler and introduce this value (in mm) into section “Size”. Then the program will calculate the adjustment for exact measuring the optotype corner size (Landolt rings)\\ optotypes being used for testing one’s acuity of vision\\.

The “Distance” is a minimal distance between a patient’s face and the screen on which one’s visual acuity is being tested. Actual pixel sizes make working at distances under one meter impossible. If you have a high quality monitor (with the screen of 17 inch. or more, and with pixels not over 0,25mm) set the distance at 1000mm. A more reliable result can be achieved at a distance of 1,5m. The length of the keyboard cables, though usually limited, can rarely make the use of the 1,5m distance possible. You can introduce 1000mm or 1,5m in accordance with the situation you find yourself in.



2.4.6 Section “Gamma” is for regulating picture contrastivity with the purpose of optimizing visual acuity computer testing procedure using the “Eye exam” program. One should move the regulator crawler to the right and to the left to make the central square minimally contrastive to its surroundings. Fig. 17 give examples of correct tuning (B) and wrong tuning (A and C).

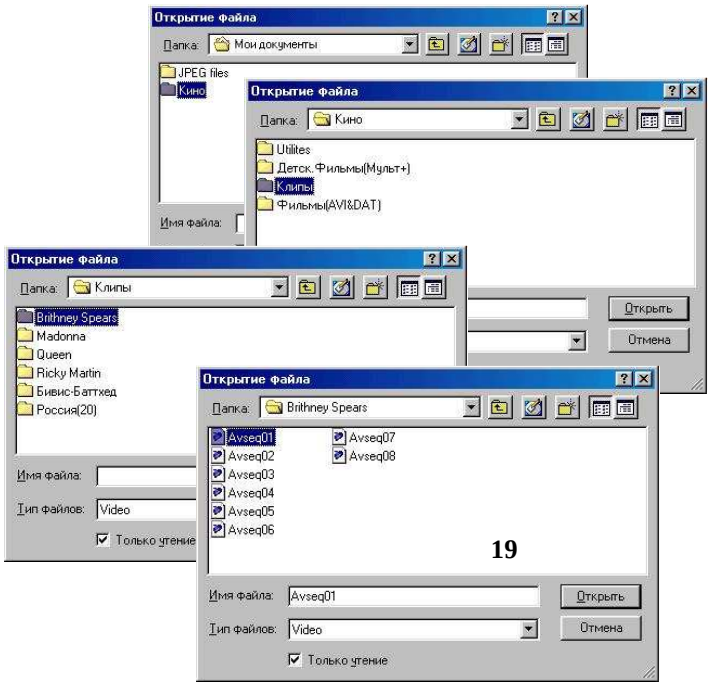


2.4.7. Section “TV ON/OFF delay” contains a constant which needs no changes.

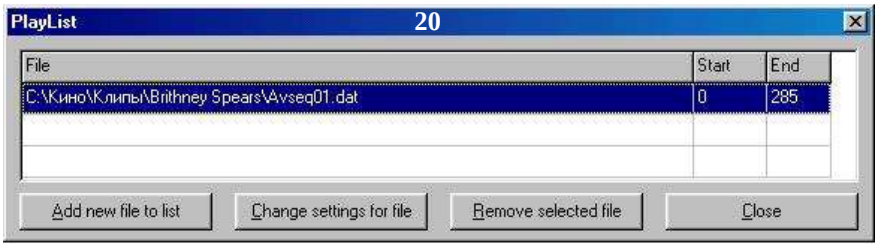
2.4.8 In section “Alternative TV” one sets a possibility of

watching a film either on the screen of the monitor (if the marking in the square is present) or on the TV screen, if a VCR is available (no marking in the square). If one opts for watching a film on the monitor screen a DVD must be available, or at least, a CD driver for films with DVD or CD disks. Another variant would be having a big size hard disk (over 20-30 Gbytes) for keeping a video-file stock. The “Alternative TV” mode enables a patient to watch movies, video-clips or any other digital video files. The hard computer disk “C” keeps 15 - 30 movies (for adults and children). They are in the folder “Movies” which contains a section called “Movies for children”, “Clips” and “Movies” (files with extensions AVI and DAT). Let us have a look at the process of setting up, taking one of the clips as an example.

Click the mouse on button “Play List” (Fig.15 gives the enumeration of movies). You will see a new window “Play List” (Fig.18) with an active button “Add new file to the list”. Press this button. A standard Windows window will appear, “Search for file” (Fig.19). From the section “My documents” choose the folder “Movie”-section “Clips”-folder “Brithney Spears”-clip N1 (Avseg01”). Then the name of the selected file will appear in the upper line of the “Play List” window (Fig. 20).



Then one has to set the beginning and the end points of the video-clip. This is done to save the patient tedious waiting until the end of the captions and other such unexciting details .To achieve this one has to press button “Change settings for file”. The screen of the monitor will turn black and in its left upper hand corner a small window will appear to set the beginning and the end of the video-file (Fig. 21). Right after the playing of the video-file will start. Moving the upper crawler with the mouse set the starting point of the video-file. The end point of the watching is set with the bottom crawler. The crawlers serve to achieve the first rough tuning level. A finer tuning of the beginner and end points can be set with buttons “Set start” and “Set end”. A video-file will start from the point at which button “Set start” was pressed and be finished at the point of pressing button “Set end”. Upon the completion of tuning press button “OK” to save them. The marks indicating its beginning and end points will appear in the upper line of the “Play List” window to the right off the name of the video-file.

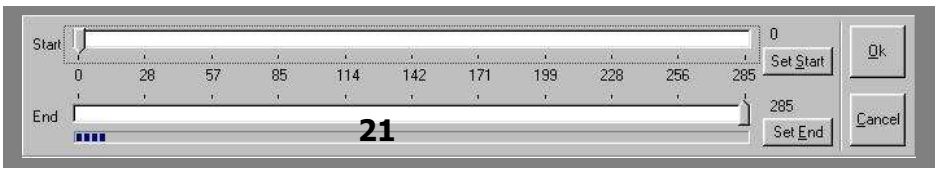


To set the next video-file the described procedure must be repeated. The records of the new video-files will appear in the corresponding lines of the “Play List” window.

The procedure described above makes it possible to organize a demonstration of a series of the most exciting scenes out of one lengthy video-file. Of a whole concert performed by a particular singer it is possible to cut out individual songs.

One must remember that some files (those with the extension .dat) consist of two files, which have to be installed successively.

2.4.9 Section “Threshold for Resistance” has the EEG-elelctrodes resistance values set at which a Warning tone is heard or the session is stopped.



2.5 The “Eye exam” button opens the program for testing one’s visual acuity. The method of examining one’s visual acuity used here is based on the classical way to determine one’s visual acuity by “the minimum separable ”, using Landolt rings. This method is not certified, though. For this reason the results obtained by this method can not be used for official reference and require an additional examination of the patient both before and after a course of treatment by certified methods of visual acuity examination, which make use of standard optotypes. Besides, one should bear in mind that visual acuity examination at 1m distance is performed in the following way. A patient is seated into a comfortable armchair in front of the screen of the monitor at a distance of 1 or 1,5 m, depending on the size and potential of one’s monitor (for distance see 2.4.5). On the screen one will see 4 type rings of various sizes with breaks in the top and bottom, in the left and in the right sides. The patient’s task is to determine the direction of a break in the ring and press the appropriate cursor button on the keyboard, as shown at Fig. 22.

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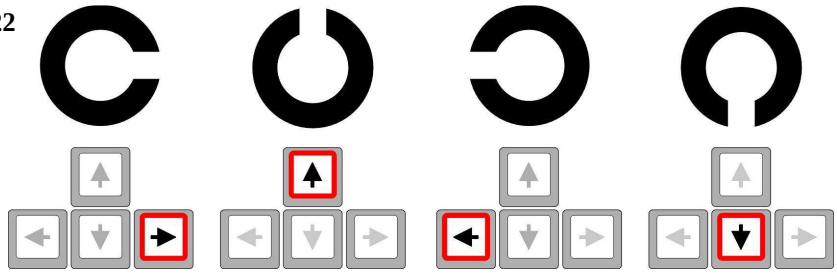


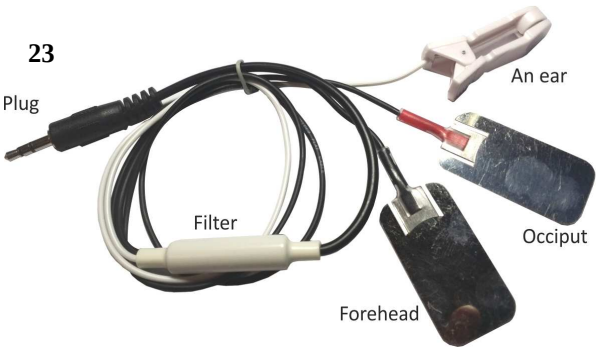
The first to appear is the window at Fig.16. The message on the screen warns a patient about the necessity of checking the distance between the screen and the patient's face. Testing begins upon pressing button "Start". The program warns a patient about the necessity of closing one of his/her eyes. Each optotype is presented for 10 sec.

Upon the completion of the testing the program saves the results into the database.

If you chose to resort to the standard table for visual acuity examination the results are to be filled in from the keyboard into the windows where the results of the "Eye-exam" program are being automatically saved (Fig.13 and 14).

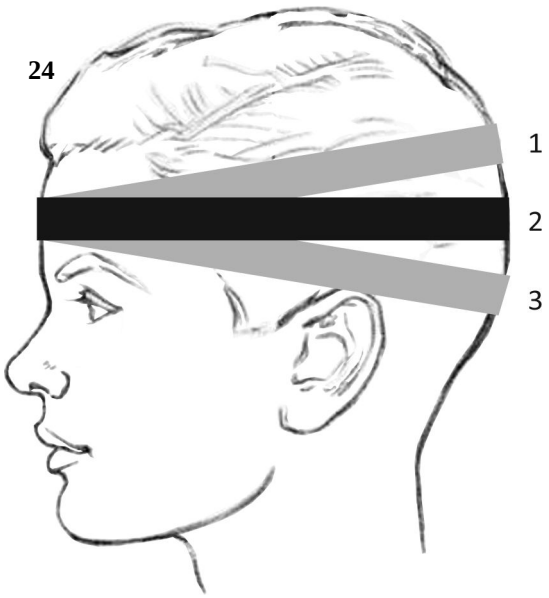
2.6 Button "Main Menu" implements the transfer to the Main Menu window. (Fig.7).

3. PREPARING A PATIENT FOR WORKING



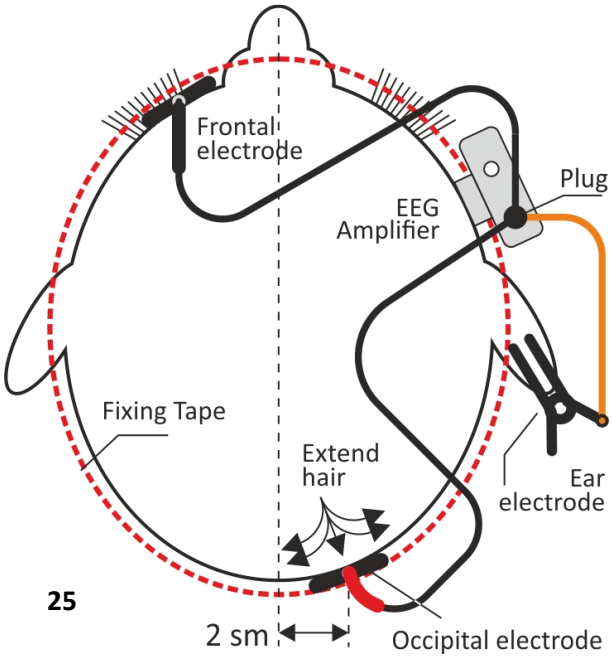
3.1 The EEG-registering head electrodes (Fig.23) are fixed on a stretching textile band that has a textile "lock"(sticker-4). The occipital electrode has a cylinder shape; the ear electrode (2) is a clip. At the front there is an indifferent electrode (3). The connection to the amplifier is done with a cylinder rod (5). The EEG-amplifier can be fixed to the patient's clothes' end or on one's head with the help of a spring clip since the cable length allows placing the amplifier comfortably.

3.2. Make a patient seated into a comfortable armchair. The back of the armchair should not interfere with the EEG registration. Setting EEG electrodes is done in the following way. First a fixing band is put on one's head. You should adjust its length with the help of the "sticker locks". (Fig. 25,B).



The band must be stretched so as to make electrodes reliably cling to the skin of the patient's head without causing any discomfort. Remember that highly sensitive individuals may faint because of prolonged compressure of the head!

Place the band along the bottom hair line; and at the back place it in the middle of the occipital tuber. The ends of the band must meet on the left side. The most frequent mistake, that of shifting the back band part down, will result in registering signals from the occipital muscles instead of EEG (see Fig.24: 1/3 indicates the wrong location of the band, 2 indicates the correct one).



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When the band has been set we start fixing electrodes. The most important step here is to fix the occipital electrode. It should be positioned on the occipital tuber 2cm to the right off the saggital surface (Fig. 25). To provide a proper contact with the skin wet a the cotton swab stick with the electrode gel enclosed here and separate the patient's hair to the right and to the left as shown at Fig. 25,B. The amount of gel should be sufficient to provide reliable contact between the electrode and the skin of the head.

Apply a drop of gel to the patient's ear lobes on both sides and fix ear electrodes, clips (Fig.25). Apply a drop of gel under the indifferent electrode positioned on the frontal area. Fix the EEG-amplifier in a convenient place and insert the plug into the amplifier seat.

3.3. Instructing the patient. Warn the patient about the duration of the session-20 min. During this time the patient must not make any jerky movements of the head as well as talk, laugh or close one's eyes. The patient's task consists in just watching the film. Let the patient choose a film to his/her taste[2]. The TV screen on which a film is being shown will now and then turn on and off. Do not worry about that. Usually the screen fades for no more than 5-7sec. No special action is required to turn the TV screen on.

If the patient loses interest in the film or there are any complaints\inconveniences the patient must tell the operator about those. The patient is to use button "Pause" in these cases.

4. RUNNING a SESSION

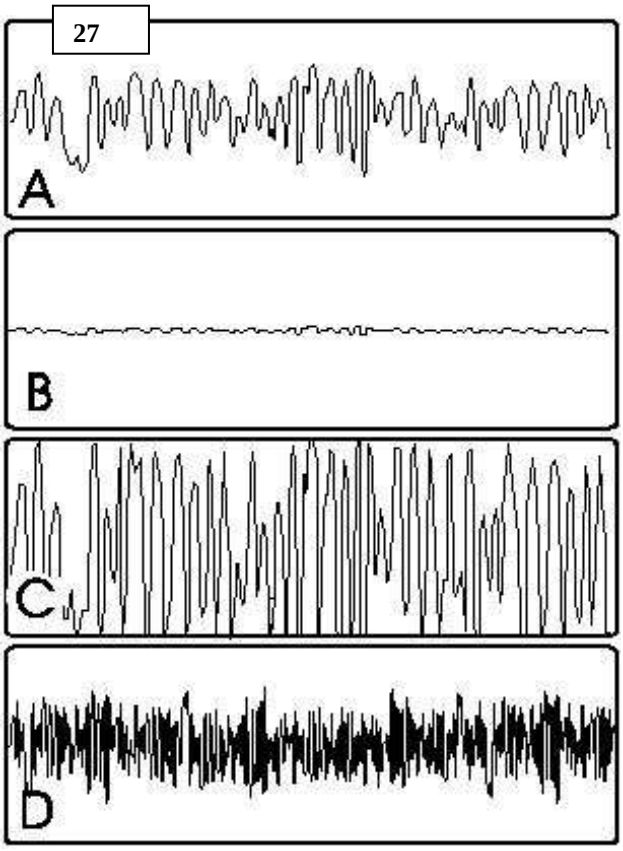
4.1 After the program has been launched click the mouse on the Splash, which will be followed by the Main Menu. Introduce the patient's name (see Fig.7-9) and click the mouse two times on the folder in front of the patient's name if the information has been filled in before. Light the "Visual acuity" with one-time click and then click button "New Session"; it will bring the program's working window (Fig.26). The functions of the buttons in the upper part of the screen have been described above. Below the buttons in the mid window a blue graph is deployed, representing the patient's EEG from the head electrodes.

[2] Make sure that a film is really exciting for the patient. This will largely determine the effectiveness of the method. Take care of the availability of a rich choice of movies for patients (cartoons, comedies, action films, erotical films, thrillers, etc.).

4.2. The EEG registration quality check. A decisive factor for a high quality EEG registration is the quality of the electrodes' contact with the skin of the patient's head. The criterion of the contact is the electric resistance between electrodes. To measure the resistance one must press button "Resistance". The button pressed, the EEG will go to be substututed by two horizontal lines. The window above the "Resistance " button will show figures indicating the amount of resistance (in KiloOhm) between the indifferent- and the ear-placed electrode (left figure) , and between the indiffernt- and the occipital electrode (right-hand figure) -Fig.10. The smaller resistance between the electrodes the better the EEG registration quality. Figures of resistance should be below 50 Kohm. At resistance over 100 Kohm. Network- (50-60 Hz) or mecanically caused artefacts are likely to come up. At resistance level over 200 Kohm the EEG registration quality is poor and the work is not very effective. The program automatically registers this level to block further work to improve the contact quality between the EEG electrodes and the skin of the head.

The EEG picture considerably varies from patient to patient. A typical EEG is at Fig. 27,A. When the EEG amplitude is either too small (Fig.27,B) or too big Pic,27,C) or there is a high amplitude intereference with the frequency of 50-60Hz (Fig.27,D) it means that the EEG registration is of poor quality ,and the manipulations with the electrodes must be repeated.

4.3. At the patient's first session it is necessary to set a mode of work for each eye. (see section 4.3, Fig.14). During the first session the window "Mode" opens independently. If correction is required the



window “Mode” can be opened by a button of the same name. Rules for setting modes are included into section **IV**.

4.4 Beginning a session. If the EEG quality is satisfactory one starts a treatment session. A session is run with the patient’s optimal optical correction. To do this one must make use of the patient’s spectacles (contact lenses) or apply trial lenses from the standard ophtalmological kit , lenses to be held by a special frame.

4.5 Press button “Start” to bring the window suggesting to close the right eye. The work is, as a rule, with each eye in turn (see further, section IV). It is for this reason that one eye is shut with a non-transparent screen which is a part of the supply set. It is located under the fixing band. If trial lenses and a special glass frame is chosen one is supposed to use standard screens, too.

4.6 The beginning of a session is accompanied by a sound signal and a graph deployment in the bottom part of the working screen. The graph represents the results of the computer analysed EEG. The oscillations on the graph are indicative of the on-line changes in the visual cortex activation level. Depending on the mode selected (relaxation or activation) the TV screen will be turned on simultaneously with either positive or negative phases in the graph oscillations.

4.7 In 10 minutes (unless set otherwise) working with the left eye ends and a message appears on the screen saying that the left eye must be closed. The work will be continued upon pressing button “Start”.

4.8 Ending working time is accompanied by a sound signal and the “The session is over” window. (Fig.13). This window suggests saving the result in the database (Save), carry out the visual acuity examination using an inbuilt visual acuity examination program “Eye exam” or close the program without saving the result (Close).

THE AUTHORS INSIST ON CHECKING ONE’S VISUAL ACUITY AT THE END OF EVERY SESSION (except the first one).

It is of little importance which method is applied for determining one’s visual acuity,be it the “Eye exam” or the table. What is important is that the selected mode of testing remains unchanged for a given patient.

IV. MANUAL FOR USE

1. General recommendations

Before using the **AMBLYOCOR** hardware complex study the technical description and the operating instructions.

One of the obligatory components of vision correction equipment is the apparatus for testing the acuity of distance vision, which is, at the doctor's option, a special visual test table or an optotype projector. Apart from the conventional measuring of the visual acuity before and after a course of treatment the authors insist on examining one's visual acuity after every session.

2. Practical recommendations.

2.1. Before sessions the patient should be examined carefully so as to identify the type of refraction anomaly and its degree. Optical correction of the patient's vision should be carried out as follows:

- in case of myopia and myopic astigmatism the optical correction corresponds to the static refraction;
- in case of hypermetropia and hypermetropic astigmatism the optimum correction is prescribed (spherical component is 1.0 D lower than the static refraction and the cylindrical component is 0.5 D lower than the static refraction), unless there are any contraindications for prescribing this correction.

DURING THE SESSION OF VIACOM-TECHNOLOGY THE PATIENT MUST WEAR GLASSES. IT IS MORE CONVENIENT TO USE TEST GLASS LENSES.

The procedure of preparing the patient for the session (application of EEG-electrodes, start-up of the program) is described in Operating procedures of the technical description and operating instructions.

2.2. Selection of modes is determined exclusively by the type of the patient's refraction anomaly:

- the ACTIVATION mode is selected in case of hypermetropia, hypermetropic astigmatism and aphakia, regardless of weather this refraction anomaly is accompanied by amblyopia or not;

- the RELAXATION mode is selected in case of myopia, myopic and mixed astigmatism, regardless of the presence of amblyopia, as well as in the case of accommodation spasm.

In some rare cases of development of functional vision disturbances with pre-existing emmetropia the ACTIVATION mode is selected (nystagmus, squint, ophtalmoplegia, asthenopia and others).

CAUTION! DO NOT CHANGE THE SESSION MODE IN THE MIDDLE OF A THERAPEUTIC COURSE!

2.3. In case of unilateral pathology (some forms of amblyopia and squinting) the patient views the movie with the affected eye only, the healthy one being occluded. The session time in this case ranges from 15 min. (younger (under 5 years) and more capricious children) to 20 min. (other patients).

In case of bilateral pathology the movie is viewed with the left and right eyes alternately (10 min. each). This is the most widespread form of work with patients (about 80% of cases).

Viewing with both eyes at the same time (20 min.) is done only with the aim of restoring the binocular vision in the case of amblyopia, after the vision acuity of the amblyopic eye has reached 0.3 - 0.4, and it occurs, as a rule, during repeated courses of VIACOM-technology

2.4. After each session the patient is tested with the optotype table or with an optotype projector. The objective of the test is to train distance vision, it lasts for 3-5 minutes. During the test the patient is allowed to screw up his eyes and may be prompted by the tester to encourage intensive visual activity.

Taking into account that the patient in the course of the training may memorize the characters, the test of vision acuity before and after the course of VIACOM-technology must be based on an unfamiliar test table (for example, Landolt rings).

3. Carrying out further therapeutic sessions and guidelines for the course of treatment.

3.1. The minimum number of daily sessions (5 times a week) making up the course of VIACOM-technology is from 12 to 35.

The smallest number of sessions is required for the treatment of accommodation spasm: 12-15.

In case of hypermetropia and hypermetropic astigmatism, depending on the gravity of the case, 15-25 sessions are held.

In case of myopia, myopic and mixed astigmatism, the number of sessions is 20-25.

In case of amblyopia and organic eye diseases, depending on the degree of vision acuity reduction, 20-30 sessions are required.

The criterion for the termination (sufficiency) of the therapeutic course is based on the results of the rough assessment of vision acuity that is analyzed in the course of daily training on the test table. If

there is no improvement in vision acuity for 5-7 sessions the course is terminated. However, the number of sessions in this case must not be less than the minimum required for this kind of pathology.

It is important to avoid intervals between the sessions of more than 3 days. The minimum frequency of sessions is 3 times a week, but the authors highly recommend that the optimum session rhythm be 5 days a week. It is allowable to hold up to 2 sessions daily with an interval of no more than 6 hours. In this way the process of vision correction is accelerated by 1.5 times, which requires an increase in the total number of sessions to 30-35.

3.2. In case of disbinocular and anisometropic amblyopia, due to their unilateral character, occlusion or penalization of the dominant eye is required during the entire period of VIACOM-technology. The occlusion should be continued in the period before the training course is repeated, in case the first course has not resulted in the elimination of amblyopia (this is the case for grave forms).

3.3. Throughout the course of VIACOM-technology permanent wear of glasses is required with optics adjusted as described in Section 2. The same applies to the period before the course is repeated, in case the first course has not resulted in the elimination of amblyopia.

3.4. In case of myopia and myopic astigmatism the permanent optic correction is discarded during the therapeutic course as the visual function increases. The normal practice for the treatment of myopia is:

- in case of myopia of less than 2.0 - 3.0 D the patient wears no glasses;

- in case of myopia from 3.0 to 6.0 D the glasses are not worn permanently. The glasses for long-distance work are decreased by 1.0 - 2.0 D;

- in case of myopia of 6.0 D and more the optical short-distance vision correction is decreased by 3.5 - 4.0 D, and the one for distance vision - by 1.0 - 2.0 D.

3.5. In the case of aphakia and organic pathology the optic correction is permanent and is not lost after the course of VIACOM-technology.

3.6. In the case of myopia the therapeutical course is repeated 1-2 times a year, depending on the gravity of the case. More frequent repetitions are recommended for young schoolchildren and teenagers during the pubertal period.

In case of hypermetropia 1-2 therapeutic courses are normally sufficient.

In case of amblyopia the number of therapeutical courses should range from 1 to 4, depending on the type and gravity of the disease. The desirable interval between the courses should not be not more than 2-3 months.

3.7. In case of organic pathology apart from the VIACOM-technology it is obligatory to carry out the treatment of the main disease, as the training only influences visual functions and, as opposed to the case of amblyopia, does not relieve the patient from the organic cause of his disease.

3.8. It should be born in mind that working in mode “Activation” the intraocular pressure can raise by 3-6 units during session. It is a reversible phenomenon. But if you give a session to a patient with hypermetropy aggravated by glaucoma take care of the patient’s use of the medicine prescribed to him\her 1-2 hours prior to the session