

OPERATION MANUAL AND DATA SHEET
DUNA-OKO, Ophthalmic LED Device

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1. APPLICATION

Duna-Okо ophthalmic LED device is designed for preservation of human vision and non-invasive treatment of human eye diseases. The device can be used in conjunction with other treatment options (medications, manual therapy, etc.) in hospitals or in a home setting.

The device is based on the method of phototherapy and the operating principles of the Duna-T device, which has already proved its efficacy. Duna-Okо device ensures the simultaneous penetration of a luminous flux of red and infrared bands with wavelength of 632.7 nm and modulated frequency of 101 Hz, which is equivalent to the light of the rising sun. This is one of the best exercises to relax the extraocular muscles and to recover the vision. This light strengthens the retina, relaxes the eye nerves, stimulates metabolism in the eyes and eliminates toxic substances in them. During the procedure the retina alternates between the states of rest and activity to strengthen the vision.

Duna-Okо device reduces the intraocular pressure and improves the blood flow to the eyeball and muscles, quickly reduces swelling of eyelids, facilitates resolution of hematomas and restoration of the tear film, relieves hypersensitivity of the eyes to bright light caused by eyestrain.

Thus, Duna-Okо device causes the following physiological responses of the eyes:

1. Restores blood circulation and lymph circulation in tissues;
2. Relieves the inflammatory process, decreases swelling and pain;
3. Reduces the risk of postoperative inflammatory complications;
4. Accelerates wound healing without formation of a rough scar;
5. Improves efficiency of rehabilitation;
6. Improves condition of skin around the eyes, smoothes small wrinkles.

INDICATIONS FOR USE

- Eyelid disorders (blepharitis, edema, abscess, hordeolum, upper eyelid ptosis, lagophthalmos, blepharospasm).
- Acute inflammatory diseases of the lacrimal apparatus.
- Diseases of the conjunctiva (conjunctivitis, retinitis, chorioretinitis, dry eye syndrome, burns of the conjunctiva).
- Diseases of the sclera (episcleritis, scleritis).
- Diseases of the cornea (keratitis, corneal dystrophy, corneal burns).
- Early stage of cataract.
- Diseases of the retina (dystrophy, detachment).
- Optic neuropathy.
- Glaucoma (in combination with drug therapy).
- Diseases of the oculomotor system (strabismus).
- Refractive disorders (nearsightedness, farsightedness, astigmatism).
- Improvement of the brain functions and normalization of sleep.
- Conditions after eye surgery.
- Allergic and herpetic eye disorders.
- Weeping eczema of the eyelid skin.
- Furunculosis.

Phototherapy with Duna-Okо device ensures complete safety of treatment in daily use; high efficacy in combination with exercises for the eyes; possibility to combine the treatment with drug therapy; excellent usability for both inpatient and outpatient settings; high tolerability; possibility to significantly reduce use of medications.

2. BASIC SPECIFICATIONS

The case of the device is made of the non-toxic, high-impact plastic. The light-emitting diode matrices are composed of red and infrared LED light generators.

Red light wavelength, nm	632.7 ± 30
Infrared light wavelength, nm	895 ± 55
Electric power of LEDs, mW	
- One LED in the wavelength range 632.7 nm ± 30 nm	0.20 to 0.30
- One LED in the wavelength range 895 nm ± 55 nm	0.15 to 0.25
Radiation area, cm ²	7 (minimum)
Rated power supply voltage, V.....	4.5
Average power consumption, V · A	1.2 (maximum)
Weight, g	360 (maximum)
Overall dimensions (without package), L×W×H, mm	210x75x20

SAFETY REQUIREMENTS

Duna-Oko device is designed and manufactured with due regard to the maximum operational safety. Maintenance of the device and all repairs must be carried out at the manufacturing plant. **Before using the device, carefully read this Operation Manual!**

The labels and the individual package of the device bear the protection rating symbol for the applied part and the symbol for the class and type of protection against electric shock hazard:



- PRODUCT OF TYPE BF



- PRODUCT OF PROTECTION CLASS II

CONTENTS OF DELIVERY

1. Duna-Oko device	1 pc.
2. Operation Manual	1 pc.
3. Individual package	1 pc.
4. USB cable	1 pc.

3. PREPARATION FOR USE

In case of the following conditions, Duna-Oko device must be used on the recommendation and/or under the supervision of a physician only:

- Eye cancer
- Extensive purulent processes

REMEMBER THAT EYE PROBLEMS ARE ASSOCIATED WITH THE GENERAL STATE OF THE BODY. Diseases of the gastrointestinal tract, liver, pancreas, parasitic infestations, chronic constipation, spine disorders, sedentary lifestyle, poor diet, bad habits, chronic fatigue and stress, sleep disorders, and infectious diseases are the factors that contribute to eye diseases.

4. PREPARATION FOR USE

The appearance of the Duna-Oko device

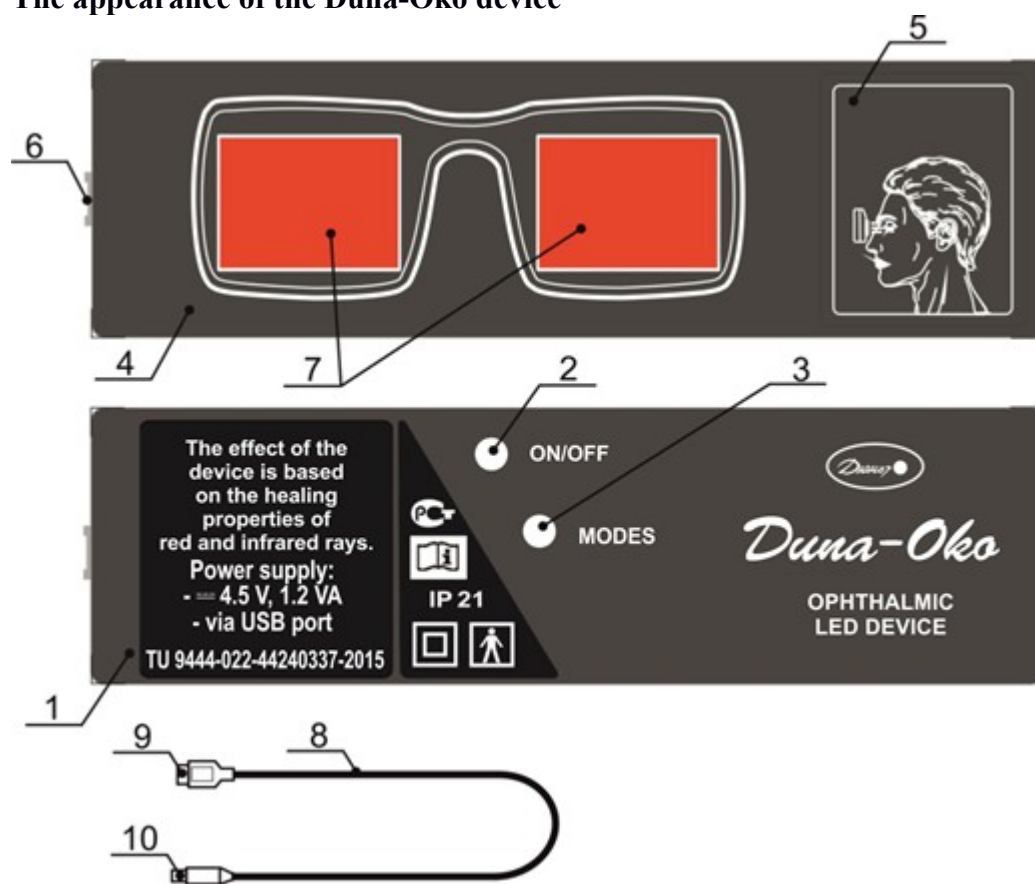


Fig. 1

- 1 – Control Panel
- 2 – On/off button
- 3 – Mode selection button
- 4 – Operating panel
- 5 – Battery compartment cover
- 6 – External power supply connector
- 7 – LED matrices
- 8 – USB cable
- 9 – PC connector (USB port)
- 10 – Device connector (6, Fig.1)

1. Insert three AA type 1.5V batteries into the battery compartment (batteries are not included into the scope of delivery!).

Caution: Check batteries every three months. If corrosion is detected, or if the matrix displays “Br” when turning the device on, replace the batteries!

The computer USB port can be used as a source of power supply.

2. Turn the power on (button 2, Fig. 1).

3. Press button 3 (Fig. 1) to select the mode of operation. After 5 seconds the device turns on in the selected mode.

Mode I – “Cyclic”: matrices are switched at 5 seconds intervals. Duration – 2 minutes.

Mode II – “Vertical Swing”: the simultaneous glowing of both matrices increases for 5 seconds and then fades.

Duration – 2 minutes.

Mode III – “Horizontal Swing”: the alternating glowing of matrices increases for 5 seconds and then fades.

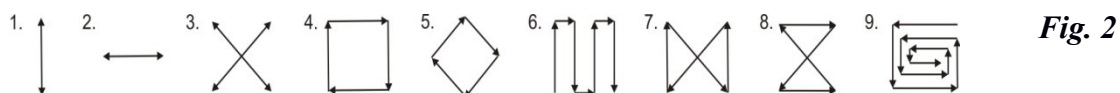
Duration – 2 minutes.

Mode IV – 9 medical figures are displayed in succession. Each figure is represented 3 times for 5 seconds (see Fig. 2).

Duration – 3 minutes.

Mode V – the above-listed modes are automatically activated in the following order: I, II, III, IV, III. Total duration – 7 minutes.

Mode V is a general-purpose mode and can be applied for treatment of any diseases.



After completion of the operation modes, the device will automatically go into the sleep mode. To restart the session, select the mode using button 3 (Fig. 1). At the end of the operation the device must be switched off (button 2, Fig. 1).

5. OPERATING PROCEDURE

GENERAL RECOMMENDATIONS

There is no age restriction for use of Duna-Oko device. Duration of a session is from 2 to 7 minutes, three times a day. Treatment is carried out either daily or in courses; the number of session depends on a diagnosis.

The device is used either in contact or non-contact way by directing it to open eyes at a distance of 30-70 mm. During the session a patient should blink frequently. If a patient feels any discomfort in his/her eyes, the device must be used with the eyelids closed.

Duration of treatment depends on the nature/stage of a disease and the patient's condition. Generally, the device is used in 10-15 day followed by breaks of 10 to 15 days throughout the year!

METHODS OF APPLICATION OF THE DUNA-OKO DEVICE

1. Visual fatigue associated with a long and intense visual stress from reading, writing, working at the computer; heaviness in the eyes, redness of eyeballs, headache after a long intense work at a close distance from the eyes.

To remove stress and fatigue of eye muscles, reduce symptoms of a stress and fatigue (eye bags and circles under the eyes), improve the brain function and normalize the sleep.

Treat with the device (modes II, III).

2. Myopia (nearsightedness) is the visual impairment, in which a person has difficulty seeing distant objects, but can clearly see near objects. Two oblique muscles encircling the eyeball are compressed when working in close proximity and are unable to relax when a person tries to focus on a distant object, while rectus muscles are loosened. The most severe complication of medium and high myopia is the detachment of the retina. Symptoms: short-sighted people have to keep an object close to their eyes and tilt their head low when reading and writing. This causes ache in eyeballs, frequent headaches, and visual fatigue.

In case of myopia, Duna-okó device restores the ability of the lens to change its curvature, normalizes the tone of eye muscles and improves a local blood flow. All this leads to removal of an abnormal muscle stress in the eye and to enhancement of visual acuity. The exception is detachment of the retina.

Treat with the device (modes II, III, IV).

3. Hyperopia (far-sightedness) is the visual impairment in which a person is not able to clearly see objects at a short distance. Four rectus muscles become overstressed and shorten the eyeball when looking at a distant object. They cannot be relaxed when looking at a nearby object, while oblique muscles are loosened. Symptoms: pain in the forehead and eyes, a feeling of pressure in the eyes, blurred and merged letters, visual fatigue.

In case of hyperopia, rays of light refracted by the lens are focused behind the retina rather than on it. Treatment of patients with hyperopia using the device increases adaptive (accommodative) abilities of the lens and efficiently relieves stress. At a low degree of hyperopia, the treatment leads to complete normalization of vision and makes it possible to get rid of glasses.

Treat with the device (modes II, III, IV).

4. Strabismus is a consequence of strained, convulsively compressed rectus muscles, which cause a deviation of the visual axis of one of the eyes from the joint fixation point. As a result, the function of information combination in the cerebral cortex is affected, i.e. each eye perceives the same object separately. Symptoms: deviation of the visual axis of one of the eyes to the nose or temple, double vision, limited eye movements, deteriorated vision in one or both eyes, visual fatigue.

The use of the device for treatment of strabismus improves vision and perception of information, activates the binocular vision, stimulates the muscle apparatus of the eye, improves a blood flow in all structures of the eye, as well as eliminates comorbidities by affecting trigger and segmental areas as a part of the therapeutic algorithm.

Treat with the device (modes I, IV).

5. Astigmatism is the irregular tension of periocular muscles, in which only one oblique muscle and only two rectus muscles are functional, and the rest of them are loosened. As a result, a shape of the eye is distorted; a patient sees a doubled object. An image may be twisted, multiple fuzzy, blurry. It is often combined with myopia.

Treat with the device (modes I, IV).

6. Conjunctivitis is the inflammation of the mucous membrane of the eye, which covers the inside of the eyelids and the front surface of the eyeball up to the cornea and has a protective function. This disorder may indicate an imbalance of the body due to excessive consumption of sugar, protein, etc. In this case, conjunctivitis is very likely to be caused by viral and bacterial infections, as well as by allergic processes. Viral conjunctivitis is often caused by adenoviruses; bacterial conjunctivitis – by bacteria such as staphylococcus, streptococcus or gonococcus. Symptoms: irritation and redness of the eye conjunctiva, itching, photophobia, lacrimation, swelling of the eyelids, mucous or purulent discharge from the eye.

Treat with the device (modes I, II).

7. Inflammatory diseases of the eyelids, the cornea and the iris. (Use on the recommendation and/or under the supervision of a physician only!) They may be caused by a purulent infection, diseases of the intestinal tract or the liver. The disease indicates a shortage of trace elements and vitamins in the body. Anti-inflammatory, anti-edematous and anti-allergic effects of Duna-Okо can be successfully used for treatment of these inflammations.

Treat with the device (modes II, III).

8. Cataract is a functional disorder of the body caused by chronic intoxication of the body or diabetes. The disease is accompanied by clouding of the lens, impairment of the vision and blindness. The major symptom of incipient cataract in elderly people is the development of myopia. In some cases, patients see “flying flies” before their eyes. As the cataract progresses, the pupil changes its color from black to gray and then to white. The patient sees the world as if through a misted glass.

At early stage of cataract, the device allows a patient not only to preserve, but also to improve the vision. At mature stages of cataract, phototherapy improves blood circulation in the retina and the optic nerve function. A preoperative preparation course improves chances for a favorable outcome of a surgery. After a surgery, Duna-oko is used to reduce the rehabilitation period

and to prevent complications related to a secondary cataract. Artificial lens is not a contraindication to the use of the device.

Treat with the device (modes II, III, IV). Duration of a course is 14-28 days followed by a break of 10 days. Then, a repeated course is indicated. An outcome is assessed after 4-6 courses.

9. Glaucoma is the eye disease, the main manifestation of which is an increase in intraocular pressure. A high intraocular pressure is associated with a disturbed outflow of the intraocular fluid and leads to disruption of a blood flow in vessels of the optic nerve, the retina and the choroid. The optic nerve is the first structure affected by this disease, which gradually leads to complete atrophy of the optic nerve. Symptoms: first a feeling of heaviness in the head in the morning, slight, transient pain in the eyeball, around the eyes, and in the affected half of the head; periodic blurred vision; rainbow-colored circles around bright lights.

The use of the device as a part of the comprehensive treatment of glaucoma leads to inhibition of the pathological process in the eyeball. This enables not only to preserve the current level of vision, but also to improve it at the early stages of the disease. A preoperative preparation course improves an outcome of a surgery. After a surgery, Duna-Okó is used to prevent complications such as secondary glaucoma, as well as to reduce a rehabilitation period and a supportive treatment.

Treat with the device (modes II, III). Duration of the course is 14 days followed by a break of 10 days. Repeated courses may be indicated, if necessary, depending on dynamics of intraocular pressure.

10. Optic neuropathy is a partial or complete destruction of functionally active optic nerve fibers, replaced by neuroglia and connective (scar) tissue. It is caused by an inflammatory or a degenerative process and leads to a decrease or loss of the vision. Symptoms: reduced visual acuity and tunnel vision.

Treatment of neuropathy with Duna-Okó enables to maintain and improve the optic nerve function by restoring conduction of nerve fibers.

Treat with the device (modes I, II). Duration of the course is 14 days. Repeated courses are conducted at 7-day intervals.

11. Postoperative conditions of the eye (cataract, glaucoma).

Treat the operated eye with the device (mode II). Duration of the course is 7 - 14 days.

6. STORAGE AND HANDLING

Transportation

Duna-Okó device can be transported by all kinds of covered vehicles in accordance with the requirements and regulations for transportation of goods applicable to each type of transport. After transportation at negative temperatures, the device should be kept at a room temperature of 20 ± 5 °C for 2 hours before using it.

Storage and care

The device must be operated and stored at a room temperature with normal humidity. The case of the device must be cleaned with a velvety dry cloth without use of chemicals. It is permitted to clean LED matrices (over the surface of the case) with 40% ethanol.

Before cleaning disconnect the device from the power supply!

WARRANTY

The manufacturer guarantees free repair within 12 months from the date of sale or the date of manufacture of the device in case of its failure, provided that the consumer observes the rules of storage, transportation and use. The warranty for the device does not cover any mechanical damages and tampering of the case.

In case of absence of the date of sale or invoice from a dealer, or loss of the data sheet, the warranty period is counted from the date of manufacture of the device. The date is determined by

the manufacturer by opening the device. After the expiry of the warranty period, the device is repaired at the manufacturing plant at the consumer's expense.

Date of issue:

Stamp (QCD) of the manufacturing plant:

Date of sale:

The name and address of the dealer:

Stamp (seal) of the dealer:

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