

REMOTE PARAORBITAL ELECTRODE

OPERATION INSTRUCTIONS

1. DESIGNATION

The remote paraorbital electrode (RPE) is intended for prophylactic and therapeutic non-invasive treatment of the human skin in the area where the paraorbitally biologically active points (BAP) are located, for implementing the trophic action of the dynamic electroneurostimulation on optical tract as well as for general regulating influence on the organism physiological systems.

It is intended for home and clinical use.

The remote paraorbital electrode will be used only together with electrostimulators of the DENAS series as well as DiaDENS for treating the paraorbital BAP areas.

2. TECHNICAL CHARACTERISTICS

- 2.1. The electrode mass, kg, not exceeding 0.1
- 2.2. The electrode overall dimensions, mm, not exceeding 170x65x60
- 2.3. The electrode cable length, mm, not exceeding 700

3. COMPLETE ASSEMBLY

The complete assembly in accordance to Table 1.

Table 1

Name	Number, items
Paraorbital electrode	1
Operation Instructions with passport and application instruction	1
Packaging	1

4. SAFETY RULES

Please read carefully all information contained in this Operation Instructions; it contains important information in respect to your safety, as well as recommendations for correct use and maintenance of the device.

The device must not be used for the treatment of patients with implanted electronic devices (for instance, cardiostimulator) or for the treatment of patients with individual intolerance of electric current. During stimulation, the patient must not be connected to any high-frequency electrical device.

5. DEVICE SYSTEM AND FUNCTION

To follow hygienic requirements, it is recommended to treat the RPE surface before starting the treatment session (for disinfecting the electrodes use standard disinfectants and soft cleaning tissue).

When working with the remote paraorbital electrode (Fig. 1, 2) it is necessary:

- 1) to connect the RPE to the dynamic electroneurostimulation apparatus; the electrode will be connected to the DENAS device through support; to the DiaDENS devices, directly;
- 2) to put the RPE operative surface on the skin surrounding the eyes providing a reliable connection of the RPE electrodes with the surface;
- 3) to turn on the device; select the action regime and stimulation frequency (see Section "Operation Instructions"). The power control (regulation) must be set individually according to the patient's sensations following contact of the electrodes with the skin surface. The threshold of pain should not be exceeded.

Further operate the device according to the recommendations contained in the Section Operation Instructions of this Operation Instructions.

Attention!!! The electrode must not be connected to any other devices apart from the DENAS and DiaDENS series devices.

Figure 1. Front view

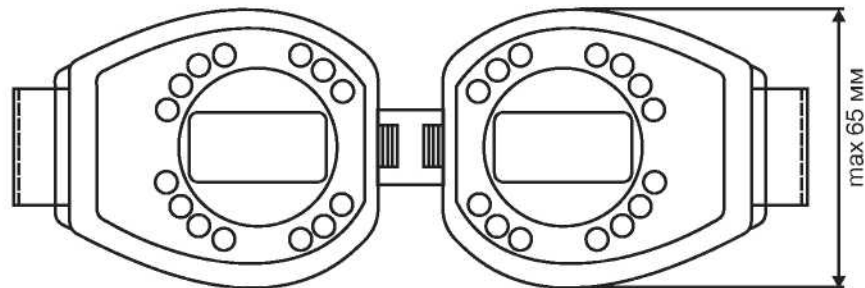
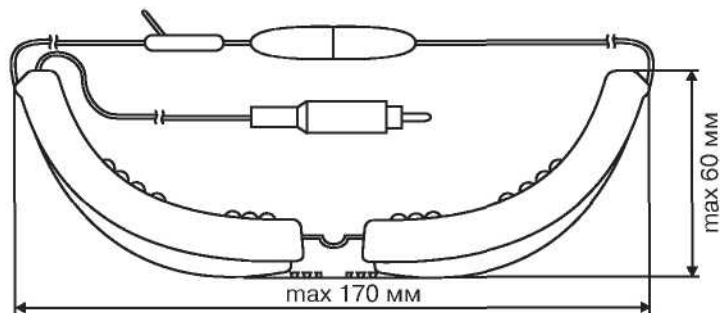


Figure 2. View from above



6. TECHNICAL MAINTENANCE

Daily technical maintenance must consist of the following operations:

- visual inspection of the RPE;
- disinfection (for cleaning the electrode, use standard disinfectants and soft cleaning tissues);
- checking the RPE functioning by connecting it to DENAS or DiaDENS devices.

7. MANUFACTURER WARRANTY

The manufacturer guarantees that the device complies with requirements of Technical Specification TU 9444-002-35266303-2005 provided that the conditions of operation, transportation and storage are observed.

7.1. Device service life: 5 years.

When operated properly, the service life can be considerably longer than that above mentioned standard.

7.2. The device limited warranty: 12 months from the date of sale.

7.3. If there is a defect found in the device during the warranty period, the retailer (manufacturer) warrants to satisfy consumer's demands as stipulated by the RF Law "On protection of consumers rights".

The retailer (manufacturer) or a company acting as a retailer (manufacturer) based on the contract concluded with the former is not liable for defects if they should occur after the delivery of the device to the user as a consequence of:

- 1) violating the rules of transportation, storage, maintenance and operation by the user, provided in this Operation Instructions;
- 2) actions of any third parties;
- 3) force major circumstances.

7.4 In the event of device failure or defect found during the warranty period or in discovering incomplete assembly, the owner must send an application for repair

(substitution) to the address of manufacturer, indicating surname, name, patronymic, address, telephone, brief description of the defect, date and conditions of its occurrence.

8. TRANSPORTATION AND STORAGE

Transporting conditions: at temperature from -50°C to +50°C, relative air humidity up to 98% at the temperature +25°C.

Storage conditions: at temperature from -50°C to +40°C, relative air humidity up to 98% at the temperature +25°C.

9. UTILISATION

All packing materials are environmentally safe can be repeatedly used.

All materials used for the device are recyclable. Submit the materials to specially designated places (consult with respective services of your region) for their collection and recycling.

10. CERTIFICATE OF ACCEPTANCE

The remote paraorbital electrode "DENS-spectacles" corresponds to Technical Specification TU9444-002-35266303-2005 and has been recognised as fit for operation.

OPERATION INSTRUCTIONS

The majority of eye diseases are indicative of some problem in the entire human organism, a consequence of impairment of its adaptive abilities, whereas the course of the disease depends on general health condition and on specifics of individual human responsiveness.

Performing the dynamic electroneurostimulation with the DENAS and DiaDENS devices using remote paraorbital electrode (RPE) for complex treatment of eye diseases permits one not only to achieve high efficiency in treating eye pathologies but also to enhance the adaptive reserves in each and every patient.

Prior to beginning of the treatment, a consultation by physician-ophthalmologist is recommended for diagnosing, prescription of medicinal therapy, control and evaluation of results prior to, in the course of, and after the treatment.

Treatment with the aid of remote paraorbital electrode will be performed around the eyes (in the area of the orbicular system of the body organ correspondence).

In the course of a therapy session, the patient should be in a comfortable position (laying or sitting). After treatment, the device must be switched off and the RPE removed.

When the diagnosis is unclear and for prophylactic purpose, it is recommended to use DENAS TEST regime (the same as above mentioned "dosed regime") or the MED programme of the DiaDENS series devices.

In the course of treatment of eye diseases, the use of the RPE is recommended in combination with treatment of universal reflex zones, liver zones and gastrointestinal tract organs, of the cervical-collar zone, the cervical circlezone and the zones of microcorrespondence, with the aid of built-in electrodes of the dynamic electroneurostimulation devices. Selecting treatment zones using built-in electrodes must be performed in compliance with the general rules of the DENS indicated in the Manual of the dynamic electrical neurostimulation.

For established diagnosis, visual fatigue conditions, with prolonged or considerable eye strain, please follow the recommendations indicated in Supplement 1.

Supplement 1 SOME RECOMMENDED WAYS OF USING THE REMOTE PARAORBITAL ELECTRODE IN OPHTHALMOLOGY

Diagnosis	Device	Regime	Session				Notes
			Duration	Action frequency	Energy level	Number	
1. Visual asthenopia (visual fatigue) prolonged or intense eye strain (reading, writing, working on a computer, etc.)	"DENAS"	Therapy*	3-5 minutes	77 Hz	ED-2*** For children of up to 7 years old - ED-1***	1 session a day for 10-14 days	Repeated courses will be recommended for treatment of eye strain, as necessary, or 3-4 courses a year
	"DiaDENS"	1. MED Programme	By the programme - individual time	10 Hz			
		2. Therapy	3-5 minutes	20 or 60 or 77 Hz**			

Notes:

* — corresponds to the previous concept of "constant regime"

** — selection of action frequencies must be performed in compliance with the general rules of the DENS.

*** — ED-1 — the first energy range, same as above mentioned "minimal energy level", ED-2 — the second energy range, same as above mentioned "comfortable energy level."