LLC “RC ART”, Yekaterinburg, Russia

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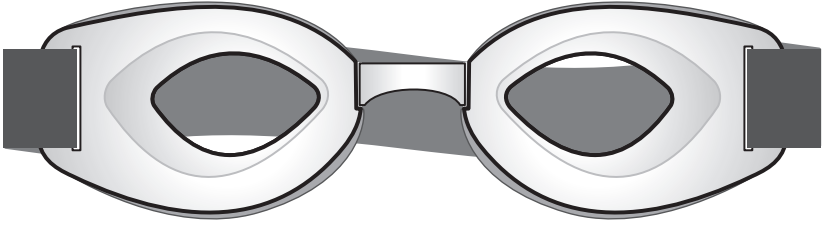
EXTERNAL PARAORBITAL ELECTRODE “DENS-GLASSES” OPERATING MANUAL

TU 9444-002-35266303-2005 RC ART 06.1-03.71-01 RE



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PART 1. SPECIFICATIONS

1.1. General Description

The External Pararobital Electrode (EPE) provides dynamic electric non-invasive neurostimulation of biologically active points located in the paraorbital area for a prophylactic and therapeutic effect.

Dynamic electric neurostimulation facilitates recovery from visual impairments caused by some eye diseases. Additionally, electric neurostimulation has a general regulating effect on the physiological systems of human organism.

The unit is intended for household and clinical use.

The External Paraorbital Electrode should only be used in combination with the DENAS*, DENAS+ and DiaDENS (DiaDENS – T, -DT, PK, -PKM) electric stimulation devices.

** The unit is connected to the DENAS device via an holder to be purchased additionally (not included in the original package).*

1.2. Specifications

Weight.....0,2 kg
Dimensions.....190x65x50 mm
Cable length.....600 mm

1.3. Package Contents

The package includes:

Name	*Quantity*
External Paraorbital Electrode “DENS-Glasses”	1
Nose Bridge	5
Owner’s manual	1
Package	1

1.4. Safety Requirements

Please read the following safety instructions! They are designed to prevent damage to property and the user! The manual contains important recommendations on proper use and care of the unit.

The unit must not be used for treatment of patients with implanted electronic devices (such as cardiac pacemaker) as well as of people with electric sensitivities.

Warning: Do not operate the unit while using another electrical medical device. This can lead to burns and irreparable damage to the device.
Before you begin stimulation, make sure the patient is not connected to any high-frequency electronic device!

The unit contains fragile components! Prevent from shock.

The unit is not waterproof. Keep away from liquids and moisture.

Do not repair the unit yourself. Refer all servicing to the manufacturer.

Terms of Transportation

The unit should be transported at a temperature between -50^{0}C and +50^{0}C, relative air humidity from 30% to 93% and pressure from 70 to 106 kPa.

Terms of storage

Store the unit at a temperature from-50^{0}C to +40^{0}C, relative air humidity from 30% to 93% and pressure from 70 to 106 kPa.

Operating environment

The unit shall be operated at about +10^{0}C to +35^{0}C, relative air humidity from 30% to 93% and pressure from 70 to 106 kPa.

Warning: If stored at a temperature below +10^{0}C, to keep the device in favourable environmental conditions to warm up for at least two hours before application.

Recycling:

All the packaging materials are environmentally-safe and can be reused.

The device is made of materials that can be recycled.

1.5. Care and Maintenance

Maintenance of the unit should include the following:

— visual check of the device;

— cleaning of electrodes (use standard disinfection detergents and a soft cloth to clean electrodes);

— check of the unit's readiness for operation when connected to the DENAS or DiaDENS devices.

1.6. Warranty

1.6.1. The manufacturer guarantees the compliance of the device with Technical Conditions TU 9444-002-35266303-2005, provided the terms of operation, transportation and storage are observed.

1.6.2. The operation lifetime of the unit is 5 years.

Observation of regulations governing the device application can considerably increase the lifetime set by the manufacturer.

1.6.3. This product is warranted for the period of 12 months from the original date of purchase.

1.6.4. The consumer is to check the package contents and perform the visual control of the device in the presence of the retailer. Complaints about the incomplete set and appearance of the device are not accepted after sale.

1.6.5. In case any defects are discovered within the warranty period, the retailer/manufacturer is under an obligation to handle the consumer's claim in line with the Consumer Protection Law.

The warranty doesn't cover the following:

1) Damage caused by any failure on the part of the consumer to comply with the rules of transportation, storage, care and operation provided by the owner's manual;

2) Damage caused by actions of the third party;

3) Damage caused by force majeure.

1.6.6. If warranty servicing is required (i.e., in case of some parts missing or malfunction of the device), an application for repair or replacement should be fully and properly filled in by the customer and presented to the manufacturer. The application must include the following information: customer's name, address, telephone number, brief description of the problem, time and conditions of its occurrence.

Warranty repairs must be carried out by the Manufacturer or Manufacturer's Service Centers.

1.7. Manufacturer's Address

Manufacturer: LLC "RC ART", 620146 Russia, Yekaterinburg, 15 Postovskogo Str. Tel: +7 (343) 267-23-30
Distributor: DENASMS.COM Tel.: +73432015405 http://www.denasms.com/ E-mail: info@denasms.com

PART 2. USER'S INSTRUCTIONS

2.1. General Information

The majority of eye diseases are evidence of adaptive dysfunction. The course of an eye disease depends on the patient's general well-being and presence of concomitant conditions.

Dynamic electric neurostimulation (DENS) delivered by the External Paraorbital Electrode is regarded as a constituent part of the prophylactic and therapeutic program in ophthalmopathy treatment.

The stimulation of the paraorbital area has a healthy influence on visual functions as well as optimizes general health.

All patients should be supervised by an ophthalmologist for making a diagnosis, adjusting multimodality treatment and monitoring and evaluating the results.

Contraindications to treatment with the EPE are described in Operation Manuals and User's Instructions to the DENAS devices.

2.2. Terms of Treatment

The application of the External Paraorbital Electrode doesn't require special conditions. During the session the patient should sit or lie in a comfortable position.

2.3. Procedural information and arrangement of the EPE

Prior to the start of treatment, wipe the surface of the electrode with a soft cloth moistened with a disinfecting liquid, (e.g. ethyl alcohol 70 %).

Figure 1. External Paraorbital Electrode. Front View

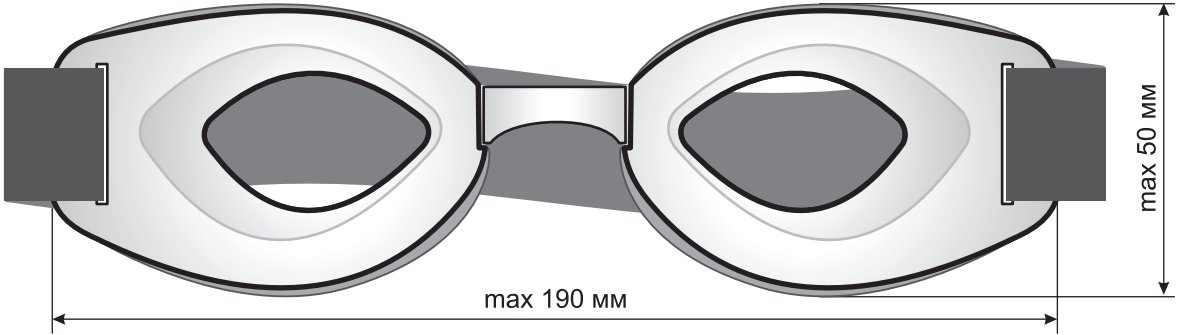


Figure 2. External Paraorbital Electrode. Top View

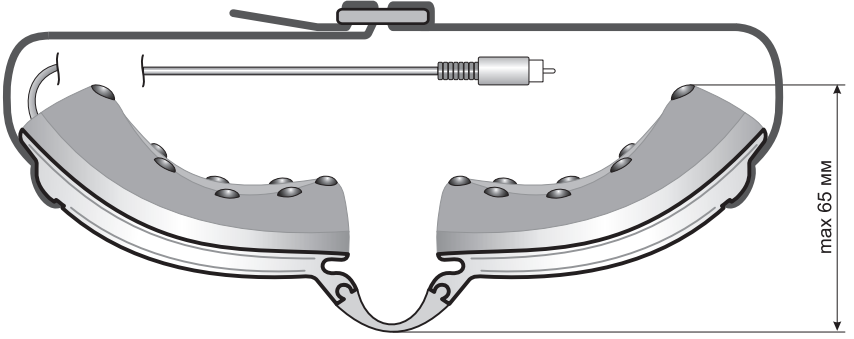
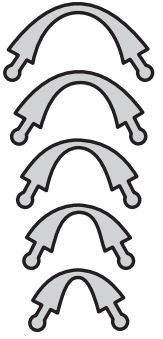


Figure 3. Nose Bridges.



1. Choose and set a nose bridge (see Fig. 3) supplied with the device.
2.Put on and anchor the unit.
3. Connect the unit:
— via a holder to the DENAS device;
— via an adaptor to the DENAS+ device;
— directly to the DiaDENS devices.
4. Turn on the device.
5. Select the operating regime and power of stimulation (see Appendix 1).
6. Start the session.
Duration of stimulation depends on the patient's age, diagnosis and intensity of symptoms (see Appendix 1).
7. When the treatment session is completed, turn off the device, put it off and disconnect of the apparatus (DENS, DENAS+ or DiaDENS).

Attention!

It is recommended that treatment schemes of chronic eye diseases with the use of the EPE include therapy of segmental and reflexogenic zones. The zones are be selected and treated with the use of inbuilt electrodes of the DENAS and the DiaDENS apparatuses in accordance with general rules described in the Operation Manuals of the appropriate apparatus.*

**See "Guidelines for Dynamic Electroneurostimulation with the DENAS, DiaDENS-T and DiaDENS-DT devices" edited by V.V. Chernyshev, Yekaterinburg, 2005.*

Appendix 1

Recommended ways of operating External Paraorbital Electrode in Ophthalmology

Diagnosis	Device	Regime	Session				Notes
			Duration	Frequency, Hz	Power Level	Number	
Visual Asthenopia. Visual fatigue caused by intense eye strain (reading, writing, working at a computer, etc.)	DENAS	Therapy	3-5 minutes	77	Comfortable power level. For children under 7– minimal power level	1 session a day within 10-14 days	Repeated courses are recommended in case of intense eye strain, or 3-4 courses a year
	Dia-DENS	Therapy	3-5 minutes	20 or 77			
		MED Program*	Time to be set by the program	10			

** MED programme is also available in the Denas+ device.*

Diagnosis	Devise	Regime	Session				Notes
			Duration	Frequency, Hz	Power Level	Number	
Presbyopy (age long-sightedness or hypermetropia)	DENAS	Therapy	3-5 minutes	77	Comfortable power level.	1 session a day within 10-14 days	Repeated course recommended in 30-40 days. After 2-3 month-interval the course should be repeated. Up to 3 or 4 courses a year
	DiaDENS	Therapy	3-5 minutes	20 or 77			
		MED program	Time to be set by the program	10			

** MED program is provided for the DENAS+ device as well.*

Diagnosis	Devise	Regime	Session				Notes
			Duration	Frequency, Hz	Power Level	Number	
Accomodation spasm, Myopia (short-sightedness), Hypermetropia, Astigmatism, Amblyopia	DENAS	Therapy	Children under 7 - 3-minutes; 8-12 years old – 5 minutes; over 12 years of age – 5-7 minutes.	77	Comfortable power level. For children under 7– minimal energy level	1 session a day within 10-14 days	3-6 repeated courses a year
	DiaDENS	Therapy		20 or 77			
		MED program*	Time to be set by the program	10			

** MED program is provided for the DENAS+ device as well.*

Diagnosis	Devise	Regime	Session				Notes
			Duration	Frequency, Hz	Power Level	Number	
Cataract	DENAS	Therapy	3-5 minutes	77	Comfortable power level.	1 session a day within 7-10 days	5-6 courses with 10-20 days interval
	DiaDENS	Therapy	3-5 minutes	20 or 77			

Diagnosis	Devise	Regime	Session				Notes
			Duration	Action Frequency, Hz	Power Level	Number	
Glaucoma	DENAS	Therapy	3-5 minutes	77	Comfortable power level.	1 session a day within 10 days	Repeated courses recommended depending on intraocular pressure dynamics
	DiaDENS	Therapy	3-5 minutes	77			

Diagnosis	Devise	Regime	Session				Notes
			Duration	Action Frequency, Hz	Power Level	Number	
Inflammatory eye diseases (acute condition and exacerbation of chronic disease)	DENAS	Therapy	5-10 minutes with 60-90 minutes breaks	77	Comfortable power level, minimal for children under 7 years	1 session a day within 10 days	Disinfect electrode before and after use
	DiaDENS	Therapy		77			