

ООО «РЦ АРТ», Екатеринбург, Россия
Электростимулятор чрескожный противоболевой портативный для воздействия на биологически активные зоны и точки со встроенными электродами

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ДЭНАС/ДЭНАС+
Руководство по эксплуатации
Часть 1. Технический паспорт
TU 9444-001-44148620-2005 РЦ АРТ 00.0-03.7-02 РЭ

LLC "RC ART", Ekaterinburg, Russia
Portable transcutaneous analgetic electrostimulator with built-in electrodes for stimulation of biologically active zones and points

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DENAS/DENAS+
Operations Manual
Part 1. Technical Passport
TU 9444-001-44148620-2005 RC ART 00.0-03.7-02 RE

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This Operations Manual is intended for the DENAS portable transcutaneous analgetic electrostimulator with built-in electrodes for stimulation of biologically active zones and points.



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1. FUNCTION

DENAS portable transcutaneous analgetic electrostimulator with built-in electrodes for stimulation of biologically active zones and points is intended for therapeutic non-invasive influence on the human skin surface and general regulating influence on physiological systems of the human body as well as for treating functional disorders within a broad spectrum of pathologies.

The DENAS device is intended for individual application and in patient care institutions.

The device is made in two versions: DENAS and DENAS+. The DENAS+ version has an additional MED mode and built-in slot for connection of remote electrodes.

2. SPECIFICATIONS

2.1. Power source:

only batteries (without accumulators) type 1.5 V LR6/AA, V.....1.5±0.2

2.2 Duration of impulse series, sec.....from 0.3 to 4.5

2.3 Pause between impulse series, sec.....2.0±0.3

2.4 Impulse frequency, Hz in the DENAS apparatus:

— in the TEST mode.....10±1

— in the THERAPY mode.....77±3

In the DENAS+ device:

— in the TEST and MED modes.....10±1

— in the THERAPY mode.....77±3

2.5 Duration of continuous operation (with new power source, item 2.1), not less than 4

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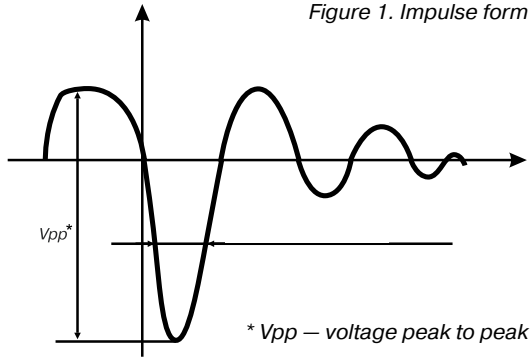
- 2.6 Weight, kg not more than.....0.3
- 2.7 Dimensions of the apparatus, mm.....not more than 195x65x45
- 2.8 Dimensions of the built-in electrodes (three electrodes are available), mm.....not more than 7x50
- 2.9 The form of impulses is in Fig. 1

Amplitude of impulse: $\approx 340 \text{ V (R = 10 kOhm)}$
 $\approx 60 \text{ V (R = 1 kOhm)}$

Amplitude of signal at the min power is 22% of amplitude of signal at max power (R=22kOhm).

2.10 The device automatically switches off not later than in min after the last touch of any of the buttons (except the button "Off") or after the last contact of the electrodes to the patient's skin.

Figure 1. Impulse form



* V_{pp} – voltage peak to peak

2.11 Electromagnetic Emissions

Emission Test	Compliance	Guidance electromagnetic Environment
RF emissions CISPR 11	Class B	The Portable electrostimulator DENAS series is suitable for use in all establishments including domestic establishments

2.12 RF Immunity

Immunity test	IEC 60601-1-2 Test Level	Compliance Level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2,5 GHz	3V/m

2.13 Electromagnetic Immunity

Immunity Test	Test Level	Compliance Level	Guidance electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	$\pm 6\text{kV}$ contact $\pm 8\text{kV}$ air	$\pm 4\text{kV}$ contact $\pm 8\text{kV}$ air	Floors should be wood, concrete, or ceramic tile. If Floors are covered with synthetic material, the relative humidity should be at least 40%. Explanation and training of staff in ESD-precautionary procedures.
Power frequency Magnetic fields IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

2.14 Recommended Separation Distances (d) between Portable and Mobile RF Communication Equipment and Portable electrostimulator DENAS series.



Frequency of Transmitter	150kHz to 80MHz	150kHz to 800MHz	800MHz to 2,5GHz
Equation	$d= 1,2 \sqrt{P}$	$d= 1,2 \sqrt{P}$	$d= 2,3 \sqrt{P}$
Rated maximum output power of Transmitter	Separation distance [m]	Separation distance [m]	Separation distance [m]
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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2.15 Operation conditions:

- ambient air temperature, °C.....from +10 to +35
- air pressure.....70-100 kPa
- relative air humidity.....30-93%

If the apparatus is stored at the temperature below 10°C, keep it under normal conditions at least for two hours before use.

The equipment fulfil the Electromagnetic compatibility (EMC) in accordance with the IEC-60601-1-2 and the additional standart of the IEC-60601-2-10.

This medical product bears the CE mark in accordance with the Medical Device Directive (MDD) 93/42/EEC.



— Device of BF type

Attention! *The apparatus contains fragile elements. Keep it safe from blows and drops.*

3. COMPLETE SET

3.1. The complete set of delivery of the DENAS device should correspond to Table 1.

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Table 1

Name		Marking	Quantity
Portable transcutaneous analgetic electrostimulator with built-in electrodes for stimulation of biologically active zones and points DENAS		RC ART 00.0-00.0 SB	1
Operations manual is divided into 2 parts for end-user performance	Technical Passport	RC ART 00.0-03.7 RE	1
	User`s Instructions	RC ART 00.0-03.7 RE	1
Case		RC ART 00.0-03.1	1
Package		-	1

3.2. The complete set of delivery of the DENAS+ device should correspond to Table 2.

Table 2

Name		Marking	Quantity
Portable transcutaneous analgetic electrostimulator with built-in electrodes for stimulation of biologically active zones and points DENAS+		RC ART 00.1-00.0 SB	1
Adapter (for connection of remote electrodes)		—	1
Operations manual is divided into 2 parts for end-user performance	Technical Passport	RC ART 00.0-03.7 RE	1
	User`s Instructions	RC ART 00.0-03.7 RE	1
Soft case		—	1
Package		—	1

4. SAFETY MEASURES

Read all the information in the present manual carefully! The manual contains important information of your safety as well as recommendations of correct usage and unit care.

4.1. The device is not electrically dangerous for the patient due to its built-in low voltage electric power source.

4.2. The device must not be used for treating patients with implanted electronic devices (for example, cardiac pacemaker) and for treating patients with individual electric current intolerance.

4.3. During stimulation the patient must not be connected to any high-frequency electric device.

4.4. Warning on potential hazards:

— simultaneous application of the device and another electric device can result in burns and possible damage of the device;

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— operation in the close proximity (e.g. 1 m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.

Attention!!! *DENAS and DENAS+ devices can only be used with those devices which are specially intended for operations together with DENAS and DENAS+ devices. Do not use other devices together with these devices.*

5. TECHNICAL MAINTENANCE

5.1. Daily technical maintenance should include the following:

- external examination of the device;
- disinfection of electrodes (use standard disinfection means and soft napless napkins to clean the electrodes).
- check of serviceability in accordance with instructions in Part 2 division 3 “Order of Work”

5.2. If the device is supposed not to be used for a long period, remove the power source from its compartment.

5.3. Replacement of power source:

- open the cover of battery block;
- extract the power source from the device;
- put in the battery block new power source according to polarity.

Use only power sources recommended by the manufacturer.

6. TROUBLESHOOTING LIST

Possible troubles and methods of their eradication are shown in Table 3.

Table 3

Device	Trouble	Possible reason	Method of eradication
DENAS	After switching the apparatus on without contact with skin, the LED "TEST"/"THERAPY" is blinking	Electrodes are dirty	Item 5.1.
DENAS+	The apparatus produces rhythmic sound signals with contact with skin	Electrodes are dirty	Item 5.1.
DENAS DENAS+	The LED of power source control is blinking or on	Battery voltage is less than 1.2 V	Change the power source

Attention! *Other troubles must be eradicated by the manufacturer or at the service centers of the manufacturer.*



7. STORAGE AND TRANSPORTATION

Conditions of transportation: Temperature from -50 to $+50^{\circ}\text{C}$, relative air humidity — up to 93% at $+25^{\circ}\text{C}$.

Conditions of storage: Temperature from -50 to $+40^{\circ}\text{C}$, relative air humidity — up to 93% at $+25^{\circ}\text{C}$.

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8. RECYCLING



All the package materials are environmental-friendly and can be reused.



— separate assemblage of electric and electronic equipment.

The old device and discharged power sources are not useless garbage! It contains valuable materials, which can be recycled in compliance with rules on environmental protection. Hand them to specially assigned centers for collection and recycling (consult your district authorities).

9. WARRANTY OF THE MANUFACTURER

9.1. The manufacturer guarantees the compliance of the device to the technical conditions TU 9444-001-44148620-2005 on condition the conditions of operation, transportation and storage are observed.

9.2. The operation lifetime is 5 years.

Observation of operation regulations can considerably increase the lifetime set by the manufacturer officially.

9.3. The warranty period of operation is 24 months from the date of sale.

9.4. The seller (manufacturer) or organization carrying out the functions of the seller (manufacturer) on a contractual basis is not responsible for the defaults should they occur after the disposal of the device as a result of:

- 1) a failure on the part of the consumer to comply with the rules of transportation, storage, care and operation provided for by the present manual;
- 2) mechanical damages;
- 3) actions of the third party;

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4) force-majeure.

9.5. Warranty obligations do not apply to products with broken manufacturer's seals.

9.6. In case of unit breakdown or malfunction within the warranty period, as well as in case if incomplete shipping is found, the owner must send the following documents to the manufacturer's address or manufacturers' representative: claim for repair (exchange) with name, address, telephone number; defects list with brief description of the malfunction, date and conditions of its appearance.