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

ДЭНАС
Руководство по эксплуатации
Часть 2. Инструкция по применению
ТУ 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

DENAS
Operations Manual
Part 2. User’s Instructions
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This User’s Instructions relate to portable transcutaneous analgetic electrostimulator with built-in electrodes for stimulation of biologically active points and zones DENAS.
1. STRUCTURE OF THE DEVICE

Fig. 1. DENAS device (front)
Fig. 2. DENAS device (back)
Fig. 3. DENAS device (side)
2. STRUCTURE AND OPERATION OF THE UNIT

2.1. The unit consists of the body 1 (Fig. 2,3) with built-in electrodes 2 (Fig. 2,3); lid 21 for power supply exchange (Fig. 2,3).

2.2. The unit has visual indication devices (Fig. 1):
— LED 6 — for indication of power supply exchange (Fig. 3);
— LED 9 («Test/Therapy») — operation mode control;
— LED 10 («End of test mode») — for control of the moment when the treatment in the test mode is over;
— LEDs 11 ...20 («Power») — control of stimulation power.

2.3. The unit has the following controls (Fig. 3):
— button 3 («On») — for switching the unit on;
— button 4 («Off») — for switching the unit off;
— button 5 («Mode») — for selecting «Therapy» and «Test» modes;
— button 7 («+») — for adding pulse power;
— button 8 («-») — for reducing pulse power.

In the “Test” mode, pulse parameters and duration of the procedure are set automatically due to biological back-up action. This provides individual dosed influence for each patient.
3. ORDER OF WORK

1) Switch the device on.
To do that press button “On”
LED “11” is on – the device is on.

2) Choose necessary mode of operation (see item 4.7. for recommendations of choosing the operation mode)

**Attention! Test mode is set in your device as preliminary.**
To switch the “Therapy” mode press “Mode” button.
When in the “Therapy” mode, LED “Test”/“Therapy” is on.
3) Apply the electrodes of the device to the part of skin to be treated (item 4.8)

4) Choose the power of treatment
   Power of treatment is set to minimum as preliminary. By pressing “+” button, you add treatment power gradually up to the maximum. LEDs showing the level of treatment power help control change of power.

   By pressing “-” button you reduce the power of treatment.
Attention! Control for adding power is carried out subjectively by the patient’s feelings when electrodes contact with the skin.

5) Carry out the procedure.
6) End of the procedure

In the “Test” mode, the device determines the duration of the procedure automatically depending on the electric resistance of skin in the subelectrode zone. After the end of the “Test” mode, you will hear a long sound signal.

The device operates in the “Therapy” mode permanently. Duration of the procedure in the “Therapy” mode is to be selected taking into account the recommendations in item 4.6. Note the time of the procedure.

The procedure is finished.
7) Switching off. Switch the device off after the procedure is finished. Press “Off” button – the device is off.
4. APPLICATION

4.1. Therapeutic action

Use of reflex zones and points for prophylaxis, treatment and functional recovery is one of the most ancient and efficient means of physio- and reflexotherapy.

Examinations show that the therapeutic action of dynamic electroneurostimulation (DENS) is based on multilevel reflex and neurochemical reactions triggering a cascade of regulatory and adaptive mechanisms of the body. This results in elimination of pain syndromes, improvement of blood circulation, anti-inflammatory actions, activation of biologically active substances and metabolic processes in tissues, normalization of the muscle and vascular tones. Dynamic electroneurostimulation provides for improvement of the general state of health, better mood and capacity for work.

Treatment is applied taking into account concomitant symptoms and syndromes:
— as an individual method of treatment with allergic reaction to pharmacotherapy and with contraindications to
application of other methods;
— as part of complex therapy in order to enhance the effect of basis drug, homeopathic and manual therapy as well as psychotherapy and other methods of treatment;
— as symptomatic treatment of different diseases and syndromes.
DENS can be applied in outpatients and steady-state conditions as well as home self- and mutual aid.

**ATTENTION!** Sharp pain of any localization can be the first and often the only sign of a serious disease. If the pain symptoms are unfamiliar and repeat, and the intensity of pain increases, one should immediately consult a doctor.

**Effects of the electroneurostimulation:**
— analgetic;
— anti-inflammatory;
— regulation of vascular tone;
— improvement of microcirculation;
— immunomodulatory and antiallergic;
— regulation of smooth and skeletal muscles tone.

4.2. **Indications:**
— pain syndromes;
— respiratory diseases, diseases of the digestive apparatus, the blood circulation system, the musculoskeletal system, the urogenital system, the nervous system, the endocrine system, the ENT, diseases of eyes and skin of adults and children;
— rehabilitation after diseases, surgical operations and traumas;
— influence of negative pathogenous factors (stresses, intensive physical and mental loads, other negative conditions).
4.3 Contraindications:

Absolute:
— individual intolerance to the electric current;
— implanted cardiostimulator;

Relative*:
— epileptic seizure;
— neoplasms of any etiology and localization (in the terminal stage of an oncological process, electrostimulation may be carried out as a palliative method (supportive therapy), including rapid relief of the pain syndrome);
— acute febrility of unclear etiology;
— vein thrombosis;
— condition of acute psychic excitement, alcoholic or drug intoxication.

**ATTENTION! Do not apply the device in the zone of direct heart projection at the front!**

* in these cases, it is recommended to use the electrostimulator only after consulting your attending doctor.
4.4. **Condition for treatment**

You do not need any special conditions for DENS treatment. The premises for electrotherapy should be dry, clean and light. Electrotherapy is taken in a comfortable sitting or lying position. After the treatment procedure, the patient should relax for 10-15 minutes.

The present manual describes zones and points of treatment to be used for dynamic electroneurostimulation with some widespread disease states. (See “The recommended zones and points of treatment”). More detailed information is provided in the Manual on DENS-therapy*.

During the procedure, the operator should hold the electrostimulator in one hand and manipulate it softly. The electrodes should always touch the patient’s skin during treatment. After each procedure, all electrodes are treated with a standard disinfecting solution (e.g. a 70% alcoholic solution). The device should be kept with dry electrodes.

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4.5. **Intensity of the electrostimulating treatment**

The level of energy treatment is determined by subjective sensations of the patient. Electrostimulation intensity is conditionally divided into three energy levels of influence: minimal, comfortable and maximal.

The first, on the threshold of sensations, minimal energy level - corresponds to low intensity of treatment, under which the patient does not have any subjective sensations or feels subtle vibrations. This level is used for treatment of small and preschool children and elderly patients.

The second, above threshold of sensations, under pain threshold, comfortable energy level - corresponds to medium intensity of treatment, under which the patient feels light pricking, vibration or light burning without pain. It is used as basic level of energy treatment.

The third, on the pain threshold, maximal energy level - corresponds to high intensity treatment, under which the patient feels expressed painful pricking or burning. Such intensity can be accompanied by involuntary contraction of
muscles close to the set electrode (myostimulating effect). It is used under “Therapy” mode only under expressed pain syndrome in teenagers and adults, or for emergency aid.

It is not recommended to carry out electropulse treatment in the range intolerable by the patient. Power of electrostimulation can be increased or reduced during the treatment course depending on the extent of the patient’s sensitivity and as the pain syndrome reduces.

4.6. Methods of application

Dynamic electroneurostimulation is applied using three methods: stable, labile and labile-stable.

Stable method of application (fixed electrodes) is used for treating small zones. With labile method of application, the built-in electrodes are moved smoothly within the application zone without taking them off the skin at 0.5–2–3 cm/sec. Movements are rectilinear, spiroid, circular and other depending on the size and shape (relief) of the zone treated.
With labile method of application fixation of built-in electrodes is allowed, e.g. in the pain zones. This is labile-stable method of application.

The degree of the apparatus pressing on the skin is defined by subjective sensations of the patient.

Average duration of one treatment procedure:
- for adults – 40 minutes;
- for children – 1 minute per one kilogram of the child's weight.

It is recommended to treat no more than three zones in one treatment procedure.

4.7. MODES OF THE DEVICE

TEST mode

TEST mode (corresponds to the former “dosed mode”) is used for searching for zones on which the electric resistance of skin is very different from the adherent zones (latent trigger zones) as well as for treating zones which
correspond to the zones of complaint (principle of symmetry).

Energy range of treatment: minimal and comfortable. Method of application is stable (electrodes are moved after
the sound signal).

It is forbidden to move electrodes of the device during its application in the “Test” mode.

**THERAPY mode**

THERAPY mode (corresponds to the former “constant mode”) is applied on the special zones by using built-in
electrodes. Energy range of application: from minimal to maximal. Methods of treatment of the chosen skin zone:
stable, labile, labile-stable.

Therapy mode is used for emergency aid, for treating localized pain syndromes and functional disorders and for
treating latent trigger zones.

The duration of the procedure in the therapy mode in the zone of direct projection of pain and functional disorder
is defined by the following reactions of the patient:
— the complaint is fully removed;
— the patient feel considerable improvement of the state of health;
— in the subelectrode zone bright reddening of skin is observed, sensation of pricking, warmth or lightness.
— the patient has fallen asleep.
The duration of treating one latent trigger zone is 1-5 minutes.

4.8. Recommended zones and points of application
4.8.1. Local zones of the lesion focus (zone of direct projection of the patient’s complaint)
One of the simplest and effective methods of DENS is treating directly the zones of detailed and localized pain zones, lesion focus or frontal surface of (skin) organ projection with disorder. The zone is to be treated in the therapy
mode until the clinical effect is achieved. For instance, for lumbodynia the electrodes are applied to the loins zone, for disorder of the knee-joint – directly to the zone of affected joint.

4.8.2. Metameric segmental zones

Position and distribution of roots of the spinal cord and nodes of the vegetative nervous system are subject to the metamerism laws. One and the same spinal limbs serve for transmitting information and innervation mechanism correspondingly from any internal organ and special skin zone (dermatome) and vice versa. The recommendation (see Table 1) allow applying DENS under the patient’s complaints in the zone of a special dermatome (Fig. 1, 2 of the Supplement) which has a regulating effect in the zone of the corresponding limb of the spine and a sympathetic ganglion and results in the required therapeutic effect.

Application in the zone of metameric and segmental zones is very easy and effective and has a scientific basis in terms of modern neurophysiology.
Table 1.

Peripheral parts of metameric and segmental zones (dermatomes) recommended for treatment with the device under pain syndromes and diseases of the musculoskeletal system

<table>
<thead>
<tr>
<th>Dermatomes</th>
<th>Symptoms and diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1 - C2</td>
<td>tension of occiput muscles, torticollis, tension and poor mobility of spinal muscles, pain in the shoulder, hemiplegia;</td>
</tr>
<tr>
<td>C3 - D1</td>
<td>affection of occiput muscles, pain in occiput, torticollis, affection of shoulder joints and muscles, back, hemiplegia;</td>
</tr>
</tbody>
</table>
| Th1 - Th2 | - tension in spinal cord,  
|           | - spasms of neck and back muscles (contraction),  
|           | - tension of occiput muscles, pain in the scapula, pain syndrome under affection of knee joints, paralysis of upper extremities; |
| Th2 - Th3     | - tension and pain of muscles of the back, loin, shoulder, occiput muscles, torticollis, intercostal neuralgia;  
<p>|              | - desensitization or analgesia of shoulder and ulnar skin. |
| Th3 - Th4    | disturbance of mobility in the neck, tension of occiput muscles, pain in the external surface of the shoulder, scapula, thorax, loins, abdomen, Lumbodynia, affection of the loins, sacral bone; |
| Th4 - Th5    | pain in the neck, affection of muscles and spine in the scapula level; |
| Th5 - Th6    | tension of back muscles and spinal cord, pain in the neck and thorax, intercostal neuralgia; pain in the spinal cord, and spasms in the back muscles (contraction); |
| Th6 - Th7    | feeling of contraction in occiput, pain in the neck and back, restriction of spine movement, contraction of back muscles, intercostals neuralgia; |</p>
<table>
<thead>
<tr>
<th>Segment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Th7 – Th8</td>
<td>pain in the muscles and joints of lower extremities, loins, paravertebral muscle contraction (cramped muscles along the spinal cord);</td>
</tr>
<tr>
<td>Th9 – Th10</td>
<td>Affection of the muscles and loins and lower extremities;</td>
</tr>
<tr>
<td>Th10 - Th11</td>
<td>- affection in the frontal abdomen, loins, - contraction and disturbance of spine movement,</td>
</tr>
<tr>
<td>Th11 – Th12</td>
<td>pain in the back, weakness in all limbs;</td>
</tr>
<tr>
<td>Th12 - L1</td>
<td>pain in the abdomen, back and spine;</td>
</tr>
<tr>
<td>L1 - L2</td>
<td>pain and contraction in the loins, contraction in the spine muscles and loins, edema of lower extremities;</td>
</tr>
<tr>
<td>L2 - L3</td>
<td>pain and tension in the neck and loins, feeling tension in the spine muscles, pain in the hip, paralysis of lower extremities, lumbodynia,</td>
</tr>
<tr>
<td>L3 - L4</td>
<td>affection of the muscles, skeleton and soft tissues of the loins;</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>L4 - L5</td>
<td>pain in the loins and backside of the pelvis, anesthesia of foot skin (Prot's disease), pain along the outer surface of the knee-joint, paralysis of lower extremities;</td>
</tr>
<tr>
<td>L5 - S1</td>
<td>paralysis of lower extremities, lumbodynia, lumbago, lumbosacral radiculitis;</td>
</tr>
<tr>
<td>S1 - S2</td>
<td>pain in the abdomen, sacral bone and hip joint, lumbago;</td>
</tr>
<tr>
<td>S2 - S3</td>
<td>pain in the sacral bone, loins, spine, affection of knee joints, pain in the joints of lower extremities;</td>
</tr>
<tr>
<td>S3 - S4</td>
<td>pain in the loins, lumbosacral radiculitis, pain in the spine;</td>
</tr>
<tr>
<td>S4 - S5</td>
<td>pain in the loins and back, sacrococcygeal pains, pain in the lateral surface of the buttock, lumbodynia, lumbosacral radiculitis, tension in the spinal muscles, weakness of legs muscles, paralysis of legs, paralysis of lower legs and foot muscles.</td>
</tr>
</tbody>
</table>
4.8.3. Zones of general treatment

These zones are included into the treatment course when it is necessary to stabilize the therapeutic effect of local and segmental reaction and obtain expressed general adaptive reaction of the organism.

1) Medium spinal line and two paravertebral lines (close to the spinal cord) – Fig. 3, 4 of the Supplement;
2) Projection of the trigeminal nerve branch on the face (Fig. 5 of the Supplement);
3) Hands and feet (hands are treated from the wrist joint to the finger-tips on the palm and back surface of the hand, feet are treated from the ankle-joint to the tip-toes on the plantar and back surfaces).

General zones are treated in the “Test” mode. After finding latent trigger zones (see below), they are treated in the “Therapy” mode.

4.8.4. Trigger zones

Dysfunction and structural disorders in internal organs result in the zones of abnormal coloring, sensitivity, in-
creased tenderness, zones of hardening, changed electroconductivity and other changes on some limited skin areas, in the muscles, tendons, periosteum which is not characteristic of a healthy organism and not found in other symmetrical parts of the body. These pathologic zones and points were named "trigger" zones.

Trigger zones (TZ) are conditionally divided into active and latent.

The doctor finds active TZ after inquiry and examination of the patient – these are local zones of referred pain and hypersensitization (e.g. Fig. 6, 7 of the Supplement).

Latent TZ are defined in the "Test" mode by the difference of indexes in the tested points. After finding, latent trigger zones are treated in the "Therapy" mode.
5. SPECIAL EMC-INFORMATION:

5.1. The use of accessories, transducers, cables and cable length other than those specified, with the exception of transducers and cables sold by JSC RC ART as replacement parts for internal components, may result in increased emission and/or decreased immunity of the Portable electrostimulator DENAS.

5.2. The Portable electrostimulator DENAS uses electromagnetic energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

The Portable electrostimulator DENAS is suitable for use in all establishments including domestic establishments.

The Portable electrostimulator DENAS should not be used adjacent to or stacked with other equipment, and that if adjacent or stacked use is necessary, the DENAS and the other equipment should be observed to verify normal operation in the configuration in which it will be used.
5.3. Electromagnetic Environment guidance

The Portable electrostimulator DENAS is suitable for use in the specified electromagnetic environment. The customer and/or the user of the DENAS should assure that it is used in an electromagnetic Environment as described below.

Electrostatic discharge (ESD): Floors should be wood, concrete, or ceramic tile. If Floors are covered with synthetic material, the relative humidity should be at least 40%.

Conducted and radiated RF: Portable and mobile RF communications equipment should be used no closer to any part of the DENAS including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter:

Recommended Separation distance \( d = 2,3 \sqrt[3]{P} \) (800 MHz to 2,5 GHz)

(The Factor 2,3 is a function of frequency)

\( P \) is the maximum output power rating of the transmitter in Watts [W] according to the transmitter manufacturer.
Power frequency magnetic field: It should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.

5.4. Description of the actions, the user must take to reduce environmental levels of the disturbance:

*Electrostatic discharge (ESD)*: A recommendation that all stuff involved receive an explanation and training in ESD precautionary procedures.

- Stuff must be made aware to precautionary procedures:
  - Used shouldn’t use synthetic clothing;
  - 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 stuff in ESD-precautionary procedures.

*Radiated RF*:

User should: Keep a separation distance of minimal approx. 3 meter with portable communication devices, such as cellular/cordless telephones with a maximum output power of 2 Watt.
ПРИЛОЖЕНИЯ
SUPPLEMENT
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Fig. 2. Segmental innervation of the human body (back).
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Fig. 6. Topography of trigger zones under some internal diseases on the frontal surface (zones of sensation of pain and hyperesthesia of Zakharyin-Ghed).
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Fig. 7. Topography of trigger zones under some internal diseases on the posterior surface (zones of sensation of pain and hyperesthesia of Zakharyin-Ghed).