RC ART LLC
Ekaterinburg, Russia

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DENS applicator
A set of detachable zone-specific electrodes

DENS·APPLICATOR

Arrangement version 2

OPERATING MANUAL

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PART 1

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Technical Passport

1. INTENDED USE

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The DENS Applicator set of detachable zone-specific electrodes is intended for treatment of pain areas, lesion foci and reflexogenous zones. These electrodes are intended for repeated application at hospitals and outpatient clinics and for individual application.

The detachable zone-specific electrodes can only be used with DENS therapy devices.

2. SAFETY RULES

Please read carefully the information contained in this Operating Manual related to your safety and recommendations for correct application and maintenance of the unit.

The DENS Applicator set of detachable zone-specific electrodes may not be used to treat patients with implanted electronic devices (such as the heart pacemaker) and to treat patients with idiosyncrasy to electric current.

The unit may not be used in the area of direct anterior projection of the heart.

During stimulation the patient should not be connected to any high frequency electric device. Simultaneous use of the unit and other electric devices may cause burns and damage the electrode.

The electrode may not be connected to any other devices, except for DENAS and DiaDENS series units.

Do not connect two or more electrodes to one device simultaneously.

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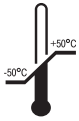
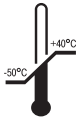
Do not bend the detachable zone-specific electrodes at an angle less than 90^0.

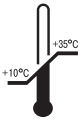
All maintenance jobs must be performed by skilled technicians at the manufacturing factory.



Transportation conditions: temperature -50 to +50 ^{0}C, relative air humidity 30 to 93 %, atmospheric pressure 70 to 106 kPa.



Storage conditions: temperature -50 to +40 ^{0}C, relative air humidity 30 to 93 %, atmospheric pressure 70 to 106 kPa.



Operating conditions: temperature +10 to +35 ^{0}C, relative air humidity 30 to 93 %, atmospheric pressure 70 to 106 kPa.

If the unit was stored at the ambient temperature below 10 ^{0}C keep it under normal climatic conditions for at least two hours before operating.

Recycling: the unit packaging materials are not hazardous for the environment; they can be recycled.

3. TECHNICAL PARAMETERS

3.1. Parameters of detachable zone-specific treatment electrode No. 3:
— max weight 50 g;
— max dimensions 100x119 mm.

3.2. Parameters of zone-specific electrode No. 4:
— max weight 50 g;
— max dimensions 170x80 mm.

3.3. Parameters of zone-specific electrode No. 5:
— max weight 50 g;
— max dimensions 131x131 mm.

3.4. Min electrode cable length 1300 mm.

4. ARRANGEMENT

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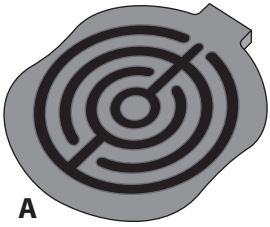
Arrangement is as shown in Table 1.

Table 1

Name	Number, pcs.
Detachable zone-specific treatment electrode No. 3	1
Detachable zone-specific treatment electrode No. 4	1
Detachable zone-specific treatment electrode No. 5	1
Short cuff	1
Medium length cuff	1
Long cuff	1
Connection cable	1
Operating manual	1



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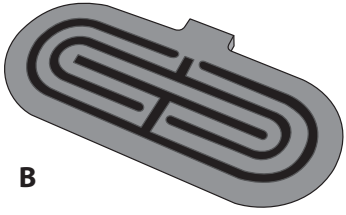
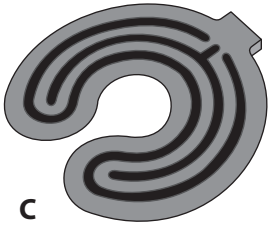


B

Detachable area-specific electrode No. 3 (picture A) and 4 (picture B) are intended for treatment:

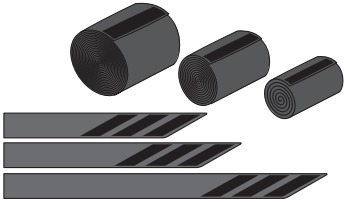
— in the direct projection of the lesion focus on the body and the extremities;

— in the paravertebral areas at the level of the damaged spine segment.



C

Detachable area-specific electrode No. 5 (picture C) is intended for treatment of the spherical surfaces (the joints).



The long cuff is intended for fixation of the detachable zone-specific electrodes on the body.

The medium length and long cuff are intended for fixation of the detachable zone-specific electrodes on the extremities.

Picture 1. Appearance and intended use of DENS applicator components

5. MAINTENANCE

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Daily maintenance must include the following steps:

— external inspection;

— disinfection (to clean the electrodes, use standard disinfectants and soft pile-free tissues);

— function check of the electrode after connection to DENAS or DiaDENS units.

6. WARRANTY

6.1. The manufacturer guarantees that the product meets the specification provided that the operation, transportation and storage conditions are complied with.

6.2. Lifetime of the product is 5 years.

Provided that the operating rules are followed, the lifetime may considerably exceed the officially established term

6.3. The guaranteed service life of the product is 6 months of the date of sale.

6.4. The buyer shall check the product for completeness and carry out visual inspection of the product upon receipt of the product in the presence of the seller. No post-purchase claims related to completeness and appearance defects shall be accepted.

6.5. If any defects are discovered during the warranty term, the Seller (Manufacturer) shall satisfy all claims made by the User as specified in the Law of the Russian Federation *On Protection of Consumer Rights*. The Seller (Manufacturer) or any company acting as such under the contract with the Seller (Manufacturer) shall not be liable for defects if they have occurred after the transfer of the unit to the consumer due to:

1) failure of the user to observe the transportation, storage, maintenance and operation rules laid forth in this Manual;
2) third parties' actions;
3) circumstances of force majeure.

6.6. In case of failure of the product during the effective term of the warranty and in case of discovery of certain components

missing, the owner shall send to the manufacturer or its representative a repair (replacement) request containing his/her full name, address and telephone number and a short description of the defect and the conditions and date of its occurrence All defects shall be removed at the manufacturer's facility or the manufacturer's service centres.

Manufacturer's address
RC ART LLC
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Ekaterinburg, Russia, 620146
Tel./fax: +7 (343) 267-23-30
e-mail: corp@denascorp.ru

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Devon, PL9 8HG
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PART 2

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Application Instruction

1.GENERAL

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It is recommended to use the detachable therapeutic zone-specific electrodes as an alternative to the integrated electrodes on the unit for stimulation of reflexogenous zones and the direct projection of the lesion focus. Using the detachable electrodes, you can:

— carry out treatment in areas that are difficult to reach without assistance;
— make the treatment comfortable and convenient where the treatment procedures have to be long or repeated many times;
— make the procedures much less work-consuming.

Applications and restrictions for the application of detachable zone-specific electrodes are identical to indications and counter-indications for the application of respective dynamic electrical nerve stimulation units and are listed in operating manuals for DENAS and DiaDENS series units.

Warning! *The electrode may not be connected to any other devices, except for DENAS and DiaDENS series units.*

Warning! *Sudden pain of any localization may be the first and often the only sign of a serious disease. That is why if pain attacks happen for the first time, occur repeatedly and pain intensity increases, consult a physician as soon as possible.*

Warning! *Do not apply the electrodes directly in areas with damaged skin (wounds, skin diseases).*

2. TREATMENT CONDITIONS

The procedure does not require any special conditions. Treatment can be delivered without anyone's assistance. The room where the procedure is carried out should be dry and warm. During the procedure, the patient may be seated in an armchair or lie in a comfortable position, making sure that the electrodes fit tightly against the skin.

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3. TREATMENT PROCEDURE USING DENS APPLICATOR

For hygienic purposes, wipe the electrode with soft pile-free tissue moistened with a standard disinfectant solution (such as 3% hydrogen peroxide solution).

Warning! *If the skin is very dry, you may slightly moisten the skin surface with the physiological salt solution or a small quantity of cream from the Malavtiline series 5 to 10 minutes before application of the detachable electrode to make sure that the electrodes are in tight contact with the skin and to enhance the treatment effect.*

3.1. Fix the detachable zone-specific electrode in the area to be treated: for example in the zone of direct projection of the most painful area in case of back pain or on the respective joint in case of joint pain. If needed, treat the respective segmental zones using the electrode.

3.2. Connect the electrode to the dynamic electrical nerve stimulation unit (if needed, use a special adapter).

3.3. Switch on the dynamic electrical nerve stimulation unit. Select the required stimulation frequency on the unit. Use the respective buttons to set the treatment intensity (see the treatment frequency and intensity setting procedure in the operating manual for the respective unit)

Warning! *When using detachable therapeutic electrodes, you can only treat in the Therapy mode.*

3.4. Carry out the procedure. The duration and number of procedures depends on the patient's age and the goals and objectives of the procedure. See recommended procedure duration in the operating manual for each particular device.

3.5. Upon completion of the procedure, switch off the unit, disconnect the electrode and take off the cuffs. Wipe the electrodes with a disinfectant solution (such as 3% hydrogen peroxide solution).

Warning! *The electrodes should be stored dry.*