

# Remote zonal electrode **DENS-APPLICATOR** OPERATION INSTRUCTIONS

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# PART 1

## TECHNICAL PASSPORT

### 1. FUNCTION

The remote zonal electrode DENS-APPLICATOR is intended for prophylactic and therapeutic noninvasive treatment of biologically active zones.

It is intended for home and clinical use.

The remote zonal electrode will be used only together with electrostimulators of the DENAS or DiaDENS series.

### 2. TECHNICAL CHARACTERISTICS

2.1. Characteristics of the zonal electrode # 1:

— mass, kg, not exceeding .....	0.1
— overall dimensions, mm, not exceeding .....	120x120
— number of metal electrodes, items	9

2.2. Characteristics of the zonal electrode # 2:

— mass, kg, not exceeding .....	0.1
— overall dimensions, mm, not exceeding .....	2200x60
— number of metal electrodes, items .....	7

2.3. Diameter of the metal electrode, mm, not exceeding 15

2.4. Length of cable of the electrode, mm, not exceeding 700

2.5. Total weight of the assembly, kg, not exceeding.....0.4

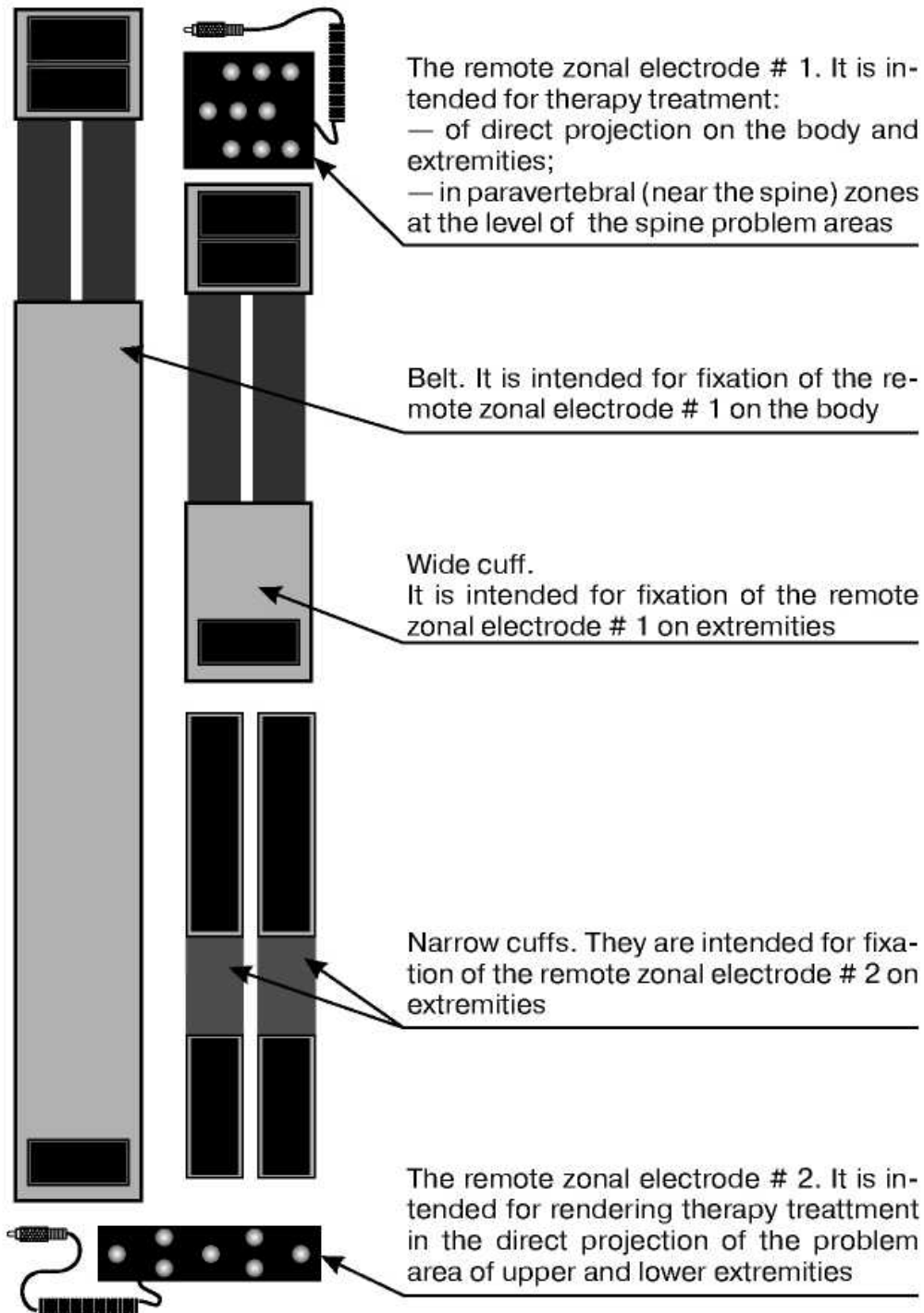
### 3. COMPLETE ASSEMBLY

The complete assembly in accordance to Table 1.


**Table 1**

Name	Number, items
The remote zonal electrode # 1	1
The remote zonal electrode # 2	1
Belt	1
Wide cuff	1
Narrow cuff	2
Operation Instructions combined with passport and instruction for application	1
Packaging	1

Figure 1. Appearance and function of the DENS-APPLICATOR assembly components



## 2. SAFETY RULES

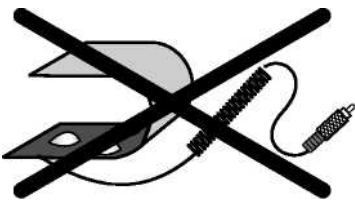
 Please read carefully the information contained in this Operation Instructions! It contains important guidelines for your safety, as well as correct use and maintenance of the device.

The device must not be used for treatment and diagnosis of the patients with implanted electronic devices (for instance, cardiostimulator) or patients with individual intolerance of electric current.

During stimulation, the patient must not be connected to any high-frequency electrical device.

**Attention!** You must not connect the electrode to any other devices except for the DENAS series or DiaDENS devices.

**Attention!** Do not simultaneously connect two and more electrodes to the device.



**Attention!** Do not bend the remote zonal electrodes # 1 and # 2 at the angle lesser than 90°.

## 5. TECHNICAL MAINTENANCE

Daily technical maintenance must consist of the following:

- visual inspection of the device;
- disinfection (for cleaning the electrode, use standard disinfectants and soft cleaning tissues);
- checking electrode function will be performed by connecting it to DENAS or DiaDENS series devices.

## 6. MANUFACTURER WARRANTY

6.1. The manufacturer guarantees that the device complies with requirements of Technological Conditions (TC) provided that the operation, transportation and storage conditions are observed.

6.2. Device service life: 5 years.

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

6.3. The device limited warranty: 24 months from the date of sale.

6.4. Complete assembly and appearance of the item will be checked upon receipt of the product in presence of retailer.

After sale, no claims on complete assembly or appearance will be accepted.

6.5. 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 consumer's rights."

Retailer (manufacturer) or a company acting as a retailer (manufacturer) based on the contract 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) breaking the rules of transportation, storage, maintenance and operation by the user, as these rules are indicated in this Operation Instructions;
- 2) actions by third parties;
- 3) force major circumstances.

6.6. In the event of the 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 manufacturer, indicating surname, name, patronymic, address, telephone, brief description of the defect, date and conditions of its occurrence.

## **7. STORAGE AND TRANSPORTATION**

Transportation 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.

## **2. UTILISATION**



All packing materials are environmentally safe can be reused.

All materials used for the device are recyclable.

## PART 2

# OPERATION INSTRUCTIONS

### 1. GENERAL CONSIDERATIONS

DENS-APPLICATOR will be used for treating areas of skin inaccessible for treatment by the patient him- or herself or when there is no time with available for applying built in electrode.

The dynamic electroneurostimulation (DENS) through the remote zonal electrode will be used for treating pain syndromes associated with diseases of muscular-skeletal (2x) system of inflammatory, degenerative or traumatic origin, and for relieving headaches.

The DENS, through the remote electrode will be used for relieving muscle tension, for prophylaxis of functional disorders of the muscular-skeletal system associated with prolonged fixed body positions during work (including working on a computer), training, flights, car trips, or when physical exercises are not feasible.

Reliable fixation of the electrode on the body will provide convenience and comfort during the therapy session: the patient can seat in comfortable position and apply DENS independently.

**Attention!** *The first and often the only sign of a serious disease might involve a sudden sharp pain of any localization. Therefore if the pain occurred for the first time and reoccurs, consult your physician immediately.*

See contraindications in respective sections of Operation Instructions for DENS-therapy devices (the devices of DENAS and DiaDENS series).

### 2. THE TREATMENT CONDITIONS

No special conditions are required for operating DENS. During the DENS-APPLICATOR session, the patient must be seated or lying down. The metal electrodes must be in permanent contact with patient's skin during the procedure.

### 3. CONDUCTING DENS-SESSION WITH DENS-APPLICATOR

To follow hygienic requirements, it is recommended to treat the metal electrode surfaces before each procedure, the electrodes will be treated with a standard disinfecting solution (e.g. 70% rubbing alcohol) applied with soft cleaning tissues.

**Attention!** *You must not connect the electrode to any other devices except for DENAS or DiaDENS series devices.*

**Attention!** *Before using the remote electrode, in order to reinforce the DENS effect, the skin in the action area may be treated with small amount of Malavtilin ointment until completely absorbed.*

When working with the remote zonal electrode it is necessary:

- 1) To fix the remote zonal electrode on the belt or cuff (see Figures 1,2):

Figure 1. Fixation of the remote zonal electrode # 1 on the belt and wide cuff.

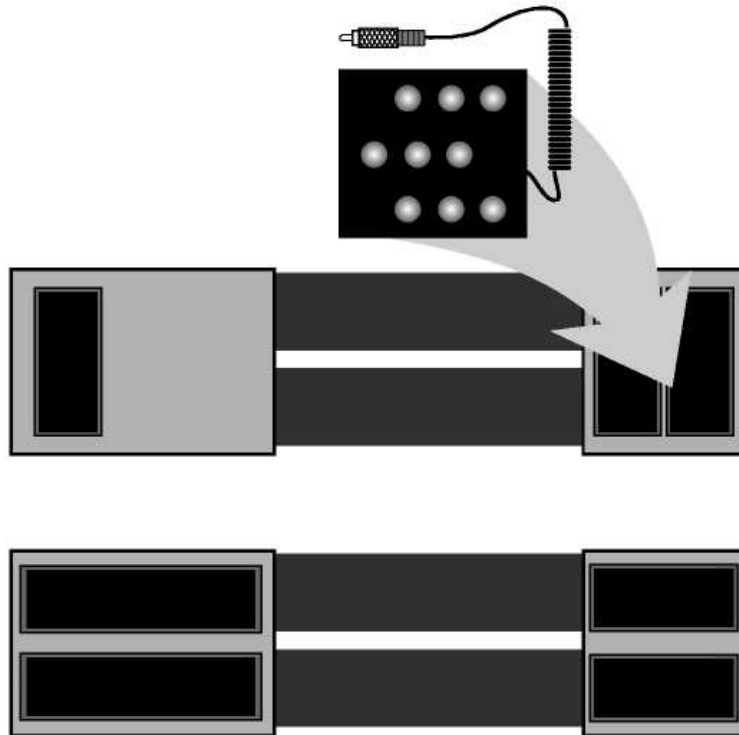
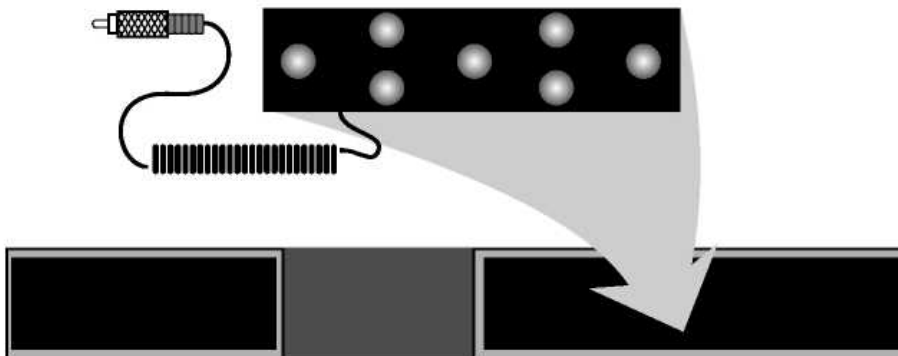
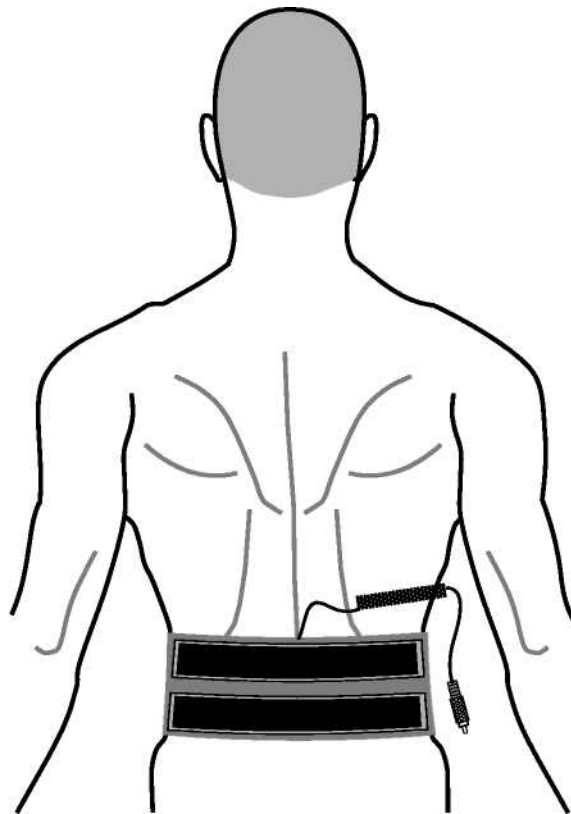


Figure 2. Fixation of the remote zonal electrode # 2 on the narrow cuff.



2) To fix the remote zonal electrode in the direct projection of a problem area: for back pain - at the area of the maximal discomfort; for joint pain - at the respective joint. The DENS can be applied to segmental problem zones (p. 4.2). The electrode must be firmly fixed upon the skin; do not shift the electrode during session.

Figure 3. Fixation of the remote zonal electrode # 1 on the body with the aid of belt in the paravertebral (spine) area in the small of the back.



The cuffs will be used for fixation of electrodes on extremities (Fig. 4, 5, 6, 7).

Figure 4. Fixation of the remote zonal electrode # 1 in the knee joint area

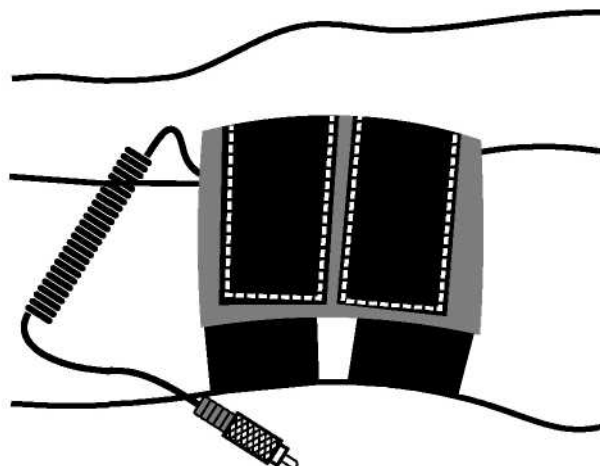


Figure 6. Fixation of the remote zonal electrode # 2 in the elbow joint area

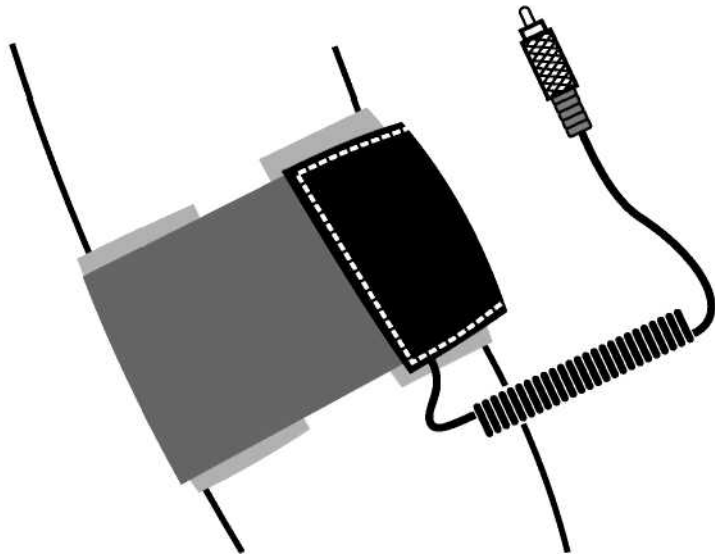
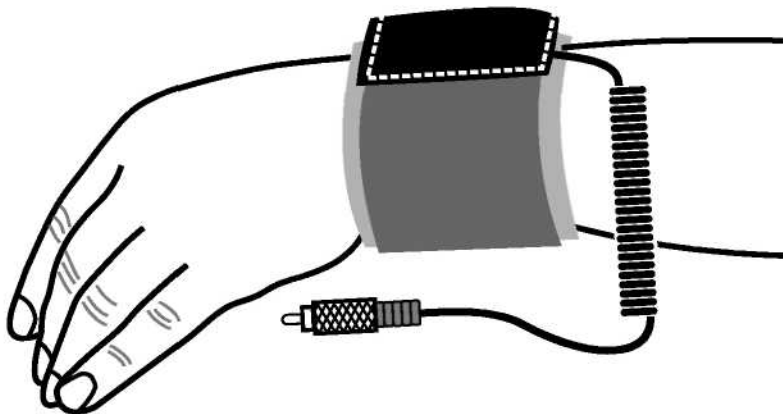


Figure 7. Fixation of the remote zonal electrode # 2 in the radiocarpal area



- 3) To connect the electrode to the dynamic electroneurostimulation device:
  - the electrode will be connected to the "DENAS" device through stand;
  - to the DENAS+ device - through the adapter;
  - to the devices of the "DiaDENS" series - directly.
- 4) To switch the device on, pushing the "On" key.
- 5) To switch on the THERAPY regime at the frequency 77 Hz (for the DENAS and DENAS+ devices) or at the frequencies 20, 60, 77, 140 or 200 Hz (for the DiaDENS series devices) and select the necessary range of energy action (see the principle of selection of the frequency and intensity of the action in the Operation Instructions for respective device).

**Attention!** *The remote therapeutic electrode must only be used in the THERAPY regime.*

Conducting the session.

The duration of procedure in the THERAPY regime, in the zone of direct projection of problem area and metamer-segmental zones, should not exceed 60 minutes per session and will depend on the patient's responses as follows:

- the complaint has been completely eliminated;
- the patient feels considerable improvement.

To relieve muscle tension due to prolonged fixed body positions, the DENS will be applied for 10-15 minutes. The action can be repeated with 1-1.5-hour intervals.

7) Having completed the session, push the "Off" key, disconnect the electrode from the device, take off the straps, and treat electrodes with disinfecting solution (e.g. 70% rubbing alcohol).

**Attention!** *Keep the electrodes dry.*

## **4. THE RECOMMENDED ZONES OF ACTION**

### *4.1. Local problem area (the zone of direct projection of the problem area)*

One of the simplest and effective ways of applying DENS involves acting directly on the area of detailed and localised pain. The zone will be treated in the THERAPY regime until clinical effect is achieved. For instance, for lumbalgia, on the small of the back zone; in knee joint damage, directly upon the damaged joint area.

### *4.2. Metamer-segmental zones*

The location and distribution of the spinal nerve roots, nerves, nervous plexuses and of the vegetative nervous system nodes are subject to the law of metamerism. The same spinal segments will serve, at that, as the innervation device and, respectively, the device transferring information from an internal organ and a certain skin area (dermatomer) and back. The existing recommendations (see Table 1 below) make it possible to apply DENS within the spinal projection and paravertebral (near the spine) zones as well as in areas of a certain dermatomer, e.g. in headache - back of the neck area (see Figure 8 below).

**Table 1.** The dermatomers recommended for treatment using the DENS-APPLICATOR  
Conventional designations:

*C - dermatomers of the spinal cord cervical segments D - dermatomers of the spinal cord thoracic segments L - dermatomers of the spinal cord lumbar segments S - dermatomers of the spinal cord sacral segments*

Skin der- matomers	Symptoms
C3, C4, D2	— headache, dizziness; — tension of the occipital muscles, pain in the back of the head, torticollis, pain in the shoulders, back, small of the back, sensation of the spine tension, muscle spasms in the neck and back (contraction), tension of occipital muscles, pain in the scapular area, pain in the knee, pain in the joints
D2,D3	— pain and tension of muscles in the areas of the back, small of the back, shoulder, occiput, torticollis, intercostals neuralgia; — reduced or absent sensitivity of the shoulder and elbow area
D3,D4	movement disorders in the neck area, tension of the occipital muscles, pain in the shoulder external surface, that of scapula, in the chest, in the small of the back area, in abdomen, pain in the sacrum and in the back
D4, D5	— headache; — diseases of the neck, pain in the scapula, in the area of shoulder and back
D5, D6	— headache, dizziness; — tension of the back and spine muscles, pain in the back and in the chest, intercos-tals neuralgia, pain in the spine and spasm of the back muscles (contractions)
D6, D7	pain in the back and in the neck, limited mobility of the spine, contractionsofthecontractionsofthe of the back muscles, intercostals neuralgia
D7, D8	pain in the small of the back and in the back, intercostals neuralgia, paravertebral muscle contraction (muscle spasm along the spine)
D9,D10	— pain in the small of the back and in the back, sensation of "unrest" in the spine area; — pain in the chest and in the hypocho-n-drium
D10.D11	pain in the abdomen, small of the in the back and in the back, contractions and limitation of the spine mobility, intercostals neuralgia
D11.D12	pain in the back
D12.L1	pain in the back and in the spine

L1,L2	— pain and contractions in the lumbar area, muscle tension in the spine and small of the back, oedemas in the lower extremities; — damage to the lower extremity joints; — pain and tension in the small of the back and in the back, sensation of tension in the spine muscles, pain in the hip, lumbalgia
S2, S3, S4	— pain in the sacrum, small of the back, spine, sensation of weakness in the knee joint, pain in the joints; — pain in abdomen, sacrum and hip joint, lumbago
S3,S4	pain in the small of the back, sciatica, pain in the spine
S4, S5	pain in the small of the back, in the back, sacral-coccygeal area, pain in the area of lateral surface of the buttock, lumbalgia, sciatica, tension of the spine muscles, weakness of the leg muscles

Figure 8. Disposition of dermatomers on the human body posterior surface

