

ООО «РЦ АРТ», Екатеринбург, Россия

RU

**Электростимулятор с внутренними  
и выносными электродами портативный  
для стимуляции БАТ и БАЗ «ДиаДЭНС-ПКМ»**

**ДиаДЭНС-ПКМ  
РУКОВОДСТВО ПО ЭКСПЛУАТАЦИИ**

**РЦ АРТ 04.0-03.11-01 РЭ  
ТУ 9444-002-35266303-2005**

LLC RC ART, Ekaterinburg, Russia

EN

**Portable electrostimulator with built-in and external  
electrodes for stimulation  
of BAZ and BAP “DiaDENS-PCM”**

**DiaDENS-PCM  
Operations Manual**

**RC ART 04.0-03.11-01 RE  
TU 9444-002-35266303-2005**

“RC ART” GmbH, Ekaterinburg, Russland

DE

**Tragbarer Elektrostimulator mit Innen- und Ausgangselek-  
troden für die Stimulation von BAP und BAZ sowie für die  
Elektropunkturdiagnostik**

**DiaDENS-PCM  
BETRIEBSANLEITUNG**

**RC ART 04.0-03.11-01 RE  
TU 9444-002-35266303-2005**

## CONTENTS

### **Part 1. Technical Passport**

1. Safety Measures.....	50
2. Function.....	53
3. Specifications.....	54
4. Complete Set.....	58
5. Apparatus Arrangement.....	59
6. General recommendations.....	63
7. Operating the Menu.....	65
8. Technical Maintenance.....	71
9. Change of power source.....	72
10. Troubleshooting List.....	73
11. Guarantees of the Manufacturer.....	74

### **Part 2. User's Instructions**

1. Main Performance Data.....	76
2. Indications and Contraindications to Application.....	77
3. Conditions of Treatment.....	78
4. Intensity of the Electrostimulating Treatment.....	78
5. Methods of Application.....	79
6. Treatment with Apparatus.....	80
7. MED (prophylaxis).....	86
8. Screening.....	88
7. Special EMC-Information.....	89
Certificate of Acceptance.....	137
Coupon for Warranty Repair.....	139

This Operations Manual is intended for the DiaDENS-PCM portable electrostimulator with built-in and external electrodes for stimulation of biologically active points and zones (BAP and BAZ).

The Operations Manual includes a Technical Passport (part 1) and User's Instructions (part 2).



**Compliance with standards:**

***This medical device is CE marked according to the Directive 93/42 /EEC on medical equipment.***

## PART 1 TECHNICAL PASSPORT

### 1. SAFETY REGULATIONS



Read carefully all information in this instruction for use that contains important information on your safety and recommendations on proper use and maintenance of the device.



The device doesn't constitute any danger because of internal power source of low voltage that is isolated from work part of the apparatus (article of type B and work part of type F).



The apparatus must not be used for treatment of patients with implanted electronic devices (for example, pacemaker) and for treatment of patients who have individual electric current intolerance.



The device use in direct front projection of heart is prohibited.



Don't switch patient to any high-frequency electric device during stimulation, simultaneous use of the device and other electric equipment can bring to burn and possible damage of the device.



Work alongside short-wave and microwave equipment can bring to instability of output parameters of the device.



You must not switch to the device any other accessories except external electrodes produced by manufacturing firm.



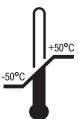
The article has fragile elements. Protect against knocks.



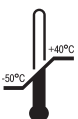
The device is not waterproof. Protect against water penetrating.



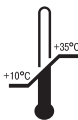
Maintenance of the device must be provided by qualified specialists in manufacturing firm.



**Transporting conditions:** temperature from  $-50^{\circ}\text{C}$  to  $+50^{\circ}\text{C}$ , relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa.



**Storage conditions:** temperature from  $-50^{\circ}\text{C}$  to  $+40^{\circ}\text{C}$ , relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa.



**Service conditions:** temperature from  $10^{\circ}\text{C}$  до  $35^{\circ}\text{C}$ , relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa.

If the device was being kept at the temperature below  $10^{\circ}\text{C}$ , keep it in normal climate conditions no less than 2 hours before use.



Utilization:

All packaging materials are not environmentally harmful, it may be used repeatedly.



Separate collection of electrical and electronic equipment.

Used device is not absolutely useless garbage! It contains valuable materials that may be used again after the utilization considering preservation of the environment requirements. Deliver it to special services (consult with appropriate services of your region) for collection and remaking.

## 2. FUNCTION

The DiaDENS-PCM apparatus is used for electrostimulation of biologically active points and zones (BAP and BAZ). The apparatus has built-in electrodes as well as a slot for connection of external electrodes — DENS-APPLICATOR\*.

The DiaDENS-PCM apparatus is intended for individual application in patient care institutions and in life conditions in compliance with the recommendations of the attending doctor.

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\* *In addition, other external electrodes produced by the manufacturer can be applied with this apparatus.*

### 3. SPECIFICATIONS

3.1. Electric impulse (fig. 1) parameters have the following output parameters:

3.1.1. Minimal impulse parameters:

- duration of the positive impulse,  $\mu\text{s}$ , not more than.....5
- amplitude of the positive impulse, V, not more than.....10
- amplitude of the negative impulse, V, not more than.....10

3.1.2. Maximal impulse parameters:

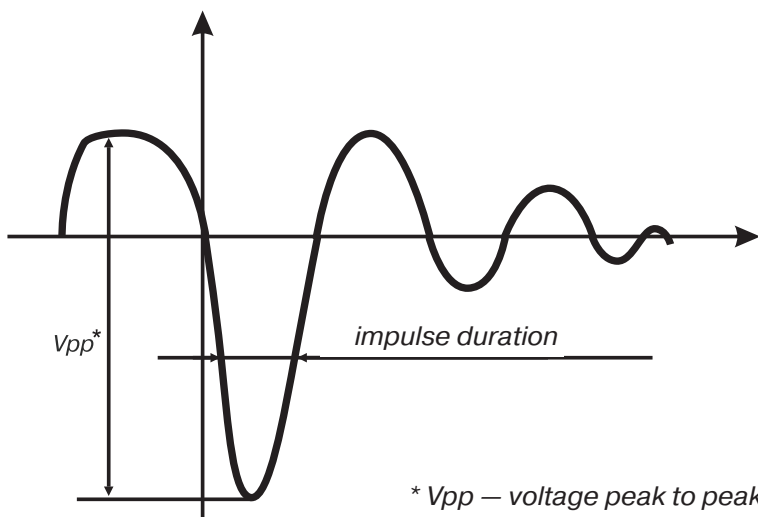
- duration of the positive impulse,  $\mu\text{s}$ ..... $500 \pm 70$
- amplitude of the positive impulse, V..... $30 \pm 10$
- amplitude of the negative impulse, V:

without load..... $350 \pm 70$

with load ( $20 \pm 5\%$ ) kOhm..... $300 \pm 70$

3.1.3. Minimum load resistance under which the parameters of the impulse keep,  $R_{\text{min}}$ .....500 Ohm

Figure 1. Impulse form



\*  $V_{pp}$  — voltage peak to peak

3.1.4. Amplitude of signal at the min power is 8% of amplitude of signal at max power ( $R=20\text{ k}\Omega$ ).

3.2. The apparatus provides the following frequencies of impulses, Hz:

3.2.1. Range 1:

—  $10\pm 1$  including for MED (prophylaxis) and SCREENING modes;

—  $20\pm 1$ ;

—  $60\pm 2$ ;

—  $77\pm 2$ ;

—  $77\pm 2$  and  $10\pm 1$ , modulated by frequency  $2\pm 0,1\text{ Hz}$  (“7710” mode);

—  $77\pm 2$  with modulation by amplitude (“77AM” mode);

—  $140\pm 3$ ;

—  $200\pm 3$

3.2.2. Range 2 – from 1,0 to 9,9 with spacing  $0,1\pm 0,05$ .

3.3. Maximum consumable current

(with 3 V voltage), mA, not more than.....300

3.4. Power supply: Battery type LR6/AA,

2 pcs, voltage, V..... $1,5\pm 0,45$

It is allowed to use corresponding accumulators with nominal voltage 1.2 V\*

3.5. Weight, kg, not more than.....0,35

3.6. Weight including external therapeutic electrodes DENS-APPLICATOR, kg, not more than.....0,8

3.7. Dimensions of the apparatus,


mm, not more than.....145x55x55

3.8. For specifications of external zonal electrodes DENS-APPLICATOR, see the Operations Manual of the Set of External Zonal Electrodes DENS-APPLICATOR.

3.9. The apparatus automatically switches off not later than in 10 min after the last touch of any of the buttons (except the

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\* *Order of Operation (types of chargers, charging methods) is given in the Manual for accumulators; period of work of the apparatus with accumulators depends on the accumulators' specifications.*

button ) or after the last contact of the electrodes to the patient's skin.

### 3.10. Electromagnetic Emissions

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

### 3.11. 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

### 3.12. Electromagnetic Immunity

Immunity Test	Test Level	Compliance Level	Guidance electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±4kV contact ±8kV 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 mag- netic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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3.13. 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



— Device of type B and work part of type F.

**4. COMPLETE SET**

The complete set of delivery of the DiaDENS-PCM apparatus should correspond to Table 1.

Table 1

Name	Quantity
Portable electrostimulator DiaDENS-PCM	1
Operations manual including a technical passport and user's instructions	1
Package	1
Power source	2
Holder lace	1

## 5. APPARATUS ARRANGEMENT

Figure 2. DiaDENS-PCM (front)

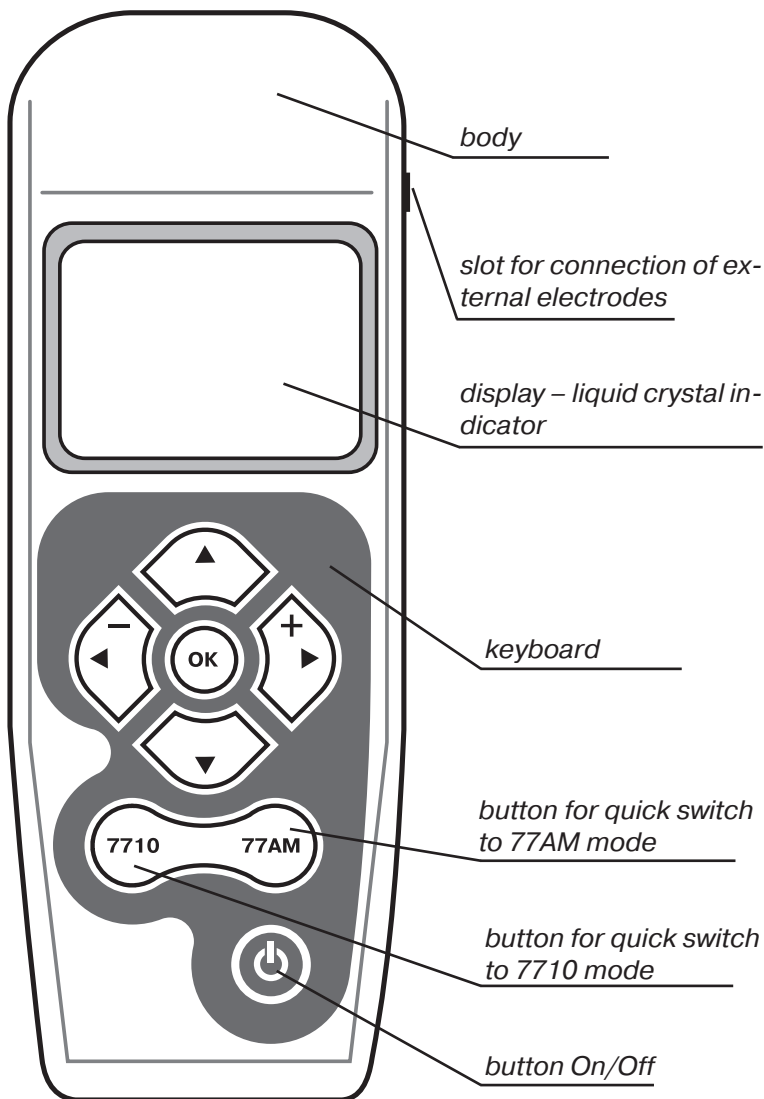
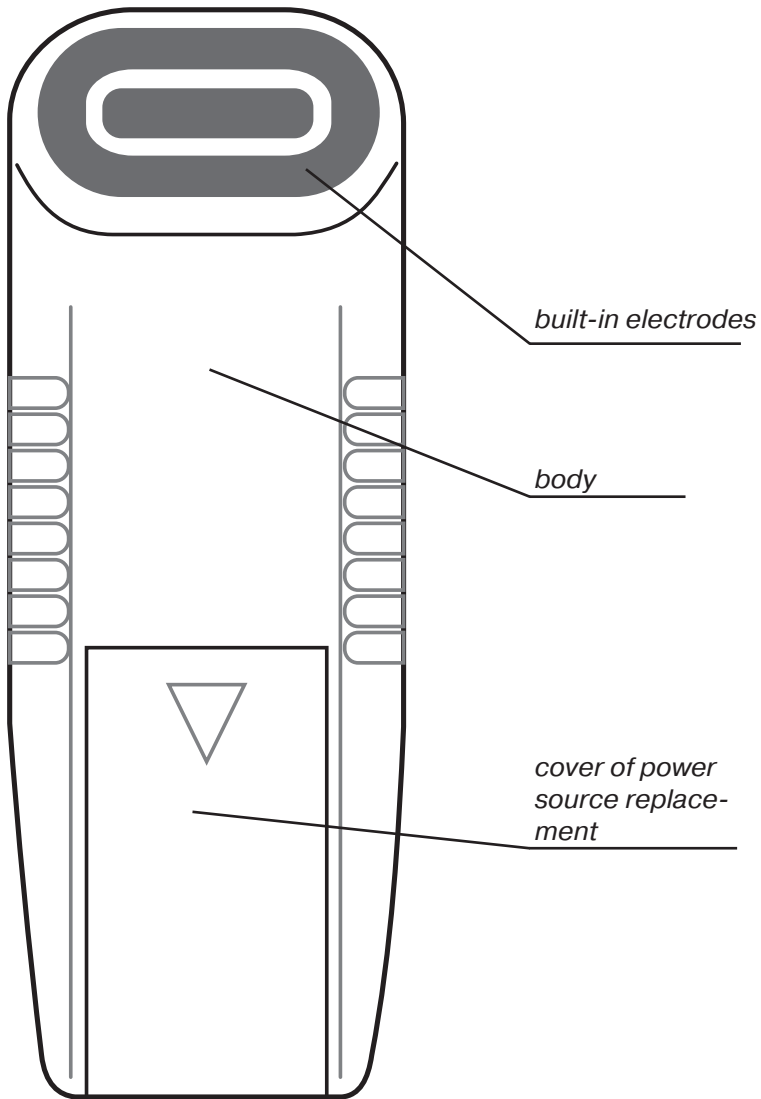







Figure 3. DiaDENS-PCM (back)






**Control buttons.** Function of these buttons depends of the apparatus operation mode:

Table 2.

Op-eration modes of appa-ratus	Button				
	Left 	Right 	Central 	Up 	Down 
When working in electrostimulation modes	Decrease of influence's power*	Increase of influence's power	Switch to apparatus menu	Switch on the timer and increase timer values by 30 seconds with every touch**	Decrease of timer's values and switch off timer if its value is equals to zero**
When working in apparatus menu	Return to previous menu's level	Confirm the action selected	Confirm the action selected	Move up in this menu's level	Move down in this menu's level
* Do not used for "SCREENING" mode ** Is used only for "THERAPY" (manual setting) mode					

**7710** — for quick switch to "7710" mode;

**77AM** — for quick switch to "77AM" mode;

 — for switching the apparatus on and off (to switch the apparatus off press and hold the button);

In addition, other external therapeutic electrodes produced by the manufacturer can be connected to the apparatus.

**ATTENTION!** External therapeutic electrodes can be used in the "EXPRESS" (express therapy) and "THERAPY" (manual setting) modes only.

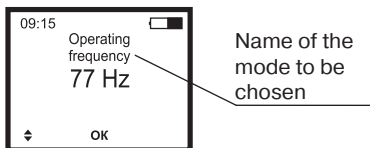
Before applying the external electrode, the treated part of skin should be wiped with a tampon moistened in water or treated with MALAVTILIN cream until its complete absorption for better contact.

**Indicator in different modes.**

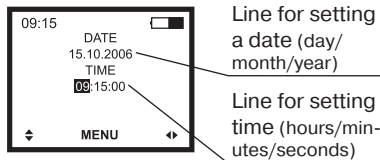
**MENU**



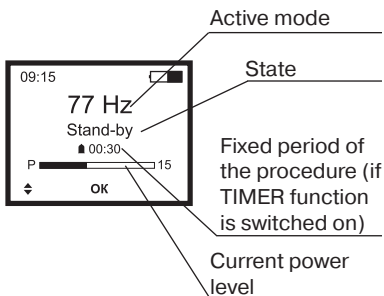
**Menu item "THERAPY"**



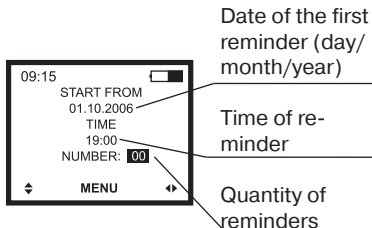
**Menu item "DATE AND TIME"**



**Indicator in therapeutic modes**




**Menu item "CALENDAR"— "REMIND"**







## 6. GENERAL RECOMMENDATIONS


### 6.1. Switching the apparatus on:

Press button . Wait for the sound signal. The apparatus automatically switch to the mode “DIRECT PROJECTION”. By pressing **OK** button during the intro the apparatus switch to basic menu.



### 6.2. Choosing the mode or function

To change the operating mode, go to menu by pressing **OK** button. Choose the necessary mode, function or value by pressing button , ,  and . Press **OK** button to open them.

### 6.3. Returning to basic menu

Press button  as many times as it is necessary to return to any above menu level.

### 6.4. Timer

Choose necessary mode (available in “THERAPY” (manual setting) mode), the display will show a “STAND-BY” message. Set the timer if necessary: switch on the timer by pressing the up button , with every subsequent pressing the timer, value will increase by 30 seconds, by every pressing of the down button  timer value will be reduced by 30 seconds. When the timer reaches zero value, it will be switched off.

During the procedure with the timer switched on, timer countdown shows the time left until the end of the procedure; with the timer switched off – the timer shows the time passed since beginning of the procedure.

After the end of the procedure with the timer switched on you will hear a sound signal. The timer will automatically switch to the value set before if electrodes have no contact with the skin surface.

### 6.5. Power

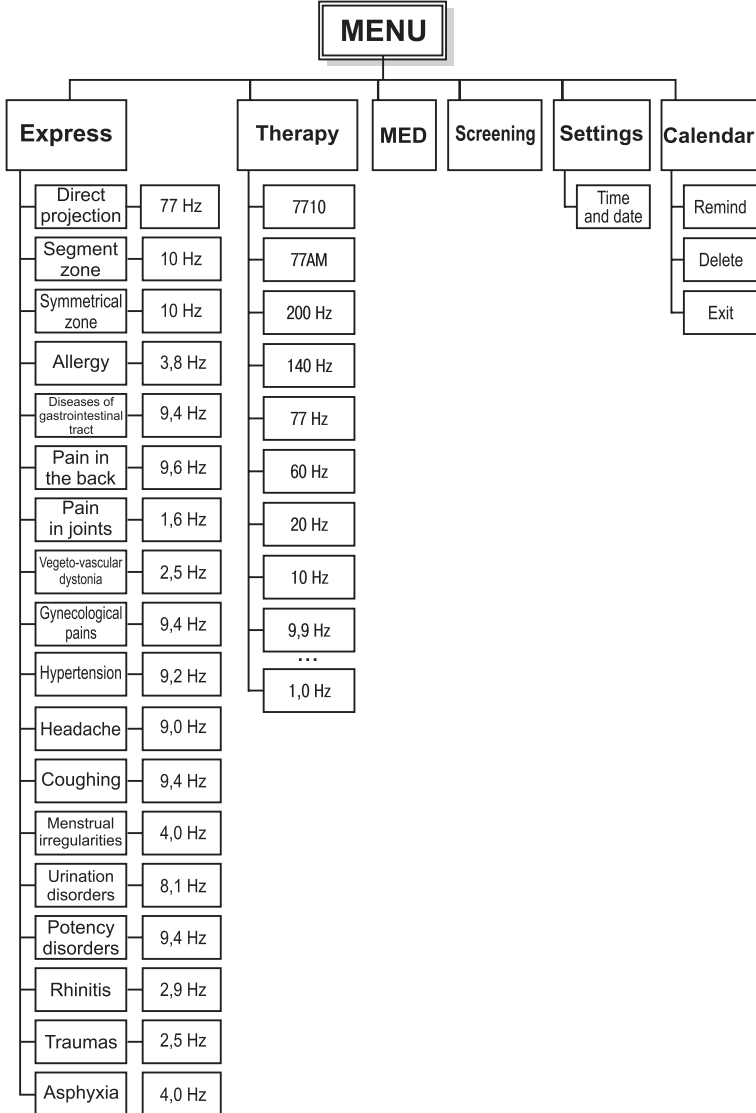
When operating any of the electrostimulation modes (“EXPRESS” (express-therapy), “THERAPY” (manual setting), “MED”), you can change power of influence: by pressing the left button ◀ (power reduction) and the right button ▶ (power increase).

### 6.6. Switching the apparatus off:

Press the ⏻ button for 1-3 seconds. The display will show “GOOD HEALTH” message and the apparatus switch off after the sound signal and “GOOD BYE” message. The apparatus will switch off.

## 7. OPERATING THE MENU

List of menu`s functions:

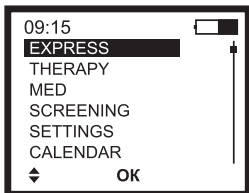


**Table of abbreviations and shortenings  
of terms on the LCD**

<b>Full name of the menu's item</b>	<b>Abbreviation/shortening on the LCD</b>
Direct projection	Direct projection
Segment zone	Segment zone
Symmetrical zone	Symmetrical zone
Allergy	Allergy
Diseases of gastrointestinal tract	GI diseases
Pain in the back	Pain in the neck
Pain in joints	Pain in joints
Vegeto-vascular dystonia	VV dystonia
Gynecological pains	Gynecology
Hypertension	Hypertens.
Headache	Headache
Coughing	Coughing
Menstrual irregularities	IMC
Urination disorders	Urination disorders
Potency disorders	Potency disorders
Rhinitis	Rhinitis
Traumas	Traumas
Asphyxia	Asphyxia

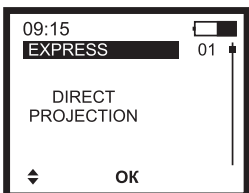
## SWITCHING ON MENU'S FUNCTION

Perform the following actions:



Menu item "EXPRESS" (express-therapy)

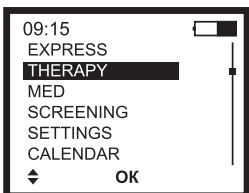
Select "EXPRESS" by pressing buttons up ▲, down ▼. Confirm the action by pressing **OK**.



Select from the list the necessary operation mode/disease to work with.

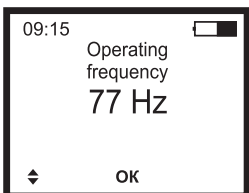
Select the item by pressing buttons up ▲, down ▼. Confirm the action by pressing **OK**.

Methods of operating with the apparatus are given in part 2, User's instructions.



Menu item "THERAPY" (manual setting)

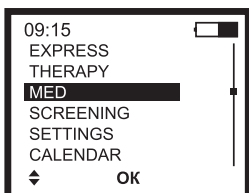
Select "THERAPY" by pressing buttons up ▲, down ▼. Confirm the action by pressing **OK**.



Select from the list the necessary operating frequency.

Select the item by pressing buttons up ▲, down ▼. Confirm the action by pressing **OK**.

Methods of operating with the apparatus are given in part 2, User's instructions.



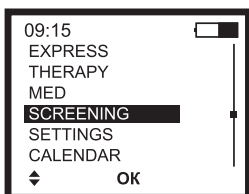
Menu item "MED"

Select "MED" by pressing buttons up ▲, down ▼. Confirm the action by pressing **OK**. Press the electrodes of the apparatus to skin.

Wait for the first signal (end of the first stage – “Test” mode). The apparatus will automatically switch to the second stage – “Therapy” mode. After the end of the second stage (5 minutes) you will hear the sound signal of the procedure end.

During the procedure the LCD shows time passed from the beginning of the current procedure.

Methods of operating with the apparatus are given in part 2, User’s instructions.



#### Menu item “SCREENING”

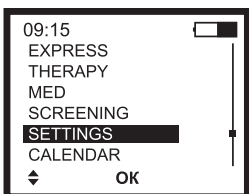
Select “SCREENING” by pressing buttons up ▲, down ▼. Confirm the action by pressing **OK**.

Press the electrodes of the apparatus to skin.

Wait for the sound signal (after 5 seconds). The LCD will show  $\Delta$ LT value during 5 seconds.

If electrodes are in contact with skin, the apparatus will automatically start measuring new  $\Delta$ LT value.

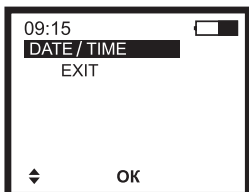
Methods of operating with the apparatus are given in part 2, User’s instructions.



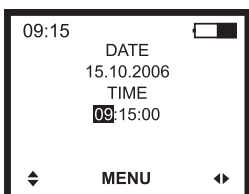
#### Menu item “SETTINGS”

This item contains the section “DATA AND TIME”.

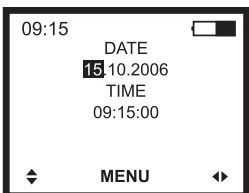
Select “SETTINGS” by pressing buttons up ▲, down ▼. Confirm the action by pressing **OK**. Confirm the action by pressing **OK**.



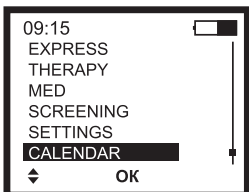
**Setting time and date**  
 Select 'DATE/TIME' by pressing buttons up ▲, down ▼. Confirm the action by pressing **OK**.



Increasing or reducing hours/minutes is made by pressing buttons ▲, ▼; selecting the parameter (hours or minutes) to be changed is made by pressing buttons ◀, ▶. Confirm the setting by pressing **OK**.



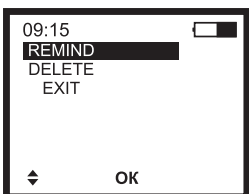
Increasing or reducing year/month/day is made by pressing buttons ▲, ▼ selecting the parameter (year, month, day) to be changed is made by pressing buttons ◀, ▶. Confirm the setting by pressing **OK**.



#### Menu item "CALENDAR"

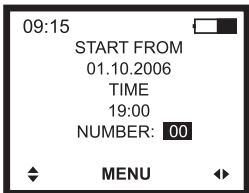
The apparatus allows setting dates and time of future procedures for treatment courses and will remind about the procedure in the fixed time with a sound signal (during 2 minutes).

Select "CALENDAR" by pressing buttons up ▲, down ▼. Confirm the action by pressing **OK**.



Sets number of procedures and time of reminding about the procedure.

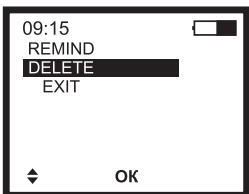
Select "REMIND" by pressing buttons up ▲, down ▼. Confirm the action by pressing **OK**.



Increasing or reducing the quantity of procedures is made by pressing buttons ▲, ▼.

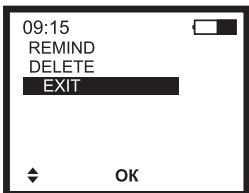
Switching between hours and minutes is made by pressing buttons ◀, ▶. Increasing or reducing hours/minutes is made by pressing buttons ▲, ▼.

Confirm the setting by pressing **OK**.



Deleting the set reminders.

Select 'DELETE' by pressing buttons up ▲, down ▼. Confirm the action by pressing **OK**.



Returning to basic menu.

If all procedures are set, select "EXIT" and press **OK**.

## 8. TECHNICAL MAINTENANCE

8.1. Daily technical maintenance should include the following:

- external examination of the apparatus;
- disinfection of electrodes.

Use standard disinfection means (e.g. 70% alcoholic solution) and soft napkins to clean the electrodes.

8.2. Check of serviceability in accordance with instructions in Part 6.

8.3. If the apparatus is supposed not to be used for a long period, remove the power source\* from its compartment (Part. 10).

8.4. The battery symbol flashes on the display and there is a pulsing sound signal. Change the battery.

**Attention!** *If power source are absent more than 10 seconds all individual settings of the user and set reminders will be deleted.*

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\* When power source is removed, the "CALENDAR" function does not provide for automatic switching on of the apparatus. The settings for current date and time will also be lost.

## 9. CHANGE OF POWER SOURCE

Change of power source:

- open battery section (Fig. 3);
- get the power sources;
- set new power sources\*, following the polarity.

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\* *Set only those power sources that are provided for this device – type LR6/AA, voltage rating 1,5 V, or appropriate accumulators with nominal voltage 1,2 V.*

## 10. TROUBLESHOOTING LIST

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

Table 3

Trouble	Possible reason	Method of eradication
The apparatus switches off or the battery symbol flashes on the display and there is a pulsing sound signal	Voltage of power sources is less than 2.1 V	Change power sources
When using an external electrode the apparatus is constantly in the STAND-BY mode	No contact between the apparatus and an external therapeutic electrode	Check contact of the slot
	Skin is dry	Treat skin with a tampon moistened with water
The apparatus does not switch on the time set in the CALENDAR function	Wrong setting of the current time and date	Set current date and time
	Power sources are discharged or absent	Change power sources
The apparatus switches on itself	Saved reminders are present	Delete existing reminders

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

## **11. GUARANTEES OF THE MANUFACTURER**

11.1. The manufacturer guarantees the compliance of the apparatus to the technical conditions TU 9444-002-35266303-2005 on condition the conditions of operation, transportation and storage are observed.

11.2. The operation lifetime is 5 years.

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

11.3. The guarantee period of operation is 24 months from the date of sale.

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 apparatus 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;

4) force-majeure.

11.4. Guarantee obligations do not apply to products with broken manufacturer's seals.

11.5. In case of unit breakdown or malfunction within the warranty period, as well as in case of 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.

## **PART 2**

# **USER'S INSTRUCTIONS**

### **1. MAIN PERFORMANCE DATA**

Application of impulse currents on reflex zones and points for prophylaxis, treatment and functional recovery is an independent method of treatment and can be applied both as a complex treatment and as mono therapy.

Numerous examinations show that the therapeutic action of the dynamic electroneurostimulation (DENS) is based on multilevel reflex and neurochemical reactions triggering a cascade of regulatory and adaptive mechanisms of the body. It 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 promotes improvement of general condition, better mood and capacity for work.

## 2. INDICATIONS AND CONTRAINDICATIONS TO APPLICATION

DiaDENS-PCM apparatus can be applied in patients of any age from newborns to people of advanced age.

### **Indications:**

- acute and chronic pain syndromes;
- traumas;
- respiratory diseases, diseases of the digestive apparatus, the ENT, the blood circulation system, the musculoskeletal system, the nervous system, the endocrine system and the urogenital systems, the eyes, skin;
- rehabilitation after diseases, surgical operations and traumas;
- increasing body adaptive capacities under influence of negative pathogenous factors, intensive physical and mental work, physical and mental overexertion, syndrome of chronic fatigue, difficulties with waking up in the morning and sleepiness during the day-time, disorders of falling asleep in the evening and insomnia, increased petulance, under depressive states, sexual dysfunction, as well as for prophylaxis of colds.

### **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 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.

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\* *In these cases it is recommended to use the electrostimulator only after consulting your attending doctor.*

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

### 3. CONDITIONS OF TREATMENT

You do not need any special conditions for treatment with DENS. Treatment procedures can be carried out both individually and with help of an operator who will carry out treatment on those zones and points, which you cannot reach yourself.

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 treatment plans with most some widespread disease states. More detailed information about DENS opportunities is provided in the Manual on Dynamic Electroneurostimulation with apparatuses DiaDENS-T and DiaDENS-DT\*.

**Attention!** Treat the apparatus electrodes with a standard disinfection means (e.g. 70% alcoholic solution) after each procedure. The electrodes of the apparatus should be kept dry.

### 4. INTENSITY OF THE ELECTROSTIMULATING TREATMENT

The level of energy treatment with impulse current is determined individually based on subjective sensations of the patient. Intensity of electrostimulation is divided into three levels of energy treatment: minimal, comfortable and maximal.

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

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\* Manual on Dynamic Electroneurostimulation with Apparatuses DiaDENS-T and DiaDENS-DT // under general edition of V.V. Chernyshev. – Ekaterinburg, 2005.

The second comfortable energy level (above threshold of sensations, under pain threshold) – 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 maximal energy level (on the pain threshold) – 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 for corporal (body) points and zones under expressed pain syndrome in teenagers and adults, or for first medical aid.

**Attention!** *It is not recommended to carry out electro-pulse 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.*

## 5. METHODS OF APPLICATION

Dynamic electroneurostimulation with DiaDENS-PCM apparatus is applied using three methods: stable, labile and labile-stable.

Stable method of application (fixed electrodes) is used for treating small zones and on places with mutated skin (rash, abscesses, burns, postoperative and post burn scars, edemas, large birthmarks and so on).

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, spiral, circular and other depending on the size and shape of the zone treated and on uninjured skin.

Labile-stabile method is a combination of both variants of treatment when electrodes are moved on skin with fixation on some places (e.g. on the zone of maximal painfulness).

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

Average duration of one treatment procedure:

- for children of the first year of life — 5-10 minutes;
- for children of 1-3 years — 10-15 minutes;
- for children of 3-5 years — 15-20 minutes;
- for children of 5-12 years — 20-25 minutes;
- for children of more than 12 years and adults — up to 40

minutes.

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

## **6. TREATMENT WITH APPARATUS**

Impact in “EXPRESS” (express-therapy) and “THERAPY” (manual setting) modes is applied for localized pain syndromes, functional disorders, for emergency aid. 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 sub electrode zone bright reddening of skin is observed, sensation of pricking, warmth or lightness.
- the patient has fallen asleep.

Power level of treatment in the THERAPY mode: from minimal to maximal. Methods of treatment of a skin zone: stable, labile, labile-stable.

### **6.1. OPERATING THE APPARATUS WITH GENERAL METHODS**

*MENU* → *Express-therapy* → *select the function*

Select necessary operation mode or disease to be treated from the list.

Press the electrodes to skin on the selected zone of treatment.

Set the power of treatment.

**Attention!** *The power increase is controlled subjectively following the patient's sensations upon contact of the electrodes with the skin surface. Do not surpass the pain threshold.*

On switching on the apparatus, power value equals zero.

To increase power of treatment press and hold ► button. The power will smoothly increase from 00 to 99 conditional units.

To reduce power of treatment press and hold ◀ button. The power will smoothly reduce.

The LCD shows power as a line with a runner, which indicates power for the current moment.

After setting the power of treatment, the message "STANDBY" will be replaced with a message about start of the "THERAPY" mode and indication of the treatment period. Which is automatically set at 5 minutes. The time countdowns (the timer show the time left till the end of 5 minutes). After 5 minutes you will hear sound signal.

Carry out treatment within the necessary time.

## 6.2. INDIVIDUAL SELECTION OF OPERATION MODES

In the "THERAPY" (manual setting) mode the following frequencies are available:

### 6.2.1. Therapeutic frequencies 200 Hz

*MENU → Therapy → 200 Hz*

200 Hz — super high frequency. It is applied in the zone of direct projection of the complaint. The effect is achieved during several first minutes and continues from several minutes up to one hour. To increase the duration of the effect after analgesia, the apparatus treatment can be continued at low or high frequencies.

Indications: acute pains connected with diseases and affection of musculoskeletal system during the acute period and pathology of the peripheral nervous system.

6.2.2. Therapeutic frequencies 60, 77 and 140 Hz

*MENU* → *Therapy* → 60 Hz

*MENU* → *Therapy* → 77 Hz

*MENU* → *Therapy* → 140 Hz

60, 77 and 140 Hz — high-frequency range. They are applied in the zone of direct projection of the complaint and segmental zones (when operating with an applicator). The effect is achieved 5-10 minutes after the start of the procedure and continues up to one hour and longer.

Indications: inflammatory and functional diseases of internal organs with moderate pain syndromes, blood circulation disorder.

6.2.3. Therapeutic frequencies 10, 20 Hz

*MENU* → *Therapy* → 10 Hz

*MENU* → *Therapy* → 20 Hz

10, 20 Hz — low-frequency range. They are applied in the zone of direct projection of the complaint, general zones and zones enhancing a system effect. The effect is achieved after 20-60 minutes and continues from several hours and longer.

Indications: diseases of internal organs, musculoskeletal system including traumas (sub-acute and remote periods), postoperative period.

6.2.4. Infra-low frequencies

*MENU* → *Therapy* → 9.9 Hz ... 1.0 Hz (*spacing* – 0.1 Hz)

Infra-low frequencies are selected by the pathology:

<b>Fre- quency, Hz</b>	<b>Pathology*</b>
1,2	Autoimmune diseases, tachycardia, weakness in knee joints
1,6	Arthritis-arthrosis
1,7	Acne, abscess, hypotension, dermatitis, parodontosis, sympathicotonic action, furunculosis, eczema

2,2	Fatigue, pustular eczema
2,5	Sleepiness, vegetative disorders, hypermenorrhea, headache, connected with diseases of paranasal sinus, hemorrhages, contusion, traumas, menorrhagia, hysteromyoma, edemas, toxic and infection liver injuries, hepatitis, cirrhosis, parodontosis, sinusitis, injuries, eczema
2,6	Viral syndrome, hemorrhoids, headaches under liver diseases, intestinal headaches, dermatitis, impotence
2,8	Nephritis, nephrolithiasis, renal colic, renal sclerosis, uremia
2,9	Rhinitis, sinusitis
3,3	Arteriosclerosis, hypertension, otosclerosis, toxic and infection liver injuries (hepatitis, cirrhosis), nephrolithiasis, renal colic, renal sclerosis, uremia, nephritis, furunculosis, hypertension connected with atherosclerosis
3,5	Cholelithiasis, nephrolithiasis, renal colic, weakness in knee joints, menorrhagia
3,6	Inflammation, grizzle, petulance
3,8	Allergy, hemorrhoids, spasms of different genesis
3,9	Neuralgias, sleep disorders (phase of falling asleep)
4,0	Adiposogenital dystrophy (obesity), asthma, viral syndrome, hemorrhoids, hypermenorrhea, endocrine headache, vertigo, hypophysial disorders, impotence, climax, menorrhagia, pancreatogenous disorders

4,6	Parathyroid gland dysfunction (calcium balance affection)
4,9	Viral syndrome, menage headache, climax, menorrhagia, obesity, rigid neck, furunculosis, menologies
5,5	Vascular headache
5,8	Otogenic headache, depressions
5,9	Spastic paralysis
6,0	Hypertension, headaches connected with liver diseases, rigid neck, extrasystole, systolic hypertension, increase capacity for work
6,3	Headaches connected with cerebral angiospasm, neuroses, petulance, cerebral contusion
6,8	Myalgias, muscle cramps
7,5	Trifacial neuralgia
7,7	Spastic paralysis
8,0	Headache of intestinal genesis, asthma, allergic bronchitis
8,1	Diuretic action (including for balance of potassium and sodium, nephrolithiasis, renal colic, nephritis, cystitis (pyelocystitis))
8,5	Insomnia
8,6	Fractures, duodenal ulcer
9,2	Hypertension, otogenic headache, nephrogenic headache, podagra, diastolic hypertension, dermatitis, spastic paralysis, renal sclerosis, uremia, furunculosis, eczema (including combined with renal disorders), diabetes mellitus

9,3	Flaccid paralysis
9,4	Adnexitis, obstructive bronchitis, hypertension, gastrogenic headache, intestinal headache, urogenital headache, endocrine headache, duodenitis, impotence, edemas, paresthesias, pareses, prostatitis, angina pectoris, erythema nodosum, furunculosis, cystitis (pyelocystitis), eczema, parametritis, gastric ulcer, ulcero-necrotic endomyocarditis
9,5	Hypertension, headache of vascular genesis, climacteric hypertension, laryngitis, parodontosis
9,6	Arthritis-arthrosis, spondylitis deformans, depressions, spinal injuries, osteochondrosis
9,7	Arthritis-arthrosis, lumbosacral radiculitis, podagra, renal sclerosis, uremia, rheumatism
9,8	Toxic and infection liver injuries, hepatitis, cirrhosis
* A.V. Samokhin, Yu.V. Gotovsky. <i>Electropuncture Diagnostics by R. Voll Method.</i> – M.: Center of Intellectual Medical Systems “IM-EDIS”, 2003. – 512 p.	

#### 6.2.5. Mode “7710”

*MENU* → *Therapy* → 7710

Or press button “**7710**” on the keyboard.

7710 mode is intended for general sedative calming effect.

Level of energy – minimal or comfortable. Method of application – stable.

#### 6.2.6. Mode “77AM”

*MENU* → *Therapy* → 77AM

Or press button “**77AM**” on the keyboard.

7710 mode is intended for general restorative effect, better mood and capacity for work.

Level of energy – minimal or comfortable. Method of application – stable.

*MENU* → *Therapy* → *Select frequency*

Select necessary frequency from the list.

Press the electrodes on skin of the selected treatment zone.

Set power of treatment.

**Attention!** *The power's increase is controlled subjectively following the patient's sensations upon contact of the electrodes with the skin surface. Do not surpass the pain threshold.*

When switching on the apparatus, power value equals zero.

To increase power of treatment press and hold ► button. The power will smoothly increase from 00 to 99 conditional units.

To reduce power of treatment press and hold ◀ button. The power will smoothly reduce.

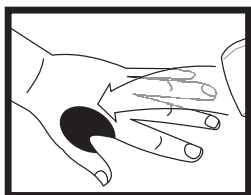
The LCD shows power as a line with a runner, which indicates power for the current moment.

After setting the power of treatment, the message "STANDBY" will be replaced with a message about start of the "THERAPY" mode and indication of the treatment period. Attention: "Timer" function is available in this mode (see item 6.4. Part 1. Technical passport).

Carry out treatment within the necessary time.

## 7. MED (PROPHYLAXIS)

*MENU* → *MED*



The MED\* mode (PROPHYLAXIS) is applied in cases of expected intensive physical and mental work, physical and mental overexertion, syndrome of chronic fatigue, difficulties with waking up in the morning and sleepiness during the day-time, inability to concentrate one's attention, for prophylaxis of colds during epidemics.

It is applied once during the treatment procedure. It is recommended to apply as course treatment: 8-12 procedures.

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\* MED – minimum effective dose

Fix electrodes on the zone HE-GU.

Set power of treatment.

Level of energy to be applied – minimal or comfortable.

**Attention!** *The power increase is controlled subjectively following the patient's sensations upon contact of the electrodes with the skin surface. Do not surpass the pain threshold.*

When switching on the apparatus, power value equals zero.

To increase power of treatment press and hold ► button. The power will smoothly increase from 00 to 99 conditional units.

To reduce power of treatment press and hold ◀ button. The power will smoothly reduce.

The LCD shows power as a line with a runner, which indicates power for the current moment.

**Attention!** *During the apparatus operation in the "MED" mode, electrodes on the patient's skin should be set in the "stable" position, i.e. they should not move.*

The electrodes being in constant contact with the skin surface, the STAND-BY message is replaced by the indication of the time interval and message about start of the first stage of the MED mode – "TEST" mode.

Upon stabilization of skin resistance in the subelectrode zone, the apparatus produces a sound signal and for several seconds the first line of the LCD fixes the time of testing.

Then the second stage of "MED" mode – a continuous stimulation during 5 minutes starts. "THERAPY" message appears on the display, and the countdown of the duration of the minimal efficient dosage is initiated. A sound signal is heard after 5 minutes of treatment in the MED program.

## 8. SCREENING

«SCREENING» mode allows selecting the most optimal zones for impact to enforce system effect of DENS. The mode allows determine the latent (hidden problem zones) trigger zones by estimation of the skin electrical resistance increase to nearby areas of the chosen zone.

Work procedure:

*MENU* → *SCREENING*

Put the electrodes of the apparatus to the chosen skin zone. Frequency (10 Hz) and power of impact is automatically set by the apparatus.

**ATTENTION!** *During work in «SCREENING» mode the electrodes must be set in “stable” way that is you may not move the electrodes during work with the apparatus.*

When the apparatus detects the contact between the electrodes and skin surface the «STAND-BY» message will be changed with the 5 second interval indication, skin electrical resistance change after the impulse sent by the apparatus is determined in 5 seconds. After 5 seconds interval the apparatus will utter short sound signal and the display will show the measurement result as a  $\Delta LT$  index (from 0 to 100 units), e.g.,  $\Delta LT = 8$ . Write down the readings.

Set the apparatus to the next zone.

The latent trigger zones are those zones where the  $\Delta LT$  index exceeds 5 units as on increase side as well as on the reduction side. For example, when testing nearby areas you get the following  $\Delta LT$  results (in units): 6, 5, 8, 20, 4, 7. In this case the zone with the index  $\Delta LT = 20$  is considered to be latent trigger one.

Detected trigger zones should be worked in “THERAPY” mode for 1-5 minute at 60 or 77 Hz frequency. Go to menu:

*MENU* → *THERAPY* → 60 Hz

or

*MENU* → *THERAPY* → 77 Hz

Put the electrodes of the apparatus on the trigger zone and conduct impact.

## 9. SPECIAL EMC-INFORMATION:

9.1. 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 DiaDENS-PCM.

9.2. The Portable electrostimulator DiaDENS-PCM 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 DiaDENS-PCM is suitable for use in all establishments including domestic establishments.

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

### 9.3. Electromagnetic Environment guidance

The Portable electrostimulator DiaDENS-PCM is suitable for use in the specified electromagnetic environment. The customer and/or the user of the DiaDENS-PCM 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  $d = 2,3 \sqrt{P}$  (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.

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

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

Staff 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 staff 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.