ДиаДЭНС®·ПКМ RU (стр. 2–88)

«TRONITEK» LLC, Ekaterinburg, Russia

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DiaDENS®·PCM

DiaDENS®·PCM DE (s.174–261)

CONTENTS

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Thank you for purchasing of the device DiaDENS-PCM.

In order to make the usage of the unit effective and safe, please, carefully read all sections of this manual.

PART 1

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Technical Passport

1. SAFETY REGULATIONS

Information contained in present operations manual is important for your safety and proper use and maintenance of the device.

The device is safe for use due to its bult-in low voltage electric power sourse isolated from the operation part of the device (article of type B with body of type F).

The device must not be used for treatment of patients with implanted electronic devices (for example, pacemakers) and for treatment of patients with individual electric current intolerance.

Use of the device in direct front projection of heart is prohibited.

Don’t treat patient with any high-frequency electric device during stimulation; simultaneous use of the device and other electric equipment can cause burns and lead to possible damage of the device.

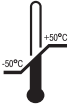
Work near short-wave and microwave equipment can bring to instability of output parameters of the device.

You must not connect to the device any other accessories except remote electrodes produced by manufacturing company.

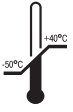
The device contains fragile components. Protect it from shocks.

The device is not waterproof. Protect it from ingress of moisture.

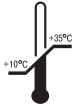
All works on maintenance and repair of the device must be executed by qualified specialists of the manufacturer.



Transport conditions: temperature from -50°C to +50°C, relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa (525 to 795 mm Hg).



Storage conditions: temperature from -50°C to +40°C, relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa (525 to 795 mm Hg.).



Operation conditions: temperature from +10°C to +35°C, relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa (525 to 795 mm Hg).

Attention! *If the device has been stored at the temperature below 10°C keep it in normal climate conditions for no less than 2 hours - before use.*

Utilization: All packaging materials are not environmentally harmful, they may be used repeatedly.

Separate collection of electrical and electronic equipment.
The device contains valuable materials which can be used repeatedly after utilization with consideration of requirements of environmental protection. They shall be delivered to specially intended for this purpose places (consult with corresponding services in your district) for collection and processing.

2. PURPOSE

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Universal transcutaneous electrostimulator DiaDENS-PCM is intended for application of system-regulating impact on physiological systems of the body and for the treatment of functional disorders under wide range of diseases. Dynamic electroneurostimulation is executed through impulses of electric current on biologically active points and zones of the human body. The device provides possibility of selection of individual treatment program as well as already prepared for use programs. The device has a built-in electrodes and a socket for connection of remote therapeutic electrodes *.

The device DiaDENS-PCM is intended for use in health care facilities and in home conditions in accordance with the instructions of a physician.

CE 0483 ***Compliance with standards:*** *This medical device is CE marked according to the Directive 93/42 /EEC on medical equipment.*

* *You can only connect to the device those remote electrodes which are produced by the company-manufacturer (see Appendix 1).*

3. SPECIFICATIONS

3.1. Electric impulse of the device have following output parameters:

3.1.1. Without load:

— amplitude of 1st phase (V) < 40;

— length of 1st phase (uS) - 22 ± 25%;

— amplitude of 2nd phase (V) - 72 ± 25%.

Comments: parameters of impulse do not change under adjustment of power and frequency.

3.1.2. With load = 20 kOhm

Power (in nominal units)	**Minimum**	**Maximum**
	1	**99**
Amplitude of 1st phase, V	≤ 40	≤ 40
Length of 1st phase, uS	6 ± 25%	530 ± 25%
Amplitude of 2nd phase, V	9 ± 25%	300 ± 25%

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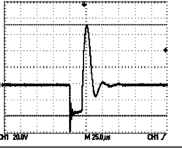
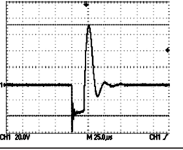
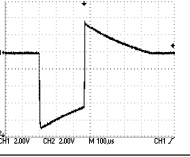
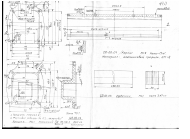
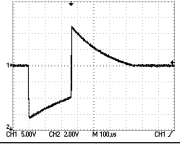
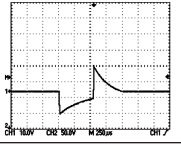
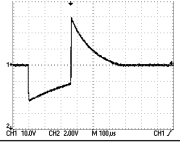
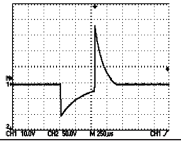
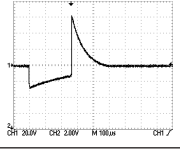
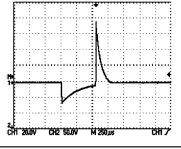
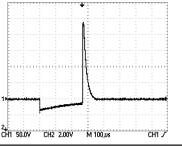
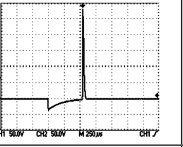
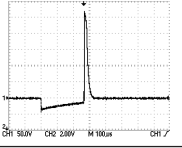
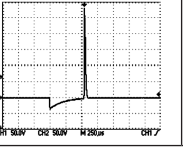
3.1.3. Dependence of impulse form from load resistance at average and maximum power levels.

Load resistance	Power level 50 units		Power level 99 units	
	Form of current	V_{p-p}	Form of current	V_{p-p}
Without load		≈110 V ± 20 %		≈110 V ± 20 %
200 Ohm		≈12 V ± 20 %		≈12 V ± 20 %

500 Ohm		≈29 V ± 20% Ieff =16 mA E_{pulse}≈110 uJ		≈30 V ± 20 % Ieff = 17 mA E_{pulse}≈205 uJ
1 kOhm		≈52 V ± 20 %		≈60 V ± 20 %
2 kOhm		≈90 V ± 20 %		≈100 V ± 20 %

10 kOhm		≈282 V ± 20 %		≈300 V ± 20 %
20 kOhm		≈310 V ± 20 %		≈330 V ± 20 %

3.2. The device provides possibility of setting of following frequencies of impulses, Hz:

3.2.1. Range 1:

— 10±1, including modes «Experess», MED (prophylaxis) and 14 «Screening»;

— 20±1; 60±2; 77±2; 140±3; 200±3;
— 77±2 and 10±1 modulated by frequency 2±0,1 (mode «77 10»);
— 77±2 with modulation by amplitude (mode «77AM»).

3.2.2. Range 2: from 1,0 to 9,9 with increment 0,1±0,05.

3.3. Maximum current consumption (under supply voltage of 3 V - no more than 300 mA.

3.4. Electrical power supply: batteries of type LR6/AA, 2 pcs., with voltage 1,5±0,45 V. It is allowed to use corresponding accumulator batteries with nominal current of 1,2 V*.

3.5. Mass of the device is no more than 0,35 kg.

3.6. Dimensions of the device are no more than 165×65×65 mm.

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* *Operations procedure (types of battery rechargers, methods of recharge) are described in instructions manual for accumulator batteries. Running time of the device under use of accumulators depends on characteristics of accumulators.*

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3.7. The device automatically switches off not later than in 10 min after the last touch of any of its buttons (except button ⏻) or after the last contact of the electrodes with patient' skin surface.

3.8. Electromagnetic emission

Test	Compliance with IEC 60601-1-2	Terms of use
RD radiation CISPR 11	Class B	Electrosimulator DiaDENS-PCM is suitable for use in health care facilities and at home

3.9. Resistance to RF-radiation

Test	IEC 60601-1-2 test conditions	Acceptable level
IEC 61000-4-6	3 Vrms from 150 kHz to 80 mHZ	3 Vrms
IEC 61000-4-3	3 V/m from 80 MHz to 2,5 GHz	3 V/m

3.10. Resistance to electromagnetic fields

Test	Test level	Level of compliance	Terms of use
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV impact	±4 kV contact ±8 kV impact	Floor should be made of wood, concrete, or ceramic tiles. If floor is covered with synthetic material the relative humidity should be at least 40%.
Magnetic fields IEC 610004-8	3 A/m	3 A/m	Parameters of magnetic fields should be at levels typical for commercial or health care buildings

3.11. Recommendations on determination of required distance between electrostimulator DiaDENS-PCM and radio equipment

Rated maximum output power of Transmitter P (W)	Radiated frequency and formula for determination of distance d (m)		
	150 khz - 80 MHz d = 1,2VP	150 khz - 800 MHz d = 1,2VP	800 MHz - 2,5 HHZ d = 2,3VP
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

3.12. Terms of use

3.12.1. Connection of remote electrodes not allowed by manufacturer (including change of length of cable, type of cable, construction of electrode) can lead to increase of electromagnetic radiation level and/or decrease of device resistance to external impacts.

3.12.2. The device DiaDENS-PCM uses electromagnetic energy only for internal functions, and due to this fact, radiation of the device is minimal and shall not impact nearest electronic equipment. The device DiaDENS-PCM shall not be used alongside other equipment. If such action is deemed necessary then DiaDENS-PCM and other equipment shall be checked for correctness of operation under joint use.

3.12.3. The device DiaDENS-PCM is intended for work in specific conditions of electromagnetic environment, and the customer (user) shall check if these conditions comply with required values.

Electrostatic discharge (ESD). Floor should be made from wood, concrete or ceramic tiles. If floor is covered with synthetic material. Then relative air humidity shall be no less than 40%.

RF-radiation. Portable and mobile devices shall be used near any part of the device DiaDENS-PCM at the distance of no less than d = 2,3 V P (800 MHz + 2,5 HHz), where P – is maximum output power according to manufacturer's information.

3.12.4. Recommended user activities

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Electrostatic discharge (ESD). The user shall not use clothes made of synthetic materials.

RF radiation. The personnel (user) shall take following safety measures: minimal distance to portable means of communication (cellular phones, cordless phones) shall be approximately 3 meters in case when output power of the devices exceeds 2 W.

4. COMPLETE SET

Item	Quantity
Electrostimulator DiaDENS-PCM	1
Operations manual	1
Consumer container	1
Battery	2

5. DEVICE ASSEMBLY

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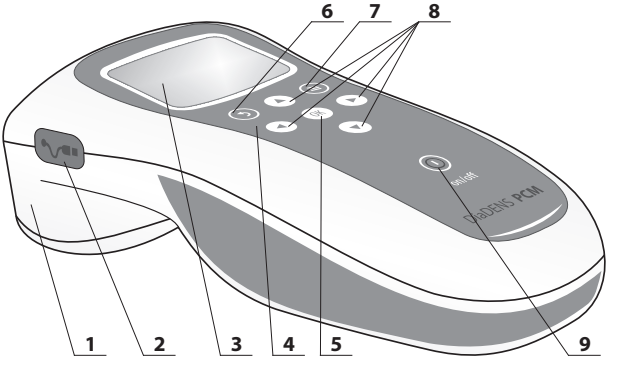

Fig. 1. The device DiaDENS-PCM (top view)

1. Body.
2. Socket for connection of remote electrodes (closed with cover).
3. Display.
4. Keyboard.
5. Button for selection of menu item (OK).
6. Button of return to previous menu item.
7. Button of return to main menu.
8. Buttons for navigation in device's menu.
9. On/Off button.

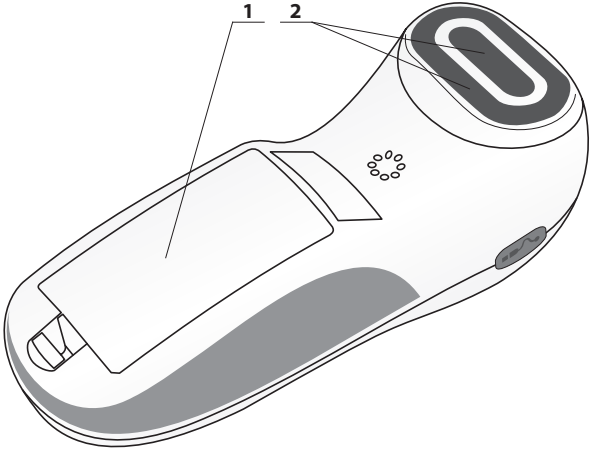

Fig. 2. The device DiaDENS-PCM (bottom view)

1. Cover of battery compartment.
2. Built-in electrode.

You can connect to the device remote therapeutic electrodes of models produced by manufacturer (see Appendix 1).

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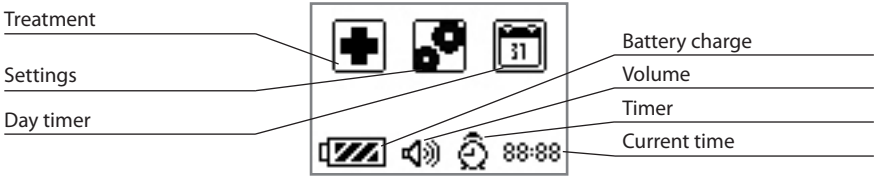
Attention! *Remote therapeutic electrodes can be used only in modes «Express» or «Therapy».*

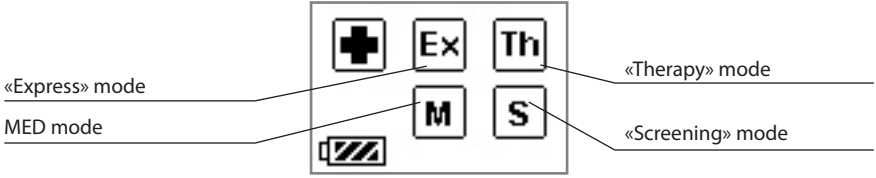
Before use of remote electrode in order to improve contact you can moister the skin in area of impact.

5.1. Appearance of display in different modes

5.1.1. Symbols of main menu of the device

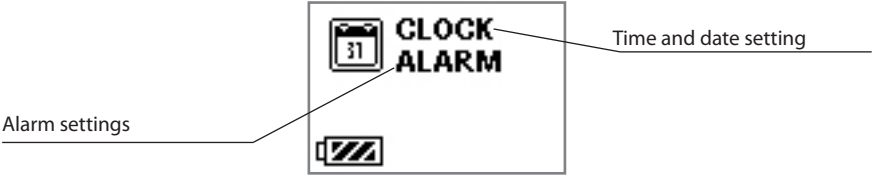


5.1.2. Symbols of menu «Treatment»



5.1.3. Items of menu «Settings»

5.1.4. Items of menu «Day timer»



6. RECOMMENDATIONS ON USE OF THE DEVICE

6.1. Switching the device on

Press button ⏻. After the sound signal and logo the device goes to statuses:

— main menu if function «Storage of last used settings» has been switched off (p.8 of the table);

— to the mode in which the device has been switched off if function «Storage of last used settings» has been switched on.

6.2. Selection of mode or function

Using navigation buttons select required mode, function or value, press button OK to open them.

6.3. Return to menu

To show the menu of above level, use button ↩. To return to main menu of the device press button ☰.

6.4. Switching the device off

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Press button ⏻ and hold it for approximately 3 seconds. On display will appear a message «Good Health» and after sound signal and a message «Good bye» the device will switch off.

7. USING THE MENU

7.1. Structure of the menu

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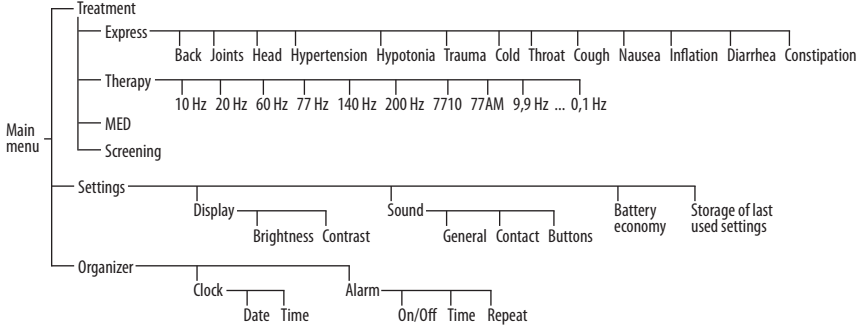

7.2. Selection of menu item

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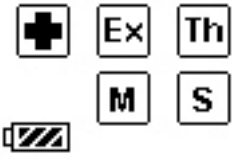
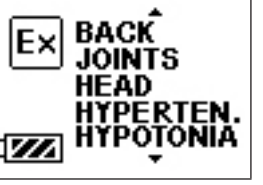
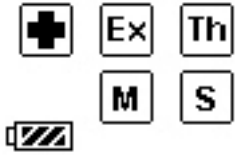
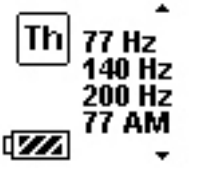
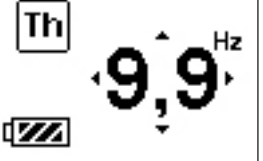
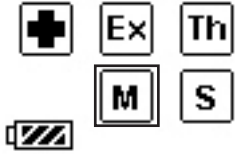
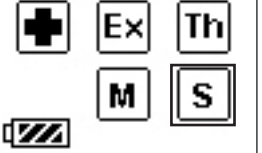
1. Menu «Express»		
1.1	With the help of navigation buttons select in menu «Treatment» section «Express» and confirm your choice by pressing the button OK	
1.2	In this section find required mode of operation/disease with buttons ▲ and ▼. Make a selection and press button OK	

1.3	The device will start select mode of operation, meanwhile, power of the device will be set to minimal level. Readjust power with buttons ▲ and ▼. Methods of operation in mode «Express» are described in detail in «Usage instruction», part 2	
2. Menu «Therapy»		
2.1	With the help of navigation buttons select in menu «Treatment» section «Therapy» and confirm your choice by pressing the button OK	

2.2	In this section find required frequency of impact with buttons ▲ and ▼, make a selection and press button OK	
2.2.1	In case of selection of infra-low frequency the device will present you the menu of infra-low frequency adjustment. With the help of navigation buttons select required frequency (first integral part, then – decimal) and press button OK to confirm your choice.	

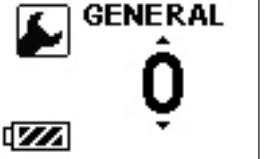
2.3	The device will start chosen mode of operation, meanwhile, power of electrostimulation of the device will be set to minimal level. Readjust power with buttons ▲ and ▼. Methods of operation in mode «Therapy» are described in detail in «Usage instruction », part 2	
3. Minimum effective dose (MED)		
3.1	With the help of navigation buttons select in menu «Treatment» section «MED» and confirm your choice by pressing the button OK	

3.2	The device will show mode MED, meanwhile, power of the device will be set to minimal level. Readjust power with buttons ▲ and ▼. Methods of operation in mode «MED» are described in detail in «Usage instruction», part 2	
4. Diagnostics mode «Screening»		
4.1	With the help of navigation buttons select in menu «Treatment» section «Screening» and confirm your choice by pressing the button OK	

4.2	The device will show mode «Screening», meanwhile, fixed power of electrostimulation will be set for the purpose of safety. Methods of operation in mode «Screening» are described in detail in «Usage instruction », part 2	
5. Menu «display settings»		
5.1	With the help of buttons ▲ and ▼ select in menu «Settings» item «display» and confirm your choice by pressing the button OK	

5.2	The device will show mode «Display settings»: adjustment of brightness and contrast. With the help of buttons ▲ and ▼ select one of adjustabile parameters and confirm your choice by pressing the button OK	
5.2.1	Adjustment of display brightness: the device provided 5 levels of brightness of display from minimal (1st level of brightness) to maximal (5th level of brightness) which can be selected by pressing buttons ▲ and ▼. ***Attention!*** *Increase of brightness leads to increase of current consumption and early replacement of batteries. Use of minimal level of brightness will allow to use batteries for a long time.*	

5.2.2	Adjustment of display contrast: the device provided 5 levels of contrast of display from minimal (1st level of contrast) to maximal (5th level of contrast) which can be selected by pressing buttons ▲ and ▼	
6. Menu «sound settings»		
6.1	With the help of buttons ▲ and ▼ in menu «Settings» select item «Sound» and confirm your choice by pressing button OK	

6.2	The device will show the menu «Sound settings»: general sound of the device, sound under contact with skin, sound under pushing keyboard buttons. With the help of buttons ▲ and ▼ select one of adjustabile parameters and confirm your choice by pressing button OK	
6.2.1	For adjustment of general sound of the device 3 sound levels are provided: mute, minimum and maximum indicated by digits 0.1 and 2 correspondingly. With the help of buttons ▲ and ▼ select one of sound levels and confirm your choice by pressing button OK. ***Attention!*** *Sound signals are generated with consideration of specified sound level. Under selected sound level «mute», sound signals will not be generated.*	

6.2.2	Setting of sound signal under contact with skin: contact of electrodes with skin can be confirmed by sound signal. With the help of buttons ▲ and ▼ switch this function on or off and confirm your choice by pressing button OK	
6.2.3	Menu navigation can be accompanied by sound signals. With the help of buttons ▲ and ▼ switch this function on or off and confirm your choice by pressing button OK	

7. Menu «Economy battery»		
7.1	With the help of buttons ▲ and ▼ in menu «Settings» select item «Economy» and confirm your choice by pressing button OK	
7.2	The device will show the menu «Economy Battery» which allows to change status of function «Economy Battery»: go to mode of reduced energy consumption at the expense of switching off highlighting (independent of selected brightness level) and decrease of time of automatic switching off if the device is not used to 1 minute. In addition, under switching on of function «Economy Battery» function «Storage of last used settings» is switched on automatically. With the help of buttons ▲ and ▼ switch this function on or off and confirm your choice by pressing button OK	

8. Menu «Storage of last used settings»		
8.1	With the help of buttons ▲ and ▼ in menu «Settings» select item «Storage of last used settings» and confirm your choice by pressing button OK	
8.2	The device will show the menu «Storage of last used settings». This item allows to change status of function «storage of last used settings». If function is switched on then the device will switch on in mode in which it has been switched off. If the function is switched off then the device will show main menu. With the help of buttons ▲ and ▼ switch this function on or off and confirm your choice by pressing button OK	

9. Menu of setting of date and time		
9.1	With the help of buttons ▲ and ▼ in menu «Day timer» select item «Clock» and confirm your choice by pressing button OK	
9.2	The device will show menu of adjustment of time and date. With the help of buttons ▲ and ▼ in menu select one of adjustabile items and confirm your choice by pressing button OK	

9.2.1	Setting of date: the device allows to adjust current date, to do so, with the help of buttons ▲ and ▼ select digit which you want to adjust and press buttons ◀ and ▶ to change digits according to actual value and confirm your choice by pressing button OK	
9.2.2	Setting of time: the device allows to adjust current time, to do so, with the help of buttons ▲ and ▼ select digit which you want to adjust and press buttons ◀ and ▶ to change digits according to actual value and confirm your choice by pressing button OK	

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10. Menu of alarm settings		
10.1	With the help of buttons ▲ and ▼ in menu «Day timer» select item «Alarm» and confirm your choice by pressing button OK	
10.2	The device will show menu of alarm settings: switching alarm on and off, adjustment of time of alarm, adjustment of alarm periodicity. With the help of buttons ▲ and ▼ in menu select one of adjustabile items and confirm your choice by pressing button OK	

10.2.1	Switching alarm on and off: this item allows to change status of function «Alarm». If function is switched on the device will emit sound signal at the time and in the period specified by user. For termination of sound signal it's necessary to switch on the device with button ⏻. With the help of buttons ▲ and ▼ switch this function on or off and confirm your choice by pressing button OK	
10.2.2	Setting of alarm time: for adjustment of time with the help of buttons ▲ and ▼ select required area and with buttons ◀ and ▶ change digits according to required value and confirm your choice by pressing button OK	

10.2.3	Adjustment of alarm periodicity: with the help of buttons ▲ and ▼ select one of variants of periodicity — single, daily, weekly (1 time per week) and in working days. Confirm your choice by pressing button OK	

7.3. Menu of quick access

Some of settings of the device are available for user through menu of quick access. Symbols of this menu are situated in bottom row of the display and menu of stimulation modes («Express», «Therapy»). Selection one of such symbols with the help of buttons ◄, ► and confirmation of choice by button OK shows to user menu of adjustment of one of these

parameters. To exit these menus press button ⓞⓚ after confirmation of parameter or button ⓑ to exit menu without storage of adjusted parameter.

Menu «Timer»		
1.	Function «Timer» is necessary in cases when it is impossible to control time of impact (electrostimulation of hard-to-reach places) or when time of stimulation is clearly specified. After activation of this function time of stimulation will be counted down. B In case when function is switched off maximum time of one session is 30 minutes. With the help of navigation buttons if you are in menu of stimulation modes («Therapy»), select symbol of menu «Timer» and confirm your choice by pressing button ⓞⓚ	

2	The device will show menu item «Timer». With the buttons ▲ and ▼ set required time of timer – from 0 to 25 minutes (discreteness – 5 minutes). In case of setting 0 minutes function is considered switched off and in modes of stimulation time will be counted in regular regime	
Menu «Volume level»		
1	Menu «Volume level» provides possibility of quick access to setting of general sound level of the device. With the help of navigation buttons if you are in menu of stimulation modes («Express», «Therapy», MED or «Screening»), select symbol of menu «Volume level» and confirm your choice by pressing button OK	

2	The device will show menu of adjustment of general sound level - 3 sound levels are provided: mute, minimum and maximum indicated by digits 0.1 and 2 correspondingly. With the help of buttons ▲ and ▼ select one of sound levels and confirm your choice by pressing button OK ***Attention!*** *Sound signals are generated with consideration of specified sound level. Under selected sound level «Mute» sound signals will not be generated*	

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Menu «Contact»		
1	Menu «Contact» provides possibility of management of function «Forced therapy» — formation of electrical impulses independent of contact of electrodes with skin. Function «Forced therapy» is switched on automatically under connection to device of remote electrodes and can be switched on at will in case of need (for example, for brittle treatment of zone). With the help of navigation buttons if you are in menu of stimulation modes («Express», «Therapy»), select symbol of menu «Contact» and confirm your choice by pressing button OK	 illuminated constantly – function of forced therapy is switched off, or remote electrodes are not connected;  flashes – forced therapy is switched on or remote electrodes are connected; absence of contact of built-in electrodes with skin. Wet your skin slightly for contact.
2	The device will show menu «Contact». With the buttons ▲ and ▼ switch this function on or off and confirm your choice by pressing button OK	

8. TECHNICAL MAINTENANCE

8.1. Daily technical maintenance should include the following:
— external examination of the device;
— disinfection of electrodes.
For purposes of disinfection use standard disinfection means (such as 3% solution of hydrogen peroxide) and soft napkins without nap to clean the electrodes.

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

8.3. If you will not use the device for a long period remove the power source from its compartment (fig. 2).

8.4. If the battery symbol flashes on the display and there is a pulsing sound signal change the battery (section 9).

Attention! *If power source is absent for more than 10 seconds all individual settings of the user, set reminders, information on current date and time will be deleted.*

9. BATTERIES REPLACEMENT

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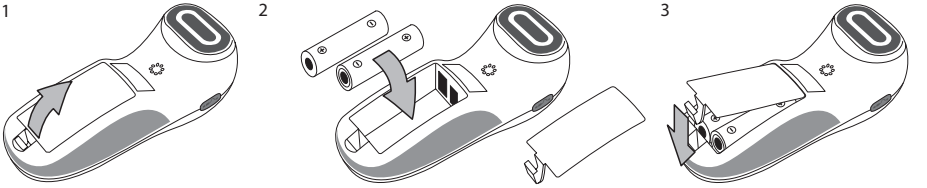
Replacement of power source:
— open battery compartment (1) and take the batteries out;
— install new batteries into the device* with consideration of polarity (2);
— close battery compartment (3).

1 2 3



∗ *Use only those batteries that are suitable for this device — type LR6/AA, voltage rating 1,5 V, or appropriate accumulators with nominal voltage 1,2 V.*

10. TROUBLESHOOTING LIST

Trouble	Possible reason	Method of elimination
1) The device does not switch on when you press button ⏻	There are no batteries	Set new batteries (see section «Batteries replacement»)
	Voltage of batteries is less than 2,1 V	Change batteries (see section «Batteries replacement»)
2) Under switching on the device emits sound signals and switches off	Voltage of batteries is less than 2,1 V	Change batteries (see section «Batteries replacement»)
	Period of time between switching on of the device and its subsequent switching on is less than 3 seconds	Wait 3 seconds after switching off the device and switch it on again

3) The device does not pass to status «Therapy» under contact of built-in electrodes with skin	Mode of stimulation is not selected	Go to menu «Express» or «Therapy» and select required mode of stimulation
	Insufficient area of contact of electrode with skin	Tightly apply built-in electrode to skin. If necessary slightly wet skin before contact
	Power level is zero	Increase power level
4) The device does not emit sound signals (under switching on of mode, change of power level, end of work and so on)	Sound is switched off	Increase volume. Go to section Settings → Sound → Volume
5) The device does not pass to status «Therapy» under use of remote electrodes	Mode of stimulation is not selected	Go to menu «Express» or «Therapy» and select required mode of stimulation
	Insufficient area of contact of electrode with skin	Tightly apply remote electrode to skin. If necessary slightly wet skin before contact
	Power level is zero	Increase power level

6) Highlighting of indicator is not working	Function «Battery preservation» is switched on	Switch off function «Battery preservation» Go to section Settings → Battery preservation
7) The device does not shot down under absence of contact of electrode with skin or nonuse of buttons for more than 10 minutes	Remote electrode is connected to the device, the device is in the mode «Therapy»	Disconnect remote electrode if you don't use it
	Function «Forced therapy» is switched on	Switch off function «Forced therapy»
8) The device switches off or symbol of battery flashes and the device emits discontinuous signal	Voltage of batteries is less than 2,1V	Change batteries (see section «Method of replacement of batteries»)

9) The device does not switch on at the time specified by the function «Alarm»	Active reminders are absent	Go to section «Alarm» and set reminders
	Voltage of batteries is less than 2,1 V	Change batteries (see section «Method of replacement of batteries»)
10) The device switches off spontaneously	Voltage of batteries is less than 2,1 V	Change batteries (see section «Method of replacement of batteries»)
11) «Quick consumption» of batteries	Off-grade batteries	Use high-quality batteries (alkaline atteries are recommended) or accumulators of corresponding unitsize with voltage of no more than 1,5 V
	Level of brightness is maximal	Decrease level of brightness. Go to section Settings → Display
	Function «Battery preservation» is switched off	Switch on function «Battery preservation». Go to section Settings → Battery preservation

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

11. MANUFACTURER'S WARRANTY

11.1. Operating time of the device — 5 years.
Under observance of operation regulations actual operation time can significantly exceed official one.

11.2. Warranty period for the device is 24 months from the date of sale.

11.3. The seller (manufacturer) or organization which acts as a seller (manufacturer) on the basis of contract with it is not responsible for the defaults should they occur after the disposal of the device as a result of:
1) failure on the part of the consumer to comply with the rules of transportation, storage, care and operation provided 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.

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11.6. 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.

Address of Manufacturer:
«TRONITEK» LLC
Ekaterinburg, 620146, Russia
Akademika Postovskogo Str., 15
Tel.: +7 (343) 267-23-30
e-mail: corp@denascorp.ru
http://www.denascorp.ru

Official representative in EU countries:
DENAS-CZ s.r.o.
Na Výhledě 886/3a, 36017 Karlovy Vary
Czech Republik
Tel./Fax:+420 353 549 285
E-Mail: denas.cz@seznam.cz
www.denas-health.com
www.denasworld.com

PART 2

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Usage Instructions

1. GENERAL PROVISIONS

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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 a 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 FOR USE

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

Indications:

— acute and chronic pain syndromes;
— traumas;
— respiratory diseases, diseases of the digestive device, diseases of ENT, blood circulation system, musculoskeletal system, nervous system, endocrine and urogenital systems, eyes, skin;
— rehabilitation after diseases, surgical operations and traumas;
— increasing body adaptive capacities under impact of negative pathogens factors, intensive physical and mental work, physical and mental overexertion, syndrome of chronic fatigue, difficulties with waking up in the morning and sleepiness during daytime, 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 seizures;
— 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, after consultation with a doctor);
— acute febrility of unclear etiology;
— vein thrombosis;
— condition of acute psychical 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.*

3. CONDITIONS FOR 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 supplied with the devices DiaDENS-T and DiaDENS-DT*.

Attention! *Treat the device electrodes with a standard disinfection means (such as 3% solution of hydrogen peroxide) after each procedure. The electrodes of the device should be kept dry.*

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

4. INTENSITY (POWER) OF ELECTROSTIMULATION

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The level of electrostimulation with impulse current is determined individually based on subjective sensations of the patient. Intensity of electrostimulation is conditionally divided into three levels.

The first *minimal level* - the patient does not have any subjective sensations or has subtle vibrations in area of impact under electrodes. This level is used when treatment shall not be intensive – for children up to 7 years old and patients with diseases of cardiovascular system (hypertension, hypotension, a syndrome of vegetative-vascular dystonia). For patients who are experiencing frequent headaches, dizziness treatment should also be carried out with minimal power.

Second *comfortable level* — patient feels light pricking, vibration or light burning without pain. It is used under treatment of weak pain and aches of medium intensity. This is the most frequently used power level.

The third *maximal level* – the patient feels expressed painful pricking or burning. Such intensity can be accompanied by involuntary contraction of muscles close to electrodes. It is used under expressed pain syndrome.

Under switching on level of power is equal to zero. To increase power you should press and hold button ⏫. Meanwhile, the power will be increased subsequently - from 0 to 99 conditional units.

To decrease power you should press and hold button ⏬. Meanwhile, the power will be decreased subsequently.

Attention! *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.*

Attention! *Control of power level is executed subjectively considering sensations of patient. You shall not exceed pain threshold.*

Attention! *For patients with hypertension, hypotension, a syndrome of vegetative-vascular dystonia as well as patients who have frequent headaches, dizziness, treatment should be carried out with minimal power level.*

5. MODALITIES

Dynamic electroneurostimulation with DiaDENS-PCM device is applied using three methods: *stabile, labile and labile-stabile*.

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).

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 THE DEVICE

Exposure in modes «Express» and «Therapy» is applied under 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;
— the patient has fallen asleep.

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

6.1. Use of the device by universal methods

MENU → Treatment → «Express» → ***Select program***

Select necessary symptom or disease to be treated from the list.

Press the electrodes to skin on the selected zone of treatment (schemes of treatment in «Express» mode are given is Appendix 2. Set the power of treatment.

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Attention! *Control of power level is executed subjectively, considering sensations of patient. You shall not exceed pain threshold.*

On switching on the device power value is equal to zero. To increase power of treatment press and hold button ▲. The power will subsequently increase from 00 to 99 conditional units. To reduce power of treatment press and hold button ▼. The power will be decreased subsequently.

After setting of power of treatment countdown of time of impact will start. The time is counted downward (indicating the time remaining until the end of stimulation of the zone). At the end of stimulation of zone alarm tells you when to rearrange the electrode to the next area of impact. Methods of treatment in «Express» mode are given is Appendix 2.

6.2. Individual selection of operation modes. In the «Therapy» mode the following frequencies are available:

6.2.1. Therapeutic frequency 200 Hz

MENU → Treatment → «Therapy» → ***200 Hz***

200 Hz — is a 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 device treatment can be continued at low or high frequencies.

Indications: acute pains associated 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 → Treatment → «Therapy» → ***60 Hz***
MENU → Treatment → «Therapy» → ***77 Hz***

MENU → Treatment → «Therapy» → ***140 Hz***

60, 77 and 140 Hz — are high-frequency range. They are applied in the zone of direct projection of the complaint and segmental zones . The effect is achieved in 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 → Treatment → «Therapy» → ***10 Hz***

MENU → Treatment → «Therapy» → ***20 Hz***

10, 20 Hz — are low frequencies. They are applied in the zone of direct projection of the complaint, general zones and zones which enhance 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 (subacute and remote periods), postoperative period.

6.2.4. Infra-low frequencies

MENU → Treatment → «Therapy» → ***9,9Hz...1,0Hz*** *(increment - 0,1 Hz)*

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Infra-low frequencies are selected by following chart:

Frequency, Hz	Pathology*
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, associated with diseases of paranasal sinus, hemorrhages, contusion, traumas, menorrhagia, hystero- myoma, edemas, toxic and infection liver injuries, hepatitis, cirrhosis, parodontosis, sinusitis, injuries, eczema

* *Samohin A.V., Gotovski Y.V. Electroacupuncture diagnostics by method of R. Foll .- Moscow: Center of intellectual medical systems «IMEDIS «, 2003.- 512 pages.*

2,6	Viral syndrome, hemorrhoids, headaches under liver diseases, intestinal headaches, dermatit is,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 associated 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 associated with liver diseases, rigid neck, extrasystole, systolic hypertension, increase capacity for work
6,3	Headaches associated with cerebral angiospasms, 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

6.2.5. Mode «77 10»

MENU → Treatment → «Therapy» → ***77 10***

7710 mode is intended for general sedative calming effect. Level of power - minimal or comfortable. Method of application - stabile.

6.2.6. Mode «77 AM»

MENU → Treatment → «Therapy» → ***77 AM***

Mode 77 AM is intended for general restorative effect, better mood and capacity for work. Level of power - minimal or comfortable. Method of application - stabile.

6.3. Program of minimum effective dose (PROPHYLAXIS)

MENU → Treatment → ***MED***

EN

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.

Fix electrodes of the device to the zone he-gu. Set power of treatment. Level of power to be applied is minimal or comfortable.

* *MED — **m**inimum **e**ffective **d**ose.*

Attention! *Control of power level is executed subjectively considering sensations of patient under contact of electrodes with skin surface. You shall not exceed pain threshold.*

Under detection of contact of electrodes of the device with skin surface countdown of period of minimum effective dose of device' impact will start.

Under switching on of the device power value is equal to zero. To increase power you should press and hold button ⏫. Meanwhile, the power will be increased subsequently - from 0 to 99 conditional units.

To decrease power you should press and hold button ⏬. Meanwhile, the power will be decreased subsequently.

Attention! *During the device operation in «MED» mode electrodes on the patient's skin should be set in the «stabile» position, i.e. they should not move.*

After the end of the program, sound signal will be generated. In average, program works 6-7 minutes.

6.4. Mode «Screening »

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

*MENU → Treatment → «**Screening**»*

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

***Attention!** During the device operation in «Screening» mode electrodes on the patient's skin should be set in the «stabile» position, i.e. they should not move during operation in mode «Screening».*

When the device detects the contact between the electrodes and skin surface indication of period of time will appear – 5 seconds during which skin electrical resistance is determined, after the impulse is sent by the device. After 5 seconds interval the device will emit short sound signal and the display will show the measurement result as a ΔLT index (in range from 0 to 100 units), e.g., ΔLT = 8.

Write down the readings. Set the device to the next zone.

The latent trigger zones are those zones where ΔLT values significantly differ – upwards or downwards. For example, under test of nearby areas you get following ΔLT results (in units): 6, 5, 8, 20, 4, 7. In this case the zone with the index ΔLT = 20 is considered to be latent trigger one.

Detected trigger zones should be additionally treated in «THERAPY» mode for 1-5 minute at 60 or 77 Hz frequency. Go to menu:

MENU → Treatment → «Therapy» → ***60 Hz***

or

MENU → Treatment → «Therapy» → ***77 Hz***

Put the electrodes of the device on the trigger zone and apply treatment.