

ООО «РЦ АРТ», Екатеринбург, Россия

Электростимулятор чрескожный противоболевой с внутренним и выносными электродами портативный для стимуляции биологически активных точек и зон, для аурикулярной диагностики и диагностики по методу Фолля

ДиАДЭНС-Т/ДТ

Руководство по эксплуатации

TU 9444-001-41006303-2003 РЦ АРТ 01.0-03.71-02 РЭ

LLC RC ART, Ekaterinburg, Russia

Analgetic transcutaneous portable apparatus with built-in and external electrodes for stimulation of biologicaly active zones and biologicaly active points, auricular and Voll's diagnostics.

DiaDENS-T/DT

Operations Manual

TU 9444-001-41006303-2003 RC ART 01.0-03.71-02 RE

“RC ART” GmbH, Ekaterinburg, Russland

Tragbarer Elektrostimulator mit Innen- und Ausgangselektroden für die Stimulation von BAP und BAZ sowie für die Elektropunkturdiagnostik

DiaDENS-T/DT

BETRIEBSANLEITUNG

TU 9444-001-41006303-2003 RC ART 01.0-03.71-02 RE

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This Operations Manual is intended for the DiaDENS transcutaneous analgetic portable electrostimulator with built-in and external electrodes for BAP and BAZ stimulation, auricular and Voll's diagnostics.

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.

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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.



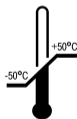
The article has fragile elements. Protect against knocks.



The device is not waterproof. Protect against water penetrating.

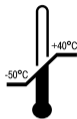


Maintenance of the device must be provided by qualified specialists in manufacturing firm.

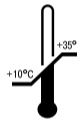


Transporting conditions: temperature from -50°C to $+50^{\circ}\text{C}$, relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa.

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Storage conditions: temperature from -50°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°C до 35°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°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 electrotherapeutic apparatus, hereinafter called APPARATUS is used to treat pain and injury areas, reflexogenic areas and acupuncture points of the body. It is recommended to use the apparatus in a complex treatment of diseases causing pain and its equivalents (paresthesia, itching, spasms), to remove postoperational and traumatic pains, muscle fatigue, to improve the microcirculation and trophism of tissues, to treat functional disorders within a broad spectrum of pathologies.

Several modes of stimulation as well as special manipulation techniques provide for safe and comfortable treatment. Dynamic electrostimulation provides for selective treatment of the functional states of internal organs and regulation of physiological functions and pain sensitivity.

The functional and compact form of the apparatus, internal power supply enable the apparatus to be operated in the inpatient and outpatient settings, field environment, during sports events, at a production site and at home, the instruction being observed.

The apparatuses are made in two versions — DiaDENS-T and DiaDENS-DT.

The DiaDENS-T version lacks auricular and Voll's diagnostics.

3. MAIN PERFORMANCE DATA

3.1. Minimal impulse parameters:

- duration of the positive impulse, μS , not more than5
- amplitude of the positive impulse, V, not more than10
- amplitude of the negative impulse, V, not more than10

3.2. Maximal impulse parameters:

- duration of the positive impulse, μS 500 ± 70
- amplitude of the positive impulse, V 30 ± 10
- amplitude of the negative impulse, V: without load 350 ± 70
- with load ($20 \pm 5\%$) kOhm 300 ± 70

3.3. Minimum load resistance under which the parameters of the impulse keep, R_{min}500 Ohm

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

3.5. The apparatus provides for the following frequencies of impulses, Hz..... 10 ± 2 ; 20 ± 2 ; 60 ± 2 ; 77 ± 2 ; 140 ± 5 ; 200 ± 5

3.6. Power source: 6F22 type battery, voltage.....	9V
It will be admissible to use storage batteries of 6F22 type, voltage at least 9 B*.	
3.7. Weight, kg, not more than.....	0.35
3.8. including an external therapeutic electrode (DiaDENS-T), kg, not more than.....	0.5
3.9. including external therapeutic and diagnostic electrodes (DiaDENS-DT), kg, not more than.....	0.7
3.10. Dimensions of the apparatus, mm, not more than	210x55x45
3.11. Dimensions of the therapeutic electrode, mm, not more than	125x10
3.12. Dimensions of the passive diagnostic electrode, mm, not more than.....	100x20
Dimensions of the active diagnostic electrode, mm, not more than	130x10
3.13. The device will be automatically switched off not later than in 10 minutes after the device has been idle or after last application of electrodes to skin surface.	

* *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.*

3.14. Electromagnetic Emissions

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

3.15. 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

3.16. Electromagnetic Immunity

Immunity Test	Test Level	Compliance Level	Guidance electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	$\pm 6\text{kV}$ contact $\pm 8\text{kV}$ air	$\pm 4\text{kV}$ contact $\pm 8\text{kV}$ 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 magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

3.17. Recommended Separation Distances (d) between Portable and Mobile RF Communication Equipment and Portable electrostimulator DiaDENS-T/DT.

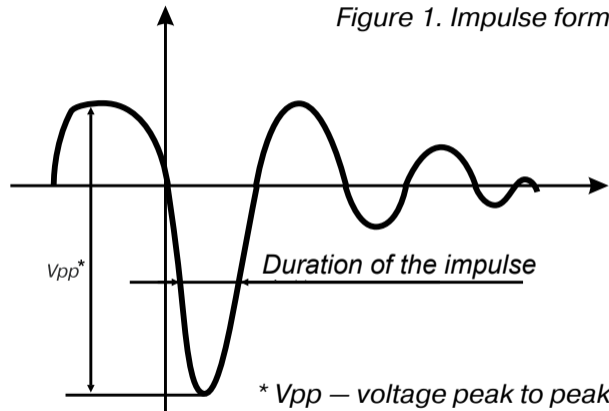
Frequency of Transmitter	150kHz to 80MHz	150kHz to 800MHz	800MHz to 2,5GHz
Equation	$d = 1,2 \sqrt{P}$	$d = 1,2 \sqrt{P}$	$d = 2,3 \sqrt{P}$
Rated maximum output power of Transmitter [w]	Separation distance [m]	Separation distance [m]	Separation distance [m]
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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3.18. The form of impulses is in Fig. 1.



— device of type B and work of type F.



4. COMPLETE SET

4.1. The version of complete set of the DiaDENS-DT device corresponds to the Table 1.

Names	Quantity
Electrostimulator "DiaDENS-DT"	1
Operation Manual	1
External therapeutic electrode	1
External diagnostic electrode	1
Container	1
Package	1
Power supply: battery of the 6F22 type	1

4.2. The version of complete set of the DiaDENS-T device corresponds to the Table 2.

Names	Quantity
Electrostimulator "DiaDENS-T"	1
Operation Manual	1
External therapeutic electrode	1
Container	1
Package	1
Power supply: battery of the 6F22 type	1

5. COMPONENT PARTS AND OPERATION

5.1. The apparatus consists of body 1 (Fig. 2, Fig. 3) with built-in electrodes 13 (Fig. 4), cover 14 (Fig. 4) for the power source replacement.

The complete set of DiaDENS-DT and DiaDENS-DT includes the external therapeutic electrode (Fig. 5.1).

ATTENTION! *The external therapeutic electrode can be applied only in the THERAPY mode (constant mode).*

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

The complete set of the DiaDENS-DT apparatus includes a diagnostic electrode (Fig. 5.2).

Fig. 2. Face appearance of the DiaDENS-DT apparatus and operating controls

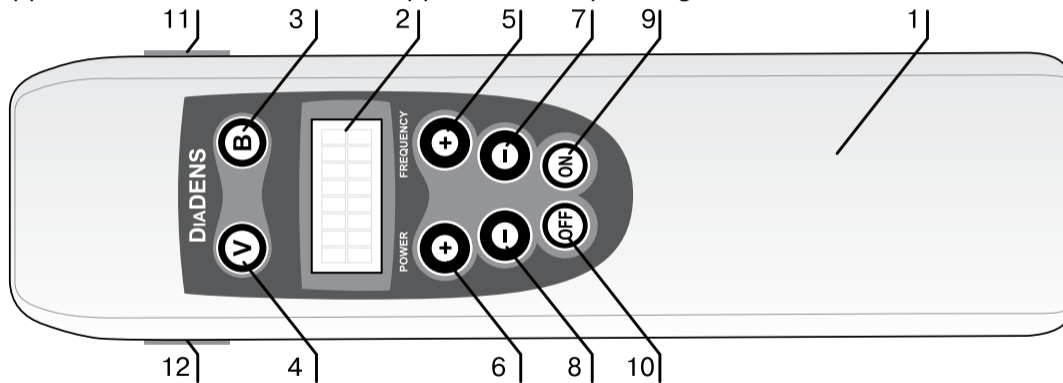


Fig. 3. Face appearance of the DiaDENST apparatus and operating controls

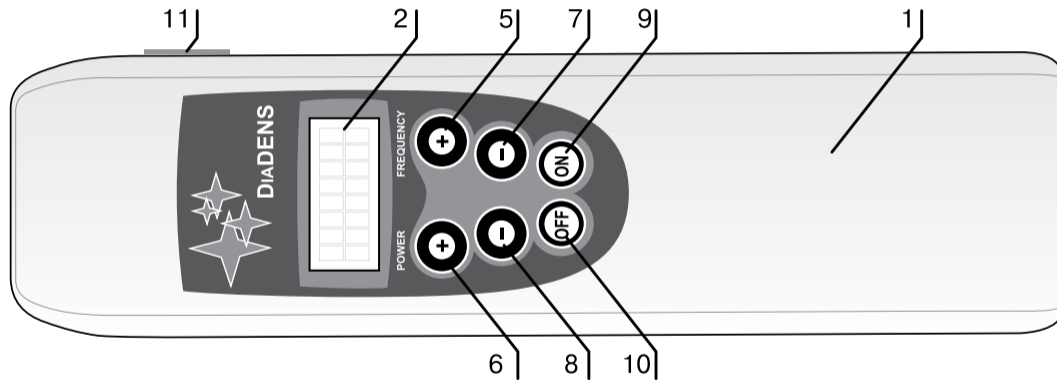


Fig. 4. Reverse appearance of the DiaDENS-DT and DiaDENS-T apparatuses

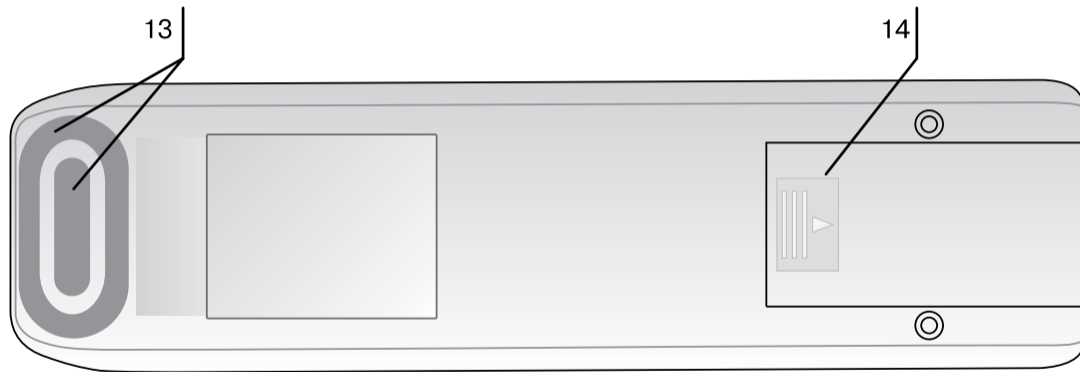


Fig. 5.1. External therapeutic electrode

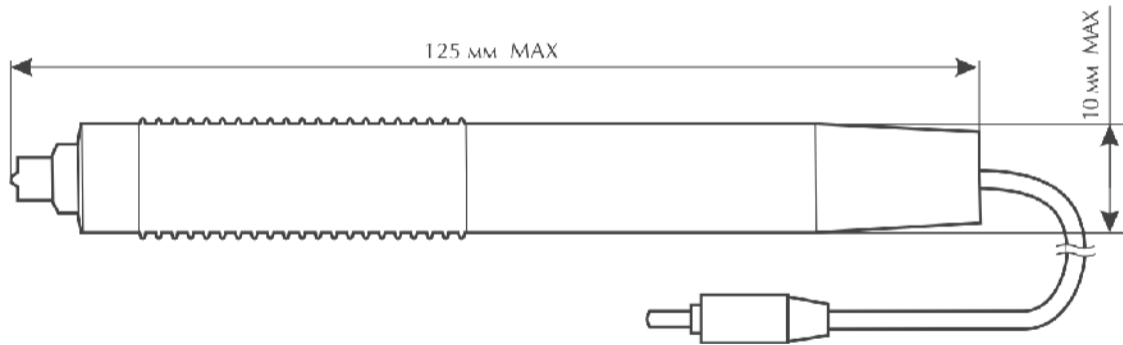
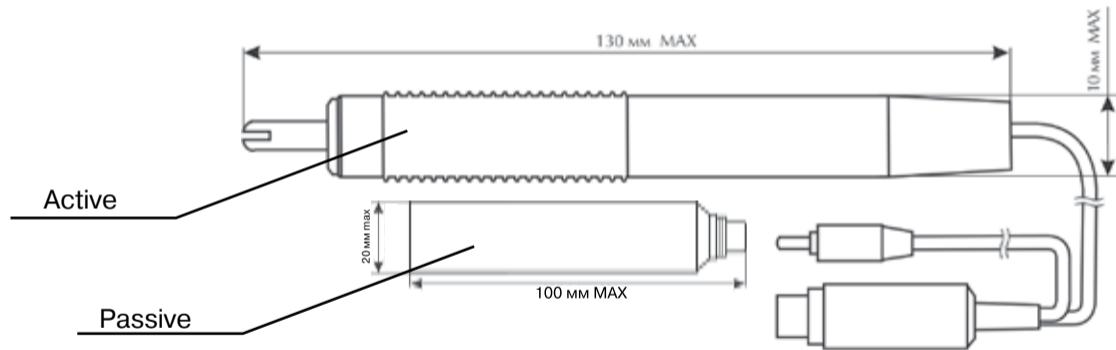


Fig. 5.2. Diagnostic electrode

5.2. The apparatus is equipped with liquid crystal display “2” (LCD) (Fig. 2, Fig. 3).

5.3. The apparatus possesses the following operating controls (Fig. 2, Fig. 3):

- button 3 (“B”) — to switch on the BIOREPER mode (DiaDENS-DT, Fig. 2);
- button 4 (“V”) — to switch on the VOLL mode (DiaDENS-DT, Fig. 2);
- button 5 (“+”) — to increase frequency in the THERAPY mode or stop treatment in the SCREENING mode (“SCR”);
- button 6 (“+”) — to increase power of stimulation;
- button 7 (“-”) — to decrease frequency in the THERAPY mode or switch to SCREENING mode (“SCR”);
- button 8 (“-”) — to decrease power of stimulation;
- button 9 (“On”) — to switch on the apparatus;
- button 10 (“Off”) — to switch off the apparatus.

5.4. The apparatus also has the following connectors (Fig. 2, Fig. 3):

- connector 11 — to connect the external therapeutic electrode;
- connector 12 — to connect diagnostic electrodes (DiaDENS-DT, Fig. 2).

6. TECHNICAL MAINTENANCE

6.1. Daily technical maintenance should include the following:

- external examination of the apparatus;
- disinfection (use standard disinfection means and soft hair-free cloths to clean the electrodes).
- check of serviceability in accordance with instructions in the Operations Manual.

6.2. If the apparatus is not to be used for a prolonged period of time, remove the power source from the compartment 14 (Fig. 4).

6.3. Having received the message “CHANGE BATTERY” change the power source (battery).

7. CHANGE OF POWER SOURCE

Change of power source:

- open battery section (Fig. 4);
- get the power source;
- set new power source*, following the polarity.

* *Set only those power sources that are provided for this device – type 6F22, voltage rating 9 V, or appropriate accumulators with nominal voltage 9 V.*

8. TROUBLESHOOTING

Possible problems and troubleshooting are presented in Table 3

Problem	Possible cause	Troubleshooting
Device automatically switches to THERAPY state from STAND-BY state	Electrodes are dirty	p. 6.1
Device switches off if the message CHANGE THE BATTERY appears, or it does not switch on	Voltage of the power supply is less than 7.9 V	Replace the power supply
When using remote electrodes, the device stays constantly in the STAND-BY state	No contact between the device and the remote therapeutic electrode	Check the contact of the slot 11 (Fig. 2)
	Dry skin	Swipe with tampon wetted with water

Device performs no measuring in the VOLL, BIOFOLL and BIOREPER modes (only for DiadENS-DT).	No contact between the device and the remote diagnostic electrode	Check the contact of the slot 12 (Fig. 2)
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Attention! All other problems will be repaired at the manufacturer's or by manufacturer service centers.

9. WARRANTY CONDITIONS

9.1. The manufacturer guarantees the conformity of the apparatus with the standard TU 9444-001-41006303-2003, when observing the conditions of its use, transportation and storage.

9.2. The length of service of this product is minimum 5 years.

When observing the operation rules, the length of service will considerably exceed the official length indicated.

9.3. This product is warranted for the period of 24 months from the original date of purchase. The warranty for the power supply is set by its manufacturer.

9.4. The warranty of the retailer (manufacturer) or that of the organization fulfilling the functions of the retailer (manufacturer) on the contract basis covers none of the following defects if they appeared after the consumer acquired the product, caused by:

- 1) violation of the rules of transportation, storage, maintenance and use stipulated in this manual, by the consumer;
- 2) actions of the third party;
- 3) force majeure circumstances.

9.5. The warranty does not cover the items with damaged manufacturer's seals.

9.6. In the event of the device failure or defect discovered during the warranty period or in the event of incomplete assembly, the owner must send an application for repair (substitution) to the manufacturer, indicating surname, name, patronymic, address, telephone, brief description of the defect, date and conditions of its occurrence.

PART 2. OPERATION MANUAL**1. GENERAL RECOMMENDATIONS**

Use of reflex zones and points for prophylactics treatment and rehabilitation of the body functions is one of the most ancient and efficient ways of physio- and reflex-therapy.

Numerous studies indicate that a multi-layer reflex and neurochemical responses triggering a cascade of regulatory and adaptive mechanisms of the organism underline the therapeutic effect of the dynamic electroneurostimulation (DENS).

The device will be used with due consideration of concomitant symptoms and syndromes:

- as an independent method of treatment the event of allergic responses to pharmacotherapy as well as in presence of contraindications for other methods;
- as a component of integrated therapy for reinforcing the effect of basic medicinal, homeopathic or manual therapy, as well as psychotherapy and other treatment techniques;
- as a symptomatic treatment for various diseases and syndromes.

Attention! *The first and often the only sign of a serious disease might often involve a sudden occurrence of pain of any localization. Therefore if the pain occurs for the first time and then repeatedly occurs again and intensifies, immediately contact your physician.*

EFFECTS OF ELECTRONEUROSTIMULATION

- anaesthetic;
- anti-inflammatory;
- regulation of vascular tone;
- improvement of microcirculation;
- antipyretic;
- immune-modulating and anti-allergy;
- regulation of smooth and skeletal muscle tone.

INDICATIONS FOR APPLICATION:

- pain syndromes;
- respiratory diseases, digestive diseases, cardiovascular, skeletal-muscle, uro-genital, nervous, endocrine systems, otolaryngology diseases, eyes and skin diseases in adults and children;
- rehabilitation and recovery following treatment, surgical interventions, and lesions;
- effects of unfavourable pathogenic factors (stress, intense physical or psycho-emotional loads, other unfavourable conditions).

CONTRAINDICATIONS:

Absolute:

- individual intolerance of electric current;
- presence of implanted cardiostimulator.

Relative*:

- epilepsy;
- neoplasms of any aetiology and localization (in advanced stages of oncological process, the electrostimulation can be performed as a palliative (auxiliary) measure including elimination of the pain syndrome;
- acute fevers of unknown aetiology;
- venous thrombosis;
- condition of acute mental excitement, alcohol or drug intoxication.

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

TREATMENT CONDITIONS

No special conditions are required for performing the DENS. The room for the electrotherapy must be dry, clean and

** in these cases, application of the electrostimulator should be first discussed with the attending physician*

well lighted. During the electrotherapy session, the patient may be seated or reclining comfortably. After the session, it is recommended to have a 10-15-minute rest.

During the procedure, the electrostimulator must be held in one hand and manipulated lightly. The device electrodes should be in permanent contact with the patient's skin during the procedure. Following each procedure, the device electrodes will be treated with a standard disinfectant (e.g. rubbing alcohol). The devices should be stored with dry electrodes.

THE ELECTROSTIMULATION INTENSITY

Determining the dynamic electroneurostimulation intensity will be done individually, based on patient's subjective feelings. The electrostimulation intensity will be conventionally divided into three energy ranges: *the minimal, comfortable and maximal those*.

The first (at the threshold of feeling), *minimal energy range* corresponds to effect of a weak intensity when the patient

feels either no subjective sensations or a slight vibration. It will be used in working with elementary school children and preschool-age children as well as with elderly patients.

The second (over the feeling threshold but lower than the pain threshold), *comfortable energy range* corresponds to the effect of medium intensity when the patient feels vibration, pleasant pricking or slight burning but no pain. It will be used as the main range of the energy effect.

The third (sensation at the pain threshold), *maximal energy range* corresponds to a high intensity effect when the patient feels painful pricking or burning. Such an intensity of effect might be followed by involuntary muscle contractions in spots near established electrode (the myo-stimulating effect). It will be only applied in THERAPY mode in the event of obvious pain syndrome in adolescents and in adults as well as for emergency treatments.

The electroimpulse effect is not recommended in the energy range intolerable for the patient. At the treatment stages, the electrostimulation power levels might be increased or decreased depending on the patient sensitivity changes and elimination of the pain syndrome.

OPERATING METHODS

The dynamic electroneurostimulation will be performed in three ways: *stable, labile and labile-stable*.

The stable method (fixed position of the electrode) will be used when treating small zonal spots. In the labile way, the built-in electrodes of the stimulator will be evenly shifted over the affected zone, maintaining constant contact between the electrode and the body surface, at the rate of 0.5 to 2-3 cm/sec. The shifting will be performed with straight, anfractuous, circular and other motions depending on the size and form (relief) of the area under treatment.

In labile method, a delay (stabilising) of the built-in electrodes will be admissible, for instance over the painful areas. Thus, the labile-stable method of action will be performed.

The pressure of the device upon the skin will depend on patient's subjective feelings.

2. MODES OF OPERATION

2.1. TEST mode

TEST mode is intended for evaluation of functional condition of the body organs and systems by means of searching

for zones where the skin electrical resistance will sharply differ from adjacent areas (the latent trigger zones (it is also intended for treatment of the skin areas symmetrical to the complaint projection (the symmetry principle).

Attention! In the TEST mode, search for latent trigger zones will be performed rather than diagnosis.

The energy range: minimal or comfortable. The operating method: stable (the electrodes will be shifted after receiving a sound signal).

The TEST mode only works at the frequency of 10 Hz. In treatment, the built-in electrodes only will be used.



DENAS MS
code +7 (343)

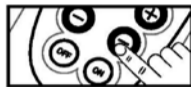
Switch on the device.

To switch the device on press the “On” key. A sound track will be played and manufacturer information will be displayed on the screen (20 sec).

STAND-BY
P00 F77

Following that, the device will switch to the STAND-BY state.

For emergency termination manufacturer information, press and hold any key (except the “Off”) until appearance on the screen of the STAND-BY state.



STAND-BY
P00 MED

Set the frequency at 10 Hz.

Press button "FREQUENCY -" until the LCD shows "MED".



STAND-BY
P00 MED

Put the electrodes on the chosen skin zone (Supplement 1).

Choose the intensity of treatment.



STAND-BY
P35 MED

When the apparatus is switched on the power of effect equals to zero.

To increase the power of effect, press and hold button "POWER +". The power smoothly increases from 00 to 99 conventional units. The LCD shows a power change in the direction from P00 to P99, e.g. 35.

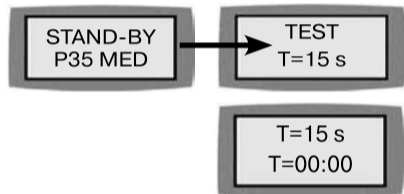


STAND-BY
P00 MED

For decreasing of the power press and hold "POWER -" key. The power will start decreasing evenly from 99 to 0. On the screen, the change of power from P99 to P00 will be shown.

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.

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



The power of effect set, the STAND-BY message is replaced by the announcement on the start of the TEST mode.

In stabilising of the skin resistance under the electrode, the device will emit a sound signal, and in the upper line of the screen for a few seconds the time of the testing action will be indicated.

In the TEST mode, you must not wait for termination of the regime if the period lasts over one minute; you must shift electrodes to the adjacent area and regard this latter area as a latent trigger one, and then to move over to treatment of the next zone.

Make records of the obtained time values in respect to the testing action in order to reveal the latent trigger zones. Those zones whose TEST values differ considerably from the majority of numbers either towards increase or decrease will be the latent trigger zones. These should necessarily be treated in the THERAPY mode during 1-5 minutes at the frequency 60 or 77 Hz. To do this press the “FREQUENCY +” key until F60 or F77 appear on the screen and treat the zones at the second (comfortable) energy level.



STAND-BY
P10 F77

2.2. SCREENING mode (SCR)

The SCREENING mode (SCR) provides quick evaluation of the zone condition prior to and after DENS-treatment. The SCREENING mode is intended for fast search of latent trigger zones. One measurement of the skin surface resistance occurs within first five seconds.

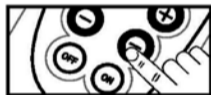
Attention! *The mode is intended for fast search of latent trigger zones rather than for diagnosing.*

The action energy range: minimal or comfortable. The operation method: stable (the electrodes will be shifted after receiving the sound signal).

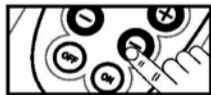
The SCREENING mode works at the frequency of 10 Hz. During the operation, the built-in electrodes only will be employed.



DENAS MS
code +7 (343)



STAND-BY
P00 MED



SCR
STAND-BY

Switch on the device.

To switch the device on press the “On” key. A sound track will be played and manufacturer information will be displayed on the screen (20 sec). For skipping manufacturer’s message, press and hold any key (except the “Off”) until STAND-BY appears on the screen.

Switch on the SCREENING mode.

To do this, press the “FREQUENCY –” key until the LCD shows “MED”.

Press the “FREQUENCY –” key one more time until the first line of the LCD shows the message “SCR”.



SCR
P00 F10

Establish the device electrodes on the selected skin area (Supplement 1).
Set the action power.
At the moment of switching the device on, the power value will be zero.



SCR
P42 F10

For increasing the power press and hold “POWER +” key. The power will start increasing evenly from 0 to 99 conventional units. On the screen, the change of power from P00 to P99 will be shown, for instance P42.



SCR
P00 F10


For decreasing of the action power press and hold “POWER –” key. The power will start decreasing evenly from 99 to 00. On the screen, the change of power from P99 to P00 will be shown.

Attention! *The power control will depend on patient's feelings, at the moment of the electrode contact with skin surface. The pain sensitivity threshold should not be exceeded.*


Attention! During operation of the device in the SCREENING mode, the electrodes on the patient's skin should be established in the "stable" way, i.e. one must not shift the device electrodes directly during its operation in the SCREENING mode.



SCR
T = 5 s



SCR
 Δ LT = 8

STAND-BY
P10 F77

When the device finds contact of the electrodes with skin surface, the message STAND-BY will be replaced with indication of the stable time interval: 5 seconds, during which changing of the trigger zone condition will be determined in response to impulse sent by the device. On termination of the 5-second period, the device emits a brief sound signal and displays measurement result in the form of index Δ LT (within the range from 0 to 100 units), e.g. = 8. Make notice of the value obtained.

Move to diagnosing the next zone.

Those zones whose Δ LT values differ considerably from the majority of numbers either towards increase or decrease will be the latent trigger zones. These zones must be treated in THERAPY mode during 1-5 minutes at the frequency of 60 or 77 Hz. To do this, press the "FREQUENCY +"

key until appearance on the screen of F60 or F77 and treat the zones at the second (comfortable) energy level.

2.3. THERAPY mode

The THERAPY mode operates at frequencies of 20, 60, 77, 140 and 200 Hz. At operation in THERAPY mode, both the zonal (with the aid of built-in electrodes) and pointed (with the aid of external electrode) action.

Recommendations for choosing therapeutic frequencies:

– 20 Hz – “low” frequency. It will be used in problem zone with direct projection, in universal zones and the zones reinforcing the systemic effect. This effect occurs within 20-60 minutes, lasting for several hours.

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

– 60, 77 and 140 Hz – “high” frequencies. These will be used in problem zone with direct projection, segmental zones, trigger zones. The effect occurs within 5-10 minutes, lasting for one or more hours. Indications: inflammatory and functional diseases of the internal organs with a moderate pain syndrome, circular disorders.

– 200 Hz – “superhigh” frequencies. These will be used in problem zone with direct projection. The effect occurs within first minutes, lasting afterwards from several minutes to one hour. To prolong the effect, after elimination of pain, the device action can be continued at low or high frequencies. Indications: sharp pain due to disease and lesion of the muscular-skeletal system in acute period and pathological condition of the peripheral nervous system.

Switch on the device.



DENAS MS
code +7 (343)

STAND-BY
P00 F77

To switch the device on press the “On” key. A sound track will be played and manufacturer information will be displayed on the screen (20 sec).

For skipping manufacturer information, press and hold any key (except the “Off”) until “STAND-BY” appears on the screen.

Set the action frequency at 20, 60, 77, 140 or 200 Hz.

On switching the device “On”, a 77 Hz frequency will be automatically set.



STAND-BY
P00 F20



STAND-BY
P77 F200



STAND-BY
P00 F200



STAND-BY
P35 F200

To set the frequency 20 and 60 Hz, press the “FREQUENCY –” key until desired frequency appears on the screen.

To set the frequency 140 and 200 Hz, press the “FREQUENCY +” key until “F 140” or “F 200” appears on the screen, respectively.

Establish the device electrodes on the selected skin area (Supplement 1).
Set the action power.

At the moment of switching the device on, the power value will be zero.

For increasing of the power press and hold “POWER +” key. The power will start increasing evenly from 0 to 99 conventional units. On the screen, the change of power from P00 to P99 will be shown, for instance P35.



STAND-BY
P00 F200

For decreasing of the action power press and hold “POWER –” key. The power will start decreasing evenly from 99 to 00. On the screen, the change of power from P99 to P00 will be shown.

Attention! *The power control will be adjusted based on patient's feelings, at the moment of the electrode contact with skin surface. The pain sensitivity threshold should not be exceeded.*

THERAPY
T=00:07

After setting the action power, the message “STAND-BY” will be replaced with the beginning of THERAPY mode and indication of the action time.

The duration of procedure in THERAPY mode, in the zone of direct projection of the pain or in functional disorder, will depend on patient's responses as follows:

- complaint is completely eliminated;
- patient feels much better;

- beneath the electrode, bright reddening of the skin occurs as well as sensation of “formication”, warmth of lightness;
- patient falls asleep.

The duration of treatment of the latent trigger zones is 1 to 5 minutes.



GOOD
HEALTH

GOOD
BYE

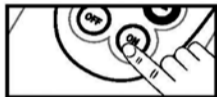
To switch the device off, press the “Off” key. The device will display the messages “GOOD HEALTH” and “GOOD BYE” and, after a musical fragment, the device will switch off.

2.4. MED mode

The MED (Minimal Effective Dose) mode will be applied for intense physical or mental work; in physical or mental strain, in chronic fatigue syndrome, difficulties getting up in the morning, drowsiness, difficulty concentrating, and as

preventive measure in cold and flu seasons.

It will be used once per session in a course treatment.



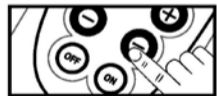
DENAS MS
code +7 (343)

Switch on the device.

To switch the device on press the “On” key. A sound track will be played and manufacturer information will be displayed on the screen (20 sec).

STAND-BY
P00 F77

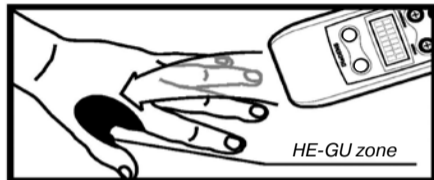
For skipping manufacturer information, press and hold any key (except the “Off”) until “STAND-BY” appears on the screen.



STAND-BY
P00 MED

Set the action frequency to 10 Hz.

To do this press the “FREQUENCY –” key until appearance of “MED” on the screen, once more press the key “FREQUENCY –” and MED mode will switch on.



Establish the device electrode on the HE-GU zone.

Set the action power.

In switching the device on, the power value is zero.



STAND-BY
P99 MED

For increasing of the power press and hold "POWER +" key. The power will start increasing evenly from 0 to 99 conventional units. On the screen, the change of power from P00 to P99 will be shown.




STAND-BY
P00 MED

For decreasing of the action power press and hold "POWER -" key. The power will start decreasing evenly from 99 to 00. On the screen, the change of power from P99 to P00 will be shown.

Attention! The power control will be adjusted based on patient's feelings, at the moment of the electrode contact with skin surface. The pain sensitivity threshold should not be exceeded.


Attention! During operation of the device in the MED mode, the electrodes on the patient's skin should be established in the "stable" way, i.e. one must not shift the device electrodes during the procedure.




TEST
T=00:03

After setting the action power, the message "STAND-BY" will be replaced with a message of beginning of the MED mode first phase: the TEST regime.

On stabilising of the skin resistance beneath the electrode, the device will emit sound signal and in the upper line of the screen for a few seconds the time of testing action will be displayed.

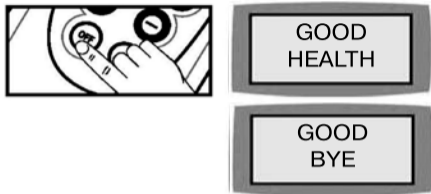


T=15
T=00:03



THERAPY
T=05:00

Then the second phase of the MED will begin: continuous stimulation for 5 minutes; a message "THERAPY" will appear and time counting will begin in respect to minimally effective dose of the device action. On termination of the 5 minute period, a sound signal will be emitted indicating completion of the MED mode.



To switch the device off, press the “Off” key. The device will display the messages “GOOD HEALTH” and “GOOD BYE” and, after a musical fragment, the device will switch off.

2.5. VOLL mode (only for DiaDENS-DT)

VOLL mode is based on the method developed by R. Voll. The Voll method is a method of electropuncture diagnosis through electric channels for evaluation of functional condition of all internal organs of the human body. The method is also intended for testing and selection of individual medicinal, homeopathic preparations and biologically active additives.

Attention! *The mode is intended for evaluation of functional condition of the organs and systems rather than diagnosings. We may discuss conditions when the function is reduced, normal or activated.*

The studies with the Voll method can be performed in several ways:

- express-evaluation of the functional condition by the end points of the meridians (which is enough for performing diagnostic procedures at home) (Supplement 2, Fig. 1, 2);
- evaluation of the functional condition by control or other points of meridians*.

Preparing for diagnosis

Two days prior to the diagnosis procedure, it is recommended that patient avoids tonics. On the day of the diagnosis, two hours before the procedure, the patient should avoid taking coffee, or tea, or food. Immediately before the procedure, it is recommended for patient to sit in a comfortable position and relax for about 15 minutes.

Prior to the session, remove all devices generating high-frequency electromagnetic fields (cell telephones, pagers,

** the methods of diagnosis by the control and other points of the channels were described in detail in the reference for this theme. These techniques, operation-wise, do not differ from the express-evaluation but demand serious theoretical and practical training of the operator-physician performing the diagnosis and will not be discussed in this Instruction.*

high-frequency ovens, TV-sets, irons, etc.). The patient will have to remove jewelry, glasses, and a watch. During the examination, the patient must be seated or reclining comfortably.

Attention! During the session, do not touch the patient with both two hands simultaneously.



DENAS MS
code +7 (343)

Switch the device on.

To do this, press “On” key. A sound track will be played and manufacturer information will appear on the screen (20 sec).

Following that, the device will go into STAND-BY mode.

For skipping manufacturer information, press and hold any key (except the “Off”) until “STAND-BY” appears on the screen.



VOLL:
000

Connect the diagnostic electrodes (Fig. 5.2) to the slot (Fig. 2).

To switch to VOLL mode press “V” key.

Attention! *The patient will hold passive electrode in his/her hand opposite to the side being tested (e.g. when testing the left hand or left foot, the passive electrode will be held by patient's right hand).*

Express-evaluation of functional condition

Wet the applicator of active diagnostic electrode with a wet tampon prior to every establishment of the electrode on the skin.

Establish the active diagnostic electrode in the projection of the measurement point, gradually enhancing the pressure of the electrode until achieving stable measurements on the screen.

Attention! *For measurement points situated on the finger and toe phalanxes, establish the active electrode at a 45° angle to the skin surface.*

Attention! *During the testing procedure measurements are made on both hands and feet.*

A deeper evaluation of the condition involves examination using the arrow drop effect.



MAX= 062
>

MAX= 062
-02>

MAX= 062
-02> -04

VOLL
000

In revealing the maximal value, without breaking contact between the electrode and the measurement point and without changing the pressure force applied to the skin, press key “POWER +”. On the screen, the maximal value “MAX=...” will appear and then the device will perform two measurements with a 1 second interval, their values indicating difference of current and the maximal magnitude of electric current. The data will stay on the screen for 3-4 seconds.

Values will be recorded in a special form (diagnostic chart) for subsequent analysis.

Then the device will return to its initial state and display message “VOLL”: the measurement procedure may be repeated for the next point.

It is not recommended to perform measurements of the same point more than 3 times in a row as this will disturb haemodynamics of this point leading to deviation of the parameters: they will no longer be accurate for diagnostic purposes.

Medicinal testing

The first measurement of the parameters will be performed with no medication. Then the substance to be tested will be placed into the contour of the passive diagnostic electrode and the measurement will be repeated for the same points.

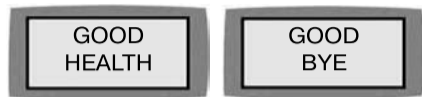
Attention! *Do not place the samples under study into the passive electrode without packaging them first, as it is not recommended to wash the electrode, whereas particles of the sample remaining on the electrode surface will distort values of measurements obtained in subsequent diagnosis.*

Comparing the parameters obtained, we may conclude on the fact how the substance under study affects the state of the meridians.

If necessary, we may continue the testing a different medicine.



To exit from "VOLL", press the "V" key.
To switch the device off, press the "Off" key.



The device will display the messages “GOOD HEALTH” and “GOOD BYE” and, after a musical fragment, the device will switch off.

Medicinal testing:

First the evaluation of energy meridian initial condition will be performed (see above).

The first measurement of the parameters will be performed with no medication. Then the substance under testing will be placed in the contour of the passive diagnostic electrode and the measurement will be repeated for the same points.

Comparing the parameters obtained, we may conclude on how the substance under study affects the condition of the meridians.

If necessary, we may continue the testing for a different medicine.

Attention! Do not place the samples under study into the passive electrode without packaging them first, as it is not recommended to wash the electrode, whereas particles of the sample remaining on the electrode surface will distort values of measurements obtained in subsequent diagnosis.



To exit from "VOLL", press the "V" key.

To switch the device off, press the "Off" key.

The device will display the messages "GOOD HEALTH" and "GOOD BYE" and, after a musical fragment, the device will switch off.



2.6. The BIOREPER mode (only for DiaDENS-DT)

Bioreper is a method of functional electropuncture auricular diagnosis (on external ear). The study will be performed at testing voltage individual for each patient, i.e. with due consideration of individual electric conductivity.

Attention! *The mode is intended for evaluation of functional condition of internal organs and systems rather than diagnosis. We can discuss conditions when the function is reduced, normal or activated.*

Highly significant will be findings for specific organs (existence of points representing concrete organs).

The technique allows us to reveal pathological conditions at “pre-disease” stage, select the optimal treatment procedure and examination, to evaluate functional condition of diseased organs and systems in dynamics, when performing another testing. Due to low current (lower than 15 μA) in measurement points, no morphological changes occur.

Preparing for diagnosis

Two days prior to the diagnosis procedure, it is recommended that patient avoids tonics. On the day of the diagnosis, two hours before the procedure, the patient should avoid taking coffee, or tea, or food. Immediately before the procedure, it is recommended for patient to sit in a comfortable position and relax for about 15 minutes.

Prior to the session, remove all devices generating high-frequency electromagnetic fields (cell telephones, pagers, high-frequency ovens, TV-sets, etc.). The patient will have to remove jewelry, glasses, and a watch. During the examination, the patient must be seated or reclining comfortably.

Attention! During the session, do not touch the patient with both hands simultaneously.

Switch the device on.



DENAS MS
code +7 (343)

To do this, press “On” key. A sound track will be played and manufacturer information will appear on the screen (20 sec).

Following that, the device will go into STAND-BY mode.

For skipping manufacturer information, press and hold any key (except the “Off”) until “STAND-BY” appears on the screen.

Connect the diagnostic electrodes (Fig. 5.2) to the slot (Fig. 2).

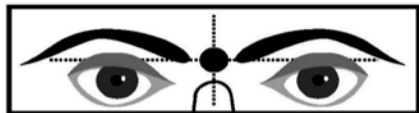
To switch on the diagnostic regime of BIOREPER method, press “B” key.

The patient will hold passive electrode in his/her hand (the patient’s hands must not touch each other or cross).

Determining of individual testing voltage.



BIOREPER:
0,0 000



Put the active electrode to In-Tan point situated on the mid-line between eyebrows on patient's nose.



BIOREPER:
10,0 196

Ut=1.96 V
10.0 μ A

Press and hold the "POWER +" key: selection of testing voltage will start, the voltage values being displayed in the lower right corner of the screen; in the lower left corner, value of proceeding current will be displayed for In-Tan point.

In the upper line of the screen, value of the testing voltage will appear: "Ut=... ", in the lower line – value of the proceeding current. This will be the individual voltage for this patient for this procedure.

The device is ready for diagnosis.

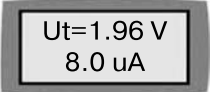


LOW
CURRENT

Attention! If the current 10 μA is not reached, then the message “LOW CURRENT” will appear and this will mean that you failed to reach *In-Tan* point; it will be necessary to change position of the active electrode.

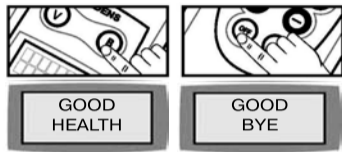
Methods of BOIREPER diagnostics

The passive electrode will be held in the palm on the side of the auricle under testing. The active electrode will be put to the auricle point of measuring (Supplement 2, Fig. 3) for period not exceeding 2-3 seconds for each point. It will be necessary to provide even and equal pressure, without slipping the electrode off the point. It is not recommended to perform measurements for the same point more than two times in a row or to perform measurement for a single point for over 5 seconds.



Ut=1.96 V
8.0 μA

The current values will be indicated in μA in the lower part of the screen; they should be recorded in a special form (diagnostic chart) for subsequent analysis.



To exit BIOREPER mode, press “B” key.

To switch the device off, press the “Off” key.

The device will display the messages “GOOD HEALTH” and “GOOD BYE” and, after a musical fragment, the device will switch off.

3. SPECIAL EMC-INFORMATION:

3.1. 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.

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

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

3.3. Electromagnetic Environment guidance

The Portable electrostimulator DiaDENS is suitable for use in the specified electromagnetic environment. The customer and/or the user of the DiaDENS 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.

3.4. 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:

- User 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.

SUPPLEMENT 1**RECOMMENDED ZONES AND POINTS OF APPLICATION**

1. Local zone of the damage focus (the zone of direct projection of the patient's complaint)

One of the simplest and most effective ways of the DENS-performance involves direct treatment of the area of detailed and localised zone of pain, damage focus or direct surface (skin) projection of the organ with disturbed function. The zone will be treated in the THERAPY mode until achieving a clinical effect. For instance, in lumbalgia, on the small of the back zone; in knee joint damage, directly upon the damaged joint area.

2. Metamer-segmental zones

The location and distribution of the spinal nervous roots, nerves, nervous plexuses and of the vegetative nervous system nodes will be subject to the law of metamerism. The same spinal segments will serve, at that, as the innervation device and, respectively, the device of information transfer from an internal organ and a certain skin area and back. The existing recommendations (Table 1) make it possible to perform the DENS in patient's complaint within the zone of a certain dermatomer (Supplement 2, Fig. 4, 5), which produces a regulating effect on the respective segment of the spinal cord and sympathetic ganglion and leads to the necessary therapeutic effect. Treatment of metamer-segmental zones is simple and efficient, and is scientifically substantiated from the standpoint of the modern neurophysiology.

Table 7

Peripheral parts of the metamer-segmental zones (dermatomers) recommended for the device treatment for pain syndromes and diseases of the locomotor system

Dermatomers	Symptoms and diseases
C1-C2	tension of the occipital muscles, torticollis, tension and poor mobility of the spine muscles, pain in the shoulder area, hemiplegia;
C3-D1	damage of muscles in the occiput area, pain in the occiput, torticollis, damage of the shoulder joints and shoulder muscles, back muscles, hemiplegia;
Th1-Th2	<ul style="list-style-type: none"> – sensation of tension in the spine, – spasms of the neck and back (contractions), – tension of the occipital muscles, pain in the scapulae area, pain syndrome in damage of knee joints, paralysis of the upper extremities;

Th2-Th3	– pain and tension of muscles in the area of the back, small of the back, shoulder, occiput, torticollis, intercostals neuralgia
Th3-Th4	movement disorders in the neck area, tension of the occipital muscles, pain in the area of the shoulder external surface, in the shoulder-blade, chest, in the lumbar area, abdomen, damage to the spine lumbar segment and sacrum;
Th4-Th5	diseases of the neck, damage of muscles and spine at the shoulder-blade level;
Th5-Th6	tension of muscles in the area of the back and spine, pain in the back and chest at respective level, intercostals neuralgia, pain in the spine and spastic muscles of the back (contracture);
Th6-Th7	sensation of tension in the occiput area, pain in the back and neck, limitation of the spine mobility, back muscles contractions, intercostals neuralgia;
Th7-Th8	damage of muscles and joints of the lower extremities, lumbar area, paravertebral muscle contracture (spastic muscles along the spine);

Th9-Th10	damage of the muscles and skeleton of the lumbar area and lower extremities;
Th10-Th11	– damage of the muscles of the anterior abdominal wall, small of the back; – contractions and mobility disturbance in the spine;
Th11-Th12	pain in the back, weakness of extremities;
Th12-L1	pain in the stomach, back and spine;
L1-L2	pain and contractions in the lumbar area, tension of the spine and small of the back muscles, oedemas of the lower extremities;
L2-L3	pain and tension in the back and small of the back, sensation of tension in the spine muscles, pain in the hip, paralysis of the lower extremities, lumbalgia;
L3-L4	damage of muscles, skeleton and soft tissues of the small of the back;

L4-L5	pain in the lumbar area and lateral part of the pelvis; anaesthesia (absence of sensitivity) of the leg skin (the Prot disease), pain on external surface of the knee joint, paralysis of the lower extremities;
L5-S1	paralysis of the lower extremities, lumbalgia, lumbago, sciatica;
S1-S2	pain in the abdomen, sacrum and hip joint, lumbago;
S2-S3	pain in the sacrum, small of the back, spine, damage of the knee joint, pain in the lower extremity joints;
S3-S4	pain in the small of the back, sciatica, pain in the spine;
S4-S5	pain in the small of the back, back, sacral-coccygeal area, pain in the area of lateral surface of the buttock, lumbalgia, sciatica, tension of the spine muscles, weakness of the leg muscles, paralysis of the legs, paralysis of muscles of the of the shin, foot.

3. Zones of general treatment

These zones will be included in the action formula when it is necessary to stabilise therapeutic effect of local and seg-

mental response and to obtain a general adaptive response of the body.

1) The back midline as well as two paravertebral lines (next to the spine) – Supplement 2, Fig. 6, 7;

2) Projections of the trigeminal nerve branch endings on the face (Supplement 2, Fig. 8);

3) Hands and feet (the hands will be treated from the radiocarpal joint to the finger tips on their palm and dorsal surfaces, the feet will be treated from the ankle-joint to the toe tips on the sole and dorsal surfaces).

The common zones will be studied in TEST mode or SCREENING mode. On finding latent trigger zones (see below), they will be treated in THERAPY mode.

4. Trigger zones

Disturbances of function and structure of internal organs will lead in certain limited skin areas, muscles, tendons, periosteum to appearance of areas with distorted coloration, disturbed sensitivity, enhanced painfulness, dense areas, changed electric conductivity and other changes usually not observed in a healthy organism, and absent in symmetrical body areas. These pathological zones and points were named the trigger zones.

The trigger zones (TZs) will be conventionally divided into active and latent.

The active TZs will be located by physician in the course of interviewing the patient and his or her examination; these are local zones of reflected painfulness and enhanced sensitivity, for instance Supplement 2, Fig. 9, 10.

The latent TZs will be determined in the TEST mode by difference of parameters in the points under testing. On finding latent trigger zones, they will be treated in the THERAPY mode.

More detailed information is presented in the following re-ference:

1. *The Manual for dynamic electrostimulation using DiaDENS-T and DiaDENS-DT devices// Chernyshev V.V., Malakhov V.V., Vlassov A.A., Nikolaeva N.B., Umnikova M.V. – Ekaterinburg, 2005 – 283 p.*

2. *The Universal Register of the DENS-therapy// Chernyshev V.V., Malakhov V.V., Riavkin A.Yu., Riavkin S.Yu. – Ekaterinburg, 2003. – 165 p.*