

TRONITEK LLC, Ekaterinburg, Russia

Trancutaneous electrostimulator for impact
on biologically active zones

Operations Manual

DENAS-CARDIO

3rd generation

<http://www.diadens.com>

Россия/ Russia	
ЕС, все страны/ EU all	
США/ USA	
Канада/ Canada	

TRTK 05.0-03.70-05 P3

TU9444-005-44148620-2006

Registration certificate of the Federal Service on Surveillance
in Healthcare № **FSR 2011/11772**

CONTENTS

1. Safety Measures
2. Function.
3. Complete Set and Apparatus Arrangement.
4. Order of Treatment.
5. Technical Maintenance

1 SAFETY MEASURES



Read all the information in the present manual carefully! The manual contains important information of your safety as well as recommendations of correct usage and unit care.



The apparatus is not electrically dangerous for the patient due to its built-in low voltage electric power source, isolated from the operational part of the apparatus (device of BF type)



The apparatus must not be used for treating patients with implanted electronic devices (for example, cardiostimulator) and for treating patients with individual electric current intolerance.



The apparatus must not be used in the area of direct projection of the heart on the front of the body.



During stimulation the patient must not be connected to any high-frequency electric device, simultaneous application of the apparatus and another electric device can result in burns and possible damage of the apparatus.

Warning! *Do not use the unit on damaged skin, as well as the presence of signs of inflammations of the skin*



Operation in the close proximity to shortwave or microwave equipment may produce instability in the stimulator output.



The apparatus contain fragile elements. Keep it from blows and drops.



It is prohibited to use of external power supply network.



The apparatus is not waterproof. Protect it from water.



All the repair works for the apparatus shall be carried by qualified personnel of the manufacturer.



Conditions of transportation: temperature from -50 to $+50^{\circ}\text{C}$, relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa



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



Operation conditions: ambient air temperature from 10°C to 35°C , relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa.

If the apparatus is stored at the temperature below 10°C , keep it under normal conditions at least for two hours before use.



Recycling:

All the package materials are environmental-friendly and can be reused.



Separate assemblage of electric and electronic equipment.

The old apparatus is not useless garbage! It contains valuable materials, which can be recycled in compliance with rules on environmental protection. Hand them to specially assigned centers for collection and recycling (consult your district authorities).

2 FUNCTION

2.1 General information

The DENAS-CARDIO apparatus is intended for therapeutic non-invasive (without damaging the skin surface) course treatment of biologically active zones by the method of dynamic electrostimulation for correction of the arterial blood pressure (AP) and normalization of the general state of health. The apparatus is intended for people of over 14 years of age with a labile form of the arterial hypertension and patients with a lasting increase of the arterial blood pressure (essential hypertension) as an additional treatment on the background of drugs taken.

The DENAS-CARDIO apparatus combines frequencies 9.2, 8.1, 3.3, 77, 20, 10 Hz which are traditionally applied for treatment of hyper-tension and a specially developed mode "77 10" intended for producing a general sedative, calming effect.

Electrostimulation with the "DENAS-CARDIO" apparatus promotes normalization of the vessel wall, dilatation of capillaries, and improvement of hemodynamics in the system of cutaneous microcirculation.

As a result of these:

- arterial pressure is being stabilized at the level acceptable for a patient;
- cenesthesia improves;
- psycho-emotional state improves;
- physical efficiency increases;
- the risk of complications of the essential hypertension is reduced;
- quality of the patient's life improves.

The DENAS-CARDIO apparatus is intended for **course** treatment of patients with arterial hypertension as an additional treatment on the background of basic drug therapy.

Attention! Even in cases of situational (single, seldom) increase of the arterial blood pressure a course treatment of not less than 10 procedures is necessary, 1-2 procedures daily. Meanwhile, in the beginning of treatment a temporary destabilization of the arterial blood pressure with its further stable reduction may be observed.

Apparatus treatment has an effect of “accumulation” that is AP becomes stable by the end of the treatment course.

22 Application

The procedure is to be carried out 1-2 times daily, better in one and the same time of the day regardless of the AP level before the procedure.

Patients with essential hypertension need repeated regular treatment courses minimum once a month (for instance from the first to the 15th day of each month).

Attention! *There is no need to control AP after the procedure.*

In compliance with international recommendations, it is recommended for patients with essential hypertension to keep a “journal of AP” and measure arterial blood pressure three time a day at one time (morning, afternoon, evening), even if the patient feels good. In case of any complaints (headache, vertigo, pain in the heart, intermission in the heart work, weakness, syncopal state and

others) an additional measurement of AP is needed.

Warning! During the treatment with the “DENAS-CARDIO” it is **forbidden** that the patient with a considerable increase of AP and high risk of vascular complications (myocardial infarction, cerebral stroke, thromboembolism) stops taking the drugs him/herself on the background of treatment with the “DENAS-CARDIO” apparatus. After having a stable hypotensive effect registered in the “journal of AP”, regimes and doses of drug treatment may be changed by the attending doctor.

Patients with seldom periodical and slight increase of the arterial blood pressure (not higher than 150 mmHg) – labile arterial hypertension – can apply the “DENAS-CARDIO” apparatus as monotherapy. Such an approach can retard and prevent the disease from converting into a stable form.

2.3 Indications for application:

- stable high arterial blood pressure of patients with essential hypertension – as an addition to complex drug treatment;
- episodic increase of AP under stressful situations, changes of weather conditions and so on in patients with a labile form of arterial hypertension.

2.4. Recommendations for application of the “DENAS-CARDIO” apparatus for course treatment: carry out 1-2 procedures a day during 10-15 days regardless of the AP indices before the procedure. With a stable form of arterial hypertension, repeat the courses monthly.

2.5. Recommendations for one-time application of the “DENAS-CARDIO” apparatus for persons with susceptibility to AP increase under ill-being: take a hypotensive medicine recommended by your attending doctor and additionally carry out treatment procedures with the “DENAS-CARDIO” apparatus every 1-1.5 hours until the complaint is eliminated. In case of long-lasting high arterial blood pressure, address the doctor.

2.6. Recommendations for application of the “DENAS-CARDIO” apparatus for patients older than 70 years of age: in the advanced age a slower rate of AP reduction. For this a recommended order of treatment with the “DENAS-CARDIO” is once a day. Treatment course – not more than 7-8 procedures. It is advisable to repeat the treatment course after 10-15 days break.

During first treatment course, AP can fluctuate a little that's why the patient shall continue taking the hypotensive medicines prescribed by the doctor.

2.7 Recommendations for application of the “DENAS-CARDIO” apparatus for patients with malignant hypertension: malignant hypertension is a stable high arterial blood pressure, more than 180 mmHg that cannot be treated with drug correction under correct and systematic taking of drugs: course duration and number of procedures per day shall be determined after consulting an attending doctor.

2.8 Contraindications to application:

Absolute:

- individual intolerance to the electric current;
- implanted cardiostimulator;

Relative — in these cases it is recommended to use the electrostimulator only after consulting your attending doctor:

- epileptic seizure;
- neoplasms of any etiology and localization;
- acute febrility of unclear etiology;
- vein thrombosis
- condition of acute psychic excitement, alcoholic or drug intoxication;

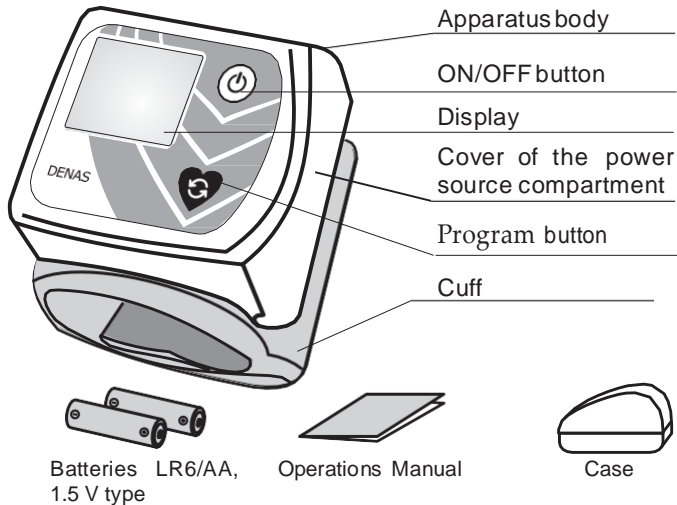
Warning! *On the background of application of the “DENAS-CARDIO” apparatus taking the drugs prescribed by the doctor is obligatory! Changing the regimes of medical treatment and reduction of doses of the drug to be taken is allowed after stable reduction of AP and after consulting your*

attending doctor only.

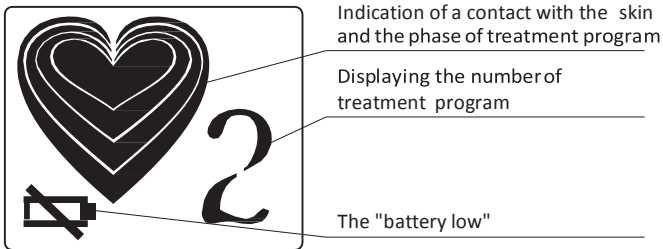
Warning! There are no trials of DENAS-therapy for pregnant women, so the device should be used only in case of absolute necessity with the specialist consultations.





Warning! In the case of deterioration of the health when using the machine, refer to a specialist.

3 COMPLETE SET AND APPARATUS ARRANGEMENT

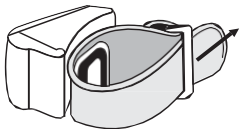


Symbols of the display:

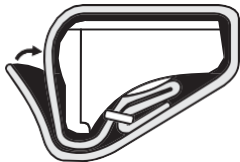


-  – The skin contact is set, the first step of program is performed;
-  – The skin contact is set, the second step of program is performed;
-  – The skin contact is set, the third step of program is performed;
-  – The skin contact is set, the procedure is finished.

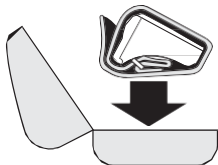
Attention! *To avoid breaking the case, fold the cuff of the apparatus in a correct way!*



Step 1. Pass the end of the cuff through the loop.



Step 2. Fold the cuff around the apparatus body that the lock element of cuff be on the side of the cover of the power source compartment



Step 3. Place the apparatus into the case

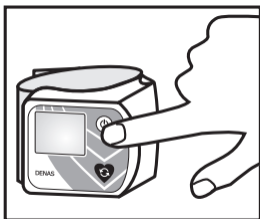
4. PROCEDURE

4.1 Preparation

4.1.1 Choose the position that is comfortable for you (sitting or lying).


Attention! It is forbidden to carry out procedures with the DiaDENS-Cardio apparatus in a standing position!

Attention! Before a session, remove all conductive elements in the stimulation area (watches, jewelry, etc.). Using the apparatus in the presence of conductive elements on the stimulation area is prohibited as it may cause an electrical burn.

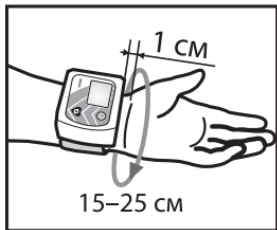


4.2 Application of the program №1

4.2.1 Take all clothing, jewellery, watches off the left forearm.

4.2.2 Switch on the apparatus with the button . After switching, programs №1 is set by

default.

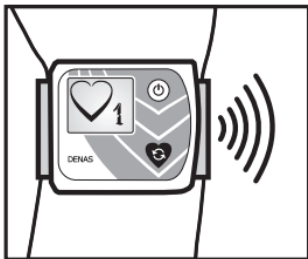


4.2.3 Holding the hand palm up, place the apparatus with the indicator up at a distance of 1 cm from the radiocarpal fold so that the electrodes touch the skin on the inner surface of the forearm. Tighten and fasten the

apparatus cuff so that the electrodes are firmly pressed to the skin. While skin contact the apparatus beeps, displays the symbol of electrode contact with the skin ♥ and begins the stimulation.

Attention! When fixing the apparatus, do not tighten the cuff too much.


4.2.4 Conduct a treatment session. A session consists of three stages, which are different in frequency, time and amplitude effect. The end of each phase is accompanied by a change in the symbols on the display



and an audio signal. Duration of the session is determined by the program and its average time is 6-7 minutes.

4.2.5 The end of the session is accompanied by an audio signal

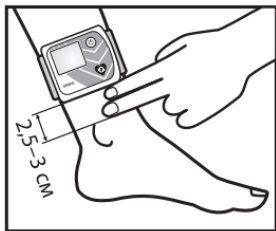
and display sign . At the

end of the session take off the apparatus and turn it off by holding the button  for 3 seconds.


Attention! When there is no skin contact and no pushing a button the apparatus turns off automatically in 3 minutes. If there is skin contact, the apparatus will automatically turn off in 3 minutes after the end of the session.

Attention! Treat the apparatus electrodes with a standard disinfection solution (for instance, alcoholic solution) after each procedure. Keep the apparatus with dry electrodes.

4.3 Application of the program №2




4.3.1 Take clothes off the left ankle and the lower part of the knee.

4.3.2 Switch on the apparatus with the button . After switching, programs №1 is set

by default. Using the button 



set the program №2.

4.3.3 Place the device electrodes on the inner surface of the lower leg at a distance of 2.5-3 cm above the protruding part of the inner ankle. Tighten and fasten the apparatus cuff so that the electrodes touch the skin. If there is skin contact the apparatus beeps, displays the symbol of skin contact  and begins the stimulation.

Attention! When fixing the apparatus do not tighten the cuff on the lower leg too much.

Attention! The apparatus cuff device is meant for arms or legs with girth no more than 22 in the place of attachment. If arms or legs girth is more than that, it is recommended to use an additional cuff.

4.3.4 Conduct a treatment session. A session consists of three stages, which are different in frequency, time and power. The end of each phase is accompanied by a change in the symbols on the display and an audio signal. Duration of the session is determined by the program and its average time is 7-8 minutes.

4.3.5 The end of the session is accompanied by an audio signal and display sign . At the end of the session take off the apparatus and turn it off by holding the button  for 3 seconds.

Attention! When there is no skin contact and no pushing a button the apparatus turns off automatically in 3 minutes. If there is skin

contact, the apparatus will automatically turn off in 3 minutes after the end of the session.

Attention! After each procedure, electrodes should be processed with standard disinfectant (for example with 3% hydrogen peroxide). Keep the device with dry electrodes.

4.4 After the session, the patient should relax for 20-30 minutes.

5 TECHNICAL MAINTENANCE

5.1 Daily technical maintenance should include the following:


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

Use standard disinfection means and soft napless napkins to clean the electrodes.

5.2 Check of service ability of the apparatus in accordance with instructions in Section 4.

5.3. If the apparatus is supposed not to be used for a long period, remove the power source from its compartment

(Section 6).

5.4. Having noticed the symbol  on the indicator, replace the power source (Section 6).

Official webstore of Denas MS Corporation:

www.diadens.com