ООО «РЦ АРТ», Россия, Екатеринбург

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Электростимулятор чрескожный
для воздействия на БАЗ

ДиаДЭНС-КАРДИО

Руководство по эксплуатации

РЦ АРТ 05.0-03.71-03 РЭ
ТУ 9444-005-44148620-2006

“RC ART” LLC, Russia, Ekaterinburg

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Transcutaneous electrostimulator
for stimulation of BAZ

DiaDENS-CARDIO

Operations Manual

RC ART 05.0-03.71-03 RE
TU 9444-005-44148620-2006

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1. FUNCTION

The DiaDENS-CARDIO apparatus is intended for therapeutic non-invasive (without damaging the skin surface) course treatment of biologically active zones of the wrist 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 DiaDENS-CARDIO apparatus combines frequency 9.2 Hz which is traditionally applied for treatment of hypertension and a specially developed mode “77 10” intended for producing a general sedative effect.

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

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.

Application:

DENS 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.

It is strongly 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 "DiaDENS-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 "DiaDENS-CARDIO" apparatus as monotherapy. Such an approach can retard and prevent the disease from converting into a stable form.

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.

Recommendations for application of the "DiaDENS-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.

Recommendations for one-time application of the "DiaDENS-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 "DiaDENS-CARDIO" apparatus every 1-1.5 hours until the complaint is eliminated. In case of long-lasting high arterial blood pressure, address the doctor.

Recommendations for application of the "DiaDENS-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 "Dia-DENS-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.

Recommendations for application of the "DiaDENS-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 adequate and systematic taking of drugs.

Course duration and number of procedures per day shall be determined after consulting an attending doctor.

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;

Attention! *On the background of application of the "Dia-DENS-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.*

2. COMPLETE SET AND APPARATUS ARRANGEMENT

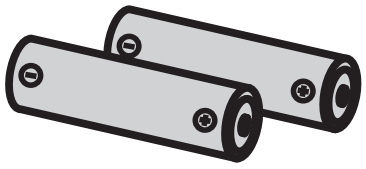
Apparatus body

Display

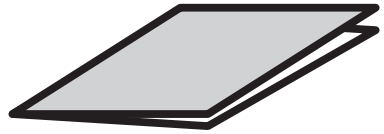
Cover of the power source compartment

ON/OFF button

Cuff



Batteries LR6/AA, 1.5 V type



Operations Manual

Case

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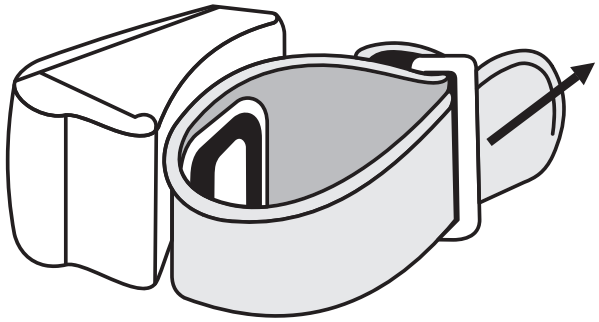
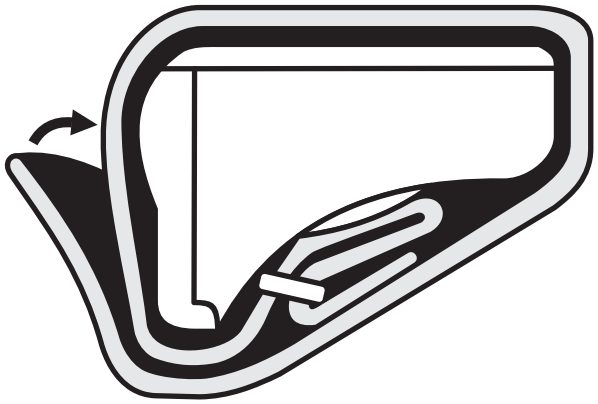
Symbols of the display:

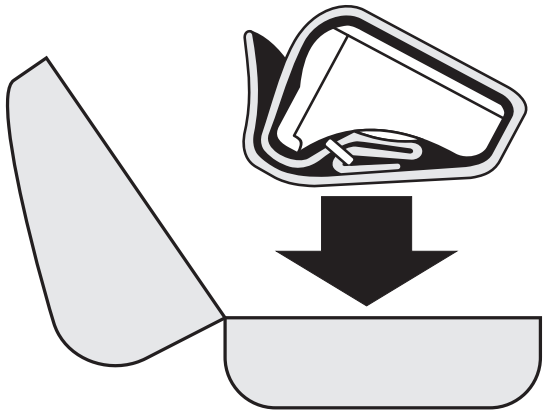
Attention! *To avoid breaking the case, fold the cuff of the apparatus in a correct way:*



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

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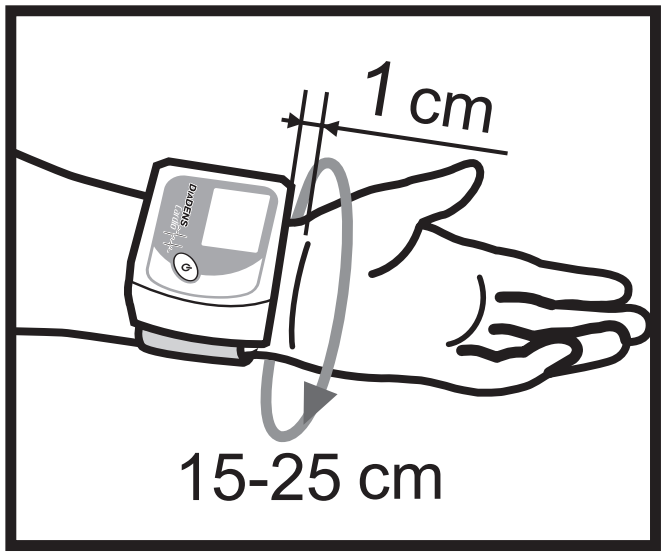
3. ORDER OF TREATMENT

Preparation. During the procedure, the patients can have a comfortable sitting or lying position. After the treatment procedure, the patient should relax for 20-30 minutes.

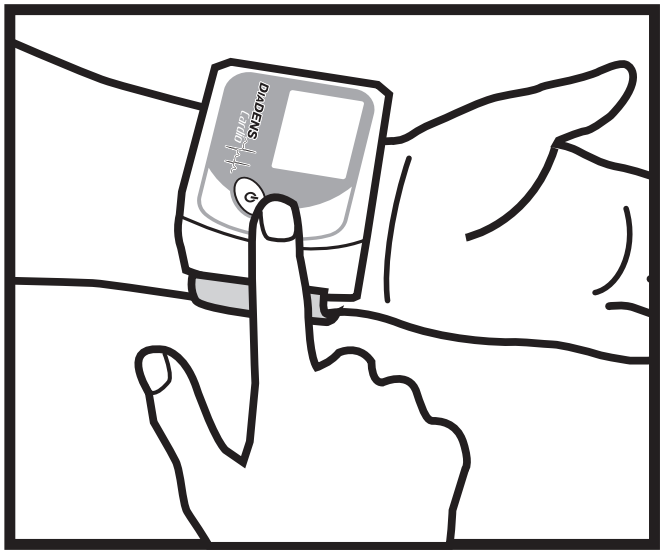
Attention! *It is forbidden to carry out procedures with the "DiaDENS-CARDIO" apparatus in a standing position!*



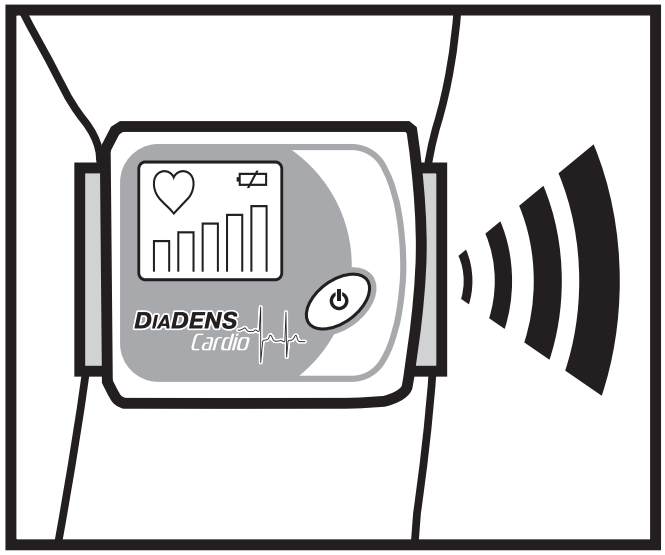
1. From the left wrist take off watches or bracelets, fold the sleeve back. Skin should be dry and clean.

2. Hold your hand with your palm up, place the apparatus on your wrist with the display up 1 cm from the wrist joint.

3. Tighten the cuff and fix it as there is no free space between the cuff and your wrist, the apparatus electrodes touching the skin surface but not binding the wrist.



4. Turn the apparatus on by pressing the ⏻ button – the apparatus will turn on and produce a sound signal and the display will show the following symbols ♡ and ▯▯▯▯▯ which indicate the contact of electrodes with skin surface and beginning of the treatment procedure.



5. Carry out the treatment procedure. The procedure consists of three stages, which are different in frequency, time and amplitude of treatment. After the end of stage, the apparatus produces a short sound signal. After the end of the procedure the apparatus produces a long sound signal and the symbol ♡ will start blinking.

The duration of the procedure is determined by the programme and is approximately 5-6 minutes.

6. Take the apparatus off.

7. Turn the apparatus off by pressing the ⏻ button holding it during 1-3 seconds, or with absence of contact with skin surface the apparatus will turn off automatically after 3 minutes.

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

4. TECHNICAL MAINTENANCE

4.1. 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.

4.2. Check of service ability of the apparatus in accordance with instructions in Part 3.

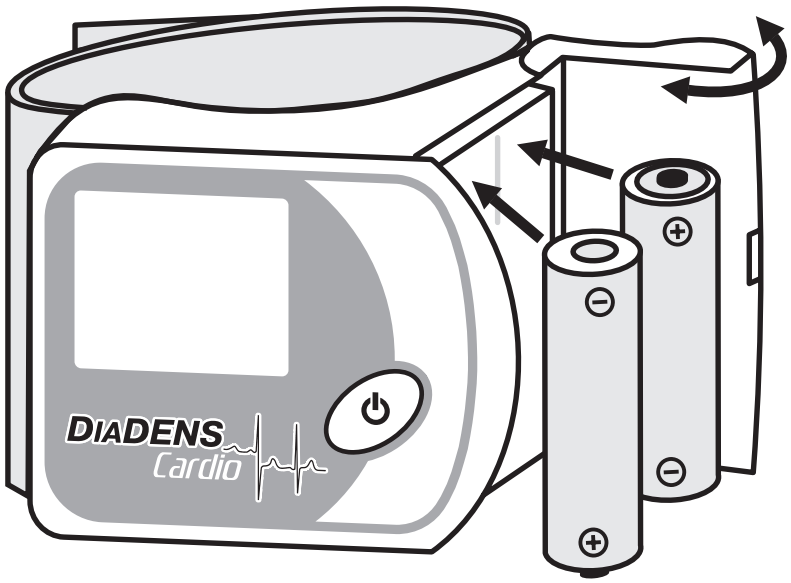
4.3. If the apparatus is supposed not to be used for a long period, remove the power source from its compartment (Part 5).

4.4. Having noticed the symbol  on the indicator, replace the power source (part 5).

5. ORDER OF REPLACING THE POWER SOURCE

When the symbol ▭ appears on the display (blinking – power source is partly discharged, on – replace power sources urgently) or if the apparatus does not turn on (the power sources are discharged), you need to replace the power sources. For this:

— open the power source compartment;



— remove the power sources;

— let the apparatus stay without power sources during 2-3 minutes;

— install new power sources*, taking into the polarity.

**install only that power sources which are intended for this device – type LR6/AA, rated voltage 1.5 V. When replacing the power sources it is recommended to use power elements of the same type and replace both elements at the same time.*

6. TROUBLESHOOTING LIST

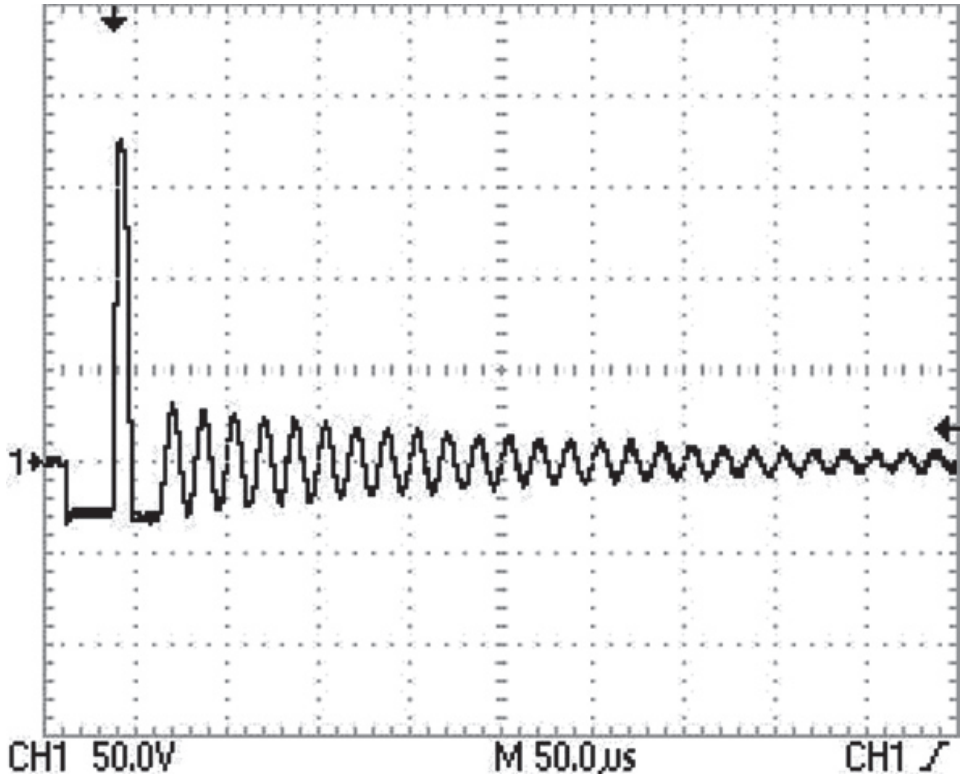
Trouble	Method of eradication
The apparatus turns off, does not turn on or the display shows the sign 	Power sources are discharged – replace power sources (part 5)
The apparatus does no turn on after replacement of power sources	Remove power sources, let the apparatus stay during 2 minutes without them and install power sources again (part 5)
The display does not show the symbol ♡ (heart) with contact with the skin surface	The skin surface is dry – wipe it with a wet tampon

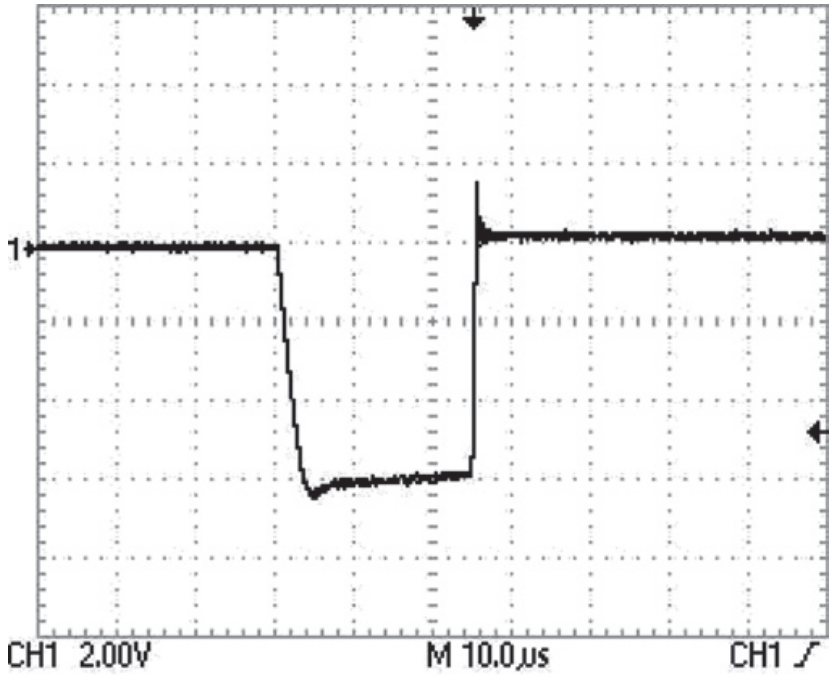
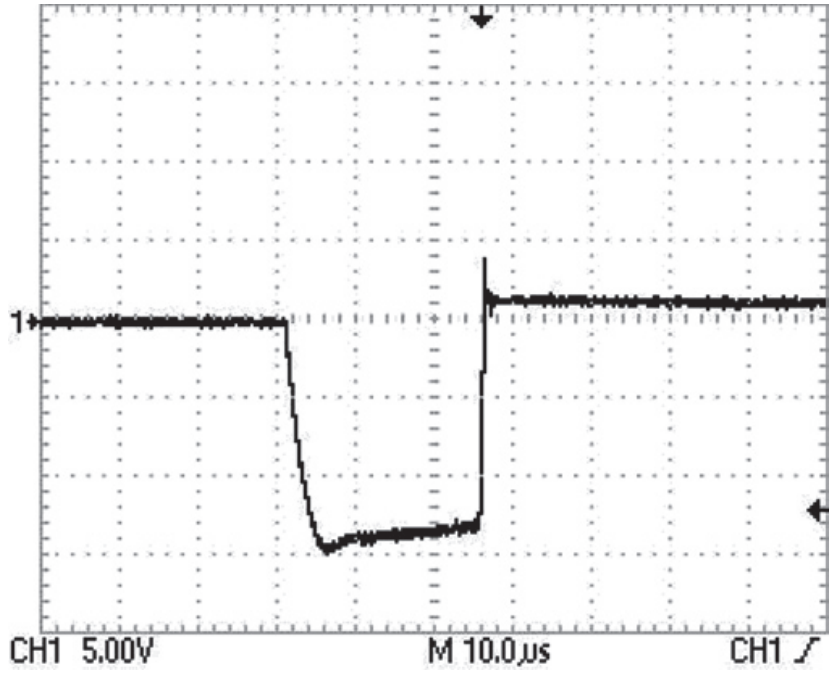
The display shows the symbol ♡ (heart) when there is no contact with skin surface	The electrodes are dirty – wipe the electrodes (item 4.1)

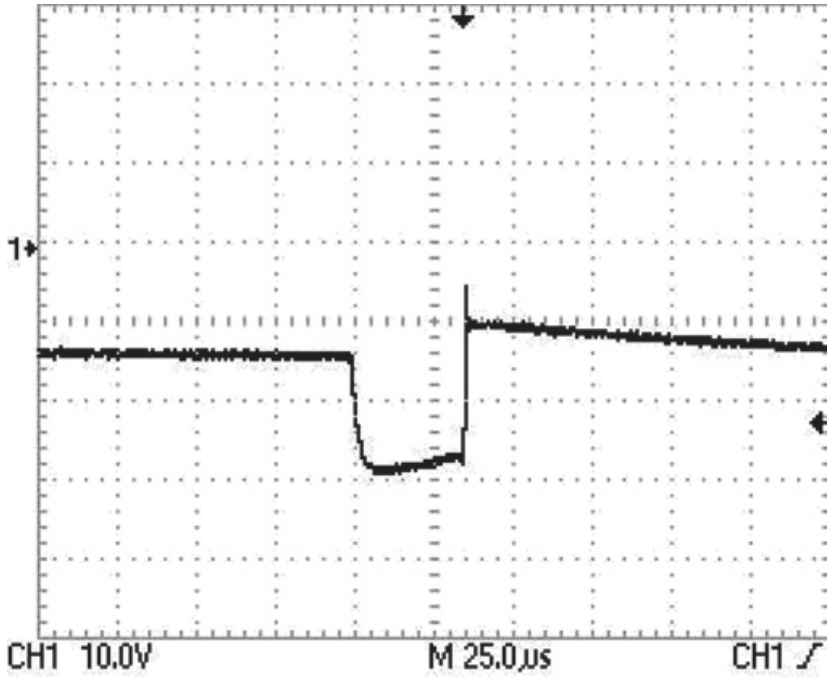
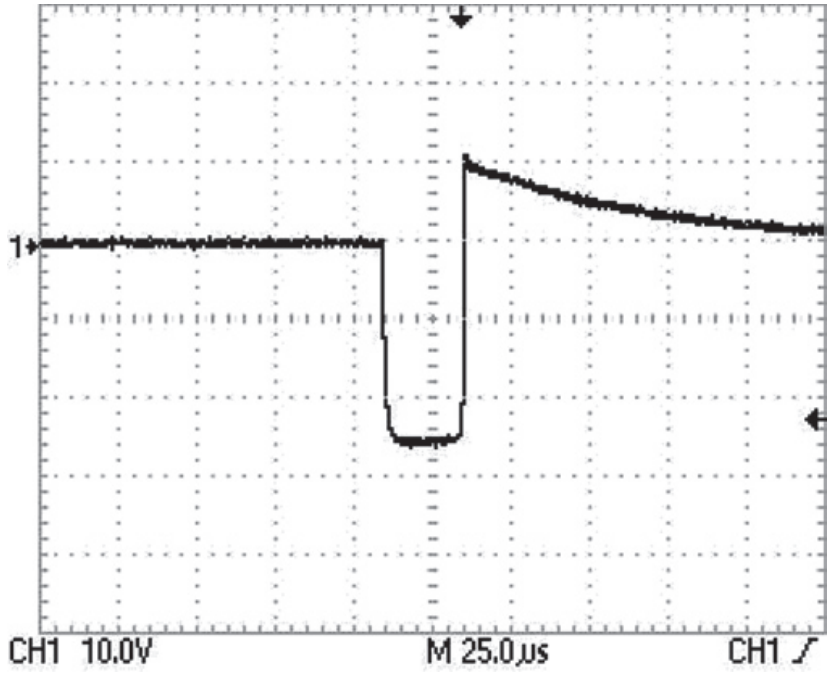
Attention! *Other troubles must be eradicated by the manufacturer or at the service centers of the manufacturer.*

7. SPECIFICATIONS

7.1. Dependence of Shape and impulse parameters on load resistance

Load resist-ance	Shape	Voltage peak-peak
Free Output		≈210 V ± 20%

200 Ohm		≈8 V ± 20%
500 Ohm		≈19 V ± 20%

1 kOhm		≈24 V ± 20%
2 kOhm		≈37 V ± 20%

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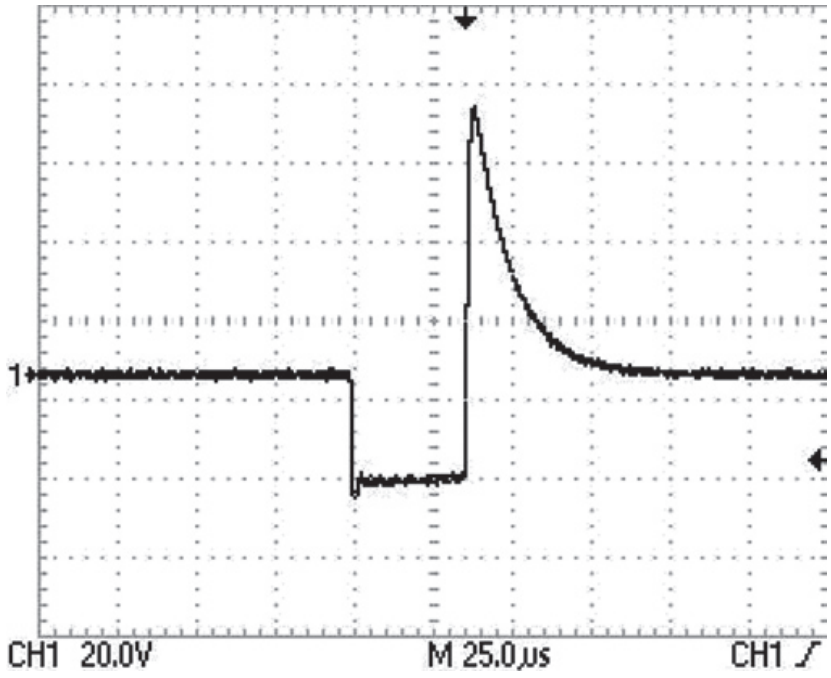
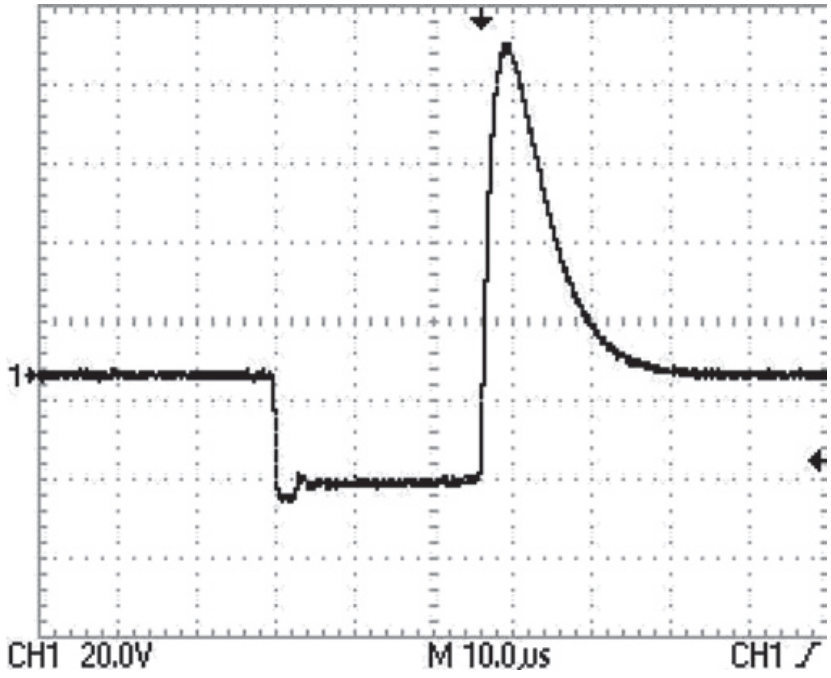
10 kOhm		≈99 V ± 20%
20 kOhm		≈116 V ± 20%

7.2. Dimensions of the apparatus, mm,
not more than.....120x110x110
7.3. Weight, kg, not more than.....0.3
7.4. Consumable current, mA, not more than.....10
7.5. Voltage of the electrostimulator
power supply, V.....3±0.6
7.6. Power supply: battery type LR6/AA,
2 pcs, voltage, V.....1.5±0.45

7.7. The apparatus automatically switches off not later than in 3 min after the last contact of the electrodes to the patient's skin or after pressing and holding the button.

7.8. The apparatus generates the following frequencies of impulses:

— 9.2±0.2 Hz — during phases I and II;

— 77±7 Hz and 10±0.5 Hz, modulated by frequency 2±0.5 Hz ("7710" mode) — phase III.

7.9. Electromagnetic Emissions

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

7.10. 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

7.11. Electromagnetic Immunity

Immunity Test	Test Level	Compliance Level	Guidance electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±4kV contact ±8kV air	Floors should be wood, concrete, or ceramic tile. If Floors are covered with synthetic material, the relative humidity should be at least 40%. Explanation and training of stuff 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.

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7.12. Recommended Separation Distances (d) between Portable and Mobile RF Communication Equipment and Portable electrostimulator DiaDENS-CARDIO.

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

 device of BF type.

8. 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.

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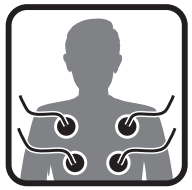


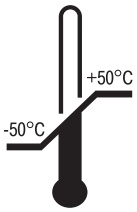
During stimulation the patient must not be connected to any high-frequency electric device, simultaneous application of the apparatus and another electric device can result in burns and possible damage of the apparatus.

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

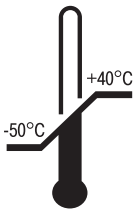
The apparatus contain fragile elements. Keep it from blows and drops.

The apparatus is not waterproof. Protect it from water.

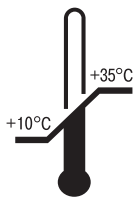
All the repair works for the apparatus shall be carried by qualified personnel of the manufacturer.



Conditions of transportation: temperature from – 50 to + 50°C, relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa



Conditions of storage: temperature from – 50 to + 40°C, relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa



Operation conditions: ambient air temperature from 10^0C to 35^0C, relative air humidity from 30 to 93%, atmospheric pressure from 70 to 106 kPa.
If the apparatus is stored at the temperature below 10^0C, keep it under normal conditions at least for two hours before use.

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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).

9. GUARANTEES OF THE MANUFACTURER

9.1. The manufacturer guarantees the compliance of the apparatus to the technical conditions TU 9444-005-44148620-2006 on condition the conditions of operation, transportation and storage are observed.

9.2. The operation lifetime is 5 years. Observation of operation regulations can considerably increase the lifetime set by the manufacturer officially.

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

9.4. The seller (manufacturer) or organization carrying out the functions of the seller (manufacturer) on a contractual basis is not responsible for the defaults should they occur after the disposal of the apparatus as a result of:

1) a failure on the part of the consumer to comply with the rules of transportation, storage, care and operation provided for by the present manual;

2) mechanical damages;

3) actions of the third party;

4) force-majeure.

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

9.6. 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.

10. SPECIAL EMC-INFORMATION

10.1. The Portable electrostimulator DiaDENS-CARDIO 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-CARDIO is suitable for use in all establishments including domestic establishments.

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

10.2. Electromagnetic Environment guidance

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

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 DiaDENS-CARDIO 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.

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

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

Stuff 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 stuff 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.

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СВИДЕТЕЛЬСТВО О ПРИЕМКЕ
CERTIFICATE OF ACCEPTANCE

Электростимулятор чрескожный для воздействия на БАЗ «ДиаДЭНС-КАРДИО»

Transcutaneous electrostimulator for stimulation of biologically active zones DiaDENS-CARDIO

Заводской номер
Serial No._____

Соответствует требованиям ТУ 9444-005-44148620-2006 и признан годным для эксплуатации.

Complies with the standards TU 9444-005-44148620-2006 and is acknowledged to be ready for operation.

Дата изготовления
Date of manufacture_____

Подпись должностного лица предприятия,
ответственного за приемку
Signature of the official
responsible for acceptance_____

RU EN

Дата продажи
Date of sale_____

Подпись продавца
Signature of the shop assistant_____

С условиями гарантии ознакомлен, изделие проверено, претензий к комплектации, внешнему виду не имею.

I received information about warranty conditions, the apparatus was checked, and I have no claims to the complete set, appearance of the apparatus

Подпись покупателя
*Signature of the customer*_____

RU EN

ТАЛОН НА ГАРАНТИЙНЫЙ РЕМОНТ
COUPON FOR WARRANTY REPAIR

Наименование: ДиаДЭНС-КАРДИО
Name: DiaDENS-CARDIO
Серийный номер изделия
Serial No._____
Дата изготовления / Date of manufacture_____
Дата покупки / Date of selling_____
Владелец / Customer_____
Адрес / Address:_____

_____

_____

_____

_____

Телефон / Phone_____ домашний / home
_____рабочий / office
Дата отправки в ремонт
Date of sending for repair_____

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Причина отправки в ремонт
Reason for repair_____

_____

_____

Отметка о ремонте
Note about repair_____

подпись должностного лица предприятия, ответственного за приемку после ремонта

Signature of the official responsible for acceptance after repair

Изделие проверено, претензий к комплектации, внешнему виду не имею.
The apparatus was checked, I have no claims to the complete set, appearance of the apparatus
Подпись покупателя
Signature of the customer_____
Дата получения / Date_____

Гарантия на отремонтированное изделие составляет 12 месяцев с момента получения изделия из ремонта. В случае, если гарантийный срок с момента приобретения изделия составляет более 12 месяцев, то гарантия исчисляется по большему сроку. А также гарантийный срок увеличивается на время нахождения изделия в ремонте.
Warranty to the repaired apparatus is 12 months from the date of taking the apparatus from the service center. In case the warranty period from the moment of selling is more than 12 months, the warranty period shall be calculated with a longer period. The warranty period will also increase for the period of repair.