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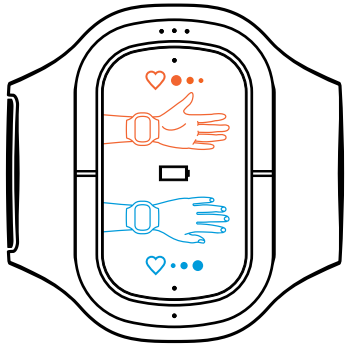
INFE 05.01-03.78-01ИП

CE 0051

INSTRUCTION FOR USE



ELECTROSTIMULATOR ABP-051

Thank you for the purchase of electrostimulator “ABP-051” (hereinafter electrostimulator “ABP-051”, electrostimulator, device).

For the effective and safe use of the device, please read carefully all the Instruction sections.

Instruction for use – the integral device part to be reviewed prior starting the device work in practice.

The manufacturer and/or seller are not liable to any adverse consequences of the device use arising due to the unintended use or failure to comply with the requirements of the present Instruction.

TABLE OF CONTENTS

1. INDICATION

Electrostimulator “ABP-051” is intended for therapeutic non-invasive (without skin damage) course exposure on wrist areas via transcutaneous electric stimulation for normalization of blood pressure only in combination with drug therapy.

Course of procedures assures:
- blood pressure normalization;
- improvement of overall health condition;
- improvement of emotional state;
- improvement of working capacity;
- increase of patient’s quality of life.

The electrostimulator is intended for the use in-patient and out-patient facilities of the health and medical care institutions and home settings.

Application — physiotherapy.

2. WORKING PRINCIPLE OF THE ELECTROSTIMULATOR

Electric current stimulation — the most universal method for excitation of receptor structures launching cascade of receptor and adaptive body mechanisms. Electric current is easily dosed per magnitude, gives opportunity to manage impulse frequency, their duration and polarity, and finally is the adequate stimulus for excitable tissues.

Electrostimulator “ABP-051” affects mainly vascular tone. It is the most effective and safe method for cardiac tone exposure. It is the most effective and safe method for blood pressure exposure. Hereby the device does not almost affect cardiac output and heart rate.

The selection of exposure areas is determined by the disorder type and convenience of the use at work in home settings, in course treatment.

Stimulation is made as the series of impulses, the number of impulse series corresponds to the set of frequencies for blood pressure normalization.

The efficiency of exposure depends on a human condition prior exposure and used area.

Tolerance to electric stimulation develops more rarely and slowly, more over, exposures of electrostimulator “ABP-051” have low intensity and duration that increases tolerability and safety of procedures.

The electrostimulator is a mobile, light and compact device allowing to make procedures in any convenient time, in any place, as well:

- acts without any subcutaneous penetration not inducing any infection risk;
- does not induce pain;
- exposure time on wrist area depends on the selected working regime;
- device construction is designed so that it may be used with one hand to facilitate operation process;
- hospitalization is not required for a course of procedures is not required.

3. INDICATIONS FOR THE USE OF ELECTROSTIMULATOR “ABP-051”

- Steady high systemic blood pressure in patients with arterial hypertension (hypertensive disease) — only as a supplement to complex drug treatment.
- Episodes of blood pressure increase in stress situations, weather changes, etc. in persons with labile arterial hypertension.
- Low blood pressure in chronic arterial hypotension (hypotensive disease) patients — as a supplement to complex drug treatment.

Attention! The device is indicated for the use in persons above 14 years.
Use the electrostimulator strictly as indicated.

4. POSSIBLE ADVERSE EFFECTS OF THE USE

Possible adverse effects of the electrostimulator use are not identified.

5. CONTRAINDICATIONS FOR THE ELECTROSTIMULATOR USE

5.1. Absolute:

- presence of an implanted pacemaker;
- individual intolerability of the electric current;
- open skin wounds or injuries in the distal third of the left forearm (macerations, wounds, burns, exanthema, etc.).

5.2. Relative:

- neoplasms (tumors) of any etiology or location;
- acute fevers of unclear etiology;
- acute psychotic, alcohol or drug-induced excitation;
- pregnancy.

6. DESCRIPTION OF THE ELECTROSTIMULATOR CONSTRUCTION

6.1. Appearance of electrostimulator “ABP-051” is presented on Fig.1a and Fig.1b.

6.2. The device uses two automatic electric current programs for course exposure on human wrist areas (see Fig.2 and Fig.3) with various frequencies.

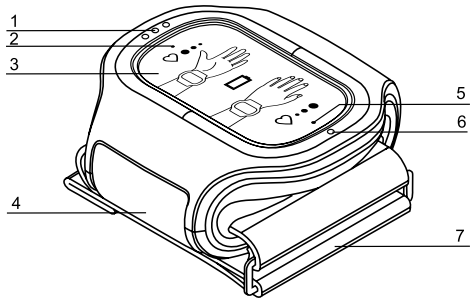


Fig.1a. Construction and appearance (top)

1— On/Off key of Program №1 (contains three relief points on the surface)
2 — LED indicator of Program №1
3 — Front panel
4 — Battery compartment lid
5 — LED indicator of Program №2
6 — On/Off key of Program №2 (contains one relief point on the surface)
7 — Cuff

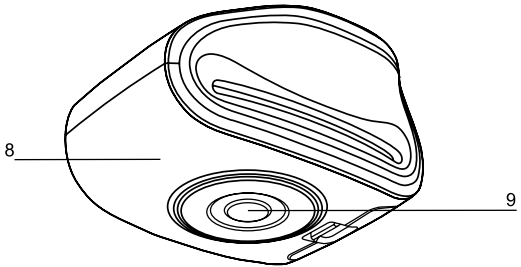


Fig.1b. Construction and appearance (bottom)

8 — Body
9 — Electrodes

Program №1:

Exposure on the inner wrist zone (see Fig.2) located on the internal side of the left wrist (the distal third of left forearm) is made to decrease blood pressure.

Apply the device to the left wrist so that the orange coloured hand symbol is on the top of the device's screen. Fix the device at the left wrist so that right rim of the electrostimulator is positioned in parallel to skin fold in the radiocarpal joint area (see Fig.2).

Program №1 launches with pressing the button shown with three relief points and is accompanied with flashing of the white LED indicator on the top part of the front panel.

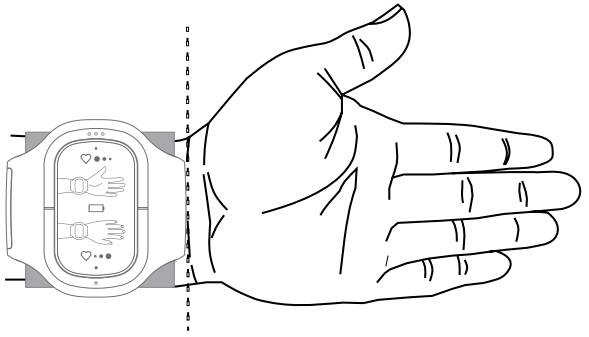


Fig.2. The inner wrist zone

Program №2:

Exposure on the outer wrist zone (see Fig.3) located on the external side of the left wrist (the distal third of left forearm) is made to increase blood pressure.

Apply the device to the left wrist so that the blue coloured hand symbol is below. Fix the device at the left wrist so that right rim of the electrostimulator is positioned in parallel to skin fold in the radiocarpal joint area (see Fig.3).

Program №2 launches with pressing the button shown with one relief point and is accompanied with flashing of the white LED indicator on the bottom part of the front panel.

After any of the programs completes, the sound signal will be heard, the LED indicator will stop flashing, the electrostimulator will be turned off automatically.

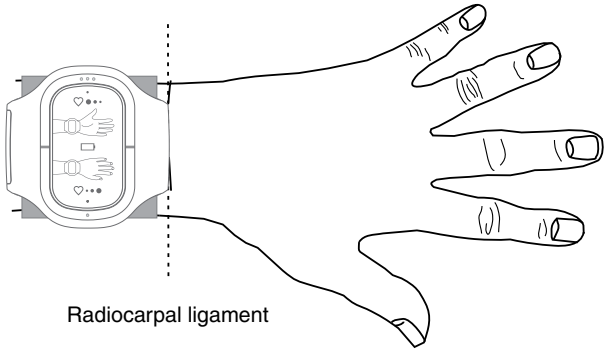


Fig.3. The outer wrist zone

7. SAFETY MEASURES FOR THE ELECTROSTIMULATOR USE

7.1. Inspect the package and the electrostimulator prior the use. Do not use the stimulator if it is damaged.

7.2. Electrostimulator use should correspond completely its direct indication.

7.3. Operation documents and device labeling contains symbols and warnings:

7.3.1. Technical requirements ТУ 9444-005-12342964-2015 is a regulatory document determining requirements to the product applicable on the territory of the Russian Federation and in the CIS countries.

7.3.2. РУ No. РЗН 2016/3776 dated March 31, 2016 is the registration certificate for a medical device issued by the Federal Service for Surveillance in the Russian Federation.

CE 0051 7.3.3. This medical device is approved by the notified body IMQ S.p.A. for the CE marking according to the Directive 93/42/EEC and its revised version concerning medical devices.

7.3.4. Device quality is confirmed in the acceptance form Declaration of conformity in system ГОСТ Р (№ РОСС RU.АИ16.Д11301 dated 24.04.2016).

7.3.5. **Attention!** Read carefully all safety information!

7.3.6. Read carefully all the information contained in the Instruction for the use related to your safety, as the recommendations on the correct use and handling of the electrostimulator.

7.3.7. Device does not pose threat for users as the internal source of low voltage isolated from the working device part is used (device of BF type).

7.3.8. During the stimulation, do not connect a patient to any high frequency electric device; the simultaneous use of the electrostimulator may lead to burns and device damage.

7.3.9. Work near short wave or microwave equipment may induce instability of output parameters of the electrostimulator.

7.3.10. Do not use the device for treatment of patients with implanted electronic devices (for example, pacemaker), for treatment of patients with individual intolerability of the electric current.

7.3.11. The device should be operated by a person being awake, adequately perceiving environmental factors. The device should not be used by persons in threshold conditions or having inadequate psychic conditions.

7.3.12. If any allergic reactions occur as the result of the device contact with skin, stop immediately using the electrostimulator and refer to a physician.

7.3.13. All device repairing works should be made by qualified specialist on the manufacturing enterprise or in authorized service centers if available. If such authorized service centers are absent, apply to the manufacturer for the repair.

7.3.14. Construction changes by a user are prohibited.

7.3.15. The device contains fragile elements. Protect from shocks.

7.3.16. The device is not waterproof. Protect from moisture penetration.

7.3.17. Keep the electrostimulator far from heating devices, avoid long-term exposure of direct sun rays at high (over +35°C) air temperature. Do not heat the device.

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

Attention! If the device is kept in environmental temperature below +10°C, let it stand in ambient temperature for at least 3 hours prior the use to prevent moisture condensate.

7.3.19. The manufacturer details are stated on page 50 of the present Instruction for the use.

7.3.20. For information related to the official representative in the EU and the Middle East countries, see section 20 of this application data sheet.

Manufacturing date and serial number are stated on page 109 of the present Instruction for the use, as well under the lid of the device battery compartment.

8. POSSIBLE USE AND PARTICULATIES OF THE ELECTROSTIMULATOR USE FOR PEOPLE WITH IMPLANTED MEDICAL DEVICES, PREGNANT, LACTATING WOMEN, CHILDREN, ADULTS WITH CHRONIC DISEASES

The device is prohibited to use:

- If an implanted pacemaker is present;
- for children below 14 years.

The device may be used:

- in pregnancy and lactation;
- in pre-existing chronic diseases if they do not refer to cl. 5.1.

9. POSSIBLE EFFECT OF THE ELECTROSTIMULATOR ON ABILITY TO DRIVE AND OPERATE MACHINERY

The studies on possible effect on ability to drive and operate machinery have not been carried out, as the electrostimulator and its components do not refer to the devices which may affect the human psychomotor condition and is not used during driving and operating machinery.

10. NECESSITY TO STORE THE ELECTROSTIMULATOR OUT OF REACH OF CHILDREN

Keep out of reach of children.

11. RECOMMENDATIONS HOW TO USE ELECTROSTIMULATOR “ABP-051”

11.1. Course of procedures

Procedures are made 1–3 times a day for 14 days; the same daytime is preferable regardless of the blood pressure level prior the procedure. Patients with hypertonic disease need recurrent regular treatment course at least once a month (for example, from the 1st to the 14th of each month).

The device has a cumulative effect, i.e. blood pressure becomes more stable to the end of the treatment course.

11.2. In the events of situational (but recurrent) blood pressure increase or decrease, a course treatment at least 14 days is required, 1–3 procedures a day. And in the beginning of the treatment, temporary destabilization of blood pressure may occur with the further consistent decrease in hypertonia or consistent increase in hypotonia.

With the diagnosis of blood hypertonia, i.e. infrequent periodic and insignificant blood pressure increase (not above 150 mmHg), electrostimulator “ABP-051” may be used as monotherapy. Such approach retards and prevents the disease progression to a stable form.

11.3. Recommendations for the use of electrostimulator “ABP-051” in patients above 70 years: more subtle rate of blood pressure decrease is required. For that, “ABP-051” exposure once a day is recommended. A treatment course is not more than 7–8 days. After 10–15 days of break, it is appropriate to repeat treatment course. During the first treatment courses, blood pressure may insignificantly vary.

11.4. Recommendations on the use electrostimulator “ABP-051” in hypertonic patients — consistently high blood pressure (above 180 mmHg) and in drug administration: course duration and number of procedures are determined after the consultation with the attending physician.

Attention! During the treatment with “ABP-051” electrostimulator, you SHOULD NOT stop taking drugs on your own decision. After getting a consistent hypotensive effect, schemes and dose of drug therapy may be changed only by the attending physician!

12. CONDITIONS AND OPERATIONAL PROCEDURE FOR ELECTROSTIMULATOR “ABP-051”

12.1. Unpack the device removing the packaging material. Check the integrity of the device via visual examination.

12.2. Procedures using the electrostimulator by a patient himself in home settings or by a medical personnel of treatment and preventive institutions do not require special preparation and special skills.

12.3. During the procedure, a patient may sit or lie in any position comfortable for him/her.

Attention! The device procedures should not be used while standing!

12.4. Take off a wrist watch or bracelets from the left wrist, free it from clothes elements.

12.5. Select the exposure area (see cl. 6.2).

12.6. Treat the device electrodes and a patient’s skin in the exposure area, with a moist napkin or tampon slightly moistened with water.

12.7. Put on the electrostimulator on the left hand depending on the exposure area as it is shown on figures below.

12.7.1. Inner wrist zone — exposure area with for patients with high blood pressure (Fig.4).

12.7.2. Outer wrist zone — exposure area for patients with low blood pressure (Fig.5).

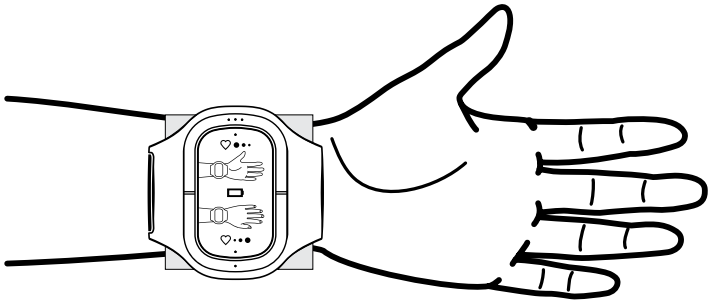


Fig.4. Electrostimulator position in the inner wrist zone for patients with high blood pressure

12.8. Draw tight the electrostimulator cuff and fix it so that no free space is left between the cuff and the wrist, and the electrostimulator electrodes touch the skin tightly but not tighten it over.

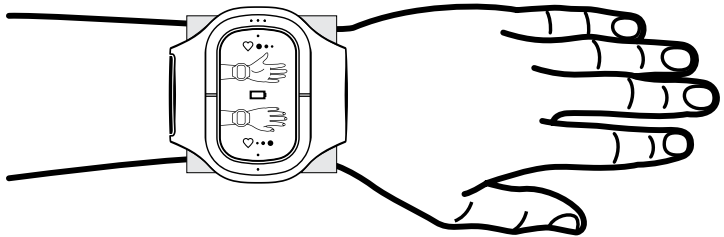


Fig.5. Electrostimulator position in the outer wrist zone for patients with low blood pressure

12.9. Turn on the electrostimulator pressing the button, pos.1 (Fig.1a) if you have high blood pressure, or button, pos.6 (Fig.1a) if you have the low blood pressure.

12.10. After the treatment procedure the sound signal will be heard, the device will shut down automatically.

When you force the electrostimulator, press and hold On/Off button in pos.1 or pos.6 (Fig.1a) pressed for over 1 second depending on active treatment program. The device will give the sound signal and turn off, the LED indicator will fade away.

12.11. Take off electrostimulator “ABP-051”. After the procedure, rest for 20–30 minutes is recommended.

Attention! After each procedure, treat the electrostimulator electrodes (see cl. 15.1.2)! The absence of good quality purification may lead to allergic reactions or skin infection when used by several users.

Attention! Keep the electrostimulator with dry electrodes!

13. TECHNICAL CHARACTERISTICS

13.1. Main technical characteristics are presented in Table 1.

Table 1

Characteristic	Value
Dimensions (without the cuff), not more, mm	75x75x40
Electrostimulator weight (including the cuff and built-in electrodes, without power supply elements), not more than, kg	0,1
Consumed power, not more, mA	200
Supply voltage, V	3±0,6
Electric power supply source	Galvanic batteries, type AAA (LR03), 2 pcs.
Degree of the device body protection	IP41
Degree of protection of the working units from electric current damage	 type BF

13.2. Exposure parameters

13.2.1. Electrostimulator “ABP-051” uses two automatic Programs №1 and №2, one of which consists of sequential series of impulses (Fig.6) differing in frequency, stimulation intervals and exposure magnitude which makes the electrostimulator effective for the use.

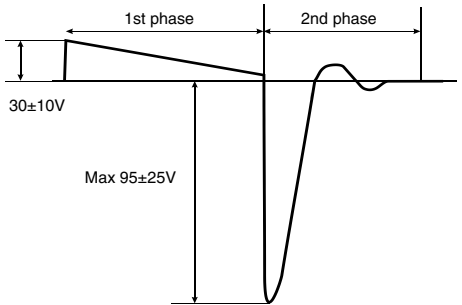


Fig.6. Impulse form and parameters

Electrostimulator “ABP-051” generates electric impulses consisting of two phases with unloaded parameters:

- maximum amplitude of the 1st impulse phase 30±10V.
- maximum amplitude of the 2nd impulse phase 95±25V.

13.2.2. Technical parameters of Program №1

Program №1 is intended for patients with high blood pressure in the range: systolic over 130 mmHg, diastolic over 80 mmHg.

Exposure area: inner wrist zone (Fig. 2).

Diameter of the exposure area: 30 mm.

Working program frequencies: 9,2Hz and 77Hz.

Total time of the program exposure – 5 minutes.

Indication: while flashing of the LED indicator in pos.2 (Fig.1a), the sound signal after the program completion.

13.2.3. Technical parameters of Program №2

Program №2 is intended for patients with hypotonia and blood pressure in the range: systolic less than 106 mmHg, diastolic less than 70 mmHg.

Exposure area: outer wrist zone (Fig.3).

Diameter of the exposure area: 30 mm.

Working program frequencies: 77Hz and 140Hz with magnitude modulation with frequency 4Hz.

Total time of the program exposure — 6 minutes.

Indication: while flashing of the LED indicator in pos.5 (Fig.1a), the sound signal after the program completion.

13.3. Electromagnetic irradiation

Test	Conformance	Use conditions
HF irradiation CISPR 11	Class B	The electrostimulator may be used in all institutions including home use.

13.4. Resistance to HF irradiation

Test	Conformance	Use conditions
IEC 61000-4-6	3 Vrms 150kHz to 80kHz	3 Vrms
IEC 61000-4-3	3V/ 80MHz to 2,5GHz	3V/m

13.5. Resistance to electromagnetic fields

Test	Test level	Conformance level	Use conditions
Electrostatic discharge (ESD) IEC 61000–4–2	±8kV contact ±15V expos.	±4kV contact ±8 V exp.	Floor should be wooden, concrete or from ceramic tiles. In the event if the floor is covered with synthetic materials — relative air humidity should be not less than 40%.
Magnetic fields IEC 1000–4–8	3A/m	3A/m	Characteristics of magnetic fields should be typical for commercial buildings and hospital settings.

13.6. Electrostimulator “ABP-051” uses electromagnetic energy only for internal functions. Due to that, the irradiation of the electrostimulator is minimum and should not affect the closest electric equipment. Electrostimulator “ABP-051” may be used in any institutions including home use.

13.7. Electrostimulator “ABP-051” should not be used together with another equipment. In the event if concurrent work of the electrostimulator and another equipment is required, the electrostimulator and equipment should be checked for correctness of the concurrent work in the conditions (working regimes) in which they will be used.

13.8. Electromagnetic conditions. The electrostimulator is intended for the work in conditions of electromagnetic environment.

13.8.1. Electrostatic discharge (ESD)

- The floor should be wooden, concrete or from ceramic. In the event if the floor is covered with synthetic materials, relative air should be not less than 40%;
- Clothes from synthetic materials should not be used.

13.8.2. HF irradiation: portable and mobile devices should be used on the distance to any part of the medical device not closer than the distance determined with the following equation:

Recommended distance $d = 2{,}3 \sqrt{P}$ (800MHz to 2,5GHz).

P — maximum power output in accordance with the manufacturer information.

13.8.2.1. Personnel (user) should take the following measures: minimum distance from portable communication means (cell phones, wireless phones) should be approximately 3 meters if the output capacity of the devices exceeds 2 W.

13.8.3. Magnetic fields: magnetic field parameters should be within the normal range for commercial buildings and conditions of medical institutions.

14. MEDICAL DEVICE SPECIFICATION

Name	Number, pcs.
Electrostimulator “ABP-051” with built-in electrodes and cuff	1
Instruction for use	1
Information brochure (optional)	1
Packing box	1
Carry case	1

Attention! Power supply elements are not included to the supply set! Use power supply elements LR03/AAA for electrostimulator “ABP-051”.

15. MAINTENANCE AND REPAIR

15.1.Maintenance:

15.1.1. External device examination. You should ensure that no shock, fall marks are present as it may lead to the device malfunction.

15.1.2. Prior and after the device use, you should purify electrodes pos.9 (Fig.1b) for electrode purification, use non-aggressive disinfectants (for example, 3% hydrogen peroxide) and soft fibreless wipes. Disinfection is made with 5-fold treatment.

15.1.3. Checking functionality of the electrostimulator in accordance with section 12.

15.1.4. The device is intended for multiple use.

15.2. Replacement of power supply elements:

When symbol ▭ flashes on the front panel or in the event when the electrostimulator does not switch on (power supply elements are unloaded severely) power supply elements should be replaced.

For that:

- Switch off the electrostimulator if it is switched on;
- Open the battery compartment as it is shown on Fig.7: press on the locktab in the direction to arrow 1 and move the battery compartment cover in direction to arrow 2;
- Withdraw power supply elements;
- Leave the electrostimulator without power supply for 2 minutes;
- Install new power supply elements following the polarity as it is shown on Fig.8. Put the battery compartment in place.

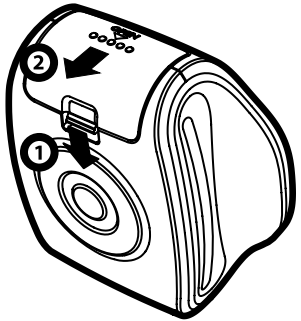


Fig.7. Order of actions to open the battery compartment

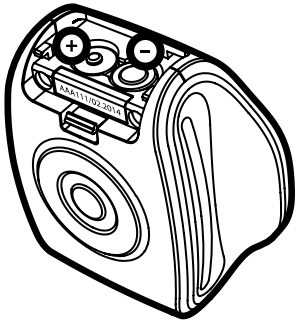


Fig.8. Polarity of power supply elements

Attention! With the long break in the use of electrostimulator — remove the power supply elements from the compartment section.

Attention! Simultaneous installation of old and new power supply elements, power supply elements of various brands to the device is prohibited. Replace power supply elements simultaneously!

Attention! Use power supply elements of only high quality! When power supply elements of low quality are used, the risk of spontaneous leakage of power supply elements is present which may disable the device (is not a warranty case) and induce risk of chemical burns.

Attention! Most power supply elements contain chemical substances which will not pose threat while exposed to open skin. When the substance gets into the skin from the leaked element, you should rinse the skin immediately which has got the substance using water and soap. When it gets into the eyes, you should immediately rinse the eyes with running water (at least 15 minutes) and refer to a physician. When the substance gets into the skin, wash it with water and soap.

15.3. Possible malfunctions and methods of their elimination. Table 2 provides conditions of the electrostimulator which may be resolved on your own.

If other malfunctions occur, contact the manufacturer representative. Do not try to eliminate them on your own!

Table 2

Malfunction	Method of elimination
Device switches off/ does not switch on	Power supply elements are unloaded — replace power supply elements (see cl. 15.2).
Device does not switch after replacement of power supply elements	Remove power supply elements, let the device stand for 2 minutes free of them, install power supply elements again following the polarity as it is shown on Fig.8.
No exposure sensations	Dry skin — wipe with a cotton swab moistened slightly with water or moist drape.
	Electrodes are contaminated — purify electrodes (see cl. 15.1.2).

Attention! Repair works for “ABP-051” electrostimulator should be made at the manufacturing enterprise or in authorized service centers if such are available. If authorized service centers are absent, apply to the manufacturer for repair.

16. SERVICE PERIOD

16.1. Service period of the device — 5 years since the manufacturing date. When operation rules are met, the service period may significantly exceed the officially established period.

16.2. After completion of the service (operation) period, the device does not pose any threat for the environment, human life and health.

17. SHIPMENT AND STORAGE

17.1. Shipment conditions:

17.1.1. Products are transported by all types of transport in roofed vehicles. Conditions for devices transportation — temperature from -50°C to +50°C, relative air humidity from 30% to 93%, atmospheric pressure from 70 kPa to 106 kPa.

17.1.2. Loading, fastening, transportation and unloading of manufactured goods should be carried out in accordance with the current regulations for each type of transport.

17.2. Storage conditions:

17.2.1. Manufactured goods should be stored in warehouse premises: temperature from -50°C to +40°C, relative air humidity from 30% to 93%, atmospheric pressure from 70 kPa to 106 kPa.

17.2.2. Storage conditions should exclude exposure of moisture and aggressive media on products.

17.2.3. Keep in a place protected from insects, rodents and direct sunlight and on the distance at least 1 m from heating devices.

17.2.4. Do not store in places contaminated or containing poisonous chemicals.

18. DISPOSAL AND DESTRUCTION

18.1. According to their hazard level, the devices should be disposed as domestic wastes.

18.2. All packaging materials do not have any hazardous environmental effect, they may be re-used.

18.3. Separate collection of electric garbage:
An old device contains precious materials which may be re-used after disposal with regards to the environment protection requirements. Discard them to the specially designed places (consult the corresponding services of your district) for their collection and re-processing.

18.4. Unused device does not have any specific caution measures while destructed. It should be disposed as domestic wastes.

18.5. Do not throw power supply elements together with domestic garbage. Dispose power supply elements in accordance with the current rules on disposal of industrial wastes.

19. MANUFACTURER WARRANTIES

19.1. Service life of the device — 5 years since the manufacture date. When operational conditions are followed, the service life can exceed significantly the officially declared one.

19.2. The warranty period is 24 months from the date of sale in all countries of the world.

19.3. Seller (manufacturer) or organization performing functions of the seller (manufacturer) based on the agreement does not responsible for the defects if they occur after the device transfer to a consumer due to:

- a consumer's breach of shipment, storage and operation rule provided with the present Instruction;
- mechanic damages;
- actions of the third parties;
- force majeure circumstances.

19.4. Warranty liabilities do not cover devices with impaired industrial seals.

If the device malfunctions in the validity period of warranty obligations, as the shortage is found, the device owner should forward the device and repair (replacement) inquiry to the manufacturing enterprise or its representative (seller) stating the surname, name, patronymic, address, phone number, date and brief description of thee malfunction, conditions of its presentation. Sending the device for repair, use the postal address (see section 20).

20. MANUFACTURER DETAILS

Inferum, LLC
Legal address:
86, Belinskogo st., apt. 487,
Ekaterinburg, Russia, 620026
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