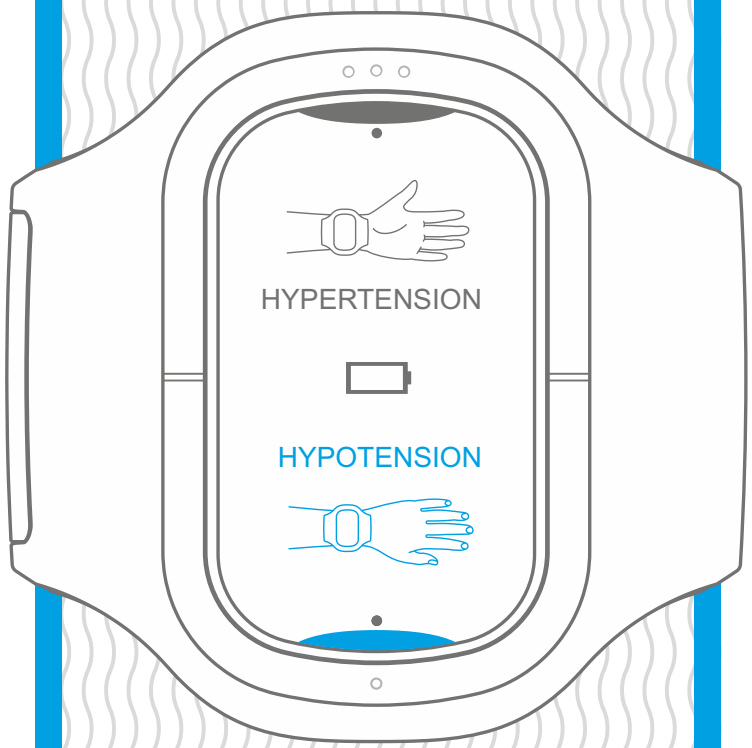


INFERUM

Operation manual

Electrostimulator «ABP-051»

ABP-051

Thank you for purchasing our Electrostimulator «ABP-051» for arterial blood pressure correction.

In order for the device to be effective and safe, please carefully read all the sections of this instruction.

Instruction for use is an integral part of this product which is must-know before the actual use of the device.

CONTENTS

1. Purpose

Electrostimulator «ABP-051» was designed for therapeutic noninvasive (without disturbance of the skin) course treatment of wrist zones by transcutaneous electrical stimulation with the aim of arterial blood pressure (ABP) correction only in combination with drug therapy.

Treatment course contributes to:

- arterial blood pressure correction;
- improvement of overall well-being;
- improvement of emotional state;
- increase of efficiency;
- reduction of meteorological dependence;
- improvement of patient's quality of life.

The electrostimulator was designed for use in treatment and preventive institutions and at home.

Area of intended use – physiotherapy.

2. Operating principle of the electrostimulator

Stimulation with electric current is the best way to activate receptor structures and to start the work of regulatory and adaptive mechanisms of the organism. It is easy to select the electric current amplitude, regulate impulse frequency, length, form, and polarity. Electric current is an adequate activator of excitable tissues.

Electrostimulator «ABP-051» exercises effect, first of all, on vascular tone. It is the most effective and safe way to correct blood pressure. In this case, the device has practically no effect on cardiac output volume or heart rate.

The choice of zones was determined by the type of disorder and usability of device at work, at home, during the course of treatment.

Stimulation is effected with a group of impulses. The number of groups corresponds with the frequencies. The treatment efficiency depends on the patient's state before the device usage.

Adaptation to electrostimulation develops less frequently and more slowly, in addition, treatment with Electrostimulator «ABP-051» has small intensity and duration; thus, portability and procedures safety increase.

Electrostimulator is a mobile, light-weight and compact device that allows you to carry out procedures at any convenient time, anywhere, as well as:

- acts without subcutaneous introduction, has no risk of infection;
- is painless;
- period of zones treating depends on the selected mode;
- system is designed to be used with one hand in order to facilitate the operation;
- no hospitalization required for the course of procedures.

3. Indications for use of Electrostimulator «ABP-051»

• Persistently high arterial blood pressure in patients with essential hypertension – as an additional treatment to comprehensive drug treatment.

• Episodic arterial blood pressure increase under stress situations, weather changes, etc. in patients with labile arterial hypertension.

• Low blood pressure in patients with hypotension – as an additional treatment to comprehensive drug treatment.

Attention! The device is indicated for use by persons over age 14.
The electrostimulator should be used strictly for the purpose intended.

4. Possible adverse effects when using

No possible adverse effects when using of electrostimulator were identified.

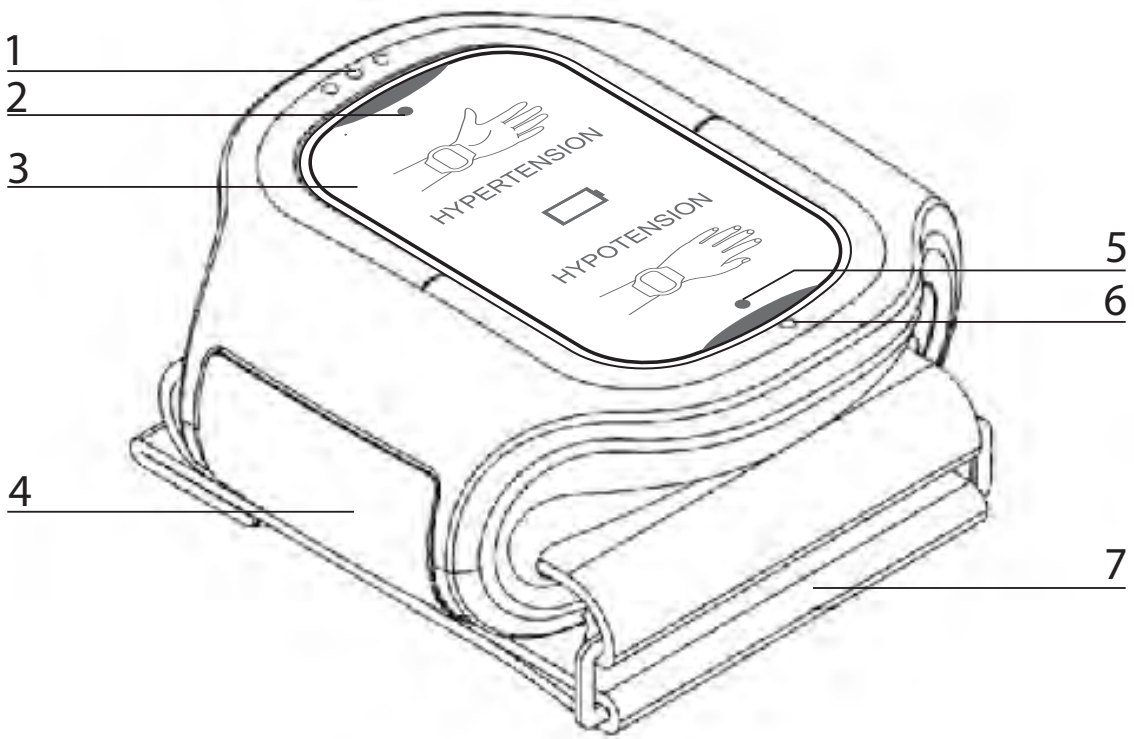
5. Contraindications for use of the electrostimulator

• implanted pacemaker;
• atrial fibrillation;
• individual intolerance to electric current;

- skin lesion in the left wrist zone;
- neoplasms (tumors) of any origin and localization;
- acute febrile conditions of unclear origin;
- acute psychic excitement, alcohol or drug abuse.

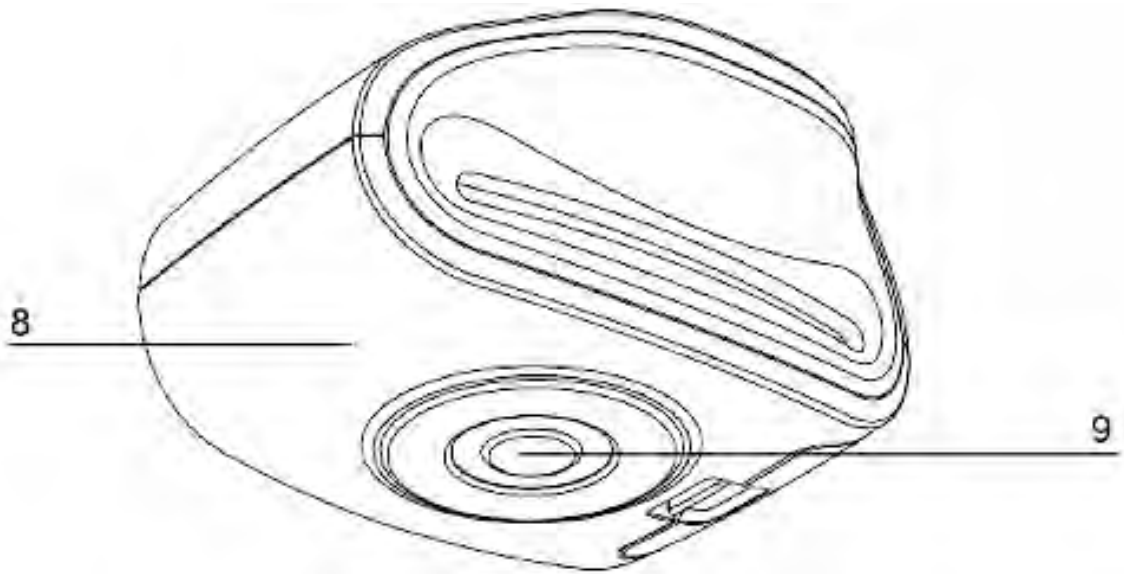
6. The electrostimulator design description

6.1. Physical configuration of Electrostimulator «ABP-051» is shown in Fig. 1a and Fig. 1b.



1 - Button On/Off for Program No. 1 (has three raised points on the surface)
2 - LED for Program No. 1
3 - Front panel
4 - Battery case cover
5 - LED for Program No. 2
6 - Button On/Off for Program No. 2 (has one raised point on the surface)
7 - Cuff

Fig.1a. Design and physical configuration (top).



8 - Housing
9 - Electrodes

Fig.1b. Design and physical configuration (bottom).

6.2. The device includes two automatic programs for the course treatment of wrist zones of the skin integument with various frequencies of the electric current.

Program No. 1:

• Zone on the inner left wrist is treated to decrease arterial pressure (Fig.2). Program No. 1 is started by pressing the button with three raised points and is accompanied by white LED flashing at the top of the device front panel.

Program No. 2:

• Zone on the outer left wrist is treated for arterial pressure increase (Fig. 3). Program No. 2 is started by pressing a button with one raised

point and accompanied by white LED flashing at the bottom of the device front panel.

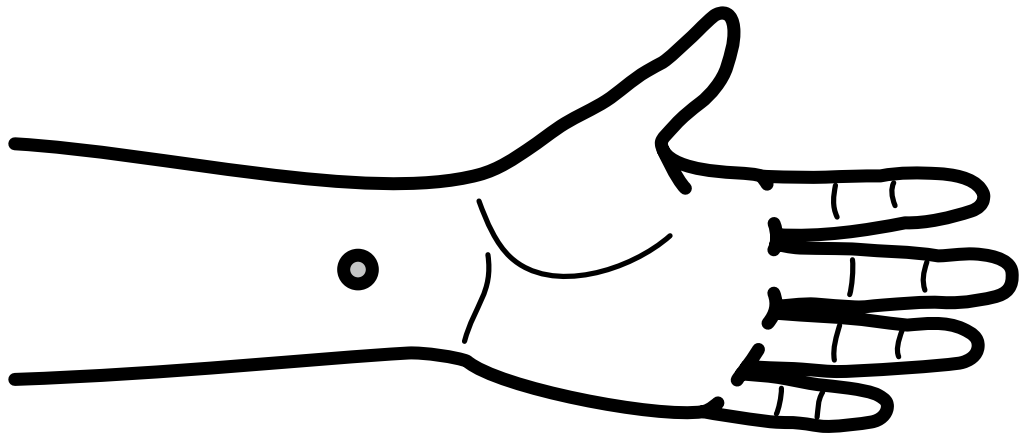


Fig. 2. Zone for patients with high arterial pressure.

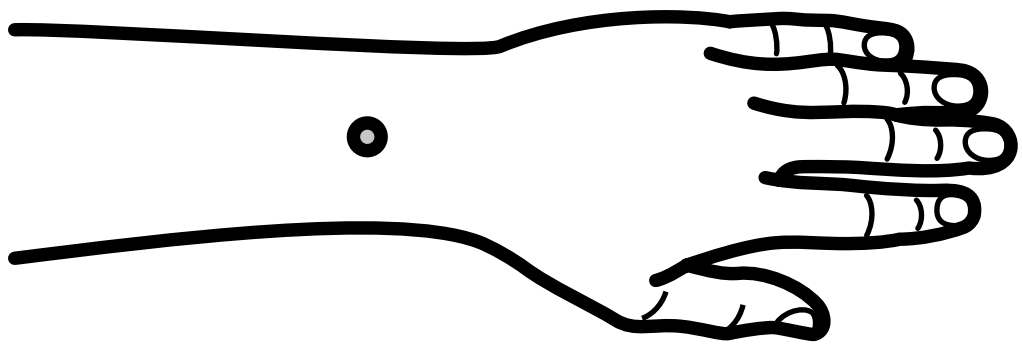


Fig. 3. Zone for patients with low arterial pressure.

After the end of any program you will hear an audio signal, the LED will stop blinking, and the electrostimulator will automatically turn off.

7. Precautions for use of the electrostimulator

7.1. Examine the packaging and the electrostimulator before using it. Do not use electrostimulator if it is damaged.

7.2. The way of use of the electrostimulator should fully correspond to its intended purpose.

7.3. The product labeling and supporting documentation contains the symbols and information relating to the safety of the electrostimulator:

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

7.3.2. РУ No. Р3Н 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.

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 as amended the Directive 2007/47/EC concerning medical devices.

CE 0051

7.3.4. The electrostimulator has passed the procedure of mandatory certification and corresponds to the national standards of the Russian Federation.

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

7.3.6. Carefully read all the information about your safety in this Operation manual, as well as recommendations on the proper use and care of the electrostimulator.

7.3.7. The device poses no hazard for users due to internal low voltage source isolated from the working part of the device (BF type product).

7.3.8. During stimulation the patient should not be connected to any high-frequency electrical device. Simultaneous use of the electrostimulator and other electrical equipment can lead to burns and possible damage of device.

7.3.9. Using near short-wave or microwave equipment may cause instability of electrostimulator output parameters.

7.3.10. The device shouldn't be used in patients with implanted electronic devices (for example, a pacemaker) and in patients with individual intolerance to electric current.

7.3.11. The device should be operated by a person who is awake and adequately evaluates environmental factors. Use of device by persons with borderline conditions or in inadequate mental states is not allowed.

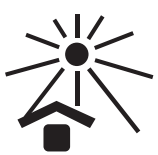
7.3.12. In case of any allergic reaction as a result of device contact with skin, you should immediately stop using the electrostimulator and consult a specialist.

7.3.13. All repair operations of the product should be carried out by qualified specialists at the manufacturer plant.

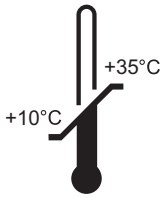
7.3.14. No changes in design made by user are allowed.

7.3.15. The product contains brittle details. Protect from impacts.

7.3.16. The product is not waterproof. Keep away from moisture.



7.3.17. Keep the electrostimulator away from heating units; avoid prolonged exposure to direct sunlight at high (more than +35°C) air temperature. Do not expose the product to heat treatment.



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

Attention! If the device was stored at ambient temperature below +10°C, keep it at room temperature in closed packaging for at least 3 hours before use in order to avoid condensation.

7.3.19. For information relating to the manufacturer, see section 20 of this Operation manual.

EC REP

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

7.3.21. For disposal information, see section 18 of this Operation manual.

7.3.22. Serial number and date of manufacture are indicated under the battery cover.

8. Indication of the opportunity and peculiarities of electro-stimulator use for people with implantable medical devices, pregnant women, nursing mothers, children, adults with chronic diseases

The use of device is not permissible:

- with an implanted pacemaker;
- for children under 14 years.

The use of device is possible:

- during pregnancy and lactation;
- with existing chronic diseases, if they are not included in p. 5.

9.Information on the possible effect of electrostimulator use on the abilities to drive and use machines

There were no studies of the possible effect on the abilities to drive and use machines because the electrostimulator and its accessories do not belong to products that may affect the psychomotor state and are not used during driving and using machines.

10.Indication of the necessity of electrostimulator storage out of the reach of children

Keep out of the reach of children.

11. Recommendations for Electrostimulator «ABP-051» use

11.1. Course of procedures

The procedures should be carried out 1-3 times a day for 14 days, preferably at the same time, regardless of the blood pressure level before the procedure. Patients with hypertonic disease need refresher regular courses of treatment at least once a month (for example, from 1st to 14th of each month).

Action has the cumulative effect, that is, blood pressure becomes stable at the end of the treatment course.

11.2. In cases of situational (and repeating) increase or decrease of arterial pressure, treatment course of at least 14 days is required, 1-3 procedures per day. At the beginning of treatment temporary arterial pressure destabilization can be observed, then followed by a steady decrease under hypertension or a steady increase under hypotension.

11.3. Under labile arterial hypertension (i.e. rare periodic and insignificant arterial pressure increase (no more than 150 mm Hg)) Electrostimulator «ABP-051» can be used as a monotherapy. This approach slows down and prevents the development of disease to a stable form.

11.4. Recommendations on the use of Electrostimulator «ABP-051» in patients over the age of 70: milder rate of blood pressure decrease is

required. For this purpose, treatment with Electrostimulator «ABP-051» is recommended once a day. Treatment course should be not more than 7-8 days. After 10-15 days of break, it is reasonable to repeat treatment course. During the first course of treatment, blood pressure may vary slightly.

11.5. Recommendations on the use of Electrostimulator «ABP-051» in patients with hypertension (persistently high blood pressure (above 180 mm Hg)) who are taking medications: the duration of course and the number of procedures per day should be determined after consultation with the attending physician.

Attention! During treatment with Electrostimulator «ABP-051» the self-withdrawal of medications is NOT permitted. After receiving of persistent antihypertensive effect, the regimens and doses of medication can be changed only by attending physician!

12. Conditions and procedure of working with Electrostimulator «ABP-051»

12.1. Unpack the device, remove packaging material. Check the integrity of device and its accessories by visual inspection.

12.2. Carrying out the procedures with the electrostimulator by the patient himself at home or by medical staff in treatment and prevention institutions does not require special training and special skills.

12.3. During the session the patient can sit or lie in a comfortable position.

Attention! You shouldn't use the device being in the upright position!

12.4. Remove watch or bracelets from the left wrist, free it from clothes elements.

12.5. Select zone (see p. 6.2).

12.6. Treat the electrodes of the electrostimulator and skin of action zone with wet wipe or with cotton ball slightly moistened with water.

12.7. Put the electrostimulator on your left arm depending on the action zone, as shown at figures below.

12.7.1. Treatment zone for patients with high arterial pressure (Fig. 4).

Fig. 4.

12.7.2. Treatment zone for patients with low arterial pressure (Fig. 5).

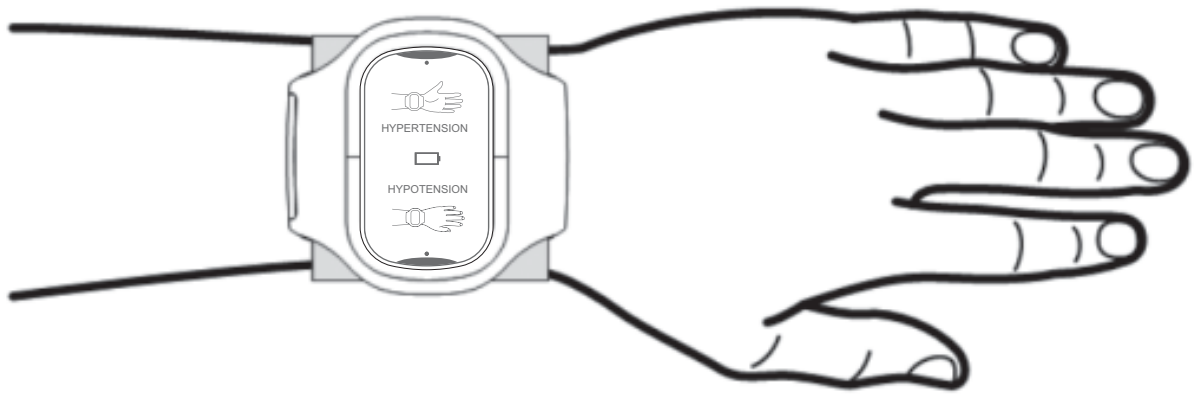


Fig. 5.

12.8. Tighten the cuff of the electrostimulator and fix it with no free space between cuff and wrist. Electrodes of the electrostimulator should tightly touch the skin, without overtightening the wrist.

12.9. Turn on the electrostimulator by pressing the button (Pos. 1 Fig. 1a) in case of high pressure, or a button (Pos. 6 Fig. 1a) in case of low pressure. The corresponding LED will light up (Pos. 2 or Pos. 5 Fig. 1a).

12.10. At the end of treatment session, an audio signal will sound, and the device will turn off automatically. The LED will turn off.

For forced shutdown of the electrostimulator, press and hold the On/Off button (Pos. 1 or Pos. 6 Fig. 1a depending on the action program) for more than 1 s. Audio signal will sound, and the device will turn off. The LED will turn off.

12.11. Remove Electrostimulator «ABP-051». It is recommended to rest for 20-30 minutes after session.

Attention! After each procedure the electrodes of the electrostimulator should be wiped (see p. 15.1.2.)! The lack of proper cleaning can lead to allergic reactions or skin infection in case of using by several patients. The electrostimulator should be stored with dry electrodes!

13.Technical characteristics

13.1.Basic technical characteristics are shown in Table 1.

Table 1

Characteristic name	Value
Measures (without cuff), not more than, mm	75 x 75 x 40
Electrostimulator weight (with cuff and internal electrodes (without batteries), not more than, kg	0,1
Input current, not more than, mA	200
Supply voltage, V	3±0,6
Power supply	Galvanic batteries of AAA type (R03), 2 pcs.

Table 1 (ctd.)

Characteristic name	Value
Body protection	**IP 41** is a degree of protection against penetration of external solid objects (protection from particles > 1.0 mm) and protection against drops of water falling vertically.
Class of protection against electric shock of working parts	 BF type

13.2. Action parameters

13.2.1. The device includes two automatic programs No. 1 and No. 2. Each program consists of a series of sequential impulses (Fig. 6) with different frequencies.

Electrostimulator «ABP-051» generates electric pulses consisting of two phases with off-load parameters:

- maximal amplitude of 1st phase of the pulse is 30 ± 10V.
- maximal amplitude of 2nd phase of the pulse is 95 ± 25V.

13.2.2. Technical parameters of program No. 1.

Program No. 1 was designed for patients with high blood pressure of the following range: systolic pressure higher than 130 mm Hg, diastolic pressure higher than 80 mm Hg.

Treatment zone: see Fig. 2.

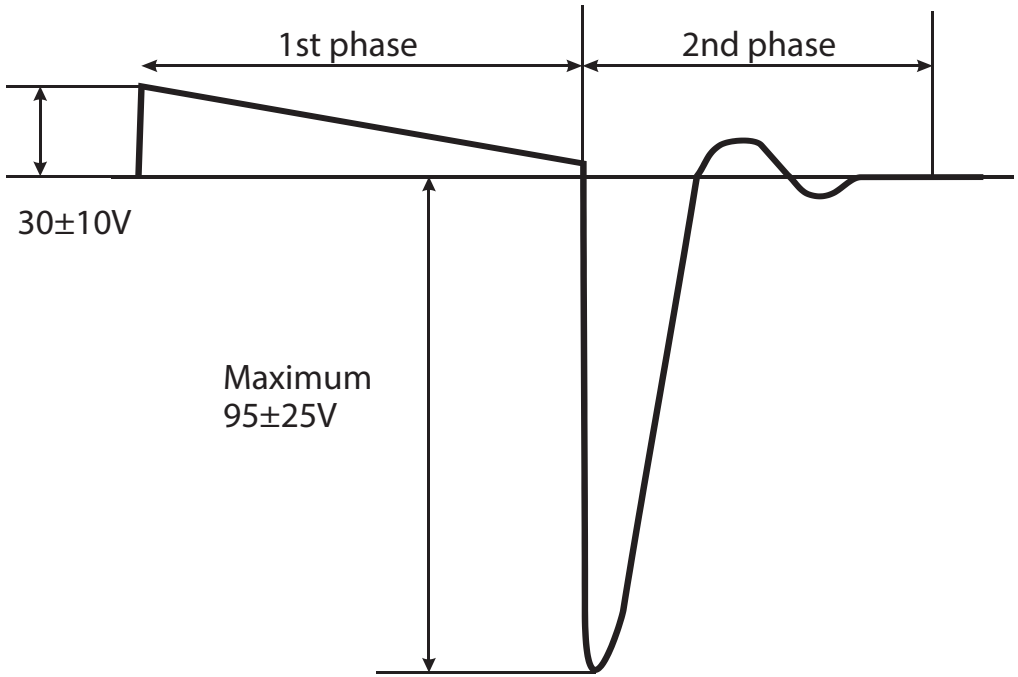


Fig. 6. Impulse from and parameters.

Treatment zone diameter: 10 mm.

Operating frequencies of the program are 9.2 Hz and 77 Hz. Total action time of the program is 5 minutes.

Indication: white LED blinking (Pos. 2 Fig. 1a), audio signal after the end of program.

13.2.3.Technical parameters of program No. 2.

Program No. 2 is intended for patients with hypotension and pressurein the following range: systolic pressure lower than 106 mm Hg, diastolic pressure lower than 70 mm Hg.

Treatment zone: see Fig. 3.

Treatment zone diameter: 10 mm.

Operating frequencies of the program are 77 Hz and 140 Hz with amplitude modulation at a frequency of 4 Hz. Total action time of the program is 6 minutes.

Indication: white LED blinking (Pos. 5 Fig. 1a), audio signal after the end of program.

13.3. Electromagnetic emission

Test	**Correspondence**	**Use conditions**
HF radiation CISPR 11	B class	Electrostimulator can be used in all instisutions, also at home.

13.4. Resistance to HF radiation

Test	**IEC 60601-1-2 Test conditions**	**Acceptable level**
IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms
IEC 61000-4-3	3V/m 80 MHZ to 2.5 GHz	3 V/m

13.5. Resistance to electromagnetic fields

Test	Test level	Correspondence level	Use conditions
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8 V air	±4kV contact ±8 V air	The floor should be wooden, concrete or of ceramic tiles. If the floor is covered with synthetic materials, the relative humidity of air should be at least 40%.
Magnetic fields IEC 1000-4-8	3A/m	3A/m	Characteristics of magnetic fields should be typical for commercial buildings and hospital conditions.

13.6. Electrostimulator «ABP-051» uses electromagnetic energy only for internal functions. In this regard, the radiation of the electrostimulator is minimal and should not influence the nearest electronic equipment. Electrostimulator «ABP-051» can be used in any institution, also at home.

13.7. Electrostimulator «ABP-051» should not be used together with other equipment. In case when the use of the electrostimulator and other equipment is required, the electrostimulator and other

equipment is required, the electrostimulator and other equipment should be checked for correct operation in the conditions (operation modes) in which it will be used.

13.8. *Electromagnetic conditions*. The electrostimulator was designed to work under certain conditions of electromagnetic environment.

13.8.1. *Electrostatic discharge (ESD):*

• The floor should be wooden, concrete or of ceramic tiles. If the floor is covered with synthetic materials, the relative humidity of air should be at least 40%;

• Do not use synthetic clothes.

13.8.2. *HF radiation:* portable and mobile devices should be used at a distance to any part of medical device no closer than the distance determined by the following expression:

Recommended distance is $d = 2.3 \sqrt{P}$ (800 MHz to 2.5 GHz).

P – maximal output power according to the manufacturer's information.

13.8.2.1. Personnel (user) should take the following steps: minimal distance to portable communication devices (cell phones, cordless telephones) should be approximately 3 meters if the output power of devices exceeds 2 W.

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

14. Medical device package contents

Name	Amount, pcs.
Electrostimulator «ABP-051» with internal electrodes and cuff	1
Operation manual	1
Informative guide	1
Inner package	1
Box	1

Attention! Batteries don't come standard with the device!
For this device please use LR03 / AAA or R03 / AAA batteries.

15.Maintenance and repair requirements

15.1. Maintenance

15.1.1. External examination of the device. It is necessary to make sure that there are no traces of bumps or falls because it may cause to malfunction of the device.

15.1.2. Before and after using the device you should clean the electrodes (Pos. 9 Fig. 1b). Use non-aggressive disinfectants (e.g. 3% hydrogen peroxide solution) and soft lint-free napkins for cleaning of the electrodes. Disinfection should be carried out with 5-time treatment with 3% hydrogen peroxide solution.

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

15.1.4. The product is designed for repeated use. In the case of malfunction, repair should be carried out by the manufacturer.

15.2. Power elements replacement:

When the symbol is blinking on the screen or when the electrostimulator does not turn on (completely discharged batteries), you need to replace the power elements. For this:

1) disconnect the electrostimulator if it is switched on;

2) open the battery chamber as shown at Fig. 7: push locktab in the direction of arrow 1 and slide battery cover in the direction of arrow 2;

3) remove batteries;

4) keep the electrostimulator without batteries for 2 minutes;

5) install new batteries, observe polarity as shown in Fig. 8. Put battery cover back.

Attention! You should remove batteries for long-term storage of device without use!

Attention! Use only high quality batteries! When using low-quality ones, there is a risk of spontaneous leakage of battery contents that can make the device inoperative (and is not covered by manufacturer's warranty) and cause the risk of chemical burns.

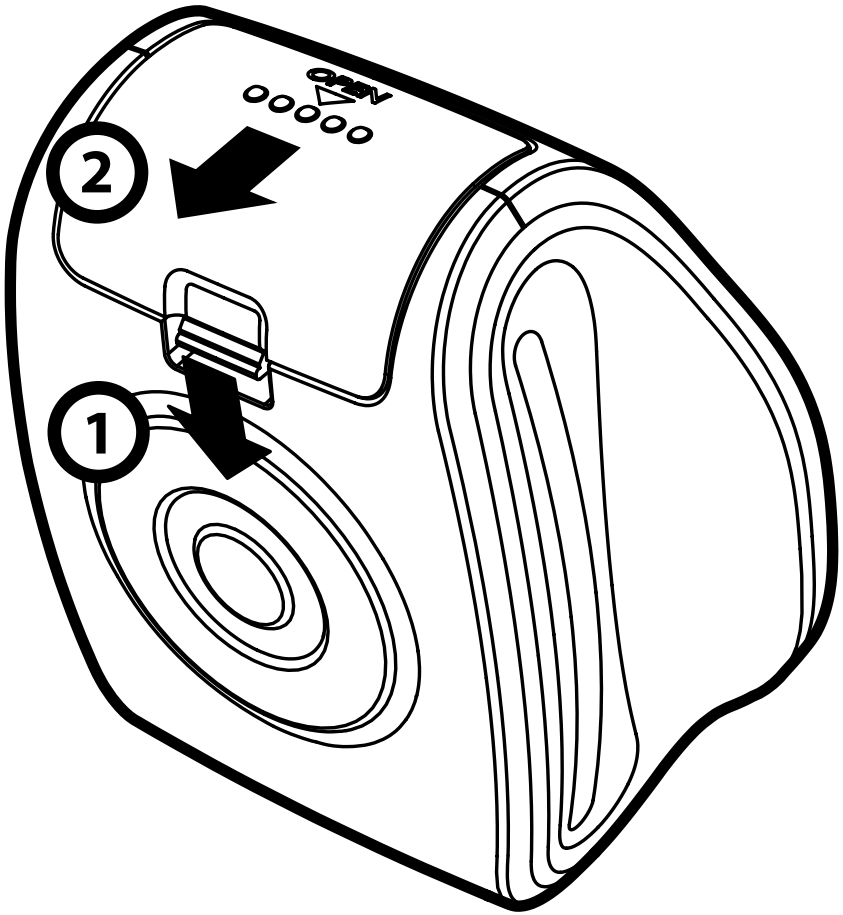


Fig.7.

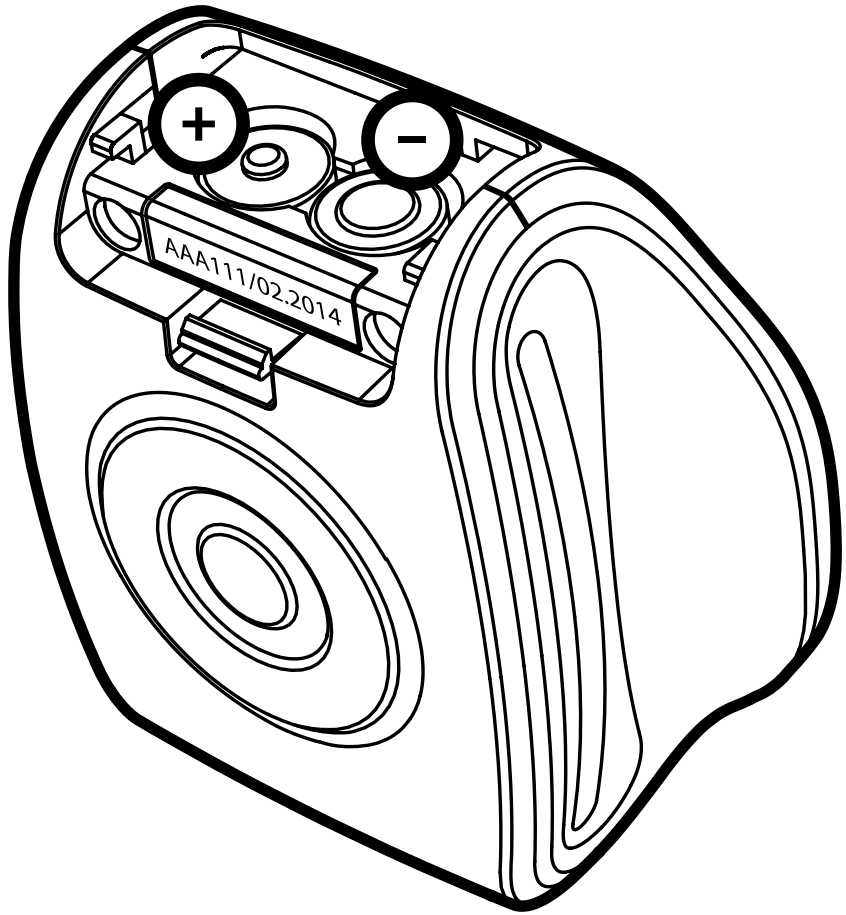


Fig.8.

15.3. Possible malfunctions and the ways of their handling.

Table 2 shows the states of electrostimulator that can be fixed by yourself. In case of other faults please contact the manufacturer's representative. Do not try to handle them by yourself!

Table 2

Fault	Way of handling
Device turns off / doesn't turn on	Batteries are discharged – you should replace the batteries.
Device doesn't turn on after batteries replacement	You should remove the batteries, keep the device for 2 minutes without them, then place them back as it is shown at Fig. 8.
No feelings of action	The skin is dry – treat it with cotton ball slightly moistened with water or wet wipe.
	Electrodes are not clean – wipe them (p. 15.1.2.).

Attention! Any other fault should be handled at the manufacturing plant or in the service centers of manufacturer.

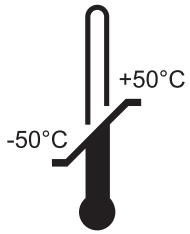
16. Service life

16.1. Service life of device is 5 years from production date. If the operating rules are observed, service life can significantly exceed the officially established one.

16.2. After the end of service life (operation) device does not pose a hazard to the environment of human life and health.

17. Transportation and storage

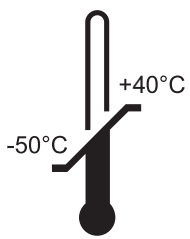
17.1. Transportation conditions:



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 to 106 kPa.

17.2.2. Storage conditions should exclude moisture or corrosive environment.

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

17.2.4. Do not store in places with contamination or toxic chemicals.

18. Disposal and removal

18.1. To be disposed of as household waste.

18.2. All packaging materials do not have toxic effect on the environment, they can be reused.

18.3. Separate collection of electrical garbage:

An old device contains valuable materials that can be reused after recycling according to the requirements of environmental protection. Bring them to special places (consult with the appropriate services of your region) for collection and processing.

18.4. The unused product requires no special measures for disposal. It is recyclable as household waste.

19. Manufacturer's warranty

19.1. Warranty period is 24 months from the date of sale.

19.2. Seller (manufacturer) or organization which on the basis of the contract performs seller (manufacturer) functions is not responsible for the defects, if they appear after device transfer to the consumer and emerge due to:

- violation by the consumer of the rules of transportation, storage, care or exploitation provided in this manual;
- mechanical damage;
- actions of third parties;
- force majeure circumstances.

19.3. Warranty responsibility does not include devices with broken factory seals.

In case of device malfunction during the warranty period, as well as detection of incomplete state, device owner should send the device and an order for repair (replacement) with his name, first name, patronymic, address, phone number, date, brief description of malfunction, and conditions of fault event to the address of manufacturer or his representative.

20. Manufacturer's address

Inferum LLC
620026, Russia, Ekaterinburg, Belinskogo Str., 86-487

Postal address:
620100, Russia, Ekaterinburg, Sibirsky Tract, 12, b. 1, of. 206
Tel./fax: +7 (343) 247-84-51
E-mail: info@inferumgroup.com
www.inferumgroup.com

EC REP

CARLAINE s.r.o.
Rybářská 839/2
360 17, Karlovy Vary,
Česká republika
info@carlaine.com

Warranty sheet

Name: Electrostimulator «ABP-051»

Model _____
Product number _____
Production date _____
Date of purchase _____
Owner _____
Address _____
Phone number _____
Date of asking for repair _____
Reason for being repaired _____
Repair mark _____
Signature of organization officer who is in charge for acceptance after repair

The product is examined, no claims against package contents or physical configuration.
Buyer's signature _____
Receipt date _____

The warranty for repaired device is 12 (twelve) months from receipt date of repaired device. If the warranty period from the moment of purchase is more than 12 (twelve) months, the guarantee should be calculated for a longer period; the warranty period is prolonged for the time of device repairing.

Acceptance mark

Electrostimulator «ABP-051» is considered usable

Serial number

Date of production

Acceptance mark

Seller's signature _____

Date of sale _____

Warranty conditions are accepted, the product is examined, no claims against package contents or physical configuration.

Buyer's signature _____

Date of purchase _____

Attention!!! Carefully examine the device upon purchase!
Defects of housing (scratches, cracks, chips) do not belong to warranty events. Device with such defects can't be exchanged, repaired or returned.

Certified Quality System ISO 13485:2012

INFE 05.01-03.72-03ИП