REPUBLIC CLINICAL DIAGNOSTIC CENTER
State-Financed Health Institution
Udmurt Republic
2018

ABP 051

Зарегистрирован
в качестве **медицинского**
изделия в РФ и ЕС

Регистрационное удостоверение
РЗН 2016/3776 от 31.03.2016.
EC Certificate № 1942/MDD от 01.09.2017.

Перевод с русского языка на английский язык

APPROVED BY

Head Physician of Budgetary Healthcare Institution of the Udmurt Republic "Republic Clinical Diagnostic Center of the Ministry of Healthcare of the Udmurt Republic"

[signature] Riashchikov S.N.

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<Round stamp with the Coat of Arms: Ministry of Healthcare of the Udmurt Republic; PSRN 1021801651321; Budgetary Healthcare Institution of the Udmurt Republic; "Republic Clinical Diagnostic Center of the Ministry of Healthcare of the Udmurt Republic">

MEDICAL APPROBATION PROTOCOL

No.15122017-02 dated December 15, 2017

Name of the tested device: Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction according to ТУ 9444-005-12342964-2015 (hereinafter referred to as the electrostimulator ABP-051).

Model: ABP-051

Registration certificate issued by the Federal Service for Supervision in Healthcare, No.РЗН 2016/3776 dated March 31, 2016;

Certificate of compliance with the European standards according to the Directive 93/42/EEC dated September 01, 2017.

Manufacturer: "Inferum" Limited Liability Company, TIN 6612040385, "Inferum" LLC, Belinskogo St. 86-487, Yekaterinburg, Sverdlovsk Region, Russia 620026

Address of the production site: 74 Mekhanizatorov St., Kamensk-Uralskiy, Sverdlovsk Region, Russia 623417.

Medical institution performing the medical approbation of the medical device:

Budgetary Healthcare Institution of the Udmurt Republic "Republic Clinical Diagnostic Center of the Ministry of Healthcare of the Udmurt Republic", 87B Lenina St., Izhevsk 426009 Russia.

License to perform medical activities No.ЛО-18-01-002032 dated June 14, 2016 issued by the Department for Medical and Pharmaceutical Business Licensing under the Government of the Udmurt Republic.

The trial was performed at the premises of the department for rehabilitation treatment and physiotherapy (Head: physiotherapist Zaitseva E.P.).

List of the experts performing medical approbation:

Head of the department for rehabilitation treatment and physiotherapy, Physiotherapist Zaitseva Elena Petrovna

Physiotherapist – Dmitrieva Tatiana Nikolaevna

Nurse supervisor – Poluektova Valentina Vasilievna

Coordinating investigator: physiotherapist Zaitseva E.P.

Applying institution: "Inferum" Limited Liability Company, TIN 6612040385, "Inferum" LLC, 86-487 Belinskogo St., Yekaterinburg, Sverdlovsk Region, Russia 620026

This clinical trial is performed in compliance with the agreed and approved plan of the clinical trial No.05062017-02/ABP-051 and other regulatory legal acts.

Approbation period:

From June 05, 2017 to December 15, 2017

Purpose and objectives of the medical approbation:

- To evaluate efficiency of the arterial blood pressure correction by the electrostimulator ABP-051 for the patients with arterial hypertension used in addition to the main drug therapy.
- To evaluate efficiency of the arterial blood pressure correction by the electrostimulator ABP-051 for the patients with hypotension.

- To evaluate efficiency of the arterial blood pressure correction by the electrostimulator ABP-051 in cases of rare periodic and minor increase in arterial blood pressure as monotherapy.
- To prepare medical approbation certificate based on the trial results for the medical device "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" following the approved clinical trial plan No.05062017-02/ABP-051.
- Conclusions based on the results of the trial.

The following documents are submitted for the medical approbation of the medical device "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" according to ТУ 9444-005-12342964-2015:

1. Application to perform medical approbation dated May 18, 2017.
2. Registration certificate for the medical device dated March 31, 2016 No.РЗН 2016/3776.
3. Certificate of conformity.
4. Clinical trial protocol in the form of analysis and evaluation of the clinical data of the medical device No.2 dated January 22, 2017: "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" according to ТУ 9444-005-12342964-2015 (European Medical Center UGMK-Zdorovje LLC, Yekaterinburg)
5. User manual INFE 05.01-03.70-О1ИП.
6. Plan of medial approbation for the medical device "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" according to ТУ 9444-005-12342964-2015 No.05062017-02 dated June 05, 2017.

1. Analysis of the clinical data documents and materials submitted by the Applicant:

1.1 The electrostimulator ABP-051 is designed for non-drug therapy of the diseases related to arterial blood pressure correction as a supplement to the comprehensive drug therapy, designed for therapeutic non-invasive (without skin penetration) course treatment by stimulation of reflexogenic zones in the left wrist area using transcutaneous electroneurostimulation method.

Classification:

The electrostimulator APP-051 has IIa class of potential risk of medical device application in accordance with GOST 31508 and Order of the Ministry of Healthcare of Russia No.4н dated June 06, 2012, and in accordance with Rule 9 of Annex IX of the Directive 1993/42/CEE as amended 2007/47/CE.

Type of the medical device according to the Nomenclature Classification of Medical Devices by Type: **181480** (according to the Order of the Ministry of Healthcare of the Russian Federation No.4н dated June 06, 2012 "On approval of the nomenclature classification of medical devices").

Code of the All-Russian Product Classifier for the medical device: **94 4410**

Marking of the product:

Marking of the product includes the following symbols and indications:

<Translation of phrases from the marking: ABP-051; ТУ 9444-005-12342964-2015; Manufactured by: Inferum LLC; LRO3/AAA; 1.5V-2 pcs.; Registration certificate No.РЗН 2016/3776 dated March 31, 2016>

Application of the medical device:

Electrostimulator ABP-051 is designed to be used in the medical and preventive treatment facilities, as well as for individual use by the patients at home for therapeutic treatment.

The device is non-sterile.

Groups of patients according to the user manual for the medical device:

Electrostimulator ABP-051 is designed for therapeutic non-invasive course treatment for arterial blood pressure correction and recovery of the overall body state.

The device is indicated for treatment of persons above 14 years old with the labile form of arterial hypertension and persons with persistent arterial blood pressure increase as a supplement treatment to taking medication.

For the patients with hypotension.

Indications:

- Persistently high arterial blood pressure in patients with essential hypertension - as an additional treatment to comprehensive drug treatment;
- Episodic arterial blood pressure increase in the situations of stress, weather changes, etc. in patients with labile arterial hypertension;
- Low blood pressure in patients with hypotension - as an additional treatment to comprehensive drug treatment;

Contraindications:

- 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

Possible side effects

Possible side effects during the period of use of this medical device were not found.

Operation technique

Electrostimulator ABP-051 is used for direct short-term contact with the patient's skin on the left wrist.

Operating principle of the device:

Transcutaneous electrostimulation is the physiotherapy methods based on the exposure to short low-frequency current pulses on the human body wrist areas, namely:

- Exposure of the wrist area on the inside of the left arm (Fig.1) is used for arterial blood pressure decrease. The operation frequency of the program: 9.2 Hz and 77 Hz. Total time of the program exposure: 5 minutes.

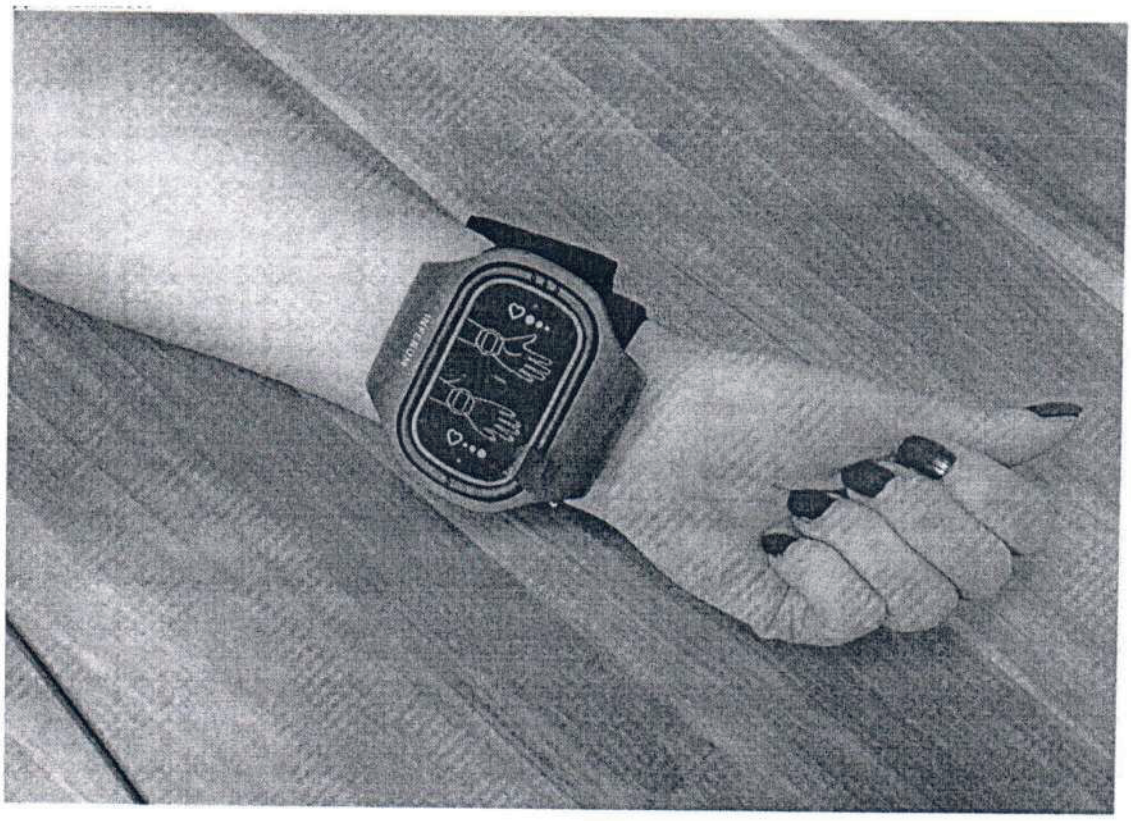

Fig.1.

- Exposure of the wrist area located on the outside of the left arm (Fig.2), is used for arterial blood pressure increase. The operating frequency of the program: 77 Hz and 140 Hz with amplitude shift keying with a frequency of 4 Hz. Total time of the program exposure: 6 minutes.

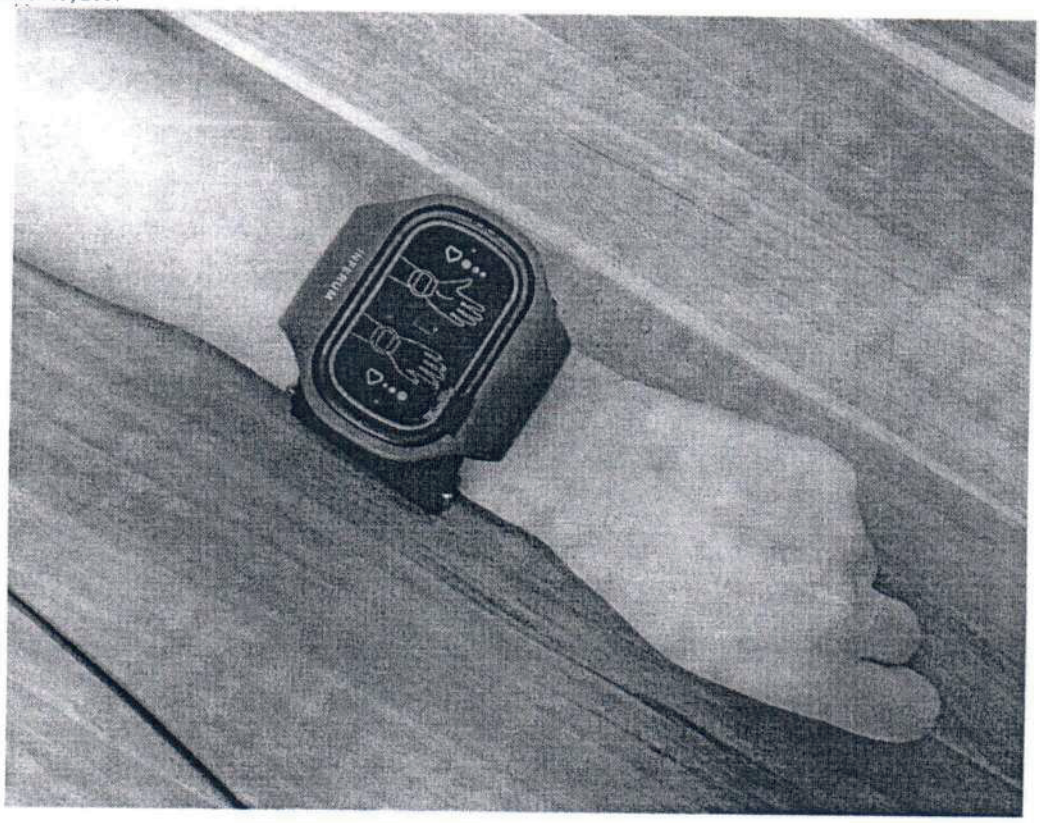

Fig.2.

Exposure takes place through the electrodes built in the body of the device when in contact with the patient's skin.

The device provides therapeutic treatment during correction with the following pressure values:

- for the patients with high arterial blood pressure within the range: systolic pressure of more than 130 mm Hg, diastolic pressure of more than 80 mm Hg.
- for the patients with hypotension and pressure within the range: systolic pressure less than 106 mm Hg, diastolic pressure of less than 70 mm Hg.

Application of the device

1. To start using Electrostimulator, first it is necessary to take own arterial blood pressure using the blood pressure monitor. Then make sure the left wrist is free from watches, bracelets and clothes. Put the device on the wrist depending on the desired area of exposure making sure there is no space between the blood pressure cuff and the wrist. The electrodes of the device should touch against the skin, but should not be too tight on the wrist.

2. Switch the device on using the ON/OFF button and select the exposure program according to the patient's diagnosis.

3. The device will begin to work on the selected area. The treatment procedure consists of several exposure phases that are different in frequency, time and amplitude of exposure. When the session has finished, a signal will sound and the device will switch off automatically.

4. For sustainable results, it is recommended to have a course of treatment consisting of no less than 14 procedures, 1-3 procedures per day.

5. Take the device off. It is recommended to have a rest for 20-30 minutes after the session.

Safety of the medical device is confirmed by the registration certificate № РЗН2016/3776 dated March 31, 2016, issued by the Federal Service for Supervision in Healthcare based on the results of examinations conducted during the registration of the medical device, as well as risk analysis provided by the manufacturer in accordance with the requirements of Directive 93/42/EEC, which considered potential hazards that can occur at every phase of the product life cycle, the probability hazards may occur, and the severity of the consequences of each hazard have been assessed. Following the results of the risk analysis, protective measures have been outlined and implemented in order to reduce the identified risks to acceptable level, and references to the documents confirming the implementation of these protective measures have been provided.

2. Data analysis relating to the use of the device in medical practice

During performance of a set of medical approbation works relating to evaluation of the safety and efficiency of Electrostimulator ABP-051 statistically significant results have been obtained.

The number of patients with the increased arterial blood pressure was 102 (58 women and 44 men). The correction sessions were conducted during nine days, on the tenth day the patients were discharged. Fig.3 shows the correction results diagrams for the general group of men and women, Fig.4 shows the separate data.

Average age:

- **in the group: 51±15.3;**

- women: 56±13;
- men: 45±16.2.

Average arterial blood pressure prior to the correction course:

- **in the group: SBP 139±19, DBP 86±12;**
- women: SBP 138±22, DBP 84±15;
- men: SBP 140±12, DBP 82±10.

Average arterial blood pressure one hour after the correction session:

- in the group: SBP 135±17, DBP 80±14;
- women: SBP 133±18, DBP 79±15;
- men: SBP 136±16, DBP 81±15.

Average arterial blood pressure after the 9 days of correction course:

- in the group: SBP 129±21, DBP 73±11;
- women: SBP 130±22, DBP 73±13;
- men: SBP 128±18, DBP 80±11.

Average arterial blood pressure on the 10th day one hour after the correction:

- **in the group: SBP 119±21, DBP 73±9;**
- women: SBP 118±14, DBP 71±7;
- men: SBP 125±18, DBP 79±11.

During the approbation process in order to reveal the placebo effect, the device simulating the functioning device and with all signs of the switched-on device was used: the led lamp was on, the audible signals were used, but the electrodes were disconnected from the circuit. The group consisted of 18 people. The result was the arterial blood pressure decrease on average by 1-2 mm Hg (both systolic and diastolic blood pressure).

All patients tolerated the procedures very well. No complications were found.

The heart rate had changed insignificantly. The group of women sometimes demonstrated a slight increase of diastolic arterial blood pressure by about 2 mm Hg during the second correction session one hour after its completion. It appeared that this occurred due to the specifics of adaptation.

The number of patients with the decreased arterial blood pressure was 22, women only, the average age was 32 years. The correction course lasted for 5-7 days. Average arterial blood pressure (see Fig.5):

- prior to the correction course: SBP 97±9, DBP 64±6;
- after the correction course: SBP 114±10, DBP 71±8.

In this case, the heart rate had insignificantly increased from 63 to 66 beats per minute.

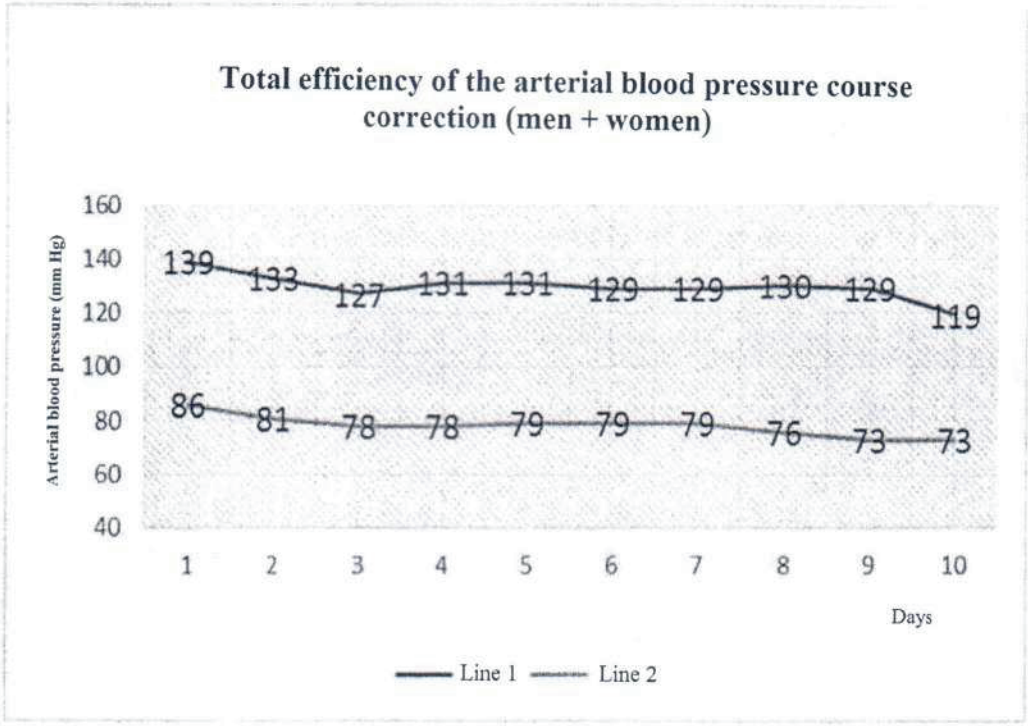

Fig.3. The diagrams show the results of the arterial blood pressure correction course in general for the total group of men and women. Line 1 – systolic blood pressure; Line 2 – diastolic blood pressure.

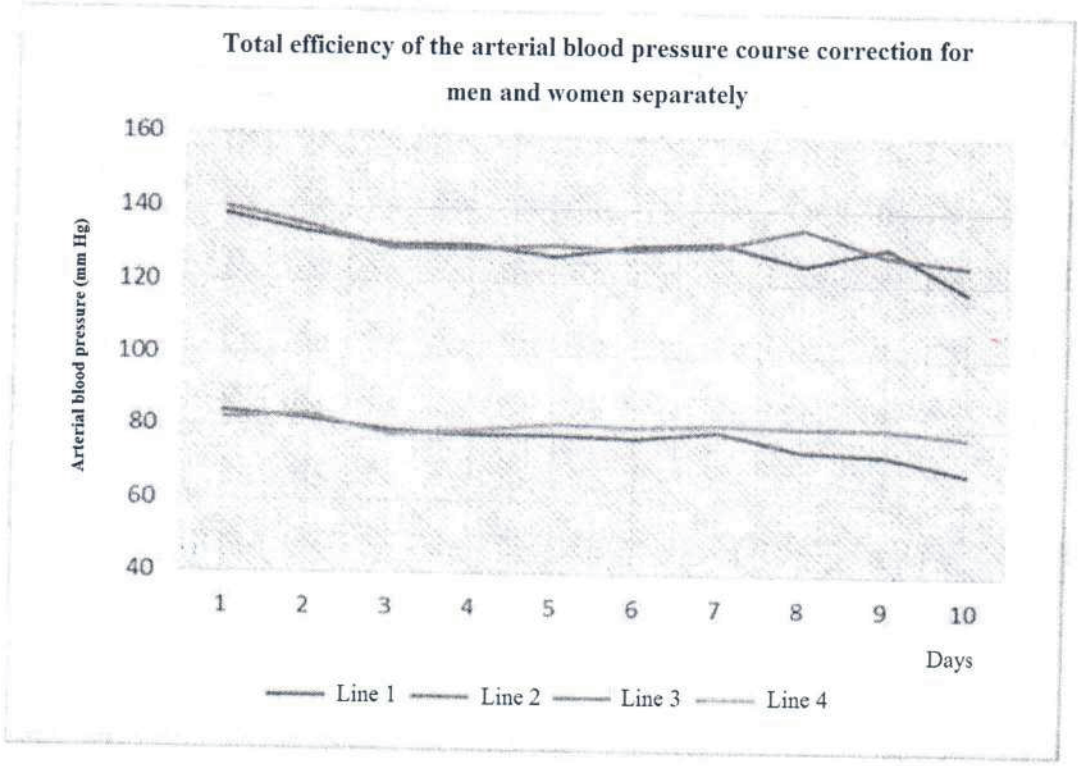

Fig.4. The diagrams show the results of the arterial blood pressure course correction in the groups of men and women separately:

- women: Line 1 – systolic blood pressure, Line 2 – diastolic blood pressure;
- men: Line 3 – systolic blood pressure, Line 4 – diastolic blood pressure.

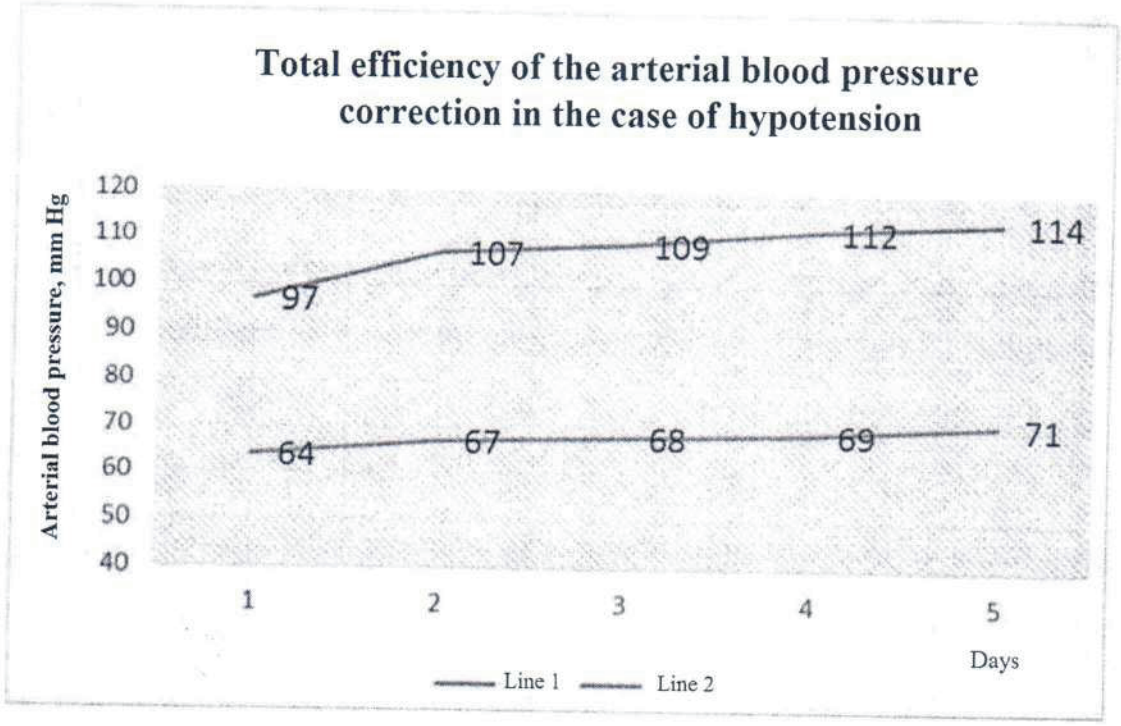

Fig.5. The diagrams show the results of the arterial blood pressure course correction in the case of hypotension in women. Line 1 – systolic blood pressure, Line 2 – diastolic blood pressure.

The diagrams show that initially the significant arterial blood pressure decrease occurs within the first three days, followed by the period of relative stabilization of arterial blood pressure up to the seventh day, followed by the period of sharper decrease and normalization of arterial blood pressure. Moreover, women were more sensitive to the procedures.

3. Conclusions based on the medical approbation results

3.1 Following the medical approbation of the medical device "Electrostimulator ABP-51" in the treatment of patients with increased or decreased arterial blood pressure, the following conclusions can be drawn:

- In the case of systolic blood pressure of more than 145 mm Hg, the application of the device allows to reduce the medication dose;
- In the case of systolic blood pressure of more than 180 mm Hg, it is recommended to use the device under the supervision of a physician;
- It is effective in the correction of hypotension;

- It is not recommended to interrupt the correction course as it may lead to increase of the course length;
- In order to increase sustainability of the effect, it can be recommended to increase the course length up to 14 days.

3.2 Application of the medical device is safe. No side effects were noted while using the device.

3.3 No therapeutic effect was observed in the "placebo group".

3.4 Medical device "Electrostimulator ABP-051" can be recommended for use both as the monotherapy and as an addition to the drug hypotension therapy.

3.5 The results of the medical approbation are reliable, because there was a control group, and the groups of participating patients were randomized by age and the degree of severity of arterial hypertension.

Conclusion:

Medical device "Electrostimulator ABP-051" COMPLIES with the requirements of regulatory documentation, technical and operation documentation of the manufacturer, as well as the intended purpose and indications determined by the manufacturer.

The results of the performed medical approbation confirm efficiency and safety of use of this medical device.

Signatures:

Head of the department for rehabilitation treatment and physiotherapy, physiotherapist	[signature]	Zaitseva E.P.
Physiotherapist	[signature]	Dmitrieva T.N.
Nurse supervisor	[signature]	Poluektova V.V.

Данный перевод с русского языка на английский язык выполнен мной, переводчиком Аликиной Дарьей Александровной. Верность перевода подтверждаю.

Аликина Дарья Александровна Аиз