## **USEFUL ADVICE**





# Electrostimulator ABP-051









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#### **USEFUL ADVICE**

Thank you for the purchase of the "ABP-051" device\*.

You are holding the unique medical physiotherapeutic "ABP-051" device which has been designed to normalise blood pressure, one of the most important parameters of human health.

Your purchase of the electrostimulator "ABP-051" means you treat your health seriously and strive for its preservation. We may not answer all your questions in this small brochure, but we think that our advice will help you to use the "ABP-051" to its maximum capability. It is important for everyone to consider the seriousness of circulatory disorders related to blood pressure problems. Understanding should make it possible to prevent severe and often lethal sequelae.

\*Device "ABP-051" is approved for medical use by the Federal Service over Surveillance in Healthcare and included to the registry of medical equipment (Registration certificate No P3H 2016/3776 dated 31 March 2016) and corresponds to Technical requirements 9444-005-12342964-2015. EU Certificate No 1942/MDD dated 1 September 2017.

110/70 mmHg

120/80 mmHg

130/90 mmHg

mmHg

DECREASED

OPTIMUM

INCREASED

HIGH



Arterial hypertension is a vicious disease and nowadays among the most prominent cardiovascular disorders. About one fourth of the world's adult population suffers from essential hypertension and its adverse related health conditions which can have serious implications on work capacity and life expectancy. The disease is hard to cure, but its development may, and can be stunted. If arterial hypertension, for example is left untreated, it can have a devastating impact on our organs, such as our brain, heart, vessels, kidney and eyes. The damage to essential organ tissues may lead to disability and even death.

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Blood pressure (BP) is measured in millimeters of mercury (mmHg) and is expressed by two levelled values: systolic pressure and diastolic pressure. The levels are often called "upper" and "lower" blood pressure.

The "ABP-051" device aims to normalise blood pressure levels from hypertension and hypotension. It has been developed and manufactured in Russia and is used in many countries worldwide. It has performed well in clinical studies and is effective, safe, compact and easy to use.





HEART







**KIDNEYS** 

VESSELS

**EYES** 

The mechanism of action is based on mild electric stimulation of left wrist skin areas. It communicates with the brain's vasomotor center which, in turn, normalizes arterial tone and finally blood pressure.

Please read the Instruction for use and following information carefully:

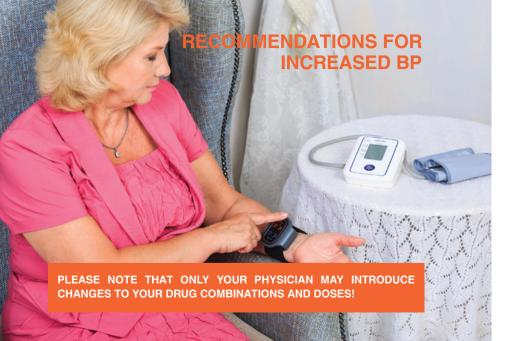
- The "ABP-051" is intended for persons above 14 years old.
- The "ABP-051" is effective for the recovery of bodily resources in people who do sports and fitness and/or have a great deal of physical exertion in their lives.
- The "ABP-051" is a new additional instrument to help with our struggle against hazardous diseases such as circulatory regulation disorders which present as arterial hypertension or hypotension. Its uniqueness lies in the fact that it is non-drug and/or invasive treatment. The mechanism draws your heartbeat to that which is maximally close to natural physiological regulation processes of cardiovascular activity.

The corrective effect is cumulative, which indicates its target therapeutic effect in recovering natural mechanisms of the vascular tone regulation.

The brochure will be useful not only to people suffering from blood pressure disorders, but also those attentively taking care of their health and/or that of their relatives.

## COURSE ADMINISTRATION OF THE "ABP-051" DEVICE PROMOTES:

- normalization and stabilization of BP disorders (both increased and decreased BP);
- decline in pain and other syndromes accompanying BP increases or decreases;
- improvement of general health condition;
- improvement of emotional state;
- improvement of working capacity;
- more rapid recovery from physical exercise and stress;
- improvement of patient's quality of life.



## RECOMMENDED COURSE OF TREATMENT FOR ARTERIAL **HYPERTENSION**

#### Course for BP normalization

The "ABP-051" device is intended for 14 days use with 1-3 sessions a day of course administration. The course should be repeated monthly.

- Stable results can be achieved only after completing a full treatment course using the "ABP-051" device.
- It should be remembered that the device has a gradually developing cumulative effect.
- If improvement is felt before completion of the recommended course, it is important to still not interrupt the treatment course.
- The "ABP-051" device is intended to be used daily when BP pressure is usually increased.
- Sessions can be repeated if necessary, 2-3 times a day.

- For hypotension of any degree, even if the pressure varies from high to decreased levels during the day when anti-hypertensive drugs are taken, the procedures of the course should be always performed in the same area.
- You should not stop taking drug products prescribed by your physician by yourself.
- Consumption of caffeine-containing substances increases blood pressure due to increases in heart rate. Therefore. if the "ABP-051" is used after a cup of coffee, the desired effects of pressure decreases may not be felt.
- We recommend maintaining your blood pressure control diary carefully. It will allow for changes in BP to be assessed dynamically and objectively and will help you and/or your physician to select further effective therapy.

## PARTICULARITIES OF USING THE "ABP-051" DEVICE FOR HYPERTENSION

- The onset of effect of a stable pressure decrease in the body's response to normalization depends on the individual particularities of each person. The particularities imply a nervous system condition, the degree of pathological disorders in BP regulation system, life style and nutrition, etc.
- Note that your BP may not change significantly after the first (usually 3-5) days of using the "ABP-051" device, but that in this event you should still continue with your normalization course.
- In the first one or two days after the device is first used, some patients may experience a short transitory BP mild increase lasting for 15-30 minutes which is related to the nervous system type or circumstances, (for example, the presence of "white coats" nearby). In such a case, it is still recommended to continue with the course of treatment.

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- During the treatment, you should strictly follow the therapy prescribed by your physician, maintain a healthy diet, abstain from smoking and excessive alcohol consumption, follow a daily regime and, if necessary, avoid unnecessarily stressful situations that provoke increases in blood pressure.
- It should be stated that the treatment's efficacy depends largely on your discipline and willingness to maintain a healthy life style. Neither drugs or the "ABP-051" can guarantee a positive outcome when these simple and erstwhile effective recommendations are not followed.
- The courses should be repeated monthly (for example, from the 1st to the 14th of each month), and in severe situations, daily usage to maintain pressure on target values.

- In some cases, for example, if occasional and insignificant BP increases not more than 150 mmHg occur, the "ABP-051" device, may be used for monotherapy. In such cases, the "ABP-051" helps to prevent disease progression. It should be again stated that the use of the "ABP-051" does not exclude or replace the importance of factors such as giving up bad habits, maintaining a healthy lifestyle, social habits, and diet.
- Course administration of the "ABP-051" device requires the effective prevention of hypertonic crises and their complications.

The manufacturer and/or seller are not liable for any adverse consequences of the device being used, which arise and/or are from unintended use or breach of the instructions included in the configuration of the electro stimulator "ABP-051".

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## PARTICULARITIES OF THE USE OF THE "ABP-051" DEVICE FOR HYPOTENSION

- Optimum course for the use of the "ABP-051" device is 14 days with 1-3 sessions a day.
- If necessary, repeat the course monthly.
- The "ABP-051" device can be used daily without breaks.
- Stable results will be experienced only after a completing a full normalization course using the "ABP-051" device. Even if improvement is felt earlier, treatment course should not be interrupted as the method has a cumulative effect which gradually develops.
- Do not stop taking drugs prescribed by your physician.

## **USE OF THE "ABP-051" DEVICE** WITH FITNESS. SPORT AND IN SERIOUS PHYSICAL EXERCISE







Single use of Program №1 (see section 6 of the instruction for use) is intended to decrease BP immediately prior to physical exercise/ training sessions. It allows you to tolerate such activities with lower increases in blood pressure, is also intended to decrease BP after training sessions or physical exercise, and allows for a reduction in recovery time.

## THE "ABP-051" DEVICE'S PROGRAMS FOR BP NORMALIZATION

Two programs of electric stimulation in the "ABP-051" device are designed the with the use of low frequency currents:

- **Program №1** is intended for a decrease of increased BP.
- Program Nº2 is used for an increase of decreased BP.

Details on the working regime of the "ABP-051" device, selection of necessary program and exposure area are all contained in the Instruction for use.

Note that each program is used strictly in accordance for usage contained in the "ABP-051" device's configuration only.

### IMPORTANT ASPECTS TO REMEMBER

- To get a stable and positive result, a course of procedures lasting at least 14 days should be taken. Courses are repeated when necessary and in severe situations the "ABP-051" should be used daily to keep your BP at the target level.
- The capacity and duration of procedures are not regulated by the user. "ABP-051" has fully automatic programmes that are switched off after any procedures are completed.
- Arterial hypertension is a serious and life-threatening disease; however it is often treated negligibly. Use of the "ABP-051" device in combination with drug therapy increases the drug's efficacy.

#### CONCLUSION

#### Dear readers!

We, inventors and manufacturers of the unique "ABP- 051" device are thankful for your purchase.

We are sure that you can improve your health and health of your relatives by using this device. Use of the device is not confined to only when you are sick, but also to assist in the recovery time you experience following physical exercise and such like.

The "ABP-051" device is easy to use, safe and effective. We hope that it will be your faithful partner for many years.

## BE HEALTHY! TAKE CARE OF YOURSELF!



#### — What is the "ABP-051"?

 The "ABP-051" is a medical physiotherapy device which aims to normalise blood pressure. It may be used people for both increased and decreased blood pressure.

#### — Can the "ABP-051" device measure pressure?

 No, it does not measure pressure which should be measured with a common tonometer. The "ABP-051" device normalizes pressure.

## — How does the "ABP-051" device normalise blood pressure?

— The device acts via electro-stimulation. There are two electrodes on the device which are fixed to the wrist and have a low frequently current. Responding to this exposure, the vasomotor centre located in the medulla alters the smooth muscle tone in the small arteries.

To decrease the tone, the blood pressure will become lower, and to increase it, the pressure will become higher.

#### — Does the "ABP-051" device affect your heart?

— The "ABP-051" does not affect your heart. The heart acts as a pump to create blood pressure in vessels. For this to occur, vascular arteries need to have smooth muscles which largely manage blood pressure. Changes in smooth pressure tone helps people with hypertension to reduce and maintain normal pressure, and people with hypotension to increase the pressure.

#### — Should the "ABP-051" device be constantly worn?

 No, it is only applied during the session. The session for people with hypertension lasts for five minutes, and for people with hypotension six minutes.

## — How many times a day is the device used, and how long does the treatment course last for?

— It is recommended to use the device 1-3 times day depending on BP level. The recommended course duration is 14 days. Treatment efficacy is assessed upon completion of the therapy course. During the treatment, depending on BP level, daily procedures may be reduced to once or twice a day. After the course, a break of 1-2 weeks is recommended.

It is important to note that any decision regarding the break's duration and/or course continuation should be made alongside an attending physician and be based on medical data. In some cases, if it is prescribed by a physician, the device may be used constantly.

#### Should the time of the session be recorded?

 No, time should not be recorded. The device has a timer which switches the device off automatically. When each program switches, a triple sound signal is heard.

## — Can the "ABP-051" device be used for prophylaxis when drugs are not vet administered?

If your upper BP value does not exceed 160 mmHg you can use the device as a prophylaxis prior to the drug's administration.

#### — Can the "ABP-051" device be used instead of drugs?

Any decision on the introduction of changes to the treatment scheme and/or drug prescriptions should be made together with your physician. In some cases you can reduce the number of drugs taken and doses of these during the use of the "ABP-051" and even may switch to the "ABP-051" completely and use it as monotherapy. It is

important to pay attention to the fact that in any case, such changes should be made with medical supervision.

## So, I should not stop taking my tablets if I have started using the "ABP-051 device?

No, you should not stop taking your tablets. We recommend that you add the device to the current therapy and monitor your pressure diary. If the pressure is lower than target values, the attending physician can reduce doses or stop some drugs.

## To what extent does the "ABP-051" device reduce blood pressure?

 As a rule, when ABP-051 is first used, blood pressure is often reduced on a 5-10 mmHg dose, in some cases it will be with a 20-22 mmHg dose. In rare cases, the pressure is not changed after its first

use, and the effect of its use will take around 10-14 days.

The main clinical aim of the "ABP-051" is to normalize the activity of a person's own mechanisms of blood pressure regulation. The change of BP values after one session may not fully reflect the device's efficacy. The maximum efficacy will be seen only after a full course is administrated. Efficacy is assessed not only on per objective values (BP values), but also per subjective values such as the improvement of your health condition, sleep normalization etc.

- What do I do if the "ABP-051" does not lead to a decrease when used, but on the contrary increases my blood pressure?
- A temporary increase blood pressure is transitory. Both a patient's nervous system type and environmental factors such stress, agitation. and the presence of "white coats" all influence short-term pressure increases, so it is important to realise that such increases are not necessarily a product defect. We recommend continuing and completing

the device's full treatment course, and after your body has adapted to it your BP should begin to normalise. Such adaptation will likely occur within the time specified above.

### — What happens if I stop using the "ABP-051" device?

"Withdrawal" symptoms do not occur when using the "ABP-051". On the contrary, use of the device provides prolonged effects which are felt after the course of treatment ceases. However, it should be understood that stopping the treatment will leave the patient without protection from pressure increases/decreases, and may result in severe complications such myocardial infarction, a stroke, or renal failure, etc.

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#### Are there any contraindications of using the "ABP-051" device?

The contraindications of using the "ABP-051" device are listed below:

Absolute contraindications:

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

**Relative contraindications:** 

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

#### — Why should I lie or sit when using the "ABP-051" device?

During a therapy session your vascular tone will be affected. Due to this, in some cases, a standing person may feel dizzy and as a result could fall and get injured.

#### — Is the "ABP-051" device used in medical institutions?

The "ABP-051" is registered as a medical device and can be used both in home settings and medical institutions (out-patient, inpatient units. etc.).

#### — Is the "ABP-051" device certified?

The "ABP-051" is a medical device registered by the Russian Federal Service for Surveillance in Healthcare. It is approved for medical use in Russia, the European Union and in several other foreign countries

#### — How has the efficacy of the "ABP-051" device been confirmed?

The device's efficacy has been shown through its continual growth of use in clinical practice and ongoing research through clinical observations. In Russia, the "ABP-051" has been widely used since 2016 and in EU countries since 2017. Many thousands of patients in Russia and abroad use it regularly and have witnessed its positive effects.

It should be stated that the treatment of arterial hypertension is a complex and multi-component process, in which all factors, not only administered drugs and the use of "ABP-051", are of great value. It is also almost impossible to expect high efficacy of both drugs and the "ABP-051" if you have a destructive life style and/or abuse coffee, cigarettes and alcohol. Moreover, the device shows maximum efficacy when administered as a treatment course.

## — Does the "ABP-051" device help rebound syndrome?

Rebound syndrome occurs immediately after the discontinuation of some anti-hypertensive drugs and is characterized by an abrupt increase of blood pressure. The "ABP-051" device helps to prevent rebound syndrome, known as "withdrawal syndrome".

### — Can the "ABP-051" be used incorrectly?

- There are two main errors which have been witnessed in usage: Firstly the device is fixed to the "wrong area" and/or the "wrong button" is pressed. Please review carefully sections 6 and 12 of the Instruction for use.
- Why should be the skin moistened prior the use of the

#### "ABP-051" device?

— The efficacy of usage can be reduced if the wrist skin is very dry as human skin has high electric resistance, therefore, skin should be moistened prior to fixing the device.

#### — How should the "ABP-051" device be handled?

You should monitor the cleanliness of the device carefully, as well as the working surface of the electrodes. The electrodes should be treated with a moist wipe regularly. If the device is used by several people, treat the electrodes with moist disinfecting wipes after each use. It is preferable not to use aggressive disinfectants or alcoholcontaining wipes.

## **FOR REMARKS**

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