

**Federal Agency of Health  
and Social Development Supervision  
Registration Certificate**

**№ ФС-2007/163**

**from 07 August 2007**

**Valid until 22 December 2011**

**Medical technology title:**

**DYNAMIC ELECTRONEUROSTIMULATION BY “DIADENS-CARDIO” APPARATUS IN TREATMENT OF PATIENTS WITH ESSENTIAL HYPERTENSION**

**Annotation:**

Physiotherapeutic method of application in patients with essential hypertension consists in transcutaneous dynamic electroneurostimulation (DENS) of reflexogenous zones and acupuncture points that are associated with the system of vascular tone regulation. Course treatment of DENS in association with complex treatment allows to raise an effectiveness of treatment of patients with essential hypertension by means of vegetative homeostasis correction (reduction of sympathetic activation, drop of central regulation, reinforcement of parasympathetic tone), to stabilize psycho-emotional state, to lower medicinal load.

Indications, contraindications and material support are stated in the enclosure\*.

**Developer/claimant:**

Co LTD “Regional Center of Adaptive Receptor Therapy”.  
(Russian Federation, 620146, Yekaterinburg city, Academic Postovsky Street, 15)

**Level/application scale:**

Treatment-and-preventive institutions of out-patient and in-patient treatment, sanatorium-and-spa institutions, reconstructive medicine and rehabilitation centers.

**Medical technology is oriented on:**

Doctors and specialists in reconstructive medicine, physiotherapists, cardiologists, physicians.

**Executive**

**N.V. Yurgel**

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(signature, seal)

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\* *Registration certificate is not valid without the enclosure.*

**Federal Agency of Health  
and Social Development Supervision**

**ENCLOSURE TO THE REGISTRATION CERTIFICATE**

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DYNAMIC ELECTRONEUROSTIMULATION BY “DIADENS-  
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SENTIAL HYPERTENSION**

**Indication:**

Essential hypertension of I and II stage.

**Contraindications:**

- serious cardio-vascular diseases (unstable stenocardia, cardiac insufficiency, myocardial infarction)
- presence of implanted pacemaker
- electric current intolerance
- epilepsy
- tumors of any aetiology and localization
- fever of unknown genesis
- liver and kidney diseases with their functions' disorders
- mental diseases
- alcoholism

**Logistical support of medical technology:**

There are two alternative versions of transcutaneous stimulator for BAZ impact: “DiaDENS-Cardio” and “DiaDENS-Cardio+”, serial number ФС022a2006/5029-06 (manufacturer - “Regional center of adaptive receptor therapy” Co LTD, Russia).

**Executive**

**N.V. Yurgel**

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(signature, seal)

**RUSSIAN SCIENTIFIC CENTER OF RECONSTRUCTIVE  
MEDICINE AND BALNEOLOGY  
MINISTRY OF HEALTH AND SOCIAL DEVELOPMENT  
OF RUSSIAN FEDERATION**

**CO LTD “REGIONAL CENTER  
OF ADAPTIVE RECEPTOR THERAPY”**

**DYNAMIC ELECTRONEUROSTIMULATION  
BY “DIADENS-CARDIO” APPARATUS IN  
TREATMENT OF PATIENTS WITH ESSENTIAL  
HYPERTENSION**

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**ANNOTATION**

Physiotherapeutic method of application in patients with essential hypertension consists in transcutaneous dynamic electroneurostimulation (DENS) of reflexogenous zones and acupuncture points that are associated with the system of vascular tone regulation. Course treatment of DENS in association with complex treatment allows to raise an effectiveness of treatment of patients with essential hypertension by means of vegetative homeostasis correction (reduction of sympathetic activation, drop of central regulation, reinforcement of parasympathetic tone), to stabilize psycho-emotional state, to lower medicinal load.

This technology is oriented on reconstructive medicine specialists, physiotherapists, cardiologists, physicians of outpatients' clinics, hospitals, sanatoria and health resorts, centers of reconstructive medicine and rehabilitation.

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## INTRODUCTION

Arterial hypertension (AH) makes a main contribution in cardio-vascular diseases incidence rise; according to WHO, these diseases cause one third of all deaths registered in the world [1].

Epidemiological situation in Russian Federation witnesses the remaining tendency of high indices of cardio-vascular diseases prevalence and death rate from them. Morbidity of adult population with diseases of blood circulation grows fast to one million of cases yearly. According to experts' forecasts, mortality from cardio-vascular system diseases will increase even further. Primarily, existing situation is associated with the growth of diseases that are characterized by blood pressure increase; sickness rate gains an epidemic characteristics.

Prevalence of AH among the population in the age range 15 years old and older makes up to 40 %. High prevalence of AH among children and teenagers attracts serious attention. Number of children registered with high blood pressure (BP) increases over 5 % yearly [2]. According to many authors, AH is one of the leading risk factors of ischemic cardiac disease development and, in turn, is independent disease that requires timely and adequate treatment.

In spite of wide range of medicamental agents that are used for treatment of AH, number of patients increases and the question of new methods of treatment search stays urgent. In connection with above-mentioned, the main purpose of AH treatment is lowering of risk of cardio-vascular complications, thereby, prolongation of life expectance of patients [3, 4]. Physiotherapy and balneotherapy, acupuncture, impact of physical factors on acupuncture points etc. are widely applied in complex treatment of AH.

It is known that response to the impact on acupuncture points is realized through activation of neurohumoral mechanisms of nervous system. Acupuncture points stimulation causes the

most expressed reaction in the range of that metamer or spinal segment in the corresponding internal organs which have the closest connection with stimulated point. However, response to the stimulation is not limited by segmental reaction. General reaction of the body that includes the main neurohumoral mechanisms of adaptation and homeostasis develops. Common generalized reaction appears as a result of peripheral signals intake in corticosubcortical structures of the brain and in reticular formation.

Afferent impulsation that goes through spinal and extraspinal (vegetative) tracts changes functional state of non-specific systems of brain (structures of limbic reticular complex – reticular formation, hypothalamus, hippocampus, etc.). Generalized reaction becomes apparent in normalization and retrimming of the content of hormones and other biological substances that are very important in regulation of physiological processes of the body [5].

Dynamic electroneurostimulation (DENS) is a method of transcutaneous electroneurostimulation that consists in reflexogenous zones and acupuncture points impact with the help of electric current impulse; the form of those impulses depends on values of full electric resistance (impedance) of the skin surface in the subelectrode area. Reflex mechanisms that are activated by irritation of receptors in reflexogenous zones and acupuncture points underlie the medical effect of DENS.

Impact on MC 6 ney-huan point by means of special current impulses causes correction of pathogenetic mechanisms of essential hypertension development, thereby, conditioning possibility of DENS-therapy application with essential hypertension. In the accessible domestic and foreign literature there is no information about DENS-therapy application on acupuncture points when suffering from essential hypertension.

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## **INDICATIONS FOR MEDICAL TECHNOLOGY UTILIZATION**

Essential hypertension of I and II stage.

## **CONTRAINDICATIONS FOR MEDICAL TECHNOLOGY UTILIZATION**

- serious cardio-vascular diseases (unstable stenocardia, cardiac insufficiency, myocardial infarction);
- presence of implanted pacemaker;
- electric current intolerance;
- epilepsy;
- tumors of any aetiology and localization;
- fever of unknown genesis;
- liver and kidney diseases with their functions' disorders;
- mental diseases;
- alcoholism.

## **LOGISTICAL SUPPORT OF MEDICAL TECHNOLOGY**

There are two alternative versions of transcutaneous stimulator for BAZ impact: “DiaDENS-Cardio” and “DiaDENS-Cardio+”, serial number ФC022a2006/5029-06 (manufacturer - “Regional center of adaptive receptor therapy” Co LTD, Russia).

Frequency 9.2 Hz that is traditionally used for hypertension treatment and specially developed regime “7710” intended for general sedative effect gaining.

## **DESCRIPTION OF MEDICAL TECHNOLOGY**

No special conditions are needed for DENS application. Dynamic electroneurostimulation of acupuncture point MC 6 ney-huan was used for treatment of essential hypertension.

Acupuncture point MC 6 ney-huan is located on the frontal surface of forearm 2 zuns over proximal radiocarpal fold between tendons and is related to the points of general action (indications: pains in the heart area, stenocardia, tachycardia, hypertension, mental disorders, sleep disorders, anxiety and manic states, etc.).

During the session patient can sit in the chair or lie in the comfortable position. Apparatus is placed on the forearm screen upwards on the distance of 1 cm from the palm. The cuff should be tightened and fixed so that electrodes from apparatus would closely touch the skin but not extra strangulating the arm.

Session consists of three phases which differ by frequency, time and amplitude of action. At the end of each phase short sound signal is heard. At the end of whole session long sound signal is heard. Duration of the session is determined by the program and makes up in average 5-6 minutes. Electrodes of apparatus should be processed with standard disinfectant solution after every session.

Apparatus should be stored with dry electrodes. Patient is recommended to rest during 10-15 minutes after the session.

DENS procedures were carried out daily. Treatment course constituted 12-15 sessions.

### **POSSIBLE COMPLICATIONS WHEN USING MEDICAL TECHNOLOGY AND WAYS OF THEIR ELIMINATION**

Provided that all the necessary rules of dynamic electroneurostimulation procedures implementation would be followed, no complications are noticed.

### **MEDICAL TECHNOLOGY USAGE EFFICIENCY**

Sixty patients with essential hypertension of I-II stages according to WHO and WSOC (2004) classification were divided into two randomized groups. All the patients got basic medicinal therapy.

The first group included 30 patients with essential hypertension of I-II stages that stayed under clinical observation and received treatment with the help of DENS-therapy. Age of patients varied from 43 to 70 years old, duration of disease was  $7.4 \pm 1.6$  years.

The second group included 30 patients with essential hypertension of I-II stages that stayed under clinical observation and

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received placebo-treatment (outwardly apparatus did not differ from the operative one, uttered sound signals but did not send electric impulses). Age of patients varied from 41 to 70 years old, duration of disease was  $7.2 \pm 1.7$  years.

Positive dynamics of clinical presentation of the disease against the background of normalization of BP daily monitoring indices was revealed using DENS-therapy (I group), which allowed to reduce doses of prescribed drugs.

Reliable lowering of headache was noticed at the 10 cm visual analogue scale (VAS) from  $4,35 \pm 0,36$  to  $1,95 \pm 0,36$  ( $P < 0,001$ ) in patients of the first group. In the second group lowering of headache intensity according to VAS was not reliable: from  $3,90 \pm 0,24$  to  $3,30 \pm 0,24$  ( $P > 0,1$ ).

Valid lowering of average daily systolic arterial pressure (SAP) ( $P < 0,05$ ) was registered after DENS-therapy course, as well as lowering of average values of SAP during the day from  $151,5 \pm 2,6$  mm Hg to  $131,8 \pm 2,2$  mm Hg ( $P < 0,01$ ) and during the night from  $132,2 \pm 3,6$  mm Hg to  $119,8 \pm 3,8$  mm Hg ( $P < 0,05$ ).

Valid lowering of hypertension time was shown within twenty-four hours: hypertension time index (HTI) SAP lowered from  $42,2 \pm 3,4$  % to  $27,2 \pm 2,1$  % ( $P < 0,01$ ), HTI of diastolic arterial pressure (DAP) lowered from  $41,5 \pm 2,2$  % to  $29,7 \pm 4,3$  % ( $P < 0,05$ ).

Lowering of HTI SAP from  $35,3 \pm 3,8$  % to  $26,3 \pm 3,4$  % ( $P < 0,01$ ) and DAP from  $34,6 \pm 4,1$  % to  $23,4 \pm 4,1$  % ( $P < 0,05$ ) during the day time was also determined. During the night time only reliable HTI lowering of SAP was shown from  $36,3 \pm 3,6$  % to  $23,7 \pm 2,9$  % ( $P < 0,05$ ).

Analyzing variability of AP index it was determined that DENS-therapy has an affect on SAP and DAP variability during the day and night time in the following way: SAP variability lowered from  $19,9 \pm 2,0$  mm Hg to  $13,0 \pm 1,5$  mm Hg ( $P < 0,05$ ) during the day time, from  $23,6 \pm 2,2$  mm Hg to  $14,6 \pm 2,1$  mm Hg ( $P < 0,05$ ) during the night time; DAP variability lowered from  $16,6 \pm 1,6$  mm Hg to  $12,8 \pm 1,2$  mm Hg ( $P > 0,05$ ) during the day

time, from  $15,7 \pm 1,2$  mm Hg to  $11,2 \pm 1,7$  mm Hg ( $P < 0,05$ ) during the night time.

Reliable data was received only in relation to the SAP average daily variability indices of AP – variability lowering from  $23,2 \pm 1,9$  mm Hg to  $14,4 \pm 3,2$  mm Hg ( $P < 0,05$ ).

After DENS-therapy course rate of morning DAP rise lowered for certain from  $12,2 \pm 1,3$  mm Hg /hour to  $6,4 \pm 1,4$  mm Hg/hour ( $P < 0,05$ ), and tendency of declining of morning SAP rise rate was determined.

Positive effect of electropulse therapy on circadian rhythm of AP was registered: «non-dippers» amount lowered from 57% to 43 %.

In the placebo-treatment group (the second group) only a tendency to the average daily SAP lowering from  $149,7 \pm 2,8$  mm Hg to  $138,3 \pm 3,8$  mm Hg ( $P > 0,05$ ) was registered.

According to daily Holter monitoring, lowering of the number of solitary ventricular (from  $201,0 \pm 11,6$  to  $140,1 \pm 31,8$ ,  $P < 0,02$ ) and supraventricular (from  $133,3 \pm 9,6$  to  $32,1 \pm 6,4$ ,  $P < 0,02$ ) extrasystoles was registered in the first group of patients.

Heart rate variability analysis data revealed an RR interval increase. RR interval increase in dynamics in patients who received DENS-therapy from  $867,2 \pm 20,6$  to  $953,1 \pm 28,8$  ms, ( $P < 0,05$ ) shows heart rate lowering because RR interval value is an inverse number for cardiac rhythm.

SDNN value (standard derivation of square root from RR intervals dispersion) in the first group of patients rose for certain after DENS-therapy course from  $54,0 \pm 4,1$  ms to  $137,0 \pm 33,3$  ms ( $P < 0,01$ ), which is also an evidence of autonomous heart rate regulation strengthening. Dx range value rose for certain after course treatment from  $321,5 \pm 63,2$  ms<sup>2</sup> to  $713,2 \pm 224,45$  ms<sup>2</sup> ( $P < 0,05$ ), which is a positive sign and shows an increase of adaptative reserves.

Normalization of heart rate variability indices was noticed only in patients of the first group. That became apparent also through spectrum components lowering which are typical for

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sympathetic activation: HF contribution (high frequency waves) to the total spectrum capacity increased percentage wise from  $12,5 \pm 1,56$  % to  $29,6 \pm 3,9$  % ( $P < 0,01$ ), vegetative balance index lowered from  $2,96 \pm 0,12$  standard units to  $2,01 \pm 0,05$  standard units ( $P < 0,05$ ).

Significant decrease of sympathetic activity was not noticed in the placebo-treatment group (the second group): percentage contribution of HF in the total spectrum capacity did not change considerably (from  $16,9 \pm 2,21$  % to  $23,06 \pm 5,34$  %,  $P > 0,1$ ). Variability range value  $Dx$  also did not reliably change after placebo treatment course (from  $238,5 \pm 39,5$  ms<sup>2</sup> to  $454,4 \pm 199,6$  ms<sup>2</sup>,  $P > 0,1$ ).

Quality of life valuation was held according to questionnaire SF-36: increase of total coefficient from  $75,7 \pm 5,6$  to  $101,4 \pm 12,6$  ( $P < 0,05$ ) was registered in patients of the first group. Significant dynamics for the patients of the second group was not registered ( $76,3 \pm 9,78$  initially and  $80,2 \pm 13,8$  after the treatment,  $P > 0,1$ ).

Spillberger test was carried out during the observation process in order to determine degree of manifestation of anxiety disorders as well as anxiety level dynamics evaluation. Lowering of reactive anxiety indices (from  $58,6 \pm 1,4$  to  $46,4 \pm 1,8$  points,  $P < 0,05$ ), as well as personality anxiety (from  $54,7 \pm 1,1$  to  $48,4 \pm 0,9$  points,  $P < 0,05$ ) was registered after DENS-therapy course. Meaningful dynamics of the stated parameters was not registered in the second group: from  $54,5 \pm 2,0$  to  $52,1 \pm 1,9$  points ( $P > 0,1$ ) and from  $56,2 \pm 2,2$  to  $52,8 \pm 2,8$  points ( $P > 0,1$ ) accordingly.

Thus, data received make it possible to consider DENS-therapy as an adequate method of efficiency increase of treatment of patients with essential hypertension of I-II stages which provides pathogenetic therapy principle, allows to lower doses and amount of medications taken by patients by lowering pharmacological load on the body.

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