

Ministry of Health of the Russian Federation
State educational institution of higher vocational education "Saint-
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Approved

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Application of the device DENAS-Vertebra under treatment of spinal diseases



Methodological recommendations

Saint-Petersburg
2011

Application of the device DENAS-Vertebra under treatment of spinal diseases: Methodical recommendations. - Saint-Petersburg: state medical university named after academic Pavlov I.P., 2011. - 20 pages.

These guidelines determine the technology of complex medical application of dynamic electricneurostimulation for patients with spinal disorders. They represent a set of different methods of application of various impact programs with impulse currents at the spine.

Included in the recommendations methods of dynamic electric-neurostimulation have a high therapeutic efficiency and significantly reduce time of treatment of patients. The recommendations are intended for physiotherapists and can be performed in conditions of a health-care sanatorium and spa institutions by nursing staff.

Author of the guidelines:

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INTRODUCTION

According to data, submitted by various researchers, majority of developed countries over the past decade has witnessed a steady increase in the number of patients with degenerative-dystrophic diseases of spine, frequency of which among the population constitutes 12-45%, and among intellectuals is as high as 80%.

It is noteworthy that over the past 20 years, average age of on-set of a disease has decreased to 27-30 years. Ache in back and lower back today from time to time is experienced by all people older than 50 years [1].

In recent years, various schemes of basic drug therapy have been tested among patients with spinal cord injuries in accordance with criteria of disease severity and quality of life. Alongside with that, it is known that drug therapy has a positive but temporary effect, which determines long period of treatment, significant costs of drugs and often leads to social exclusion. Despite the fact that doctors widely and successfully use under treatment of patients with spinal diseases some physical methods, they are not included in basic schemes at present time. This is due to lack of justification for their effectiveness, as well as due to priority use of new drugs, which does not allow to determine healing physical factors that have syndromic pathogenetic orientation and significant clinical efficacy [3, 4].

High risk of side effects of conducted drug therapy among patients with spinal diseases and surgical treatment of hernias of intervertebral discs in combination with significant reduction in quality of life of patients determine actuality of search for new promising methods of non-drug treatment of patients with spi-

nal diseases, which include dynamic electroneurostimulation. High efficiency under formation of analgesic, neurostimulating, miocorrecting and trophostimulating therapeutic effects create real scientific background for its use among patients with spinal cord injuries [2,5].

Widespread distribution and social significance of spinal diseases, lack of efficiency and side effects of drug therapy and surgery actualize application of method of dynamic electroneurostimulation, in which the parameters of electrical impulses vary depending on impedance of tissues in impact area.

Series of current impulses of different frequencies, which varies depending on capacitance value of tissues in area of stimulation, selectively affect sentient and motional guides of spinal roots and trophic fibers, which are included in their composition.

Under application of impulses of alternating current, comparable by their characteristics (shape, amplitude and frequency) with action potentials of single nerve fibers of a certain type, their excitement begins, which leads to changes in local microcirculation and skin trophism through local and segmental-reflex responses. Followed by it increase of capacitance of electrodes, located under back tissues, leads to a decrease in frequency of impulses of alternating current. Consequently, dynamics of parameters of biocontrolled impact is determined by software-programmable changes of electrical properties of patient tissues in a large area in form of "traveling wave".

Under dynamic electroneurostimulation of peripheral nerve guides, ascendant impulse flows lead to activation of basic actiniceptive brain structures of central gray matter and dorsal raphe nucleus, which receive polysynaptic afferent inputs mainly at A β -fibers. These currents inhibit capacity of impulse

flows at nociceptive nerve guides, reduce amplitude of evoked potentials in dorsal raphe nucleus and induce release by brain-stem neurons of endogenous opioids that inhibit conduction of impulsation, arriving at brain by thin A δ - and C-afferents. Suppressing ectopic activity of pain source and activating antinociceptive system, impulse currents effectively cut short pain for 3-4 hours [3].

Procedures of biocontrolled dynamic electroneurostimulation improve coordination of muscles movement, activate microcirculation in them and improve muscle balance with formation of an adequate dynamic muscle stereotype of body position, both at rest and in motion.

INDICATIONS AND CONTRAINDICATIONS FOR USE OF MEDICAL TECHNOLOGY

INDICATIONS For USE OF MEDicAL TechnoloGY

Procedure of dynamic electroneurostimulation is intended for patients with degenerative-dystrophic diseases (osteocondro-sis, deforming spondylarthrosis) and injuries of spinal cord and large joints with pain and reflex syndromes, associated with them degenerative diseases of blood vessels and internal organs, as well as disorders of posture in order to achieve the locomotor-correcting, hypalgesic, regenerative-reparative and metabolic ef-fects of treatment.

ConTrAINDicATIonS For USE Of MedicAL TEchnoloGY

Absolute:

- idiosyncrasy;
- presence of an implanted pacemaker.

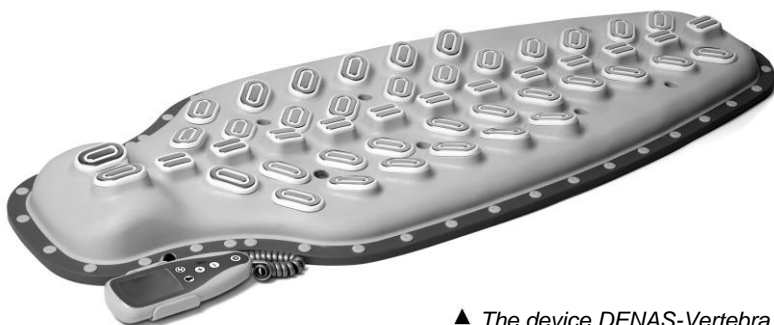
Relative:

- neoplasms of any etiology;
- acute fevers of unknown origin;
- status epilepticus;
- status of acute mental, alcohol or drug intoxication;
- vein thrombosis.

It is forbidden to use the device in direct front projection of the heart, as well as under presence of skin lesions in area of impact.

FINANCIAL AND LOGISTICAL SUPPORT OF MEDICAL TECHNOLOGYe

Electroneurostimulation method is implemented through application of device of dynamic electrostimulation and electro-massage DENAS-Vertebra, which is permitted for medical application by the Federal service on surveillance in healthcare and social development, and included in the Register of medical equipment (registration certificate № FSR 2010/08179, dated July 6, 2010), produced by LLC "Regional Center of adaptive-receptor therapy".



▲ *The device DENAS-Vertebra*

DESCRIPTION OF MEDICAL TECHNOLOGY

Procedure of dynamic electroneurostimulation among patients with spinal cord injuries and diseases is carried out with the help of the device DENAS-Vertebra, consisting of a platform (mod-ule) of electroneurostimulation and control panel. The base of the device is soft and durable Bergaflex platform with built in it 48 registration-stimulating electrode systems, arranged through all regions of spine: from neck to sacrum. With the help of electrodes, impulses affect tissues with frequencies of 20, 60, 77, 140 and 200 Hz. Electrode systems are located on the platform at different heights and different angles, and form a surface, as much as possible congruent to back surface and spinal curvature. The device DENAS-Vertebra has 4 automated programs that are adapted for treatment of patients with spe-cific nosological forms.

Program A is used to stimulate the muscles of back in condi-tions of overwork, under strenuous physical work, defatigation, chronic fatigue syndrome (duration 23 min.).














Program B is used under severe pain in the back, associated with injuries of spine, back muscles, internal organs (duration 23 min.).


Program C is used under prolonged or intense stress on back muscles, diseases of spine and internal organs (duration 26 min.).

Program D is used under acute backache, associated with spi-nal cord injury (duration 10 minutes).

METHOD OF PROCEDURES CONDUCTION

Programs are adjusted before beginning of the procedure with the help of control panel, connected with the platform. Control panel display shows necessary information about the program, course of the procedure, parameters of impact.

1. Place the device on a firm and flat, stable surface (couch), which has sufficient area.
2. Cover electrode surface of electrostimulation block with sanitary napkin.
3. Turn the device on with the help of button  on control panel.
4. Select program of impact with the help of button .
5. Press button  to select area of impact (for programs B, C and D).
6. Place undressed up to the waist patient in such a way that his back will be on the device, press buttons  and  to set desired power of impact and start the procedure. During the procedure, the patient should feel large painless vibration.
7. If necessary, for ease of use, set level of audio alarm with the help of two buttons  and , or  and . Volume level is reflected on the display of the device: no image, ; ).
8. Under presence of good contact of electrodes with skin in the area of impact, symbol  will appear on the display of control panel.
9. Upon completion of the procedure, device will beep and auto-matically turn off.
10. Turn off the device with button .
11. Conduct treatment of electrode platform surface with disinfectant (3% hydrogen peroxide).

1. Under application of the device, nurse must comply with general safety requirements according to "SSBT. Departments, physiotherapy rooms". OST 42-21-16-86.
2. Before the procedure, the patient should be instructed that under appearance of discomfort, dizziness, big painful vibration, he should press the button  on control panel.
3. In case of failure of the device, it shall be immediately turned off and disconnected from power supply.

EFFECTIVENESS OF APPLICATION OF MEDICAL TECHNOLOGY

Quality of life of patients has been assessed with the help of standard questionnaire SF-36, recommended by WHO, which contains 36 questions, 8 scales. The scale of physical functioning (PF) estimates: self-care, walking, carrying of heavy objects, climbing stairs, bending body, as well as heavy physical exertion, role physical functioning (RPF) - role of physical problems in restriction of activity, pain (P) intensity of pain and its effect on the ability to engage in normal activities; general health (GH) patient's condition at present moment and prospect of treatment, viability (V) - implies assessment of feeling of full of might, energy, or, on the contrary, feeling of exhaustion; social functioning (SF) - satisfaction with level of social activity; role emotional functioning (REF) involves assessment of extent to which emotional state interfere with work or other daily activities, mental health (MH) - characterizes mood, presence of depression, anxiety [3].

Table 1

Characteristics of patients of nosological groups

<i>Index</i>		<i>Number of Patients</i>
Age	40-50 years	33
	51-60 years	21
	Over 60 years	4
Gender	Male	38
	Female	20
Roentgen logic stage	0	
	I	7
	II	42
	III	9
	IV	
Total		58

In addition to above mentioned methods, following research-es have been carried out - an electrocardiogram, echocardiogram, roentgen examination of chest, ultrasound investigation of abdomen, general urinalysis, complete blood count for assessment of impact of conducted therapy on functioning of vital organs and systems. As a basic therapy for all patients of control group, drug therapy has been conducted (nonsteroidal anti-inflammatory drugs, analgesics, antispasmodics and other drugs – according to indications). After a course of dynamic electrostimulation, overall condition of patients has improved significantly, reflex syndromes has decreased (lumbago, sciatica and lumbodysnia), positive trend in reconstruction of changes in reflex and sensitive areas has been revealed. During dynamic electrostimulation significant uniform decrease in pain syndrome has been noted, reduction of pain during palpation of paravertebral points, as well as reduced sensitivity to pain. Improvement of overall condition of patients after a course of dynamic electrostimulation has allowed to completely cancel drug therapy with analgesics among 30% of patients. Regression of objective signs of pain after a course of dynamic electro-stimulation has correlated with a decrease in severity of reflex symptoms ($r = 0,54$) and regression of motor function disorders (Table 2).

Table 2

Comparative effectiveness of patients treatment

Index	Experimental group (n=36)		Control group (n=22)	
	Before treatment	After treatment	Before treatment	After treatment
VAS at rest, mm	31,7 ± 6,2	20,9 ± 5,4*	32,1 ± 5,1	26,7 ± 5,7*
VAS while walking, mm	52,6 ± 9,5	30,5 ± 7,4**	51,4 ± 9,1	37,2 ± 8,5*
Rate of motor function disorder, points	2,6 ± 0,4	1,4 ± 0,4*	2,6 ± 0,4	1,9 ± 0,4
Manifestation rate of paravertebral muscles exertion , points	2,3 ± 0,4	1,5 ± 0,4*	2,2 ± 0,3	1,9 ± 0,4
Reflex syndromes intensity.				
Lumbago	2,5 ± 0,1	1,4 ± 0,1	2,4 ± 0,3	1,5 ± 0,1
sciatica	2,4 ± 0,2	1,8 ± 0,2	2,6 ± 0,3	1,4 ± 0,2
lumbodynia.	2,7 ± 0,3	1,8 ± 0,2	2,7 ± 0,3	1,8 ± 0,2
Demand for NSAID, mg/d	50,0 ± 5	23 ± 4*	50,0 ± 7	28 ± 5*
Quality of life indi- cator according to SF-36, points	62 ± 5	87 ± 6**	63 ± 4	72 ± 4*

* Reliability of differences in comparison with baseline (p < 0,05).

** Reliability of differences in comparison between groups (p < 0,05).

After a course of dynamic electroneurostimulation procedures, most patients of experimental group have reported pronounced relief of pain and regression of disease symptoms in comparison with patients of control group.

Dynamics of clinical syndromes among patients, who have osteochondrosis and spondylarthrosis in experimental and control groups, are shown in Table 3.

Table 3

*Dynamics of clinical parameters
in patients suffering from dorsopathies (Δ , points)*

<i>Index</i>	<i>Experimental group (n=36)</i>	<i>Control group (n=22)</i>
Rate of motor function disorder	$1,8 \pm 0,2$	$1,2 \pm 0,2^*$
Manifestation rate of paravertebral muscles exertion	$2,1 \pm 0,2$	$1,1 \pm 0,2^*$
Manifestation rate of muscle weakness	$0,8 \pm 0,3$	$0,9 \pm 0,3$
<i>Reflex syndromes intensity</i>		
A. Cervicalgia	$1,8 \pm 0,2$	$1,6 \pm 0,4$
B. Cervical cranialgia	$1,3 \pm 0,3$	$0,7 \pm 0,2^*$
C. Cervicobrachialgia	$1,8 \pm 0,3$	$1,7 \pm 0,4$
D. Lumbago	$1,4 \pm 0,6$	$0,9 \pm 0,1^*$
E. Lumbodynia	$1,2 \pm 0,5$	$1,2 \pm 0,3$
F. Sciatica	$1,5 \pm 0,8$	$1,3 \pm 0,4$

* Významnost rozdílů ve srovnání s výchozími hodnotami ($p < 0,05$).

** Významnost rozdílů při porovnání skupin ($p < 0,05$).

After a course of dynamic electroneurostimulation procedures, among 85% of patients positive dynamics of qualitative characteristics of renovasography (RSG) have been noted: increase of amplitude of anacrotic and decaying limbs, accelerated rapid ascent of its ascendant part, sharp top, pronounced notch and more clear additional waves. Among patients of experimental group, increase in blood filling value BF and specific peripheral blood flow SPBF, have been noted. Degree of increase of BF and SPBF among patients under impact of dynamic electrostimulation has been significantly different from similar parameters among patients in control group. Significant differences ($p < 0.05$) has been also noted between dynamics of growth of RSG amplitude of anacrotic limb of both limbs (A2), reduced blood flow time (T) and ratio of amplitudes of anacrotic and decaying limbs (A2/A4), registered among patients under impact of investigated factors, in comparison with changes in these values in control groups. Consistent correlation between dynamics of integral characteristics of regional blood flow (BF and SPBF) and regression of pain syndrome ($r = 0,55$) have been also revealed.

Changes in RSG values among patients with spinal cord injuries shows that under impact of dynamic electrostimulation more pronounced positive changes in all components of regional blood flow appear - of pulse blood filling of tissues, specific peripheral blood flow, tone and elasticity of blood vessels and venous outflow. Similar in direction but less pronounced changes have been registered in control group of patients.

Multidimensional regression analysis has allowed to receive a model of forecast for performance of dynamic electrostimulation, which depends on severity of pain, as well as duration of disease. The degree of impact of these factors on dispersion of investigated factor has constituted more than 65%, whereas in control groups similar dependence has been less significant.

The results of conducted researches has allowed to verify hyp-algesic, reparative-regenerative, vasoactive effects of dynamic electrostimulation. They are most pronounced in patients up to 40 years old, whose weight ranges from 70 to 90 kg with duration of disease over 5 years. Among such patients dynamic electrostimulation exercises significant influence on peripheral nervous system, normalizing processes of excitation, inhibition, and reducing appearance of sympathicotonia.

Effectiveness of complex restorative treatment of osteochon-drosis with inclusion of dynamic electrostimulation has consti-tuted 87% (in control group - 65%, correspondingly, $p < 0,05$ by criterion of Spearman).

Thus, dynamic electroneurostimulation device DENAS-Vertebra can be used effectively in various health care and spa facilities as monotherapy, as well as in complex rehabilitation treatment of patients with degenerative-dystrophic diseases of spine.

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Серия АА



0000301

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ
ЗДРАВООХРАНЕНИЯ И СОЦИАЛЬНОГО РАЗВИТИЯ

РАЗРЕШЕНИЕ

НА ПРИМЕНЕНИЕ НОВОЙ МЕДИЦИНСКОЙ ТЕХНОЛОГИИ

ФС № 2010/015

от « 27 » января 2010 г.

«Динамическая электростимуляция»

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(620146, г. Екатеринбург, ул. Академика Постовского, 15).

Показания к использованию медицинской технологии:

Лечебное и профилактическое применение при различных заболеваниях и синдромах с целью получения обезболивающего, спазмолитического, вегетокорректирующего, иммуномодулирующего и общеукрепляющего эффектов.

Противопоказания к использованию медицинской технологии:

- Имплантированный кардиостимулятор.
- Индивидуальная непереносимость электрического тока.
- Эпилептический статус.
- Новообразования любой этиологии.
- Лихорадка неясного генеза.
- Венозный тромбоз.
- Состояние острого психического, алкогольного или наркотического возбуждения.

Возможные осложнения при использовании медицинской технологии и способы их устранения:

- Раздражение кожи в области постановки электродов – перед процедурой необходимо убедиться, что электроды устанавливаются на чистую кожу, а сами электроды обработаны дезинфицирующим раствором.
- Аллергическая реакция на компоненты металла электродов – симптоматическая терапия.

Руководитель

(подпись, печать)

Н.В.Юргель





ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ

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и подтверждает, что изделие медицинского назначения
(изделие медицинской техники)

Аппарат динамической электростимуляции и электромассажа
ДЭНАС-Вертебра по ТУ 9444-013-44148620-2010
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и социального развития

Е.А. Тельнова

009685



Application of the device DenAS-Vertebra under treatment of spinal diseases

Methodological recommendations

St. Petersburg
2011

DENAS-VERTEBRA



Professional functions in a home environment!

DENAS-Vertebra is a device used for the treatment of acute and chronic back pain, as well as for the correction of functional disorders caused by internal organ diseases, for rehabilitation after diseases and surgical interventions, and to enhance the adaptive capacity of the organism subject to intense physical and psycho-emotional strain.

The device is designed to provide a fundamentally new method of electrical stimulation based on "running waves", with the optional connection of up to 48 electrodes.

It features 4 automated programs:

Program A – Prevention and treatment of stress, neurosis, correction of sleep disorders, comprehensive treatment of cardiovascular, bronchopulmonary and gastrointestinal tract disorders; boosting of the overall immunity of the organism.

Program B – Severe pain in the area of the back and neck related to an illness or injury of the spine and back muscles, pain caused by internal organ diseases, and physical stress.

Program C – Pain in the area of the back and neck, overstraining of muscles (fatigue, soreness), exacerbation of chronic internal organ diseases.

Program D – Emergency treatment of localised back pain.

Due to its unique and innovative technology, DENAS-Vertebra has been registered as a medical device for the treatment of spinal diseases*

*The Use of DENAS-Vertebra for Spinal Treatment: Methodical Recommendations. - Pavlov First Saint Petersburg State Medical University, 2011. - 20 p.

Application

When using the device, keep in mind that systematic treatment yields the most noticeable therapeutic effects. While some diseases require 6-8 procedures, others 8-12 and rarely even 14-20 procedures.

The device may be used:

- As the basic treatment method in case of drug intolerance or contraindications to the use of other methods
- As a part of comprehensive therapy to enhance the effects of other treatment methods
- For the symptomatic treatment for various diseases and syndromes

There are contraindications for use. To ensure that procedures utilising the DENS instruments are carried out correctly and that an ideal combination with other treatment methods is determined, it is necessary to familiarise with the instructions for use or to consult a specialist.

Characteristics:

The set includes:

- DENAS-Vertebra (electrostimulation module and control panel)

- Instructions for use
- Protective sheet
- LR6/AA type battery
- Lightweight aluminium case for storage and transport

Technical specifications:

Power source: 1.5V LR6/AA (2 pcs)

220V (via power adapter)

Weight: maximum 5.18kg

Control panel – 180g

Electrostimulation unit – 5kg

Dimensions: Control panel – 140x55x28mm

Electrostimulation unit – 900x365x70mm

Pulse repetition frequency:

20, 60, 77, 140, 200Hz

Company-manufacturer:

The group of companies "DENAS",
OOO «TRONITEK» (OOO "RC ART", 620146, Russia)
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