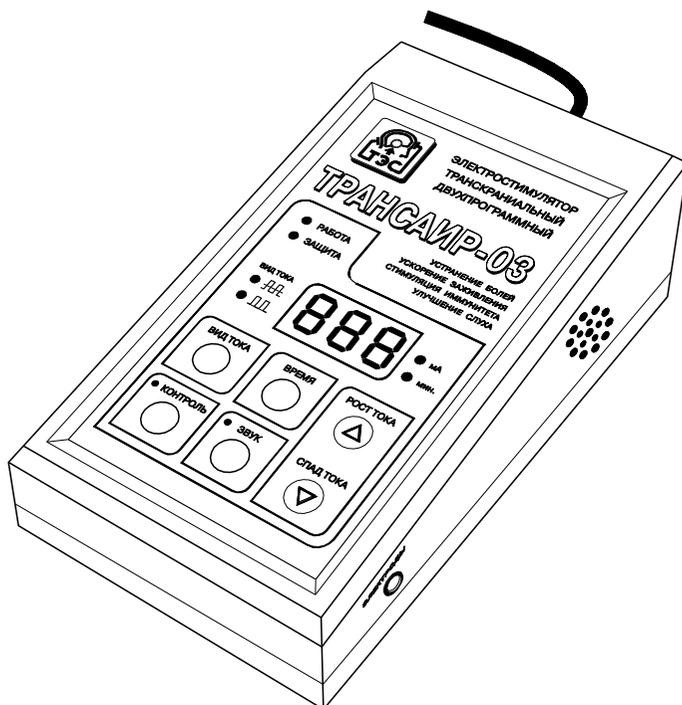




Russian Academy of Sciences
Centre for Transcranial
Electric Stimulation (TES Centre)
Pavlov Institute of Physiology

TRANSCRANIAL
PULSED ELECTRIC STIMULATOR
TRANSAIR-03



USER'S GUIDE
MEDICAL USE INSTRUCTION

**TRANSCRANIAL
PULSED ELECTRIC STIMULATOR
“TRANSAIR-03”
(two programmed)
USER'S GUIDE
BMEA.941514.003 P**

1. Purpose of use

1.1. “Transair-03” Unit is developed to perform treatment procedures based on non-invasive transcranial electric stimulation of brain defense (endorphinergic) structures during physical therapeutic technique.

1.2. Unit can be used in in-patient and out-patient facilities, according to the medical prescription, strictly under medical surveillance.

2. Specification and Functions.

2.1. Specification:

2.1.1. Stimulating Current Circuit:

1 Mode: Rectangular bipolar impulses

2 Mode: Rectangular monopolar impulses

2.1.2. Output range of control:

Impulse bipolar current From 0 To 3,00 mA

Impulse monopolar current From 0 To 3,00 mA

2.1.3. Procedure Duration Setup From 5 To 40 min

2.1.4. Timer sampling period setup 5 min.

2.1.5. Electric power 220 W, 50 Hz

2.1.6. Dimensions: 200x111x64 mm

2.1.7. Weight, up to 0.5 kg

2.1.8. Operating life at least 5 years

2.1.9. Mean life at least 3000 hours

2.1.10. According to the Electrical Safety Qualification Level the Unit is GOST P50267.0-92: portable, regular housing, continuous rating of machine, Class II Type BF for power-line supply.

2.2. Service functions

2.2.1. Performance Monitoring.

2.2.2. Voice Aid while Setup mode of action.

2.2.3. Digital display shows:

- applied electric pulse current intensity;

- time remained.

2.2.4. LED shows type of applied stimulating current as well as Unit mode of action.

2.2.5. Automated gradual shutdown control of stimulating current after procedure.

2.2.6. Patient protection – Automated gradual reduction of the stimulating current in case of circuit discontinuity.

3. Standard set contains:

1. "TRANSAIR-03" unit,	1
2. Set of electrodes	1
3. Set of cotton pads	3
4. Certificate of equipment, medical instructions,.....	1
5. CD-disk with recorded psychotherapy session.....	1
6. Proceedings on "Transcranial electrostimulation", Vol. 1, 2	2
7. Packing.....	1

The exterior of the Unit, Electrodes and pads is shown in Fig. 1, 2, 3, respectively.

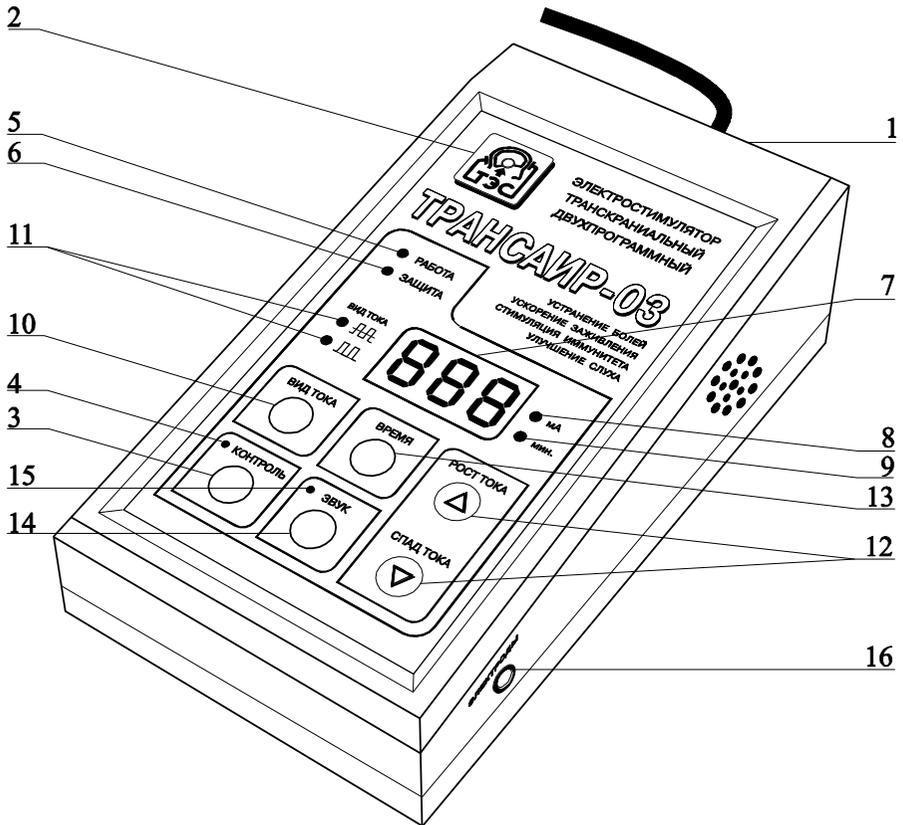


Fig.1. Exterior of the TRANSAIR-03 Unit.

3.1. Description of Buttons, LEDs and Indicator

N	Buttons and LEDs	Usage
1	Power switch	On/off power supply.
2	LED “TES”	Indication of power supply On.
3	Button “CONTROL”	Switch to the Performance Monitoring Mode (noncollocated).
4	LED “CONTROL”	Indication of Performance Monitoring Mode On.
5	LED “RUNNING”	Indication of the applied current is at electrodes if it is a medical procedure, and current under disconnected electrodes if it is Control mode.
6	LED “PROTECTION”	Indication of the Protection Mode On if current flow disturbances occur or button “CONTROL” is off.
7	Digital indicator	Indication of parameters of electric stimulation (current magnitude and time remained to the end of procedure).
8	LED “mA”	Indication of running digital indicator in the mode of displaying the running magnitude of the stimulating current.
9	LED “min.”	Indication of the working digital indicator displaying Time.
10	Button “Current mode”	Switch to stimulating current type (bipolar or monopolar pulses).
11	LEDs «Current mode» 	Indication of the chosen stimulating current mode: - bipolar pulses; - monopolar pulses.
12	Buttons “CURRENT UP”, “CURRENT DOWN”	Control of stimulating current magnitude.
13	Button “TIME”	Setup of procedure duration. Time control remained to the end of procedure or Performance Monitoring Mode.
14	Button “SOUND”	On/off for the Voice Aid Mode.
15	LED “SOUND”	Indication of Voice Aid Mode.
16	Socket “ELECTRODES”	Connect electrodes to the Unit.

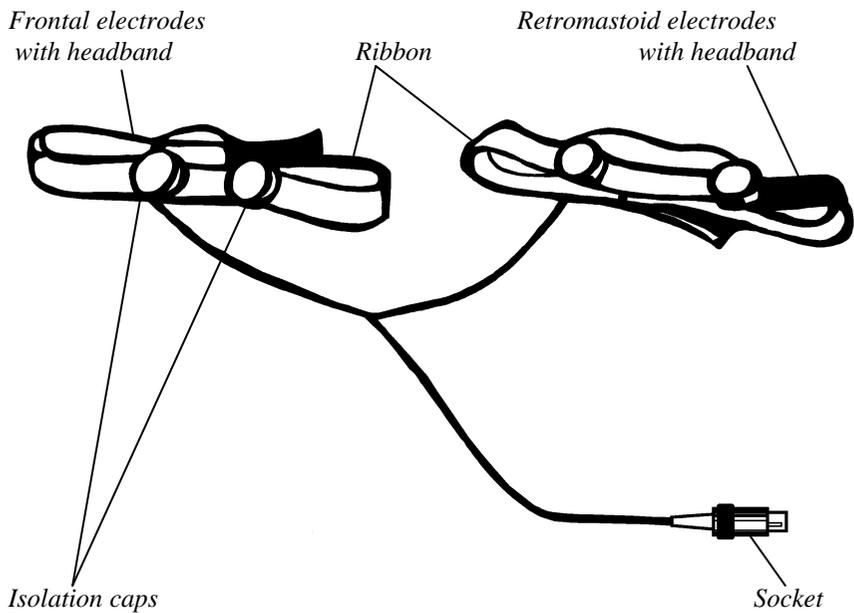
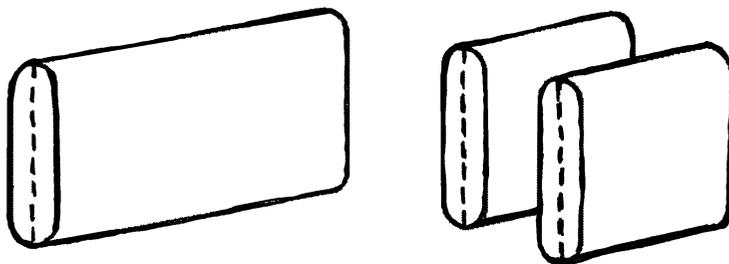


Fig.2. Electrodes.



Major (frontal) – 1 item

Minor (retromastoid) – 2 items

Fig.3. Cotton pads.

4. Safety precautions

- 4.1. Design of the Unit provides with complete electrical safety for a patient as well as medical staff.
- 4.2. Before reading Certificate of equipment and Medical instructions it is forbidden to use the Unit.
- 4.3. It is forbidden to keep the working Unit with open housing.
- 4.4. Before start-up or in case of malfunctions the Unit should be checked (5.2).
- 4.5. It is forbidden to use and connect malfunctioning Unit to Patient.
- 4.6. It is forbidden to soak the Pads with any liquids excepting tap water.
- 4.7. It is not allowed to replace set electrodes with custom-made electrodes.
- 4.8. In case the Unit was transported or kept at low temperature before start-up it is necessary to keep it at room temperature for at least 3 hours.
- 4.9. It is forbidden to use the Unit if it is installed in the room together with running ultra-high-frequency therapy apparatus, diathermy machine or any other high-frequency equipment. All such devices should be located in another room at distance as far as 20 meters from TRANSAIR Unit.

5. Work sequence

5.1. Preparation of the Unit for Start-up.

- 5.1.1. Before Start-up or after keeping it long time unplugged you should examine the exterior of the Unit to find out if:
 - a) a seal is not broken;
 - b) Set Items correspond to Description, Paragraph 3;
 - c) any visual mechanical damage of the Unit, mains cable, socket, and Electrodes.
- 5.1.2. Put the Unit in convenient place. Disinfect electrodes by using 3% hydrogen peroxide solution together with 0.5% washing liquid (Mr. Muscle or similar). Swab should not be soaked.
- 5.1.3. All procedures should be performed only after thorough reading of Certificate of equipment and Medical instructions.

5.2. Checking Procedure.

- 5.2.1. Before connecting the Unit to the power supply you have to be sure that Switch of Electric Power is "Off".
- 5.2.2. Switch on the Unit by putting the key in "On" position. While doing this digital indicator will display zeros, and LEDs are highlighted: Power supply Switch On LED, "CURRENT MODE ", "mA", "SOUND".

	<p>5.2.3. Press button ‘CONTROL’ and hold it while performing the Checking Procedure. During the procedure: LED ‘CONTROL’ will highlight accompanied with Voice Aid command ‘checking’. Timer will be automatically set up for 3 minutes (checking should be complete within this period of time).</p>
	<p>5.2.4. Press and hold the button ‘CURRENT UP’: it is accompanied with Voice Aid command ‘current up’, and starting from 0.20 mA the green LED ‘RUNNING’ will flash. Make sure that magnitude of electric current is going up on the digital display. Increase current value until reaching max 3.00 mA. Release button ‘CURRENT UP’, and make sure that its value does not change.</p>
	<p>5.2.5. Press button ‘TIME’, and the LED will show time remained to the end of Checking Procedure (3-2-1 min.), whereas LED ‘min’ will highlight accompanied with the Voice Aid command ‘time’. In 3 sec after releasing the button ‘TIME’ LED will start again to display set up magnitude of current, LED ‘min’ will fade out, and LED ‘mA’ will highlight.</p>
	<p>5.2.6. Press button ‘CURRENT DOWN’ and make sure that value of electric current started to decrease. It will be accompanied with the Voice Aid command ‘current down’. Release the button ‘CURRENT DOWN’ at any value above 0.20 mA, and make sure that decrease of electric current stopped.</p>
	<p>5.2.7. Release button ‘CONTROL’. It will activate safety function, which is accompanied with the Voice Aid command ‘safety’, flashing of LED ‘PROTECTION’, automatic electric current reset to zero, together with zeros blinking on the digital display.</p>

5.2.8. Checking Procedure is completed. Put the power supply key in position “OFF”, and disconnect the Unit from the mains supply.

ATTENTION!

Before running medical procedure a patient should remove any metal clips or earrings out of ears.

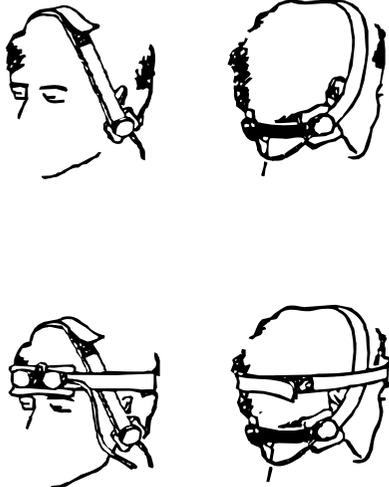
While placing electrodes on head make sure that you do not have hairs underneath it.

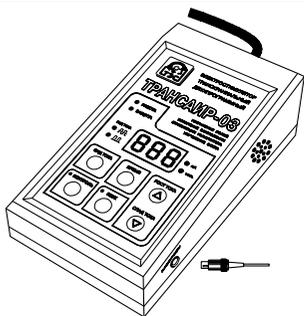
Avoid any contact of metal parts of electrodes with skin.

5.3. Carrying out Procedures.

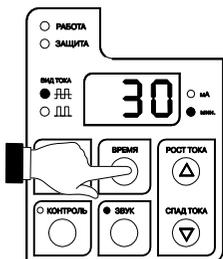
5.3.1. Make sure that power supply key in “OFF”, connect the Unit to the mains.

5.3.2. Turn on the power by putting the power supply key in position “On”. During the procedure zeros will be indicated on digital display, and LEDs began to flash: power On LED, “CURRENT MODE ”, “mA”, “SOUND”.

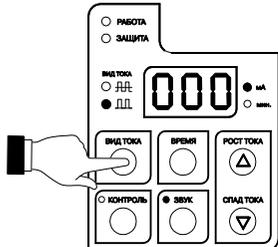
	<p>5.3.3. Fix electrodes on patient’s head. To do this you need:</p> <ul style="list-style-type: none">a) Moisten the Pads abundantly with tap water of room temperature, and squeeze it out slightly;b) Minor (retromastoid) gaskets should face white side up to patient’s skin free of hairs behind ears. Place over these Pads the headband with retromastoid electrodes so that neither cables nor hairs are beneath them. Fix headband with Velcro closure;c) Major (frontal) Pad put white side up to patient’s skin of forehead, with its lower edge being at the level of eyebrows. Place headband with frontal electrodes above the Pad, and fix it with Velcro closure.
--	--



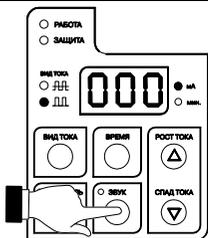
5.3.4. Connect electrodes to the Unit, inserting them into the sockets “ELECTRODES”.



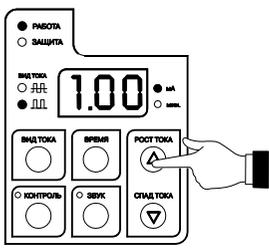
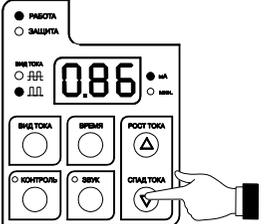
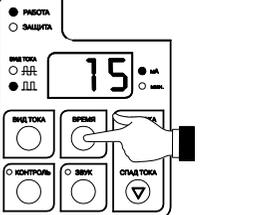
5.3.5. Set duration of procedure that you need, ranging from 5 to 40 min. For this, press button “TIME”. Each pressing will add per 5 min to set up time. After duration for 40 min it will be changed with 0 min, going in circle. After the magnitude of current started to increase it is impossible to change TIME mode. If you set up 0 min the Unit is out of work.

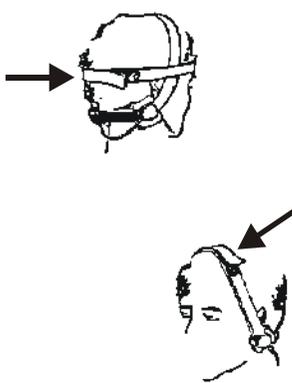


5.3.6. Change mode of stimulating current by pressing button “CURRENT MODE”. While switching on the Unit will display automatically pre-installed Mode of bipolar pulse current, which is accompanied with LED “” “ON”. If you switched to single-polarity pulse current, then press button “CURRENT MODE”, that will highlight LED “”.



5.3.7. When TES-procedure is supposed to be accompanied with hearing of psychomusic therapy, then mode of Voice Aid should be switched off. To do this you have to press button “SOUND”, which make LED “SOUND” to fade out.

	<p>5.3.8. Start to find out the value of stimulating current for a patient. For this press button “CURRENT UP” and increase its magnitude until you reached stepwise the necessary value, which is based on patient’s feelings. At level of 0.2 mA the set programme is being started and countdown will begin. It is accompanied with highlighting LED “RUNNING”, that keeps flashing until the end of procedure.</p>
	<p>5.3.9. To decrease magnitude of stimulating current use button “CURRENT DOWN”.</p>
	<p>5.3.10. By pressing button “TIME” indicator will display digits corresponding to time (min) remained till the end of procedure. In 3 sec after releasing the button indicator will start back showing a value of the running current.</p>

	<p>5.3.11. When time of procedure is up the Unit will start to gradually decrease magnitude of current till zero, which is accompanied with Voice Aid command “end of session”.</p> <p>5.3.12. Procedure is completed now. Disconnect electrodes from the Unit.</p> <p>5.3.13. Take all electrodes and Pads off patient’s head following such sequence: a) take off the frontal electrodes and major (frontal) pad; b) take off retromastoid electrodes and minor pads.</p> <p>5.3.14. After procedure is finished the pads should be washed out and boiled without adding any soap or washing powder. After that pads must be thoroughly dried up. Otherwise, gaskets can be treated in hot-air sterilizer or by using general instructions for cleaning of physiotherapeutical equipment.</p>
---	---

5.3.15. Put the power supply key in position “OFF”, and disconnect the Unit from the mains. If patients are being treated in row you may not switch off the Unit for at least 6 hours. After that you should turn off the Unit for 30-40 min.

5.4. Procedure counter.

5.4.1. The Unit records all the procedures that it performed. Procedure counter is not automatically reset to zero. The Unit counts only procedures that fit to a number of criteria: duration is at least 15 min, stimulating current – at least 0.2 mA.

5.4.2. To check the procedure counter:

a). Switch power supply key in position “ON”, simultaneously holding button “CONTROL”;

b). Counter status will be displayed on digital LED. Max. number of recorded procedures is 999. After that, counter will be reset to zero.

5.4.3. Counter status is displayed only under pressing button “CONTROL”. While releasing button “CONTROL” the Unit will be switched back to the normal mode of action, ready for running a new procedure.

6. Common troubles and remedies.

In case of trouble is revealed during Unit is working:

You may firstly check possible remedies in case of trouble in the Table “Common troubles and remedies” (Section 6, User’s Guide). If you find in the table a way how to fix it do it yourself.

Otherwise, contact Technical Support by calling/Fax to the TES Center +7 (812) 328-42-51.

If the staff from TES center recommended to you to send your Unit to the repair office you have to:

6.1. Coordinate delivery method with the staff of TES Center.

TES Center itself sends out and receives customer’s TES Units under warranty at expenses of TES Center. For this you should provide with complete mail address, where the Unit must be sent out for repair, working hours, contact person of the office.

Otherwise, transportation of the Unit out of warranty is being made at expenses of Customer.

6.2. Also, electrodes, Certificate of equipment, Report of Revealed Troubles (from institutions) or Letter of Described Troubles (from individual users) must be enclosed.

6.3. Draw up inventory (one exemplar is enclosed to the Unit and sent out to the TES Center, whereas the second exemplar is kept at your home). If an inventory list is missing, TES Center is not responsible for completion of the set delivered for repair.

6.4. Properly wrap up the Unit to be sent out.

According to the GOST 50444 medical unit “TRANSAIR” should be packed into the box made of timber-based sheet or corrugated paperboard. In case of incorrect wrapping TES center is not responsible for any damage happened during delivery of unit.

TES Center has the Right to refuse in providing a Repair Service in case of:

1. The model of unit is not produced for at least 5 years;
2. Cost of repair for unit is more than 25% of its price;
3. Unit was fixed by customer or in repair offices which are not authorized by TES Center for such service.

Common troubles and remedies

Revealed trouble	Probable cause	Remedies
<p>When plugging the Unit into mains and pressing button “ON” green LED of “Switch-on” at the center of TES logo-type does not flash. Unit does not respond and not get turned on.</p>	<p>Loss of voltage in electric mains.</p>	<p>Make sure that electric power is in the mains cord by plugging any working electric appliance.</p>
	<p>No contact in plug of main cord.</p>	<p>Check the quality of contact.</p>
<p>While pressing button “ON” the Unit is turned on, at Checking Procedure corresponds to Paragraph 5.2. However, in mode “RUNNING” electric current is not supplied to the patient’s electrodes, or it does not going up under pressing button “CURRENT UP”.</p>	<p>No contact in electrode sockets.</p>	<p>Check contact in the socket.</p>
	<p>Discontinuity of electrode cords..</p>	<p>Check cords and repair disconnection.</p>
	<p>Discontinuity of electric cords under electrode isolation caps.</p>	<p>Check contact by unscrewing electrode isolation caps.</p>
	<p>Pads dried up or soaked insufficiently.</p>	<p>Abundantly soak the pads and less intensively squeeze them.</p>
	<p>Loose adjoining of electrodes to gaskets as well as pads to head.</p>	<p>Fix tighter headband with electrodes and pads around head.</p>

7. Acceptance Certificate

Unit "TRANSAIR-03"

Construction number _____ tested and certified for operation and maintenance.

Date of manufacture « ____ » _____ 200 .

Stamp here QC Department Representative _____

8. Warranty

8.1. Manufacturer guarantees that "TRANSAIR-03" Unit complies technical conditions TU 9444-001-31048207-98 if customer subject to the operating rules, storage and transportation.

8.2. Guarantee period covers 12 months since date of putting into operation or when guaranteed shelf life expires (guaranteed shelf life is 6 months since date of manufacture).

8.3. Manufacturer is responsible to provide with free-of-charge repair service or to replace Unit within guarantee period if customer subject to operating rules, storage and transportation.

8.4. Manufacturer does not accept claims if Item has mechanical damage or seals are broken.

8.5. For repair under warranty or purchase please contact:

Russia, Saint Petersburg, 199034, Makarov embankment, 6, "TES Center"

Tel./Fax +7 (812) 328-42-51. E-mail: tes-sale@infran.ru, tes@infran.ru

Unit "TRANSAIR-03"

Construction number _____

Shipping day: « ____ » _____ 200 .

Certified by _____ / _____ /

Stamp here

«Утверждаю»

Руководитель Федеральной службы
по надзору в сфере здравоохранения и
социального развития



MEDICAL USE INSTRUCTION
on
Transcranial Pulsed Electric Stimulator
“Transair-03”
ВМЕА.941514.003 II

1. Purpose

- 1.1. “TRANSAIR-03” Unit is designed for carrying out therapeutic procedures of non-invasive transcranial electric stimulation of brain defense (endorphinergic) structures during physical therapeutic technique.
- 1.2. Unit can be used in in-patient and out-patient facilities, according to the medical prescription, strictly under medical surveillance.

2. Basic indications for application

- 2.1. Pain syndromes of different aetiology, including spondylogenic neuralgia, fibromyalgia, stomalgia, headaches, pains orofacial, postoperative, traumatic (including after burns).
- 2.2. Pain syndromes associated with diseases of visceral organs, chronic pain syndromes under oncologic conditions etc.
- 2.3. Disturbed psychophysiologic condition: neurologic, psychoneurotic, neurosis-like and depressive syndromes of nonorganic genesis, psychosomatic disorders, reactive anxiety, chronic fatigue syndrome, posttraumatic syndrome, increased fatigability and performance decrement among healthy persons, deterioration in quality of life.
- 2.4. Hypertension disease (stage I-II), hypotension, vasomotor dystonia (hypertonic/hypotonic type).
- 2.5. Posttraumatic and postoperative wounds, burns, varicose and trophic ulcers.
- 2.6. Acute non-complicated heart attack.
- 2.7. Gastric and duodenal ulcers, gastritis, duodenitis.
- 2.8. Toxic hepatosis, chronic diffuse liver diseases, including post-infection and alcoholic cirrhosis, irritable bowel syndrome, intestinal dysmotility.
- 2.9. Sensorineural hearing loss, buzzing in ears.
- 2.10. Allergic and vasomotor rhinitis, pollen fever.
- 2.11. Spasm of accommodation, mild myopia.
- 2.12. Post-abstinence insane violation, pathologic addiction to alcohol and opiates.

- 2.13. Menstrual disorders in girls during puberty, premenstrual syndrome, recent and late pregnancy toxicosis, dysfunctional uterine bleeding, menopausal disorders.
- 2.14. Attention Deficit Hyperactivity Disorder in children, tic hyperkinetic disorders, enuresis, relapses of chronic diseases of nasopharynx in sickly children.
- 2.15. Itching dermatosis of different localization, superficial seborrhea, palmoplantar psoriasis, increased fragility and loss of hair.
- 2.16. Reduced productivity of athletic work-out session.
- 2.17. Post-stress immunodepression, including due to physical and psychologic overstrain, time lag desadaptation, impaired acclimatization.

3. Basic contra-indications

- 3.1. Convulsive state, epilepsy.
- 3.2. Brain traumas and brain tumors, infectious diseases of central nervous system.
- 3.3. Hydrocephaly
- 3.4. Acute psychiatric disorders
- 3.5. Hypertension, stage III, hypertensive crisis.
- 3.6. Thyrotoxicosis.
- 3.7. Atrial fibrillation.
- 3.8 Skin lesions at the site of applied electrodes.
- 3.9. Implanted electrostimulators.
- 3.10. Age under 5 years.

4. Mode of action of transcranial pulsed electrostimulation. Specific features of “Transair-03” Unit

4.1. Features of transcranial pulsed electrostimulation

One of the features of electric impact created by “TRANSAIR-03” Unit is that it produces special electric square-wave pulses, that have fixed frequency and length. Also, position of electrodes around patient’s head is strictly fixed – negative electrode is always located on the forehead, whereas positive one – behind the ears.

Thus, patient does not need specify parameters for TES session (excepting magnitude of current) and position of electrodes, that substantially simplifies a process of treatment. Altogether, the whole procedure becomes completely safe.

The proposed approach for performing transcranial pulsed electrostimulation is known in medical literature as TES-therapy. There was shown that electric current coming out of the Unit penetrates patient’s skin and soft tissues of head, skull. It influences anti-nociceptive structures located in brain. Hereby, it induces activation of defense system of brain.

It was found that starting at 10–15 after TES session release of opioid peptides (β -endorphin), is increased which is associated with marked increased levels in brain, cerebrospinal fluid and blood. Also, aside from opioidergic pathway serotonergic neurotransmitter pathways are involved.

4.2. Events that are responsible for development of the central therapeutic effects

4.2.1. ANALGESIA

It is mediated by stimulation of endorphinergic structures within anti-nociceptive system. Flux of ascendant nociceptive impulses can be in part or completely blocked at different levels. Analgesic effect is not dependent on location of the pain area, and it is enhanced in case of more intensive pain.

Analgesia is blocked by using of blockers of opioid receptors (e.g. Naloxone), and is not developed in case of tolerance to morphine or other opiates.

Despite the fact that analgetic effect of TES-therapy is based on stimulation of endorphinergic structures it does not elicit addiction or propensity to the procedures. In contrast, while keeping TES therapy the duration of anti-nociceptive effect prolongs [1–8].

4.2.2. ANTI-STRESS EFFECT

This phenomenon was studied on experimental stress model in animals: by neuronal reaction to immobilization and cold stress, gastric stress ulcers. Remarkable decrease of signs as well as complications of stress can be achieved during analgetic mode [9, 10]. Such effect is blocked by Naloxone, but enhanced by d-aminoacids having inhibitory effect on enkephalinase activity, which are known to hamper turnover of opioid peptides.

4.2.3. CONTROL OF CENTRAL REGULATION OF BLOOD CIRCULATION

It is mediated by a stabilizing effect of β -endorphin on activity of vasomotor center residing at the ventrolateral area of medulla oblongata. The effect is revealed as decreased amplitude of stimulating signals from blood vessels together with control of blood pressure [11–13]. It can be blocked by Naloxone, has max. strength during analgetic mode.

4.2.4. REMOVAL OF ALCOHOL ABSTINENCE SYNDROME

It is fully developed when applying stimuli similar to those that induce analgetic mode. Such effects are proved to stringently correlate with increased blood levels of β -endorphine. After TES therapy a significant reduction of depression as well as addiction can be found [14–16].

4.3. Events that are responsible for development of the peripheral therapeutic effects

4.3.1. STIMULATION OF TISSUE REPAIR

While studying experimental skin lesions they were documented to heal quicker (epithelium, connective tissue), experimental gastric ulcers, regeneration of cut-off nerve fibers, regeneration of hepatocytes. Such effect is mediated by opioid pathway, because it is revealed at max. level under analgetic mode of stimulation. It can be blocked by Naloxone. This effect has been proved in clinical observations by documenting healing of gastric and duodenal ulcerative defects, skin burns, accelerated cicatricial processes in myocardium under heart attack, as well as treatment of sensorineural hearing loss caused by damage of auditory nerve. [10,17–21].

4.3.2. ENHANCED IMMUNITY, ANTI-ALLERGIC EFFECT

TES therapy has an immunomodulating effect at the inductive phase of antibody production, especially if immune response was compromised. Also, stimulation of neutrophil phagocytic activity, activation of NK cells together with reduced function of CTL was found. Thus, TES therapy is able to substantially enhance cellular immunity. In case of post-operative patients

percentage of postsurgical suppurative complications was significantly reduced. Also, an inhibitory effect on growth of implanted malignant tumours was described in experiment. Moreover, clinical picture of a number of allergic diseases was found to be improved: pollen fever, vasomotor rhinitis, bronchial asthma, asthmatic bronchitis, skin allergies. Immunomodulatory effect of TES therapy also mediated by β -endorphine impact, that can be blocked by Naloxone [22–29].

4.4. Events that are responsible for development of central and peripheral therapeutic effects

5.4.1. ITCHING DERMATOSIS AND NEURODERMATITIS

Mode of action for TES-therapy is based on activation of opioid- and serotonergic pathways. There was shown that TES therapy normalizes activity of hypophysis-genital glands-adrenal gland system. It leads to effective amelioration of itching, with developing anti-stress effect. Moreover, healing of excoriations is enhanced. It also allow to to perform prophylaxis of pustulous complications.

4.4.2. PRIMARY ARTHROSIS DEFORMANS

By applying TES-therapy pain in joints will be eliminated. It induces decongestive effect that improves epiphyseal blood circulation, thus, increasing a magnitude of passive and active movements [30, 31].

5. Description of procedure

Hereby we describe the sequence of action before TES session:

- a). Preparation of patient for TES-session;
- b). Preparation of TRANSAIR Unit for usage;
- c). How to choose a programme and how to run a TES-session.

5.1. Preparation of patient for TES session

5.1.1. Before starting TES session make sure that patient has no contra-indications.

5.1.2. Patients with contra-indications listed in Paragraph 4 of the Medical Use Instruction, are not allowed for TES-therapy.

5.1.3. TES-therapy may be applied to a patient in case of lacking recent head traumas. When pads and electrodes are fixed to the patient's head skin should be clean and free of lesions.

5.1.4. Before TES session patient should remove any metal clips or earrings out of ears.

5.1.5. In order to reduce a natural anxiety of patient and to improve TES session efficacy it is recommended to listen to a session of psychomusic therapy, that may introduce into principle of TES therapy without performing actual electrostimulation. If patient wishes psychomusic therapy may further accompany TES sessions.

5.2. Preparation of TRANSAIR Unit for usage

5.2.1. Plug the Unit into the mains cord 1 min before starting TES session.

5.2.2. Disinfect electrode surfaces fro session. If necessary disinfect exterior of the Unit by swab soaked in 3% hydrogen peroxide solution together with 0.5% washing liquid followed by wiping with 1% chloramine solution. Swabs should be squeezed out.

5.2.3. When the Unit is not running for more than 30 min it should be switched off.

5.3. How to run a TES session

5.3.1. Therapy should be performed in calm conditions of in-patient and out-patient facilities. Patient may sit or lay on its back.

ATTENTION!

AVOID: direct contact between electrodes and patient's skin; reduction of sheets within pads; use of white flannel covering pad that faces patient's skin; pads being soaked with sodium chorine solution, sodium carbonate or any other liquids excepting tap water.

5.3.2. The first TES session is considered to be an introductory that helps a patient to adapt to the procedure. During the 1st session stimulating current must be used at minimum, ranging within 0.5–1.0 mA, for 15–20 min. Even though patient may not have any subjective feelings magnitude of current should not be higher than 1 mA.

5.3.3. The main criteria as to how correctly find out an individual regimen for each patient are tolerability as well as positive clinical effect. After starting from 0.5–1.0 mA during the 1st procedure a magnitude of current after that could be increased by 0.2–0.4 mA as compared with the previous procedure. Also, it must be based on clinical effect and patient's condition that is estimated after each procedure. Individual magnitude of current is found out according to the feelings of a patient. In vast majority the appropriate magnitude of current is supposed to be reached if patient started to feel tingling or slight vibration beneath the electrodes. It is important to keep this sensing at the same level during the whole procedure, and avoid too strong reaction.

5.3.4. In case when a therapeutic effect after TES treatment is obvious, all further sessions can be carried out under the same value of current that provided it.

5.3.5. Starting from the 2nd procedure duration can be extended for up to 30–40 min. TES therapy can be applied once a day or every other day. In case of severe pain syndromes it is possible to perform TES sessions twice a day with 12 hours interval.

5.3.6. When TES session is complete a patient should rest for 15–20 min.

5.3.7. Standard course has 6–12 sessions. If necessary it can be repeated in 2–3 weeks (e.g., oncopathology). In case of chronic or seasonal conditions TES course should be repeated in 3–4 months. Physician prescribes as many sessions as necessary. Usually it should not be more than 50–60 sessions a year.

5.3.8. Please, find below in Paragraph 8 proposed regimens of “TRANSAIR-03” Unit that may be applied to cure different diseases and syndromes.

5.4. Usage of TES-therapy in combination with other treatment

5.4.1. TES sessions are well combined with traditional therapeutic methods: medicated, physiotherapeutic, balneological, manual therapy etc. Due to the intrinsic mode of action TES-therapy allows to significantly reduce usage of drugs or completely avoid them, in particular, analgesic and antidepressant drugs, immunostimulators, hormonal remedies etc. Because of identical mode of action **it is useless to simultaneously** apply TES therapy together with acupuncture, as well as morphine-based analgesic drugs and Essentiale. Acupuncture may be applied after completing TES sessions: it may be considered as an additional therapeutic approach to strengthen the treatment.

6. Patient's condition during and after therapeutic course

6.1. When TES sessions are recommended for treatment a physician should rely on indications and contraindications. If TES procedure is carried out strictly according to the operating rules, TES procedure is well tolerated, and does not give rise to any complications.

During TES treatment after the first sessions most patients start to feel improved overall condition, sleeping, mood. Pain sense is weakened or fully vanished.

However, some categories of patients (often those who have chronic diseases) start to feel a slight relapse of the chronic condition. It may be a sign of recovery process, that began after first TES sessions. If such subjective feeling occur it is recommended to complete the full TES course. In case when patient's condition deteriorates TES treatment must be stopped. Patient should be visited by physician.

6.2. During TES procedure a patient may sense the following feelings:

- slight tingling beneath electrodes, modest vibration;
- frontal pad slips down on eyes;
- twinkling sensation.

While TES procedure it is recommended to hear a session of psychomusic therapy enclosed to Standard Set, or any other relaxing music. If patient prefers TES course may be performed in silence.

6.3. After TES session some patients may start feeling minor dizziness. At the place of the electrode application there may appear modest erythema, that recover spontaneously. Altogether, after TES session resting period for 15-20 min is recommended. In case of erythema it is recommended to massage an area, and use moisturizing cream.

6.4 If a patient started to feel a mild headache after 1–2 TES sessions usually it means that individual tolerance dose of magnitude of current was exceeded. Avoid TES sessions until headaches disappear. After that sessions should be continued when applying minimum magnitude of current until patient “begin to respond” (approx. 0.5–0.8 mA), once a day or every other day.

6.5. In rare cases of lack of satisfactory therapeutic effect after using TES sessions it is possible to assume that patient's diagnosis was not exact or that a major condition is not an indication to apply TES therapy. If it happens a patient should visit a physician to correct diagnosis.

It is worth mentioning that in case of chronic, long-lasting or/and smoldering course of pathology, e.g. sensorineural hearing loss, vertebrogenous syndromes etc. TES sessions should be repeated with an interval of 3-4 months. It is due to the fact that an improvement in patient's condition may be revealed after repetitive courses.

7. Recommendations on usage of “TRANSAIR-03” Unit in case of different diseases

Diseases and syndromes	Regimen
<p>Neurological Diseases and syndromes</p> <ol style="list-style-type: none"> 1. Post-stress conditions, depressions, increased fatigability, performance decrement, vegetative-vascular disorders. 2. Spondylogenic radicular and visceral pains: <ul style="list-style-type: none"> - lumbosacral radiculitis; - cervical and thoracic osteochondrosis. 3. Trigeminal neuralgia. 4. Posttraumatic and post-herpes neuritides. 5. Headaches: <ul style="list-style-type: none"> - episodes of migraine; - postconcussion syndrome; - cerebral arachnoiditis; - diencephalic syndrome. 	<p>6–12 sessions per course, once a day or every other day, for 30–40 min. Bipolar current 1.0–2.0 mA</p>
<p>Surgery, traumatology</p> <ol style="list-style-type: none"> 1. Post-operative, traumatic wounds, burns 2. Trophic ulcers 3. Sports traumas. 	<p>5–7 sessions per course 1–2 times a day, for 30–40 min. Monopolar current 1.0–3.0 mA</p>
<p>Gastroenterology</p> <ol style="list-style-type: none"> 1. Gastric and duodenal ulcers. 2. Gastritides and gastroduodenitides. 3. Liver and pancreas diseases. 	<p>8–10 sessions per course, up to 2 times a day in case of severe pain, for 30–40 min. Bipolar or monopolar current 1.0–2.5 mA</p>
<p>Other medical conditions and syndromes</p> <ol style="list-style-type: none"> 1. Hypertension I-II stage, hypotension, neurocirculatory dystonia. 2. Bronchial asthma. 3. Primary arthrosis deformans, osteochondrosis. 	<p>6–12 sessions per course, once a day or every other day, for 30 min. Bipolar current up to 2 mA</p>
<p>Dental diseases and syndromes</p> <ol style="list-style-type: none"> 1. Trigeminal neuralgia and neuritis (true or acquired after dentistry). 2. Paresthesia of mouth and tongue mucosa. 3. Herpetic cheilitis. 4. Temporomandibular arthritis and arthrosis. 5. Post-operative pains after tooth extraction, skin papilloma. 	<p>6–12 sessions per course, once a day, for 30 min. Bipolar current 1.0–2.0 mA or monopolar current up to 1 mA</p>

Ophthalmological diseases and syndromes 1. Chronic ocular pains caused by acute increase of intraocular pressure under terminal glaucoma. 2. Spasm of accommodation.	6–10 sessions per course, once a day, for 30 min. Bipolar current 1.0–2.0 mA
Diseases of ororhinilarygology 1. Sensorineural hearing loss. 2. Vasomotor rhinitis.	10–15 sessions per course, once every 2 days, for 30 min. Bipolar current up to 1 mA
Obstetric-gynecologic diseases and disorders 1. Toxicoses of recent pregnancy with symptoms of: – nausea, vomit, salivation; – hypotonia; – neurocirculatory asthenia. 2. Neurocirculatory disorders, headaches during pre-menopause. 3. Premenstrual syndrome (pains, fatiguability, change of mood).	3–7 sessions per course, once a day, for 30 min. monopolar current up to 2 mA
Skin diseases 1. Itch, itching dermatosis. 2. Neurodermitis. 3. Cutaneous allergic conditions.	6-14 sessions per course, once a day, for 30–40 min. Bipolar current 1.0–2.0 mA
Alcoholic and drug addiction 1. Post-abstinence syndrome. 2. Secondary insane violation. 3. Craving to alcohol and opium.	5–10 sessions per course, once a day, for 30–40 min. monopolar current up to 3 mA
Pain syndromes in oncologic patients 1. Chronic pain syndromes in oncologic patients. 2. Post-operative pains in oncologic patients. 3. Pains caused by chemotherapeutic and radiation therapy.	14–20 sessions per course, 1–2 times a day for 30 min. monopolar current up to 3 mA Course may be repeated in 3–4 weeks

Comments:

If necessary a course of treatment maybe repeated, usually in 3-4 months. In Table we show only recommended parameters for current mode and its magnitude. Such parameters must be found out for each patient individually basing on patient's feelings as well as on treatment response. In most cases magnitude of current is considered to be appropriate if tingling or slight vibration occur at the site where electrodes have been applied. During a procedure medical staff should maintain such feelings at bearable level for patient. If necessary medical staff may change magnitude of current, according to Paragraph 5.3, Certificate of equipment.

8. References.

1. New method of transcranial electric anesthesia. Transactions of the Conference. L., 1987, 60 p. (In Russian).
2. Zabolotnyh V.A., Lebedev V.P., Mishina N.M., Petrova E.P., Afoshin O.A., Stackevich M.A. Use of transcranial electric anesthesia in patients with cephalgias of different origin. *Voprosy kurortologii, fizioterapii i lech. fiz-ry.* 1986, N 2, p. 40-44. (In Russian).
3. Sorokoumov V.A., Gretzov S.I., Voytenko R.I., Skorometz A.A., Lebedev V.P., Katznelson Ya.S., Kokin G.S. Relief of pain syndrome and autonomic reactions to pneumoencephalography and pneumomyelography by using transcranial electric anesthesia. Complex treatment of neurogenic pain syndromes. *Proc. Leningrad Neurosurgery Inst. im. A. L. Polenova, L.*, 1986, p.49-51. (In Russian).
4. Voytenko R.I., Kokin G.S., Lebedev V.P., Ty'shkevich T.G. Transcranial electric anesthesia in treatment of pain syndrome caused by damage of peripheral nerve fibers. *Functional neurosurgery. Proc. Leningrad Neurosurgery Inst. im. A. L. Polenova. L.*, 1987, p.76-81. (In Russian).
5. Gretzov S.I., Katznelson Ya.S., Kirsanova G.V., Gurchin F.A., Starikova I.O., Lebedev V.P., Sorokoumov V.A. Use of transcranial electric anesthesia in treatment of spondylogenic pain syndromes. *J. nevropatologii i psihiatrii im. S.S. Korsakova.* 1987, vol. 12, p.1800-1804. (In Russian).
6. Akimov G.A., Lebedev V.P., Shapkin V.I., Odinak M.M., Volkov A.K., Katznelson Ya.S. Use of transcranial electric effect in treatment of pain neurologic syndromes. *Voenn.-med. j.* 1989, vol. 3, p.27-28. (In Russian).
7. Lebedev V.P. Transcranial electric anesthesia. In: "Pain syndrome", Ed. V.A. Mihaylovich, Yu.D. Ignatov. L., 1990, p.162-172. (In Russian).
8. Kiryanova T.D. Transcranial electric anesthesia in treatment of craniofacial pain syndromes. *Avtoref. diss. kand. med. nauk S.-Peterburg*, 1992, p.16. (In Russian).
9. Lebedev V.P., Rychkova S.V., Kozlowski D. Transcranial electric stimulation suppresses c-fos gene expression in forebrain as well as gastric mucosal ulceration caused by restraint stress in rats. *Abstr. 1st International Stress Congr. Washington, 1994*, p.58. (In English).
10. Aleksandrova V.A., Rychkova S.V., Lebedev V.P. et al. Role of transcranial electric stimulation of the brain opioid structures in regeneration of gastric and duodenal mucosal ulceration under model conditions and in patients. *Mejdnarodn. Med. Obzory.* 1994, p.58-68. (In Russian).
11. Akimov G.A., Zabolotnyh V.A., Lebedev V.P., Zabolotnyh I.I. et al. Transcranial electric stimulation in treatment of vegetative-vascular dystonia. *J. nevropatologii i psihiatrii im. S. S. Korsakova.* 1991, Vol.91, N 7, p.75-78. (In Russian).
12. Lebedev V.P., Katznelson Ya.S., Lebedeva A.V., Kiryanova T.D., Zabolotnyh V.A. Changes of central blood hemodynamics in human during usage of Transcranial electric stimulation of the brainstem opioid system. *Fiziologiya cheloveka.* 1991, Vol.17, N3, p.41-46. (In Russian).

13. Lebedev V.P., Krasnyukov A.V., Katznelson Ya.S. et al. Analgetic mode of transcranial electric stimulation influences somatosympathic reflexes. *Fiziol. jurn. im. I. M. Sechenova*. 1992, Vol.78, N 11, p.40-54. (In Russian).
14. Grinenko A.YA., Krupitski E.M., Lebedev V.P., Katznelson Ya.S. et al. Application of transcranial electric stimulation to arrest alcoholic abstinence syndrome. *Fiziologiya cheloveka*. 1988, vol.14, issue 2, pp.212-218. (In Russian).
15. Krupitski E.M., Grinenko A.Ya., Lebedev V.P., Katznelson Ya.S. et al. Transcranial electric stimulation in treatment of alcoholic abstinence syndrome: clinical efficacy, physiologic and biochemical mechanisms. *Mediko-biologicheskie problemy alkogolizma*. M., 1988, pp.65-69. (In Russian).
16. Grinenko A.Ya., Krupitski E.M., Shabanov P.D. et al. Unconventional therapy of alcoholism. SPb, «Gippokrat», 1993, 190 p.. (In Russian).
17. Ilinskiy O.B., Lebedev V.P., Savchenko A.B., Spevak S.E., Solovieva A.I. Non-invasive transcranial electric stimulation of anti-nociceptive system in tissue repair. *Fiziol. j. im. I.M. Sechenova*. 1987, vol.73, N 1-2, p.223-229. (In Russian).
18. Akoev G.N., Ilinskiy O.V., Kolosova L.I., Lebedev V.P. et al. Transcranial electric stimulation of the brain opioid structures in regeneration of peripheral nerves. *Neyrofiziologiya*. 1990, Vol.22, p.76-79. (In Russian).
19. Pavlov V.A., Karev V.A., Lebedev V.P., Katznelson Ya.S. Capacity of drug-free correction of blood β -endorphin in patients with heart attack. M., 1989, p.71-72. (In Russian).
20. Golikov A.P., Pavlov V.A., Karev V.A., Polumiskov V.Yu., Lebedev V.P., Katznelson Ya.S. et al. The role of transcranial electric stimulation of opioid system in reparative processes in patients with heart attack. *Kardiologiya*. 1989, Vol.29, N 12, pp.45-48. (In Russian).
21. Rozenblyum A.S., Kraeva N.I., Lebedev V.P., Tsurulnikov E.M. Transcranial electric stimulation in treatment of patients with sensorineural hearing loss. *J. ushnyh, nosovyh, gorlovy'h boley*. 1991, N 1, p.31-36. (In Russian).
22. Lebedeva A.V., Dovnar T.E., Katznelson Ya.S., Martalog V.F. Immunocorrection elicited by transcranial electric stimulation of brain opioid system in pulmonology. *Tez. dokl. II s'ezda terap. Kirgizii*. Frunze, 1988, pp.97-98. (In Russian).
23. Grickevich N.L., Gurchin G.V., Katznelson Ya.S. et al. Nonspecific body resistance developing during transcranial electric stimulation working at analgetic mode. *Patologich. fiziol. i e'ksperim. terapiya*. 1991, vol.6, pp.10-12. (In Russian).
24. Lebedev V.P., Kade A.H., Borovikov O.V. et al. Immunomodulatory effect of transcranial electric stimulation during immunodepression. *Tez. I Mejdunar. konf. po immunoreabilitacii*. Sochi, 1992, p.82. (In Russian).
25. Lebedev V.P., Kade A.H., Borovikov O.V. et al. Role of endogenous neuropeptides in regulation of immunity. *Tez. I Immunolog. konf. Rossii*. Novosibirsk, 1992, p.271. (In Russian).
26. Rubcovenko A.V. Immunotropic effects of transcranial electric stimulation. *Avtoref. kand. diss.*, Krasnodar, 1996. (In Russian).

27. Aleksandrov V.A., Lebedev V.P., Kovalevski A.V., Savchenko A.B., Ushmorov A.G. The role of the enhanced secretion of endogenous opioid peptides caused by transcranial electric stimulation on growth of implanted tumors. Chemotherapy of tumors in USSR. M., 1987, N 49, pp.197-202. (In Russian).
28. Bakman A.M., Manihas G.A. Transcranial electric stimulation used to manage chronic pain syndrome in oncologic patients. Abstr. IV Intern. Congr. «Paradigms of pain». Tel-Aviv, 1994, p.100. (In English).
29. Zabolotnyh I.I., Lebedev V.P., Zabolotnyh V.A. Application of transcranial electric stimulation in treatment of allergic diseases. In.: Mediko-social'naya e`kspertiza i reabilitaciya invalidov, SPb, 1996, vol. 4, p. 56-59. (In Russian).
30. Zabolotnyh I.I., Zabolotnyh V.A., Lebedev V.P., Katznelson Ya.S. Application of transcranial electric stimulation of the brainstem opioid system in treatment of primary arthrosis deformans. Tez. dokl. IV Vses. s`ezda revmatologov. Minsk, 1991, p.251. (In Russian).
31. Zabolotnyh I.I. Primary arthrosis deformans. «Nauka», L., 1990,65 p. (In Russian).

9. Priority Documents

1. Registered scientific discovery (Diploma # 237).

Author of discovery: Lebedev V.P. "Selective Transcranial Electric effect on Brain Protective System of Human and Animals". Priority: 10.11.1996.

2. USSR Author Inventor's Certificate # 1074543

Lebedev V.P., Katsnelson Ya.S., Leosko V.A., Baranovskiy A.L., Shlemis G.I.
Method of general electric analgesia. Priority: 18.01.1982

3. USSR Author Inventor's Certificate # 1522500

Lebedev V.P., Ilinskiy O.B., Savchenko A.B., Spevak A.B., Solov'eva A.I., Obolenskiy P.I., Raznatovski K.I., Katsnelson YA.S., Dovnar T.E., Pohodzey I.V., Levashov YU.N., Leosko V.A., Rozenblyum A.S., Kraeva N.I., Cirul'nikov E.M., Zabolotny'h V.A., Zabolotny'h I.I.

Method of stimulation of antinociceptive system. Priority: 01.08.1985

4. USSR Author Inventor's Certificate # 1489719

Grinenko A.Ya., Krupicki E.M., Paley A.I., Lebedev V.P., Katsnelson Ya.S.
Rapid relief of alcoholic abstinence syndrome. Priority: 06.03.1986

5. USSR Author Inventor's Certificate # 1389780

Zabolotnyh V.A., Zabolotnyh I.I., Lebedev V.P.
Treatment of neurocirculatory dystonia. Priority: 23.07.1986

6. USSR Author Inventor's Certificate # 1507404

Golikov A.P., Ryabinin V.A., Polumiskov V.YU., Pavlov V.A., Karev V.A., Trofimov A.K., Ilinski O.B., Lebedev V.P., Katsnelson Ya.S.
Treatment of patients with acute heart attack. Priority: 21.07.1987

7. Russian Federation Inventor's Patent# 2159639

Lebedev V.P., Malygin A.V.
Method of Transcranial Electric Stimulation of Brain Endorphin structures. Priority: 05.01.2000.

8. Russian Federation Inventor's Patent # 2214842

Tsirulnikov E.M., Lebedev V.P., Malygin A.V., Ignatov V.S.
Treatment of sensorineural hearing loss. Priority: 29.10.2002.

9. Russian Federation Useful Model Certificate # 16826

Lebedev V.P., Malygin A.V.
Device for transcranial electric stimulation. Priority: 01.11.2000

10. Brief list of Institutions that were involved in Research and Clinical trials of Method of Treatment “Transcranial Pulsed Electric Stimulation” by using “Transair” Units

1. Saint-Petersburg State Pavlov Medical University (Clinic of nervous diseases, surgical stomatology).
2. Russian Research Center of Pulmonology (laboratory of anaesthesiology), Saint-Petersburg.
3. Russian Military Medical Academy (clinic of nervous, skin, children’s diseases, chairs of physiology of diving and aerospace medicine).
4. Polenov Research Institute of Neurosurgery (departments of anaesthesiology and surgery of peripheral nerves).
5. Saint-Petersburg Hospital # 1 (department of cardiology), Hospital #18 (department of gastroenterology).
6. Leningrad District Clinical Hospital (department of physiotherapy).
7. Leningrad District Diagnostic and Treatment Center of Reproduction and Planned Parenthood.
8. Saint-Petersburg Research Hospital of Ear, Nose, Throat and Speech (department of audiology).
9. Saint-Petersburg Institute of Human Brain, Russian Academy of Sciences (department of neurosurgery).
10. Saint-Petersburg Institute of Improvement of Professional Skills (department of physiology, department of therapy).
11. Leningrad District Narcological Dispensary.
12. Saint-Petersburg Neuropsychiatric Dispensary 1.
13. Petrov Institute of Oncology, Ministry of Health, Russian Federation (department of pre-clinical trials, department of anaesthesiology).
14. Saint-Petersburg Oncologic Dispensary (anti-pain service).
15. Research Institute of Industrial and Naval Medicine.
16. Institute of Toxicology, Ministry of Health, Russian Federation, Saint-Petersburg.
17. Sklifosovsky Research Institute of Medical Ambulance (burns unit, department of urgent cardiology, gastroenterology), Moscow.
18. Burdenko Central Military Hospital (department of anaesthesiology), Moscow.
19. All-Russian Cardiologic Research Center (cell laboratory), Moscow.
20. Research Institute of Experimental Medicine, Russian Academy of Medical Sci (department of non-specific resistance), Saint-Petersburg.
21. Hospitals at: Baltic Plant [Saint-Petersburg], Kalinin Plant [Saint-Petersburg], Gorky Automobile Plant [Nizhny Novgorod].

22. Medical Academy of Postgraduate Education (departments of pediatrics, dermatology, obstetrics and gynecology), Saint-Petersburg.
23. Volgograd State Medical University (Department of clinical pharmacology, propedeutics of internal diseases, obstetrics and gynecology).
24. Kuban State Medical Academy (Department of pathologic physiology) Krasnodar.
25. Kemerovo State Medical Academy (Department of outpatient pediatrics).
26. Rostov State Medical University (Department of otorhinolaryngological diseases).
27. Filatov Institute of Eye Diseases and Tissue Therapy, Ukraine Academy of Medical Sciences, Odessa.

USER'S GUIDE
Transcranial Pulsed Electrostimulator “Transair-03”
BMEA.941514.003 P

1. Purpose of use.....	2
2. Specification and Functions.....	2
2.1. Specification:.....	2
2.2. Service functions.....	2
3. Standard set	3
4. Safety precautions.....	6
5. Work sequence	6
5.1. Preparation of the Unit for Start-up.....	6
5.2. Checking Procedure.....	6
5.3. Carrying out Procedures.....	8
5.4. Procedure counter.....	11
6. Common troubles and remedies.....	12
7. Acceptance Certificate.....	14
8. Warranty.....	14

MEDICAL USE INSTRUCTION
Transcranial Pulsed Electric Stimulator “Transair-03”
BMEA.941514.003 II

1. Purpose	18
2. Basic indications for application.....	18
3. Basic contra-indications.....	19
4. Mode of action of transcranial pulsed electrostimulation. Specific features in usage of “Transair-03” Unit.....	19
4.1. Features of transcranial pulsed electrostimulation.....	19
4.2. Pathways that are responsible for development of the central therapeutic effects.....	17
4.3. Pathways that are responsible for development of the therapeutic effects in periphery	17
4.4. Pathways that are responsible for development of central and peripheral therapeutic effects	18
5. Description of procedure	18
5.1. Preparation of patient for TES-session.....	18
5.2. Preparation of TRANSAIR Unit for usage.....	18
5.3. How to run a TES-session	19
5.4. Usage of TES therapy in combination with other treatment.....	19
6. Patient’s condition during and after therapeutic course	20
7. Recommendations on usage of “TRANSAIR-03” Unit during different diseases	21
8. References	23
9. Priority Documents.....	29
10. Brief list of Institutions that were involved in Research and Clinical studies of Method of Treatment “Transcranial Pulsed Electrostimulation” after usage of “Transair” Units	26

