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USER'S GUIDE
Transcranial Pulsed Electric Stimulator “Transair-05”
TU 9444-005-44333151-2005 BMEA.941514.005 PЭ

1. Purpose of use

“Transair-05” Unit was designed to carry out treatment procedures based on transcranial electrostimulation of brain defense mechanisms, TES-therapy.

2. Specification and Service Functions

2.1. Specification

2.1.1. Stimulating Current:

- Rectangular bipolar impulses;
- Rectangular monopolar impulses;
- Constant current;
- Combination of Rectangular monopolar impulses with constant current.

2.1.2. Output range of control:

- Rectangular bipolar impulsesfrom 0 to 5,00 mA
- Rectangular monopolar impulsesfrom 0 to 5,00 mA
- Constant current.....from 0 to 5,00 mA
- Combination of rectangular monopolar impulses with constant current.....from 0 to 10,00 mA
- Range of deviation under frequency modulation..... 74-80 Hz

2.1.3. Procedure Duration Setup from 5 to 60 min.

2.1.4. Timer sampling period setup..... 5 min.

2.1.5. Electric power 220 W, 50 Hz

2.1.6. Dimensions..... 290 x 200 x 155 mm

2.1.7. Weight..... 2 kg

2.1.7. Operating life is at least 5 years. Mean life is at least 3000 hours.

2.1.8. 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. Basic Functions

2.2.1. Modes of action of therapeutic modality (stimulation):

- bipolar impulses without frequency modulation;
- bipolar impulses with frequency modulation;
- monopolar impulses without frequency modulation;
- monopolar impulses with frequency modulation;
- constant current;
- combination of monopolar impulses without frequency modulation with constant current;
- combination of monopolar impulses with frequency modulation with constant current.

2.2.2. Manual setup of stimulating current intensity.

2.2.3. Setup of procedure duration.

2.3. Service functions

2.3.1. Automated checking procedure of working capacity.

2.3.2. Voice Aid while Setup mode of action and performance.

2.3.3. Digital display shows:

- applied electric pulse current intensity;
- constant current intensity;
- real-time pulse frequency;
- time remained;
- Voice Aid volume.

2.3.4. Light indicators shows type of applied stimulating current as well as running mode of action.

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

2.3.6. Patient safety – automated gradual reduction of the stimulating current in case of circuit discontinuity.

3. Standard set contains

3.1. “Transair-05” Unit	1
3.2. Set of electrodes	1
3.3. Set of pads	12
3.4. User’s guide, medical use instruction	1
3.5. Collected works on “Transcranial electrostimulation”, Vol. 1, 2	per 1
3.6. Packing	1

4. The exterior of the Unit and its controls

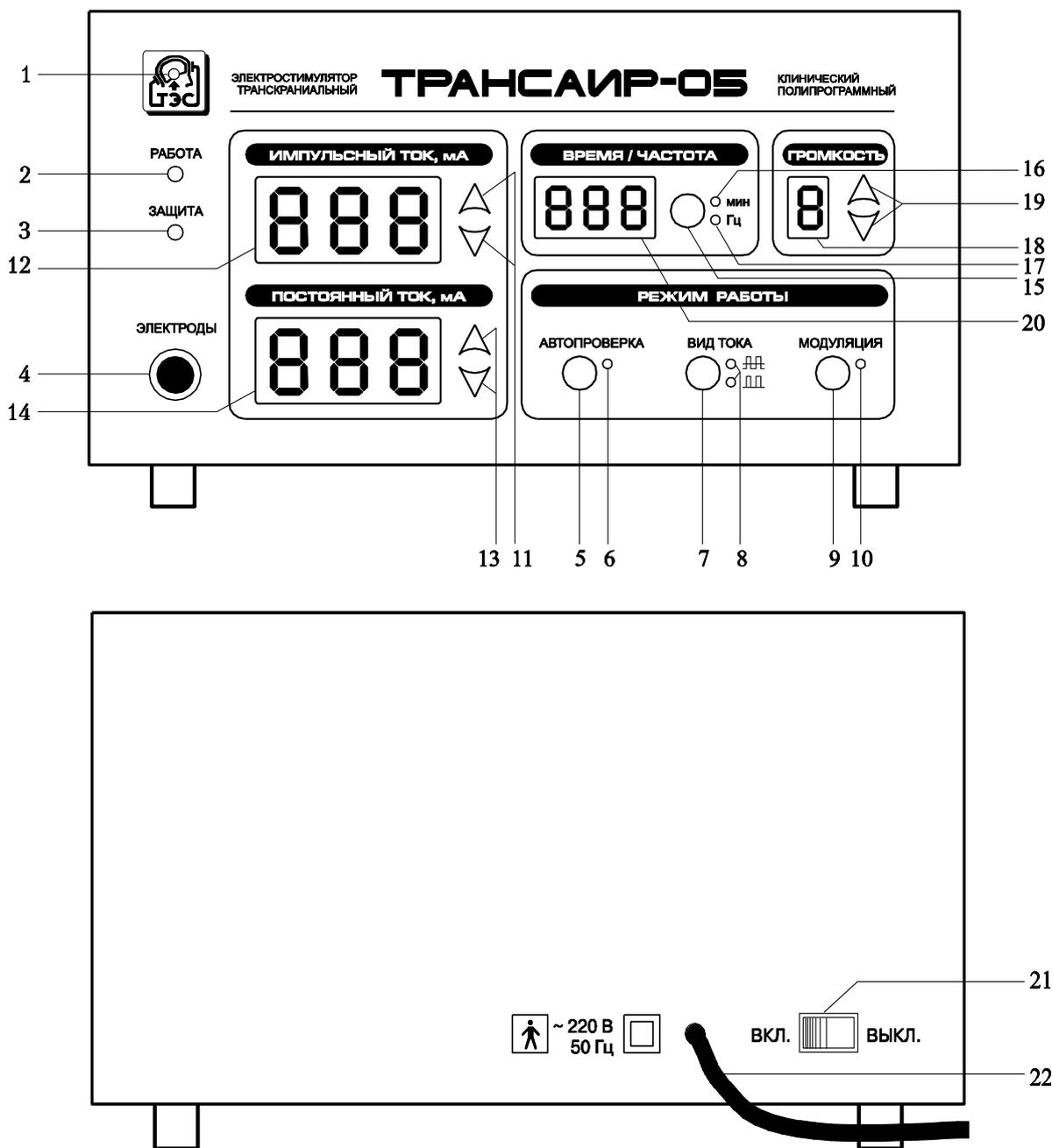
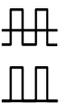


Fig. 1. Controls of “Transair-05” Unit and indicators.

Table 1. Description of Controls indicators and LEDs.

Controls indicators and LEDs	Usage
1. LED "POWER"	Indication power supply On.
2. LED "RUNNING".	Indication of the applied current is at electrodes. Therapeutic mode of action is in effect.
3. LED "PROTECTION".	Indication of Safety Mode On.
4. Socket "ELECTRODES".	Connect electrodes to the Unit.
5. Button "AUTOCHECKING"».	Automated checking procedure of working capacity is On.
6. LED "AUTOMATED CHECKING"	Indication of automated checking procedure of working capacity.
7. Button "CURRENT MODE". 	Choose mode stimulating (therapeutic) current: - bipolar current; - monopolar current; - monopolar current with constant current.
8. LEDs "CURRENT MODE".	Indication of the chosen stimulating (therapeutic) current mode: - bipolar current; - monopolar current; - monopolar current with constant current.
9. Button "MODULATION".	Frequency modulation of stimulating (therapeutic) current is On.
10. Indicator "MODULATION".	Indication of frequency modulation is On.
11. Button "CONTROL" of stimulating current intensity. 	- electric current UP; - electric current DOWN.
12. Indicator "IMPULSE CURRENT, mA".	Indication of running stimulating current in mA.
13. Button CONTROL of constant current intensity. 	- electric current UP; - electric current DOWN.
14. Indicator "CONSTANT CURRENT, mA".	Indication of running constant current in mA.
15. Button "TIME/FREQUENCY".	Mode TIME/FREQUENCY is On: - mode "TIME"– duration of session setup which is displayed on LED "TIME/FREQUENCY"; - mode "FREQUENCY" – indication of frequency of running stimulating current is on LED "TIME/FREQUENCY".
16. LED "min.".	Indication of the working digital indicator "TIME/FREQUENCY", in mode "time display".
17. LED "Hz".	Indication of the working digital indicator "TIME/FREQUENCY", in mode "pulse frequency of stimulating current".
18. Indicator "TIME/FREQUENCY"	Indication of procedure duration, time remained to the end (min), or frequency of stimulating impulse current (Hz).

19. Buttons for volume control of Voice Aid.		- volume UP; - volume DOWN.
20. Indicator of volume control of Voice Aid.		Digital indication for volume of Voice Aid (arbitrary units, ranging from 0 to 7).
21. Power switch “ON/OFF”.		On/off power supply.
22. Mains cord.		Connection of Unit to electric mains (220W, 50Hz).

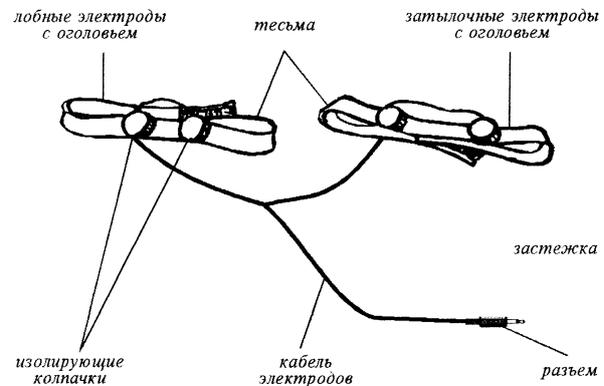
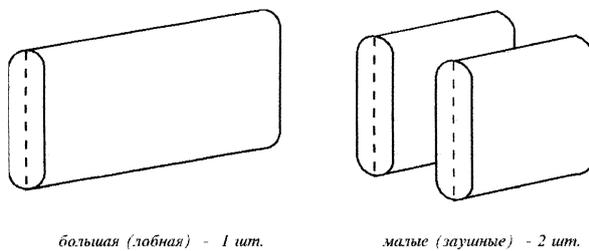


Fig.2. Set of Pads

Fig.3. Electrodes.

5. Safety precautions

- 5.1. Design of the Unit provides with complete electrical safety for a patient as well as medical staff.
- 5.2. Before reading Certificate of equipment and Medical instructions it is forbidden to use the Unit.
- 5.3. 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.
- 5.4. It is forbidden to keep the working Unit with open housing.
- 5.5. Automated checking Procedure should be performed before medical usage (see 6.2.).
- 5.6. It is forbidden to soak the Pads with any liquids excepting tap water.
- 5.7. It is forbidden to connect malfunctioning Unit to Patient.
- 5.8. It is not allowed to replace set electrodes supplied with the Unit with custom-made electrodes.

6. Work sequence

6.1. Preparation of the Unit for Start-up.

- 6.1.1. Before usage of Unit thoroughly read Medical Use Instruction and Certificate of equipment.
- 6.1.2. Before Start-up or after keeping it long time unplugged you should examine the exterior of the Unit to check that:

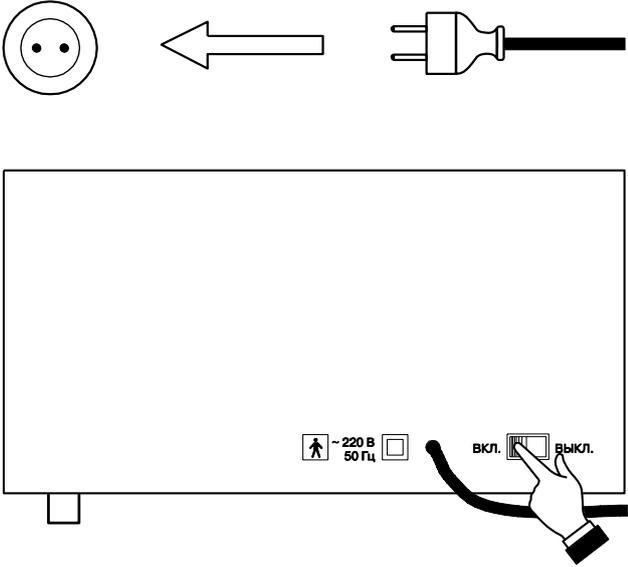
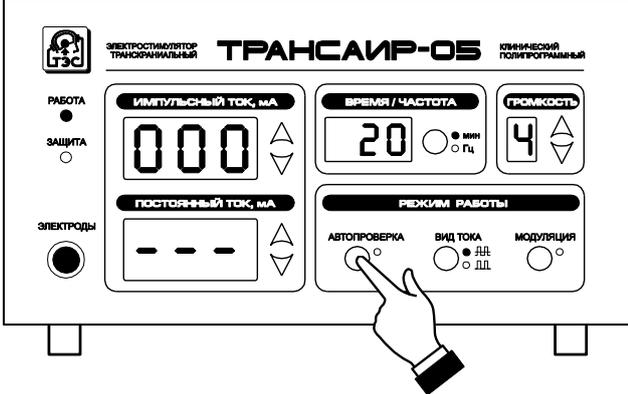
- a seal is not broken;
- there is no visual mechanical damage of the Unit, mains cable, socket, and headband with electrodes;
- set items correspond to Description, Paragraph 3.

6.1.3. 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 be soaked.

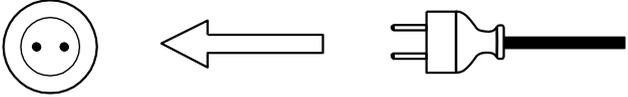
6.1.4. In case the Unit was transported or kept at low temperature before start-up it is necessary to keep it at room temperature for at least 3 hours.

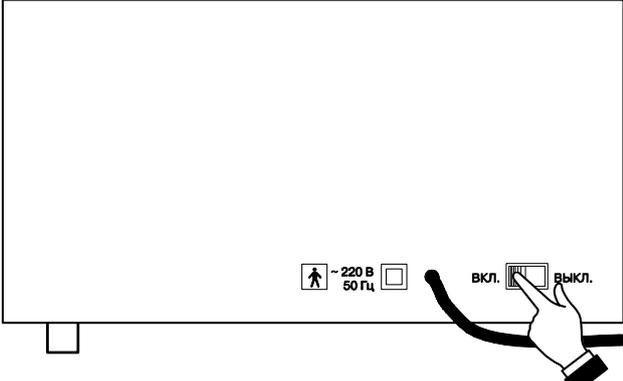
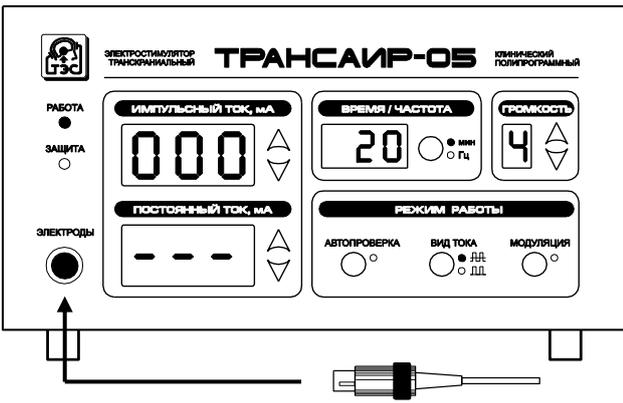
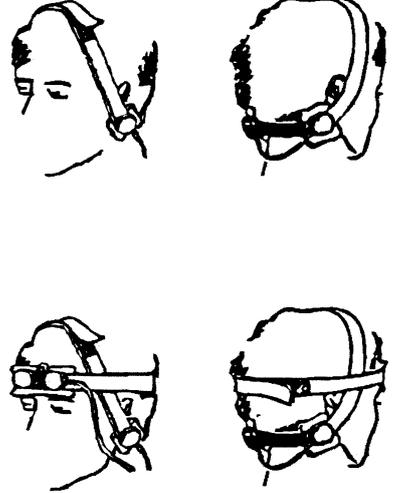
6.2. Checking Procedure.

The Unit is designed to perform automated checking procedure. During this procedure all modes of action are being sequentially checked on internal load equivalent.

	<p>To perform checking procedure of the Unit:</p> <p>6.2.1. Connect the Unit to electric mains (220W) via the mains cord with socket.</p> <p>6.2.2. Switch power on by putting power key in position “ON”.</p> <p>During this: <i>Digital indicators display:</i></p> <ul style="list-style-type: none"> - “IMPULSE CURRENT, mA” - digits “0.00”; - “CONSTANT CURRENT, mA” - “---“; - “TIME/FREQUENCY” - “20”, denoting duration of session; - “VOLUME” - digits (ranging from “0” to “7”), denoting Voice Aid volume, arbitrary units. <p><i>LEDs start to highlight:</i></p> <ul style="list-style-type: none"> - “Power ON/OFF indicator”; - “min.”; - “CURRENT MODE”  bipolar impulses.
	<p>6.2.3. Press button “AUTO-CHECKING”. Voice Aid command “AUTO-CHECKING” is being heard, “AUTO-CHECKING” indicator is highlighted, and “AUTO-CHECKING” is being started.</p> <p>6.2.4. After “AUTO-CHECKING” is complete: proceed to carry out a procedure according to Paragraph 6.3. If the Unit is not to be used, switch it off, by putting power key “ON/OFF” in position “OFF”, and unplug it.</p>

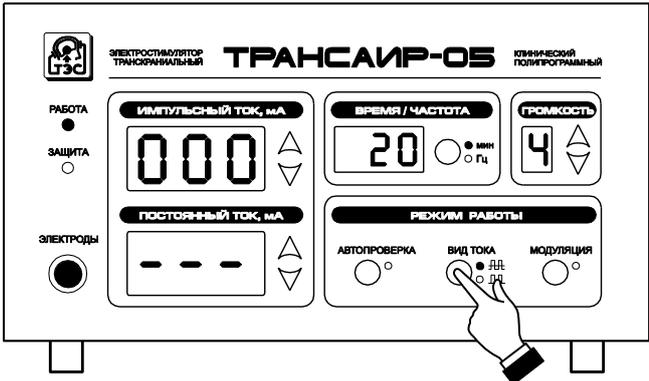
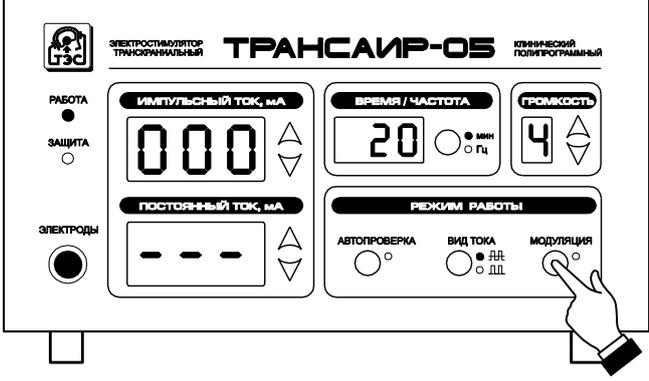
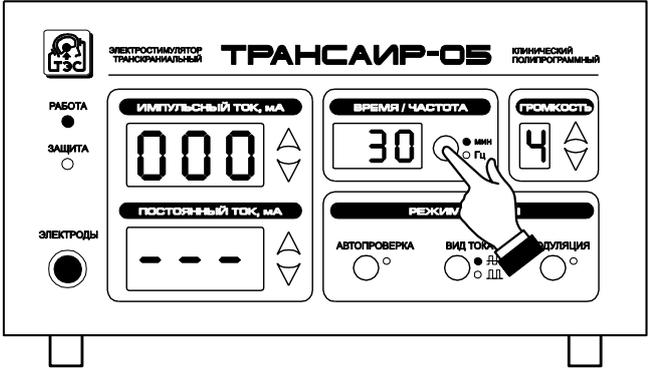
6.3. Carrying out Procedures.

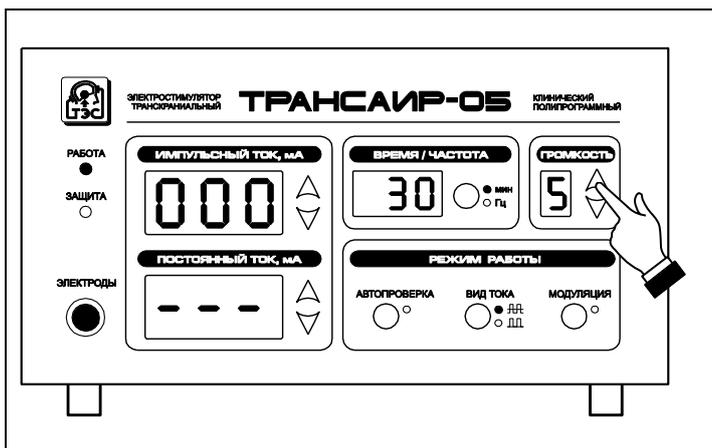
	<p>6.3.1. Connect the Unit to the mains cord (220 W) via socket.</p> <p>6.3.2. Switch power on, by putting key “ON/OFF” in position “ON”. While doing this:</p>
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 <p>~220 В 50 Гц</p> <p>ВКЛ. ВЫКЛ.</p>	<p><i>Digital display show:</i></p> <ul style="list-style-type: none"> - “IMPULSE CURRENT, mA” - digits “0.00”; - “CONSTANT CURRENT, mA” - “---“; - “TIME/FREQUENCY” - digits “0.00”; - “VOLUME” - digits (ranging from “0” to “7”), denoting Voice Aid volume, arbitrary units. <p><i>LEDs start to highlight:</i></p> <ul style="list-style-type: none"> - “Power ON/OFF indicator”; - “min.”; - “CURRENT MODE”  bipolar impulses.
 <p>ЭЛЕКТРОСТИМУЛЯТОР ТРАНСФОРМАЦИОННЫЙ ТРАНСАНП-05 КЛИНИЧЕСКИЙ ПОЛИГРАММНЫЙ</p> <p>РАБОТА ● ЗАЩИТА ○</p> <p>ИМПУЛЬСНЫЙ ТОК, мА: 000</p> <p>ПОСТОЯННЫЙ ТОК, мА: ---</p> <p>ВРЕМЯ / ЧАСТОТА: 20</p> <p>ГРОМКОСТЬ: 4</p> <p>РЕЖИМ РАБОТЫ</p> <p>АВТОПРОВЕРКА ○ ВИД ТОКА: <input checked="" type="radio"/> ПП <input type="radio"/> ДД</p> <p>МОДУЛЯЦИЯ ○</p> <p>ЭЛЕКТРОДЫ</p>	<p>6.3.3. Connect electrodes tightly to the Unit, by plugging into pinhole “ELECTRODES” until clicking position.</p>
	<p>6.3.4. Fix electrodes on patient’s head. To do this you need:</p> <ol style="list-style-type: none"> Moisten the retromastoid pads abundantly with warm / room temp. tap water (not boiled), and place them on mastoid processes; Put a headband with occipital electrodes over the pads, and fix them with Velcro closure above forehead; Moisten the frontal pad and place it over forehead so that its lower edge should be at the level of eyebrows; Put a headband with frontal electrodes over the frontal pad, and fix them with Velcro closure.

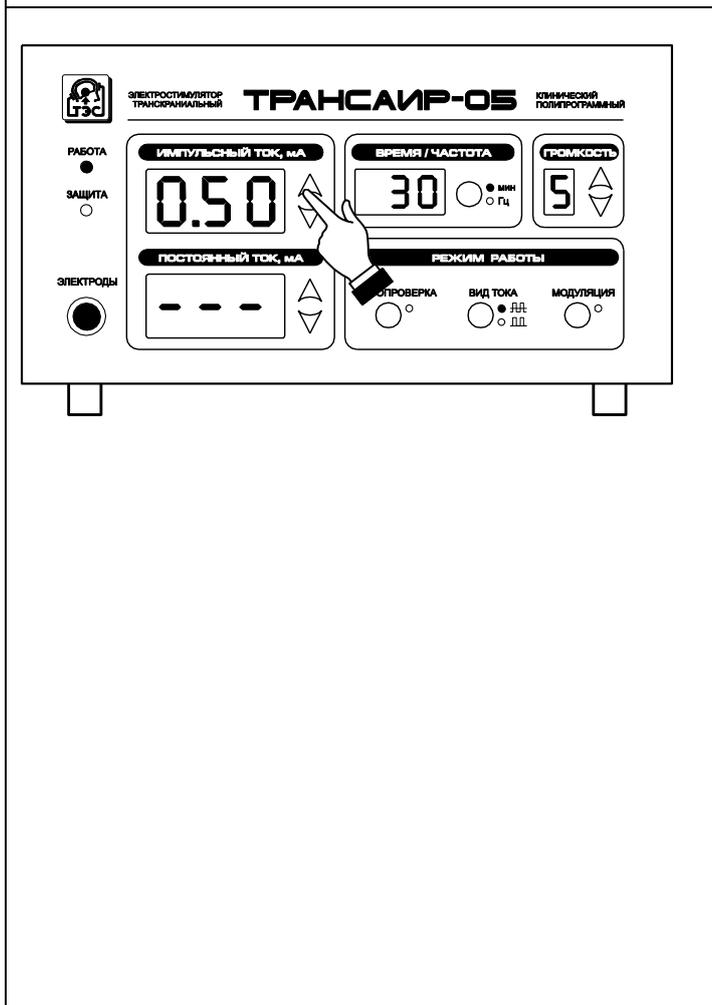
ATTENTION!

1. Skin at the site of fixing electrodes should not be damaged.
2. Before running medical procedure a patient should remove any metal clips or earrings out of ears.
3. While placing electrodes on head make sure that you do not have hairs underneath it.
4. Avoid any contact of metal parts of electrodes with skin.

	<p>6.3.5. Choose mode of stimulating current. Current mode “bipolar impulses” is automatically activated when the Unit is switched on. Indicator “CURRENT MODE” is highlighted . If “monopolar impulses” / “monopolar impulses in combination with constant current” / “constant current” mode is chosen, then press button “CURRENT MODE”. Voice Aid command “MONOPOLAR IMPULSES” is being heard, LED “CURRENT MODE” is highlighted .</p>
	<p>Choose mode of frequency modulation for stimulating current. Current mode without frequency modulation is automatically activated when the Unit is switched on. If mode with frequency modulation is chosen, then press button “MODULATION”. LED “MODULATION” is highlighted, Voice Aid command “MODULATION” is being heard.</p>
	<p>6.3.7. Set up duration of session by using button “TIME/FREQUENCY” (each pressing adds up 5 min more). Duration of session is displayed on digital indicator “TIME/FREQUENCY”, and Voice Aid command “TIME” is being heard. Recommended duration of 1st session – 20 min, further – 30 min, until otherwise prescribed by physician. You can change duration of session only before it started.</p>

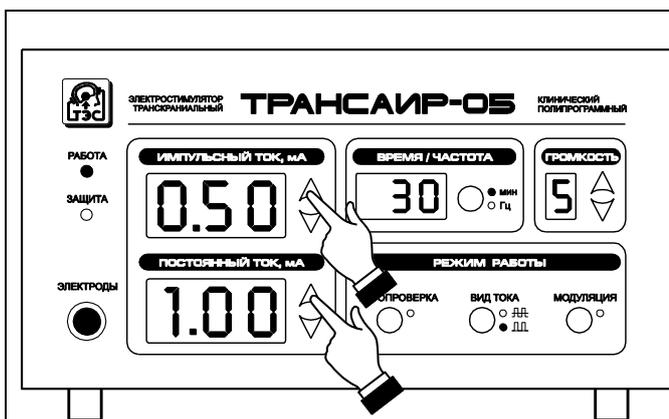


6.3.8. By using buttons Δ or ∇ control Voice Aid volume.



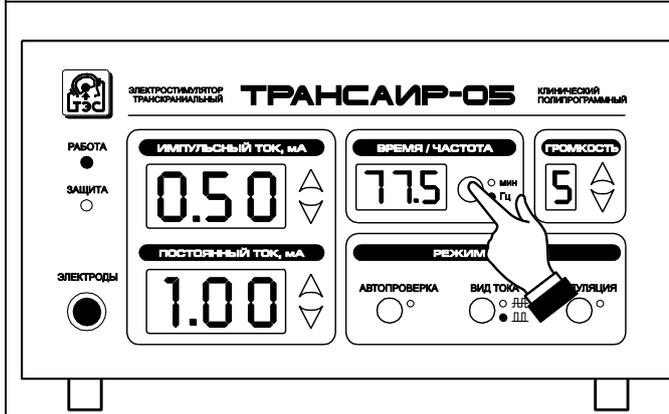
6.3.9. Start to find out a value of stimulating current for a patient.

- 1). If you choose to use bipolar impulse mode (LED “CURRENT MODE” is highlighted $\square\square\square$): press button Δ “IMPULSE CURRENT” (to increase impulse current value). Voice Aid command “CURRENT IS UP” is being heard. Keep increasing current value until patient started to feel tingling or slight vibration beneath the electrodes (current intensity is approx. 1mA). When patient started to adapt current intensity may further be increased. In case a patient tolerates bad the applied current intensity, press button ∇ “IMPULSE CURRENT” to decrease current value until unpleasant feelings beneath the electrodes disappear. It is accompanied with Voice Aid command “CURRENT IS DOWN”.
- 2). If you choose to use monopolar impulse mode (indicator “CURRENT MODE” is highlighted $\square\square$): proceed as described in 3.6.9.1). Note: in this case tingling and slight vibration beneath the electrodes may start to appear at lower current intensity (approx. 0.3-0.5 mA), and are more intensive.



3). If you choose a combined mode – combination of monopolar impulses with constant current (indicator $\square\square\square$ “CURRENT MODE” is highlighted), press button \triangle “CONSTANT CURRENT” (to increase constant current value). Voice Aid command “CURRENT IS UP” is being heard. Keep increasing current value until 1mA. After that press button \triangle “IMPULSE CURRENT” (to increase impulse current value). Voice Aid command “CURRENT IS UP” is being heard. Keep increasing current value until 0.5 mA. In case of further increase of current value medical staff should constantly check subjective feelings of patient. Under all circumstances ratio constant/impulse current must be maintained at 1:1 or 2:1 level.

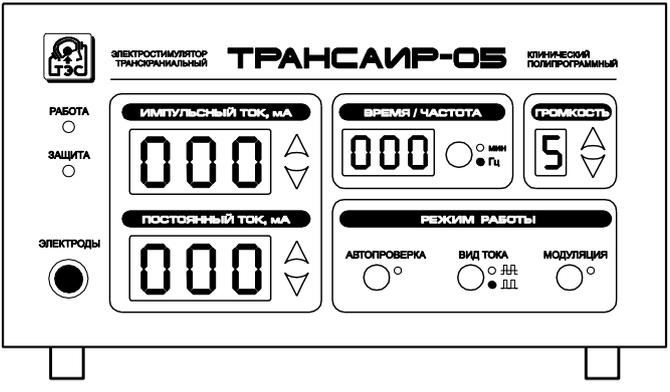
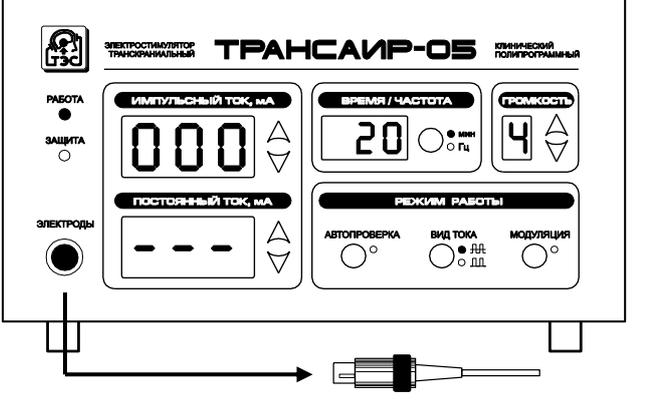
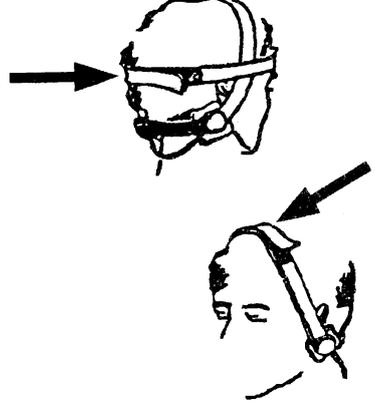
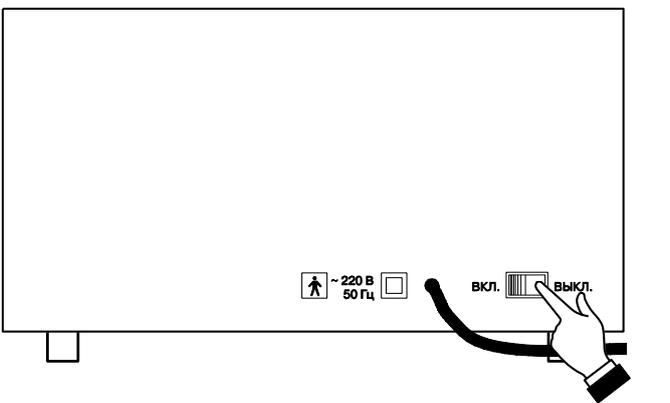
4). If you choose constant current mode, press button \triangle “CONSTANT CURRENT”. After that proceed as in 6.3.9.1.



6.3.10. During procedure LED “TIME/FREQUENCY” displays digits corresponding to time remained to the end of session. Indicator “min.” is highlighted. In case you would like to control a value of stimulating current frequency, press button “TIME/FREQUENCY”. After that, Voice Aid command “FREQUENCY” is being heard. Indicator “min.” is off, and indicator “Hz” is highlighted. LED “TIME/FREQUENCY” displays the following digits:

- 77.5 – if you choose mode without frequency modulation;
- interchange of digits within a range of 75.5-79.5 – if you choose mode with frequency modulation.

Press button “TIME/FREQUENCY” to return back to “TIME” display mode. Voice Aid command “TIME” is being heard. Indicator “Hz” is off, and indicator “min.” starts to highlight. Indicator “TIME/FREQUENCY” displays time remained to the end of procedure.

	<p>6.3.11. When procedure is complete LED “TIME/FREQUENCY” displays digits “0.00”. Voice Aid command “PROCEDURE COMPLETE” is being heard. Indicator “RUNNING” is off. Automated gradual shutdown of stimulating current is in process, and digital indicators display decrease of values until reaching zero value. Voice Aid command is being heard that may be switched off by pressing any button on the front console of the Unit.</p>
	<p>6.3.12. Disconnect electrodes from the Unit.</p>
	<p>6.3.13. Take off the electrodes of patient’s head following such sequence: a) take off the frontal electrodes and major frontal pad; b) take off occipital electrodes and minor retromastoid pads. After procedure is finished the pads should be washed out or boiled without adding any soap or washing powder.</p>
	<p>6.3.14. Switch off the Unit by putting power key “ON/OFF” in position “OFF”. 6.3.15. Disconnect the Unit from the mains socket.</p>

6.4. Procedure counter

6.4.1. The Unit records all the procedures that were carried out. Procedure counter keeps the recorded information in nonvolatile memory, so that if the Unit is switched off it does not automatically reset to zero value. 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.

6.4.2. To check the procedure counter:

- a). Switch power supply key at the rear side of the Unit in position “ON”, simultaneously holding button “AUTOCHECKING”;
- b). Counter status will be displayed so that: thousands of procedures – are on digital indicator “IMPULSE CURRENT, mA”, values less than thousands of procedures – are on digital indicator “CONSTANT CURRENT, mA”.

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

7. 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”, page 16. If you find in the Table a way how to fix it do it yourself.

Otherwise, contact Technical Support at the TES Center by phone/Fax: (812) 328-42-51.

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

7.1. 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 beyond 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 persons) must be enclosed.

7.3. 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.

7.4. 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. the model is not included into the State Register of Medical Goods;
3. cost of repair for Unit is more than 25% of its price;
4. 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, external manifestations	Probable cause	Remedies
When pressing power key “ON/OFF” green LED of “Switch-on” at the center of TES logotype does not flash.	Loss of voltage in electric mains.	Make sure that electric power is in the mains cord by plugging any working electric appliance.
	No contact in plug of main cord.	Check the quality of contact.
Stimulating electric current is not supplied to the patient’s electrodes while electric current is supplied in mode “AUTOCHECKING”.	No contact in electrode sockets.	Check the quality of contact (firm contact) in the socket “ELECTRODES”.
	Discontinuity of electrode cords.	Check cords and repair disconnection.
	Discontinuity of main cord with metal parts of electrodes.	Check contact under electrode caps by unscrewing them.
	Pads soaked insufficiently.	Abundantly soak the pads.
	Loose adjoining of electrodes and pads to head.	Fix headband with electrodes tighter around head.

8. Acceptance Certificate

Unit “TRANSAIR-05”	
Construction number _____ Date of manufacture _____	
Tested and certified for operation and maintenance.	
Stamp here	QC Department Representative _____

9. Warranty

9.1. Manufacturer guarantees that “TRANSAIR-05” Unit complies technical conditions TU-9444-31048207-96 if customer subject to the operating rules, storage and transportation.

9.2. Guarantee period covers 12 months since date of purchase.

9.3. 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.

9.4. Warranty repair must be performed only by the Manufacturer. In case when repair is performed by any other facility (or private individual) warranty will be nullified.

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

9.6. For repair under warranty or purchase please contact:

**199034, Saint Petersburg, Makarov embankment, 6, LLC "TES Center"
Tel./Fax (812) 328-42-51.**

Unit "TRANSAIR-05", Construction number _____,

Shipping date: " ____ " _____ 20____.

Stamp here

Certified by _____

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

9.8. Beyond warranty Manufacturer can provide a repair service, but customer will be charged. Way of payment depends if a customer is an Institution (wire transfer) or a private individual (mail transfer or cash).

«Утверждаю»

Руководитель Федеральной службы
по надзору в сфере здравоохранения и
социального развития



Medical Use Instruction on Transcranial Pulsed Electric Stimulator “Transair-05” BMEA.941514.005 II

1. Purpose

10.1. The Instruction is compiled for Transcranial Pulsed Electric Stimulator “Transair-05”.

10.2. Transcranial Pulsed Electric Stimulator “Transair-05” is designed for carrying out therapeutic procedures of non-invasive transcranial electrostimulation of brain defense (endorphinergic) pathways during physical therapeutic technique.

10.3. 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. Acute, subacute and chronic pain syndromes: radiculitis, osteochondrosis, neuralgia, trigeminal neuritis, headaches including migraine, phantom pains, as well as pains in oncologic patients.

2.2. Stress conditions of different origin, depression, anxiety, performance decrement, chronic fatigue syndrome.

2.3. Hypertension disease (stage I-II), Hypotension, vegetative-vascular dystonia.

2.4. Sensorineural hearing loss, including occupational form.

2.5. Traumatic and postoperative wounds, burns and ulcers, including gastric and duodenal ulcers, trophic ulcers.

2.6. Diffuse itching dermatoses, neurodermitides, eczema, seborrhea.

2.7. Stimulation of immune system in patients with immunodeficiency.

2.8. Primary osteoarthritis.

2.9. Alcohol abstinence syndrome, alcohol affective disorders, pathologic addiction to alcohol. Opium addiction.

2.10. Recent pregnancy toxicosis.

2.11. Climacteric neurosis.

2.12. Allergic conditions: pollen fevers, diathesis, vasomotor rhinitis, bronchial asthma.

3. Basic contra-indications

- 3.1. Convulsive state, epilepsy.
- 3.2. Traumas and brain tumors, infectious diseases of central nervous system.
- 3.3. Hypertensive disease stage III, hypertensive crisis.
- 3.4. Hydrocephaly.
- 3.5. Acute psychiatric disorders.
- 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” Unit

4.1. Features of transcranial pulsed electrostimulation

One of the features of electric impact mediated by “TRANSAIR” 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 to specify parameters for TES session (excepting current intensity) 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 electric stimulation in medical literature is referred to as TES therapy. There was shown that electric current coming out of the Unit penetrates skin and soft tissues of patient’s head as well as skull. It influences brain anti-nociceptive receptors. Hereby, it induces activation of brain defense systems.

It was found that as early as 10–15 min after starting TES session a release of opioid peptides is increased (β -endorphine), which is associated with their marked increased levels in brain, cerebrospinal fluid and blood. Also, aside from opiate pathway serotonin- as well cholinergic neurotransmitter pathways are involved.

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

4.2.1. ANALGESIA

It is mediated by stimulation of opioid receptors of anti-nociceptive system. Flux of ascendant nociceptive impulses can be in part or completely blocked at different levels. Analgetic effect is not dependent on location of the pain senses, and it is enhanced in case of more intensive constant pain.

Analgesia is blocked by using inhibitor of opioid receptors, Naloxone, and 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 opioid pathways 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 of action [9, 10]. Such effect is blocked by Naloxone, but enhanced by d-aminoacids having central effect on nervous system, 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 opioids 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 developed when applying stimuli similar to those that induce analgetic mode. Such effects are proved to be of opioid origin, and 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. Pathways that are responsible for development of the peripheral therapeutic effects

4.3.1. STIMULATION OF REPARATION

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 experiments by documenting healing of gastric and duodenal ulcerative defects, skin burns, accelerated cicatricial processes in myocardium caused by 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 tumors 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 is also mediated by analgetic impact that can be blocked by Naloxone [22–29].

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

4.4.1. 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 allows to perform prophylaxis of pustulous complications.

4.4.2. PRIMARY ARTHROSIS DEFORMANS

TES-therapy eliminates pain in joints. Also, it induces decongestive effect that improves epiphyseal blood circulation, thus, increasing a magnitude of passive and active movements [30, 31].

5. Description of procedure

While starting to apply TES therapy the major aims of physician should be as follows: to empirically find out an optimal current intensity, duration of each session, frequency of sessions.

Hereby we describe the sequence of action before TES session:

- Preparation of patient for TES-session;
- Preparation of TRANSAIR Unit for usage;
- 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 before 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 colored 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 current intensity 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 current intensity 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 current intensity is found out according to the feelings of a patient. In vast majority the appropriate current intensity 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-hour 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 for TES therapy 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, analgetic, 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 analgetic 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. However,

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 listen to 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 recovers 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 it means usually that individual tolerance dose of current intensity was exceeded. Avoid TES sessions until headaches disappear. After that sessions should be continued when applying minimum current intensity 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, vertebragenous 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-05” 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 vegetative 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.</p> <p>Bipolar current 1.0–3.0 mA</p> <p>In case of severe pain syndromes current is higher than 3.0 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.</p> <p>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.</p> <p>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, vegetative-vascular 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.</p> <p>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.</p> <p>Bipolar current 1.0–2.0 mA</p> <p>Or Monopolar current up to 1 mA</p>
<p>Ophthalmological diseases and syndromes</p> <ol style="list-style-type: none"> 1. Chronic ocular pains caused by acute increase of intraocular pressure under terminal glaucoma. 2. Spasm of accommodation. 	<p>6–10 sessions per course, once a day, for 30 min.</p> <p>Bipolar current 1.0–2.0 mA</p>
<p>Diseases of ENT organs</p> <ol style="list-style-type: none"> 1. Sensorineural hearing loss. 2. Vasomotor rhinitis. 	<p>10–15 sessions per course, once every 2 days, for 30 min.</p> <p>Bipolar current up to 1 mA</p>

<p>Obstetric-gynecologic diseases and disorders</p> <ol style="list-style-type: none"> 1. Toxicoses of recent pregnancy with symptoms of: <ul style="list-style-type: none"> – nausea, vomit, salivation; – hypotonia; – neurocirculatory asthenia. 2. Vegetative-vascular disorders, headaches during pre-menopause. 3. Premenstrual syndrome (pains, fatiguability, change of mood). 	<p>3–7 sessions per course, once a day, for 30 min. Monopolar current up to 2 mA</p>
<p>Skin diseases</p> <ol style="list-style-type: none"> 1. Itch, itching dermatosis. 2. Neurodermitis. 3. Cutaneous allergic conditions. 	<p>6-14 sessions per course, once a day, for 30–40 min. Bipolar current 1.0–2.0 mA</p>
<p>Alcoholism and opium addiction</p> <ol style="list-style-type: none"> 1. Abstinence and post-abstinence syndrome. 2. Secondary insane violation. 3. Morbid attraction to alcohol and opiates. 	<p>5–10 sessions per course, once a day, for 30–40 min. Monopolar current up to 5 mA</p>
<p>Pain syndromes in oncologic patients</p> <ol style="list-style-type: none"> 1. Chronic pain syndromes in oncologic patients. 2. Post-operative pains in oncologic patients. 3. Pains caused by chemotherapeutic and radiation therapy. 	<p>14–20 sessions per course, 1–2 times a day for 30 min. Monopolar current up to 5 mA Course may be repeated in 3–4 weeks</p>

Comments:

If it is necessary a course of treatment maybe repeated, usually in 3-4 months. In Table we show only recommended parameters for current mode and its intensity. Such parameters must be found out for each patient individually basing on patient’s feelings as well as on treatment response. In most cases current intensity 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 keep on such feelings at bearable level for patient. If necessary medical staff may change current intensity, according to Paragraph 5.3, Certificate of equipment.

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9. Priority Documents

1. Registered scientific discovery (Diploma # 237).

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2. USSR Inventor's Certificate # 1074543

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Method of Transcranial Electric Stimulation of Brain Endorphine pathways. Description of the Unit. Priority: 05.01.2000.

8. Russian Federation Inventor's Certificate # 2214842

Cirul'nikov E.M., Lebedev V.P., Maly'gin A.V., Ignatov V.S.
Treatment of sensorineural hearing loss. Description of the Unit. Priority: 29.10.2002.

9. Russian Federation Useful Model Certificate # 16826

Lebedev V.P., Maly'gin A.V.
Description of device for performing transcranial electrostimulation. Priority: 01.11.2000.

10. Brief list of Institutions that were involved in Research and Clinical studies of Method of Treatment “Transcranial Pulsed Electrostimulation” 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, chair of physiology of diving and aerospace medicine).
4. Polenov Research Institute of Neurosurgery (department 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, 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.
Institute Of Toxicology, Ministry of Health, Russian Federation, Saint-Petersburg.
15. Sklifosovsky Research Institute of Medical Ambulance (burns unit, department of urgent cardiology, gastroenterology), Moscow.
16. Burdenko Central Military Hospital (department of anaesthesiology), Moscow.
17. All-Russian Cardiologic Research Center (cell trophics laboratory), Moscow.
18. Research Institute of Experimental Medicine, RAMS (department of non-specific resistance), Saint-Petersburg.
19. Hospitals at: Baltic Plant [Saint-Petersburg], Kalinin Plant [Saint-Petersburg], JSC Gorky Automobile Plant, Nizhny Novgorod.
20. Medical Academy of Postgraduate Education (Department of pediatrics), Saint-Petersburg.
21. Volgograd State Medical University (Department of clinical pharmacology, propedeutics of internal diseases, obstetrics and gynecology).
22. Kuban State Medical Academy (Department of pathologic physiology) Krasnodar.
23. Kemerovo State Medical Academy (Department of outpatient pediatrics).
24. Rostov State Medical University (ENT-diseases Department).
25. Philatov Institute of Eye Diseases and Tissue Therapy, Ukraine Academy of Medical Sciences, Odessa.