USER'S GUIDE

Transcranial Pulsed Electric Stimulator "Transair-04"

TU 9444-005-44333151-2005

BMEA.941514.004 РЭ

1. Purpose of use

"TRANSAIR-04" was designed to carry out brain electrostimulation via cutaneous electrodes in order to selectively activate brain protective structures.

The Unit can be used to inhibit pain syndromes of different etiology, treatment of neurocirculatory dystonia, hypertension disease (stage I-II), hypotension , alcohol withdrawal syndrome, to enhance immune system, accelerate healing of wounds, burns, gastric ulcers, acute non-complicated heart attack, to treat diffuse itching dermatosis and other skin diseases, sensorineural hearing loss, vasomotor rhinitis, toxicoses of pregnancy, primary osteoarthrosis deformans.

2. Specification and Service Functions

2.1. Specification

Stimulating Current.....Rectangular bipolar impulses
.....Rectangular monopolar impulses
Rectangular monopolar impulses with constant current, fixed ratio 1 : 1

Output range of control (working values):

- pulsed bipolar current .....from 0 to 5,00 mA
- pulsed monopolar current .....from 0 to 5,00 mA
- pulsed monopolar current with constant current (in total) .....from 0 to 5,00 mA

Procedure Duration Setup ..... from 5 to 60 min
Timer sampling period setup ..... 5 min
Electric power ..... 220 W, 50 Hz
Dimensions ..... 290 x 200 x 120 mm
Weight..... 1,5 kg
Operating life .....at least 5 years
Mean life ..... at least 3000 hours

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

Performance Monitoring.
Voice Aid while Setup mode of action.

Digital displays show: applied electric pulse current intensity (indicator-Current); pulse frequency of stimulating current (indicator-Time/Frequency); set up duration of session (indicator-Time/Frequency); time remained to the end of session (indicator-Time/Frequency); LEDs of mode of stimulating current and running regimen.

Automated gradual shutdown control of stimulating current after procedure.

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

3. Standard set contains:

3.1. "TRANSAIR-04" unit. 1
3.2. Set of electrodes. 1
3.3. Set of pads. 12
3.4. Certificate of equipment 1
3.5. CD-disk with recorded psychotherapy session. 1
3.6. Packing.....1

4. The exterior of the Unit and its controls

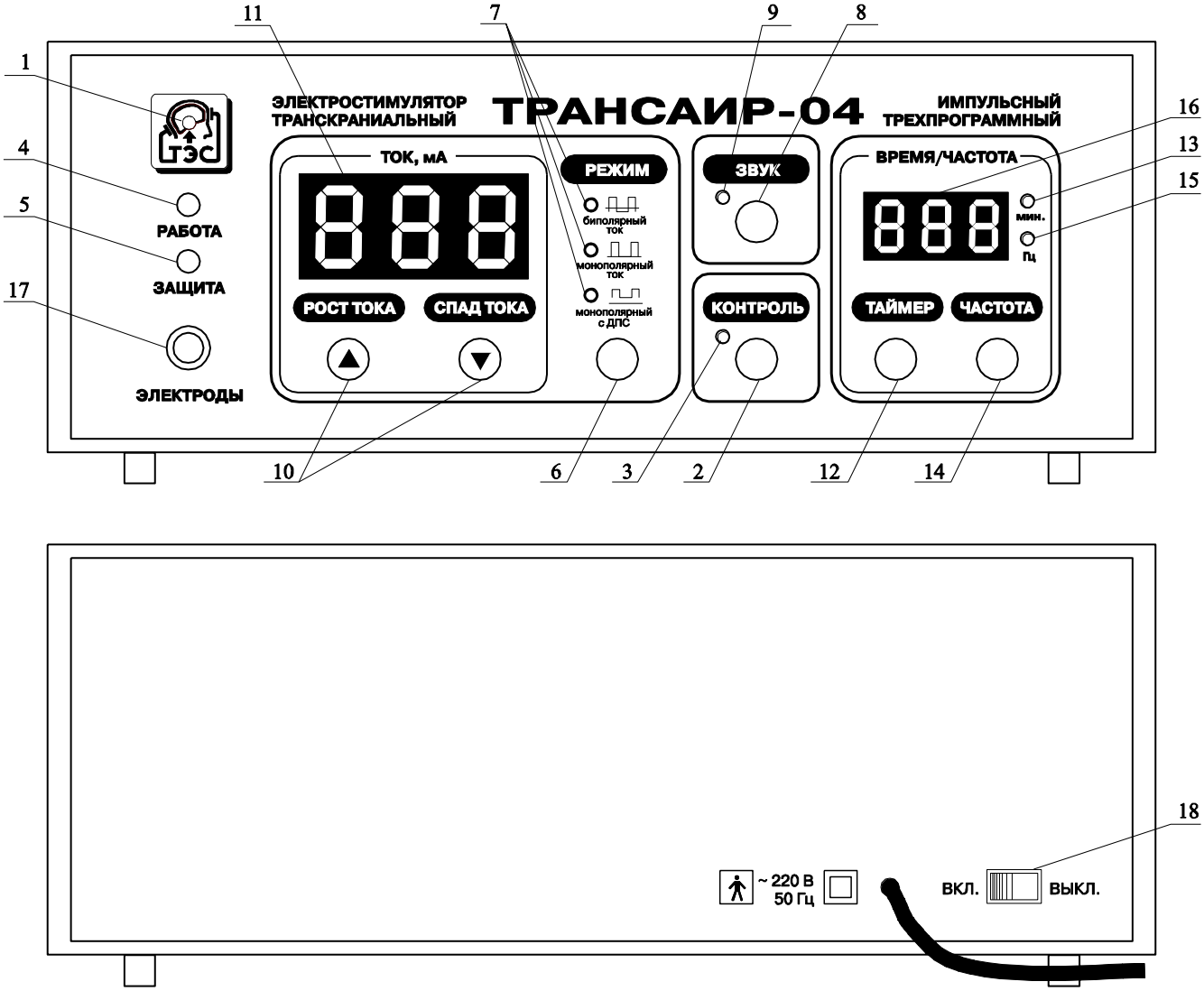
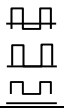


Fig. 1. Front panel with Controls of Unit and indicators and rear panel.

LEDTable 1.Description of Controls indicators and LEDs.

Table 1.

Controls indicators and LEDs	**Usage**
1. LED “TES”	Indication of power supply On.
2. Button “CONTROL”	Switch to the Performance Monitoring Mode (noncollocated).
3. LED “CONTROL”	Indication of Performance Monitoring Mode On.
4. LED “RUNNING”	Indication of the applied current is at electrodes.
5. LED“PROTECTION”	Indication of the Safety Mode On if current flow disturbances occur or button “CONTROL” is off.
6. Button “MODE”	Choose mode of stimulating current
7. LEDs Current mode: 	Indication of the chosen stimulating current mode: bipolar current; monopolar current; monopolar current with constant current.
8. Button “SOUND”	On/off for the Voice Aid Mode.
9. LED “SOUND”	Indication of Voice Aid Mode.
10. Buttons “CURRENT UP”, “CURRENT DOWN”	Control of stimulating current magnitude.
11. Indicator “Current, mA”	Indication of running stimulating current in mA.
12. Button “TIMER”	Setup of procedure duration. Time control remained to the end of procedure or Performance Monitoring Mode.
13. LED “min.”	Indication of the working digital indicator “TIME/FREQUENCY”, in mode “time display”.
14. Button “FREQUENCY”	Controls pulse frequency of stimulating current.
15. LED “Hz”	Indication of the working digital indicator “TIME/FREQUENCY”, in mode “pulse frequency of stimulating current”.
16. Indicator “TIME/FREQUENCY”	Indication of procedure duration, time remained to the end (min), or frequency of stimulating current (Hz).
17. Socket “ELECTRODES”	Connect electrodes to the Unit.
18. Power switch (rear side)	On/off power supply.

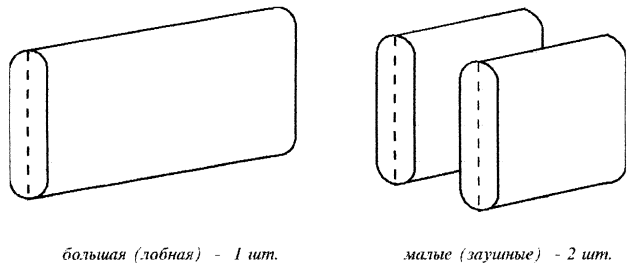


Fig.2. Set of Pads

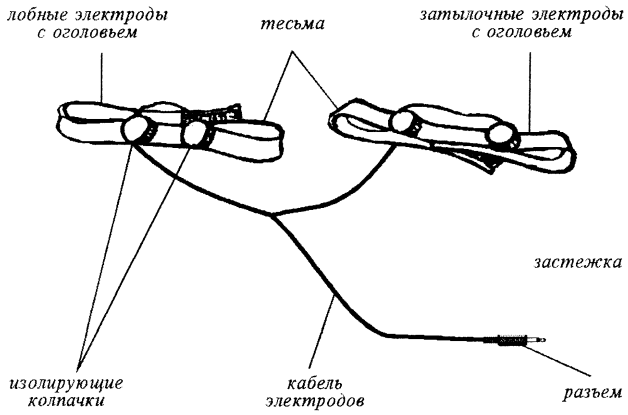


Fig.3. Electrodes.

5. Safety precautions

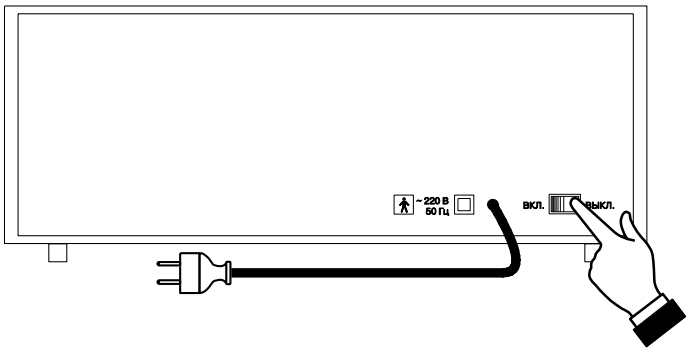
5.1. Design of the Unit provides with complete electrical safety for a patient as well as medical staff.
5.2. Before reading Certificate of equipment and Medical instructions it is forbidden to use the Unit.
5.3. It is forbidden to keep the working Unit with open housing.
5.4. Automated checking Procedure should be performed before medical usage (see 6.2.)
5.5. It is forbidden to soak the Pads with any liquids excepting tap water.
5.6. It is forbidden to connect malfunctioning Unit to Patient.
5.7. It is not allowed to replace set electrodes with custom-made electrodes.
5.8. 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.
5.9. 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.

6. Work sequence

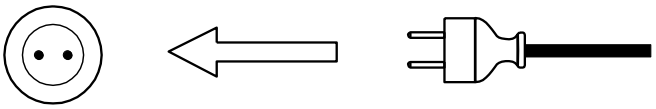
6.1. Preparation of the Unit for Start-up.

6.1.1. 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.
6.1.2. 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; set items correspond to Description, Paragraph 3; any visual mechanical damage of the Unit, mains cable, socket, and Electrodes.
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 not be soaked.
6.1.4. All procedures should be performed only after thorough reading of Certificate of equipment and Medical instructions.

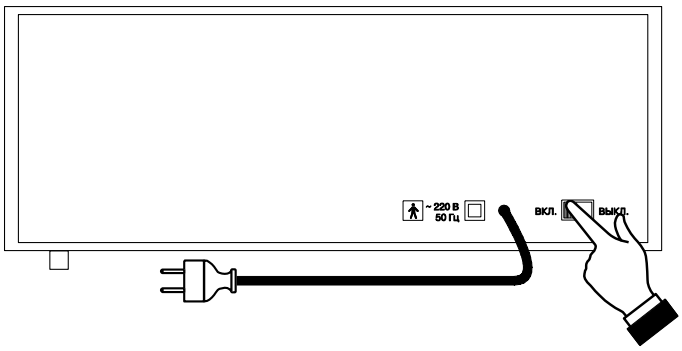
6.2. Checking Procedure



6.2.1. Make sure that key “POWER” put in position “OFF”.

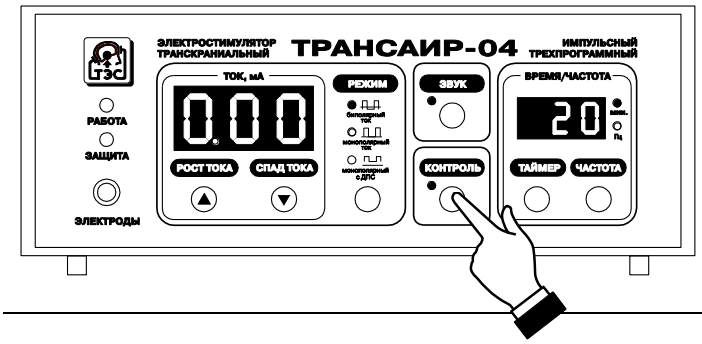


6.2.2. Connect the Unit to the mains cord via socket.



6.2.3. Switch power on by putting key “POWER” at the rear side in position “ON”

6.2.4. Digital indicators show:
“CURRENT, mA” – digits “0.00”,
“TIME/FREQUENCY” – “20”.
LEDs :
“TES”
“MODE bipolar current”,
“SOUND”,
“min”.



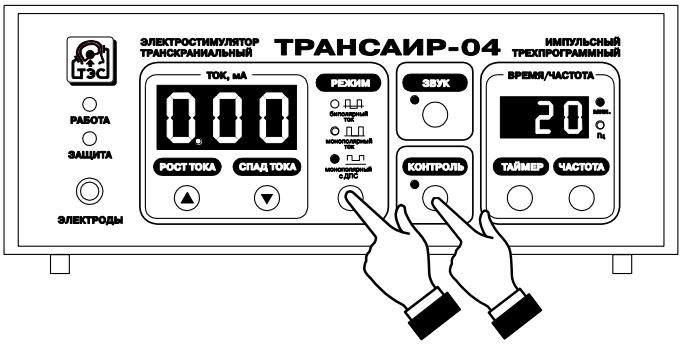
6.2.5. Check the running Unit in mode “bipolar pulses”.
For this press button “CONTROL”.
Voice Aid command is being heard “AUTOCHECKING”, LED “CONTROL” is highlighted, i.e. Checking Procedure in mode “bipolar pulses” is in progress.
If Unit is in service Voice Aid command is being heard “END OF CHECKING.”

a) b)

6.2.6. Check the running Unit in mode "monopolar pulses".

a) For this press button "MODE" so that indicator "monopolar current" is highlighted, which is accompanied by Voice Aid command "MONOPOLAR"

b) press button "CONTROL". Voice Aid command is being heard "AUTOCHECKING", LED "CONTROL" is highlighted. If Unit is in service Voice Aid command is being heard "END OF CHECKING."



a) b)

6.2.7. Check the running Unit in mode "monopolar pulses in combination with constant current".

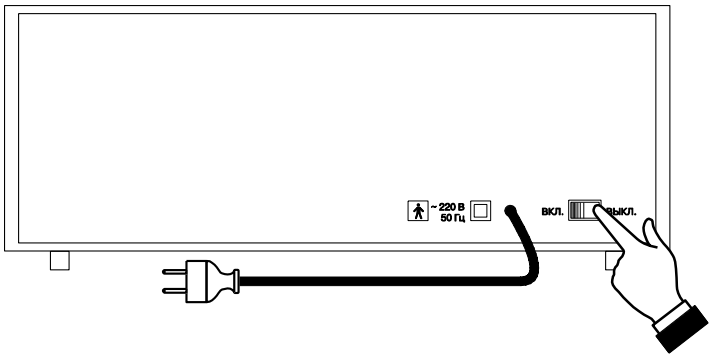
For this:

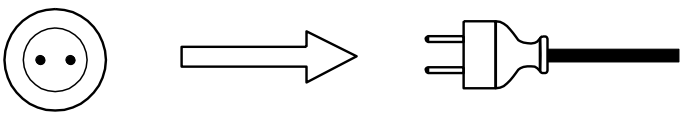
a) press button "MODE" so that indicator "monopolar current with additional direct current" is highlighted. Voice Aid command is being heard "MONOPOLAR CURRENT WITH direct current";

b) press button "CONTROL", so that LED "CONTROL" is highlighted. Voice Aid command is being heard "AUTOCHECKING".

If Unit is in service Voice Aid command is being heard "END OF CHECKING."

In case of Unit malfunctioning was found during running modes of autochecking, then Voice Aid command is not being heard "END OF CHECKING", and Unit will not further respond to pressing any buttons until it will be switched off.

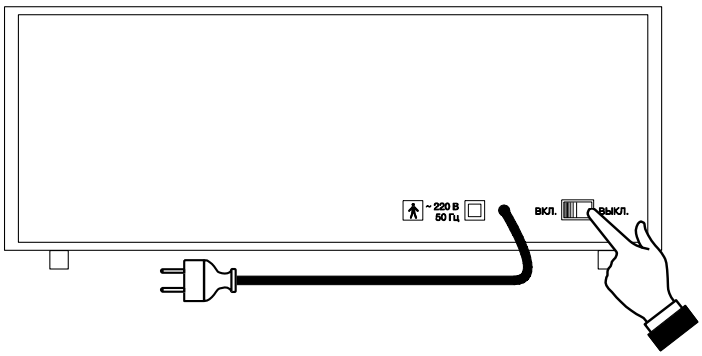




6.2.8. After Autochecking mode is completed, and if you want to use the Unit so you may start carrying out a session according to Paragraph 6.3.

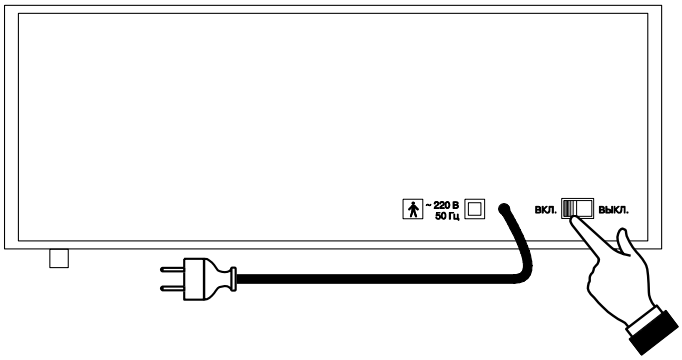
If you do not want to use it, so switch it off by putting the key "POWER" to position "OFF". Unplug the Unit.

6.3. Carrying out Procedures



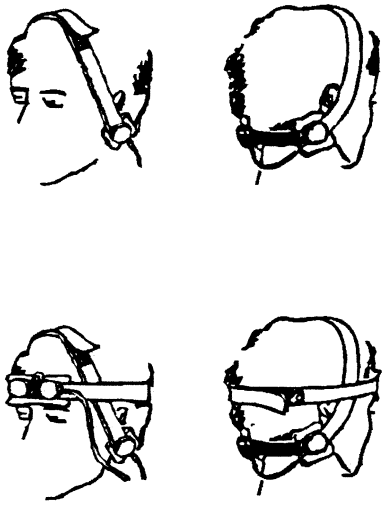
6.3.1. Make sure that key “POWER” is in position “OFF.

6.3.2. Connect the Unit to the mains cord via socket.



6.3.3. Switch power on, by putting key “POWER” at the rear side to position “ON”.

6.3.4. Digital display shows:
“CURRENT, mA” – digits “0.00”,
“TIME/FREQUENCY” – “20”.
LEDs will highlight: “TES”, “MODE bipolar current”, “SOUND”, “min”.



6.3.5. Fix electrodes on patient’s head. To do this you need:
1). Moisten the Pads abundantly with warm tap water and place them on mastoid processes so that no hairs are beneath them;
2). Put a headband with retromastoid electrodes over the pads, and fix them with Velcro closure above forehead;
3). Moisten the frontal pad and place it over forehead so that the its lower edge should be at the level of eyebrows;
4). Put a headband with frontal electrodes over the 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.

6.3.5. Connect electrodes to the Unit by putting them into sockets “ELECTRODES”.

6.3.6. Choose mode of stimulating current. For this, press button “MODE” until LED at the level of chosen current is highlighted.

6.3.7. Set up duration of session by using button “TIMER” (each pressing adds up 5 min more). Recommended duration of 1st session – 20 min, further – 30 min, until it is prescribed by physician. You can change duration of session only before it started.

6.3.8. If 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.

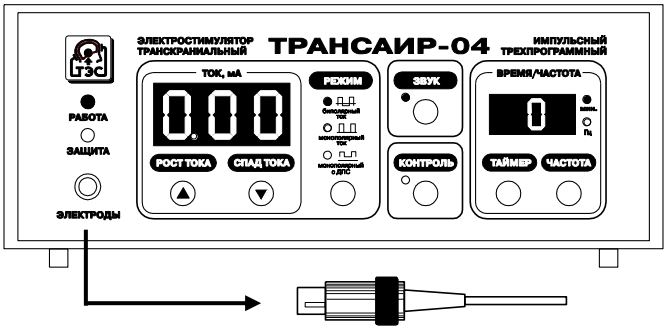
6.3.9. Start to find out the value of stimulating current for a patient. For this press button “ ▲ ” (“CURRENT UP”). Increase its magnitude until a patient started to sense tingling or slight vibration under the electrodes. While adapting to the running current you may further increase its magnitude. For 1st session recommended current is approx. 1 mA. After reaching a value 0.2 mA set up programme will start, and countdown will begin. It is accompanied with flashing LED “RUNNING”, that stops only at the end of session.

6.3.10. To decrease stimulating current use button “CURRENT DOWN”.

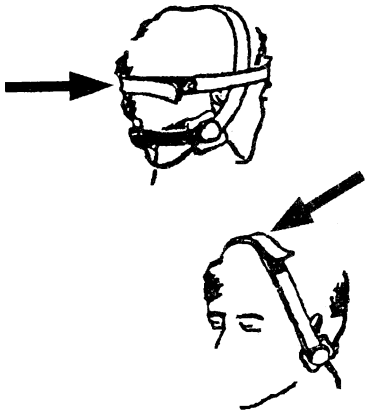
6.3.11. While carrying out the procedure indicator “TIME/FREQUENCY” shows digits, that correspond to time remained to the end of session.

6.3.12. By pressing button “FREQUENCY” for several seconds indicator “TIME/FREQUENCY” will show digits that correspond to pulse frequency of stimulating current. It will then be followed by digits, that correspond to time remained to the end of session.

6.3.13. 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". You will see that indicator "TIME/FREQUENCY" displays "0", indicator "CURRENT" – "0.00" mA, and LED "RUNNING" will fade out.

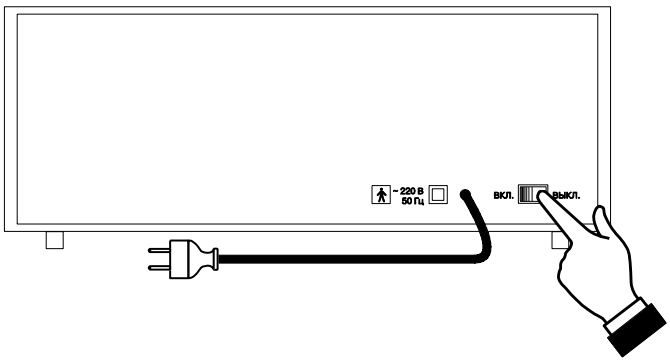


6.3.14. Disconnect electrodes from the Unit.

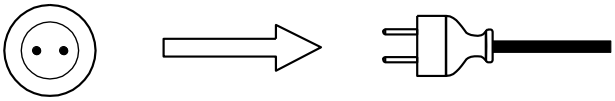


6.3.15. Take off the electrodes of patient's head following such sequence:
1) take off the frontal electrodes and major pad;
2) take off retromastoid electrodes and minor pads.

After procedure is finished the pads should be washed out or boiled without adding any soap or washing powder.



6.3.16. Switch off the Unit by putting key "POWER" in position "OFF".



6.3.17. Unplug the Unit from the mains socket[1].

After usage pads should be dried up.

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 14). 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:

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 is being made at expenses of Customer.

7.2. 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. 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
When plugging the Unit into mains and pressing button "ON" green LED of "Switch-on" at the center of TES logotype does not flash. Unit does not respond and not get turned on.	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.
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".	No contact in electrode sockets.	Check contact in the socket.
	Discontinuity of electrode cords..	Check cords and repair disconnection.
	Discontinuity of electric cords under electrode caps.	Check contact by unscrewing electrode caps.
	Pads dried up or soaked insufficiently.	Abundantly soak the pads and less intensively squeeze them.

8. Acceptance Certificate

Unit "TRANSAIR-04"

Construction number_____ tested and certified for operation and maintenance.

Date of manufacture «_____» _____ 200 .

Stamp here QC Department Representative _____

9. Warranty

9.1. Manufacturer guarantees that "TRANSAIR-04" 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. Warrantly 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:
Russia, Saint-Petersburg 199034, Makarov embankment, 6, "TES Center" Tel./Fax +7 (812) 328-42-51.

Unit “TRANSAIR-04”

Construction number _____

Shipping day: «____» _____ 200 .

Certified by _____ /_____/

Stamp here

9.7. 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).

Medical Use Instruction on
Transcranial Pulsed Electric Stimulator "Transair-04"
BMEA.941514.004 И

10. Purpose

10.1. The Instruction is compiled for Transcranial Pulsed Electric Stimulators "Transair", presented hereinafter "Transair-04".
10.2. Transcranial Pulsed Electric Stimulator "Transair-04" is designed for carrying out therapeutic procedures of non-invasive transcranial electrostimutation 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.

11 Brief list of Institutions that were involved in Research and Clinical studies 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, chair of physiology of diving and aerospace medicine).
4. Polenov Research Institute of Neurosurgery (departments of anaesthesiology, surgery of peripheral nerves).
5. Saint-Petersburg Hospital # 1 (department of cardiology), Hospital #18 (department of gastroenterology).
6. Saint-Petersburg Research Hospital of Ear, Nose, Throat, Speech (department of audiology).
7. Saint-Petersburg Institute of Human Brain, Russian Academy of Sciences (department of neurosurgery).
8. Saint-Petersburg Institute of Improvement of Professional Skills (department of physiology, department of therapy).
9. Leningrad District Narcological Dispensary.
10. Saint-Petersburg Neuropsychiatric Dispensary 1.
11. Petrov Institute of Oncology, Ministry of Health, Russian Federation (department of pre-clinical trials, department of anaesthesiology).
12. Saint-Petersburg Oncologic Dispensary (anti-pain service).
13. Sklifosovsky Research Institute of Medical Ambulance (burns unit, department of urgent cardiology, gastroenterology), Moscow.
14. Burdenko Central Military Hospital (department of anaesthesiology), Moscow.
15. All-Russian Cardiologic Research Center , Moscow.
16. Research Institute of Experimental Medicine, Russian Academy of Medical Sciences (department of non-specific resistance), Saint-Petersburg.

17. Hospitals at: Baltic Plant [Saint-Petersburg], Kalinin Plant [Saint-Petersburg], JSC Gorky Automobile Plant, Nizhny Novgorod.
18. Medical Academy of Postgraduate Education (Department of pediatrics, dermatology, obstetrics and gynecology), Saint-Petersburg.
19. Volgograd State Medical University (Department of clinical pharmacology, therapy, obstetrics and gynecology)
20. Kuban State Medical Academy (Departments of pathologic physiology? neurology) Krasnodar.
21. Filatov Institute of Eye Diseases and Tissue Therapy, Ukraine Academy of Medical Sciences, Odessa.

12. Basic indications for application

12.1. Management of acute, subacute and chronic pain syndromes: radiculitis, osteochondrosis, neuralgia, trigeminal neuritis, headaches of different etiology, including migraine, phantom pains as well as pain syndrome in patients with oncologic diagnosis.
12.2. Stress conditions, depression, aanxiety, performance decrement, chronic fatigue syndrome.
12.3. Hypertension disease (stage I-II), Hypotension, neurocirculatory dystonia.
12.4. Sensorineural hearing loss, including professional loss.
12.5. Posttraumatic and postoperative wounds, burns, ulcers, including Gastric and duodenal ulcers, trophic ulcers.
12.6. Diffuse itching dermatosis, neurodermitis, eczema, seborrhea.
12.7. Depression of immune system under immunodeficiency.
12.9. Primary osteoarthrosis.
12.10. Alcohol withdrawal syndrome, alcohol affective disorders, pathologic addiction to alcohol. Opium addiction.
12.11. Recent pregnancy toxicosis.
12.12. Climacteric neurosis.
12.13. Allergic conditions: pollen fever, diathesis, vasomotor rhinitis, bronchial asthma.

13. Basic contra-indications

13.1. Convulsive state, epilepsy.
13.2. Traumas and brain tumors, infectious diseases of central nervous system.
13.3. Hydrocephaly.
13.4. Acute psychiatric disorders.
13.5. Hypertensive disease stage III, hypertensic crisis
13.6. Thyrotoxicosis.
13.7. Atrial fibrillation.
13.8 Skin lesions at the site of applied electrodes.
13.9. Implanted electrostimulators.
13.10. Age under 5 years.

14. Mode of action of transcranial pulsed electric stimulation. Specific features of “Transair” Unit

14.1. Features of transcranial pulsed electrostimulation

On of the features of electric impact created by “TRANSAIR-04” Unit is that it produces special electric square-wave pulses, that have fixed frequency and length and direct current. 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 electric stimulation 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 systems of brain.

It was found that starting at 10–15 after TES session release of opioid peptides (ß-endorphin) is increased, which is associated with marked increased levels in brain, cerebro-spinial fluid and blood. Also, aside from opiatergic and serotoninergic neurotransmitter structures are involved.

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

14.2.1. ANALGESIA

It is mediated by stimulation of opioid receptors within 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, 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 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].

14.2.2. 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 central effect on nervous system, which are known to hamper turnover of opioid peptides.

14.2.3. 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.

14.2.4. 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 ß-endorphine. After TES therapy a significant reduction of depression as well as addiction can be found [14–16].

14.3. Pathways that are responsible for development of the peripheral therapeutic effects

14.3.1. 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 cicatrical processes in myocardium under heart attack, as well as treatment of sensorineural hearing loss caused by damage of auditory nerve. [10,17–21].

14.3.2. 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 analgetic impact, that can be blocked by Naloxone [22–29].

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

14.4.1. ITCHING DERMATOSIS AND NEURODERMATITIS

Mode of action for TES-therapy is based on activation of opioid- and serotoninergic 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 prophilaxis of pustulous complications.

14.4.2. 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].

15. Description of procedure

Most of attention a physician should pay to finding out an appropriate magnitude of stimulating current, duration of procedure, and rate of sessions.

In general these steps include:

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

15.1. Preparation of patient for TES-session

15.1.1. Before staring TES session make sure that patient has no contra-indications.

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

15.1.3. 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.

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

15.1.5. 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.

15.2. Preparation of TRANSAIR Unit for usage

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

15.2.2. 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.

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

15.3. How to run a TES-session

15.3.1. 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.

15.3.2. 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.

15.3.3. The main criteria as to how correctly find out an individual regimen for each patient are tolerability ass 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.

15.3.4. 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.

15.3.5. 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.

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

15.3.7. 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.

15.3.8. Please, find below proposed regimens of "TRANSAIR" Unit that may be applied to cure different diseases and syndromes.

15.4. Usage of TES therapy in combination with other treatment

15.4.1. 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.

16. Patient's condition during and after therapeutic course

16.1. 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.
16.2. 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.
16.3. 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.
16.4 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 excessed. 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.
16.5. 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.

17. Recommendations on usage of "TRANSAIR-04" Unit in case of different diseases

Diseases and syndromes	Regimen
Neurological Diseases and syndromes 1. Post-stress conditions, depressions, increased fatigability, performance decrement, vegetative-vascular disorders. 2. Spondylogenic radicular and vegetative pains: - lumbosacral radiculitis; - cervical and thoracic osteochondrosis. 3. Trigeminal neuralgia. 4. Posttraumatic and post-herpetic neuritides. 5. Headaches: - episodes of migraine; - postconcussion syndrome; - cerebral arachnoiditis; - diencephalic syndrome.	6–12 sessions per course, once a day or every other day, for 30–40 min. Bipolar current 1.0–2.0 mA
Surgery, traumatology 1. Post-operative, traumatic wounds, burns 2. Trophic ulcers 3. Sports traumas.	5–7 sessions per course 1–2 times a day, for 30–40 min. Monopolar current 1.0–3.0 mA
Gastroenterology 1. Gastric and duodenal ulcers. 2. Gastritides and gastroduodenitides. 3. Liver and pancreas diseases.	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
Other medical conditions and syndromes 1. Hypertension I-II stage, hypotension, vegetative-vascular dystonia. 2. Bronchial asthma. 3. Primary arthrosis deformans, osteochondrosis.	6–12 sessions per course, once a day or every other day, for 30 min. Bipolar current up to 2 mA
Dental diseases and syndromes 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.	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

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 ENT organs 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
Alcoholism and opium 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 +additional direct current up to 5 mA
Pain syndromes in oncologic patients 1. Chronic pain syndromes in oncologic patients. 2. Post-operative pains in oncologic patients. 3. Pains caused by chemotherapeuty and radiation treatment.	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

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.

References (check website)

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. Mejdunarodn. 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., Krasyukov 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 repare. 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., Tsirulnikov 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

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**
   Zabolotny'h 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 structurs. Priority: 05.01.2000.
8. **Russian Federation Inventor's Patent # 2214842**
   Cirul'nikov 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. Priority: 01.11.2000