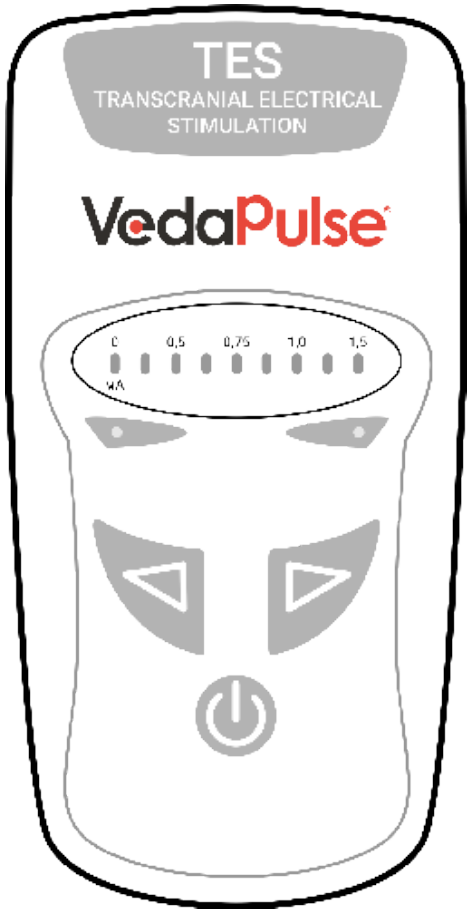
VedaPulse®

USER MANUAL



VedaPulse-TES
(DOCTOR TES-03)

Transcranial Pulsed Bipolar Electric Stimulator

OOO «Biokvant»
2021

VedaPulse

Contents:

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1. Purpose of use

Transcranial Pulsed Bipolar Electric Stimulator 'DOCTOR TES-03' is intended for non-invasive selective transcranial electrical stimulation (TES) of endorphinergic structures of the brain.

The device is used in physiotherapy for therapeutic, neurological, otorhinolaryngological, gynecological, pediatric, and other diseases in order to normalize the psychophysiological state, to relieve pain syndromes of various origins, to accelerate the healing of organs and tissues with their injuries of various nature, to improve regional and systemic circulation, to stimulate immunity, to prevent and treat alcoholism and opium addiction, to normalize vegetative and hormonal status.

2. Basic technical data and service functions

2.1 Specifications

Stimulating current	Rectangular bipolar impulses
Current intensity adjustment range, mA	From 0,02 to 1,5
Automatic session timer, minutes	30
Electric power	'Crona' type battery 7,3–9 V
Dimensions (L×W×H), mm	115×60×40
Weight, with battery, kg	No more than 0,15
Service life, years	No less than 5
Average runtime, hours	No less than 2,000

2.2 Services

- Automatic monitoring of the device performance;
- Display of the effective stimulating current intensity on the LED indicator scale;
- Automatic smooth shutdown of the stimulating current at the end of the procedure (in 30 minutes);
- Low battery LED indicator;
- Multi-level patient protection system (see table 4).

3. Standard set contains:

3.1 Electronic unit of the device ‘DOCTOR TES-03’, pcs.....1
3.2 Self-adhesive electrodes with cable, sets.....1
3.3 User’s manual, pcs.....1
3.4 Packaging, pcs.....1

4. Exterior of the DOCTOR TES-03 body and its controls

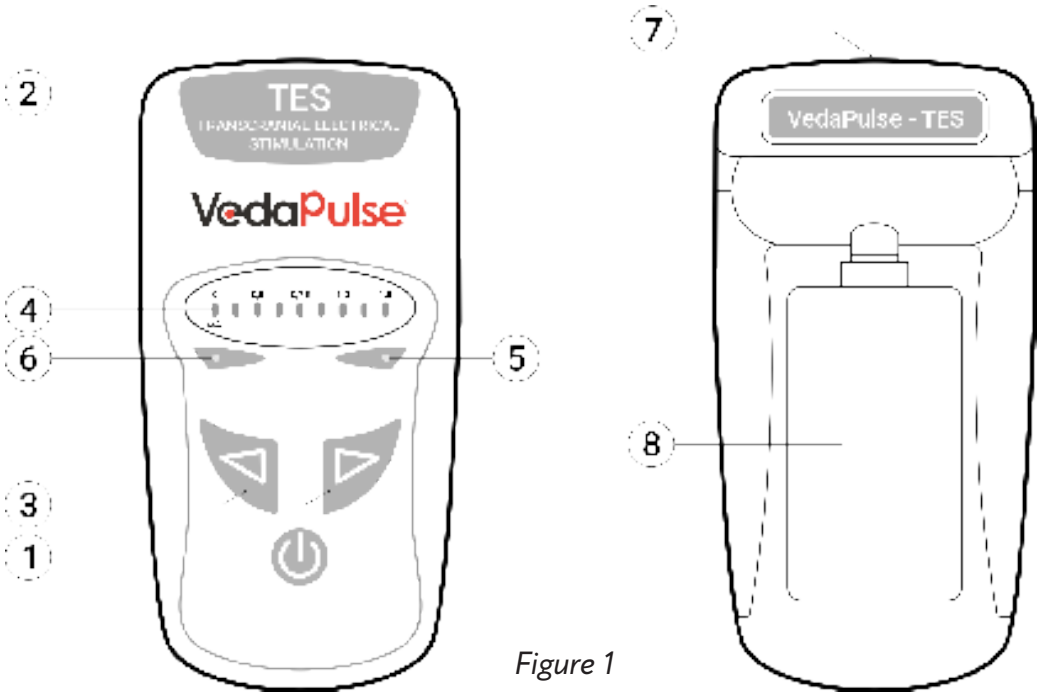

Figure 1

Control or display unit	Purpose
1 – On/Off button ⏻	Indicates power supply
2 – Green ‘Power’ LED indicator	Flashes in the procedure mode
3 – ‘Set current intensity’ buttons	Stimulating current adjustment: < – decrease current > – increase current
4 – Blue LED indicators of the current intensity in mA	Stimulating current indicator
5 – Yellow ‘Battery’ LED indicator	Battery status indication: **Not lit** - sufficient battery capacity, you can perform the procedure; **Blinks** - insufficient battery capacity, you need to replace the battery

6 – Red ‘Protection’ LED indicator	Blinks when the protection is activated in case of current outages in the electrode circuit
7 – Patient cable socket	Connects electrodes to the device
8 – Battery compartment cover	Opens to replace the battery

5. Safety precautions

5.1 The design of the device ensures proper safety for the user.

5.2 It is forbidden to use the device without first reading this manual.

5.3 It is forbidden to turn on the device when the housing is open.

5.4 It is forbidden to use a faulty device.

5.5 Do not use the device in damp areas (such as bathrooms).

5.6 It is forbidden to wet the silicone cushions on the electrodes with any liquids other than plain water.

5.7 It is not allowed to replace the electrodes from the package with any other electrode types.

5.8 If the device has been stored or transported at low temperatures, keep it at room temperature for at least 2 hours before switching it on.

6. Work sequence

6.1 Prepare the unit for operation

6.1.1 In case the unit was transported or stored at low temperatures or high humidity, it is necessary to keep it at room temperature for at least 2 hours before switching on.

6.1.2 Before switching the device on for the first time, or after storing it for a long time, examine the exterior of the unit to check that a seal is not broken; package contents; no visual mechanical damage of the unit and/or electrodes.

6.1.3 Place the device in a convenient location. Disinfect the device box: wipe it with a tampon moistened in a 3% solution of hydrogen peroxide with addition of 0.5% detergent solution. Tampon should be squeezed out.

6.1.4 Self-adhesive electrodes are individual and do not require disinfection. If they lose their adhesive properties, wash the gel surface with warm water, then dry them for 3-5 minutes in the air. Boiling is not allowed!

6.1.5 Start the work after reviewing this manual.

6.2 Performance check (automatic)

6.2.1 Make sure that there is a connected power cell in the battery compartment or connect the battery to the appropriate pins. To do this, remove the battery compartment cover (fig. 1). Place the excess wire in the battery compartment. Plug the power cord connector to the battery, place the battery in the device compartment, and close the cover until it clicks.

6.2.2 Switch on the device. To do this, click the 'On/Off' ⏻ button (fig. 1):
• For several seconds, the device will undergo an automatic performance check, i.e. on the 'mA' current indicator (fig. 1), the LEDs from 0 to 1.5 mA and then from 1.5 to 0 mA will light up sequentially. Only the leftmost LED remains lit afterwards;
• You will hear a beeping sound, indicating the end of the auto-check procedure. The device is ready for operation.

6.2.3 If you are going to perform a TES procedure, read paragraph 9.

6.2.4 If you do not wish to perform a TES procedure, switch off the device with the 'On/Off' ⏻ button (fig. 1).

6.3 Preparation of electrodes

Electrode system (fig. 2) consists of:
• gel electrodes;
• contact wires.

The electrodes include:
• one big frontal (on forehead) (13);
• two small postaural (placed behind ears) (14).

In order to assemble the electrode system, it is necessary to:
• unpack the contact wires and electrodes;
• connect the plugs (19, 20) of the contact wires with the same color electrode sockets (15, 16);
• connect the plug of the contact wire (18) to the socket (fig. 1) on the device box.

The electrode system is ready for operation.

A properly assembled electrode system does not need to be checked. If the electrodes or contact wires themselves are mechanically damaged, they must be replaced in a service center or by the manufacturer.

Gel electrodes are individual, but reusable. Their conductive properties are preserved for up to 1 year. During operation and storage, the sticky gel layer may become dirty

or dry. To restore the adhesive properties, rinse the gel surface under a gentle stream of cool water for 20-30 seconds. Place the electrodes to dry with the gel side facing up for 10-15 minutes, and then glue them to a transparent plastic plate. After this manipulation, the adhesion and working resistance of the electrodes will be restored. It is acceptable to flush the electrodes before each procedure. Before using, dry the non-working (reverse) surface of the electrodes with a napkin or cloth.

Note: The electrodes must not be boiled!

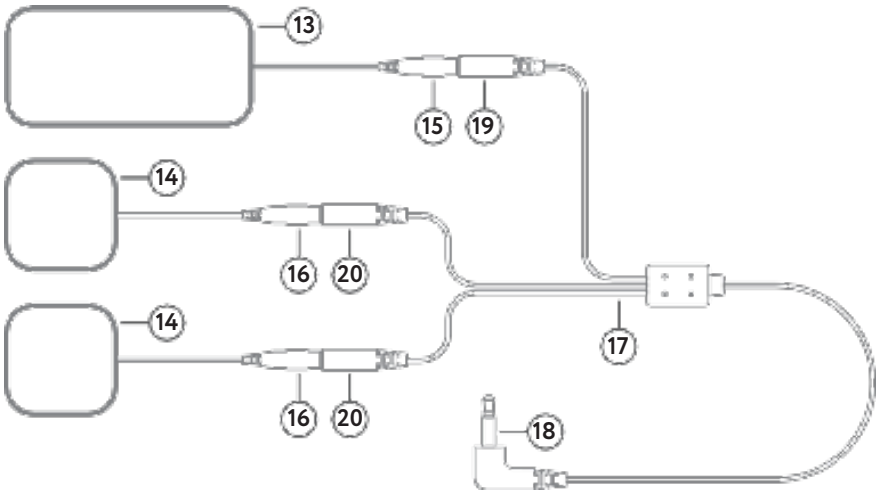

Figure 2

6.4 Checking the performance of electrodes

6.4.1 Connect the electrode cable with the cable plug (fig. 2) to the device socket (fig. 1).

6.4.2 Switch on the device with the 'On/off' ⏻ button (fig. 1). Wait until the device is ready for operation.

6.4.3 If self-adhesive electrodes are used with the patient's cable (fig. 2), the patient's cable should be checked. To do this, connect the white plug with any colored plug, making contact with metal parts.

6.4.4 Press and hold the 'Increase current' > button (fig. 1). With fault-free electrodes, the current will gradually increase from 0 mA to 1.5 mA, which will be indicated by the successively illuminated LED indicators of current increase. Release the button.

NOTE! In case electric current does not change, refer to the tables 3 and 4 of the actual manual for troubleshooting. If a problem is not listed in the manual, contact the manufacturer or service center.

6.4.5 Press the 'Decrease current' button < (fig. 1) and control the current reduction from 1,5 mA to 0 mA on the current indicator (fig. 1). Release the button.

6.4.6 If you are not performing TES session, disconnect the wires from the electrodes and the device. Switch off the device.

ATTENTION! Check electrodes only in case you have doubts that the device operates properly.

Note: the device requires power battery of 'Crona' type to operate. Due to the low current consumption, one new battery allows performing at least 20 procedures. It is recommended to disconnect the battery and remove it from the compartment in case the device is not used for a long time.

7. Indications for use

7.1 Immersion in transcendental states by activating the production of opioid hormones in the body (meditation, breathing practices);

7.2 Normalization of psychophysiological status in anxiety states and disorders due to antidepressant and sedative effect;

7.3 Correction of sleep disorders and reduction of fatigue;

7.4 Restoration and improvement of cognitive functions in patients with psychoneurological pathology (defective memory, mental performance and other cognitive functions);

7.5 Correction of psychosomatic disorders, complex therapy of psychosomatic pathologies;

7.6 Release from addictions (pharmacological, alcoholic, tobacco smoking);

7.7 Restoration of neuroplasticity for people in mature age (40+), patients who have received a brain injury or stroke;

7.8 Relief of pain syndromes in neurology (spondylogenic pain, radiculitis, osteochondrosis, headaches, postoperative pain, arthrosis pain, household injury, etc.);

7.9 Restoring the balance of the endocrine system;

7.10 Immunomodulatory effect.

8. Basic contradictions for application

8.1 Convulsive state, epilepsy, acute mental disorders;

8.2 Traumas and brain tumors, infectious diseases of central nervous system (acute stage);

8.3 Hypertensive disease stage III, hypertensive crisis;

8.4 Hydrocephaly;

8.5 Hyperthyrosis;

8.6 Atrial fibrillation;

8.7 Skin lesions at the site of applied electrodes;

8.8 Implanted pacemakers, including cardiostimulators;

8.9 Age under 5 years.

9. Operational procedure

9.1 General recommendations

9.1.1 It is recommended to perform TES therapy, when a patient is in a comfortable lying or sitting position.

9.1.2 First session is supposed to be an introductory and aimed at adapting a patient to a procedure. Thus, intensity of stimulating current must be used at minimum, ranging between 0,2 - 0.5 mA, for 15–20 min (stop time manually by slowly decreasing current to 0 mA).

9.1.3 The main criteria of an acceptable individual regimen for each patient are both good tolerance of the sessions and positive clinical effect. After the first procedure, the current can be gradually increased by 0.2-0.4 mA, compared to each previous session, up to a maximum of 1.5 mA, noting the effect and condition after each procedure.

9.1.4 If the result is positive after 1-3 procedures, treatment is continued at the same current values at which the result was obtained. If a positive result is not achieved after 5-6 procedures, consult to your attending physician.

9.1.5 In case of any deterioration of health during TES therapy, treatment should be discontinued, and further consultation to your attending physician is required.

9.1.6 After the end of each procedure, rest for 15-20 minutes is recommended. In case of possible redness of the skin under the electrodes, massage the skin and lubricate with a cosmetic moisturizer.

9.2 How to carry out procedures

9.2.1 Switch on the device by pressing the 'On/Off' ⏻ button (fig. 1) and wait for it to be ready for operation.

9.2.2 Make sure that the Battery indicator (fig. 1) is not lit or flashing.

9.2.3 Attach the electrodes to the head.

Process:

• Peel off the frontal rectangular electrode (size 5*9 cm) from the plastic base and place it gel side in the middle of the forehead horizontally, so that the hair and wire do not get under the electrode and ensure uniform adhesion to the skin (fig. 3.1).

• Peel off both square electrodes (size 5 cm), that are placed behind ears, from the plastic base and apply them with a gel layer on the skin of the mastoid behind the ears (wires down), so that hair and wires do not get under the electrodes and their uniform adhesion to the skin is ensured (figs 3.2 and 3.3).

• With a little tension, put on the fabric headband, as shown in fig. 3. A fabric headband (bandana) is used exclusively for additional fixation of the electrodes on the skin during the procedure (fig. 3.4).

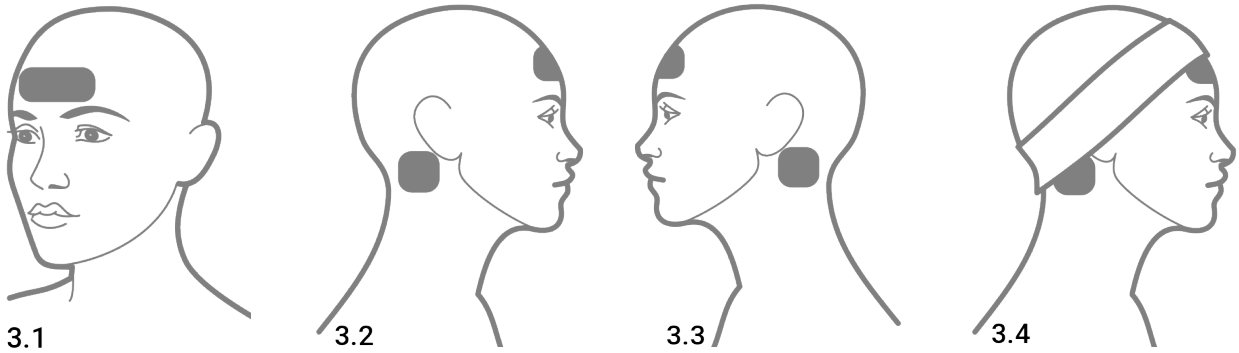

Figure 3

Attention! The skin should not be damaged in the places where the electrode is applied. A patient should remove any clips or earrings from ears, and make sure that no hair or wires get under the metal and gel parts of the electrodes and cushions. Do not allow the metal parts of the electrodes to meet the skin.

9.2.4 Connect the electrodes to the patient's cable (by color) and the device.

9.2.5 Start the procedure by selecting the amount of stimulating current. Click on the button > 'Increase current' (fig. 1) and increase the current until there is a slight tingling sensation or a subjective feeling of flashing light. At the same time, 'Power' LED will start flashing (fig. 1). The current will be indicated by the LEDs of the current growth scale that light up sequentially.

If during the procedure the current level begins to cause discomfort, its intensity should be reduced. To do this, click on the button < 'Decrease current' (fig. 1) until unpleasant sensations disappear.

Recommended current value for the first procedure is not more than 0.5 mA. For next procedures - not more than 1.5 mA. Approximate current values for various indications are shown in summary Table 2.

9.2.6 After procedure is completed, the device will automatically reduce current to 0 mA, and sound signal will be heard.

9.2.7 Disconnect the electrodes from the device. Remove the frontal electrodes first, then the ones behind ears.

If electrodes with cushions were used during the procedure, it is recommended to rinse or boil cushions without soap after. Self-adhesive electrodes should be lightly rinsed with cool running water for 10-15 seconds, dried for 4-5 minutes and glued to the base.
9.2.8 Switch off the device by pressing the 'On/Off' ⏻ button (fig. 1).

Table 2. Current intensity and duration of treatment session in various diseases

Diseases and syndromes	Treatment regimen
Neurological diseases and syndromes: 1. Stress-induced disorders, depression, reactive anxiety, sleep disorders, decreased performance. 2. Spondylogenic pinched and vegetative pain; • lumbosacral radiculitis; • thoracic and cervical spine osteochondrosis. 3. Trigeminal neuralgia. 4. Posttraumatic and postherpetic neuritis. 5. Headaches: • Tension headaches; • Migraine attacks; • Diencephalic syndrome; • Conditions following an ischemic stroke in the presence of positive dynamics, lasting at least 4 weeks.	6-12 sessions per course, once a day or every other day, for 30 min. Current up to 1.5 mA.
Surgery, traumatology: 1. Postoperative, traumatic wounds, burns. 2. Trophic ulcers. 3. Sports injuries.	5-7 sessions per course, once or twice per day, for 30-60 min.

Gastroenterology: 1. Stomach and duodenal ulcers. 2. Gastritis and gastroduodenitis. 3. Liver and pancreas chronic diseases. 4. Gastroesophageal reflux disease. 5. Irritable bowel syndrome.	10-15 sessions per course, once or twice per day, for 30 min. Current up to 1.5 mA.
Other therapeutic diseases and syndromes: 1. Hypertension I – II stages, hypotension, vegetative vascular dystonia. 2. Dyscirculatory encephalopathy. 3. Osteochondrosis, fibromyalgia, arthritis, arthrosis.	6-12 sessions per course, once per day, for 30 min. Current up to 1.0 mA.
Dentistry: 1. Trigeminal neuralgia and neuritis (true and acquired as a result of dental treatment). 2. Paresthesia of the oral and tongue mucosa. 3. Herpetic cheilitis. 4. Arthritis and osteoarthritis of the temporomandibular joint. 5. Postoperative pain due to tooth extraction.	6-12 sessions per course, once per day, for 30 min. Current up to 1.0 mA.
Ophthalmology: 1. Acute and chronic ocular pains associated with increased intraocular pressure in terminal glaucoma. 2. Cyclospasm.	6-10 sessions per course, once per day, for 30 min. Current up to 1.0 mA.
Diseases of ENT organs: 1. Sensorineural hearing loss, tinnitus aurium. 2. Vasomotor rhinitis. 3. Chronic nosebleeds.	10-15 sessions per course, once per 2 days, for 30 min. Current up to 1.0 mA.
Obstetrics and Gynecology: 1. Vomiting during recent pregnancy. 2. Premenstrual syndrome (pain, fatigue, mood changes). 3. Vegetative vascular disorders, headaches, menopausal disorders. 4. Urinary incontinence in women.	10-12 sessions per course, once per day, for 30 min. Current up to 1.5 mA.
Dermatology: 1. Itch, itching dermatosis. 2. Neurodermatitis. 3. Allergic skin manifestations. 4. Superficial seborrhea. 5. Psoriasis. 6. Lichen planus, including the oral cavity.	6-14 sessions per course, once per day, for 30 min. Current up to 1.5 mA.
Narcology: 1. Post-abstinence affective disorders. 2. Morbid attraction to alcohol and opiates consumption.	10-15 sessions per course, once per 3 days, for 30 min. Current up to 1.5 mA.

Note:
The recommended treatment duration and current intensity in the table were established during long-term clinical studies. In each specific case, the current intensity is selected individually. Herewith, the minimum current value is considered sufficient, when light tingling sensation, and weak vibration sensations appear in the places where the electrodes are applied. Make sure that these sensations during the procedure do not disappear during the procedure, but also do not become unpleasant or unbearable. In this case, the intensity of the stimulating current should be reduced until the feeling is comfortable.

Note:
If the protection system is activated during the procedure (the 'Protection' indicator lights up and the stimulating current gradually decreases to 0 mA on the 'Stimulating current' scale indicators), refer to Table 3 to eliminate the reason for the interruption of the procedure.

10. Common troubleshooting

If during the preparation of the device for operation, auto-checking of its operability, checking of electrodes or during the procedure, any inconsistency in the operation of the device is detected, you should refer to Tables 3, 4 for common troubles and remedies.

If the problem origin corresponds to those listed in the table, correct it yourself, following the instructions.

If the trouble is not listed in the table, please contact Biokvant Ltd. by phone +7 (913) 452-09-03 or by e-mail support@vedapulse.com to receive consultation.

Warranty repair and delivery of warranty devices to and from the consumer is carried out by Biokvant Ltd. without payment by the consumer.

Sending non-warranty devices for repair and back to the consumer is carried out at the expense of the consumer (included in the repair cost). Along with the device, the electrodes, passport, certificate of detected troubles (from organizations) or a letter describing the troubles (from individuals) should be sent in its original packaging. The attachment is listed in duplicate. Biokvant Ltd. is not responsible for the completeness of the equipment sent to repair without an attachment list.

Biokvant Ltd. is not liable for devices damaged during transfer in case of incorrect packing.

Table 3.

Fault	Probable cause	Resolution
When the device is turned on, the green 'Power' indicator does not light up, auto-checking procedure is not on (the LED track does not light up).	Low battery	Replace the battery
The device is being switched on, auto-checking procedure is in process (the current indicator LED light up alternately) however LED 'Battery' is blinking.	Low battery	Replace the battery
At the start of the procedure, when the 'current up' button is pressed, the red 'Protection' indicator flashes if no increase occurs.	There is no contact in the electrode connector. No contact of the electrodes with the scalp.	Check the quality of the contact in the 'Electrodes' connector: the electrode connector must be firmly inserted into the 'Electrodes' connector of the device. Remove and re-put the electrodes, fixing them tightly on the head.
	Breakage in the electrode wires.	Check the wires and fix the breakage or replace the wire with a new one.
Не удается добиться увеличения тока вCurrent increase cannot be achieved during the procedure.	The cushions were not wet or dried during the procedure.	Wet the cushions thoroughly or wash the self-adhesive electrodes.
	Poor fit of electrodes and cushions to the head.	Fit the headband holding the electrodes more tightly.

Table 4. Multi-level security system

Type of protection	Manifestation	User's Actions
Protection against accidental disconnection of the electrodes from the device.	During the procedure, the electrodes are accidentally removed from the device connector (for example, when the device falls), the device will immediately go into sleep mode with a complete current shutdown. Only the '0 mA' LED is lit.	Switch the device off and on again. Check the device in auto-checking mode. Check the electrodes for broken wires. If the device is in order and there is no wire breakage, perform the procedure.
Low battery protection.	The 'Battery' indicator starts flashing during the procedure.	Continue the procedure. When finished, switch off the device and replace the battery.
	When the device is switched on, the 'Battery' indicator does not light up, the device is not tested, in the procedure mode the 'TES' indicator does not blink.	Switch off the device and replace the battery.
Protection against breakage of electrodes, poor contact on the 'Electrodes' socket connector, loose fit, drying of gaskets or self-adhesive electrodes.	Automatic reduction of current to a certain amount or to 0 mA, the attempt to regain the current again fails. The 'Protection' light flashes.	If the current has decreased slightly (for example, when the pads are dry or loose), attach the electrodes with the pads more tightly to the head or continue the procedure. If the current drops to zero, disconnect the electrodes from the device, switch off the device, check the electrodes for wire breakage, moisten the cushions (Table 2). If a breakage is detected, contact the manufacturer.

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11. Warranty

The Seller guarantees that the device meets the requirements of technical specifications, provided that the consumer complies with the rules of operation, storage and transportation of the device.

Guarantee period covers 12 months since the date of purchase.

The Seller undertakes to carry out free repair or replacement of the device during the warranty period of operation in compliance with the rules of operation, storage and transportation of the device.

Warranty repair of the device is carried out only by the Seller. If the device is repaired by another organization (or an individual), the warranty for the device is not valid. The Seller does not accept claims for the device with mechanical damage, violation of the integrity of the seal.

After the warranty period expires, the Seller performs paid repair of the device. Organizations make payments according to the invoice issued. Individuals – by postal transfer or in cash according to the calculation.

Address for repair requests or purchases: 14, 1st pereulok Parkhomenko, Novosibirsk, 630108 Russian Federation, +7 (913) 452-04-05, mail@vedapulse.com

11. Disposal instructions

The device should be disassembled by type of materials, disinfected, and disposed in accordance with local legislation requirements, as solid household waste of Class A.