DENAS-PCM Pro

PART II

INSTRUCTIONS FOR USE

English Translation

Sections 15-17 and application-zone appendices
from TRTK 23.0-03.70-02 RE

Translation notice. This is an English translation prepared from the manufacturer's Russian-language operating manual. It is not represented as an official English edition issued by TRONITEK. For regulatory, medical, warranty, or safety interpretation, consult the manufacturer's original Russian manual.

15 General Information

The device may be used for various diseases and syndromes to obtain analgesic, antispasmodic, vascular, anti-inflammatory, trophic and general regulatory effects, as stated in the manufacturer's Russian manual.

The device is intended for use in healthcare and preventive-care institutions and in domestic conditions in accordance with a physician's directions. Medical personnel and individual users should use the device only after becoming familiar with the Operating Manual.

Treatment may be performed with the built-in electrode or with remote electrodes (see Appendix A). The connector accepts the supplied remote self-adhesive electrodes and compatible remote therapeutic electrodes manufactured for the DENAS system.

The manufacturer states that effectiveness may increase when the device is used as a course of treatment rather than as isolated procedures.

16 Intended Purpose, Indications, Contraindications and General Directions for Use

16.1 Intended Purpose

The DENAS-PCM Pro Universal Transcutaneous Electrostimulator is intended for dynamic electroneurostimulation over a wide range of frequencies, with the possibility of using preset automated programs or selecting an individualized treatment program.

16.2 Indications for Use Stated in the Source Manual

• Acute and chronic pain syndromes: acute pain of various locations, postoperative pain, chronic headache, dental pain, back and neck pain, and joint pain.

• Injuries: bruises, fractures, dislocations, and rehabilitation after sports injuries.

• Respiratory conditions: cough, choking/dyspnea, and difficulty breathing.

• Digestive-system conditions: abdominal pain, heartburn, nausea, vomiting, abdominal bloating, constipation, and diarrhea.

• ENT conditions: nasal congestion, difficulty with nasal breathing, sore throat, and hoarseness.

• Cardiovascular conditions: arterial hypertension and arterial hypotension.

• Musculoskeletal conditions: muscle pain; ligament, tendon, and muscle injuries; back and neck pain; postural disorders; joint pain and stiffness; consequences of injuries.

• Nervous-system conditions: headache, dizziness, migraine, vegetative-vascular dystonia, weather sensitivity, impaired performance, and sleep disorders.

• Genitourinary conditions: kidney-area pain, urinary disorders, painful or irregular menstruation, inflammatory conditions, erectile dysfunction, and prostatitis.

• Skin-related conditions: urticaria, acute allergic reactions, insect bites, and cellulite.

• Rehabilitation after illness, surgical procedures, and injuries.

• Support of adaptive capacity during adverse environmental factors, intensive physical or mental work, fatigue, chronic-fatigue syndrome, difficulty falling asleep/insomnia, increased irritability, depressive states, sexual-function disorders, and prevention of colds, as stated in the source manual.

16.3 Contraindications

Absolute contraindications

• Individual intolerance to electric current.

• Presence of an implanted cardiac pacemaker.

Relative contraindications - use should be agreed with the treating physician

• Status epilepticus.

• Neoplasms of any etiology or location.

• Acute febrile conditions of unclear etiology.

• Venous thrombosis.

• States of acute mental, alcohol-related, or drug-related excitation.

The manufacturer states that no adverse effects have been identified when the operating conditions and instructions in the manual are followed.

16.4 General Directions

WARNING / IMPORTANT. Do not discontinue medications prescribed by a physician because of use of DENAS-PCM Pro. Any change in a medication regimen should be made only in consultation with the treating physician.

WARNING / IMPORTANT. Remote therapeutic electrodes may be used only in Frequencies and Programs modes.

No special conditions are required for a procedure. Treatment may be performed independently or with the assistance of another person. After a procedure, the source manual recommends resting for approximately 10-15 minutes.

To improve electrode-to-skin contact, the skin may be lightly moistened with water before treatment.

16.4.1 Methods of applying the electrodes

Stable method. The electrode remains stationary on the selected zone throughout the treatment period. This method is used for small treatment zones and biologically active points. On larger areas the electrode may be moved sequentially from one adjacent area to another.

Labile method. The electrode is moved smoothly over the selected zone at approximately 0.5 to 2-3 cm/s using straight, circular, or other movements with light pressure.

Labile-stable method. Movement is combined with brief stationary pauses at selected locations, for example at points of maximum pain.

16.4.2 Recommended duration

When the immediate objective is rapid relief, such as analgesia, the criterion for sufficient treatment is disappearance or substantial reduction of the complaint. During a course of procedures, the source manual provides the following approximate total durations:

Age	Total session	Typical time per zone
Under 1 year	5-10 min	1-3 min
1-3 years	10-15 min	3-5 min
3-5 years	15-20 min	5-7 min
5-12 years	20-25 min	7-9 min

Age	Total session	Typical time per zone
Over 12 years and adults	Up to 30-40 min	10-15 min

16.4.3 Stimulation power / intensity

Minimum level. No sensation or only a slight vibration. The source manual recommends this level for children under 12 and in certain cardiovascular or neurologic situations.

Comfortable level. Above the sensory threshold, producing painless vibration, tingling, or mild burning. The source manual describes this as the level most commonly used.

Maximum level. Sensations approach the pain threshold and may include pronounced burning or tingling and involuntary muscle contraction. The source manual describes this level for severe pain syndromes.

WARNING / IMPORTANT. Individual sensitivity may change during a session as pain decreases. Adjust power as necessary, but do not exceed the patient's pain-tolerance threshold.

16.5 Automated Programs - Application

Program	Treatment zone(s)	Manufacturer's stated use
Allergy	Epigastric abdominal area; C7 area	Urticaria, acute allergic reactions, insect bites
Pain	Painful area	Chronic headache, dental pain, back/neck pain, joint pain
Severe Pain	Painful area	Acute pain of various locations; postoperative pain
Bloating	Anterior abdominal wall	Abdominal bloating
VSD	Cervical-collar zone	Vegetative-vascular dystonia, weather sensitivity, impaired performance/sleep
Gynecologic Pain	Painful abdominal area	Painful menstruation
Gynecology	Soles; cervical-collar; lumbosacral	Menstrual irregularity; inflammatory conditions
Hypertension	C2 and C7 areas	Arterial hypertension
Hypotension	Cervical-collar zone	Arterial hypotension
Head	C2; cervical-collar; hand head-zone (Su-Jok)	Headache, dizziness, migraine
Throat	Hand neck-zone (Su-Jok); submandibular zone	Sore throat, hoarseness
Diarrhea	Anterior abdominal wall; lumbosacral	Diarrhea
GI Pain	Painful abdominal area	Abdominal pain, heartburn
Constipation	Anterior abdominal wall; lumbosacral	Constipation
Cough	Submandibular zone; jugular notch	Cough
Muscles	Area of injury or pain	Muscle pain; ligament, tendon and muscle injury
Muscles / Sports	Affected muscle area	Muscle pain; altered muscle tone
Runny Nose	Hand nose-zone (Su-Jok); nasal wings/sinus projections	Nasal congestion; impaired nasal breathing
Potency	Lumbosacral; cervical-collar; feet	Erectile dysfunction; prostatitis
Kidneys	Lumbosacral; feet	Kidney-area pain; urinary disorders
Back	Spinal projection / painful area	Back and neck pain; postural disorders

Program	Treatment zone(s)	Manufacturer's stated use
Joints	Affected joint; corresponding segmental zone	Joint pain/stiffness; consequences of injury
Nausea	Epigastrium; right and left hypochondria	Nausea, vomiting
Trauma	Affected body area	Bruises, fractures, dislocations; rehabilitation after sports injuries
Choking / Dyspnea	Jugular notch; C7	Choking/dyspnea; difficulty breathing
Cellulite	Problem area: abdomen, buttocks, thighs	Cellulite

16.6 Frequency Modes

Frequency / mode	Manufacturer's description in the Russian manual
1.0-4.0 Hz	Directed influence on lymphoid, bone, and connective tissue.
4.0-7.0 Hz	Directed influence on structures of the autonomic nervous system.
7.0-9.9 Hz	Correction of function of parenchymal organs.
10 / 20 Hz	General regulatory action; applications in acute and rehabilitation periods; stabilization or enhancement of effects of other frequencies.
60 / 77 Hz	General-purpose frequencies for pronounced local complaints; applications involving analgesia, local/regional blood flow, and inflammatory processes.
125 / 140 Hz	Musculoskeletal conditions and neuralgias accompanied by pronounced pain.
200 Hz	Rapid analgesia for musculoskeletal conditions, neuralgia, and injuries.
7710	For signs of arterial hypertension, hypertensive-type vegetative dystonia, and sleep disorders.
7720	For normalization of autonomic support and reduction of swelling.
77AM	For signs of hypotonic or atonic states of internal organs.

16.7 MED - Minimum Effective Dose

MED is an automated program described by the manufacturer for rehabilitation and prevention during physical overstrain, psycho-emotional overload, chronic-fatigue syndrome, and certain internal-organ conditions, including prevention of colds during epidemic periods.

The source manual recommends MED at least once daily for a course of approximately 8-12 days. Recommended power is minimum or comfortable.

MED consists of two phases. An audible signal is produced at the end of each phase.

WARNING / IMPORTANT. MED is performed only with the built-in electrode. Keep the electrode stationary on the skin throughout the MED procedure. Do not exceed the pain-sensitivity threshold.

16.8 Screening

Screening is intended to assist in selecting treatment zones and identifying latent trigger zones by comparing changes in electrical characteristics of the skin at different points.

When skin contact is detected, a five-second measurement begins. At the end of the interval, the device sounds and displays a ΔLt value from 0 to 100. Record the value, lift the electrode for 1-2 seconds, and move it to the adjacent area.

Areas whose values differ substantially upward or downward from surrounding measurements are treated by the source manual as latent trigger zones. The manual recommends additional stimulation of identified trigger zones for approximately 1-5 minutes at 60 or 77 Hz.

WARNING / IMPORTANT. Keep the electrode stationary during each Screening measurement.

17 Operating Procedure

17.1 Preparation for Use

Remove the protective film from the display if it is still present. Clean the electrodes before use.

WARNING / IMPORTANT. Before and after every procedure, treat the built-in device electrode as described in the maintenance section of the Operating Manual. An untreated electrode may contribute to cross-infection if the device is shared.

The source manual specifies cleaning with a 3% hydrogen peroxide solution with addition of 0.5% detergent solution, using a soft lint-free wipe. Store the device with a dry electrode.

17.2 Installing Batteries

Install two LR6/AA 1.5 V batteries in the battery compartment, observing the polarity markings. Close the compartment securely.

WARNING / IMPORTANT. Do not connect the device to an external mains power source.

17.3 Patient Position

During a procedure the patient may sit or lie in a comfortable position.

WARNING / IMPORTANT. The source manual advises against performing DENAS-PCM Pro procedures while standing, in order to reduce the risk associated with an unfavorable patient reaction.

17.4 Switching the Device On

Press the power button. After the audible signal and startup screen, the device opens the Main Menu if the Memory function is disabled. If Memory is enabled, the device opens the therapeutic mode that was active when it was switched off.

17.5 Selecting a Mode or Function

Use the navigation buttons to select the required program, frequency, MED, Screening, Constructor, Favorites, Children's Doctor, or Settings. Confirm the selection with the menu-selection button.

17.6 Returning Through Menus

Use the Back button to return to the preceding menu. Use the Main Menu button to return directly to the Main Menu.

17.7 Switching the Device Off

Press and hold the power button for approximately three seconds. The display shows the shutdown screen; after an audible signal the device switches off.

17.8 Connecting and Using Self-Adhesive Electrodes

Connect the cable to the self-adhesive electrode and then to the device connector. Place the electrode on clean, intact skin in the selected treatment zone.

WARNING / IMPORTANT. Self-adhesive electrodes are intended for individual use to reduce the risk of cross-infection. They may be reused by the same user while the adhesive and conductive layers remain intact.

WARNING / IMPORTANT. Do not apply alcohol-containing or oily substances to self-adhesive electrodes. Do not apply oils or creams to the skin before using them, because these substances can damage the adhesive layer and accelerate electrode wear.

Appendix A - Compatible Remote Therapeutic Electrodes

Accessory	Purpose
Remote zonal therapeutic electrodes	Non-invasive stimulation of painful areas, lesion areas, reflexogenic zones, and intact skin; secured using conductive straps where applicable.
Remote therapeutic foot electrode	Stimulation of reflexogenic zones on the plantar surfaces of the feet.
Remote therapeutic massage electrodes	Stimulation of painful areas, injury areas, reflexogenic zones, and acupuncture points.
Remote paraorbital therapeutic electrode	Non-invasive stimulation of biologically active points around the eyes in the paraorbital zone.
Remote point therapeutic electrode	Stimulation of biologically active points.

Appendix B - Atlas of Application Zones

The manufacturer's original Russian manual contains anatomical drawings for the following zones. This English edition translates the zone captions and instructions. For precise visual localization, compare these descriptions with the corresponding illustrations in the Russian original.

Program	Translated zone description
Allergy	Zone 1: epigastric abdominal area. Zone 2: area of the 7th cervical vertebra.
Pain / Severe Pain	Treat the painful area. For a large area, move the electrode sequentially over adjacent points.
Bloating	Anterior abdominal wall.
VSD	Cervical-collar zone.
Gynecologic Pain	Painful abdominal area.
Gynecology	Zone 1: soles. Zone 2: cervical-collar zone. Zone 3: lumbosacral zone.
Hypertension	Zone 1: area of C2. Zone 2: area of C7.
Hypotension	Cervical-collar zone.
Head	Zone 1: C2. Zone 2: cervical-collar zone. Zone 3: hand projection of the head according to Su-Jok.
Throat	Zone 1: hand projection of the neck according to Su-Jok. Zone 2: submandibular area.
Diarrhea	Zone 1: anterior abdominal wall. Zone 2: lumbosacral zone.
GI Pain	Painful abdominal area.
Constipation	Zone 1: anterior abdominal wall. Zone 2: lumbosacral zone.
Cough	Zone 1: submandibular area. Zone 2: jugular notch.
Muscles	Area of muscle injury or pain.
Muscles / Sports	Affected muscle area; the source atlas provides self-adhesive-electrode placement examples.
Runny Nose	Zone 1: hand projection of face/nose according to Su-Jok. Zone 2: nasal wings and projections of the paranasal sinuses.
Potency	Zone 1: lumbosacral. Zone 2: cervical-collar. Zone 3: feet. The source states that this program is unavailable when Children's Doctor is enabled.
Kidneys	Zone 1: lumbosacral. Zone 2: feet.

Program	Translated zone description
Back	Cervical spine for neck pain; thoracic/lumbar/sacral spine for back pain. The source atlas distinguishes areas according to pain presentation.
Joints	Zone 1: affected joint. Zone 2: lower back for lower-limb joints or cervical-collar area for upper-limb joints.
Nausea	Epigastric region and right/left hypochondria.
Trauma	Around the affected area. Do not apply directly to wounds or broken skin.
Choking / Dyspnea	Zone 1: jugular notch. Zone 2: C7.
Cellulite	Affected area. The source describes courses of at least two weeks per zone: abdomen, buttocks, outer thighs, posterior thighs, and anterior thighs.

WARNING / IMPORTANT. The source atlas repeatedly specifies that the built-in electrode and remote electrodes are applied to bare, intact skin. Do not stimulate through damaged skin.

Important Translation and Use Note

This document reproduces Part II - Instructions for Use - from the Russian DENAS-PCM Pro Operating Manual in English-language form. Medical indications and therapeutic claims above are translations of the manufacturer's source manual and are not independent claims by the translator.

For use in the United States, this translated document should not be represented as FDA-approved labeling or as an official manufacturer-issued U.S. Instructions for Use unless that status is separately verified.

For contraindications, implanted electronic devices, pregnancy, serious medical conditions, unusual reactions, or questions about whether electrical stimulation is appropriate, consult a qualified healthcare professional and the manufacturer's current official instructions.