Content

Dear Customer!

Thank you for shopping with us. Device for Thermal Vibromassage Magnetotherapy of Inflammatory Prostate Diseases (further mentioned as the Device) which belongs to the line of physio-therapeutic apparatuses produced at Yelatma Instrument-Making Enterprise.

NOTICE. All user's manuals should be carefully studied prior to the Device first application and strictly followed it in the process of the device operation in order to assure the device correct and safety operation. When passed on to the third man the Operating Manual should be enclosed to Device.

The present Operating Manual is a document identifying the basic parameters and technical characteristics of MAVIT Device.

Special training of the medical personnel is not required.

1. THE DEVICE INTENDED USE

1.1 General Information

1.1.1 MAVIT Device for Thermal Vibromassage Magnetotherapy of Inflammatory Prostate Diseases is designed to treat inflammatory prostate diseases in the period of sub-acute stage of disease and at the phase of remission in – and out- patient departments as well as **in home conditions under medical administration and follow –up.** It can be recommended for home use only in cases that are not associated with rectum mucosa damage. The treatment can be taken as simultaneously with the application of antibacterial, anti-inflammatory, immunomodulatory and adaptogen medicaments so in mono-therapy regimen.

1.1.2 The Device should be used under the following operating conditions:

- ambient temperature: from + 10 ºC up to + 35 ºC;
- air humidity at +25 ºC: max. 80%
- atmospheric pressure: from 84 to 106.7 kPa (630-800 Hg).

1.2. Indications for application

- chronic prostatitis (non-exacerbated stage);
- prostatovesiculitis;
- urethroprostatitis;
- copulative dis-function;
- chronic prostatitis with prostate gland benign hyperplasia

1.3. Contraindications:

- acute prostatitis;
- chronic prostatitis acute condition;
- prostate malignant tumors;
- diagnosed or suspected active prostate tuberculosis;
- acute rectum inflammatory diseases;
- rectum malignant tumors;

2. SPECIFICATIONS

2.1. Surface temperature of the applicator service area being immersed into liquid with temperature from 36 ºC to 38 ºC is between 38,5 ºC and 42 ºC.

2.2. Peak value of pulsed magnetic field magnetic induction radial component on the surface of the applicator service area is in the range 3 - 30 mTl.

Monopolar impulses recurrence rate changes in cycles from (25±5)Hz to (100±20)Hz with cycle duration (12±2)s, average pulses ratio is in the ranges 3 – 11.

2.3.Applicator vibration amplitude in the operating mode (ON-OFF indicator (light emitting diode) is actuated) - from 0,01 to 0,1 mm.;

2.4. Vibration rate changes in cycle from (25±5)Hz to (100±20)Hz.

2.5. Device run cycle time (ON-OFF indicator (light emitting diode) is actuated) is (30±2) min.
2.6. Alternating current mains voltage:
☐~220V (-10%; +10%) or ~230V (-10%;+6%), frequency 50Hz
☐~120V (-10V; +10V), frequency 60Hz
2.7. Power consumption: max. 5VA.
2.8. The Device operates in the intermittent cycle (1 hour run is followed with 20 minutes break) during 6 hours with following 1 hour break.
2.9. Electrical safety of the Device is in conformity with the requirements of IEC 60601-1 and its safety corresponds to class II, BF type.
2.10. Mean-time-between-failures is at least 3000 hours.
2.11. Mean lifetime is not less than 5 years.
2.12. Overall dimensions:
- power supply unit, max: 119x100x65 mm.
- applicator, max: 18x24x142mm.

2.13. Weight of the Device power supply unit, max: 600 g.
2.14. Weight of the applicator with the patient's cable is not more than 60 g.

3. COMPLETE SET

The complete set of the Device includes:
- MAVIT Device;
- Operating Manual.

4. ARRANGEMENT AND OPERATION

MAVIT device (Fig. 1) consists of a power-supply unit (1) with "POWER" light emitting diode, indicating the unit connection to alternating–current mains (2); ON/OFF button (5) activating and dis-activating applicator operating mode (heat, magnetic field and vibration) which both is being signaled with lighting of "RUN" light emitting diode (4) and activation of timer, defining run cycle time, that is followed with lighting of "ON/OFF" light emitting diode (3); mains cord (6) and patient`s cable (7) on it. The patient's cable is (2.0±0.1)m length, the length of mains cord is (2.0±0.1).

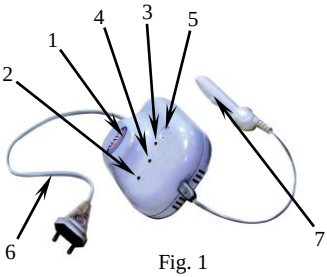

Fig. 1

Note: When applicator is disconnected from power supply unit or in the case of malfunction "RUN" light emitting diode becomes dim.

The power supply unit case and cover is made of shock-resistant polystyrene

The applicator is made of medical elastron and contains the electromagnet with a moving core inside; the winding of the electromagnet acts simultaneously as a heating element and a magnetic field source.

Applicator configuration coincides with that of the underlying anatomic cavity both of rectum and prostate gland.

Applicator is inserted into rectum of the patient so that its working area is to be close to the prostate gland in the area of mucous tunic adjacency to the rectum. Its fixation is provided for physiologically. Therapeutic principle of the Device implies combined action of pulsed magnetic

field, heating and vibration massage on the prostate gland, as a result we have a number of beneficial effects:
- increased metabolic and regeneration processes in tissues
- improved local blood circulation enhancing regional blood flow to the diseased area thus promoting arresting of inflammatory process.

Attention: it is impossible to check up temperature of an applicator working zone precisely with mercury or spirit thermometer or other similar measuring device in home conditions

MARKING

The following signs are marked on the power supply body:

"Class II device"
The sign indicating that electrical safety of the device is of Class II according to IEC 60601-1;

"Caution, see the user's manual";

"BF type device"
The sign indicating the device electric shock safety: BF type according to IEC 60601-1.

EN ISO 10993-1:2009+Cor.1:2010
EN 60601-1:2006+AC:2010
CE 0044 DIN EN ISO 15223-1:2013
EN 60601-1-8:2007 +AC:2010
EN 60601-1-11:2010

MAVIT DEVICE PHYSIOLOGICAL AND CLINICAL EFFECTS

The purpose of chronic prostatitis complex treatment is to remove inflammatory process in prostate gland, to eliminate pathogenic organism microbe, to improve prostate functional state and patient rehabilitation in whole. In an effort to make medicamentous treatments more efficient such treatment modes of local physiotherapy as exposure as transrectal hyperthermia, electromagnetic field, micromassage are mostly used in medical practice

Thermal influence, hyperthermia of a prostate through rectum, in particular, is the recognized method of treatment of chronic prostatitis, benign hyperplasia of a prostate gland in the period of dynamic follow-up on the patient and is considered as one coming into international therapeutic standards. Accepted terminology defines hyperthermia as a method to keep in tissues the temperature in the range from +40 °C up to +45 °C, that makes a good effect both on microcirculation (improves blood circulation) and stimulation of immunity in surrounding tissues.

Among the physical factors which is used to treat chronic prostatitis treatment, magnetotherapy is one of commonly used methods. Local magnetic field effect has anti-inflammatory, anti-edematous, sedative and trophico-regenerative action.

MAVIT is recommended to be applied for chronic prostatitis and does not counterindicative for benign hyperplasia of prostate gland under the doctor - urologist or andrologist administrations and control. The stimulation of prostate muscular elements and pelvic floor muscles contractive ability results in regeneration of their tone and promotes secretion adequate evacuation that is important to remove congestive effects in prostate and to reduce irritation of lower urinary tracts. Local influence of such type is achieved with the help of vibration effect in the tissues surrounding prostate gland and in prostate gland itself.

MAVIT device designed to treat patients with chronic prostatitis allows to use three physical local join factors on prostate - hyperthermia, pulsed magnetic field and mechanic micro-vibration.

Device consists of power supply unit connected on to household electric mains and working element – applicator, both are joined with electric cable. The temperature on the surface of applicator being in operating condition is in the rages of 38,5 – 42 °C. Besides, the working element serves as the source of mechanical vibration with vibration frequency from 20 to 100 Hz and generator of pulsed magnetic field with frequency from 20 to 100 Hz. and induction from 3 to 30 mTl.

Therapeutic effect of local physical influence with MAVIT device results in:

- improvement of tissue microcirculation in prostate gland and tissues surrounding it;
- analgetic effect both of vibration factor and pulsed magnetic field;
- reduction of spastic and edematic components accompanying inflammatory process.

These effects are realized by complex joint action of hyperthermia, pulsed magnetic field and vibration on the prostate gland and nervous structures of pelvic nerve plexus, that is prostate plexus. The latter is situated in the tissue surrounding gland on the side and back prostate surface and can be easily reached with the help of working part of the device applicator being in operating mode.

Influence on the mentioned prostate gland structures, being involved in formation of the symptoms of lower urinary tracts diseases, allows to reduce inflammatory process and promotes to

recover male sexual potency. Besides, local physiotherapeutic action on prostate gland, its innervation apparatus and tissues surrounding it intensifies effects of antibacterial and anti-inflammatory treatment of chronic prostatite and prostate gland on the background of prostate gland benign hyperplasia. The result of such exposure there is improvement of micro-circulation in the prostate tissue, edema reduction, increase of antibiotics concentration with their joint application.

Patients with chronic prostatitis in the phase of inflammatory process attenuation and in the phase of remission after treatment procedures carried out with the help of MAVIT note reduction both of pain sensation, discomfort, feeling of urination, improvement of urinary stream tension and sexual potency. During treatment procedures the patient feels the pleasant sense of heat in the influenced zone which is kept for a long time after taken procedure termination. Vibration is revealed itself in slight "trembling" on the applicator service part.

6. SAFETY MEASURES

First you should carefully study operating manual and only after that operate the device.

Use the Device only in places suitable for its connection to the mains` operated socket avoiding patient's cable tension. Otherwise use power extender of industrial production

Be sure that the mains-operated plug is in serviceable condition and mains voltage is

☐~220V (-10%; +10%) or ~230V (-10%;+6%), frequency 50Hz

☐~120V (-10V; +10V), frequency 60Hz

Protect the Device from moisture, impact or shaking.

Grounding when operating the Device is not required.

CAUTION!

1. There should be no cracks and chips on the body of the device.

2. There may be the signs of material outflow on the working surface of the device body, which are not be considered as the body's damage and have nothing to do with the device serviceability.

3. There should be no any cracks and breaks on the surface of mains operated cord.

IT IS FORBIDDEN:

- to operate the device with damaged case and / or applicator;
- to remove the outer cover of the power supply unit when operating the Device
- to operate the device with damaged mains operated cord and patient cable;
- to lift and carry the device by mains cord.
- penetration of disinfection solution inside the power supply unit
- cable tension connecting power supply unit and working element.

7. GENERAL PHYSIO-THERAPEUTIC PROCEDURES

- treatment procedures are to be carried out regularly at the fixed time, each procedure is followed with 30-60 minutes rest.
- treatment or prophylactic courses can be repeated after the expiration of 2 months
- it is forbidden to take alcohol during the treatment course;
- it is not allowed to take sedative and psychoactive agents while taking take procedures if you take the latter not regularly or their doses exceed those prescribed by the doctor.
- try to avoid the heavy physical activity.
- don't take procedures on the background of neurasthenia or overwork.

8. PREPARATION OF THE DEVICE FOR APPLICATION

8.1 Disinfection and sterilization procedures recommended for treatment-and-prophylactic institutions

8.1.1. Disinfection of outer surfaces of the Device should be carried out prior to its first application and later on when necessary by wiping it twice with 10 minutes interval with clean fabric cloth moistened with 3%-solution of hydrogen peroxide or Veltosept agent. Disinfection of applicator and the adjacent 10-15 cm length part of the patient's cable is to be carried out by the method of its immersing into the solution for the time stated in the methodical instructions for a particular agent application.

CAUTION: Disinfection of the power-supply unit by its immersing into the solution is forbidden

8.1.2 In case, when patient has rectum mucous membrane injury (anal fissures, mucosa damage in hemorrhoids, etc.) prior to the procedure the predisinfected probe and the adjacent portion of the patient's cable 10-15 cm in length should be subjected to presterilization treatment with 1-1.5% Veltolen solution followed by sterilization in 6%-solution of hydrogen peroxide (the exposure time of 360 minutes at the temperature of solution of 18 °C; 180 minutes at the temperature of solution of 50 ±2 °C) according to the methodical instructions for a particular agent application.

8.1.3. Disinfection and sterilization procedures being completed, the Device should be dried up.

8.2 Disinfection of the device in home conditions.

8.2.1 Disinfection of outer surfaces prior to the first application and later on, if required, is to be made according to item 8.1.1.

8.2.2. Disinfection being completed, the Device should be dried up.

Note. Darkening of the treated applicator surface and the adjacent part of the patient's cable surface after disinfection and sterilization should not be considered as a defect.

9. OPERATING PROCEDURE

First you should prepare the device and only after that you can start treatment procedure.

If the device was stored in the cold premise or transported at the temperature below +10 °C, it is necessary to warm it up to the room temperature for 4 hours.

You should make disinfection of the working element by the procedure of item 8.1.1.

In the cases stated in the item 8.1.2 it is allowed to use only sterile applicator in the condition of clinic and sanitary-and prophylactic institutions. So it is necessary to carry out pre-sterilisation cleaning and sterilisation of applicator and part of patient cable adjacent to it by the procedure of item 8.1.2.

The order of operating procedure:

9.1. Procedure is to be taken after patient`s bowel and urinary bladder emptying.

9.2. Inset the probe-applicator into protective coating (condom).

9.3. Connect patient`s cable connector to the device power supply unit.

9.4. Connect power supply unit to the mains. Actuation is accompanied with light emitting diode (indicator) "POWER" lighting.

9.5. The patient should be on the couch in supine position with half-bent legs.

9.6. Smear condom surface with sterile vaseline.

9.7. Insert the applicator into the rectum so that its operating surface having special flattening was directed upward to provide the best contact of working element to the rectum wall in the area adjacent to the prostate and, accordingly, attain maximal effect of taken procedure.

9.8. Press “ON/OFF” button to activate running condition (mode). The activation is followed with “RUN” and “ON/OFF” indicators (light emitting diode) lighting.

Note. If “RUN” indicator does not light, it is necessary to check the quality of applicator’s cable connection to the power supply unit.

9.9. During the procedure patient feels the sensation of pleasant warmth and comfort, besides sedative effect is noted.

9.10. The procedure time is 20-30 minutes on doctor-urologist’s prescription. The course of treatment includes 7-9 procedures being carried out every other day.

Upon (30±2) minutes termination there appear sound signal, applicator heating, magnetic field and vibration dis-activates and “RUN” and “ON/OFF” indicators become dim (light off).

9.11. Unplug the power-supply unit from the mains “POWER” indicator lights off.

9.12. Disconnect patient’s cable connector from the device power supply unit.

9.13. Remove the applicator from the rectum and take off the protective coat (the latter is not reused)

9.14. Make the disinfection both of applicator and the adjacent to it (10-15 cm.) part of the patient’s cable surface and put it back into case.

9.15. Repeated course is allowed to be carried out after the expiration of 2 months.

10. MAINTENANCE

The servicing procedures should be carried out by the operating personnel. Maintenance order is shown in Table 1.

Table 1

Name of the works under maintenance	Periodicity	Item in Operating Manual
1. Inspection of outward appearance on the lack of mechanic damages on the thermomagnetic probe, power-supply unit and patient's cable.	Once a week	-
2. Cleaning from dust and contamination, disinfection both of the power-supply body and the patient's cable.	Once a month	Item 8.1.1.

11. STORAGE AND TRANSPORTATION

11.1. The Device should be stored in Manufacture's transit pack under the following conditions:

- environment temperature: from +40 ºC to -50 ºC;
- relative humidity: up to 98% at +25 ºC;
- atmospheric pressure: from 84 to 106.7 kPa (630-800 mmHg);
- absence of acid vapors, alkalis and other aggressive admixtures in the air.

11.2. The Device in Manufacture's transit pack can be transported by rail, air (except unheated compartments), water (except sea vessels) and motor transport in covered transportation facilities in compliance with the transport regulations.

11.3. Transport conditions:

- ambient temperature: from +50 ºC to -50 ºC;
- relative humidity: up to 100% at +25 ºC;
- atmospheric pressure: from 84 to 106.7 kPa (630-680 mmHg)

11.4.The packed devices in transit should be prevented from the exposure of atmospheric precipitation and mechanical damage.

12. ACCEPTANCE CERTIFICATE

ULP-01-" ELAT" Device for Thermal Vibromassage Magnetotherapy of Inflammatory Prostatic Diseases serial number _____ meets technical specification ГИКС.941519.102 and recognized as ready-for-service.

Date of output_____ Stamp

_____

(signature of a person responsible for acceptance)

ULP-01-"ELAT" Device for Thermal Vibromassage Magnetotherapy of Inflammatory Prostatic Diseases is packed according to the requirements of design documentation.

Date of packing _____

Packed by _____ Stamp

13. MANUFACTURER'S WARRANTY

The manufacturer guarantees the device quality to meet the requirements of the operating manual with of proper observation by the customer storage, transportation and operation rules and conditions.

Warranty period is 24 months from the date of selling

Within the warranty period the manufacturer free of charge undertakes to repair or to replace the defective device or its parts free of charge on presentation of acceptance certificate.

Warranty provisions:

The warranty is only valid with correctly filled-in acceptance certificate quoting the serial number, date of sale and clear stamp of trading organization.

The Sellers` liability does not cover the cases, as:

- the device shows the evidence of unauthorized action (attempt to repair by non-authorized servicing company);
- unauthorized changes the device` s design;
- the device shows the signs of mechanical damages
- damage due to liquid, dirty, foreign objects penetration inside the device;
- damage as a result of improper application: non-conformity a mains power parameters to the State standards

The manufacturer forwards the electric circuit diagram and other technical files are being sent on the authorized servicing centers request.