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***Dear Customer!***

Thank you for purchasing this VERA (UTMpk-01 "PARA") Device for Rectum Thermomagnetic Therapy (further mentioned as the Device) which belongs to the family of medical apparatuses produced at Yelatma Instrument-making Enterprise.

**IMPORTANT. Operating manual should be carefully studied prior to the first application of the Device and followed strictly in the process of its operation. This will assure its correct and safety performance. When passed to a third man the Device should be accompanied with the Operating Manual.**

The present Operating Manual is a document certifying the basic parameters and technical characteristics of the VERA (UTMpk-01 " PARA") Device.

Special training of the service staff is not required.

## 1. PURPOSE OF THE DEVICE

### 1.1 General Information

1.1.1 VERA Device for Rectum Thermomagnetic Therapy is designed to treat rectum diseases at in- and out- patient departments as well as at home under physician's care. It can be recommended for home use only in cases that are not associated with rectum mucosa damage.

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

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

**1.2 Indications for use**

The Device is indicated for treatment of:

- chronic hemorrhoids;
- anal fissures;
- postoperative conditions following the dissection of anal fissures, rectum fistulas, hemorrhoids.

**1.3 Contraindications**

- acute or exacerbated hemorrhoids;
- anal bleeding;
- benign or malignant tumors of rectum and urogenital system**.**

## 2. SPECIFICATIONS

2.1 Surface temperature of probe service area at liquid temperature in the thermostat of 36-37°C depending on the operating conditions:

*Operating mode "1" – from 37.5 to 40.5°C;*

*Operating mode "2" – from 38 to 41°C;*

*Operating mode "3" – from 38.5 to 41.5°C.*

Peak value of magnetic induction radial constituent for pulsed magnetic field over the surface of the probe service area lies in the range of 10 – 30 mT.

2.2 Recurrence rate of monopolar pulses changes in cycles from (2565)Hz to (100620)Hz with cycle duration of (1062)s and duty ratio of pulses in the range of 2 – 11.

2.3 Mains voltage: ~220V610% or ~230V610%, frequency 50V.

2.4 Power consumption: not more than 10VA.

2.5 The Device operates in the repetitive transitory mode (40 minutes' work followed by 20 minutes' pause) during 6 hours with subsequent 1 hour's break.

2.6 Electrical safety of the Device is in conformity with the requirements of IEC 601-1-88 and its safety corresponds to class II of BF type.

2.7 Mean-time-between-failures is at least 3000 hours.

2.8 Mean service life is not less than 8 years.

2.9 Overall dimensions of the Device when enclosed in the case are maximum 200x150x80 mm.

2.10 Weight of the Device when enclosed in the case is not more than 600 g.

2.11 Probe weight is not more than 50 g.

## 3. COMPLETENESS

The complete set of the Device includes:

- VERA Device;
- Operating Manual.

## 4. ARRANGEMENT AND PERFORMANCE

Operating principle of the Device implies generating a pulsed magnetic field and heating the service area of the probe, technical characteristics being as indicated in items 2.1, 2.2.

The Device (Fig. 1) comprises a power-supply unit and a probe connected by the patient's cable of (260.1)m in length.

Thermal conditions and probe magnetic field are activated by pressing buttons "1", or "2", or "3" and are light-indicated.

Power supply body manufactured of shock-resistant polystyrene is reinforced with a plug providing connection with the mains socket.

The probe is made of medical plastic compound and involves the electromagnet the winding of which acts as a heating element, too.

The probe is inserted into patient's rectum, its fixation being provided both due to its design features and physiological aspects.

The therapeutic procedure comprises simultaneous heat and pulsed magnetic field effect resulting in stimulation of tissue metabolic and recovery processes, improvement of local circulation, pain relief, inhibition of inflammatory process and healing the wounds.


Fig.1

*Marking*

The following marks are applied to the power supply body:

"Class II device"

The mark indicating that electrical safety of the device complies with Class II according to IEC 601-1-88;

"Caution, refer to the user's manual";

"BF type operating part"

The mark indicating that device operating part according to degree of electrical shock protection is BF GOST P 50267.0-92 (IEC 601-1-88) type.

## 5. SAFETY MEASURES

5.1 The Device should be used only after the present Operating Manual has been carefully studied.

5.2 Use the Device only in places suitable for connecting the plug to a socket without tensioning the patient's cable.

5.3 Do not expose the Device to moisture, shocks or shaking.

5.4 Grounding when operating the Device is not required.

5.5 **WARNING.** Do not remove the outer cover of the power source when operating the Device.

5.6 The Device should only be used on doctor's orders.

## 6. PREPARATION OF THE DEVICE FOR APPLICATION

*6.1 Disinfection and sterilization procedures recommended for treatment-and-prophylactic institutions.*

6.1.1 Disinfection of outer surfaces of the Device should be carried out prior to its first application and henceforth when necessary by wiping it twice with 10 minutes' interval using a clean cloth moistened with 3%-solution of hydrogen or 10%-solution of Gigasept FF or by immersing the probe and the adjacent portion of the patient's cable (10-15 cm) into Veltocept for 15 minutes; the procedure should be performed according to the instructions for a particular agent application.

**CAUTION:**

*1. Disinfection of the power-supply unit by its immersing into the solution* ***is not allowed.***

*2. Gigasept FF is recommended to be used for wiping outer surfaces twice.*

6.1.2 In case of rectum mucosa damages (anal fissures, mucosa damage in hemorrhoids, etc.) prior to the procedure the disinfected probe and the adjacent portion of the patient's cable 10-15 cm in length should undergo presterilization treatment with 1-1.5% -solution of Veltolen or 2%- 4%- or 5%-solution of Lizetol AF followed by sterilization in 6%-solution of hydrogen peroxide with the exposure time of 180 minutes or 3%-solution of Gigasept FF with the exposure time of 600 minutes according to the instructions for a particular agent.

Veltolen and Lyzetol AF can be used for disinfection.

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

Surface darkening of the treated probe and the adjacent portion of the patient's cable should not be considered as a defect.

*6.2 Disinfection of the Device at home*

6.2.1. Outer surfaces of the Device should be disinfected prior to its first application and henceforth when necessary as indicated in item 6.1.1.

6.2.2. The disinfection procedure being completed, the Device should be dried up.

Surface darkening of the treated probe and the adjacent portion of the patient's cable should not be considered as a defect.

*6.3 Preparation for use*

6.3.1 If the Device was stored or transported at temperature lower than +10°C it should be kept at room temperature for at least 4 hours before its application.

## 7. OPERATING PROCEDURE

7.1 Remove the Device out of the case.

If necessary, disinfect the probe and the adjacent portion of the patient's cable 10-15 cm in length as indicated in item 6.1.1.

When used at treatment-and-prophylactic institutions (see item 6.1.2) the probe and the adjacent portion of the patient's cable should be exposed to presterilization treatment and sterilization as indicated in item 6.1.2.

7.2 Enclose the probe into the protective coating (a condom).

7.3 Connect the cable plug to the power-supply unit.

7.4 Connect the power-supply unit to the mains ("Power" indicator lights on).

7.5 Set the desired thermal conditions of the probe pressing one of the buttons: “1”, “2” or “3”. “Operation” indicator and a corresponding mode indicator “1”, “2” or “3” light on.

Magnetic field of the probe is activated simultaneously with the thermal conditions.

7.6 The patient should be in a lateral position.

7.7 Insert the probe into the rectum to the depth of its service area.

7.8 The procedure should last for 15 minutes. The course of treatment involves 8-12 procedures daily and can be repeated in 2 months.

7.9 The procedure being over, disconnect the power-supply unit from the mains. All the indicators will go off.

7.10 Disengage the patient’s cable from the power-supply unit.

7.11 Remove the probe from the rectum and take off the protective coating.

7.12 Disinfect the probe and the adjacent portion of the patient’s cable 10-15 cm in length; disinfection of the protective coating (a condom) should be performed separately before its utilization according to item 6.1.1.

7.13 Enclose the Device into the case.

## 8. MAINTENANCE

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

Table 1

| Name of the operation | Periodicity | Item in OM |
|---|---|---|
| 1. Inspection of the Device for mechanical damages on the thermomagnetic probe, power-supply unit and patient's cable. | Once a week | - |
| 2. Cleaning from dust and dirt. Disinfection of the power-supply body and the patient's cable. | Once a month | item 6.1.1. |

## 9. STORAGE AND TRANSPORTATION

9.1 The Device should be stored in Manufacture's package under the following conditions:

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

9.2 The Device in Manufacturer's transport package can be conveyed by rail, air (with the exception of unheated compartments), water (with the exception of sea vessels) and motor transport in covered transportation facilities in compliance with the transport regulations.

9.3 Transportation conditions:

- ambient temperature: between +50°C and -50°C;

-relative humidity: up to 100% at +25°C;
-atmospheric pressure: between 84 and 106.7 kPa (630-680 mmHg)

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

## 10. ACCEPTANCE CERTIFICATE

VERA Device for Rectum Thermomagnetic Therapy serial number _____ is recognized as ready-for-service.

Date of output_____ Stamp

_____
(signature of a person responsible for acceptance)

VERA Device for Rectum Thermomagnetic Therapy is packed according to the requirements of design blueprints and specifications.

Date of packing _____

Packed by _____ Stamp

## 11. MANUFACTURER'S WARRANTY

The manufacturer guarantees the quality of the device to conform to the Operating Manual requirements if the User follows the conditions and regulations of storage, transportation and operation.

*The guaranteed service life is 12 months since the date of purchase.*

Within the warranty period the Manufacturer shall repair or replace the defective device and its components free of charge on presentation of the acceptance certificate. The warranty is only valid with correctly filled-in acceptance certificate quoting the serial number, date of sale and a clear stamp of a trading organization.

The warranty is void if:

- the device shows evidence of alien interference or repair attempt by an unauthorized servicing center;
- unauthorized changes into the design or construction of the device have been introduced;
- the device shows mechanical damages;
- the device is damaged through introduction of alien objects, substances or liquids;
- the damage of the device is caused by nonconformity of mains parameters to the State standards.

The Manufacturer forwards the electric diagrams, description and other service records to the authorized servicing centers on request.