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Dear Customer!

Thank you for purchasing this ALP-01 “PRA” Applicator Device for Thermal Vibromassage Magnetotherapy of Inflammatory Prostatic Diseases (further mentioned as the Device) which belongs to the family of medical apparatuses produced at Yelatma Instrument-making Enterprise.

The Device is recommended for application by RF Ministry of Public Health (Minutes No 11 of 18 December, 2000 issued by the Committee for Apparatuses and Devices used in physiotherapy).

IMPORTANT. All the instructions 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 ALP-01 “PRA” Device.

Special training of the service staff is not required.

When purchasing the Device be sure to check its completeness, to inspect it for mechanical damages and to see if the Operating Manual contains Warranty Coupons with the stamp of the selling organization, seller’ signature and the date of purchase.

1.PURPOSE OF THE DEVICE

1.1. General Information

1.1.1. ALP-01 “PRA” Applicator Device for Thermal Vibromassage Magnetotherapy of Inflammatory Prostatic Diseases is designed to treat inflammatory prostatic 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:

- chronic prostatitis (nonexacerbated);
- prostatovesiculitis;
- urethroprostatitis;
- copulative function disorder.

1.3. Contraindications:

- acute prostatitis;
- exacerbated chronic prostatitis;
- prostatic abscess;
- malignant prostate and rectum tumors;
- active prostate tuberculosis diagnosed or suspected;
- acute rectum inflammatory diseases.

2. SPECIFICATIONS

2.1. Surface temperature of the applicator service area when immersed into liquid at temperature from 36°C to 38°C is between 37°C and 42°C.

2.2. Peak value of magnetic induction radial constituent for pulsed magnetic field over the surface of the applicator service area lies in the range of 3 - 30 mTl.

Recurrence rate of monopolar pulses changes in cycles from (2565)Hz to (100620)Hz with cycle duration of (1062)s, duty ratio of pulses being in the range of 3 – 11.

2.3. Applicator vibration amplitude is in the range from 0.01 to 0.1 mm. Vibration rate changes from (2565)Hz to (100620)Hz.

2.4. Mains voltage: 220V610%, frequency: 50V.

2.5. Power consumption: not more than 10VA.

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

2.7. Electrical safety of the Device is in conformity with the requirements of GOST P 50267.0-92 and its safety corresponds to class II of BF type.

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

2.9. Mean service life is not less than 8 years.

2.10. Overall dimensions of the Device when enclosed in the case are maximum 160x125x80 mm.

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

2.12. Weight of the applicator with the patient's cable is not more than 60 g.

3. COMPLETENESS

The complete set of the Device includes:

- ALP-01 «PRA» Device;
- Operating Manual.

4. ARRANGEMENT AND PERFORMANCE

Operating principle of the Device implies generating a pulsed magnetic field, heating the service area of the applicator and its vibration, technical characteristics being as indicated in items 2.1- 2.3.

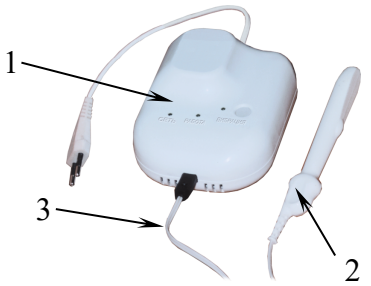
The Device (Fig. 1) comprises a power-supply unit and an applicator connected by the patient's cable of (2.0+/-0.1)m in length. Applicator vibration is activated by pressing "Vibration" button located on the body of the power-supply unit which is light-indicated.

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

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

The applicator should be inserted into the patient's rectum so as to locate its service area in the zone of rectum mucosa contiguous to the prostate, applicator fixation being provided physiologically.

Simultaneous thermal, pulsed magnetic field and vibratory massage effects on the prostate promote tissue metabolic and recovery processes and improve local circulation resulting in arresting inflammatory process.



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 GOST P 50267.0-92 (IEC 601-1-88);

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

"BF type device".

The mark indicating that electric shock safety of the device complies with BF type according to GOST P 50267.0-92 (IEC 601-1-88).

5. SAFETY MEASURES

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

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

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

Grounding when operating the Device is not required.

CAUTION. Do not remove the outer cover of the power source when operating the Device.

WARNING! 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 of the patient's cable (10-15 cm) into Veltocept (TU9392-003-23984186-97) 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 minutes' interval using a clean cloth moistened with 3%-solution of hydrogen peroxide (GOST 177-88) or 10%-solution of Gigasept FF ("Shulke and Mayr", Germany), or by immersing the probe and the adjacent portion rectum mucosa damages (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 undergo presterilization treatment with 1-1.5% -solution of Veltolen (TU9392-002-23984186-97) or 2%-4% or 5%-solution of Lizetol AF ("Shulke and Mayr", Germany) followed by sterilization in 6%-solution of hydrogen peroxide **(GOST** 177-88) with the exposure time of 180 minutes or 3%-solution of Gigasept FF ("Shulke and Mayr", Germany) 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 applicator 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 applicator 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 applicator 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 will light on. "OPERATION" indicator will signal activation of magnetic field and applicator heating.

7.5. The patient should be in supine position.

7.6. Insert the applicator into the rectum with its operating surface directed upward so as to contact with the rectum wall in the area adjacent to the prostate.

7.7. Press the "VIBRATION" button which activates applicator vibration and switches on the "VIBRATION" indicator.

7.8. The procedure should last for 30 minutes. The course of treatment involves 7-9 procedures daily and can be repeated in 2 months.

7.9. The procedure being over, press the “VIBRATION” button which discontinues applicator vibration and switches off the “VIBRATION” indicator.

7.10. Disconnect the power-supply unit from the mains. This is followed by deactivating a magnetic field and applicatorheating: the “POWER” and “OPERATION” indicators will light off.

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

7.12. Remove the applicator from the rectum and take off the protective coating.

7.13. Disinfect the applicator 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.The protective coating should not be reused.

7.14. 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 Manufacture'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. Transport 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

ALP-01 “PRA” Applicator Device for Thermal Vibromassage Magnetotherapy of Inflammatory Prostatic Diseases BIRM.941519.005 serial number _____ complies with the technical requirements of BIRM.941519.005 TU and is recognized as ready-for-service.

Date of output_____ Stamp

_____
(signature of a person responsible for acceptance)

ALP-01 “PRA” Applicator Device for Thermal Vibromassage Magnetotherapy of Inflammatory Prostatic Diseases is packed according to the requirements of design blueprints and specifications.

Date of packing _____

Packed by _____ Stamp

11. MANUFACTURER' 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 guarantee coupon. The warranty is only valid with correctly filled-in guarantee coupon 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.