The contents

Dear purchaser!

You have bought "UTL-01-"ELAT" device for Thermotherapy of Accessory Nose and Laryngeal Sinuses", that is one of the series of the medical devices, produced in Yelatemsky Instrument-making plant.

The device is recommended for use by the new medical devices Committee of the Public Health Ministry of Russian Federation (protocol № 5. 9.06.2001).

Attention! Before using this device, read the instructions and recommendations carefully.

The knowledge of the device and how it works helps to use it right and safely. In the case of passing the device to other people, let them have the instructions as well.

The instructions are the document, which certificates the main parameters and technical characters of device for Thermotherapy of Accessory Nose and Laryngeal Sinuses UTL-01-"ELAT" (onward - device).

Besides, the instructions establish the rules of application and exploitation of the device according to "The instructions of the application of device for Thermotherapy of Accessory Nose and Laryngeal Sinuses UTL-01-"ELAT", ratified by the Administration of scientific research of the Public Health Ministry of Russian Federation.

When buying the device, make sure that there are a stamp of a shop, a legible sign of a shop-assistant or a stamp of a shop-assistant and the date of the purchase in the talon of indemnity.

Check the stamp on the device and the completeness.

Remember, if you loose the instruction, you have no right to repair it free of charge.

Joint-stock company "Yelatemsky Instrument-making plant" expresses its gratitude for Your choice.

1. ASSIGNMENT OF THE DEVICE

1.1. General items

1.1.1. The device is designed to warm-up the antrum of Highmore, the frontal sinusinand the larynx in out-patient and in-patient departments and at home.

1.1.2. The device may be operated by the middle qualification medical personnel or by patient himself, according to the doctor's instructions.

1.1.3. The device is ought to be sold wholesale and retail.

1.1.4. It must be used in living quarters or places like that, where the temperature of the air is 10-35 °C and relative humidity 80% when 25 °C.

1.2. Indication to application

The device is designed to treat the following diseases*:*

1) acute rhinitis;

2) chronicle rhinitis – phases: exacerbation, discontinuous exacerbation and remission;

3) chronicle rhynosinusitis – phases: discontinuous exacerbation and remission;

4) acute and chronicle sinuitis – phases: discontinuous exacerbation and remission;

5) acute and chronic tonsillitis in the attenuated exacerbation phase;

6) acute and chronicle maxillary sinusitis – phases: discontinuous exacerbation;

7) acute and chronicle maxillary frontal sinusitis metopantritis – phases: discontinuous exacerbation.

If the process is acute or the chronicle disease is in the phase of exacerbation, it is recommended to use mode "1" of the device (look item 4.2.3.).

In the phase of discontinuous exacerbation, one may use mode "1" or "2".

In the phase of remission of the chronicle disease, one should choose mode “2” or “3”.

1.3. Contraindications:

- acute inflammatory processes in the effected tissues;
- nasal bleeding or predisposition to it;
- pustular skin disorders in the effected area;
- active tuberculosis;
- neoplasms;
- increased skin sensitivity to thermal effects.

2. SPECIFICATIONS

2.1. Surface temperature of the heating element under normal operating conditions without contact with the patient’s body:

- operating conditions «1» (switch position «1»): in the range of (40±5) °C;

- operating conditions «2» (switch position «2»): in the range of (47±5) °C;

- operating conditions «3» (switch position «3»): in the range of (55±5) ° C.

2.2. Power supply is realized due to electrical AC system with the 50Hz frequency, 220V (-10%, + 10%) or 230V (-10%,+6%) voltage.

2.3. Power consumption – not more than 10VA.

2.4. The time needed to get ready – not more than 10min.

2.5. The regime of the device-work is repeat-short time during 6 hours, 50 minutes – works, 10 minutes – doesn’t work.

2.6. Safety class according to IEC 601-1-88 is II, type BF.

2.7. The outer surfaces of the power supply body and patient's cable are resistant to disinfection with one of the agents indicated in Table 1 or any other agent recommended to be used for disinfection of apparatus-and device surfaces.

Table 1

At treatment-and-prophylactic institutions		For home usage	
Agent name	Producer	Agent name	Producer
Alaminol	SRC RF "NIOPIK", Russia	Hydrogen peroxide	Russia
Bianol	SRC RF "NIOPIK", Russia	Chloramine B	"Ufakhimprom" public company Russia
Veltolen	"VELT" close company, Russia	Veltocept	"VELT" close company Russia
Veltocept	"VELT" close company, Russia		
Lyzafin	"PETROSPIRT" close company, Russia		
Lyzoformin 3000	Russia, "PETROSPIRT" close company & "Lyzoform Dr Hans Rosemann GmbH", Germany		
Hydrogen peroxide	Russia		
Chloramine B	"Ufakhimprom" public company, Russia		

The outer surfaces of the heating element and adjacent part of the patient's cable of (10-15) cm are resistant to disinfection with 3%-solution of hydrogen peroxide and 1%-solution of Chloramine B or Veltocept.

2.8. In average, it will work no less than 1500 hours.

2.9. In average, it will work no less than 5 years.

2.10. Overall dimensions of the power-supply unit: max 95x85x65 мм.

2.11. The weight with the case is no more, than 0,32kg.

2.12. Application potential risk class - 2a.

3. COMPLETENESS

In the set of the device are included:
- device FEYA.
- instructions.

4. DEVICE AND PRINCIPLE OF WORK

4.1. Physiological mechanism of the local thermal influence

The virus respiratory diseases appear very often because the organism doesn't have strong immunity, while the virus develops inside the sells of the mucous membrane. Among non-specific factors of protection is the arise of the temperature: the best temperature for the development of the virus is 35-37 °C, and if the temperature 40-42 °C, the virus doesn't populate and starts to dye.

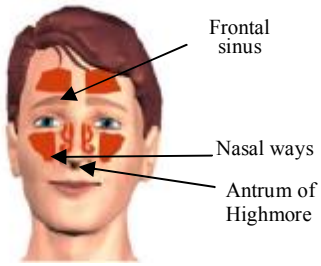
The protection reaction of the organism – the arise of the temperature of the body (hot flush), killing the virus, tells on the state of the patient in a bad way, especially his nervous system; promotes to kill the virus, but prolong the disease.

The device FEYA enables to arise the temperature locally, without the arise of the temperature of the whole body.

If the device influences locally on the otorhinolaryngologic organs:

1) The blood vascular become wider reflexly, that speeds-up blood circulation and prevents venous congestion in the mucous membrane;

2) the substance metabolism improves in the region of face near the nose and accessory sinuses;



3) The regeneration of the cover of the mucous membrane speeds-up and that stops the aggression of the virus;

4) The face organs are a very important reflex zone for the whole organism, so warm influence on the face tells on the work of the breathing-organs, cardiovascular system, nervous system quit well. This influence helps to fight against the virus and speeds-up the recovery.

In the moment of epidemics of the flue, you may warm up the nasal cavity before going to bed for 15-20 minutes, this decreases the probability of the appearance and spread of the diseases, so UTL-01-"ELAT" is a good prophylactic means. All these effects are achieved by means of local, also very important, regulated in "endurable" diapason (40-43 °C) and unlimited, in time, influence.

When working, one usually feels some pleasant warmth. Sometimes one feels weak pain, which corresponds to the recovery of the adequate reaction of the organism to the inner disturbances (the pain passes very quickly), if there is a nervous knot in this region.

When treating chronicle diseases, the pain may become more acute during the first 3-5 days, but then the pain passes gradually.

4.2. Arrangement of the Device

4.2.1. The Device consists of a power-supply unit and a heating element which are connected by the patient's cable of (2,1±0,1)m in length having a sliding switch for the selection of corresponding operating conditions.

4.2.2. The body of the power supplier is made of solid polystyrene and reinforced with a switch-plug, that connects the device with a socket of the electric system.

4.2.3. The temperature (operating conditions) is set using a sliding switch which should be positioned accordingly.

The positions of the controls in relation to the operating conditions are shown in Table 2.

Table 2

Operating conditions	Sliding switch position
1	"1"
2	"2"
3	"3"

4.2.4. The warming-up element consists of two flexible connected elastic warming-up plates of a special form, which are put on the necessary region.

Note. Please, at treatment use the auxiliary holder for heating element as it is shown on fig.1

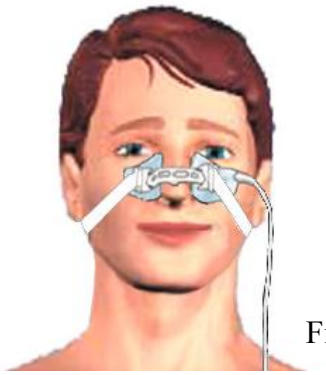


Fig. 1

4.3. Marks

There are the following marks on the body of the device:

"The device is of the class II".
The mark shows that the device correspond to the safety class II according to IEC 601-1-88;

"Attention, pay attention to the instructions";

"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. CAUTION

5.1. Make use of the device only after reading the instructions.

5.2. Use the device only in the places, where it is easy to plug the switch plug in the socket, without extending the cable of the patient.

5.3. There is no need to ground the device.

5.4. Don't strike or shake the device, keep away from moisture.

5.5. It is **FOBIDDEN** to make use of the device, with the broken body of the power supplier.

6. OPERATION

6.1. Preparation of the Device for application

At treatment-and-prophylactic institutions the Device should be prepared for operation as follows:

1) If the Device was stored or transported at a temperature lower than +10°C it should be kept at a room temperature (between 10 °C and 35 °C) for at least 4 hours before its application;

2) Disinfection of the power-supply unit (body) and the patient's cable should be carried out prior to the first application of the Device and henceforth when necessary by wiping it twice with 10 minutes' interval using a clean cloth moistened with the solution of one of the agents indicated in item 2.7 (Table 1);

Information of the ways to prepare working solutions, article washing conditions to remove the agent remains as well as safety measures to follow when working with these agents can be found in methodical instructions for their use;

3) Prior to the first application of the Device disinfect the heating element and the adjacent part of the patient's cable (10-15 cm) by wiping them twice with 10-minutes' interval using a clean cloth moistened with 3%-solution of hydrogen peroxide, or 1%-solution of chloramine B, or Veltocept.

WARNING! *Disinfection of the power-supply unit by its immersing into the solution is not allowed;*

4) set the Device into disengaged position;

5) insert the plug into the mains socket;

6) activate the Device choosing operating conditions «1»;

7) in 10 minutes the Device is ready for use.

Preparation of the Device to be used at home:

1) If the Device was stored or transported at a temperature lower than +10°C it should be kept at room temperature (between 10 °C and 35 °C) for at least 4 hours before its application;

2) Disinfection of the power supply unit (body) and the patient's cable should be carried out prior to the first application of the Device and henceforth when necessary by wiping it twice with 10 minutes' interval using a clean cloth moistened with the solution of one of the agents indicated in item 2.7 (Table 1);

3) prior to the first application of the Device disinfect the heating element and the adjacent part of the patient's cable (10-15 cm) by wiping them twice with 10-minutes' interval using a clean

cloth moistened with 3%-solution of hydrogen peroxide, or 1%-solution of chloramine B, or Veltocept.

WARNING! *Disinfection of the power-supply unit by its immersing into the solution is not allowed;*

4) set the Device into disengaged position;

5) insert the plug into the mains socket;

6) activate the Device choosing operating conditions «1»;

7) in 10 minutes the Device is ready for use

6.2. Operation

1) Put the warming-up element on the skin in the region of the sick organ.

2) Choose the best temperature according to your feelings – "1" is the lowest temperature and "3" is the highest temperature. The continuance of the procedure is 20 – 30 min. every day.

3) The procedure being over, switch off the Device and remove the plug out of the mains socket.

4) Disinfect the heating element and the adjacent portion of the patient's cable (10-15 cm) as indicated in item 6.1.

5) Enclose the Device into the case.

Rhinitis (Running nose)

There are acute and chronicle rhinitis.

Acute rhinitis is the inflammatory process in the mucous membrane of the nose.

Chronicle rhinitis in the phase of exacerbation, discontinuous exacerbation and remission – prolonged or repeated inflammation of a mucous membrane of nose.

Symptoms of rhinitis : at first the feeling of light discomfort, dryness in the nasopharynx , nasal itch. Nasal breathing is hard, the patient squeezes, running eyes, the timbre of the voice changes, there are a lot of liquid nasal discharge.

At prolonged (Chronicle) rhinitis, in the phase of subsiding of the exacerbation, on the first place the difficulty of nasal

respiration appears owing to edema of a mucosa.

The warming up element is put on the both sides of the bridge of the nose and is fixed in this position by the fingers or special fixing shelves, which are situated on the surface of the warming-up plates, and other help devices (a string, elastic and so on.).

The procedure should be repeated 2-3 times a day, it's better do it in the morning and evening before going to bed. The time of the procedure 15-20 minutes. The treatment would we effective, if the patient would stay at a warm place at least 20-30 minutes after the procedure.

The procedure should be done for 12-14 days. The conditions of the discontinuance of the treatment – the patient can breathe through the nose freely and smell well. discontinuous exacerbation and remission

According to the doctor's prescription, one may take some remedies, usually some drops, and mustard baths for legs.

Sinuitis

There are acute and chronicle sinuitis.

Acute sinuitis is the inflammation of the maxillary (antrum of Highmore) sinus.

Chronical sinuitis in the phase of discontinuous exacerbation and remission is prolonged or repeated inflammation of sinuses.

The symptoms of the sinuitis: the feeling of tense or pain in the sick sinus the patient can't breathe and smell through the nose, nasal discharge, photophobia and running eyes.

The warming up element is put on the both sides of the bridge of the nose and is fixed in this position by the fingers or special fixing shelves, which are situated on the surface of the warming-up plates, and other help devices (a string, elastic and so on.).

Choose the position of the button-switch according to your feelings. Mode "1" is the equivalent of the lowest temperature, mode "3" – the highest temperature. The procedure should be

repeated 2-3 times a day, it's better do it in the morning and evening before going to bed. The time of the procedure 15-20 minutes. The treatment would we effective, if the patient would stay at a warm place at least 20-30 minutes after the procedure.

It is possible to make use of some other remedies according to the doctor's prescription.

Tonsillitis (angina)

There are acute and chronicle tonsillitis.

Acute tonsillitis is the inflammation of the faucial tonsils.

Chronical tosillitis – the prolonged or repeated inflammation of palate tonsils.

The symptoms of the angina: the scratchy feeling in the throat, the feeling of a foreign body in the region of the tonsils, an unpleasant smell out of the throat, pain, when swallowing.

The warming up element is put on the both sides of the bridge of the nose and

Choose the position of the button-switch according to your feelings. Mode "1" is the equivalent of the lowest temperature, mode "3" – the highest temperature. The procedure should be repeated 2-3 times a day, it's better do it in the morning and evening before going to bed. The time of the procedure 15-20 minutes. The treatment would we effective, if the patient would stay at a warm place at least 20-30 minutes after the procedure.

Prophylaxis: people, who are often sick, should warm up the throat and the accessory nasal sinus.

At the same time with this treatment, the patient may gargle the mouth or make use of some other kinds of treatment, according to the doctor's prescriptions.

Frontal sinusitis metopantritis (sinuitis)

There are acute and chronicle frontal sinuitis metopantritis.

Acute frontal sinuitis metopantritis is the inflammation of the frontal sinus of the nose.

Chronicle frontal sinuitis metopantritis is the prolonged or repeated inflammation of frontal sinuses.

Symptoms: pain in the region of the forehead, especially in the morning, it's difficult to breathe through the nose, photophobia, the patient doesn't smell.

The warming up element is put on the frontal sinus, above the eyebrows and is fixed in this position by the fingers or special fixing shelf, which are situated on the surface of the warming-up plates and other help devices (a string, elastic and so on.).

Choose the position of the button-switch according to your feelings. Mode "1" is the equivalent of the lowest temperature, mode "3" – the highest temperature. The procedure should be repeated 2-3 times a day, it's better do it in the morning and evening before going to bed. The time of the procedure 15-20 minutes. The treatment would we effective, if the patient would stay at a warm place at least 20-30 minutes after the procedure. The patient may use some other remedies at the same time with the device, according to the doctor's prescription.

7. MAINTENANCE SERVICE

7.1. The owner of the device fulfills the maintenance service.

7.2. The order of the maintenance service is given in the table 3.

Table 3

The type of the work	Periodicity
1. Checking the body of the device.	Every time before using
2. Cleaning from dust and mud, disinfection.	Not less ofter than once amonth

8. STORAGE AND TRANSPORTATION

The device is permitted to be stored in unheated storage at air temperature from +40 C to –50 C, air relative humidity –98% at air temperature +25 C or 80% at air temperature +20 C.

The device can be transported by all types of closed transport facilities at conditions as follows:

-air temperature - -50 C - +50 C;

-air relative humidity –100% at air temperature +25 C or 80% at air temperature +20 C.

9. CERTIFICATE OF ACCEPTANCE

Device for Thermotherapy of Accessory Nose and Laryngeal Sinuses FEYA

Plant number_____

is recognized as ready-for-serevice

Date of output _____

Place for the Stamp

Device for Thermotherapy of Accessory Nose and Laryngeal Sinuses FEYA is packed according to the norms of the documentation.

Date of boxing _____

Packer_____

Place for the Stamp

The boxed device has been accepted by

_____

(sign)

10. MANUFACTURER'S WARRANTY

10.1. The manufacture guarantees, that the device would correspond to the characteristic features described in the operating manual, in the case of following all the rules and circumstances conditions of keeping, transportation and exploitation.

The guarantee time of exploitation – 12 months from the date of sale.

During the guarantee time the plant-manufacture repairs or replacesthe device, if the owner presents acceptance certificate.

10.2. Conditions of guarantee.

10.2.1. The guarantee is valid, if there is a right and correctly filled talon, with the mentioning of the plant number of the device, the date of sale and clear stamp of the trading organization.

10.2.2. The guarantee is not valid in the following cases:

- if there are some marks of anyone's interference or there was an attempt to fix the device in a not authorize service center;
- if there were found any changes of the construction or the scheme;
- if there are some mechanical damages;
- if there are damages, the reason for which was some things, liquids or substances, which have got inside;
- if the damages are the result of unconformity of the electrical system on request.

10.3. The electrical schemes, description and the other technical documentation to the authorize service centers on request.