# INSTRUCTION FOR USE (IFU)

## Low-Intensity VHF-UHF Therapy Apparatus

# BIOL

UA.TR.039

**KHARKIV**
**Version 3.0**

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# CONETNT

## SYMBOLS AND SIGNS

| | | | |
|---|---|---|---|
|  | Warning |  | Prohibition |
|  | Obligatory action |  | Sample sign for obligatory actions |
|  | Be sure to read the instruction | IP20 | Degree of protection of the device against penetration of solid objects |
|  | Protective ground |  | Working part of type BF |
| ON | To turn the power on | 100-240VAC | Supply voltage of the device |
| OFF | To turn the power off | T4AL250V | A fuse |
|  | Manufacturer | OK | Enter a value |
|  | Date of manufacture | SN | Serial number of the device |
|  | It is disposed as used electronic equipment |  | CLASS II<br>IEC 60417-5172 |

# 1 GENERAL REVIEW

## 1.1 INTENDED USE

The device BIOL is intended for the treatment of adult patients as part of complex therapy to reduce the postoperative and rehabilitation period in patients due to the analgesic effect and accelerating the healing process, make more efficient the recovery process after the cerebrovascular insult (CVI)/stroke, modulate the patient's immune system, accelerate the healing of wounds and injuries, use as a supporting means in the treatment and prophylactic of viral diseases (herpes, cytomegalovirus, etc.).

## 1.2 RECOMMENDATIONS FOR USE

Individual use of the device is recommended by the appointment of a physician, taking into account contraindications. The doctor determines the duration and number of sessions, as well as controls the progress of treatment according to the clinical data of the patient.

Therapy with low-intensity VHF-UHF electromagnetic radiation (waves of meter and decimetre range) is recommended for the treatment of patients in the complex therapy, considering its analgesic and immunomodulating effect, for such diseases:

- √ cerebrovascular insult (CVI)/strokes (in a process of rehabilitation);
- √ subacute and chronic inflammatory diseases: bronchitis, pneumonia, cholecystitis, salpingitis, benign prostatic hyperplasia, etc.;
- √ acute, subacute and chronic inflammation without the purulent process of the paranasal sinuses, middle ear, tonsils and the oral cavity;
- √ diseases of the cardiovascular system: primary and secondary hypertension, rheumatism, etc.;
- √ injuries and diseases of joints and spine of different genesis: arthritis, arthrosis, parasynovitis, epicondylitis, bursitis, back pain, sprains, bruises, myositis, tenosynovitis, etc.;
- √ diseases of the nervous system: plexitis, radicular pain, vibration disease, etc.;
- √ inflammatory diseases of tissues: mastitis, post-operative infiltration, bruises etc.;
- √ nonhealing wounds and immunity deficiency.

The medical device intended used as a supporting means in the treatment and prophylactic of viral diseases and increasing the effectiveness of the immune system.

The apparatus is recommended for use in the medical institutions, medical and preventive treatment facilities, health resorts and rehabilitation centers, in-patient and out-patient clinics.

## 1.3 CONTRAINDICATIONS

*Proper examination and diagnosis must be performed, before starting treatment with the device. Please keep up to date with the latest developments and medical publications on devices with low-intensity electromagnetic radiation for detailed information on contraindications and side effects not known at the time of the device's manufacture. Contraindications listed in this section are given at the time of writing of the Instruction. No claims regarding the completeness of this list of contraindications are accepted. Before carrying out the procedures, a medical specialist should be convinced of the expediency of using this procedure, the responsibility for which he bears personally.*

**The use of the device is contraindicated if a patient has the following signs or pathologies:**

- ⊗ Pregnancy is an absolute contraindication for use;
- ⊗ Individual intolerance of the procedure and/or discomfort during the procedure are the indication for its cancellation;
- ⊗ Bleeding, the threat of bleeding and the use of anticoagulants: violation of blood clotting, namely hemophilia, hemorrhage, hemorrhoid and ulcers with a risk of bleeding, open wounds and injuries etc. and the use of anticoagulants, especially marcoumar;

- ⊗ Thrombosis and threat of thrombosis of deep veins, phlebitis, varicose veins (allowed by a doctor's prescription);
- ⊗ Peripheral vascular diseases and cardio-circulatory failure, including occlusive vascular disease, obliterating arteriosclerosis and thromboangiitis obliterans (Buerger disease), in which organic occlusion and ischemia are evident, etc;
- ⊗ Treatment with hormones should be finished at least 6 weeks before the first procedure with the device;
- ⊗ Presence of inflammatory processes that are accompanied by the formation of pus, swelling of the tissues and the presence of foreign bodies in the affected area;
- ⊗ Heart disorders, including unstable angina, paroxysmal cardiac arrhythmia;
- ⊗ Epilepsy
- ⊗ Peptic ulcer.

### 1.4 SIDE EFFECTS

Side effects have not been detected. Adverse effects of using the device are possible in case of neglect of the requirements for contraindications.

## 2 WARNINGS AND SAFETY PROVISIONS

### 2.1 SAFETY SIGNS ON THE DEVICE

The device is protected by reinforced insulation and has no galvanic connection to the ground

**IP20** Degree of protection against external influences.

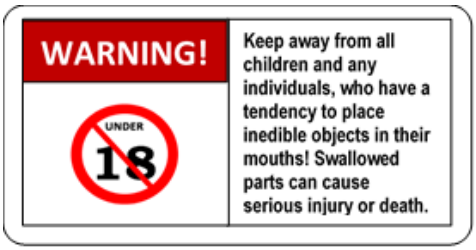
### 2.2 WARNINGS AND SAFETY PROVISIONS

The user must have the proper technical and medical qualifications and know the user's manual of this device in order to use this device. All maintenance procedures recommended by the manufacturer must be performed by personnel with appropriate approvals.

It is allowed to use the device in medical centers, in rehabilitation and sports medicine centers, SPA centers, massage rooms for adult patients (18 years and older).

The operator must inspect the housing of the electronic unit, as well as the power cord to ensure there is no external damage. Operation of the device with a damaged casing or a power cord is prohibited!

This device complies with the requirements of the electrical safety standard EN 60601-1: 2010.
It is necessary to connect the device to the mains supply in accordance with the national electrical safety regulations.



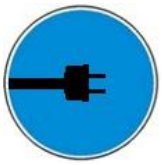

The device must be placed beyond the reach of a patient, especially children

Certified and safe materials are used for the device.

ATTENTION! Modification of the product is not allowed!

CAUTION! To avoid the risk of electric shock, the product must only be connected to a main supply that has a protective ground.

Disconnect the device from the power supply, before performing any cleaning or maintenance work. The means of simultaneous electrical separation of the supply circuits of the device from the circuits of the supply network is the mains switch of the device.



Connect the device only to a working socket with a rated voltage within the range 100 - 240V 50-60Hz. The location of the device should ensure that there is no tension on the power cord, unhindered connection and disconnection of the power cord from the mains are to be ensured to quick disconnection of the device from the mains in emergency situations.

Do not allow humidity to enter the electronics housing. Do not expose the device to dampness, vibration, or shock.

It is prohibited to use the device in a potentially explosive atmosphere, i.e. in the presence of a mixture of flammable anesthetic gas with air, oxygen or nitrogen oxide.
It is prohibited to use the device in rooms where flammable and potentially explosive substances are stored or used.

Potentially, there is a risk of passing microbes through the surface of the housing of the device. It is recommended to clean it regularly!

The patient should be properly located for treatment. It is necessary to monitor a patient's state during the procedure.

It is allowed to use the device only after studying this IFU!

It is prohibited to use the medical device in an oxygen-rich environment.

### 2.3 MEASURES TO PREVENT DAMAGE OF EQUIPMENT AND THE DEVICE

Connect the device to the mains through a circuit breaker with the characteristic "C" and a rated current of not more than 6A.

The placement of the device must ensure uninterrupted connection and disconnection of the power cord from the mains. Avoid the situation when the power cord is under the feet of a user or patient! Do not allow the mechanical load on the power cable and the device's enclosure (compression, stretching, stepping on, etc)!

It is prohibited to cover the device during operation.

It is forbidden to disconnect the device during operation from the mains network.

This device complies with the requirements of electrical safety and EMC (IEC 60601-1: 2005-12 3rd ed.). As a rule, the level of emitted electromagnetic interference is not sufficient to disrupt the operation of most devices. However, it should exclude the operation of the device in close proximity to sensitive equipment. It is recommended to place the device no closer than 3m to such equipment.

The device must be stored in a place protected from the direct sunshine.

It is necessary to exclude contact of the device with different solvents, gasoline, kerosene and other substances that can destroy or damage the device housing.

It is forbidden to install the device on slippery surfaces to prevent the device from falling.

## 3 BRIEF DESCRIPTION OF THE DEVICE

The therapeutic action on tissues and inner organs of a patient by low intensity electromagnetic field with frequency band of 100-1,500 MHz.

Emitted electromagnetic waves result have the oscillatory effect in the human body, thus stimulating activity of the physical and chemical processes in the body. The penetrating ability of UHF waves in tissue is 8-11 cm on average. Skin and subcutaneous fat thickness have no significant influence on the reflection and absorption coefficients of the waves.

### 3.1 FUNCTIONAL DIAGRAM OF THE DEVICE

Functional diagram of the device BIOL (Pic. 3.1) includes radio frequency generator modules and module of emmiters, operation mode processor, sensor of emission, control panel and power supply unit.

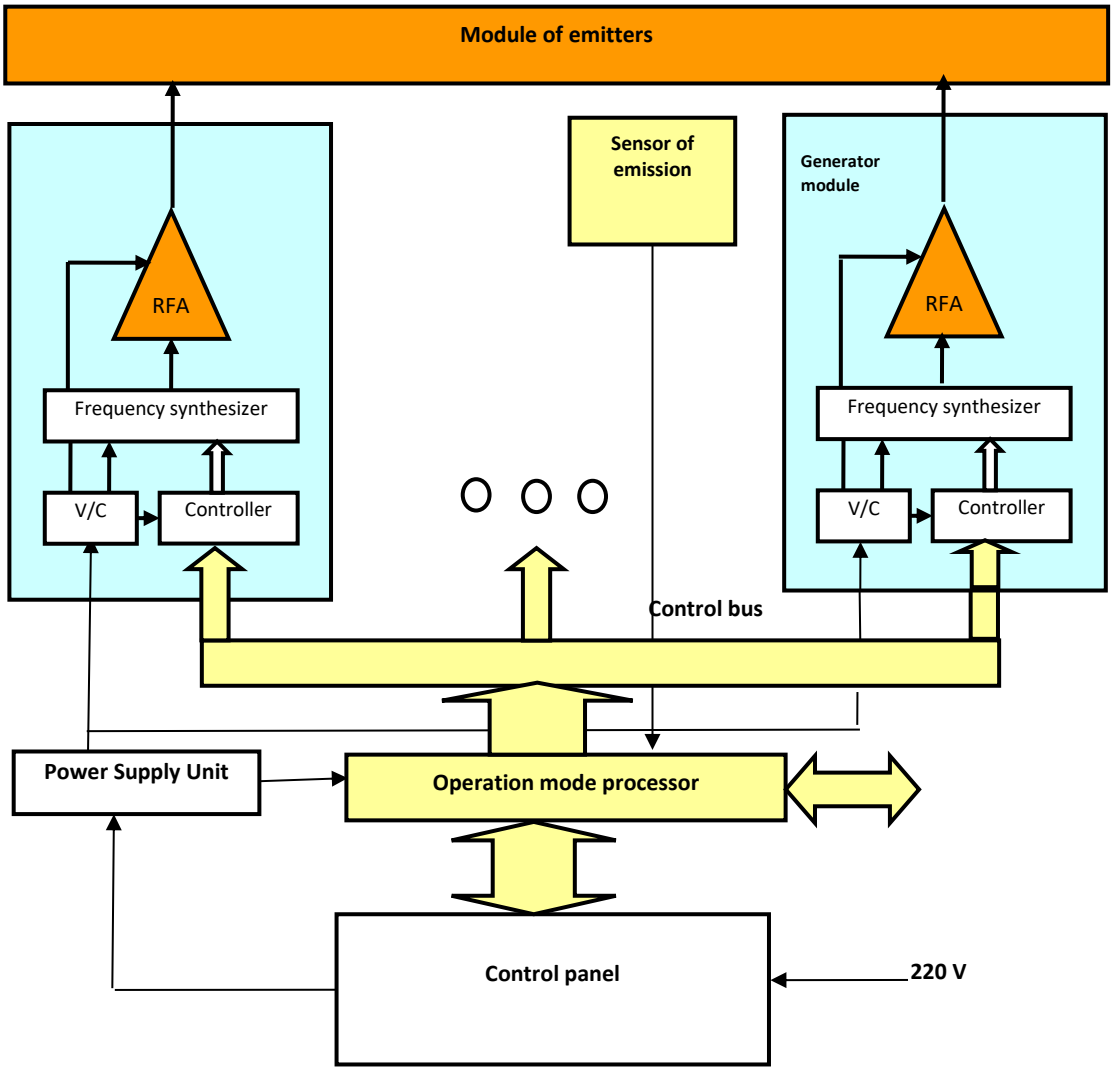
Generator modules are designed to generate radio-frequency signals, amplify those signals and match them to the radiating aerials, which are located in the radiator module. The signal is generated by frequency synthesizer microchip. The center radiated frequency value, deviation and the law of frequency variation are defined by the controller.

Control over the generator module controllers is carried through control bus of the operation mode processor. The switch-on sequence of the generators, session time, center frequency values and the law of their variation, as well as other parameters, are set according to the chosen operation mode. The control panel lets choose two possible operation modes: "Therapy" and "Rehabilitation". The mode "Preparing" is run automatically after each switching on the device and provides self-testing and diagnostics of the hardware.

Using the control panel, you can switch on/off the apparatus, choose operation mode (Therapy/Rehabilitation), and set the session time. The control panel indicator is used to visualize parameters of the assigned mode of operation, and, after the beginning of the session, time to finish the session and the total time of the device's working.

A built-in sensor of emission provides sequential control over the emitted radio signal in the "Preparing" mode.

A power supply unit is designed to generate stabilized DC voltage of 5 V. Voltage converters (V/C) of the generator modules provide the formation of boosting DC voltage, which is necessary for the operation of the modules. Radio frequency amplifiers (RFA) are designed to amplify a signal, generated by the signal synthesizers, to the rated power value.




Picture 3.1 Functional Diagram of the device BIOL

# 4 BEFORE USING THE DEVICE BIOL

## 4.1 THE LIST OF PREPARATORY ACTIONS

Before using the device BIOL, it is necessary to do the following:

- √ Make sure that the power supply network is used with a protective ground; that the voltage in the network is in the range 100 - 240V, 50 - 60 Hz. The device BIOL is intended for connection to type F (Schuko) sockets (European socket with CEE 7/4 grounding, DIN 49440 standard).

A suitable adapter is required to connect the device to other types of sockets; in any case, the presence of a protective ground in the power socket is mandatory!

- √ Ensure the presence and storage of 70 - 96% water-alcohol solution to clean the device.
- √ Ensure the presence and storage of medical alcohol wipes or cotton pads for cleaning the device.
- √ Ensure the presence and storage of wet wipes for a screen that does not contain alcohol to clean the display of the device BIOL.
- √ Organize the workplace of the operator so that the device is placed on a solid, smooth, dry and not slippery surface to comply with the measures listed in paragraph 2.3.
- √ Remove the device from its packaging. Check if there is no damage to the housing of the device and the power cord. Check that the power switch is in the position "Off" (the button on the front panel is in the "not pressed" position.)
- √ Connect the power cord to the power connector on a back panel of the electronic unit, plug the power cord into a power socket.

### 4.2 THE OPERATOR'S QUALIFICATION

The device BIOL is intended for use by the operators having special knowledge in the field of application of this device and trained about the proper application of the device, as well as the operators who have practical skills in working with similar medical equipment.

The operator should have main physical and cognitive abilities, such as sight, hearing and literacy. A tremor in hands of the operator is an obstacle for the device use, as the parameters of a session could not be set.

Besides, the operator must take into account the manufacturer's recommendations (Chapter 1, item 1.2 "Indications for use" and item 1.3 "Contraindications") to be aware of the latest developments and medical publications for detailed information on contraindications and side effects, not known at the time of manufacture.

The operator has to take the appropriate training regarding the correct operation of the device before working with it:

- √ Intended use of the device with practical exercises;
- √ The mechanism of action and function of the device;
- √ Setting up of the working modes;
- √ Recommendations for use of the device;
- √ Contraindications and side effects;
- √ An explanation of alerts in all modes of operation;
- √ Method of functional verification of the device.

Further recommendations for the scope of training may vary depending on the country. Please contact your local representative of "Biopromin" LTD for detailed information on training.

## 5 OPERATION OF THE DEVICE BIOL

In a process of the device application, the operator must be in a satisfactory physical and emotional state (after a sufficient rest), should not take in psychotropic substances, analgesics, opiates, sleeping pills, drugs or alcohol for at least 48 hours before performing procedures using the device.

### 5.1 A PATIENT'S LOCATION

The patient should be at a distance of 1.5-2 meters from the device from any side in a convenient position (sitting, lying, etc.).

### 5.2 AN OPERATOR'S LOCATION

The operator is not recommended to be within a radius of 3m around the device during the treatment session.

### 5.3 RECOMMENDED OPERATING MODES

The device BIOL is pre-programmed for two main working modes, namely:

| «THERAPY» | «REHABILITATION» |
|---|---|
| The mode, which is used for treatment | The mode, which is used for prevention of diseases |

### 5.4 SWITCHING THE DEVICE ON

5.4.1 Connect the power cord to the device and plug it into the power supply.

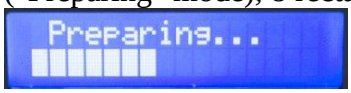
5.4.2 Press the power button on the front panel of the device:


The red indicator on the button will light up

5.4.3 The information on the process of preparing the device for work will be displayed ("Preparing"), during which the automatic self-testing and diagnostics of the device are carried out:


5.4.4 Upon completion of preparing, the device is ready to be used "Ready" and it goes into the standby mode of setting the session parameters. The information about the total operating time of the device is displayed "Total: XXh XXm" (total operating time in hours (h) and minutes (m) since it was manufactured)::

When preparing the device for work, during the self-testing and diagnostics ("Preparing" mode), 8 rectangles must be displayed successively..




In the absence of at least one of the rectangles, the device is to be repaired. Further use of the device is prohibited. Contact the manufacturer!

## 5.5 DESCRIPTION OF CONTROL MEANS

The only one control element of the device is the knob (encoder), which rotates both clockwise and counterclockwise (without restriction), and also pressed (as a button). It is located on the front of the device to the right of the display.


## 5.6 SETTING UP THE PARAMETERS OF SESSION

To prevent damage to the knob-encoder, do not apply excessive force when pressed, avoid impacts and strokes. Keep the device in the supplied bag. Put a damper compactor around the knob-encoder when transporting (included in the delivery set).

### *5.6.1 Setting the operating mode*

Press the knob-encoder perpendicular to the front panel, the same as you press the normal button.

The Menu will appear on the display: «Rehabilitation» or «Therapy» mode will be displayed


To switch the mode from “Therapy” to “Rehabilitation” or vice versa, roll the knob-encoder left or right. Once the menu you need is displayed, press the encoder-knob, as a normal button. The operating mode of the device is set.

### *5.6.2 Setting the time of session*

After setting up the mode of operation, the menu for time setting will be displayed (duration of a session).


First you need to set the duration of the session in ***hours*** - «Enter hours…». To start, press the encoder-knob, as a normal button. Then rotate the knob-encoder left or right to select the required number of hours for a session. Set hours by pressing the knob-encoder, as a button.

*Notice: If the duration of the session does not exceed one hour, then set the number 0 (zero) to the "Enter hours ..." field, according to the instructions above.*

The next step is to set the number of ***minutes*** of the required operating time – it is done the same as for the hours, by rotating and pressing the knob-encoder (described above).

After setting the time of operation (both hours and minutes), the session begins and the information about set mode ("Therapy" or "Rehabilitation") and time of session "Time: " is displayed.


The operating time of the device on the display will gradually decrease (the timer works in the opposite direction): from the set number to zero.

At the end of the set working time (session), a short beep will sound and the unit will go into the "Ready" mode automatically. The device is ready again to set the parameters of a new session.

## 5.7 SHUTDOWN AND STORAGE

To shut down the device BIOL properly, press the power button, which is located on the front panel of the device to the right. The LED on the button goes out. Then you can unplug the power cord and place the device in a portable protective case and put a damper compactor around the knob-encoder (included in the delivery set).

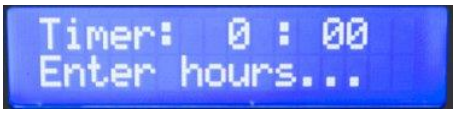
## 5.8 MESSAGES ON THE DISPLAY


Automatic mode of preparation of the device to work, which includes self-testing and diagnostics of hardware are carried out – “Preparing”

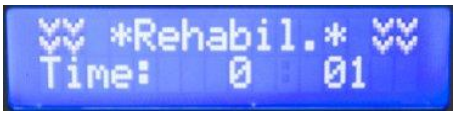

Standby mode - the device is ready for setting the mode of operation and time of session – “Ready”


The mode for diseases prevention - «Rehabilitation»


The mode for diseases treatment - «Therapy»




Menu to setup the time of a session




Indication of the device's operation in the set mode «Rehabilitation»


Power indication of the device (the red indicator on the button is light when the device is turned on)..


Power indication of the device (the red indicator on the button isn’t light when the device is turned off).

Sound signal

The short beep is sound when any of the operating mode is completed and the device is switched to the “Ready” mode.

# 6 MAINTENANCE OF THE DEVICE

## 6.1 CLEANING

Regular cleaning of the device ensures its reliable and trouble-free operation.
Before cleaning and/or repair, disconnect the device from the mains.
In general, external cleaning of the device's housing is carried out depending on the frequency of the device use.
All the details that are in contact with the operator must be cleaned with medical alcohol wipes or cotton pads soaked in 70-96% water-alcohol solution.
It is very important to avoid an enter of liquids inside the device.
It is necessary to keep clean the ventilation slots of the device.
Only special non-woven wipes for LCD monitors are allowed to clean the TFT display. Those wipes should not contain alcohol.

## 6.2 FUSE REPLACEMENT

If the device does not work, after connecting to a power supply and turning on, so it is necessary to check and replace a fuse/fuses: maybe one of them is failed (swelled). The fuse holders are located on the back panel of the device. Please follow these steps to replace the fuse:

- √ Unplug the power cord from the power socket.
- √ Unlock one of the fuse holders on the panel.
- √ Remove the damaged fuse from the holder.
- √ Install a new fuse in the holder (type T4AL250V or T4AH250V).
- √ Lock the fuse holder back into the panel

## 6.3 MAINTENANCE AND SAFETY CHECK

Preventive maintenance is not necessary. However, regular maintenance can help to identify possible defects at an early stage and thus to increase safety and to extend the life of the device.

It is recommended to perform functional checks and safety checks of the device at least once a year. If the national safety regulations for medical devices require a more frequent periodicity of tests and inspections, so it is necessary to follow national regulatory documents. Functional and safety checks are carried out at the producing factory or at authorized service centers.

## 6.4 DISPOSAL AND ENVIRONMENTAL PROTECTION

In case of failure and impossibility of further use of the device BIOL, it is disposed of as used electronic equipment. Please dispose of the apparatus in accordance with the current regulations in your country.

**PACKAGING DISPOSAL**: Packaging components (cardboard, expanded polystyrene, etc.) are classified as solid waste and therefore they can be easily recycled by using recycling processes. Before sending the components to special recycling centers, it is necessary to check local regulations in that regard in order to comply with them fully.

**PRODUCT DISPOSAL**: The device BIOL consists of various materials. Nevertheless, all of them (metal, plastic, electrical conductors, printed circuit boards, chips, etc.) do not contain hazardous substances and they can be sent to special recycling centers in the same way as electronic equipment. Before sending the components to special recycling centers, it is necessary to check local regulations in that regard in order to comply with them fully.

### 6.5 REPAIR

Only personnel who has an appropriate authorisation from the company «Biopromin» LTD can carry out repairs of faulty devices BIOL. Only the spare parts indicated by «Biopromin» LTD must be used for that. The personnel with appropriate authorisation may include «Biopromin» LTD staff and technician specialists of sales representatives who have permission from «Biopromin» LTD.

### 6.6 LIFETIME

Considering the characteristics of similar equipment on the market, as well as the actual period of the device BIOL being marketed (since 2013), the following lifetime period is established for the device, with the obligatory compliance with conditions of packaging, storage, transportation and use:

• 5 years or 2 500 working hours - for the electronic unit of the BIOL;

The probability of failure of the components and accessories of the device increases after exceeding of the lifetime.

## 7 COMPLETION AND RECOMMENDED SERVICE MATERIALS

### 7.1 COMPLETE SET OF THE DEVICE

The device BIOL complete set includes the following:

- √ Electronic unit BIOL;
- √ Power cable;
- √ Bag (case) for transportation and storage of the device BIOL;
- √ Instruction for Use with warranty card

### 7.2 RECOMMENDED MATERIALS FOR SERVICE AND MAINTENANCE

It is recommended to use the following items for cleaning:

- √ 70 - 96% water-alcohol solution and cotton pads;
  OR
- √ Medical alcohol wipes

It is recommended to use wet wipes for monitors that do not contain alcohol to clean the display of the device BIOL.

## 8 DEVICE APPEARANCE

# 9 TECHNICAL DESCRIPTION

## 9.1 CLASSIFICATION

By the way of protection against electric shock, the device belongs to the class I with a working part of type BF.

The degree of protection against external influences is IP20.

The operating mode of the electronic unit of the device is long.

In terms of the degree of risk of medical use, the device belongs to class IIa according to the Technical Regulation No. 753 and the Directive 2007/47/ EC which amendments the Directive 93/42 / EEC.

## 9.2 TECHNICAL DATA

| **The electronic unit** | |
|---|---|
| Input voltage of the network | 100-240 VAC 0.35-0.2 A |
| Network frequency | 50/60 Hz |
| The mains fuse type | T4AH250V or T4AL250V |
| Electricity consumption | max. 15V.A |
| Total output power | 0.1 W |
| The ambient temperature during the operation process | 5 – 40 °C |
| The ambient temperature during a storage and transportation | -25 ° C without relative humidity control + 70 ° C with relative humidity control<br>This class 7K3 as described in IEC/TR 60721-4-7:2001 |
| Ambient air pressure | 700-1060 hectopascal |
| Air humidity | 15%-93%, without condensation |
| Total weight | 2,0 kg. |
| Net weight | 1,5 kg. |
| Dimensions of the device BIOL (D / W / H) | 260x180x65 mm. |
| Protection against water penetration | IP20 |
| Software version | V.1.0 |

The mains switch of the device is the means of simultaneous electrical separation of the power circuits of the device BIOL from the supply network circuits.

## 9.3 TRANSPORTATION AND STORAGE

Transportation and storage of the device BIOL are only permitted in the manufacturer's packaging.

You should avoid shaking and impacting of the package during transportation and storage.

Storage and transportation conditions of the device are the following:

- √ from -25 ° C (without relative humidity control) up to + 70 ° C (with relative humidity control);

- √ relative humidity 15% -93% without condensation;
- √ And also, the absence of aggressive impurities that cause corrosion in the air.

## 10 WARRANTY TERMS

The warranty for the device BIOL is 36 months from the date of sale.

The warranty does not cover cables and fuses.

The manufacturer or the authorized representative provides the free repair of malfunctions or replacement of the device during the warranty period if there is a detection of manufacturing defects or defects in materials. The warranty for such a device does not apply if faults are caused by the user, due to a violation of the operating rules of the device described in this IFU, or the device was misused.

The warranty also does not cover damages caused by the user violating the storage and transportation rules set out in this IFU, as well as the force majeure.

Warranty claims are accepted only on the condition that the device is returned in its complete configuration, in its pure form, without external mechanical damages and traces of disassembly/opening.

Transportation costs and the risk of accidental loss during the delivery of the returned product shall be borne by the customer.

**ATTENTION! It is not allowed to make any changes in the design of the device. Any unauthorized opening, repair or modification of the system by unauthorized personnel releases the manufacturer from obligations and responsibility for the safe operation of the device. In this case, the warranty is automatically declared invalid even before the expiration of the warranty period. The warranty is cancelled if the customer has made a modification or made any uncoordinated changes to the software of the device without the written consent of the company «Biopromin» LTD.**

For all questions regarding the operation of the device, please contact our customer service:
**«BIOPROMIN» LTD**
Provulok Kinnyi 8a, 61001 Kharkiv, Ukraine
e-mail: biopromin@yahoo.com.ua
tel. +38-057-755 43 35

## 11 POSSIBLE ERRORS AND MALFUNCTIONS. TROUBLESHOOTING

| | Error / problem | Possible reasons | Indicators / Disposal |
|---|---|---|---|
| E1 | The device does not turn on | No power supply | -Check the presence of an electrical current in the mains. In case of absence, try again later.<br>- Check the connection of the power cord to the device and to an electrical outlet.<br>- Check the network cable for defects if there are any and replace it. |
| | | The refractory fuses are defective or missing | Check the installed refractory fuses; replace the damaged ones or install the missing ones. |
| E2 | Less than 8 indicator rectangles appeared on the display after run the device, in the process of Preparing<br>  | One (or more) internal generator is defective. | The device must be repaired at the factory. Send the device to the nearest authorized service center or representative office of LTD BIOPROMIN or to the manufacturer. |

## 12 CHECKLIST

| No | Date of verification / control Warranty / post-warranty service | Remark | Note | Performer | Sign |
|---|---|---|---|---|---|
| 1. | | | | | |
| 2. | | | | | |
| 3. | | | | | |

## 13 PRODUCT ACCEPTANCE PROTOCOL

The device BIOL, No **B**_____ complies with the technical requirementsand is completely serviceable.
The warranty period is 36 months from the date of delivery of the equipment.

Date of manufacture "_____" _____ 20___.

(signature) (First name and Last name)

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URL: www.biopromin.com

**Authorized representative in European Union: "ONKOCET Ltd."**
4 Kutuzovova str., 90201 Pezinok, Slovakia,
tel.: +421 (2) 44 64 09 77
E-mail: onkocet@onkocet.eu
URL: www.onkocet.eu

## 14 PACKING LIST

The device BIOL, No **B** _____ is packed in the company «BIOPROMIN» LTD in accordance with the technical requirements.

Date of packing «_____» _____ 20_____.

A packer:

Signature First name and Last name

**"Biopromin" LTD**
Provulok Kinnyi 8a, Kharkiv,
61001, Ukraine
Tel.: +38 (057) 755 43 35
E-mail: biopromin@yahoo.com.ua
URL: www.biopromin.com

**Authorized representative in the European Union: "ONKOCET Ltd."**
4 Kutuzovova str., 90201 Pezinok, Slovakia,
tel.: +421 (2) 44 64 09 77
E-mail: onkocet@onkocet.eu
URL: www.onkocet.eu

## 15 WARRANTY CERTIFICATE

For repair (replacement) during the warranty period
Medical Equipment - **BIOL**

Serial number of the device
B_____

Date of manufacture
«_____» _____20___

Date of purchase
«_____» _____20___

Signature and seal of the seller

Date of commissioning
«_____» _____20___

Signature

The operating time of the device
_____ [*hour:min*]

Signature

The warranty for the device BIOL is 36 months from the date of sale.

The warranty does not cover power cables and fuses.

The manufacturer or his authorized representative performs free repair of malfunctions or replacement of the device during the warranty period, if there is detection of manufacturing defects or defects in materials. The warranty for such a device does not apply if there are faults caused by the user, due to a violation of the operating rules of the device described in this manual, or the usage of the device for other purposes.

The warranty also does not cover damages caused by the user violating the storage and transportation rules set out in this manual, as well as the force majeure.

Warranty claims are accepted only on condition that the device is returned in its complete configuration, in its pure form, without external mechanical damages and traces of disassembly / opening.

Transportation costs and the risk of accidental loss during the delivery of the returned product shall be borne by the customer.

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**Authorized representative in the EU**
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URL: www.onkocet.eu

All valid permits and certificates are available on the manufacturer's website www.biopromin.com

## 16 LABELLING



## 17 DOCUMENT HISTORY AND VERSION CONTROL

| Version | Version Date | Summary of changes | Author | Related documents |
|---|---|---|---|---|
| 1.0 | 2011-12-02 | Created | Team, listed on the title | |
| 2.0 | 2018-04-12 | Information added | **Проведена реструктуризація настанови** | |
| 3.0 | 2020-06-25 | Labelling is corrected to comply with the IEC 60601-1 ed.3.1 in regards to the requirements for obligatory reading of IFU | Team, listed on the title | Clause 16 |
| | | It is prohibited to use the MD in an oxygen-rich environment. | | Clause 2.2 |
| | | Change address | | Clause 10, 13-15, page 2 |

**Read the IFU carefully before using the device!**