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Low Intensity Microwave and Decimeter Wave Therapy Apparatus “BIOL”

Operation Manual

АЛТА. 941529.001



Kharkiv, Ukraine
2016



UA.TR.039

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Present Operation Manual (OM) is a document, which contains information about design, operating principle, and characteristics of a medical-purpose product - Low Intensity Microwave and Decimeter Wave Therapy Apparatus «BIOL» AJTA. 941529.001 (hereinafter referred to as the Device), instructions, which are necessary for correct and safe operation, maintenance, storage and transportation of the apparatus.

The staff is admitted to the apparatus operation only upon familiarization with this manual.

1. DESCRIPTION AND OPERATION OF THE DEVICE «BIOL»

1.1. Purpose of the device «BIOL»

The apparatus is designed for 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 in the oscillatory effect in the human body, thus stimulating activity of the physical and chemical processes in the body. Penetrating power of the decimeter waves in tissue makes up 8-11 cm at an average. Skin and subcutaneous fat thickness have no significant influence on reflection coefficient and absorption coefficient of the decimeter waves.

1.2. Fields of application of the device «BIOL»

The device is intended for modulating of immune system of a patient, treatment of viral diseases (herpes, cytomegalovirus, etc.), reducing of postoperative and rehabilitation period, removing of pain syndrome.

Individual usage of the device is recommended by a doctor's prescription, who determines the duration and number of sessions, and monitors the progress of treatment according to the patient's clinical tests.

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

1.3. Technical and operating performance characteristics

Main technical characteristics are indicated in the Table 1.

Table 1 — technical characteristics of a medical-purpose product - Low Intensity Microwave and Decimeter Wave Therapy Apparatus «BIOL»

Characteristic	Value
Supply voltage of AC network of 50 Hz (V)	220±22
Power, consumed from network, not more (V·A)	15
Frequency band of electromagnetic oscillations, emitted by the apparatus (MHz)	100...1500
Number of generators	8
Electromagnetic radiation level at 1.2 m from the apparatus, not more ($\mu\text{W}/\text{cm}^2$)	2,5
Total rated output power (W)	0,1
Time for setting of operation mode from switch-on point, not more (s)	30
Timer setup tolerance at procedure duration up to 60 minutes (s)	±60
Timer setup tolerance at procedure duration above 60 minutes (s)	±120
Mean time to failure, not less (hours)	2500
Overall dimensions of the apparatus (mm)	260x180x65
Weight without spare parts and accessories, not more (kg)	1,5
Weight of complete equipment set, not more (kg)	2,0

Operating performance characteristics of the device:

Depending on the potential usage risk, the apparatus falls into Class “II a” according to DSTU 4388.

With reference to protection against electric shock, the apparatus corresponds to Class II of products without applied part, Type B according to DSTU 3798 (IEC 601-1-88).

As to operation conditions, the apparatus falls into climatic modification category for temperate cold climate 4.2 according to GOST 15150, but it is designed for operation at temperatures stipulated by GOST 20790.

In regard to response to the mechanical actions, the apparatus falls into group 2 according to GOST 20790.

In respect of failure effect, the apparatus belongs to Class B according to RD 50-707.

As for electromagnetic compatibility provision, the apparatus meets requirements of DSTU IEC 60601-1-2.

Running time is not more than 12 hours per day.

1.4. Completeness

Basic delivery set of the device «BIOL» includes:

Description	Designation	Quantity
1. Device «BIOL»	АЛТА. 941529.001	1
2. Operation Manual	АЛТА. 941529.001 HE	1
3. Case	АЛТА. 941529.003	1

1.5. Construction and design of the device «BIOL»

1.5.1. Functional chart of the device is shown on the fig.1

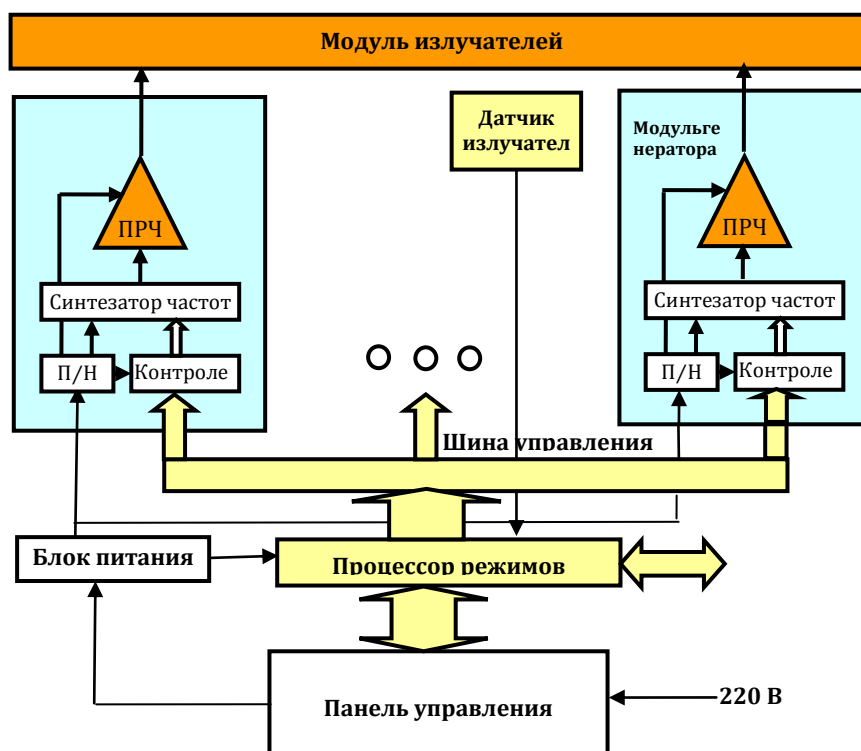


Fig. 1. Functional chart of the device «BIOL»

1.5.2. Operating principle of the device «BIOL»

Functional chart of the apparatus includes radio frequency generator modules and radiator modules, operation mode processor, radiation detectors, control panel and power 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. 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 provides three possible choices of main operation modes: “Therapy”, “Rehabilitation” and “Preparing”.

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

A built-in radiation detector provides the sequential control over the radiated radio signal in the Preparing mode.

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

1.5.3. Design of the device «BIOL»

Appearance of the device is shown on a Fig.2.



Fig.2 Appearance of the device «BIOL»

A GAINTA apparatus casing G758(V) with dimensions of 260x180x65 is made of fire-resistant polycarbonate with air holes. Protection class is IP65(IEC529). Operating temperature range: - 40+125°C. Electronic plates of the apparatus are mounted into the

internal guide slots of casing. Front and back panels of the casing are made of ABS-plastic with operating temperature range of: - 20+100°C. 4 rubber-coated legs 5 mm high are fixed to the lower part of the casing.

The casing back panel has power connection sockets of 220 V 50(60 Hz) and a fuse housing mounted on it.

Power button with an integral indicating light-emitting diode of the apparatus status, mode selector knob with an integral pushbutton to confirm mode selection and liquid-crystal display (LCD) of the apparatus settings are situated on the front panel (control panel).

2. GENERAL INSTRUCTIONS AND SAFETY PROVISIONS FOR USE

2.1. General rules and safety provisions

2.1.1.General rules

2.1.1.1 It is prohibited to use the device:

- when an ambient temperature is above +35 °C or below +10 °C;
- when an air humidity is above 95%;
- in premises with aggressive media;
- in dust-loaded premises;
- on prolonged exposure to direct sunlight;
- on exposure to strong electric and magnetic fields;
- under conditions which do not exclude penetration of water in the apparatus.

2.1.2.Safety provisions

2.1.2.1 It is necessary to observe precautions while operating and maintaining the device.

- ***It is prohibited to use*** the device with damaged external insulation of the working cables;
- Check the state of the casing before start operating the device. There should be no cracks or mechanical damage to the casing;
- Protect the apparatus against moisture condensation. With abrupt change of ambient temperature, it is necessary to wait at least 30 min for evaporating of the condensed moisture;
- Socket outlets, used to feed power to the device, must match to the relevant power cable plugs;
- Prevent the power cable from being twisted or clamped. Do not place the power cable in those locations, where it can be easily damaged;
- DO NOT use liquids and spray cleaners to clean the casing;
- Do NOT place the apparatus on unstable surface;
- Restarting of the apparatus must be performed not sooner than 20 seconds after switching off.

2.1.2.2. ***It is prohibited*** to use the apparatus under explosion-dangerous conditions, particularly in the premises with highly inflammable anesthetic drugs.

2.2 Preparation of the device for use

- Place the device on an even surface at a distance not less than 1...2.5 m from a patient;
- Connect a power cable of the device using the socket on the casing back panel;
- Make sure, the power button on the front panel of the device is in the “Power off” position;
- Connect a power cable plug to the circuit of 220 V 50 Hz;
- Press the power button. To be sure the command is being executed, it is necessary to pay attention to a LED, which is built-in into the power button, it should light;
- Make sure that there are running letters «**Biopromin LTD Biol**» on the LCD and the **Preparing** mode has started.

2.3. Functional test of the device

Generally, functional test is carried out during switching on of the apparatus for the first time at the beginning of work shift after preparatory work is performed (par. 2.2).

The test consists in the sequential switching on of the generator modules, measuring of emission level by means of the built-in emission detector and comparison of the obtained results with factory-set parameters.

The self-testing (**preparing**) is carried out automatically at every switching on of the apparatus.

Running order of the generator modules is indicated by sequential appearance of dark rectangles in the bottom line of a liquid crystal display. Upon completion of the check, you will see a sign “**Preparing...OK**”. After that, the apparatus exits Preparing mode, and the record “**Ready. Total xxxh yym**” appears on the liquid crystal display screen. There is an indication of the overall worked time of the apparatus (hours – **h**, minutes - **m**) in the bottom line of the liquid crystal display.

Inoperability of a certain generator module is indicated by the absence of the corresponding rectangle.

In case the functional test shows inoperability of any generator, the device is not allowed for working; it is the subject to return to the manufacturer for repairing.

2.4. Procedure of working in «Therapy» и «Rehabilitation» modes

In technical terms, the modes differ only due to the composition of frequency groups, which are being used. The device’s operation procedure is the same for both modes.

To operate in the Therapy/Rehabilitation mode, it is necessary to:

- Perform preparation of the device for a work according to par.2.2;

- Ensure the functional test has finished successfully (par.2.3.);
- Press shortly a mode selector. On the screen, you will see a sign “MENU: Therapy” and hear short signal of confirmation;
 - or select Rehabilitation mode, turning the mode selector to the right, until corresponding record appears on the screen;
 - Confirm selection of the mode by short pressing of the mode selector;
 - Enter the time of session as follows: after displaying an invitation to enter hours of a session duration: «Enter hours...», set the session time in complete hours (from 0 to 11), by turning the mode selector, and confirm setting by short pressing to the mode selector. A beep of confirmation will sound and an invitation to enter minutes of the session duration: «Enter minutes...» will appear. The procedure is the same as for hours' setting. Finally, a sign of the selected mode will appear, as well as the countdown timer (it shows remain time of therapeutic/rehabilitation session).

The session has begun.

The session has begun.

In case you need to readjust previously set parameters of the selected operation mode, it is necessary to return to the beginning of programming by long pressing of the mode selector. Command acceptance is confirmed by a long tone signal.

The same actions should be done in case of termination of the session, earlier than set time.

When the set session time will expire, you will hear three tone signals, generators will be disconnected. Updated overall worked time will be displayed in the bottom line of the display.

3. MAINTENANCE

3.1. General instructions and safety provisions

It is required to observe the following precautions while maintaining the device:

- a) ***It is prohibited to maintain*** the device with damaged external insulation of the power cables;
- b) Check the state of the casing before start maintaining the device. There should be no cracks, mechanical damage, condensed moisture;
- c) Prevent the power cable from being twisted or clamped.

3.2. Cleaning and disinfection of the apparatus components

WARNING! Before start cleaning and disinfecting the device, unplug the power cable.

Clean the casing with wet and wringed cloth, dampened with soft soap solution. For disinfection, use disinfectants, which were approved by the Ministry of Health.

It is prohibited to use phenol-based and hydrogen peroxide compound-based disinfectants. It is not allowed to use ether, petrol, propanol and acetone.

Prevent penetration of water into the device.

3.3. Maintenance procedure

3.3.1. The technicians and engineers of an institution, where the apparatus is used, should maintain the device. To maintain operability and running order of the device, it is required to

- keep to the schedule of periodic testing strictly;
- perform testing of the device in compliance with test procedure, described in the present Operating Manual.

General characteristics of the maintenance actions are indicated in Table 2.

Table 2. Maintenance of the device «BIOL»

Actions	Periods of maintenance at:		
	Intended use	Storage	Transportation
1. Check of external state of the apparatus	Daily	-	-
2. Cleaning dust and dirt from surfaces of the apparatus	Weekly	-	-
3. Functional check of the apparatus as per par. 2.2 and 2.3.	Daily	-	-
4. Preservation	-	Before storage	Before transportation
5. Periodic testing	Yearly or once in	-	-

Before every use, hold a visual inspection of the device and power cable for mechanical damages and penetration of water into the device. The device can be used only after all detected faults are eliminated by the service maintenance department.

Warranty services are provided by manufacturer - "BIOPROMIN" Ltd (located at 50 Khalturina Str., 61038 Kharkiv, Ukraine).

The device is tested while being released by the manufacturer, before setting the device into operation after repair and in the process of operation upon expiration of 2500 hours of working (but not less than once a year).

4. SPECIFIC TROUBLES AND TROUBLESHOOTING METHODS

4.1. The device "BIOL" is classified as a precision measuring instrument, and its repair should be performed only by the manufacturing company.

4.2. Possible troubles and troubleshooting methods are listed in Table 3.

Herein are listed only those troubles, detection and elimination of which do not require intrusion of the manufacturing company or authorized organizations.

During repair, electrical safety precautions must be observed.

Table 3. Specific troubles and troubleshooting methods

Trouble	Possible cause	Troubleshooting methods
Apparatus doesn't switch on	Power cable is defective or damaged	Replace the cable
	Fuse 1A of the device's power unit is blown	Replace the fuse
While preparing, there is no indicator of working order of one or more generators	Generator module has broken down	Contact service maintenance department of your institution or RPC Biopromin Ltd.
	Radiation detector is defective or damaged	Contact service maintenance department of your institution or RPC Biopromin Ltd.

4.3. Any other faults, which are not listed in the above table, should be eliminated by the manufacturer or authorized organizations with their own facilities.

5. TRANSPORTATION, STORAGE, DISPOSAL

5.1. Transportation of the device to a customer is carried out by the manufacturer or duly authorized company. Transportation is carried out in the original package, by all types of passenger transport with artificially controlled climate; by covered vehicles, in accordance with the shipping rules applicable for the type of vehicle being used.

In terms of climatic factors, transport conditions must comply with Group 5 of storage conditions as per GOST 15150.

In terms of mechanical factors, transport conditions must comply with requirements of Group 1 as per GOST 20790.

5.2. Storage of the device. The device must be stored in the original package.

Storage conditions must comply with requirements of Group 2 as per GOST 15150.

There must be no dust, acid fumes, alkali vapor and other injurious additives in the storage rooms.

Storage life is 1 year at most.

5.3. Disposal. Component parts and materials, which make up the apparatus, are sent to disposal pursuant to the existing laws.

5.3.1 Toxic materials are not used in the constructional parts of the apparatus. While disposing, follow general safety precautions for works.

5.3.2 Before sending the apparatus to disposal, it is required to remove all parts, which contain precious materials.

6. RESOURCES, OPERATIONAL LIFE, STORAGE TIME AND MANUFACTURER WARRANTIES

6.1. Mean time to failure, not less (hours) 2500.

6.2. Average operational life – at least 5 years.

6.3. Average storage time in the manufacturer packaging in heated space within average operation life limits - at least 1 year.

6.4. Indicated resources, operational life and storage time are valid provided that the user observes the conditions and regulations of storage, transportation, and operation, stipulated in the operation documentation.

6.5. Manufacturer warranties

6.5.1. The manufacturer shall ensure compliance of the device with the technical specification provided that a user meets the requirement for its transportation, operation and storage.

6.5.2. Guaranteed service life is 12 months from the date of selling the device to a customer by the manufacturer or an authorized company.

6.5.3. The manufacturer is relieved from warranty responsibility if a user dismantled the device or in case of mechanical damages caused by a user.

6.5.4. Post-warranty service of the apparatus is carried out by the manufacturer under separate agreements.

Regarding delivery and maintenance of the device, please contact: "BIOPROMIN Ltd", 50 Khalturina Str., apt. 2, 61038 Kharkiv. Phone/Fax: (057) 7554335, www.biopromin.com, E-mail: bioluch@yahoo.com

7.CERTIFICATES

Орган з оцінки відповідності Державне підприємство
"Український медичний центр сертифікації"
Міністерства охорони здоров'я України

СЕРТИФІКАТ ВІДПОВІДНОСТІ
Забезпечення функціонування комплексної системи
управління якістю
(Технічний регламент щодо медичних виробів, Додаток 3, виключаючи пункти 8-11)

№ UA.TR.039.065-15

Виробник: Товариство з обмеженою відповідальністю "БІОПРОМІНЬ"
61038, м. Харків, вул. Халтуріна, 50, Україна

Виробництво: 61001, м. Харків, провулок Повстання 8а, Україна

Продукція: Апарати медичні діагностичні та терапевтичні
(дивись додаток)

Орган з оцінки відповідності ДП "УМЦС" заявляє, що зазначений виробник впровадив систему управління якістю на етапах розробки, виробництва і остаточної перевірки виробів відповідно до Додатку 3, виключаючи пункти 8-11, Технічного регламенту щодо медичних виробів, який затверджено постановою Кабінету Міністрів України від 02.10.2013 № 753. Система управління якістю виробника повністю відповідає відповідним положенням цього Технічного регламенту та підлягає періодичному нагляду.
Для розповсюдження на ринку виробів класу ризику III додатково обов'язковим є Сертифікат перевірки проекту.

Звіт: № 065/064-15 від 28.12.2015 р.

Дата видачі: 30.12.2015 р.
Дійсний до: 29.12.2020 р.

Керівник органу з оцінки відповідності
 Лобідєв М.С.

 Чинність сертифіката можна перевірити в базі даних органу з оцінки відповідності (www.umcs.org.ua)

Орган з оцінки відповідності Державне підприємство "Український медичний центр сертифікації" (ДП "УМЦС")
юр. адреса: 02160, Україна, м. Київ, просп. Возз'єднання, 7-а; факт. адреса: 01042, м. Київ, вул. Чигоріна, 18; тел. (044) 285 83 83
Призначений на проведення робіт з оцінки відповідності вимогам технічних регламентів
(наказ від 29.08.2014 № 1044 Мінекономрозвитку України, номер призначеного органу UA.TR.039)
Акредитований НААУ на сертифікацію продукції та систем управління якістю (атестати акредитації № 10101 та № 80018).

СЕРТИФІКАТ • CERTIFICATE • ZERTIFIKAT • INTYG • CERTIFICATO • IGAZOL S • CERTIFICADO • CERTIFIK T • ПІСГОПОНІККО

8. PACKING LIST. WARRANTY CARD.

Low Intensity Microwave and Decimeter Wave Therapy Apparatus «BIOL»A/ITA. 941529.001
 name of the device designation

Serial Number _____

is attested and checked as it is required by the existing technical documentation of the manufacturer. The device is manufactured and accepted in accordance with mandatory requirements of the national (state) standards, existing technical documentation, and is qualified as fit for service.

Manufactured _____
 Date Month Year

Sold _____
 Date Month Year

 signature name and position

Stamp.

<p style="text-align: center;">Warranty Card</p> <p style="text-align: center;"><i>Filled by a seller/authorized service center:</i></p> <p style="text-align: center;">Date of selling « _____ » _____</p> <p style="text-align: center;">_____</p> <p style="text-align: center;">Date of request « _____ » _____</p> <p style="text-align: center;">_____</p> <p style="text-align: center;">Device's working time _____ hours</p> <p style="text-align: center;">Description of a problem</p> <p>_____</p> <p>_____</p> <p>_____</p> <p style="text-align: center;"><i>filled by the manufacturer:</i></p> <p style="text-align: center;">repaired/replaced:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p style="text-align: center;">Date of returning to a customer</p> <p>_____</p> <p>Notes about warranty: _____</p> <p>_____</p>	<p style="text-align: center;">Warranty Card</p> <p style="text-align: center;"><i>Filled by a seller/authorized service center:</i></p> <p style="text-align: center;">Date of selling « _____ » _____</p> <p style="text-align: center;">_____</p> <p style="text-align: center;">Date of request « _____ » _____</p> <p style="text-align: center;">_____</p> <p style="text-align: center;">Device's working time _____ hours</p> <p style="text-align: center;">Description of a problem</p> <p>_____</p> <p>_____</p> <p>_____</p> <p style="text-align: center;"><i>filled by the manufacturer:</i></p> <p style="text-align: center;">repaired/replaced:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p style="text-align: center;">Date of returning to a customer</p> <p>_____</p> <p>Notes about warranty: _____</p> <p>_____</p>
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