OZONE THERAPY DEVICE

MEDOZONS-BEAUTY

Technical Passport

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1. Basic information about the device and technical data

1.1 Basic information

1.1.1 The ozone therapy device Medozons-Beauty manufactured according to TU 32.50.21-001-05785847-2017 (hereinafter – the device) is designed to produce an ozone-oxygen gas mixture for local and systemic ozone therapy procedures approved by order of the Ministry of Health and Social Development of the Russian Federation dated 27.12.2011 N1664н (Registered in the Ministry of Justice of the Russian Federation on January 24, 2012, Registration No. 23010).

The values of the concentration of ozone in the ozone-oxygen mixture (hereinafter – O3/O2), the flow-rate and the duration of the production of the mixture, as well as the operating mode are set by the operator by means of the device controls and are indicated on the display.

For the production of O3/O2, gaseous oxygen is used, technical and medical, in accordance with GOST 5583.

The ozone destructor built into the device, which converts ozone to oxygen, ensures that the ozone content in the residual O3/O2 is reduced to a level not exceeding the maximum allowable concentration (MAC) according to GOST 12.1.005.

The device is intended for use in stationary conditions of medical, preventive, research and other medical institutions.

1.1.2 The device complies with the requirements of GOST R 50444-92, the documentation set and TU 32.50.21-001-05785847-2017.

1.1.3 For electrical safety, the device complies with the requirements of GOST R 50267.0 for class I with a working part of type B.

1.1.4 For electromagnetic compatibility (EMC), the device complies with GOST R IEC 60601-1-2.

1.1.5 Installation of the electrical part of the device complies with RDT 25.106.

1.1.6 During operation the device is resistant to climatic factors in accordance with GOST 15150 and clause 7.15 of GOST R 50444 for the performance of category 4.2 (temperate and cold climate) and to mechanical impacts for group 2 in accordance with GOST R 50444.

1.1.7 During transportation in the manufacturer's packaging the device is resistant to climatic factors for storage conditions 5 in accordance with GOST 15150 and to mechanical impacts in accordance with GOST R 50444.

1.1.8 The outer surfaces of the device are resistant to disinfection according to MU 287-113 with 3 % hydrogen peroxide solution according to GOST 177 with the addition of 0,5% detergent according to GOST 25644.

1.2 Basic technical data

1.2.1 The device operates from a single-phase AC network with a frequency of 50 Hz and a voltage of (220±22) V.

1.2.2 The power consumed by the device from an alternating current network with a voltage of 242 V does not exceed 150 W.

1.2.3 Dimensions of the device are 410 x 300 x 180 mm.

Dimension tolerance is ± 10 mm.

1.2.4 The weight of the device (with a power cord) is 10 kg.

Permissible weight deviation is ± 0,3 kg.

1.2.5 The device should provide operation in the following modes:

- **TEST –** the units of the device are tested;
- **TASK** – the procedure is selected, and the parameters of the procedure are set;
- **REACHING CO_3** – preparation of O3/O2 without delivery to the outlet ports;
- **DELIVERY O_3 –** production of O3/O2 with a given ozone concentration and volumetric flow rate to the outlet nozzle (Outlet) or to the syringe filling port (Dispenser).

1.2.6 The device provides input of values of the set operating parameters:

- values of the ozone concentration in O3/O2;
- values of the volumetric flow rate of O3/O2;
- duration of the procedure for the production of O3/O2 with a given concentration;
- selection of the outlet port for delivery of O3/O2.

1.2.7 The device produces O3/O2 with the concentration of ozone in the O3/O2:

- from 0,1 to 50 mg/l at a flow-rate of O3/O2 of 1,5 l/min;
- from 0,2 to 60 mg/l at a flow-rate of O3/O2 of at least 0,4 l/min;
- from 0,3 to 70 mg/l at a flow-rate of O3/O2 less than 0,4 l/min.

The deviation of ozone concentration in the O3/O2 at the outlet of the device from the set value, not more than:

- ±0,1 mg/l in the range of ozone concentrations in the O3/O2 from 0,1 to 1,0 mg/l;
- ±10 % at ozone concentrations in the O3/O2 from 1,0 to 10,0 mg/l;
- ±15 % at ozone concentrations in the O3/O2 above 10 mg/l.

The deviation of the volumetric flow rate of O3/O2 from the set value is not more than ± 0,2 l/min in the entire range of volumetric flow rate of O3/O2.

The built-in timer of the device allows the operator to set the duration of the procedure for the production of O3/O2 with a given concentration in the range from 1 to 120 min.

The error in setting the time of the procedure for the production of O3/O2 is not more than ± 4 sec per 10 min of operation.

1.2.8 The device is operable at oxygen (air) pressures at the inlet of its gas supply system in the range from 0,4 kgf/cm^2 to 1,5 kgf/cm^2 (bar or atm).

1.2.9 The concentration of ozone in the residual O3/O2 at the outlet of the ozone destructor built into the device is not more than 0,1 mg/m^3 (MAC according to GOST 12.1.005-88).

1.2.10 The device provides the indication of the following messages, modes and parameters of the device operation:

– message **OXYGEN NOT READY** at oxygen pressure values in the gas supply system that do not meet established standards;

– value of the set ozone concentration in the O3/O2 (mg/l) on the display board **“CONCENTRATION, mg/l”**;

– value of the set volumetric flow rate of O3/O2 (l/min) on the display board "**FLOW-RATE, l/min**";

– time until the end of the procedure for the production of O3/O2 on the display board “**TIME, min:sec**”.

1.2.11 The device gives a continuous sound signal at the end of the procedure and when the message **OXYGEN CLOSED** is displayed.

1.2.12 The pneumatic system of the device ensures tightness at an oxygen pressure of not more than (1.5±0,1) kgf/cm^2 (bar or atm).

1.2.13 The device provides continuous operation for 8 hours (continual operation in accordance with GOST 50267.0-92).

The device is ready for operation for no more than 10 min after switching on.

2. Information about materials and purchased items having contact with the human body

2.1 The device set includes accessories that come into direct or indirect (through the ozone-oxygen mixture) contact with the human body:

– Chamber “shoulder-shank”, chamber “hand”, chamber “foot”. Material: Plasticized film of the RK brand according to TU 2245-432-00208947-2005. Manufacturer: Scientific Research Institute of Chemistry and Technology of Polymers named after Academician V. A. Kargin with a pilot plant (Russia);

– Tube of plasticized polyvinyl chloride 4x1.5 (length 2 m). Material: PM1/42 in accordance with TU2247-041-100641390-2007. Manufacturer: JSC "BIOCHIMPLAST".

3. Completeness

Table 1 – Supply set of the device

Name	Document designation	Q-ty, pcs.
Ozone therapy device Medozons-Beauty	BCAT.941137.001	1
Destructor*	BCAT.941713.001	1
Chamber "shoulder-shank” (D = 250 mm, L = 700 mm)*	BCAT.943129.002	1
Chamber “hand” (D = 250 mm, L = 400 mm)*	BCAT.943129.003	1
Chamber “foot” (D = 350 mm, L= 620 mm)*	BCAT.943129.004	1
Power cord	CAB 504-2PBF	1
Tube of plasticized polyvinyl chloride 4x1.5 (length 2 m)	ТУ2247-041-100641390-2007	1
Technical passport	BCAT.941137.000 ПС	1
Instruction manual	BCAT.941137.000 РЭ	1

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* To be supplied by customer order

4. Marking

4.1 Each device has a label that indicates the following:

- name or trademark of the manufacturer;
- device name and model designation;
- device number according to the numbering system of the manufacturer;
- nominal supply voltage;
- power consumption;
- symbol of the type of protection for the working part (GOST R 50267.0, Appendix D);
- date of manufacture;
- TU designation.

4.2 The transport packaging has the following marking:

- name or trademark of the manufacturer or supplier;
- device name and model designation;
- year and month of packing;
- TU designation.

5. Resources, life time and storage time, manufacturer's (supplier's) warranties

Mean time between failures (MTBF) is not less than 1500 hours.

Average life time is at least 5 years, taking into account the replacement of purchased items and components with a life time shorter than the life time of the device.

Storage time (without re-preservation) is twelve months from the date of shipment in the manufacturer’s packaging in the warehouse.

The indicated resources, life time and storage time are valid if the user follows the requirements of the current operational documentation.

Warranty period of operation is 12 months from the date of putting the device into operation.

The date of putting the device into operation should be noted in Table 4 of the present passport. In the absence of such a mark, the warranty period is 18 months from the date of shipment of the device to the buyer.

The manufacturer guarantees that the quality of the device meets the requirements of this documentation provided that the user follows the terms and conditions of operation, repair, maintenance, storage and transportation established by operational documents.

The manufacturer does not bear warranty obligations in case of device failure if:

– the device has external damage or broken seals which are not intended for opening during operation [if the repair was carried out by a service center authorized by the manufacturer of the device, the passport should have a stamp of this enterprise];

– the passport of the device is not presented upon submission of a claim;

– the device was disassembled or subjected to other interferences in the design, not provided in the operational documentation.

6. Information about the manufacturer

Limited liability company

Research and Production Enterprise "ElectroHydroSystems"

Address: 607232, Nizhny Novgorod region, Arzamas, ul. Pobedy, 6/1, office 1.

7. Conservation

Information on preservation, de-preservation and re-preservation of the device upon release (if necessary), operation and repair are indicated in Table 2.

Table 2 – Conservation

Date	Description of work	Period of validity, years	Position, last name and signature

8. Certificate of packing

Ozone therapy device Medozons-Beauty _____ № _____
modification factory number

Packed at ElectroHydroSystem LLC in accordance with the requirements provided in the current technical documentation.

_____ _____ _____
position signature full name

_____
year, month, date

9. Certificate of acceptance

Ozone therapy device Medozons-Beauty _____ № _____
modification factory number

Produced and accepted in accordance with the mandatory requirements of state standards, applicable technical documentation and approved as suitable for operation.

Head of Quality Department

Stamp _____ _____
signature full name

_____
year, month, date

Head of the enterprise

TU 32.50.21-001-05785847-2017
designation of the production document

Stamp

_____ _____
signature full name

_____
year, month, date

10. Notes on operation and storage

10.1 Storage conditions of the device should comply with storage conditions 2 (C) according to GOST 15150-69 for products of group 4.2 (temperate and cold climate): air temperature from minus 50 to +40 °C, relative air humidity up to 98 % at a temperature of +25 °C.

During warehousing and storage, boxes with devices should not be subjected to sharp shocks and the effects of precipitation.

The method of laying boxes during storage should exclude their movement and fall. During storage, it is allowed to stack boxes with devices in no more than three rows. Boxes should be in the position corresponding to the handling signs.

10.2 After transportation or storage at negative temperatures, the device should be kept in a transport packaging in normal climatic conditions according to GOST 15150-69 (at air temperature from +15 to +35 °C) for at least 12 hours.

During the initial start-up and after a long (more than 20 days) downtime, the device should be “warmed up”: for 10-15 minutes start the SYRINGE procedure with an ozone concentration of 60-70 mg/l and an ozone flow-rate of 1 l/min.

10.3 Do not use the device with damaged seals.

During the entire life time of the device, the user should keep the seals of the manufacturer or the authorized organization that performed the repair work (see Table 2). The representative of the organization that made the adjustment or repair of the device should make a mark in Table 3 of this passport.

If the user damaged the seals of the device during its warranty period, the manufacturer is not responsible for the correct operation of the device and all responsibility for its safe operation lies with the user. In this case, payment to the manufacturer for the repair of the device is made by the user or buyer.

10.4 The device should be operated by medical personnel who are familiar with this passport, instruction manual and guidelines for the therapeutic use of the device.

10.5 **WHEN USING THE DEVICE, THE SAFETY MEASURES AND OPERATIONAL LIMITATIONS** specified in the instruction manual should be followed, since the mains supply voltage of the device is dangerous for the operating personnel, and gaseous oxygen is used during the operation of the device.

10.6 Plugging in and unplugging the power cord to the device plug and to the power socket should be carried out only when the device is switched off.

Table 3 – Information about the work performed during the operation of the device

Date	Description of work and reason for its implementation	Position, last name, signature and stamp	
		of the person who completed the work	of the person who checked the work

10.7 When operating the device, it is necessary to follow the general safety requirements for equipment working with gaseous oxygen in accordance with GOST 12.2.052-81.

10.8 The room for working with the device should be equipped with supply and exhaust ventilation.

The maximum allowable concentration (MAC) of ozone in the air of the working area of the room according to GOST 12.1.005-88 should not exceed 0,1 mg/m^3; hazard class 1 according to GOST 12.1.007.

Monitoring of ozone in the air of the working area should be carried out constantly. If ozone exceeds the MAC level, operation is prohibited.

10.9 It is not allowed getting water to the inside of the device, as well as to the connectors of the components of the device.

10.10 When carrying out welding work in the premises of a medical institution, the device should be de-energized.

10.11 The frequency and content of the maintenance of the device should comply with the section "Maintenance" of the instruction manual.

Information on the maintenance and repair of the device during its life time should be given in Table 4 of this passport.

10.12 It is forbidden to carry out repairs and adjustments of the device by specialists of organizations that have not concluded a contract for maintenance and repair of the device with the manufacturer or supplier.

10.13 When describing a failure of a component of the device during operation (in the case of a claim to the manufacturer for the quality of the device), it is necessary to indicate in detail the nature and conditions of the manifestation of the defect:

- name and address of the claimant;
- operating time of the device to failure;
- information indicated in all information windows of the display;
- **DESCRIPTION OF THE CONDITIONS OF THE FAILURE MANIFESTATION (OPERATING MODE OF THE DEVICE; FAILURE TO PERFORM OPERATIONS ON SEPARATE OR SEVERAL ITEMS OF THIS PASSPORT);**
- **OTHER INFORMATION FACILITATING TO ESTABLISH THE CAUSE OF A FAILURE OF THE COMPONENT OF THE DEVICE.**

11. Disposal information

11.1 The device does not contain elements, substances and materials dangerous to life, human health and the environment and does not require special safety measures during disposal.

11.2 Disposal is carried out on a general basis, and if there is a program for the collection and treatment of waste determined by local authorities, disposal is carried out in accordance with this program as for household electrical appliances that do not contain elements hazardous to the environment.