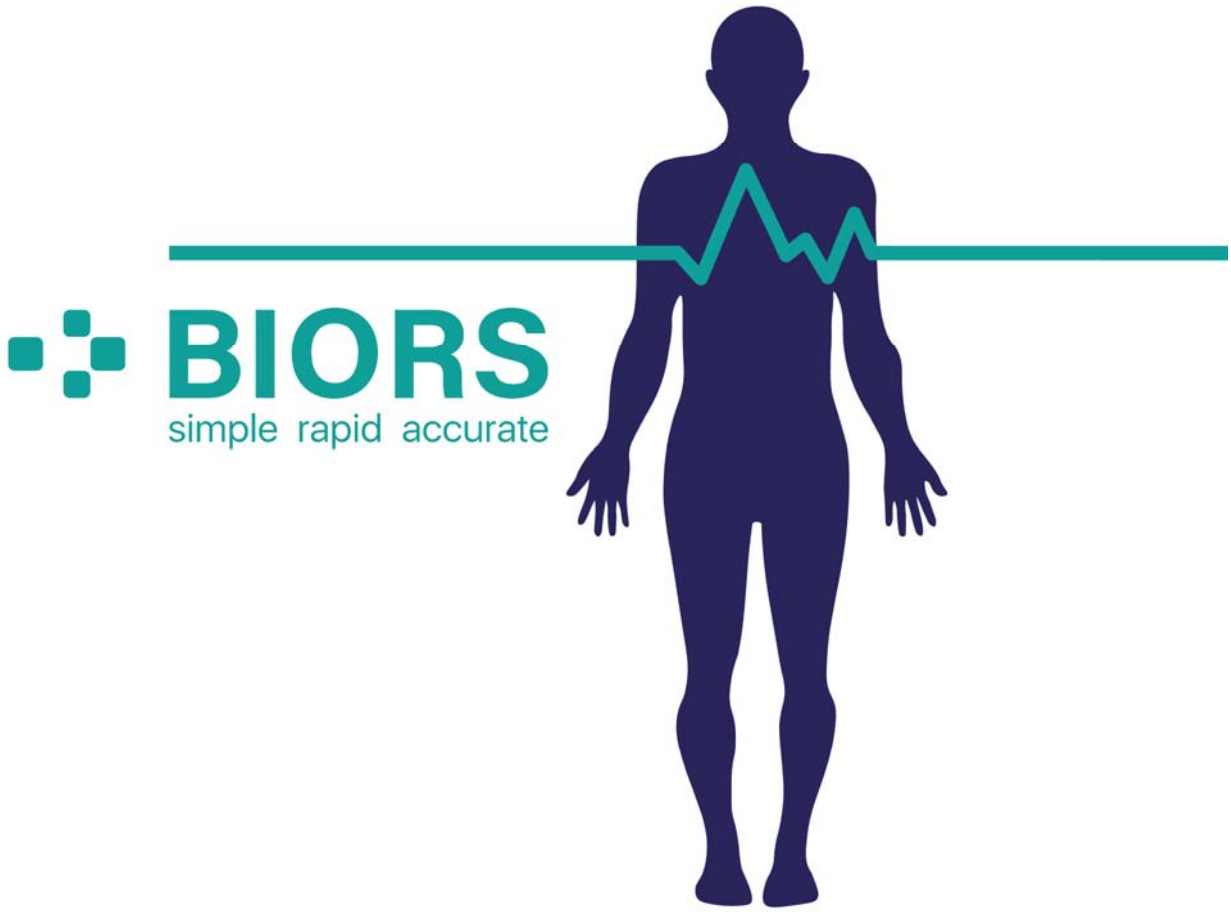
Hardware-software complex

Bioscanner Wellness

PASSPORT



www.bioscaner.com

1. General instructions

The present Technical Passport is designed for information purposes related to hardware-software complex *Bioscanner Wellness* (henceforth referred as '*Bioscanner*') for noninvasive measurement of a person's biological parameters with the subsequent computer processing of results of measurement.

The Passport is a document ensuring conformance of the main parameters and performance specifications guaranteed by the manufacturer and containing information regarding the operation of the device (running time, operation conditions, maintenance, repair designs and other data for the entire period of operation).

Please, keep this passport for the entire period of device operation.

The user should thoroughly read and understand the present Technical Passport and User Manual before using this device. Successful operation, longevity and operating safety can be ensured only under the conditions specified in the Technical Passport.

All records should be filled only with ink, clearly and neatly. Erasures, crossed-out words and corrections unauthenticated by signature are not acceptable.

2. General information about device

Hardware-software complex *Bioscanner Wellness* (henceforth referred as '*Bioscanner*') designed for the estimation of the functional status of professional athletes or goers to fitness centers, athletic halls, gyms, health clubs, pools, visitors in health resorts and other health and fitness centers, as well as for home use to monitor Body Mass Index, digital analysis of pulse wave, calculation of the heart rate variability, evaluation of haemodynamics, visualization of electrocardiogram and overall estimation of the functional status of the human body. The Bioscanner can also be used to select a balanced and proper nutrition in beauty salons, spa centers and sanatoriums.

Bioscanner is controlled by computer that is running Microsoft Windows operating system, with installed software '*Bioscanner*'. The software is not designed for use with Android, Linux, MacOs and other operating systems that do not relate to Windows family.

Trade name of device:	Hardware-software complex *Bioscanner Wellness*
Designation (type, model):	*Bioscanner-04*
Name of the manufacturer:	BIORS LLC
Address of the manufacturer:	127282 Russia, Moscow, ul. Polyarnaya, 31 G, blok 1
The device is certificated.	**Д-RU.ЦС01.В.05283**

3. Main parameters and characteristics of *Bioscanner.*

Parameter name	Value
Interface of connection and data transfer	USB port, external port RS-232
Voltage supply from PC USB port, V	5
Nominal current consumption, A, not more than	0.8
Data transfer rate, Mbit/s	2.1 max
Operation mode setup time, min, not more than	6
Weight, kg, not more than ABS case BOPLA Botego BO 51406 Metal case	 3 4
Overall device dimensions (depth, width, height), mm ABS case BOPLA Botego BO 51406 Metal case	 137 x 240 x 50 145 x 205 x 45
Each procedure's duration, min, not more than	20 ± 10 %
Pulseoxymeter	
Overall sensor dimensions, not more than, mm	65 x 40 x 30

Measuring range of the blood oxygen saturation, %	70–100
Sensor wavelengths (optical and infrared wavelength band), nm	660, 940
Flux power, mW, not more than	0.8
Bioimpedance analyzer	
The measuring method	tetrapolar
Amplitude of bioimpedance probe voltage, V, not more than	+ 5/– 5
Measuring range of active resistance, Ohms	70–800
Measuring range of reactive resistance, Ohm	30–90
Probe frequency range, kHz	10–100
Electrosomatograph	
Number of registered leads	22
Voltage at Rh = 100 kOhm, V	0.64
Short-circuit current, μA, not more than	12.8
Electrocardiograph	
10 registered leads	RA, LA, RL, LL, V1....V6
Input voltage range, mV	0.03–10.00
Range of sensitivity (for entire aperture), mV	± 200
Input impedance, for all inputs except R, Mohm, not less than	5
Common-mode rejection ratio, dB, not less than	115
Measurement error of the voltage, mV, not more than	± 15 %
Direct current in ECG measurement circuit, μA, not more than	0.1
A/D converting, bit	24
Self-noise level, mV, not more than	0.007

***Bioscanner* is produced in two embodiments:**

I. Metal case of *Bioscanner* is made of stainless steel or alloy steel on request, by LLC Construktiv Center company, Moscow, Russian Federation (*Bioscanner-04M* embodiment).
II. Plastic case BOPLA Botego BO 51406 is made of plastics by Phoenix Mecano AG, Bünde, Germany (*Bioscanner-04П* embodiment).

4. Individual device characteristics

Establishing clinical diagnosis based on conducted examination with the use of *Bioscanner* is unacceptable. All recommendations given by the program after completion of measurements are recommendatory in nature. It is strongly prohibited to treat a patient only on the basis of given automatic report: any therapeutic intervention should be based only upon doctor's prescription at medical facility.

Relative contraindications are:

1. Age under one year old and over 75 years old;
2. Large number of recording artifacts;
3. Too high mobility of examined person;
4. Bright room light can adversely impact SpO2 measurement. The sensor should be shaded from the direct sunlight if it is necessary.
5. Nail polish or artificial nails can lead to inaccuracy of device measurements during evaluation of SpO2.
6. Examination is not permitted when a person has hypotension, significant vasoconstriction, severe anemia or hypothermia.
7. Examined person should not have a cardiac arrest or be in shock.

Conducting of **electrosomatography and bioimpedansometry** is not recommended in the following cases:

- when a person has a heart pacemaker or other implanted device as well as metal implants (including metal jewelry and piercing jewelry);
- severe skin damage and/or skin disease in places of contact between electrodes and skin;
- pregnancy;
- idiosyncrasy of electric current;

– absence of limb (due impossibility of using electrodes).

There are no contraindications for diagnostic techniques as pulseoxymetry and HRV. However, there are some contraindications regarding interpretation of the results obtained during examination. Such absolute contraindication is the presence of artificial heart pacemaker in a patient (if it is the main pacemaker there is no point in having VHR test).

Warnings and precautions when the device is running in the pulseoxymeter mode:

It is prohibited to sterilize the device in autoclave, use ethylene oxide or immerse the sensor within the fluid because it can lead to obtaining inaccurate measured data.

It is prohibited to use a pulseoxymeter in an explosive environment.

The sensor of the pulseoxymeter should not be placed on the same side as blood pressure cuff, artery or venous catheter.

It is prohibited to fix a sensor on the limb using adhesive tape.

The temperature of the applied part of the pulseoxymeter should not exceed 41 ºC.

There are no contraindications for conducting standard electrocardiography. However, the procedure itself can be difficult to implement in patients with complex chest traumas, severe obesity or in cases when there are too much hair on the chest (due poor electrode-to-skin contact). Besides, if a patient has a heart pacemaker, it can lead to significant ECG data corruption.

There are contraindications for conducting exercise ECG:

acute period of myocardial infarction, acute infectious disease, worsening of arterial hypertension, coronary artery disease, chronic heart failure, complex arrhythmias, possible aortic dissection, decompensation (worsening course) in diseases of other organs and systems (digestive, respiratory, urinary track systems).

5. Lifetime

An average lifetime of *Bioscanner* must be at least 5 years under keeping of service rules in compliance with the requirements of operational documentation. Criterion of limit state should be an impossibility or technical and economic inexpediency of repair if its value exceeds 60 % of the cost of a new *Bioscanner*.

Specified no-failure operating time for *Bioscanner* is 1100 hours.

Mean time between failures for *Bioscanner* is 2200 hours.

Note. Device failure is an impossibility of further use without repair.

6. Packaging and transportation

Devices are packed into individual containers excluding the possibility of mechanical damage to them and direct influence of moisture, dust and dirt.

Devices and their component parts are packed into metal, plastic or leatherette lodgement case with rigid frame as well as into individual packing boxes and polythene film.

As a packaging may be used other boxes, special containers and other means of packing.

Additional means of packing can be used when packing: inserts made of expanded polystyrene and other materials.

It is possible to use other means of packing, including obtained as an import or produced in accordance to the drawings of device manufacturer, that meet the specific needs with regard to the necessary strength.

Placed in plastic bag packing list, operational documentation and shipping documents are enclosed in each shipping box.

Devices may be transported by any means of transportation which ensure protection of packed items from atmosphere precipitation, climatic factors and mechanical damage.

Containers in vehicles must be placed and fixed so as to ensure a stable position and prevent any movements in order to avoid strikes against each other and the sides of vehicle.

The environment should not be explosive or contain oil splashes, metal dust, current-conducting dust, aggressive gases and vapours in corrosion-causing concentrations.

Loading and unloading should be done in accordance with the requirements of operational documentation.

7. Operation conditions

Bioscanner should be used for purposes and within the limits established by the present Passport and operational documentation.

Establishing clinical diagnosis based on conducted examination with the use of *Bioscanner* is unacceptable. All recommendations given by the program after completion of measurements are recommendatory in nature.

Repair of *Bioscanner* or its individual components is performed by the manufacturer.

(!) Strongly prohibited:

- *to prescribe or conduct treatment only on the basis of given automatic report: any therapeutic intervention should be based only upon doctor's prescription at medical facility.*
- *to conduct measurements of a person with implanted electronic devices (cardiostimulator, heart pacemaker etc.)*
- to allow mechanical damages of *Bioscanner during use.*
- to allow ingress of moisture into device during disinfection. It is necessary to protect the device from moisture, mechanical shock and vibration.
- to operate the device with damaged case.
- to open the case and replace device components.

Device use guidelines and safety requirements are presented in operational documentation.

In case the device was exposed to freezing temperatures it is necessary to keep it at room temperature at least 4 hours before turning it on.

Enterprises operating the device are fully responsible for the proper handling, monitoring and supervision of device performance.

(!) Common troubles and remedies:

Name of trouble, manifestation and additional signs	**Possible cause**	**Remedy**
Dirtiness of *Bioscanner* unit	Overall dirtiness of *Bioscanner* unit during use.	It is necessary to disinfect surfaces of all components and the case of *Bioscanner* electronic unit using hydrogen peroxide 3 % with addition of detergent, a kind of Lotos 0,5 %, or chloramine solution 1 %.
Dirtiness of sensors contacting with patient	Overall dirtiness after completion of measurements	Immediately after completion of measurements or at least 15 minutes before conducting new diagnostic and therapeutic procedures it is necessary to disinfect sensors using hydrogen peroxide 3 % with addition of detergent, a kind of Lotos 0,5 %, or chloramine solution 1 %.
Bioscanner is cooled	*Bioscanner* was exposed to freezing temperatures	It is necessary to remove transport packaging and keep the device at room temperature at least 4 hours for condensate removal.
It is impossible to access information from sensors	Poor contact to the patient's skin	1. Clean up the sensor. 2. Achieve close contact of the sensor. 3. Wet the place of contact between skin and metal part of the sensor with 10 % saline solution. 4. Check mode activation in the program.

8. Storage

Component parts of *Bioscanner* should be stored in transport packaging, in heated storage rooms.

The environment should not be explosive or contain oil splashes, metal dust, current- conducting dust, aggressive gases and vapours in corrosion-causing concentrations.

Loading and unloading should be done in accordance with the requirements of operational documentation.

9. *Bioscanner* equipment

Generally the delivery of hardware-software complex includes components presented in Table:

Name	**Number, pcs**
1. *Bioscanner* electronic unit	1
2. Footpad electrodes	2
3. Cylindrical electrode	2
4. Head electrode (double, on a belt)	1
5. Cable for the electrosomatograph	3

6. Cable for the bioimpedance analyzer	2
7. Disposable electrodes for the bioimpedance analyzer (Fiab, Italy) F9049	100
8. Silicone fingertip sensor for the pulseoxymeter (SpO2), adult	1
9. 10-lead ECG cable, color code, European version. Schiller compatible. Defibrillator proof.	1
10. Reusable limb electrode (clip electrode), adult	4
11. Chest suction ECG electrodes Ø 24 mm	6
12. USB-cable for connecting *Bioscanner* to PC, 2.0 B male to USB A male 1,8 m	1
13. Flash drive with installation files and operational documentation	1
14. Passport	1
15. Case (consumer packaging)	1

10. Disposal

Devices and materials used to manufacture *Bioscanner* do not pose a risk to human life and health as well as for environment both while in operation and after the end of the performance life.

Components and materials used to manufacture *Bioscanner* are in accordance with RoHS Directive (Directive2002/95/EU) regarding use of certain hazardous substances in electronic equipment.

Material and chemical waste management and installation of supply and exhaust ventilation system in working rooms should be in accordance with Sanitary Rules and Regulations as well as requirements for environment protection.

Bioscanner does not contain toxic or expensive materials and can be disposed in a conventional way.

Material waste can be disposed on a contractual basis with enterprise having a waste disposal license.

Fig. 1 Device *Bioscanner Wellness*. *Bioscanner-04M embodiment.* (Attention: the manufacturer has the right to change overall device dimensions without notice to customer).

11. Warranty

The manufacturer guarantees operation of the *Bioscanner* if user meets conditions of proper operation, storage and transportation. Guarantee service life is 12 (twelve) months from the date of shipping to ultimate consumer.

Warranty storage period prior to initial operation is 24 (twenty four) months from the moment of purchase of *Bioscanner* or from the moment of manufacture (in the absence of note of purchase in the Passport)

In the absence of date of purchase in the Passport warranty period is calculated from the date of manufacture.

Within the warranty period the manufacturer free of charge undertakes to repair or replace the defective device or its parts (functional units) except in cases when the failure is caused by non-compliance with the requirements of User Manual.

The guarantee does not cover consumer packaging (metal, plastic or leatherette lodgement case with rigid frame), cables, wires, electrodes, sensors and other expendable materials.

The warranty is considered as no longer valid in following cases:

- the user does not observe the rules of operation, transportation and storage;
- detecting of external mechanical, chemical and other damages of *Bioscanner* or individual components caused by the user;
- detecting of signs of rough usage, malicious damage or unauthorized changes the structural design of *Bioscanner*;
- detecting of signs of repair attempts by non-affiliated non-authorized companies or individuals;

- liquids, foreign objects and insects getting inside the device;
- device failure as a result of force majeure circumstances;
- the user does not observe the safety rules, operation and storage conditions described in the Passport and/or User Manual;
- factory seals on the case of *Bioscanner* are broken;
- in absence of manufacturer's stamp and the date of manufacture in the Passport.

Ground for terminating the warranty coverage:

- device misconnection;
- factory seals on the case of *Bioscanner* or its components are broken;
- non-compliance with the technical conditions and requirements of User Manual;
- presence of mechanical damages;
- natural disasters (lightning, flood etc.);
- signs of the impact of aggressive agents or insects;
- signs of unauthorized actions;
- any modifying the structural design of *Bioscanner* by user.

The manufacturer has the right to make changes in the structural design of *Bioscanner* not affecting the main technical parameters and device reliability without notice.

Claims on product quality are accepted from customer upon the presentation of a Passport for *Bioscanner* with date of manufacture and date of purchase.

In case of problems with software or hardware (program is unstable: hang-up, disorderly close-down, data transfer delay or glitch, etc.) please send to customer support e-mail **biors@bioscaner.com** the following information:

a. Who and when bought our complex;
b. What embodiment of *Bioscanner* is used;
c. Version number of our software installed on your computer;
d. Information about Windows system on your computer;
e. What antivirus programs are installed or specify absence of antivirus software;
f. In detail, point by point describe your actions before emergence of the problem. It would be advisable to attach to that letter program screenshots with error descriptions. A screenshot can be taken by pressing PrtScn button on the keyboard when you see needed image on the screen. Then taken screenshot can be pasted into a document in Word or Paint (Edit Menu −Paste), saved with a filename of your choice and send us as an attachment to e-mail.

Correct operation of *Bioscanner* and its software is not guaranteed if there is counterfeit software and/or game software, free antivirus programs and similar software of other firms installed on user's computer.

THE ACCEPTANCE AND SELLING CERTIFICATE

Hardware-software complex *Bioscanner Wellness* serial number

№_____

accepted in accordance with the mandatory requirements of the state standards, current technical documentation and it is acceptable for use.

Date of manufacture ____ _____20___

Signature of the person responsible for the acceptance and device operation

_____

stamp here

Date of sale ____ _____20___

stamp here