DIGITAL PORTABLE TONOMETER OF INTRAOCULAR PRESSURE TROUGH THE EYELID

diaton®

Operation Manual

PART I
Technical Specifications. Maintenance
Datasheet Specifications
БИРМ.941329.003РЭ

The present Operation Manual consisting of two parts is the operation document for the diaton® digital portable tonometer of Intraocular pressure trough the eyelid (hereinafter referred to as the tonometer).

Part I contains the tonometer's technical specifications, maintenance procedure and datasheet specifications.

Part II acts as the user's guide containing the information necessary for correct application of the tonometer.

All the instructions listed in the Operation Manual must be considered prior to use of the tonometer and must be carefully followed.

diaton® tonometer is protected with Russian and US patents for invention. It was awarded the Gold medal at the World Salon of Inventions in Brussels and in Geneva and is certified in Russia, member states of EC, the USA, and other countries.

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The tonometer complies with requirements of the following Directives: MDD 93/42/EEC of July 14, 1993 / MDR 2017/745 of April 5, 2017.

⚠ **ATTENTION!**

In case of any serious incidents related to the use of the tonometer, report the issue to the manufacturer or a competent authority of the Member State of the Union having jurisdiction over the registered location of the user and (or) the patient.

1 Application

1.1 diaton® digital portable tonometer of Intraocular pressure trough the eyelid is designed for medical use and is used for transpalpebral measurement of true intraocular pressure (hereinafter referred to as IOP) in children and adults without anesthetics.

1.2 The Tonometer can be used in health facilities, and can also be used during mass screening programs.

1.3 Tonometer operating conditions:

- ambient temperature + 10 °C to + 35 °C;
- relative humidity 30% to 90%;
- atmospheric pressure 800 hPa to 1,060 hPa (600-795 mm Hg).

1.4 During the usage, protect the tonometer from contamination, impacts and exposure to aggressive substances. Switch the tonometer off before putting it into the storage case. Timely replace discharged batteries according to the instructions of the Operation Manual.

1.5 It is prohibited to operate the tonometer near devices producing strong magnetic fields (CT scanner, powerful electric motors, high powered magnets, etc.).

2 Specifications

2.1 Technical specifications

2.1.1 Digitally displayed IOP measurement range ……..5-60 mm Hg.

Accuracy of IOP measurements in the range from 5 to 20 mm Hg… ±2 mm Hg;

in the range from 20 to 60 mm Hg……..±10%

2.1.2 Time of single IOP measurement, sec, not more than ……..…. 3.

2.1.3 Deviation of the tonometer body from the vertical position for the angle from (4,5±1,5°) to (45±5°) is indicated by an intermittent audible alarm.

No audible signal is produced when the deviation of the tonometer body from the vertical position is less than 3° and more than 50°.

2.1.4 The kit includes a testing device (pressure control device) intended for checking of operability and performance of the tonometer.

2.1.5 Electrical safety characteristics of the Tonometer comply with EN 60601-1:2006/AC:2010. The device is designed according to the appropriate protection class and is classified as a device with type B applied part and an internal power supply source.

2.1.6 Supply voltage, V……..……3

2.1.7 Supply current, mA, not more than ……..…….1

2.1.8 Number of measurements using one set of batteries, not less than …1500

2.1.9 Indication of battery discharge.

2.1.10 Average service life, years, not less than.....5

2.1.11 Dimensions, mm, not more than.....173.5 x 25.5 x 19.5

2.1.12 Weight, g, not more than……89

2.2 Clinical justification of specifications.

Clinical justification of the specifications is performed in the framework of the clinical trial carried on in compliance with ISO 8612 standard.

82 patients (164 eyes) had their IOP measured during the trial.

The average device-to-device difference and standard deviation (Goldmann and diaton® tonometer) were 0.60 mm Hg and 3.12 mm Hg.

The scatterplot and Bland-Altman plot are shown in Fig.1.

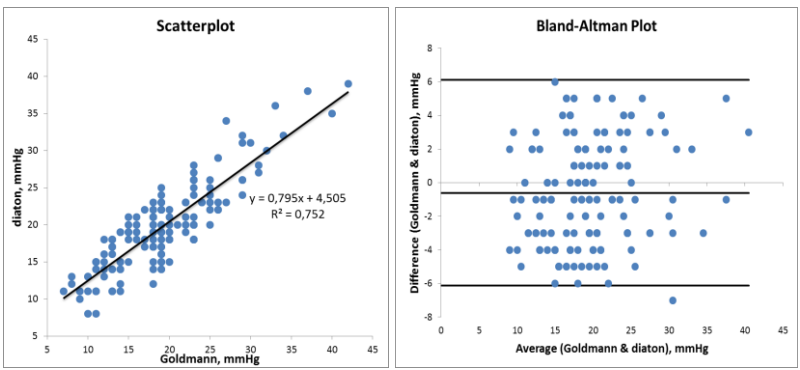


Figure 1

3 Scope of Delivery

3.1 The contents of the tonometer kit are given in Table 1.

Table 1.

Part number	Name	Q-ty	Serial number	Notes
1 БИРМ.941329.003-01	diaton® digital portable tonometer of Intraocular pressure through the eyelid (export option),including:	1		
БИРМ.713131.001	- cap	3	-	
БИРМ.404711.005	- pressure selector	1	-	
CR2032 «VARTA»	- battery	1	-	It is possible to use other types of batteries with similar size and voltage.
БИРМ.323366.015-04	- storage case	1	-	
БИРМ.467361.001-01	- tutorial CD	1	-	The language of the delivered materials corresponds to the language of the contract.
2 БИРМ.941329.003РЭ	- Operation manual. Part I	1	-	The language of the delivered documentation corresponds to the language of the contract.
БИРМ.941329.003РЭ1	- Operation manual. Part II	1	-	

Table 1 (continued).

Part number	Name	Q-ty	Serial number	Notes
3 БИРМ.941329.003Д12	User's Guide	1	-	The language of the delivered materials corresponds to the language of the contract
4 ВИАМ.305646.007	Packaging	1	-	
5 ВИАМ.305646.035	Packaging	1	-	Export delivery, or according to the customer's request
6 БИРМ.296444.001	Screwdriver	1	-	
7 ВИАМ.323229.017	Box	1	-	Used for multi-delivery in Russia. For export multi-delivery conditions of the delivery contract apply.

3.2 Appearance of the Tonometer is shown in Fig.2.

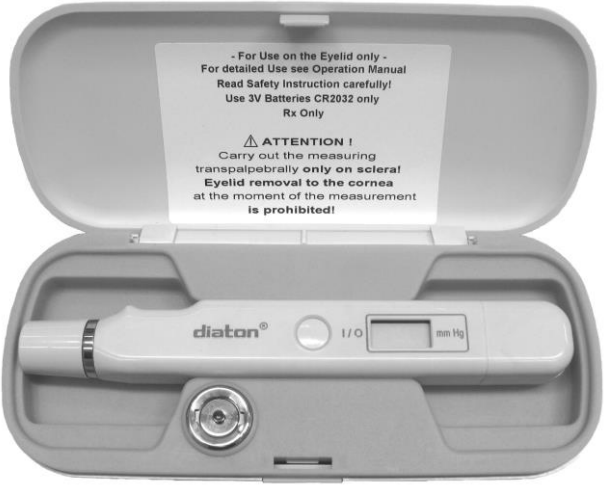


Figure 2 –Tonometer in the Storage Case

4 Packaging

4.1 The Tonometer in the storage case is packed into a packing box according to the requirements of ГОСТ Р 50444-92 and the manufacturer's technical documentation. For transportation purposes it is packed in transportation package with the packing list being enclosed.

5 Maintenance of the Tonometer

5.1 The maintenance is performed by the personnel working with the Tonometer. The maintenance procedures are shown in Table 2.

Table 2.

Maintenance procedure	Frequency	OM point
1. Functional test	Once a day before operation	OM Part II, point 5.3
2. Inspection of the exterior of the tonometer for mechanical damage	Once a week	-
3. Disinfection of the tonometer exterior surface	Once a month	OM Part II, point 5.4
4. Cleaning of the battery compartment contacts	Once a year	-
5. Battery inspecting and replacement	When necessary	OM Part II, point 5.1
6. Cleaning of the rod mechanism from dust and dirt.	Quarterly	OM Part II, point 5.2
Notes: 1. The rod mechanism does not require lubrication. 2. When inserting the battery strictly observe the polarity as indicated on the battery and in the battery compartment, follow instructions from OM Part II, point 5.1		

5.2 **ATTENTION!**

Clean the rod mechanism of the tonometer at least once in a quarter!

Simultaneous cleaning of the rod mechanism of two and more tonometers is FORBIDDEN.

Cleaning the Tonometer rod mechanism from dust and dirt must be carried out as follows (Fig.3).

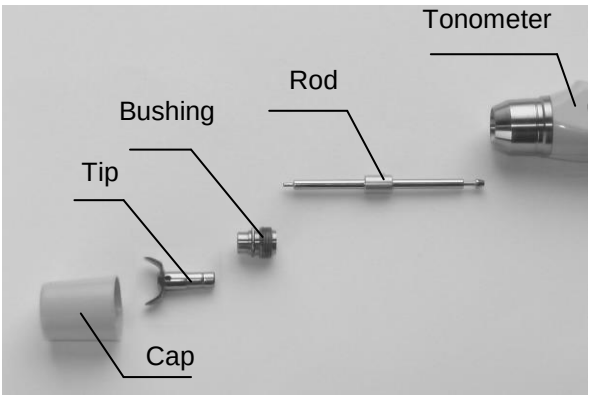


Figure 3. Preparation of the Tonometer for Cleaning of the Rod Mechanism

- take the Tonometer out of the storage case, remove the cap;
- holding the Tonometer with the tip facing down, make sure that the rod is not fixed (projected from the tip). If this is not the case, move the tip up with your free hand until the rod is unlocked;
- holding the Tonometer body with one hand, remove the tip away with your free hand by pulling it along the axis applying force;
- turn the Tonometer into horizontal position; using the screwdriver included in the delivery set unscrew the bushing by screwing it counter-clockwise, and remove the rod;
- wipe the tip and the rod using a cloth damped with ethyl alcohol;
- twist the cloth damped with ethyl alcohol into a rope and clean the orifices in the tip and the bushing.

ATTENTION!

When cleaning the rod mechanism, do not use absorbent cotton or other fibrous materials.

Put the cleaned parts on a clean cloth and assemble the rod mechanism holding the parts using the cloth to prevent direct contact.

The assembling procedure is as follows:

- holding the Tonometer with the opening facing up, install the rod and make

sure that the rod moves freely;

- mount the bushing by screwing it clockwise until bumping but do not apply excessive force;
- mount the tip and make sure that it is fixed and can rotate on its axis when force is applied;
- check the Tonometer operational integrity according to point 5.3 of Part II of the Operation Manual.

⚠ **ATTENTION!** IT IS FORBIDDEN TO USE (REPLACE) RODS FROM OTHER TONOMETERS.

6 Routine Repairs

6.1 Possible malfunctions and troubleshooting procedures are shown in Table 3.

Table 3.

Description of consequences of malfunctions and faults	Possible causes	Troubleshooting
1. “U” symbol is displayed after pressing the “Operation” button.	Battery voltage is low	Replace the battery
2. No indication is displayed after pressing the “Operation” button.	1. The battery compartment contacts are dirty 2. The battery contacts are dirty 3. The battery is discharged	1. Clean the battery compartment contacts 2. Clean the battery contacts 3. Replace the battery
3. A value other than 20 ± 2 or The «H» symbol is displayed when checking the the operational integrity of the Tonometer.	1. The rod mechanism is dirty	1. Clean the rod mechanism according to point 5.2; if the cleaning doesn’t help, the tonometer must be repaired
	2. The rod mechanism is faulty	2. The Tonometer’s repair must be done in specialized service centers or at the manufacturing enterprise.

6.2 Data on Repairs Carried out by the Manufacturer or at the Repairer's Offices.

Table 4.

Date	Reason for repairs	Repairs details	Warranty extention details	Name of the repairer Job title, signature, print name, stamp

Verification

Verification of the tonometer is carried out according to verification methodology БИРМ.941329.003МП by a local Center of Standardization and Verification in accordance with the set practice; the data are recorded in Table 5a.

Table 5a.

Name of measuring device	Serial number	Date of manufacture	Verification			Note
			Date	Date of next verification	Signature	
diaton® digital portable tonometer of intraocular pressure trough the eyelid БИРМ.941329.003-01						

7 Storage, Transportation and Disposal

7.1 The product is to be stored in the manufacturer's transportation package under the following conditions:

- ambient temperature — -10°C to +55°C;
- relative humidity — 10 % to 95 %;
- atmospheric pressure — 700 hPa to 1,060 hPa (525 - 795 mm Hg);
- the air must not contain fumes of acids, alkalis and other aggressive impurities.

7.2 The Tonometer may be transported in the manufacturer's transportation packing by train, plane (with the exception of unheated compartments), ship (with the exception of sea vessels) and motor vehicles according to transportation regulations.

7.3 Transportation conditions:

- ambient temperature — -40 °C to +70 °C ;
- relative humidity — 10 % to 95 % ;
- atmospheric pressure — 500 hPa to 1,060 hPa (375 - 795 mm Hg).

7.4 During transportation, the packed Tonometers must not be exposed to atmospheric precipitation or mechanical impacts.

7.5 If the device is planned not to be used for a long time, remove the battery from the battery compartment.

7.6 The device contains materials which can be disposed of. Use obsolete devices according to the local legislation.

Do not burn or dispose of the batteries in ways you would use for regular wastes. Dispose of the wastes according to the local legislation.

8 Electromagnetic Compatibility Recommendations

The tonometer is intended to be used in health facilities and other establishments and places suitable for performing intraocular pressure measurements.

In terms of the protection class the Tonometer is classified as a device with type B applied part and an internal power supply source according to EN 60601-1.

As per EN 55011 the tonometer is classified as a device of Group 1 Class B. The Tonometer employs RF energy only to perform its internal functions. Its radio frequency interference level is low, and most likely will not cause malfunctions of electric equipment operating nearby.

ATTENTION: Avoid operation of the Tonometer near equipment with a high radio frequency and electromagnetic interference level as it may cause its improper performance. If such circumstances cannot be avoided, check the Tonometer according to point 5.3 of БИРМ.941329.003РЭ1 prior to its use to make sure that the Tonometer functions properly.

ATTENTION: Portable radio-communication equipment (including peripheral devices, such as antenna cables and external aerials), if any, must operate not closer than 30 cm (12 inches) away from the Tonometer. Otherwise, malfunctions and faults of the Tonometer may occur.

The Tonometer is compliant with the following standards:
EN 60601-1-2:2015
EN 55011:2009
EN 61000-4-2:2009
EN 61000-4-3:2006 +A1:2008 +A2:2010
EN 61000-4-8:2010

9 Marking

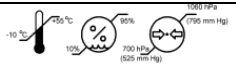
9.1 The markings of the Tonometer, consumer package (packing box) and transportation package confirm to the requirements of GOST R 50444-92, Directives 2012/19/EU, 2011/65/EU, and technical documentation.

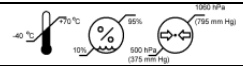
Table 8. Symbol Description

Symbol	Description
	Refer to manual
	Type B applied part
CE	CE marking

	Waste electrical and electronic equipment
	Manufacturer

Table 8 (continuation). Symbol Description

Symbol	Description
EC REP	Authorized Representative in the European Community
	Date of manufacture
REF	Reference number
SN	Serial number
	Refer to the operation manual
	Warning
	Storage conditions



Conditions of transportation

(01) 4650195010016 — Numeric UDI-DI

(11) XXXXXX — Date of manufacture: YYMMDD

(21) YYYY — Serial number

DataMatrix code

Identification code in GS1 Russia

10 Packing Certificate

diaton® digital portable tonometer of intraocular pressure trough the eyelid

БИРМ.941329.003-01 N_____
Serial number

Packed by_____JSC RSIE_____
Manufacturer's name or code

according to requirements of the technical documentation.

23

_____ _____ _____
job title signature print name

_____
year, month, date

11 Certificate of Acceptance

diaton® digital portable tonometer of intraocular pressure trough the eyelid

БИРМ.941329.003-01 _____ was manufactured and
Designation Serial number

accepted according to specifications ТУ 9441-011-12191956-98 and is recognized as exploitable.

Head of Inspection Department

Stamp _____ _____
signature print name

_____
year, month, date

cut line for export delivery

General Manager of the Enterprise _____
delivery document

Stamp

_____ _____
signature print name

_____
year, month, date

12 Manufacturer's Warranty

12.1 The manufacturer guarantees that the quality of the Tonometer meets the requirements of the specifications ТУ 9441-011-12191956-98 provided that the user observes the rules of storage, transportation, and operation mentioned in the Operation Manual.

12.2 The operation warranty period is 24 months from the date of the shipment or selling if the tonometer has been bought through a distributive network, if the contract does not stipulate otherwise.

12.3 During the warranty period repairs of the Tonometer are realized at the manufacturing enterprise or at the repairer's offices.

12.4 The warranty does not apply to the battery.

The user shall replace the batteries on his own after the warranty period of the battery expires or the battery discharges.

12.5 Warranty period — 24 months.

Notes

Notes