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EASYTON

TRANSPALPEBRAL DIGITAL TONOMETER
for intraocular pressure measurement

CE 0044

Operating Manual

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EASYTON Tonometer is covered by Russian Federation's Patent No. 2335234.

The tonometer complies with all the security requirements provided by IEC 60601-1:2005 and IEC 60601-1-2:2014-04 international standards.

The tonometer conforms with the European Economic Community Directive 93/42/EEC.

Thank you for purchasing EASYTON transpalpebral digital tonometer for intraocular pressure measurement (*below referred to as the Tonometer*).

Indication for the tonometer usage:

The Tonometer Easyton is indicated for the measurement of intraocular pressure in human eyes.

The Tonometer is a medical measuring instrument which is approved for usage at healthcare facilities as an individual means of IOP control.

Please make sure to carefully study the Operating Manual before starting to use the Tonometer. Please consult your attending doctor regarding the values of intraocular pressure which are specific to you personally.

⚠ **Caution!** Federal law restricts this device to sale by or on the order of a physician.

IOP measurement is taken through closed eyelid and does not require any anaesthesia.

Tonometer usage is contraindicated in the following cases:

• pathological conditions of the upper eyelid (inflammatory conditions, scars, eyelid deformities);

• evident scleral and/or conjunctival pathology in the area of the Tonometer rod's action;

• any diseases and conditions that prevent the patient from accepting and/or maintaining a sitting position, including:

- severe or critical general condition of the patient due to various reasons;
- skeletal injuries with damage to the bones of the pelvis and/or spine;
- diseases accompanied by a pronounced violation of the strength and tone of the muscles involved in positioning of the body (strokes and their consequences, injuries and diseases of the brain, myasthenia, etc.);
- postoperative period requiring restrictions of the patient's body position (surgical interventions on the small pelvis area, early postnatal period, etc.).

⚠ **Precaution!**
The Tonometer should not be used on eyes with biomechanical properties altered by prior surgery or disease.

⚠ KEY SAFETY TIPS

- Make sure to examine the Tonometer body and rod for presence of mechanical damages. Using the Tonometer if any of these damages have been detected is **PROHIBITED**.
- Protect the Tonometer from shock and impact. When carrying the Tonometer around, put it into the plastic case, with the protective cap over its working part.
- Avoid penetration of moisture inside the Tonometer. In case if a liquid did get inside the device, let it dry at room temperature for at least 4 hours before using it again and check its functionality on the tester.
- Avoid high temperatures.
- Avoid thermal shock. This may cause malfunctioning of the Tonometer.
- Do not use the Tonometer in the shower and bathroom.

⚠ **Attention!** An exclamation point symbol displayed in the Tonometer window, accompanied by continuous beeping sound, is a signal of its inoperable condition and of excessive pressure load of the rod upon the eyelid, which may cause painful sensations for a patient.

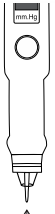
1. DESCRIPTION AND DESIGN FEATURES. OPERATING PRINCIPLE

When placing the Tonometer rod on the eyelid and applying light pressure to the device, the rod is slightly immersed inside the device and the formation of a measuring vibrational effect begins.

The vibration frequency of the «rod-eye» ligament depends on the IOP.

The higher the IOP, the greater the frequency of vibrations.

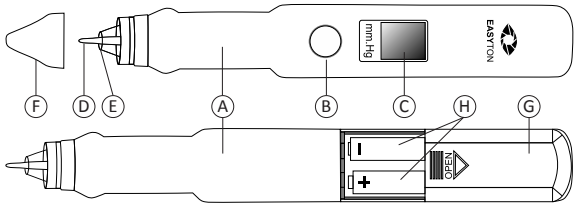
The Tonometer registers the vibration frequency, recalculates it into the IOP value and displays it on its indicator.



Schematic representation of the Tonometer rod movements

Figure 1

Key Design Features



A. Tonometer body
B. On/Off button
C. Display window
D. Vibrator rod
E. Buffer ring
F. Protective cap
G. Battery case cover
H. Batteries
I. Case box
J. Tester

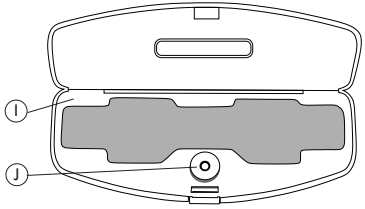


Figure 2

Display Symbols

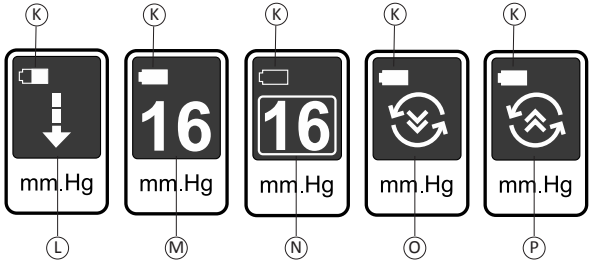


Figure 3

K. Battery level indication

L. Ready-for-operation indication

M. Measured IOP reading

N. Square frame around the reading value = unstable positioning of the Tonometer, or the patient's eyelid or eye

O. IOP value below the measurement range (below 7 mmHg)

P. IOP value above the measurement range (above 50 mmHg)

Complete Set

• EASYTON Tonometer	1
• Built-in tester case	1
• 1.5 V battery standard size AAA, R03	2
• Operating Manual	1
• Retail packaging	1

Important Facts on Intraocular Pressure

Intraocular pressure measurement is a method of eye health diagnostics used in ophthalmology. Intraocular pressure generally has 3 basic conditions:

- normal
- hypertension (high pressure)
- hypotension (hypotony)

Statistically, the normal range of true IOP (P_0) is within 10 to 21 mmHg. IOP may be irregular or may change in the course of the day. The normal value may vary in the range of 2-2.5 mmHg.

2. PREPARATION FOR OPERATION

2.1. Battery Installation and Replacement

The current battery status is marked with the power level indicator in the top left corner of the Tonometer display.

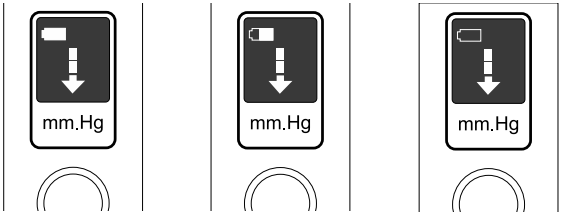


Figure 4

If the batteries are discharged, the Tonometer will not switch on.

Batteries are to be replaced with the Tonometer switched off.

If you plan to use the device again only in a few months' time, make sure to take the batteries out.

1 Turn the Tonometer over so that its front panel is facing downwards.

2 Slide the battery case cover in the direction of the arrow marked on it.

3 Insert / replace the two AAA batteries in such a way so that their «+» (positive) and «–» (negative) contacts would match the polarities marked inside the battery case.

4 Put the battery case cover back on.

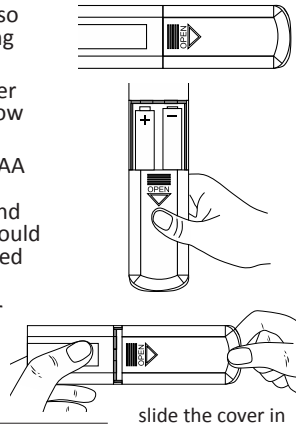


Figure 5

⚠ **Attention!** Immediately after inserting the batteries, switch the Tonometer on and off by shortly pressing the On/Off button.

This is done to check proper installation of the batteries, and the Tonometer is set into the micro-consumption mode.

2.2. Functionality Checkup Using the Tester

The Tonometer functionality is to be checked on the tester at least *once a week*, as well as in the following cases:

- after long idle periods
- after dropping the device
- after changing the batteries
- in any other cases when you doubt if the Tonometer works properly

To check the Tonometer functionality on the tester, do as follows:

1 Open the Tonometer case.

2 Take the device out and put the opened case with the tester on a table.

3 Position the Tonometer with the rod up and take the protective cap off.

4 Shortly press the On/Off button to switch the Tonometer on.

5 A moving arrow displayed in the Tonometer window indicates its readiness for operation.

6 Hold the Tonometer with your fingers by the cylinder-shaped part of its housing.

7 Place the Tonometer with the measuring rod down and position its housing so as to be able to see the readings on the display.

8 Position the Tonometer **vertically** above the tester. The heel of the hand holding the device should rest against the table surface.

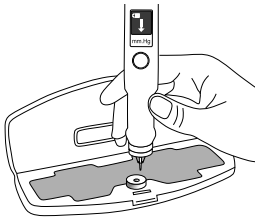
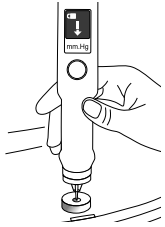


Figure 6

⚠ **Attention!** Upright positioning of the Tonometer (allowed deviation from vertical axis should not exceed 15 degrees) must be preserved during all measurements.

9 Keeping the heel of the hand fixed on the table, insert the device rod down into the center of the tester pinhole. Dip the Tonometer buffer ring as far down as it can go into the circular groove of the tester. The lower surface of the Tonometer ring should be aligned with the circular groove surface as much as possible.
At this point, the measuring mode is actuated, which is perceived by the hand as light vibration. Meanwhile, the pressure value is displayed in the Tonometer window.



ready-for-operation

Figure 7

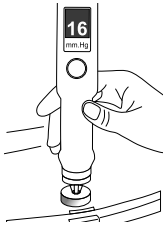
10 Keeping the device fixed in this position, keep an eye on the digital value of the pressure displayed in the Tonometer window. The measuring mode will continue until the device is lifted away from the tester. The digital reading on the display should not diverge from the one listed in the «Specifications» section of this Manual by more than two units.

11 Raise the Tonometer above the tester. The measuring mode is thus completed, and the measured value is captured on the display.

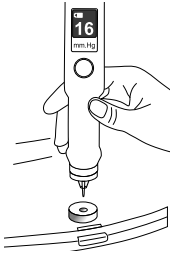
12 The measuring can be repeated for as many times as needed, following Clauses 9, 10, and 11 of this section.

13 Deactivate the Tonometer by shortly pressing the On/Off button.

14 Put on the protective cap, with the Tonometer rod turned upwards, and put the device into its case.



measurement mode
Figure 8



measurement completed
Figure 9

2.3. Disinfection

Please disinfect the Tonometer while it is switched off.

Disinfection of the buffer ring and Tonometer rod should be performed before and after each new patient's IOP measurement.

To perform the disinfection procedure, do as follows:

1 Pour use the Rapicide PA disinfeccting solution into tray.

2 Holding the Tonometer with the rod down, treat the buffer ring and the lower part of the rod immerse in solution for at least 15 minutes.

⚠ **Attention!** Only the working parts of the Tonometer need to be immersed, at a distance not exceeding 1 cm from the edge of the ring (see Figure 10).

---

3 Remove disinfected the Tonometer from the tray using aseptic procedure and rinse them in sterile water.

4 Thoroughly rinse the buffer ring and the lower part of the rod by immersing it in a large volume of water and keep it immersed for a minimum of 1 minute.

5 Manually flush the buffer ring and the lower part of the rod with large volumes of rinse water. Avoid penetration of moisture inside the Tomometer.

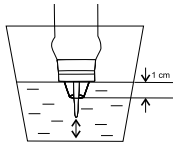


Figure 10

Disinfection of the **outer surfaces of the Tonometer body** (others than the rod and the buffer ring) is performed as may be needed, using 3% hydrogen peroxide solution mixed with 0.5% solution of a household detergent.
After disinfection, wipe the outer surfaces of the display with a dry sterile cloth.

The process of disinfection of the tonometer was validated and was recognized as acceptable by the results of tests in the mycobiological laboratory.

⚠ **Attention!** Avoid penetration of the disinfectant solution inside the Tonometer.

3. DEVICE APPLICATION PROCEDURE

3.1. Pre-Measurement Steps

1 Take the Tonometer out of its case.

2 Position the Tonometer with the rod up and take the protective cap off.

3 Disinfect the Tonometer (see Cl. 2.3).

4 Shortly press the On/Off button to switch the Tonometer on. When activated, the Tonometer produces a beeping sound.

5 Check for presence of a moving arrow on the Tonometer display, which indicates its readiness for measuring.

6 Check the Tonometer functionality using the tester (see Cl. 2.2).

7 Before measuring, the patient should be in a sitting position with his head tilted back so that the position of the head was as close to horizontal as possible.

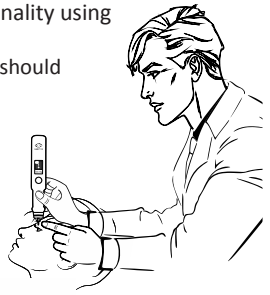


Figure 11

3.2. Measuring Procedure

- Hold the activated Tonometer with your fingers by the cylinder-shaped part of its housing.
- Place the device with its rod facing downwards. Turn the Tonometer so as to be able to see the readings on the display.
- Stand at the patient's side slightly behind them.
- The patient's gaze must be fixed at a test object (for instance, their own hand), heir eye gaze line making up an angle of 45° from upright direction.

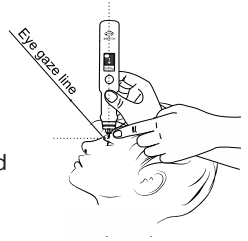


Figure 12

- The heel of the hand holding the Tonometer should rest against the patient's forehead. The smoothness and preciseness of movements required for the measuring process is achieved by resting the hand against the patient's head (forehead), as well as trained through continuous usage.
- Stretch the upper eyelid with a finger of your free hand in a way to ensure alignment of the upper eyelid edge with the upper corneal edge. Fixate and hold the eyelid in this position, without pressing on the eyeball.

⚠ **Attention!** Avoid slipping of the eyelid onto the cornea while taking the measurement!

- The vertical position of the instrument rod on the surface of the eye is an essential condition for the accuracy of IOP measurement. Place the Tonometer rod on the upper eyelid of the patient 2-3 mm from its edge (in the sclera region), holding the tonometer body strictly vertically. The contact area of the tonometer rod should fall on the upper portion of the sclera corresponding to corona ciliaris in Meridian 12 (Figure No 14). Recommended installation points are indicated in the figure.

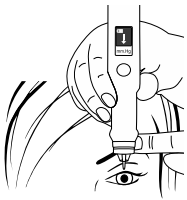


Figure 13

- Holding the Tonometer vertically down, **smoothly** lower it down by 2-3 mm. At this point, dynamic force is actuated, which is perceived as light vibration. During the measuring process, make sure that the buffer ring does not touch the eyelid, but remains 2-3 mm above the eyelid surface. Avoid slipping of the eyelid onto the cornea while taking the measurement.

Figure 14

⚠ **Attention!** When the Tonometer is lowered too far down, it produces a continuous single-tone beep, which stops automatically when the device is raised high enough for measuring.

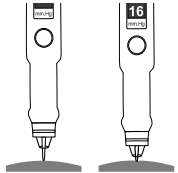


Figure 15

- 1 or 2 seconds after lowering the Tonometer down, it produces a beep indicating that the measurement is completed, and the measured IOP value is displayed in its window. The measuring process will continue until the device is lifted away.
To end the process, lift the device up. At the moment when the measurement is taken, the device produces another beep, and the measured IOP value is displayed in the window.

- In case if the sound signal didn't come off at all or came off with a delay of more than 3 seconds, the measuring needs to be repeated.
- Deactivate the Tonometer by shortly pressing the On/Off button. Put the protective cap back on, with the Tonometer rod up, and put the device back into its case.

⚠ **Attention!** If the positioning of the Tonometer, the patient's eyelid or eye, is unstable during the measuring process, the resulting reading may appear on the display in a square frame. If this happens, the measurement needs to be re-taken.

Figure 16

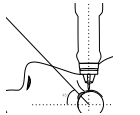
⚠ **Attention!** To obtain the most accurate IOP measurement results, the following conditions must be observed:

• The Tonometer body should be positioned strictly upright.
When measuring, try to hold the tonometer body strictly upright, avoiding its deviation by more than 15 degrees.

Figure 17

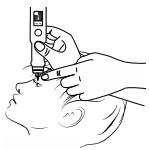
• The Tonometer rod should be positioned at right angle against the eye surface.
To achieve that, align the Tonometer rod axis with the geometric center of the eyeball.

Figure 18



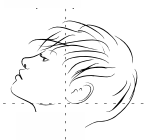
• Smoothness and preciseness of movements during the measuring process.
These can easily be achieved when the hand holding the Tonometer is resting against the patient's head (forehead).

Figure 19



• The patient's position at the time of measurement.
At the time of the measurement, the patient should be in a sitting position with his head tilted back so that the position of the head is as close to horizontal as possible.

Figure 20



4. POSSIBLE ERRORS AND TROUBLESHOOTING

Problem	Possible cause	Troubleshooting method
The Tonometer does not switch on	The batteries are dead	Replace the batteries
	The batteries are seated incorrectly	Insert the batteries with due regard to the polarity markings (+ / -)
	The contact of the batteries is unstable	Replace the batteries. Clear the contacts of the battery holders using an erasing rubber
	The On/Off button is broken	Repair at a maintenance service facility
	The Tonometer itself is broken	Repair at a maintenance service facility
The Tonometer readings obtained with the tester deviate from the values specified in the Manual by more than 2 units	The Tonometer is de-calibrated	Calibration at a maintenance service facility
	The Tonometer is broken	Repair at a maintenance service facility
After the measurement is completed (and the Tonometer lifted up), the vibration action does not stop or stops only after a notable delay (more than a second)	The rod motion sensor is de-calibrated	Calibration at a maintenance service facility
When switching the Tonometer on, it does not display any indications, and an alarm signal is produced	The Tonometer display is broken	Repair at a maintenance service facility
The batteries run low too soon (in less than 30 days)	Excessive power consumption	Repair at a maintenance service facility

5. MAINTENANCE SERVICE AND MINOR REPAIRS

Maintenance Procedure

	Procedure	Frequency
1.	Routine inspection	At least once a day
2.	Cleaning from dust and dirt	As may be necessary
3.	Functionality checkup	Before each IOP measurement procedure
4.	Battery changing	When the symbol «▭» appears on the display

During routine inspection, make sure to check the integrity of the Tonometer body and to check for mechanical damages of the vibrator rod.
The Tonometer functionality checkup is to be done as described in the clause titled «Tonometer Functionality Checkup Using the Tester».

⚠ Do not attempt any repairs by yourselves. Should you have any doubts regarding correct operation of the device, please contact the Manufacturer or its representative office.

Minor Repairs

Minor repairs of the Tonometer are provided by the Manufacturer or its representative facility, after a technical inspection of the malfunction nature and degree has been performed by the Manufacturer's experts.

The following may indicate presence of a malfunction:

- mechanical damages of the Tonometer housing and (or) vibrator rod;
- divergence of the Tonometer readings obtained with the tester from the ones listed in the «Specifications» section;
- absence of readings on the display despite presence of the sound of the rod vibration specific for measuring;
- absence of the power level indication symbols.

During minor repairs, troubleshooting is done by replacement or recovery of the parts and elements; adjustment of the Tonometer is conducted to ensure its compliance with the parameters listed in this Manual. Upon completion of the repairs, the Tonometer is returned to the user, and its warranty period is renewed starting from the date of return.

Safety Measures

No special precautions are required while conducting the repairs.

6. SPECIFICATIONS

Parameter	*Parameter value*
Device	Transpalpebral digital tonometer for intraocular pressure measurement
Model	EASYTON
IOP readings range, mmHg	7-50
Accuracy, mmHg, within the range of: **7-23 mmHg** **above 23 mmHg**	 ±2 ±5
Repeatability (coefficient of variation), %	≤8,1
Accuracy of display, mmHg	1
Display unit	Millimeter of mercury (mmHg)
IOP measurement time, sec, max	2
Power consumption during measurement, mA, max	100
Power supply: No. of elements and voltage	2 × 1.5V, standard size AAA, R03
Display	LCD
Data output	Display window
Overall dimensions (L×H×W) mm, max	173 × 27 × 21
Weight, g, max	88, incl. batteries
Operating conditions: **operating temperatures range, °C** **relative air humidity,%, max** **atmospheric pressure, mmHg**	 from +10 to +35 80 630-800
Mean service life, no less than	5 years

Tonometer readings obtained with the tester in the IOP measurement _____ ±2 mmHg.

(to be filled in at device acceptance)

7. STORAGE AND TRANSPORTATION

The Tonometer may be stored in a closed non-heated room at a temperature from -50 °C to +40 °C and relative air humidity of up to 98% (at a temperature of + 25 °C).

The device can be transported by all covered vehicles in microclimatic regions with a moderately cold climate at ambient air temperatures from -50 °C to +50 °C.

⚠ **Attention!** After a long storage or transportation at temperatures below +10 °C, keep the Tonometer in a room at a temperature from +10 to +35 °C for at least 4 hours.

8. MARKING

The Tonometer is marked with the following symbols:


Refer to the operating manual


The Tonometer's working part is the sufficiently protected against electric shock


The product is licensed with Approval Certificate of Measuring Instruments

EAC Compliant with CU TR 020/2011 Technical Regulations of the Customs Union

CE 0044 Compliant with MDD 93/42/EEC

Safety and effectiveness of the tonometer in the intended environment of use is supported by testing that was conducted in accordance with the following standards:

ISO 10993-1 «Medical products. Assessment of medical products biological effect. Part 1. Assessment and investigation»

ISO 10993-9 Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products

ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

ISO 10993-11 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

ISO 10993-12 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

ISO 15223-1:2016 Medical Devices – Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied – Part 1: General Requirements

IEC 60601-1-2:2014 (4th edition) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

IEC 61000-4-2:2012 Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test

IEC 61000-4-3:2006+AMD1:2007+AMD2:2010 Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test

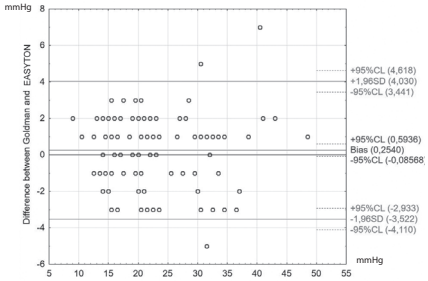
IEC 61000-4-8:2009 Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test

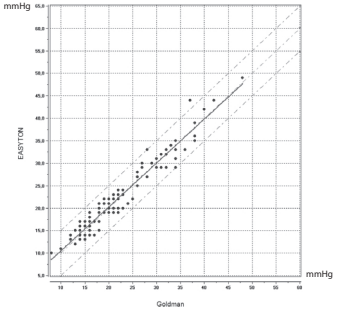
CISPR 11:2009 +A1:2010 Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement

DIN EN ISO 15223-1:2013 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2012)

ANSI Z80.I0-2014 Ophthalmic instruments. Tonometers

During pre-market testing process the comparability testing to a Goldman type reference tonometer was performed on eyes in according to ANSI Z80.10-2014 and satisfied results was reached. The resulting Pearson correlation coefficient is more 95% (see pictures below). This indicates the high accuracy of the EASYTON tonometer compared to the Goldman tonometer. As a result of the tests, the required accuracy and repeatability of the measurements were confirmed.





9. MANUFACTURER'S WARRANTY

The Manufacturer hereby guarantees that the quality of the Tonometer conforms to the requirements stated in the Operating Manual, provided that the conditions of proper storage, transportation, and usage are met by the Customer. Guaranteed service life (warranty period) is 24 months from the date of sale.

Within the warranty period, the Manufacturer shall repair or replace the defective Tonometer free of charge, upon presentation of the warranty service coupon.

Warranty provisions

The warranty is only valid if the Customer has a correctly filled-in warranty coupon, with the factory serial number and date of sale indicated, and a vivid stamp of the trading company.

The warranty does not cover the following cases:

- if the Tonometer bears traces of outside interference or repair attempts by non-authorized servicing companies;
- if unauthorized changes into the design or construction of the Tonometer have been detected;
- if the Tonometer has any mechanical damages;
- if the Tonometer has been damaged as a result of penetration of foreign objects, substances or liquids.

The batteries are not covered by this warranty.
When the service life or operational life cycle of the batteries expires, the Customer is to replace them of their own accord.
The guaranteed shelf life is 24 months.

Please send a faulty Tonometer for repairs, together with the Operating Manual and an enclosed explanatory note, to the Manufacturer's representative at the following address:

_____

_____

For any questions on the device quality and maintenance service, please contact the Manufacturer's representative.

10. ACCEPTANCE CERTIFICATE

EASYTON transpalpebral digital tonometer for intraocular pressure measurement factory serial number _____ is manufactured and accepted in compliance with the technical specification GIKS.941329.102 TS and is hereby validated as ready-for-service.

Software version No. GIKS.17-0104.3.

Date of production _____ Stamp

_____

(signature of a person responsible for acceptance)

EASYTON transpalpebral digital tonometer for intraocular pressure measurement is packed according to the requirements specified in the design documentation.

Date of packing _____

Packed by _____ Stamp

11. APPENDIX A

Table 1

Manufacturer's manual and declaration – electromagnetic emission		
The tonometer is intended for use in the electromagnetic environment specified below. The purchaser of the tonometer should ensure its use in the specified electromagnetic environment		
Electromagnetic emissions test	Compliance	Electromagnetic environment – instructions
Radio-interferences according to CISPR 11	Group 1	The tonometer uses radio-frequency energy only to perform internal functions. The emission level of the radio frequency interference is low and might not lead to disturbances in the functioning of the electronic equipment located close to it
Radio-interferences according to CISPR 11	A Classes	The tonometer is suitable for use in all the locations, not used for domestic purposes and not connected to low-voltage distribution networks
The harmonic current components of IEC 61000-3-2	Not applied	

Table 2

Manufacturer's manual and declaration – interference resistance			
The tonometer is intended for use in the electromagnetic environment specified below. The purchaser or user of the tonometer should ensure its use in the specified electromagnetic environment.			
Interference resistance test	The test level according to IEC 60601	Compliance level	Electromagnetic environment – instructions
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV – contact discharge ±2,4,8,15 kV – air discharge	Complies	The floor in the facility must be covered with wood, concrete or ceramic tiles. If the floor is covered with synthetic material, relative humidity must be minimum 30%
Electrical fast transient/burst according to IEC 61000-4-4	±2 kV – for powersupply lines ±1 kV – for input-output lines	Not applied	Power quality in mains in accordance with the typical conditions of a commercial or hospital environment
High energy microsecond pulse interferences according to IEC 61000-4-5	±2 kV	Not applied	Power quality in mains must be provided in accordance with the typical conditions of the commercial or hospital environment
Voltage dips, average interruptions and voltage fluctuations in the input power lines according to IEC 61000-4-11	- U_H=0%, 0,5 cycle (0,45,90,135,180,225,270 and 315 dagrees - U_H=0%, 1 cycle - U_H=70%; 25/30 cycles (0 dagrees) - U_H=0%, 250/300 cycle	Not applied	Power quality in mains in accordance with the typical conditions of a commercial or hospital environment If the user of the device needs to provide seamless operation in the conditions of possible interruptions of the line voltage, it is recommended to power the device from an uninterruptive power supply or battery
Power frequency magnetic field (50/60 Hz) according to IEC 61000-4-8	30 A/m	Complies	The levels of power frequency magnetic field must be provided in accordance with the typical conditions of the commercial or hospital environment
Note: U_H – is the voltage level of the mains until test exposure is applied			

Table 3

Manufacturer's manual and declaration – interference resistance			
The tonometer is intended for use in the electromagnetic environment specified below. The customer or the user of the tonometer should ensure its use in the specified electromagnetic environment.			
Interference resistance test	The test level according to IEC 60601	Compliance level	Electromagnetic environment – instructions
Conducted disturbances induced by RF fields according to IEC 61000-4-6	3 V (root-mean-square) in-band from 150 kHz to 80 MHz	Not applied	Evaluation of the effectiveness of the effect on conducted interference induced by radio-frequency electromagnetic fields
Radio-frequency electromagnetic field according to IEC 61000-4-3	3 V/m in-band from 80 MHz to 2.7 GHz	Complies	The distance between the mobile radiotelephone communication systems used and any element of the tonometer, including the cables, should not be less than the recommended separation distance which is calculated in accordance with the expressions below with reference to the frequency of the transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ (from 80 to 800 MHz); $d = 2,3\sqrt{P}$ (from 800 MHz to 2.7 GHz). Where d is the recommended separation distance, m b); P is the nominal maximum transmitter output power, W, as specified by the manufacturer. The field density in the propagation of radio waves from stationary radio transmitters, according to the results of observations of the electromagnetic situation a), should be lower than the level of correspondence in each frequency band b). The effect of interference may occur near the equipment marked with the symbol 

a) The field density in the propagation of radio waves from stationary radio transmitters, such as base stations of radio telephone networks (cellular / wireless), and surface-mobile radios, amateur radio stations, AM and FM broadcast transmitters, television transmitters can not be determined by calculation with sufficient accuracy. This requires practical measurements of field density. If the measured values at the location of the tonometer exceed the applicable levels of compliance, the operation of the tonometer should be monitored to verify their normal functioning. If a deviation from normal functioning is detected during the observation process, then it may be necessary to take additional measures, such as reorienting or moving the tonometer.

b) Field density should be less than 3 V/m out of band from 150 kHz to 80 MHz.

Notes: 1. A greater value of the field density is applied at frequencies of 80 and 800 MHz.

2. The expressions are not applicable in all the cases. The propagation of electromagnetic waves is affected by absorption or reflection from structures, objects and people.

In the case of an electromagnetic disturbance, essention performance will be lost, namely:

1) cancellation (stop) or suspension of measuring function or false alarms or change of operational mode;

2) visible signs of deterioration of functioning (monitor failure, where interference conceals the image produced by physiological signal, or physiological signal is unrecognizable, delaying the buttons response, etc.), launching any unintended function;

3) the extreme values of 10 consecutive readings on the control device differs from each other by no more than 2 mmHg

– it is necessary to turn off the tonometer and take repeated measurements in a place excluding extreme EMC exposure.

Counterfoil for Warranty Service Coupon
for repairs (replacement) within the warranty period
EASYTON transpalpebral digital tonometer for intraocular pressure measurement

Withdrawn on «____» _____ 20____ r.

Repair shop (customer service center) specialist _____ Name, signature

Manufacturer's Address:
«Yelatma Instrument Making Enterprise», JSC
391351, 25 Yanina st., Yelatma, Kasimov district, Ryazan region, Russia
Tel/fax: +7 (4912) 293-418, +7 (49131) 2-04-57

WARRANTY SHEET

for repairs (replacement) within the warranty period EASYTON transpalpebral digital tonometer for intraocular pressure measurement

Manufacturing date _____ No. _____

Purchased _____
(to be filled in by the trading organization)

Put in operation _____
(date, signature)

Accepted for warranty service by the service center

Date _____ City _____

Released after repairs _____
(date, signature)

Stamp

Signature of the Head of Repair Center _____
(signature)

Signature of the Owner _____
(signature)

The present warranty sheet should be sent to the Manufacturer and serves as the basis for the invoice to reimburse repair costs within warranty period.

Counterfoil for Warranty Service Coupon
for repairs (replacement) within the warranty period
EASYTON transpalpebral digital tonometer for intraocular pressure measurement

Withdrawn on «____» _____ 20____ r.

Repair shop (customer service center) specialist _____ Name, signature

Manufacturer's Address:
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(date, signature)

Stamp

Signature of the Head of Repair Center _____
(signature)

Signature of the Owner _____
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Date _____ City _____

Released after repairs _____
(date, signature)

Stamp

Signature of the Head of Repair Center _____
(signature)

Signature of the Owner _____
(signature)

The present warranty sheet should be sent to the Manufacturer and serves as the basis for the invoice to reimburse repair costs within warranty period.

Disposal of the Device

Upon termination of its service life, the device is subject to disposal as electronic waste at specialized recycling stations. Disposal of the device together with household waste is prohibited. For more detailed information, please consult your local authorities, the service for household waste collection, or the store where you have purchased the device.

Dispose of the used batteries with special care, since they contain toxic metals and chemicals which may be released into the environment as their housing decays.

Proper disposal of a worked-out product and used batteries helps prevent potential negative consequences for the environment and human health.

After completion of their service life, the products used in medical facilities are to be disposed of in accordance with the rules stipulated in the Sanitary Regulations.