M2124.29 dated 02.05.2023

Easyton Package Labeling

Prepared by

V. Pinchukova Tuccur

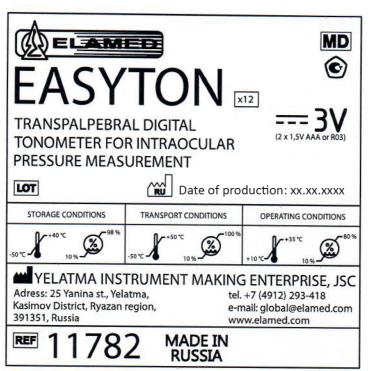
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Date: 02.05.2023

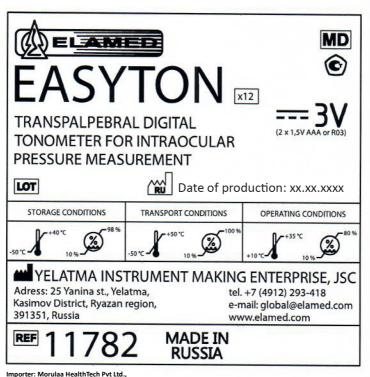
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Date: 2.05. 23



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Importer License Number: XXXXX

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Transpalpebral digital tonometer for intraocular pressure measurement Tonometer zur Messung des Augeninnendrucks Tonomètre de la pression intraoculaire
Tonometro per misurare la pressione intraoculare
Tonómetro de presión intraocular
Akispūdžio matavimo tonometras
Tonometru pentru măsurarea presiunii intraoculare
Tonometr cyfrowy do pomiaru ciśnienia wewnątrzgałkowego

User Manual
Bedienungsanleitung
Manuel d'utilisation
Manuale d'uso
Manual de Instrucciones
Naudojimo instrukcija
Instructiuni de exploatare
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Attention! Before using Tonometer remove the liner under protective ring that protects the device's rod during transportation



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

The Tonometer is intended for the measurement of intraocular pressure (IOP) through a closed eyelid, both on children and adults.

The Tonometer is a medical measuring instrument which is approved for usage both at healthcare facilities and in home conditions as an individual means of IOP control

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

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 using the Tonometer at high temperatures and sudden temperature changes. This may cause malfunctioning of the Tonometer.
- Using the Tonometer in the shower and bathroom is **PROHIBITED**.

Attention! An exclamation point symbol displayed in the Tonometer window, accompanied by continuous single-tone beeping alarm sound signal, 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. INDICATIONS FOR USE

Intraocular pressure (IOP) measurement through the eyelid

2. CONTRAINDICATIONS

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.

3. DESCRIPTION AND DESIGN FEATURES. OPERATING PRINCIPLE

The Tonometer is intended for measuring intraocular pressure for adults and children.

IOP measurement is taken through closed eyelid, which prevents any contact with sclera and other anatomical structures of the eye, and does not require any anaesthesia.

This technique allows to use the Tonometer for measuring IOP in clinically difficult cases, including:

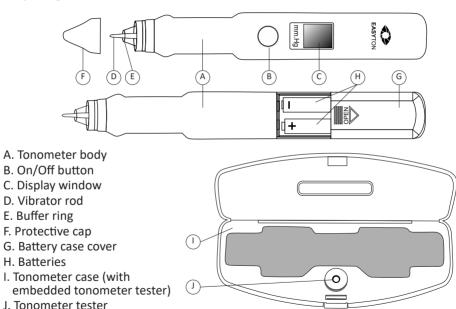
- idiosyncrasy of local anesthetics
- after laser refractive surgical interventions on the cornea

The Tonometer can be used with contact lens. The Tonometer's operating principle is based on measuring intraocular pressure by means of registering the frequency of forced vibrations of the eye membranes (sclera and cornea) under the action of the Tonometer's vibrator rod.

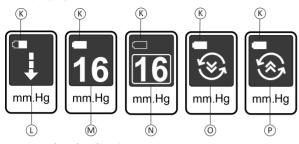
When measuring, the rod is placed in the sclera area onto the eyelid and compresses it with a weight of about 10g. Thus, a single interconnected biomechanical «rod-eye» system is formed, the vibration frequency of which is determined by the actual intraocular pressure.

The period of vibrations is read by the Tonometer and used to calculate the IOP value. The results are shown on the display.

Key Design Features







- 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)

Scope of Delivery

EASYTON transpalpebral digital tonometer for intraocular pressure measurement	1
Tonometer case (with embedded tonometer tester)	1
1.5V alkaline battery standard size AAA, R03	2
User Manual	1
Retail package	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.

4. PREPARATION FOR OPERATION

After storage or transportation at temperatures below +10 °C or above +35 °C, keep the device in a room at a temperature from +10 °C to +35 °C for at least 4 hours prior to plugging it in.

4.1. Battery Installation and Replacement

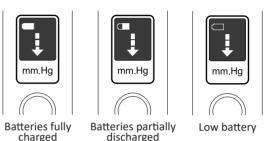
The current battery status is marked with the charge level indicator in the top left corner of the Tonometer display.

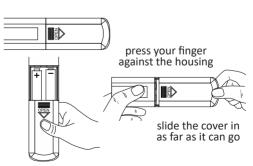
If the batteries are discharged, the Tonometer will not switch on.

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.
- 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.





↑ 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.

4.2 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. Holding the Tonometer with the rod down, treat the buffer ring and the lower part of the rod with a sterile cloth moistened with a disinfectant solution based on ethyl alcohol, which does not enter into reaction with the metal

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 5% solution of a household detergent.

2. Wipe the buffer ring and the lower part of the rod with a dry sterile cloth.

After disinfection, wipe the outer surfaces of the indicator housing 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.

4.3. 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:

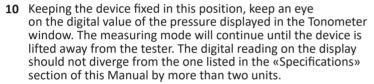
- after long idle periods
- after dropping the device
- after changing the batteries
- in any other cases when you doubt if the Tonometer works properly

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

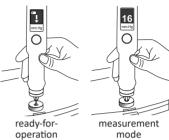
- 1 Open the Tonometer case.
- **2** Take the device out and put the opened case with the tester on a table.
- 3 Position the Tonometer with the rod up and take the protective cap off.
- 4 Shortly press the On/Off button to switch the Tonometer on.
- 5 A moving arrow displayed in the Tonometer window 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.
- 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.



- 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.





5. DEVICE APPLICATION PROCEDURE

5.1. 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. 4.2).
- 4 Shortly press the On/Off button to switch the Tonometer on. When activated, the Tonometer produces a beeping short sound signal.
- 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. 4.3).

5.2. 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.
- Attention! IOP measuring can be done with the patient either seated or in a supine position. It is essential that the patient's head is tilted back, as close to horizontal position as possible.



- The patient's gaze must be fixed at a test object (for instance, their own hand), their eye gaze line making up an angle of 45-50° from upright direction.
- 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
 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.

 Place the Tonometer rod on the eyelid in the scleral area, 2-3 mm away from the eyelid edge.

The Tonometer can take measurements on any available spot of the sclera through the eyelid. There are, however, certain spots which are recommended for measuring because of their convenience both for the doctor and the patient.











 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.



 $\overline{\wedge}$

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

- 1 or 2 seconds after lowering the Tonometer down on to the eyelid, it produces a beep
 indicating that the measurement process is beginning and the current 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 the device is lifting up, beep
 indicating that the measurement process is stopped. At this moment 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.
- Disinfect the Tonometer (see Cl. 4.2).

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.



5.3. Requirements for Accurate Measuring Results

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 strictly upright, avoiding its deviation by more than 15 degrees.
- The patient's position at the time of measurement.

At the time of the measurement, the patient should be either in a sitting with his head tilted back or in a supine position so that the position of the head is as close to horizontal as possible.

 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).

• The Tonometer rod should be positioned at the right angle against the eye surface.

To achieve that, align the Tonometer rod axis with the geometric center of the eyeball.

The Tonometer can be equipped with two silicone pressure gauges of different hardness for training in use.









6. POSSIBLE ERRORS AND TROUBLESHOOTING

Problem	Possible cause	Troubleshooting method
The Tonometer does not switch on	Low batteries	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 decalibrated	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

7. 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 replacement	When the symbol «□» appears on the display

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.

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».

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.

8. MARKING

The Tonometer is marked with the following symbols:



Warnings and precautions related to safety and operating efficiency



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



The product is licensed with Approval Certificate of Measuring Instruments



User Manual. Please read the User Manual carefully



Voltage

MD

Medical Device

Manufacturer

AN I

Date of manufacture

SN

Serial number

9. SPECIFICATIONS

DeviceTranspalpebral digital Tonometer for intraocular pressure measurement

Model EASYTON

IOP readings range, mmHg 7-50

Accuracy, mmHg, within the range of:

7-23 mmHg ±2 above **23** mmHg ±5

Repeatability (coefficient of variation), % ≤8,1 Accuracy of display, mmHg 1 IOP measurement time, sec, max 2

Display unit Millimeter of mercury (mmHg)

Power consumption during

measurement, mA, max 150

Power supply:

No. of elements and voltage, V two alkaline battery 1.5V, standard size AAA, R03

Display OLED

Data outputDisplay windowOverall dimensions (L×H×W) mm, max173 × 27 × 21Weight, g, max88, incl. batteries

Operating conditions:

operating temperatures range, °C from +10 to +35 relative air humidity,%, max atmospheric pressure, mmHg 630-800

Mean shelf life, no less than 5 years

10. LIST OF STANDARDS

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:

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

EN 60601-1 «Electrical medical products. Part 1. Safety general requirements taking into account of basic functional characteristics».

EN 60601-1-2 «Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests».

ISO 8612 «Ophthalmic instruments. Tonometers».

EN 62304 – «Medical device software – Software life cycle processes».

During pre-market testing process the comparability testing to a Goldmann-type reference tonometer was performed on 132 eyes and satisfied results was reached. The resulting Pearson correlation coefficient is 97%. This indicates the high accuracy of the EASYTON tonometer compared to the Goldmann tonometer. During the bench tests, pressure measurements were carried out using certified standard eyes models. As a result of the tests, the required accuracy and repeatability of the measurements were confirmed.

11. ANNEX A

Table 1

Manufacturer's manual and declaration - electromagnetic emission 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. Electromagnetic Compliance Electromagnetic environment – instructions emissions test Radio-interferences according to Group 1 The Tonometer uses radio-frequency Special International Committee for energy only to perform internal functions. Radio-Electronic Interferences 11 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 A Classes The Tonometer is suitable for use in all the Radio-interferences according to Special International Committee for locations, not used for domestic purposes Radio-Electronic Interferences 11 and not connected to low-voltage distribution networks The harmonic current components Not applied of IEC 61000-3-2

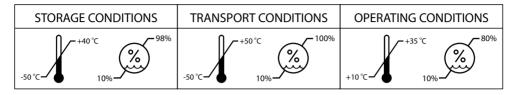
Manufacturer's manual and declaration – interference resistance			
The Tonometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Tonometer should ensure its use in the specified electromagnetic environment.			
Interference resistance test	The test level according to IEC 60601	Compliance level	Electromagnetic environment – instructions
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°) - U _H =0%, 1 cycle - U _H =70%; 25/30 cycles (0°) - 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.

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 (150 kHz - 80 MHz) 6 V (ISM & Amateur)	Not applied	The distance between the mobile radiotele- phone communication systems used and any element of the device, 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 transmit- ter.
Radio-frequency electromagnetic field according to IEC 61000-4-3	10 V/m (80 MHz - 2.7 GHz)	Complies	The field density in the propagation of radio waves from stationary radio transmitters, according to the results of observations of the electromagnetic situation, should be lower than the level of correspondence in each frequency band. The effect of interference may occur near the equipment marked with the symbol ((•))

12. STORAGE AND TRANSPORTATION



↑ 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.

13. MANUFACTURER'S WARRANTY

The Manufacturer hereby guarantees that the quality of the Tonometer conforms to the requirements stated in the User 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 nonauthorized 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 User 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.

14. 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.

Warranty sheet for repair or replacement works within warranty period EASYTON transpalpebral digital tonometer for intraocular pressure measurement

20_

surname and signature

Accepted on « Shop foreman Manufacturer's address: 25, Yanina str., Yelatma, 391351, Ryazan region, Russia JSC «Yelatma Instrument Making Enterprise» Tel: +7 (4912) 293-418

WARRANTY SHEET

for repair (replacement) within 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	e by the service center	
Date	City	
Released after repairs		
	(date, signature)	
Stamp		
	Signature of the Head of Repair Center	
		(signature)
	Signature of the Owner	
	ÿ <u>—</u>	(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.