EASYTON Tonometer is covered by Russian Federation's Patent No. 2335234.
The device is compliant with all the security requirements provided by IEC 60601-1:2005 and IEC 60601-1-2:2007-03 international standards.
The tonometer conforms with the European Economic Community Directive 93/42/EEC.

Das EASYTON-Tonometer ist patentrechtlich geschützt (Patent der RF No. 2335234).
Das Tonometer entspricht allen Sicherheitsforderungen im Sinne internationaler Normen IEC 60601-1:2005 und IEC 60601-1-2:2007-03. Das Tonometer entspricht den Anforderungen der europäischen Richtlinie für Medizinprodukte 93/42/EEC.

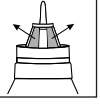
Le tonomètre EASYTON est protégé par le brevet de la Russie № 2335234.
Le tonomètre est conforme à toutes les normes de sécurité prévues par les standards internationaux IEC 60601-1:2005 et IEC 60601-1-2:2007-03. Le tonomètre est conforme à la directive de la Communauté économique européenne 93/42/EEC.

Il tonometro EASYTON è protetto dal brevetto della Russia n. 2335234.
Il tonometro soddisfa tutti i requisiti di sicurezza previsti dalle norme internazionali IEC 60601-1:2005 e IEC 60601-1-2:2007-03. Il tonometro soddisfa i requisiti della direttiva 93/42/CEE della Comunità Economica Europea.

El Tonómetro EASYTON está protegido por la Patente № 2335234 de Rusia.
El Tonómetro cumple todos los requerimientos de seguridad previstos en los Estándares Internacionales IEC 60601-1:2005 y IEC 60601-1-2:2007-03. El Tonómetro cumple todos los requerimientos de la Directiva 93/42/EEC de la Comunidad Económica Europea.

TABLE OF CONTENTS

⚠ **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 measuring true and tonometric 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 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.

Use the QR code to watch the training video

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.

⚠ 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

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

The Tonometer can measure IOP in two modes:
- tonometric IOP measuring mode (Maklakov's scale)
- true IOP measuring mode (Goldmann scale)

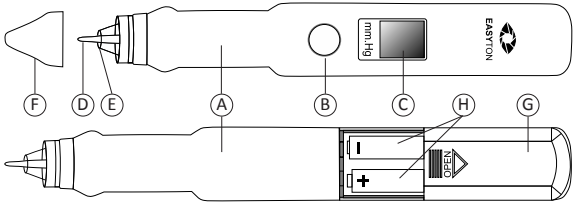
IOP measurement is taken through closed eyelid, which prevents any contact with sclera or cornea, and does not require any anaesthesia.

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.

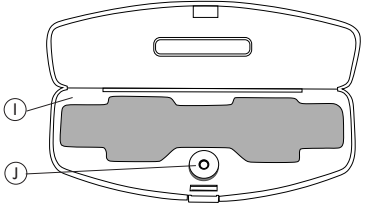
During the measuring process, the rod is placed onto the eyelid, pressed against it with the weight of about 10 g, and fixated over the eye sclera or cornea. The vibrations are set off by a short electromagnetic pulse affecting the vibrator rod. The rod motion is transmitted on to the eye through eyelid in the form of a momentary impact which incites forced vibrations of the eye membranes.

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

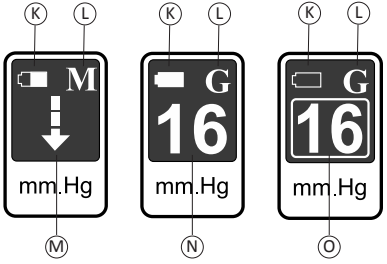
Key Design Features



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



Display Symbols



K. Battery level indication
L. Current IOP measurement mode:
«M» = «tonometric» (Maklakov's scale);
«G» = «true» (Goldmann scale)
M. Ready-for-operation indication
N. Measured IOP reading
O. Square frame around the reading value = unstable positioning of the Tonometer, or the patient's eyelid or eye.

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)

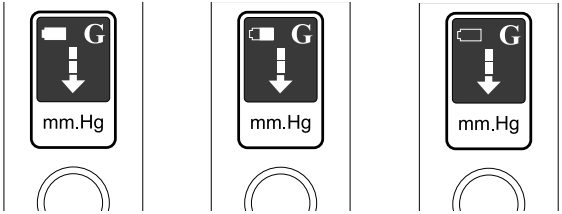
Statistically, the normal range of true IOP (P_0) is within 10 to 21 mmHg, while the tonometric IOP level (P_t) ranges from 12 to 25 mmHg. Regardless of its basic condition, IOP may be irregular or may change in the course of the day. The normal value may vary in the range of 2-2.5 mmHg.

2. PREPARATION FOR OPERATION

ENG

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.



Batteries fully charged | Batteries partially discharged | Low battery

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

Batteries are to be replaced with the Tonometer switched off.

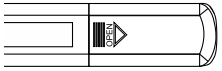
If you plan to use the device again only in a few months' time, make sure to take the batteries out.

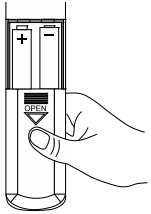
1 Turn the Tonometer over so that its front panel is facing downwards.

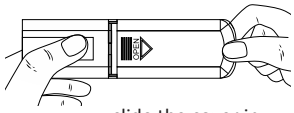
2 Slide the battery case cover in the direction of the arrow marked on it.

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.







press your finger against the housing

slide the cover in as far as it can go

⚠ **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.

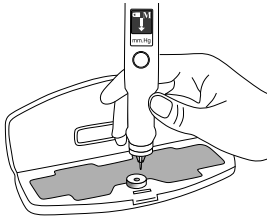
4 Shortly press the On/Off button to switch the Tonometer on.

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.

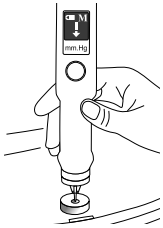
7 Place the Tonometer with the measuring rod down and position its housing so as to be able to see the readings on the display.

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



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

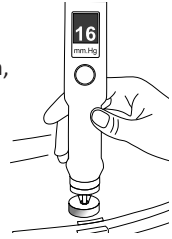
9 Keeping the heel of the hand fixed on the table, insert the device rod down into the center of the tester pinhole. Dip the Tonometer buffer ring as far down as it can go into the circular groove of the tester. The lower surface of the Tonometer ring should be aligned with the circular groove surface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



ready-for-operation

the pressure value is displayed in the Tonometer window.

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.



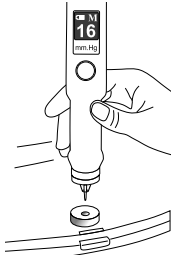
measurement mode

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 completed

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. 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.

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

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 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.

3. DEVICE APPLICATION PROCEDURE

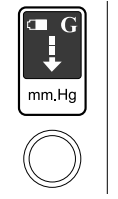
3.1. Tonometer Measuring Mode Setup

EASYTON Tonometer is provided with two options for IOP measuring.

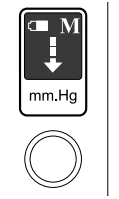
The «M» or «G» symbol in the top right section of the display indicates the current measurement mode.

The Goldmann IOP scale is pre-set by the Manufacturer by default. The previously set measuring mode remains active until the next mode change.

Deactivation of power supply does not cause change of the mode set earlier.



G
(true) IOP:
Goldmann scale

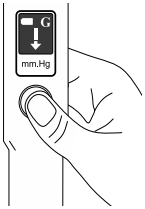


M
(tonometric) IOP:
Maklakov's scale
with a weight
load of 10 g

Changing of the measuring mode can be done at any time.

To change it, do the following:

1. Briefly press the On/Off button to switch the Tonometer on.
2. When a moving arrow appears on the Tonometer display, press the On/Off button and hold it down for about 5 seconds until the mode symbol on the display changes automatically.
3. Shut the Tonometer down by releasing the On/Off button.
4. Re-activate the Tonometer and make sure that the previously changed mode is still on.



Hold the button down for 5 seconds

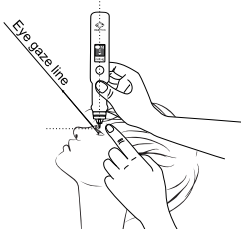
3.2. Pre-Measurement Steps

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).

3.3. Measuring Procedure

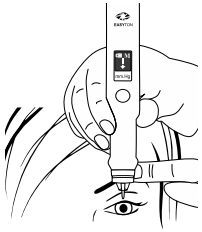
- Hold the activated Tonometer with your fingers by the cylinder-shaped part of its housing.
- Place the device with its rod facing downwards. Turn the Tonometer so as to be able to see the readings on the display.
- Stand at the patient's side slightly behind them.

⚠ **Attention!** IOP measurements are made while the patient is seated. It is essential that the patient's head is tilted back, as close to horizontal position as possible.



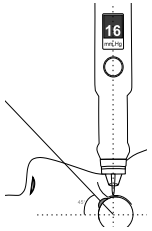
- The patient's gaze must be fixed at a test object (for instance, their own hand), their eye gaze line making up an angle of 45° from upright direction.

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

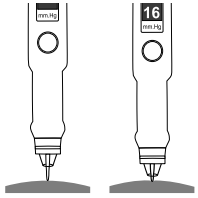


The Tonometer can take measurements on any available spot of the sclera through the eyelid.

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. Avoid slipping of the eyelid onto the cornea while taking the measurement.



⚠ **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.

- 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.

3.4. Requirements for Accurate Measuring Results

To obtain the most accurate IOP measurement results, the following conditions must be observed:

• **The Tonometer body should be positioned strictly upright.** Try to preserve the angular deviation from vertical axis at 15 degrees max., especially at the initial stage of the device application.

• **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.

• **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).

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	
(Goldmann scale), mmHg	7-50
(Maklakov's scale), mmHg	15-53
Absolute permissible error limits for IOP measurements	
(Goldmann), mmHg, within the range of:	
7-23 mmHg	±2
above 23 mmHg	±5
(Maklakov), mmHg, within the range of:	
15-28 mmHg	±2
above 28 mmHg	±5
Measurement modes:	
IOP: Goldmann scale	G (True)
IOP: Maklakov's scale	M (Ton)
IOP measurement time, sec, max	2
Power consumption during measurement, mA, max	100
Power supply:	
No. of elements and voltage, V	2 × 1.5, 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	from +10 to +35
relative air humidity,%, max	80
atmospheric pressure, mmHg	630-800
Mean service life, no less than	5 years

Tonometer readings obtained with the tester in the Goldmann IOP measurement mode _____ +/-2 mmHg.

(to be filled in at device acceptance)

7. 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


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:

EN ISO 10993.1-2011 «Medical products. Assessment of medical products biological effect. Part 1. Assessment and investigation».

EN 60601-1-2006 «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 Second edition 2009 Ophthalmic instruments. Tonometers.

During pre-market testing process the comparability testing to a Goldmanntype 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.

8. 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 regionswith 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.

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.17-0103.3.

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

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

ENG

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.

11. APPENDIX A

Table 1

Manufacturer's manual and declaration – electromagnetic emission		
These devices are intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure its use in the specified electromagnetic environment.		
Electromagnetic emissions test	Compliance	Electromagnetic environment – instructions
Radio-interferences according to Special International Committee for Radio-Electronic Interferences 11	Group 1	The device 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 Special International Committee for Radio-Electronic Interferences 11	B Classes	The device is suitable for use in all the locations, including residential buildings and buildings directly connected to a distribution network that supplies residential buildings
The harmonic current components of IEC 61000-3-2	Not applied	

Table 2

Manufacturer's manual and declaration – interference resistance			
These devices are intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	±6 kV – contact discharge ±8 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	±1 kV when applying «wire-to-wire» interference ±2 kV when applying «wire-to-ground» interference	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	<5% U_H (voltage dip>95% U_H) during 0.5 of period 40% U_H (voltage dip 60% U_H) during 5 periods 70% U_H (voltage dip 30% U_H) during 25 periods <5% U_H (voltage dip >95% U_H) during 5 s	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	3 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			
These devices are intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	3 V	The distance between the mobile radiotelephone 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 transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$
Radio-frequency electromagnetic field according to IEC 61000-4-3	3 V/m in-band from 80 MHz to 2.5 GHz	3, V/m	$d = 1,2\sqrt{P}$ (from 80 to 800 MHz); $d = 2,3\sqrt{P}$ (from 800 MHz to 2.5 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 device exceed the applicable levels of compliance, the operation of the device 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 device.
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.

Table 4

Recommended values for separation distance between portable and mobile radio frequency communication means and the device

The device is intended for use in an electromagnetic environment in which the levels of radiated interference are monitored. The purchaser or the user of the device can avoid the effects of electromagnetic interference providing a minimum separation distance between portable and mobile radio frequency communication devices (transmitters) and the device, as recommended below, taking into account the maximum output power of transmission equipment

Nominal maximum power output of the transmitter, P, W	Separation distance d, m, depending on the frequency of the transmitter		
	$d = 1,2\sqrt{P}$ in-band from 150 kHz to 80 MHz	$d = 1,2\sqrt{P}$ in-band from 80 to 800 MHz	$d = 2,3\sqrt{P}$ in-band from 800 MHz to 2.5 GHz
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

Notes: 1. A greater value of the field density is applied at frequencies of 80 and 800 MHz.
2. The reduced expressions are applicable in all the cases. The propagation of electromagnetic waves is affected by absorption or reflection from structures, objects and people.
3. At determining recommended values of separation distance d for transmitters with nominal maximum power output, which is not mentioned in the table, the nominal maximum output power P in Watts specified in the transmitter manufacturer's documentation is substituted into reduced expressions.