ENGLISH

icare tonometer ONE

USER'S AND MAINTENANCE MANUAL

Icare® ONE (Model: TA02) INSTRUCTION MANUAL v1.12 01/14 EN

CE 0044

This device complies with:
Medical Device Directive 93/42/EEC
Canadian Medical Device Regulations

Made in Finland

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TABLE OF CONTESTS

SAFETY INSTRUCTIONS

WARNING!
The tonometer must not come into contact with the patient's eyes, except for the probes, which may do so for a fraction of a second during measurement. Do not bring the tonometer into contact with the eye or push it into the eye (the tip of the probe should be 4-8mm, or 5/32-5/16 inch, from the eye).

WARNING!
The device probe tips have not been evaluated for the presence of endotoxins. The probe tips are for single-use only, and are packaged sterile.

WARNING!
The Icare ONE Tonometer (TA02) is intended to be used only under supervision and control of the health care professional only.

WARNING!
Health care professionals must inform patients not to modify or discontinue their treatment plan without receiving instructions from the health care professional.

WARNING!
Do not change your medication or dosage without consulting your doctor.

WARNING!
IOP accuracy and repeatability are unknown for patients with corneal astigmatism > 3.00 D of astigmatism, irregular astigmatism and keratoconus.

WARNING!
Patients with hearing loss may not detect signals that indicating correct measurements.

WARNING!
Patients with physical challenges may experience difficulty in using the hand-held tonometer.

WARNING!
No modification of this equipment is allowed

CAUTION!
Before using the tonometer read this manual carefully. Keep it for future use. It contains important information on using and servicing the tonometer.

CAUTION!
Federal (US) law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

- When you have opened the package, check for any external damage or faults, particularly for damage to the case. If you suspect that there is something wrong with the tonometer, contact the dealer.
- Use the tonometer only for measuring intraocular pressure. Any other use is improper and the manufacturer cannot be held liable for any damage arising from improper use, or for the consequences thereof.
- Never open the casing of the tonometer, except for the battery compartment or to change the probe base.
- Never use the tonometer in wet or damp conditions nor allow the tonometer to get wet.
- The probe base, battery compartment cover, screws, collar and probes are so small that a child could swallow them. Keep the tonometer out of the reach of children.
- Do not use the device near inflammable substances, including flammable anesthetic agents.
- Certain microbiological agents (for example, bacteria) can be transmitted from the forehead, eye or cheek support. To avoid this, the forehead and cheek support and eye piece must be cleaned for each new patient with disinfectant, for example an alcohol solution.
- The tonometer conforms to EMC requirements (IEC 60601-1-2), but interference may occur in it if used near (<1m) a device (such as a cellular phone) causing high-intensity electromagnetic emissions. Although the tonometer's own electromagnetic emissions are well below the levels permitted by the relevant standards, they may cause interference in other, nearby devices, for example, sensitive sensors.
- If the device is not to be used for a long time, remove its batteries, as they may leak. Removing the batteries restores the device to normal measurement mode.
- For every patient to be measured take a new probe to avoid cross contamination of bacteria or viruses and infection of the eye
- Use probes taken only from original intact packaging. Sterility of the probe cannot be guaranteed once the seal is compromised.
- The tonometer probes are labeled single-use only. Re-sterilization or re-use of the probe can result in incorrect measurement or damage to the probe head.
- Be sure to dispose of the single-use probes properly (for example, in a container for disposable needles). Probes may become contaminated with micro-organisms after one-time use.
- Do not connect the USB cable during measurements. When connected it is impossible to perform measurement.
- Do not change the batteries or probe base when the USB-cable is connected.
- Batteries, packaging materials and probe bases must be disposed of according to local regulations. Use only original probes (see Figure 5) and accessories.

INDICATIONS FOR USE

Icare ONE tonometer (TA02) is indicated for the monitoring of intraocular pressure (IOP) of the human eye. It is intended to be used by health care professionals and by patients under supervision and control of the health care professional. Patient use is by prescription only.

USAGE CONTRAINDICATIONS

The TA02 tonometer is contraindicated in the presence of the following conditions:
Corneal Scarring, Microphtalmos, Buphthalmos, Nystagmus, Keratoconus, abnormal central corneal thickness, and topical anesthetics.

INTRODUCTION

Icare ONE tonometer is intended to monitor intra-ocular Pressure (IOP) of the human eye. It is indicated to be used by health care professionals and by patient under prescription use only.

It is based on a patented, induction-based rebound method, which allows intraocular pressure (IOP) to be measured accurately, rapidly and without an anesthetic.

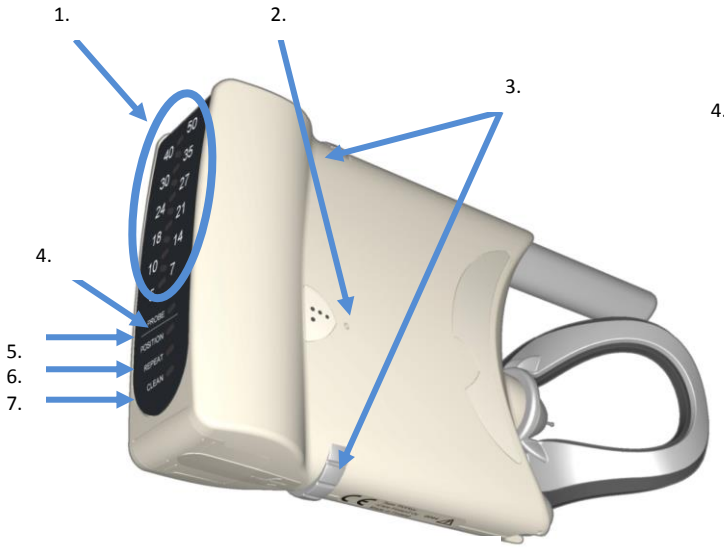
Icare One uses sterilized disposable probes in order to reduce the risk of microbiological contamination to a negligible level.
Intraocular pressure changes are due to the effects of pulse, breathing, eye movements, and body position. Several measurements are taken using the handheld device within fractions of a second to average the micro changes of IOP that occur during measurement. In the automated mode, six pre-programmed measurements are needed to obtain an accurate reading.

Icare ONE tonometer can be used by glaucoma patients to monitor their intraocular pressure. Results are stored in the internal memory of the tonometer and can be transferred to a PC through a USB cable using the Icare LINK software. Consult your doctor to interpret the results of the self-measurement.

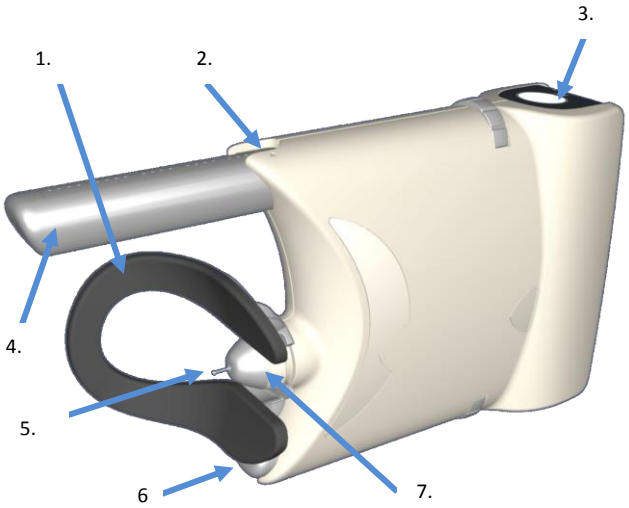
PACKAGE CONTENTS

The package contains:

- Icare ONE tonometer
- 10 sterilized single-use probes
- 2 eye supports (small and large)
- 2 Batteries
- USB cable
- User manual
- Instructions for downloading Icare LINK software
- Warranty card
- Carry-on case
- Mode switch key



1. IOP indicator LEDs
2. Mode switch
3. Forehead/cheek support adjustment wheel
4. PROBE ERROR LED
5. POSITION ERROR LED
6. REPEAT ERROR LED
7. CLEAN ERROR LED

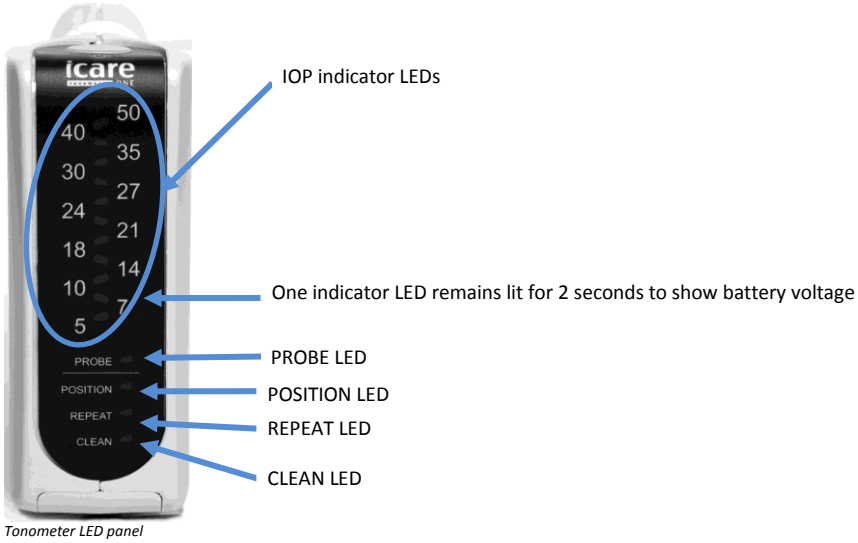


1. Eye support
2. Support position indicator
3. Measurement button
4. Forehead support
5. Probe
6. Cheek support
7. Probe base

TURNING THE DEVICE ON

Press the measurement button to turn the tonometer on. All LEDs are displayed briefly.
One of the lower IOP indicator LEDs remains lit for 2 seconds while other LEDs switch off. The LED indicates the battery voltage.

- GREEN = OK
- YELLOW = REDUCED
- RED = LOW, change battery



Tonometer LED panel

Following a brief pause, the PROBE LED blinks to remind the user to load the single use probe into the tonometer prior to measurement.

Accuracy of display: display is divided into 11 ranges:

- 5-7 mmHg
- 7-10 mmHg
- 10-14 mmHg
- 14-18 mmHg
- 18-21 mmHg
- 21-24 mmHg
- 24-27 mmHg
- 27-30 mmHg
- 30-35 mmHg
- 35-40 mmHg
- 40-50 mmHg

SETTING UP THE TONOMETER BEFORE TAKING MEASUREMENTS

Before taking measurements your tonometer, the measurement position must be adjusted correctly by health care professional. Set-up includes:

- Choosing a measurement mode
- Adjustment of the measurement position
- Loading the probe before each measurement

CHOOSING A MEASUREMENT MODE

The device can operate in two modes:

Normal

- Normal mode is used to take individual measurements one at a time. The measurement button must be pressed once to initiate each of the six measurements to obtain final IOP reading. Normal mode is generally used when measurements are taken by someone other than the patient.

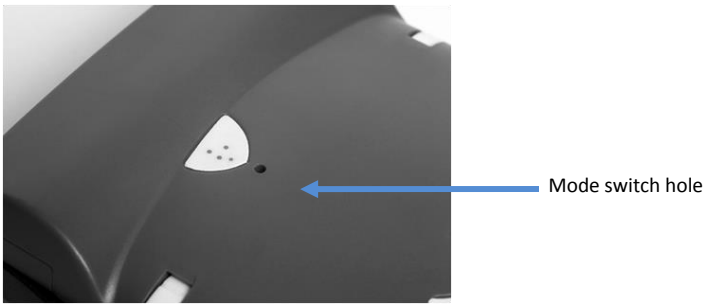
Automatic

- Automatic mode is especially useful in self tonometry. In automatic mode a single press of the measurement button initiates the measurement function and the tonometer takes six measurements automatically to obtain final IOP reading.

⚠ NOTE!
Device is designed to perform six subsequent movements of probe to cornea /measurements after which the device calculates the final IOP range. The final IOP range is displayed on device LED panel.

To change the measurement mode:

1. Turn on the tonometer.
2. Insert a straight pin into the mode switch hole on the side of the tonometer.



Measurement mode switch

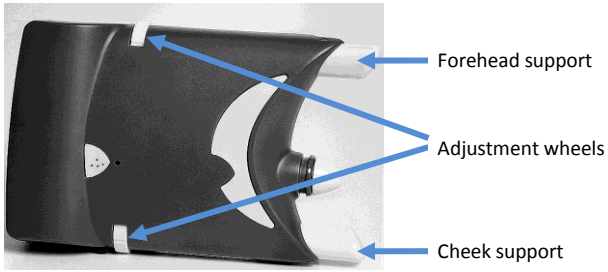
3. Push the switch with mode switch key provided with the tonometer on the bottom of the mode switch hole of the tonometer until the mode change signal is heard. The switch must be pressed for approximately three seconds for the mode to change.

The audible sound indicates the measurement mode:

- one beep: normal mode
- three beeps: automatic mode

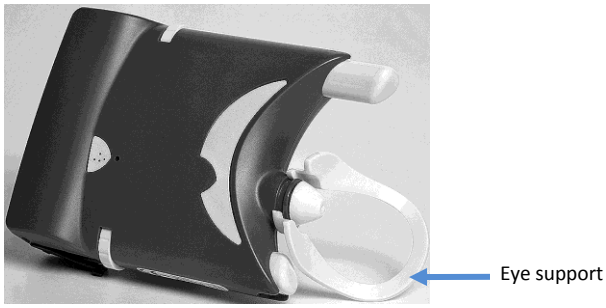
ADJUSTING THE MEASUREMENT POSITION

The tonometer has two adjustable supports, one for the forehead and one for the cheek as shown in figure. These supports are adjusted to ensure accurate measurement distance and alignment. Adjust the supports using the adjustment wheels, so the distance from the tip of the probe to the surface of the cornea is 4-8 mm (5/32-5/16 inch) and the probe is horizontal.



Tonometer forehead and cheek supports with adjustment wheels

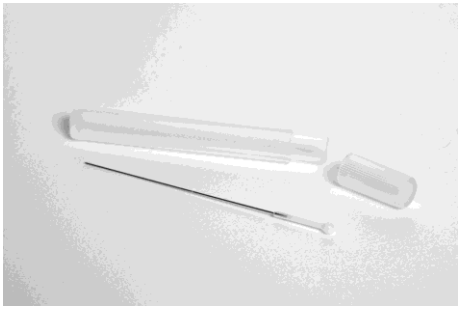
An optional eye support can be used for easy alignment and additional stability during measurement. When the eye support is used, the cheek support is not used and needs to be adjusted to minimum setting. The eye support can be used for both eyes by rotating it from one side.



Forehead and eye support, with the cheek support in minimum position

LOADING THE PROBE

The Icare ONE tonometer TA02 uses disposable tonometer probes as shown in figure. Each probe is meant for single use only. The probes are packed individually in blister.



Disposable tonometer probe and probe container

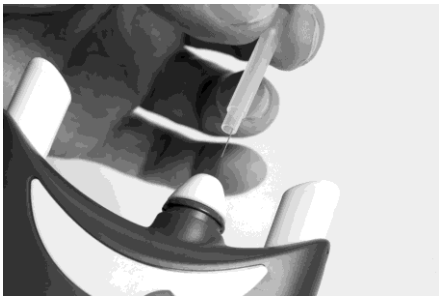
To load the probe:

1. Open the lid of the probe container as shown in figure.

⚠ CAUTION!
To prevent contamination do not touch the probe tip with fingers.

Open the probe container

2. Insert the probe into the probe base by turning the probe container upside down as shown in figure.



Inserting probe into probe base

3. After the probe has been inserted, be careful not to point the tonometer downward to prevent the probe from falling out.

4. Press the measurement button once to activate the inserted probe. During activation the device magnetizes the probe (probe moves rapidly back and forth).

Once the probe is activated, the PROBE LED remains lit. The tonometer is now ready to take a measurement.

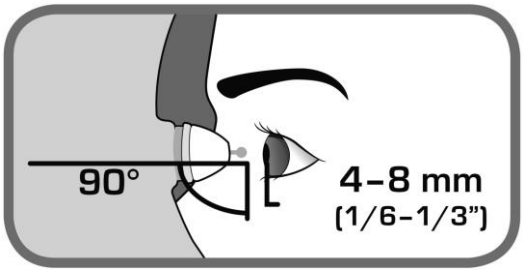
MEASURING INTRAOCULAR PRESSURE

- A measurement sequence is a set of six measurements. The measurement value, shown after all six measurements are taken, is displayed on LED display. The measurement value is an average of four successful interim measurements of those six interim measurements performed. The highest and the lowest value is left out from final value displayed. If there is too much variation in average (SD) error code REPEAT is lit on LED display. See error messages and indicators.

- In the automatic mode the six measurements in a sequence are taken automatically and in the normal mode the user must take each measurement individually until all six measurements are taken.

  To measure intraocular pressure:

1. Check that the tonometer is set up correctly and the measurement position is adjusted by a doctor or a nurse.
2. The patient should relax, and look straight ahead at a specific point while keeping eyes wide open.



Patient with the tonometer correctly positioned

3. Bring the tonometer near the eye in front of a wall mirror as shown in Figure (Measurement step). Move the tonometer closer so that the forehead and cheek support touch the skin. The distance from the tip of the probe to the center of the cornea must be 4-8 mm (5/32-5/16 inch).

4. Press the measurement button lightly to perform the measurement, taking care not to shake the tonometer. The tip of the probe should make contact with the central cornea. The way you take measurements depends on the chosen mode.

- In **Automatic** mode, press the measurement button **once** to perform the measurement. A long beep indicates the end of one measurement sequence (six measurements). In automatic mode single measurement values are not shown.
- In **Normal** mode, press the measurement button to take one individual measurement at a time. A short beep sounds after each measurement. A long beep sounds when the six measurement sequence is complete.

In addition to showing the IOP range, the accurate IOP value is stored in the internal memory.

Icare ONE is constantly controlling the measurement position. When too far or near from eye or if the measurement angle is too tilted, the tonometer beeps twice and displays a red LED indicating an error (Position). Press the measurement button again to clear the error message and follow the corrective actions according to indicators described on page 10.

In normal mode a value is shown briefly after each successful measurement. When the six measurements in sequence are completed and the measurement result is valid, the final value range is displayed. If there is too much variation between the measurements, the REPEAT ERROR LED is displayed and the measurement needs to be performed again. The device stores the quality of the measurement in its internal memory, which is only accessible by downloading to a PC using the Icare® LINK software.

A new measurement needs to be taken if:

- REPEAT ERROR LED is displayed, for example, if the probe made contact with the eyelid.
- Encountering unusual values, for example, over 22 mmHg or below 8 mmHg.

The tonometer's internal memory stores the time and date of a measurement, the measurement result and the quality level of the measurement. This information can be uploaded to a PC through a USB cable using Icare® LINK software. The tonometer is taken to a health care professional who can transfer the data.

⚠ NOTE
When using Icare LINK software, it assumes by default that the first accepted measurement is for the right eye and the second accepted measurement is for the left eye.

MEASUREMENT STEP

Measurement position

PATIENT USE INSTRUCTIONS

- When taking measurements:

⚠ NOTE
Before performing self tonometry the patient must have the tonometer set up by a health care professional. The doctor or nurse has adjusted the distance between the tip of the probe and the center of the cornea with the forehead and cheek support to be 4-8 mm, (5/32-5/16 inch).

⚠ NOTE
The tonometer must be held in a vertical position. Angle of inclination has limited to ± 22° to ensure reliable outcome.

- Doctor or nurse has adjusted the measurement position.
- Doctor or nurse has demonstrated to the patient how to use the tonometer

1. Switch on the unit, load the probe
2. Go in front of a wall mirror
3. Take the tonometer in your hand with the white main button pointing upwards
4. Move the tonometer sideways toward your eye so that you see in the mirror the white tip of the probe in front of the black pupil
5. Move the tonometer closer so that the forehead and cheek supports touch the skin
6. Check that the white tip of the probe is seen in front of the center of the cornea (pupil)
7. Turn the tonometer from the sideway position so that the tonometer with the loaded probe points straight to the center of the cornea (pupil)
8. Open your eyes wide and try not to blink your eye while measuring
9. Press the measurement button once. You will get the final result after the probe touched you eye for six times and after one long beep. In automatic mode the six interim measurements are taken in sequence.

⚠ CAUTION!
Always perform measurement on RIGHT eye first followed by LEFT eye. Complete the RIGHT eye measurement sequence before changing to the LEFT eye.

A new measurement needs to be taken if:

- REPEAT ERROR LED is displayed, for example, if the probe made contact with the eyelid.
- Encountering unusual values, for example, over 22 mmHg or below 8 mmHg.

ERROR MESSAGES AND INDICATORS

Icare Tonometer ONE display panel shows the following LEDs:

LED	State	Description and Action
PROBE	BLUE blinking BLUE lit	Load probe Ready to use
POSITION	RED lit	Check distance and alignment
REPEAT	RED lit	Standard deviation too high – repeat the whole measurement sequence
CLEAN	RED lit	Clean or change the probe base

DIFFERENCES BETWEEN PROFESSIONAL USER AND THE PATIENT USING THE ICARE ONE TONOMETER

Instructions for the health care professional

1. Check that the tonometer is set up correctly by a doctor or a nurse.
2. The patient should relax, and look straight ahead at a specific point while keeping eyes wide open.
3. Bring the tonometer near the eye. Move the tonometer closer so that the forehead and cheek support touch the skin. Check that the white tip of the probe is seen in front of the center of the cornea (pupil). The distance from the tip of the probe to the center of the cornea must be 4-8 mm (5/32-5/16 inch).
4. Press the measurement button lightly to perform the measurement, taking care not to shake the tonometer. The tip of the probe should make contact with the central cornea (pupil). The way you take measurements depends on the chosen mode.
5. In normal mode a value is shown briefly after each successful measurement. When the six measurements in sequence are completed and the measurement valid, the final value of IOP is displayed. If there is too much variation between the measurements, the REPEAT ERROR LED is displayed and the measurement needs to be performed again. The device stores the quality of the measurement in its internal memory, which is only accessible by downloading to a PC using the Icare LINK software.
6. A new measurement needs to be taken if:

   REPEAT ERROR LED is displayed, for example, if the probe made contact with the eyelid.
   Encountering unusual values, for example, over 22 mmHg or below 8 mmHg.

7. The tonometer's internal memory stores the time and date of a measurement, the measurement result and the quality level of the measurement. This information can be uploaded to a PC through a USB cable using Icare® LINK software. If a patient does not have the software, the tonometer is taken to a health care professional who can transfer the data.

NOTE: When using Icare LINK software, it assumes by default that the first accepted measurement is for the right eye and the second accepted measurement is for the left eye. In case you end up taking multiple measurements for some reason, the eye details can be incorrect and must be fixed (See Icare LINK user manual).

Instruction for the patient

1. Switch on the unit, load the probe
2. Go in front of a wall mirror
3. Take the tonometer in your hand with the white main button pointing upwards
4. Move the tonometer sideways toward your eye so that you see in the mirror the white tip of the probe in front of the black pupil
5. Move the tonometer closer so that the forehead and cheek supports touch the skin
6. Check that the white tip of the probe is seen in front of the center of the cornea
7. Turn the tonometer from the sideway position so that the tonometer with the loaded probe points straight to the center of the cornea (pupil)
8. Open your eyes wide and try not to blink your eye while measuring
9. Press the measurement button once. You will get the final result after the probe touched you eye for six times and after one long beep. In automatic mode the six interim measurements are taken in sequence.

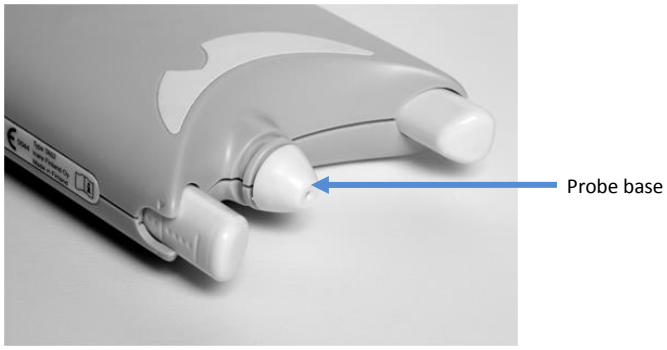
   A new measurement needs to be taken if:

   REPEAT ERROR LED is displayed, for example, if the probe made contact with the eyelid.

CLEANING AND DISINFECTION

The forehead and cheek supports and the eye support must be cleaned for each new patient with disinfectant for example 70% alcohol solution using wipe. Do not immerse the tonometer in water or other liquid.

If the tonometer displays a CLEAN error (CLEAN LED), the probe base (see Figure below) may be dirty or dusty. To clean the probe base first unscrew the probe base off the tonometer. Carefully inject isopropyl alcohol (rubbing alcohol) through the top of the probe base. Dry the probe base by injecting air into the probe base and drying the part gently. If it is not possible to clean the probe base, then replace it with a new one.

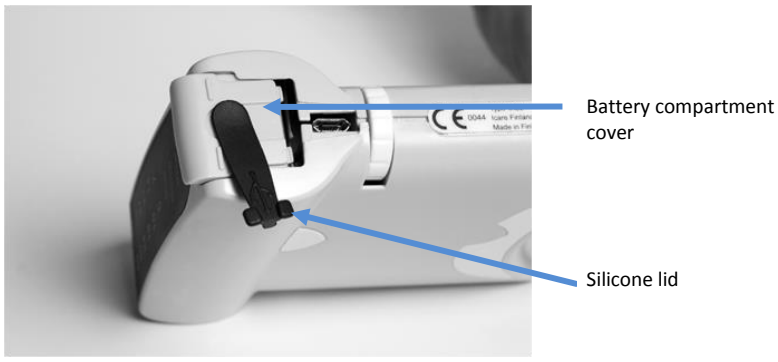


Tonometer probe base

Tonometer probe base unscrewed

CHANGING THE BATTERIES

Lift the silicone lid that protects the USB-port and keeps the battery compartment cover in place. Open the battery compartment cover by pressing the silicone lid slightly and sliding the battery compartment cover as shown in figure.



Opening the silicone lid and battery cover

Insert two CR123A lithium batteries in the correct order: (+) end upwards as shown in figure. Close the cover firmly and press the silicone lid in place to cover the USB port.

⚠ NOTE

Make sure you use batteries with built-in PTC protection, For Example Energizer Lithium Photo 123 3V CR123A.

Inserting new batteries

SERVICE PROCEDURES

Replace the batteries when the device indicates low battery voltage.

Clean or change the probe base if the probe does not move smoothly (CLEAN LED is lit).

NOTE
No other service procedures can be carried out by the user. All other service and repair must be carried out by the manufacturer or a certified service center.

SPARE PARTS

- Single-use probes (10 included with the tonometer when purchased)
- Probe base kit
- Eye supports
- Mode switch key
- USB cable
- Batteries
- carry on case

These can be purchased from a local distributor of Icare products.

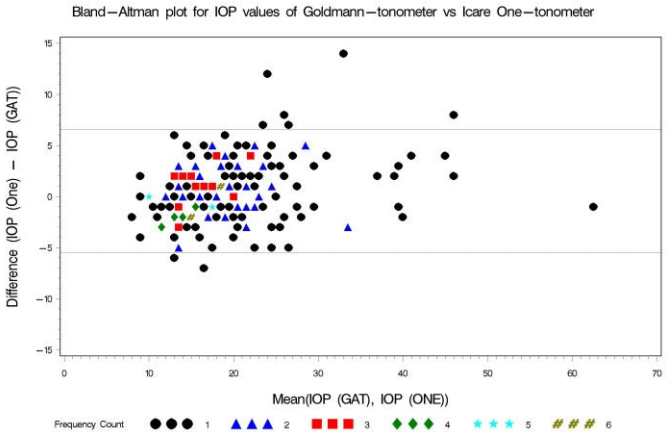
TECHNICAL AND PERFORMANCE DATA

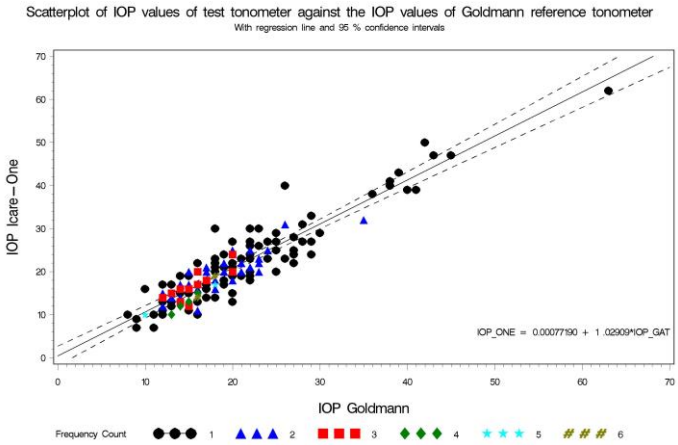
- Type TA02
- The device conforms to CE regulations
- Dimensions: approximately 11 cm x 8 cm x 3 cm
- Weight: approximately 150 g
- Power supply: 2•CR123 batteries (make sure you use batteries with built-in PTC protection, For Example Energizer Lithium Photo 123 3V CR123A)
- Measurement range: 5-50 mmHg
- Display range: 5-50 mmHg
- Accuracy (95% tolerance interval relatively to manometry): ± 1.8 mmHg
- Repeatability (coefficient of variation): < 9% @ IOP ≤20 mmHg
  < 3% @ IOP >20 mmHg
- Accuracy of display: display is divided into 11 ranges:
  5-7 mmHg
  7-10 mmHg
  10-14 mmHg
  14-18 mmHg
  18-21 mmHg
  21-24 mmHg
  24-27 mmHg
  27-30 mmHg
  30-35 mmHg
  35-40 mmHg
  40-50 mmHg
- Display unit: mmHg
- The serial number is located on the inside of the battery compartment cover
- There are no electrical connections from the tonometer to the patient
- The device has BF-type electric shock protection

- Operation environment
  Temperature: +10 °C to +35 °C
  Relative humidity: 30 % to 90 %
  Atmospheric pressure: 800 hPa – 1060 hPa
- Storage environment
  Temperature: -10 °C to +55 °C
  Relative humidity: 10 % to 95 %
  Atmospheric pressure: 700 hPa – 1060 hPa
- Transport environment
  Temperature: -40 °C to +70 °C
  Relative humidity: 10 % to 95 %
  Atmospheric pressure: 500 hPa – 1060 hPa

CLINICAL PERFORMANCE DATA

Performance data is obtained from a clinical study, performed according to ANSI Z80 and ISO 8612 for tonometers.
The mean of paired difference (Goldmann-Icare ONE tonometer) were 0.6 (≤16 mmHg 0.1; >16<23 1.0; ≥23 0.8) and and standard deviation is 3.1





SYMBOLS

- Caution

- Keep dry

- See operating instructions for more information

- Manufacturing date

- BF-type device

- Lot number

- Single-use disposable

- Sterilized using irradiation

- Serial number

- Stand by

- Use by <date>

- Do not discard this product with other household-type waste.
- Send to appropriate facility for recovery and recycling.
- EU WEEE (European Union Directive for Waste of Electronic and Electrical Equipment)