icare tonometer

ENGLISH

USER'S AND MAINTENANCE MANUAL

TONOMETER

Icare® TA01i
INSTRUCTION MANUAL v2.2 04/12 EN

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

Made in Finland

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INDICATIONS FOR USE

The Icare tonometer TA01i is intended to be used for the measurement of intraocular pressure in the human eye.

INTRODUCTION

The Icare tonometer is used in the diagnosis, follow up and screening of glaucoma. It is based on a new, patented, induction-based rebound method, which allows intraocular pressure (IOP) to be measured accurately, rapidly and without an anesthetic.

Since single-use probes are used for measurement, there is no risk of microbiological contamination. Intraocular pressure changes due to the effects of the pulse, breathing, eye movements and body position. Because measurements are taken using a handheld device in fractions of a second, several measurements are needed to obtain an accurate reading and there fore the software is pre-programmed for six measurements.

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 1/6 – 1/3 inch, from the eye).

⚠ CAUTION

Read this manual carefully, since it contains important information on using and servicing the tonometer.

Retain this manual for future use.
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 manufacturer or distributor.
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.
This manual contains instructions for replacing batteries and changing the probe base.
Never use the tonometer in wet or damp conditions.
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 inflammable anesthetic agents.
Prior to each measurement, check that a new disposable probe from an intact package is being used.
Be sure that the probe contains the small plastic round tip in front.
Certain microbiological agents (e.g. bacteria) can be transmitted from the forehead support.
To avoid this, the forehead support should be cleaned regularly with a disinfectant, e.g. an alcohol solution.
The tonometer conforms to EMC requirements (IEC 60101-1-2: 2001), 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, e.g. sensitive sensors.
If the device is not to be used for a long time, we recommend that you remove its AA batteries, since they may leak. Removing the batteries will not affect the subsequent functioning of the tonometer.
Be sure to dispose of the single-use probes properly (e.g. in a container for disposable needles), because they may contain micro-organisms from the patient.
Batteries, packaging materials and probe bases must be disposed of according to local regulations.

⚠ CAUTION

Federal law (U.S.) restricts this device to sale by or on the order of a physician.

PARTS OF THE TONOMETER

1. Forehead support
2. Forehead support adjusting wheel
3. Display
4. Collar
5. Selector button
6. Measurement button
7. Probe base
8. Central groove

TURNING THE TONOMETER ON AND LOADING THE PROBE

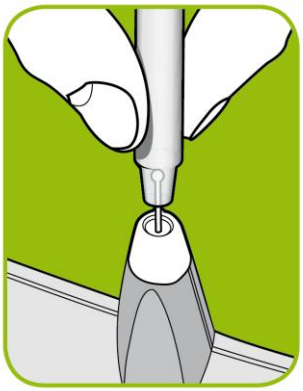
Place the wrist strap into the wrist strap attachment. Place the wrist strap around your wrist and secure it. The wrist strap protects the tonometer from dropping onto the floor accidentally. Insert batteries into the tonometer (page 9).

Press the measurement button to turn the tonometer ON. The tonometer display will display all of the LCD segments (see the figure beside). Check that all of the segments are functional in the four-digit, sevensegment LCD display.

Following a brief pause, the display will show “LoAd,” reminding the user to load the single use probe into the tonometer prior to measurement.

Load the probe in the following way:

Open the probe tube by removing the cap and insert the probe into probe base as shown in the image. After the probe has been inserted, be careful not to point it down before activating the tonometer in order to prevent the probe from falling out. Activate by pressing the easurement button once and the tonometer will be ready for measurement when 00 appears on the display. After activating the probe is magnetized and will not fall out.

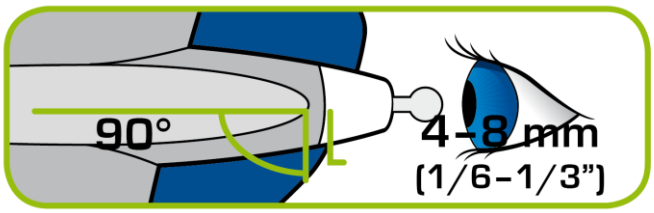


To obtain firm support for the patient’s forehead, in order to obtain an accurate measurement at the right distance, you can adjust the forehead support by turning the forehead support adjusting wheel.

MEASUREMENT

*Since local anesthetic may lower the tonometer reading, we recommend that you refrain from using an anesthetic when performing measurements.

Ask the patient to relax and look straight ahead at a specific point. Bring the tonometer near the patient’s eye. The central groove should be in a horizontal position, and the distance from the eye to the front part of the collar should be the length of the collar. In other words, the distance from the tip of the probe to the patient’s cornea (see picture) should be 4-8 mm (1/6-1/3 inch).



If necessary, adjust the distance by turning the forehead support adjusting wheel. 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. Six measurements are made consecutively. After each successful measurement, you will hear a short beep. Once the six measurements have been performed, the IOP will be shown on the display after the ‘P’.

If there is an erroneous measurement, the tonometer will beep twice and display an error message. Press the measurement button to clear the error message. If several erroneous measurements appear, see error messages (page 10).

To obtain the most accurate reading, six measurements are required, but the result is also displayed after the first measurement, which can usually be considered valid. The measurement values displayed are average values for all previous measurements (1.-5.). Single measurement values are not shown. Should there be variation between the measurements, ‘P’ will flash on the display after the sixth measurement.

Following the performance of the entire measurement, a new measurement series can be begun by pressing the measurement button. The tonometer will then be ready for the next measurement series (00 will show on the display, see page 8).

If the user doubts the validity of the measurement (for example, if the probe made contact with the eyelid, or missed the central cornea etc.), we recommend that he/she make a new measurement. In addition, when encountering unusual values (for example over 22mmHg or below 8 mmHg) we recommend the performance of a new measurement to verify the result.

*Badouin C, Gastaud P. Influence of topical anesthesia on tonometeric values of intraocular pressure. Ophthalmologica 1994;208:309-313

DISPLAY AFTER MEASUREMENTS

Before	After the second measurement	After the sixth measurement
00	**2.13**	**P 13**

After the sixth measurement, the letter P appears on the display, followed by the IOP (Intraocular pressure) reading.

If the P is blinking, it means that the standard deviation of the measurements is greater than normal.

P_ (line down) The standard deviation of the different measurements has a slightly greater value than normally, but the effect on the result is unlikely to be relevant.

P-(line in the middle) The standard deviation of the different measurements is clearly greater than normal, but the effect on the result is probably irrelevant. A new measurement is recommended if the IOP is over 19 mmHg.

P¯(line up) The standard deviation of the different measurements is great and a new measurement is recommended.

OTHER FUNCTIONS

Accessing old measurement value

From the starting position, press the right or left selector button until 'Old' appears on the display. Then press the measurement button. You can now 'scroll' through the old values by pressing the selector buttons (right=older, left=more recent, from 0-9).

To exit the old values search, press the measurement button.
The display will now show the word 'Old'. Press either selector button to access other functions (00=measurement, End=turning OFF).

Turning the tonometer OFF

Press either selector button until the display shows 'End'. Press the measurement button for two seconds - the display will show 'byE' and the tonometer will switch off. The used probe will be partially ejected. Use the used package to remove it from the tonometer. Ensure that you dispose of the probe properly.

Replacing the probe base

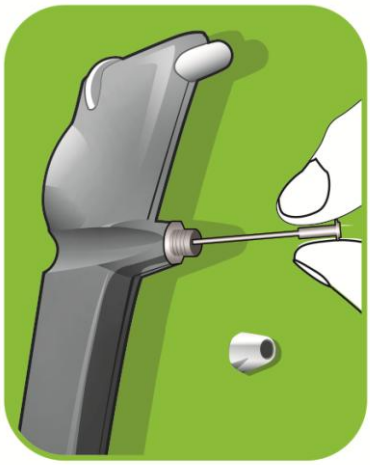
After several months of use, dust may collect in the probe base, affecting the probe movement. The probe base should be replaced if the probe no longer moves smoothly.

Unscrew the probe base collar and put it in a safe place.

Remove the probe base by tilting the tonometer downwards and pull the probe base out of the tonometer.

Insert a new probe base into the tonometer.

Screw the collar in, to lock the probe base.



Replacing the batteries

Unscrew the battery compartment locking screw with a screwdriver or a small coin.

Remove the battery compartment cover. Remove the old batteries.

Insert a new set of batteries (four AA batteries). Do not use rechargeable batteries, since they may not function properly (the inner resistance of some rechargeable batteries is too high). Insert the batteries in accordance with the diagrams inside the battery compartment, with the +terminals pointing downwards on the display side of the tonometer (the rear side), and the -terminals pointing downwards on the measurement side (the front side).

Replace the battery compartment cover and secure it by screwing it in lightly using the coin or screwdriver. Take care not to use excessive force when screwing the cover into place.

Battery compartment cover

Error messages

To clear error messages, press the measurement button, after which the measurement can be repeated. The following messages may appear:

MESSAGE	STATE	DESCRIPTION
bAtt	The batteries are low.	Replace the batteries.
E 01	The probe did not move at all.	If this error message is repeated, turn the tonometer so that the collar faces down for a short time. If the error message is repeated, remove the probe base and replace it with new ones (see page 9).
E 02	The probe did not touch the eye.	The measurement was taken from too far away.
E 03	The probe speed was too low.	The measurement was taken from too far away or the tonometer was tilted too far upwards.
E 04	The probe speed was too high.	The tonometer was probably tilted downwards. Make sure that the central groove is in the horizontal position.
E 05	The contact with the eye was too “soft.”	The probe probably made contact with the eyelid.
E 06	The contact with the eye was too “hard.”	The probe made contact with the opening eyelid or calcification in the cornea.
E 07	The probe measurement signal detected by the tonometer was unusual.	The probe may have made contact with a peripheral part of the cornea or the probe was twisted or otherwise inserted incorrectly. If this error message repeats, remove and replace the probe.
E 09	Bad data.	An erroneous measurement for a reason other than those described in E01−E07.

SERVICE PROCEDURES

Replace the batteries when the <bAtt> message appears.
Change the probe base if the probe does not move smoothly.
No other service procedures can be carried out by the user. All other servicing and repairs must be carried out by the manufacturer or certified service facilities.
The device can be cleaned with a damp cloth containing disinfectant.

TECHNICAL INFORMATION

Type: TA01i.
The device conforms to CE regulations.
Dimensions: 13 – 32 mm (W) * 45 – 80 mm (H) * 230 mm (L).
Weight: 155 g (without batteries), 250 g (4 x AA batteries).
Power supply: 4 x AA batteries.
Measurement range: 7-50 mmHg, display range: 0-99 mmHg (IOP estimation beyond the measuring range).
Accuracy (95 % tolerance interval relative to manometry): ±1.2 mmHg (≤20 mmHg) and ±2.2 mmHg (>20 mmHg).
Repeatability (coefficient of variation): <8 %.
Accuracy of display: 1.
Display unit: Millimeter mercury (mmHg).
The serial number is on the back of the battery compartment cover.
There are no electrical connections from the tonometer to the patient.
The device has B-type electric shock protection.
Storage/transportation environment:
Temperature +5 to +40 °C.
Rel. humidity 10 to 80 % (without condensation).

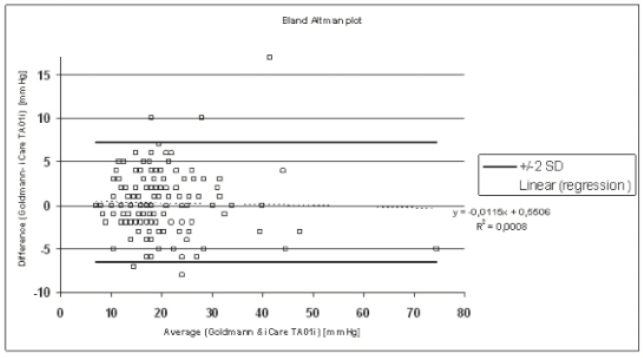
SPARE PARTS AND SUPPLIES

Single-use probes.
Probe base replacement kit.

WARNING -Indicates that important operating instructions are included in this Instruction Manual.

PERFORMANCE DATA

The performance data is obtained from a clinical study, performed according to American National Standard ANSI Z80.10-2003 and International Standard ISO 8612.2 for tonometers. The study was performed ain the Department of Ophthalmology, Helsinki University Central Hospital. In the study, 158 patients were measured. The mean paired difference and standard deviation (Goldmann-Icare) were -0.4 mmHg and 3.4 mmHg. A scattergram and Bland-Altman plot of the results is shown below.



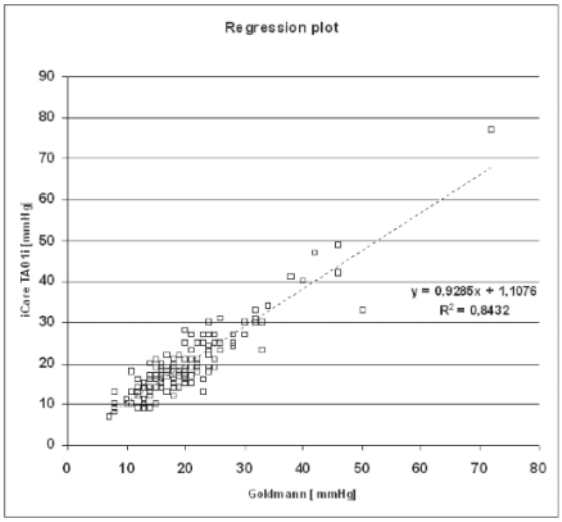
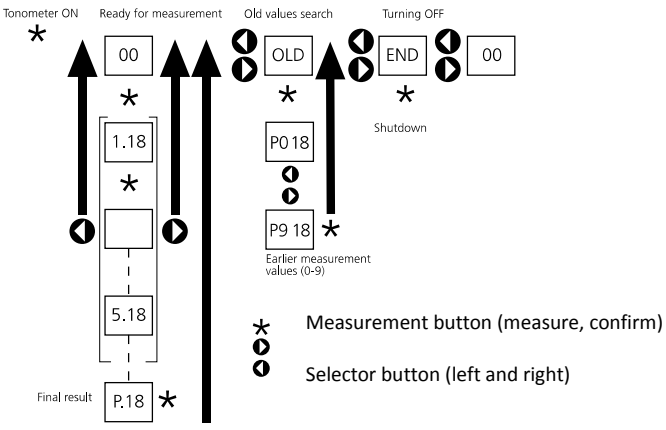


DIAGRAM OF TONOMETER FUNCTIONS



MAINTENANCE

Follow local regulations and recycling instructions regarding the disposal or recycling of the Icare tonometerand accessories.

Returning the Icare tonometer for servicing /repair

Contact Icare Finland's Technical Services Department (see www.icarefinland.com) or your local Icare representative for shipping instructions. Unless otherwise instructed by Icare Finland, there is no need to ship accessories along with the tonometer. Use a suitable carton with the appropriate packaging material to protect the device during shipment.

Return the device using any shipping method that includes proof of delivery.

Service

WARNING

The tonometer should only be opened by qualified service personnel. It contains no userserviceable parts, apart from the batteries and a probe base. The Icare tonometerrequires no routine servicing or calibration other than changing the batteries at least every 12 months or changing the probe base. If servicing is necessary, contact qualified service personnel or your local Icare representative.

Periodic Safety Checks

We recommend that the following checks be performed every 24 months.
Equipment inspection for mechanical and functional damage.
Inspection of safety labels for legibility.

Cleaning

CAUTION

Do not spray, pour or spill liquid onto the Icare® Tonometer, its accessories, connectors, switches or openings in the chassis.

When surface-cleaning and disinfecting the tonometer, follow your institution's procedures or:

The Icare tonometermay be surface-cleaned using a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water. Lightly wipe the surfaces of the tonometer.

- The probe base can be cleaned separately, outside the tonometer, by carefully injecting isopropyl alcohol through the probe base. Dry the probe base by injecting some air carefully into the probe base and heating the part gently, for example with a hairdryer.

Patents and copyrights

US Patent No 6,093,147 and patents pending. The Icare tonometer is also protected by the applicable copyright laws.

Symbols

	Attention!!! See instructions	LOT	Lot number
SN	Serial number		Manufacturing date
	Single use only	STERILE R	Sterilized using radiation
	B-type device		Keep dry