

icare
HOME



INSTRUCTION
MANUAL

FOR HEALTH CARE
PROFESSIONALS

ENGLISH

Icare® HOME (Model: TA022) INSTRUCTION MANUAL TA022-036 USA-2.0

The information in this document is subject to change without prior notice.

In a conflict situation the English version prevails.

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This device complies with:

Medical Device Directive 93/42/EEC

Canadian Medical Device Regulations

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1. SAFETY INSTRUCTIONS

WARNING!

Do not push the tonometer into the eye (the tip of the probe should be 4-8mm, or 5/32-5/16" , from the eye).

WARNING!

Keep the tonometer out of the reach of children, because the probe base, battery compartment cover and probes are so small that a child could swallow them.

WARNING!

The probe tips are for single-use only, and are packaged sterile.

WARNING!

To prevent contamination, do not touch the bare probe, do not use a probe if it touches a non-sterile surface like a table or a floor.

WARNING!

The Icare HOME Tonometer is indicated for use only under supervision of a health care professional.

WARNING!

Patients must be certified and trained for the procedures described in this manual prior to the device being prescribed for home use.

WARNING!

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

WARNING!

For cybersecurity do not connect to the USB port except when uploading patient measurement data using the Icare LINK software or when upgrading the HOME TA022 software using the Icare LINK software. Also the tonometer does not allow you to take any measurements when the USB is connected. All other traditional cybersecurity controls (anti-virus software, malware software, separate network for the device, etc.) do not apply since the device is stand alone, is not networked, and does not contain operating system software.

WARNING!

Do not change the batteries or probe base when the USB cable is connected.

WARNING!

No modification of this equipment is allowed.

 WARNING!

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

 WARNING!

Use only the original and certified probes made by the manufacturer. The probes are for single-use (one per testing session only). Each testing session is defined by one successful measurement in both eyes (or only one eye measurement if indicated). Use probes taken only from the intact, original packaging. The manufacturer cannot guarantee sterility of the probe once the seal is compromised. Re-sterilization or re-use of the probe could result in incorrect measurement values, in the breakdown of the probe, cross-contamination of bacteria or viruses, and infection of the eye. Re-sterilization or re-use will void all responsibilities and liabilities of the manufacturer concerning the safety and effectiveness of the tonometer.

 WARNING!

The probe should be replaced if it contacts or is suspected of having contacted the eyelashes or eyelid such as might occur during a blink.

 WARNING!

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

 WARNING!

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

 PRECAUTION!

- *The patient should be instructed to thoroughly wash and dry their hands with soap and a clean towel prior to handling the probe.*
- *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 who sold the tonometer to you.*
- *Use the tonometer only for measuring intraocular pressure. Any other use is improper and the manufacturer is not liable for any damage arising from improper use, or for the consequences of such use.*
- *Never open the casing of the tonometer, except for the battery compartment.*
- *Never allow the tonometer to get wet.*
- *Do not use the tonometer near flammable substances, including flammable anesthetic agents.*
- *Certain microbiological agents (for example, bacteria) can be transmitted from the forehead or cheek support. To prevent this, clean the forehead and cheek support for each new patient with disinfectant. See the chapter 'Cleaning and disinfection'.*

 **PRECAUTION!**

- *The tonometer conforms to EMC requirements (IEC 60601-1-2), but interference may occur within the tonometer if used near (<1m) a device causing high intensity electromagnetic emissions, such as a cellular phone. 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 you do not use the tonometer for a long time, remove the batteries, as they may leak.*
- *Be sure to dispose of the single-use probes properly (for example, in a bin for metal waste).*
- *Batteries, packaging materials and probe bases must be disposed of according to local regulations.*
- *Make sure you use batteries with built-in PTC protection, for example Energizer Lithium Photo 123 3V CR123A.*
- *Do not cover the eye recognition transmitters or sensor during the measurement, for example with fingers. Keep your hand, hair etc. and objects such as pillows away from the temple side of your eye, as they produce an infrared reflection that causes an error.*
- *The tonometer turns off automatically after 3 minutes if it is not used.*
- *Do not carry out any other service procedures than those described in the chapters 10-12. Leave all other service and repairs to the manufacturer or a certified service center.*
- *Update the tonometer's time to your local time. It is done automatically by performing the steps 1 and 2 under section 8. Reading the measurement data.*
- *Icare HOME tonometer is not intended for routine clinical use.*
- *As the Icare HOME is intended to acquire serial measurements of intraocular pressure over an extended period of time, individual IOP measurements are not to be considered separate from their associated IOP curves. This IOP measurement tool is an adjunct to the standard of care and does not replace the conventional methods used to diagnose and manage patients nor should it alter the follow-up schedule otherwise indicated for a particular patient.*
- *Bench testing of the Icare HOME tonometer on model eyes showed that there was no impact on probe function and performance with 30 repeated uses within a single testing session. The impact on probe function and performance when the probe is repeatedly used over 30 times is unknown.*

2. INDICATIONS FOR USE

The Icare HOME tonometer is a prescription device intended as an adjunct to the routine clinical monitoring of intraocular pressure (IOP) of adult patients.

3. CONTRAINDICATIONS

Patients with any of the following conditions should not be prescribed the HOME tonometer:

- 1) Active ocular infection including infectious conjunctivitis
- 2) Recent ocular trauma including corneal laceration or corneal/scleral perforation
- 3) Inability to demonstrate proficiency with Icare Home tonometer after training and failure to complete certification procedures. Patients for whom initial agreement between GAT and HOME measurements in the clinic is poor should not be prescribed the Icare HOME device for home use.
- 4) Disabling arthritis or limited motor coordination affecting self-handling of the Icare tonometer
- 5) Blepharospasm
- 6) Nystagmus

4. WARNING

Patients with the following conditions are generally not eligible for use of the HOME tonometer as they have the potential to introduce unsafe conditions during use or to impair measurement acquisition:

- 1) Uncorrected near visual acuity of 20/200 or worse
- 2) Only one functional eye
- 3) Poor or eccentric fixation
- 4) Hearing impairment to the extent that the individual cannot hear and converse with others without an assistive aid and/or sign language
- 5) Contact lens use
- 6) Dry eyes
- 7) Keratoconus
- 8) Microphthalmos
- 9) Buphthalmos
- 10) Cataract extraction within last 2 months

5. PRECAUTION

The safety and effectiveness of the Icare HOME tonometer has not been evaluated for patients with:

- 1) High corneal astigmatism $>3d$
- 2) History of prior incisional glaucoma surgery or corneal surgery including corneal laser surgery
- 3) Corneal scarring
- 4) Central corneal thickness greater than 0.60mm or less than 0.50mm
- 5) Known history of difficulty in obtaining Goldmann IOP measurements or any factors that might contribute to inaccurate Goldmann IOP measurements (e.g. lid squeezing or tremor)

6. INTRODUCTION

The Icare HOME tonometer is a hand-held device for self-use.

The tonometer uses the rebound method. A small and light single-use probe makes contact with the eye very briefly. The tonometer measures the deceleration of the probe and the rebound time, and calculates the IOP from these parameters.

A measurement sequence includes six measurements. The probe moves to the cornea and back during every measurement. As a result, after the six measurements the tonometer calculates the final IOP and stores it with other information in the tonometer's memory, including date, time, eye identification (right or left) and measurement quality.

The Icare HOME tonometer can record over one thousand measurement results. You can copy the recorded measurement information to a PC through a USB cable.

7. PACKAGE CONTENTS

WARNING!

Keep the tonometer out of reach of children, because the probe base, battery compartment cover and probes are so small that a child could swallow them.

PRECAUTION!

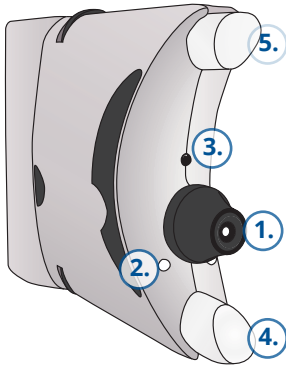
When you have opened the package, check for any external damage or faults, particularly for damage to the case. If you suspect that there is something wrong with the tonometer, contact the dealer who sold the tonometer to you.

The package contains:

- Icare HOME tonometer
- 10 sterilized single-use probes
- 2 batteries
- USB memory stick including the instruction manual for health care professionals and the Icare LINK software
- USB cable for connecting the Icare HOME tonometer to a PC with Icare LINK software
- Instructions for downloading the Icare LINK software
- Patient guide
- Support position tags
- Warranty card
- Carrying case
- Wrist strap
- Probe base cleaning container

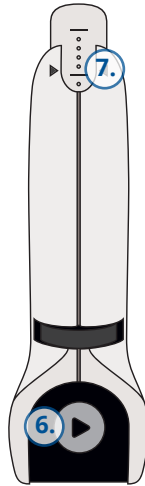
8. BEFORE YOU START

Find the main parts, buttons and indicator lights of the tonometer in the below figures.



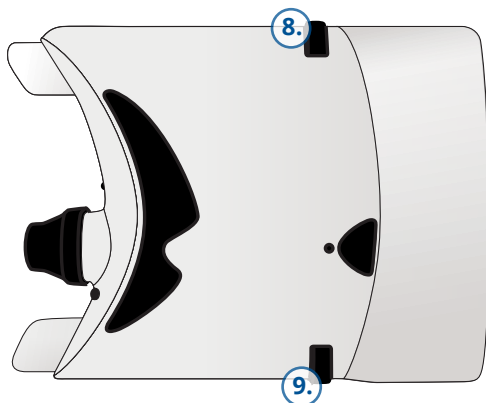
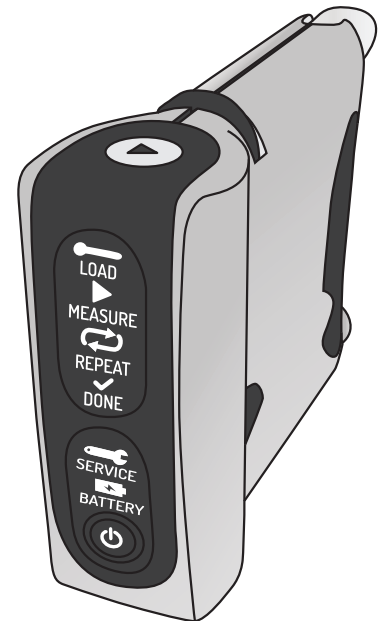
FRONT PARTS

1. Probe base incorporating indicator light
2. Eye recognition transmitter
3. Eye recognition sensor
4. Cheek support
5. Forehead support



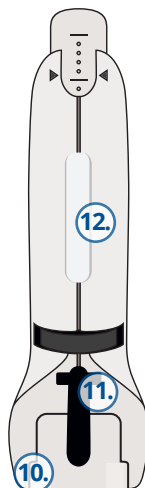
TOP PARTS

6. Measurement button
7. Forehead support position indicator



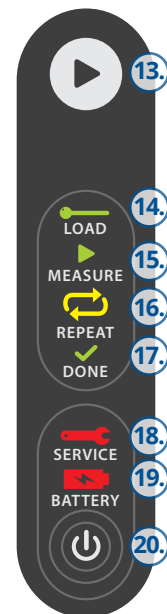
SIDE PARTS

8. Forehead support adjustment wheel
9. Cheek support adjustment wheel



BOTTOM PARTS

10. Battery cover
11. Silicone lid (USB cover)
12. Type label



BACK PANEL

13. Measurement button
14. LOAD light
15. MEASURE light
16. REPEAT light
17. DONE light
18. SERVICE light
19. BATTERY light
20. POWER button

9. SETTING UP THE TONOMETER

Setting up your Icare HOME tonometer is easy, with few steps. The following subchapters describe how you get started.

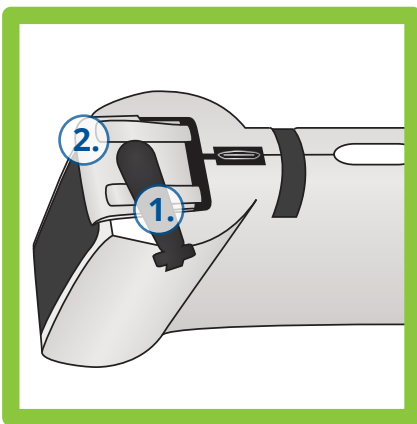
9.1 INSTALLING OR CHANGING THE BATTERY



PRECAUTION!

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

Update the tonometer's time to your local time. It is done automatically by performing the steps 1 and 2 under section 8. Reading the measurement data.



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 the figure left.

1. Silicone lid
2. Battery cover

Opening the silicone lid and battery cover



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



2 x CR123A

Inserting new batteries

9.2 TURNING THE TONOMETER ON



PRECAUTION!

The tonometer turns off automatically after 3 minutes if it is not used.

Press the power button (20) to turn the tonometer on. The lights (14-19) are turned on briefly. Following a brief pause, the Load light flashes on the back panel to remind the user to load the single-use probe into the tonometer prior to measurement.

9.3 LOADING THE PROBE

⚠ PRECAUTION!

The patient should be instructed to thoroughly wash and dry their hands with soap and a clean towel prior to handling the probe.

⚠ WARNING!

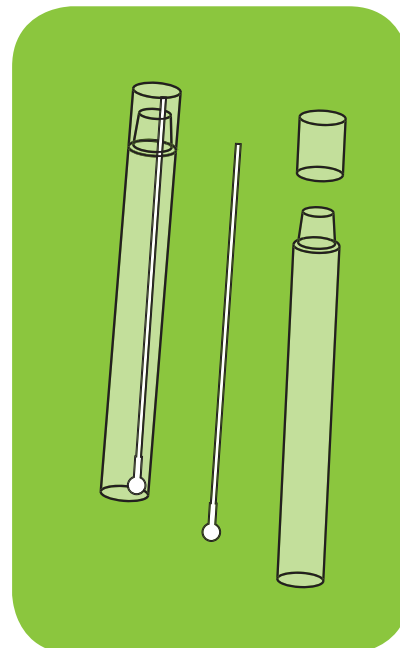
To prevent contamination, do not touch the bare probe, do not use a probe if it touches a non-sterile surface like a table or a floor.

⚠ WARNING!

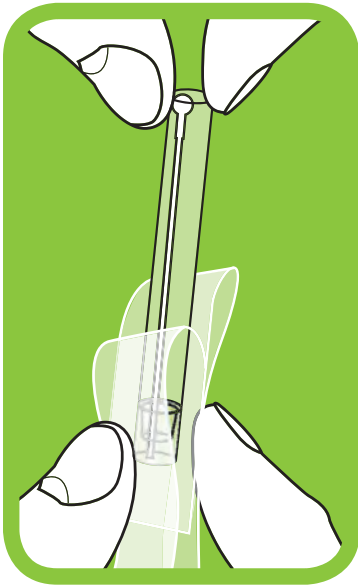
Use only the original and certified probes made by the manufacturer. The probes are for single-use (one per testing session only). Each testing session is defined by one successful measurement in both eyes (or only one eye measurement if indicated). Use probes taken only from the intact, original packaging. The manufacturer cannot guarantee sterility of the probe once the seal is compromised. Re-sterilization or re-use of the probe could result in incorrect measurement values, in the breakdown of the probe, cross-contamination of bacteria or viruses, and infection of the eye. Re-sterilization or re-use will void all responsibilities and liabilities of the manufacturer concerning the safety and effectiveness of the tonometer.

The Icare HOME tonometer uses single-use probes that are packed in a plastic tube (container) and wrapped in blister packs as shown in the figures below.

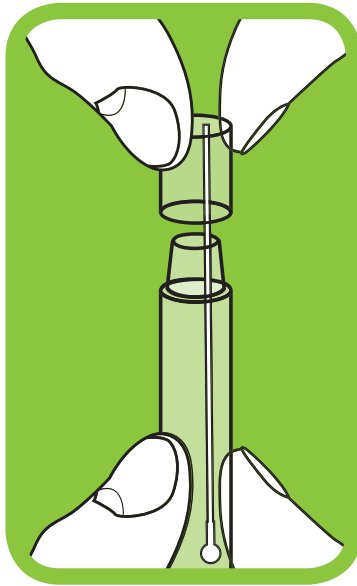
After using the tonometer to measure IOP, the user can remove the probe either by powering off the device and allowing the probe to slide out of the probe base or by pulling the probe out of the probe base. The probe can be discarded by placing the probe back in its container and disposing of it properly.



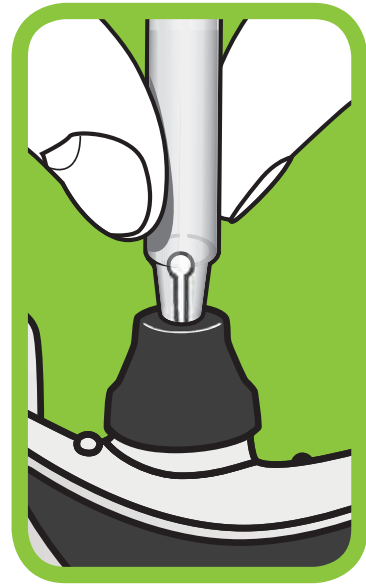
To load the probe:



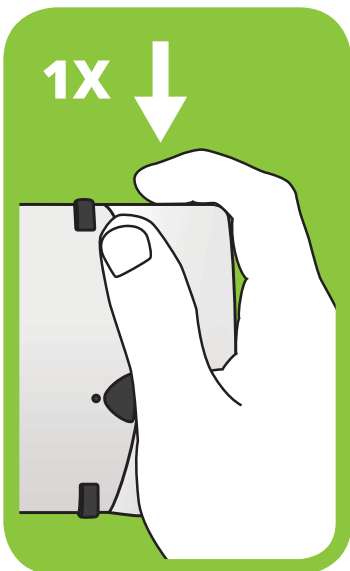
1. Unwrap the probe.



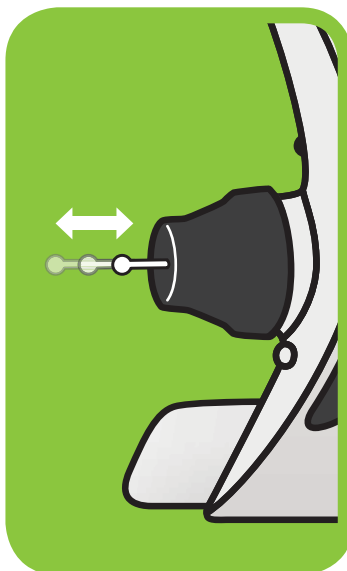
2. Remove the lid of the probe container as shown in the figure above. Point the tonometer upward.



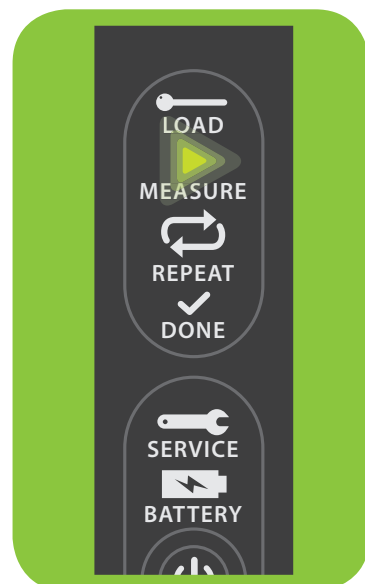
3. Drop the probe into the probe base (1) by turning the probe container upside down.



4. Press the measurement button (13) briefly (1 second) to activate the probe.



5. The probe moves rapidly back and forth.

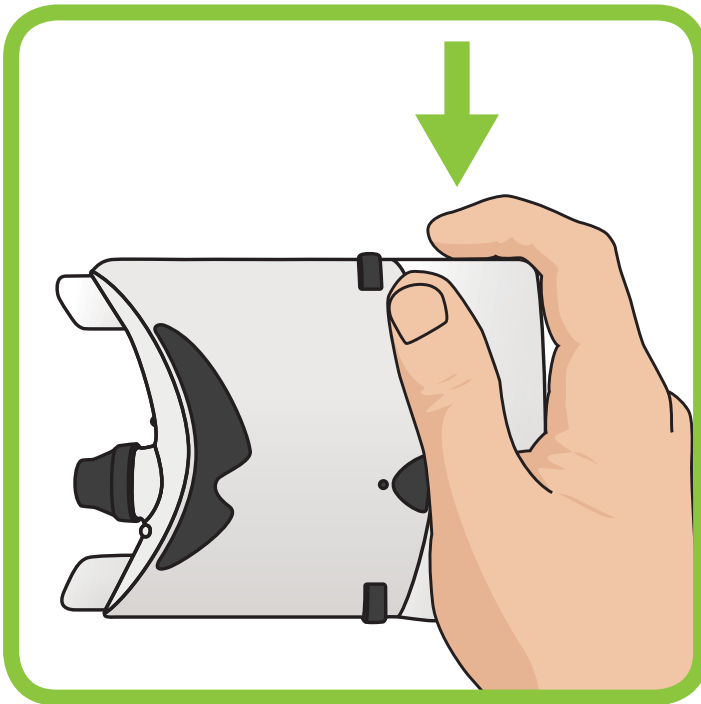


6. See that the Measure light (15) flashes. If so, the probe is loaded correctly and ready for measurement.

10. USING THE TONOMETER

10.1 CHOOSING THE MEASUREMENT MODE

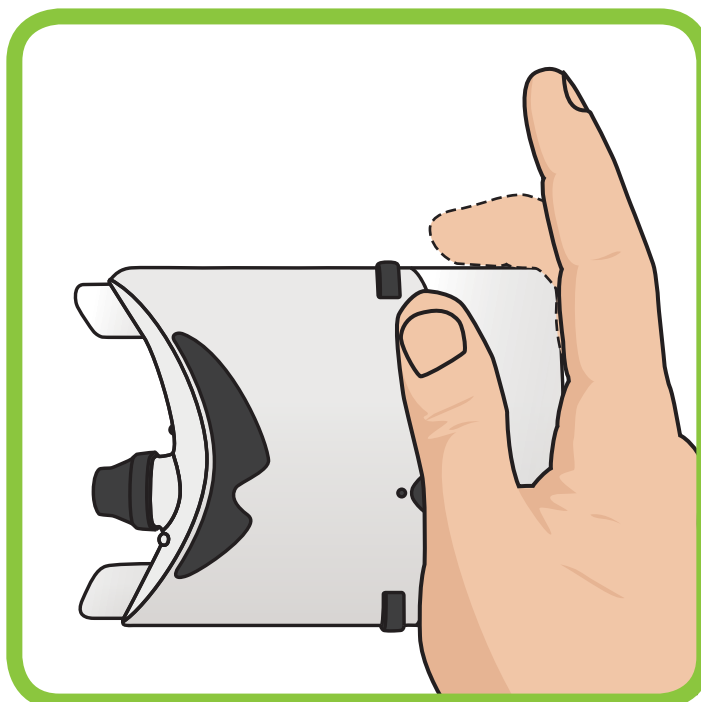
The tonometer can operate in two modes:



Series mode, press the measurement button constantly.

Series mode

The series mode is especially useful in self-tonometry. In the series mode, keeping the button pressed down (see figure left) initiates the measurement function, and the tonometer takes six rapid measurements one after the other to obtain the final IOP reading. The button must be pressed for at least 3 seconds.



Single mode, press the measurement button briefly (1 second) for each of the six measurements.

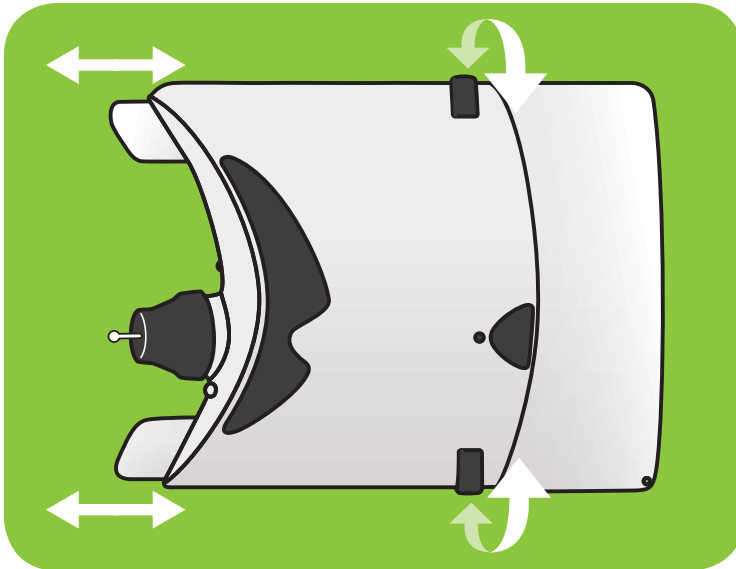
Single mode

You can use the single mode to take individual measurements one at a time. The single mode is especially useful for those patients who tend to blink heavily. Here you press the measurement button briefly (1 second) for each of the six measurements to obtain the final IOP reading (see figure left).

10.2 ADJUSTING THE MEASUREMENT POSITION

⚠ WARNING!

Do not push the tonometer into the eye (the tip of the probe should be 4-8mm, or 5/32-5/16", from the eye).

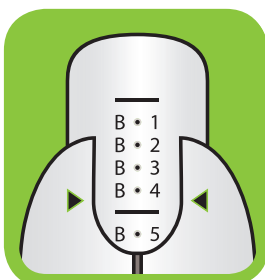
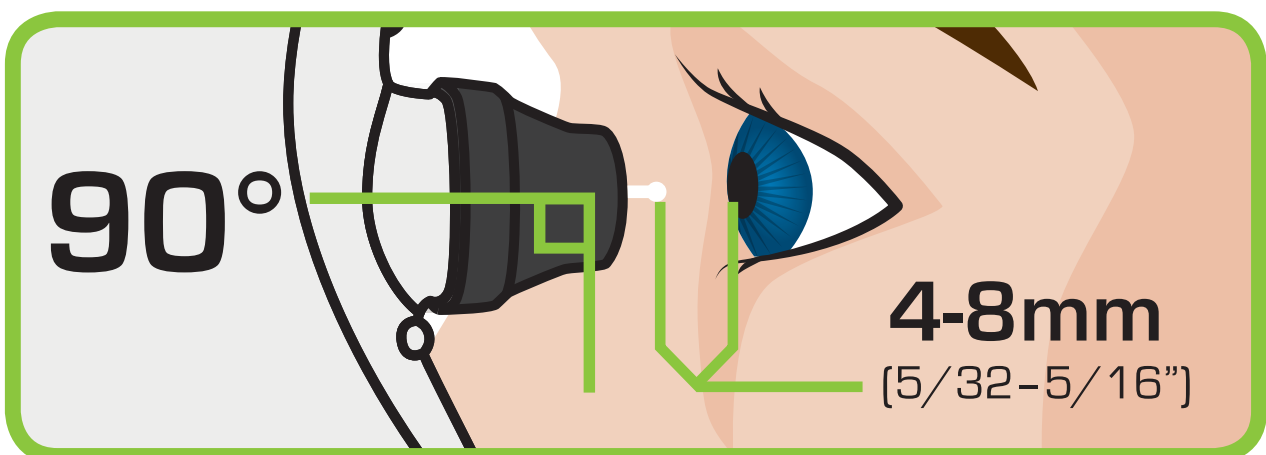


Tonometer forehead and cheek supports with adjustment wheels.

The tonometer has two adjustable supports (4-5), one for the forehead and one for the cheek, as shown in the figure left. The supports are for ensuring accurate measurement distance and alignment.

To adjust the measurement position for your patient:

1. Adjust the supports using the adjustment wheels as shown in the above figure.
2. Keep the probe horizontal and pointing perpendicularly to the center of the cornea.
3. Set the distance between the tip of the probe and the center of the cornea to be 4-8mm (5/32-5/16") as shown in the below figure.



4. Read the distance setting (forehead A•1, A•2, etc., cheek B•1, B•2, etc.) between the arrows on the scale (7) of the supports, see the figure left, and write it down on a support position tag for the patient.
5. Do the same for the other eye as well unless only one eye needs monitoring.
6. Verify that the support positions are correct each and every time the patient comes in for a clinic visit.

10.3 AUTOMATIC EYE RECOGNITION

PRECAUTION!

Do not cover the eye recognition transmitters or sensor during the measurement, for example with fingers. Keep your hand, hair etc. and objects such as pillows away from the temple side of your eye, as they produce an infrared reflection that causes an error.

The tonometer includes an automatic eye recognition system that identifies which eye, right or left, you are measuring. The system has two infrared LED transmitters just below the probe base and one infrared LED sensor above the probe base, as in the figure below. The right-hand transmitter sends invisible infrared light to the right and the left-hand transmitter to the left. The infrared light reflects from your nose to the sensor. The sensor knows from which transmitter the reflected infrared light came, and thus which eye you are measuring. The resulting eye indication is included in the data that you can transfer to a PC, as described in the section 9.



Eye recognition system components.

EYE RECOGNITION COMPONENTS

1. Left and right infrared transmitter.
2. Infrared sensor.

10.4 TAKING THE MEASUREMENTS

⚠️ WARNING!

Do not push the tonometer into the eye (the tip of the probe should be 4-8mm, or 5/32-5/16", from the eye).

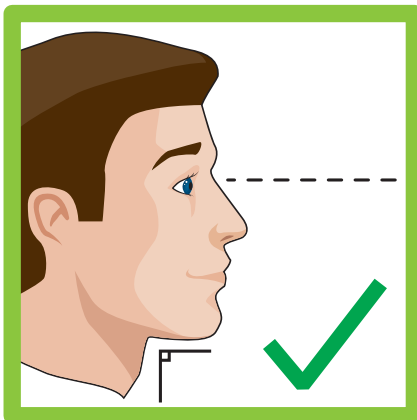
⚠️ WARNING!

The probe should be replaced if it contacts or is suspected of having contacted the eyelashes or eyelid such as might occur during a blink.

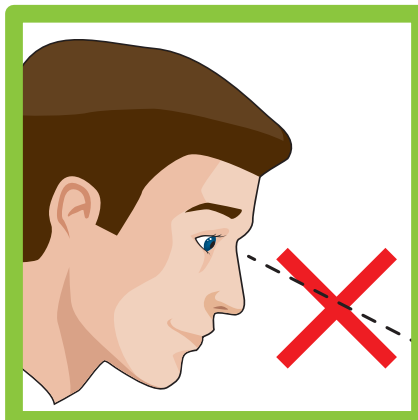
The probe will make a gentle and brief contact with the eye when you take the measurement. No topical anesthetic is needed. The recommended frequency of measurements is 3-4 daily with a maximum of 5-6.

To measure intraocular pressure:

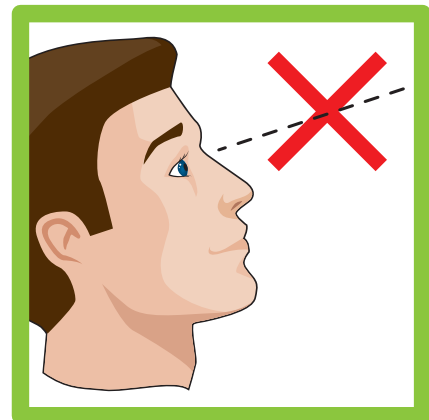
1. Check that the **Measure** light (15) still flashes on the back panel.
2. If the **Measure** light does not flash, press the **power button** (20) and wait until the Measure light illuminates again.
3. The patient should look straight ahead at a specific point while keeping eyes wide open as shown in the below figure.



Correct head and eye position.

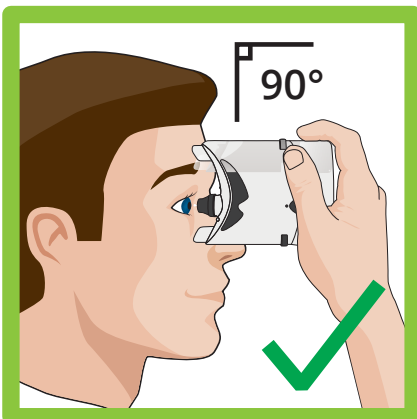


Incorrect head and eye position.

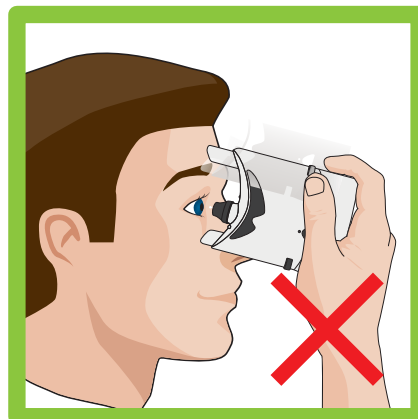


Incorrect head and eye position.

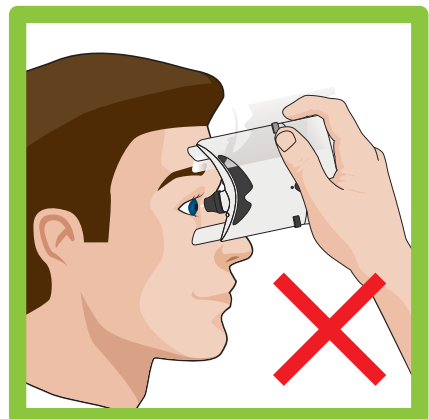
4. Bring the tonometer near the eye, the probe pointing perpendicular to the center of the cornea without a vertical or horizontal tilt. The position is correct when the probe base light is green and appears symmetrically in the center of the patient's view. See the below figures.



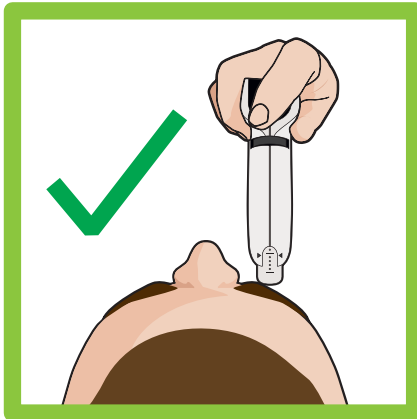
Correct measurement position.



Incorrect measurement position.



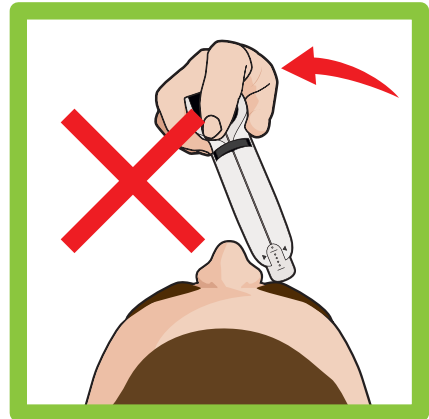
Incorrect measurement position.



Correct measurement position.



Incorrect measurement position.



Incorrect measurement position.



Correct alignment of the tonometer.

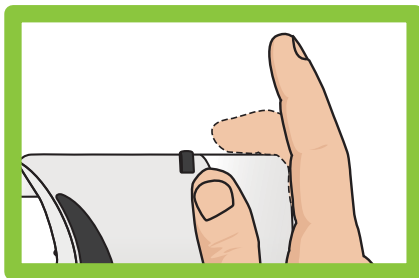


Incorrect alignment of the tonometer.



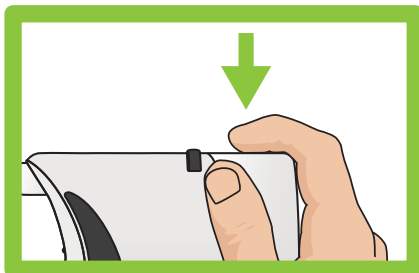
Incorrect alignment of the tonometer. Readjust so that you see only the front of the tonometer and the green light symmetrically in the center of your view.

5. Press the measurement button:



Single mode:

Press the button briefly (1 second) and you hear a short beep, repeat it to take one measurement at a time till you hear a long beep and see the Done light (17) illuminated on the back panel.



Series mode:

Keep the measurement button down to obtain the sequence of six measurements till you hear a long beep and see the Done light illuminated on the back panel. The button must be pressed for at least 3 seconds.

6. If both eyes are measured repeat steps 1-5 using your other eye.
7. If an error occurs, press the Measure button briefly (1 second) and continue the measurement. See also section 9 Trouble shooting.
8. Press the power button for three seconds to turn the tonometer off. The probe slides out of the probe base.
9. Remove and discard the used probe properly.

11. READING THE MEASUREMENT DATA

WARNING!

For cybersecurity do not connect to the USB port except when uploading patient measurement data using the Icare LINK software or when upgrading the HOME TA022 software using the Icare LINK software. Also the tonometer does not allow you to take any measurements when the USB is connected. All other traditional cybersecurity controls (anti-virus software, malware software, separate network for the device, etc.) do not apply since the device is stand alone, is not networked, and does not contain operating system software.

The tonometer stores information on every complete measurement sequence of six measurements. The stored information includes the calculated final eye pressure reading in mmHg, time and date of the measurement, identification of the eye (right or left) and the quality level of the measurement.

Uploading is easy:



1. Start Icare LINK software in your PC.



2. Connect the tonometer to the PC using the USB cable. The Load and Measure lights will flash. If no lights flash or the Service and Battery lights flash, reconnect the USB cable.
3. The internal clock of the tonometer is automatically updated to the PC's time by the Icare LINK software at this point.

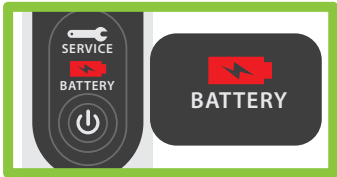


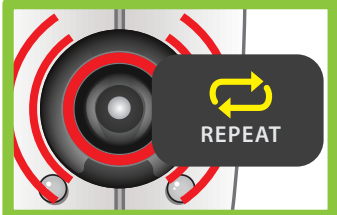



4. Copy the data to a selected patient in the Icare LINK software.

More information about **Icare LINK software**
<http://www.icaretonometer.com/products/icare-link/>

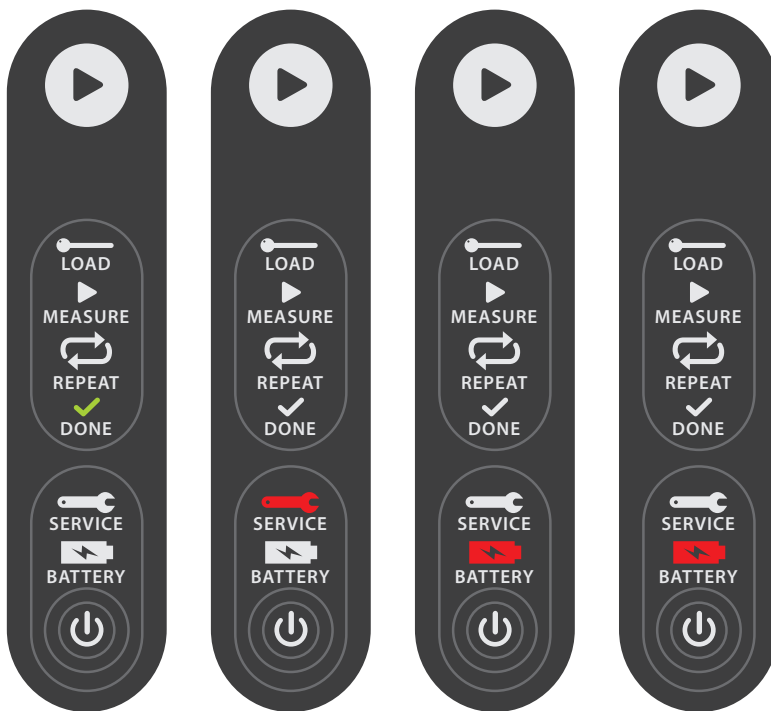
12. TROUBLESHOOTING

The tonometer automatically monitors and controls the measurement position and speed of the probe during the measurements, and indicates errors with sounds and lights. The following table instructs you in error situations and explains what the different lights and sounds mean. The indicator lights are also presented in the figure after the table below.

Error light	Error sound	Reason	Action
Battery 	No.	Battery is soon empty.	Prepare to change batteries.
Battery light is flashing	No.	Battery is empty.	Change batteries.
Probe base light is solid red. 	No.	Too much vertical tilt.	Press the measurement button again to clear the error message. Position the tonometer horizontally so that the probe base light is green.
Probe base light is flashing red and Measure light turns off. 	Two long beeps.	a) Probe is too far from or too near the eye. b) Probe movement was not perpendicular to the cornea.	Press the measurement button again to clear the error message. a) Set the correct distance 4-8mm (5/32-5/16") between the probe tip and the center of the cornea. b) Set the probe perpendicular to the center of the cornea.
Repeat light is flashing and Probe base light is flashing red. 	Two long error beeps.	a) Too much IOP deviation during the measurement, because the user did not keep the tonometer stable. b) Eye was not recognized.	Press the measurement button again to clear the error message. a) Repeat the measurement b) Do not move the tonometer during the measurements, remove your hand or fingers from the infrared transmitters and sensor, move the patient's hair away from his/her temple side of the eye. If the eye still does not get recognized contact the seller to arrange sending the device for service.
Service light is flashing and Probe base is flashing red. 	Two long beeps.	Incorrect or dirty probe or probe base.	Change the probe, clean or change the probe base or contact the seller to arrange sending the device for service.



OFF	INITIALIZE	LOAD PROBE	MEASURE	REPEAT
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DONE	SERVICE	LOW BATTERY	EMPTY BATTERY
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13. REPLACING THE PROBE BASE

Replace the probe base every twelve months. Replace or clean the probe base if the Service light flashes.

Instructions for replacing the probe base:

- Turn off the tonometer.
- Unscrew the probe base collar and put it in a safe place.
- Remove the probe base by tilting the tonometer downwards and use your fingers to 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.

14. CLEANING THE PROBE BASE

You can reuse the probe base after careful cleaning. Clean the probe base every six months. Clean or replace the probe base if the Service light flashes.

Instructions for cleaning the probe base:

- Fill the probe base cleaning container or other clean container with 70-100% isopropyl alcohol.
- Turn the power off.
- Unscrew the probe base collar.
- Invert the probe base over the container, drop in the probe base into the container and let soak for 5-30 minutes.
- Remove the probe base from alcohol.
- Dry the probe base by blowing clean canned or compressed air into the hole in the probe base. This will additionally remove possible residual dirt.
- Insert the probe base into the tonometer.
- Screw the collar in, to lock the probe base.

15. CLEANING AND DISINFECTION

You must clean the forehead and cheek supports for each new patient. Use a wipe dampened with a 70-100% isopropyl alcohol solution. Do not immerse the tonometer in water or other liquid. The tonometer must not be immersed or cleaned using too much water.

PRECAUTION!

Do not carry out any other service procedures than those described in the chapters 10-12. Leave all other service and repairs to the manufacturer or a certified service center.

16. ACCESSORIES

Part number	Product Description	Weight	Dimensions
540	Probe base	4g	7 mm x 38 mm
TA022-001	Probe base collar	2g	20 mm x 15 mm
560	Wrist strap	3g	270 mm x 10 mm x 10 mm
TA022-044	Carrying case	210g	270 mm x 135 mm x 60 mm
7179	Battery cover	3g	26 mm x 23 mm x 7 mm
TA022-035	Patient guide	33g	210 mm x 90 mm x 2 mm
571	Battery 3 V, CR123A	17g	17 mm x 35 mm
TA022-037	Support position tags	40g	70 mm x 41 mm x 13 mm
575	USB cable	23g	1m
113	Box of 50 probes	55,14g	8,2 x 19,5 x 3,5 cm

17. LIFETIME

The expected service life of the device is 5 years. The maintenance described in the chapters 10-12 is required during the the expected service life. The shelf life of the probes in their intact original packaging is 3 years.

We also recommend that you inspect the device for mechanical and functional damage and the safety labels for legibility annually/every 12 months.

18. TECHNICAL AND PERFORMANCE DATA

Type:TA022

Dimensions: approximately 11cm x 8cm x 3cm.

Weight: approximately 150g.

Power supply: 2 x CR123 non-rechargeable batteries (make sure you use batteries with built-in PTC protection, for example Energizer Lithium Photo 123 3V CR123A).

Measurement range: 5-50 mmHg.

Accuracy and precision (bench study): Icare performed testing to evaluate the accuracy and precision of the Home tonometer in its intended measuring range in accordance with ANSI Z80.10 "Ophthalmic Instruments – Tonometers". The testing was performed by measuring a manometrically controlled test eye. The pressure in the test eye was adjusted by a hydrostatic head and controlled manometrically by an attached calibrated pressure sensor as reference. The measurements were taken using the Icare HOME and additionally verified by a reference tonometer.

Differences between Icare HOME and actual pressure in model eyes were observed to be within 1 mmHg in the pressure range 10-30 mmHg. At the extremes of the measuring range, the differences were observed to be 2 mmHg at the 5 mmHg level and 2-3 mmHg at the 40 and 50 mmHg levels. Similarly, the precision of the device was observed to be better within the pressure range 10-50 mmHg (i.e. CV of 0.0% - 5.5%) as compared to the 5 mmHg pressure level (i.e. CV of 8.1%).

The serial number is located on the inside of the battery compartment cover.
The lot number of the probes is on the side of the probe box and the blister packing.
There are no electrical connections from the tonometer to the patient.
The tonometer has BF-type electric shock protection.

Operation environment:

Temperature: +10 °C to +35 °C
Relative humidity: 30% to 90%
Atmospheric pressure: 800hPa – 1060hPa

Storage environment:

Temperature: -10 °C to +55 °C
Relative humidity: 10% to 95%
Atmospheric pressure: 700hPa – 1060hPa

Transport environment:

Temperature: -40 °C to +70 °C
Relative humidity: 10% to 95%
Atmospheric pressure: 500hPa – 1060hPa

Environmental restrictions for professional use include:

- Medivac vehicles or similar where vibration or noise levels are so high that the user cannot hear error signals.

Environmental restrictions for lay operators (patients):

- Environments where noise is so high that the user cannot hear the error signals.

Mode of operation: continuous

18.1 CLINICAL PERFORMANCE DATA

Summary: A prospective, observational, multi-center clinical trial was conducted to assess the safety of the Icare HOME tonometer and to determine the measurement agreement between self-measured IOP with the Icare HOME tonometer and clinic-measured IOP by Goldmann applanation tonometry (GAT) and by the Icare TA01i tonometer, as well as repeatability (variability between measurements taken by the same operator and the same device) of the Icare HOME tonometer compared to that of the other two methods. Performance goals for agreement as found in ANSI Z80.10-2009 were used. 460 participants age 40 or older were enrolled across five US sites and 385 eyes of 385 participants found to be eligible. Data from 376 eyes were included in the effectiveness analyses. All participants must have had a pre-existing diagnosis of glaucoma or 'glaucoma suspect.' Participants were trained by study staff as part of the certification procedure on how to use the Icare HOME tonometer. After a 10-minute break, the participants were asked to make three self-measurements without any direct supervision or interaction. Study staff then acquired three measurements on the Icare TA01i tonometer, then an eye care professional took two GAT measurements (a third if the first two were not within 2 mm Hg of each other). Other testing procedures included auto-refraction, auto-keratometry, discomfort assessment using the Visual Analog Scale (VAS) questionnaire, assessment of fluorescein staining of the cornea and Oxford scheme grading of any corneal epithelial defects, and corneal pachymetry.

The mean difference and standard deviation (Icare HOME - GAT) were -0.53 mmHg and 2.43 mmHg, respectively. All ANSI performance goals were met as less than 5% of measurements fell outside ± 5 mmHg at each pressure range and less than 1% fell outside ± 7.5 mmHg at each pressure range. The HOME CV% was comparable for the low and medium IOP range

(~10% for each bin) and smaller for the high IOP range (~7.5%). No adverse events (including corneal abrasions) were recorded in this study population of 383 eyes. Only certified users were able to proceed to self-testing. A failure rate of 10.7% of the training/certification was found in a large clinical study. Self-testing was limited to a single session 10 minutes after certification.

Methods: This study aimed to determine the agreement between the self-measured IOP (full simulated home use by the patient) using the Icare HOME tonometer and the clinic-measured IOP using GAT, as well as between the Icare HOME and the FDA-cleared Icare TA01i tonometer. The study further aimed to assess the precision of the Icare Home device compared to GAT and the Icare TA01i tonometer, and to record and analyze individual patient complaints as well as clinical observations of corneal epithelial defects or other adverse events (AEs) when using the Icare HOME self-tonometer. The study was designed according to ANSI Z80.10 "Ophthalmic Instruments – Tonometers". Only one eye from each subject was enrolled into the study. Where both eyes were eligible, the eye with higher pressure on the last two clinic visits was used. If the pressure was equal in both eyes, then a random assignment of the right or left eye was used.

Results: Subjects were recruited at five study sites. 10.7% (49/460) of subjects were unable to demonstrate proficiency with the Icare Home tonometer after training and failed to complete the certification procedures described in the protocol. The reasons for failing certification were: three Home readings differed by > 7mmHg (0.7%), the first Home reading and the GAT measurement differed by > 5mmHg (6.3%), subject requested to stop, (0.7%), and subject unable to use the device (3.0%). As a result, the Icare HOME labeling includes the same training and certification procedures described in the protocol for the patient to be eligible for home-use of the tonometer. Among the 383 subjects who completed the series of validation measurements, 376 (98.2%) were included in the effectiveness analyses. Seven subjects were excluded from the effectiveness analysis per the pre-specified reasons in the study protocol (i.e. less than three Home IOP measurements being acquired and the series of GAT measurements demonstrated too much variability).

Inclusion criteria were as follows:

Patients with pre-existing diagnosis of "glaucoma" or "glaucoma suspect" in the study eye(s):

- Glaucoma suspects will include patients being followed for elevated IOP, for risk factors for developing glaucoma, or for possible optic nerve damage.
- Glaucoma patients will have confirmed optic nerve damage with visual field loss consistent with glaucomatous optic neuropathy.

Exclusion criteria were as follows:

- Age < 40 years
- Uncorrected Near Visual Acuity (UCNVA) of 20/200 (binocular)
- Subjects with only one functional eye
- Subjects having poor or eccentric fixation in the study eye
- Hearing impaired to the extent that the individual cannot hear and converse with others without an assistive aid and/or sign language

- High corneal astigmatism >3D in the study eye(s) based on their current refractive prescription if available. Those without a prescription will undergo auto-refraction to obtain Keratometry readings.
- Disabling arthritis or limited motor coordination limiting self-handling of the Icare Home tonometer
- Lack of comprehension or willingness to use the tonometer as instructed
- Corneal scarring
- History of prior incisional glaucoma surgery or corneal surgery, including corneal laser surgery in the study eye
- Microphthalmos
- Buphthalmos
- Contact Lens Use
- Symptoms of Dry Eye Syndrome and signs of dry eye on examination of cornea
- Known history of difficulty in obtaining Goldmann IOP measurements or any factors that might contribute to inaccurate Goldmann IOP measurements (e.g. lid squeezing or tremor)
- Nystagmus
- Keratoconus
- Any other corneal or conjunctival pathology or infection
- Central corneal thickness greater than 0.60 mm or less than 0.50 mm in the study eye
- Inability to demonstrate proficiency with Icare Home tonometer after training and failure to complete certification procedures described in the attachment to this protocol
- Cataract Extraction within last 2 months in study eye

Table 1 provides demographics of the completed eligible subjects and distribution of intraocular pressures.

Table 1. Demographics of the completed eligible subjects and distribution of IOP.

Demographics		Overall
Age	N	383
	Mean (SD)	66.1 (12.6)
	Min, Max	35, 95
Gender	Male	171 (44.6%)
	Female	212 (55.4%)
Race	Asian Indian	2 (0.5%)
	Black/African American	70 (18.3%)
	Black/African American, American, American Indian or Alaska Native	1 (0.3%)
	Black/African American, White	1 (0.3%)
	Chinese	15 (3.9%)
	Chinese, Korean	1 (0.3%)
	Filipino	8 (2.1%)
	Filipino, Japanese	1 (0.3%)
	Japanese	157 (41.0%)
	Korean	9 (2.3%)
	Native Hawaiian	1 (0.3%)
	Other Asian	5 (1.3%)
	Vietnamese	1 (0.3%)
	White	108 (28.2%)
Refused	3 (0.8%)	

Demographics		Overall
	Not Spanish/Hispanic/Latino	355 (92.7%)
	Mexican, Mexican Am., Chicano	16 (4.2%)
	Puerto Rican	2 (0.5%)
	Other Spanish/Hispanic/Latino	10 (2.6%)
Handedness	Right	355 (92.7%)
	Left	23 (6.0%)
	Ambidextrous	5 (1.3%)
Study Eye	OD (Right)	206 (53.8%)
	OS (Left)	177 (46.2%)
IOP Group	≤ 16 mmHg	146 (38.1%)
	> 16 to <23 mmHg	169 (44.1%)
	≥ 23 mmHg	68 (17.8%)

% = Count ÷ N × 100. 9 eyes had IOP ≥ 30 mmHg.

Table 2 provides descriptive statistics for the IOP measurements from the Icare Home, GAT, and TA01i.

Table 2. Descriptive Statistics of IOP Measurements (Effectiveness Analysis Cohort)

Device	Statistics	≤ 16 mmHg	> 16 to <23 mmHg	≥ 23 mmHg	Overall
Home First Measurement	N	143	167	66	376
	Mean	12.44	18.26	26.18	17.44
	SD	3.18	2.91	5.52	6.01
	Median	12.00	18.00	25.00	17.00
	IQR	5.00	4.00	5.00	6.50
	Minimum	3.00	11.00	20.00	3.00
GAT Mean/Median Measurement	Maximum	20.00	27.00	51.00	51.00
	N	143	167	66	376
	Mean	12.86	18.99	26.41	17.96
	SD	2.17	1.78	4.86	5.50
	Median	13.00	18.50	24.50	17.50
	IQR	3.00	3.00	3.00	7.00
GAT First Measurement	Minimum	5.00	16.50	23.00	5.00
	Maximum	16.00	22.50	53.00	53.00
	N	143	167	66	376
	Mean	13.29	18.31	24.71	17.53
	SD	2.60	2.84	5.10	5.18
	Median	13.00	18.00	23.00	17.00
TA01i Mean/Median Measurement	IQR	3.00	5.00	5.00	7.00
	Minimum	5.00	11.00	18.00	5.00
	Maximum	20.00	25.00	50.00	50.00
	N	143	167	66	376
	Mean	12.93	19.14	26.53	18.07
	SD	2.36	1.77	4.92	5.56
TA01i First Measurement	Median	13.00	19.00	25.00	18.00
	IQR	4.00	3.00	3.00	7.00
	Minimum	6.00	16.00	22.00	6.00
	Maximum	20.00	23.00	53.00	53.00
	N	143	167	66	376
	Mean	13.27	18.11	24.80	17.44
TA01i First Measurement	SD	2.64	2.97	5.58	5.32
	Median	13.00	17.00	23.00	17.00
	IQR	3.00	4.00	5.00	7.00
	Minimum	6.00	12.00	17.00	6.00
	Maximum	20.00	25.00	53.00	53.00

Mean/Median: the median was used if the eye had three measurements. Otherwise, the mean was used if the eye had two measurements.

Table 3 provides the limits of agreement between the HOME tonometer and the two reference tonometers. All ANSI performance goals were met as less than 5% of measurements fell outside ± 5 mmHg at each pressure range and less than 1% fell outside ± 7.5 mmHg at each pressure range.

Table 3. Limits of Agreement between Home and Reference Effectiveness Analysis Cohort.

Group	N	Home	Reference	Difference	95% CI for Mean	95% LOA for Mean	Outside ± 5 mmHg	Outside ± 7.5 mmHg
		Mean (SD)	Mean (SD)	Mean (SD)	Difference	Difference	n (%)	n (%)
Reference: GAT (Mean/Median Measurement)								
≤ 16 mmHg	143	12.44 (3.18)	12.86 (2.17)	-0.42 (2.54)	-0.84, -0.00	-5.50, 4.65	4 (2.8%)	1 (0.7%)
> 16 to <23 mmHg	167	18.26 (2.91)	18.99 (1.78)	-0.73 (2.36)	-1.09, -0.37	-5.45, 3.99	7 (4.2%)	0 (0.0%)
≥ 23 mmHg	66	26.18 (5.52)	26.41 (4.86)	-0.23 (2.39)	-0.81, 0.36	-5.00, 4.55	1 (1.5%)	0 (0.0%)
Overall	376	17.44 (6.01)	17.96 (5.50)	-0.53 (2.43)	-0.77, -0.28	-5.39, 4.34	12 (3.2%)	1 (0.3%)
Reference: GAT (First Measurement)								
≤ 16 mmHg	143	12.44 (3.18)	12.93 (2.36)	-0.49 (2.55)	-0.91, -0.07	-5.59, 4.61		
> 16 to <23 mmHg	167	18.26 (2.91)	19.14 (1.77)	-0.87 (2.46)	-1.25, -0.50	-5.80, 4.06		
≥ 23 mmHg	66	26.18 (5.52)	26.53 (4.92)	-0.35 (2.41)	-0.94, 0.25	-5.18, 4.48		
Overall	376	17.44 (6.01)	18.07 (5.56)	-0.64 (2.49)	-0.89, -0.38	-5.62, 4.35		
Reference: TA011 (Mean/Median Measurement)								
≤ 16 mmHg	143	12.44 (3.18)	13.29 (2.60)	-0.85 (2.60)	-1.28, -0.42	-6.06, 4.35		
> 16 to <23 mmHg	167	18.26 (2.91)	18.31 (2.84)	-0.05 (2.56)	-0.44, 0.34	-5.16, 5.07		
≥ 23 mmHg	66	26.18 (5.52)	24.71 (5.10)	1.47 (3.07)	0.72, 2.22	-4.67, 7.61		
Overall	376	17.44 (6.01)	17.53 (5.18)	-0.09 (2.78)	-0.37, 0.19	-5.65, 5.48		
Reference: TA011 (First Measurement)								
≤ 16 mmHg	143	12.44 (3.18)	13.27 (2.64)	-0.83 (2.64)	-1.26, -0.39	-6.10, 4.45		
> 16 to <23 mmHg	167	18.26 (2.91)	18.11 (2.97)	0.16 (2.65)	-0.25, 0.56	-5.14, 5.45		
≥ 23 mmHg	66	26.18 (5.52)	24.80 (5.58)	1.38 (3.30)	0.57, 2.19	-5.22, 7.98		
Overall	376	17.44 (6.01)	17.44 (5.32)	-0.00 (2.87)	-0.29, 0.29	-5.74, 5.73		

N is the number of eyes with measurements from both devices.

Difference = HOME - Reference. 95% confidence interval (CI) for mean difference is based on t-distribution.

95% limits of agreement (LOA) = mean difference ± 2 difference SD.

% = $(n / N) \times 100$.

The first HOME IOP measurement of each study eye was used in the analysis.

Mean/Median: the median was used if the eye had three measurements. Otherwise, the mean was used if the eye had two measurements.

Table 4 provides the limits of agreement between Icare HOME and GAT by central corneal thickness. Icare HOME slightly underestimates IOP compared to GAT over the corneal thickness range 500-600 μm .

Table 4. Limits of Agreement between HOME and GAT by Central Corneal Thickness (CCT) Effective Analysis

CCT Group	N	Home	GAT	Difference	95% CI for Mean Difference	95% LOA for Mean Difference	Outside ± 5 mmHg	Outside ± 7.5 mmHg
		Mean (SD)	Mean (SD)	Mean (SD)			n (%)	n (%)
500-520	94	17.43 (5.70)	18.01 (5.28)	-0.59 (2.46)	-1.09, -0.08	-5.50, 4.33	3 (3.2%)	0 (0.0%)
521-540	100	16.52 (6.50)	16.87 (5.99)	-0.35 (2.03)	-0.75, 0.06	-4.40, 3.71	1 (1.0%)	0 (0.0%)
541-560	95	17.98 (6.55)	18.28 (5.93)	-0.30 (2.59)	-0.83, 0.23	-5.47, 4.87	3 (3.2%)	0 (0.0%)
561-580	57	17.70 (5.53)	18.61 (4.72)	-0.91 (2.86)	-1.67, -0.15	-6.64, 4.81	4 (7.0%)	1 (1.8%)
581-600	30	18.33 (4.03)	19.25 (3.87)	-0.92 (2.22)	-1.75, -0.09	-5.36, 3.53	1 (3.3%)	0 (0.0%)
Overall	376	17.44 (6.01)	17.96 (5.50)	-0.53 (2.43)	-0.77, -0.28	-5.39, 4.34	12 (3.2%)	1 (0.3%)

N is the number of eyes with measurements from both devices. Difference = HOME - Reference. 95% confidence interval (CI) for mean difference is based on t-distribution. 95% limits of agreement (LOA) = mean difference $\pm 2 \times$ difference SD. % = $n \div N \times 100$. The first HOME IOP measurement of each study eye was used in the analysis. The Mean/Median of GAT was used in the analysis: the median was used if the eye had three measurements. Otherwise, the mean was used if the eye had two measurements.

Precision: Table 5 provides the repeatability analyses for all measurements in the effectiveness analysis cohort. The HOME CV% was comparable for the low and medium IOP range ($\sim 10\%$ for each bin) and smaller for the high IOP range ($\sim 7.5\%$).

Table 5. Repeatability - All Measurements of Effectiveness Analysis Cohort

Group	Number of Subjects	Mean	Repeatability		
			SD	Limit	CV%
HOME					
≤ 16 mmHg	143	12.7	1.6	3.6	10.07
> 16 to < 23 mmHg	167	18.4	3.7	5.4	10.44
≥ 23 mmHg	66	26.7	4.1	5.7	7.61
Overall	376	17.7	3.0	4.8	9.76
GAT					
≤ 16 mmHg	143	12.9	0.8	2.5	6.97
> 16 to < 23 mmHg	167	19.0	0.7	2.4	4.46
≥ 23 mmHg	66	26.4	2.6	4.5	6.07
Overall	376	18.0	0.9	2.6	5.18
TA01i					
≤ 16 mmHg	143	13.3	0.9	2.6	7.08
> 16 to < 23 mmHg	167	18.3	1.4	3.3	6.37
≥ 23 mmHg	66	24.9	2.1	4.1	5.87
Overall	376	17.6	1.3	3.2	6.53














All statistics are estimated from a random-effect model with study eye and error as the random effect. Mean = Intercept of the ANOVA model. Repeatability SD = Square root of the residual variance. Repeatability limit = $2.8 \times$ Repeatability SD.

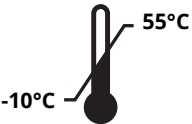
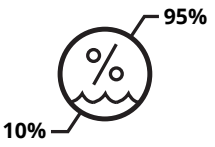
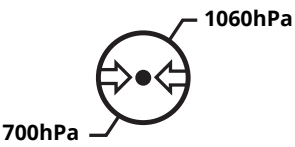
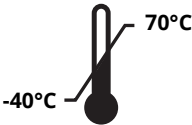
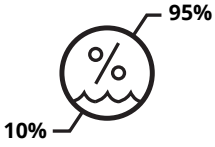
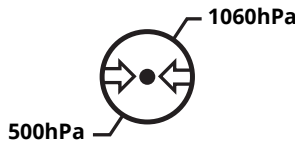
Safety: No adverse events (including corneal abrasions) were recorded in this study population of 383 eyes.

Anterior corneal epithelial grading was performed at baseline and after each attempt to measure IOP using the Oxford Scheme (a scale from 0-5) illustrated in the study protocol. It should be noted that these findings represent a “worst case scenario” as during the study visit subjects underwent more HOME measurements in a short period of time compared to what would be experienced by patients in real world use of the device. Nonetheless, under these study conditions, only 5% of eyes experienced an increase in staining after certification compared to baseline and only one eye (0.3%) experienced an increase of two grades or more which is generally considered a clinically significant change due to variability in the slit lamp grading scales. After the series of three HOME measurements (bringing the total of HOME measurements to four plus the one GAT certification measurement), the number of eyes experiencing an increase in staining increased to 11.3%; however, only five (1.3%) eyes experienced a clinically significant increase in staining. Furthermore, it should be noted that GAT induced an increase of two grades or more in two study eyes which is not unexpected. After all HOME measurements had been taken, no subject experienced an increase of three grades or more in staining compared to baseline.

Before certification, after certification, and after the series of HOME validation measurements, subjects were asked to rate eye discomfort by placing a vertical mark on the VAS horizontal line to indicate the level of eye discomfort. 0% corresponds to “no discomfort” and 100% corresponds to “maximal discomfort”. There was essentially no change in discomfort following the certification procedures (which consisted of three HOME measurements and one GAT measurement) and the series of three HOME validation measurements. The median change from baseline was zero and the maximum increase was only 23 units on the 100 point VAS scale.

19. 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)
	Manufacturer		
Rx Only	Federal law (U.S.) restricts this device to sale by or on the order of a physician.	IP22	Protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water.
Class 1 LED product	This product meets the power requirements for a Class 1 LED product to IEC/EN 60825-1 (2001) under normal operating conditions and those of single fault failure.		

			Storage environment
			Transport environment
Temperature limits	Humidity limits	Atmospheric pressure limits	

20. ELECTROMAGNETIC DECLARATION

WARNING!

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.


WARNING!


Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Icare HOME is class B equipment and needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided below.

Guidance and manufacturer's declaration IEC 60601-1-2: Edition 4.0; 2014-02 - Electromagnetic emissions		
Icare HOME (TA022) is intended for use in a home healthcare environment with electromagnetic characteristics specified below. The user of the Icare HOME (TA022) should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	Icare HOME (TA022) is battery operated and uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B	Icare HOME (TA022) is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	Power level of Icare HOME (TA022) is below standard requirement, batteries are not rechargeable
Voltage fluctuations flickering emissions IEC 61000-3-3	Not applicable	Icare HOME (TA022) batteries are not rechargeable

Guidance and manufacturer's declaration IEC 60601-1-2: Edition 4.0; 2014-02 - Electromagnetic immunity			
Icare HOME (TA022) is intended for use in a home healthcare environment with electromagnetic characteristics specified below. The customers or users of Icare HOME (TA022) should assure that it is used in such environment			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2kV, ±4kV, ±8kV, ±15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast Transients / burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	Not applicable	Icare HOME (TA022) tonometer is not operational when connected to an external computer, Icare HOME (TA022) batteries are not rechargeable
Surge IEC 61000-4-5	±1 kV for line(s) to line(s) ±2 kV for line(s) to earth	Not applicable	Icare HOME (TA022) tonometer is not operational when connected to an external computer, Icare HOME (TA022) batteries are not rechargeable
Voltage dips, short interruption and voltage variations on power supply lines IEC 61000-4-11	0 % UT for 0.5 cycle (1 phase) 0 % UT for 1 cycle 70 % UT for 25/30 cycles (50/60 Hz) 0 % UT for 250/300 cycles (50/60 Hz)	Not applicable	Icare HOME (TA022) tonometer is not operational when connected to an external computer, Icare HOME (TA022) batteries are not rechargeable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. WARNING: Sources of power frequency magnetic field should be used no closer than 15 cm (6 inches) to any part of Icare HOME (TA022), including cables specified by the manufacturer. Otherwise, degradation of the performance could result.

Guidance and manufacturer's declaration IEC 60601-1-2: Edition 4.0; 2014-02 – Electromagnetic immunity			
Icare HOME (TA022) is intended for use in a home healthcare environment with electromagnetic characteristics specified below. The customer or the user of the Icare HOME (TA022) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-Guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 6 V	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Icare HOME (TA022), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Icare HOME (TA022) including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and manufacturer's declaration IEC 60601-1-2: Edition 4.0; 2014-02 - Electromagnetic immunity			
Icare HOME (TA022) is intended for use in a home healthcare environment with electromagnetic characteristics specified below. The customer or the user of the Icare HOME (TA022) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-Guidance
Proximity fields from RF wireless communications equipment IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz	27 V/m	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device ¹ , including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	430 - 470 MHz 28 V/m; (FM ± 5 kHz, 1 kHz sine) PM; 18 Hz	28 V/m	
	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	9 V/m	Interference may occur in the vicinity of equipment marked with the following symbol: 
	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	28 V/m	
	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	28 V/m	
	9 V/m		

APPENDIX 1. ICARE HOME TONOMETER TRAINING PROCEDURES FOR CERTIFICATION OF HEALTH CARE PROVIDERS (HCP)

All health care providers must receive training from a certified trainer and be certified prior to performing tonometry or training others to perform self-measurement tonometry with the Icare HOME tonometer.

STEP 1 – The system components

- 1. Open the case and identify the system components by explaining what they are for** (tonometer, single-use probes, case, batteries, Icare LINK software, user documentation).
- 2. Install batteries to the tonometer as instructed in the Icare HOME user documentation.**
- 3. Install Icare LINK software to your PC as instructed in the Icare LINK user documentation.**

STEP 2 – Instruct the HCP

- 1. Show and explain the tonometer's user interface, including icons and status indicators:**
 - Off: no lights, no signals.
 - Press power button: all indicator lights illuminate after a short time, and you hear a long beep.
 - Load probe: when the green Load light flashes on the back panel.
 - Measure: when the green Measure light flashes on the back panel, you are meant to take a measurement. At the same time, the probe base light is green if the tonometer's position is horizontal enough, otherwise it is red. Explain that if there is an error in your measurement, the probe base light flashes red and you hear two long error beeps.
 - Repeat: when the yellow Repeat light flashes on the back panel, you need to repeat the measurement. At the same time, the probe base light flashes red and you hear two short beeps. The reason is either too much deviation in your measurement or the automatic eye recognition system could not recognize the eye because of the incorrect position of the tonometer.
 - Done: when the green Done light illuminates on the back panel, and you hear a long beep and the probe base light goes out, the measurement is completed.
 - Service: when the Service light and the probe base light flash red on the back panel and you hear two long error beeps, the tonometer needs service. At the same time the probe base light flashes red.
 - Low battery: when the red Battery light illuminates on the back panel, the battery charge is low and you should soon change the batteries.
 - Empty battery: when the red Battery light flashes on the back panel, the battery is empty and you must ask for a battery change.

2. Turning the tonometer on:

- Press the power button. All indicator lights on the back panel will flash once and you will hear a short beep.
- The Load light will flash alone when the tonometer is ready to load the probe.
- The tonometer turns off automatically after 3 minutes if you do not use it.

3. Loading the probe:

- Unwrap the probe.
- Remove the lid of the probe container.
- By holding the probe container drop the probe into the probe base without touching the probe.
- Press the measurement (play) button briefly (1 second) to activate the probe.

4. Adjusting the measurement distance:

- Carefully, without touching the patient's eye, set the distance between the tip of the probe and the center of the cornea for the patient at 4-8mm (5/32-5/16") by turning knobs to adjust forehead and cheek support positioning as needed.
- Write the settings down on a support position tag for the patient.
- Repeat for the patient's other eye.

5. Explain and show illustrations for how to position the tonometer (use a separate illustration sheet from the labeling for this):

- Sit or stand in front of a mirror and hold the tonometer sideways in front of your face.
- Align probe tip with center of cornea and rotate the tonometer until probe tip points straight at cornea.
- Make sure probe base light is green. If probe base light is red, make sure you are facing straight ahead (i.e., head held at a 90° angle) and tilt tonometer until probe base light turns green.
- The probe base light does not turn red in response to horizontal deviations. For this reason make sure the probe is centered in sight to ensure the probe contacts the center of cornea during measurement even if the probe base light is green. If the probe is not centered in your sight, repeat 5 and 6. This is very important because the tonometer with the probe must not be tilted more than 10 degrees away from the center of the cornea and without visualizing the probe base light it is difficult to judge the horizontal angle of the device.

6. Explain how to take the measurement:

- Explain that the Measure light will flash when the tonometer is ready to measure.
- Explain that the user must take six individual measurements for the IOP result and that the results are stored in the tonometer.
- Explain that the measurement button must be depressed to obtain the sequence of 6 measurements until a long beep is heard and the green "Done" light is illuminated on the back panel. The probe base light turns off at the same time.

7. Show and explain how to collect, display and store the results (for HCPs only):

- Start Icare LINK software in your PC by clicking the Icare LINK icon
- Connect the tonometer to the PC using the USB cable. The Load and Measure lights will flash. If no lights flash or the Service and Battery lights flash, reconnect the USB cable.
- (The internal clock of the tonometer is automatically updated to the PC's time by the Icare LINK software at this point).
- Icare LINK software's device tab opens and you see the results.
- Copy the results to a selected patient (it can be the default patient "- New patient-" that you can rename afterwards).
- The Measurements tab opens showing the copied results with date and time information that all is now stored to the PC.

STEP 3 – Rehearsal

1. Position the tonometer on your (HCP trainer) own eye.
2. Ask HCPs, if a given training session includes multiple health care providers, to observe and learn.
3. Load a new probe, ask the HCPs to position the tonometer and take some self-measurements as instructed and demonstrated.
4. Observe each HCP and, if necessary, correct the position while the HCP positions the tonometer, say to the HCP that this is the correct position and ask the HCP to try again.
5. Repeat 1-3 for up to ten times until the HCPs show consistent device positioning.

STEP 4 – Reference measurement

1. Load a new probe and carefully measure the IOP of the HCP with the tonometer once in each eye.

STEP 5 – Test measurement

1. Load a new probe and ask the same HCP to measure his/her own IOP three times in each eye with the same tonometer used in the reference measurement.
2. Observe if the positioning is correct. Do not supervise or interact.

STEP 6 – Certification

Connect device to computer and view the readings in the Icare LINK software.

The HCP passes the training and is certified for performing tonometry on patients with the device and for training others in self-use of the device if the following conditions are met:

- a. The reading taken by the trainer and the first of the three readings taken by the HCP differ by 5 mmHg or less.
- b. The range (max-min) of the three readings taken by the HCP is 5 mmHg or less in case the first reading is 7-23 mmHg or 7 mmHg or less in case the first reading is >23 mmHg.
- c. The positioning of the tonometer was correct during self-use as determined by the trainer.

HCP's name: Date (dd mm yy):

CERTIFICATION 0 = Pass; 1 = Fail

APPENDIX 2. ICARE HOME TONOMETER TRAINING PROCEDURES FOR CERTIFICATION OF THE PATIENT FOR SELF-USE

All patients must receive training from a certified health care professional (HCP and be certified prior to performing self-tonometry. It is recommended that the health care provider re-administers this training and certification at periodic intervals if there is a concern about the ability of a particular patient to obtain reliable IOP measurements. A failure rate of 10.7% of the training certification was found in the clinical measurement validation study. Please refer to page 23 for an accounting of reasons for certification failure.

STEP 1 – Instruct the patient

1. Show and explain the tonometer's user interface, including icons and status indicators:

- Off: no lights, no signals.
- Press power button: all indicator lights illuminate after a short time, and you hear a long beep.
- Load probe: when the green Load light flashes on the back panel.
- Measure: when the green Measure light flashes on the back panel, you are meant to take a measurement. At the same time, the probe base light is green if the tonometer's position is horizontal enough, otherwise it is red. Explain that if there is an error in your measurement, the probe base light flashes red and you hear two long error beeps.
- Repeat: when the yellow Repeat light flashes on the back panel, you need to repeat the measurement. At the same time, the probe base light flashes red and you hear two short beeps. The reason is either too much deviation in your measurement or the automatic eye recognition system could not recognize the eye because of the incorrect position of the tonometer.
- Done: when the green Done light illuminates on the back panel, and you hear a long beep and the probe base light goes out, the measurement is completed.
- Service: when the Service light and the probe base light flash red on the back panel and you hear two long error beeps, the tonometer needs service. At the same time the probe base light flashes red.
- Low battery: when the red Battery light illuminates on the back panel, the battery charge is low and you should soon change the batteries.
- Empty battery: when the red Battery light flashes on the back panel, the battery is empty and you must ask for a battery change or a working tonometer from the HCP.

2. The HCP turns on the tonometer:

- Press the power button. All indicator lights on the back panel will flash once and you will hear a short beep.
- The Load light will flash alone when the tonometer is ready to load the probe.

3. The HCP loads the probe:

- Unwraps the probe.
- Removes the lid of the probe container.
- Drops the probe into the probe base without touching the probe by holding the probe container.
- Presses the measurement (play) button briefly (1 second) to activate the probe.

4. Explain and show illustrations for how to position the tonometer (use a separate illustration sheet from the labeling for this):

- Sit or stand in front of a mirror and hold the tonometer sideways in front of your face.
- Align probe tip with center of cornea and rotate the tonometer until probe tip points straight at cornea.
- Make sure probe base light is green. If probe base light is red, make sure you are facing straight ahead (i.e. head held at a 90° angle) and tilt tonometer until probe base light turns green.
- The probe base light does not turn red in response to horizontal deviations as illustrated in the figure on the right. For this reason make sure the probe is centered in sight to ensure the probe contacts the center of cornea during measurement even if the probe base light is green. If the probe is not centered in your sight, repeat steps 5 and 6. This is very important because the tonometer with the probe must not be tilted more than 10 degrees away from the center of the cornea and without visualizing the probe base light it is difficult to judge the horizontal angle of the device.

5. Explain how to take the measurement:

- Explain that the Measure light will flash when the tonometer is ready to measure.
- Explain that the user must take six individual measurements for the IOP result and that the results are stored in the tonometer.
- Explain to the patient that the measurement button must be depressed to obtain the sequence of 6 measurements until a long beep is heard and the green "Done" light is illuminated on the back panel. The probe base light turns off at the same time.

STEP 2 – Demonstrate measurements from your (HCP's) own eye

1. Position the tonometer on your (HCP) own eye as instructed above.
2. Ask the patient to observe and learn.

STEP 3 – Supervised patient use of the icare home

1. Load a new probe and carefully, without touching the patient's eye, choose the eye and set the distance between the tip of the probe and the center of the cornea for the patient at 4-8mm (5/32-5/16") by turning knobs to adjust forehead and cheek support positioning as needed. Write the settings down on a support position tag for the patient.
2. Ask the patient to position the tonometer on the chosen eye and take some self-measurements as instructed and demonstrated.
3. Observe and, if necessary, correct the position while the patient positions the tonometer, say to the patient that this is the correct position and ask the patient to try again.
4. Repeat 1-3 for up to 10 times until the patient shows consistent device positioning. If the patient cannot consistently measure after this point the patient will be considered to be unable to measure the IOP using the HOME device.

STEP 4 – Self-measurement by the patient

1. Load a new probe and ask the patient to measure his/her IOP three times with the same Icare HOME tonometer.
2. Observe if the positioning is correct. **Do not supervise or interact.**

STEP 5 – Measurement of patient's IOP by HCP

1. The HCP measures the IOP of the patient once with the GAT tonometer.

STEP 6 – Certification

Connect device to computer and view the readings in the Icare LINK software. The patient passes the training and is certified for self-use if the following conditions are met:

- a. The first of the three HOME readings taken by the patient and the GAT result measured by the HCP differ by 5 mmHg or less.
- b. The range (max-min) of the three readings taken by the patient is 7 mmHg or less.
- c. The positioning of the tonometer was correct during self-use as determined by the HCP.

Patient ID: Date (dd mm yy):

CERTIFICATION 0 = Pass; 1 = Fail EYE 0 = Right; 1 = Left, 2 = Both

icare

VISIONARY IN VISION

Icare Finland is the original developer and global leader in handheld tonometry. Our patented technology (over 20 patents/patent applications) combined with ISO 13485 certified quality system has made us a respected player in our field of expertise.

The advanced Icare® product line offers reliable, high precision, reproducible accuracy in measuring intraocular pressure in any circumstances, in both experienced and inexperienced hands. A variety of Icare® tonometers are available for several uses:

Icare® ic100, Icare® TA01i, Icare® HOME, Icare® TONOVET, Icare® TONOLAB

Made in Finland.



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