

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

Belongs to:

Icare HOME (Model: TA022) PATIENT GUIDE TA022-035 USA-2.0

Date of printing:

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GLOSSARY

Goldmann Applanation Tonometry = the standard eye test that can detect your eye pressure (IOP) .

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Tonometer = a device for measuring your IOP.

mmHg = units of measurement for the pressure in your eye.

Position tag = support positions for your eyes are written on it.

Probe = tonometer's single-use item that lightly touches your eye.

Probe base light = light ring that assists you to position the probe.

Shelf life = the time the probe remains sterile in its intact packing.

Cornea = the eye's outermost dome shaped clear layer.

Forehead/cheek supports = tonometer's adjustable supports.

Expected service life = expected life time before replacement.

Electromagnetic immunity = tonometer's ability to withstand

INTRODUCTION

This guide will teach you how to use the Icare HOMF tonometer.

disturbances from other electrical equipment.

The Icare HOME tonometer is a prescription device intended to be used in addition to routine clinical monitoring of intraocular pressure (IOP) of adult patients.

You must be certified and trained by a health care professional for the procedures described in this manual prior to the device being prescribed for home use.

The health care professional will provide you with a support position tag that has the correct distance settings for you if you accidently change the distance by mistake or you need to have different distance settings to measure your other eye. You should keep the tag with the tonometer.

Please note that patients for whom initial agreement between Goldmann applanation tonometry (GAT) and Icare HOME measurements in the clinic is poor (difference of more than 5 mm Hg) should not be prescribed the Icare HOME device for home use.

HOW DOES THE TONOMETER WORK

4

The tonometer measures your eye pressure using a disposable probe that gently contacts your eye during the measurement. You may need a mirror to help you determine the correct measurement position. The recommended frequency of measurements is 3-4 times per day with a maximum of 5-6 times per day.

A complete measurement is a series of six very rapid measurements. It may take from several seconds to a minute to take the measurement. The probe moves to the cornea and back during each of the six rapid measurement. After the series of six measurements, the tonometer calculates your final eye pressure and stores it in the tonometer's memory.

The probe is disposable, but you can use the same probe for both eyes if the health care professional instructed you to measure both eyes. Dispose of the probe in a normal trash container or a metal waste bin after you have taken the measurements for both eyes.

The tonometer includes infra-red eye recognition sensors to identify which eye, right or left, you are measuring. It is important not to cover these sensors with your fingers, hand, hair etc., because covering the sensors causes an error. It is also important to keep objects such as pillows away from the temple side of your eye, as they produce an infrared reflection that causes an error.

It is important that you carefully read all instructions in this guide before using the tonometer.

CONTRAINDICATIONS

You should not be prescribed the HOME tonometer if you:

- Have an active ocular infection (for example, pink eye)
- Had recent trauma to your eye
- Cannot demonstrate you are able to use the Icare HOME tonometer after training and fail to complete the certification procedures. This includes poor agreement between Goldmann applanation tonometry (GAT) and Icare HOME measurements.
- Have disabling arthritis or difficulty handling the Icare tonometer
- Have a severe difficulty in opening your eyes including abnormal contractions or twitches of the eyelid
- Have involuntary, rapid and repetitive movement of the eyes

RISKS

You are likely not eligible for use of the HOME tonometer if you:

- Have poor uncorrected near vision
- · Have only one working eye
- Have poor or off-center visual fixation
- Have poor hearing without an aid and/or communicate using sign language
- Use contact lens
- Have dry eyes
- Have Keratoconus (a corneal disorder)
- Have a congenitally (from birth) small eye
- Have an enlarged eye from childhood glaucoma
- Had a cataract removed within last 2 months

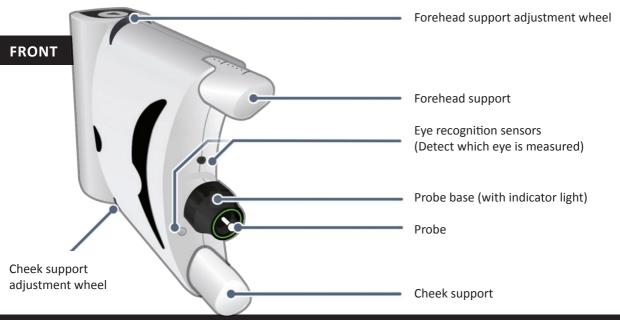
The safety and effectiveness of the Icare HOME tonometer has not been evaluated for patients with:

- High corneal astigmatism
- History of prior invasive glaucoma surgery or corneal surgery including corneal laser surgery (for example, LASIK)
- Corneal scarring
- Very thick or very thin corneas
- Patients for whom there is already difficulty in obtaining clinical IOP measurements (for example, due to eyelid squeezing or tremor)

BENEFITS

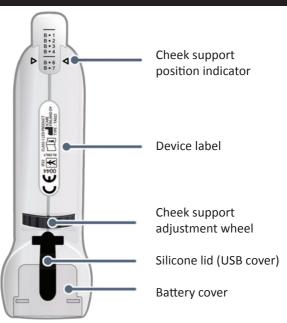
You can take measurements of your eye pressure at various times during the day and night with the lcare HOME tonometer. These measurements taken outside your office visits may help your doctor determine whether you have glaucoma or have a better understanding of your glaucoma, if you already have a glaucoma diagnosis.

TONOMETER OVERVIEW



BACK BOTTOM





PREPARING THE TONOMETER FOR USE

Make sure the forehead and cheek support positions match the positions your eye care professional wrote on the support position tag for you.

The support position tag is found in the Icare tonometer carrying case. If needed, turn the support wheels to your set support settings.

Press and release the Power button to power on the tonometer. All indicator lights on the back panel will flash once and you will hear a short beep.

The LOAD indicator will continue to flash indication that the tonomoter is ready to load the probe.

3 Gather <u>new</u> probe and unwrap package.

MARNING

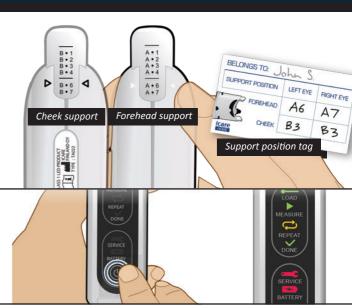
- Use only original and certified probes made by the manufacturer.
- Do not touch the probe.
- The shelf life of the probes is 3 years.
- Use a new, unused probe after measurements for both eyes have been taken.
- You should thoroughly wash your hands with soap and water and dry them with a clean towel prior to handling the probe.

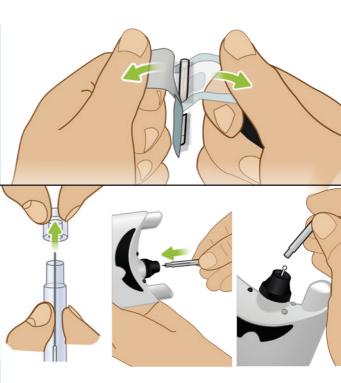
Hold the probe container upright, with the container cap on top and uncap the container, tilt the container to allow the probe to drop into the probe base, then press the Measure button briefly (1 second).

The flash indicator light stops once the probe is loaded and the MEASURE indicator starts to flash when the tonometer is ready to measure. Keep the probe container to reuse when ready to dispose of the probe.

MARNING

- Do not touch the probe.
- Do not point the tonometer down.
- Do not use the probe if it touches a nonsterile surface like table or floor.





POSITIONING THE TONOMETER

5 Stand in front of a mirror and hold the tonometer sideways in front of your face. This will help you to align the tonometer to your eye.

MARNING

Make sure that the probe or any part of the tonometer does not contact your eyes.

Align the probe tip with center of cornea and rotate the tonometer until the probe tip points straight at cornea.

WARNING

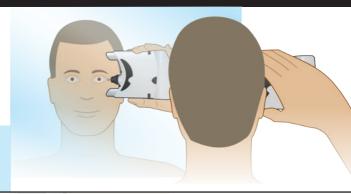
Make sure that the probe or any part of the tonometer does not contact your eyes.

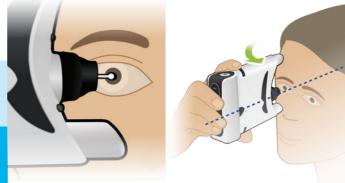
PRECAUTION

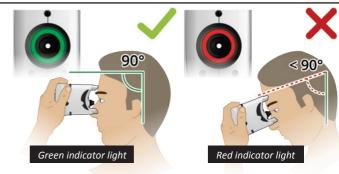
Do not cover the eye recognition sensors, because covering the sensors causes an error.

Make sure the probe base light is green.

If the probe base light is red, make sure you are facing straight ahead (i.e., head held at a 90° angle) and tilt the tonometer until the probe base light turns green.



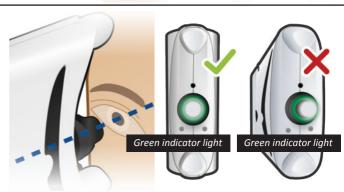




Make sure the probe is centered in sight to ensure the probe contacts the center of the cornea during measurement.

If the probe is not centered in your sight,

If the probe is not centered in your sight, repeat steps 5 and 6.



COMPLETING THE MEASUREMENT

14

Press the Measure button > to measure 9 pressure (probe will contact eye during measurements).

Press and hold the button (3 seconds) to collect 6 measurements in a row, or press the button briefly (1 second) 6 times to collect one measurement at a time.

PRECAUTION

If an error occurs (two short beeps and the probe base light is flashing red), press the Measure button briefly (1 second) and continue measurement.

10 When the measurement ends successfully, you will hear a long beep, the probe base light will power off, and the Done light illuminates.

> After using the tonometer to measure your eye pressure, you can remove the probe by powering off the device and allowing the probe to slide out of the probe base. Place the probe back in its container and dispose of it in a normal trash container or a metal waste bin.

↑ WARNING

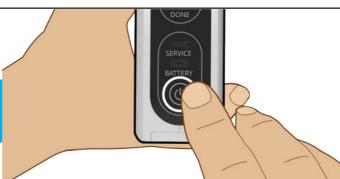
You should replace the probe if it comes into contact with your eyelashes or eyelid or you suspect it did.

- 11 If your doctor instructed you to measure both eyes, repeat steps 1 through 10 using your other eye. Use a new, unused probe after measurements for both eyes have been taken.
- After completing all measurements, power 12 off the tonometer by pressing and holding the Power button down until you hear 3 short beeps.

PRECAUTION

The tonometer will power off automatically if unused for 3 minutes.





ERROR MESSAGE



Probe base indicator light is solid red and the Measure indicator light turns off.

Cause: Tonometer is not held straight.

SOLUTION

- **1.** Make sure you are facing straight ahead (i.e., head held at a 90° angle).
- **2.** Adjust the tonometer's tilt angle until probe base light turns green.



Probe base indicator light is flashing red and you hear 2 beeps.

Cause: Tonometer is too far from or too close to eye or not held straight.

- **1.** Press the Measure button \triangleright to clear error.
- **2.** Adjust the forehead/cheek supports for correct distance.
- **3.** Repeat measurement.



Probe base indicator light is flashing red and Repeat light is flashing and you hear 2 beeps.

Cause: Too much variation between measurements or eye recognition failed.

- **1.** Press the Measure button \blacktriangleright to clear error.
- 2. Make sure the eye recognition sensors or temple side of the eye are not covered as covering them causes the eye recognition to fail and the error.
- **3.** Repeat measurement.



Probe base indicator light is flashing red and Service light is flashing and you hear 2 beeps.

Cause: The probe or probe base is dirty or damaged.

Contact the health care professional you received your tonometer from or a certified service center to have the tonometer serviced.

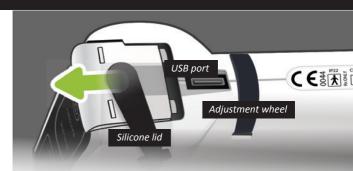


Battery light is flashing. Cause: Battery power is low.

Change the battery. See pages 18-19 for instructions.

REPLACING THE BATTERIES

1 Lift silicone lid from battery cover then slide battery cover open.



Remove used batteries and insert 2 new CR123A lithium batteries.

Make sure the batteries' positive end (+) is facing the battery cover. Rechargeable batteries should not be used.



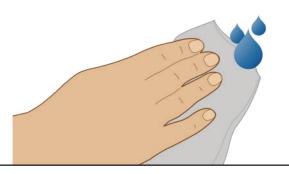
3 Slide the battery cover back over the battery opening and insert the silicone lid back into the USB port.



CLEANING THE TONOMETER

Slightly dampen a cloth or paper towel with water.

Make sure to remove excess water from the cloth or paper towel.



Clean the tonometer with the damp cloth or paper towel.

Make sure the batteries' positive end (+) is facing the battery cover.

PRECAUTION

Do not immerse the tonometer in water or any other liquid.

I PRECAUTION

Any maintenance services other than battery replacement and cleaning must be performed by the manufacturer or a certified service center.

PRECAUTION

The expected service life of the device is 5 years.





CLINICAL PERFORMANCE DATA

A study was conducted with 383 patients performing self-measurements with the Icare HOME tonometer. A summary of the study findings are below:

- No complications (including corneal abrasions) were recorded.
- The eye pressure ranges measured were ≤16 mmHg, >16 to <23 mmHg and ≥23 mmHg (mmHg is the unit of measure for eye pressure).
- The average difference of Icare HOME versus the gold standard measurement method (Goldmann measurement device that is used in eye clinics) was approximately 0.5 mmHg (the average pressure measurement in the study was approximately 18 mmHg with a range of 5 to 50 mmHg).
- Compared to the Goldmann tonometer, 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 Icare HOME's variability (difference of repeat measurements) on the same eye was ~10% for the low and medium pressure range and ~7.5% for the high pressure range.
- Only certified users were able to proceed to self-testing. 10.7% of the patients failed to pass training/certification.
- In this study, self-testing was limited to a single session 10 minutes after certification.

GETTING SUPPORT

If you have any questions or problems using the lcare tonometer, call the service center:

Place other appropriate contact information

of the supplier of the device or other source of

888-389-4022 (toll-free)

or email: **service@icare-usa.com** or visit Icare at: .

supplies here:



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.

ICARE FINLAND OY

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