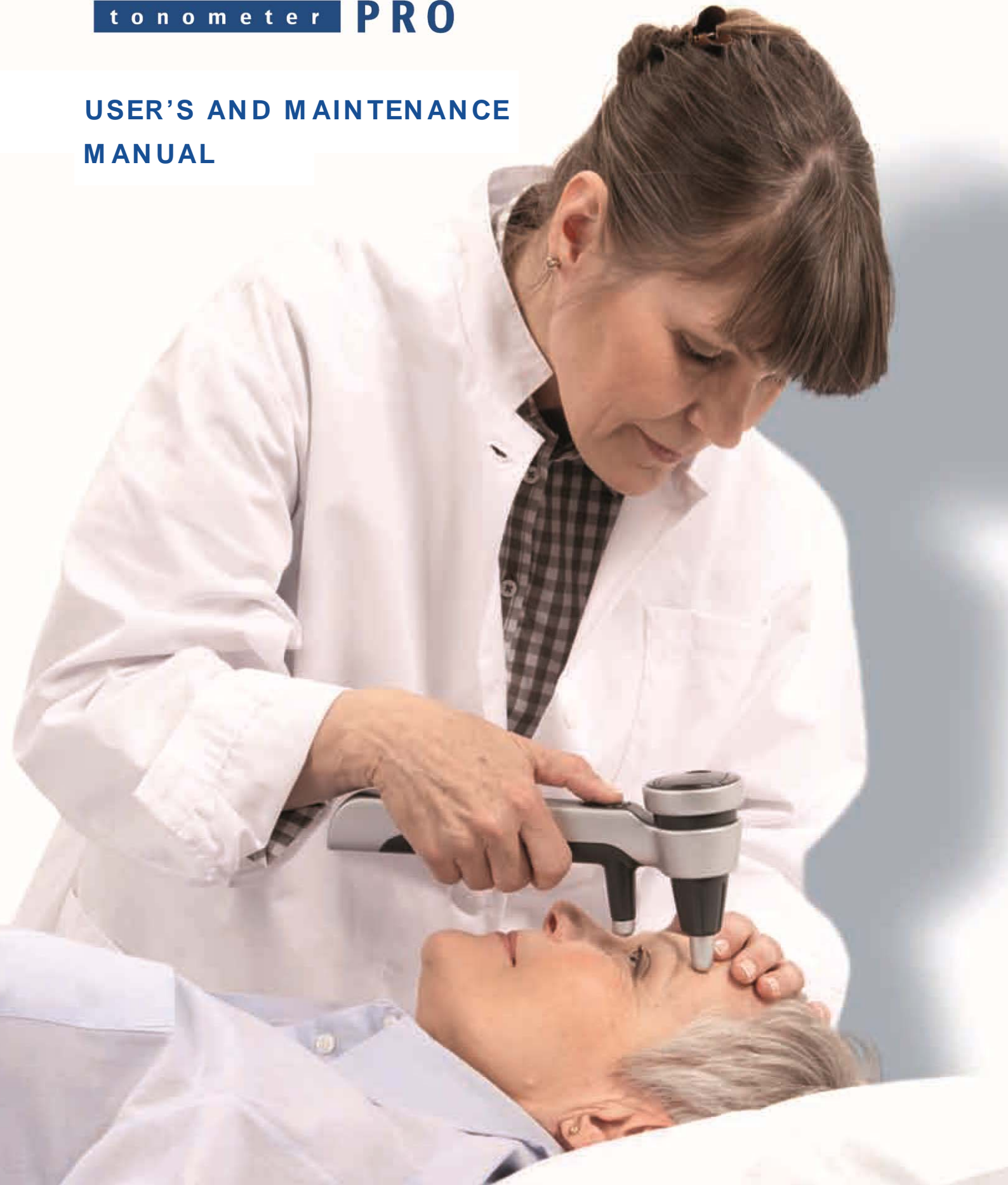


icare

tonometer PRO

ENGLISH

USER'S AND MAINTENANCE MANUAL



Icare® PRO (Model: TA03) INSTRUCTION MANUAL v1.1 01/12 EN



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

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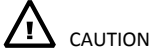
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SAFETY INSTRUCTIONS



WARNING

The tonometer must not come into contact with the patient's eyes, except for the probes, which may do so for a fraction of a second during measurement. Do not bring the tonometer into contact with the eye or push it into the eye (the tip of the probe should be 3–7 mm, or 1/8 – 2/7 inch, from the eye).



CAUTION

Do not connect the USB cable during measurement.



CAUTION

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



CAUTION

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



CAUTION

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



CAUTION

To avoid cross contamination of bacteria or viruses and infection of the eye, take a new probe for every patient measured. Use probes taken only from original intact packaging. The sterility of the probe cannot be guaranteed once the seal is compromised. Resterilization or re-use of the probe could result in incorrect measurement values or in the break-down of the probe.



CAUTION

Do not connect Icare PRO tonometer to any charger or equipment other than the docking station (TX01) provided with the tonometer.



CAUTION

Do not touch the USB cable terminal and patient simultaneously.



CAUTION

Do not place a docking station (TX01), charger, USB cable or PC together with the tonometer in patient environment. The distance from a patient must be more than 1.8m/6 ft.

- When you have opened the package, check for any external damage or faults, particularly for damage to the case. If you suspect that there is something wrong with the tonometer, contact the manufacturer or distributor.
- Use the tonometer only for measuring intraocular pressure. Any other use is improper and the manufacturer cannot be held liable for any damage arising from improper use, or for the consequences thereof.
- Never open the casing of the tonometer except for to change the probe base.
- Never use the tonometer in wet or damp conditions.
- The probe base, screws, collar and probes are so small that a child could swallow them. Keep the tonometer out of the reach of children.
- Do not use the device near inflammable substances, including inflammable anesthetic agents.
- Prior to each measurement, check that a new disposable probe from an intact package is being used.
- Certain microbiological agents (for example, bacteria) can be transmitted from the forehead support. To avoid this, the forehead support must be cleaned for each new patient with disinfectant, for example, an alcohol solution.
- The tonometer conforms to EMC requirements (IEC 60601-1-2), but interference may occur if used near (<1m) a device (such as a cellular phone) causing high-intensity electromagnetic emissions. Although the tonometer's own electromagnetic emissions are well below the levels permitted by the relevant standards, they may cause interference in other, nearby devices, for example, sensitive sensors.
- Be sure to dispose of the single-use probes properly (for example, in a container for disposable needles), because they may contain micro-organisms from the patient.
- Dispose of the device, components and accessories according to applicable local regulations.
- Usage contraindications: Corneal Scarring, Microphthalmos, Buphthalmos, Nystagmus, Keratoconus, abnormal central corneal thickness.

INDICATIONS FOR USE

The Icare PRO tonometer TA03 is intended to be used by health care professionals to measure intraocular pressure (IOP) in the human eye.

INTRODUCTION

The Icare PRO tonometer is used in the diagnosis, follow-up and screening of intraocular pressure.

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

The Icare PRO tonometer has a built-in inclination sensor that allows downward measuring of a patient in a supine position as well as in the normal upright position.

The tonometer can also record and store over one thousand measurement results, which can be viewed directly in the tonometer and/or transferred to a PC through a USB cable.

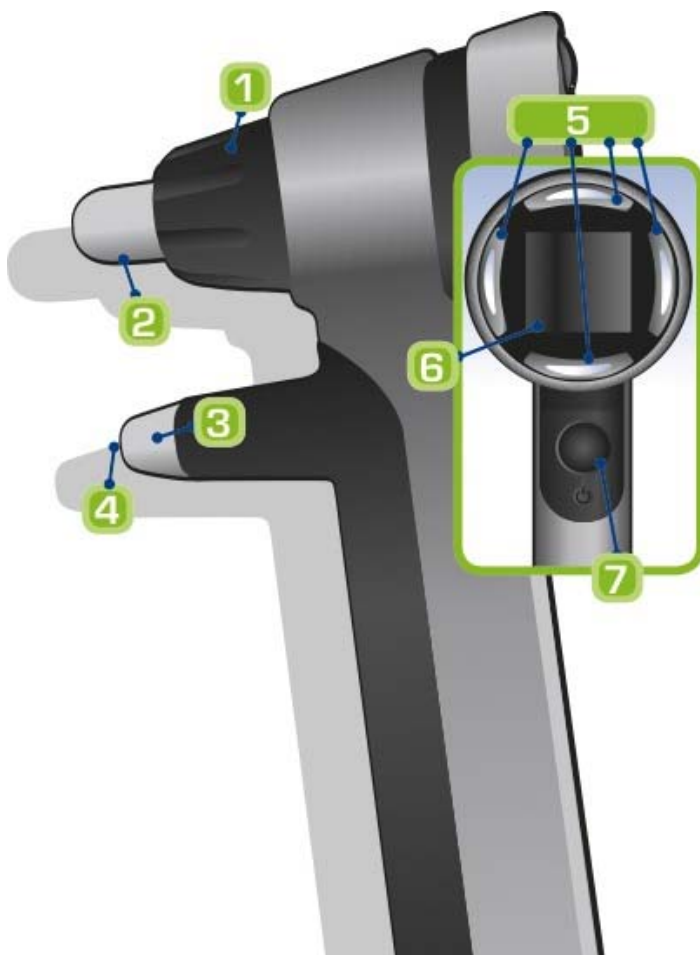
Single-use probes are used for measurement to minimize the risk of microbiological contamination.

Intraocular pressure changes due to the effects of the pulse, breathing, eye movements and body position. As measurements are taken using a handheld device in fractions of a second, several measurements are needed to obtain an accurate reading and therefore the device is pre-programmed for six measurements.

PACKAGE CONTENTS

The package contains:

- Icare PRO tonometer
- USB cable for connecting to a PC with Icare LINK software
- LINK software on USB memory stick
- Docking station (model TX01)
- Charger
- Spare parts (probe base and probe holder)
- 100 sterilized single use probes
- User manual
- Warranty certificate
- Instructions for downloading LINK software and registration of the device
- Aluminium box



1. Forehead support adjustment wheel
2. Forehead support
3. Collar
4. Probe base
5. Navigation buttons: Up, Down, Left and Right
6. Display
7. Main button

BEFORE USING

Read this manual carefully before starting to use the tonometer. Make sure the battery is fully charged before using the tonometer for the first time. See , Charging the battery.

TURNING THE DEVICE ON



Main menu

Press the main button to turn the tonometer on. The tonometer will show a welcome screen followed by the menu. The menu has four items:

- **Measure**
- **History**
- **Settings**
- **Turn off**

NAVIGATING

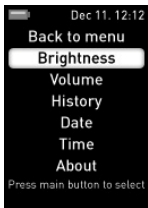
There are navigation buttons (left, right, up and down) and a main button, which are used to navigate through the menus in the tonometer. A navigation button is lit when available.



NOTE

The left button is typically used to go back to the previous menu when there is no 'Back to menu' item in the menu.

SETTINGS



Use the Settings menu to change the tonometer's settings.

To access settings, go to **Menu** → **Settings** and press the main button to confirm.



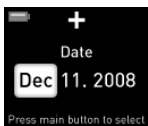
Brightness - Change the display brightness

1. Increase or decrease brightness using the up/down navigation buttons and press the main button to confirm.



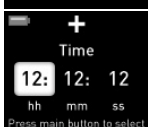
Volume - Turn the tonometer sounds on or off

1. Select on or off using the left/right navigation buttons and press the main button to confirm. If the sound is off you do not hear the beep when a measurement is taken.



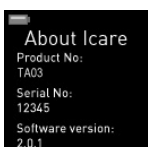
Date - Set the date

1. Select the month/day/year you want to change using the left/right navigation buttons.
2. Change month/day/year using the up/down navigation buttons.
3. Press the main button to confirm.



Time - Set the time

1. Select the hour/minute/second you want to change using the left/right navigation buttons.
2. Change hour/minute/second using the up/down navigation buttons.
3. Press the main button to confirm.



About - Shows important information about your Icare PRO tonometer

SETTING UP THE TONOMETER BEFORE TAKING MEASUREMENTS

Before taking measurements your tonometer must be set up correctly. Set-up includes:

- Loading the probe
- Adjusting the measurement position



Disposable tonometer probe in blister pack

LOADING THE PROBE

The Icare PRO tonometer uses disposable tonometer probes. Probes are packaged into blister packs as shown in the figure. Each probe is meant for single use only.

To load the probe:

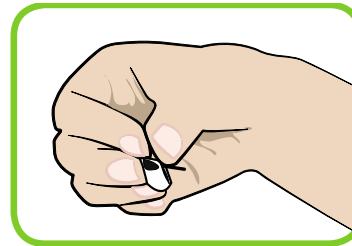
1. Press the main button to turn on the tonometer. The Welcome screen displays followed by the main menu.
2. Go to **Measure** and press the main button. An insert new probe message displays.
3. Partially open the package.



CAUTION

Do not touch the probe directly to prevent contamination.

4. Insert the probe from the partially opened package.
5. Keep the blister in between your finger and probe, and press lightly. Be careful not to bend the probe. To check probe is correctly inserted tilt unit backward and forward.
6. Go to **Measure** and press the main button once to activate the inserted probe. During activation the device magnetizes the probe (probe moves rapidly back and forth). Once the probe is activated, the tonometer is ready for measurement.



NOTE

If the tonometer is left idle, it turns off automatically after 3 minutes.

ADJUSTING THE MEASUREMENT POSITION

The Icare PRO tonometer has a built-in inclination sensor that allows downward measuring of a patient in a supine position as well as in the normal upright position. The tonometer has an adjustable forehead support, as shown in. The support is adjusted to ensure accurate measurement distance and alignment.



Adjustable forehead support



Patient with the tonometer correctly positioned



Measuring supine patient

Adjust the forehead support using the adjustment wheel, so the distance from the tip of the probe to the surface of the cornea is 3-7mm (1/8-2/7 inch). When the tonometer is tilted to measure a supine patient the probe is automatically held in place. When measuring a supine patient, an arrow appears in the display that indicates the vertical position of the device.

MEASURING INTRAOCULAR PRESSURE (IOP)

A measurement sequence is a set of six measurements. Six measurements are necessary to obtain the most accurate reading but the result is also displayed after each measurement. The measurement value, shown after six measurements are taken, displays an average value.



NOTE

Anesthetic is not required when performing measurements. If used it may lower the tonometer reading.

To measure intraocular pressure:

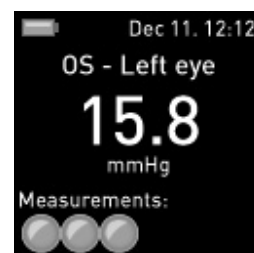
1. Check that the tonometer is set up correctly. Setting up the tonometer before taking measurements.
2. Go to **Menu** → **Measure** and press the main button. Select the eye you want to measure using the left and right navigation buttons and press the main button to confirm.
3. Tell the patient to relax and look straight ahead at a specific point while keeping eyes wide open.
4. Bring the tonometer near the eye. The distance from the tip of the probe to the cornea must be 3-7mm (1/8-2/7 inch) as shown in Figure 10. If necessary, adjust the distance using the forehead support.
5. Press the main button lightly to perform one individual measurement, taking care not to shake the tonometer. The tip of the probe should make contact with the central cornea. A short beep sounds after each measurement and an interim result is shown on the display.
6. Repeat step 5 six times. Once the six measurements are complete, the final IOP is displayed.
7. Press the main button.
8. Choose YES to continue measuring the other eye of the same patient. Select the eye you want to measure with the navigation button and the press the main button (OD/OS).
9. If you do not want to continue measuring, choose NO. The results are saved and you can turn off the device from the main menu.



An indication of the reliability of the measurement is displayed below the IOP result. If the variation between the measurements is within normal limits, the numerical deviation is shown in green. If the variation is slightly high, the deviation is shown in yellow and a high variation is shown in red. If there is a high variation the tonometer suggests repeating the measurement. The results of the six individual measurements can be viewed by pressing the navigation down button.

A new measurement needs to be taken if:

- The validity of the measurement is in doubt, for example, if the probe made contact with the eyelid or missed the central cornea.
- The variation is high and the numerical deviation is shown in red.
- When encountering unusual values, for example, above 22 mmHg or below 8 mmHg.



MEASUREMENT HISTORY



History contains the results of previous measurements.

To access measurement history:

1. Go to **Menu** → **History** and press the main button to confirm. The most recent measurement is displayed.
2. View previous/next measurements using the up/down navigation buttons.
3. Press left/right/main button to return to the menu.






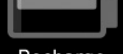
ERROR MESSAGES

If an error occurs, the Icare PRO tonometer shows it on the display. Error messages are explained in the following table:



WARNING

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

<p>Incorrect hit!</p>  <p>Remeasure</p>	The probe does not make clean contact with cornea, for example, the probe hit an eyelid or eyelashes.
<p>Distance was too long!</p> 	Distance between probe and cornea is too great or the probe does not hit cornea at all.
<p>Distance was too short!</p> 	Distance between probe and cornea is too short.
<p>Incorrect position!</p> 	Positioning of tonometer is incorrect.
<p>Probe didn't move properly!</p>  <p>Check the probe and base</p>	Probe does not move correctly or does not move at all. If the error repeats, change the probe base and probe holder.
<p>Battery low!</p>  <p>Recharge</p>	Battery is low. Recharge the battery by placing the tonometer in the docking station.
<p>Turn power off and clean tonometer</p>	This error message is given if probe is continuously not moving smoothly or stops moving. Change the probe base and probe holder.

TURNING THE TONOMETER OFF

Press either navigation button until the display shows 'Turn off'. Press the main button - the display will show 'bye' and the tonometer will switch off. The used probe will be partially ejected. Use the used package to remove it from the tonometer. Ensure that you dispose of the probe properly.

CLEANING AND DISINFECTING

If the tonometer indicates that the probe is not moving smoothly or that the tonometer needs cleaning, the probe base and/or probe holder may be dirty or dusty. Change the probe base and probe holder by unscrewing the probe cover and replacing the parts with new ones.

The forehead support must be wiped for each new patient with disinfectant, for example, an alcoholic solution.

Do not immerse the tonometer in water or other solution.

SERVICE PROCEDURES

Change the probe base and probe holder if the probe does not move smoothly (a clean error message is shown). No other service procedures can be carried out by the user. All other service and repair must be carried out by the manufacturer or a certified service center.

Before sending the device for service, make sure you have transferred your measurement data to a PC using LINK software when necessary.

CHARGING THE BATTERY

When the battery is low an error message indicates that you must recharge it. Place the tonometer in the docking station that is provided with your tonometer.



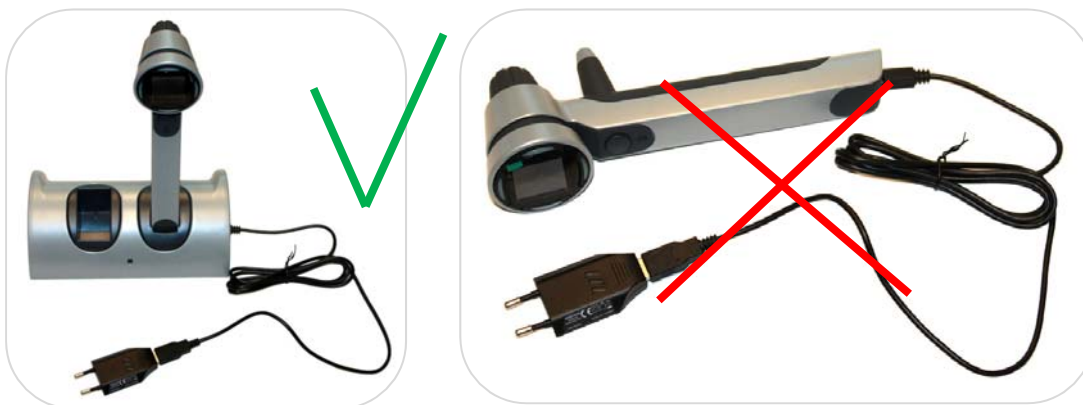
Attach the docking station to a PC using a USB cable. Charging the battery fully takes approximately one hour. When a green light is blinking in the upper navigation button, the tonometer is charging. When the green light is constant, charging is complete. Do not charge the tonometer within the patient's environment.

Avoid extreme conditions. High and low temperatures will reduce the capacity of the battery. In order to recharge at maximum rate LINK software must be installed. See installation instructions in LINK User Manual or a separate installation instruction sheet provided with the software. Use only a PC that complies to the IEC 60950 standard or the charger provided. To charge Icare PRO tonometer without a PC is possible with the charger/adapter provided with your tonometer. Connect the USB cable to the USB charger and the docking station. To charge Icare PRO, place the tonometer in the docking station.

ICARE PRO TONOMETER'S SEPARATE CHARGER/ ADAPTER

To charge Icare PRO tonometer without PC is possible with the charger/adapter provided with your tonometer. Connect the USB cable to USB charger and the docking station. To charge place Icare PRO tonometer to docking station (see the image on the right side).

- Do not charge directly the tonometer with the adapter
- Charge Icare PRO tonometer outside the patient environment
- Use only the charger provided by your Icare PRO tonometer.



NOTE

Do not charge the tonometer directly with the adapter and the USB cable.



NOTE

Charging the tonometer is only allowed outside the patient environment (1.8 m/6 ft).

SPARE PARTS AND CONSUMABLES

- Icare PRO probes, 100 pieces per package
- Probe base kit (includes probe base and probe holder)

TECHNICAL AND PERFORMANCE DATA

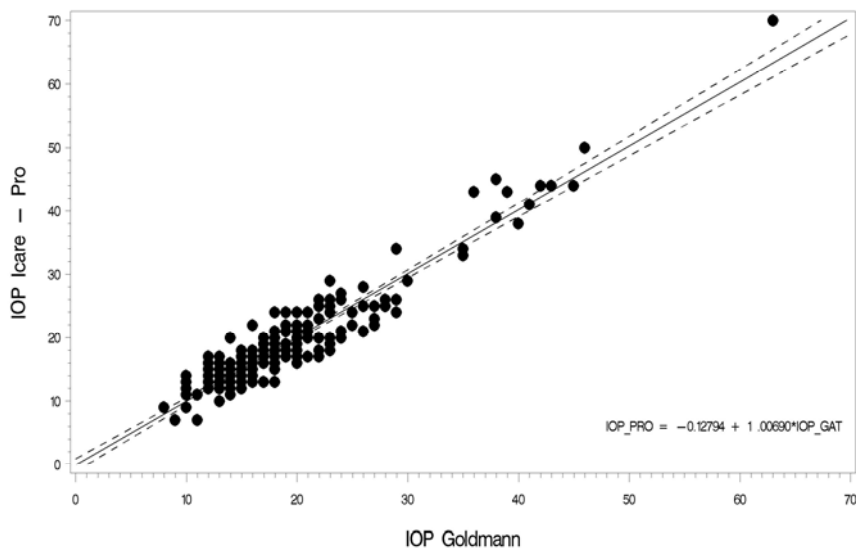
- Type TA03
- The device conforms to CE regulations
- Dimensions: 225 mm x 46 mm x 90 mm (8.9" x 1.8" x 3.5")
- Weight: 275 g (9.7 oz.)
- Power supply: rechargeable Lithium Ion battery. Up to 1000 measurements can be performed with a fully charged battery.
- Measurement range: 5-50 mmHg
- Display range: 1-99.9 mmHg
- Accuracy: ± 1.2 mmHg (≤ 20 mmHg) and ± 2.2 mmHg (> 20 mmHg)
- Repeatability (coefficient of variation): $< 8\%$
- Accuracy of display: 0.1 mmHg
- Display unit: mmHg
- The serial number can be shown on the screen (Settings/About)
- There are no electrical connections from the tonometer to the patient
- The device has BF-type electric shock protection
- Operation environment
 - Temperature: $+10$ °C to $+35$ °C
 - Relative humidity: 30 % to 90 %
 - Atmospheric pressure: 800 hPa – 1060 hPa
- Storage environment
 - Temperature: -10 °C to $+55$ °C
 - Relative humidity: 10 % to 95 %
 - Atmospheric pressure: 700 hPa – 1060 hPa
- Transport environment
 - Temperature: -40 °C to $+70$ °C
 - Relative humidity: 10 % to 95 %
 - Atmospheric pressure: 500 hPa – 1060 hPa

CLINICAL PERFORMANCE DATA

Performance data is obtained from a clinical study, performed according to ANSI Z80 and ISO 8612 for tonometers. The estimate of the effect of the reference tonometer on the Icare PRO tonometer value is close to one; the coefficient of determination is $R_2 = 0.890$. The mean of paired difference (Goldmann-Icare PRO tonometer) were 0.0 (≤ 16 mmHg 0.4; $> 16 < 23$ -0.4; ≥ 23 -0.3) and standard deviation is 2.7.

15 Scatterplot of IOP values of test tonometer against the IOP values of Goldmann reference tonometer

With regression line and 95 % confidence intervals (identical observations shown only once)



Regression Equation:
 $IOP_PRO = -0.127989 + 1.006903 * IOP_GAT$

SYMBOLS



Caution



See operating instructions for more information.



BF-type device



Single-use disposable



Serial number



Use by <date>



Keep dry



Manufacturing date



Lot number



Sterilized using irradiation



Stand by



Do not dispose of in household waste.