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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 bring the tonometer into contact with the eye or push it into the eye (the tip of the probe should be 4-8mm, or 5/32-5/16”, 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 tonometer probe tips have not been evaluated for the presence of endotoxins. 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 (TA022) is indicated for use only under supervision of a health care professional.

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

⚠️ WARNING!
Do not connect the USB cable during measurement, because the tonometer does not allow you to take any measurements when the USB is connected.

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

⚠️ WARNING!
No modification of this equipment is allowed.

⚠️ WARNING!
Use only the original and certified probes made by the manufacturer. The probes are for single-use (single pair of measurement sequences) only. 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!
Federal (US) law restricts this device to sale by or on the order of a physician or properly licensed practitioner.
**WARNING!**
The safety and effectiveness of the Icare HOME tonometer has not been evaluated for patients with:

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. High corneal astigmatism >3D
6. Disabling arthritis or limited motor coordination affecting self-handling of the Icare tonometer.
7. Lack of comprehension or willingness to use the tonometer as instructed.
8. Corneal scarring.
9. History of prior incisional glaucoma surgery or corneal surgery, including corneal laser surgery.
10. Microphthalmos.
12. Contact Lens Use
13. Dry eyes.
15. Nystagmus.
17. Central corneal thickness greater than 0.60mm or less than 0.50mm.
18. Age < 40 years old.

**NOTE!**
- 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’.
- 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 container for disposable needles).
- 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 your 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 you do not use it.
- Do not carry out any other service procedures. 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.

**2. INDICATIONS FOR USE**

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

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. High corneal astigmatism >3D
6. Disabling arthritis or limited motor coordination affecting self-handling of the Icare tonometer
7. Lack of comprehension or willingness to use the tonometer as instructed
8. Corneal scarring
9. History of prior incisional glaucoma surgery or corneal surgery, including corneal laser surgery
10. Microphthalmos
11. Buphthalmos
12. Contact Lens Use
13. Dry eyes
14. Blepharospasm
15. Nystagmus
16. Keratoconus
17. Central corneal thickness greater than 0.60mm or less than 0.50mm
18. Age < 40 years old

The Icare HOME tonometer is a prescription device intended for monitoring of intraocular pressure (IOP) of the human eye. It is indicated for use by patients or their caregivers under supervision of an eye care professional.
3. INTRODUCTION

The Icare HOME tonometer is a hand-held device for self-use. The great advantage is that a topical anesthetic is not needed.

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 for management of your glaucoma patients.

4. 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.

⚠️ NOTE!
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 and registration of the tonometer
- Patient guide
- Support position tags
- Warranty card
- Carrying case

5. BEFORE YOU START

Find the main parts, buttons and indicator lights of the tonometer in the below figures.
6. SETTING UP THE TONOMETER

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

6.1 INSTALLING OR CHANGING THE BATTERY

**NOTE!**
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 silicon lid that protects the USB port and keeps the battery compartment cover in place. Open the battery compartment cover by pressing the silicon lid slightly and sliding the battery compartment cover as shown in the figure left.

1. Silicon lid
2. 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 silicon lid in place to cover the USB port.

6.2 TURNING THE TONOMETER ON

**NOTE!**
The tonometer turns off automatically after 3 minutes if you do not use it.

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.

6.3 LOADING 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 (single pair of measurement sequences) only. 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 and wrapped in blister packs as shown in the figures left.
7. USING THE TONOMETER

7.1 CHOOSING THE MEASUREMENT MODE

The tonometer can operate in two modes:

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.

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).

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.
7.2 ADJUSTING THE MEASUREMENT POSITION

**WARNING!**
Do not bring the tonometer into contact with the eye or push it into the eye (the tip of the probe should be 4-8mm, or 5/32-5/16", from the eye).

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.

7.3 AUTOMATIC EYE RECOGNITION

**NOTE!**
Do not cover the eye recognition transmitters or sensor during the measurement, for example with your 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.
### 7.4 TAKING THE MEASUREMENTS

**WARNING!**
*Do not bring the tonometer into contact with the eye or push it into the eye (the tip of the probe should be 4-8mm, or 5/32-5/16", from the eye).*

The probe will make a gentle and brief contact with the eye when you take the measurement. No topical anesthetic is needed.

**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.

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.

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.

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.
9. Dispose of the used probe.
8. READING THE MEASUREMENT DATA

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/

9. 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 below the table.

<table>
<thead>
<tr>
<th>Error light</th>
<th>Error sound</th>
<th>Reason</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery</td>
<td>No.</td>
<td>Battery is soon empty.</td>
<td>Prepare to change batteries.</td>
</tr>
<tr>
<td>Battery light is flashing No.</td>
<td>Battery is empty.</td>
<td>Change batteries.</td>
<td></td>
</tr>
<tr>
<td>Probe base light is solid red. No.</td>
<td>Too much vertical tilt.</td>
<td>Press the measurement button again to clear the error message.</td>
<td>Position the tonometer horizontally so that the probe base light is green.</td>
</tr>
<tr>
<td>Probe base light is flashing red and Measure light turns off. Two long beeps.</td>
<td>a) Probe is too far from or too near the eye. b) Probe movement was not perpendicular to the cornea.</td>
<td>Press the measurement button again to clear the error message.</td>
<td>a) Set the correct distance 4-8mm (5/32-5/16&quot;) between the probe tip and the center of the cornea. b) Set the probe perpendicular to the center of the cornea.</td>
</tr>
<tr>
<td>Repeat light is flashing and Probe base light is flashing red. Two long error beeps.</td>
<td>a) Too much IOP deviation during the measurement, because the user did not keep the tonometer stable. b) Eye was not recognized.</td>
<td>Press the measurement button again to clear the error message.</td>
<td>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.</td>
</tr>
<tr>
<td>Service light is flashing and Probe base is flashing red. Two long beeps.</td>
<td>Incorrect or dirty probe or probe base.</td>
<td>Contact the seller to arrange sending the device for service.</td>
<td></td>
</tr>
</tbody>
</table>
10. ICARE HOME TONOMETER TRAINING PROCEDURES FOR CERTIFICATION OF HEALTH CARE PROVIDERS (HCP) AND CAREGIVERS

All health care providers and caregivers 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 or caregiver

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**

**HCP:**
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.

**CAREGIVER:**
6. Position the tonometer on another trainer's eye.
7. Ask the caregiver to observe and learn.
8. Load a new probe and ask the caregiver to position the tonometer on another trainer's eye and to take some measurements as instructed and demonstrated.
9. Observe and, if necessary, correct the position while the caregiver positions the tonometer, say to the caregiver that this is the correct position and ask the caregiver to try again.
10. Repeat 1-3 for up to ten times until the caregiver shows consistent device positioning.

**STEP 4 - Reference measurement**

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

**CAREGIVER:**
2. Load a new probe and carefully measure the IOP of another trainer once in each eye with the tonometer.
STEP 5 – Test measurement

HCP:
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.

CAREGIVER:
1. Load a new probe and ask the caregiver to measure IOP three times in each eye with the same tonometer on the same trainer used in the reference measurement. 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 7 mmHg or less.
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

CAREGIVER:

The Caregiver passes the training and is certified for performing tonometry on patients with 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 Caregiver differ by 5 mmHg or less.
b. The range (max-min) of the three readings taken by the Caregiver is 7 mmHg or less.
c. The positioning of the tonometer was correct during measurement as determined by the trainer.

Caregiver's name: __________________________ Date (dd mm yy): __________

CERTIFICATION □ 0 = Pass; 1 = Fail

11. 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.

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 and you hear two long error beeps, the tonometer needs service. At the same time the probe base light flashes red.
   - 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.

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
3. 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
12. CLEANING AND DISINFECTION

NOTE!
Do not carry out any other service procedures. Leave all other service and repairs to the manufacturer or a certified service center.

You must clean the forehead and cheek supports for each new patient. Use a wipe dampened with a 70% 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.

13. ACCESSORIES

<table>
<thead>
<tr>
<th>Part number</th>
<th>Product Description</th>
<th>Weight</th>
<th>Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>540</td>
<td>Probe base</td>
<td>4g</td>
<td>7 mm x 38 mm</td>
</tr>
<tr>
<td>TA022-001</td>
<td>Probe base collar</td>
<td>2g</td>
<td>20 mm x 15 mm</td>
</tr>
<tr>
<td>560</td>
<td>Wrist strap</td>
<td>3g</td>
<td>270 mm x 10 mm x 10 mm</td>
</tr>
<tr>
<td>TA022-044</td>
<td>Carrying case</td>
<td>210g</td>
<td>270 mm x 135 mm x 60 mm</td>
</tr>
<tr>
<td>7179</td>
<td>Battery cover</td>
<td>3g</td>
<td>26 mm x 23 mm x 7 mm</td>
</tr>
<tr>
<td>TA022-035</td>
<td>Patient guide</td>
<td>33g</td>
<td>210 mm x 90 mm x 2 mm</td>
</tr>
<tr>
<td>571</td>
<td>Battery 3 V, CR123A</td>
<td>17g</td>
<td>17 mm x 35 mm</td>
</tr>
<tr>
<td>TA022-037</td>
<td>Support position tags</td>
<td>40g</td>
<td>70 mm x 41 mm x 13 mm</td>
</tr>
<tr>
<td>575</td>
<td>USB cable</td>
<td>23g</td>
<td>1m</td>
</tr>
</tbody>
</table>

14. 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 (95% tolerance interval relatively to manometry): ±1,2 mmHg (<20 mmHg) and ±2,2 mmHg (≥20 mmHg).
Repeatability (coefficient of variation): < 8%.

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
15. SYMBOLS

- Caution
- Keep dry
- See operating instructions for more information
- Manufacturing date
- BF-type device
- Lot number
- Single-use disposable
- Sterilized using irradiation
- Stand by
- 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)
- Use by <date>
- Serial number
- Manufacturer

16. ELECTROMAGNETIC DECLARATION

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 - Electromagnetic emissions

<table>
<thead>
<tr>
<th>RF emissions CISPR 11</th>
<th>Group 1</th>
<th>Icare HOME is battery operated and use RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>Icare HOME 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.</td>
</tr>
</tbody>
</table>

### Guidance and manufacturer's declaration - Electromagnetic immunity

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment-Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>± 6 kV contact ± 8 kV air</td>
<td>Complies Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>Complies Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
<td></td>
</tr>
</tbody>
</table>
### Guidance and manufacturer’s declaration – Electromagnetic immunity

Icare HOME is intended for use in the electromagnetic environment specified below. The customer or the user of the Icare HOME should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment-Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Icare HOME, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td></td>
<td>80MHz to 2,5 GHz</td>
<td>3 V/m Portable and mobile RF communications equipment should be used no closer to any part of the Icare HOME, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
<td></td>
</tr>
</tbody>
</table>

**Recommended separation distance**

\[ d = \frac{1.2 \sqrt{P}}{ } \]

- For 80 MHz to 800 MHz
- For 800 MHz to 2,5 GHz

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

**NOTE 1** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Icare HOME is used exceeds the applicable RF compliance level above, the Icare HOME should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Icare HOME.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

### Recommended separation distances between portable and mobile RF communications equipment and Icare HOME

Icare HOME is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Icare HOME can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Icare HOME as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>0,01</td>
<td>0,12</td>
</tr>
<tr>
<td>0,1</td>
<td>0,38</td>
</tr>
<tr>
<td>1</td>
<td>1,2</td>
</tr>
<tr>
<td>10</td>
<td>3,8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance can be estimated using the equation applicable to the frequency of the transmitter, where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.