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www.icaretonometer.com
INDICATIONS FOR USE

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

INTRODUCTION

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

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

SAFETY INSTRUCTIONS

⚠️ WARNING
The tonometer must not come into contact with the patient’s eyes, except for the probes, which may do so for a fraction of a second during measurement. Do not bring the tonometer into contact with the eye or push it into the eye (the tip of the probe should be 4-8mm, or 1/6 – 1/3 inch, from the eye).

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

⚠️ WARNING
Never spray, pour or spill liquid onto the Icare tonometer, its accessories, connectors, switches or openings in the chassis. Dry any liquid on the surface of the tonometer immediately.

⚠️ WARNING
Use of any accessories and cables other than those specified in the manufacturer’s documentation, with the exception of cables sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the Icare TA01i tonometer.

⚠️ WARNING
Use of any accessory or cable with the Icare TA01i tonometer other than those specified may result in increased emissions or decreased immunity of the Icare TA01i tonometer.

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

Retain this manual for future use.
When you have opened the package, check for any external damage or faults, particularly for damage to the case. If you suspect that there is something wrong with the tonometer, contact the manufacturer or distributor.
Use the tonometer only for measuring intraocular pressure. Any other use is improper and the manufacturer cannot be held liable for any damage arising from improper use, or for the consequences thereof.
Never open the casing of the tonometer, except for the battery compartment or to change the probe base.
This manual contains instructions for replacing batteries and changing the probe base.
Never use the tonometer in wet or damp conditions.
The probe base, battery compartment cover, screws, collar and probes are so small that a child could swallow them. Keep the tonometer out of the reach of children.
Do not use the device near inflammable substances, including inflammable anesthetic agents.
Prior to each measurement, check that a new disposable probe from an intact package is being used.
Be sure that the probe contains the small plastic round tip in front.
Certain microbiological agents (e.g. bacteria) can be transmitted from the forehead support.
To avoid this, the forehead support should be cleaned regularly with a disinfectant, e.g. an alcohol solution.
The tonometer conforms to EMC requirements (IEC 60101-1-2: 2001), but interference may occur in it if used near (<1m) a device (such as a cellular phone) causing high-intensity electromagnetic emissions. Although the tonometer’s own electromagnetic emissions are well below the levels permitted by the relevant standards, they may cause interference in other, nearby devices, e.g. sensitive sensors.
If the device is not to be used for a long time, we recommend that you remove its AA batteries, since they may leak. Removing the batteries will not affect the subsequent functioning of the tonometer.
Be sure to dispose of the single-use probes properly (e.g. in a container for disposable needles), because they may contain micro-organisms from the patient.
Batteries, packaging materials and probe bases must be disposed of according to local regulations.
To obtain firm support for the patient’s forehead, in order to obtain an accurate measurement at the right distance, you can adjust the forehead support by turning the forehead support adjusting wheel.

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

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

PARTS OF THE TONOMETER

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

TURNING THE TONOMETER ON AND LOADING THE PROBE

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

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

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

Load the probe in the following way:

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

MEASUREMENT

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

Ask the patient to relax and look straight ahead at a specific point. Bring the tonometer near the patient’s eye. The central groove should be in a horizontal position, and the distance from the eye to the front part of the collar should be the length of the collar. In other words, the distance from the tip of the probe to the patient’s cornea (see picture) should be 4-8 mm (1/6-1/3 inch).
If necessary, adjust the distance by turning the forehead support adjusting wheel. Press the measurement button lightly to perform the measurement, taking care not to shake the tonometer. The tip of the probe should make contact with the central cornea. Six measurements are made consecutively. After each successful measurement, you will hear a short beep. Once the six measurements have been performed, the IOP will be shown on the display after the ‘P’.

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

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

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

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


**DISPLAY AFTER MEASUREMENTS**

<table>
<thead>
<tr>
<th>Before</th>
<th>After the second measurement</th>
<th>After the sixth measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>00</td>
<td>2.13</td>
<td>P 13</td>
</tr>
</tbody>
</table>

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

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

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

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

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

**OTHER FUNCTIONS**

**Accessing old measurement value**

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

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

**Turning the tonometer OFF**

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

**Error messages**

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

**DIAGRAM OF TONOMETER FUNCTIONS**

- **Tonometer On:** Ready for measurement
- **Old value recall**
- **Turning Off:**
- **Measurement button (measure, confirm)**
- **Selector button (left and right)**

**TECHNICAL INFORMATION**

Type: TA01i.
The device conforms to CE regulations.
Dimensions: 13 – 32 mm (W) * 45 – 80 mm (H) * 230 mm (L).
Weight: 155 g (without batteries), 250 g (4 x AA batteries).
Power supply: 4 x AA non-rechargeable batteries (e.g. alkaline).
Measurement range: 7-50 mmHg, display range: 0-99 mmHg (IOP estimation beyond the measuring range).
Accuracy (95 % tolerance interval relative to manometry): ±1.2 mmHg (≤20 mmHg) and ±2.2 mmHg (>20 mmHg).
Repeatability (coefficient of variation): <8 %.
Accuracy of display: 1.
Display unit: Millimeter mercury (mmHg).
The serial number is on the back of the battery compartment cover.
There are no electrical connections from the tonometer to the patient.
The device has B-type electric shock protection.
Operation environment:
- Temperature: +10 °C to +35 °C
- Relative humidity: 30 % to 90 %
- Atmospheric pressure: 800 hPa-1,060 hPa
Storage environment:
- Temperature: -10 °C to +55 °C
- Relative humidity: 10 % to 95 %
- Atmospheric pressure: 700 hPa-1,060 hPa
Transport environment:
- Temperature: -40 °C to +70 °C
- Relative humidity: 10 % to 95 %
- Atmospheric pressure: 500 hPa-1,060 hPa
Mode of operation: continuous.
PERFORMANCE DATA

The performance data is obtained from a clinical study, performed according to American National Standard ANSI Z80.10-2003 and International Standard ISO 8612-2 for tonometers. The study was performed in the Department of Ophthalmology, Helsinki University Central Hospital. In the study, 158 patients were measured. The mean paired difference and standard deviation (Goldmann-icare) were -0.4 mmHg and 3.4 mmHg. A scattergram and Bland-Altman plot of the results is shown below.

ACCESSORIES

<table>
<thead>
<tr>
<th>SKU</th>
<th>PRODUCT DESCRIPTION</th>
<th>WEIGHT</th>
<th>DIMENSIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>104</td>
<td>BOX OF 100 PROBES</td>
<td>89,10 g</td>
<td>5,3 x 10,3 x 3,6 cm</td>
</tr>
<tr>
<td>102</td>
<td>BOX OF 100 PROBES (ONLY USA)</td>
<td>89,10 g</td>
<td>5,3 x 10,3 x 3,6 cm</td>
</tr>
<tr>
<td>7210</td>
<td>PROBE BASE COLLAR</td>
<td>1g</td>
<td>11 mm x 10 mm</td>
</tr>
<tr>
<td>540</td>
<td>PROBE BASE</td>
<td>4g</td>
<td>7 mm x 38 mm</td>
</tr>
<tr>
<td>550</td>
<td>TABLE STAND</td>
<td>52g</td>
<td>73 mm x 52 mm x 38 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>500</td>
<td>ALUMINIUM CASE</td>
<td>700g</td>
<td>240 mm x 280 mm x 72 mm</td>
</tr>
<tr>
<td>7171</td>
<td>BATTERY COVER &amp; SCREW</td>
<td>4g</td>
<td>42 mm x 17 mm x 13 mm</td>
</tr>
<tr>
<td>7000</td>
<td>THREAD PLATE</td>
<td>1g</td>
<td>4 mm x 10 mm x 3 mm</td>
</tr>
<tr>
<td>543</td>
<td>PROBE BASE CLEANING CONTAINER</td>
<td>3g</td>
<td>5,6 cm x 2 cm</td>
</tr>
<tr>
<td>561</td>
<td>SILICON GRIP - WHITE</td>
<td>26g</td>
<td>135 mm x 46 mm x 23 mm</td>
</tr>
<tr>
<td>562</td>
<td>SILICON GRIP - PINK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>563</td>
<td>SILICON GRIP - GREEN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>564</td>
<td>SILICON GRIP - BLUE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MAINTENANCE

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

⚠️ WARNING

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

Replace the probe base every twelve months. Clean or replace the probe base if the error messages E01 or E03 are displayed.

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.

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 error messages E01 or E03 are displayed.

Instructions for cleaning the probe base:
- Fill the probe base cleaning container or other clean container with 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.
- Insert the probe base into the tonometer.
- Screw the collar in, to lock the probe base.

Cleaning the tonometer

⚠️ WARNING
Never spray, pour or spill liquid onto the Icare tonometer, its accessories, connectors, switches or openings in the chassis. Dry any liquid on the surface of the tonometer immediately.

Icare TA01’s surfaces have been tested and found chemically resistant to the following liquids:
- 100 % 2-propanol
- Mild soap solution
- 95% Pursept solution

Cleaning instructions for surfaces:
- Turn the power off.
- Dampen a soft cloth with one of the liquids mentioned above.
- Lightly wipe the surfaces of the tonometer with the soft cloth.
- Dry the surfaces with a dry soft cloth.

Replacing the batteries

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

Remove the battery compartment cover. Remove the old batteries.

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

Replace the battery compartment cover and secure it by screwing it in lightly using the coin or screwdriver. Take care not to use excessive force when screwing the cover into place.
Returning the Icare tonometer for servicing /repair

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

Periodic Safety Checks

We recommend that the following checks be performed every 24 months.

- Equipment inspection for mechanical and functional damage.
- Inspection of safety labels for legibility.

Applicable in Germany only: Messtechnische Kontrolle nach MPG (Medizinproduktegesetz) alle 24 Monate.

PATENTS AND COPYRIGHTS

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

SYMBOLS

- **Attention!!! See instructions**
- **LOT**
- **Serial number**
- **Manufacturing date**
- **Single use only**
- **Sterilized using radiation**
- **B-type device**
- **Keep dry**
- **Manufacturer**
- **Storage environment**
- **Transport environment**

ELECTROMAGNETIC DECLARATION

**WARNING**

Use of any accessories and cables other than those specified in the manufacturer’s documentation, with the exception of cables sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the Icare TA01i tonometer.

**WARNING**

Use of any accessory or cable with the Icare TA01i tonometer other than those specified may result in increased emissions or decreased immunity of the Icare TA01i tonometer.
TA01i is class B equipment and needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in user and maintenance manual.

<table>
<thead>
<tr>
<th>Guidance and manufacturer’s declaration-Electromagnetic emissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>TA01i is intended for use in the electromagnetic environment specified below. The user of the TA01i should assure that it is used in such an environment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
</tr>
<tr>
<td>Harmonic emissions</td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
</tr>
<tr>
<td>Voltage fluctuations flickering emissions</td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guidance and manufacturer’s declaration-Electromagnetic immunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Icare TA01i is intended for use in the electromagnetic environment specified below. The customers or users of Icare TA01i should assure that it is used in such environment</td>
</tr>
<tr>
<td>Immunity test</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Electrostatic discharge (ESD)</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
</tr>
<tr>
<td>Electrical fast Transients/burst</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
</tr>
<tr>
<td>Surge</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
</tr>
<tr>
<td>Voltage dips, short interruption and voltage variations on power supply lines</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
</tr>
</tbody>
</table>
Guidance and manufacturer's declaration – electromagnetic immunity

Icare TA01i is intended for use in the electromagnetic environment specified below. The customer or the user of the Icare TA01i 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 IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3V/m</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Icare TA01i, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Conducted RF IEC 61000-4-6</td>
<td>3Vrms 150 kHz to 80 MHz</td>
<td>NOT APPLICABLE</td>
<td></td>
</tr>
</tbody>
</table>

Recommended separation distance

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

where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and \( d \) is the recommended separation distance in metres (m).

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:

![Radio Wave 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 TA01i is used exceeds the applicable RF compliance level above, the Icare TA01i 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 TA01i.

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

Recommended separation distances between portable and mobile RF communications equipment and Icare TA01i

Icare TA01i is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Icare TA01i can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Icare TA01i 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 800 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 \( d \) in metres (m) 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.