Icare® PRO (Model: TA03) INSTRUCTION MANUAL TA03-003 EN-3.0
The information in this document is subject to change without prior notice.
In a conflict situation the English version prevails.

**TABLE OF CONTENTS**

1. SAFETY INSTRUCTIONS ................................................................................................................4
2. INDICATIONS FOR USE ..................................................................................................................5
3. INTRODUCTION ..............................................................................................................................6
4. PACKAGE CONTENTS ........................................................................................................................6
5. BEFORE USE ......................................................................................................................................7
6. SETTING UP THE TONOMETER BEFORE TAKING MEASUREMENTS ...........................................7
   6.1 TURNING THE TONOMETER ON ..................................................................................................8
   6.2 NAVIGATING ................................................................................................................................8
   6.3 LOADING THE PROBE .................................................................................................................8
   6.4 ADJUSTING THE MEASUREMENT POSITION ..............................................................................9
7. MEASURING INTRAOCULAR PRESSURE (IOP) .................................................................................9
   7.1 RESULTS ......................................................................................................................................10
   7.2 SETTINGS .....................................................................................................................................11
   7.3 MEASUREMENT HISTORY ...........................................................................................................12
8. TROUBLESHOOTING .......................................................................................................................12
9. REPLACING THE PROBE BASE .....................................................................................................13
10. CLEANING THE PROBE BASE ......................................................................................................13
11. CLEANING THE TONOMETER ......................................................................................................14
12. PERIODIC SAFETY CHECK .............................................................................................................14
13. MAINTENANCE ..................................................................................................................................14
14. CHARGING THE BATTERY ..............................................................................................................15
15. ACCESSORIES ...............................................................................................................................16
16. TECHNICAL DATA ..........................................................................................................................16
17. CLINICAL PERFORMANCE DATA ...............................................................................................17
18. SYMBOLS .......................................................................................................................................18
19. ELECTROMAGNETIC DECLARATION ..............................................................................................19
This device complies with:
Medical Device Directive 93/42/EEC
Canadian Medical Device Regulations

Copyright © 2015 Icare Finland Oy
Made in Finland

Icare Finland Oy
Äyritie 22, FI-01510 Vantaa, Finland
Tel. +358 9 8775 1150, Fax +358 9 728 6670
www.icaretonometer.com, info@icarefinland.com
1. SAFETY INSTRUCTIONS

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

⚠️ WARNING!
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 – 9/32 of an inch, from the eye).

⚠️ WARNING!
To prevent contamination, avoid touching it directly.

⚠️ 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!
Do not connect the USB cable during measurement.

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

⚠️ WARNING!
The probes are for single use only. Use probes taken only from the original, intact packaging. The manufacturer cannot guarantee the sterility of the probe once the seal is compromised. Re-sterilization or re-use of the probe could result in incorrect measurement values or in the breakdown of the probe and will void all of Icare Finland Oy’s responsibilities and liabilities related to the safety and effectiveness of the device.

⚠️ WARNING!
Do not touch the USB cable terminal and patient simultaneously.

⚠️ WARNING!
When using a PC to charge your Icare PRO, keep both the PC and Icare PRO 1.5m/5 ft. or more from the patient.

⚠️ WARNING!
No modification of this equipment is permitted.

⚠️ WARNING!
The probe base, screws, collar and probes are small enough to be swallowed by a child. Keep the tonometer out of the reach of children.
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 PRO (TA03) tonometer.

WARNING!
Use of any accessory or cable with the Icare PRO (TA03) tonometer other than those specified may result in increased emissions or decreased immunity of the Icare PRO (TA03) tonometer.

NOTE!
- When you have opened the package, check for any external damage or flaws, 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 is not responsible for any damage arising from improper use, or for the consequences thereof.
- Never open the casing of the tonometer except in order to change the probe base.
- Do not use the device near inflammable substances, including inflammable anesthetics.
- Certain microbiological agents (for example, bacteria) can be transmitted from the forehead support. To avoid this, clean the forehead support for each new patient with disinfectant; see the chapter ‘Cleaning the tonometer’.
- The tonometer conforms with EMC requirements (IEC 60601-1-2), but interference may occur if it is used near (<1m) a device (such as a cellular phone) which gives off 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, such as sensitive sensors.
- Be sure to dispose of the single-use probes properly (for example, in a container for disposable needles), because they may contain microorganisms transferred from the patient.
- Dispose of the device, components and accessories in accordance with the applicable local regulations.
- If you do not use the tonometer when it is switched on, it will turn off automatically after 3 minutes.
- No anesthetic is required when performing measurements.

2. INDICATIONS FOR USE

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

- Only one functional eye.
- Poor or eccentric fixation in one eye.
• High corneal astigmatism (i.e. in the case of eyes for which an oval contact image is displayed when examined using the Goldmann tonometer).
• Corneal scarring.
• A history of incisional glaucoma surgery or corneal surgery, including corneal laser surgery.
• Microphthalmos.
• Buphthalmos.
• Contact lenses.
• Dry eyes.
• Squeezed lids (blepharospasm).
• Nystagmus.
• Keratoconus.
• Any other corneal or conjunctival pathology or infection.
• A central corneal thickness greater than 0.600 mm or less than 0.500 mm

The Icare PRO tonometer is a prescription-based device intended for measuring intraocular pressure (IOP) in the human eye. It is indicated for use by health care professionals.

3. INTRODUCTION

The Icare PRO tonometer is a hand-held device. It uses a small and light single-use probe that makes contact with the eye very briefly, removing the need for a topical anesthetic.

The Icare PRO tonometer allows you to measure supine patients and patients in a normal upright (sitting/standing) position.

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 onto the cornea and back during each measurement. As a result, after six measurements the tonometer calculates the final IOP and stores it with other information, such as the date, time, eye identification (right or left) and measurement quality, in the tonometer’s memory.

The Icare PRO tonometer records and displays over one thousand measurement results, their times and dates as well as quality information associated with the measurement. You can copy the recorded measurement information onto a PC via a USB cable.

4. PACKAGE CONTENTS

⚠️ WARNING!
The probe base, screws, collar and probes are small enough to be swallowed by a child. Keep the tonometer out of the reach of children.
NOTE!
When you have opened the package, check for any external damage or flaws, particularly for damage to the case. If you suspect that there is something wrong with the tonometer, contact the manufacturer or distributor.

The package contains:
- An Icare PRO tonometer
- A USB cable for connecting to a PC onto which the Icare LINK software has been installed
- A copy of the Icare LINK software on a USB memory stick
- A table stand for holding the Icare PRO at rest on a table and protecting the probe base from dust
- A USB charger
- An additional probe base with a probe holder
- 100 sterilized single use probes in a box
- An instruction manual on the USB memory stick
- A warranty certificate
- Instructions for downloading LINK software and registration of the device
- An aluminum case
- A probe base cleaning container

5. BEFORE USE

Read this manual carefully before starting to use the tonometer. Locate the main parts and buttons of the tonometer in the picture below.

6. SETTING UP THE TONOMETER BEFORE TAKING MEASUREMENTS

Before taking measurements, your tonometer must be set up correctly. Set-up includes:
- Turning the tonometer on
- Loading the probe
• Adjusting the measurement position

6.1 TURNING THE TONOMETER ON

Press the main button (7) 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

6.2 NAVIGATING

The tonometer has navigation buttons (5) and a main button (7) for navigating through the menus. Each navigation button has a light that switches on when the navigation button is active for use. If you wish to return to the previous menu and there is no ‘Back to menu’ item in the menu, use the left navigation button.

6.3 LOADING THE PROBE

⚠️ WARNING!
To prevent contamination, avoid touching the probe directly.

The Icare PRO tonometer uses single-use tonometer probes. These probes are contained in blister packs, as shown in the figure on the right.

To load the probe:

1. Go to Measure and press the main button. The message ‘Insert new probe’ will be displayed.
2. Partially open the probe blister pack.
3. Insert the probe into the tonometer from the partially opened pack, without touching the probe.
4. Keeping the probe with its partially opened pack between your index finger and thumb, lightly press the probe into the probe base until you feel it stop and lock. Be careful not to bend the probe. Tilt the unit backwards and forwards, to check that the probe has been correctly inserted.
5. Go to Measure and press the main button (7) once to activate the inserted probe. During activation, the device will magnetize the probe (the probe will move rapidly backwards and forwards). Once you have activated the probe, the tonometer will be ready to perform measurements.
6.4 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 3–7 mm, or 1/8 – 9/32 of an inch, from the eye).

⚠️ NOTE!
If you do not use the tonometer when it is switched on, it will turn off automatically after 3 minutes.

The Icare PRO tonometer allows measurements to be performed on supine patients and patients in a normal upright (sitting/standing) position. To adjust the position of the patient:

1. Ask the patient to look straight ahead with both eyes open and keeping his or her chin in a horizontal position.

2. To ensure that the measurements are correct, keep the probe as perpendicular to the center of the cornea as possible.

3. If you need to correct the position of the patient, the device will display an error message.

4. The tonometer has an adjustable forehead support to ensure that the measurement distance and alignment are correct. Adjust the forehead support using the adjustment wheel, so that the distance from the tip of the probe to the surface of the cornea is 3-7mm (1/8 – 9/32 of an inch).

5. When you are measuring the intraocular pressure of a supine patient, the probe will not drop because the tonometer will hold the probe in place. Once the probe is in the right position, an arrow will appear on the display indicating that the position of the probe is sufficiently vertical for the performance of a successful measurement.

7. MEASURING INTRAOCULAR PRESSURE (IOP)

A measurement sequence is a series of six measurements.

⚠️ NOTE!
No anesthetic is required when performing measurements.

⚠️ NOTE!
If you do not use the tonometer, it will switch off automatically after 3 minutes.
To measure intraocular pressure:

1. Check that the tonometer is set up correctly.

2. Go to **Menu → Measure** and press the main button. Use the left and right navigation buttons to select the eye you want to measure and press the main button to confirm.

3. Tell the patient to relax and look straight ahead at a specific point while keeping his or her 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 – 9/32 of an inch), as shown in the figure on the right. If necessary, adjust the distance using the forehead support. Keep the probe perpendicular to the center of the cornea.

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 will sound after each measurement and the device will display a reading.

6. Repeat step 5 six times. Once the six measurements are complete, the device will display the final IOP reading.

7. Press the main button.

8. Choose YES to continue measuring the other eye of the same patient. Use the navigation button to select the eye you want to measure and then press the main button (OD/OS).

9. If you do not want to continue measuring, choose NO. You can turn off the device from the main menu, or leave it idle.

### 7.1 RESULTS

The device displays the reading after each measurement within the series of six as an average of the measurements taken until then. The reading shown after the sixth measurement is an average of four readings calculated after discarding the highest and lowest reading.

The device displays a color and a text indication of the reliability of the IOP reading. If the deviation between measurements is within normal limits, the color will be green and the text will read ‘Deviation: OK’. If the deviation is slightly high, the reliability indication color will be yellow and the text will read ‘Deviation: DEVIATION’. If the deviation is high, the color will be red and the text will read ‘Deviation: REMEASURE’. The table below explains each reliability indication.
<table>
<thead>
<tr>
<th>DISPLAYED TEXT</th>
<th>DISPLAYED COLOR</th>
<th>DEVIATION</th>
<th>DESCRIPTION</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deviation: OK.</td>
<td>Green.</td>
<td>&lt; 15 % of the IOP.</td>
<td>No or insignificant deviation.</td>
<td>-</td>
</tr>
<tr>
<td>Deviation: DEVIATION.</td>
<td>Yellow.</td>
<td>15-25 % of the IOP.</td>
<td>Slight deviation; the effect of the deviation is unlikely to be relevant to the result unless the IOP is 19 or higher.</td>
<td>If the IOP is 19 or higher, take a new measurement.</td>
</tr>
<tr>
<td>Deviation: REMEASURE.</td>
<td>Red.</td>
<td>&gt;25 % of the IOP.</td>
<td>The deviation is too high.</td>
<td>Take a new measurement.</td>
</tr>
</tbody>
</table>

### 7.2 SETTINGS

Use the Settings menu to change the tonometer’s settings. To access the settings, go to **Menu → Settings** and press the main button to confirm.

**Brightness** - Change the display brightness
Increase or decrease the brightness using the up/down navigation buttons and press the main button to confirm.

**Volume** - Turn the tonometer sounds on or off
Select on or off using the left/right navigation buttons and press the main button to confirm. If the sound is off you will not hear the beep.

**Date** - Set the date
1. Select the month/day/year you want to change, by using the left/right navigation buttons.
2. Change the month/day/year, by 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, by using the left/right navigation buttons.
2. Change the hour/minute/second, by using the up/down navigation buttons.
3. Press the main button to confirm.
About – Shows the serial number of and software version in your Icare PRO tonometer.

7.3 MEASUREMENT HISTORY

The history contains the results of previous measurements.

To access the measurement history:
1. Go to **Menu --> History** and press the main button to confirm. You will see the most recent measurement.
2. View the previous/next measurements by using the up/down navigation buttons.
3. Press the left/right/main button to return to the menu.

8. TROUBLESHOOTING

The tonometer automatically monitors and controls the measurement position and speed of the probe during measurements, and uses messages and signals to indicate errors. The following table contains instructions to be followed in error situations.

<table>
<thead>
<tr>
<th>Error message</th>
<th>Error signal</th>
<th>Reason</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Incorrect hit!" /></td>
<td>Two short beeps.</td>
<td>The probe did not make clean contact with the cornea, because the probe hit an eyelid or eyelashes.</td>
<td>Ensure that the eye is open, press the main button to clear the message and measure again.</td>
</tr>
<tr>
<td><img src="image" alt="Distance was too long!" /></td>
<td>Two short beeps.</td>
<td>The distance between the probe and the cornea was too great or the probe did not make contact with the cornea at all.</td>
<td>Ensure that the distance is 3-7 mm, press the main button to clear the message and measure again.</td>
</tr>
<tr>
<td><img src="image" alt="Distance was too short!" /></td>
<td>Two short beeps.</td>
<td>There was too little distance between the probe and the cornea.</td>
<td>Ensure the distance is 3-7 mm, press the main button to clear the message and measure again.</td>
</tr>
<tr>
<td><img src="image" alt="Incorrect position!" /></td>
<td>Two short beeps.</td>
<td>The tonometer was tilted too much.</td>
<td>Position the probe so that it is perpendicular to the center of the cornea, press the main button to clear the message and measure again.</td>
</tr>
<tr>
<td>Two short beeps.</td>
<td>The probe did not move correctly or did not move at all, because the probe and/or probe base is dirty, bent or twisted.</td>
<td>Check that the probe and probe base are intact. Press the main button to clear the message and measure again. If the error repeats, follow the instructions in sections 9 and 10.</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Two short beeps.</td>
<td>The battery is low.</td>
<td>Re-charge.</td>
<td></td>
</tr>
<tr>
<td>Two short beeps.</td>
<td>The probe continuously fails to move smoothly or stops moving, because the probe and/or probe base is dirty, bent or twisted.</td>
<td>Follow the instructions in section 9, press the main button to clear the message and measure again.</td>
<td></td>
</tr>
</tbody>
</table>

### 9. REPLACING THE PROBE BASE

Replace the probe base and probe holder every six months. Replace or clean the probe base if the tonometer displays the probe base error ‘Probe didn’t move properly’.

Instructions for replacing the probe base and probe holder:
- Turn off the tonometer.
- Unscrew the probe base collar and put it in a safe place.
- Remove the probe base and the probe holder by tilting the tonometer downwards and use your fingers to pull the probe base and the probe holder out of the tonometer.
- Lay the tonometer on a table, the probe base and forehead support facing up.
- Carefully without twisting, insert a new probe base and probe holder into the tonometer.
- Carefully without twisting the probe base, screw the collar back in, in order to lock the probe base.

### 10. CLEANING THE PROBE BASE

You can reuse the probe base after careful cleaning. Clean the probe base every three months. Clean or replace the probe base if the tonometer displays the probe base error ‘Probe didn’t move properly’.

Instructions for cleaning the probe base:
11. 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 PRO’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.

12. PERIODIC SAFETY CHECK

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

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

13. MAINTENANCE

Only the manufacturer or a certified service center can carry out any service and repairs other than those mentioned above. Before sending the device for servicing, make sure that you have stored your measurement data in a PC onto which LINK software has been installed.
14. CHARGING THE BATTERY

When the battery is low, an error message will indicate that you must recharge the battery. A full charge takes approximately one hour. If a green light is blinking on the upper navigation button, this means that the tonometer is charging. When the green light is constant, the device is completely charged. There are four alternative ways of charging the battery:

1. Connect the USB cable between the Icare PRO and the charger. Select a suitable plug from the alternatives and attach it to the charger. Connect the charger to the mains. When charging is complete, disconnect the charger from the mains.

2. If you have the optional docking station, use the USB cable to connect the USB charger to the docking station. Insert the Icare PRO into the docking station. Connect the charger to the mains. When the Icare PRO is completely charged, disconnect the charger from the mains.

3. Turn on a PC that has the Icare LINK software installed and running. Keep the PC and Icare PRO 1.5 m or more away from the patient. Use the USB cable to connect the Icare PRO to the PC, in order to charge the Icare PRO using the PC.

4. Turn on a PC that has the Icare LINK software installed and running. Use the USB cable to connect the optional docking station to the PC. Keep the PC and Icare PRO 1.5 m or more away from the patient. Insert the Icare PRO into the docking station to begin charging it using the PC.
15. ACCESSORIES

<table>
<thead>
<tr>
<th>Part number</th>
<th>Product Description</th>
<th>Weight</th>
<th>Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>542</td>
<td>Probe base + probe holder</td>
<td>4g</td>
<td>7 mm x 34 mm</td>
</tr>
<tr>
<td>7215</td>
<td>Probe base collar</td>
<td>1g</td>
<td>14 mm x 12 mm</td>
</tr>
<tr>
<td>572</td>
<td>Docking station</td>
<td>900g</td>
<td>190 mm x 120 mm x 50 mm</td>
</tr>
<tr>
<td>573</td>
<td>Micro USB charger</td>
<td>118g</td>
<td>Charger Unit: 58 mm x 37 mm x 44 mm US/Japan: 30 mm x 40 mm x 26 mm EU: 37 mm x 40 mm x 44 mm Australia: 40 mm x 33 mm UK: 47mm x 50 mm x 36 mm</td>
</tr>
<tr>
<td>575</td>
<td>USB cable</td>
<td>23g</td>
<td>1 m</td>
</tr>
<tr>
<td>520</td>
<td>Aluminum case</td>
<td>1050g</td>
<td>335 mm x 265 mm x 90 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>120</td>
<td>Probe box</td>
<td>9g</td>
<td>10,1 cm x 4,6 cm x 1,5 cm</td>
</tr>
</tbody>
</table>

16. TECHNICAL DATA

- Type designation 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 internal polymer Li-ion battery 3.7V 480mAh. Up to 500 measurements can be made with a fully charged battery.
- Measurement range: 5-50 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 between the tonometer and the patient
- The device has BF-type electric shock protection
- Charger input 100-240 V ~50/60 Hz 300 mA, Output 5.0 V=1,200 mA
- 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
17. CLINICAL PERFORMANCE DATA

Performance data was obtained from a clinical study, performed in accordance with the ISO 8612 standard for tonometers. It was estimated that the reference tonometer had an effect of close to one on the Icare PRO tonometer value; the coefficient of determination is $R^2 = 0.890$. The mean of the paired difference (Goldmann-Icare PRO tonometer) was 0.0 (≤16 mmHg 0.4; >16<23 -0.4; ≥23 -0.3) and the standard deviation was 2.7.

![Scatterplot of IOP values of test tonometer against the IOP values of Goldmann reference tonometer](image1)

Regression Equation:

$IOP_{PRO} = -0.02764 + 1.09895 * IOP_{GAT}$

![Bland–Altman plot for IOP values of Goldmann—tonometer vs. Icare Pro—tonometer](image2)

Reproducibility Count:

- 1
each other
18. SYMBOLS

See operating instructions for more information.

Manufacturing date

Lot number

BF-type device

Sterilized using irradiation

Single-use disposable

Stand by

Serial number

Do not dispose of in household waste.

Use by <date>

Manufacturer

Keep dry

Warning

Storage environment

Transport environment
19. 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 PRO (TA03) tonometer.

⚠️ WARNING!
Use of any accessory or cable with the Icare PRO (TA03) tonometer other than those specified may result in increased emissions or decreased immunity of the Icare PRO (TA03) tonometer.

Icare PRO (TA03) is class BF-type equipment and needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in user manual.

<table>
<thead>
<tr>
<th>Guidance and manufacturer’s declaration—Electromagnetic emissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Icare PRO (TA03) is intended for use in the electromagnetic environment specified below. The user of the Icare PRO (TA03) should assure that it is used in such an environment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RF emissions CISPR 11</th>
<th>Group 1</th>
<th>Icare PRO (TA03) is battery operated and uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>Icare PRO (TA03) 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>
<tr>
<td>Harmonic emissions</td>
<td>NOT APPLICABLE</td>
<td>Power level of Icare PRO (TA03) is below standard requirement</td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>flickering emissions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Guidance and manufacturer’s declaration—Electromagnetic immunity

Icare PRO (TA03) is intended for use in the electromagnetic enivironment specified below. The customers or users of Icare PRO (TA03) should assure that it is used in such enviroment
<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>± 6 kV contact ± 8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%</td>
</tr>
<tr>
<td>Electrical fast Transients/burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>NOT APPLICABLE</td>
<td>Icare PRO (TA03) tonometer is not operational when connected to an external power supply</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV for line(s) to line(s) ±2 kV for line(s) to earth</td>
<td>NOT APPLICABLE</td>
<td>Icare PRO (TA03) tonometer is not operational when connected to an external power supply</td>
</tr>
<tr>
<td>Voltage dips, short interruption and voltage variations on power supply lines IEC 61000-4-11</td>
<td>&lt;5 % $U_T$ (&gt;95 % dip in $U_T$) for 0,5 cycle 40 % $U_T$ (60 % dip in $U_T$) for 5 cycles 70 % $U_T$ (30 % dip in $U_T$) for 25 cycles &lt;5 % $U_T$ (&gt;95 % dip in $U_T$) for 5 s</td>
<td>NOT APPLICABLE</td>
<td>Icare PRO (TA03) tonometer is not operational when connected to an external power supply</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
### Guidance and manufacturer’s declaration – Electromagnetic immunity

Icare PRO (TA03) is intended for use in the electromagnetic environment specified below. The customer or the user of the Icare PRO (TA03) 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 80MHz to 2,5 GHz</td>
<td>3V/m</td>
</tr>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3Vrms 150 kHz to 80 MHz</td>
<td>NOT APPLICABLE</td>
</tr>
</tbody>
</table>

Portable and mobile RF communications equipment should be used no closer to any part of the Icare PRO (TA03), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

**Recommended separation distance**

\[
d = 1.2 \sqrt{P} \\
d = 1.2 \sqrt{P} 80 \text{ MHz to } 800 \text{ MHz} \\
d = 2.3 \sqrt{P} 800 \text{ MHz to } 2.5 \text{ GHz}
\]

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:

\[\begin{array}{c}
\text{Radiated RF} \\
\text{Conducted RF}
\end{array}\]

**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 PRO (TA03) is used exceeds the applicable RF...
compliance level above, the Icare PRO 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 PRO (TA03).

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 PRO (TA03)

Icare PRO (TA03) is intended for use in an electromagnetic environment in which radiated RF-disturbances are controlled. The customer or the user of the Icare PRO (TA03) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Icare PRO (TA03) 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>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td>800 MHz to 2,5 GHz</td>
</tr>
<tr>
<td>$d = 1.2 \sqrt{P}$</td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td>$d = 2.3 \sqrt{P}$</td>
<td></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>
<tr>
<td>100</td>
<td>23</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.