TONOMETER

Icare® ic100

INSTRUCTION MANUAL TA011-047 EN-1.2

The information in this document is subject to change without prior notice. In a conflict situation the English version prevails.

This device complies with:
Medical Device Directive 93/42/EEC
Canadian Medical Device Regulations
RoHS Directive 2011/65/EU

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Made in Finland

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SAFETY INSTRUCTIONS

WARNING
The tonometer must not come into contact with the patient’s eyes, except for the probes, which may do so for a fraction of a second during measurement. Do not push the tonometer 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 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.

WARNING
Never immerse the Icare tonometer, 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 other than those specified in the manufacturer’s documentation, with the exception of items sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the Icare ic100 tonometer.

WARNING
Use of any accessory with the Icare ic100 tonometer other than those specified may result in increased emissions or decreased immunity of the Icare ic100 tonometer.

WARNING
Use only the original and certified probes made by the manufacturer. The probes are for single-use (one per testing session) 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.

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

Retain this manual for future use.
Do not use anesthetic to numb the eye, because no anesthetic is required when performing measurements and anesthetic can affect the measurement results.
If you do not use the tonometer, it will switch off automatically after 3 minutes.
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 intracocular 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 if it is broken.
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, clean the forehead support after each patient 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.

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

The Icare ic100 tonometer is intended to be used for the measurement of intraocular pressure of the human eye.

INTRODUCTION

The Icare ic100 tonometer is used in the diagnosis, follow up and screening of glaucoma. It is based on a 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.

PACKAGE CONTENTS

⚠️ 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:
- Icare ic100 tonometer
- 4 x AA batteries
- 100 single use probes in a box
- wrist strap
- silicone grip
- IOP pad
- aluminum case
- screw driver
- probe base plug
- spare probe base
- probe base cleaning container
- quick guide
- USB memory stick including instruction manuals
- warranty card

PARTS OF THE TONOMETER

1. Forehead support
2. Probe base
3. Collar
4. Display
5. Forehead support adjusting wheel
6. Navigation buttons
7. Measure button
8. Select button
TURNING THE TONOMETER ON

Place the wrist strap around your wrist and secure it. The wrist strap protects the tonometer from dropping onto the floor accidentally.

To turn the tonometer on press the Select or Measure button. Illustrations of these alternative ways of starting:

![Pressing the Select button](image1)
![Pressing the Measure button](image2)

LOADING THE PROBE

Step 1. Open the probe tube by removing the cap and insert the probe into the probe base as shown in the image.

Step 2. After loading the probe the tonometer will be ready for measurement when Play-symbol appears on the display.

PROBE BASE LIGHT INDICATION

The tonometer includes a ring shaped probe base light which will inform the status of the device. The probe base light will show the inclination of the device after the probe has been inserted and activated.

The probe base light will also indicate by blinking red if there is an error in measurement or the deviation of the measurement cycle (a series of six individual measurements) is too high.
MEASUREMENT

**NOTE**
If you do not use the tonometer, it will switch off automatically after 3 minutes.

**NOTE**
No anesthetic is required when performing measurements. *Since local anesthetic may lower the tonometer reading, we recommend that you refrain from using an anesthetic when performing measurements.

**STEP 1.** Ask the patient to relax and look straight ahead at a specific point. Bring the tonometer near the patient’s eye.

![Correct head and eye position.](image1)

![Incorrect head and eye position.](image2)

**STEP 2.** The device should be in a horizontal position. Keep the probe horizontal and pointing perpendicularly to the center of the cornea. The distance from the tip of the probe to the patient’s cornea (see picture) should be 4-8 mm (5/32 - 5/16 inch).

If necessary, adjust the distance by turning the forehead support adjusting wheel.

![Correct alignment of the tonometer and green probe base light indication.](image3)

![Incorrect alignment of the tonometer and red probe base light indication.](image4)

If probe base light indication is set OFF green arrows will indicate the correct alignment of the tonometer.

If probe base light indication is set OFF red arrows will indicate the incorrect alignment of the tonometer.
**STEP 3.** You may perform the measurement in single or series mode.

**Single mode:** Press the Measure 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 should be made consecutively, blue segments will be lit after every successful measurement. After each successful measurement, you will hear a short beep.

**Series mode:** Keep the Measure button down to obtain the sequence of six measurements, blue segments will be lit after every successful measurement.

To obtain the most accurate reading, six measurements are required. The measurement values displayed before the final result are average values for all previous measurements (1.-5.). Single measurement values are not shown.

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

**STEP 4.** Once the six measurements have been performed, you will hear a long beep. The final IOP will be shown on the display rounded by green (perfect) or yellow (some variation) segments. If variation is too big, Repeat will be displayed.

The displayed result is an average of four measurements as the highest and the lowest reading are discarded before the average calculation.

The colors green and yellow as well as repeat indication are related to the standard deviation (SD) of the four remaining measurements.

The equivalence between the displayed color/repeat indication and SD is following:

- Green: SD less or equal to 2.5
- Yellow: SD higher than 2.5 and less or equal to 3.5
- Repeat: SD higher than 3.5
- Repeat is also displayed for SD higher than 2.5 and less or equal to 3.5 if the IOP result is higher than 19.

**STEP 5.** Following the performance of the entire measurement, a new measurement series can be begun by pressing the Measure button. The tonometer will then reactivate the probe and be ready for the next measurement series with the Play symbol on the display. The measurement sequence can be aborted by pressing the Select button.

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 makes a new measurement. In addition, when encountering unusual values (for example over 22mmHg or below 8 mmHg) we recommend taking of a new measurement to verify the result.

### MENU FUNCTIONS

Scrolling between the Menu functions starts from the MEASURE display, press either of the Navigation buttons located around the Select button.

Menu functions are MEASURE, HISTORY, SOUND, LIGHT, LANGUAGE and INFO

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>LOAD</th>
<th><strong>MEASURE – Access to measurement</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Press the Select button to access.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If the probe is not loaded the LOAD display appears.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tonometer is ready for measurement when Play-symbol display appears.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To exit, press the Select button.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HISTORY</th>
<th>17 mmHg</th>
<th>18 mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HISTORY – Old measurements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Press the Select button to access.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scroll through the old values by pressing either of the Navigation buttons.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Value colors green and yellow are related to Standard deviation (SD).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To exit, press the Select button.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SOUND</th>
<th>ON</th>
<th>OFF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SOUND – Setting of Tonometer buzzer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blue text and symbol is active setting.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Press the Select button to access.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turn the sound ON and OFF by pressing either of the Navigation buttons.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To accept selection, press the Select button.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LIGHT</th>
<th>ON</th>
<th>OFF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LIGHT – Setting of Collar indication light</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blue text and symbol is active setting.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Press the Select button to access.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turn the light ON and OFF by pressing either of the Navigation buttons.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To accept selection, press the Select button.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LANGUAGE</th>
<th>SVENSKA</th>
<th>DEUTSCH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LANGUAGE – Language setting</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blue text is active setting.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Press the Select button to access.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scroll through the language options by pressing either of the Navigation buttons.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To accept selection, press the Select button.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INFO</th>
<th>SN 1509A001</th>
<th>SW 1.00 A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INFO – Device information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Press the Select button to access.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serial number (SN) of the tonometer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Software version (SW) of the tonometer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To exit, press the Select button</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### TURNING THE TONOMETER OFF

Press the Select button until the display shows the End-symbol.

If you do not use the tonometer, it will switch off automatically after 3 minutes.
## ERROR AND INFO MESSAGES
The following messages may appear:

<table>
<thead>
<tr>
<th>MESSAGE</th>
<th>DESCRIPTION</th>
<th>ACTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>🍀ΐcaff</td>
<td>Battery charge is low.</td>
<td>Prepare to replace the batteries.</td>
</tr>
<tr>
<td>💼 CHANGE</td>
<td>The batteries are empty.</td>
<td>Turn the tonometer OFF by pressing Select button. Replace the batteries.</td>
</tr>
<tr>
<td>💼 CHANGE</td>
<td>The probe did not move.</td>
<td>Change the probe. The probe was twisted or otherwise inserted incorrectly. To clear error messages, press the Measure button, after which the measurement can be repeated.</td>
</tr>
<tr>
<td>💼 CLEAN CHANGE</td>
<td>The probe did not move properly for several times during the measurement sequence.</td>
<td>Remove and clean the probe base or replace it with new one as instructed in Replacing/cleaning the probe base. To clear error messages, press the Measure button, after which the measurement can be repeated.</td>
</tr>
<tr>
<td>🔴 TOO FAR</td>
<td>The probe did not touch the eye.</td>
<td>Adjust correct measurement distance 4-8 mm. The measurement was taken from too far away.</td>
</tr>
<tr>
<td>🔴 TOO NEAR</td>
<td>Too short measurement distance between the probe and the cornea.</td>
<td>Adjust correct measurement distance 4-8 mm. The measurement was taken from too close. To clear error messages, press the Measure button, after which the measurement can be repeated.</td>
</tr>
<tr>
<td>🔴 REPEAT</td>
<td>The probe did not move properly. 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, measure again. To clear error messages, press the Measure button, after which the measurement can be repeated.</td>
</tr>
<tr>
<td>⚠️ SERVICE</td>
<td>Internal error detected.</td>
<td>Turn the tonometer OFF by pressing Select button. Contact the seller to arrange sending the device for service.</td>
</tr>
</tbody>
</table>
**MEASUREMENT FLOW CHART**

1. **Turn Tonometer ON by pressing Select or Measure button**

2. **Load Probe**

3. **Ready to measure**

4. **Measure 6 times by pressing Measure button**
   (blue color bar shows the progress)

5. **Successful measurement**

6. **Repeat the measurement**

7. **Tonometer OFF by pressing Select button >3 seconds**
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 g</td>
<td>53 x 109 x 36 mm</td>
</tr>
<tr>
<td>7217</td>
<td>Probe base collar, Icare ic100</td>
<td>4 g</td>
<td>18 x 18 mm</td>
</tr>
<tr>
<td>540</td>
<td>Probe base</td>
<td>1 g</td>
<td>7 x 38 mm</td>
</tr>
<tr>
<td>559</td>
<td>Wrist strap with lock</td>
<td>4 g</td>
<td>10 x 10 x 270 mm</td>
</tr>
<tr>
<td>525</td>
<td>Aluminium case, Icare ic100</td>
<td>800 g</td>
<td>240 x 280 x 72 mm</td>
</tr>
<tr>
<td>7169</td>
<td>Battery cover &amp; screw, Icare ic100</td>
<td>6 g</td>
<td>110 x 25 x 12 mm</td>
</tr>
<tr>
<td>623</td>
<td>IOP pad, Icare ic100</td>
<td>38 g</td>
<td>50 x 53 x 16 mm</td>
</tr>
<tr>
<td>543</td>
<td>Probe base cleaning container</td>
<td>3 g</td>
<td>20 x 56 mm</td>
</tr>
<tr>
<td>565</td>
<td>Silicon grip - white, Icare ic100</td>
<td>26 g</td>
<td>45 x 35 x 113 mm</td>
</tr>
<tr>
<td>548</td>
<td>Screw driver, Icare</td>
<td>15 g</td>
<td>16 x 90 mm</td>
</tr>
<tr>
<td>577</td>
<td>USB memory stick</td>
<td>44 g</td>
<td>98 x 11 x 93 mm</td>
</tr>
<tr>
<td>544</td>
<td>Probe base plug</td>
<td>1 g</td>
<td>19 x 11 mm</td>
</tr>
</tbody>
</table>

TECHNICAL INFORMATION

Type: TA011
Dimensions: 24 - 29 mm (W) * 35 - 95 mm (H) * 215 mm (L).
Weight: 140 g (without batteries), 230 g (4 x AA batteries).
Power supply: 4 x AA non-rechargeable batteries, 1.5V alkaline LR6.
Measurement range: 7-50 mmHg
Accuracy: ±1.2 mmHg (≤20 mmHg) and ±2.2 mmHg (>20 mmHg).
Repeatability (coefficient of variation): <8 %.
Accuracy of display: 1 mmHg.
Display unit: Millimeter mercury (mmHg).
The serial number is on the inside of the battery compartment cover.
There are no electrical connections from the tonometer to the patient.
The device has BF-type electric shock protection.

Operation environment:
Temperature: +10 °C to +35 °C
Relative humidity: 30 % to 90 %
Atmospheric pressure: 800 hPa-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.
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/CLEANING THE PROBE BASE

Replace the probe base every twelve months. Clean the probe base every six months. Clean or replace the probe base if the error message Clean Change is displayed.

Instructions for replacing the probe base:
- Replace every twelve months.
- 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.

Instructions for cleaning the probe base:
- Clean every six months.
- 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.
- Dry the probe base by blowing clean canned or compressed air into the hole in the probe base. This will additionally remove possible residual dirt.
- Insert the probe base into the tonometer.
- Screw the collar in, to lock the probe base.

CLEANING THE TONOMETER

⚠️ WARNING

Never immerse the Icare tonometer, 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 ic100'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.

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 (Medizinproduktgesetz) alle 24 Monate.

SYMBOLS

Attention!!! See instructions

See operating instructions for more information

Serial number

Single use only

BF-type device

Lot number

Manufacturing date

Sterilized using radiation

Keep dry

Manufacturer

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)

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 ic100 tonometer.

WARNING
Use of any accessory or cable with the Icare ic100 tonometer other than those specified may result in increased emissions or decreased immunity of the Icare ic100 tonometer.
TA011 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 Instruction for use manual.

### GUIDANCE AND MANUFACTURER’S DECLARATION—ELECTROMAGNETIC EMISSIONS

<table>
<thead>
<tr>
<th>RF emissions CISPR 11</th>
<th>Group 1</th>
<th>Icare ic100 (TA011) is intended for use in the electromagnetic environment specified below. The user of the Icare ic100 (TA011) should assure that it is used in such an environment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>Icare ic100 (TA011) 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></td>
</tr>
<tr>
<td>Voltage fluctuations flickering emissions</td>
<td>NOT APPLICABLE</td>
<td></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)</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</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>NOT APPLICABLE</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV for line(s) to line(s) ±2 kV for line(s) to earth</td>
<td>NOT APPLICABLE</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Voltage dips, short interruption and voltage variations on power supply lines</td>
<td>&lt;5 % UT (&gt;95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles &lt;5 % UT (&gt;95 % dip in UT) for 5 s</td>
<td>NOT APPLICABLE</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</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 ic100 (TA011) is intended for use in the electromagnetic environment specified below. The customer or the user of the Icare ic100 (TA011) should assure that it is usuch an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
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</tr>
</thead>
</table>
| Radiated RF IEC 61000-4-3 | 3 V/m 80MHz to 2,5 GHz | 3V/m             | Portable and mobile RF communications equipment should be used no closer to any part of the Icare ic100 (TA011), 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 MHz to 800 MHz  
   \( d = 2.3 \sqrt{P} \) 800 MHz to 2.5 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 a should be less than the compliance level in each frequency range a. Interference may occur in the vicinity of equipment marked with the following symbol: |
| Conducted RF IEC 61000-4-6 | 3Vrms 150 kHz to 80 MHz | NOT APPLICABLE   |                                      |

**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.

a 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 ic100 (TA011) is used exceeds the applicable RF compliance level above, the Icare ic100 (TA011) 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 ic100 (TA011).

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

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**RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND ICARE ic100**

Icare ic100 (TA011) is intended for use in an electromagnetic environment in which radiated RF-disturbances are controlled. The customer or the user of the Icare ic100 (TA011) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Icare ic100 (TA011) 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, m</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>d=1,2 VP</td>
<td>d=1,2 VP</td>
</tr>
<tr>
<td>0.01</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>0.1</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>1</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>10</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>100</td>
<td>NOT APPLICABLE</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.

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