

icare
ic100

INSTRUCTION MANUAL
ENGLISH



TONOMETER

Icare® ic100

INSTRUCTION MANUAL TA011-089 US 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

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 5/32 – 5/16 inch, from the eye).



WARNING

The tonometer should only be opened or accessed 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 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 this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



WARNING

Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



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 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 drop the device as it may break if dropped. Use the wrist strap to avoid dropping. 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), 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.

No part of the tonometer or probes are made with natural rubber latex.



NOTE

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

PRECAUTIONS

None known.

SPECIAL PATIENT POPULATIONS

None known.

INTENDED USE

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

CONTRAINDICATIONS

None known.

INTRODUCTION

The Icare ic100 tonometer is based on a patented, induction-based rebound method, which allows intraocular pressure (IOP) to be measured accurately, rapidly and without an anesthetic.

The tonometer uses the rebound method. A small and light single-use probe makes contact with the eye very briefly. The tonometer measures the deceleration of the probe and the rebound time, and calculates the IOP from these parameters.

A measurement sequence includes six measurements. The probe moves to the cornea and back during every measurement. As a result, after the six measurements the tonometer calculates the final IOP and stores it in the tonometer's memory.

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
- additional probe base collar
- probe base cover
- 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

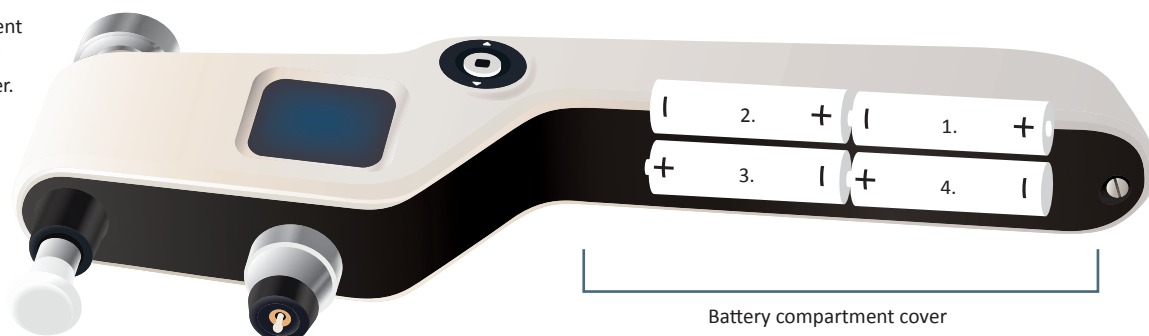


INSTALLING OR CHANGING THE BATTERIES

Unscrew the battery compartment locking screw with a screwdriver. Remove the battery compartment cover. Place the wrist strap into the wrist strap attachment at the end of the tonometer.

Insert a new set of four AA batteries. Insert the batteries accordance with the picture below. Do not use rechargeable batteries.

Replace the battery compartment cover and secure it by screwing it in lightly using the screwdriver. Take care not to use excessive force when screwing the cover into place.



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.

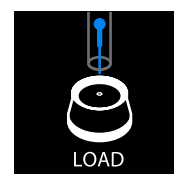
To turn the tonometer on press the Select or Measure button. The following are illustrations of these two alternative ways of starting the tonometer:



Pressing the Select button

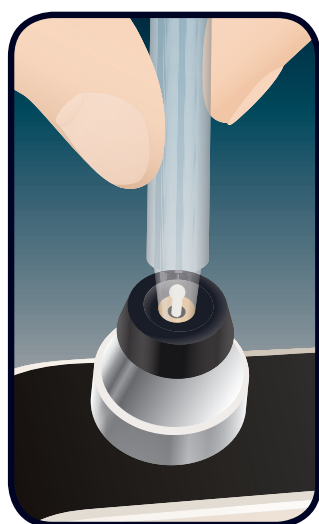


Pressing the Measure button

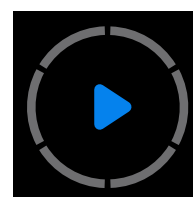


LOADING THE PROBE

Step 1. Remove the probe base cover (do not dispose of the cover) and 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 probe base light serves two purposes. First, it helps guide alignment of the device by showing a red light when the device is in the wrong position (i.e. too much vertical tilt) and a green light when the orientation is correct. Second, it indicates errors (see section Error and Info Messages) in addition to the display during the measurement sequence. When any of these errors occurs, the probe base light flashes red until the error is cleared by pressing the "Measure" button. The probe base light flashes red also when the text REPEAT with the yellow repeat symbol come on the display indicating a measurement sequence with too high deviation.

MEASUREMENT



NOTE

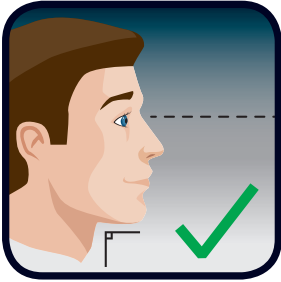
If you do not use the tonometer, it will switch off automatically after 3 minutes.



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.



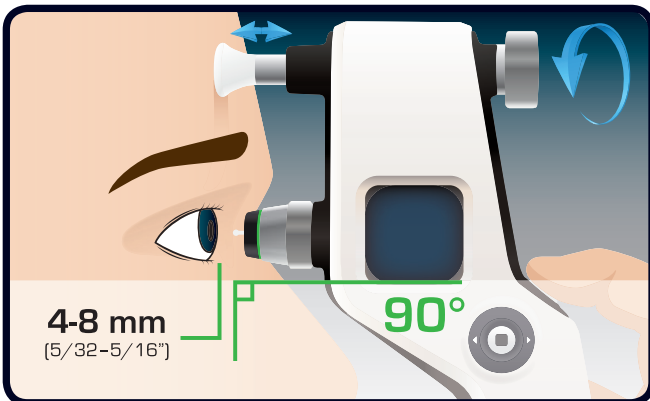
Correct head and eye position.



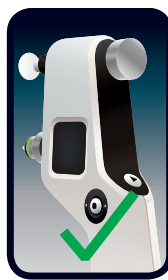
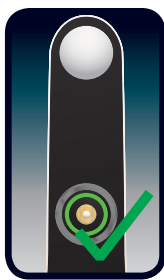
Incorrect head and eye position.



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).

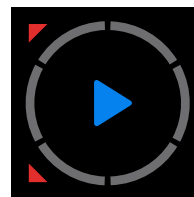
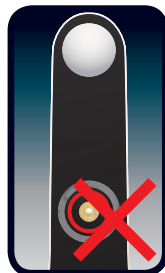


If necessary, adjust the distance by turning the forehead support adjusting wheel.



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

Correct alignment of the tonometer and green probe base light indication.



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

Incorrect alignment of the tonometer and red probe base light indication.

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.

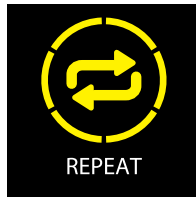
Series mode: Keep the Measure button down to obtain the sequence of six measurements, blue segments will be lit after every successful measurement.

To obtain the final 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.

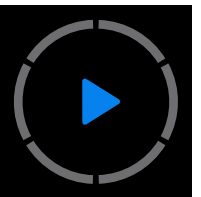
STEP 4. Once the six measurements have been performed, you will hear a long beep. The final IOP will be shown on the display rounded by green (perfect) or yellow (some variation) segments. If variation is too big, Repeat will be displayed.



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 probe's motion parameters of the four remaining measurements.

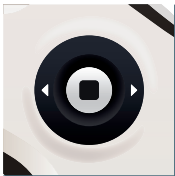
STEP 5. Following the performance of the entire measurement, a new measurement series can be begun by pressing the Measure button. The tonometer will then reactivate the probe and be ready for the next measurement series with the Play symbol on the display. The measurement sequence can be aborted by pressing the Select button. Place the probe base cover back to cover the probe base when the tonometer is not in use.



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.), it is recommended that he/she repeat the measurement. In addition, when encountering unusual values (for example, very high or very low values) it is recommended that a repeat measurement be taken either with the Icare tonometer or an alternative method to verify the result.

*Badouin C, Gastaud P. Influence of topical anesthesia on tonometric values of intraocular pressure. *Ophthalmologica* 1994;208:309-313.

MENU FUNCTIONS



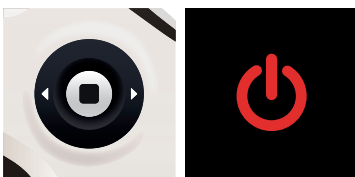
Scrolling between the Menu functions starts from the **MEASURE** display, press either of the Navigation buttons located around the Select button.

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

 MEASURE	 LOAD		MEASURE – Access to measurement Press the Select button to access. If the probe is not loaded the LOAD display appears. Tonometer is ready for measurement when Play-symbol display appears. To exit, press the Select button.
 HISTORY	 17 mmHg	 18 mmHg	HISTORY – Old measurements Press the Select button to access. Scroll through the old values by pressing either of the Navigation buttons. Value colors green and yellow are related to Standard deviation (SD). To exit, press the Select button.
 SOUND ON	 ON	 OFF	SOUND – Setting of Tonometer buzzer Blue text and symbol is active setting. Press the Select button to access. Turn the sound ON and OFF by pressing either of the Navigation buttons. To accept selection, press the Select button.
 LIGHT ON	 ON	 OFF	LIGHT – Setting of Probe base light Blue text and symbol is active setting. Press the Select button to access. Turn the light ON and OFF by pressing either of the Navigation buttons. To accept selection, press the Select button.
 LANGUAGE ENGLISH	 SVENSKA	 DEUTSCH	LANGUAGE – Language setting Blue text is active setting. Press the Select button to access. Scroll through the language options by pressing either of the Navigation buttons. To accept selection, press the Select button.
 INFO		SN 1509AJ001 SW 1.00.A	INFO – Device information Press the Select button to access. Serial number (SN) of the tonometer. Software version (SW) of the tonometer. To exit, press the Select button

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 on the display:

MESSAGE	DESCRIPTION	ACTIONS
	Battery charge is low.	Prepare to replace the batteries.
	The batteries are empty.	Turn the tonometer OFF by pressing Select button. Replace the batteries.
	The probe did not move.	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.
	The probe did not move properly for several times during the measurement sequence.	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.
	The probe did not touch the eye.	Adjust correct measurement distance 4-8 mm. The measurement was taken from too far away.
	Too short measurement distance between the probe and the cornea.	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.
	The probe did not move properly. The probe did not make clean contact with the cornea, because the probe hit an eyelid or eyelashes.	Ensure that the eye is open, measure again. To clear error messages, press the Measure button, after which the measurement can be repeated.
	Internal error detected.	Turn the tonometer OFF by pressing Select button. Contact the seller to arrange sending the device for service.

MEASUREMENT FLOW CHART



ACCESSORIES

SKU	PRODUCT DESCRIPTION	WEIGHT	DIMENSIONS
104	Box of 100 probes	89 g	53 x 109 x 36 mm
7217	TA011/TV011 collar	4 g	18 x 18 mm
7218	TA011/TV011 collar narrow	1 g	17 x 18 mm
540	Probe base	4 g	7 x 38 mm
559	Wrist strap with lock	4 g	10 x 10 x 270 mm
525	Aluminum case, Icare ic100	800 g	240 x 280 x 72 mm
7169	Battery cover & screw, Icare ic100	6 g	110 x 25 x 12 mm
623	IOP pad, Icare ic100	38 g	50 x 53 x 16 mm
543	Probe base cleaning container	3 g	20 x 56 mm
565	Silicone grip - white, Icare ic100	26 g	45 x 35 x 113 mm
548	Screw driver, Icare	15 g	16 x 90 mm
577	USB memory stick	44 g	98 x 11 x 93 mm
544	Probe base cover	1 g	19 x 11 mm

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 of 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: $+10^{\circ}\text{C}$ to $+35^{\circ}\text{C}$

Relative humidity: 30 % to 90 %

Atmospheric pressure: 800 hPa-1,060 hPa

Storage environment:

Temperature: -10°C to $+55^{\circ}\text{C}$

Relative humidity: 10 % to 95 %

Atmospheric pressure: 700 hPa-1,060 hPa

Transport environment:

Temperature: -40°C to $+70^{\circ}\text{C}$

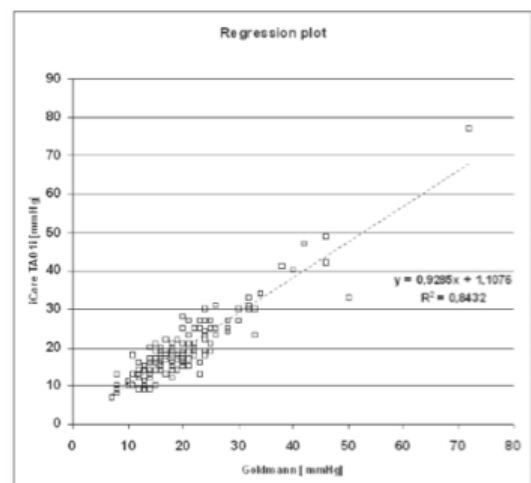
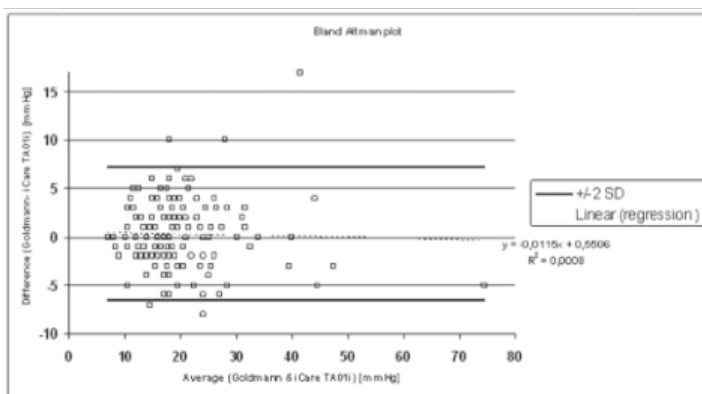
Relative humidity: 10 % to 95 %

Atmospheric pressure: 500 hPa-1,060 hPa

Mode of operation: continuous

PERFORMANCE DATA

The performance data is obtained from a clinical study, performed with the predicate device Icare TA01i tonometer (K063873) 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 70-100 % 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:

- 70-100 % isopropyl alcohol
- 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

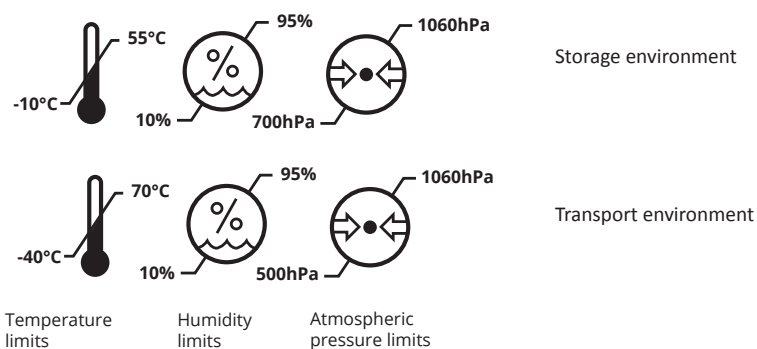
Contact Icare Finland's Technical Services Department (see www.icaretonometer.com) or your local Icare representative for shipping instructions. Unless otherwise instructed by Icare Finland, there is no need to ship accessories along with the tonometer. Use a suitable carton with the appropriate packaging 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.

SYMBOLS

	Attention!!! See instructions		Lot number
	See operating instructions for more information		Manufacturing date
	Serial number		Sterilized using radiation
	Single use only		Keep dry
	BF-type device		Manufacturer
Rx Only	Federal law (U.S.) restricts this device to sale by or on the order of a physician.		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)



ELECTROMAGNETIC DECLARATION



WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



WARNING

Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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

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.

RF emissions CISPR 11	Group 1	Icare ic100 (TA011) is battery operated and use RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B	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
Harmonic emissions IEC 61000-3-2	NOT APPLICABLE	
Voltage fluctuations flickering emissions IEC 61000-3-3	NOT APPLICABLE	

GUIDANCE AND MANUFACTURER'S DECLARATION—ELECTROMAGNETIC IMMUNITY

Icare ic100 (TA011) is intended for use in the electromagnetic environment specified below. The customers or users of Icare ic100 (TA011) should assure that it is used in such an environment

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast Transients/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	NOT APPLICABLE	NOT APPLICABLE
Surge IEC 61000-4-5	± 1 kV for line(s) to line(s) ± 2 kV for line(s) to earth	NOT APPLICABLE	NOT APPLICABLE
Voltage dips, short interruption and voltage variations on power supply lines IEC 61000-4-11	< 5 % UT (> 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 < 5 % UT (> 95 % dip in UT) for 5 s	NOT APPLICABLE	NOT APPLICABLE
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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 used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-Guidance
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.
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	NOT APPLICABLE	Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ 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 ^b. Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

^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.

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.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter, m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0,01	NOT APPLICABLE	0.12	0.23
0,1	NOT APPLICABLE	0.38	0.73
1	NOT APPLICABLE	1.2	2.3
10	NOT APPLICABLE	3.8	7.2
100	NOT APPLICABLE	12	23

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.

NOTES