ENGLISH

iCare IC100

Instruction Manual

icare

TONOMETER
iCare IC100

The information in this document is subject to change without prior notice. Should a conflict situation arise concerning a translated document, the English language version shall prevail.

CE **0598**

This device complies with:
Medical Device Regulation (MDR) 2017/745
RoHS Directive 2011/65/EU
Radio equipment directive 2014/53/EU

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Contents

1 Safety information

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 must not be dropped. To avoid dropping the tonometer and to ensure safe handling, always use the wrist strap to keep the tonometer attached to your wrist when in use. If the tonometer is dropped and the tonometer casing opens, press the casing to close the openings.

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

WARNING! The tonometer must be switched off when the probe base is changed.

WARNING! The probe base must be changed, not cleaned.

WARNING! Changes or modifications not expressly approved by Icare Finland Oy could void the user's authority to operate the equipment.

WARNING! Never immerse the tonometer in liquid. Do not spray, pour, or spill liquid on the tonometer, its accessories, connectors, switches, or openings in the cover. Immediately remove any liquid from the surface of the tonometer.

WARNING! Use only the original, certified probes supplied by the manufacturer. The probes are for single-use (one per measurement session) only. Each testing session is defined by one successful measurement in both eyes, but in case either eye is inflamed or infected the healthy eye should be measured first. Use only intact probes taken only from the intact, original packaging. Re-use of a probe could result in incorrect measurement values, damage to the probe, cross-contamination by bacteria or viruses or infection of the eye. Re-use of probes voids all responsibilities and liabilities of the manufacturer concerning the safety and effectiveness of the tonometer.

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! Do not use probes without a plastic tip. Do not use deformed probes. Contact the manufacturer or local distributor if you notice faulty probes or probe packages.

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! The tonometer device must not come into contact with the patient's eyes. When adjusting the forehead resting support for the tonometer, do not accidentally push the tonometer or probe into the eye. The tonometer's forehead resting support needs to be adjusted to maintain the tip of the probe about 5 mm, or about 3/16 inch, from the eye. During measurement, only the probe makes contact with eye, for a fraction of a second.

WARNING! To prevent contamination, keep unused probes in their box, do not touch the bare probe, do not use a probe if it touches a non-sterile surface like a table or a floor. Do not use the touched or dropped probe, dispose of it properly (e.g. in containers for disposable needles).

WARNING! Removing, covering or defacing any label or sign of the device voids all responsibilities and liabilities of the manufacturer concerning the safety and effectiveness of the tonometer.

WARNING! Servicing or maintenance actions must not be performed while the tonometer is in use.

WARNING! The tonometer must not be repaired or re-assembled by any other than the manufacturer or its authorized service center. If the tonometer is broken, do not use it. Take it to an authorized iCare service center for repair.

WARNING! Sources of power frequency magnetic field should be used no closer than 15 cm (6 inches) to any part of the iCare IC100 (TA011) tonometer, including cables specified by the manufacturer. Otherwise, degradation of the performance could result.

WARNING! Use of eye drops right before the measurement or topical anesthesia may affect the measurement result.

WARNING! Interference may occur in the vicinity of equipment marked with the non-ionizing radiation symbol.

WARNING! The iCare IC100 tonometer should not be used in medical vehicles or similar environments where there is vibration and/or noise levels are so high that the user cannot hear error signals.

PRECAUTION! Report any serious incidents related to the tonometer to your competent health authority and the manufacturer or the manufacturer's representative.

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

PRECAUTION! 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.

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

PRECAUTION! Check the packaging for any external damage before opening. 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.

PRECAUTION! 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.

PRECAUTION! Never open the casing of the tonometer, except for the battery compartment or to change the probe base.

PRECAUTION! This manual contains instructions for replacing batteries and changing the probe base.

PRECAUTION! Never use the tonometer in wet or damp conditions.

PRECAUTION! 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.

PRECAUTION! Do not use the device near inflammable substances, including inflammable anesthetic agents.

PRECAUTION! Prior to each measurement, check that a clean new disposable probe from an intact package is being used.

PRECAUTION! Be sure that the probe contains the small plastic round tip in front.

PRECAUTION! The tonometer conforms to EMC requirements (IEC 60601-1-2: 2014), 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.

PRECAUTION! 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.

PRECAUTION! 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.

PRECAUTION! Batteries, packaging materials and probe bases must be disposed of according to local regulations.

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

PRECAUTION! Use only the types of battery specified in the Technical Information section of this instruction manual.

PRECAUTION! The measurement method of the iCare IC100 tonometer is based on magnetic induction and therefore an external magnetic field in line with the probe may prevent the measurement. In such case the tonometer will continuously ask to repeat the measurement. Situation can be solved either by removing the source of interference from the vicinity of the device or by performing the measurement in different location with no such interference.

PRECAUTION! Do not use the device if it appears to be damaged or malfunctioning. The device must be delivered to service for repair.

PRECAUTION! Certain microbiological agents (for example, bacteria) can be transmitted from the forehead support. To prevent this, clean the forehead support with disinfectant for each new patient.

2 Intended use

The iCare IC100 tonometer is intended to be used for the measurement of intraocular pressure of the human eye.

3 Possible limitations of use

WARNING! The iCare IC100 tonometer should not be used in medical vehicles or similar environments where there is vibration and/or noise levels are so high that the user cannot hear error signals.

Some conditions may cause limitations to the use of the iCare IC100 tonometer. The safety and effectiveness of the iCare IC100 tonometer has not been evaluated for patients with:

- Only one functional eye
- Poor or eccentric fixation
- Contact lens use
- Dry eyes
- Keratoconus
- Microphthalmos
- Buphthalmos
- Nystagmus
- Cataract extraction within last 2 months
- High corneal astigmatism > 3d
- History of prior incisional glaucoma surgery or corneal surgery including corneal laser surgery
- Corneal scarring
- Central corneal thickness greater than 0.60 mm or less than 0.50 mm

The iCare IC100 tonometer should be used only in stable, non-vibrating environment.

4 Introduction

PRECAUTION! Report any serious incidents related to the tonometer to your competent health authority and the manufacturer or the manufacturer's representative.

The iCare IC100 tonometer is based on a patented, induction-based rebound method, which allows intraocular pressure (IOP) to be measured by a healthcare professional 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.

Device GTIN can be found printed on the device cover accompanied with serial number and the date of manufacture. For more information about the iCare IC100 tonometer or for ordering a paper version of the instruction manual corresponding the device GTIN or for downloading electronic version, visit www.icare-world.com/ifu. To download the instruction manual, scan the QR-code accompanied with the Consult instructions for use -symbol and the web address on the side of the tonometer.

5 Package contents

PRECAUTION! Check the packaging for any external damage before opening. 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.

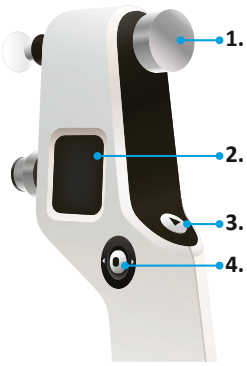
Check the sales packaging condition before taking the tonometer or probes into use. If the package appears damaged, contact the manufacturer or your distributor.

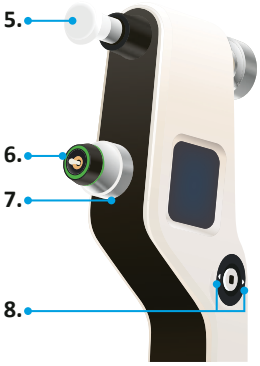
The package contains:
- iCare IC100 tonometer
- 4 x AA alkaline batteries
- Carrying case
- IOP pad
- Quick guide
- Screwdriver
- Spare probe base
- Probe base cover
- 100 single-use probes
- Warranty card
- Wrist strap

6 Parts of the tonometer

WARNING! Removing, covering or defacing any label or sign of the device voids all responsibilities and liabilities of the manufacturer concerning the safety and effectiveness of the tonometer.

1. Forehead support adjusting wheel
2. Display
3. Measure button
4. Select button
5. Forehead support
6. Probe base and probe base light
7. Collar
8. Navigation buttons





7 Installing or changing the batteries

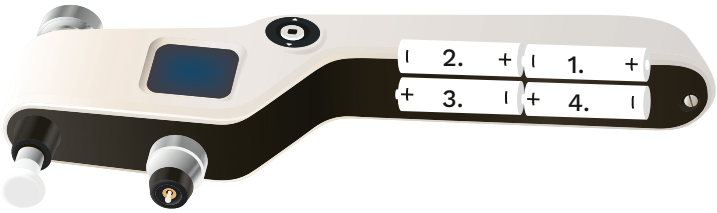
PRECAUTION! If the device is not to be used for a long time, we recommend that you remove its AA batteries, since they may leak. Removing the batteries will not affect the subsequent functioning of the tonometer.

PRECAUTION! Use only the types of battery specified in the Technical Information section of this instruction manual.

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 according to the figure 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.

8 Turning the tonometer on

WARNING! The tonometer must not be dropped. To avoid dropping the tonometer and to ensure safe handling, always use the wrist strap to keep the tonometer attached to your wrist when in use. If the tonometer is dropped and the tonometer casing opens, press the casing to close the openings.

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 figures show two alternative ways of starting the tonometer:

Pressing the Select button

Pressing the Measure button

9 Loading the probe

WARNING! Do not use probes without a plastic tip. Do not use deformed probes. Contact the manufacturer or local distributor if you notice faulty probes or probe packages.

WARNING! To prevent contamination, keep unused probes in their box, do not touch the bare probe, do not use a probe if it touches a non-sterile surface like a table or a floor. Do not use the touched or dropped probe, dispose of it properly (e.g. in containers for disposable needles).

PRECAUTION! Be sure that the probe contains the small plastic round tip in front.

STEP 1. Remove the probe base cover by pulling, not turning, (do not dispose of the cover) and open the probe tube by removing the cap. Insert the probe into the probe baseaccording to the figure below.

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

10 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 Chapter 14 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.

11 Measurement

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! Use only the original, certified probes supplied by the manufacturer. The probes are for single-use (one per measurement session) only. Each testing session is defined by one successful measurement in both eyes, but in case either eye is inflamed or infected the healthy eye should be measured first. Use only intact probes taken only from the intact, original packaging. Re-use of a probe could result in incorrect measurement values, damage to the probe, cross-contamination by bacteria or viruses or infection of the eye. Re-use of probes voids all responsibilities and liabilities of the manufacturer concerning the safety and effectiveness of the tonometer.

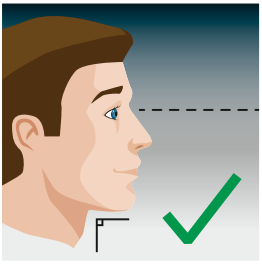
PRECAUTION! If you do not use the tonometer, it will switch off automatically after 3 minutes.

PRECAUTION! 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.

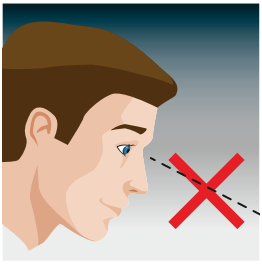
PRECAUTION! Prior to each measurement, check that a clean new disposable probe from an intact package is being used.

PRECAUTION! Do not use the device if it appears to be damaged or malfunctioning. The device must be delivered to service for repair.

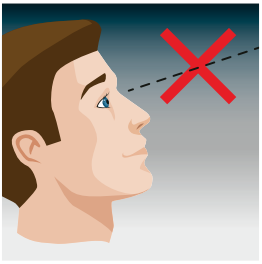
STEP 1. Ask the patient to relax and look straight ahead at a specific point. Bring the tonometer near the patient's eye.



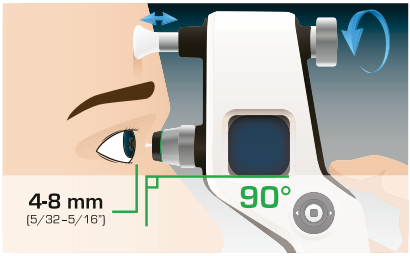
Correct head and eye position.



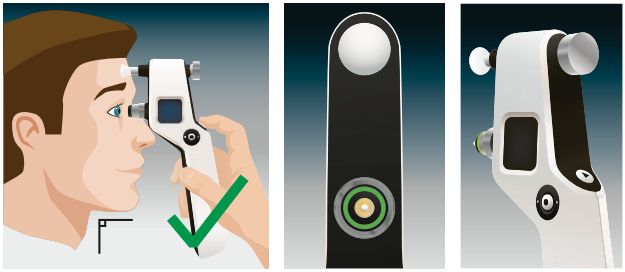
Incorrect head and eye position



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 should be 4-8 mm (5/32 - 5/16 inch).

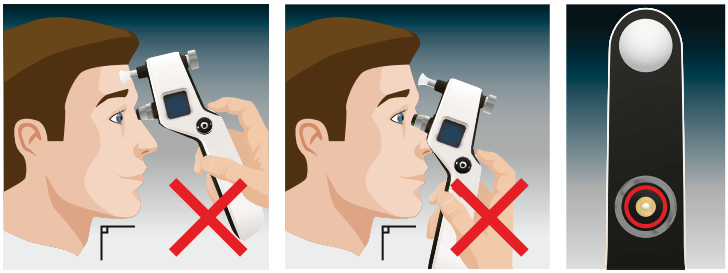


If necessary, adjust the distance by turning the forehead support adjusting wheel.



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

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



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

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, keeping the tonometer still and steady. 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 in mmHg will be shown on the display rounded by green (good quality of measurements) or yellow (some variation) segments. If variation is too big, the Repeat-symbol 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.

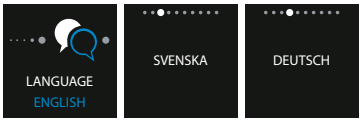
If you doubt the validity of any of the tonometer's displayed measurements of IOP (for example, if you suspect that the probe missed the central cornea or made contact with the eyelid), it is recommended that you repeat the measurement. In addition, if you observe an unusually high or low displayed value of IOP, it is recommended that you make another measurement, either with the iCare tonometer or using an alternative method in order to verify the unusual reading.

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

12 Menu Functions

Scrolling between the Menu functions starts from the MEASURE display. Pressing either of the Navigation buttons located around the Select button changes the displayed menu. The Select button is for activating a selection.

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

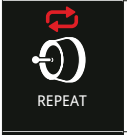
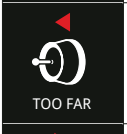
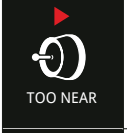
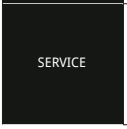
	**MEASURE – Access to measurement** Press the Select button to access. If the probe is not loaded the LOAD display appears. Tonometer is ready for measurement when Play symbol display appears. To exit, press the Select button.
	**HISTORY – Old measurements** Press the Select button to access. Scroll 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 – 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 – 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 – 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 – 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

13 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.

14 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 the Select button. Replace the batteries.
	The probe did not move properly or did not make clean contact with the cornea.	Measure again or change the probe. To clear error messages, press the Measure button, after which the measurement can be repeated.
	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. If the error keeps recurring, change also the probe base as instructed in Replacing the probe base.
	The probe did not touch the eye.	Adjust correct measurement distance 4-8 mm. The measurement was taken from too far away. To clear error messages, press the Measure button, after which the measurement can be repeated.
	Too short measurement distance between the probe and the cornea.	Adjust correct measurement distance to about 5 mm. The measurement was taken from too close. To clear error messages, press the Measure button, after which the measurement can be repeated.
	Internal error detected.	Turn the tonometer OFF by pressing the Select button. Contact the seller to arrange sending the device for service.

15 Measurement flow chart

Turn the tonometer ON by pressing the Select or Measure button

This is displayed if you pressed the Select button, pressing of the Measure button would lead you directly to Load Probe

Load probe

Ready to measure

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

Successful measurement

Repeat the measurement

Turn the tonometer OFF by pressing the Select button for >3 seconds

16 Accessories, detachable parts and other supplies

Order accessories, parts and other supplies by contacting either the manufacturer or your local distributor.

SKU	Product description	Weight	Dimensions
Accessories			
104	Probe iCare TP01, 100 pcs/box	89 g	53 x 109 x 36 mm
107	Probe iCare TP01, 600 pcs/box	531 g	126 x 211 x 55 mm
Parts			
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 32 mm
559	Wrist strap with lock	4 g	10 x 10 x 270 mm
7169	Battery cover & screw, iCare IC100	6 g	110 x 25 x 12 mm
Other supplies			
548	Screw driver	15 g	16 x 90 mm
565*	Silicone grip, white	26 g	45 x 35 x 113 mm
544	Probe base cover	1 g	19 x 11 mm
619b	IOP pad	38 g	50 x 53 x 16 mm
525	Aluminium case, iCare IC100	800 g	240 x 280 x 72 mm

* Not available in EU.

17 Technical information

WARNING! Changes or modifications not expressly approved by Icare Finland Oy could void the user's authority to operate the equipment.

NOTE: A separate service manual is available for service personnel.

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, 1.5 V 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).
Use classification: multiple patient multiple use

NOTE! If the packaging is exposed to environmental conditions outside of those specified in this manual, contact the manufacturer.
The serial number is on the tonometer's outer cover. There are no electrical connections from the tonometer to the patient. All the parts of the tonometer are applied parts and the tonometer has BF type electric shock protection. The LOT number of the probes is on the side of the probe box.

The tonometer and its materials are compliant with RoHS Directive 2011/65/EU. The tonometer and its parts are not made of natural rubber latex.

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

18 Performance data

The performance data of iCare IC100 is obtained from a clinical study, performed according to the American National Standard ANSI Z80.10-2014 and International Standard ISO 8612 for tonometers. The study was performed at the Manipal University, India. In the study, 151 patients were measured in sitting position. The mean paired difference and standard deviation (iCare-Goldmann) were -0.48 mmHg and 1.68 mmHg.

19 Maintenance

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

WARNING! Servicing or maintenance actions must not be performed while the tonometer is in use.

WARNING! The tonometer must not be repaired or re-assembled by any other than the manufacturer or its authorized service center. If the tonometer is broken, do not use it. Take it to an authorized iCare service center for repair.

PRECAUTION! Do not use the device if it appears to be damaged or malfunctioning. The device must be delivered to service for repair.

PRECAUTION! 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.

19.1 Recycling

PRECAUTION! 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.

PRECAUTION! Batteries, packaging materials and probe bases must be disposed of according to local regulations.

Do not dispose of the tonometer with household waste. Send it to an appropriate facility for recovery and recycling. The tonometer should be recycled as electronic waste.

The separate collection and recycling of your product or its battery at the time of disposal help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.

The sales package and the probe boxes are carton and can be recycled. Waste carton generally includes paper, carton, and cardboard packages. Recycle according to local laws and regulations.

19.2 Replacing the probe base

WARNING! The tonometer must be switched off when the probe base is changed.

WARNING! The probe base must be changed, not cleaned.

Replace the probe base every six months. If the error message Change is shown on the display screen more than two times in a row after changing the probe, replace the probe base before resuming use of the device.

Instructions for replacing the probe base:

- Turn off the tonometer.
- Unscrew the probe base collar and put it in a safe place.
- Remove the probe base by tilting the tonometer downwards and use your fingers to pull the probe base out of the tonometer.
- Insert a new probe base into the tonometer.
- Screw the collar in, to lock the probe base.

19.3 Cleaning the tonometer

WARNING! Never immerse the iCare tonometer in liquid. Do not spray, pour or spill liquid onto the iCare tonometer, its accessories, connectors, switches or openings in the chassis. Remove any liquid appearing on the surface of the tonometer immediately.

PRECAUTION! Certain microbiological agents (for example, bacteria) can be transmitted from the forehead support. To prevent this, clean the forehead support with disinfectant for each new patient.

iCare IC100's surfaces have been tested and found chemically resistant to the following liquids:

- 70-100 % isopropyl alcohol
- 70 % ethanol

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.

19.4 Returning the iCare tonometer for servicing / repair

Contact the seller of the tonometer for shipping instructions. Unless otherwise instructed, there is no need to ship any accessories with the tonometer. Use a suitable cardboard or similar box with the appropriate packaging material to protect the device during shipment. Return the device using any shipping method that includes proof of dispatch and delivery.

19.5 Periodic Safety Checks

We recommend that the following checks be performed every 12 months.

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

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

20 Symbols

	General warning sign		Consult operating instructions
	Serial number		Single use only
	BF-type device	**Rx Only (US)**	Federal law (U.S.) restricts this device to sale by or on the order of a physician.
	Lot number		Manufacturing date
	Keep dry		Manufacturer
	Do not dispose of this product with household waste. Send to appropriate facility for recovery and recycling. EU WEEE (European Union Directive for Waste of Electronic and Electrical Equipment).		Refer to the instruction manual
	Temperature limits		Atmospheric pressure limits
	Humidity limits		Product is a medical device
	Recyclable package material	**IP24**	Protected against access to hazardous parts with a finger. Protected against solid foreign objects of 12.5 Ø mm or greater. Protected against splashing water.
CE 0598	CE marking accompanied with the notified body identification number.		The Regulatory Compliance Mark (RCM), in Australia and New Zealand
	QR code accompanied with the Consult instructions for use -symbol and the web address on the side of the tonometer to download the electronic manual		

21 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.

WARNING! Sources of power frequency magnetic field should be used no closer than 15 cm (6 inches) to any part of the iCare IC100 (TA011) tonometer, including cables specified by the manufacturer. Otherwise, degradation of the performance could result.

PRECAUTION! The tonometer conforms to EMC requirements (IEC 60601-1-2: 2014), 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.

PRECAUTION! The measurement method of the iCare IC100 tonometer is based on magnetic induction and therefore an external magnetic field in line with the probe may prevent the measurement. In such case the tonometer will continuously ask to repeat the measurement. Situation can be solved either by removing the source of interference from the vicinity of the device or by performing the measurement in different location with no such interference.

The iCare IC100 (TA011) tonometer is a 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.

Portable and mobile RF communications equipment can affect the iCare IC100 (TA011) Tonometer

The Essential Performance of the iCare IC100 (TA011) tonometer is to measure the Intraocular Pressure (IOP) with specified accuracy and display the measurement results.

Guidance And Manufacturer's Declaration IEC 60601-1-2:2014; Edition 4.0 - Electromagnetic Emissions		
iCare IC100 (TA011) is intended for use in a professional healthcare environment with electromagnetic characteristics specified below. The user of the iCare IC100 Tonometer (TA011) should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	iCare IC100 (TA011) 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
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	NOT APPLICABLE
Voltage fluctuations flickering emissions IEC 61000-3-3	NOT APPLICABLE	NOT APPLICABLE

Guidance And Manufacturer's Declaration IEC 60601-1-2:2014; Edition 4.0 - Electromagnetic Immunity			
iCare IC100 (TA011) is intended for use in a professional healthcare environment with electromagnetic characteristics			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2kV, ± 4kV, ± 8kV, ± 15 kV air	± 8 kV contact ± 15 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 100 kHz repetition frequency	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	0 % UT for 0.5 cycle (1 phase) 0 % UT for 1 cycle 70 % UT for 25/30 cycles (50/60 Hz) 0 % UT for 250/300 cycles (50/60 Hz)	NOT APPLICABLE	NOT APPLICABLE

Guidance And Manufacturer's Declaration IEC 60601-1-2:2014; Edition 4.0 - Electromagnetic Immunity			
iCare IC100 (TA011) is intended for use in a professional healthcare environment with electromagnetic characteristics			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. WARNING: Sources of power frequency magnetic field should be used no closer than 15 cm (6 inches) to any part of iCare IC100 (TA011), including cables specified by the manufacturer. Otherwise, degradation of the performance could result. The measurement method of the iCare IC100 tonometer is based on magnetic induction and therefore an external magnetic field in line with the probe may prevent the measurement. In such case the tonometer will continuously ask to repeat the measurement. Situation can be solved either by removing the source of interference from the vicinity of the device or by performing the measurement in different location with no such interference.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	NOT APPLICABLE	NOT APPLICABLE
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	3 V/m	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iCare IC100 (TA011) including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance And Manufacturer's Declaration Iec 60601-1-2:2014; Edition 4.0 - Electromagnetic Immunity			
iCare IC100 (TA011) is intended for use in a professional healthcare environment with electromagnetic characteristics specified below. The user of the iCare IC100 Tonometer (TA011) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Proximity fields from RF wireless communications equipment IEC 61000-4-3	380 - 390 MHz 27 V/ m; PM 50%; 18 Hz	27 V/m	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iCare IC100 (TA011) including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Interference may occur in the vicinity of equipment marked with the following symbol: 
	430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz	28 V/m	
	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	9 V/m	
	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	28 V/m	
	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	5100 - 5800 MHz 9 V/ m; PM 50%; 217 Hz	9 V/m	

TA011-047-EN-5.0
2025-09-25

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