ENGLISH

iCare IC200

Instruction Manual

icare

TONOMETER
iCare IC200

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 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! 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! Quick Measure accuracy and repeatability are not clinically validated, and the results may not exactly match the default measurement mode's results. Use the default measurement primarily with all patients and if the default measurement is unsuccessful repeat the IOP measurement with Quick Measure. The Quick Measure result is indicative.

WARNING! The incorrect alignment error indication is disabled when Quick Measure is used. Keep the tonometer perpendicular to the center of the cornea to get reliable IOP measurement results.

WARNING! No quality indication is shown for the result when Quick Measure is used. Make sure that the measurement is done as instructed in this manual to ensure a reliable IOP measurement result.

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

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

WARNING! Use of this equipment adjacent to, or stacked with, other equipment may result in improper operation and should be avoided. 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! Interference may occur in the vicinity of equipment marked with the non-ionizing radiation symbol.

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

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 the floor. Do not use the touched or dropped probe, dispose of it properly (e.g. in containers for disposable needles).

WARNING! Connection of the IC200 tonometer to IT networks including other equipment could result in previously unidentified risks to patients, operators, or third parties.

WARNING! The responsible organization should identify, analyze, evaluate, and control any additional risks resulting from the IC200 tonometer connected to IT networks including other equipment.

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! 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.

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

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.

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

PRECAUTION! If the tonometer is not used for 3 minutes, it will automatically switch itself off (the probe may then fall out).

PRECAUTION! Check the packaging for any external damage before opening. After removing the device from its packaging, visually inspect the tonometer for any external damage, particularly for possible damage to the device casing. If you suspect damage to the tonometer, contact the manufacturer or distributor.

PRECAUTION! Use the tonometer only for measuring intraocular pressure, any other use is improper. The manufacturer cannot be held liable for any damage arising from improper use of the tonometer, or any consequences thereof.

PRECAUTION! Never open the casing of the tonometer, except for battery replacement or changing the probe base. This manual contains instructions for replacing batteries and changing the probe base.

PRECAUTION! Keep the tonometer out of reach of children. The probe base, battery compartment cover, screws, collar and probes are small objects and may be accidentally swallowed.

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

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

PRECAUTION! Prior to each new patient to be measured, check that a new disposable probe from an intact package is being used. After inserting the probe in the probe base, visually inspect the probe to ensure that the small plastic round tip is visible at the front. Do not use a probe without the plastic tip.

PRECAUTION! The tonometer conforms to EMC requirements (IEC 60101-1-2), performance of the tonometer may be affected if it is used near to (<1 m) another electrical device, such as a cellular phone, emitting high-intensity electromagnetic radiation. The tonometer's own electromagnetic emissions are well below the maximum levels permitted by the relevant standards. Nevertheless, the tonometer may cause interference in the operation of highly sensitive devices in the immediate vicinity.

PRECAUTION! If the device is not intended to be used for a long period of time, it is recommended to remove the batteries from the battery compartment. Removing the batteries will not affect the subsequent functioning of the tonometer.

PRECAUTION! Used probes cannot be recycled. Dispose of used probes properly (e.g. in containers for disposable needles or in a bin for metal waste).

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

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

PRECAUTION! The measurement method of the iCare IC200 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! The responsible organization should maintain proper IT security practices like up-to-date virus protection, firewall and data protection in the systems where iCare EXPORT is used.

PRECAUTION! Changes to the IT network could introduce new risks requiring additional analysis by the responsible organization. The changes include:

- changes in the IT-network configuration
- connection of additional items to the IT-network
- disconnecting items from the IT-network
- update or upgrade of equipment connected to the IT-network

PRECAUTION! The measurement data transfer may be interrupted during electromagnetic disturbance. In such case, reconnect the tonometer to the computer. If this does not solve the issue, perform the data transfer in other location with no such interference. The measurement data will not be deleted from the device before the data is transferred successfully.

PRECAUTION! Non-ME equipment (computer) used in the system for transferring data must comply with the electromagnetic emission and immunity requirements for multimedia equipment: CISPR 32 and CISPR 35.

2 Intended use

The iCare IC200 tonometer is intended to be used for the measurement of intraocular pressure of the human eye.

3 Possible limitations of use

Some conditions may cause limitations to the use of the iCare IC200 tonometer. The safety and effectiveness of the iCare IC200 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 IC200 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 IC200 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 iCare IC200 tonometer allows for a patient's IOP to be measured for patients in the supine position as well as in upright (sitting or standing) positions.

With the iCare rebound measurement method, a miniature, light-weight probe is launched in a direction perpendicular to the surface of the center of the cornea of the eye. The probe is composed of a medical grade plastic tip and a metal shaft. The metal shaft is magnetized prior to measurement. During a measurement, the probe can be considered to act like a moving magnet that induces an electric signal in the surrounding coil allowing for highly accurate measurement of the probe's motion. After launching, the probe briefly makes contact with the cornea and bounces back. The tonometer records multiple parameters covering the motion of the probe, including deceleration and rebound time. Using a proprietary algorithm, the device is able to calculate the eye's IOP.

A displayed IOP reading is derived from the results from a sequence of six individual IOP measurements and calculations, made each of the six times the probe hits the cornea and rebounds. The displayed IOP measurement is also stored in the tonometer's memory for later retrieval.

The iCare IC200 tonometer incorporates a Bluetooth® module which allows wireless connectivity to Bluetooth-supported printers or for data transfer.

No part of the tonometer or probes contain natural rubber latex.

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 IC200 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 content

PRECAUTION! Check the packaging for any external damage before opening. After removing the device from its packaging, visually inspect the tonometer for any external damage, particularly for possible damage to the device casing. If you suspect damage to 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 iCare IC200 package contains:

- iCare IC200 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 Features and parts of the tonometer

1. Forehead support
2. Probe base
3. Locking collar
4. Display screen
5. Adjustment wheel for forehead support
6. User interface Navigation buttons
7. Select button
8. Measure button

7 Taking the device into use

Before using the iCare IC200 tonometer for the first time, attach the wrist strap and insert the batteries.

7.1 Installing the wrist strap

Thread the string loop at the end of the wrist strap through the two holes at the bottom of the device (see figure below). Take hold of the end of the wrist strap, turn it back and bring it through the loop. Finally, pull the wrist strap to tighten the loop.

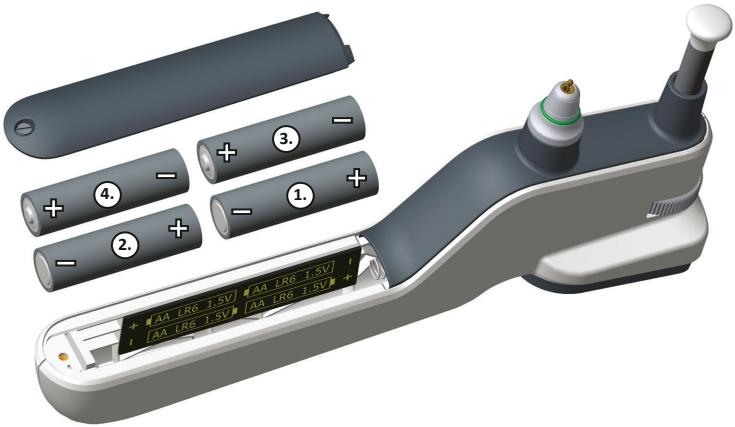
WARNING! The tonometer must not be dropped. To avoid dropping the tonometer and to ensure safe handling, always use the wrist strap to keep the tonometer attached to your wrist when in use. If the tonometer is dropped and the tonometer casing opens, press the casing to close the openings.

7.2 Installing the batteries for the first time

Unscrew the battery compartment locking screw with the screwdriver supplied. Remove the battery compartment cover. Insert a new set of four AA 1.5 V batteries (LR6). Insert the batteries according to the figure below. Take care to observe correct polarity.

Replace the battery compartment cover. Secure the cover in place by tightening the locking screw. Take care not to use excessive force (torque) when tightening the screw.

PRECAUTION! Use only the battery type which is specified in technical specification section of this instruction manual.



7.3 Turning the tonometer on

The tonometer can be activated in one of two ways. Either press the Select or the Measure button once. The following figure sequences illustrate the two alternative ways of starting the tonometer:

After pressing the Select button

After pressing the Measure button

The device displays the time and date during the start-up sequence. If either the time and/or date are incorrect, set the correct time and/or date as instructed in the User Interface Functions section of this instruction manual, or by connecting the tonometer through Bluetooth to a printer or computer.

7.4 Patient ID

You may choose to assign an ID number to any measurement. The ID may help to verify afterwards which measurement belongs to which patient in the device's measurement history. Press the Select button to get to the Measure view from the Load view unless you were already in the Measure view. Press the right Navigation button three times to get to the Patient ID view, press the Select button again and select a number by the Navigation buttons. Press the Select button to get back, press the left Navigation button two times to get to the Measure view and finally press the Select button to get to the Load view.

8 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, do not touch the bare probe, do not use a probe if it touches a non-sterile surface like a table or the floor. Do not use the touched or dropped probe, dispose of it properly (e.g. in containers for disposable needles).

PRECAUTION! Prior to each new patient to be measured, check that a new disposable probe from an intact package is being used. After inserting the probe in the probe base, visually inspect the probe to ensure that the small plastic round tip is visible at the front. Do not use a probe without the plastic tip.

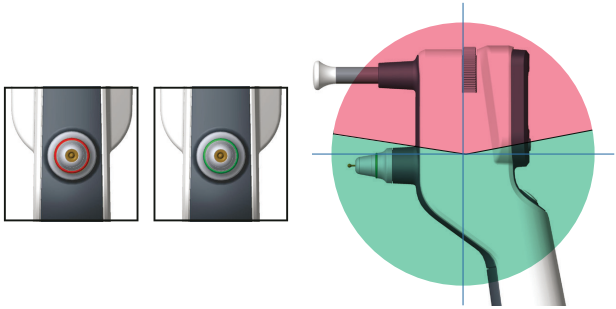
Remove the yellow protective cover from the probe base by pulling (not by turning as turning may unscrew the locking collar). Retain the probe base cover (do not discard). The probes are supplied in protective probe tubes. Take a new probe tube and hold the tube with its cap upright. Remove the protective cap. Insert the probe into the tonometer's probe base by carefully turning the probe tube upside-down, allowing the probe to slide into the probe base (see figure). The tonometer will magnetize the probe and hold it in the probe base.

A probe can be loaded into the iCare IC200 tonometer even if the device has not yet been turned on. In this case, the tonometer recognizes that a probe has been inserted when entering the measurement sequence and automatically displays the eye side selection menu.

9 Probe base indicator light

The probe base indicator can emit either red or green light when the tonometer is on. The probe base indicator light serves two purposes: Firstly, the indicator helps guide alignment of

the tonometer device and probe by emitting a red light – if the device is tilted too far up – or a green light when the orientation of the device is acceptable.



Secondly, the indicator light color changing to red can communicate an error situation during the measurement sequence, in addition to messages shown on the device's display screen (see Chapter 13 Error and info messages).

10 Measurement

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.

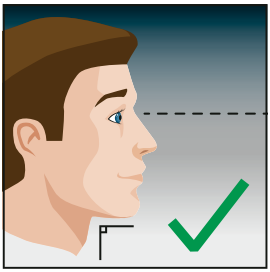
WARNING! Use of eye drops right before the measurement or topical anesthesia may affect the measurement result.

PRECAUTION! If the tonometer is not used for 3 minutes, it will automatically switch itself off.

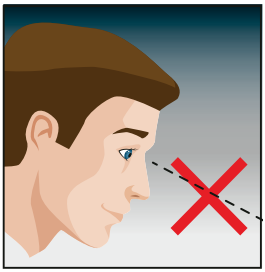
10.1 Default measurement

When measuring, the tonometer and probe need to be positioned approximately perpendicular to the surface at the center of the cornea of the eye.

STEP 1. Ask the patient to relax. Whether seated or standing, ask the patient to assume a straight and upright posture of their head and neck. Ask the patient to look straight ahead at a specific point. Bring the tonometer in front of the patient's eye.



Correct head and eye position.



Incorrect head and eye position.

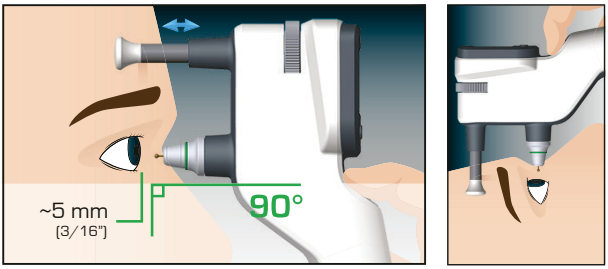
STEP 2. You may choose to annotate the measurement result with the eye's side (right/left) information. Note that the device's default selection is NO eye side information. Select between the OD (right eye) and the OS (left eye) by pressing the Navigation buttons.

The tonometer is now ready to measure, indicated by the Play symbol displayed on the screen. If you have selected and confirmed the eye side or the patient ID, this information is also displayed on the screen.

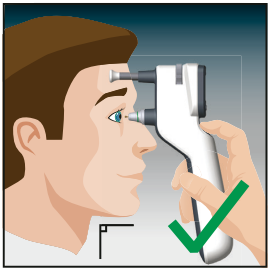
Ready to measure display with the eye's side selection options: OD, no information, OS.

Patient ID selected

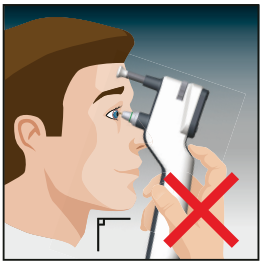
STEP 3. Ensure that the forehead support is fully extended by turning the forehead support adjustment wheel. In order to perform a successful measurement, the distance from the tip of the probe to the patient's cornea (see picture) should be about 5 mm (about 3/16 inch). Bring the tonometer in front of the patient's eye with the probe pointing to the center of the cornea until the forehead support touches the forehead. Do not accidentally push the tonometer or probe into the eye. Adjust the probe-cornea distance for your patient by turning the forehead support adjustment wheel.



Always adjust the position of the tonometer so that the probe is pointing towards the center of the cornea and is perpendicular to the surface of the cornea.



Correct device position.



Incorrect device position.

STEP 4. An IOP measurement can be performed using the tonometer either in Single Mode or in Series Mode. Each IOP measurement is calculated from six individual and consecutive rebound measurements:

Single Mode: Press the Measure button gently but firmly. Keep the tonometer still and steady. The tip of the measurement probe will make contact with the central cornea. Take six measurements. The grey segments of the circle on the display screen will turn blue one by one. In addition, the device will emit a short "beep" sound after each successful measurement.

Series Mode: Press and hold the Measure button down. The device will automatically make a series of measurements. After the first successful measurement, one segment of the circle will be lit blue, additional segments will turn blue as the tonometer continues to measure. Measuring in Series Mode will take just a few seconds.

If the tonometer detects an error occurring during the measurement, it will beep twice and an error message will be displayed. To remove the error message from the display, press the Measure button and proceed to the measurements. For more information about error messages, see Chapter 13 Error and info messages in this manual.

STEP 5. Once six measurements have been successfully made, the tonometer will emit one long beep sound. The final IOP measurement is displayed in large digits, in mmHg, inside a colored circle on the display screen. The colors indicate the quality of the IOP measurement. Green indicates “good” (a low variation of the observed parameters of probe motion during the four individual measurements used in the calculation of the final IOP), yellow indicates “acceptable” measurement quality.

If the variation in the measurements is too high, the tonometer will display the Repeat symbol on the display screen. A new measurement series can be initiated by pressing the Measure button once.

The values from the first to the fifth value displayed before the sixth value are running average values. The sixth value is the final IOP value which is calculated from the best four individual measurements (the worst two individual measurements are discarded).

STEP 6. After an IOP measurement has been successfully made from one eye, you may measure the IOP in the other eye (or make a repeat measurement in the same eye) by repeating the steps 1-5 above. The device does not automatically switch from one eye to another after one eye is measured, e.g. from OD to OS.

When you have finished your IOP measurement session, hold the device so that the probe is horizontally or slightly downward tilted, press the Select button for three seconds to turn the tonometer off. The probe comes out from the probe base and you can remove it. Discard the probe (according to instructions). Retrieve the probe base cover and place over the probe base.

NOTE: When the tonometer is not in use, always keep the probe base covered to protect the probe base from contamination.

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.

If you are unable to complete six successful measurements in a sequence, the measurement process can be terminated by pressing the Select button once. In such an instance, the results of the measurement attempt can be viewed in the device's HISTORY menu. Note that in cases of unfinished measurements, IOP data from the individual steps are displayed with no indication of measurement validity.

10.2 Quick Measure

WARNING! Quick Measure accuracy and repeatability are not clinically validated, and the results may not exactly match the default measurement mode's results. Use the default measurement primarily with all patients and if the default measurement is unsuccessful repeat the IOP measurement with Quick Measure. The Quick Measure result is indicative.

WARNING! The incorrect alignment error indication is disabled when Quick Measure is used. Keep the tonometer perpendicular to the center of the cornea to get reliable IOP measurement results.

WARNING! No quality indication is shown for the result when Quick Measure is used. Make sure that the measurement is done as instructed in this manual to ensure a reliable IOP measurement result.

The iCare IC200's Quick Measure feature measures the patient's IOP with fewer rebound measurements and a faster measurement cycle. In Quick Measure, the probe is released with shorter intervals between measurements than in the default measuring mode. The purpose of Quick Measure is to enable the IOP measurement of patients whose IOP cannot be measured with the default measurement for any reason (such as lack of cooperation or the patient cannot keep the eye open long enough).

Quick Measure takes two or three rebound measurements: two rebound measurements if both results are within 2 mmHg, and a third measurement if the difference between the first two measurements is greater than 2 mmHg. The IOP result is calculated as the median of the measurements and is shown as a whole number without decimals.

To perform a measurement using Quick Measure, navigate in the main menu to Quick Measure (to the right of the default Measure) and select it by either pressing on the Select button or the Measure button. Once you have selected the Quick Measure, load an iCare probe as instructed in Chapter 8 Loading the probe, and perform the measurement as you would when using the default Measure function. After 2 or 3 rebound measurements, the IOP reading is shown on the display.

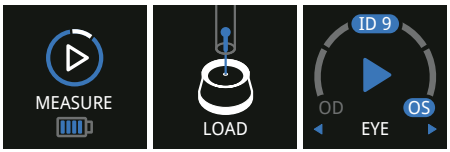
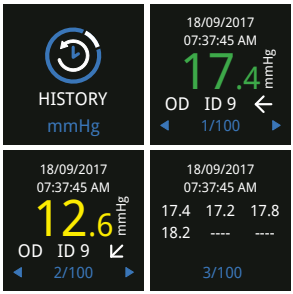
Quick Measure has been tested in a bench test with a manometrically controlled test cornea. The test was done by measuring a manometrically controlled artificial cornea. The test pressures (7, 10, 20, 30, 40, and 50 mmHg) covered the specified measurement range of the default measurement mode.

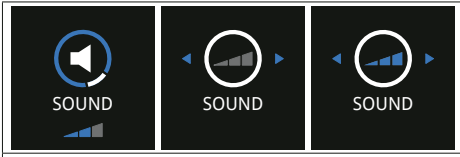
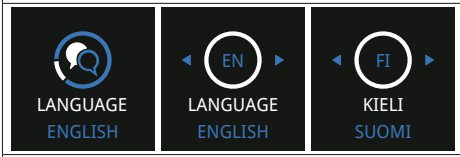
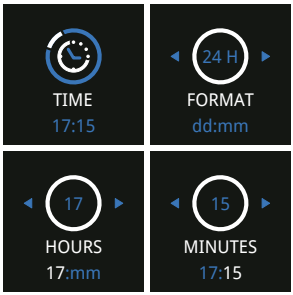
The test results demonstrate high agreement with the default measurement, see section 10.1 Default measurement. The maximum difference between Quick Measure mode and the default measurement mode is 0.57 mmHg at 10 mmHg membrane pressure. Maximum difference between operators was observed at a 40 mmHg membrane pressure (1 mmHg).

Quick Measure can be distinguished from the default Measure by its magenta color, and the Quick Measure symbol ▷▷ that is always visible on the display. In the measurement history, the measurements taken with the Quick Measure are also identified with the Quick Measure symbol.

11 User interface functions

The iCare IC200 tonometer device uses a large, color display screen as part of its user interface. Three buttons below the screen allow the user to control the device. Pressing either of the two Navigation buttons (left/right arrows) allows for changing a selection in a displayed menu, the center Select button is for activating a selection. The large Measure button located on the handle is used for starting the measurement function.

	**MEASURE – Access to the measurement feature** If no probe is detected in the probe base, the “LOAD” text and graphics are displayed. After a probe is loaded, the eye side to be measured first can be selected. The tonometer is ready for measurement when the Play symbol appears on the display screen.
	**QUICK MEASURE – Access to the Quick Measure feature** If no probe is detected in the probe base, the “LOAD” text and graphics are displayed. After a probe is loaded, the eye side to be measured first can be selected. The tonometer is ready for measurement when the Quick Measure symbol appears on the display screen.
	**HISTORY – Previous measurements** The latest measurement is displayed first in HISTORY. The color of the displayed result indicates the measurement quality. The horizontal arrow indicates the patient’s standing or sitting position, the oblique arrow a reclined position, and the vertical arrow supine position.
	**PATIENT ID – Add an identification to a measurement** The user can assign an ID number from one to ninety-nine to any measurement. If a Patient ID is selected, it will be shown during the measurement sequence and in the device’s measurement HISTORY.
	**BLUETOOTH – Wireless connection** The tonometer can be paired with a Bluetooth® printer for printing the measurement results or with a computer for transfering the measurement results. For details, see the Bluetooth® section of this document.

	**SOUND – Adjusting the beep volume** The tonometer offers three sound levels, in addition to a silent mode. The sound level is indicated with a 3-level bar.
	**LIGHT – Adjusting the Probe base light brightness** The intensity of the Probe base light can be adjusted to one of three levels, or switched to OFF state. The intensity of the light is indicated with a 3-level bar.
	**BRIGTHNESS – Adjusting the brightness of the display screen** The brightness of the display screen can be set to one of three levels. The brightness level is indicated with a 3-level bar.
	**LANGUAGE – Language setting** The user can change the language of the user interface from several languages.
	**DATE – Setting of the date displayed on the device** The date shown on the device can be set in one of several formats: IS0 8061 (Y-M-D), USA (M/D/Y) and the common (D.M.Y). However, setting the date is always performed in the standard format order of: YEAR → MONTH → DAY.
	**TIME – Setting of the device time** The time displayed on the device can be selected to be either in the 12- or 24-h format. Setting the time is made in the sequence: FORMAT → HOURS → MINUTES.
	**INFO – Device and System information** This INFO screen displays the device serial number (SN). Pressing the Select button shows the installed software version (SW) of the tonometer.

12 Bluetooth

The IC200 (TA031) device has a Bluetooth functionality for wireless printing and data transfer to a computer. This section describes how the printing to a Bluetooth printer and sending (exporting) the measurement results to the computer is performed via the Bluetooth® functionality of the device.

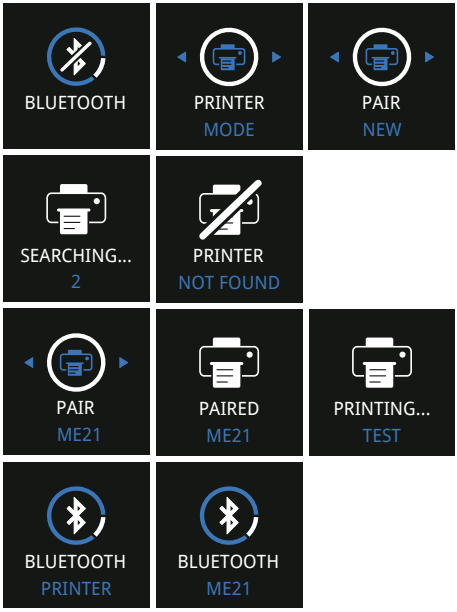
12.1 Printer

To print you first need to pair the IC200 with a Bluetooth (Classic) printer. Pairing means that you create a connection between the IC200 device and the printer.

The connection (pairing) is automatically stored, and if disconnected, resuming is fast and simple by activating the connection. Once the printer has been paired and the printer mode is active the measurement can be printed out either straight after completed measurement sequence or from the HISTORY menu.

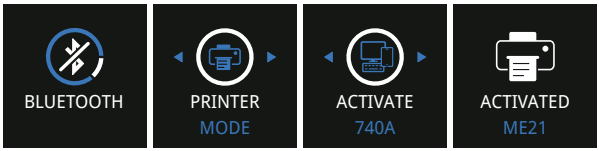
To pair the IC200 with the printer:

- Make sure the printer is turned ON
- Using the Navigation buttons select the Bluetooth menu, press the Select button and select PRINTER MODE.
- Using the Navigation buttons select PAIR NEW.
- IC200 starts to search for Bluetooth printer(s). Number in SEARCHING... screen will increase as printer(s) are found. The searching can be cancelled by pressing the Select button.
- PAIR with the printer's id, for instance ME21, appears when printer(s) are found and ready for pairing.
- Using the Navigation buttons select the desired printer.
- Press the Select button to pair the desired printer.
- PAIRED appears when a Bluetooth connection is formed.
- The printer prints out a test page to verify the connection. If the test page is not printed out, check that there is paper in the printer, the lid is closed and the printer is otherwise ready for printing.
- Once the test page has been printed, the device returns to main menu and displays the BLUETOOTH PRINTER and the printer's id in turn on the screen.



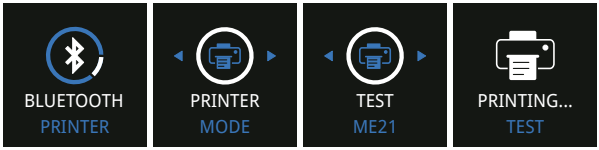
To activate the pairing with the printer:
(if Bluetooth is turned off)

- Go to PRINTER MODE.
- Press the Select button and ACTIVATE appears.
- Press the Select button to activate the printer mode and the connection with the paired printer.



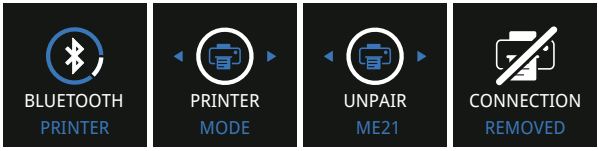
To test the activated printer:

- Go to PRINTER MODE and press the Select button.
- Navigate with the Navigation buttons to TEST.
- Press the Select button to print a test page.



To remove the pairing: (printer connection)

- Go to PRINTER MODE and press the Select button.
- Navigate to UNPAIR.
- Press the Select button to remove the pairing between the IC200 device and the printer.



To print the results to the paired printer right after the completed measurement:

- Navigate with the Navigation buttons to PRINT.
- Press the Select button to print out the measurement result.

To print the results to the paired printer from the HISTORY:

- Navigate with the Navigation buttons to PRINT.
- Press the Select button to print out the measurement result.

To turn off Bluetooth: (to save batteries, pairing is not removed)

- Go to BLUETOOTH and press the Select button.
- Navigate with the Navigation buttons to TURN OFF.
- Press the Select button to turn off Bluetooth.

The printed receipt contains the following information: tonometer model and serial number, measurement date and time, patient ID, eye side, measurement position, measurement result and quality of measurement. When printing Quick Measure results, the quality indicator is replaced with “Quick Measure” text.

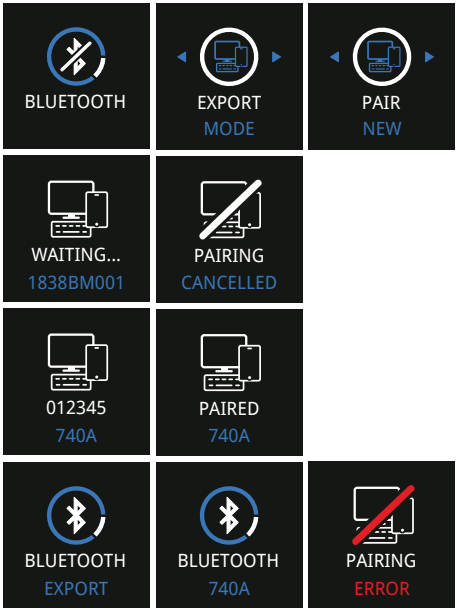
12.2 Export

PRECAUTION! The responsible organization should maintain proper IT security practices like up-to-date virus protection, firewall and data protection in the systems where iCare EXPORT is used.

To export the measurement results you first need to pair the IC200 with the computer having a Bluetooth (Low Energy) functionality and the iCare EXPORT software running. Pairing means that you create a connection between the IC200 device and the computer. The connection (pairing) is automatically stored, and if disconnected, resuming is fast and simple by activating the connection. Once the computer has been paired, the export mode is active and the iCare EXPORT software is running on the computer, measurements are sent.

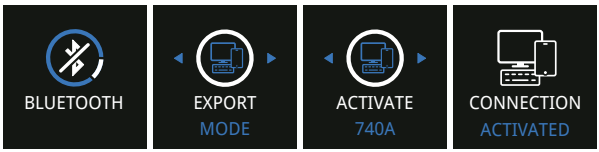
To pair the IC200 device with the computer:

- Open the Bluetooth settings of the computer you want to pair the IC200 device with and make sure the Bluetooth is ON.
- Navigate into the Bluetooth menu of the IC200 device and select EXPORT MODE.
- Select PAIR NEW.
- The IC200 will display WAITING... <serial number of the IC200 device>. The pairing can be canceled by pressing the Select button.
- The IC200 is now available for pairing and visible as a Bluetooth device in the computer.
- Select the IC200 device from the device list of the iCare EXPORT software.
- The pass key and the mac id of the connection, for instance 740A, will appear on the display of the IC200 device for 30 seconds.
- Enter the pass key to the iCare EXPORT software to pair the devices.
- After a successful pairing, the IC200 device will display PAIRED with the mac id.
- The device returns to main menu and displays the BLUETOOTH EXPORT and the mac id in turn on the screen.
- If the pass key is incorrect, IC200 will display PAIRING ERROR. The error needs to be acknowledged by pressing the Select button.



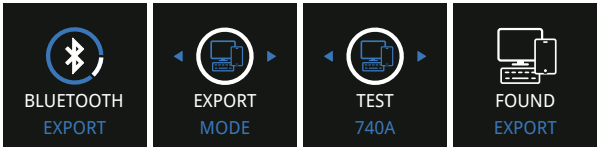
To activate the pairing with the computer:
(if Bluetooth is turned off)

- Go to EXPORT MODE.
- Press the Select button and ACTIVATE appears.
- Press the Select button to activate the export mode and the connection with the paired computer.



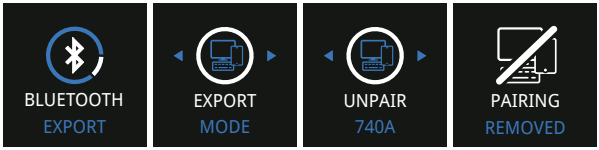
To test the activated computer:

- Go to EXPORT MODE and press the Select button.
- Navigate to TEST and press the Select button.
- FOUND EXPORT or NOT FOUND EXPORT will appear to indicate the connection status.



To remove the pairing:
(computer connection)

- Go to EXPORT MODE and press the Select button.
- Navigate to UNPAIR.
- Press the Select button to remove the pairing between the IC200 device and the computer.



To export (send) the measurement results:

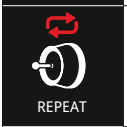
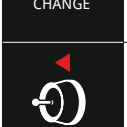
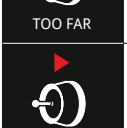
- Make sure pairing is activated (see above) and the computer connected to internet.
- Select the IC200 device in the iCare EXPORT software.
- At this point measurements are sent to cloud for further management with software.
- You will also be able to set software to send measurements to cloud from the IC200 device as you take measurements.

To turn off Bluetooth:
(to save batteries, pairing is not removed)

- Go to BLUETOOTH and press the Select button.
- Navigate with the Navigation buttons to TURN OFF.
- Press the Select button to turn off Bluetooth.

13 Error and info messages

The following messages may appear on the display screen:

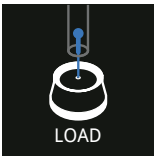
Message	Description	Actions
	Battery charge is low.	Prepare to replace the batteries.
	The batteries are empty.	Turn the tonometer OFF by pressing the Select button. Replace the batteries.
	The probe was not perpendicular to the cornea or the probe hit an eyelid or eyelashes.	Ensure the eye is open and the probe points towards the center of the cornea and is perpendicular to the surface of the cornea. To clear error messages, press the Measure button, after which the measurement can be repeated.
	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 to about 5 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.

Message	Description	Actions
SERVICE	Internal error detected.	Turn the tonometer OFF by pressing the Select button. Contact the seller to arrange sending the device for service. Write down the service ID shown on the display.
 PRINTER ERROR	Printer loses power during connection or it is OFF.	Acknowledge with the Select button. Look for solution from the printer, not the IC200.
 PAIRING ERROR	The pass key is incorrect or pairing is removed from the computer end when the user tries to connect from IC200.	For incorrect pass key acknowledge with the Select button. For partially removed pairing remove the pairing from both the IC200 and computer. Renew the pairing.
 NOT FOUND EXPORT	The iCare EXPORT software was not active when testing the connection.	Displayed for 2 seconds. Run the iCare EXPORT software on the computer and test again.
 NOT FOUND 740A	The Bluetooth connection was not active when testing the connection.	Displayed for 2 seconds. Make sure the Bluetooth is ON also at the computer end.
 CONNECTION LOST	The connection to the computer is lost.	In 2 seconds the IC200 returns to the screen previously used. Try to reconnect.
 PAIRING CANCELLED	The Select button was pressed to exit the pairing on the EXPORT MODE.	In 2 seconds the IC200 returns back to the PAIR NEW screen.

14 Measurement flow chart

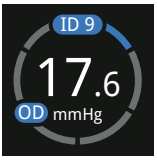
Turn the tonometer ON by pressing the Select or Measure button

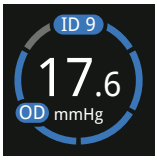
This is displayed if you pressed the Select button, pressing of the Measure button would lead you directly to Load Probe



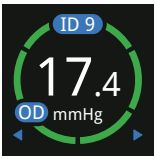
Load probe

Ready to measure and eye side selection

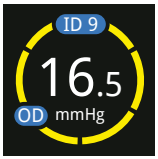


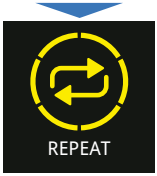


Measure 6 times by pressing the Measure button (blue color bar shows the progress)



Successful measurement





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

15 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			
7216	Probe base collar	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	6 g	110 x 25 x 12 mm
Other supplies			
548	Screwdriver	15 g	16 x 90 mm
567*	Silicone grip, dark gray	26 g	45 x 35 x 113 mm
544B	Probe base cover, iCare IC200	1 g	19 x 11 mm
619B	IOP pad	38 g	50 x 53 x 16 mm
527	Aluminum case, iCare IC200	800 g	240 x 280 x 72 mm

***** Not available in EU.

16 Technical information

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

Type: TA031
Dimensions: 43 mm (W) x 104 mm (H) x 214 mm (L).
Weight: 165 g (without 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: 0.1 mmHg.
Display unit: Millimeters of mercury (mmHg).
Mode of operation: continuous.
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.

Operation environment:
Temperature: +10 °C to +35 °C
Relative humidity: 30 % to 90 %
Atmospheric pressure: 800 hPa to 1,060 hPa

Transport environment:
Temperature: -40 °C to +70 °C
Relative humidity: 10 % to 95 %
Atmospheric pressure: 500 hPa-1,060 hPa

Storage environment:
Temperature: -10 °C to +55 °C
Relative humidity: 10 % to 95 %
Atmospheric pressure: 700 hPa to 1,060 hPa

The serial number is on the tonometer's outer cover. The LOT number of the probes is on the side of the probe box. There are no electrical connections from the tonometer to the patient. The device has BF-type electric shock protection. The single use probe and the forehead support of the device are considered as applied parts. 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. The tonometer's internal clock is synchronized manually or through connection to an IT network.

16.1 IT-network specifications

WARNING! Connection of the IC200 tonometer to IT networks including other equipment could result in previously unidentified risks to patients, operators, or third parties.

WARNING! The responsible organization should identify, analyze, evaluate, and control any additional risks resulting from the IC200 tonometer connected to IT networks including other equipment.

PRECAUTION! Changes to the IT network could introduce new risks requiring additional analysis by the responsible organization. The changes include:

- changes in the IT-network configuration
- connection of additional items to the IT-network
- disconnecting items from the IT-network
- update or upgrade of equipment connected to the IT-network

To transfer the measurement data (measurement history) from the IC200 tonometer to a host device, the tonometer must be connected to responsible organizations IT Network over Bluetooth. The IC200 tonometer is designed to work stand-alone without the Bluetooth connection. The IC200 tonometer is designed such that network failures will not prevent the IC200 tonometer from working normally.

Required characteristics of the IT-network:
Printer: Bluetooth® Classic, ESC/POS communication protocol.
Computer: Bluetooth® 4.0 (or greater) Low Energy support.

Connection is secured by link authentication. The responsible organization is strongly recommended to maintain virus protection up to date on the computers used. The responsible organization is also recommended to install security updates to the used web browsers and computers when available.

System requirements for iCare CLINIC:
- Internet connection
- Minimum web browser versions: Edge (90 and later), Chrome (v 58 and later), Firefox (v 53 and later) and Safari (5.1.7 and later)

Check the iCare software instruction manuals for the latest software system requirements.

Minimum computer requirements for iCare EXPORT:
- x86 or x64 1 GHz Pentium processor or equivalent
- 512 MB RAM
- 512 MB of hard disk space (in addition, 4.5 GB if .NET not already installed)
- USB 2.0 connection
- 800 x 600 resolution display with 256 colors
- DirectX 9 compatible graphics card
- .NET Framework 4.6.1 or greater
- Operating System: Windows 10 or Windows 11
- Internet connection

Intended Information Flow:
Measurement data is collected by the IC200 tonometer. This data is sent via Bluetooth connection either to a wireless printer (Bluetooth Classic), or to the computer (Bluetooth Low Energy, BLE) which has the iCare Export application installed. The iCare EXPORT will transfer the data into the iCare CLINIC software.

Operators can then access the data by using the iCare CLINIC software with a web browser in an internet connected device.

Potential Hazardous situations resulting from the failure of the IT-network:
- If the Bluetooth connection is lost during data transfer, no data is lost from the device. The measurement data can still be found from the device history and transferred once the connection is re-established.
- Failure or misconfiguration of the IT-network may result in data not being transferred causing inconvenience to the operators.

17 Performance data

17.1 Default measurement

The performance data was obtained from a clinical study performed according to ANSI Z80.10-2014 and ISO 8612. The study was performed in the East West Eye Institute, 420 E Third St. Suite 603, Los Angeles, CA 90013, USA. The study analysis included 152 eyes. The mean paired difference and standard deviation (iCare-GAT) in sitting position were 0.52 mmHg and 1.72 mmHg. A scatterplot and Bland-Altman plot of the results is shown in Figure 1 and Figure 2." (Figure 1 = deming regression IC200 vs. GAT, Figure 2 = Bland-Altman plot IC200 vs. GAT).

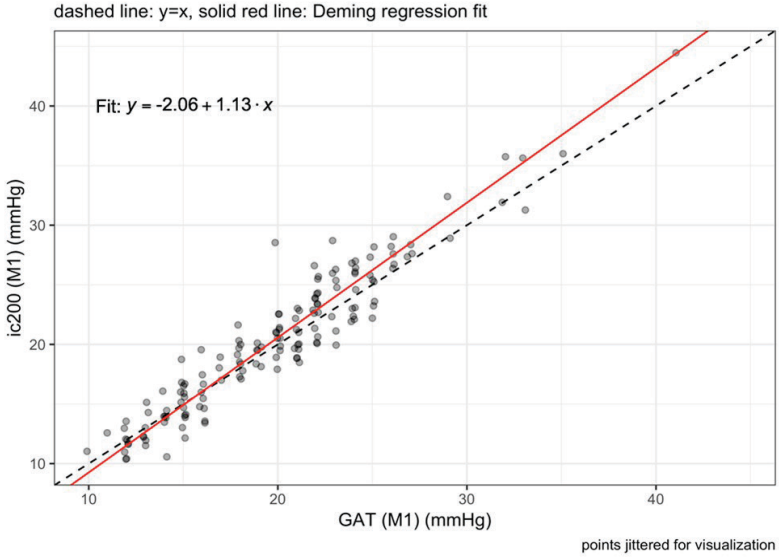


Figure 1

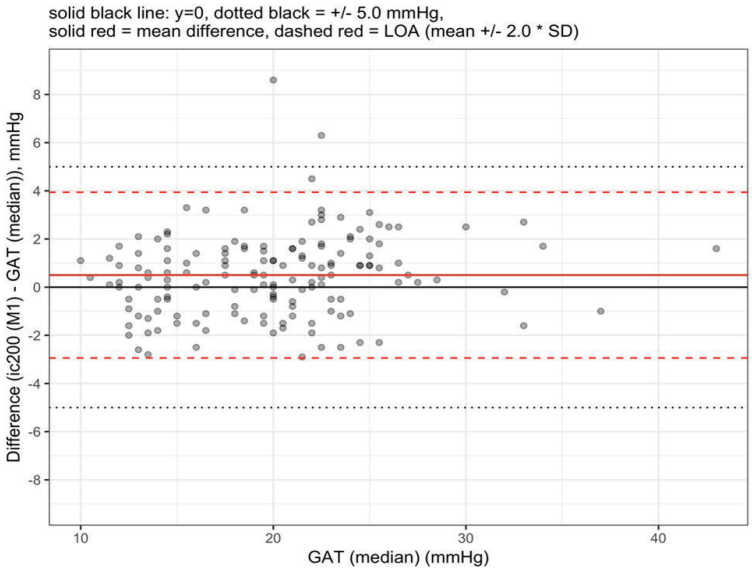
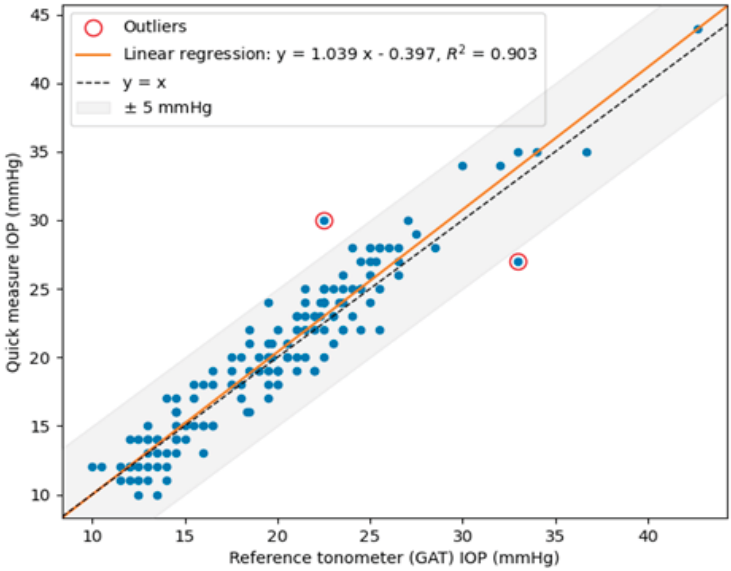
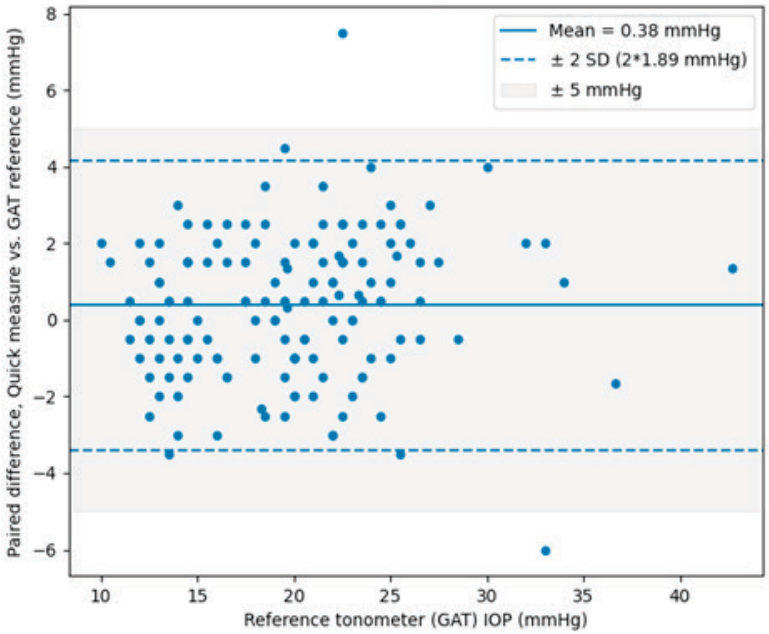


Figure 2

17.2 Quick Measure

Quick Measure performance data was obtained from a retrospective clinical data analysis in which Quick Measure function was retrospectively compared to the clinical data of iCare IC200. In the analysis Quick Measure met ANSI Z80.10:2014 performance goals per GAT reference tonometer. A scatterplot and Bland-Altman plot of the results with Quick Measure function presented on the y-axis and the reference tonometer presented on the x-axis are shown in the following figures.





18 Maintenance

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

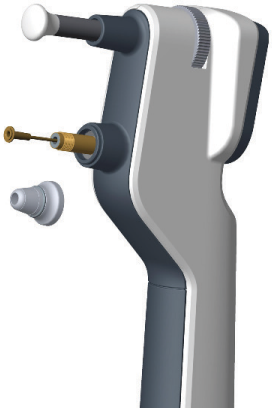
WARNING! The tonometer should only be opened by qualified service personnel. It contains no user-serviceable parts, apart from the batteries and a probe base. The iCare tonometer requires no routine servicing or calibration other than changing the batteries at least every 12 months and the probe base.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

WARNING! 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! Keep the tonometer out of reach of children. The probe base, battery compartment cover, screws, collar and probes are small objects and may be accidentally swallowed.

19 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.

Change the probe base after 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 power off from the tonometer.
- By hand, unscrew the probe base collar and place it in a safe location.
- Pull the probe base out of the tonometer using thumb and fingers.
- Insert a new probe base into the tonometer.
- Screw the collar down until it firmly locks the probe base.

20 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.

To help avoid possible cross-contamination and infection, clean the tonometer's forehead support after each patient with a disinfectant. The outer surfaces of the iCare IC200 tonometer may be safely cleaned with the following liquids:

- 70-100 % isopropyl alcohol
- 70 % ethanol

Instructions for cleaning the tonometer's surface:

- Turn the power off.
- Dampen a soft cloth with one of the permitted cleaning fluids.
- Lightly wipe the surfaces of the tonometer.
- Remove residual fluid using a soft, dry cloth.

21 Returning the iCare tonometer for service or 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.

22 Periodic safety checks

Every 12 months we recommend that the tonometer is checked for correct function as well as visually inspected for mechanical damage and legibility of the safety labels.

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

23 Symbols

	General warning sign		Lot number
	Consult operating instructions		Manufacturing date
	Serial number		Sterilized using irradiation
	Single use only		Keep dry
	Use by		Non-ionizing radiation
IP24	Protected against access to hazardous parts with a finger. Protected against solid foreign objects of 12.5 □ mm or greater. Protected against splashing water.		Manufacturer
	Type BF applied part		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).
Rx Only (US)	Federal law (U.S.) restricts this device to sale by or on the order of a physician.		Refer to the instruction manual
	Technical conformity mark and certification number of the Ministry of Internal Affairs and Communications of Japan (MIC).		Product is a medical device
	Temperature limits		Humidity limits
	Atmospheric pressure limits		Bluetooth communication
	The Regulatory Compliance Mark (RCM), in Australia and New Zealand		Recyclable package material
	National Communications Commission (NCC) mark of Taiwan		CE marking accompanied with the notified body identification number.

	Korea Certification (KC) mark		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

24 Information to the user regarding the radio communication part of the device

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

The iCare IC200 (TA031) device contains a Bluetooth transmitter working at frequencies between 2.402 GHz and 2.480 GHz. Due to the limited size available on the device, many of the relevant approval markings are found in this document.

Bluetooth Module Information:

Item	Specification
Bluetooth Module	RN4678 Bluetooth 4.2 Dual Mode
Communication	Classic (BR/EDR) and Low Energy (LE)
Radio Frequency (RF) Range	2.402 GHz – 2.480 GHz
Output Power	< 2.5 mW (4 dBm), Class 2
Antenna Gain	1.63 dBi
Effective Radiated Power	< 2.2 mW (3.4dBm)
Transmitting Distance	10 meters (30 feet)

The Device Contains a module with:
FCC ID: A8TBM78ABCDEFGH
IC: 12246A-BM78SPPS5M2
MIC: 202-SMD070

Statement of Compliance:
This device complies with Part 15 of the FCC rules and RSS-210 of Industry Canada.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference,
2. This device must accept any interference received, including interference that may cause undesired operation

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

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This Product operates in the unlicensed ISM band at 2.4GHz. In case this Product is used around the other wireless devices including microwave and wireless LAN, which operate same frequency band of this Product, there is a possibility that interference occurs between this Product and such other devices. If such interference occurs, please stop the operation of other devices or relocate this Product before using this Product or do not use this product around the other wireless devices.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Icare Finland Oy is under license.

Other trademarks and trade names are those of their respective owners.

25 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, transducers and cables 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.

PRECAUTION! The measurement method of the iCare IC200 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! The measurement data transfer may be interrupted during electromagnetic disturbance. In such case, reconnect the tonometer to the computer. If this does not solve the issue, perform the data transfer in other location with no such interference. The measurement data will not be deleted from the device before the data is transferred successfully.

PRECAUTION! Non-ME equipment (computer) used in the system for transferring data must comply with the electromagnetic emission and immunity requirements for multimedia equipment: CISPR 32 and CISPR 35.

The iCare IC200 (TA031) 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 following tables.

Portable and mobile RF communications equipment can affect the iCare IC200 (TA031) tonometer.

The Essential Performance of the iCare IC200 (TA031) tonometer is to measure the Intraocular Pressure (IOP) with specified accuracy and to display the measurement results.

Guidance And Manufacturer's Declaration IEC 60601-1-2:2014; Edition 4.0 - Electromagnetic Emissions		
iCare IC200 (TA031) is intended for use in a professional healthcare environment with electromagnetic characteristics specified below. The user of the iCare IC200 tonometer (TA031) should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	iCare IC200 (TA031) 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 IC200 (TA031) 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 IC200 (TA031) is intended for use in a professional healthcare environment with electromagnetic characteristics specified below. The user of the iCare IC200 tonometer (TA031) 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	± 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

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 IC200 (TA031), including cables specified by the manufacturer. Otherwise, degradation of the performance could result. The measurement method of the iCare IC200 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.

Guidance And Manufacturer's Declaration Iec 60601-1-2:2014; Edition 4.0 - Electromagnetic Immunity			
iCare IC200 (TA031) is intended for use in a professional healthcare environment with electromagnetic characteristics specified below. The user of the iCare IC200 tonometer (TA031) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
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 IC200 (TA031) 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 IC200 (TA031) is intended for use in a professional healthcare environment with electromagnetic characteristics specified below. The user of the iCare IC200 tonometer (TA031) 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 IC200 (TA031) 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	

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