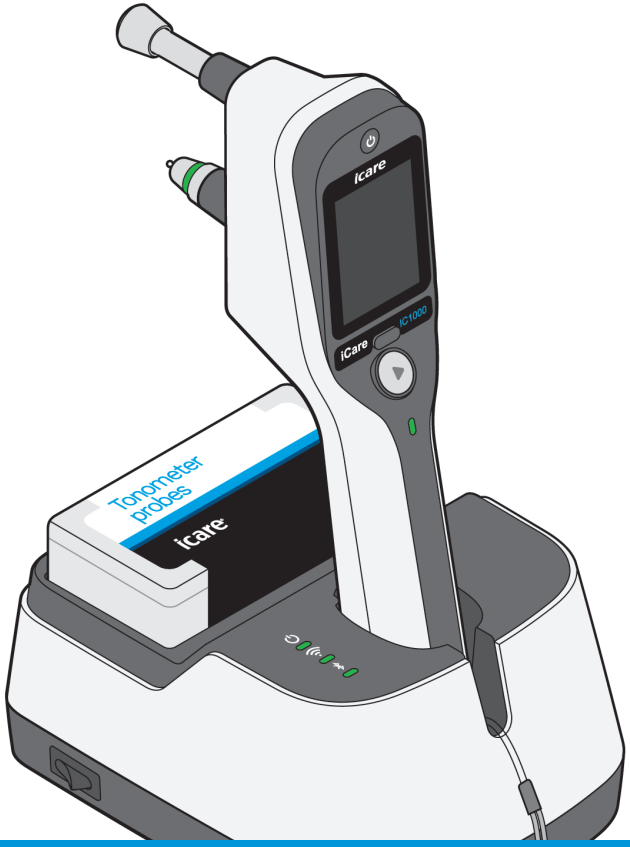
ENGLISH

iCare IC1000



Instruction Manual

icare

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TONOMETER

iCare IC1000

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.



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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1 Safety information

WARNING! The iCare IC1000 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.

WARNING! Keep the device out of the reach of children. The probe base, probe base collar, probe base cover, and probes are small objects and can be accidentally swallowed, causing suffocation.

WARNING! Keep the USB and Ethernet cables out of the reach of children and pets due to the risk of strangulation.

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

WARNING! Do not connect to iCare IC1000 tonometer any items that have not been specified as being part of or compatible with the device.

WARNING! The tonometer (apart from the battery compartment cover) and cradle should only be opened by qualified iCare service personnel. The there are no user serviceable parts, except from the probe base and the user replaceable battery. The tonometer does not require any routine servicing or calibration other than changing the probe base every six months. If there is a reason to believe that the servicing of the tonometer is necessary, contact the manufacturer or local distributor.

WARNING! To avoid a risk of an electric shock, do not touch simultaneously the patient and the charging pin, or the USB port, or the Ethernet port.

WARNING! Only probes are intended for contacting the eye. Do not move the tonometer too close to the patient's eye and avoid touching the eye with other parts of the tonometer. Do not push the tonometer into the eye.

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

WARNING! The tonometer or cradle must not be dropped. To avoid dropping any of the devices and to ensure safe handling, handle them with care. Always use the wrist strap with the tonometer to keep the it attached to your wrist when in use. If the tonometer or cradle is dropped and the casing opens, press the casing to close the openings.

WARNING! Do not use the tonometer or cradle if any of the devices appear to be damaged or malfunctioning. The damaged device must be delivered to service for repair.

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 only original and certified probes made by the manufacturer. The probes are for single-use (single pair of measurement sequences) only. Each

session is defined by one successful measurement in both eyes, but in case either eye is inflamed or infected, measure the healthy eye first. The probes must not be cleaned.



WARNING! Only use intact probes taken from an 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! To prevent contamination, keep unused probes in their box. Do not touch a bare probe. Do not use a probe if it touches a non-sterile surface such as a table or a floor.



WARNING! The tonometer or cradle must not be repaired or re-assembled by any other than the manufacturer or its authorized service center. If you notice changes in the tonometer's or cradle's performance or it is broken, do not use them. Ship them to an authorized iCare service center for repair.



WARNING! Servicing or maintenance actions must not be performed while the device 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! Never immerse the tonometer, cradle or accessories in liquid. Do not spray, pour, or spill liquid on the tonometer, cradle, accessories, connectors, switches, or openings in the cover. Immediately remove any liquid from the surface of the devices.



WARNING! Do not modify the tonometer or cradle in any way. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the tonometer or cradle.



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.



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



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



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 tonometer, including cables specified by the manufacturer, to avoid the degradation of performance.

WARNING! The measurement method of the tonometer is based on a magnetically induced motion of a probe and therefore an external magnetic or radiated RF electromagnetic field disturbing the probe may prevent the measurement. In such a case the tonometer continuously displays error messages during measurement and asks you to repeat the measurement. Situation can be solved either by removing the source of interference from the vicinity of the tonometer or by performing the measurement in different location with no such interference.

WARNING! Connection of the iCare 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 iCare tonometer connected to IT networks including other equipment.

WARNING! Read and follow the battery replacing instructions before replacement of the tonometer battery, as incorrect polarity could result in a hazardous situation.

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

PRECAUTION! When removing the tonometer or cradle from its packaging, and each time before use, visually inspect the device for any external damage, particularly for possible damage to the device casing. If you suspect damage to the device, contact the manufacturer or the distributor of the device.

PRECAUTION! Eye detection is based on the difference of infrared reflections received from the transmitters: the nose side reflects more than the temple side. If the transmitters become dirty, the recognition may be interfered.

PRECAUTION! Do not cover the eye recognition transmitters or sensor during the measurement, for example with your fingers. Make sure that the patient's face is not covered by hair or a scarf, as they can produce an infrared reflection that causes an error.

PRECAUTION! Take care not to cover the camera with your finger. If the camera lens becomes dirty, the functionality may be impaired.

PRECAUTION! To ensure the correct functioning of the tonometer, change the probe base every six months.

PRECAUTION! The probe base may function improperly if dirt or liquid gets inside it.

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

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 tonometer before the data is transferred successfully.

2 Intended use

The iCare IC1000 tonometer is a device intended to be used for the measurement of the intraocular pressure of the human eye.

The iCare IC1000 tonometer is intended to be used by healthcare professionals such as but not limited to ophthalmologists, optometrists, trained ophthalmic technicians and nurses.

3 Possible limitations of use

WARNING! The iCare IC1000 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.

NOTE! Characteristics such as age or weight of the patient do not limit the use of the iCare IC1000 tonometer.

Patients with any of the following conditions should not be measured with the iCare IC1000 tonometer:

- Active ocular infection including infectious conjunctivitis
- Blepharospasm

The safety and effectiveness of rebound tonometry has not been evaluated for patients with*:

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

- Known history of difficulty in obtaining Goldmann IOP measurements or any factors that might contribute to inaccurate Goldmann IOP measurements for example, tremor.

NOTE! When not in use, it is recommended to keep the tonometer in its carrying case to protect it from dirt and direct sunlight that might cause damage to the device.

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 IC1000 tonometer can be used with following accessory devices: IC1000 SmartCradle, IC1000 ChargingCradle, and a compatible printer. The same medical power supply can be used with tonometer and both cradles.

The iCare IC1000 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 IC1000 tonometer allows a patient's IOP to be measured for patients in upright (sitting) or supine positions.

With the iCare rebound measurement method, a miniature, light-weight, single-use 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 the measurement. During the measurement, the probe can be considered to act like a moving magnet that induces an electric signal in the surrounding coil allowing for a 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.

The displayed IOP reading is derived from the results from a sequence of six individual probe rebounds. The displayed IOP measurement is also stored in the tonometer's memory for later retrieval.

The iCare IC1000 tonometer has a rechargeable battery. The battery can be charged directly from a medical power supply using a USB cable and tonometer USB-C port. The battery can also be charged in the IC1000 SmartCradle and or IC1000 ChargingCradle powered by a medical power supply.

Device GTIN can be found printed on the device cover accompanied with serial number and the date of manufacture. For more information about the tonometer or its accessories 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.

4.1 Clinical benefits

With the iCare IC1000 tonometer you can measure the patient's eye pressure with the rebound technology. The measurement method does not require special training for the operator or any topical anesthetics and is quick and painless. The rebound technology enables measurements to be done also on patients who may be difficult to measure with other IOP measurement methods, such as children.

This eye pressure measurement tool is an adjunct to the standard of care and does not replace the conventional methods used to diagnose and manage patients, nor should it alter the follow-up schedule otherwise indicated for a particular patient.

4.2 Essential performance

The essential performance of the iCare IC1000 tonometer is to measure intraocular pressure with specified accuracy, to display measurement results or error conditions and to transfer the measurement data.

If the essential performance of the tonometer is lost or degraded due to electromagnetic disturbances, the tonometer continuously displays error messages during the measurement and asks you to repeat the measurement.

4.3 Sales package contents

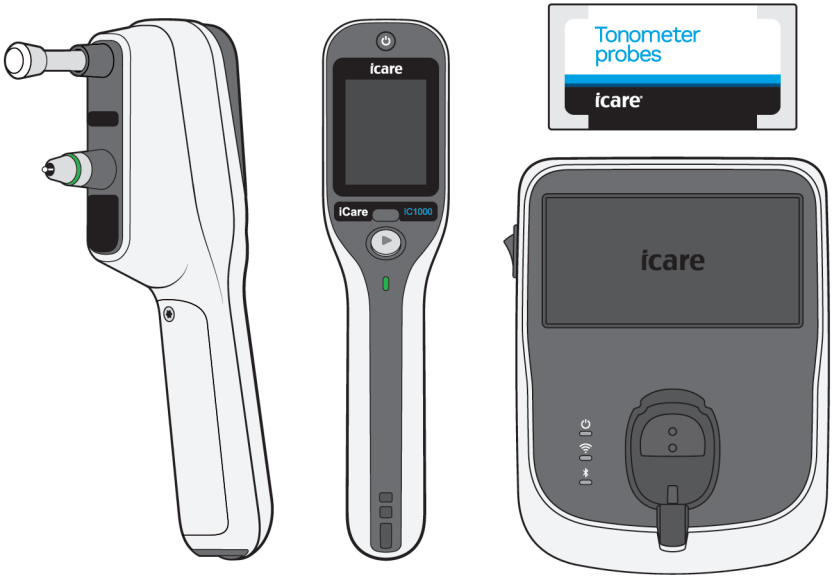
WARNING! Keep the device out of the reach of children. The probe base, probe base collar, probe base cover, and probes are small objects and can be accidentally swallowed, causing suffocation.

WARNING! Keep the USB and Ethernet cables out of the reach of children and pets due to the risk of strangulation.

PRECAUTION! When removing the tonometer or cradle from its packaging, and each time before use, visually inspect the device for any external damage, particularly for possible damage to the device casing. If you suspect damage to the device, contact the manufacturer or the distributor of the device.

NOTE! Use only the parts (such as medical power supply, regional AC plugs and cables) provided by the manufacturer.

Before using the tonometer, check the sales packaging, including the probe box. If the packaging is damaged, unintentionally opened before use, or exposed to environmental conditions outside those specified in this manual, do not use the product and contact the manufacturer or your distributor for further instructions.



The iCare IC1000 Sales package contains:

- iCare IC1000 tonometer
- Carrying case
- Quick Guide
- Box with 100 single-use probes
- Spare probe base
- Probe base cover
- Medical power supply
- Regional AC plugs
- USB-cable for power supply
- Screwdriver Torx TX8
- Wrist strap

IC1000 SmartCradle and ChargingCradle are not included in the tonometer set. They can be purchased separately.

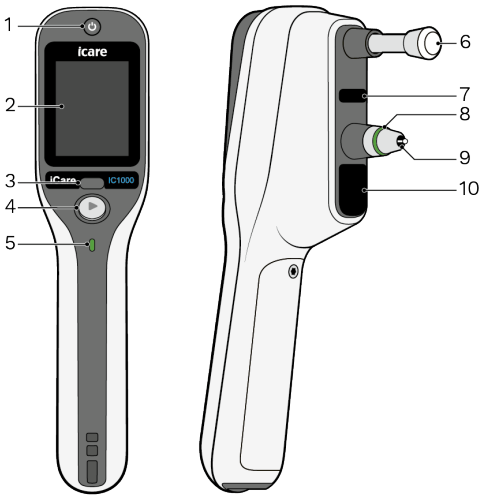
4.4 Device parts

4.4.1 Tonometer

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

WARNING! Do not connect to iCare IC1000 tonometer any items that have not been specified as being part of or compatible with the device.

1. Power button
2. Touchscreen display
3. USB port and cover
4. Measure button
5. Status indicator light
6. Forehead support
7. Infrared leds
8. Probe base light
9. Probe base collar
10. Camera and infrared sensors/leds



Tonometer touch screen button	Purpose	Functionality
← →	Left and Right navigation buttons	Used to navigate the tonometer menu.
■	Select button	Used to activate the desired function such as entering submenus.
↺	Return button	Used to navigate back to the previous menu or screen.
•••	Option button	Used to access additional features or settings related to the current function.
✕	End button	Used to terminate the current operation or session.
OD OS	OD and OS selection buttons	Used to select the eye side of the measured eye if the eye detection fails.
✕ ✓	No and Yes buttons	No button is used to decline the selection. Yes button is used to confirm the selection.
AUTO AUTO	Automatic measure button – ON/OFF	The toggle button is utilized to switch between **Automatic Probe Launch Mode** and **Manual Probe Launch Mode**: **Automatic Probe Launch Mode (AUTO)**: Mode is activated by default when the toggle button is positioned to the left.

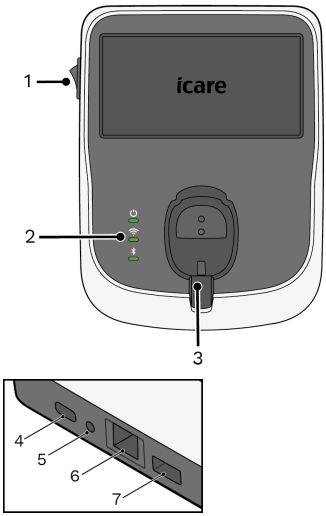
Tonometer touch screen button	Purpose	Functionality
		Manual Probe Launch Mode: Mode is activated when the toggle button is moved to the right, at which point the AUTO indicator will be crossed out.
	Normal Measure/Quick Measure button	The slider is utilized to switch between **Normal Measure** and **Quick Measure**. **Normal Measure**: Activated when the toggle button is positioned to the left. Normal Measure is on by default. **Quick Measure**: Activated when the toggle button is moved to the right.

4.4.2 SmartCradle (accessory)

IC1000 SmartCradle is a device for holding the tonometer and accessories between use, sending measurement results into the iCare cloud software and charging the tonometer battery.

The cradle contains Ethernet, USB type A and type C connectors.

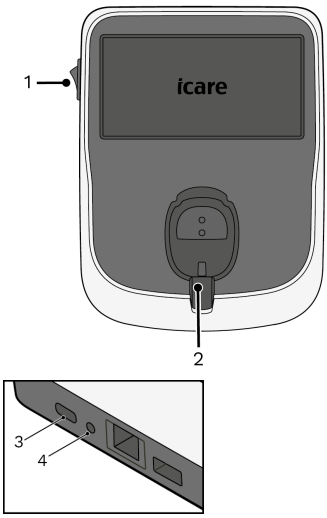
1. ON/OFF switch
2. Cradle LEDs
3. Charging station
4. USB type C connector (for charging the device)
5. Pinhole reset
6. Ethernet connector
7. USB type A connector with protective plug (for USB memory stick only)



4.4.3 ChargingCradle (accessory)

IC1000 ChargingCradle is a device for holding the tonometer and accessories between uses and charging the tonometer battery.

1. ON/OFF switch
2. Charging station
3. USB type C connector (for charging battery)
4. Pinhole reset



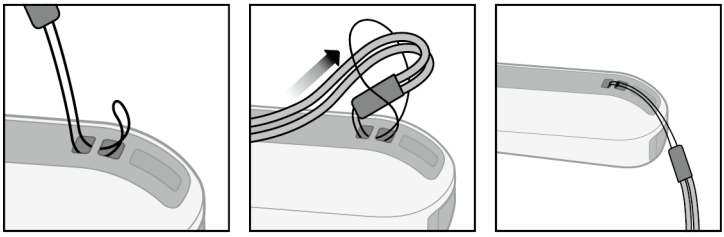
5 Take the product into use

5.1 Install the wrist strap

WARNING! The tonometer or cradle must not be dropped. To avoid dropping any of the devices and to ensure safe handling, handle them with care. Always use the wrist strap with the tonometer to keep the it attached to your wrist when in use. If the tonometer or cradle is dropped and the casing opens, press the casing to close the openings.

Before you use the iCare IC1000 tonometer for the first time, attach the wrist strap.

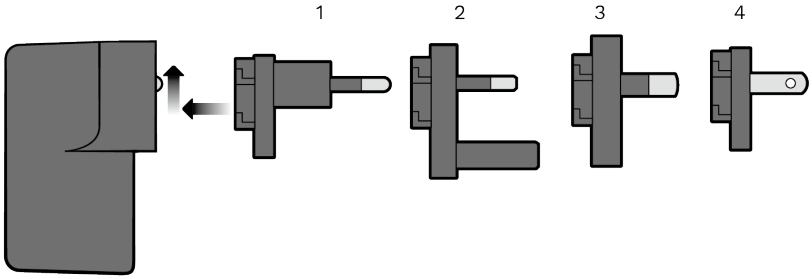
1. Thread the string loop at the end of the wrist strap through the two holes at the bottom of the device (see figure below).
2. Take hold of the end of the wrist strap, turn it back and bring it through the loop.
3. Pull the wrist strap to tighten the loop.



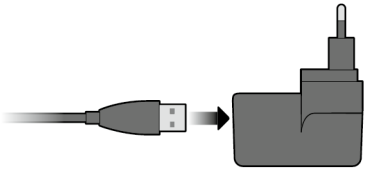
5.2 Prepare the power supply

Prepare the power supply before you charge the tonometer battery:

1. Attach your region's AC plug to the medical power supply. (1. EU, 2. United Kingdom, 3. Australia, 4. US)



2. Plug in the USB cable to a medical power supply and the power supply to a mains power.



5.3 Charge the tonometer battery

WARNING! To avoid a risk of an electric shock, do not touch simultaneously the patient and the charging pin, or the USB port, or the Ethernet port.

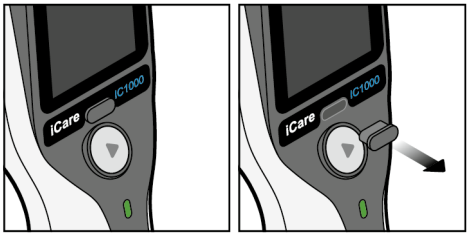
WARNING! The tonometer (apart from the battery compartment cover) and cradle should only be opened by qualified iCare service personnel. The there are no user serviceable parts, except from the probe base and the user replaceable battery. The tonometer does not require any routine servicing or calibration other than changing the probe base every six months. If there is a reason to believe that the servicing of the tonometer is necessary, contact the manufacturer or local distributor.

Charge the tonometer battery before taking a measurement. The iCare IC1000 tonometer is charged with a USB cable or in the cradle. You cannot take measurements while the tonometer battery is charging.

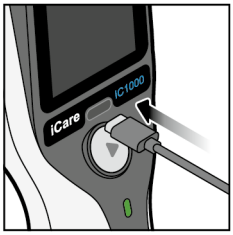
NOTE! The performance of the rechargeable battery decreases in long term use and when the device is not used for a long period of time.

To charge the tonometer with a USB cable:

1. Remove the USB port cover and put the tonometer to a place where it cannot fall while charging.



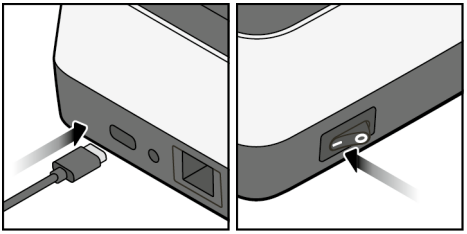
2. Plug in the USB cable to the tonometer. The tonometer's status indicator light starts to flash if the battery is not full.



3. The status indicator light stops flashing when the battery is full. The status indicator light stays on.
4. The tonometer is ready for measurement and the USB cable can be unplugged.

To charge the tonometer in the cradle:

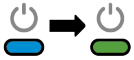
1. Make sure that the cradle is connected to a power supply and turned on.



NOTE! Put the cradle to a location where it is easy to disconnect the power supply from the mains electricity if needed.

2. With SmartCradle:

   If you are using the SmartCradle for the first time, the power indicator turns blue and starts the power on. The power on takes about 25 seconds. When the power indicator has a solid green light, the cradle is ready to use.



With ChargingCradle:

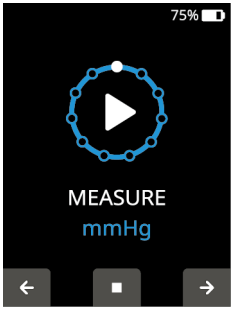
If you are using the ChargingCradle for the first time, the power indicator turns green.

3. Place the tonometer to its designated spot in the cradle. The tonometer's status indicator light starts to flash.



4. The status indicator light turns off when the battery is full.
5. The tonometer is ready for measurement and can be removed from the cradle.

The battery charge level is shown on the upper right corner of the display when the device is on:



Battery status on tonometer display					
	When charging		100% - 76%		75% - 51%
	50% - 26%		25% - 6%		5% - 1%
Indicator battery light level					
	100% - 26%		25% - 6%		5% - 1%

Battery status on tonometer display	
Indicator light operation when charging	
	The pulsating light indicates that the tonometer battery is charging. Pulsating light color depends on the battery level.

If the tonometer's battery life decreases and you suspect the device battery should be changed, contact the manufacturer or your local distributor. Due to battery life optimization, the cradle will not charge the tonometer if the battery charge is high enough (approx. 90 %).

6 Prepare for measurement

WARNING! The tonometer or cradle must not be dropped. To avoid dropping any of the devices and to ensure safe handling, handle them with care. Always use the wrist strap with the tonometer to keep the it attached to your wrist when in use. If the tonometer or cradle is dropped and the casing opens, press the casing to close the openings.

WARNING! Do not use the tonometer or cradle if any of the devices appear to be damaged or malfunctioning. The damaged device must be delivered to service for repair.

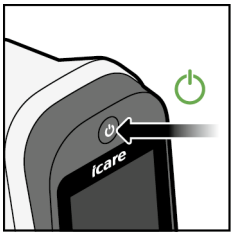
PRECAUTION! Report any serious incidents related to the tonometer to your competent health authority and the manufacturer or the manufacturer's representative.

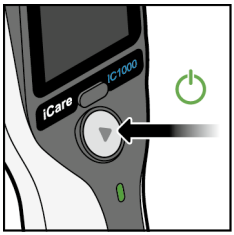
6.1 Switch on the tonometer

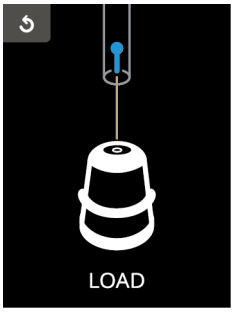
To switch on the tonometer:

Press ⏻ or ▶. The device display turns on and shows the time and date during the start-up sequence. The text LOAD is shown on the display.

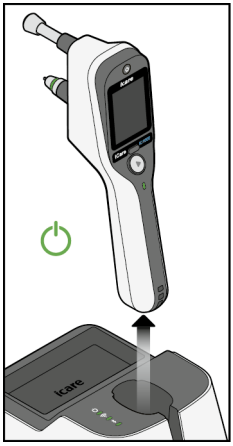
If either the time and/or date are incorrect, set the correct time and/or date as instructed in Tonometer settings on page 29.







Alternatively, the tonometer switches on when you lift it from the cradle.



6.2 Insert 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! Use only original and certified probes made by the manufacturer. The probes are for single-use (single pair of measurement sequences) only. Each session is defined by one successful measurement in both eyes, but in case either eye is inflamed or infected, measure the healthy eye first. The probes must not be cleaned.

WARNING! Only use intact probes taken from an 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.

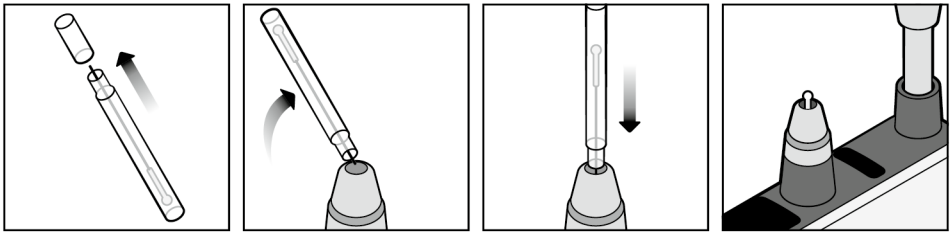
WARNING! To prevent contamination, keep unused probes in their box. Do not touch a bare probe. Do not use a probe if it touches a non-sterile surface such as a table or a floor.

The tonometer comes with a box of 100 probes for measuring the IOP. Each probe is individually stored in a separate container until use. A new probe must be used for each measurement.

Before you insert the probe, remove the probe base cover by pulling, not turning. Turning the cover may unscrew the probe base collar.

Make sure that the text LOAD is shown on the display.

To insert the probe:



1. Remove the probe container cap. Keep the container.
2. Keep the tonometer in one hand and the probe container in another.
3. Turn the container sideways to align it with the probe base collar. Turn it upside down to insert the probe.
4. The tonometer magnetizes the probe and holds it in place.
5. When the probe is loaded, the tonometer screen goes into the measurement mode.

6.3 Select measurement mode

6.3.1 Measurement modes

The iCare IC1000 includes two measurement modes: Normal Measure and Quick Measure. Tap the toggle button to switch between measurement modes.



In the Normal Measure, you take six individual rebound measurements. The final IOP is calculated from the six measurements and is shown on the display after the sixth measurement is taken. Normal Measure is on by default and is indicated with blue play symbol.



The Quick Measure measures the patient's IOP with fewer rebound measurements and a faster measurement cycle. The purpose of Quick Measure is to enable the IOP measurement of patients whose IOP cannot be measured with the Normal Measure for any reason (such as lack of cooperation or the patient cannot keep the eye open long enough). Quick Measure is indicated with two magenta colored play symbols.



6.3.2 Automatic probe launch mode



The iCare IC1000 includes an Automatic Probe Launch Mode (AUTO Mode). If the AUTO Mode feature is on, the tonometer takes measurements automatically when tonometer is aligned in the correct position. You can turn the AUTO Mode on or off from the toggle button. Normal Measure and Quick Measure can both be used when the Automatic Probe Launch Mode is active.

7 Take a measurement

7.1 Position the tonometer and measure the eye pressure

WARNING! Only probes are intended for contacting the eye. Do not move the tonometer too close to the patient's eye and avoid touching the eye with other parts of the tonometer. Do not push the tonometer into the eye.

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

PRECAUTION! Take care not to cover the camera with your finger. If the camera lens becomes dirty, the functionality may be impaired.

NOTE! Before you measure, make sure that the wrist strap is placed around the wrist and tightened with the lock on the wrist strap.

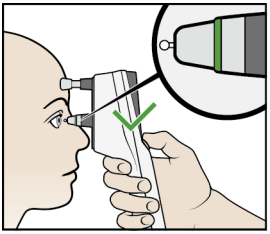
The iCare IC1000 tonometer includes an alignment guide that directs you put the tonometer to the correct measurement position.

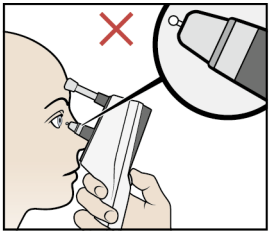
NOTE! When the AUTO Mode is on, the measurements are taken automatically when tonometer is in correct position. Measurements can also be taken manually when the automatic measure is ON by pressing the measure button.

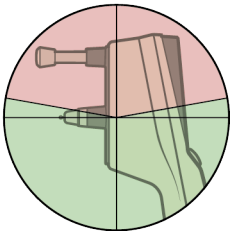
The measurement position is correct when

- the device inclination status is correct: the device points straight in the horizontal plane (patient sitting) or downwards (patient lying down),
- it is aimed perpendicularly to the center of the cornea and
- the probe is about 5 mm from the eye.

The tonometer screen and green probe base light show the inclination status (device's angle).









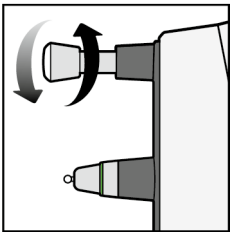
Correct device inclination: measure-symbol is displayed, and probe base light is solid green.



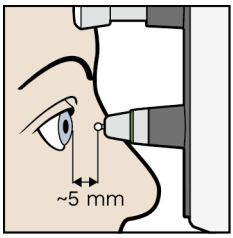
Incorrect device inclination: measure-symbol is blocked, and probe base light is OFF.

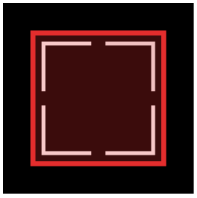
To adjust the tonometer to correct measuring position:

1. Rotate the forehead support to adjust the length.

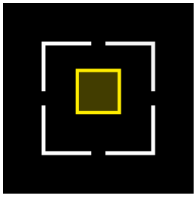


2. Ask the patient to relax and look straight ahead.
3. Bring the tonometer in front of the patient's eye. Set the forehead support to the patient's forehead.
4. Adjust the forehead support until the probe is about 5 mm from the eye.



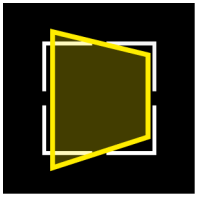


Too near



Too far

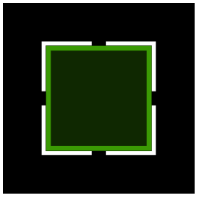
5. Align the tonometer at a 90-degree angle to the patient's face. If your position is not perpendicular the alignment guide shows the incorrect angle.



Rotate

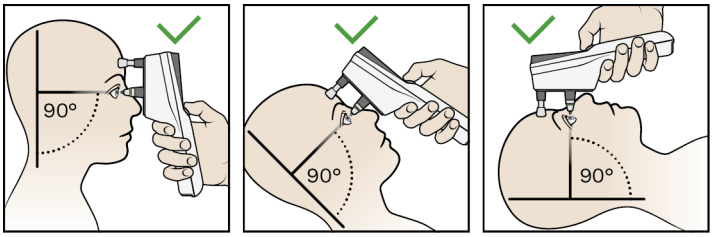


Rotate



Measure

Measurement can be taken in multiple angles.



6. When the measurements are taken the result is shown on the screen. After 2 seconds, the tonometer switches back to the measurement mode. Measure the other eye, if needed.

Press ··· to access previous measurements when you are measuring or to reject all measurements taken during the same measurement round.

Press ✕ when you want to stop measuring.

7.2 Manual measurement

When the AUTO Mode is off, position the tonometer in front of the patient's eye and take the measurements manually.

1. Position the tonometer in front of the patient's eye.

2. Press ▶ 6 times (single mode) or hold down ▶ (series mode) until the tonometer has taken 6 measurements.

   If the Quick Measure mode is on, press ▶ 2 or 3 times.



Measurement progress on the user interface

NOTE! If you receive a measurement error notification, press ▶ to acknowledge the error. Make the necessary corrections and repeat the measurement.

3. When the measurements have been taken, you hear a longer beep. The measurement sequence is completed.



4. Measurement result is shown for 2 seconds.
5. The device returns to measurement mode. Take another measurement, if needed.

   Your previous measurement of OD and OS are shown on the screen. Green color indicates good measurement quality. Yellow color indicates acceptable measurement quality. Magenta color indicates Quick Measure measurement.



Measurement mode showing previous measurements

Press ··· to access previous measurements when you are measuring or to reject all measurements taken during the same measurement round.

Press ✕ or when you want to stop measuring.

7.3 Check the measurement result

After a successful measurement, the measurement result is shown on the display. The quality of the measurement is indicated with a color:

	Green: good measurement quality
	Yellow: acceptable measurement quality
	Yellow, text REPEAT: The variation between the measurements was too high. Repeat the measurement.
	Magenta: Quick measure results are always shown in magenta color. Quick Measure mode does not have quality indicators.
	Viewing results during the measurement round shows the measurement result, time of the measurement, which eye (right or left) was measured, and the quality of the measurement indicated by a color. The measurements can be browsed by pressing the navigation buttons. Press ··· to access the measurements during the measurement round.

The tonometer stores the calculated eye pressure reading in mmHg, the time and date of the measurement, which eye (right or left) was measured and the quality of the measurement indicated by a color.

The data collected by tonometer can be transferred to the iCare cloud software.

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 or lashes), 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.

7.4 Errors during measurement

If the probe base light flashes and you hear multiple beeps, the measurement was not successful. The display and sounds indicate the source of the error.



Error shown on the user interface

If the AUTO Mode is on, the error messages other than CHANGE are automatically acknowledged after 2 seconds.

If the AUTO Mode is off, look at the display and press ▶ to acknowledge the error. Make the necessary corrections and repeat the measurement.

Error message	Explanation	Actions
 TOO FAR	The probe did not touch the eye.	The measurement was taken from too far away. Adjust the correct measurement distance to about 5 mm. Press ▶ to clear the error message and continue measuring.
 TOO NEAR	Tonometer was too close to the eye.	Adjust the correct measurement distance to about 5 mm. If the error occurs during measurement sequence, press ▶ to clear the error message and continue measuring.
 REPEAT	The probe did not move properly or did not make clean contact with the cornea.	Measure again or change the probe. Press ▶ to clear the error message and continue measuring.
CHANGE 	The probe did not move.	Change the probe. The probe was twisted or otherwise inserted incorrectly. Press ▶ to clear the error message and continue measuring. If the error keeps recurring, change also the probe base as instructed in Replace the probe base on page 40.

Error message	Explanation	Actions
 INCORRECT ALIGNMENT	The probe was not perpendicular to the cornea, or the probe hit an eyelid or eyelash.	Make sure that the eye is open, the probe points towards the center of the cornea and is perpendicular to the surface of the cornea. Press ▶ to clear the error message and continue measuring.
 REPEAT OD or OS	The other eye was detected in the same measurement sequence.	Measure only the same eye inside same measurement sequence. Press ▶ to clear the error message and continue measuring. Do not cover the eye recognition transmitters or sensor during the measurement.

7.5 Eye recognition

PRECAUTION! Eye detection is based on the difference of infrared reflections received from the transmitters: the nose side reflects more than the temple side. If the transmitters become dirty, the recognition may be interfered.

PRECAUTION! Do not cover the eye recognition transmitters or sensor during the measurement, for example with your fingers. Make sure that the patient's face is not covered by hair or a scarf, as they can produce an infrared reflection that causes an error.

The tonometer includes automatic eye recognition to identify which eye, right or left, you are measuring. The eye recognition is done by the tonometer infrared sensors.

If the automatic eye recognition does not recognize the eye, you can choose the correct eye after the measurement.

If the automatic eye recognition fails, press OD (patient's right eye) or OS (patient's left eye) on the screen to select the measured eye.

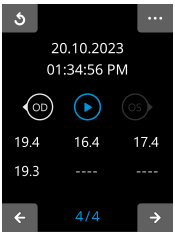


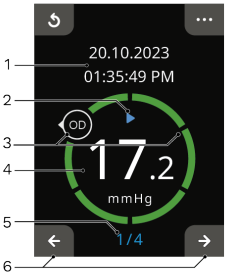
7.6 View the measurement history

1. Navigate to the main menu.
2. Press ← → until you see HISTORY.
3. Press ■ to access HISTORY.
4. Press ← → to view your previous measurements.
5. To exit the view, press ↺.







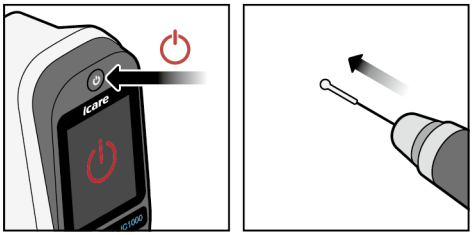


1. Date and time
2. Measurement mode indicator (Normal measure ▶, Quick Measure ▶▶)
3. Measured eye (right or left)
4. IOP result in mmHg (quality indicated by the color of the circle)
5. Number of measurements in the device memory (showing a maximum of 100 latest measurements)
6. Navigation buttons

7.7 Switch off the tonometer and remove the probe

When you have completed the measurements, turn off the tonometer and dispose of the probe.

1. Press ⏻ for 1 second. The tonometer shows the POWER OFF screen, and the probe is ejected out of the tonometer.



2. Discard the probe.

3. Press the probe base cover back over the probe base collar to prevent dirt from getting in.

   Store the tonometer in the carrying case or in the cradle between use.

   NOTE! When the tonometer is not used it shuts down automatically after 3 minutes. The device does not eject the probe when it shuts down automatically. You can change the automatic shutdown time from tonometer settings.

See Recycling on page 43 for instructions on how to recycle the probe and container.

8 Tonometer settings

1. Press to turn the tonometer on or lift it from the cradle.
2. Press to access the main menu.
3. Press to move between the various settings positioned in the main menu.
4. To select a setting, press .
5. To exit the settings, press .

Screen	Settings	Actions
	Time	1. To change the time, press until you see TIME. Press . 2. Press to navigate to the time format, time zone, hour and minutes you want, and press on each to confirm.
	Date	1. To change the date, press until you see DATE. Press . 2. Press to navigate to the date format, year, month and day you want, and press on each to confirm.
	Language	1. To change the language, press until you see LANGUAGE. Press . 2. Press until you see the language you want, and press .
	Sound	1. To change the volume level, press until you see SOUND. Press . 2. Press until you hear the volume level you want, and press .

Screen	Settings	Actions
	Display brightness	1. To change the display brightness, press ← → until you see BRIGHTNESS. Press ■. 2. Press ← → until you see the brightness level you want, and press ■.
	Probe base light	1. To change the probe base light, press ← → until you see LIGHT. Press ■. 2. Press ← → until you see the brightness level you want, and press ■.
	Automatic shutdown	1. To change the automatic shutdown time, press ← → until you see AUTO-OFF. Press ■. 2. Press ← → until you see the time you want for the automatic shutdown, and press ■.
	Info	To browse Device Serial Number and Software Version, press ← →. Scan the QR code on the first page of the INFO menu to access the electronic instruction manual at www.icare-world.com/ifu.

8.1 Device serial number and software version

1. Press ⏻ to turn the tonometer on or lift it from the cradle.
2. Press ↺ to access the main menu.
3. Press ← → until you see INFO on the display and press ■ to enter INFO menu.
4. Press to view device serial numbers and software versions.
5. To exit the view, press ↺.

NOTE! For the SmartCradle information to be visible in the INFO menu, the SmartCradle needs to be paired and connected to the tonometer.

9 Pairing via Bluetooth (SmartCradle)

NOTE! Bluetooth functions are only available with the SmartCradle.

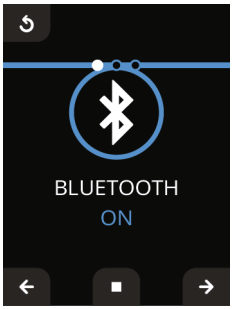
9.1 Pair the SmartCradle

1. Make sure that the SmartCradle is on.

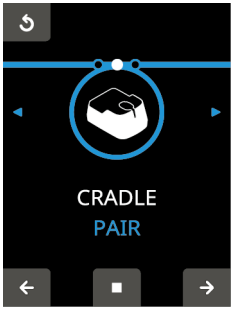
2. Turn on the tonometer. Navigate to the Bluetooth menu in the tonometer user interface. Press ■.



3. Make sure that the Bluetooth state is ON.



4. Press ← → until you see CRADLE. Press ■.

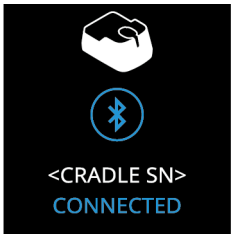


5. Put the IC1000 tonometer into the SmartCradle.



6. The tonometer and SmartCradle connect.
7. When the display shows PAIRED the Bluetooth pairing is established. When the display shows the text CONNECTED the Bluetooth connection is established.





You can now make software updates to the IC1000 tonometer.

9.2 Bluetooth notifications and errors

Bluetooth menu symbols					
	SMARTCRADLE		PRINTER		BLUETOOTH
	The connection symbol appears on the top row when the tonometer is connected to SmartCradle.				

Bluetooth notification			
Screen	Text	Explanation	Actions
	PAIRED	Tonometer paired with the SmartCradle or printer.	No actions needed.
	PAIRING ERROR	Error during SmartCradle pairing.	Acknowledge the notification by pressing ■. Try to pair SmartCradle again. If pairing again does not work, turn off Bluetooth and turn it back on to try again.
	PAIRING REMOVED	Pairing removed from the SmartCradle or printer.	No actions needed.
	CONNECTED	Tonometer connected with the SmartCradle or printer.	No actions needed.
	DISCONNECTED	Connection disconnected from the SmartCradle or printer.	Make sure that the devices are on and that they are within 10 meters of each other.
	BLUETOOTH ERROR or PRINTER ERROR	Error during pairing or connection	Acknowledge the notification by pressing ■. Try to pair again. If pairing again does not work, turn off Bluetooth and turn it back on to try again. Make sure that the printer is on.
	NOT FOUND	Printer cannot be found via Bluetooth.	Make sure that the printer is on and press ■ to search for printers.

9.3 Transfer measurements to cloud software (optional)

After you have paired the iCare IC1000 tonometer with the SmartCradle, you can connect your tonometer in the iCare cloud software. After pairing the IC1000 tonometer with SmartCradle and connecting SmartCradle to your network, measurement data can be uploaded to the iCare cloud software. Tonometer registration and account setup are performed in the iCare cloud software.

See the IC1000 SmartCradle quick guide for more information on how to complete the connection to iCare cloud software and how to register your tonometer.

For further information, read the instructions for iCare cloud software.

9.4 Turn Bluetooth on or off

Bluetooth is on by default on the tonometer. When you are not using Bluetooth to connect the tonometer or to transfer measurement results, turn off Bluetooth to save the tonometer battery.

To turn Bluetooth on or off on the tonometer:

1. Press ⏻ to turn the tonometer on or lift it from the cradle.
2. Press ↺ to access the main menu.
3. Press ← → in the main menu until you see BLUETOOTH. Press ■.
4. Press ← → until you see BLUETOOTH. Press ■.
5. Press ← → until you see BLUETOOTH OFF or BLUETOOTH ON. Press ■.
6. To exit the Bluetooth menu, press ↺.

9.5 Unpair the Bluetooth connection

You can unpair the tonometer and the SmartCradle or the printer from the Bluetooth menu.

1. Press ⏻ to turn the tonometer on or lift it from the cradle.
2. Press ↺ to access the main menu.
3. Press ← → in the main menu until you see BLUETOOTH. Press ■.
4. Press ← → until you see the device you want to unpair (CRADLE or PRINTER). Press ■.
5. Press ← → until you see UNPAIR. Press ■.
6. To exit the Bluetooth menu, press ↺.

10 Print the measurement data

10.1 Pair the tonometer and printer

1. Press ← → in the main menu until you see BLUETOOTH. Press ■.
2. Press ← → until you see PRINTER. Press ■.
3. If you have not paired a printer before, you see text PAIR. Press ■. The tonometer starts searching for printers.
4. After the tonometer has found printers, press ← → to search for the printer you want. Press ■ to pair the printer.
5. PAIRED appears when the Bluetooth connection is formed.
6. The selected printer prints a test print 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.
7. If the test print is ok, the device returns to the Bluetooth menu.

The pairing is maintained unless you manually unpair the tonometer and the printer.

See 9.4 Unpair the Bluetooth connection for instructions on how to unpair the connection.

10.2 Print the measurement results

When the printer and the device are connected and Bluetooth is turned on on the device, you can print a measurement immediately after a successful measurement from the session history or later from the measurement history.

To print a result from the session history (printer paired with tonometer):

1. Press ← → to choose the measurement result that you want to print.
2. Press ··· to select the measurement. Sub-menu opens.
3. Press ← → to navigate to PRINT RESULT.
4. Press ■ to print selected measurement result.

To print a result from the session history (printer not paired with tonometer):

1. Press ← → to choose the measurement result that you want to print.
2. Press ··· to select the measurement. Sub-menu opens.
3. Press ← → to navigate to PRINT SELECTED.
4. Press ■ to print selected measurement result. Printer menu opens.
5. Pair the tonometer and printer according to instructions in 10.1 Pair the tonometer and printer.

To print a result from the measurement history:

1. Navigate to the main menu.

2. Press ◀ ▶ until you see HISTORY. Press ■.
3. Press ◀ ▶ to choose the measurement result that you want to print.
4. Press ··· to open the sub-menu.
5. Press ■ to print out the measurement result.

The printed receipt contains the tonometer model and serial number, measurement date and time, measured eye and the measurement result and quality of measurement.

You can turn off Bluetooth from the Bluetooth menu to save the tonometer battery.

11 Troubleshooting

Screen	Text	Explanation	Actions
	SERVICE	Internal error.	Write down the service ID shown on the display. Switch off the tonometer. Contact the distributor or Icare Finland to arrange service for the tonometer.
	LOW	Tonometer's battery is low (5%).	Tonometer battery is very low. Press ■ or ▶ to clear the message. Charge the tonometer battery.
	CHARGE	Tonometer's battery is empty (0%). Tonometer switches off	Charge the tonometer battery. See chapter 5.3 Charge the tonometer battery.

Tonometer reset: If the tonometer stops working, reboot the device. Press ▶ and ⏻ for 20 seconds. The device reboots.

11.1 SmartCradle troubleshooting

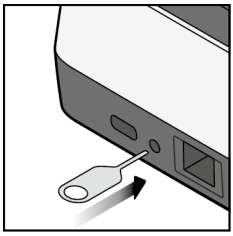
SmartCradle indicator lights		
⏻	📶	ᛒ
POWER	WLAN	BLUETOOTH

Indicator light	Meaning	Indicator light	Meaning
	No light. The SmartCradle is off.		POWER LED is solid green when the cradle

Indicator light	Meaning	Indicator light	Meaning
			is ON and cradle SW is operating normally.
	Power indicator light is blue. The SmartCradle is turning on. If the light does not turn green in 30 seconds, the start-up has failed. Turn the SmartCradle off and on and try again.		All indicator lights flash blue. Service error. Contact your authorized service center.
Ethernet connector indicator lights			
	Pulsating orange light indicates Ethernet/LAN activity.		
	Green light indicates Ethernet/LAN link/ speed. In this case 10/100.		

Reboot: press the reset button shortly to reboot the SmartCradle. Power led flashes.

Factory reset: hold the reset button for 6 seconds until all the light indicators turn off. The SmartCradle resets and turns on.



11.2 Software update with SmartCradle

Necessary updates including security updates can be applied with the software update feature. The SmartCradle and tonometer software is updated over the air (OTA update) or with a USB stick provided by the manufacturer.

If a software update is available, it is offered automatically when the tonometer is turned on. Press ✓ to update or ■ to decline. You can check for updates manually in the INFO menu.

Software update OTA

You see the text SYSTEM UPDATE if the SmartCradle finds an available system update.

1. Press ✓ on the screen to start the update.
2. When the update is processed, the tonometer reboots.
3. If the software update is successful, the tonometer screen shows a blue checkmark.
4. Press ■ to finish the update.

If the update fails, the tonometer screen shows the text ERROR. Press to return to the previous screen.

You can check for SmartCradle software updates from the tonometer's INFO menu.

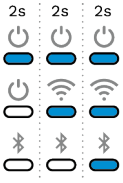
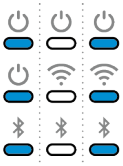
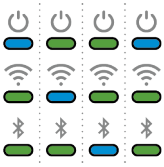
1. In the tonometer main menu, press ← → until you see INFO. Press ■.
2. Press ← → until you see CHECK FOR UPDATES.
3. Press CHECK FOR UPDATES on the screen.
4. If a system update is available, you see SYSTEM UPDATE.
5. Press ✓ on the screen to start the update.
6. If the software update is successful, the tonometer screen shows a blue checkmark.
7. Press ■ to finish the update.

Software update with a USB

1. Make sure that the tonometer is placed in the SmartCradle.
2. Remove the connector plug from the USB type A port.
3. Insert the USB stick to the USB type A connector in the SmartCradle.
4. You see the text TONOMETER UPDATE on the tonometer's screen.
5. Press ✓ on the screen to start the update.
6. When the update is processed, the tonometer reboots.
7. If the software update is successful, the tonometer screen shows a blue checkmark.
8. Press ■ to finish the update.
9. If the update fails, the tonometer screen shows the text ERROR. Press ■ to return to the previous screen. Remove the USB stick and reinsert to try again.

11.3 SmartCradle indicator lights

SmartCradle indicator lights			
	POWER LED is solid green when the SmartCradle is ON and SmartCradle SW is operating normally.		All three LEDs are ON for 1 second after factory reset is successfully done. Then SmartCradle reboots.
	WLAN/LAN LED is solid green when the SmartCradle has active		POWER LED is solid blue when the SmartCradle

SmartCradle indicator lights			
	connection to the internet.		SW is waking up after switching power ON.
	WLAN/LAN LED is pulsating (green) when the SmartCradle is trying to connect to internet. Sequence ON 1 second/ OFF 1 second.		WLAN/LAN LED is solid blue when the SmartCradle's WLAN/LAN has an error state.
	WLAN/LAN LED is pulsating (green) when the SmartCradle is transferring data to the cloud. Sequence ON 0,25 second/ OFF 0,25 second.		BLUETOOTH LED is solid blue when the SmartCradle's Bluetooth has an error state.
	BLUETOOTH LED is solid green when the SmartCradle has active Bluetooth connection with tonometer.		ALL the three LEDs turn blue alternately every 2 seconds if the reset button is held down. After 6 seconds LEDs turn off.
	BLUETOOTH LED is pulsating (green) when the SmartCradle is trying to connect via Bluetooth. Sequence ON 1 second/ OFF 1 second.		All three LEDs are pulsating (blue) when SmartCradle has a service error state. Sequence: ON 1 second/ OFF 1 second until reset/ power off.
	BLUETOOTH LED is pulsating (green) when the tonometer is transferring data to the SmartCradle. Sequence ON 0,25 second/ OFF 0,25 second.		ALL three LEDs are solid (blue) when configuration or SW update has failed. LEDs are on until power is switched off.
	All three LEDs are pulsating (green) after configuration or SW update is OK. Sequence ON 1 second/ OFF 1 second until USB stick is removed.		Two of the three LEDs are solid (green) when SW update is in progress. One of the LEDs is solid blue, and it changes position in order every 1 second.

12 Maintenance

WARNING! The tonometer or cradle must not be repaired or re-assembled by any other than the manufacturer or its authorized service center. If you notice changes in the tonometer's or cradle's performance or it is broken, do not use them. Ship them to an authorized iCare service center for repair.

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

12.1 Replace the probe base

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

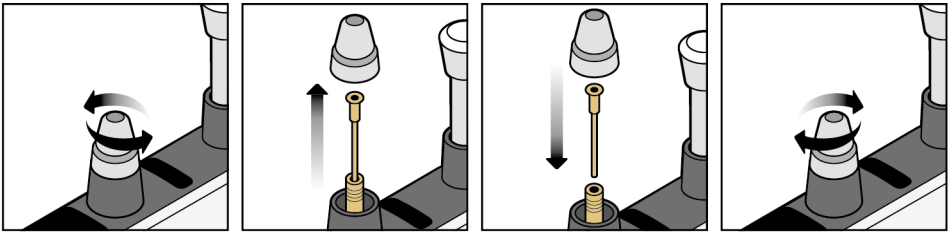
WARNING! The probe base must be changed, not cleaned.

PRECAUTION! To ensure the correct functioning of the tonometer, change the probe base every six months.

PRECAUTION! The probe base may function improperly if dirt or liquid gets inside it.

Change the probe base every 6 months. Change the probe base if the tonometer constantly prompts REPEAT or CHANGE error.

1. Switch off the tonometer.



2. Unscrew the probe base collar by hand and put it to a safe location.

3. Pull the probe base off using your thumb and forefinger.

4. Insert a new probe base into the tonometer.

5. Screw the collar back to the tonometer. Do not use excesive force when you tighten the collar.

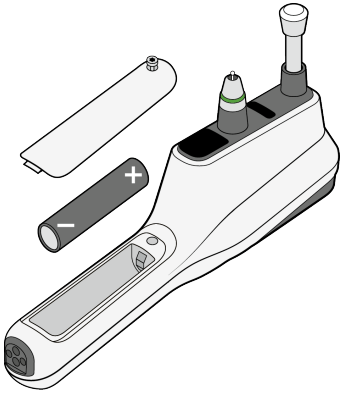
6. Dispose of the used probe base.

12.2 Replace the battery

WARNING! Read and follow the battery replacing instructions before replacement of the tonometer battery, as incorrect polarity could result in a hazardous situation.

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

Turn off the tonometer before you replace the battery.



1. Unscrew the battery compartment locking screw with the screwdriver supplied with the tonometer.
2. Remove the battery compartment cover. Remove the old battery from the tonometer.
3. Insert the new battery according to the figure. Make sure that the battery is installed with the correct polarity.
4. Replace the battery compartment cover.
5. Tighten the locking screw to secure the cover. Do not use excessive force when you tighten the screw.

12.3 Cleaning

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

To prevent cross-contamination, disinfect the outer surfaces of the tonometer and cradle using 100% isopropyl alcohol or 70% ethanol once a week.

To clean the tonometer or cradle:

1. Turn the device off.
2. Attach the probe base cover to the tonometer. Cover must be attached to ensure that the device works as intended after cleaning.

3. Dampen a soft cloth with one of the permitted cleaning fluids. Ensure that the cloth is not overly wet, as excessive moisture may damage the device.
4. Lightly wipe the surfaces of the devices. Make sure to wipe the charging contact surface at the end of the tonometer handle.
5. Remove residual fluid using a soft, dry cloth.

12.4 Lifetime

The expected service life of the iCare IC1000 tonometer, SmartCradle and ChargingCradle is 5 years. The maintenance procedures described in this document are required during the expected service life.

Inspect the tonometer and cradle for mechanical and functional damage and the safety labels for legibility and integrity every 12 months. Contact the manufacturer or local distributor if you detect any damage or deterioration. If any of the devices is damaged, do not use it.

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

12.5 Returning for service or repair

WARNING! The tonometer or cradle must not be repaired or re-assembled by any other than the manufacturer or its authorized service center. If you notice changes in the tonometer's or cradle's performance or it is broken, do not use them. Ship them to an authorized iCare service center for 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 a proof of dispatch and delivery.

12.6 Warranty

Warranty information for the iCare tonometers and accessories is available at the iCare website.

You can access the warranty cards from the QR code:

www.icare-world.com/product-warranty-center.

12.7 Recycling

Do not dispose of the tonometer or cradles in household waste. Send them to an appropriate facility for recovery and recycling. The tonometer and cradle 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, animal welfare and the environment.

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

When you recycle iCare probes, take into consideration your hospital's or clinic's specific guidelines in addition to local laws and regulations.

Probes are mostly metal. They can be disposed or recycled metal according to local laws and regulations.

The probe containers and plastic probe boxes are polypropylene. Dispose or recycle them as plastic according to local laws and regulations.

13 Accessories, 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	iCare Probe TP01, 100 pcs	89 g	53 x 109 x 36 mm
690	IC1000 SmartCradle	725 g	165 x 124 x 84 mm
691	IC1000 ChargingCradle	715 g	165 x 124 x 84 mm
Parts			
540	Probe base	4 g	7 x 32 mm
Other supplies			
511	Carrying case, iCare IC1000	703 g	275 x 235 x 76 mm
997	Ethernet cable, CAT 5e, male to male	48 g	1,5 m
7216	Probe base collar	1 g	17 x 18 mm
553	Power supply	100 g	74 x 39 x 49 mm
557A	Regional plug adapters, EU	21 g	32 x 30 x 48 mm

SKU	Product description	Weight	Dimensions
557B	Regional plug adapters, USA	10 g	32 x 31 x 28 mm
557C	Regional plug adapters, UK	20 g	48 x 41 x 35 mm
557D	Regional plug adapters, AUS	15 g	40 x 40 x 30 mm
575C	USB cable for power supply, Type C male to A male	50 g	1,5 m
559	Wrist strap with lock	4 g	10 mm x 10 mm x 270 mm
548B	Screwdriver Torx TX8	15 g	16 mm x 90 mm
558	Silicone grip package (2 pcs)	30 g	114 mm x 35 mm

SKU: Stock Keeping Unit

14 Technical information

14.1 Technical description

WARNING! Do not modify the tonometer or cradle in any way. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the tonometer or cradle.

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

Type:

Tonometer: TA032
SmartCradle: TX03
ChargingCradle: TX04

Dimensions (length x width x height):
Tonometer: 118 x 50 x 213 mm
SmartCradle: 165 x 124 x 84 mm
ChargingCradle: 165 x 124 x 84 mm

Weight:

Tonometer: With battery: 240 g
Without battery: 195 g
SmartCradle: 725 g
ChargingCradle: 715 g

Power supply:

Tonometer: Li-ion battery, rechargeable 3.6-3.7 V/3350-3500 mAh. Replaceable by the user.

Supported printer model:

Mode of operation: Continuous

Use classification: multiple patient multiple use

IP classification: IPX0 (device is not protected against liquids)

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

Available from the manufacturer:
BAK Battery BAKTH 18650CR-1S-CT
Commercially available:
Keeppower P1835J, Jauch LR1865HB, Nitecore NL1834, Fenix ARB-L18-3400

Cradle: AC/DC medical power supply, model no: GEM12I05-USB or GMPU12UI-1-USB
Input: 100-240VAC, 50/60Hz, 0.4-0.2A
Output: 5V = 2.4A, 12W MAX.
Mains isolation device: medical power supply with regional plug

Display unit: millimeters of mercury (mmHg)

Environmental restrictions for the iCare IC1000 system:

Operation environment (TA032):

- Temperature from +10°C to +35°C
- Relative humidity from 30% to 90%, non-condensing
- Atmospheric pressure: 800hPa – 1060hPa

Operation environment (TX03, TX04):

- Temperature from +10°C to +35°C
- Relative humidity from 30% to 90%
- Atmospheric pressure: 800hPa – 1060hPa

Storage environment (TA032):

- Temperature from -10°C to +35°C
- Relative humidity from 10% to 75%, non-condensing
- Atmospheric pressure: 700hPa – 1060hPa

Storage environment (TX03, TX04):

- Temperature from -10°C to +55°C
- Relative humidity from 10% to 95%
- Atmospheric pressure: 700hPa – 1060hPa

Transport environment (TA032):

- Temperature from -20°C to +60°C
- Relative humidity from 10% to 95%
- Atmospheric pressure: 500hPa – 1060hPa

Transport environment (TX03, TX04):

- Temperature from -40°C to +70°C
- Relative humidity from 10% to 95%
- Atmospheric pressure: 500hPa – 1060hPa

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 fully charged battery for the tonometer is expected to last approximately 400 measurements in normal use. The serial number is located on the bottom or side cover depending on the device. The lot number of the probes is on the side of the probe box. The single-use probe and the forehead support of the device are applied parts. There are no electrical connections from the tonometer to the patient.

The iCare IC1000 tonometer, IC1000 SmartCradle and IC1000 ChargingCradle were tested according to the recommendations of IEC TS 60601-4-2:2024, Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

The tonometer is suitable for use within the patient environment. Only IEC 60950-1 or IEC 60601-1 certified devices can be connected into network in the patient environment.

IT network specifications

WARNING! Connection of the iCare 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 iCare 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

iCare IC1000 (TA032) is intended for use in a professional healthcare environment. To transfer measurement data from the iCare IC1000 tonometer to a host system, the SmartCradle must be connected to the organization's IT network. The iCare IC1000 tonometer can be operated independently of the SmartCradle, but data transfer to the IT network requires a functioning network connection through the SmartCradle. The iCare IC1000 tonometer is designed so that SmartCradle or network failures do not prevent the tonometer from performing measurements normally.

To print measurement data from the iCare IC1000 tonometer, the printer must be paired with the tonometer over a Bluetooth connection. The iCare IC1000 tonometer can be used normally without a Bluetooth connection, but printing functionality will not be available.

The system is designed so that any Bluetooth connection failures or interruptions will not prevent normal operation of the iCare IC1000 tonometer.

Software Bill of Materials (SBOM)

The SBOM is available from the manufacturer's website www.icare-world.com.

Intended information flow

The iCare IC1000 tonometer collects measurement data. This data is sent via Bluetooth connection (Bluetooth Low Energy, BLE) to the SmartCradle or a wireless printer.

Tonometer's internal clock is set manually from the tonometer settings. SmartCradle synchronizes time via NTP.

Potential hazardous situation resulting from the failure of the IT network

If the IT network connection is lost during the data transfer, no data is lost from the tonometer. The measurement data can still be found from the tonometer memory and transferred once the connection is re-established.

Failure or misconfiguration of the IT network may result in data not being transferred.

Required characteristics of the IT network

SmartCradle: LAN/WLAN, internet connection

Printer: Bluetooth® 3.0/4.0 BLE

It is recommended that the responsible organization maintain IT network security by applying established IT security best practices appropriate to its operating environment.

Information regarding the radio communication part of the tonometer

The iCare IC1000 (TA032) tonometer contains a Bluetooth transmitter working at frequencies between 2.402 GHz and 2.480 GHz. Bluetooth pairing between the tonometer and the SmartCradle uses NFC (Near-Field Communication) technology. Due to the limited size available on the device, many of the relevant approval markings are found in this document.

Bluetooth Module Information (tonometer):

Item	Specification
Bluetooth Module	ANNA-B112 module
Communication	Bluetooth Low Energy (BLE) 5.0
Radio Frequency (RF) Range	2.402 GHz – 2.480 GHz
Output Power	< 2.5 mW (4 dBm)
Antenna Gain	0.5 dBi
Effective Radiated Power	< 0.4 mW (-4.85 dBm)
Transmitting distance	10 meters
Market specific information of the Bluetooth module	FCC ID: XPYANNAB1 IC: 8595A-ANNAB1 MIC: 204-810005

NFC Reader Information:

Item	Specification
NFC Reader IC	ST25R95
Communication	Near Field Communication (NFC)
Frequency Range	13.553 MHz - 13.567 MHz
Type of Modulation	ASK
Output Power	< 55 mW
Antenna Type	FPC coil antenna with ferrite

Item	Specification
Effective Radiated Power (ERP)	< 0.58nW (-62.4dBm)
Market specific information of the NFC system	

Wifi and Bluetooth Module Information (SmartCradle):

Item	Specification
Bluetooth Module	Azurewave AW-CM276NF Wi-Fi / Bluetooth module
Communication	Bluetooth Low Energy (BLE) 5.0
Wi-Fi version	Wi-Fi 802.11ac/a/b/g/n
Bluetooth version	Bluetooth 5.0 (BR/EDR), BLE
Wi-Fi RF Range	Dual-Band 5 GHz and 2.4GHz
Wi-Fi Bandwidth	Up to 866.7 Mbps
Wi-Fi Channel Bandwidth	20/40/80 MHz
Radio Frequency (RF) Range	Wi-Fi 2.4G: 2412 - 2484 MHz Wi-Fi 5G: 5180 - 5825 MHz Bluetooth: 2402 - 2480 MHz
Output Power	Wi-Fi 2.4G: 18.5 dBm Max. Wi-Fi 5G: 15 dBm Max. Bluetooth: 4 dBm Max.
Antenna Gain	2.4 GHz: 0.9 dBi 5 GHz: 4.5 dBi
Effective Radiated Power	Wi-Fi 2.4G: 17.25 dB Wi-Fi 5G: 17.35 dB Bluetooth: 2.75 dB
Transmitting distance	10 meters
Market specific information of the Bluetooth module	FCC ID: UAY-W8997-M1216 IC: W8997-M1216 MIC: 020-170034

14.2 Performance data

14.3 Symbols and trademarks

	General warning sign		Refer to the instruction manual
	Single-use only		Date of manufacture
	Manufacturer		Keep dry
	Temperature limit		Atmospheric pressure limitation
	Humidity limitation		Bluetooth communication
	Product is a medical device		National Communications Commission (NCC) mark of Taiwan
	Recyclable package material		Batch code LOT number
	Serial number		Class II equipment
	Type B applied part		Technical conformity mark and certification number of the Ministry of Internal Affairs and Communications of Japan (MIC)
RX Only (U.S.)	Federal law (U.S.) restricts this device to sale by or on the order of a physician.		The Regulatory Compliance Mark (RCM), in Australia and New Zealand
	For indoor use only		CE marking accompanied with the notified body identification number.

GTIN	Global Trade Item Number		Waste from Electrical and Electronic Equipment
	Consult instructions for use		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
	Korean Certification (KC) mark		Non-ionizing electromagnetic radiation

14.4 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.

14.5 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.

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

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

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 tonometer, including cables specified by the manufacturer, to avoid the degradation of performance.

WARNING! The measurement method of the tonometer is based on a magnetically induced motion of a probe and therefore an external magnetic or radiated RF electromagnetic field disturbing the probe may prevent the measurement. In such a case the tonometer continuously displays error messages during measurement and asks you to repeat the measurement. Situation can be solved either by removing the source of interference from the vicinity of the tonometer 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 tonometer before the data is transferred successfully.

iCare IC1000 (TA032) and accessories (SmartCradle TX03 and ChargingCradle TX04) are intended for use in a professional healthcare environment with electromagnetic characteristics specified below. The user of the iCare IC1000 tonometer (TA032) and accessories should assure that they are used in such an environment.

GUIDANCE AND MANUFACTURER'S DECLARATION IEC 60601-1-2:2014+A1:2020: EDITION 4.1 – ELECTROMAGNETIC EMISSIONS		
Conducted and radiated RF emissions CISPR 11	Group 1	iCare IC1000 (TA032) is battery operated and uses RF energy only for its

GUIDANCE AND MANUFACTURER'S DECLARATION IEC 60601-1-2:2014+A1:2020: EDITION 4.1 – ELECTROMAGNETIC EMISSIONS		
		internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby equipment.
	Class B	iCare IC1000 (TA032) 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.
Conducted emissions CISPR 32	Class B	Ethernet
Harmonic emissions IEC 61000-3-2	Class A	-
Voltage fluctuations flickering emissions IEC 61000-3-3	Complies	-

GUIDANCE AND MANUFACTURER'S DECLARATION IEC 60601-1-2:2014+A1:2020: EDITION 4.1 – ELECTROMAGNETIC IMMUNITY			
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	± 2 kV 100 kHz repetition frequency	Mains power quality should be similar to that of a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION IEC 60601-1-2:2014+A1:2020: EDITION 4.1 – ELECTROMAGNETIC IMMUNITY			
	± 1 kV 100 kHz repetition frequency	± 1 kV 100 kHz repetition frequency	Ethernet
Surge IEC 61000-4-5	± 1 kV for line(s) to line(s)	± 1 kV for line(s) to line(s)	Mains power quality should be similar to that of a typical commercial or hospital environment.
Voltage dips, short interruption and voltage variations on power supply lines IEC 610004-11	0 % UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle 70 % UT for 25/30 cycles (50/60 Hz) 0 % UT for 250/300 cycles (50/60 Hz)	0 % UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle 70 % UT for 25/30 cycles (50/60 Hz) 0 % UT for 250/300 cycles (50/60 Hz)	Mains power quality should be similar to that of a typical commercial or hospital environment.
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 IC1000 (TA032), including cables specified by the manufacturer, to avoid the degradation of performance. The measurement method of the iCare IC1000 tonometer is based on magnetic induction and therefore an external magnetic field in line with the

GUIDANCE AND MANUFACTURER'S DECLARATION IEC 60601-1-2:2014+A1:2020: EDITION 4.1 – ELECTROMAGNETIC IMMUNITY			
			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 610004-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3V 6V 80 MHz 80 % AM at 1 kHz	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 IC1000 (TA032) including cables specified by the manufacturer, to avoid the degradation of performance.
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 IC1000 (TA032) including cables specified by the manufacturer, to avoid the degradation of performance. Interference may occur

GUIDANCE AND MANUFACTURER'S DECLARATION IEC 60601-1-2:2014+A1:2020: EDITION 4.1 – ELECTROMAGNETIC IMMUNITY			
			in the vicinity of equipment marked with the following symbol: 
Proximity fields from RF wireless communications equipment IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	27 V/m 28 V/m 9 V/m 28 V/m 28 V/m 28 V/m 9 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 IC1000 (TA032) including cables specified by the manufacturer, to avoid the degradation of performance. Interference may occur in the vicinity of equipment marked with the following symbol:  The measurement method of the iCare IC1000 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

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			interference from the vicinity of the device or by performing the measurement in different location with no such interference.
Proximity magnetic fields IEC 61000-4-39	134,2 kHz, 65 A/m 13,56 MHz, 7,5 A/m	134,2 kHz, 65 A/m 13,56 MHz, 7,5 A/m	The measurement method of the iCare IC1000 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.

15 Annex 1 iCare TP01 Probe technical information

ENGLISH

Intended use

iCare TP01 probe is intended to be used as a single-use accessory when measuring intraocular pressure of the human eye with an iCare tonometer. It is intended to be used by healthcare professionals in a professional healthcare environment.

Residual risks

WARNING! Keep the probes out of the reach of children. The probes are small objects and can be accidentally swallowed, causing suffocation.

Technical description

WARNING! Do not touch an iCare TP01 probe with bare hands.

WARNING! iCare TP01 probe is for single-use only. 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.

iCare TP01 tonometer probe is compatible with iCare tonometers for professional use. For possible limitations of use, refer to the tonometer manuals.

Type: TP01
Description: Single-use, non-sterile
Lifetime: 3 years from the date of manufacture
Shelf life: no expiration date

Environmental restrictions for the iCare TP01 probe:

Operation environment:

- Temperature from +10°C to +35°C
- Air pressure from 800 hPa to 1060 hPa
- Relative humidity from 30% to 90%

Storage environment:

- Temperature from -10°C to +55°C
- Air pressure from 700 hPa to 1060 hPa
- Relative humidity from 10% to 95%

Transport environment:

- Temperature from -40°C to +70°C
- Air pressure from 500 hPa to 1060 hPa
- Relative humidity from 10% to 95%

Symbols specific to TP01 probe

	Do not use if the package is damaged and consult the instructions for use.		

CE 0598

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