ENGLISH

iCare TONOVET Pro

Instruction Manual

TONOMETER
iCare TONOVET Pro

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

This device complies with:

RoHS Directive 2011/65/EU

Radio equipment directive 2014/53/EU

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Contents

1 Intended use

The iCare TONOVET Pro tonometer is used in the intraocular pressure (IOP) measuring in the veterinary medicine. The iCare TONOVET Pro tonometer is intended for veterinary use only.

2 Possible limitations of use

Some conditions may cause limitations to the use of the TONOVET Pro. The effectiveness and safety of the TONOVET Pro has been evaluated for patients with healthy eyes.

The effectiveness has not been evaluated for patients with:

- Dry eye
- Anterior lens luxation
- Diffuse corneal edema
- Corneal scarring
- Abnormal corneal thickness

The safety has not been evaluated for patients with:

- Corneal perforation
- Stromal corneal ulcer
- Corneal infection
- Corneal descemetocele

Use the TONOVET Pro tonometer only in stable and non-vibrating environment.

3 Introduction

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

PRECAUTION! Report any serious incidents related to the tonometer to the manufacturer or the manufacturer's representative.

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

The iCare TONOVET Pro tonometer allows a wider range of downward measurement angles.

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. After launching, the probe briefly makes contact with the cornea and bounces back. The tonometer measures the deceleration of the probe and the rebound time, and calculates the IOP from these parameters.

The iCare TONOVET Pro has two measurement modes: Default Measure and Quick Measure. In Default Measure the measurement sequence consists of six individual measurements. After six measurements the tonometer calculates the final IOP. In Quick Measure the measurement consists of two or three individual measurements from which the final measurement is calculated. With the both measurements modes, the final result is shown on the display and stored in the tonometer's memory for later retrieval.

The iCare TONOVET Pro tonometer incorporates a Bluetooth® module which allows wireless connectivity to Bluetooth-supported printers.

The iCare TONOVET Pro tonometer has settings for a dog, cat, rabbit, and horse.

For more information about the iCare TONOVET Pro, visit www.tonovet.com.

4 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.

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

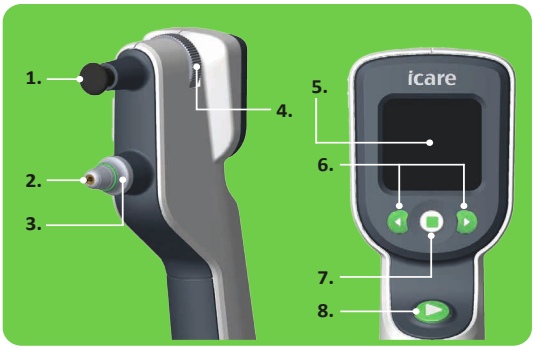
Check the sales packaging condition before taking the tonometer or probes into use. If the package appears damaged, contact your distributor.

The iCare TONOVET Pro package contains:

- iCare TONOVET Pro 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
- Silicone grip

5 Buttons and parts of the tonometer

1. Measuring support
2. Probe base
3. Probe base collar
4. Adjustment wheel for measuring support
5. Display screen
6. Navigation buttons
7. Select button
8. Measure button



6 Taking the device into use

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

6.1 Attaching the wrist strap

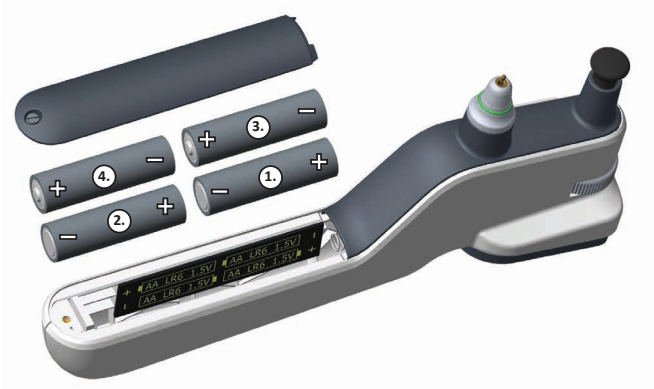
1. Thread the string loop at the end of the wrist strap through the two holes at the bottom of the device (see figure below).
2. Take hold of the end of the wrist strap, turn it back and bring it through the loop.
3. To tighten the loop pull the wrist strap.

6.2 Installing the batteries for the first time

PRECAUTION! Remove the batteries from the battery compartment, if you do not intend to use the tonometer for a month or a longer period of time. Removing the batteries temporarily does not affect the subsequent functioning of the tonometer.

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

1. Unscrew the battery compartment locking screw with the supplied screwdriver.
2. Remove the battery compartment cover. Insert a new set of four AA 1.5 V batteries (LR6).
3. Insert the batteries according to the figure below. Take care to observe correct polarity.
4. Replace the battery compartment cover.
5. Secure the cover in place by tightening the locking screw. Do not use excessive force when tightening the screw.



6.3 Turning the tonometer on

Tonometer can be activated in two ways:

- press the Select button once
- press the Measure button once

See the following figures on how the tonometer behaves when you use either one of the two alternative ways to activate the tonometer.

After pressing the Select button

After pressing the Measure button

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.

7 Changing the setting for different species

To change the setting for different species press the Select button to access the menu. Press Navigation buttons and select SETTING by pressing the Select button.

Use the Navigation buttons to toggle the settings. To select a species, press the Select button. To start measuring, use the Navigation buttons to return to MEASURE.

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, for example, in containers for disposable needles.

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.

PRECAUTION! Before measuring any new patient, make sure to use a new disposable probe from an intact package. 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! Used probes cannot be recycled. Dispose of used probes properly (e.g. in containers for disposable needles or in a bin for metal waste).

Step 1. Remove the yellow protective cover from the probe base by pulling. Do not remove it by turning, because turning can unscrew the probe base collar. Retain the probe base cover, do not discard it. The probes are supplied in protective probe tubes.

Step 2. Take a new probe tube and hold the tube with its cap upright.

Step 3. Remove the protective cap.

Step 4. 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.

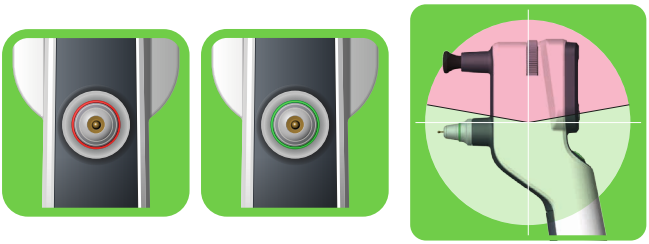
A probe can be loaded into the iCare TONOVET Pro tonometer even if the device has not yet been turned on. In this case, the tonometer recognizes that a probe has been inserted when entering the measurement sequence and automatically displays the measurement mode selection menu.

After loading the probe, the tonometer is ready for measurement when the Play-symbol and the active species setting appear on the display.

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.

- The indicator light helps guide alignment of the tonometer 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.



- If the indicator light changes to red, it can mean an error has occured during the measurement sequence. In this case, also an error message appears on the display.

10 Taking the measurements

WARNING! The tonometer must not come into contact with the patient's eyes, except for the probes, which may do so for a fraction of a second during measurement. Do not push the tonometer into the eye (the tip of the probe should be 4-8 mm, or 5/32 - 5/16 in., from the eye).

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

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.

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

PRECAUTION! Use the tonometer only for measuring intraocular pressure of animals, 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.

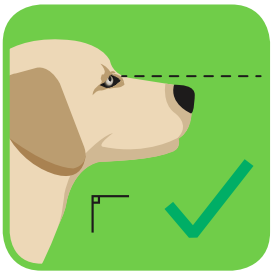
PRECAUTION! Do not use the device near inflammable substances, including inflammable anesthetic agents.

10.1 Using Default Measure

NOTE! Avoid excessive restraining, as it may alter the IOP. Hold the patient's head as lightly as possible and be careful not to put pressure on the neck or the eye ball. If the patient wears a collar, make sure it is not too tight or remove it for the 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.

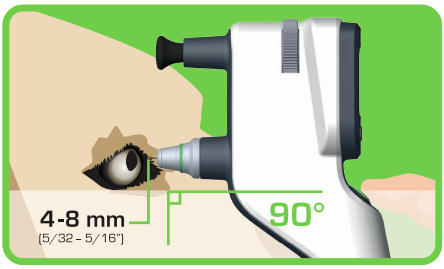
STEP 1. Bring the tonometer near the patient's eye.

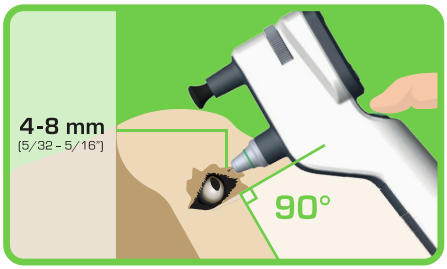


Correct head and eye position.

Incorrect head and eye position.

STEP 2. To perform a successful measurement, the distance from the tip of the probe to the patient's cornea (see picture) should be about 4-8 mm (about 5/32 - 5/16 in.). Bring the tonometer in front of the patient's eye with the probe pointing to the center of the cornea.





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.

STEP 3. An IOP measurement can be performed using the tonometer either in Single Mode or in Series Mode. In the Default measurement, IOP measurement is calculated from six individual rebound measurements. In the Quick Measure, IOP measurement is calculated from two or three individual rebound measurements.

Single Mode. Press the Measure button gently but firmly. Keep the tonometer still and steady. The tip of the probe will make contact with the central cornea. Take six measurements in the Default Measure. The grey segments of the circle will turn green one by one after each successful measurement, and will hear a short beep.

Series Mode. Press and hold the Measure button down. The device makes automatically a series of measurements. After the first successful measurement, one segment of the circle will turn green and additional segments turn green as the tonometer continues to measure. Measuring in Series Mode will take just a few seconds. Error messages are not shown when the measure button is pressed down, except if the first measurement is unsuccessful.

If the tonometer detects an error occurring during the measurement, it beeps twice and an error message is displayed. To remove the error message from the display in either Single- or Series Mode, press the Measure button. This clears the error message and repeats the measurement. Pressing Select button clears

the error without repeating the measurement. For more information about error messages, see Chapter 13 Error and info messages in this manual.

STEP 4. Once six measurements have been successfully made, the tonometer makes one long beeping 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 measurement quality. 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.

Red indicates weak measurement quality, which means that the variation in the measurements is very high.

To initiate a new series of measurements, press the Measure button once.

Good measurement quality

Acceptable measurement quality

Weak measurement quality

A running average is shown for the values from the second measurement to the fifth measurement. The sixth value is the final IOP value which is calculated from the best four individual measurements (the worst two individual measurements are discarded).

NOTE: The final result is calculated based on a proprietary algorithm and it is not an average of the interim results.

ONE SHORT BEEP —
Indicates a correct single measurement.

DOUBLE BEEP — —
Indicates an incorrect single measurement. (See error messages from instruction manual).

LONG BEEP ——
Indicates that six succesful measurements are done and the IOP result is available on the display.

STEP 5. After an IOP measurement has been successfully made from one eye, you can measure the IOP from the other eye or repeat the measurement in the same eye. Follow the steps 1-4.

STEP 6. 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.

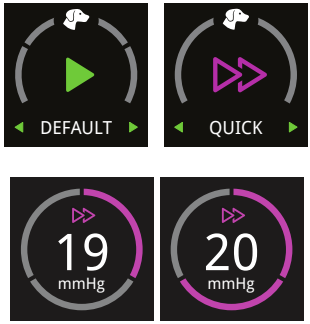
10.2 Using Quick Measure

WARNING! Quick Measure accuracy and repeatability are not clinically validated, and the results may not exactly match the results of the Default Measure. Use primarily the Default Measure with all patients. Repeat the IOP measurement with the Quick Measure, if the Default Measure is unsuccessful.

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.

The iCare TONOVET Pro's 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 Default Measure 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.



STEP1. To perform a measurement using Quick Measure, enter the measurement mode and press navigation button to see the Quick Measure icon. Chosen species is displayed in the icon and to change the species, follow the instructions in chapter 8.

STEP2. To start the measurement, press the Measure button. After 2 or 3 rebound measurements, the IOP reading is shown on the display.

Good measurement quality

Acceptable measurement quality

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.

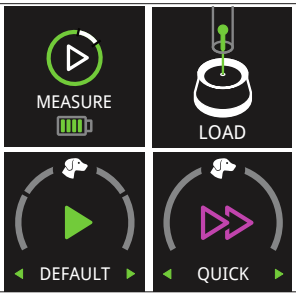
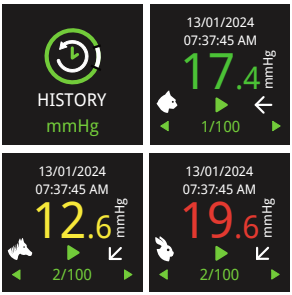
The test results demonstrate high agreement with the default measurement, for more information see chaper 10.1 Using Default Measure. The maximum difference between Quick Measure mode and Default Measure mode is 0.57 mmHg at 10 mmHg membrane pressure. The maximum difference between operators was observed 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 TONOVET Pro tonometer uses a large, color display screen as part of its user interface. Three buttons below the screen allow the user to control the device.

- Use the two Navigation buttons (left and right arrows) to change the selection in a displayed menu.
- Use the Select button in the center to activate the selection.
- Use the large Measure button on the handle to start the measurement function.

<table>
<tr>
<td> 
</td>
<td>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 measurement mode can be selected.
• The tonometer is ready for measurement when the Play symbol appears on the display screen. Press the Select button to return to the menu.</td>
</tr>
<tr>
<td> 
</td>
<td>SETTING – Selecting species
• Previously selected species symbol is displayed.
• To select another species, press the Select button and use the Navigation buttons to scroll through the settings. To accept the selection, press the Select button.</td>
</tr>
<tr>
<td> 
</td>
<td>HISTORY – Previous measurements
• The latest measurement is displayed first in HISTORY.
• The color of the displayed result indicates the measurement quality.
• The arrow indicates the tonometer’s measurement angle.</td>
</tr>
<tr>
<td> 
</td>
<td>BLUETOOTH – Wireless connection
• The tonometer can be paired with a Bluetooth® printer for printing the measurement results. For details, see the Bluetooth® section of this document.</td>
</tr>
<tr>
<td> 
</td>
<td>SOUND – Adjusting the beep volume
• The tonometer offers three sound levels and a silent mode.
• The sound level is indicated with a 3-level bar.
• Use the Navigation buttons to select the volume level. To accept the selection, press the Select button.</td>
</tr>
</table>

LIGHT – Adjusting the Probe base light brightness

- The intensity of the Probe base light can be adjusted to any of the three levels or the base light can be switched off entirely by selecting OFF.
- The intensity of the light is indicated with a 3-level bar.
- Go to the Light settings and press the Select button. Use the Navigation buttons to adjust the light intensity.

BRIGHTNESS – Adjusting the brightness of the display screen

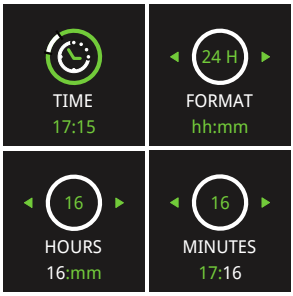
- There are three levels of brightness in the display screen you can use. The brightness level is indicated with a 3-level bar.
- Go the Brightness settings and press the Select button. Use the Navigation buttons to adjust the brightness.

LANGUAGE – Language setting

- The language of the user interface can be changed. There are several languages available.
- Go to the Language settings and press the Select button.
- Use the Navigation buttons to change the language. Press the Select button to activate your language selection.
- The language of the tonometer can be changed to following languages: English, Finnish, Swedish, German, Italian, Spanish, Portuguese, French, Russian, Japanese, Chinese and Korean.

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

- Either 12- or 24-h format can be selected for the time displayed on the device.
- 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).
- Press the Select button to see the software version of the tonometer.
- Press the right navigation button to see the QR-code that opens tonovet.com/eifu website.

12 Wireless Printing

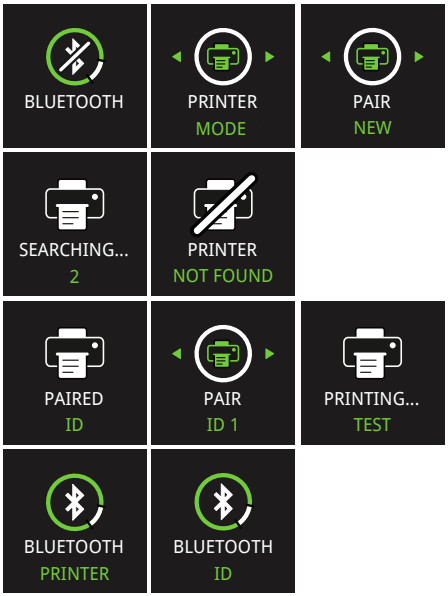
The TONOVET Pro (TV031) device has a Bluetooth functionality for wireless printing. This section describes how to print to a Bluetooth printer.

12.1 Printer

To print the measurement results from TONOVET Pro, you must first pair it with a Bluetooth (Classic) printer. Pairing establishes a connection between the TONOVET Pro device and the printer.

After pairing the printer and activating printer mode, measurements can be printed immediately after completing the sequence or from the HISTORY menu.

12.2 Pairing the tonometer with the printer



STEP 1. Make sure the printer is turned ON.

STEP 2. Use the Navigation buttons to select the Bluetooth menu, press the Select button and select PRINTER MODE.

Use the Navigation buttons to select PAIR NEW.

STEP 3. TONOVET Pro starts to search for Bluetooth printer(s). Number in SEARCHING... screen will increase as printer(s) are found. To cancel the searching, press the Select button.

STEP 4. When printers are identified and are ready for pairing, the printer ID will appear under the 'PAIR' option. Use the Navigation buttons to select the printer you want to use.

STEP 5. Press the Select button to pair the tonometer with the printer you want to use.

STEP 6. When the Bluetooth connection is formed, PAIRED appears on the display.

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 the main menu and displays the BLUETOOTH PRINTER and the printer's id in turn on the screen.

12.3 Reactivating the pairing with the printer

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.

12.4 Testing the activated printer

To test the activated printer:
- Go to PRINTER MODE and press the Select button.
- Use the Navigation button to go to TEST.
- Press the Select button to print a test page.

12.5 Removing a pairing to a printer

To remove the pairing (printer connection):
- Go to PRINTER MODE and press the Select button.
- Go to UNPAIR.
- Press the Select button to remove the pairing between the TONOVET Pro device and the printer.

12.6 Printing measurement results to paired printer immediately after the measurement

- Press the Navigation button in the measurement result screen to go to print menu.
- Press the Select button in the PRINT menu to print out the measurement result.

12.7 Printing measurement results from HISTORY

- Navigate to HISTORY menu and press select.
- Use the Navigation buttons to find the measurement that is to be printed.
- Press the Select button to go to PRINT menu.
- Press the Select button to print out the measurement result.

12.8 Turning Bluetooth connection off

The Bluetooth connection can be turned off to save batteries. Note that the pairing is not removed when the Bluetooth is turned off.
- Go to BLUETOOTH and press the Select button.
- Use the Navigation buttons to go to TURN OFF.
- Press the Select button to turn off Bluetooth.

The printout gives the following information:

- tonometer model and serial number
- measurement date and time
- measurement position
- measurement result and quality of measurement.

When printing Quick Measure results, the quality indicator is replaced with “Quick Measure” text.

13 Error and info messages

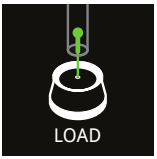
The following messages may appear on the display screen. When any error, except CHANGE and CLEAN CHANGE, occurs during the measurement, press the Select button to clear the error or press the Measure button to repeat the measurement.

Message	Description	Actions
	Battery charge is low.	Prepare to replace the batteries.
 CHANGE	The batteries are empty.	Turn the tonometer OFF by pressing the Select button. Replace the batteries.
 INCORRECT ALIGNMENT	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. Clear the error as instructed above.
 REPEAT	The error was caused by an external factor during the measurement.	Repeat the measurement as instructed above.
 REPEAT	The probe did not move properly or did not make clean contact with the cornea.	Measure again or change the probe. Clear the error as instructed above.
 CHANGE	The probe did not move.	Change the probe. The probe was twisted, inserted incorrectly or it was dirty. Press the measure button to clear the error. This magnetizes the probe. If the error keeps recurring, change also the probe base. For instructions, see 18.1 Replacing or cleaning the probe base.
 CLEAN CHANGE	The probe did not move properly for several times during the measurement sequence.	Remove and clean the probe base or replace it with new one as instructed in Replacing or cleaning the probe base. To clear the error message, press either Select or Measure button. Device then returns to menu.
 TOO FAR	The probe did not touch the eye.	The measurement was taken from too far away. Adjust measurement distance to about 4-8 mm (5/32-5/16 in.). Clear the error as instructed above.
 TOO NEAR	The measurement distance was too short between the probe and the cornea.	The measurement was taken from too close. Adjust measurement distance to about 4-8 mm (5/32-5/16 in.). Clear the error as instructed above.
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. Press the Select button to clear the error message. Check that the printer receives enough power or turn the printer on.

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 directly to Load Probe.



Load probe Ready to measure and measurement mode selection.

Default Measure mode

Ready to measure and measurement mode selection (NOTE the species setting). Press arrow keys to switch between Default and Quick modes.

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

Successful measurement.

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

Quick Measure mode

Measure 2-3 times by pressing the Measure button (magenta color bar shows the progress).

Successful measurement.

15 Accessories, detachable parts and other supplies

To order accessories, parts, and other supplies, contact your local distributor.

Item	Product description	Weight	Dimensions
Accessories			
103	iCare TONOVET Probes, TVP01, 100 pcs/box	89 g	53 x 109 x 36 mm
Parts			
7216	Probe base collar	1 g	17 x 18 mm
540	Probe base	4 g	7 x 38 mm
559	Wrist strap with lock	4 g	10 x 10 x 270 mm
7169	Battery cover & screw	6 g	110 x 25 x 12 mm
Other supplies			
548	Screwdriver	15 g	16 x 90 mm
563	Silicone grip, green	26 g	45 x 35 x 113 mm
544B	Probe base cover, iCare TONOVET Pro	1 g	19 x 11 mm
624	IOP pad	38 g	50 x 53 x 16 mm
527	Aluminum case, iCare TONOVET Pro	800 g	240 x 280 x 72 mm
680	Printer	499 g	172 x 182 x 55 mm
670	Tonometer Stand	1 455 g	312 x 155 x 115 mm
998	Quick Guide	19 g	210 x 148 mm

16 Technical information

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

Type: TV031
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 - 60 mmHg
Accuracy: ± 2.5 mmHg (7 - 30 mmHg) and ± 10% (>30 - 60 mmHg)
Repeatability (coefficient of variation): < 8%
Display range: 0-99 mmHg (IOP is estimated when outside of the measurement range)
Accuracy of display: 0.1 mmHg
Display unit: Millimeters of mercury (mmHg)
Mode of operation: continuous

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 inside of the battery compartment 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 measuring 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 TONOVET Pro tonometer to IT networks including other tonometers 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 TONOVET Pro tonometer connected to IT networks including other tonometers.

Required characteristics of the IT network:
Printer: Bluetooth® Classic, ESC/POS communication protocol.

Connection is secured by link authentication.

Intended Information Flow:
Measurement data is collected by the TONOVET Pro tonometer. This data is sent via Bluetooth connection to a wireless printer (Bluetooth Classic).

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 in 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

The performance data was obtained from multiple measurements performed in various locations around the world. In total 66 dogs, 60 cats, 137 rabbits and 63 horses took part in the measurements. The comparison was conducted between TONOVET Pro and TONOVET Plus 2.0 using the Default measurement mode.

- Figure 1 = Bland-Altman plot TONOVET Pro vs. TONOVET Plus dog calibration
- Figure 2 = Bland-Altman plot TONOVET Pro vs. TONOVET Plus cat calibration
- Figure 3 = Bland-Altman plot TONOVET Pro vs. TONOVET Plus rabbit calibration
- Figure 4 = Bland-Altman plot TONOVET Pro vs. TONOVET Plus horse calibration

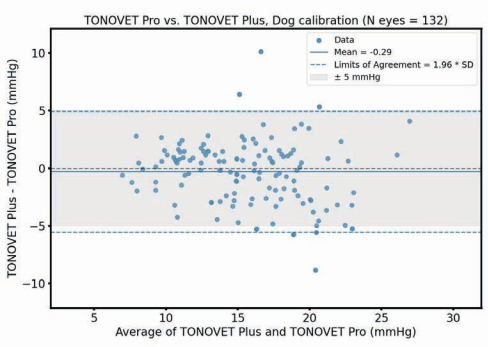


Figure 1. Dog calibration

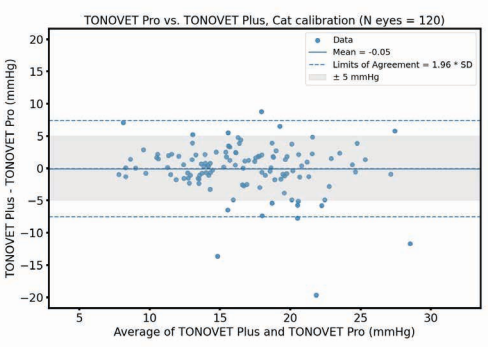


Figure 2. Cat calibration

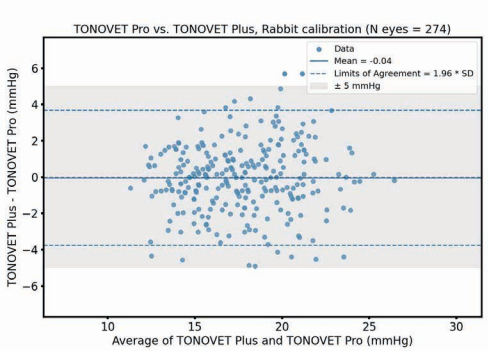


Figure 3. Rabbit calibration

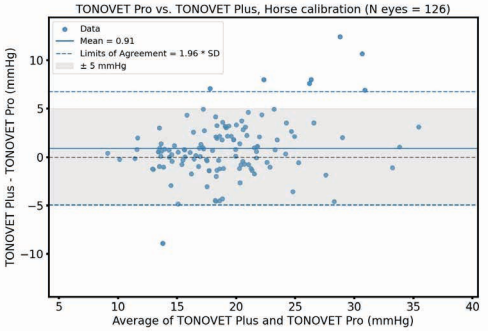


Figure 4. Horse calibration

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.

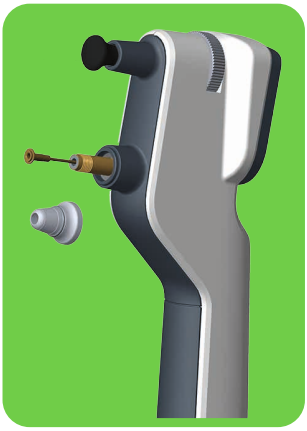
PRECAUTION! The probe base, battery compartment cover, screws, collar, and probes are so small that an animal could swallow them. Keep the tonometer out of the reach of animals.

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

18.1 Replacing or cleaning the probe base

WARNING! Switch off the tonometer before you change the probe base.



During the use some dirt may collect in the probe base, affecting the probe movement. **Replace the probe base every 12 months. Clean the probe base every 3 months**. The cleanest probe base is a new probe base.

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.

18.1.1 Replacing the probe base

Instructions for replacing the probe base:
STEP 1. Turn power off from the tonometer.

STEP 2. By hand, unscrew the probe base collar and place it in a safe location.

STEP 3. Remove the probe base by tilting the tonometer downwards and pulling the probe base out of the tonometer.

STEP 4. Insert a new probe base into the tonometer.

STEP 5. Screw the collar down until it firmly locks the probe base.

18.1.2 Cleaning the probe base

Clean every 3 months.

STEP 1. Fill the spare probe base container or other clean container with 70-100 % isopropyl alcohol.

STEP 2. Turn the power off.

STEP 3. Unscrew the probe base collar.

STEP 4. Remove the probe base by tilting the tonometer downwards and pulling the probe base out of the tonometer.

STEP 5. Insert the probe base into the cleaning container and let soak for 5–30 minutes.

STEP 6. Remove the probe base from the cleaning container.

STEP 7. Dry the probe base by blowing clean canned or compressed air into the hole in the probe base. This will additionally remove possible residual dirt.

STEP 8. Insert the probe base into the tonometer.

STEP 9. To lock the probe base into its place, screw back the probe base collar.

18.2 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 measuring support. To prevent this, clean the measuring support with disinfectant for each new patient.

To help avoid possible cross-contamination and infection, clean the tonometer with a disinfectant. The outer surfaces of the iCare TONOVET Pro tonometer can be safely cleaned with the following liquids:

- 70-100% isopropyl alcohol
- 70% ethanol

Cleaning the tonometer surface:
- Turn the power off.
- Dampen a soft cloth with one of the liquids listed above.
- Lightly wipe the surfaces of the tonometer.
- Remove residual fluid using a soft, dry cloth.

18.3 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.

18.4 Periodic safety checks

Do the following checks to the tonometer every 12 months:

- Make sure that it functions correctly.
- Inspect the tonometer visually for any mechanical damage and legibility of the safety labels.

19 Symbols

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.


General warning sign


Consult operating instructions

Serial number


Single use only


CE mark


Humidity limitation


Temperature limitation

Lot number


Manufacturing date


Keep dry


Type BF applied part


Manufacturer


Waste from Electrical and Electronic Equipment


Atmospheric pressure limitation

National Communications Comission (NCC) mark of Taiwan

Technical conformity mark and certification number of the Ministry of Internal Affairs and Communications of Japan (MIC)

The Regulatory Compliance Mark (RCM), in Australia and New Zealand

Recyclable package material

Bluetooth communication

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

20 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 tonometer.

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

The iCare TONOVET Pro (TV031) 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.

21 Electromagnetic declaration

WARNING! Use of this tonometer adjacent to or stacked with other tonometers should be avoided because it could result in improper operation. If such use is necessary, this tonometer and the other tonometers 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 tonometer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this tonometer and result in improper operation.

PRECAUTION! The measurement method of the iCare TONOVET Pro 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! 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.

The iCare TONOVET Pro (TV031) 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 TONOVET Pro (TV031) tonometer.

The Essential Performance of the iCare TONOVET Pro (TV031) 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 TONOVET Pro (TV031) is intended for use in a professional veterinary environment with electromagnetic characteristics specified below. The user of the iCare TONOVET Pro tonometer (TV031) should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	iCare TONOVET Pro (TV031) 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 TONOVET Pro (TV031) 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 TONOVET Pro (TV031) is intended for use in a professional veterinary environment with electromagnetic characteristics specified below. The user of the iCare TONOVET Pro tonometer (TV031) 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 TONOVET Pro (TV031), including cables specified by the manufacturer. Otherwise, degradation of the performance could result. The measurement method of the iCare TONOVET Pro 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 TONOVET Pro (TV031) is intended for use in a professional veterinary environment with electromagnetic characteristics specified below. The user of the iCare TONOVET Pro tonometer (TV031) 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 TONOVET Pro (TV031) 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 TONOVET Pro (TV031) is intended for use in a professional veterinary environment with electromagnetic characteristics specified below. The user of the iCare TONOVET Pro tonometer (TV031) 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 TONOVET Pro (TV031) 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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