

Canon

Full Auto Tonometer

TX-20

TX-20P

Instructions for Use

CE 2797
UK
CA 0086

For European Union

Important Information

- This product must only be used by a doctor or a legally qualified person.
- The user is responsible for managing the usage and maintenance of medical equipment. We suggest that a dedicated individual is assigned responsibility for maintenance to ensure that this product is kept in good condition and can be used safely.
- Connection of a system that uses this product to a network could result risks to patients, operators, or third parties. A dedicated individual who is assigned responsibility for maintenance should assess these risks in advance. The responsible person should also assess the risks when changes to the network (including changes in the network configuration, addition or disconnection of items to the network, or update or upgrade of equipment connected to the network) occur after connection.

Patient Target Group

- Pediatric and adult patients who can hold their head against the forehead rest and chin rest while capturing (including pregnant and breast-feeding women), who do not meet contraindications, and regardless of gender.

Indications

- This device is indicated for using for the measurement of intraocular pressure and central corneal thickness(TX-20P only) to assist in the diagnosis.

1 Introduction

Features

The Canon Full Auto Tonometer has full auto-alignment for intraocular pressure measurement and optical corneal thickness measurement (TX-20P only).

Indications for Use

The Canon Full Auto Tonometer is intended to be used for the measurement of intraocular pressure and central corneal thickness of the human eye (TX-20P only) and the results will be provided for diagnosis.

Composition

- Full Auto Tonometer
- Power cord

Optional products

Chin rest paper—500 sheets

Printing paper—10 rolls

2 Safety

Regulatory Information

Device Classification

Type of protection against electric shock	Class I equipment
Degree of protection against electric shock	Type B applied parts (Chin rest, forehead rest)

CE marking

This device complies with the following:

- Regulation (EU) 2017/745
- Directive 2011/65/EU

For European Union

Notification of Serious Incident

Any serious incident (defined in Article 2(65) of the Regulation (EU) 2017/745) that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Electronic Instructions for Use

Instructions for use are available on the website for viewing and download by customers.

- <https://global.canon/en/ifu/medcom/index.html>

For details, please contact your sales representative or local Canon dealer.

Safety Precautions

To prevent injuries and data loss, operate this product correctly by following the safety precautions.

Do not leave alcohol, thinner, or any flammable chemicals near the instrument.

Do not place this product near a flammable solvent. Fire may result if the solvent spills or evaporates and makes contact with the internal electric parts. Some disinfectants are flammable. Be sure to take precautions when using them.

Do not clean this product with flammable solvent.

For safety reasons, before cleaning this product, be sure to turn off the power of all the devices and unplug the power cord from the AC outlet. Do not use alcohol, benzene, thinner or any other flammable solvent.

Otherwise, fire or electric shock may result.

Do not touch conductive parts of non-medical equipment and the patient simultaneously.

Otherwise, electric shock may result.

Use an isolation transformer for LAN connections.

If the LAN connector is being used to connect to a network, connect an isolation transformer for networks between this product and network devices (HUB etc.) and between network devices.

If this is not done, there is a risk of short circuits or malfunctioning devices. Ask your sales representative or local Canon dealer to connect it to a network.

Do not install in locations exposed to water, steam, moisture or dust.

Doing so may cause problems or malfunctions.

Do not install in locations exposed to salt, sulfur or corrosive gas.

Doing so may result in corrosion of the instrument, problems or malfunctions.

Do not install in locations that are unstable or exposed to vibration.

The vibration may knock over the instrument or the instrument may become unbalanced and fall, resulting in a malfunction or injury.

Do not put your hands or fingers near the measurement unit.

Your hand or fingers may be pinched and injured.

Similarly, instruct the patient not to place his/her hands or fingers on the base.

Ensure that the entire system conforms to IEC 60601-1.

Use the computer and other equipment that conform to the system standard IEC 60601-1 or IEC 62368-1 for this product. Be sure that the entire system conforms to IEC 60601-1. Be sure to also use an isolation transformer conforming to IEC 60601-1 when a computer conforming to IEC 62368-1 is used.

Otherwise, electric shock may occur. Ask your sales representative or local Canon dealer to connect it to a computer.

Keep the forehead rest and chin rest clean.

To prevent the risk of infection, wipe the forehead rest with disinfectant ethanol for each patient. To ensure cleanliness, replace the chin rest paper for each patient. If the chin rest paper is not being used, be sure to disinfect the chin rest for each patient.

For details on how to disinfect, consult a specialist. The forehead rest may be corroded if a disinfectant other than those above is used.

Be sure to turn off the power when not in use.

For safety reasons, be sure to turn off the power of all the devices when this product is not being used.

Also, unplug the power plug from the AC outlet and put on the cover when this product is not going to be used for a long time.

Otherwise, dust or any foreign matter may accumulate and result in fire.

Do not touch the measurement unit and the chin rest while they are moving.

The measurement unit and the chin rest move when the power is turned on, full auto is set, or the CHIN REST button is pressed. Do not touch the measurement unit or the chin rest while they are moving. Keep the patient's chin away from the chin rest.

Use the product's packaging to transport it.

Use this product packing materials to protect it from vibration and shocks when it is transported on a cart, in a vehicle, or if shipped over long distances.

Vibration or shock may cause a breakdown or damage this product.

For details, contact your sales representative or local Canon dealer.

Do not measure an eye whose cornea is frail due to corneal disease or surgery.

Otherwise, complications may occur.

Use the indentations for lifting and moving this product.

When lifting this product, hold it on the bottom and keep it level. Do not hold it by the head rest, nozzle or LCD monitor, as they may come off and result in injury.

Turn off the power and unplug the power cord before connecting cables.

Always turn off the power and unplug the power cord before connecting the cables of any external devices to this product.

If this is not done, there is a risk of damage.

Always disinfect the nozzle after measuring an infected patient's eyes.

A patient's tears may get on the nozzle and cause a secondary infection. Always use a cotton swab or other appropriate material that has been treated with disinfectant ethanol to wipe the nozzle.

Make sure to select the position where the nozzle stops for each patient.

Look from the side of the patient when setting the stop position to see that the patient's forehead and chin are firmly against the forehead rest and chin rest. If the stop position is not set correctly, the nozzle may contact the patient's eye and result in injury.

Do not touch the cutter of the printer.

Do not touch or allow the patient to touch the cutter of the printer. Otherwise, it may result in injury.

Do not touch the area around the printer or open the paper cover during or immediately after printing.

The printer's thermal head and the surrounding area are very hot during and immediately after printing. To prevent burns, wait for the printer to cool before opening the paper cover to replace printing paper.

Notes on Using This Product

Before Use

- Sudden heating of the room in cold areas will cause condensation to form on the optical component of the nozzle and corneal thickness measurement unit (TX-20P only) and on optical parts inside the instrument. In this case, wait until condensation disappears before performing a measurement.

During Measurement

- Describe to the patient what to expect during measurement so he/she will not be surprised by the sudden air puff. Demonstrate the intensity of the air puff by having the patient place a finger in front of the nozzle and then press the CHECK button.
- The measurement unit automatically moves after the power is turned on. Do not prevent movement of the measurement unit by holding it or placing something near it. Do not let the patient place his/her chin on the chin rest until the measurement unit stops.
- It is recommended that a hard copy of the printout be made if you wish to store it for a long time, because printouts on thermal printing paper are apt to deteriorate.

After Use

- Turn off the power, put the cap over the optical component of the nozzle and corneal thickness measurement unit (TX-20P only) in order to prevent dust from attaching to it, and place the dust cover over the instrument.

During Cleaning and Disinfection

- If the surface of the optical component of the nozzle and corneal thickness measurement unit (TX-20P only) is wiped when dust or dirt is on it, it will be scratched. Also, do not wipe the optical component with alcohol, including disinfectant ethanol or silicone-coated paper. Otherwise, the surface will be corroded or stained.
- Use neutral detergent for cleaning the outside of this product. Do not use other than the above.
- Do not use neutral detergent for cleaning the LCD monitor. See below for LCD cleaning instructions.

LCD Monitor

- Approximately 99.99% of the dots in high-technology LCD monitors are functional. About 0.01% of the dots may be missing or might appear as a bright spot. This is not a malfunction.
- The polarization plate on the surface of the monitor is very fragile. Be careful when handling it and do not press or rub any hard objects against it.
- Wipe water or saliva from the polarization plate on the monitor's surface immediately; leaving it for a long time may cause distortion or discoloration.
- If the surface is dirty, use something soft, such as an absorbent cotton cloth, with a small amount of ethanol, and lightly wipe it.

Environment of use

- Use, store, and transport this product in an environment that is within the range of the following conditions. Use the original packaging to store or ship it.

	Temperature	Humidity	Atmospheric pressure
Environment of use	10 to 40°C	30 to 90% RH (no condensation)	700 to 1060 hPa
Storage and transportation environment	-30 to 50°C	10 to 95% RH (no condensation)	600 to 1060 hPa

- Do not install, store, or leave this product in a very hot or humid environment. Also, do not use this product outside. Doing so may cause a malfunction or misoperation.
- When this product is not being used, attach the nozzle cap and place the dust cover over this product.

Installation

- Request your sales representative or local Canon dealer to install this product.
- A strong shock to this product may put it out of alignment. Please handle the unit carefully.

Disposal

Disposal of this product in an unlawful manner may have a negative impact on human health and on the environment. Therefore, when disposing of this product, be absolutely certain to follow the procedure which conforms with the laws and regulations applicable to your area.

Only for European Union and EEA (Norway, Iceland and Liechtenstein)

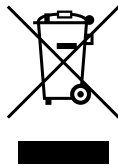


This symbol indicates that this product is not to be disposed of with your household waste, according to the WEEE Directive (2012/19/EU) and national legislation. This product should be handed over to a designated collection point, e.g., on an authorized one-for-one basis when you buy a new similar product or to an authorized collection site for recycling waste electrical and electronic equipment (EEE). Improper handling of this type of waste could have a possible negative impact on the environment and human health due to potentially hazardous substances that are generally associated with EEE. At the same time, your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, waste authority, approved WEEE scheme or supplier where you purchased the product.

The information above, including information on batteries, is on our website in the official languages of each EU country.

Please access <https://global.canon/en/ifu/medcom/envfile/weee-battery-eu.pdf>.

Only for the United Kingdom












This symbol indicates that this product is not to be disposed of with your household waste, according to the UK Waste Electrical and Electronic Equipment Regulations. This product should be handed over to a designated collection point, e.g., on an authorized one-for-one basis when you buy a new similar product or to an authorized collection site for recycling waste electrical and electronic equipment (EEE). Improper handling of this type of waste could have a possible negative impact on the environment and human health due to potentially hazardous substances that are generally associated with EEE. At the same time, your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, waste authority, approved WEEE scheme or supplier where you purchased the product.

The information above, including information on batteries, is on our website.

Please access <https://global.canon/en/ifu/medcom/envfile/weee-battery-uk.pdf>.

Symbols on the labels and their meanings

The following table describes the symbols and indications on this product.

	Alternating current	
	Type B	
	Product that WEEE directive, Directive on Waste Electrical and Electronic Equipment, requires separate collection. The directive is effective in the European Union only.	
	Symbol for "Consult instructions for use".	
	This symbol indicates medical device which complies with the Regulation (EU) 2017/745	
	Symbol for "Authorised Representative in the European Community".	
	Manufacturer's name and address	
	Month and year of manufacture	Example: November 2014
	Serial number in six digits	Example: 123456

3 Basic Operations

Connecting Cables

- 1 Make sure that the power switch is off.
- 2 Connect a USB cable to input patient IDs with USB devices.
- 3 Connect an RS-232C cable or LAN cable to send measurement results to an external device.
- 4 Connect the power cord.
- 5 Insert the power plug all the way into an AC outlet.

Preparations Prior to an Examination

- 1 Remove the dust cover and the nozzle cap and check the printing paper.
- 2 Turn on the power.
- 3 Adjust the tilt of the monitor.
- 4 Disinfect the forehead rest and the chin rest.

Patient Setup

- 1 Disinfect the forehead rest and the chin rest.
- 2 Have the patient sit down.
- 3 Instruct patients to remove their glasses or contact lenses if they are wearing them.
- 4 Input the patient ID.
- 5 Press the R/L button to decide which eye to measure.
- 6 Place the patient's chin on the chin rest and forehead against the forehead rest.
- 7 Move the chin rest with the CHIN REST button so that the patient's eye is aligned with the height adjustment mark.
- 8 Press the LIMITER button to set the position where the nozzle stops.
- 9 Have the patient stare at the eye fixation lamp.

Measuring

- 1 Use the operation lever and the measurement unit vertical movement ring to display the patient's pupil in the monitor.
- 2 Have the patient stare at the eye fixation lamp.
- 3 Press the measurement button.

Finishing an Examination

- 1 Turn off the power switch.
- 2 Clean the nozzle.
- 3 Disinfect the forehead rest and the chin rest.
- 4 Put the cap on the nozzle and cover the equipment with the dust cover.

4 Maintenance

Daily Inspections

Perform the following inspections before using this product to ensure that it is used safely and correctly.

If a problem is found during the inspection and you are unable to correct the problem, please contact your sales representative or local Canon dealer.

Checks before turning on the power

Check the following items before turning on the power.

Cables

- 1) The power cord and connection cable are not damaged and their insulation is not torn.
- 2) The power cord is fully and securely inserted into the AC connector on the main unit and the AC outlet.

Main unit

- 1) There are no scratches or dirt on the nozzle or objective lens. Clean the nozzle and objective lens if they are dirty.
- 2) There is no dirt on the monitor. Clean the monitor if it is dirty.
- 3) The forehead rest is disinfected.
- 4) The chin rest paper is loaded.
If the chin rest paper is not being used, disinfect the chin rest.
- 5) The printing paper is loaded.
- 6) The covers and other parts are neither damaged nor loose.

Checks after turning on the power

Check the following items after turning on the power.

- 1) The power lamp lights.
- 2) The chin rest moves up and down smoothly as the CHIN REST button is pressed.
- 3) The measurement unit moves smoothly in all directions (forward, back, left, right, up, and down) as the operation lever and the measurement unit vertical movement ring are operated.

Cleaning and Disinfection

Nozzle

When dust or dirt is stuck on the tip of or inside the nozzle, press the CHECK button to blow it off.

Optical Component of Corneal Thickness Measurement Unit (TX-20P only) and Nozzle Component

When dust or dirt is stuck on the tip of or inside the nozzle, press the CHECK button to blow it off.

- 1 Blow away any dust or dirt.
Remove the brush from the blower brush and blow off the dust on the optical component.
- 2 Wipe the optical component.
Slightly dampen a lens cleaning paper with lens cleaner and lightly wipe the optical component.
Wipe it again if it needs it.

Forehead Rest / Chin Rest

Clean the intended parts with a sanitized gauze or a similar material that is moistened with disinfectant.

Exterior and monitor screen of this product

Clean the exterior, rollers, and monitor screen as follows if they are dirty.

- 1 Turn off the power.
Turn off the power switch and disconnect the power cable from AC receptacle.
- 2 Wipe the exterior and rollers.
Wipe them with a soft cloth that has been soaked in diluted neutral detergent and firmly wrung out.
Then, wipe the exterior and rollers again with a cloth that has been soaked in water and firmly wrung out.
- 3 Wipe the monitor screen.
Wipe it lightly with a soft cloth such as an absorbent cotton rag dampened with a small amount of ethanol.

Appendix

Specifications

Intraocular pressure measurement	
Measurement type	Air-puff type
Operation distance	11 mm
Range of intraocular pressure measurement	0 to 80 hPa (0 to 60 mmHg)
30 mode	0 to 40 hPa / 33 to 80 hPa changes automatically (0 to 30 mmHg / 25 to 60 mmHg changes automatically)
60 mode	33 to 80 hPa (25 to 60 mmHg)
Accuracy	According to EN ISO 8612: 2009
Range of compensated intraocular pressure calculation	0.0 to 99.9 hPa (0.0 to 99.9 mmHg)
Displayed unit of intraocular pressure	1 hPa / regular measurements and compensated intraocular pressure measurements: 0.1 hPa (1 mmHg / regular measurements and compensated intraocular pressure measurements: 0.1 mmHg) * 1.33 hPa = 1 mmHg
Corneal thickness measurement (TX-20P only)	
Measurement type	Optical projection
Range of corneal thickness measurement	150 to 1300 μ m
Displayed unit of corneal thickness	10 μ m (regular measurements: 1 μ m)
Observation range	13.2 x 10 mm or more
Movement range	
Measurement unit	Front/back: 40 mm Right/left: 90 mm Up/down: 30 mm
Chin rest	60 mm
Power supply rating	AC 100 V to 240 V, 50/60 Hz, 0.8 A to 0.4 A

EMD (Electromagnetic Disturbances)

This product is designed and tested to comply with IEC 60601-1-2 (EN 60601-1-2) which is applicable regulations regarding EMD for medical devices and need to be installed and put into service according to the following information.

1. Medical electrical equipment needs special precautions regarding EMD and needs to be installed and put into service according to the information provided in the manual.
2. This product is suitable for use in hospital (professional healthcare facility) environments, with the exception of environments near active HF SURGICAL EQUIPMENT or the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of ELECTROMAGNETIC DISTURBANCES is high.
3. To maintain the optimum EMD performance, use only the designated cables.

Name	Type	Length	Remarks
AC Power Cord	Non-Shielded	3.0 m	Supplied
RS-232C Cable	Shielded	1.5 m	Not supplied
USB Ten Key Board	TK-TCM003SV	0.5 m	Not supplied
LAN Cable	Non-Shielded	50 m	Not supplied

4. **WARNING:**
Use of accessories, transducers and cables other than those specified or provided by Canon sales representative or local Canon dealer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
5. **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.
6. **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 this product, including cables specified by Canon sales representative or local Canon dealer. Otherwise, degradation of the performance of this equipment could result.
7. Due to electromagnetic disturbances, it may be necessary for the customer or the user of this product to take the measurement again or to restart the equipment, the software or the computer.

Electromagnetic Emission

This product is intended for use in the electromagnetic environment specified below.

The customer or the user of this product should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment – Guidance
RF emissions EN 55011 CISPR11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electromagnetic equipment.
RF emissions EN 55011 CISPR11	Class B	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions EN IEC 61000-3-3*	Complies	

* Not applicable to regions where the rated voltage is less than 220 V.

Warranty and Repair Service

Service life

The service life of this product is eight years if specified inspections and maintenance are performed.

Technical Description

For the technical description, see the operation manual of the product.



BT8-2590-EN01

Canon

Manufacturer:



CANON INC.

30-2, Shimomaruko 3-chome, Ohta-ku, Tokyo 146-8501, Japan

Telephone: (81)-3-3758-2111