

USER MANUAL
AUTO KERATO-REFRACTO TONOMETER

TRK-3 OMNIA

INTRODUCTION

Thank you for purchasing the TOPCON AUTO KERATO-REFRACTO TONOMETER TRK-3 OMNIA.

INDICATIONS FOR USE

TRK-3 OMNIA is a combination of the non-contact tonometer and pachymeter. The device is indicated for automatic measurement of intraocular pressure without contacting the eye (with less than 3 diopters of corneal astigmatism); and measurement of central corneal thickness.

FEATURES

This instrument features the following:

- The position of the control panel can be adjusted to accommodate the user's preferred position.
 - An alignment is performed automatically by auto alignment function.
 - The measurement results can be output to a personal computer (PC), etc.
-

PURPOSE OF THIS MANUAL

This manual provides an overview of the basic operation, troubleshooting, checking and cleaning of the TOPCON AUTO KERATO-REFRACTO TONOMETER TRK-3 OMNIA. To get safe use of the instrument, read DISPLAYS AND SYMBOLS FOR SAFE USE and GENERAL SAFETY INFORMATION. Keep this manual at hand for future reference.

[CAUTION] Federal law restricts this device to sale by or on the order of a physician.

TRADEMARKS

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1. No part of this manual may be copied or reprinted, in whole or in part, without prior written permission.
 2. The contents of this manual are correct to the best of our knowledge. Please inform us of any ambiguous or erroneous descriptions, missing information, etc.
 3. This manual is original instructions.
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









DISPLAYS AND SYMBOLS FOR SAFE USE















In order to encourage the safe use of the instrument and to avoid danger to the operator and others as well as damage to properties, warnings are described in the manual and marked on the instrument body. We suggest you thoroughly understand the meaning of the following displays/icons and Safety Cautions, as well as read the manual, and strictly observe the instructions.

DISPLAY

Display	Meaning
 CONTRAINDICTION	Situations in which the device should not be used because the risk of use clearly outweighs any possible benefit.
 WARNING	Incorrect handling by ignoring this display may lead to a risk of death or serious injury.
 CAUTION	Incorrect handling by ignoring this display may lead to personal injury or physical damage.
 NOTE	Useful functions to know. Paying attention to these will prevent the noted problems.

SYMBOL

Symbol	Description	Description (French)
	Alternating Current	Courant alternatif
	Off (power: disconnection from the main power supply)	Éteint (courant: coupure avec le secteur)
	On (power: connection to the main power supply)	Allumé (courant: raccordement sur le secteur)
	Type B applied part	Partie appliquée du Type B
	General warning sign	Symbole d'avertissement général
	Refer to instruction manual/booklet	Voir le manuel/la brochure
	Consult instructions for use or consult electronic instructions for use.	Consulter le mode d'emploi ou le mode d'emploi électronique.
	Manufacturer	Fabricant
	Date of manufacture	Date de fabrication
	Serial number	Numéro de série
	Unique Device Identification (UDI)	Identification unique des dispositifs (IUD)

Symbol	Description	Description (French)
	Humidity limitation	Limite d'humidité
	Atmospheric pressure limitation	Limite de pression atmosphérique
	Temperature limit	Limite de température
	Keep away from sunlight	Tenir à l'abri du soleil
	Fragile, handle with care	Fragile manipuler avec soin
	Keep dry	Garder au sec
	This way up	Vers le haut
	Maximum number of identical packages which may be stacked on one another, where "n" is the limiting number.	Nombre maximum d'emballages identiques pouvant être empilés les uns sur les autres, où "n" est le nombre limite.
	General symbol for recovery/recyclable. (for the package)	Symbole général de tri sélectif. (pour l'emballage)
	Recycling symbol for plastic in the package. Low density polyethylene	Symbole de recyclage du plastique dans l'emballage. Polyéthylène basse densité
	Recycling symbol for plastic in the package. Polypropylene	Symbole de recyclage du plastique dans l'emballage. Polypropylène
	Recycling symbol for plastic in the package. Polystyrene	Symbole de recyclage du plastique dans l'emballage. Polystyrène
	United States Federal law restricts medical devices to sale by or on the order of a licensed healthcare practitioner. (See 21 Code of Federal Regulations (CFR) sec. 801.109(b)(1))	La loi fédérale des États-Unis n'autorise la vente de dispositifs médicaux que par ou sur ordonnance d'un professionnel de la santé autorisé. (Voir 21 Code of Federal Regulations (CFR) sec. 801.109(b)(1))
	CSA listing mark	Marque de cotation CSA

GENERAL SAFETY INFORMATION



CONTRAINDICATION

Ensuring the Safety of Patients and Operators

To prevent corneal damage by air pressure, do not perform tonometry measurements on a patient with a fragile cornea such as a patient who recently had a corneal disease or who recently had a corneal surgery and whose cornea has not recovered enough to allow air blowing.



WARNING

Ensuring the Safety of Patients and Operators

Be careful not to hit the patient's eyes or nose with the instrument during operation. The patient may be injured.

Preventing Electric Shocks and Fires

To avoid fire and electric shock, install the instrument in a dry place free of water and other liquids.

To avoid fire and electric shock, do not put cups or other containers with liquids near the instrument.

To avoid fire in use, do not use the power inlet, power connector, or power plug with dust or liquid adhering to or accumulating on them.

To avoid fire in the event of an instrument malfunction, immediately turn OFF the POWER switch "O" and disconnect the power plug from the outlet if you see smoke coming from the instrument, etc. Do not install the instrument where it is difficult to disconnect the power plug from the outlet. Ask your dealer for service.

To avoid fire and electric shock, do not open the cover. Ask your dealer for service.

Modification of this instrument is not permitted.

If the product is used for a long period of time with the power plug plugged into the outlet, dust may collect between the outlet and the power plug, causing electric leakage due to the adhesion of water and causing a fire. Clean the space between the outlet and the power plug regularly.
(There is a risk of electric leakage or fire due to the accumulation of dust and the adhesion of moisture.)

To avoid injury from electric shocks, do not connect anything other than the specified external equipment to the external I/O terminals.


Be sure to connect the power plug to an AC 3-pin receptacle equipped with grounding. Connection with receptacle without grounding may cause fire and electric shock in case of short-circuiting.

Connect only items that have been specified as part of the ME system or that have been specified as being compatible with the ME system.

Regarding use on Patients

Do not use the device to measure intraocular pressure in highly astigmatic eyes (with more than 3 diopters of corneal astigmatism) since use in such eyes can result in inaccurate and undependable tonometry IOP measurements.

Proposition 65 warning statement

 **WARNING:** This product can expose you to chemicals including Lead, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

CAUTION

Important caution

The following patients need extra attention.
Patients with infectious disease such as Keratoconjunctivitis Epidemica

Ensuring the Safety of Patients and Operators

When operating the chinrest up/down button, be careful not to pinch the patient's hand. The patient may be injured.

When operating the instrument, use much care so that operator's finger or hand is not pinched between the reverse side of forehead rest, a measuring head and an intraocular pressure measurement window. Or the operator may be injured.

To avoid injury to the operator, be careful not to get the finger or hand of the operator who is opening the eyelids caught in the instrument.

Each time one patient is changed to another, replace the chinrest tissue with a new one.

To avoid injury to the operator, do not open or close the printer cover while the built-in printer is operating.

To avoid injury to the patient, be careful not to touch the patient when operating the control lever.

To avoid injury to the patient, be careful not to move the patient's face while the main body unit is in alignment operation.

When moving the instrument, two people should lift from the bottom of the device. One person lifting the device may cause harm to his back or injury by falling parts.

When holding the bottom of the instrument, avoid touching a projection of screws to prevent injury.

To prevent damage and injury, do not hold anything but bottom. If you hold, it may cause to catch the finger or to damage the instrument by falling.

To prevent damage and injury, do not install the instrument on an uneven, unsteady or sloped surface.

To prevent injury, when setting an instrument on an instrument table, pay attention not to catch a finger between the instrument and the table.

When installing the main body unit on an adjustable instrument table, etc., make sure that the chinrest does not protrude from the top plate. When a load is applied to the chinrest, the instrument may tip over and cause injury.

Do not operate a touch panel during barcode data entering by barcode reader. If you enter data when tapping the button on the touch panel, the barcode may not be read normally.

Do not align, measure, or output data during barcode data entering by barcode reader. If you enter data during these operations, the barcode may not be read normally.

Take care not to enter the wrong patient information. It may be mistaken for information from another patient.

To avoid potential injury in case of malfunction, including a paper jam, be sure to shut off the power before attempting to repair the built-in printer.

To avoid potential injury caused by the edges and metal parts of the built-in printer, do not touch the built-in printer body while the printer is in operation or when replacing the printer paper.

Before measuring, check if there is any foreign matter on and around the measuring nozzle. If there is any, it may enter and damage the patient's eye during the measurement.

To avoid injury when operating the instrument, be careful about the cover not to catch the fingers of the patient. Tell this to the patient, too.

Before measuring, set the safety stopper to prevent the intraocular pressure measuring window from hitting the patient's eye.
Set it respectively for the right and left eyes.

Set the safety stop from the side of the instrument.
Setting operations from other positions, it is not easy to check positions of the eye and intraocular pressure measuring window, may cause injury by touching intraocular pressure measuring window to a patient.

When switching the left and right eyes by the control lever, be sure to return the measuring head to the backward side by tilting the control lever to the backward before moving the measuring head to the left or right. It causes injury by hitting the patient's eyes or nose.
Do not use or apply any aerosol-type cleaner near the instrument. If a drop of cleaner remains inside the measuring nozzle, the patient's eye may be injured during measurement.
To clean the intraocular pressure measuring window glass, measuring nozzle and the glass inside the measuring nozzle, use ethanol. Using other chemicals may cause damage to the patient's eye during measurement.
Do not use in environments where device that generates strong magnetic fields, such as MRI device is installed.
Please make sure patients remove the contact lenses before any measurement with the device.

Preventing Electric Shocks
To avoid electric shocks, do not insert metal objects into the instrument body through the vent holes or gaps.
To avoid electric shocks, do not handle the power plug with wet fingers.
The power cord in standard accessories for this instrument cannot use besides this instrument.
To avoid electric shocks, do not touch the external connection terminal and the patient at the same time.
When connecting this instrument to a commercially available personal computer, use a personal computer that conforms to IEC 62368-1, and use an insulating device that conforms to IEC 60601-1 in the patient environment.
Do not connect an additional power strip or an extension cord to the system.
The total 1kVA is the maximum allowable load of the auxiliary power supply socket for the insulation transformer, which is provided for the system. Do not connect the device exceeding this capacity.
Use the auxiliary power supply socket of the insulation transformer to power only a device that will be a component of the system.
It is dangerous to connect any device which is not used as a component of the system, to the insulation transformer.
When the insulation transformer is not used, the personal computer and the monitor for the personal computer must be installed out of the patient environment.
Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
Do not remove the enclosures. Laser high-power is radiated.

Ensuring Security
When connecting this instrument to an external device through LAN, apply the security update to the external device, make use of anti-virus software and take other countermeasures against computer virus properly. When connecting this instrument to an external device through LAN, set the ID and password of the user to the external device. When outputting data to the shared folder on an external device from this instrument, set a proper user ID and password to the shared folder. Do not connect anything other than the specified external devices to the external I/O terminals. Information such as patient ID may be leaked.
The entered patient ID will be displayed on the control panel. Do not leave the device with the control panel displayed for long periods of time. If you might be away from the instrument, set the 'Power Save Timer' to a short duration such as 1 minute. This will automatically clear the patient ID and measurement data, protecting the information from unintended disclosure. Please handle printouts included patient ID with care. The patient ID information may be leaked.
When using this instrument in an environment where a third person can see it, turn the control panel so that it cannot be seen by a third person. Please handle printouts included patient ID with care so that it cannot be seen by a third person. The patient ID information may be leaked.
When connected with an IT network, ensure the appropriate and sufficient security to prevent the infection with malware and a computer virus, the leak of information, etc. There is a risk of data leakage.
Do not connect any USB storage device that is not checked with the anti-virus software to the USB port of this instrument.

To avoid leakage of personal information, erase the data before discarding the storage device.
If you need information about SBOM, ask your dealer. Information can be provided in xlsx and SPDX-Lite formats.
Vulnerability and software update information is available at the following link. https://topconhealthcare.com/product-updates/
The manufacturer or your dealer will provide you with information about the end of security support for the device.
Software updates include security updates such as SOUPs, etc. The user shall apply the latest software.
If there is a possibility that some security incident has occurred, disconnect the device from the hospital network and take initial action according to hospital policy, such as running anti-virus software and checking access logs, if necessary.
User shall implement password authentication and other access control for servers on the network, and disable legacy versions of the SMB communication protocol. User shall enable SMB protocol encryption for the shared folders and TLS1.2 or other encryption for SQL server TCP/IP communication.

Electromagnetic Compatibility (EMC)
This instrument has been tested (with 100/120/230V) and found to comply with IEC 60601-1-2:2014+AMD1:2020 (Ed.4.1). This instrument radiates radio frequency energy within standard and may affect other devices in the vicinity. If you have discovered that turning on/off the instrument affects other devices, we recommend you change its position, keep a proper distance from other devices, or plug it into a different outlet. Please consult your authorized dealer if you have any additional questions.
The external devices to be connected must comply with the corresponding EMC standards(e.g. CISPR 32/CISPR 35). The patient may be injured. It may affect other devices in the vicinity.

HOW TO USE THIS MANUAL

- Read the instructions on pages 1 to 13 before using the instrument.
- If you would like an overview of the system, begin by reading “BASIC OPERATIONS” (page 38).
- Regarding connection to various devices, see “CONNECTING EXTERNAL I/O TERMINALS” on page 32.
- For setting various functions, see “SETTING FUNCTIONS ON SETUP SCREEN” on page 97.

The Abbreviation used in this manual.

Abbreviation	original meaning
REF	Refractometer: Measurement of Spherical refractive power, Astigmatic refractive power and Direction of astigmatic axis
KRT	Keratometer: Measurement of Cornea curvature radius, Direction of corneal principal meridian and Corneal refractive power
TONO	Tonometer: Intraocular pressure measurement
PACHY	Pachymeter: Cornea thickness measurement

GENERAL MAINTENANCE INFORMATION

Do not perform any maintenance work while the instrument is in use on a patient.

USER MAINTENANCE

To maintain the safety and performance of the equipment, never attempt to repair or perform maintenance. These tasks should be performed by an authorized service representative. Maintenance tasks that can be performed by the user are as follows; for details, follow this manual’s instructions.

CLEANING THE MEASURING WINDOW

The glass surface of the REF/ KRT measuring window and the intraocular pressure measuring window can be cleaned. For details, see “CLEANING THE INTRAOCULAR PRESSURE MEASURING WINDOW GLASS” on page 113.

CLEANING THE MEASURING NOZZLE AND WINDOW GLASS INSIDE THE MEASURING NOZZLE

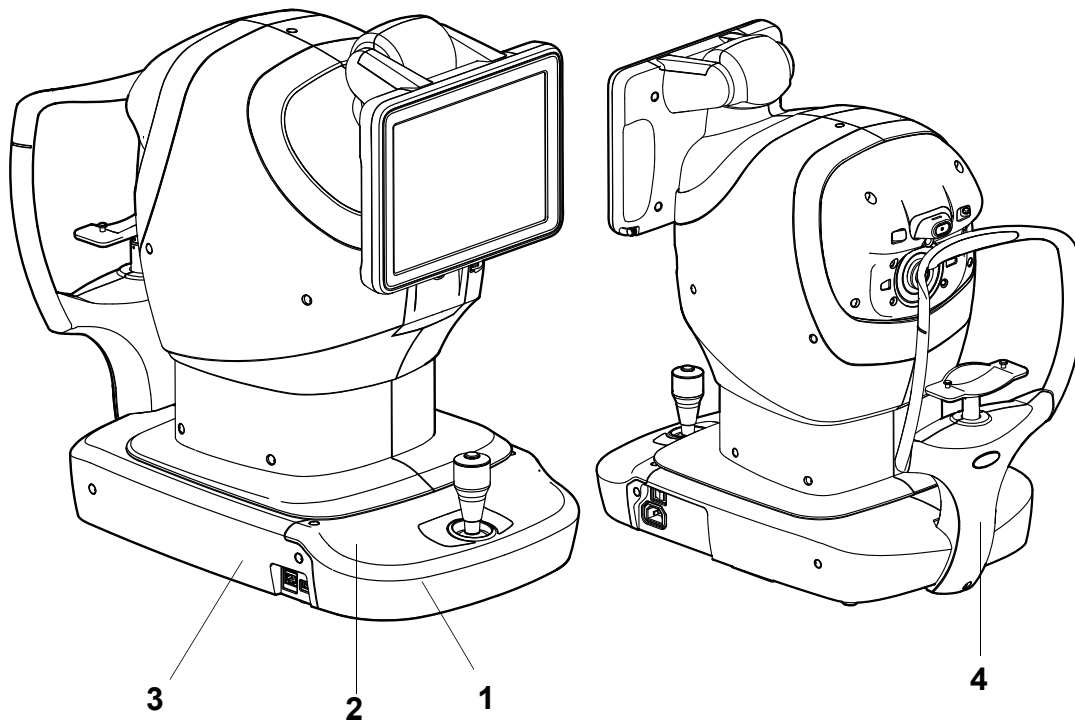
Regarding the measuring nozzle and the glass surface inside the measuring nozzle, cleaning is allowed. For details, see “CLEANING THE MEASURING NOZZLE AND THE GLASS INSIDE THE MEASURING NOZZLE” on page 114.





DISCLAIMERS

- TOPCON shall not take any responsibility for damage due to fire, earthquakes, actions by third persons and other accidents, or damage due to negligence and misuse by the user and any use under unusual conditions.
- TOPCON shall not take any responsibility for damage derived from inability to properly use this instrument, such as loss of business profit and suspension of business.
- TOPCON shall not take any responsibility for damage caused from using this instrument in a manner other than that described in this manual.
- Diagnoses made shall be the responsibility of pertaining doctors and TOPCON shall not take any responsibility for the results of such diagnoses.
- TOPCON shall not take any responsibility for damage due to a computer virus.
- The customer shall take the responsibility to save data and perform backup in case data should be lost. When the customer has obtained data through this software and has saved or backed up the data in a server or personal computer, TOPCON shall not take any responsibility for the loss of the data, loss of profit or other damages on the customer.

POSITIONS OF WARNING AND CAUTION INDICATIONS

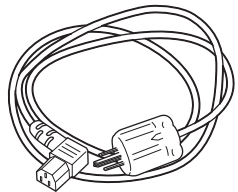
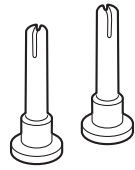
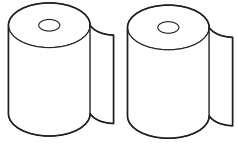
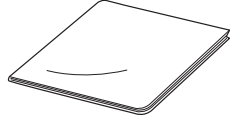
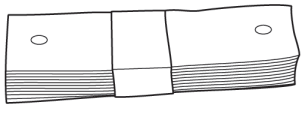

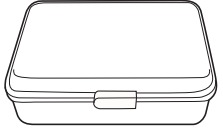

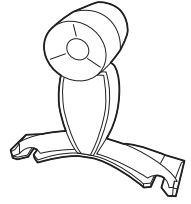
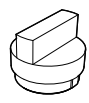
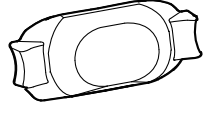
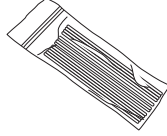
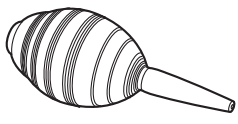
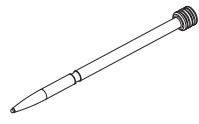
To ensure safety, this instrument provides warning displays. Use the instrument correctly by observing the display instructions. If any of the following display labels are missing, contact your TOPCON dealer at the address listed on the back cover.



No.	Label	Meaning	Signification
1		WARNING To avoid fire and electric shock, do not open the cover. Ask your dealer for service.	MISE EN GARDE Ne pas ouvrir le couvercle pour éviter les blessures causées les incendies et par un choc électrique. Demander au revendeur d'effectuer le service.
2		WARNING Be careful not to hit the patient's eyes or nose with the instrument during operation. The patient may be injured.	MISE EN GARDE Prendre garde de ne pas frapper les yeux ou le nez du patient avec l'instrument pendant l'opération.
		CAUTION When operating the chinrest up/down switch, be careful not to pinch the patient's hand. The patient may be injured.	PRÉCAUTION Prendre garde de ne pas pincer la main du patient en opérant le commutateur haut/bas du support de jugulaire. Le patient pourrait être blessé.
3		WARNING To avoid injury from electric shocks, do not connect anything other than the specified external equipment to the external I/O terminals.	MISE EN GARDE Pour éviter les blessures causées par un choc électrique, ne connectez rien d'autre que l'équipement externe spécifié aux bornes d'E/S externes.
4		Degree of protection against electric shock: TYPE B APPLIED PART	Degré de protection contre les chocs électriques: TYPE B PARTIE D'APPLICATION

STANDARD ACCESSORIES

The following are standard accessories. Make sure that all these items are included (quantity).

<p>Power cord (1)*</p> 	<p>Chinrest tissue pin (2)</p> 
<p>Printer paper (2)</p> 	<p>Monitor cleaner (1)</p> 
<p>Chinrest tissue (1)</p> 	<p>Dust cover (1)</p> 
<p>Accessory case (1)</p> 	<p>User manual, Cleaning procedure (1 each)</p> 
<p>Model eye (1)</p> 	<p>REF/KRT measuring window cap (1)</p> 
<p>Intraocular pressure measuring window cap (for TONO/PACHY) (1)</p> 	<p>Applicator (1)</p> 
<p>Blower (1)</p> 	<p>Stylus pen (1)</p> 

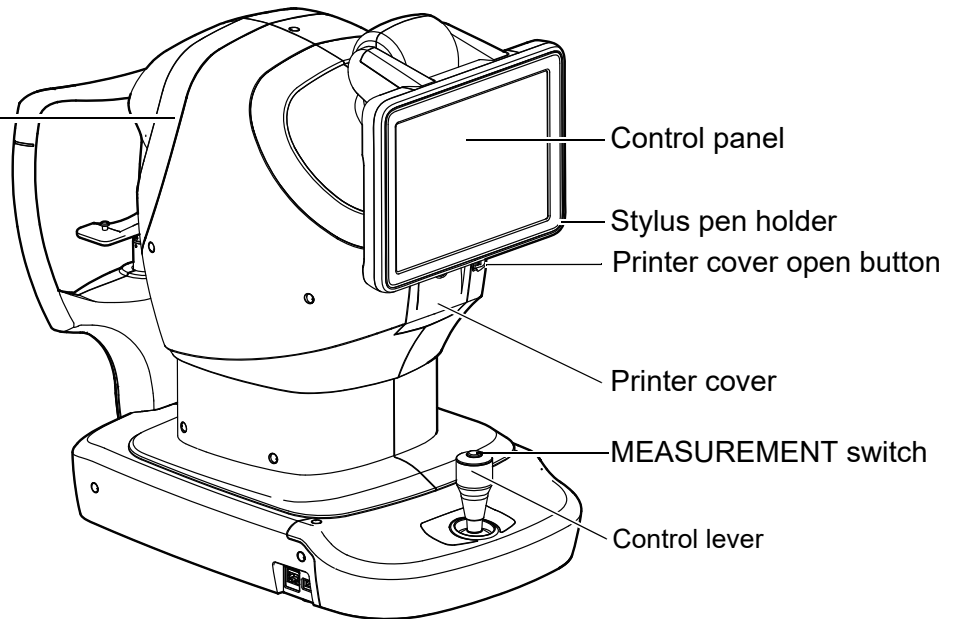
* By the case a plurality of power cords may have been packed.

COMPONENTS

COMPONENT NAMES

Main body unit

Measuring head

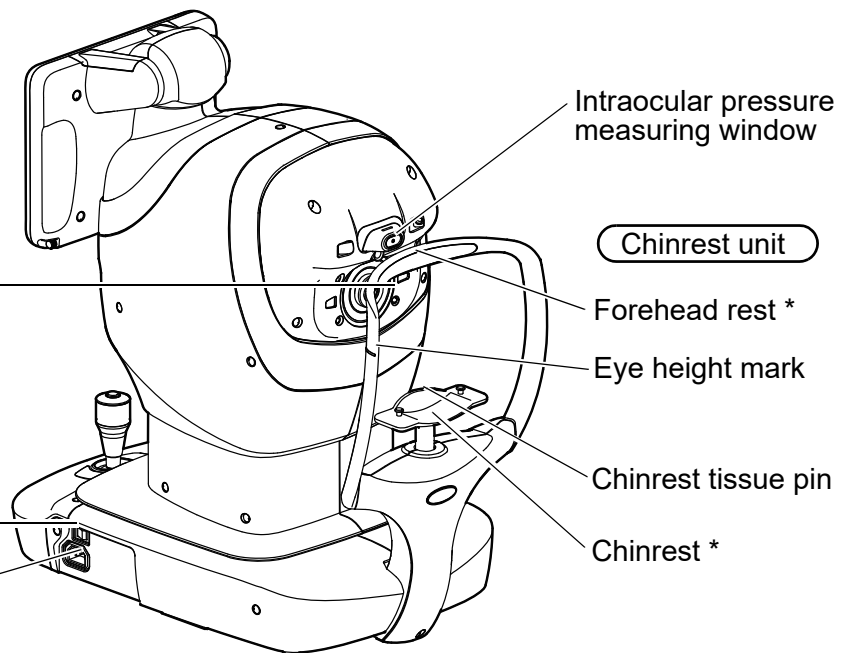


Measuring window
(for REF/KRT)

Power supply unit

POWER switch

Power inlet

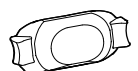


* Parts of contact the patient: Type B applied part

REF/KRT measuring window cap



Intraocular pressure measuring window cap (for TONO/PACHY)




COMPOSITION OF PARTS WHICH CONTACT THE HUMAN BODY

- Forehead rest : Silicone rubber
- Chinrest : Acrylonitrile butadiene styrene resin
- Chinrest tissue : Paper
- Chinrest tissue pin : Polyamide resin(PA)

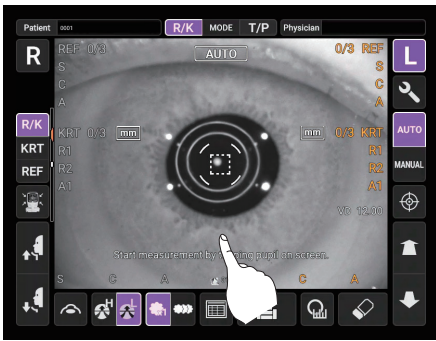
OPERATION METHOD OF CONTROL PANEL

The control panel is designed as a touch panel for performing various operations and settings. It displays images and shows information, including set conditions and measurement results.

 NOTE	<ul style="list-style-type: none"> Operate the control panel by your fingers or the accessory stylus pen. Do not use any sharp tool such as a ball point pen. The touch panel may be damaged to cause an incorrect operation. Do not touch two points on a control panel simultaneously.
---	--

Tap → To select any relevant item.

Continue to press → Used for continuous moving.
(Moving of chinrest and measuring head)



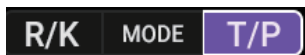
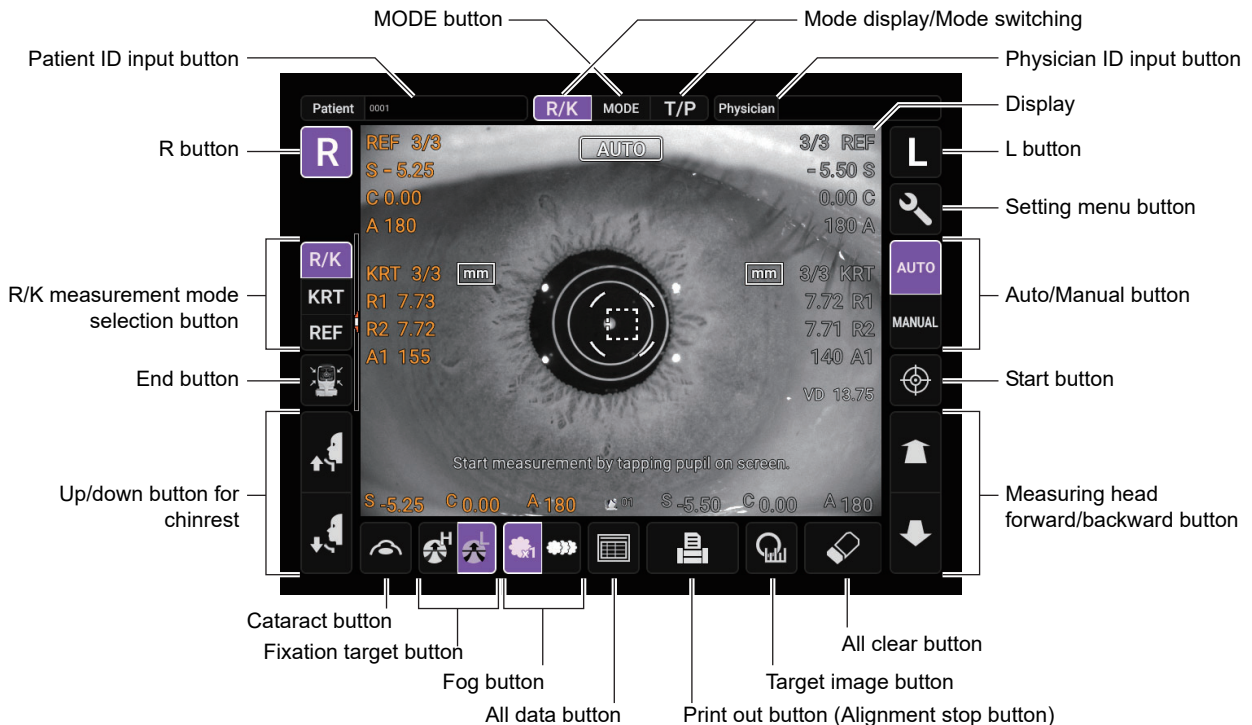
Touch the screen softly with a finger.



Continue to touch the screen softly with a finger.

CONTROL PANEL COMPONENTS (IN REF/KRT MEASUREMENT MODE)

MEASUREMENT SCREEN



Mode display/Mode switching

.....Switch the mode to R/K measurement or T/P measurement.



Patient ID input button

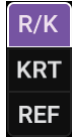
.....Displays the software keyboard. Enter the ID, name, etc.

Physician ID input button

.....Displays the software keyboard. Enter the ID, name, etc. Displayed when “Physician ID” and “Use Physician ID” are set to ON on the Setup screen.

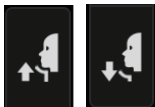


R/L button.....Selects the right/left eye. By tapping the button, the main body moves to the selected direction. The selected button is framed in purple. The layout where the R/L button is displayed reverses according to the position of the control panel.



R/K measurement mode selection button

.....Selects each measurement REF, KRT.



Up/down button for chinrest.....Moves the chinrest up/down.



End buttonThe chinrest and measuring head move to the last position. Turn off the power when the movement to the last position has completed.

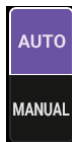


Measuring head forward/backward button

.....Moves the measuring head closer to/away from the patient's eye. The forward and backward operations reverse according to the position of the control panel.



Start buttonStarts measurement.



Auto/Manual button.....Switches between Auto mode and Manual mode.

If “AUTO” is displayed on the control panel it is in Auto mode, if “MANUAL” is displayed it is in Manual mode.



Mode button.....Selects and sets each measurement of REF, KRT, TONO, and PACHY.



Cataract button.....If it is difficult to measure due to cataract (lens opacity) or obstruction of eyelids, eyelashes, blinking, etc., tap this button to enable cataract mode and adjust the amount of light to make measurement easier. The CAT icon appears in the upper part of the control panel, and the button frame changes to purple.



Fixation target buttonBrightness of the fixation target can be changed.



Fog buttonChanges setting temporarily to perform fogging only in the first measurement or each time in the continuous measurement.



All data buttonDisplays all measurement data on the screen.



Print out buttonPrints measurement results. Tap the button when no measurement data is present to feed the paper.



Alignment stop button.....Displayed during an alignment or measurement, the alignment or measurement operation is stopped.



Target image buttonOpens the target image view screen.



All clear buttonClears all measurement data.



Setting menu button.....Shifts to the setting menu screen.

MONITOR SCREEN

MEASUREMENT SCREEN

The diagram shows a measurement screen with the following labeled components:

- Number of measurements/settings:** REF 3/3
- Refractive power measurement result:** S -5.25, C 0.00, A 180
- Number of reading/setting (KRT):** KRT 3/3
- Corneal curvature radius measurement result:** R1 7.73, R2 7.72
- * Eye Height mark:** A1 155
- Y-axis position:** A1 155
- D/mm unit display:** mm
- Alignment mark:** The central dashed box on the eye image.
- Outer alignment mark:** The larger dashed circle on the eye image.
- VD (Vertex distance):** VD 13.75
- Typical value of measurement:** S -5.25 C 0.00 A 180
- Device ID number:** 01

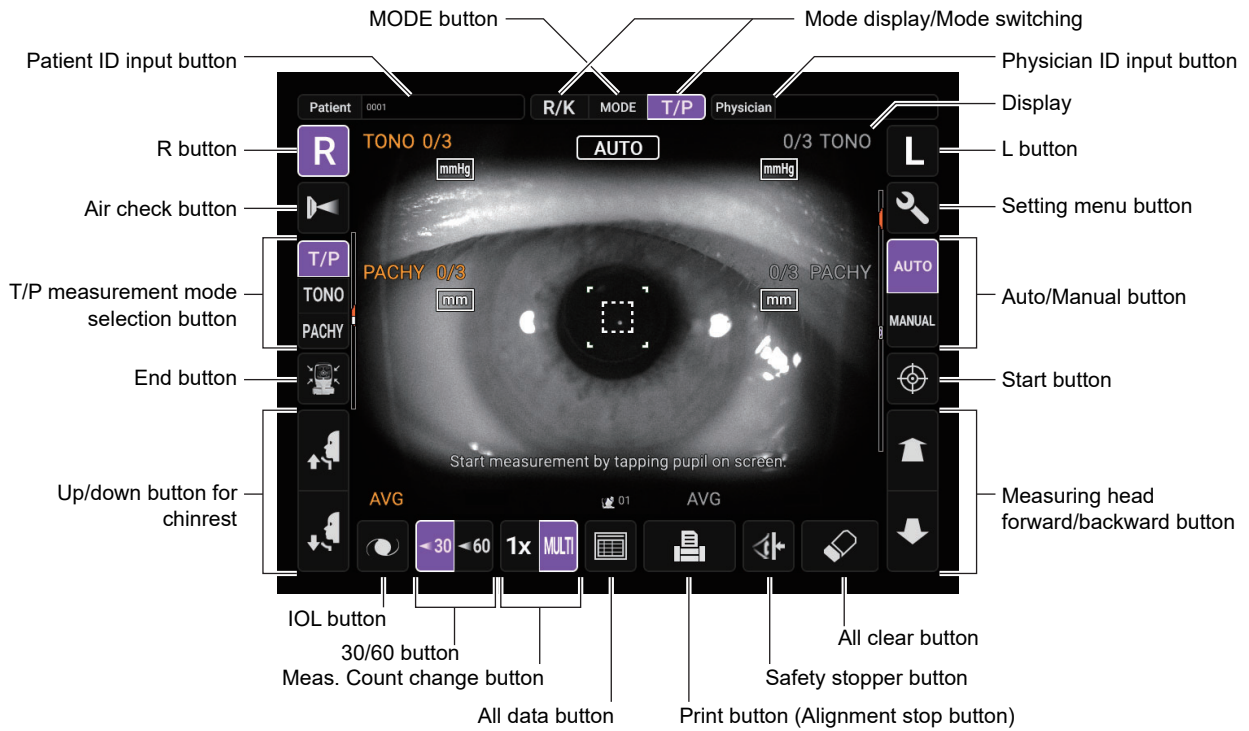
Additional text on the screen includes: "Start measurement by tapping pupil on screen." and "AUTO" button.

* Eye Height mark: Shows the position of the eye height mark on the chinrest.

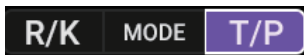
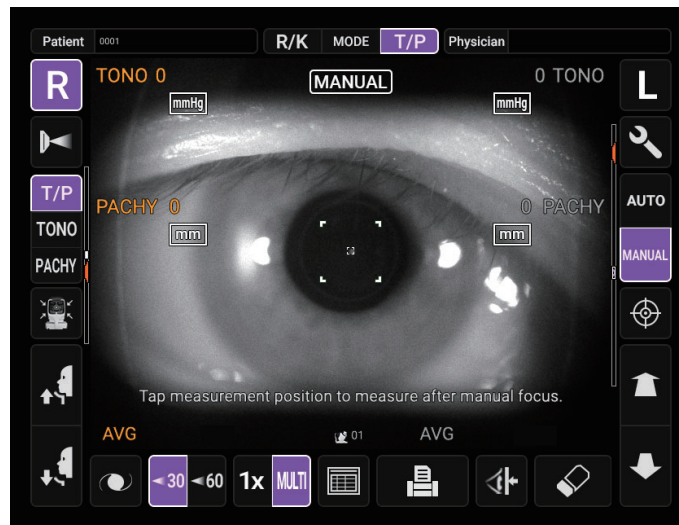
CONTROL PANEL COMPONENTS (IN TONO/PACHY MEASUREMENT MODE)

MEASUREMENT SCREEN

AUTO MODE



MANUAL MODE



Mode display/Mode switching

.....Switch the mode to R/K measurement or T/P measurement.



Patien ID input button

.....Displays the software keyboard. Enter the ID, name, etc.



Physician ID input button

.....Displays the software keyboard. Enter the ID, name, etc.
Displayed when “Physician ID” and “Use Physician ID” are set to ON on the Setup screen.

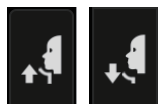


R button/L button.....Selects the right/left eye. By tapping the button, the main body unit moves to the selected direction. The selected button is framed in purple. The layout where the R/L button is displayed reverses according to the position of the control panel.



T/P measurement mode selection button

.....Selects each measurement TONO, PACHY.



Up/down button for chinrest.....Moves the chinrest up/down.



Air check button.....Perform air check. Check if the measurement system inside the instrument is working properly.



End button.....The chinrest and measuring head move to the last position. Turn off the power when the movement to the last position has completed.



Measuring head forward/backward button

.....Moves the measuring head closer to/away from the patient's eye. The direction of movement is reversed according to the position of the control panel.



Start button.....Starts measurement.



Auto/Manual button.....Switches between Auto mode and Manual mode.

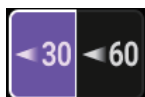
If "AUTO" is displayed on the control panel it is in Auto mode, if "MANUAL" is displayed it is in Manual mode. The name of the selected mode ("Auto" or "Manual") is displayed on the control panel.



Mode button.....Selects and sets each measurement of REF, KRT, TONO, and PACHY.



IOL button.....If alignment does not work with a patient who has an IOL, tapping this button may allow the measurement. When this button is selected, the IOL icon appears in the upper part of the control panel, and the button frame changes to purple. Sets the brightness of the LED for IOL. Refer to "OPTIONAL OPERATIONS" on page 71.



30/60 button.....Switches the range of intraocular pressure values to be measured between 7-30 mmHg and 30-60 mmHg.



Meas. Count change buttonSwitches the measurement count between one-time measurement and preset measurement count.
 - Preset measurement count (Runs the preset number of measurements)
 - One-time measurement (This is the factory default setting)



All data buttonDisplays all measurement data on the screen.



Print out buttonDisplayed when the instrument is in measurement standby. Use this button to print out measurement results or output data to the network. Tap the button to feed the paper if there are no measured value.



Alignment stop buttonDisplayed during an alignment only, the alignment operation is stopped and the measuring head moves backward.



All clear buttonClears all measurement data.



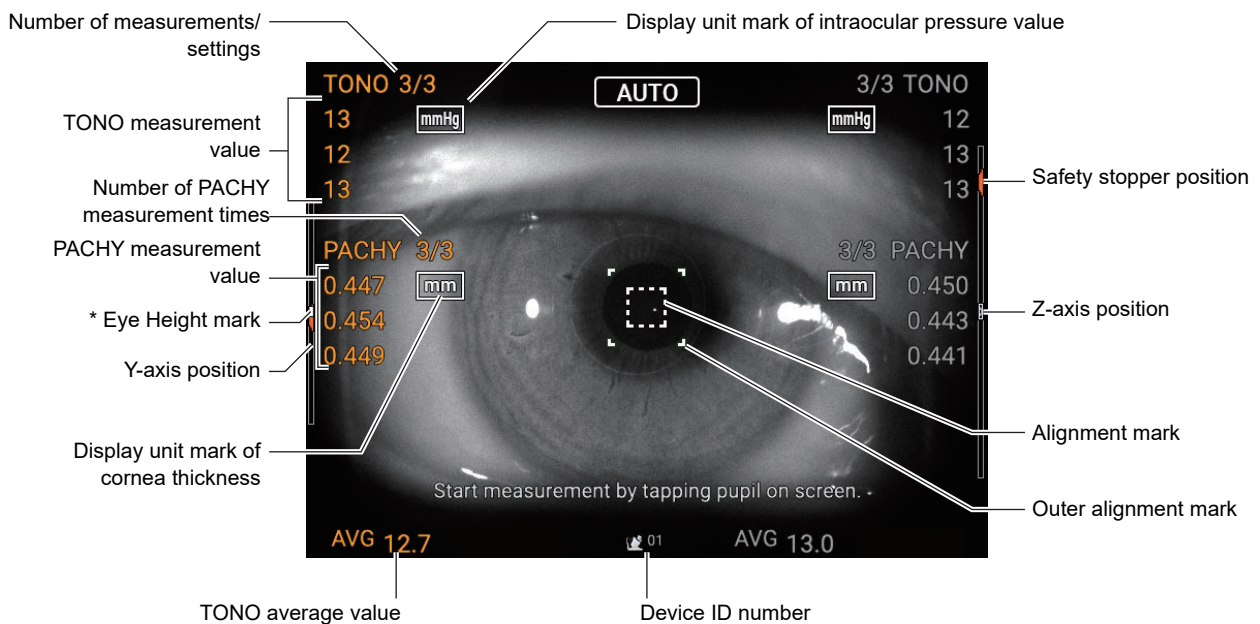
Safety stopper buttonSwitches to the setting screen of the safety stopper position to prevent the measuring window glass from hitting the patient's eye during the measurement.



Setting menu buttonShifts to the setting menu screen.

MONITOR SCREEN

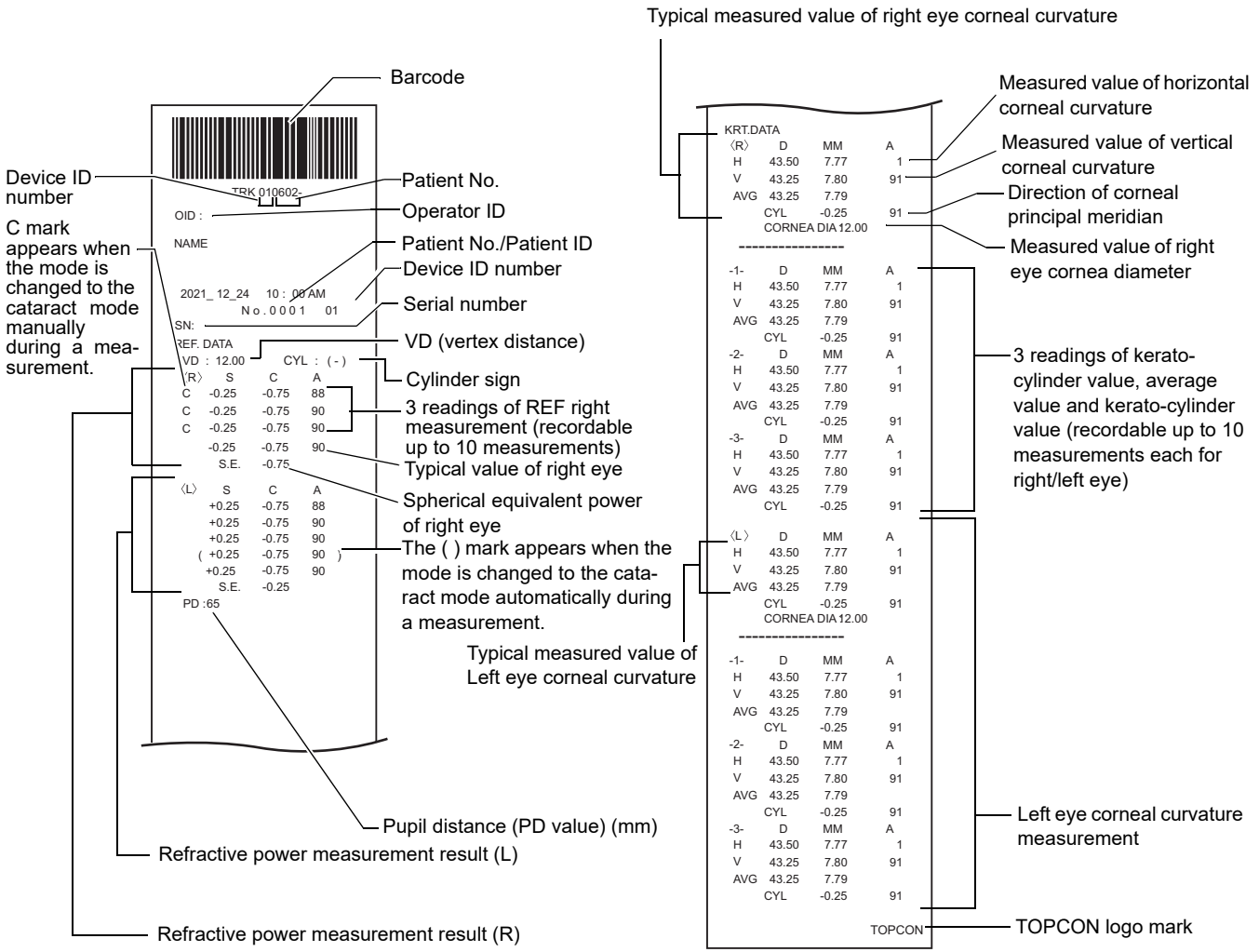
MEASUREMENT SCREEN




* Eye Height mark: Shows the position of the eye height mark on the chinrest.

PRINTER OUTPUT (IN REF/KRT MEASUREMENT MODE)

KRT typical value style and KRT print data are HV

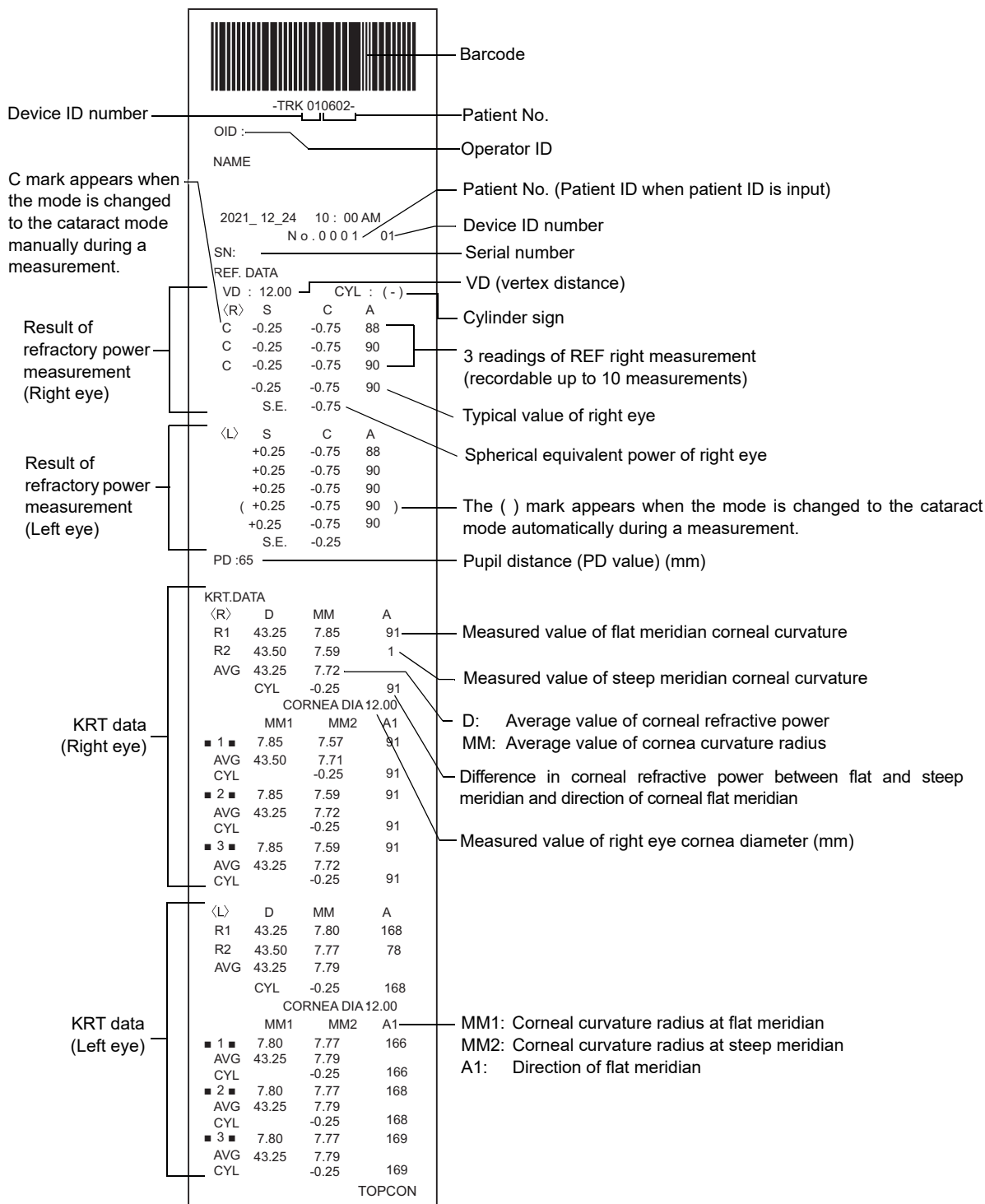




NOTE

- C mark appears when the Cataract button is selected by manual operation. Adding the C mark occurs only for REF measurement values.
- The () mark is attached when the measurement cannot be performed normally due to cataract, eyelids, eyelashes, blinking, etc. and the mode automatically switches to cataract mode. The () mark appears only on REF measurements.

KRT typical value style and KRT print data are R1R2



NOTE

- C mark appears when the button is selected by manual operation. Adding the C mark occurs only for REF measurement values.
- The () mark is attached when the measurement cannot be performed normally due to cataract, eyelids, eyelashes, blinking, etc. and the mode automatically switches to cataract mode. The () mark appears only on REF measurements.

PRINTOUT FORMAT SETTING

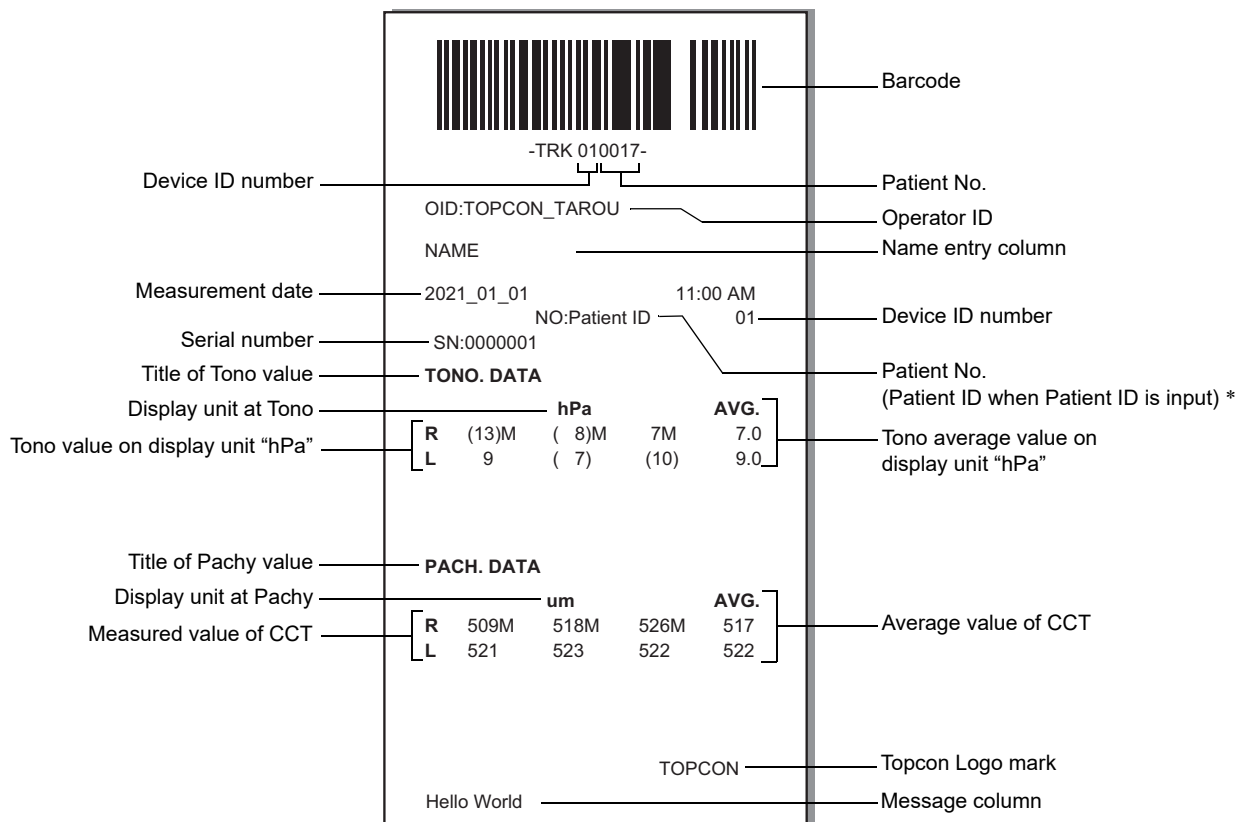
Printout format can be changed by tapping "Print" in the Settings screen. For Print settings, see "SETTING FUNCTIONS ON SETUP SCREEN" on page 97.

	ITEM	INITIAL	PRESET		
			All	Avg	Classic
Common	Barcode	OFF	OFF	OFF	OFF
	Operator ID	OFF	OFF	OFF	OFF
	Name	ON	ON	ON	ON
	Date	ON	ON	ON	ON
	Patient No/Patient ID	ON	ON	ON	ON
	Device ID number	OFF	OFF	OFF	OFF
	Serial number	ON	ON	ON	ON
	TOPCON logo	ON	ON	ON	ON
	Message	OFF	OFF	OFF	OFF
	Message data	NULL	NULL	NULL	NULL
	Line space	0	0	0	0
	Auto Cut	ON	ON	ON	ON
REF/KRT	Print order	DATA	DATA	DATA	DATA
	Include error data	OFF	OFF	OFF	OFF
	VD	ON	ON	ON	ON
	Cylinder sign	ON	ON	ON	ON
	REF format	ALL	ALL	AVG	ALL
	S.E.	ON	ON	ON	ON
	PD	ON	ON	ON	ON
	KRT print order	D/mm	D/mm	D/mm	D/mm
	KRT format	ALL	ALL	AVG	AVG
	KRT style	R1R2	R1R2	R1R2	HV
	KRT print format	R1R2	R1R2	R1R2	HV
	KRT average	ON	ON	ON	ON
	CYL	ON	ON	ON	ON
Cornea diameter	ON	ON	ON	ON	
REF	VD	ON	ON	ON	ON
	Cylinder sign	ON	ON	ON	ON
	REF format	ALL	ALL	AVG	ALL
	S.E.	ON	ON	ON	ON
	PD	ON	ON	ON	ON
KRT	KRT print order	D/mm	D/mm	D/mm	D/mm
	KRT format	ALL	ALL	AVG	ALL
	KRT style	R1R2	R1R2	R1R2	HV
	KRT print format	R1R2	R1R2	R1R2	HV
	KRT average	ON	ON	ON	ON
	CYL	ON	ON	ON	ON
	Cornea diameter	ON	ON	ON	ON

*: Depending on the destination, preset values differ.

PRINTER OUTPUT (IN TONO/PACHY MEASUREMENT MODE)

Printed example when “Printer order” of “Print” is set to “SIMPLE”



* As for the patient No., the result of the printing will differ depending on whether the patient ID is inputted or not inputted.

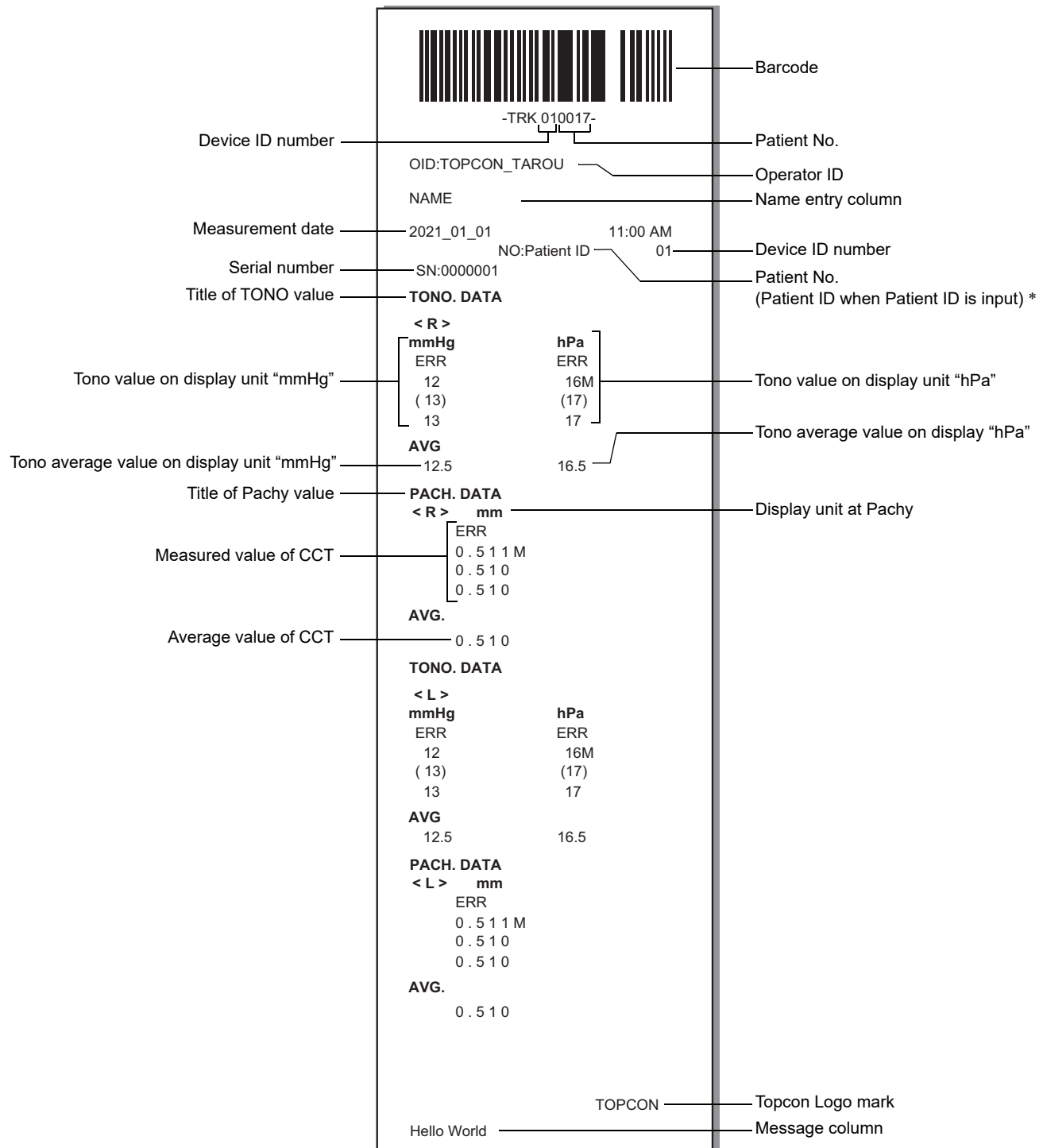
Input: Patient ID is printed.

Not input: Patient No. (starts from 0001, automatically added +1 upon completion of measurement) is printed.

NOTE

- The “M” mark is printed on the value measured by manual measurement or measured by start button in Auto mode. (In the error of ERR, OVER, etc., the “M” mark is not printed.)
- The value with low reliability is outputted with the () mark.
- When “SIMPLE” is selected for “Print order” in “Printer(T/P)”, the “mmHg at hPA” setting in “Printer(T/P)” does not function.
- “Average value of CCT” is for clinical use. “Measured value of CCT” (individual CCT measurement values) is for reference to show how the “Average value of CCT” comprises.

Printed example when "Printer order" of "Print" is set to "R/L"



 **NOTE**

- The "M" mark is printed on the value measured by manual measurement or measured by start button in Auto mode. (In the error of ERR, OVER, etc., the "M" mark is not printed.)
- The value with low reliability is outputted with the () mark.
- "Average value of CCT" is for clinical use. "Measured value of CCT" (individual CCT measurement values) is for reference to show how the "Average value of CCT" comprises.

Printed example when "Printer order" of "Print" is set to "DATA"

The image shows a printed output from a device, enclosed in a rectangular frame. At the top is a barcode. Below it, the text "-TRK 010017-" is centered. The output is organized into several sections:

- Header Information:**
 - Device ID number: -TRK 010017-
 - Patient No.: 01
 - Operator ID: TOPCON_TAROU
 - Name entry column: NAME
 - Device ID number: 2021_01_01
 - Patient No. (Patient ID when Patient ID is input)*: NO:Patient ID 01
 - Serial number: SN:0000001
 - Title of TONO value: TONO.DATA
- TONO DATA:**
 - mmHg:**
 - < R > mmHg
 - ERR
 - 12M
 - (13)
 - 13
 - AVG 12.5
 - mmHg:**
 - < L > mmHg
 - ERR
 - 12
 - 10M
 - 11M
 - AVG 11.0
 - hPa:**
 - < R > hPa
 - ERR
 - 16M
 - (17)
 - 17
 - AVG 16.5
 - hPa:**
 - < L > hPa
 - ERR
 - 16
 - 13M
 - 14M
 - AVG 14.3
- PACHY DATA:**
 - mm:**
 - < R > mm
 - ERR
 - 0.511M
 - 0.510
 - 0.510
 - AVG 0.510
 - mm:**
 - < L > mm
 - ERR
 - 0.510
 - 0.509 M
 - 0.508 M
 - AVG 0.509
- Footer:**
 - TOPCON (Topcon Logo mark)
 - Hello World (Message column)

 **NOTE**

- The "M" mark is printed on the value measured by manual measurement or measured by start button in Auto mode. (In the error of ERR, OVER, etc., the "M" mark is not printed.)
- The value with low reliability is outputted with the () mark.
- "Average value of CCT" is for clinical use. "Measured value of CCT" (individual CCT measurement values) is for reference to show how the "Average value of CCT" comprises.

PREPARATIONS

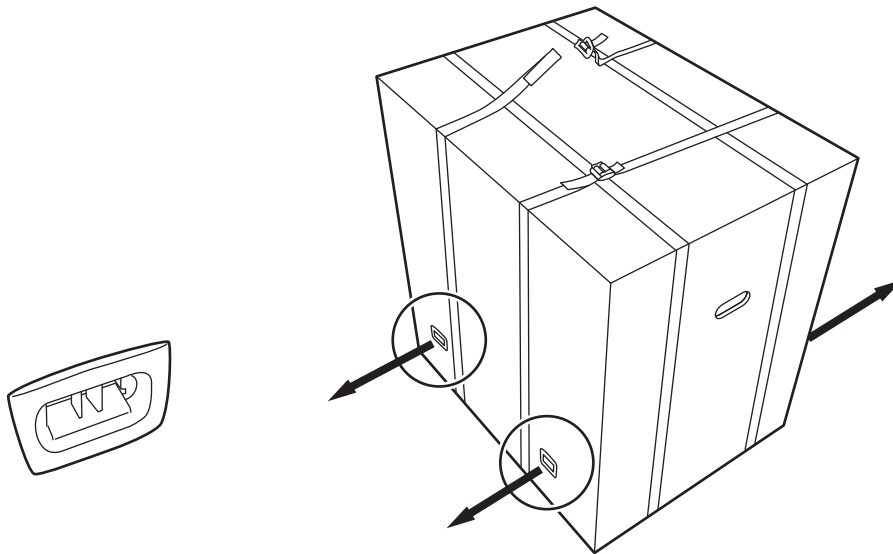


NOTE

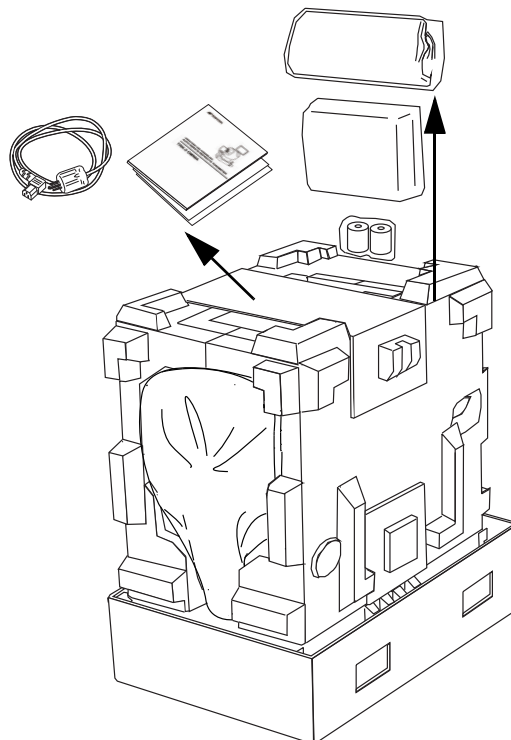
- If the packaged box is damaged, please consult your authorized dealer or the offices listed on the back cover.
- If the packaged box has been opened, please consult your authorized dealer or the offices listed on the back cover.
- If the packaged box is wet, please consult your authorized dealer or the offices listed on the back cover.

UNPACKING PROCEDURE

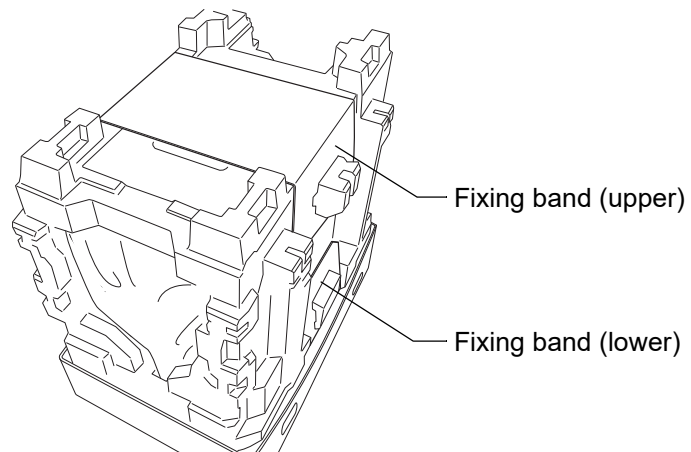
- 1** Remove the fixing band and joint, then pull up the outer carton only



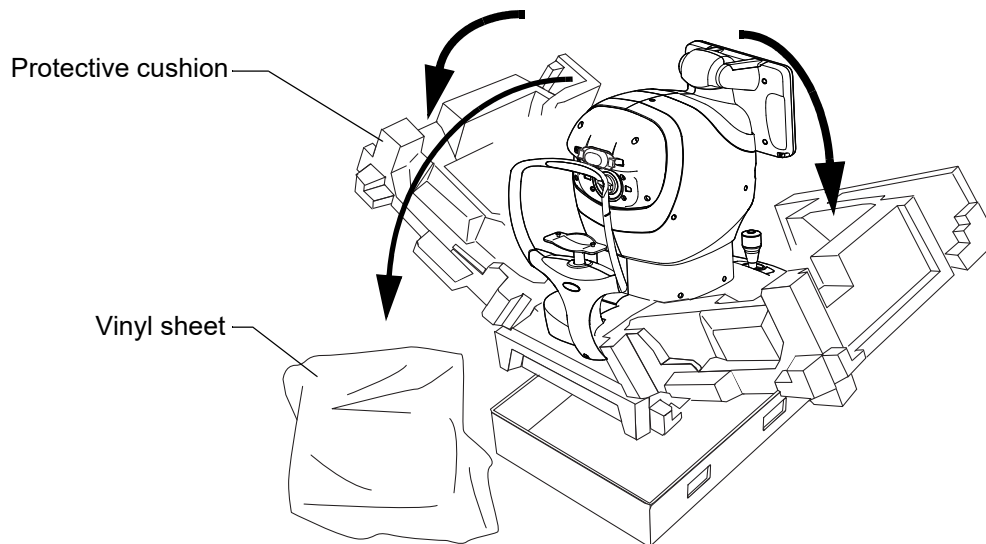
- 2** Take out the standard accessories.



- 3** After removing the joint, pull up the outer carton only.
Remove the upper and lower bands fixing the inner packing material.



- 4** Open the protective cushion to the right and left, then take off the vinyl sheet.

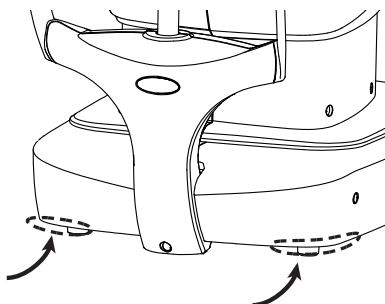


INSTALLATION

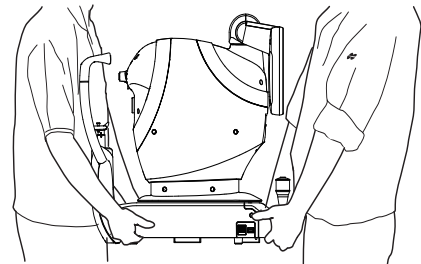
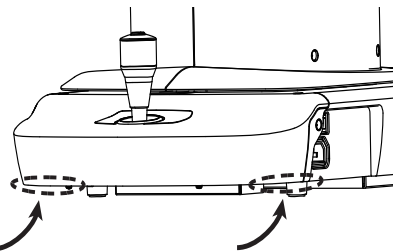
CAUTION

- When moving the instrument, two people should lift from the bottom of the device. One person lifting the device may cause harm to his back or injury by falling parts.
- When holding the bottom of the instrument, avoid touching a projection of screws to prevent injury.
- To prevent damage and injury, do not hold anything but bottom. If you hold, it may cause to catch the finger or to damage the instrument by falling.
- To prevent damage and injury, do not install the instrument on an uneven, unsteady or sloped surface.
- To prevent injury, when setting an instrument on an instrument table, pay attention not to catch a finger between the instrument and the table.
- When installing the main body unit on an adjustable instrument table, etc., make sure that the chinrest does not protrude from the top plate. When a load is applied to the chinrest, the instrument may tip over and cause injury.

- 1** Firmly hold the designated position of the instrument with both hands and place it on the adjustable instrument table.

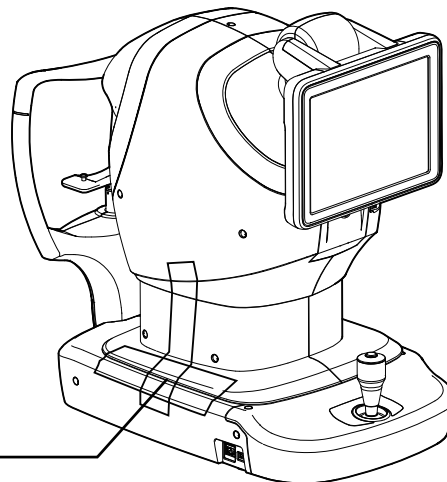


Holding positions



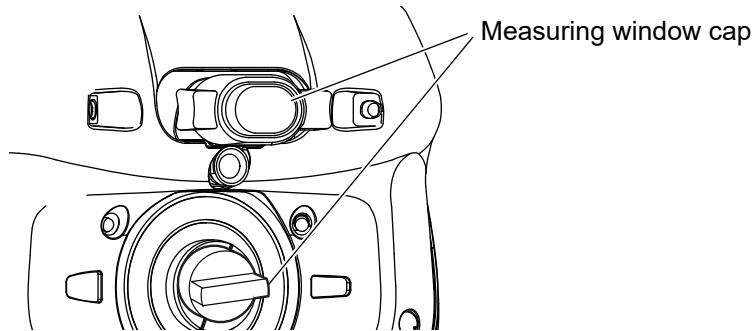
Holding the instrument

- 2** Remove the tape for transportation.



Tape for transportation

- 3 Remove the measuring window caps.



CONNECTING POWER CORD



WARNING

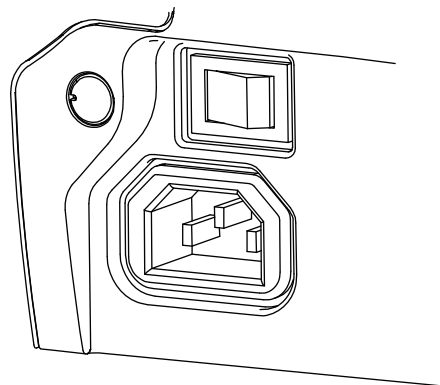
Be sure to connect the power plug to an AC 3-pin receptacle equipped with grounding. Connection with receptacle without grounding may cause fire and electric shock in case of short-circuiting.



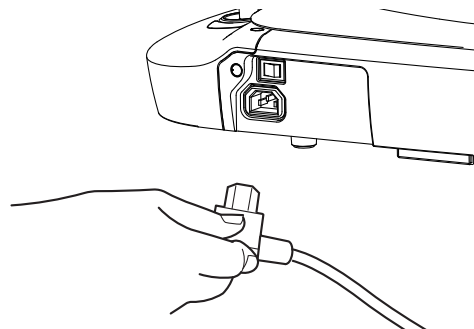
CAUTION

- To avoid electric shocks, do not handle the power plug with wet fingers.
- The power cord in standard accessories for this instrument cannot use besides this instrument.

- 1 Make sure the POWER switch of the instrument is OFF.





- 2 Connect the power cord to the Power inlet.

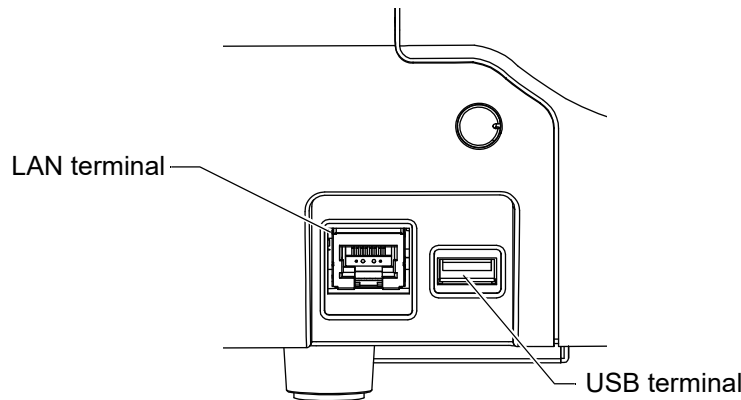


- 3 Insert the power cord plug into the commercial power (the 3-pin AC grounding receptacle.)
- 4 Turn the POWER switch ON.

CONNECTING EXTERNAL I/O TERMINALS

 WARNING	To avoid injury from electric shocks, do not connect anything other than the specified external equipment to the external I/O terminals.
--	--


 CAUTION	<ul style="list-style-type: none">• To avoid electric shocks, do not touch the external connection terminal and the patient at the same time.• When connecting this instrument to a commercially available personal computer, use a personal computer that conforms to IEC 62368-1, and use an insulating device that conforms to IEC 60601-1 in the patient environment.
--	--




DATA OUTPUT

This instrument can be connected to a personal computer (PC) and other external devices via LAN.

- 1** Connect the connection cord to the output terminal of this instrument.
- 2** Connect the other end of the connection cord to a personal computer, etc.


 NOTE	If an external device infected with a virus is connected to this product, this instrument may also be infected with the virus. Before connecting, make sure that the external device is not infected with a virus.
---	--

DATA INPUT

 CAUTION	<ul style="list-style-type: none">• Do not operate a touch panel during barcode data entering by barcode reader. If you enter data when tapping the button on the touch panel, the barcode may not be read normally.• Do not align, measure, or output data during barcode data entering by barcode reader. If you enter data during these operations, the barcode may not be read normally.• Take care not to enter the wrong patient information. It may be mistaken for information from another patient.
--	--

This instrument can be connected to a barcode reader via USB.

- 1** Connect the barcode reader to the input terminal of the instrument.

 NOTE	<ul style="list-style-type: none">• Please use a barcode reader with the following interface specifications.<ul style="list-style-type: none">Connector shape : USB (type A)Interface : USBPower supply : USB bus power• Please connect USB devices while the POWER switch of this instrument is OFF. It may not correctly recognize USB devices if this instrument is in operation.• For questions about connections, contact your TOPCON dealer.
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PRINTER PAPER SETTING

CAUTION

- To avoid injury to the operator, do not open or close the printer cover while the built-in printer is operating.
- To avoid potential injury in case of malfunction, including a paper jam, be sure to shut off the power before attempting to repair the built-in printer.
- To avoid potential injury caused by the edges and metal parts of the built-in printer, do not touch the built-in printer body while the printer is in operation or when replacing the printer paper.

NOTE

- The paper has a front side and a back side. If the paper is loaded on the opposite side, it will not print.
- Be sure to use the specified printer paper. If you use the paper other than the specified, the printer may be broken or the instrument may not be able to use.

- For printing paper, use the following paper specified by TOPCON.

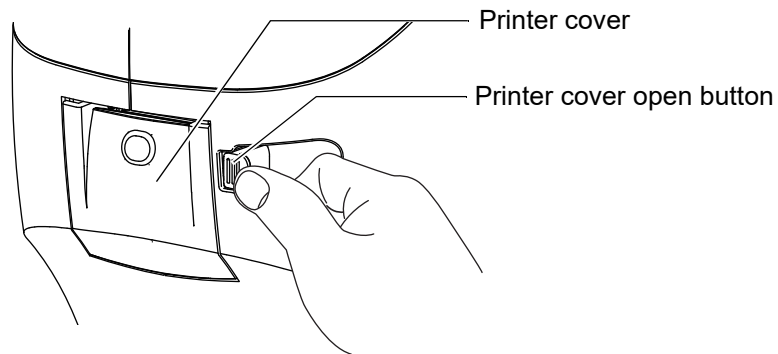
Item name	Product code
Printer paper	448004001

Product No.: TP50KJ-R (manufactured by Nippon Paper Industries Co., Ltd.)

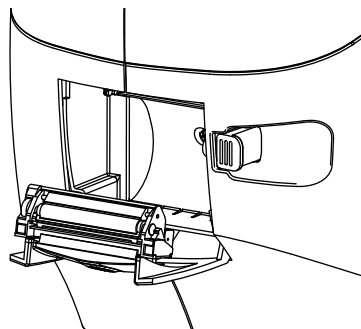
(Paper Width: 58mm, Roll Outer Diameter: ϕ 48mm or less)

When ordering any consumable, contact our agent where you purchased the product, or our particular department as indicated in this manual with the Item Name, Item Code and Quantity.

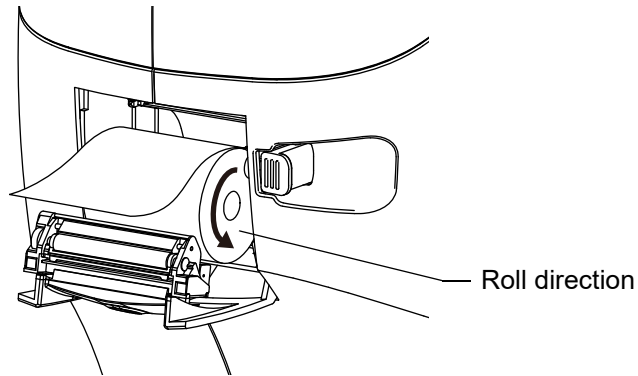
- 1** Press the printer cover open button to open the printer cover.



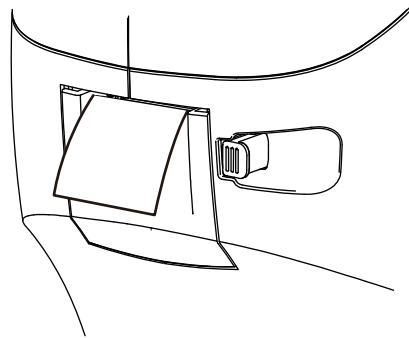
- 2** Open the printer cover to the limit.



- 3** Insert the printer paper in the direction shown below and pull out the paper end to your side by 7 to 8cm.



- 4** Bring the paper into the center, then close the printer cover.



NOTE

In case the printer cover is not firmly closed, printing will not start.

SUPPLYING THE CHINREST TISSUE

Set the chinrest tissue by chinrest tissue pins.

For details, See "REPLACING THE CHINREST TISSUE" on page 116.

TRANSPORTING OF THE INSTRUMENT

When the instrument is transported, the instrument should be set as packing mode. In the case that packing mode is required, call your service engineer.


RESTORE DEFAULT SETTINGS

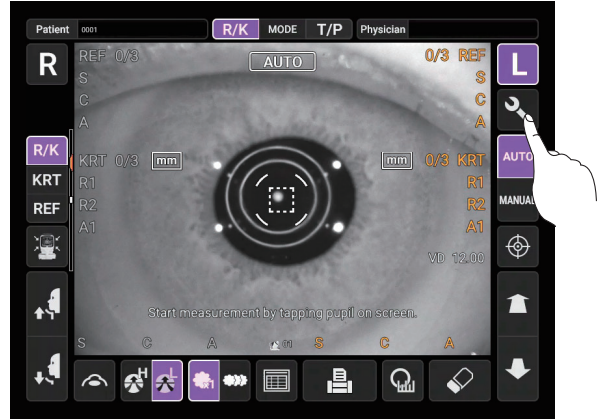
If resetting the region to be used is required such as by setting the wrong region, perform the following operation.



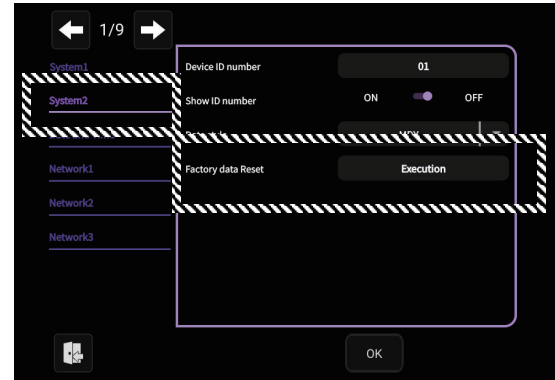
NOTE

If the factory default is carried out, clear the setting information of all users.

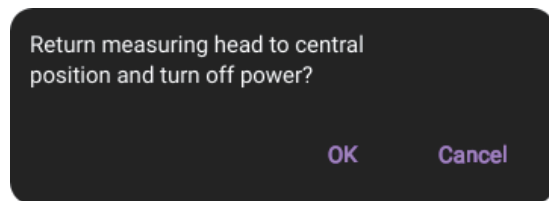
- 1 Tap the **Setting menu** button . Setup screen is displayed.



- 2 Select the “Factory data Reset” for “System 2” on the setup screen, tap the **Execution** button.
 - * Even if the screen is displayed in a different language or different layout from the illustration, the “Factory data Reset” is always displayed in the bottom description of the “System 2”.



- 3 A message appears. Press the **OK** button to return the measurement head to the last position. Wait until the measurement head has completed the movement.



- 4 Turn off the power and turn on the power again, you can set the region after starting.

RECOVERY FROM POWER SAVE STATUS

This instrument adopts the power save system for saving electric power. When the instrument is not operated for a set time, the control panel becomes a screensaver. When the device enters the power save status and the control panel switches to a screensaver, the measurement data and patient ID are automatically cleared to protect the information from unintended disclosure.

- 1 Tap the control panel or operate the control lever.
The power saving is cancelled and measurement is enabled.

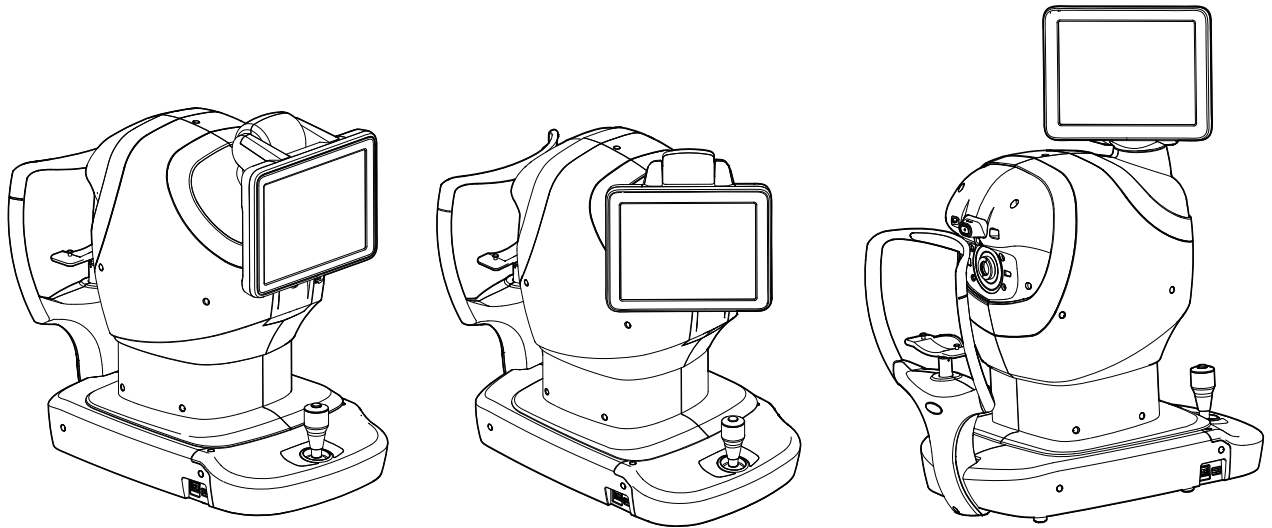


NOTE

The time to start the power save status can be changed at “Auto power save” for “System 1” on the setup screen. (See page 101).

ADJUSTING THE CONTROL PANEL POSITION

Tapping the control panel controls operations including chinrest up-and-down movements, alignment and measurement. It is possible to change the control panel position in the up-and-down and right-and-left directions. Adjust the control panel position optionally.



NOTE

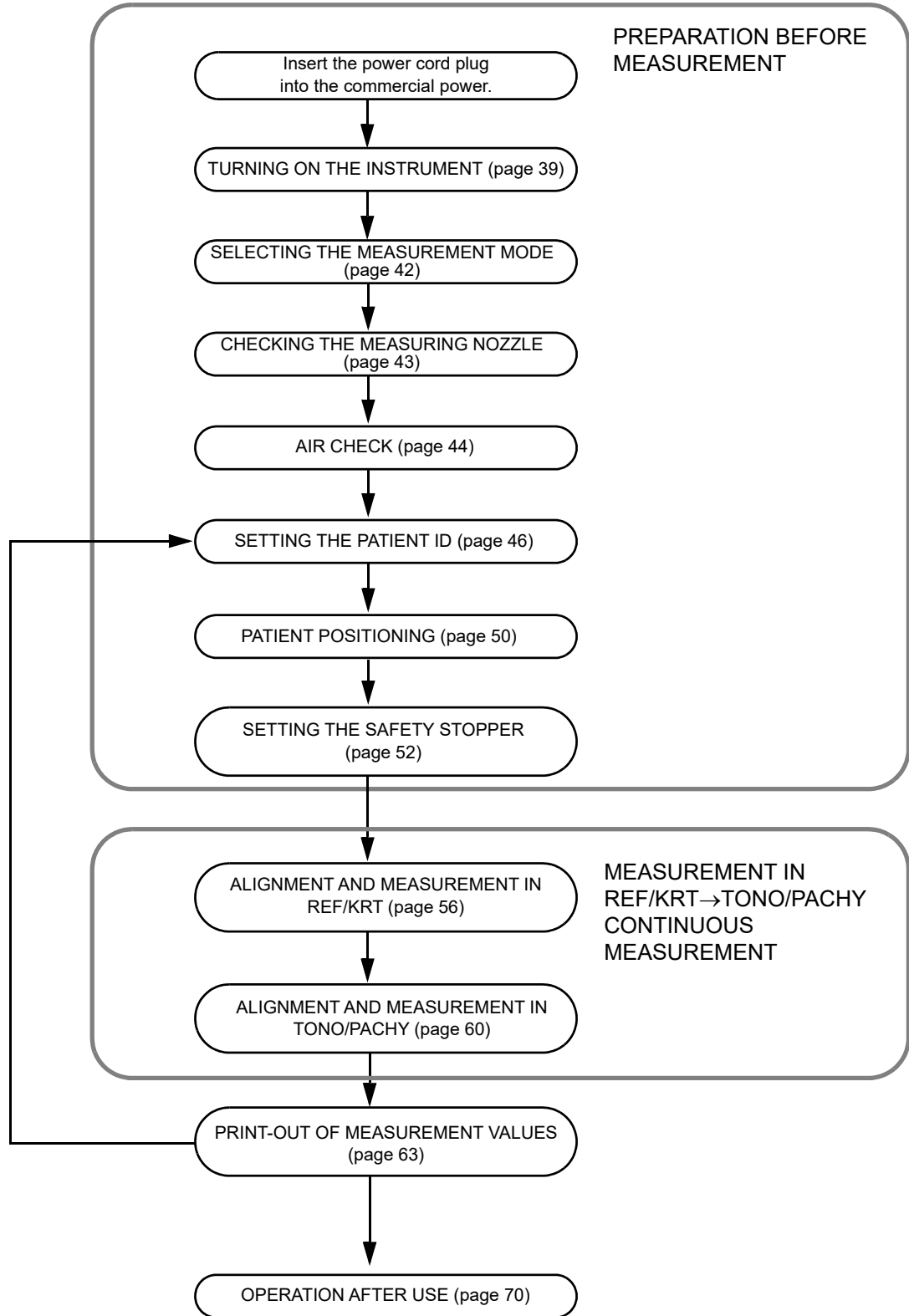
- The layout of (R) button/ (L) button is reversed according to the position of the control panel.
- The moving direction is changed by tapping according to the position of the control panel.



BASIC OPERATIONS

OPERATION FLOW CHART

MEASURING PROCEDURE IN REF/KRT → TONO/PACHY CONTINUOUS MEASUREMENT



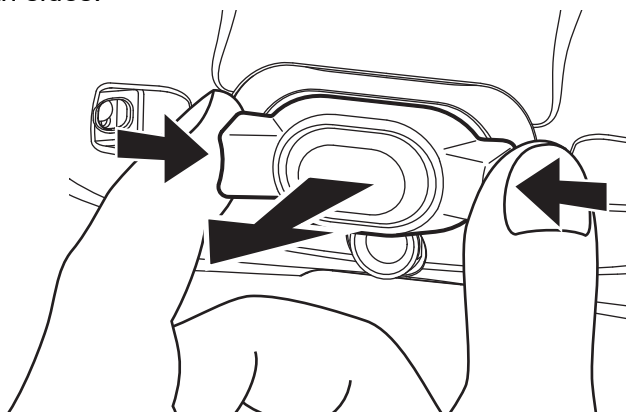
PREPARATION BEFORE MEASUREMENT

NOTE

- Do not put the patient's chin on the chinrest until the power is on.
- If the POWER switch is turned ON immediately after turning OFF the POWER switch, it may be unable to restart by the protective function of power supply. Please turn ON the POWER switch after waiting 3 seconds or more, when the POWER switch is turned OFF.

TURNING ON THE INSTRUMENT

- 1** Plug the power cord into a commercial power source (3-pin AC inlet with grounding).
For the details of the connection, refer to “CONNECTING POWER CORD” on page 31.
- 2** If connecting external device is required, connect the external device and turn on the device.
- 3** If the measuring window cap is attached, remove it.
Remove the intraocular pressure measuring window cap while pressing the left and right protrusions from both sides.



NOTE

- When attaching and removing the intraocular pressure measuring window cap, do not apply any load to the measuring nozzle.
- If strong force is applied to the measuring nozzle, the measuring nozzle may bend.

- 4** Press on the POWER switch.

- 5** The title screen and Measurement screen are displayed and the confirmation message of setting of safety stopper is displayed in a few seconds.
Check the displayed contents and press button.

Checking pressure used for tonometry.
Air will come out of nozzle three times.
Avoid putting face on chin rest until complete.

OK

 **NOTE**

- When pressing button, air automatically come out from the measurement nozzle and the check is performed.
- The check is performed three times in a row.

- 6** A confirmation message for the safety stopper setting is displayed.

 **NOTE**

- Refer to page 52 for SETTING THE SAFETY STOPPER.
- If button is tapped, the confirmation message of setting of safety stopper is displayed upon power ON at next time, too.
- If button is tapped, the confirmation message of setting of safety stopper is not displayed upon power ON from next time.

For the safety of the patient,
please be sure to set the safety stopper
before measuring.

Will this message be displayed at startup
from the next time?

OK

Cancel

- 7** Press the button or Cancel button to return to the Measurement screen.

 **NOTE**

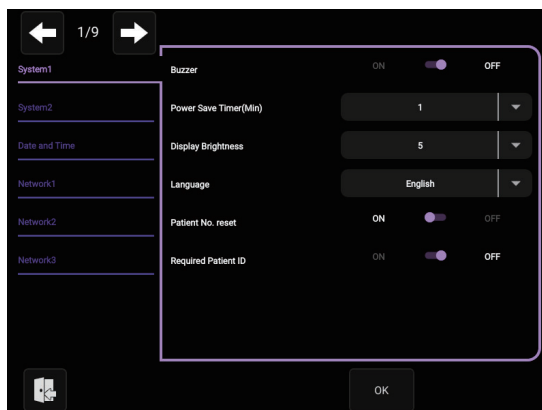
BRIGHTNESS ADJUSTMENT OF CONTROL PANEL

- The control panel is optimally adjusted when shipped.
- For control panel brightness adjustment, see “Display Brightness” of “System1” on the Setup screen (page 101).

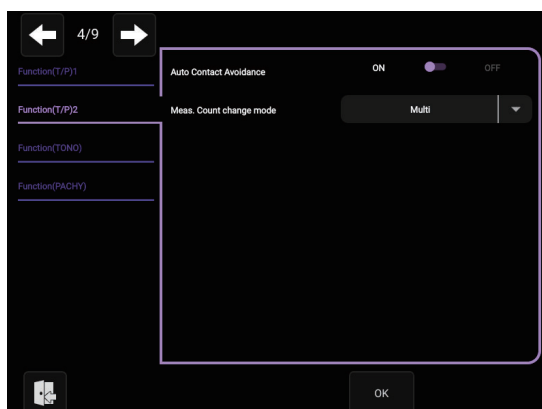
SETTING THE AUTO CONTACT AVOIDANCE FUNCTION

This instrument has an automatic contact avoidance function that detects when the measurement nozzle is too close to the patient during T/P measurement, then automatically stops the movement and retracts the measurement. This function is enabled at the factory.

- 1 Shifts to the setting menu screen.



- 2 Set the "Auto Contact Avoidance Function" listed in "Function(T/P)2" on page 4/9.



- 3 Tap the **OK** button to confirm the setting.

SELECTING THE MEASUREMENT MODE

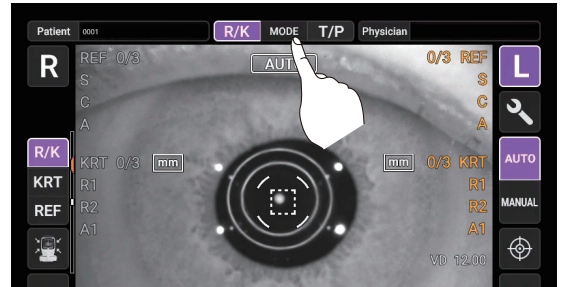
This instrument has R/K measurement and T/P measurement, each of which has the following measurement modes.

- R/K: REF/KRT measurement mode
REF (Measurement of Spherical refractive power, Astigmatic refractive power and Direction of astigmatic axis), and KRT (Measurement of Cornea curvature radius, Direction of corneal principal meridian and Corneal refractive power)
- T/P: TONO/PACHY measurement mode
TONO (Intraocular pressure measurement) and PACHY (Cornea thickness measurement)

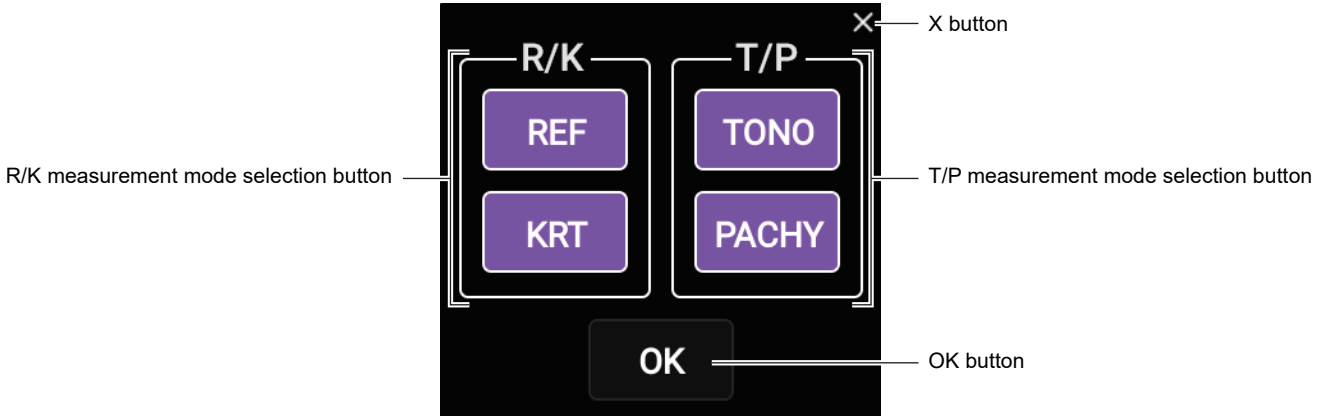
For R/K, continuous measurement of REF and KRT or separate measurement of REF and KRT, and for T/P, continuous measurement of TONO and PACHY or separate measurement of TONO and PACHY can be set for each of the left and right eyes.

Before shipment, the default setting is REF/KRT→TONO/PACHY for continuous measurement of both eyes by single eye.

- 1 Check the Measurement screen.
- 2 Tap the **MODE** button on the control panel.




Displays the measurement mode selection screen.





- The **R/K measurement mode selection** button and **T/P measurement mode selection** button displayed in purple are the measurement items to be performed. By tapping, you can select or cancel the measurement item to be performed.
- For example, if you want to measure only the REF, tap the **R/K measurement mode selection** button or **T/P measurement mode selection** button so that only the measurement items you want to perform are purple.

- 3** Tap the **OK** button to confirm the setting.

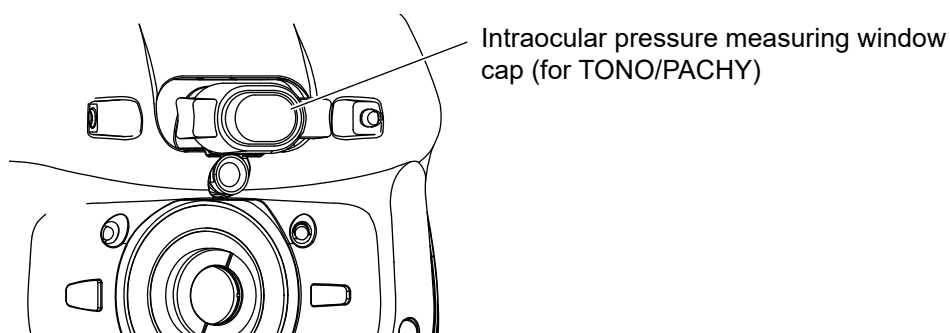
<p> NOTE</p>	<ul style="list-style-type: none"> • In case no mode is changed, tap X button to close the measurement mode selection screen. • Long-press the mode button to display the measurement mode selection screen where you can select "R/K-T/P", "R/K", or "T/P". <div data-bbox="805 369 1129 586" data-label="Image"> </div>
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CHECKING THE MEASURING NOZZLE

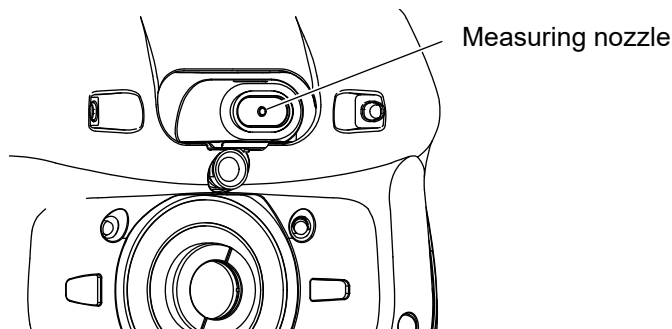
Before TONO/PACHY measurement, a check of the measuring nozzle is required.

<p> CAUTION</p>	<p>Before measuring, check if there is any foreign matter on and around the measuring nozzle. If there is any, it may enter and damage the patient's eye during the measurement.</p>
<p> NOTE</p>	<ul style="list-style-type: none"> • When attaching and removing the intraocular pressure measuring window cap, do not apply any load to the measuring nozzle. • If strong force is applied to the measuring nozzle, the measuring nozzle may bend.

- 1** Remove the intraocular pressure measuring window cap.



- 2** Check if there is any foreign matter on and around the measuring nozzle. If there is any, turn OFF the POWER switch, clean it off and then turn ON the POWER switch.
For cleaning, see “CLEANING THE MEASURING NOZZLE AND THE GLASS INSIDE THE MEASURING NOZZLE” on page 114.



AIR CHECK

Before TONO/PACHY measurement, an air check is required.

This instrument is equipped with a function for checking correct operations of the measurement system inside the instrument.

- 1** On the measurement standby screen of Auto mode in T/P mode, tap the **Air check** button.



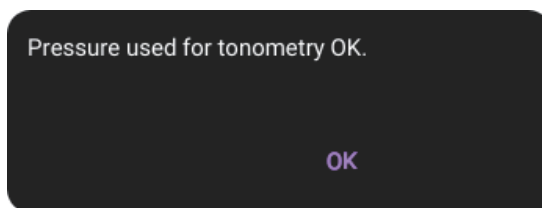
- 2** Then, the confirming message of Air check/End operation is displayed.

Check air pressure used for TONO measurement?
NOTE: Air comes out of nozzle.


OK Cancel

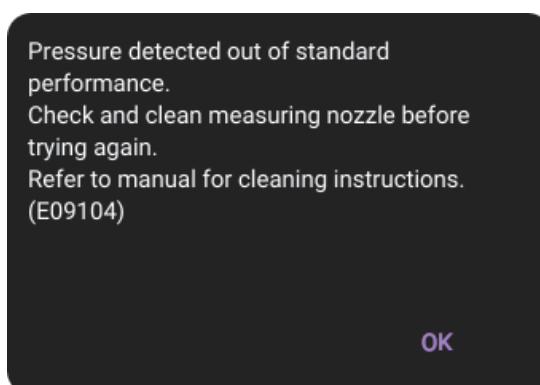
- 3** Press the **OK** button. Then, air comes out from the measuring nozzle automatically.

- 4** Make sure the message box of “Pressure used for tonometry OK.” is displayed on the control panel.



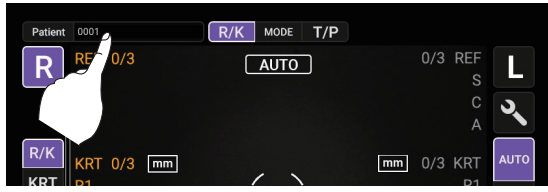
- 5** Press the button, return to Measurement screen.

 NOTE	<p>If “Pressure detected out of standard performance. Check and clean measuring nozzle before trying again. Refer to manual for cleaning instructions. (E09104)” is displayed, the condition is not normal. Check if there are any obstacles in front of the measuring nozzle.</p> <p>If there is any, remove it, press the <input type="button" value="OK"/> button and do the check again. If there is no object, a failure is suspected. Turn the POWER switch to OFF, unplug the power cord, and call your dealer or TOPCON at the address printed on the back cover of this manual.</p>
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SETTING THE PATIENT ID

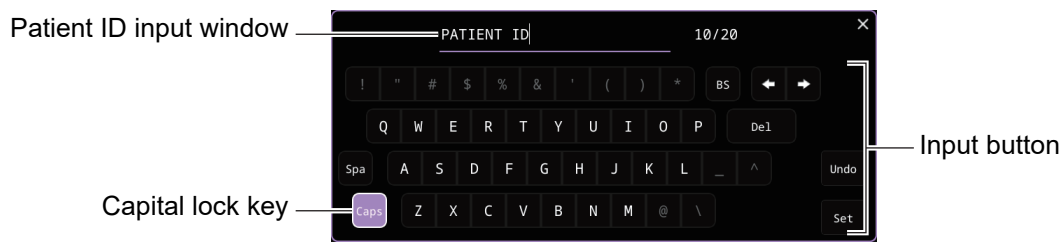
1 Tap the Patient ID input button on the control panel.



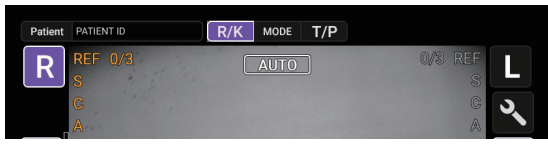
2 Tap the button and the patient ID input screen will pop up.



3 Press the Patient ID input window and enter the Patient ID using the input buttons. Press the Set button after entering the ID to complete the entry.



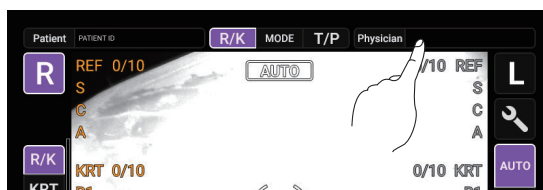
4 Return to the Measurement screen, and confirm that the patient ID is updated.



NOTE	<p>If an ID is read using the barcode reader while the patient ID input screen is displayed, the patient ID input screen closes automatically after the reading is completed, and the Measurement screen appears. Reading the Patient ID using a barcode reader without displaying the patient ID input screen will automatically fill the Patient ID field.</p>
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SETTING THE PHYSICIAN ID

- 1 Tap the **Physician ID input** button on the control panel.



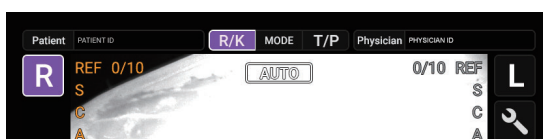
- 2 Tap the button and the physician ID input screen will pop up.



- 3 Press the Physician ID input window and enter the Physician ID using the input buttons. Press the **Set** button after entering the ID to complete the entry.



- 4 Return to the Measurement screen, and confirm that the physician ID is updated.



NOTE

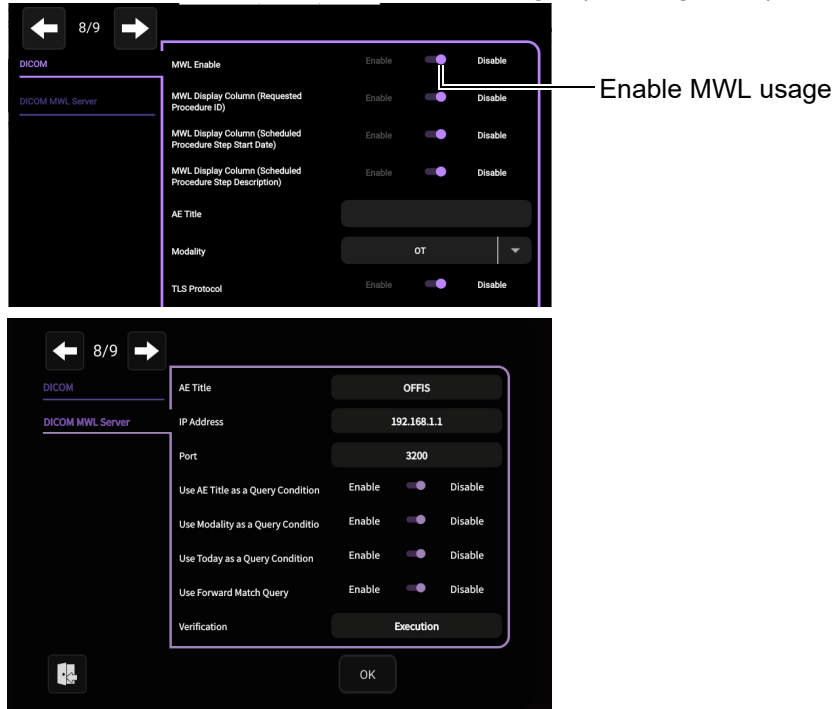
- The Physician ID input field is displayed when “Physician ID” and “Use Physician ID” are set to ON on the Setup screen.
- If an ID is read using the barcode reader while the physician ID input screen is displayed, the physician ID input screen closes automatically after the reading is completed, and the Measurement screen appears.

SETTING THE PATIENT ID (USING MWL)

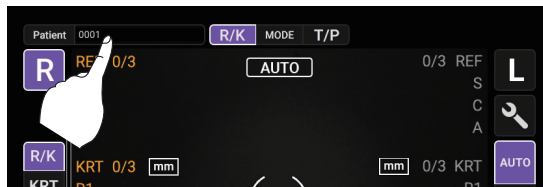
1 DICOM settings

Make the necessary settings in advance.

See "LIST OF SETUP ITEMS" for details on various settings. (see page 101)



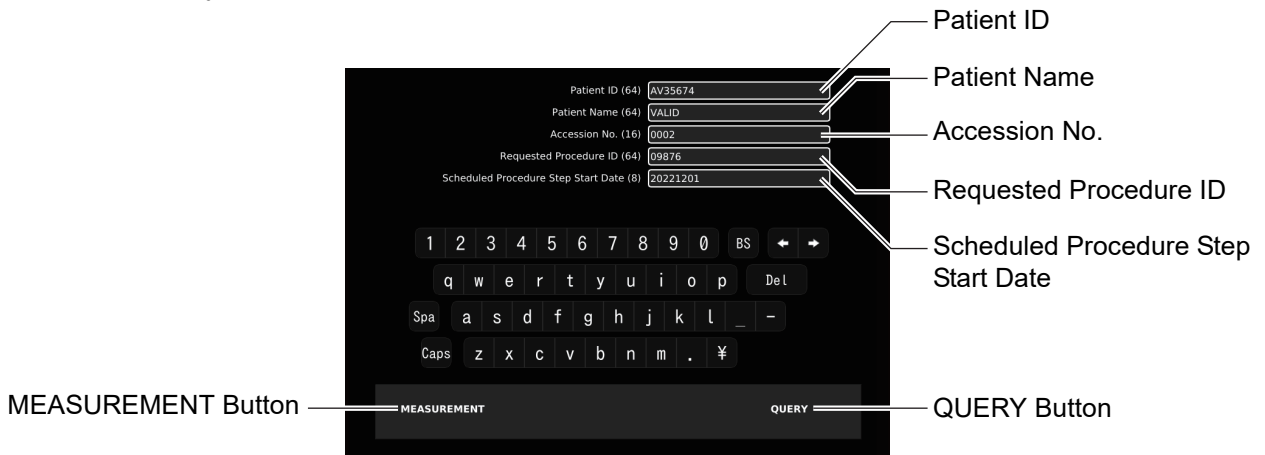
2 Press the **Patient ID Enter** button on the control panel.



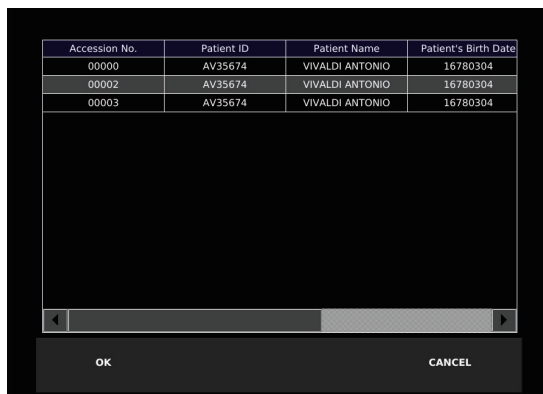
3 Enter the necessary search conditions and press the **QUERY** button.

It is also possible to set the Patient ID without running a query.

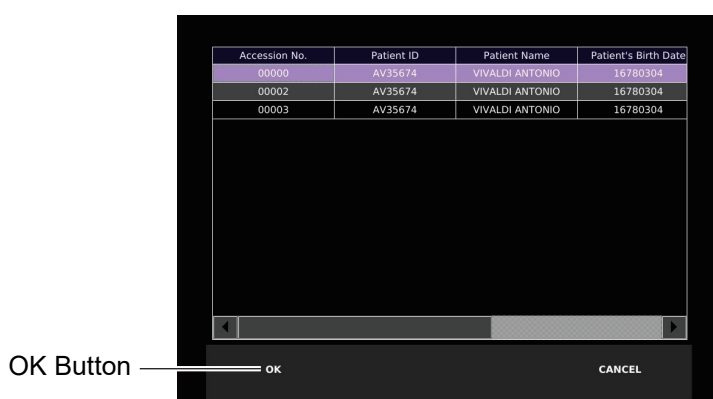
If you do not want to execute the QUERY, enter it in the Patient ID field and press the **MEASUREMENT** button. The Patient ID field on the measurement screen is updated to the ID you set.



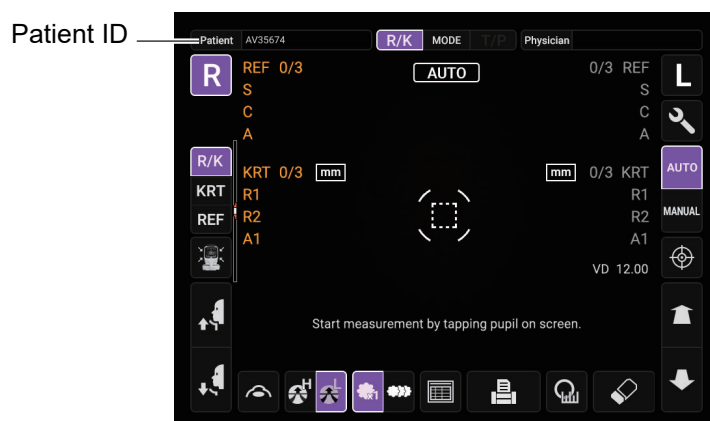
4 The search results screen appears.



5 Select the required patient ID and press the **OK** button.



6 Go back to the measurement screen and make sure the patient ID is updated.



PATIENT POSITIONING

 **CAUTION**

- Each time one patient is changed to another, replace the chinrest tissue with a new one.
- To avoid electric shocks, do not touch the external connection terminal and the patient at the same time.
- When operating the chinrest up/down button, be careful not to pinch the patient's hand. The patient may be injured.
- To avoid injury when operating the instrument, be careful about the cover not to catch the fingers of the patient. Tell this to the patient, too.
- Please make sure patients remove the contact lenses before any measurement with the device.

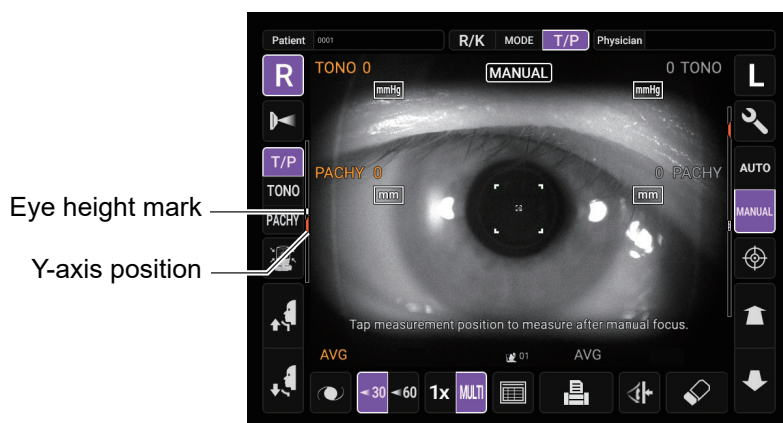
 **NOTE**

- Adjust the height of the adjustable instrument table so that the patient can sit on the chair comfortably. Otherwise, correct measurement values may not be obtained.
- Before starting measurement, explain the function so patients are not surprised by the air puff.
- When operating the instrument, be careful that the instrument does not touch the patient's eye or nose. If touched, clean the instrument following "CLEANING THE INTRAOCULAR PRESSURE MEASURING WINDOW GLASS" on page 113.
- If no patient ID is registered, a "patient No." is assigned automatically in order of examination.

1 Check the Measurement screen.

2 Make sure that the Y-axis position on the screen is at the eye height mark.

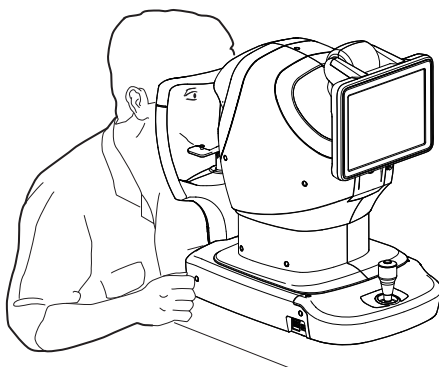
If the Y-axis position is above the eye height mark, keep pressing the lower part of the control panel display, and if it is below the center position, keep pressing the upper part of the control panel display, to move the measurement head to a position where the Y-axis position comes to the eye height mark.



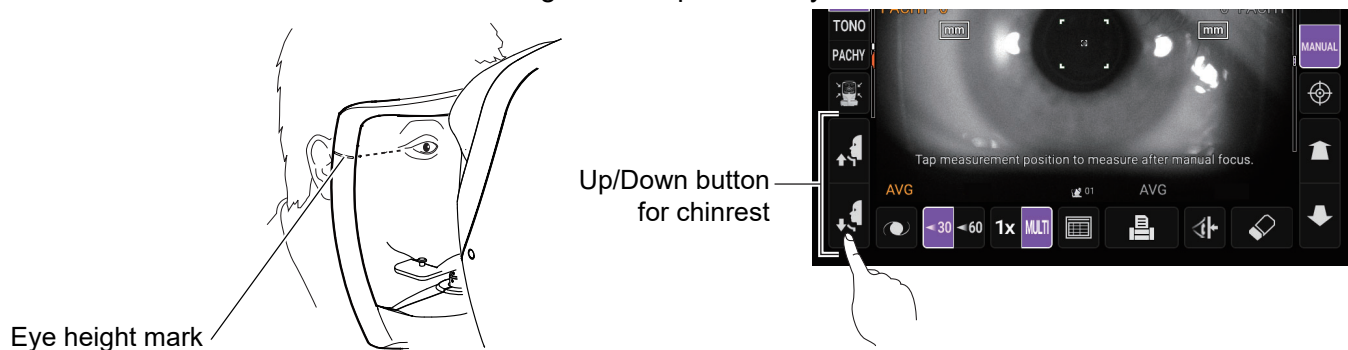
3 Take off one sheet of chinrest tissue on the chinrest. If the tissue has run out, please supply new chinrest tissues.

4 Wipe the dirt from forehead rest.


- 5** Have the patient sit in front of the instrument.
- 6** Adjust the adjustable instrument table or the chair height for the patient to put his/her chin on the chinrest comfortably.
- 7** Place the patient's chin on the chinrest and check that his/her forehead is touching to the forehead rest.



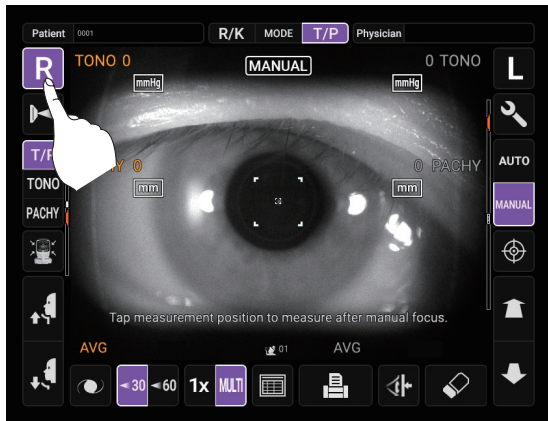
- 8** Press the **UP/DOWN** button to adjust the chinrest height until the eye height mark of the chinrest reaches the same height as the patient's eye.



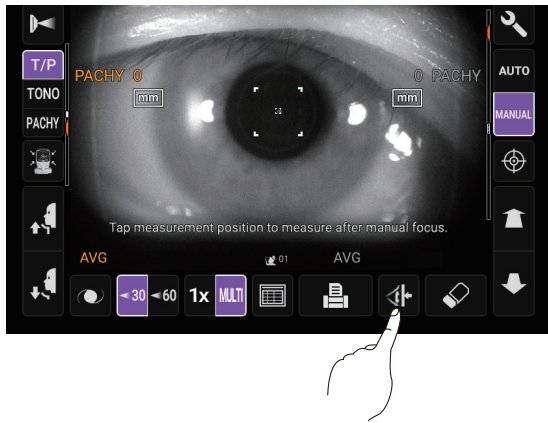
SETTING THE SAFETY STOPPER


 CAUTION	<ul style="list-style-type: none"> • Before measuring, set the safety stopper to prevent the intraocular pressure measuring window from hitting the patient's eye. Set it respectively for the right and left eyes. • Set the safety stop from the side of the instrument. Setting operations from other positions, it is not easy to check positions of the eye and intraocular pressure measuring window, may cause injury by touching intraocular pressure measuring window to a patient.
--	--

1 Select the right/left eye by tapping the **(R)** button/**(L)** button.

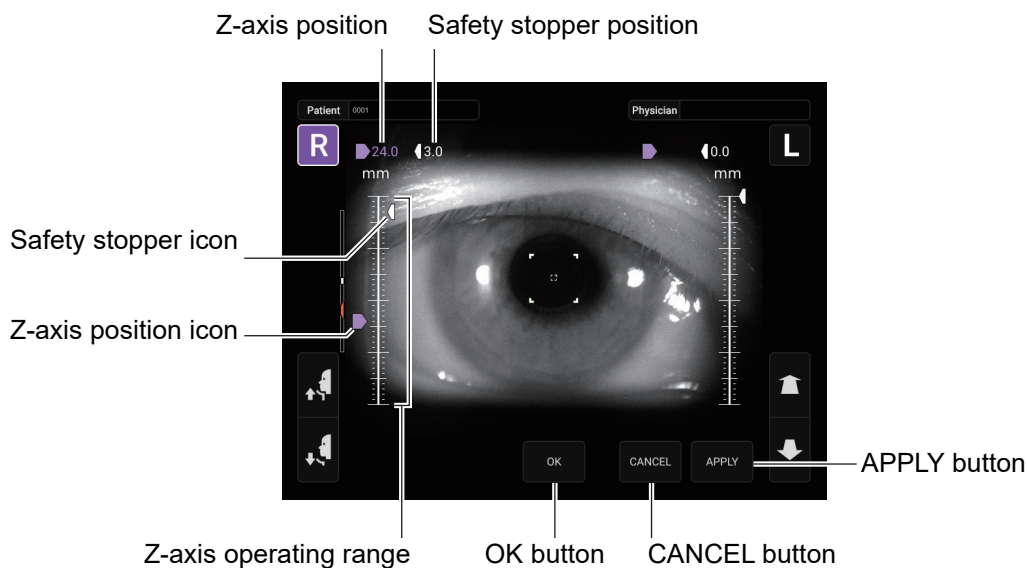


2 Tap the **Safety Stopper** button on the control panel.

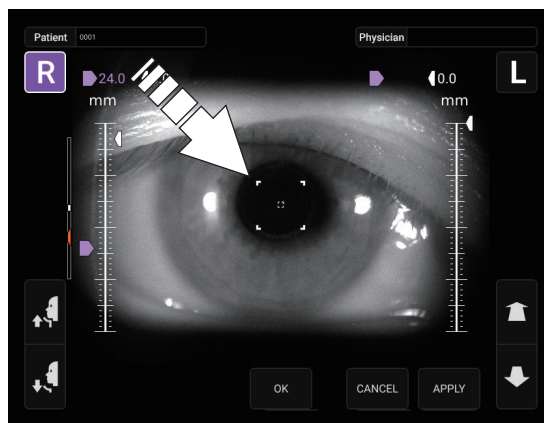
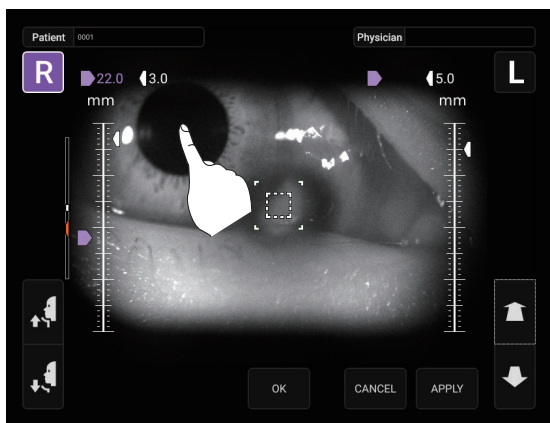


 NOTE	<p>Set the safety stopper respectively for the right/left eye.</p> <p>If measurement is performed by setting the safety stopper only for one eye, or without setting the safety stopper at all, the intraocular pressure measuring window might hit the patient's eye.</p>
---	--

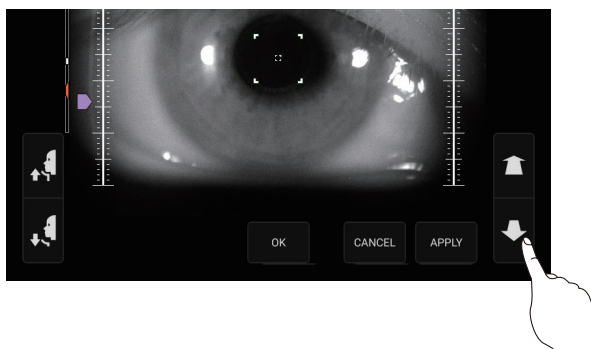
3 When the **Safety Stopper** button is tapped, the Safety Stopper screen is called up.



4 Operating the control panel, set the center of the Measurement screen to the cornea center of the patient.

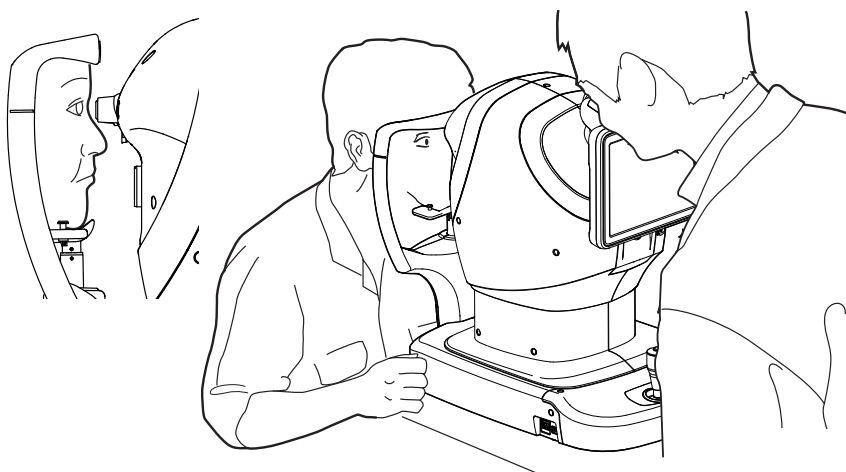


- 5** By tapping the **Measuring head forward/backward** button, adjust the position of the z-axis position icon for the right/left eyes.

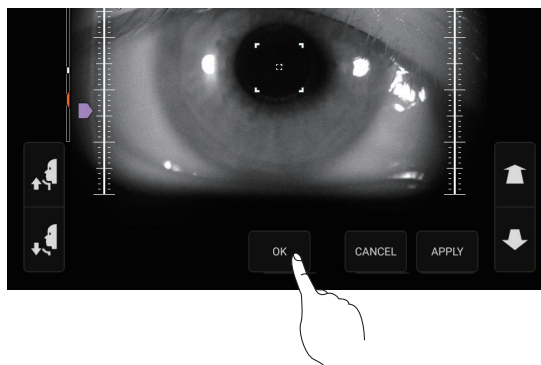
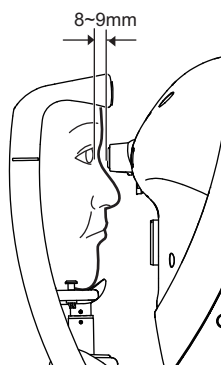


At this moment, confirm alternately the distance between the patient's eye and the measuring nozzle and the safety stopper screen, and adjust the position of the z-axis position icon.

NOTE



- 6** At a position where the measuring nozzle is 8-9mm from the cornea, tap the **OK**/**APPLY** button and thereby set the position of the safety stopper.



- 7** Return to the Measurement screen and confirm that the position of the safety stopper position icon is changed, push the main unit a little forward by operating the **Measuring head forward/backward** button of the control panel, and then confirm that a message "Safety stopper limit" is displayed on the screen. Setting is complete if the main unit does not go forward any more.

MEASUREMENT IN REF/KRT→TONO/PACHY CONTINUOUS MEASUREMENT MODE

In this mode the measurement is performed continuously left and right eye in REF/KRT and TONO/PACHY.

Before shipment the default setting is following order; right eye in REF/KRT, left eye in REF/KRT, left eye in TONO/PACHY and right eye in TONO/PACHY. When the measurement switches REF/KRT to TONO/PACHY, it takes about 6-7 seconds for vertical movement of the measuring head.

- Auto mode: Mode for automatic alignment and measurement.
- Manual mode: Mode for manual alignment and measurement using the control panel or control lever.



CAUTION

When operating the instrument, use much care so that operator's finger or hand is not pinched between the reverse side of forehead rest, a measuring head and an intraocular pressure measurement window. Or the operator may be injured.



NOTE

- Auto mode may not be possible, in cases where the eyelid and the eye-lashes cover the pupil.
If this occurs, the operator should tell the patient to open their eyes as wide as possible, or lift the eyelid to allow for measurement.
- Auto mode may not be possible due to frequent blinks or existing abnormalities in the corneal surface caused by corneal disease etc. In this case, select Manual mode.
- The intraocular pressure varies due to heart beats and tears. So, if it is not possible to obtain exact measurement values by measuring only once or twice, it is recommended to perform intraocular pressure measurements several times.
- When operating the instrument, be careful that the instrument does not touch the patient's eye or nose. If touched, clean the instrument as specified in "CLEANING THE COMPONENTS THAT COME INTO CONTACT WITH THE PATIENT/OPERATOR" on page 112.
- If the patient is wearing make up on the eyelid or around the eyelid using glitter, the auto alignment may not function properly.
In this case, select Manual mode.
- If the instrument is moved before the measurement values are displayed, it might cause an incorrect measurement.
- If area far away from the pupil is tapped, the instrument may touch the patient's eye, eyelid or nose due to auto alignment.

CHECKING THE MEASUREMENT MODE –REF/KRT→TONO/PACHY CONTINUOUS MEASUREMENT MODE

1

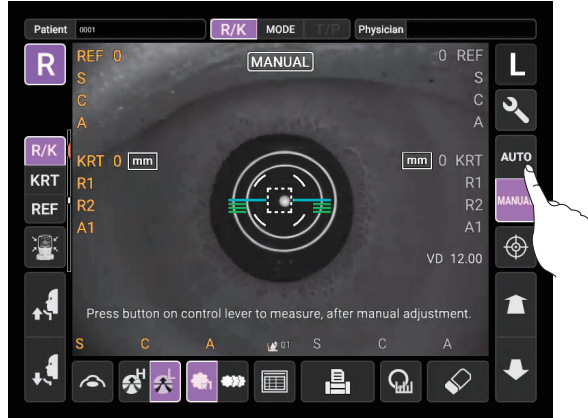
Make sure that R/K or T/P is displayed for the mode display on the control panel.

2

If the display is other than "R/K→T/P", tap the **MODE** button and change to the "R/K→T/P" mode.

SETTING THE AUTO MODE IN REF/KRT

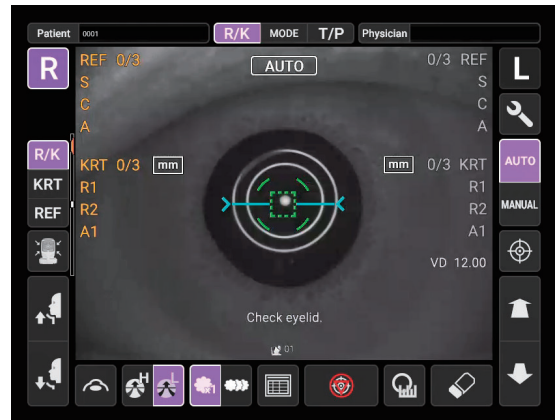
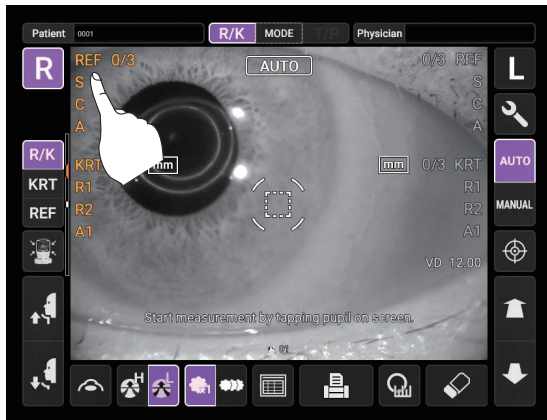
- 1 Check the Measurement screen. If the Auto/Manual button is “AUTO”, the mode is Auto mode.
- 2 If “MANUAL” (Manual mode) is displayed, tap it and change to the Auto mode.



ALIGNMENT AND MEASUREMENT IN REF/KRT

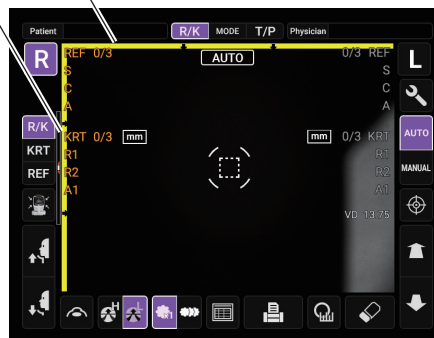
Alignment can be operated from the control panel.

- 1 When the pupil is displayed, tap the display around the pupil. The measuring head moves to display the pupil image and alignment dot on the center of the screen. Then tell the patient to look at red-roof house.



- If the pupil is not displayed on the control panel, move the measuring head by press the control panel, checking the eye height mark on the measurement window as a guide (See page 50).
- When the measuring head has reached the limit of movement (vertical/lateral directions), a yellow-colored limit mark appears on the control panel corner, showing it is the movement limit in that direction. Check the position of the patient's face and the height of the chinrest, and tap the display to move the measuring head to a position that alignment is possible.

Limit mark



NOTE

- When the measuring head is at the limit of movement in the forward direction, "NEAR LIMIT" is displayed and the buzzer sounds, and when it is at the limit of movement in the backward direction, "FAR LIMIT" and the blue arrow prompting movement in the forward direction are displayed. Check the position of the patient's face and the height of the chinrest, and using the **Measuring head forward/backward** button, move the measuring head to a position that alignment is possible.



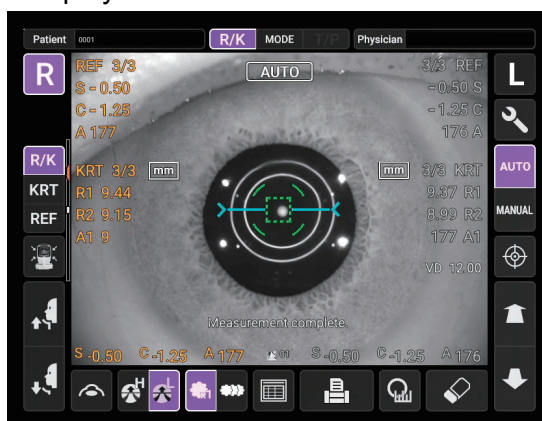
Limit of movement in the forward direction



Limit of movement in the backward direction

Measuring head forward/backward button

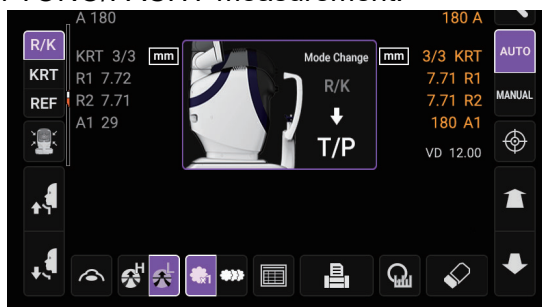
- 2** Alignment starts automatically, and measurement is performed. Move the measuring head to the other eye measurement position automatically and measurement is performed. The measurement results are displayed.



NOTE

- When the “Full Auto” of “R/L mode” is selected in the “Function(R/K)1” on the Setup screen, the instrument measuring head moves automatically to the other eye side for measuring. If the patient closes or blinks their eyes at the time of the right-and-left eye change, the change may be unable to be performed correctly. If the “Manual” of “R/L mode” is selected, press the **(R)** button or **(L)** button of the other eye side. If the “Auto (RL)” of “R/L mode” is selected, the measuring head moves automatically to the other eye side, however a measurement is not performed.
- When “Alignment error occurred. Focus manually and tap pupil on screen to restart measurement. (E03003)” is displayed, please confirm if the patient's eye fits normal conditions for measuring. Then tap the pupil on the control panel again.
- If measurement values were not obtained for the set measurement count due to measurement errors, an additional measurement is performed. For the additional measurement, see page 104.
- To stop alignment or measurement in the middle, tap the **Alignment stop** button. It is possible to stop alignment or measurement also by tapping the control panel anywhere, while an **Alignment stop** button is displayed. When “Alignment stopped. Tap pupil on screen to continue measurement.” is displayed, please tap the pupil on the control panel again.

- 3** After Right/Left eye continuous measurement is complete, the measuring head moves downward for stand-by of TONO/PACHY measurement.

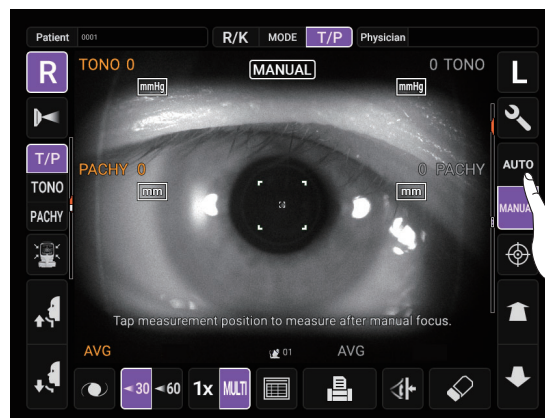


NOTE

In R/K→T/P continuous measurement mode TONO/PACHY measurement starts automatically. This only occurs when the “R/L mode” setting in “Function(R/K)1” is other than “Manual”.

SETTING THE AUTO MODE IN TONO/PACHY

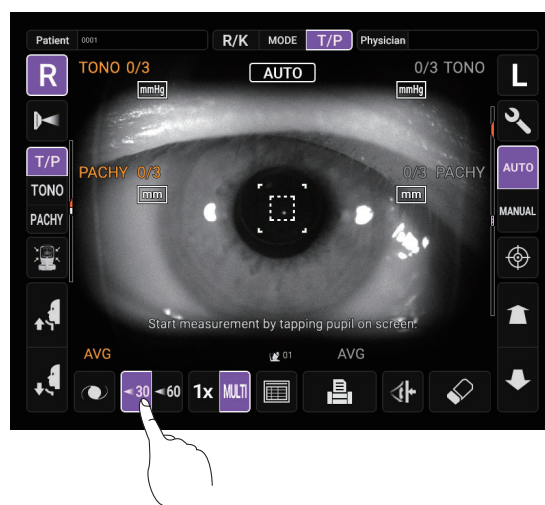
- 1 Check the Measurement screen. If the button is “AUTO”, the mode is Auto mode.
- 2 If “MANUAL” (Manual mode) is displayed, tap it and change to the Auto mode.



SETTING THE MEASURING RANGE

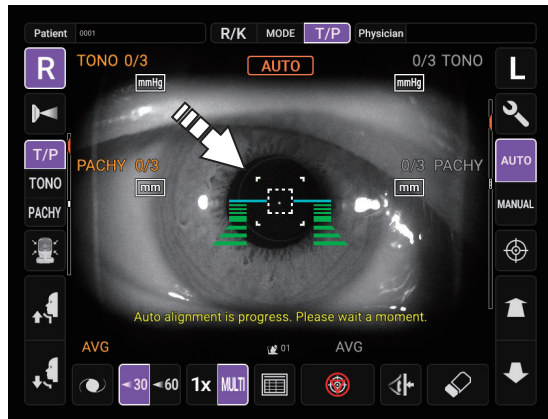
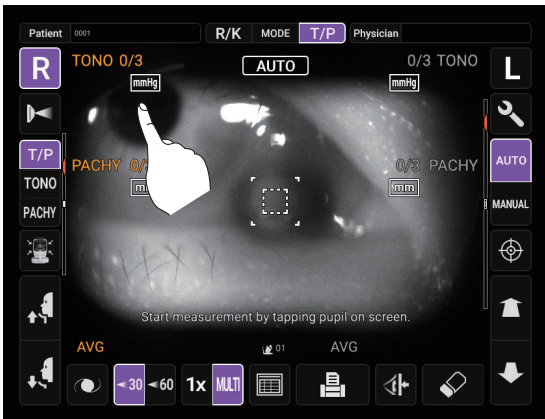
In this instrument, the measuring range can be switched in 2 steps between “7-30” and “30-60”. Normally, “7-30” is used, but if the patient's intraocular pressure is high, switch it to “30-60”. The default setting is “7-30” upon power on.

- 1 Check the Measurement screen.
- 2 Tap the button and set the measuring range.



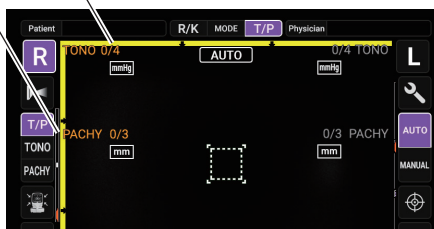
ALIGNMENT AND MEASUREMENT IN TONO/PACHY

1 When the pupil is displayed, tap the display around the pupil. The measuring head moves to display the pupil image and alignment dot on the center of the screen.



- If the pupil is not displayed on the control panel, move the measuring head by press the control panel, checking the eye height mark on the measurement window as a guide (See page 50).
- When the measuring head has reached the limit of movement (vertical/lateral directions), a yellow-colored limit mark appears on the control panel corner, showing it is the movement limit in that direction. Check the position of the patient's face and the height of the chinrest, and tap the display to move the measuring head to a position that alignment is possible.

Limit mark



- When the measuring head is at the limit of movement in the forward direction, "Reaching set limit of stopper. Move measuring head." is displayed, and when it is at the limit of movement in the backward direction, "FAR LIMIT" and the blue arrow prompting movement in the forward direction are displayed. If the position is detected, "TOO CLOSE" is displayed at a position closer than 4 mm to the patient's eye. Check the position of the patient's face and the height of the chinrest, and using the **Measuring head forward/backward** button, move the measuring head to a position that alignment is possible.

NOTE



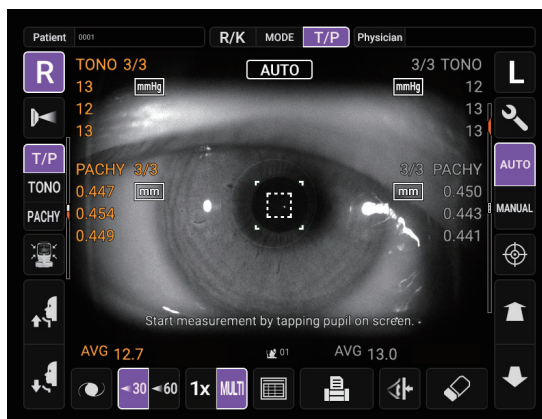
Limit of movement in the forward direction



Limit of movement in the backward direction

2 Alignment starts automatically. While moving the main body toward the patient, the focus of Measurement screen is changed, then measurement is performed.

The measuring head moves automatically to the other eye side and measurement is performed. The measurement results are displayed.




NOTE

- When the “Full Auto” of “R/L mode” is selected in the “Function(T/P)1” on the Setup screen, the instrument measuring head moves automatically to the other eye side for measuring. If the patient closes or blinks their eyes at the time of the right-and-left eye change, the change may be unable to be performed correctly. If the “Manual” of “R/L mode” is selected, press the **(R)** button or **(L)** button of the other eye side. If the “Auto (RL)” of “R/L mode” is selected, the measuring head moves automatically to the other eye side, however a measurement is not performed.
- Auto Print (available only under Auto mode)
When the “Auto Print” is set to “ON” in the “Printer(Common)1” on the Setup screen, measurement results are printed out automatically after measuring the right and left eyes. (See page 106.)
- When “Tap measurement position to measure after manual focus.” is displayed, please confirm if the patient's eye fits normal conditions for measuring. Then tap the pupil on the control panel again.
- When the alignment status has continued for more than 30 seconds, “Alignment error occurred. Focus manually and tap pupil on screen to restart measurement. (E03003)” is displayed and the alignment stops.
- To stop alignment in the middle, tap the **Alignment stop** button. It is possible to stop alignment also by tapping the control panel anywhere, while an **Alignment stop** button is displayed. When “Alignment stopped. Tap pupil on screen to continue measurement.” is displayed, please tap the pupil on the control panel again.
- When PACHY measurement is performed, AUTO/MANUAL display is changed to “PACHY measurement in progress.”. When TONO measurement is performed, the mark is changed to “TONO measurement in progress.”. The mark indicates the current status of measurement.
- If the alignment status has continued for more than 5 seconds in PACHY measurement, the measurement stops to change to TONO measurement.
- If the start button is tapped before all PACHY measurements are complete, PACHY data is not measured for remaining number of times is treated as error data.

DISPLAYING MEASUREMENT VALUES

With regard to measurement values, for REF, KRT, TONO and PACHY, data of the latest measurement (only for TONO/PACHY, latest 3 measurements) are displayed on the control panel.

- numerical value only: Measurement was done correctly.
- numerical value with []: When the reliability of measurement is low. (only TONO)
- ERROR: Measurement was not done correctly.
- OVER: When IOP value exceeds 60 mmHg.

 NOTE	<ul style="list-style-type: none"> • In TONO average value display, low-reliability numerical data with [] are not added to average value calculation. However, if all measurement data are numerical data with [], average value calculation is done using these data. • For explanation of the messages on the control panel screen, refer to “MESSAGE LIST” on page 118. • When data is printed out, the values measured using the Start button or the control lever’s MEASUREMENT switch are displayed with an M mark next to them. (TONO/PACHY only) • When the “Auto Print” is set to the “OFF” in the “Printer(Common)1” on the Setup screen, print out measurement results by tapping the <input type="button" value="Print out"/> button, as necessary.
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PRINT-OUT OF MEASUREMENT VALUES

NOTE

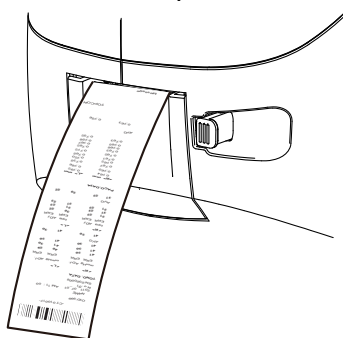
- To avoid a paper jam in the printer, do not feed the paper if it is partly cut or wrinkled.
- To avoid discoloring of the printer paper (particularly the recording area) during storage, use a polypropylene bag and not one containing plasticizer (PVC, etc.).
- To avoid discoloring of the printer paper (particularly the recording area) after pasting, use water-soluble glue and not one containing solvent.
- Since the printer paper is thermosensitive, it is not suitable for keeping records for a long period. If necessary, prepare copies separately.

This instrument can print out measurement values with a printer.

1 Check the Measurement screen.

2 Tap the button on the control panel.

Measurement values on the monitor are printed out.



NOTE

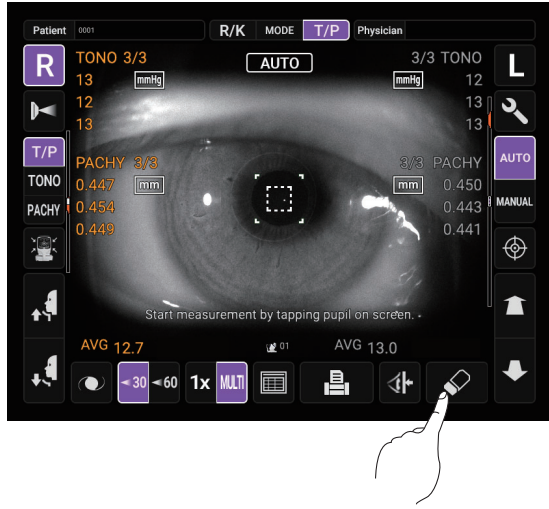
- When a red line is printed at the edge of the printer paper, replace it with a new one. For details about the replacement of the printer paper, see **PRINTER PAPER SETTING** on page 34. 58mm wide printer paper (example: TP50KJ-R, Nippon Paper) is recommended.
- When “Close printer cover” is displayed, the printer cover is open, so close the printer cover securely.
- When the “Auto Print” is set to “ON” in the “Printer(Common)1”, measurement is performed under Auto mode, and measurement results are printed out automatically. (See page 106.)
- When the “Auto Cut” is set to “OFF” in the “Printer(Common)2” and you need to cut a printer form, the way is that erase the measurement value by tapping the button, and tap the button to cut.
- When the button is tapped again after all the data is cleared by printing out the measuring data, the previous measuring data is printed out.
- All measured data is printed out. If printing out of only individual measurement data (REF measurement data, KRT measurement data or TONO measurement data only) is required, change the measurement mode to the individual measurement for desired measurement data by tapping the button. Then perform measurement and print out.

END OF MEASUREMENT

Tell the patient a measuring is end and leave from the instrument.

CLEARING MEASUREMENT VALUES

- 1 Tap the **All clear** button on the control panel.
All measurement values of both eyes are cleared.



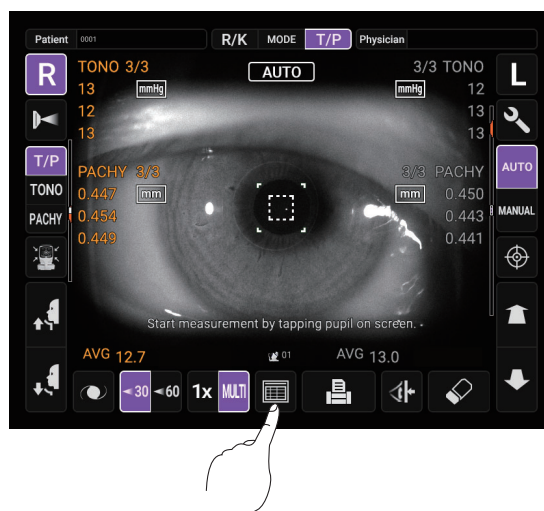
NOTE

After clearing the measurement values, the measuring head moves to the “Meas. Start: Standby Pos.” position selected in the “Function(Common)1” on the Setup screen. (See page 103.)

DISPLAYING ALL MEASUREMENT DATA

It is possible to confirm all measurement data.

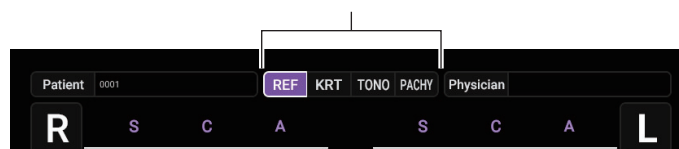
- 1 Tap the **All data** button.



- 2 The Data Display screen is displayed.

- 3 Use the **REF / KRT / TONO / PACHY switching** button to select the measurement data you want to display.

REF / KRT / TONO / PACHY switching button



- 4 Tap the **Exit** button to finish displaying the data and return to the Measurement screen.

-5.25	0.00	180	7	-5.50	0.00	180
-5.25	0.00	180	8	-5.50	0.00	180
-5.25	0.00	180	9	-5.50	0.00	180
-5.25	0.00	180	10	-5.50	0.00	180
-5.25	0.00	180	AVG	-5.50	0.00	180

The table displays measurement data for both eyes (Right and Left) across multiple trials (7-10) and an average (AVG). The values are consistent across all trials. A small icon of a window with an arrow is visible in the bottom left corner of the data display area.

REF MEASUREMENT DATA

Right eye REF / KRT / TONO / PACHY switching button Left eye

Measurement count

Measurement item

Measurement result values

Exit button

Measurement average values

Patient 0001		REF / KRT / TONO / PACHY switching button				Physician		
R	S	C	A		S	C	A	L
	-5.25	0.00	180	1	-5.50	0.00	180	
	-5.25	0.00	180	2	-5.50	0.00	180	
	-5.25	0.00	180	3	-5.50	0.00	180	
	-5.25	0.00	180	4	-5.50	0.00	180	
	-5.25	0.00	180	5	-5.50	0.00	180	
	-5.25	0.00	180	6	-5.50	0.00	180	
	-5.25	0.00	180	7	-5.50	0.00	180	
	-5.25	0.00	180	8	-5.50	0.00	180	
	-5.25	0.00	180	9	-5.50	0.00	180	
	-5.25	0.00	180	10	-5.50	0.00	180	
		-5.25	0.00	180	AVG	-5.50	0.00	180

C mark appears when the mode is changed to the cataract mode manually during a measurement.

When Cataract mode starts automatically during the measurement, figures will be put in ().

Patient 0001		REF / KRT / TONO / PACHY switching button				Physician		
R	S	C	A		S	C	A	L
	-5.25	0.00	180	1	-5.50	0.00	180	
	-5.25	0.00	180	2	-5.50	0.00	180	
	-5.25	0.00	180	3	-5.50	0.00	180	
	-5.25	0.00	180	4	-5.50	0.00	180	

NOTE If there is no measurement data, the data table shows blank.

KRT MEASUREMENT DATA

Right eye REF / KRT / TONO / PACHY switching button Left eye

Patient 0001 REF **KRT** TONO PACHY Physician

Measurement count R R1 R2 A1 1 R1 R2 A1 L

Measurement item

Measurement result values

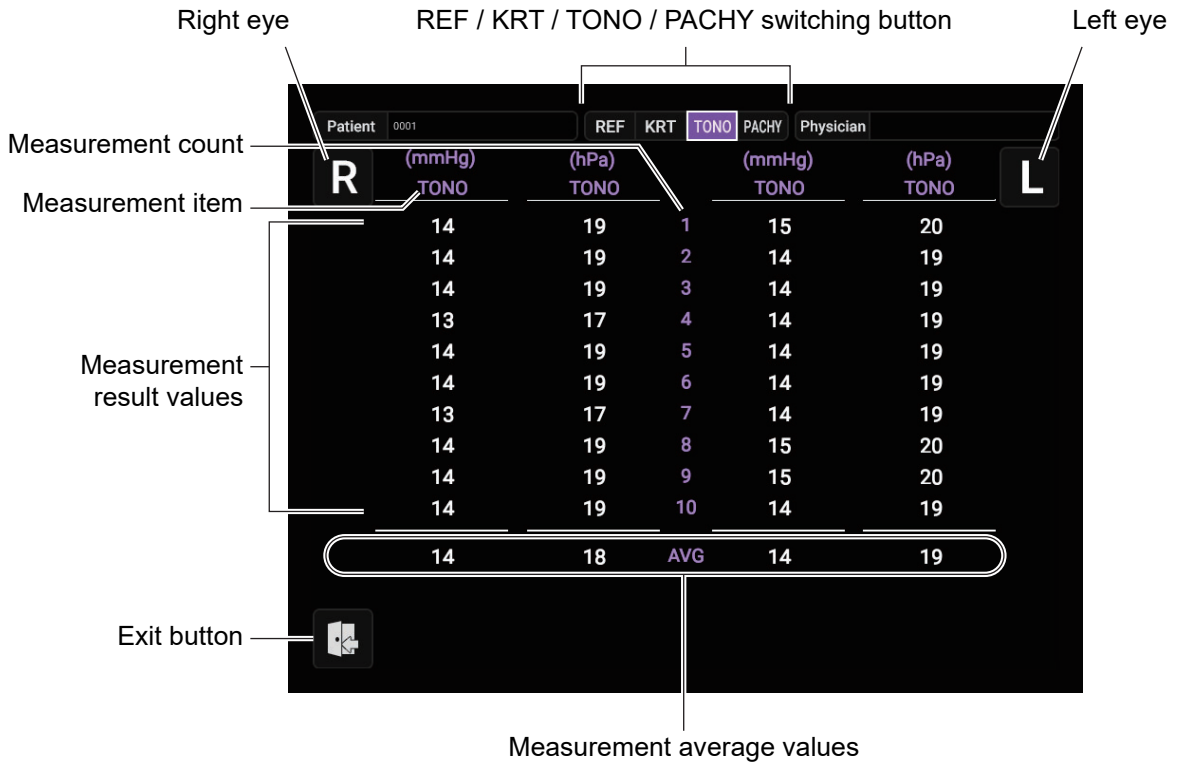
43.75	43.75	130	1	43.75	43.75	155	
43.75	43.75	130	2	43.75	43.75	180	
43.75	43.75	120	3	43.75	43.75	110	
43.75	43.75	150	4	43.75	43.75	180	
43.75	43.75	180	5	43.75	43.75	130	
43.75	43.75	180	6	43.75	43.75	180	
43.75	43.75	135	7	43.75	43.75	155	
43.75	43.75	115	8	43.75	43.75	155	
43.75	43.75	125	9	43.75	43.75	180	
43.75	43.75	180	10	43.75	43.75	180	
43.75		43.75	130	AVG	43.75	43.75	155

Exit button

Measurement average values

TONO MEASUREMENT DATA

- The display unit is varied according to the Settings of setup.
Setup item: TONO display unit in intraocular pressure measurement “mmHg” in TONO measurement mode



NOTE TONO and PACHY measurement data that is obtained through measurement started by the Start button or the control lever’s MEASUREMENT switch, or measurement in Manual mode, is displayed in orange.

PACHY MEASUREMENT DATA

- The display unit is varied according to the Settings of setup.

Right eye REF / KRT / TONO / PACHY switching button Left eye

Patient 0001 REF KRT TONO PACHY Physician

Measurement count R PACHY (mm) L PACHY (mm)

Measurement item

Measurement count	Right eye PACHY (mm)	Measurement item	Left eye PACHY (mm)
1	0.562	1	0.564
2	0.564	2	0.565
3	0.562	3	0.565
4	0.561	4	0.564
5	0.562	5	0.565
6	0.562	6	0.566
7	0.562	7	0.566
8	0.561	8	0.565
9	0.562	9	0.565
10	0.562	10	0.565
Average	0.565	AVG	0.562

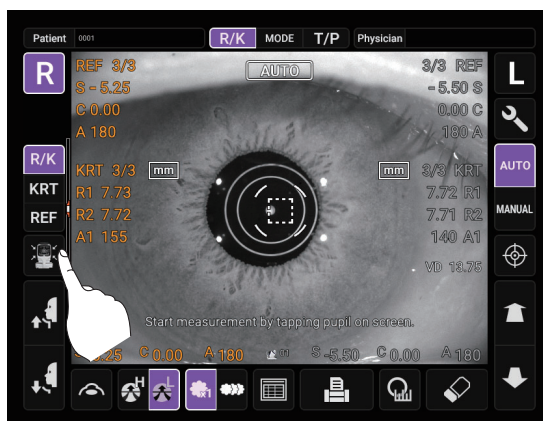
Measurement result values

Exit button

Measurement average values

OPERATION AFTER USE

- 1 Tap the **End** button on control panel.



- 2 A confirmation message for the end operation is displayed.

Return measuring head to central position and turn off power?

OK Cancel

- 3 Tap the **OK** button. Return the chinrest and measuring head to their last positions.
- 4 The message of “End of operation in progress. Please wait until complete.” is displayed.
- 5 The operation is complete, then the message of “End of operation complete. Please turn power off on unit.” is displayed.
- 6 Turn the POWER switch to off.
- 7 If external device is connected, turn off the device.
- 8 Unplug the power cord from a 3-pin AC inlet with grounding.



NOTE

When the instrument is not used for a long period of time, unplug the power cord, and detach the cable connected to the external I/O terminal.

OPTIONAL OPERATIONS

DISPLAYING THE PATIENT ID (PATIENT No.) OR OPERATOR ID

Up to 20 characters of “Patient ID” or “Operator ID” managed by hospitals can be registered and displayed on the control panel or printer output.


If no patient ID is inputted, the patient No. of each patient is allocated automatically.

When “Required Patient ID” is set to ON, the message “MANDATORY field missing: Patient ID. (E09201)” appears at the time of data output. This prevents the entry of the patient ID from being forgotten.

When “Required Physician ID” is set to ON, the message “MANDATORY field missing: Physician ID. (E09202)” appears at the time of data output. This prevents the entry of the physician ID from being forgotten.

Setting “Fixed Physician ID” to ON enables you to always use the ID entered in “Input Fixed Phy. ID”. If the same physician is using the instrument at all times, this saves the physician from having to enter the physician ID at every startup.

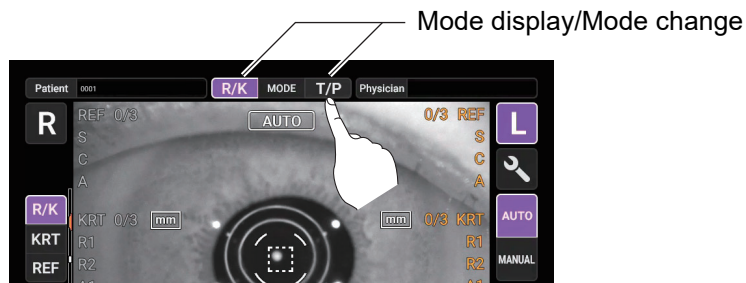
- 1 Tap button.
- 2 Tap keyboard on the screen and enter characters. Tap button and fix the input value.


 NOTE	<ul style="list-style-type: none">• Patient ID is reset when measurement values are printed or if the <input type="text" value="All clear"/> button is tapped.• Patient No. reset condition can be selected such that the patient No. is reset upon power on or not, at “Patient No. reset” in the “System 1” on the setup screen. (See page 101)
--	--

ONE TOUCH OPERATION FOR MODE CHANGE

REF/KRT measurement mode and TONO/PACHY measurement mode can be changed by one touch operation.

- 1 Check the Measurement screen.
- 2 Tap the button to change to REF/KRT measurement mode or TONO/PACHY measurement mode.



 NOTE	<p>If you measured TONO/PACHY measurement first by tapping the <input type="text" value="Mode display/Mode change"/> button to select TONO/PACHY measurement mode under REF/KRT → TONO/PACHY continuous measurement mode, REF/KRT measurement is not performed continuously. After TONO/PACHY measurement, change to REF/KRT measurement mode by tapping the <input type="text" value="Mode display/Mode change"/> button again.</p>
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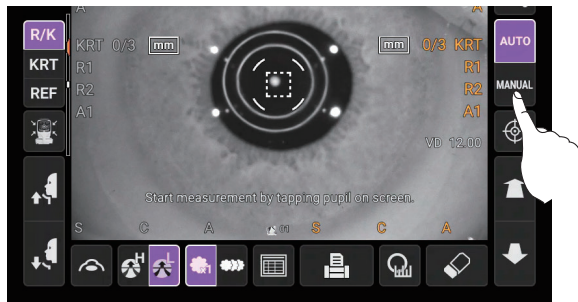
MANUAL MODE IN REF/KRT

NOTE

- Adjust the height of the instrument table so that the patient can sit comfortably. Otherwise, correct measurement values may not be obtained.
- If the instrument is moved before measurement values are displayed, it may cause incorrect measurement results.
- Be careful not to get the finger or hand of the operator who is opening the eyelids caught in the device.

SETTING MANUAL MODE

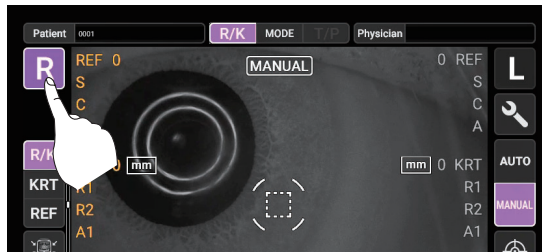
- 1 Check the Measurement screen. If the button is “MANUAL”, the mode is Manual mode.
- 2 If “AUTO” (Auto mode) is displayed, tap it and change to “MANUAL”.



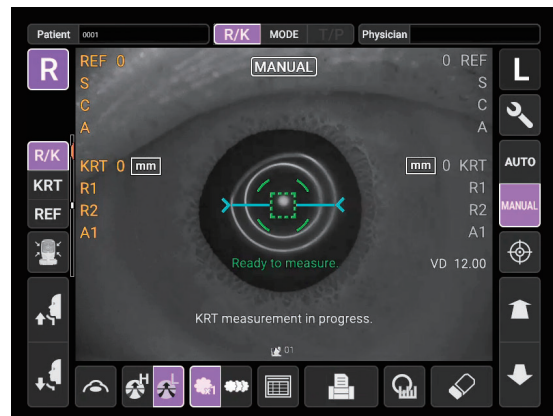
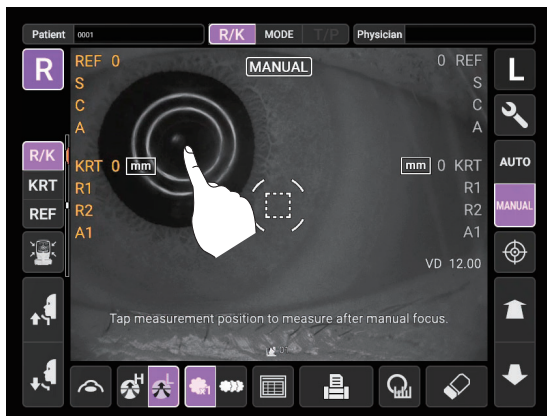
ALIGNMENT AND MEASUREMENT

Alignment is operated on the control panel.

- 1 Select the right/left eye by tapping the button/ button.

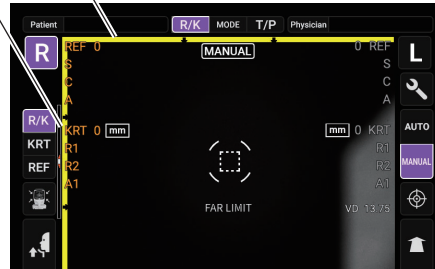


- 2 When the pupil is displayed, tap the display around the pupil. The measuring head moves to the position where the pupil image and the alignment dot are at the center of the screen. Then tell the patient to look at red-roof house.



- If the pupil is not displayed on the control panel, move the measuring head by pressing the control panel, checking the eye height mark on the measurement window as a guide (See page 50).
- When the measuring head has reached the limit of movement (vertical/lateral directions), a yellow-colored limit mark appears on the control panel corner, showing it is the movement limit in that direction. Check the position of the patient's face and the height of the chinrest, and tap the display to move the measuring head to a position that alignment is possible.

Limit mark

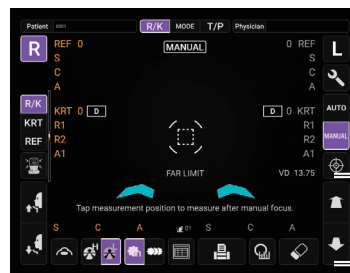


NOTE

- When the measuring head is at the limit of movement in the forward direction, "NEAR LIMIT" is displayed and the buzzer sounds, and when it is at the limit of movement in the backward direction, "FAR LIMIT" and the blue arrow prompting movement in the forward direction are displayed. Check the position of the patient's face and the height of the chinrest, and using the **Measuring head forward/backward** button, move the measuring head to a position that alignment is possible.



Limit of movement in the forward direction



Limit of movement in the backward direction

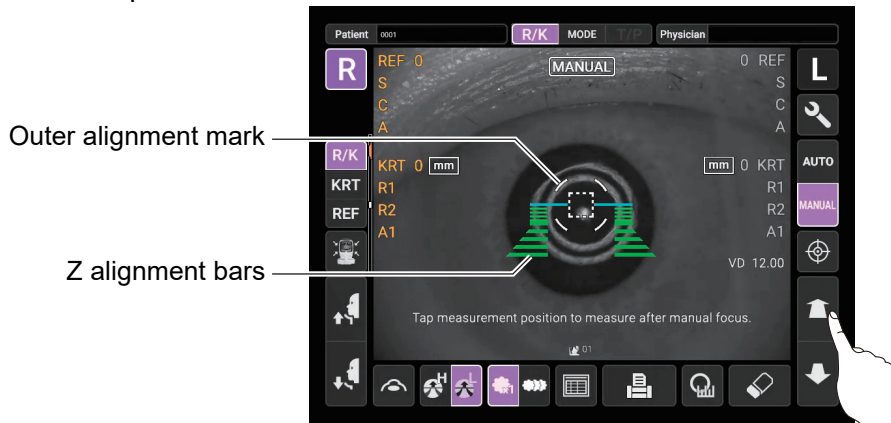
Measuring head forward/backward button

- If "Touch Measure" is set to "ON" in "Function(R/K)1", the measurement starts only by tapping the screen (See page 104).

3 Tap the **Measuring head forward/backward** button and focus on the patient's eye. The alignment dot is reflected off-focus on the cornea.



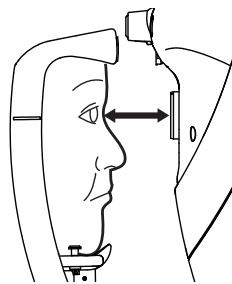
- 4** When the main body unit is brought closer to the patient's eye, Z alignment bars appear on the control panel screen.



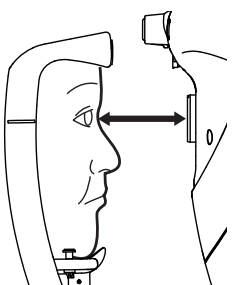
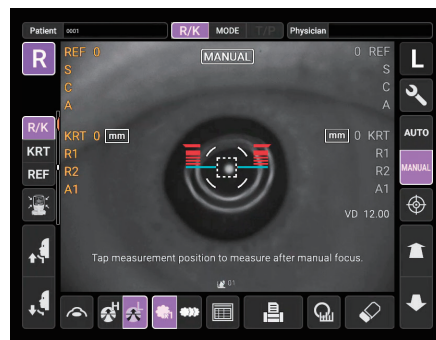
NOTE

Do not allow the eyelash and eyelid to cover the outer alignment mark to ensure stable measurement. Otherwise, correct measurement values may not be obtained.

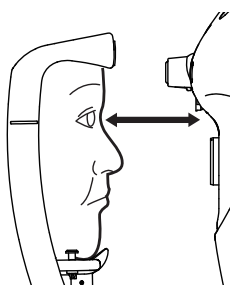
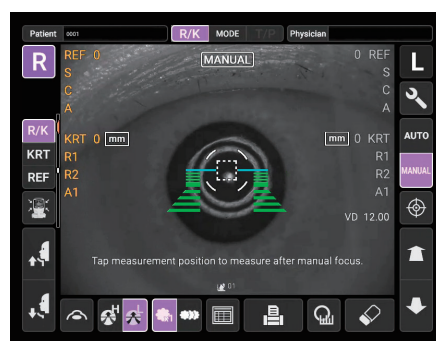
If the instrument is too close to the patient's eye in comparison with the optimal alignment position, Z alignment red bars appear on the upper side of the center horizontal bar (light blue). If it is too far, Z alignment green bars appear on the lower side of the center horizontal bar (light blue). The number of bars are reduced accordingly as the optimal alignment reference position comes closer. If the instrument is completely off the alignment range, Z alignment bars and horizontal bar (light blue) do not appear.



Too close



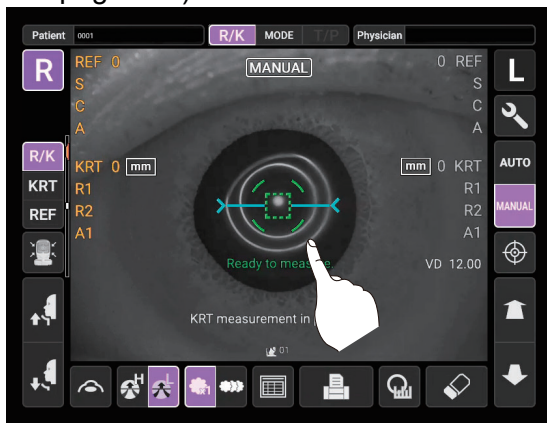
Too far



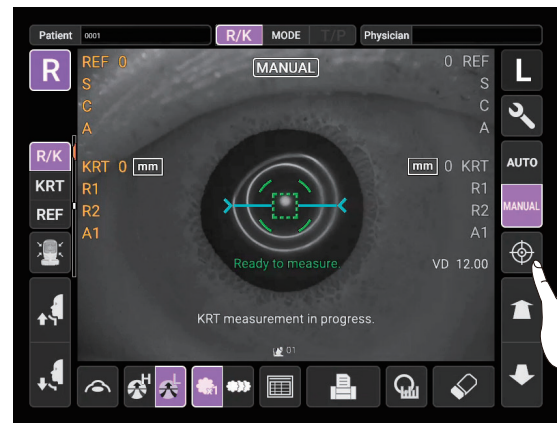
Off the alignment range



- 5** When the alignment dot becomes smaller in size and “Ready to measure” is displayed, tap the button to start measurement.
If “Touch Measure” is set to “ON”, the measurement starts only by tapping the screen. (See page 104)



“Touch Measure” is ON

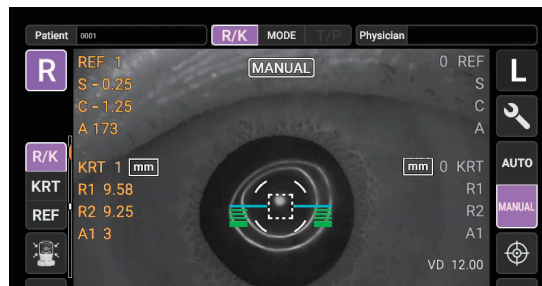


“Touch Measure” is OFF

NOTE

- Even if the alignment is not correct, measurement can be performed by tapping the button. To ensure correct measurement with high accuracy, try to get correct alignment.
- If the instrument is moved before measurement values are displayed, it may cause incorrect measurement result.
- When rotating the control panel to operate it at the upper part of the instrument, do not press the button too hard, so as not to lose the alignment.

- 6** Measurement is performed and measurement values are displayed on the control panel.



DISPLAYING MEASUREMENT VALUES

With regard to measurement values, data of the latest measurement is displayed on the control panel.

- numerical value only: Measurement was done correctly.
- ERROR: Measurement was not done correctly.
- OVER-SPH: When spherical power exceeds $-25D$ or $+22D$.
- OVER-CYL: When Cylindrical power exceeds $\pm 10D$.
- NO TARGET: When there is no target or the eye image is too dark.
- AGAIN: When there is more than $\pm 5D$ difference from previous measurement value.
- NO CENTER: When center of eye can not be found.
- ALIGN ERR: When the alignment is significantly failed during the measurement.

NOTE

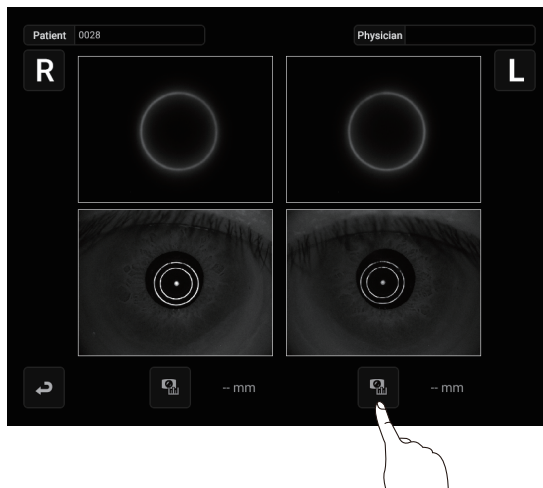
For explanation of the messages on the control panel screen, refer to “MESSAGE LIST” on page 118.

MEASUREMENT OF CORNEA DIAMETER (IN REF/KRT)

1 Tap the **Target image** button.

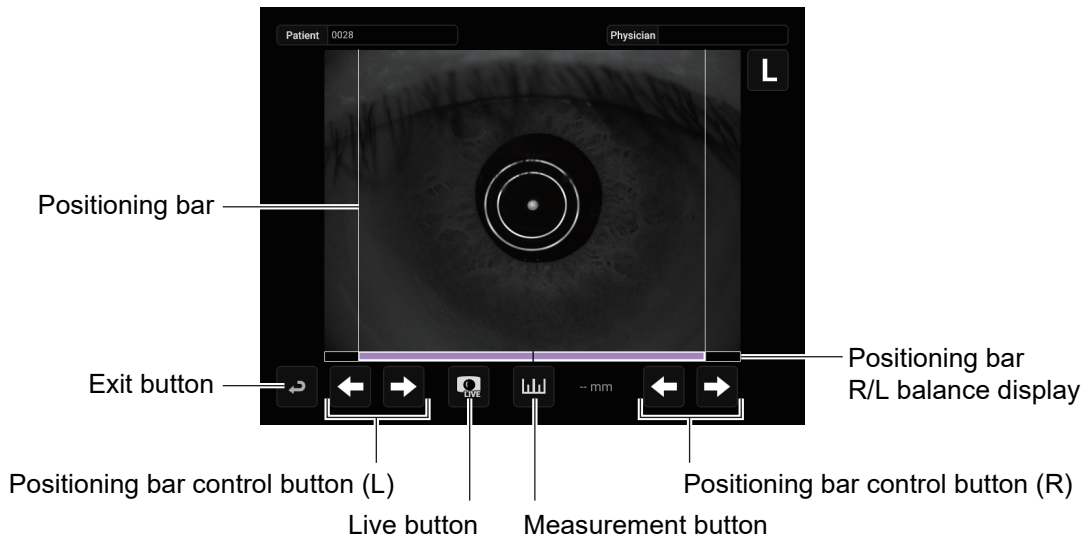


2 Tap the **Cornea diameter measurement** button.

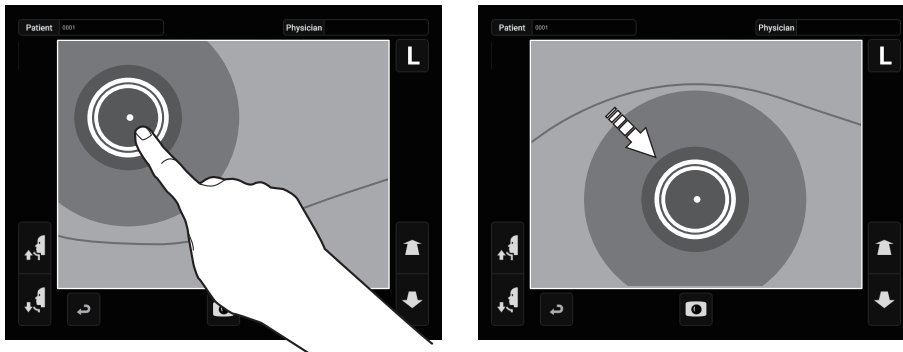


NOTE The last measured image can be checked on this screen.

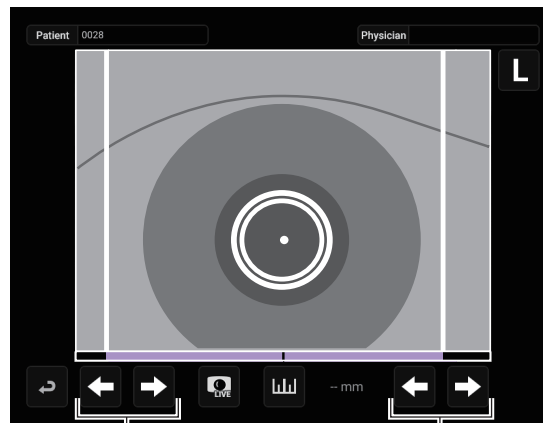
3 The Cornea Diameter Measurement screen is displayed.



- 4** If it has been measured, a still image is displayed, and if it has not been measured, “No Image” is displayed. Press the **Live** button to see the Live image. When the pupil is displayed, tap near the pupil. The measuring head moves to the position the pupil image and alignment dot are at the center of the screen. Press the **Capture** button to take the still image.



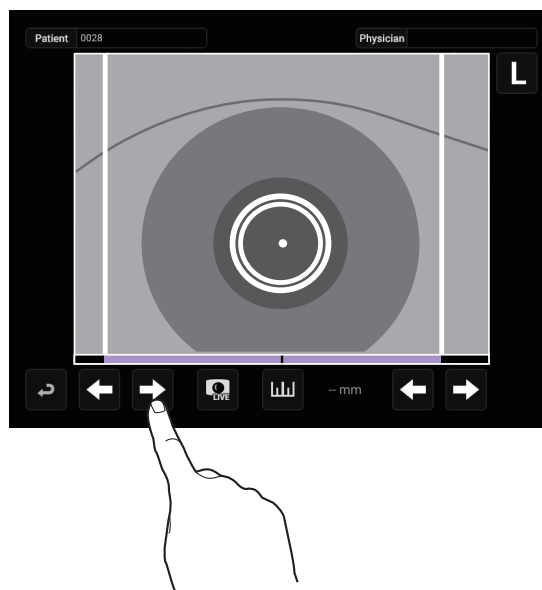
- 5** Tap either the left or right **Positioning bar control** button to move the positioning bar.



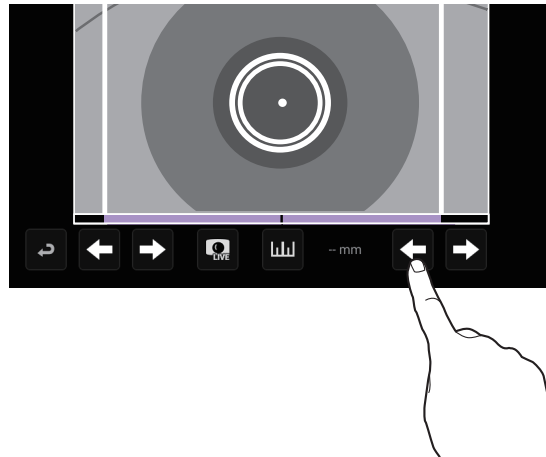
Positioning bar control button (L)

Positioning bar control button (R)

- 6** Use the left **Positioning bar control** button to move the left positioning bar to the left end of the iris as seen from the control panel side.



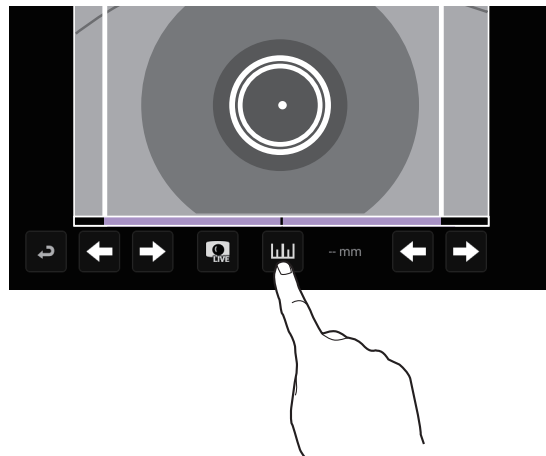
- 7 Use the right **Positioning bar control** button to move the right positioning bar to the right end of the iris as seen from the control panel side.



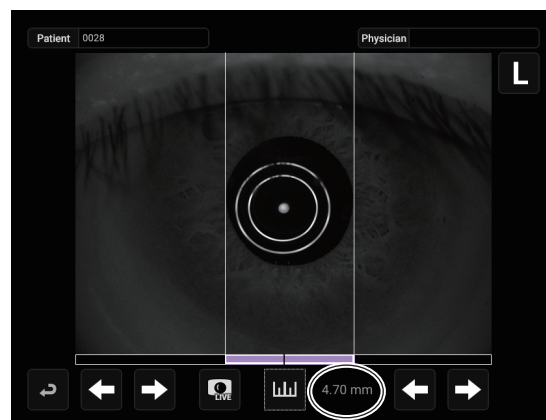
NOTE

It is possible to move the positioning bar by tapping the positioning bar R/L balance display.

- 8 Tap the **Measurement** button.



- 9 The Cornea diameter is displayed.



- 10 Tap the **Exit** button to return to the Measurement screen.

NOTE

On this screen, tapping the **(R)** button or **(L)** button does not move to the opposite eye measurement position.

MANUAL MODE IN TONO/PACHY



CAUTION

Be careful not to get the finger or hand of the operator who is opening the eyelids caught in the device.

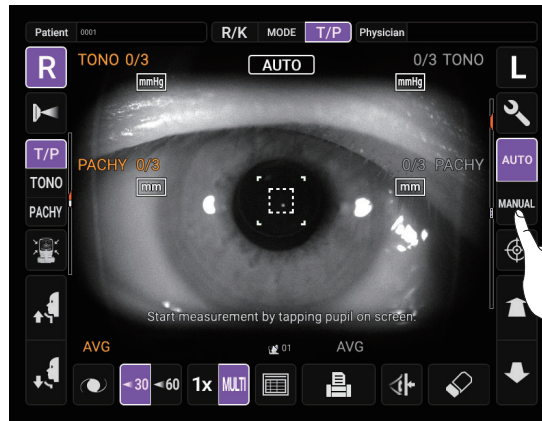


NOTE

- Adjust the height of the instrument table so that the patient can sit comfortably. Otherwise, correct measurement values may not be obtained.
- Do not perform measurement if the patient holds their breath or is nervous. Otherwise, correct measurement values may not be obtained.
- If the instrument is moved before measurement values are displayed, it may cause incorrect measurement results.

SETTING THE MANUAL MODE

- 1 Check the Measurement screen. If the **Auto/Manual** button is “MANUAL”, the mode is Manual mode.
- 2 If “AUTO” (Auto mode) is displayed, tap it and change to “MANUAL”.



SETTING THE MEASURING RANGE

In this instrument, the measuring range can be switched in 2 steps between “7-30” and “30-60”. Normally, “7-30” is used, but if the patient's intraocular pressure is high, switch it to “30-60”. The default setting is “7-30” upon power on.

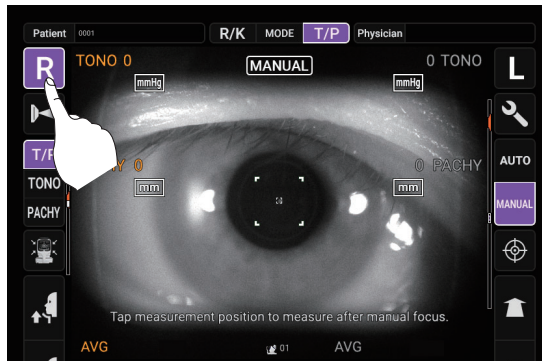
- 1 Check the Measurement screen.
- 2 Tap the **30/60** button of the control panel and set the measuring range.



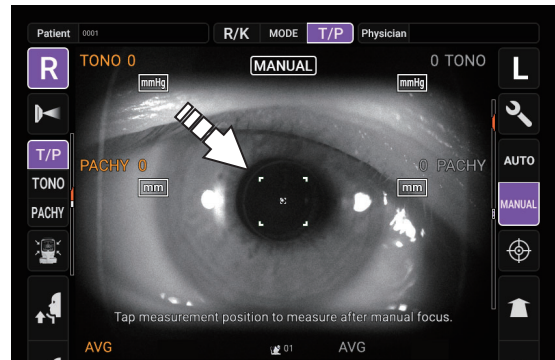
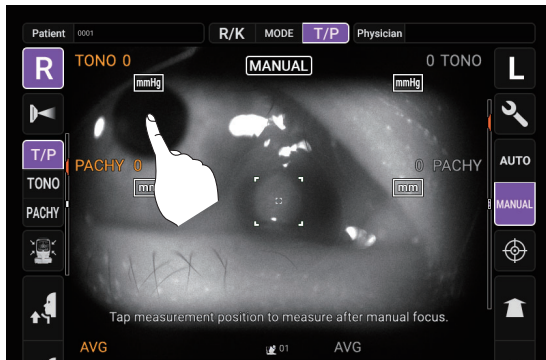
ALIGNMENT AND MEASUREMENT

Alignment is operated on the control panel.

- 1 Select the right/left eye by tapping the (R) button/(L) button.



- 2 When the pupil is displayed tap the pupil. The measuring head moves to the position the pupil image and alignment dot are at the center of the screen.



NOTE

- Depending on the alignment condition, the alignment mark is displayed differently:
 - White: When alignment is insufficient/out of the measuring range
 - Green: When alignment is within the measuring range in all directions (front/rear, right/left, top/bottom)
- If the pupil is not displayed on the control panel, move the measuring head by pressing the control panel, checking the eye height mark on the measurement window as a guide (See page 50).
- When the measuring head has reached the limit of movement (vertical/lateral directions), a yellow-colored limit mark appears on the control panel corner, showing it is the movement limit in that direction. Check the position of the patient's face and the height of the chinrest, and tap the display to move the measuring head to a position that alignment is possible.

Limit mark



When the measuring head is at the limit of movement in the forward direction, “Reaching set limit of stopper. Move measuring head.” is displayed, and when it is at the limit of movement in the backward direction, “FAR LIMIT” is displayed. If the position is detected, “TOO CLOSE” is displayed at a position closer than 3 mm to the patient’s eye. Check the position of the patient’s face and the height of the chinrest, and using the **Measuring head forward/backward** button, move the measuring head to a position that alignment is possible.

NOTE

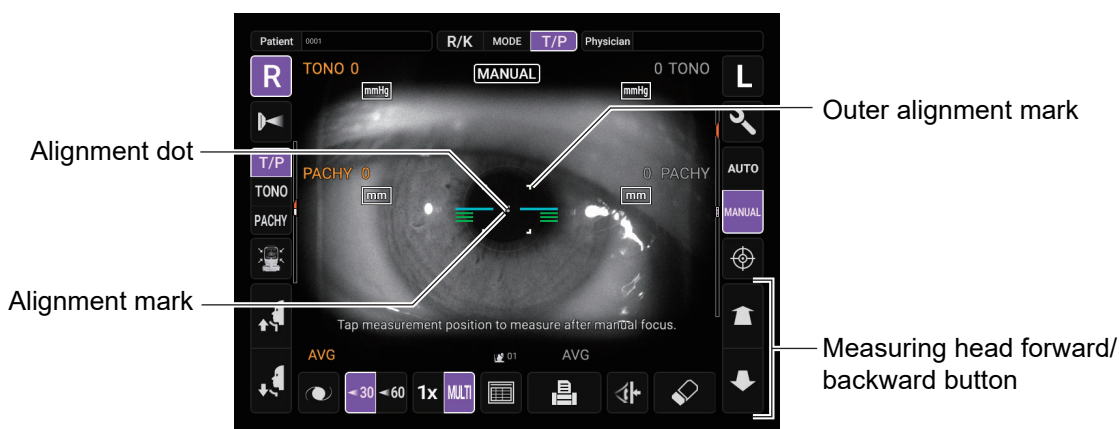


Limit of movement in the forward direction



Limit of movement in the backward direction

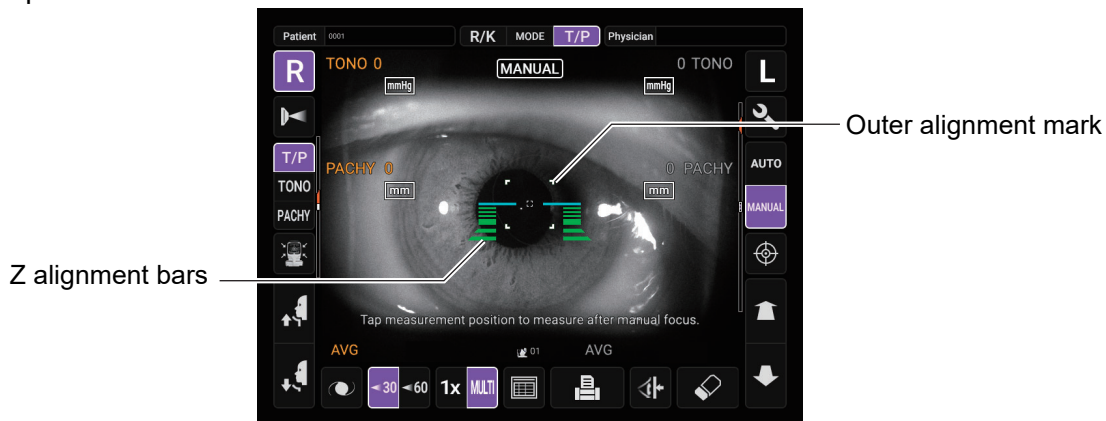
- 3 Tap the **Measuring head forward/backward** button and focus on the patient's eye. The alignment dot is reflected off-focus on the cornea.



NOTE

As the main body approaches the patient, focus of Measurement screen changes.

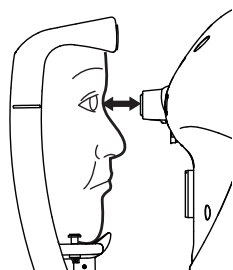
- 4** When the main body is brought closer to the patient's eye, Z alignment bars appear on the control panel screen.



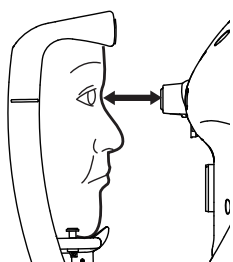
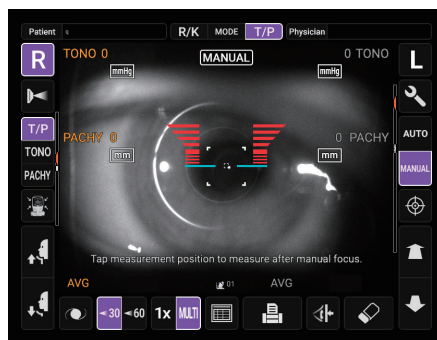
NOTE

Do not allow the eyelash and eyelid to cover the outer alignment mark to ensure stable measurement. Otherwise, correct measurement values may not be obtained.

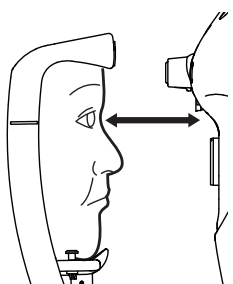
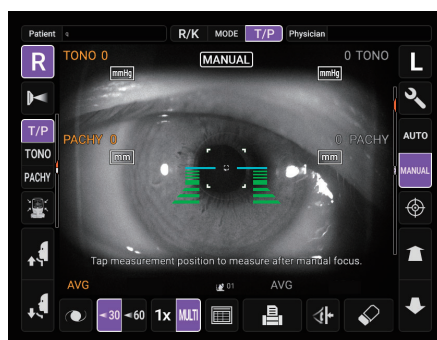
If the instrument is too close to the patient's eye in comparison with the optimal alignment position, Z alignment red bars appear on the upper side of the center horizontal bar (light blue). If it is too far, Z alignment green bars appear on the lower side of the center horizontal bar (light blue). The number of bars are reduced accordingly as the optimal alignment reference position comes closer. If the instrument is completely off the alignment range, Z alignment bars and horizontal bar (light blue) do not appear.



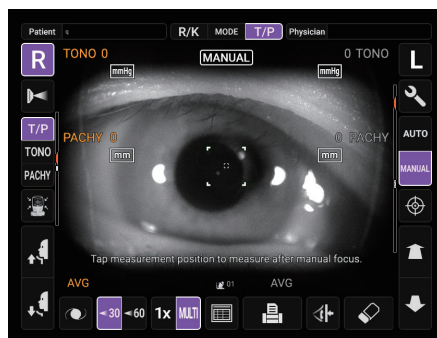
Too close



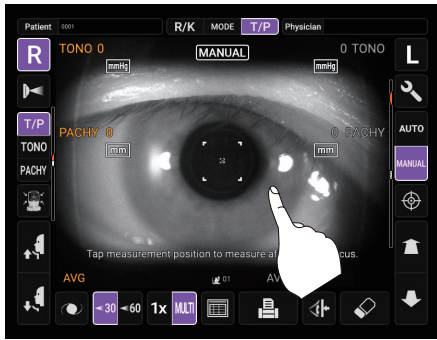
Too far



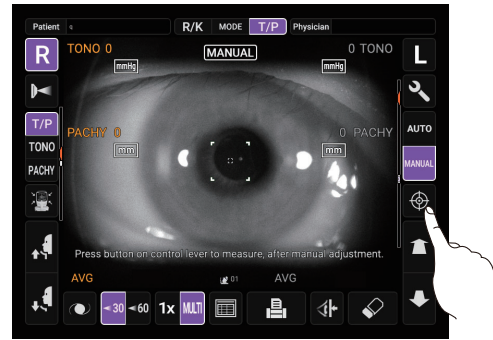
Off the alignment range



- 5 Measurement starts by tapping the button. If “Touch Measure” is set to “ON”, the measurement starts only by tapping the screen. (See page 105)



Touch Measure is ON

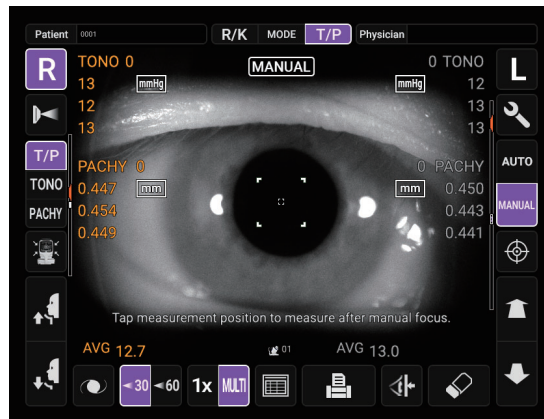


Touch Measure is OFF

NOTE

- Even if fine alignment has not been achieved, measurement can be performed by tapping the button. To ensure correct measurement, try to get fine alignment.
- When rotating the control panel to operate it at the upper part of the instrument, do not press the button too hard, so as not to lose the alignment.

- 6 Measurement is performed and measurement values are displayed on the control panel.



DISPLAYING MEASUREMENT VALUES

With regard to measurement values, for both TONO and PACHY, data of the latest three measurements are displayed on the control panel.

- numerical value only: Measurement was done correctly.
- numerical value with []: When the reliability of measurement is low.(only TONO)
- ERROR: Measurement was not done correctly.
- OVER: When IOP value exceeds 60 mmHg.




NOTE

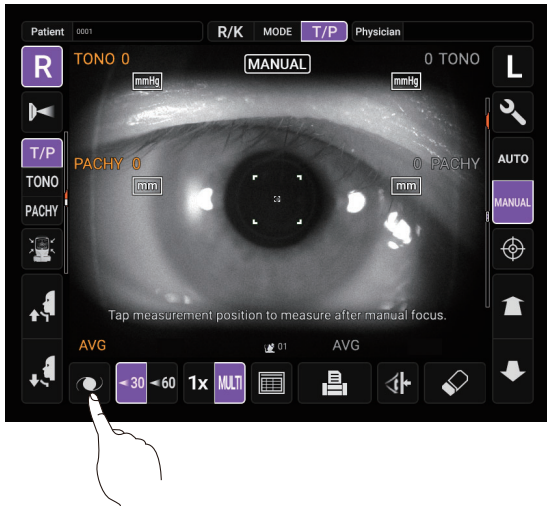
- In TONO average value display, low-reliability numerical data with [] are not added to average value calculation. However, if all measurement data are numerical data with [], average value calculation is done using these data.
- In the data printout, manual measurement values will have M marks beside them.
- For explanation of the messages on the control panel screen, refer to “MESSAGE LIST” on page 118.

IOL MODE IN TONO/PACHY

NOTE Alignment may not be performed normally with IOL inserted eye. If it occurs, carry out measurement in IOL mode.

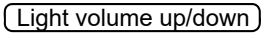
SETTING THE IOL MODE

- 1 Check the Measurement screen. If  is displayed, IOL mode is set.
- 2 If no  is displayed, tap the  button to change to IOL mode.




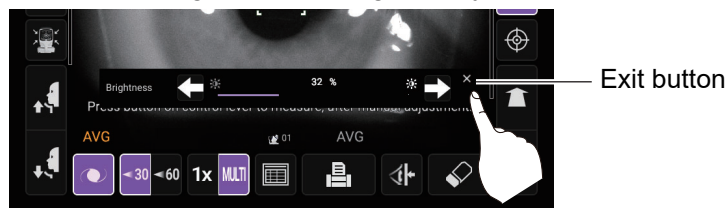
IOL mode display

SETTING THE IOL LED BRIGHTNESS

- 1 If the alignment dot is difficult to see, adjust the LED brightness by touching the  button for "Brightness" or the light gauge to make it easier to check the alignment dot.



- 2 Tap the  button, the LED brightness setting display disappears.

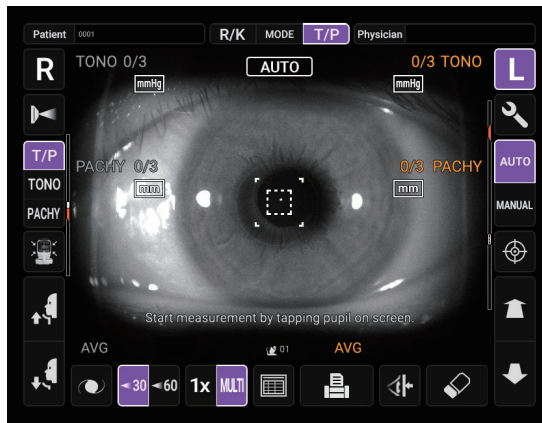


NOTE The value sets at "Brightness" remains in "IOL LED Brightness" in the "Function(T/P)1" on the Setup screen.

ONE-EYE MEASUREMENT MODE

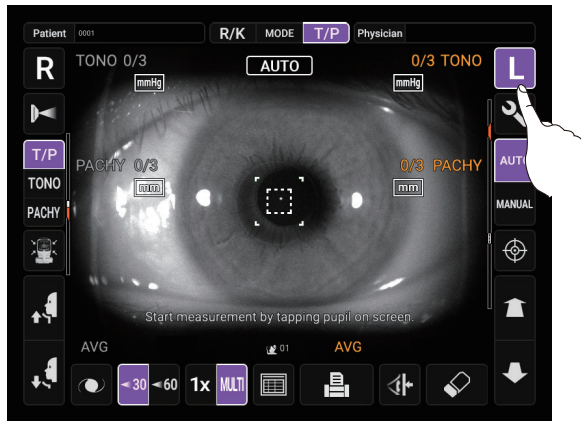
In auto mode, one eye measurement only can be measured.

The (R) button or (L) button side displayed in purple indicates the current measurement position.

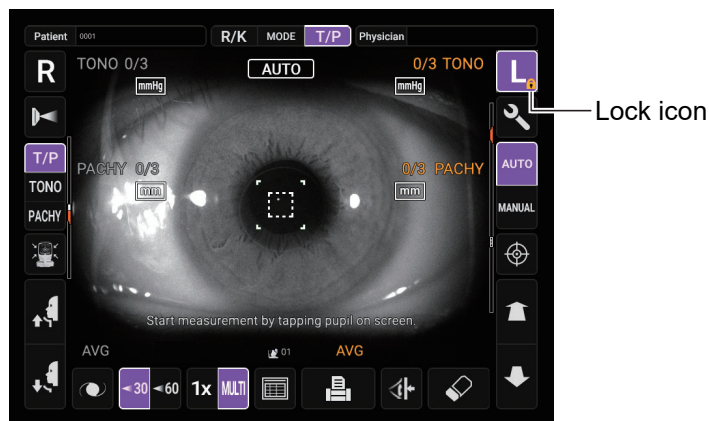


TO MEASURE ONLY THE LEFT EYE

1 Tap the (L) button to move the measuring head to the Left.



2 When the moving is finished, tap the (L) button again to display the lock icon in (L) on the screen.




NOTE When the lock icon is displayed, it does not automatically move to the other eye even after the measurement of one eye is completed.

3 To unlock, tap the (L) button again. The lock icon disappears.

TO MEASURE ONLY THE RIGHT EYE

The operation procedure is the same as when measuring only the left eye.



When the lock icon  is displayed (one-eye measurement mode), you can switch between the left and right eyes while keeping the locked state by tapping the **(R)** button or **(L)** button.

INPUT USING USB

This instrument can input ID numbers from a barcode reader, etc. via the USB.

- 1** Check the connection of USB IN.
For connection, refer to “CONNECTING EXTERNAL I/O TERMINALS” on page 32.
- 2** Input the patient ID on the measurement and Patient ID input screens from an external device.
The inputted patient ID is displayed on the screen.

OUTPUT USING LAN


This instrument can output data to a PC, etc. via the LAN interface.


- 1** Connect the network cable to LAN OUT.
For connection, refer to “CONNECTING EXTERNAL I/O TERMINALS” on page 32.
- 2** Set up of LAN connection settings.
For details, refer to “LAN connection” on page 102.
- 3** Perform measurements.
- 4** Tap the **Print out** button of the control panel.
Output is completed.



- For explanation of messages during communication refer to the “MESSAGE LIST” on page 118.
- All measured data is outputted. If outputting of only individual measurement data (REF measurement data, KRT measurement data or TONO measurement data only) is required, change the measurement mode to the individual measurement for desired measurement data by tapping the **Measurement mode** button. Then perform measurement and output.

OPERATING THE CONTROL LEVER

 <p>CAUTION</p>	<p>When switching the left and right eyes by the control lever, be sure to return the measuring head to the backward side by tilting the control lever to the backward before moving the measuring head to the left or right. It causes injury by hitting the patient's eyes or nose.</p>
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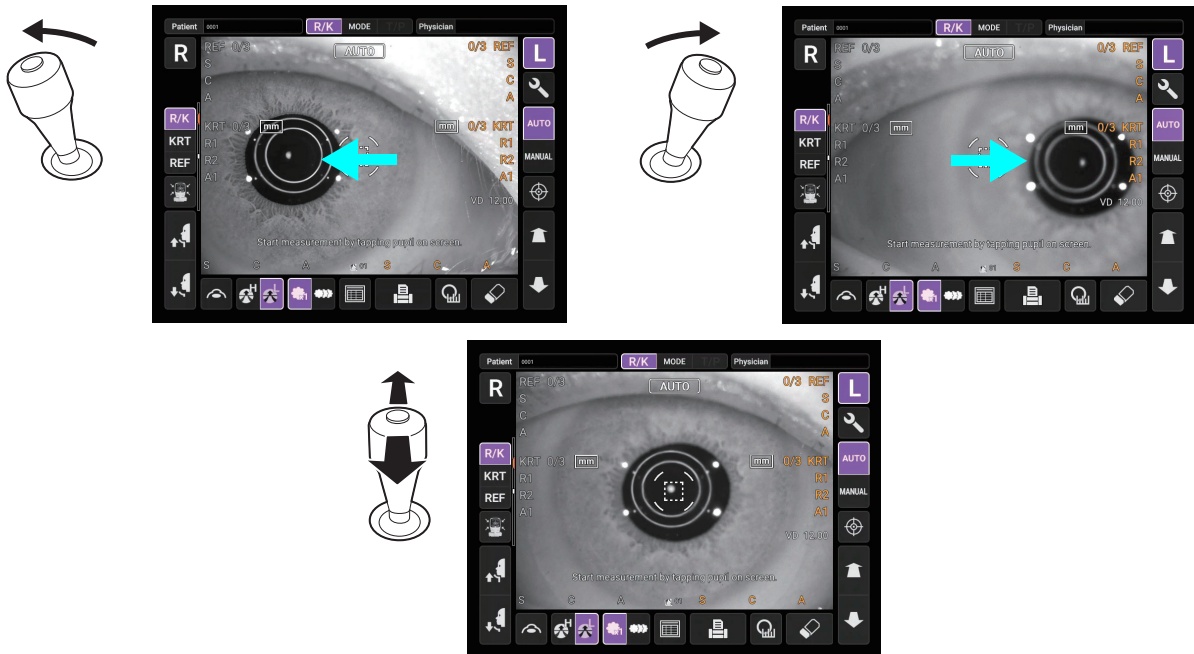
 <p>NOTE</p>	<p>When using the control lever, please set the control panel in the location of the opposition to a patient. (The location that the center of the control panel is right above the control lever.)</p>
--	---

OPERATING THE CONTROL LEVER

The control lever can perform the following operations:

1 Back-forth and right-left movements

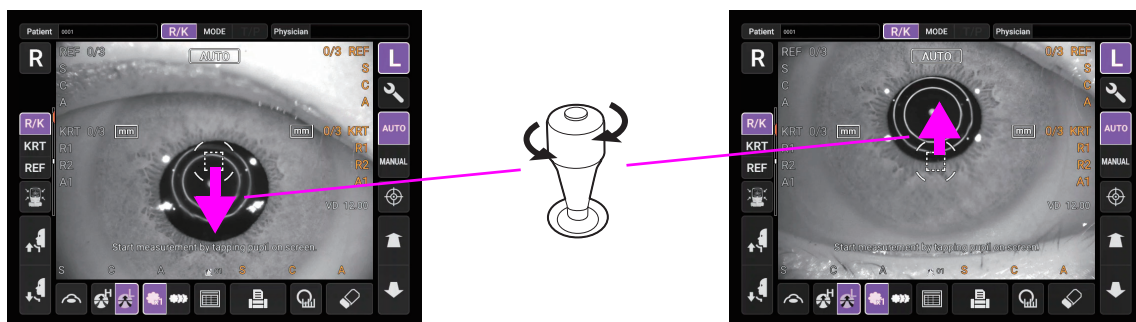
When the control lever is inclined in any direction, the main body moves in the tilted direction.



The focus on the screen can be adjusted by tilting control lever backward and forward.

2 Vertical movement

When the control lever is rotated, the main body moves up and down. Turning the lever clockwise will raise the main body and turning counterclockwise lowers it.



3 Measurement operation

Measurement starts by pressing the MEASUREMENT switch at the top of the control lever.



MANUAL MODE IN REF/KRT



Set the “Change to M by lever” setting to ON to automatically switch to Manual model when the control lever is touched. Refer to “Change to M by lever” on page 103.

When the control lever is operated, the following three ways can be selected by setting “Change to M by lever”.

- OFF: Operation by the control lever is possible while keeping the auto mode (continuous measurement mode). See page 55 for “Continuous measurement mode”.
- ON: From left and right eye selection to alignment and measurement *, everything is done manually.
- Semi-auto: By operating the control lever of the operator, when the instrument is brought close to the patient’s eye, the position is automatically adjusted by auto alignment and the measurement* is automatically performed.

* When “Auto Shoot” in “Function(Common)2” on the Setup screen is set to ON, operate the control lever to automatically start measurement once the alignment is complete. Refer to “Auto Shoot” on page 103.

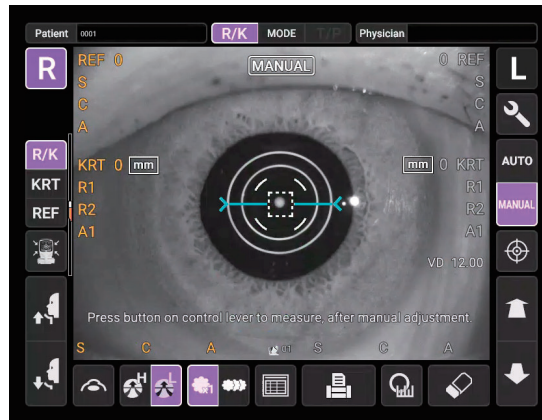
1 Check the Measurement screen. If the button is “MANUAL”, the mode is Manual mode.

2 If “AUTO” (Auto mode) is displayed, tap it and change to “MANUAL”.

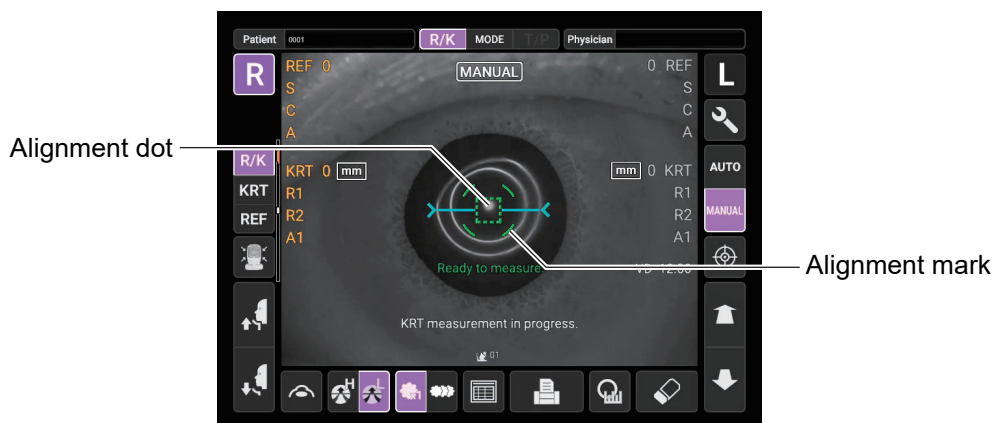


ALIGNMENT AND MEASUREMENT

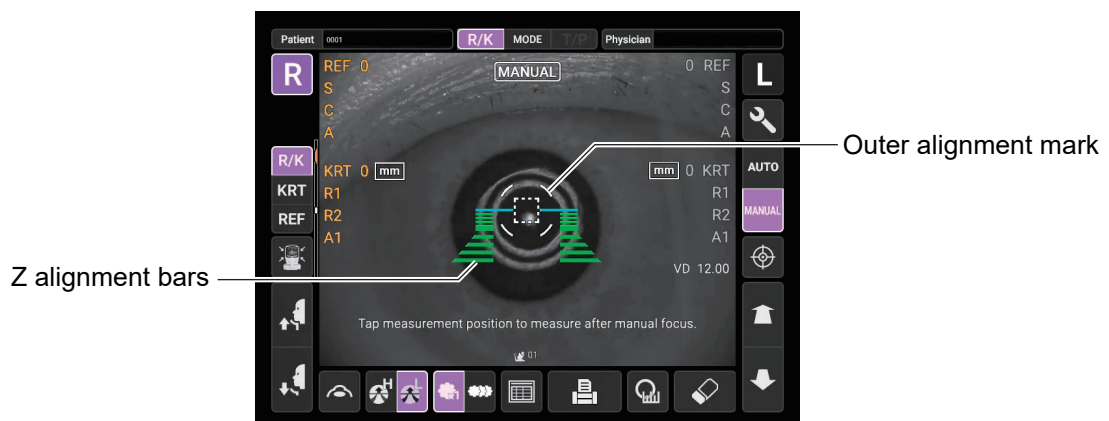
- 1 Select the right/left eye by tapping the **(R)** button/**(L)** button or operating the control lever.
- 2 Align the pupil display to the center of the screen.
Use the control lever to align the center of the pupil within the alignment mark. At this time, tell the patient to look at red-roof house.



- 3 While watching the anterior image, focus on the patient's eye by tilting control lever back and forth. The alignment dot is reflected off-focus on the cornea.



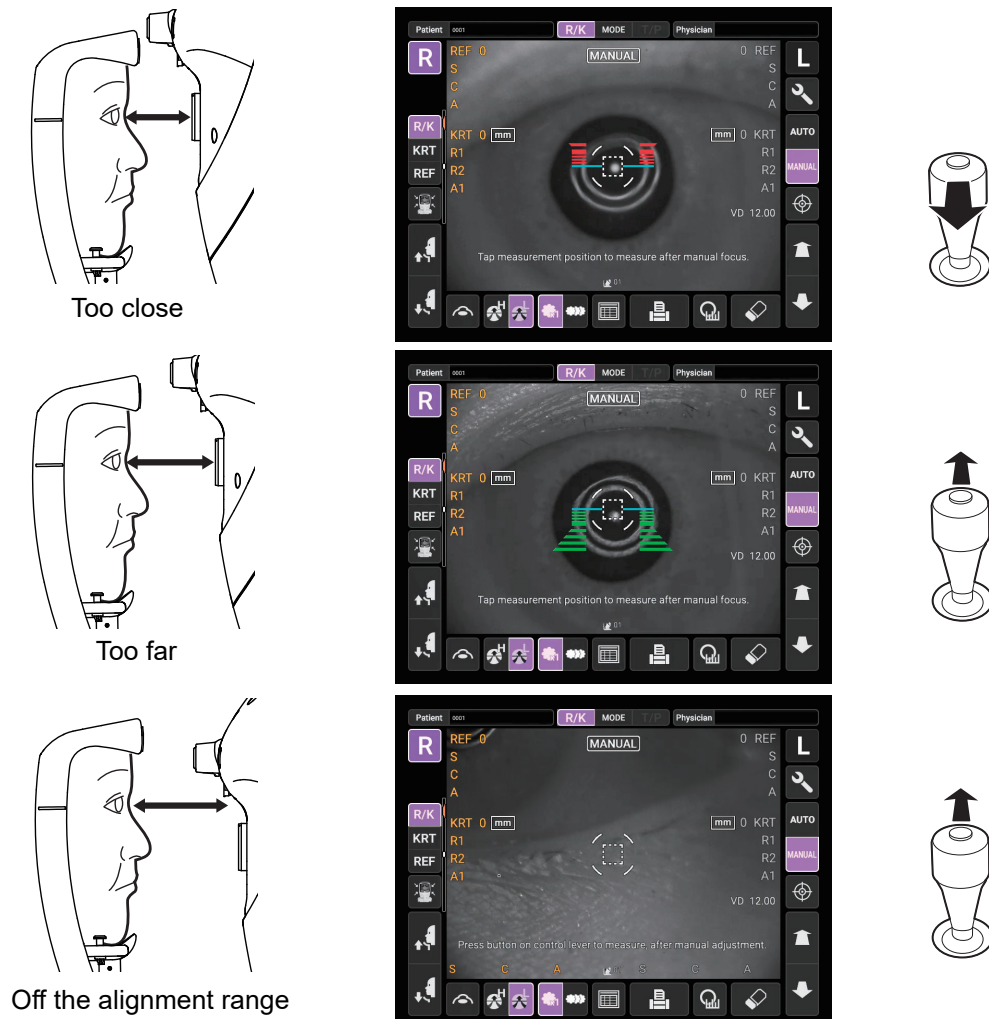
- 4 When the alignment dot reaches within alignment mark, Z alignment bars appear on the control panel screen.



NOTE

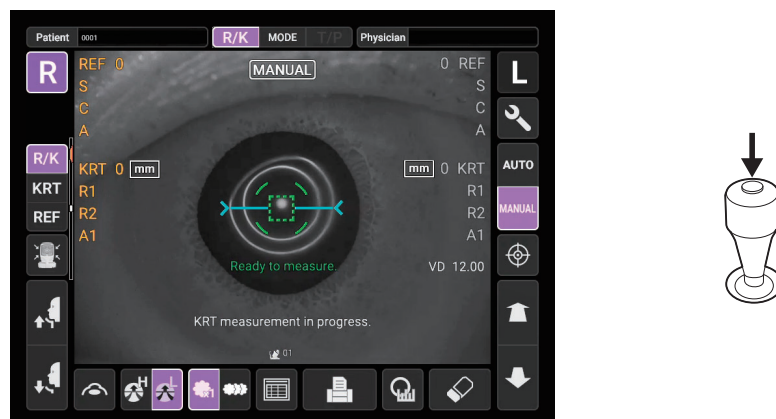
Do not allow the eyelash and eyelid to cover the outer alignment mark to ensure stable measurement. Otherwise, correct measurement values may not be obtained.

If the instrument is too close to the patient's eye in comparison with the optimal alignment position, Z alignment red bars appear on the upper side of the center horizontal bar (light blue). If it is too far, Z alignment green bars appear on the lower side of the center horizontal bar (light blue). The number of bars are reduced accordingly as the optimal alignment reference position comes closer. If the instrument is completely off the alignment range, Z alignment bars and horizontal bar (light blue) do not appear.

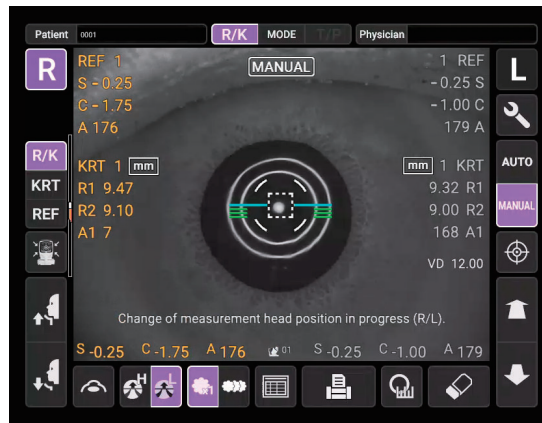


5 When the red or green Z alignment bars disappear and the alignment mark is turned green, the automatic measurement is performed or press the MEASUREMENT switch.

* When "Auto Shoot" in "Function(Common)2" on the Setup screen is set to ON, operate the control lever to automatically start measurement once the alignment is complete. Refer to "Auto Shoot" on page 103.



Measurement is performed and measurement values are displayed on the control panel.

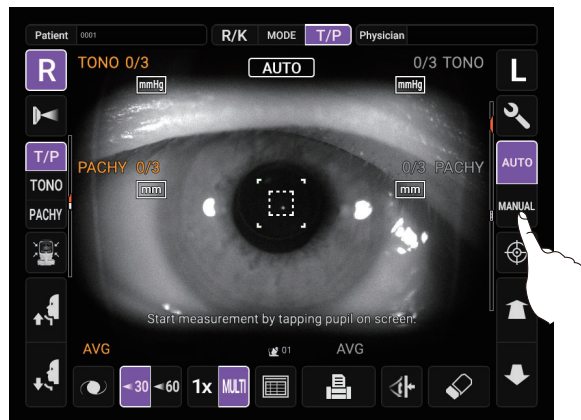


NOTE

If you press and hold the MEASUREMENT switch of the control lever in the manual mode of REF/ KRT, perform the measurement once, over and over again.

MANUAL MODE IN TONO/PACHY

- 1 Check the Measurement screen. If the **Auto/Manual** button is “MANUAL”, the mode is Manual mode.
- 2 If “AUTO” (Auto mode) is displayed, tap it and change to “MANUAL”.



SETTING THE MEASURING RANGE

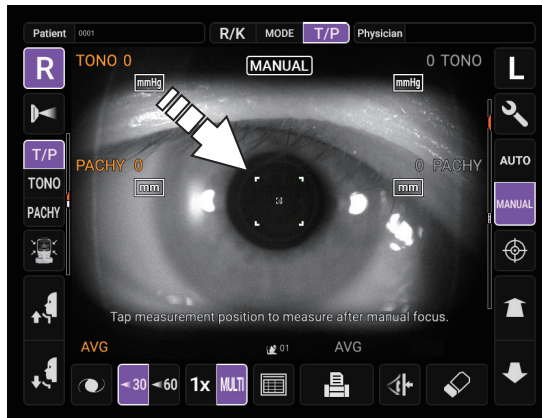
In this instrument, the measuring range can be switched in 2 steps between “7-30” and “30-60”. Normally, “7-30” is used, but if the patient’s intraocular pressure is high, switch it to “30-60”. The default setting is “7-30” upon power on.

- 1 Check the Measurement screen.
- 2 Tap the **30/60** button of the control panel and set the measuring range.

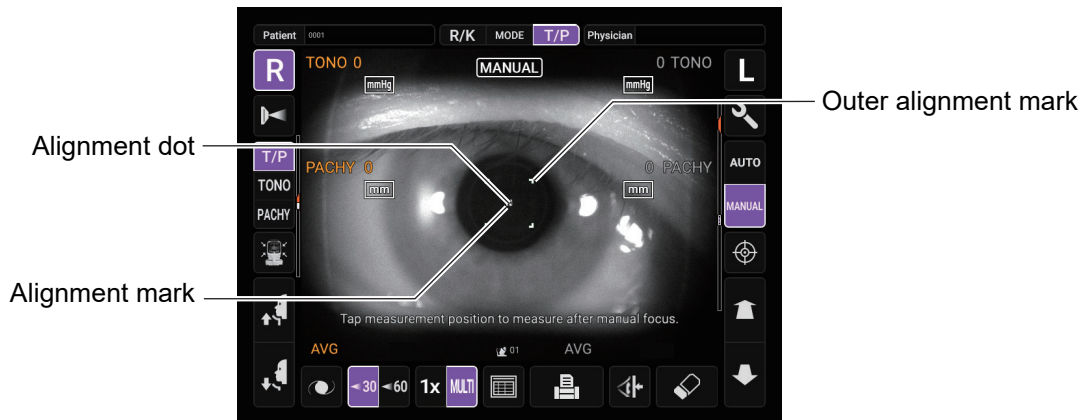


ALIGNMENT AND MEASUREMENT

- 1 Select the right/left eye by tapping the **(R)** button/**(L)** button or operating the control lever.
- 2 Use the control lever to align the center of the pupil within the alignment mark. At this time, tell the patient to look at the green alignment dot.



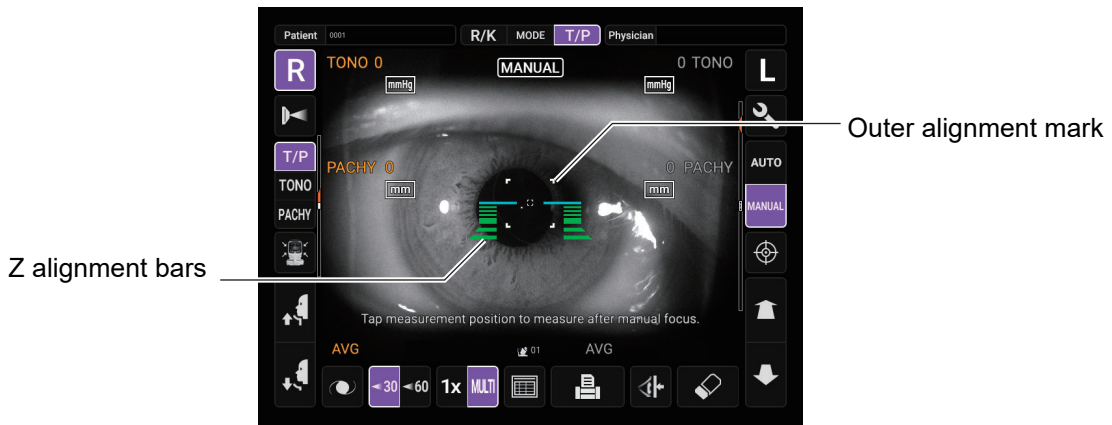
- 3 While watching the anterior image, focus on the patient's eye by tilting control lever back and forth. The alignment dot is reflected off-focus on the cornea.



NOTE

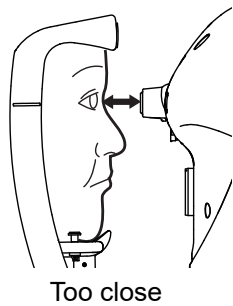
As the main body approaches the patient, focus of Measurement screen changes.

4 The Z alignment bars appear when the alignment dot reaches within the alignment mark.

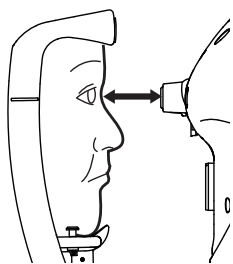
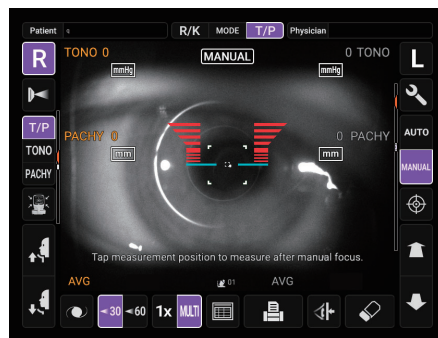


NOTE Do not allow the eyelash and eyelid to cover the outer alignment mark to ensure stable measurement. Otherwise, correct measurement values may not be obtained.

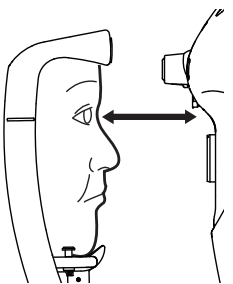
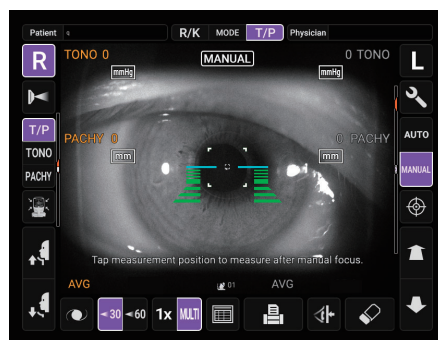
If the instrument is too close to the patient's eye in comparison with the optimal alignment position, Z alignment red bars appear on the upper side of the center horizontal bar (light blue). If it is too far, Z alignment green bars appear on the lower side of the center horizontal bar (light blue). The number of bars are reduced accordingly as the optimal alignment reference position comes closer. If the instrument is completely off the alignment range, Z alignment bars and horizontal bar (light blue) do not appear.



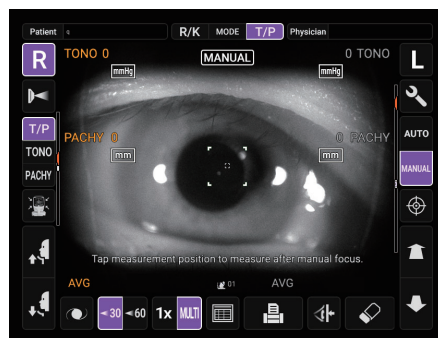
Too close



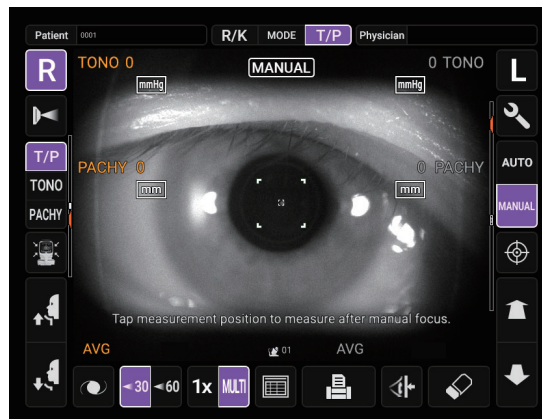
Too far



Off the alignment range



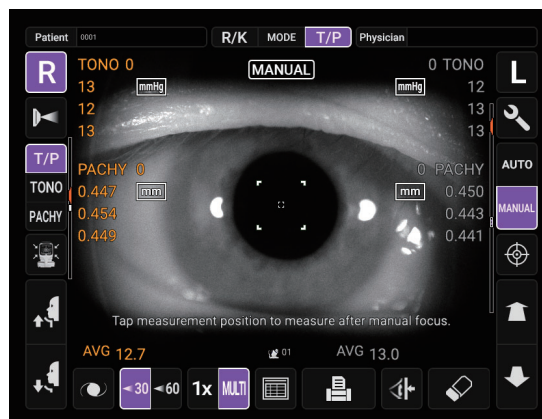
- 5** When the red or green Z alignment bars disappear and the alignment mark is turned green, the automatic measurement is performed or press the MEASUREMENT switch.
- * When “Auto Shoot” in “Function(Common)2” on the Setup screen is set to ON, operate the control lever to automatically start measurement once the alignment is complete. Refer to “Auto Shoot” on page 103.



NOTE

- Even if fine alignment has not been achieved, measurement can be performed by pressing the MEASUREMENT switch. To ensure correct measurement, try to get fine alignment.
- It cannot be measured again for 1.5 seconds after the measurement.
- Even if you press and hold the MEASUREMENT switch of the control lever in the manual mode of TONO/ PACHY, it will not measure repeatedly (only once).

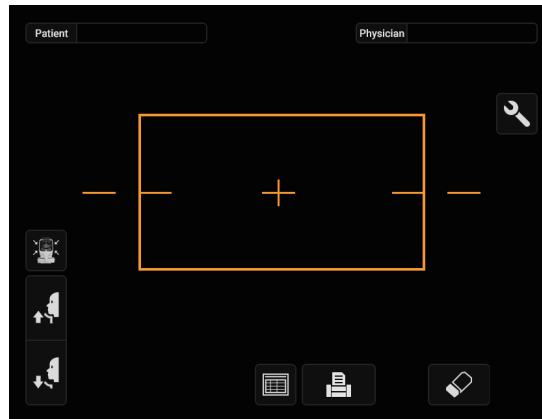
- 6** Measurement is performed and measurement values are displayed on the control panel.



ADJUSTING THE HEIGHT OF THE CHINREST BY WIDE-ANGLE ANTERIOR OBSERVATION IMAGE

If “Wide Angle” on the “Stand by screen” of the “Function(Common)2” of the setting screen is selected, it can adjust the chinrest position before measurement.

The wide-angle anterior observation image screen is displayed when the power is turned on or when the button is pressed.



- 1** Press the button for chinrest and adjust so that the center of the patient's eye is level with the horizontal bar on the screen.
- 2** Tap the area where the screen image is displayed to move to the Stand by screen.

SETTING FUNCTIONS ON SETUP SCREEN

OPERATING THE SETUP SCREEN

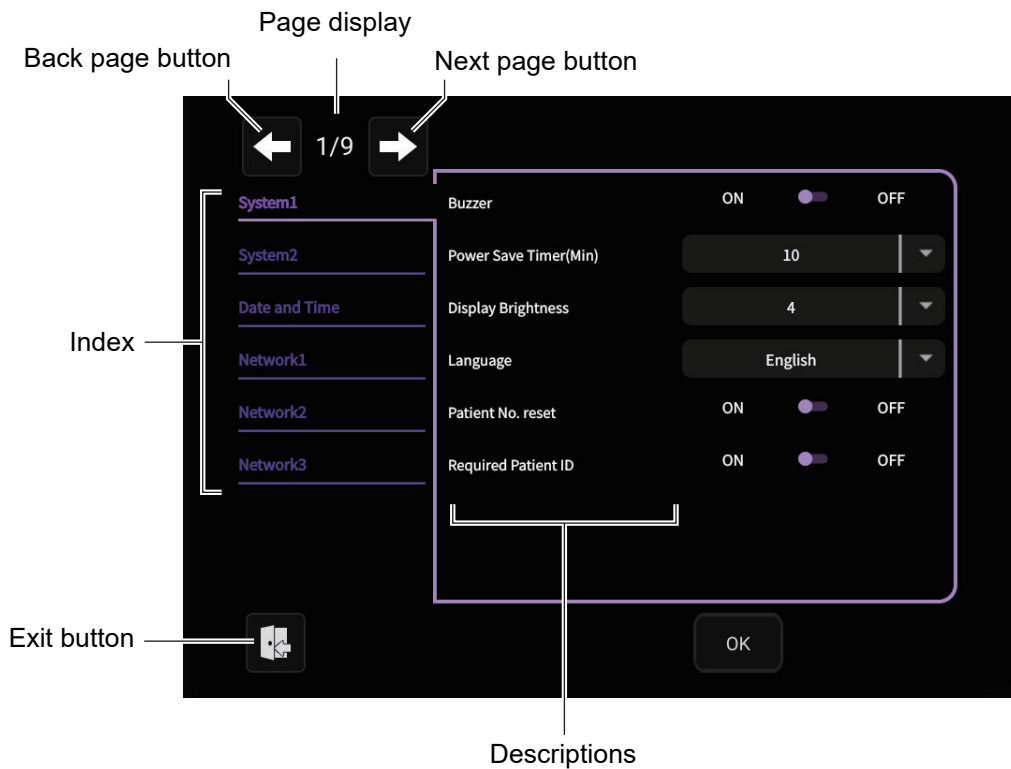
Various functions can be set on the SETUP screen.

PREPARATIONS FOR SETTING

- 1 Make sure that the power cord is connected.
For connection, refer to “CONNECTING POWER CORD” on page 31.
- 2 Turn ON the POWER switch.
- 3 Tap the Settings button on the control panel.

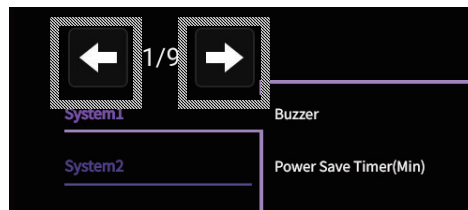


The SETUP screen is displayed.

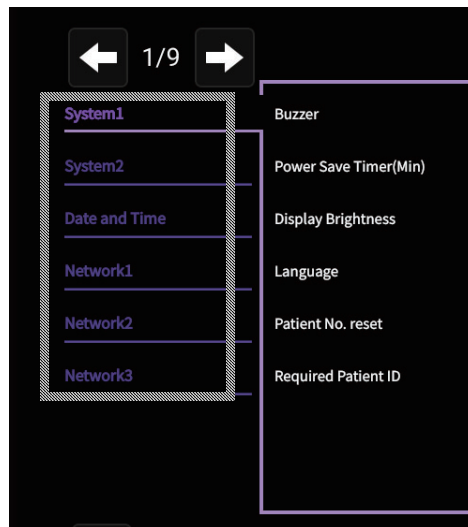


OUTLINE OF SETUP SCREEN OPERATIONS

- 1 Use the **Next page** button and **Back page** button to display the required page until the setting field you want to check or change is displayed in the **Index**.



- 2 Tap the **Index** and select the required setting field.



- 3 Check the display of the setting descriptions for which you want to change the setting.



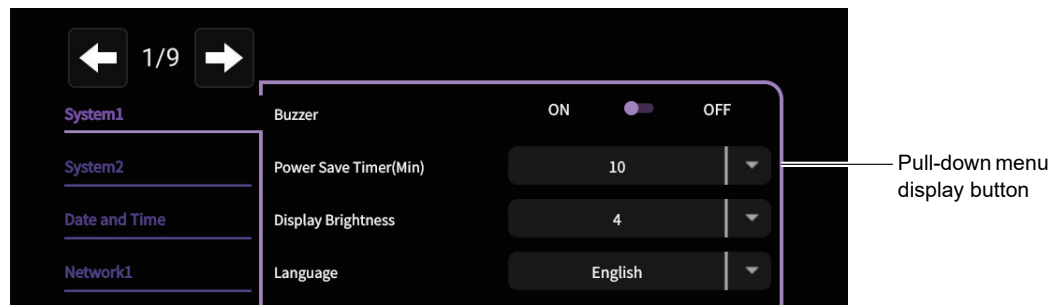
- 4 If the **ON/OFF** button appears in the Setting change operation part, tap **ON** button or **OFF** button to change the setting.



Instead of the **ON/OFF** button for the setting change operation part, the setting item may be selected from the pull-down menu. Alternatively, a numeric keypad for input (number key) and a keyboard may be displayed in a pop-up window.

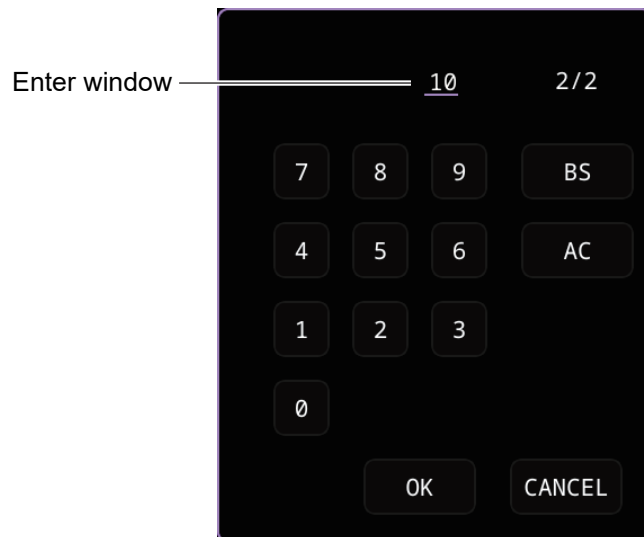
PULL-DOWN MENU:

Tap the **Pull-down menu display** button and select from the displayed pull-down menu.



NUMBER KEY:

Tap Number Key on the screen and enter the number. If there are several windows to enter, tap the window to enter the figure by Number Key. Tap the **OK** button to fix the input value.



KEYBOARD:

Tap the keyboard on the screen and enter characters. If there are several windows to enter, tap the window to enter the figure by keyboard. Tap the **OK** button to fix the entry.



5 Tap the **OK** button to fix the setting change.



NOTE

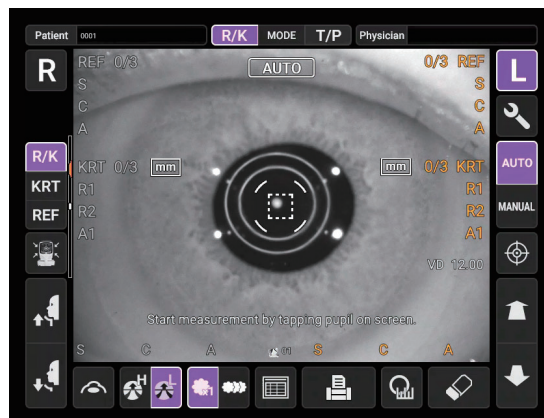
The set value is updated when the **OK** button is pressed.

RETURNING TO THE MEASUREMENT SCREEN

1 Tap the **Exit** button.



2 The Measurement screen is displayed.



LIST OF SETUP ITEMS

The setup items consist of 30 indexes over 9 pages, divided by the items to be set up.

System1

Descriptions	Options	Details	Initial value
Buzzer	OFF	Buzzer (operation sound) does not sound.	
	ON	Buzzer (operation sound) sounds.	✓
Power Save Timer (Min)	OFF	Power save function is not used.	
	1	Power save status in 1min. after last operation.	
	5	Power save status in 5min. after last operation.	
	10	Power save status in 10min. after last operation.	✓
	20	Power save status in 20min. after last operation.	
	30	Power save status in 30min. after last operation.	
	60	Power save status in 60min. after last operation.	
Display Brightness	1	The brightness of control panel is set up.	
	2		
	3		
	4		✓
	5		
Language	English	Set language to English	✓
	Japanese	Set language to Japanese	
Patient No. reset	OFF	Patient No. is not reset upon power on.	✓
	ON	Patient No. is reset upon power on.	
Required Patient ID	OFF	Patient ID is not required.	✓
	ON	Patient ID is required.	

System2

Descriptions	Options	Details	Initial value
Device ID number	1-99 Set by number display	Sets the Device ID number.	01
Show ID number	OFF	Device ID is not displayed.	✓
	ON	Device ID is displayed.	
Date style	YMD	Print in Year/Month/Day format.	
	MDY	Print in Month/Day/Year format.	✓
	DMY	Print in Day/Month/Year format.	
Factory data Reset	Execute	All setting is reset to the factory default settings, and stops. Patient number is reset to 1. After the execution, please turn the power on again.	–

Date and Time

Descriptions	Options	Details	Initial value
Date and Time (YMD)	Set by number display	Sets date and time in Year/ Month/ Day Hour: Minute: Second format.	Installation date/ time

Function(Common)1

Descriptions	Options	Details	Initial value
Meas. Start: A/M Select	Manual	Default measurement mode is Manual.	
	Auto	Default measurement mode is Auto.	✓
Meas. Start: Mode Select	RK→TP	Default measurement mode is R/K→T/P continuous measurement.	✓
	R/K	Default measurement mode is R/K measurement.	
	T/P	Default measurement mode is T/P measurement.	
Meas. Start: Keep Prev. Mode	INIT	Mode is applied according to the following setting at the time of starting measurement: "Mode selection at Function(Common)1/Measurement start" "Mode selection at Function(T/P)1/Measurement start"	✓
	PREV	Measurement mode set by "MODE button" is applied at the time of starting measurement.	
Change to M by lever	OFF	Even if using control lever, auto mode function is available under control lever operation.	
	ON	If touching control lever, change to the manual mode automatically.	
	Semi-auto	By operating the control lever before tapping near the pupil in auto mode (starting measurement in auto mode), it is possible to add the auto mode operation of the instrument to the manual operation by the operator.	✓
Chinrest height	High	Sets the chinrest position at the time of startup.	
	Center		
	Low		✓
R/L notation	R/L	Right/left eyes is displayed by R/L.	✓
	OD/OS	Right/left eyes is displayed by OD(R)/OS(L).	
Meas. Start: Standby Pos.	RIGHT	Waiting at the initial position for right eye measurement.	✓
	LEFT	Waiting at the initial position for left eye measurement.	
	LAST	Waiting at the last position of the measured eye.	
Pupil distance	58mm 60mm 62mm 64mm 66mm 68mm 70mm 72mm 74mm Set by pull-down menu display button.	Sets the pupil distance between right and left eyes. (Setting is required when R/L mode is "Full Auto" or "Auto (RL)".)	68mm

Function(Common)2

Descriptions	Options	Details	Initial value
Auto Shoot	OFF	Measurement does not start automatically when the position is measurable in manual mode.	
	ON	Measurement starts automatically when the position is measurable in manual mode.	✓
Stand by screen	Standard Angle	Set the Standby screen to the Standard Angle.	✓
	Wide Angle	Set the Standby screen to the Wide Angle.	

Function(R/K)1

Descriptions	Options	Details	Initial value
Cont. Cycle	1-10 Set by number display	The number of continuous measurements.	3
Add Measure	0-99 Set by number display.	When the measurement is error, set the number of times of remeasurement.	1
Continuous fog	Every time	Continuous fog is applied every time.	
	Once	Continuous fog is applied only once before the 1st measurement.	✓
R/L mode	Manual	The other eye button is used to manually switch between right and left eyes in continuous measurement mode.	
	Full Auto	Right and left eye switching is automatically performed in continuous measurement mode before measurement.	✓
	Auto (RL)	Right and left eye switching is automatically performed in continuous measurement mode, but no measurement is performed.	
Touch Measure	OFF	Touch measurement is not performed in Manual mode.	
	ON	Touch measurement is performed in Manual mode.	✓
Sph/Cyl step	0.12	Sph/Cyl is displayed by 0.12D step.	
	0.25	Sph/Cyl is displayed by 0.25D step.	✓
Axis step	1	Axial angle is displayed by 1° step.	✓
	5	Axial angle is displayed by 5° step.	
Cylinder sign	-	Cylinder sign is "-".	✓
	+	Cylinder sign is "+".	
	MIX	Cylinder sign is "-" and "+".	

Function(R/K)2

Descriptions	Options	Details	Initial value
Model Eye Measure Mode	Execute	Clears the measurement value and transitions to measurement standby for model eye measurement.	-
Eyelid function	OFF	Disables the eyelid function.	
	ON	Enables the eyelid function.	✓
Eyelid Force Meas. time	0-99 Set by number display.	Set the time [Second] from when the eyelid detection message is displayed until the forced measurement starts.	99

Function(REF)

Descriptions	Options	Details	Initial value
VD	0.00	VD value is set to 0mm (contact lens).	
	12.00	VD value is set to 12.00mm (eyeglass lens).	
	13.75	VD value is set to 13.75mm (eyeglass lens).	✓
REF average	OFF	REF average is not displayed.	✓
	ON	REF average is displayed.	

Function(KRT)

Descriptions	Options	Details	Initial value
D or mm	D	D (diopter) of corneal refractive power.	
	mm	mm of corneal curvature.	✓
HV or R1R2	HV	Corneal curvature radius measurement result on screen is displayed by HV.	
	R1R2	Corneal curvature radius measurement result on screen is displayed by R1R2 (flat/steep meridian).	✓
KRT Display Unit	OFF	KRT unit is not shown.	
	ON	KRT unit is shown.	✓

Function(T/P)1

Descriptions	Options	Details	Initial value
Meas. Start: Measure Mode	TONO	TONO is selected for the measurement mode at the start of T/P measurement when "Meas. Start: Keep Prev. Mode" is INIT.	
	T/P	TONO/PACHY is selected for the measurement mode at the start of T/P measurement when "Meas. Start: Keep Prev. Mode" is INIT.	✓
R/L mode	Manual	The other eye button is used to manually switch between right and left eyes in continuous measurement mode.	
	Full Auto	Right and left eye switching is automatically performed in continuous measurement mode before measurement.	✓
	Auto (RL)	Right and left eye switching is automatically performed in continuous measurement mode, but no measurement is performed.	
Touch Measure	OFF	Touch measurement is not performed in Manual mode.	
	ON	Touch measurement is performed in Manual mode.	✓
IOL LED Brightness	0-100 Set by number display	Sets brightness of alignment dot in IOL mode.	28
Meas. Data recording way	Data on credibility	Measurement data is displayed in the order from low to high credibility.	
	Data without error	The measurement data without error is displayed.	
	Data with error	All the measurement data (including data with error) is displayed.	✓

Function(T/P)2

Descriptions	Options	Details	Initial value
Auto Contact Avoidance	OFF	The measurement nozzle does not stop automatically when it approaches the patient.	
	ON	Automatically stops operation when the nozzle approaches the patient.	✓
Meas. Count change mode	1×	Sets the Meas. Count change mode at the start of measurement to one-time measurement.	
	Multi	Sets the Meas. Count change mode at the start of measurement to the preset number of measurements.	✓

Function(TONO)

Descriptions	Options	Details	Initial value
Cont. cycle(TONO)	1-10 Set by number display	The number of continuous measurements (TONO).	3
Show Tono average	OFF	Tono average value is not displayed.	
	ON	Tono average value is displayed.	✓
Tono display Unit	mmHg	Display in mmHg	✓
	digit	Display in digit	
	hPa	Display in hPa	
	Torr	Display in Torr	
Press average Mode	Integer	Displays the average intraocular pressure value as an integer.	✓
	Real	Displays the average intraocular pressure value as a real number.	
Low Credibility Measure	No Including	The value of low credibility is excluded from count cycle.	
	Including	The value of low credibility is included to count cycle.	✓

Function(PACHY)

Descriptions	Options	Details	Initial value
Cont. cycle (PACHY)	1-10 Set by number display	The number of continuous measurements (PACHY).	3
Pachy display Unit	mm	Display in mm	✓
	µm	Display in µm	

Printer(Common)1

Descriptions	Options	Details	Initial value
Printer	OFF	Internal printer is disabled.	
	ON	Internal printer is active.	✓
Auto Print	OFF	Data is not automatically printed out after the continuous measurement mode is completed.	
	ON	Data is automatically printed out after the continuous measurement mode is completed.	✓
Barcode	OFF	Barcode is not printed.	✓
	ON	Barcode is printed.	
Physician ID	OFF	Physician ID is not printed.	✓
	ON	Physician ID is printed.	
Name	OFF	"Name" space is not available.	
	ON	"Name" space is available.	✓
Date	OFF	Date is not printed.	
	ON	Date is printed.	✓
Patient No/Patient ID	OFF	Patient No. / Patient ID is not printed.	
	ON	Patient No. / Patient ID is printed.	✓

Printer(Common)2

Descriptions	Options	Details	Initial value
Device ID number	OFF	Device ID number is not printed.	✓
	ON	Device ID number is printed.	
Serial number	OFF	Serial No. is not printed.	
	ON	Serial No. is printed.	✓
TOPCON logo	OFF	TOPCON logo is not printed.	
	ON	TOPCON logo is printed.	✓
Message	OFF	Message is not printed.	✓
	ON	Message is printed.	
Message data	Set by keyboard display	String of up to 72 characters.	NULL
Line space	0-24 Set by number display	Line space is set in dot units.	0
Auto Cut	OFF	Printed out printer paper is not automatically cut.	
	ON	Printed out printer paper is automatically cut.	✓

Printer(R/K)1

Descriptions	Options	Details	Initial value
Preset (All)	Execution	Print format of preset is All. Refer to page 24 for details on the presetting.	
Preset (Avg)	Execution	Print format of preset is Avg. Refer to page 24 for details on the presetting.	
Preset (Classic)	Execution	Print format of preset is Classic. Refer to page 24 for details on the presetting.	
Print order	R/L	Both REF and KRT measurement value are printed in order of right eye and left eye.	
	DATA	Measurement values are printed in terms of REF or KRT.	✓
Include error data	OFF	"Error" data is not printed.	✓
	ON	"Error" data is printed.	
VD	OFF	VD (Vertex distance) value is not printed.	
	ON	VD (Vertex distance) value is printed.	✓
Cylinder sign	OFF	Cylinder sign is not printed.	
	ON	Cylinder sign is printed.	✓
REF format	ALL	All the measurement value is printed.	✓
	AVG	Only averaged is printed.	

Printer(R/K)2

Descriptions	Options	Details	Initial value
S.E.	OFF	S.E.is not printed.	
	ON	S.E. is printed.	✓
PD	OFF	PD (pupil distance) value is not printed.	
	ON	PD (pupil distance) value is printed.	✓
KRT print order	D/mm	KRT data is printed as follows, D (corneal refractive power)/mm (corneal curvature).	✓
	mm/D	KRT data is printed as follows, mm (corneal curvature)/D (corneal refractive power).	
KRT format	ALL	All the measurement value is printed.	✓
	AVG	Only the average values are printed.	
KRT style	HV	Kerato style in print out is HV (horizontal/vertical).	
	R1R2	Kerato style in print out is R1R2 (flat/steep meridian).	✓
KRT print format	HV	KRT measurement result is printed in HV (horizontal/vertical).	
	R1R2	KRT measurement result is printed in R1 R2 (flat/steep meridian).	✓
KRT average	OFF	KRT average value is not printed.	
	ON	KRT average value is printed.	✓

Printer(R/K)3

Descriptions	Options	Details	Initial value
CYL	OFF	Does not print the difference in refraction between R1 and R2 and its axial direction.	
	ON	Prints the difference in refraction between R1 and R2 and its axial direction.	✓
Cornea diameter	OFF	Does not print the cornea diameter.	
	ON	Print the cornea diameter.	✓

Printer(REF)

Descriptions	Options	Details	Initial value
VD	OFF	VD (Vertex distance) value is not printed.	
	ON	VD (Vertex distance) value is printed.	✓
Cylinder sign	OFF	Cylinder sign is not printed.	
	ON	Cylinder sign is printed.	✓
REF format	ALL	All the measurement value is printed.	✓
	AVG	Only average is printed.	
S.E.	OFF	S.E.is not printed.	
	ON	S.E. is printed.	✓
PD	OFF	PD (pupil distance) value is not printed.	
	ON	PD (pupil distance) value is printed.	✓

Printer(KRT)

Descriptions	Options	Details	Initial value
KRT print order	D/mm	KRT data is printed as follows, D (corneal refractive power)/mm (corneal curvature).	✓
	mm/D	KRT data is printed as follows, mm (corneal curvature)/D (corneal refractive power).	
KRT format	ALL	All the measurement value is printed.	✓
	AVG	Only the average values are printed.	
KRT style	HV	Kerato style in print out is HV (horizontal/vertical).	
	R1R2	Kerato style in print out is R1R2 (flat/steep meridian).	✓
KRT print format	HV	KRT measurement result is printed in HV (horizontal/vertical).	
	R1R2	KRT measurement result is printed in R1 R2 (flat/steep meridian).	✓
KRT average	OFF	KRT average value is not printed.	
	ON	KRT average value is printed.	✓
CYL	OFF	Does not print the difference in refraction between R1 and R2 and its axial direction.	
	ON	Prints the difference in refraction between R1 and R2 and its axial direction.	✓
Cornea diameter	OFF	Cornea diameter is not printed.	
	ON	Cornea diameter is printed.	✓

Printer(T/P)

Descriptions	Options	Details	Initial value
Printer order	R/L	The order is right eye and left eye regardless of the TONO measurement value and PACHY measurement value.	
	DATA	TONO measurement value and PACHY measurement value are separately printed.	
	SIMPLE	Print in the SIMPLE format.	✓
mmHg Display on hPa	OFF	mmHg is not printed on hPa.	
	ON	mmHg is printed on hPa.	✓

Physician ID

Descriptions	Options	Details	Initial value
Use Physician ID	OFF	Physician ID is not used.	✓
	ON	Physician ID is used.	
Physician ID request	OFF	Physician ID is not required.	✓
	ON	Physician ID is required.	
Fixed Physician ID	OFF	Physician ID is not fixed.	✓
	ON	Physician ID is fixed.	
Input Fixed Phy. ID	20 characters Set by keyboard display	Input fixed physician ID.	NULL

DICOM

Descriptions	Options	Details	Initial value
MWL Enable	Enable	Use MWL.	
	Disable	Dose not use MWL.	✓
MWL Display Column (Requested Procedure ID)	Enable	Use Requested Procedure ID.	
	Disable	Dose not use Requested Procedure ID.	✓
MWL Display Column (Scheduled Procedure Step Start Date)	Enable	Use Scheduled Procedure Step Start Date.	
	Disable	Dose not use Scheduled Procedure Step Start Date.	✓
MWL Display Column (Scheduled Procedure Step Description)	Enable	Use Scheduled Procedure Step Description.	
	Disable	Dose not use Scheduled Procedure Step Description.	✓
AE Title	Set in keyboard display	Set the AE title on the TRK-3 side with a string of up to 16 characters.	NULL
Modality	AR	Set up AR.	
	DOC	Set up DOC.	
	KER	Set up KER.	
	OT	Set up OT.	✓
TLS Protocol	Enable	Use TLS Protocol.	
	Disable	Does not use TLS Protocol.	✓

DICOM MWL Server

Descriptions	Options	Details	Initial value
AE Title	Set in keyboard display	Set the AE title for MWL Server with a string of up to 16 characters.	NULL
IP Address	Set in numeric keypad display	Set the IP address of the MWL Server.	0.0.0.0
Port	1~65535 Set in numeric keypad display	Set the port number of the MWL Server.	63001
Use AE Title as a Query Condition	Enable	Use AE Title as a Query Condition.	
	Disable	Dose not use AE Title as a Query Condition	✓
Use Modality as a Query Condition	Enable	Use Modality as a Query Condition.	
	Disable	Dose not use Modality as a Query Condition.	✓
Use Today as a Query Condition	Enable	Use Today as a Query Condition.	✓
	Disable	Dose not use Today as a Query Condition.	
Use Forward Match Query	Enable	Use Forward Match Query.	✓
	Disable	Dose not use Forward Match Query.	
Verification	Execution	Perform an interaction check.	

Basic

Descriptions	Options	Details	Initial value
Serial No	-	Serial No is displayed.	-
Region Code	-	Region Code is displayed.	-
System	-	Version of the system is displayed.	-


System Version

Descriptions	Options	Details	Initial value
Main Application	–	Version of the main application is displayed.	–
GUI	–	Version of the GUI application is displayed.	–

Export

Descriptions	Options	Details	Initial value
Setting File	Export	Setting File is exported to the external USB device. Follow the message for operation.	–
System Log	Export	System Log is exported to the external USB device. Follow the message for operation.	–

MAINTENANCE

 CAUTION	To prevent damage and injury, do not install the instrument on an uneven, unsteady or sloped surface.
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MAINTENANCE CHECKUPS

Maintenance of this instrument includes maintenance items by the user and maintenance items by the manufacturer.

USER MAINTENANCE ITEMS

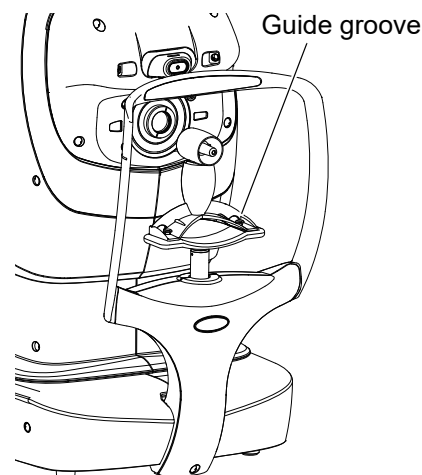
Item	Inspection time	Contents
Inspection	Before using	<ul style="list-style-type: none"> • The instrument works properly. • The measuring window must be free of stains and/or flaws. • Confirm whether the foreign object is attached to the measuring nozzle and the area around the measuring nozzle. • Air check • Confirm that the safety stopper setting and measuring nozzle do not move to the patient's side beyond the safety stopper setting position.
Cleaning	When the part is stained	<ul style="list-style-type: none"> • Measuring window • Instrument cover, control panel, etc.
Replacement	As required	<ul style="list-style-type: none"> • Printer paper

MANUFACTURER MAINTENANCE ITEMS

Item	Checking time	Contents
Cleaning each component	Within 12 months	<ul style="list-style-type: none"> • Cleaning outer covers • Cleaning the optical system • Cleaning Power supply unit
Operation check	Within 12 months	<ul style="list-style-type: none"> • Checking the main body operation • Checking for looseness of the chinrest unit
Accuracy check	Within 12 months	<ul style="list-style-type: none"> • Confirming the intraocular pressure measurement functions (using special tools) • Confirming the cornea thickness measurement functions (using special tools)

INSPECTION OF MEASUREMENT ACCURACY

- When using, measure the attached model eye and check the accuracy.
- How to set the model eye
Insert the guide groove of the model eye into the chinrest tissue pin.
- Set the display step of spherical/cylindrical refractive power to 0.12D and measure.



NOTE

If the measurement result is significantly different from the value displayed on the model eye, call your dealer or TOPCON at the address printed on the back cover of this manual.

MAINTENANCE AFTER USE

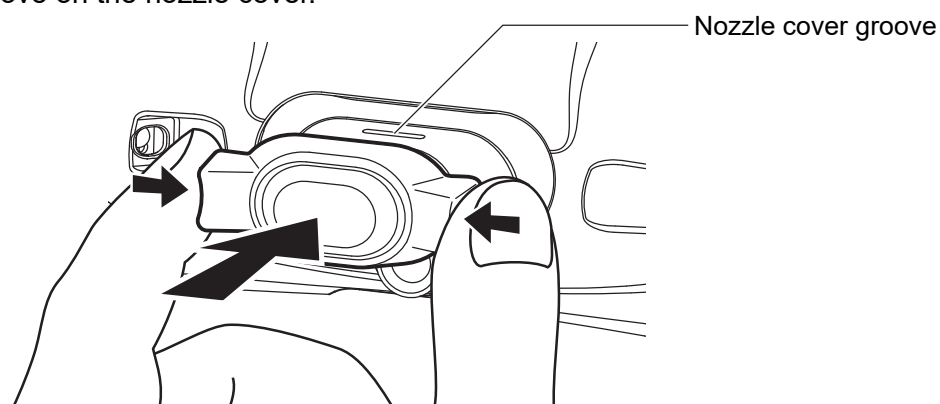
- After using, refer to “HOW TO CLEAN THIS INSTRUMENT” on page 112.
- For this instrument, dust may cause errors. When not in use, replace the measuring window cap and dust cover.
- Change the chinrest tissue every time the patient changes.
- When not in use, turn off the POWER switch.

NOTE

When using the dust cover, tap the button and move the chinrest and measuring head to their last positions.

ATTACH THE INTRAOCULAR PRESSURE MEASURING WINDOW CAP

- Pinch the left and right protrusions of the intraocular pressure measuring window cap and place it over the nozzle cover.
- At this time, make sure that the claw on the inside of the intraocular pressure measuring window cap fits into the groove on the nozzle cover.



NOTE


- When attaching and removing the intraocular pressure measuring window cap, do not apply any load to the measuring nozzle.
- If strong force is applied to the measuring nozzle, the measuring nozzle may bend.


HOW TO CLEAN THIS INSTRUMENT

CLEANING THE COMPONENTS THAT COME INTO CONTACT WITH THE PATIENT/OPERATOR

- Clean with clean gauze soaked in rubbing alcohol before and after use and every time the patient/operator changes.
- If it is extremely dirty, dissolve the neutral detergent for tableware in lukewarm water, squeeze a cloth soaked in it, and wipe it.


CLEANING THE INSTRUMENT COVER

 CAUTION	Do not use or apply any aerosol-type cleaner near the instrument. If a drop of cleaner remains inside the measuring nozzle, the patient's eye may be injured during measurement.
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 NOTE	Do not clean plastic parts with solvents. Benzine, thinner, ether and gasoline may cause discoloring and decomposition.
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- 1** If the instrument cover, control panel, etc. get soiled, wipe the surface clean with a dry cloth.
- 2** If the instrument cover is noticeably stained, wipe the surface with a damp cloth which is moistened in a tepid water solution of neutral detergent.

CLEANING THE CONTROL PANEL

 NOTE	<ul style="list-style-type: none">• Since the control panel screen is a touch panel, be sure to turn off the POWER switch before wiping. The touch panel responds and the instrument malfunctions.• When the monitor cleaner has become dirty, wash it. When washing, rinse it thoroughly so no detergent is left. If any detergent remains, it may cause uneven wiping.
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CONTAMINATION BY DUST

Remove the dust with a soft brush, and wipe with the attached monitor cleaner.

CONTAMINATION BY FINGERPRINTS

Wipe with the attached monitor cleaner.

If the stain still remains, moisten the monitor cleaner with water and then wipe off the stain.


CLEANING THE MEASURING WINDOW


Cleaning the REF/KRT measuring window

- When foreign matters adhere to the measuring window
Blow off the foreign matters with a blower.
- When fingerprints or foreign matters adhere to the measuring window
Blow off the foreign matters with a blower and lightly wipe the surface with camera lens cleaner on a clean gauze.

CLEANING THE INTRAOCULAR PRESSURE MEASURING WINDOW GLASS

To secure auto alignment and correct measurement values, clean the intraocular pressure measuring window glass after each day's work.

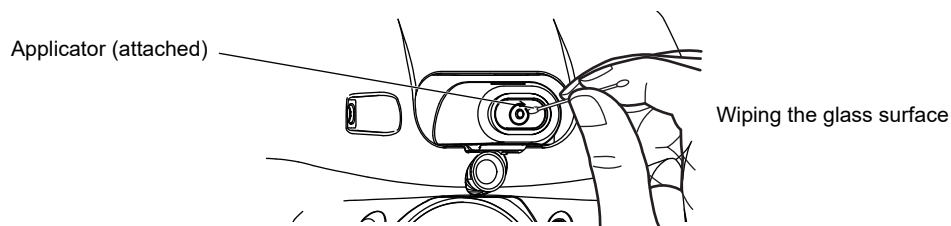
 CAUTION	To clean the intraocular pressure measuring window glass, measuring nozzle and the glass inside the measuring nozzle, use absolute ethanol(99.5%). Using other chemicals may cause damage to the patient's eye during measurement.
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 NOTE	<ul style="list-style-type: none">• Do not apply unreasonable force to the measuring nozzle while cleaning.• Be sure to use only the attached applicator.
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- 1** Blow air to the glass surface of the intraocular pressure measuring window using a blower which is a standard accessory of TRK-3 OMNIA to remove foreign matters first.
- 2** When fingerprints or foreign matters adhere to the intraocular pressure measuring window, prepare absolute ethanol (Concentration:99.5%).
- 3** Immerse the tip of an applicator which is also a standard accessory in absolute ethanol (Concentration:99.5%) for 5 seconds.



- 4** Wipe the glass surface lightly from the center outward with the applicator moistened with absolute ethanol to remove foreign matters.




- 5** Using a new applicator, repeat "method 3" and "method 4" five times (use a new applicator each time).


 NOTE	To ensure thorough removal of foreign matters from the intraocular pressure measuring window glass, be sure to replace the applicator and use a new one for each of these repeated wiping operations.
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- 6** Wipe the glass surface lightly from the center outward with a new dry applicator. Repeat this five times to completely dry moisture of the ethanol (use a new dry applicator each time).
- 7** The Cleaning is completed when foreign matters is thoroughly removed.
If stains cannot be removed easily, call your dealer.

CLEANING THE MEASURING NOZZLE AND THE GLASS INSIDE THE MEASURING NOZZLE

- If there is any foreign matter on or around the measuring nozzle, it may enter and damage the patient's eye during the measurement. If there is any, clean the measuring nozzle.
- When the glass inside the measuring nozzle becomes stained, it makes the fixation target unclear, causing errors in auto alignment and measurement values. If the fixation target is unclear or measurement values with parentheses are frequent, clean the glass inside the measuring nozzle.


 CAUTION	<p>To clean the intraocular pressure measuring window glass, measuring nozzle and the glass inside the measuring nozzle, absolute ethanol(99.5%). Using other chemicals may cause damage to the patient's eye during measurement.</p>
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 NOTE	<ul style="list-style-type: none"> • Do not apply unreasonable force to the measuring nozzle while cleaning. • To avoid problems, do not leave the cotton fibers inside. • Be sure to use only the attached applicator.
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- 1** Prepare absolute ethanol (Concentration:99.5%) .
- 2** Immerse the tip of an applicator in absolute ethanol (Concentration:99.5%) for 5 seconds.
- 3** Insert the applicator into the measuring nozzle, lightly touch the glass surface inside the measuring nozzle, and turn the applicator five times to remove foreign matters.



- 4** Using a new applicator, repeat “method 2” and “method 3” five times (use a new applicator each time).

 NOTE	<p>The used applicator contains foreign matters and it only scatters foreign matters if used again; the light transmittance is not improved at all. Be sure to replace the applicator and use a new one for each of these repeated cleaning operations.</p>
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- 5** Insert a new dry applicator into the measuring nozzle and wipe the measuring nozzle lightly five times to completely dry moisture of the ethanol.

6 If the fixation target is clearly seen, cleaning is completed. If stains cannot be removed easily, call your dealer.



NOTE

- When the glass inside the measuring nozzle becomes stained, it makes the fixation target unclear. "Alignment operation stopped for patient's safety. Check positional relations between patient's eyes and measuring head. (E17001)" is displayed on the control panel screen during use.
- Cleaning of external input / output device
Clean according to each instruction manual.

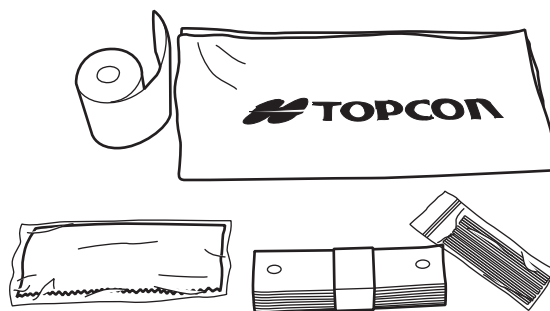
ORDERING CONSUMABLE ITEMS

ORDERING CONSUMABLE ITEMS

When ordering consumable items, tell the product name, product code and quantity to your dealer or TOPCON at the address listed on the back cover.

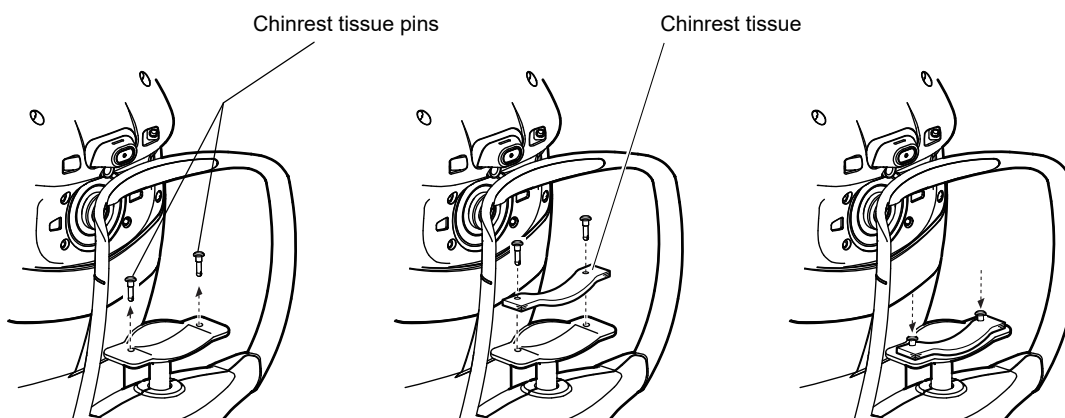
Product name	Product code
Chinrest tissue	403104082
Monitor cleaner	448001001
Dust cover	404969011

Product name	Product code
Applicator	416018606
Printer paper	448004001



REPLACING THE CHINREST TISSUE

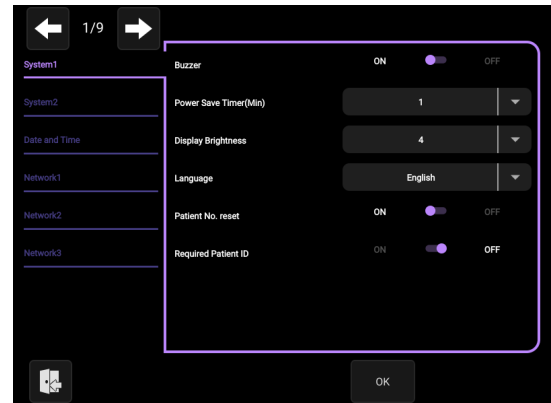
When the chinrest tissue has run out, pull off the chinrest tissue pins and replace it with new chinrest tissue.



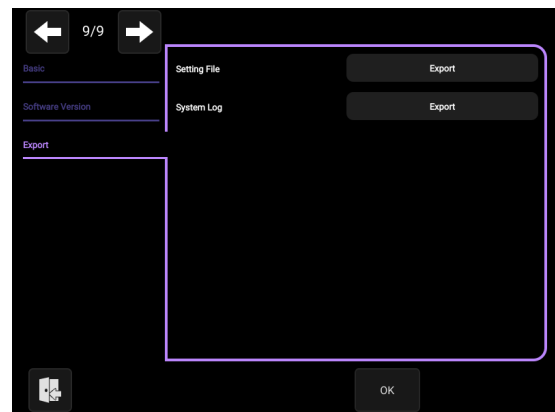
DEVICE LOG INFORMATION

Logs can be exported to a maintenance USB flash drive designated by Topcon.

1 Shifts to the setting menu screen.



2 Tap the [Export] button of “System Log” listed in “Export” on page 9/9.



TROUBLESHOOTING

MESSAGE LIST

Initializing. Please wait...	Displayed when the main unit is being initialized at startup.
Printer device might not be under normal operations after initialization. Tap OK if using without printer. Else, please reboot off/on system. (E01003)	An error has occurred with the built-in printer. The printer may not be working properly, but you can continue to use it. Even if you want to continue using the instrument, please contact your service personnel as soon as possible.
Failure to start network connection. Check network cable and connection settings. (E01004)	Displayed when the initialization of the network connection fails. Check if the LAN cable connection and network settings are correct.
System detected to not be under normal operations after initialization. Please reboot off/on system. (E01005)	Displayed when there is a problem with the internal storage. Please turn the power of the main unit off and then on again. If this message is displayed repeatedly even after turning the power off and then on again, contact your service personnel.
System detected to not be under normal operations after initialization. Please reboot off/on system. (E01101)(E01102)(E01103)	Displayed when the connection between the auto-alignment sensor and this instrument is abnormal or not connected. Please turn the power of the main unit off and then on again. If this message is displayed repeatedly even after turning the power off and then on again, contact your service personnel.
Chin rest failed to work properly. Please reboot off/on system. (E01104)	Displayed when the connection between the chinrest and this instrument is abnormal or not connected. Please turn the power of the main unit off and then on again. If this message is displayed repeatedly even after turning the power off and then on again, contact your service personnel.
For the safety of the patient, please be sure to set the safety stopper before measuring. Will this message be displayed at startup from the next time?	Displayed to prompt the setting of the safety stopper. Set the safety stopper.
System detected to not be under normal operations after initialization. Please reboot off/on system. (E01202)	Displayed when the connection between the target fixation sensor and the device is abnormal or not connected. Please turn the power of the main unit off and then on again. If this message is displayed repeatedly even after turning the power off and then on again, contact your service personnel.
Checking air pressure used for TONO measurement. Air will come out of nozzle three times. Avoid putting face on chin rest until complete.	Check the air pressure used for TONO measurement. Air comes out of the measuring nozzle three times. Please do not put face on chinrest until complete.
Return measuring head to central position and turn off power?	Displayed to prompt confirmation whether to move the chinrest and the measurement head to their last positions.
End of operation in progress. Please wait until complete.	Displayed that the end operation is in progress.
End of operation complete. Please turn power off on unit.	Displayed when the end operation is completed.
Measurement complete.	Displayed when normal measurement is completed for the set number of times.

Start measurement by tapping pupil on screen.	Displayed when "Full Auto" measurement is possible. Tap the pupil to start measurement automatically.
Ready to measure.	Displayed when measurement can be performed in Manual mode.
Tap measurement position to measure after manual focus.	Displayed as instruction of the measurement procedure in manual mode. Tap the measuring head forward/backward button to adjust the measuring head position, and then tap the measurement point.
Press button on control lever to measure, after manual adjustment.	When "Touch measure" in "Function(R/K)1" on the Setup screen (3/9) and "Function(T/P)1" on the Setup screen (4/9) is "OFF", it is displayed as instruction of the measurement procedure in manual mode. Tap the measuring head forward/backward button to adjust the measuring head position, and then tap the start button.
Auto alignment is progress. Please wait a moment.	Displayed while auto-alignment is performed in R/K and T/P measurement modes.
Alignment error occurred. Focus manually and tap pupil on screen to restart measurement. (E03003)	Displayed when the XYZ positions are not aligned. Tap the measuring head forward/ backward button to adjust the measuring head position, and then tap the pupil again to align the pupil with the center of the screen.
Measurement interrupted due to covering eyelids of patient. Try again with patient's eyes wide open. (E03004)	Displayed when the patient's eyelids cover the pupil. Tell the patient to open their eyes as wide as possible.
Alignment stopped. Tap pupil on screen to continue measurement.	Displayed when Alignment stop button is tapped.
Reaching set limit of stopper. Move measuring head.	Displayed when the measuring head position has reached the safety stopper.
Check eyelid.	Displayed when the subject's eyelid is over the pupil. Instruct the subject to keep the eye open wider.
Focus error occurred. Focus forward/backward manually and tap pupil on screen to restart measurement. (E03008)	Displayed when the Z position cannot be detected in T/P measurement mode. Tap the measuring head forward/backward button to adjust the measuring head position, and then tap the pupil again on the screen to bring it to the center of the screen.
NEAR LIMIT	Displayed when the measuring head is too close to the patient's eye. Move the instrument as far from the patient's eye.
TOO CLOSE	Displayed when the measuring head is too close to the patient's eye. Move the instrument as far from the patient's eye.
FAR LIMIT	Displayed when the measuring head is too far from the patient's eye. Move the instrument as close to the patient's eye.
Measurement mode cannot be established. Select one or more of REF / KRT / TONO / PACHY. (E05001)	None of the measurement modes, REF / KRT / TONO / PACHY, is selected. Select one or more of REF / KRT / TONO / PACHY.
KRT measurement in progress.	Displayed while measuring the cornea curvature radius.
REF measurement in progress.	Displayed while measuring the spherical refractive power.
PACHY measurement in progress.	Displayed while measuring cornea thickness measurement.
TONO measurement in progress.	Displayed while measuring the intraocular pressure measurement.
Please tap the camera icon.	Displayed when the image for corneal diameter measurement can be taken with alignment.
Measurement stopped. Tap pupil on screen to continue.	Displayed when measurement is stopped during measurement. If you want to continue the measurement, tap the pupil again.

Start alignment by tapping pupil on screen.	Displayed on the Capture screen for corneal diameter measurement. Tap the pupil on the screen if you need alignment.
Change of measurement head position in progress (R/L).	Displayed while switching the measurement target eye of the measuring head.
Safety stopper set out of range. Change to within 0 mm to 30 mm. (E09001)	Displayed when the Z-axis position when the OK / Apply button is pressed is outside the range of 0 mm to 30 mm on the safety stopper screen. Please set within the range.
Check air pressure used for TONO measurement? NOTE: Air comes out of nozzle.	Displayed for confirmation of whether to perform an air check.
Air pressure used for TONO measurement OK.	Displayed when the normal operation of the air check is confirmed. Press the OK button.
Air pressure detected out of standard performance. Check and clean measuring nozzle before trying again. Refer to manual for cleaning instructions. (E09103)(E09104)	Displayed when an anomaly occurred during air check. Check the measuring nozzle for any foreign matter.
MANDATORY field missing: Patient ID. (E09201)	Displayed when "Required Patient ID" of "System 1" on the Setup screen (1/9) is set to "ON" and trying to output without inputting the patient ID. Enter the patient ID before outputting.
MANDATORY field missing: Physician ID. (E09202)	Displayed when "Physician ID request" of "Physician ID" on the Setup screen (7/9) is set to "ON" and trying to output without inputting the physician ID. Enter the physician ID before outputting.
Printer paper end. Refill if necessary and try again.	Printer paper is used up. Supply printer paper.
Close the printer cover before the measurement.	The printer cover is open. Close the cover until it clicks.
Data output via the network...please wait for a while.	Displayed while outputting data via the network.
Data output via network complete.	Displayed when the output of data via the network is completed.
Confirm setting "Preset(All)"? Note: This sets printing out all measured results.	Set the print settings of the built-in printer to All format.
Confirm setting to "Preset(Avg)"? Note: This prints out only average measuring results.	Set the print settings of the built-in printer to Avg format.
Confirm setting "Preset (Classic)"? Note: This changes print out of the measuring result form of equivalent to conventional RM KR-8900 Classic2.	Set the print settings of the built-in printer to Classic format.
No data to output.	Displayed when there is no data to be output while attempting manual printing with the printer set to OFF.

Output data settings not set. Confirm settings.	Displayed when all output settings are OFF. Confirm that the output setting is in the correct way.
Printer failure. Turn off/on unit and try again. (E10010)	Displayed when the printer unit does not move normally, such as when the cutter does not move, so call your service personnel.
Error occurred during printer output. Check that the printer cover is not open. After checking, output the data again. (E10011)	Displayed when an error occurs during printer output. Check to see if the printer cover is open and try outputting again.
Error occurred during printer output. The printer ran out of paper. Please refill the paper and output again. (E10012)	Displayed when an error occurs during printer output. Refill the printer paper and output again.
Please wait until the next measurement is ready.	Displayed during initialization of measurement data and measurement environment. Please wait.
The data has been cleared because no operation has been performed for a certain period of time. When the OK button is tapped, the measuring head moves. Please be careful.	Displayed when the power save is triggered when a measurement is performed or when the patient ID is set. Pressing the OK button initializes the measurement environment.
Change in settings detected and are not saved. Confirm to discard settings to exit screen.	Not saved after changing the settings. To cancel the setting and exit from the Setting screen, press the OK button.
There is data being edited. Do you want to discard it?	After adjusting the alignment bar in the Corneal Diameter Measurement screen, the Measure button was not pressed, or after adjusting the safety stopper position in the Safety Stopper screen, the Apply button was not pressed. If you want to discard the adjusted value, press the OK button.
Applying network settings. Please wait for a moment.	Displayed when the connection settings are being applied due to a change made to the network settings.
Incorrect setting value (1-223 for first octet). (E12002)	Displayed when the first octet of "IP address", "Default gateway", "Primary DNS server" or "Secondary DNS server" of "Network 3" on the Setup screen (1/9), and "IP address" of "DICOM MWL Server" on the Setup screen (8/9) is set to a value out of the specified input range. Enter a value within the input range.
Incorrect setting value. Enter value between 0 and 255 for IP address. (E12003)	Displayed when any octet other than the first octet in "IP address", "Default gateway", "Primary DNS server" or "Secondary DNS server" of "Network 3" on the Setup screen (1/9), and "IP address" of "DICOM MWL Server" on the Setup screen (8/9) is set to a value out of the specified input range. Enter a value within the input range.
Incorrect setting value. Enter value between 0 and 255 for IP address. (E12004)	Displayed when the "Subnet mask" of "Network 3" on the Setup screen (1/9) is set to a value that does not conform to the input rule. Enter a value that conforms to the "Subnet mask" input rule.
Provide valid number value NNN to NNN.	Displayed when an attempt has been made to set a value outside of the specified setting range. Enter a value within the specified input range.

<p>“Fixed Physician ID” setting is now turned on. If you want to change the Physician ID, turn off “Fixed Physician ID”.</p>	<p>Displayed when “Fixed Physician ID” of “Physician ID” on the Setup screen (7/8) is set to ON and trying to enter the physician ID. Set the Fixed Physician ID to OFF if you need to enter the physician ID.</p>
<p>Connection error(E14101)</p>	<p>Displayed in case of a network error other than errors E14102 through E14112 and E14115. Call your service personnel.</p>
<p>Duplicate IP address detected. Confirm in settings. (E14102)</p>	<p>Displayed when the IP address is duplicated. Confirm that the IP address setting of main instrument is in the correct way.</p>
<p>Cannot access network shared folder. Check LAN cable connections. (E14103)</p>	<p>The network connection cannot be confirmed. Check the LAN cable connection of the main unit, hub, and other devices.</p>
<p>File creation error(E14104)</p>	<p>Failed to create the file. Make sure that write permission of the shared folder is set correctly and that each setting value of the shared folder is set correctly.</p>
<p>File write error(E14105)</p>	<p>Failed to write the file. Make sure that free space of the shared folder and that write permission of the shared folder is set correctly.</p>
<p>Failure to start network connection. Check network cable and connection settings. (E14106)</p>	<p>Displayed when the initialization of the network connection fails. Check if the LAN cable connection and network settings are correct.</p>
<p>Failure to stop network connection. Check network cable and connection settings. (E14107)</p>	<p>Displayed when the initialization of the network connection fails. Check if the LAN cable connection and network settings are correct.</p>
<p>Failure to rebuild network connection. Check network cable and connection settings. (E14108)</p>	<p>Displayed when the initialization of the network connection fails. Check if the LAN cable connection and network settings are correct.</p>
<p>Failure to assign IP address. Change IP in setting to a fixed address or confirm DHCP server is running. (E14109)</p>	<p>Failed in IP address auto assignment. Set a fixed IP address, or check if the DHCP server is running.</p>
<p>TIMEOUT response from DHCP server. Contact local network administrator. (E14110)</p>	<p>Displayed when communication to the DHCP server fails. Please contact your network administrator of the facility.</p>
<p>NAK response from DHCP server. Contact local network administrator. (E14111)</p>	<p>Displayed when communication to the DHCP server fails. Please contact your network administrator of the facility.</p>
<p>Host name error(E14112)</p>	<p>Failed to resolve the host name of the shared folder connection destination. Confirm that entered host name or DNS server settings are correct.</p>
<p>Reconnecting with network. Please wait.</p>	<p>Failed to connect to the shared folder, network connection is resetting. After the message disappears, please tap the print out button again and output data. If the message appears repeatedly, check whether the address, folder name, user name, and password of the destination are correct.</p>
<p>Mount error(E14115)</p>	<p>The network connection cannot be confirmed. Check whether the shared folder name, user name, and password are correct. Also, check the network settings and shared folder firewall.</p>

<p>Error occurred during network setup. Check settings or connections.</p> <p>Shared Folder1 : Shared Folder2 : Shared Folder3 :</p>	<p>Displayed when any of the shared folder settings fail. Errors that occurred for each folder are displayed. Please check the network settings and connection. For details of the errors, check the description of each error.</p>
<p>Error occurred during network output. Check settings or connections. After checking, output again.</p> <p>Shared Folder1 : Shared Folder2 : Shared Folder3 :</p>	<p>Displayed when data output to any of the shared folder fails. Errors that occurred for each folder are displayed. Please check the network settings and connection. Then output again. For details of the errors, please check the description of each error.</p>
<p>Error occurred during network output. Check settings or connections. After checking, output again.</p> <p>Shared Folder1 : Shared Folder2 : Shared Folder3 :</p> <p>Rebuild: Rebuild network connection Close: Check the network settings</p>	<p>Displayed when data output to any of the shared folder fails. Errors that occurred for each folder are displayed. Please check the network settings and connection. Then output again. For details of the errors, please check the description of each error. Touching the Rebuild button will attempt to rebuild the network. However, it will not output again.</p>
<p>Alignment operation stopped for patient's safety. Check positional relations between patient's eyes and measuring head. (E17001)</p>	<p>Alignment was stopped because the measuring head was too close to the eye. Check the positional relations between the patient's measuring eyes and the measuring head.</p>
<p>Measuring operation stopped for patient's safety. Check positional relations between patient's eyes and measuring head. (E17002)</p>	<p>Measuring operation was stopped because the measuring head was too close to the eye. Check the positional relations between the patient's measuring eyes and the measuring head.</p>
<p>Measuring nozzle glass stain detected. Refer to manual for cleaning instructions. (E17101)</p>	<p>Displayed when a blot is detected on the measuring nozzle and the glass inside the measuring nozzle in T/P measurement mode. Clean the measuring nozzle and the glass inside the measuring nozzle by referring to "CLEANING THE MEASURING NOZZLE AND THE GLASS INSIDE THE MEASURING NOZZLE" on page 114.</p>
<p>The battery for the clock may be low power. Check the time setting. (E17103)</p>	<p>Displayed when the battery for the built-in clock becomes run down. - When the battery consumed, confirm the difference in time and adjust it. - When the battery becomes completely consumed, to verify whether time stopping occurred and call your service personnel.</p>
<p>Error [aaaa : bbbb cccc-dddd] Reboot by turning off/on power. (E17106)</p>	<p>Displayed when a part that is not operating normally is detected by the operation check inside the main unit. Contact your service personnel.</p>
<p>A query in progress. Please wait until complete.</p>	<p>Information is being retrieved from the server based on the entered search criteria. Please wait.</p>
<p>Not find the query location. Check the network connection. (E18002)</p>	<p>Displayed when the server is not found or when communication has timed out. Check the connection settings and attempt intercommunication check. After successful intercommunication, execute QUERY again.</p>

Patient ID isn't selected. Select Patient ID in query result.	Displayed when a patient is not selected on the search result screen. Select a patient for measurement and press the OK button.
Success intercommunication check with MWL server.	Displayed upon successful intercommunication check with the server.
Failure intercommunication check with MWL server. (E18005)	Displayed upon failed intercommunication check with the server.
ALL modified user settings successfully deleted. Return device to factory settings?	Reset the settings of the main unit to return to the factory default settings. To execute the process, press the OK button.
Device returned to factory settings. OK to turn off and on unit.	Displayed when the factory reset is complete. Please turn the power of the main unit off and then on again for the setting to take effect.
Do you want to execute it?	You can execute the function. To execute the function, press the OK button.
Execution processing failed. (E91024)	Function execution failed. Check the execution conditions for the function.
Executing. Please wait for a moment.	Function is being executed. Please wait for the completion of execution.
OVER-SPH	Spherical power exceeds -25D or +22D. Measurement cannot be performed for out of measuring range.
OVER-CYL	Cylindrical power exceeds $\pm 10D$. Measurement cannot be performed for out of measuring range.
NO TARGET	Displayed when there is no target or the eye image is too dark. You should tell the patient to open their eyes as wide as possible, and tell not to move the eyes as possible. Then perform the measurement again. Even if you cannot perform the measurement after above manner, it may be possible to measure by changing to the cataract mode(CAT).
ALIGN ERR	Displayed when the alignment is significantly failed during the measurement. You should tell the patient to open their eyes as wide as possible, and tell not to move the eyes as possible. Then perform the measurement again.
AGAIN	Displayed when there is more than $\pm 5D$ difference from the previous measurement value. You should tell the patient to open their eyes as wide as possible, and tell not to move the eyes as possible. Then perform the measurement again.
NO CENTER	Displayed when center of eye can not be found. You should tell the patient to open their eyes as wide as possible, and tell not to move the eyes as possible. Then perform the measurement again.
ERROR	Displayed when the patient blinks or otherwise moves his/her eye during measurement. If this message appears while correctly measuring the standard accessory model eye in REF/KRT, an instrument malfunction may have occurred. Contact your service personnel.
OVER-R	Corneal curvature exceeds 5.00-10.00mm. Measurement cannot be performed for out of measuring range.
OVER	Displayed when IOP value exceeds 60 mmHg.

AIR CHECK

If a problem is suspected, do the air check.

If the result is “Pressure detected out of standard performance. Check and clean measuring nozzle before trying again. Refer to manual for cleaning instructions. (E09103)”, call your dealer or TOPCON at the address printed on the back cover of this manual. For details about the air check, see “AIR CHECK” on page 44.

TROUBLE-SHOOTING OPERATIONS



WARNING

- Modification of this instrument is not permitted.
- To avoid fire and electric shock, do not open the cover. Ask your dealer for service.

If a problem is suspected, use the following check list.

If following the instructions does not improve the condition, or if your problem is not included in the list, contact your dealer or TOPCON at the address on the back cover.

CHECK LIST

Trouble	Condition	Check	Page
Control panel does not turn on.	Power cord is disconnected.	Is power cord unplugged?	31
		Is power cord connected to the instrument?	31
Control panel is not clear.	The image is dark.	Confirm the brightness by “Control panel brightness.”	101
A malfunction is found in a movable part.	Strange sounds are coming. Moving parts are not smooth.	Do not move it forcibly. Instead, call a service personnel.	Back cover
Printing is not done.	Paper comes out without printing.	Confirm the direction of the paper roll. If the direction is incorrect, insert it again correctly.	34
	Paper does not come out.	If “Paper end” is displayed on the screen, replenish the printer paper.	34

PRINTER PAPER JAM



CAUTION

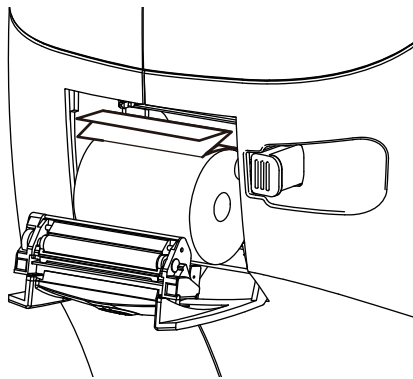
- To avoid injury to the operator, do not open or close the printer cover while the built-in printer is operating.
- To avoid potential injury in case of malfunction, including a paper jam, be sure to shut off the power before attempting to repair it.
- To avoid potential injury in case of malfunction, including a paper jam, be sure to shut off the power before attempting to repair the built-in printer.



NOTE

If the printer paper is jammed in the printer, printing will stop and the jam should be cleared.

- 1** Shut off the power and open the printer cover, take out the jammed paper pieces.



NOTE

After shutting off the power and removing the jammed printer paper, turn the power on again, and then tap the **Print out** button to feed the paper.

SPECIFICATIONS AND PERFORMANCE

REF measurement	
Measuring range	<p>Spherical refractive power: -25 D to +22 D (Display value resolution: 0.12 D or 0.25 D)</p> <p>Astigmatic refractive power: 0D to ±10 D (Display value resolution: 0.12 D or 0.25 D)</p> <p>Direction of astigmatic axis: 0° to 180° (Display value resolution: 1° or 5°) (where, spherical refractive power + astigmatic refractive power ≤ +22 D, or spherical refractive power + astigmatic refractive power ≥ -25 D)</p> <p>The dioptric powers are indicated with reference wavelength $\lambda_d = 587.56$ nm.</p>
Measurable minimum pupil diameter	Φ2.0 mm
PD measuring range	20 mm to 85 mm (Display value resolution: 1 mm)
KRT measurement	
Measuring range	<p>Cornea curvature radius: 5.00 mm to 10.00 mm (Display value resolution: 0.01 mm)</p> <p>Corneal refractive power: 67.50D to 33.75D (Display value resolution: 0.12D or 0.25D) (where, corneal refractive power = 1.3375)</p> <p>Direction of corneal principal meridian: 0° to 180° (Display value resolution: 1° or 5°)</p>
Corneal diameter measurement	
Measuring range	2.00 mm to 14.00 mm (Display value resolution: 0.25 mm)
Intraocular pressure measurement	
Measuring range	7 mmHg to 60 mmHg (Display value resolution: 1 mmHg)
	Average value resolution: 1 mmHg or 0.1 mmHg
Measuring mode	7 to 30 mmHg or 30 to 60 mmHg, selectable range
Corneal thickness measurement	
Measuring range	0.400 mm to 0.730 mm (Display value resolution: 0.001 mm)

Conformity standards

- ISO 8612:2009 Ophthalmic instruments–Tonometers
- ISO 10342:2010 Ophthalmic instruments–Eye refractometers
- ISO 10343:2014 Ophthalmic instruments–Ophthalmometers: Type B
- ANSI Z80.10-2014 for Ophthalmics–Ophthalmic Instruments–Tonometers (except for the requirement for "highly astigmatic eyes (>3 D of corneal astigmatism)" in B5.3 of Annex B)
- ANSI Z80.36-2021 for Ophthalmics–Light Hazard Protection For Ophthalmic Instruments

GENERAL INFORMATION ON USAGE AND MAINTENANCE

INTENDED PATIENT POPULATION

The patient who undergoes an examination by this instrument must maintain concentration for a few minutes and keep to the following instructions:

- To fix the face to the chinrest, forehead rest.
- To keep the eye open.
- To understand and follow instructions when undergoing an examination.

However, patients who are able to perform the above actions but have any of the product's contraindications are excluded.

INTENDED USER PROFILE

Ophthalmologists, optometrists, orthoptists (ORT), Ophthalmic Medical Assistant (OMA), other certified healthcare professionals*, or persons who received training under the guidance of a doctor.

* Other certified healthcare professionals; Qualified person authorized to use this product by local laws and regulations.

ENVIRONMENTAL CONDITIONS OF USE

Temperature:	10°C to 35°C
Humidity:	30% to 90% (without condensation)
Pressure:	800 hPa to 1060 hPa

STORAGE, USAGE PERIOD

1. Environmental conditions

Temperature:	-10°C to 55°C
Humidity:	10% to 95% (without condensation)
Pressure:	700 hPa to 1060 hPa

2. When storing the instrument, ensure that the following conditions are met:

- (1) The instrument must not be splashed with water.
- (2) Store the instrument away from environments where pressure, temperature, humidity, ventilation, sunlight, dust, salty/sulfurous air, etc. could cause damage.
- (3) Do not store or transport the instrument on a slanted or uneven surface or in an area where it is subject to vibrations or instability.
- (4) Do not store the instrument where chemicals are stored or gas is generated.

3. Normal life span of the instrument:

8 years from delivery providing regular maintenance is performed [TOPCON data]

Follow the respective handling methods for the transportation and storage conditions of external I/O devices.

TRANSPORT CONDITIONS

Temperature:	-40°C to 70°C
Humidity:	10% to 95%
Pressure:	700 hPa to 1060 hPa

ELECTRIC RATING

Source voltage: AC 100 V–240 V
Frequency: 50–60 Hz
Power input: 80 VA

DIMENSIONS AND WEIGHT

Dimensions: 332–422 mm (W) × 569–658 mm (D) × 504–760 mm (H)
Weight: 23.2 kg

SYSTEM CLASSIFICATION

- Types of protection against electric shock:
This instrument is classified as Class I equipment.
Class I equipment does not depend only on basic insulation for protection against electric shock, but also provides a means of connection to a protective earth system so that metal parts that come into contact do not become conductive if the basic insulation fails.
- Grade of protection against electric shock:
This instrument is classified as Type B applied part.
Type B applied part provides a specified grade of protection to prevent electric shock, particularly for reliability against current leaks, measuring current and protective earth current (in case of Class I equipment).
- Degree of protection against harmful intrusion of water (IEC 60529): IPX0
This instrument does not provide protection against intrusion of water.
- Classification according to the method(s) of sterilization or disinfection recommended by the manufacturer: not applicable.
This instrument has no part to be sterilized or disinfected.
- Classification by safety of use in air/flammable anesthetic gas, oxygen or nitrous oxide/flammable anesthetic gas atmosphere
 - Equipment not suited for use in air/flammable anesthetic gas, oxygen or nitrous oxide/flammable anesthetic gas atmosphere
 - This instrument should be used in an environment free of flammable anesthetic gas and other flammable gases.
- Classification according to the mode of operation: Continuous operation.
Continuous operation is the operation under normal load for an unlimited period, without the specified limits of temperature being exceeded.
- Class of laser product: Class 1 laser product according to IEC 60825-1:2007, IEC 60825-1:2014
Class 1 equipment is a laser product which is safe under the rationally predictable operation conditions, and keeps safety for human eyes even if any optical system (lens or telescope) is used as a condensing unit.



OPERATION PRINCIPLE

Refractometry:

The light source (SLD) for refraction measurement incorporated in the measuring head emits luminous flux for refraction measurement and project it onto the retina. The camera incorporated in the measuring head receives the reflected image from the retina. The instrument software installed in the measuring head performs arithmetic processing of the reflected image and calculates the spherical refractive power, the astigmatic refractive power and the direction of astigmatic axis necessary for the correction lens to correct the vision of the subject eye to normal vision.

Keratometry:

The light source (LED) for keratometry illumination incorporated in the measuring head emits light and project a kerato-ring onto the cornea. The camera incorporated in the measuring head receives the reflected image from the cornea. The instrument software installed in the measuring head performs arithmetic processing of the reflected image and calculates the corneal curvature radius. The instrument software also calculates the corneal refractive power and the direction of corneal principal meridian from the corneal curvature radius.

Tonometry:

The light source (LED) for applanation detection incorporated in the measuring head emits luminous flux for applanation detection and project it onto the cornea. The measuring nozzle of the intraocular pressure measuring window blows air onto the cornea. The applanation sensor incorporated in the measuring head detects that a certain area of the cornea becomes planar by the air. Then, the pressure sensor incorporated in the measuring head detects the amount of pressure required to flatten the certain area of the cornea. The instrument software installed in the measuring head performs arithmetic processing based on the detected amount of pressure and calculates the intraocular pressure value.

Pachymetry:

The light source (LED) for pachymetry measurement incorporated in the measuring head emits slit light and project it onto the cornea obliquely. The line sensor incorporated in the measuring head receives the reflected lights from the front and back surfaces of the cornea. The instrument software installed in the measuring head performs arithmetic processing based on the received lights and calculates the corneal thickness.

Corneal diameter measurement:

The kerato-ring illumination emitted from the kerato-illumination light source (LED) built into the measurement head is projected into the subject's eye, and the reflected image (anterior image) is received by the camera built into the measurement head and displayed on the control panel.

After aligning the positioning bar in the anterior images displayed on the control panel, the corneal diameter is calculated by the software built in the measurement head when a user presses the measurement button.

Pupil distances (PD):

The left-right position of the Measuring head at the completion of right eye REF measurement sets XR. The left-right position of the Measuring head at the completion of left eye REF measurement sets XL.

The absolute amount ($|XR-XL|$) of measuring head movement in the left-right direction is calculated as the distance between pupil (mm) in the software installed in the measuring head.

SUMMARY OF PERFORMANCE TESTING

Clinical Data - Tonometry

A prospective clinical study was conducted, at a U.S. clinical site, to confirm that the tonometer function of the TRK-3 OMNIA conforms to the tonometry standards, ISO 8612:2009 and ANSI Z80.10-2014 (except for the requirement for "highly astigmatic eyes (>3 D of corneal astigmatism)" in B5.3 of Annex B). "8.Clinical Performance" of the FDA guidance document, "Tonometers - Premarket Notification [510(k)] Submissions (issued on March 27, 2006) and the Extent of Recognition in the FDA Supplementary Information Sheet (FR Recognition List Number 040, FR Recognition Number 10-96, Date of Entry 08/14/2015) were also taken into consideration.

The sample size was at least 120 eyes from 120 subjects, including at least 40 eyes in each of the categories of low IOP (7-16 mmHg), intermediate IOP (>16 mmHg to <23 mmHg), and high IOP (>23 mmHg) and at least 2 eyes with IOP of 30 mmHg or higher. Eligibility criteria were defined by tonometer standards, and included participants aged 22 years or older, with the main exclusion criteria being those with corneal scarring, corneal surgery including corneal laser surgery, keratoconus, and central corneal thickness greater than 0.6 mm or less than 0.5 mm, and corneal astigmatism greater than 3D.

A total of 125 subjects were enrolled in the study and 120 subjects completed the study with all valid measurements. **Table A** shows the demographics.

Table A: Demographics

Parameter	Low IOP (7 to 16 mmHg) (N=40)	Intermediate IOP (> 16 to < 23) (N=40)	High IOP (≥ 23) (N=40)	Total (N=120)
Age (Years)				
N	40	40	40	40
Mean (SD)	50.9 (14.7)	56.0 (13.6)	62.2 (11.2)	56.4 (13.9)
Median	55	57	65	59
(Min, Max)	(24, 71)	(27, 80)	(25, 85)	(24, 85)
Age Range				
22 - 30 years	15.0% (6/40)	2.5% (1/40)	2.5% (1/40)	6.7% (8/120)
31 - 40 years	12.5% (5/40)	12.5% (5/40)	2.5% (1/40)	9.2% (11/120)
41 - 50 years	12.5% (5/40)	22.5% (9/40)	2.5% (1/40)	12.5% (15/120)
51 - 60 years	25.0% (10/40)	22.5% (9/40)	30.0% (12/40)	25.8% (31/120)
61 - 70 years	32.5% (13/40)	20.0% (8/40)	37.5% (15/40)	30.0% (36/120)
>70 years	2.5% (1/40)	20.0% (8/40)	25.0% (10/40)	15.8% (19/120)
Sex				
Male	45.0% (18/40)	45.0% (18/40)	37.5% (15/40)	42.5% (51/120)
Female	55.0% (22/40)	55.0% (22/40)	62.5% (25/40)	57.5% (69/120)
Race				
American Indian Or Alaska Native	2.5% (1/40)	7.5% (3/40)	0.0% (0/40)	3.3% (4/120)
Asian	10.0% (4/40)	5.0% (2/40)	5.0% (2/40)	6.7% (8/120)
Black Or African American	7.5% (3/40)	22.5% (9/40)	75.0% (30/40)	35.0% (42/120)

Parameter	Low IOP (7 to 16 mmHg) (N=40)	Intermediate IOP (> 16 to < 23) (N=40)	High IOP (≥ 23) (N=40)	Total (N=120)
Hawaiian Or Other Pacific Islander	5.0% (2/40)	2.5% (1/40)	0.0% (0/40)	2.5% (3/120)
White	75.0% (30/40)	60.0% (24/40)	20.0% (8/40)	51.7% (62/120)
Not Disclosed	0.0% (0/40)	2.5% (1/40)	0.0% (0/40)	0.8% (1/120)
Ethnicity				
Hispanic Or Latino	17.5% (7/40)	12.5% (5/40)	2.5% (1/40)	10.8% (13/120)
Not Hispanic Or Latino	82.5% (33/40)	85.0% (34/40)	97.5% (39/40)	88.3% (106/120)
Not Disclosed	0.0% (0/40)	2.5% (1/40)	0.0% (0/40)	0.8% (1/120)
Study Eye				
OD	55.0% (22/40)	57.5% (23/40)	40.0% (16/40)	50.8% (61/120)
OS	45.0% (18/40)	42.5% (17/40)	60.0% (24/40)	49.2% (59/120)

The IOP between the test tonometer TRK-3 OMNIA and the reference tonometer (Goldmann Applanation Tonometer) in eyes without high corneal astigmatism was compared over the three IOP ranges and there was no study eye with IOP exceeding the tolerance of paired differences (± 5.0 mmHg) in all IOP ranges, as shown in **Table B**.

Table B: Summary of the tonometer study

IOP range (mmHg)		Number of study eyes	Number of eyes within the tolerance of paired differences	Number of eyes outside the acceptable range (%)		Mean and Standard deviation of differences between TRK-3 and GAT (mmHg)
Low IOP	7 to 16	40	40	0	(0.0)	2.10 (1.68)
Intermediate IOP	>16 to <23	40	40	0	(0.0)	-0.20 (1.40)
High IOP	≥23	40	40	0	(0.0)	-2.45 (1.81)

The TRK-3 OMNIA conforms to all the requirements of ISO 8612:2009 and ANSI Z80.10- 2014 (except for the requirement for "highly astigmatic eyes (>3 D of corneal astigmatism)" in B5.3 of Annex B). For the safety evaluation, no subjects experienced adverse events in this study.

Clinical Data - Pachymetry

Topcon conducted a prospective comparative clinical study, at a U.S. clinical site, to compare the agreement and precision of the pachymeter function between TRK-3 OMNIA and SP-1P Specular Microscope (K142417). Participants age 22 years or older were enrolled and assigned to one of three groups: 1) “Normal Cornea”, 2) “Abnormal Cornea”, and 3) “Glaucoma”. The sample size was 30 eyes of 30 subjects for each group. Key enrollment criteria for 2) were to include at least one eye with corneal abnormality, to include (but not limited to) corneal transplants, abnormal corneal shape, long term (>3 years) daily contact lens use, post keratorefractive surgery and dry eye. Key enrollment criteria for 3) were to include eyes with visual field defect(s) consistent with glaucomatous optic nerve damage.

A total of 108 subjects were consented and 105 subjects were enrolled in the study; 90 subjects completed the study with valid pachymetry readings (central corneal thickness, CCT, in micron), 30 subjects in each study group. **Table C** shows the demographics.

Table C: Demographics

	Normal Cornea	Abnormal Cornea	Glaucoma
	Total	Total	Total
	(N=30)	(N=30)	(N=30)
Age (years)			
N	30	30	30
Mean(SD)	40.0 (14.8)	44.2 (17.6)	64.9 (8.9)
Min, Max	24, 69	24, 82	45, 82
Median	36.5	40	66
Age Range			
22 - 30 years	12 (40.00%)	9 (30.00%)	0 (0.00%)
31 - 40 years	4 (13.33%)	6 (20.00%)	0 (0.00%)
41 - 50 years	6 (20.00%)	5 (16.67%)	3 (10.00%)
51 - 60 years	4 (13.33%)	3 (10.00%)	6 (20.00%)
61 - 70 years	4 (13.33%)	4 (13.33%)	14 (46.67%)
>70 years	0 (0.00%)	3 (10.00%)	7 (23.33%)
Sex			
Male	8 (26.67%)	4 (13.33%)	14 (46.67%)
Female	22 (73.33%)	26 (86.67%)	16 (53.33%)
Race			
Asian	5 (16.67%)	6 (20.00%)	1 (3.33%)
Black or African American	3 (10.00%)	10 (33.33%)	25 (83.33%)
Not Disclosed	1 (3.33%)	0 (0.00%)	1 (3.33%)
White	20 (66.67%)	12 (40.00%)	3 (10.00%)
White, Asian	1 (3.33%)	2 (6.67%)	0 (0.00%)
Ethnicity			
Hispanic or Latino	7 (23.33%)	2 (6.67%)	3 (10.00%)
Not Disclosed	0 (0.00%)	0 (0.00%)	1 (3.33%)
Not Hispanic or Latino	23 (76.67%)	28 (93.33%)	26 (86.67%)

Of the abnormal cornea eyes tested in this study, all 30 had clinically significant slit lamp cornea findings. 3 (10.0%) had corneal transplants, 6 (20.0%) had various abnormal corneal shapes including 2 (6.7%) scarring, 10 (33.3%) had long term daily contact lens use, 8 (26.6%) had a form of post keratorefractive surgery, and 1 (3.3%) had corneal ring. All 30 eyes were CXL, 7 (23.3%) had dry eye, 1 (3.3%) had opacity, 1 (3.3%) had Guttata, and 1 (3.3%) had Pterygium.

Agreement between TRK-3 OMNIA and SP-1P was evaluated by the mean difference and corresponding standard deviation, the 95% LOA, Bland-Altman plots, and the Deming regression for each subject population. A summary of the agreement study is provided in **Table D**.

Table D: Summary of agreement of CCT between TRK-3 OMNIA and SP-1P

TRK-3 OMNIA Mean (SD)	SP-1P Mean (SD)	Mean Difference (SD)	95% Limits of Agreement	Correlation (R ²)
Normal Cornea (N=30)				
533.7 (34.68)	533.6 (34.35)	0.1 (6.12)	(-11.9, 12.1)	0.969
Abnormal Cornea (N=30)				
512.8 (50.17)	516.7 (46.64)	-4 (9.32)	(-22.2, 14.3)	0.969
Glaucoma (N=30)				
500.4 (24.18)	501.2 (23.05)	-0.8 (6.82)	(-14.2, 12.6)	0.92

The analysis of precision used a two-way random-effect ANOVA model to estimate the repeatability and reproducibility limits, and coefficient of variation of CCT by subject population and study device. A summary of the precision study is provided in **Table E**.

Table E: Summary of precision of CCT between TRK-3 OMNIA and SP-1P

	CCT	TRK-3 OMNIA	SP-1P
Normal Cornea (N=30)	Overall Mean	533.5	533.5
	Repeatability SD	2.405	7.402
	Repeatability SD as % of the Mean	0.45%	1.39%
	Repeatability Limit	6.735	20.726
	Repeatability Ratio	0.325 (2.405 / 7.402)	
	Reproducibility SD	3.318	7.69
	Reproducibility SD as % of the Mean	0.62%	1.44%
	Reproducibility Limit	9.291	21.533
Reproducibility Ratio	0.431 (3.318 / 7.690)		
Abnormal Cornea (N=30)	Overall Mean	513.7	515.7
	Repeatability SD	2.83	10.799
	Repeatability SD as % of the Mean	0.55%	2.09%
	Repeatability Limit	7.925	30.236
	Repeatability Ratio	0.262 (2.830 / 10.799)	
	Reproducibility SD	3.762	10.826
	Reproducibility SD as % of the Mean	0.73%	2.10%
	Reproducibility Limit	10.533	30.313
Reproducibility Ratio	0.347 (3.762 / 10.826)		

	CCT	TRK-3 OMNIA	SP-1P
Glaucoma (N=30)	Overall Mean	499	501
	Repeatability SD	3.384	4.895
	Repeatability SD as % of the Mean	0.68%	0.98%
	Repeatability Limit	9.475	13.705

As shown in the table above, the repeatability SD and reproducibility SD of TRK-3 for all three groups are less than those of SP-1P (both the repeatability ratio and reproducibility ratio are less than 1), indicating that the variability of TRK-3 is less than that of SP-1P.

The overall results of agreement and precision analysis support the substantial equivalence of TRK-3 OMNIA to SP-1P. For the safety evaluation, no subjects experienced adverse events in this study.

Bench Testing – Tonometry

The bench testing for the tonometry function was conducted evaluate the accuracy, repeatability, and reproducibility of the TRK-3 OMNIA in its intended measuring range in accordance with section 7 “Bench Testing” of Guidance for Industry and FDA Staff Tonometers- Premarket Notification [510(k)] Submissions (Document issued on: March 27, 2006).

The intraocular pressures (IOPs) of model eyes manometrically pressure-controlled by the manometer model eye system and the IOPs of the model eyes measured by TRK-3 OMNIA were compared.

The following shows the summary.

<Accuracy>

The accuracy test assessed TRK-3 OMNIA’s intraocular pressure (IOP) measurements against manometric reference values across seven pressure levels (7–60 mmHg) using three TRK-3 OMNIA. For each level, three model eyes were tested with ten measurements each.

The widest 95% tolerance interval of the three TRK-3 OMNIA is shown in the table below. Even the results of the widest error range are within ± 2.5 mmHg and meet the criteria. This indicates TRK-3 OMNIA has sufficient accuracy.

Summary of the accuracy test					
	Manometric IOP [mmHg]	Lower 95% tolerance interval [mmHg]	Upper 95% tolerance interval [mmHg]	Acceptance criteria	Result
7-30 Range	7	-1.34	1.05	The 95% tolerance interval to manometry within the range of ± 2.5 mmHg	Pass
	10	-0.34	1.49		Pass
	20	-0.77	1.31		Pass
	30	-1.13	1.40		Pass
30-60 Range	30	-1.70	1.64		Pass
	40	-1.69	1.77		Pass
	50	-2.18	2.12		Pass
	60	-2.38	1.97		Pass

<Repeatability>

Repeatability was evaluated by having a single operator use three TRK-3 OMNIA units to measure IOP across seven pressure levels (7–60 mmHg). For each level, three model eyes were tested with ten measurements each.

The mean IOP and SD of all data obtained by three devices, and 95% tolerance interval calculated from them are shown in the table below. All 95% tolerance interval are within ± 2.5 mmHg and meet the criteria. This indicates TRK-3 OMNIA has sufficient repeatability.

Summary of repeatability							
	Manometric IOP [mmHg]	Mean IOP [mmHg]	SD [mmHg]	Lower 95% tolerance interval [mmHg]	Upper 95% tolerance interval [mmHg]	Acceptance criteria	Result
7-30 Range	7	6.9	0.59	-1.29	1.00	The 95% tolerance interval to manometry within the range of ± 2.5 mmHg	Pass
	10	10.5	0.36	-0.19	1.21		Pass
	20	20.2	0.42	-0.61	1.05		Pass
	30	30.0	0.51	-0.99	1.01		Pass
30-60 Range	30	30.1	0.61	-1.08	1.31		Pass
	40	40.2	0.64	-1.08	1.45		Pass
	50	50.2	0.67	-1.13	1.51		Pass
	60	59.8	0.78	-1.76	1.31		Pass

<Linearity>

Linearity was evaluated using same data above plotting measurements with manometric IOP. All the correlation coefficient of three TRK-3 OMNIA are 0.999. This indicates TRK-3 has sufficient linearity.

<Reproducibility>

Reproducibility was assessed by analyzing variability across devices and operators. Three operators measured IOP using three TRK-3 units on one model eye per pressure level. Measurements were analyzed for device and operator variability.

The mean IOP, and SD of all data obtained by three devices, and 95%CI calculated from them are shown in the table below. All 95% tolerance interval are within ± 2.5 mmHg and meet the criteria. This indicates TRK-3 has sufficient reproducibility.

Summary of reproducibility							
	Manometric IOP [mmHg]	Mean IOP [mmHg]	SD [mmHg]	Lower 95% tolerance interval [mmHg]	Upper 95% tolerance interval [mmHg]	Acceptance criteria	Result
7-30 Range	7	7.6	0.34	-0.07	1.26	The 95% tolerance interval to manometry within the range of ± 2.5 mmHg	Pass
	10	10.6	0.25	0.11	1.10		Pass
	20	20.6	0.40	-0.16	1.40		Pass
	30	29.8	0.38	-0.94	0.54		Pass
30-60 Range	30	30.5	0.52	-0.51	1.52		Pass
	40	40.2	0.73	-1.19	1.68		Pass
	50	50.1	0.68	-1.25	1.43		Pass
	60	59.5	0.69	-1.84	0.85		Pass

Bench Testing - Pachymetry

The focus of this internal study was to demonstrate that the performance data of the TRK-3 OMNIA is accuracy and agreement over the complete stated measuring range of 400 µm to 730 µm.

The company performed bench testing to evaluate the accuracy of CCT by measuring model eyes with TRK-3 OMNIA and the agreement of measured CCT values between test device and predicated device (Topcon SP-1P: K142417).

Results:

For accuracy, there was no test device that exceeded the tolerance ($\pm 10\mu\text{m}$ for less than 600 μm and $\pm 25 \mu\text{m}$ for 600 μm ore more) of the reference device in the measurement range of 400-730 μm .


Maximum Difference to the nominal value of three test devices (TRK-3 OMNIA)			
Nominal CCT [μm]	Maximum Difference [μm]	Acceptance Criteria [μm]	Result
372	4.0	Within ± 10.0	Pass
464	-0.9		
564	0.9		
639	2.3	Within ± 25.0	Pass
733	-2.9		

For agreement, a comparison of TRK-3 OMNIA and the predicated device showed that all correlation coefficients were larger than 0.7.

Correlation Coefficient	Acceptance Criteria	Result
1.000	0.7 or more	Pass
1.000		
1.000		

DISPOSAL

Please follow your national or regional law for environmentally safe disposal of electrical and electronic equipment.

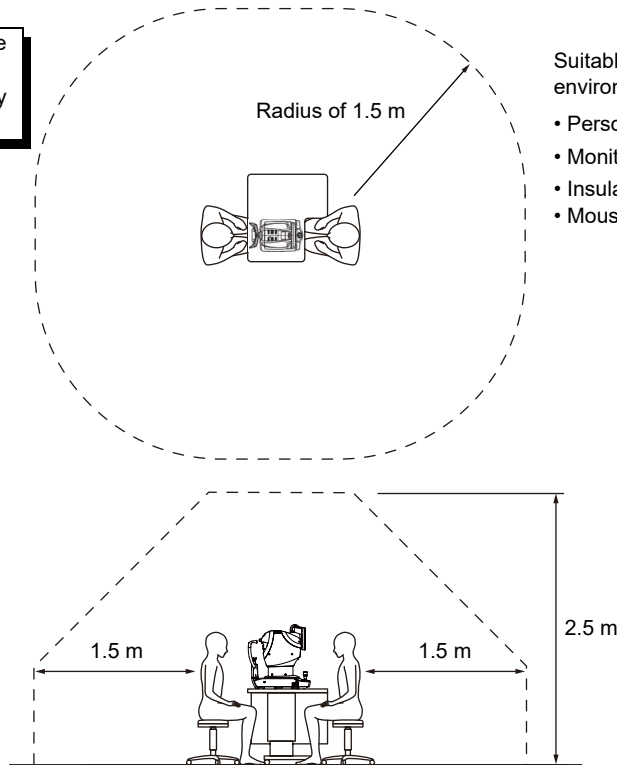
 NOTE	This Product Contains a coin cell. You cannot replace batteries by yourself. When you need to replace and/or dispose batteries, contact your dealer or TOPCON listed on the back cover.
	This product contains a CR Lithium Battery which contains Perchlorate Material-special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate Note; This is applicable to California, U.S.A. only

PATIENT ENVIRONMENT

When the patient or inspector comes into contact with the devices (including the connecting devices) or when the patient or inspector is in contact with the person that touches the devices (including the connecting devices), the patient environment is shown below.

In the patient environment, use devices conforming to IEC 60601-1. If you are compelled to use any device not conforming to IEC 60601-1, use an insulation transformer.

Do not use multiple outlet strip in the patient environment.
Be sure to connect the power supply to commercial power.



Suitable device to use in the patient environment

- Personal computer^(Note 1) ^(Note 2)
- Monitor display for PC^(Note 1)
- Insulation transformer^(Note 3)
- Mouse

Note 1: Use the personal computer conforming to IEC 62368-1.

Note 2: Do not remove the cover from the personal computer.


Note 3: Use the insulation transformer conforming to IEC 60601-1.

<b style="font-size: 1.2em;">WARNING	<p>Connect only items that have been specified as part of the ME system or that have been specified as being compatible with the ME system.</p>
<b style="font-size: 1.2em;">CAUTION	<ul style="list-style-type: none"> • Do not connect an additional power strip or an extension cord to the system. • The total 1kVA is the maximum allowable load of the auxiliary power supply socket for the insulation transformer, which is provided for the system. Do not connect the device exceeding this capacity. • Use the auxiliary power supply socket of the insulation transformer to power only a device that will be a component of the system. • It is dangerous to connect any device which is not used as a component of the system, to the insulation transformer. • When the insulation transformer is not used, the personal computer and the monitor for the personal computer must be installed out of the patient environment.

REQUIREMENTS FOR THE EXTERNAL DEVICE


The external device connected to the digital interfaces must comply with the respective IEC or ISO standards (e.g. IEC 62368-1 for data processing equipment and IEC 60601-1 for medical equipment). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. In addition, the external devices to be connected must comply with the corresponding EMC standards (e.g. CISPR 32/CISPR 35). Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, contact your dealer or TOPCON (see the back cover).

IT NETWORK ENVIRONMENT

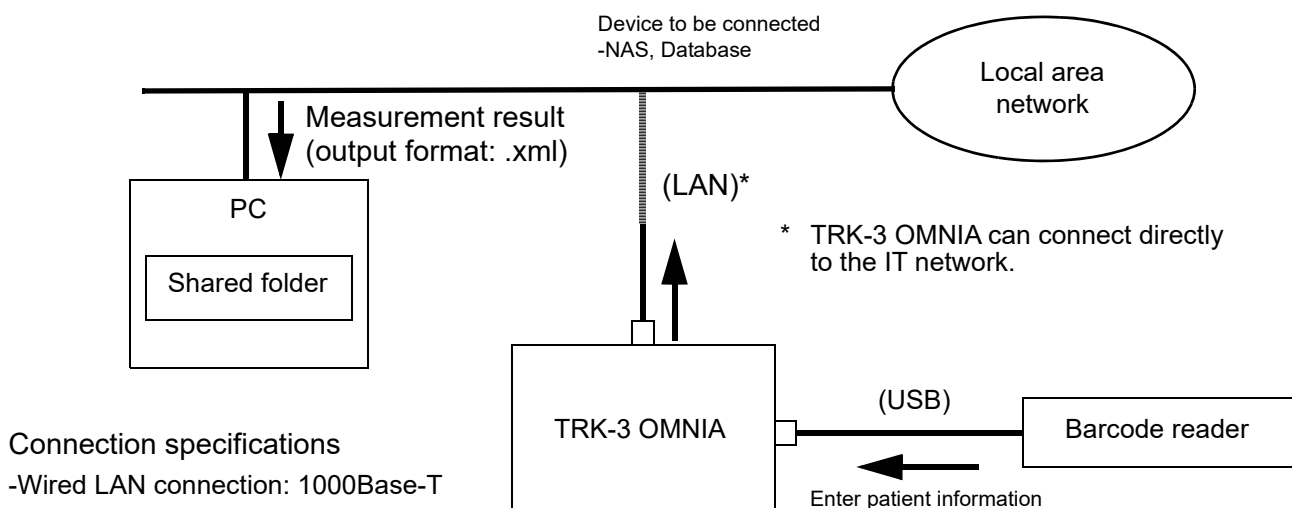
 CAUTION	<ul style="list-style-type: none">• When connected with an IT network, ensure the appropriate and sufficient security to prevent the infection with malware and a computer virus, the leak of information, etc. There is a risk of data leakage.• User shall implement password authentication and other access control for servers on the network, and disable legacy versions of the SMB communication protocol. User shall enable SMB protocol encryption for the shared folders and TLS1.2 or other encryption for SQL server TCP/IP communication.
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The TRK-3 OMNIA can be connected to an IT network such as a personal computer or refractor (brand name “COMPU VISION CV-5000”) to output measurement results and patient information by operating the main unit.

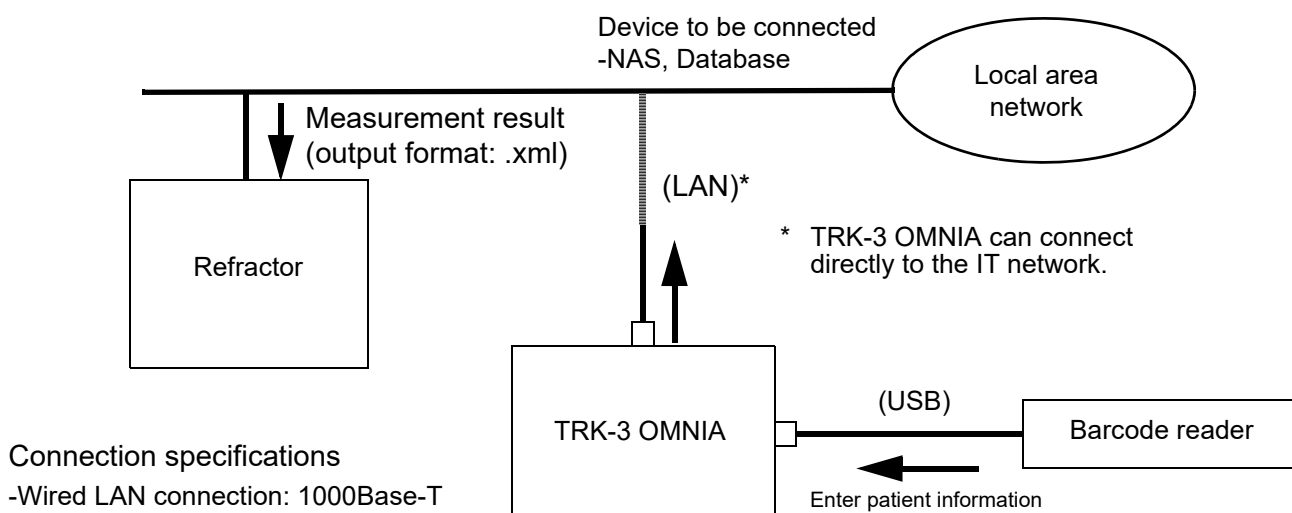
- Refer to the figure below for the characteristics, configuration, technical specification, intended information flow and route when connected with an IT network.
- If the IT network connection device fails, I/O data may not be exchanged.
- If the IT network fails, it may cause the following troubles.
 - Measurement data and patient information cannot be output due to poor connection (LAN), and data may be lost.
 - Poor connection (USB) may cause a failure of input of patient information with barcode reader.
- When the IT network has been changed after the connection, a new risk may occur. So an additional analysis is necessary.
- The change of IT network includes the following items:
 - Change in the IT network configuration;
 - Connection of additional items to IT network;
 - Removal of items from IT network;
 - Update of the device connected with IT network;
 - Upgrade of the device connected with IT network.

 NOTE	The data output destination must have server functionality that supports SMB 3.0 or higher. When connecting to the CV-5000, make sure that its server functionality supports SMB version 3.0 or higher.
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WHEN SAVING MEASUREMENT RESULTS FROM THE MAIN UNIT TO A SHARED FOLDER



WHEN SAVING MEASUREMENT RESULTS FROM THE MAIN UNIT TO THE REFRACTOR



INPUT / OUTPUT INTERFACE SPECIFICATIONS

Interface	Specification	Use
LAN (RJ-45)	1000Base-T	Communication with externally connected devices (TCP / IP)
USB	USB 2.0	Interface for patient ID input

SPECIFICATIONS OF ISOLATION TRANSFORMER TO BE CONNECTED

Item	Operating specifications
Input voltage	AC 100V / 110V / 120V (for 100V region) AC 220V / 230V / 240V (for 200V region)
Frequency	50Hz / 60Hz
Phase number	Single-phase
Secondary capacity	1kVA
Others	Conforms to IEC 60601-1

ELECTROMAGNETIC COMPATIBILITY

This product conforms to the EMC standard IEC 60601-1-2:2014+AMD1:2020 (Ed.4.1).

The expected electromagnetic environment for the whole life cycle is home medical treatment environment.

- a) MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.
- b) Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
- c) The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or SYSTEM as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or SYSTEM.
- d) The EQUIPMENT or SYSTEM should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the EQUIPMENT or SYSTEM should be observed to verify normal operation in the configuration in which it will be used.
- e) The use of the ACCESSORY, transducer or cable with EQUIPMENT and SYSTEMS other than those specified may result in increased EMISSION or decreased IMMUNITY of the EQUIPMENT or SYSTEM.
- f) Do not use the devices generating electromagnetic waves within 30cm from all the parts of the instrument and system. Those devices may have influence on this instrument.

Item	Length (m)	Shield	Ferrite core
AC power cord (AC100 / 120V)	1.5	No	No
AC power cord (AC230 / 240V)	3.0	No	No
Power cord (for computer)	1.5	No	Yes
Power cord (for AC adapter)	1.0	No	No
LAN cable	8.0	Yes	Yes
Barcode reader cable	1.5	Yes	Yes
Personal computer	—	—	—
USB barcode reader	—	—	—
AC adapter	—	—	—

Guidance and manufacturer's declaration - electromagnetic emissions		
The TRK-3 OMNIA is intended for use in the electromagnetic environment specified below. The customer or the user of the TRK-3 OMNIA should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The TRK-3 OMNIA 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 electronic equipment. The TRK-3 OMNIA is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions IEC 61000-3-2	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity

The TRK-3 OMNIA is intended for use in the electromagnetic environment specified below.
The customer or the user of the TRK-3 OMNIA should assure that it is used in such an environment.

Immunity test	Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 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 transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines Repetition frequency 100kHz	± 2 kV for power supply lines ± 1 kV for input/output lines Repetition frequency 100kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and Voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle (with phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T for 1 cycle 0° 70% U_T for 25/30 cycles 0° 0% U_T for 250/300 cycles	0% U_T for 0.5 cycle (with phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T for 1 cycle 0° 70% U_T for 25/30 cycles 0° 0% U_T for 250/300 cycles	Main power quality should be that of a typical commercial or hospital environment. If the user of the TRK-3 OMNIA requires continued operation during main power interruptions, it is recommended that the TRK-3 OMNIA be powered from an uninterruptible power supply or battery.
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.

NOTE U_T is the a.c. main voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The TRK-3 OMNIA is intended for use in the electromagnetic environment specified below.
The customer or the user of the TRK-3 OMNIA should assure that it is used in such an environment.

Immunity test	Test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3Vrms 150kHz to 80MHz</p> <p>6Vrms Within ISM band and amateur radio band of 150kHz to 80MHz</p> <p>10V/m 80MHz to 2.7GHz Proximity electromagnetic field from radio communication equipment ^{a)}</p>	<p>3Vrms 150kHz to 80MHz</p> <p>6Vrms Within ISM band and amateur radio band of 150kHz to 80MHz</p> <p>10V/m 80MHz to 2.7GHz Proximity electromagnetic field from radio communication equipment ^{a)}</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the TRK-3 OMNIA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \frac{6}{E} \sqrt{P}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the radiation electromagnetic field level in volt/meter (V/m).</p>
<p>Proximity magnetic fields IEC 61000-4-39</p>	<p>30kHz CW 8A/m</p> <p>134.2kHz PM2.1kHz 50% 65A/m</p> <p>13.56MHz PM50kHz 50% 7.5A/m</p>	<p>30kHz CW 8A/m</p> <p>134.2kHz PM2.1kHz 50% 65A/m</p> <p>13.56MHz PM50kHz 50% 7.5A/m</p>	<p>The exterior surface of the TRK-3 OMNIA should be kept at least 0.15m from RF emitters such as RFID readers.</p>

NOTE 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) The table below shows the proximity electromagnetic field from radio communication equipment.

Test frequency [MHz]	Band [MHz]	Equipment	Modulation	Maximum output (W)	Distance (m)	Immunity test value [V/m]
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ±5kHz 1kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN820 CDMA850 LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800 CDMA1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

SAFETY OF LASER PRODUCTS

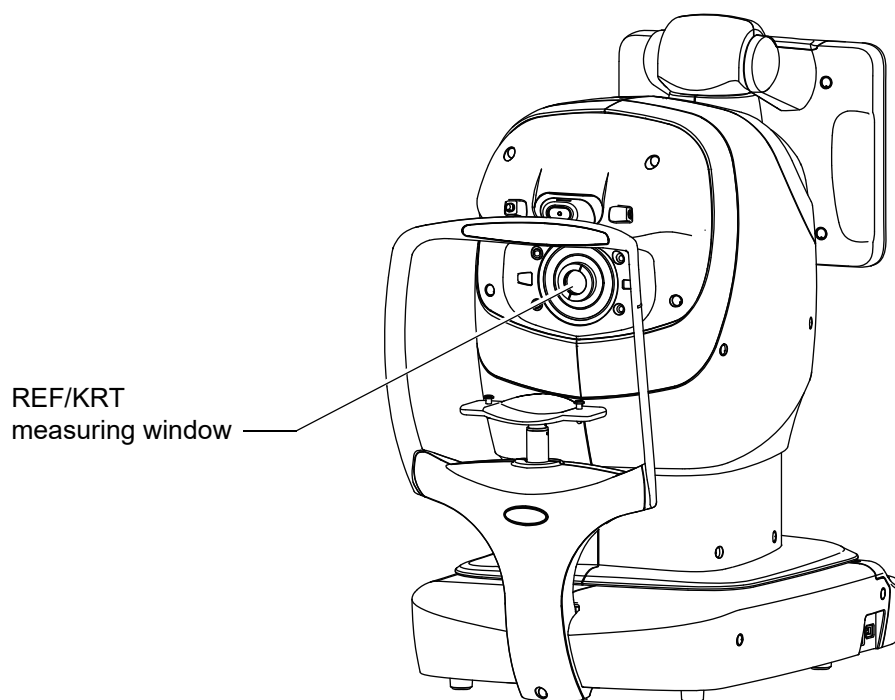


CAUTION

- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- Do not remove the enclosures. Laser high-power is radiated.

Light source	REF measurement	
	Laser product class	Class 3B
	Output power	14.6 mW (CW)
	Wavelength	875 nm
	Beam divergence (2θ)	H: 11deg (0.19 rad) V: 36deg (0.63 rad)

* The laser beam is emitted from the REF/KRT measuring window.



REFERENCE MATERIAL

ABOUT THE BARCODE AND THE QR CODE OF THE BACK COVER

The barcode and the QR code of the back cover indicates the parts management code of the manual.



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DCMTK https://support.dcmtoolkit.org/docs/file_copyright.html
jQuery <https://jquery.com/license/>
libxml2 <https://gitlab.gnome.org/GNOME/libxml2/-/wikis/home>
OpenSSL <https://www.openssl.org/source/license.html>

Please provide the following information when contacting us regarding questions about this instrument:

- Model name: TRK-3 OMNIA
- Serial No.: Marked on the rating nameplate.
- Period of use: Please inform us of the date of purchase.
- Defective condition: Please provide us with as much detail as possible.

AUTO KERATO-REFRACTO TONOMETER TRK-3 OMNIA
USER MANUAL

Revision 3.00
Date of issue 2025-11-17

Published by TOPCON CORPORATION
75-1 Hasunuma-cho, Itabashi-ku, Tokyo, 174-8580 Japan.

AUTO KERATO-REFRACTO TONOMETER

TRK-3 OMNIA

About Us
<https://global.topcon.com/about/group/>

Manufacturer

 **TOPCON CORPORATION**

75-1 Hasunuma-cho, Itabashi-ku, Tokyo, 174-8580 Japan.
Phone: +81-(0)3-3558-2522/2506 Fax: +81-(0)3-3966-5106 www.topcon.co.jp

Parts management code



1056211-01-C

Printed in Japan 2511