Tomey

OA-2000

Operation Guide

Tomey Corporation
OA-2000_OG_V4D5B_EN

TOMEY

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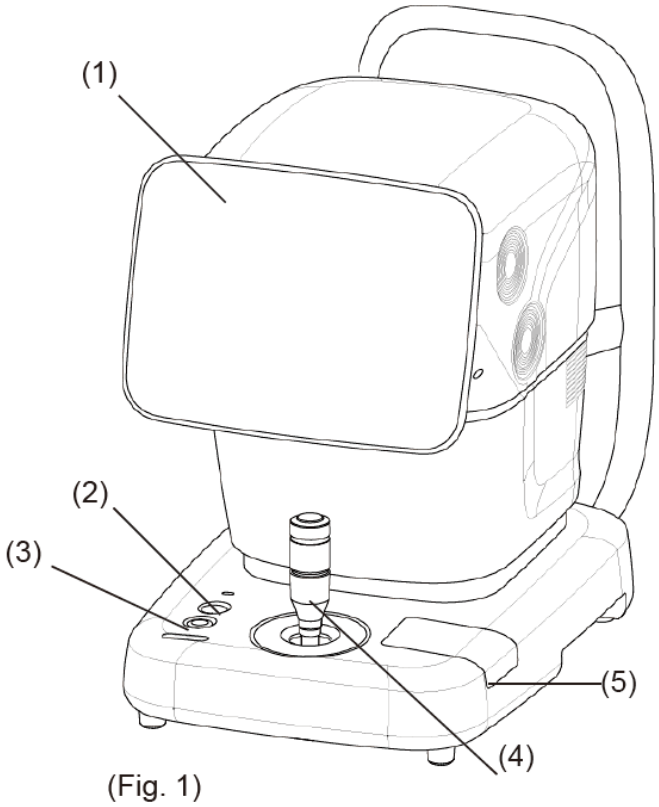
1. NAMES AND FUNCTIONS

1.1 Physician's side



(Fig. 1)

(1) LCD and touch panel

Displays data or is used to perform operations. The display angle can be adjusted.

(2) Power lamp

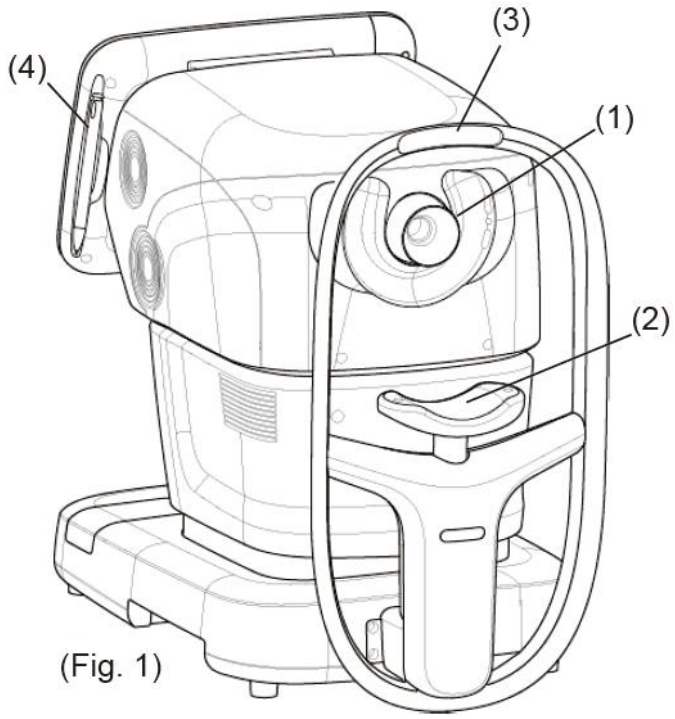
(3) Chin rest up/down button

(4) Joystick

Moves the head in all directions. A measurement button is incorporated at the top of the joystick.

(5) Built-in printer

1.2 Patient side



(Fig. 1)

(1) Measurement window

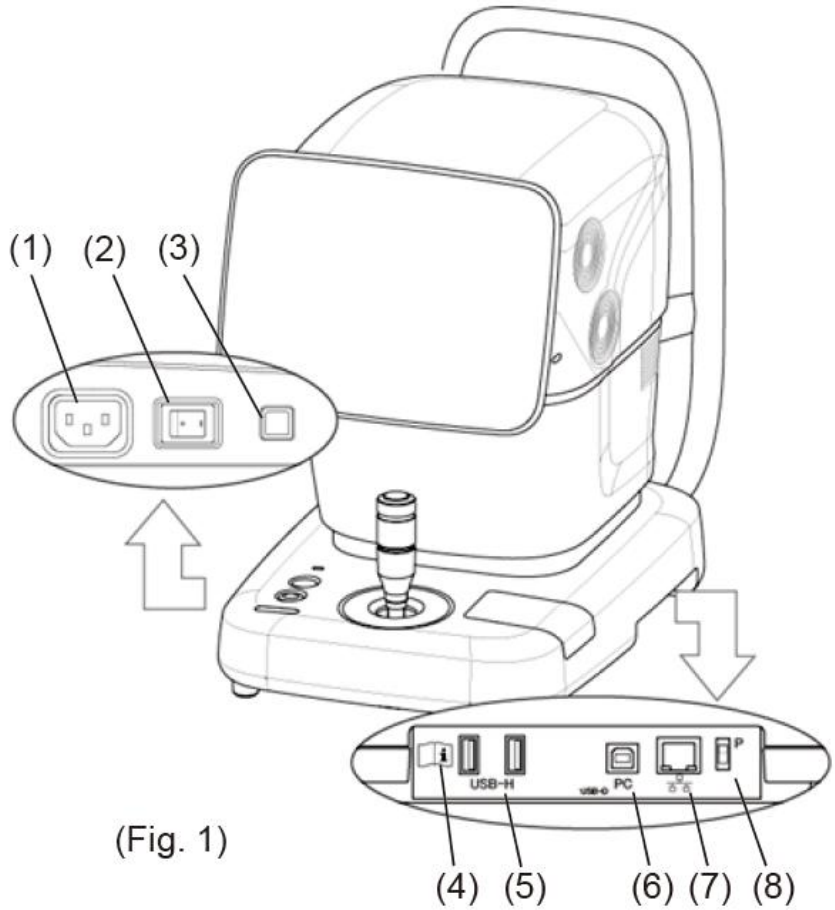
(2) Chin rest

(3) Forehead pad

(4) Touch pen

The touch pen holder is a magnet type.

1.3 Sides of the main unit



(Fig. 1)

(1) Power socket

(2) Power switch

(3) Packing button

Holding this button for 3 seconds moves the head to a set position in preparation for packing.

(4) SD card slot

(5) USB-H connector

Connector for measurement unit, USB flash memory, and external ID input device.

(6) USB-D connector (PC)

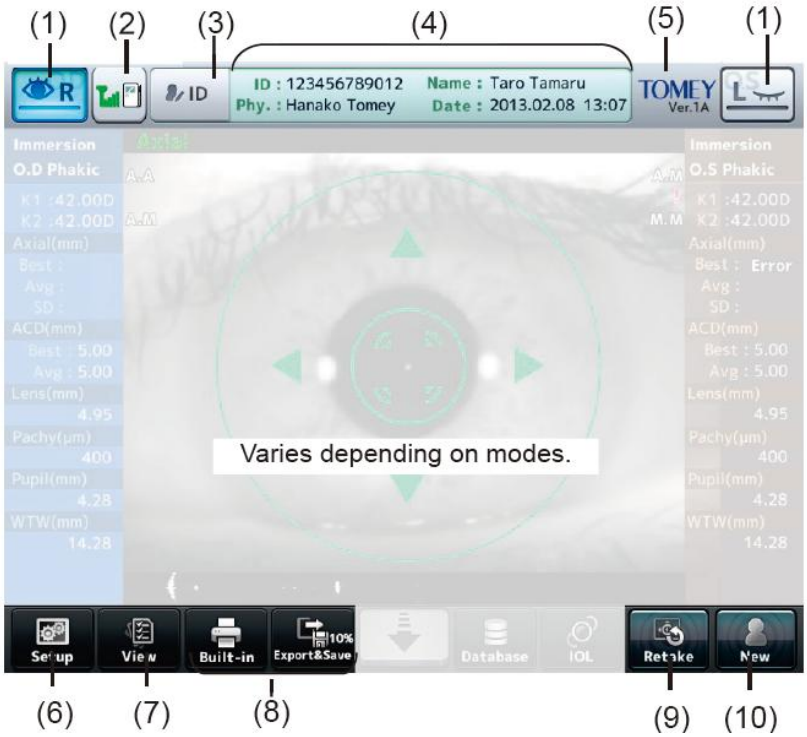
Connect a personal computer, etc. here.

(7) LAN connector

(8) Maintenance switch

Tomey service personnel use this switch for maintenance. Do not change the setting.

1.4 Basic structure and common items



(1) Eye display field (eye selection button)

(2) AL-4000 communication status field

The status of communication with AL-4000 is displayed with the following icons.

Communicating via wireless access	Communicating via USB	Communication stopped	COMMUNICATION NOT POSSIBLE *
			

* Operation not possible. System settings are required for connection.

(3) "ID" button

Opens the patient information input screen.

(4) Patient information field

(5) Version

The version of the software installed in this instrument is displayed.

(6) "Setup" button

Displays the setting screen.

(7) "View"/" Measure" button

"View" button on the measurement screen and "Measure" button on the view screen.

(8) Print, Export & Save buttons

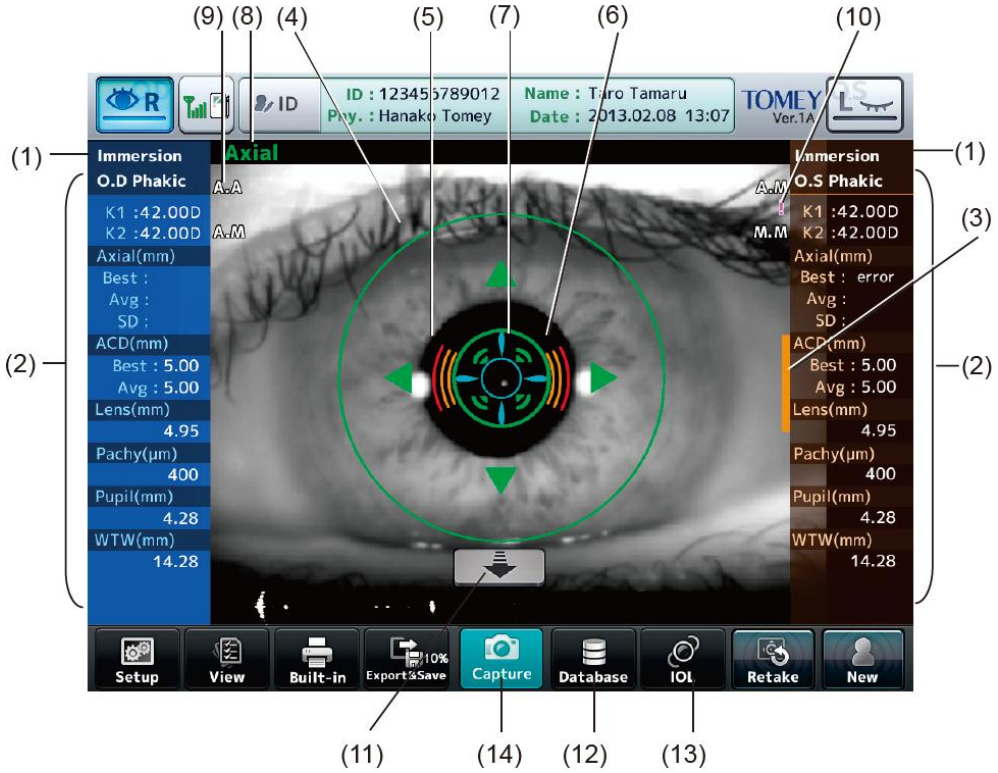
(9) "Retake" button

Deletes the measurement data currently displayed and measures the same eye again.

(10) "New" button

1.5 Screens in optical mode

a) Measurement screen



(1) Measured eye display field

(2) Measurement data display

(3) Measuring head position limit

Appears when the measuring head is near the limit of its movable range. The bar appears at the top, bottom, right, or left of the screen according to the position of the measuring head.t

(4) Auto Alignment ring

Indicates the effective range of Auto Alignment.

(5) Focus indicator

Displays the distance between the head and the patient's eye.

- Horizontal bars mean that the head is too far from the eye.
- Vertical bars mean that the head is too close to the eye.

(6) Auto Alignment mark

(7) Alignment OK mark

(8) Measurement item

Item being measured flashes.

(9) Auto/Manual

Measurement modes (Auto or Manual) for keratometer measurement data and axial length measurement data are displayed. The first letter represents the alignment mode and the second letter represents the measurement mode.

A.A: Auto Alignment / Auto Measurement

A.M: Auto Alignment / Manual Measurement

M.A: Manual Alignment / Auto Measurement

M.M: Manual Alignment / Manual Measurement

(10) Low reliability mark

One of the following symbols appears when the number of low reliability data sets exceeds the majority.

・When low reliability data sets have exceeded the majority: “!” in black

・When reliability of all data is low: “!” in pink

・When there are multiple higher peaks detected in the axial length measurement: “!” is shown in pink.

・When all data returns an error due to the conditions of the subject for measuring: “error”

When all data returns an error due to dust: “error 1”

When all data returns an error due to other factors: “error 2 - 4”

The reliability mark is shown beside the keratometer measurement and axial length measurement in the measurement data display field.

(11) Head retreat button

The head retreats while this button is held.

(12) “Database" button

Displays the data management screen.

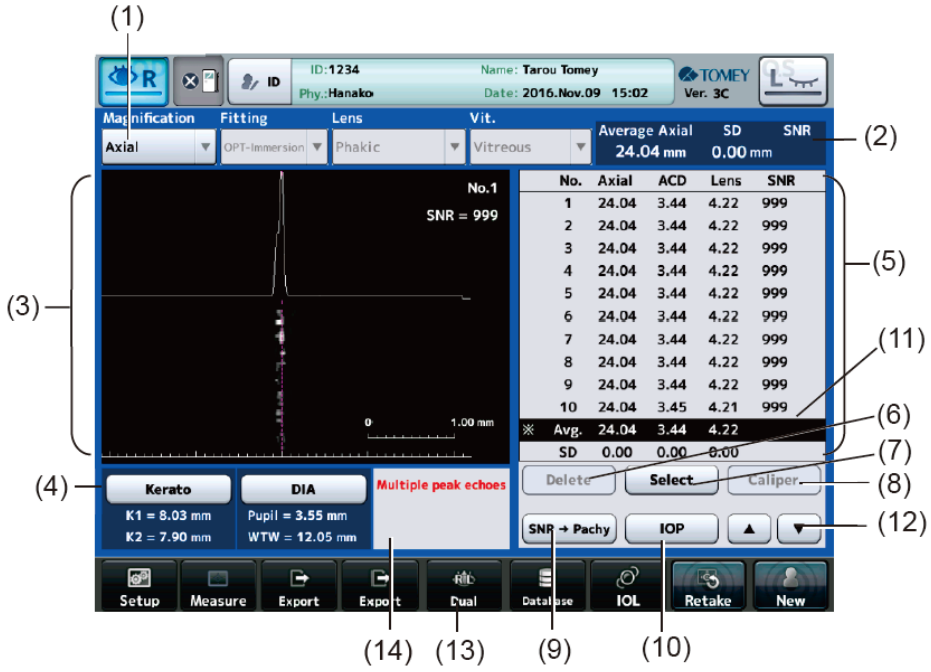
(13) “IOL” button

Opens the IOL power calculation screen.

(14) “Capture” button

It has the same function as the measurement button at the top of the joystick. Used for manual measurement.

b) Axial length view screen



(1) Display area selection button

Enlarges and displays the image of the selected section.

Axial length / anterior chamber depth, lens / corneal thickness / All.

(2) Axial length measurement data display

(3) Scanned image / waveform display area

(4) View screen switch button

(5) Measurement data display

Lists measurement data of axial length, anterior chamber depth, lens, and corneal thickness, and the relevant averages, and standard deviations.

(6) "Delete/Restore" button

Deletes or recovers the measurement data.

(7) "Select" button

The measurement data at the cursor position is selected to be used for calculating IOL power. The selected measurement data is indicated by an "*".

(8) "Caliper" button

(9) "Pachy -> SNR" switch button

(10) "IOP" button

(11) Selection cursor

(12) Selection cursor UP/DOWN buttons

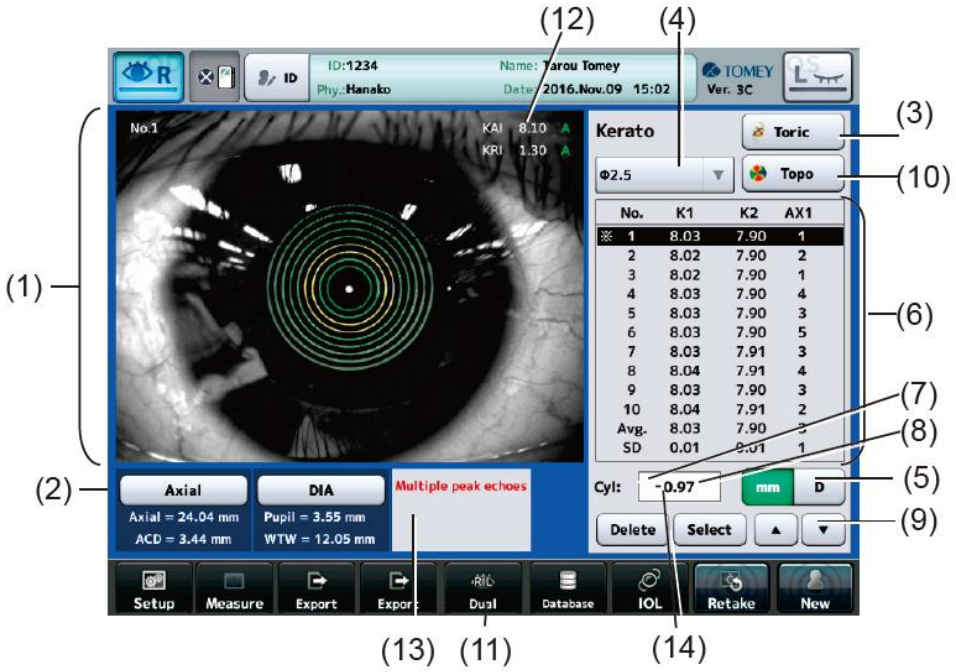
(13) "Dual" button

Displays the R/L alignment display screen.

(14) "Error" display

Describes errors that occurred during axial length measurement of the eye.

c) Keratometer measurement view screen



(1) Ring projection image display field

An image with rings projected is displayed.

(2) View screen switch button

(3) "Toric" button

Displays the toric auxiliary functions.

(4) Measurement position display selector

Select the measurement position to be displayed.

ϕ 2.0mean / φ2.5 / φ3.0

When "φ2.0mean" is selected, only the average is displayed.

(5) Unit selector

Select the unit for indications.

mm / D

(6) Measurement data display

K1, K2, AX1, and their averages and standard deviations are displayed.

(7) "Delete/Restore" button

Deletes or recovers the measurement data.

(8) "Select" button

The measurement data at the cursor position is selected to be used for calculating IOL power. The selected measurement data is indicated by an "*".

(9) Selection cursor UP/DOWN buttons

(10) "Topo" button

Displays the TopoMap screen.

(11) "Dual" button

Displays the R/L alignment display screen.

(12) KAI/KRI

KAI represents asymmetry of the corneal shape and KRI represents regularity / irregularity of the corneal shape.

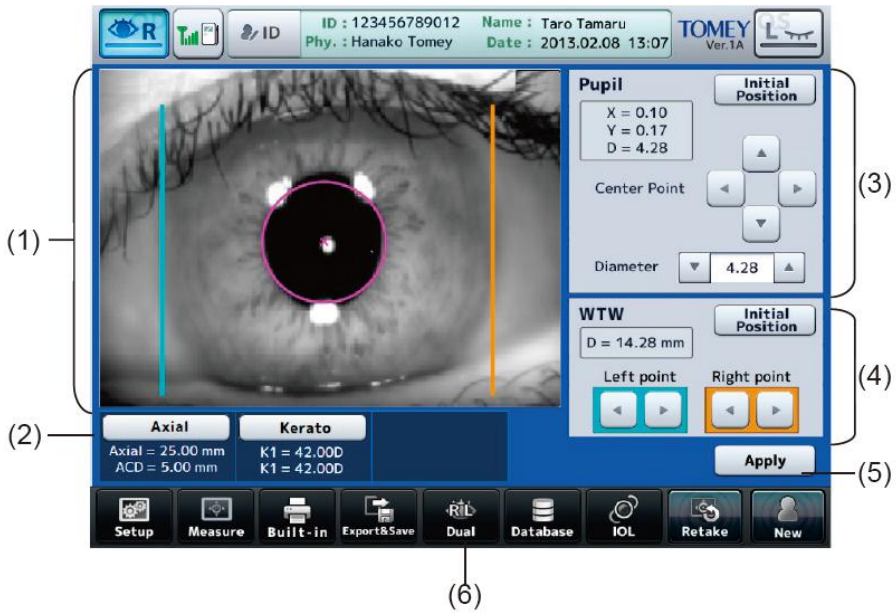
(13) Axial error

Displays errors that have occurred during axial length measurement by the subject currently in choice.

(14) Cyl

Displays the Cyl of the measurement under selection. + − display can be changed with the device settings.

d) Pupil diameter and corneal diameter view screen



(1) Image display field

(2) View screen switch button

(3) Pupil diameter

(4) Corneal diameter

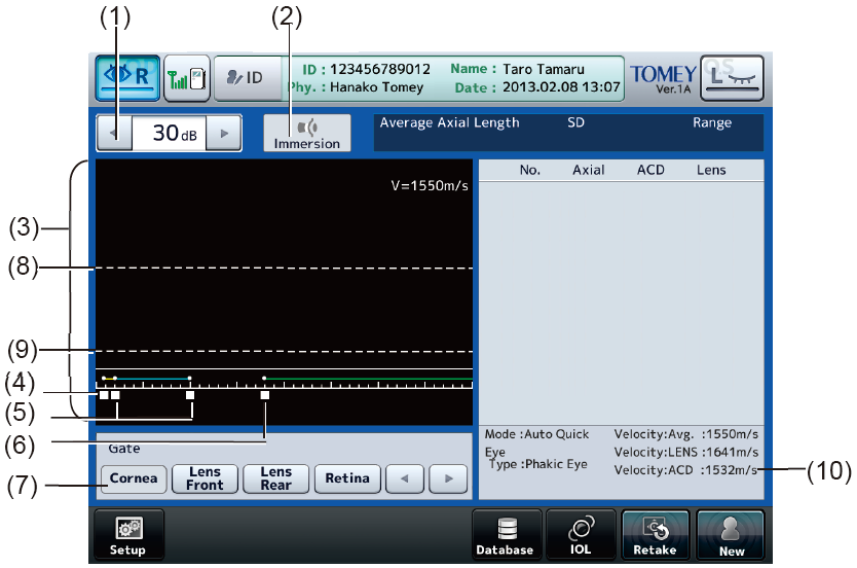
(5) "Apply" button

(6) ”Dual” button

Displays the R/L alignment display screen.

1.6 Screens in each ultrasound mode

a) Axial length measurement screen



(1) Gain display/adjustment field

(2) Mode display – Contact/Immersion

(3) Waveform display area

(4) Corneal gate cursor (only in immersion mode)

The waveform on the right of this cursor position is measured as the waveform of the cornea.

(5) Lens gate cursor

The waveform between these two cursors is the waveform of the lens.

(6) Retina gate cursor

The waveform on the right of this cursor position is measured as the waveform of the retina.

(7) Gate cursor movement button

Moves the gate cursor.

(8) Level cursor/level line

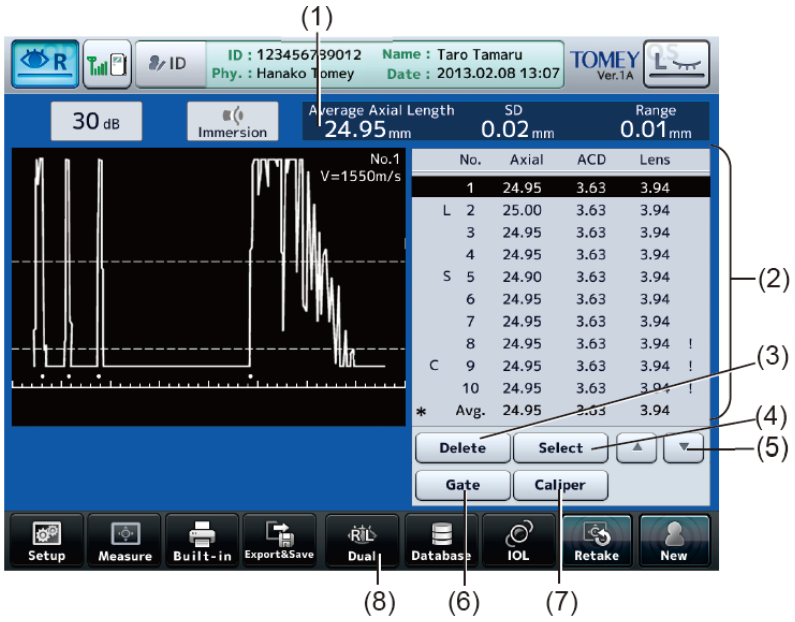
Measurement data will be taken when the waveform rises above this cursor/line position.

(9) Measurement cursor/measurement line

The distance at this cursor/line should be taken as the measurement data.

(10) Measurement conditions display field

b) Axial length view screen



(1) Axial length measurement data display

Displays measurement conditions and measured axial length.

(2) Measurement data display

The axial length, anterior chamber depth, lens, and their average values are listed.

(3) "Delete/Restore" button

Deletes or recovers the measurement data.

(4) "Select" button

The measurement data at the cursor position is selected to be used for calculating IOL power. The selected measurement data is indicated by an "*".

(5) Selection cursor UP/DOWN buttons

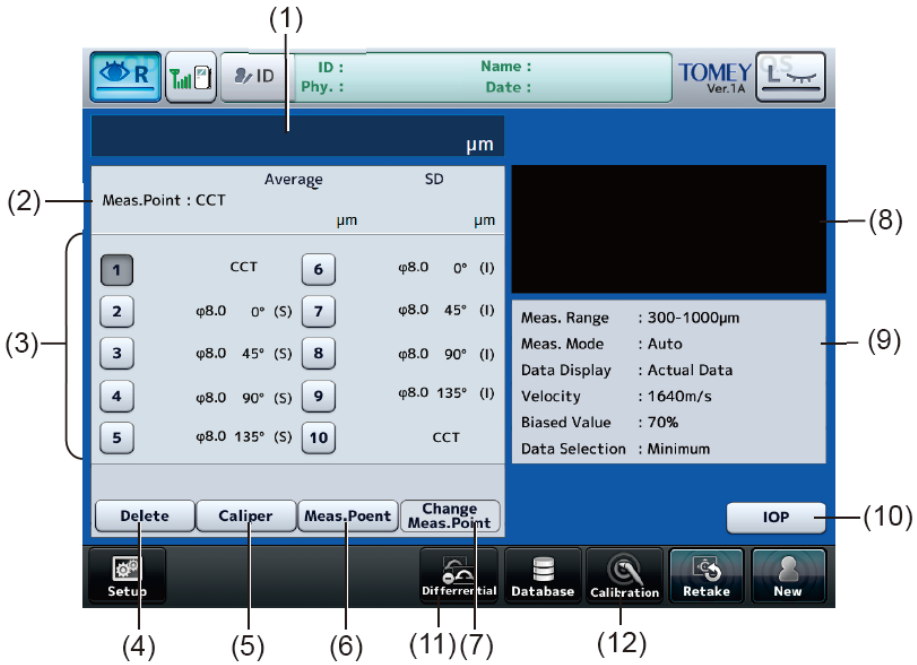
(6) "Gate" button

(7) "Caliper" button

(8) "Dual" button

Displays the R/L alignment display screen.

c) Corneal thickness measurement screen



(1) Real-time data display field

Displays the actual measurements of the uploaded measurement points. The latest uploaded data are displayed during the measurement process.

(2) Corneal thickness data display

(3) Measurement data display

(4) "Delete/Restore" button

(5) "Caliper" button

(6) "Meas. Point (measurement point)" button

(7) "Change Meas. Point" button

(8) Measurement waveform display field

(9) Measurement conditions display field

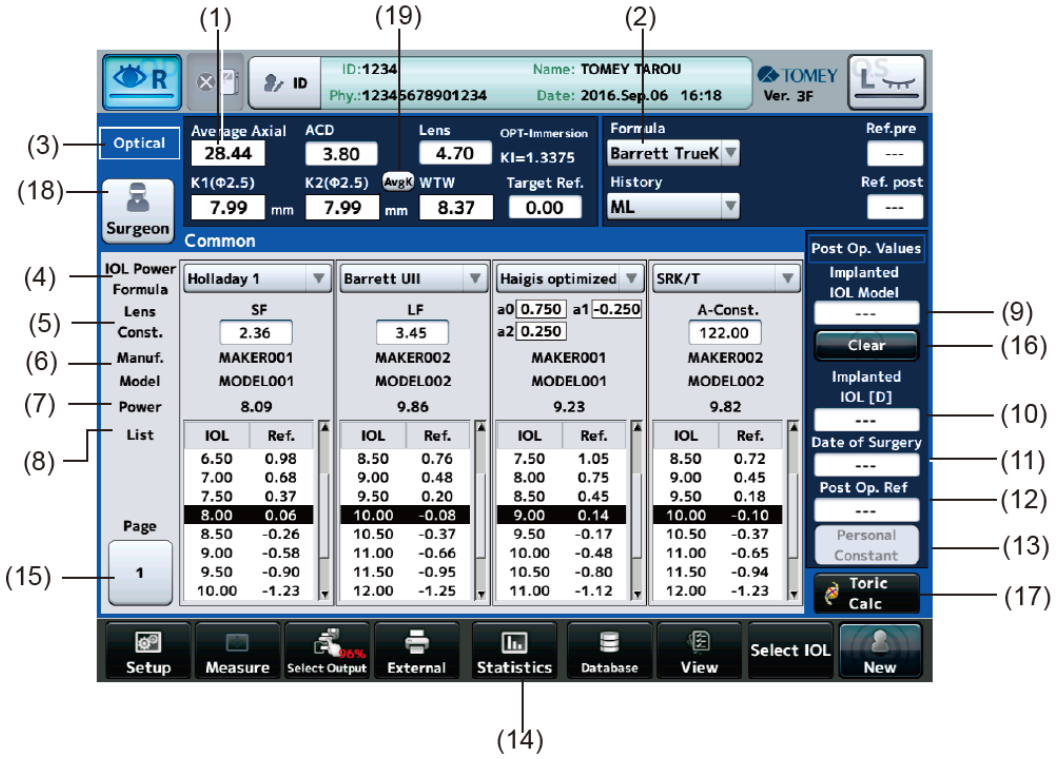
(10) "IOP" button

(11) "Subtraction" button

(12) "Calibration" button

Calibrates the sensitivity of pachymetry probes.

1.7 IOL power calculation screen



(1) Parameter field

Enter the following parameters used for calculating IOL power.

Average Axial (axial length / ACD (anterior chamber depth) / K1 / K2 / WTW / Lens / Target Ref. (expected refractive power).

(2) Clinical History Method parameter input field

(3) Measurement mode display/measurement data type button

Switches the display between optical measurement data and ultrasound measurement data.

(4) "IOL Power Formula" (formula selection) button

Select a formula for the IOL power calculation here. Formulae listed in the pull down menu can be set in the system setup. [Refer to "3.6 b) Selecting IOL power formula"].

(5) Lens Const. (lens constant) input field

Displays various optical lens constants corresponding to the adopted IOL power formula.

(6) Model and manufacturer name

(7) IOL Power display field

Displays the calculated IOL power that complies with the entered "Target Ref."

(8) List (IOL data list display) field

The IOL standards based on calculation results and estimated refractive power post-surgery to implant the IOL are listed.

(9) Implanted IOL Model input field

(10) Implanted IOL [D] (IOL power) input field

(11) Date of Surgery input field

(12) Post Op. Ref (post-operation eye refractive power) input field

(13) "Personal Constant" screen display button

(14) ”Statistics” screen display button

(15) ”Page” button

Touch the “Page” button to change the pages.

(16) ”Clear” button

Hold this button for 1 or 2 seconds to clear the selection of implanted IOL models.

(17) ”Toric Calc” button (Toric Calculation Screen button)

(18) ”Surgeon” button

Select a surgeion from the registered surgeon list.

Select the IOL data list and IOL calculation formula according to the selection of the surgeon.

(19) Keratometer value display switch button

Switches the keratometer value display (K1/K2 or AvgK).

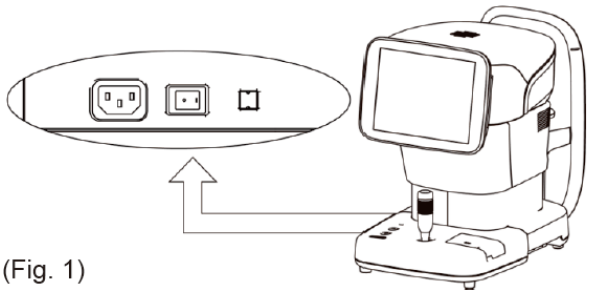
2. OPERATING PROCEDURES

2.1 Connections

2.1.1 Connections for accessory

a) Power code

Insert the connector of the power cord into the power socket on the side of the main unit in the correct direction. Connect all three pins of the plug.



(Fig. 1)

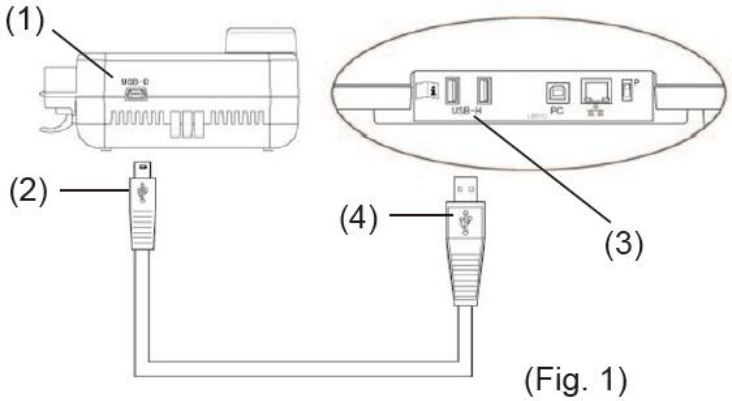
b) Connect the axial length and corneal thickness measurement instrument AL-4000

- Check that either or both of connected devices is in new patient mode before starting to communicate the patient information and measurement data. Communication cannot be started while both devices have information and measurement data for the last patient.

Connection methods with AL-4000 include USB connection (wired) and wireless connection.

[USB connection]

1) Plug the USB cable plug B (2) into the USB-D connector (1) at the top of AL-4000 in the correct orientation.
2) Plug the USB cable plug A (4) into any of the USB-H connectors (3) on the side of the main unit, making sure the orientation is correct.

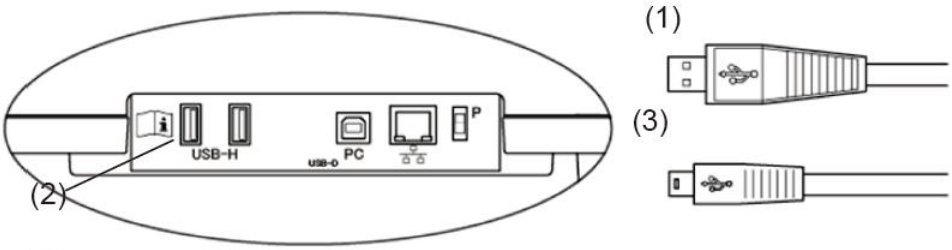


(Fig. 1)

[Wireless connection]

Refer to "2.1.2 Connetcting the AL-4000" to make settings.

c) External digital printer



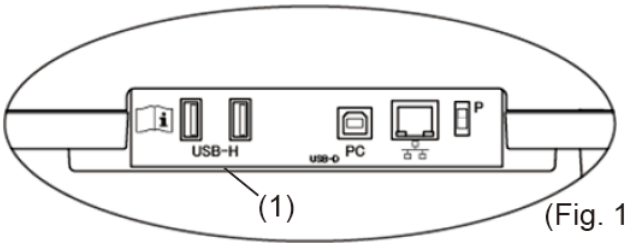
(Fig. 1)

[Video printer]

1) Insert the cable plug A(1) of the USB-H cable into the USB connector (2) on the side of the main unit in the correct orientation.
2) Connect the other cable plug B (3) of the USB cable to a video printer. Follow the instruction manual of the video printer for details on how to connect the printer.

d) External ID input device

Plug the connector of the external ID input device (e.g. barcode reader, card reader, keypad, and keyboard) into the USB-H terminal (1) on the side of the main unit, checking the correct orientation.

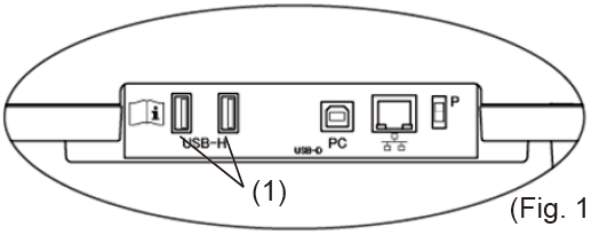


(Fig. 1)

e) Connecting OKULIX USB dongle

- Use the OKULIX USB dongle specialized for this instrument included in the package.
- Connect the OKULIX USB dongle directly to the instrument without using a USB hub.

Connect the OKULIX USB dongle to the USB-H connector terminal (1) on the side of the instrument.



(Fig. 1)

f) Connecting the personal computer

- The inspection data receiving software “DATA Transfer” (included in the package) is required for data communication with the instrument.
- Refer to the corresponding operation manual for installation, settings, and operation of DATA Transfer
- Connection setting on the System Setup screen must be completed before connecting DATA Transfer. Refer to "6.4 d) PC (PC connection)" to make settings.
- Be sure to make network settings with the consent of your network administrator.

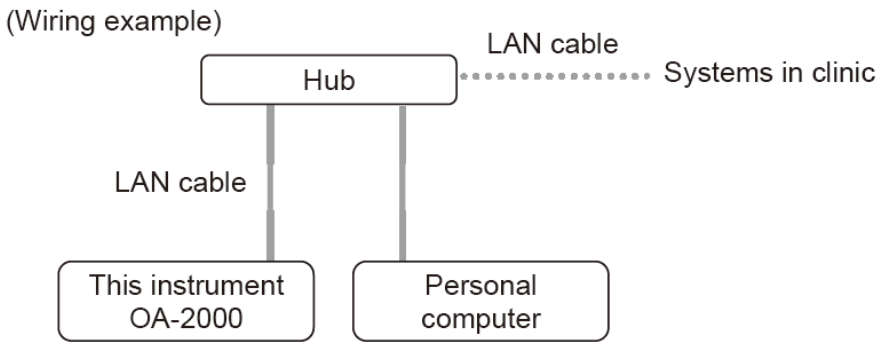
There are two methods to connect with a personal computer: LAN connection and USB connection.

[Connecting LAN cables]

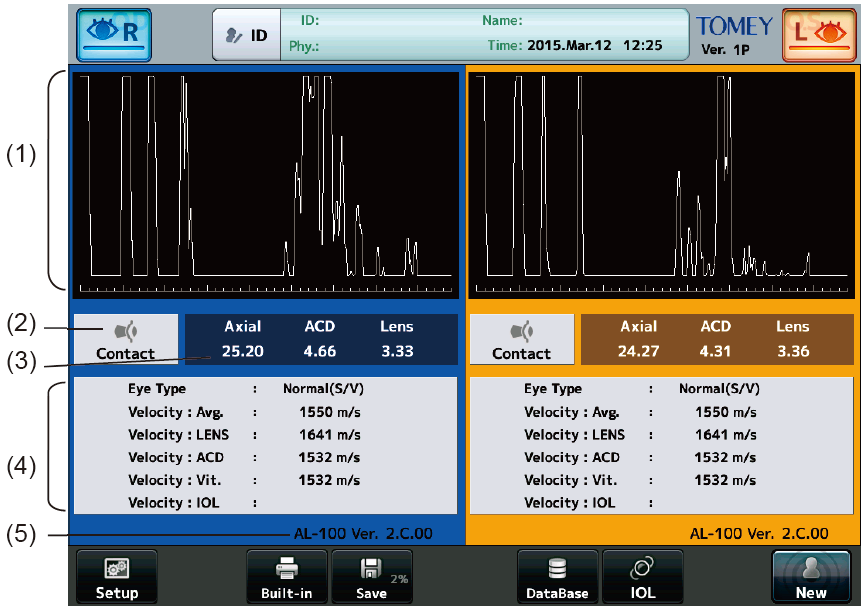
- For LAN connection, be sure to connect the unit to a computer via a hub. The unit does not work correctly if directly connected to a computer.

Prepare the following items.

- LAN cables (straight type, category 5 or higher): 2
- A network hub (A 100MHz switching hub recommended): 1
- A computer with TOMEY Link or DATA Transfer installed: 1



g) AL-100 measurement data review screen



(1) Waveform display field

(2) Mode display field – Contact / Immersion

(3) Axial length measurement data field

(4) Measurement condition display field

(5) AL-100 version

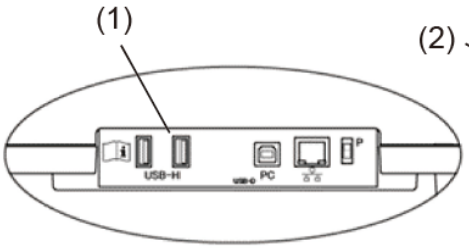
h) Connection with Biometer AL-100

- The following settings are required in Biometer AL-100. Refer to the Biometer AL-100 instruction manual for the settings.

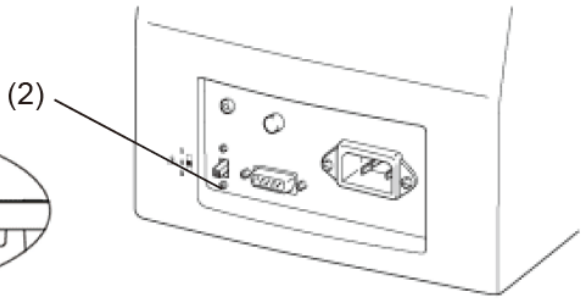
  BAUD RATE: 38400
  DATA LENGTH: 8 Bit
  PARITY: NONE
  STOP BIT: 1 bit

Use a serial cable (Dsub 9 pins, crossover cable, male + female) and USB serial conversion cable for connection.

1) Connect the serial cable and USB serial conversion cable.
2) Insert the USB plug into any of the USB-H connectors (1) on the side of the main unit, and insert the serial cable plug into the Communication Cable Terminal (2) on the back of the AL-100.



(Fig. 1　Side of OA-2000)



(Fig. 2　Back of AL-100)

2.1.2　Connecting the AL-4000

a) Wireless communication setting

Refer to "6.4 f) AL-4000 wireless settings" to make the settings.

b) Connection for wireless communication

- Check that either or both connected devices are in new patient mode before starting to communicate the patient information and measurement data. Communication cannot be started while both devices have information and measurement data for the last patient.
- When connecting a device with a USB cable during wireless communicating, wireless connection is changed to a wired connection.

[Automatic connection upon startup]

When the AL-4000 is selected as the "connection place" in this instrument, wireless communication automatically starts when both the AL-4000 and this instrument are turned on. However, if the AL-4000 has already started wireless communication with another device, this instrument cannot start wireless communication.

Refer to "6.4 f) AL-4000 wireless settings" for how to set "automatic connection upon startup."

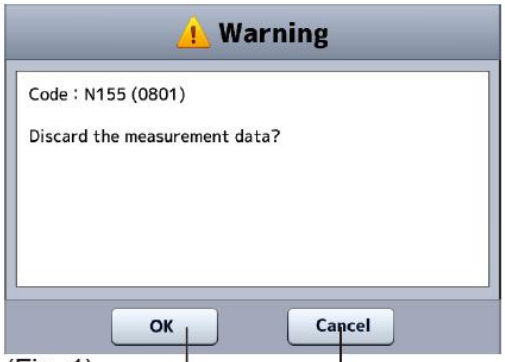
Refer to the Operation Guid of the AL-4000 for how to set the AL-4000.

[No communication state]

A confirmation screen appears if any measurement data remains in this instrument when attempting to connect to the AL-4000 in new patient mode. (Fig. 1)

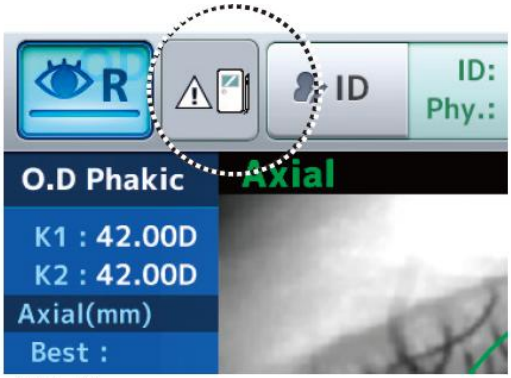
Click the "OK" button (1) to delete the data in this instrument and connect to the AL-4000.

Click the "Cancel" button (2) to stop communication. (Fig. 2)



(Fig. 1)

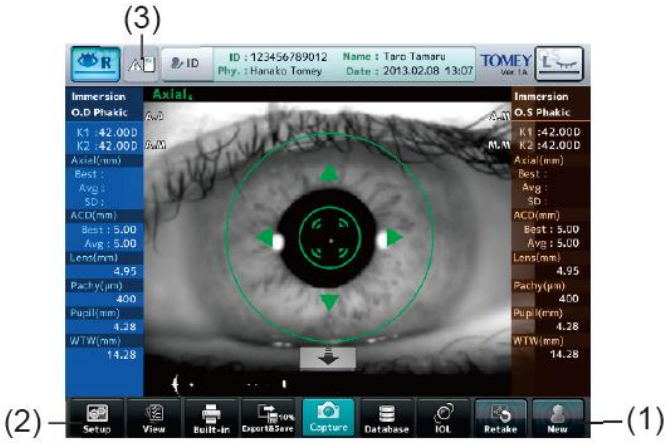
(1) (2)



(Fig. 2)

[Resuming communication from the no communication state]

1) Click the “New” button (1) to clear the existing data.
2) Select the same measurement mode as that of the AL-4000 using the “Setup” button (2).
3) Click the “AL-4000 communication check” button (3) to resume communication.



(Fig. 3)

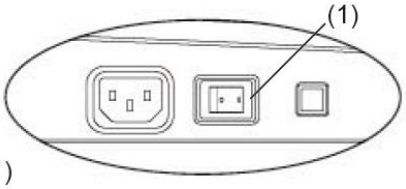
2.2 Preparation

2.2.1 Turning the power on and adjustment after turning the power on

a) Turning the power on

- To restart the system, turn the power off, wait for ten seconds or so, and turn it on again.

1) Turn on the power switch (1) on the side of the main unit.
2) The startup screen (Fig. 2) appears and then displays the optical measurement screen.



(Fig. 1)

(Fig. 2)

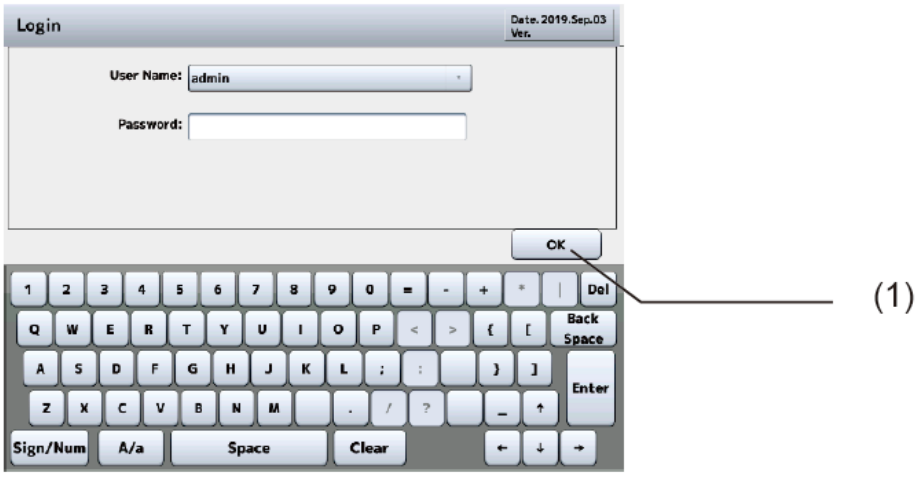
b) Pre-use inspection

- If the inspection result is unsuccessful, accurate measurement or measurement itself may not be possible. Contact your local distributor.

Align the model eye by placing it on the chin rest according to the installation guide displayed on the measurement screen. Perform a pre-use inspection using the model eye

c) Login screen

- When using the instrument for the first time, change the admin user's password (admin).
- The first time you log in use [**User Name: admin**] and [**Password: admin**].
- This login function may not be provided for some delivery destinations.



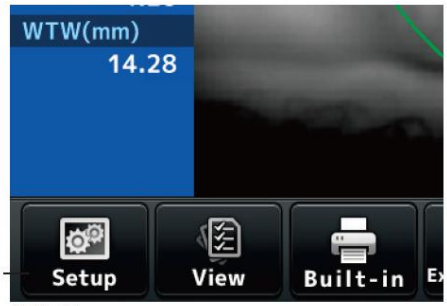
After selecting the login user, enter their password and press the [OK] button (1).
The measurement screen appears. (Refer to "6.1 General")

d) Adjustment after turning power on

The brightness of the monitor can be adjusted appropriate to illumination in the examination room. (Refer to "6.1 General")

2.2.2 Switching between optical (OPT) mode and ultrasound (US) mode

Touching the "Setup" button (1) on each screen displays the setup screen (Fig. 2) (Fig. 3).
Touching any of the mode buttons (2) opens the measurement screen corresponding to the selected measurement mode.
Data obtained on this screen is retained after switching between the ultrasound (US) mode and the optical (OPT) mode.



(1)

(Fig. 1)

(Fig. 2) (2)

(Fig. 3)

(2)

2.2.3 Entering patient data

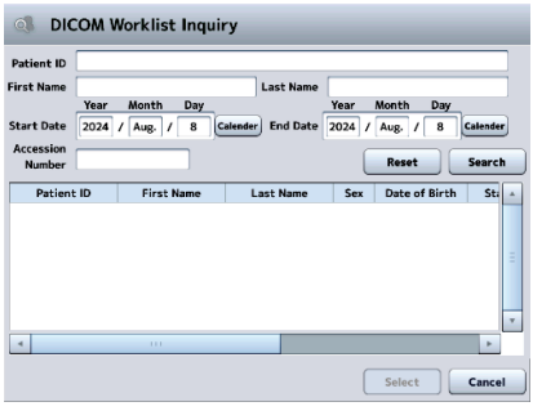
- Only the first 14 digits of the ID number are displayed in the patient information field. Check that the ID number is correct on the patient information entry screen.
- The network support system “DICOM Connect” (optional) is required to use the patient information query function. “DATA Transfer” provided with the machine is not available for query of the patient data.

1) Touch the “ID" button (1) to open the Patient Information screen (Fig. 2).

(Fig. 1)

(Fig. 2)

2) Enter the patient information using an external ID input device such as a barcode reader or the software keyboard (2) shown on the screen. After entering the subject's ID, press the "ID Query" button (3) to query the subject's information from the ID query source according to the device settings. The result will be displayed.
3) If TOMEY Link or database is selected as the query source in the device settings, the ID query starts as soon as ID is entered. If DICOM is selected, DICOM Worklist Inquiry screen (fig.3) will be displayed.

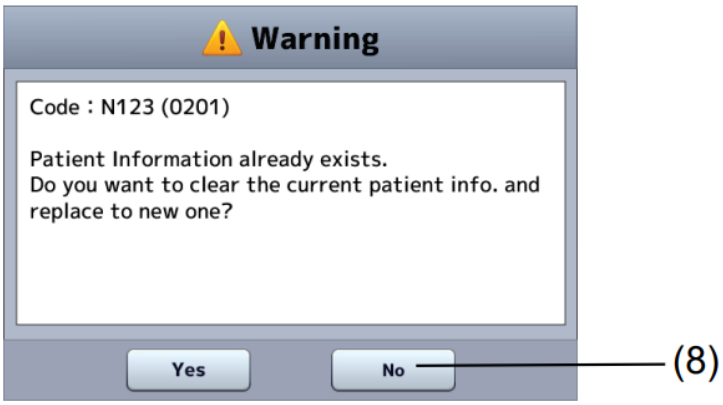


(Fig. 3)

4) Touch the "Internal Memory Patient Search" button (4) to display the patient list (Fig. 4) saved in the memory. A search can be performed in the internal memory of the instrument or the connected external memory. The memory subject to search can be set according to “3.9.4 c) Media options / Data output format.” Use the search function (5) in the Patient List screen (Fig. 4) to search IDs and patient names in the internal memory.
Select the required patient and touch the "Select" button to update the patient information.

(Fig. 4)

5) After the patient information is entered, touch the "OK" button (7) to apply the entered data and return to the previous screen (Fig. 1). If an ID number is entered while the patient information and measurement data already exist, the confirmation screen (Fig 5) appears.



(Fig. 5)

6) Touch the “No” button (8) on the confirmation screen (Fig. 5) or the “No” button on the Patient Information screen (Fig. 2) to ignore the entered data and return to the previous screen (Fig. 1)

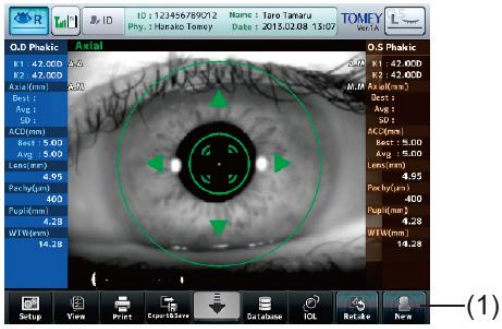
Entry of the patient ID from an external ID input device (barcode reader etc.) is accepted on the following screens.

- Patient Information screen
- Each measurement screen or view screen

Re-entry of the patient ID is not accepted after the examination data is output.

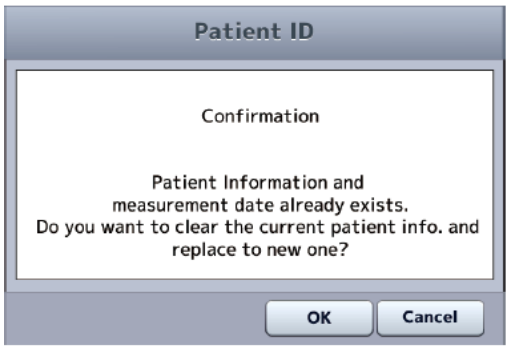
2.2.4 Clear all measurement data (preparation for measuring a new patient)

- The deleted measurement data cannot be restored. Carefully check the data before deleting it.
- Be sure to touch the “New” button to delete all the measurement data for the previous patient before measuring another patient. If the measurement data of the next patient is captured without touching the “New” button, the patient information will not match the measurement data.



(Fig. 1)

1) When the “New” button (1) is held for approximately 1 second and a beep sounds, the patient information (ID, name, and sex) and measurement data is all deleted and the measurement screen appears.
The patient’s eye selection screen (Fig. 2) appears in any of the ultrasound modes.



(Fig. 2)

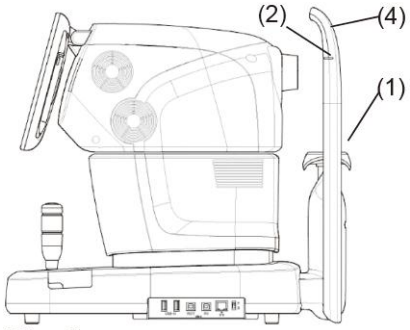
2) Select an eye and start new measurements.

2.2.5 Selecting an eye

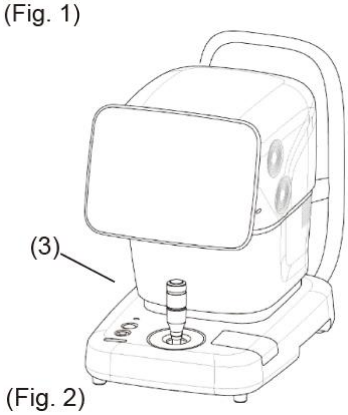
(Fig. 1)

Touch either eye selection button (1) to select “R (right)” or “L (left)."

2.2.6 Patient's eye height adjustment



(Fig. 1)



(Fig. 2)

1) Have the patient place their face on the chin rest (1). Adjust the chin rest height so that the height of the corner of the eye is aligned with the eye level mark (2).

2) Press the chin rest button (3) at the front of the main unit (Fig. 2) to move the chin rest up and down.

3) When the patient's eye height is adjusted, lightly press the patient's forehead against the forehead pad (4) to secure the patient's position.

3. MEASUREMENT MODE

3.1 Optical measurement mode

Refer to "2.2.2 Switching between optical (OPT) mode and ultrasound (US) mode" for the method to switch to optical measurement mode.

- Calibration may be conducted automatically in optical measurement mode in order to smoothly perform measurement. No operation is available during calibration. Restart the operation after the message "Calibrating…" displayed during calibration disappears.

3.1.1 Setting measurement conditions

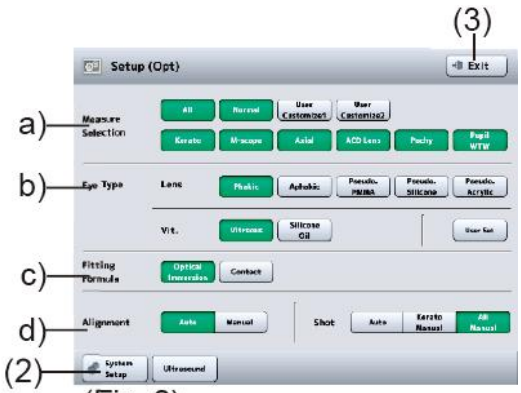
- Settings made on the Setup (OPT) screen are only effective for the eye currently selected. Settings cannot be made for both eyes simultaneously. Complete necessary settings for each eye.

Touch the "Setup" button (1) at the lower left of the screen to open the Setup (OPT) screen (Fig. 2).

Settings made on the Setup (OPT) screen are effective for only one measurement. The settings will return to the status set on the System Setup (2) screen when one measurement is completed. Refer to "6. SYSTEM SETUP" for the "System Setup" button (2).

Touch the "Exit" button (2) after setting is completed to apply selected contents and return to the measurement screen (Fig. 1).

(Fig. 1)



(Fig. 2)

a) Selecting measurement items

The following 6 items can be measured simultaneously in optical measurement mode.

*** Axial length** *** Pupil/corneal diameter**

*** Kerato** *** Anterior chamber depth, lens**

*** Corneal thickness** *** M-Scope**

Select the item to be measured.

Touch the “All” button to select all items. Touch any of the “Standard," Customize 1,” and “Customize 2” buttons to select the measurement items preset in the system setup. [Refer to “6.2 c) Settings for various measurements”]

b) Selecting inspection eye

Select the type of eye to be examined according to the patient’s eye.

[Crystalline lens]

*Phakic eye

Select this in the case of phakic eyes.

*Aphakic eye

Select this in the case of aphakic eyes.

*IOL (PMMA)

Select this when a PMMA IOL is implanted.

*IOL (silicon)

Select this when a silicon IOL is implanted.

*IOL (acryl)

Select this when an acrylic IOL is implanted.

* User settings

Select this when registering optional materials for IOL eyes.

[Vitreous body]

* Vitreous body

* Silicon oil

Select an appropriate option according to the material of the vitreous body.

- Axial length is calculated based on the specified model eye in silicon oil mode.Therefore, the calculation result may be different from the actual axial length.

c) Selecting fitting formula

A fitting formula can be selected.

d) Setting Auto Alignment and Auto Measurement

- Use Manual mode only when measurement must be performed even though the sight-fixing condition is unstable. Correct alignment is difficult in Manual mode and measurement errors easily occur.

Follow the procedures below to make settings for Auto Alignment and Auto Measurement.

3.1.2 Alignment

- Measurement results may be affected if the patient's eyelid and/or eyelashes cover the automatic alignment ring during measurement.
- Ask the patient to open their eyes wide or have the physician lightly hold the patient's upper eyelid with their fingers.
- Auto Alignment may not be effective when the patient blinks frequently during measurement. Ask the patient to refrain from blinking during measurement.
- Ask the patient to look directly into the fixation light in the measurement window. If the patient looks in a different direction or moves, the measurement may not be conducted correctly.
- This instrument is designed to perform measurement in Auto mode to ensure higher accuracy through standard operation. However, Auto Alignment may not be particularly effective when insufficient light is reflected due to deformation or inflammation of the cornea. In this case, conduct measurement manually.
- The reflection in the center of the cornea may not be clearly viewed when any deformation and/or inflammation of the cornea is severe. In this case, an error may occur even in Manual mode.

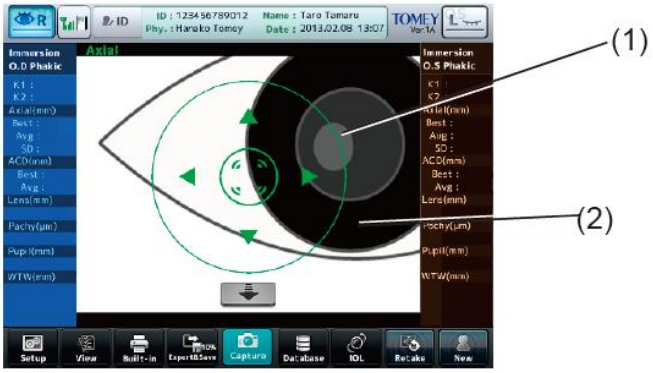
a) Auto Alignment setting

Refer to "3.1.1 Setting measurement conditions"

b) Positioning by Touch Alignment

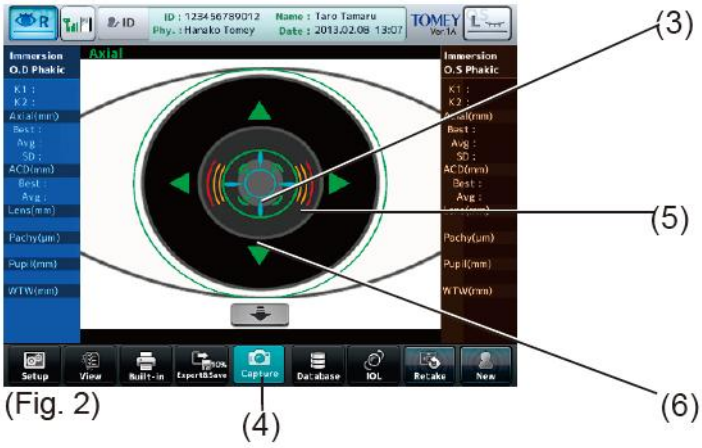
- When moving an image up, down, left and right using Touch Alignment, touch the panel and release your finger immediately. Do not press the panel continuously.

1) Use Touch Alignment or the joystick to position the patient's eye on the screen.
2) Lightly touch the center of the cornea (1) on the screen. The measuring head moves so that the patient's eye is positioned in the center of the screen. When the center of the cornea (1) enters the alignment ring (2) with Auto Alignment turned on, focusing in the X and Z axes automatically starts.



(Fig. 1)

3) Perform alignment in the Y axis. Pressing the center of the screen (3), advances the measuring head towards the patient. Touch the measuring head retract button (4) to retract the measuring head towards the physician.



(Fig. 2)

4) When the focus indicator (5) appears while Auto Alignment is activated, focusing in the Y axis starts automatically. When alignment conditions are optimal, the alignment OK mark (6) is displayed.

c) Positioning by the joystick

- This instrument is designed to perform measurement in Auto mode to ensure higher accuracy through standard operation. However, Auto Alignment may not be particularly effective when insufficient light is reflected due to deformation or inflammation of the cornea. In this case, conduct measurement manually.
- The reflection in the center of the cornea may not be clearly viewed when deformation and/or inflammation of the cornea is severe. In this case, an error may occur even in Manual mode.

There are two types of operations - general operation for roughly positioning the measuring head and fine operation for finely adjusting the position of the measuring head.

[General operation]

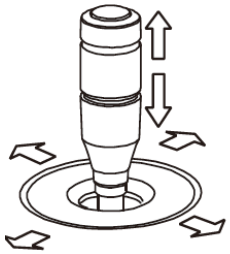
Moving the joystick moves the measuring head back, forth, left, and right.

Slide the up/down ring vertically to move the head up and down. (Fig. 1)

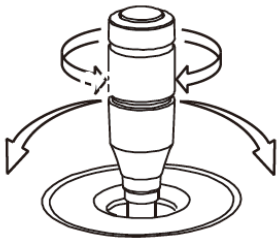
[Fine operation]

Tilting the joystick moves the measuring head in the tilting direction.

Rotate the up/down ring to move the head up and down. (Fig. 2)



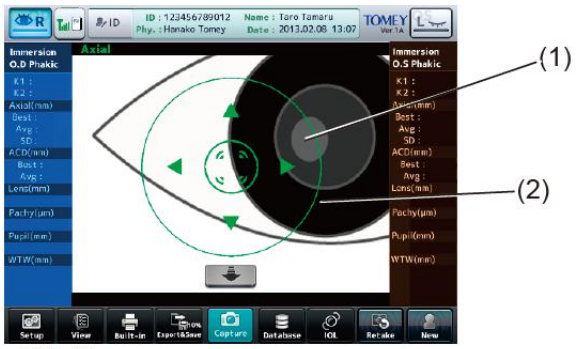
(Fig. 1)



(Fig. 2)

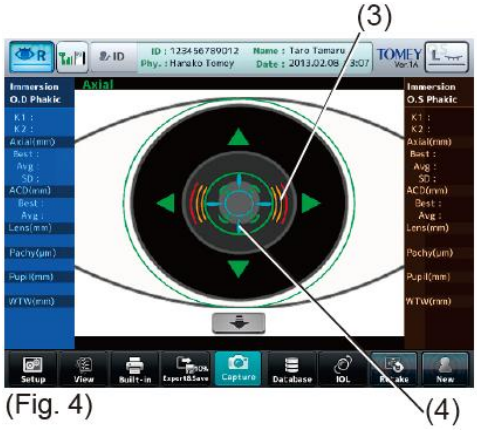
Clockwise
The head rises.
Counterclockwise
The head lowers.

1) Operate the joystick so the center of the pupil (1) enters the target ring (2).



(Fig. 3)

2) Move the joystick back and forth to move the measuring head so that the focus indicator (3) on the screen becomes small.
   When the focus indicator (3) is shown horizontally, the measuring head is too far from the eye; when the focus indicator is shown vertically, the measuring head is too close to the eye. When the focus indicator (3) does not appear, align the focus with the iris.
3) When alignment conditions are optimal, the alignment OK mark (4) is displayed.

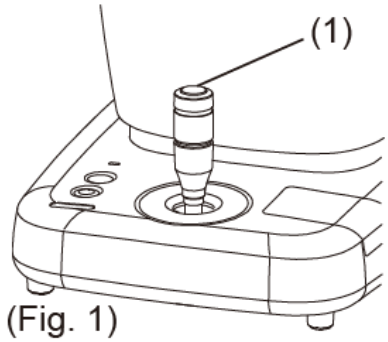


(Fig. 4)

3.1.3 Measurement

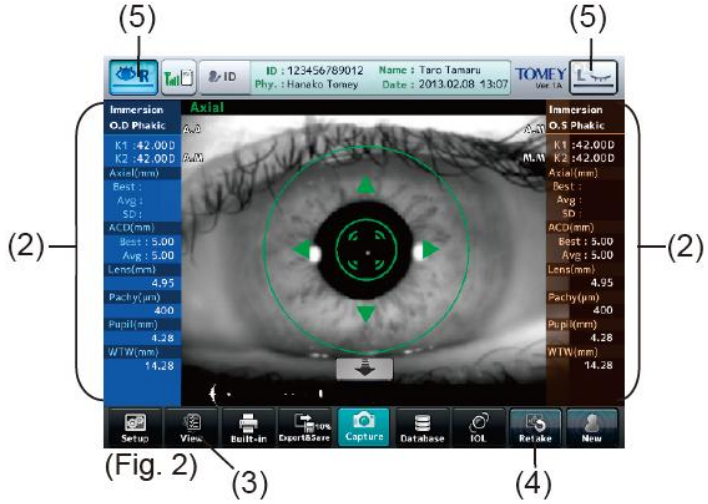
- Be sure to touch the “New” button to delete all the measurement data of the previous patient before measuring another patient. If new measurement is started without deleting the previous data, the measurement data of the previous patient may be included.
- When an attention message pertaining to the measurement is displayed after measurement, follow the directions in the message to check the measurement data.
- If the measurement value is output when measuring axial length, be sure to check waveforms and images on the view screen to confirm that the retinal pigment epithelium is being measured. In particular, when SNR is low and an "!" mark has appeared, the possibility that other tissue is measured by mistake increases. Open the caliper screen to check details.
- If any problem is found on waveforms when measuring axial length, be sure to perform other examinations.
  When the patient has ocular fundus diseases, tissues other than the retinal pigment epithelium (e.g. macular pucker) may be captured. If an uncertain waveform is found when measuring axial length, be sure to perform other examinations (e.g. ultrasonic axial length measurement unit)
- When the difference between left and right in the axial length measurement is more than 1 mm, be sure to perform other examinations (e.g. ultrasonic axial length measurement unit).
- When there are multiple higher peaks detected in the axial length measurement, the retinal pigment epithelium may not have been detected correctly. Check that the retinal pigment epithelium has been detected on the caliper screen.
  Check that the retinal pigment epithelium is being measured correctly on the caliper screen. When measurement is incorrect, use the caliper function to correct the measurement point.
- As for measurement of the radius of corneal curvature, if the difference between measurement values on the left and right eyes is significant or any problem is found on the cornea during the preliminary examination, be sure to check the image of the measurement ring pattern on the view screen.
- If reliability of measurement values is low when measuring the radius of corneal curvature, check the measurement ring pattern. If any problem is found, be sure to perform other examinations.
- Do not determine application of LASIK based only on measurements by this instrument and be sure to refer to other examinations.
- Do not determine IOL types or ICL sizes based only on measurements by this instrument and be sure to refer to other examinations.

1) Adjust the patient's eye height and ask the patient to look at the red lamp in the measurement window. (Refer to "2.2.6 Patient's eye height adjustment") When capturing an image immediately after having the patient blink and open their eye widely, partial gaps in the color code map due to breakage of the tear film or insufficient opening of the eye can be reduced.
2) Perform alignment. (Refer to "3.1.2 Alignment")
   If measurement is in auto mode, measurement starts automatically after alignment is complete. If measurement is in manual mode, press the measurement button (1) on the joystick (Fig. 1) after alignment is complete to start measurement.
   The number of times the data is taken per measurement can be set in system setup. (Refer to "6. SYSTEM SETUP")



(Fig. 1)

3) When measurement has been completed, the measured data (2) appears. A representative value appears here. Press the "View" button (3) to look at all data taken for each measurement item.



(Fig. 2)

4) Hold the "Retake" button (4) for approximately 1 second until a beep sounds to delete the last measurement data and measure the same eye again.
5) Touch the eye display button (5) to change the eye to be measured. The measuring head moves toward the selected eye.

3.1.4 Browsing and editing axial length measurement

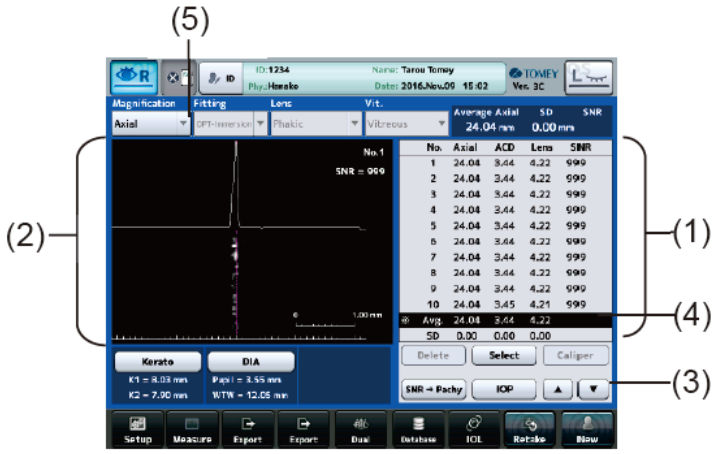
Touch the "View" button (1) at the lower left of the measurement screen (Fig. 1) to open the axial length view screen (Fig. 2).

Touch the “Measure" button (2) on the view screen (Fig. 2) to return to the measurement screen (Fig. 1).

(Fig. 1) (1)

(Fig. 2) (2)

a) Browsing measurement values



(Fig. 1)

1) Measurement values (1) and scanned image / waveform (2) are displayed with the average data selected when the screen appears. Touch the data selection buttons (3) to move the cursor (4).

   The following marks are assigned to the measurement data.

   * : Data used for calculating IOL power

   ! : Data with low reliability

   C : Calipered data

2) Touch the display area selection button (5) to show the image at magnification and position where the selected section can be checked.

   Axial / ACD, Lens / Corneal thickness / All

b) Deleting and recovering measurement values

(Fig. 1)

1) Touch the “Delete” button (1) to delete the data selected with the cursor and the data color changes to gray. The data deleted here is excluded from the integral calculus value and average.
2) To recover the deleted data, move the cursor to the data. Touch the “Recall” button (2) to cancel deletion.
3) When returning to the measurement screen after deleting the data, measurement can be performed and data can be uploaded for the number of deleted datasets.

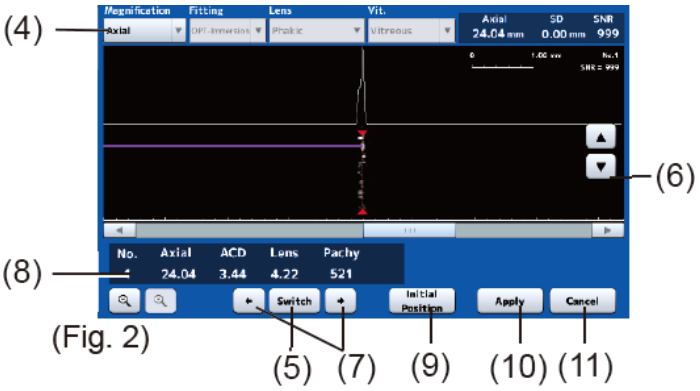
c) Caliper function

- Values measured and displayed using the caliper function are rough estimates and may differ from the actual measurement results.

This function is used to measure the distance at an arbitrary section of the measurement waveform. 4 dotted caliper lines appear, and the distance between these 2 points is displayed. The selected and active caliper line is displayed in red and the other lines are displayed in yellow.

(Fig. 1)

1) Use the selection cursor movement buttons (1) to move the selection cursor (2) to the data which is to be measured.
2) Touch the "Caliper" button (3) to open the caliper screen (Fig. 2).



(Fig. 2)

3) Select the display area (4). The following caliper lines will be displayed.

Axial length :	Front of cornea, retina
Anterior chamber depth / lens :	Front of cornea, front of crystalline lens, back of crystalline lens
Corneal thickness :	Front of cornea, back of cornea

4) Touch the “Switch” button (5) of the active caliper line to select the caliper line to be changed. The selected caliper line is displayed in red but the other lines are displayed in yellow.
5) Use the selection buttons (6) on the right of the scanned image to change the waveform to be displayed. Select the position where the peak of the waveform to be calipered can be best confirmed.
6) Touch the caliper line movement buttons (7) to change the caliper line position. The changed measurement data is displayed in the edit data display field (8) along with the movement of the caliper line.
   The distance between the cornea caliper line and the retina caliper line is displayed in Axial length, the distance between the cornea caliper line and the caliper line for the front of the crystalline lens is displayed in ACD, and the distance between the caliper line for the front of the crystalline lens and the caliper line for the back of the crystalline lens is displayed in Lens.
7) If you have edited it mistakenly, touch the “Initial Position” button (9) to cancel the changes made, and the caliper line will return to the position before the editing.
8) When you touch the “Apply” button (10), the changes made are applied, the measurement data is overwritten with the edited measurement data, and the caliper screen is closed. Touching the “Cancel” button (11) will discard the changes made, and the caliper screen is closed.

d) Selecting specific measurement data to be used for calculating IOL power

The average value is normally adopted for the measurement data to be used in calculating the IOL power, but specific measurement data can also be selected.

(Fig. 1)

1) Use the selection cursor movement buttons (1) to move the selection cursor (2) to the measurement data which is to be used in calculating the IOL power. To use the average value in IOL power calculation, move the selection cursor (2) to the average data.
2) When the “Select” button (3) is touched, it is selected as the data to be used in calculating the IOL power, and a “*” appears on the left of the data.

3.1.5 Browsing corneal thickness measurement values and correcting IOP

(Fig. 1)

1) Touch the “Pachy -> SNR” button (1) to switch the measurement data list between Pachy and SNR.
2) Touch the “IOP" button (2) to open the intraocular pressure correction screen (Fig. 2). When a measurement has already been completed at this point, the measured value is displayed in the CCT field (3).

(Fig. 2)

3) The input fields of parameter 1 (4) and parameter 2 (5) for the intraocular pressure correction formula become active when touched, and the keypad appears. Also, when a formula selection button (6) is touched, the parameters already set are displayed in the intraocular pressure correction formula.

[Input range]

* Parameter 1 : 0 - 1500

* Parameter 2 : 0.0000 - 1.0000

4) Enter the intraocular pressure data. The keypad appears when the entry field (7) is touched.

[Input range]

* Intraocular pressure data : 1 - 60.0 (mmHg)
: 1.33 - 79.99 (hPa)

The unit for display can be changed according to "6.2 c) Settings for various measurements"

5) Touch the "Back" button (8) to close the intraocular pressure correction screen (Fig. 2) and return to the previous screen.

3.1.6 Browsing and editing keratometer measurement

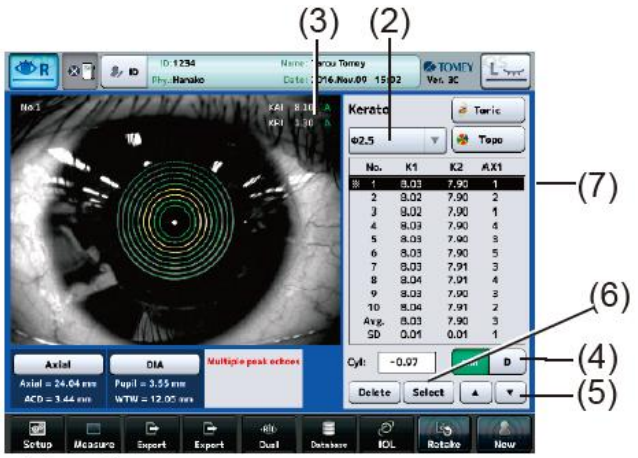
a) Browsing measurement values

- The corneal irregular astigmatism display function is a simple measurement using keratometer measurement. This function does not detect all cases of corneal irregular astigmatism. If any deformity exists on the corneal shape, measurement or correct measurement may not be possible.
- Because the corneal irregular astigmatism display function requires more information than keratometer measurement, corneal irregular astigmatism may not be able to be measured even though keratometer measurement can be performed.

(Fig. 1)

1) Touch the "Kerato" button (1) on each view screen to open the kerato view screen (Fig. 2).

The default view for measurement position is determined by the fitting formula used in the measurement. Immersion shows φ2.5 mm. Other fitting fomulae show φ3.0 mm.



(Fig. 2)

2) Touch the measurement position display button (2) to select the section to be displayed.

φ2.0mean /φ2.5 /φ3.0

φ2.0mean displays only mean values.

When measurement position φ3.0 is selected, the indexes of KAI and KRI (3) measured by keratometer measurement are displayed. KAI represents asymmetry of the corneal shape and KRI represents regularity / irregularity of the corneal shape. A larger value for this index means irregular astigmatism.

Possibility of corneal irregular astigmatism is shown as levels A, B, and C.

Level A : Improbable to be corneal irregular astigmatism such as keratoconus

Level B : Slightly probable to be corneal irregular astigmatism such as keratoconus

Level C : Highly probable to be corneal irregular astigmatism such as keratoconus

Thresholds for levels A, B, and C are as shown below.]

	A (Green)	B (Yellow)	C (Red)
KAI	0.0 - 23.4	23.5 - 29.0	29.1 -
KRI	0.0 - 4.4	4.5 - 5.2	5.3 -

(Refer to "7.5 Corneal irregular astigmatism index")

3) Touch the "mm/D" button (4) to change the unit for display.
4) "*" is shown for the data used for IOL power calculation. To select the desired data, move the cursor to the desired data using the cursor button (5) and then touch the "Select" button (6). The specified data is selected for IOL power calculation.
If the measurement value lacks reliability because the patient's eyelid and/or eyelashes interfered with the measuring point etc., "!" appears (7).

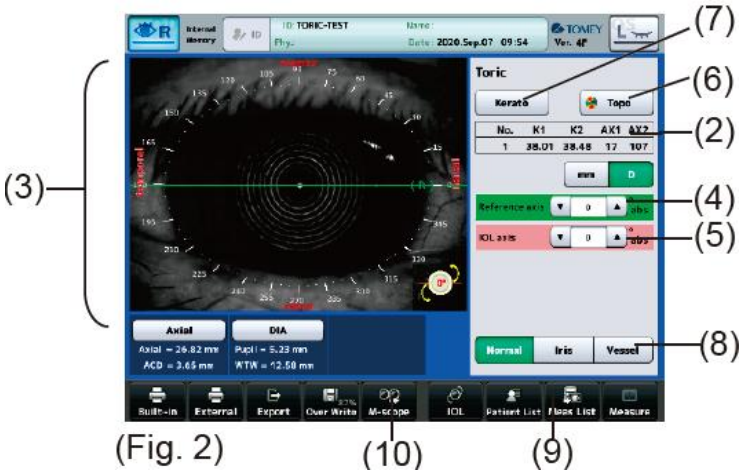
b) Deleting and recovering measurement values

Refer to "3.1.4 Browsing and editing axial length measurement"

c) Auxiliary function for Toric lens

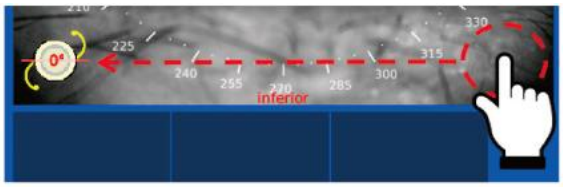
(Fig. 1)

1) Touch the "Toric" button (1) on the kerato view screen to open the auxiliary function screen for eyes with a toric lens (Fig. 2).



(Fig. 2)

2) Measurement values (2) selected on the kerato view screen appear. In addition, the axis angle line for the characteristic point (green) and the IOL axis angle icon (yellow) are shown on the camera image (3).
3) Enter an angle to the input field of the axis angle line for the characteristic point (green) (4) to change the displayed position on the camera image.
4) Enter an angle to the input field of the IOL axis angle (5) to change the display of the IOL axis angle icon on the camera image. The displayed ion can be changed by touching it if the icon is in the way when viewing.



(Fig. 3)

5) Touch the "Topo" button (6) to display the TOPO view screen.Touch the “Kerato” button (7) to return to the kerato review screen (Fig. 1).

[M-Scope Function]

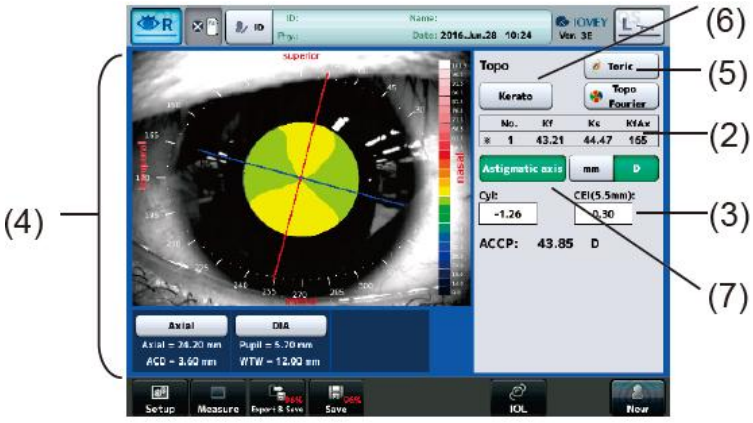
Available only during capture.

1) Touch the M-Scope switching buttons (8) to change the display image when M-Scope capturing.
2) Touch the “M-Retake” button (9) to recapture the M-Scope image.
3) Touch the “M-scope” button (10) to export the measurement data for surgical microscope.

d) Topography function

(Fig. 1)

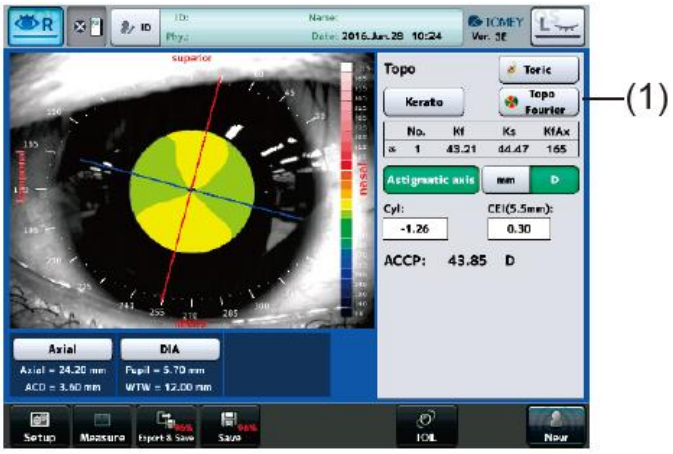
1) Touch the “Topo” button (1) on the Topo view screen to open the view screen (Fig. 2).



(Fig. 2)

2) Measurement values (2) selected on the kerato view screen, and the astigmatism axis angle and corneal eccentricity (3) are shown. The single map and scale are shown in the image display field (4).
3) If you touch the “Astigmatic axis” button (7), you can switch between displaying or not displaying flat meridian / steep meridian.
4) Touch the “Toric” button (5) to open the Toric lens auxiliary function screen. Touch the “Kerato” button (6) to return to the kerato review screen (Fig. 1).

e) Topo Fourier function



(Fig.1)

1) Touch the “Fourier Map” button (1) on the Topo view screen to open the Topo Fourier screen (Fig. 2).

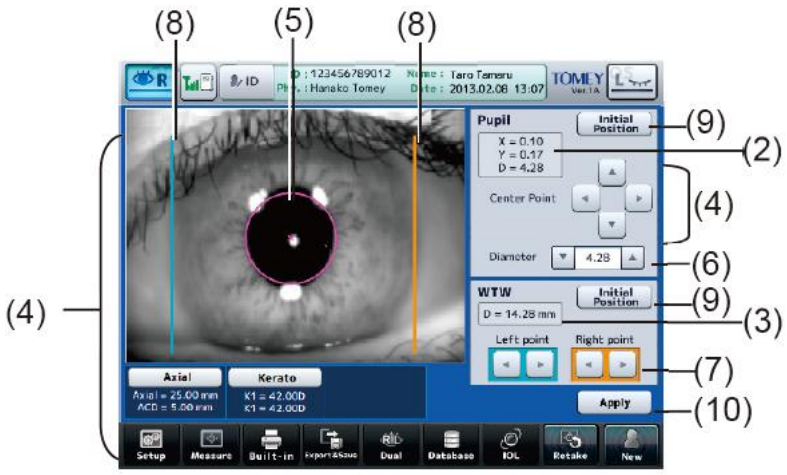
(Fig.2)

2) On the Topo Fourier analysis screen, the constant term is displayed as “Spherical equ.” the first order term as “Asymmetry” the second order term as “Regular astigmatism” and higher order terms as “Higher order irregularity” in the Fourier map display area (2).
3) Individual component values of φ3 mm/φ5.5 mm are shown numerically in the Fourier index display area (3).
4) Touch the "Kerato" button (4) to open the Kerato view screen and the “Toric” button to open the Toric view screen.
   Touch the “Topo” button (6) to return to the Topo view screen (Fig. 1).

3.1.7 Browsing and editing pupil diameter and corneal diameter measurement values

(Fig. 1)

1) Touch the "DIA" button (1) on each view screen to open the pupil/corneal diameter view screen (Fig. 2).



(Fig. 2)

2) Measured pupil diameter (2) and corneal diameter (3) are shown. The fitting circle and center point for analyzing the pupil diameter, and measurement lines for analyzing the corneal diameter are shown on the CCD image.
3) Touch any of the Center Point buttons (4). The circle (5) moves on the image, and the X and Y values of the measurement (2) change accordingly. Touch the circle (5) on the image to move the center point of the circle to the touched point.
4) Touch the up/down arrow buttons for the diameter editing tool (6) to change the diameter of the circle (5).
5) Touch the Left point and Right point arrow buttons of the corneal diameter editing tool (7). The measurement lines (8) on the image move accordingly and the corneal diameter value (3) changes.
6) Touch the “Initial Position” button (9) to reset each value to the status, when the pupil/corneal diameter view screen opened.
7) Touch the “Apply” button (10) to apply the changes. Return to the original positions is not possible after the “Apply” button is touched.

3.2 Ultrasound axial length measurement mode

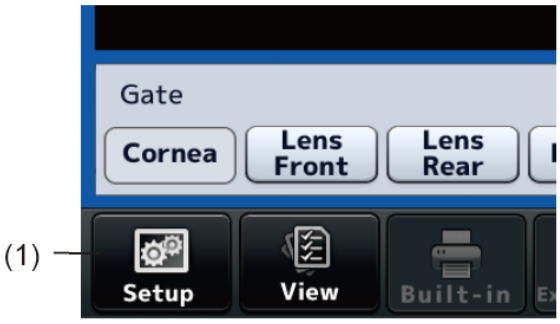
Refer to "2.2.2 Switching between optical (OPT) mode and ultrasound (US) mode" for the method to switch to ultrasound measurement mode.

3.2.1 Setting measurement conditions

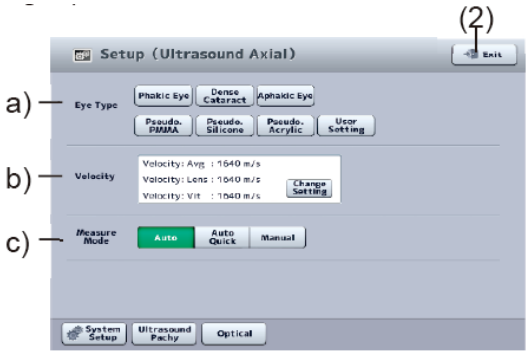
- Settings made here are only effective for the eye currently selected. Settings cannot be made for both eyes simultaneously. Complete necessary settings for each eye.

Touch the "Setup" button (1) to display the Setup (Ultrasound Axial) screen (Fig. 2). Set items related to operation conditions.

Touch the "Exit" button (2) after setting is completed to apply selected contents and return to the measurement screen (Fig. 1).



(Fig. 1)



(Fig. 2)

a) Selecting inspection eye

Select the inspection eye from the following 7 options.

* Phakic eye

  Select this for a normal eye or when the crystalline lens nucleus is comparatively soft, such as an eye in the initial stages of cataracts.

* Dense cataract eye

  Select this when the crystalline lens nucleus of the inspection eye is comparatively hard, such as an eye with dense cataracts, whereby it is difficult to take measurements in the mode used for a phakic eye with an echo reflected in the crystal lens.

* Aphakic eye

  Select this in the case of aphakic eyes.

* IOL eye (PMMA)

  Select this when a PMMA IOL is implanted.

* IOL eye (silicon)

  Select this when a silicon IOL is implanted.

* IOL eye (acryl)

  Select this when an acrylic IOL is implanted.

* User Setting

Select this when registering optional materials for IOL eyes. Register the settings on the converted acoustic velocity setting screen. (Refer to “Setting converted acoustic velocity.”)

“Anterior Chamber Depth” and “Lens” are not measured for an aphakic eye and “Lens” is not measured for an IOL eye. The instrument may not recognize waveforms on the back of the crystal lens due to multi-echoes in the crystal lens in an eye with dense cataracts.

Inspection eye	Axial length	ACD (anterior chamber depth)	Lens
Phakic eye (Average acoustic velocity, divisional acoustic velocity)	○	○	○
Dense cataract eye	○	○	△
Aphakic eye	○	*	*
IOL eye (All materials)	○	○	*

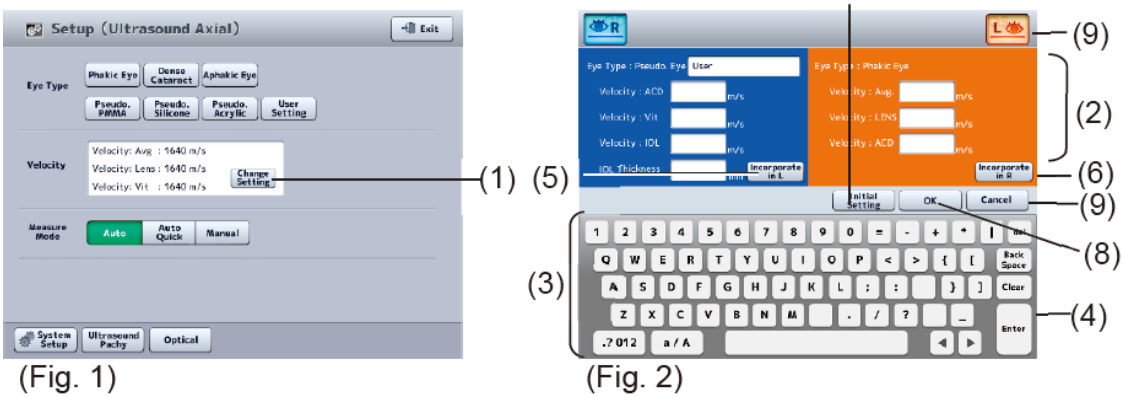
○ : Measurements are displayed.

△ : Measurements may not be displayed.

* : Measurements are not displayed

b) Setting converted acoustic velocity

Touch the “Change Setting” button (1) to open the setting change screen (Fig. 2).



(Fig. 1) (Fig. 2)

1) Entry boxes (2) for the acoustic velocities required for the measurement eye currently selected appear. Enter the converted sonic velocity using the software keyboard (3).

2) After entry, touch the “Enter” key (4) to move to the next entry box. Also, by touching the “Incorporate in L” button (5) or the “Incorporate in R” button (6), the data entered will be applied to the other eye.
3) Touch the “Initial Setting” button (7) to enter the initial settings.
4) Touch the "OK” button (8) to apply the entry and return to the Setup (Ultrasound Axial) screen. Touch the “Cancel” button (9) to discard the entry and return to the Setup (Ultrasound Axial) screen with the previous sonic velocity still set.

(Initial setting and setting range of converted acoustic velocity)

- Phakic eye

Average acoustic velocity for axial length:	1,550m/s, 1,500 - 1,600m/s
Crystal lens acoustic velocity:	1,641m/s, 1,540 - 1,740m/s
Anterior chamber depth acousticvelocity:	1,532 m/s, 1,430 - 1,630m/s
Vitreous acoustic velocity:	1,532 m/s, 800 - 2,000 m/s

(Sectional velocity only)

- Dense cataract eye

Average acoustic velocity for axial length:	1,548m/s, 1,500 - 1,600m/s
Crystal lens acoustic velocity:	1,629m/s, 1,540 - 1,740m/s
Anterior chamber depth acoustic velocity:	1,532 m/s, 1,430 - 1,630m/s

- Aphakic eye

Average acoustic velocity for axial length:	1,532 m/s, 1,430 - 1,630m/s

- IOL eye

Implanted lens acoustic velocity	(Acryl):	2,200m/s, 800 - 3,000m/s
	(Silicon):	1,049m/s, 800 - 3,000m/s
	(PMMA):	2,718m/s, 800 - 3,000m/s
Anterior chamber depth acoustic velocity:		1,532 m/s, 1,460 - 1,630m/s
Vitreous acoustic velocity:		1,532 m/s, 800 - 2,000 m/s
IOL thickness	(Acryl):	0.80 mm, 0.10 - 4.00 mm
	(Silicon):	1.00mm, 0.10 - 4.00 mm
	(PMMA):	0.80 mm, 0.10 - 4.00 mm

c) Measurement mode

Set the measurement mode.

* Auto

  Select this for normal measurements.

* Auto quick

  Select this when measurement is difficult.

* Manual

  Select this when measurement is difficult in Auto and Auto quick modes.

d) Setting contact/immersion mode

Complete the settings for contact mode and immersion mode referring to "6.2 c) Settings for various measurements"

3.2.2 Measurement

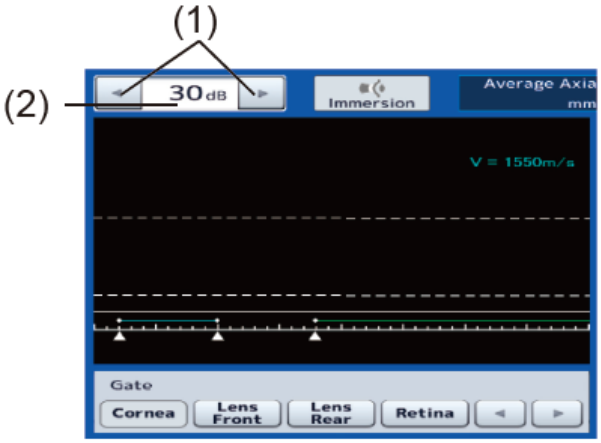
See the user manual of the AL-4000 for the actual measurement procedure. This section describes the operations that can be performed with this instrument during measurement.

- The converted acoustic velocity directly affects the measurement data. Check that the desired value is set before starting measurement.
- Check the settings in contact mode and immersion mode before starting measurement. In immersion mode, apply an ultrasound media such as cornea protective agent so that the clearance between the cornea and the contact section of the biometry probe is approximately 2.0 – 5.0 mm.
- The automatic measurement function is an auxiliary function to take measurements more easily. This is not a function for making actual clinical evaluations. The physician must assess the measurement result before using it.
- Be sure to touch the "New" button to delete all the measurement data of the previous patient before measuring another patient. If new measurement is started without deleting the previous data, the measurement data of the previous patient may be included.

a) Setting gain

- Settings made here are only effective for the eye currently selected. Settings cannot be made for both eyes simultaneously. Complete necessary settings for each eye.

Adjust the waveform height according to the gain settings. The gain and the waveform height increases as the gain value increases.

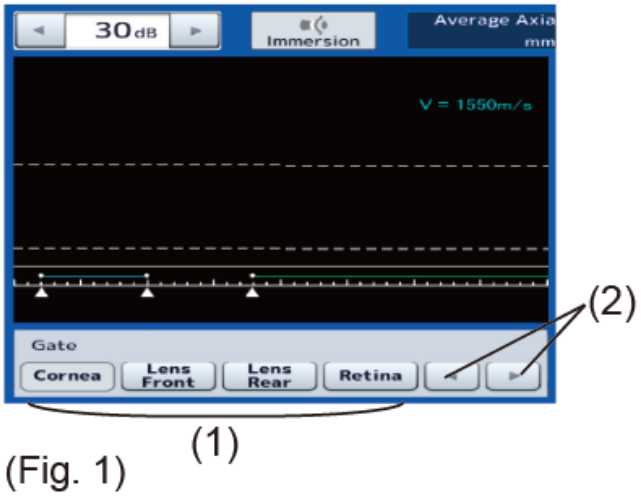


(Fig. 1)

Touch the gain adjustment buttons (1) to change the gain. The setting continues to change while the button is held. The set value is displayed in the gain display (2).

b) Setting gate cursor

- Settings made here are only effective for the eye currently selected. Settings cannot be made for both eyes simultaneously. Complete necessary settings for each eye.

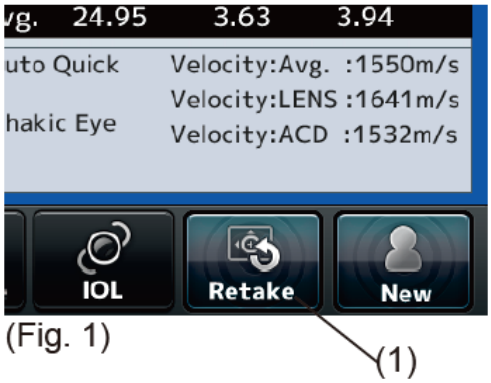


(Fig. 1)

1) Select a gate cursor to be adjusted by touching the gate selection buttons (1). The selected and active cursor is displayed in red but the other cursors are displayed in white.
2) Touch the gate cursor movement buttons (2) to set the active gate cursor position.

c) Re-measurement of the same patient

Retain the patient information and delete only the measurement data for each eye. Delete all data while referring to "2.2.4 Clear all measurement data (preparation for measuring a new patient)" when the patient is changed.

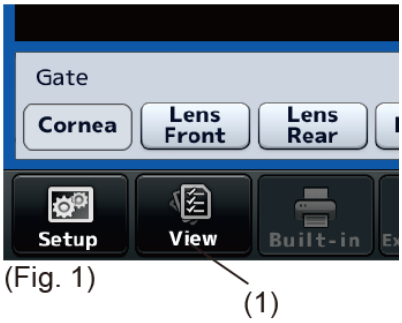


(Fig. 1)

Hold the "Retake" button (1) for approximately 1 second until a beep sounds to delete the data. The patient information and the measurement data of the eye not being measured will be retained.

3.2.3 Checking waveforms after measurement

a) Displaying waveform of arbitrary measurement data



(Fig. 1)

1) When all necessary measurement data is captured or when the "View" button (1) is touched, the edit screen (Fig. 2) opens.

(Fig. 2)

2) The waveform measured at the selected cursor (2) is displayed in the waveform display field (3). Touch the selection cursor movement buttons (4) to move the selection cursor (2) up or down.

The following marks are assigned to the measurement data.

* : Data used for calculating IOL power

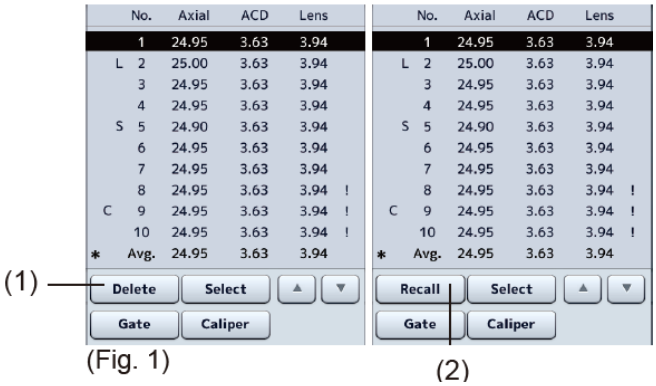
! : Data with low reliability

L : Longest axial length

S : Shortest axial length

C : Calipered data

b) Deleting and recovering measurement values



(Fig. 1)

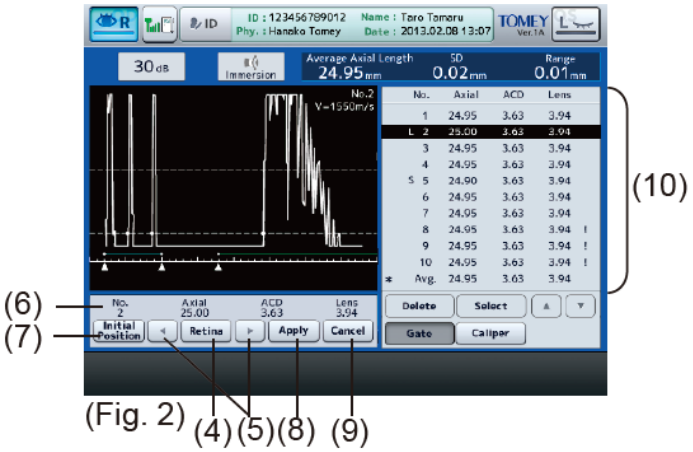
1) Touch the “Delete” button (1) to delete the data selected with the cursor and the data color changes to gray. The data deleted here is excluded from the average.

2) To recover the deleted data, move the cursor to the data. Touch the “Recall” button (2) to cancel deletion. However, once the screen returns to the measurement screen, the deleted data cannot be restored by the “Return” button even if the screen is switched to the edit screen again.

c) Gate change function

(Fig. 1)

1) 1) Use the selection cursor movement buttons (1) to move the selection cursor (2) to the data to be changed. Touch the “Gate” button (3) to open the gate change screen (Fig. 2).

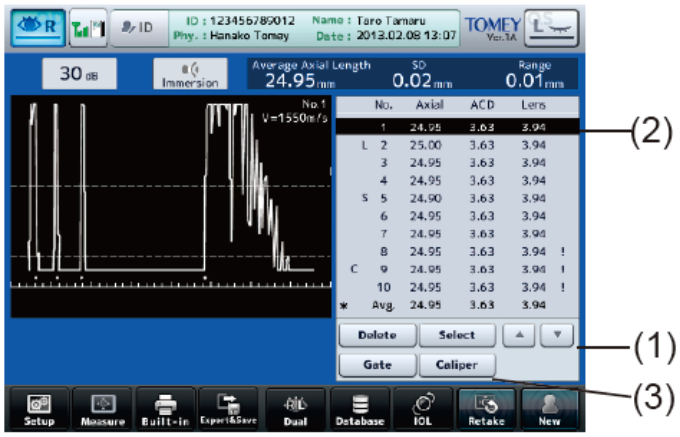


2) Touch the gate cursor selection buttons (4) to select the gate cursor to be changed. The selected and active gate cursor is displayed in red but the other cursors are displayed in white.
3) Touch the “gate cursor movement” buttons (5) to change the position of the active gate cursor. The changed measurement data is displayed in the edit data display field (6) along with the movement of the gate cursor.
4) If you have edited it mistakenly, touch the “Initial Position” button (7) to cancel the changes made, and the gate cursor will return to the position before the editing.
5) When you touch the “Apply” button (8), the changes made are applied, the measurement data displayed in the measurement data display field (10) is overwritten with the edited measurement data, and the gate change screen is closed. If the “Cancel” button (9) is touched, the changes made are discarded and the gate change screen is closed.

d) Caliper function

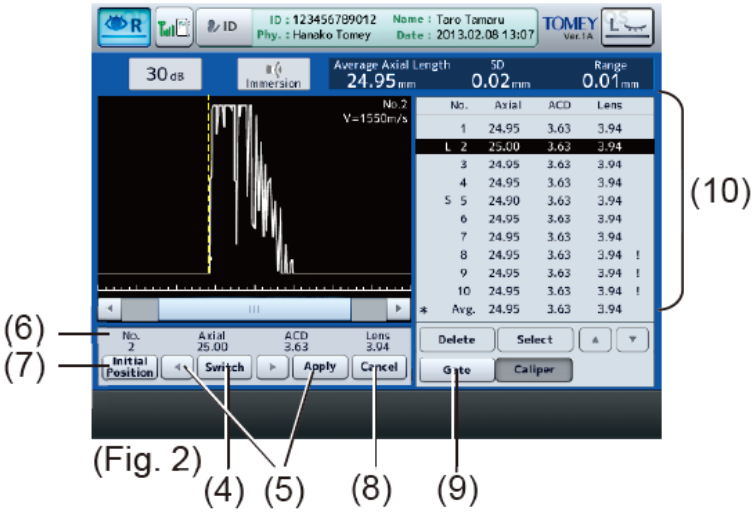
- Values measured and displayed using the caliper function are rough estimates and may differ from the actual measurement result.

This function is used to measure the distance of the measurement waveform. Three dotted caliper lines (four lines in Immersion mode) appear and the distance to the selected caliper line is displayed.



(Fig. 1)

1) Use the selection cursor movement buttons (1) to move the selection cursor (2) to the data to be measured. Touch the “Caliper” button (3) to open the caliper screen (Fig. 2).

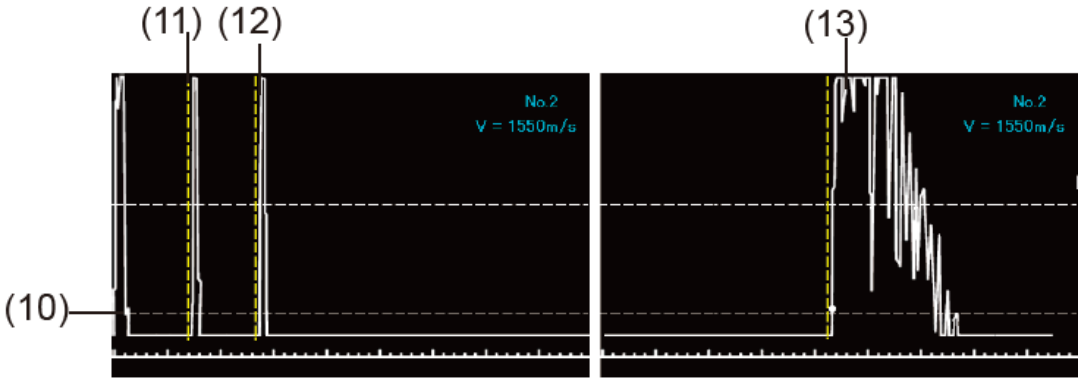


(Fig. 2)

2) Touch the “Switch” button (4) of the active caliper line to select the caliper line to be changed. The selected caliper line is displayed in red but the other lines are displayed in yellow.
3) Touch the caliper line movement buttons (5) to change the active caliper line position. The changed measurement data is displayed in the edit data display field (6) along with the movement of the caliper line.
4) If you have edited it mistakenly, touch the “Initial Position” button (7) to cancel the changes made, and the caliper line will return to the position before the editing.
5) When you touch the “Apply” button (8), the changes made are applied, the measurement data displayed in the edit data display field (6) is overwritten with the measurement data specified by the cursor (2), and the caliper screen is closed. Touching the “Cancel” button (9) will discard the changes made, and the caliper screen is closed.

*** In Contact Lens mode (Fig. 3)**

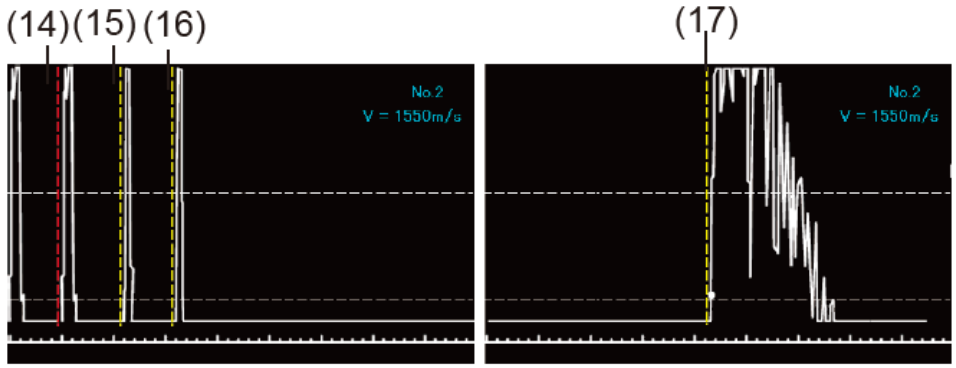
The distance between the start line of the waveform (0 mm point) (10) and the retina caliper line (13) is shown in the axial length field, the distance between the start line of the waveform (10) and the caliper line for the front of the crystalline lens (11) is shown in the ACD (anterior chamber depth) field, and the distance between the caliper lines for the front of the crystalline lens (11) and for the back of the crystalline lens (12) is shown in the Lens field.



(Fig. 3)

*** In Immersion mode (Fig. 4)**

The distance between the cornea caliper line (14) and the retina caliper line (17) is displayed in Axial length, the distance between the cornea caliper line (14) and the caliper line for the front of the crystalline lens (15) is displayed in ACD, and the distance between the caliper line for the front of the crystalline lens (15) and the caliper line for the back of the crystalline lens (16) is displayed in Lens.



(Fig. 4)

e) Selecting specific measurement data to be used for calculating IOL power

The average value is normally adopted for the measurement data to be used in calculating the IOL power, but specific data can also be selected.

(Fig. 1)

1) Use the selection cursor movement buttons (1) to move the selection cursor (2) to the data which is to be used in calculating the IOL power. To use the average value in IOL power calculation, move the selection cursor (2) to the average data at the bottom.
2) When the “Select” button (3) is touched, it selects the data to be used in calculating the IOL power, and an “*” appears on the left of the data.

3.3 Ultrasound corneal thickness measurement mode

Refer to "2.2.2 Switching between optical (OPT) mode and ultrasound (US) mode" for the method to switch to ultrasound corneal thickness measurement mode.

3.3.1 Setting the data type to be displayed

Select the measurement data type to be displayed from the following three options.

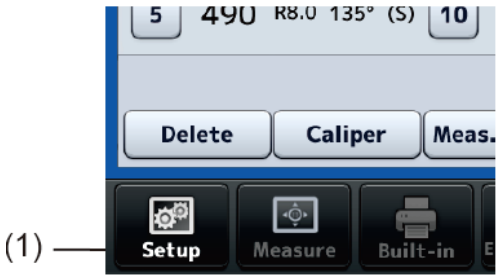
* Latest : Displays the last measurement data taken.
* Minimum : Displays the minimum value of measurement data.
* Average : Displays the average of measurement data.

Make settings referring to "6.2 C) Settings for various measurements"

3.3.2 Setting measurement conditions

- Settings made here are only effective for the eye currently selected. Settings cannot be made for both eyes simultaneously. Complete necessary settings for each eye.

Touch the "Setup" button (1) to display the Setup (Ultrasound Pachy) screen (Fig. 2). Set items related to operation conditions. Touch the "Exit" button (2) after setting is completed to apply selected contents and return to the measurement screen (Fig. 1).



(Fig. 1)

(Fig. 2)

a) Measurement range

Select the measurement range from the following 3 options.

* 150 - 350 µm
* 300 - 1000 µm
* 900 - 1500 µm

b) Selecting measurement values to be displayed

Select measurement values to be displayed from the following 2 options.

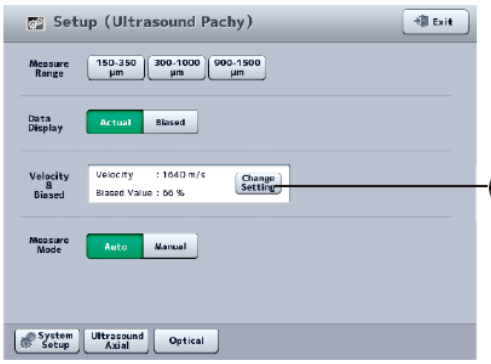
* Actual measurement
* Bias value

c) How to display converted acoustic velocity and bias values

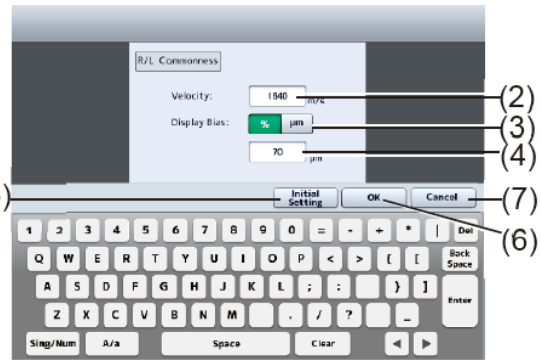
Select how to display the bias value from the following two options.

* Percentage bias: Converts the actual measurement using the preset bias rate (percentage) and displays the result.
* Plus/minus bias: Adds/subtracts the preset correction value to/from the actual measurement, and displays the result.

1) Touch the “Change Setting” button (1) on the Setup (Ultrasound Pachy) screen to display the screen for setting converted sonic velocity and bias values (Fig. 2).



(Fig. 1)



(Fig. 2)

2) When the converted sonic velocity entry field (2) is touched, it activates. Enter the converted sonic velocity using the software keyboard. Initially, it is set to 1640 m/s.
   Input range of converted acoustic velocity: 1400 - 2000 m/s
3) Touch the "Display of Bias" button (3) to select the percentage bias (%) or plus/minus bias (µm).
   Using the software keyboard, enter the bias rate when percentage bias is selected, or the correction (4) when plus/minus bias is selected. Initially, the bias rate is set to 70 % and the correction is set to 0 µm.
   Input range of bias rate: 60 - 130%
   Input range of correction: -600 - +450µm
4) When a value is entered for one eye, the setting for the other eye is automatically changed. Touch the “Initial Setting” button (5) to enter the initial settings.
5) Touch the “OK” button (6) to apply the entered settings and close the setting change screen. Touch the “Cancel” button (7) to discard the entered settings and close the setting change screen.

d) Measurement mode

Set the measurement mode.

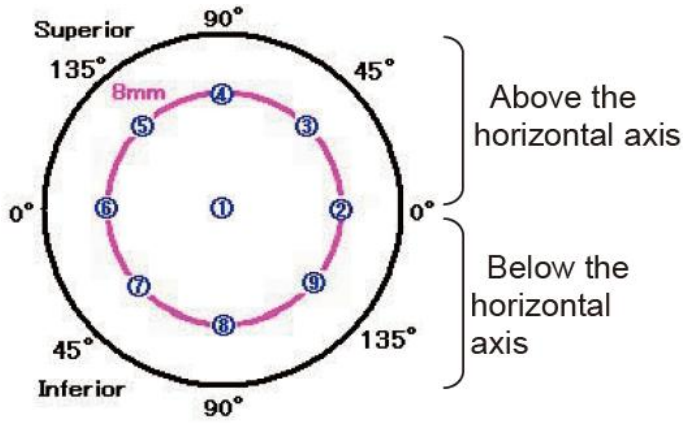
* Auto
* Manual

Select manual measurement when it is difficult to measure in Auto mode or when measurement values are captured while not intentionally performing a measurement.

Refer to the AL-4000 Operation Guid.

3.3.3 Displaying and setting measurement points

This function displays and sets the location of measurement points.



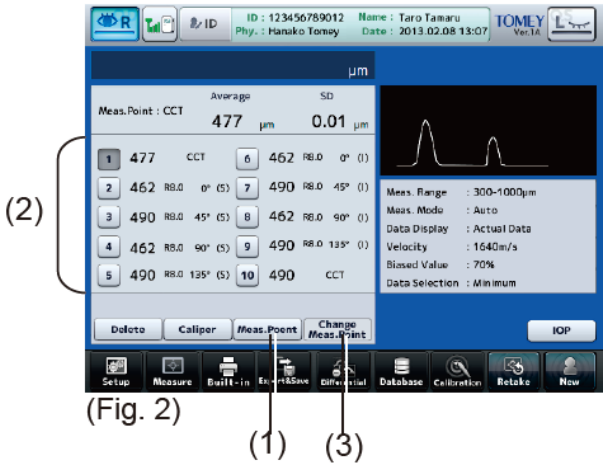
(Fig. 1)

The measurement point indicates “diameter – angle – S/I.”

* Radius : Radius from the center (mm)
* Angle : The upper and lower angles (°) when regarding the horizontal axis as zero degrees
*S/I : Section above the horizontal axis (Superior), section below the horizontal axis (Inferior)

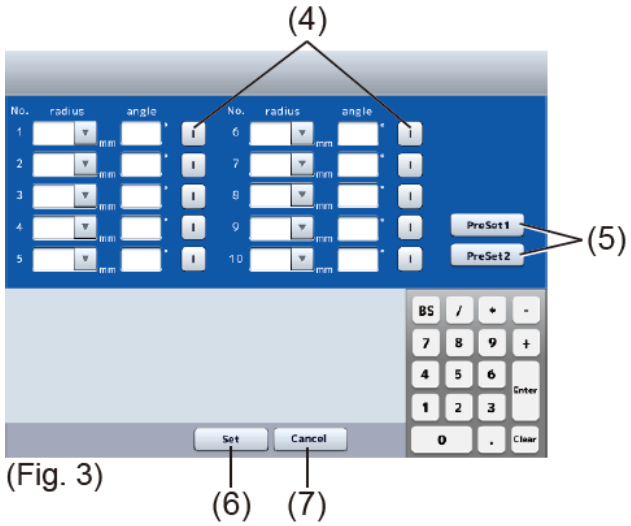
The center point is indicated as “CCT.”

1) Touch the "Meas. Point" button (1) to display measurement points in the measurement data display field (2).



(Fig. 2)

2) Touch the “Change Meas. Point” button (3) to open the measurement point change screen (Fig. 3) to change the measurement point.



(Fig. 3)

3) When the desired input field on the measurement point change screen (Fig. 3) is touched, the field is activated. Set values using the keypad and the like. As for the setting of “S/I,” the indication switches between “S” and “I” each time the S/I button (4) is touched.
4) Touch the Preset button (5) to set the value preset in system settings. [Refer to “3.9.2 c) Settings for various measurements.”]
5) Touching the “Set” button (6) will apply the changes made, and the measurement point change screen (Fig. 3) is closed. Touching the “Cancel” button (7) will cancel the changes made, and the measurement point change screen (Fig. 3) is closed.

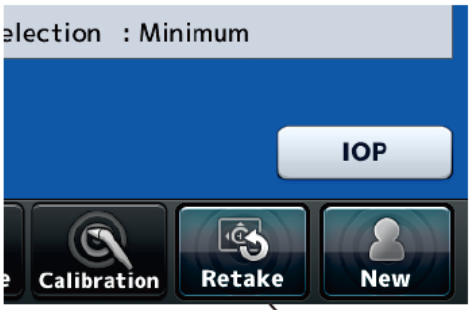
3.3.4 Measurement

See the user manual of the AL-4000 for the actual procedure of measurement. This section describes the operations that can be performed with this instrument during measurement.

- The converted acoustic velocity directly affects the measurement data. Check that the desired value is set before starting measurement.
- The measurement data can be displayed as the actual measurement or a bias value. Check the setting of the data display mode.
- The automatic measurement function is an auxiliary function to take measurements more easily and is not a function used to actually make clinical evaluations. The physician must assess the measurement result before using it.
- Be sure to touch the “New” button to delete all the measurement data of the previous patient before measuring another patient. If new measurement is started without deleting the previous data, the measurement data of the previous patient may be included.

a) Re-measurement of the same patient

Retain the patient information and delete only the measurement data for each eye. Delete all data while referring to “2.2.4 Clear all measurement data (preparation for measuring a new patient)” when the patient is changed.



(Fig. 1)

Hold the “Retake” button (1) for approximately 1 second until a beep sounds to delete the data. The patient information and the measurement data of the eye not being measured will be retained.

3.3.5 Checking the measurement data

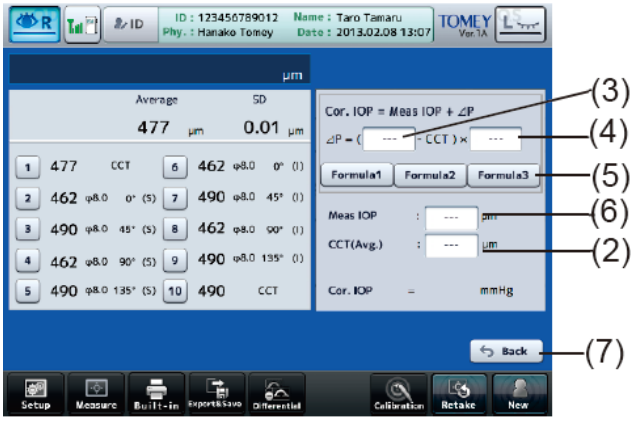
a) Intraocular pressure correction

This instrument automatically starts calculation and displays the result when all items required for calculating the intraocular pressure correction are set.

(Fig. 1)

1) Touch the “IOP” button (1) to open the intraocular pressure correction screen (Fig. 2). When a measurement has already been completed at this point, the measured value is displayed in the CCT field (2).

   However, if measurement points are set and two or more “CCTs” are included, the average of the CCTs is displayed. When measurement points are not set, the average of all memory numbers is displayed.



(Fig. 2)

2) The input fields of parameter 1 (3) and parameter 2 (4) for the intraocular pressure correction formula become active when touched, and the keypad appears. Also, when a formula selection button is touched, the already set parameters are displayed in the intraocular pressure correction formula.

   [Input range]

   * Parameter 1 : 0 - 1500

   * Parameter 2 : 0.0000 - 1.0000

3) Enter the intraocular pressure data. The keypad appears when the entry field (6) is touched.

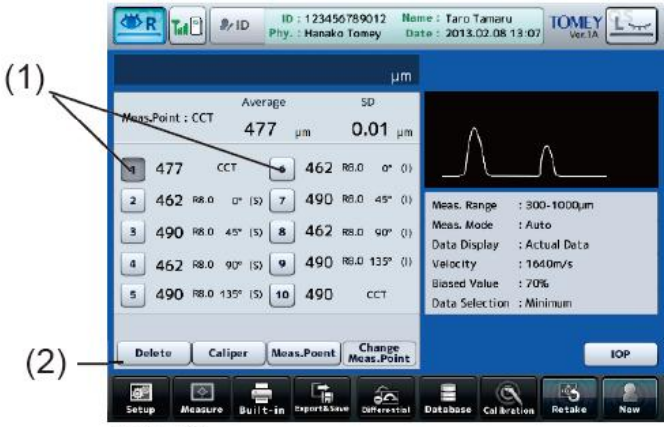
[Input range]

* Intraocular pressure data : 1 - 60.0 (mmHg)

: 1.33 - 79.99 (hPa)

4) Touch the “Back” button (7) to close the intraocular pressure correction screen (Fig. 2) and return to the previous screen.

b) Deleting part of measurement data

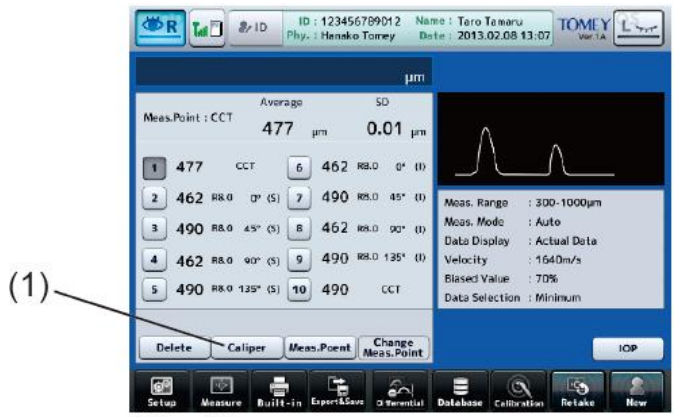


(Fig. 1)

1) Touch a memory number button (1) to select the measurement data to be deleted.
2) Touch the “Delete” button (2) to delete the selected measurement data, and the average and the standard deviation of the corneal thickness are recalculated.
3) If you have deleted data mistakenly or want to cancel the deletion, select that data number and you will see that the “Delete” button (2) will change to the “Return” button. Touch the “Return” button to cancel the deletion. When new measurement data is captured, however, the deleted data cannot be restored by pressing the “Return” button.

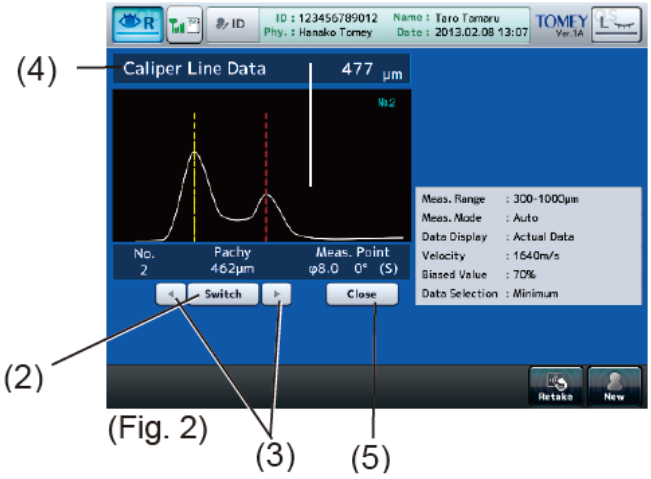
c) Caliper function

The caliper function is for temporary reference and cannot store the calipered data.



(Fig. 1)

1) Touch the "Caliper" button (1) to display the caliper screen (Fig. 2).

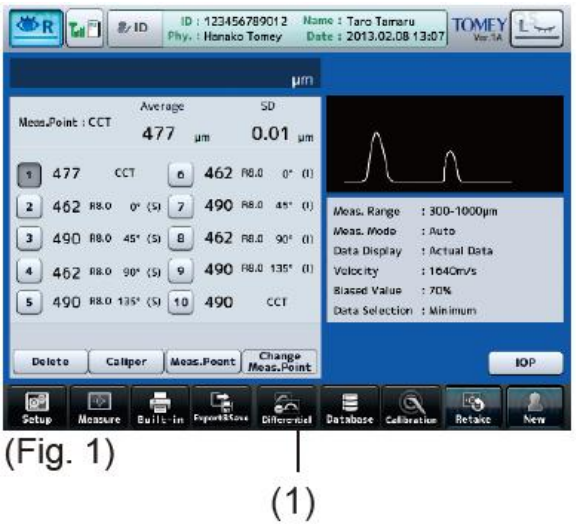


(Fig. 2)

2) Touch the “Switch” button (2) to select a caliper line to be adjusted. The active caliper line is displayed in red and the other caliper line in yellow.
3) Touch the “active caliper line movement” button (3) to change the position of the active caliper line. In conjunction with the movement of the caliper line, the distance between the caliper lines (4) is displayed.
4) Touch the “Close” button (5) to close the caliper screen (Fig. 2) and return to the previous screen (Fig. 1).

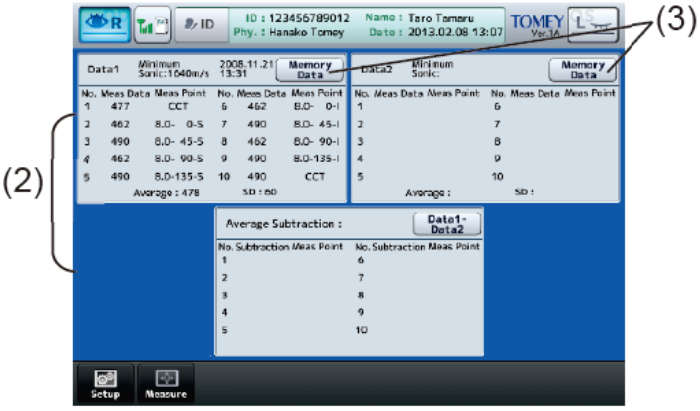
d) Subtraction display function

This function displays the value difference between the 2 selected measurement data.



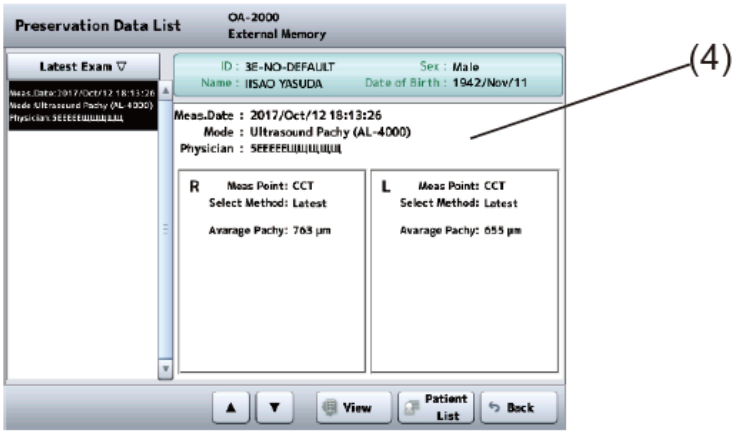
(Fig. 1)

1) Touch the “Differential” button (1) to open the subtraction display screen (Fig. 2). When a measurement has already been completed at this point, the measured values are displayed in the data 1 display field (2).



(Fig. 2)

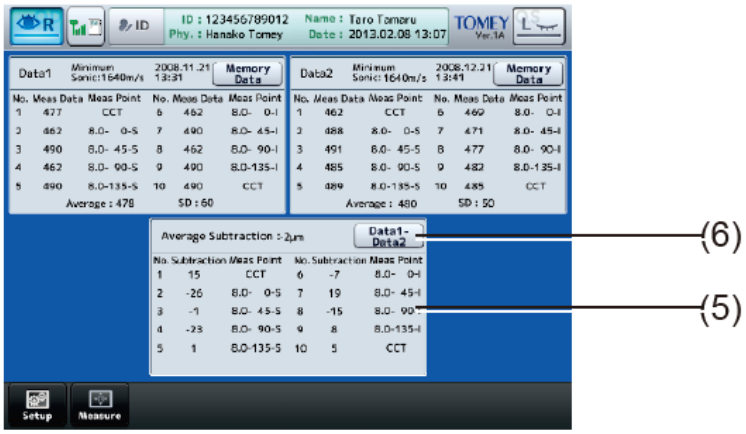
2) The measurement data being stored can be selected as Data 1 or Data 2. Touch the "Memory Data" button (3) to display a list of measurement data being stored in a USB memory. (Fig. 3) If a patient ID has not been selected, however, it displays a list of patient IDs stored in a USB memory. Refer to “5.3 Saved data management”



(Fig. 3)

3) Touch the “Data Display” button (4) to display the selected measurement data in the subtraction display screen.

4) When measurement data are selected in Data 1 and Data 2, the value difference between Data 1 and Data 2 is displayed in the subtraction display field (5). If measurement points have been selected, however, only the difference values of the memory numbers whose measurement points match in both data are displayed.



(Fig. 4)

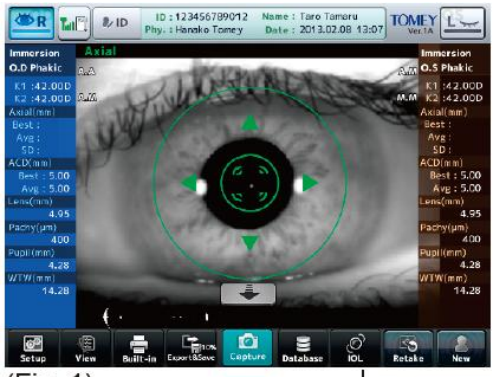
5) When the “Data 1 - Data 2” button (6) is touched, the indication on the button will change to “Data 2 - Data 1,” and the value difference of Data 2 - Data 1 will be displayed.

4. IOL POWER CALCULATION

- When using biometry results for calculation of the IOL power, the physician must assess the measurement result beforehand.
- This instrument's limited capacity to display the volume of digits generated in internal calculations in their entirety, may cause some errors.
- Complex numbers may be generated for the SRK/T formula. In this case, the "√ section" is calculated as zero and an asterisk "*" is shown on the right of the calculation result.
- Refer to "5. EXPORT, PRINT AND SAVE" for waveforms printed and exported from the IOL calculation screen.
- OKULIX calculates IOL power using keratometer measurement values. When no keratometer measurement value is available, the OKULIX screen does not open.
- The OKULIX screen does not open when the USB dongle is not connected.
- The Barrett formula is available only after purchasing the license and performing installation.

This instrument automatically starts calculation and displays the result when all items required for IOL power calculation are set. In addition, this instrument is designed to execute 12 types of IOL power calculations and OKULIX calculation.

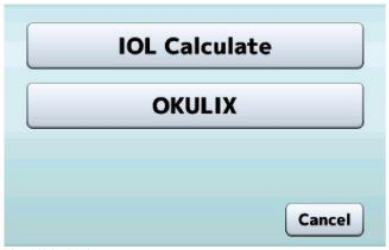
Touch the "IOL" button and select the desired calculation on the selection screen (Fig. 2). The screen last selected will open automatically for the next operation. Touch the "IOL Selection" button (2) on each calculation screen to open another calculation screen.



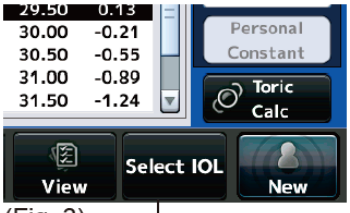
(Fig. 1)

(1)

IOL Calculate	Barrett Universal Ⅱ formula Barrett TrueK formula Haigis standard formula Haigis optimized formula Hoffer® Q formula Holladay 1 formula SRK/T formula Olsen formula Shammas-PL formula SRK/T Double K
OKULIX	OKULIX



(Fig. 2)



(Fig. 3)

(2)

4.1 Setting the eye to be measured

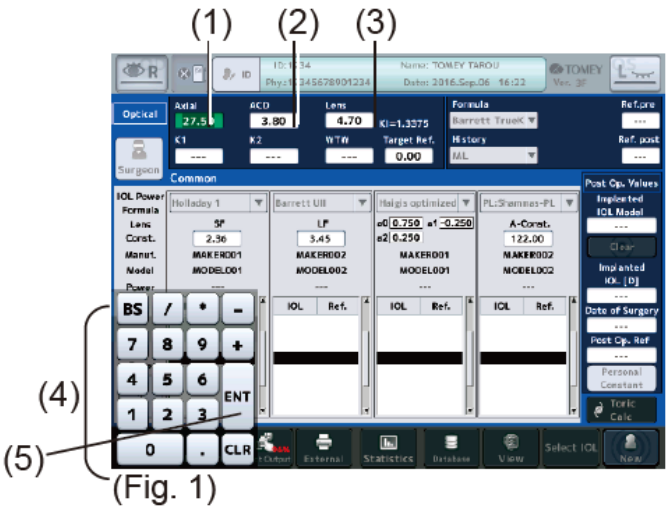
Refer to “2.2.5 Selecting an eye”.

4.2 IOL power calculation

4.2.1 Entering calculation parameters

a) Axial length, anterior chamber depth or lens

When measurement of an axial length, anterior chamber depth or lens is completed, the measurement data is automatically present and cannot be entered manually. [Refer to “3.1.4 Browsing and editing axial length measurement "] When measurement has not yet been performed, enter the data as follows:



(Fig. 1)

1) Touch the axial length input field (1), ACD input field (2) or lens input field (3) to activate each. The keypad (4) appears.Touch the “Enter” key (5) to enter the data.

[Input range]

Axial length :	13.00 - 45.00 mm
Anterior chamber depth :	0.00 - 10.00 mm
Lens :	2.00 - 8.00mm

b) Corneal refractive power and radius of corneal curvature (K1/K2)

When keratometer measurement is completed, the measurement data is automatically present and cannot be entered manually. [Refer to “3.1.4 Browsing and editing axial length measurement "]

When measurement has not yet been performed, enter the data as follows:

(Fig. 1)

1) Touch the K1 input field (1) or the K2 input field (2) to activate it. The keypad (3) appears. Touch the “Enter” key (4) to apply the data.

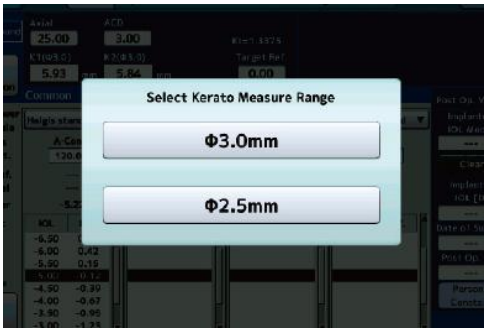
[Input range]

Corneal refractive power : 30.00 - 60.00D

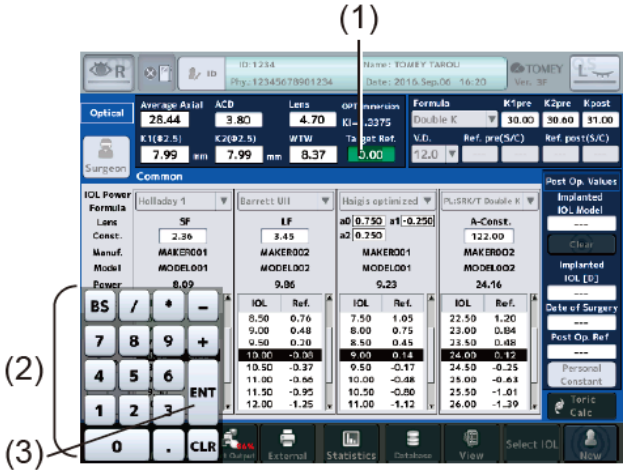
Radius of corneal curvature : 5.00 - 11.00 mm

2) Touch the keratometer value display switch button (5) to change between the K1/K2 display and the AvgK display.

3) The φ value can only be selected when the instrument is in ultrasonic wave measurement mode and after keratometer measurement. Touch the keratometer value display field (6), and the keratometer measurement position selection screen appears.



c) Target Ref.



(Fig. 1)

1) Touch the Target Ref. input field (1) to activate it. The keypad (2) appears. Touch the "Enter" key (3) to enter the data.

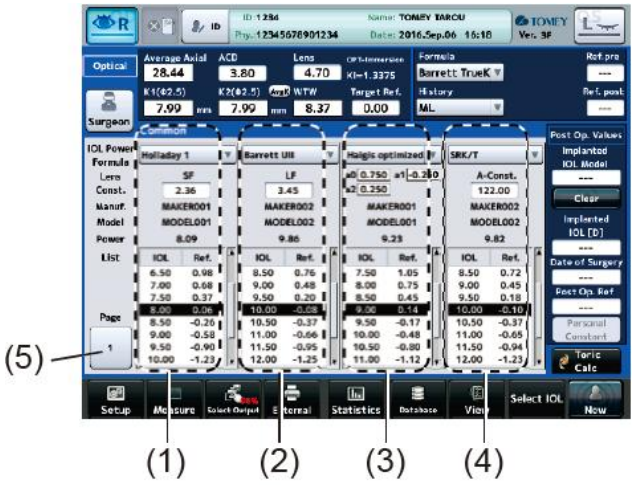
[Input range]

Angle : -30.00 - +10.00

2) The entered value is stored in the main unit, and is not cleared even when the power is turned off.

d) Lens constants (A-constant/SF/ACD-constant/a0・a1・a2)

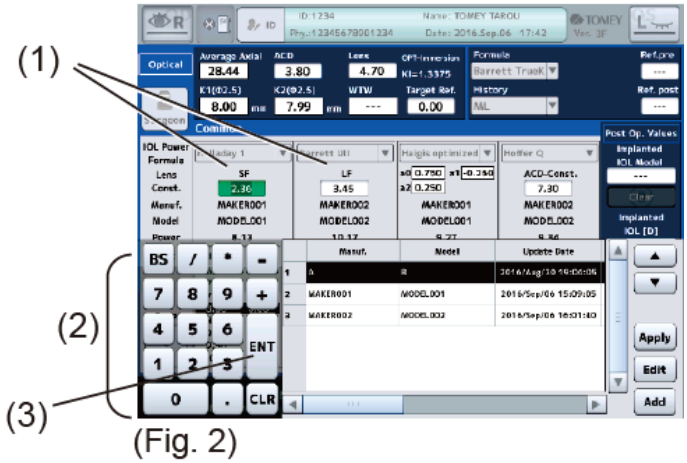
Enter various lens constants for IOL according to the formula. This instrument is able to calculate up to 8 constants simultaneously. Contents in the calculation result display field (1) - (4) change as the page is switched by touching the page button (5). There are 2 ways to enter the lens constants. One is to enter them directly using the keypad, and the other is by selecting them from the IOL data list.



(Fig. 1)

* Entering using keypad

The lens constants a0, a1, and a2 in the Haigis optimized formula cannot be entered directly using the keypad. Refer to “Entering through IOL data list” below.



(Fig. 2)

1) Touch an input field (1) to activate it. The keypad (2) appears. Touch the “Enter” key (3) to apply the data.

[Input range]

A-constant : 100.00 - 130.00

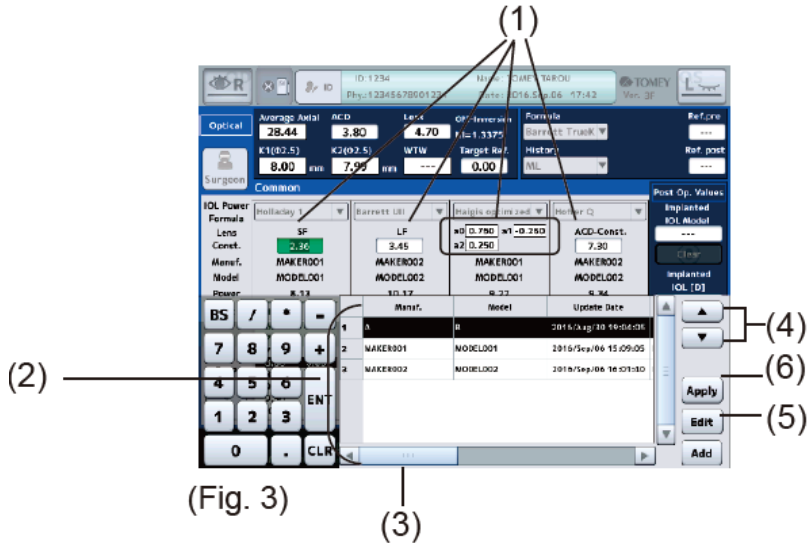
ACD-constant : 0.00 - +10.00

SF : - 5.00 - + 10.00

LF : - 2.00 - + 5.00

* Entering through IOL data list

When IOL data has already been registered in “IOL data registration”, you can select data from the IOL data list.



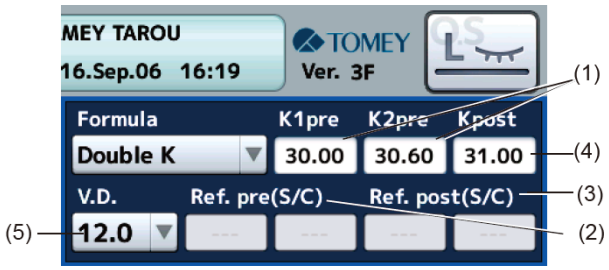
(Fig. 3)

1) Touch an input field (1) to activate it. The IOL data list (2) appears.
2) You can check the registration content by sliding the IOL data list being displayed with the scroll bar (3).
3) Select data using the “IOL data selection” buttons (4).
4) Touch the "Edit" button (5) to display the screen for editing the registration content.
5) Touch the “Apply” button (6) to apply the lens constants and to display them on the previous screen.

e) Entering parameters for Clinical History Method

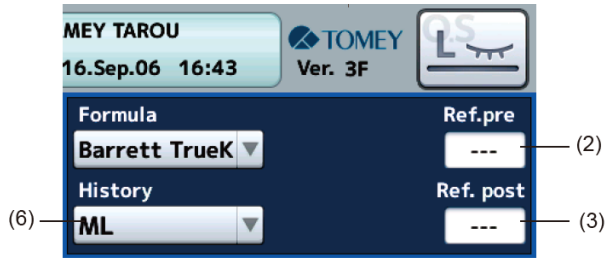
Activated only when SRK/T Double K or Barrett is selected as the formula.

[Parameters for DoubleK formula]



(Fig. 1)

[Parameters for Barrett formula]



(Fig. 2)

1) Select the formula and the parameter input forms are displayed.
2) Enter the corneal refractive power or radius of corneal curvature pre-surgery for correcting the refractive power in K1pre and K2pre fields (1).
3) Manually enter eye refractive power before refractive correction surgery in Ref.pre (S,C)(2) and eye refractive power after refractive correction surgery in Ref.post (S,C) (3).
4) When values are entered in K1Pre, K2Pre, Ref.pre (S,C), and Ref.post (S,C), the calculation starts automatically and the corneal refractive power or radius of corneal curvature after the refractive power correction surgery is displayed in Kpost (4). The data can be entered directly. However, Ref.pre (S,C) and Ref.post (S,C) cannot be entered.

5) Select the distance between the verticies (V.D.) (5), History (6) from the pulldown menu.

VD: CL / 12.0 / 13.5 / 14.0 / 15.5 / 16.0

History: ML / HL / RK

ML: Myopic Lasik (Myopic correction LASIK)

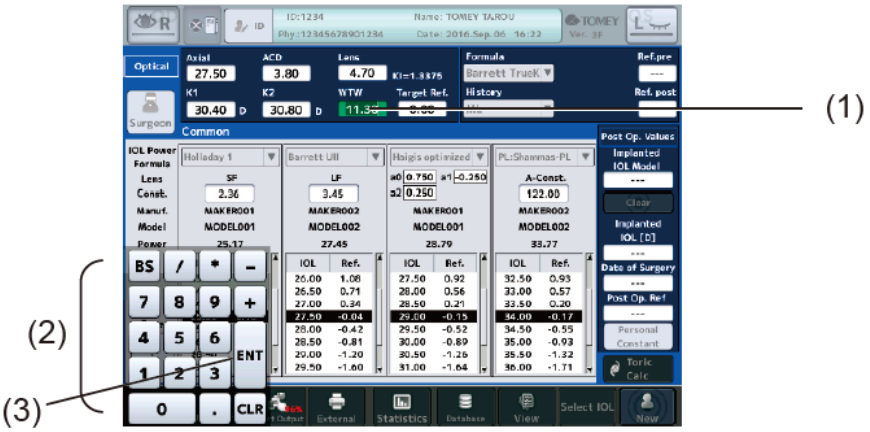
HL: Hyperopic Lasik (Hyperopic correction LASIK)

RK: Radial Keratotomy (Radial keratotomy)

f) WTW

When measurement of the corneal diameter is completed, the measurement data is automatically present and cannot be entered manually. [Refer to "3.1.4 Browsing and editing axial length measurement "]

When measurement has not yet been performed, enter the data as follows:



(Fig. 1)

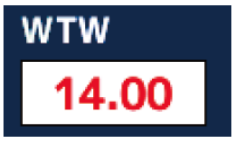
1) Touch the WTW input field (1) to activate it. The keypad (2) appears. Touch the "Enter" key (3) to apply the data.

[Input range]

Corneal diameter: 8.00 - 14.00 mm

2) A warning message appears when the measured corneal diameter is outside the standard range.

Check the detection position on the pupil/corneal diameter view screen before calculating IOL.

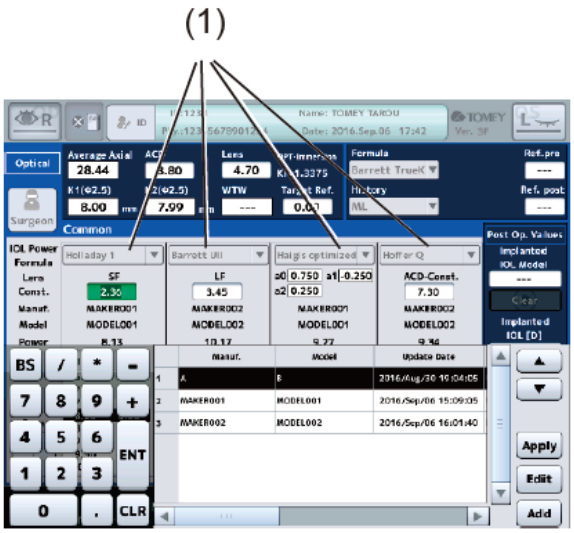


(Fig. 2)

4.2.2 Setting a calculation formula

Touch the calculation formula pull-down button (1) and select a formula.
(When selecting OKULIX, use the IOL select button on the lower part of the screen.)
The following 11 types of IOL power calculation formulae are provided with this instrument.
IOL calculation formulae listed in the pull-down menu can be set according to "6.3.b) Selecting IOL power formula"

*Barrett Universal II formula (optional)
* Barrett TrueK formula (optional)
*Haigis standard formula
* Haigis optimized formula
* Hoffer® Q formula
* Holladay 1 formula
* Olsen formula
* SRK/T formula
* Shammas-PL formula
* SRK/T Double K formula
* OKULIX



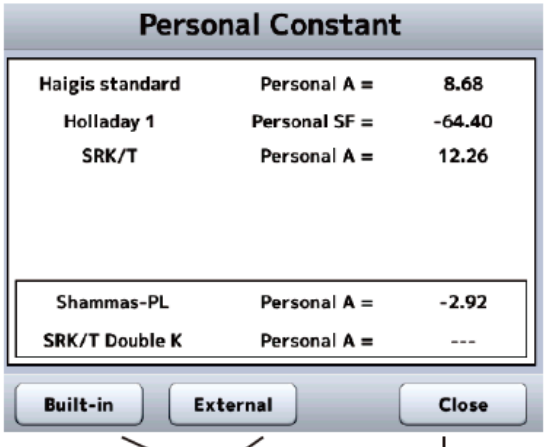
(Fig. 1)

4.2.3 Entering data after surgery

Select the name of the IOL type that was actually implanted in the surgery.

(Fig. 1)

1) Select the type of implanted IOL. When the entry field (1) is touched, it is activated. Select the name of the IOL type that was actually implanted in the surgery from the IOL list.
2) Enter the implanted IOL power (2), date of surgery (3), and refractive power post-surgery (4). The keypad or calendar appears when the input field is touched.
3) When the “Personal Constant” button (5) is touched, the Personal Value screen (Fig. 2) appears. Touch the “Print” button (6) to print the personal constants only. Touch the “Close” button (7) to close the Personal Value screen and return to the previous screen.



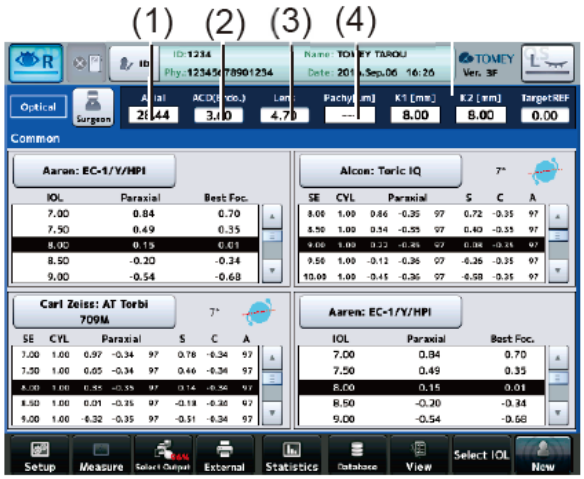
(Fig. 2)

4.3 OKULIX

- When using the OKULIX calculation result to select IOL, accurately determine the selection by also examining cataract surgery methods, other inspections and other IOL power calculation formulas. In particular, in the case of the cornea of a sound eye without having had surgery to correct refractive power of the cornea such as LASIK, carefully compare the OKULIX calculation result with the result of SRK/T formula etc. and, if there is a significant difference, examine them with due care.

a) Entering optical data on OKULIX screen

When an axial length, anterior chamber depth, lens, and corneal thickness measurement is completed, the measurement data is entered automatically and cannot be entered manually. When measurement has not yet been performed, enter the data as follows.



(Fig. 1)

1) Touch the axial length input field (1), the ACD endothelium input field (2), the lens input field (3), or the Pachy field (4) to activate it. The keypad appears.
Enter the data and touch the “Enter” key on the keypad to apply the data.

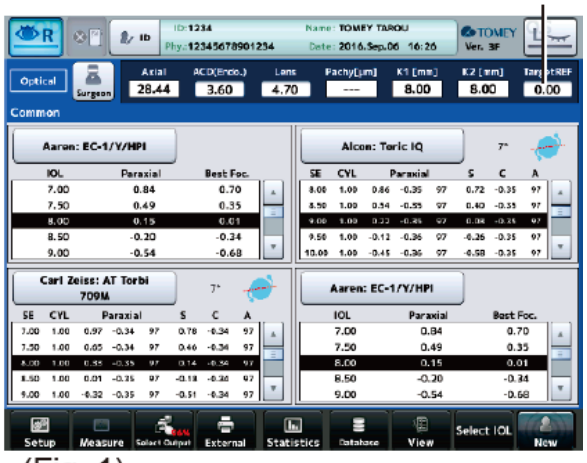
b) Entering ultrasound data on OKULIX screen

When an axial length and anterior chamber depth, and lens measurement is completed, the data in the Axial, ACD(Epi.), or Lens fields are automatically present and cannot be entered manually. When entering Pachy data manually, the ACD (Endo.) is automatically calculated.

(Fig. 1)

c) Entering target Ref.

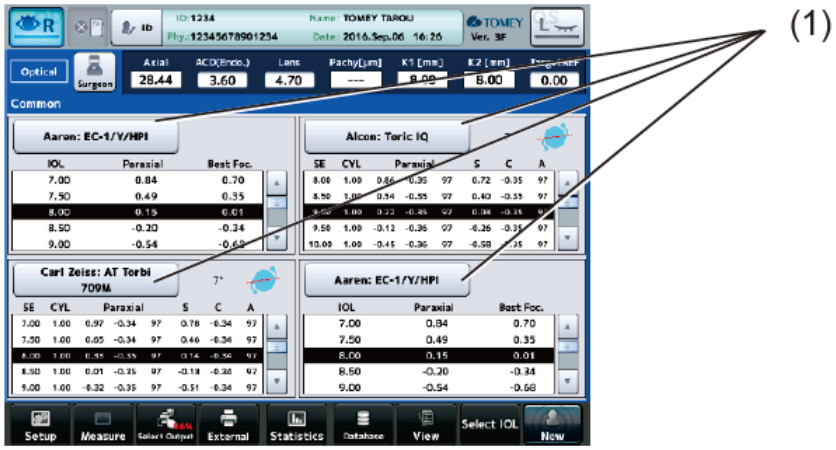
(1)



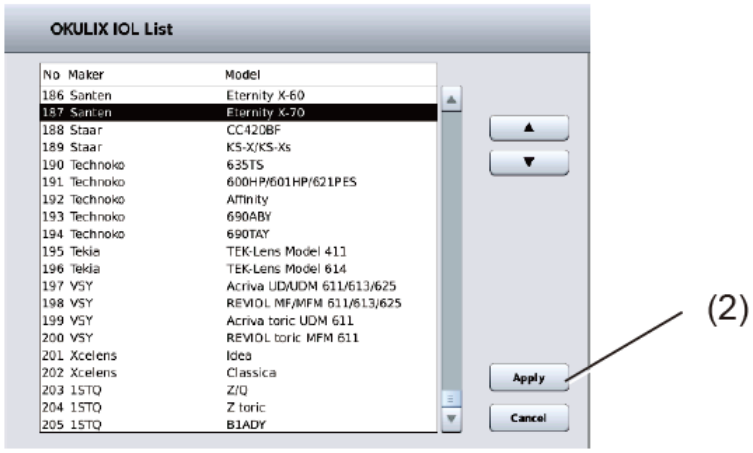
(Fig. 1)

1) Touch the Target Ref. input field (1) to activate it. The keypad appears. Enter the data and touch the “Enter” key on the keypad to apply the data.
The entered value is stored in the main unit, and is not cleared even when the power is turned off.

d) Selecting IOL



(Fig. 1)



(Fig. 2)

1) Touch the IOL data field (1). The IOL List screen (Fig. 2) appears and allows you to select the desired IOL data. Select the data and touch the “Apply” key (2) to apply the data.

   The entered value is stored in the main unit, and is not cleared even when the power is turned off.

4.4 Toric IOL calculation

- This function is available only after purchasing the license of the Barrett formula and performing installation.

a) IOL power calculation

(Fig. 1)

Toric IOL calculation uses the calculation results shown on the IOL calculation screen.

First, calculate the IOL power on the IOL calculation screen.

When IOL power calculation has been executed, the “Toric Calc” button (1) is activated.

b) Toric IOL calculation screen

(Fig. 2)

1) Enter K1/Kf Axis and K2/Ks Axis (1).

This step is not needed when K1/Kf Axis and K2/Ks Axis (1) have been measured.

[Input parameters]

K1/Kf Axis : 0 - 179°

K2/Ks Axis : 0 - 179°

* The difference between K1/Kf Axis and K2/Ks Axis must be always 90°.

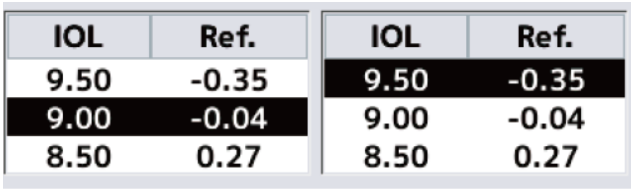
2) Enter the incision data.
Values for the incision axis and SIA (surgically induced astigmatism) can be set on each page.

[Input parameters]

Incision axis : 0 - 359°

SIA : 0.00 - 2.00 D

3) The IOL power values calculated on the IOL calculation screen are shown in the IOL calculation result list (3).Select the IOL power value to be used for Toric IOL calculation.
Touch the screen to change the selection.



IOL	Ref.
9.50	-0.35
9.00	-0.04
8.50	0.27

IOL	Ref.
9.50	-0.35
9.00	-0.04
8.50	0.27

The result of Toric IOL calculation is shown in the IOL Axis (IOL axis angle) field (4) and Toric IOL calculation result list (5).

* The IOL power calculation result obtained by the “SRK/T Double K formula” cannot be used for Toric IOL calculation.

c) Toric Planning screen

(Fig. 3)

(Fig. 4)

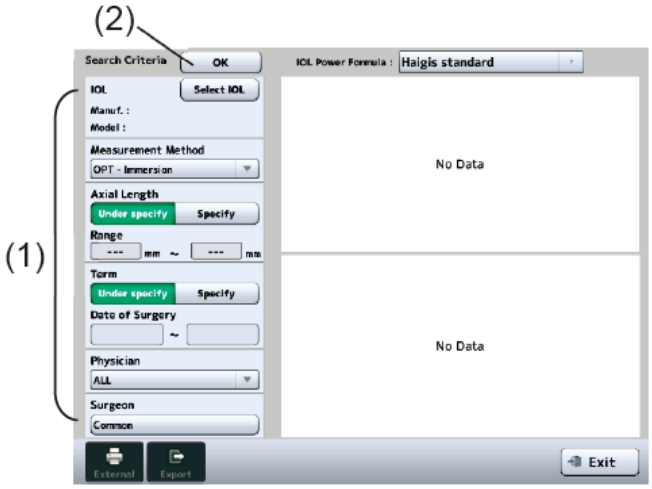
1) Toric IOL calculation results are used on the Toric Planning screen.
   Complete calculation on the Toric IOL calculation screen first.
2) Select calculated values to be used on the Toric Planning screen.
   Touch the IOL Model input field (1) to activate it.
   Select a model for which the calculation results are shown.
3) When the IOL model is selected, the corresponding calculation values are shown in the selected value field (3).
   Hold the Clear button (2) for 1 or 2 seconds to clear the entered data.
4) Select the calculation value to activate the Toric Planning screen button (4). Press this button to open the Toric Planning screen (Fig. 4).

4.5 Statistics processing

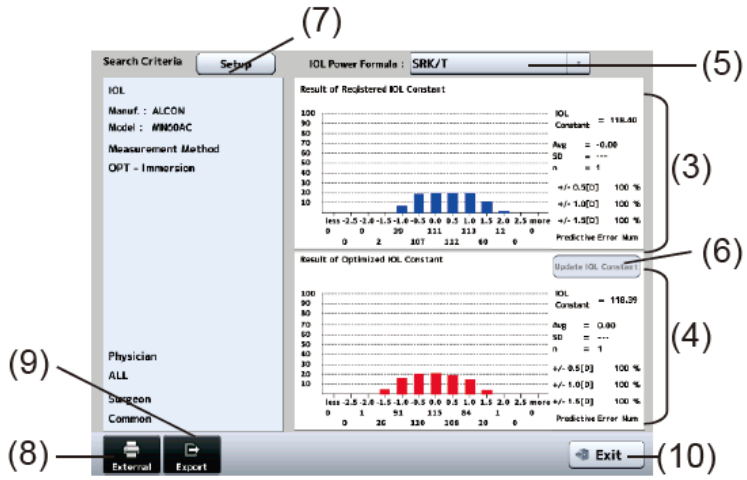
- The lens constant registered on this screen will be used for the next IOL calculation. Carefully check the data before registration.

Statistics processing can be performed on this screen using the examination data accumulated by the clinic of facility. Predictive errors when using the registered lens constant are calculated and a histogram is displayed. In addition, the optimized lens constant can be calculated and registered according to the statistics processing result.

Calculation results when lens constants are entered manually are excluded from statistics processing.



(Fig. 1)



(Fig. 2)

1) Set filter conditions (1) for targets subject to statistics processing.

IOL : Select IOL. Touch the “Select IOL” button. The IOL data selection screen appears to allow you to select an IOL model.

Measurement Method : Optical-contact / Optical-contact 2 / Opticalimmersion / Optical path length / Ultrasound

Axial length : Set the target axial length range.

Term (data extraction term) : Set the term applicable to statistics processing.

Surgeon : The registered physician IDs are displayed in the pull-down menu. “All” includes all physicians.

2) After all the conditions are set, touch the “OK” button (2). Statistics processing is performed and the result appears on the right side of the screen.
   The histogram (3) in the upper section shows registered lens constants and the statistics processing results of those lens constants. When lens constants are not registered, the results do not appear.
   - Registered lens constant
   - Histogram of predictive error in refractive power
   - Average of predictive error in refractive power (Avg)
   - Standard deviation of predictive error in refractive power (SD)
   - No. of data sets (n)

   The histogram (4) in the lower section shows the average of lens constants optimized by statistics processing and predictive results of processing when the average is used.
   - Average (Avg) of optimized lens constant
   - Histogram of predictive error in refractive power
   - Average of predictive error in refractive power (Avg)
   - Standard deviation of predictive error in refractive power (SD)
   - Number of data (n)
   - Percentage that predictive errors in refractive power fall under +/-0.5 [D], +/-1.0 [D], or +/-1.5 [D]
3) Select an IOL power formula (5). Available formulae are:
   - Haigis standard formula
   - Haigis optimized formula
   - Holladay 1 formula
   - SRK/T formula
   - Shammas-PL formula
   - SRK/T Double K formula
4) Click the “Update IOL Constant” button (6) to register the optimized lens constant for the target manufacturer, model, physician, and formula. When the button is touched, the IOL data change confirmation screen appears.
   Click the “OK” button to complete registration.
5) Touch the “Setup” button (7) to re-set filter conditions.
6) Touch the “External” button (8) to print the displayed results. Touch the "Export” button (9) to export the displayed resul.
7) Touch the “Exit” button (10) to close the statistics processing screen.

5. EXPORT, PRINT, AND SAVE

Assign functions to 2 buttons for export, print, and save provided on the operation screen before executing the export, print, and save functions. [Refer to "6.4 a) Setting functions of save, export, and print buttons"]

The print and export buttons work according to the preset functions when touched after measurement.

(Fig. 1)

Button 1 Button 2

Export	Export	Built-in	Print
Save	Save	Export&Save	Export&Save
Export&Int.	Export&Print	Save&Int.	Print&Save
ALL(Int.)	ALL (export, print, and save)	Select Output	Select Output

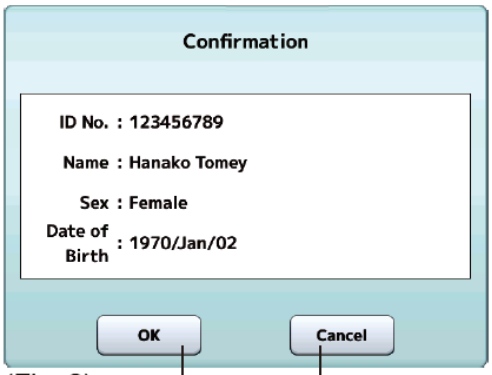
5.1 Export

- The inspection data receiving software "DATA Transfer" (included in the package) is required for data communication.
- Refer to the corresponding operation manual for the DATA Transfer settings.
- Connection setting is required for connecting with DATA Transfer. Refer to "6.4 d) PC (PC connection)" to make settings.
- Data cannot be sent in some configurations if the ID number is not entered. Refer to "6.1 General"
- It is recommended to send data after entering the ID number. The data can be sent without ID numbers entered; however, the corresponding patient may not be identified from the inspection file output from DATA Transfer. When the data was sent without entering the ID number, check the content of the inspection file immediately after sending the data, and move and save the file in an appropriate location.
- Waveforms of the same form as those to be printed out are output. Refer to "5.2 Printing" for details.

1) Touch the "Export" button (1) to open the Transmission confirmation screen (Fig. 2).

(Fig. 1)

(1)



(Fig. 2)

(2) (3)

2) The transfer confirmation screen (Fig. 2) displays patient ID, patient name, and sex. Touch the "Send" button (2) to start sending data.
   Touching the "Cancel" button (3) returns you to the previous screen without sending data.
3) When data transfer is completed, the message “Complete” appears. If an error is displayed, refer to “9. TROUBLESHOOTING”.

5.2 Printing

The printer and printing type can be selected in the system setup. Refer to “6.4 b) Selecting and setting printer”.

- Different waveforms are printed depending on the screen.

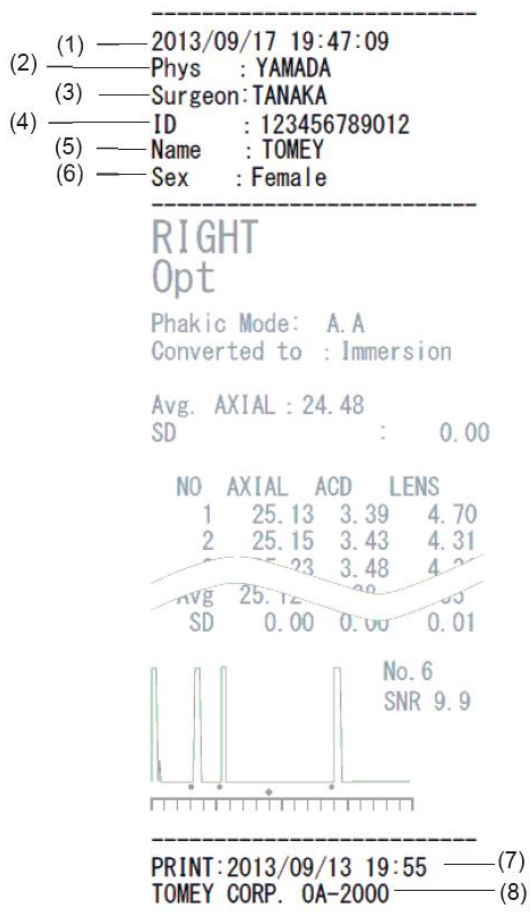
Optical mode

Measurement screen: Waveform No. 1 is printed.
View screen: Waveform displayed on the screen is printed.
IOL screen: Waveform No. 1 is printed when entering the IOL screen from the measurement screen. The waveform displayed on the view screen is printed if entering the IOL screen from the view screen.

Ultrasound (US) mode

Measurement screen: The waveform which is the closest to the average is output.
View screen: Waveform displayed on the screen is printed.
IOL screen: The waveform the closest to the average value is printed when entering the IOL screen from the measurement screen. The waveform displayed on the view screen is printed if entering the IOL screen from the view screen.

a) Common items



(1) Measurement date and time

(2) Physician name

(3) Surgeon name

(4) Patient ID

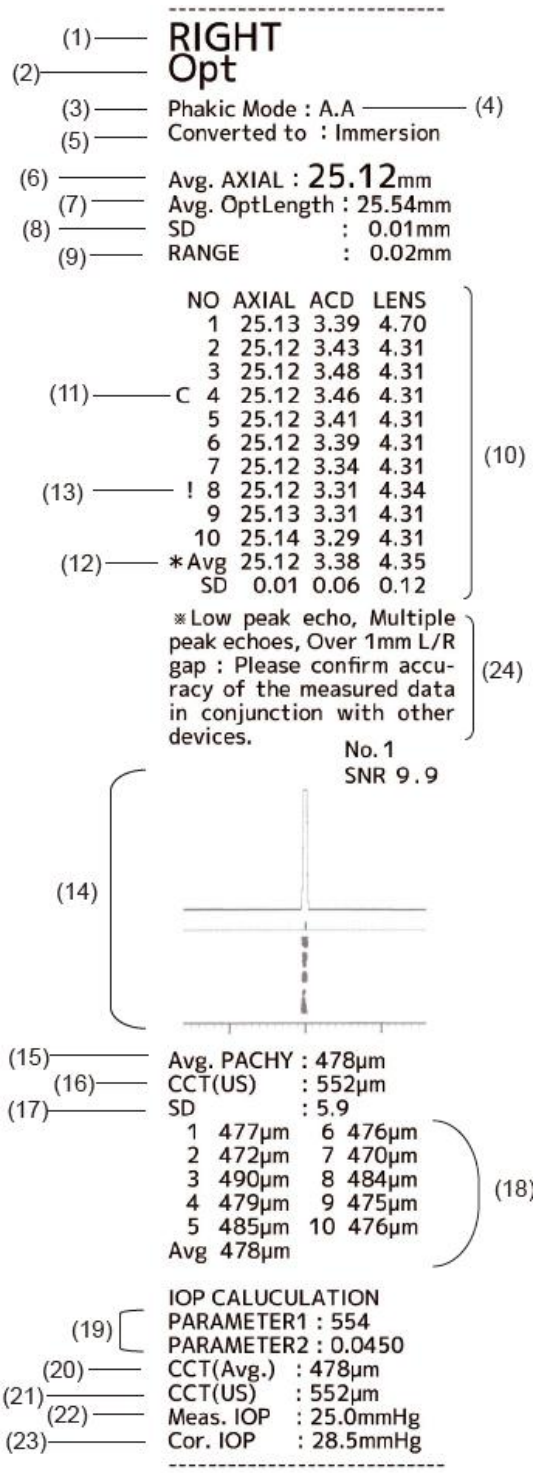
(5) Patient name

(6) Sex

(7) Printed date and time

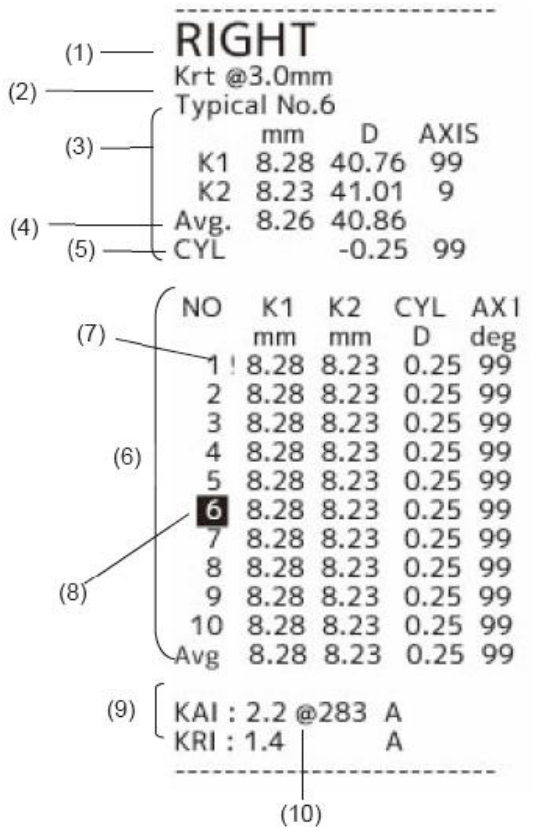
(8) Product Name

b) Example of printout for optical (axial length, ACD, lens, corneal thickness)



(1) Measurement eye (right eye/left eye)
(2) Measurement method
(3) Measurement eye
(4) Measurement mode
Auto (A) / Manual (M)
(5) Fitting
Immersion / Contact / Optical length
(6) Average axial length
(7) Average optical distance
(8) Standard deviation of axial length
(9) Difference between shortest axial length and longest axial length
(10) Axial length, anterior chamber depth, measurement value of lens
(11) Caliper mark
(12) Value used for IOL calculation
(13) Low reliability mark
(14) Waveform
(15) Average corneal thickness
(16) Ultrasound correction for corneal thickness
(17) Standard deviation of corneal thickness
(18) Corneal thickness measurement value
(19) Intraocular pressure correction parameter
(20) Average corneal thickness
(21) Ultrasound correction for corneal thickness
(22) Intraocular pressure
(23) Corrected intraocular pressure
(24) Reminder pertaining to measurement results

c) Example of printout for optical measurement (kerato)



(1) Measurement eye (right eye/left eye)

(2) Kerato measurement position

(3) Selected measurement value

(4) Keratometer average value

(5) Corneal astigmatism

(6) Measurement value

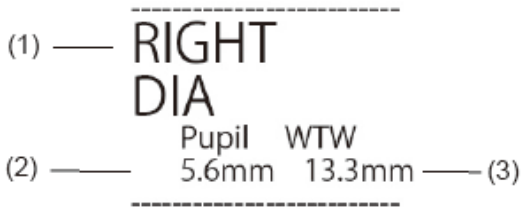
(7) Low reliability mark

(8) Memory number of representative value

(9) Corneal irregular astigmatism index

(10) Corneal irregular astigmatism angle

d) Example of printout for optical measurement (pupil/corneal diameter)



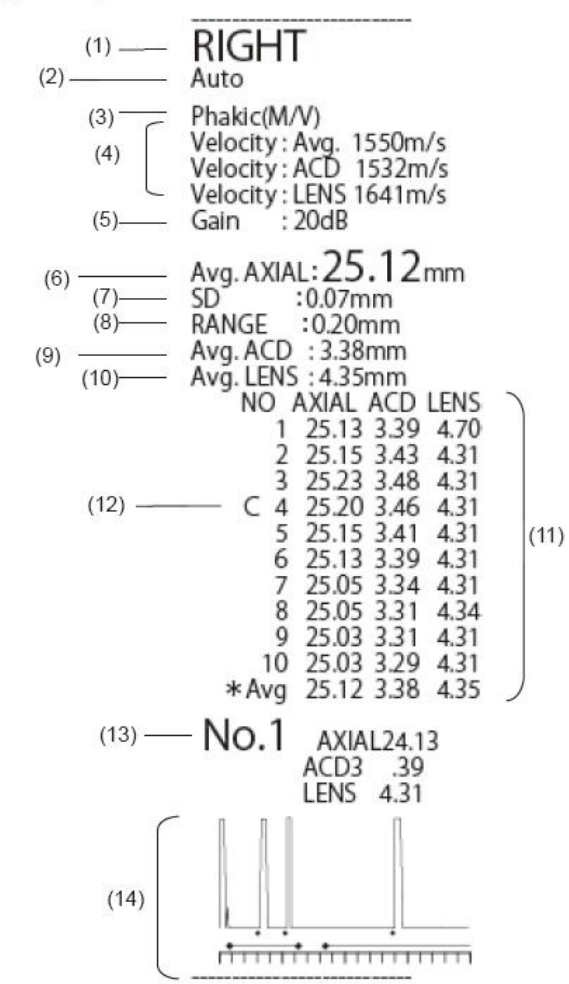
(1) Measurement eye (right eye/left eye)

(2) Pupil diameter

(3) Corneal diameter

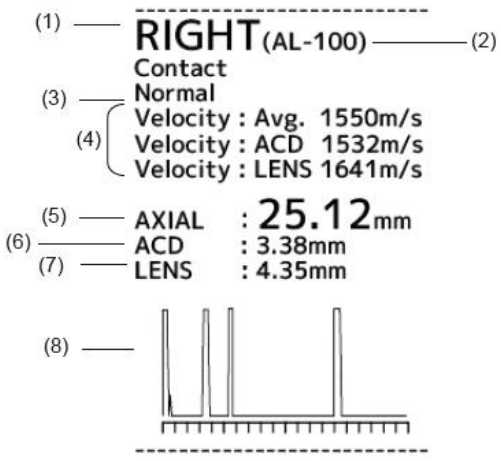
e) Example of printout for ultrasound measurement (axial length)

[AL-4000]



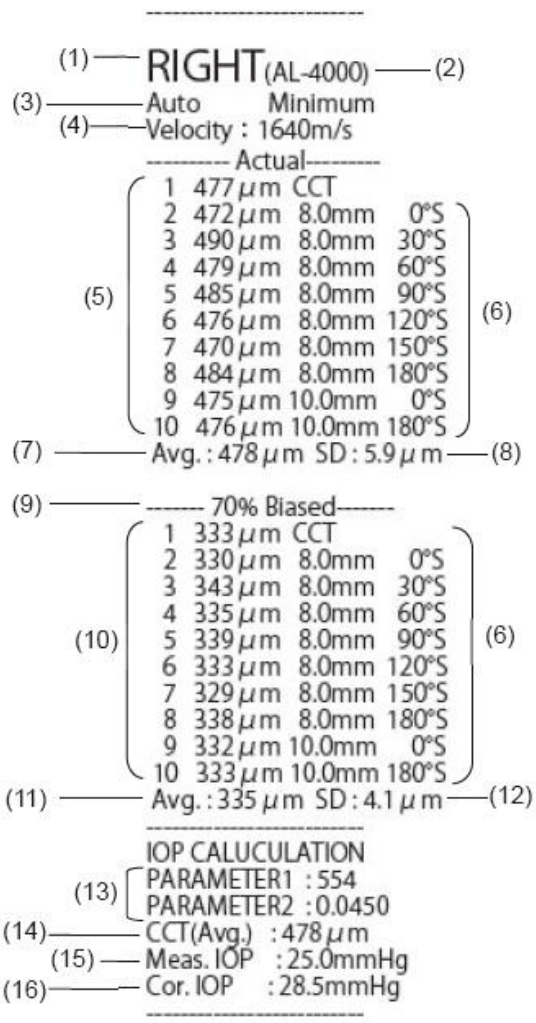
(1) Measurement eye (right eye/left eye)
(2) Measurement method
(3) Patient's eye
(4) Converted sonic velocity
(5) Gain
(6) Average axial length
(7) Standard deviation of axial length
(8) Difference between shortest axial length and longest axial length
(9) Average anterior chamber depth
(10) Average lens thickness
(11) Measurement data (axial length/anterior chamber depth/crystalline lens thickness)
(12) Caliper mark
(13) Value used for IOL calculation
(14) Waveform

[AL-100]



(1) Measurement eye (right eye/left eye)
(2) Measuring instrument model
(3) Patient's eye
(4) Converted sonic velocity
(5) Axial length
(6) ACD (anterior chamber depth)
(7) Lens thickness
(8) Waveform

f) Example of printout for ultrasound measurement (corneal thickness)



(1) Measurement eye (right eye/left eye)

(2) Model of measuring instrument

(3) Measurement mode / Type of displayed data

(4) Converted acoustic velocity

(5) Actual measurement in each memory slot

(6) Measurement point of measurement data

(7) Average of actual measurements

(8) Standard deviation of actual measurements

(9) Bias value display method and bias rate or correction

(10) Bias Value (for each memory)

(11) Average of bias values

(12) Standard deviation of bias values

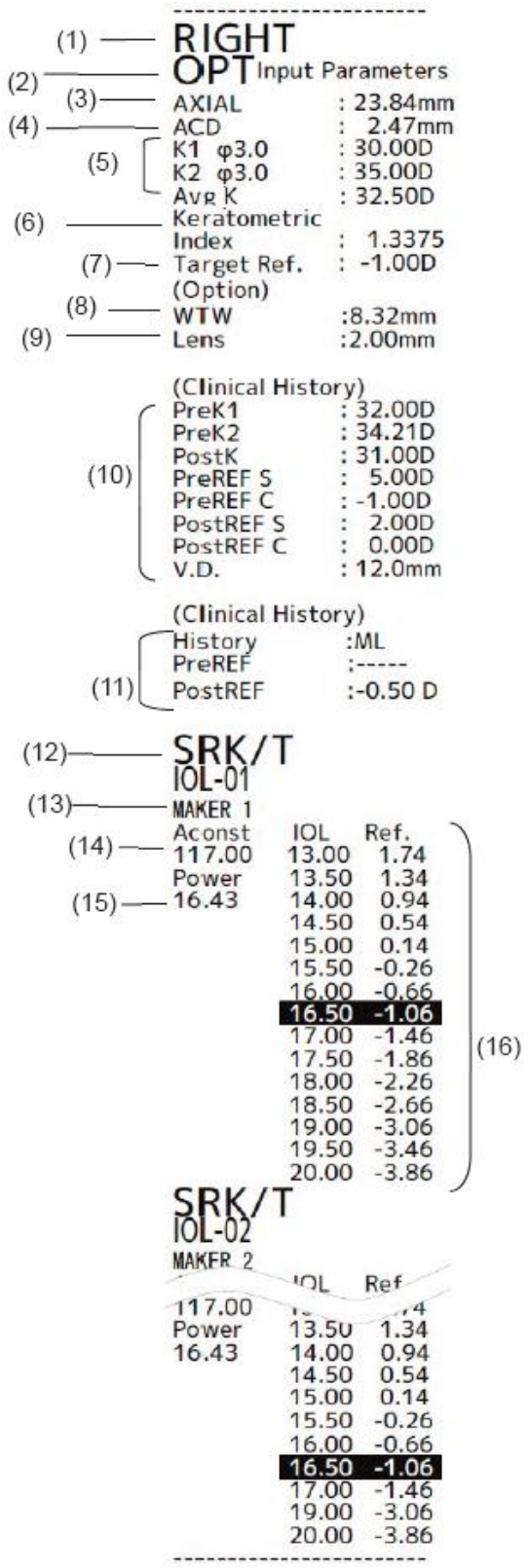
(13) Intraocular pressure correction parameter

(14) Average corneal thickness

(15) Intraocular pressure

(16) Corrected intraocular pressure

g) Printout of IOL power calculation



(1) Measurement eye (right eye/left eye)

(2) US/OPT display

(3) Axial length

(4) ACD (anterior chamber depth)

(5) Corneal refractive power or radius of corneal curvature

(6) Cornea equivalent refractive index

(7) Target Ref. post-surgery

(8) WTW (Corneal diameter)

(9) Lens thickness

(10) Parameters printed when SRK/T Double K is selected

(11) Paremeters printed when Barrett formula is selected

(12) Formula name

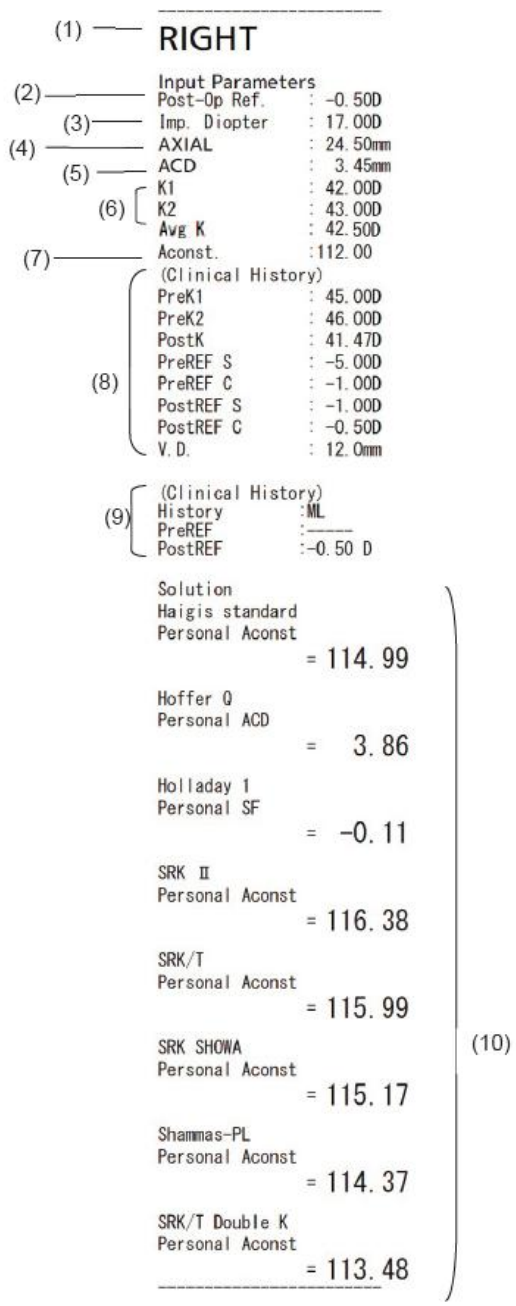
(13) IOL model name

(14) Lens constant

(15) Calculation result

(16) IOL standard (15 levels) and estimated refractive power postsurgery

h) Printout of personal constants



(1) Measurement eye (right eye/left eye)

(2) Eye refractive power postsurgery

(3) Power of the implanted IOL

(4) Axial length

(5) ACD (anterior chamber depth)

(6) Corneal refractive power or radius of corneal curvature

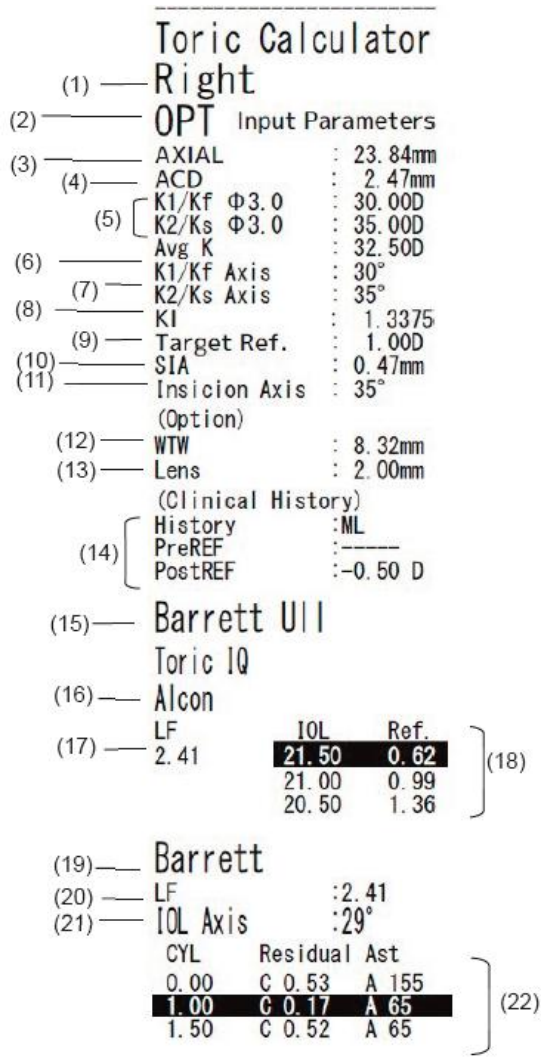
(7) Lens constant

(8) Parameters for SRK/T Double K

(9) Parameters for Barrett formula

(10) Calculation result

i) Printout of toric IOL calculation



(1) Measurement eye (right eye/left eye)
(2) US/OPT display
(3) Axial length
(4) ACD (anterior chamber depth)
(5) Corneal refractive power or radius of corneal curvature
(6) Axial angle of flat meridian
(7) Axial angle of steep meridian
(8) Cornea equivalent refractive index
(9) Expected refractive power
(10) Surgically induced astigmatism
(11) Incision axis
(12) Corneal diameter
(13) Lens thickness
(14) Parameters when Barrett formula is selected
(15) IOL power formula name
(16) IOL model name, manufacturer name
(17) Lens constant for IOL power calculation
(18) IOL standard (3 levels) and estimated refractive power post-surgery
(19) Toric IOL calculation formula
(20) Lens constant for Toric IOL calculation
(21) IOL axial angle
(22) IOL standard (3 levels) and estimated residual astigmatism post-surgery

5.3 Saved data management

a) Selecting storage

The internal memory of this instrument or external memory connected to this instrument can be selected.

Set the storage referring to "6.4 c) Media options / Data output format" When the internal memory is selected for storage, the used storage capacity is shown as a % on the button.

If the used storage capacity exceeds 90%, the value turns red.

b) Saving

Touch the "Save" button (1) on each screen to save the data to the selected storage.

(Fig. 1)

(1)

c) Browsing saved data

1) Touch the "Database" button (1) on each screen to open the Database screen (Fig. 2).

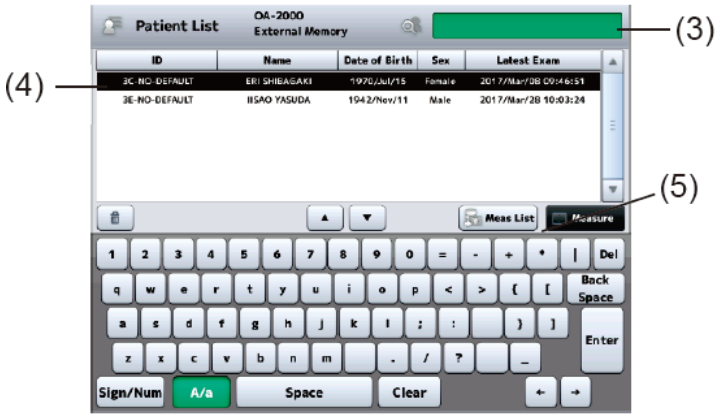
(Fig. 1)

(1)

(2)

(Fig. 2)

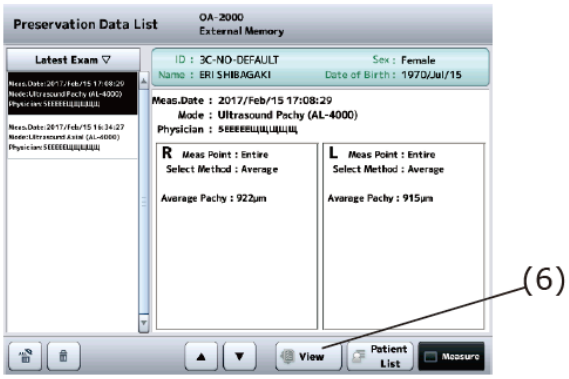
2) Touch the "Patient List" button (2) to display the Patient List screen (Fig. 3) in the internal memory of this instrument, external memory, and internal memory of AL-4000.



(Fig. 3)

3) When characters are entered in the search field (3), the patient ID and name are retrieved and the result appears. Touch the title of the line (4) to change the order of the list. Touching this button sorts the data in ascending order or descending order.

4) Touch the “Measurement List” button (5) to open the Preservation Data List (measurement data list of selected patient ID) screen (Fig. 4).



(Fig. 4)

5) Touch the "View" button (6) to display the view screen (Fig. 5). The data can be viewed and edited on this screen.

(Fig. 5)

(7) (9) (8) (10)

6) Touch the “Over Write” button (7) to overwrite the existing data with the edited contents.
7) Touch the “Meas. List” button (8) to return to the Preservation Data List screen (Fig. 4). Touch the “Patient List” button (9) to return to the Patient List screen (Fig. 3).
8) Touch the “Measure” button (10) to move to the measurement screen.

d) Deleting saved data

[Delete all on Database screen]

Refer to “6.4 g) Database”.

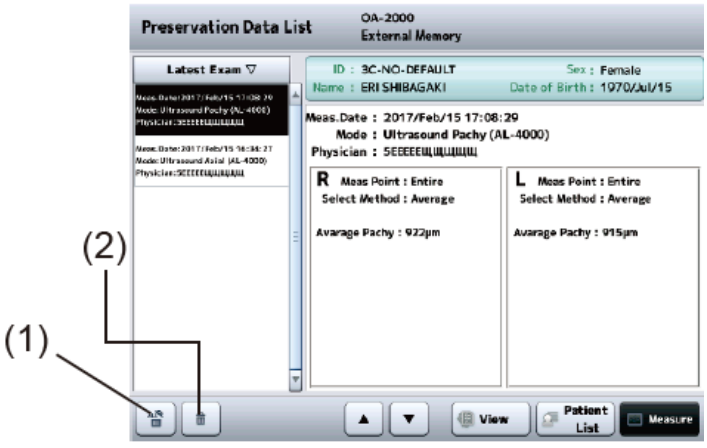
[Deleting data on Patient List screen]

Touch the “Delete” button (1) to delete the selected patient ID and measurement data.

(Fig. 1)

[Deleting data on Preservation Data List screen]

Touch the “ALL Delete” button (1) to delete the selected measurement data of the selected patient ID. (The patient ID remains.) Touch the “Delete” button (2) to delete the selected measurement data only.



(Fig. 1)

e) Transferring saved data

- Some USB flash memorie is not recognized when connected to this instrument.

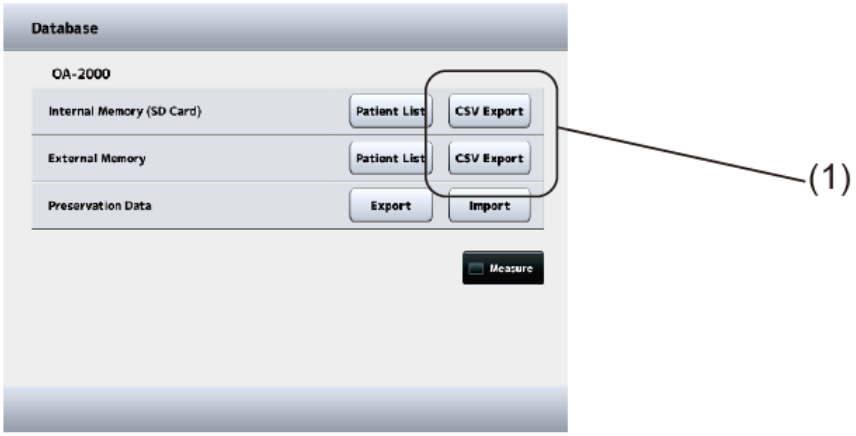
When an external memory is connected to this instrument, the data saved in the internal memory can be transferred to the external memory.
Touch the “Export” button (1) to start copying the data in the internal memory to the connected external memory.
Touch the "Import" button (2) to start copying the data in the connected external memory to the internal memory.

(Fig. 1)

f) CSV output

- Some USB flash memorie is not recognized when connected to this instrument.

Detailed lists of data saved in internal and external memories can be saved in an external memory as CSV files. The output of the data starts when the “CSV output button” (1) is pressed.



(Fig. 1)

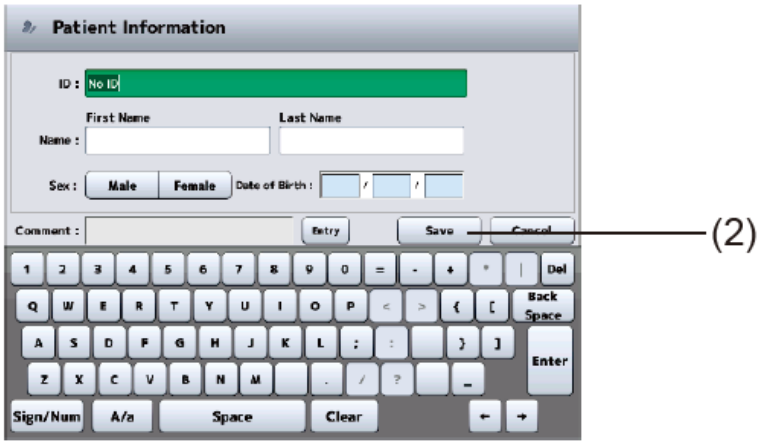
g) Changing ID

- Examination data are saved or deleted when changing ID. Do not turn off the power when ID is being changed. Otherwise, the data may be damaged. Backup the data as necessary.
- Be sure to confirm the modification before saving the changed ID.

1) Hold the grayed out patient information button (1) briefly on the view screen to open the patient information entry screen (Fig. 2).

(Fig. 1)

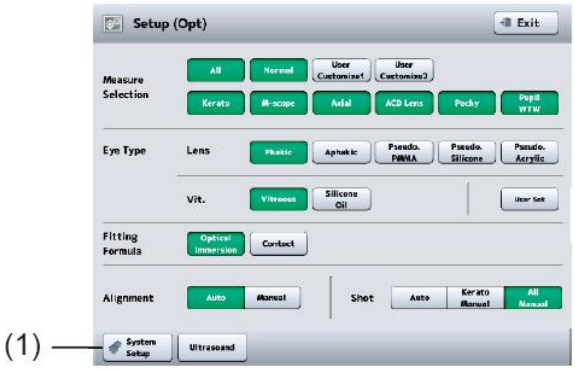
2) Enter the ID and touch the [Save] button (2) to change the ID of the examination data currently displayed.



(Fig. 2)

6. SYSTEM SETUP

Touch the “System Setup” button (1) on the Setup screen (Fig. 1) in each mode to open the System Setup screen (Fig. 2).



(Fig. 1)

(Fig. 2)

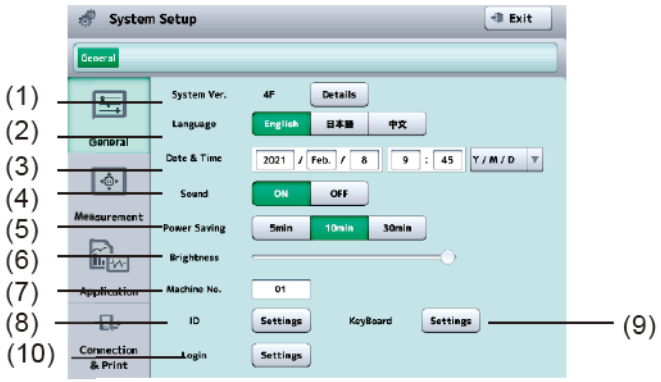
1) The system setup consists of 4 major categories.
   - General ····· Language, time, version information, etc.
   - Measurement ··· Settings related to measurement
   - Application ····· Calculation, analysis, and correction
   - Connection & Print ··· Connection and printing

   Touch the menu tab (2) to open the corresponding setup screen.
   The setup screen is configured as a tree. The displayed location is shown in the address bar (3) and you can jump to the specified screen by touching the displayed characters.

2) Touching the “Exit” button (4) will reflect the changes made and open the measurement screen.

6.1 General

Set general functions here. Select the General tab.



(Fig. 1)

(1) System Ver.

Displays the version information. The version information of the ultrasound measurement unit AL-4000 is also displayed.

(2) Language

Selects the language.

(3) Date & Time

Set the display format of the date and the date and time. The key pad appears when the input field is touched.

(4) Sound

Set whether to generate sound when operating the screen.

(5) Power Saving

This function automatically turns off the LCD when the instrument is not operated for a specified time. Touch the monitor screen to return to normal status.

Sets the time to automatically turn off the LCD.

5 mins / 10 mins / 30 mins

(6) Brightness

Set the brightness of the monitor screen.

(7) Machine No. Setting

Set the number to identify each instrument when multiple instruments of the same model are installed.

(8) ID

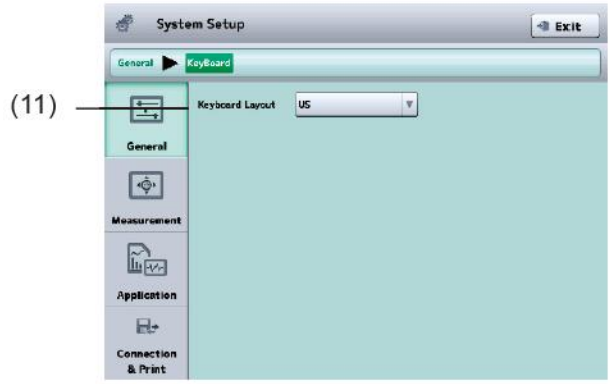
Open the setup screen for patient IDs.

(9) Keyboard Settings

Touching the “Settings” button (9) displays the Keyboad Layout setting screen (Fig. 2).

(10) Login Setting

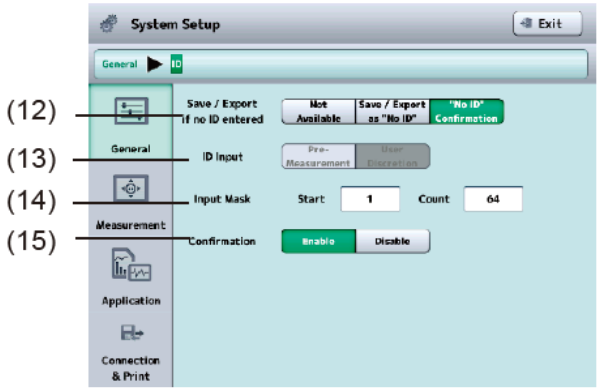
Press the “Settings” button (10) and the login setting screen (Fig.4) appears.



(Fig. 2)

(11)Keyboard Layout

Open the Keyboard Layout screen.



(Fig. 3)

(12)Save/Export if no ID entered

Set how the patient ID must be handled when saving and sending examination data to TOMEY Link.

Not Available: Select this when ID numbers are always required. Data cannot be saved or sent when the ID is not entered.

Save/Export as “No ID”: Select this when the ID is usually entered, but data can also be saved and sent without entering the ID. Data is saved and sent with the ID as “No ID” when the ID is not entered.

“No ID” Confirmation: Select this when no special attention is paid to entry of the ID. The transfer confirmation screen appears, but the inspection data is automatically saved and sent. Data is saved and sent with the ID as “No ID” when the ID is not entered.

(13)ID INPUT

Set whether to display the patient information input screen before measurement when starting measurement for a new patient.

Pre-Measurement: Displays the patient information entry screen before starting measurement.

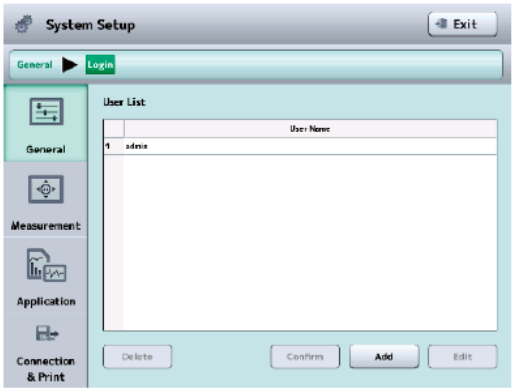
User Discretion: Displays the measurement screen.

(14)Input Mask

Sets which part of the character string should be recognized as the ID number when entering the ID number from a barcode. If it starts from “0” or “1”, the characters from the very beginning are identified as the ID number.

(15)Confirmation

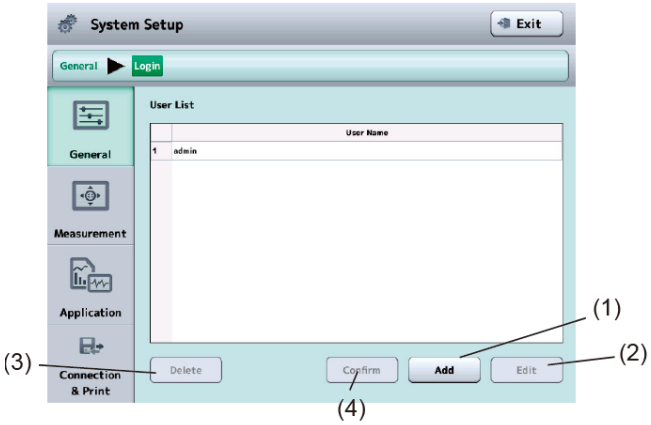
Use this field to display the Patient information confirmation screen when saving the inspection data or sending the inspection data to TOMEY Link.



(Fig. 4)

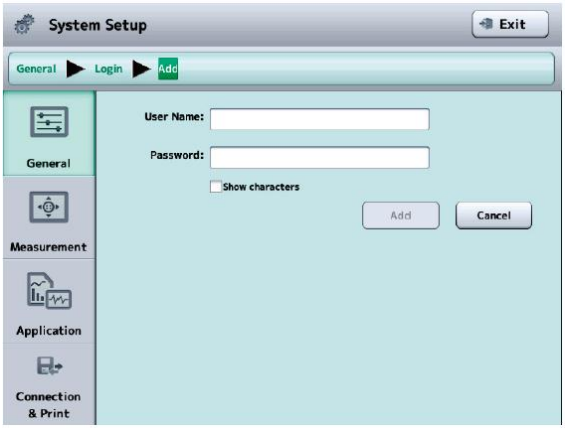
[Login settings]

Login users of the instrument are managed here.



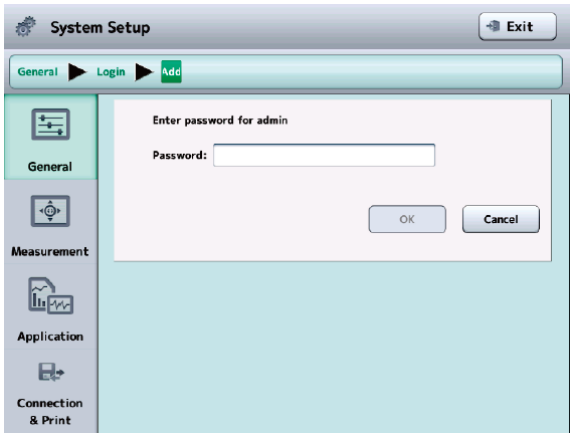
- When using the instrument for the first time, change the admin **user’s password (admin)**.
- The first time you log in use [**User Name: admin**] and [**Password: admin**].
- If you have forgotten the admin user’s password, please contact our local distributor.
- The user name “admin” cannot be deleted.

a) Adding users



Press the [Add] button (1), and the user registration screen appears.
Enter “user name” and “password”, and press the [Add] button.

b) Editing user information/password



Select the target user, and press the [Edit] button (2). The Login screen appears.
Enter the target user’s password. When the correct password is entered, the information and password of this user can be edited.

c) Deleting user information

Select the target user, and press the [Delete] (3) button.
The Login screen appears. Enter the target user’s password.
When the correct password is entered, this user is deleted.

d) Login operation when you have forgotten the user password

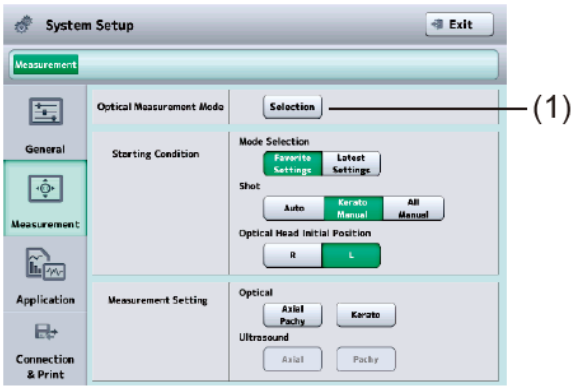
This operation is performed when the registered user has forgotten their password. Select the target user you want to check their password, and press the [Confirm] button (4).
The Login screen appears. Enter the admin user’s password.
When the correct password is entered, the target user’s password is displayed.

6.2 Measurement

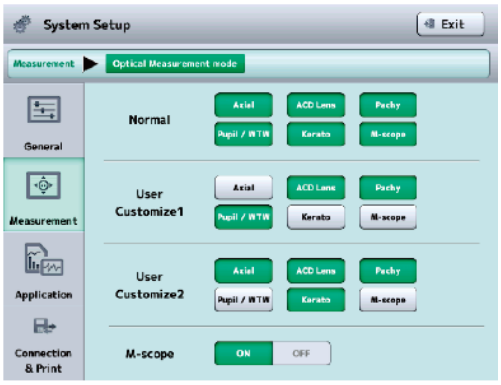
Make settings related to measurement on this screen. Select the Measurement tab.

a) Optical Measurement Mode - Selection

Select measurements to be performed in optical mode. Touch the “Selection” button (1) to open the measurement mode setup screen (Fig. 2).

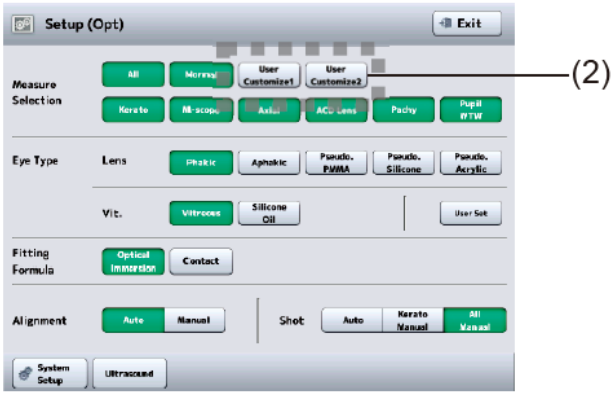


(Fig. 1)



(Fig. 2)

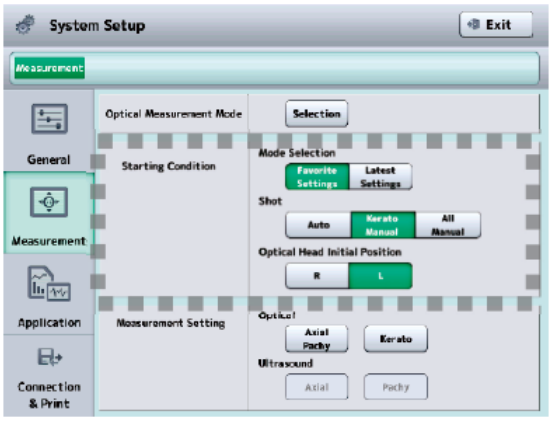
3 patterns can be prepared. Measurement modes selected here will be effective when specified in Measure Selection (2) on the Setup screen (Fig. 3).



(Fig. 3)

b) Starting Condition

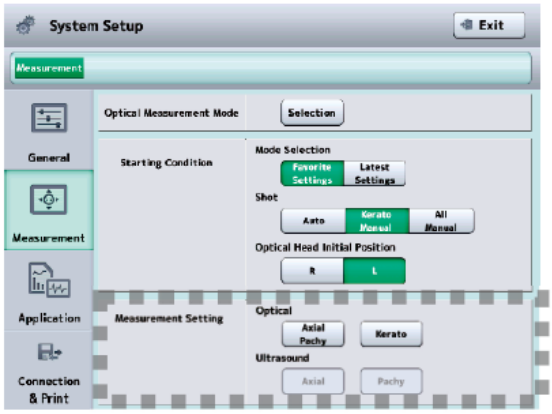
Set the measurement mode when power is turned on and when the measurement mode is switched.



(Fig. 1)

[Mode Selection]	Favorite Settings	The system starts with measurement contents selected on the mode selection screen.
	Latest Settings	The system starts with measurement contents active when power was turned off last time.
[Shot]	Auto	The system starts with automatic measurement.
	Kerato Manual	Only kerato is started by manual measurement, and others are started by automatic measurement.
	All Manual	The system starts with manual measurement.
[Optical Head Initial Position]	The optical head initial position is set.	
	R	Activate with the head moved to the right eye.
	L	Activate with the head moved to the left eye.

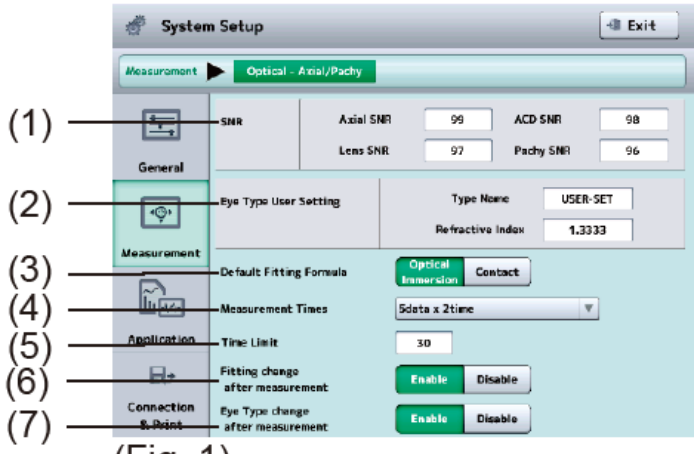
c) Settings for various measurements



(Fig. 1)

[Optical]	Axial Pachy / Kerato	Opens the setup screen for optical measurement of axial length and corneal thickness.
	Kerato	Opens the setup screen for keratometer measurement.
[Ultrasound]	Axial	Opens the setup screen for ultrasound measurement of axial length.
	Pachy	Opens the setup screen for ultrasound measurement of corneal thickness.

[Optical – Axial/Pachy]



(Fig. 1)

(1) SNR

Assigns a low reliability mark to data with an SNR smaller than the preset value.

		Input range	Default setting
Axial SNR	SNR of retina waveform	2 - 99	3
ACD SNR	SNR of waveform on the front of crystalline lens	2 - 99	3
LENS SNR	SNR of waveform on the back of crystalline lens	2 - 99	3
Pachy SNR	SNR of waveform on the back of cornea	2 - 99	3

(2) Eye Type User Setting

Set the average refractive index of the eye to be measured.

(3) Default fitting formula

Set the fitting formula for normal operation.

This selection changes the default view for the kerato measurement position.

Immersion: φ2.5 mm

Other fitting fomulae: φ3.0 mm

(4) Measurement Times

Set the number of data sets taken per measurement.

10 data x 1 time: Load 10 data sets once.

5 data x 2 times: Load 5 data sets twice.

When “5 data x 2 times” is selected in auto measurement mode, 5 data sets are loaded after alignment is completed and measurement starts. Then, alignment is performed again, 5 data sets are loaded, and measurement is completed.

(5) Time Limit

Set the time limit for loading the preset number of datasets.

Input range: 10 - 60 (s)

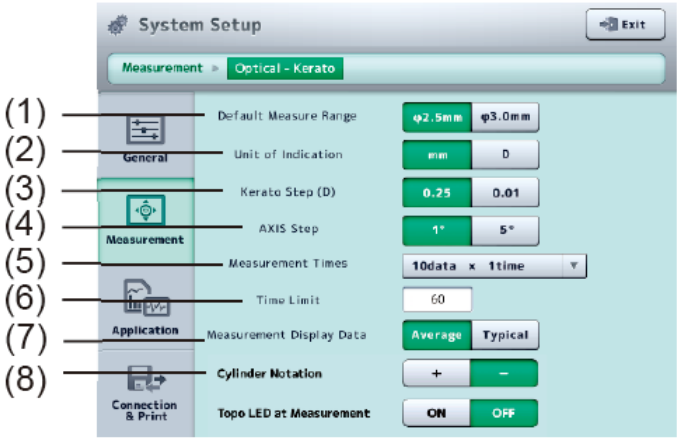
(6) Fitting change after measurement

Set whether or not a fitting change is permitted.

(7) Eye type after measurement

Set whether to allow changing the measurement eye after measurement

[Optical – Kerato]



(Fig. 1)

(1) Default Measure Range

Set a normal measurement position.

φ2.5 mm /φ3.0 mm

(2) Unit of Indication

Set the unit normally used for indications.

mm / D

(3) Kerato Step (D) (unit for measurement – diopter)

Sets the indication units for the measurement value of corneal refractive power.

0.25 / 0.01

(4) AXIS Step (unit for angle)

Sets the display units for the corneal astigmatism axial angle.

1° / 5°

(5) Measurement Times

Set the number of data sets taken per measurement.

10 data x 1 time: Load 10 data sets once.

5 data x 2 times: Load 5 data sets twice.

3 data x 3 times: Load 3 data sets 3 times.

3 data x 1 times: Load 3 data sets once.

1 data x 5 times: Load 1 data set 5 times.

1 data x 10 times: Load 1 data set 10 times.

When “5 data x 2 times” is selected in auto measurement mode, 5 data sets are loaded after alignment is completed and measurement starts.

Then, alignment is performed again, 5 data sets are loaded, and measurement is completed.

(6) Time Limit

Set the time limit for loading the preset number of datasets.

Input range: 10 - 60 (s)

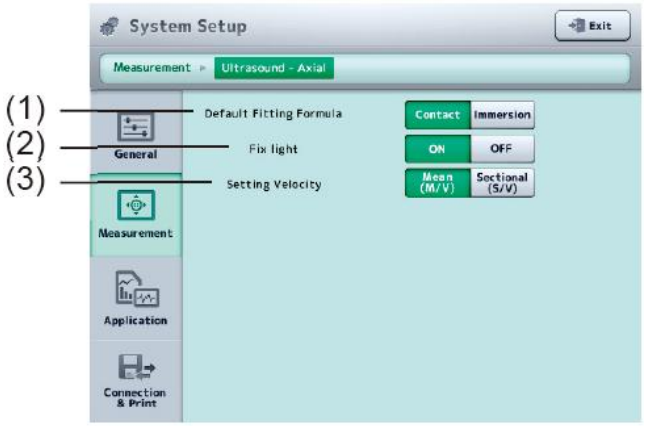
(7) Measurement Display Area

Average / Typical

(8) Cylinder Notation

Cyl is displayed with a set sign + or -.

[Ultrasound – Axial]



(Fig. 1)

(1) Default fitting formula

Set the fitting formula for normal operation.

Contact / Immersion

(2) Fix light

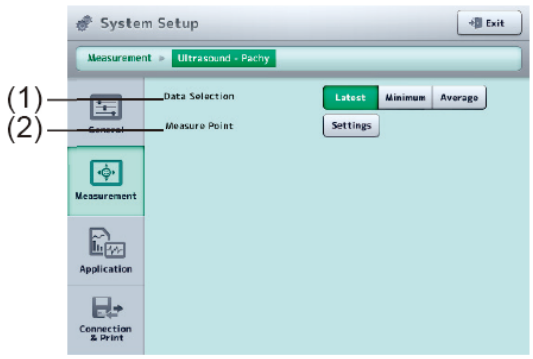
Select whether the fix light in the biometry probe is turned on or off.

ON / OFF

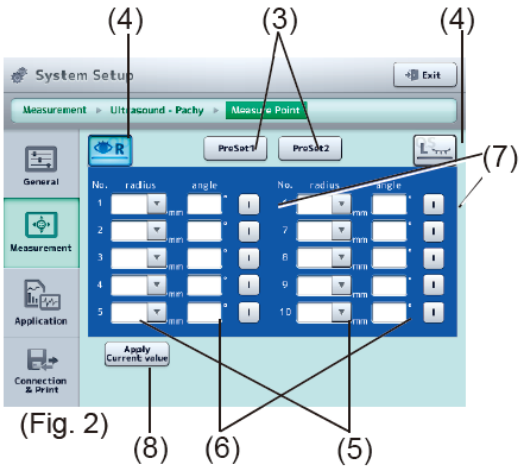
(3) Setting Velocity

Mean Velocity (M/V) / Sectional Velocity (S/V) e.

[Ultrasound – Pachy]



(Fig. 1)



(Fig. 2)

(1) Data Selection Method

Select the measurement data type to be displayed.

Latest / Minimum / Average

(2) Measure Point

Opens the measurement setup screen (Fig. 2).

(3) PreSet1 / PreSet2

Changes the selected preset measurement point.

(4) Eye selection

Changes the preset measurement point of the selected eye.

(5) Radius input field

Specify the radius distance from the center of the measurement point.

Touch the input field. The keypad appears. Touch the "▼" on the right of the input field. The pull-down menu appears. Select CCT or enter the desired value using the keypad.

Input range: 0.1 - 15.0 mm

(6) Angle input field

Enter the angle from the horizontal axis at the measurement point. The key pad appears when the input field is touched.

Input range: 0 - 179

(7) S/I selection button

The mode alternates between "S" and "I" every time you touch the button.

(8) "Apply Current Value" button

Enters the measurement points currently being used in each field on the measurement screen.

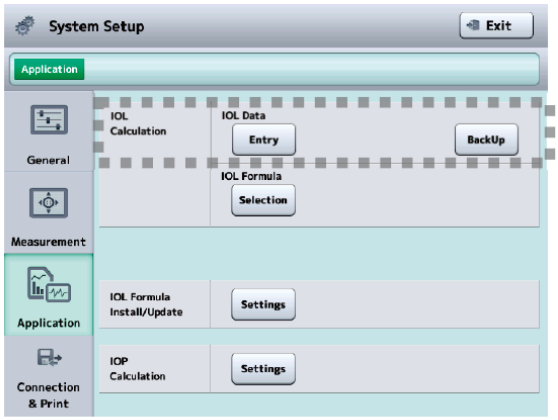
6.3 Application

Make settings related to measurement of calculation, correction, etc. Select the Application tab.

a) Registering IOL data

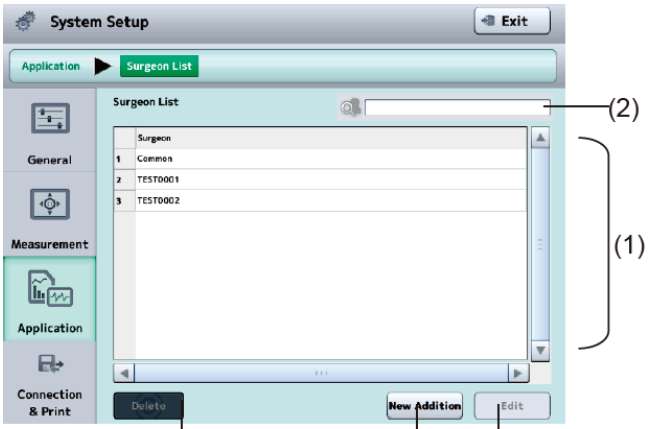
Registers the IOL data to each measurement method.

Touch each button to open the corresponding registration screen (Fig. 2).



(Fig. 1)

[Surgeon List]



(Fig. 2)

(1) Surgeon List

The registered surgeons are displayed.

(2) Surgeon Search

(3) Delete button

Delete the selected surgeon.

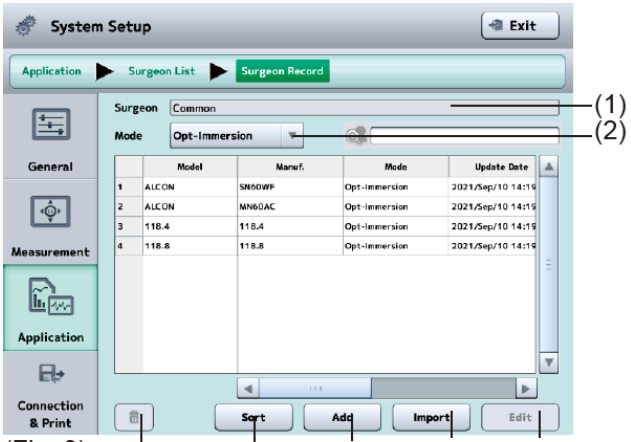
(4) New Addition button

Open the Surgeon Record screen and add the new surgeon.

(5) Edit button

Open the Surgeon Record screen and edit the selected surgeon information.

[Surgeon Record]



(Fig. 3)

(1) Surgeon input field

Edit the surgeon name other than Common.

(2) Mode button

The IOL data list of the selected mode.

(3) Delete button

Delete the selected IOL data list.

(4) Add button

Add the IOL data list.

Newly Add: Newly add the IOL data list. (Manual input)

Add from the surgeon list: Copy and add the IOL data list that the other surgeon uses.

Add from the other mode list: Copy the IOL data list that the selected surgeon uses and add it as the new measurement mode.

(5) Import button

Add the IOL data list from the external memory.

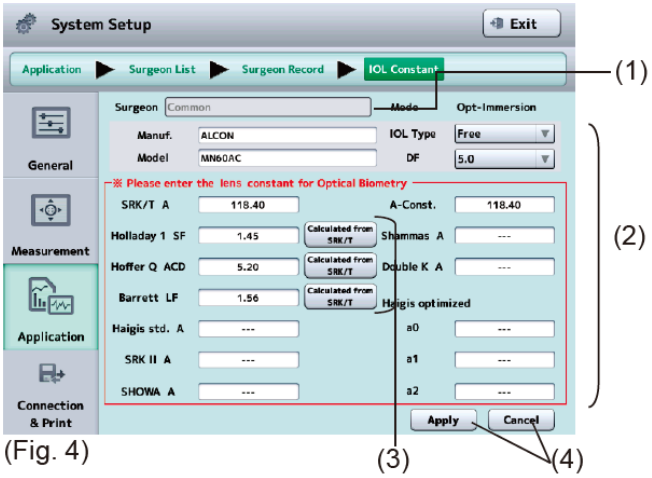
(6) Edit button

Open the Surgeon Record screen and edit the selected IOL data list.

(7) Sort button

Sort the IOL data list.

[IOL Constant]



(Fig. 4)

(1) Surgeon display field

(2) IOL data input field

Enter each item. The software keyboard appears when the entry field is touched.

(3) "Calculated from A-Const"/"Calculated from SRK/T" button

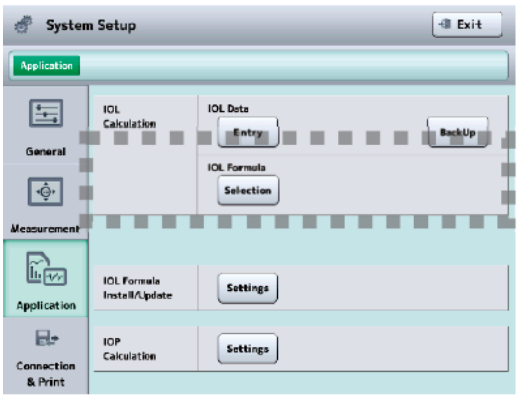
Calculates the values corresponding to SF, ACD constants and LF. The calculated values are displayed in the respective input boxes.

(4) Apply / Cancel button

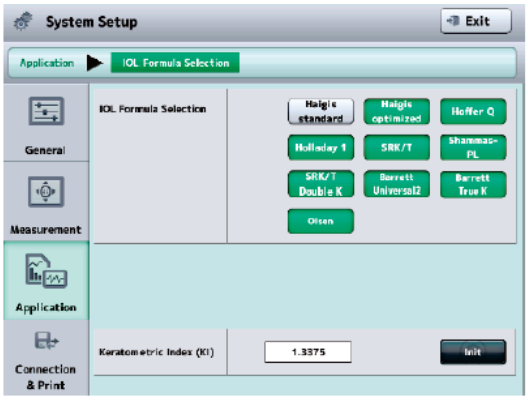
Register or cancel the entered value.

b) Selecting IOL power formula

Select the IOL formula to be used on the IOL power calculation screen. The selected formulae will be displayed in the pull-down menu on the IOL power calculation screen. Touch the “Selection” button to open the IOL Formula Selection screen (Fig. 2).



(Fig. 1)



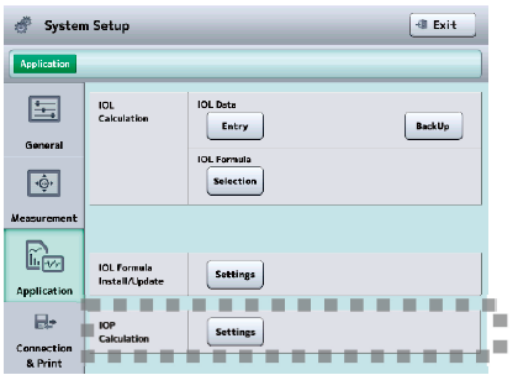
(Fig. 2)

When Haigis standard is selected, setting items for a1 and a2 appear.

(Fig. 3)

c) Setting IOP formula

Register the intraocular pressure correction formula to be used for the intraocular pressure correction. The formula set here can be selected on the intraocular pressure correction screen. Touch the “Settings” button to open the selection screen (Fig. 2).



(Fig. 1)

(Fig. 2)

(1) Intraocular pressure correction formulas

Register the intraocular pressure correction formula to be used for the intraocular pressure correction.

	Input range
IOP correction formula name	Up to 10 characters
Parameter 1	0 - 1500
Parameter 2	0.0000 - 1.0000

(2) Indication Unit

mmHg / hPa

(3) CCT (Ultrasound)

Set the CCT ultrasound correction value.

View: ON / OFF

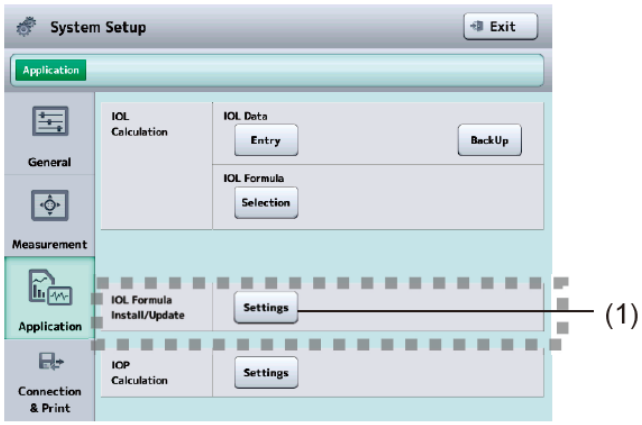
Export: Enable / Disable

Offset: Input range 0 - 30

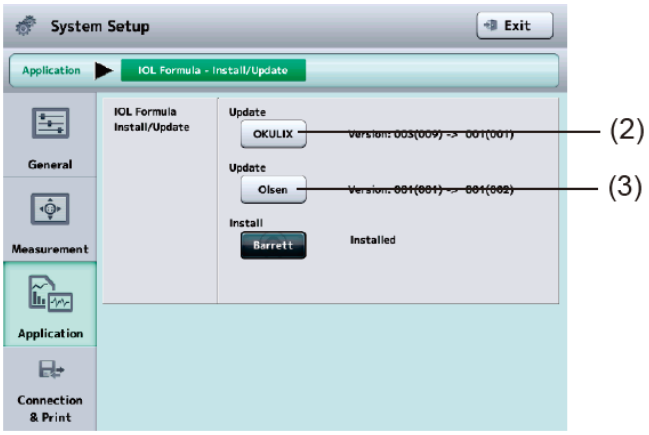
“Default" button: Set the offset value to 16 μm.

d) IOL Formula Install/Update function

The current specific IOL formula version can be checked, updated and installed.



(Fig. 1)



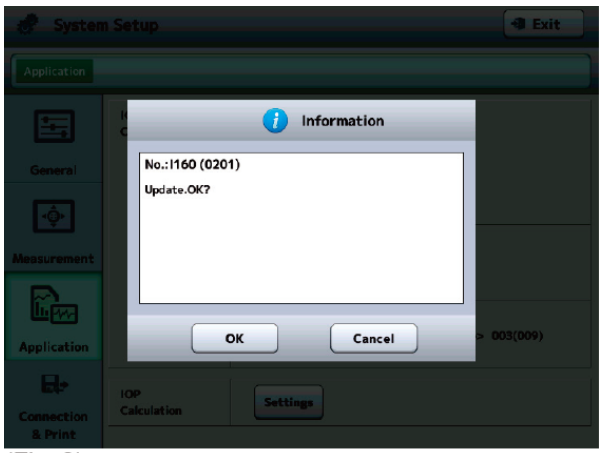
(Fig. 2)

[Confirming installation of each formula]

1) Touch the IOL formula Install/Update “Settings” button (1).
2) Installation and update status of IOL formulae can be confirmed. (Fig. 2)n

[Updating OKULIX]

1) Create a folder named OKULIX on the USB flash memory (top level).
   Copy the updated file into this folder.
2) Connect the prepared USB flash memory to the instrument.
   The current version and new versions of OKULIX available are displayed.
3) Touch the “Update - OKULIX” button (2).
   The update confirmation screen appears. Touch the “OK” button.
   OKULIX is updated.



(Fig. 3)

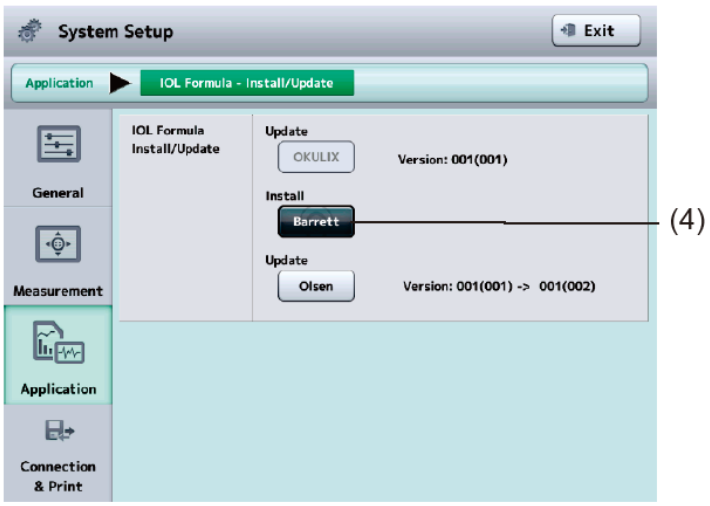
[Olsen Update Procedures]

Basic procedures are the same as those of OKULIX.

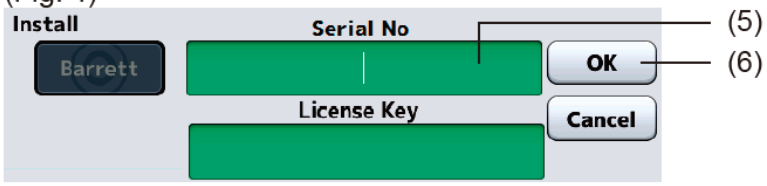
1) Create the [libOlsen] folder in the top directory of the USB flash memory.
   Put the update file in this folder.
2) When the USB flash memory preparation is completed, connect it to the instrument.
   The current Olsen version and the applicable update versions are displayed.
3) Touch the “Update - Olsen” button (3).
   The update confirmation screen appears. Touch the “OK” button.
   The Olsen update starts.

[Installing Barrett formula]

The Barrett formula becomes available after entering the license key.

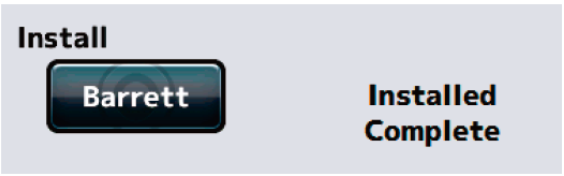


(Fig. 4)



(Fig. 5)

1) Hold the “Install - Barrett” button (4) for 1 or 2 seconds.
   The Serial number/License key entry field (5) appears.
   Enter the Serial number/License key and touch the “OK” button (6).
2) When the correct License Key is entered, the following message appears on the side of the button:



(Fig. 6)

* If the Barrett formula is not shown on the IOL calculation screen after installation, check the IOL formula list on the application screen.

6.4 Connection & Print

Make settings related to connection, saving, export, and printing on this screen.

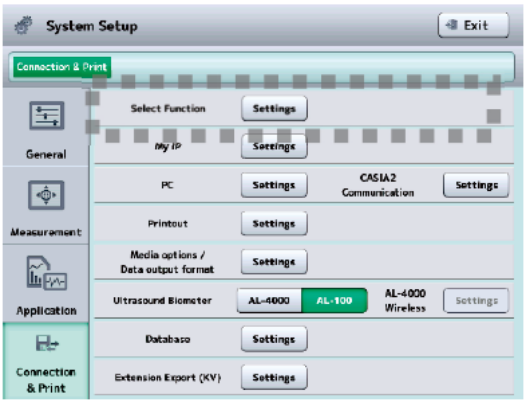
Select the Connection & Print tab.

a) Setting functions of save, export, and print buttons

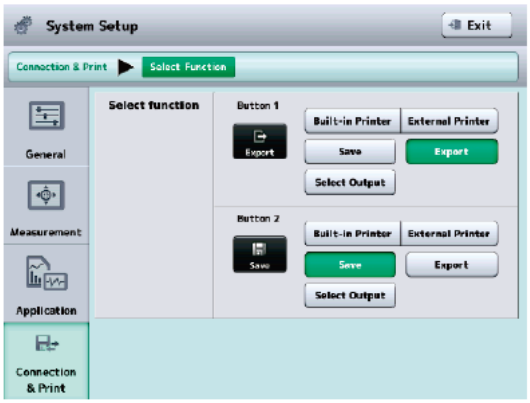
Assign functions to 2 buttons for saving, export, and print provided on each screen (Fig. 1).

(Fig. 1)

Touch the “Function settings of button” to open the System Setup screen (Fig. 3).



(Fig. 2)



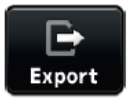
(Fig. 3)

Select the function to be assigned to each of two buttons. The button icon changes according to the selections.

The symbol of the print button varies depending on the selected printer as shown below.

Built-in printer: Built-in

External printer: External



Export

Print

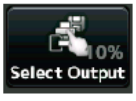
Save

Export&Save

Export&Print

Print&Save

Export, print, and save



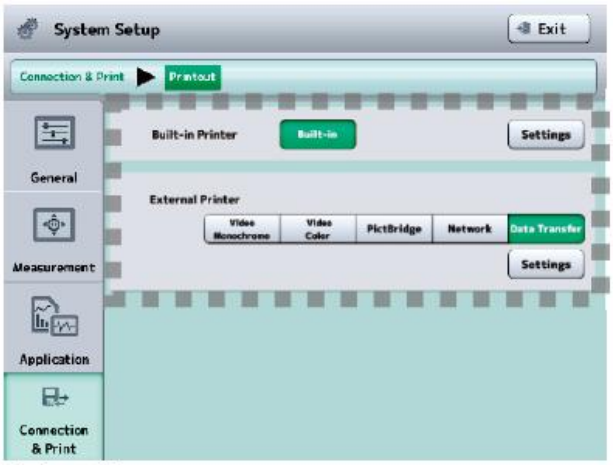
Select Output

b) Selecting and setting printer

The printer used for printing can be selected here.

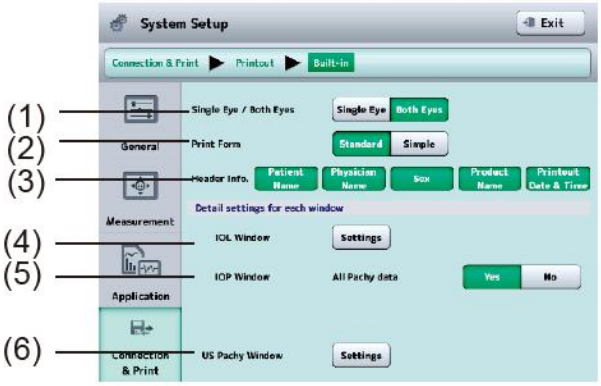
The built-in printer, video monochrome printer, video color printer, or network printer can be selected. Touch the “Setting” button to open the Setup screen for each printer.

There are no setting items for the video color printer.



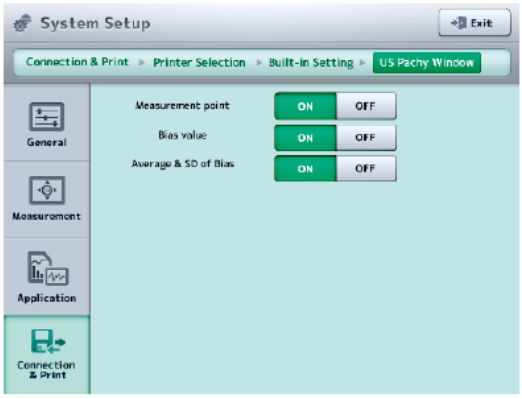
(Fig. 1)

[Built-in printer setting]



(Fig. 1)

(Fig. 2)



(Fig. 3)

(1) Single Eye / Both Eyes

Set whether to print the data of the displayed eye only or the data of both eyes.

Single Eye / Both Eyes

(2) Print Form

Select the display form of printing.

Standard / Simple

(3) Header Info.

Select items to always be printed.

Patient Name / Physician Name / Sex / Product Name / Printout Date & Time

(4) IOL Window (IOL power calculation screen)

Make settings for printing from the IOL power calculation screen.

Touch the “Settings” button to open the System Setup screen (Fig. 2).

IOL data number:	3 / 9 / 15
Appending Measurement data:	Yes / No
Select Calculation Result at Printing:	Yes / No
Kerato φ 2.0mm:	Yes / No

(5) IOP Window (intraocular pressure correction screen)

Set whether to print the measurement data on the intraocular pressure correction screen.

Yes / No

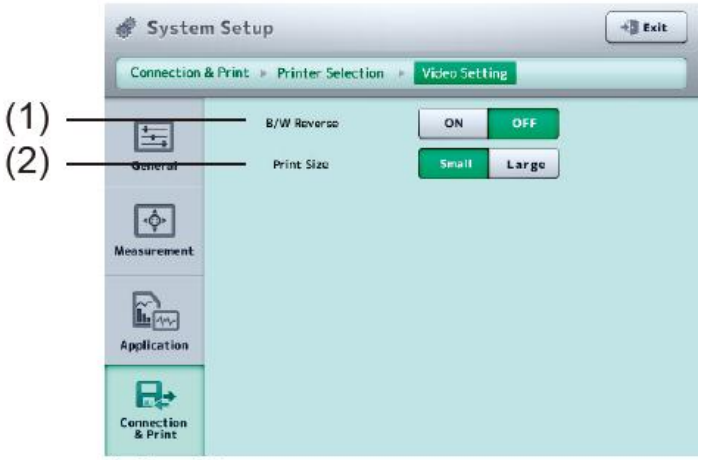
(6) US Pachy Window (ultrasound corneal thickness measurement)

Make settings for printing on the ultrasound corneal thickness measurement screen.

Touch the “Settings” button to open the System Setup screen (Fig. 3).

Measurement point (for each memory):	ON / OFF
Bias value (for each memory):	ON / OFF
Average & SD of Bias: (average and standard deviation of bias value)	ON / OFF

[Video monochrome printer setting]



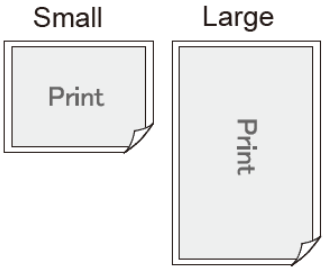
(Fig. 1)

(1) B/W Reverse (black/white reverse printing)

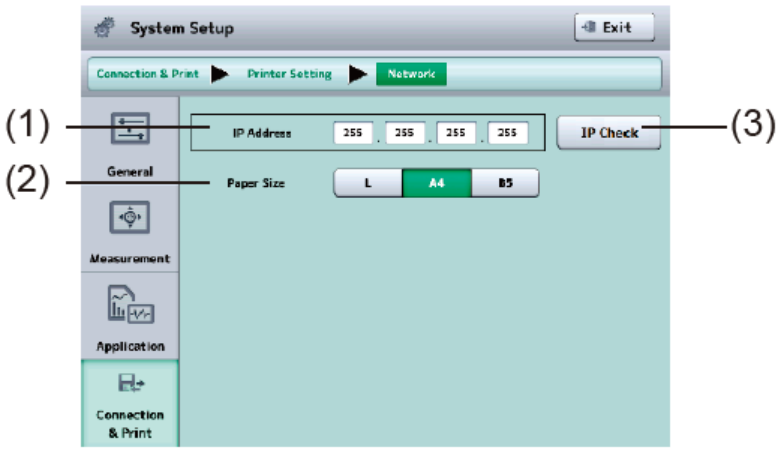
ON / OFF

(2) Print Size

Small / Large



[Network printer setting]



(Fig. 1)

(1) IP Address

Set the IP address of the printer to be connected.

Touch the input field to display the keyboard.

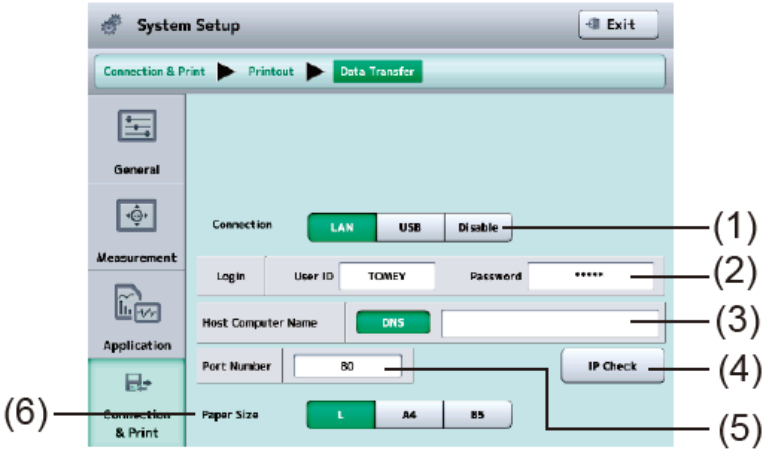
(2) Paper Size

L / A4 / B5

(3) IP Check

Performs a connection test

[Setting Data Transfer printer]



(Fig.1)

(1) Connection permission and selection of cable type

(2) Login Tomey Link

(3) Host IP address

(4) "Connection Test" button

(5) Port number

(6) Paper Size

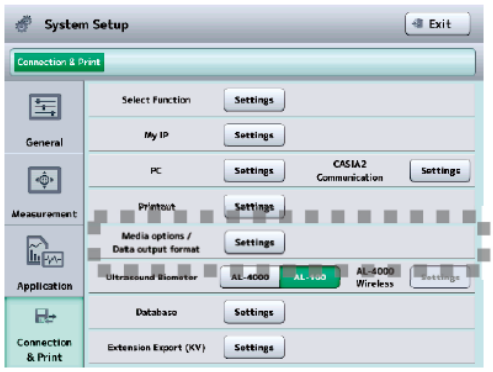
L / A4 / B5

Set this to the appropriate setting for the printer.

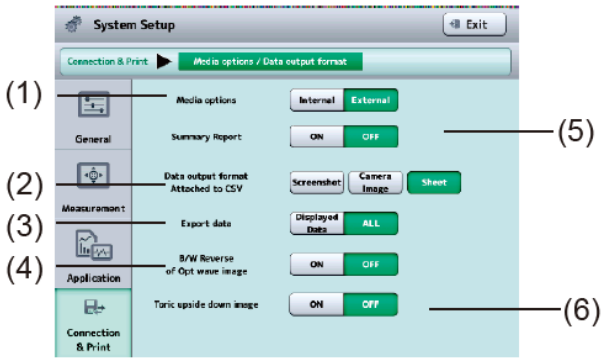
* Refer to “6.4 d) PC (PC connection)” for details of functions (1) to (5).

c) Media options / Data output format

Select the storage and set the output format. Touch the “Setting” button to open the System Setup screen (Fig. 2).



(Fig. 1)



(Fig. 2)

(1) Media options

Internal: Saves the data to the instrument’s built-in SD card. Max. capacity to be saved: 16 GB

External: Saves the data to an external USB flash memory connected to the instrument.

(2) Data output format

Screen shot: Outputs a captured image of the screen.

Camera image: Outputs a CCD image.

List Form: Outputs an image with measurement data.

(3) Export data

Displayed data: Exports only the displayed measurement data.

ALL: Exports all measurement data.

(4) B/W Reverse of Opt wave image

Selects whether to reverse a waveform image (black and white) to be exported to Data Transfer/Tomey Link. Select ON to display the waveform in black on the white background. Select OFF to display the waveform in white on the black background.

(5) Summary report

Defines output settings for the summary report.

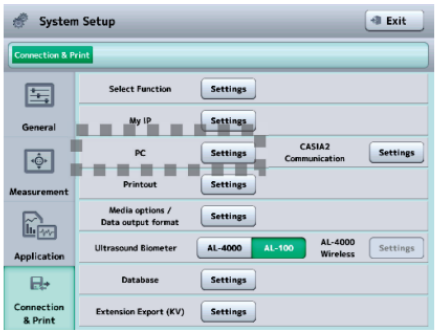
When “ON” is selected, the summary report is output regardless of the “Data output format” (2) and “Export data” (3) settings.

(6) Toric upside down image

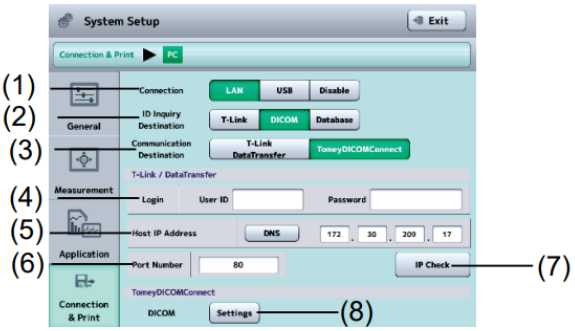
Select the top and bottom inversion of Toric images and form print images to Export on Data Transfer/Tomey Link. When “ON” is selected, the upward and downward views of Toric images are displayed.

d) PC (PC connection)

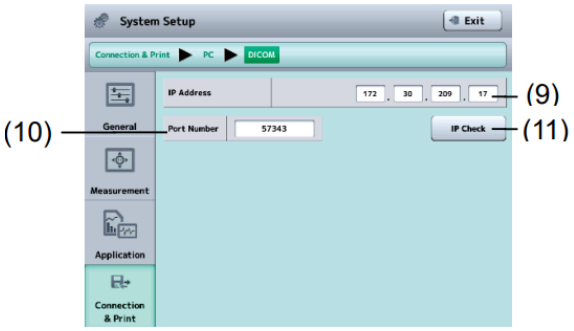
Make connection settings to export data to a personal computer with Data Transfer or DICOMConnect installed. Touch the “Setting” button to open the System Setup screen (Fig. 2).



(Fig. 1)



(Fig. 2)



(Fig. 3)

(1) Connection permission and selection of cable type

LAN: Use a LAN cable for connection. When “LAN” is selected here, all items listed on this screen need to be set.

USB: Use a USB cable for connection. Set the Login User ID and Password. Items other than the above do not need to be set.

Disable: Not connected to a PC.

(2) Auto Inquiry

Set the query destination of the patient ID.

(3) LAN communication destination

Set the LAN communication destination.

Select the communication destination according to the tool being used on the PC.

(4) Login TOMEY Link

Set the user ID and password to log in to the TOMEY Link. Maximum number of characters to be entered for the user ID or password is 16.

(5) Host IP address

Set the IP address of the PC to be connected. Touch the “DNS” button to specify the PC name. A DNS server must be running in the LAN environment to enable connection using the DNS.

Touch the input field to display the keyboard.

(6) Port number

A port number can be set.

Input range: 0 - 65535

Default setting: 80

(7) "IP Check" button

Performs a connection test.

(8) DICOM settings

Moves to the DICOM setup screen.

(9) SCP IP Address

Set the IP address of the server (SCP) configured for DICOM.

(10) Port number

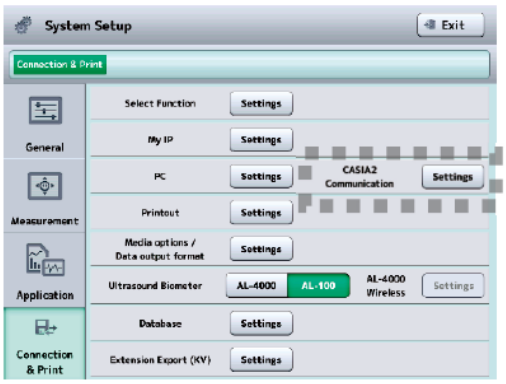
Set the port number used for DICOM communication.

(11) Connection Test button

Sends the message “C-ECHO-RQ” to the server (SCP) configured for DICOM. During DICOM communication, C-ECHO service is conducted to check connection between the server and terminal ends.

e) CASIA2 communication setting

Select the ultrasound biometer and make settings for wireless communication with the ultrasound measurement unit AL-4000. Connection can be established automatically upon startup of the instrument when the information of the AL-4000 to be connected is registered in the connection location list and “Permit” is selected for Wireless Communication.



(Fig.1)

(Fig.2)

(1) Port No.

Set the port number.

Range: 0 - 065535

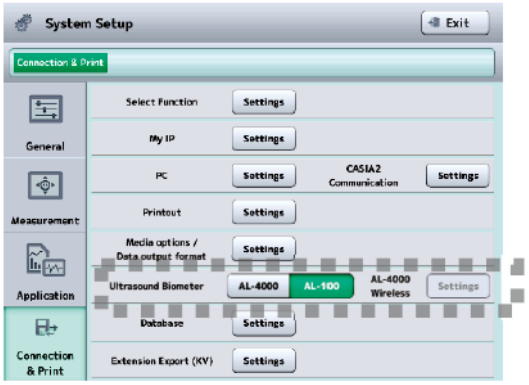
Default: 8080

f) AL-4000 wireless setting

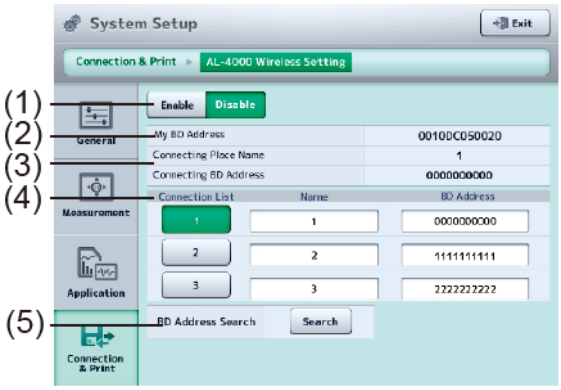
Select the ultrasound biometer and set for wireless communication with the ultrasound measurement unit AL-4000. Connection can be established automatically upon startup of the instrument when the information of the AL-4000 to be connected is registered in the connection location list and “Permit” is selected for Wireless Communication.

- While the System Setup screen is opened on a device during wireless communication with AL-4000, operation of the other device is disabled. Disable wireless communication and press the measurement button to open the System Setup screen on both devices at the same time.

Select the model of the ultrasound biometer. When AL-4000 is selected, settings for wireless communication can be made.



(Fig. 1)



(Fig. 2)

(1) Connection permission

Enable / Disable

(2) My BD Address

The BD address of this instrument is displayed.

(3) Connecting Place Name; Connecting BD Address

The connecting location name and BD address currently connected are displayed. These fields are blank when nothing is connected.

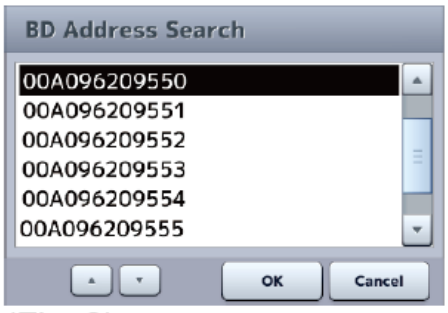
(4) Connection List

Register connecting locations. Touch the Name or BD Address field to open the keyboard. Select the number to set the item as the connecting location.

(5) BD Address Search

Touch the “Search” button to search for AL-4000 ultrasound measurement units in proximity to your device and display their BD addresses. (Fig. 3)

Touch the “OK” button to add the selected BD address to the Connection List.

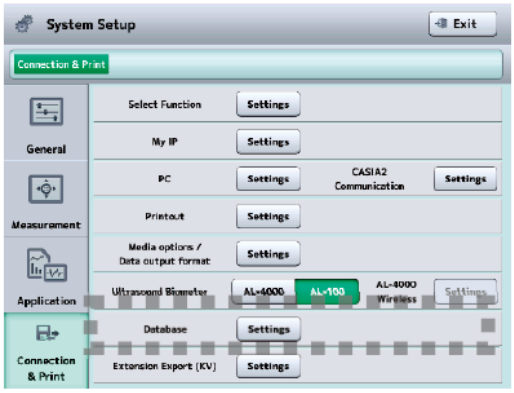


(Fig. 3)

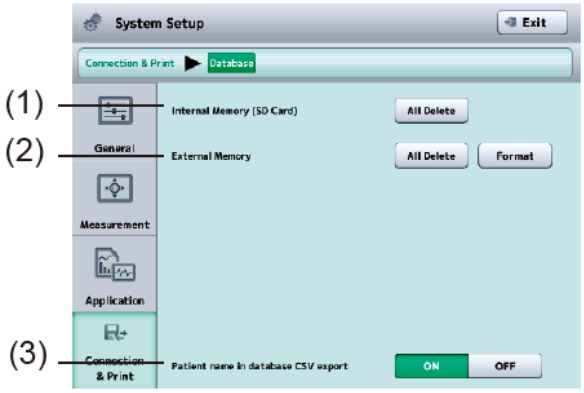
g) Database

Delete all data in the memory and initialize the memory.

Touch the “Setting” button to open the System Setup screen (Fig. 2).



(Fig. 1)



(Fig. 2)

(1) Internal Memory (SD Card)

All Delete

(2) External Memory

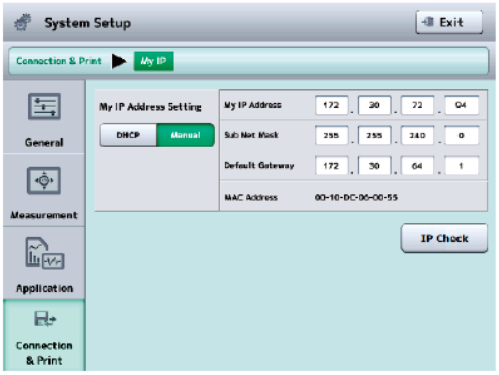
All Delete / Format

(3) Patient name in database CSV export

ON: The output of the patient's name is performed during CSV en bloc output.

OFF: Does not output the patient's name during CSV en bloc output.

h) My IP Address setting



(Fig. 1)

(1) My IP Address Setting

Selects either of DHCP (dynamic IP) or MANUAL (static IP) in the IP Setting Type. When "Manual" is selected, set My IP Address, Sub Net Mask, and Default Gateway.

(2) "IP Check" button

Performs a duplicate IP address check.

Setting Examples

When only this instrument and a computer running Data Transfer are connected to the network, the following settings can be used

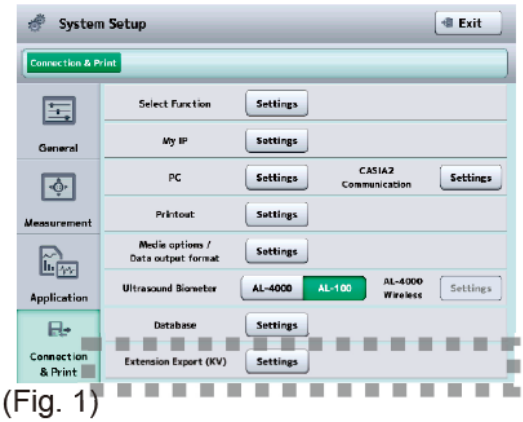
1) Check the computer IP address.
Check and record the IP address and subnet mask of the computer with DATA Transfer installed. Refer to the DATA Transfer operation manual for details.

2) Set settings on the Instrument
The settings shown in the table below describe an example when the IP address of the computer with DATA Transfer installed is "192.168.2.128" and the subnet mask is "255.255.255.0." The IP setting method in this case is "Manual."

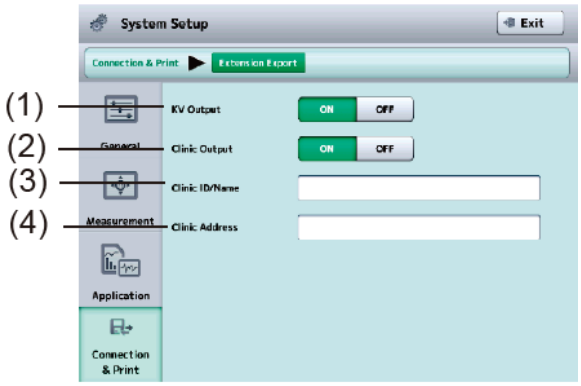
	Computer settings				Instrument (EM-4000) settings			
(Local) IP address	192	168	2	128	192	168	2	129
	Check these on the DATATransfer screen.				Same value as computer setting			(*1)
Subnet mask	255	255	255	0	255	255	255	0
	Check these on the DATATransfer screen.				Same value as computer setting			
Default gateway	---				0	0	0	0
					All "0"			
Host IP address	---				192	168	2	128
					IP address of computer			

*1: An arbitrary number from 1 to 255 excluding numbers used by the computer (128in this example)

i) Extension Export



(Fig. 1)



(Fig. 2)

(1) KV Output

ON: When the ultrasonic measurement data is output, the product information is also output.

OFF: Product information is not output at the same time when ultrasonic measurement data is output.

(2) Clinic Output

ON: Outputs clinic information.

OFF: Does not output clinic information

(3) Clinic ID/Name

Set the clinic ID and name.

(4) Clinic Address

Set the address of the clinic.

7. TECHNICAL INFORMATION

7.1 IOL power calculation formula

7.1.1 SRK/T formula

1. Implanted IOL power (D) for emmentropization

$$P_{emme} = \frac{1000na \cdot X}{(L1 - C1)Y}$$

2. Implanted IOL power (D) for ametropia

$$P_{amet} = \frac{1000na\{X - 0.001REF(V \cdot X + L1 \cdot r)\}}{(L1 - C1)\{Y - 0.001REF(V \cdot Y + C1 \cdot r)\}}$$

3. Predicted refractive power post-surgery (D)

$$REF_{iol} = \frac{1000na \cdot X - P \cdot Y(L1 - C1)}{na(V \cdot X + L1 \cdot r) - 0.001P(L1 - C1)(V \cdot Y + C1 \cdot r)}$$

Where:

X = na • r – L1 (nc – 1)

Y = na • r – C1 (nc – 1)

L1 : Visual axial length (mm)
= L + (0.65696-0.02029L)

L : Axial length (mm)

REF : Target Ref. post-surgery (D)

W : Calculated corneal diameter (mm)
= -5.41 + 0.58412LC + 0.098K

LC : Corrected axial length (mm)
L ≦ 24.2 → LC = L
L > 24.2 → LC = -3.446 + 1.716L - 0.0237L²

C1 : Estimated anterior chamber depth post-surgery (mm)
= H + Ofst.

Ofst :Calculated distance from the iris surface to the optical surface of the implanted IOL (including corneal thickness) (mm)
= ACD const – 3.336
= (0.62467A – 68.747) - 3.336

H : Height of cornea dome (mm)
$= r - \sqrt{r^2 - W^2/4}$

A : A-Constant

K : Average corneal refractive power (D)
= (K1 + K2)/2

r :Radius of corneal curvature (mm)
= {(KI - 1) × 1000}/K

KI : Cornea equivalent refractive index

P : Implanted IOL power (D)

V : Vertex distance (mm)
= 12

na : Aqueous humor and vitreous refractive index
= 1.336

nc : Corneal reflective index
= 1.333

4. Personal A-Constant

$$A = \left(-b + \sqrt{b^2 - 4ac}\right) / 2a$$

Where:

a : $0.62467^2\ \alpha$

b : $0.62467\ \{2\alpha\ (H - 72.083)\} + \beta\}$

c : $\alpha(H - 72.083)^2 + \beta(H\text{-}72.083) + r$

α : $P\ (1 - nc) + 0.001P \bullet AREF\ \{V\ (nc - 1) - r\}$

β : $P\ [na \cdot r + L1\ (nc - 1)$
$+ 0.001AREF\ \{L1 \cdot r + V \cdot L1\ (1 - nc) - na \cdot V \cdot r\}]$

r : $na\ [1000X - P \cdot L1 \cdot r + AREF$
$\{0.001P \cdot V \cdot L1 \cdot r - (V \cdot X + L1 \cdot r)\}]$

AREF : Refractive power of eye after surgery (D)

7.1.2 Holladay 1

1. Implanted IOL power (D)

$$P = \frac{1000na\{X - 0.001REF(V \cdot X + L2 \cdot r)\}}{(L2 - C2 - SF)[Y - 0.001REF\{V \cdot Y + r(C2 + SF)\}]}$$

2. Predicted refractive power post-surgery (D)

$$REF_{iol} = \frac{1000na \cdot X - P \cdot Q \cdot Y}{na(V \cdot X + L2 \cdot r) - 0.001P \cdot Q\{V \cdot Y + r(C2 + SF)\}}$$

Where:

X : na • r – L2 (nc – 1)

Y : na•r - (nc - 1)(C2 + SF)

Q : L2 – C2 -SF

na : Aqueous humor and vitreous refractive index
= 1.336

nc : Corneal reflective index
= 4/3

L : Axial length (mm)

K : Average corneal refractive power (D)
= (K1 + K2)/2

r : Radius of corneal curvature (mm)
= {(KI - 1) × 1000}/K

KI : Cornea equivalent refractive index

SF : Distance from the iris surface to the optical center of the implanted IOL (mm)

REF : Target Ref. post-surgery (D)

V : Vertex distance (mm)
= 12

P : Implanted IOL power (D)

L2 : Corrected axial length (mm)
= L + 0.2

C2 : Anatomic anterior chamber depth; distance from the corneal vertex to the iris surface (mm)
= 0.56 + Rag – $\sqrt{Rag^2 - AG^2/4}$
r < 7 → Rag = 7
r ≧ 7 → Rag = r
AG = 12.5L / 23.45
AG > 13.5 → AG = 13.5

3. Personal SF

$$SF = \{-BQ - \sqrt{BQ^2 - 4AQ \cdot CQ}\}/(2AQ) - C2$$

Where:

AQ = (nc-1) - 0.001AREF {V(nc - 1) - r}

BQ = 0.001AREF {L2•V(nc - 1) - r(L2 - V•na)}
- {L2(nc - 1) + na•r}

CQ1 = 0.001AREF[V{na•r - L2(nc - 1)} + L2•r]

CQ2 = 1000na{na•r – L2(nc - 1) - CQ1}/P

CQ3 = L2•na•r-0.001AREF•L2•V•r•na

CQ = CQ3-CQ2

AREF : Refractive power of eye post-surgery (D)

4. Corresponding SF

SF = 0.5663A - 65.60
or
SF = 0.9704 ACDcon – 3.595

Where:

A : A-Constant

7.1.3 Hoffer® Q formula

1. Implanted IOL power (D)

$$P = \frac{1336}{L - C - 0.05} - \frac{1.336}{\frac{1.336}{K + R} - \frac{C + 0.05}{1000}}$$

Where:

$$R = \frac{Rx}{1 - 0.012Rx}$$

2. Target Ref. post-surgery (D) when wearing glasses

$$Rx = \frac{R}{1 + 0.012R}$$

Where:

$$R = \frac{1.336}{\frac{1.336}{\frac{1336}{L - C - 0.05} - P} + \frac{C + 0.05}{1000}} - K$$

C : Predicted anterior chamber depth post-surgery (ACD)
= X + Y

Where:

$X = C1 + 0.3 \times (L - 23.5) + (\tan K)^2$

$Y = 0.1M \times (23.5 - L)^2 \times \tan\{0.1(G - L)^2\}$ - 0.99166

L ≦ 23.0 → M = + 1, G = 28

L > 23.0 → M = - 1, G = 23.5

L > 31.0 → L = 31

L < 18.5 → L = 18.5

P : Implanted IOL power (D)

L : Axial length (mm)

C1 : ACDcon or Personal ACD (mm)

K : Average corneal refractive power (D)
= (K1 + K2)/2

r : Radius of corneal curvature (mm)
= {(KI - 1) × 1000}/K

KI : Cornea equivalent refractive index

Rx : Target Ref. post-surgery (D) when wearing glasses

3. Personal ACD

$$ACD = \frac{L + N - \sqrt{(L - N)^2 + \frac{4 \cdot 1336(N - L)}{P}}}{2} - 0.05$$

Where:

$$N = \frac{1336}{K + R} \qquad R = \frac{AREF}{1 - 0.012AREF}$$

AREF : Refractive power of eye post-surgery (D)

7.1.4 Haigis Standard / Haigis optimized

1. Implanted IOL power (D)

$$P = \frac{1000na}{L-d} - \frac{na}{\frac{na}{z} - \frac{d}{1000}}$$

Where:

$$Z = DC + \frac{REF}{1 - \frac{REF \cdot V}{1000}}$$

d = a0 + a1·ACD + a2·L (ACD ≠ 0)
d =(a0 – 0.241·a1) + (a2 + 0.139·a1)L (ACD = 0)
a0 = 0.62467A – 72.434….*

$$DC = \frac{1000(nc-1)}{RC}$$

2. Estimated refractive power post-surgery (D)

$$REF_{iol} = \frac{1000(1000Y - DC \cdot X)}{V(1000Y - DC \cdot X) + 1000X}$$

Where:

$X = d^2 \cdot P + 1000L \cdot na - d \cdot L \cdot P$

$Y = na\,(1000 \cdot na - L \cdot P + d \cdot P)$

na	: Aqueous humor and vitreous refractive index
	= 1.336
nc	: Corneal reflective index
	= 1.3315
A	: A-Constant
RC	: Average radius of corneal curvature (mm)
	= (r1 + r2)/2
R	: Radius of corneal curvature (mm)
	= {(KI - 1) × 1000}/K
K	: Corneal refractive power (D)
KI	: Cornea equivalent refractive index
DC	: Average corneal refractive power (D)
L	: Axial length
ACD	: Anterior chamber depth (mm)
REF	: Target Ref. post-surgery (D)
V	: Vertex distance (mm)
	= 12
P	: Implanted IOL power (D)
a1	: 0.4…※
a2	: 0.1…※

* The Haigis optimized formula uses the registered a0, a1, and a2 for calculation.

3. Personal A-Constant

$$A = \frac{d - a1 \cdot ACD - a2 \cdot L + 72.434}{0.62467} \quad \text{(ACD≠0)}$$

$$A = \frac{d - L(a2 + 0.139 \cdot a1) + 0.241 \cdot a1 + 72.434}{0.62467} \quad \text{(ACD=0)}$$

Where:

$$d = \frac{P(L \cdot z + 1000na) - \sqrt{P^2(L \cdot z + 1000na)^2 - 4P \cdot z(1000L \cdot na \cdot z + 1000L \cdot na \cdot P - 1000^2 \cdot na^2)}}{2P \cdot z}$$

$$Z = DC + \frac{AREF}{1 - \frac{AREF \cdot V}{1000}}$$

$$DC = \frac{1000(nc-1)}{r}$$

AREF : Refractive power of eye post-surgery (D)

7.1.5 SRK/T Double K

1. Implanted IOL power (D) for emmentropization

$$P_{emme} = \frac{1000na \cdot X}{(L1 - C1)Y}$$

2. Implanted IOL power (D) for ametropia

$$P_{amet} = \frac{1000na\{X - 0.001REF(V \cdot X + L1 \cdot r_{post})\}}{(L1 - C1)\{Y - 0.001REF(V \cdot Y + C1 \cdot r_{post})\}}$$

3. Predicted refractive power post-surgery (D)

$$REF_{iol} = \frac{1000na \cdot X - P \cdot Y(L1 - C1)}{na(V \cdot X + L1 \cdot r_{post}) - 0.001P(L1 - C1)(V \cdot Y + C1 \cdot r_{post})}$$

Where:

$X = na \cdot r_{post} - L1\ (nc - 1)$

$Y = na \cdot r_{post} - C1\ (nc - 1)$

L1 : Visual axial length (mm)
= L + (0.65696-0.02029L)

L : Axial length (mm)

C1 : Estimated anterior chamber depth post-surgery (mm)
= H + Ofst.

Ofst : Calculated distance from the iris surface to the optical surface of the implanted IOL (including corneal thickness) (mm)
= ACD const – 3.336
= (0.62467A – 68.747) - 3.336

H : Height of cornea dome (mm)
$= r_{pre} - \sqrt{r_{pre}^2 - W^2/4}$

W : Calculated corneal diameter (mm)
= -5.41 + 0.58412LC + 0.098K_{pre}

LC : Corrected axial length (mm)
L ≦ 24.2 → LC = L
L > 24.2 → LC = -3.446 + 1.716L - 0.0237L^2

A : A-Constant

K_{pre} : Average corneal refractive power (D) before refractive correction surgery
= $(K1_{pre} + K2_{pre})/2$

r_{pre} : Radius of corneal curvature (mm) before refractive correction surgery
= $\{(KI - 1) \times 1000\}/ K_{pre}$

KI : Cornea equivalent refractive index

K_{post} : Average corneal refractive power (D) after refractive correction surgery
= $(K1_{post} + K2_{post})/2$

r_{post} : Radius of corneal curvature (mm) after refractive correction surgery
= $\{(KI - 1) \times 1000\}/ K_{post}$

P : Implanted IOL power (D)

na : Aqueous humor and vitreous refractive index
= 1.336

nc : Corneal reflective index
= 1.333

REF : Target Ref. post-surgery (D)

V : Vertex distance (mm)
= 12

4. Personal A-Constant

$$A = \left(-b + \sqrt{b^2 - 4ac}\right)/ 2a$$

Where:

a : $0.62467^2\alpha$

b : $0.62467 \{2\alpha(H - 72.083)\} + \beta\}$

c : $\alpha(H - 72.083)^2 + \beta(H-72.083) + r$

α : $P (1 - nc) + 0.001P \cdot AREF \{V (nc - 1) - r\}$

β : $P [na \cdot r + L1 (nc - 1)$
$+0.001AREF \{L1 \cdot r+V \cdot L1(1-nc)-na \cdot V \cdot r\}]$

r : $na [1000X - P \cdot L1 \cdot r + AREF$
$\{0.001P \cdot V \cdot L1 \cdot r - (V \cdot X + L1 \cdot r)\}]$

AREF : Refractive power of eye post-surgery (D)

7.1.6 Shammas-PL formula

1. Implanted IOL power (D) for emmentropization

$$P_{emme} = \frac{1336}{L - 0.1(L-23) - (C+0.05)} - \frac{1}{\frac{1.0125}{Kc} - \frac{C+0.05}{1336}}$$

2. Implanted IOL power (D) for ametropia

$$P_{amet} = \frac{1336}{L - 0.1(L-23) - (C+0.05)} - \frac{1}{\frac{1.0125}{Kc + REFc} - \frac{C+0.05}{1336}}$$

3. Predicted refractive power post-surgery (D)

$$REFciol = \frac{1.0125 \times 1336\left[1336 - P\{Lc - (C+0.05)\}\right]}{1336 \cdot Lc - P(C+0.05)\{Lc - (C+0.05)\}} - Kc$$

L : Axial length (mm)

C = pACD = (0.5835 × A) - 64.40

A : A-Constant

Kc = 1.14 × K - 6.8

K : Average corneal refractive power (D)

= (K1 + K2)/2

R : Radius of corneal curvature (mm)

= {(KI - 1) × 1000}/K

KI : Cornea equivalent refractive index

REFc : Refractive power at corneal refractive surface

$$= \frac{1000}{\frac{1000}{REF} - VD}$$

REF : Target Ref. post-surgery (D)

P : Implanted IOL power (D)

Lc = L-0.1(L-23)

VD : Vertex distance (mm)

= 12

4. Personal A-Constant

$$A = \frac{1}{0.5835}\left[\frac{1336 \cdot a}{2} + \frac{Lc}{2} - \frac{1336}{2}\sqrt{\left(a + \frac{Lc}{1336}\right)^2 - \frac{4}{1336}\left\{Lc\left(a + \frac{1}{P}\right) - \frac{1336 \cdot a}{P}\right\}} - 0.05 + 64.4\right]$$

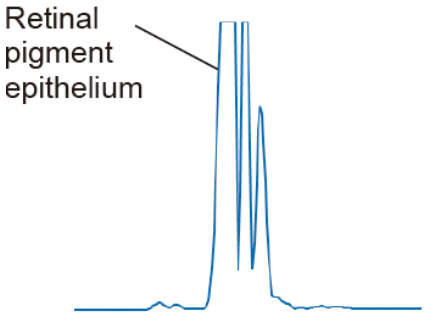
$$a = \frac{1.0125}{Kc + AREFc}$$

AREFc: Eye refractive power at corneal refractive surface

$$= \frac{1000}{\frac{1000}{AREF} - VD}$$

AREF: Eye refractive power post-surgery (D)

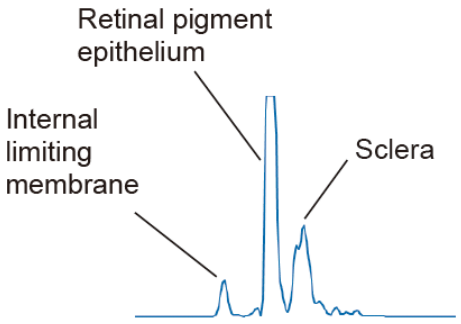
7.2 Verification when measuring axial length



(Fig.1) Retina waveform example 1

OA-2000 measures the distance from the lacrimal fluid on the corneal surface to the retinal pigment epithelium (RPE) as the axial length. Normally, the waveform height and width of the internal limiting membrane and choroid are smaller than those of the retinal pigment epithelium. (Fig. 1)

Reflection from the internal limiting membrane (ILM) may be received depending on the condition of the retina. (Fig. 2)



(Fig.2) Retina waveform example 2

If the waveform of the internal limiting membrane is larger than that of the retinal pigment epithelium, the resultant axial length may be shortened by 0.15 – 0.35 mm.

If values of the axial length are varied or individual waveforms seem to show that the retinal pigment epithelium was not correctly captured, thoroughly evaluate the measurement data, referring to the following points.

- Take measurement again.
- Compare the data with the measurement taken in ultrasound A mode.
- Check for the presence of ocular fundus diseases.

7.3 Ultrasound conversion formula

The axial length measurement displayed in Contact mode or Immersion mode of the OA-2000 is the value calculated by converting the optically obtained axial length to an ultrasound axial length value, using a correction formula developed based on clinical results. Therefore, the converted ultrasound axial length value includes measurement errors due to the difference between the optical measurement principle/method and ultrasound measurement principle/method.

- Formula for conversion to ultrasound axial length in Contact mode

  AXIAL(Contact) = {OptLength － 1.4687} / 0.9581

  When {OptLength - AXIAL(Contact)} ≧ 0.75mm

  AXIAL(Contact) = OptLength － 0.75

- Formula for conversion to ultrasound axial length in Immersion mode

  AXIAL(Immersion) = {OptLength － 1.3304} / 0.9573

  OptLength = OPL/Naxl

  OPL: Optical path length

  Naxl: Average refractive index of eye

Difference between optical and ultrasound measurement principles/methods

- Retina thickness

  The thickness from the corneal epithelium to the retinal pigment epithelium is measured by the optical method, while the thickness from the corneal epithelium to the internal limiting membrane is measured by the ultrasound method. Therefore, the retina thickness and axial length measured by the optical method become longer than the values measured by the ultrasound method.

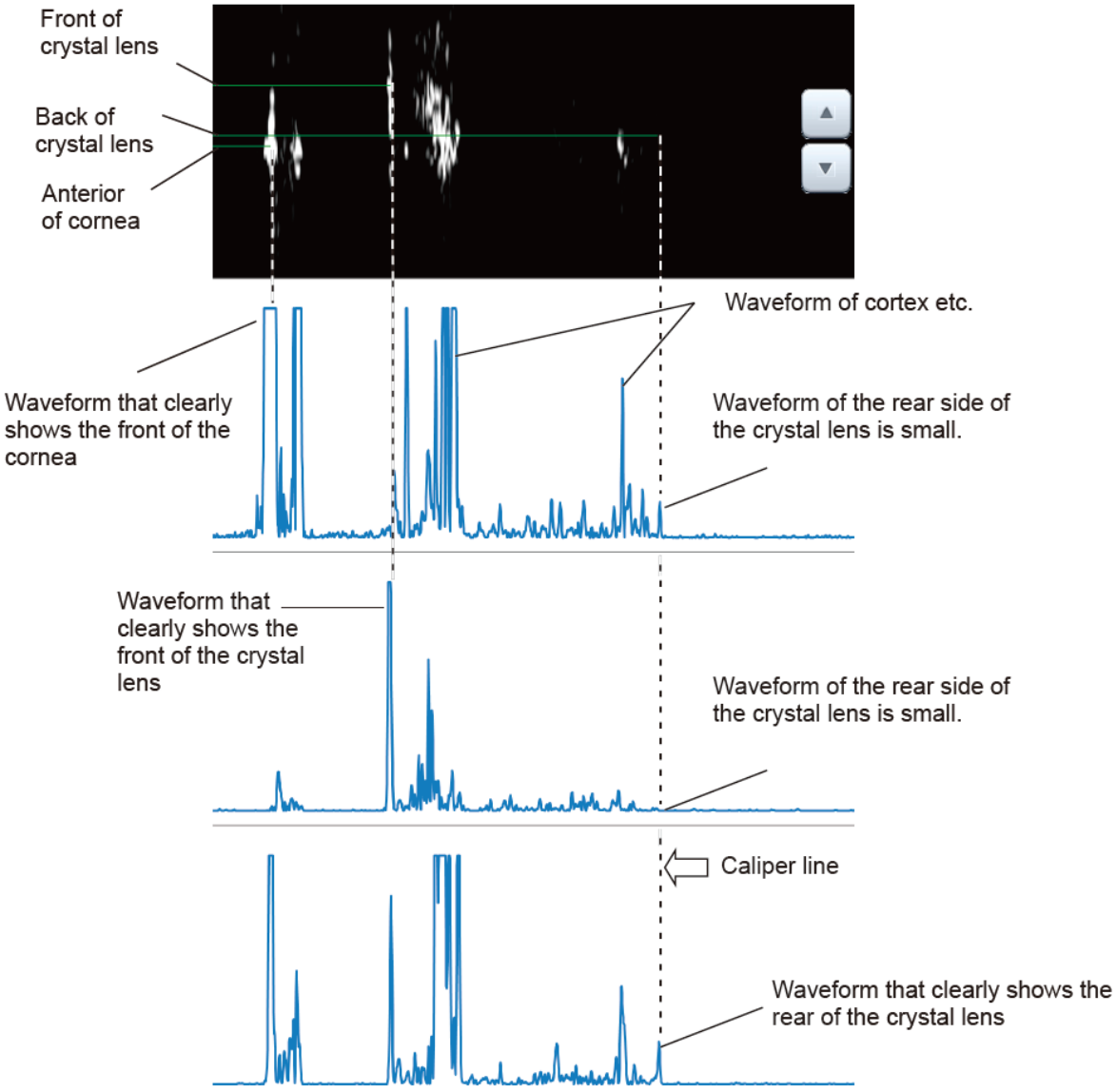
- Pressure on retina

  The optical method performs non-contact measurement, but the probe contacts the retina directly or indirectly. Therefore, the axial length measured by the ultrasound method tends to be shorter due to pressure on the retina.

- Measurement axis

  Since the optical method requires fixing the patient's sight to the light source, a stable visual axis can be captured during measurement. On the other hand, although the fixation light is used for the ultrasound method, the optic axis where the reflection of the retina waveform becomes the strongest is captured during actual measurement.

7.4 Verification when measuring anterior chamber depth and crystalline lens thickness



Since there are many waveforms of the cortex etc. of the crystalline lens when measuring an eye with cataracts, the front and rear of the crystalline lens may not be captured.
In this case, adjust the waveform display line on the scanned image up and down, find and display the position where the largest waveforms are shown, and move the caliper line to the point of the front of the crystalline lens.

7.5 Corneal irregular astigmatism index

Corneal irregular astigmatism index

This is the index that simply quantitates the data of the corneal irregular astigmatism which cannot be found by ordinary keratometer measurements (K1, K2, and AX) according the keratometory image. There are 2 indices (KAI and KRI) as shown below, and each of them shows the level of irregular astigmatism.

KAI (Kerato-Asymmetry Index)

One of the corneal irregular astigmatism indices which shows asymmetry of the cornea. This index is calculated from the discrepancy between the center of the approximate ellipse of the keratometer measurement point and the XY alignment measurement point equivalent to the corneal vertex position. The value increases for asymmetrical corneal shape such as when a part of the cornea protrudes like keratoconus.

KRI (Kerato-Regularity Index)

One of the corneal irregular astigmatism indices that indicates the regularity (irregularity) of the cornea. This index is calculated from the discrepancy between the keratometer measurement point and its approximate ellipse. The value increases when the corneal shape is irregular such as in eyes with corneal transplantation or CL-induced problems.

8. TROUBLESHOOTING

Check the following first when you encounter any problems.
If the problem is not solved even after checking the applicable item listed below, contact your local distributor to request inspection and/or repair.

Do not remove the cover of the instrument. You may be directly exposed to high voltage sections.

Do not take any actions other than those specified below.

8.1 Common items

- The instrument does not start when the power switch is turned on.

Cause1: Problem with the power plug

1) Check that the power plug is firmly connected to the outlet. Check that there are no flaws in the power cord, such as cracks or tears.

Cause2: Problem with the power outlet.

2) Check that power is supplied to the outlet to which the power cord is connected.

Cause3: Faulty fuse

3) Check that fuses are not blown. If blown, replace the fuse (refer to "8.2.1 Fuses"). When the new fuse is blown again, the instrument may be out of order. Contact your local distributor to request inspection and/or repair.

- Nothing appears on the monitor screen.

Cause1: The auto power off function, which automatically turns off the screen when the instrument is not operated for the specified time, has been activated.

1) Touch the Monitor screen.

Cause2: The maintenance switch on the side is in the P (up) position.

2) Turned off the power, return the maintenance switch to the lower position, and then turn on the power.

- The whole monitor screen is dark and not easy to see.

Cause1: The brightness of the monitor is low.

1) Adjust the brightness of the screen using the brightness setting of the screen described in "6.1 General".

- The clock displayed has stopped.

Cause1: Stored data is displayed.

1) While displaying stored data, the date and time of measurement of the data is shown. When closing the screen, the current time is displayed.

- The data cannot be printed by the video printer.

Cause1: Printer paper

1) Check for the remaining printer paper. Verify that printer paper is correctly set as described in the instruction manual of the video printer.

Cause2: USB cable

2) Verify that the USB cable is correctly connected to the main unit and the video printer. For correct connection, refer to "2.1.1 Connections for accessory".

Cause3: Setting the output printer

3) Set "Video Monochrome" to select a monochrome printer as the output destination when pressing the PRINT button; set “Video Color” when the output destination is a color printer. Refer to “6.4 b) Selecting and setting printer” for setting details.

- The brightness and color of printouts from the video printer are remarkably different from that of the screen display.

Cause1: Setting of the video printer is not appropriate.

1) Adjust the contrast, brightness, and color as described in the instruction manual of the video printer.

- The data cannot be printed by the built-in printer.

Cause1: Printer paper

1) Check for the remaining printer paper. Verify that printer paper is set correctly as described in "8.2.2 Printer paper".

Cause2: Setting the output printer

2) Set "built-in printer" to the destination to which output is directed when "Print button" is pushed. Refer to “6.4 b) Selecting and setting printer” for setting details.

Cause3: The printer cover is open

3) Check that the printer cover is completely closed.

Cause4: The printer paper is not set in the correct direction.

4) Check that the printer paper is set correctly. (Refer to "8.2.2 Printer paper").

- A different button to the one touched on the touch panel becomes active.

Cause1: The touch panel is not calibrated correctly.

1) Turn on the power, touching the touch panel. When startup of the instrument is completed while your finger is in contact with the touch panel, calibration of the touch panel will complete.

- An error message “Connect the USB cable again” appears and measurement cannot be performed.

Cause1: The USB cable that connects AL-4000 and this instrument is disconnected.

1) Connect the USB cable again. Communication is resumed and measurement can be started.

- Nothing is displayed on the screen of this instrument when inputting IDs in the external ID input device.

Cause1: USB cable

1) Verify that the USB cable of the external ID input instrument is correctly connected to the main unit. For correct connection, refer to "2.1.1 Connections for accessory".

Cause2: A screen which does not receive an ID input appears.

2) Entry of ID from an external ID input instrument is accepted only on a screen where the patient information is displayed. Input ID only when this screen is displayed.

- Data cannot be saved in the internal memory.

Cause1: The ID is not entered

1) The instrument uses the ID as a file name. Enter the ID and then save the data.

Cause2: There is not enough space available in the internal memory. (The confirmation screen appears when attempting to save the data.).

2) Delete unnecessary data in the internal memory and save the data again.

Cause3: An external memory is not connected even though the storage is set to an external memory.

3) Connect an external memory. Or, change the storage to the internal memory.

- The message “Internal error occurred” is displayed and measurement cannot be performed.

Cause1: The SD card is not inserted properly.

1) Remove the SD card and insert it again.

Cause2: A problem has occured in the instrument.

2) Reboot the instrument. If the error message is displayed again, contact your local distributer, and inform them of the error number.

8.2 Optical measurement

- Measurement cannot be performed. Stable measurements cannot be obtained. Measurements are largely different from those taken before.

Cause1: The measurement window is dirty.

1) Check that the measurement window is clean.

Cause2: A problem has occurred in the instrument.

2) Contact your local distributor.

Cause3: The system is not correctly calibrated.

3) Calibrate the system. (Refer to “3.1 Optical measurement mode”)

8.3 Ultrasound measurement

- Measurement cannot be performed in Auto mode.

Cause1: The mode is set to Manual.

1) Set to auto measurement (Auto or Auto quick). (Refer to "3.2.1 Setting measurement conditions").

Cause2: Noise is generated in the peripheral area.

2) If there is any source of noise (devices such as a motor, laser surgical equipment, etc.) near the instrument, move it away from the instrument.

Cause3: Patient's sight is unstable.

3) Use the fixlight in the biometry probe or on the chin rest to guide the sight of the patient.

Cause4: The contact section of the biometry probe is damaged.

4) If damaged, immediately stop measurement and contact your local distributor.

- Measurement cannot be performed in Manual mode.

Cause1: The mode is set to auto measurement (Auto or Auto quick).

1) Set to Manual mode. (Refer to "3.2.1 Setting measurement conditions").

- Measurements are unstable or inappropriate.

Cause1: The converted acoustic velocity is not set appropriately.

1) Check the setting of the converted acoustic velocity. A different converted acoustic velocity can be set for right and left eyes. Check the setting for both eyes.

Cause2: The retina waveform gate cursor is not set in an appropriate position

2) Set the retina waveform gate cursor on the immediate left of the actual retina waveform. Make sure that there are no unnecessary waveforms between the retina gate cursor and retina waveform.

- Monitoring sound does not go off.

Cause1: The volume is set to "Mute (Off)" for the AL-4000 measuring unit.

1) Set the volume to a level other than “Mute (Off)” as described in the Operation Guid for the AL-4000 measuring unit.

- Noise interferes with waveforms.

Cause1: Noise is generated in the peripheral area.

1) If there is any source of noise (devices such as a motor, laser surgical equipment, etc.) near the instrument, move it away from the instrument.

9. CONSUMABLES AND OPTIONAL EQUIPMENT

The following spare parts and accessories are available from your local distributor of this instrument.
Contact your local distributor to order them.

- Printer paper
  Specify the paper type as "Built-in printer paper for OA-2000 (58 mm)."

- Chin rest paper (100 sheets/set)

- Fuse
  Specify the fuse type as "Fuse for OA-2000."

（End of Document）