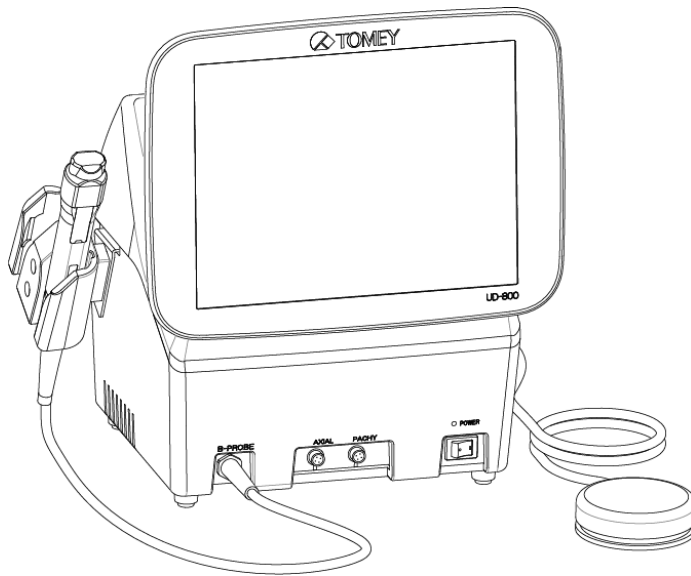


INSTRUCTION MANUAL

ULTRASONIC A/B SCANNER
AND PACHYMETER

UD-800



Read this manual thoroughly before using the instrument to ensure proper and safe operation.

Contact Tomey Corporation or your local distributor if you have any questions or you encounter any problems during operation.

Note

- *Always follow the operation procedures described in this manual.*
- *Keep this manual in a readily accessible location while operating the instrument.*
- *Contact your local distributor if you lose this manual.*



i. Important safety information



- *Do not install this instrument in a location where explosives or flammable substances are used or stored. Otherwise, fire or explosion may occur.*
- *Do not remove the cover of the instrument. Otherwise electric shock may result.*
- *Do not disassemble or modify the instrument. Otherwise electric shock may result.*



- *Disconnect the power cord from all the connected devices before installing and/or servicing the instrument. Otherwise, electric shock may result.*
- *Sterilize probes and the eye cup before use.*
- *Do not use probes and the eye cup with its contact section damaged. Measurement error may occur, as well as the cornea or eyelid may be injured.*
- *Do not commence service or maintenance work while the instrument is being used for a patient.*



- *Do not place water or chemicals on the instrument. Any water or chemicals entering the instrument may cause electric shock or failure.*
- *Do not allow water or chemicals to splash on probes, except for the tip cap. Any water or chemicals entering the instrument may cause electric shock or failure.*
- *Use only the specified data terminal for connection of the instrument. Using another type of terminal may result in failure of the instrument.*
- *This instrument is a diagnostic/measuring device specially designed for ophthalmology. Never use the instrument for other purposes.*
- *The terminal for connecting the instrument to external devices is not isolated from the internal circuit. Inappropriate wiring may damage the internal circuit. Never touch any of these terminals and the patient at the same time. Be sure to contact Tomey or your local distributor before using the external output terminal.*
- *When operating this instrument connected to other devices, use only devices that satisfy IEC60601-1 or equivalent safety requirements, or that conform to IEC60950 and whose power source is isolated with an isolation transformer, in order to satisfy the relevant safety requirements for medical equipment.*

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ii. How to read this manual

Outline

This manual is structured as follows.

1. PRIOR TO USE

Describes safety precautions and important information to be understood before installing and using the instrument.

2. NAMES AND FUNCTIONS

Describes names and functions of each section of the instrument.

3. OPERATION PROCEDURES

Describes information required for installing and using the instrument.

4. TECHNICAL INFORMATION

Describes useful technical information about the instrument.

5. INSPECTION AND MAINTENANCE

Describes procedures for replacing consumable parts, etc. that the user of the instrument should normally conduct.

6. TROUBLESHOOTING

Describes how to solve problems.

7. CONSUMABLES AND OPTIONAL EQUIPMENT

Describes consumable parts and optional equipment.

8. SPECIFICATIONS

Describes the specifications of the instrument.

Symbols used in this manual

Sentences accompanied with the symbols below indicate the following:



- *This is a precaution that, if unheeded, will result in a hazardous situation where there is an imminent danger of serious injury or death.*



- *This is a precaution that, if unheeded, could result in a hazardous situation where there is a possibility of serious injury or death.*



- *This is a precaution that, if unheeded, may result in a situation where there is a possibility of minor or moderate injury or damage to property.*



- *This is an additional instruction which may contain a special precaution on company policy related, either directly or indirectly, to the safety of personnel or to the protection of property.*

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1. PRIOR TO USE

Note

- *Read this manual thoroughly before using this instrument to ensure proper and safe operation.*
- *Always follow the operation procedures described in this manual.*
- *Check that there are no devices that generate a strong magnetic field near the instrument. A strong magnetic field may cause noise and affect measurement.*
- *Do not place any other objects on this instrument.*

1.1 Precautions for operation

- *Allow only qualified operators to use the instrument.*
- *When using the IOL calculation result to select intraocular lenses, also thoroughly examine cataract surgery methods and other inspections to determine the selection.*
- *The ultrasound images may contain artifacts. If the image is doubtful, consider other examinations to carefully determine whether to adopt the value.*
- *Precautions when installing the instrument and accessories*



- *Install the instrument in a location free of water or chemicals. Any water or chemicals entering the instrument or devices may cause electric shock or failure.*
- *Do not install the instrument in a location where chemicals are stored or gases may occur. Any chemicals or vapor entering the devices may result in fire.*
- *Check the frequency, voltage, and allowable current (or power consumption) of the power source. Otherwise, fire or electric shock may occur.*
- *Connect the power plug to a grounded 3-pin outlet. Otherwise, a short circuit due to failure of the instrument may result in electric shock.*
- *Do not place any heavy object on the power cord or squash the power cord. Fire or electric shock may occur.*

-
- *Fully insert the power plug into the outlet. Faulty contact, allowing any metal to contact the exposed terminal of the plug, or dust accumulated on the exposed terminal of the plug may result in fire or electric shock.*
 - *Conduct grounding work correctly. Otherwise, you may get electric shock.*
 - *Do not connect a device with data transmission specifications that are not compatible. Fire or electric shock may occur. Contact Tomey Corporation or your local distributor before using the instrument while connected to another device.*
 - *If there is a problem with the instrument, turn off the power switch and disconnect the power plug. Install the instrument in a place where this can be performed smoothly.*
 - *Install the instrument in a location not subject to direct sunlight, high temperature and humidity, or air containing dust, salt, and/or sulfur. Otherwise, failure or malfunction may occur.*
 - *Install the instrument in a leveled stable location free of vibration or mechanical impact. Otherwise, measurement cannot be conducted correctly. Also, the instrument may topple or fall, resulting in fire or a serious accident.*
 - *Install the instrument in a location with ample clearance from other devices to allow smooth inspection.*



■ **Precautions during operation**



- *Do not allow water or chemicals to splash onto the B mode probe, except for the tip cap. Any water or chemicals entering the instrument may cause electric shock or failure.*

■ **Precautions before operation**



- *Check the electrical contact of switches, polarity, dial setting, and meters, and that the instrument is working correctly.*
- *Check that all cables are connected correctly.*
- *Since simultaneous use of multiple devices can cause misdiagnosis or result in a hazardous situation, exercise caution when using this instrument.*
- *Check the sections that the patient will directly touch.*
- *Check that the instrument is correctly grounded.*
- *Check that the date set in the instrument conforms to the actual operation date and time.*

■ Precautions during operation



- Do not place any container with liquid in it on the instrument. Any liquid entering the instrument may cause electric shock or failure.
- Do not allow the patient to touch the terminals for connecting the instrument to external devices.



- Do not lean on the instrument or press the instrument from the top. The instrument may topple over, resulting in mechanical failure or injuries.
- Be extremely careful not to take too much time or too many measurements, as this can stress the patient.
- Constantly observe that both the instrument and patient are free of problems.
- If a problem with the instrument or the patient occurs, take appropriate action, such as stopping the device, to ensure the patient's safety.
- Do not allow the patient to touch the instrument.
- If any smoke, offensive odor, or abnormal sound occurs, turn off the instrument immediately, disconnect the power plug from the outlet, and contact your local distributor or Tomey Corporation.

■ Precautions after operation



- Do not place any container with liquid in it on the instrument. Any liquid entering the instrument may cause electric shock or failure.



- Do not use organic solvents such as thinner, benzene, or acetone to clean the instrument. Fire or electric shock may occur. (These solvents may also corrode the resin or coating on the cover of the instrument.)
- Follow the specified procedures to return the operation switch, dial, etc. to their original positions and turn the instrument off.
- Hold the plug when disconnecting the power plug from the outlet to avoid placing excessive force on the cord. Pulling the cord may damage the inner core wires, resulting in electric shock or fire.
- When disconnecting cords, do not apply too much force to them, for example, do not hold and pull the cord.
- Refer to "5.6 Storing" for instructions on the storage of the instrument.
- Clean the instrument at the end of operation in preparation for the next use.

-
- *Clean and neatly arrange the accessories and cables.*

■ ***If any failure occurs in the instrument, immediately stop operation, indicate the failure in the instrument, and contact your local distributor for repairs.***



- *Do not modify the instrument. Doing so may cause electric shock or failure of the instrument. There is a high-voltage section in the instrument. Touching this section will result in death or serious injuries.*
- *Disconnect the power cord from the outlet when replacing fuses. Otherwise, you may get electric shock, resulting in death or serious injuries.*



- *Use the power cord and fuses provided with the instrument or specified by Tomey to ensure safety. Also, do not use the accessories provided with the instrument for other equipment.*



- *Conduct regular inspections of the instrument and components.*
- *When any instrument failure occurs, indicate the failure, and contact your local distributor to request inspection and repair. Do not attempt to repair the instrument yourself.*
- *When the instrument has not been in use for 1 month or longer, check that the instrument is operating correctly and safely before starting operation. Refer to "5.3 Inspection" in this manual for the relevant procedures.*

1.2 Checking package contents

Open the package and check that the required quantity of the following items is included and they are not damaged. If any item is missing or damaged, contact your local distributor as soon as possible.

Note ■ *Keep the box and packing materials for use when moving or transporting the instrument.*

■ *When taking the instrument out of the box, pull the outer box upward and then remove the packing materials. Be careful not to lift the instrument up by directly holding the head, chin rest, forehead pad, joystick, or cables. The instrument may be damaged.*

- Main unit
- 10MHz B probe 1
- Power code 1
- Foot switch 1
- Printer paper 1
- Ultrasound gel 1
- Fuse 4
- (Two are included as accessories)
- Dust cover 1
- Instruction manual (this manual) 1
- DATA Transfer installation CD 1
- DATA Transfer startup guide 1

1.3 Glossary

[ACD]	: Anterior chamber measurement
[Acrylic]	: Acrylic lens
[Aphakic]	: Aphakic eye
[AVG]	: Average value
[Axial]	: Axial length measurement
[B-Mode]	: B mode image diagnosis
[Calibration]	: Calibration of B mode probes and pachymetry probes
[CCT]	: Corneal center thickness
[Contact]	: Method of taking measurements by directly applying the contact section of the biometry probe to the center of the cornea
[Clinical History Method]	: Method of calculating the corneal refractive power before refractive correction surgery. This is used together with the Double K Method.
[D]	: Diopter. The unit of refractive power representing the level of myopia, hyperopia, or astigmatism. Reciprocal of the focal length measured in meters.
[DATA Transfer]	: System to output the examination data created by TOMEY products as a file
[Export]	: To send measurement data to DATA Transfer or Tomey Link.
[FREEZE]	: Status where ultrasound waves are not transmitted
[Immersion]	: Measurement mode when applying cornea protective agent between the contact section of the axial length probe and the cornea.
[IOL]	: Intraocular lens
[K1]	: Radius of corneal curvature of minor meridian [mm or D]
[K2]	: Radius of corneal curvature of major meridian [mm or D]
[Obj.]	: Section to be measured
[Pachy]	: Measurement of corneal thickness
[Pre]	: Before refractive power correction surgery
[Phakic]	: Phakic eye

[PL]	: Abbreviation of POST LASIK
[PMMA]	: PMMA lens
[Post]	: After refractive power correction surgery
[Ref.]	: Reference section
[Silicone]	: Silicone lens
[SNR]	: S/N (signal to noise) ratio A larger value represents less noise, meaning higher quality signals can be obtained.
[TOMEY Link]	: Digital medical record system to manage data measured with Tomey products
[VD] (Vertex distance)	: Distance between corneal vertexes [mm] Represents the distance between the corneal vertex and the posterior surface of the lenses to be prescribed. When (VD=CL), vertex distance is calculated as 0 mm.
[Auto Power Off function]	: The LCD turns off automatically when no operation is conducted for a specified time. (Auto power off mode) Touch any button to return to Normal mode.
[Caliper]	: Manually move the measurement point.
[Gray scale]	: Indicates the range of gradation values to be measured in images represented in shades from white to black.
[Gain]	: Adjusts amplification, brightness of images, and amplitude of waveforms.
[Gate]	: Specifies the range of waveforms to be detected.
[Smoothing]	: This function smoothes the continuation of images and reduces noises, improving the image quality.
[Measurement point]	: Indicates the point where corneal thickness is measured, specified by diameter and angle.
[Touch panel]	: Allows you to make various settings, etc. by directly touching the monitor.
[Harmonic]	: Image composition method for ultrasound diagnosis which uses harmonic components of ultrasonic waves.
[Bias value]	: Value obtained by converting actual measurements using a specified percentage or correction value

[Vector A mode]	:	Indicates the direction of ultrasonic wave transmission and displays the A mode waveform.
[Real time]	:	Status where ultrasound waves are transmitted

1.4 Overview

This instrument is designed as an ophthalmology device with functions to retrieve ultrasound topographic images of living tissues using ultrasound waves generated from an ultrasound transducer built into the probe, to retrieve A mode waveforms and to measure axial length and corneal thickness.

B mode image diagnosis function

- From the B mode probe connected to the main unit, images and displays the tissue of the scanned eyeball cross section generating and scanning ultrasound waves into the eyeball and using ultrasonic echoes reflected from each tissue inside the eyeball.

Biometry function

- The measurement probe connected to this instrument transmits ultrasound waves to the inside of an eyeball and then receives ultrasound echoes reflected by the tissue boundary surface in the eyeball.
- The time required for the ultrasound wave to be transmitted from the front of the cornea to the measurement section is measured, and the length of the living tissue is calculated based on the preset converted acoustic velocity.

L: Length of living tissue

V: Converted sound speed

t: Measurement time

- With an IOL power calculation function, this instrument has various IOL power formulae applicable to ordinary cataract surgery and/or cataract surgery of eyes with corrected corneal refractive power, and provides data necessary to determine IOL power.

Pachymetry function

- Function to measure corneal thickness in the same manner as measurement of axial length

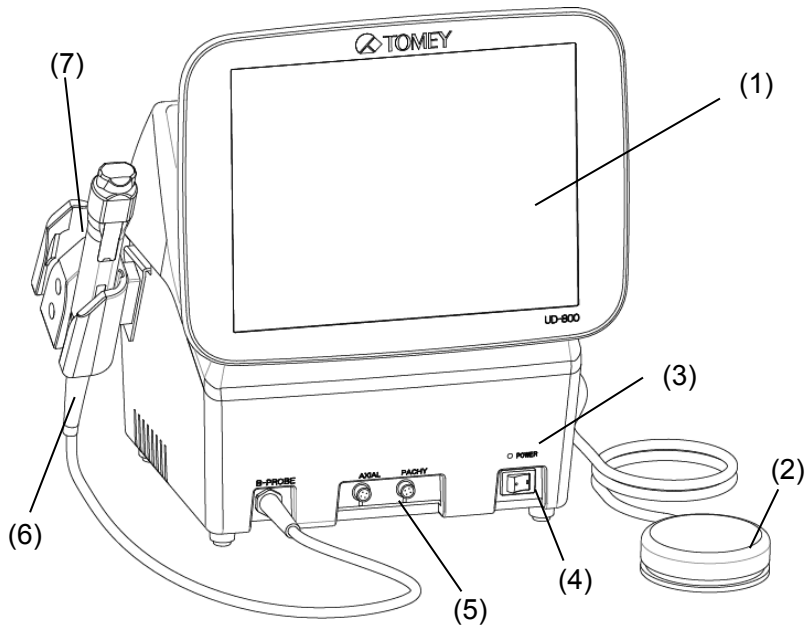
A mode diagnosis

- Function to identify areas with pathological changes by observing A mode waveforms

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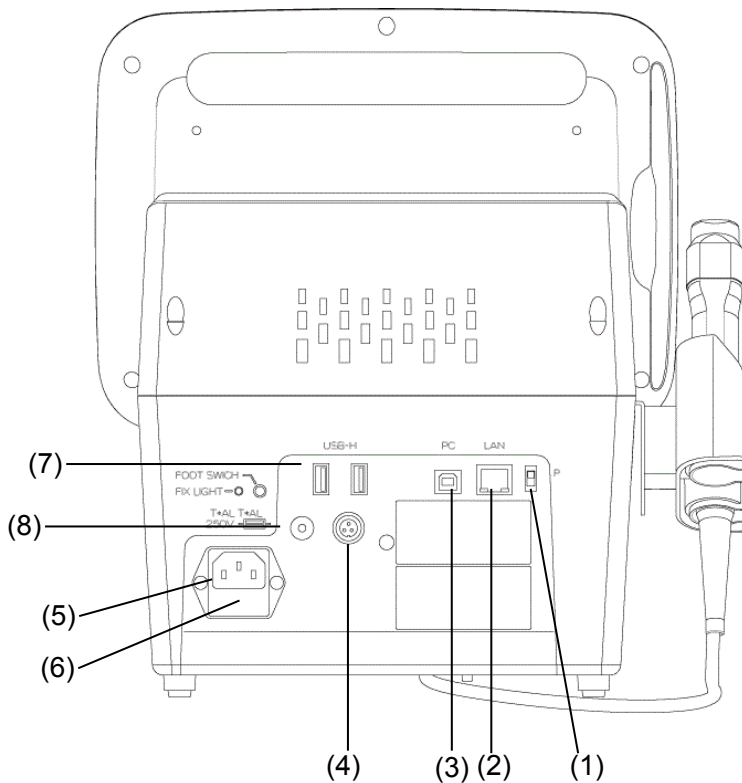
2. NAMES AND FUNCTIONS

2.1 Front of the main unit



- (1) LCD and touch panel
- (2) Foot switch
- (3) Power LED
- (4) Power switch
- (5) Biometry probe connector / Pachymetry probe connector
- (6) Probe
- (7) Probe holder

2.2 Back of the main unit



(1) Maintenance switch

Our service personnel use this switch for maintenance. Never touch this switch.

(2) LAN connector

(3) USB-D connector (PC) Connect a personal computer here.

(4) Foot switch connector

(5) Inlet

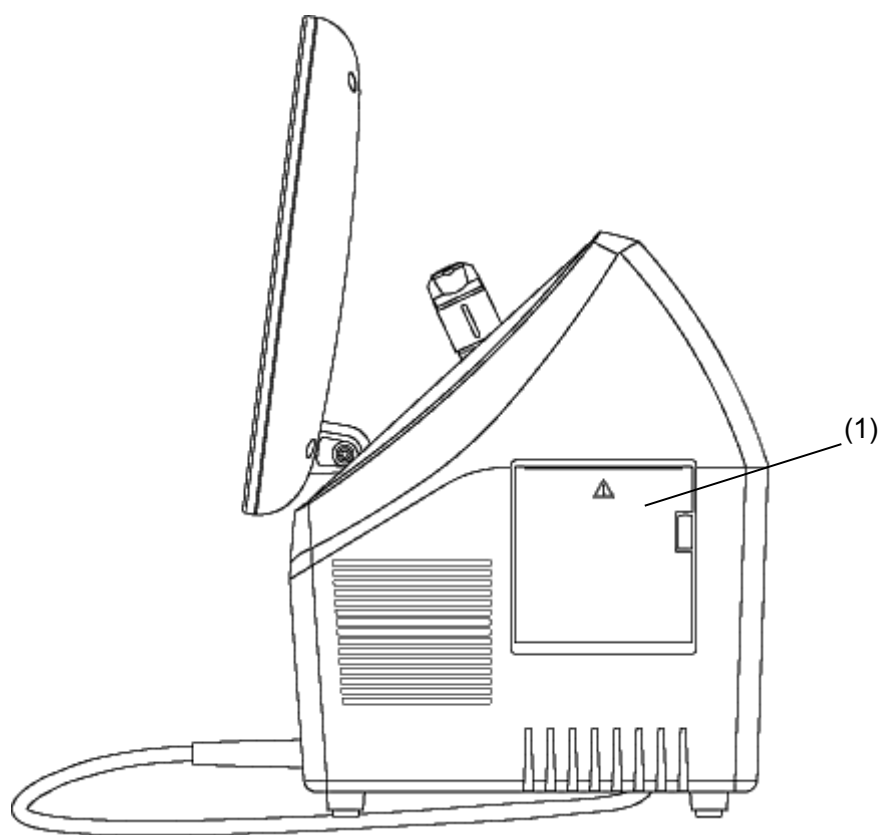
(6) Fuse holder

(7) Connector for external storage media such as USB flash memory, a video printer, and an external ID input device, etc.

(8) Connector for fixlight

Connect the external fixlight of the special chin rest here.

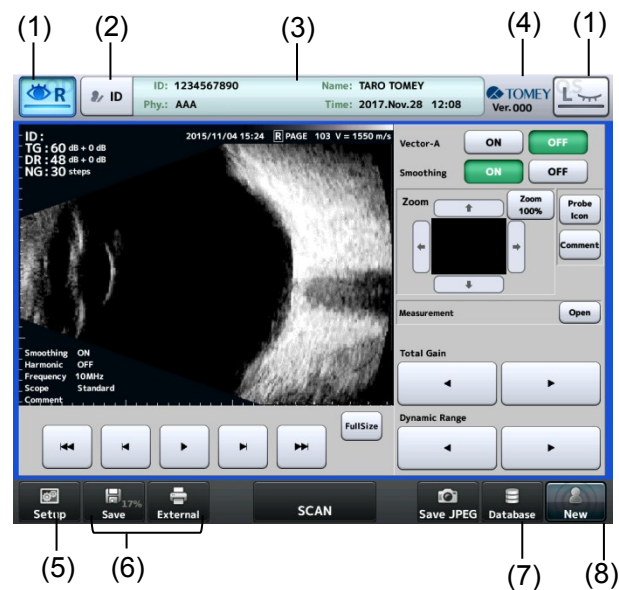
2.3 Sides of the main unit



(1) Built-in printer

2.4 Screen

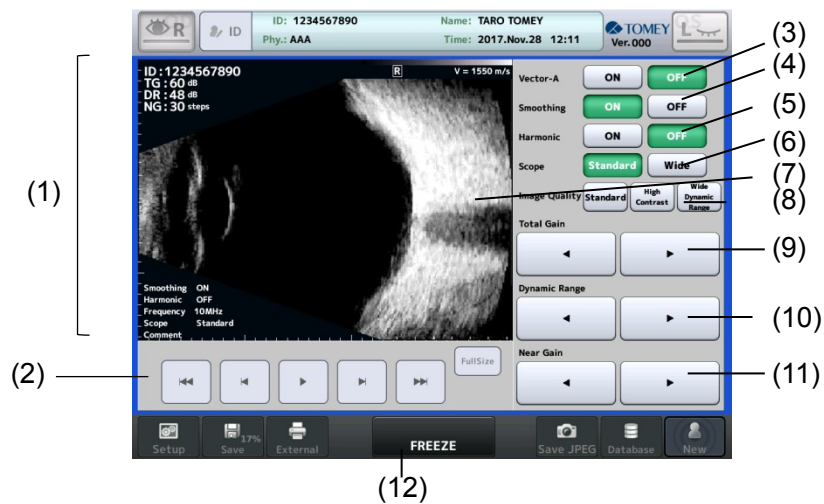
2.4.1 Common items



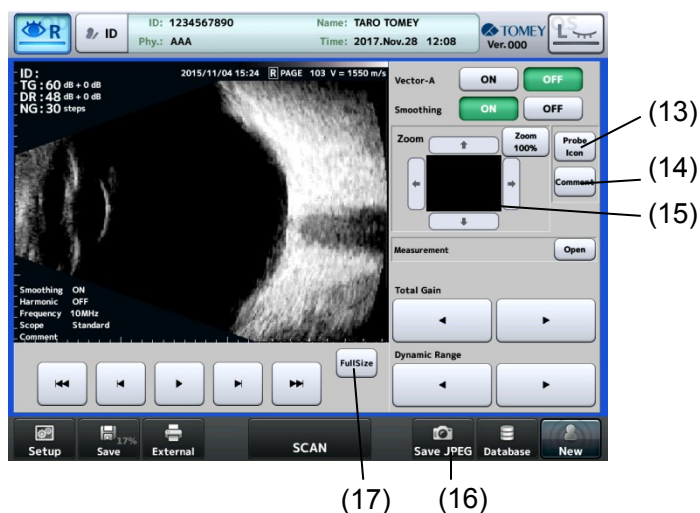
- (1) Eye button (eye selection button)
- (2) Patient information button Moves to the patient information input screen.
- (3) Patient information field
- (4) Version Displays the version of the system.
- (5) "Setup" button Moves to the Setup screen.
- (6) Print / Export / Save buttons
- (7) Database button Moves to the Patient List screen.
- (8) Touch and hold this button to delete the examination data of both eyes and the patient's information.

2.4.2 B mode image diagnosis screen

(Real-time screen)



(FREEZE screen)

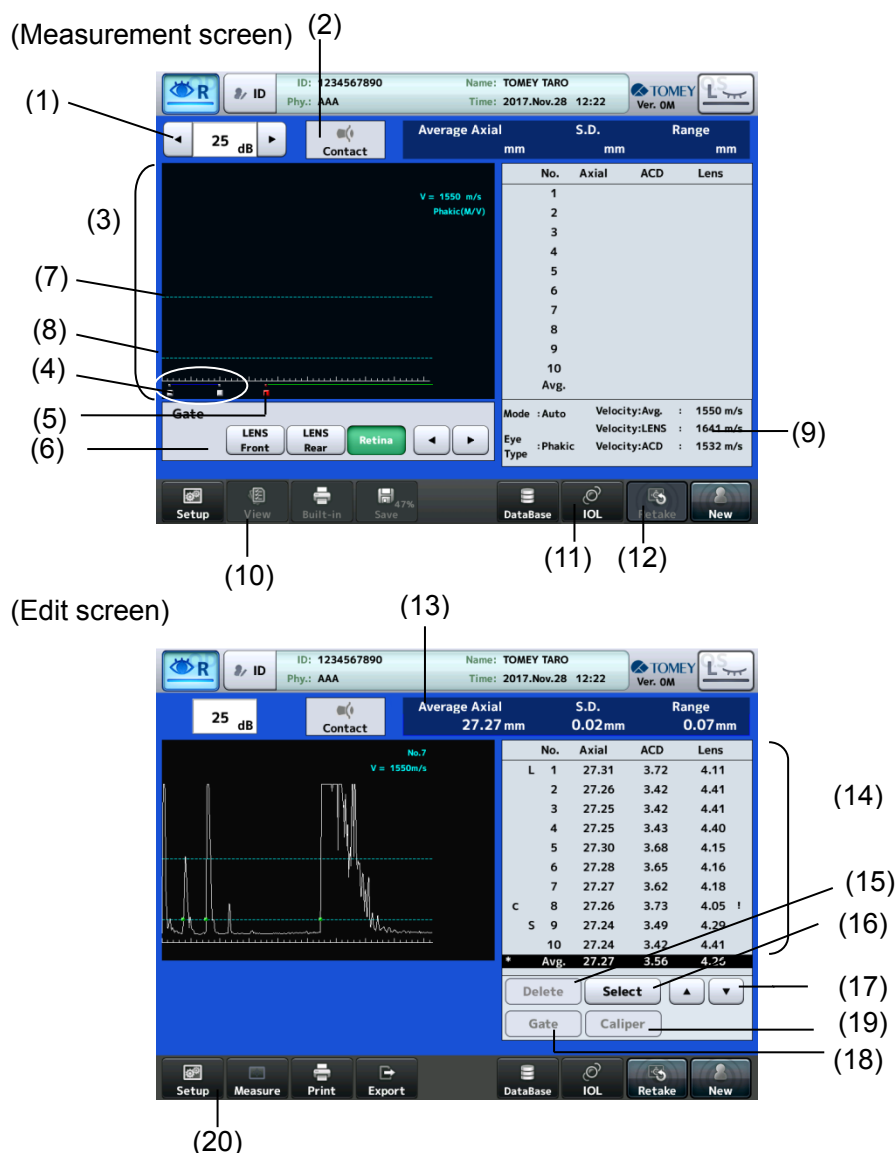


- (1) Image monitor Displays an image and the following information. Patient ID, inspection date/time, eye to be examined (R/L), image page No., converted acoustic velocity Total gain (TG) / Dynamic range (DR) / Near gain (NG) Settings for smoothing, harmonic, gradation characteristics, frequencies and scope of the image<
- (2) Buttons for playing movie
- (3) Vector- A
Select ON to display a vector-A line and vector waveforms.
- (4) Smoothing
Makes links between screens smooth.
- (5) Harmonic
Mode to extract harmonic components and create the image
- (6) Scope

Select the image display depth. Standard / Wide

- (7) Vector- A tool Operate the Vector-A line.
- (8) Image Quality Preset values of gains and dynamic ranges. Standard / High contrast / Wide dynamic range
- (9) Total Gain 20-80dB
- (10) Dynamic Range 30-70dB
- (11) Near Gain 1-60step
- (12) FREEZE / FREEZE cancel button
- (13) Probe Icon button Displays the probe set angle.
- (14) "Comment" button Allows you to enter a comment.
- (15) Zoom function Enlarges and displays the image being shown.
- (16) Save JPEG button Saves the image in Jpeg format.
- (17) FullSize button Zooms the image to full screen.

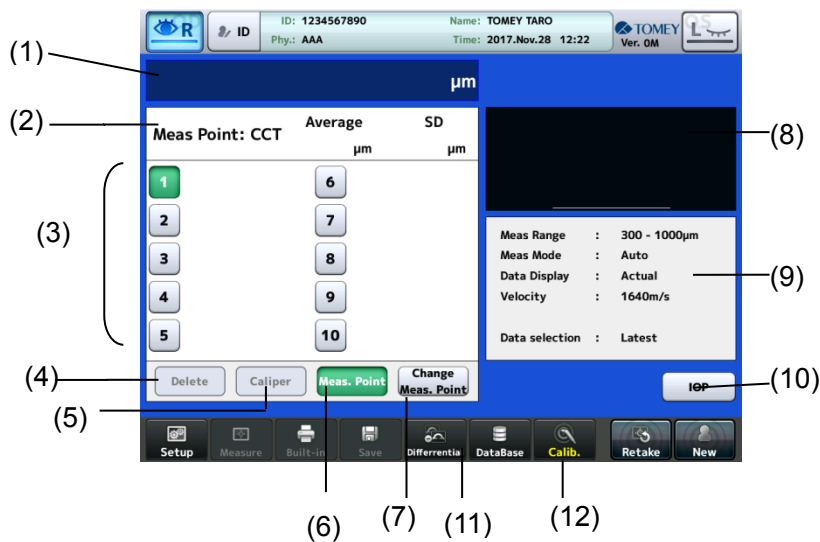
2.4.3 Axial length measurement/view screen



- (1) Gain display/adjustment field
- (2) Mode display – Contact/Immersion
- (3) Waveform display area
- (4) The waveform between these two cursors is the waveform of the lens.
- (5) The waveform on the right of this cursor position is measured as the waveform of the retina.
- (6) Gate cursor movement button Moves the gate cursor.
- (7) Measurement data will be taken when the waveform rises above this cursor/line position.
- (8) Measurement cursor/measurement line The distance at this cursor/line should be taken as the measurement data.
- (9) Measurement conditions display field
- (10) "View" button Displays the view screen.

-
- (11) "IOL" button
Opens the IOL power calculation screen.
 - (12) Deletes the measurement data currently displayed and measures the same eye again.
 - (13) Axial length measurement data display Displays measurement conditions and measured axial length.
 - (14) Measurement data display The axial length, anterior chamber depth, lens, and their average values are listed.
 - (15) "Delete/Restore" button Deletes and recovers the measurement data.
 - (16) The measurement data at the cursor position is selected to be used for calculating IOL power.
The selected measurement data is indicated by an "**".
 - (17) Selection cursor UP/DOWN buttons
 - (18) "Gate" button
 - (19) "Caliper" button
 - (20) "Measure" button

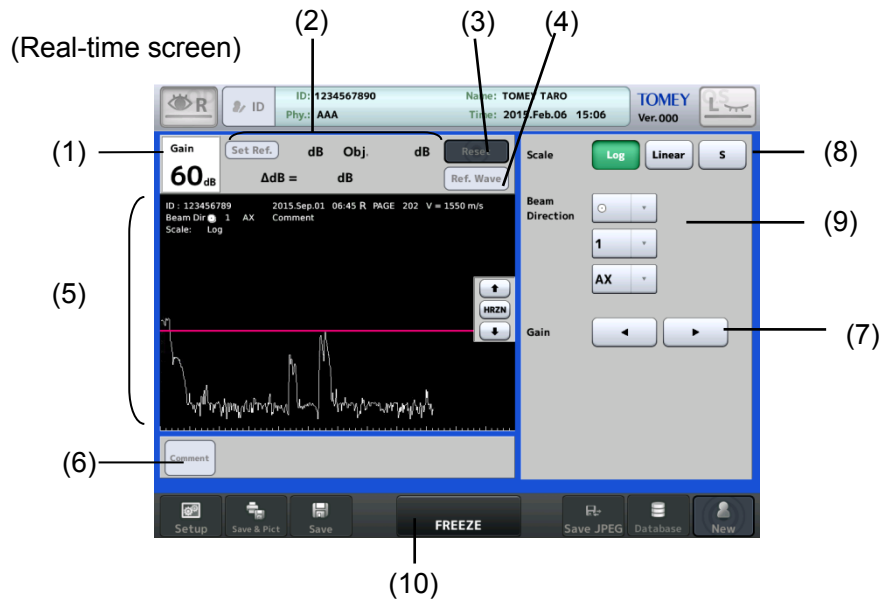
2.4.4 Pachymetry screen



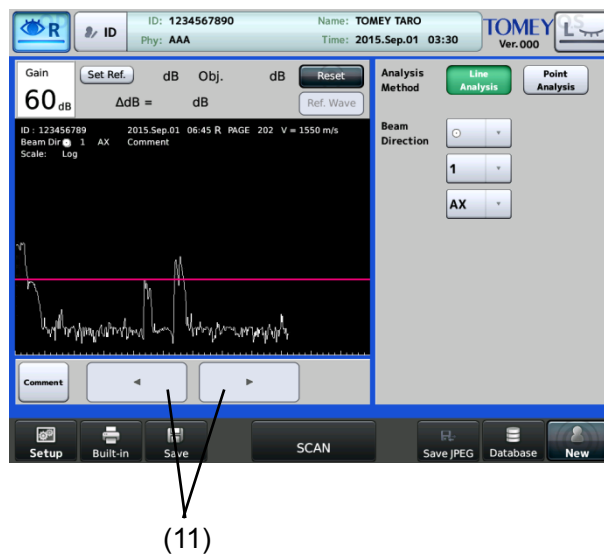
- (1) Displays the actual measurements of the loaded measurement points. The latest loaded data are displayed during a measurement process.
- (2) Corneal thickness data display
- (3) Measurement data display
- (4) "Delete/Restore" button
- (5) "Caliper" button
- (6) "Meas. Point" button
- (7) "Change Meas. Point" button
- (8) Measurement waveform display field
- (9) Measurement conditions display field
- (10) "IOP" button
- (11) "Differential" button
- (12) "Calib." button

Calibrates the sensitivity of pachymetry probes.

2.4.5 A-Diag measurement screen



(FREEZE screen)



- (1) Gain
- (2) Displays tools for analysis of the line or point.
- (3) Hold this button briefly to delete "Ref." data and open the loading screen.
- (4) "Ref. Wave" button
- (5) Waveform display area Displays a waveform and the following information. Patient ID, inspection date/time, eye to be examined (R/L), image page No., converted acoustic velocity Point to which the probe is applied, direction of the ultrasound beams, probe type, beam direction, comment
- (6) "Comment" button
Allows you to enter a comment.
- (7) Gain adjustment 0 - 80dB

-
- (8) Scale selection Log / Linear / S
 - (9) Select the point to which the probe is applied and the direction of beams that are to be displayed in the waveform display field.
 - (10) FREEZE / FREEZE cancel button
 - (11) "Frame-by-frame" button

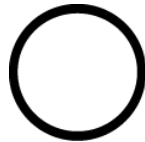
2.5 Symbols used for marking



Refer to instruction manual.



“ON” (power)



“OFF” (power)



Type B attached part



Grounding (earth)

3. OPERATION PROCEDURES

3.1 Preparation before use

3.1.1 Connections

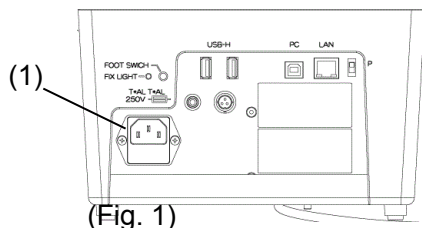


- *The power connector completely isolates the instrument from the commercial power source. If there is a problem with the instrument, turn off the power switch and disconnect the power connector. Install the instrument in a place where this can be performed smoothly.*



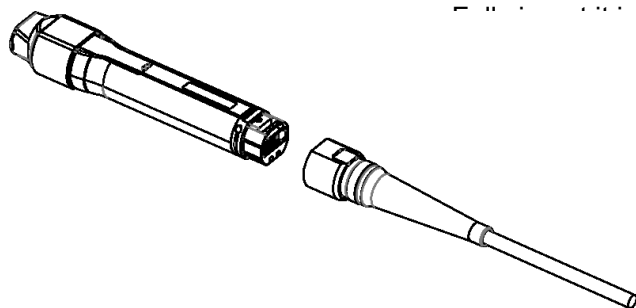
- *Faulty connection of the instrument and relevant accessories may result in fire, electric shock, or fatal accident. Turn off all devices and disconnect the power plugs from the outlet before connection.*
- *The connector needs to be inserted in a specific direction. Check the direction and firmly insert the connector.*

a) Connection of the power cord



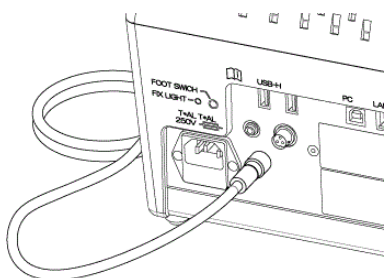
- 1) Insert the connector of the power cord into the power socket (1) in the correct orientation. Connect all three pins of the plug.

b) Connecting the probe cable



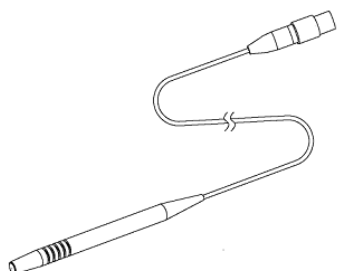
- " " " " the correct direction. Press the unlock button
cting the probe cable.

c) Connecting the foot switch



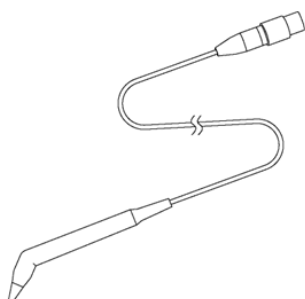
- Insert the footswitch connector into the footswitch connector on the back of the instrument, aligning the notches of the connectors.
- Turn the fixture (3) of the connector clockwise until it stops to secure the connector.

d) Connecting the biometry probe / A-scan diagnosis probe



Insert the connector of the biometry probe into the biometry probe/A-scan diagnosis probe connector, indicated by “Axial” on the front of the instrument, in the correct orientation.

e) Connecting the pachymetry probe



Insert the connector of the pachymetry probe into the pachymetry probe connector, indicated by “Pachy” on the front of the instrument, in the correct orientation.

f) Connecting an external digital printer



Note ■ *Use only the specified printer and cables. Use a video signal cable or remote cable to connect this instrument to a device conforming to IEC60601-1 or JIS T 0601-1, or conforming to IEC60950-1 and with a power source isolated by an isolation transformer.*

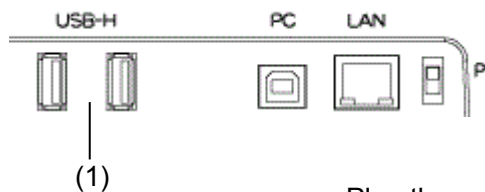
- Video printer

Insert the cable plug A (1) of the USB cable into the USB connector on the side of the main unit in the correct orientation.

Connect the other cable plug B (2) of the USB cable to the video printer.

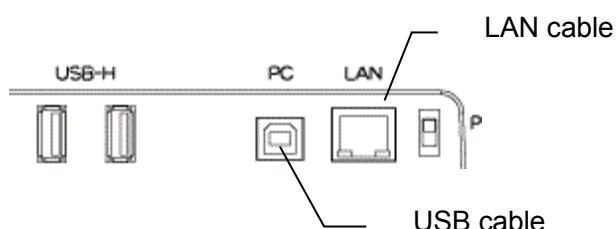
Follow the instruction manual of the video printer for details on how to connect the printer.

g) 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.

h) Connecting the personal computer



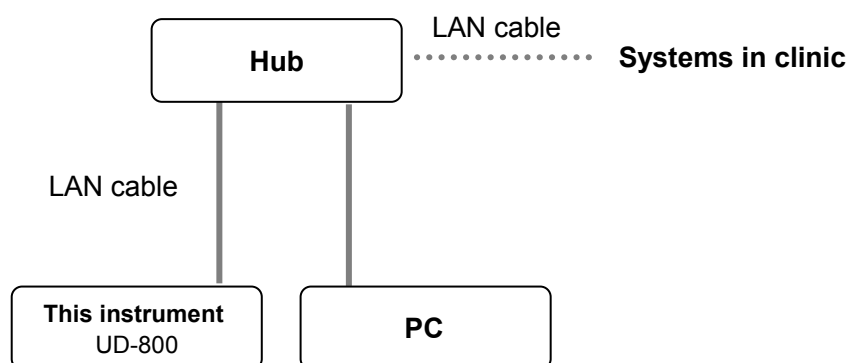
- Note** ■ The network support system “TOMEY Link” (optional) or the examination data receiving software “DATA Transfer” (included in the package) is required for data communication with the instrument.
- Refer to the corresponding operation manual for installation, settings, and operation of TOMEY Link and DATA Transfer.
- Connection settings on the Setup screen must be completed in advance to connect with TOMEY Link and DATA Transfer. Refer to “3.9.4 Connecting & Printing” for the setting method.
- Be sure to make network settings under the consent of your network administrator.
- 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.

• Connecting LAN cables

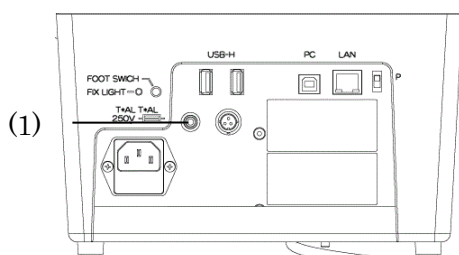
Prepare the following items.

- 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

(Wiring example)



i) Connecting of the power plug of the Fixation Lamp for Chin Rest



- 1) The Fixation Lamp is interlocked with the ON/OFF power source for the instrument.
- 2) Insert the Power plug (1) for Chinrest fixation lamp into the terminal marked with "FIX LIGHT" provided at the rear side of the main unit.

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

a) Turning the power on

- 1) Turn on the power switch (1) on the front of the main unit.
- 2) The startup screen (Fig. 1) appears and then the measurement screen in the mode used last time appears.



(Fig. 1)

b) Adjustment after turning power on

The brightness of the monitor can be adjusted to suit the illumination in the examination room (see "3.9.1 General").

3.1.3 Switching modes

Note ■ *When the mode is changed, all data captured in the previous measurement mode is deleted.*



Touching the "Setup" button (1) on each screen displays the setup screen. Select any of the mode selection buttons (2) as desired to enter each mode.

There are following modes:

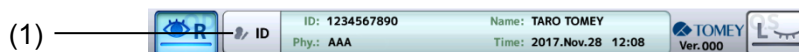
- B-Mode: B mode image diagnosis
- Axial : Axial length measurement
- Pachy : Measurement of corneal thickness
- A-Diag : A-scan diagnosis

3.1.4 Entering the patient data

Note

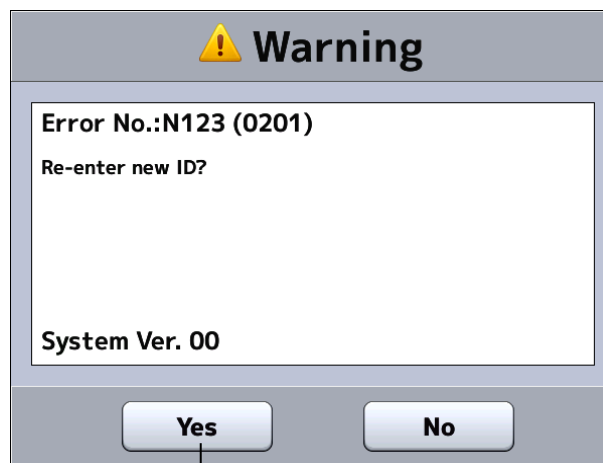
- When entering new patient information, carefully check that the same ID is not registered in the database or other electronic medical records.
- Only the first 14 digits of the ID number are displayed in the patient information field. Check that the ID number is correct on the patient information entry screen.
- The network support system “TOMEY Link” (optional) is required to use the patient information query function. “DATA Transfer” provided with the instrument is not available for query of the patient data.
- For details on the TOMEY Link Server settings, refer to the TOMEY Link instruction manual.
- Appropriate connection settings are required for connection with TOMEY Link. Refer to “3.9.4 c) PC setting” to make settings.
- Once examination data is output (printed, exported or saved), the ID cannot be changed.

- 1) Touch the patient information button (1) to open the Patient Information screen (Fig. 2).
 - When both the patient information and examination data exist, a warning message (Fig. 3) appears indicating you are about to overwrite data when the patient information button is touched. Touch the “Yes” button (7) to overwrite the data.



(Fig. 1)

(Fig. 2)



(Fig. 3) (7)

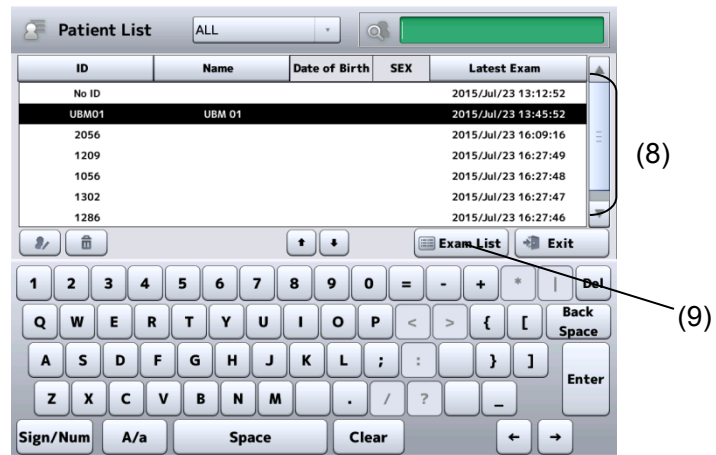
2) Enter necessary data.

- Entry method 1: Software keyboard
Patient's ID, name, sex, and date of birth can be entered using the software keyboard on the Patient Information screen (Fig. 2).
If the entered ID is already recorded in the memory, the corresponding name, sex, and date of birth is automatically recalled from the memory in the main unit when the ID is entered.
- Entry method 2: Database (USB memory stick)
The patient can be selected from the list saved in the database (USB memory stick).
Touch the "Patient Search" button (2) on the Patient Information screen (Fig. 2) to open the Patient List screen (Fig. 4). Touch the desired patient in the list (8) and then the "Select" button (9).
- Entry method 3: Inquiry to TOMEY Link
Enter the ID and touch the "Tomey Link Inquiry" button (3) on the Patient Information screen (Fig. 2). The patient information read from TOMEY Link in the personal computer appears. The inquiry reference can be changed to "DiscomWorkList" on the System Setup screen.

- Entry method 4: External ID input device

Data can be entered using a barcode reader, card reader, or keypad.

The barcode reader and card reader are also available on the measurement screen in addition to the Patient Information screen (Fig. 2)



(Fig. 4)

- 3) Touch the "OK" button on the Patient Information screen (Fig. 2), designate the patient information, and return to the previous screen.
 - Touch the "Cancel" button (5) to discard the edited information and return to the previous screen.

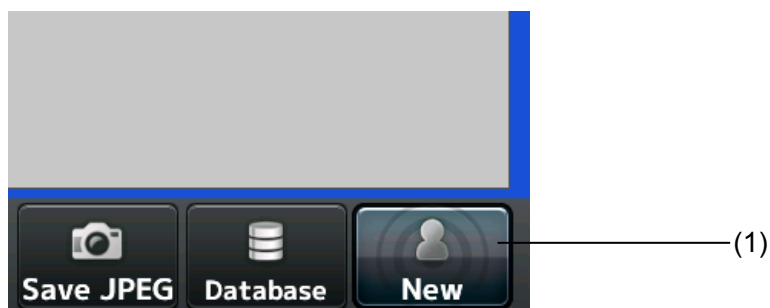
3.1.5 Deleting all measurement data (measurement preparation for other patient)

Note ■ *The deleted examination data cannot be restored. Carefully check the data before deleting it.*

■ *Be sure to touch the “New” button to delete the data for the previous patient before measuring a new patient. If a new measurement is started without deleting the previous data, the data for the previous patient may be included.*

1) Touch the “New” button for a while.

The patient information (ID, name, sex, and date of birth) and relevant examination data is deleted, and the measurement screen appears.



3.1.6 Selecting an eye



Select an eye using the eye selection button (1).

3.2 B mode image diagnosis

Refer to “3.1.3 Switching modes” for how to enter B mode image diagnosis.

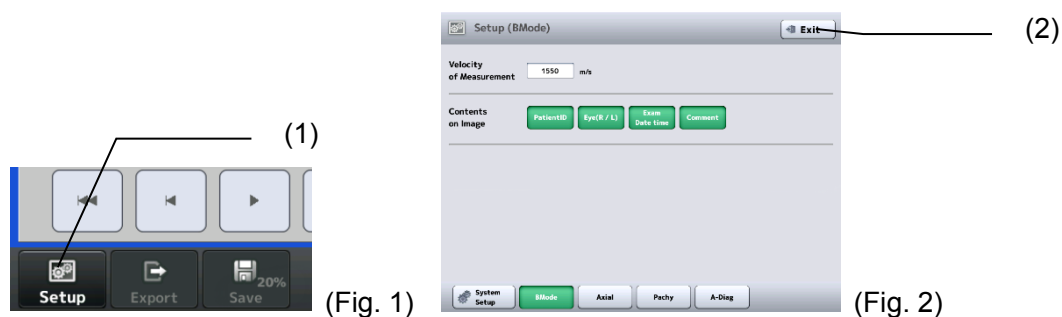


■ When the probe is changed, all unsaved data captured by the previous probe is deleted. Be very careful when performing initialization.

The instrument automatically detects the connected probe.

3.2.1 Settings related to measurement

Touch the "Setup" button (1) to display the Setup (Ultrasound Pachy) screen (Fig. 2). Touch the "Exit" button (2) after settings are completed to apply the selected contents and return to the measurement screen (Fig. 1).



a) Acoustic velocity during measurement

Set the acoustic velocity used during measurement by the measurement function.

b) Settings for items displayed in image

Selects the items to be displayed in the image monitor.

Patient ID / Patient's eye / Measurement date/time / Comment / Focus marker (40 MHz only)

3.2.2 Displaying probe angle

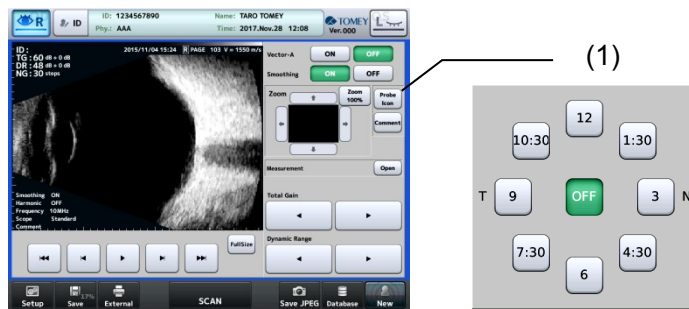
Indicates the angle that the probe was set against the eye.



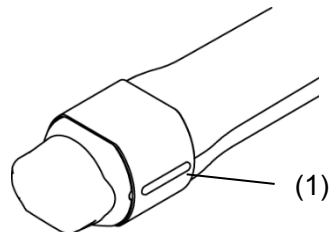
■ Confirm that the displayed probe angle matches the probe angle captured in the picture.

- 1) Touch the "Probe Icon" button (1) or the probe icon shown on the image to open the probe angle selection screen. The selected angle is shown in the lower right of the monitor. "N" means nasal (nose) and "T" means temporal (ear).

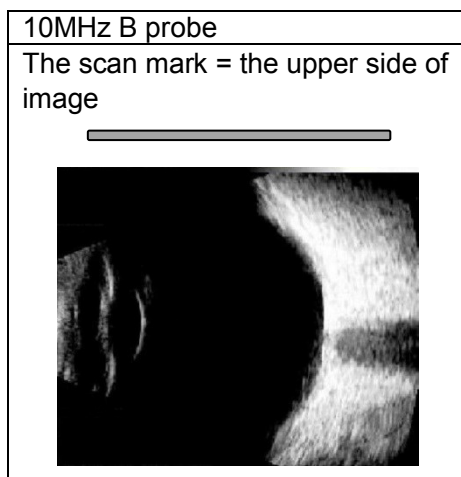
2) Touch the “OFF” button to hide the probe icon.



<Relationship between the displayed image and the probe angle>

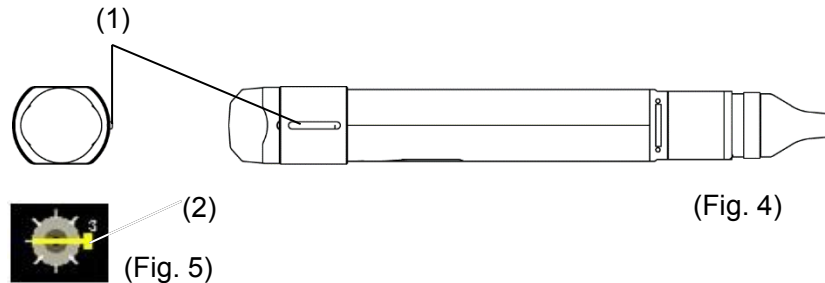


The B mode probe has a mark (1) that indicates the scanning direction. The relationship between the scan direction mark and the image captured by the probe is as shown below:



<Understanding the probe angle mark>

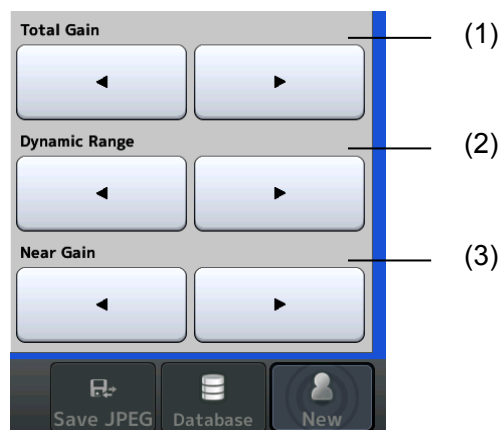
The scan direction mark (1) on the B mode probe is indicated by the extending section (2) of the probe angle mark.



3.2.3 Gain adjustment

Note ■ Settings made here are only effective for the eye currently selected.

Examine the ultrasound image when you make any fine adjustment of the gain.



a) TOTAL Gain (1)

Sets the echo sensitivity of the overall image. (Adjustment range: 20 - 80 dB)

b) Dynamic Range (2)

Adjusts the dynamic range of the image. (Adjustment range: 30 - 70 dB)

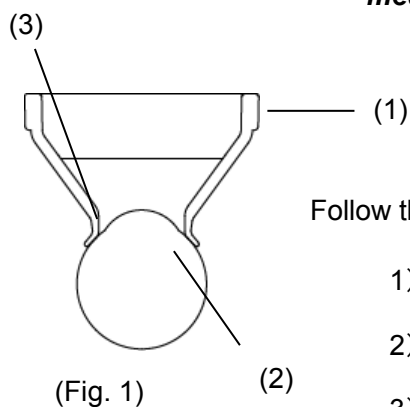
A higher dynamic range makes the black and white contrast weaker. A lower dynamic range makes the black and white contrast stronger and creates a high contrast image.

c) Near Gain (3)

Sets the echo reflection sensitivity in the neighborhood of the anterior eye and vitreous.

3.2.4 Patient preparation

- Note** ■ *Cooperation by the patient is required to perform examination smoothly. Explain the examination method to the patient before starting the examination to help them relax.*
- *Make sure that the air is not mixed in when applying the ultrasound diagnosis gel. When you observe unnecessary echoes, apply sufficient ultrasound diagnosis gel again.*
- *When you use an eye cup, use one with the size appropriate for the patient. Leaked saline solution may cause an indirect contact infection.*
- *Make sure that air bubbles do not mix in when you inject ultrasound media in the eye cup.*



Follow the procedure below to use an eye cup.

- 1) Lay the patient on the back and apply topical anesthesia.
- 2) Apply the contacting part of the eye cup (1) to the eye (2).
- 3) Pour the saline solution (3) gently to the eye cup.

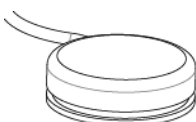
3.2.5 Obtaining ultrasonic image



- **Do not allow water or chemicals to splash on probes, except for the tip cap. Any water or chemicals entering the instrument may cause electric shock or failure.**



- **Be sure that the screw is not loose when you use the arm. Otherwise the probe attached to the arm may drop to be damaged or may drop to damage an eye ball or eye lid of the patient. Operating the arm directly with your hand may injure your finger pinched by the arm.**
- **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.**
- **Releasing a freeze by touching the FREEZE button or stepping on the foot switch deletes all images previously obtained. Be very careful when performing initialization.**



(1)

- 1) When the instrument is in FREEZE mode, touch the “FREEZE cancel” button (1) or step on the foot switch to release FREEZE mode.
- 2) Apply an appropriate amount of the ultrasound diagnosis gel to the contact section of the B mode probe.
- 3) Apply the B mode probe directly to the lid of the examined eye.

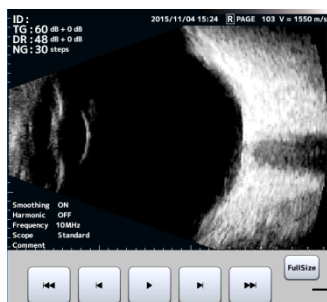
3.2.6 Various functions

Available functions vary depending on the measurement status. See the following table:

10MHz			
Playing Movie	FREEZE	Comment	FREEZE
Vector-A	FREEZE Real-time	Smoothing	FREEZE Real-time
Zoom	FREEZE	Measurement	FREEZE
Export	FREEZE	Print	FREEZE
Save in USB memory stick	FREEZE	Save in JPEG format	FREEZE
Measurement	FREEZE	Scope	Real-time
Full screen	FREEZE		

a) Playing Movie

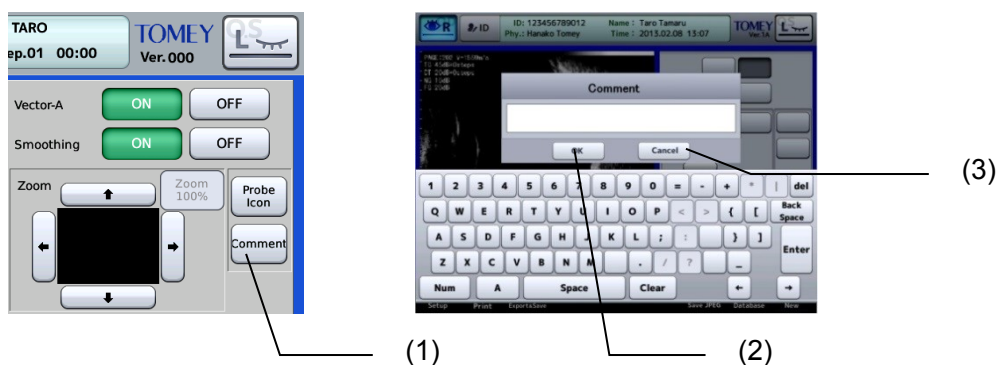
Up to 200 images per eye for the patient are saved in the 10-MHz B probe. This function executes video playback operations and frame advance/reverse using the playback buttons. The “Stop” button is shown while a video is playing.



Playbacktool

b) Commenting

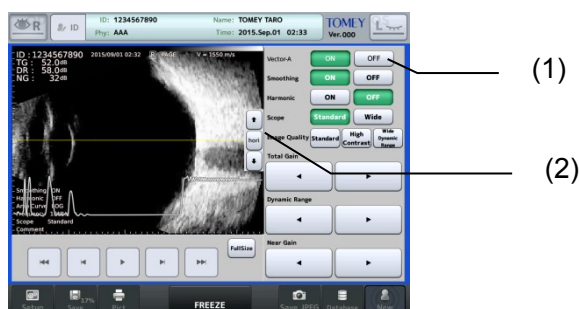
- 1) Touching the "Comment" button (1) displays the input comment window and the software keyboard.
- 2) Enter a comment and touch the “OK” button (2) to save the entered comment and close the comment input window.
- 3) Touching the “Cancel” button (3) will discard the changes made.



c) Vector mode-A

This function displays captured mode-A waveforms of the image.

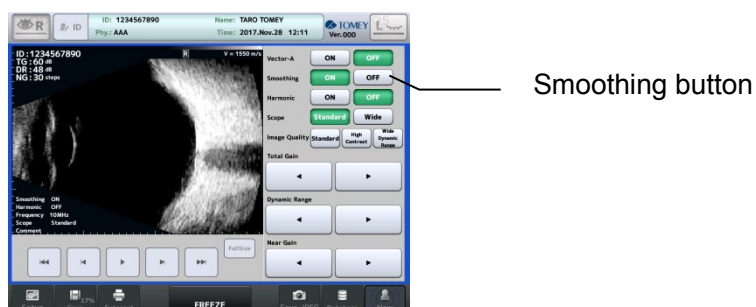
Please note that the zoom and measurement functions cannot be used when vector mode-A is on.



- 1) Selecting "ON" for "Vector-A" (1) displays the cursor line and the mode-A waveform for the line position on the monitor.
- 2) The mode-A waveform of the cursor line position is shown on a real-time basis as you move the cursor line by touching the "Move Cursor Line up (or down)" button (2).
- 3) Touching a position on the screen moves the cursor to that position.
Touching the "HRZN" button moves the cursor line to the center.

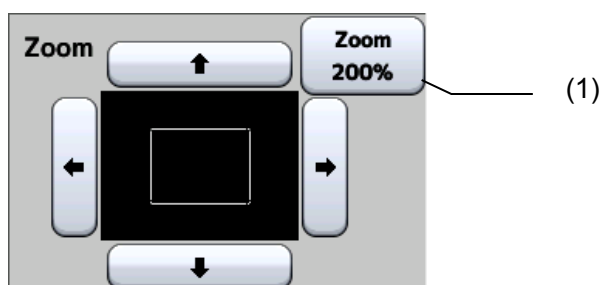
d) Smoothing

This function smooths the continuation of images and reduces noises, improving the image quality. This function does not suit for viewing videos that include fast movements.



e) Zoom

This function magnifies the displayed image. Vector mode-A cannot be used when zoom is used.



The navigation monitor displays the whole image, and the area zoomed in the monitor is indicated by a frame. Moving the frame moves the displayed area accordingly.

Touching the “Zoom” button (1) alters the magnification between 100% and 200%.

f) Measurement

This function measures lengths, angles, and areas of the image displayed on the monitor.



■ ***When you use the result of this function for operations and medical treatments, make a comprehensive decision considering the results of other measurement devices and differences between left and right.***

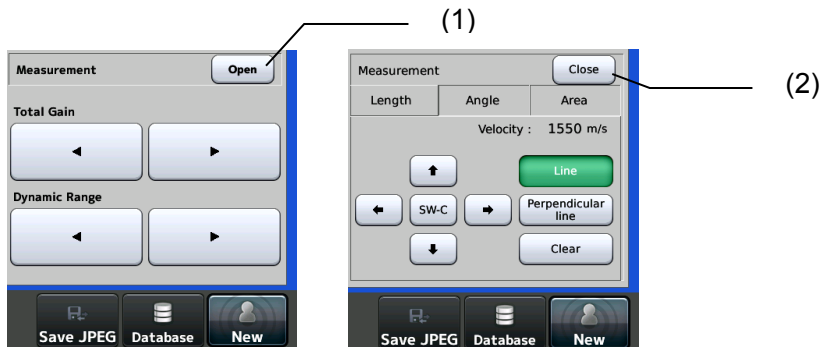


■ ***The zoom function is not available during measurement. Apply the zoom function and then take measurement to measure on the enlarged image.***

■ ***The Vector-A display and smoothing function are not available during measurement.***

■ ***The measurement points and results are all deleted when the measurement tool is closed, and they cannot be recovered.***

- 1) Open the measuring tool by touching the “Open” button (1) in “Measurement” in the FREEZE menu.
- 2) Select a tab to display a measurement tool (length, angle, or area).
- 3) Touching the “Close” button (2) closes the measuring tool screen.



[Length measurement]

This function measures and displays the distance between two arbitrary points in an image.



Touching two points in the image automatically calculates the slant distance between the two points and displays the result in the image.

Touching the screen again changes the position of the active caliper (blue) and the angle is re-calculated.

The following tools are available.

SW-C button : Switches the active caliper (blue).

Cursor button : Moves the active caliper (blue).

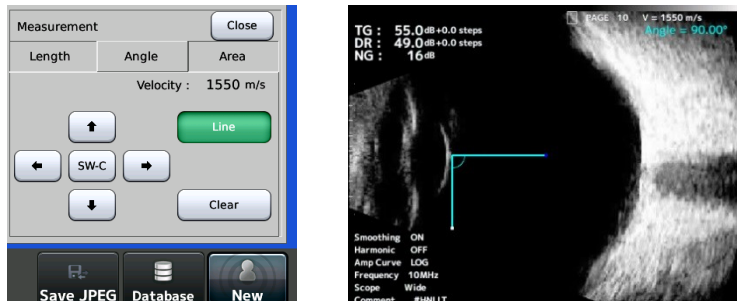
Line button : Shows/hides the line between the caliper marks.

Perpendicular Line button : Shows/hides a line perpendicular to the above line.

Clear button : Deletes the measurement result.

[Angle measurement]

This function measures and displays the angle determined by three arbitrary points in an image.



Touching three points in the image automatically calculates an angle (acute angle) regarding the second point as the center and displays the resultant angle in the image.

Touching the screen again changes the position of the active caliper (blue) and the angle is re-calculated.

The following tools are available.

SW-C button : Switches the active caliper (blue).

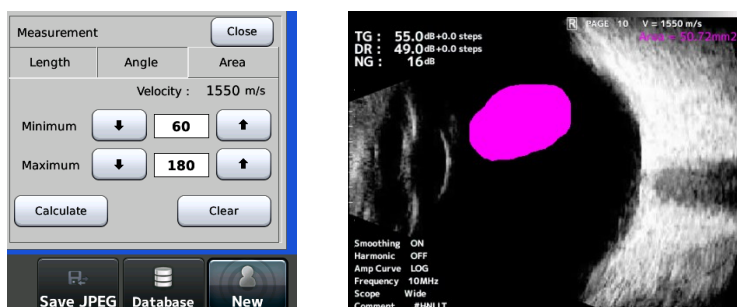
Cursor button : Moves the active caliper (blue).

“Line” button : Shows/hides the line between the caliper marks.

“Clear” button : Deletes the measurement result.

[Area measurement]

This function measures a target area and displays the result. The target area can be defined freehand in the screen. The gradation value range can also be specified. Measurement is not performed if the specified area does not form a closed shape.



The following tools are available.

Gray level setting : Set the range of gradation.

Calculate button : Re-calculates the area.

Clear button : Deletes the measurement result.

g) Harmonic

This mode transmits 10MHz ultrasound (fundamental wave) and extracts twofold frequencies (harmonic ingredients) for creation of the image.

This mode creates images with better resolution in the azimuth direction (vertical direction in the image) and with less artifacts, providing a more faithful rendering of the tissue.

This mode, therefore, suits for obtaining clear structure images of an optic papilla, macular area, and tumor.

h) Scoping

This function selects the image display depth from “Standard” and “Wide.”

Choose one that suits the observation target area.

i) Preset values of gains and dynamic ranges

Preset values of each gain can be set in this instrument. Select a preset setting from Image Quality.



[Standard]

Each gain is set to the standard value.

[High Contrast]

This preset setting creates images of high contrast. However, its gradation granularity is low, not suited for observing subtle differences of tissues. This mode mainly suits observation of a retina.

[Wide Dynamic Range]

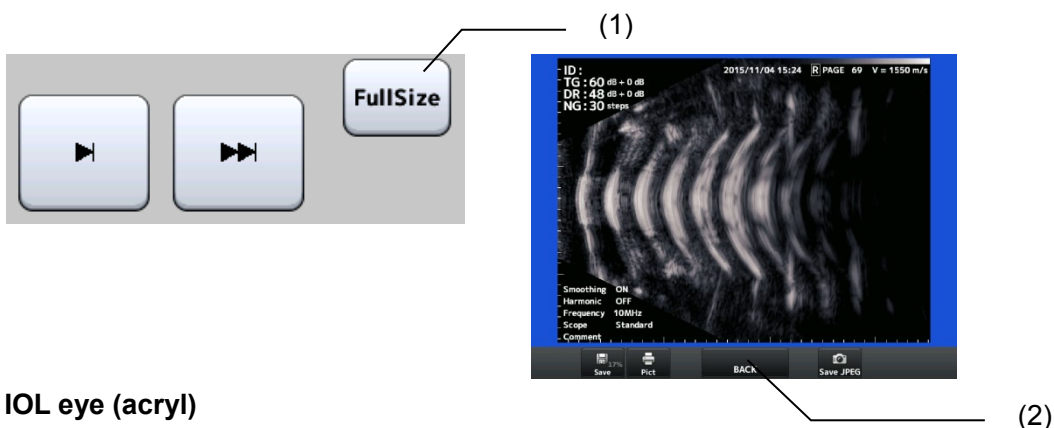
Its gradation granularity is high, so that it suits observation of subtle differences of tissues. This mode, however, tends to capture unnecessary echoes and artifacts (virtual images created by inflections and reflections of ultrasound beams). This mode mainly suits the observation of opacity and bleeding in a corpus vitreum.

j) Full screen display

This function zooms the measurement data to the maximum size on the screen.

Note ■ *The zoom function is not available while the full screen function is activated. Return to the measurement screen to edit the data.*

- 1) Touch the "FullSize" button (1) to open the Full Size screen.
- 2) Select a tab to display a measurement tool (length, angle, or area).
- 3) Touch the "Back" button (2) to return to the measurement screen.



• IOL eye (acryl)

Select this when there is an acrylic IOL implant.

• User Setting

Select this when registering optional materials for IOL eyes.

Register the settings on the converted acoustic velocity setting screen. (Refer to "3.3.1 b)

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 multiple echoes in the crystal lens in an eye with dense cataracts.

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

3.3 Biometry function

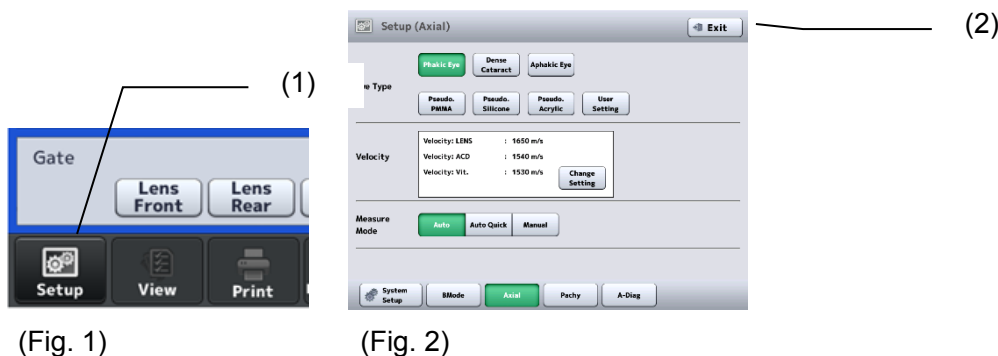
Refer to “3.1.3 Switching modes” for how to enter biometry mode.

3.3.1 Setting measurement conditions

Note ■ *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).



a) Selecting the eye type to be examined

Select the eye to be examined from the following 7 options according to the patient's eye.

- **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 eye to be examined is comparatively hard, such as an eye with dense cataracts, and it is difficult to take measurements in the mode used for a phakic eye due to 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 “3.3.1 b) 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 multiechoes in the crystal lens in an eye with dense cataracts.

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

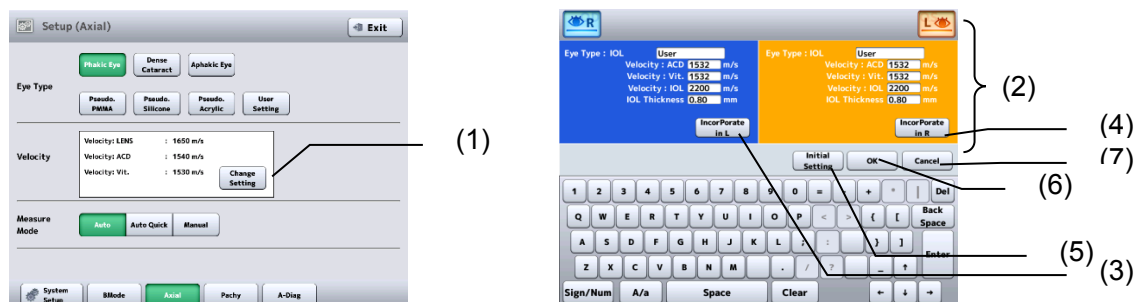
○ : Measurements are displayed.

△ : 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. 1).



(Fig. 1)

- 1) Entry boxes (2) for the acoustic velocities required for the eye currently selected appear. Enter the converted acoustic velocity using the software keyboard.
- 2) After entry, touch the "Enter" key to move to the next entry box. Also, by touching the "Incorporate in L" button (3) or the "Incorporate in R" button (4), the data entered will be applied to the other eye.
- 3) Touch the "Initial Setting" button (5) to enter the initial settings.
- 4) Touch the "OK" button (6) to apply the entry and return to the Setup (Ultrasound Axial) screen. Touch the "Cancel" button (7) 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 acoustic velocity	:	1,532 m/s, 1,430 - 1,630m/s
Vitreous acoustic velocity (divisional velocity only)	:	1,532 m/s, 800 - 2,000 m/s
- 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.

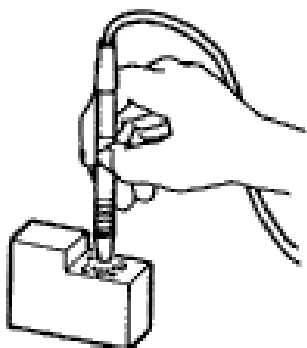
- Auto
Select this for normal measurements.
- Auto Quick
Select this when measurement is difficult. The conditions for "Measurement Complete" will have greater variation than those of Auto.
- Manual
Select this when measurement is difficult in Auto and Auto quick modes.
A foot switch is required for measurement.

d) Setting contact/immersion mode

Complete the settings for contact mode and immersion mode referring to "3.9.2 Measurement."

3.3.2 Operation check

Note *This biometry test piece cannot measure or calibrate the accuracy of the instrument.*



(Fig. 1)

- 1) The biometry test piece provided with the instrument allows you to check the operation of the instrument.
- 2) Select "Aphakic eye" for the eye type to be measured.
- 3) Wet the surface of the test piece and set the biometry probe perpendicular to the surface to start measurement.

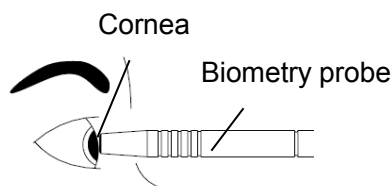
3.3.3 Preparation for measurement

Note *Cooperation by the patient is required to perform measurement smoothly. Explain the measurement method to the patient before starting measurement to help them relax.*

- 1) Check the measurement condition settings and operation as needed.
- 2) Apply topical anesthesia to the eye to be examined.
- 3) Have the patient sit down on a chair or lie on their back so that they are in a comfortable position while measurement is performed.

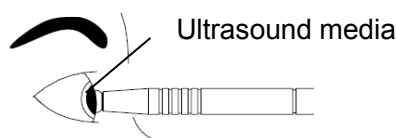
3.3.4 Precautions for measurement

a) Handling the biometry probe in contact/immersion modes



<Contact mode>

Directly apply the contact section of the biometry probe perpendicularly to the center of the cornea.

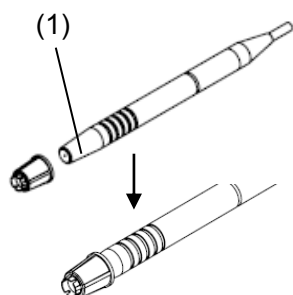


<Immersion mode>

When the immersion attachment is not used

Apply the axial length probe perpendicular to the corneal center where corneal protective media, etc. is applied.

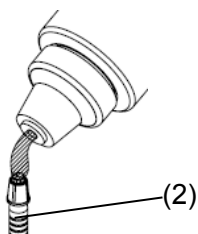
Make sure that the clearance between the cornea and the contact section of the axial length probe is approximately 2.0 – 5.0 mm.



When the immersion attachment is used

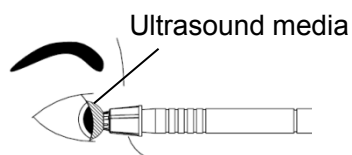
Note ■ *When putting the corneal protective media in the cup at the tip of the immersion attachment, pay extreme attention not to allow air to enter the cup.*
If air is in the cup, measurement cannot be performed or correct measurement cannot be obtained.

(Fig. 1)



(Fig. 2)

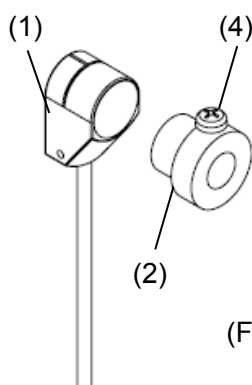
- 1) Lightly apply the corneal protective media etc. to the contact section (1) of the biometry probe and cover the probe with the immersion attachment (Fig. 1).
- 2) Put the corneal protective media (2) in the cup at the tip of the immersion attachment until it rises slightly.
- 3) Set the tip of the immersion attachment perpendicular to the center of the cornea, referring to the biometry probe axis and visual axis. The appropriate position is where the tip of the immersion attachment does not contact the cornea (Fig. 3).



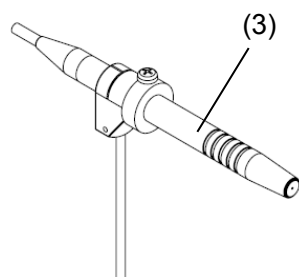
(Fig. 3)

b) Attaching the biometry probe to the applanation tonometer

Use the attachment for applanation tonometer provided with the instrument when measuring axial length with the applanation tonometer.



(Fig. 1)



(Fig. 2)

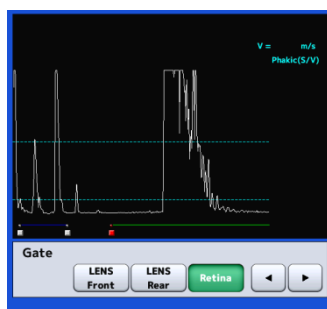
- 1) Firmly hold the prism attachment section (1) of the applanation tonometer with your fingers so that it does not move.
- 2) Insert the applanation tonometer attachment (2) into the prism attachment section from the patient side (Fig.1).
- 3) Insert the biometry probe (3) into the attachment from the physician side, tighten the plastic screw (4) with a screwdriver and secure the biometry probe to the attachment (Fig. 2).
- 4) Secure the measurement knob of the applanation tonometer to the following positions to prevent pressure on the cornea.
 - 10 mmHg when the intraocular pressure of the eye is 20 mmHg or lower
 - 10 mmHg lower than the intraocular pressure when the intraocular pressure of the eye is 20 mmHg or higher

c) Selecting the retina waveform

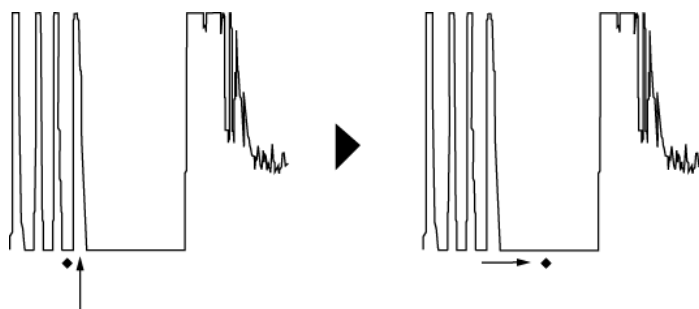
Note

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.

Set the retina gate cursor to the left of the retina waveform when there is a waveform between the waveform on the back of the crystal lens and retina waveform and the instrument cannot recognize the original retina waveform. The instrument recognizes a waveform on the right of the retina gate cursor as the retina waveform and conducts measurement.



Select "Retina" and touch the gate cursor movement button to move the retina gate cursor to the left of the retina waveform.



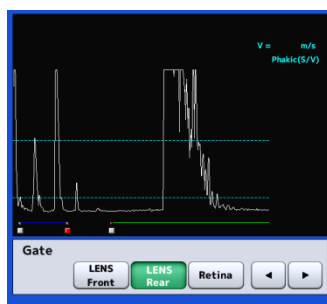
Waveform generated
in the vitreous

Move the cursor to the left
of the retina waveform.

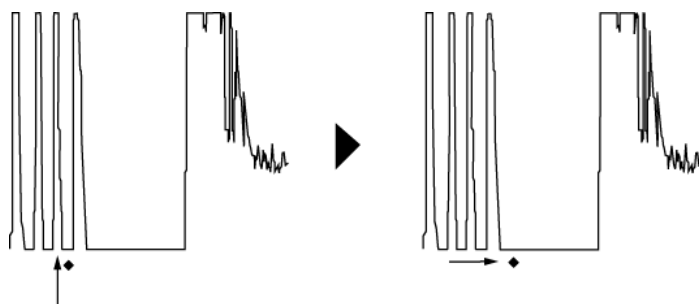
d) Selecting the waveform on the back of the lens

Note ■ *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.*

Set the gate cursor for the back of the lens to the right of the waveform on the back of the lens when there are multiple waveforms in the crystal lens and the instrument cannot recognize the original waveform on the back of the lens. The instrument recognizes a waveform on the left of the gate cursor for the back of the lens as the waveform on the back of the lens and conducts measurement. The gate cursor on the back of the lens can be set only when the eye type is set to “Phakic eye” or “Dense cataract.”



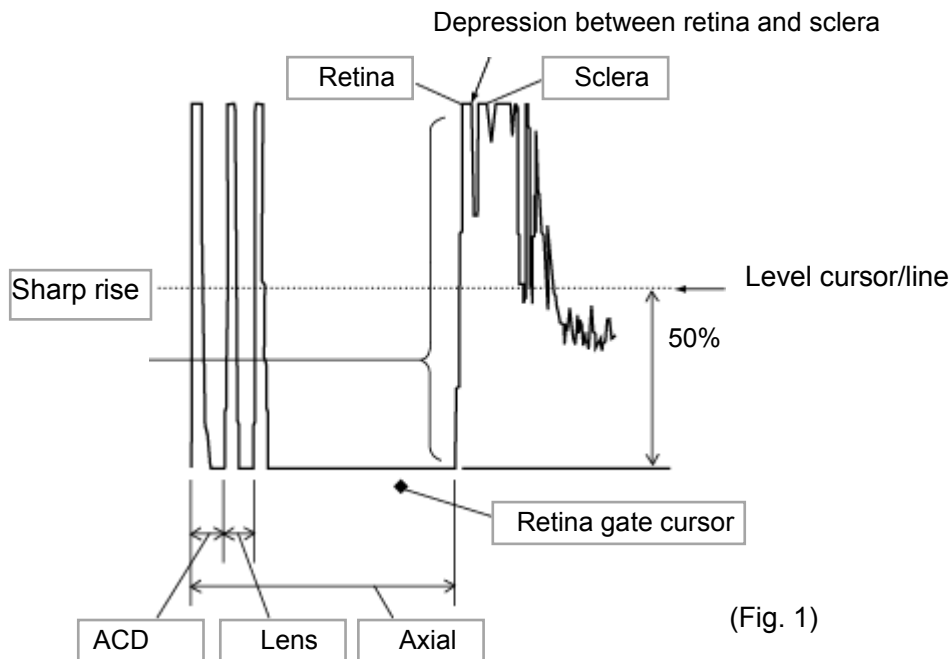
Select “LENS Rear” and touch the cursor movement button to move the lens rear gate cursor to the right of the lens rear waveform.



Waveform generated
in the crystal lens

Move the cursor to the right of
the waveform of the back of the lens.

e) What is a good waveform?



[Contact mode]

The instrument recognizes a waveform as a good one if conditions 1) to 3) listed below are satisfied and captures the measurement data in auto measurement mode.

- 1) Each of the following waveforms rises above the level cursor/line position.

- Eye with initial stage cataracts

Waveform on the front of crystal lens / Waveform on the back of crystal lens /

Retina waveform

- Dense cataract eye

Waveform on the front of crystal lens / Retina waveform

- Aphakic eye

Retina waveform

- IOL eye

Waveform on the front of crystal lens / Retina waveform

- 2) The retina waveform rises vertically. (Ultrasound wave reaches the retina perpendicularly.)

When the waveform slopes upward, the measurement tends to be long.

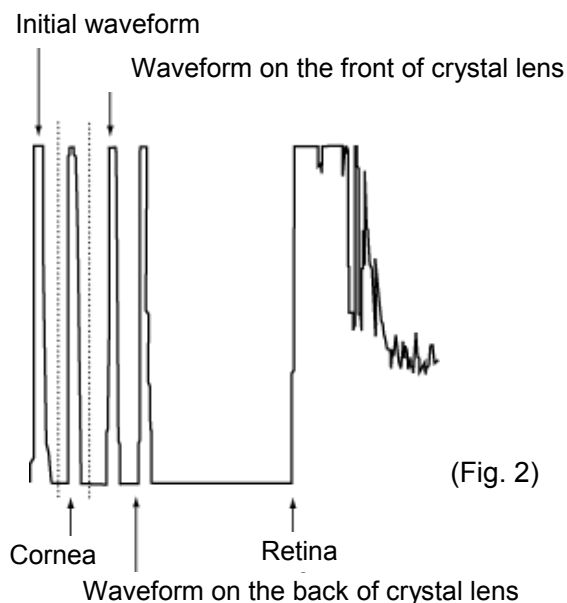
- 3) Within the measurement range

The following is not a requirement for capturing the measurement data, but a method to confirm that the ultrasound wave correctly captures the geometrical axis and ideal waveforms are taken.

- i. When the retina waveform spikes, the ultrasound wave reaches the retina perpendicularly.
- ii. When the waveforms on the front/back of the crystal lens spike, the ultrasound wave correctly captures the geometrical axis.
- iii. When the retina waveform can be distinguished from the sclera waveform, the ultrasound wave reaches the retina perpendicularly. Because the depression between two waveforms (choroid) cannot be confirmed when the gain is set high, etc., these waveforms may not need to be distinguished from each other.
- iv. When there is no tailing that follows the initial waveform (cornea waveform), the biometry probe directly contacts the retina. When there is a layer of tears or cornea protective agent between the probe and cornea, tailing occurs after the cornea waveform. In this case, the measurement data may be unstable or tends to be longer.

[Immersion mode]

The following conditions are added to conditions (1) to (3) in contact mode for automatic measurement in immersion mode.



-
- 4) The cornea waveform is formed within 2.0 – 5.0 mm from the initial waveform.

(Range between the dotted lines in the illustration)

The following is not a requirement for capturing the measurement data, but a method to confirm that ideal waveforms are taken. Check the following together with items i – iv in contact mode.

- v. There are no unnecessary waveforms between the initial waveform and cornea waveform. An unnecessary waveform appears when air bubbles are contained in the ultrasound media in the cup at the tip of the immersion attachment or the media placed between the biometry probe and cornea.

3.3.5 Measurement:



- *Sterilize the biometry probe before use.*
- *Do not use the biometry probe with its contact section damaged. Measurement error may occur, and the cornea may be injured.*
- *Immersion attachment is a disposable part. Do not reuse it. Otherwise, you may contract diseases.*

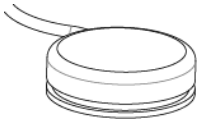


- *The converted acoustic velocity directly affects the measurement data. Check that the desired value is set before starting measurement.*
- *Check the settings in contact mode and immersion mode before starting measurement. In immersion mode, apply an ultrasound media such as cornea protective agent so that the clearance between the cornea and the contact section of the biometry probe is approximately 2.0 – 5.0 mm.*
- *Be very careful not to apply pressure to the cornea when taking measurement. Also, do not apply too much cornea protective agent if used. The measurement data may be affected.*
- *The automatic measurement function is an auxiliary function to take measurements more easily. This is not a function for making actual clinical judgments.*
- *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) Auto measurement

A waveform that satisfies the conditions is captured and up to 10 values are displayed. 20 or more data sets are captured and measurement is completed when variations are within a specific value.

b) Manual measurement

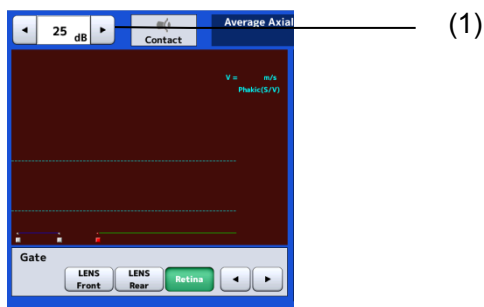


- 1) The instrument beeps when the capturing conditions are satisfied. Press the foot switch to capture the measurement data.
- 2) Press the foot switch again to proceed to the next measurement and take measurements in a similar manner. When 10 data sets are taken, a beep goes off and measurement is completed.

c) Setting gain

Note ■ *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.



Touch the gain adjustment buttons (1) to change the gain.

d) Setting gate cursor

Note ■ *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.*

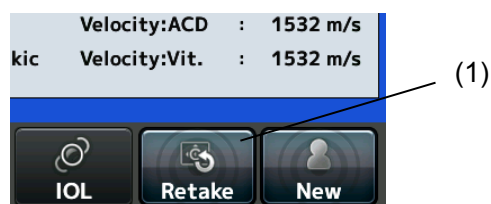


-
- 1) Select a gate cursor to be adjusted by touching the gate selection buttons (1).
The selected and active cursor is displayed in red but the other cursors are displayed in white.
 - 2) Touch the gate cursor movement buttons (2) to set the active gate cursor position.

e) Settings for re-measurement of the same patient

Note ■ *The deleted data cannot be restored. Carefully check the data before deleting it.*

Retain the patient information and delete only the measurement data for each eye.
Delete all data referring to “3.1.5 Deleting all measurement data (measurement preparation for other patient)” when the patient is changed.

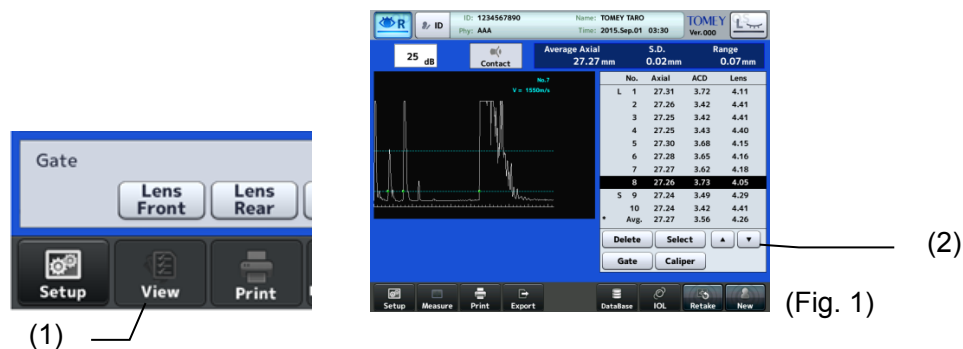


Touch the “Retake” button (1) for approximately 1 second until a beep sounds to delete the data. It retains the patient information and the measurement data of the eye other than the inspected eye being displayed.

3.3.6 Checking waveforms after measurement

a) Displaying waveform of arbitrary measurement data

After all necessary measurement data is captured or when the “View” button (1) is touched, the edit screen (Fig. 1) opens.



- 1) The waveform measured at the selection cursor is displayed. Touch the selection cursor movement buttons (2) to move the cursor up or down.

The following marks are assigned to the measurement data.

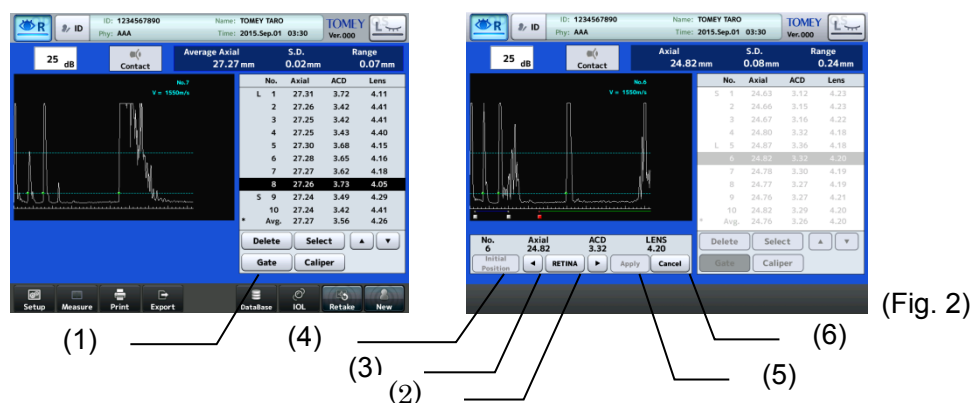
- * : Data used for calculating IOL power
- L : Longest axial length
- S : Shortest axial length
- C : Callipered data

b) Deleting and recovering measurement values



- 1) Touch the “Delete” button (1) to delete the data at the selection cursor. 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 using the “Return” button even when the screen is switched to the edit screen again.

c) Gate change function

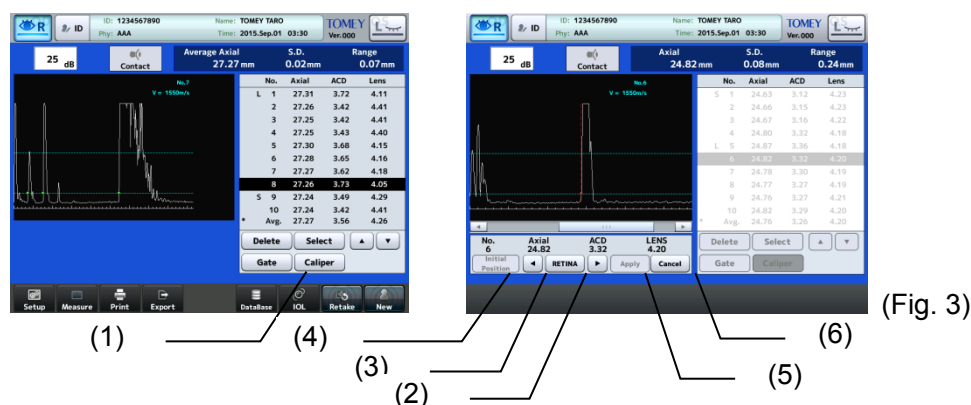


- 1) Touch the “Gate” button (1) to open the change gate screen (Fig. 2).
- 2) Touch the gate cursor selection buttons (2) to select the gate cursor to be changed.
- 3) Touch the “gate cursor movement” buttons (3) to change the position of active gate cursor. The modified measurement data is displayed in the edit data display field along with the movement of the gate cursor.
- 4) Touch the “Initial position” button (4) to discard changes.
- 5) Touch the “Apply” button (5) to define the changes and closes the change gate screen. If the “Cancel” button (6) is touched, the changes made are discarded and the change gate screen is closed.

d) Caliper function

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

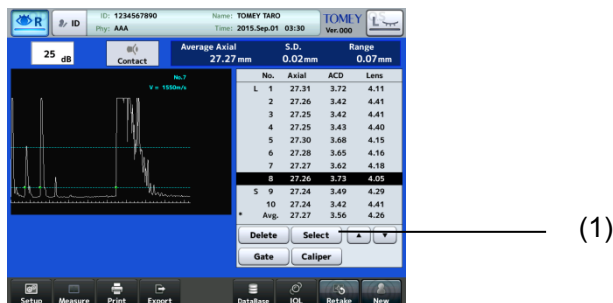
This function is used to measure the distance of the measurement waveform. Dotted caliper lines appear and the distance to the selected caliper line is displayed.



- 1) Touch the "Caliper" button (1) to open the caliper screen (Fig. 3).
- 2) Touch the "Switch" button (2) to select the caliper line to be changed.
- 3) Touch the caliper line movement buttons (3) to change the active caliper line position. The modified measurement data is displayed in the edit data display field (4) along with the movement of the caliper line.
- 4) Touch the "Initial position" button (4) to discard changes.
- 5) Touching the "Apply" button (5) will apply the changes made and close the caliper screen. Touching the "Cancel" button (6) will discard the changes made, and the caliper screen is closed.

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.



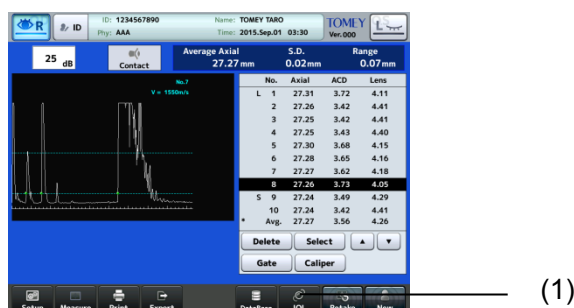
- 1) Move the selection cursor to the data which is to be used in calculating the IOL power. To use the average value in IOL power calculation, move the selection cursor to the average data at the bottom.
- 2) When the "Select" button (1) is touched, it is selected as the data to be used in calculating the IOL power, and a "*" appears on the left of the data.

3.4 IOL power calculation

Note ■ When using measurement results for calculation of the IOL power, the physician must examine the measurement result beforehand.

■ Refer to "3.8 Export, print, and save" for waveforms printed and exported from the IOL calculation screen.

Touch the "IOL" button (1) located on each screen to open the IOL power calculation screen.



3.4.1 Calculation

Note ■ When using measurement results for calculation of the IOL power, the physician must examine the measurement result beforehand.

■ Calculation by this instrument may cause some errors due to the number of significant digits in internal calculations.

■ 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.

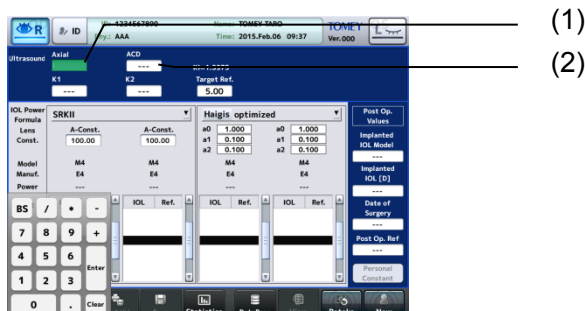
This instrument automatically starts calculation and displays the result when all items required for IOL power calculation are set.

3.4.2 Entering calculation parameters

a) Axial length and anterior chamber depth

When an axial length and anterior chamber depth measurement is completed, the measurement data is already entered automatically and cannot be entered manually.

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



- 1) Touch the axial length input field (1) or the ACD input field (2) to activate it. Enter the data and touch the “Enter” key to apply the data.

[Input range]

Axial length : 13.00 - 45.00 mm

Anterior chamber depth : 0.00 - 10.00 mm

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



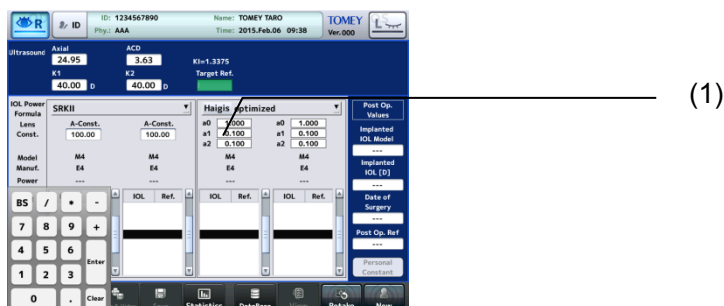
- 1) Touch the K1 input field (1) or K2 input field (2) to activate it. Enter the data and touch the “Enter” key to apply the data.

[Input range]

Corneal refractive power : 30.00 - 60.00D

Radius of corneal curvature : 5.00 - 11.00 mm

c) Target Ref.



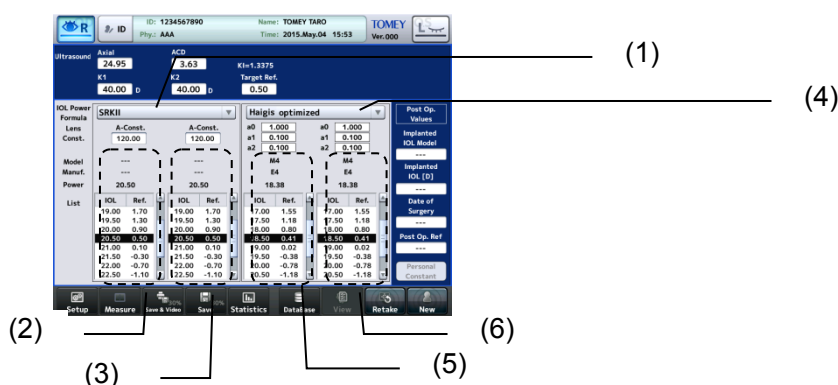
- 1) When the converted sonic velocity entry field (1) is touched, it is activated. Enter the data and touch the “Enter” key to apply the data.

[Input range] Angle : -30.00 - +10.00

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 4 constants for 1 formula simultaneously. The formula (1) corresponds to lenses (2) and (3), and the formula (4) corresponds to lenses (5) and (6). There are 2 ways to enter the values. One is to enter them directly using the keypad, and the other is by selecting them from the IOL data list.



• 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.



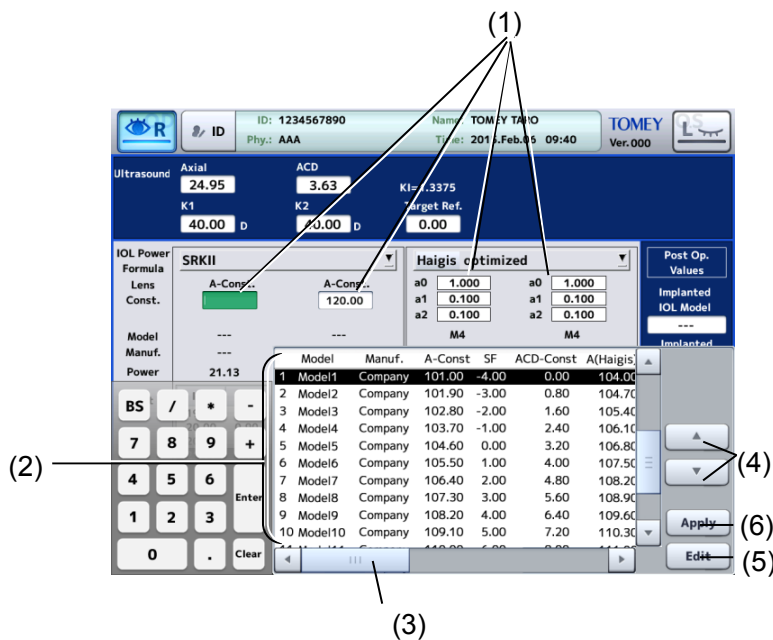
- 1) Touch an input field (1) to activate it. The keypad (2) appears. Enter the data and touch the “Enter” key to apply the data.

[Input range]

A-constant : 100.00 - 130.00
 ACD-constant : 0.00 - + 10.00
 SF : - 5.00 - + 10.00

■ Entering through IOL data list

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



- 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 is selected as the formula.

The screenshot shows the TOMY IOL Master software interface. At the top, there is a header bar with patient information: ID: 1234567890, Name: TOMY TARD, Time: 2015.Feb.06 09:44, and Ver.000. Below this, there are several input fields for patient data. The main area is divided into sections for 'Ultrasound', 'IOL Power', and 'Haigis optimized'. The 'IOL Power' section is currently selected, showing 'Double K SRK/T' as the formula. It includes fields for 'A-Const.', 'A-Const.', 'Model', 'Manuf.', and 'Power'. The 'Haigis optimized' section shows a table of IOL and Ref. values. On the right side, there is a 'Pos. Op. Values' pull-down menu. Numbered callouts (1) through (4) point to specific fields: (1) points to K1pre, (2) points to Ref.post, (3) points to Kpost, and (4) points to the 'Pos. Op. Values' pull-down menu.

- 1) Enter the corneal refractive power or radius of corneal curvature before the surgery for correcting the refractive power in K1pre and K2pre fields.
- 2) Manually enter eye refractive power before refractive correction surgery in Ref.pre (S,C) (1) and eye refractive power after refractive correction surgery in Ref.post (S,C) (2).
- 3) 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 (3). The data can be entered directly. However, Ref.pre (S,C) and Ref.post (S,C) cannot be entered.
- 4) Select the distance between the vertexes (V.D.) from the pull-down menu (4).
C.L./12.0/13.5/14.0/15.5/16.0

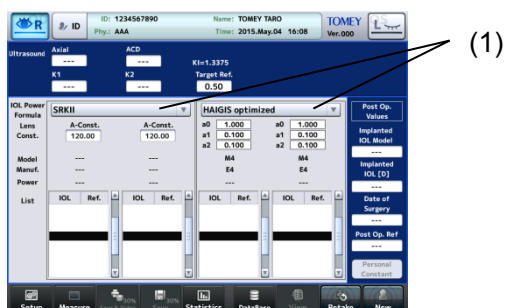
3.4.3 Setting calculation formula

Touch the calculation formula pull-down button (1) and select a formula.

The following 9 types of IOL power calculation formulae are provided with this instrument.

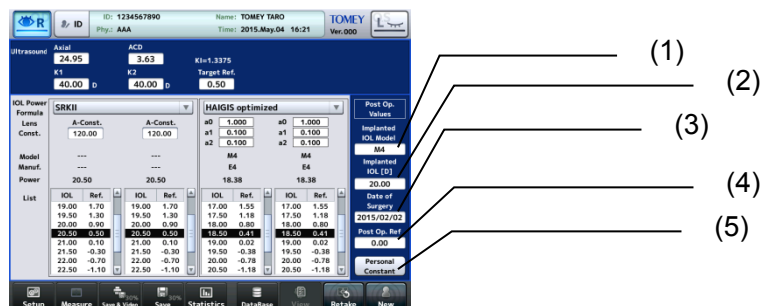
The IOL calculation formulae listed in the pull-down menu can be set as described in “3.9.3 b) Selecting IOL power formula.”

- Haigis standard formula
- Haigis optimized formula
- Hoffer® Q formula
- Holladay 1 formula
- SRK-II formula
- SRK/T formula
- SRK SHOWA formula
- Shammas-PL formula
- SRK/T Double K formula

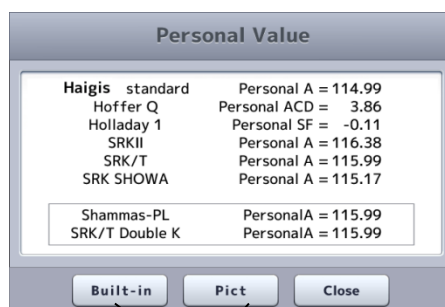


3.4.4 Entering data after surgery

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



- 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 after 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. 1) appears. Touch the "Print" button (6) to print the personal constants only.



(Fig. 1)

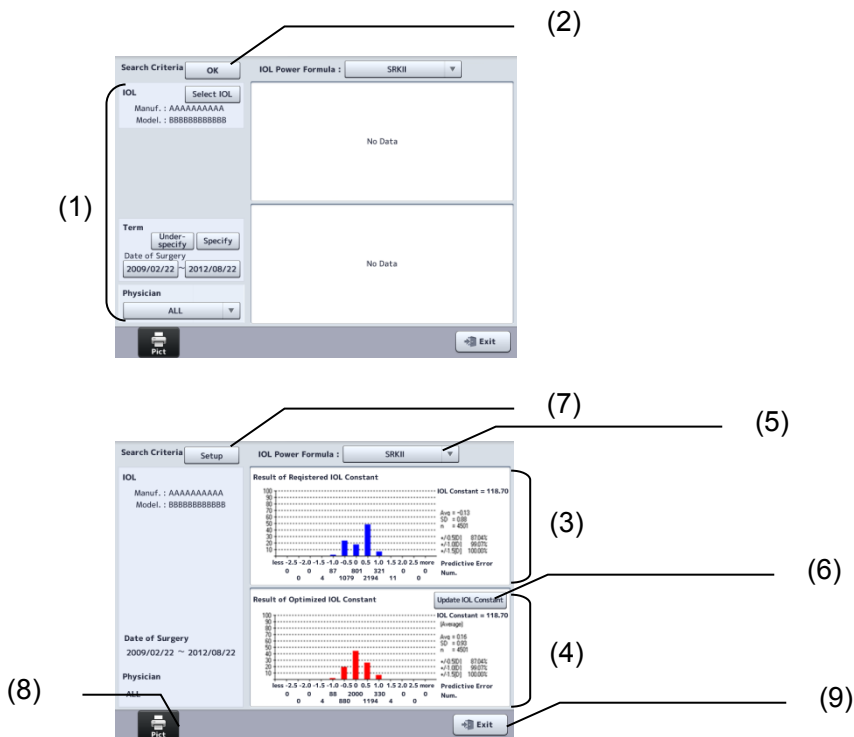
(6)

3.5 Statistical processing

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

Statistical processing can be performed on this screen using the examination data accumulated in the facilities. Predictive errors when using the registered lens constant are calculated and the histogram is displayed. In addition, the optimized lens constant can be calculated and registered according to the statistical processing result.

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



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

- IOL : Select IOL. Touch the "Select IOL" button. The IOL data selection screen appears to allow you to select an IOL model.
- Term (data extraction term) : Set the term subject to statistical processing.
- Physician : The registered physician IDs are displayed in the pull-down menu. "All" includes all physicians.

-
- 1) After all the conditions are set, touch the “OK” button (2). Statistical 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 statistical processing results of those lens constants. When lens constants are not registered, the result does 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 statistical 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]
 - 2) Select an IOL power formula (5). Available formulae are as follows.
 - Haigis standard formula
 - Haigis optimized formula
 - Hoffer[®] Q formula
 - Holladay 1 formula
 - SRK-II formula
 - SRK/T formula
 - SRK SHOWA formula
 - Shammas-PL formula
 - SRK/T Double K formula
 - 3) 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.
 - 4) Touch the “Setup” button (7) to re-set filter conditions.
 - 5) Touch the “Print” button (8) to print the displayed results.
 - 6) Touch the “Exit” button (9) to close the statistical processing screen.

3.6 Pachymetry function

Refer to “3.1.3 Switching modes” for how to enter pachymetry mode.

3.6.1 Setting the data type to be displayed

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

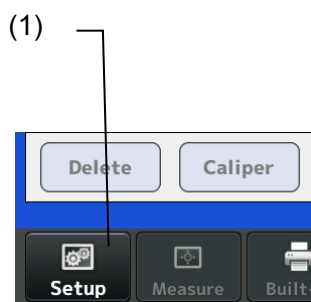
- Latest : Displays the last measurement data taken.
- Minimum : Displays the minimum value of measurement data.
- Average : Displays the average of measurement data.

Make settings, referring to the instrument settings “measurement settings.”

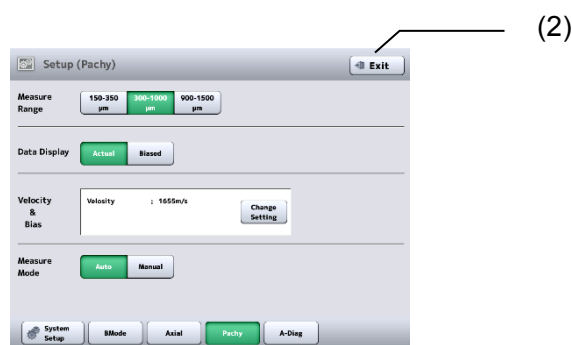
3.6.2 Setting measurement conditions

Note ■ *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 - 350μm
- 300 - 1000μm
- 900 - 1500μm

b) Selecting measurement values to be displayed

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

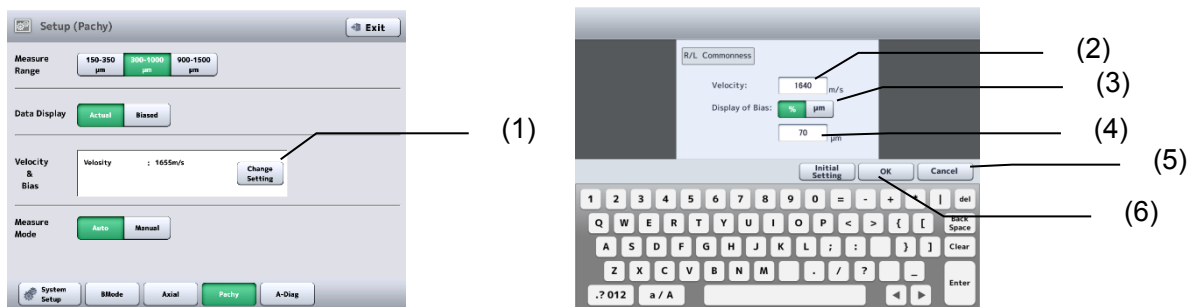
- Actual measurement
- Bias value

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 or 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 value (Fig. 3).



(Fig. 3)

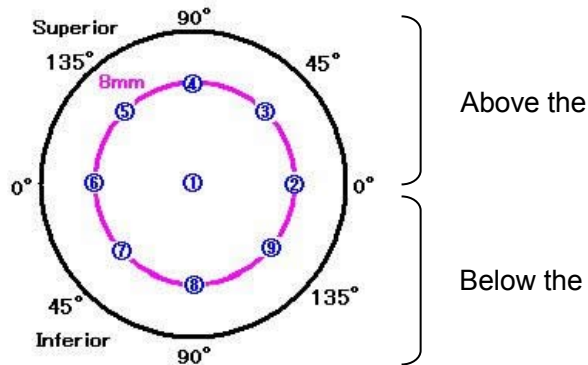
- 2) When the converted sonic velocity entry field (2) is touched, it is activated. Enter the converted sonic velocity using the software keyboard. Input range of converted acoustic velocity: 1400 - 2000 m/s
- 3) Touch the "Display of Bias" button (3) to select the percentage bias (%) or plus/minus bias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

d) Measurement mode

Set the measurement mode.

- Auto mode : Select this for measurement in Auto mode.
- Manual mode : Select this when measurement is difficult in Auto mode.

3.6.3 Displaying and setting measurement points

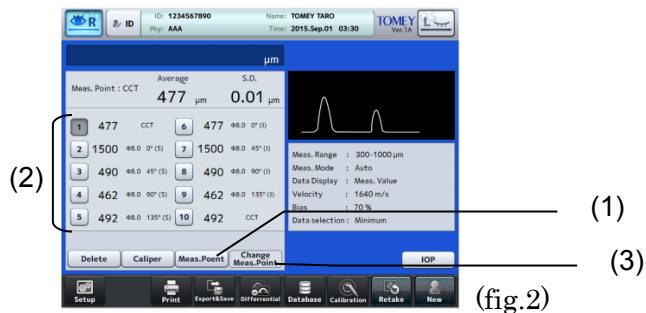


The measurement point indicates “diameter – angle – S/I.”

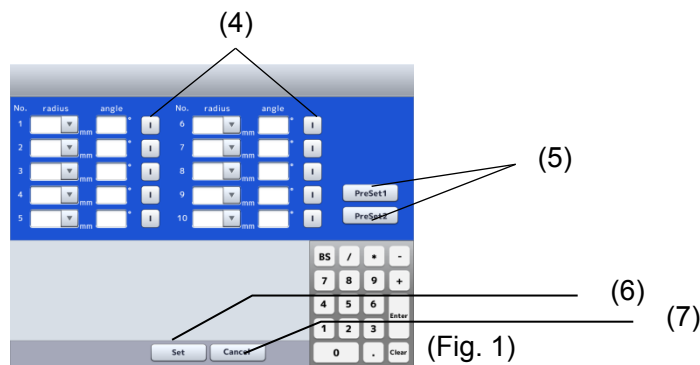
- Radius : Radius from the center (mm)
- Angle : The upper and lower angles (°) when regarding the horizontal axis as zero degrees
- S/I : Section above the horizontal axis (Superior), section below the horizontal axis (Inferior)

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).



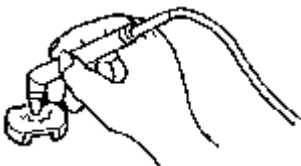
- 2) Touch the “Change Meas. Point” button (3) to open the measurement point change screen (Fig. 1) to change the measurement point.



- 3) Touch the input field to activate it. 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 preset values. (Refer to "3.9.2 d) Measurement setting Axial.")
- 5) Touch the "Set" button (6) to define the settings. Touch the "Cancel" button (7) to discard the settings and close the measurement point change screen.

3.6.4 Operation check

Note ■ *The corneal thickness test piece is for operation checks. This test piece cannot measure or calibrate the accuracy of the instrument.*



(Fig. 1)

The corneal thickness test piece allows you to check the operation of the instrument.

- 1) Select "Auto" for the measurement mode.
- 2) Place the test piece in water and set the pachymetry probe perpendicularly to start measurement.

3.6.5 Preparation for measurement

Note ■ *Cooperation by the patient is required to perform measurement smoothly. Explain the purpose of the examination and measurement method to the patient before starting measurement to help them relax.*

- 1) Check the measurement condition settings and operation as needed.
- 2) Apply topical anesthesia to the eye and have the patient sit down on the chair or lie on their back so that they are in a comfortable position while measurement is performed.

3.6.6 Measurement:



■ *Sterilize the pachymetry probe before use.*

■ *Do not use the pachymetry probe with its contact section damaged. Measurement error may occur, and the cornea may be injured.*



■ *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.*

■ *When the surface of the cornea is dry, wet it with saline solution.*

■ *The automatic measurement function is an auxiliary function to take measurements more easily and is not a function used to actually make clinical judgment. The physician must examine the measurement result before using it.*

a) Auto measurement

- 1) Set the pachymetry probe perpendicular to the point to be measured.
- 2) The instrument automatically starts capturing measurement data when capturing conditions are satisfied.
- 3) A beep sounds when the measurement data is captured.
- 4) When 20 sets of measurement data are captured, a beep sounds twice to indicate completion of measurement.
- 5) When the pachymetry probe is removed from the cornea, the next memory slot enters standby mode. Measurement is completed and the next memory slot enters standby mode when the probe is removed from the cornea even before 20 data sets are captured.
- 6) Take measurements for all 10 memory allotments in the same manner.
- 7) When retaking measurements in a specific memory slot during or after measurement, touch the desired memory number to enter standby mode and perform measurement again.

b) Manual measurement

- 1) Set the pachymetry probe perpendicular to the point to be measured.
- 2) The instrument beeps when the capturing conditions are satisfied.

- 3) Step on the foot switch to capture measurement data. A beep sounds when the measurement data is captured.
- 4) Repeat measurements in the same manner. When 10 sets of measurement data are taken, a beep sounds to indicate completion of measurement.
- 5) To take measurement data in the next memory slot before 10 sets of measurement data have been taken, touch the next memory number to enter standby mode and perform measurement.
- 6) When the pachymetry probe is removed from the cornea, the next memory slot enters standby mode.

c) Re-measurement of the same patient

Note ■ *The deleted data cannot be restored. Carefully check the data before deleting it.*

Retain the patient information and delete only the measurement data for each eye. Delete all data referring to “3.1.5 Deleting all measurement data (measurement preparation for other patient)” when the patient is changed.

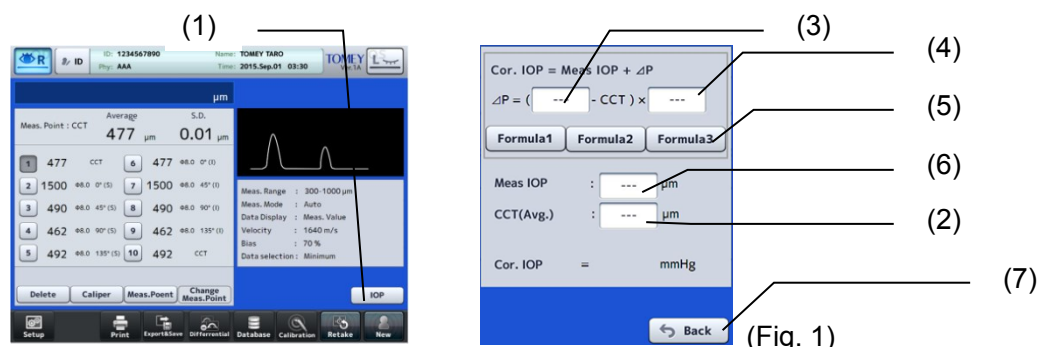


Touch the “Retake” button (1) for approximately 1 second until a beep sounds to delete the data. The patient information is retained and the measurement data of the eye other than the inspected eye being displayed.

3.6.7 Checking 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.



- 1) Touch the “IOP” button (1) to open the intraocular pressure correction screen (Fig. 1). 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 in them, the average of the CCTs is displayed. When measurement points are not set, the average of all memory numbers is displayed.

- 2) The input fields of the 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 (5) 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

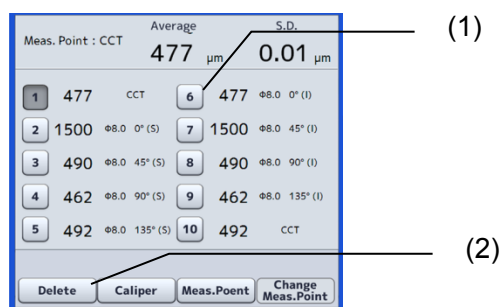
- 3) Enter the intraocular pressure data. Touch the input field (6). The keypad appears.

[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. 1) and return to the previous screen.

b) Deleting part of measurement data

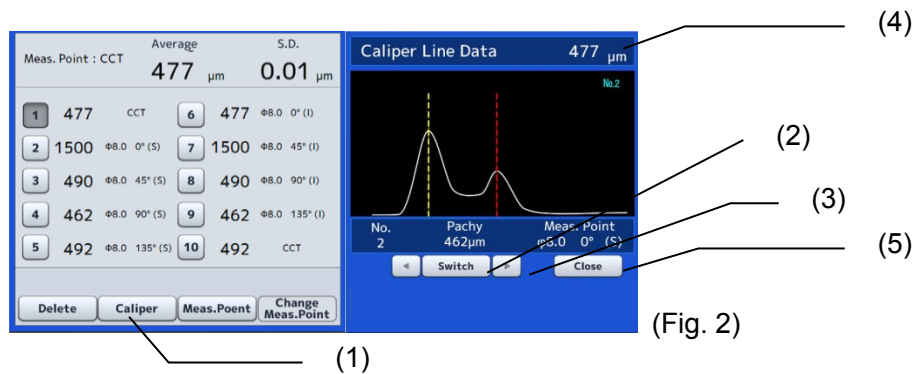


- 1) Touch a memory number button (1) to select the measurement data to be deleted.
- 2) Touch the “Delete” button (2) to delete the selected measurement data, and the average and the standard deviation of the corneal thickness are recalculated.
- 3) If you have deleted data mistakenly or want to cancel the deletion, select that data number and you will see that the “Delete” button (2) will change to the

“Return” button (3). 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

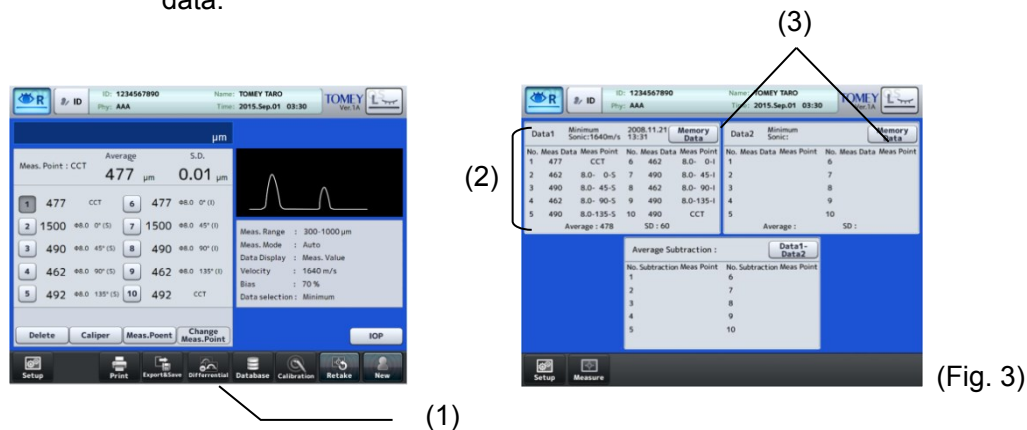
The caliper function is for temporary reference and cannot store the callipered data. The caliper screen cannot be opened while a bias value is selected.



- 1) Touch the "Caliper" button (1) to display the caliper screen (Fig. 2).
- 2) Touch the “Switch” button (2) to select a caliper line to be adjusted.
- 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.

d) Difference display function

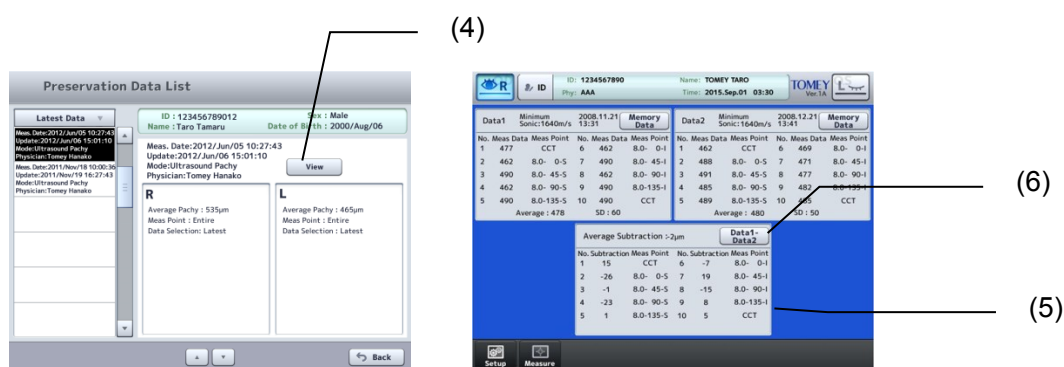
This function displays the difference value between the 2 selected measurement data.



- 1) Touch the “Differential” button (1) to open the difference display screen (Fig. 3).
- 3) When a measurement has already been completed at this point, the

measured values are displayed in the data 1 display field (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 stored in a USB memory. (Fig. 4) If a patient ID has not been selected, however, the Preservation Data List screen (a list of patient IDs stored in a USB memory) opens. Refer to “3.8.3 Saved data management.”



(Fig. 4)

- 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 difference value between Data 1 and Data 2 is displayed in the difference 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.
- 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 difference value of Data 2 - Data 1 will be displayed.

3.7 A mode diagnosis

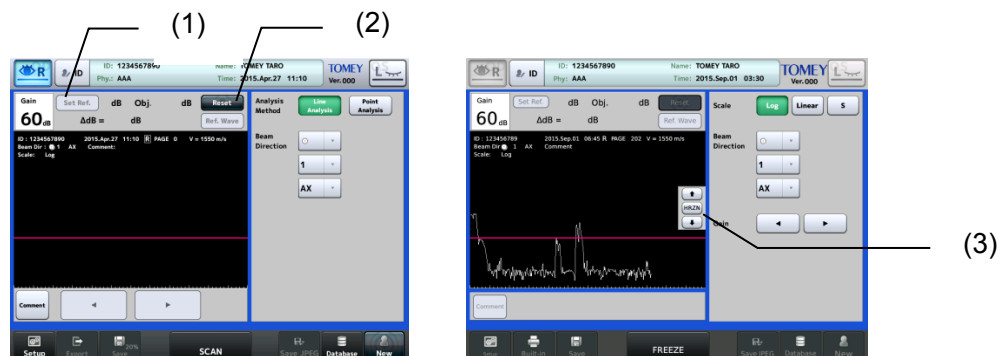
3.7.1 Connecting the probe

Connect the A-scan diagnosis probe to the instrument.

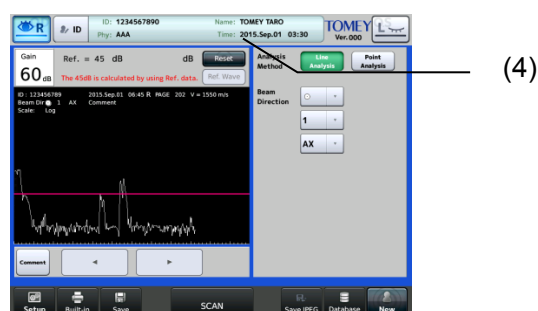
3.7.2 Switching to A mode diagnosis function

Refer to “3.1.3 Switching modes” for how to enter A mode diagnosis mode.

3.7.3 Registering Ref. Data



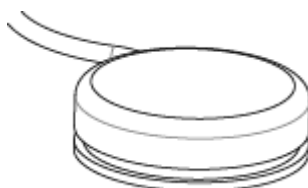
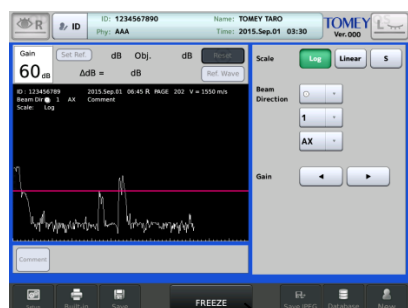
Load the reference data for line analysis. Loading of data and adjustment of gains will be described later. Adjust the line position with the “HRZN” (select line position) button (3) as needed and touch the “Set Ref.” button (1) to register the line position after freezing. The registered Ref. data will be retained even after turning power off. Hold the “Reset” button (2) briefly to delete the data.



After registration, touching the “Ref. Wave” button (4) displays the message “The Δ dB is calculated by using Ref. data” and reference waveforms.

3.7.4 Measurement:

Note ■ CVCooperation by the patient is required to perform examination smoothly. Explain the examination method to the patient before starting the examination to help them relax.



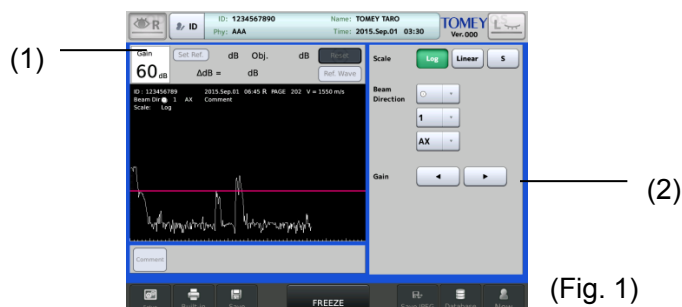
(1)

Apply an appropriate amount of cornea protective agent to the contact section of the A-scan diagnosis probe, and apply the probe to the eye to be examined. Adjust the total gain, and touch the “FREEZE” button (1) or step on the foot switch to capture waveforms.

3.7.5 Setting gain

Note ■ Settings made are only effective for the eye currently selected.

Adjust the waveform height according to the gain settings.

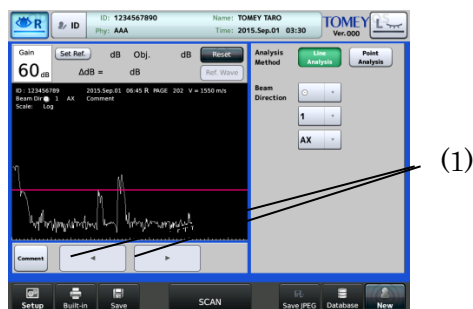


(Fig. 1)

The gain value (1) shown in the upper left of the measurement screen (Fig. 1) can be adjusted with the gain adjustment buttons (2).

The applicable setting range is 0 - 80 dB.

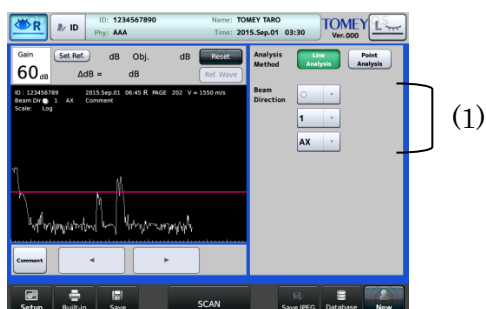
3.7.6 Switching data display



This instrument stores waveforms for up to 100 data sets. Captured waveform data is displayed in order every time the frame advance/retract buttons (1) is touched.

3.7.7 Setting the beam direction

Use the beam direction tabs (1) to change the position to apply the probe or the direction of the ultrasound beam, or to display the position of a point of note (with pathological changes, etc.).



Probe set angle selection button: 9 directions

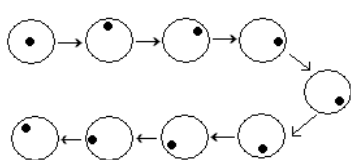
Beam direction 1: This helps indicate the angle of the meridian.

1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12

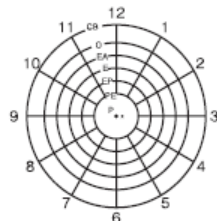
Beam direction 2: This helps to specify a notable point in an eyeball.

AX, P, PE, EP, E, EA, O, CB

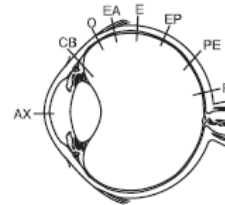
(Probe set angle)



(Beam direction 1)

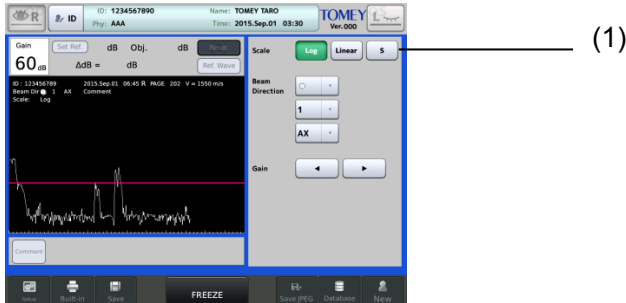


(Beam direction 2)



3.7.8 Gradation characteristics function

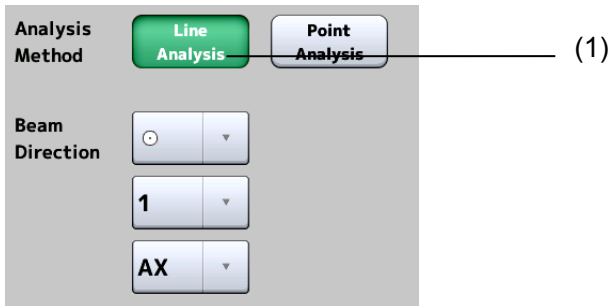
When executing line analysis, select “Log, Linear or S” (1) for the gain curve that converts ultrasound waves obtained by receiving ultrasound wave echoes generated from the ultrasound transducer.



3.7.9 Analysis functions

a) Line analysis

- 1) Select “Line Analysis” (1) for Analysis Method.



- 2) Select “LINE” for Analysis Method.

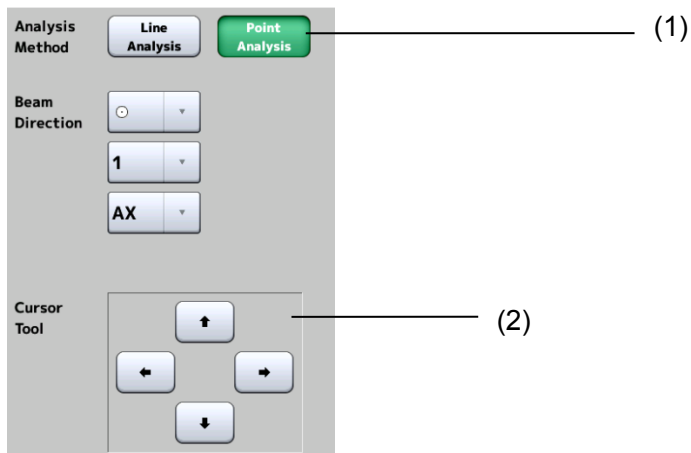
If the reference waveform is not yet registered, register it referring to the aforementioned “Registering Ref. Data.”



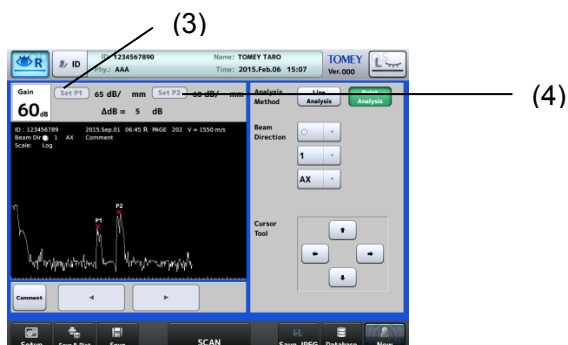
- 3) Take a measurement. Adjust the gain so that the peak of the target section is aligned with the light height and take measurements.
The gain when measuring the target section, reference gain, and the difference between them are shown (2).

b) Point analysis

- 1) Select "Point Analysis" (1) for Analysis Method.



- 2) After measurement is completed, the "X" cursor appears on the waveform monitor. Move the cursor by touching the screen or using the cursor movement button (2), and touch the "SetP1" button to set the gain value at the cursor position as P1.



- 3) Move the cursor to the next point position and touch the "SetP2" button (4) to set the gain as P2. Two gains and the difference between them are shown.
- 4) When the point position needs to be corrected, move the cursor and touch the "SetP1" or "SetP2" button again. The point position is overwritten and the difference is re-calculated.

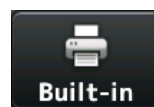
3.8 Export, print, and save

Set desired functions to 2 buttons for Export, Print, and Save provided on the operation screen before executing the export, print, and save functions. (Refer to “3.9.4 a) Setting functions of save, export, and print buttons.”)

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



Export



Print



Save



Export & Save



Export & Print



Save & Print



ALL (internal)

3.8.1 Export

Note ■ The network support system “TOMEY Link” (optional) or the examination data transfer software “DATA Transfer” (included in the package) is required for data communication.

■ Refer to the corresponding operation manual for the TOMEY Link and DATA Transfer settings.

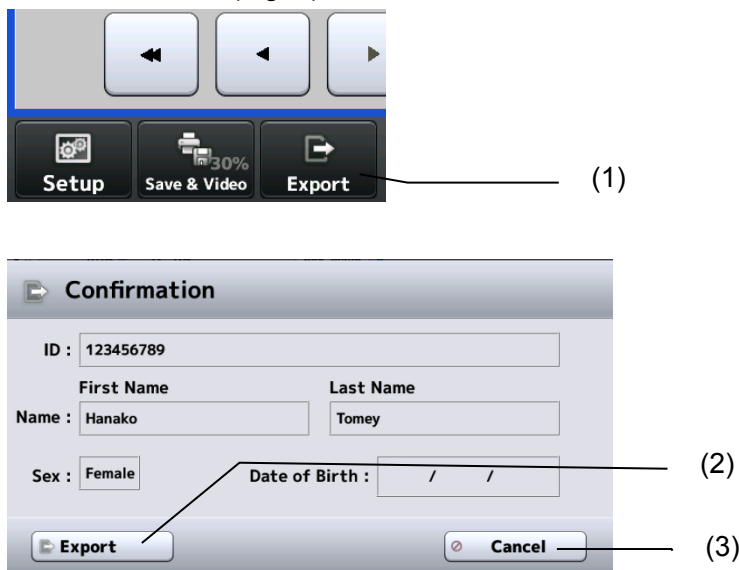
■ Connection setting is required for connecting with TOMEY Link and DATA Transfer. Refer to “3.9.4 c) PC setting” to make settings.

■ **Data cannot be sent in some configurations if the ID number is not entered. Refer to “3.9.1 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 traced 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. In addition, when data is sent to TOMEY Link, all data without ID numbers is regarded as data of the same patient, so must be handled with great care to avoid mishandling.**

■ **Waveforms of the same form as those to be printed out are output. Refer to “3.8.2 Print” for details.**

- 1) Touch the “Export” button (1) to open the Transmission confirmation screen (Fig. 2).



(Fig. 2).

- 2) The transfer confirmation screen (Fig. 1) displays patient ID, patient name, and sex. Touch the "Export" button (2) to start sending data. Touching the "Cancel" button (3) returns you to the previous screen without sending data.

3.8.2 Print

The printer and printing type can be selected in the system setup. Refer to “3.9.4 b) Selecting and setting printer.”

[Printing by built-in printer]

Note ■ *Different waveforms are printed depending on the screen in biometry mode.*

Waveforms to be printed on each screen are as below.

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) — YMD:2015/Jun/17 19:47:09
 (2) — UD-800 Ver.00
 (3) — Clinic ID/Name:
 (4) — TOMEY CLINIC
 Clinic Address:
 ABCDEFGHIJKLMNOPQRSTU
 (5) — ID : 123456789012
 (6) — Name : TOMEY TARO
 (7) — Sex : Female
 (8) — Phys : YAMADA

RIGHT

Auto

Phakic(M/V)

Velocity : Avg. 1550m/s

Velocity : ACD 1532m/s

Velocity : LENS 1641m/s

Gain : 20dB

Avg. AXIAL : **25.12**mm

SD : 0.07mm

RANGE : 0.20mm

Avg. ACD : 3.38mm

Avg. LENS : 4.35mm

NO AXIAL ACD LENS

1 25.12 3.39 4.70

25.12 3.39 4.35

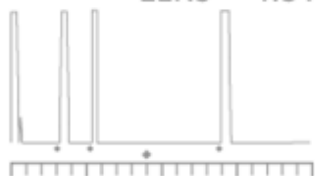
Avg 25.12 3.39 4.35

No.6

AXIAL 24.13

ACD 3.39

LENS 4.31



Print:2015/Jun/19 19:55

TOMEY CORP.

Probe:Axial 10MHz

Frequency : 10MHz

Measuring Fault : 0.1mm

Resolution : 0.6mm

Time Distance : 0.1s

Running Time : 0.13us

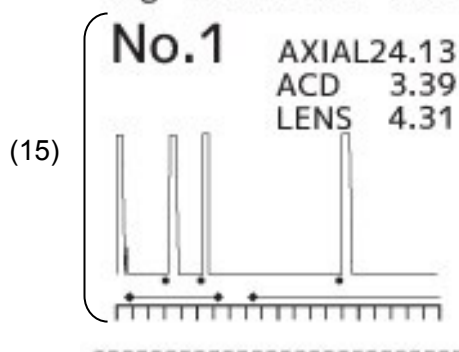
- 1) Measurement date and time
- 2) Product Name
- 3) Clinic ID/Name
- 4) Address of clinic
- 5) Patient ID
- 6) Patient's name
- 7) Sex
- 8) Physician's name
- 9) Printing date/time
- 10) Character string defined by user
- 11) Measurement information

b) Example printout of axial length

(1) — **RIGHT**
 (2) — Auto
 (3) — Contact
 (4) — Phakic(M/V)
 (5) — Velocity : Avg. 1550m/s
 Velocity : ACD 1532m/s
 Velocity : LENS 1641m/s
 (6) — Gain : 20dB
 (7) — Avg. AXIAL: **25.12**mm
 (8) — SD : 0.07mm
 (9) — RANGE : 0.20mm
 (10) — Avg. ACD : 3.38mm
 (11) — Avg. LENS : 4.35mm

NO	AXIAL	ACD	LENS
1	25.13	3.39	4.70
2	25.15	3.43	4.31
3	25.23	3.48	4.31
(13) — c 4	25.20	3.46	4.31
5	25.15	3.41	4.31
6	25.13	3.39	4.31
7	25.05	3.34	4.31
8	25.05	3.31	4.34
9	25.03	3.31	4.31
10	25.03	3.29	4.31
(14) — * Avg	25.12	3.38	4.35

- 1) Measurement eye (right eye/left eye)
- 2) Measurement mode
- 3) Contact immersion
- 4) Measured eye type
- 5) Converted acoustic velocity
- 6) Gain
- 7) Average axial length
- 8) Standard deviation of axial length
- 9) Difference between shortest axial length and longest axial length
- 10) Average anterior chamber depth
- 11) Average lens thickness
- 12) Measurement data (axial length/anterior chamber depth/crystal lens thickness)
- 13) Caliper mark
- 14) Value used for calculating IOL
- 15) Waveform



c) Example printout of corneal thickness

(1) —	RIGHT
(2) —	Auto Minimum
(3) —	Velocity : 1640m/s
----- Actual-----	
(4) {	1 477µm CCT
	2 472µm 8.0mm 0°S
	3 490µm 8.0mm 30°S
	4 479µm 8.0mm 60°S
	5 485µm 8.0mm 90°S
	6 476µm 8.0mm 120°S
	7 470µm 8.0mm 150°S
	8 484µm 8.0mm 170°S
	9 475µm 10.0mm 0°S
	10 476µm 10.0mm 170°S
(6) —	Avg. : 478µm SD : 5.9µm (7)
----- 70% Biased-----	
(9) {	1 333µm CCT
	2 330µm 8.0mm 0°S
	3 343µm 8.0mm 30°S
	4 335µm 8.0mm 60°S
	5 339µm 8.0mm 90°S
	6 333µm 8.0mm 120°S
	7 329µm 8.0mm 150°S
	8 338µm 8.0mm 170°S
	9 332µm 10.0mm 0°S
	10 333µm 10.0mm 170°S
(10) —	Avg. : 335µm SD : 4.1µm (11)

(12) {	IOP CALCULATION
(13) —	PARAMETER1 : 554
(14) —	PARAMETER2 : 0.0450
(15) —	CCT(Avg.) : 478µm
	Meas. IOP : 25.0mmHg
	Cor. IOP : 28.4mmHg

- 1) Measurement eye (right eye/left eye)
- 2) Measurement mode / Type of displayed data
- 3) Converted acoustic velocity
- 4) Actual measurement in each memory slot
- 5) Measurement point of measurement data
- 6) Average of actual measurements
- 7) Standard deviation of actual measurements
- 8) Bias value display method and bias rate or correction
- 9) Bias Value (for each memory)
- 10) Average of bias values
- 11) Standard deviation of bias values
- 12) Intraocular pressure correction parameter
- 13) Average corneal thickness
- 14) Intraocular pressure
- 15) Corrected intraocular pressure

d) Printout of IOL power calculation

```

(1)  RIGHT
      Input Parameters (US)
(2)  AXIAL      : 23.84mm
(3)  ACD       : 2.47mm
(4)  K1        : 30.00D
      K2        : 35.00D
(5)  Keratometric
      Index     : 1.3375
(6)  Target Ref. : -1.00D
      (Clinical History)
      PreK1     : 32.00D
      PreK2     : 34.21D
      PostK      : 31.00D
(7)  Pre REF S  : 5.00D
      Pre REF C  : -1.00D
      Post REF S  : 2.00D
      Post REF C  : 0.00D
      V.D.      : 12.0mm

(8)  SRK/T
(9)  IOL-01
      MAKER 1
(10) Aconst    IOL  Ref.
      117.00   13.00 1.74
(11) Power     13.50 1.34
      16.43    14.00 0.94
           14.50 0.54
           15.00 0.14
           15.50 -0.26
           16.00 -0.66
           16.50 -1.06
           17.00 -1.46
           17.50 -1.86
           18.00 -2.26
           18.50 -2.66
           19.00 -3.06
           19.50 -3.46
           20.00 -3.86

      SRK/T
      IOL-02
      MAKER 2
      Aconst    IOL  Ref.
      117.00   13.00 1.74
      Power     13.50 1.34
      16.43    14.00 0.94
           14.50 0.54
           15.00 0.14
           15.50 -0.26
           16.00 -0.66
           16.50 -1.06
           17.00 -1.46
           17.50 -1.86
           18.00 -2.26
           18.50 -2.66
           19.00 -3.06
           19.50 -3.46
           20.00 -3.86
  
```

- 1) Measurement eye (right eye/left eye)
- 2) Axial length
- 3) ACD (anterior chamber depth)
- 4) Corneal refractive power or radius of corneal curvature
- 5) Cornea equivalent refractive index
- 6) Target Ref. after surgery
- 7) Parameters printed when SRK/T Double K is selected
- 8) Formula name
- 9) IOL model name, manufacturer name
- 10) Lens constant
- 11) Calculation result
- 12) IOL standard (15 levels) and estimated refractive power after surgery

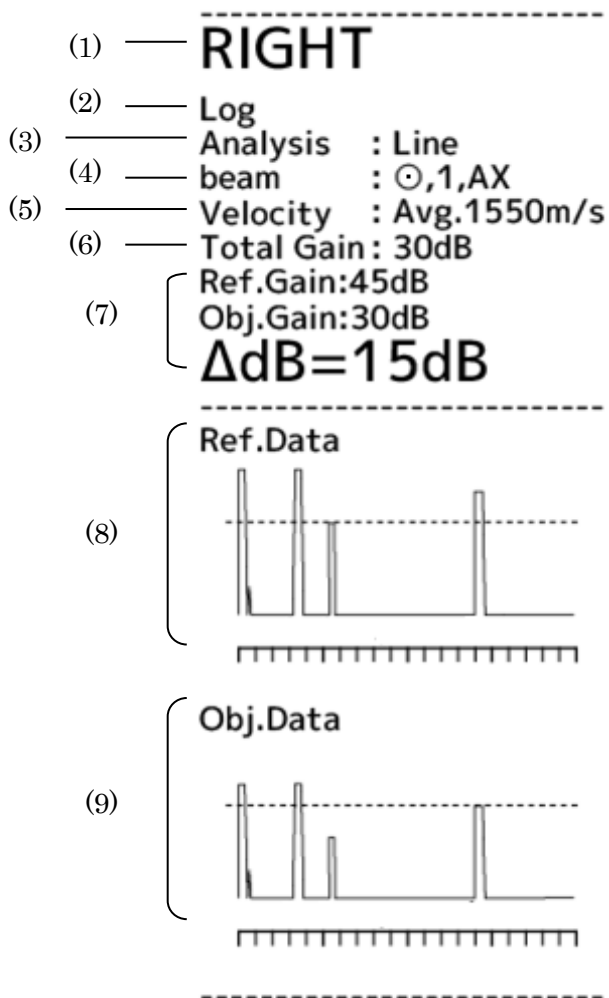
(12)

e) Printout of personal constants

(1)	Personal Value	
	RIGHT	
	Input Parameters	
(2)	Post-Op Ref.	: -0.50D
(3)	Imp. Diopter	: 17.00D
(4)	AXIAL	: 24.50mm
(5)	ACD	: 3.45mm
(6)	K1	: 42.00D
	K2	: 43.00D
(7)	Aconst.	: 112.00
	(Clinical History)	
(8)	PreK1	: 45.00D
	PreK2	: 46.00D
	PostK	: 41.47D
	PreREF S	: -5.00D
	PreREF C	: -1.00D
	PostREF S	: -1.00D
	PostREF C	: -0.50D
	V.D.	: 12.0mm
	Solution	
	Haigis std	
	Personal Aconst.	= 114.99
	Hoffer Q	
	Personal ACD	= 3.86
	Holladay 1	
	Personal SF	= -0.11
	SRK II	
	Personal Aconst.	= 116.38
	SRK/T	
	Personal Aconst.	= 115.99
	SRK SHOWA	
	Personal Aconst.	= 115.17
	Shammas-PL	
	Personal Aconst.	= 114.37
	SRK/T Double K	
	Personal Aconst.	= 113.48

- 1) Measurement eye (right eye/left eye)
- 2) Post-operation eye refractive power
- 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) Calculation result

f) Example printout for A-diagnosis



- 1) Measurement eye (right eye/left eye)
- 2) Gradation characteristics (Log / Liner / S)
- 3) Analysis method (Line / Point)
- 4) Beam direction
- 5) Acoustic velocity
- 6) Total gain
- 7) Analysis result (Ref, Gain, Obj. Gain, ΔdB)
- 8) Ref. Data waveform
- 9) Obj. Data waveform

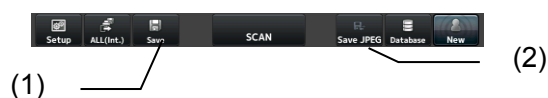
3.8.3 Saved data management

a) Saving

Note

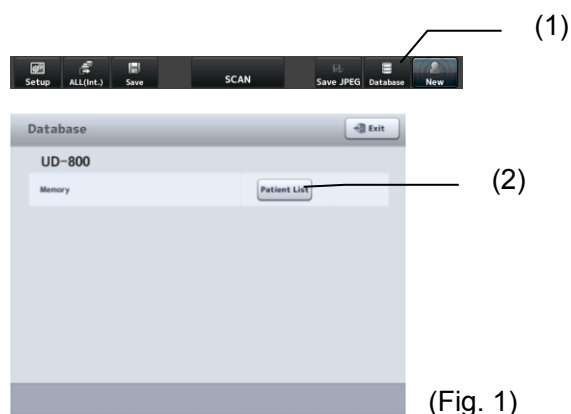
- **Always enter the ID number when saving the measurement data.**
- **Data saved in a USB memory device may be automatically erased after a long period of use. Consider the USB memory as a temporary storage, and make a backup for important data.**
- **Do not remove the external storage medium during data saving. This may destroy not only the data being saved, but also other data in the external storage medium.**

Touch the “Save” button (1) on each screen or step on the foot switch to save the measurement data. On the B mode screen, touching the “Save JPEG” button (2) saves only an image in JPEG format.

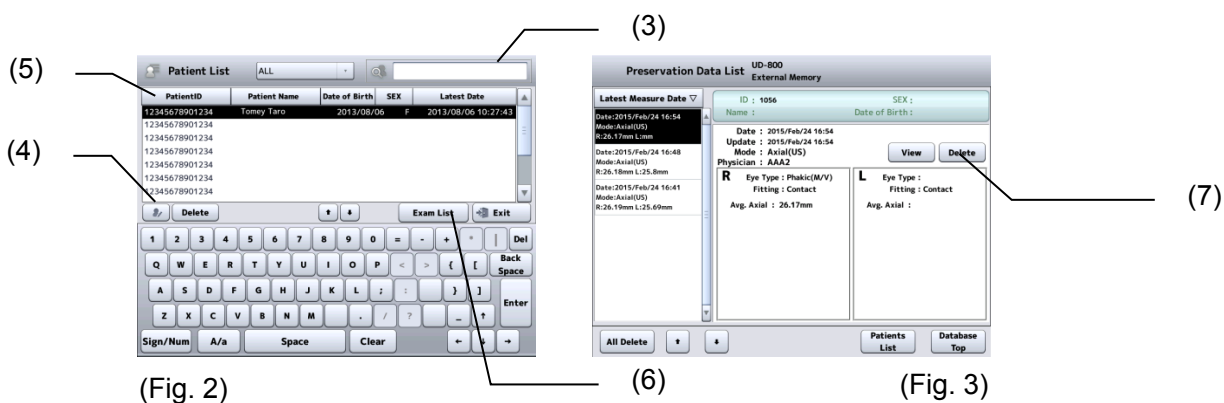


b) Browsing saved data

- 1) Touch the “Database” button (1) on each screen to open the Database screen (Fig. 1).



- 2) Touch the “Patient List” button (2) to open the Patient List screen (Fig. 2) saved in the USB memory stick.



- 3) When characters are entered in the search field (3), the patient ID and name are searched and the result appears. Touch the patient information button (4) to open the Patient Information screen and check details of the patient information. Touch the title of the line (5) 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 (6) to open the Preservation Data List (measurement data list of selected patient ID) screen (Fig. 3).
- 5) Touch the "View" button (7) to display the view screen (Fig. 4). The data can be viewed and edited on this screen.



- 6) Touch the "Meas. List" button (8) to return to the Preservation Data List screen (Fig. 3). Touch the "Patient List" button (9) to return to the Patient List screen (Fig. 2).

c) Deleting saved data



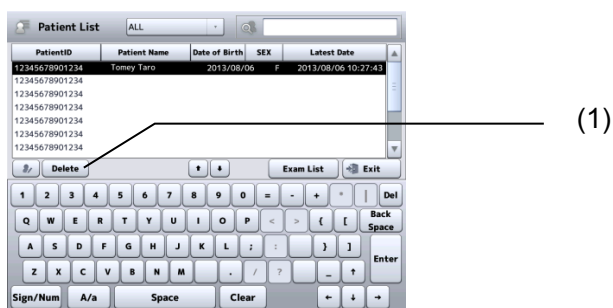
■ ***When any patient information is deleted, all the measurement data saved with the patient ID is also deleted, regardless of the mode being displayed. Be sure to check the contents saved before deleting them.***

[Delete all on Database screen]

Refer to “d) Database setting” in “3.9.4 Connecting & Printing.”

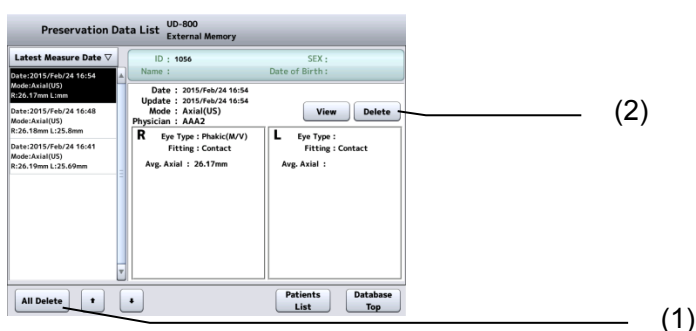
[Deleting data on Patient List screen]

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



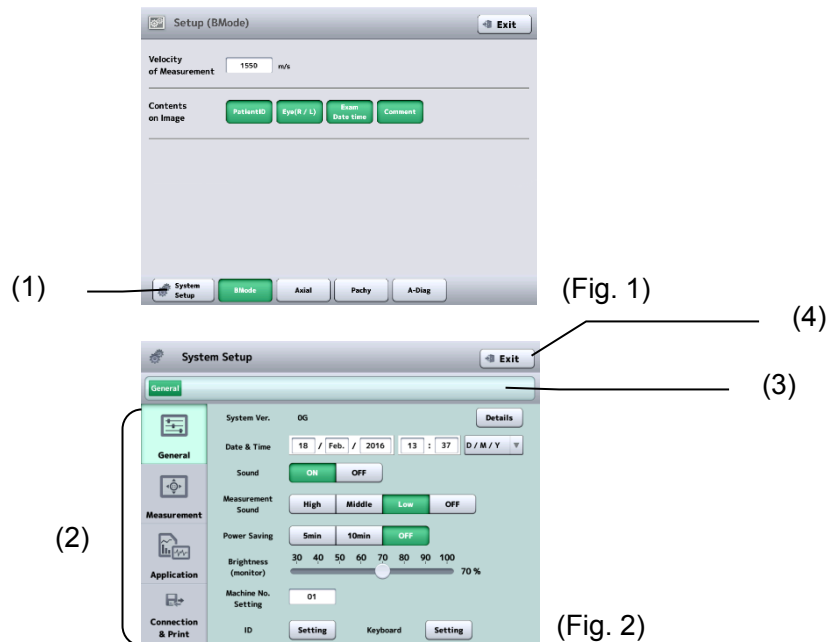
[Deleting data on Preservation Data List screen]

Touch the “All Delete” button (1) to delete the selected patient ID and measurement data, and return to the Patient List screen. Touch the “Delete” button (2) to delete the selected measurement data only.



3.9 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).



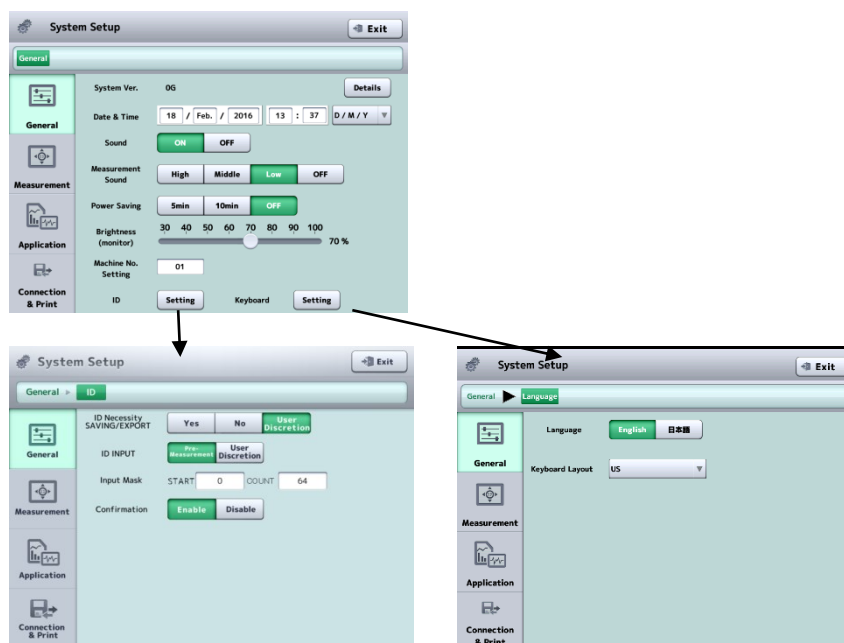
- 1) The system setup consists of 4 major categories.
 - General ... Time, version information, etc.
 - Measurement ... Time, version information, etc.
 - Application ... Calculation, analysis, and correction
 - Connection & Print ... Connection and printing

Touch the menu tab (2) to open the corresponding setup screen. The setup screen has a tree configuration. 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.

3.9.1 General

Set common items here. Select the General tab.



(1) System Ver.

Displays the version information.

(2) Date & Time

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

(3) Sound

Set whether to emit sounds when operating the screen.

(4) Measurement Sound

Set whether to emit sounds and the sound volume when taking measurements.

(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 / OFF

(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) ID Necessity SAVING/EXPORT

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

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

Yes : 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 : Select this when entry of the ID is optional. The transfer confirmation screen appears, but the examination data is automatically saved and sent. Data is saved and sent with the ID as "No ID" when the ID is not entered.

(10) ID INPUT

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

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

No : Displays the measurement screen.

(11) Input Mask

Set 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.

(12) Confirmation

Select whether to open the patient information confirmation screen when saving or sending the examination data to TOMEY Link.

(13) Keyboard

Open the keyboard setup screen for patient's name and physician's name. The data can be entered with the selected keyboard.

(14) Key arrangement setting

Select the software keyboard type.

(15) Language Setting

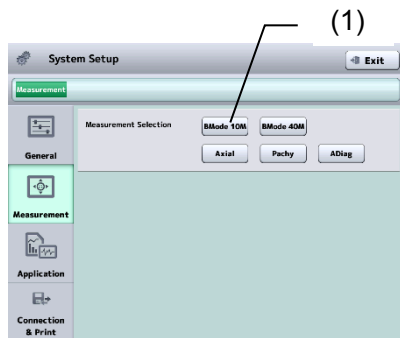
Select the display language for the instrument.

3.9.2 Measurement

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

a) Measurement Selection: B-Mode 10MHz

Touch the “B-Mode 10MHz” button (1) to make settings for 10 MHz



- Starting Condition

Set the default condition of the instrument when power is turned on and when the measurement mode is switched.

Latest Setting : The system starts with values set when power was last turned off.

Favorite Setting : The system starts with setting values shown in the setting display.

Touch the “Apply Current Setting” button (2) to show setting values on the last real-time screen in the setting display.

- Foot Switch (Two Button)

Select functions of the two-button foot switch.

All functions selected by one operation of the foot switch are executed.

Export : ON/OFF

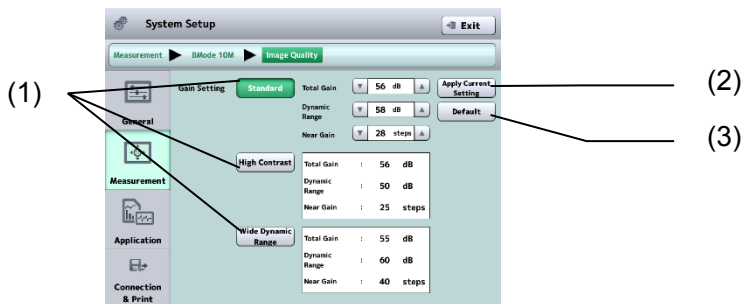
Print : ON/OFF

Save : ON/OFF

Save JPEG : ON/OFF

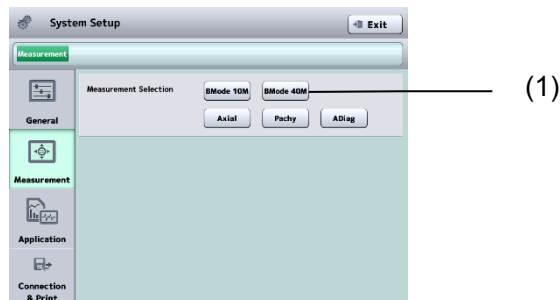
- Image Quality Setting

Open the Image Quality setting screen and set preset values of each gain and dynamic range. Select Standard, High Contrast or Wide Dynamic Range (1). The corresponding control tools appear on the right. Touch the “Apply Current Setting” button (2) to apply the setting values shown on the current screen for each box. Touch the “Default” button to return to the default settings.



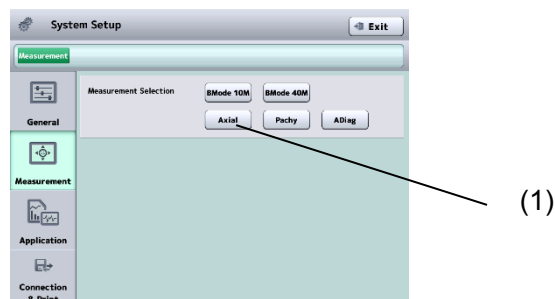
b) Measurement Selection: B-Mode 40MHz

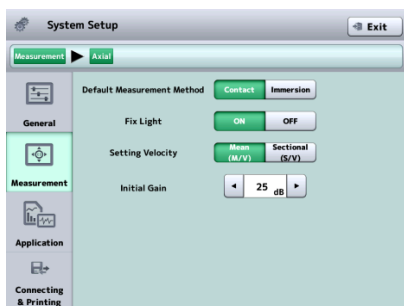
Touch the “B-Mode 40MHz” button (1) to make settings for 40MHz. Settings are the same as for “Measurement Setting B-Mode 10_10MH.”



c) Measurement Setting: Axial

Touch the “Axial” button (1) to make settings for “Axial.”





(1) Default Measurement Method

Set the measurement method normally used.

Contact / Immersion

(2) Fix light

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

ON / OFF

(3) Setting Velocity

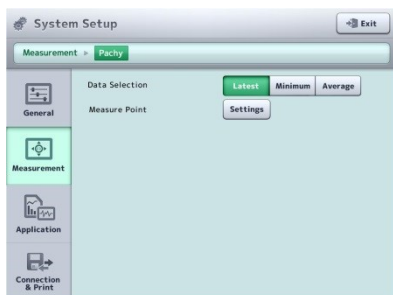
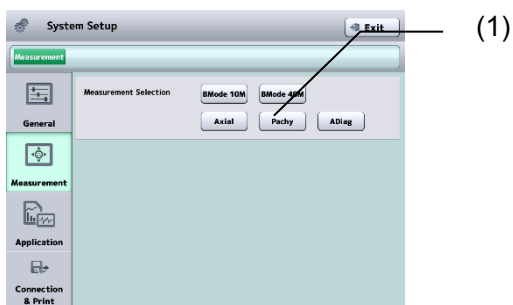
Mean Velocity (M/V) / Sectional Velocity (S/V)

(4) Initial Gain

Set the gain when axial length mode is started and when a new patient is examined.

d) Measurement Setting: Pachy

Touch the “Pachy” button (1) to make settings for “Pachy.”



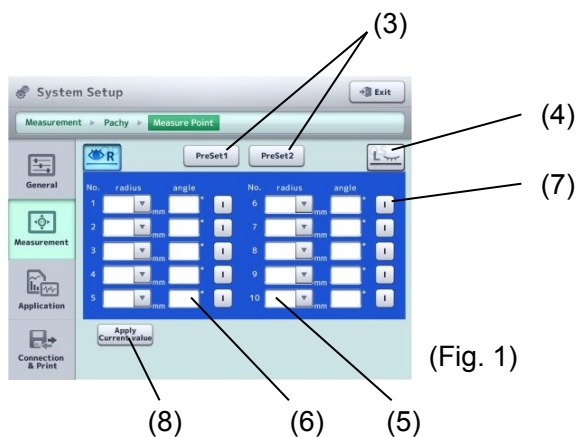
(1) Data Selection Method

Select the measurement data type to be displayed.

Latest / Minimum / Average

(2) Measure Point

Opens the measurement setup screen (Fig. 1).



(Fig. 1)

(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 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 keypad appears when the input field is touched.

Input range: 0 - 179

(7) S/I selection button

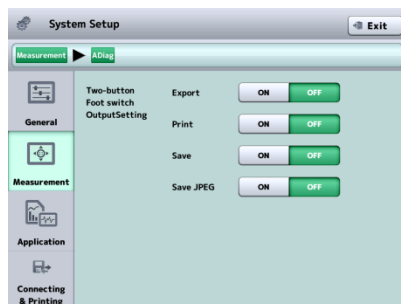
The mode alternates between “S” and “I” every time you touch the button.

(8) “Apply Current Value” button

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

e) Measurement Setting: A-Diag

Touch the “A-Diag” button (1) to make settings for “A-Diag.”



- Foot Switch (Two Button)

Select functions of the two-button foot switch.

All functions selected by one operation of the foot switch are executed.

Export: ON/OFF

Print: ON/OFF

Save: ON/OFF

Save JPEG: ON/OFF

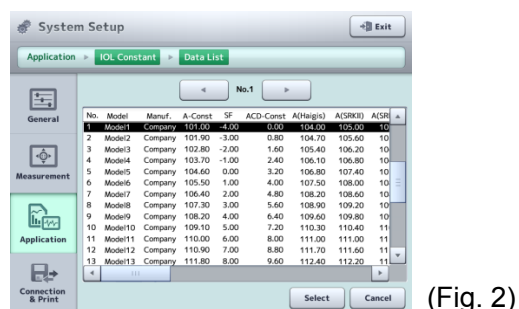
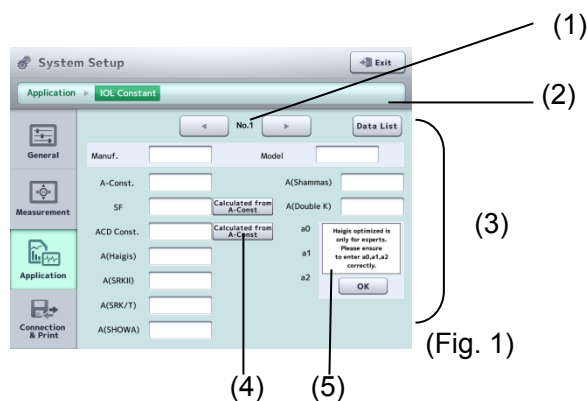
3.9.3 Application

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



a) Registering IOL data

Touch the IOL Constant “Setting” button to open the System Setup – IOL Constant screen (Fig. 1).



(1) Data list No.

Set the registration number of the IOL data list.

(2) “Data List” button

The IOL data list (Fig. 2) is displayed.

(3) IOL data input field

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

(4) “Calculated from A-Const” button

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

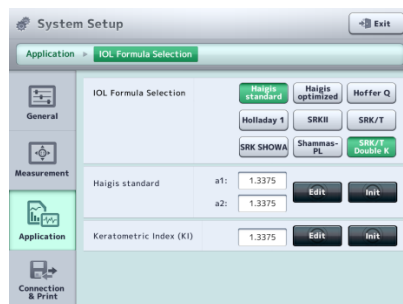
(5) Warning message

Displays warnings for determination of a0, a1, and a2.

When the “OK” button is touched, the warning message disappears and the input field appears.

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. 3).

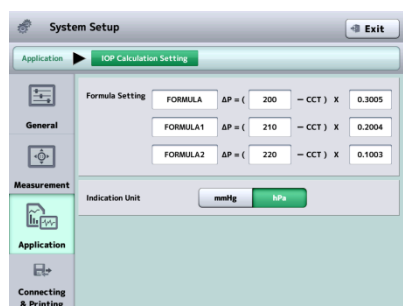


(Fig. 3)

When Haigis Standard is selected, the a1 and a2 setting fields are displayed. When SRK/T Double K is selected, the setting field for cornea equivalent refractive index (Keratometric Index KI) is displayed.

c) Setting IOP formula

Register the intraocular pressure correction formula to be used for the intraocular pressure correction. The IOP correction formula set here can be selected on the IOL correction screen. Touch the “Selection” button to open the IOL Formula Selection screen (Fig. 4).



(Fig. 4)

(1) Intraocular pressure correction formulas

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

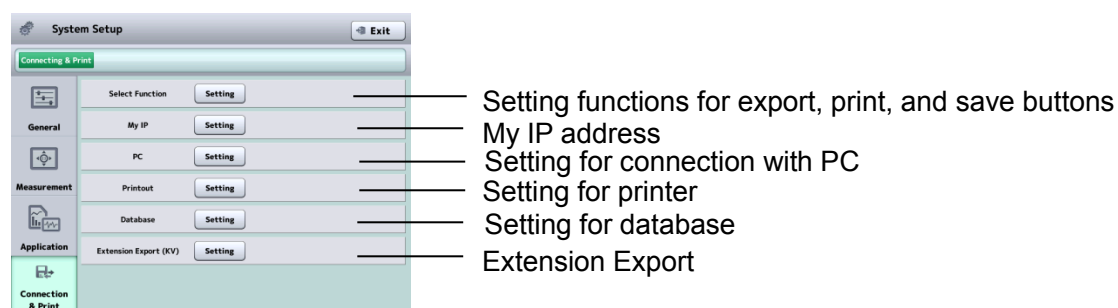
	Input range
IOP correction formula name	: Up to 10 characters
Parameter 1	: 0 - 1500
Parameter 2	: 0.0000 - 1.0000

(2) Indication Unit mmHg / hPa

3.9.4 Connecting & Printing

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

Select the Connection & Print tab.



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

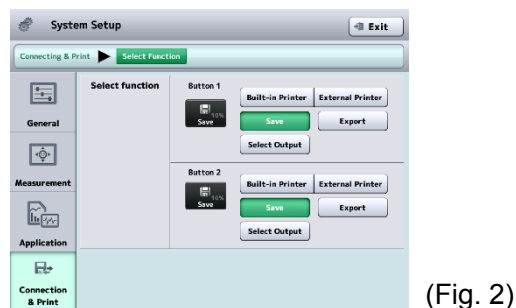
Assign functions to 2 buttons for saving, export, and print provided on each screen (Fig. 1).



Button 1

Button 2

Touch the "Setting" button for Function settings for button to open the System Setup screen (Fig. 2).

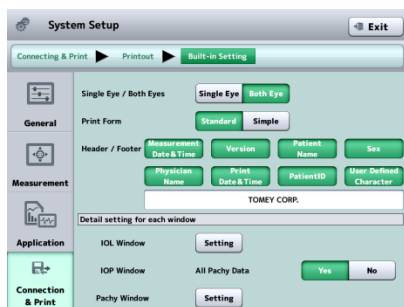


Select the function to be assigned to each of two buttons. The button icon changes according to the selections.

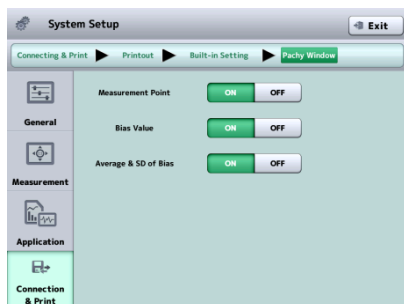
b) Selecting and setting printer

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

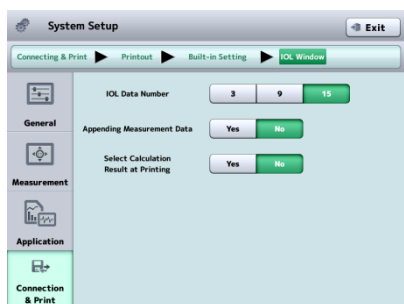
[Built-in]



(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.

Inspection date and time / Version / Patient's name / Sex /

Physician's name / Printing date and time / Patient ID / User-defined
character

(4) IOL Window (IOL power calculation screen)

Make settings for printing from the IOL power calculation screen.

Touch the "Setting" button to open the System Setup screen (Fig. 3).

IOL data number : 3 / 9 / 15

Appending Measurement : Yes / No
data

Select Calculation Result at : Yes / No

Printing

(5) IOP Window (intraocular pressure correction screen)

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

Yes / No

(6) Pachymetry measurement

Make settings for printing on the pachymetry screen.

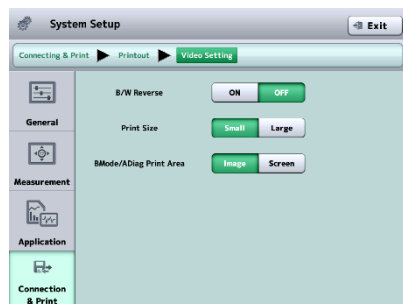
Touch the "Setting" button to open the System Setup screen (Fig. 2).

Measurement Point (for each : ON / OFF
memory)

Bias Value (for each memory) : ON / OFF

Average & SD of Bias (average : ON / OFF
and standard deviation of bias
value)

[Video]



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

ON / OFF

(2) Print Size

Small / Large

Small



Large

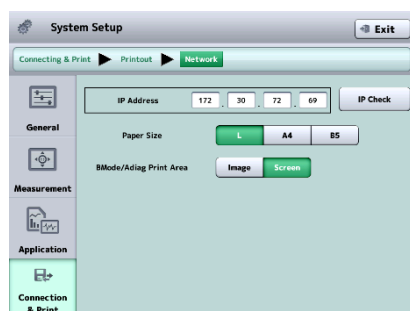


(3) "Print" button

Set the area to be printed in B-Mode

Image / Screen

[Network printer setting]



(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) Print Area

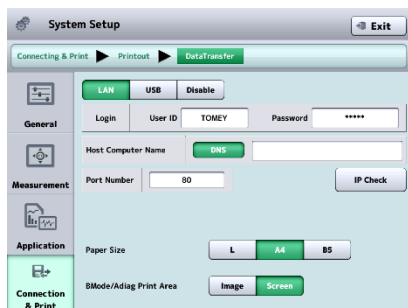
Set the area to be printed in B-Mode.

Image / Screen

(4) IP Check button

Performs a connection test.

[Data transfer printer setting]

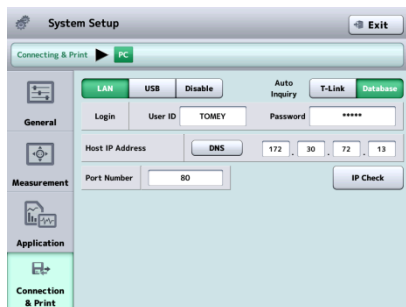


- (1) Connection permission and selection of cable type
- (2) Login to Tomey Link
- (3) Host IP address
- (4) “Connection Test” button
- (5) Port number
- (6) Paper size
L / A4 / B5
Set this according to the printer setting.
- (7) B-Mode printing area
Set the area to be printed in B mode.
Image / Screen

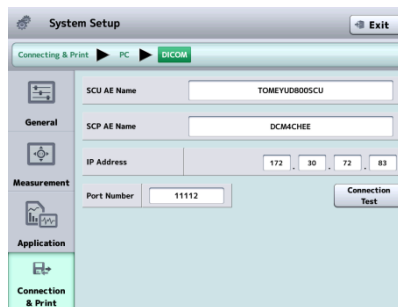
*Refer to “d) PC setting” for details on functions (1) to (5).

c) PC setting

Make connection settings and DICOM connection settings to export data to a personal computer with TOMEY Link or Data Transfer installed. Touch the “DICOM Setting” button to move to the DICOM setup screen (Fig. 2).



(Fig. 1)



(Fig. 2)

(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 with PC.

(2) Auto Inquiry

Set the auto inquiry reference for the patient's ID.

(3) 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.

(4) 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.

(5) Port number

A port number can be set.

Input range: 0 - 65535

Default setting: 80

(6) "Connection Test" button

Performs a connection test.

(7) DICOM - Settings

Moves to the DICOM settings screen.

(8) SCU AE Name

Title of DICOM Application Entity.

Conforms to the DICOM standard, and is used for communicating connection between AEs for bilateral certification.

When registered on the server (SCP), unauthorized access is prevented, and registered users can identify this application on the network.

(9) SCP AE Name

Set the title of the DICOM Application Entity compatible with the DICOM server (SCP).

DICOM communication is generally conducted by combinations of IP address, port number and AE title. Be sure to set this SCP AE name.

Check the DICOM Conformance Statement before setting the AE title of the communication destination.

(10) SCP IP Address

Set the IP address of the DICOM compatible server (SCP).

(11) Port Number

Set the port number used for DICOM communication.

(12) "Connection Test" button

Sends a "C-ECHO-RQ" message to the DICOM compatible server (SCP).

During DICOM communication, C-ECHO service is conducted to check connection between the server and terminal ends.

d) Database setting



The external storage media is initialized.

(1) External memory

Initialization

[About initialization function]

- The initialization function of this instrument deletes all data in the external storage media. Deleted data cannot be recovered. Check the data carefully before deleting it.
- The initialization function of this instrument only deletes the data. It does not format the external storage media. Use a PC when formatting is necessary.
- The type of format available on the UD-800 is "FAT32."

File system: FAT32、

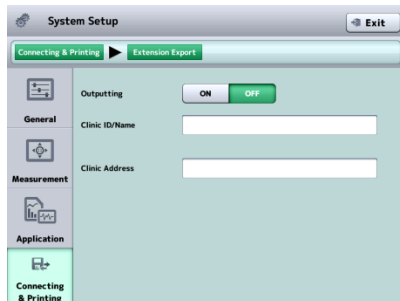
Allocation unit size: Standard

Format option: Uncheck "Quick format."

Note: "Quick format" is not recommended as defective sectors cannot be checked.

e) Extension Export

Sets whether to output information related to the clinic and measurement techniques.



- (1) Outputting
ON / OFF
- (2) Clinic ID / Name
Set the clinic ID and name.
- (3) Clinic Address
Set the address of the clinic.

f) My IP



- (1) IP Address
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
Example

■ **When only this instrument and the Tomey Link Server or 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) 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 settings			
(Local) IP address	192	168	2	128	192	168	2	129
	Check these on the DATA Transfer screen.				Same value as computer setting			(*1)
Subnet mask	255	255	255	0	255	255	255	0
	Check these on the DATA Transfer 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 (128 in this example)

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4. TECHNICAL INFORMATION

4.1 IOL power calculation formula

4.1.1 Haigis optimized / Haigis Standard

1. Implanted IOL power (D)

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

Where:

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

$$d = a_0 + a_1 \cdot ACD + a_2 \cdot L \quad (ACD \neq 0)$$

$$d = (a_0 - 0.241 \cdot a_1) + (a_2 + 0.139 \cdot a_1)L \quad (ACD = 0)$$

$$a_0 = 0.62467A - 72.434 \dots^*$$

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

2. Estimated refractive power after surgery (D)

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

Where:

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

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

$$na : \text{Aqueous humor and vitreous refractive index} \\ = 1.336$$

$$nc : \text{Corneal reflective index} \\ = 1.3315$$

$$A : \text{A-Constant}$$

$$RC : \text{Average radius of corneal curvature (mm)} \\ = (r_1 + r_2)/2$$

$$r : \text{Radius of corneal curvature (mm)} \\ = \{(Kl - 1) \times 1000\}/K$$

$$K : \text{Corneal refractive power (D)}$$

$$Kl : \text{Cornea equivalent refractive index}$$

$$DC : \text{Average corneal refractive power (D)}$$

L : Axial length

ACD : Anterior chamber depth (mm)

REF : Target Ref. after 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

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

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

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 after surgery (D)

4.1.2 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. after surgery (D) when wearing glasses

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

Where:

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

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

Where:

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

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

$$L \leq 23.0 \rightarrow M = +1, G = 28$$

$$L > 23.0 \rightarrow M = -1, G = 23.5$$

$$L > 31.0 \rightarrow L = 31$$

$$L < 18.5 \rightarrow L = 18.5$$

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)
= {(K1 - 1) × 1000}/K

K1 : Cornea equivalent refractive index

Rx : Target Ref. after 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:

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

AREF : Refractive power of eye after surgery (D)

4.1.3 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 after 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 : $na \cdot r - L2(nc - 1)$

Y : $na \cdot r - (nc - 1)(C2 + SF)$

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)
= $\{(K1 - 1) \times 1000\}/K$

K1 : Cornea equivalent refractive index

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

REF : Target Ref. after 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)

$$= 0.56 + Rag - \sqrt{Rag^2 - AG^2 / 4}$$

$$r < 7 \rightarrow Rag = 7$$

$$r \geq 7 \rightarrow Rag = r$$

$$AG = 12.5L / 23.45$$

$$AG > 13.5 \rightarrow AG = 13.5$$

3. Personal SF

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

Where:

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

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

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

$$CQ2 = 1000na\{na \cdot r - L2(nc - 1) - CQ1\}/P$$

$$CQ3 = L2 \cdot na \cdot r - 0.001AREF \cdot L2 \cdot V \cdot r \cdot na$$

$$CQ = CQ3 - CQ2$$

AREF : Refractive power of eye after surgery (D)

4. Corresponding SF

$$SF = 0.5663A - 65.60$$

or

$$SF = 0.9704 ACD_{con} - 3.595$$

Where:

A : A-Constant

4.1.4 SRK-II formula

1. Implanted IOL power (D) for emmetropization

$$P_{emme} = A1 - 0.9K - 2.5L$$

2. Implanted IOL power (D) for ametropia

$$P_{amet} = P_{emme} - REF \cdot CR$$

3. Predicted refractive power after surgery (D)

$$REF_{iol} = (P_{emme} - P) / CR$$

Where:

$L < 20.0$	$\rightarrow A1 = A + 3$
$20.0 \leq L < 21.0$	$\rightarrow A1 = A + 2$
$21.0 \leq L < 22.0$	$\rightarrow A1 = A + 1$
$22.0 \leq L < 24.5$	$\rightarrow A1 = A$
$24.5 \leq L$	$\rightarrow A1 = A - 0.5$

$$P_{emme} \leq 14 \rightarrow CR = 1.00$$

$$P_{emme} > 14 \rightarrow CR = 1.25$$

A : A-Constant

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

r : Radius of corneal curvature (mm)
 $= \{(K1 - 1) \times 1000\} / K$

K1 : Cornea equivalent refractive index

L : Axial length (mm)

P : Implanted IOL power (D)

REF : Target Ref. after surgery

4. Personal A-Constant

$$A = P + AREF \cdot RF + 2.5L + 0.9K - COR$$

Where:

AREF: Eye refractive power after surgery (D)

RF : Refractive factor

$$P > 16 \rightarrow RF = 1.25$$

$$P \leq 16 \rightarrow RF = 1$$

COR : Correction value

$$L < 20.0 \rightarrow COR = 3$$

$$20.0 \leq L < 21.0 \rightarrow COR = 2$$

$$21.0 \leq L < 22.0 \rightarrow COR = 1$$

$$22.0 \leq L < 24.5 \rightarrow COR = 0$$

$$24.5 \leq L \rightarrow COR = -0.5$$

4.1.5 SRK/T formula

1. Implanted IOL power (D) for emmetropization

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

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 after 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:

$$X = na \cdot r - L1(nc - 1)$$

$$Y = na \cdot r - C1(nc - 1)$$

L1 : Visual axial length (mm)

$$= L + (0.65696 - 0.02029L)$$

L : Axial length (mm)

REF : Target Ref. after surgery (D)

W : Calculated corneal diameter (mm)

$$= -5.41 + 0.58412LC + 0.098K$$

LC : Corrected axial length (mm)

$$L \leq 24.2 \rightarrow LC = L$$

$$L > 24.2 \rightarrow LC = -3.446 + 1.716L - 0.0237L^2$$

C1 : Estimated anterior chamber depth after surgery (mm)

$$= H + \text{Ofst.}$$

Ofst: Calculated distance from the iris surface to the optical surface of the implanted IOL (including corneal thickness) (mm)

$$= \text{ACD const} - 3.336$$

$$= (0.62467A - 68.747) - 3.336$$

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)
 $= \{(KI - 1) \times 1000\}/K$
 KI : Cornea equivalent refractive index
 P : Implanted IOL power (D)
 V : Vertex distance (mm)
 $= 12$
 n_a : Aqueous humor and vitreous refractive index
 $= 1.336$
 n_c : 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 : $\alpha (H - 72.083)^2 + \beta (H - 72.083) + \gamma$
 α : $P (1 - n_c) + 0.001P \cdot AREF \{V (n_c - 1) - r\}$
 β : $P [n_a \cdot r + L1 (n_c - 1) + 0.001AREF \{L1 \cdot r + V \cdot L1 (1 - n_c) - n_a \cdot V \cdot r\}]$
 γ : $n_a [1000X - P \cdot L1 \cdot r + AREF \{0.001P \cdot V \cdot L1 \cdot r - (V \cdot X + L1 \cdot r)\}]$

AREF : Refractive power of eye after surgery (D)

4.1.6 SRK SHOWA formula

1. Implanted IOL power (D)

$$\begin{aligned} L < 22.0 & : P = A - 2.5L - 0.9K + 1.4 - 1.45REF \\ 22.0 \leq L < 24.5 & : P = A - 2.5L - 0.9K - 1.67REF \\ 24.5 \leq L < 27.0 & : P = A - 2.5L - 0.9K + 0.71 - 1.25REF \\ 27.0 \leq L & : P = A - 2.5L - 0.9K - 1.69REF - 1.69 \end{aligned}$$

2. Predicted refractive power after surgery (D)

$$\begin{aligned} L < 22.0 & : R = (A - 2.5L - 0.9K + 1.4 - P)/1.45 \\ 22.0 \leq L < 24.5 & : R = (A - 2.5L - 0.9K - P)/1.67 \\ 24.5 \leq L < 27.0 & : R = (A - 2.5L - 0.9K + 0.71 - P)/1.25 \\ 27.0 \leq L & : R = (A - 2.5L - 0.9K - 1.69 - P)/1.69 \end{aligned}$$

L : Axial length

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

r : Radius of corneal curvature (mm)
 $= \{(K1 - 1) \times 1000\}/K$

K1 : Cornea equivalent refractive index

REF : Target Ref. after surgery (D)

A : A-Constant

P : Implanted IOL power (D)

3. Personal A-Constant

$$\begin{aligned} L < 22.0 & : A = P + 2.5L + 0.9K - 1.4 + 1.45AREF \\ 22.0 \leq L < 24.5 & : A = P + 2.5L + 0.9K + 1.67AREF \\ 24.5 \leq L < 27.0 & : A = P + 2.5L + 0.9K - 0.71 + 1.25AREF \\ 27.0 \leq L & : A = P + 2.5L + 0.9K + 1.69AREF + 1.69 \end{aligned}$$

AREF : Eye refractive power after surgery (D)

4.1.7 Shammass-PL formula



■ This formula is for POST LASIK.

1. Implanted IOL power (D) for emmetropization

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

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 after surgery (D)

$$REF_{C_{iol}} = \frac{1.0125 \times 1336 [1336 - P\{Lc - (C + 0.05)\}]}{1336 \cdot Lc - P(C + 0.05)\{Lc - (C + 0.05)\}} - Kc$$

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)

= {(K1 – 1) × 1000}/K

K1 : Cornea equivalent refractive index

REFc : Refractive power at corneal refractive surface

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

REF : Target Ref. after 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: Refractive power of the eye at corneal refractive surface

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

AREF : Eye refractive power after surgery (D)

4.1.8 SRK/T Double K

Note ■ This formula is for POST LASIK.

1. Implanted IOL power (D) for emmetropization

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

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 after 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 after 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)

$$= -5.41 + 0.58412LC + 0.098K$$

LC : Corrected axial length (mm)

$$L \leq 24.2 \rightarrow LC = L$$

$$L > 24.2 \rightarrow LC = -3.446 + 1.716L - 0.0237L^2$$

A : A-Constant

-
- K_{pre} : Average corneal refractive power (D) before refractive correction surgery
 $= (K1 + K2)/2$
- r_{pre} : Average radius of corneal curvature (mm) before refractive correction surgery
 $= \{(K1 - 1) \times 1000\} / K_{pre}$
- $K1$: Cornea equivalent refractive index
- K_{post} : Average corneal refractive power (D) after refractive correction surgery
 $= (K1_{post} + K2_{post})/2$
- r_{post} : Average radius of corneal curvature (mm) after refractive correction surgery
 $= \{(K1 - 1) \times 1000\} / K_{post}$
- P : Implanted IOL power (D)
- na : Aqueous humor and vitreous refractive index
 $= 1.336$
- nc : Corneal reflective index
 $= 1.333$
- REF : Target Ref. after 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 : $\alpha (H - 72.083)^2 + \beta (H - 72.083) + \gamma$
- α : $P (1 - nc) + 0.001P \cdot AREF \{V (nc - 1) - r\}$
- β : $P [na \cdot r + L1 (nc - 1) + 0.001AREF \{L1 \cdot r + V \cdot L1 (1 - nc) - na \cdot V \cdot r\}]$
- γ : $na [1000X - P \cdot L1 \cdot r + AREF \{0.001P \cdot V \cdot L1 \cdot r - (V \cdot X + L1 \cdot r)\}]$

AREF : Refractive power of eye after surgery (D)

4.2 How to calculate axial length using the biometry function

4.2.1 Phakic eye

The axial length measurement is obtained using the following formulae.

<When using the average acoustic velocity>

$$L = \frac{V \cdot t}{2}$$

L : Axial length measurement
V : Average acoustic velocity for axial length
t : Measurement time

<When using the divisional acoustic velocity>

$$L = \frac{V_{acd} \cdot t_{acd}}{2} + \frac{V_{lens} \cdot t_{lens}}{2} + \frac{V_{vit} \cdot t_{vit}}{2}$$

L : Axial length measurement
 V_{acd} : Anterior chamber depth acoustic velocity
 V_{lens} : Crystal lens acoustic velocity
 V_{vit} : Vitreous acoustic velocity
 t_{acd} : Time for measuring anterior chamber depth
 t_{lens} : Time for measuring crystal lens
 t_{vit} : Time for measuring vitreous

4.2.2 Dense cataract eye

Take the axial length measurement in the same manner as when using the average acoustic velocity for a phakic eye.

4.2.3 Aphakic eye

Take the axial length measurement in the same manner as when using the average acoustic velocity for a phakic eye.

4.2.4 IOL eye

[Default setting for acoustic velocity at delivery (changeable)]

- IOL acoustic velocity (reference)

Acrylic	: 2,200m/s
Silicone	: 1,049m/s
PMMA	: 2,718m/s

* The acoustic velocity varies depending on materials, makers, and temperature.

- Vitreous acoustic velocity : 1,532 m/s

- Anterior chamber depth acoustic velocity : 1,532 m/s

The axial length measurement is obtained using the following formulae.

$$Lp = \frac{V_{acd} \cdot t_{acd}}{2} + Th + \frac{V_{vit} \cdot t_{vit}}{2}$$

$$t_{vit} = t_{axl} - t_{acd} - \frac{2Th}{V_{IOL}}$$

Lp : Axial length measurement

Th : Center thickness of IOL (entered by user)

V_{IOL} : IOL acoustic velocity

V_{acd} : Anterior chamber depth acoustic velocity

V_{vit} : Vitreous acoustic velocity

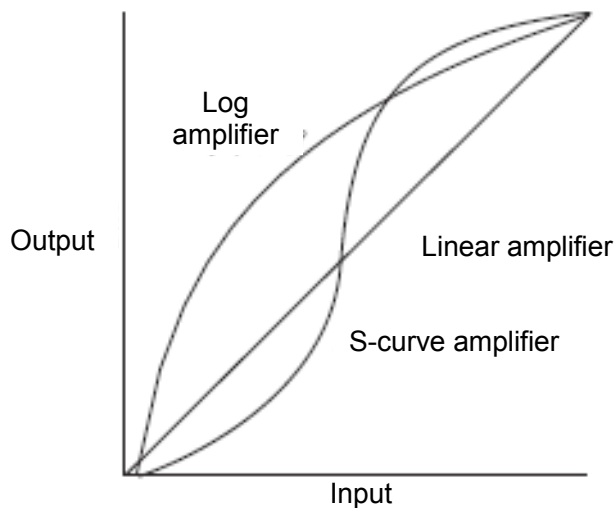
t_{axl} : Measurement time

t_{acd} : Time for measuring anterior chamber death

t_{vit} : Time for measuring a vitreous

4.3 Amplifier characteristics of the A-scan diagnosis

The I/O characteristics of the log amplifier, linear amplifier, and S-curve amplifier selected for the A-scan diagnosis are as shown below.



4.4 Ultrasonic wave output

- MI (mechanical index)

MI is a parameter that indicates the mechanical effects of ultrasound waves on biological tissue. Mechanical effects are, for example, movement (or flow) around air bubbles compressed when an acoustic pressure wave of the ultrasonic wave passes through biological tissue, or energy released when cavitation temporarily bursts the air bubbles.

- TIS (thermal index of soft tissue)

TIS is a parameter that indicates the thermal effects of ultrasound waves on biological tissue. Thermal effects mean an increase in the tissue temperature due to emission of ultrasonic waves.

5. INSPECTION AND MAINTENANCE

5.1 Warranty

One-Year Limited Warranty

The seller warrants this product to be free from defects in material and workmanship under the normal use of this product for one (1) year or other term complying with local regulations from the date of invoice issued by Seller to the original purchaser.

Lamps, paper and other consumable items shall not be covered by this warranty. This warranty also shall NOT apply if the product has not been installed, operated or maintained in accordance with the INSTRUCTION MANUAL of Tomey Corporation (here in after called "Tomey"). Neither seller nor Tomey shall be liable for any damages caused by purchaser's failure to follow instruction for proper installation, use and maintenance of product.

This warranty is only applicable to the new product and DOES NOT cover any damage resulting from or caused by accident or negligence, abuse, misuse, mishandling, improper modification of this product, by persons other than personnel duly authorized by Tomey, not to a product whose serial number or batch number is removed, altered or effaced.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED (INCLUDING SPECIFICALLY, WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE), AND ALL OTHER OBLIGATION AND LIABILITY ON THE PART OF SELLER AND TOMEY. NEITHER SELLER NOR TOMEY SHALL BE LIABLE FOR INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES UNDER ANY CIRCUMSTANCES OR FOR MORE THAN REPAIR, REPLACEMENT OR REFUND OF THE PURCHASE PRICE OF DEFECTIVE GOODS.

5.2 Operation life

This instrument is designed to have an operation life of 8 years when operated under the appropriate environment and it is adequately inspected and serviced.

5.3 Inspection



- *When there is a problem, correct waveforms or images may not be obtained correctly. Contact Tomey or your local distributor immediately for repair or replacement.*
- *Be sure to hold the connector when removing the measurement probe from the main unit. Holding and pulling the cord may damage the inner core wires.*
- *Do not touch the connector of the measurement probe, otherwise the probe may be damaged.*

5.4 Routine maintenance



- *Hold the plug when disconnecting the power cord from the outlet to avoid applying excessive force on the cord. Pulling the cord may damage the inner core wires, resulting in electric shock or fire.*



- *Do not use organic solvents such as thinner, benzene, or acetone to clean the instrument and accessories. These solvents may damage the surface of the instrument.*
- *Disconnect the power plug from the outlet and place the dust cover over the main unit when not used for long periods.*
- *Place the dust cover over the main unit when not being used.*

5.4.1 Maintenance of measurement probes



- *Be sure to hold the connector when removing the probe from the main unit. Holding and pulling the cord may damage the inner core wires.*
- *Never touch the connector, otherwise the probe will be damaged.*
- *Attach the protective cap to the probe and place it in the probe holder when not used.*

a) Appearance check

- Check that the contact section of the probe is not damaged.
- Check that the connector is firmly inserted and the cable is not damaged.

b) Cleaning

Note

■ *Use absorbent cotton to clean the contact section of the measurement probe. Otherwise, the contact section may be damaged.*

■ *Holding and pulling the cord may damage the inner core wires.*

■ *Do not clean the connecting section of the connector.*

- When cleaning the main body of the measurement probe, wipe it with absorbent cotton dampened with antiseptic soap and water or alcohol, and then with cotton dampened with water.
- When cleaning the tip of the measurement probe, wipe it with absorbent cotton dampened with alcohol, and then with cotton dampened with water.
- Wipe cords with a well wrung cloth dampened with water.
- Completely remove water after cleaning.

c) Sterilization

Note

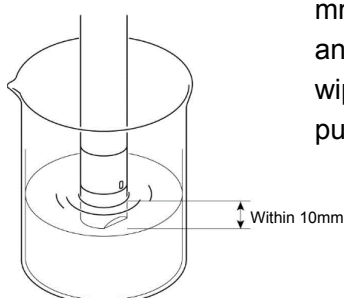
■ *Effective chemicals vary depending on the types of germs and viruses. Select appropriate chemicals and immersion time based on the guidelines, articles, literature, etc. provided by local administrative organizations and/or societies.*

■ *Do not use EOG sterilizer for the biometry probe and eye cup.*

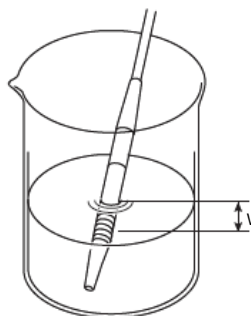
■ *Never use a high-pressure steam sterilizer.*

■ *Follow the instruction manual for the EOG sterilizing conditions. Otherwise, safe sterilization cannot be assured.*

- The B mode probe can be sterilized by wiping or immersing the section up to 10 mm from the contact section using the following chemicals. As for the biometry and pachymetry probes, the section up to 15 mm from the contact section can be wiped and immersed in the following chemicals. Thoroughly rinse the probe with purified water after sterilization.



- Alcohol
- Sodium hypochloride (0.5% solution)



- Immerse the whole eye cup in alcohol or sodium hypochloride solution (0.5%), rinse them with purified water to completely remove chemicals, and thoroughly dry them.

When sterilizing the pachymetry probe with EOG, remove the protective cap from the tip of the probe and put the whole probe in a sterilizing pack.

<Sterilization conditions>

EOG : Mixture of ethylene oxide gas (20%) and carbonic acid gas (80%)

Sterilization temperature : $50 \pm 5^\circ\text{C}$

Sterilization pressure : $(9.8 \pm 0.98) \times 10^4 \text{ Pa}$

Sterilization time : $5 \pm 1 \text{ hours}$

Aeration time : 10 hours or longer

5.4.2 Cleaning and Disinfection of measurement probes (for Europe)

[Specific Section for European continent]

Note

■ Follow the legal requirements and regulation in the country.

■ Refer to the instruction manual concerning test-fluid for detail.

a) Cleaning

Note

■ Holding and pulling the cord may damage the inner core wires.

■ Do not clean the connecting section of the connector.

- When cleaning the main body of the measurement probe and, wipe it with a suitable fluid eg. "Cleanisept® Wipes" and then wipe with cotton dampened with water
- Wipe the cord with a well wrung cloth dampened with water and remove water after cleaning.

b) Disinfection

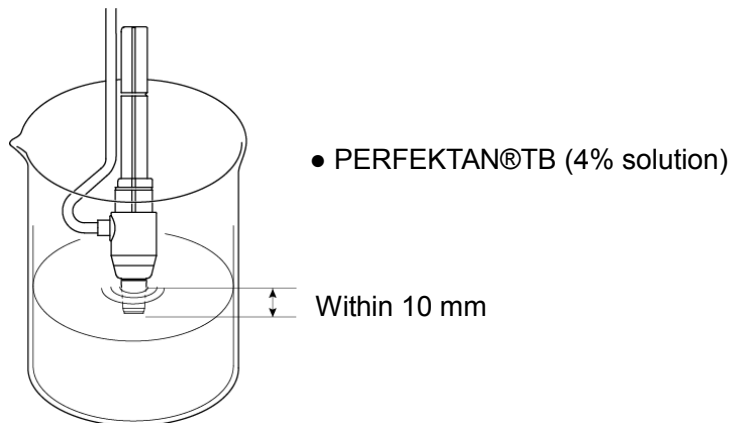
Note

■ Effective chemicals vary depending on the types of germs and viruses. Select appropriate chemicals and immersion time based on the guidelines, articles, literature, etc. provided by local administrative organizations and/or societies.

■ **A high-pressure steam sterilizer is acceptable only for the immersion attachment.**

- The Ultrasound probe (biometry probe, pachymetry probe, and A-scan diagnostic probe) can be disinfected by immersing the contact section of the probe tip in suitable cleaning fluids.

©Biometer / A-diagnostic probe/Pachy probe



One clinically tested cleaning product would be:

- PERFEKTAN®TB
(4% concentration and an exposure times of 30 min)

Antimicrobial Properties Perfektan® TB is:

- bactericidal (incl. MRSA=multi resistant Staphylococcus aureus) -
tuberculocidal - fungicidal (C. albicans), levurocidal - virus inactivating incl.
HBV/HIV/BVDV/HCV/Papova - Polyoma/Adeno virus - sporicidal Thoroughly
rinse the probe with purified water and thoroughly dry it after cleaning.

5.4.3 Maintenance of main unit

Note

■ *When disconnecting cords, do not apply excessive force on the cord; for example, do not hold and pull the cord to disconnect it.*

■ *Do not touch the connection terminal surface of the main unit or measurement probe.*

- Wipe off dirt on the main unit by lightly rubbing with a well wrung cloth dampened with water and then with a dry cloth. When it is very dirty, clean it by lightly rubbing with a well wrung cloth dampened with diluted neutral detergent. Then, wipe it with a cloth dampened with water and then with a dry cloth.

Note

■ *Do not leave any water, chemicals, etc. remaining on the touch panel as the surface of the touch panel is vulnerable to moisture. The surface of the touch panel may be damaged and unable to maintain the appropriate performance.*

- Wipe off dirt on the surface of the touch panel with a dry soft cloth. When it is very dirty, lightly wipe it with a soft cloth dampened with alcohol. Further, wipe it with a dry soft cloth to completely remove moisture.

5.5 Replacing consumables

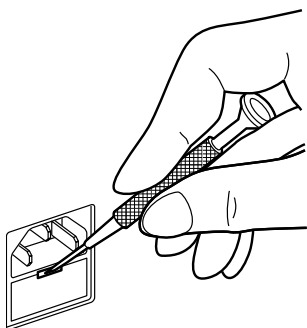
5.5.1 Fuses



■ **Disconnect the power cord from the outlet when replacing fuses. Otherwise you may get electric shock, resulting in death or serious injuries.**

■ **Use fuses specifically designed for this instrument.**

■ **When the instrument does not work correctly after fuses have been replaced, there may be other causes of the problem. Turn off the instrument immediately and contact your local distributor.**



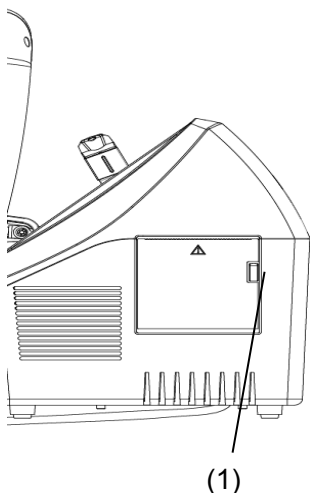
- 1) Turn power off and disconnect the power plug from the outlet.
- 2) Disconnect the power plug from the power terminal.
- 3) Insert a flat screwdriver into the groove of the fuse holder under the power terminal and remove the holder case.
- 4) Replace the blown fuse with a new one.
- 5) Install the fuse holder in the reverse order of removal.

5.5.2 Printer paper



■ **Always use genuine TOMEY paper for the printer. Using other types of paper may cause printer failure.**

■ **Do not pull paper forcibly. Trying to pull the paper out may cause printer failure. Touch the "PRINT" button without any data stored to feed blank paper.**



Replace the paper roll according to the procedure below when red lines appear on the edges of the printer paper.

- 1) Press the button (1) to open the printer cover.
- 2) Remove the old printer paper roll and install a new roll. If the paper roll is installed in the wrong direction, nothing will be printed.
- 3) Close the printer cover with the end of the paper protruding 2 mm from the outlet. Press the cover firmly until you hear a click.

5.6 Storing



- *Install the instrument in a location free of water or chemicals. Any water or chemicals entering the instrument may cause electric shock or failure.*



- *Do not store the instrument in a location where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and result in fire.*
- *Disconnect the power cord from the outlet to ensure safety when the instrument is not operated for 1 month or longer.*
- *Store the instrument in a location not subject to direct sunlight, high temperature and humidity, or air containing dust, salt and/or sulfur. Otherwise, failure or malfunction may occur.*
- *Store the instrument in a leveled stable place free of vibration or mechanical impact. Otherwise, measurement cannot be conducted correctly. The instrument may also topple or fall, resulting in fire or a fatal accident.*
- Clean and dry the measurement probe, attach the protective cap, and place it in the probe case for storage.
- When the instrument is not used for a while, check that the instrument is operating correctly before starting operation again.

Storage conditions

- Ambient temperature range $-20 - +50^{\circ}\text{C}$
- Relative humidity range 45 - 85%

5.7 Disposal



- *Keep the box and packing materials for use when moving or transporting the instrument.*
- *Keep the packing materials and box together.*
- *When disposing of the packing materials, sort them by type and abide by local government rules and regulations.*
- *A board with a lithium battery is used in the instrument. Since handling of lithium batteries varies depending on governing bodies, follow relevant laws and local rules.*

6. 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. Otherwise you may get electric shock.***



■ ***Do not take any actions other than those specified below.***

6.1 Common items

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

?Cause 1 Problem with the power plug

Solution ➡ 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.

?Cause 2 Problem with the power outlet

Solution ➡ Check that power is supplied to the outlet to which the power cord is connected.

?Cause 3 Blown fuse

Solution ➡ Check that fuses are not blown. If blown, replace the fuse (refer to “5.5.1 Fuses”). When the new fuse is blown again, the instrument may be faulty. Contact your local distributor to request inspection and/or repair.

- Nothing appears on the monitor screen.

?Cause 1 The auto power off function, which automatically turns off the screen when the instrument is not operated for the specified time, has been activated.

Solution ➡ Touch the monitor screen.

? Cause 2 The maintenance switch on the side is in the P (up) position.

Solution ➡ Turn off the power, return the maintenance switch to the down position, and then turn on the power.

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

? Cause 1 The brightness of the monitor is low.

Solution ➡ Adjust the brightness of the screen using the screen brightness setting described in "3.9.1 General."

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

? Cause 1 Printer paper.

Solution ➡ Check the remaining printer paper.

? Cause 2 Setting the output printer

Solution ➡ Set "built-in printer" to the destination to which output is directed when "Print button" is pushed. Refer to "3.9.4 b) Selecting and setting printer" for setting details.

? Cause 3 The printer cover is open.

Solution ➡ Check that the printer cover is completely closed.

? Cause 4 The printer paper is not set in the correct direction.

Solution ➡ Check that the printer paper is set correctly. (Refer to "5.5.2 Printer paper")

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

? Cause 1 The touch panel is not calibrated correctly.

Solution ➡ Contact your local distributor.

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

?Cause 1 USB cable.

Solution ➡ Verify that the USB cable of the external ID input instrument is correctly connected to the main unit. For correct connection, refer to "3.1.1 g) External ID input device."

?Cause 2 A screen which does not receive an ID input appears.

Solution ➡ Entry of ID from an external ID input instrument is accepted only on a screen where the patient information is displayed. Input ID after displaying such screens.

- Data cannot be saved.

?Cause 1 The ID is not entered.

Solution ➡ The instrument uses the ID as a file name.
Enter the ID and then save the data.

?Cause 2 There is not enough space available in the memory.
(The confirmation screen appears when attempting to save the data.)

Solution ➡ Delete unnecessary data in the memory and save the data again.

6.2 B mode image diagnosis

- B mode images are dark and not easy to see.

?Cause 1 The setting of the total gain is low.

Solution ➡ Increase the total gain value.

- Ultrasound images are not clear or exact.

?Cause 1 The B mode probe is not connected correctly.

Solution ➡ Check that the B mode probe is firmly connected.

? Cause 2 Gel for ultrasound diagnosis is not used or is insufficient.

Solution ➡ Apply gel for ultrasound diagnosis to the tip of the probe. If the problem is not solved even after the protective agent is applied, apply more.

? Cause 3 Noise is generated in the peripheral area

Solution ➡ 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.

- The vector A mode waveform is not displayed.

? Cause 1 Functions for which cannot be used concurrently are attempted to be effective.

While the following functions are effective, the vector A mode function cannot be enabled.

- Zoom function
- Measurement function

Solution ➡ Disable the above functions.

- A probe error is displayed when starting operation or switching to the B mode image diagnostic function.

? Cause 1 The B mode probe is not connected correctly.

Solution ➡ Check that the B mode probe is firmly connected.

- No comment is displayed on images.

? Cause 1 The display setting of comments is "hidden".

Solution ➡ Turn on the display of comments as described in "3.2.1 b) Settings for items displayed in image."

- Freezing cannot be canceled when stepping on the foot switch.

? Cause 1 The foot switch is not connected correctly.

Solution ➡ Verify that the foot switch is connected firmly and locked.

-
- The instrument enters FREEZE mode although the foot switch is not pressed.

? Cause 1 The auto freezing function is activated.

Solution ➡ When there is no entering from a user in the real time mode for a long time, freeze mode is automatically entered. When you want to return to real time mode, cancel freezing by touching the “FREEZE” button or stepping on the foot switch.

6.3 Biometry function

- The axial length cannot be measured.

? Cause 1 The biometry probe is not connected correctly.

Solution ➡ Correctly connect the probe until it is locked.

? Cause 2 The measurement conditions in immersion mode are not satisfied. (In the case of immersion mode)

Solution ➡ In immersion mode, data is captured when a corneal waveform is within 2.0 - 5.0 mm from the initial waveform. Place the cornea protective agent or immersion attachment between the cornea and the tip of the biometry probe to satisfy these conditions.

? Cause 3 The biometry probe is directly applied to the cornea without using a cornea protective agent or immersion attachment. (In the case of immersion mode)

Solution ➡ Use the immersion attachment or cornea protective agent for measurement in immersion mode.

- Measurement cannot be performed in Auto mode.

? Cause 1 The mode is set to Manual.

Solution ➡ Set to Auto mode.

? Cause 2 Noise is generated in the peripheral area.

Solution ➡ 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.

?Cause 3 Patient's sight is unstable.

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

?Cause 4 The contact section of the biometry probe is damaged.

Solution ➡ If damaged, immediately stop measurement and contact your local distributor.

● Measurement cannot be performed in Manual mode.

?Cause 1 The foot switch is not connected correctly.

Solution ➡ Connect the foot switch correctly until it is locked as described in "3.1.1 c) Connecting the foot switch."

?Cause 2 The mode is set to Auto.

Solution ➡ Set to Manual mode.

● Measurements are unstable or inappropriate.

?Cause 1 The biometry probe is not connected correctly.

Solution ➡ Correctly connect the probe until it is locked.

?Cause 2 The retina gate cursor is not set in an appropriate position.

Solution ➡ Set the retina 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.

?Cause 3 The biometry probe is not applied appropriately.

Solution ➡ Apply the probe to the center of the cornea perpendicularly so that the retina waveform spikes.

?Cause 4 Too much corneal protective agent is applied. (In the case of contact mode)

Solution ➡ When too much cornea protective agent is applied, a gap is formed between the biometry probe and cornea, and the measurement result may tend to be longer. Apply appropriate amount of cornea protective agent.

? Cause 5 The immersion attachment is used. (In the case of contact mode)

Solution ➡ Select immersion mode and take measurements.

? Cause 6 The biometry probe is directly applied to the cornea without using the cornea protective agent. (In the case of immersion mode)

Solution ➡ Use the immersion attachment or cornea protective agent for measurement in immersion mode.

? Cause 7 The converted acoustic velocity is not set appropriately.

Solution ➡ 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.

? Cause 8 The contact section of the biometry probe is damaged.

Solution ➡ If damaged, immediately stop measurement and contact your local distributor.

● Monitoring sound does not stop.

Data is captured even while the probe does not contact the eyeball.

? Cause 1 The tip of the biometry probe is wet.

Solution ➡ Remove drops of water.

● Monitoring sound does not go off.

? Cause 1 The measurement sound is set to “OFF.”

Solution ➡ Set the volume to an option other than “OFF” as described in “3.9.1 General.”

-
- The probe error confirmation screen appears when the power is turned on.

? Cause 1 The biometry probe is not connected correctly.

Solution ➡ Correctly connect the probe until it is locked.

- The fixlight in the biometry probe is turned off.

? Cause 1 Lighting of the fixlight is set to “OFF.”

Solution ➡ Set to ON as described in “3.9.2 c) Measurement Setting : Axial.”

6.4 Pachymetry function

- The probe error confirmation screen appears when the power is turned on or the pachymetry probe is calibrated.

? Cause 1 The pachymetry probe is not connected correctly.

Solution ➡ Correctly connect the probe until it is locked.

- The error message “Out of range!” appears and measurement cannot be performed.

? Cause 1 The measurement range setting is not correct.

Solution ➡ Touch the “Meas Range” button to set the measurement range appropriately.

- Stable measurements cannot be obtained. Appropriate measurements cannot be obtained.

? Cause 1 The pachymetry probe is not connected correctly.

Solution ➡ Correctly connect the probe until it is locked.

? Cause 2 The pachymetry probe is not applied appropriately.

Solution ➡ Apply the pachymetry probe perpendicular to the cornea at the position to be measured.

? Cause 3 The converted acoustic velocity is not set appropriately.

Solution ➡ Check that the converted acoustic velocity is set correctly. (Refer to “3.6.2 c) How to display converted acoustic velocity and bias values.”)

?Cause 4 The contact section of the pachymetry probe is damaged.

Solution ➡ If damaged, immediately stop measurement and contact your local distributor.

?Cause 5 The pachymetry probe is not calibrated correctly.

Solution ➡ Thoroughly wipe the tip of the pachymetry probe and press the sensitivity calibration button to re-calibrate the probe.

● Measurement cannot be performed in Auto mode.

?Cause 1 The measurement mode is set to Manual.

Solution ➡ Switch the mode to auto measurement mode.

● The measureable point does not move immediately when the pachymetry probe is removed from the cornea.

?Cause 1 The tip of the pachymetry probe is wet.

Solution ➡ Thoroughly remove any drops of water.

● Monitoring sound does not stop. Data is captured even while the probe does not contact the eyeball.

?Cause 1 The tip of the pachymetry probe is wet.

Solution ➡ Thoroughly remove any drops of water.

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7. CONSUMABLES AND OPTIONAL EQUIPMENT

7.1 Spare parts

Ultrasound gel

Fuse

Specify the fuse type as "Fuse for UD-800."

Built-in printer paper

Specify the paper type as "TOMEY common printer (58 mm)."

7.2 Optional parts

40MHz UBM probe

Probe cap membrane

Syringe

PROBE Arm

Eye cup

Biometry probe (with case and test piece)

Immersion attachment

Pachymetry probe (with case and test piece)

A-scan diagnosis probe (with case)

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8. SPECIFICATIONS

8.1 Specifications

B mode image diagnosis 10MHz B-Probe

- Frame rate
 - Basic mode : 20 frame / sec
- Maximum number of pages in a movie
 - 200 pages x 2
- Image display range
 - Standard : 35.2mm / 52° (at ultrasound velocity=1550 m/sec)
 - Wide : 48.0mm / 52°(at ultrasound velocity=1550 m/sec)
- Resolution
 - Lateral accuracy : 0.6mm
 - Axial accuracy : 0.6mm
- Distance measurement
 - [Distance accuracy between cursors]**
 - Lateral accuracy : ±0.5mm
 - Axial accuracy : ±0.5mm
 - [Minimum distance unit between cursors]**
 - Normal: : 0.055mm step(velocity=1550 m/sec)
 - Wide : 0.075mm step(velocity=1550 m/sec)
- Acoustic lines
 - 131 lines(step by 0.4°)
- Color scale
 - 256 scale level
- Scan Type : Sector scanning
- Transducer type : 2-ring
- Transducer frequency : 10MHz

Biometry / IOL power calculations

●Measurement range

■ Axial length	: 15.00 - 45.00mm
■ ACD	: 1.80 - 7.00mm
■ Lens thickness	: 2.00 - 6.00mm

●Accuracy

■ Measurement Accuracy	: ± 0.1 mm
■ Measurement Resolution	: 0.01 mm

●Factory setting of the converted velocity

■ Average velocity of the axial length	
Phakic Eye	: 1,550m/s
Dense Cataract	: 1,548m/s
Aphakic	: 1,532 m/s
■ Lens velocity	
Phakic Eye	: 1,641m/s
Dense Cataract	: 1,629m/s
■ ACD velocity	
Phakic Eye	: 1,532 m/s
Dense Cataract	: 1,532 m/s
IOL Eye	: 1,532 m/s
■ Velocity of vitreous	
Phakic Eye	: 1,532 m/s
(In case of sectional velocity)	
IOL Eye	: 1,532 m/s
■ IOL velocity	
Acrylic	: 2,200m/s
Silicone	: 1,049m/s
PMMA	: 2,718m/s
User	: 2,200m/s
■ IOL thickness	
Acrylic	: 0.80mm
Silicone	: 1.00mm
PMMA	: 0.80mm
User	: 0.80mm

- IOL power calculation

- Haigis standard
- Haigis optimized
- Hoffer[®]Q
- Holladay 1
- SRK II
- SRK/T
- SRK SHOWA
- Shammas-PL
- SRK/T Double K

- Biometry probe

- Type : Solid state
- Fix light : Built in the probe, Red LED
- Transducer frequency : 10MHz
- Tip diameter : 5.3mm ϕ
- Dimension / Weight : 8mm ϕ × 100mm / 30g

Pachymetry

- Measurement range : 150 to 1,500 μ m

- Accuracy

- Measurement Accuracy : $\pm 5\mu$ m
- Measurement Resolution : 1 μ m

- Percent bias/plus minus bias setting range

- Percent bias : 60 - 130%
- Plus minus bias : -600 to +450 μ m

- Factory setting and setting range of the converted velocity

: 1,640m/s / 1,400 to 2,000m/s

- Pachymetry probe

- Type : Solid state
- Transducer frequency : 20MHz
- Tip diameter : 1.5mm with an angle of 45°
- Dimension / Weight : 8.8mm ϕ × 90mm / 40g

A-scan Diagnosis

- Measurement range : 60mm
- A-Scan diagnostic probe
 - Type : Solid state
 - Transducer frequency : 10MHz
 - Tip diameter : 6.0mmφ
 - Dimension / Weight : 8mmφ × 100mm / 30g

Dimensions and weights

- Dimension : 310(W)×326(H)×214(D) mm
- Weight : 6.0kg

Display

- TFT LCD : 10.4 inches, color touch screen

Power source

- Input Voltage : 100-240VAC
- Frequency : 50/60 Hz
- Power Consumption : 120 VA

8.2 Quantity of ultrasonic energy

Ispta.3 : 17 mW/cm² or less
 Isppa.3 : 28 W/cm² or less
 MI : 0.23 or lower

Standards for ultrasonic wave output in an eyeball based on the 510(k) guidelines of FDA

Ispta.3 : Spatial peak temporal average strength

Isppa.3 : Spatial peak pulse average strength

MI : Mechanical index

The ultrasound wave output table based on IEC60601-2-37 is as shown below.

Ultrasound wave output table (IEC60601-2-37)

Index label			MI:	TIS Scan
			10M B probe	10M B probe
Maximum index value			0.207	0.06481
Associated acoustic parameters	pr,α[Mpa]		0.648	N/A
	P[mW]		N/A	0.06671
	Min.of [Pα(zs),I _{ta} ,α(zs)]		N/A	N/A
	Zs		N/A	N/A
	Zbp		N/A	N/A
	Zb		N/A	N/A
	Z at max.I _{pi} ,α [cm]		1.85	N/A
	deq(zb)		N/A	N/A
	fawf[MHz]		9.83	9.83
	Dim of Aaprt [cm]	X	N/A	0.52
		Y	N/A	0.52
Other information	Td[us]		0.131	N/A
	Prr[Hz]		2620	N/A
	Pr at max.I _{pi} [MPa]		1.2113	N/A
	deq at max.I _{pi}		N/A	N/A
	I _{pa} ,α at max.MI [W/ cm ²]		12.227	N/A
Operating control conditions	Control		N/A	N/A

Index label			MI			TIS Non-scan($A_{aprt} \leq 1\text{cm}^2$)		
			Axial	Pachy	A-Diag	Axial	Pachy	A-Diag
Maximum index value			0.175	0.136	0.129	1.8×10^{-3}	0.449×10^{-3}	3.6×10^{-3}
Associated acoustic parameters	pr, α [Mpa]		0.557	0.629	0.386	N/A	N/A	N/A
	P[mW]		N/A	N/A	N/A	0.0373	4.42×10^{-3}	0.0542
	Min.of [P α (zs),lta, α (zs)]		N/A	N/A	N/A	N/A	N/A	N/A
	Zs		N/A	N/A	N/A	N/A	N/A	N/A
	Zbp		N/A	N/A	N/A	N/A	N/A	N/A
	Zb		N/A	N/A	N/A	N/A	N/A	N/A
	Z at max.lpi, α [cm]		1.36	0.05	1.36	N/A	N/A	N/A
	deq(zb)		N/A	N/A	N/A	N/A	N/A	N/A
	fawf[MHz]		10.147	21.362	8.91	10.147	21.362	8.91
	Dim of Aaprt [cm]	X	N/A	N/A	N/A	0.4	0.19	0.48
		Y	N/A	N/A	N/A	0.4	0.19	0.48
Other information	Td[us]		0.303	0.0815	0.171	N/A	N/A	N/A
	Prr[Hz]		1200	4000	640	N/A	N/A	N/A
	Pr at max.lpi [MPa]		0.897	0.653	0.586	N/A	N/A	N/A
	deq at max.lpi		N/A	N/A	N/A	N/A	N/A	N/A
	lpa, α at max.MI [W/ cm ²]		5.427	8.893	2.606	N/A	N/A	N/A
Operating control conditions	Control		N/A	N/A	N/A	N/A	N/A	N/A

8.3 Noise

The instrument generates machine noise while operating when:

- Turning power on
- Performing self diagnosis
- Printing out data
- Using the keys
- Inserting, detecting, storing data to, and removing a USB memory
- Generating errors

8.4 Operating environment

Operate the instrument under the following environmental conditions.

- | | |
|------------------------|------------------------------------|
| ■ Installation | : Indoors, not in direct sunlight |
| ■ Temperature | : +10°C - +35°C |
| ■ Humidity | : 30 – 75% |
| ■ Atmospheric pressure | : 800 -1060 hPa |
| ■ Power fluctuation | : less than ±10% of normal voltage |

Store and/or transport the instrument in the instrument's box under the following environmental conditions.

- | | |
|---------------|-----------------|
| ■ Temperature | : -20°C - +50°C |
| ■ Humidity | : 45 - 85% |

8.5 Classification of ME equipment

Protection against electric shock
: Class I ME equipment

Applied parts
: B applied parts (the tip of 10MHz B probe, the tip of the 40MHz UBM probe, the tip of the biometry probe, the tip of the pachymetry probe, the tip of the A-Scan diagnostic probe)

IP Code
: IP20 (Main unit) IP41 (10MHz B probe except connector, biometry

probe except connector, pachymetry probe except connector, A-Scan diagnostic probe except connector) IP47 (the tip of 10MHz B probe, the tip of the biometry probe, the tip of the pachymetry probe, the tip of the A-Scan diagnostic probe) IP21 (40MHz UBM probe except connector, Foot switch) IP27 (the tip of 40MHz UBM probe)

Mode of Operation

: Continuous operation

8.6 Declaration of Conformity to EMC



- *When using specified accessories or cables excluding internal parts sold as repair parts of TOMEY Corporation, electromagnetic emission of the UD-800 may increase or electromagnetic immunity may decrease.*
- *When using handheld or portable communication equipment, locate it more than 30cm(12inches) away from the UD-800. It may degrade the performance of the UD-800 if the equipment is located closer.*
- *Do not use the UD-800 adjacent to or stacked on other equipment. If it needs to be adjacent to or placed on other equipment, it must be confirmed that UD-800 operates correctly in such location.*



- *The UD-800 falls under Group 1, Class B according to EN 55011(CISPR 11). This means that the UD-800 does not generate RF energy intentionally in the form of electromagnetic irradiation, inductive coupling and/or capacitive coupling for processing of materials or inspection/analysis, and that it is suitable for use in facilities directly connected to a low-voltage power network that supplies power to general household facilities and buildings used for home use.*
- *The UD-800 can be used in a specialized health care facility such as hospitals and clinics (except anywhere near the source of a strong EMI) and a general commercial facility such as eye glasses stores.*
- *The UD-800 requires special attention for EMC and needs to be installed, serviced and used based on the following information.*
- *Do not use cables other than those provided or specified by TOMEY Corporation.*
- *The person who connects additional equipment to the signal I/O section as part of the medical system, shall take responsibility for ensuring the system conforms to IEC/EN 60601-1-2 requirements.*

Cable list

Name	Specification	Length	Note	Essential
AC Power Cord	Unshielded	2.5m	Accessories	
Foot Switch Cable	shielded	1.6m	Accessories	
USB cable	shielded	1.8m	Not accessories	
USB cable	shielded	1.2m	Not accessories	
USB cable	shielded	1.8m	Not accessories	
B Probe Cable	shielded	1.6m	Accessories	
Biometry Probe Cable	shielded	1.8m	Not accessories	
PACHY Probe Cable	shielded	1.8m	Not accessories	

performance :

Display B mode image of the retina, vitreous body and anterior chamber that enable the physician to diagnose the presence of diseases.

Display the correctly measured axial length and perform IOL calculation.

Display the correctly measured corneal thickness.

Display A mode waveforms of the retina and vitreous body that enable the physician to diagnose the presence of diseases.

<EMISSIONS>

Test	Standard	Compliance
		HOME HEALTHCARE ENVIRONMENT
Conducted Emissions	CISPR 11	Group 1 Class B
Radiated Emissions	CISPR 11	Group 1 Class B
Harmonic distortion	IEC 61000-3-2	Harmonic Class A
Voltage fluctuations and flicker	IEC 61000-3-3	Complies

<IMM
UNITY
>
Table
1

【ENCLOSURE PORT】

Test	Standard	IMMUNITY TEST LEVELS
		HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80MHz – 2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table 2
RATED power frequency magnetic fields	IEC 61000-4-8	30 A / m 50Hz or 60Hz

Table 2 【Test specifications for ENCLOSURE PORT IMMUNITY to
RF wireless communications equipment】

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V / m)
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ±5kHz deviation 1kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800 / 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1 720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1 845						
1 970						
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b / g / n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5 240	5 100 - 5 800	WLAN 802.11 a / n	Pulse modulation 217Hz	0.2	0.3	9
5 500						
5 785						

Table 3 【Input a.c. power PORT】

Test	Standard	IMMUNITY TEST LEVELS
		HOME HEALTHCARE ENVIRONMENT
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V 0.15MHz - 80MHz 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T ; 1 cycle and 70% U_T ; 25 / 30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T ; 250 / 300 cycle

Table 4 【Signal input / output parts PORT】

Test	Standard	IMMUNITY TEST LEVELS
		HOME HEALTHCARE ENVIRONMENT
Electrical fast transients / bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

Table 5 【PATIENT coupling PORT】

Test	Standard	IMMUNITY TEST LEVELS
		HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

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Original instructions

