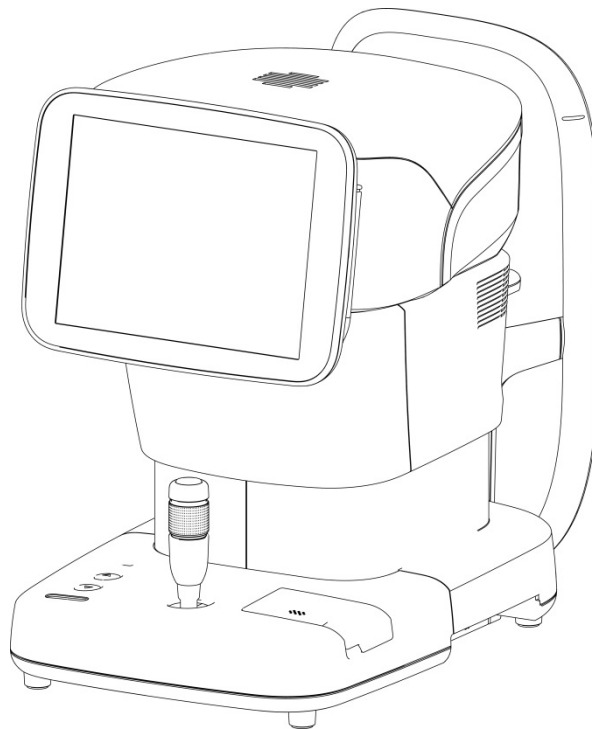


INSTRUCTION MANUAL

Specular Microscope EM-4000



Read this manual thoroughly before using the instrument to ensure proper and safe operation. Contact Tomey Corporation or our 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 our local distributor if you lose this manual.***



i Important Safety Information



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



- *Disconnect the power cord from the instrument before servicing the instrument. Otherwise, you may get an electric shock.*



- *Do not place water or chemicals on the instrument. Any water or chemicals entering the instrument may cause an electric shock or failure.*
- *Only use the specified terminal for connection of the instrument. Using another type of terminal may result in failure of the instrument.*
- *This instrument is a diagnostic/capturing device specifically designed for ophthalmology. Never use the instrument for other purposes.*
- *A metal blade is attached to the printer cover. Touching this blade may result in injuries, so be sure to pay utmost attention when handling the printer cover.*
- *The terminal for connecting the instrument to external devices is not isolated from the internal circuit. Inappropriate wiring may damage the internal circuit. Contact us or our local distributor before using the instrument while connected to another device.*

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. INSPECTION AND MAINTENANCE

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

5. TROUBLESHOOTING

Describes how to solve problems.

6. CONSUMABLES AND OPTIONAL EQUIPMENT

Describes consumable parts and optional equipment.

7. 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 additional information which may contain special precautions on company policies related, either directly or indirectly, to the safety of personnel or to the protection of property.*

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1. PRIOR TO USE



- *Read this manual thoroughly before using the instrument to ensure proper and safe operation.*
- *Always follow the operation procedures described in this manual.*
- *Check that there are no devices that generate strong magnetic field near the instrument. A strong magnetic field may cause noise and affect the capture of images.*

1.1 Precautions for operation

- *Only allow qualified operators to use the instrument.*
- *Precautions when installing the instrument*



- *Install the instrument in a location free of water or chemicals. Any water or chemicals entering the instrument may cause an electric shock or failure.*
- *Do not install 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.*
- *Check that the frequency, voltage, and allowable current (or power consumption) of the power source are appropriate. 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.*
- *When operating this instrument connected to other devices, only use devices that comply with IEC60601-1 or that comply with IEC60950-1 and whose power source is isolated with an isolation transformer. Furthermore, all devices should be configured to comply with the standard IEC60601-1 ME system. Anyone who connects any additional device to the communication connector will be considered a person configuring a medical system, and is therefore responsible for complying with the requirements of an IEC60601-1 ME system. Contact us or our local distributor before connecting the instrument to another device with a communication connector.*
- *Do not connect a device with data transmission specifications that are not compatible. Fire or electric shock may occur. Contact us or our local distributor before using the instrument while connected to another device.*
- *Conduct grounding work correctly. Otherwise you may get an electric shock.*



- Do not hold the head, chin rest, forehead pad, or joystick when moving the instrument. These components are detachable and the instrument may drop, resulting in injuries.
- 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, images cannot be captured correctly. Also, the instrument may topple over or fall down, resulting in fire or a serious accident.
- Install the instrument between the patient and physician so that they can face each other.
- Install the instrument in a location with ample clearance from other devices to allow smooth inspection.

■ Precautions before using the instrument



- Check that the instrument works properly by inspecting switch and button operations, display, and printing.
- Check that all cables are connected correctly.
- Check the sections that the patient will directly touch.
- Peel off the top sheet of chin rest paper and clean the forehead pad with a cloth dampened with alcohol before capturing images.
- 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.



- If any smoke, offensive odor, or abnormal sound occurs, turn the instrument off immediately, disconnect the power plug from the outlet, and contact us or our local distributor.
- Do not operate the joystick, touch panel, and membrane button panel during the initial motion performed before the capture screen appears after the power switch is turned on. If the initial motion is not completed correctly, malfunction may be caused when capturing images.
- When moving the head and/or chin rest of the instrument, pay attention to the position of the patient's face, and patient's and physician's hands and fingers. Otherwise, they may be injured by the movement of the head or chin rest.

-
- *Do not allow any person to place their hands or fingers in the clearance under the head or the section immediately under the chin rest. Their hands or fingers may be caught and injured.*
 - *Never insert fingers or objects through the capture window. Malfunction or failure of the instrument or faulty analysis results may occur.*
 - *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 careful to not exceed the diagnosis time.*
 - *Always check that there is no problem with the instrument and patient to ensure safety.*
 - *If any problem is found with the instrument or patient, take appropriate action, such as stopping operation, to maintain patient safety.*
 - *Immediately stop capturing images if the patient shows any signs of photosensitive epilepsy.*
 - *Faulty fixing of the sight, eyelid drooping, trichiasis, corneal diseases, etc. may affect the analysis result or measurement of corneal thickness. When the captured image is unclear, use another image for analysis or capture another image. If the measurement result of the corneal thickness is doubtful, review the inspection result by performing measurement again or another inspection.*
 - *When using captured images or analysis results obtained with this instrument for diagnosis, also refer to the results of other examinations. Capturing conditions may affect the precision of images or analysis result.*
 - *Do not use the “central corneal thickness” and “ultrasonic correction for central corneal thickness” output from this instrument to directly correct the eye refractive power. Other examination methods should also be used in conjunction with the above.*
 - *Do not allow the patient to touch the instrument.*
 - *Peel off the top sheet of chin rest paper and clean the forehead pad with a cloth or the like dampened with alcohol before capturing an image for the next patient.*

■ 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 can also corrode the resin or coating of the instrument cover.)*
- *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.*
- *Disconnect the power plug from the outlet to ensure safety when the instrument is not operated for long periods.*

-
- Refer to "4.6 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 our local distributor for repairs.**



- Do not modify the instrument. Touching the internal circuit may result in death or serious injuries
- Disconnect the power cord from the outlet when replacing fuses. Otherwise, you may get an 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.



- When any failure occurs in the instrument, indicate the failure in the instrument and contact our local distributor for inspection and repairs. Do not attempt to repair the instrument yourself.
- Conduct regular inspections of the instrument and components.
- When the instrument is not used for 1 month or longer, check that the instrument is operating correctly and safely before starting operation. Refer to "4.3 Inspection" in this manual for the checking procedures.

1.2 Checking package contents

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 by directly holding the head, chin rest, forehead pad, or joystick. The instrument may be damaged.**

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 our local distributor as soon as possible.

● Main unit SPECULAR MICROSCOPE EM-4000	1
● Power cord	1
● Touch pen	1
● SD card (installed in the main unit)	1
● Fuse (2 fuses are installed in the main unit.)	4
● Chin rest paper	1
● Pins for chin rest paper	2
● Printer paper (1 paper is installed in the main unit.)	2
● Dust cover	1
● Instruction manual (this manual)	1
● Data Transfer installation CD	1
● Data Transfer Starting Guide	1

1.3 Glossary

[6A]	: Percentage of cell hexagonality. Percentage of hexagonal cells in analyzed endothelium tissues
[AA/AS]	: Auto Alignment / Auto Shot
[AA/MS]	: Auto Alignment / Manual Shot
[AVG]	: Average area Average area of analyzed endothelium tissues
[Basic mode]	: Capture mode in which the image selection screen appears when capturing is completed. This mode is for users to observe 16 captured images of endothelium tissues and select only one from them.
[CCT]	: Central corneal thickness
[CCT (US)]	: Ultrasound correction for central corneal thickness The reference value expected when measuring the same central corneal thickness using our ultrasound-type central corneal thickness measuring instrument
[CD]	: Cell density The number of analyzed endothelium tissues in 1 mm ²
[Core method]	: Analysis method to calculate values such as CD (cell density) by extracting trace lines of cells referring to the center of the cell entered by the physician
[CV]	: Fluctuation coefficient Fluctuation coefficient of areas of analyzed endothelium tissues. Value calculated by dividing the standard deviation with the average area.
[D.A.AVG]	: Average area of dark area Average area of analyzed dark area
[D.A.CV]	: Fluctuation coefficient of dark area Fluctuation coefficient of the analyzed dark area. Value calculated by dividing the standard deviation with the average area.
[D.A.Density]	: Dark area density The number of cells in 1 mm ² of the analyzed dark areas
[D.A.MAX]	: Maximum size of dark area The area of the largest cell in the analyzed dark area
[D.A.MIN]	: Minimum size of dark area The area of the smallest cell in the analyzed dark area
[D.A.NUM]	: Number of dark areas The number of analyzed dark areas
[D.A.Ratio]	: Dark area ratio Ratio of the dark area relative to the total area. The total area is the sum of the analyzed dark area and the area of the analyzed endothelium tissues.
[D.A.SD]	: Standard deviation of dark area Standard deviation of the analyzed dark area
[DATA Transfer]	: System to output the examination data obtained with our product as a file

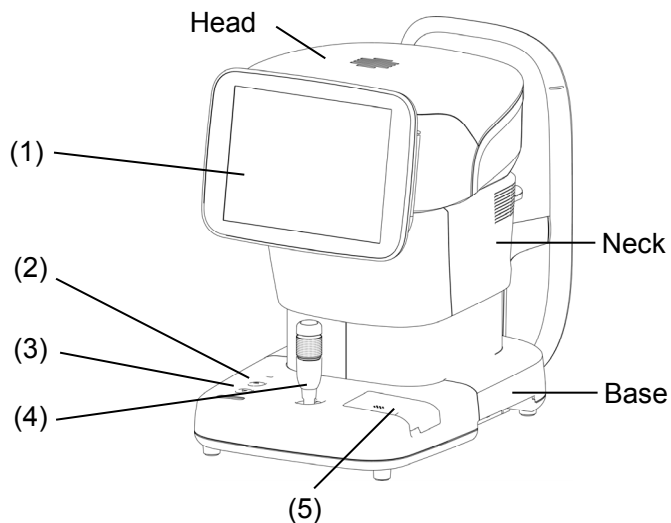
[Dark area]	: Black circle area to be observed by the specula microscope
[Dark area analysis]	: Analysis method to calculate values related to the dark area (D.A.Density, etc.) by automatically extracting dark areas from the captured image
[L-count method]	: Analysis method to calculate values such as CD (cell density) according to the area and cell center entered by the physician
[MA/MS]	: Manual Alignment / Manual Shot
[MAX]	: Maximum area The area of the largest cell in the analyzed endothelium tissues
[MIN]	: Minimum area The area of the smallest cell in the analyzed endothelium tissues
[NUM]	: Number of cells The number of analyzed endothelium tissues
[Quick mode]	: Capture mode in which the image selection screen does not appear when capturing is completed. This mode is for users who do not wish to observe 16 images of endothelium tissues.
[SD]	: Standard deviation Standard deviation of the area of analyzed endothelium tissues
[TOMEY Link]	: System for electronic medical records that controls the examination data obtained with our products
[Auto Alignment]	: Function to automatically align the sight in up/down/right/left/focus directions
[Auto Shot]	: Function to automatically capture an image when the sight in the up/down/right/left/focus directions is optimized
[Auto Analysis]	: Analysis method to calculate values such as CD (cell density) by automatically extracting trace lines of cells on the captured image
[Power-save]	: This is a function to automatically turn off the monitor when the instrument is not operated for a specified time. Touch the monitor to return to normal status.
[Touch Alignment]	: Function to move the measuring head by touching the screen. This is used for rough alignment.
[Manual Alignment]	: Manual alignment
[Manual Shot]	: To capture images manually
[Rx only]	: This symbol on the label of this device states "Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner."

1.4 Overview

This instrument is designed to observe and analyze corneal endothelium by capturing an image of corneal endothelium tissues without making contact, analyzing the captured image, and calculating data such as cell density. In addition, this instrument also measures the central corneal thickness while capturing an image of corneal endothelium tissues. The patient places their chin on the chin rest and looks into the fixation light in the capture window. The instrument automatically starts fine alignment when the physician roughly aligns the corneal center and captures an image. An image can be captured manually using the joystick if a problem with the eyes makes automatic operation impossible.

2. NAMES AND FUNCTIONS

2.1 Physician's side



(1) LCD monitor and touch panel

Displays screens. Touch displayed buttons to operate the instrument.

The tilting angle of the monitor can be adjusted.

(2) Power lamp

The lamp stays lit while the power is turned ON.

(3) Chin rest up/down button

Press the button to move the chin rest up and down.

(4) Joystick

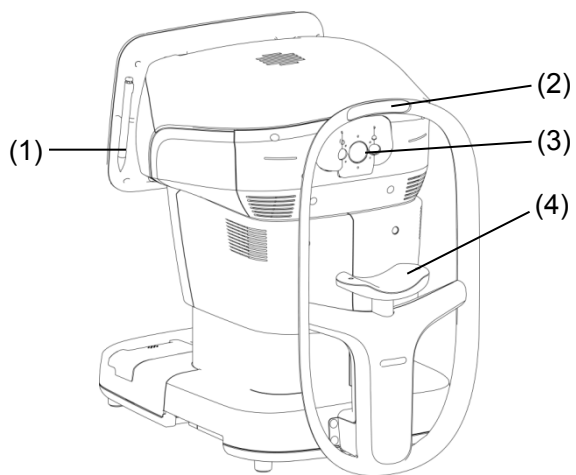
Performs alignment.

Use the capture button on the top of the joystick when capturing an image manually.

(5) Built-in printer

Thermal printer with automatic cutter. Prints the examination data.

2.2 Patient's side



(1) Touch pen

Use this when selecting cells etc. The touch pen is provided with a magnet and can be attached to the side of the monitor.

(2) Forehead pad

Have the patient lightly apply their forehead to this pad to fix their head while capturing an image.

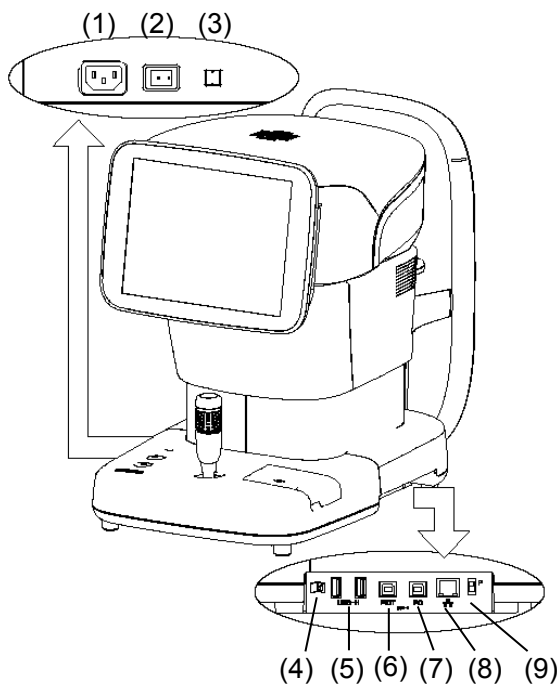
(3) Capture window

Radiates light for capturing images and receives the light reflected from the patient's eye.

(4) Chin rest

Have the patient to place their chin on this rest.

2.3 Sides of the main unit



(1) Power socket

Connect the power cord here.

(2) Power switch

Turns the instrument on and off.

(3) Packing button

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

(4) SD card slot

An SD card used to save the examination data is inserted here.

(5) USB-H connector

Connect the video printer and external ID input device here.

(6) USB-D connector (PICT)

Connect the Pict Bridge printer here.

(7) USB-D connector (personal computer)

Connect the personal computer etc. here.

(8) LAN connector

Used for connection to Ethernet.

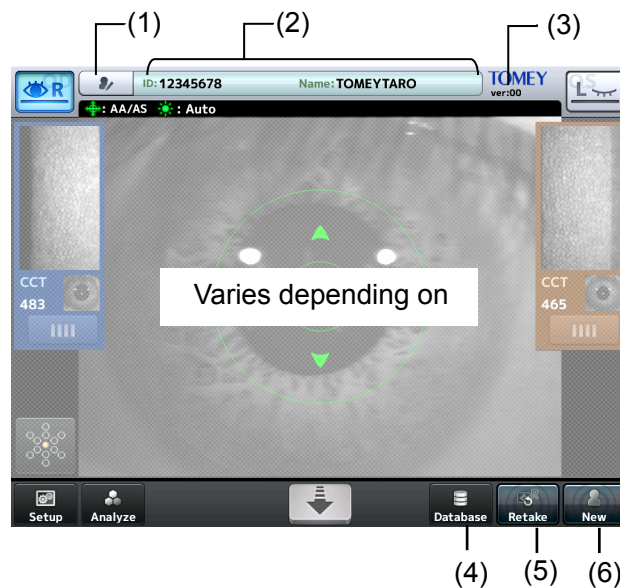
(9) Maintenance switch

Our maintenance personnel use this switch when servicing the instrument.

Never touch this switch.

2.4 Screen

2.4.1 Basic structure and common items



(1) Patient information button

Moves to the patient information input screen.

(2) Patient information field

Displays the ID and name of the patient.

(3) Version

Displays the version of the system.

(4) "Database" button

Moves to the Patient List screen.

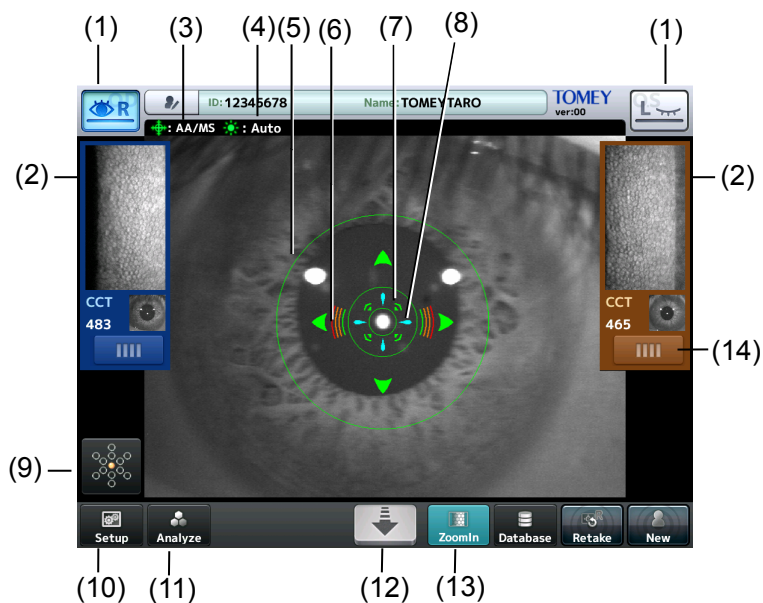
(5) "Retake" button

Touch and hold this button to delete the examination data of the selected patient's eye and start capturing another image.

(6) "New" button

Touch and hold this button to delete the examination data of both eyes and the patient's information, and start capturing an image.

2.4.2 Capture screen



(1) Eye selection button

Displays which side (left or right eye) the head is placed. Touch this button to move the head right and left.

(2) Thumbnails

Displays the captured image of the endothelium and anterior chamber, and central corneal thickness.

(3) Alignment/capture setting

Displays the setting for alignment and capture.

- AA/AS: Auto Alignment / Auto Shot
- AA/MS: Auto Alignment / Manual Shot
- MA/MS: Manual Alignment / Manual Shot

(4) Capture light setting

Displays the setting for the strength of light for capturing an image of the endothelium.

- Auto: Brightness is automatically adjusted.
- High: Maximum brightness
- Low: Minimum brightness

(5) Auto Alignment ring

Displayed when Auto Alignment is ON.

(6) Focus indicator

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

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

(7) Auto shot mark

Shown in auto shot mode.

(8) Alignment OK mark

Shown when alignment is optimum.

(9) Fixation light button

The preset fixation light position is shown on this button in orange.

Touch this button to open the Fixation Light screen.

(10) "Setup" button

Moves to the Setup screen.

(11) "Analyze" button

Performs automatic analysis and moves to the R/L eye analysis screen.

(12) Head retreat button

The head retreats while this button is touched.

(13) "ZoomIn" button

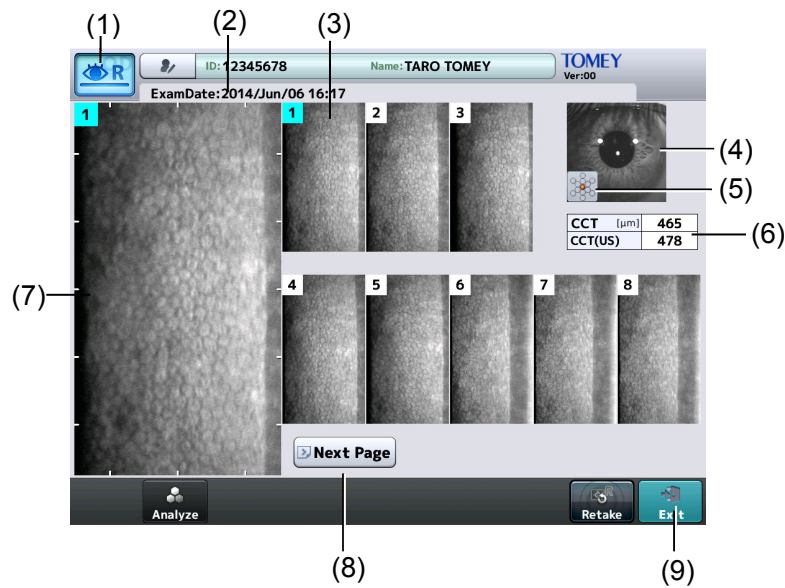
Switches the image shown by the live camera from the anterior chamber to endothelium tissues.

This button appears in MS (Manual Shot) mode.

(14) Image selection button

Moves to the image selection screen.

2.4.3 Image selection screen



(1) Inspected eye

Displays which patient's eye (right or left) corresponds to the displayed examination data.

(2) Exam Date-Time

Displays the date and time when capturing the image.

(3) Thumbnails

Displays 8 out of 16 captured images of the endothelium as thumbnails.
Images are numbered from 1 to 16 in the order of the capture quality.

(4) Image of anterior chamber

Displays the captured image of the anterior chamber.

(5) Fixation light position

Displays the fixation light position when the image was captured.

(6) Central corneal thickness

Displays the thickness in the center of the cornea of the captured image.

(7) Selected image display field

Displays 1 enlarged image out of 16 images of the endothelium selected for analysis.

(8) "Next Page" button

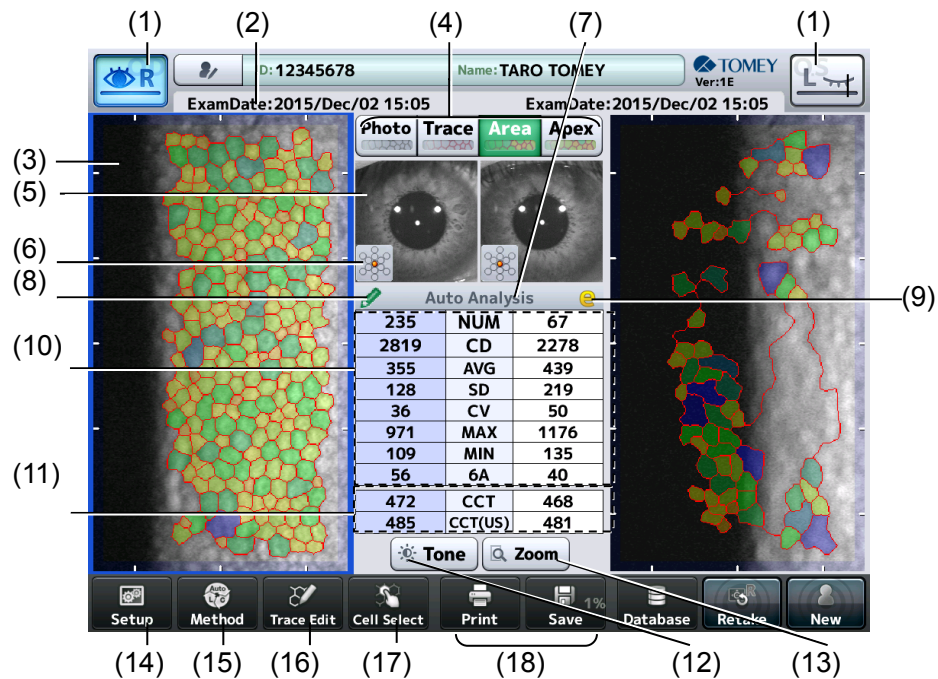
Recalls the remaining 8 captured images included in the next page.

(9) "Exit" button

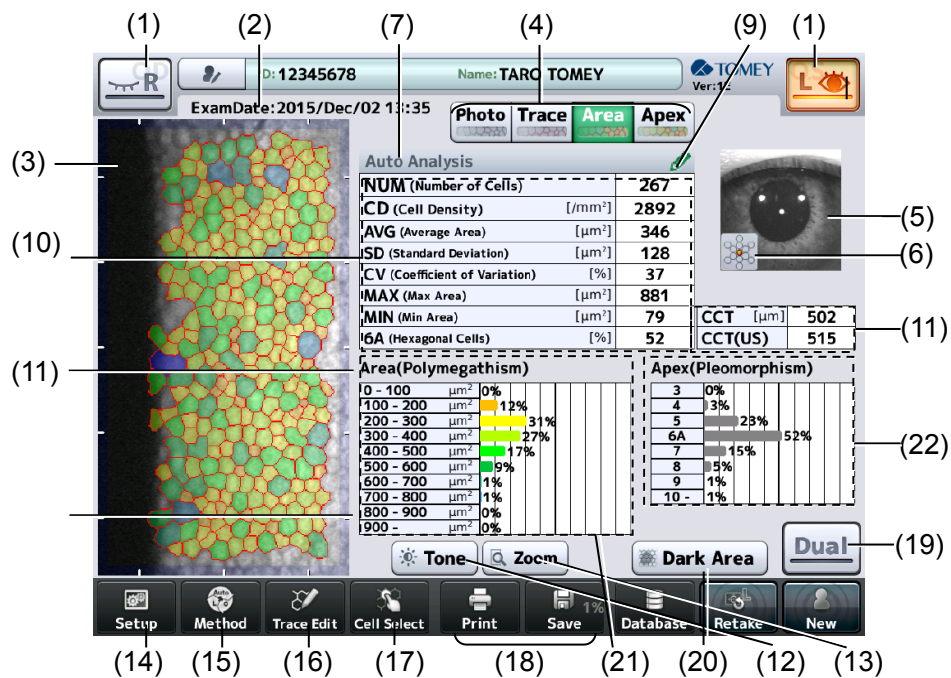
Closes the image selection screen and returns to the capture screen.
The selected image is designated for analysis.

2.4.4 Analysis screen

a) R/L eye analysis screen



b) Single eye analysis screen



(1) Eye selection button

Shows the selected eye (right or left) by color. Touch this button to move to the single eye analysis screen.

(2) ExamDate

Displays the date and time when capturing the image.

(3) Image of endothelium

Touching the image switches selection of the eye. The endothelium image of the selected eye is outlined with a color frame.

(4) “Photo/Trace/Area/Apex” buttons

Photo: Displays the captured image of the endothelium.

Trace: Displays extracted trace lines on the image of the endothelium.

Area: Displays an endothelium image color-coded according to cell sizes.

Apex: Displays an endothelium image color-coded according to cell shapes.

(5) Image of anterior chamber

Displays a captured image of the anterior chamber.

(6) Fixation light position

Displays the fixation light position when the image was captured.

(7) Analysis method

Displays the analysis method used for the displayed analysis results.

(8) Edit mark

Shown when the result of automatic analysis is edited.

(9) Reliability mark

The reliability level for automatic analysis is displayed. Refer to “3.4.1 Auto Analysis” for details of reliability.

(10) Analysis results

Displays the results of analysis of the displayed endothelium image.

Refer to “3.4.1 Auto Analysis” for details of each analysis result.

(11) Central corneal thickness

Displays the thickness in the center of the cornea of the captured image.

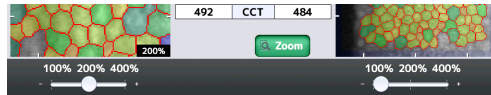
(12) “Tone” button

Brightness and contrast of the captured image can be adjusted. Touching this button shows the image quality adjustment bar. Brightness and contrast can be adjusted within the range from -2 to +2. Touch the “Tone” button again to return to the original screen.



(13) "Zoom" button

Enlarges the image of the endothelium. Touching this button shows the magnification adjustment bar. 100%, 200%, 400% can be selected. When the enlarged image is displayed, the image moves so that the tapped point comes to the center of the frame. Touch the "Zoom" button again to return to the original screen.



(14) "Setup" button

Moves to the Setup screen.

(15) "Method" button

Switches analysis methods.

(16) "Trace Edit" button

Opens the Trace Edit screen.

(17) "Cell Select" button

Opens the cell selection screen.

(18) "Print/Export/Save" buttons

Two buttons can be selected from "Print," "Export," and "Save" using the system setup function. Refer to "3.7.4 Connection & Print" for the setting method.

- Print: Prints the displayed examination data.
- Export: Transfers the examination data to the personal computer.
- Save: Transfers the patient information and examination data to the database.

(19) R/L eyes button

Moves to the R/L eyes analysis screen.

(20) "Dark Area" button

Moves to the dark area analysis screen.

(21) Area (Polymegathism)

Distribution of cells according to their sizes is displayed using a histogram.

(22) Apex (Plemorphism)

Distribution of cells according to their shapes is displayed using a histogram.

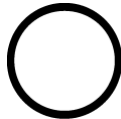
2.5 Symbols used for marking



Refer to instruction manual.



“ON” (power)



“OFF” (power)



Type B applied part



Grounding (earth)

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3. OPERATION PROCEDURES

3.1 Safety precautions



- *The power plug 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 plug. Install the instrument in a place where this can be performed smoothly.*



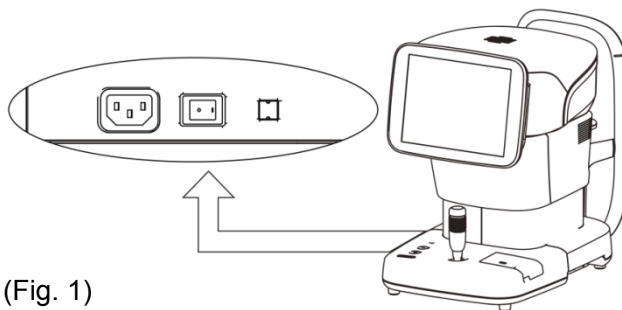
- *Install the instrument so that the user can use the system under optimal conditions. Carefully connect the devices so that the wiring is not disconnected unintentionally during operation, and does not hinder operation of the instrument.*

3.2 Preparation before use

3.2.1 Connections

a) Power cord

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



(Fig. 1)

b) External digital printer



- *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 insulated transformer.*

- Video printer

Insert the cable plug A (1) of the USB cable into the USB connector (2) on the side of the main unit in the correct orientation.

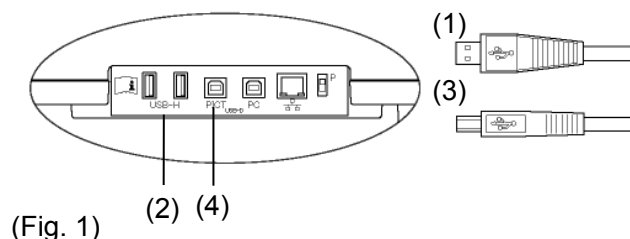
Connect the other cable plug B (3) of the USB cable to the video printer.

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

- PictBridge printer

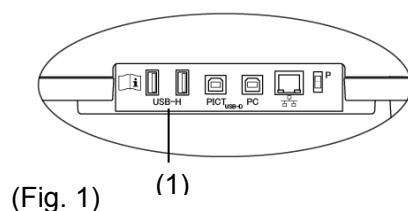
Insert the cable plug B (3) of the USB cable into the USB connector (PICT) (4) on the side of the main unit in the correct orientation.
Connect the other cable plug A (1) of the USB cable to the printer.

Refer to the instruction manual of the PictBridge printer for details on how to connect the printer.



c) 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.



d) Connecting the personal computer

Note

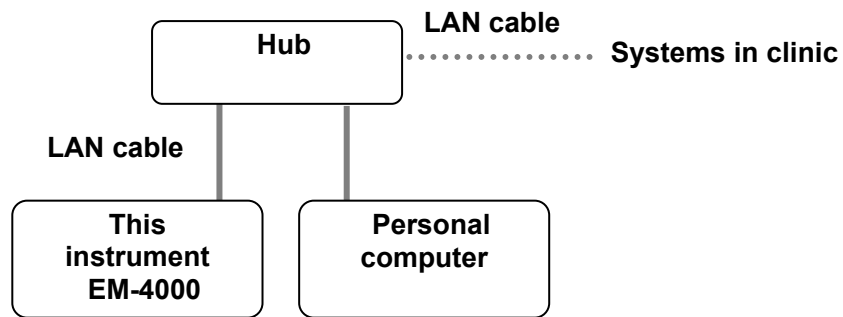
- The network support system “TOMEY Link” (optional) or the inspection data receiving software “DATA Transfer” (included in the package) is required for data communication with the Machine.
- Refer to the corresponding operation manual for installation, settings, and operation of TOMEY Link and DATA Transfer.
- Connection setting on the System Setup screen must be completed before connecting TOMEY Link and DATA Transfer. Refer to “3.7.4 Connection & Print” 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)

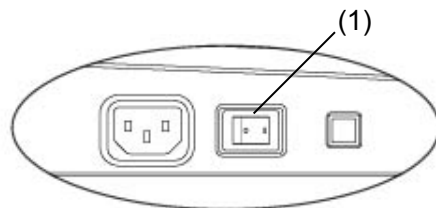


(Fig. 1)

3.2.2 Starting/shutting down the instrument

a) Startup

- 1) Turn on the video printer and/or PictBridge printer if using them.
- 2) Turn ON (I) the power switch of the EM-4000.
 - The startup screen (Fig. 2) appears and then the capture screen appears.



(Fig.1)



(Fig.2)

b) Shutdown

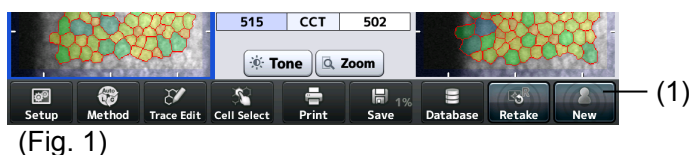
- 1) Turn OFF (O) the power switch of the EM-4000.
 - To pack the instrument, move the head to a specific storage position with the packing button and then turn the power off. Refer to “2.3 Sides of the main unit” for how to perform packing.
- 2) When the video printer and/or PictBridge printer is connected, turn them off.

3.2.3 Clearing the last examination data (preparation for a new 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 examination data for the previous patient before capturing images for a new patient. Otherwise, the data for the previous patient may be included.*
- *This operation does not clear examination data saved in the database. Refer to “3.6.2 Deleting examination data” to delete the examination data in the database.*

- 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 capture screen appears.



3.2.4 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 Machine is not available for query of the patient data.*
- *For details on the TOMEY Link Server settings, refer to the TOMEY Link instruction manual.*
- *Connection setting on the System Setup screen must be completed before connecting with TOMEY Link. Refer to “3.7.4 Connection & Print” for the setting method.*
- *Once examination data is output (printed, saved, or exported), 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 (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 (SD card)
The patient can be selected from the list saved in the database (SD card). 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.
- 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 capture screen in addition to the Patient Information screen (Fig. 2)

ID	Name	Date of birth	Sex	Latest Exam
000012_89012...	OPQRSTUVWXYZ...	2015/May/23	F	2015/Jun/03 22:23:32
000013_89012...	GHIJKLMNOPQR...	2015/May/22	M	2015/Jun/03 10:23:32
000014_89012...	YZABCDEFGHIJK...	2015/May/20	F	2015/Jun/02 22:23:32
000015_89012...	QRSTUVWXYZA...	2015/May/19	M	2015/Jun/02 10:23:32
000016_89012...	IJKLMNOPQRSTU...	2015/May/17	F	2015/Jun/01 22:23:32
000017_89012...	ABCDEFGHIJKLM...	2015/May/16	M	2015/Jun/01 10:23:32

(Fig. 4)

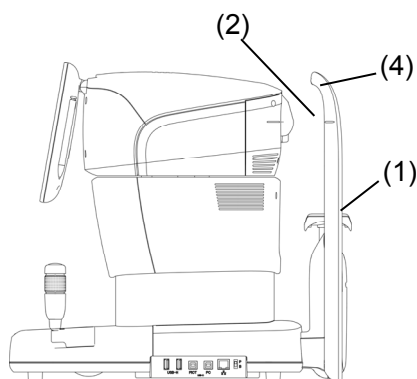
-
- 3) Touch the "OK" button on the Patient Information screen (Fig. 2), designate the patient information, and return to the previous screen.
 - Touch the "Cancel" button (5) to discard the edited Information and return to the previous screen.

3.2.5 Patient's eye height adjustment

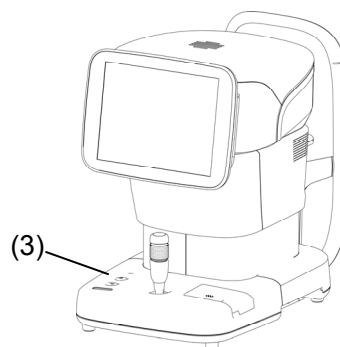


- ***When moving the head and/or chin rest, pay attention to the position of the patient's face, hands, and fingers. Otherwise, they may be injured by the movement of the head or chin rest.***
- ***The chin rest paper is provided to keep the chin rest clean. Use this paper for the chin rest as well as the patient to use this instrument comfortably.***
- ***Peel off the top sheet of chin paper and clean the forehead pad with a clean cloth before capturing images for the next patient. Clean the forehead pad with a cloth dampened with alcohol as needed.***

- 1) Have the patient place their face on the chin rest (1). Adjust the chin rest height so that the height of the corner of the eye is aligned with the eye level mark (2). Press the chin rest button (3) at the front of the main unit (Fig. 2) to move the chin rest up and down.
- 2) When the patient's eye height is determined, lightly push the patient's forehead against the forehead pad (4) to secure the patient's position.



(Fig. 1)

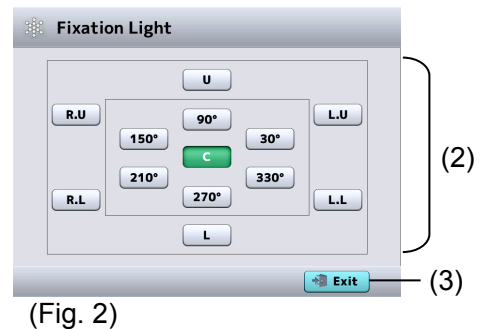
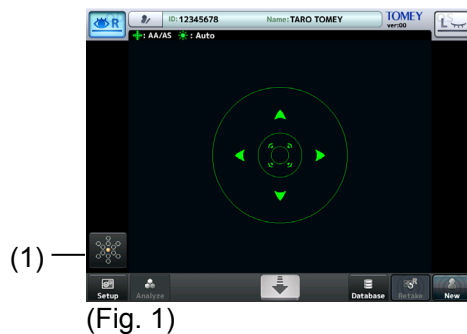


(Fig. 2)

3.2.6 Setting the fixation light position

The fixation light to fix the patient's eye can be turned on in the center, 6 directions in the periphery, and 8 parafovea directions. The center light is normally used for capturing images, but the peripheral and parafovea positions are effective when an image cannot be taken with the light in the center or when capturing an image at optional positions.

- 1) Touch the fixation light button (1) to display the Fixation Light screen (Fig. 2).

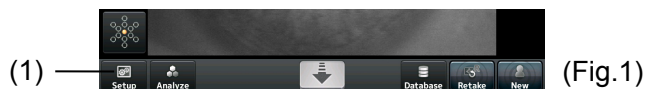


- 2) Touch the appropriate button (2) to select the lighting position.
 - Descriptions on each button represent the direction viewed from the patient.
C : Center, U : Up, R.U : Upper right, R.L : Lower right,
L : Bottom, L.L : Lower left, L.U : Upper left
- 3) Touch the "Exit" button (3) to close the Fixation Light screen.
 - The position of the lit fixation light is shown in orange on the fixation light button (1) on the capture screen.

3.2.7 Setting capturing conditions

Settings for capturing images can be changed temporarily. Temporary settings made as described below will be initialized when the "New" button is touched.

- 1) Touch the "Setup" button (1) to display the Setup screen (Fig. 2).



- 2) Select the setting of each item using corresponding buttons.
 - Setting items a) through d) will be described later.
- 3) Touch the "Exit" button (2) to close the Setup screen..

a) Alignment

Note ■ When "Manual" is selected for "Alignment," "Auto" cannot be selected for "Shot."

Auto	The Auto Alignment function is active. Alignment in up/down/right/left/focus directions is automatically performed.
Manual	The Auto Alignment function is not active. Use the Touch Alignment function or joystick to conduct focusing.

b) Shot

Auto	The Auto Shot function is active. An image is captured automatically when the sight in the up/down/right/left/focus directions is optimized
Manual	The Auto Shot function is not active. Use the capture button on the monitor or joystick button to capture an image.

c) Light Power

Auto	The power of the light for capturing an image of the endothelium is adjusted automatically.
High	The power of the light for capturing an image of the endothelium is set to the maximum level.
Low	The power of the light for capturing an image of the endothelium is set to the minimum level.

d) Measure Mode

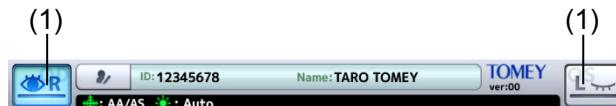
Note ■ Perform system setup to maintain the capture mode setting. Refer to "3.7.2 Measurement" for the system setup procedures.

Quick	Capture mode in which the image selection screen does not appear when capturing is completed. This mode is for users who do not wish to observe 16 images of endothelium tissues.
Basic	Capture mode in which the image selection screen appears when capturing is completed. This mode is for users to observe 16 captured images of endothelium tissues and select only one from them.

3.3 How to capture images

3.3.1 Selecting the eye to be measured

- 1) Touch the eye selection button (1) on the capture screen.



(Fig. 1)

3.3.2 Alignment



- **Do not allow any person to place their hands or fingers in the clearance between the head and neck or neck and base, or the section under the chin rest. Their hands or fingers may be caught and injured.**



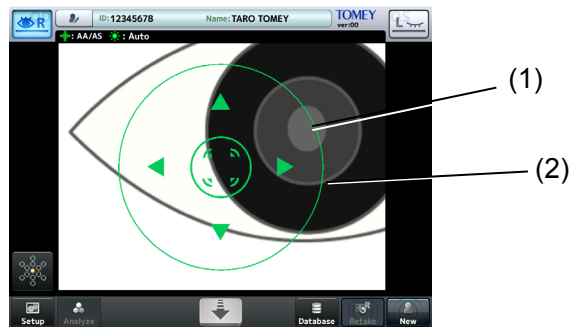
- **The Auto Alignment function may not work correctly when eyelids and eyelashes cover the pupils. Ask the patient to open their eyes wide or have the physician lightly hold the patient's upper eyelid with their fingers.**
- **Auto Alignment may not work correctly when the patient blinks frequently. Ask the patient to stop blinking while capturing images.**
- **Ask the patient to look at the fixation light. If the patient looks in a different direction or moves, alignment may not be conducted correctly.**
- **Auto Alignment is set as the standard setting to capture better images. In some rare cases auto alignment cannot be performed because of a shortage of reflection light due to deformation and/or inflammation of the cornea. In this case, use manual mode.**

a) Alignment using touch panel



- **When moving an element up, down, left and right using the touch panel, touch the panel and release your finger immediately. Do not press the panel continuously. Press the panel continuously when moving the element back and forth.**

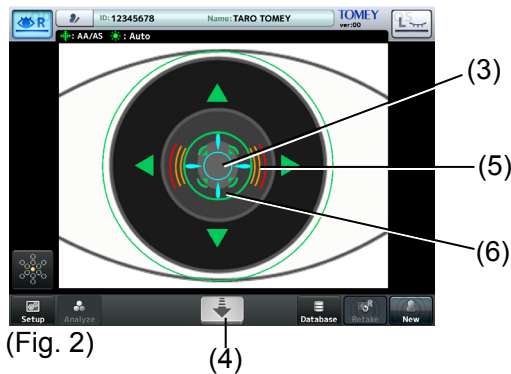
- 1) Display the patient's eye.
 - Operate the touch panel or the joystick to show the patient's eye on the screen. (Fig. 1)
- 2) Perform alignment in up, down, left, and right directions.
 - Lightly touch the pupil center (1) of the patient's eye displayed on the screen. The head moves so the patient's eye is positioned in the center of the screen.
 - When the center of the pupil (1) approaches the center of target ring (2) with Auto Alignment turned on, focusing in the up/down and left/right directions automatically starts.



(Fig. 1)

3) Perform alignment in front and back directions.

- Touch the center of the alignment mark (3) to move the head toward the patient. Touch the head retract button (4) to retract the head toward the physician.



(Fig. 2)

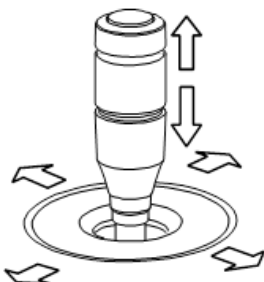
4) When the cornea approaches the optimum alignment position, the focus indicator (5) appears.

- A horizontal focus indicator means that the head is too far from the eye.
- A vertical focus indicator means that the head is too close to the eye.
- When Auto Alignment is active, focusing in the front-back directions starts automatically when the cornea approaches the optimum alignment position.

5) When the optimum alignment position is found, the alignment OK mark (6) appears.

b) Alignment using joystick

There are two types of operations - rough operation for moving the head into rough position and fine operation for finely adjusting the position of the head.

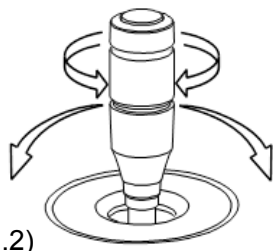


(Fig.1)

[Rough operation]

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

When the up/down ring is slid up and down, the head moves up and down.



(Fig.2)

[Fine operation]

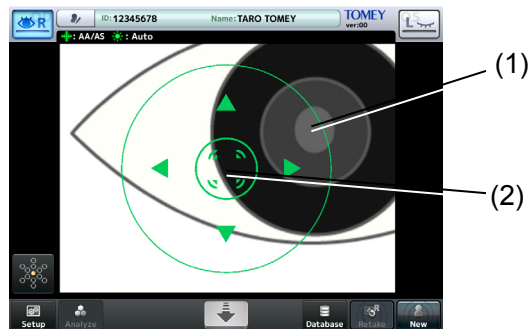
Tilting the joystick moves the head in the tilting direction.

Turn the up/down ring to move the head up and down.

Clockwise : The head rises.

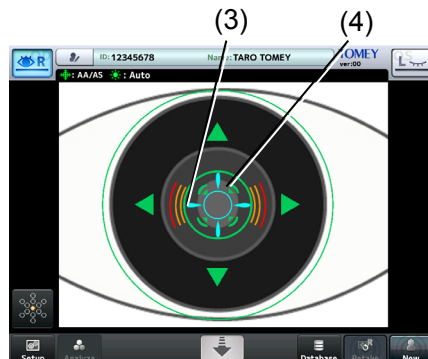
Counterclockwise : The head lowers.

- 1) Operate the joystick to move the head so the center of the pupil (1) appears in the center (2) of the target ring.



(Fig. 3)

- 2) Move the joystick back and forth to perform alignment. When the cornea approaches the optimum alignment position, the focus indicator (3) appears.
 - A horizontal focus indicator means that the head is too far from the eye.
 - A vertical focus indicator means that the head is too close to the eye.
 - When Auto Alignment is set, focusing in the front-back directions starts automatically when the cornea approaches the optimum alignment position.
- 3) When the optimum alignment position is found, the alignment OK mark (4) appears.



(Fig. 4)

3.3.3 Capturing endothelium tissue image



■ **Stop capturing images immediately if the patient shows any signs of photosensitive epilepsy.**

■ **A good image of the endothelium tissues may not be captured, and the analysis result or corneal thickness value may become unreliable due to faulty fixing of the sight, eyelid drooping, trichiasis, corneal diseases, etc. When the captured image is unclear, select or capture another image.**



■ **This instrument is designed to perform auto shot as the standard setting to perform highly precise measurement.**

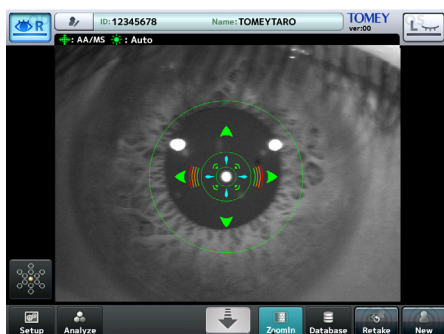
■ **In rare cases, a good image of the endothelium may not be taken due to cornea deformation and/or corneal opacity. In this case, perform manual operation.**

a) Auto Shot

- 1) No operation is required.
 - Image is captured automatically when alignment has been completed.
- 2) The following screen appears when capturing has been completed.
 - In Quick mode
 - The capture screen (refer to 2.4.2) appears when an image of one eye has been captured. Touch the eye selection button again to capture an image of the other eye.
 - The R/L eye analysis screen (refer to 2.4.4) appears when images of both eyes have been captured.
 - In Basic mode
 - The image selection screen (refer to 2.4.3) appears when capturing has been completed.

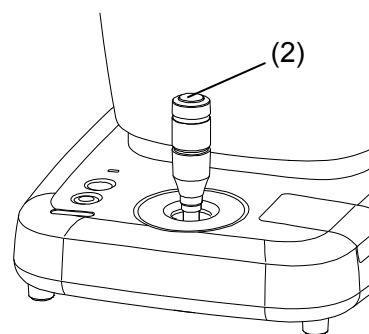
b) Manual Shot

- 1) After alignment is completed (refer to 3.3.2), touch the “ZoomIn” button (1) on the capture screen (Fig. 1) or press the button on the joystick (2) to display the live endothelium image (Fig. 3).
 - Touch the “ZoomOut” button (4) on the live endothelium image screen (Fig. 3) to return to the live anterior chamber image screen (Fig. 1).

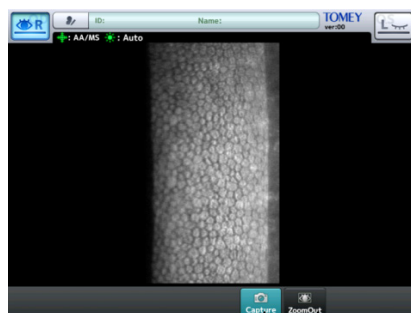


(Fig. 1)

(1)



(Fig.2)



(Fig. 3)

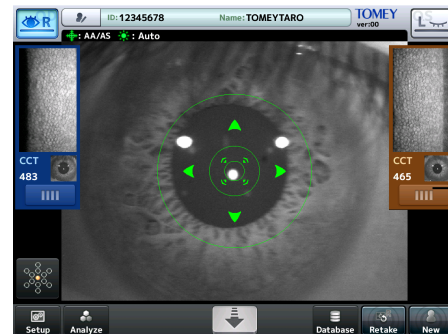
(3) (4)

- 2) Check the endothelium image to be captured on the live endothelium image, and touch the “Capture” button (3) or press the joystick button (2) to start capturing.
 - If the capture position needs to be finely adjusted, operate the joystick and adjust the position before touching the “Capture” button (2).
- 3) The following screen appears when capturing has been completed.
 - In Quick mode
 - Return to the capture screen (refer to 2.4.2) when an image of one eye has been captured. Touch the eye selection button again to capture an image of the other eye.
 - The R/L eye analysis screen (refer to 2.4.4) appears when images of both eyes have been captured.
 - In Basic mode
 - The image selection screen (refer to 2.4.3) appears when capturing has been completed.

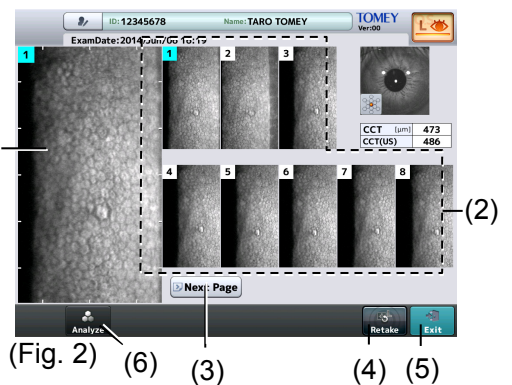
3.3.4 Selecting image

Select an image to be analyzed from the 16 captured images of the endothelium.

Touch the image selection button (1) on the capture screen (Fig. 1). The image selection screen (Fig. 2) appears. In Basic mode, the image selection screen (Fig. 2) appears every time an image of an eye is captured.



(Fig. 1)



(Fig. 2)

- 1) Touch the thumbnail (2) of captured images to select the image to be used for analysis.
 - The selected image is displayed in the image display field (3) on the left of the screen.
 - If there is no appropriate image among the 8 images on the first page, touch the "Next Page" button (3) to select the optimum image from the 8 images on the next page.
 - If there is no appropriate image in the 16 images, touch and hold the "Retake" button (4) to capture images again.
- 2) When the endothelium image to be used for analysis is selected, touch the "Exit" button (5) and return to the capture screen.
 - The image selected at this time is designated for analysis.
 - Touch the "Analysis" button (6) to open the R/L eye analysis screen without returning to the capture screen.

3.4 Analysis

3.4.1 Auto Analysis

Auto Analysis is to calculate values such as CD (cell density) by automatically extracting trace lines of cells on the captured image



■ **Check that the trace line of cells is correctly detected on the captured image.**
The trace line cannot be extracted on some images.

■ **Perform any of the following operations if the trace line is not extracted correctly.**

- **Retake**

ure an image again if the images are not clear.

- **Correcting trace line**

Correct and redraw the incorrect images.

Refer to “3.4.1 Editing trace line” for how to edit the trace line..

- **Selecting cell**

Exclude cells with trace lines extracted incorrectly from the target of analysis.

Refer to “3.4.1 c) Selecting cells” for how to select cells.

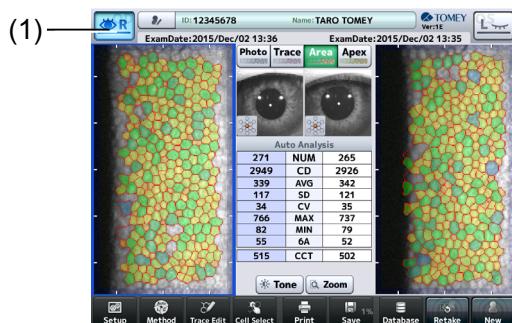
- **Changing analysis method**

Perform analysis with the L-count method or Core method. Refer to “3.4.2 L-count method” and “3.4.3 Core method” for the operation of the L-count method and Core method.

a) How to recognize capacity data

• R/L eye fracture screen

When touching the “Analyze” button on the capture screen or image selection screen, the captured image is analyzed automatically and the R/L eye analysis screen (Fig. 1) appears. In Quick mode, the image selection screen appears when images of both eyes have been captured.



(Fig. 1)

- Single eye analysis screen

Touch the eye selection button (1) on the R/L eye analysis screen (Fig. 1). The single eye analysis screen (Fig. 2) appears. Distribution according to cell sizes and shapes is shown in a histogram on the single eye selection screen.



(Fig. 2)

- Checking analysis value

The displayed endothelium image is automatically analyzed and resultant values are displayed on the R/L eye analysis screen and single eye analysis screen.

Abbr eviation	Item	Unit	Details
NUM	Number of cells	Pieces	The number of analyzed endothelium tissues
CD	Cell density	/mm ²	The number of analyzed endothelium tissues in 1 mm ²
AVG	Average area	μm ²	The average area of analyzed endothelium tissues
SD	Standard deviation	μm ²	Standard deviation of the area of analyzed endothelium tissues
CV	Fluctuation coefficient	%	Fluctuation coefficient of the area of analyzed endothelium tissues Value calculated by dividing the standard deviation with the average area.
MAX	Maximum area	μm ²	The area of the largest cell in the analyzed endothelium tissues
MIN	Minimum area	μm ²	The area of the smallest cell in the analyzed endothelium tissues
6A	Percentage of cell hexagonality.	%	Percentage of hexagonal cells in analyzed endothelium tissues

- A hyphen (-) is displayed for all analysis values if the cell trace line could not be extracted by automatic analysis.

- Checking central corneal thickness

The measured central corneal thickness is shown on the R/L eye analysis screen and single eye analysis screen.

Abbr eviation	Analysis item	Unit	Details
CCT	Central corneal thickness	μm	Central corneal thickness
CCT (US)	Ultrasonic correction for central corneal thickness	μm	The reference value expected when measuring the same corneal thickness using the ultra-sound corneal thickness measuring instrument

- A hyphen (-) is shown in CCT and CCT (US) when CCT cannot be measured.
- It can be set on the System Setup screen whether to show "CCT (US)" or not. Refer to "3.7.3 Application" for setting method. The initial setting is OFF.
- CCT (US) is calculated by adding a specific thickness (offset value) to CCT. The offset value can be changed on the System Setup screen. Refer to "3.7.3 Application" for setting method. The initial setting is "13μm."

- Checking distribution according to sizes/shapes

Distribution according to cell sizes and shapes obtained by automatically analyzing the displayed image of endothelium tissues is displayed using a histogram on the single eye analysis screen.

- The class width of distribution according to cell sizes can be set on the System Setup screen. Refer to "3.7.3 Application" for setting method. The initial setting is "100 μm²."
- If the cell trace line cannot be extracted correctly by automatic analysis, neither a bar nor a number is displayed on the histogram.

- Changing displayed image

The displayed endothelium image is automatically analyzed and resultant images are displayed on the R/L eye analysis screen and single eye analysis screen. Use the following buttons to change the image.

Abbreviation	Item	Details
Photo	Captured image	Displays the captured image.
Trace	Cell trace line	Displays trace lines of extracted endothelium tissue in red. The trace line of the dark area is shown in blue when the dark area is extracted. Refer to "1.3 Glossary" for dark area.
Area	Area-specific	Displays an endothelium image color-coded according to cell area.
Apex	Shape specific	Displays an endothelium image color-coded according to cell shapes.

- The image to be displayed immediately after automatic analysis can be selected on the System Setup screen. Refer to "3.7.3 Application" for setting method. The initial setting is "Area."

- Checking fixation light position

The position of the fixation light when capturing an image is shown on the R/L eye analysis screen and single eye analysis screen with icons shown below.

- It can be set on the System Setup screen whether to indicate the position for capturing an image with a black square on the icon. Refer to "3.7.3 Application" for setting method. The initial setting is OFF.

(1) Indication of fixation light position: OFF

Center						
Parafova	30° 	90° 	150° 	210° 	270° 	330° 
Peripheral	U 	L.U 	L.L 	L 	R.L 	R.U 

(2) Indication of fixation light position: ON

Center						
Parafova	30° 	90° 	150° 	210° 	270° 	330° 
Peripheral	U 	L.U 	L.L 	L 	R.L 	R.U 

- Checking reliability

The displayed endothelium image is automatically analyzed and resultant reliability is displayed on the R/L eye analysis screen and single eye analysis screen. The reliability is categorized into 3 levels and indicated by the mark corresponding to each level as listed below.

Reliability mark	Description
No mark	The reliability for automatic analysis is high because cells are clearly captured over a wide range and cell trace lines are extracted precisely by automatic analysis.
e	Because the range of captured cells is slightly less or visibility of captured images is slightly poor, some cell trace lines are not extracted correctly by automatic analysis and the resultant reliability is slightly lower.
E	Because the range of captured cells is small and visibility of captured images is poor, cell trace lines are not extracted correctly by automatic analysis and the resultant reliability is low.

When “e” or “E” is displayed, perform any of the following actions according to the captured image condition.

- Retake
Capture an image again if the images are not clear.
- Correcting trace line
Correct and redraw the incorrect images. Refer to “3.4.1 Editing trace line” for how to edit the trace line.
- Selecting cell
Exclude cells with trace lines extracted incorrectly from the target of analysis. Refer to “3.4.1 c) Selecting cells” for how to select cells.
- Changing analysis method
Perform analysis with the L-count method or Core method. Refer to “3.4.2 L-count method” and “3.4.3 Core method” for the operation of the L-count method and Core method.

The reliability mark does not appear when the following analytical calculations are conducted.

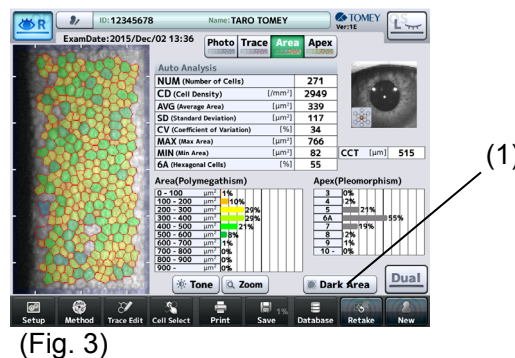
- When a trace line is edited
- When a cell is selected
- Analysis using the L-count method
- Analysis using the Core method

It can be set on the System Setup screen whether to show the reliability or not.

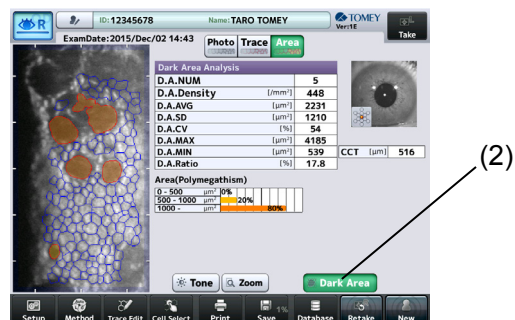
Refer to “3.7.3 Application” for setting method. The initial setting is OFF.

● Checking dark area analysis

Touch the “Dark Area” button (1) on the single eye analysis screen (Fig. 3). The dark area analysis screen (Fig. 4) appears. Touch the “Dark Area” button (2) on the dark area analysis screen (Fig. 3) to return to the single eye analysis screen.



(Fig. 3)



(Fig. 4)

The following analysis results obtained by automatically extracting dark areas from the displayed image of endothelium are displayed on the dark area analysis screen (Fig. 4).

- Dark area analysis image

Use the following buttons to change the image.

Abbreviation	Item	Details
Photo	Captured image	Displays the captured image.
Trace	Cell trace line	Displays trace lines of extracted dark areas.. Displays trace lines of endothelium tissue in blue.
Area	Area-specific	Displays the extracted dark area color-coded according to area sizes.

- Dark area analysis value

The analysis results of the displayed dark area in endothelium.

Abbreviation	Item	Unit	Details
D.A.NUM	Number of dark areas	Pieces	The number of analyzed dark areas
D.A.Density	Dark area density	/mm ²	The number of cells in 1 mm ² of the analyzed dark area
D.A.AVG	Average area of dark area	μm ²	Average area of analyzed dark areas
D.A.SD	Standard deviation of dark area	μm ²	Standard deviation of the analyzed dark area
D.A.CV	Fluctuation coefficient to dark area	%	Fluctuation coefficient of the analyzed dark area. Value calculated by dividing the standard deviation with the average area.
D.A.MAX	Maximum size of dark area	μm ²	The area of the largest cell in the analyzed dark areas
D.A.MIN	Minimum size of dark area	μm ²	The area of the smallest cell in the analyzed dark areas
D.A.Ratio	Dark area ratio	%	Ratio of the dark area size relative to the total area. The total area is the sum of analyzed dark area and the area of analyzed endothelium tissue.

- Distribution according to sizes of dark area

Distribution according to sizes of dark areas automatically extracted is shown in a histogram.

Analysis in the dark area can be set to ON or OFF in the item “Dark Area Analysis” on the System Setup screen.

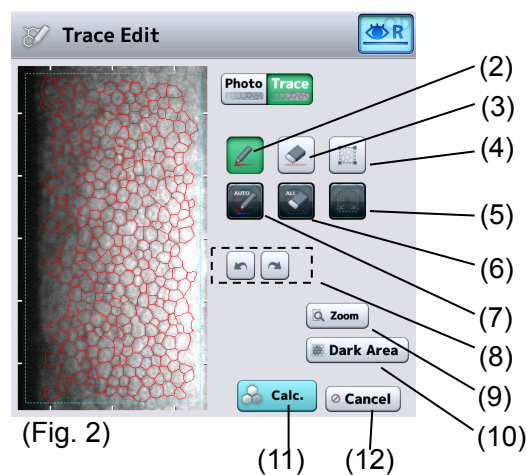
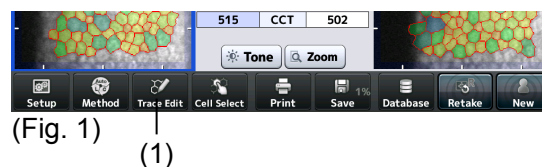
- The initial setting is “ON.”
- The “Dark Area” button does not appear on the single eye analysis screen if this item is set to OFF. Namely, the dark area analysis screen (Fig. 3) cannot be called.
- Refer to “3.7.3 Application” for setting method.

b) Editing trace line

Trace lines of endothelium tissues extracted by automatic analysis can be edited.

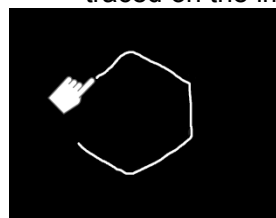
Edit marks appear on the analysis screen when the trace line is edited. Refer to “2.4.4 Analysis screen” for details of edit marks.

Touch the “Trace Edit” button (1) on the analysis screen (Fig. 1) to open the Trace Edit screen (Fig. 2).



(2) Pencil button

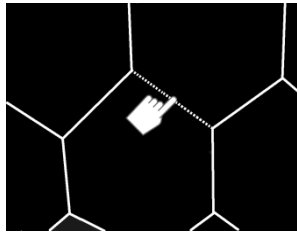
Adds trace lines shown in red. Straight lines or curves are drawn as traced on the image.



(Fig. 3)

(3) Eraser button

Deletes trace lines shown in red. Touch the line in the image to delete it.



(Fig. 4)

(4) Analysis range selection button

Specifies the range to be analyzed. Specify an area to be analyzed by selecting two opposing points in an area where the shape of the cell can be confirmed.

When "100 μm " is set to "L-count range" of the system setup items, touch the center of the 100 μm -square frame. Refer to "3.7.3 Application" for the system setup.

(5) Whole range button

Pressing and holding this button specifies the whole range of the image of the displayed endothelium tissues.

(6) All clear button

Pressing and holding this button deletes all trace lines of endothelium tissues and dark areas currently displayed.

(7) Automatic selection button

Pressing and holding this button deletes all trace lines of endothelium tissues and dark areas currently displayed, and then displays trace lines of automatically extracted endothelium tissues and dark areas.

(8) Undo/Redo button

Returns or proceeds to the condition immediately before or after respectively.

(9) "Zoom" button

Enlarges the image of the endothelium.

Refer to "2.4.4 Analysis screen" for operation of this button.

(10) "Dark Area" button

Switches the trace lines to be edited. Touching this button changes the target trace line (red) from the endothelium tissue to dark area. Touch the button again to return the setting.

(11) "Calc. (calculation)" button

Performs calculation for analysis using the edited trace line and returns to the analysis screen. Returns to the dark area analysis screen when the "Dark Area" button is activated.

(12) "Cancel" button

Returns to the analysis screen without applying the edited contents. Returns to the dark area analysis screen when the "Dark Area" button is activated.

c) Selecting cells

Cells used for analysis can be selected from endothelium tissues extracted by automatic analysis.

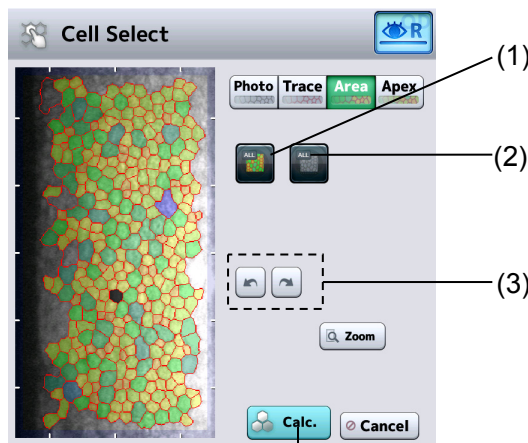
Edit marks appear on the analysis screen when cells are selected. Refer to “2.4.4 Analysis screen” for details of edit marks.

Touch the “Cell Select” button (1) on the analysis screen (Fig. 1) to open the Cell Select screen (Fig. 2). Selected cells are displayed in colors, and cells not selected are displayed without color or in gray.

Touch a cell on the image of the endothelium to select it.



(Fig. 1)



(Fig. 2)

(1) All selection button

Selects all cells automatically extracted.

(2) All cancel button

Cancels selection of all cells automatically extracted.

(3) Undo/Redo button

Returns or proceeds to the condition immediately before or after respectively.

(4) “Calc. (calculation)” button

Performs calculation for analysis using the edited trace line and returns to the analysis screen. Returns to the dark area analysis screen when the “Dark Area” button is activated.

3.4.2 L-count method

The L-count method is an analysis method to calculate values such as CD (cell density) according to the area and cell center entered by the physician

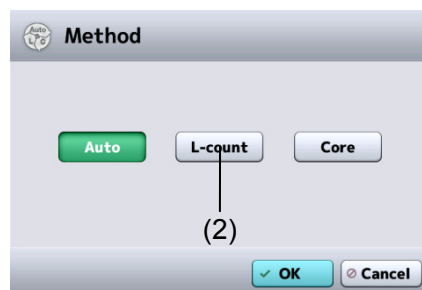
a) Switching to L-count method

- 1) Touch the “Method” button (1) on the analysis screen to open the Method screen (Fig. 2).



(1)

(Fig. 1)



(2)

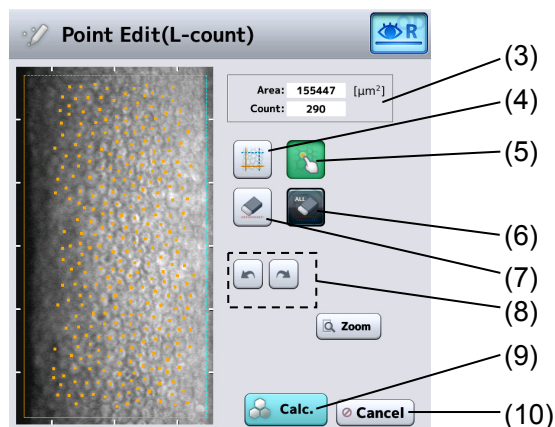
(Fig. 2)

- 2) Touch the “L-count” button (2) and then the “OK” button to open the Point Edit (L-count) screen (Fig. 3).

b) Editing range and point



- **The L-count assist function is designed to help users operate points. Be sure that the user themselves check points selected by the L-count assist function before adding or deleting them.**
- **Place a point according to the procedures below. Incorrect calculation results may be shown if points are not selected correctly.**



(Fig. 3)

1) Specify the range.

- Touch the range selection button (4) to activate it. Touch two opposing points of the area (rectangle) subject to calculation on the image of the endothelium.
- When "100 μm " is set to "L-count range" of the system setup items, touch the center of the 100- μm -square frame. Refer to "3.7.3 Application" for the system setup.
- The area of the specified range is shown in the Area field (3).
- When "L-count Assist" in the system setup is set to ON, cells in the selected range are simply extracted and dots appear on the cells.

2) Place a dot on a cell.

- Touch the cell selection button (5) to activate it. Specify the center of all cells in the specified range using the touch pen.
- An orange dot appears at the touched point.
- The number of current dots appears in the "Count" field (3).
- To delete a dot, touch the eraser button (7) to activate it and then touch the dot to be deleted.
- Touching and holding the all delete button (6) deletes all dots displayed.
- Touch the undo/redo buttons (8) to undo and/or redo the operation to specify dots.

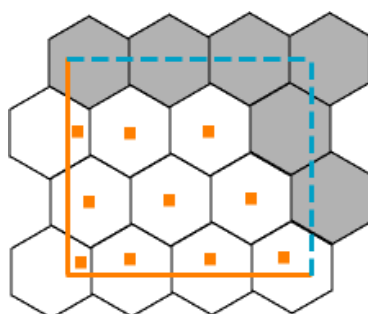
3) Touch the "Calc. (calculation)" button (9) to close the Point Edit screen.

- The calculation results are displayed on the analysis screen.
- Touching the "Cancel" button (10) will discard the edited point information, and return you to the analysis screen.

Note

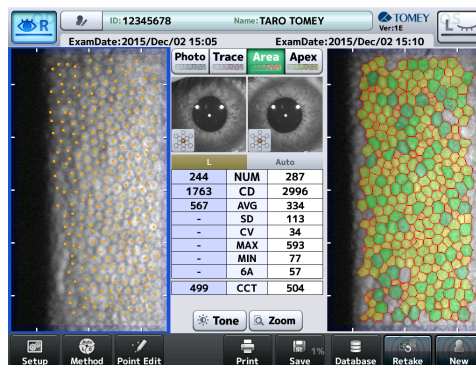
■ *The range line in the L-count method is shown in orange (solid line) and light blue (dotted line).*

■ *To specify cells, point to cells of which trace lines are crossed with an orange solid line. Do not point to cells if their trace lines are crossed with a light blue dotted line.*



(Fig. 4)

c) How to read analysis results



(Fig. 5)

Three analysis values (NUM, CD, and AVG) are calculated in the L-count method. Analysis values are displayed on the analysis screen (Fig. 5).

- A hyphen (-) is shown for analysis values other than NUM, CD, and AVG.
- The analyzed image (Area, Apex) is not output.
- Touch the "Point Edit" button and open the Point Edit screen to edit points again.
- When analyzing another eye by the L-count method, touch the image of the endothelium to change the eye, touch the "Point Edit" button, and then edit points on the Point Edit screen.

3.4.3 Core method

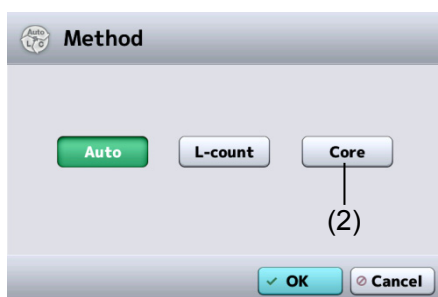
The Core method is an analysis method to calculate values such as CD (cell density) by extracting the outline of the cell referring to the center of the cell entered by the physician

a) Switching to Core method

- 1) Touch the “Method” button (1) on the analysis screen to open the Method screen (Fig. 2).



(1)
(Fig. 1)



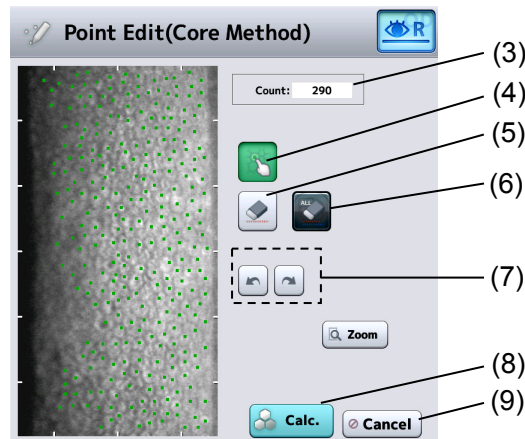
(Fig. 2)

- 2) Select the “Core” button (2). Touch the “OK” button to open the Point Edit (Core Method) screen (Fig. 3).

b) Editing point

Note

- *Be sure to observe the following precautions when specifying dots in the Core method. Incorrect results may be displayed.*
- *The number of points should be 50 or more. The recommended number of points is 100 or more.*
- *Point to the center of the cell as much as possible. The accuracy of analysis results lowers as the point position deviates from the center.*
- *Determine the range for pointing in advance and then specify the point in all cells included in the determined range. If cells are not specified, the CD (cell density) will be calculated as smaller than the actual value. It is recommended to specify cells from the top center area to bottom center area, and then the surrounding cells clockwise in order to specify all cells.*



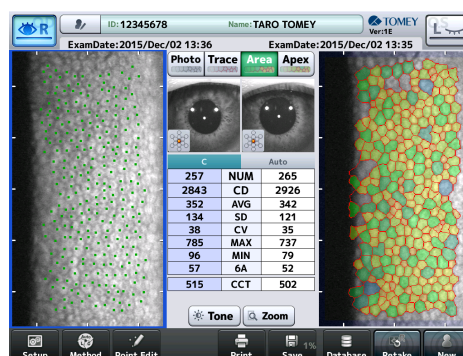
(Fig. 3)

- 1) Place a dot on a cell.
 - Touch the cell selection button (4) to activate it. Specify the center of each cell using the touch pen.
 - A green dot appears at the touched point.
 - The "Count" field (3) increases the number of dots every time a cell is specified.
 - To delete a dot, touch the eraser button (5) to activate it and then touch the dot to be deleted.
 - Touching and holding the all delete button (6) deletes all dots displayed.
 - Touch the undo/redo buttons (7) to undo and/or redo the operation to specify dots.
- 2) Touch the "Calc. (calculation)" button (8) to close the Point Edit screen.
 - The result of calculation is displayed on the analysis screen.
 - Touching the "Cancel" button (9) will discard the edited point information, and return you to the analysis screen.

c) How to read analysis results

Note

■ **The NUM value becomes smaller than the number of dots in the analysis result of the Core method. Dots near the outermost circumference are not used for analysis.**



(Fig. 4)

The same analysis values as those by automatic analysis are calculated in the Core method. Analysis values are displayed on the analysis screen (Fig. 4).

- The analyzed image (Area, Area, Apex) is not output.
- Touch the "Point Edit" button and open the Point Edit screen to edit points again.
- When analyzing another eye by the Core method, touch the image of the endothelium to change the eye, touch the "Point Edit" button, and then edit points.

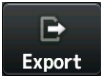
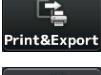
3.5 Export, Print, and Save

Two functions from Export, Print, and Save can be assigned to two buttons provided at the bottom center of the analysis screen. Those functions are assigned on the System Setup screen. Refer to “3.7.4 Connection & Print” for the setting method.



(Fig. 1)

Functions that may be assigned to a button are as follows.

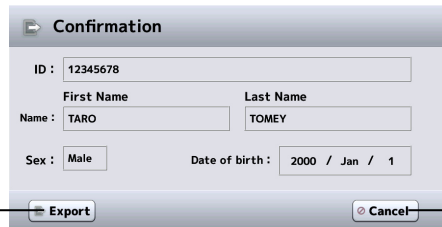
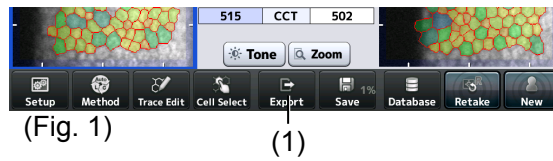
	Export		Print
	Save		Save & Export
	Print & Export		Print & Save
	ALL (Export, Print, and Save)		

3.5.1 Export

Note

- The network support system “TOMEY Link” (optional) or the inspection data receiving 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 settings on the Setup screen must be completed in advance to connect with TOMEY Link and DATA Transfer. Refer to “3.7.4 Connection & Print” for the setting method.
- Data cannot be sent using some settings in the system related to entry of ID if the ID number is not entered. Refer to “3.7.1 General” for settings on the System Setup screen.
- 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 was sent to TOMEY Link, all data without an ID number is regarded as data of the same patient so that they must be handled with great care to avoid mishandling.

- 1) Touch the "Export" button (1) to display the Confirmation screen (Fig. 2).

A screenshot of a 'Confirmation' dialog box. It has a title bar with a play icon and the word 'Confirmation'. The form contains: 'ID : 12345678' in a text field; 'First Name' and 'Last Name' labels above 'Name : TARO' and 'TOMEY' text fields; 'Sex : Male' with a dropdown menu; and 'Date of birth : 2000 / Jan / 1' with a date picker. At the bottom are 'Export' (labeled with a line and '(2)') and 'Cancel' (labeled with a line and '(3)') buttons.

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

3.5.2 Print

Touch the “Print” button to start printing from the built-in printer, video printer, or PictBridge printer.
Select the desired printer in the system setup. Refer to “3.7.4 Connection & Print” for the setting of the printer.

a) Example of printout from built-in printer

The printing format for the built-in printer can be selected in the system setup. Refer to “3.7.4 Connection & Print” for the setting of printing format.

Header

(1) — YMD:2014/Jun/19 17:54:21

(2) — EM-4000 Ver.00

(3) — ID :12345678

(4) — Name:TOMEY TARO

(5) — Sex :Male

(6) — RIGHT LEFT

(7) — FIX C I C

(10) — * [Auto] [Auto] e — (11)

(12) {

NUM	310	204
CD	2759	2181
AVG	362	459
SD	149	402
CV	41	88
MAX	1312	5153
MIN	73	104
6A	42	39

}

(1) Examination date/time

(2) Model name; version

(3) Patient ID

(4) Patient's name

(5) Sex

(6) Eye (R/L)

(7) Fixation light position

(8) Image of endothelium

(9) Analysis method

(10) Edit mark

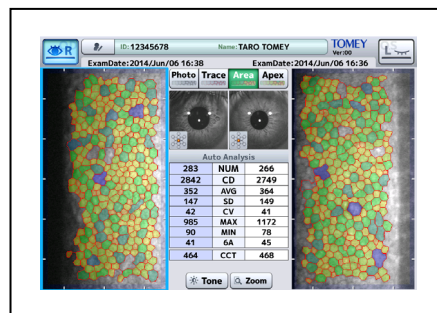
(11) Reliability mark

(12) Analysis results

	(13)	—	CCT	494	508	(13) Central corneal thickness
	(14)	—	CCT (US)	507	521	(14) Ultrasonic correction for central corneal thickness
	(15)	{	DA NUM	0	7	(15) Dark area analysis value
			DAD	0	623	(16) Dark area analysis setting
			DA AVG	0	1606	(D) : Dark area analysis ON
			DA SD	0	1596	(A) : Analysis as endothelium ON
			DA CV	0	99	(17) Printing date/time
			DA MAX	0	5153	(18) Character string defined by user
			DA MIN	0	299	
			DA Ratio	0.0	10.7	
	(16)	—	(D) (A)			
Footer	(17)	—	Print:2014/Jun/19 17:54			
	(18)	—	TOMEY CORP.			

b) Printout from video printer

The monitor screen is printed from the video printer and PictBridge printer. Buttons provided at the bottom of the screen are not printed.



3.5.3 Save

Note

- **Always enter the ID number before saving the examination data.**
- **Turn off the instrument when inserting or removing the SD card. Inserting or removing the SD card while the instrument is on may damage the saved data.**
- **The data saved in the SD card may be damaged due to SD card corruption or instrument failure. Backup the data as necessary.**

Touch the “Save” button (1) on the analysis screen to save the examination data of both eyes to the database (SD card inserted in the base of the main unit).



(Fig. 1)

(1)



(Fig. 2)

- The used storage capacity of the SD card is shown in % on the “Save” button (Fig. 2).
- If the used storage capacity of the SD card exceeds 90%, the character color turns red. Use this indication as a reference for replacement of the card.

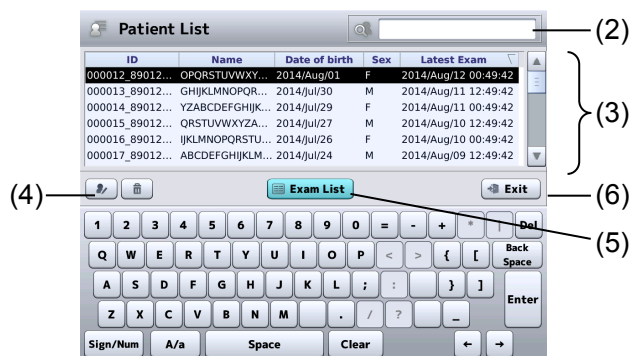
3.6 Database

3.6.1 Browsing examination data

- 1) Touch the "Database" button (1) on the analysis screen to open the Patient List screen (Fig. 2).

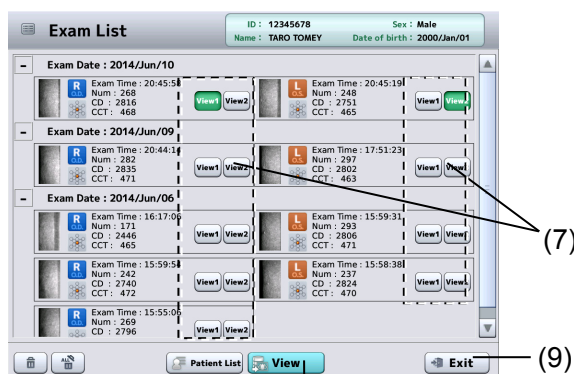


(Fig. 1)



(Fig. 2)

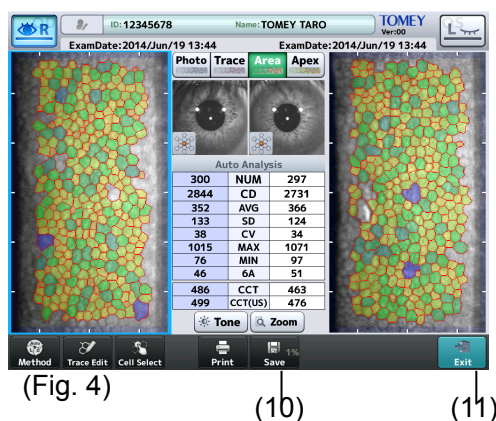
- 2) Touch the patient list window (3) to select the patient.
 - The selected line turns black.
 - Enter a search string into the search box (2). Possible patients are found from the patient IDs and names in the database, and listed in the patient list window.
 - Touch any of the titles at the top of the patient list window (ID, Name, and Date of birth) to sort patients.
 - Touch the patient information button (4) to open the Patient Information screen and check details of the patient information.
 - Touch the "Exit" button (6) to return to the previous screen.
- 3) Touch the "Exam List" button (5) to open the Exam List screen (Fig. 3) of the selected patient.



(Fig. 3)

(8)

- 4) Select the data to be browsed using the "View 1" or "View 2" button.
 - The examination data selected by the "View 1" or "View 2" button is shown on the left or right side of the R/L eye view screen respectively.
 - Touch the "Exit" button (9) to return to the Exam List screen.
- 5) Touch the "View" button (8) to display the selected examination data on the R/L eye view screen.
 - Functions of the buttons on the R/L eye view screen are the same as those on the R/L eye analysis screen. Refer to "2.4.4 Analysis screen" for operation of the buttons on the R/L eye analysis screen.
 - Edit the analysis result and touch the "Save" button (10) to overwrite the existing examination data with the edited contents.
 - Touch the "Exit" button (11) to return to the Exam List screen.



3.6.2 Deleting examination data

Note ■ When the patient information is deleted, all examination data saved with that patient's ID will be deleted. Be sure to check the contents saved before deleting them.

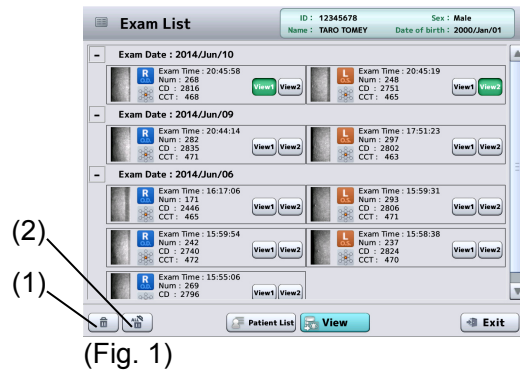
a) Deleting data on Patient List screen

- Touch the delete button (1) to delete the selected patient ID and captured images.



b) Deleting data on Exam List screen

- Touch the delete button (1) to delete the captured image data selected by the “View 1” and “View 2” buttons.
- Touch the all clear button (2) to delete all examination data of the selected patient. The patient information is not deleted.



(Fig. 1)

3.6.3 Changing ID

Note

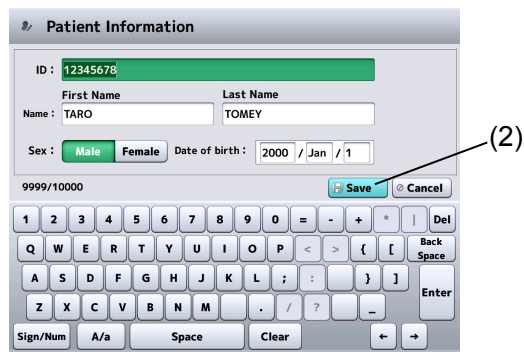
- Examination data are saved or deleted when changing ID. Do not turn off the power when ID is being changed. Otherwise, the data may be damaged.
- The data saved in the SD card may be damaged due to SD card corruption or instrument failure. Backup the data as necessary.

- 1) On the R/L eyes view screen or single eye view screen, hold the grayed out patient information button (1) briefly to open the patient information entry screen (fig. 2).



(Fig. 1)

-
- 2) Enter the ID number and push the save button (2) to change the current examination data ID number.



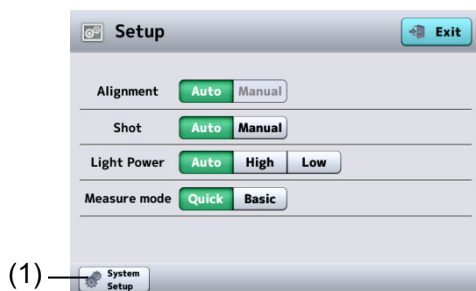
The image shows a 'Patient Information' form. At the top, the title 'Patient Information' is displayed. Below it, there is a green bar containing the ID number '12345678'. Underneath the green bar, there are two input fields for 'First Name' and 'Last Name'. The 'First Name' field contains 'TARO' and the 'Last Name' field contains 'TOMEY'. Below these fields, there are two radio buttons for 'Sex', with 'Male' selected. To the right of the sex buttons is a 'Date of birth' field with the date '2000 / Jan / 1'. Below the date field, there is a text field containing '9999/10000'. To the right of this text field are two buttons: 'Save' and 'Cancel'. An arrow points from the number '(2)' to the 'Save' button. Below the form is a virtual keyboard with buttons for numbers 1-0, letters Q-Z, and special keys like 'Del', 'Back Space', 'Enter', 'Sign/Num', 'A/a', 'Space', and 'Clear'.

(Fig. 2)

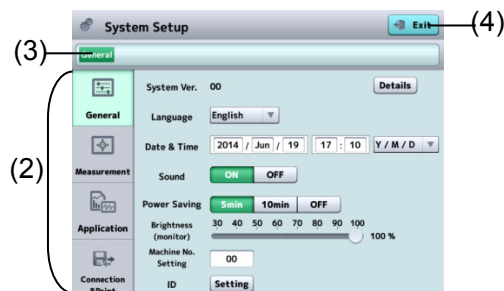
3.7 System setup

The “system setup” function is provided in this instrument to change various settings. “System setup” settings are retained even when the instrument is turned off.

- 1) Open the System Setup screen. Touch the “System Setup” button (1) on the Setup screen (Fig. 1) to open the System Setup screen (Fig. 2).



(Fig. 1)



(Fig. 2)

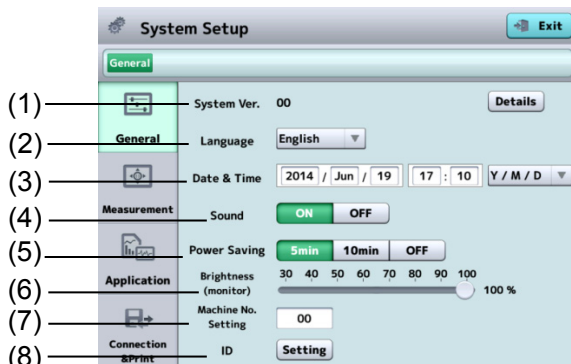
- 2) The system setup consists of 4 major categories.
 - General Language, time, version information, etc.
 - Measurement ... Capture of images and operation
 - Application Analysis and correction
 - Connection & Print ... Connection and printing

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.

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

3.7.1 General

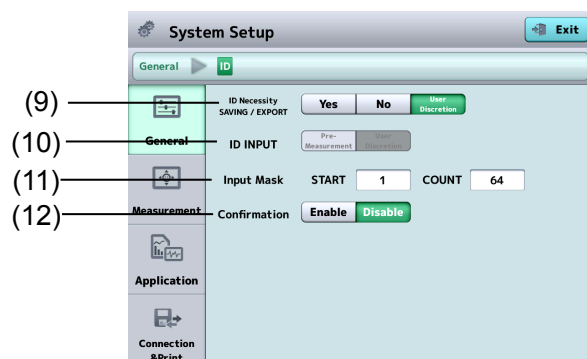
Set general settings for the instrument. Select the “General” tab.



(Fig. 1)

- (1) System Ver.
Displays the version of the system.

- (2) Language
Selects the language.
- (3) Date & Time
Set the display format of the date and the date and time. The key pad appears when the input field is touched.
- (4) Sound
Set whether to emit sounds when capturing an image and operating the screen.
- (5) Power Saving (auto power off function)
Automatically turns off the monitor when no operation is performed for a specified time. Touch the monitor screen to return to normal status. Set the time until the auto power off function is activated.
5 mins / 10 mins / OFF
- (6) Brightness (monitor)
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
Opens the System Setup screen (Fig. 2) for patient IDs.



(Fig. 2)

- (9) ID Necessity, SAVING / EXPORT
Set how the ID must be handled when saving and sending examination data to TOMEY Link.

Indispe nsable	:	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 inspection 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 capturing images when starting to capture images for a new patient. When “(9) ID Necessity, SAVING / EXPORT” setting is “No”, this setting is automatically set to “No” and cannot be selected.

- Yes : Opens the patient information entry screen before capturing images.
- No : Opens the capture screen.

(11) Input Mask

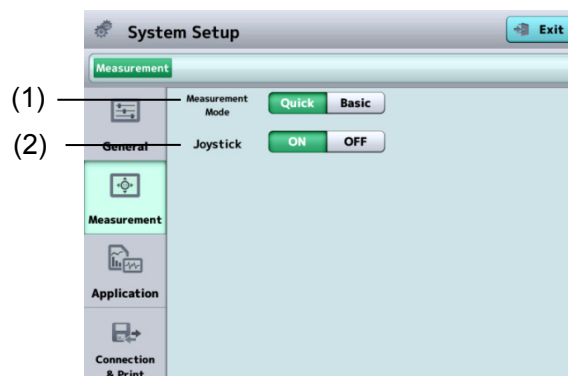
Sets which part of the character string should be recognized as the ID number when entering the ID number from a barcode. If it starts from “0” or “1”, the characters from the very beginning are identified as the ID number.

(12) Confirmation

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

3.7.2 Measurement

Make settings related to capturing images. Select the “Measurement” tab.



(Fig. 1)

(1) Measurement mode

Sets the mode for capturing images.

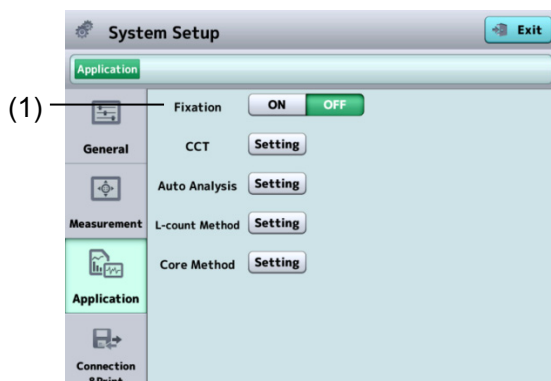
- Quick : Capture mode in which the image selection screen does not appear when capturing is completed. This mode is for users that do not need to look at all 16 images of the endothelium tissues.
- Basic : Capture mode in which the image selection screen appears when capturing is completed. This mode is for users who want to look at all 16 captured images of the endothelium tissues and select only one from them.

(2) Joystick

Activates or deactivates the joystick.

3.7.3 Application

Make settings related to display and analysis. Select the “Application” tab.



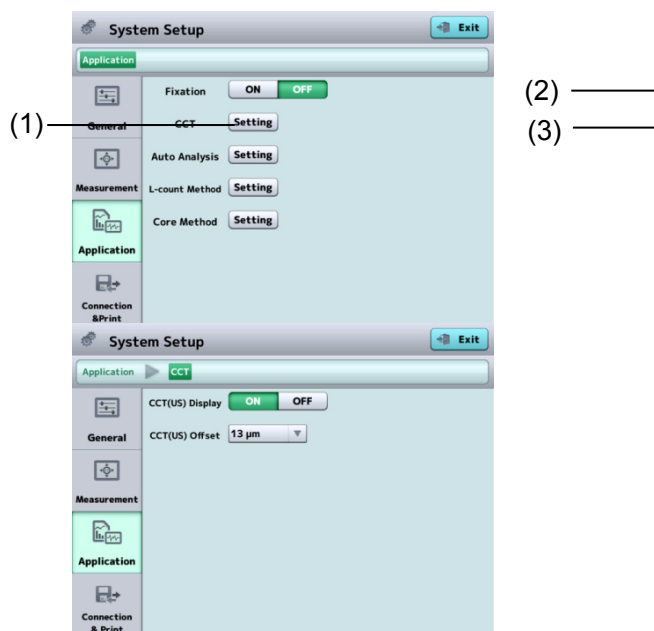
(Fig. 1)

(1) Fixation

Sets whether to show the fixation light position for capturing images on the fixation light position of the analysis screen.

a) CCT

Touch the “Setting” button (1) of “CCT” to display the System Setup screen (Fig. 2).



(Fig. 1)

(Fig. 2)

(2) CCT (US) Display

Sets whether to display the ultrasound correction value of the central corneal thickness.

The initial setting is OFF.

(3) CCT (US) Offset

Sets the offset for ultrasound correction of central corneal thickness.

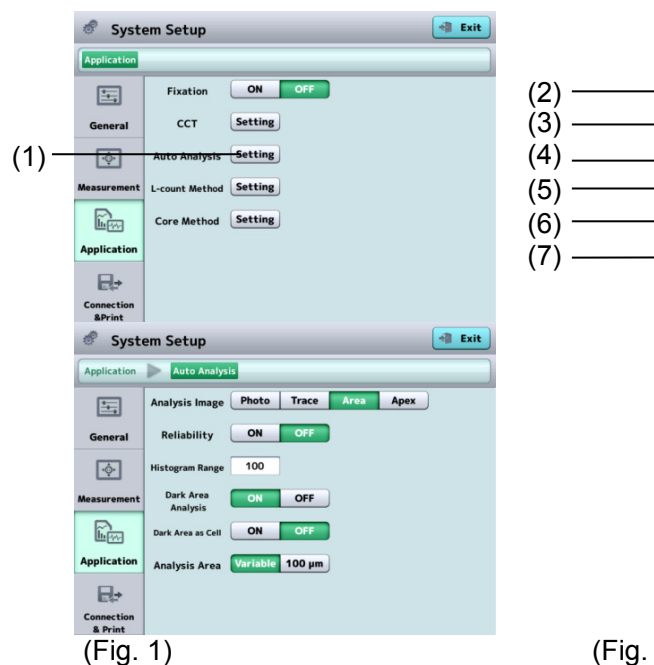
Initial setting : 13 µm

Setting range : 0 µm - 30 µm (in increments of 1 µm)

This item is not displayed when “(2) CCT (US) Display” is set to OFF.

b) Auto Analysis

Touch the “Setting” button (1) of “Auto Analysis” to open the System Setup screen (Fig. 2).



(Fig. 1)

(Fig. 2)

(2) Analysis result

Sets images (Photo, Trace, Area, or Apex) to be shown immediately after analysis is completed.

(3) Reliability

Set whether to display the reliability mark on the screen.

(4) Histogram Range

Set the range displayed by a histogram of area-specific distribution.

Initial setting : 100 μm^2

Setting range : 1 - 999 μm^2 (in increments of 1 μm^2)

(5) Dark Area Analysis

Turns the dark area detection function on and off.

Dark areas are not detected when set to OFF.

(6) Dark Area as Cell

Sets whether to regard detected dark areas as endothelium tissues and include them in analysis of endothelium tissues. This item is not displayed when “(5) Dark Area Analysis” is set to OFF.

(7) Analysis Area

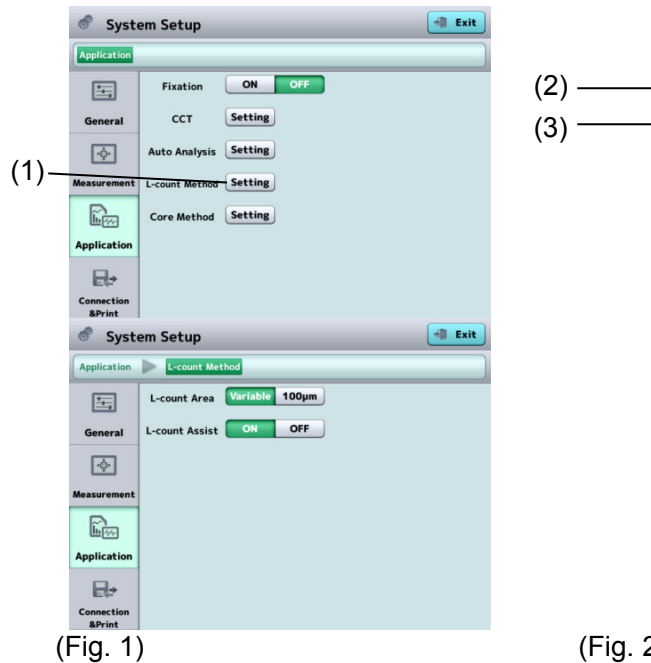
Sets how to specify the range using the analysis range selection button of the auto analysis/edit trace line function.

Variable : Set the analysis range by specifying two opposing points.

100 μm : Set the analysis range to 100 μm^2 regarding a point specified on the image of endothelium tissues as the center.

c) L-count Method

Touch the “Setting” button (1) of “L-count Method” to open the System Setup screen (Fig. 2).



(2) L-count Area

Sets how to specify the range for analysis by the L-count method.
Variable : Set the analysis range by specifying two opposing points.

100 µm : Set the analysis range to 100µm² regarding a point specified on the image of endothelium tissues as the center.

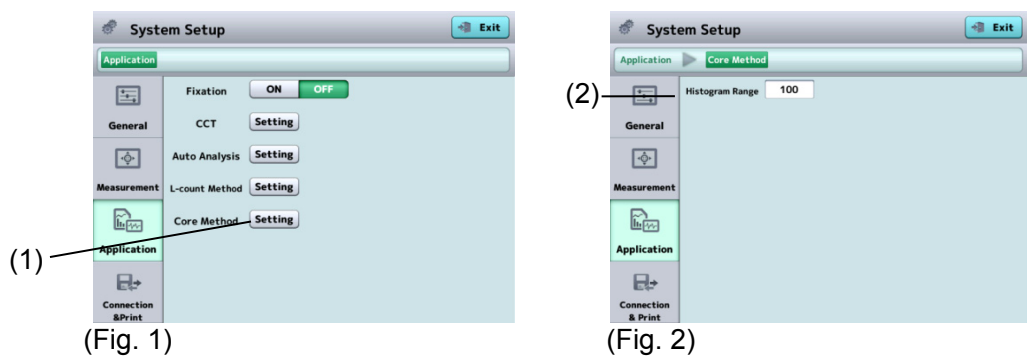
(3) L-count Assist

Turns the L-count assist function on and off.

Cells are automatically selected after the range is specified when set to ON.

d) Core Method

Touch the “Setting” button (1) of “Core Method” to open the System Setup screen (Fig. 2).



(2) Histogram Range

Set the range displayed by a histogram of area-specific distribution.

Initial setting : 100 μm^2

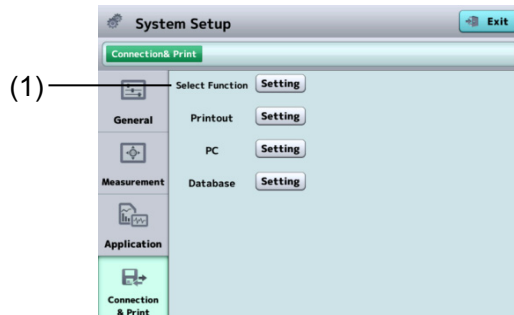
Setting range : 1 - 999 μm^2 (in increments of 1 μm^2)

3.7.4 Connection & Print

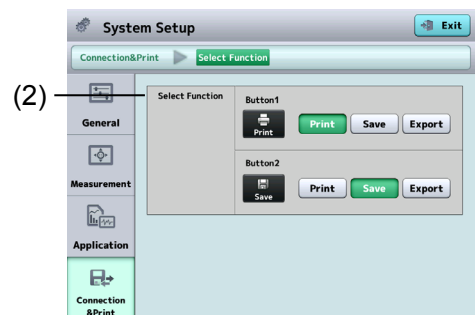
Make settings related to connection, saving, export, and printing on this screen. Select the Connection & Print tab.

a) Select Function

Touch the “Setting” button (1) of “Select Function” to open the Select Function screen (Fig. 2).



(Fig. 1)



(Fig. 2)

(2) Select Function

Select functions of two buttons at the bottom center of the analysis screen (Fig. 3).

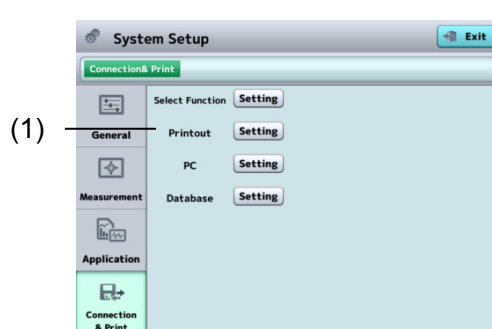


(Fig. 3)

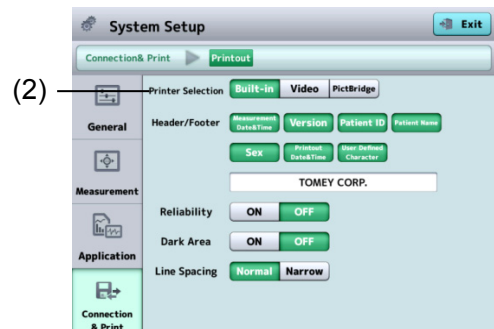
(Button 1) (Button 2)

b) Printout

Touch the “Setting” button (1) of “Printout” to open the System Setup screen related to printers (Fig. 2).



(Fig. 1)



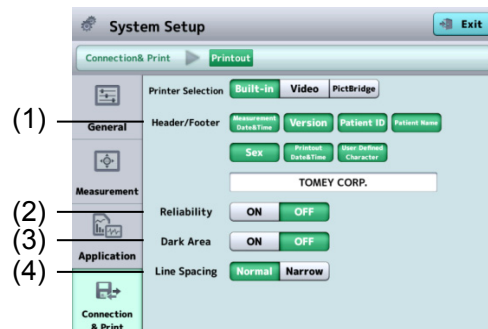
(Fig. 2)

(2) Printer Selection

Select the printer to be used. Three types of printers are available: built-in printer, video printer, and PictBridge printer.

When the printer is selected, printer-specific setting items appear. There are no special setting items for the PictBridge printer.

[Built-in]



(Fig. 1)

(1) Header/Footer

Set the items to be printed in the header and footer area.

Refer to “3.5.2 a) Example of printout from built-in printer” for details of printing items.

(2) Reliability

Set whether to show the reliability mark.

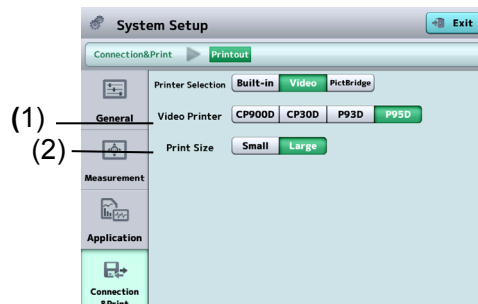
(3) Dark Area

Set whether to print the dark area analysis values.

(4) Line Spacing

Set the line spacing for printing.

[Video]



(Fig. 1)

(1) Video Printer

Select the type of video printer.

Four types of video printers are available as follows.

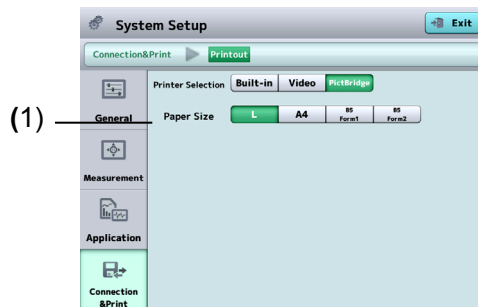
CP900D	:	Mitsubishi CP900D, color
CP30D	:	Mitsubishi CP30D, color
P93D	:	Mitsubishi P93D, monochrome
P95D	:	Mitsubishi P95D, monochrome

(2) Print Size

Set the printing size.

This item is displayed only when “P93D” or “P95D” is selected in item (1).

[PictBridge settings]



(Fig. 1)

(1) Print Size

Set the printing size.

L / A4 / B5 Form 1 / B5 Form 2

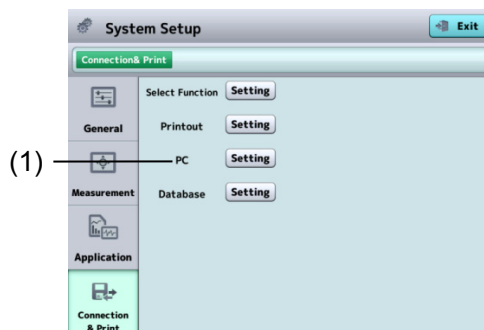
B5 Form 1: When the paper feed tray is centered.

B5 Form 2: When the paper feed tray is left-aligned.

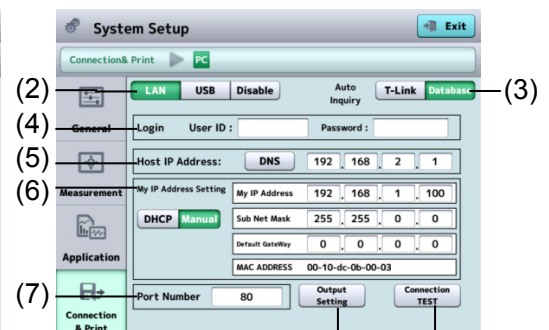
c) PC

Make connection settings to export data to a personal computer with TOMEY Link or Data Transfer installed.

Touch the "Setting" button (1) of "PC" to open the System Setup screen related to PC (Fig. 2).



(Fig. 1)



(Fig. 2)

(2) 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.

Disable : Not connected

The initial setting is "Disable."

(3) Auto Inquiry

T-Link : The patient information corresponding to the entered ID is retrieved from TOMEY Link.

Database : The patient information corresponding to the entered ID is retrieved from the database in the SD card of the main unit.

(4) Login

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

(5) Host IP address

Set the IP address of the personal computer to be connected. This item is displayed only when “LAN” is selected. Touch the “DNS” button to specify the personal computer name. A DNS server must be running in the LAN environment to enable connection using the DNS.
Touch the input field to display the keyboard.

(6) My IP Address Setting

Selects either 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.

This item is displayed only when “LAN” is selected in item (2).

(7) Port number

A port number can be set. This item is displayed only when “LAN” is selected in item (2).

Initial setting : 80

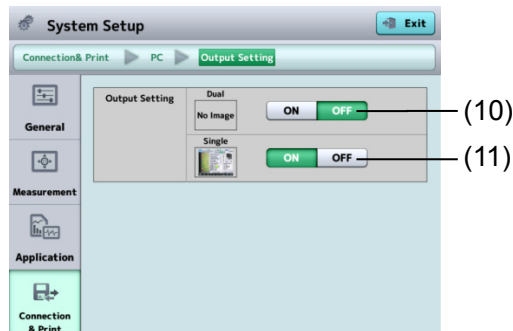
Input range : 0 - 65535

(8) "Connection Test" button

Performs a connection test.

(9) "Output Setting" button

Open the System Setup – Output Setting screen (Fig. 3).



(Fig. 3)

(10) "Dual" button

Set whether or not to output the JPEG image on the R/L eye analysis screen to the personal computer.

(11) "Single" button

Set whether or not to output the JPEG image on the single eye analysis screen to the personal computer.

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) Set settings on the Instrument.

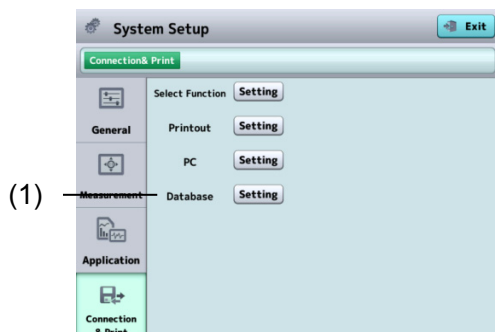
The settings shown in the table below describe an example when the IP address of the computer with DATA Transfer installed is "192.168.2.128" and the subnet mask is "255.255.255.0." The IP setting method in this case is "Manual."

	Computer settings				Instrument 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			

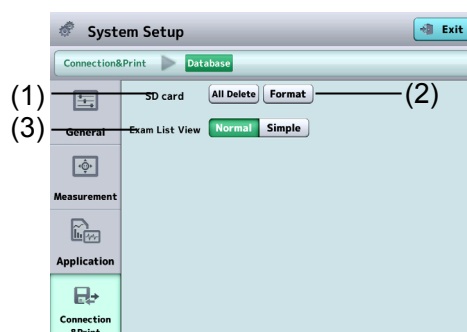
*1: An arbitrary number from 1 to 255 excluding numbers used by the computer (128 in this example)

d) Database

Touch the “Setting” button (1) of “Database” to open the System Setup screen related to the database (Fig. 2).



(Fig. 1)



(Fig. 2)

- (1) SD card "All Delete" button
All patient and examination data are deleted.
- (2) SD card "Format" button
Format the SD card inserted in the main unit. All examination data is deleted.
- (3) Exam List View
 - Normal : Displays thumbnails of images of the endothelium on the Exam List screen.
 - Simple : Doesn't display thumbnails of images of the endothelium on the Exam List screen.

4. INSPECTION AND MAINTENANCE

4.1 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.

4.2 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.

4.3 Inspection

Note

■ *When there is a problem, measurement may not be performed correctly. Contact TOMEY or our local distributor immediately for repair.*

■ *When measuring the imitation eyes, check that there is no dust or stain on them.*

To make sure that the internal functions operate correctly and performance is maintained, use the imitation eyes to check the accuracy before using the instrument.

Inspect method Use the chin rest pins to fix the imitation eyes to the chin rest. Perform measurement in the same manner as measuring a patient's eyes. Check that the measured values are within the range specified on the imitation eyes.

4.4 Routine maintenance



- *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.*



- *Do not use organic solvents such as thinner, benzene, or acetone to clean the instrument. These solvents may damage the surface of the instrument.*
- *Clean the inner surface of the capture window with a soft cloth from time to time. High quality images may not be captured if the optical section of the instrument becomes dirty.*
- *Place the dust cover over the main unit when not being used.*
- *Disconnect the power plug from the outlet and place the dust cover over the main unit when not used for long periods.*
- *Spray glass cleaner onto a soft cloth to clean the monitor on the main unit.*
- *Gently wipe (do not rub) sections that patients touch directly, such as the forehead pad and chin rest, with cotton dampened with alcohol.*
- *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.*

Daily maintenance

Main unit	Gently wipe the surface using a soft cloth dampened and thoroughly wrung out, and then wipe the surface using a dry cloth.
Touch panel	Wipe the touch panel using a soft, dry cloth.

For heavy dirt

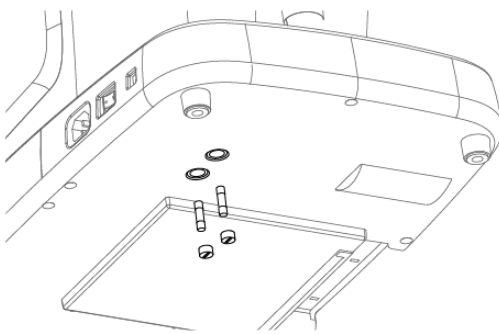
Main unit	Remove dirt from the surface by gently rubbing it using a cloth dampened with diluted neutral detergent and thoroughly wrung out. Then, remove detergent from the surface using a cloth dampened and thoroughly wrung out, and wipe the surface using a dry cloth.
Touch panel	Remove dirt by lightly wiping the touch panel using a soft cloth dampened with alcohol. Further, wipe it using a dry soft cloth to completely remove moisture.

4.5 Replacing consumables

4.5.1 Fuses



- **Disconnect the power cord from the outlet when replacing fuses. Otherwise you may get an 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 our local distributor.**



(Fig.1)

- 1) Turn power off and disconnect the power plug from the outlet.
- 2) Disconnect the power plug from the power terminal.

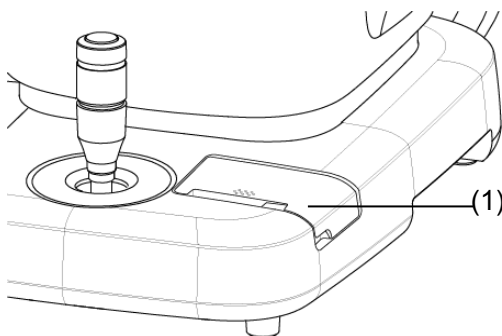
Insert a flat screwdriver or coin into the slot on the fuse case located at the bottom of the main unit. Turn the screw counterclockwise to remove it.
- 3) Replace the blown fuse with a new one.
- 4) Install the fuse holder in the reverse order of removal.

4.5.2 Built-in printer paper



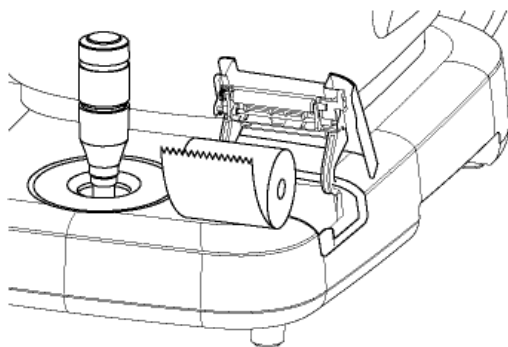
- **Always use genuine TOMEY paper for the printer. Using other types of paper may cause printer failure.**
- **Do not pull paper forcibly. Trying to pull the paper out may cause printer failure. Touch the "PRINT" button without any data stored to feed blank paper.**

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



(Fig.1)

- 1) Push the latch (1) on the printer cover upward to open it.



(Fig.2)

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

4.6 Storing



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



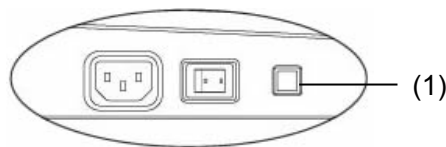
- **Do not store the instrument in a location where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and result in fire.**
- **Disconnect the power plug from the outlet to ensure safety when the instrument is not operated for long periods.**
- **Store the instrument 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, images cannot be captured correctly. The instrument may also topple over or fall down, resulting in fire or a fatal accident.**



- **Place the dust cover over the main unit when not being used. High quality images may not be captured if the optical section in the instrument becomes dirty.**

Completely lower the head to the lower dead center when storing the instrument.

Pressing the packing button (1) for 3 seconds automatically returns the head to the lower dead center. Turn power off.



<Storage conditions>

- | | | |
|-----------------------------|---|-------------|
| - Ambient temperature range | : | -20 - +60°C |
| - Relative humidity range | : | 10 - 95% |

4.7 Disposal



- **Keep the box and packing materials for use when moving or transporting the instrument.**
- **Keep the packing materials and the box together.**
- **When disposing of the main unit and/or packing materials, sort them by material type and abide by local government rules and regulations.**
- **A lithium battery is used in the instrument. Handling of the lithium battery varies depending on governing bodies. Follow relevant laws and local rules and regulations, or contact our local distributor or representative.**

5. 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 our local distributor to request inspection and/or repair.



■ ***Do not remove the cover of the instrument. Otherwise you may get an electric shock.***



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

5.1 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 “4.5.1 Fuses”). When the new fuse is blown again, the instrument may be faulty. Contact our 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 ➡ Turned 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 brightness setting of the screen described in "3.7.1 General."

- **The data cannot be printed by the video printer.**

? Cause 1 Printer paper.

Solution ➡ Check the remaining printer paper. Verify that printer paper is correctly set as described in the instruction manual of the video printer.

? Cause 2 USB cable.

Solution ➡ Verify that the USB cable is correctly connected to the main unit and the video printer. Refer to "3.2.1 Connections" for correct connection.

? Cause 3 Setting the output printer

Solution ➡ Set "Video" for the output destination when the "Print" button is touched. Refer to "3.7.4 Connection & Print" for the correct setting.

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

? Cause 1 Setting of the video printer is not appropriate.

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

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

? Cause 1 Printer paper.

Solution ➡ Check the remaining printer paper. Verify that printer paper is set correctly as described in "4.5.2 Built-in printer paper."

? Cause 2 Setting the output printer

Solution ➡ Set "Built-in" for the output destination when the "Print" button is touched. Refer to "3.7.4 Connection & Print" for the correct setting.

?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 “4.5.2 Built-in printer paper” for the correct setting.

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

?Cause 1 The touch panel is not calibrated correctly.

Solution ➡ Contact our local distributor.

- **Nothing is displayed on the screen of this instrument when inputting IDs from 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. Refer to “3.2.1 Connections” for correct connection.

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

Solution ➡ Open the screen that receives the external ID input device and then input IDs.

Refer to “3.2.4 Entering the patient data” for the screen that receives the external ID input device.

- **Data cannot be saved in the database.**

?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 SD card. (The confirmation screen appears when attempting to save the data.)

Solution ➡ Delete unnecessary data in the SD card and save the data again.

- **Communication with TOMEY Link or DATA Transfer cannot be performed properly.**

? Cause 1 Cable is not connected properly.

Solution ➡ Check that the connectors of the instrument and/or connected device are plugged in properly.

? Cause 2 TOMEY Link or DATA Transfer is not running.

Solution ➡ Check that TOMEY Link or DATA Transfer (including the relay software when connected via USB) is running correctly. Refer to the instruction manual of TOMEY Link or DATA Transfer for details.

? Cause 3 TOMEY Link or DATA Transfer is in an error state.

Solution ➡ Check that no error is current in TOMEY Link or DATA Transfer (including the relay software when connected via USB). Refer to the instruction manual of TOMEY Link or DATA Transfer for details.

? Cause 4 The HUB is not turned on (in the case of LAN connection).

Solution ➡ Turn on the HUB.

? Cause 5 The instrument or TOMEY Link or DATA Transfer settings are not correct.

Solution ➡ Refer to “3.7.4 Connection & Print” and make correct settings.

6. CONSUMABLES AND OPTIONAL EQUIPMENT

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

- Built-in printer paper
Specify the paper type as "TOMEY common printer (58 mm)."
- Chin rest paper (100 sheets/set)
- Fuse
Specify the fuse type as "Fuse for EM-4000."

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7. SPECIFICATIONS

7.1 Specifications

7.1.1 Capturing scope

0.25×0.54mm (W x H)

7.1.2 Central corneal thickness measurement accuracy

±10μm

7.1.3 Central corneal thickness measurement range

300 - 1000μm

7.1.4 Main unit

- Display 10.4" color LCD
- Dimensions and weight 309 (W) x 491 (D) x 450 (H) mm, approx. 22 kg
- Voltage 100 V AC - 240 V AC
- Frequency 50/60Hz
- Consumption power 100 VA

7.2 Operating environment

Operate the instrument under the following environmental conditions.

- Installation : Indoors, not in direct sunlight
- Temperature : +10°C - +40°C
- Humidity : 30 - 75%
- Atmospheric pressure : 800 - 1060hPa
- Power fluctuation : less than 10% of normal voltage

Store the instrument under the following environmental conditions.

- Temperature : -20°C - +60°C
- Humidity : 10 - 95%

Transport the instrument in the instrument's box under the following environmental conditions.

- Temperature : -20°C - +60°C
- Humidity : 10 - 95%

7.3 Classification

Protection against electrical shock: Class I ME equipment

Applied parts : B applied parts (Forehead pad, Chin rest)

IP Code : IP10

Mode of Operation : Continuous operation

7.4 Declaration of Conformity to EMC



- *The EM-4000 belongs to Group 1 and B equipment in accordance with IEC/EN60601-1-2.*
- *The EM-4000 is a group 1, class B product according to EN55011(CISPR11). This means that the EM-4000 does not generate and/or use intentionally radio-frequency energy, in the form of electromagnetic radiation, inductive and/or capacitive coupling, for the treatment of material or inspection/analysis purpose and that it is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.*
- *The EM-4000 requires special precautions regarding EMC and need to be installed, put into service and used according to the following information.*
- *Do not use any cables other than the cables that provided or specified by Tomey.*
- *The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Tomey as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EM-4000.*
- *Portable and mobile RF communications equipment can affect the EM-4000.*
- *The EM-4000 should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the EM-4000 should be observed to verify normal operation in the configuration in which it will be used.*
- *Anyone who connects additional equipment to the signal input/output parts, configuration a medical system, is responsible that the system complies with the requirements of IEC/EN60601-1-2.*

● Cable List

No.	cable	Maximum length [m]	Remarks
1	AC code	2.5	Unshielded

● Accessory List

No.	name	model	manufacture
1	AC code	E32-0025	KDK ELECTRIC WIRE

- Basic performance
 - Corneal endothelial cell density calculated by analysis of captured image is indicated properly.
 - Measurement data of central corneal thickness is indicated properly.

Caution: Medical electrical equipment.

EMC (Electro Magnetic Compatibility) must be considered before any medical electrical equipment is installed or put into service. Follow the information in the accompanying documentation when installing and operating the EM-4000.

Caution: Portable or mobile RF communication equipment can effect Medical Electrical equipment.

Guidance and manufacturer's declaration - electromagnetic emissions

Table 201

The EM-4000 is intended for use in the electromagnetic environment specified below.

The customer or the user of the EM-4000 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The EM-4000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The EM-4000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
			Table 202
The EM-4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the EM-4000 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge(ESD) IEC 61000-4-2	$\pm 6\text{kV}$ contact $\pm 8\text{kV}$ air	$\pm 6\text{kV}$ contact $\pm 8\text{kV}$ air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ Burst IEC 61000-4-4	$\pm 2\text{kV}$ for power supply lines $\pm 1\text{kV}$ for input/output lines	$\pm 2\text{kV}$ for power supply lines $\pm 1\text{kV}$ for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 1\text{kV}$ differential mode $\pm 2\text{kV}$ common mode	$\pm 1\text{kV}$ differential mode $\pm 2\text{kV}$ common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips , short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\%$ UT ($> 95\%$ dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles $< 5\%$ UT ($> 95\%$ dip in UT) for 5 sec	$< 5\%$ UT ($> 95\%$ dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles $< 5\%$ UT ($> 95\%$ dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EM-4000 requires continued operation during power mains interruptions, it is recommended that the EM-4000 is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE : UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration electromagnetic immunity

Table 204

The EM-4000 is intended for use in the electromagnetic environment specified below.
The customer or the user of the EM-4000 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V rms 150kHz to 80MHz	3 V rms	Portable and mobile RF communication equipment should be used no closer to any part of the EM-4000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. B Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5GHz	3 V/m	

Note1 : At 80MHz and 800MHz, the higher frequency range applies.

Note2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EM-4000 is used exceeds the applicable RF compliance level above, the EM-4000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EM-4000.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EM-4000

Table 206

The EM-4000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EM-4000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EM-4000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 : At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Original instructions

