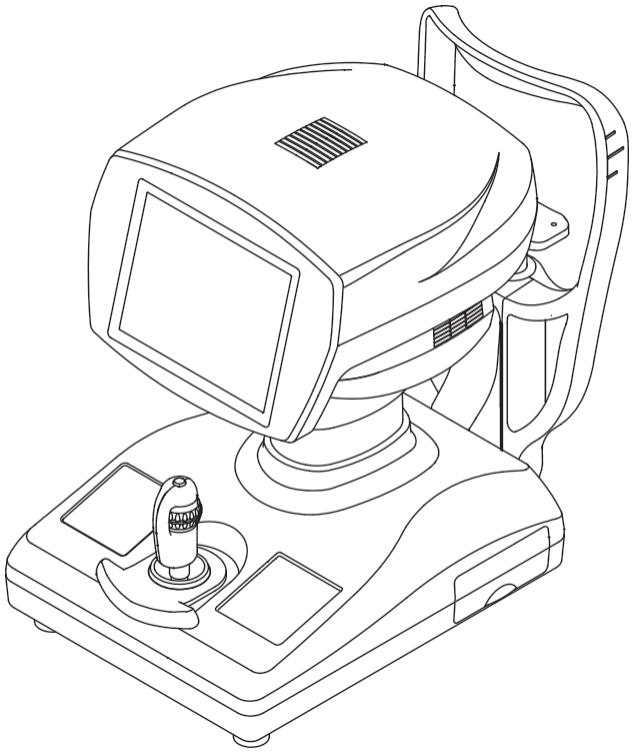
INSTRUCTION MANUAL

SPECULAR MICROSCOPE

REM 3000



Carefully read this instruction manual before using this instrument to ensure correct and safe operation.
If you have questions about operations, please contact RODENSTOCK or our local distributor.

Note

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

RODENSTOCK

602F9090-00

i Important Safety Information

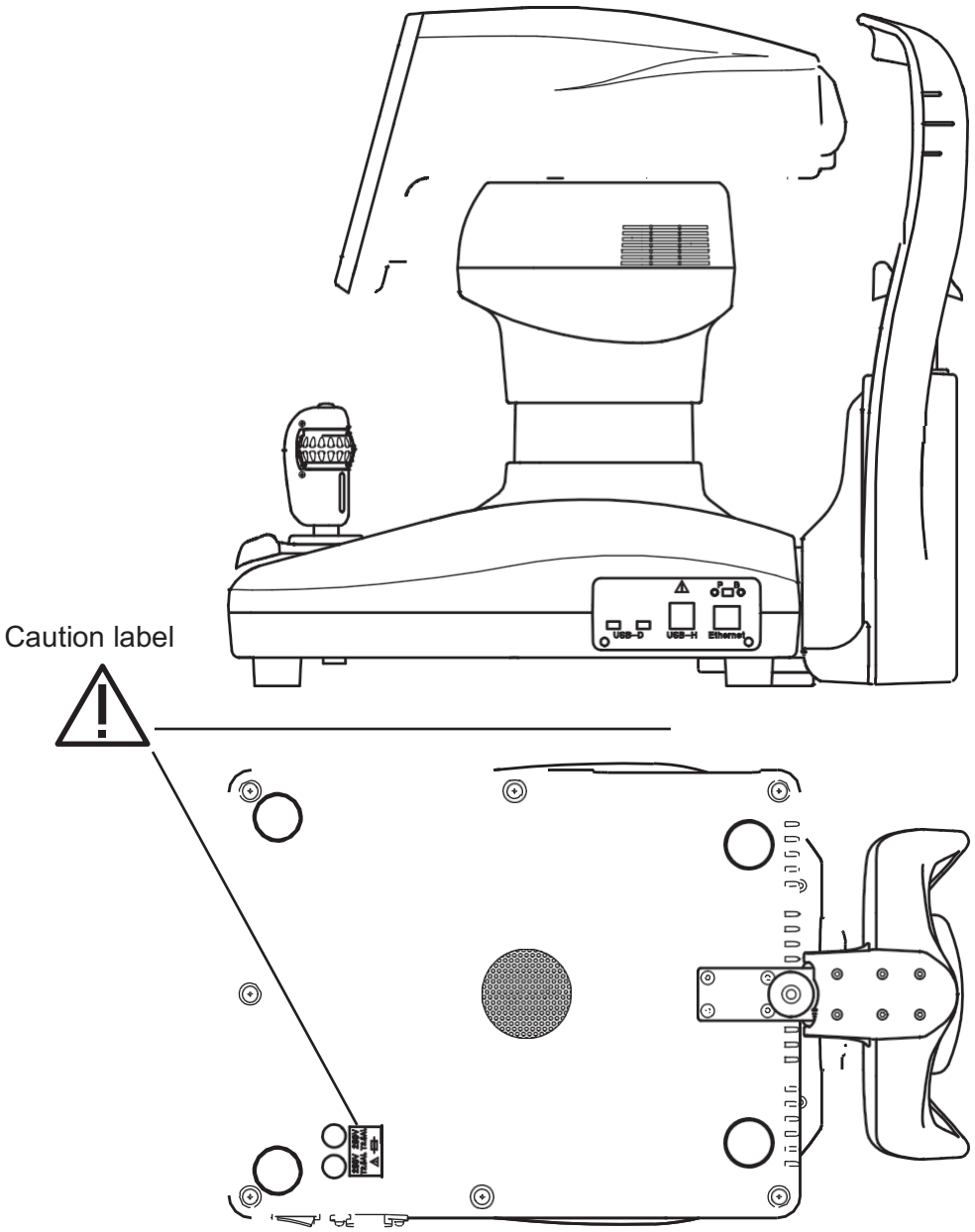
- ***Do not install this instrument in a location where explosives or inflammable substances are used or stored. Otherwise, fires or explosion may occur.***
- ***Do not remove the cover of the instrument. Otherwise, you may be directly exposed to high voltage sections.***
- ***Do not disassemble or modify the instrument. Otherwise, you may be directly exposed to high voltage sections.***
- ***Do not look straight at any alignment laser light emitted from the measuring section.***

- ***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/measuring device specially designed for ophthalmology. Never use the instrument for other purposes.***
- ***The external output terminal is not isolated from the internal circuit. Inappropriate wiring may damage the internal circuit. If you wish to connect this instrument to other devices, contact our local distributor or RODENSTOCK.***

■ ***Never damage or cause caution labels provided for the instrument to become illegible. A caution label is provided on the back side of the instrument.***

■ ***If a label is damaged or becomes illegible, please contact RODENSTOCK or our local distributor.***



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 OF PAR TS AND COMPONENTS
   Describes names and functions of each section of the instrument.

3. PERATION PROCEDURES
   Describes information required for installing and using the instrument.

4. TECHNICAL INFORMATION
   Describes useful technical information about the instrument.

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

6. TROUBLESHOOTING
   Describes how to solve problems.

7. CONSUMABLES AND OPTIONAL EQUIPMENT
   Describes consumable parts and optional equipment.

8. SPECIFICATIONS
   Describes the specifications of the instrument.

9. INDEX
   Refer to the index when needed.

SYMBOLS USED IN THIS MANUAL

The symbols below indicate the following:

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

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

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

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

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1. PRIOR TO USE

Note

- ***Read this manual thoroughly before using the instrument to ensure proper and safe operation.***
- ***Always follow the operation procedures described in this manual.***
- ***Check that there is no device that generates strong magnetic fields near the instrument. Strong magnetic fields may cause noise and affect the measurement.***

1.1 Precautions for operation

- ***Only allow adequately skilled operators to use the instrument.***
- ***Precautions for 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 place where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and ignite.

Check the frequency, voltage, and allowable current (or power consumption) of the power source. Operating the instrument connected to an inappropriate power source may cause fire or an electric shock.

Connect the power plug to a grounded 3P-outlet. Otherwise, a short circuit due to failure of the instrument may result in an electric shock.

Do not place any heavy object on the power cord or squash the power cord. Connecting such a device may cause fire or an electric shock.

Completely insert the power plug into the outlet. Faulty contact, allowing any metal to contact exposed plug terminals, or dust accumulated on exposed plug terminals may result in fire or an electric shock.

Do not connect any device with data transmission specifications that are not compatible with the instrument. Connecting such a device may cause a fire or an electric shock. If you wish to connect this instrument to other devices, contact our local distributor or RODENSTOCK.

Ground the instrument appropriately. Otherwise you may get an electric shock.

Caution

Do not hold the head unit, chin rest, forehead pad, or joystick when lifting 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 with significant dust, salt, and/or sulfur content. These may cause failure or malfunction of the instrument.

Install the instrument in a level and stable location free of vibration and mechanical impacts to ensure correct capturing, and prevent the instrument from falling or being dropped, which can result in fire or fatal accidents.

Install the instrument between the patient and physician so that they can face with each other.

Install the instrument in a location that it is sufficiently clear of any other equipment that may interfere with the examination when using the instrument.

■ *Precautions before using the instrument*

Caution

Check that all cables are connected correctly and completely.

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.

Check that the instrument is correctly grounded.

Check that the date set in the instrument conforms to the actual operation date and time.

Note

When the room temperature lowers to 10°C or below in winter, turn the instrument on and warm it up before starting operation. Low temperature may affect the image quality.

■ *Precautions during operation*

WARNING

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

Do not operate the joy stick, touch panel, and membrane switch during initial operation until the capture screen appears after turning the power switch on. If the initial operation is not complete properly, malfunction may occur during capturing.

Caution

If any smoke, offensive odor, or abnormal sound occurs, turn off the instrument immediately, disconnect the power plug from the outlet, and contact our local distributor or RODENSTOCK.

When moving the head unit and/or chin rest of the instrument, pay attention to the position of the patient's face, hands, and fingers. The patient may be injured by the moving section of the instrument.

Do not allow any person to place their hands or fingers in the clearance under the head unit or the section under the chin rest. Their hands or fingers may be crushed and injured.
Do not place any finger or object through the capturing window. These may cause malfunction or failure of the instrument and/or an inaccurate analysis result.
Do not lean on the instrument or press on the instrument from the top. The instrument may fall, resulting in mechanical failure or injuries.
Complete the capturing within the prescribed time and number of repetitions.
Observe both the instrument and patient to ensure there are no problems. If a problem with the instrument or the patient occurs, take appropriate action such as stopping the machine to ensure the safety of the patient.
Halt the operation immediately if the patient shows any sign of photosensitive epilepsy while capturing images.
Poor fixation, blepharoptosis, trichiasis, or corneal disease may cause inaccurate analysis results or corneal thickness measurements.
If the captured image is not clear, analyze another image or capture a new image.
When using the photographing and analysis results by this instrument for diagnosis, also conduct other examinations and carefully consider the results of those examinations to make final judgment. Capturing conditions may affect the precision of captured images or analysis results.
Do not use the "corneal thickness" and "ultrasonic correction for 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 dampened with alcohol before 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 an electric shock or failure.

Do not use organic solvents such as thinner, benzene, or acetone to clean the instrument. This may cause fire or an electric shock. (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 applying excessive force on the cord. Pulling the cord may damage inner core wires, resulting in electric shock or fire.

Disconnect the power plug when the instrument is not operated for a long period of time.
Refer to "5.6 Storing" for instructions on storing the instrument.

Clean the instrument appropriately at the end of operation to get ready for the next operation.
Clean and neatly arrange the accessories and cables.
If any smoke, offensive odor, or abnormal sound occurs, turn off the instrument immediately, disconnect the power plug from the outlet, and contact our local distributor or RODENSTOCK.

- ***If any instrument failure occurs, stop operation immediately, indicate the failure, and contact our local distributor to request repair.***

Never modify the instrument. Doing so may cause electric shock or failure of the instrument. The instrument contains high-voltage sections. Touching these sections will result in death or serious injuries.
Disconnect the power plug 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 RODENSTOCK to ensure safety. Also, do not use the accessories provided with the instrument for other equipment.

When any instrument failure occurs, indicate the failure, and contact our local distributor to request inspection and repair. 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, refer to "5.3 Inspection" in this manual and check that the instrument is operating correctly and safely before starting operation.

1.2 Checking contents of package

Open the package and check that the specified amount of the following items are included in the package and are not damaged. If any item is missing or damaged, contact our local distributor as soon as possible.

Note

- ***Keep the box and packing materials for use when moving or transporting the instrument.***
- ***When taking the instrument out of the box, pull the outer box upward and then remove the packing materials. Be careful not to lift the instrument by directly holding the head unit, chin rest, forehead pad, or joystick. Otherwise, the instrument could be damaged.***

- Main unit 1
- Power code 1
- Fuses (2 fuses are installed in the main unit) 4
- Chin rest paper 1
- Pins for Chin rest paper 2
- Dust cover 1
- INSTRUCTION MANUAL (this book) 1
- DATA Transfer Installation CD 1
- DATA Transfer startup guide 1

1.3 Glossary

[AA] : Auto Alignment. (Refer to [Auto Alignment].)

[AS] : Auto Shot. (Refer to [Auto Shot].)

[AVG] : Indicates the average dimension of the analyzed endothelial cells.

[CCT] : Corneal thickness.

[CCT(US)] : Ultrasonic correction for corneal thickness. The reference value expected when measuring the same corneal thickness using our ultrasonic pachymeter (SP-100, etc.).

[CD] : Indicates the density of the analyzed endothelial cells as the number of cells per 1 mm^2.

[CV] : Indicates the coefficient of variation of the analyzed endothelial cells, derived by dividing standard deviation by the average dimension.

[DAD] : Density of the analyzed dark area represented as the number of cells per 1 mm^2.

[DATA Transfer] : System that outputs the examination data from RODENSTOCK products to digital files.

[Dark Area] : Black circle area to be observed by the specula microscope.

[L-count] : Method where the physician performs analytical calculation by selecting cells on the screen.

[MA] : Manual Alignment. (Refer to [Manual Alignment].)

[Max] : Indicates the dimension of the largest analyzed endothelial cell.

[Min] : Indicates the dimension of the smallest analyzed endothelial cell.

[MS] : Manual Shot. (Refer to [Manual Shot].)

[Number] : Indicates the number of analyzed endothelial cells.

[Polymegathism] : Represents the difference in sizes and shows the distribution of endothelial cell dimensions in a histogram.

[Plemorphism] : Represents plemorphism and shows the distribution of endothelial shapes in a histogram.

[Quick mode] : Stores captured images of a right eye and left eye in the memory, and allows you to display, print, and/or send the image data of both eyes.

[Ratio] : Displays the ratio of the dark area size relative to the total area. The total area is the sum of the analyzed dark area and the area of analyzed endothelium tissues.

[SD] : Indicates the standard deviation of the analyzed endothelial cell dimensions.

[Standard mode] : Temporarily stores captured images of ten eyes (regardless of right or left eye) in the memory.

[Auto Mode] : Mode that automatically conducts alignment and capturing.

[Auto Alignment] : Function that automatically aligns the sight in up/down/right/left focus directions.

[Auto Shot] : Function that automatically starts measurement when the patient's eyes are within the measuring range.

[Auto Power Off] : Function that automatically turns the LCD off, with only the power lamp flashing, when the instrument is not operated for the specified time (Auto Power Off mode). Touch any button to return to Normal mode.

[Touch Alignment] : Allows you to move the head unit by touching the screen. This is used for rough alignment.

[Touch Panel] : Allows you to make various settings and execute the touch alignment function by directly touching the screen.

[Manual Mode] : Mode that manually conducts alignment, switching to an enlarged screen, and image importing.

[Manual Alignment] : Mode that allows you to perform alignment manually.

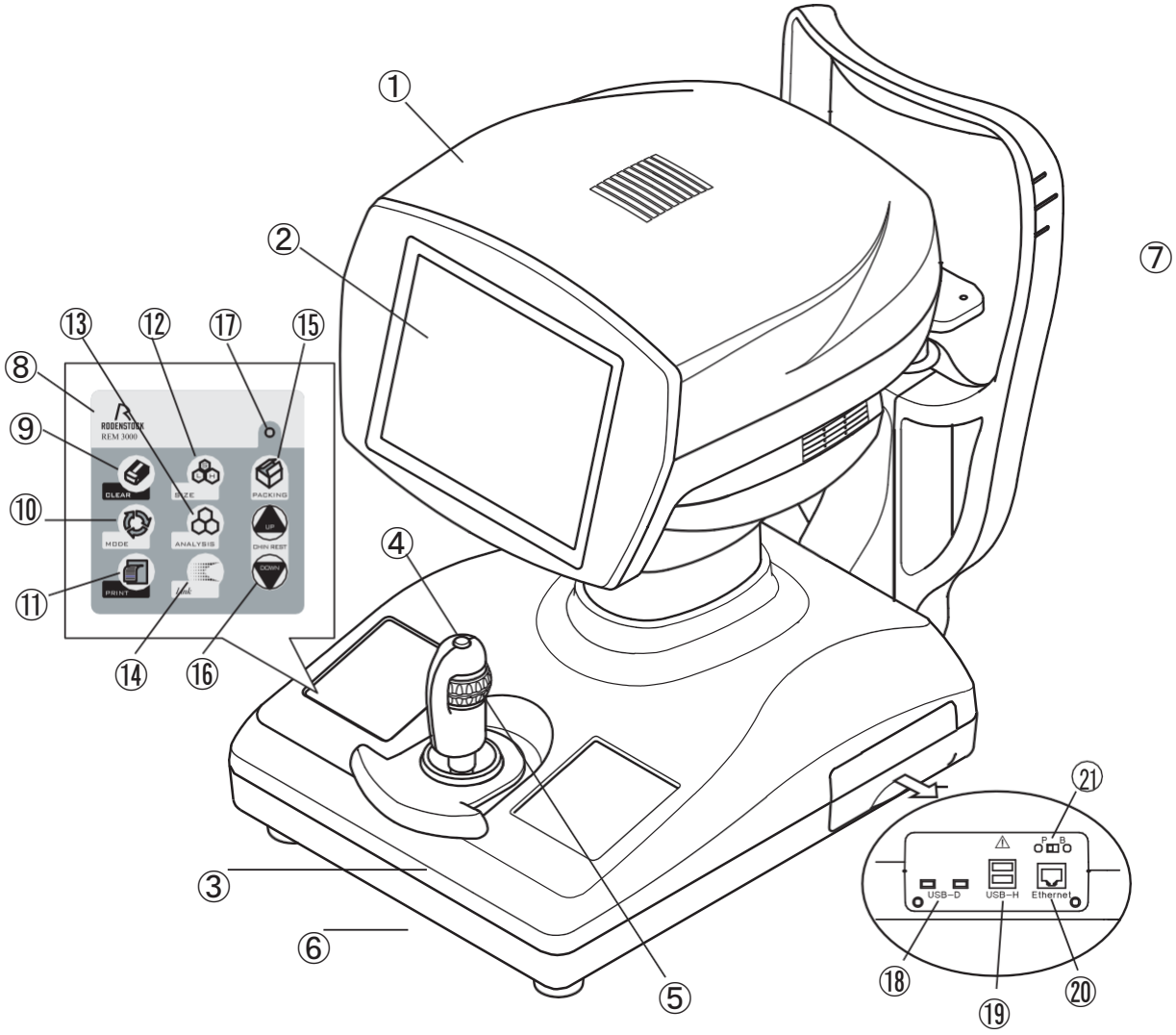
[Manual Shot] : Mode that allows you to capture images manually.

1.4 Outline of operation

The REM 3000 is a Corneal Endothelium Analyzer, which captures images of the corneal endothelial cells of a patient's eye, automatically analyzes captured images, and calculates the cell density. It is also equipped with a corneal thickness measurement function.
The patient places her chin on the chin rest and looks into the sight-fixing lamp in the capturing window.
After the physician observes the patient's eye on the monitor screen and roughly aligns the capturing position, fine alignment and capturing are automatically conducted.
When the endothelial cells cannot be captured automatically, align the capturing position with the joystick and press the joystick button to start capturing.
Once the capturing process begins, a green LED will shine on the patient's eye and a corneal endothelial image will be captured. By pushing the ANALYSIS switch after the image has been captured, various parameters for cell dimensions and cell shapes will be automatically calculated.

2. NAMES AND FUNCTIONS OF PARTS AND COMPONENTS

2.1 Physician's side



(1) Head unit

Section that conducts image capture.

(2) Monitor / touch panel

Displays the capturing screen and various setting screens. Touch the touch panel buttons shown on the monitor to make various settings and operate the instrument.

(3) Joystick

Tilting the joystick to the right, left, back, and forth moves the head unit to the right, left, forward, and backward for fine positioning.

(4) Joystick button

Starts capturing images.

(5) Up/down ring

Moves the head unit up and down. Moving the ring up and down moves the head unit for rough positioning. Turning the ring moves the head for fine positioning.

(6) Hand rest

Place your hand on the rest to operate the joystick. Sliding the rest forward, backward, to the right, and left moves the head unit in the corresponding direction for rough positioning.

(7) Eye level mark

Reference mark when aligning the height of the patient's eye

(8) Membrane switch

Used to make various settings and operations.

(9) “CLEAR” switch

Deletes all the examination data.

(10) “MODE” switch

Switches the alignment mode between automatic and manual.

(11) “PRINT” switch

Prints the captured result on a connected external printer.

(12) “ANALYSIS” switch

Analyzes the captured endothelial image automatically.

(13) Link switch

Connects to the external devices to send data.

(14) “PACKING” switch

Pressing this button for 3 seconds moves the head unit to the lowest position for packing (lower dead center).

(15) “CHIN REST” switch

Touching the UP and DOWN buttons moves the chin rest up and down respectively.

(16) Power lamp

Stays lit while the instrument is turned on.

(17) USB-D connectors

Connect the PC and printer here. There are two ports.

(18) USB-H connector

Connects the barcode reader, card reader, and supported digital printers. There are two ports.

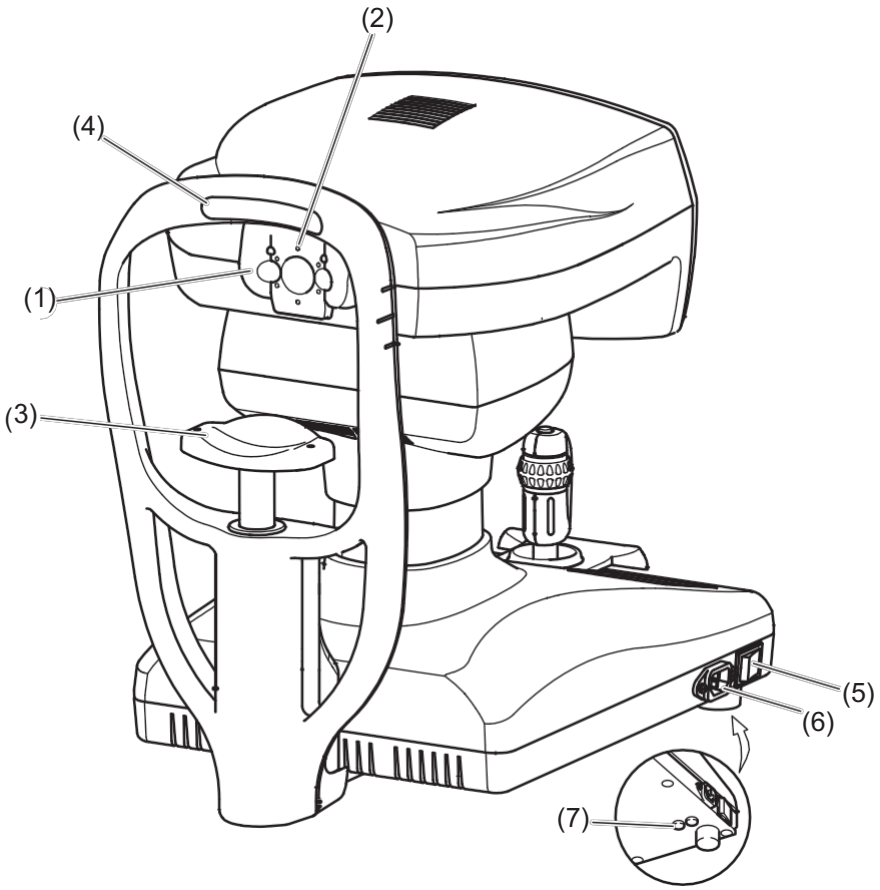
(19) LAN connector

Connect the LAN cable here.

(20) Maintenance switch

This switch is reserved for use by servicemen performing maintenance work. Do not operate this switch.

2.2 Patient's side



(1) Capturing window

The patient's endothelium is illuminated and captured through the capturing window.

(2) Peripheral sight-fixing lamp

When an image of the cornea periphery is being captured, the patient is prompted to stare at the peripheral sight-fixing lamp.

(3) Chin rest

The patient places their chin on this rest.

(4) Forehead pad

The patient presses their forehead against this pad.

(5) Power switch

Press the [I] or [O] side to turn the instrument on or off respectively.

(6) Power socket

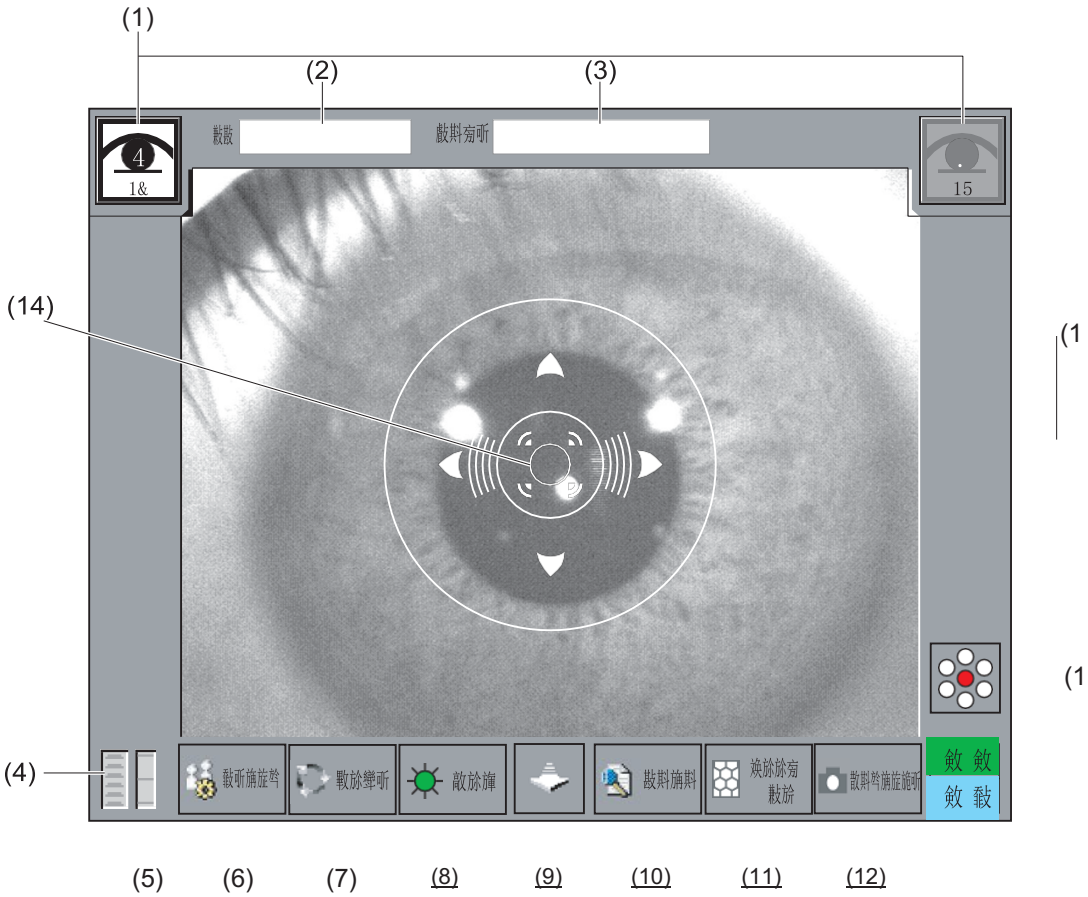
Connect the power cord here.

(7) Fuse holder

Insert the fuses here.

2.3 Screen

<Capturing Screen>



(1) Eye display button [R]/[L]

Displays the right or left eye on which the head unit is positioned, using the corresponding color. Touch this icon to move the head unit when changing the eye to be examined.

(2)ID number [ID] Displays the ID number.

(3)Patient's name [Name]

Indicates the patient's name.

(4) Chin rest height

Displays the current chin rest height according to the preset 6 levels.

(5) Head unit height

Displays the current head unit height according to the preset 11 levels.

(6) “Setup” button

Sets operation conditions for each function.

(7) “Mode” button

Switches the alignment mode between automatic and manual.

(8) Illumination light adjusting button

Adjusts the brightness of the illumination light.

(9) Head unit retract button

Retracts the head unit while the button is pressed.

(10) “Data” button

Recalls the data saved in the memory. This button does not appear in Quick mode.

(11) “Zoom” button

Switches the anterior eye segment image to the endothelial image when the manual mode is used.

(12) “Capture” button

Captures the endothelial image when the button is pushed in manual mode viewing a zoom-in endothelial image.

(13) Sight-fixing button

Displays the currently set position of the sight-fixing lamp. Push this button to select the position of the sight-fixing lamp.

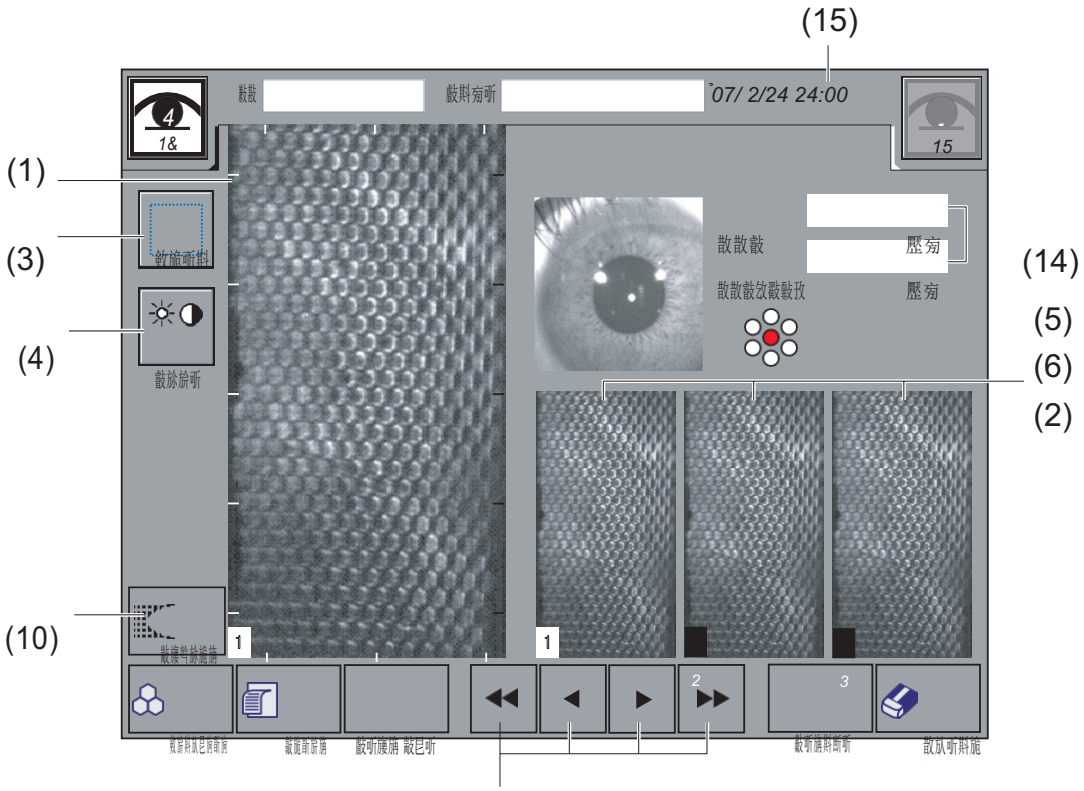
(14) Target ring

Index reference used when aligning the patient's eye position for capturing the image. When Touch Alignment is ON, the head unit moves toward the eye while this icon is pressed.

(15) Focus indicator

Displays the distance between the head unit and the patient's eye. When bars appear horizontally, the head unit is too far from the eye. When bars appear vertically, the head unit is too close to the eye.

<Captured Image Selection Screen>



(1)Selected Image display

Displays the selected image.

(2) Captured image list

15 captured images are displayed from the best condition to the worst.

(3) “Area” button

Manually specifies the area to be analyzed from the captured image.

When performing analytical calculation using the L-count function, touch the “Area” button, and the “L-count” button appears.

(4) “ Tone” button

Adjusts brightness for displaying captured endothelium images.

(5) Anterior eye segment image display

Displays the captured anterior eye segment image.

(6) Sight-fixing lamp position display at the time of capturing

Displays the position of the sight-fixing lamp when the image was captured.

(7) “Analysis” button

Automatically analyzes the selected endothelial image being displayed and zoomed in the left pane of the screen.

(8) “PRINT” button

Prints the captured result on a connected external printer.

(9) “Next Eye” button

Moves to the capturing of the next image. The currently captured images will be saved to the memory.

(10) “Export” button

Executes data communication with external devices.

(11) “Arrow” button

Selects the image to be analyzed out of the 15 captured images.

(12) “Retake” button

Retakes the images. In that case, the currently displayed image will not be saved. This button does not appear in Quick mode.

(13) “CLEAR” button

Deletes all the examination data when held down.

(14) Measured corneal thickness and ultrasonic correction for corneal thickness

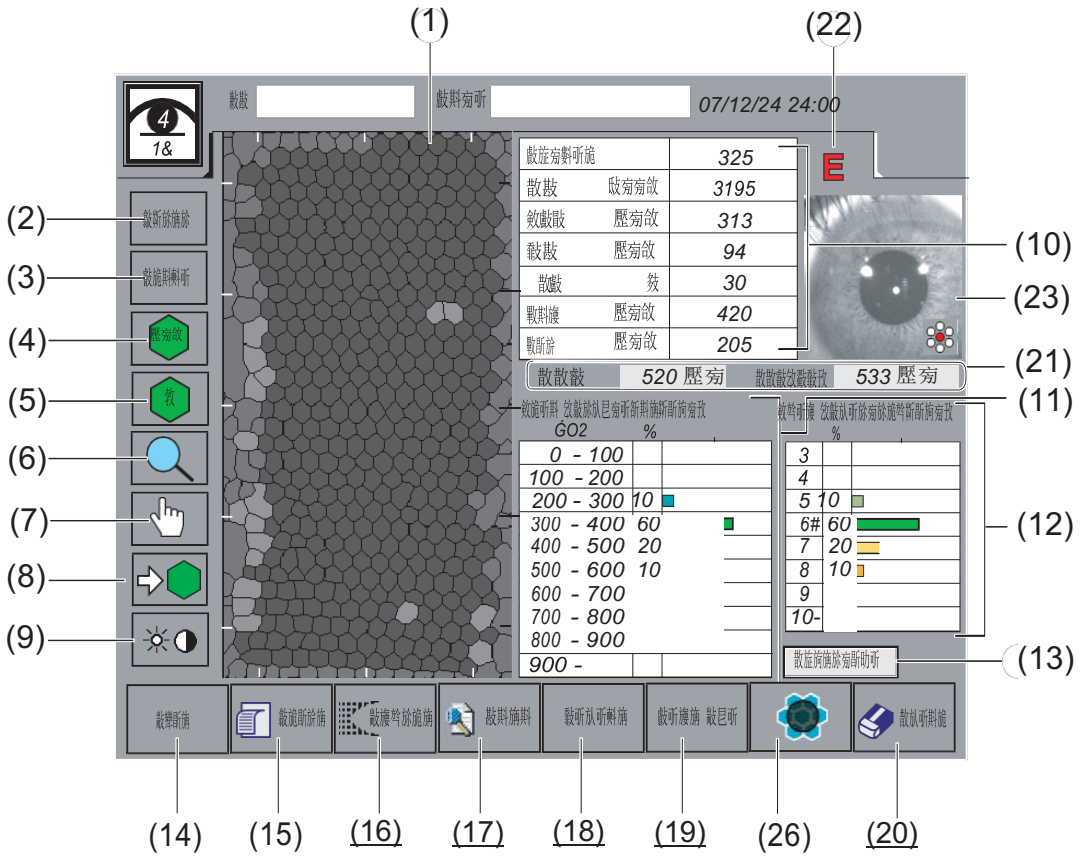
CCT : Measured corneal thickness

CCT (US) : The reference value expected when measuring the same corneal thickness using our ultrasonic pachymeter (SP-100, etc.). This item can be set to be displayed or hidden. (Refer to “3.6.2 Function.”)

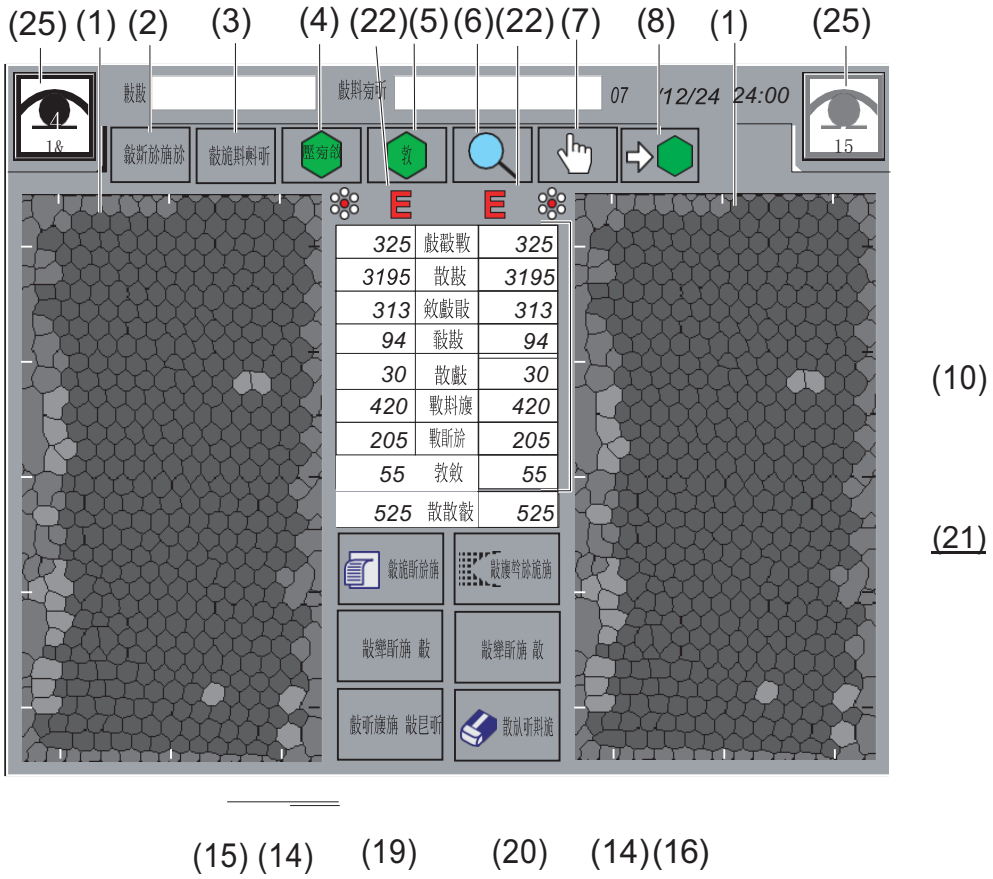
(15) Captured date form

Displays the date and time when the image was captured.

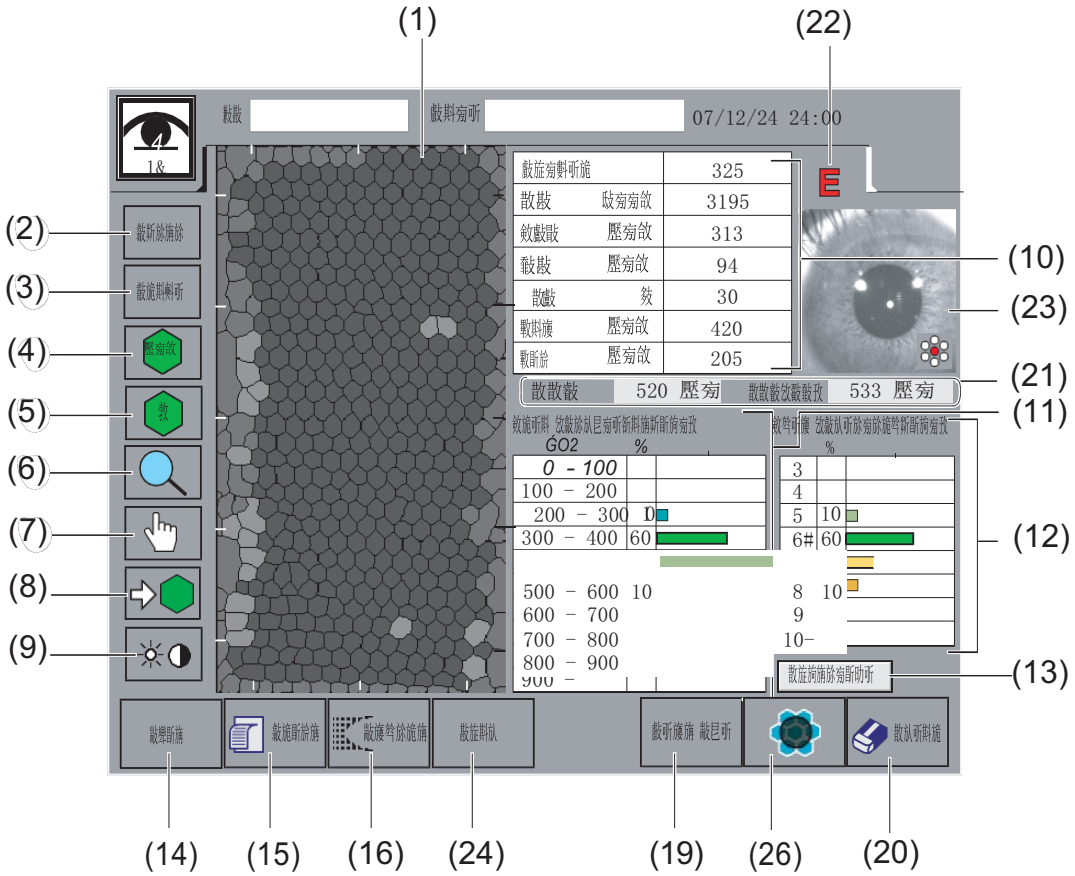
<Analytical result screen: Standard mode>



<Analytical result screen: Standard mode>



<Analytical result Screen: Display of both eyes in Quick mode>



(1) Image display

Displays the image.

(2) “Photo” button

Displays the raw endothelial image.

(3) “Trace” button

Displays the extracted edges.

(4) Display by dimension button

According to the analysis result, each cell dimension is color coded and displayed.

(5) Display by shape button

According to the analysis result, each shape is color coded and displayed.

(6) Enlarge and Reduce buttons

Enlarges or reduces the size of the displayed image.

(7) Move button

Moves the displayed area on the screen when the image is enlarged.

(8) Select/Disabling button

Selects or disables the cells to be used for analytical calculation.

(9) “Tone” button

Adjusts the brightness of the captured endothelial image on the screen.

(10) Analysis Result

Displays the numerical values of the analysis result. Refer to “1.3 Glossary” for the description of each item.

(11) Polymegathism

Shows the distribution of cell dimensions in a histogram.

(12) Plemorphism

Shows the distribution of cell shapes in a histogram.

(13) “Customize” button

Changes the numerical values of the polymegathism at the physician's discretion.

(14) Edit / Edit R / Edit L (Edit) button

Opens the edit screen to allow you to manually edit trace lines of endothelium tissue that were extracted automatically.

(15) “PRINT” button

Prints the captured result on a connected external printer.

(16) “Export” button

Connects to the external devices to send data.

(17) “Data” button

Recalls the data saved in the memory.

(18) “Select” button

Returns to the captured image selection screen where you can select other images.

(19) “Next Eye” button

Moves to the capturing of the next image. The currently captured images will be saved to the memory.

(20) “CLEAR” button

Deletes the examination data and the next capturing process is conducted.

(21) Measured corneal thickness and ultrasonic correction for corneal thickness

CCT : Measured corneal thickness

CCT (US) : The reference value expected when measuring the same corneal thickness using our ultrasonic pachymeter (SP-100, etc.). This item can be set to be displayed or hidden. (Refer to “3.6.2 Function.”)

(22) Reliability mark

The reliability level for automatic analysis is automatically determined and displayed. (Refer to “3.3.11 Displaying reliability.”)

(23) Anterior eye segment image display

Displays a captured anterior eye segment image.

(24) “Dual” button

Switches the screen from the one-eye result display screen in Quick mode to the both-eye result display screen.

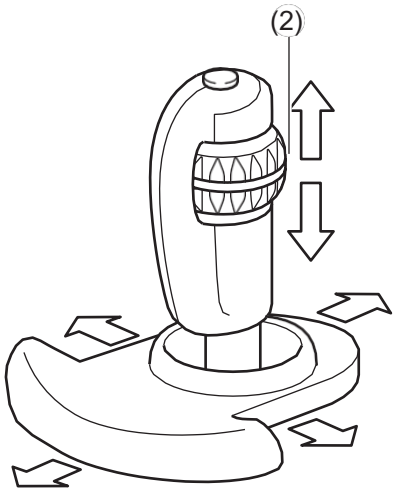
(25) R/L display; switching button

In Quick mode, not only displays the images of both the right (R) and left (L) eyes, but also moves the one-eye analytical result screen when the button is pressed.

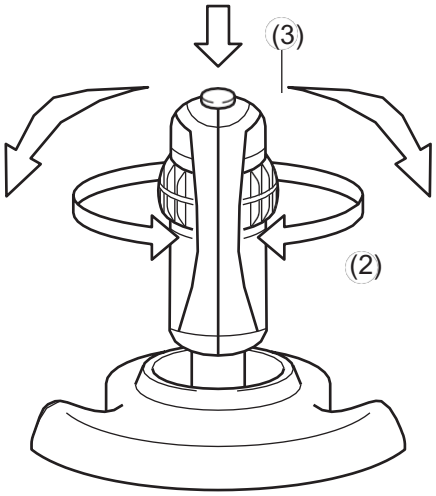
(26) “Dark Area” button

Automatically analyzes the dark area and opens the Dark Area Analysis screen.

2.4 Operation of the joystick



(Fig. 1)



(Fig. 2)

There are two types of operations - rough operation for moving the head unit into rough position and fine operation for finely adjusting the position of the head unit. The joystick button for capturing the image is located on the top of the joystick.

<Rough operation>

Forward, backward, right, and left

Slide the hand rest (1) in the direction the head unit is to be moved. The further you slide the rest, the faster the head moves.

Up and down

Slide the up/down ring (2) in the direction the head unit is to be moved.

<Fine operation>

Forward, backward, right, and left

Tilt the joystick in the direction the head unit is to be moved.

Up and down

Turn the up/down ring (2).
Clockwise … Raises the head unit.
Counterclockwise … Lowers the head unit.

<Starting capturing process>

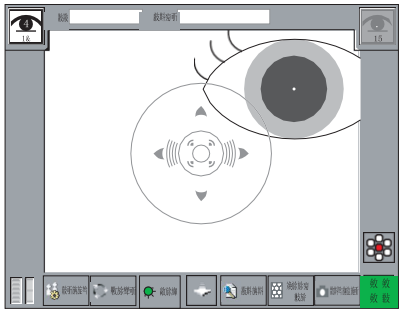
Press the joystick button (3) to start the capturing process.

2.5 Touch Alignment

Touch Alignment is a function for alignment using the touch panel. This is available in all alignment modes.

Note

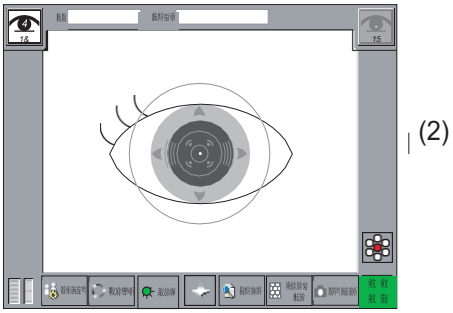
- ***The Touch Alignment function is used for rough positioning. For fine operation, It is recommended to make adjustments with the joystick or use the Auto Alignment function together with the Touch Alignment function when fine operation is needed.***
- ***When moving an element using the touch panel, touch the panel and release your finger immediately without pressing the panel continuously.***
- ***Do not press hard against the touch panel or with a sharp edged object. Otherwise the panel may be damaged.***



(Fig. 1)

Up and down, right, and left

When directly touching the panel, the head unit moves so the touched point moves to the center. Touch the point where the center of the pupil (1) is shown. The pupil center (1) moves to the center of the screen.



(Fig. 2)

Forward/backward (focus)

Keep touching the target ring (2) in the center of the screen to move the head unit forward to the patient's eye and focus the image. The head unit stops when you release your finger from the screen.

Press the head unit retract button (3) to retract the head unit.

3. OPERATION PROCEDURES

3.1 Installation

3.1.1 Precautions for 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 place where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and ignite.***

- ***Do not hold the head unit, chin rest, forehead pad, or joystick when lifting 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 with significant dust, salt, and/or sulfur content. These may cause failure or malfunction of the instrument.***
- ***Install the instrument in a level and stable location free of vibration and mechanical impacts to ensure correct capturing, and prevent the instrument from falling or being dropped, which can result in fire or fatal accidents.***

3.1.2 Precautions for connecting the power cord

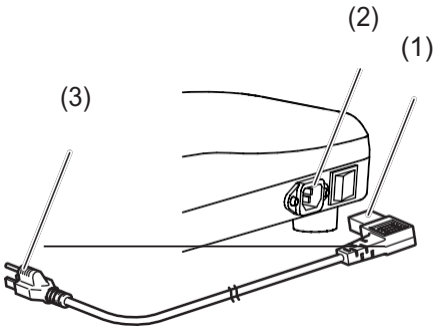
- ***Connect the power plug to a grounded 3P-outlet. Otherwise, a short circuit due to failure of the instrument may result in an electric shock.***
- ***Do not place any heavy object on the power cord or squash the power cord. This may cause fire or an electric shock.***
- ***Completely insert the power plug into the outlet. Faulty contact, allowing any metal to contact exposed plug terminals, or dust accumulated on exposed plug terminals may result in fire or an electric shock.***
- ***Check the frequency, voltage, and allowable current (or power consumption) of the power source. Operating the instrument connected to an inappropriate power source may cause fire or an electric shock.***

3.2 Preparation before use

3.2.1 Connecting the power cord

Note

- ***The correct orientation of the power cord is shown. Make sure that the orientation is correct, and that the cord is firmly plugged in.***



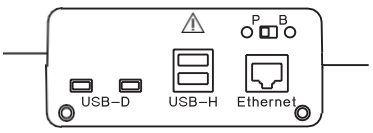
(Fig. 1)

Plug the power cord connector (1) into the power socket (2) on the side of the instrument.
On the plug side, connect all three pins (3).

3.2.2 Connecting an external digital printer

Note

- ***The correct orientation of the power cord is shown. Make sure that the orientation is correct, and that the cord is firmly plugged in.***
- ***Use only the specified printer and cables. Use a printer in conformity with IEC60601-1 or a printer meeting IEC950 and isolated with an insulation transformer to avoid possibilities of electrical shock.***



(2) (1)

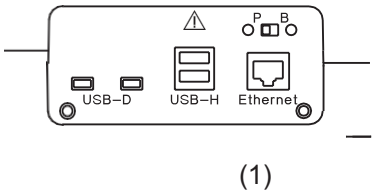
(Fig. 1)

For a Mitsubishi digital printer, plug the connector into the USB-H terminal (1) on the side of the instrument, using the correct orientation.
For non-Mitsubishi digital printers, plug the connector into the USB-D terminal (2) on the side of the instrument, using the correct orientation.

3.2.3 Connecting external ID input device

Note

- ***The correct orientation of the power cord is shown. Make sure that the orientation is correct.***



(1)

(Fig. 1)

Plug the connector of the external ID input device (barcode reader, card reader, numeric keypad, keyboard) into the USB-H terminal (1) on the side of the instrument, using the correct orientation. (Fig.1)

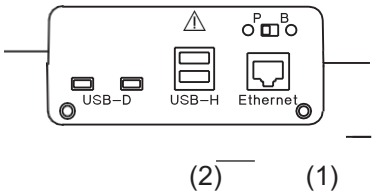
3.2.4 Connecting DATA Transfer

Note

- ***For details about the data communication, refer to "3.6 Data communication."***
- ***Refer to the corresponding instruction manual for settings for DATA Transfer.***
- ***The correct orientation for the LAN cable and the USB cable is shown. Make sure that the orientation is correct, and that the cord is firmly plugged in.***
- ***The instrument is not provided with optional cables. Provide optional cables.***

A LAN cable is required to connect to DATA Transfer.

a) Connecting LAN cables



(2) (1)

(Fig. 1)

For connection to DATA transfer on a LAN, the type of LAN cables used varies depending on the method of connection. Provide the following type of LAN cables depending on the method of connection.

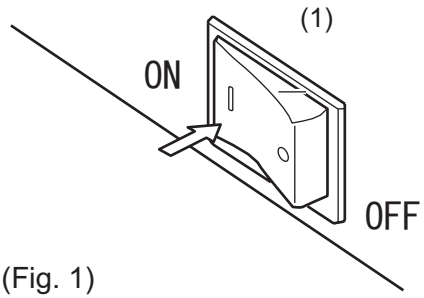
- When connecting via a HUB:
  Straight type, Cat.5 or more

- When connecting directly to a computer:
  Cross type, Cat.5 or more

Plug one end of a cable into the LAN connector (1) on the side of the instrument, and plug the other end of the cable to the LAN connector of a HUB or computer to which to run the HUB or DATA Transfer, using the correct orientation.

Green lamp (2) lights up when the instrument is on and the LAN connection is established.

3.2.5 Starting



(Fig. 1)

Turn on the power switch (1).

The power lamp lights and the title screen appears. The head unit also moves to its initial position.

3.2.6 Setting

Refer to “3.6 Settings” and set the capturing conditions.

3.3 Capturing Images

3.3.1 Precautions

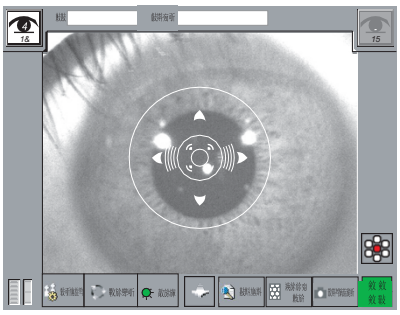
Tell the patient to remove their eyeglasses or contact lenses, and explain the capturing procedure before starting the capturing process.

3.3.2 Entering patient information

Note

- ***If the patient information is already entered for the captured data and you wish to replace the patient information using the following method, make sure that both the patient information and measurement data belong to the same patient.***
- ***Only the last 14 digits of the ID are shown in the ID field on the capturing screen. Be sure to check that the ID is correct on the Patient Information screen.***

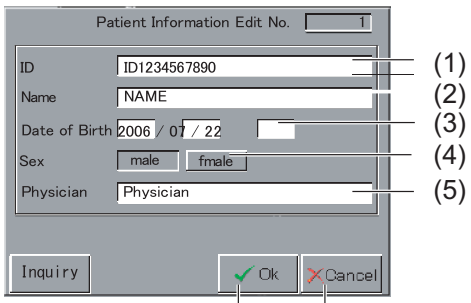
a) Entering patient information with the touch panel



(Fig. 1)

1) By touching the ID field (1) or Name field (2) on the top of each screen, the patient information entry screen (Fig. 2) is displayed. Enter ID number and patient's name as necessary.

2) Touch the ID field (1), Name field (2), Date of Birth field (3) or Physician field (5). The alphabetic keypad appears. Enter the ID, patient's name, date of birth, and physician's name as needed. However, period "." and space cannot be used in ID numbers. (Refer to "3.3.2(d) Entering characters.")



(Fig. 2)

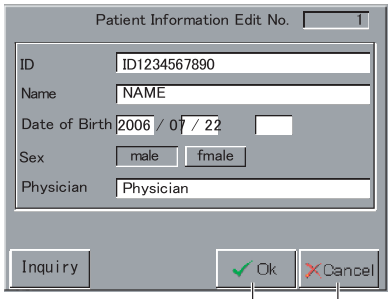
3) Press either the "male" or "female" Sex button (4) depending on the sex of the patient.

4) After the patient information is entered, touch the "OK" button (6) to apply the entered information and return to the capturing screen. Press the "Cancel" button (7) to clear the entered information and return to the capturing screen.

b) Entering ID numbers with external ID input devices

Note

■ ***Entering data using external ID input devices (barcode reader, card reader, numeric keypad, keyboard) is only possible when the patient information entry screen is displayed.***



(Fig. 1) (1) (2)

1) If an ID number is entered using an external ID input device on the patient information entry screen (Fig. 1), the entered ID appears.

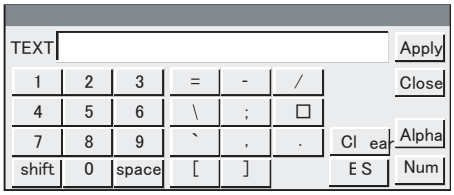
2) After the patient information is entered, touch the “OK” button (1) to apply the entered information and return to the capturing screen. Touch the “Cancel” button (2) to clear the entered information and return to the capturing screen.

c) Entering characters

Characters can be entered using the keyboard displayed on the screen. Either the alphabetic keyboard or the numeric keyboard is displayed, depending on what you are entering..

<Alphabetic keyboard>

Numeric keyboard



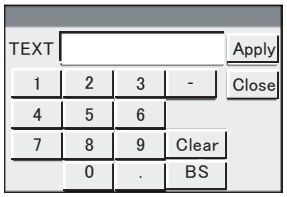
(Fig. 1)

Alphabetic mode

(Fig. 2)

“TEXT” field : Displays what has been entered.
“Apply” button : Applies what is entered in the “TEXT” field and returns to the previous screen.
“Close” button : Cancels what is entered in the “TEXT” field and returns to the previous screen.
“Apply” button : Applies what is entered in the “TEXT” field and returns to the previous screen.
“Alpha” button : Switches to alphabetic entry mode.
“Num” button : Switches to numeric entry mode.
A - Z, 0 - 9 buttons : Registers characters and numbers in the input field.
“CLEAR” button : Deletes what is entered in the input field.
“BS” button : Deletes a character from what has been entered.
“del” button : Deletes a character from what has been entered.

<Numeric keyboard>



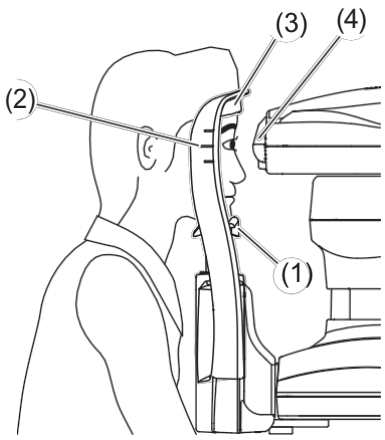
(Fig. 3)

“TEXT” field : Displays what has been entered.
“Apply” button : Applies what is entered in the “TEXT” field and returns to the previous screen.
“Close” button : Cancels what is entered in the “TEXT” field and returns to the previous screen.
0 - 9 buttons : Registers numbers in the input field.
“CLEAR” button : Deletes what is entered in the input field.
“BS” button : Deletes a character from what has been entered.

3.3.3 Patient's eye height adjustment

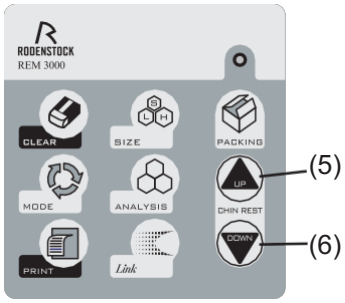
Note

- ***When moving the head unit and/or chin rest of the instrument, pay attention to the position of the patient's face, hands, and fingers. The patient may be injured by the moving section of the instrument.***
- ***The chin rest paper is provided to keep the chin rest clean. Use this paper for the chin rest so that the patient feels comfortable using this instrument.***
- ***Peel off the top sheet of chin rest paper and clean the forehead pad and capturing window with a cloth dampened with alcohol before the next patient.***

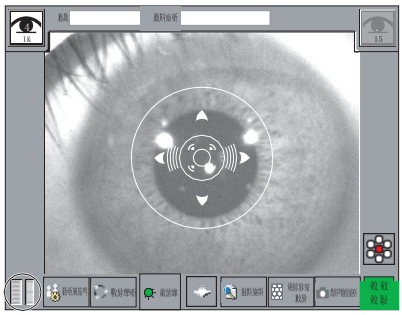


(Fig. 1)

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 eye level mark (2).
   Touch the “CHIN REST UP” button (5) on the membrane switch panel to raise the chin rest; “CHIN REST DOWN” button (6) to lower the chin rest.



(Fig. 2)

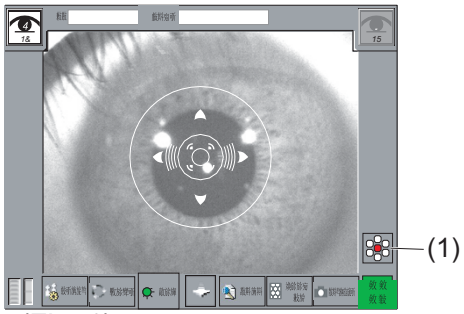


(Fig. 1)

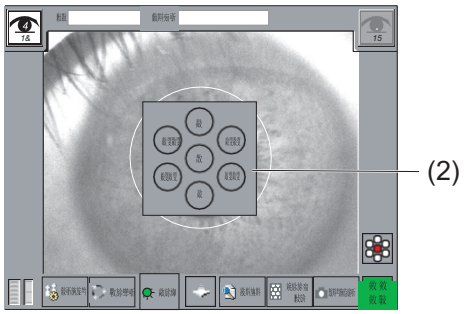
The positions of the chin rest and head unit can be checked by the height mark (7) in the lower left corner of the capturing window. The right and left indicators indicate the head height and chin rest height respectively. When the head height indicator is positioned in the center of the mark, the capturing window (4) and the eye level mark (2) are aligned at the same height.

2) When the patient's eye height is determined, lightly push the patient's face against the forehead pad (3) to secure the patient's position.

3.3.4 Changing sight-fixing lamp position



(Fig. 1)



(Fig. 2)

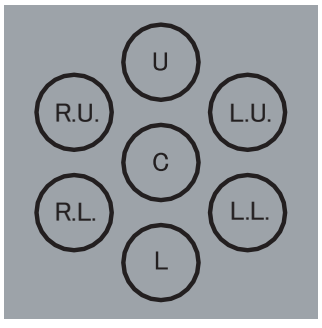
Usually, the center of the pupil is captured. However, the position of the sight-fixing lamp can be changed to 6 other positions when a normal capture is not possible, or when a different area is to be captured.

Press the sight-fixing lamp button (1) on the capturing screen to display seven types of the sight-fixing lamp buttons (2). (Fig. 2)

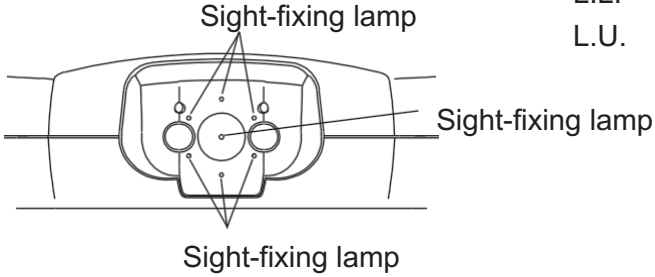
A red dot shows the position of a sight-fixing lamp. Press any of the sight-fixing lamp buttons (2) to change the position of a sight-fixing lamp and return to the capturing screen (Fig. 1). At this time, the sight-fixing lamp button (1) shows the position of the selected sight-fixing lamp.

The sight-fixing lamp targets the following positions when viewed by the patient. (Fig. 4)

C : Center
U : Upper
R.U. : Right Upper
R.L. : Right Lower
L : Lower
L.L. : Left Lower
L.U. : Left Upper



(Fig. 4)



(Fig. 3)

3.3.5 Alignment

Caution

- ***Do not allow any person to place their hands or fingers in the clearance under the head unit or the section under the chin rest. Their hands or fingers may be crushed and injured.***

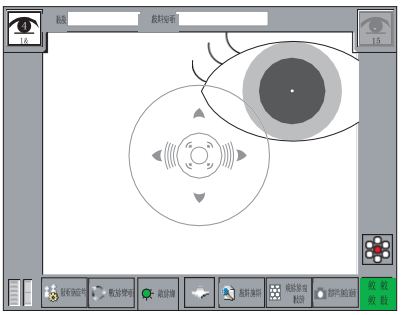
Note

- ***Eyelid or eyelash covering the cornea prevents capturing of a good endothelial image and/or getting accurate analysis results. Ask the patient to open their eyes wide or have the physician lightly hold the patient's upper eyelid.***
- ***Auto Alignment may not be effective when the patient blinks frequently during the capturing process. Ask the patient to stop blinking during the capturing process.***
- ***Ask the patient to look at the sight-fixing lamp in the capturing window. If the patient looks at a wrong direction or moves, the image capture may not be correctly conducted.***

<Positioning by Touch Alignment>

Note

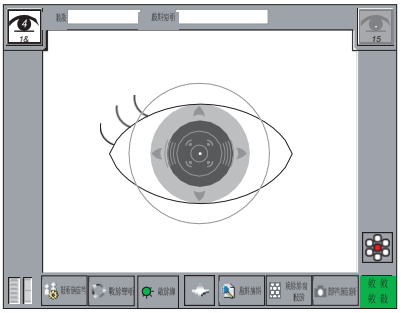
- ***When moving an element using the touch panel, touch the panel and release your finger immediately without pressing the panel continuously.***



(Fig. 1)

1) Use Touch Alignment or the joystick to position the patient's eye on the screen.

2) Lightly touch the center of cornea (1) on the screen.
The head unit moves so the patient's eye is positioned in the center of the screen. When the target center-point (2) in the center of the cornea enters the alignment ring (3), focusing in the X and Z axes automatically starts.



(Fig. 2) (5)

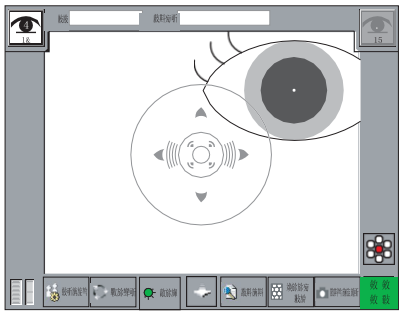
3) When the head unit is on the physician's side and the focus indicator (4) does not appear, press the center of the screen.
Pressing the screen moves the head unit toward the patient and the focus indicator (4) appears.
Press the head unit retract button (5) to retract the head unit.

4) When the focus indicator (4) appears on the screen, focusing in the Y axis automatically starts.

<Positioning by the joystick>

Note

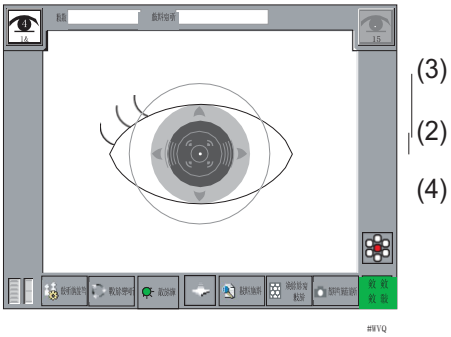
- ***The auto mode is the normal way to capture more precise images with this instrument. However, auto alignment may not work properly if there is not adequate reflection due to corneal disorders, etc. If this happens, use manual mode instead.***
- ***If the patient is suffering from severe cornea opacity, the endothelial image may not be captured even using manual mode.***



(Fig. 1)

1) Operate the joystick so the center of the cornea (1) enters the target ring (3). The target center-point (2) appears. (Refer to “2.4 Operation of the joystick.”)

2) Move the joystick back and forth to move the head unit so the focus indicator (4) on the screen becomes small. When the focus indicator (4) is shown horizontally, the head unit is too far from the eye; when the focus indicator is shown vertically, the head unit is too close to the eye.



(Fig. 2) (5)

3) When the focus indicator (4) does not appear, align the focus with the target center-point (2) or the iris.

3.3.6 Capturing endothelial images

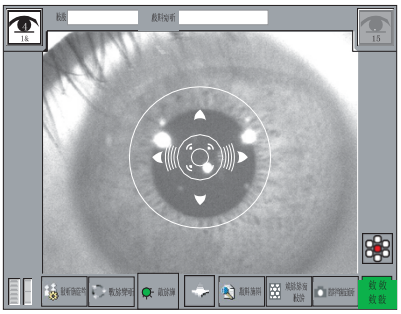
Caution

- ***Halt the operation immediately if the patient shows any sign of photosensitive epilepsy while capturing images.***
- ***Poor fixation, blepharoptosis, trichiasis, or corneal disease may cause inaccurate analysis results or corneal thickness measurements.***
- ***If the captured image is not clear, select another image or capture a new image.***

Note

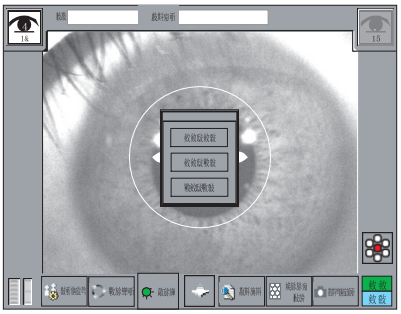
- ***Use manual mode only when unavoidable, even when the sight of the patient is unstable. It is difficult to ensure accurate alignment in manual mode, resulting in frequent capturing errors.***

a) Selecting auto and manual modes



(1)

(Fig. 1)



(2)

(3)

(Fig. 2)

Press the “Mode” button (1) on the capturing screen to select the auto mode or manual mode.

Touch the “AA/AS,” “AA/MS,” or “MA/MS” button (2) to select the appropriate mode.

[AA/AS] : Auto Alignment/Auto Shot

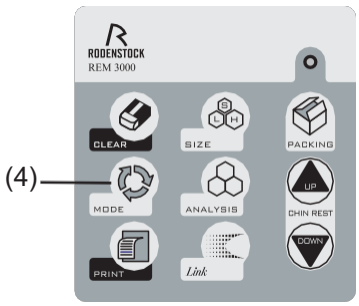
[AA/MS] : Auto Alignment/Manual Shot

[MA/MS] : Manual Alignment/Manual Shot

The selected mode will be displayed at the lower right corner (3).

The mode display (3) is colored when Auto mode is selected and white when Manual mode is selected.

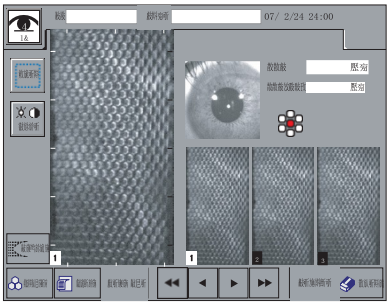
Press the MODE switch (4) of the membrane switch to sequentially change a desired mode from one mode to another.



(4)

(Fig. 3)

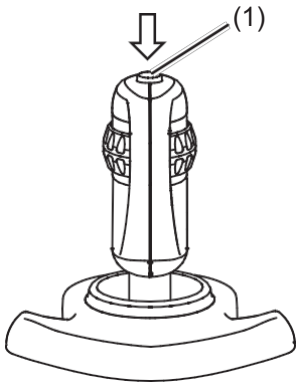
b) Capturing the endothelial image in auto mode



(Fig. 1)

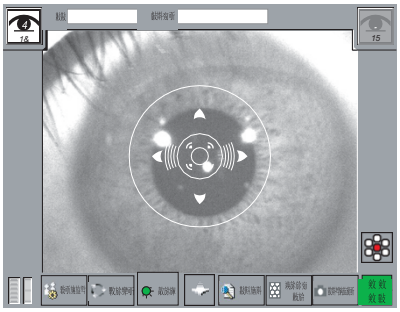
After a position is roughly aligned, the alignment process starts automatically. When the alignment is completed, the endothelial image capturing process starts.
After the capturing process ends, a captured image selection screen (Fig. 1) appears.

c) Capturing the endothelial image in manual mode



(Fig. 1)

- AA/MS (Auto Alignment/Manual Shot)
  Perform the Auto Alignment until epithelium anterius cornea is reached. After the Auto Alignment is completed, press the joystick button (1) on the top of the joystick to change the screen to a zoom-in image of an endothelium. Press the joystick button (1) again to start the capturing process. Pressing the “Zoom In” button (2) and the “Capture” button (3) in the capturing screen will also start the capturing process, too.
  If a corneal endothelium image disappears from a zoom-in image of an endothelium, pressing the “Zoom Out” button in the capturing screen to return to an anterior eye segment image. Perform the alignment process again.
  After the capturing process ends, the captured image selection screen appears.



(Fig. 2) (2) (3)

- MA/MS (Manual Alignment/Manual Shot)
  Perform the alignment process in manual mode.
  Operate the Touch Alignment function and the joystick to perform the alignment process. (Refer to “3.3.5 Alignment.”)
  Capture images in the same manner as in AA/MS mode after alignment is completed.

d) When image capturing is difficult

When proper alignment cannot be performed or a good image cannot be obtained, the probable causes are as follows. In such cases, take appropriate measures according to the cause.

Blinking or nystagmus

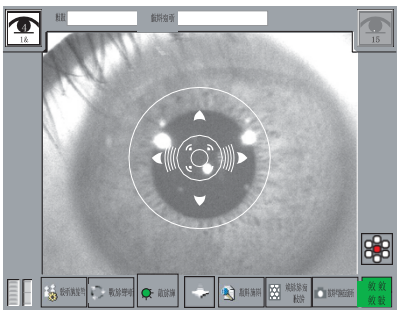
Instruct the patient to fix their view on the sight-fixing lamp and restart the capturing process. If the patient's eye moves too much due to nystagmus, etc., and the auto alignment does not work properly, change the position of the sight-fixing lamp and try capturing the image again. (Refer to “3.3.4 Changing sight-fixing lamp position.”)

Eyelid or eyelash is on the alignment ring

Ask the patient to open her eyes wide, or have the physician lightly hold the patient's upper eyelid, and try the capturing process again.

e) Adjusting the intensity of the illuminating light

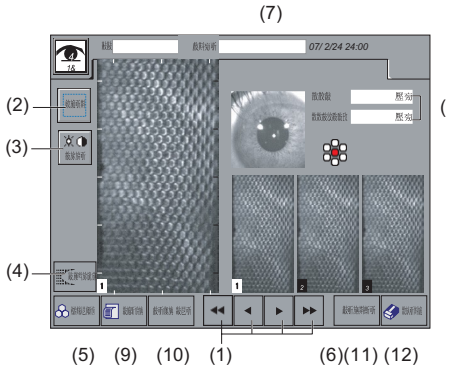
Press the illuminating light adjustment button (1) to set the brightness of the illuminating light to “High” “Low” or “Auto.”



(Fig. 2) (1)

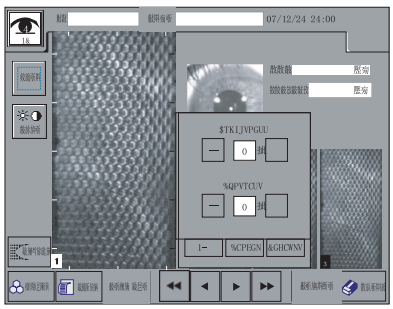
The initial setting is “Auto.”
When the setting to “Auto,” the machine is going to adjust the brightness to capture the suitable image automatically.
Change the setting to “High” when the captured image is too dark.
Change the setting to “Low” when the captured image is too bright.

3.3.7 Captured Image Selection



(Fig. 1)

After the capturing process is completed, the captured image selection screen appears. The best image of capturing results is displayed in the left pane of the screen. A maximum of 15 images are displayed in the lower right corner of the screen in the order of image quality starting with a good one. These images are numbered 1 through 15 in the order of image quality starting with a good one. An image can be sent or brought back by pressing the arrow button in the lower right corner of the screen. An image displayed in the left pane of the screen becomes an object of analysis.



(Fig. 2)

“Area” button (2)

Limits the area to be analyzed. Select two opposing points to specify the area to be analyzed on the screen when “Variable” is set, and specify a frame of 100μm around when “100μm” is set. Keep touching the “Area” button for a while to select the entire area of the captured image again.

Touching the “Area” button on the captured image selection screen allows you to perform analytical calculation using the L-count function. Refer to “3.3.10 Analytical calculation using the L-count function” for the L-count operation procedure.

“Tone” button (3)

Displays the image quality adjustment panel in which the adjustment can be made for the brightness and contrast of the captured image. (Fig. 2)

Use the “-” or “+” button for Brightness/Contrast to adjust image quality. Pressing the “Default” button returns the Brightness/Contrast values to their default values. Pressing the “OK” button confirms the changes made and returns to the previous screen. Pressing the “Cancel” button returns to the previous screen without anything confirmed.

Brightness range : -2 - +2
Contrast range : -2 - +2

“Export” button (4)

Executes data communication with external devices.

"Analysis" button (5)

The edges of the cells are automatically detected, and only valid outlines are selected to calculate cell sizes and numbers. After the analysis has been completed, the analysis result is displayed. If areas are not limited with the "Area" button (4), all areas of a captured image will be analyzed.

Sight-fixing lamp position display at the time of capturing (6)

Displays the position of the sight-fixing lamp when the image was captured.

Anterior eye segment image display (7)

Displays the captured anterior eye segment image.

Measured corneal thickness and ultrasonic correction for corneal thickness (8)

CCT : Measured corneal thickness

CCT(US) : The reference value expected when measuring the same corneal thickness using our ultrasonic pachymeter (SP-100, etc.). This item can be set to be displayed or hidden. (Refer to "3.6.2 Function.")

"Print" button (9)

Prints the captured result on a connected external printer.

"Next Eye" button (10)

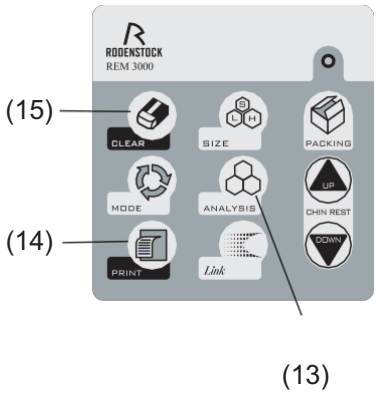
The analyzed image will be saved and the capturing screen will be displayed. 10 batches of data can be saved. When the number of saved data exceeds this limit, the oldest data will be deleted accordingly.

"Retake" button (11)

Displays a capturing screen without saving an on-screen image.

"CLEAR" button (12)

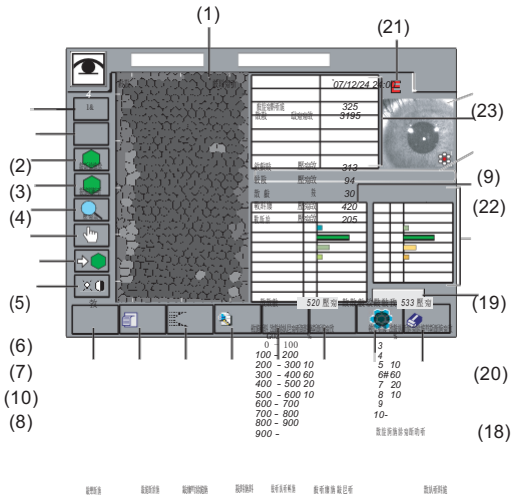
Erases all the saved examination data and displays a capturing screen.



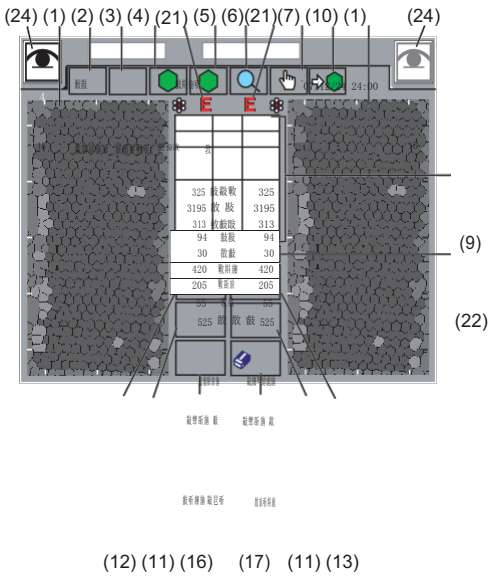
(Fig. 3)

Pressing the ANALYSIS button (13), PRINT button (14) and CLEAR button (15) on the membrane button panel performs the same operation as the “Analysis” button (5), “Print” button (9) and “Clear” button (12) respectively.

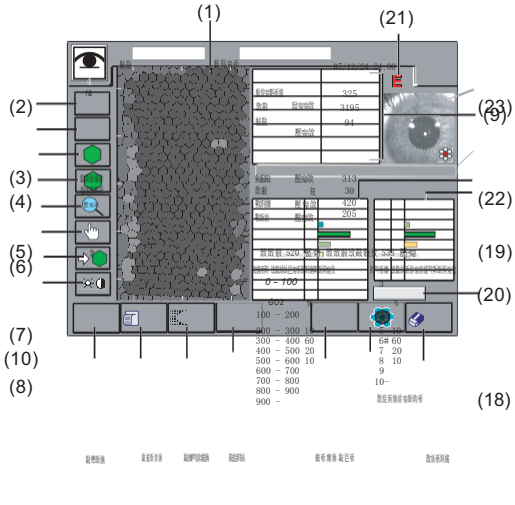
3.3.8 Analysis result screen



(Fig. 1-a: Standard mode)



(Fig. 1-b: Both-eye display in Quick mode)



An endothelial image (1) is displayed in the left of the screen when the result of one eye is shown.

Analysis results (9) are displayed at the upper right of the screen. A distribution by the polymegathism (19) and a distribution by the plemorphism (20) are displayed at the lower right of the screen. (Polymegathism and plemorphism histograms are not displayed when analytical calculation is performed using the L-count function.)

When the result of both eyes is shown in Quick mode, an endothelial image of the right eye and that of the left eye is displayed on the left and right of the screen respectively. (Fig. 1-b: Both-eye display in Quick mode)

"Photo" button (2)

Displays the raw endothelial image.

"Trace" button (3)

Displays trace lines of extracted endothelium tissue in red.

(Edges are not displayed when analytical calculation is performed using the L-count function.)

Display by dimension button (4)

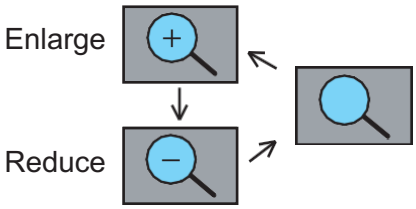
Displays the analyzed endothelial cell dimensions that are color-coded in the same color as the bar for a distribution by the polymegathism (19).

(Color-coded are not displayed when analytical calculation is performed using the L-count function.)

Display by shape button (5)

Displays the analyzed endothelial cell shapes that

(Fig. 1-c: One-eye display in Quick mode)



(Fig. 2)

are color-coded in the same color as the bar for a distribution by the plemorphism (20).
(Color-coded are not displayed when analytical calculation is performed using the L-count function.)

Enlarge and Reduce buttons (6)

While an endothelial image is zoomed in, touching the on-screen endothelial image after pressing this button can zoom the endothelial image in or out the on-

screen. (Fig. 2)

Move button (7)

Touching on an on-screen endothelial image after pressing this button can change the center position of image display. Keep touching the Move button again to return to the initial position.

"Tone" button (8)

Displays the image quality adjustment panel with which to adjust the brightness and contrast of an captured image. (Refer to "3.3.7 Captured image selection screen.")

Analysis results (9)

The following analysis results are listed.

Number : The number of analyzed endothelial cells CD : The density of the analyzed endothelial cells (number of cells per 1 mm^2)

AVG : The average dimension of the analyzed endothelial cells

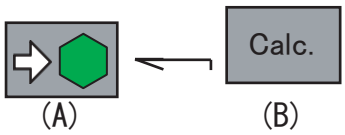
SD : The standard deviation of the analyzed endothelial cell dimensions

CV : The coefficient of variation of the analyzed endothelial cells, derived by dividing the average dimension by the standard deviation

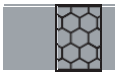
Max : The dimension of the largest analyzed endothelial cell

Min : The dimension of the smallest analyzed endothelial cell

When the result of both eyes is displayed in Quick mode, the analytical calculation result of the right eye is shown on the left and that of the left eye is shown on the right. Only "Number," "CD," and "AVG" are displayed when analytical calculation is performed using the L-count function.



(Fig. 3)



(Fig. 4)

"Select/Cancel" button (10)

Selects or cancels the cells to be used for analytical calculation. Touching the on-screen cells to be changed after pressing the "Select/Cancel" button (10) cancels the cells being selected for analytical calculation, or selects the cells being not selected for analytical calculation. At this time, the display of the "Select/Cancel" button (10) changes from (A) to (B) (Fig. 3). The indication of the "Tone" button (8) changes to the all invalid button (C) (Fig. 4). Keep touching the (C) button to cancel all cells being selected at once. After the select/cancel is completed, pressing this button starts the analytical calculation and displays the analytical calculation results (9).

Edit / Edit R / Edit L button (11)

Edits the automatically extracted edges of endothelial cells in manual mode. (Refer to "3.3.9 Editing the extracted edges.") Touch the Edit R and Edit L buttons to move to the edit screen of the right and left eyes respectively.

"Print" button (12)

Prints the captured result on a connected external printer.

"Export" button (13)

Connects to the external devices to send data.

"Data" button (14)

Recalls the data saved in the memory.

"Select" button (15)

Returns to a captured image selection screen for selecting other images.

"Next Eye" button (16)

Saves the analyzed image and displays the capturing screen.

"CLEAR" button (17)

Erases all the saved examination data and displays a

capturing screen.

“Customize” button (18)

Allows you to optionally change the upper and lower limits of the distribution by the polymegathism.
Touch the “Customize” button to display the setting screen. Touching the “Upper” (upper limit) or “Lower” (lower limit) field shows the alphabetic keypad. Enter an optional number in each field within the range from 1 to 9999. Touch the “OK” button to display the histogram of the set range. Touch the “Cancel” button to ignore the entered numbers and close the Customize setting screen.

Reliability mark (21)

The reliability level for automatic analysis is automatically determined and displayed on the screen. Refer to “3.3.11 Displaying reliability.”

Corneal thickness measurement (22)

Displays the measured corneal thickness data.

Anterior eye segment image (23)

Displays a captured anterior eye segment image.

R/L display; switch button (24)

In Quick mode, not only displays the images of both the right (R) and left (L) eyes, but also moves the one-eye analytical result screen when the button is pressed.

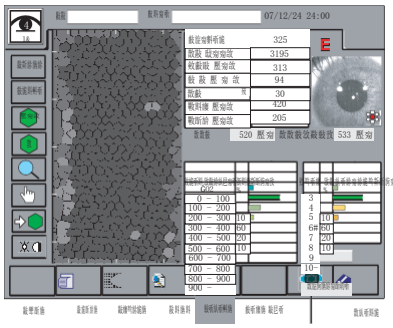
“Dual” button (25)

Changes the one-eye result display screen to the both-eye result display screen in Quick mode.

“Dark Area” button (26)

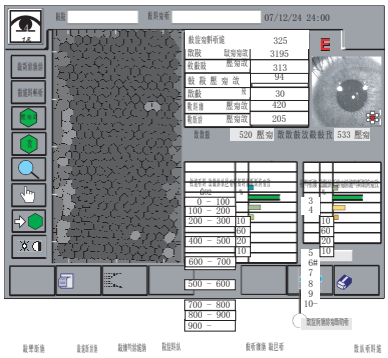
Automatically analyzes the dark area and opens the Dark Area Analysis screen.

3.3.9 Dark Area Analysis screen



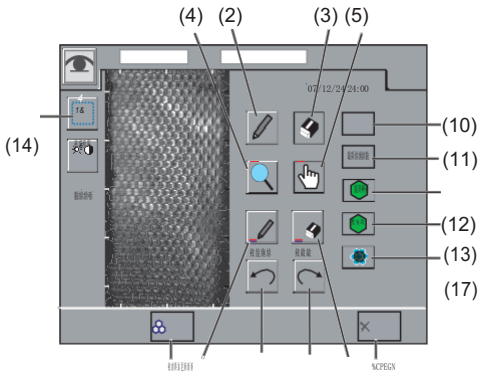
(1)

(Fig. 1-a: Standard mode)

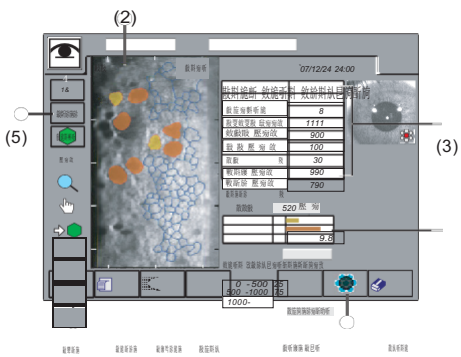


(1)

(Fig. 1-b: Both-eye result display in Quick mode)



(Fig. 2-a: Standard mode)



( )
6
)(Fig. 2-b: Quick mode)

(
7

The result of analysis in the dark area is displayed on this screen. Touch the dark area button (1) on the analysis result screen. The Dark Area Analysis screen (Fig. 2) appears.i

In Quick mode, the Dark Area Analysis screen can be opened only from the single eye result screen.

The endothelium image (2) is shown on the left side of the analysis result screen. The analysis result (3) is shown in the upper right section and the polymegathism histogram (4) in the lower right section.

"Trace" button (5)

Displays trace lines of the dark area in red and those of extracted endothelium tissue in blue.

Analysis results (3)

The results of analysis calculation are shown as below.

Number : The number of analyzed dark areas

DAD : Density of the analyzed dark area represented as the number of cells per 1 $mm^{2.}$

AVG : Average area of analyzed dark areas

SD : Standard deviation of the area of analyzed dark areas

CV : Fluctuation coefficient of the area of analyzed dark areas; standard deviation divided to be the average area

Max : Largest area of tissue among all analyzed dark areas

Min : Smallest area of tissue among all analyzed dark areas

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.

"Edit" button (6)

(4)

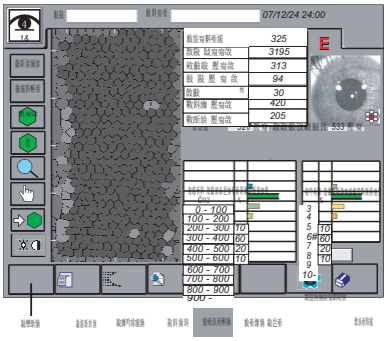
Opens the edit screen.

creen (Fig. 1).

"Edit" button (7)

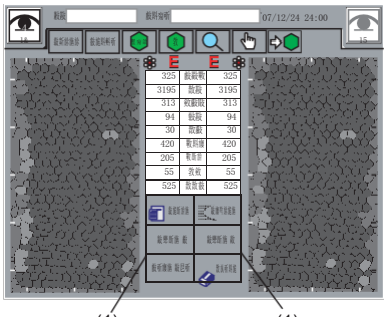
Opens the analysis results

3.3.10 Editing the extracted edges



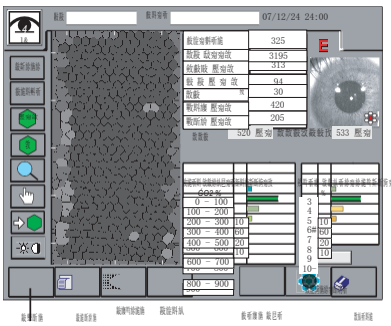
(1)

(Fig. 1-a: Standard mode)



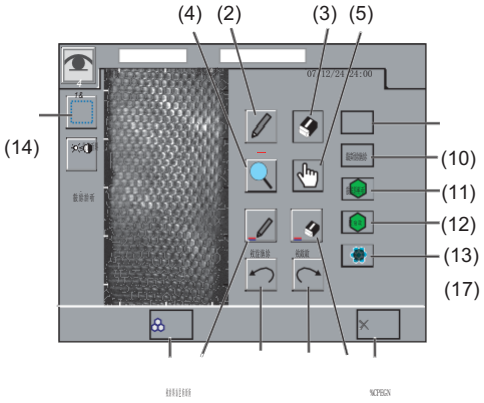
(1) (1)

(Fig. 1-b: Both-eye result display in Quick mode)



(1)

(Fig. 1-c: One-eye result display in Quick mode)



The automatically extracted edges of endothelial cells can be manually edited. Press the “Edit” button (1) on the analytical result screen to display the editing screen (Fig. 2).

Pencil button (2)

Adds trace lines shown in red. A straight line or curve is drawn as traced in the image (Fig. 3).

Eraser button (3)

Deletes trace lines shown in red. Touch an edge line to delete it from the image (Fig. 4).

Enlarge / Reduce button (4)

Pressing the icon alters the button types of enlarge, reduce, and standard in this order (Fig. 5).
The Enlarge button enlarges the image, centered on the point touched.
The Reduce button reduces the image, centered on the point touched.

Move button (5)

The image is shifted, centered on the touched area.

Auto Trace button (6)

Holding this button for an extended time deletes all trace lines of endothelium tissue and dark areas currently displayed, and then displays trace lines of automatically extracted endothelium tissue and dark areas.

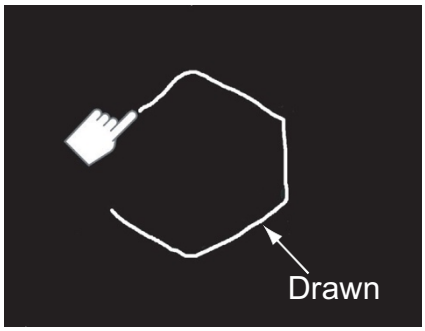
All Clear button (7)

Holding this button for an extended time deletes all trace lines of endothelium tissue and dark areas currently displayed.

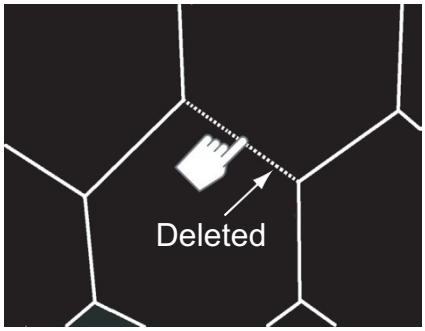
Undo button (8)

the operation previously taken will be cancelled.

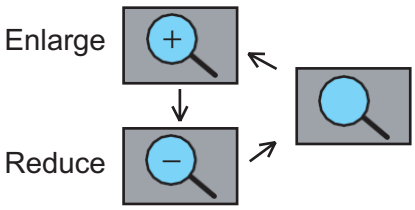
(7) (16)
(15) (6) (8) (9)
(Fig. 2) Redo button (9)



(Fig. 3)



(Fig. 4)



(Fig. 5)

The cancelled operation will be executed again.

Photo button (10)

Displays the endothelial cells image.

Trace button (11)

Displays the traced image.

Display by dimension button (12)

Displays the image with each cell dimension color-coded.

Display by shape button (13)

Displays the image with each cell shape color-coded.

“Area” button (14)

Limits the area to be analyzed. Select two opposing points to specify the area to be analyzed on the screen when “Variable” is set, and specify a frame of 100µm around when “100µm” is set. Keep touching the “Area” button for a while to select the entire area of the captured image again.

“Analysis” button (15)

Performs analytical calculations of edited edge lines and returns to the analysis result screen.
Returns to the Dark Area Analysis screen when the dark area button is activated.

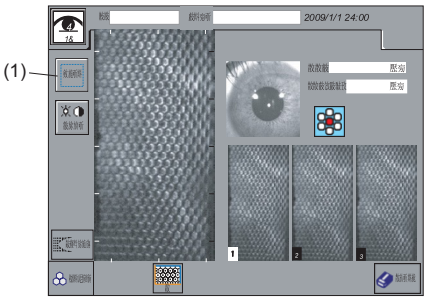
“Cancel” button (16)

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

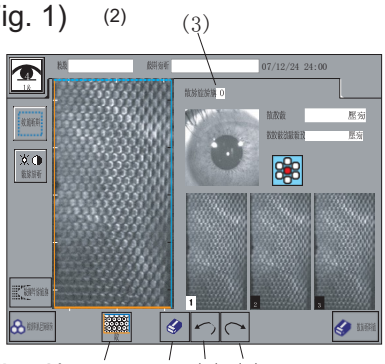
“Dark Area” button (17)

Switches the trace lines to be edited.
The trace line alternates between the endothelium tissue and dark area when you touch the button.

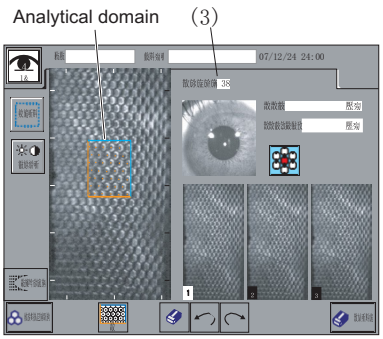
3.3.11 Analytical calculation using the L-count function



(Fig. 1)



(Fig. 2)



(Fig. 3)

Using the L-count function allows the physician to select cells in the image within the specified area and calculate the cell density by touching the cells on the screen with a stylus pen.

<When using L-count function on captured image selection screen>

"Area" button (1)

When endothelial cells have been captured, the captured image selection screen appears. Touch this button, and the "L-count" button (2) appears (Fig. 1).

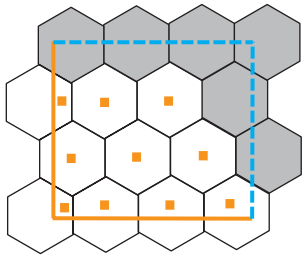
"L-count" button (2)

Touching the "L-count" button (2) activates L-count operation mode, and the "Counted cells display field" (3), "Eraser" button (4), "Undo" button (5), and "Redo" button (6) are displayed (Fig. 2).

Specify an area to be analyzed by selecting two opposing points in an area where the shape of the cells can be confirmed. (Specified by a 100μm-sided frame when "100μm" is set.)

Touch all cells in the specified area one at a time with stylus pen. Check that orange points appear on the touched cells and the value in the "Counted cells display field" (3) increases accordingly (Fig. 3).

When the L-count Assist function is activated on the setting screen, cells are roughly selected automatically when the analysis range is specified. Check that the selected cells are correct, and add or delete point(s) if necessary. Refer to "3.6.2 Function" for details of settings on the setting screen.



(Fig. 4)

Note

- ***When selecting cells using the L-count function, touch the cells on the orange line indicating the specified area (left side or bottom of the frame), and do not touch the cells on the blue dashed line (top or right side of the frame). (Do not touch the gray cells in Fig. 4.)***
- ***The L-count Assist function is an auxiliary function for the L-count function. Note that the physician must select cells individually.***

"Counted cells display field" (3)

Indicates the number of cells selected and touched by the physician on the screen. Cell density is calculated using this value and the area of the range to be analyzed.

"Eraser" button (4)

To delete the orange points on touched cells, touch the "Eraser" button (4), and then touch the points to be deleted. These are deleted and the value in the "Counted cells display field" decreases accordingly. To select the cells again, touch the "Eraser" button (4) again. The status returns to the cell selection mode.

"Undo" button (5)

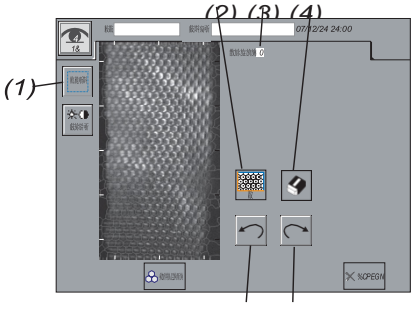
Cancels cell selection operations by touching the screen, one operation at a time.

"Redo" button (6)

Executes operations cancelled by the "Undo" button (5), one operation at a time.

<When using L-count function on captured image selection screen>

Similar to when using the L-count function on the captured image selection screen, touch the "Area" button (1), and the "L-count" button (2) appears, allowing you to perform analytical calculation using the L-count function on the edit screen (Fig. 5).



(Fig. 5)

3.3.12 Displaying reliability

The reliability level for automatic analysis is automatically determined and displayed.
Select “ON” for the “Reliability” setting on the Setup screen to display the reliability level. (Refer to “3.6.2 Function.”)

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 outlines 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 outlines are not extracted correctly by automatic analysis and the resultant reliability is slightly lower.

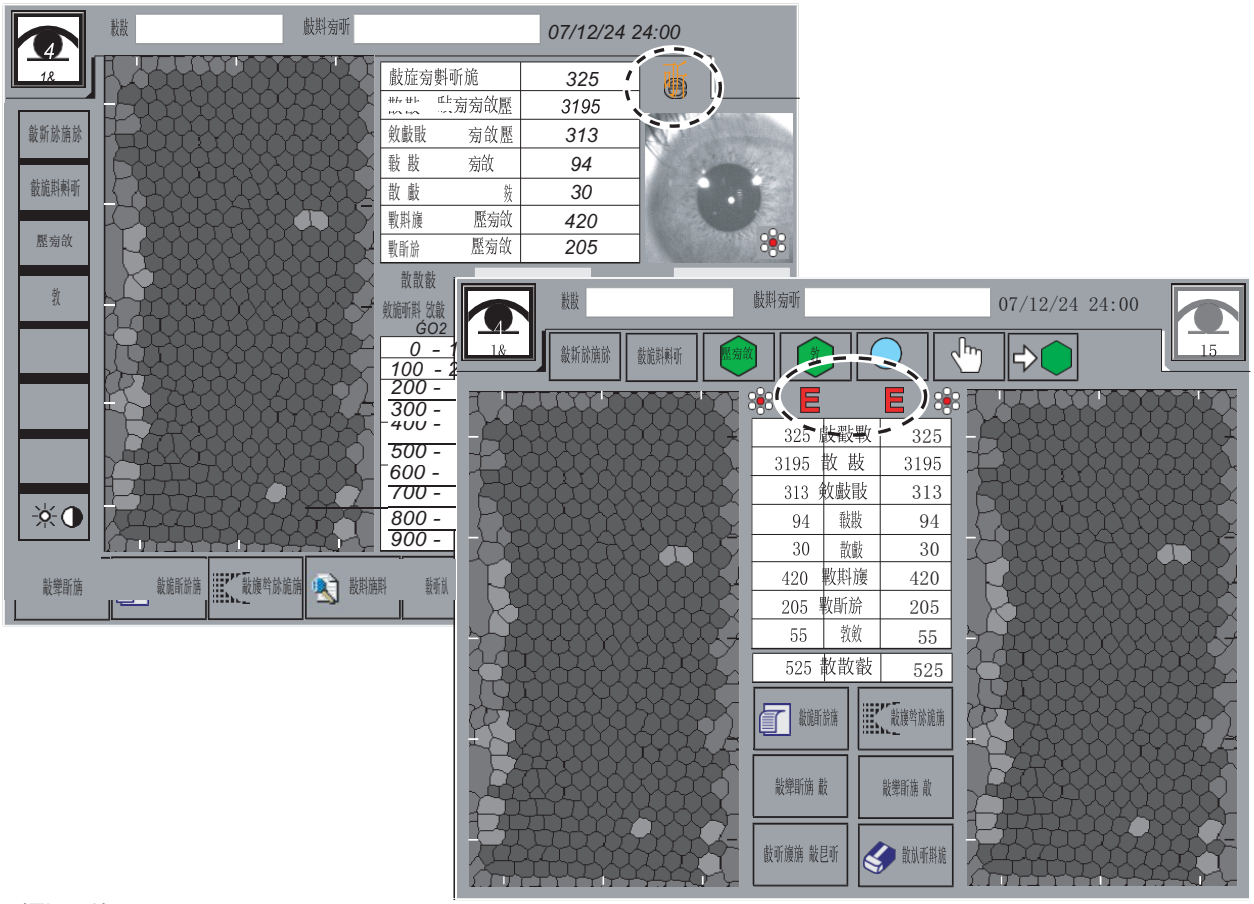
E : Because the range of captured cells is small and visibility of captured images is poor, cell outlines are not extracted correctly by automatic analysis and the resultant reliability is low.

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

- ***Touch the “Select” button to return to the captured image selection screen and perform automatic analysis again using another image. (Refer to “3.3.7 Captured image selection screen.”)***
- ***Correct analysis calculation results using the Select/Cancel button. (Refer to “Select/Cancel buttons” of “3.3.8 Analysis result screen.”)***
- ***Edit cell outlines using the “Edit/Edit R/Edit L” button. (Refer to “3.3.9 Editing outline extraction result.”)***
- ***Perform analysis using the L-count function. (Refer to “3.3.10 Analytical calculation using the L-count function.”***
- ***Capture another image or perform automatic analysis again.***

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

- ***Analytial calculation using the selection/release button***
- ***Editing cell outlines using the "Edit/Edit R/Edit L" button***
- ***Analysis using the L-count function***



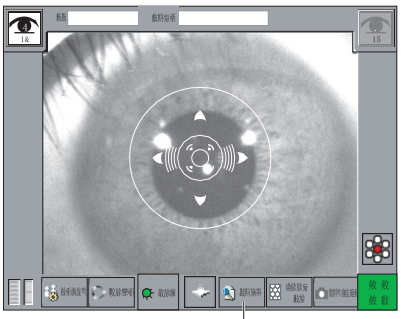
(Fig. 1)

3.4 Recalling data in the memory

Recall the captured data stored in the memory.

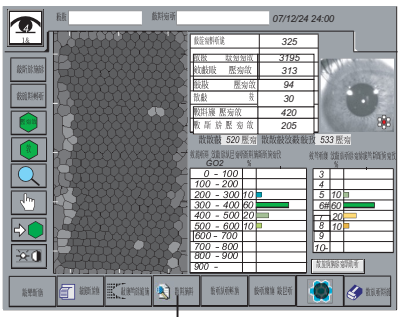
Note

- ***Touch the "CLEAR" button to delete all data stored in the memory.***
- ***This function is available only in Standard mode.***



(Fig. 1) (1)

Touch the "Data" button (1) on the touch panel. The Data List screen (Fig. 3) opens.
Displays a maximum of 10 captured images.



(Fig. 2) (1)

"Analysis" button (2)

Select an image on the touch panel and touch the "Analysis" button (2) to display the analysis result screen (Fig. 2).

"Print" button (3)

Prints the displayed image on a connected external printer.

"Export" button (4)

Select an image on the touch panel and touch the "Export" button to send the data to external equipment. (Refer to 3.5.1 Sending examination data.")

(2) (3) (4) (5) (6) (7)
(Fig. 3)

"Next Eye" button (5)

Displays the captured image.

"Delete" button (6)

Select an image on the touch panel and touch the "Delete" button (6) to delete the selected image.

"Clear" button (7)

Erases all the saved examination date and displays the capturing screen.

3.5 Data communication

Examination data can be sent or received from external equipment or external computers.

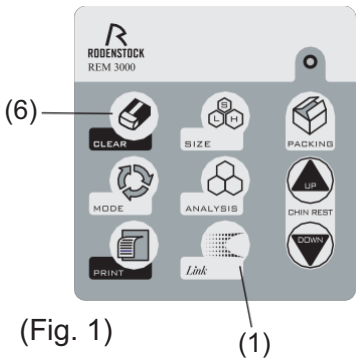
Note

- ***The examination data retrieval software "DATA Transfer" (provided with the instrument) is required for data communication with the instrument.***
- ***Refer to the corresponding instruction manual for settings for DATA Transfer.***
- ***In order to connect to the DATA Transfer, special setting is needed. Refer to "3.2.4 Connecting DATA Transfer" and "3.6.4 Export," and make settings.***

3.5.1 Sending examination data

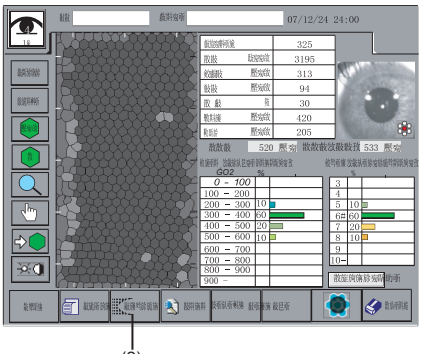
Note

- ***Check that the ID is correct before sending the data. If the ID is incorrect, the data may be processed as the data of another patient.***
- ***For data communication, it is advisable to enter an ID number. Data can be sent without an ID number entered. However, it is possible that the patient's data in question cannot located within all the examination data being put out from DATA Transfer. If data is sent without an ID number being entered, check the examination data immediately after it has been sent, and move and save the data file to an appropriate location.***

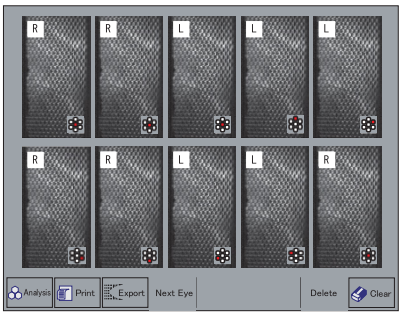


(Fig. 1)

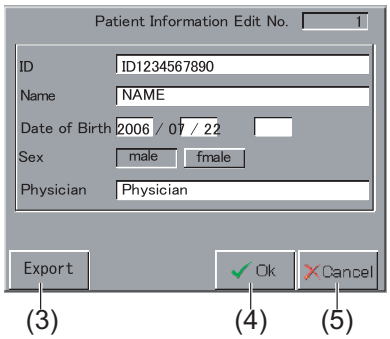
1) After the capturing process, press the Link switch (1) of the membrane switch (Fig. 1) or the "Export" button (2) in each screen (Fig. 2 and Fig. 3) to display a data transfer confirmation screen (Fig. 4). In the data transfer confirmation screen, patient information can be edited. (Refer to "3.3.2 Entering patient information.")



(Fig. 2)



(Fig. 3)



(Fig. 4)

2) After patient information is confirmed, press the “Export” (3) button to start sending the examination data. Press the “OK” button (4) to confirm the on-screen patient information and return to a previous screen. Press the “Cancel” button (5) to return to a previous screen without anything confirmed. Pressing the CLEAR switch (6) of the membrane switch (Fig. 1) erases all patient information and captured data, and displays a capturing screen.

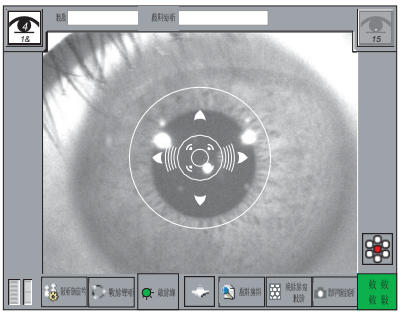
3) When the data are sent normally, “COMPLETE” message is displayed and the display returns to the previous screen.

3.6 Setting

The operation conditions can be set here.

Note

■ ***After changing the settings, be sure to touch the "Save & Exit" button to exit the screen. If the "Cancel" button is touched, no changes are made to the settings and the conditions previously set are still effective.***

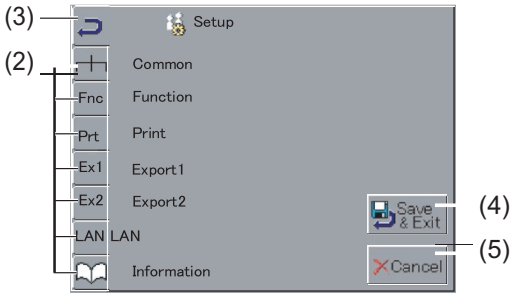


(1)

(Fig. 1)

Touch the "Setup" button (1) on the capturing screen to display the Setup (Permanent) screen (Fig. 2). Touch one of the icons (2) listed on the left of the screen to select the setting item and set conditions as needed on the corresponding screen.

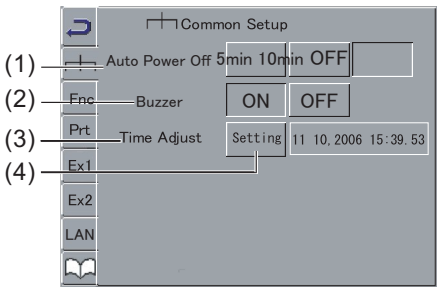
Touch the return icon (3) after setting is complete to return to the previous screen. Touch the "Save & Exit" button (4) to save the new settings and return to the capturing screen (Fig. 1). Touching the "Cancel" button (5) returns you to the capturing screen without changing any settings.



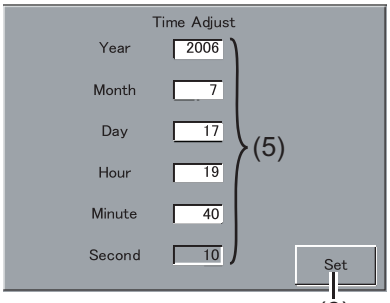
(Fig. 2)

Common	: Items related to operational conditions
Function	: Items related to various functions
Print	: Items related to printer
Export 1	: Items related to data output
Export 2	: Items related to data output
LAN	: Items related to LAN connections
Information	: Product information

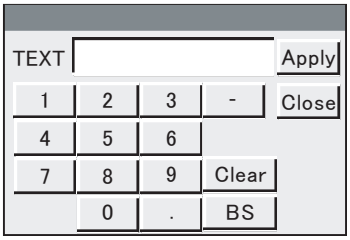
3.6.1 Common



(Fig. 1)



(Fig. 2)



(Fig. 3)

Auto power off setting (1)

Sets the time to enter the Power Off mode.

5 min : Enters Auto Power Off mode when the instrument is not operated for 5 minutes.

10 min : Enters Auto Power Off mode when the instrument is not operated for 10 minutes.

OFF : Does not enter Auto Power Off mode.

Buzzer setting (2)

ON : Enables the buzzer sound.

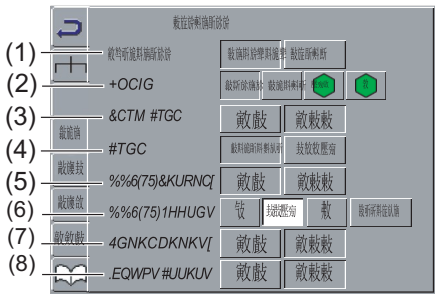
OFF : Disables the buzzer sound.

Time Adjust (3)

Sets the current date and time.

Touch the “Setting” button (4). The Time Adjust screen (Fig. 2) appears. Touching any of the date/time fields (5) displays the keypad (Fig. 3) for you to change the setting. After adjusting the date and time, touch the “Set” button (6) to save the setting and return to the previous screen (Fig. 1).

3.6.2 Function



(Fig. 1)

Operation setting (1)

Sets the sequential operation for capturing, analyzing, printing, and issuing the data.

Standard : Mode to capture, analyze, print, and output the data sequentially for each eye, as a rule; equipped with the function to temporarily store up to 10 captured images in the memory.

Quick : Mode to capture images of both eyes, and then analyze, print, and output the data at once. Only one image each of the right and left eyes is temporarily stored in the memory.

Image setting (2)

Sets the image display immediately after analysis.

Photo : Displays an endothelial image.

Trace : Displays an image for tracing.

µm2 : Displays an image with the cell size color-coded.

6 : Displays an image with the cell shape color-coded.

Dark Area setting (3)

ON : Includes the dark area in the calculation for analyzing endothelium tissue.

OFF : Does not include the dark area in the calculation for analyzing endothelium tissue.

Area setting (4)

Sets the image display immediately after analysis.

Variable : Requires you to specify two opposing points to specify an area to be analyzed on the screen.

100µm : Requires you to specify an area to be analyzed on the screen using a frame of 100µm around.

CCT (US) Display (5)

ON : Displays the ultrasonic correction value for corneal thickness.

OFF : The ultrasonic correction value for corneal thickness is not displayed.

CCT (US) Offset (6)

Set the offset value for the ultrasonic correction value for corneal thickness.

When “CCT (US) Display (4)” is set to ON, the setting button is displayed.

Default : 13µm

Setting range : 0 - 3µm

Reliability (7)

ON : Displays Reliability mark

OFF : Reliability mark is not displayed.

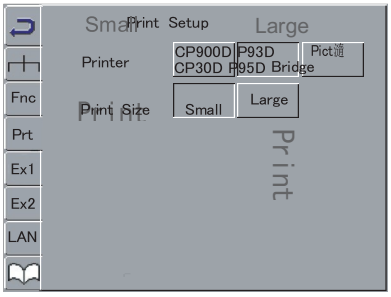
Lcount Assist (8)

Sets whether to roughly select cells in advance automatically when executing the L-count function.

ON : Automatically selects and displays cells.

OFF : Does not select cells automatically.

3.6.3 Printer

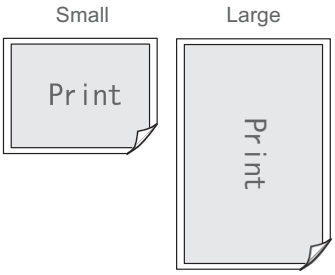


(Fig. 1)

Set the type of printer that will be connected.

CP900D CP30D : Selected when a Mitsubishi digital printer CP900D or CP30D is connected to the instrument.

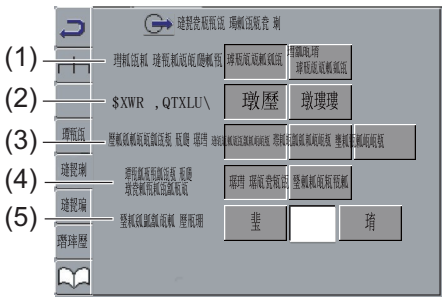
P93D P95D : Selected when a digital monochrom printer P93D or P95D is connected to the instrument.
The size of printing can be chosen when choosing the button.



(Fig. 2)

PictBridge : Selected when a PictBridge-compliant printer is connected to the instrument.

3.6.4 Export



(Fig. 1)

DATA Transfer (1)

Connect : Connects with DATA Transfer.
Disconnect : Does not connect.

Auto Inquiry (2)

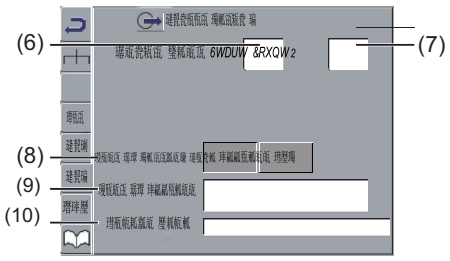
Sets whether or not patient information inquiry will be performed automatically when ID is entered.
ON : Queries the Link automatically for patient information, when the ID number is confirmed.
OFF : Does not query automatically when the ID number is confirmed.

Necessity of ID (3)

ID entry conditions to send the measured data will be set on the send confirmation screen.
Essentially : Set only when it is necessary that an ID be entered. Unless the ID is entered, the data cannot be sent.
Basically : This is set when enabling the data to be sent without an ID (normally an ID must be set). If an ID is not entered, the data will be sent as “NO ID.”
Rarely : Set when you do not want to be concerned about ID entry. The send confirmation screen will be displayed but the measured data will be sent automatically. If an ID is not entered, the data will be sent as “NO ID.”

Priority of Operation (4)

Sets whether to display the patient information screen automatically or not, in order to enter an ID before starting the capturing process.
ID Input : Displays the patient information screen automatically.
Measurement : Does not display the patient information screen automatically.



(Fig. 2)

Machine No. (5)

In case there is more than one instrument, a number is set for differentiation.

Start (6)

Sets from which character an ID is to be recognized when an ID is entered from a barcode. If the value is 0 or 1, characters from the very beginning are to be identified as the ID.

Count (7)

Specifies the maximum number of digits for the ID (1 - 64 digits) when an ID is entered from a bar code.

Host IP Setting Type (8)

This setting enables you to select an IP address or computer name when specifying the host computer.

Address : Specifies the host computer with the IP address (9).

DNS : Specifies the host computer with the computer name (10). To use DNS, a DNS server must be running on the LAN environment.

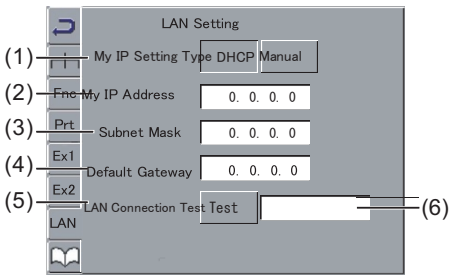
Host IP Address (9)

Specified when Address is selected in Host IP Setting Type (8).

Domain Name (10)

Specified when DNS is selected in Host IP Setting Type (8).

3.6.5 LAN



(Fig. 1)

My IP Setting Type (1)

This setting enables you to select whether or not DHCP is used for setting the IP address (local address, subnet mask, default gateway).

DHCP : Setting with DHCP (dynamic IP).

Manual : Manual setting (fixed IP).

My IP Address (2), Subnet Mask (3), Default Gateway (4)

When Manual is selected as My IP Setting Type (1), local address, subnet mask, default gateway are specified.

LAN Connection Test (5)

Touch this button to confirm the connection with the server. The result is displayed on (6).

Connection Status of LAN Communication (6)

Shows the status of LAN communication.

Connect : Shows that it is connected.

Check LAN Cable : Shows that it is disconnected. Even when this is displayed, the connection test will be continued for 60 seconds.

Server not found : Cannot communicate with the server PC software.

Example

- If only this instrument and a computer receiving DATA Transfer are connected to the network, they can be set as follows.

1) Checking the computer's IP address

Check and note the IP address and subnet mask of the computer on which the DATA Transfer software is installed. For details on how to check these items, refer to the DATA Transfer instruction manual.

2) Setting method for this instrument

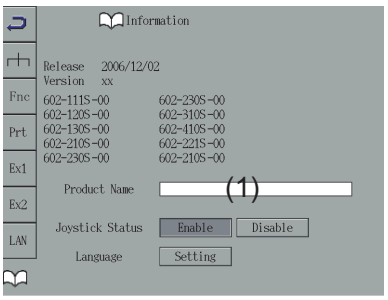
The example shown in the table below is for a computer with the DATA Transfer

software installed having IP address [192.168.2.128] and subnet mask [255.255.255.0]. The IP setting method is Manual.

	Computer setting				Instrument setting			
(Local) IP address	192	168	2	128	192	168	2	130
	Check the DATA Transfer screen				Same value as the computer			(*1)
Subnet mask	255	255	255	0	255	255	255	0
	Check the DATA Transfer screen				Same value as the computer			
Default gateway	----				0	0	0	0
					All 0s			
Server IP address	----				192	168	2	128
					Computer's IP address			

*1: Any number between 1 to 255 except the number used by the computer (In this example, 128).

3.6.6 Information



(Fig. 1)

Displays the product information.
Touch the product name display field (1) to display the alphabetic keyboard and enter the name of the product. (Refer to “3.3.2(d) Entering characters.”)

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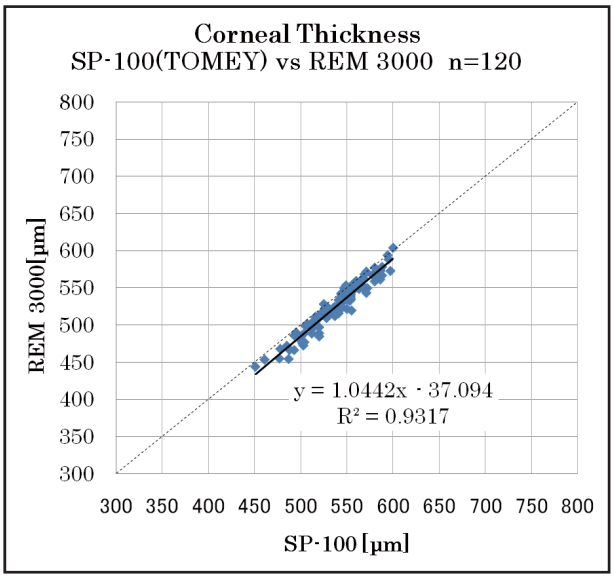
4. TECHNICAL INFORMATION

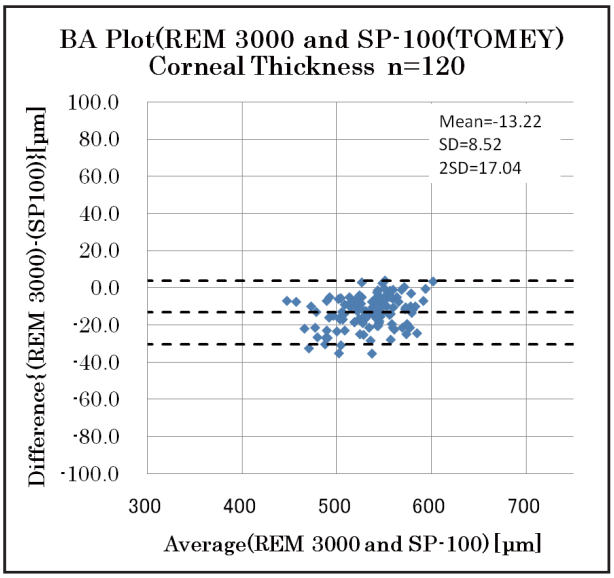
<Automatic Analysis of Endothelial Cells>

All cells extracted from the distortion of edge lines are identified as being valid or invalid, and the dimensions and shapes of valid cells are calculated.

<Ultrasonic Correction for Corneal Thickness>

The following shows the result of comparison between the corneal thickness of 120 normal eye samples (with no corneal diseases or corneal transplants) measured by this instrument and that measured by TOMEY ultrasonic pachymeter SP-100.





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5. INSPECTION AND MAINTENANCE

5.1 Warranty

One-Year Limited Warranty

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

Lamps, paper and other consumable items shall not be covered by this warranty.

This warranty also shall NOT apply if the product has not been installed, operated or maintained in accordance with the INSTRUCTION MANUAL of Tomey Corporation (here in after called “Tomey”). Neither seller not 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 duty 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, EXPRESS OR IMPLIED (INCLUDING SPECIFICALLY, WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE), AND ALL OTHER OBLIGATION AND LIABILITY ON THE PART OF SELLER AND TOMEY. NEITHER SELLER NOR TOMEY SHALL BE LIABLE FOR INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES UNDER ANY CIRCUMSTANCES OR FOR MORE THAN REPAIR, REPLACEMENT OR REFUND OF THE PURCHASE PRICE OF DEFECTIVE GOODS.

5.2 Durable years

This instrument is designed to be durable for 8 years when operated under the appropriate environment and adequately inspected and serviced.

5.3 Inspection

Note

- ***Good endothelial images may not be obtained if the instrument has any defects. Contact our local distributor or RODENSTOCK for necessary repairs as soon as possible.***

5.4 Routine maintenance

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

Note

- ***Do not use organic solvents such as thinner, benzene, or acetone to clean the instrument. These solvents may damage the surface coating of the instrument.***
- ***Disconnect the power cord and place the dust cover over the main unit when the instrument is not operated for more than a month.***
- ***Ensure that any optical components, such as the capturing window, are not exposed to dust, fingerprints, etc. Otherwise, the capturing accuracy will be deteriorate.***
- ***Place the dust cover over the main unit when not being used.***

5.4.1 Forehead pad/Chin rest

Note

- ***Gently wipe the sections that patients directly touch, such as the forehead pad or chin rest, with a soft cloth dampened with alcohol before starting measurement for a new patient.***

5.4.2 Outer surface

When the outer surface of the instrument becomes dirty, clean it with a dry, soft cloth. When very dirty, clean the surface using a cloth dampened with diluted neutral detergent and thoroughly wrung out, and then wipe the surface with a dry cloth.

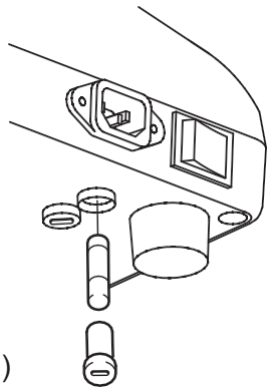
Note

- ***Clean the monitor of the main unit using a soft cloth with glass cleaner applied.***

5.5 Replacing consumables

5.5.1 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 the REM 3000.***
- ***When the instrument does not work correctly after fuses are 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.

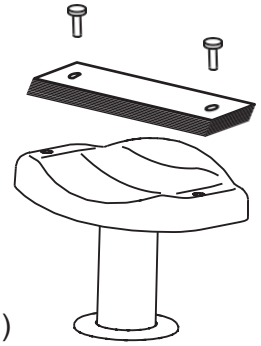
2) Disconnect the power cord from the outlet.

3) Insert a coin or similar in the slot on the fuse case located at the bottom of the main unit. Turn the screw counterclockwise to remove it.

4) Replace the blown fuse with a new one.

5) Reverse the procedure above to install the fuse holder.

5.5.2 Chin rest paper



(Fig. 1)

1) 1) Remove the two chin rest paper pins.

2) Place new chin rest paper on the chin rest and secure the paper with the paper pins again.

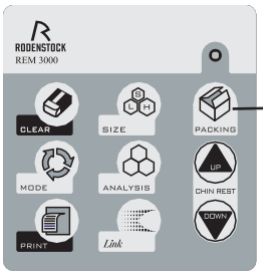
5.6 Storing

- ***Store 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 place where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and ignite.***
- ***Do not hold the head unit, chin rest, forehead pad, or joystick when lifting the instrument. These components are detachable and the instrument may drop, resulting in injuries.***
- ***Disconnect the power cord from the outlet to ensure safety when the instrument is not operated for 1 month or longer.***
- ***Store the instrument in a location not subject to direct sunlight, high temperatures and humidity, or air with significant dust, salt, and/or sulfur content. These may cause failure or malfunction of the instrument.***
- ***Store the instrument in a level and stable location free of vibration and mechanical impacts to ensure correct capturing, and prevent the instrument from falling or being dropped, which can result in fire or fatal accidents.***

- ***Place the dust cover over the main unit when not being used. The capturing accuracy will be deteriorate if the optical section in the instrument becomes dirty.***

Completely lower the head unit to lower dead center when storing the instrument.
Touch the “PACKING” button (1) of the membrane switch for 3 seconds to return the head unit to lower dead center.
Turn the power off.



(Fig. 1)

5.7 Disposal

Note

- ***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 packing materials, sort them by type and disposed them as directed by relevant laws and local rules and regulations.***

6. TROUBLESHOOTING

Check the following first when you find problems with the instrument. If the problem is not solved even after checking the applicable item listed below, contact our local distributor.

■ ***Do not remove the cover of the instrument.***
Otherwise, you may be directly exposed to high voltage sections.

Note

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

■ ***If the problem is not solved even after checking the applicable item listed below, contact our local distributor.***

- The power lamp or monitor does not turn on when the power switch is turned on.

  ? Cause 1 Faulty power plug

  Solution Check that the power plug is firmly connected to the instrument and power outlet.
  Check that the power cord is not cracked, torn, etc.

  ? Cause 2 Power not supplied

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

  ? Cause 3 Blown fuse

  Solution Check for blown fuses, and replace fuses as needed. (Refer to “5. 5. 2 Fuses.”) If the replaced fuse blows again, there may be other problems. Contact our local distributor for repair.

- The monitor is dark when the power switch is turned on.

  Cause 1) Auto Power Off, which automatically turns off the display when the instrument is not operated for a specific time, is ON.

  Solution ➡ Touch the LCD.

- The error message “Internal Error.” is displayed.

  Cause 1) There are problems with the internal functions of the instrument.

  Solution ➡ Stop using the instrument and contact our local distributor.

- The error message “Calender/ Clock Error.” is displayed.

  Cause 1) There are problems with the date/clock function.

  Solution ➡ Contact our local distributor.

- The error message “Chin Rest Error.” is displayed.

  Cause 1) There are problems with the chin rest elevator.

  Solution ➡ Contact our local distributor.

- The error message “Joy Stick Error.” is displayed.

  Cause 1) There are problems with the joystick.

  Solution ➡ Contact our local distributor.

- The error message “Alignment Motor Error.” is displayed.

  Cause 1 There are problems with the alignment movement function.

  Solution Contact our local distributor.

- The error message “Unknown Error.” is displayed.

  Cause 1 An error of unknown origin has occurred.

  Solution Stop using the instrument and contact our local distributor.

- The error message “External Communication Error.” is displayed.

  Cause 1 Poor cable connection

  Solution Check t he cables connected t o the instrument, and the other ends connected to other instruments.

  Cause 2 DATA Transfer is not running.

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

  Cause 3 There may be an error in DATA Transfer.

  Solution Check that there is no error in DATA Transfer (including the relay software when being connected via USB). Refer to the instruction manual of DATA Transfer for details.

Cause4 T he HUB is not t urned on. (W hen connected to a LAN.)

Solution Turn on the HUB.

Cause5 The settings for the instrument and DATA Transfer are not correct.

Solution Refer to “3.6.4 Export” and make settings properly.

7. CONSUMABLES

Contact our local distributor to order any of the following consumables.

- Chin rest paper (100 sheets/set)

- Fuse
  Specify the fuse type as “Fuse for REM 3000.”

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8. SPECIFICATIONS

8.1 Specifications

8.1.1 Capturing scope

0.25×0.54mm

8.1.2 Corneal thickness measurement accuracy

±10μm

8.1.3 Main unit

- Stroke of moving section: 88 mm (X axis); 40 mm (Y axis); 50 mm (Z axis)
- Stroke of chin rest: 70mm
- Data output format: Printer/LAN/USB
- Display: 8.4” color LCD
- Dimensions and weight: 308 (W) x 493 (D) x 453 (H) mm, approx. 18 kg

8.1.4 Power source

- Voltage: 100 V AC - 240 V AC
- Frequency: 50/60Hz
- Consumption power: 100 VA - 130VA

8.2 Noise

The instrument generates machine noise when:

- Turning power on
- Moving the capturing unit
- Moving the chin rest

8.3 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 : 700 to 1060 hPa
- Power fluctuation : Less than ±10 of nominal voltage

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

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

8.4 Classification

Protection against electrical shock:

- Class I ME equipment

Applied parts:

- B applied parts (Forehead pad, Chin rest)

IP Code:

- IP20 (Main unit)
- IP10 (Capturing window)

Mode of Operation:

- Continuous operation

8.5 Declaration of Conformity with EMC

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 REM 3000.

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

Guidance and manufacturer's declaration - electromagnetic emissions

Table 201

The REM 3000 is intended for use in the electromagnetic environment specified below.
The customer or the user of the REM 3000 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The REM 3000 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 REM 3000 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 REM 3000 is intended for use in the electromagnetic environment specified below. The customer or the user of the REM 3000 should assure that it is used in such an environment.

Immunity test	IEC 60601 test levell	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge(ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV 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	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV line(s) to line(s) ± 2kV line(s) to earth	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 REM 3000 requires continued operation during power mains interruptions, it is recommended that the REM 3000 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 REM 3000 is intended for use in the electromagnetic environment specified below.
The customer or the user of the REM 3000 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 REM 3000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 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 REM 3000 is used exceeds the applicable RF compliance level above, the REM 3000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the REM 3000.

[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 REM 3000

The REM 3000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the REM 3000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the REM 3000 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.

9. INDEX

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