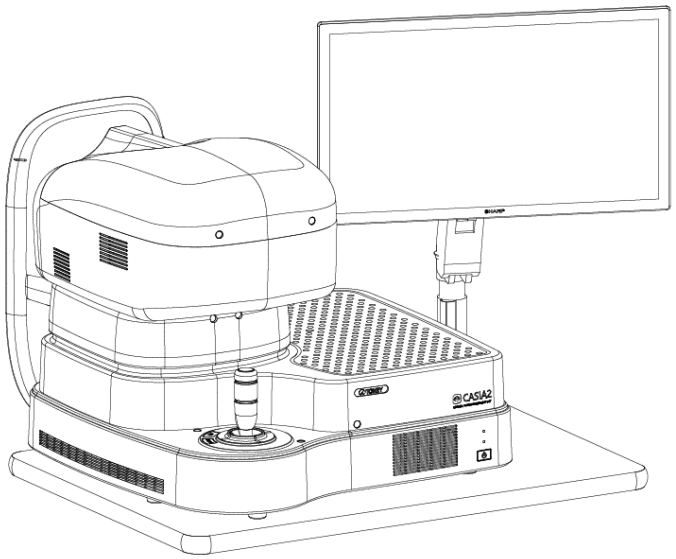
INSTRUCTION MANUAL

Cornea/Anterior Segment OCT

CASIA2



Read this manual thoroughly before using the instrument to ensure proper and safe operation.
Contact Tomey Corporation or your local distributor if you have any questions or you encounter any problems during operation.

Note

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

TOMEY

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i. Important safety information



- ***Do not install this instrument in a location where explosives or flammable substances are used or stored. Fire or explosion may occur.***
- ***Do not remove the cover of the instrument. Otherwise electric shock may occur.***
- ***Do not disassemble or modify the instrument. You may risk direct exposure to high voltage sections.***



- ***Disconnect the power cord from all the connected devices before installing and/or servicing the instrument. Otherwise, electric shock may occur.***
- ***Do not place the attached AC-Adapter directly on the floor when in use.***
- ***Do not connect a plug-in socket or extension cord to the attached AC-Adapter.***
- ***Use only the specified data terminal for connection of the instrument. Using another type of data terminal may result in failure of the instrument.***
- ***Do not physically contact with the patient while touching the connection terminal of this instrument, related monitor or external HDD. Otherwise electric shock may occur.***
- ***Do not commence service or maintenance work while the instrument is being used for a patient.***



- ***Do not place water or chemicals on the instrument. Any water or chemicals entering the instrument may cause electric shock or failure.***
- ***This instrument is a diagnostic/measuring device specially designed for ophthalmology. Never use the instrument for other purposes.***
- ***The terminal for connecting the instrument to external devices is not isolated from the internal circuit. Inappropriate wiring may damage the internal circuit. Contact Tomey or your local distributor before using the instrument connected to another device.***
- ***When operating this instrument connected to other devices not described in this document, only use devices that satisfy IEC60601-1 or equivalent safety requirements or that conform to IEC60950 and whose power source is insulated with the attached AC-Adapters, in order to satisfy the safety requirements regarding medical equipment.***
- ***AC-Adapters differ between the touch panel LCD monitor and the external HDD. Connect in correct pairs to prevent failures.***

ii. How to read this manual

Outline

This manual is structured as follows.

1. **PRIOR TO USE**
   Describes safety precautions and important information to be understood before installing and using the instrument.

2. **NAMES AND FUNCTIONS**
   Describes names and functions of each section of the instrument.

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

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

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

6. **TROUBLESHOOTING**
   Describes how to solve problems.

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

8. **SPECIFICATIONS**
   Describes the specifications of the instrument.

Symbols used in this manual

Sentences accompanied with the symbols below indicate the following:



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



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



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



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

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1. PRIOR TO USE

Note

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

1.1 Precautions for operation

- ***Allow only well-trained operators to use the instrument.***

- ***Fully examine the measured data for tracing results. In particular, if the difference between measurement values for the left and right eyes is significant or any problem is found in the anterior chamber during preliminary examination, check the tracing and/or reliability on the check screen. If the measurement result is not conclusive, review the inspection result by performing measurement again or performing another inspection.***

- ***When using data taken by this instrument for diagnosis or determination of treatment, proceed carefully by taking measurements multiple times and/or conducting other examinations.***

- ***When using the data taken by this instrument to select intraocular lenses, thoroughly determine the selection by also examining cataract surgery methods and other inspections. If incorrect measurement data is used to select intraocular lenses, further surgery might be required.***

- ***When using the data taken by this instrument to calculate the degree of intraocular lenses, use the value of the axial length***

measured with the instrument that its measurement accuracy is guaranteed. If incorrect measurement data is used to calculate the degree of intraocular lenses, further surgery might be required.

- ***When using the data taken by this instrument for refractive correction surgery, thoroughly determine the selection by also examining surgery methods and other inspections. Refractive correction surgery conducted according to incorrect measurements or analysis results may result in further surgery or severe complication such as keratoectasia.***

- ***Precautions when installing the instrument and accessories***



- *Install the instrument in a location free of water or chemicals. Any water or chemicals entering the instrument or devices may cause electric shock or failure.*
- *Do not install the instrument in a location where chemicals are stored or gases may occur. Any chemicals or vapor entering the device may result in fire.*
- *Check the frequency, voltage, and allowable current (or power consumption) of the power source. Otherwise, fire or electric shock may occur.*
- *Connect the power plug to a grounded 3-pin outlet. Otherwise, a short circuit due to failure of the instrument may result in electric shock.*
- *Do not place any heavy object on the power cord or compress the power cord. Fire or electric shock may occur.*
- *Fully insert the power plug into the outlet. Faulty contact, allowing any metal to contact the exposed terminal of the plug, or dust accumulated on the exposed terminal of the plug may result in fire or electric shock.*
- *Conduct grounding work correctly. Otherwise, electric shock may occur. Do not connect a device with data transmission specifications that are not compatible. Fire or electric shock may occur. Contact Tomey Corporation or your local distributor before using the instrument.*



- *Do not hold the head, chin rest, forehead pad, joystick, or cables when moving the instrument. These components are detachable and the instrument may drop, resulting in injuries.*
- *Install the instrument in a location not subject to direct sunlight, high temperature and humidity, or air containing dust, salt, and/or sulfur. Otherwise, failure or malfunction may occur.*
- *Install the instrument in a stable, level location free of vibration or mechanical impact. Otherwise, measurement cannot be conducted correctly. Also, the instrument may topple over or fall down, resulting in fire or serious accident.*
- *Place the instrument between the patient and physician so that they can face each other.*
- *Install the instrument in a location with ample clearance from other devices to allow smooth inspection.*
- *Check the frequency, voltage, and allowable current (or power consumption) of the power source.*
- *The AC adapter for the touch panel LCD is different from that for the external HDD. Connect the correct adapter. Incorrect connection may result in failure of the instrument.*

Precautions before operation



- *Check that the instrument works properly by inspecting switch and button operations, display, and printing.*
- *Check that all cables are connected correctly.*
- *Since simultaneous use of multiple devices can cause misdiagnosis or result in a hazardous situation, exercise caution when using this instrument.*
- *Check the sections that the patient will directly touch.*
- *Peel off the top sheet of chin rest paper and clean the forehead pad with a cloth dampened with alcohol before measurement.*
- *Check that the instrument is correctly grounded.*

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

■ *Precautions during operation*



- *Do not place any container with liquid in it on the device. Any liquid entering the instrument may cause electric shock or failure.*
- *Always check that the device is operating correctly and monitor the patient to ensure safety.*
- *If any problem is found concerning either the instrument or patient, take appropriate action, such as stopping operation, to maintain patient safety.*
- *When moving the head and/or chin rest of the measuring unit, pay attention to the position of the patient's face, hands, and fingers. Otherwise, movement of the head or chin rest may cause injury.*
- *Do not allow any person to place their hands or fingers in the clearance under the head, the space immediately under the chin rest, measurement window, or moving section. Hands or fingers may be caught and injured.*
- *Do not allow the patient to touch the external connection terminal. Do not lean on the instrument or press on the instrument from the top. The instrument may topple over, resulting in mechanical failure or injuries.*
- *Peel off the top sheet of chin paper and clean the forehead pad with a clean cloth before measuring the next patient. Clean the forehead pad and chin rest with a cloth dampened with alcohol as needed.*
- *If any smoke, offensive odor, or abnormal sound occurs, turn off the instrument immediately, disconnect the power plug from the outlet, and contact your local distributor or Tomey Corporation.*

■ *Precautions after operation*



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

- *When disconnecting cords, avoid applying too much force: for example, do not hold and pull the cord.*
- *Refer to "5.4 Routine maintenance" and “5.6 Storing” for instructions on the cleaning and storage of the instrument.*

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



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



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



- *Conduct regular inspections of the instrument and components.*
- *When the instrument is not in use for 1 month or longer, check that the instrument is operating correctly and safely before restarting operation. Refer to "5.3 Inspection" in this manual for the relevant procedures.*

1.2 Checking package contents

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

Note

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

- Main unit 1
- Power cord..... 1
- Touch panel LCD monitor..... 1
- External HDD..... 1
- Keyboard 1
- USB Mouse..... 1
- OKULIX dongle..... 1
- Model practice eye 1
- Chin rest paper 1
- Pins for chin rest paper..... 2
- Dust cover (Main unit) 1
- Dust cover (LCD monitor)..... 1
- Fuses 2
- HDMI cable 1
- AC-Adapter (External HDD) 1
- Power cord (External HDD)..... 1
- AC-Adapter (LCD monitor) 1
- Power cord (LCD monitor)..... 1
- Instruction manual (this document)..... 1

1.3 Glossary

[A/B scan]	:	The number of A-mode scans per image scanned in B-mode
[A scan]	:	Scanning to obtain the depth of the patient's eye by radiating light into the eye
[B/C scan]	:	The number of B-mode scanned images per 3D image data
[B scan]	:	Scanning to capture tomographic images by repeating A-mode scanning while scanning positions linearly on the patient's eye
[B-scanned image]	:	A tomographic image captured by B-mode scan
[C-scanned image]	:	Tomographic image sliced perpendicular to the depth direction
[Horizontal image]	:	A tomographic image sliced in a horizontal direction
[Rotation image]	:	A tomographic image sliced in an optional direction
[SE]	:	Equivalent spherical degree (Refer to [Equivalent spherical degree].)
[VD]	:	Corneal vertex distance (distance between the corneal vertex and the posterior surface of the lens)
[Vertical image]	:	A tomographic image sliced in a vertical direction
[Z-Off]	:	Function to automatically align the sight in up/down/right/left directions Alignment in back/forth (depth) direction is not conducted.
[Auto Alignment]	:	Function to automatically align the sight in back/forth (depth) direction. Automatic alignment in up/down/right/left directions only can also be conducted by selecting [Z-Off].
[Auto Shot]	:	Function that automatically starts measurement when the patient's eyes are within the measuring range
[Shift Average]	:	Function to reduce random noise by overlapping and averaging adjacent tomographic images of a 3D image

[Peripheral sight-fixing target]	:	Optotype to guide the direction of the patient's sight up, down, right and left
[Scanning direction]	:	Direction of B-mode scan
[Adjustment load sight-fixing target]	:	Optotype to guide the adjustment of the patient's eye
[Equivalent spherical degree]	:	Calculated from the refractometer value SPH+CYL/2
[Radial scan]	:	Scanning method to obtain a 3D image by repeating B-mode scan in a radial direction
[Raster scan]	:	Scanning method to obtain a 3D image by repeating B-mode scan in a horizontal or vertical direction

1.4 Overview

This instrument is a three-dimensional OCT (optical coherence tomography) image diagnosis unit that captures a three-dimensional image of the anterior section of the patient's eye by high-speed scanning without making contact with the eye. This instrument has the following features.

[Image capture]

- 3D mode to capture 3D images
- 2D mode to capture 2D images
- Movie mode to capture video

[Measurement]

- Capturing while monitoring the front and tomographic images of the patient's eye
- Automatic alignment function to align positions automatically
- Auto shot function to start measurement automatically

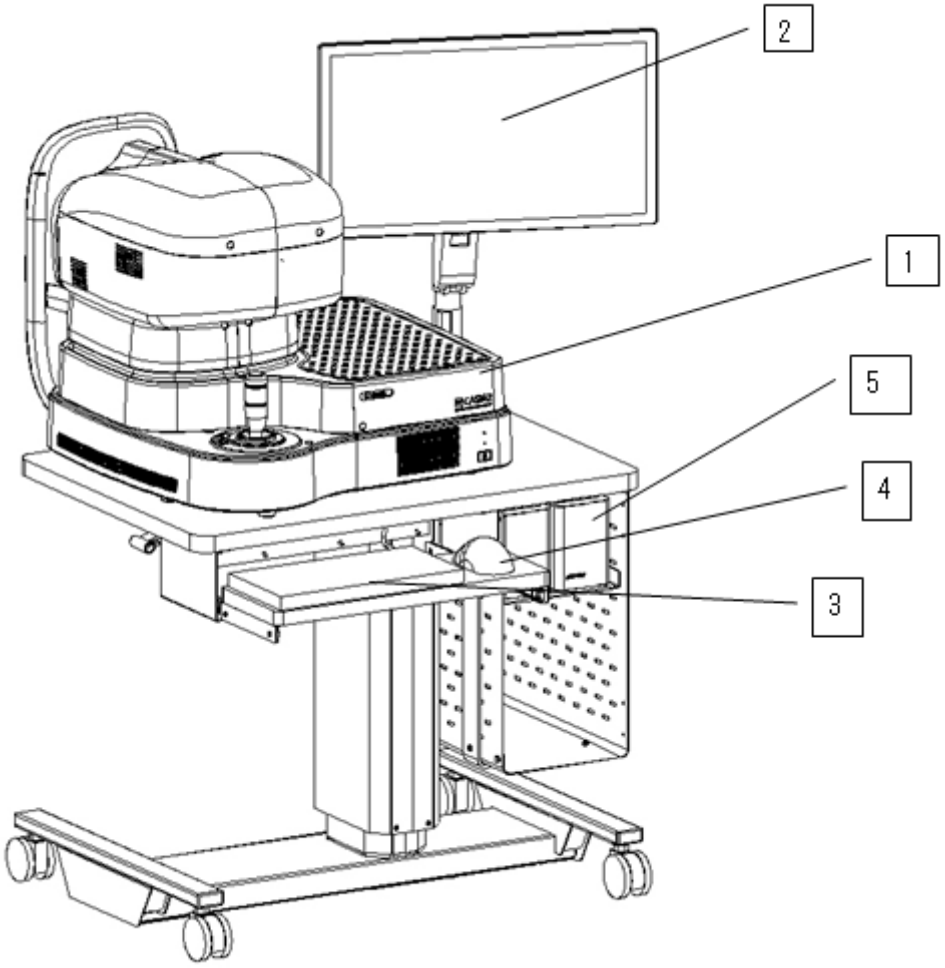
[Data management]

- Save after checking images
- Viewer screen only for viewing the data
- DB screen only for data management

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2. NAMES AND FUNCTIONS

2.1 System overview



(1) Main unit

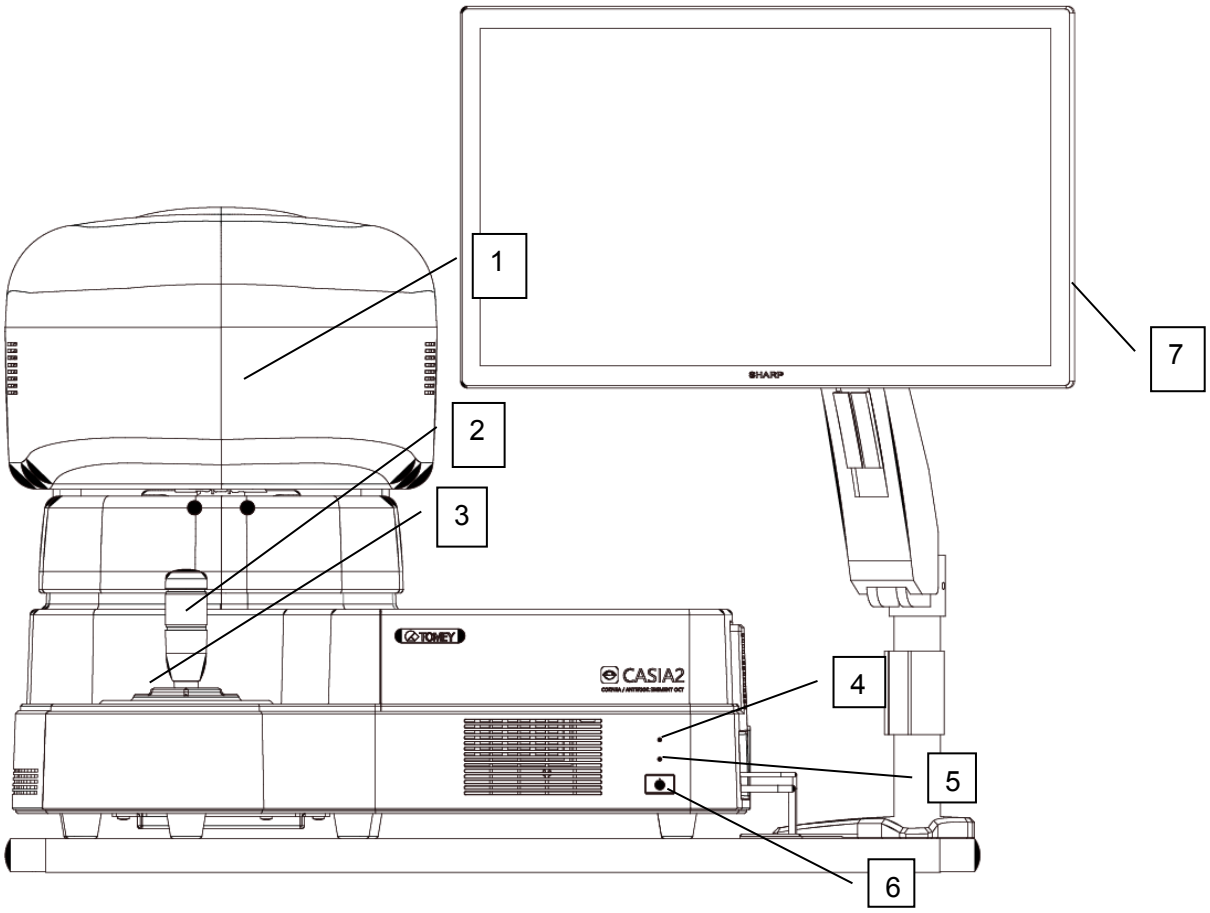
(2) Touch panel LCD monitor

(3) Keyboard

(4) Mouse

(5) External HDD

2.2 Physician's side



(1) Head

(2) Joystick

(3) Chin rest up/down button

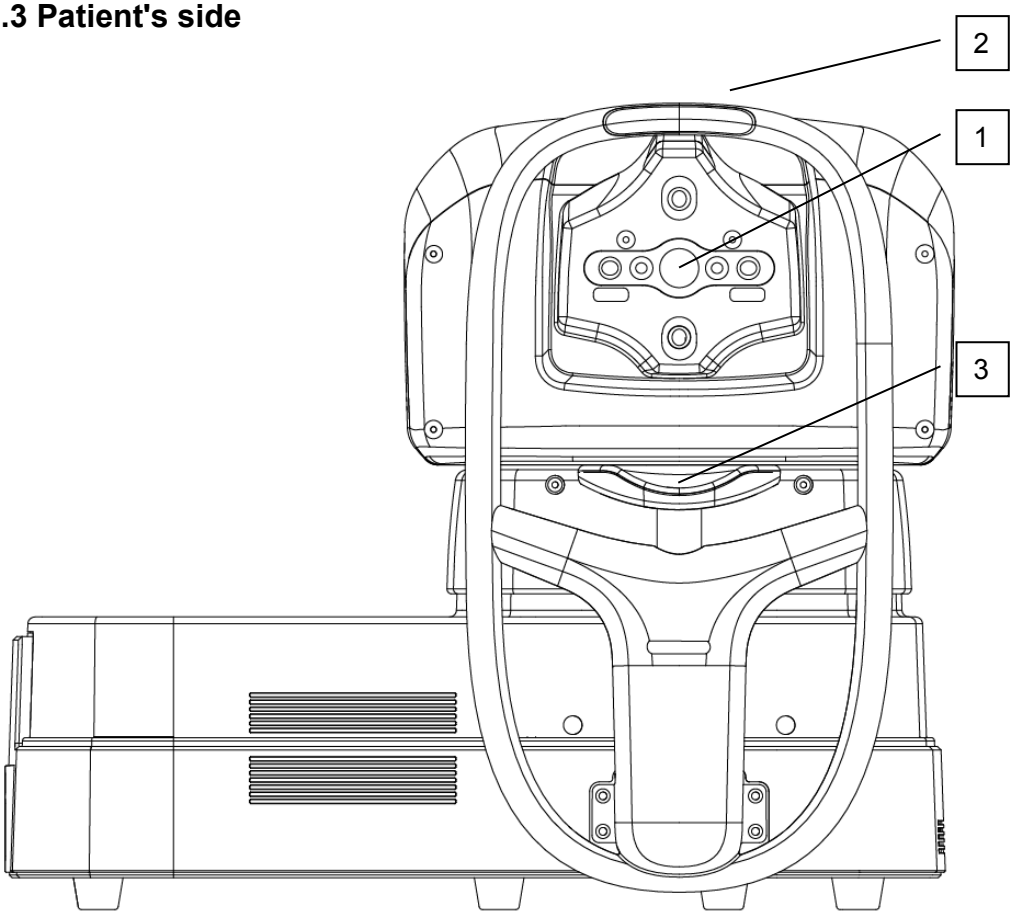
(4) SSD access lamp (blue)

(5) Power lamp (green)

(6) Power switch

(7) Monitor power switch

2.3 Patient's side

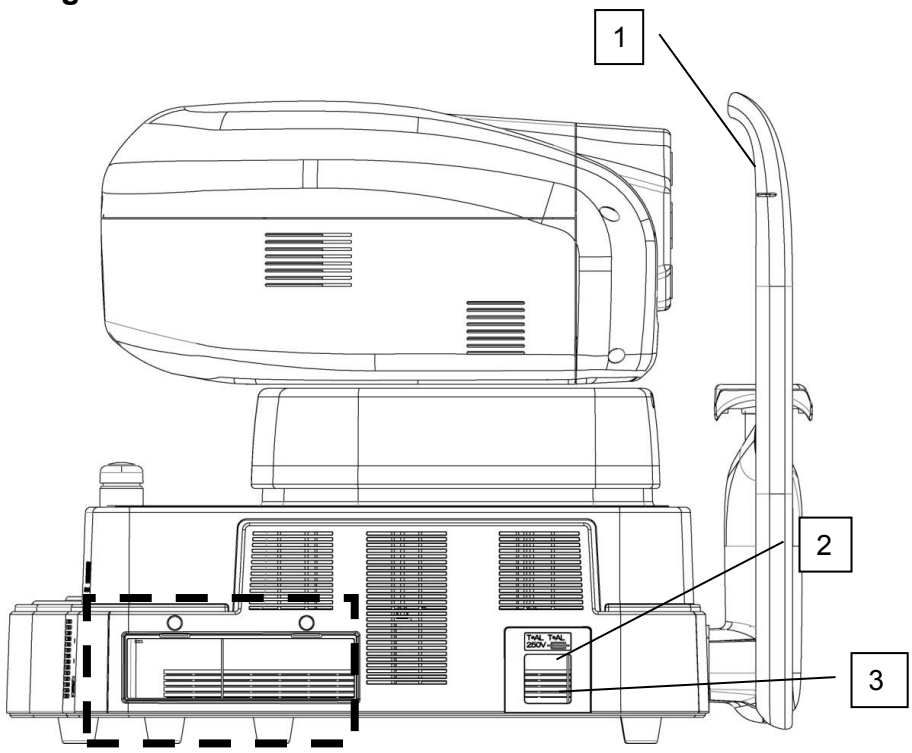


(1) Measurement window

(2) Forehead pad

(3) Chin rest

2.4 Right



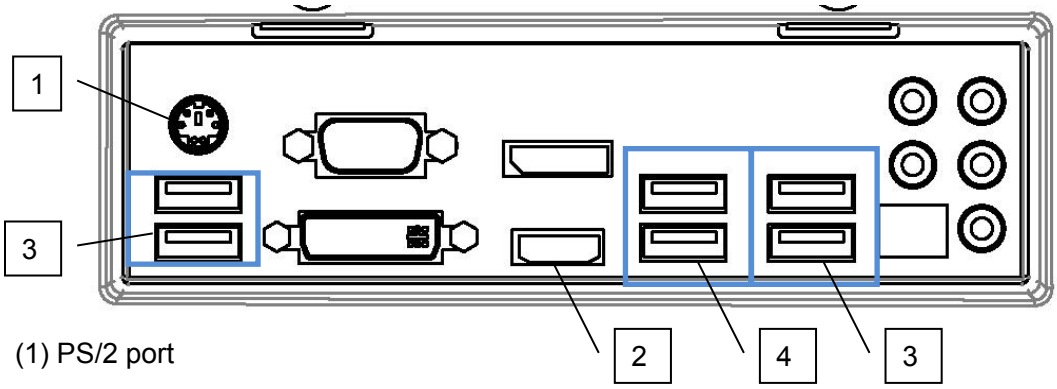
(1) Eye level mark

Adjust the height of the chin rest so that the patient's eyes are aligned with this mark.

(2) Power socket

(3) Fuse holder

Enlarged image of section enclosed in dotted line



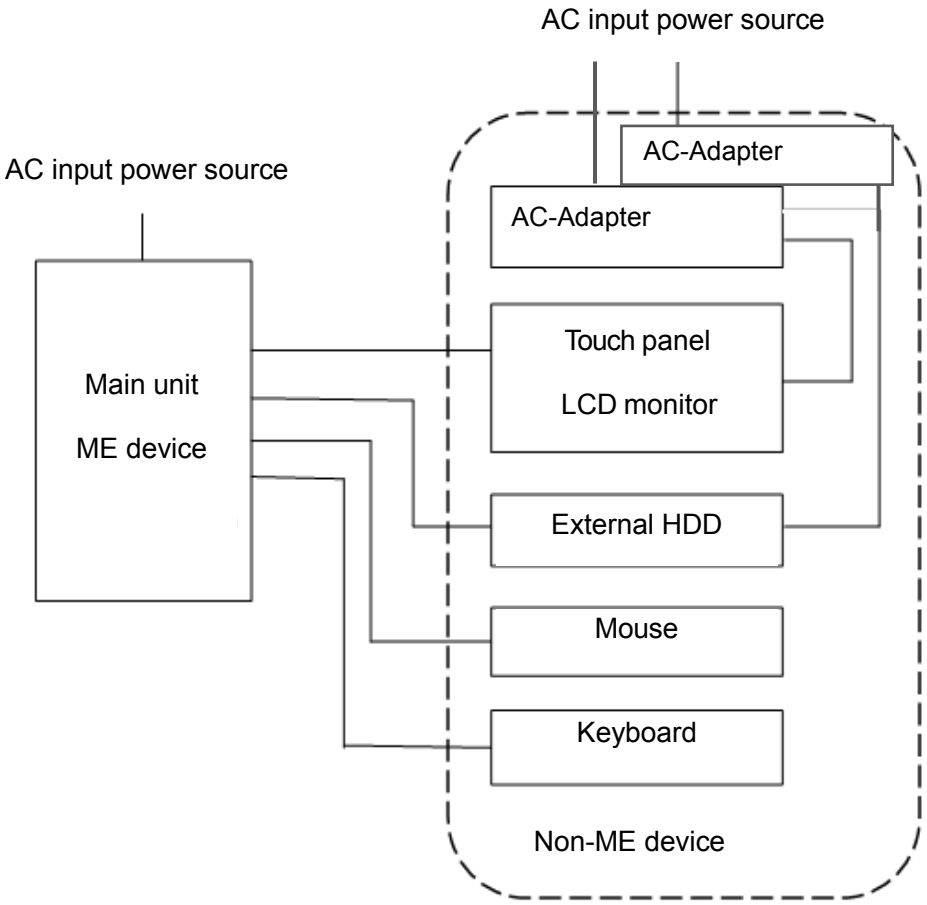
(1) PS/2 port

(2) HDMI terminal

(3) USB 2.0 port

(4) USB 3.0 port

2.5 System connection diagram

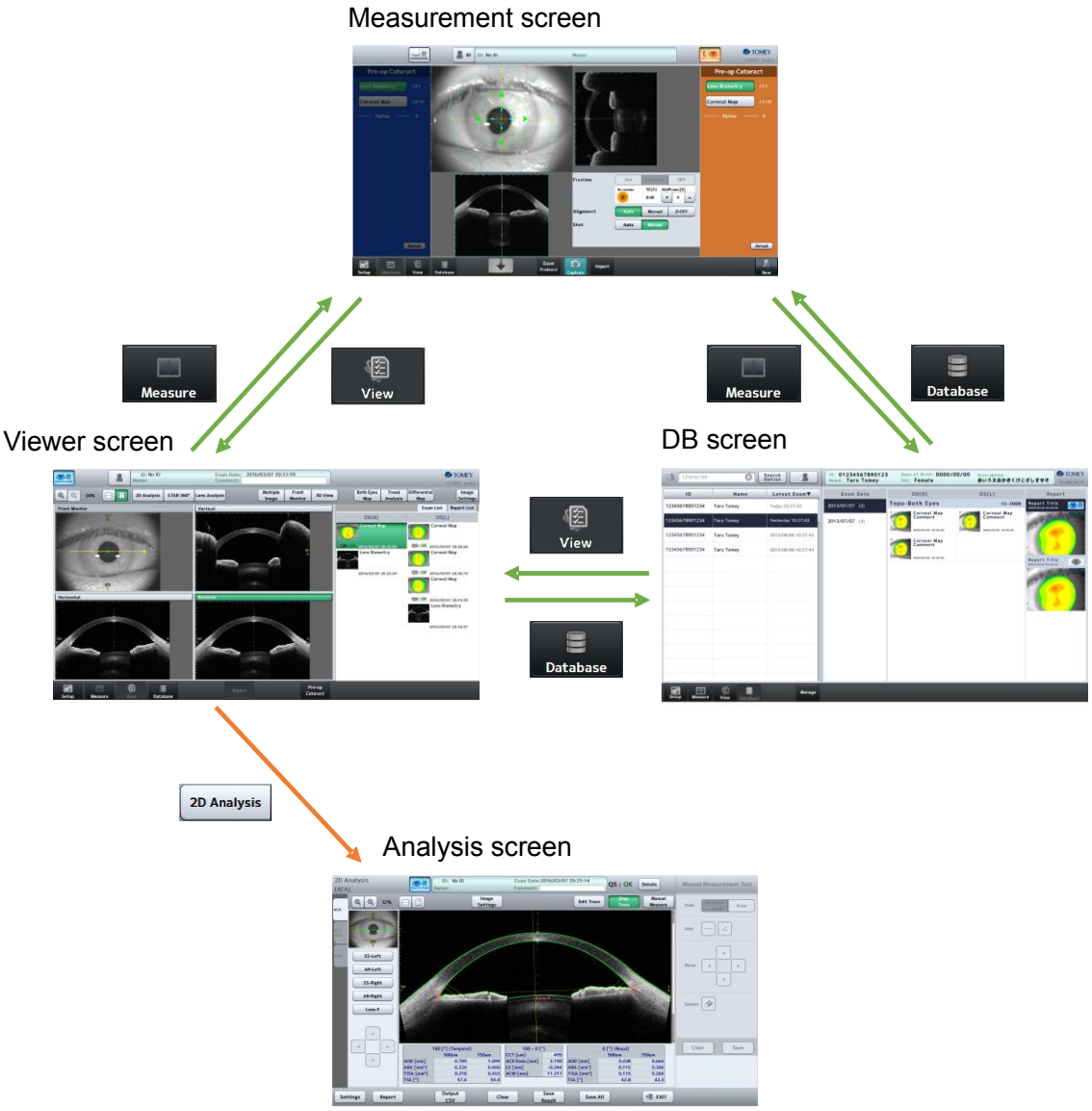


2.6 Screen

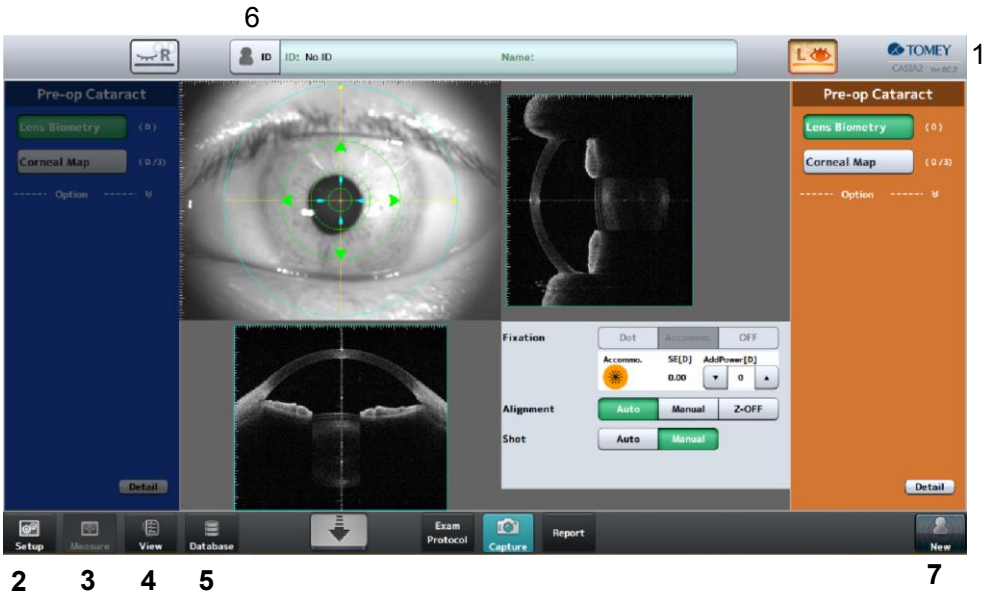
2.6.1 Screen configuration

The CASIA2 has a "measurement screen," "viewer screen" and "database screen." The measurement screen is mainly used for capturing images. The viewer screen is for browsing and analyzing the examination data. The database screen is for editing the patient information or examination data.

Switching main screens (correlation chart)



2.6.2 Common indicators



(1) Version

Displays the software version of this instrument.

(2) “Setup” button

Displays the System Setup screen and allows you to make various settings for the instrument.

(3) "Measure" button

Displays the measurement screen.

(4) “View” button

Displays the viewer screen.

(5) “Database” button

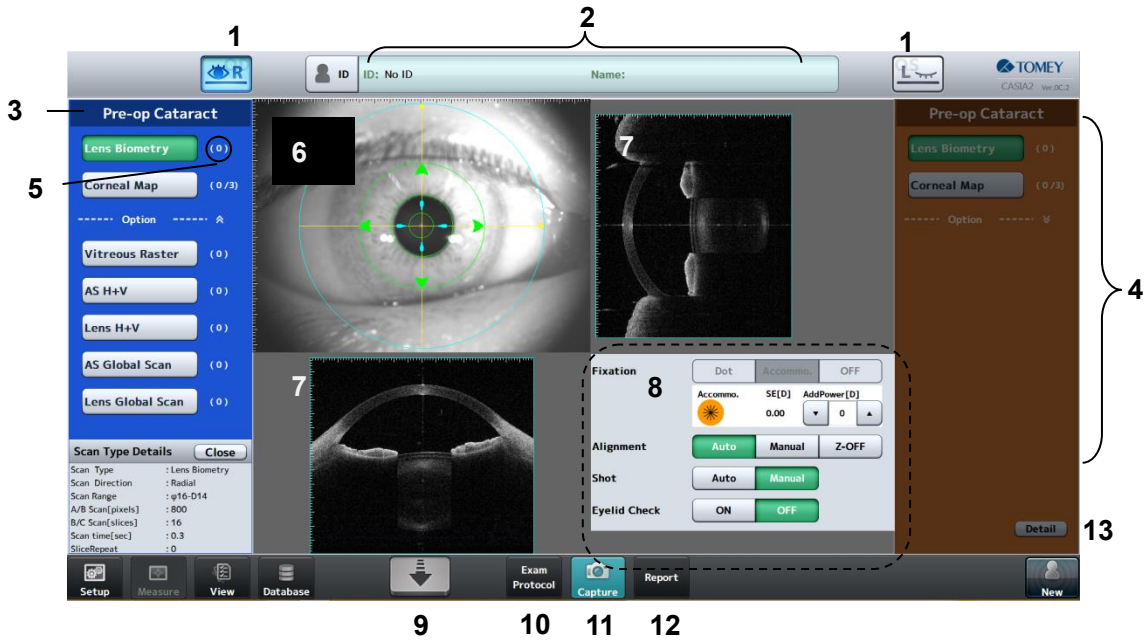
Displays the database screen.

(6) “ID” button

Displays the patient list screen.

(7) “New” button

2.6.3 Measurement screen



(1) Eye selection button

The head moves to the corresponding side when the button is tapped.

(2) Patient information field

(3) Examination protocol name field

(4) Scan type field

Select a scan type for image capture. The selected scan type turns green.

(5) Number of times measurement data is saved

(6) Anterior eye section image field

When the image is tapped, the head moves so that the tapped point comes to the center. The head moves forward when the center of the image is held briefly.

(7) OCT live image field

The head moves along a line drawn on the image.

(8) Measurement settings

(9) Head retract button

The head retracts while this button is pressed down.

(10) “Exam Protocol” button

Displays the examination protocol screen and allows you to select an examination protocol.

(11) “Capture” button

Starts measurement and displays “2.6.4 Preview screen” when measurement is completed. This button changes to a “Stop” button when recording video. Tap the “Stop” button to end recording.



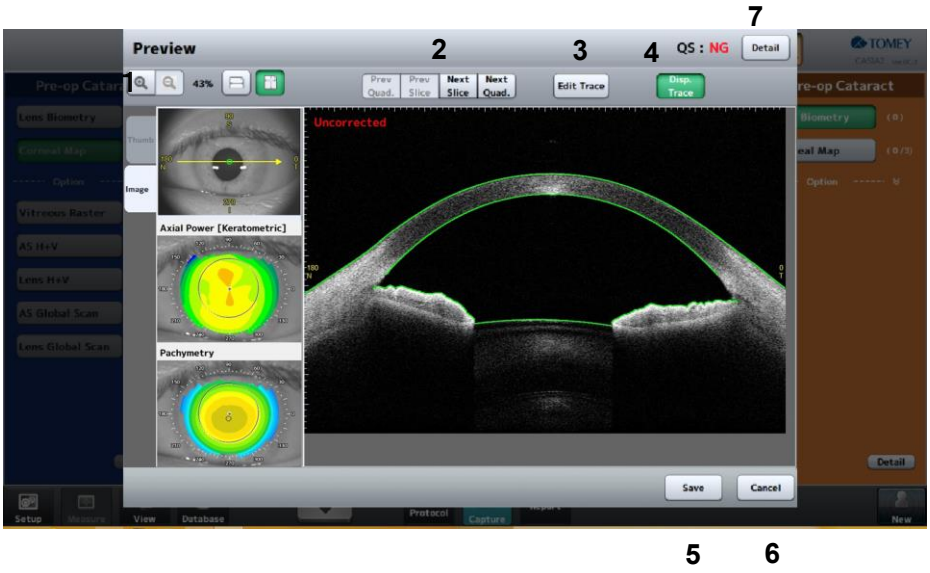
(12) “Report” button

Displays the “2.6.10 Report screen.”

(13) “Detail” button

Displays detailed information of the scan.

2.6.4 Preview screen



(1) Zoom buttons

(2) Slice selection buttons

(3) “Edit Trace” button

Displays the trace correction screen and allows you to correct faulty trace lines.

(4) “Disp. Trace” button

Displays and hides trace lines.

(5) "Save" button

Saves the measurement data and returns to the measurement screen.

(6) "Cancel" button

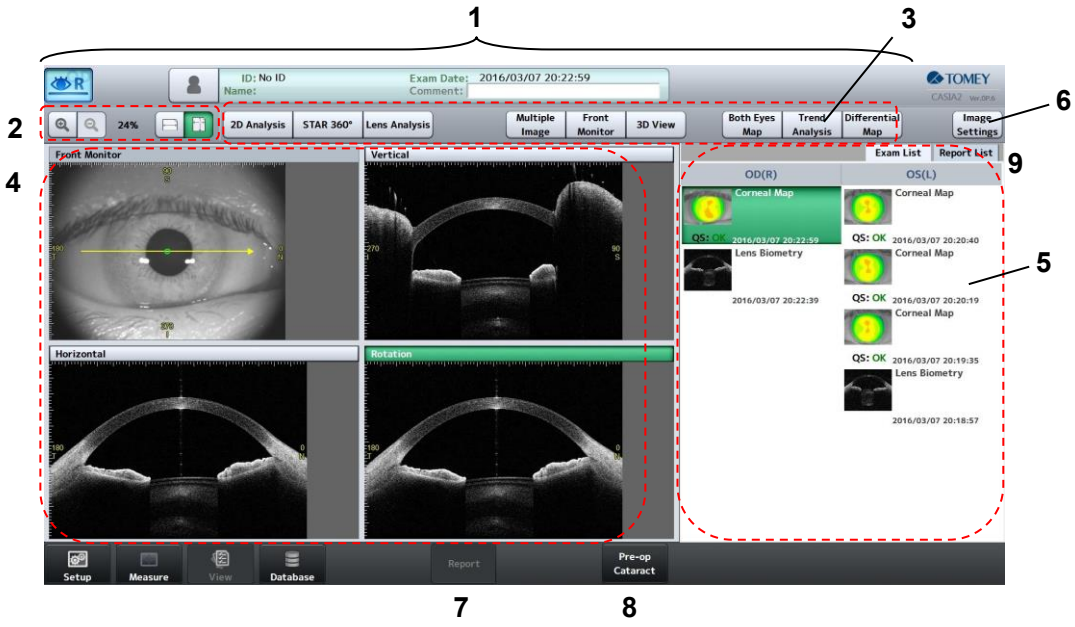
(7) QS field

The QS result of the examination data is shown here. It is recommended to measure again when the result is NG.

2.6.5 Viewer screen

The following operations can be conducted on the viewer screen.

- Browse saved examination data
- Display the report
- Execute various analyses and applications



(1) Examination information field

The information of the patient's eye and examination date is displayed here.

(2) Zoom buttons

(3) Analysis buttons

Displays the corresponding analysis screen.

(4) Image display field

The anterior eye section image and OCT cross section image of the examination data selected in the examination data list are displayed here. Drag the arrow on the image to change the slice of the OCT image. You can also pinch-in/out on the image to zoom in/out.

(5) Examination data list

The examination data of the selected patient is listed here. Tap the examination data to be viewed. For Corneal Map data, the corneal shape analysis screen appears when the examination data is double-tapped. Also, select the "Report List" tab on the upper right corner to recall the report list and check the created report.

(6) "Image Settings" button

Enter settings for displaying an OCT cross section image. Enter settings on the System Setup screen to change the default settings.

(7) "Report" button

Displays the report screen.

(8) Application button

Touching the button displays the corresponding analysis application screen.

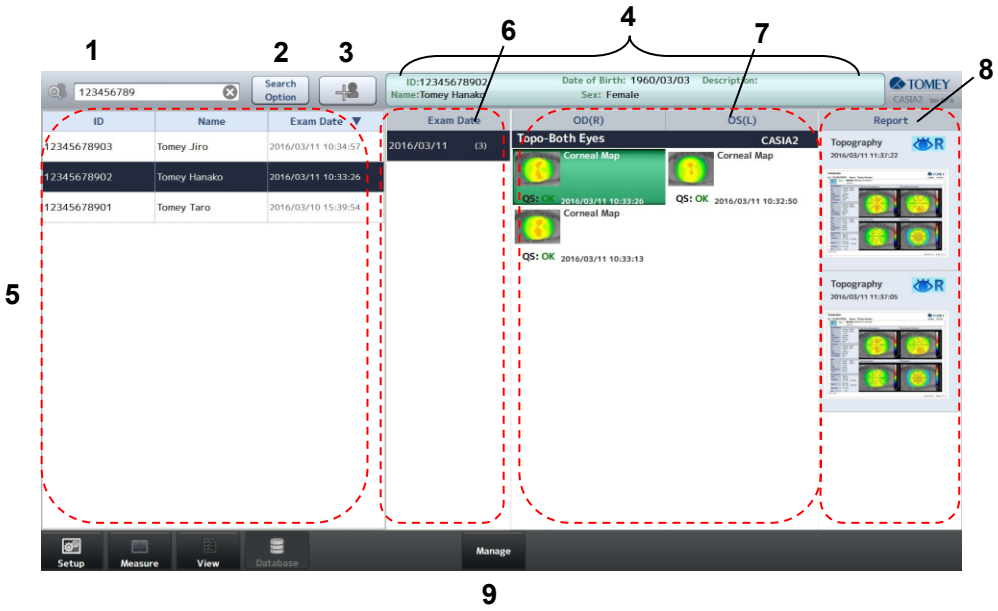
(9) Switch examination data list and report list

Switch between the saved examination data list and report list.

2.6.6 Database screen

The following operations can be conducted on the database screen.

- Browse examination data list
- Edit patient information
- Manage examination data, such as export, import and delete



(1) Patient search field

(2) “Search Option” button

Displays the Search Option screen.

(3) New patient button

Displays the Patient Information screen.

(4) Patient information field

(5) Patient list

(6) Measurement date and time

(7) Examination data list

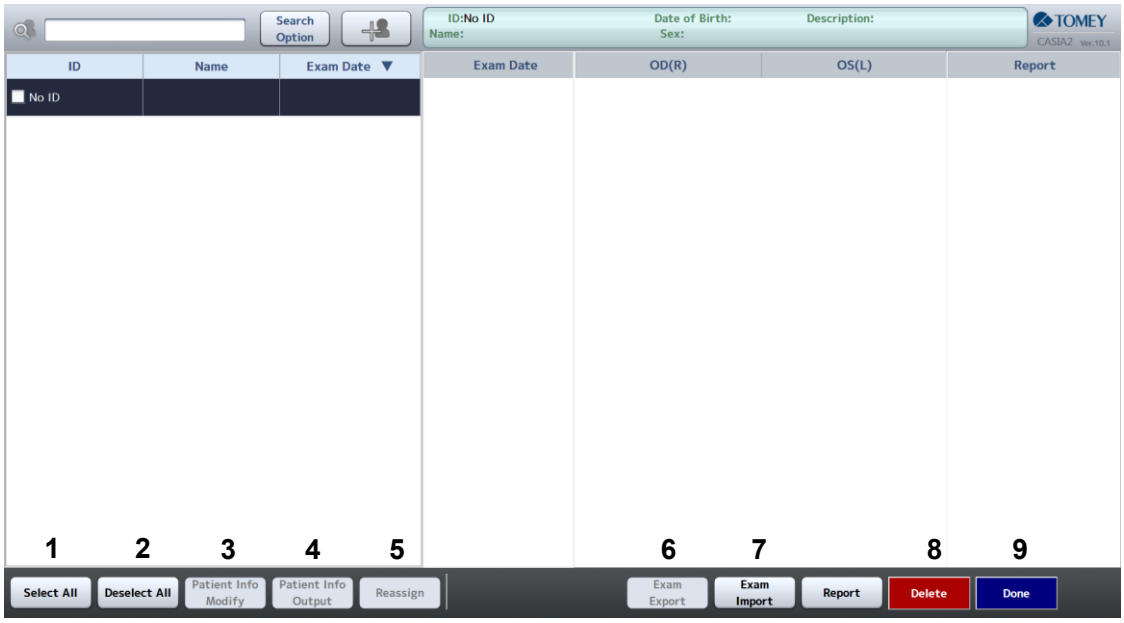
(8) Report list

The list of output reports is displayed here. Double-tap a report to open the Report screen.

(9) “Manage” button

Enters management mode. The patient information and examination information can be edited, or examination information can be output in management mode.

Database screen in management mode



(1) “Select All” button

Enter check marks for all IDs.

(2) “Deselect All” button

Deletes all check marks

(3) “Patient Info Modify” button

Displays the Patient Information screen corresponding to the selected ID.

(4) “Patient Info Output” button

Outputs the patient information corresponding to the selected ID.

(5) “Reassign” button

Displays the patient list screen and allows you to select the patient ID to be moved.

(6) “Exam Export” button

Exports the selected examination data. The screen to select a folder for storage appears.

(7) “Exam Import” button

Lists folders to be imported on the popup screen.

(8) “Delete” button

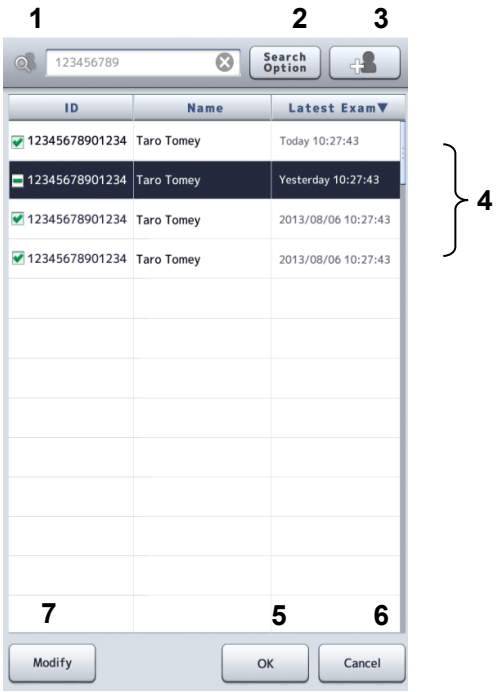
Deletes the selected data. Data is moved to the recycle folder.

(9) “Done” button

Exits management mode and returns to the previous screen.

2.6.7 Patient list screen

The patient list screen appears when the “ID” button is tapped on the measurement screen or viewer screen.



(1) Patient search field

(2) “Search Option” button

(3) New patient button

(4) Patient list

(5) "OK" button

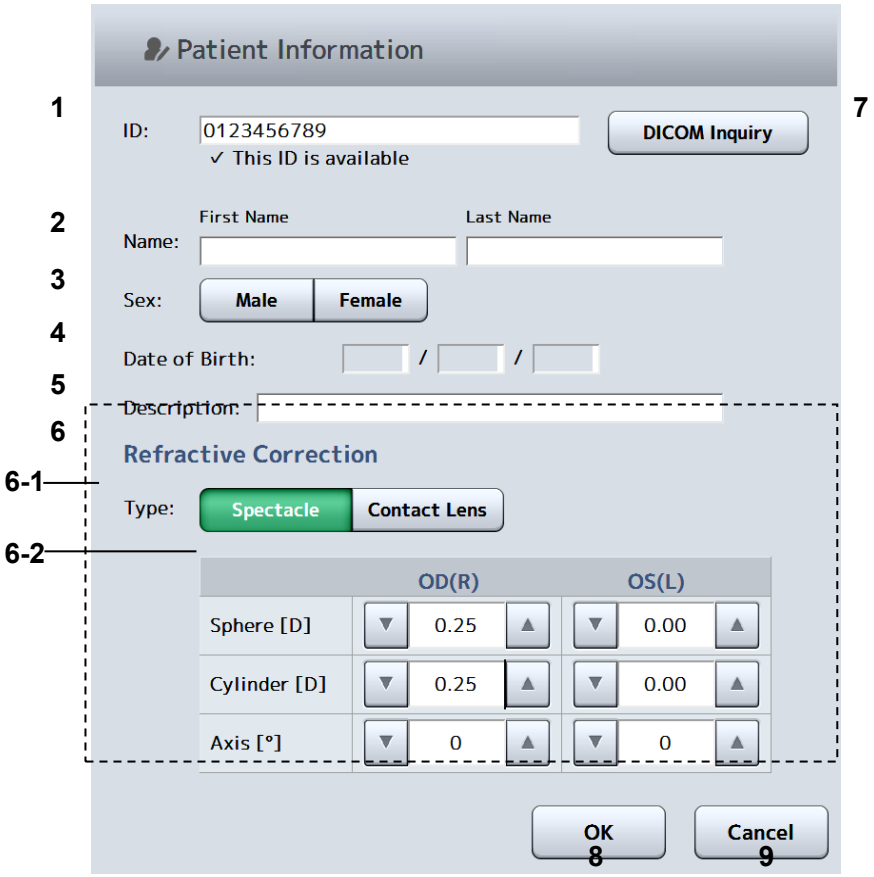
(6) "Cancel" button

(7) “Modify” button

Displays the Patient Information screen and allows you to edit the patient data.

2.6.8 Patient Information screen

The Patient Information screen appears when the ID entered in the patient list is of a new patient and the “OK” button is touched, or when the “Modify” button is touched.



(1) ID field

(2) Name field

(3) Gender selection button

(4) Date of Birth field

(5) Description field

(6) Refractive Correction

6-1: Type selection button: Select the type of refractive correction.

6-2: Value field

(7) "DICOM Inquiry" button

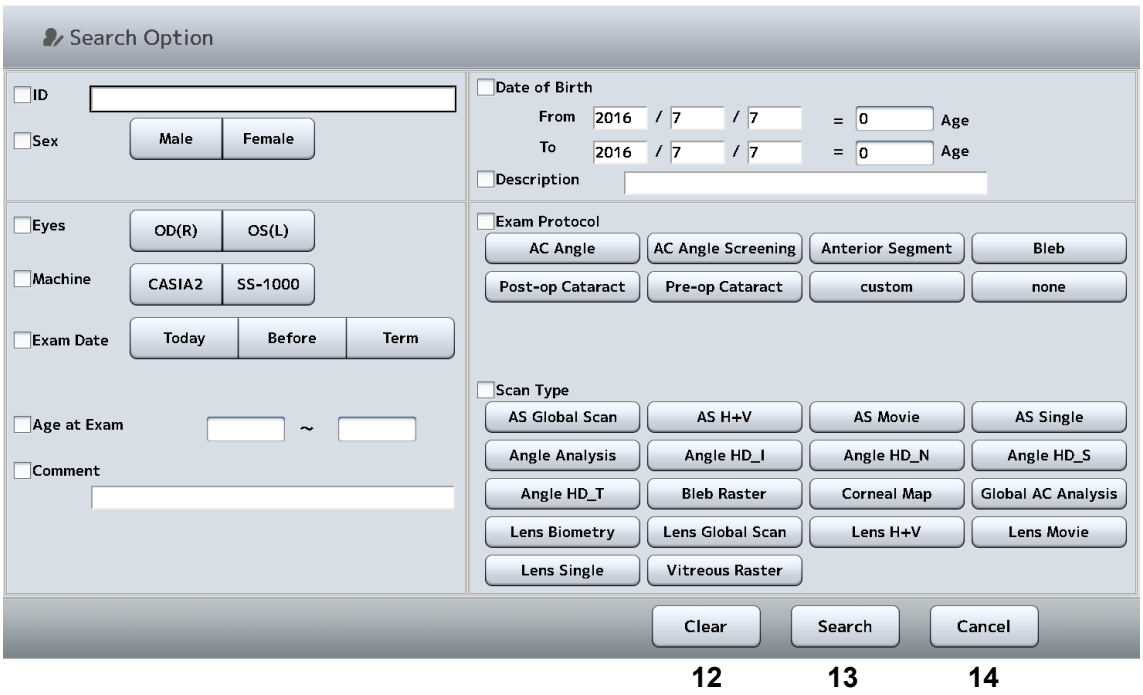
Allows you to select the patient information from the DICOM work list.

(8) "OK" button

(9) "Cancel" button

2.6.9 Search Option screen

When the “Search Option" button is tapped, a refined search using more detailed information is executed and the search result is displayed.



Search condition list

(1) ID

(2) Sex

(3) Date of Birth

(4) Description

(5) Eyes

(6) Machine

(7) Exam Date

(8) Age at Exam

(9) Comment (on examination data)

(10) Exam Protocol

(11) Scan Type

(12) “Clear” button

Deletes all contents entered on this screen.

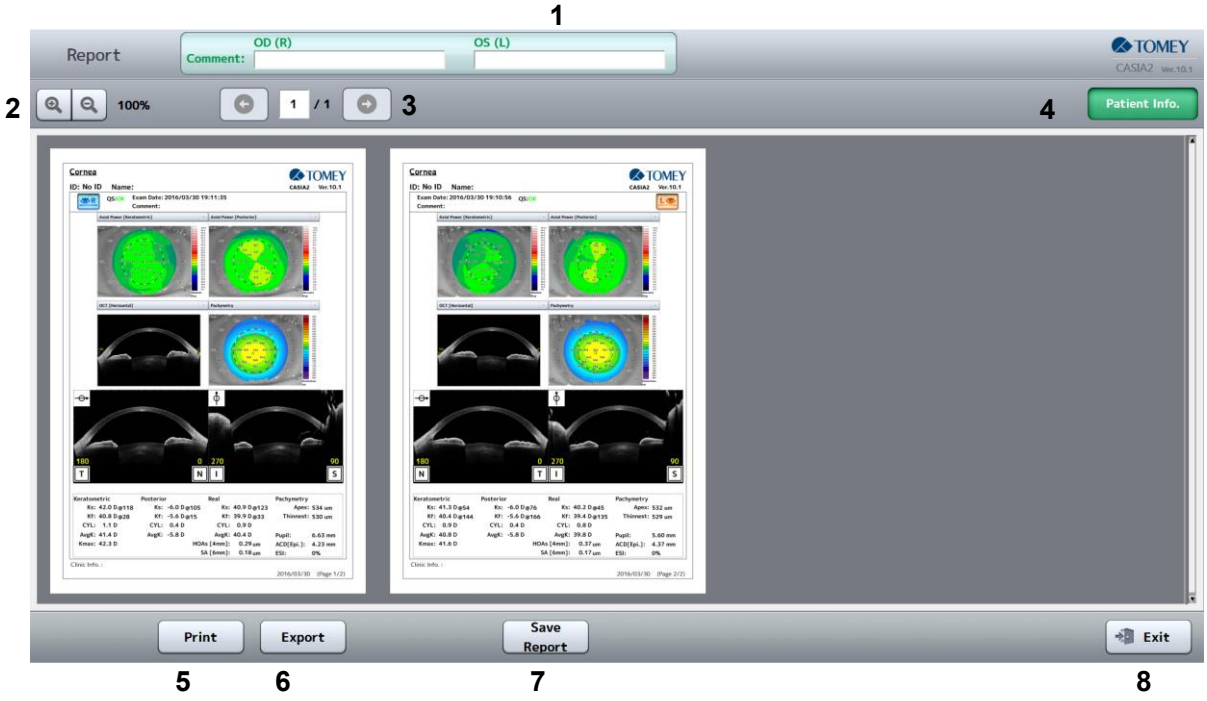
(13) "Search" button

Executes search and returns to the previous screen.

(14) "Cancel" button

Returns to the previous screen.

2.6.10 Report screen



(1) Comment display/entry field

Comments on the examination data are displayed for the right and left eyes.

(2) Zoom buttons

(3) Page buttons

(4) “Patient Info.” button (to display/hide patient information)

(5) "Print" button

(6) “Export” button

Exports the report to the destination set on the System Setup screen.

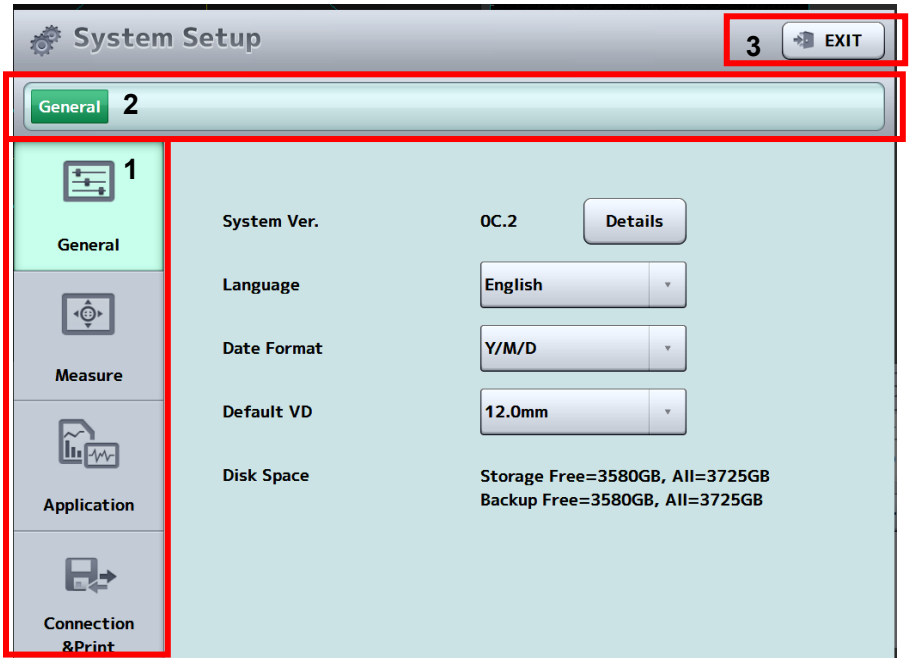
(7) “Save Report” button

(8) “Exit” button

2.6.11 System Setup screen

Enter settings for this instrument on this screen. “System setup” settings are retained even when the instrument is turned off.
System setup consists of 4 major categories.

- General … Language, version information, etc.
- Measure … Capture of images and operation
- Application … Analysis
- Connection & Print … Connection and printing



(1) Menu tab

Displays the corresponding screen.

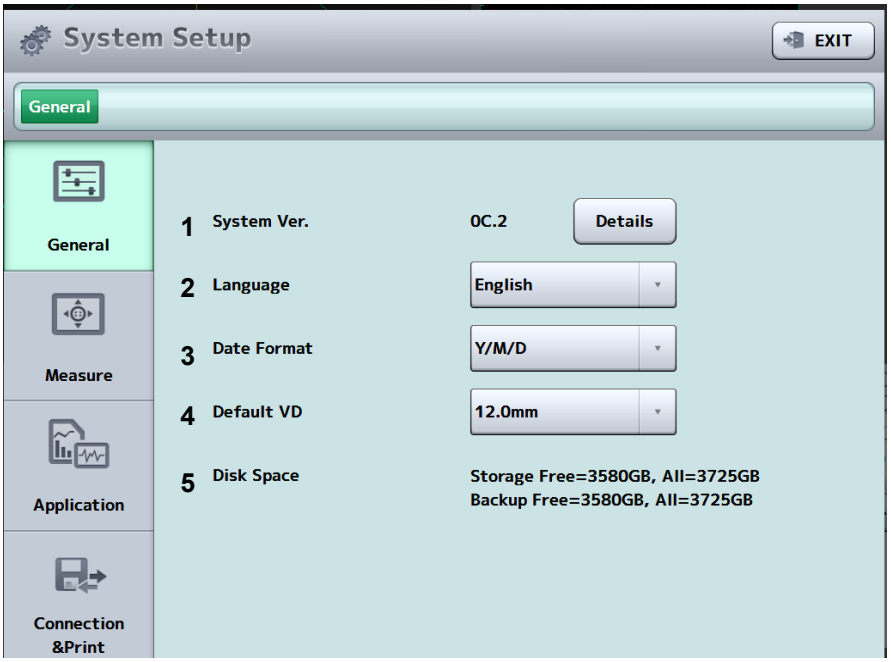
(2) Address bar

The setup screen has a tree configuration. Tap the character to display the corresponding System Setup screen.

(3) “Exit” button

Applies the changes and returns to the previous screen.

a) General



(1) System Ver.

(2) Language (for display)

(3) Date Format

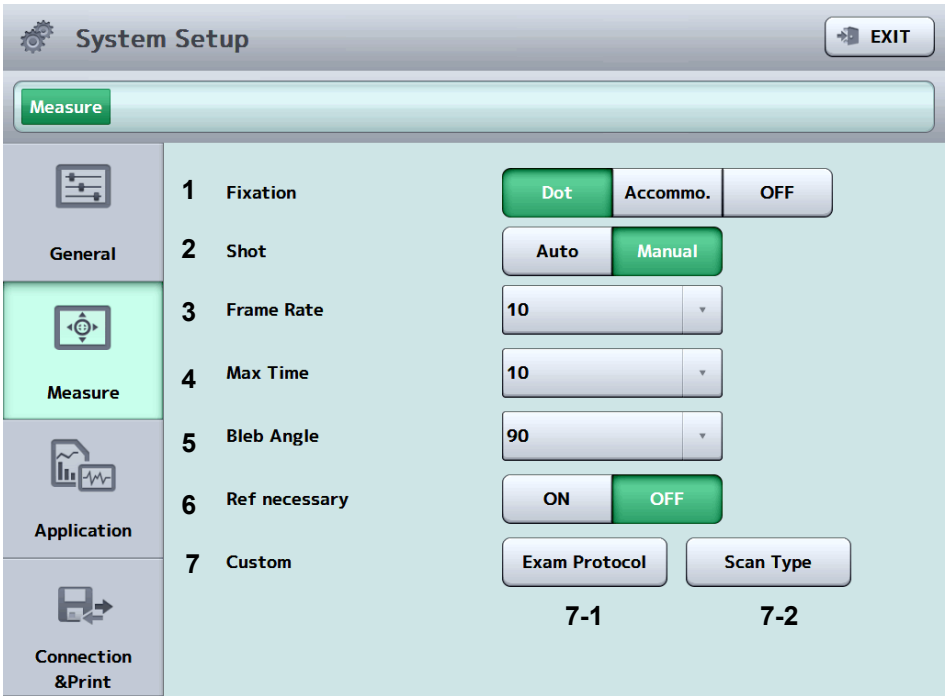
(4) Default VD

Set the vertex distance when using the adjustment load sight-fixing target.

(5) Disk Space

"Free capacity / Total capacity" of the external HDD is displayed.

b) Measure



(1) Fixation

Perform initial settings for the fixation type. This setting will not be applied when the fixation setting depends on the scan type.

(2) Shot

Perform initial settings for the auto shot function. This setting is made when selecting a patient and applicable only when the scan type is Corneal Map, Lens, Biometry or Angle Analysis.

(3) Frame Rate

Set the frame rate of the data in Movie mode.

(4) Max Time

Set the maximum recording time of the data in Movie mode. The available value varies depending on the frame rate setting.

(5) Bleb Angle

Perform initial settings for the scanning direction when the scan type is Bleb Raster.

(6) Ref necessary

Set whether to open the refractive power entry screen when starting Lens Biometry measurement.

(7) Custom

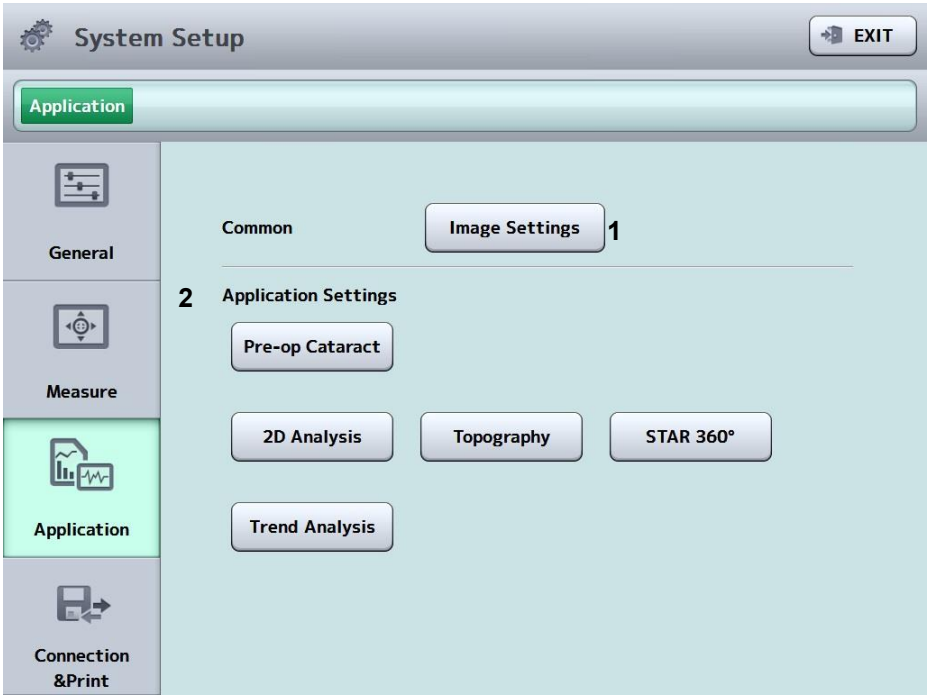
7-1 Exam Protocol

Set the examination protocol to be shown on the examination protocol screen that opens from the measurement screen. In addition, examination protocols can be customized.

7-2 Scan Type

Make custom settings for the scan type.

c) Application



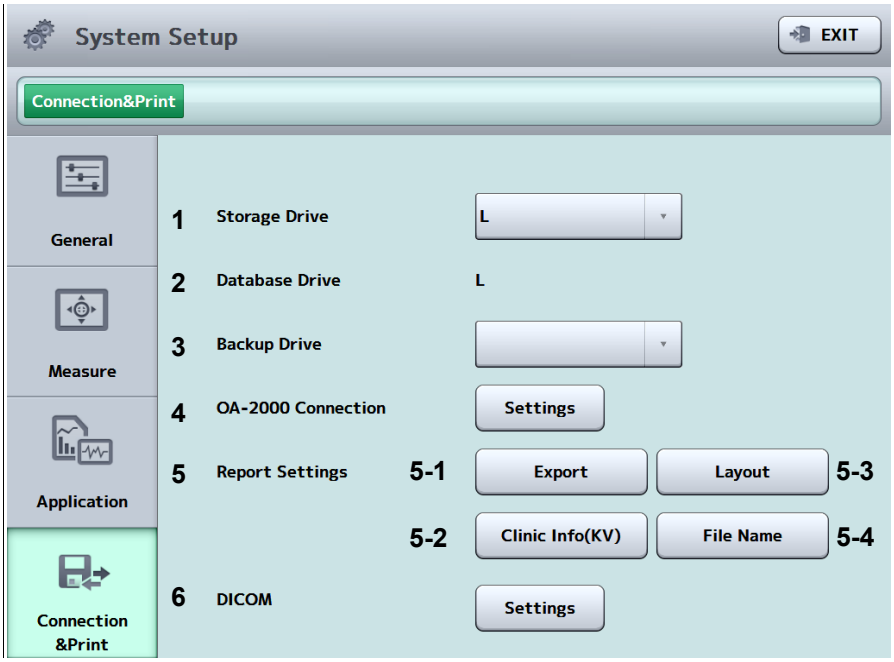
(1) Image Settings

Enter initial settings for displaying OCT images on the viewer screen.

(2) Application Settings

Enter settings for each analysis application.

d) Connection & Print



(1) Storage Drive

Set the drive used to save data.

(2) Database Drive

(3) Backup Drive

Set the drive used for backup.

(4) OA-2000 Connection

Set the IP address and port of the OA-2000.

(5) Report Settings

5-1 Export : Enter settings used to output a report.

5-2 Layout : Enter settings for the layout of the report.

5-3 Clinic Info : Enter settings for displaying the clinic information.

5-4 File name : Set the default file of the report to be output.

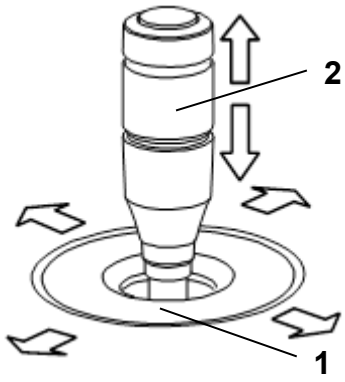
(6) DICOM

Make settings for DICOM communication. Refer to “DICOM Setting Manual" for the setting procedure.

2.7 Operation of the joystick

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

<General operation>



(Fig. 1)

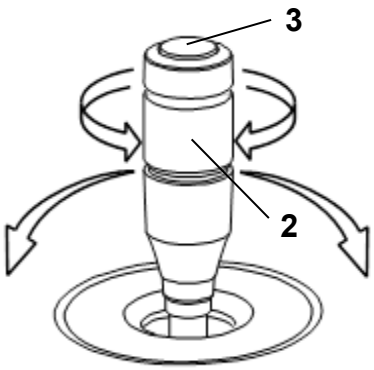
Forward, backward, right, and left

Slide the hand rest (1) in the direction the head 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 measuring head is to be moved.

<Fine operation>



(Fig. 2)

Forward, backward, right, and left

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

Up and down

Turn the up/down ring (2).

Clockwise The head rises.

Counterclockwise The head lowers.

Press the joystick button (3) to start capturing.

2.8 Touch operation

The following touch operations are available on the CASIA2.

A) Tap

Lightly touch and release the screen quickly.

B) Holding

Touch the screen and keep your finger on the screen for 1.5 seconds or longer.

C) Drag

Touch the screen and slide your finger in the desired direction.

Remove your finger from the screen after stopping the motion.

D) Flick

The motion as if brushing dust off the screen is called a "flick." Flick the screen to quickly scroll the patient list or examination data list displayed on the screen.

E) Pinch-in/out

"Pinch-in" is to touch the screen with two fingers and pull them closer together, and is used to shrink the image. Conversely "pinch-out" is to spread your fingers apart on the screen, and is used to enlarge the image.

2.9 Symbols used for marking



Refer to instruction manual.



Power standby



B-type attachment section



Grounding (earth)



Caution



Manufacturer and month of manufacture



“Refer to the instruction manual”
Failure to follow the operating instructions exposed patients or operators to unacceptable risk.

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3. OPERATION PROCEDURES

3.1 Safety precautions

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 electric shock or failure.***
- ***Do not install the instrument in a location where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and result in fire.***



- ***Be sure to transport the instrument with two or more operators. In this case, do not hold the head, chin rest, forehead pad, joystick, or cables. These components are detachable and the instrument may drop, resulting in injuries.***
- ***Install the instrument in a location not subject to direct sunlight, high temperature and humidity, or air containing dust, salt, and/or sulfur. Otherwise, failure or malfunction may occur.***
- ***Install the instrument in a stable, level location free of vibration or mechanical impact. Otherwise, measurement cannot be conducted correctly. Also, the instrument may topple over or fall down, resulting in fire or a serious accident.***
- ***Install the instrument so that the user can use the system under optimal conditions. Carefully connect the devices so that the wiring is not disconnected unintentionally during operation, and does not hinder operation of the instrument.***

3.1.2 Precautions for connecting the power cord



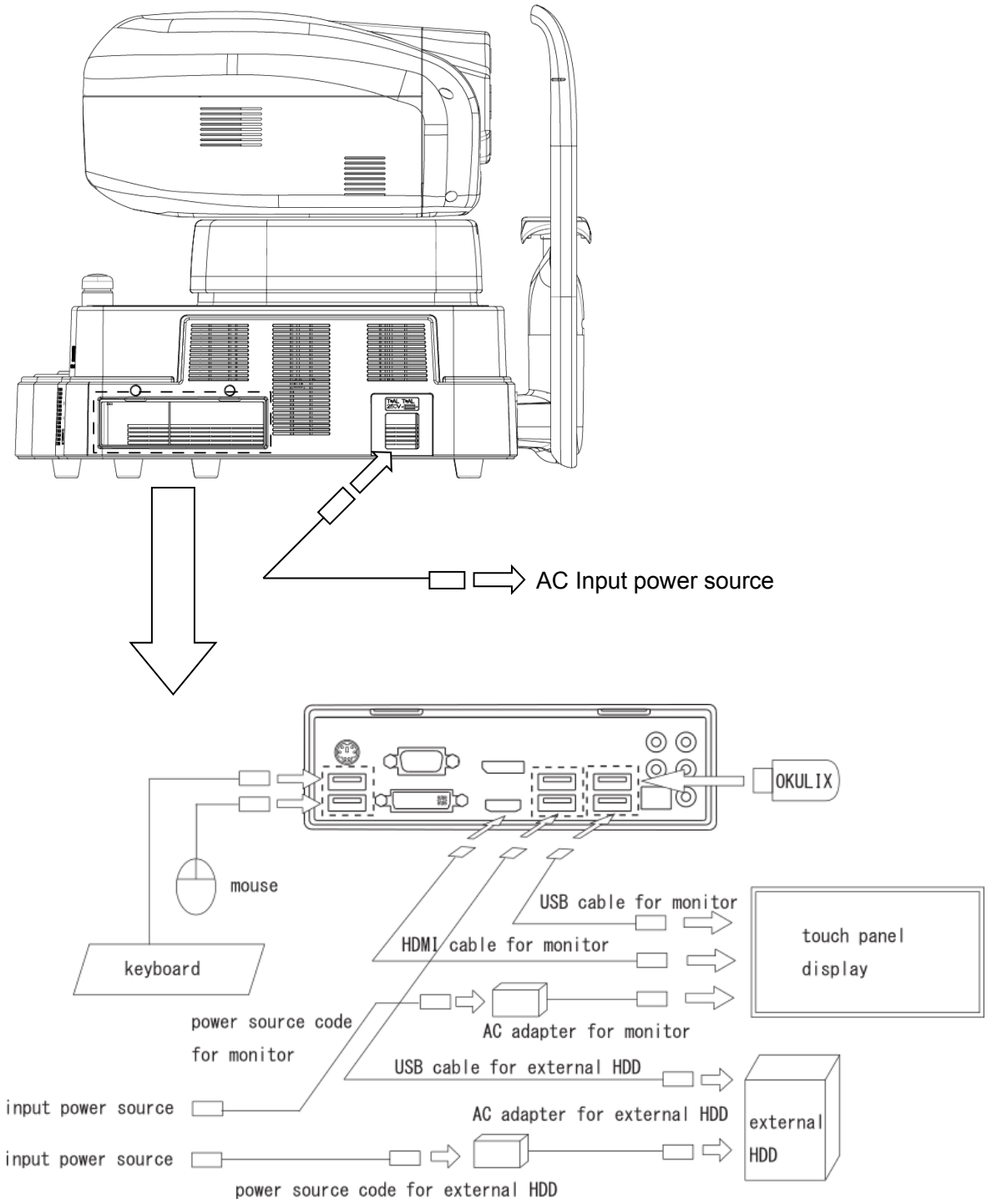
- ***Check the frequency, voltage, and allowable current (or power consumption) of the power source. Otherwise, fire or electric shock may occur.***
- ***Connect the power plug to a grounded 3-pin outlet. Otherwise, a short circuit due to failure of the instrument may result in electric shock.***
- ***Do not place any heavy object on the power cord or compress the power cord. Fire or electric shock may occur.***
- ***Fully insert the power plug into the outlet. Faulty contact, allowing any metal to contact the exposed terminal of the plug, or dust accumulated on the exposed terminal of the plug may result in fire or electric shock.***
- ***The power connector completely isolates the instrument from the commercial power source. If there is a problem with the instrument, turn off the power switch and disconnect the power connector. Install the instrument in a place where this can be performed smoothly.***



- ***The AC adapter for the LCD of the touch panel is different from that for the external HDD. Connect the correct adapter. Incorrect connection may result in failure of the instrument.***

3.1.3 Connecting the power cord and other cables

Connect the power cord and other cables as shown below.



Note Check the color of the mark before connecting to HDD or LCD. Select the correct cable, otherwise the device may break.

3.2 Starting up/shutting down the instrument

a) System startup

1) Press the power button.
2) The startup screen appears and then the measurement screen appears.



b) Closing the system

1) Press the power button. The measurement head automatically moves to the lower dead center, the chin rest moves to the bottom, and then the system closes.
2) Turn off the monitor.

3.3 Measurement

Capture the examination data on the measurement screen.

(1) Entering the patient data

The patient list screen appears when the instrument is started, measurement is newly taken (the "New" button is touched briefly) or the ID button is touched, and allows you to select a patient. Refer to "2.6.7 Patient list screen" for screen details.

Note

- ***Check the refractive power correction value when "Lens Biometry" is selected for the scan type. Measurement accuracy may decrease as an adjustment is applied for the patient's eye.***

(2) Selecting examination protocol

When the patient is selected, the examination protocol screen appears and allows you to select an examination protocol. When an examination protocol is selected, the scan type list required for examination appears on the measurement screen.

(3) Patient's eye height adjustment

CAUTION

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

Have the patient place their chin on the chin rest. Adjust the chin rest height so that the height of the corner of the eye is aligned with the eye level mark.
Press the "UP" button on the side of the joystick to raise the chin rest; or the "DOWN" button to lower the chin rest.
When the patient's eye height is adjusted, lightly press the patient's forehead against the forehead pad to secure the patient's position.

(4) Selecting an eye
Tap the eye selection button to move the head to the position of the patient's eye.

(5) Fixation target instructions
Ask the patient to look at the fixation target. The type of fixation target can be changed in the fixation setting field. Settings may not be changed for some scan types.

(6) Alignment



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



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

shortage of reflection light due to deformation and/or inflammation of the cornea. In this case, use manual mode. In this case, conduct alignment manually.

Align the patient's eye with the measurement position, checking the front image of the anterior eye section and OCT image.

(7) Capturing

After alignment of the section to be measured is completed, press the capture button to start capturing an image. The preview screen appears after images are captured. In auto shot mode, capturing automatically starts when the focus is aligned with the corneal vertex.

(8) Checking/Saving measurement data

Check the examination data on the preview screen. When the examination data influences the analysis result, "NG" appears in the reliability (QS) field. Carefully check the examination data and save it or recapture another image.

Note

- ***Fully examine the measured data for tracing results. In particular, if the difference between measurement values for the left and right eyes is significant or any problem is found on the anterior chamber during the preliminary examination, check the tracing and/or reliability on the check screen. If the measurement result is not conclusive, review the inspection result by performing measurement again or performing another inspection.***

- ***It may be difficult to trace the border when capturing an image of an eye with opacity or malformation such as corneal disease, shallow anterior chamber, aphakic eye, pseudophakic eye or dense cataract eye.***

- ***The following artifact may appear on the OCT image, but this does not indicate any failure.***

- ***When the measurement light enters the cornea, sclera, conjunctiva or intraocular lens perpendicularly, a bright line appears in the depth direction.***
- ***Ghost noise may occur in areas with strong reflection such as cornea, sclera, conjunctiva and iris.***

(9) Change the scan type listed in the scan type list and repeat the steps.

(10) Output

When all measurements are completed for the scan types listed in the examination protocol, tap the “Report” button to output the report. The sections required for the examination are automatically analyzed and the Report screen appears. The data can be saved and output from the Report screen.

Note

- ***When using the data taken by this instrument for diagnosis or determination of treatment, proceed carefully by taking measurements multiple times and/or conducting other examinations.***

- ***When using this instrument to select intraocular lenses, thoroughly determine the selection by also examining cataract surgery methods and performing other inspections. If incorrect measurement data is used to select intraocular lenses, further surgery might be required.***

- ***When using the data taken by this instrument for refractive correction surgery, thoroughly determine the selection by also examining surgery methods and performing other inspections. Refractive correction surgery conducted according to incorrect measurements or analysis results may result in further surgery or severe complication such as keratoectasia.***

4. TECHNICAL INFORMATION

“Measurement principles”

This instrument adopts the Fourier domain method that splits the light from the light source and directs that light toward the reference mirror (reference light) and toward the patient’s eye (measurement light) using the interferometer at the head of the measurement unit, and then matches the reflected light and detects interference signals of each waveform (spectrum interference signal).

Spectrum interference signals change according to the difference in time required for the reference light and measurement light to reach the detector. Using this change, the instrument measures the depth of the patient’s eye. Specifically, the instrument calculates the difference in time needed for the reference light and measurement light to reach the detector and converts the result to the depth data by applying a Fourier conversion to the spectrum of interference signals.

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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 are not 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 instructions 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, maintenance by persons other than personnel duly authorized by Tomey, nor to a product whose serial number or batch number is removed, altered or effaced.

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

Note

- ***This instrument includes a Windows® personal computer, but do not perform the following. Otherwise, the operation and performance of the instrument, data transfer, etc. may not be conducted correctly.***

  - Update of Windows®

- Installation of resident type applications such as security software

- Installation of other applications or driver software that we do not specify

- Change in folder configuration or data file by operating Windows®

- Creation of Windows® user account

- Change in settings that may affect the performance of Windows® (power saving setting etc.)

We shall not be held responsible for any problems if it is recognized that any of the above actions has been performed.

- ***If Windows® is updated or security software is installed for an unavoidable reason, pay extreme attention and take measures such as making a restore point of the system in advance so that the system can be restored to the state before the change if any problem occurs.***

- ***Failures may occur if the personal computer in CASIA2 is infected with a virus. When connecting a network (wired/wireless), external storage media (USB memory, CD-ROM), etc., pay extreme attention such as by scanning the drive to be connected beforehand.***

  We shall not be held responsible for any failures caused by virus infection during the use of the instrument.

- ***"Back-up" is to make a copy of data in external storage media (USB memory, hard disk, CD-ROM) in order to protect the saved data such as measurement results.***

It is recommended to back up the saved data periodically in external storage media (USB memory, hard disk, CD-ROM) as daily maintenance.

The back-up data can minimize the damage if the data is destroyed or deleted due to unexpected problems or accidents such as mis-operation, shocks occurring to the main unit or storage media containing the saved data, damage to the hardware due to dropping, lighting and virus infection.

We will not provide any warranty coverage for the lost data if the saved data is destroyed or deleted due to problems.

5.2 Operation life

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

5.3 Inspection

Note

- ***When there is a problem, appropriate OCT images may not be obtained. Contact Tomey or your local distributor immediately for repair.***
- ***When measuring the imitation eyes, check that there is no dust or stain on them.***

Check that the lens in the measurement window on the patient's side is clean and free of damage. *If the lens is contaminated or damaged, measurement may not be performed correctly. Perform measurement by using the model eyes provided in the package in order to inspect these points.* (Refer to "5.3.1 Calibration checks.")

Be sure to inspect the items described above before starting the inspection for the day.

Turn off the instrument and relevant accessories, and unplug the instrument and plugs of all the AC-Adapters before conducting maintenance and inspection with the outer cover of the accessory opened.

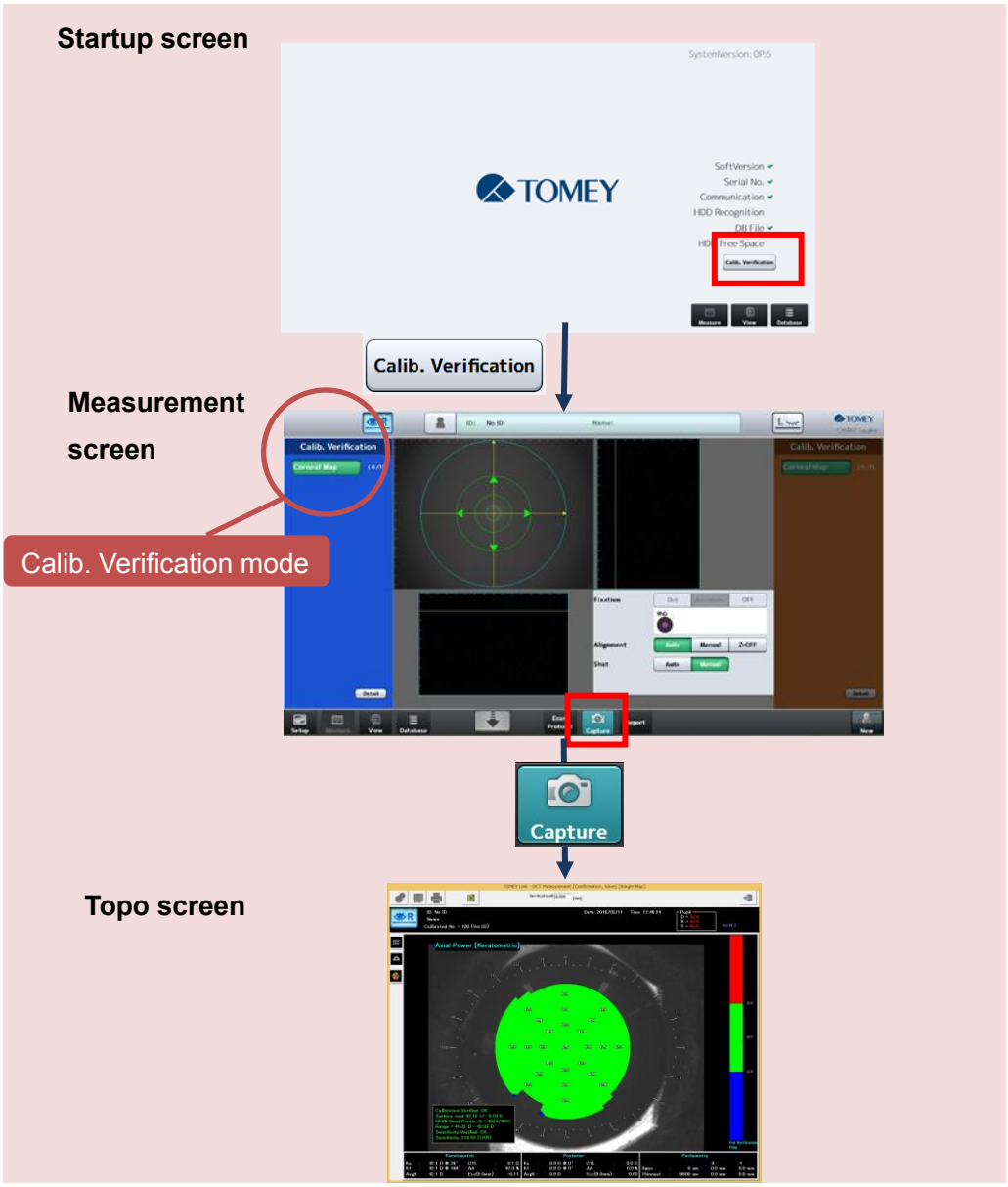
5.3.1 Calibration checks

You may check calibration conditions for corneal shape analysis and various types of scans. Always use the model eyes provided in the package for calibration.

Follow the procedures below for calibration checks.

1) Click the "Calib. Verification" button on the startup screen to enter verification mode.
2) Measurement screen
   Measure the model eyes provided in the package using the "Corneal Map" scan type.

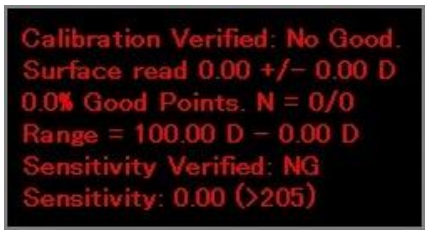
3) Measure the model eyes provided in the package using the "Corneal Map" scan type. (Refer to "3.3 Measurement.")



5.3.2 Results check



(Fig.1)



(Fig.2)

1) Analysis is performed automatically. If calibration has been performed correctly, the message “Calibration Verified: OK” appears. (Fig.1) If the error message “Calibration Verified: No Good” (Fig.2) appears, check that the model eye is not dirty or damaged, and perform measurement again. If the error message “No Good” still appears, contact Tomey Corporation or your local distributor.

5.4 Routine maintenance



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

Note

- ***Do not use organic solvents such as thinner, benzene, or acetone to clean the instrument and accessories. These solvents may damage the surface of the instrument.***
- ***Disconnect the power cord and place the dust cover over the main unit when the instrument is not in operation for 1 month or longer.***
- ***Do not touch the optical parts of the measurement window, etc. and keep these parts free from dust. Fingerprints and dust will affect measurement accuracy.***
- ***Place the dust cover over the main unit when not in use.***

5.4.1 Forehead pad and chin rest

Note

- ***Before starting measurement for a new patient, gently wipe, without rubbing, sections that patients touch directly, such as the forehead pad and chin rest, with a cloth dampened with alcohol.***

5.4.2 Exterior

When the instrument or accessories get dirty, wipe them with a soft, dry cloth. When it is very dirty, clean it using a well wrung cloth dampened with diluted neutral detergent, and then wipe it with a dry cloth.

Note

- ***Spray glass cleaner onto a soft cloth to clean the instrument and the associated monitor.***

5.5 Replacing consumables

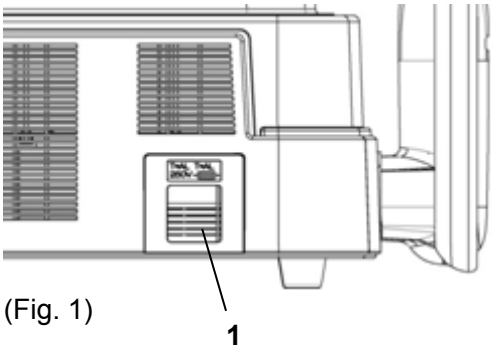
5.5.1 Fuses

WARNING

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

Note

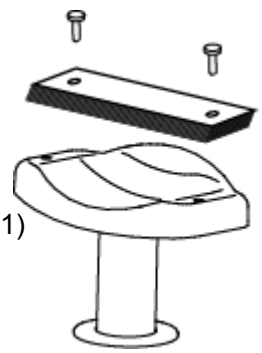
- ***Use fuses of the type indicated on the side of the fuse holder. Always replace two fuses together. Using another type of fuse may result in failure or fire.***
- ***When the instrument does not work correctly after fuses have been replaced, there may be other causes of the problem. Turn off the instrument immediately and contact your local distributor.***



(Fig. 1)

1) Turn power off and disconnect the power plug from the outlet.
2) Disconnect the connector of the power cord from the outlet.
3) Insert a flat screwdriver into the groove of the fuse holder (1) under the power terminal and remove the holder case.
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) 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.

5.6 Storing



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



- ***Do not store the instrument in a location where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and result in fire.***
- ***Do not hold the head, chin rest, forehead pad, joystick, or cables when moving this 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 temperature and humidity, or air containing dust, salt, and/or sulfur. Otherwise, failure or malfunction may occur.***
- ***Store the instrument in a stable, level place free of vibration or mechanical impact. Otherwise, measurement cannot be conducted correctly. Also, the instrument may topple over or fall down, resulting in fire or a serious accident.***

Note

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

5.7 Disposal

Note

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

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6. TROUBLESHOOTING

Check the following first if you encounter any problems. If the problem is not solved even after checking the applicable item listed below, contact your local distributor.



- ***Do not remove the cover of the instrument. Otherwise, direct exposure to high voltage sections may occur.***

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 your local distributor to request inspection and/or repair. Extracting the log data can be helpful. Refer to "6.2 Extracting log data."***
- ***This instrument includes a Windows® personal computer, but do not perform the following. Otherwise, the operation and performance of the instrument, data transfer, etc. may not be conducted correctly.***

  - Update of Windows®
  - Installation of resident type applications such as security software
  - Installation of other applications or driver software that we do not specify
  - Change in folder configuration or data file by operating Windows®
  - Creation of Windows® user account
  - Change in settings that may affect the

performance of Windows® (power saving setting etc.)
We shall not be held responsible for any problems if it is recognized that any of the above actions has been performed.

- ***If Windows® is updated or security software is installed for an unavoidable reason, pay extreme attention and take measures such as making a restore point of the system in advance so that the system can be restored to the state before the change if any problem occurs.***

- ***Failures may occur if the personal computer in CASIA2 is infected with a virus. When connecting a network (wired/wireless), external storage media (USB memory, CD-ROM), etc., pay extreme attention such as by scanning the drive to be connected beforehand.***
  We shall not be held responsible for any failures caused by virus infection during the use of the instrument.

- ***"Back-up" is to make a copy of data in external storage media (USB memory, hard disk, CD-ROM) in order to protect the saved data such as measurement results.***
  It is recommended to back up the saved data periodically in external storage media (USB memory, hard disk, CD-ROM) as daily maintenance.
  The back-up data can minimize the damage if the data is destroyed or deleted due to unexpected problems or accidents such as mis-operation, shocks occurring to the main unit or storage

media containing the saved data, damage to the hardware due to dropping, lighting and virus infection.

We will not provide any warranty coverage for the lost data if the saved data is destroyed or deleted due to problems.

6.1 Troubleshooting

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

Cause 1 Problem with the power plug

Solution Check that the power plug is firmly connected to the main unit and outlet. Check that there is no problem with the power cord, such as cracks or tears.

Cause 2 Power is not supplied.

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

Cause 3 Faulty fuse

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

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

Cause 1 The power setting of Windows® is set to “Turn off the display” (the display is automatically turned off when not operated for a specified time).

Solution Touch the monitor screen. Alternatively, move the mouse or press a key on the keyboard.

- Error code “W805 (0501)” occurs on the CASIA2 startup screen.

Cause 1 The external HDD is not connected correctly.

Solution Verify that the USB cable is correctly connected.

Solution Check that the external HDD is turned on.

- Error code “W805 (0401)” occurs on the CASIA2 startup screen.

Cause 1 There is not enough available storage space on the external HDD.

Solution Another external HDD needs to be added. Contact your local distributor.

●Error of code “R806(0201)” occurs on the preview screen after capturing.

Cause 1 The power setting of Windows® is set to “power saving mode.”

Solution Change the power setting of Windows® to “high performance” and turn power on again.

Cause 2 Application other than CASIA2 is activated.

Solution Close or uninstall the applications other than CASIA2, and turn power on again.If a resident type application such as security software is in operation, turn off the setting while the instrument is operated.

●CASIA2 does not operate correctly.

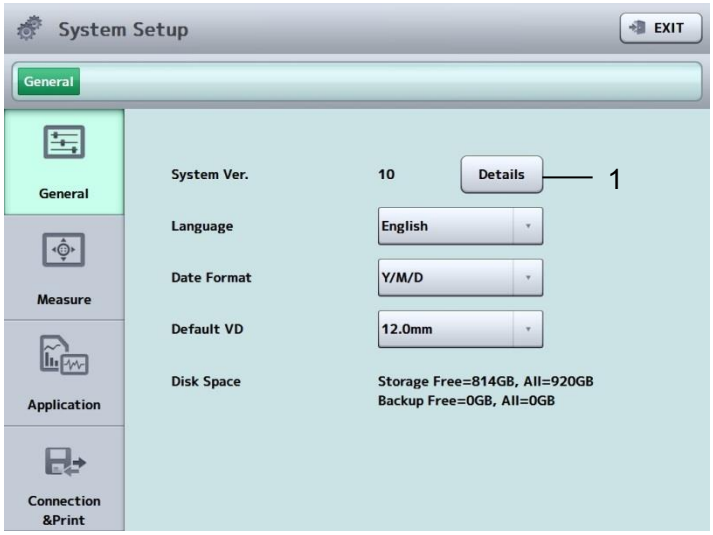
Cause 1 The printer connection cable is faulty.

Solution Check that the printer connection cable is firmly connected to the personal computer and printer.
Or check that the cable is not damaged.

Cause 2 Printer driver error

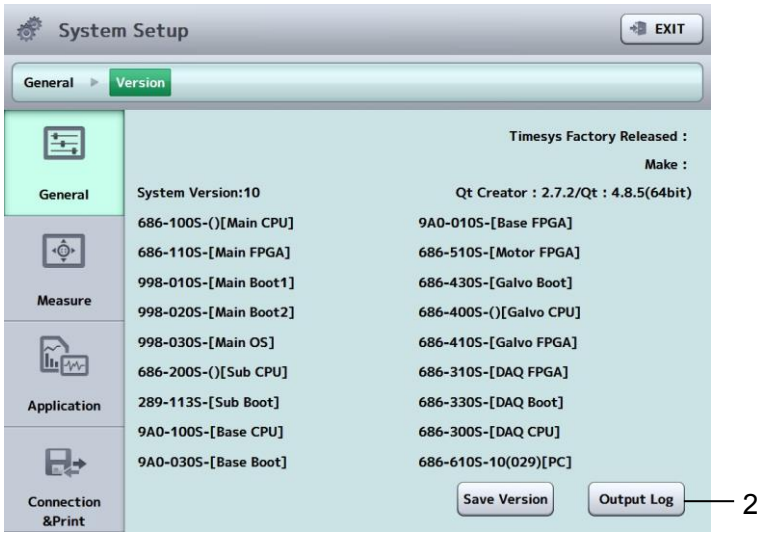
Solution Check that the Windows® printer driver selected on your personal computer is suitable for the printer connected. Select the correct printer driver.

6.2 Extracting log data



(Fig.1)

1) Open the “General” tab on the System Setup screen and tap the “System Version” button (1).



(Fig. 2)

2) The version information details are displayed. Tap the “Output Log” button (2).

3) The confirmation screen listing the log data opens on the desktop. Tap the “OK" button.

4) A “TomeyLog” folder is created on the desktop. Submit the data in this folder to us.

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7. CONSUMABLES AND OPTIONAL EQUIPMENT

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

- Chin rest paper (100 sheets/set)

- Fuse (2) (250 VAC, T2.5 AH)
  Specify the fuse type as "Fuse for CASIA2."

- External HDD
  Specify the HDD type as "External HDD for CASIA2."

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8. SPECIFICATIONS

8.1 Specifications

8.1.1 Main unit

● Resolution	Axial (Depth)	10μm or less (in tissue)
	Transverse	30μm or less (in tissue)
● Scan speed	50,000 A scans/second	
● Scan Range	Depth	13mm
	Radial	16mm in diameter
	Transverse	Raster: 12 x 12 mm
● Light source	Type of light source	Swept Laser Source
	Center Wavelength	1310nm
	Output power less than	6mW
● Dimensions and weight	530(W) x 560(D) x 455(H)mm, Approx. 33kg	

8.1.2 Power source

● Voltage	100V AC -240V AC
● Frequency	50/60Hz
● Power consumption	170VA

8.2 Energy information

Measurement light source

- Maximum power 6mW
  Class 1 Laser Product (IEC60825-1: 2007)

8.3 Operating environment

Operate the instrument under the following environmental conditions.

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

Store the instrument under the following environmental conditions.

- Temperature -10°C ~ +55°C
- Humidity 10 ~ 95%

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

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

8.4 Classification

Protection against electrical shock	Class1 ME equipment
Applied parts	B applied parts (Forehead pad, Chin rest)
IP Code	IPX0
Mode of Operation	Continuous operation

8.5 Declaration of Conformity to EMC



- ***When using specified accessories or cables excluding internal parts sold as repair parts of TOMEY Corporation, electromagnetic emission of the CASIA2 may increase or electromagnetic immunity may decrease.***
- ***When using handheld or portable communication equipment, locate it more than 30cm(12inches) away from the CASIA2. It may degrade the performance of the CASIA2 if the equipment is located closer.***
- ***Do not use the CASIA2 adjacent to or stacked on other equipment. If it needs to be adjacent to or placed on other equipment, it must be confirmed that CASIA2 operates correctly in such location.***



- ***The CASIA2 falls under Group 1, Class B according to EN 55011(CISPR 11). This means that the CASIA2 does not generate RF energy intentionally in the form of electromagnetic irradiation, inductive coupling and/or capacitive coupling for processing of materials or inspection/analysis, and that it is suitable for use in facilities directly connected to a low-voltage power network that supplies power to general household facilities and buildings used for home use.***
- ***The CASIA2 can be used in a specialized health care facility such as hospitals and clinics (except anywhere near the source of a strong EMI) and a general commercial facility such as eye glasses stores.***
- ***The CASIA2 requires special attention for EMC and needs to be installed, serviced and used based on the following information.***
- ***Do not use cables other than those provided or specified by TOMEY Corporation.***
- ***The person who connects additional equipment to the signal I/O section as part of the medical system, shall take responsibility for ensuring the system conforms to IEC/EN 60601-1-2 requirements.***

Cable list

Name	Specification	Length	Note
AC Power Cord	Unshielded	2.5m	Accessories
HDMI cable	Shielded	2.0m	Accessories
USB2.0 cable	Shielded	2.0m	Accessories
USB3.0 cable	Shielded	1.0m	Accessories
LAN cable	Unshielded	3.0m	Not accessories
Keyboard cable	Unshielded	1.5m	Accessories
Mouse cable	Unshielded	1.5m	Accessories
AC Power Cord (Monitor AC adapter)	Unshielded	2.0m	Accessories
AC Power Cord (HDD AC adapter)	Unshielded	2.0m	Accessories
DC cable (Monitor AC adapter)	Unshielded	1.2m	Accessories
DC cable (HDD AC adapter)	Unshielded	1.2m	Accessories
Monitor	—	—	Accessories
External HDD	—	—	Accessories

Essential performance：

- Captured OCT images are appropriately displayed.
- Corneal curvature, depth of anterior eye section, corneal thickness and crystal lens thickness detected on the captured image are correctly displayed.
- RL information and patient information are correctly displayed.
- There is no abnormal output of photo-radiation.

<EMISSIONS>

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

<IMMUNITY>

Table 1【ENCLOSURE PORT】

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

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

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

Table 3【Input a.c. power PORT】

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

Table 4【Signal input / output parts PORT】

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

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