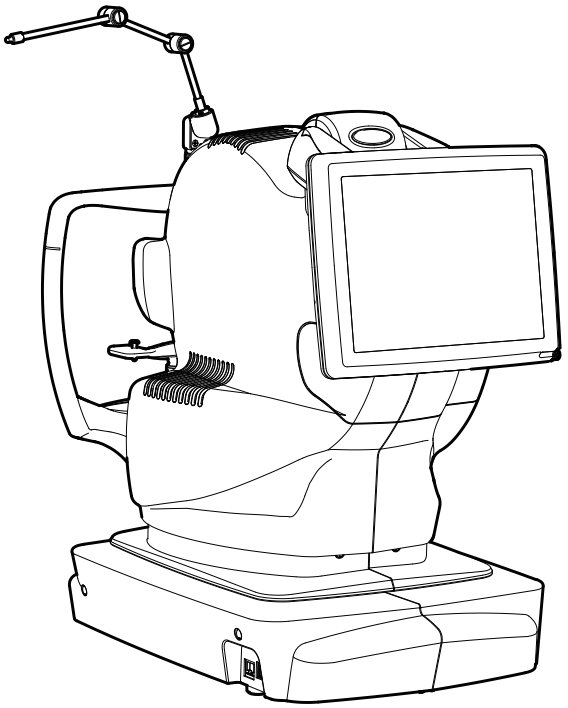
TOPCON



USER MANUAL (for instrument body)
3D OPTICAL COHERENCE TOMOGRAPHY

3D OCT-1 (Type: Maestro2)

Version 1.1x

INTRODUCTION

Thank you for purchasing 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2).
3D OCT-1 (Type: Maestro2) is hereafter referred as “the instrument”.
“Type:Maestro2” is an identifier.
Please also refer to the user manual of the software (IMAGEnet6 for OCT).

INTENDED USE / INDICATIONS FOR USE

The Topcon 3D Optical Coherence Tomography, 3D OCT-1 (Type: Maestro2) is a non-contact, high-resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying, and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions.
It is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of posterior ocular structures, including the retina, retinal layers, macula, and optic nerve head. It is also indicated for in-vivo viewing, axial cross-sectional and three-dimensional imaging of anterior ocular structures, including the cornea.
It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of full retinal thickness, ganglion cell + inner plexiform layer thickness, ganglion cell complex thickness, circumpapillary retinal nerve fiber layer thickness in the human retina to a database of known normal subjects.
It is indicated as an aid in the visualization of vascular structures of the posterior segment of the eye.
The Topcon 3D Optical Coherence Tomography, 3D OCT-1 (Type: Maestro2) is indicated for use as a diagnostic device to aid in the diagnosis, documentation, and management of ocular health and diseases.

FEATURES

This instrument is a photographic device used to observe, photograph and record the image of the fundus and anterior segment and the tomogram of the fundus and presents an electronic image for diagnosis.
The instrument must be used under the condition that it is connected to a personal computer (hereinafter, “PC”) in which the accessory software (IMAGEnet6 for OCT) is installed.
By mounting the attachment for anterior segment, which is an optional accessory, onto the instrument, you can observe, photograph and record the tomogram of anterior segment. (The attachment for anterior segment is an optional accessory.)
The built-in digital camera will take a picture of the fundus and anterior segment.
After photographing, the images and tomograms of the fundus and anterior segment can be recorded in the PC.
The observed/photographed images are displayed on the control panel.
The instrument has the automatic alignment function and the manual alignment function.

PURPOSE OF THIS MANUAL

This manual outlines the 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2), including operating procedures, troubleshooting, maintenance and cleaning.
Before using the instrument, carefully read the “DISPLAYS AND SYMBOLS FOR SAFE USE” and the “GENERAL SAFETY INFORMATION” to familiarize yourself with the features of the instrument and to ensure that you operate it efficiently and safely.
Always keep this User Manual at hand.

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1. No part of this manual may be copied or reprinted, in whole or in part, without prior written permission.
2. The contents of this manual are correct to the best of our knowledge. Please inform us of any ambiguous or erroneous descriptions, missing information, etc.
3. This manual is original instructions.

CONTENTS

DISPLAYS AND SYMBOLS FOR SAFE USE

To encourage safe and proper use and to prevent injury to the operator and others or potential damage to property, important messages are put on the instrument body and inserted in the manual.
We suggest that everyone understand the meaning of the following displays, icons and text before reading the “GENERAL SAFETY INFORMATION” and observe all listed instructions.

DISPLAY

Display	Meaning
⚠ CONTRAINDICATION	Situations in which the device should not be used because the risk of use clearly outweighs any possible benefit. “Situations” indicate the following conditions of the patient: disease symptoms, primary illness, complication, past medical history, family history, physical constitution, etc.
⚠ WARNING	Incorrect handling by ignoring this display may lead to a risk of death or serious injury.
⚠ CAUTION	Incorrect handling by ignoring this display may lead to personal injury or physical damage.
NOTE	Noted points to prevent the breakdown of the instrument or other troubles and useful functions to know.

SYMBOL

Symbol	Description	Description (French)
~	Alternating Current	Courant alternatif
○	Off (power: disconnection from the main power supply)	Éteint (courant: coupure avec le secteur)
|	On (power: connection to the main power supply)	Allumé (courant: raccordement sur le secteur)
	Type B applied part	Partie appliquée du Type B
	General warning sign	Symbole d'avertissement général
	Refer to instruction manual/ booklet	Voir le manuel/la brochure
	Date of manufacture	Date de fabrication
SN	Serial number	Numéro de série
	Manufacturer	Fabricant
EC REP	Authorised Representative in the European Community	Représentant autorité pour l’Union européenne

Symbol	Description	Description (French)
	Unique Device Identification (UDI)	Identification unique des dispositifs (IUD)
	Humidity limitation	Limite d'humidité
	Atmospheric pressure limitation	Limite de pression atmosphérique
	Temperature limit	Limite de température
	Fragile, handle with care	Fragile manipuler avec soin
	Keep dry	Garder au sec
	This way up	Vers le haut
	General symbol for recovery/recyclable. (for the package)	Symbole général de tri sélectif. (pour l'emballage)
	Recycling symbol for plastic in the package. Low density polyethylene	Symbole de recyclage du plastique dans l'emballage. Polyéthylène basse densité
	Recycling symbol for plastic in the package. Polypropylene	Symbole de recyclage du plastique dans l'emballage. Polypropylène
	Recycling symbol for plastic in the package. Polystyrene	Symbole de recyclage du plastique dans l'emballage. Polystyrène
	Indicates that the product conforms to the requirements of the Medical Device Regulation (EU) 2017/745 and of the other applicable Union legislation	Indique que le produit est conforme aux exigences du Règlement (UE) 2017/745 relatif aux dispositifs médicaux et des autres lois applicables de l'Union Européenne
	WEEE label The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.	Marquage des DEEE Il s'agit d'un symbole indiquant que le produit ne doit pas être éliminé avec les déchets non triés, mais doit être envoyé dans des installations de collecte séparées destinées à la valorisation et au recyclage.
	EU Battery Directive Battery users must not dispose of batteries as unsorted general waste, but treat properly.	Directive européenne sur les batteries Les utilisateurs de batteries ne doivent pas jeter les batteries comme des déchets généraux non triés, mais les traiter correctement.

GENERAL SAFETY INFORMATION

⚠ CONTRAINDICATION

This instrument must not be used for the following patients:
- Patients who are hypersensitive to light
- Patients who recently underwent photodynamic therapy (PDT)
- Patients taking medication that causes photosensitivity.

⚠ WARNING

Ensuring the Safety of Patients and Operators
Be careful not to hit the patient's eyes or nose with the instrument during operation. The patient may be injured.

Preventing Electric Shocks and Fires
To avoid fire and electric shock, install the instrument in a place free of water and other liquids.
To avoid fire and electric shock, do not put cups or vessels containing liquids near the instrument.
Be sure to connect the power plug to an AC 3-pin receptacle equipped with grounding. Connection to a receptacle without grounding may cause electric shock in the case of shortcircuiting.
To avoid fire in the event of an instrument malfunction, immediately turn OFF (○) the Power switch and unplug the cable if you see smoke coming from the instrument or if you detect other problems. Don't install the instrument where it is difficult to unplug the cable from the instrument body. Ask your dealer for repairs.
To avoid electric shock and fire, do not disassemble, modify or repair the equipment. Ask your dealer for repairs.

⚠ CAUTION

Ensuring the Safety of Patients and Operators
Use this instrument carefully on the following patients. • Patients who have epidemic corneitis, conjunctivitis or any other infectious disease • Patients who are taking medications that cause light hypersensitivity.
When operating the chinrest up/down button, be careful not to pinch the patient's hand to avoid possible injury.
When opening the patient's eye, be careful for operating the instrument. The patient may be injured.
When using the remote operations, the end user should be careful not to hit the patient’s eyes or nose with the instrument in a situation where they can directly check the patient’s condition.
When using the remote operation via wireless communication, please use it in an environment where there are no obstacles or wireless interference. The patient may be injured.

Preventing Electric Shocks and Burn
To avoid electric shock, do not insert metal objects into any vents and/or slots of the instrument.
To avoid electric shock, do not open the instrument. Request service from an authorized Topcon distributor. [Electric shock may cause an injury]
To prevent the instrument from malfunctioning, do not drop any liquid into the vent. Electric shock may cause an injury.

Ensuring Security
• When connecting this instrument to an external device through LAN, apply the security update to the external device, make use of anti-virus software and take other countermeasures against computer virus properly. • Do not connect any USB storage device that is not checked with the anti-virus software to the USB port of this instrument. • When connecting this instrument to an external device through LAN, set the ID and password of the user to the external device.

Misdiagnosis
Users should not rely solely on images made using this instrument in making decisions regarding diagnosis or other therapeutic procedures, but should rely on their own expertise and judgment. The pertaining doctors should take the responsibility for diagnoses. [There is a risk of misdiagnosis]
When making diagnoses, check the accompanying data (patient ID, name, etc.) of images. To prevent wrong diagnoses [There is a risk of misdiagnosis]

Electromagnetic Compatibility (EMC)
This instrument has been tested (with 100/120/230V) and found to comply with IEC 60601-1-2:2014+AMD1: 2020 (Ed.4.1). This instrument radiates radio frequency energy within standard and may affect other devices in the vicinity. If you have discovered that turning on/off the instrument affects other devices, we recommend you change its position, keep a proper distance from other devices, or plug it into a different outlet. Please consult your authorized dealer if you have any additional questions.

HOW TO USE THIS MANUAL

- Read the instructions on pages 1 to 9 before using the instrument.
- Regarding connection to various devices, see “CONNECTING THE EXTERNAL I/O TERMINALS” on page 46.
- If you would like an overview of the system, begin by reading “BASIC OPERATIONS” (page 48).

GENERAL MAINTENANCE INFORMATION

Do not perform any maintenance work while the instrument is in use on a patient.

USER MAINTENANCE

To maintain the safety and performance of the equipment, never attempt to repair or perform maintenance. These tasks should be performed by an authorized service representative.
Maintenance tasks that can be performed by the user are as follows; for details, follow the manual’s instructions.

Cleaning the objective lens:

The objective lens may be cleaned by the user. For details, see “Cleaning the objective lens” on page 121.

Countermeasure to keep the electromagnetic compatibility

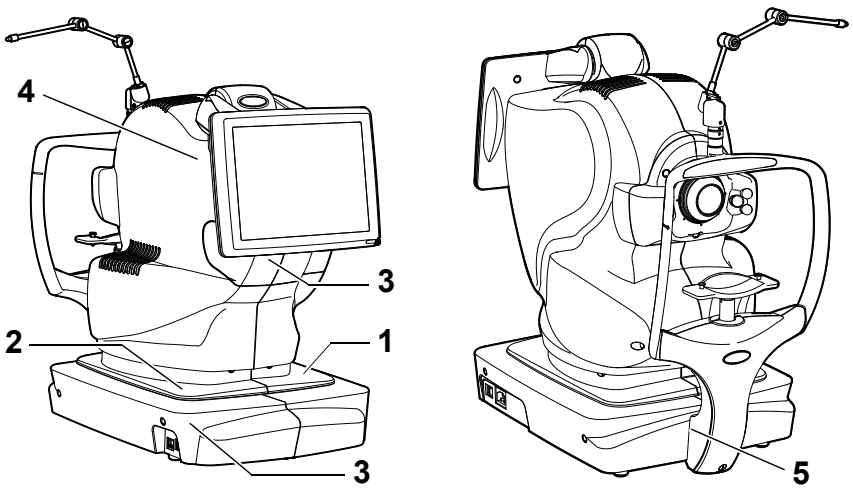
To ensure the electromagnetic compatibility of the instrument and system, periodically check the connection status of the power supply including the protective earth cable.

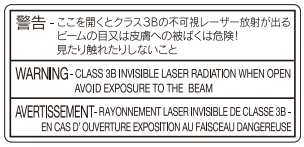
DISCLAIMERS

- TOPCON shall not take any responsibility for damage due to fire, earthquakes, actions by third persons and other accidents, or damage due to negligence and misuse by the user and any use under unusual conditions.
- TOPCON shall not take any responsibility for damage derived from inability to properly use this instrument, such as loss of business profit and suspension of business.
- TOPCON shall not take any responsibility for damage caused from using this instrument in a manner other than that described in this manual.
- Diagnoses made shall be the responsibility of pertaining doctors and TOPCON shall not take any responsibility for the results of such diagnoses.

POSITIONS OF WARNING AND CAUTION INDICATIONS

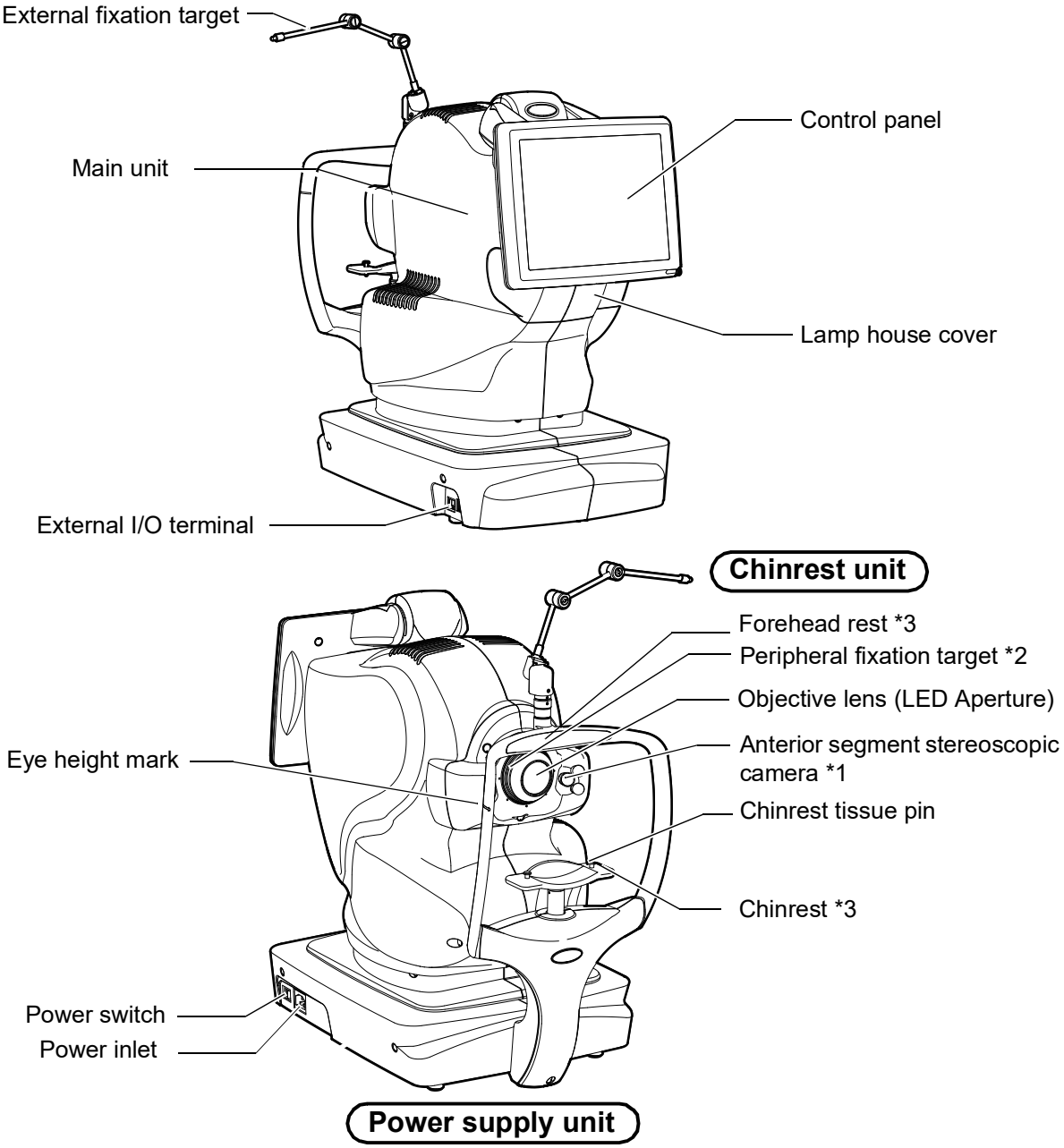
To ensure safety, this instrument provides warning and caution indications. Use the instrument correctly by observing these indications instructions. If any of the following these indications are missing, contact your TOPCON dealer at the address listed on the back cover.



No.	Label	Meaning	Signification
1		**WARNING** Be careful not to hit the patient's eyes or nose with the instrument during operation.	**MISE EN GARDE** Prendre garde de ne pas frapper les yeux ou le nez du patient avec l'instrument pendant l'opération.
2		**CAUTION** When operating the chinrest up/down switch, be careful not to pinch the patient's hand. The patient may be injured.	**PRÉCAUTION** Prendre garde de ne pas pincer la main du patient en opérant le commutateur haut/bas du support de jugulaire. Le patient pourrait être blessé.
3		**CAUTION** To avoid injury caused by electric shock, do not open the cover. Ask your dealer for service.	**PRÉCAUTION** Ne pas ouvrir le couvercle pour éviter les blessures causées par un choc électrique. Demander au revendeur d'effectuer le service.
4		WARNING - CLASS 3B INVISIBLE LASER RADIATION WHEN OPEN AVOID EXPOSURE TO THE BEAM.	AVERTISSEMENT - RAYONNEMENT LASER INVISIBLE DE CLASSE 3B - EN CAS D'OUVERTURE EXPOSITION AU FAISCEAU DANGEREUSE
5		Degree of protection against electric shock : TYPE B APPLIED PART	Degré de protection contre les chocs électriques : TYPE B PARTIE D'APPLICATION

SYSTEM DIAGRAM

COMPONENT NAMES



*1: This unit is placed at the right and left sides of objective lens.
*2: There are eight targets around the objective lens.
*3: TYPE B APPLIED PART

COMPOSITION OF PARTS THAT COME IN CONTACT WITH THE PATIENT

Main unit

Forehead rest	: Silicone rubber
Chinrest	: Acrylonitrile butadiene styrene resin (ABS)
Chinrest tissue	: Paper
Chinrest tissue pin	: Polyamide resin

Attachment for anterior segment

Forehead rest	: Silicone rubber

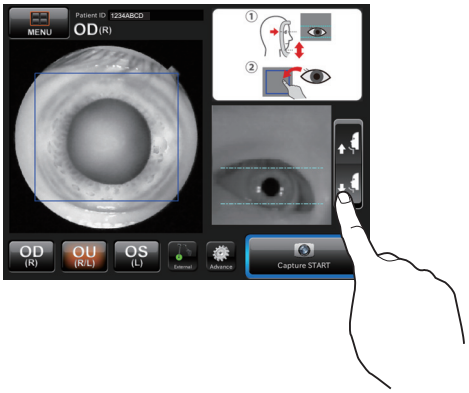
OPERATION METHOD OF CONTROL PANEL

NOTES	Operate the control panel with your fingers or the attached touch pen. Do not use any sharp tools; e.g. ball point pen. The touch panel may be damaged to cause an incorrect operation.

Tap → To select any relevant item.

Touch the screen softly with a finger.

Continue to press → Used for continuous moving.
(Moving of chinrest and main unit)



Continue to touch the screen softly with a finger.

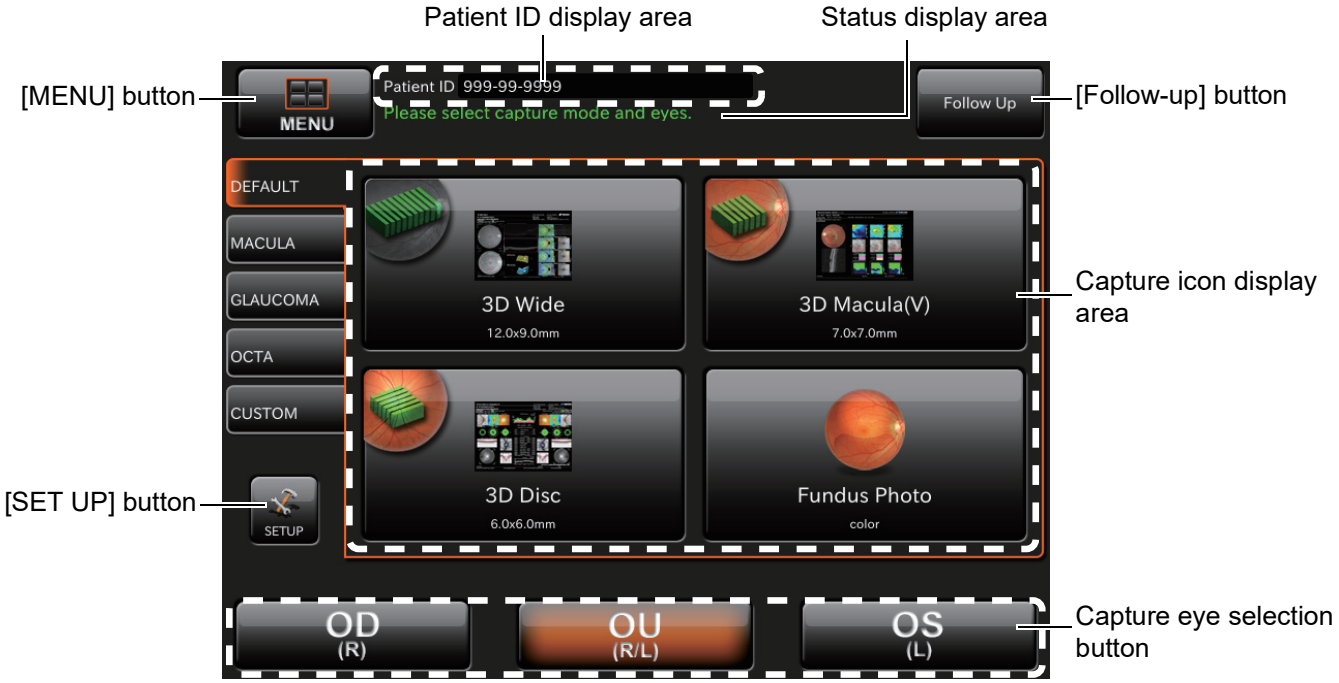
NAMES ON THE CONTROL PANEL

■ Display areas and functions on the control panel

The control panel is designed as a touch panel. Information is displayed on the control panel and you can perform a variety of operations by touching the screen.

■ Capture icon selection screen

You can select the optimal mode for various types of photography.



[MENU] button	:	Shifts to the capture icon selection screen. This does not operate on the capture icon selection screen.
Patient ID display area	:	Displays the patient ID.
[SET UP] button	:	Shifts to the setting menu screen.
Status display area	:	Displays the message.
Capture icon display area	:	By selecting a tab, the capture icons registered in each tab are displayed. When color fundus photography is set to OFF the fundus image among the capture icons is displayed in monochrome.
Capture eye selection button	:	Select an eye to be captured.

[Follow-up] button : • Each time you press this button, “Follow-up ON” (button is orange) and “Follow-up OFF” (button is black) is changed each other. In case of “ON”, Follow-up photography is done. In case of “OFF”, it is not done.
• Follow-up photography is applied to the following cases.
  • Line
  • 5 Line Cross
  • Radial
  • 3D Macula
  • 3D Macula (V)
  • 3D Optic disc
  • 3D Wide
  • 3D Wide (H)
• When selecting the photography icon to which Follow-up photography is unapplied, Follow-up photography is not done even if this button is set to “ON”.
• When the [Follow-up] button is set to “ON”, “Follow up” is displayed in yellow on the capture icon which is applicable to Follow-up photography.

NOTE	Follow-up photography function in the instrument is as follows: the system searches the same position as the scan position of the latest data captured in the past including the preceding day by using the live IR image of the present photography to decide the scan position. * Follow-up photography cannot be performed with the data captured on the current day.

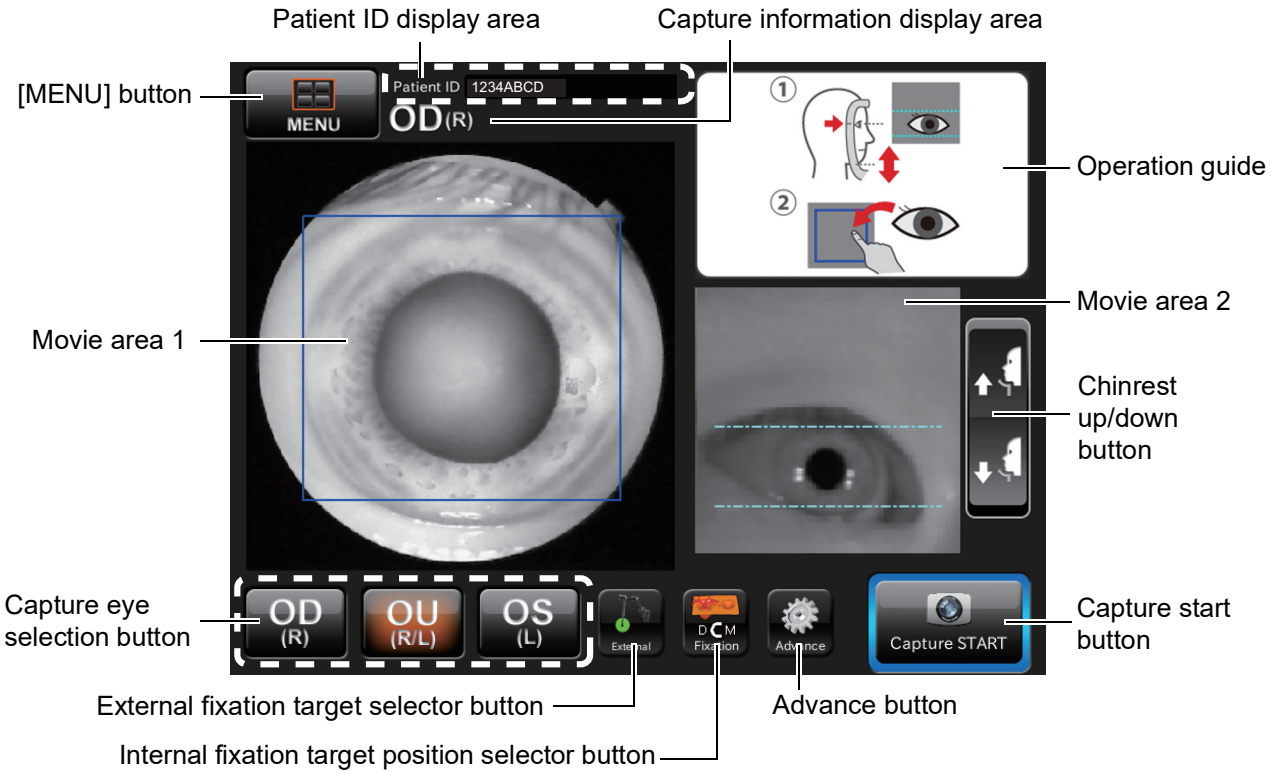
Reading the base line data for Follow-up photography

- Tap the photography icon (to which the Follow-up mode is applied) on condition that the [Follow-up] button is ON (orange). The system reads the last photography data (base line data) that is relevant to the entered patient ID and the selected photography icon.

- When relevant data does not exist, normal photography is performed.

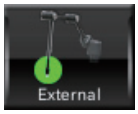
■ Photography screen (Chinrest adjustment)

As watching the anterior segment observation image and the image of the anterior segment stereoscopic camera, adjust the chinrest.



[MENU] button	:	Shifts to the capture icon selection screen.
Patient ID display area	:	Displays the patient ID.
Capture information display area	:	Displays the captured eye and picture angle.
Operation guide	:	Displays how to operate this screen.
Movie area 1	:	Displays the anterior segment observation image. Touch the pupil to be within the frame.
Movie area 2	:	Displays the image of the anterior segment stereoscopic camera, which is nearer to the captured eye than the other. Align the eye height to the canthus marker of the chinrest unit with the lines on the screen as standard.
Chinrest up/down button	:	Moves the chinrest up and down. Press the upper part of the button, and the chinrest moves up. Press the lower part of the button, and the chinrest moves down.
Capture eye selection button	:	Select an eye to be captured.

External fixation target selector button : Tap this button, and the external fixation target is selected. Displays the status (ON/OFF) of the external fixation target. You can change ON/OFF of the external fixation target with this button.



Displays the status of the internal fixation target.
(Background is gray.)

Displays the status of the external fixation target.
(Background is orange.)

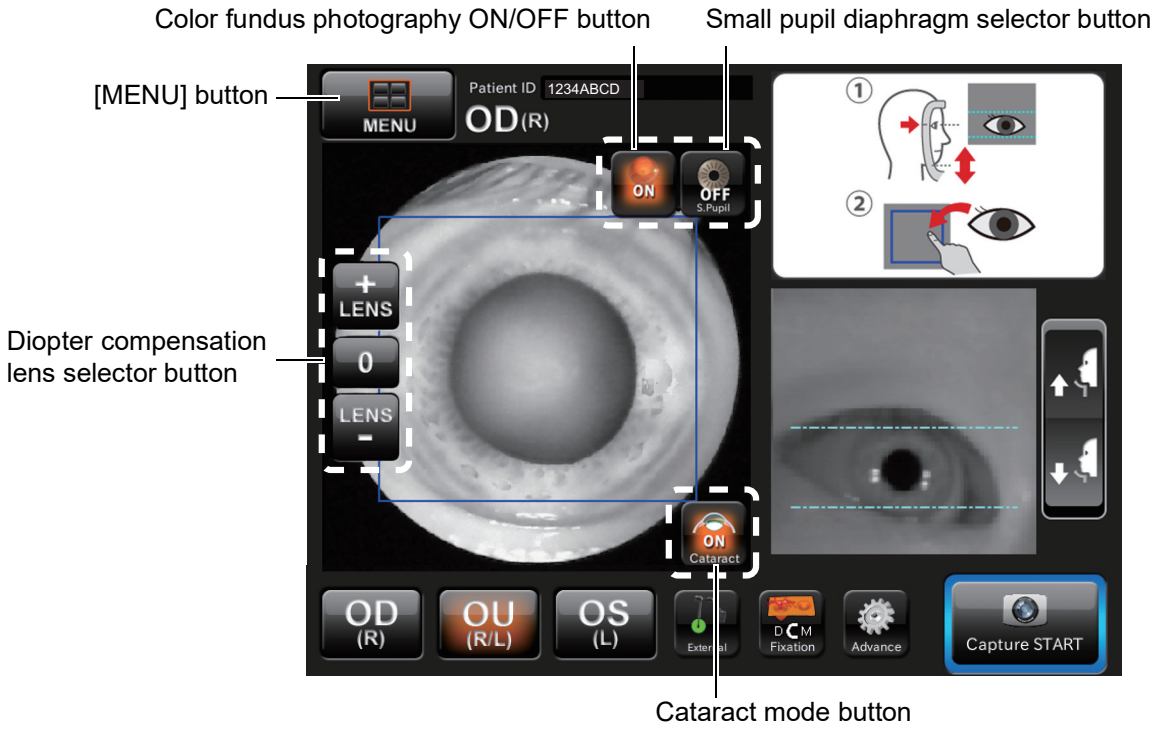
Internal fixation target position selector button : Tap this button, the picture position is changed to “D” (optic disc center), “C” (the middle position of optic disc and macula) and “M” (macula center) in this order.
(*) This button is displayed in color fundus photography.

Advance button : Tap this button, and the “Advance” mode is accessed. In the “Advance” mode, the following operations can be performed: selecting the small pupil diaphragm, turning ON/OFF the color fundus photography(*), changing the diopter compensation lens, and selecting the “Cataract” mode.
(*) When function is used and when the color fundus photography function is OFF, the color fundus photography ON/OFF button is not displayed.

Capture start button : Starts photographing.

■ Photography screen (Chinrest adjustment): Advance mode

When you set “ON” for the “Advance” mode on the screen where you adjust the chinrest as watching the anterior segment observation image and the image of the anterior segment stereoscopic camera, this screen appears.



Small pupil diaphragm selector button : Displays the small pupil diaphragm status (ON/OFF). You can change the ON/OFF status of the small pupil diaphragm. When the pupil diameter of the patient is small (pupil diameter is approx. ϕ4.0mm or less), set it to ON and take a picture.
When the color fundus photography is done (excluding the color fundus photography when taking the fundus tomogram), the automatic small pupil (diaphragm) function can be set. While this function is set, the small pupil diaphragm is automatically set to ON and the instrument takes a color picture of fundus if the pupil diameter is small (pupil diameter is approx. ϕ4.0mm or less). After taking a picture, it is set to OFF.
When you set this function, in the color fundus photography mode, it is not necessary to set the small pupil diaphragm to ON with this button even if the pupil diameter is small.

Color fundus photography ON/OFF button : You can turn ON/OFF the color fundus photography. When the color fundus photography function is OFF, this button is not displayed.

Diopter compensation lens selector button : Tap [+LENS] to increase the power. Tap [-LENS] to decrease the power. The center button displays “No compensation lens”.

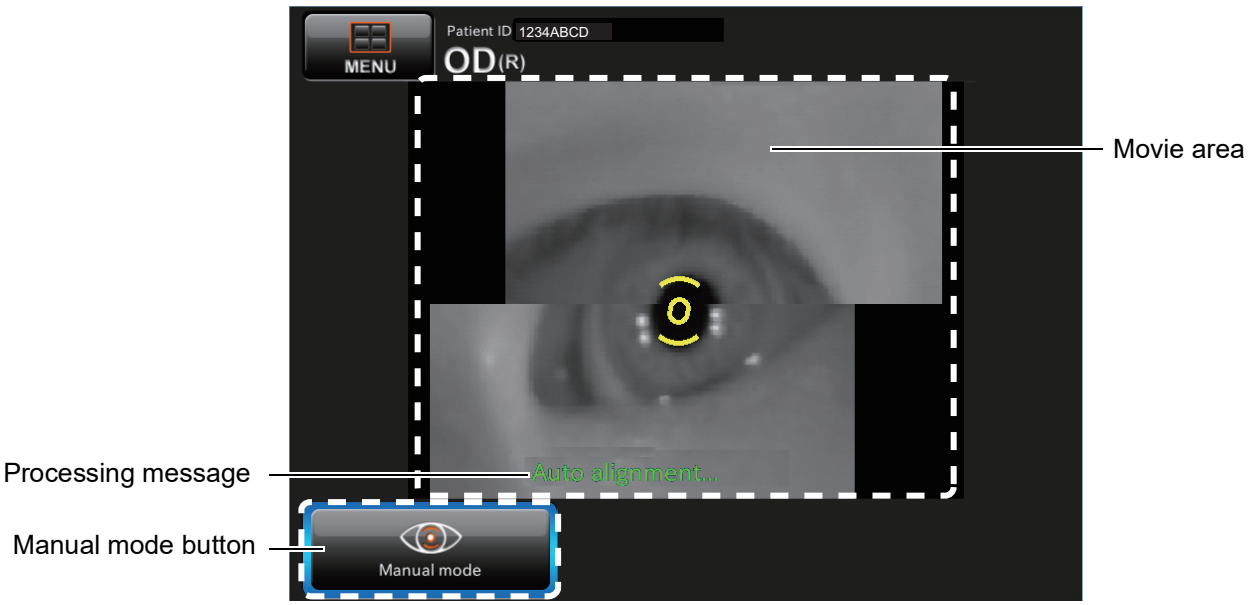
NOTE	When the patient's eye has a strong myopia, set the diopter compensation lens selector button to (-). When the patient's eye has a strong hyperopia, set the diopter compensation lens selector button to (+). Compensation range: 0 : -13 – +12D – : -12 – -33D + : +11 – +40D

Cataract mode button : You can select the execution of automatic optimizing in the “Cataract” mode. Set “ON” for the “Cataract” mode and tap the [Capture START] button. Automatic optimizing is performed in the “Cataract” mode. The “Cataract” mode is kept until the patient is changed to another. When the patient is changed to the next, default is set again.
(The “Cataract” mode performs optimizing by moving the base up and down or right and left when a clear tomogram cannot be obtained.)

■ Photography screen (Automatic alignment to pupil)

CAUTION	To avoid injury of the patient, be careful not to hit the patient with the instrument during automatic alignment.

This screen is used to perform automatic alignment to pupil. Alignment is performed by the image of the right and left anterior segment stereoscopic cameras.

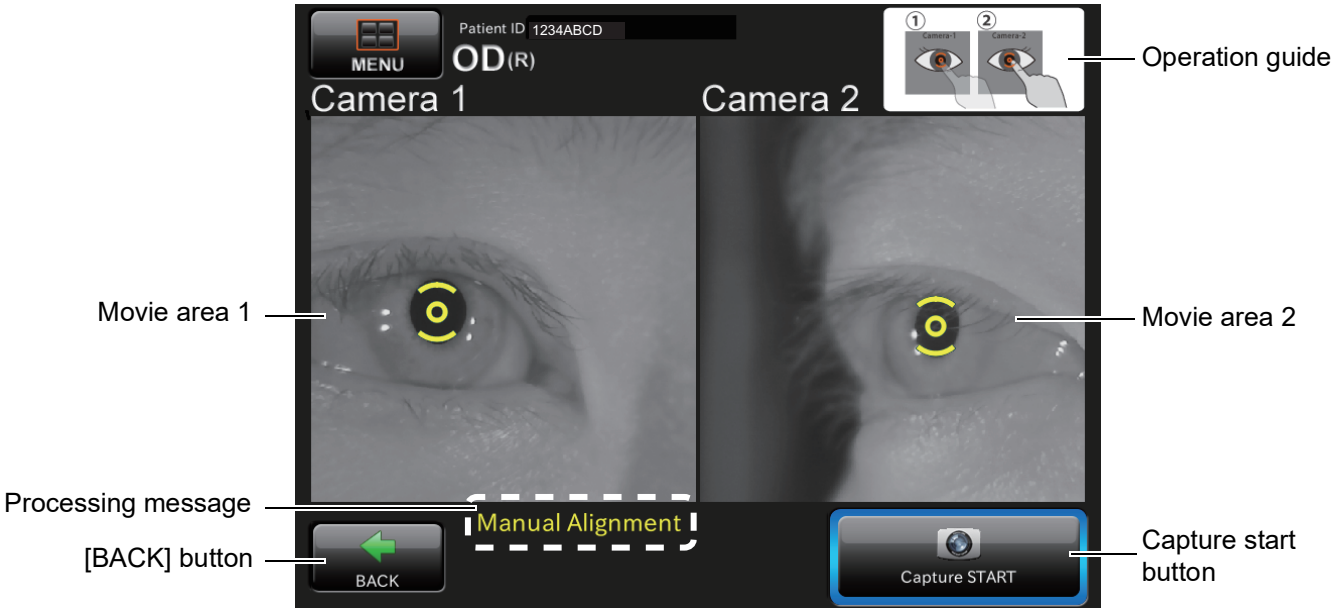


Movie area	:	Displays the image of the right/left anterior segment stereoscopic camera.
Manual mode button	:	Tap the [Manual mode] button. The system stops automatic adjustment of the captured eye and shifts to the “Manual adjustment mode” screen where you can adjust the captured eye manually.
Processing message	:	Displays the current processing status.

NOTE	When opening the eyelid (opening the eyelid by hand), be careful not to touch the anterior segment stereoscopic camera by hand. If your hand touches it, automatic alignment is not performed normally from time to time.

■ Photography screen (Manual alignment to pupil)

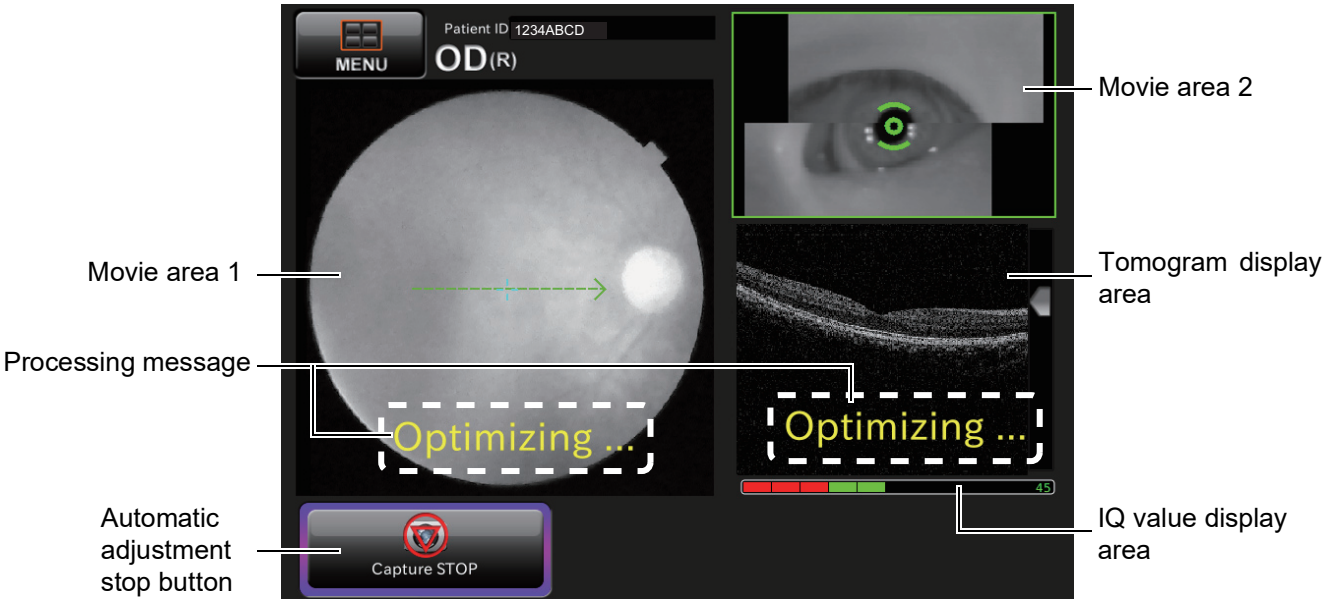
This screen is used to perform manual alignment to pupil. Tap the pupil displayed on Camera 1 and Camera 2.



Operation guide	:	Displays how to operate this screen.
Movie area 1	:	Displays the image of the anterior segment stereoscopic camera 1.
Movie area 2	:	Displays the image of the anterior segment stereoscopic camera 2.
Processing message	:	Displays the current processing status.
[BACK] button	:	Returns to the photography screen (Chinrest adjustment).
Capture start button	:	Starts photographing. Tap the screen of Camera 1/Camera 2, and it is active.

■ Photography screen (Automatic optimizing)

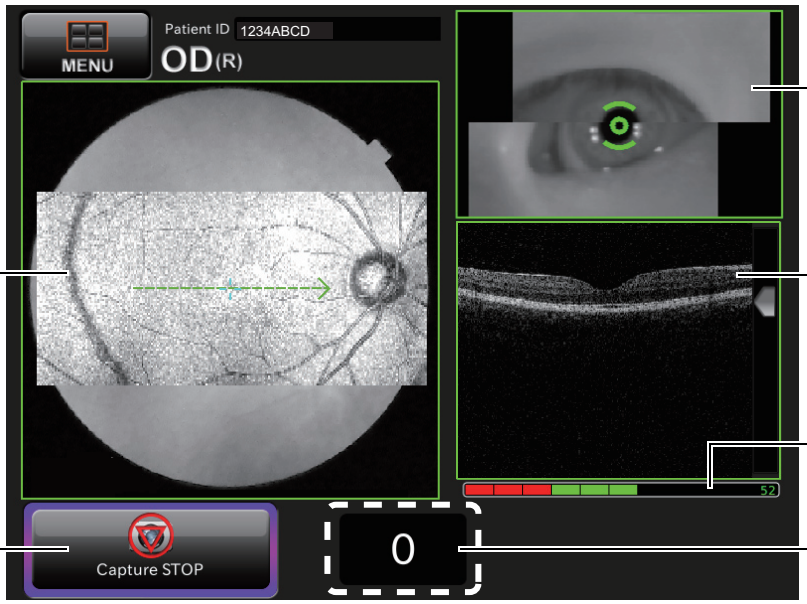
This screen is used to perform automatic optimizing to fundus.



Movie area 1	:	Displays the fundus image or the anterior segment observation image. When optimizing is successful, the area is encircled with a green frame.
Movie area 2	:	Displays the image of the anterior segment stereoscopic camera. When alignment is successful, the pupil mark is green and the area is encircled with a green frame.
Tomogram display area	:	Displays the interference figure. When optimizing is successful, the area is encircled with a green frame.
Processing message	:	Displays the current processing status.
IQ value display area	:	Displays the IQ value of the interference figure with a bar and a numerical value.
Automatic adjustment stop button	:	Tap the [Capture STOP] button. The system stops automatic adjustment and shifts to the “Manual adjustment mode” screen where you can perform adjustment manually.

■ Photography screen (waiting for fundus capture to start)

This screen shows the status while for the fundus capture to start. Make sure that all areas are encircled with green frames. When the green frame is not displayed, tap the [Capture STOP] button to stop photographing.



Movie area 1	:	Displays the fundus image or the anterior segment observation image. When interference is not good, the green frame is not displayed for the area.
Movie area 2	:	Displays the image of the anterior segment stereoscopic camera. When alignment is not correct, the green frame is not displayed for the area and the pupil mark is orange.
Tomogram display area	:	Displays the tomogram. When interference is not good, the green frame is not displayed for the area.
IQ value display area	:	Displays the IQ value of the interference figure with a bar and a numerical value.
Automatic adjustment stop button	:	Tap the [Capture STOP] button. The system stops automatic adjustment and shifts to the “Manual adjustment mode” screen where you can perform adjustment manually.
Auto shoot timer	:	This is the countdown timer until photographing starts. When this timer shows “0”, the system takes a picture automatically.

NOTE	When you keep the state of displaying the photography screen, noises may appear in the image on the tomogram display area. In this case, please select the [MENU] button to return to the capture icon selection screen and capture the image again. In the case of “OCT Angiography” or “SMART Track”, the photographing time is longer than usual. Carry out the following operations if necessary. • When the tomogram moves up, tap the tomogram live image area to modify the Z lock position (tomogram display position) downward. • When you cannot perform photographing smoothly due to the patient's eye, fixation status or others, press the capture start button again. It is possible to cancel tracking and carry out photographing.

Photography with “3D Optic disc” and “3D Wide”

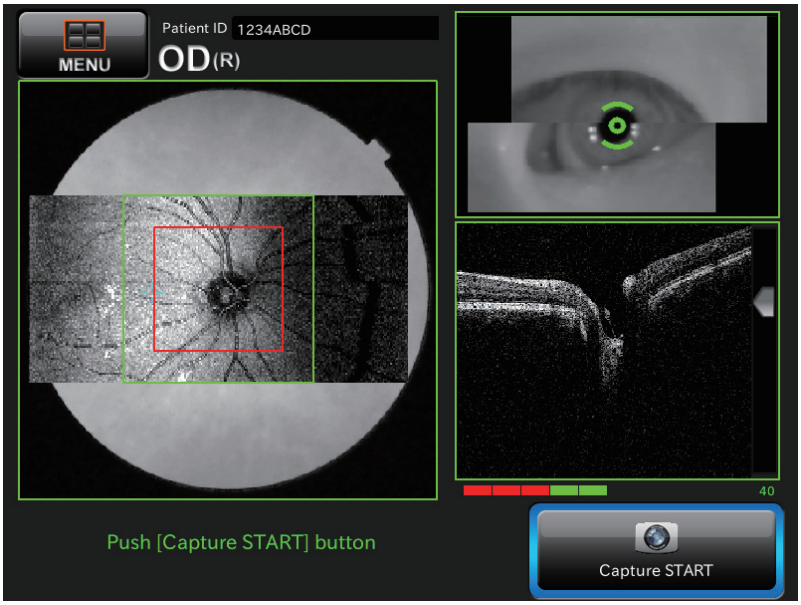
When you perform the photography with “3D Optic disc” and “3D Wide”, the following screens appear. Make sure that the optic disc is within the red frame on the screen. If the optic disc is not so, press the [Capture STOP] button. On the photography screen (manual adjustment mode), by using the internal fixation position adjustment button and the external fixation target, adjust the fixation position to place the patient's optic disc within the red frame.

3D Optic disc photography

3D Wide photography

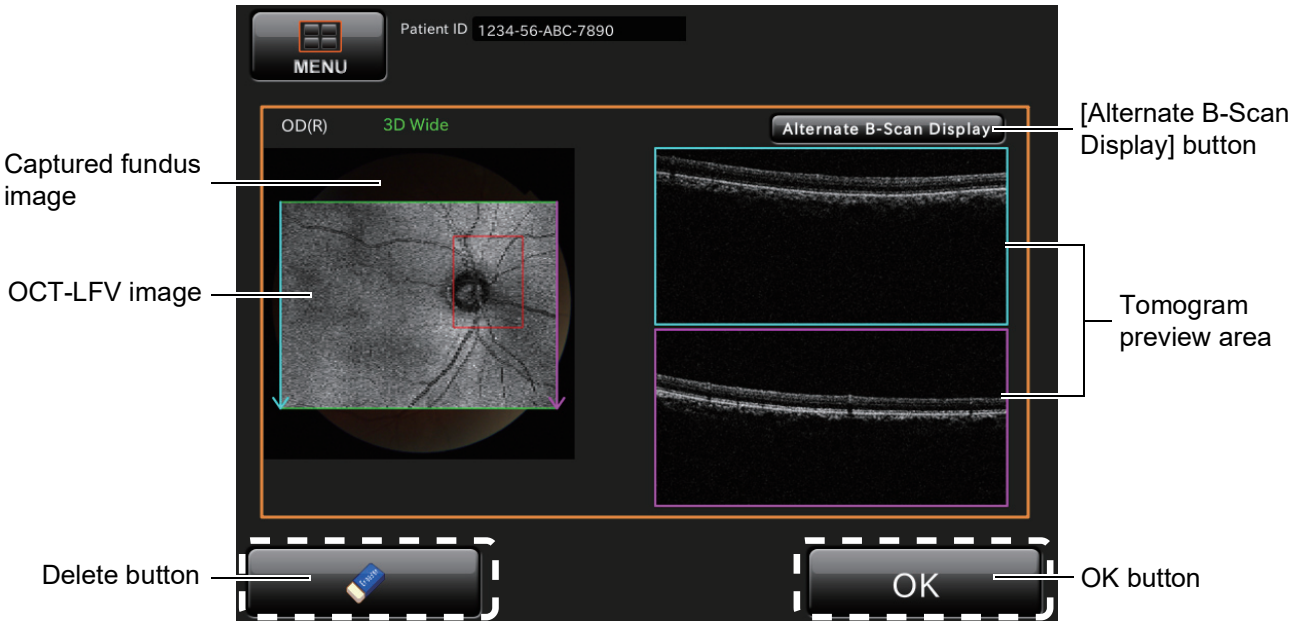
In the Cataract mode:

In the cataract mode, the following screen appears. Check the image. If there is no problem, press the [Capture START] button to take a picture.



■ Photography result display (The system shifts to the next photographic capture session by tapping the [OK] button.)

Preview is displayed per shooting. In the case of both eyes, the system shifts to the next photographic capture session by tapping the [OK] button.
When color fundus photography is set to OFF the color fundus photography image is changed to the IR fundus photography image.

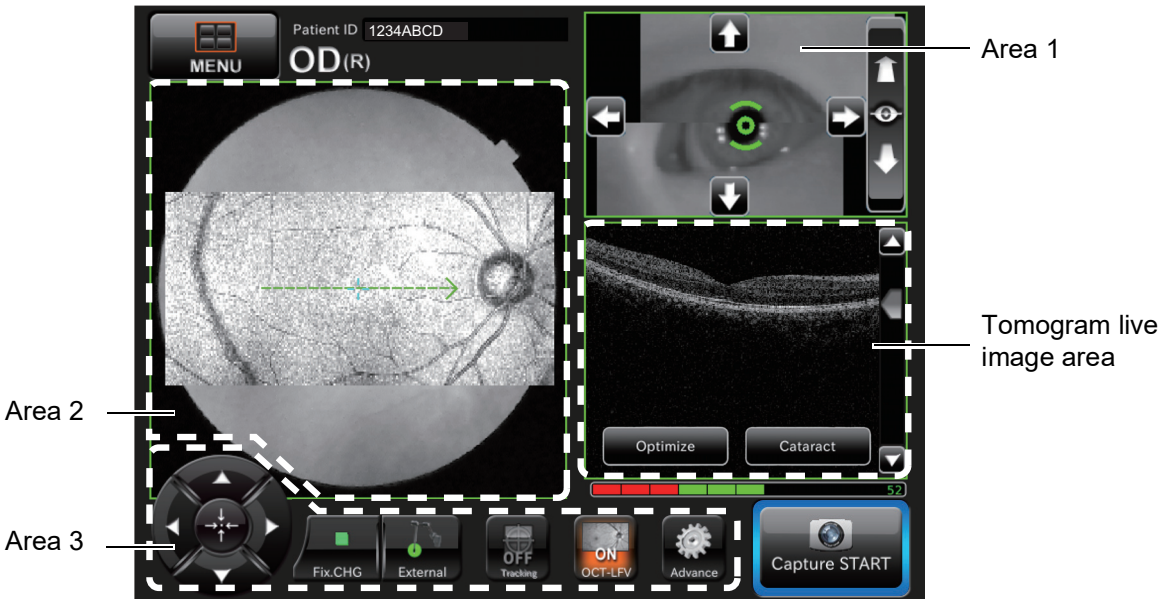


Tomogram preview area	:	Displays the preview of the captured tomogram. When there are two or more captured image data in the case of “5 Line Cross” scan, “Radial” scan, “3D” scan or others, the preview of the representative image is displayed. In the photography with “3D” scan, the images at both ends are representative images
[Alternate B-Scan Display] button	:	This button is displayed only for the “3D Wide” scan. The B-Scan images at both ends displayed on the tomogram preview area are changed to the images which are a little inside (approx. 1.5mm) from both ends.
OCT-LFV image	:	This is displayed only for the “3D” scan. The OCT-LFV image captured during photography is displayed. It is possible to display/hide the OCT-LFV image by tapping the captured fundus image.
Captured fundus image	:	Displays the fundus image captured at each photography operation.
OK button	:	Shifts to the next photographic capture session.
Delete button	:	Deletes the photography result.

NOTE	• The image displayed on the instrument is a simplified image. For the scan position, the roughly computed position is shown. Diagnose the patient's eye with the external personal computer. • When the preview display is set to “OFF”, this screen does not appear. • When “3D scan” and “OCT Angiography” are selected, the “scanned range” on the color fundus photography image does not always meet the position specified by the scan position adjustment mode due to the fixation status during photography. In this case, check if the captured OCT-LFV image includes the specified position. If not, perform photographing again.

■ Photography screen (Manual adjustment mode)

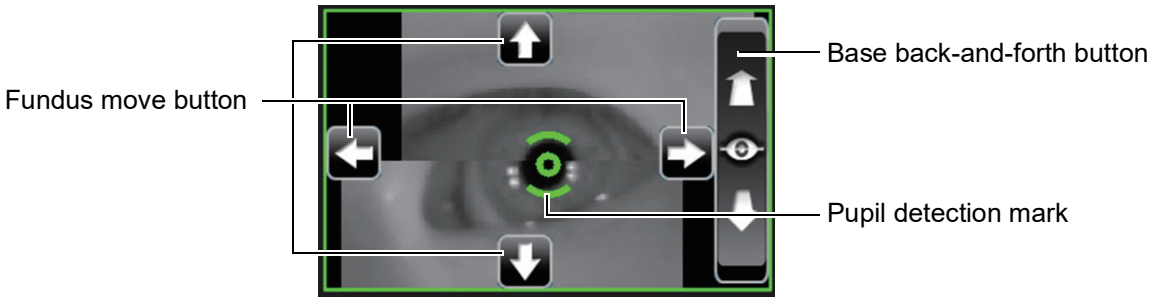
This screen is used to perform adjustment manually.



Area 1	:	Displays the image of the anterior segment stereoscopic camera and performs alignment with the fundus move button and the base back-and-forth button.
Area 2	:	Displays the fundus or anterior segment live image and the scan pattern, which is set in the selected capture icon, with an interrupted line. The right/left eye and flash level are displayed and you can adjust the illumination level in the control panel. (Refer to page 27.) Displays the scan position adjustment range and the fine adjustment buttons in the scan position adjustment mode. You can adjust the scan position in the control panel. (Refer to page 34.)
Area 3	:	Displays the buttons to switch on/off the small pupil diaphragm and change the internal fixation target, etc.
Tomogram live image area	:	Displays the tomogram live image and IQ value. You can perform a variety of operations on the live image. (Refer to page 29.)

Area 1

Area 1 displays the image of the anterior segment stereoscopic camera and performs alignment with the fundus move button and the base back-and-forth button. When alignment is correct, the area is encircled with a green frame.



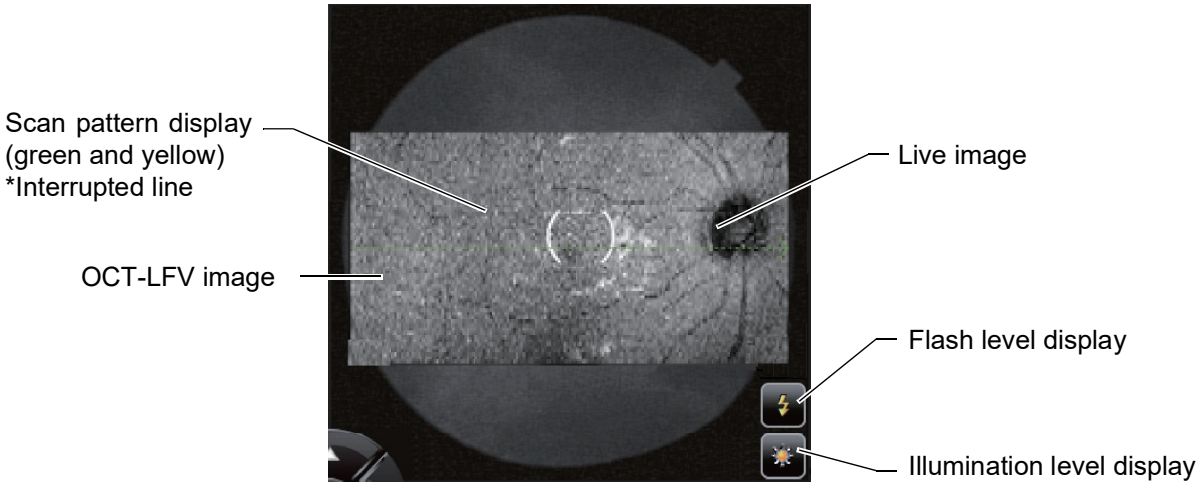
- Base back-and-forth button:
  Press the upper part of the button, and the base comes near the patient. Press the lower part of the button, and the base moves away from the patient.
- Fundus move button:
  Tap the upper, lower, right and left buttons on the screen to adjust the whole fundus position finely. The displayed pupil image moves in the tapped arrow direction. Keep pressing the button, and the moving speed is higher.
- Pupil detection mark:
  This is displayed when the pupil is detected. When alignment is correct, this mark is green. When alignment is not correct, this mark is orange.

NOTE	In the case of OCT Angiography, you can operate Base back-and-forth button and Fundus move button during photography. If the patient's eye move, please align the eye using Base back-and-forth button and Fundus move button.

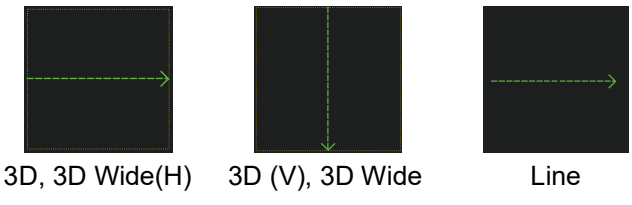
Area 2

Area 2 displays the fundus/anterior segment live image.

Area 2 on the manual adjustment mode screen displays the fundus or anterior segment live image, flash level, illumination level and the graphic image of the scan pattern, which is set in the selected capture icon, with an interrupted line. You can adjust the flash level and illumination level by the control panel. Moreover you can set the capture position and focus for fundus.



- Live image:
  Displays the live image of the fundus or anterior segment.
- Scan pattern display (green and yellow):
  Displays the graphic image of the scan pattern, which is set in the selected capture icon. The green line shows the scan position and the arrow shows the scan advance direction. (The arrow direction for the right eye is reversed for the left eye.)
  The yellow line is displayed for the scan patterns except “Line”. For “3D”, the yellow line shows the scan range and, for other scan patterns, the scan position in addition to the position indicated by the green line. When scan is performed once, it is done at the positions indicated by the green and yellow lines.
  The length or size of the line is changed according to the set scan size.



- Illumination level display
  Displays the illumination level by four steps (value: 1 - 4). You can adjust the illumination level by tapping the screen. (Refer to page 78.)

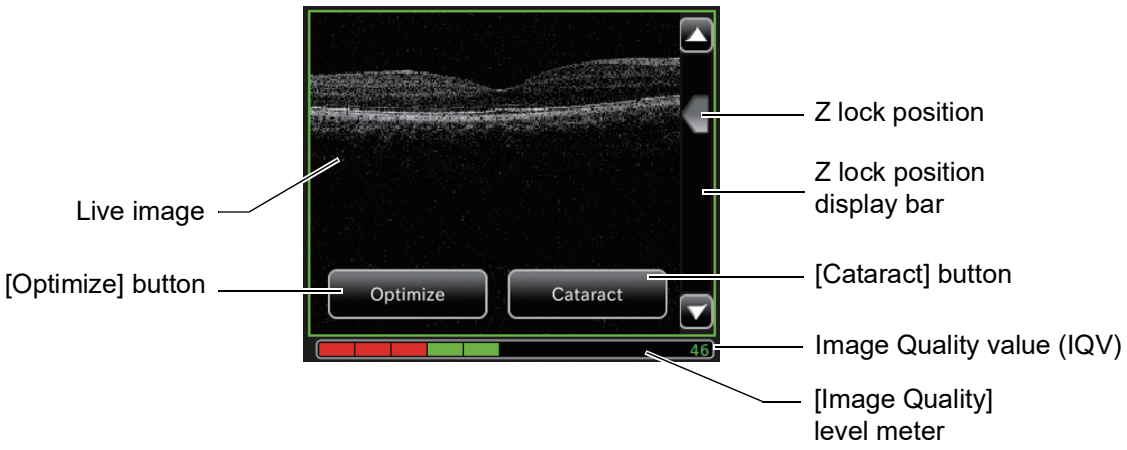
- Flash level display:
  Displays the flash level in nine steps (value range: -4 - +4). You can adjust the flash level by tapping the screen. (Refer to page 78.)
  While the xenon lamp power supply is being charged, the icon blinks. When charging is finished, the icon is lit.

NOTE	• When color fundus photography is set to OFF the flash level is not displayed. • The flash level can be set in nine steps (-4 to +4). When the instrument is first turned on, the flash level is set to “level 0”. • When the flash level is raised by 1 step, the flash level is increased by about 20%.

- OCT-LFV image:
  When “ON” is set for “OCT-FLV”, the OCT-LFV image is displayed.

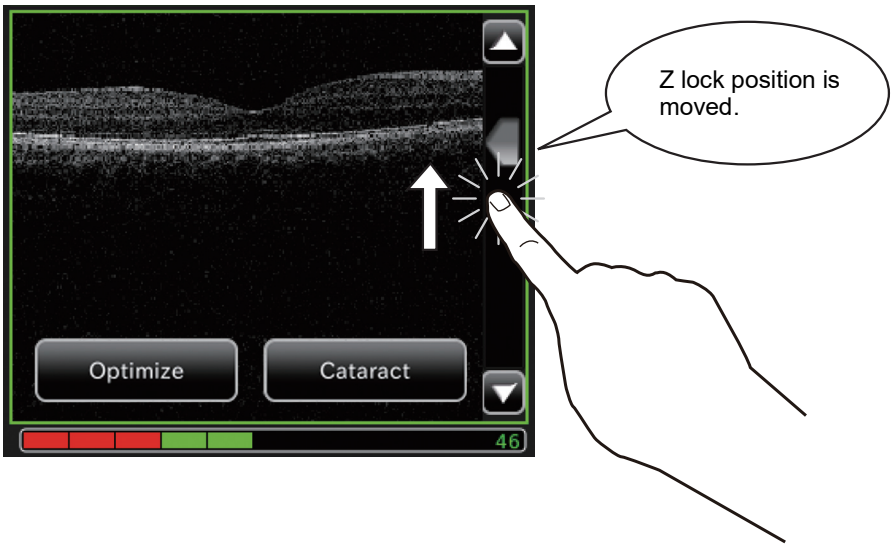
Tomogram live image area

This area displays the tomogram live image. Perform the operation on the live image.



- Z lock position : Displays the center position of the displayed tomogram. After the processing of “Auto Z (Z Lock)” and “Auto Polarization”, the tomogram live image is placed in the Z lock position.

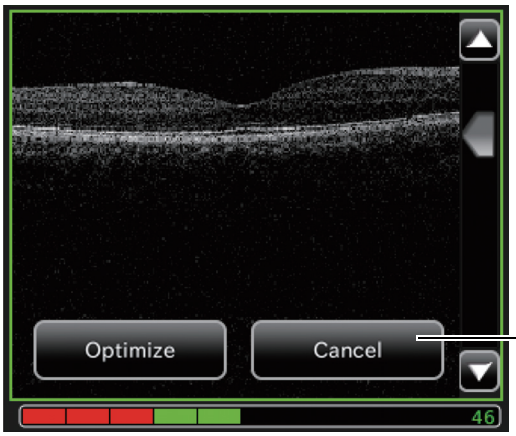
- Z lock position display bar : Indicates the Z lock position changeable range. By tapping an optional position on the bar, you can move the center position of the displayed tomogram to the tapped position.



- Image Quality value (IQV) : Displays the “Image Quality” level with a value.

NOTE	Image Quality value (IQV) is the image quality evaluation standard peculiar to TOPCON. IQV shows the image quality of the tomograms obtained by the instrument with a value quantitatively. When you need a tomogram applicable to image analysis or other processing, the IQV must be 30 or higher. If the IQV is 30 or higher, the tomogram has a proper image quality. If the IQV is less than 30, image analysis can be performed for the tomogram but the reliability on the analysis result is reduced. So the tomogram is not applicable for analysis.

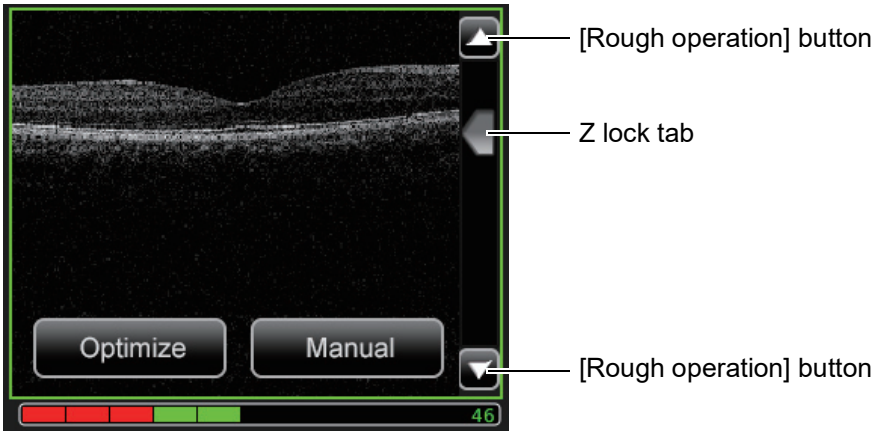
- [Image Quality] level meter : Displays the “Image Quality” level with a meter.
- Live image : Displays the live tomogram image.
  “Color display” is possible. “Monochrome display” is initially set.
- [Optimize] button : You can perform optimizing again by this button.
- [Cataract] button : When a clear tomogram cannot be obtained because of opaque optic media or others, optimizing is performed by moving the base up and down or right and left.
- [Cancel] button : The [Cancel] button is displayed during optimizing. Press this button, and optimizing is stopped.



[Cancel] button of “Cataract” mode

NOTE	• While the “Optimize” mode is being executed, the “Cataract” mode is not accessed by tapping the [Cataract] button. While the “Cataract” mode is being executed, the “Optimize” mode is not accessed by tapping the [Optimize] button. After the operation of each mode has been finished, tap the button of the desired mode.

- [Manual] button : Press the [Manual] button and operate the Z lock tab and [Rough operation] button to perform optimizing. This button is displayed only when the “Advance” mode is set.



NOTE	• When pressing the [Manual] button, the Z lock tab indicates the position against the prism operating range. (Refer to page 115.) The Z lock tab when pressing the [Manual] button does not have the function to move the displayed tomogram center position.

Area 3

In Area 3, set or change the small pupil diaphragm and the internal fixation target.
Set or change the data with the following buttons.

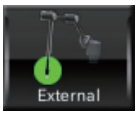
- Internal fixation target position adjustment button
  Tap the upper, lower, right and left buttons when the fixation target is displayed. The target position can be moved. After 3 seconds have passed since the last operation, the fixation target disappears on the fundus image. (*)

  * When you select “CONSTANT” after tapping the buttons in the following order “[SET UP] (setting menu) button” → “PAGE 2: Photography Setting” → “Fixation” → “TYPE”, the fixation target does not disappear.

- Fixation target shape selector button
  Tap this button, and two types (“point” and “cross”) of the shape the patient sees are changed to each other. The display on the screen is not changed.

- External fixation target selector button

  Tap this button, and the external fixation target is selected. You can change ON/OFF of the external fixation target with this button and the status (ON/OFF) of the external fixation target is displayed. When the external fixation target is ON, the internal fixation target shape selector button is faded out and displayed in gray. The shape of the internal fixation target cannot be changed even if you tap the button in this status.



Displays the status of the internal fixation target. (Background is gray.)

Displays the status of the external fixation target. (Background is orange.)

- Tracking button

  When Follow-up photography is done, the [TRACKING] button is ON and this status cannot be changed. The same position as the base line is searched according to the IR image.

  <OCT Angiography or SMART Track>

  When selecting the scan pattern “OCT Angiography” or “SMART Track”, you can change state of the [TRACKING] button. When the [TRACKING] button is set to “ON”, the position specified by the scan position adjustment mode is searched according to the IR image and OCT image during photography.

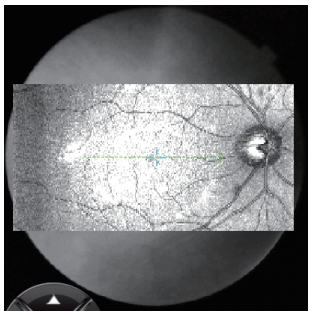
  When the [TRACKING] button is set to “OFF”, detect only signal intensity change during photography. If the change is detected, the OCT image is taken again from the scan position where the change is detected.

- OCT-LFV image ON/OFF

  You can select whether the OCT-LFV image should be displayed or not while the live image is being displayed. When “ON” is set for the OCT-LFV image, it is displayed on the live image in Area 2.

OCT-LFV image: ON

OCT-LFV image: OFF



NOTE	The OCT-LFV image is made of the tomogram. After optimizing is successful, the OCT-LFV image is displayed. It is effective when it is difficult to see blood vessels on the fundus observation image.

- [Advance] button
  Set this button to “ON” when performing the advanced adjustment in the manual adjustment mode. You can adjust focus, flash level and illumination level. You can also change the picture angle and the status of the small pupil diaphragm. Set “ON/OFF” of the “Advance” mode with this button.

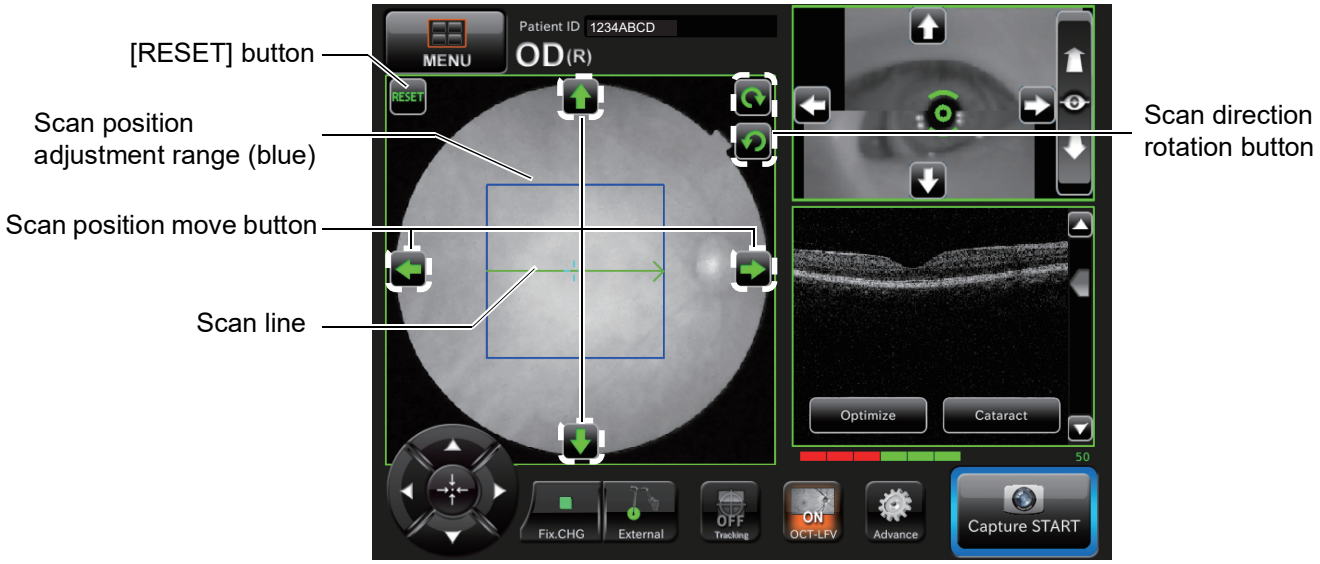
Advance mode: ON

Advance mode: OFF

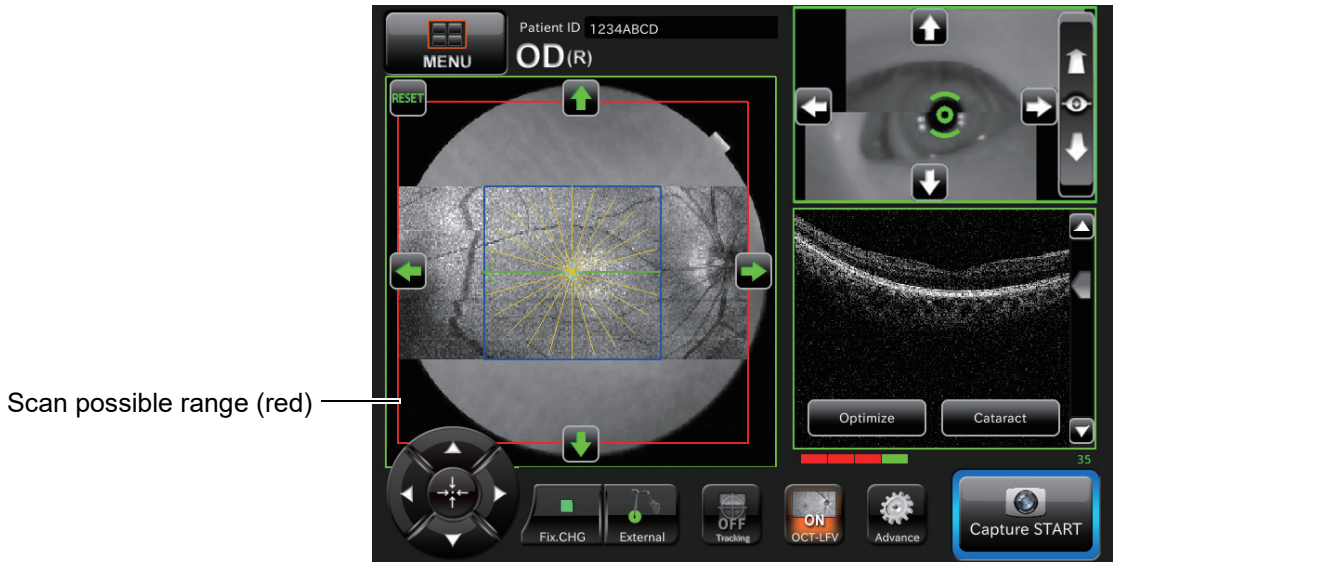
■ Photography screen (Tomogram scan position: Manual adjustment)

Tap the fundus/anterior segment live image area in Area 2, and the system shifts to the scan position adjustment screen. Tap the inside of the adjustment range, and you can change the scan position without using the buttons. Changing the scan position is valid except “3D scan”.

- In “Line” scan



- In “Radial” scan

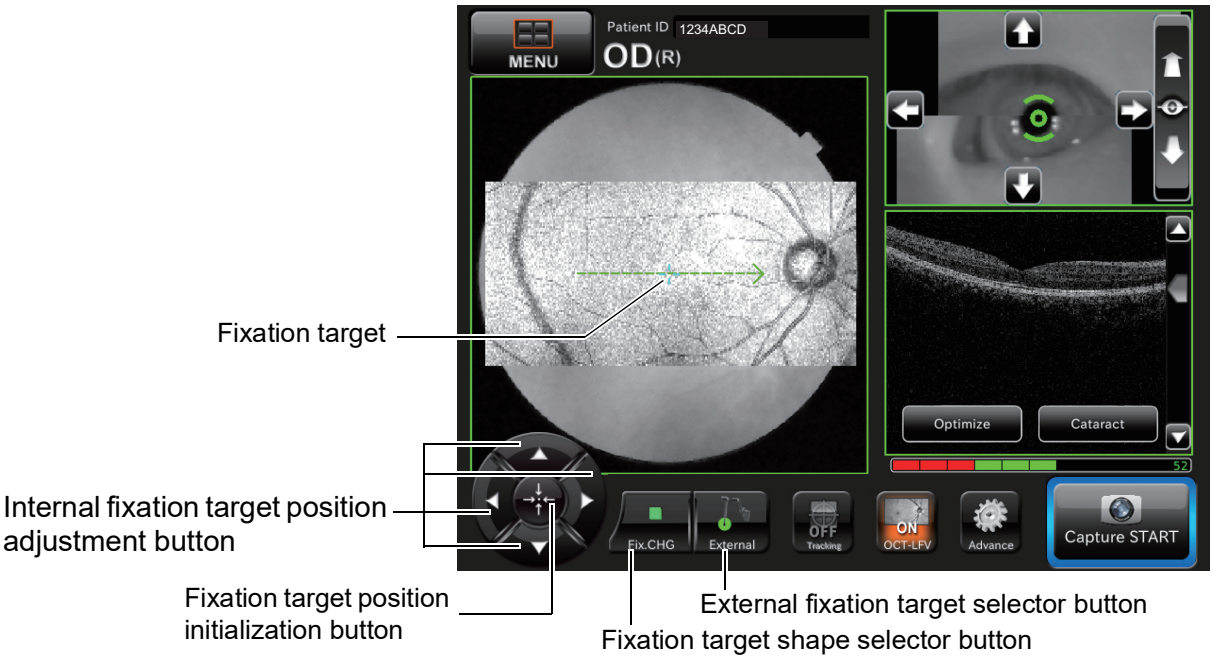


[RESET] button	:	Tap the [RESET] button. The change is discarded and the scan position is reset to the initial status.
Scan position move button	:	Tap the upper, lower, right and left buttons on the fundus image to adjust the scan position finely. Moving the scan position can be done in all scan patterns except “3D”.
Scan line	:	Displays the scan position and direction.
Scan direction rotation button	:	Tap the upper button, and the scan direction rotates clockwise. Tap the lower button, and the scan direction rotates counterclockwise. Rotation of scan direction can be done in all scan patterns except “3D” and “Radial”.

Scan position adjustment range (blue)	:	Displays the range for the “scan width × scan width” of the scan line at the focal point on the fundus. In the case of a tomogram within this range, you can obtain the sufficient output sensitivity.
Scan possible range (red)	:	Displays the range of “12.0mm×12.0mm” at the focal point on the fundus. This is the maximal range where you can obtain a tomogram with this instrument. The edge of the scan line cannot exceed this range. The scan possible range (red) is displayed in “Radial” and “5 Line Cross” scans.

NOTE	• To adjust the scan position finely, use the fine adjustment buttons around the image. • In “3D” scan, the scan position cannot be adjusted.

■ Photography screen (Internal fixation target position: Manual adjustment)



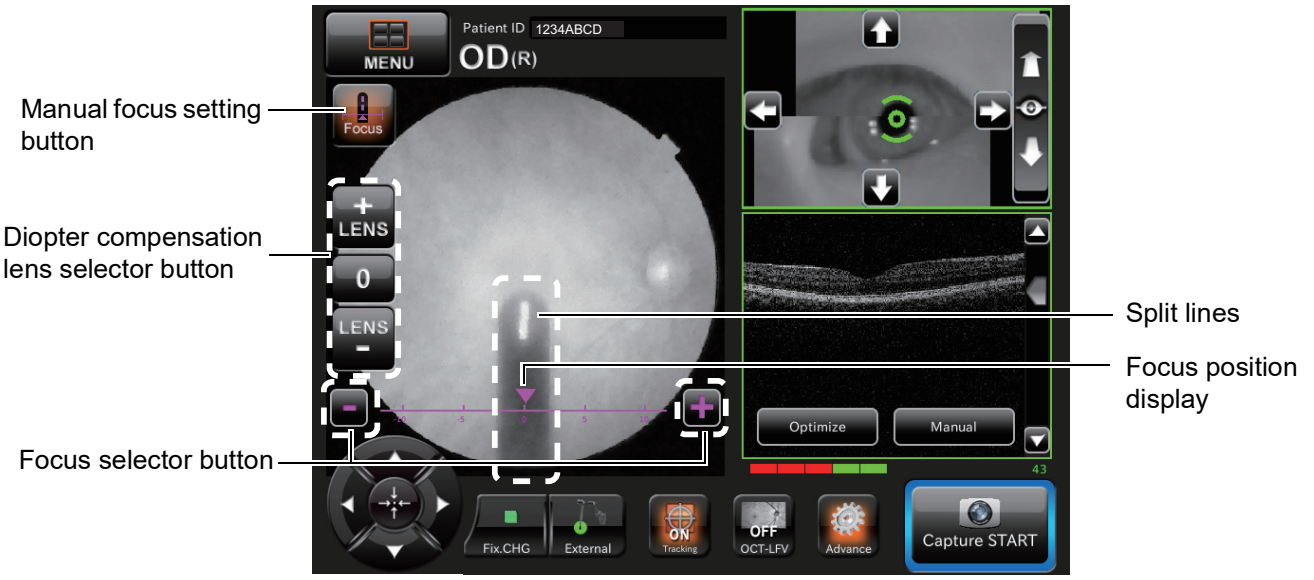
Fixation target	:	Indicates the fixation target position.
Internal fixation target position adjustment button	:	Tap the upper, lower, right and left buttons when the fixation target is displayed. The target position can be moved. After 3 seconds have passed since the last operation, the fixation target disappears on the fundus image. (*)
Fixation target position initialization button	:	If the fixation target is not displayed, it is displayed and its initial position is not changed. Tap this button when the fixation target is displayed. The fixation target is reset to its initial position. After 3 seconds have passed since the last operation, the fixation target disappears on the fundus image. (*) The button color is not changed.
Fixation target shape selector button	:	If the fixation target is not displayed, it is displayed on the fundus and its shape is not changed. Tap this shape selector button when the fixation target is displayed, and the target shape will change to "•" and "×" alternately. After 3 seconds have passed since the last operation, the fixation target disappears on the fundus image. (*) The button color is not changed.
External fixation target selector button	:	The fixation target is changed to the external one. When this button is selected, the fixation target disappears on the fundus image. When the external fixation target is valid, the button color changes to orange. When the external fixation target is ON, the internal fixation target shape selector button is faded out and displayed in gray. The shape of the internal fixation target cannot be changed even if you tap the button in this status. Tap the internal fixation target position adjustment button, and the external fixation target is changed to the internal one.

* When you select "CONSTANT" after tapping the buttons in the following order "[SET UP] (setting menu) button" → "PAGE 2: Photography Setting" → "Fixation" → "TYPE", the fixation target does not disappear.

NOTE	When the external fixation target is used, operate the arm to guide the patient's eye to the correct position.

■ Photography screen (Focus: Manual adjustment)

Press the [Focus] button, and the system shifts to the Focus manual adjustment screen. This screen is displayed only when the [Advance] button is ON.



Manual focus setting button	:	Tap this button, and you can set the focus manually. After the given time (3 seconds) has passed, the manual focus mode is canceled.
Diopter compensation lens selector button	:	Tap [+LENS] to increase the power. Tap [-LENS] to decrease the power. The center button displays “No compensation lens”.

NOTE	
	When the patient's eye has a strong myopia, set the diopter compensation lens selector button to (-). When the patient's eye has a strong hyperopia, set the diopter compensation lens selector button to (+). Compensation range: 0 : -13 – +12D – : -12 – -33D + : +11 – +40D

Split lines	:	Split lines are displayed. This display is changed according to the focus selector button.
Focus selector button	:	Changes focus.
Focus position display	:	Displays the current focus. Tap the plus button, and the focus moves rightward. Tap the minus button, and it moves leftward. Drag the Focus position display “▼” to move Focus position display to right or left.

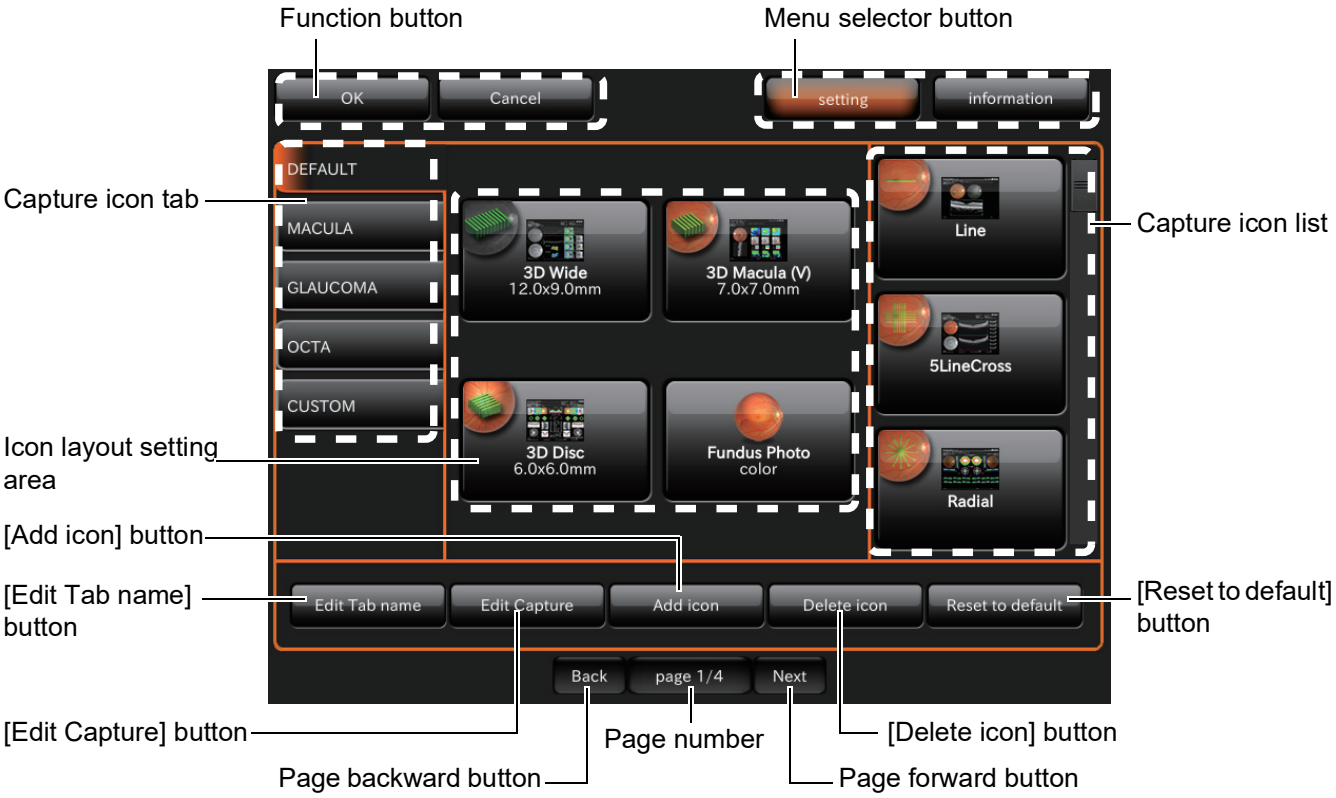
■ Photography screen (Picture angle change/adjustment)

Picture angle selector button : This is displayed in color fundus photography, peripheral fixation target photography and anterior segment photography. Set this button to “ON”, and “30°” is displayed in the photography information display area. The system enlarges the fundus or anterior segment image to be equal to the picture angle 30° and takes a picture.

■ Setting menu screen

You can set many kinds of data for this instrument on this screen.
On the capture icon selection screen, which is the initial screen, press the [SET UP] button. This screen appears.

- Capture select screen
  Set the icon display on the capture icon select screen and the parameters for each capture icon.

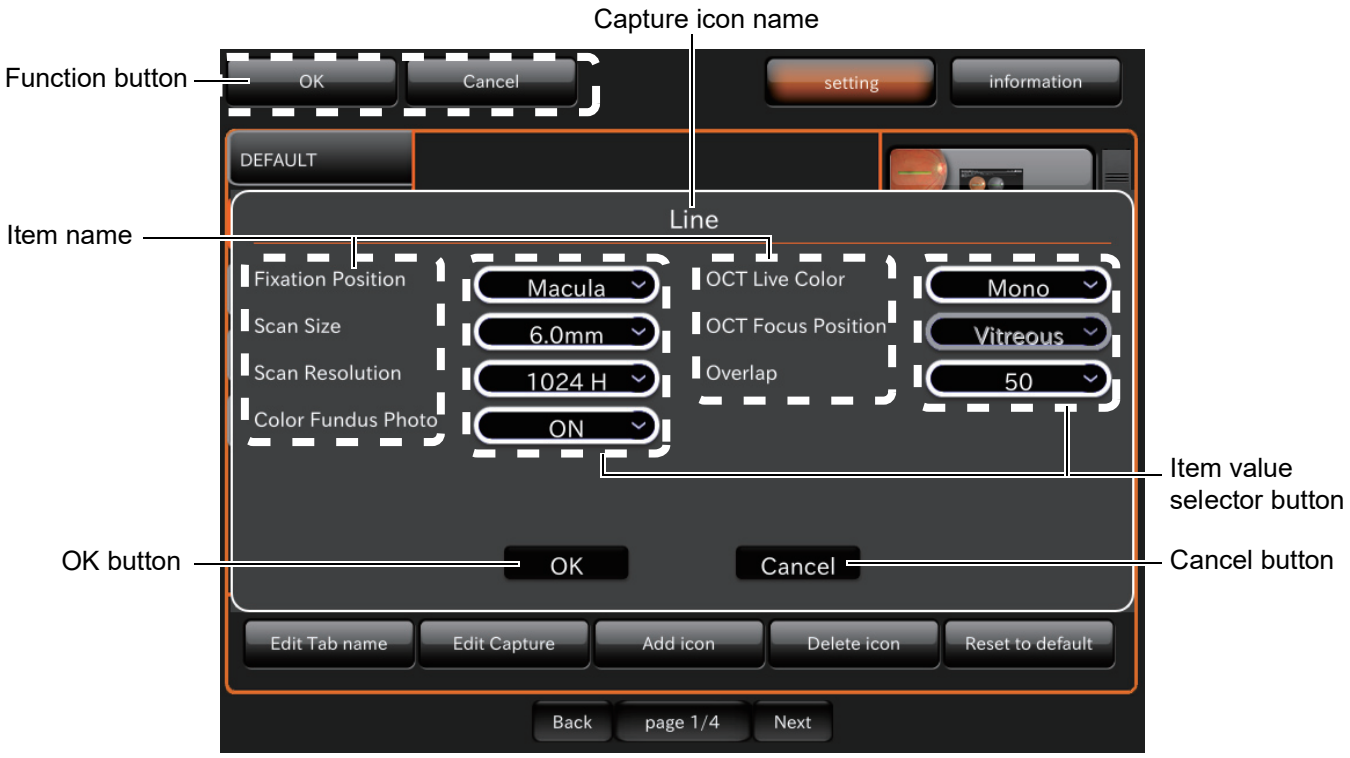


Function button	:	Saves and cancels the setting.
Menu selector button	:	You can change the setting screens for the photography mode and for the information to each other.
Capture icon list	:	Displays all the capture icons. You can view the hidden capture icons using the scroll bar at the right.
Page number	:	Displays the current setting menu page's number in page order.
Icon layout setting area	:	Sets the icons that will be displayed on the Capture icon selection screen, which is the initial screen.
Page forward/backward button	:	Shifts to the other pages in the setting menu.
[Edit Capture] button	:	Shifts to the parameter setting screen to check and change the parameters for the capture icon selected in the icon layout setting area.
Capture icon tab	:	Select a tab, and the photography icons, which are registered in each tab, are displayed.

[Add icon] button	:	Adds the icon, which is selected on the capture icon list, to the icon layout setting area. When you select a capture icon in the icon layout setting area, the icon is added to the left side or upper right corner of the capture icon.
[Delete icon] button	:	Deletes the capture icon, which is selected in the icon layout setting area. After deleting, the remaining capture icons are placed in order on the left.
[Edit Tab name] button	:	Changes the name of the capture icon tab.
[Reset to default] button	:	Returns the changed capture icon to the default.

■ Parameter setting screen

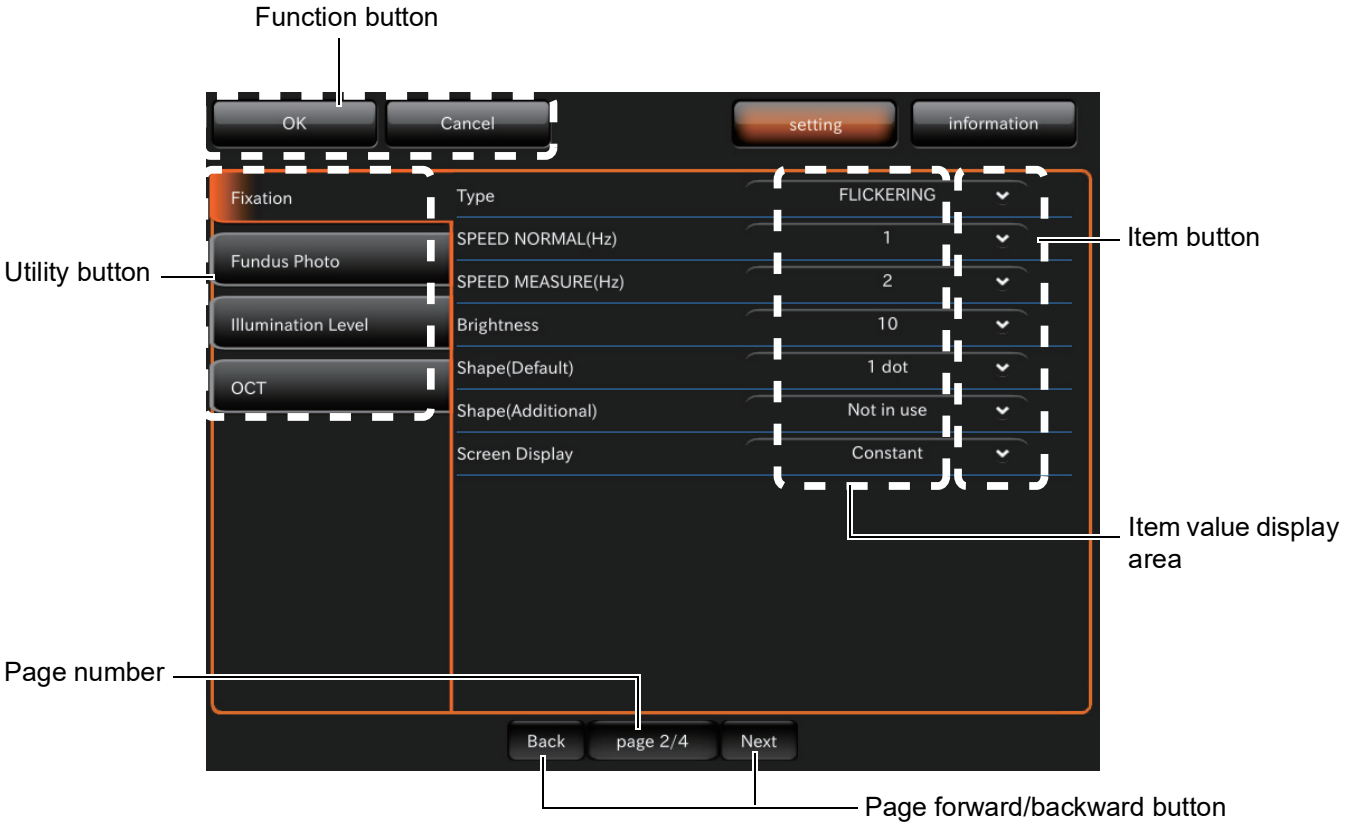
Set the parameters for the capture icon selected in the icon layout setting area.



Function button	:	Saves and cancels the setting.
Display of the capture icon name	:	Displays the selected capture icon name.
Item name	:	Displays the objective items of the parameters for the selected capture icon.
Item value selector button	:	Displays the set value of each item. Select the desired item.
OK button	:	Validates the changed contents and returns to the menu screen.
Cancel button	:	Returns to the menu screen. The changed contents are not validated.

■ Photography setting screen • Auto operation setting screen • System setting screen

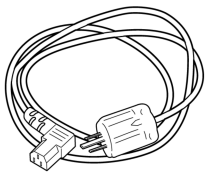
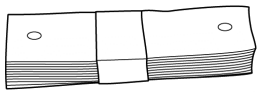
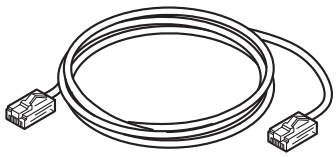
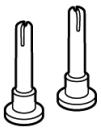
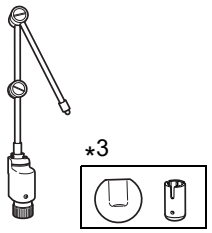
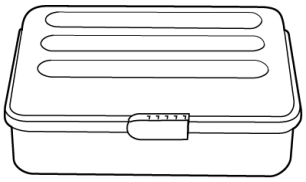
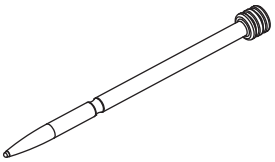
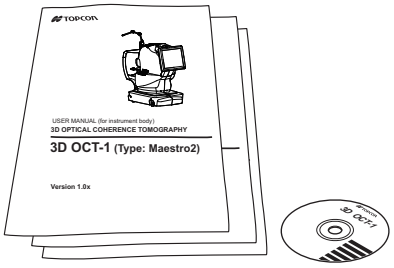
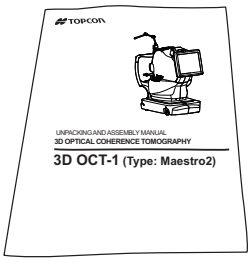
You can set data about photography and system.



Function button	:	Saves and cancels the setting.
Page number	:	Displays the current setting menu page's number in page order.
Utility button	:	Displays the objective items on the current setting menu page. Select the desired item.
Page forward/backward button	:	Shifts to other pages in the setting menu.
Item button	:	Changes the set status of the selected item.
Item value display area	:	Displays the current set status of each item.

STANDARD ACCESSORIES

Upon unpacking, make sure that all the following standard accessories are included.
Figures in ( ) are the quantities.

<table>
<tr><td>Power cord (1)*1
  </td><td>Chinrest tissue(1)
  </td><td>Monitor cleaner (1)
  </td></tr>
<tr><td>LAN cable (1)
  </td><td>Chinrest tissue pin (2)
  </td><td>External fixation target (1)*2
  </td></tr>
<tr><td>Dust cover (1)
  </td><td>Accessory case (1)
  </td><td>Stylus pen (1)
  </td></tr>
<tr><td colspan="2">User manuals (Instrument body / Software (IMAGEnet6 for OCT)) (1 each)
Instruction manuals (Instrument body / Software (IMAGEnet6 for OCT)) (1 each)*4
Installation manual (Software (IMAGEnet6 for OCT)) (1)
Software (IMAGEnet6 for OCT) DVD (1)
  </td><td>Unpacking and assembly manual (1)
  </td></tr>
</table>

*1 More than one power cord can be included on certain occasions.
*2 This product has a configuration in which an external fixation target is a standard accessory and a configuration in which it is an optional accessory.
*3 When it is difficult for a patient to see the external fixation target, please use the external fixation target shield plate.
*4 Instruction manual is not included in the standard accessories for some areas.

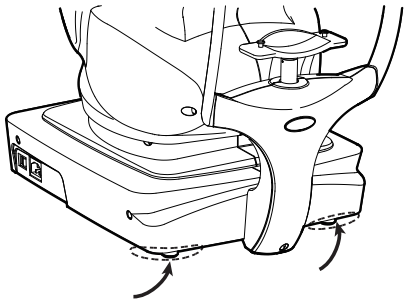
PREPARATIONS

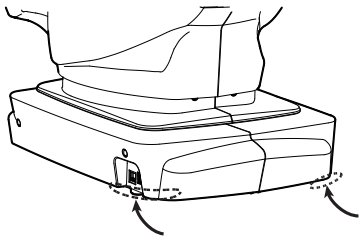
INSTALLATION

⚠CAUTION	• Be sure to carry the instrument with two people and hold the bottom of instrument. If you carry the instrument alone, it may be heavy, hurt your back, drop instrument and cause injuries. Be careful about the convex part of the bottom side when holding the instrument. If you hold other than the bottom side, it may cause the instrument to fall and damage. • To prevent damage and injuries, do not install the instrument on an uneven, unsteady or sloped surface. • When setting an instrument on an instrument table, pay attention not to catch the fingers between the instrument and the table.

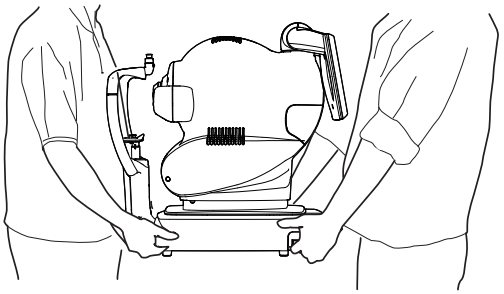
NOTE	• If you have Chinrest unit during transportation, unpacking or at installation, Chinrest unit can get out a position. Due to this reason, there may affect the performance of the auto alignment. • Do not place the instrument in an area where it will be exposed to direct sunlight. Automatic alignment may not be performed correctly.

1 Firmly hold the instrument at the position shown below and place it on the automatic instrument table.





Holding positions



Holding the instrument

CONNECTING THE POWER CORD

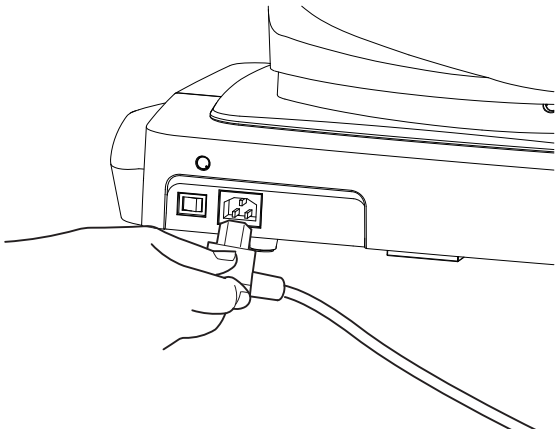
⚠WARNING	• Be sure to connect the power plug to an AC 3-pin receptacle equipped with grounding. Connection to a receptacle without grounding may cause electric shock in the case of shortcircuiting.

⚠CAUTION	• To avoid electric shocks, do not handle the power plug with wet fingers. • To avoid electric shock, use the power cord packed together with this instrument.

1 Make sure the POWER switch of the instrument is turned OFF.

2 Connect the power cord to the Power inlet.

3 Insert the power cord plug into the 3-pin AC grounding receptacle.



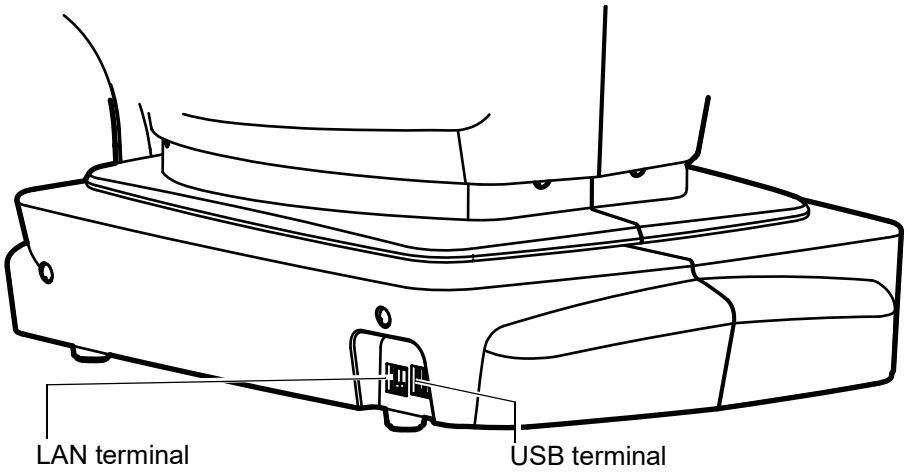
CONNECTING THE EXTERNAL I/O TERMINALS

NOTE	Use the external device conforming to IEC 62368-1. For connecting to an external device, contact your TOPCON dealer or the offices listed on the back cover.

DATA OUTPUT

This product can be connected to a personal computer (PC) and other external devices via LAN.

1 Insert the LAN cable into the external I/O terminal of the instrument.



2 Connect the other end of the LAN cable to the PC, etc.

RECOVERY FROM POWER SAVE STATUS

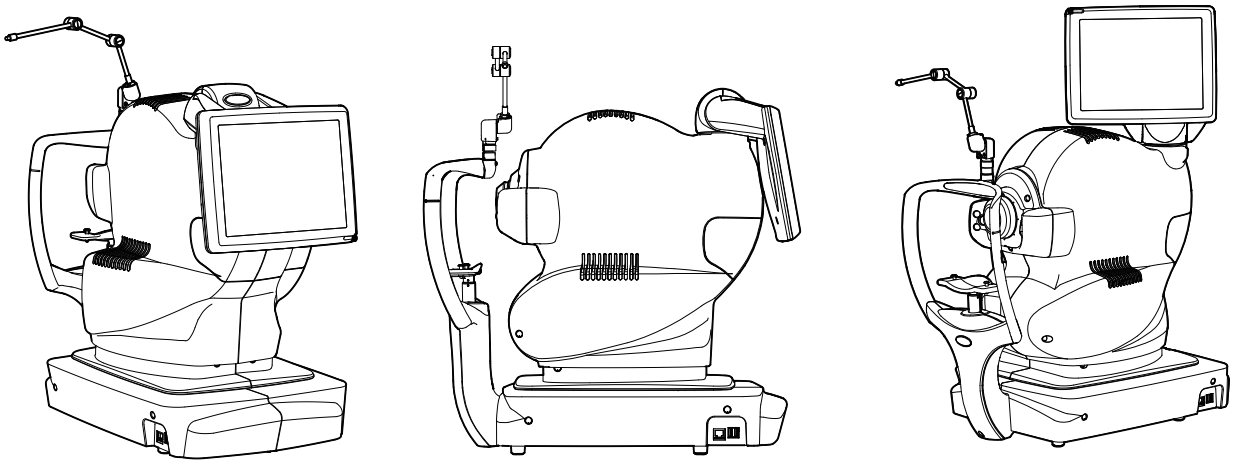
This instrument adopts the power save system for saving electric power. When the instrument is not operated for a set time, the control panel becomes a power save.

1 Tap the control panel.
In a few seconds, the measurement screen will be displayed and measurement is enabled.

NOTE	The time to start the power save status can be changed in the System setting menu “Power Save Timer (Min)”.

ADJUSTING THE CONTROL PANEL POSITION

The control panel may be positioned by swinging and tilting the control panel to your desired position. Touching the control panel controls operations including chinrest movements, alignment and measurement.



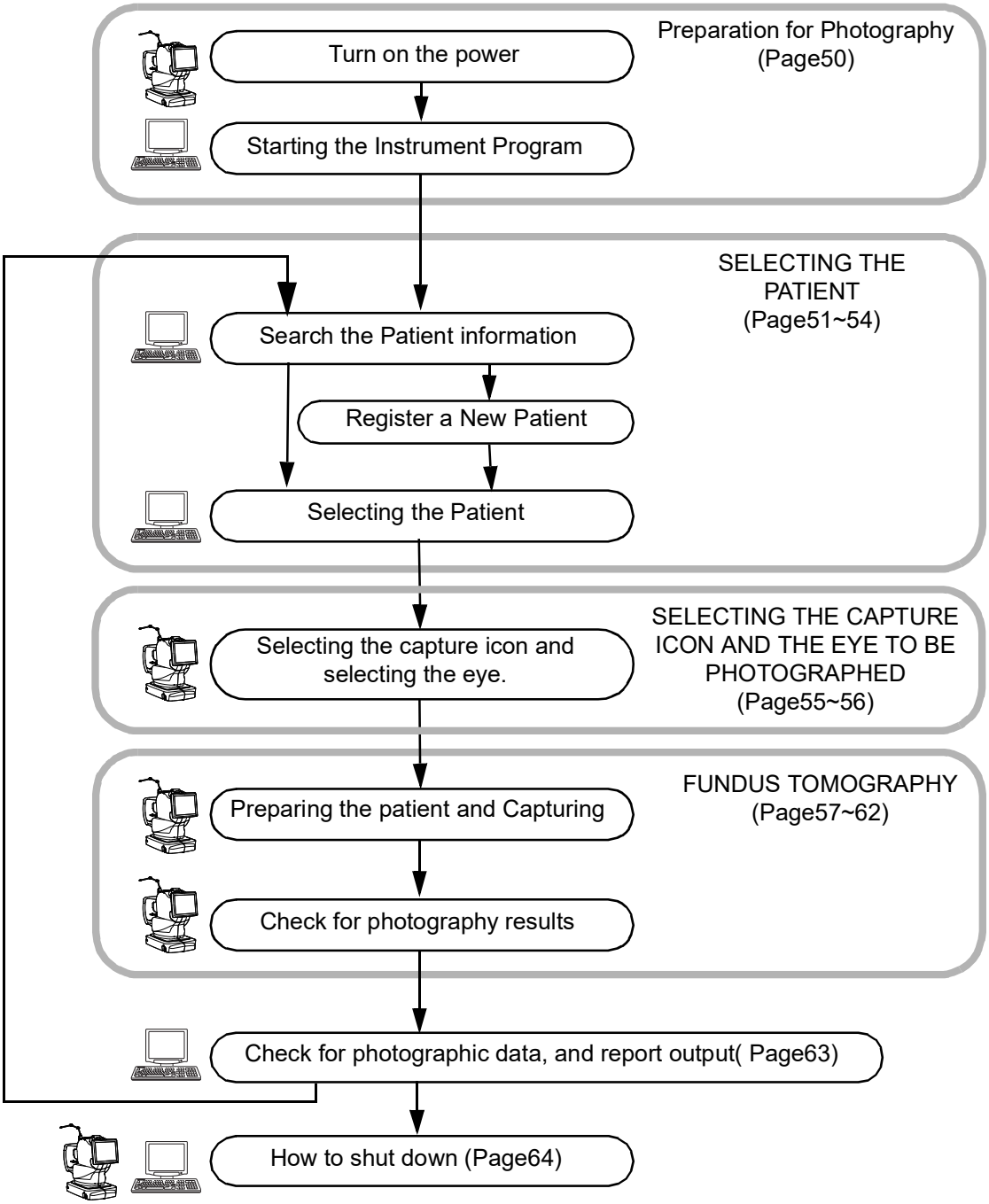
BASIC OPERATIONS

FLOW OF OPERATION

The following is the standard operating procedure example that is used in conjuction with a personal computer installed the dedicated software.

:Operations of instrument body

:Operations of PC

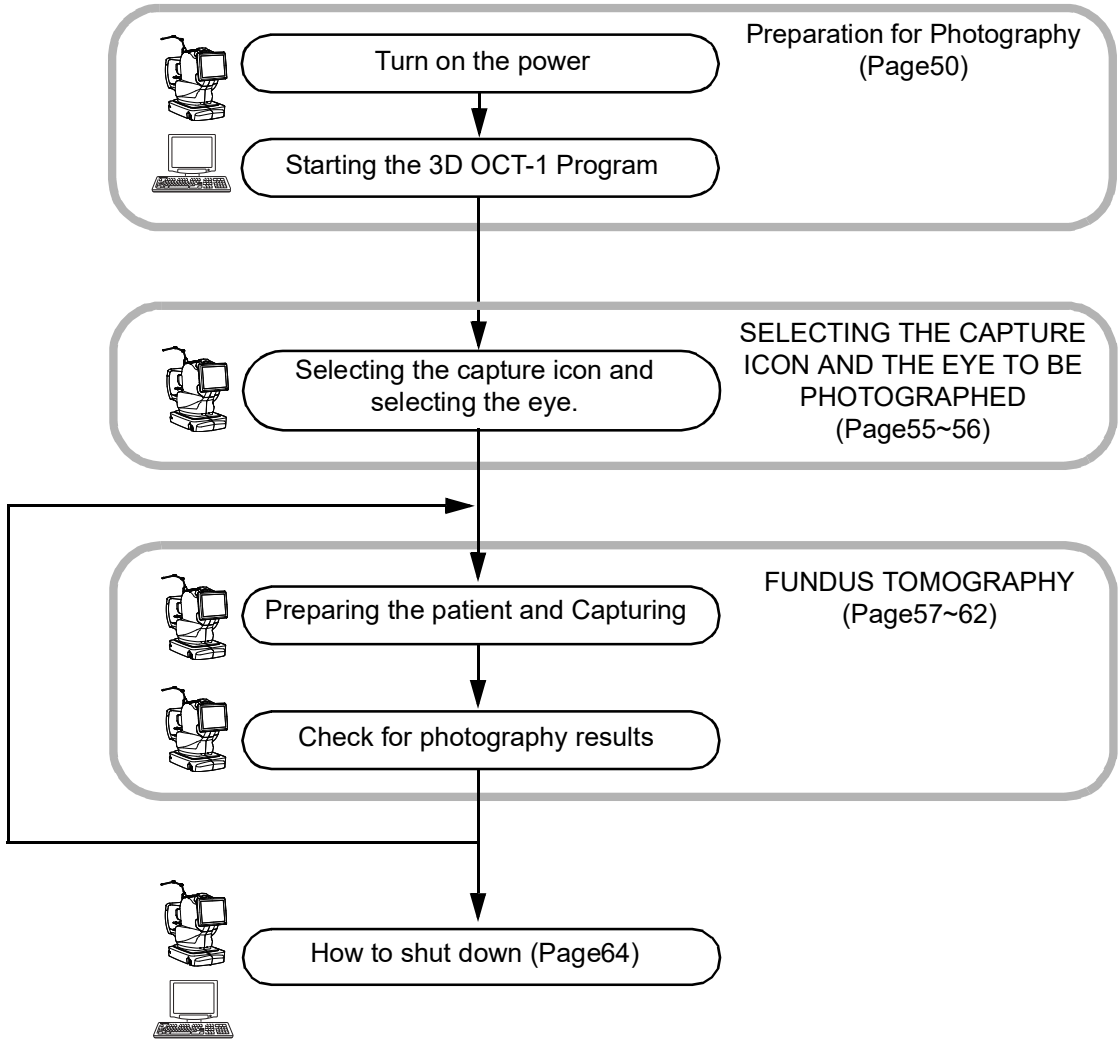


NOTE	For remote operation, refer to “User manual:IMAGEnet6 for OCT”.

When the “Custom-2” mode is set for the work flow setting (option setting), an example of use is shown below.

:Operations of instrument body

:Operations of PC



NOTE	• When the “Custom-2” mode is set for the work flow setting (option setting), the patient information is not managed by the instrument and the analysis software on personal computer. This mode only exports captured data to external system. It is supposed that patient information is managed by the external system. • For setting the “Custom-2” mode (setting on the instrument and the personal computer), contact your dealer or the TOPCON office at the address listed on the back cover. • When selecting the capture icon, the following message may be displayed. In that case, please wait a while and select the capture icon again. “Failed to start the external PC software. Please try again.”

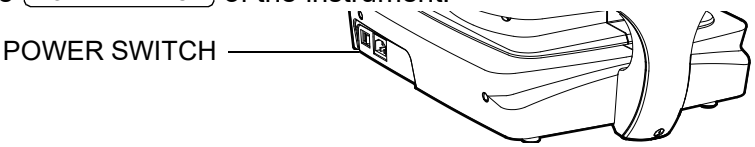
PREPARATION FOR PHOTOGRAPHY

Turn ON the power

1 Check the power cord connection.

For details, see “CONNECTING THE POWER CORD” on page 45.

2 Turn ON the [POWER SWITCH] of the instrument.



3 Confirm that the Title screen is displayed and then, in several tens of seconds, the capture icon selection screen should be displayed.

NOTE	After the Title screen is displayed, the screen is blank for about 10 seconds because the built-in graphics are initialized. This is not a trouble.

To Start the Special Software

1 First, connect a personal computer to the instrument and install the special software, which is an accessory of the instrument, to the personal computer. Then, turn on the personal computer.

2 Double-click the [IMAGEnet 6] icon 

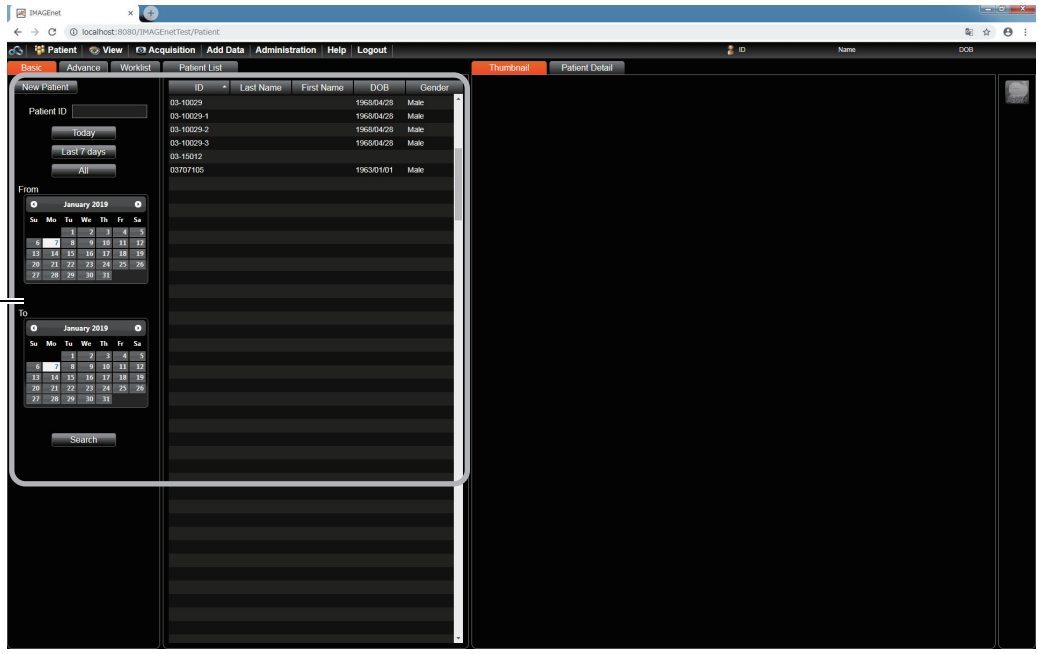
on the desktop. The special software starts.

SELECTING THE PATIENT

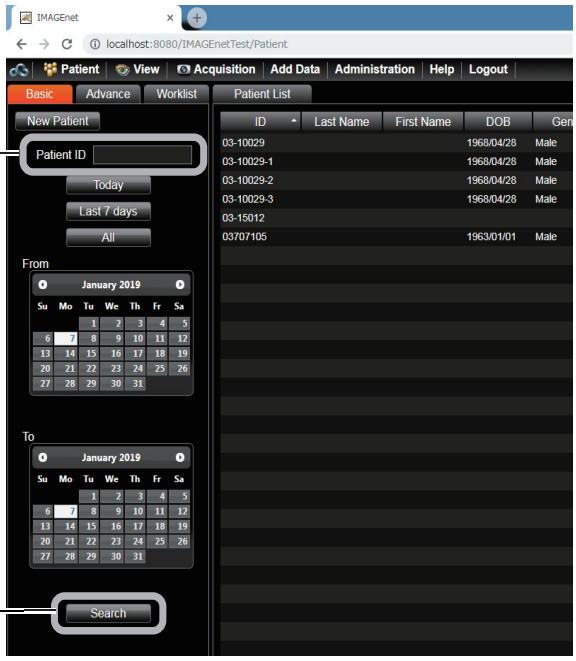
NOTE	For details, refer to “User manual: IMAGEnet6 for OCT”.

Search the Patient information

If the patient information already exists in database, select the patient from the Search Patient panel.



1 Enter the patient ID, and click the [patient Search] button.



* Result of the search, if there is no appropriate patient, new patient registration screen will show automatically.

Register a New Patient

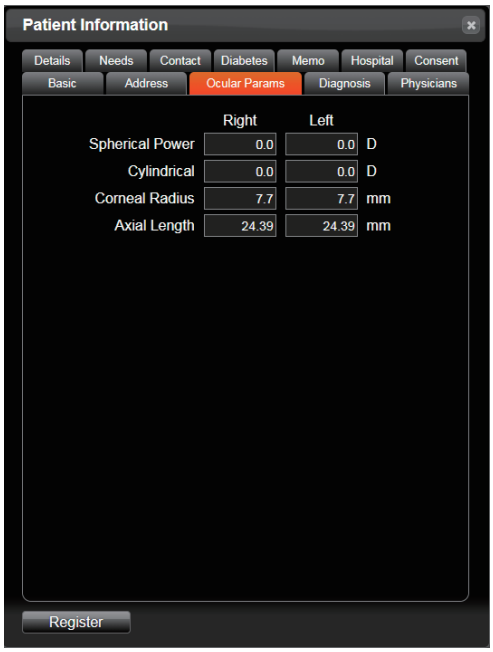
Register the patient information for new patients.

NOTE	When entering the patient ID through the instrument, a bar code reader, a card reader, IMAGEnet, Multi-Viewer, etc., you must use only the alphabet, numerals and “-”. Moreover, the following symbols cannot be used for the patient ID. " \ / : 'Space' * ? . <> | _ ! # $ % & ¥ If you use a patient ID which does not meet the above conditions, the report cannot be output correctly from time to time.

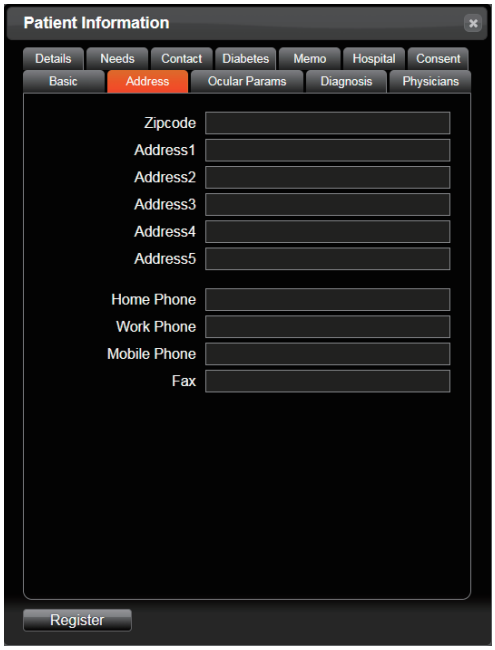
1 Enter the patient information in the dialog box, as desired.

Be sure to input the ID.

2 You can enter the eyeball refraction data to [Ocular Parameters.].



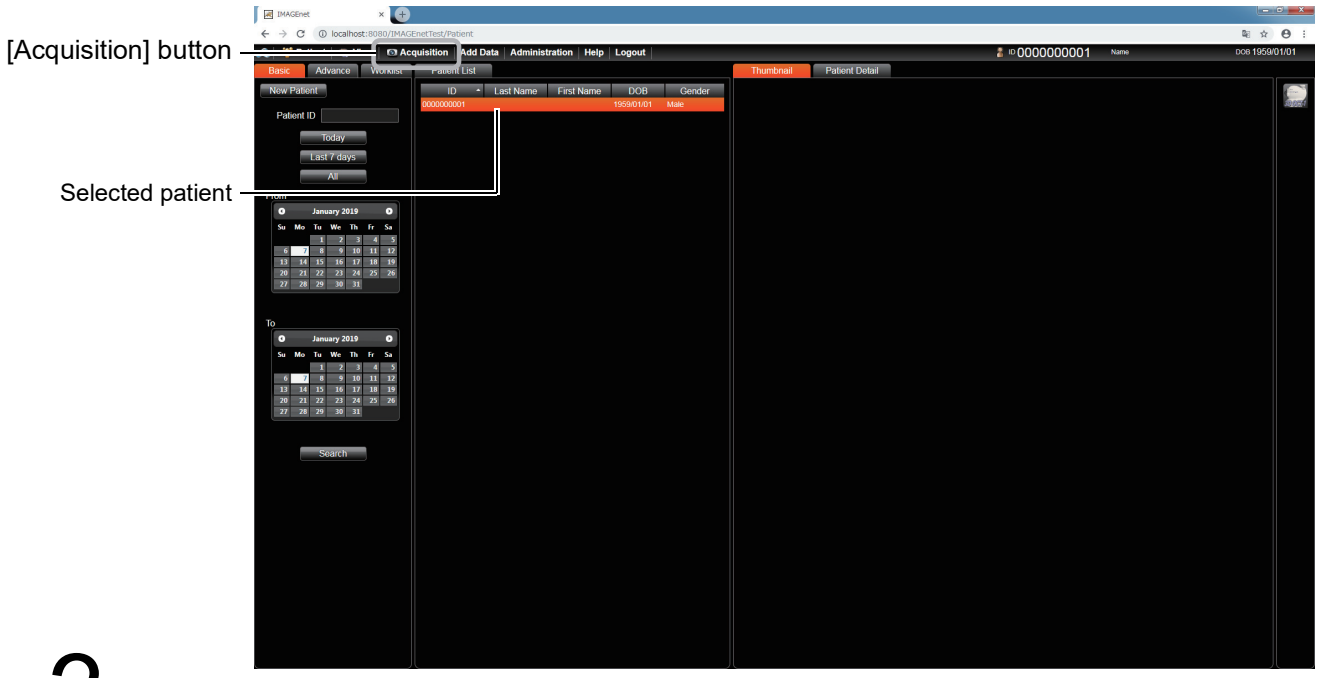
3 To add additional patient information, click More... .



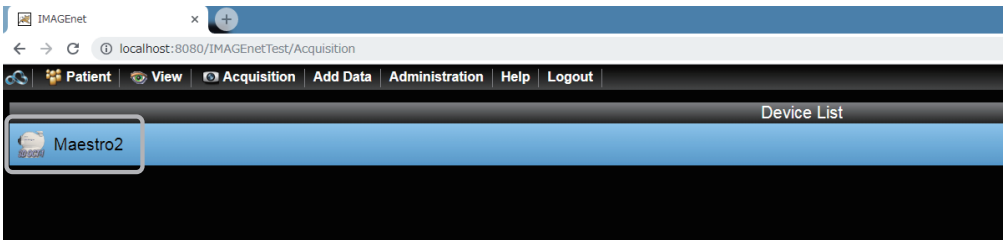
4 Click [Register].

Selecting the Patient

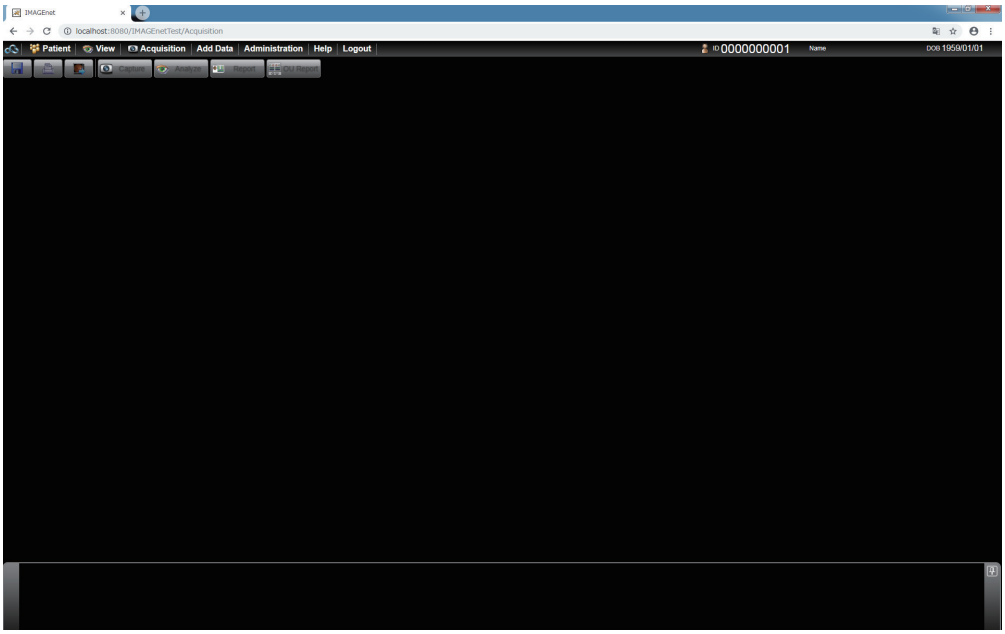
1 Select the patient from the Search Patient panel. Then, click the [Acquisition] button.



2 Select Maestro2.



3 Photography screen appears.

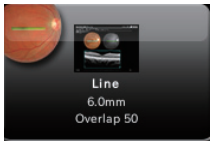
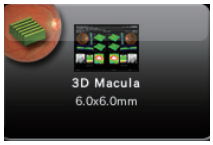
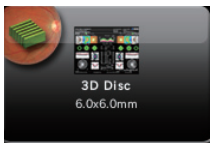


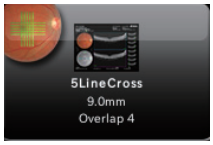
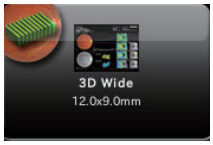
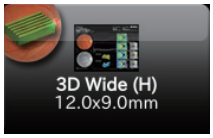
SELECTING THE CAPTURE ICON AND THE EYE TO BE PHOTOGRAPHED

Selecting the capture icon and the eye to be photographed

1 On the capture icon selection screen, which is the initial screen, tap and select the fundus tomogramcapture icon.

You can select and display a capture icon from the icons shown in the following table.

Capture icon	Capture icon name	Scan length	Scan resolution	Fixation position	Color Anterior Photography	Over Scan Count
	Line	6.0mm	1024H	Macula	-	50
	Radial	Dia. 6.0mm	1024	Macula	-	4
	3D Macula	6.0×6.0mm	512×128	Macula	-	-
	3D Macula(V)	7.0×7.0mm	512×128	Macula	-	-
	3D Optic disc	6.0×6.0mm	512×128	Disc	-	-

Capture icon	Capture icon name	Scan length	Scan resolution	Fixation position	Color Anterior Photography	Over Scan Count
	5Line Cross	9.0mm	1024	Macula	-	4
	3D Wide	12.0×9.0mm	512×128	Wide	-	-
	3D Wide (H)	12.0×9.0mm	512×128	Wide	-	-
	OCT Angiography *	3.0×3.0mm	320×320	Macula	-	-

* To display the image of “OCT Angiography”, the license of “OCT Angiography” for “IMAGEnet6 for OCT” is necessary.

2 Select an eye to be captured.

Capture eye selection button

FUNDUS TOMOGRAPHY

	Misdiagnosis
⚠CAUTION	Pay attention to the following points during photography. [The image may be low quality, leading to misdiagnosis.] Under the following photography conditions, there is a bright spot on the center of the picture. • The patient's pupil is small. (This condition includes the case of “When the small pupil diaphragm is set to ON”.) • The flash level is high. • Alignment is not adjusted properly. To improve these conditions, carry out the following operations. • Darken the room to enhance dilation. (When using mydriatic, follow the judgment of a doctor and the instruction manual about medicine.) • Adjust alignment for the position where the flare is the least visible on the monitor screen. • Set the flash level to the lowest setting the environment will allow. Then, take a picture.

NOTE	To ensure correct imaging, adjust the table height so the patient can relax with his/her chin placed centrally on the Chinrest.

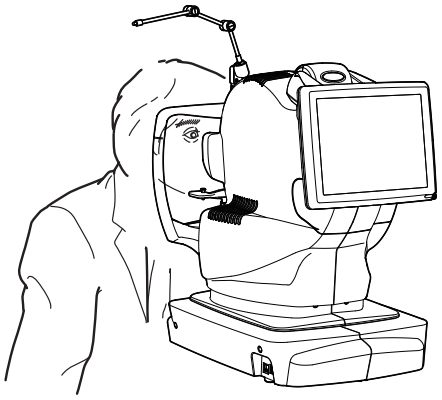
Preparing the patient and capturing

⚠CAUTION	• When moving the Chinrest up and down, be careful not to pinch the patient's hand to avoid possible injury. • When moving the main unit by auto/manual alignment, the external fixation target will be pushed by the measuring head. Be careful to prevent the external fixation target from hitting the patient.

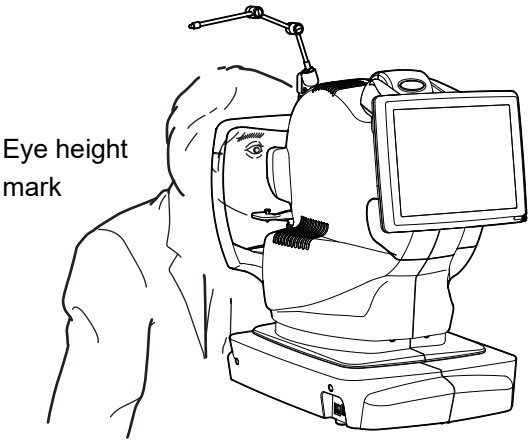
NOTE	• If the patient wears glasses or contact lenses, have him/her remove them first. • When automatic photography is NG, the manual adjustment mode is automatically accessed.

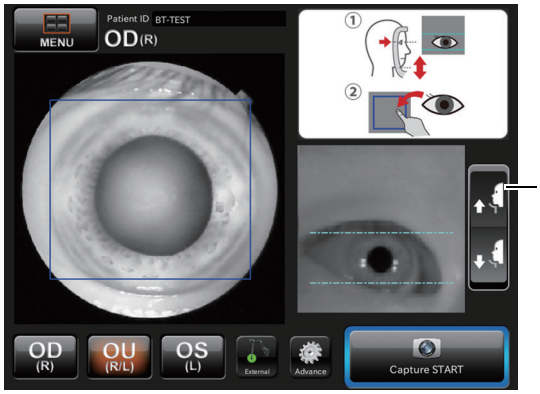
1 Seat the patient comfortably on an exam stool or chair in front of the instrument.

2 Adjust the table height or chair height so the patient can relax with his/her chin placed centrally on the chinrest.
Let the patient rest his/her chin on the chinrest.



3 Adjust the chinrest height by adjusting the chinrest up/down button so the outside corner of the patient's eye is level with the Eye height mark on the chinrest post.
Let the patient rest his/her forehead on the forehead rest.
Tap the screen to place the pupil within the blue frame.





NOTE	In the photography with “optic disc” as the fixation target, the peripheral fixation targets are lit to guide the patient's eye to the correct position easily when taking a picture.

4 Instruct the patient to look at the green light (internal fixation target).

5 After the preparation has been completed, press the [Capture START button]. Automatic alignment starts.

6 After automatic alignment, automatic focus starts.

NOTE	• When automatic operation is not possible for certain reasons, the manual adjustment screen is automatically accessed. You can also access the manual adjustment screen by tapping the [Capture STOP button]. For operation on the manual screen, refer to “■ Operation on the manual adjustment screen” on P.76.

7 After the preparation for photography has been completed, AUTO SHOOT TIMER begins to count. Then, after the given time has passed, photography is executed.

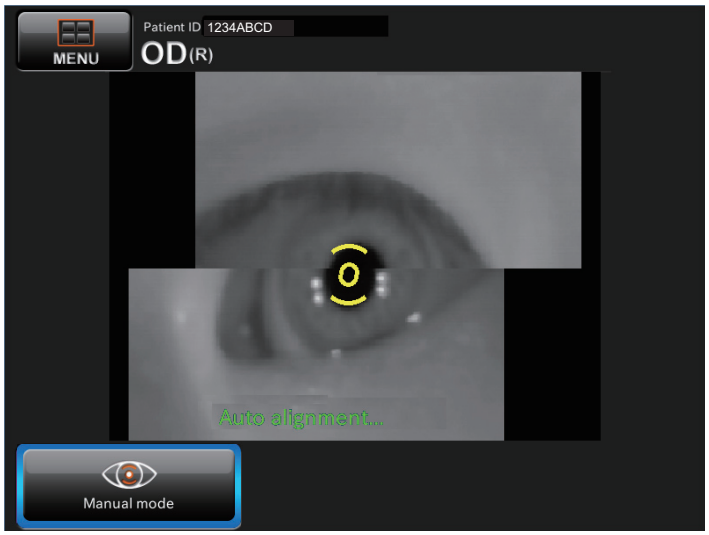
8 The result of photography is displayed.

NOTE	• The following modes are also provided: Mode not to display the photography result; Mode to display the results after all the specified pictures have been taken; Mode to cancel the preview function after the given time has passed.

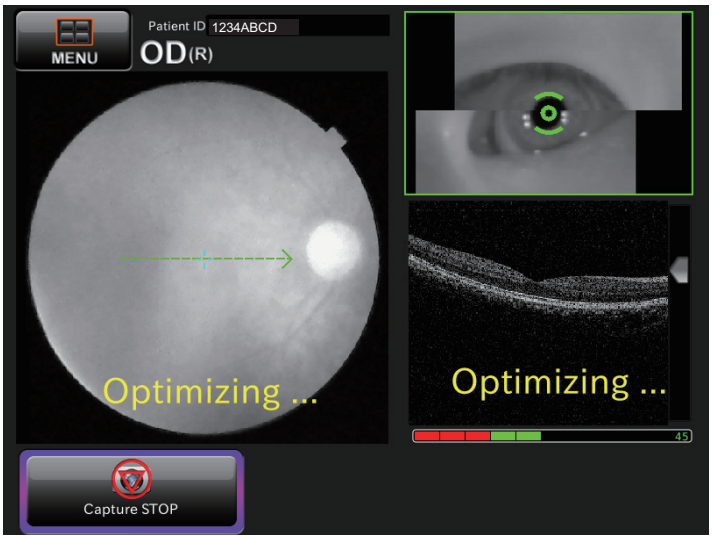
■ Photography screen (OCT automatic photography)

After adjusting the chin position with the chinrest up/down button, press the capture start button. Automatic photography starts. The following steps are automatically executed in the order listed below.

1 Alignment to pupil is performed automatically.



2 Automatic focus and automatic optimizing to fundus are performed automatically.



3 The system shifts to the waiting status for the capture start and the capture timer starts. After the given time has passed on the capture timer, photography starts automatically.

4 After the photograph is taken, the result is automatically displayed.
When color fundus photography is set to OFF the color fundus photography image is changed to the IR fundus photography image.

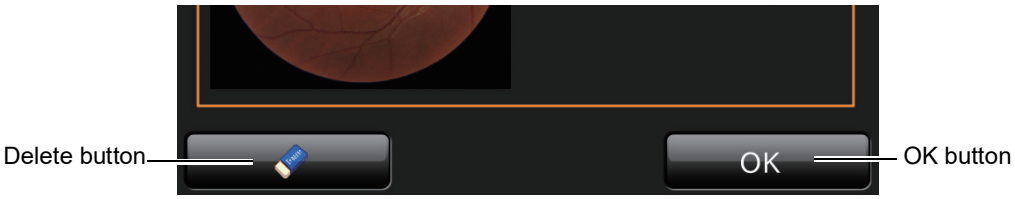
Check for photography result

1 When the photography result is OK. : Tap the [OK] button.

Where OU photography is selected, shift to the photography for the other eye. To photograph the other eye, operate as indicated in step *4* and below on page 58.

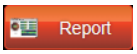
Where single eye is selected or both eyes have been photographed, back to the step [Selecting the capture icon and selecting the eye] on page 55.

When the photography result is not OK.: Tap the [Delete] button to delete photographic data.



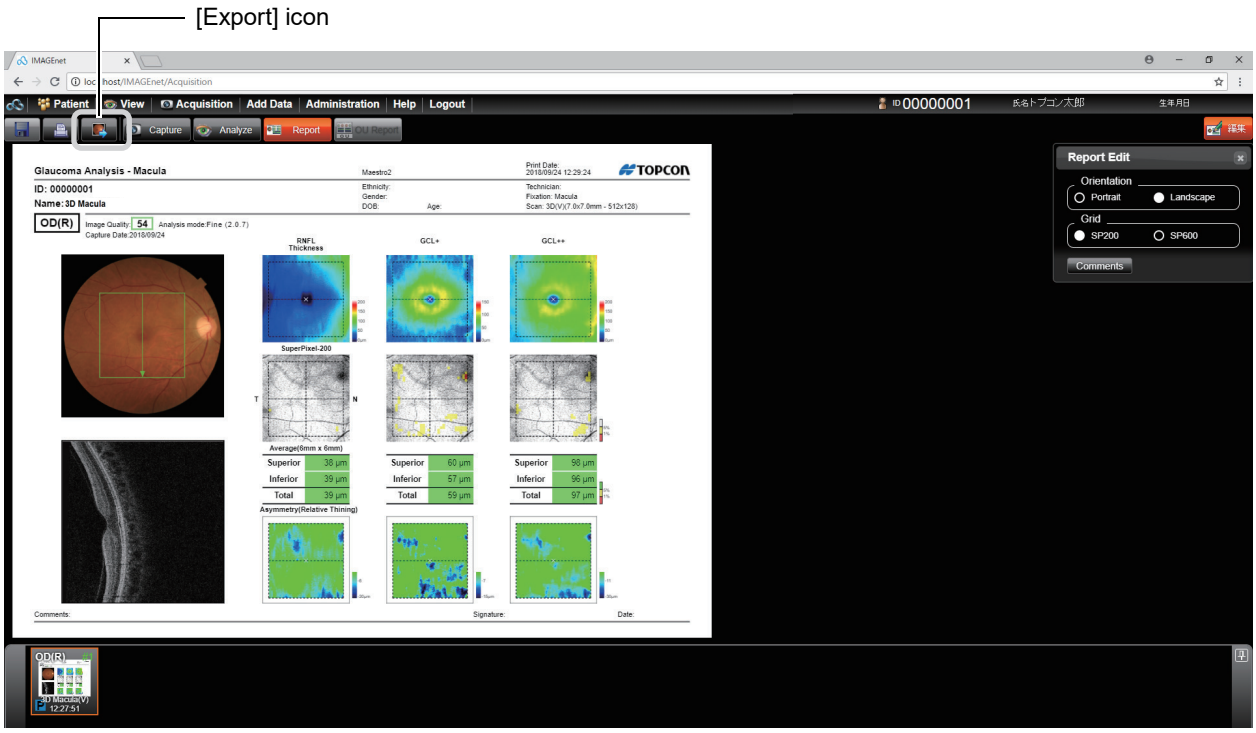
2 After the necessary photograph is taken, let the patient move away from the instrument body.

Check for photographic data and report output

1 Select the thumbnail that has been analyzed, and click [Report] button 

.

2 After displaying the report, click the [Export] icon.



3 After finishing the export, click the [Patient] button to back to the patient searching screen (page 51).

HOW TO SHUT DOWN

Shutting down the personal computer

1 Close the window to finish the special software.

2 Turn off the personal computer according to its regular shut down method.

Shutting down the instrument

1 Turn OFF (○) the [POWER SWITCH] of the instrument.

NOTE	• When the instrument is not in use for a long time, unplug the power cords of the instrument, external recording device and others from the outlet and remove the cords from each device. • This instrument adopts a “Power save method” (P.47). If you use the instrument continually all day, it is recommended that you use it without turning off the [POWER SWITCH].

OBJECTIVE OPERATIONS

COLOR FUNDUS PHOTOGRAPHY

⚠CAUTION	Misdiagnosis
	Pay attention to the following points during photography. [The image may be low quality, leading to misdiagnosis.] Under the following photography conditions, there is a bright spot on the center of the picture. • The patient's pupil is small. (This condition includes the case of “When the small pupil diaphragm is set to ON”.) • The flash level is high. • Alignment is not adjusted properly. To improve these conditions, carry out the following operations: • Darken the room to enhance dilation. (When using mydriatic, follow the judgment of a doctor and the instruction manual about medicine.) • Adjust alignment for the position where the flare is the least visible on the monitor screen. • Set the flash level to the lowest setting the environment will allow. Then, take a picture.

Selecting the capture icon

On the capture icon selection screen, which is the initial screen, select the fundus photography capture icon.

Icon	Capture icon	Fixation position
	Fundus Photo	Center

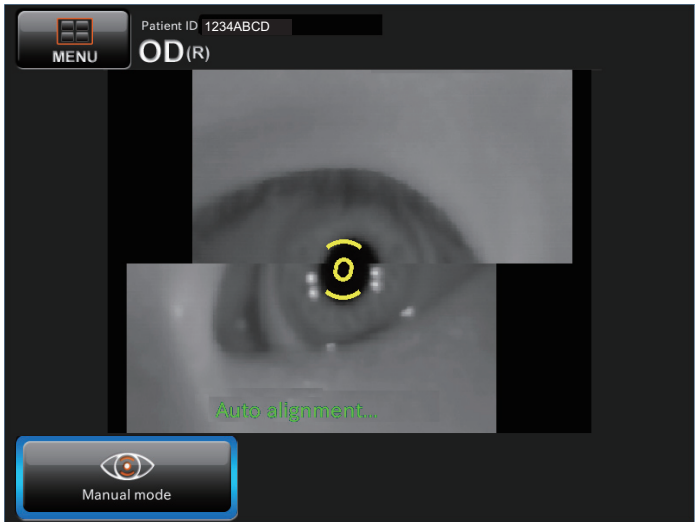
Setting up the patient

Refer to “Preparing the patient and capturing” on page 57.

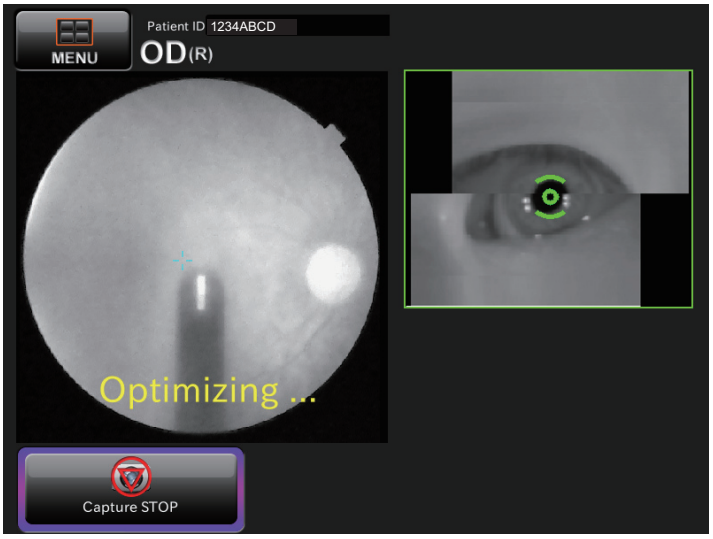
■ Photography screen (Color fundus automatic photography)

After adjusting the chin position with the chinrest up/down button, press the capture start button. Automatic photography starts. The following steps are automatically executed in the order listed below.

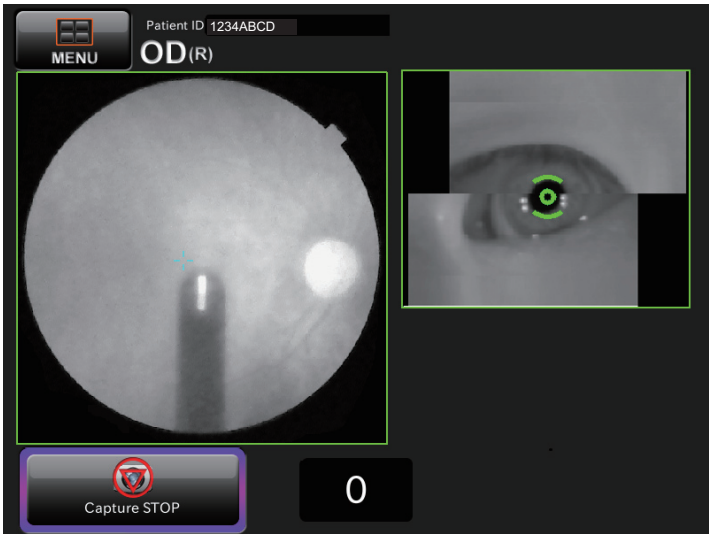
1 Alignment to pupil is performed automatically.



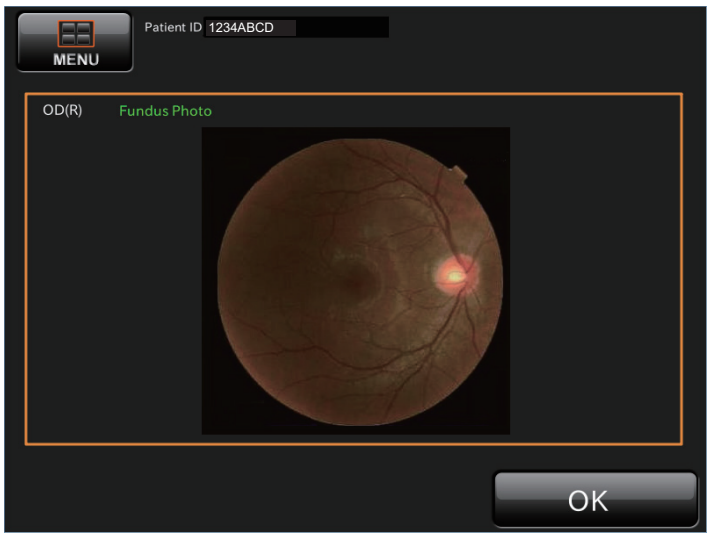
2 Automatic focus to fundus is performed automatically.



3 The system shifts to the waiting status for the capture start and the capture timer starts. After the given time has passed on the capture timer, photography starts automatically.

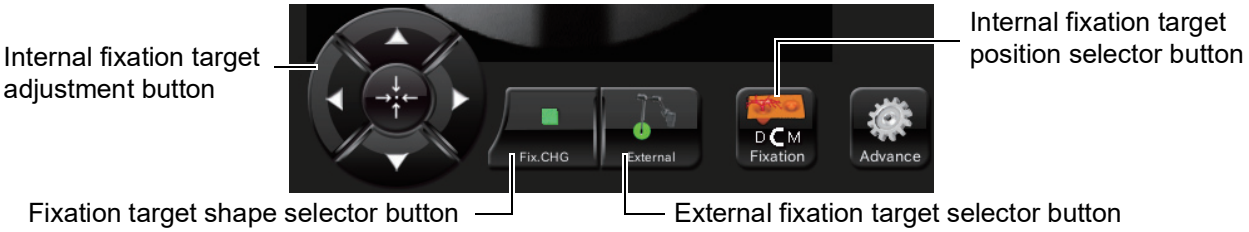


4 After the photograph is taken, the result is automatically displayed.



Setting the picture position

Using the [INTERNAL FIXATION TARGET POSITION SELECTOR BUTTON] on Area 3 of the photography screen (color photography), set the picture position. Each time you press the [INTERNAL FIXATION TARGET POSITION SELECTOR BUTTON], the picture position is changed to “D” (optic disc center), “C” (the middle position of optic disc and macula) and “M” (macula center) in this order. Set the picture position to “C” for the middle position of optic disc and macula, “M” for macula, and “D” for optic disc.



COLOR ANTERIOR SEGMENT PHOTOGRAPHY

⚠CAUTION	To avoid injury of the patient, be careful not to bump the patient's eye or nose with the instrument and external fixation target when operating the control panel.

Selecting the capture icon

On the capture icon selection screen, which is the initial screen, select the anterior segment photography capture icon.

Icon	Capture icon	Fixation position
	Anterior Photo	External fixation target

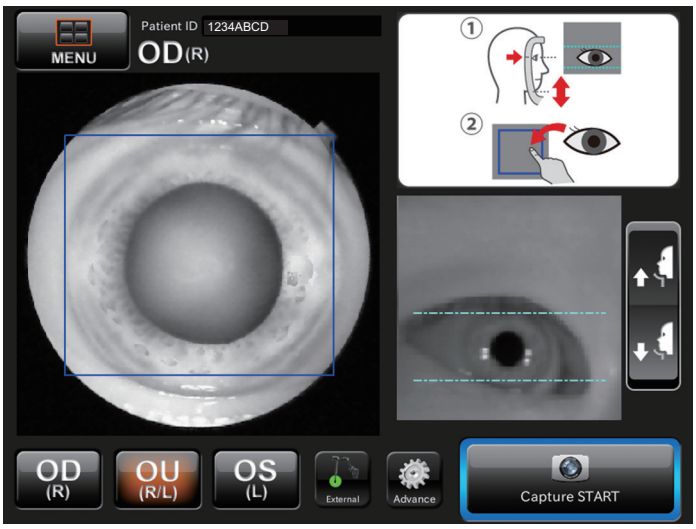
Setting up the patient

Refer to “Preparing the patient and capturing” on page 57.

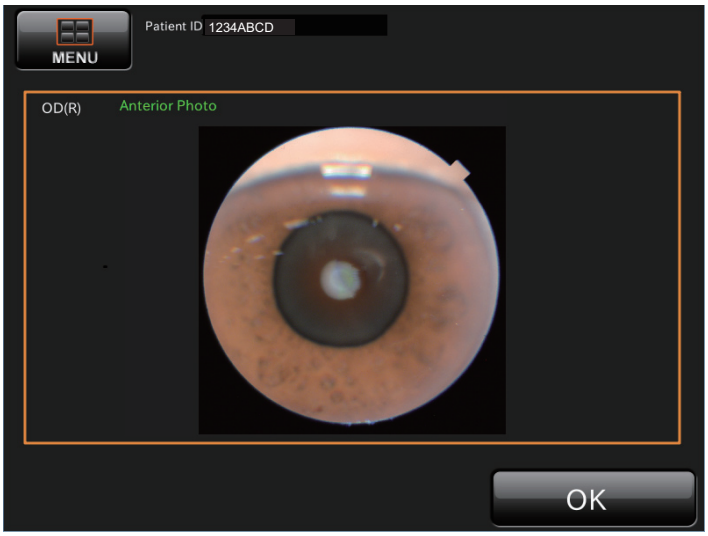
■ Anterior segment photography

After adjusting the chin position with the chinrest up/down button, press the capture start button. The system shifts to the manual adjustment screen.

1 Perform adjustment so that the anterior segment image can be seen clearly by making use of the following method : Lead the fixation of the patient's eye by using the external fixation target or giving oral instructions to the patient.
Then, press the capture start button to start the photography.



2 After the photograph is taken, the result is automatically displayed.



FUNDUS PERIPHERAL PHOTOGRAPHY

⚠CAUTION	To avoid injury of the patient, be careful not to bump the patient's eye or nose with the instrument and external fixation target when operating the control panel.

Selecting the capture icon

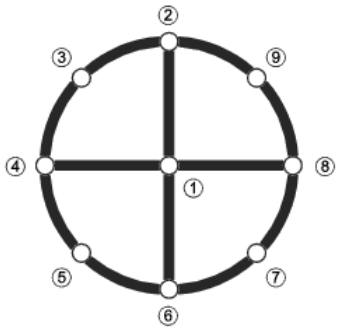
On the capture icon selection screen, which is the initial screen, select the fundus peripheral photography icon.

Icon	Capture icon	Fixation position
	Fundus peripheral photography	--

Setting the picture position

- The fixation position can be changed in nine directions with the following buttons. On the button, the capture count is displayed at each fixation position. These buttons are displayed on the chinrest adjustment screen and the manual adjustment mode screen.

- You can set the following six fixation patterns on the setting menu. For setting, refer to page 90.



Fixation pattern	Lighting place
4X	③ ⑤ ⑦ ⑨
4+	② ④ ⑥ ⑧
5X	① ③ ⑤ ⑦ ⑨
5+	① ② ④ ⑥ ⑧
8	② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨
9	① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨

NOTE	The automatic small pupil function does not work. When binocular photography is selected, the first eye will be photographed.

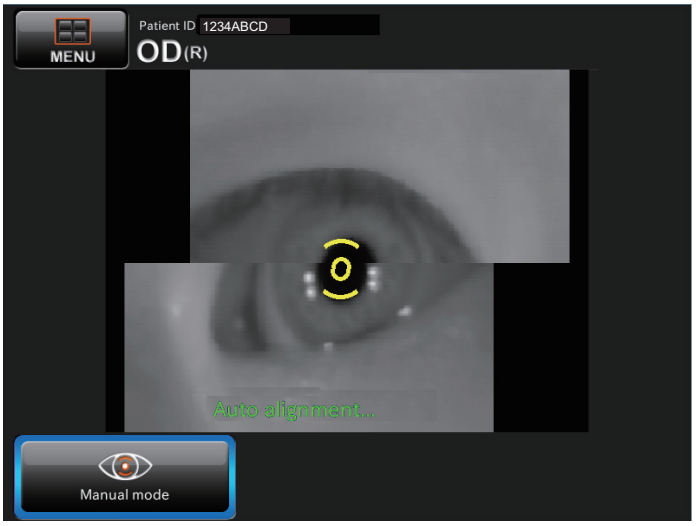
Setting up the patient

Refer to “Preparing the patient and capturing” on page 57.

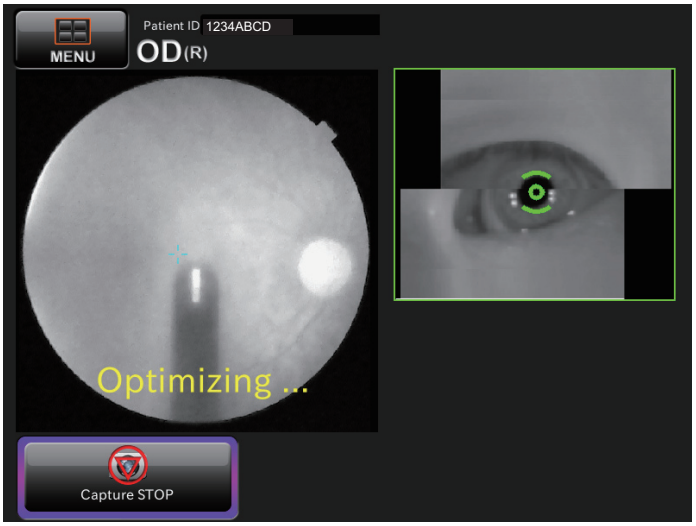
■ Peripheral photography

After adjusting the chin position with the chinrest up/down button, press the capture start button. Automatic photography starts. Before starting the photography, make sure that the desired fixation target is selected. The following steps are automatically executed in the order listed below.

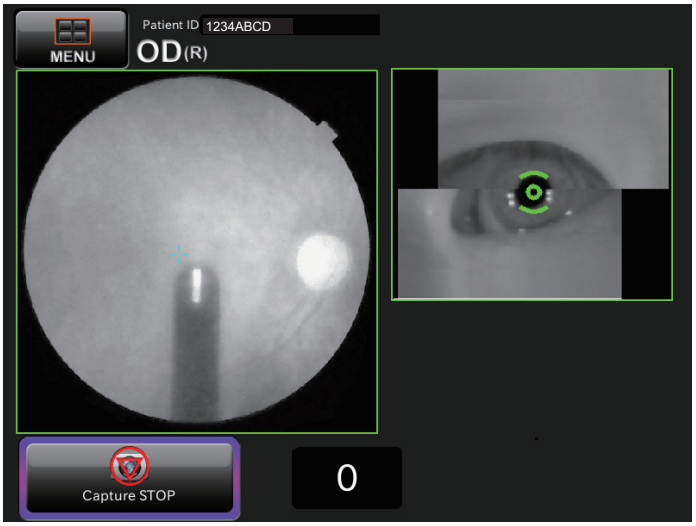
1 Alignment to pupil is performed automatically.



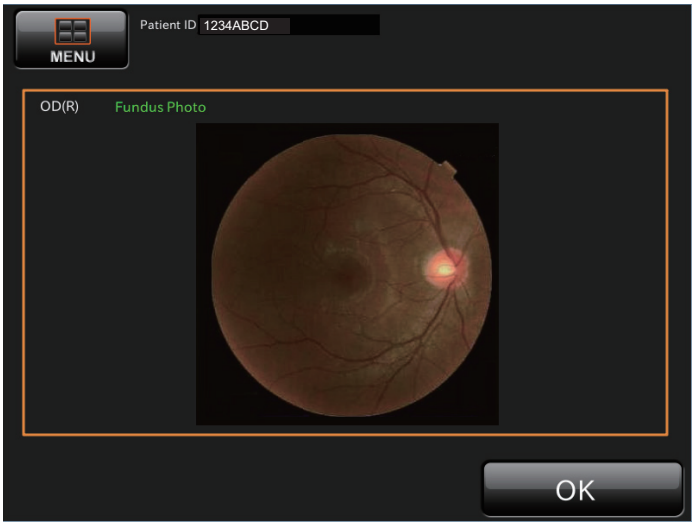
2 Automatic focus to fundus is performed automatically.



3 The system shifts to the waiting status for the capture start and the capture timer starts. After the given time has passed on the capture timer, photography starts automatically.



4 After the photograph is taken, the result is automatically displayed.
Press the [OK] button, and the system returns to the screen where the next fixation position is selected. To return to the scan selection screen, press the [MENU] button.



■ Photography screen (when automatic photography has failed)

If an error message is displayed during automatic photography, perform adjustment by manual photography. Then, press the capture start button to continue the photography.

- If an error has occurred during automatic alignment to pupil:
  If the patient's face or eye cannot be detected or the pupil center is not tracked, the following messages are displayed.

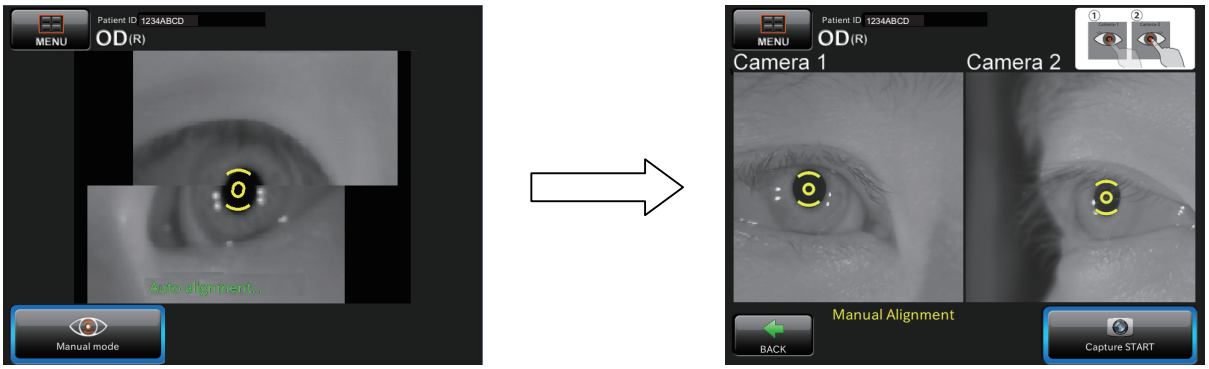
When the eyelid is not opened fully

When the eye fixation is not stabilized

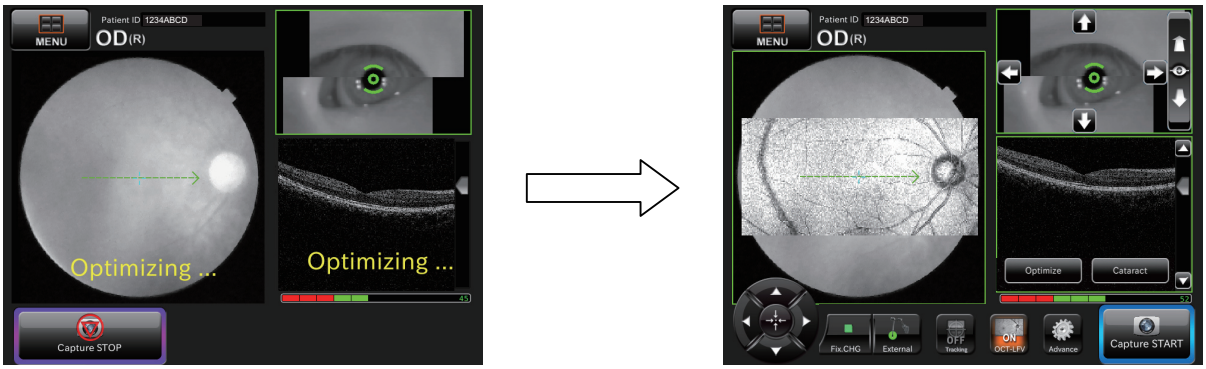
Perform one of the following operations.

- Set the patient properly, press the [Retry] button and perform automatic alignment again according to the message.
- Press the [Manual] button to shift to the manual adjustment mode.

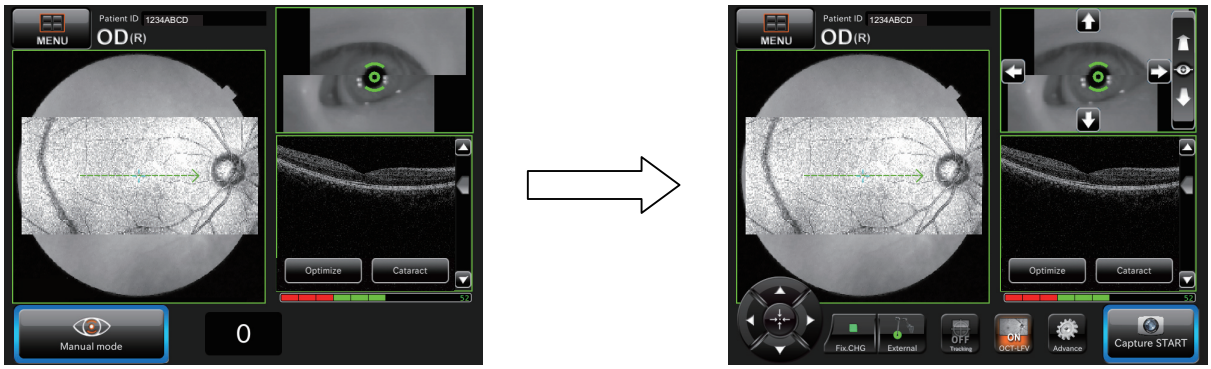
After tapping the pupil in the movie area, press the capture start button to continue the photography.



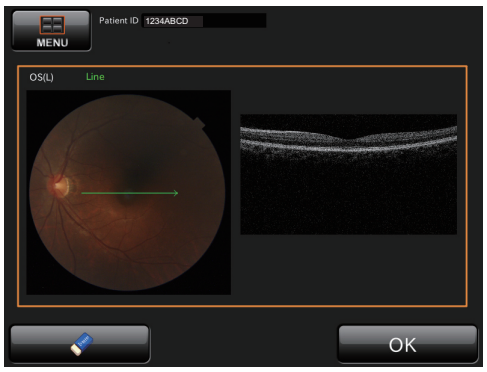
- If an error has occurred during automatic focus and automatic optimizing:
  If automatic photography has failed, shift to the manual adjustment mode. After adjusting, press the capture start button to continue the photography.



- If an error has occurred during the following process: The system shifts to the waiting status for the capture start and the capture timer starts. After the given time has passed on the capture timer, photography starts automatically.
  If any trouble such as blink is detected right before photography, shift to the manual adjustment mode. After adjusting, press the capture start button to continue the photography.



- After the photograph is taken, the result is automatically displayed.
  When color fundus photography is set to OFF the color fundus photography image is changed to the IR fundus photography image.



■ Operation on the manual adjustment screen

During manual adjustment, the photography screen is shown below. See P.25.

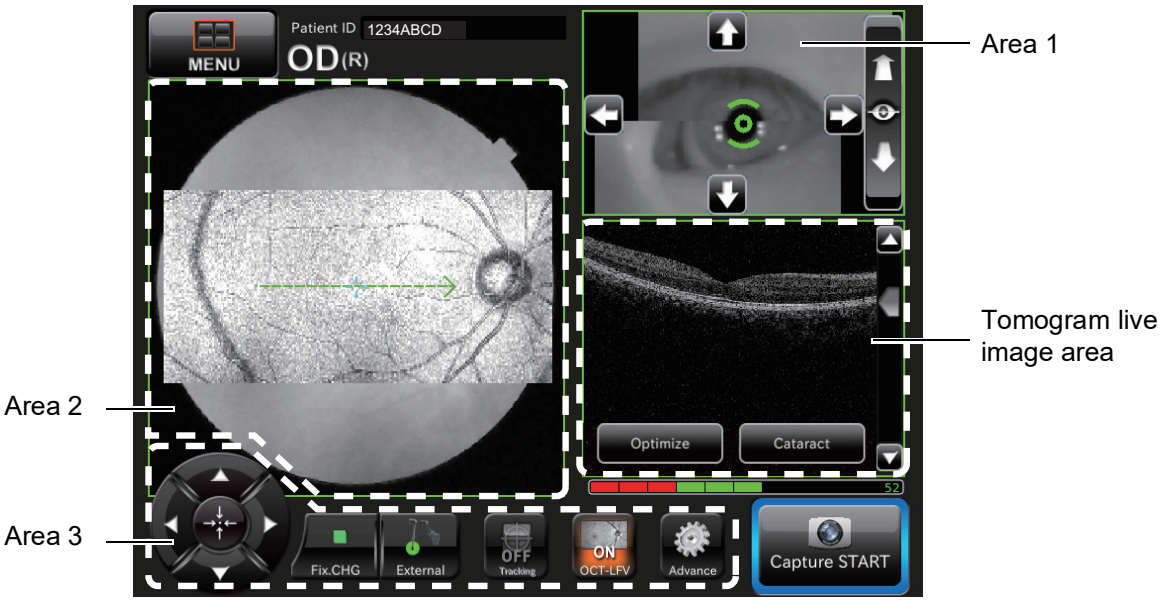
For details of each operation, refer to each photography screen.

For setting the flash level, refer to “Photography screen (Manual adjustment mode)” (P.25).

For adjusting the scan position, refer to “Photography screen (Tomogram scan position: Manual adjustment)” (P.34).

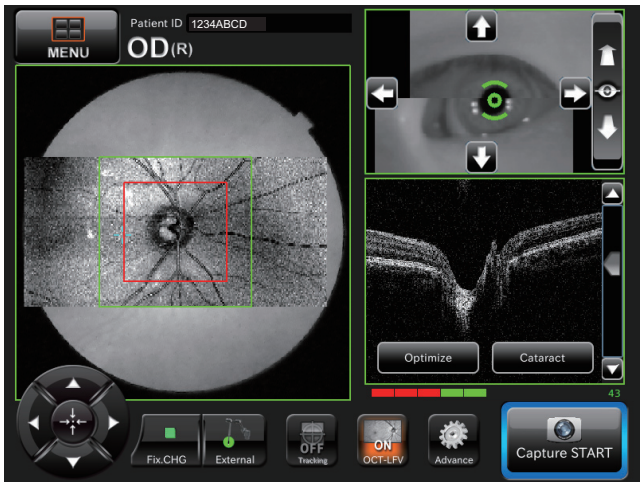
For changing the internal/external fixation target, refer to “Photography screen (Internal fixation target position: Manual adjustment)” (P.36).

For changing the diopter compensation lens, refer to “Photography screen (Focus: Manual adjustment)” (P.37).

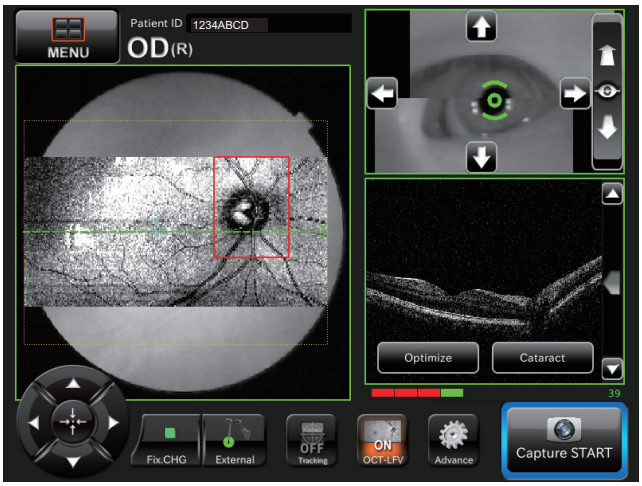


Photography with “3D Optic disc”, “3D Wide” and “3D Wide (H)”

When you perform the photography with “3D Optic disc”, “3D Wide” and “3D Wide (H)”, the following screens appear. Make sure that the optic disc is within the red frame on the screen. If the optic disc is not so, by using the internal fixation position adjustment button on Area 3 and the external fixation target, adjust the fixation position to place the patient's optic disc within the red frame.



3D Optic disc photography



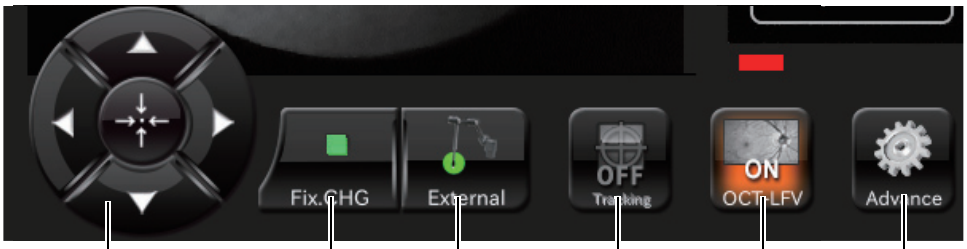
3D Wide photography
3D Wide (H) photography

Setting the picture position

If necessary, you can change the default picture position, which is set according to the selected capture icon, to the external fixation target.
There are the following three changing methods. Please change the picture position by your desired method.

- **Changing by using the internal/external fixation target selector button**
  Change the internal fixation target to the external fixation target.

  1 Tap the [EXTERNAL FIXATION TARGET SELECTOR BUTTON] on Area 3 of photography screen (OCT photography), and the target is changed to the external fixation target. Change to the desired picture position. For the details of display, refer to P.31.



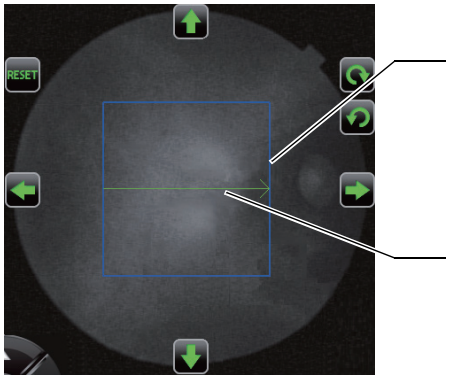
Internal fixation target adjustment button
Fixation target shape selector button
External fixation target selector button
Tracking button
OCT-LFV image ON/OFF
[Advance] button

- **Changing by using the internal fixation target position adjustment button (control panel)**
  Change the picture position by adjusting the internal fixation target position finely.

  1 Press the [INTERNAL FIXATION TARGET POSITION ADJUSTMENT BUTTON] on Area 3 of the photography screen (OCT photography) to access the internal fixation target adjustment mode. The internal fixation target is displayed on Area 2. Perform adjustment by pressing the upper, lower, right and left arrow buttons. For the details of display, refer to page 36.

- **How to adjust the scan position**
  Use this method when changing the scan position in a large degree or changing it with fine adjustments.

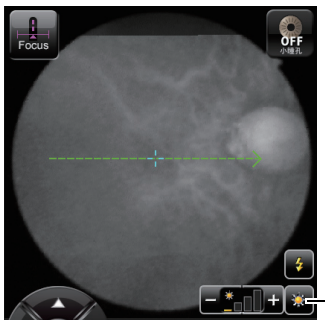
  1 Tap the fundus/anterior segment live image area on Area 2 of the photography screen (OCT photography) to access the scan position adjustment mode. On Area 2, the graphic image of the selected scan shape and range is displayed with a solid line. Perform adjustment by pressing the upper, lower, right and left arrow buttons or the rotation buttons. For the details of the display, refer to page 34.



Scan position adjustment range (blue)
Scan pattern display

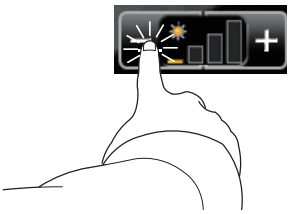
Setting the illumination level

Press the [Advance] button on Area 3 of the photography screen (OCT photography). Tap the “+” of the [Illumination level] display on the fundus/anterior segment live image area, and the illumination level increases. Tap the “-”, and the illumination level decreases.

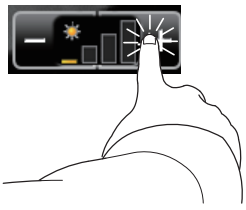


Illumination level display

Illumination level decreases.



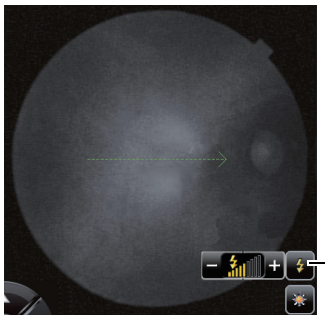
Illumination level increases.



Setting the flash level

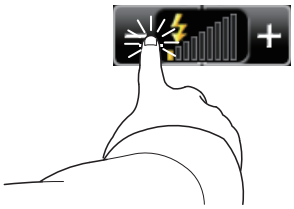
NOTE	To avoid discomfort to the patient, do not brighten the photography light more than necessary.

Press the [Advance] button on Area 3 of the photography screen (OCT photography). Tap the “+” of the [Flash level] display on the fundus/anterior segment live image area, and the flash level increases. Tap the “−”, and the flash level decreases.
When color fundus photography is set to OFF the flash level is not displayed and cannot be adjusted.

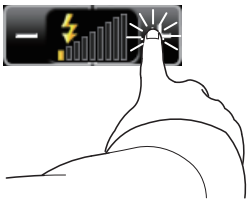


Flash level display

Flash level decreases.



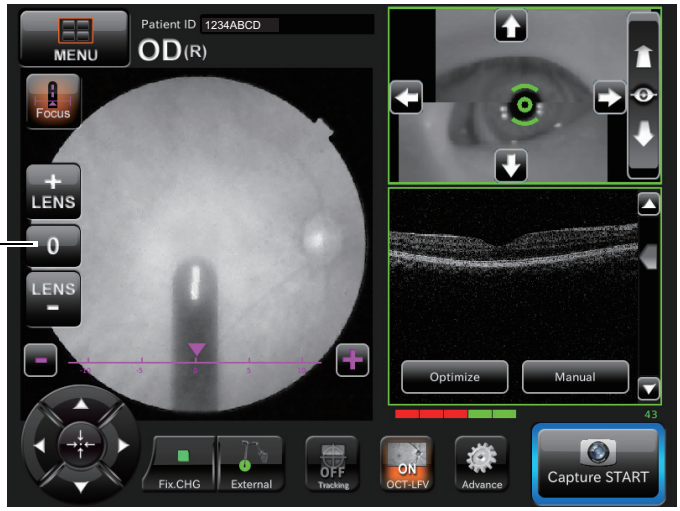
Flash level increases.



Changing the diopter compensation lens

Press the [Advance] button on Area 3 of the photography screen (OCT photography). Then, press the [Manual focus setting button] on the fundus/anterior segment live image area. Tap the diopter compensation lens selector button and change the diopter compensation lens for the patient's eye.

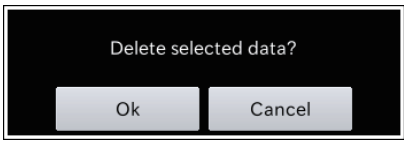
Diopter compensation lens selector button



DELETING DATA

[Delete] button

Press the [Delete] button ([Rescan] button when the “Custom-1” mode is set for the work flow setting (option setting)) while the preview screen is being displayed. The following check message is displayed. Press [OK], and the data that is displayed on the preview screen is deleted.
When color fundus photography is set to OFF the color fundus photography image is changed to the IR fundus photography image.

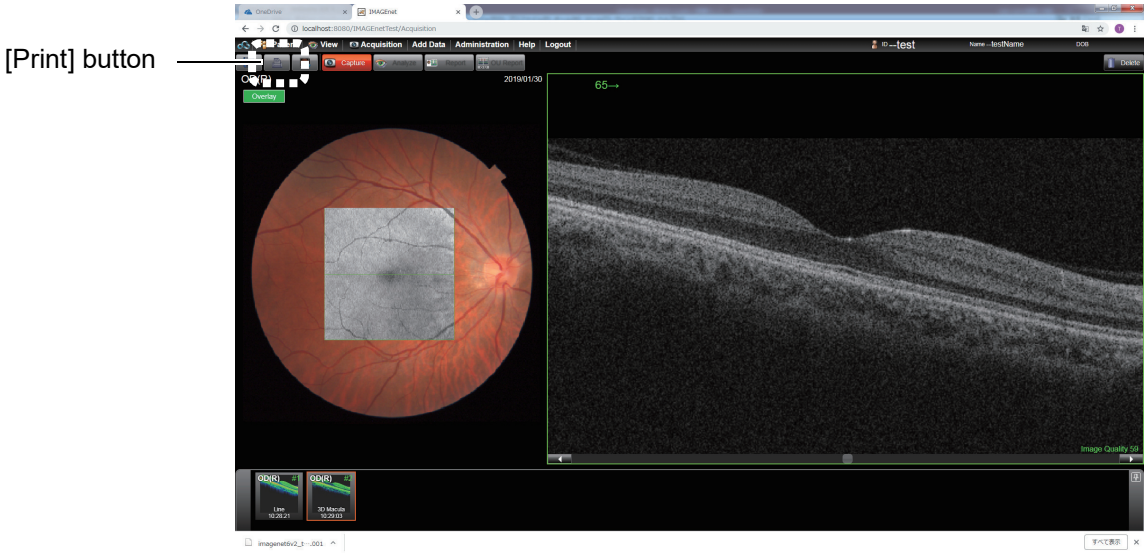


SAVING DATA

Data is saved on the personal computer. For details, refer to the instruction manual (for “IMAGEnet6 for OCT”).

PRINTING DATA

Data is printed on the personal computer. To print the analysis result, tap the [Print] button. The screen being displayed is printed.



DETAILS OF THE SETTING MENU

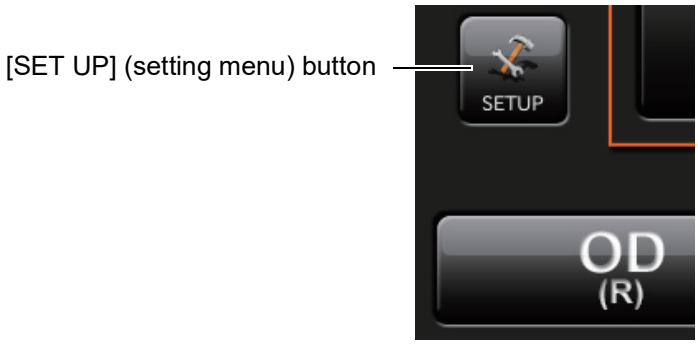
On the setting menu screen, you can set a variety of data.

Preparation for setting

1. Check the power cord connection.
   For details, see “CONNECTING THE POWER CORD” on page 45.
2. Turn ON (I) the [POWER SWITCH] of the instrument.

Displaying the setting menu screen

1. Check the capture icon selection screen, which is the initial screen.
2. Press the [SET UP] button on the capture icon selection screen.



3. Check the setting menu screen.

Returning to the capture icon selection screen:

1. Press the [Cancel] button.
2. Return to the capture icon selection screen.

PAGE 1: Capture Icon Setting

On the “PAGE 1” screen, set the icon display for the capture icon, which is displayed on the capture icon selection screen, and the parameters for each capture icon. For details on the buttons, refer to page 39 and page 41.

- PAGE 1: Initial screen

- How to delete the displayed icon:

1 Tap and select the capture icon to be deleted in the icon layout setting area. (It is highlighted.)

2 Press the [Delete icon] button.

3 Make sure that the icon is deleted. The remaining icons are moved to the left side or upper right corner.

- How to add the displayed icon

1 Tap and select the capture icon to be added from the capture icon list. (It is highlighted.)

2 Press the Add icon button.

3 Make sure that the icon is added.

- How to check and change the parameters for the icons:

1 Tap and select the icon of the capture icon for which the parameters should be checked and changed in the icon layout setting area. (It is highlighted.)

2 Press the Edit Capture button at the bottom of the screen.

3 The parameter setting screen appears.

4 Tap the item button whose setting should be changed. The selectable item values are displayed. Tap and change the value to the desired one. Press the [OK] button to decide the change. If you press the [Cancel] button, the value before changing is set again and the system exits from the parameter setting screen.

Item buttons for setting parameters

(1) Scan Pattern

Scan pattern means the shape or kind to be scanned. It is classified into the following 6 kinds:

Line:	Scans linearly.
3D:	You can scan the range (Scan Size) with the horizontally-set resolution (Scan Resolution) and display the scanned object as a stereograph.
3D (V):	You can scan the range (Scan Size) with the vertically-set resolution (Scan Resolution) and display the scanned object as a stereograph.
3D Wide (H):	You can scan the range (Scan Size) with the horizontally-set resolution (Scan Resolution) and display the scanned object as a stereograph.
3D Wide:	You can scan the range (Scan Size) with the vertically-set resolution (Scan Resolution) and display the scanned object as a stereograph.
5 Line Cross:	Scans with five lines in each of horizontal and vertical directions at regular intervals crosswise.
Radial:	Scans radially with 12 radial lines.

(2) Scan Size

"Scan Size" means the length or range to scan.

(3) Scan Resolution

"Scan Resolution" means the data quantity to be read by scanning. In the "Line" and "Radial" scans, it is the data for one line. In the "3D" scan, it is the data for each side of "Length×Width". As the scan resolution is higher, a more detailed tomogram can be obtained and at the same time the data quantity is increased. So, it takes a longer time to process the read data and the saved data is increased.

(4) Color Fundus Photography

You can set whether the color fundus photography should be done.

(5) Fixation Position

Set the fixation position of the patient. There are five selectable items for setting, "Disc" (optic disc), "Center", "Macula", "Wide" and "External" (external fixation target). When "Disc" is set, the optic disc is positioned at the center of the photography screen for the fixation target. When "Center" is set, the middle position between the optic disc and macula is positioned at the center, and when "Macula" is set, macula is positioned at the center. When "Wide" is set, the middle position between "Center" and "Macula" is positioned at the center. When "External" is set, the internal fixation target is turned off and the external fixation target is used.

(6) Over Scan Count

"Over Scan Count" means the following function: The data is read several times at one position for one scanned line. Two or more tomograms at one position are obtained and are displayed in the overlapped status. Consequently the tomogram with better contrast than usual can be obtained.

(7) Color Anterior Photography

This can be set only when “Fundus Photography” is selected.

Takes a color picture of anterior segment.

The fixation position is set to “External” (external fixation target) and this cannot be changed.

(8) Step

This is valid only when the “5 Line Cross” capture icon is selected, and it means the interval of the vertical or horizontal five scan lines. The settable range is 0.15mm, 0.20mm, 0.25mm, 0.30mm and 0.35mm. In the initial setting of this instrument, “0.25mm” is set.

(9) OCT Live Color

You can set “color display” or “monochrome display” for the live image.

In the initial setting of this instrument, “monochrome display” is set for all the live images.

(10) OCT Focus Position

You can set the OCT focus position.

In anterior segment photography, “Deep pos” is fixed for “Line” scan and “Cornea” is fixed for “Radial” scan.

(11) Repetition

Number of scans for each line for OCT Angiography is displayed. You can choose from 3 or 4.

In the initial setting of this instrument, “4” is set.

(12) Tracking

You can set whether to perform tracking during photography.

When tracking is ON, corrects the shift of the scan position during photography (SMART Track).

You can cancel by pressing the photography button once during photography.

PAGE 2: Photography Setting

On the “PAGE 2” screen, you can set a variety of data for photography. For the details on each button, refer to page 42.

- PAGE 2: Initial screen

On PAGE 2, the items shown in the following table are assigned to the buttons on each layer.

Utility button	Item button	Item selector button	At shipment
Fixation	TYPE • Changes lighting/blinking of the internal fixation target.	CONSTANT (Lighting)	
		FLICKERING (Blinking)	○
	SPEED NORMAL (Hz) • This is valid when the internal fixation target is set to “FLICKERING” (Blinking). • Set the blinking speed for all other states except when photographing.	1 - 8	1
	SPEED MEASURE (Hz) • This is valid when the internal fixation target is set to “FLICKERING” (Blinking). • Set the blinking speed for photographing.	1 - 8	2
	Brightness • Sets the brightness of the internal fixation target.	1-10	10
	Shape (Default) • Sets the shape of the internal fixation target.	1 dot	○
		X	
	Shape (Additional)	Not in use	○
		4 dot rectangle	
		Cross	
	Screen Display	Constant	○
		Given time	

Utility button	Item button	Item selector button	At shipment
Fundus Photo	Blink Detection Level	OFF	
		LOW	○
		Normal	
	OCT+Color Mode • Changes the color fundus image quality (High/Normal/Low).	High ISO	○
		Normal ISO	
		Low ISO	
	Flash Level (OCT+Color Mode)	1.0 - 16.0W•s	*1
	Gain (OCT+Color Mode)	0 - 9, BS, AC *2	*1
	Color Mode	High ISO	○
		Normal ISO	
		Low ISO	
	Flash Level (Color Mode)	1.0 - 16.0W•s	*1
	Gain (Color Mode)	0 - 9, BS, AC *2	*1
	Adjust Flash at Peripheral Photo	0 - +4	+1
	Adjust Flash at 30° Mask Photo	-4 - +4	-1
	Peripheral Photo Sequence	Chinrest screen	○
		Capture screen	
	Peripheral Photo Pattern	4X	
		4+	
		5X	
		5+	
		8	
		9	○
	Peripheral Photo Fixation Move	AUTO, MANUAL	AUTO
Illumination Level	OCT Photo (Normal)	1-4	3
	OCT Photo (Tracking)	1-4	3
	Fundus Photo	1-4	3
OCT	Z lock position Settable range: 120 - 765	0 - 9, BS, AC (*2)	250
	Z lock position - 3D Wide Settable range: 120 - 765	0 - 9, BS, AC (*2)	450
	Z lock position - OCT Angiography Settable range: 120 - 765	0 - 9, BS, AC (*2)	250
	OCT-LFV	ON, OFF	ON
	OCT-LFV (Scan Adjust)	ON, OFF	ON

*1: For the flash level and Gain of each image quality at shipment, refer to the table below.

Image quality	Flash level		Gain	
	Settable range	Setting at shipment	Settable range	Setting at shipment
High	1.0 - 16.0W•s	4.0W•s	0 - 36	0
Normal	1.0 - 16.0W•s	2.0W•s	0 - 36	6
Low	1.0 - 16.0W•s	1.0W•s	0 - 36	12

*2: Ten keys are displayed.

PAGE 3: Auto Operation

On the “PAGE 3” screen, set the Auto functions. For details on each button, refer to page 42.

- PAGE 3: Initial screen

On PAGE 3, the items shown in the following table are assigned to the buttons on each layer.

Utility button	Item button	Item selector button	At shipment
Auto Alignment	ON/OFF	ON, OFF	ON
	ACTION	Disconinuous	
		Continuous	○
	Timeout (Sec)	OFF, 10, 20, 30	20
Focus	ON/OFF	ON, OFF	ON
	Timeout (Sec)	OFF, 10, 20, 30	10
	One Touch Auto Focus	OFF	
		one time	○
		sequence	
	OCT Focus	Split	
		OCT	○
		Split + OCT	
	OCT: Retry	ON, OFF	ON
Small Pupil • This function is usable only when the color fundus capture icon is selected. • When the pupil diameter of the patient is small (pupil diameter is approx. ϕ4.0mm or less), the small pupil diaphragm is automatically set and the instrument takes a color picture of the fundus. After taking a picture, the small pupil diaphragm is automatically removed. When you set the small pupil diaphragm selector button to “ON” on Area 1 of the photography screen (color photography), the above automatic setting is not done.	ON/OFF	OFF	○
		ON	
	Magnification mode	45° mask	○
		30° mask	

Utility button	Item button	Item selector button	At shipment
Auto Optimize	ON/OFF	OFF	
		ON	○
	Auto Z • Detects the retina position automatically, and always displays the fundus tomogram clearly during observation.	OFF	
		ON	○
	Z-lock After Auto Z • After “Auto Z”, the photographed fundus image is fixed.	OFF	
		ON	○
	Auto Pola • Adjusts the output sensitivity of the fundus tomogram to the optimum automatically.	OFF	
		ON	○
Auto Operation	Auto Shoot Timer (sec)	1, 3, 5, 8, 10, 15	3
	OU Capture	Right eye → Left eye	○
		Left eye → Right eye	
		OFF	
	Show Preview	OFF	
		ON	○
	Preview method *1	Both eyes	
		One eye (with timer)	
		One eye	○
	Preview Timer (sec) *2	3, 5, 10	5
	Check Alignment Result	OFF	
		ON	○
	Check Alignment Timeout *3	3, 5, 10	5
	AutoShoot	OFF	
		ON	○
	AutoShoot(Angiography)	OFF	
		ON	○
Auto Tracking	ON/OFF	OFF	
		ON	○
Auto Cataract	ON/OFF	OFF	
		ON	○

*1: When “ON” is set for “Preview”, it is valid to change setting for this item.

*2: When “ON” is set for “Preview” and “Each eye (with timer)” is set for “Preview method”, it is valid to change setting for this item.

*3: When “ON” is set for “Alignment check”, setting for this item is valid.

PAGE 4: System Setting

On the “PAGE 4” screen, set the system. For details on each button, refer to page 42.

- PAGE 4: Initial screen

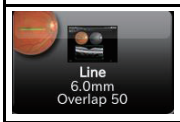
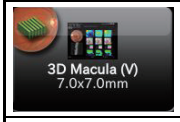
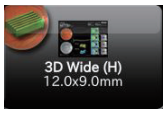
On PAGE 4, the items shown in the following table are assigned to the buttons on each layer.

Utility button	Item button	Item selector button	At shipment
System Setting	Measurement Sound Sets ON/OFF for the measurement sound.	OFF	
		ON	○
	Power Save Timer (Min.) Sets the time until the power save function is ON.	0 - 60 (At intervals of 5 minutes)	10
	Display Brightness Sets the brightness of control panel. (After changing the setting, tap the [Send] button.)	1 - 10	5
	Packing Mode Tap the [Start] button, and the main unit and chin-rest move to be in the packaged status.	Start	-
	Language Sets the display language.	Japanese (JP) / English (US)	English (US)

Capture icon protocol

The following table shows the parameters in each capture icon.

▢: Initial set value

Capture Icon	Capture Icon name	Color Fundus Photography	Scan Size	Scan Resolution	Fixation Position	OCT Focus Position	Overlap	Color Anterior Photography	Step	OCT Live Color	Repetition	Tracking
	Line	OFF [ON]	9.0mm [6.0mm]	[1024H] 1024V	[Macula] Center Disc	Vitreous	None [50]	-	-	[Mono] Color	-	-
	Radial	OFF [ON]	Dia. 6.0mm	1024	[Macula] Center Disc	Vitreous	4	-	-	[Mono] Color	-	-
	5Line Cross	OFF [ON]	[9.0mm] 6.0mm	1024	[Macula] Center Disc	Vitreous	[4] Cross16	-	0.15mm 0.20mm [0.25mm] 0.30mm 0.35mm	[Mono] Color	-	-
	3D Macula	OFF [ON]	6.0×6.0mm	512×128	Macula	Vitreous	-	-	-	[Mono] Color	-	[OFF] ON
	3D Macula(V)	OFF [ON]	7.0×7.0mm	512×128	Macula	Vitreous	-	-	-	[Mono] Color	-	[OFF] ON
	3D Optic disc	OFF [ON]	6.0×6.0mm	512×128	Disc	Vitreous	-	-	-	[Mono] Color	-	[OFF] ON
	3D Wide	OFF [ON]	12.0×9.0mm	512×128	Wide	Vitreous	-	-	-	[Mono] Color	-	[OFF] ON
	3D Wide (H)	OFF [ON]	12.0×9.0mm	512×128	Wide	Vitreous	-	-	-	[Mono] Color	-	[OFF] ON
	Fundus	-	-	-	Macula [Center] Disc Internal *2	-	-	[OFF] ON *3	-	-	-	-
	Fundus peripheral photography	-	-	-	-	Vitreous	-	-	-	-	-	-
	OCT Angiography	OFF [Color]	[3.0×3.0mm] 4.5×4.5mm 6.0×6.0mm	[320×320]	[Macula] Center Disc	Vitreous	-	-	-	[Mono] Color	3 [4]	-

*1: The item button that has no selectable items is not displayed.

*2: When “ON” is set to “Color Anterior Photography”, “Internal” is fixed.

*3: When “ON” is set to “Color Anterior Photography”, the instrument takes a picture of the anterior segment.

BEFORE REQUESTING SERVICE

TROUBLESHOOTING

Messages during operation

Error message
The built-in battery may have run out. Please contact your service representative with Message ID.
There is a possibility that the communication in the main unit has been interrupted. Please reboot the machine. If this message continues to appear, please contact your service representative with Message ID.
Communication between the main unit and the PC has been interrupted. The LAN cable is possibly not connected or the PC software is not activated. Please reconnect the LAN cable and restart the PC software. If this message continues to appear, please contact your service representative with Message ID.
Please optimize again. If optimization can not be performed automatically, adjust the Z lock position manually and optimize.
Detected blink while capturing fundus image. Please try again.
The sensitivity of the tomogram may be lower. Would you continue? If this message continues to appear, please contact your service representative with Message ID.
Light source error occurred. Please turn OFF the power and contact your service representative with Message ID for repair.
There is a possibility that the light source for fundus camera is running out of battery. Please reboot the machine. If this message continues to appear, please contact your service representative with Message ID.
GALVANO error occurred. Please turn OFF the power and contact your service representative with Message ID for repair.
Internal error occurred. Please turn OFF the power and contact your service representative with Message ID for repair.
Lamp house cover is off. Please turn the power switch OFF and close the cover.
Internal FAN error occurred. Please turn OFF the power and contact your service representative with Message ID for repair.
There is a possibility that the connection in the main unit has been interrupted. Please reboot the machine. If this message continues to appear, please contact your service representative with Message ID.
Failed in auto focus. Please push [Optimize] button and execute auto focus again,or manually adjust focus.
Tracking for follow-up photography has failed. Check the fundus image and perform photography again.

Troubleshooting

⚠WARNING	• To avoid electric shock and fire, do not attempt disassembling, rebuilding and/or repairs on your own. Ask your dealer for repairs.

⚠CAUTION	• Do not remove the covers from the main unit, chinrest unit or power supply unit. You may receive an electric shock. • Do not remove the covers from the main unit. Your eye may be exposed to the invisible LASER radiation.

When an error is encountered, review the Check List below.
After following the instructions below, if you still have difficulty or if the problem does not fall into any of the categories listed below, contact your dealer or TOPCON (see the back cover).

Check List

Problem	Condition	Check	Page
Control panel does not work.	• Power cord is not connected to the outlet or instrument.	Connect power cord.	45
Control panel is not clear.	• Image is dark.	Adjust brightness (“Display Brightness” in setting menu).	94
		Tap the [Illumination level] display on the control panel to adjust the illumination level.	78
		Darken room and thoroughly dilate patient's pupil.	----
Periphery of captured image is dark.	• Alignment is incorrect.	Adjust alignment.	58
	• Patient’s pupil is not large enough.	Darken room and thoroughly dilate patient's pupil.	----
Captured image is flared all over. (The whole image is covered by light.)	• Alignment is incorrect.	Adjust alignment.	58
	• Opacity in patient's eye.	Flare cannot be removed.	----
Captured image is whitened.	• Patient blinked at the moment the photograph was taken.	Take another picture.	----
Captured image has a dim white spot.	• Objective lens is stained.	Clean lens.	121
	• Eyelashes were in the patient's eye the moment the photograph was taken. (Dim light was seen at the screen bottom the moment the alignment was done.)	Let the patient open their eye wider and take the picture again. If not wide enough, open the eyelid (i.e., Take picture holding eyelid open).	----
Photographic image is dark all over.	• Flash level is insufficient.	Tap the [Flash level] display on the control panel to adjust the flash level.	78
	• Xenon set screws are loose.	Consult your dealer.	118
	• Xenon lamp has served its life.	Consult your dealer.	118

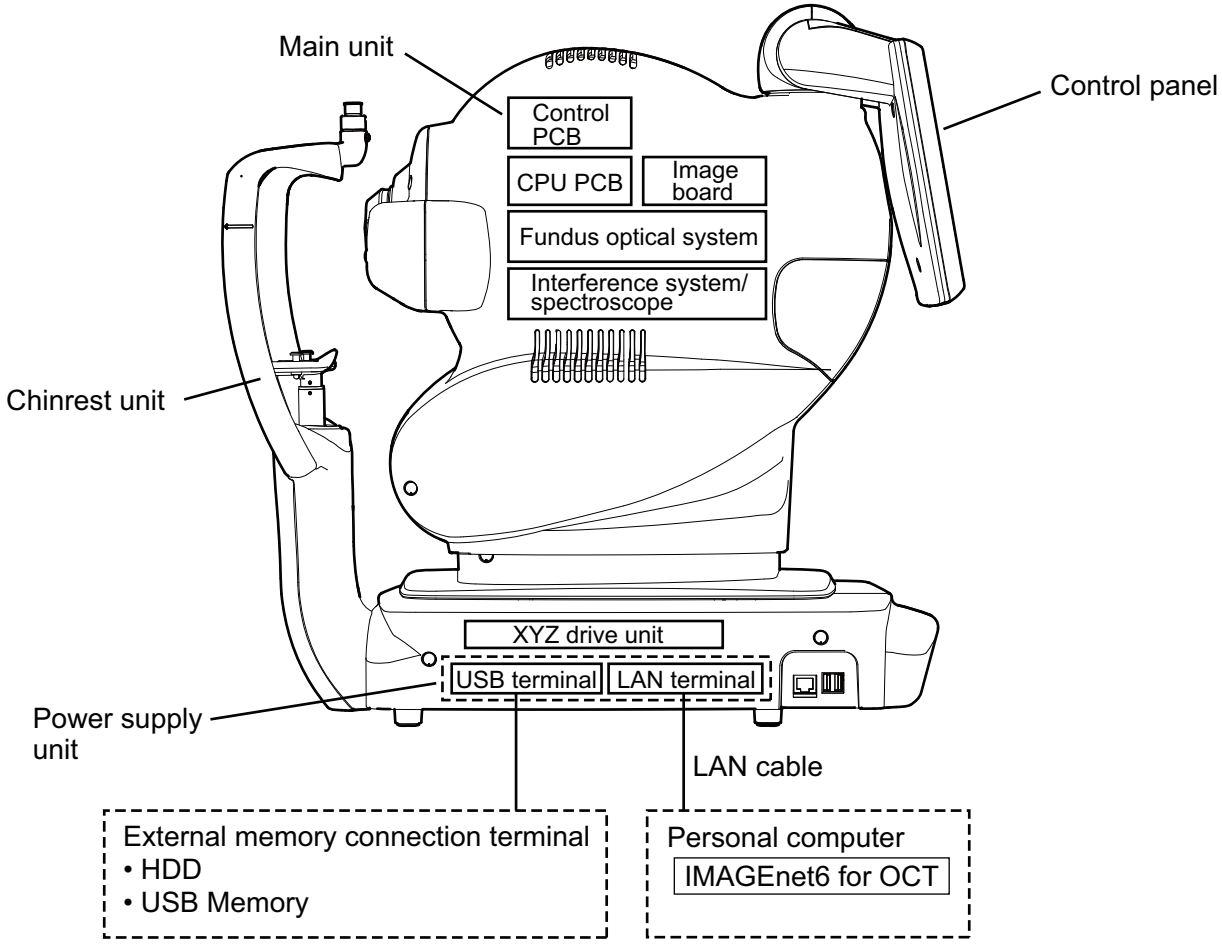
Problem	Condition	Check	Page
Internal fixation target cannot be seen.	• Alignment is incorrect.	Adjust alignment.	58
	• Internal fixation target is set to the “D” or “M” side.	Press the internal fixation target position selector switch to move it to “C”.	31
	• External fixation target is set.	Press the internal fixation target position selector switch to move it to “D” or “C”, “M”.	31
Split lines cannot be seen.	• Patient's pupil is not large enough.	Darken room and thoroughly dilate patient's eye.	----
Xenon lamp does not turn on.	• Xenon lamp has served its life.	Consult your dealer.	118
Cannot get patient's pupil center.	• Patient's face position is incorrect. (The chin and forehead are not correctly on the rests, or the patient faces sideways.)	Have patient adjust his/her position accordingly.	57
	• Patient's face height is incorrect.	Adjust face height (chinrest up/down button on the control panel).	57
Nothing is recorded on the external recording device.	• Anomaly in external recording device.	Check power supply, settings, etc.	----
	• Cable connections are incorrect.	Check and correct cable connections.	46
A black shadow appears at the center of the photographed image.	• Does the patient have myopia of -10D or more?	This shadow always appears because of the optical principle of the product. It does not indicate any trouble.	----
	• Is the reflection from the fundus very strong in the patient’s eye?		
A white spot appears at the center of the fundus observation live image on the instrument's monitor.	• Does the patient have myopia of -10D or more?	This bright spot always appears because of the optical principle of the product. It does not indicate any trouble. It does not appear on the photographed image.	----
	• Patient’s pupil is not large enough.		
A black spot appears on the IR anterior segment observation image.	• The IR illumination light is set at high level.	This black spot always appears because of the optical principle of the product. It does not indicate any trouble.	----

SPECIFICATIONS AND PERFORMANCE

SYSTEM DIAGRAM

This instrument is composed of the following three units.

- Main body unit
- Power supply unit
- Chinrest unit



SPECIFICATIONS BY ITEMS

Item	Specifications
Observation & photographing of the fundus	
• Type of photography	Color, Red-free (Note 1) & IR (Note 3)
• Picture angle for photography	45° ±5% or less 30° or equivalent (digital zoom)
• Operating distance	34.8 ±0.1mm (when taking a picture of fundus)
• Photographable diameter of pupil	Normal pupil diameter : ϕ4.0mm or more Small pupil diameter : ϕ3.3mm or more
• Fundus image resolution (on fundus)	Center : 60 lines/mm or more Middle (r/2) : 40 lines/mm or more Middle (r) : 25 lines/mm or more IR photography : Center: 5 lines/mm or more (Note 3)
Observation & photographing of the fundus tomogram	
• Scan range (on fundus)	Horizontal direction 3 – 12mm ±5% or less Vertical direction 3 – 9mm ±5% or less
• Scan pattern	3D scan (horizontal/vertical) Linear scan (Line-scan/Cross-scan/Radial-scan)
• Scan speed	50,000 A-Scans per second
• Lateral resolution	20μm or less
• In-depth resolution	6μm or less
	Pixel spacing:2.6μm ±2%
• Photographable diameter of pupil	ϕ2.5mm or more
Observation & photographing of the fundus image/fundus tomogram	
• Fixation target	Internal fixation target: Dot matrix type organic ELD display The display position can be changed and adjusted. The displaying method can be changed. Peripheral fixation target: This is displayed according to the internal fixation target displayed position. External fixation target
Observation & photographing of anterior segment	
• Type of photography	Color & IR (Note 3)
• Operating distance	62.6 ±0.1mm (when taking a picture of anterior segment) (Note 2)
Observation & photographing of the anterior segment tomogram	
• Operating distance	62.6 ±0.1mm (when taking a picture of anterior segment) (Note 2)
• Scan range (on cornea) (Note 2)	Horizontal direction 3 – 6mm ±5% or less Vertical direction 3 – 6mm ±5% or less
• Scan pattern	Linear scan (Line-scan/Radial-scan)
• Scan speed	50,000 A-Scans per second
• Fixation target	External fixation target

(Note 1) Digital red-free photography that processes a color image and displays it in pseudo-red-free condition
(Note 2) When the attachment for anterior segment is included in the system configuration
(Note 3) This is used only for recording the position where a tomogram is captured.

OTHER SPECIFICATIONS

Measurable range of dioptric power for the patient's eye	
Without the diopter compensation lens Note 1)	-13D to +12D (in fundus photography)
When the concave compensation lens is used	-12D to -33D (in fundus photography)
When the convex compensation lens is used	+11D to +40D (in fundus photography)
The pixel pitch on fundus	
	6.9 μm (in color fundus photography)
SLD light source	
Medium	Super luminescence diode (SLD)
Class of laser	Class 3B
Wavelength	840nm
Base movement	
	Back-and-forth 40mm, Right-and-left 100mm
Base up-and-down movement	
	30mm
Chinrest movement	
	67mm

Note 1) The area where the split lines are used.

Agency Compliance
ISO 15004-1 : 2006
ISO 15004-2 : 2007
ISO 16971 : 2015
ISO 10940 : 2009

SAFETY OF LASER PRODUCT

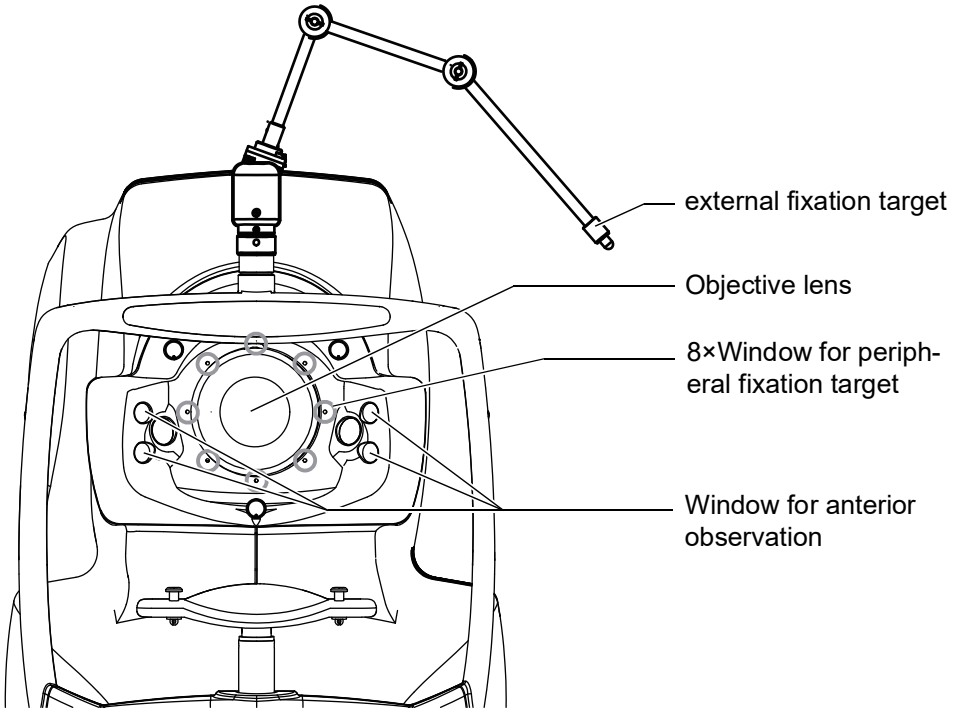
⚠WARNING	• Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure. • Do not remove the enclosures. High-power light is radiated.

Class of LASER product	CLASS1 LASER PRODUCT		
LASER PRODUCT	SLD		
	Aperture of laser		Objective lens*
	Output of cornea		600μW
	Wavelength		840nm
	Half width		50nm
	Beam divergence		0.82mrad
	Pulse ＊Worst case	Burst Frequency	43.59Hz
		Pulse Frequency	50kHz
		Pulse width	6μs
LASER light source	Output		12mW
	Class of laser		Class 3B
	Wavelength		840nm
	Half width		50nm
	Beam divergence		0.26rad
	Pulse width		CW

Class of LED product	CLASS1 LED PRODUCT	
LED OUTPUT	IR LED (for fundus observation)	
	Aperture of LED	Objective lens*
	Output of cornea	210μW
	Wavelength	770nm
	Half width	25nm
	Beam divergence	0.79rad
	Pulse width	CW
	SPLIT LED (for split)	
	Aperture of LED	Objective lens*
	Output of cornea	0.971μW
	Wavelength	740nm
	Half width	30nm
	Beam divergence	15mrad
	Pulse width	CW
	ANT OBS LED (for anterior observation)	
	Aperture of LED	Window for anterior observation*
	Output of cornea	80μW
	Wavelength	950nm
	Half width	50nm
	Beam divergence	35mrad
	Pulse width	CW
	ZEN FIX LED (for peripheral fixation target)	
	Aperture of LED	Window for peripheral target*
	Output of cornea	0.03μW
	Wavelength	570nm
	Half width	30nm
	Beam divergence	44mrad
	Pulse width	CW
	EXT FIX LED (for external fixation target)	
	Aperture of LED	-
	Output of cornea	60μW
	Wavelength	563nm
	Half width	30nm
	Beam divergence	0.785rad
	Pulse width	CW

LED light source	IR LED (for fundus observation)	
	Output	124mW
	Wavelength	770nm
	Half width	25nm
	Beam divergence	0.24rad
	SPLIT LED (for split)	
	Output	100mW
	Wavelength	740nm
	Half width	30nm
	Beam divergence	0.17rad
	ANT OBS LED (for anterior observation)	
	Output	4mW
	Wavelength	950nm
	Half width	50nm
	Beam divergence	1.4rad
	ZEN FIX LED (for peripheral fixation target)	
	Output	40mW
	Wavelength	570nm
	Half width	30nm
	Beam divergence	1rad
	EXT FIX LED (for external fixation target)	
	Output	120.5μW
	Wavelength	563nm
	Half width	30nm
	Beam divergence	0.785rad

*: LED & LASER light is output from Objective lens, Window for anterior observation, Window for peripheral target, external fixation target.



ELECTROMAGNETIC COMPATIBILITY

This product conforms to the EMC standard IEC 60601-1-2:2014+AMD1:2020 (Ed.4.1). The expected electromagnetic environment for the whole life cycle is home medical treatment environment.

a) MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.
b) Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
c) The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or SYSTEM as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or SYSTEM.
d) The EQUIPMENT or SYSTEM should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the EQUIPMENT or SYSTEM should be observed to verify normal operation in the configuration in which it will be used.
e) The use of the ACCESSORY, transducer or cable with EQUIPMENT and SYSTEMS other than those specified may result in increased EMISSION or decreased IMMUNITY of the EQUIPMENT or SYSTEM.
f) Do not use the devices generating electromagnetic waves within 30cm from all the parts of the instrument and system. Those devices may have influence on photography.

Item	Cable shielded	Ferrite core	Length (m)
AC power cord (for the instrument)100V/120V	No	No	1.5
AC power cord (for the instrument)230V/240V	No	No	3.0
AC power cord (for personal computer)	No	No	2.0
AC power cord (for display)	No	No	2.0
AC power cord (for ME ISOLATION TRANSFORMER)	No	No	1.5
LAN cable	No	Yes	3.0
Display cable	Yes	No	1.8
Mouse cable	Yes	No	1.8
Keyboard cable	Yes	No	2.0
FG cable	No	No	2.0
Personal computer	–	–	–
USB memory	–	–	–
USB memory	–	–	–
Display	–	–	–
Mouse	–	–	–
Keyboard	–	–	–
ME ISOLATION TRANSFORMER	–	–	–
Model eye	–	–	–

Guidance and manufacturer's declaration - electromagnetic emissions		
The instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the instrument should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The instrument 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 emissions CISPR 11	Class B	The instrument is suitable for use in all establishments including domestic 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 fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the instrument should assure that it is used in such an environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines Repetition frequency 100kHz	± 2 kV for power supply lines ± 1 kV for input/output lines Repetition frequency 100kHz	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Main 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	0% U_T for 0.5 cycle (with phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T for 1 cycle 0° 70% U_T for 25/30 cycles 0° 0% U_T for 250/300 cycles	0% U_T for 0.5 cycle (with phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T for 1 cycle 0° 70% U_T for 25/30 cycles 0° 0% U_T for 250/300 cycles	Main power quality should be that of a typical commercial or hospital environment. If the user of the instrument requires continued operation during main power interruptions, it is recommended that the instrument be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. main voltage prior to application of the test level.			

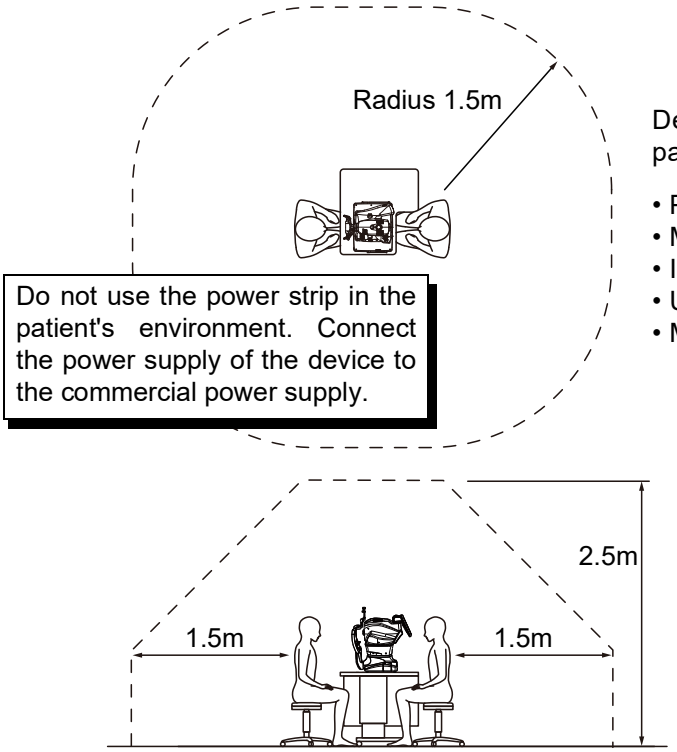
Guidance and manufacturer's declaration - electromagnetic immunity			
The instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the instrument should assure that it is used in such an environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 6Vrms Within ISM band and amateur radio band of 150kHz to 80MHz 10V/m 80MHz to 2.7GHz Proximity electromagnetic field from radio communication equipment a)	3Vrms 150kHz to 80MHz 6Vrms Within ISM band and amateur radio band of 150kHz to 80MHz 10V/m 80MHz to 2.7GHz Proximity electromagnetic field from radio communication equipment a)	Portable and mobile RF communications equipment should be used no closer to any part of the instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the radiation electromagnetic field level in volt/meter (V/m).
Proximity magnetic fields IEC 61000-4-39	30kHz CW 8A/m 134.2kHz PM2.1kHz 50% 65A/m 13.56MHz PM50kHz 50% 7.5A/m	30kHz CW 8A/m 134.2kHz PM2.1kHz 50% 65A/m 13.56MHz PM50kHz 50% 7.5A/m	The exterior surface of the instrument should be kept at least 0.15m from RF emitters such as RFID readers.
NOTE 1	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

a) The table below shows the proximity electromagnetic field from radio communication equipment.

Test frequency [MHz]	Band [MHz]	Equipment	Modulation	Maximum output (W)	Distance (m)	Immunity test value [V/m]
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ±5kHz 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 iDEN820 CDMA850 LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800 CDMA1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

PATIENT'S ENVIRONMENT

When the patient or inspector comes into contact with the devices (including the connecting devices) or when the patient or inspector is in contact with the person that touches the devices (including the connecting devices), the patient's environment is shown below.
In the patient's environment, use devices conforming to IEC 60601-1. If you are compelled to use any device not conforming to IEC 60601-1, use an insulation transformer.



Devices applicable to the patient's environment

- Personal computer (Note 1) (Note 2)
- Monitor for personal computer (Note 1)
- Insulation transformer (Note 3)
- USB memory
- Mouse

Note 1: Use the personal computer conforming to IEC 62368-1.
Note 2: Don't remove the cover from the personal computer.
Note 3: Use the insulation transformer conforming to IEC 60601-1.
Note 4: The Tablet PC used for remote connection is used for operation from outside the patient environment.

⚠WARNING	Don't connect any device which is not recognized as one component of the system.

⚠CAUTION	Preventing Electric Shocks
	• Pay attention to the following points in the patient environment. [Electric shock may cause an injury.] • Don't connect an additional power strip or an extension cord to the system. • The total 1kVA is the maximum allowable load of the auxiliary power supply socket for the insulation transformer, which is provided for the system. Don't connect the device exceeding this capacity. • Use the auxiliary power supply socket of the insulation transformer to power only a device that will be a component of the system. • It is dangerous to connect any device which is not used as a component of the system, to the insulation transformer. • When the insulation transformer is not used, the personal computer and the monitor for the personal computer must be installed out of the patient's environment.

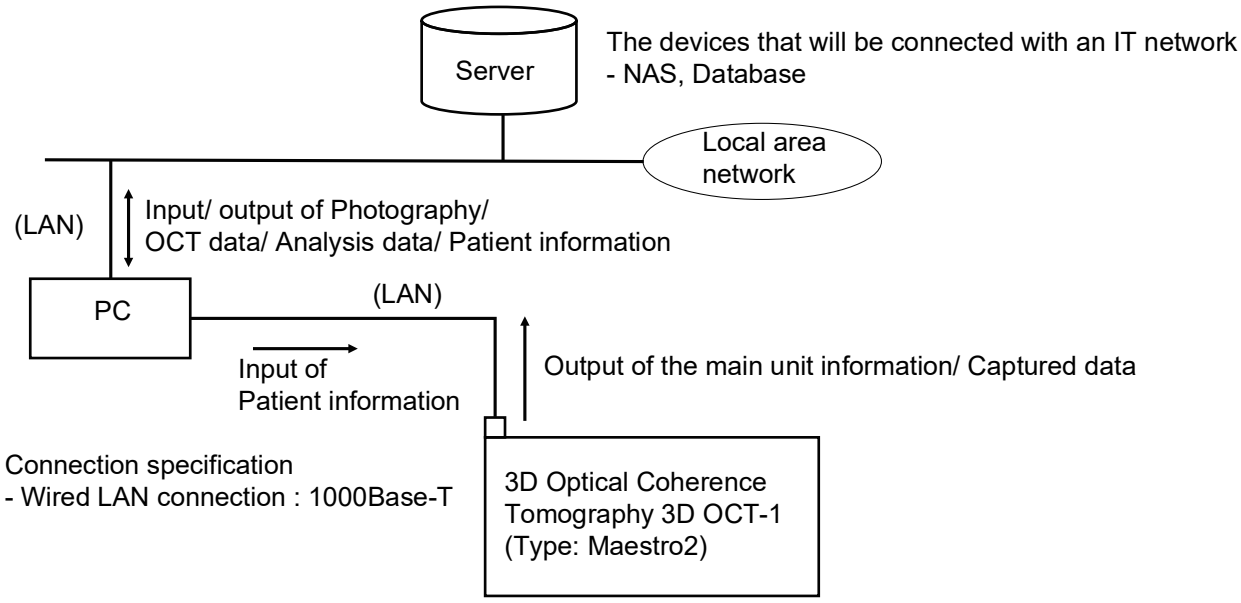
Requirements for the EXTERNAL DEVICE

The external device connected to the analog and digital interfaces must comply with the respective IEC or ISO standards (e.g. IEC 62368-1 for data processing equipment and IEC 60601-1 for medical equipment).

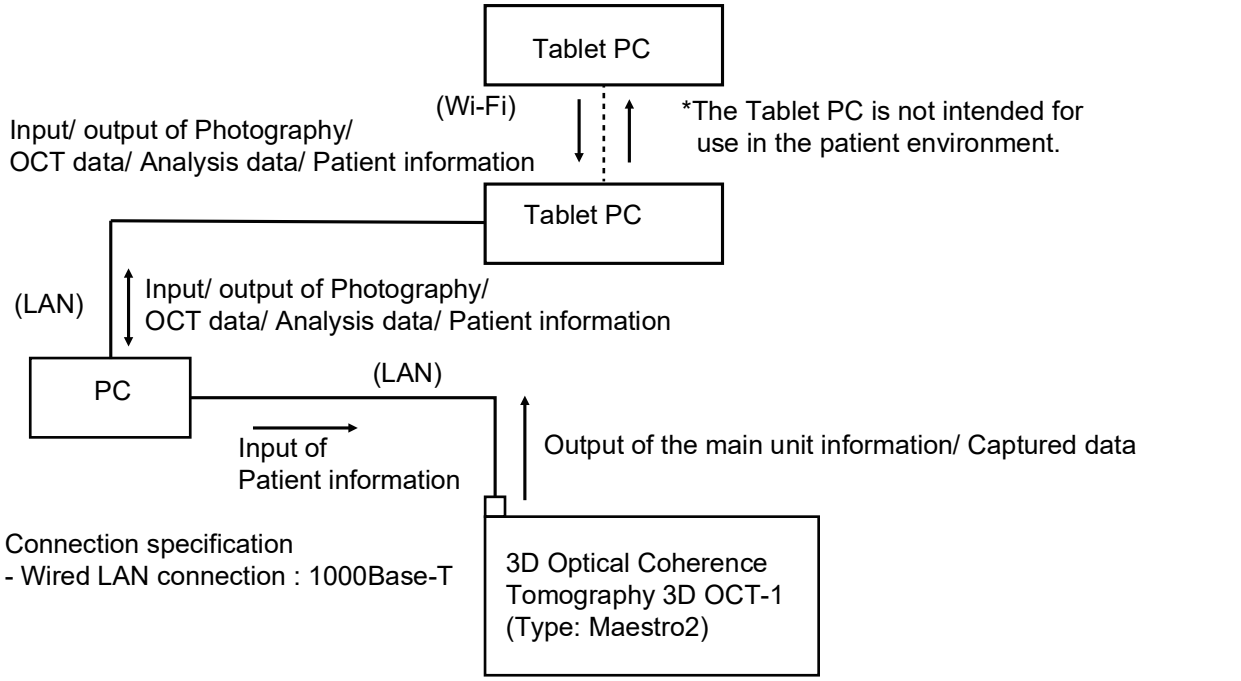
Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. In addition, the external devices to be connected must comply with the corresponding EMC standards (e.g. CISPR 32/CISPR 35). Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, contact your dealer or TOPCON (see the back cover).

IT NETWORK ENVIRONMENT

- 3D Optical Coherence Tomography 3D OCT-1(Type: Maestro2) is connected with an external personal computer (PC). PC can be connected with Database and NAS in order to input/ output photography, OCT data, Analysis data and other data.
- An external personal computer (PC) is connected with the Tablet PC via a Wi-Fi router in order to input / output photography, OCT data, and Analysis data and other data.
- Refer to the figure below for the characteristics, configuration, technical specification, intended information flow and route when connected with an IT network.
- When connected with an IT network, ensure the appropriate and sufficient security to prevent the infection with a computer virus, the leak of information, etc.
- When any failure occurs in IT systems, some troubles may be caused by it. For example, the input data/output data cannot be sent/received to/from the devices connected with network.
    - Poor connection (LAN) may cause a failure of device control. There is a risk that an examination cannot be continued with the device.
    - Poor connection (LAN) may cause a failure of output of measured data, patient information and device information. There is a risk of data loss.
    - Poor connection (USB) may cause a failure of input of patient information with barcode reader. There is a risk that the device cannot be used.
- When connected with an IT network with which a device other than 3D Optical Coherence Tomography 3D OCT-1(Type: Maestro2) is connected, the patient, the operator or the third party may suffer unexpected and unacceptable risks. Before using 3D Optical Coherence Tomography 3D OCT-1(Type: Maestro2), it is recommended to identify, analyze, evaluate and manage these risks.
- When the IT network has been changed after the connection, a new risk may occur. So an additional analysis is necessary.
- The change of IT network includes the following items:
    - Change in the IT network configuration;
    - Connection of additional items to IT network;
    - Removal of items from IT network;
    - Update of the device connected with IT network;
    - Upgrade of the device connected with IT network.



PC supports not only wired connection but also wireless connection configuration as below.



SPECIFICATIONS OF THE PERSONAL COMPUTER TO BE CONNECTED

Please refer to the user manual of the software (IMAGEnet6 for OCT).

⚠CAUTION	• User shall take necessary and appropriate precautions and exercise the reasonable degree of care in safeguarding user ID and password assigned to each employee of User who use the software (IMAGEnet6 for OCT) and operates the computer on which the software (IMAGEnet6 for OCT) runs, to prevent unauthorized use or access by any third party. • User shall take necessary and appropriate precautions and exercise the reasonable degree of care in safeguarding the database administrator password used in the software (IMAGEnet6 for OCT) to prevent unauthorized use or access by any third party. • If the software (IMAGEnet6 for OCT) is used on computer which is connected to the network, User shall have appropriate security to prevent leakage of information and infection by computer viruses. • The data and/or database files obtained through the software (IMAGEnet6 for OCT) based on client-server configuration may be placed on network. User shall be responsible for access control of the files as well as the folders that record such files. • User shall properly manage computers, devices and media that record data obtained through use of the software (IMAGEnet6 for OCT) and back up data to prevent theft or unauthorized use by any third party.

SPECIFICATIONS OF WIRELESS DEVICE (COMMERCIAL PRODUCT) FOR REMOTE OPERATION

Please refer to the user manual of the software (IMAGEnet6 for OCT).

SPECIFICATIONS OF THE INSULATION TRANSFORMER TO BE CONNECTED

Item	Spec.
Input voltage	AC100V/110V/120V (for the 100V system area) AC220V/230V/240V (for the 200V system area)
Frequency	50Hz/60Hz
Phase	Single phase
Secondary capacity	1k VA
Others	IEC 60601-1

GENERAL INFORMATION ON USAGE AND MAINTENANCE

INTENDED PATIENT POPULATION

- 5 years or older (Persons with suspected posterior or anterior ocular structure disorders or other ocular diseases)
- The patient who undergoes an examination by this instrument must maintain concentration for a few minutes and adhere to the following instructions:
  - After his/her face to the chinrest, forehead rest.
  - Keep the eye open.
  - Understand and follow instructions when undergoing an examination.

  If the patient does not conform to these conditions, it is not possible to take a picture correctly.

INTENDED USER PROFILE

Healthcare professional who received relevant education and training in the relevant medical field.

ENVIRONMENTAL CONDITIONS FOR USE

Temperature : 10°C to 35°C
Humidity : 30% to 90% (non-condensing)
Pressure : 800hPa to 1060hPa

For external input / output devices, use those that operate under the above conditions.

STORAGE, USAGE PERIOD

1. Storage (without wrapping (without package))
   * Temperature : 10°C to 40°C
   Humidity : 10% to 95% (without dew condensation)
   Pressure : 700hPa to 1060hPa
   * THIS INSTRUMENT DOES NOT MEET THE TEMPERATURE REQUIREMENTS OF ISO 15004-1 FOR STORAGE. DO NOT STORE THIS INSTRUMENT IN CONDITIONS WHERE THE TEMPERATURE MAY RISE ABOVE 40°C OR FALL BELOW 10°C.
2. When storing the instrument, ensure that the following conditions are met:
   (1) The instrument must not be splashed with water.
   (2) Do not store the instrument in an environment where air pressure, temperature, humidity, ventilation, sunlight, dust, salty/sulfurous air, etc. could cause damage.
   (3) Do not store or transport the instrument on a slanted or uneven surface or in an area where it is subject to vibrations or instability.
   (4) Do not store the instrument where chemicals are stored or gas is generated.
3. Normal life span of the instrument:
   8 years from delivery providing regular maintenance is performed (according to the self-certification [TOPCON data])

   For the conditions about transportation and storage of the external input / output devices, follow the instructions in the user manual of each device.

ENVIRONMENTAL CONDITIONS FOR PACKAGING IN STORAGE

Temperature : -20°C to 50°C
Humidity : 10% to 95%
Pressure : 700hPa to 1060hPa

ENVIRONMENTAL CONDITIONS FOR PACKAGING IN TRANSPORTAION

Temperature : -40°C to 70°C
Humidity : 10% to 95%
Pressure : 700hPa to 1060hPa

ELECTRIC RATING

Source voltage : AC 100 - 240V
Frequency : 50-60Hz
Power input : 70 - 150VA

DIMENSIONS AND WEIGHT

Dimensions : 340 - 480mm (W) × 543 - 680mm (D) × 530 - 735mm (H)
Weight : 25kg

SYSTEM CLASSIFICATION

- Types of protection against electric shock:
  This instrument is classified as Class I equipment.
  Class I equipment does not depend only on basic insulation for protection against electric shock, but also provides a means of connection to a protective earth system so that metal parts that come into contact do not become conductive if the basic insulation fails.
- Grade of protection against electric shock:
  This instrument is classified as Type B applied part.
  Type B applied part provides a specified grade of protection to prevent electric shock, particularly for reliability against current leaks, measuring current and protective earth current (in case of Class I equipment).
- Degree of protection against harmful ingress of water: IPX0
  The instrument has no protection against ingress of water. (The degree of protection against harmful ingress of water defined in IEC 60529 is IPX0.)
- Classification according to the method(s) of sterilization or disinfection recommended by the manufacturer: not applicable.
  The instrument has no part to be sterilized or disinfected.
- Classification according to the degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide:
  - Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
  - The instrument should be used in environments where no flammable anesthetics and/or flammable gases are present.
- Classification according to the mode of operation: Continuous operation.
  Continuous operation is the operation under normal load for an unlimited period, without the specified limits of temperature being exceeded.
- Class of Laser product: Class 1 Laser product according to IEC 60825-1:2007, IEC 60825-1:2014.
  Class 1 equipment is a Laser product which is safe under the rationally predictable operation conditions, and keeps safety for human eyes even if any optical system (lens or telescope) is used as a condensing unit.

Class of insulation transformer

- Types of protection against electric shock:
  Class I equipment
- Grade of protection against electric shock:
  This device is not equipped with the part applied to this protection grade.

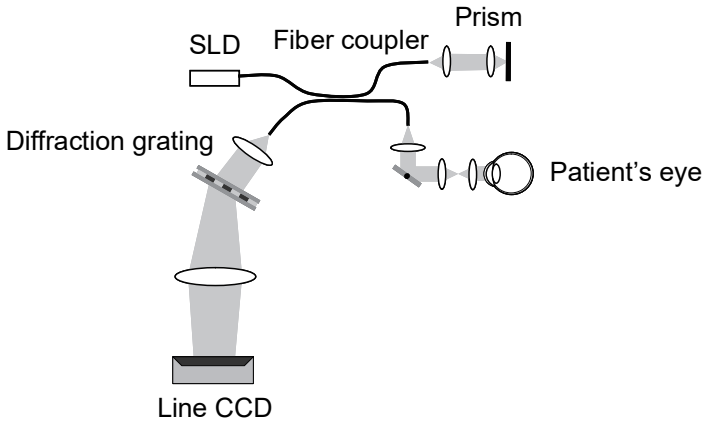
OPERATION PRINCIPLE

The patient's eye is illuminated by near-infrared light which is emitted through the fundus illumination optical system (IR LED). The fundus observation/photography optical system forms an image on the image sensor (fundus observation camera) and the image can be observed on the control panel. The system works as follows: when operating the buttons which are displayed on the control panel by the software, the photographic light which is emitted through the fundus illumination optical system, illuminates the patient's eye. The image which is received by the image sensor (fundus photography camera) built in the fundus observation/photography optical system is recorded as an electronic fundus image. One can also set “digital zoom” that extracts and saves the center of the photographed image (equivalent to the angle of view of 30°) through software.

The posterior/anterior segment tomogram is obtained by using the optical interference phenomenon. Near-infrared light which is emitted by the SLD is separated by the fiber coupler. One portion of the separated light is guided to the Corner-cube prism and is reflected by it before returning to the fiber coupler. The other portion of the light is guided into the eye and is reflected by the posterior/anterior segment tissues before returning to the fiber coupler. When the two reflected portions of lights join and overlap, a low interference wave with differing amplitude is generated. This wave is separated by the diffraction grating and is then converted into the electric signal by the linear image sensor. This signal is then processed to observe, photograph, and record the posterior/anterior segment tomogram.

The OCT-Angiography image is generated from multiple B-scans, where each B-scan is taken multiple times at the same location, based on quantification of motion contrast.

Using the sensor built in the auto alignment optical system (anterior segment observation LED and camera), the auto alignment function detects the positions of the pupil and the instrument. Then, the instrument is moved to a position applicable to photography. There are two autofocus functions, “Split autofocus function” and “OCT autofocus function”. The user should select and use one of them. The split autofocus function detects the reflected image of the split lines projected to the fundus. Then, the lens in the observation/photography optical system is moved to a proper position by the autofocus mechanism to adjust focus correctly. In the case of the OCT autofocus function, the lens in the observation/photography optical system is moved to a proper position by the autofocus mechanism to get the optimum image quality level (coefficient calculated by S/N ratio) of the observed posterior tomogram. So the focus is adjusted correctly. By continuously photographing, recording, and processing the posterior/anterior segment tomogram, analysis such as three-dimensional display, fundus image displays, or quantitative measurement is conducted.



CHECKPOINTS FOR MAINTENANCE

1. Regularly maintain and check the instrument and its parts.
2. When using the instrument after a prolonged period of inactivity, confirm normal and safe operation beforehand.
3. To take a good picture, be careful not to stain the objective lens with fingerprints or dust.
4. When this instrument is not in use, cap the objective lens and cover the instrument with the dust cover.
5. When the objective lens is stained, clean it according to “Cleaning the objective lens” in this manual.

DISPOSAL

- When disposing of the instrument's parts, follow the local regulations for disposal and recycling.

NOTE

This symbol is applicable for EU member countries only.
To avoid potential damage to the environment and possibly human health, this instrument should be disposed of (i) for EU member countries - in accordance with WEEE (Directive on Waste Electrical and Electronic Equipment), or (ii) for all other countries, in accordance with local disposal and recycling laws.

This Product Contains a coin cell.
You cannot replace batteries by yourself. When you need to replace and/or dispose batteries, contact your dealer or TOPCON listed on the back cover.

EU Battery Directive
This symbol is applicable for EU members states only.

Battery users must not dispose of batteries as unsorted general waste, but treat properly.
If a chemical symbol is printed beneath the symbol shown above, this chemical symbol means that the battery or accumulator contains a heavy metal at a certain concentration.
This will be indicated as follows:
Hg: mercury(0.0005%), Cd: cadmium(0.002%), Pb: lead(0.004%)
These ingredients may be seriously hazardous to human and the global environment.

MAINTENANCE

⚠CAUTION	To prevent the instrument from falling and to avoid injury, install the instrument on a level surface.

NOTE	Do not contact the attachment for anterior segment with rubber products during storage. The material may deteriorate.

DAILY CHECKUPS

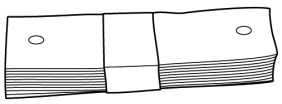
- Dust is a formidable foe to the instrument.
  To ensure the production of fine images, care should be taken not to allow fingerprints and/or dirt to get on the objective lens.
- Each time one patient is changed to another, replace the chinrest tissue with new one.
- When not in use, be sure to cap the objective lens and cover the instrument with the dust cover.
- Before using the instrument, check if the objective lens is clean. If the objective lens is stained, clean it following the instructions for “Cleaning the objective lens” on page 121.
- When not in use, always turn the [POWER SWITCH] OFF (○).

ORDERING CONSUMABLES

- When ordering consumables and spare parts, contact your dealer or TOPCON (see the back cover) and tell them the article name, article code and quantity.

Article name	Article code
Chinrest tissue	403104082
Dust cover	404969011

Dust cover



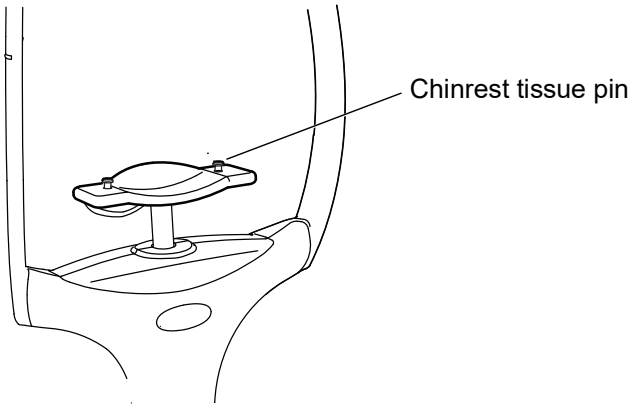
Chinrest tissue

REPLACING THE XENON LAMP

⚠**WARNING**	To avoid electric shock and burns, do not replace the lamp by yourself. Ask your dealer for repairs.

REFILLING THE CHINREST TISSUE

- When the chinrest tissue is used up, pull out the chinrest tissue pin and refill the chinrest tissue.



MAINTENANCE BY THE DEALER

Item	Inspection interval	Details
Cleaning each unit	Within 12 months from the last maintenance	• Cleaning the external section • Cleaning the optical system • Cleaning the base unit
Checking the operation	Within 12 months from the last maintenance	• Anterior segment observation function • Internal fixation target • Display on the screen • Adjusting the observation illumination • Fundus observation (by test eye) • Fundus tomography (by test eye)
Checking the light intensity	Within 12 months from the last maintenance	• Checking the xenon light intensity (by special tool) • Checking the SLD light intensity (by special tool)

CLEANING

Cleaning the external cover, control panel and other parts

NOTE	• Turn off the power switch and remove the power cord before cleaning the instrument. • Do not spray liquid on the instrument. The instrument may be damaged or those that come into contact with the instrument may be injured by electric shock. • Do not spray the cleaner solution directly toward the instrument. If the solution comes into the instrument through a vent or others, the instrument may malfunction. • When the instrument is not in use, turn off the power switch. • To prevent the plastic parts of the instrument body from discoloring and deteriorating, do not use volatile solvents for cleaning, such as benzine, thinner, ether, gasoline, etc. • Do not apply the lubricating oil such as instrument oil to the sliding board. It may deteriorate and affect the operability adversely.

1 When the external cover and control panel screen become stained, clean them with a dry cloth.

2 If the external cover or the control panel is badly stained, prepare a tepid solution of neutral detergent. Moisten a cloth and wring it thoroughly. Then, wipe the cover or panel with the cloth.

Cleaning of the parts which come into contact with the patient

- Before using the instrument, clean the forehead rest unit and chinrest unit.
  Mix neutral detergent in tepid water. Moisten a cloth and wring it thoroughly. Then, wipe the forehead rest and chinrest with the cloth.

Cleaning the control panel

NOTE	• The control panel is a touch panel. Before wiping it, turn off the power switch. If not, the touch panel responds to the wiping action and may cause a trouble in operation. • When the monitor cleaner is dirty, wash and re-use it. Rinse the monitor cleaner until the cleanser does not remain on it any more. If the cleanser remains on the monitor cleaner, the control panel is not wiped uniformly from time to time.

When the control panel is stained by dust or the like

First, remove dust lightly with a soft brush, etc. Then, wipe the screen lightly with the dry monitor cleaner, which is an accessory.

When the monitor screen is stained by fingerprints or the like

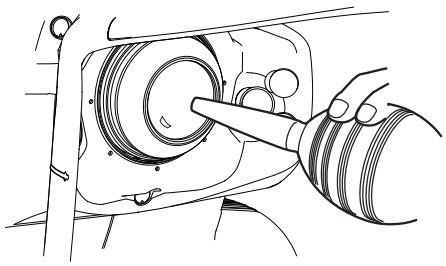
Wipe the screen lightly with the dry monitor cleaner, which is an accessory.
If the fingerprints are not removed well, moisten the monitor cleaner with a little water and then wipe the screen with it.

Cleaning the objective lens

NOTE	• The recommended cleaning paper is Cotton Ciegal. • Don't use the following methods because the objective lens may be damaged. - Wiping without blowing away dust and dirt by using a blower - Wiping with your wrist watch and finger ring on your hand and finger - Wiping with a dry cleaning paper - Wiping with a cleaning paper wound around a rod-shaped thing - Wiping the lens by grasping with fingernails - Contacting the blower end with the objective lens • Do not blow away dust by breathing toward the objective lens. Saliva may be stuck to the objective lens surface. • If the center of the objective lens is not wiped properly, the photographed fundus image will be adversely affected by this stained lens. • If the objective lens is still stained though you have cleaned it by the method mentioned here, contact your dealer.

To check the stain, darken the room. Illuminate the objective lens with a flashlight, etc. and watch it from the diagonally front position to check the stain.

Dust and dirt adhered to the surface



1 Blow off dust or dirt using a blower.

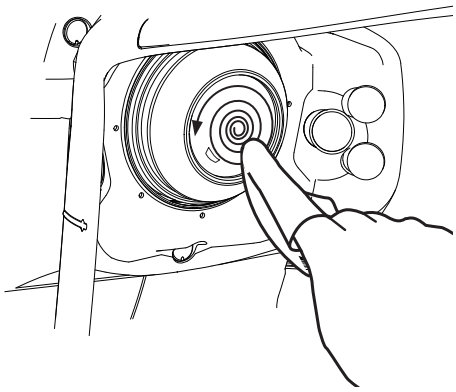
* Only when the stain cannot be removed by a blower and the photographed fundus image is adversely affected, wipe the objective lens by the following procedure.
When the stain cannot be removed easily, do not try to clean the objective lens forcedly but contact your dealer.

Tears, fingerprints and others that cannot be removed by blower

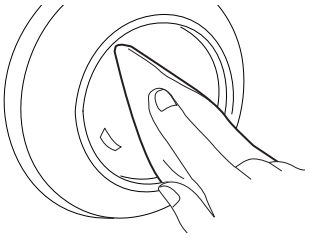
1 Blow off dust or dirt using a blower.

2 Wind a cleaning paper (Cotton Ciegal*) around your finger and moisten the cleaning paper with the specified lens cleaner (Ethanol for Disinfection).
As pressing the center of the objective lens, wipe the lens surface with this moistened cleaning paper slowly and circularly outwards to remove dust and dirt.

3 Replace the cleaning paper with a new one and wipe the objective lens until no stain is seen on the lens surface.



4 To clean the lens corner, fold the cleaning paper and taper it. Using the taper end of the cleaning paper, wipe the corner.



* Cotton Ciegal (Manufacturer: CHIYODA CO., LTD.)

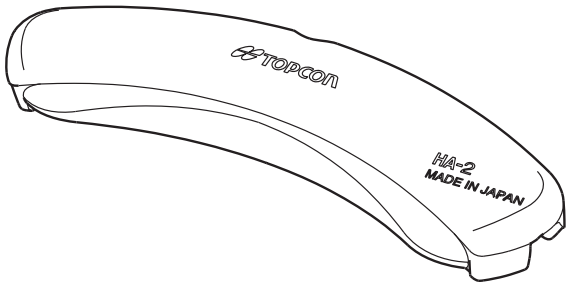
Cleaning of external input / output device

Clean according to each instruction manual.

OPTIONAL ACCESSORIES

ATTACHMENT FOR ANTERIOR SEGMENT HA-2

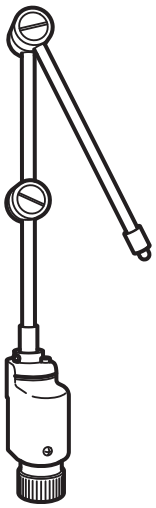
By mounting this attachment onto the instrument's forehead rest, it is possible to take a tomogram of anterior segment.
For mounting the attachment onto the instrument, refer to the user manual of “ATTACHMENT FOR ANTERIOR SEGMENT HA-2”.



Specifications
- Dimensions: 180 (Width) × 35 (Height) × 61 (Depth) mm
- Weight: 125g
- Material: Silicone rubber

EXTERNAL FIXATION TARGET EF-2

Mount this product to the connector on the chin rest unit of the main body, and use it to guide the patient's eye appropriately during the photography.



Specifications
- Dimensions: 46 (Width) × 331 (Height) × 25 (Depth) mm (when extended)
- Weight: 97g
- Material: Aluminum

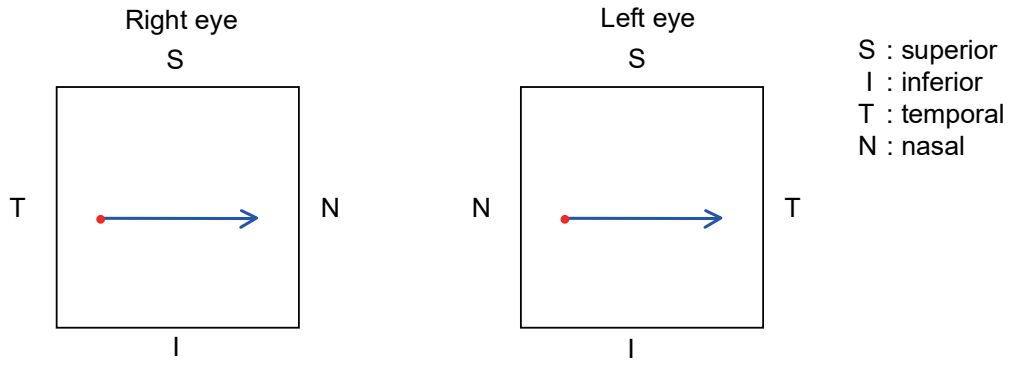
*This product has a configuration in which an external fixation target is a standard accessory and a configuration in which it is an optional accessory.

REFERENCE MATERIAL

SCAN PATTERN SPECIFICATIONS

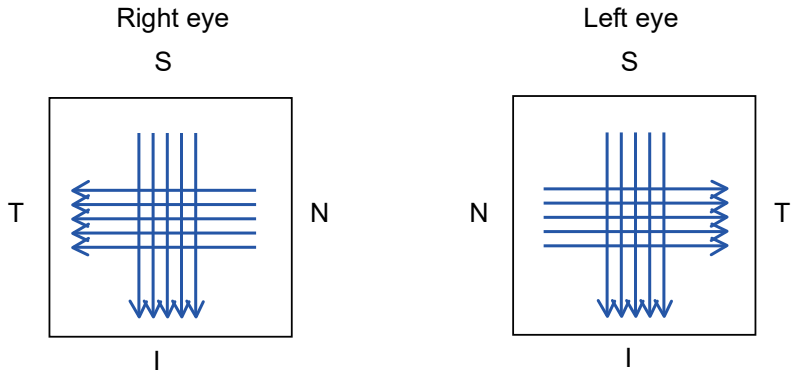
Line Scan

In the scan range, move on the line (arrowed line in the figure below), which connects the coordinates of the given start point and end point, by the step divided by the given resolution. Be sure to move from the start point to the end point.



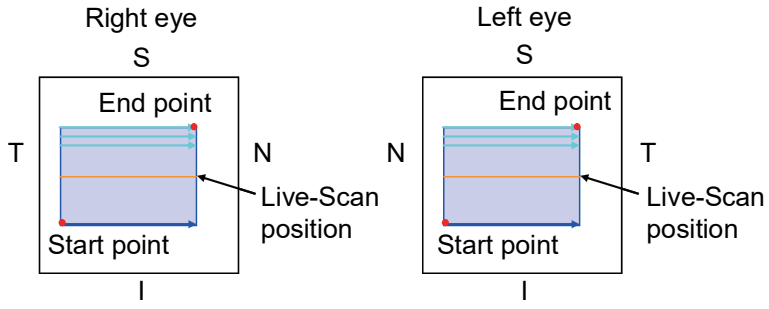
5 Line Cross Scan

In the scan range, move on the five cross lines (arrowed line in the figure below), which pass through the center point, by the step divided by the given resolution. “9.0mm” is initially set for the scan length. Be sure to move from the start point to the end point.

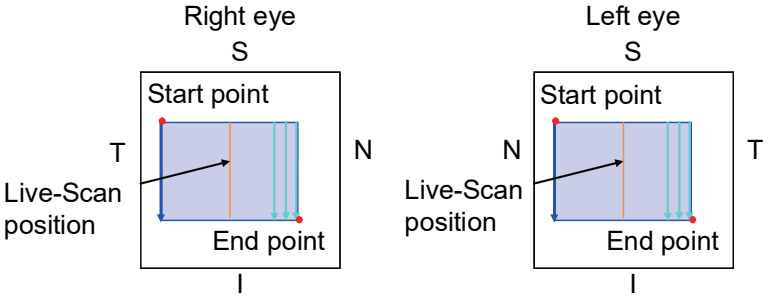


3D Scan

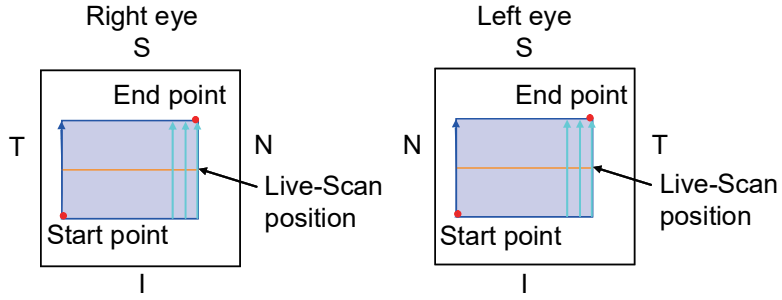
Move on the inside of the square, which is composed of the given start point and end point, horizontally and vertically by the step divided by the given resolution.
The scan for [3D Macula], [3D Disc] and [3D Wide (H)] is shown below. (“6.0×6.0mm” is initially set for the scan length in both of these scans.)



The scan for [3D Macula (V)] is shown below. (Scan length, “7.0×7.0mm” is fixed.)

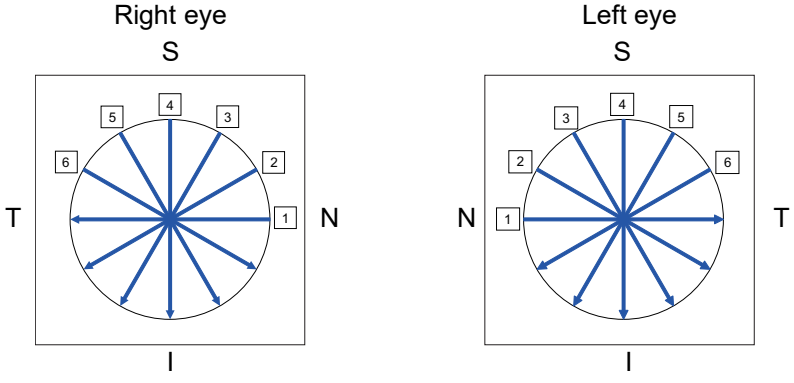


The scan for [3D Wide] is shown below. (Scan length, “12.0×9.0mm” is fixed.)



Radial Scan

In the scan range, perform scanning by the specified diameter and by the step divided by the given resolution. “6.0mm” is fixed for the scan length. The start point for Line-Scan and rotating direction are reversed for each of right and left eyes. For the right eye, rotation is done counterclockwise in the horizontal direction. For the left eye, rotation is done clockwise in the horizontal direction.



TYPE OF PLUG

Country	Voltage/frequency	Type of plug
Mexico	110V/50Hz	Type C/E
Argentina	220V/60Hz	Type A
Peru	220V/60Hz	Type A
Venezuela	110V/50Hz	Type C/E
Bolivia & Paraguay	220V/60Hz	Type A (Most common) Type H (Infrequently)
Chile	220V/60Hz	Type A
Colombia	110V/50Hz	Type C
Brazil	220V/60Hz 127V/60Hz	Type A Type C
Ecuador	110V/50Hz	Type C/E
Canada	120V/60Hz	Type A (Hospital Grade)

ABOUT THE BARCODE AND THE QR CODE OF THE BACK COVER

The barcode and the QR code of the back cover indicates the parts management code of the manual.

RELATION BETWEEN THE SETTING OF THE ILLUMINATION/FLASH LEVEL AND MAXIMUM RADIANCE

When the maximum radiance is “1”, the ratio of radiance is shown below in the setting of the illumination/ flash level.

Illumination level

Display level	Ratio of radiance
1	0.354
2	0.500
3	0.707
4	1.000

Flash level (in OCT+Color photography and Color photography)

Display level (High)	Display level Normal (0dB)	Display level Low (6dB)	Setting of the flash level (W·s)	Ratio of radiance
			16.0	1.00
			14.0	0.87
			11.0	0.73
			9.6	0.61
+4			8.1	0.52
+3			6.8	0.43
+2			5.7	0.36
+1			4.8	0.31
0	+4		4.0	0.25
-1	+3		3.4	0.22
-2	+2		2.9	0.18
-3	+1		2.4	0.15
-4	0	+4	2.0	0.13
	-1	+3	1.7	0.11
	-2	+2	1.4	0.09
	-3	+1	1.2	0.08
	-4	0	1.0	0.06

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IPA font: http://ipafont.ipa.go.jp/
libxml: http://www.xmlsoft.org/

Please provide the following information when contacting us regarding questions about this instrument:

- Model name: 3D OPTICAL COHERENCE TOMOGRAPHY
  3D OCT-1 (Type: Maestro2)
- Serial No.: This is printed on the rating nameplate on the right side of the power supply unit.
- Period of use: Please inform us of the date of purchase.
- Defective condition: Please provide us with as much detail as possible on the problem.

3D OPTICAL COHERENCE TOMOGRAPHY
3D OCT-1 (Type: Maestro2)

USER MANUAL
Revision 9
Date of issue: 2023-12-22

Published by TOPCON CORPORATION

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3D OPTICAL COHERENCE TOMOGRAPHY

3D OCT-1 (Type: Maestro2)

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