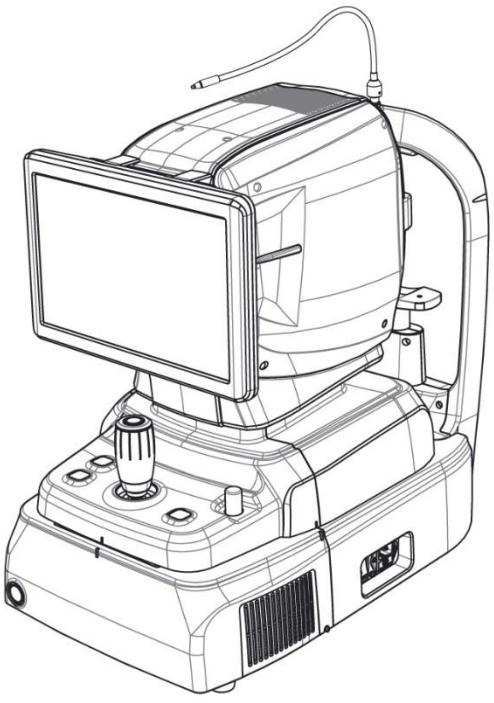
Huvitz

OPTICAL COHERENCE TOMOGRAPHY

HOCT-1F/1

USER MANUAL



■ IMPORTANT NOTICE

This product may malfunction due to electromagnetic waves caused by portable personal telephones, transceivers, radio-controlled toys, etc. Be sure to avoid having objects such as, which affect this product, brought near the product.

The information in this publication has been carefully checked and is believed to be entirely accurate at the time of publication. HUVITZ assumes no responsibility, however, for possible errors or omissions, or for any consequences resulting from the use of the information contained herein.

HUVITZ reserves the right to make changes in its products or product specifications at any time and without prior notice, and is not required to update this documentation to reflect such changes.

■ Revision History

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A			First issued

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CONTENT

1 SAFETY PRECAUTIONS 5

1.1. Overview 5

2 Symbol Information 6

2.1. Usage Precautions 8
2.2. Environmental Considerations 11
2.3. Safety Precautions 13

3 INTRODUCTION 15

3.1. System Outline 15
3.2. Intended Use 15
3.3. Classification 15
3.4. Contraindications 15
3.5. Patient requirements 15
3.6. Operating Principles 16
3.6.1. Fundus image 16
3.6.2. The anterior segment/fundus tomogram 16
3.7. Applied Standard List 16

4 System Overview 17

4.1. Configuration and Functions 17
4.2. Main Body Screen Description 20
4.2.1. OCT/Fundus mode (HOCT-1F only) 20
4.2.2. OCT mode 23
4.2.3 Fundus mode (HOCT-1F only) 24

5 Installation Procedure 25

5.1. System installation 25

6 Operation 28

6.1. Software 28
6.2. SETUP Mode 30
6.3. General Operation 33
6.4. Anterior segment image operation (optional) 45
6.4.1. Preparation for anterior segment operation 45
6.4.2. Capturing anterior segment 46
6.5. Analyze 51
6.5.1. Entering Analysis screen 51
6.5.2. OCT Macular 3D Analysis screen 52
6.5.3. OCT Disc 3D Analysis screen 63
6.5.4. OCT Anterior Line Analysis screen 74
6.5.5. Fundus Analysis screen 82
6.6. Maintenance 91
6.6.1. After operation 91
6.6.2. Cleaning 93
6.6.3. Replacement of consumables and fuse 94
6.6.4. Calibration 94
6.6.5. Self-diagnosis using Model eye 95

7 Troubleshooting Guide 99

8 Specifications and Accessories 100

8.1. Standard Accessories 100
8.2. Specifications 101
8.3. Drawings of System 102

9 EMC INFORMATION.....103
10 SERVICE INFORMATION 105
11 SOFTWARE LICENSE AGREEMENTS.....106

1

1 SAFETY PRECAUTIONS

1.1. Overview

Safety is everyone's responsibility. The safe use of this instrument is largely dependent upon the installers, users, operators, and managers. It is prerequisite to read and understand these specifications before installing, using, cleaning, fixing or revising. Fully understanding the whole instructions must be the first priority. For this reason, the following safety notices have been placed appropriately within the text of this manual to highlight safety related information or information requiring special emphasis. All users, operators, and maintainers must be familiar with and pay particular attention to all signs of Warnings and Cautions.

⚠ WARNING

"Warning" indicates the presence of a hazard that could result in severe personal injury, death or substantial property damage if ignored.

⚠ CAUTION

"Caution" indicates the presence of a hazard that could result in minor injury, or property damaged if ignored.

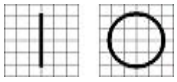
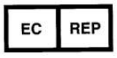
⚠ NOTE

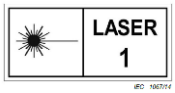
This is used to emphasize essential information.
Be sure to read this information to avoid operating the device incorrectly.

2

2 Symbol Information

The International Electro technical Commission (IEC) has established a set of symbols for medical electronic equipment which classify a connection or warn of any potential hazards. The classifications and symbols are shown below.

	I and O on power switch represent ON and OFF respectively.
	Type B Isolated patient connection.
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the appropriate User's or Service Manual.
	Identifies the point where the system safety ground is fastened to the chassis. Protective earth connected to conductive parts of Class I equipment for safety purposes.
	Indicates the Manufacturer
	Indicates the date of manufacture
	Authorized Representative in the European Community
	Temperature Limitation
	Keep DRY
	Warning: Crushing or insert of hand
	UL Mark
	CE Mark

	Class I Laser Product
CE RoHS	CE for RoHS RoHS Directive Compliance 2011/65/EU
	WEEE indicating separate collection for electrical and electronic equipment

2.1. Usage Precautions

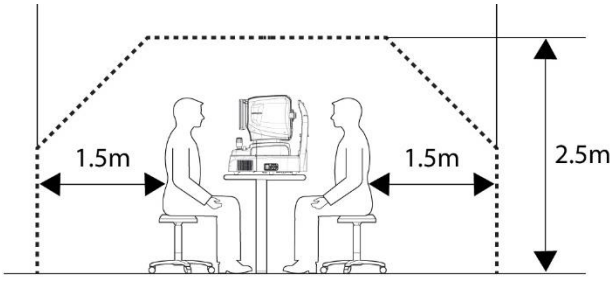
This equipment has been developed and tested in conformity with domestic & international safety standards and regulations, which guarantees the high stability of this product. This guarantees a very high degree of safety for this device. The legislator expects us to inform the user expressively about the safety aspects in dealing with the device. The correct handling of this equipment is imperative for its safe operation. Therefore, please read carefully all instructions before switching on this device. For more detailed information, please contact our Customer Service Department or one of our authorized representatives.

⚠ CAUTION

For use of equipment in rated voltage less than 125Vac, minimum 6A, Type SJT or SVT, 18/3AWG, 10A, max 3.0m long: One end with Hospital Grade Type, NEMA 5-15P Other end with appliance coupler. For use of equipment in rated voltage less than 250Vac, minimum 6A, Type SJT or SVT, 18/3AWG, 10A, max 3.0m long: One end terminated with blade attachment plug(HAR) Type, NEMA 6-15P.

⚠ CAUTION

Use instrument that comply with IEC60601-1 in the patient environment. [The figure below show]

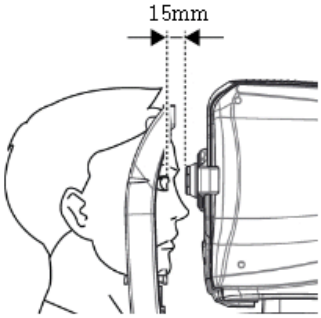


If and instrument that does not comply with IEC 60601-1 is to be used, use an isolation transformer.

If a person handling a conductive part of the system comes into contact with a patient at the same time, hazard may occur due to leakage current exceeding the value specified in the applicable standard. Be careful not to touch patients when connecting or removing the power plug or cable connectors.

CAUTION

During the Anterior segment image operation, pull the joystick toward the operator before adjusting the alignment. Move the body to align patient's eye. Move the body slowly while watching patient's eye and body, because working distance is just 15mm that the front lens is very close to patient's eye.



CAUTION

This instrument includes lithium battery. This hazardous material needs to be disposed of properly to limit environmental pollution. Please contact to the professional waste disposal company.

CAUTION

Do not install any software on OCT built-in computer without our consent.
The manufacturer is not responsible for any failure due to random installation.

⚠ CAUTION

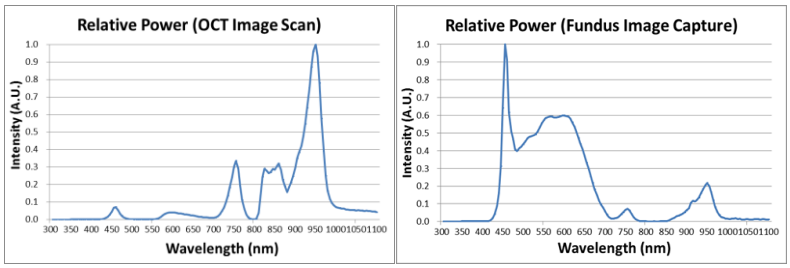
The equipment is a Class I LED Product. The LED used for the equipment is safe under expected use conditions including situation such as looking into the LED using optical equipment.
However, observe the following precautions when using the equipment

- Do not direct LED beams to human eyes when unnecessary.
- Do not look into the objective lens for a prolonged time.
- Class 3R invisible LED radiation when Optical system subassembly open.
  Avoid exposure to the beam.
- The longer the duration of exposure and the greater the number of pulses, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum output will exceed the safety guideline after 9.9 x 10^7 sec for Retina IR, 5.3 x 10^7 sec for Working dot(Manual Focusing), 4.1 x 10^7 sec for Kerato ring(Auto / Manual Tracking), 9.5 x 10^7 sec for Kerato focus(Auto/Manual Tracking), 1.0 x 10^8 sec for Split focus(Optimizing), 9.1 x 10^5 sec for external fixation lamp, 4.8 x 10^7 sec for SLD Laser(OCT scanning), 1,936,114 pulses for the light source of fundus image capture

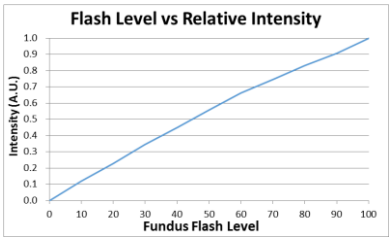
Note 1: The exposure time and number of pulses from all light sources is cumulative and additive.

Note 2: If the intensity of any of the light sources is reduced to 50% of the maximum intensity, the exposure time or number of pulses for that light source to reach the exposure guideline is doubled. This linear relationship can be used to determine the time to reach the exposure guideline for the combination of light sources at various intensity settings.

Note 3: The weighted retinal radiant exposure guideline is 10 J/cm2



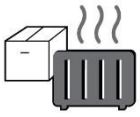
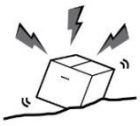
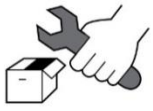
<Spectrum output of all light source during measurement (maximum light intensity)>



<Relationship between fundus flash level and maximum light intensity>

2.2. Environmental Considerations

Avoid the following environments for operation or storage:

	Where the instrument is exposed to water vapor. Don't operate the instrument with wet hands Indoor use only.
	Where the instrument is exposed to direct sunlight.
	A place where the equipment can be exposed to direct ultraviolet.
	Where there are big changes in temperature. Optimal temperature range for normal operation is from 10°C to 35°C (Humidity : 30 ~ 90%).
	Where there is hot equipment nearby.
	Where the humidity is extremely high or there is a ventilation problem.
	Where the instrument is exposed to excessive shocks or vibrations.
	Where the instrument is exposed to chemical material or explosive gas.
	Be cautious so that things like dust and metal do not fall inside the instrument.
	Don't disassemble or open the product. HUVITZ does not take responsibility for the possible problems

	Be careful not to block the fan of the instrument.
	Don’t plug the AC power cable into the outlet unless all parts of the instrument are completely connected. Otherwise, it will cause severe damage on the instrument.
	Pull out the power cable with holding the plug, not the cord. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

For the normal operation of the instrument, please keep the ambient temperature is 10℃ ~ 35℃, humidity is 30% ~ 90% and atmospheric pressure is 800 ~ 1060hpa. For the Transportation of the instrument, please keep the ambient temperature is -40℃ ~ 70℃, humidity is 10% ~ 95% and atmospheric pressure is 500 ~ 1060hpa. For the Storage of the instrument, please keep the ambient temperature is -10℃ ~ 55℃, humidity is 10% ~ 95% and atmospheric pressure is 700 ~ 1060hpa. Avoid environments where the equipment is exposed to excessive shocks or vibrations.

2.3. Safety Precautions

1. This is an electric medical device. Use is limited to doctors or persons qualified by the law of each country

2. Do not make a diagnosis base on a single captured image. Doctors are responsible for making the final diagnosis based on the present and past medical records of the patient such as captured images. Without sufficient information, proper diagnosis may not be made.

3. When instrument is send back to A/S center for repair or maintenance, or before authorized service man is arrived at the place for repair or maintenance, wipe the surfaces of the instrument (especially, the areas that come into contact with the patient) with a clean cloth dampened with rubbing alcohol.

4. This equipment must not be used in an area that is in danger of explosions and in the presence of flammable, explosive, or volatile solvent such as alcohol, benzene or similar chemicals.

5. Do not place or store this instrument in humid area. Do not expose the device to water splashes, dripping water, or sprayed water. Do not place containers with fluids, liquids, or gases on top of this instrument.

6. The instrument must be operated by a trained and qualified person or under his or her supervision.

7. Repair of this instrument must be conducted by HUVITZ's service technicians or other authorized persons.

8. Maintenance by users must observe the User's Manual and Service Manual. Any additional maintenance may only be performed by HUVITZ's service technicians or other authorized persons.

9. Manufacturers are responsible for the safety, reliability, and performance of this instrument only when the following requirements are fulfilled.
   (1) When the instrument has been installed in a proper area, following the manual.
   (2) When the instrument has been operated and maintained according to the manual and service manual.

10. Manufacturers are not responsible for the damages caused by unauthorized alterations. Such tampering will forfeit any rights to receive services during the term of guarantee.

11. This instrument must be connected with the accessories supplied by HUVITZ. If you are to use other accessories, their safety or usability must be checked and proved by their manufacturers or HUVITZ.

12. Only those who have undergone proper training and instructions are authorized to install, use, operate, and maintain this instrument.

13. Keep the User's Manual and Service Manual in a place easily accessible at all times for persons operating and maintaining the equipment.

14. Do not apply excessive force to cable connections. If the cable does not connect easily, make sure that the connector (plug) is appropriate for the receptacle (socket). If you caused any damage to a cable connector(s) or receptacle(s), let the damage(s) be repaired by an authorized service technician.

15. Please do not pull on any cable. Always grab the plug when disconnecting cables.

16. Before you use, check the exterior of the instrument and its conditions.

17. Do not block any ventilation outlet necessary for proper heat dissipation.

18. If smoke, sparks or any abnormal noise or smell is noticed coming from the instrument, please switch the power off immediately and pull out the plug.

19. When you carry this product, please use a hand cart. If you want to move the product to other area, please contact customer service center.

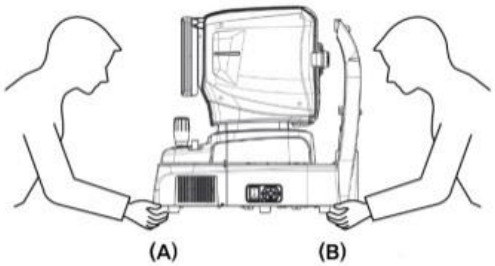
20. To avoid the risk of electric shock, this instrument must only be connected to protective earth.

21. Do not place the instrument where it is difficult to operate the disconnecting device. (disconnecting device: power cable)

22. The equipment may be impaired if it is used in a manner not specified by the manufacturers or manual.

23. External equipment intended for connection to signal input, signal output or other connectors of this instrument, shall comply with relevant IEC Standard (e.g., IEC60950 for IT equipment and IEC60601-1 series for medical electrical equipment). In addition, all such combination-system-shall comply with the standard IEC60601-1 harmonized national standard or the combination. If, in doubt, contact qualified technician or your local representative. The operator should not touch the patient and accessible male parts of the SIP/SOP connectors simultaneously.

24. When you carry this product, please hold on left(A) and right(B) bottom of the product.



3

3 INTRODUCTION

3.1. System Outline

The Huvitz Optical Coherence Tomography HOCT-1F, HOCT-1 is a non-contact, high-resolution tomographic and bio-microscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional and three dimensional imaging, color fundus imaging(HOCT-1F only) and measurement of posterior ocular structures, including the retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, ganglion cell complex, macula, 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

3.2. Intended Use

The HOCT-1F, HOCT-1 is intended for use as a diagnostic device to aid in the check and management of ocular diseases such as macular holes, cystoid macular edema, diabetic retinopathy, aged related macular degeneration, and so on, which are occurred at a macular, an optic disk, an inner structure of retina, and a cornea

3.3. Classification

- Classification of product : Class II according to Annex IX (Rule 10) of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC
- Resistance against electric shock : Class I (earthed)
- Protection class against electric : Type B(Head rest, chinrest paper)
- Classification of Laser Product : Class 1 (laser based on IEC 60825-1:2014 Standard)

3.4. Contraindications

- Patients who are hypersensitive to light.
- Patients who recently underwent photodynamic therapy
- Patients taking medication that causes photosensitivity

3.5. Patient requirements

The patient who undergoes and 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

3.6. Operating Principles

3.6.1. Fundus image

The anterior of an eye is illuminated by IR light, the posterior of an eye is illuminated by an infrared light and a white LED, of which lightings are emitted by the fundus illumination optical system. The fundus observation/photography optical system forms and makes an image with image sensors, which images are observed and manipulated with the display panel.

3.6.2. The anterior segment/fundus tomogram

Formation of anterior chamber cross-sectional image, retinal cross-sectional image, and fundus image
To form retinal cross-sectional images (OCT images) and fundus images (OCT Phase Fundus images), the system main body scans light over the eye to obtain interference light. The obtained interference light is dispersed into individual wavelengths and detected by the line image sensor. The detected light is converted to signals, and then computed to form images. With the anterior segment adapter (optional), a fundus tomogram can be formed

3.7. Applied Standard List

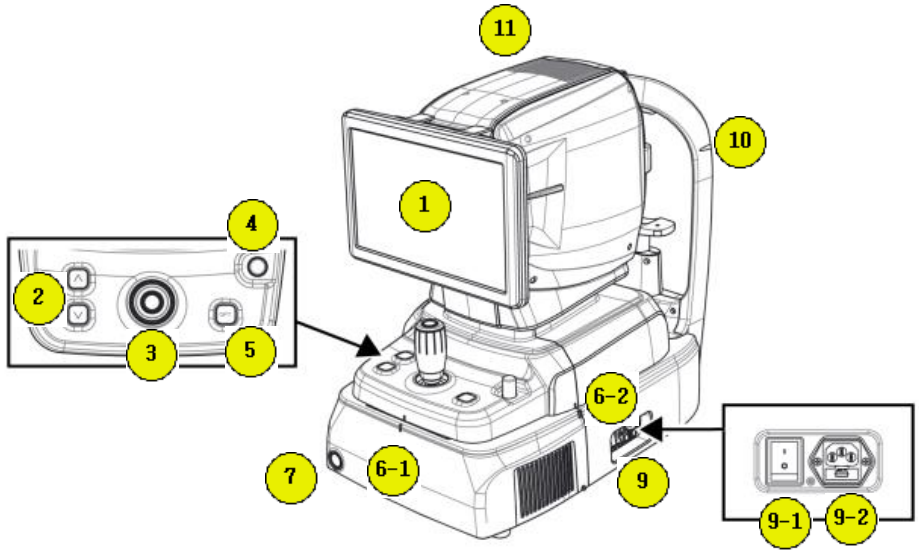
- IEC/EN 60601-1: MEDICAL ELECTRICAL EQUIPMENT
  – Part 1: General requirements for safety
- IEC/EN 60601-1-2: Medical electrical equipment Part1: General requirements for safety
  - Collateral Standard: Electromagnetic Compatibility-Requirements and tests
- ISO15004-1: Ophthalmic instruments
  - Fundamental requirements and test methods
    General Requirements applicable to all Ophthalmic instrument
- ISO15004-2: Ophthalmic instruments-Fundamental requirements and test methods
  – Part 2: Light hazard protection
- ISO 10940: Ophthalmic instruments - Fundus Cameras
- ISO 16971: Ophthalmic instruments - Optical Coherence Tomography for the posterior segment of the human eye

4

4 System Overview

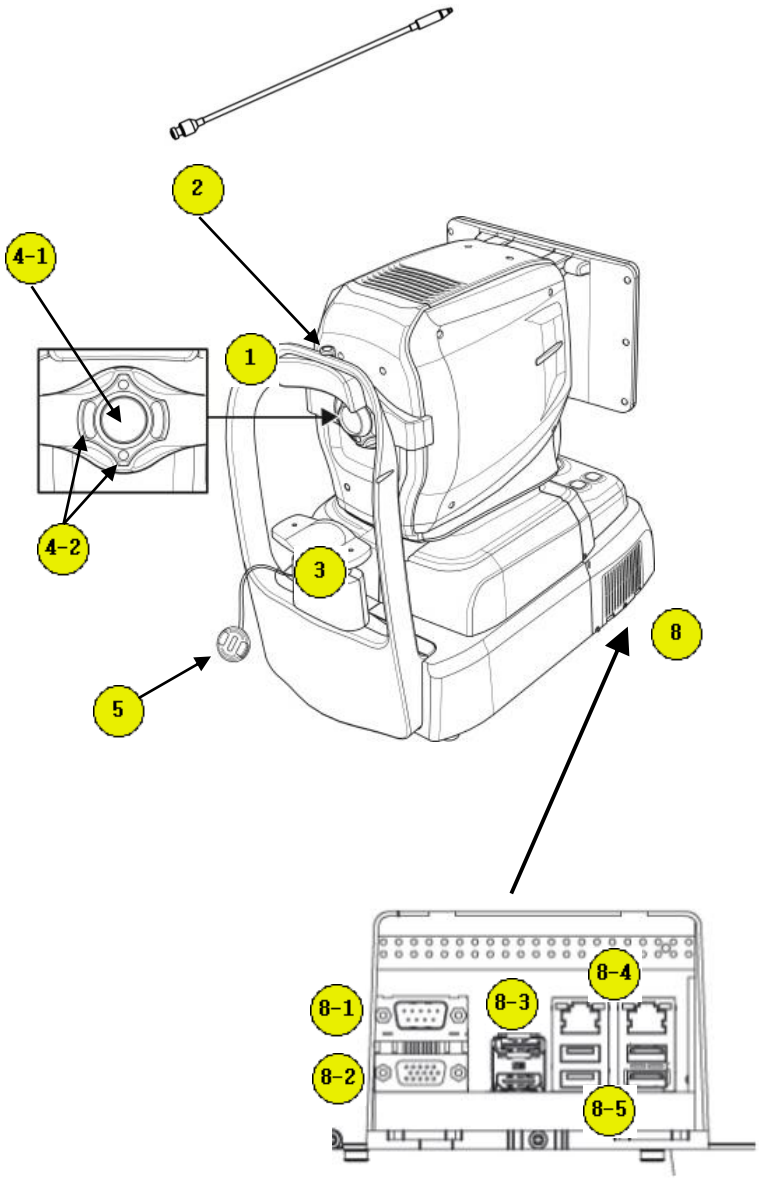
4.1. Configuration and Functions

Front View



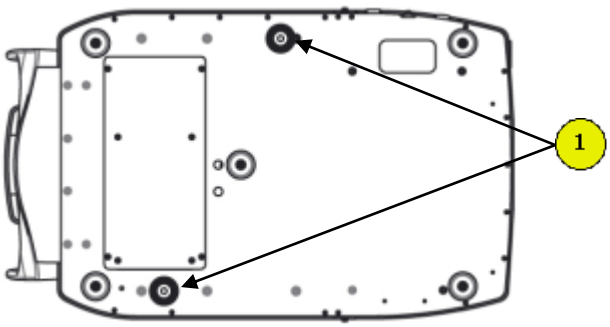
No	Part	Name	Description
1	Display	LCD	Monitor for displaying captured image and user interface icon.
2	Body	Chinrest button	Button for moving chinrest up and down.
3		Joystick	Joystick for aligning body to patient's eye. Button for capturing image.
4		User Lock	Lock for fixing body to base frame.
5		OPT button	Button for optimizing OCT signal
6-1 6-2		Align index mark	Mark for indicating center of body and base.
7	Base	Power button	Button for turning power of internal PC on/off. When the power is on, white light is lit.
9-1		Power switch	Switch for power on/off.
9-2		Power inlet	Inlet for connecting power cable.
10	Headrest	Eye level mark	Mark for indicating base height of patient's eye.
11	Body	Heat vent	Window for emitting internal heat.

Rear View



No	Part	Name	Description
1	Headrest	Forehead rest	Rubber for fix patient's head.
2		External LED	External LED for fixing patient's eyes.
3		Chinrest	For fixing patient's chin.
4-1	Body	Objective lens	Lens for passing illumination light from body and reflected light from patient's eye.
4-2		Mirering Focus LED	LEDs for checking working distance.
5	Headrest	Objective lens cap	Cap for protecting objective lens.
8	Base	External port	Port for communicating internal or external device.
8-1		RS-232 port	Port for communicating internal PC board and main board.
8-2		RGB port	Port for external display device.
8-3		DP port	Port for communicating external DP device.
8-4		LAN port	Port for external network (2 ports)
8-5		USB port	Port for internal or external USB device (4 ports)

Bottom View

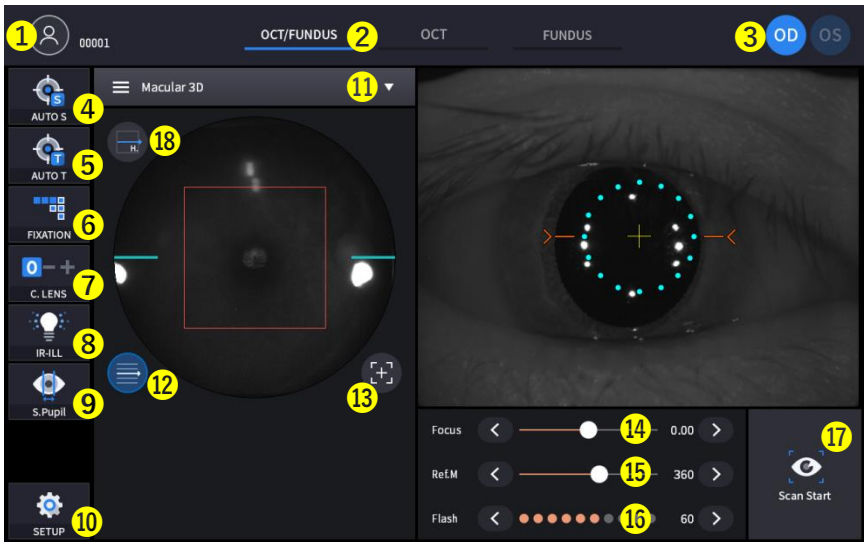


No	Part	Name	Description
1	Base	Packing lock	Lock for fixing body and base during transportation. (2 points)

4.2. Main Body Screen Description

4.2.1. OCT/Fundus mode (HOCT-1F only)

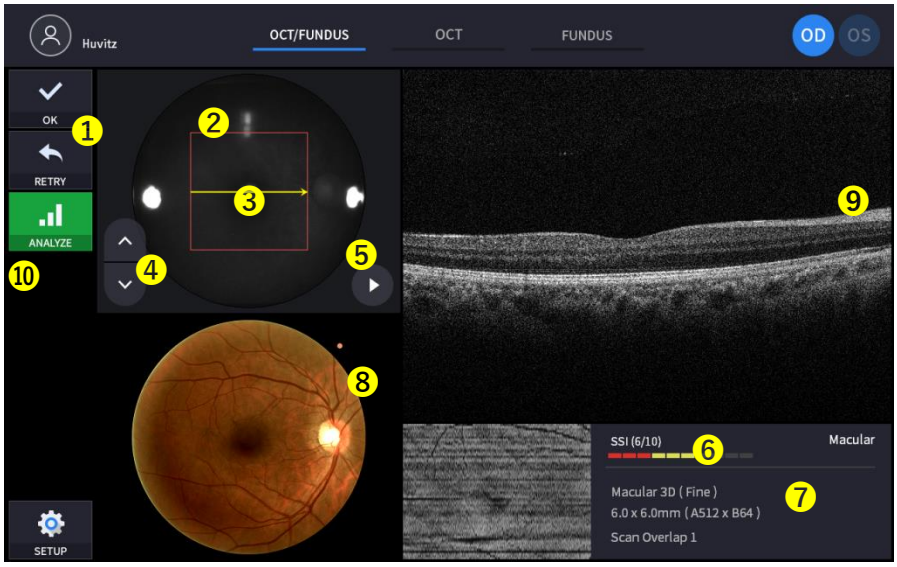
Observation screen



No	Name	Function
1	Patient information	Shows the information of patient ID and name. Go back to patient list by clicking the icon.
2	Observation mode	Show current observation mode. - OCT/Fundus: Capture OCT and Fundus image simultaneously. - OCT: Capture OCT image. - Fundus: Capture Fundus image.
3	OD/OS	Show current eye position. - OD: right eye - OS: left eye
4	AUTO S	Show auto shooting selection status.
5	AUTO T	Show auto tracking selection status.
6	FIXATION	Select position of internal fixation target.
7	C LENS	Show compensation lens status. 0: No compensation lens is used. -: Minus compensation lens is used. +: Plus compensation lens is used.
8	IR-ILL	Select brightness level of IR light for fundus observation. Normal / Bright mode is toggled by clicking.
9	S.Pupil	Show small pupil mode selection status for fundus image.
10	SETUP	Move to user setup mode.
11	Capture region	Select capture region and capture mode - Fundus/OCT or OCT mode: Macular, Disk, Anterior - Fundus mode: Single, Panorama

12	Scan range	Toggle whether scan range is displayed or not.
13	Reset scan position	Reset scan position to center.
14	Focus	Move in accordance with focus of patient’s eye.
15	Ref.M	Move reference mirror position for OCT scan.
16	Flash	Change brightness level of white light for capturing fundus image.
17	Scan Start	Start OCT scan.
18	Scan direction	Horizon, vertical changes are possible.

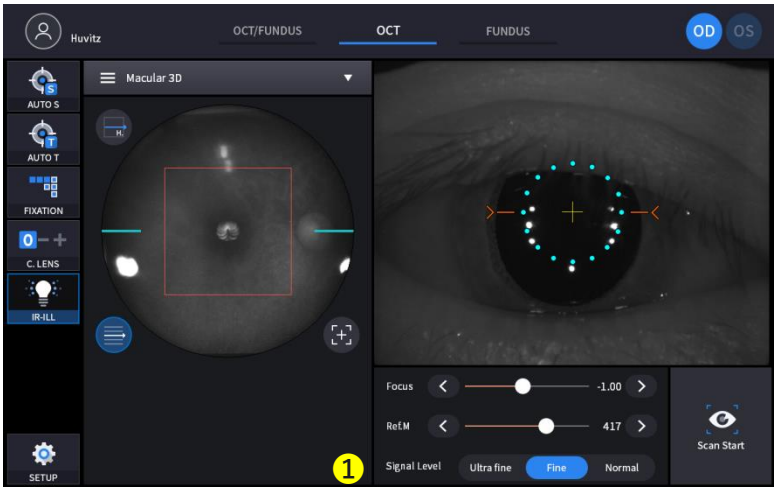
Confirmation screen



No	Name	Function
1	Image selection	Decide validity of current image. - OK: Save current image. - RETRY: Discard current image and retry capturing.
2	Scan range	Show OCT scan range.
3	Scan position	Show scan position of current OCT scan image displayed on the right.
4	Move scan position	Change previous/next OCT scan image.
5	Play image	Display captured OCT scan image continuously.
6	SSI	SSI: Scan Signal Index Show quality index of scan image.
7	Scan information	Display setting information of scan image.
8	Fundus image	Show captured fundus image.
9	OCT image	Show captured OCT image.
10	Analyze	Save the camera DATA and enter the analysis screen

4.2.2. OCT mode

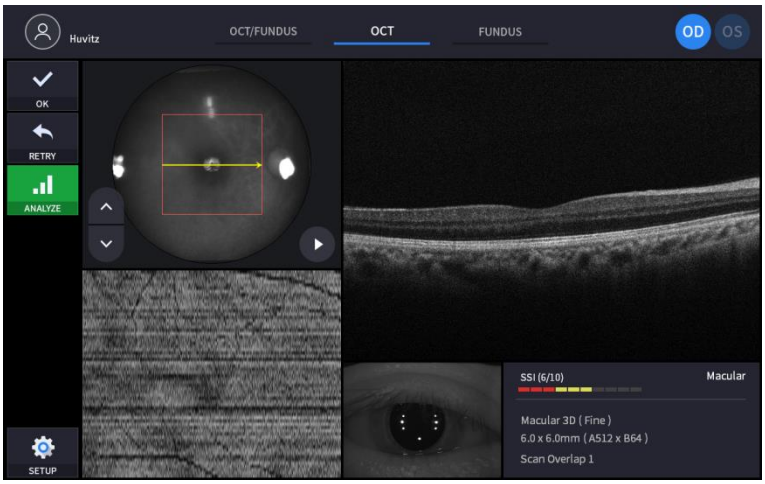
Observation screen



(Refer '4.2.1. OCT/Fundus mode – Observation screen' for uncommented item)

No	Name	Function
1	Signal Level	Mode can be changed

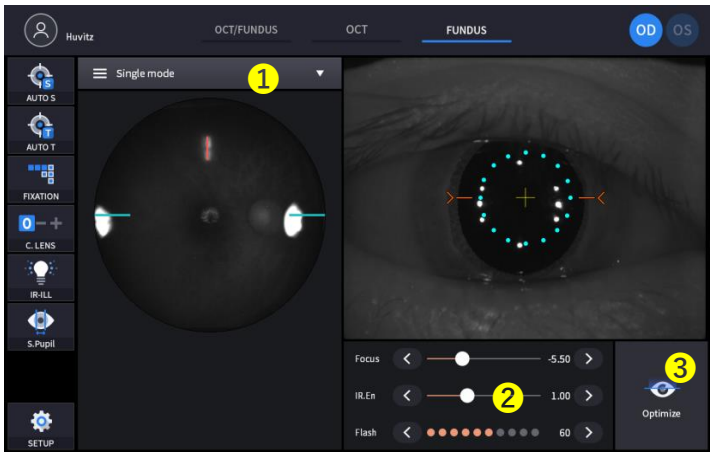
Confirmation screen



(Refer '4.2.1. OCT/Fundus mode – Confirmation screen' for uncommented item)

4.2.3 Fundus mode (HOCT-1F only)

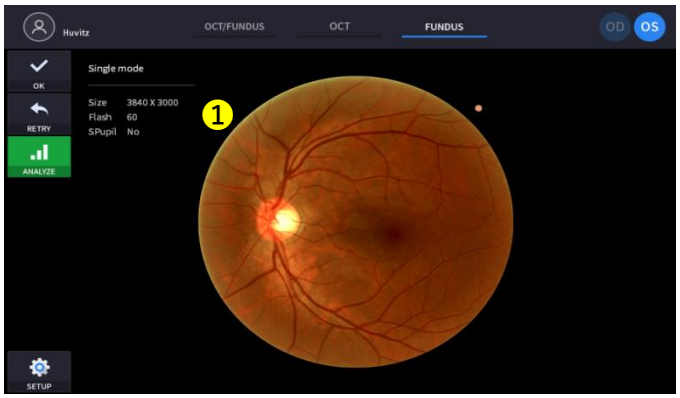
Observation screen



(Refer '4.2.1. OCT/Fundus mode – Observation screen' for uncommented item)

No	Name	Function
1	Capture mode	Select capture mode. - Single: Capture one fundus image. - Panorama: Capture maximum 7 images and stitch it.
2	IR.En	Change brightness of IR fundus image
3	Optimize	Find focus position automatically by split focus image.

Confirmation screen



(Refer '4.2.1. OCT/Fundus mode – Confirmation screen' for uncommented item)

No	Name	Function
1	Fundus information	Display setting information of fundus image.

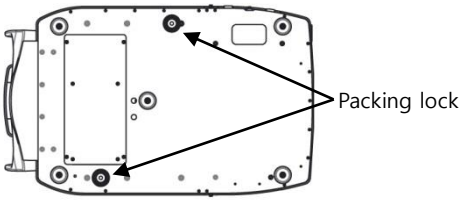
5

5 Installation Procedure

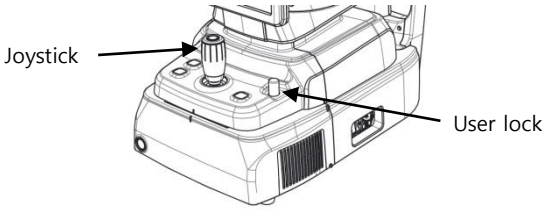
5.1. System installation

① Place the main body unit on a stable table.

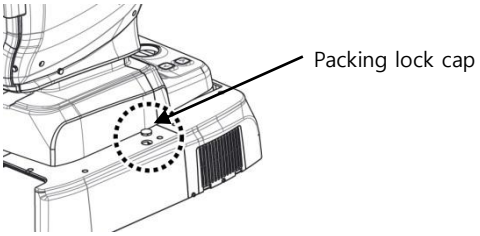
② Loosen the two packing lock screw under the main body.



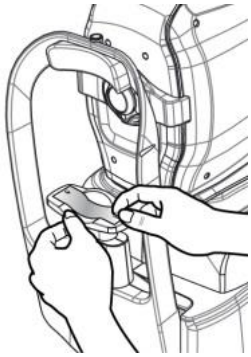
③ Unscrew the user lock lever on the body.



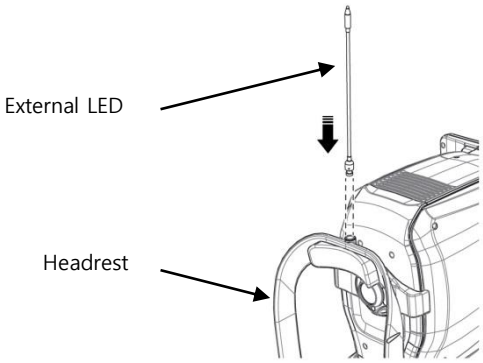
④ Attach two base packing lock cap while moving body left and right with joystick.



⑤ Attach the chinrest paper to the chinrest.

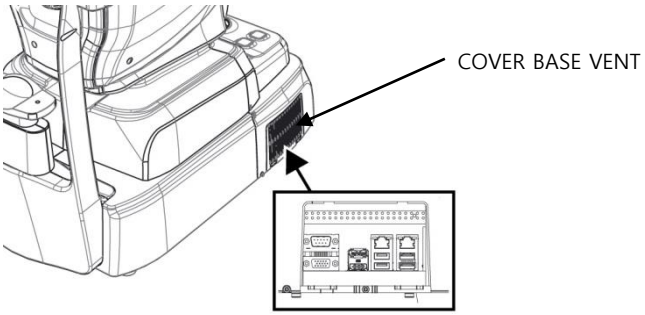


⑥ Attach external LED to the headrest (A).



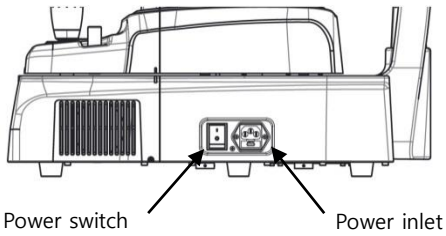
⑦ If needed, connect external devices.

- Open ‘COVER BASE VENT’ on the left bottom of base with screw driver.
- Connect communication cable of external device.
- Close ‘COVER BASE VENT’ with screw driver.

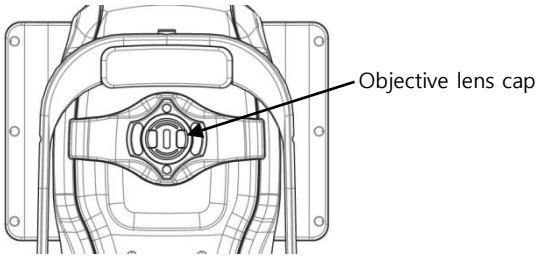


⑧ Check the power switch on the bottom right of base is off. (O position).

⑨ Connect power cable to power inlet. Also, connect the other side of power cable to electric outlet.



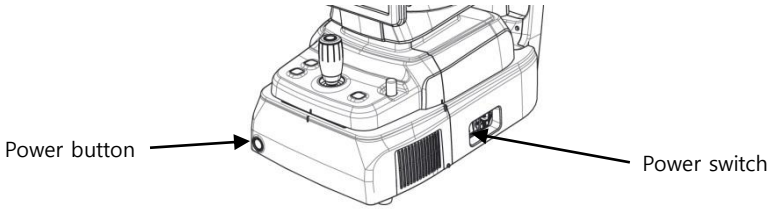
⑩ Remove objective lens cap, and check objective lens is clean,



⑪ If external devices are connected, turn on external devices first.

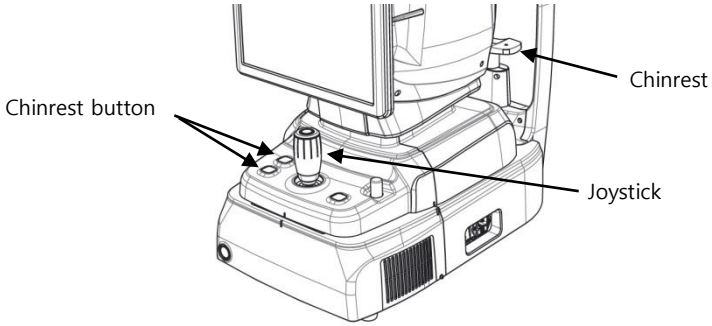
⑫ Turn on the main body by pressing power switch (I position)

⑬ Turn on the internal PC by pressing power button.



⑭ Check there is no error during initialize process.
Wait for until the initialization is complete.

⑮ Check the movement of body with joystick. Also, check the movement of motorized chinrest with chinrest button.

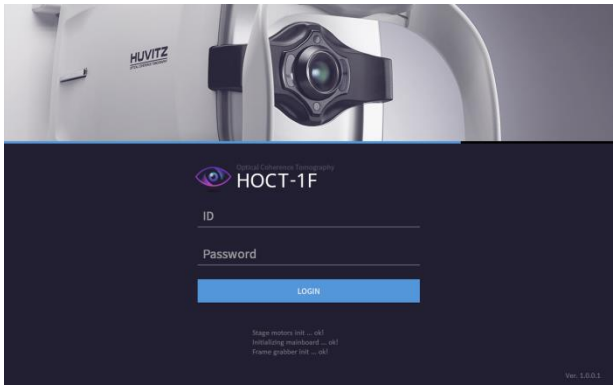


6

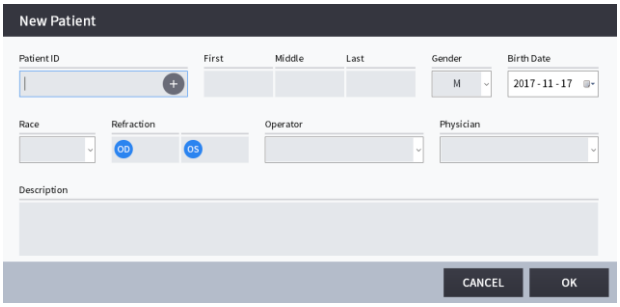
6 Operation

6.1. Software

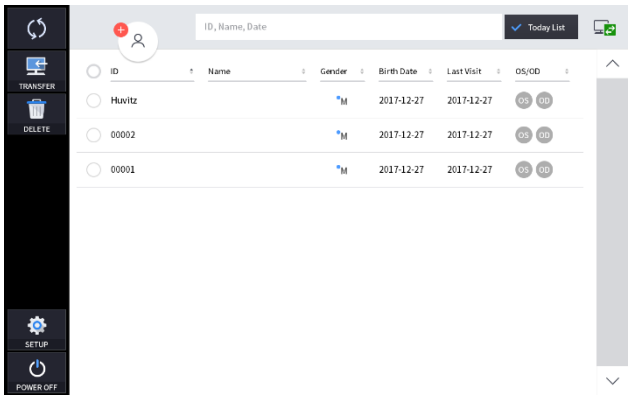
① Input user ID and password for login.



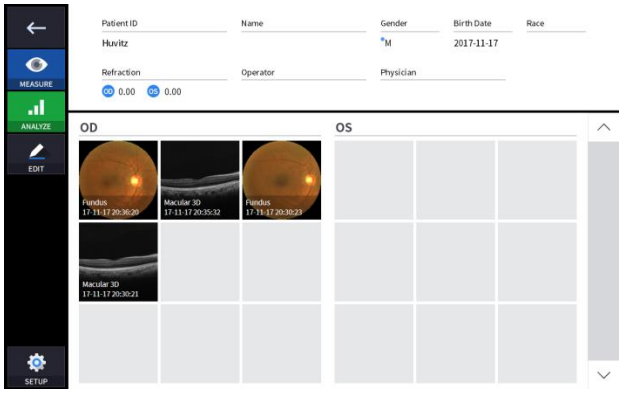
② Press resist patient icon ( ) and input patient information. If patient is resisted already, skip this step.



③ Select patient and check patient information is correct.



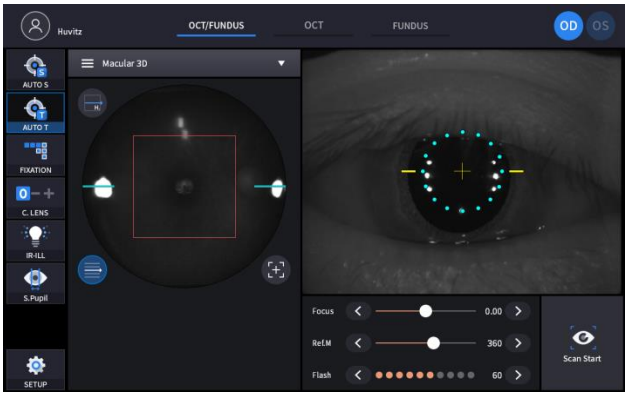
④ When you select a patient, the screen changes.



⑤ Enter observation mode by pressing measure icon (

).

The screen of observation mode is as follow.



6.2. SETUP Mode

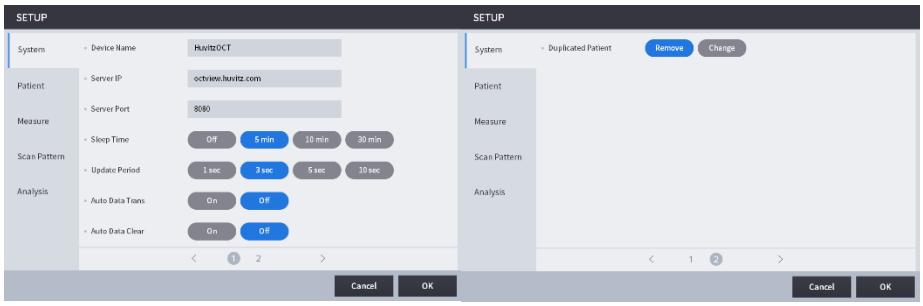
[To choose the section to setup]

- Setup mode consists of five sections: System, Patient, Measure, Scan Pattern, and Analysis. You can select the section to setup from the left side.
- You can navigate the setup items with the page move buttons[< , >] or the page numbers[1 , 2] at the bottom

[To change settings]

- Select the item to change
- To press OK button[OK] will save all the changes made and exit the setup screen
- To press CANCEL button[Cancel] will discard the changes and exit the setup screen

1. System Settings

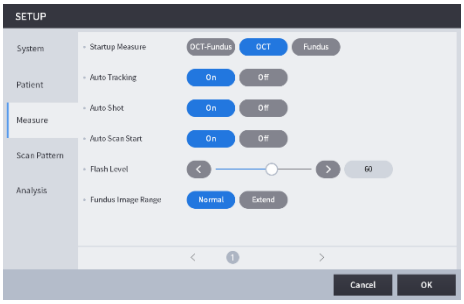


Device Name	Set Device Name
Server IP	Web Viewer Server IP address setting
Sever Port	Web Viewer Server port setting
Sleep Time	Sleep mode setting
Update Period	Web Viewer patient information update period setting
Auto Data Trans	Set the function to transfer the measured data to Web Viewer automatically
Auto Data Clear	Set the function to delete the data transferred to Web viewer from HOCT device automatically
Duplicated Patient	Set processing when ID duplicate patient is created in Web Viewer

2. Patient Settings

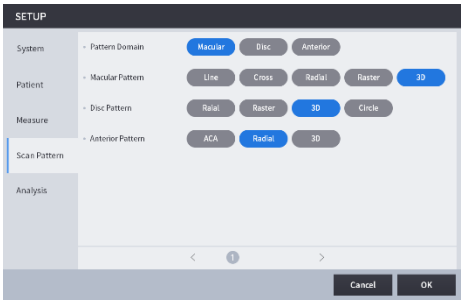
Patient List Size	Number of patients to be displayed per pages
Today List	Today List(List of patients visited today) settings
PID Prefix	The function to set the prefix of the automatically generated patient ID
PID Postfix	The function to set the postfix of the automatically generated patient ID
PID Number Length	The function to set the length of automatically generated patient id
Date Format	Format of the date (Year, Month, Day)

3. Measure Settings



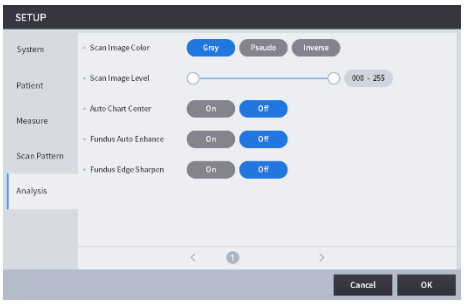
Startup Measure	Set the initial mode of measurement
Auto Tracking	Auto Tracking ON/OFF setting
Auto Shot	Auto Shot ON/OFF setting
Auto Scan Start	Auto Scan Start ON/OFF setting
Flash Level	Adjust the flash level value of the fundus camera
Fundus Image Range	Fundus Image Range setting (Normal : 42.7° Extend :42.75°)

4. Scan Pattern Settings



Pattern Domain	Set the default pattern domain of OCT scan measurement to be either macular, disc, or anterior.
Macular Pattern	Set the default scan pattern of the macular domain
Disc Pattern	Set the default scan pattern of the disc domain
Anterior Pattern	Set the default scan pattern of the anterior

5. Analysis Settings

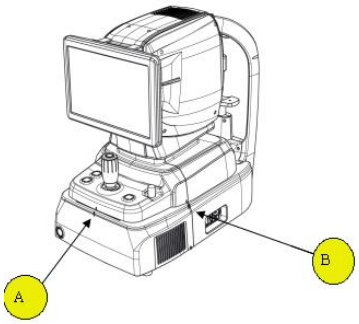


Scan Image Color	Set the default representation mode of Bscan image to be either gray, pseudo color, or inversed gray.
Scan Image Level	Adjust the gray level values of Bscan image
Auto Chart Center	To move the center of the ETDRS or RNFL chart to the detected center of the macular or the disc
Fundus Auto Enhance	Apply the standard values of brightness, contrast, UB, and VR to the measured fundus image automatically
Fundus Edge Sharpen	Apply edge sharpening function to the measured fundus image automatically

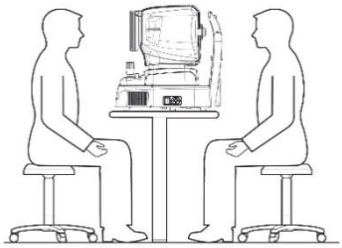
6.3. General Operation

1. Clean headrest and chinrest with a clean cotton swab or gauze. Remove a single sheet of chinrest paper if the chinrest paper is used.

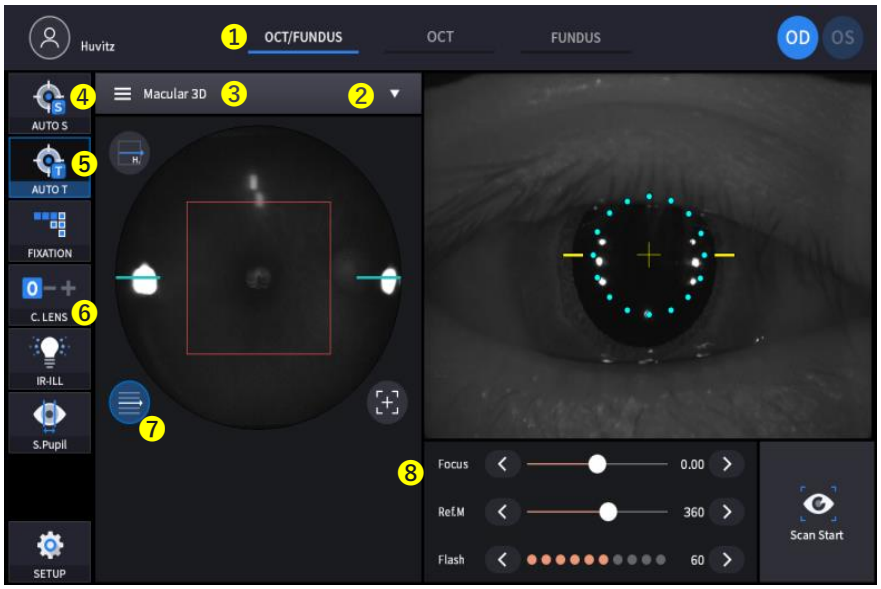
2. Align left/right index mark (B) and front index mark (A) of body and base with joystick.

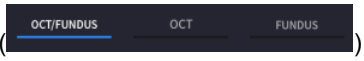


3. Let the patient sit in front of instrument.



4. Set the mode and environment as following.



4-1. Set capture mode with the capture mode tabs(

)

OCT/Fundus (HOCT-1F only)	Capture OCT and fundus image simultaneously.
OCT	Capture OCT image.
Fundus (HOCT-1F only)	Capture Fundus image.

4-2. Set capture region with the capture region combo box(

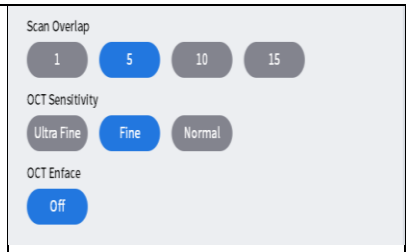
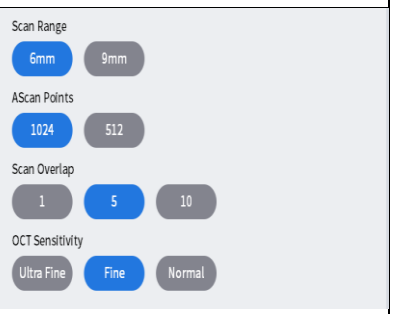
)

OCT/Fundus **OCT**	Macular, Disc, Anterior
Fundus	Single, Panorama

4-3. In OCT or OCT/Fundus mode, set scan type and options for the selected scan region.

Scan region	Scan type	Available option
Macular	Macular Line Scan along a line for macular	
	Macular Cross Scan along horizontal lines and vertical lines for macular	
	Macular Radial Scan along 12 radial lines centered at macular	

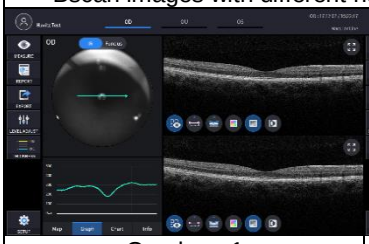
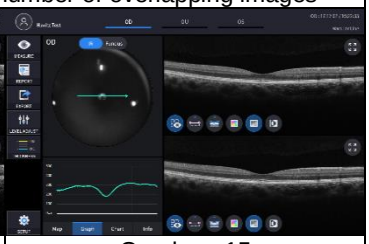
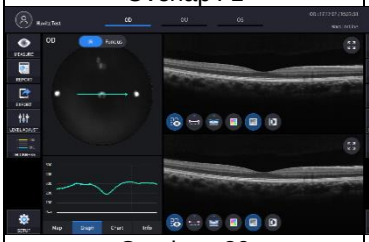
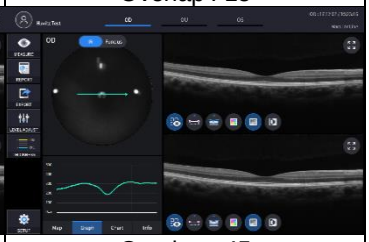
Macular	Macular Raster Scan along 24 lines in the square area centered at macular	
	Macular 3D Scan a rectangular area closely	
Disc	Disc Radial Scan along 12 radial lines centered at disc	
	Disc Raster Scan along 24 lines in the square area centered at disc	
Disc	Disc 3D Scan a rectangular area closely	

	Disc Circle Scan along a circle centered at optic disc	
Anterior	ACA Line Scan along a line for cornea	
	Anterior Radial Scan along 12 lines for cornea	
	Anterior 3D Scan a rectangular area closely	

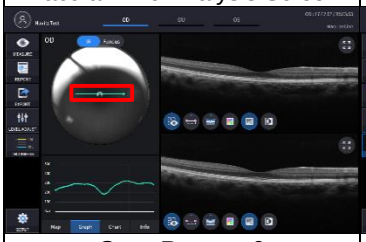
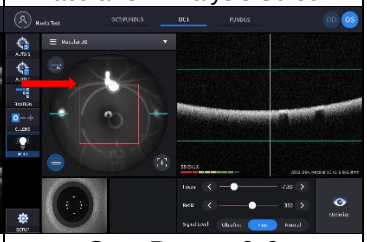
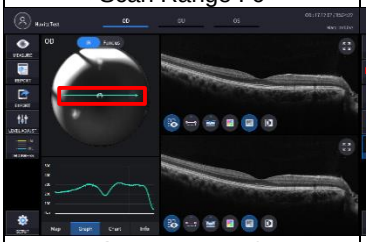
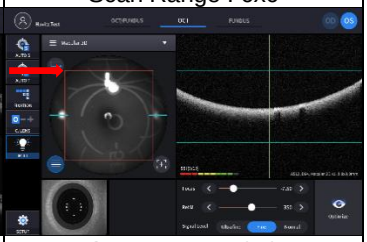
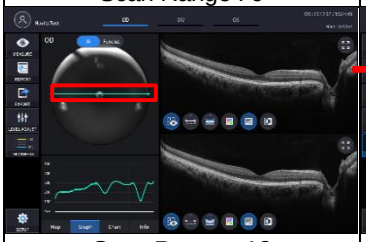
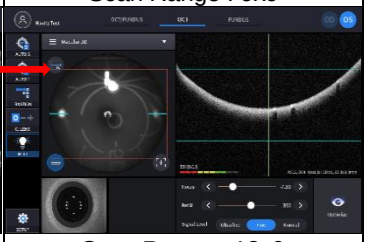
<Scan Options>

- Range: Choose scan range from 6mm, 9mm, or 12mm.
- AScan Points: Choose the number of A-scans that constitute one B-scan. Possible options are 1024, 512, or 256.
- Bscan Lines: Choose the number of B-scans that constitute one measurement. Possible options depend on the number of A-scans set.
- Overlap: Choose the number of B-scans to be averaged to produce one B-scan image. Possible options are enumerated.
- Direction: Set a direction which is horizontal or vertical.
- Space: Set an interval between neighboring scan lines.
- Enface: Set on or off for a live enface image.
- Sensitivity: Choose scan quality from normal, fine, or ultra fine. The latter produce better image but take longer.

- Scan Overlap : Increase image resolution by overlapping multiple Bscan images.

Bscan images with different number of overlapping images	
	
< Overlap : 1 >	< Overlap : 15 >
	
< Overlap : 30 >	< Overlap : 45 >

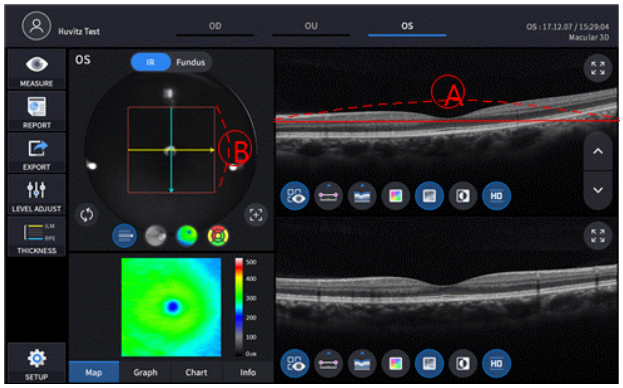
- Scan Range : Select the size of area to be measured

Bscan images of each Scan Ranges	
Macular Line Analysis Screen	Macular 3D Analysis Screen
	
< Scan Range : 6 >	< Scan Range : 6x6 >
	
< Scan Range : 9 >	< Scan Range : 9x9 >
	
< Scan Range : 12 >	< Scan Range : 12x9 >

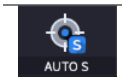
- Ascan, Bscan : Number of horizontal and vertical scan points in the scan area

Ascan : The number of Ascans that constitute one Bscan

Bscan : Total number of Bscans in the scan range



4-4. Set auto shooting mode.

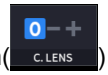
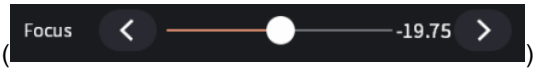
	Auto shooting is on.
	Auto shooting is off.

- If auto shooting mode is on, image is optimized and captured automatically when aligned and focused to the patient's eye properly.
- Auto shooting is not supported for anterior capture mode.

4-5. Set auto tracking mode.

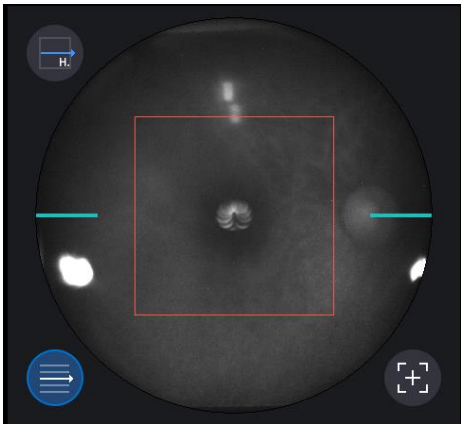
	Auto tracking is on.
	Auto tracking is off.

- If auto tracking is on, patient's eye is automatically tracked to center and focused when patient's eye is inside tracking region.
- Auto tracking is not supported for anterior capture mode.

4-6. Set compensation lens mode on() if the eyesight of patient is out of -13 to 13 diopter. Once the compensation mode is on, you need to fit the focus with the focus slide bar () manually.

0	No compensation lens is used.
-	Minus compensation lens is used.
+	Plus compensation lens is used.

4-7. Check scan range by clicking scan range icon( ) if needed.



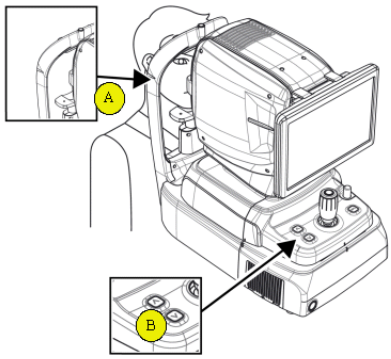
- This icon is not supported in fundus mode.

4-8. Set the diopter of patient by Focus icon

(

) if needed.

5. Align patient's eye to eye level mark on headrest.
   5-1. Let the patient's chin put on the chinrest.
   5-2. Let the patient's forehead adhere to headrest.
   5-3. Move up or down chinrest with the chinrest button (B) on the body to fit the level of patient's eye to the eye level mark (A) on the headrest.

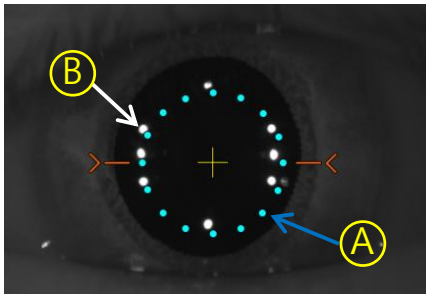


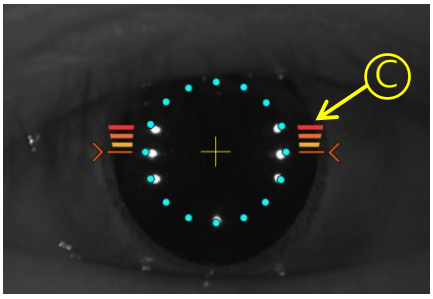
6. Instruct patient to watch internal fixation LED to fix patient eyes. Also, instruct patient to open eye widely, not to blink.

7. Move body with joystick until patient's eye appears on the screen.

8. Set the alignment and focus.

8-1. Move the body up/down and left/right with joystick until ring of 16 blue align dot (A) and ring of 8 white Mire dot (B) are concentric. When two rings are concentric, focus indicator bar (C) appears. Move the body back and forth with joystick until the focus indicator bar disappears.

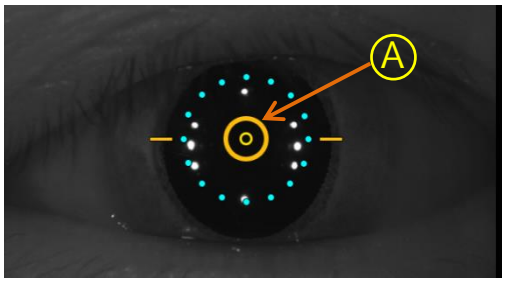




8-2. If the pupil of patient is smaller than 16 blue align dot, press S-pupil icon(

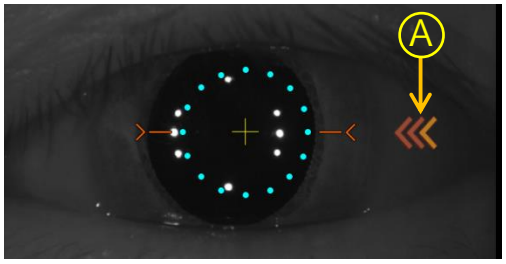
) to capture in small pupil mode

8-3. Move joystick little by little until orange target mark (A) appears.



8-4. If auto tracking is on, alignment and focus is automatically accomplished in tracking region.

8-5. If orange arrow (A) appears during auto tracking, it means auto tracking module go to the limit of tracking region. In that case, move body to the arrowed direction with joystick.



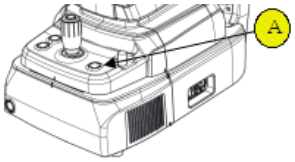
9. Capture image and check image quality (in OCT/Fundus mode)

9-1. When alignment and focus is done, press scan start icon (

) to start OCT scan.
If alignment and focus is in good condition, scan start function is accomplished automatically, and scan start icon changes to optimize icon (

)

9-2. Optimize OCT signal by pressing optimize icon on the screen or optimize button on the body (A).

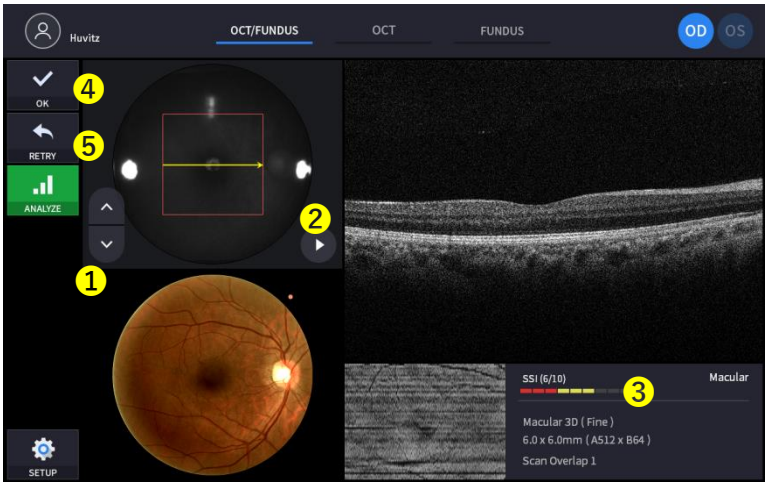


9-3. Adjust the vertical position of retina image in the screen by moving reference mirror using slide bar. (

)

9-4. Press the button on joystick to capture image.
If auto shooting is on, '9-2. Optimize' and '9.4 Capture' is accomplished automatically.

9-5. Check the result and decide to store or discard and retry.

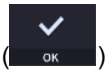


① Check previous/next OCT image by pressing move scan position button (
).

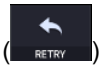
② Check continuous OCT image continuously by pressing play image button (
).

③ Check SSI for image quality.
SSI(Scan Signal Index) indicates level of image quality. SSI means signal to background ratio and displayed on a scale of 10 with a bar graph. SSI larger than 8 means 'Good', 5~8 means 'Normal', less than 5 means 'Poor' in general.
We recommend capture normal or good status in general. When image looks

satisfactory though the SSI is low, you can ignore SSI and save the result.

④ If the image is satisfactory, press OK icon (

) to save image.

⑤ If the image is not satisfactory, press retry icon (

) and retry image capturing.

A. If fundus image result too bright or too dark because of lighting, regulate the flash intensity using flash icon(

) in observation mode.

B. If fundus image is too dark because of small pupil size of patient, try small pupil mode by using small pupil icon (

) in observation mode.

C. Try moving internal fixation target position by pressing fixation icon (

) and changing position of green cross (
) if needed.
When green cross position changes, the position of internal fixation target is also changed.

D. Try to change scan position by dragging scan range while scan range icon turned on. If reset scan position icon(
) is pressed, scan position moves to the default center position.

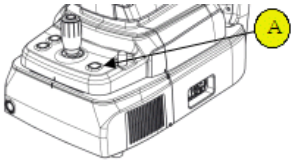
10. Capture image and check image quality (in OCT mode)

10-1. When alignment and focus is done, press scan start icon (

) to start OCT scan.
If alignment and focus is in good condition, scan start function is accomplished automatically, and scan start icon changes to optimize icon(

)

10-2. Optimize OCT signal by pressing optimize icon on the screen or optimize button on the body (A).

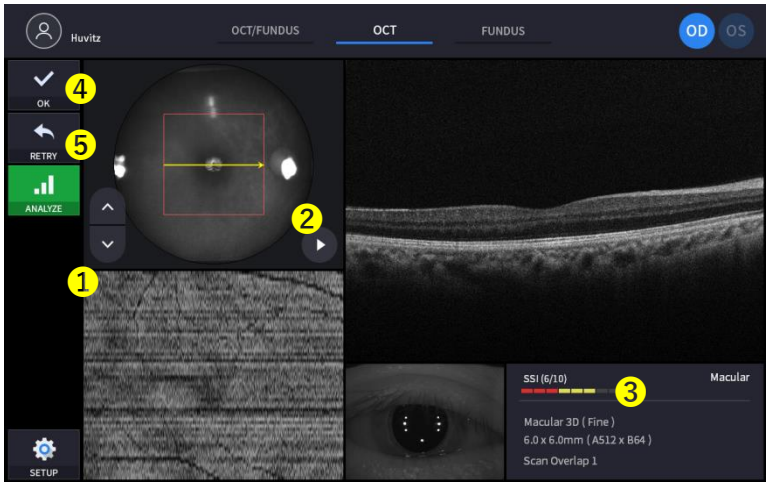


10-3. Adjust the vertical position of retina image in the screen by moving reference mirror using slide bar. (

).

10-4. Press the button on joystick to capture image.
If auto shooting is on, '10-2. Optimize' and '10.4 Capture' is accomplished automatically.

10-5. Check the result and decide to store or discard and retry.



① Check previous/next OCT image by pressing move scan position button ( ) if needed.

② Check continuous OCT image continuously by pressing play image button ( ) if needed.

③ Check SSI for image quality if needed.
SSI(Scan Signal Index) indicates level of image quality. SSI means signal to background ratio and displayed on a scale of 10 with a bar graph. SSI larger than 8 means 'Good', 5~8 means 'Normal', less than 5 means 'Poor' in general.
We recommend capture normal or good status in general. But, you don't have to retry when image is satisfactory but SSI is low, because SSI depends on patient's eye conditions.

④ If the image is satisfactory, press OK icon ( ) to save image.

⑤ If the image is not satisfactory, press retry icon ( ) and retry image capturing.

A. Try moving internal fixation target position by pressing fixation icon ( ) and changing position of green cross ( ) if needed.
When green cross position changes, the position of internal fixation target is also changed.

B. Try to change scan position by dragging scan range while scan range icon turned on. If reset scan position icon( ) is pressed, scan position moves to the default center position.

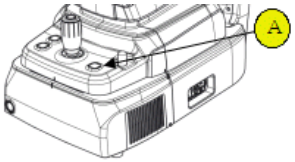
11. Capture image and check image quality (in Fundus mode)

11-1. Change the brightness of IR monochrome screen by pressing IR.En icon

(

) if needed.

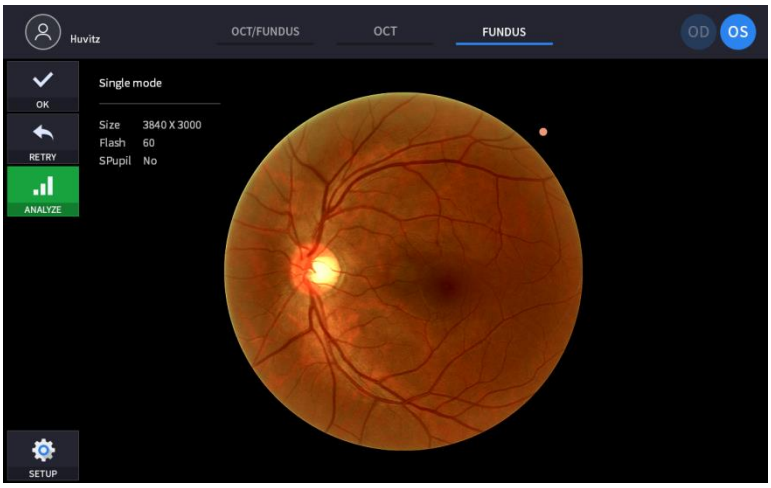
11-2. Change focus position by pressing optimize icon on the screen or optimize button on the body (A).

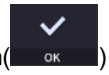


11-3. Press the button on joystick to capture image.

If auto shooting is on, '11-2. Optimize' and '11.3 Capture' is accomplished automatically.

11-4. Check the result and decide to store or discard and retry.



If the image is satisfactory, press OK icon(

) to save image.

① If the image is not satisfactory, press retry icon (

) and retry image capturing.

A. If fundus image result too bright or too dark because of lighting, regulate the flash intensity using flash icon(

) in observation mode.

B. If fundus image is too dark because of small pupil size of patient, try small pupil mode by using small pupil icon (

) in observation mode.

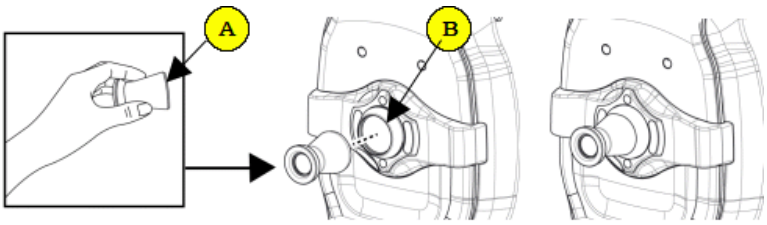
C. Try moving internal fixation target position by pressing fixation icon (

) and changing position of green cross ( ) if needed.
When green cross position changes, the position of internal fixation target is also changed.

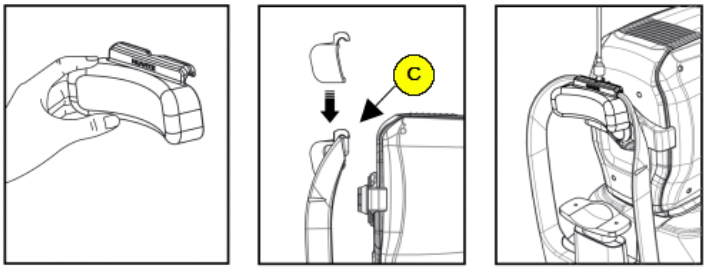
6.4. Anterior segment image operation (optional)

6.4.1. Preparation for anterior segment operation

1. Check the lens surface of anterior segment adapter is clean.
2. Thread anterior segment adapter (A) to objective lens holder (B), and check there is no tilting or misalignment of adopter. Don't lock it too hard.



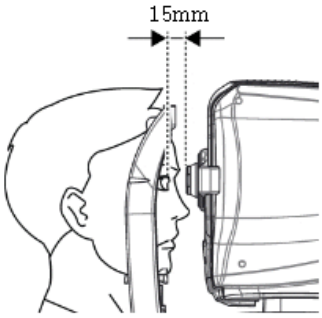
3. Check anterior headrest rubber is clean.
4. Hang anterior headrest rubber to headrest of instrument (C) first, then press anterior headrest rubber to be fixed firmly.
5. Check the mounted anterior headrest rubber does not incline.



6.4.2. Capturing anterior segment

1. The first procedure is same as '6.1 General Operation: procedure 2 ~ 7'.
   - On the anterior mode, function of auto shooting and auto tracking is not available.

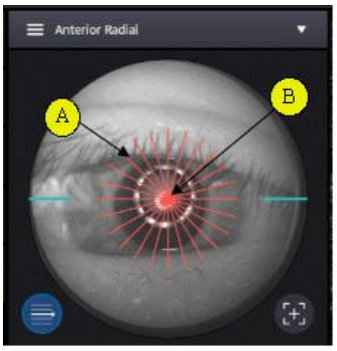
2. Move the body to align patient's eye. Move the body slowly while watching patient's eye and body, because working distance is just 15mm that the front lens is very close to patient's eye.



3. Capture image and check image quality (in anterior radial or anterior 3D mode)

   3-1. Alignment and focus

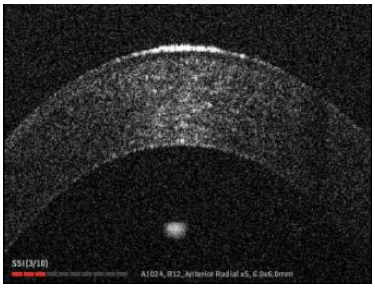
   ① Move body with joystick slowly to align anterior scan line (A) and center of patient's eye (B)



   ② Start OCT scan by pressing scan start icon (

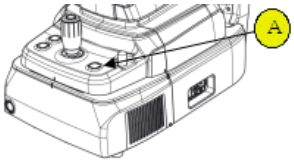
).

   ③ Move body with joystick slowly until section of cornea appears on the screen.



   3-2. Measuring curvature of cornea

   ① Optimize OCT signal by pressing optimize icon on the screen (
) or optimize button on the body (A).



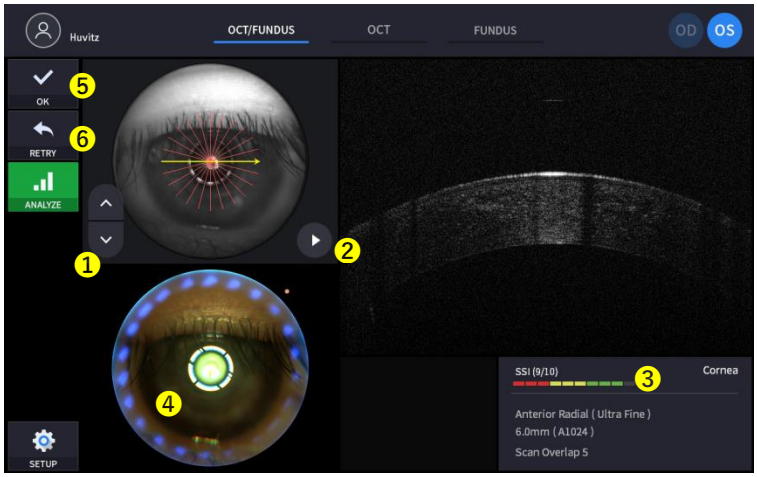
② For enhancing OCT signal, move position of reference mirror by pressing arrow of REF.M icon (

) if needed.

-This function available on OCT/Fundus mode.

③ Press the button on joystick to capture image.

3-3. Check image quality



① Check previous/next OCT image by pressing move scan position button ( ) if needed.

② Check continuous OCT image continuously by pressing play image button ( ) if needed.

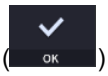
③ Check SSI for image quality if needed.

SSI(Scan Signal Index) indicates level of image quality. SSI means signal to background ratio and displayed on a scale of 10 with a bar graph. SSI larger than 8 means ‘Good’, 5~8 means ‘Normal’, less than 5 means ‘Poor’ in general.

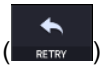
We recommend capture normal or good status in general. But, you don’t have to retry when image is satisfactory but SSI is low, because SSI depends on patient’s eye conditions.

④ Check image quality

-This function available on OCT/Fundus mode.

⑤ If the image is satisfactory, press OK icon (

) to save image.

⑥ If the image is not satisfactory, press retry icon (

) and retry image capturing.

A. If fundus image result too bright or too dark because of lighting, regulate the flash intensity using flash icon(

) in observation mode.

B. Try moving internal fixation target position by pressing fixation icon (

) and changing position of green cross (
) if needed.
When green cross position changes, the position of internal fixation target is also changed.

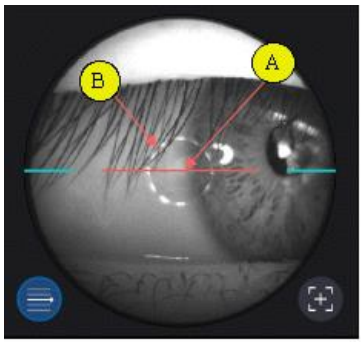
C. Try to change scan position by dragging scan range while scan range icon turned on. If reset scan position icon(
) is pressed, scan position moves to the default center position.

4. Capture anterior chamber angle image and check image quality (in ACA line mode)

4-1. Alignment and focus

① Guide patient to gaze left-hand side or right-hand side according to the interested part.

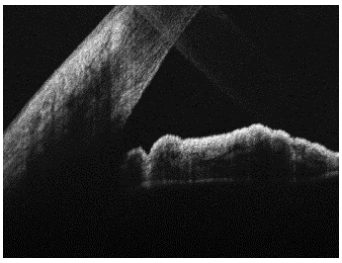
② Move body with joystick slowly to align anterior scan line (A) and objective area of capturing (B).



③ Start OCT scan by pressing scan start icon (

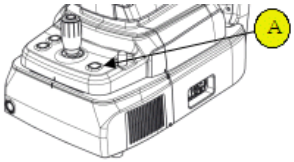
).

④ Move body with joystick slowly until anterior chamber appears on the screen.



4-2. Measuring anterior chamber angle

① Optimize OCT signal by pressing optimize icon on the screen (
) or optimize button on the body (A).



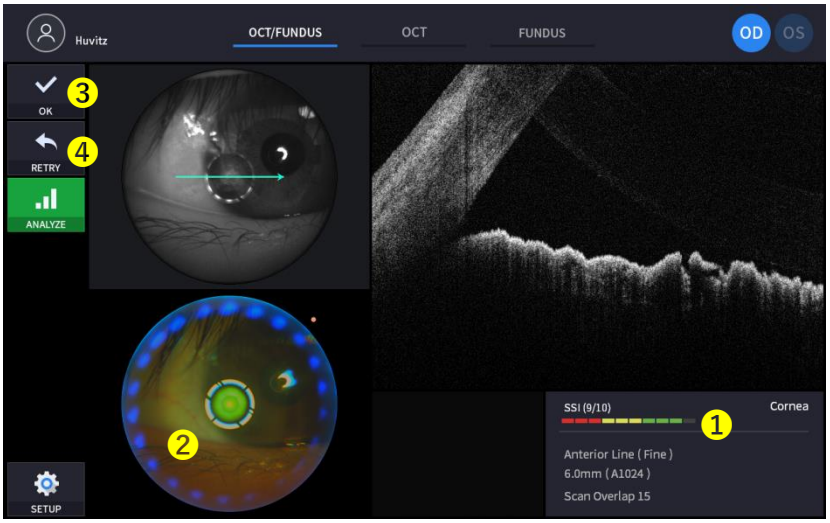
② For enhancing OCT signal, move position of reference mirror by pressing arrow of REF.M icon (

) if needed.

-This function available on OCT/Fundus mode.

③ Press the button on joystick to capture image.

4-3. Check image quality



① Check SSI for image quality if needed.

SSI(Scan Signal Index) indicates level of image quality. SSI means signal to background ratio and displayed on a scale of 10 with a bar graph. SSI larger than 8 means 'Good', 5~8 means 'Normal', less than 5 means 'Poor' in general.

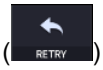
We recommend capture normal or good status in general. But, you don't have to retry when image is satisfactory but SSI is low, because SSI depends on patient's eye conditions.

② Check image quality.

-This function available on OCT/Fundus mode.

③ If the image is satisfactory, press OK icon (

) to save image.

④ If the image is not satisfactory, press retry icon (

) and retry image capturing.

A. If fundus image result too bright or too dark because of lighting, regulate the flash intensity using flash icon(

) in observation mode.

B. If fundus image is too dark because of small pupil size of patient, try small pupil mode by using small pupil icon (

) in observation mode.

C. Try moving internal fixation target position by pressing fixation icon (

) and changing position of green cross ( ) if needed.
When green cross position changes, the position of internal fixation target is also changed.

D. Try to change scan position by dragging scan range while scan range icon turned on. If reset scan position icon( ) is pressed, scan position moves to the default center position.

5. Repeat procedure for the other eye if needed.
6. When capturing anterior segment is done, remove anterior segment adapter and anterior headrest rubber. Store in a designated case to prevent loss and scratch.

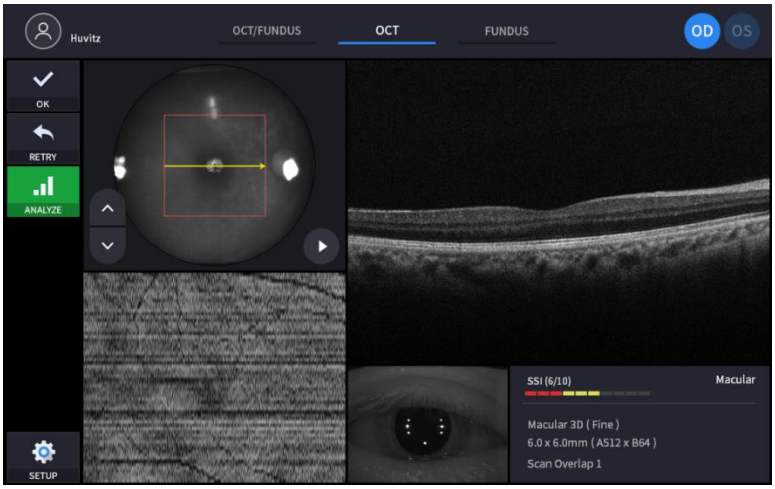
6.5. Analyze

6.5.1. Entering Analysis screen

1. Analysis immediately after scanning

To enter analyze mode from measurement confirm screen, press the analyze icon (

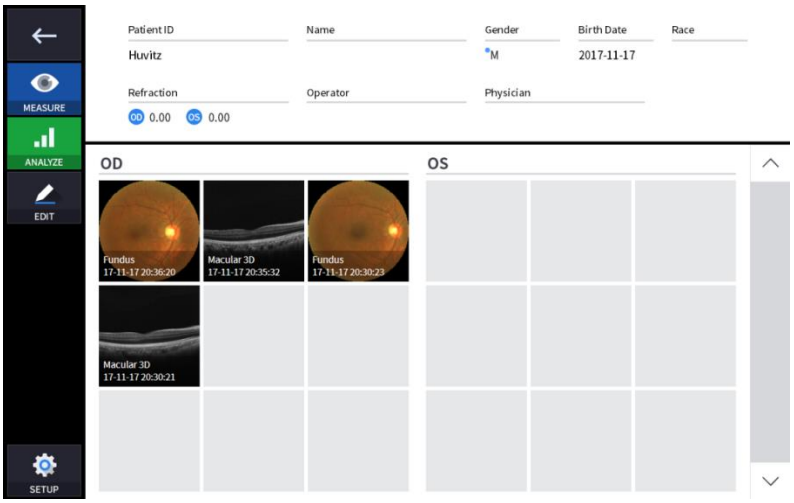
) from the captured image screen.



2. Analysis from measurement list

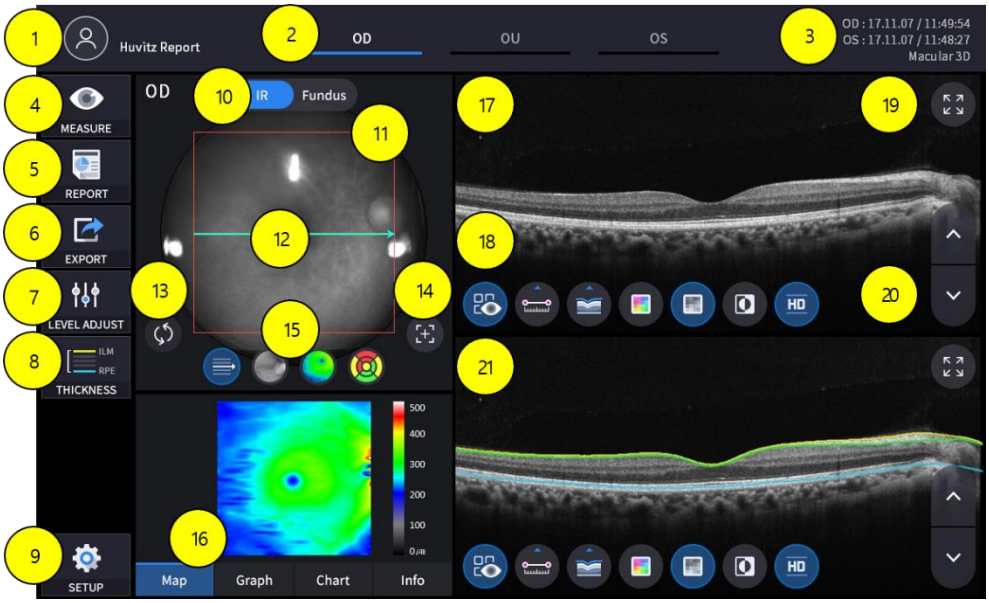
Select a measurement to analyze by clicking and press the analyze button(

), or simply double click on a measurement.



6.5.2. OCT Macular 3D Analysis screen

1. Composition of screen



No	Name	Function
1	Patient information	Shows the information of patient ID and name. Go back to patient list by clicking the icon
2	OD / OU / OS	Indicates which side of eye is showing. You can move to the measurement of the other side or the both sides by selecting unhighlighted tabs - OD: right eye, OS: left eye , OU: both eyes
3	Date	Displays the date the measurement was taken
4	MEASURE	Moves to capture screen after finishing analysis
5	REPORT	Moves to report screen of the current measurement
6	EXPORT	Capture current screen and store it
7	LEVEL ADJUST	Adjust contrast of Bscan
8	THICKNESS	Select the analysis range between ILM <-> GCL / ILM <-> RPE
9	SETUP	Moves to User setting screen
10	IR / Fundus	Select between IR Fundus/Color Fundus if color fundus result is available
11	Scan range	The range on retina the current OCT measurement scanned
12	Scan position	Indicates the position of the displayed Bscan on retina
13	Pattern Center	Moves ETDRS Chart center to the center of pattern domain
14	Auto Position	Moves ETDRS Chart center to the Macular position
15	Overlay Control	Displays Scan direction and position, Enface, Thickness Map, ETDRS Chart range on IR Fundus / Color Fundus

16	Analyze Control	Shows Thickness Map, Graph, ETDRS Chart, Info
17	Bscan-1	Bscan screen
18	Bscan Tool	Tools for Bscan analysis
19	Full Screen	Switch Bscan image to a Full screen
20	Move scan position	Move to the previous or the next Bscan image
21	Bscan–2	Another Bscan screen to display position different from Bscan-1

1-2. Select analyze mode choosing OD / OU / OS icon (

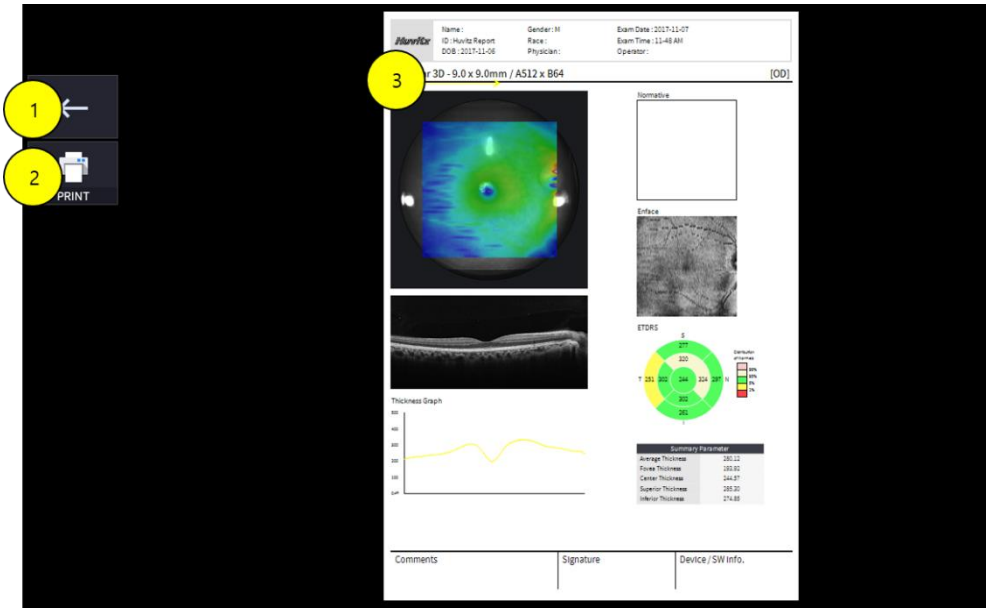
)

OD	Right eye Analysis
OU	Both eyes Analysis
OS	Left eye Analysis

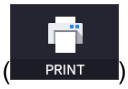
When selecting OU(

) among OD / OU / OS, screen changes to OU analysis screen shown below.

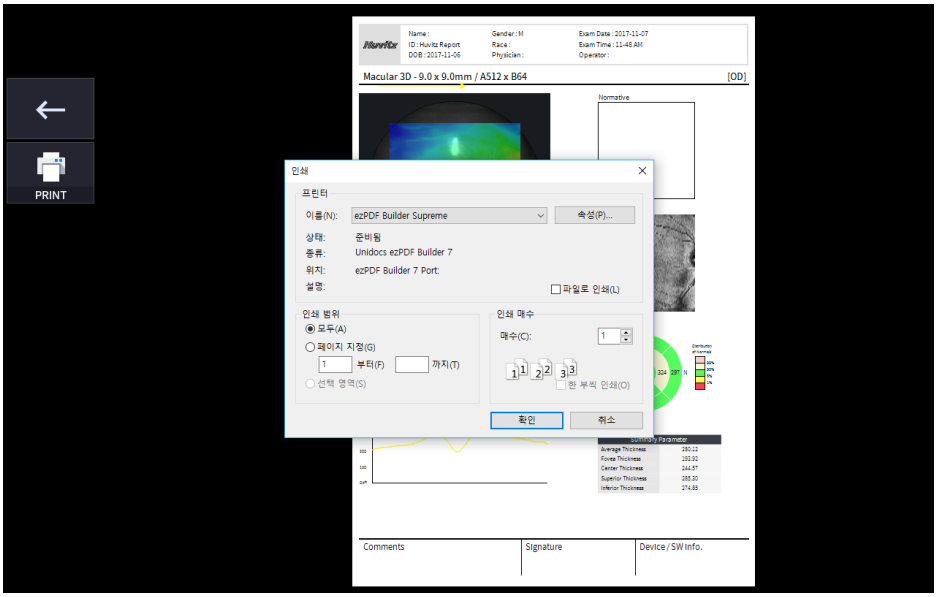
1-5.1. Select REPORT icon (REPORT) shows REPORT screen shown below

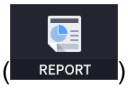


No	Name	Function
1	Previous screen	Go back to analysis screen
2	PRINT	Save the current report showing as PDF file or print to a connected printer
3	Report Preview	Preview of generated report

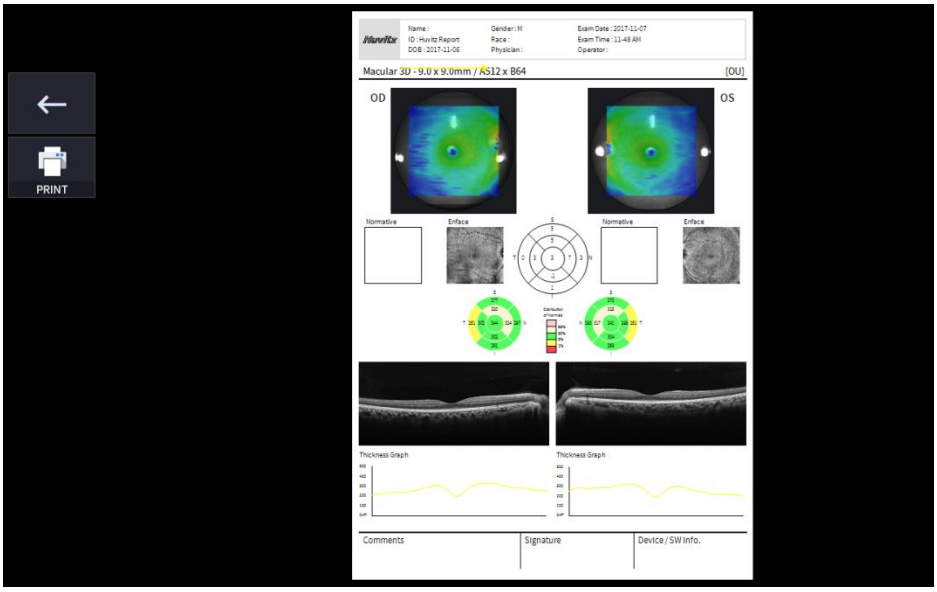
1-5.2. Selecting PRINT icon (

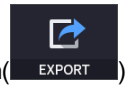
) shows printer option window



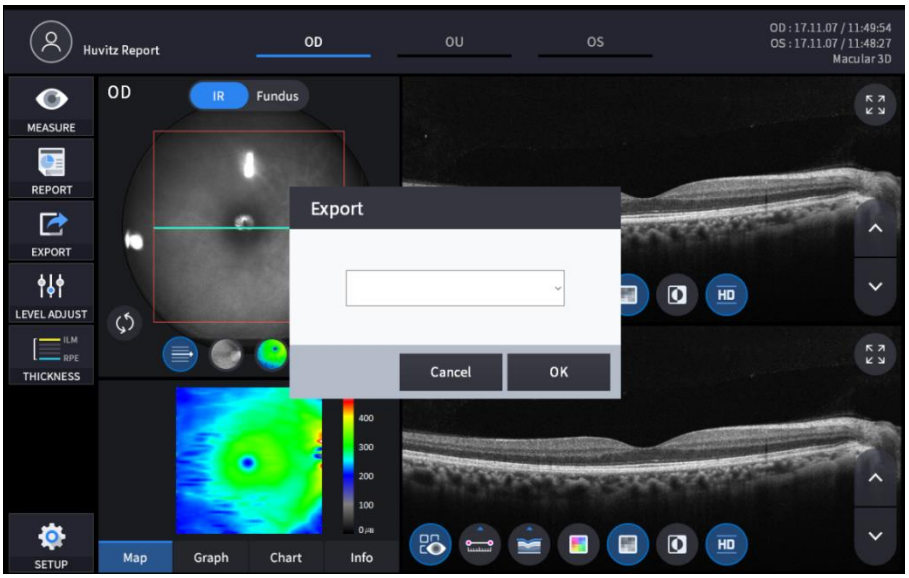
1-5.3. Select REPORT icon (

) at OU screen to change to REPORT screen



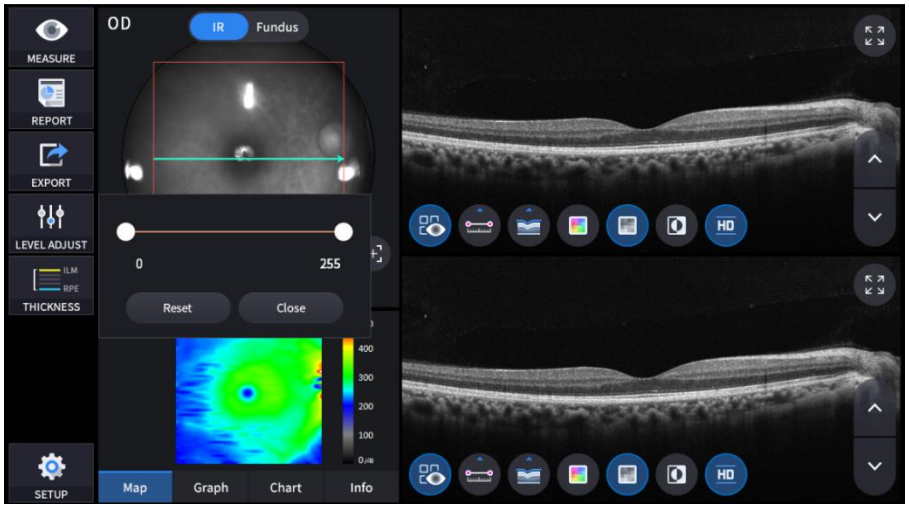
1-6. Selecting EXPORT icon(

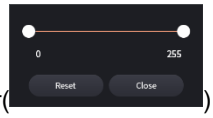
) shows a pop-up window shown below and the current screen shot is captured and stored in user-selected folder.



1-7. Selecting LEVEL ADJUST icon(

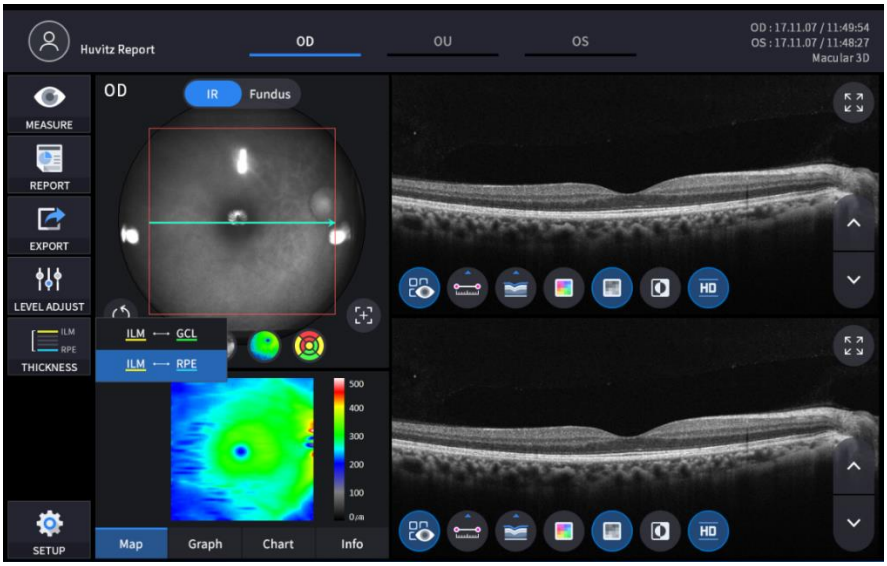
) shows an adjustable pop-up window shown below.



- Use Slide Bar(

) to control Bscan Contrast

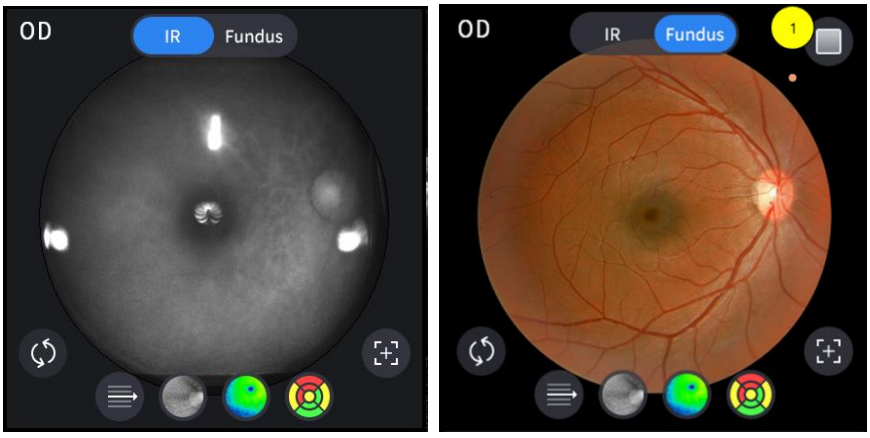
1-8. Selecting THICKNESS icon (ILM RPE THICKNESS) shows a pop-up window shown below



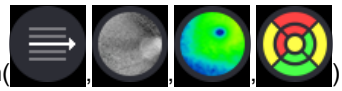
ILM <-> GCL	Set Analysis criteria to ILM ~ GCL
ILM <-> RPE	Set Analysis criteria to ILM ~ RPE

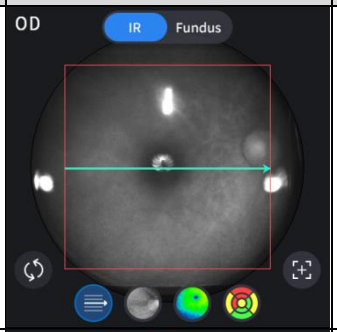
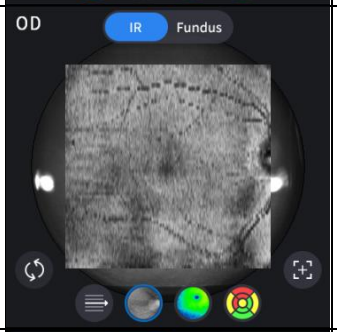
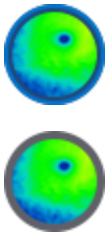
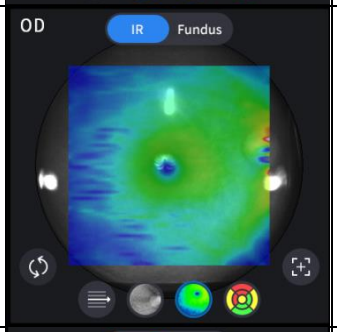
- Analysis results will be displayed according to each setting value

1-10. Fundus image can be chosen from monochromatic IR fundus image or color fundus image. (IR , Fundus)

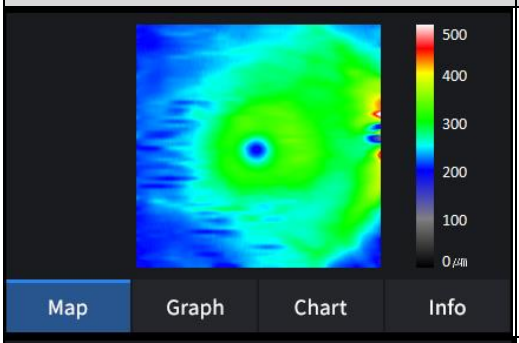
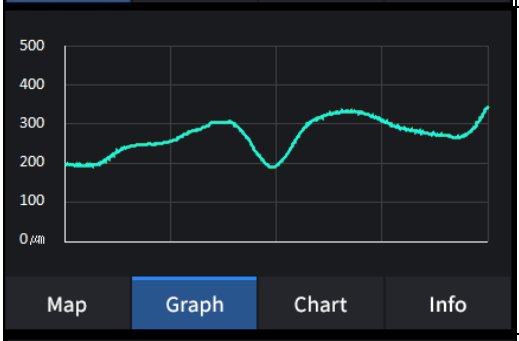
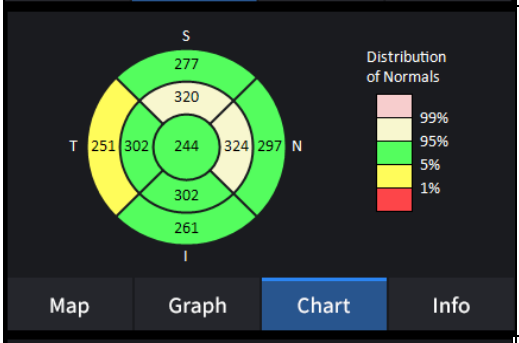
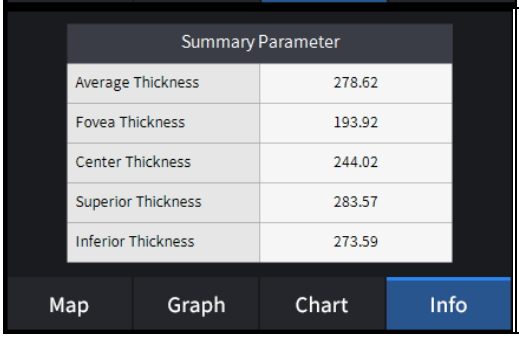


No	Name	Function
1	Red Free	Shows Red Free image from Color Fundus

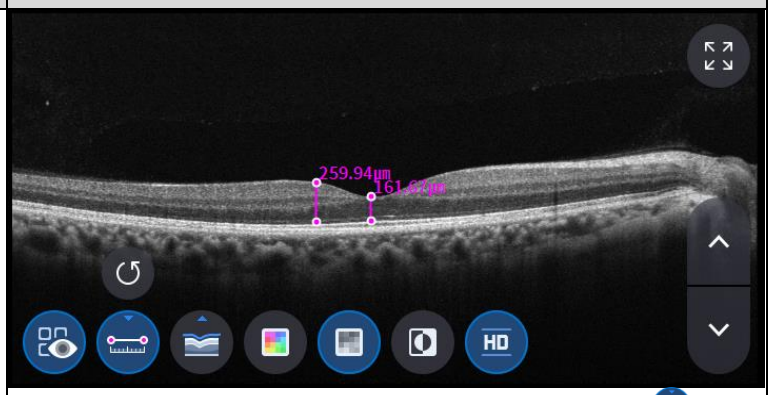
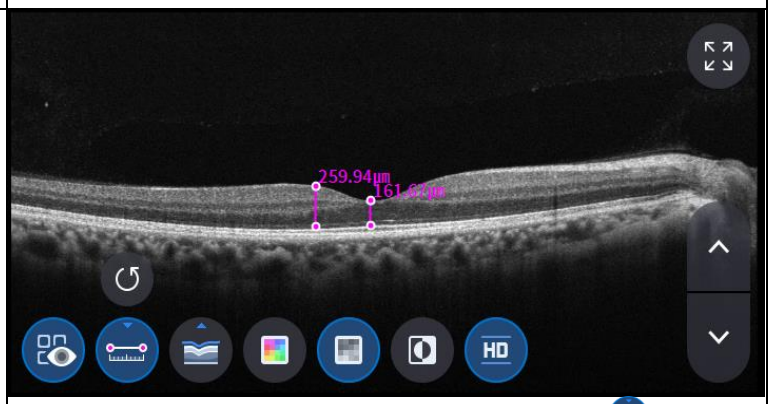
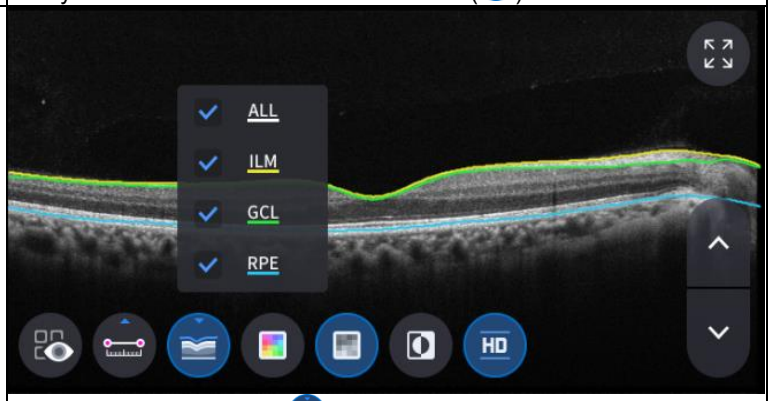
1-15. Select Overlay Control icon() to make the analysis result overlayed on Macular image

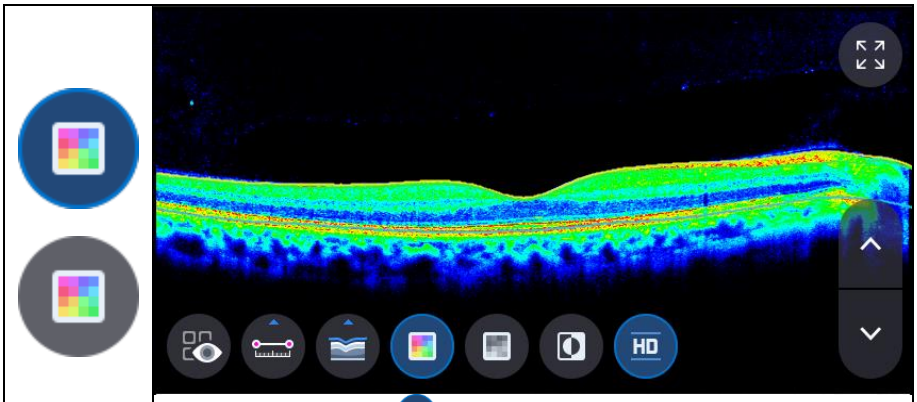
Icon ON / OFF	ON screen	Function
		- Displays Scan Domain - Displays Scan Direction
		- Displays enface image
		- Displays thickness map image
		- Displays ETDRS Chart

1-16. Select analysis tool icon(Map , Graph , Chart , Info) to show the analysis result

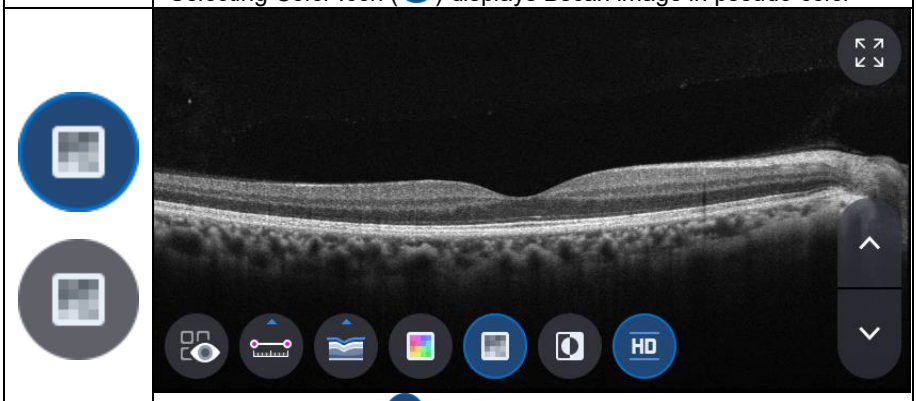
Analyze Screen	Function
	- Displays thickness map in pseudo color.
	- Displays thickness based on the previously set Thickness Layer (ILM <-> RPE / ILM <-> GCL)
	- Displays ETDRS Chart
	Displays following measured values - Average Thickness - Fovea Thickness - Center Thickness - Superior Thickness - Inferior Thickness

1-18. Select Bscan analysis tool(, , , , , , ,) on Bscan image to analyze the Bscan currently displayed.

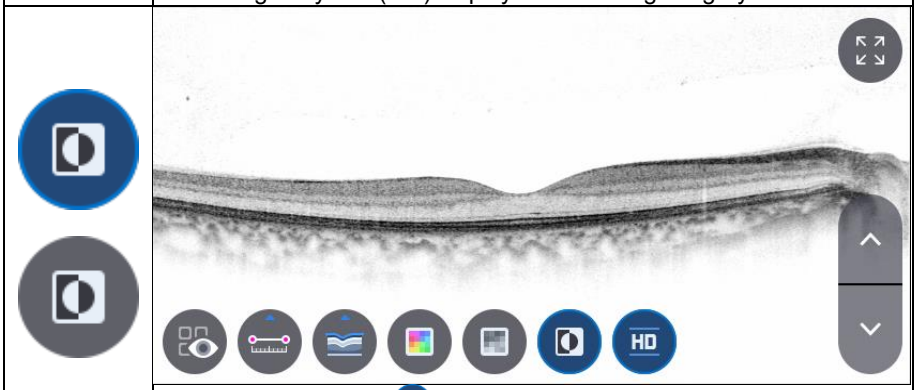
Icon ON / OFF	Screen and Function
	 - ON : Shows the length measured using measurement icon( ) - OFF: Hides the measurements
	 - Selecting two points with the length measurement icon( ) ON on Bscan screen shows the length between the two points - Latest data can be deleted by selecting Undo Icon( ) - Only usable with measurement result Icon( ) ON
	 - Click Segmentation icon( )to show Bscan Layer. ALL, ILM, GCL, RPE are selective



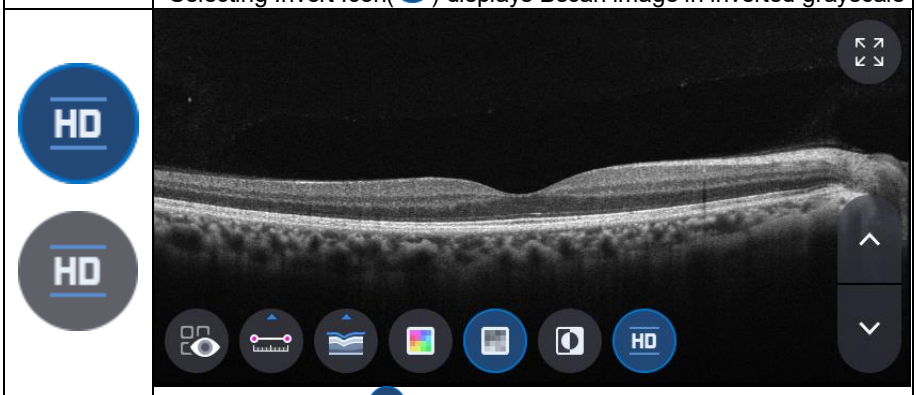
- Selecting Color Icon ( ) displays Bscan image in pseudo color



- Selecting Gray Icon( ) displays Bscan image in grayscale

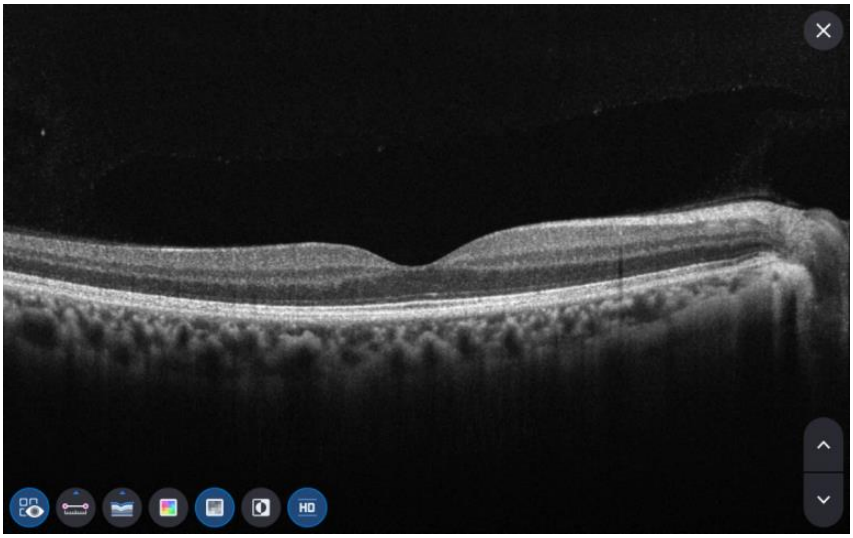


- Selecting Invert Icon( ) displays Bscan image in inverted grayscale



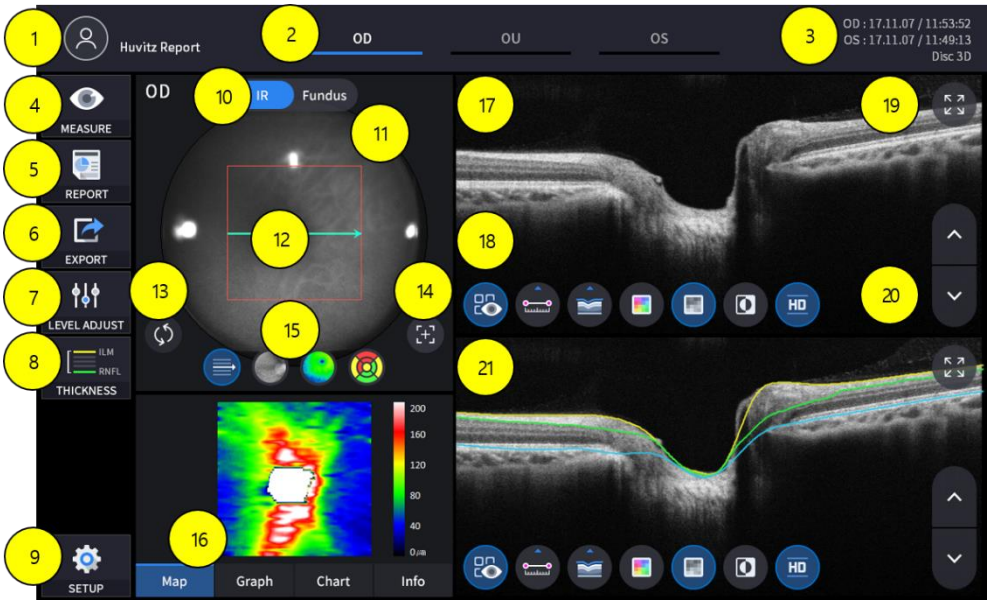
- Selecting HD Icon( ) indicates HD quality Bscan image

1-19. Selecting FULL Screen Icon( ) shows the current Bscan image in full screen



6.5.3. OCT Disc 3D Analysis screen

1. Composition of screen



No	Name	Function
1	Patient information	Shows the information of patient ID and name. Go back to patient list by clicking the icon
2	OD / OU / OS	Indicates which side of eye is showing You can move to the measurement of the other side or the both sides by selecting unhighlighted tabs - OD: right eye, OS: left eye , OU: both eyes
3	Date	Displays the date the measurement was taken
4	MEASURE	Moves to capture screen after finishing Analysis
5	REPORT	Moves to report screen of the current measurement
6	EXPORT	Capture current screen and store it
7	LEVEL ADJUST	Adjust contrast of Bscan
8	THICKNESS	Select the analysis range between ILM <-> RNFL / ILM <-> RPE
9	SETUP	Moves to User setting screen
10	IR / Fundus	Select between IR Fundus/Color Fundus if color fundus result is available
11	Scan range	The range on retina the current OCT measurement scanned
12	Scan position	Indicates the position of the displayed Bscan on retina
13	Pattern Center	Moves RNFL Chart center to the center of pattern domain
14	Auto Position	Moves RNFL Chart center to the Disc position
15	Overlay Control	Displays Scan direction and position, Enface, Thickness Map, RNFL Chart range on IR Fundus / Color Fundus

16	Analyze Control	Shows Thickness Map, TSNIT Graph, RNFL Chart, Info
17	Bscan-1	Bscan screen
18	Bscan Tool	Tools for Bscan analysis
19	Full Screen	Switch Bscan image to a Full screen
20	Move scan position	Move to the previous or the next Bscan image
21	Bscan–2	Another Bscan screen to display position different from Bscan-1

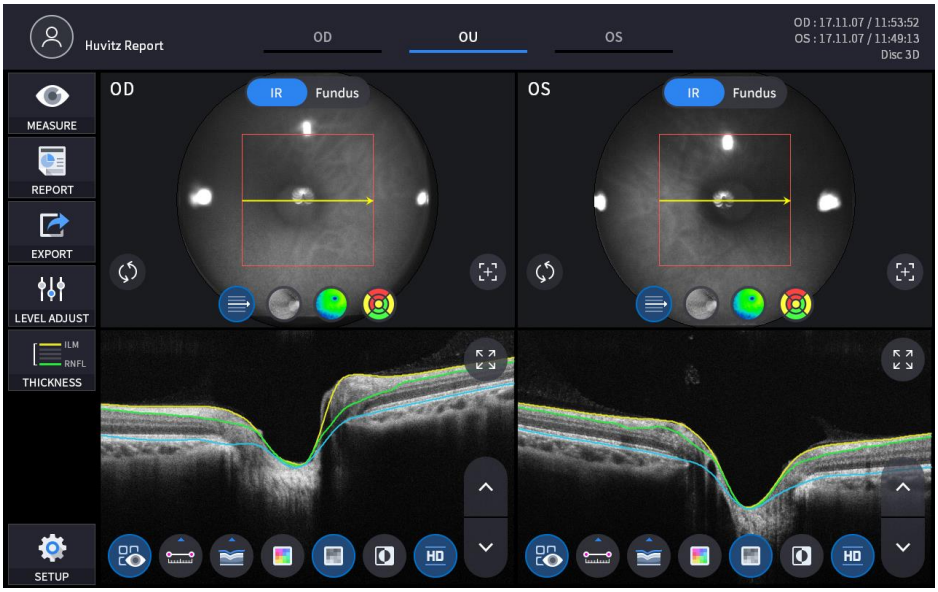
1-2 Select analyze mode choosing OD / OU / OS icon (

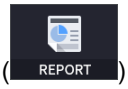
)

OD	Right eye Analysis
OU	Both eyes Analysis
OS	Left eye Analysis

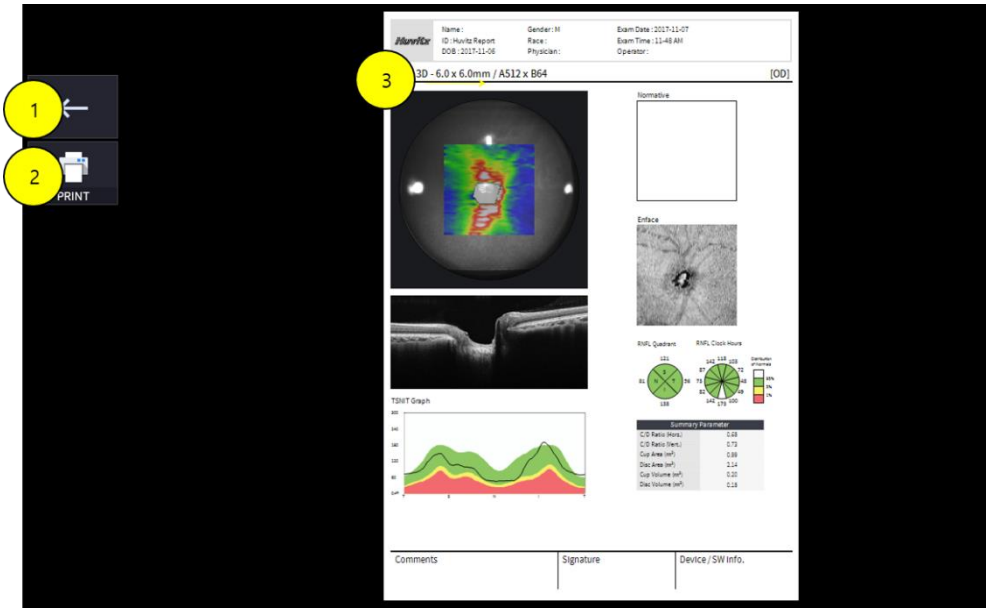
When selecting OU(

) among OD / OU / OS, screen changes to OU analysis screen shown below.

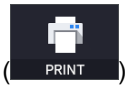


1-5.1. Select REPORT icon (

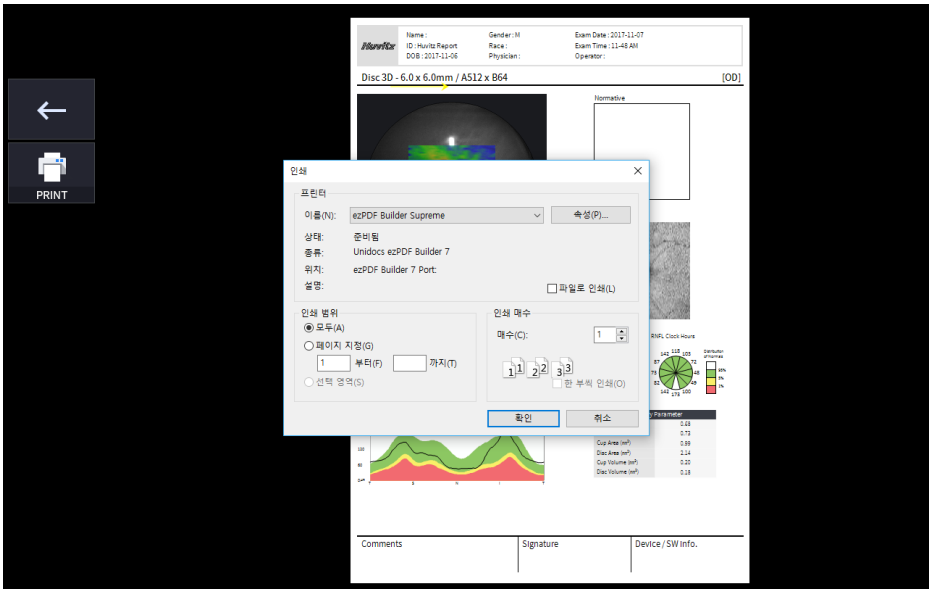
) shows REPORT screen shown below

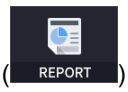


No	Name	Function
1	Previous screen	Go back to analysis screen
2	PRINT	Save the current report showing as PDF file or print to a connected printer
3	Report Preview	Preview of generated report

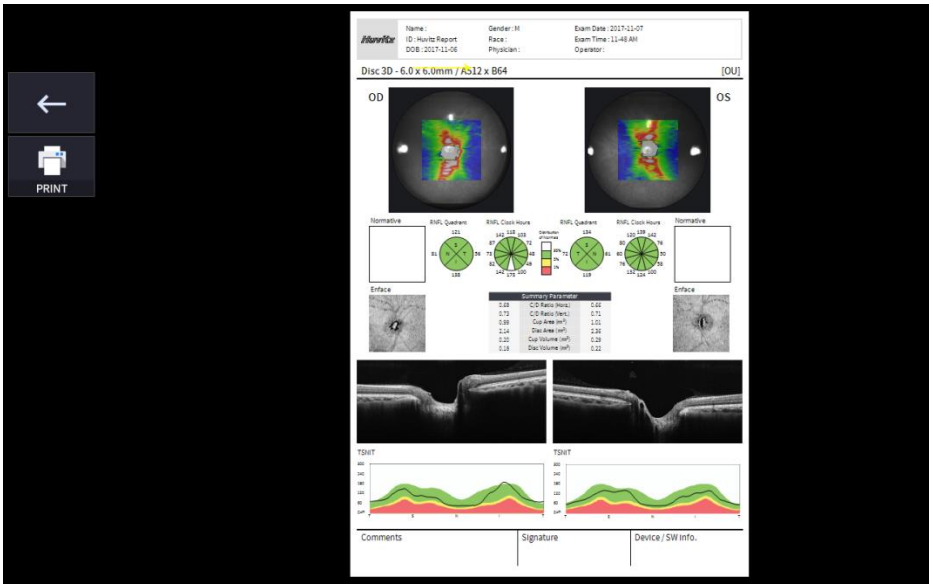
1-5.2. Selecting PRINT icon (

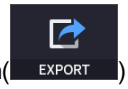
) shows printer option window



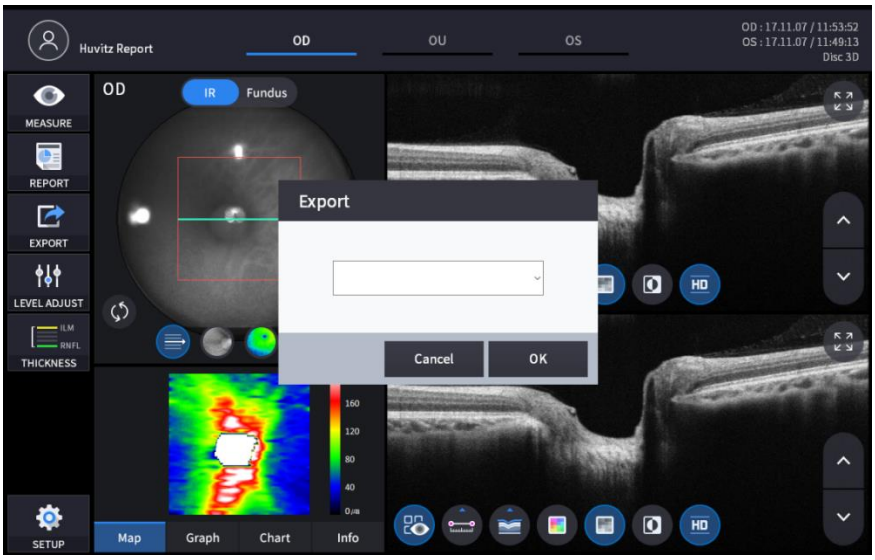
1-5.3. Select REPORT icon (

) at OU screen to change to REPORT screen



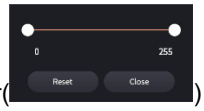
1-6. Selecting EXPORT icon(

) shows a pop-up window shown below, and the current screen shot is captured and stored in user-selected folder.



1-7. Selecting LEVEL ADJUST icon(

) shows an adjustable pop-up window shown below.

- Use Slide Bar(

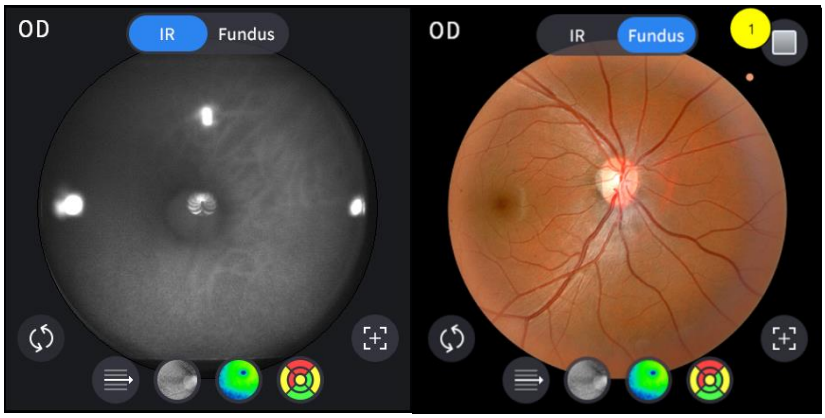
) to control Bscan Contrast

1-8. Selecting THICKNESS icon (ILM RNFL THICKNESS) shows a pop-up window shown below

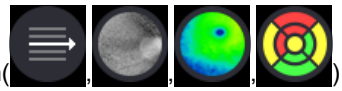
ILM <-> RNFL	Set Analysis criteria to ILM ~ RNFL
ILM <-> RPE	Set Analysis criteria to ILM ~ RPE

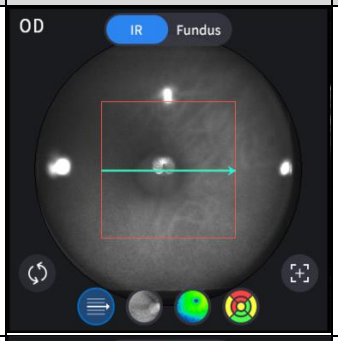
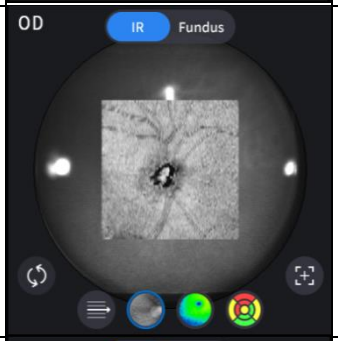
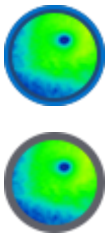
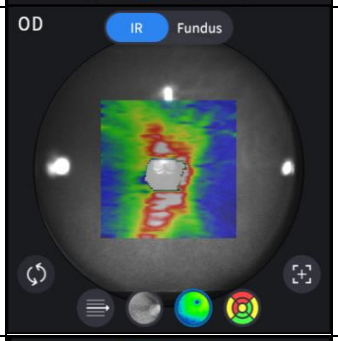
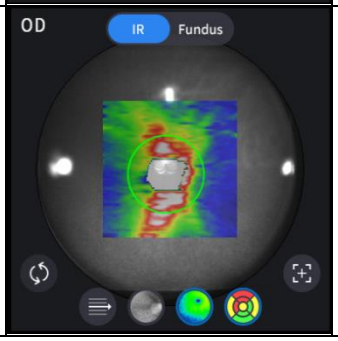
- Analysis results will be displayed according to each setting value

1-10. Fundus image can be chosen from monochromatic IR fundus image or color fundus image. (IR , Fundus)

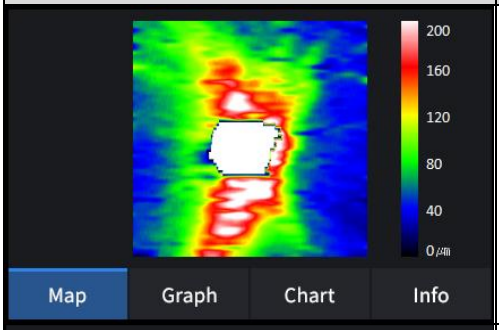
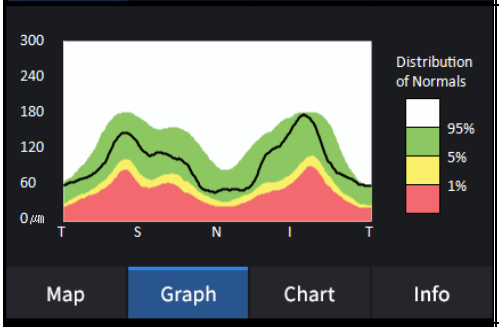
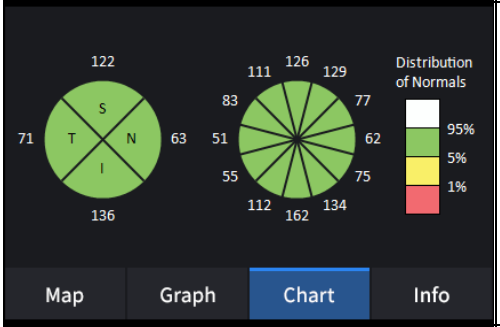
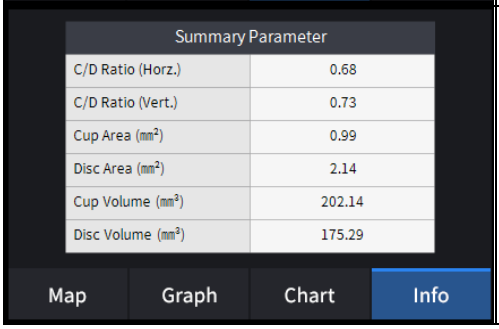


No	Name	Function
1	Red Free	Shows Red Free image from Color Fundus

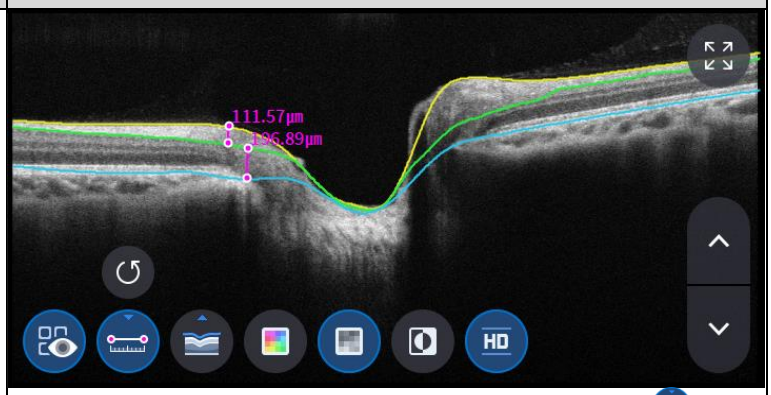
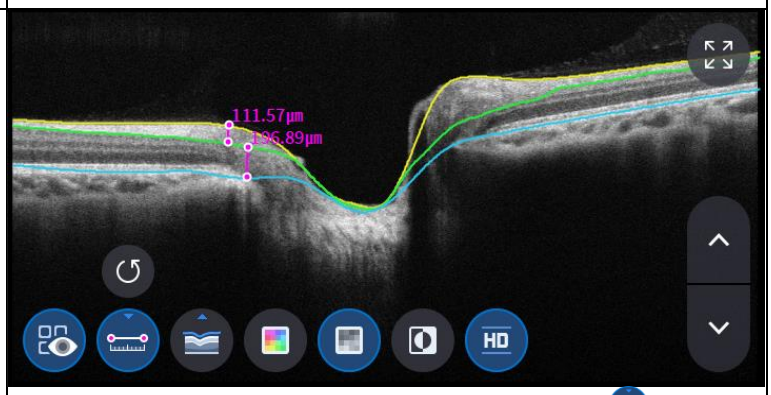
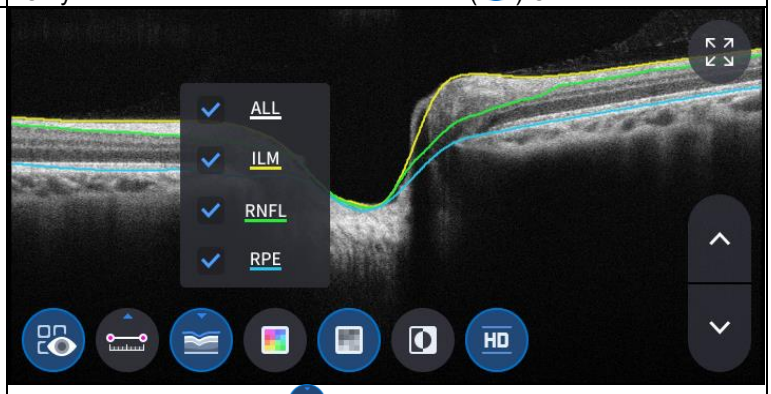
1-15. Select Overlay Control icon() to make the analysis result overlayed on Disc image.

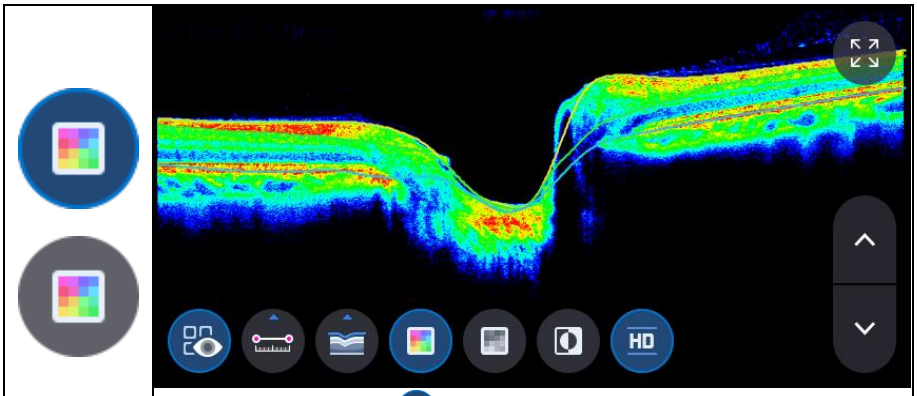
Icon ON / OFF	ON screen	Function
		- Displays Scan Domain - Displays Scan Direction
		- Displays enface image
		- Displays thickness map image
		- Displays TSNIT Range

1-16. Select analysis tool icon(Map , Graph , Chart , Info) to show the analysis result

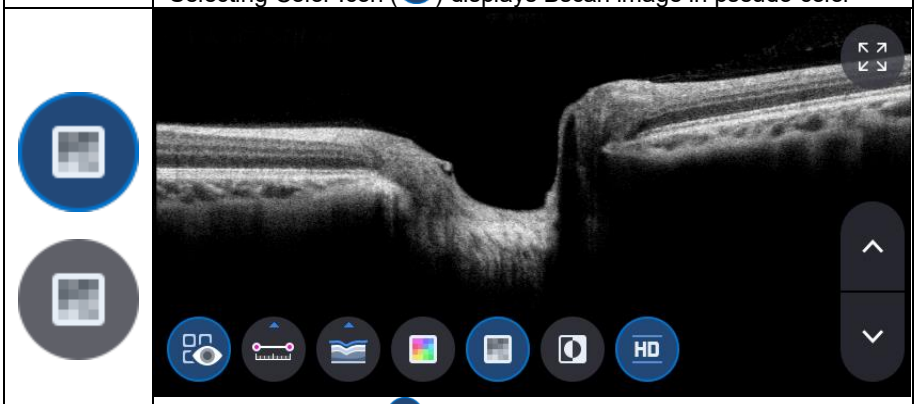
Analyze Screen	Function
	- Displays thickness map in pseudo color.
	- Displays TSNIT Graph
	- Displays RNFL Chart
	Displays following measured values - C/D Ratio (Horz.) - C/D Ratio (Vert.) - Cup Area - Disc Area - Cup Volume - Disc Volume

1-18. Select Bscan analysis tool(, , , , , ,) on Bscan image to analyze the Bscan currently displayed

Icon ON / OFF	Screen and Function
	 - ON : Shows the length measured using measurement icon( ) - OFF: Hides the measurements
	 - Selecting two points with the length measurement icon( ) ON on Bscan screen shows the length between the two points - Latest data can be deleted by selecting Undo Icon( ) - Only usable with measurement result Icon( ) ON
	 - Click Segmentation icon( )to show Bscan Layer. ALL, ILM, RNFL, RPE are selective

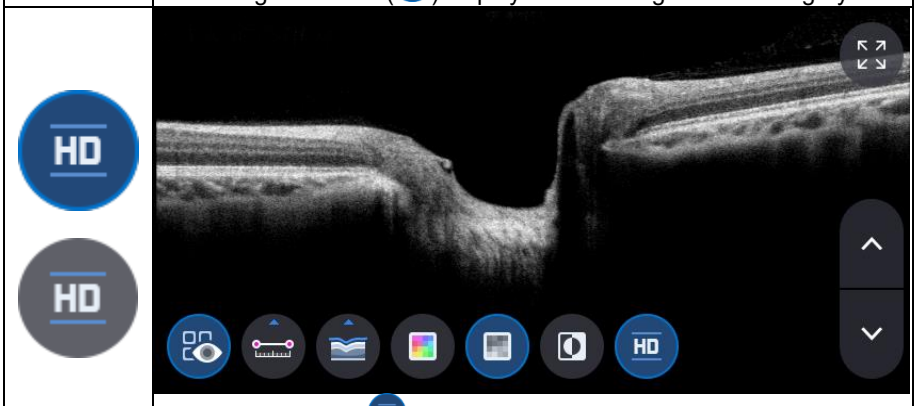


- Selecting Color Icon ( ) displays Bscan image in pseudo color



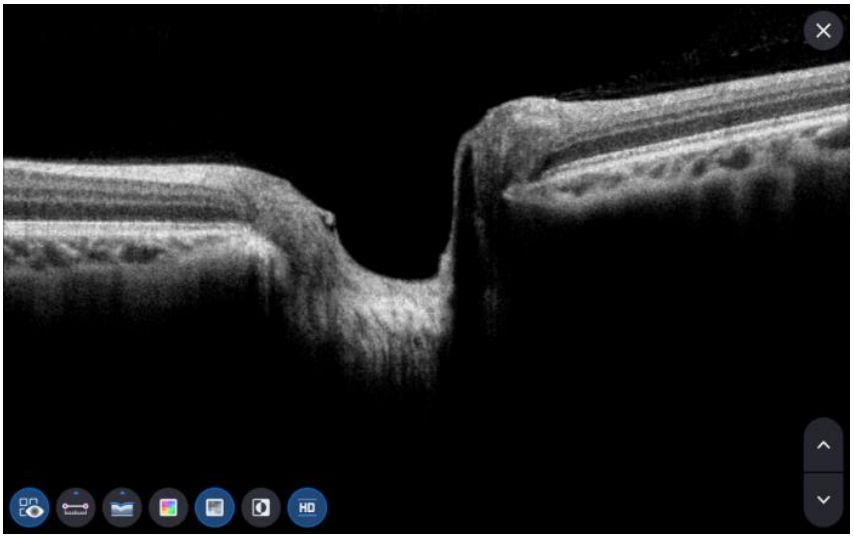
- Selecting Gray Icon( ) displays Bscan image in grayscale

- Selecting Invert Icon( ) displays Bscan image in inverted grayscale



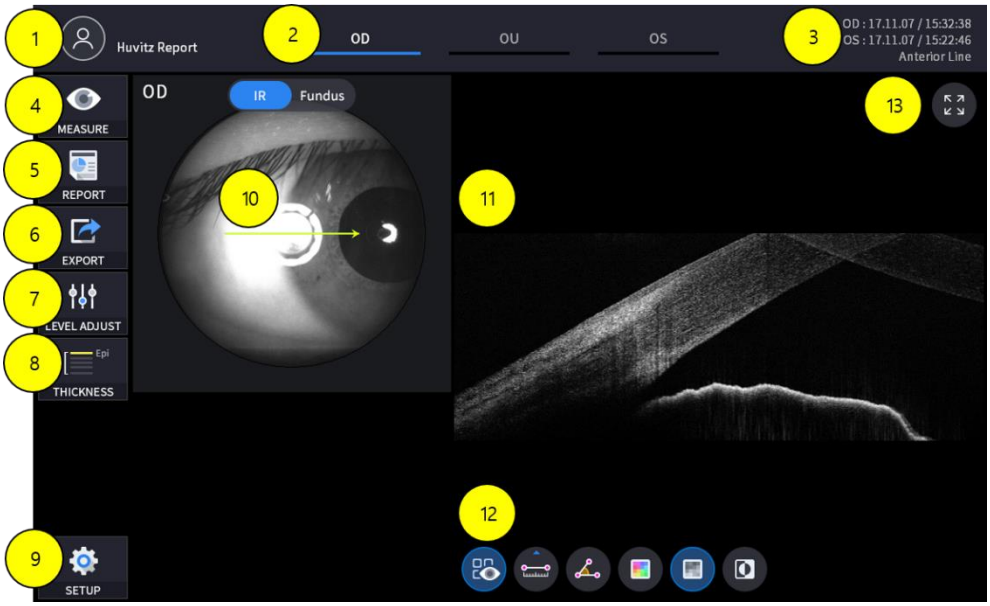
- Selecting HD Icon( ) indicates HD quality Bscan image

1-19. Selecting FULL Screen Icon( ) shows the current Bscan image in full screen



6.5.4. OCT Anterior Line Analysis screen

1. Composition of screen

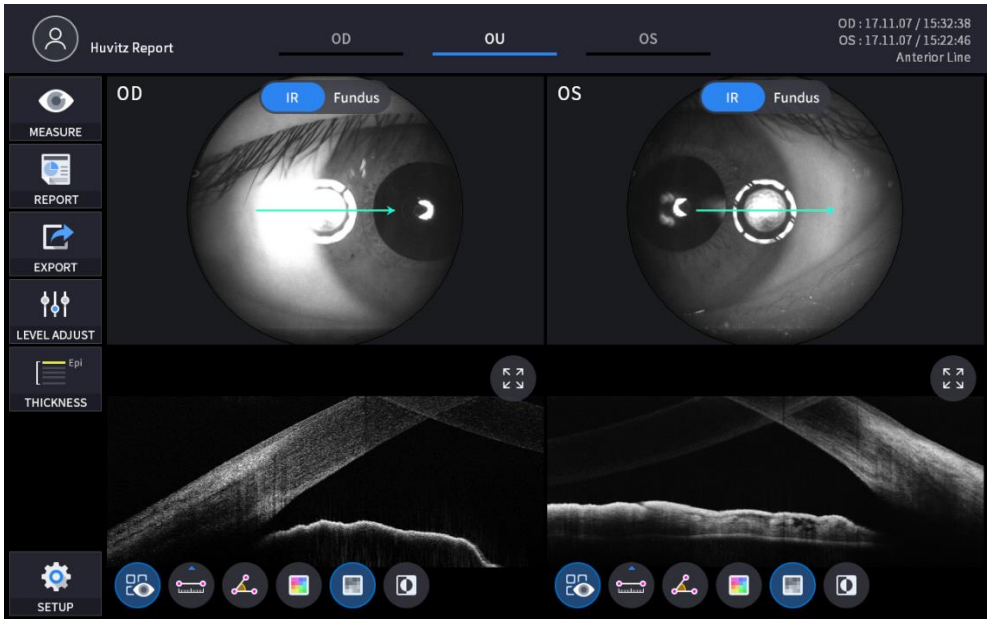


No	Name	Function
1	Patient information	Shows the information of patient ID and name. Go back to patient list by clicking the icon
2	OD / OU / OS	Indicates which side of eye is showing You can move to the measurement of the other side or the both sides by selecting unhighlighted tabs - OD: right eye, OS: left eye , OU: both eyes
3	Date	Displays the date the measurement was taken
4	MEASURE	Moves to capture screen after finishing Analysis
5	REPORT	Moves to report screen of the current measurement
6	EXPORT	Capture current screen and store it
7	LEVEL ADJUST	Adjust contrast of Bscan
8	THICKNESS	Select the analysis range between Epi <-> Bowman's / Epi <-> Endo
9	SETUP	Moves to User setting screen
10	Scan position	Indicates the position of the displayed Bscan on retina
11	Bscan-1	Bscan screen
12	Bscan Tool	Tools for Bscan analysis
13	Full Screen	Switch Bscan image to a Full screen

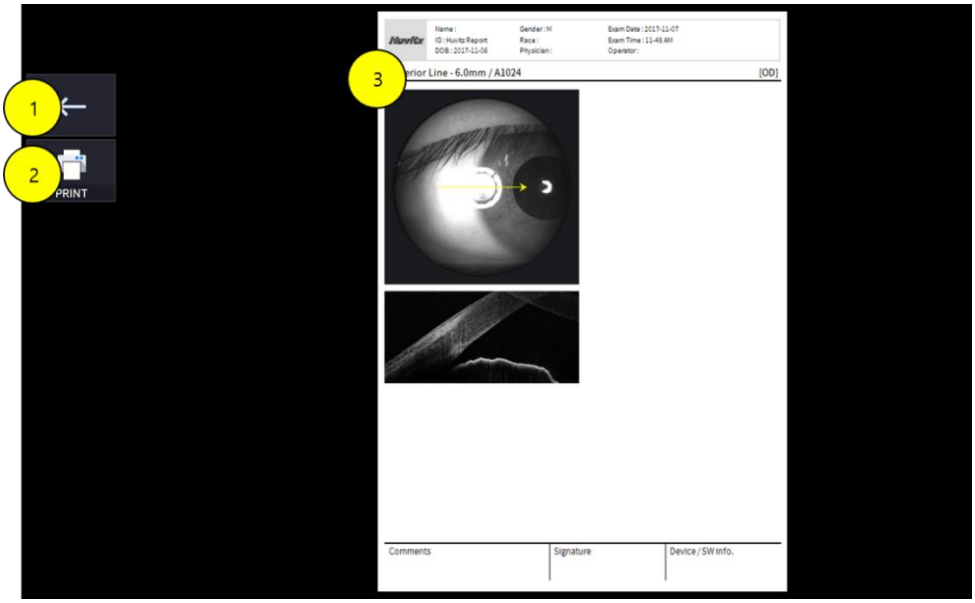
1-2. Select analyze mode choosing OD / OU / OS icon (OD, OU, OS)

OD	Right eye Analysis
OU	Both eyes Analysis
OS	Left eye Analysis

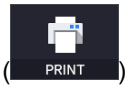
When selecting OU(OU) among OD / OU / OS, screen changes to OU analysis screen shown below.



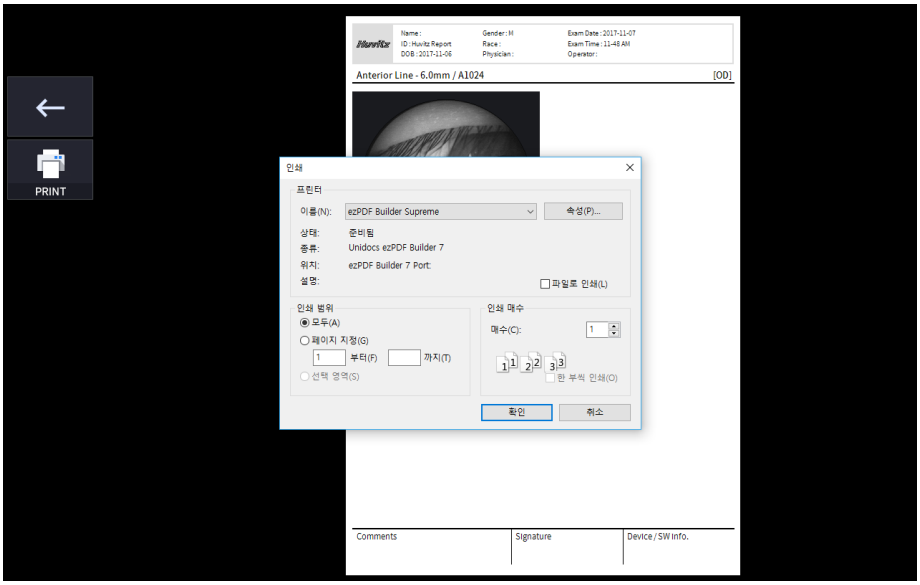
1-5.1. Select REPORT icon (REPORT) show REPORT screen shown below

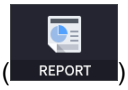


No	Name	Function
1	Previous screen	Go back to analysis screen
2	PRINT	Save the current report showing as PDF file or print to a connected printer
3	Report Preview	Preview of generated report

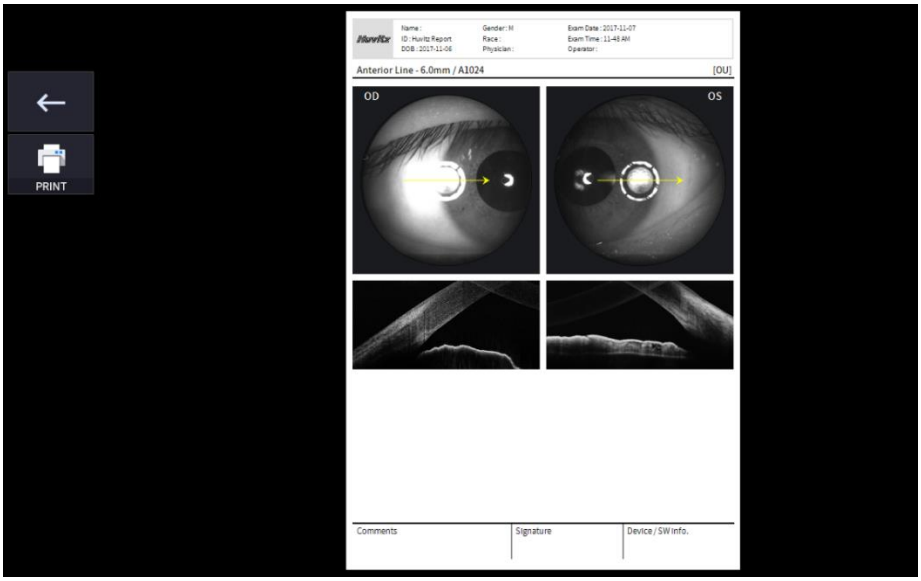
1-5.2. Selecting PRINT icon (

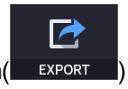
) shows printer option window



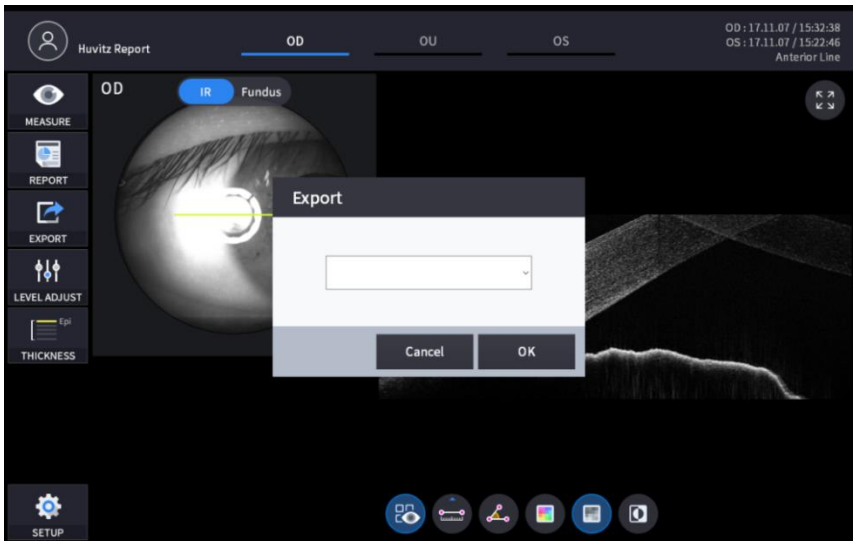
1-5.3. Select REPORT icon (

) at OU screen to change to REPORT screen



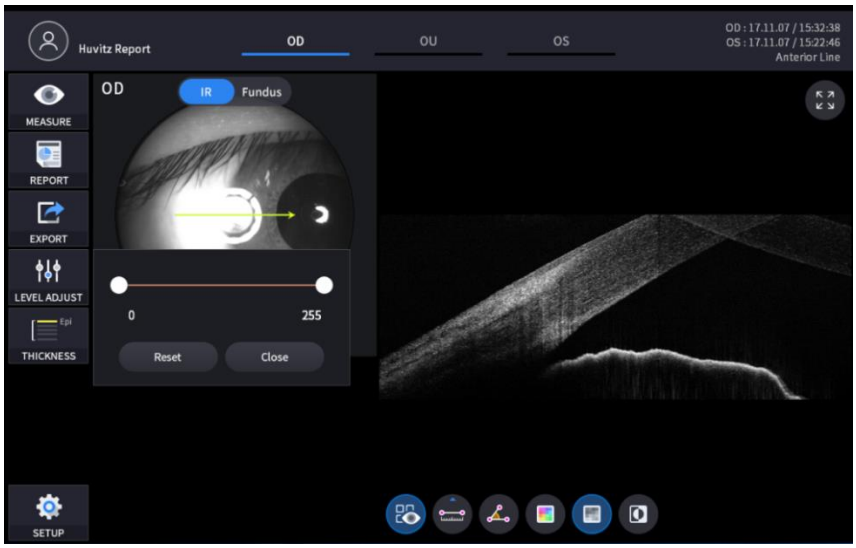
1-6. Selecting EXPORT icon(

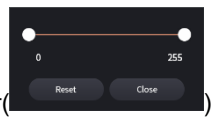
) shows a pop-up window shown below, and the current screen shot is captured and stored in user-selected folder.



1-7. Selecting LEVEL ADJUST icon(

) shows an adjustable pop-up window shown below.

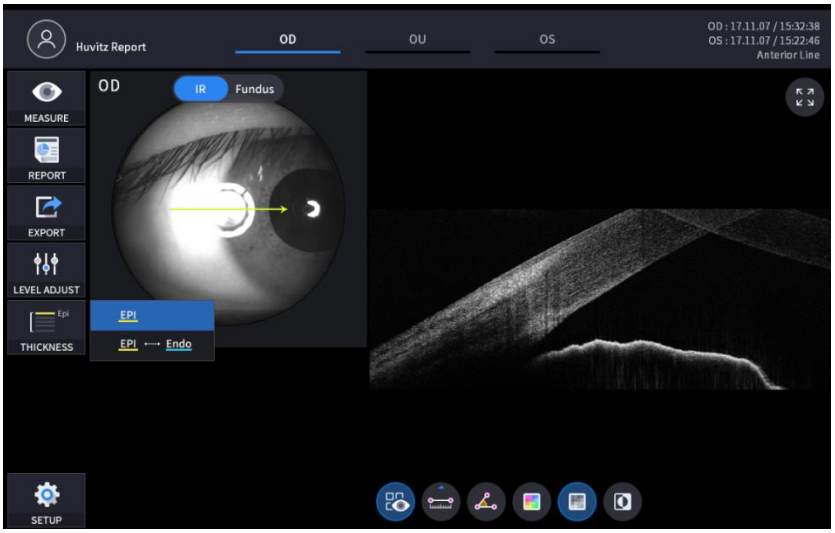


- Use Slide Bar(

) to control Bscan Contrast

1-8. Selecting THICKNESS icon (

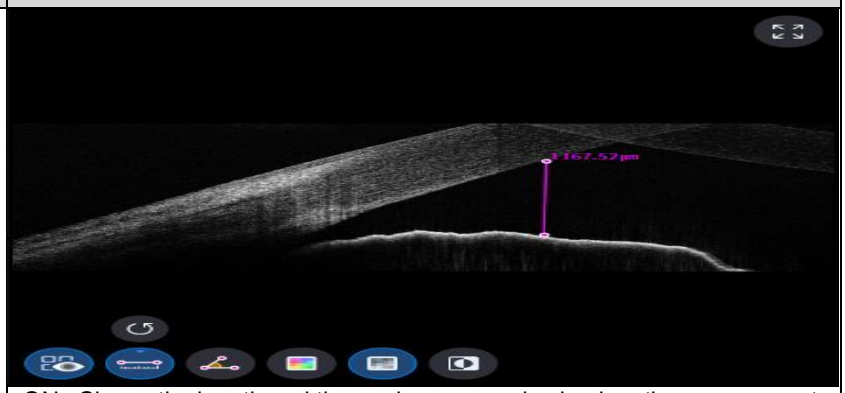
) shows a pop-up window shown below

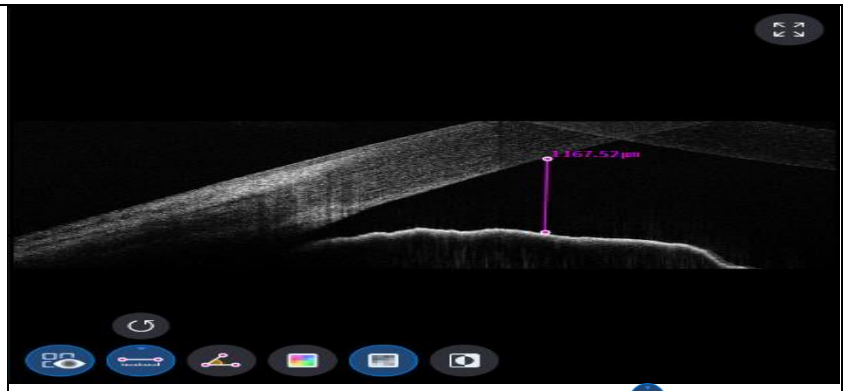


EPI	Set Analysis Criteria to EPI ~ Bowman's
EPI <-> Endo	Set Analysis Criteria to EPI ~ Endo

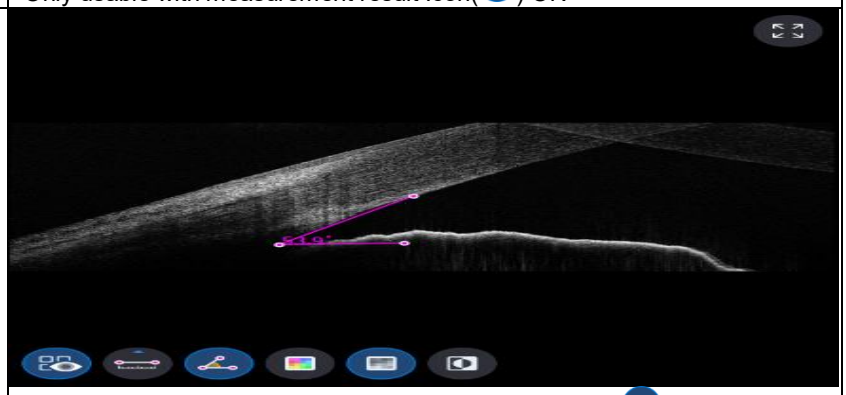
- Analysis results will be displayed according to each setting value

1-12. Select Bscan analysis tool( ) on Bscan image to analyze the Bscan currently displayed

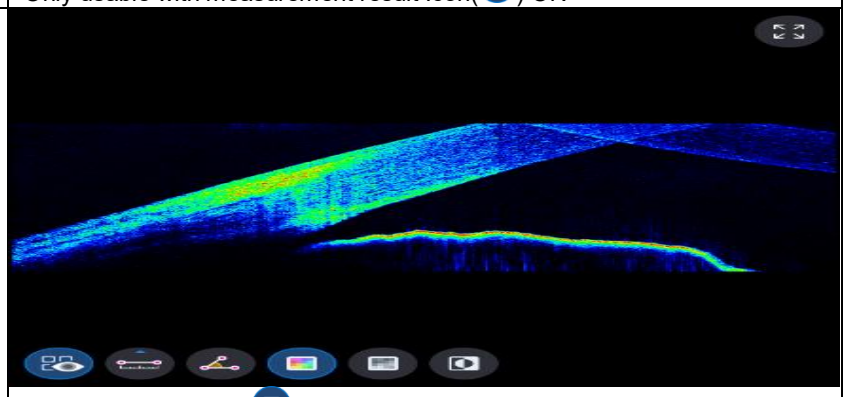
Icon ON / OFF	Screen and Function
 	 - ON : Shows the length and the angle measured using length measurement icon( ) and angle measurement Icon( ) - OFF : Hides the measurements



- Selecting two points with the length measurement Icon( ) ON shows the length between the two points
- Latest data can be deleted by selecting Undo Icon( )
- Only usable with measurement result Icon( ) ON

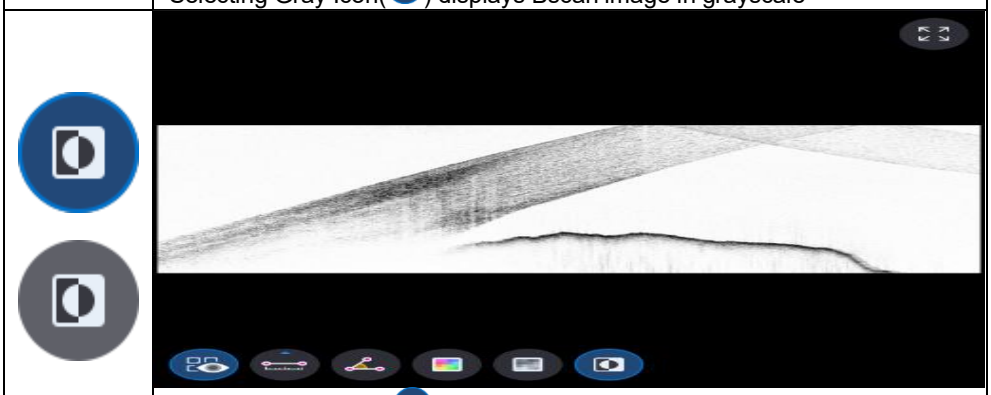


- Selecting three points with the angle measurement Icon( ) ON shows the angle made by the three points.
. Latest data can be deleted by selecting Undo Icon( )
- Only usable with measurement result Icon( ) ON



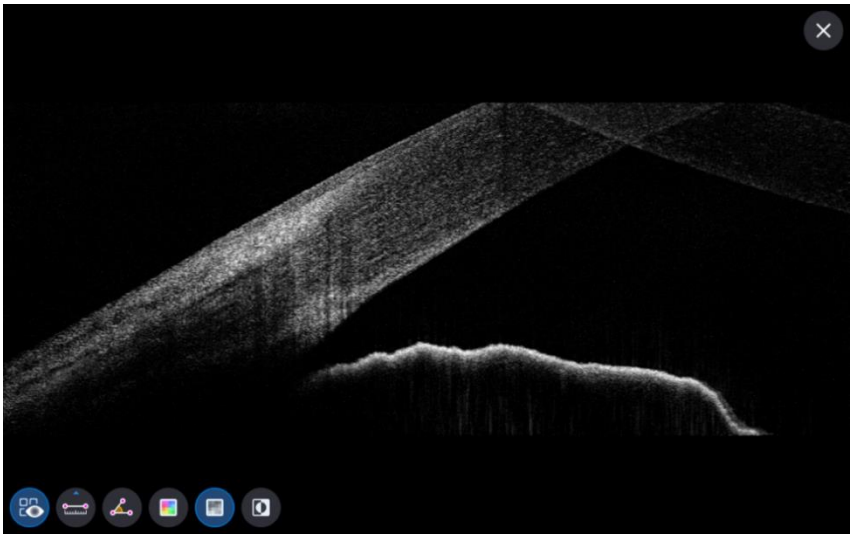
- Selecting Color Icon ( ) displays Bscan image in pseudo color

- Selecting Gray Icon( ) displays Bscan image in grayscale



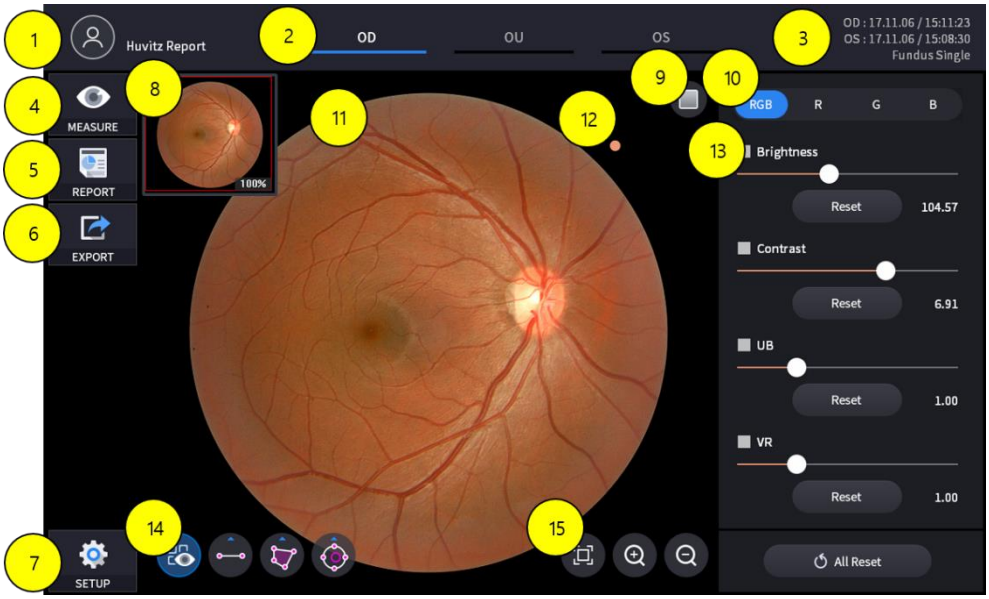
- Selecting Invert Icon( ) displays Bscan image in inverted grayscale

1-13. Selecting FULL Screen Icon( ) shows the current Bscan image in full screen



6.5.5. Fundus Analysis screen

1. Composition of screen



No	Name	Function
1	Patient information	Shows the information of patient ID and name. Go back to patient list by clicking the icon
2	OD / OU / OS	Indicates which side of eye is showing You can move to the measurement of the other side or the both sides by selecting unhighlighted tabs - OD: right eye, OS: left eye , OU: both eyes
3	Date	Displays the date the measurement was taken
4	MEASURE	Moves to capture screen after finishing Analysis
5	REPORT	Moves to report screen of the current measurement
6	EXPORT	Capture current screen and store it
7	SETUP	Changes to User setting screen
8	Navigation	Indicates the position of fundus image displayed in main screen(11) when it's magnified.
9	Red Free	Analyze Fundus Image using Red Free
10	RGB Channel	Selection of RGB Channel
11	Fundus Image	Shows captured Fundus Image
12	Direction Indication Mark	Indicates the orientation of the Fundus image. Mark always locates on the right upper side of the image.
13	Adjustment Control	Adjusting function of Brightness, Contrast, UB, VR
14	Measurement Tool	Length, Area, C/D Ratio measurement function on Fundus Image screen
15	Magnification tool	Magnifying and Analyzing function of Fundus Image

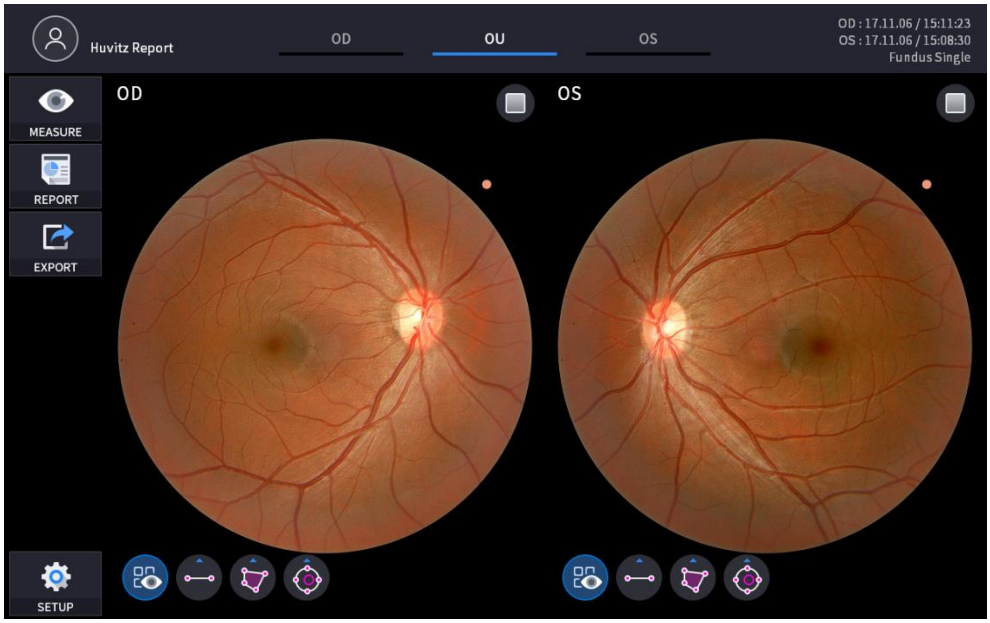
1-2. Select analyze mode choosing OD / OU / OS icon (

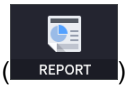
)

OD	Right eye Analysis
OU	Both eyes Analysis
OS	Left eye Analysis

When selecting OU(

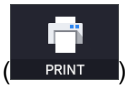
) among OD / OU / OS, screen changes to OU analysis screen shown below



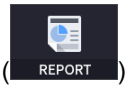
1-5.1. Select REPORT icon (

) shows REPORT screen shown below

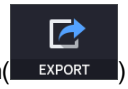
No	Name	Function
1	Previous screen	Go back to analysis screen.
2	PRINT	Save the current report showing as PDF file or print to a connected printer
3	Report Preview	Preview of generated report

1-5.2 Selecting PRINT icon (

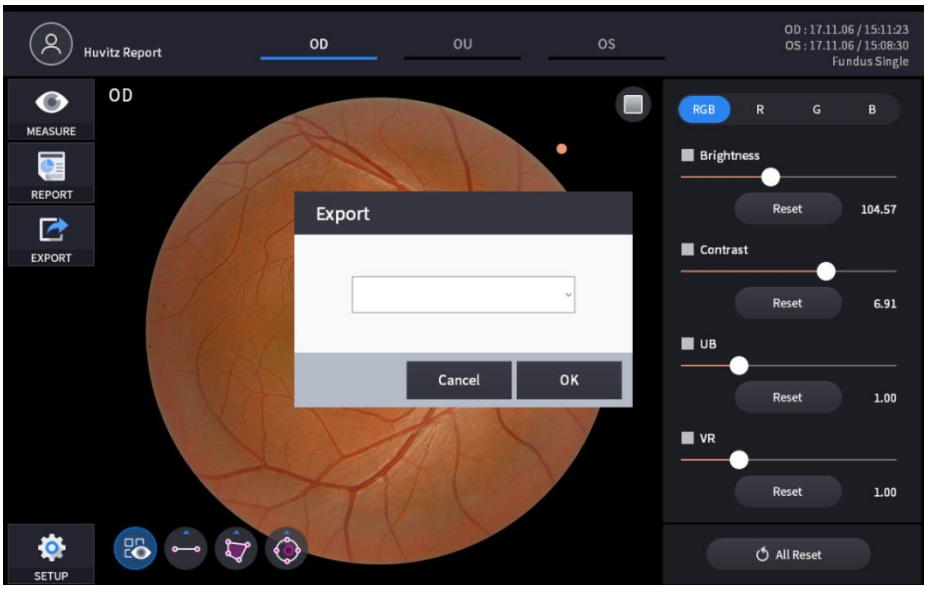
) shows printer option window

1-5.3. Select REPORT icon (

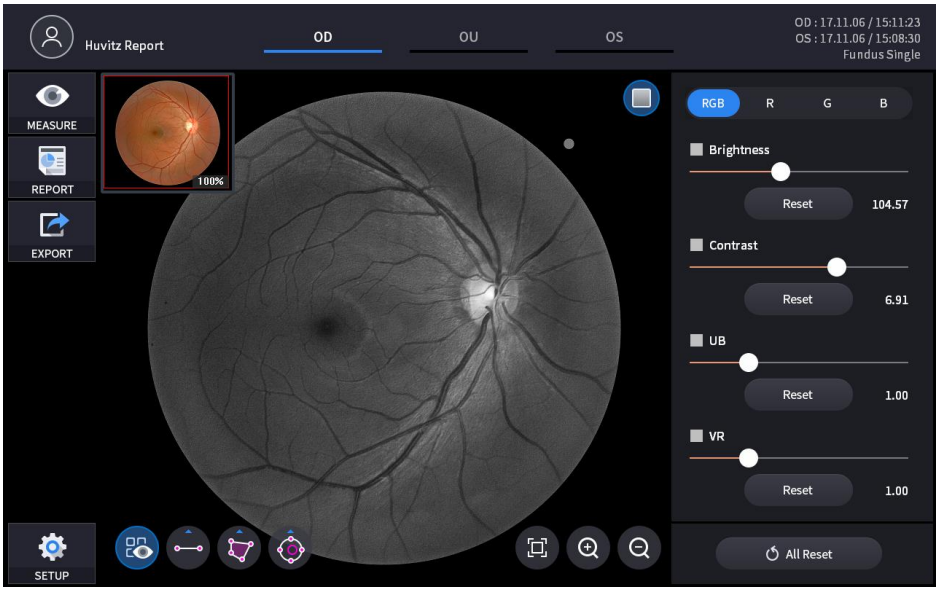
) at OU screen to change to REPORT screen

1-6. Selecting EXPORT icon(

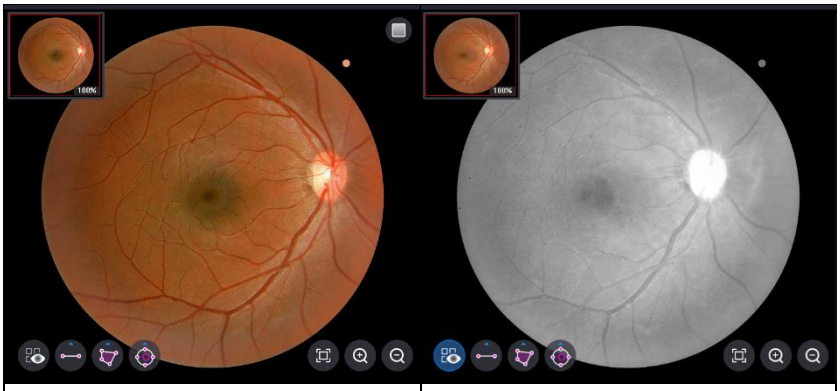
) shows a pop-up window shown below,
and the current screen shot is captured and stored in user-selected folder.



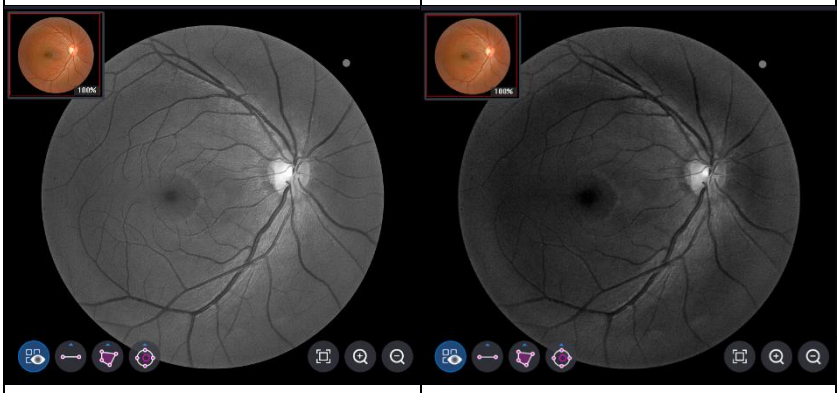
1-9. Use Red Free ON / OFF icon(,) to analyze Fundus Image with Red free Screen



1-10. By selecting one of the RGB channels, only selected channel displayed in monochromatic image.



<RGB Channel> | <R Channel>



<G Channel> | <B Channel>

1-13. Images can be adjusted using Slide Bar(

,

,

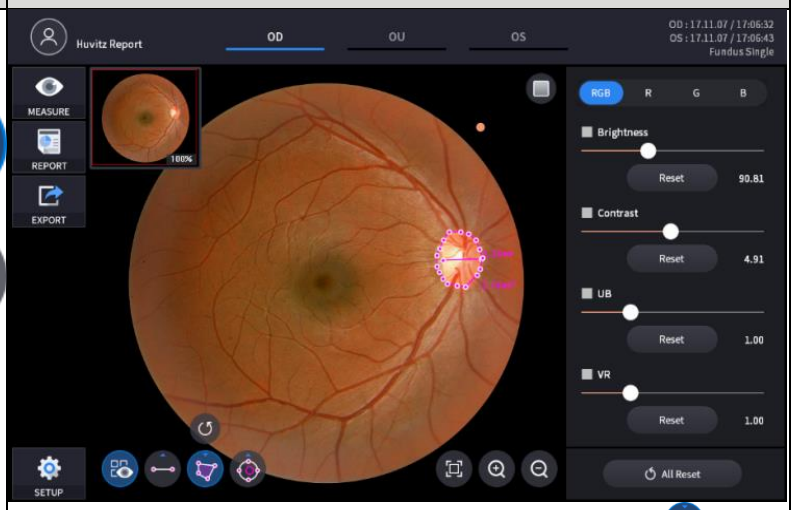
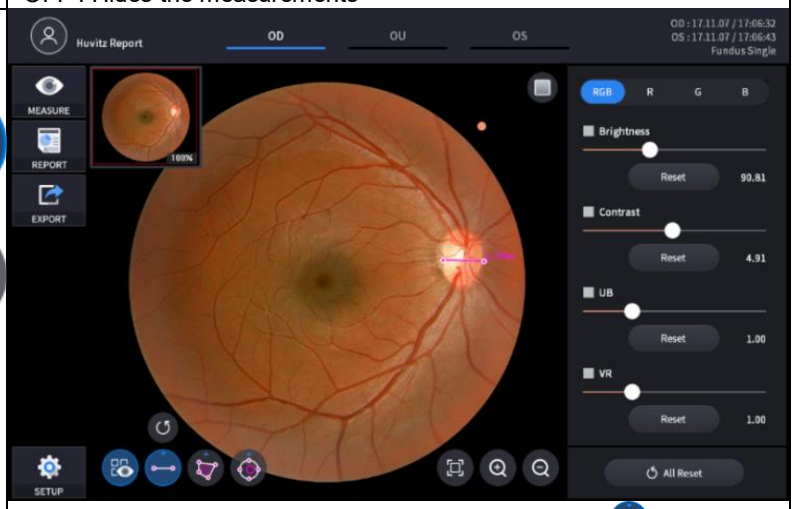
,

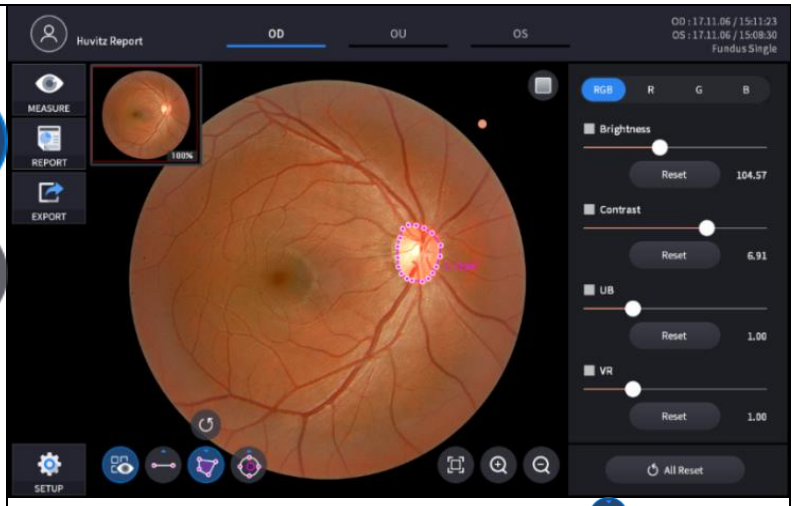
) of Adjustment Control

	Adjustment of Brightness
	Adjustment of Contrast
	Adjustment of UB
	Adjustment of VR
	Resetting of individual Adjustment
	Resetting of all Adjustment

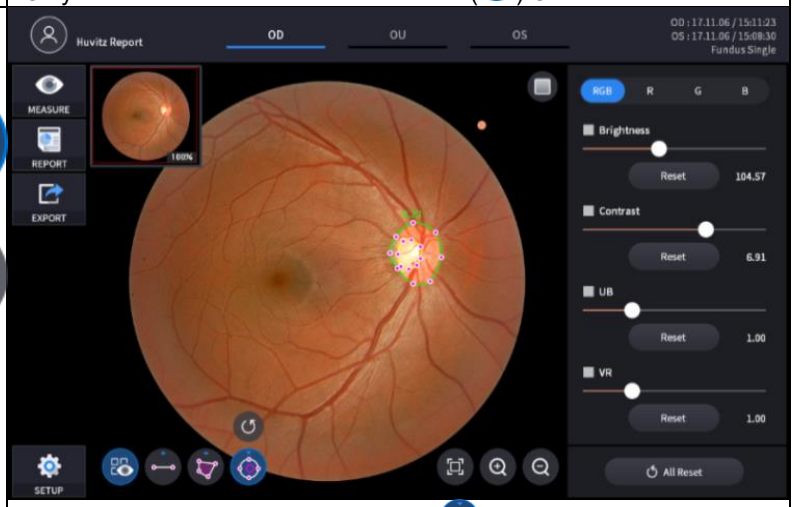
1-14. Length, Area, C/D Ration can be measured using Measurement Tool Icon

(, , ,)

Icon ON / OFF	Screen and Function
	 - ON : Shows results measured by length measurement Icon ( ), area measurement Icon( ), C/D ration measurement Icon( ) on Fundus Image - OFF : Hides the measurements
	 - Selecting two points with the length measurement icon( ) shows the length between the two points - Latest data can be deleted using Undo Icon( ) - Only usable with measurement result Icon( ) ON

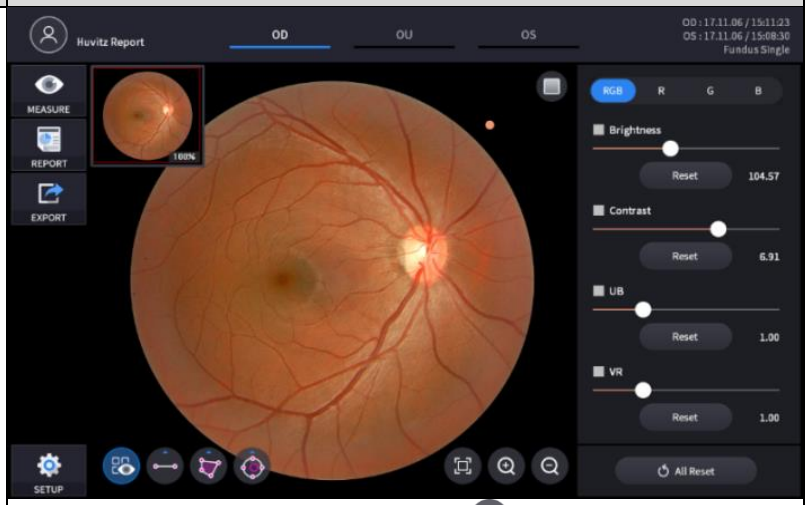
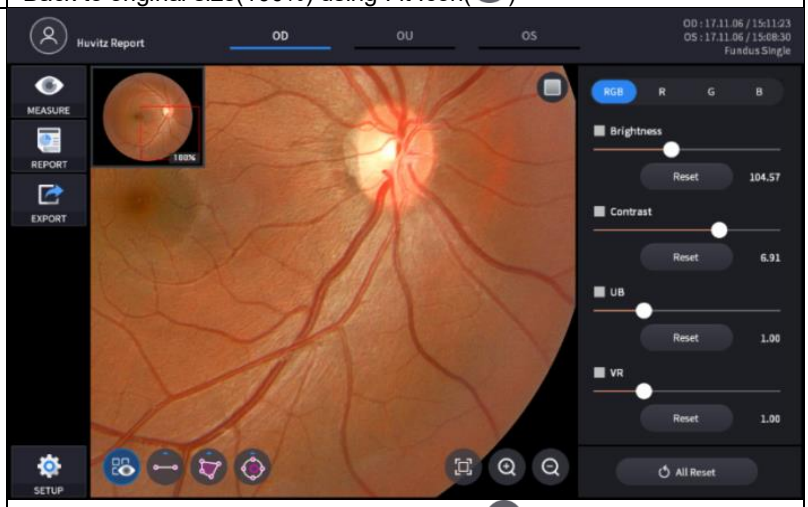


- Selecting a region with the Area measurement icon( )shows the area of the region
- Latest data can be deleted using Undo Icon( )
- Only usable with measurement result Icon( ) ON



- With C/D ratio measurement switch on( ), clicking a point on the fundus image produces two concentric circles at the point. C/D ratio is calculated as the ratio of area of the two circles. The shape and size of each circles are adjusted by dragging the marks on the circles.
- Latest data can be deleted using Undo Icon( )
- Only usable with measurement result Icon( ) ON

1-15 Magnified Image analysis is possible by selecting magnifying Icon (, ,)

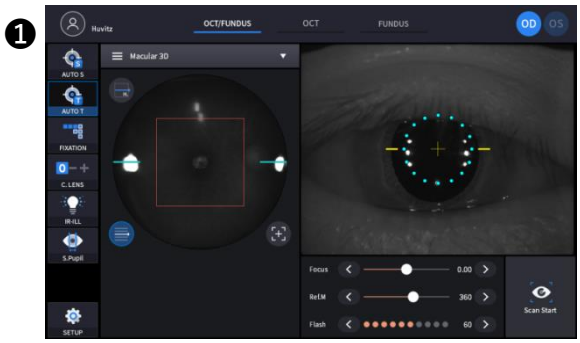
Icon	Screen and Function
	 - Back to original size(100%) using Fit Icon( )
	 - Magnify Fundus Image using Zoom In Icon( ) - Magnified image can be dragged and be moved to any position - Maximum magnification ratio is 200%.
	 - Reduce the magnified image using zoom out icon( ) - Image will not be reduced to smaller than the original size

6.6. Maintenance

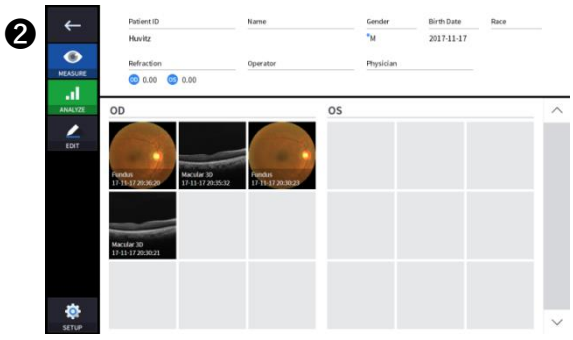
6.6.1. After operation

1. Exit HOCT software and Power off.

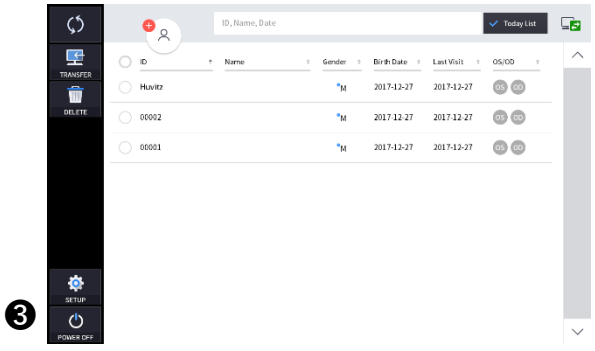
① Select the Patient information icon ( ) in the upper left corner of the screen.



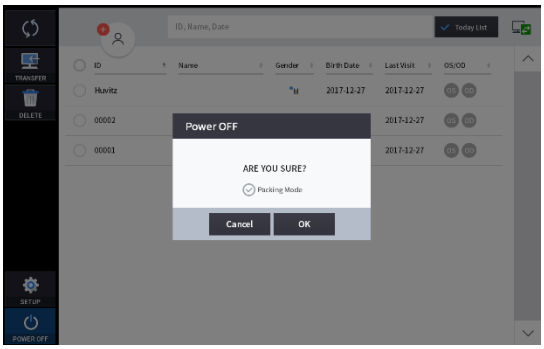
② Select the Previous screen icon ( ) in the upper left corner of the screen.



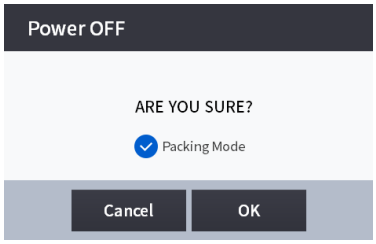
③ Select the Power Off icon ( ) from the bottom left corner of the screen.



④ Selecting POWER OFF icon(POWER OFF) shows a pop-up window show below.



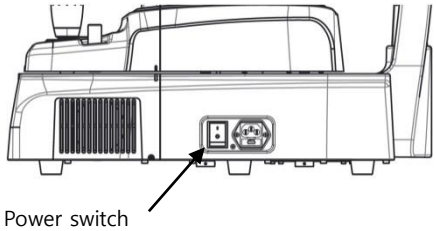
⑤ Checking the Packing Mode will move Chinrest and the body of HOCT to the lowest position before Power off (This is for packaging.)



NOTE

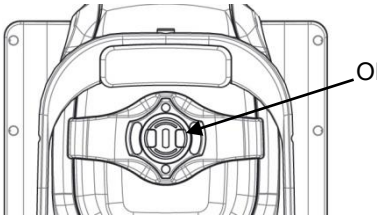
Be sure to select the Packing Mode in order to place the equipment in the packing box.

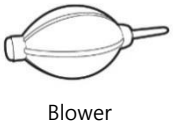
2. Turn off external devices (monitor, etc.) if any external device is connected.
3. Turn the power switch off(O) on the base plate.



6.6.2. Cleaning

1. Cleaning objective lens and anterior segment adopter
   ① Cover the objective lens with lens cap to protect the lens from external pollution.
   ② Use blower for removing dust on the surface of lens.



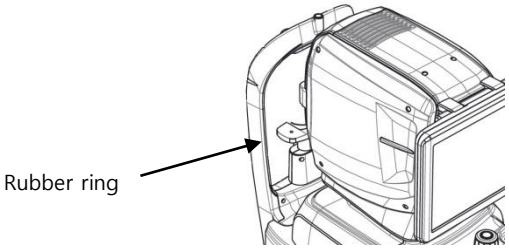


   ③ To remove smear on the surface of lens, use lens cleaning paper or cotton swab moistened with alcohol.
   ④ Do not use a metal or hard stick. Also do not use rubbing alcohol because coating of lens may be damaged or removed.
   ⑤ If Anterior segment adapter is used for patients with any infectious disease, be sure to clean the Anterior segment adapter with cotton swab moistened with alcohol to prevent secondary infection.

2. System exterior
   ① Keep system exterior clean with soft cloth. For severe stains, wipe with a soft cloth with neutral detergent diluted with water. Do not use organic solutions such as thinner or benzene.
   ② Wipe the touch screen with dry soft cloth. Do not use sponge or cloth soaked with large amount of liquid.
   ③ Do not press hard or place magnetic objects near the touch screen.

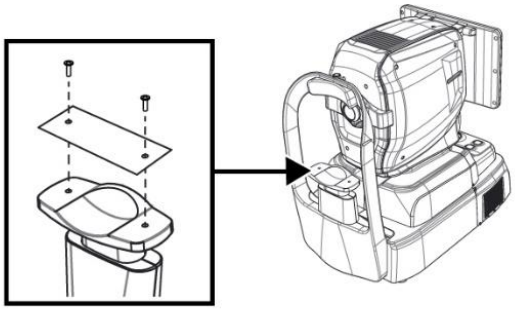
3. Part of patient contact
   ① Wipe the headrest and the chinrest with a clean cotton swab or gauze. For severe stains, use a soft cloth with alcohol.
   ② Remove a single sheet of chinrest paper if the chinrest paper is used.

4. Others
   ① Cover device with dustcover for unused storage for a long time.
   ② Clean headrest and chinrest with alcohol before sending device to authorized agent or Huvitz for maintenance.
   ③ The rubber ring inserted to conceal the wires may be out during use. It can be used either by inserting it again or by removing it.



6.6.3. Replacement of consumables and fuse

1. Replacing chinrest paper
   ① Pull out two fixing pins from chinrest.
   ② Put a new chinrest paper on the chinrest.
   ③ Insert two fixing pins into the chinrest paper hole.
   ④ Attach the chinrest paper to the chinrest.



2. Replacing fuse
   ① Ensure the power switch of device off (O).
   ② Remove power cable from inlet.
   ③ Pull out fuse holder in the inlet with a tweezers.
   ④ Replace two new fuses in the fuse holder. Be sure to check the fuse specification for the replacement (250V T 3.15AL).
   ⑤ Insert fuse holder into the inlet.

6.6.4. Calibration

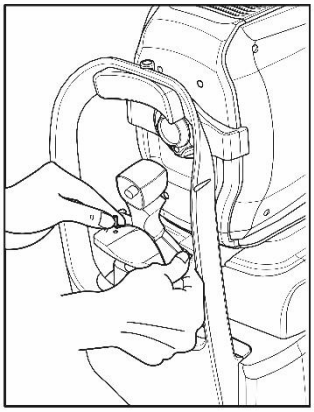
Note: Huvitz recommends to calibrate the system once a year.
Contact to the HUVITZ's service technicians or other authorized experts

6.6.5. Self-diagnosis using Model eye

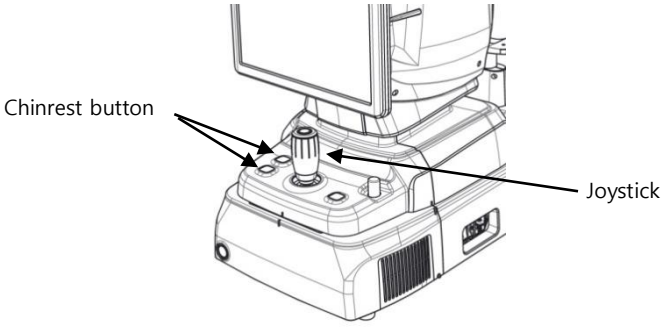
1. How to mount Model eye

① Remove chinrest paper.

② Mount Model eye as shown below and then fix it using two paper pins.

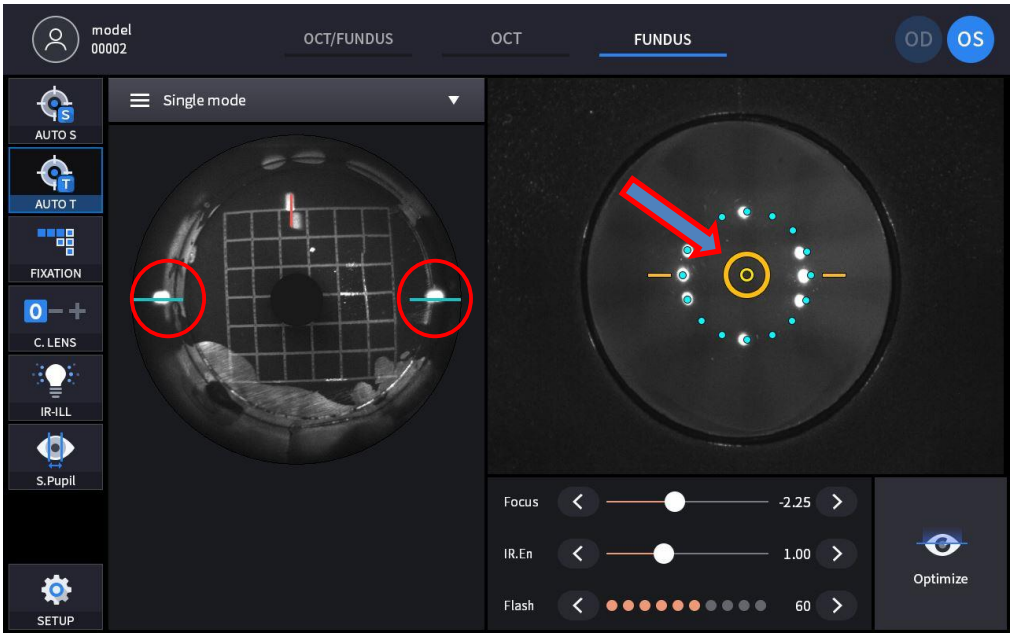


③ Align the center of the Model eye with the objective lens using joystick and chinrest button.



2. Checking working distance

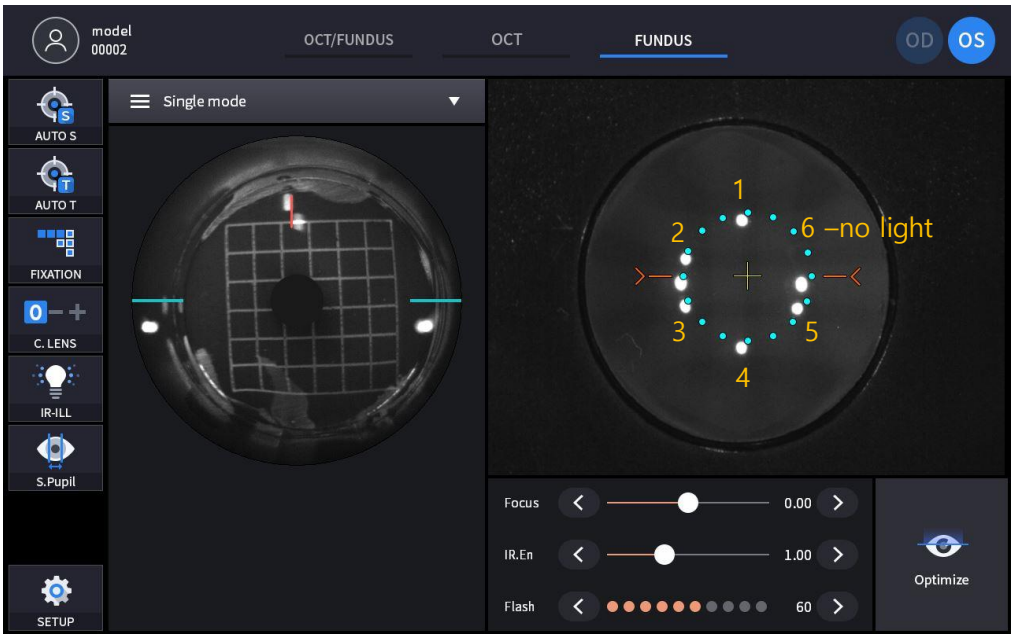
① Select FUNDUS measurement in MEASURE mode.



- At anterior screen, align the device till the target mark (circular orange) appears which indicated the Model eye and the device's alignment and focusing is correct.
- Align the device till the working dot marked red on the left IR screen to be positioned on the blue guide line and also the size to be smallest while maintaining the target mark (circular orange) to be displayed.
- KERATO SETUP shall be performed when the Working dot is extremely distorted while the target mark (circular orange) displayed.

3. Checking anterior lightning LED

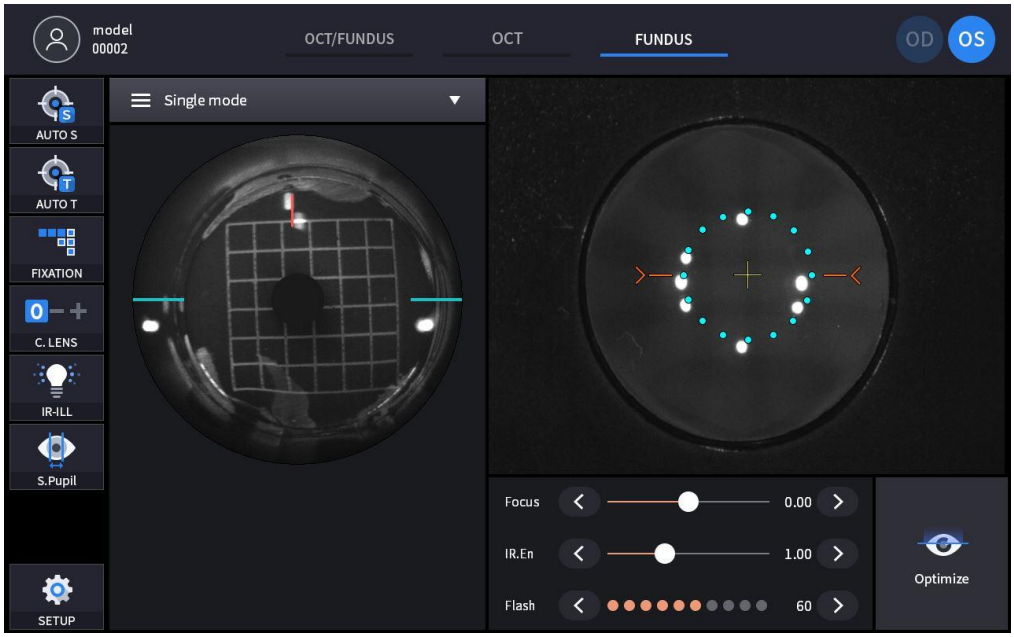
① Select FUNDUS measurement in MEASURE MODE.



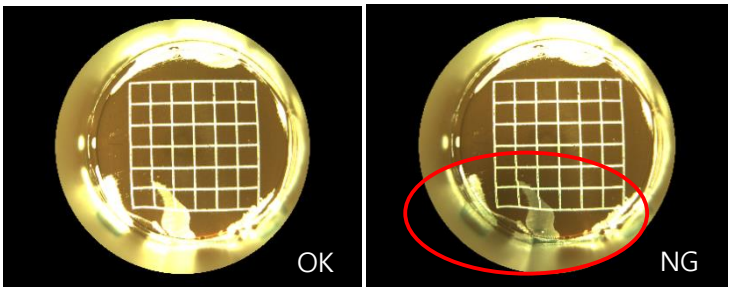
- Check anterior lighting LED. They consist of six dots except two center dots out of eight dots at anterior screen.
- KERATO SETUP shall be performed after changing LED when there is a problem with the LED and the LED shows OFF as number six shown in the picture.

4. Check Fundus Camera

① Select FUNDUS Mode and measure Fundus.

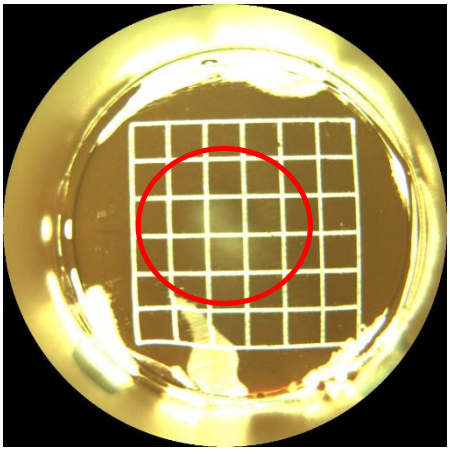


② Check if there are asymmetric areas as right picture from the measured images.



- If there are some, re-boot the device and measure again.

③ Check if there are any blurriness or smear as below picture from the scanned images.

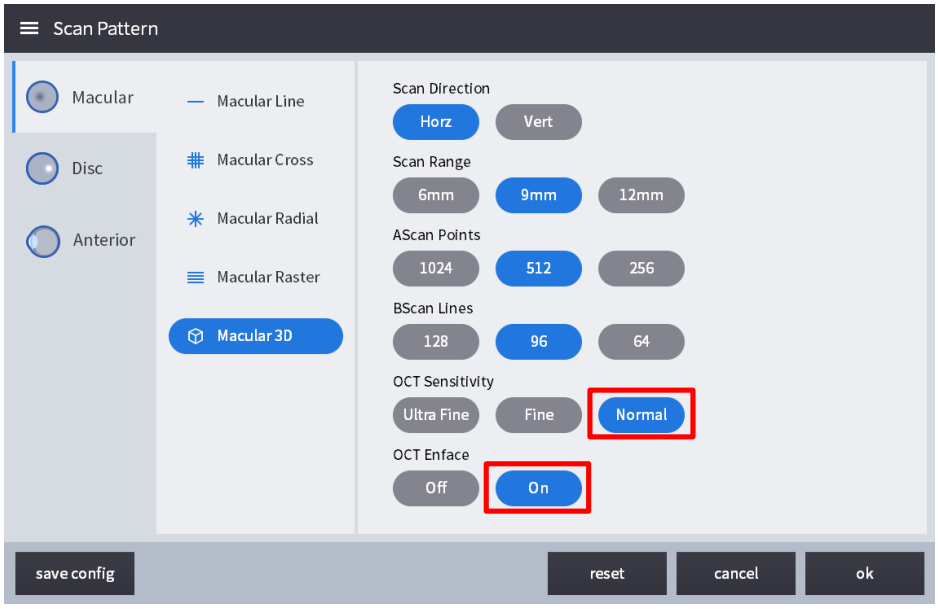


- If blurriness or smear appears, clean the finger prints or stain on the objective lens.

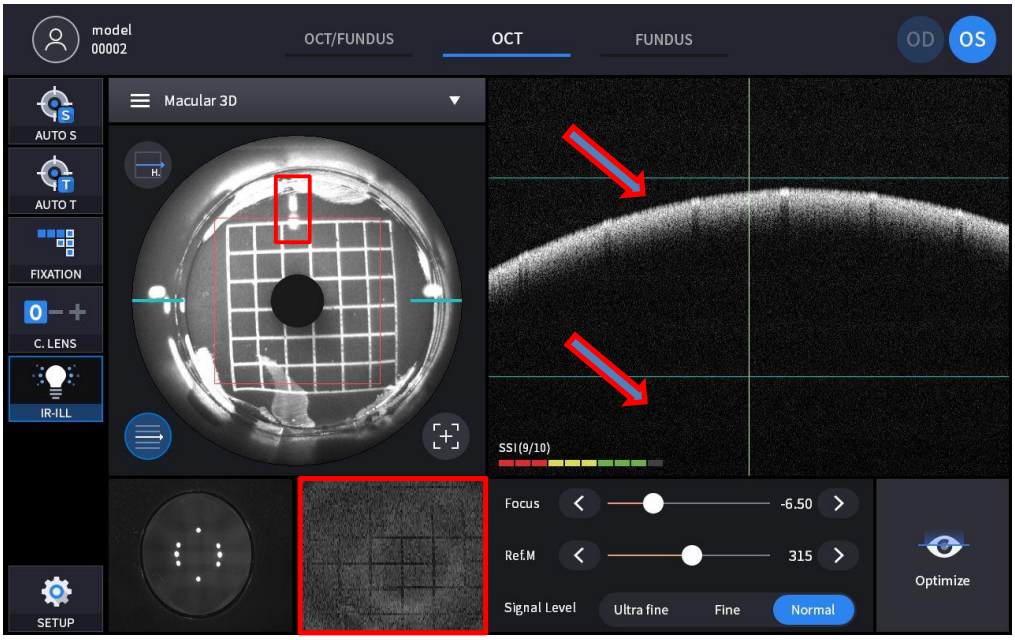
5. Check OCT Scan

① Select OCT Scan in MESURE Mode.

② Select Macular 3D at Scan Pattern and change the OCT Sensitivity to Normal as below picture and then turn the OCT Enface option to On.



③ Scan will start automatically when the alignment and focusing is correct, and let the Bscan, IR Fundus and real time Enface screen to be displayed as below picture using Optimize function,



- Check if the Split Focus is aligned as straight line in IR FUNDUS screen.
- Check if the Retina image of the Bscan screen is in between the green guidelines.
- Check if the real time enface video marked with red rectangle shows grid pattern.

7

7 Troubleshooting Guide

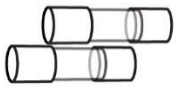
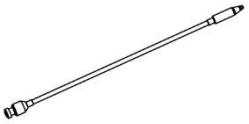
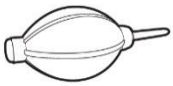
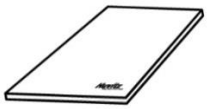
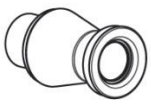
Should the device function improperly, attempt to correct the problem according to the following table before contacting sales distributor.
Contact a sales distributor after turning off the power when the device does not resume normal operation even after taking the following measures.

Problem	Cause	Solution
The screen does not turn on.	The power cable may not connected.	Check the connection of the power cable.
	The power switch may not be turned on.	Check whether the power switch is turned on.
The screen does not turn on even though the system power is on	The system may be in sleep mode.	Restore the system from sleep mode by touching the screen.
The screen suddenly turns off		
The image of the intended part cannot be captured.	The patient may not be looking at the fixation target at the time of image capture	Instruct the patient to focus on the fixation target.
	The intended part may be outside the range for image captures.	Insert a compensation lens.
The quality of the captured image is low.	The objective lens or the lens of Anterior segment adapter may be contaminated.	Perform the cleaning.
	The patient's eyelid or eyelashes may be interfering with image capture.	Ask the patient to open their eyes wider. If the patient cannot open their eyes wider, lift the patient's lid, paying attention not to press against eyeballs.
The captured image is dark.	Alignment to and focus on the anterior eye front may not proper.	Manipulate the joystick to align the working dot to the center of the target mark.
	The amount of light for image capture may not be sufficient.	Increase flash intensity.
The internal fixation target is blurred.	The internal fixation target may be blurred because of compensation lens.	Remove compensation lens.

8

8 Specifications and Accessories

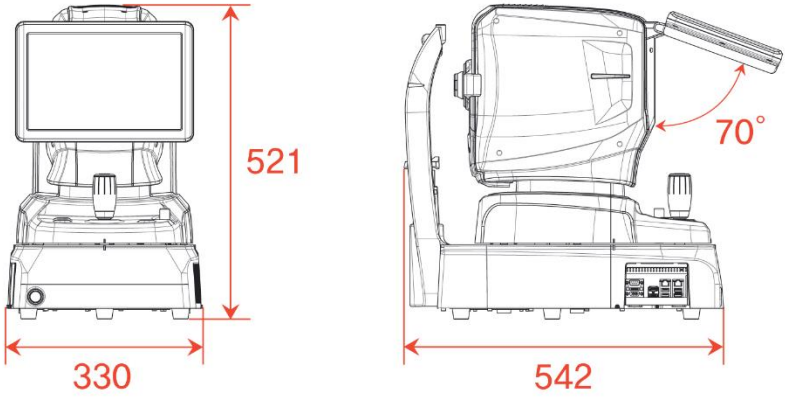
8.1. Standard Accessories

Chinrest paper	Touch pen	Power cable
 Fuse (250V T 3.15A)	Dust cover	 External LED
 Blower	 User manual	Packing lock cap
Model Eye		
anterior headrest rubber (optional)	 Anterior segment adapter (optional)	USB memory (optional)

8.2. Specifications

OCT	
Principle	Spectral domain OCT, Fundus digital photography
Light source	840 nm
Scan speed	Max. 68,000 A-scan/sec.
Resolution in tissue	20 um(Lateral), 7 um(z-axis) at index 1.36
Scan Range	X: 6 ~ 12 mm, Y: 6 ~ 9 mm, Z: 2.34 mm
Display resolution	X: 5.85 um, Y: 23.40 um, Z: 3.05 um
Minimum pupil diameter	2.5 mm
Scan patterns	Macular: Macular Line, Macular Cross, Macular Radial, Macular 3D, Macular Raster Disk: Disc Circle, Disc Radial, Disc 3D, Disc Raster
Optical power at cornea	≤ 650 uW
Acquisition time of 3D image	1.4 sec. (Normal mode, A512 x B96)
Depth Accuracy (measuring 1mm glass)	±3%
Fundus Camera (HOCT-1F)	
Type	Non-mydriatic fundus camera
Resolution	60 line pair/mm (center), 40 line pair/mm (middle), 25 line pair/mm (periphery)
Angle of view	45˚
Camera	Built-in 12Mega pixel, Color
Minimum pupil diameter	4.0 mm (Normal mode), 3.3 mm (Small pupil mode)
Flash light	White light, 10 levels
Pixel pitch at fundus	4.63 um
Common specification	
Working distance	33 mm
Display	12.1 inch, 1280x800 pixel, Touch panel color LCD
Dioptric compensation for patient's eye	-33D ~ +33D total -13D ~ +13D with no compensation lens +7D ~ +33D with plus compensation lens -33D ~ -7D with minus compensation lens
Internal fixation target	LCD (internal), White LED (external)
Fundus illumination light	760 nm
Horizontal movement	70 mm (back and forth), 100 mm (left and right)
Vertical movement	30 mm
Chinrest movement	62 mm (up and down), motorized
Auto tracking	30mm (up and down), 10 mm (right and left), 10mm (back and forth)
Power supply	AC 100 - 240 V, 50/60 Hz, 1.6 - 0.7 A
PC	Built in computer
LCD Tilting Angle	70˚
External port	2 USB, 1 DP, 1 RGB, 2 LAN
Dimensions	330(W) x 542(D) x 521(H) mm
Mass	30 kg
Anterior segment adapter (optional)	
Working distance	15 mm
Scan range	6 ~ 9 mm (width), 2.3 mm (depth)
Scan pattern	ACA line, Anterior Radial, Anterior 3D

8.3. Drawings of System



9

9 EMC INFORMATION

Manufacturer announcement – electromagnetic waves trouble

- **Electromagnetic waves trouble**

  HOCT-1/1F should be used in the below mentioned electromagnetic wave environment. HOCT-1/1F purchaser or user needs to confirm whether HOCT-1/1F is used in this type of environment.

Trouble test	Question of appropriateness
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker IEC 61000-3-3	Complies

- **Electromagnetic waves tolerance**

  HOCT-1/1F is to be used in the below designated electromagnetic wave environment. HOCT-1/1F customer and user need to guarantee that the HOCT-1/1F will be used in this type of environment.

Tolerance test	IEC 60601 test level	Appropriateness level
Electrostatic discharge(ESD) IEC 61000－4－2	contact ±8 kV in the air ±15 kV	contact ±8 kV in the air ±15 kV
Electric rapid transients/bust IEC 61000－4－4	power supplying line ±2 kV input/output line ±1 kV	power supplying line ±2 kV input/output line ±1 kV
Surge IEC 61000－4－5	between lines ±1 kV between line and grounding ±2 kV	differential mode ±1 kV common mode ±2 kV
Voltage dip, instantaneous interruption, voltage fluctuation at the power input line IEC 61000－4－11	For 0.5 cycle < 5 %UT(UT's > 95 % decrease) For 5 cycle, 40 % UT(UT's 60 % decrease) For 25 cycle, 70 %UT(UT's 30 % decrease) For 5 seconds < 5 % UT(UT's > 95 % decrease)	For 0.5 cycle < 5 %UT(UT's > 95 % decrease) For 5 cycle, 40 % UT(UT's 60 % decrease) For 25 cycle, 70 %UT(UT's 30 % decrease) For 5 seconds, < 5 %UT(UT's > 95 % decrease)
Power frequency magnetic field (50/60 Hz) IEC 61000－4－8	30 A/m	30 A/m
Other UT is the a.c. power voltage for before approving the test level.		

- **Electromagnetic waves tolerance**

  HOCT-1/1F is to be used in the below mentioned electromagnetic wave environment. HOCT-1/1F purchaser or user needs to confirm whether HOCT-1/1F is sued at this environment.

Tolerance test	IEC 60601 test conditions	Appropriateness level
Conductivity RF electromagnetic field IEC 61000－4－6	3 Vrms 150 kHz～80 MHz	3 Vrms
Radioactivity RF electromagnetic field tolerance IEC 61000－4－3	10 V/m 80 MHz～2.7 GHz scope	10 V/m

10

10 SERVICE INFORMATION

Repair: If the problem is not solved in spite of the settlement according to the contents of chapter 7, please contact to Huvitz's agent with the information on the following items.

1.1 Name of Equipment Type: Optical Coherence Tomography HOCT-1F/ HOCT-1
1.2 Typical No.of Equipment: Typical number consisted of 8 digits and characters written on its name plate.
1.3 Explanation on its symptom: Description in detail.

Supply of parts required for repair:

1.4 The preservation period of parts required for repair of this machine is by seven(7) years after stopping to produce the product.

Parts to be repaired by qualified service manpower:

1.5 Parts below are consumable in their characteristics, or the quality of them shall degraded after the long time use. User should not replace them by him or herself. Please contact to Huvitz`s agent for the replacement if these parts are consumed enough or degraded by the longtime use.

1.6 Back up battery for clock and data.

How to Contact HUVITZ Co., Ltd

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11

11 SOFTWARE LICENSE AGREEMENTS

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