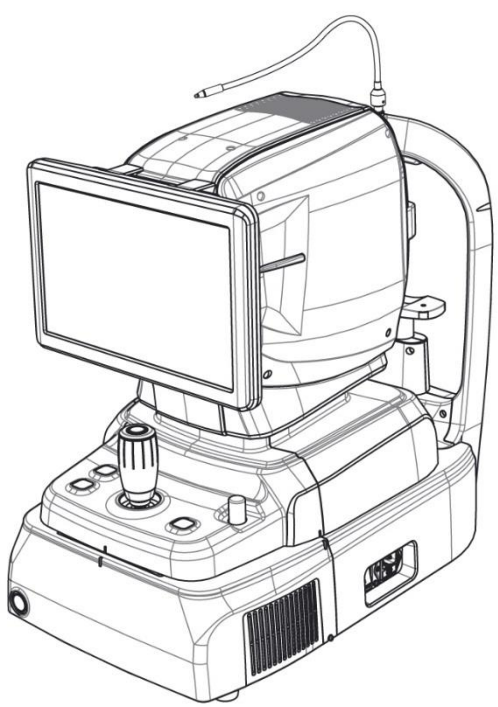
Huvitz

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

Revision	Date	Approval	Description
A	2017.11.21		First issued

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38, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea

CONTENT

1

1 SAFETY PRECAUTIONS

1.1. For Safe Use

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.

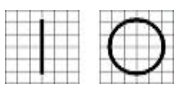
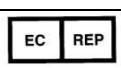
⚠ NOTE

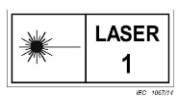
This is used to emphasize essential information.
Be sure to read this information to avoid operating the device incorrectly.

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

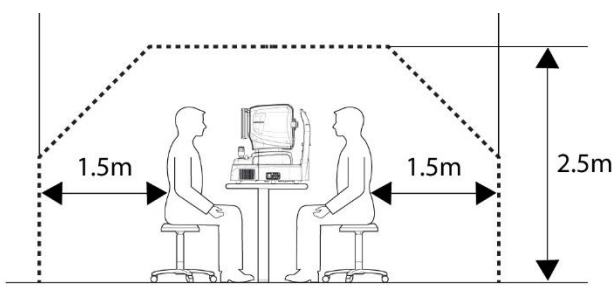
This equipment has been developed and tested in conformity with domestic & international safety standards and regulations, which guarantees the high stability of this product. This guarantees a very high degree of safety for this device. The legislator expects us to inform the user expressively about 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]

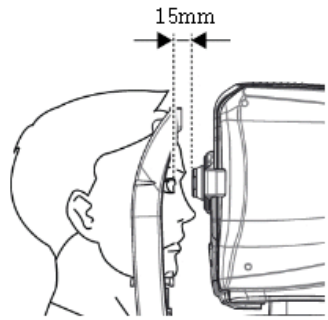


If and instrument that does not comply with IEC 60601-1 is to be used, use an isolation transformer.

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 of instrument slowly while watching patient's eye to prevent the anterior segment adapter from coming into contact with the patient's face or eye.



⚠ CAUTION

This instrument include lithium battery. This hazardous materials need to be disposed of properly to limit environmental pollution. please contact to the professional waste disposal company

⚠ 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 an optical equipment.

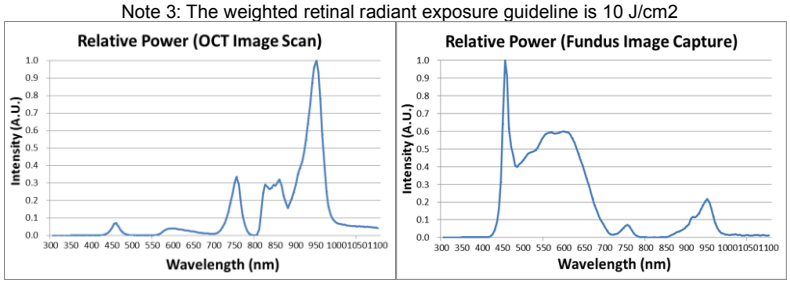
However, observe the following precautions when using the equipment

- 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

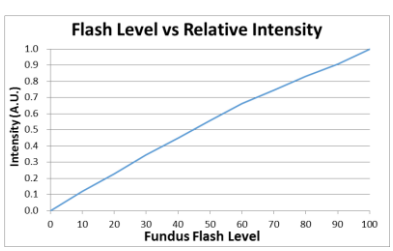
Note 1: The exposure time and number of pulses from all light sources is cumulative and additive.

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



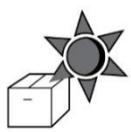
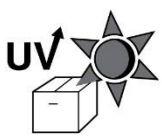
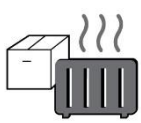
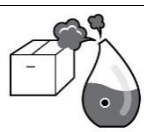
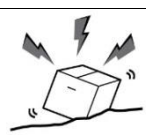
<Spectrum output of all light source during measurement (maximum light intensity)>

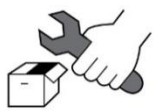
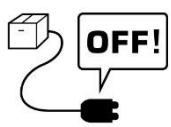
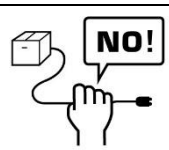


<Relationship between fundus flash level and maximum light intensity>

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 a 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 cord 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 cord 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

This instrument has been developed and tested according to safety standards as well as national and international standards. This guarantees a very high degree of safety for this device. HUVITZ is legally required to inform the users of all the information regarding safety. Observance of the instructions is the requirement for the safety. Therefore, please read carefully all instructions before switching on this instrument. For more detailed information, please contact our Customer Service Department or one of our local agencies.

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 (a) in an area that is in danger of explosions and (b) 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.

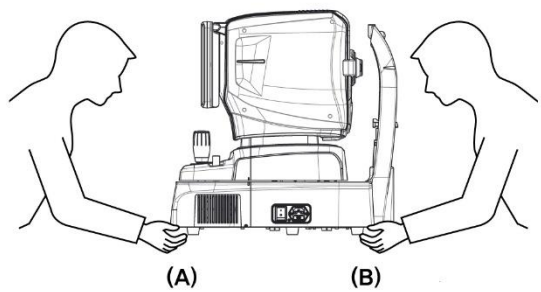
21. Do not place the instrument where it is difficult to operate the disconnecting device. (disconnecting device: power cord)

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

23. The equipment must be operated only by, or under direct supervision of properly trained and qualified person/s.

24. 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.

25. When you carry this product, please hold on left and right bottom of the product. If you want the product to be installed on another place, please call A/S center.



3

3 BEFORE USE

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. Intended Patient population

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 condition, it is not possible to take a picture correctly

3.6. Intended User Profile

This is an electric medical device. Use under doctor or ophthalmologist's guide.

3.7. Operating Principles

3.7.1. 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.

3.7.2. 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

3.8. Applied Standard List

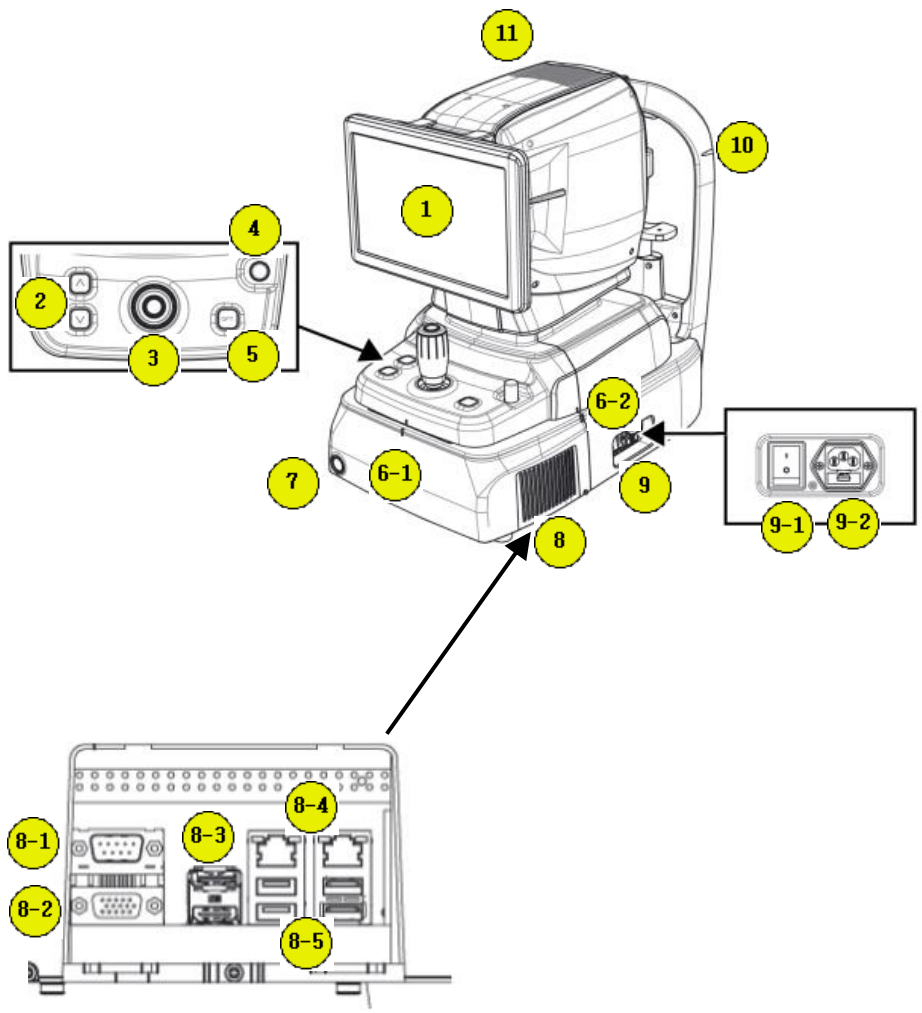
- IEC/EN 60601-1: MEDICAL ELECTRICAL EQUIPMENT
  – Part 1: General requirements for safety
- IEC/EN 60601-1-2: Medical electrical equipment Part1: General requirements for safety
  - Collateral Standard: Electromagnetic Compatibility-Requirements and tests
- ISO15004-1: Ophthalmic instruments
  - Fundamental 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

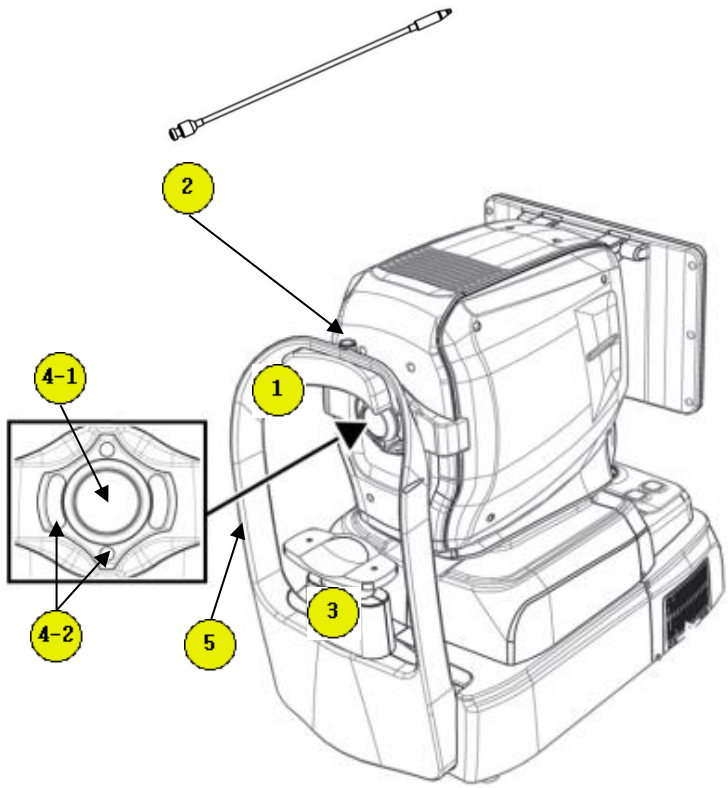
4.1. Configuration and Functions

Front View



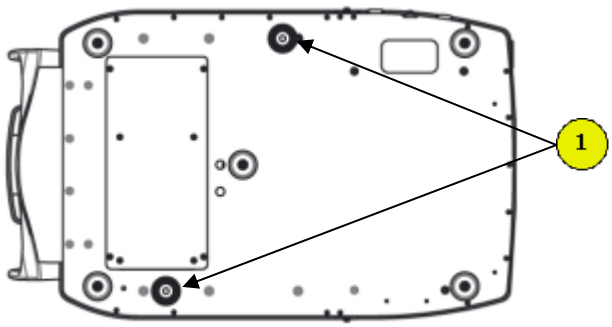
No	Part	Name	Description
1	Display	LCD	Monitor for displaying captured image and user interface icon.
2	Body	Chinrest button	Button for moving chinrest up and down.
3		Joystick	Joystick for aligning body to patient's eye. Button for capturing image.
4		User Lock	Lock for fixing body to base frame.
5		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.
8		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)
9-1		Power switch	Switch for power on/off.
9-2		Power inlet	Inlet for connecting power cord.
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.

Bottom View

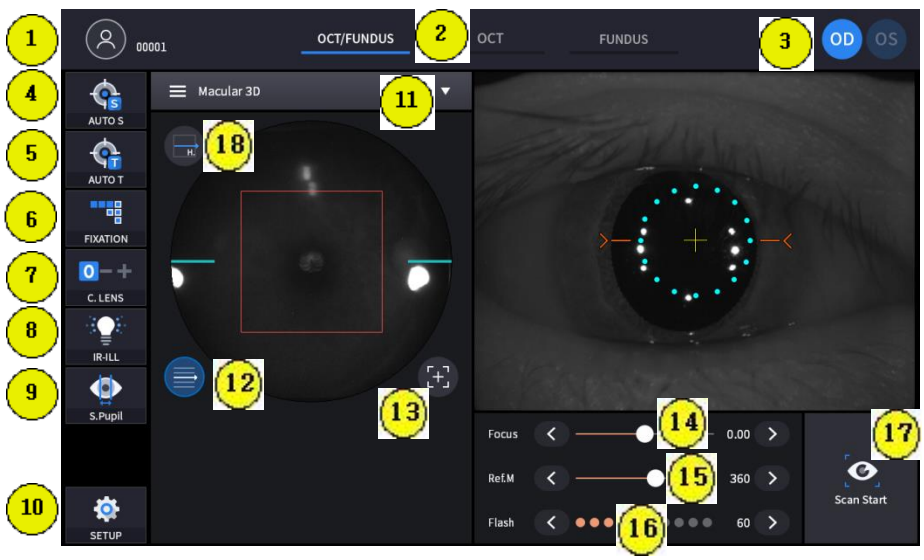


No	Part	Name	Description
1	Base	Packing lock	Lock for fixing body and base during transportation. (2 points)

4.2. Main Body Screen Description

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

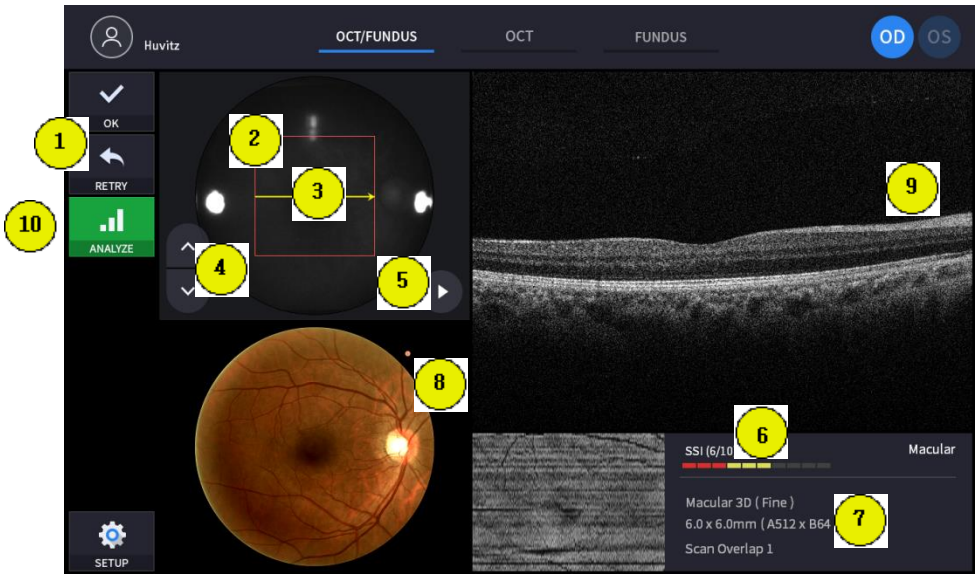
Observation screen



	Name	Description
1	Patient information	Show patient name and ID number. Can be moved to select/resist patient mode by clicking.
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

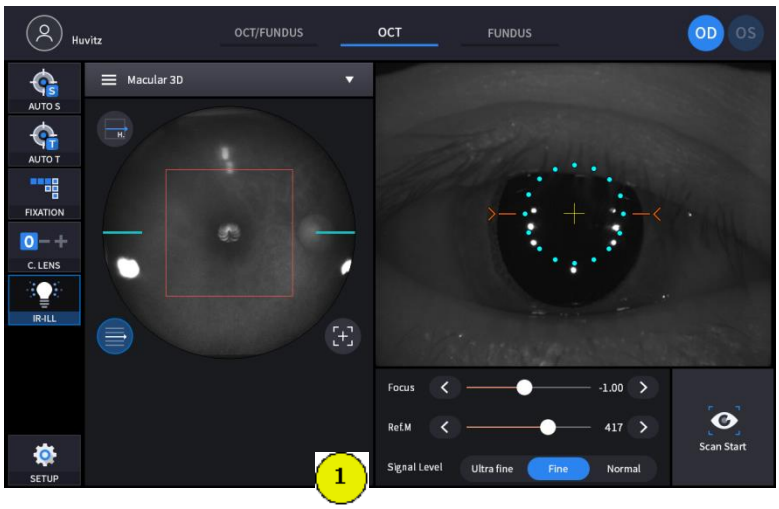


(Refer '3.2.1. OCT/Fundus mode – Observation screen' for uncommented item)

	Name	Description
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	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



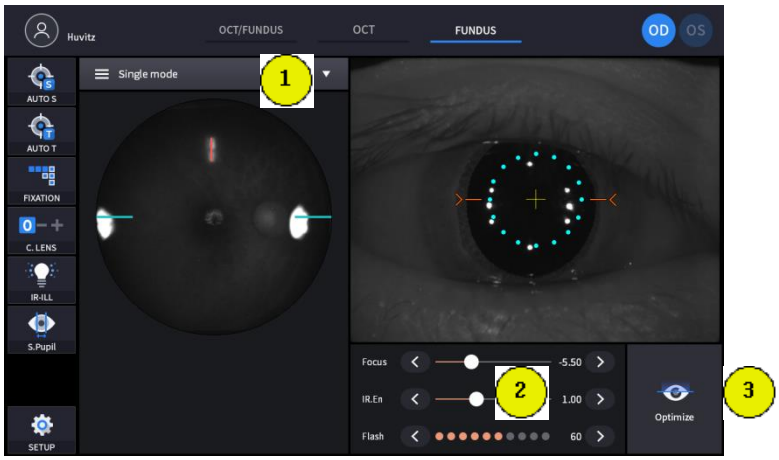
(Refer '3.2.1. OCT/Fundus mode – Observation screen' for uncommented item)

	Name	Description
1	Signal Level	Mode can be changed

Confirmation screen

(Refer '3.2.1. OCT/Fundus mode – Confirmation screen' for uncommented item)Fundus mode (HOCT-1F only)

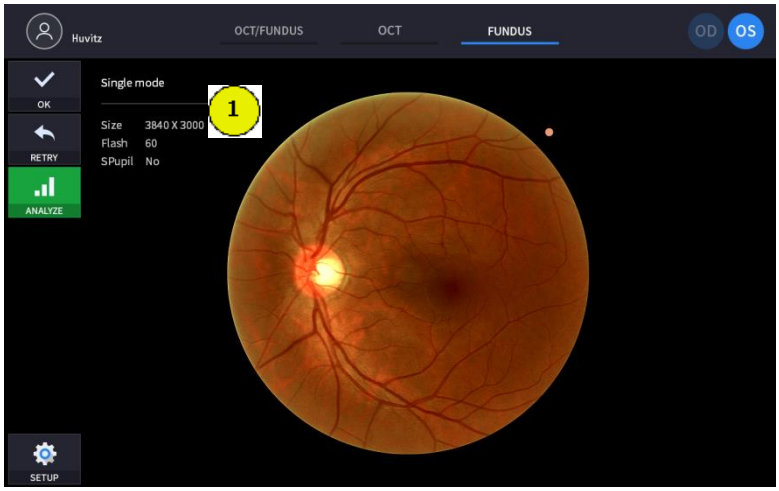
Observation screen



(Refer '3.2.1. OCT/Fundus mode – Observation screen' for uncommented item)

	Name	Description
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 fundus image
3	Optimize	Find focus position automatically by split focus image.

Confirmation screen



(Refer '3.2.1. OCT/Fundus mode – Confirmation screen' for uncommented item)

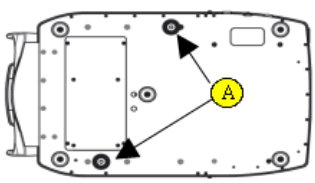
	Name	Description
1	Fundus information	Display setting information of fundus image.

5

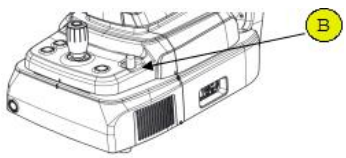
5 Installation Procedure

5.1. System installation

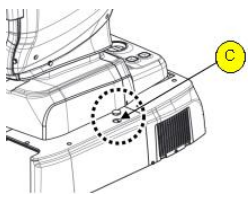
① Place the main body unit on a stable table.
② Loosen the two packing lock screw (A) under the main body.
③ Unscrew the user lock lever (B) on the body.
④ Attach two base packing lock cap(C) while moving body left and right with joystick.



Packing lock screw

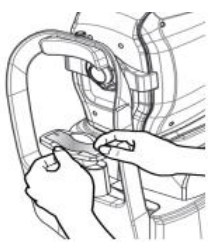


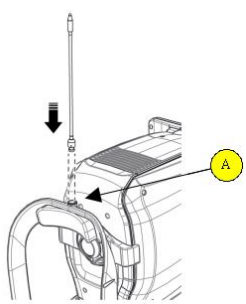
User lock lever



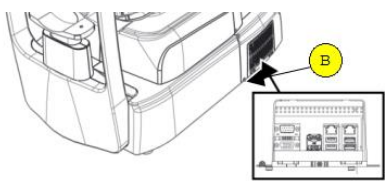
Packing lock cap

⑤ Attach the chinrest paper to the chinrest.
⑥ Attach external LED to the headrest (A).
⑦ If needed, connect external devices.
- Open Communication cover (B) on the right bottom of base with screw driver.
- Connect communication cable of external device.
- Close communication cover (B) with screw driver.


Chinrest paper



External LED

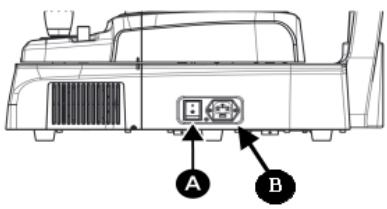


Communication port cover

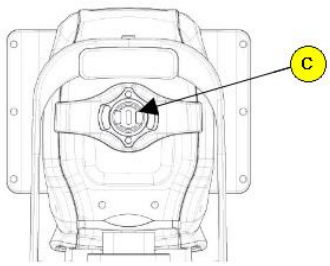
⑧ Check the power switch (A) on the bottom right of base is off. (O position).

⑨ Connect power cord to power inlet (B). Also, connect the other side of power cord to electric outlet.

⑩ Remove objective lens cap (C), and check objective lens is clean,



Power switch and inlet



Objective lens cap

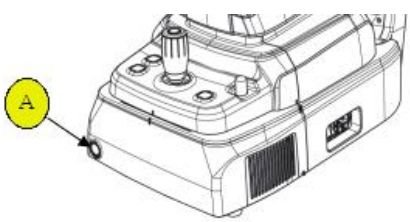
⑪ If external devices are connected, turn on external devices first.

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

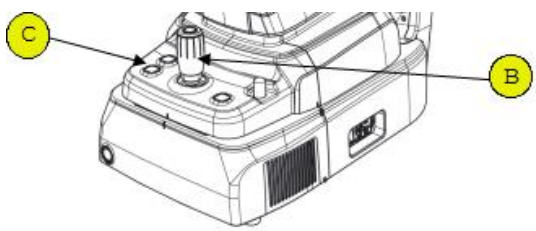
⑬ Turn on the internal PC by pressing power button (A).

⑭ Check there is no error during initialize process.

⑮ Check the movement of body with joystick (B). Also, check the movement of motorized chinrest with chinrest button (C)



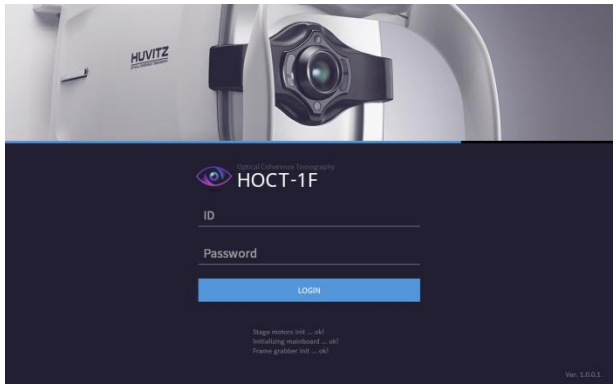
Power button



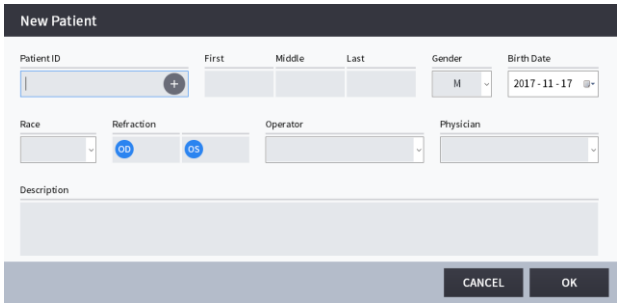
Joystick and chinrest button

5.2. Software

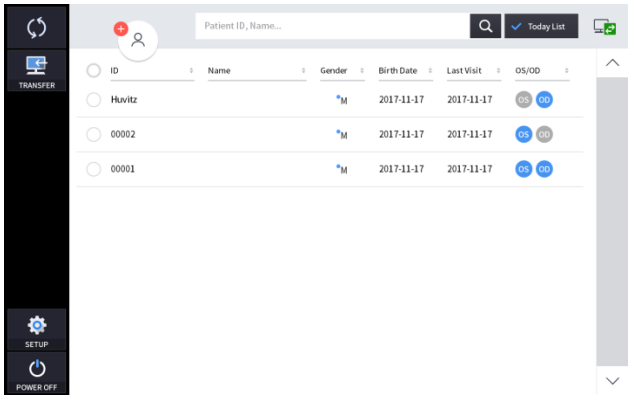
① Input user ID and password for login.



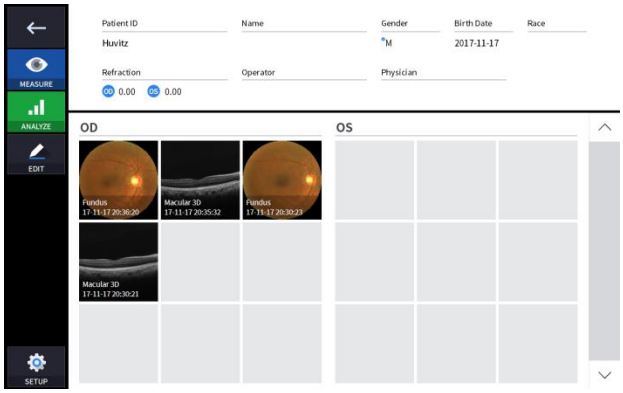
② Press resist patient icon ( ) and input patient information. If patient is resisted already, skip this step.



③ Select patient and check patient information is correct.



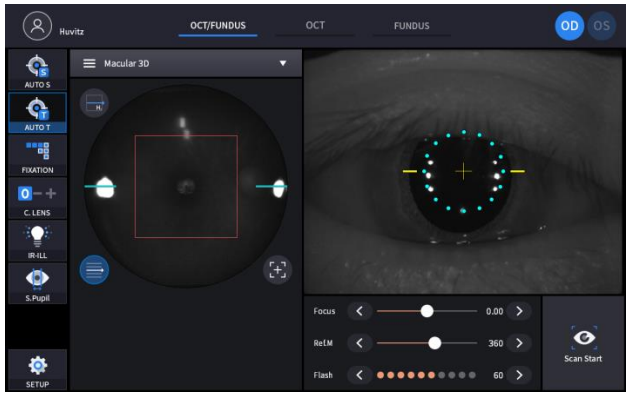
④ When you select a patient, the screen changes.



⑤ Enter observation mode by pressing measure icon (

).

The screen of observation mode is as follow.

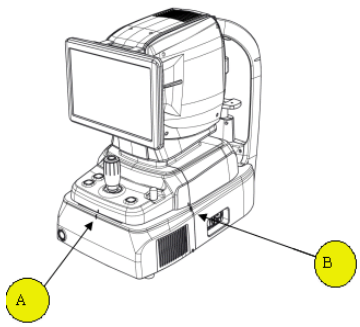


6

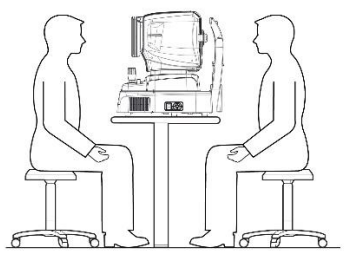
6 Operation

6.1. General Operation

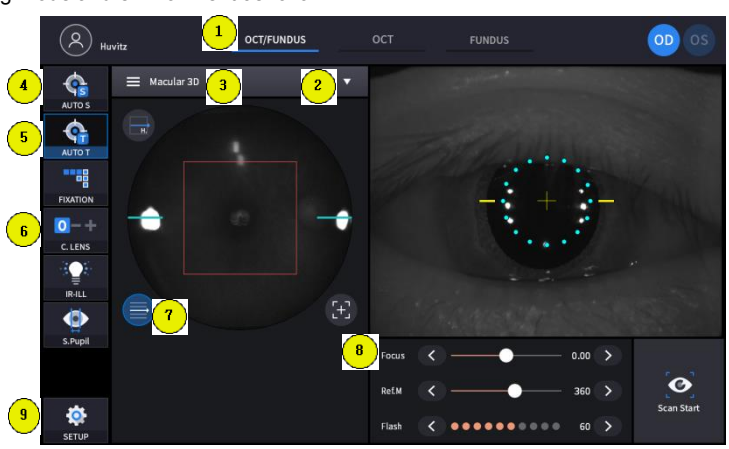
1. Clean headrest and chinrest with a clean cotton swab or gauze. Remove a single sheet of chinrest paper if the chinrest paper is used.
2. Align left/right index mark (A) and front/rear index mark (B) of body and base with joystick.

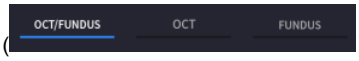


3. Let the patient sit in front of instrument.



4. Setting mode and environment as follow.



4-1. Set capture mode by capture mode icon (

)

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

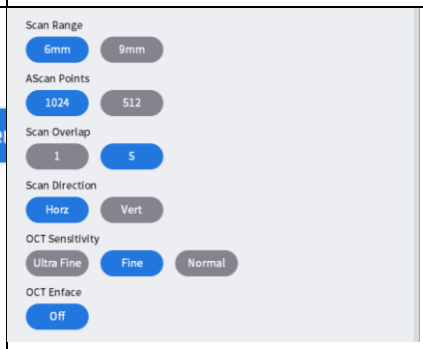
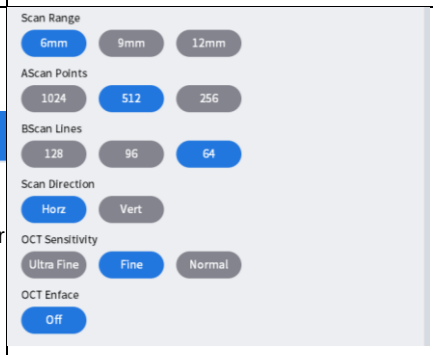
4-2. Set capture region by capture region icon (

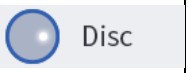
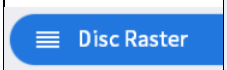
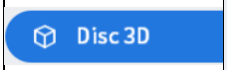
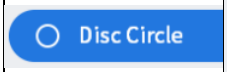
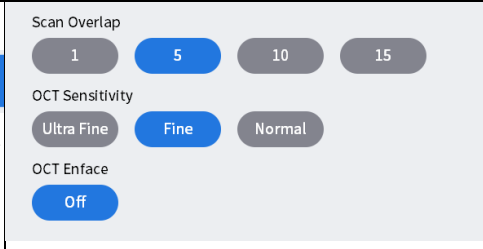
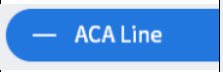
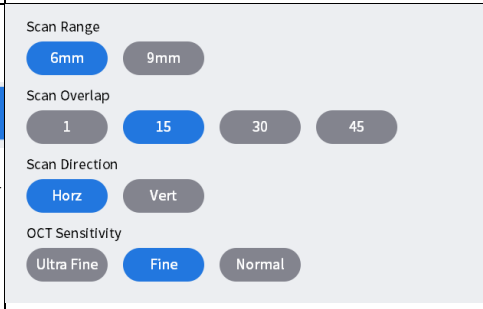
)

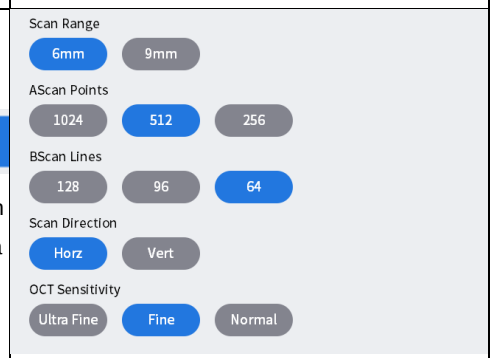
OCT/Fundus	**Macular, Disc, Anterior**
OCT	
Fundus	Single, Panorama

4-3. In OCT or OCT/Fundus mode, set scan type and option of scan region.

Scan region	Scan type	Available option
Macular	Macular Line Scan along a line for macular	Scan Range: 6mm, 9mm, 12mm Scan Overlap: 1, 15, 30, 45 Scan Direction: Horz, Vert OCT Sensitivity: Ultra Fine, Fine, Normal OCT Enface: Off
	Macular Cross Scan along horizontal lines and vertical lines for a macular	Scan Range: 6mm, 9mm, 12mm Scan Overlap: 1, 5, 10, 15 Space Between: 0.15mm, 0.20mm, 0.25mm, 0.30mm, 0.35mm OCT Sensitivity: Ultra Fine, Fine, Normal OCT Enface: Off

	Macular Radial Scan along 12 lines based on one center for a macular	
Macular	Macular Raster Scan along several lines for a macular	
	Macular 3D Scan along more than 100 lines for a macular	
Disc	Disc Radial Scan along 12 lines based on one center for an optic disk	

<table>
<tr><td rowspan="3">  </td><td> 
Scan along several lines for an optic disk</td><td>  </td></tr>
<tr><td> 
Scan along more than 100 lines for an optic disk</td><td>  </td></tr>
<tr><td> 
Scan along a circle for an optic disk</td><td>  </td></tr>
<tr><td>  </td><td> 
Scan along a line for a cornea</td><td>  </td></tr>
</table>

	Anterior Radial Scan along 12 lines for a cornea	
	Anterior 3D Scan along more than 100 lines for a cornea	

<Scan Options>

- Range: Set a scanning range which is one of 6mm, 9mm, or 12mm.
- A-Scan: Set a number of A-scan which is one of 1024, 512, or 256.
- B-Scan: Set a number of B-scan which is one of 1024, 512 or 256
- Overlap: Set a number of a scan, and make an average of all repeated scans.
- Direction: Set a direction which are horizontal or vertical.
- Space: Set an interval between neighboring scan lines.
- Enface: Set on or off for a live enface image.
- Sensitivity: Set a scanning speed which is one of normal, fine, or ultra fine.

4-4. Set auto shooting status if needed.

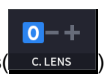
	**Auto shooting is on.**
	Auto shooting is off.

- If auto shooting is on, image is automatically optimized and captured when alignment and focus of patient's eye is done.
- In anterior capture mode, auto shooting is not supported.

4-5. Set auto tracking status if needed.

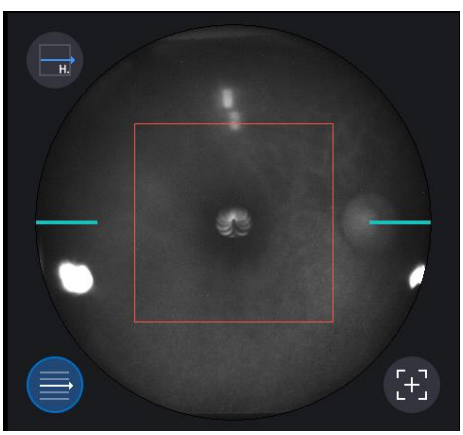
	**Auto tracking is on.**
	Auto tracking is off.

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

4-6. Set compensation lens status() if needed.

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.

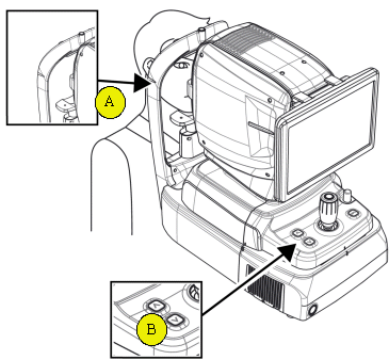
4-9 Pushing SETUP button, it enters USER SETUP mode.

If you want to change, then touch selections.

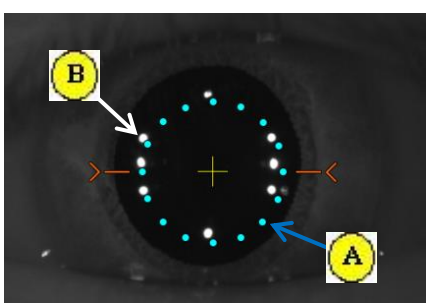
Push [OK] button, save automatically and the SETUP window disappears.

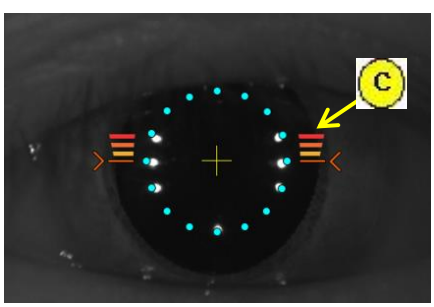
Item	Subdivision	Selections	Note
System	Device Name	HuvitzOCT	
	Server IP	127.0.01	
	Server Port	80	
	Sleep Time	Off 5min 10min 30min	
	Update Period	1sec 3sec 5sec 10sec	
	Auto Data Trans	On Off	
	Auto Data Clear	On Off	
	Duplicated Patient	Remove Change	
	Packing Mode	On Off	
Patient	Patient List Size	50 100 150 200	
	Today List	On Off	
	PIP Prefix		
	PIP Postfix		
	PIP Number Length	5 6 7 8	
	Data Format	YMD MDY DMY	
Measure	Startup Measure	OCT-Fundus OCT Fundus	
	Auto Tracking	On Off	
	Auto Shot	On Off	
	Auto Scan Start	On Off	
	Flash Level		
	Fundus Image Range	Normal Extend	
	Preview Cross Scan	On Off	
Scan Pattern	Pattern Domain	Macular Disc Anterior	
	Macular Pattern	Line Cross Radial Raster 3D	
	Disc Pattern	Radial Raster 3D Circle	
	Anterior Pattern	ACA Radial 3D	
Analysis	Scan Image Color	Gray Pseudo Inverse	
	Scan Image Level		
	Auto Chart Center	On Off	
	Fundus Auto Enhance	On Off	
	Fundus Edge Sharpen	On Off	

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 height of chinrest by chinrest button (B) on the body until the patient's eye is on the same level of eye level mark (A)



6. Instruct to patient to watch internal fixation LED to fix patient eyes. Also, instruct to 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 ring are concentric, focus indicator bar (C) appears. Move the body back and forth with joystick until focus indicator bar is disappeared.

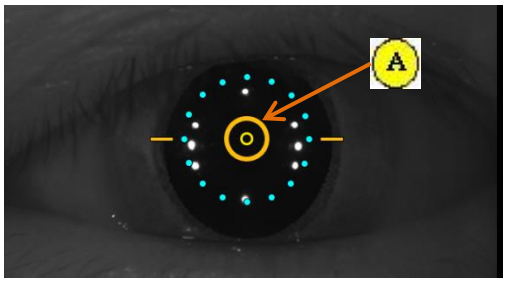




   8-2. If the pupil of patient is smaller than 16 blue align dot, press S.pupil icon(

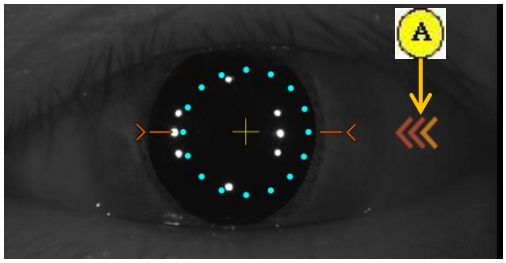
) for capturing small pupil mode.

8-3. Move joystick slightly 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.



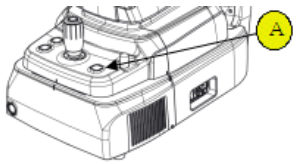
9. Capture image and check image quality (in OCT/Fundus mode)

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

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

)

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

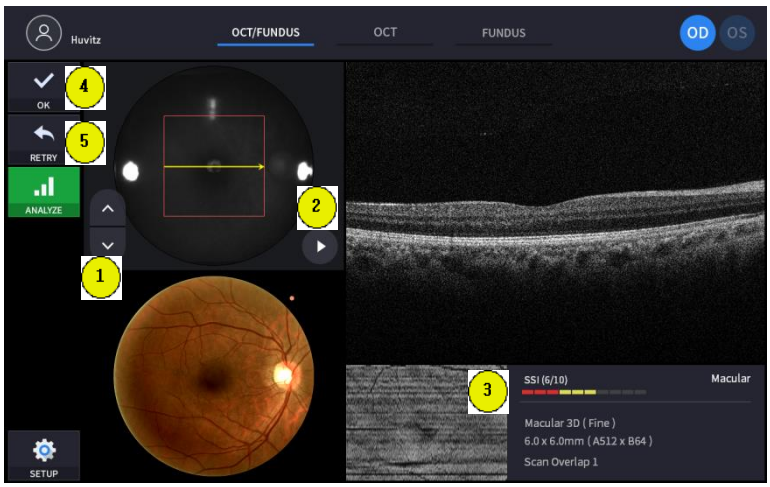


9-3. For enhancing OCT signal, move position of reference mirror by pressing arrow of REF.M icon (

) if needed.

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

9-5. Check image quality and process image.



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. If fundus image is too bright or too dark because of flash, change 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 changing scan position by dragging scan range while scan range icon turns on. If reset scan position icon (
) is pressed, scan position become default center position.

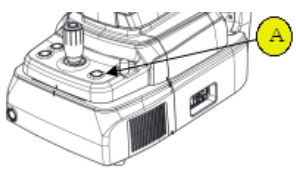
10. Capture image and check image quality (in OCT mode)

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

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

)

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

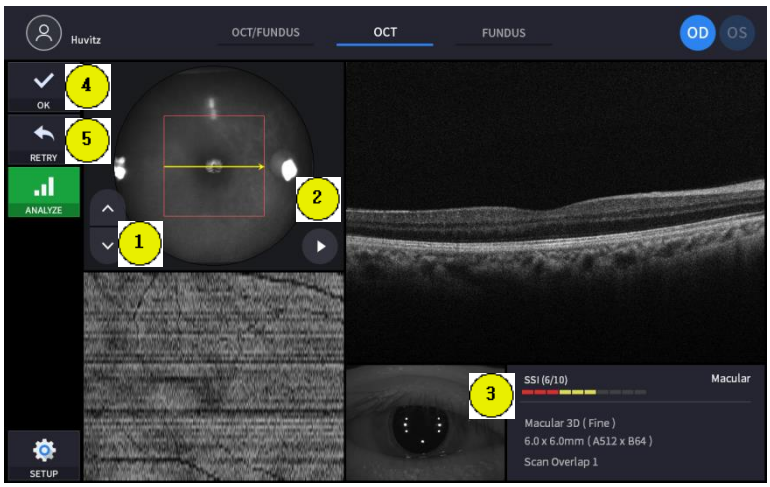


10-3. For enhancing OCT signal, move position of reference mirror by pressing arrow of REF.M icon (

) if needed.

10-4. Press joystick to capture image.
If auto shooting is on, '10-2. Optimize' and '10.5 Capture' is accomplished automatically.

10-5. Check image quality and process image.



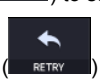
① Check previous/next OCT image by pressing move scan position button () if needed.

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.

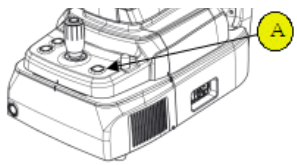
B. Try changing scan position by dragging scan range while scan range icon

turns on. If reset scan position icon ( ) is pressed, scan position become default center position.

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

11-1. Change the brightness of fundus image by pressing IR.En icon ( ) if needed.

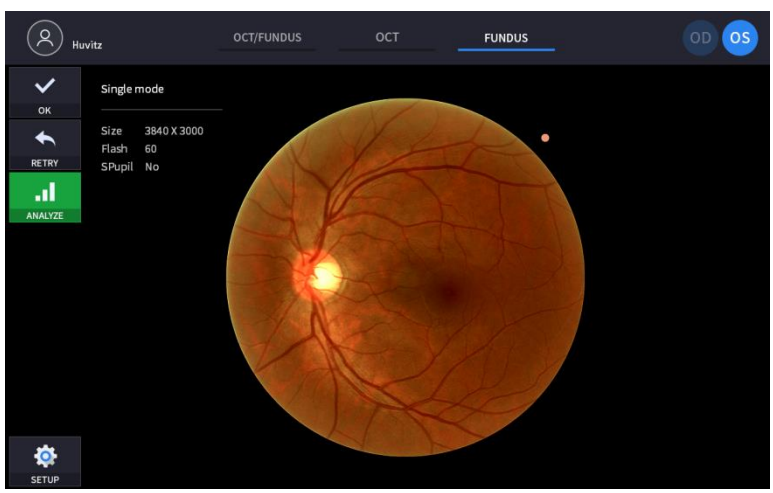
11-2. Change focus position by pressing optimize icon on the screen or optimize button on the body (A).



11-3. Press joystick to capture image.

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

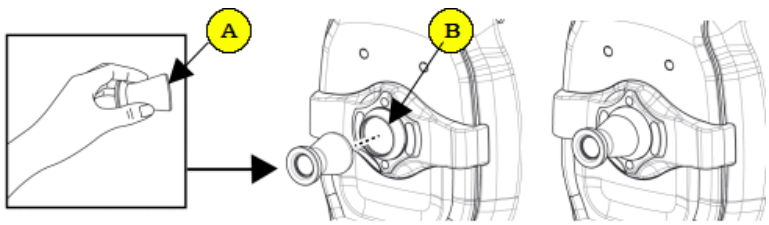
11-4. Check image quality and process image.



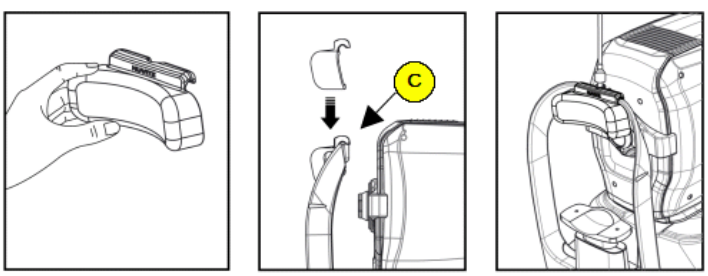
6.2. Anterior segment image operation (optional)

6.2.1. 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.

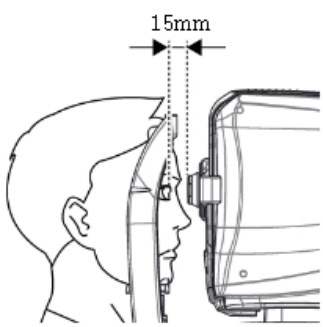


3. Check Anterior headrest rubber is clean.
4. Hang anterior headrest rubber to headrest of instrument (C) first, then press anterior headrest rubber to be fixed firmly.
5. Check the mounted anterior headrest rubber does not incline.



6.2.2. Capturing anterior segment

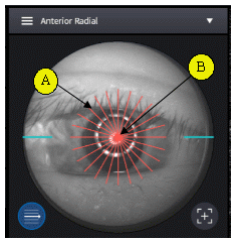
1. The first procedure is same as '5.1 General Operation: procedure 2 ~ 7'.
   - On the anterior mode, function of auto shooting and auto tracking is not available.
2. Move the body to align patient's eye. Move the body slowly while watching patient's eye and body, because working distance is 15mm so that body and patient's eye is very close.



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

3-1. Alignment and focus

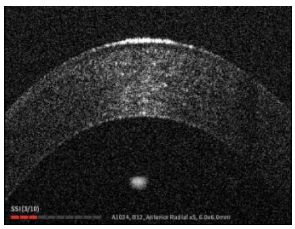
① Move body with joystick slowly to align anterior scan line (A) and center of patient's eye (B)



② Start OCT scan by pressing scan start icon (

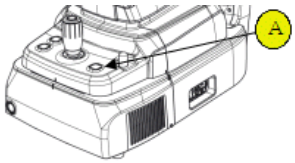
).

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).



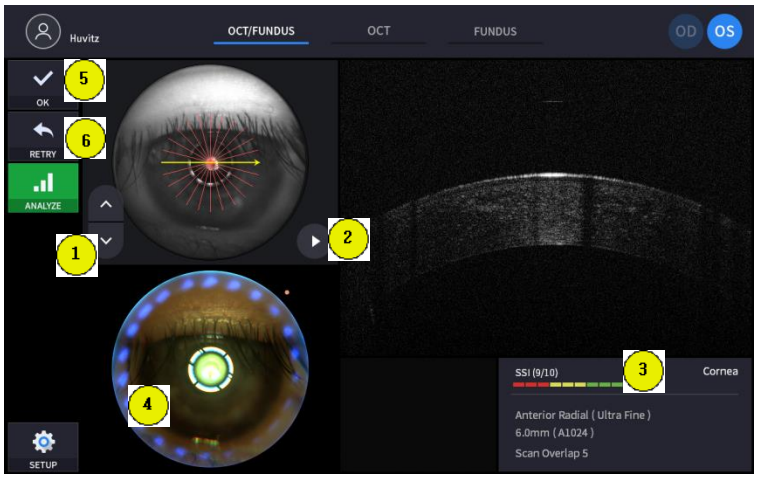
② For enhancing OCT signal, move position of reference mirror by pressing arrow of REF.M icon (

) if needed.

- This function available on OCT/Fundus mode.

③ Press joystick to capture image.

3-3. Check image quality



① The procedure is same as '9.5. Check image quality and process image' of front section.

② Check previous/next OCT image by pressing move scan position button () if needed.

③ Check continuous OCT image continuously by pressing play image button () if needed.

④ 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.

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 is too bright or too dark because of flash, change 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.

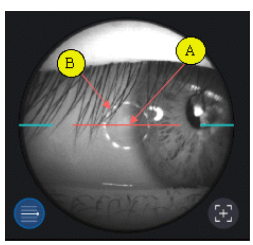
D. Try changing scan position by dragging scan range while scan range icon turns on. If reset scan position icon (
) is pressed, scan position become default center position.

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

4-1. Alignment and focus

① Instruct patient to watch eyes for proper capturing area (nasal or temporal).

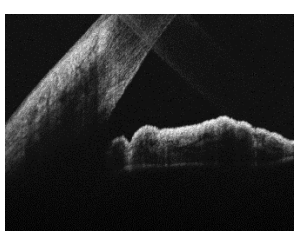
② Move body with joystick slowly to align anterior scan line (A) and objective area of capturing (B).



③ Start OCT scan by pressing scan start icon (

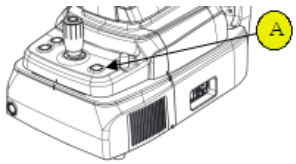
).

④ Move body with joystick slowly until ACA(anterior chamber angle) 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).



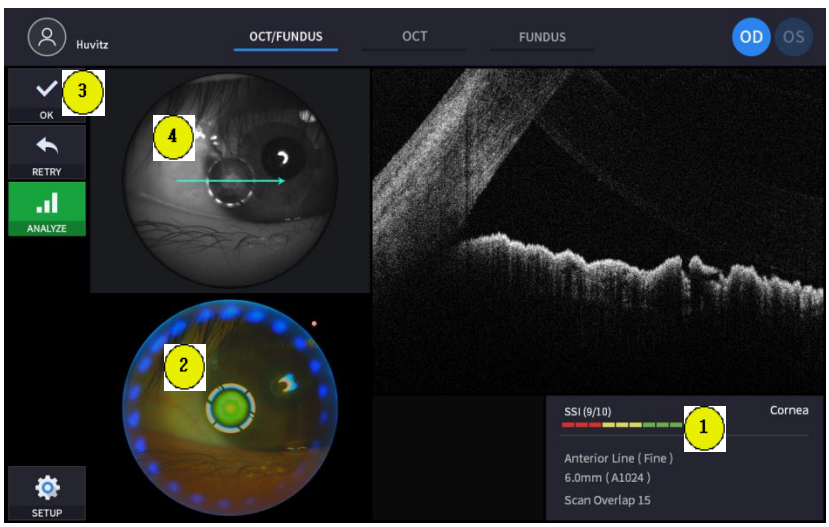
② For enhancing OCT signal, move position of reference mirror by pressing arrow of REF.M icon (

) if needed.

- This function available on OCT/Fundus mode.

③ Press joystick to capture image.

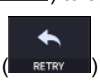
4-3. Check image quality



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 If the image is satisfactory, press OK icon (

) to save image.

③ If the image is not satisfactory, press retry icon (

) and retry image capturing.

A. If fundus image is too bright or too dark because of flash, change 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 changing scan position by dragging scan range while scan range icon turns on. If reset scan position icon (
) is pressed, scan position become default center position.

5. Repeat procedure 2 ~ 4 for the other eye if needed.
6. When capturing anterior segment is done, remove Anterior segment adapter and Anterior headrest rubber in reverse order of ‘5.2.1. Preparation for anterior segment operation’.

6.3. Maintenance

6.3.1. After operation

1. Exit HOCT software.
2. Turn off external devices (monitor, printer, etc.) if any external device is connected.
3. Select 'Shut down' in screen for exiting Windows.
4. Turn power switch off (O) in the base plate.

6.3.2. Cleaning

1. Cleaning objective lens and anterior segment adopter
   - ① Cover objective lens cap for protecting 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 with chopstick or cotton swab and moisten it 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 for protecting secondary infection.

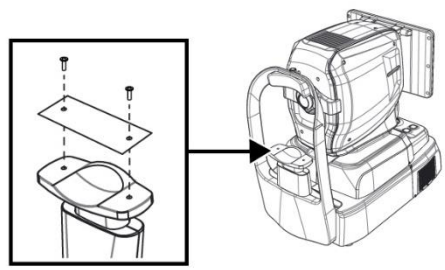
2. System exterior
   - ① Keep system exterior clean with a soft close. For severe stains, wipe with a soft cloth with neutral detergent diluted with water. Do not use organic solutions such as thinner or benzene.
   - ② Wipe the touch screen with dry soft cloth. Do not use sponge or cloth soaked with 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.

6.3.3. 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 cord 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.

6.3.4. Calibration

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

7

7 Troubleshooting Guide

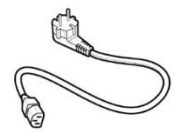
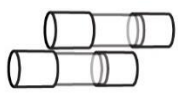
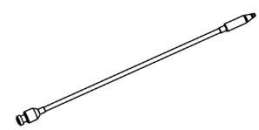
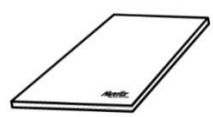
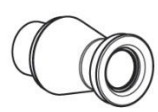
If problems occur, Please review the following list and take remedial action as needed. If you cannot solve the problem after checking the entire list, please contact HUVITZ

Problem	Cause	Solution
The screen does not turn on.	The power cord may not connected.	Check the connection of the power cord.
	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 system may be in sleep mode.	Restore the system from sleep mode by touching the screen.
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 are 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

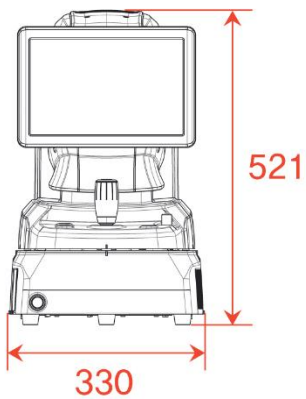
		
Chinrest paper	Touch pen	Power cable
		
Fuse (250V T 3.15A)	Dust cover	External LED
		
Blower	User manual	Packing lock cap
		
anterior headrest rubber (optional)	Anterior segment adapter (optional)	USB memory (optional)

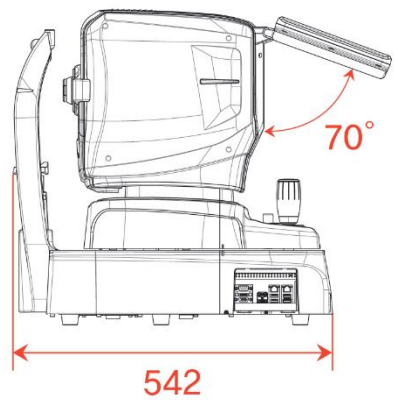
8.2. Specifications

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

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10 SERVICE INFORMATION

Repair: If the problem is not solved in spite of the settlement according to the contents of chapter 9, 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.
- Back up battery for clock and data.

How to Contact HUVITZ Co., Ltd

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EU Representative

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