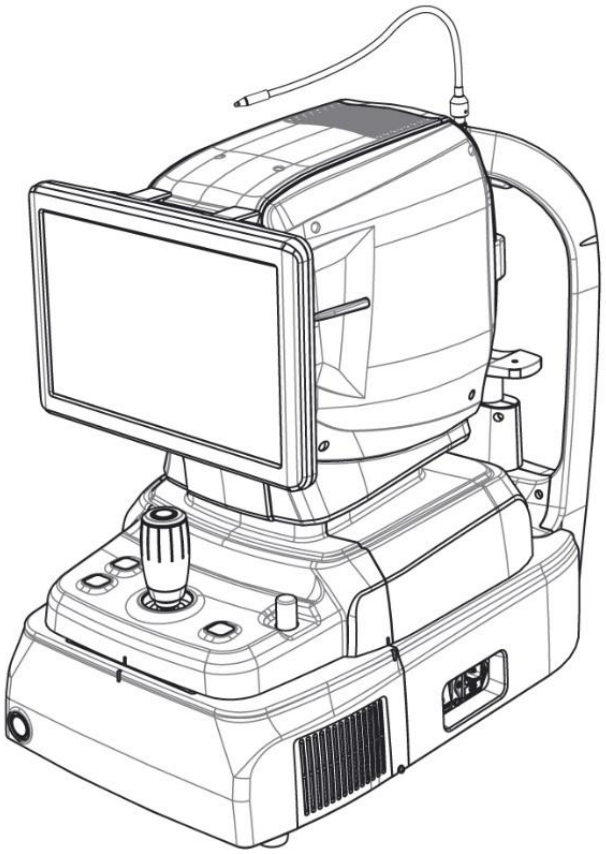
SWE

Huvitz

FUNDUS CAMERA

HFC-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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(2024/01/22)

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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.

"Warning" indique la présence d'un danger pouvant entraîner des blessures graves, la mort ou des dommages matériels importants s'il est ignoré.

⚠ CAUTION

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

"Caution" indique la présence d'un danger pouvant entraîner des blessures légères ou des dommages matériels en cas d'ignorance.

⚠ NOTE

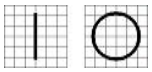
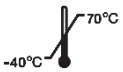
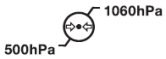
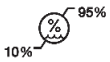
This is used to emphasize essential information.

Be sure to read this information to avoid operating the device incorrectly.

2

Symbol Information

The International Electrotechnical 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.

Symbol	Indication
	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. (Ce symbole identifie une note de sécurité. Assurez-vous de comprendre la fonction de ce contrôle avant de l'utiliser. La fonction de contrôle est décrite dans le manuel d'utilisation ou d'entretien approprié.)
	I and O on power switch represent ON and OFF respectively. (O sur l'interrupteur d'alimentation représentent respectivement ON et OFF.)
	Temperature Limitation (Limitation de température)
	Atmospheric pressure limitation (Limitation de pression atmosphérique)
	Humidity limitation (Limite d'humidité)
	Stack direction (Direction de la pile)
	Keep DRY (Garder au sec)
	Fragile , handle with care (Fragile, manipuler avec soin)
	Keep away from sunlight (Tenir à l'écart de la lumière du soleil)
	Stack layer limit (Limiter la couche de pile)
	CE Mark (Marque CE)
	Use no hook (N'utilisez aucun crochet)

	WEEE Symbol – EU only Disposal of your old appliance When this crossed-out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC. All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities. The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health. For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the product. (Symbole WEEE- EU seulement Mise au rebut de votre ancien appareil Lorsque ce symbole de poubelle barrée est joint à un produit, cela signifie que le produit est couvert par la directive européenne 2002/96 / CE. Tous les produits électriques et électroniques doivent être éliminés séparément du flux des déchets municipaux via des installations de collecte désignées par le gouvernement oules autorités locales. L'élimination correcte de votre ancient appareil aidera à prévenir les conséquences negatives potentielles sur l'environnement et la santé humaine. Pour plus d'informations sur l'élimination de votre ancient appareil, veuillez contacter votre mairie, le service d'élimination des déchets ou le magasin où vous avez acheté le produit.)
	Authorized representative in the European Community – EU ONLY (Représentant autorisé dans la Communauté européenne- EU seulement)
	Manufacturer (Fabricant)
	Date of manufacture (Il indique l'année de fabrication et le fabricant.)
	Refer to instruction manual/booklet (Se reporter au manuel d'instructions / brochure)
	Type B Isolated patient connection (Type B Connexion patient isolée.)
	Warning: Crushing or insert of hand (Attention: écrasement ou insertion de la main)
	QR code (QR code)

	Alternating Current (Courant alternative)
	Consult instructions for use (Consulter les instructions d'utilisation)
	The United States and Canada have mutual-recognition agreements. Therefore, if certified using a Canadian specification (CSA) for UL, the certification mark for the product will be a C-UL certification mark which means CSA specification compliance as follows. (Les États-Unis et le Canada ont conclu des accords de libre-échange. Par conséquent, si l'on obtient une certification au moyen d'une spécification canadienne (CSA) pour l'AMT, la marque de certification pour le produit sera une marque de certification C-UL, ce qui signifie la conformité de la spécification CSA comme suit.)
	CE for RoHS RoHS Directive Compliance 2011/65/EU (CE pour les RoHS Respect de la directive en matière de conformité 2011 / 65 / CE)
	Caution: Federal law restricts this device to sale by or on the order of a physician (Attention : la loi fédérale limite la vente de cet appareil par ou sur l'ordre d'un médecin)
	Authorized representative in Switzerland (Représentant autorisé dans la Suisse)
	To indicate this product is Medical device (Pour indiquer que ce produit est un dispositif medical)

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.

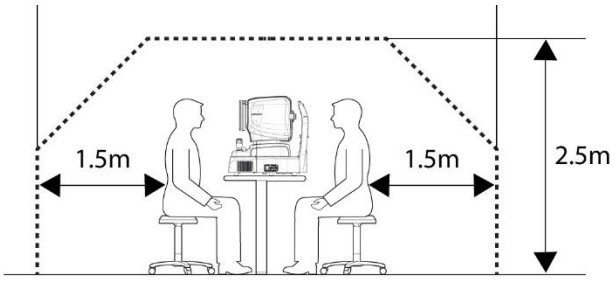
⚠ WARNING

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.

Pour l'utilisation d'équipements à une tension nominale inférieure à 125 Vca, minimum 6 A, type SJT ou SVT, 18 / 3AWG, 10 A, max 3,0 m de long: une extrémité avec type hospitalier, NEMA 5-15P Autre extrémité avec coupleur d'appareil.
Pour l'utilisation d'équipement à une tension nominale inférieure à 250 Vca, minimum 6 A, type SJT ou SVT, 18 / 3AWG, 10 A, max 3,0 m de long: une extrémité se termine par un bouchon de fixation de lame (HAR) de type NEMA 6-15P.

⚠ WARNING

Use instrument that comply with IEC60601-1 in the patient environment. [The figure below show]
Utilisez un instrument conforme à la norme IEC60601-1 dans l'environnement du patient. [La figure ci-dessous montre]



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.

Si un instrument non conforme à la CEI 60601-1 doit être utilisé, utilisez un transformateur d'isolement.
Si une personne manipulant une partie conductrice du système entre en contact avec un patient en même temps, un danger peut se produire en raison d'un courant de fuite dépassant la valeur spécifiée dans la norme applicable.
Veillez à ne pas toucher les patients lors de la connexion ou du retrait de la fiche d'alimentation ou des connecteurs de câble.

⚠ 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.

Cet instrument comprend une pile au lithium. Cette matière dangereuse doit être éliminée correctement pour limiter la pollution de l'environnement. Veuillez contacter la société professionnelle d'élimination des déchets.

⚠ CAUTION

Do not install any software on equipment without our consent.
The manufacturer is not responsible for any failure due to random installation.

N'installez aucun logiciel sur l'équipement sans notre accord.
Le fabricant n'est pas responsable de toute défaillance due à une installation aléatoire.

⚠ CAUTION

This equipment is a meets ISO 15004-2 Group1 specifications.
Cet équipement est conforme aux spécifications ISO 15004-2 Group1.

- 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 9.9×10^7 sec for Retina IR, 5.3×10^7 sec for Working dot(Manual Focusing), 4.1×10^7 sec for Kerato ring(Auto / Manual Tracking), 9.5×10^7 sec for Kerato focus(Auto/Manual Tracking), 1.0×10^8 sec for Split focus(Optimizing), 9.1×10^5 sec for external fixation lamp, 1,936,114 pulses for the light source of fundus image capture.

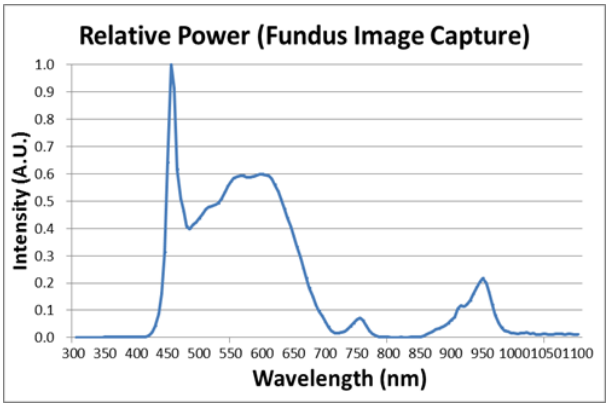
  Note 1: The exposure time and number of pulses from all light sources is cumulative and additive.
  Note 2: If the intensity of any of the light sources is reduced to 50% of the maximum intensity, the exposure time or number of pulses for that light source to reach the exposure guideline is doubled. 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

- Plus la durée d'exposition est longue et plus le nombre d'impulsions est élevé, plus le risque de lésions oculaires est grand. L'exposition à la lumière de cet instrument lorsqu'il est utilisé à la sortie maximale dépassera les directives de sécurité après 9,9 x 107 s pour la rétine IR, 5,3 x 107 s pour le point de travail (mise au point manuelle), 4,1 x 107 s pour l'anneau Kerato (suivi automatique / manuel) , 9,5 x 107 s pour la mise au point Kerato (suivi automatique / manuel), 1,0 x 108 s pour la mise au point divisée (optimisation), 9,1 x 105 s pour la lampe de fixation externe, 1 936 114 impulsions pour la source lumineuse de capture d'image du fond d'œil.

Remarque 1: Le temps d'exposition et le nombre d'impulsions de toutes les sources lumineuses sont cumulatifs et additifs.

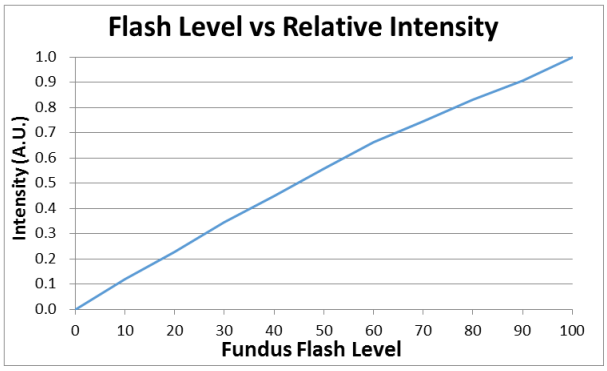
Remarque 2: Si l'intensité de l'une des sources de lumière est réduite à 50% de l'intensité maximale, le temps d'exposition ou le nombre d'impulsions pour que cette source de lumière atteigne la ligne directrice d'exposition est doublé. Cette relation linéaire peut être utilisée pour déterminer le temps nécessaire pour atteindre la ligne directrice d'exposition pour la combinaison de sources lumineuses à divers réglages d'intensité.

Remarque 3: La ligne directrice pondérée d'exposition au rayonnement rétinien est de 10 J/cm2



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

<Sortie spectrale de toutes les sources lumineuses pendant la mesure (intensité lumineuse maximale)>



<Relationship between fundus flash level and maximum light intensity>

<Relation entre le niveau de flash du fond d'œil et l'intensité lumineuse maximale>

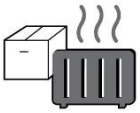
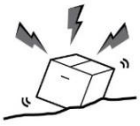
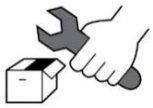
Intended User Profile

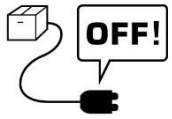
The device must be operated only by a, or under direct supervision of properly trained and qualified person/s such as ophthalmologist

a. Age: adult (> 21 years of age)
b. Occupation: Optometrist, ophthalmologist
c. Level of training: Recommend completing training how to use the device
d. Education: Basic training is required for the use of equipment. (Obtains a certificate of qualification such as optics, medical school, etc., after completing a certain amount of education)

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% (with non-condensing) 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% (with non-condensing) and atmospheric pressure is 700 ~ 1060hpa.

Avoid environments where the equipment is exposed to excessive shocks or vibrations.
Do not expose products or packing to environmental conditions outside of those specified above.

2.3. Safety Warnings

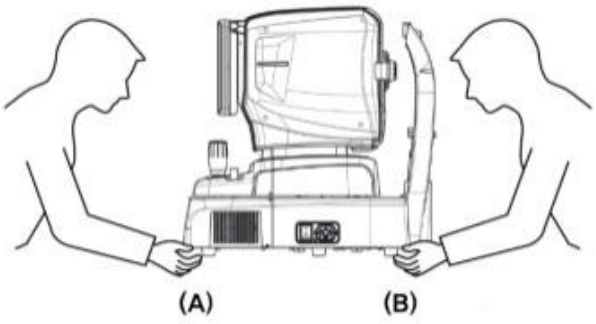
⚠ WARNING

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. 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.
4. 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.
5. The device must be operated by a trained and qualified person or under his or her supervision.
6. Repair of this instrument must be conducted by HUVITZ's service technicians or other authorized persons.
7. 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.
8. 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.
9. 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.
10. Only those who have undergone proper training and instructions are authorized to install, use, operate, and maintain this instrument.
11. 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.
12. Please do not pull on any cable. Always grab the plug when disconnecting cables.
13. Do not block any ventilation outlet necessary for proper heat dissipation.
14. 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.
15. To avoid the risk of electric shock, this instrument must only be connected to protective earth.
16. Do not place the instrument where it is difficult to operate the disconnecting device. (disconnecting

device: power cable)

17. 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.

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



19. Do not touch directly if an operator has a hand injury or a significant allergic reaction to the material used in the operation contact part.

Part Name	Material
LCD Touch pannel	Glass
Joystick / button	ABS + Silicon, Aluminum(A6061 T6) + Anodizing
Power switch	PC + PA66
Cover	ABS
Chin Rest	ABS

20. Do not measure to patients who are sensitive to light. (ex> photophobia)

21. 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 parts that come into contact with the patient) with a clean cloth dampened with rubbing alcohol.

22. In the event of a serious incident involving the device, the user shall report it to the manufacturer and the competent authority of the Member State in which the user and/or patient are established.

23. If a user uses power save supported by Windows 10 except for the power save in User setting, it causes some trouble in HFC-1. The manufacturer isn't responsible for the problem.

24. User must not change the setting supported by the manufacturer, this change might make some trouble in HFC-1. The manufacturer isn't responsible for the problem.

25. In the event of a serious incident involving the device, the user shall report it to the manufacturer and the competent authority of the Member State in which the user and/or patient are established.

26. When packing box is unintentionally open before use or damaged, please call A/S center.

27. Make sure that you always have an up to date virus scanner and firewall installed on your system.

28. Avoid resetting or turning off the PC when the HFC-1 running.

29. Even if back up is set to be performed, if the power is not turned on or if the backup location cannot be found, backup is not performed.

30. The connection of the electronic interface to an IT network that includes other equipment could result in previously unidentified risks to patients, users or third parties. The RESPONSIBLE ORGANIZATION is advised to identify, analyze, evaluate and control these RISKS.

31. Subsequent changes to the IT-NETWORK could introduce new RISKS and require additional analysis. Changes to the IT-NETWORK include:
1) changes in IT-NETWORK configuration
2) addition of items (hardware and/or software platforms or software applications to the IT-NETWORK
3) removal of items from the IT-NETWORK
4) update of hardware and/or software platforms or software applications on the IT NETWORK
5) upgrade of hardware and/or software platforms or software applications on the ITNETWORK

1. Il s'agit d'un appareil médical électrique. L'utilisation est limitée aux médecins ou aux personnes qualifiées par la loi de chaque pays

2. Ne faites pas de diagnostic de base sur une seule image capturée. Les médecins sont chargés d'établir le diagnostic final sur la base des dossiers médicaux actuels et passés du patient, tels que les images capturées. Sans informations suffisantes, un diagnostic approprié ne peut être établi.

3. Cet équipement ne doit pas être utilisé dans une zone à risque d'explosion et en présence de solvants inflammables, explosifs ou volatils tels que l'alcool, le benzène ou des produits chimiques similaires.

4. Ne placez pas et ne stockez pas cet instrument dans un endroit humide. N'exposez pas l'appareil à des projections d'eau, à des gouttes d'eau ou à de l'eau pulvérisée. Ne placez pas de récipients contenant des fluides, des liquides ou des gaz sur le dessus de cet instrument.

5. L'appareil doit être utilisé par une personne formée et qualifiée ou sous sa supervision

6. La réparation de cet instrument doit être effectuée par les techniciens de service HUVITZ ou d'autres personnes autorisées

7. La maintenance par les utilisateurs doit respecter le manuel de l'utilisateur et le manuel de service. Toute maintenance supplémentaire ne peut être effectuée que par les techniciens de service HUVITZ ou d'autres personnes autorisées

8. Les fabricants ne sont pas responsables des dommages causés par des modifications non autorisées. Une telle altération perdra tout droit de recevoir des services pendant la durée de la garantie.

9. Cet instrument doit être connecté aux accessoires fournis par HUVITZ. Si vous devez utiliser d'autres accessoires, leur sécurité ou leur utilisation doit être vérifiée et prouvée par leurs fabricants ou HUVITZ.

10. Seuls ceux qui ont suivi une formation et des instructions appropriées sont autorisés à installer, utiliser, utiliser et entretenir cet instrument.

11. N'appliquez pas de force excessive sur les connexions des câbles. Si le câble ne se connecte pas facilement, assurez-vous que le connecteur (fiche) est adapté à la prise (prise). Si vous avez causé des dommages à un ou plusieurs connecteurs ou prises de câbles, faites réparer les dommages par un technicien de maintenance agréé.

12. Veuillez ne tirer sur aucun câble. Saisissez toujours la fiche lorsque vous débranchez les câbles.

13. Ne bloquez aucune sortie de ventilation nécessaire à une bonne dissipation de la chaleur.

14. Si de la fumée, des étincelles ou un bruit ou une odeur anormale est remarqué provenant de l'instrument, veuillez éteindre immédiatement et débrancher la prise.

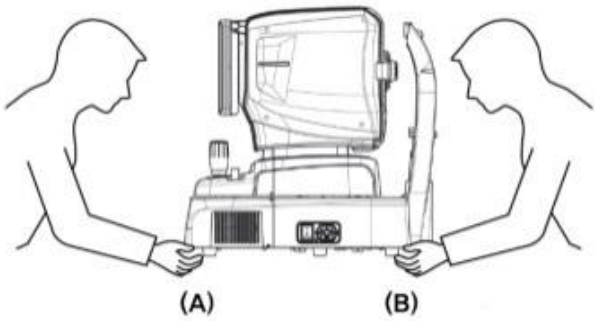
15. Pour éviter tout risque de choc électrique, cet instrument doit uniquement être connecté à la terre de protection.

16. Ne placez pas l'instrument là où il est difficile de faire fonctionner le dispositif de déconnexion. (dispositif

de déconnexion: câble d'alimentation)

17. Les équipements externes destinés à la connexion à l'entrée, à la sortie de signaux ou à d'autres connecteurs de cet instrument doivent être conformes à la norme CEI pertinente (par exemple, IEC60950 pour les équipements informatiques et IEC60601-1 pour les équipements électromédicaux). De plus, tous ces systèmes combinés doivent être conformes à la norme nationale harmonisée IEC60601-1 ou à la combinaison. En cas de doute, contactez un technicien qualifié ou votre représentant local. L'opérateur ne doit pas toucher simultanément le patient et les parties mâles accessibles des connecteurs SIP / SOP.

18. Lorsque vous transportez ce produit, veuillez tenir en bas à gauche (A) et à droite (B) du produit.



19. Ne pas toucher directement si un opérateur a une blessure à la main ou une réaction allergique importante au matériau utilisé dans la pièce de contact de fonctionnement.

Part Name	Material
LCD Touch pannel	Glass
Joystick / button	ABS + Silicon, Aluminum(A6061 T6) + Anodizing
Power switch	PC + PA66
Cover	ABS
Chin Rest	ABS

20. Ne mesurez pas les patients sensibles à la lumière. (ex> photophobie)

21. Lorsque l'instrument est renvoyé au centre A / S pour réparation ou maintenance, ou avant que le technicien agréé ne soit arrivé sur place pour réparation ou maintenance, essuyez les surfaces de l'instrument (en particulier, les pièces qui entrent en contact avec le patient) avec un chiffon propre imbibé d'alcool à friction.

22. En cas d'incident grave impliquant le dispositif, l'utilisateur le signale au fabricant et à l'autorité compétente de l'État membre dans lequel l'utilisateur et / ou le patient sont établis.

23. Si un utilisateur utilise l'économie d'énergie prise en charge par Windows 10, à l'exception de l'économie d'énergie dans le paramètre Utilisateur, cela provoque des problèmes dans HFC-1. Le fabricant n'est pas responsable du problème.

24. L'utilisateur ne doit pas modifier le paramètre pris en charge par le fabricant. Cette modification peut entraîner des problèmes dans le HFC-1. Le fabricant n'est pas responsable du problème.

25. En cas d'incident grave impliquant le dispositif, l'utilisateur le signale au fabricant et à l'autorité compétente de l'État membre dans lequel l'utilisateur et/ou le patient sont établis.

26. Lorsque la boîte d'emballage est ouverte par inadvertance avant utilisation ou endommagée, veuillez appeler le centre A/S.

27. Assurez-vous que vous disposez toujours d'un antivirus et d'un pare-feu à jour installés sur votre système.

28. Évitez de réinitialiser ou d'éteindre le PC lorsque le HFC-1 est en cours d'exécution.

29. Même si la sauvegarde est configurée pour être effectuée, si l'alimentation n'est pas allumée ou si l'emplacement de sauvegarde est introuvable, la sauvegarde n'est pas effectuée.

30. La connexion de l'interface électronique à un réseau informatique comprenant d'autres équipements pourrait entraîner des risques non identifiés auparavant pour les patients, les utilisateurs ou des tiers.Même si la sauvegarde est configurée pour être effectuée, si l'alimentation n'est pas allumée ou si l'emplacement de sauvegarde est introuvable, la sauvegarde n'est pas effectuée.Il est conseillé à l'ORGANISME RESPONSABLE d'identifier, d'analyser, d'évaluer et de contrôler ces RISQUES.

31. Des modifications ultérieures du RÉSEAU INFORMATIQUE pourraient introduire de nouveaux RISQUES et nécessiter une analyse supplémentaire.
    Les modifications apportées au RÉSEAU INFORMATIQUE comprennent:
    1) modifications de la configuration IT-NETWORK
    2) ajout d'éléments (plates-formes matérielles et/ou logicielles ou applications logicielles au RÉSEAU INFORMATIQUE
    3) suppression d'éléments du RÉSEAU INFORMATIQUE
    4) mise à jour des plates-formes matérielles et/ou logicielles ou des applications logicielles sur le RÉSEAU INFORMATIQUE
    5) mise à niveau des plates-formes matérielles et/ou logicielles ou des applications logicielles sur le RÉSEAU INFORMATIQUE

2.4. Safety Cautions

⚠ CAUTION

1. 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.

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

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

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

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

1. Les fabricants ne sont responsables de la sécurité, de la fiabilité et des performances de cet instrument que lorsque les exigences suivantes sont remplies.
   (1) Lorsque l'instrument a été installé dans une zone appropriée, en suivant le manuel.
   (2) Lorsque l'instrument a été utilisé et entretenu conformément au manuel et au manuel d'entretien.

2. Conservez le manuel de l'utilisateur et le manuel d'entretien dans un endroit facilement accessible à tout moment pour les personnes qui utilisent et entretiennent l'équipement.

3. Avant d'utiliser, vérifiez l'extérieur de l'instrument et ses conditions.

4. Lorsque vous transportez ce produit, veuillez utiliser une charrette à bras. Si vous souhaitez déplacer le produit vers une autre zone, veuillez contacter le service clientèle.

5. L'équipement peut être endommagé s'il est utilisé d'une manière non spécifiée par les fabricants ou le manuel.

3

INTRODUCTION

3.1. System Outline

HFC-1 Fundus camera is a non-contact, high-resolution bio-microscopic imaging device. It is indicated for in-vivo viewing, color fundus image using a color camera without the use of mydiatic agents. HFC-1 Fundus camera captures fundus image to assist a clinician for diagnostic examinations.

The Huvitz Fundus camera has the following features:

- Auto shoot-image is optimized and captured automatically when aligned and focused to the patient's eye properly.
- Auto tracking-alignment and focus is automatically accomplished in tracking region.
- Pupil mode- Normal mode is 4.0mm, Small pupil mode is 3.3 mm.
- Capture mode- Single Macular mode provides capturing one fundus image for macular. Single Disc mode provides capturing one fundus image for Optic Disc. Widefield-Panorama mode provides the stitching function for maximum 7 adjacent images captured individually.
- 12 inch, color and touch screen provides high quality images and easy to operate GUI available to the operator.

The HFC-1 software controls all system functions including the followings:

- To take color picture in fundus
- To provide user interfaces in order to take a color fundus picture.
- To analyze the color fundus picture taken.
- To display focusing state and move to focus position automatically.
- To manage patient information
- To support user setup for operation environment.

3.2. Intended Use

HFC-1 fundus camera is intended to capture digital images for the anterior and retina segment of the eye without the use of a mydriatic agent. It is intended for use as an aid to clinicians in the evaluation and diagnosis of ocular health.

3.3. Classification

- Classification of product: Class IIa according to Annex VIII (Rule 10) of the Medical Device Regulation 2017/745
  Class II according to FDA 21 CFR 886.1120
- Resistance against electric shock: Class I (earthed)
- Protection class against electric: Type B (headrest, chinrest paper)
- Classification of Light hazard: Group I (EN/ISO15004-2 Standard)

3.4. Contraindications

This device should not be used for:

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

There is no any known residual risk other than risks arising from violating contraindication.
But, when unexpected event occurs or you encounter different problems, please contact your local distributor or Authorized Representatives.

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, headrest.
- 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

The anterior of an eye is illuminated by IR light, the retina of an eye is illuminated by 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. 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

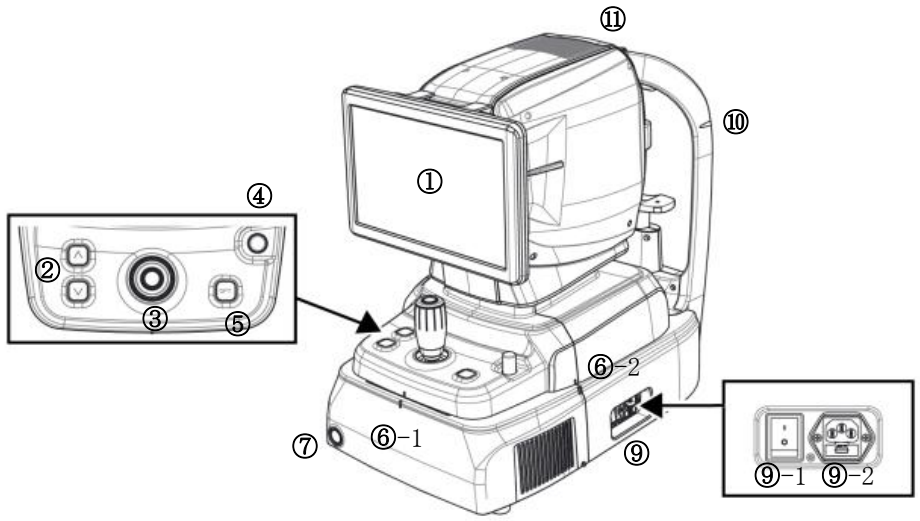
- ISO 10940: Ophthalmic instruments - Fundus Cameras

4

System Overview

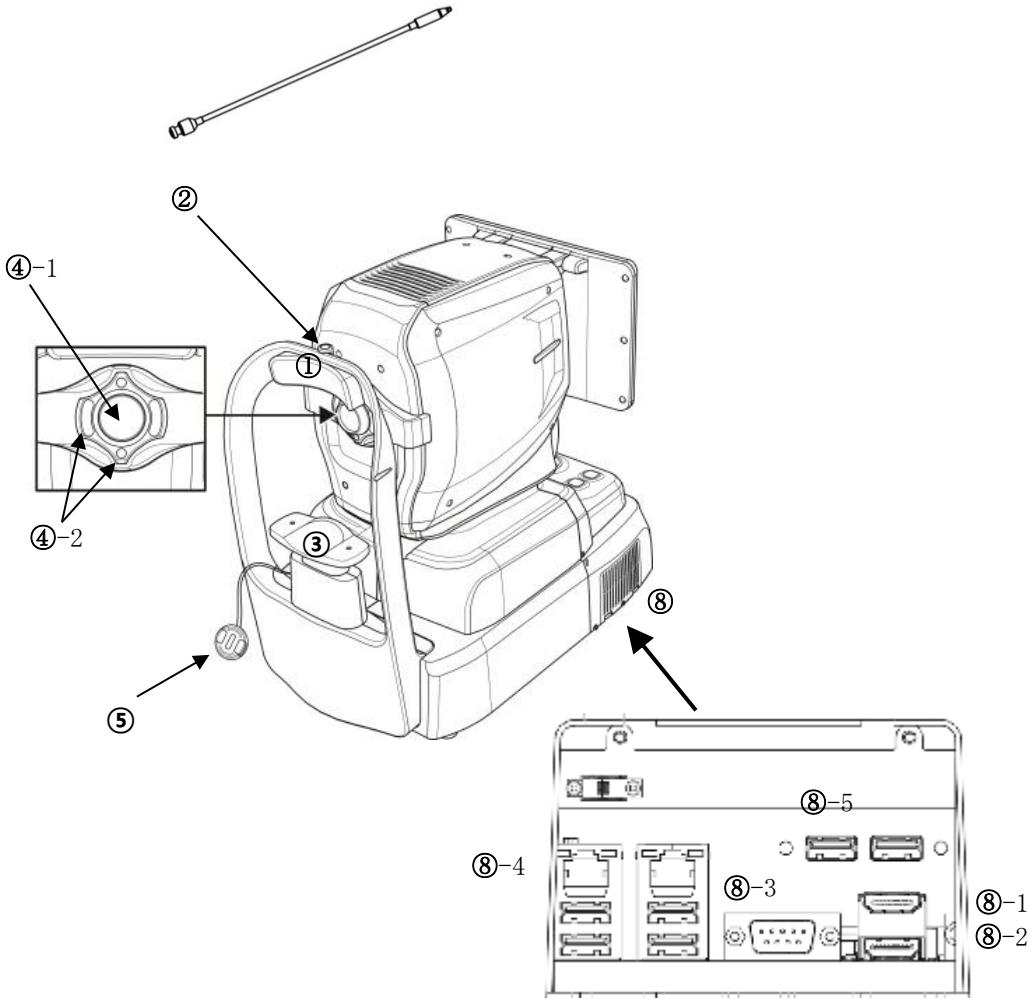
4.1. Configuration and Functions

Front View



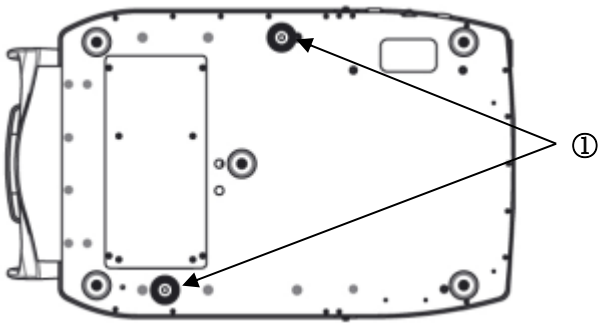
No	Part	Name	Description
1	Display	LCD	Monitor for displaying captured image and user interface icon.
2	Body	Chinrest button	Button for moving chinrest up and down.
3		Joystick	Joystick for aligning body to patient's eye. Button for capturing image.
4		User Lock	Lock for fixing body to base frame.
5		OPT button	Button for optimizing 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	Headrest	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		External Monitor port	Port for connecting external monitor.
8-2			
8-3		RS-232 port	Port for communicating internal PC board and main board.
8-4		LAN port	Port for external network
8-5		USB port	Port for internal or external USB device

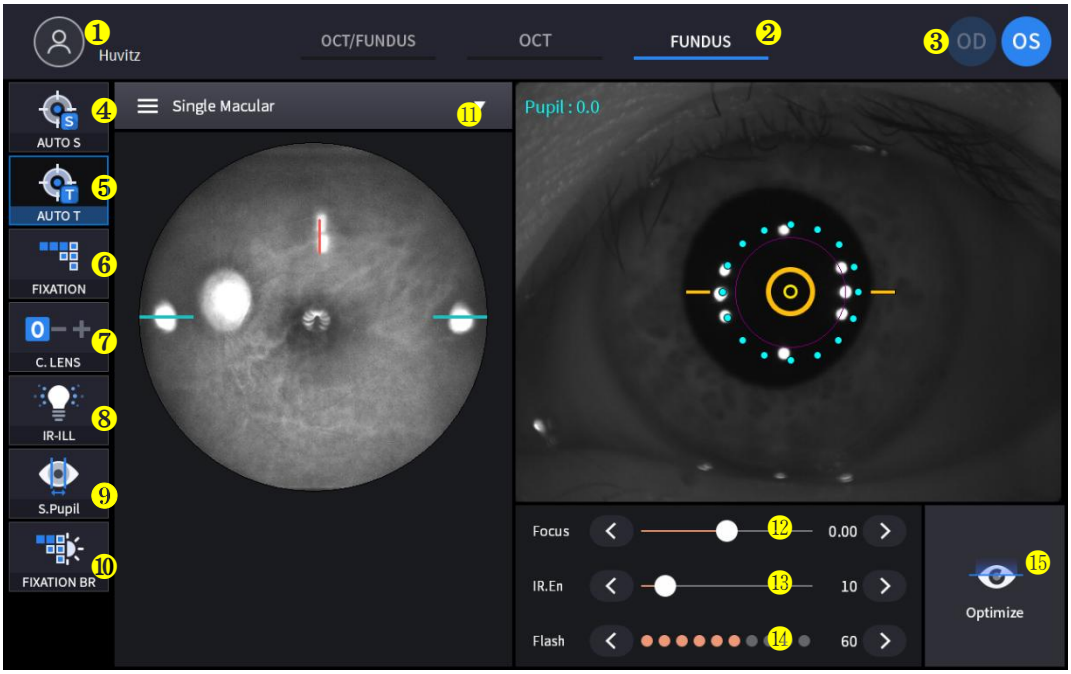
Bottom View



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

4.2. Main Body Screen Description

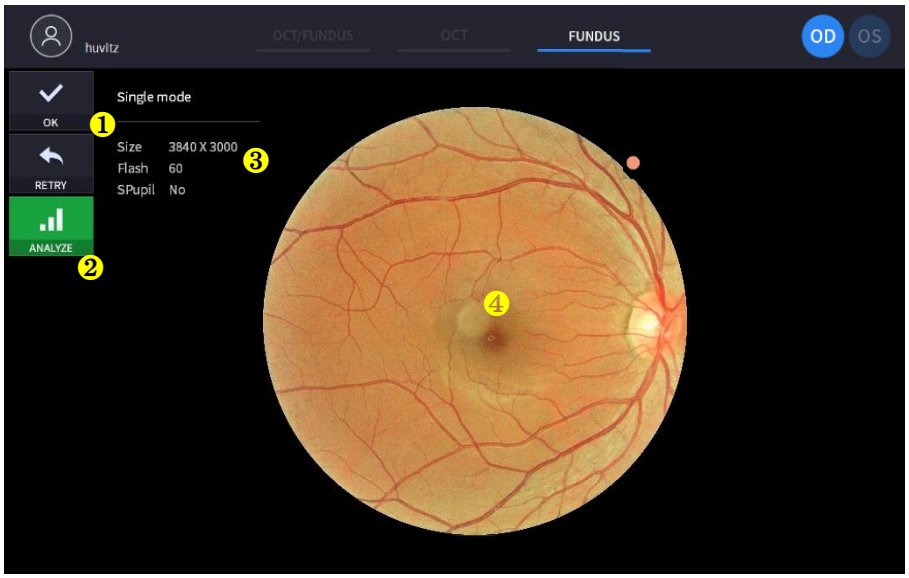
Observation screen



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. 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	FIXATION BR	Control Fixation brightness.
11	Capture mode	Select capture mode. - Single Macular: Capture one fundus image for Macular. - Single Disc: Capture one fundus image for Optic Disc. - Stereo Macular: Capture 2 fundus images for Macular stereo analysis. - Stereo Disc: Capture 2 fundus images for Disc stereo analysis. - Widefield Panorama: Capture maximum 7 images and stitch it.

12	Focus	Move in accordance with focus of patient's eye.
13	IR.En	Change brightness of IR fundus image
14	Flash	Change brightness level of white light for capturing fundus image.
15	Optimize	Find focus position automatically by split focus image.

Confirmation screen



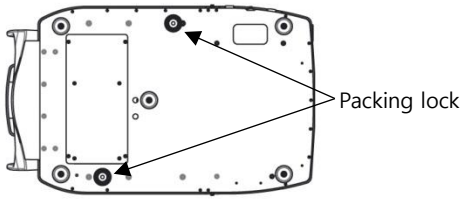
No	Name	Function
1	Image selection	Decide validity of current image. - OK: Save current image. - RETRY: Discard current image and retry capturing.
2	Analyze	Save the camera DATA and enter the analysis screen
3	Fundus information	Display setting information of fundus image.
4	Fundus image	Show captured fundus image.

5

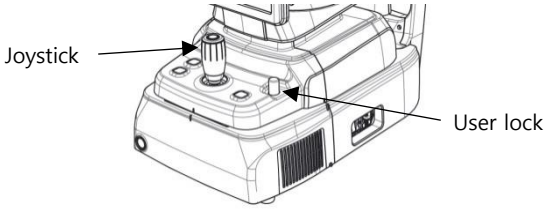
Installation Procedure

5.1. System installation

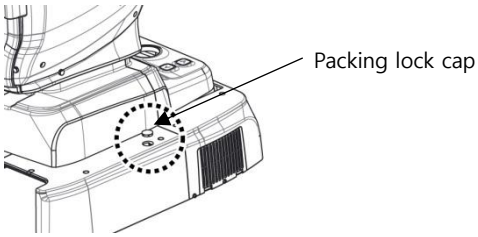
1. Place the main body unit on a stable table.
2. Loosen the two packing lock screw under the main body.



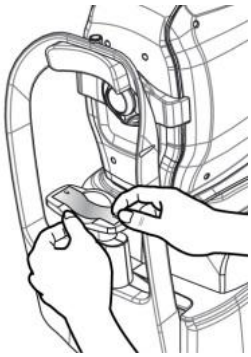
3. Unscrew the user lock lever on the body.



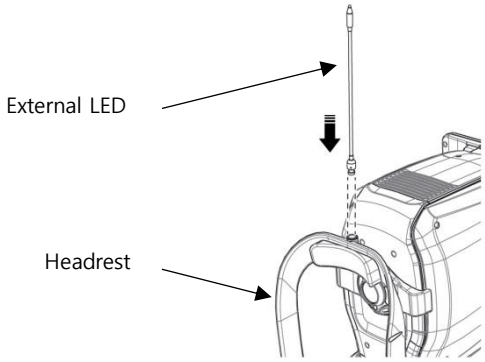
4. Attach two base packing lock cap while moving body left and right with joystick.



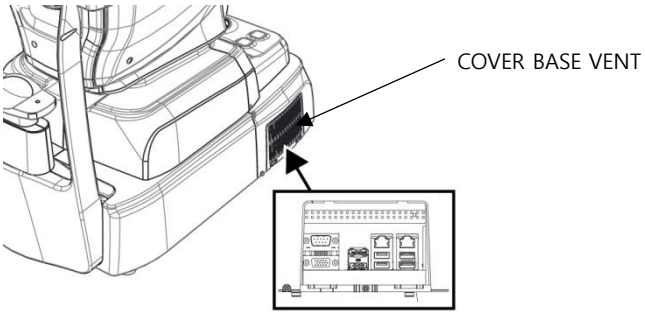
5. Attach the chinrest paper to the chinrest.



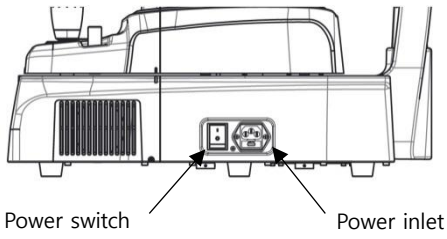
6. Attach external LED to the headrest .



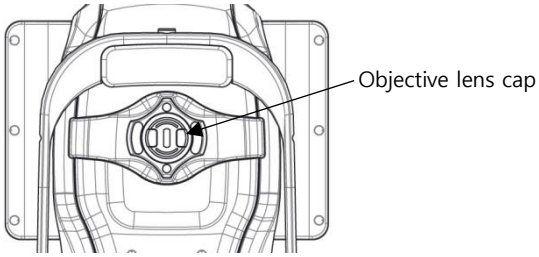
7. If needed, connect external devices.
   (1) Open ‘COVER BASE VENT’ on the left bottom of base with screw driver.
   (2) If needed, connect mouse or keyboard
   (3) Connect communication cable of external device.
   (4) Close ‘COVER BASE VENT’ with screw driver.



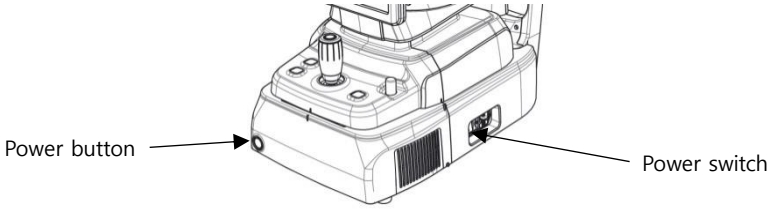
8. Check the power switch on the bottom right of base is off. (O position).
9. Connect power cable to power inlet. Also, connect the other side of power cable to electric outlet.



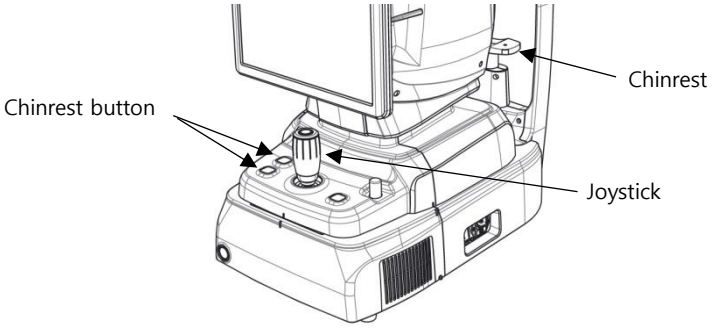
10. Remove objective lens cap, and check objective lens is clean,



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.

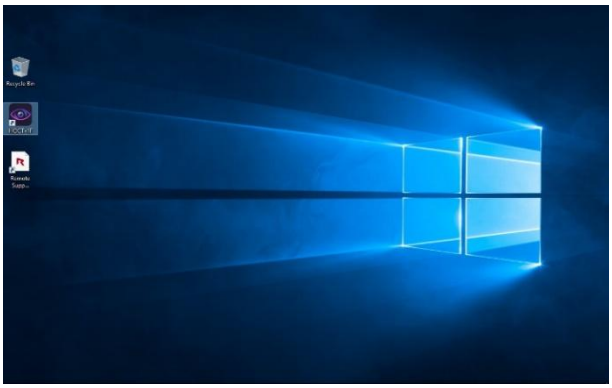


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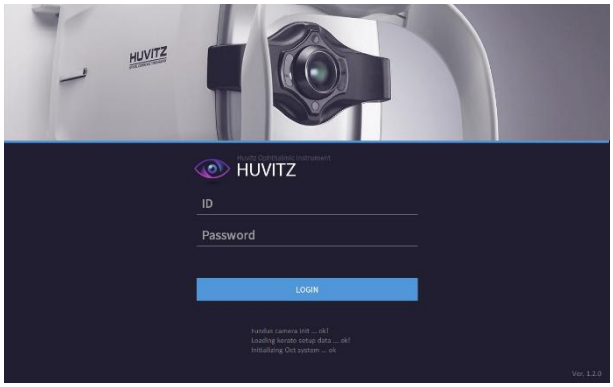
Operation

6.1. Software

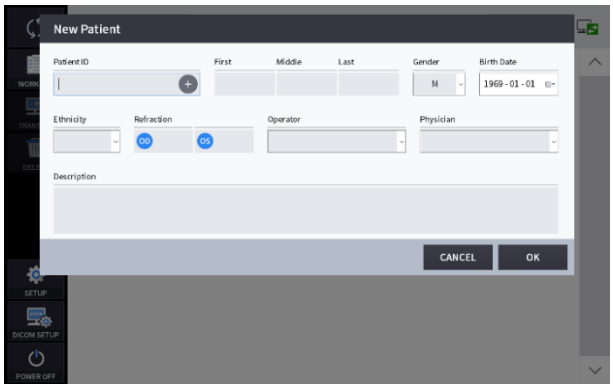
1. Double-click the program icon on the LCD screen.



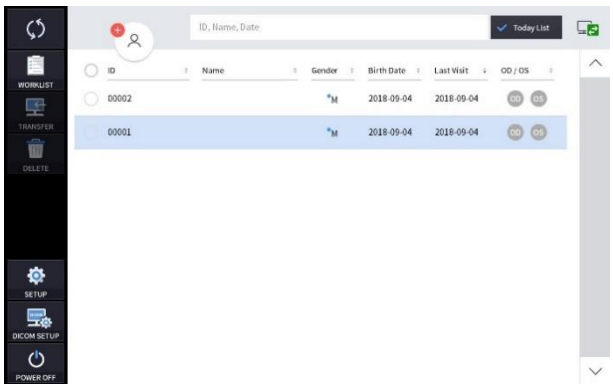
2. When the initialization is complete, "Initializing Oct system...ok" will appear at the bottom of the screen. After initialization, log in by entering the ID and password.



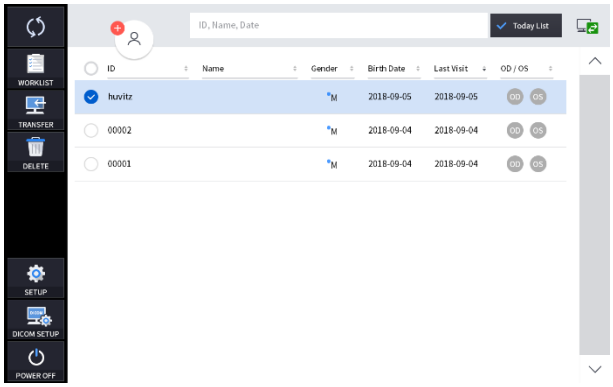
3. Press register patient icon ( ) and input patient information. If patient is resisted already, skip this step.



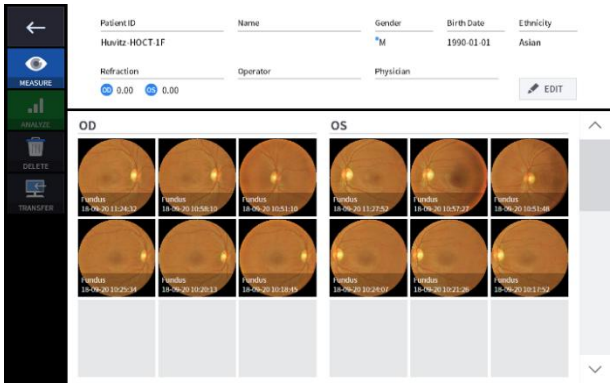
4. Select patient and check patient information is correct.



5. If you want to send patient information to a web viewer or delete patient information, select the circle next to the ID and press the TRANSFER icon or DELETE icon.

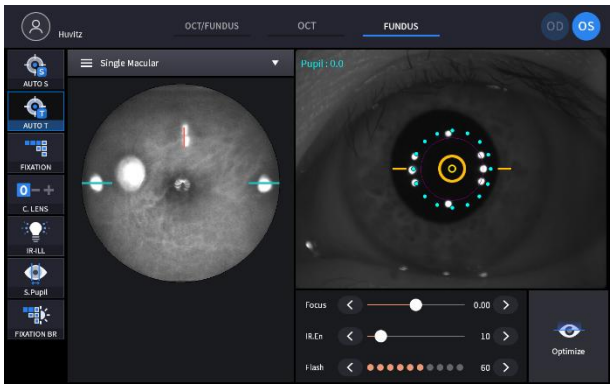


6. When you select a patient, the screen changes.



7. Enter observation mode by pressing measure icon (

).
The screen of observation mode is as follow.



6.2. SETUP Mode

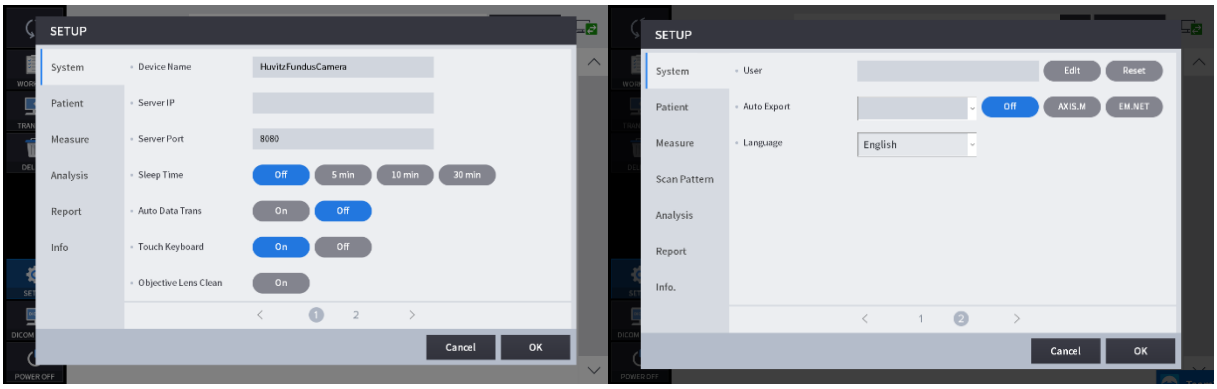
[To choose the section to setup]

- Setup mode consists of seven sections: System, Patient, Measure, Analysis, Report and info. 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]

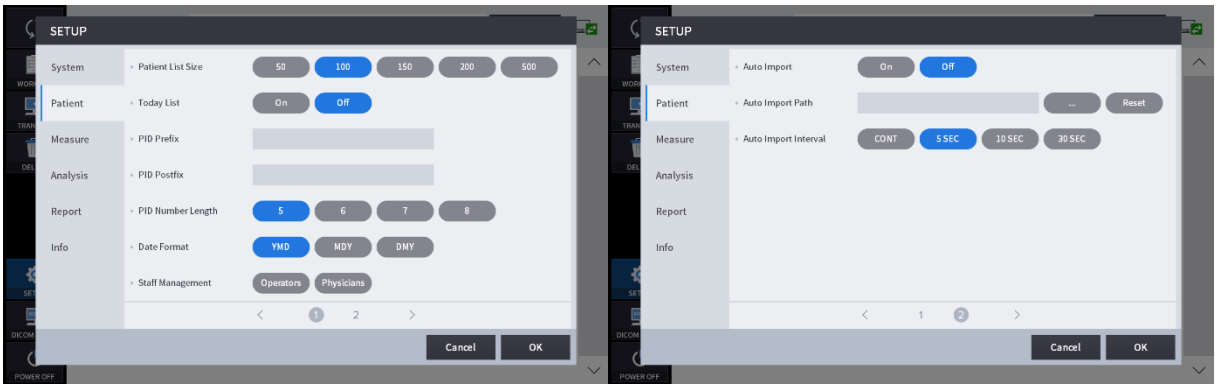
- Select the item to change.
- To press OK button [OK] will save all the changes made and exit the setup screen.
- To press CANCEL button [Cancel] will discard the changes and exit the setup screen.

1. System Settings



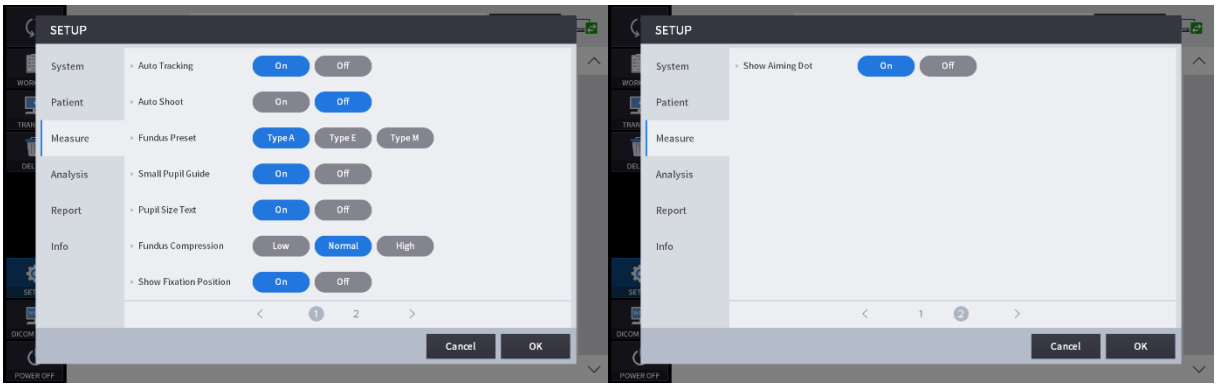
Device Name	Set Device Name.
Server IP	Web Viewer Server IP address setting.
Sever Port	Web Viewer Server port setting.
Sleep Time	Sleep mode setting.
Auto Data Trans	Set the function to transfer the measured data to Web Viewer automatically.
Touch Keyboard	Touch Keyboard ON/OFF setting.
Objective Lens Clean	When this option is turned on, the Light is turned on for convenient cleaning of the Objective Lens.
User	Set User ID and Password for Login.
Auto Export	Auto export setting
Language	Language setting.

2. Patient Settings



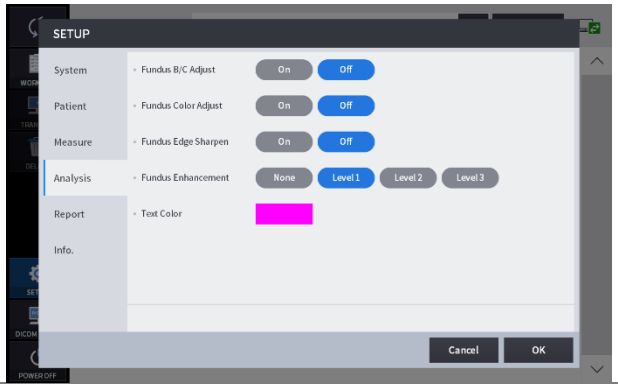
Patient List Size	Number of patients to be displayed per pages.
Today List	Today List (List of patients visited today) settings.
PID Prefix	The function to set the prefix of the patient ID.
PID Postfix	The function to set the postfix of the patient ID.
PID Number Length	The function to set the length of patient ID.
Date Format	Format of the date (Year, Month, Day).
Staff Management	Register staffs
Auto Import	Auto import setting
Auto Import Path	Assign the import path
Auto Import Interval	Set the interval of auto import

3. Measure Settings.



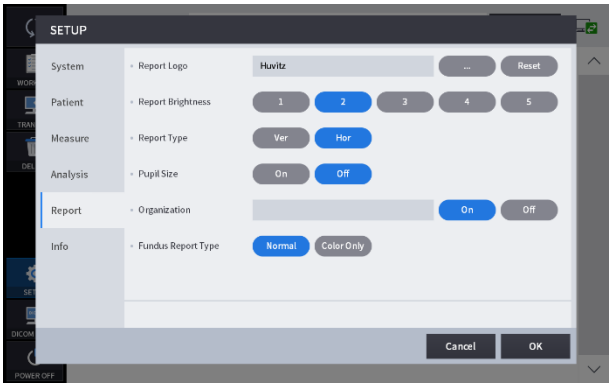
Auto Tracking	Auto Tracking ON/OFF setting.
Auto Shoot	Auto Shoot ON/OFF setting.
Fundus Preset	Set fundus Preset.
Small Pupil Guide	Small Pupil Guide ON/OFF setting.
Pupil Size Text	Pupil Size Text ON/OFF setting.
Fundus Compression	Set the Fundus image compression ratio.
Show Fixation Position	Show Fixation Position ON/OFF setting.
Show Aiming Dot	Show Aiming Dot ON/OFF setting.

4. Analysis Settings



Fundus B/C Adjust	Apply the standard values of brightness and contrast to the measured fundus image automatically.
Fundus Color Adjust	Apply the standard values of UB and VR to the measured fundus image automatically.
Fundus Edge Sharpen	Apply edge sharpening function to the measured fundus image automatically.
Fundus Enhancement	Set the enhancement level of Fundus image
Text Color	Set the measurement value text(ruler value) color.

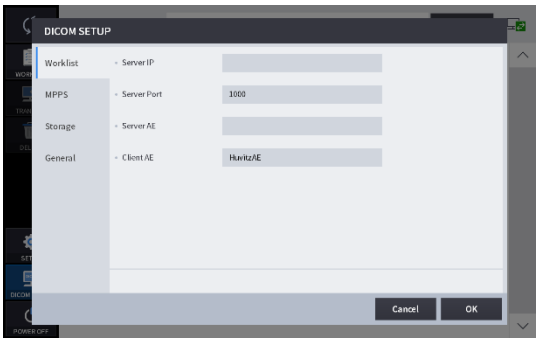
5. Report Settings



Report Logo	Set the report logo image.
Report Brightness	Set the report print brightness.
Report Type	Set the orientation of report print.
Pupil Size	Set the pupil size information.
Organization	Assign the organization.
Fundus Report Type	Decide the type of fundus image.

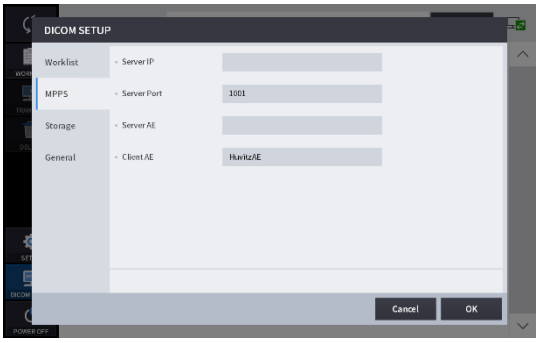
6.3. DICOM SETUP Mode

1. Worklist Setting



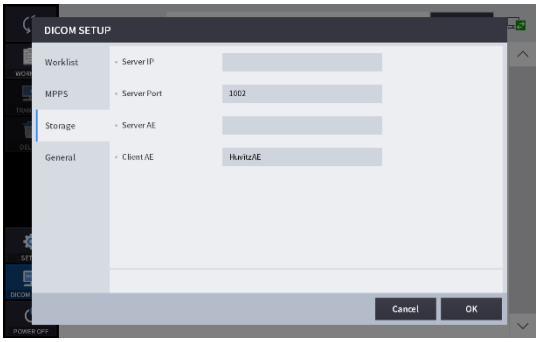
Server IP	IP Address of the PC where the server program is installed.
Server Port	Set Port Number.
Server AE	Set Server AE.
Client AE	Set Client AE.

2. MPPS Setting



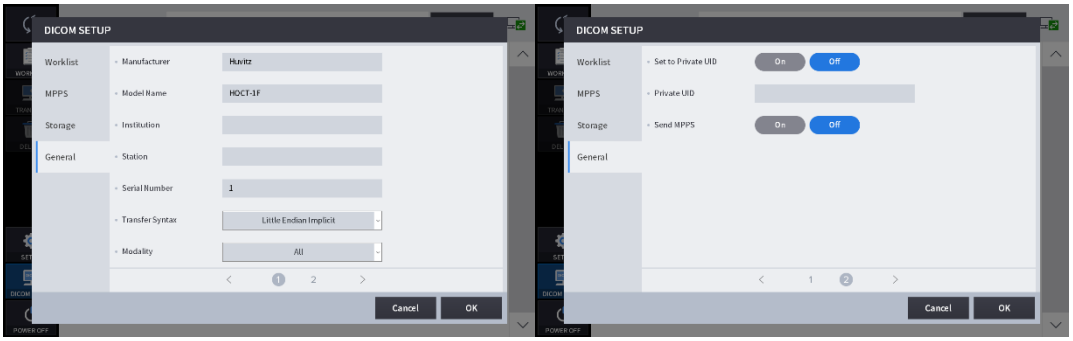
Server IP	IP Address of the PC where the server program is installed.
Server Port	Set Port Number.
Server AE	Set Server AE.
Client AE	Set Client AE.

3. Storage Setting



Server IP	IP Address of the PC where the server program is installed.
Server Port	Set Port Number.
Server AE	Set Server AE.
Client AE	Set Client AE.

4. General Setting

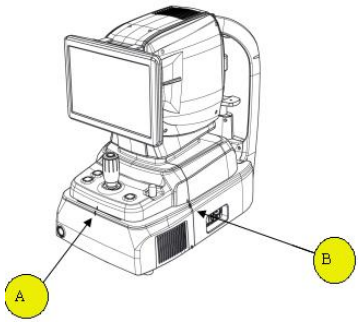


Manufacturer	Set the name of the manufacturer.
Model Name	Set the Model Name.
Institution	Set the name of the institution.
Station	Set the name of the Station.
Serial Number	Set the Serial Number.
Transfer Syntax	Set the Transfer Syntax.
Modality	Set the Modality.
Set to Private UID	Set Private UID ON/OFF setting.
Private UID	Set the Private UID.
Send MPPS	Set Send MPPS ON/OFF setting

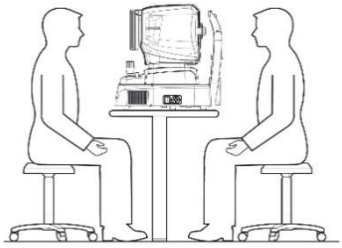
6.4. General Operation

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.

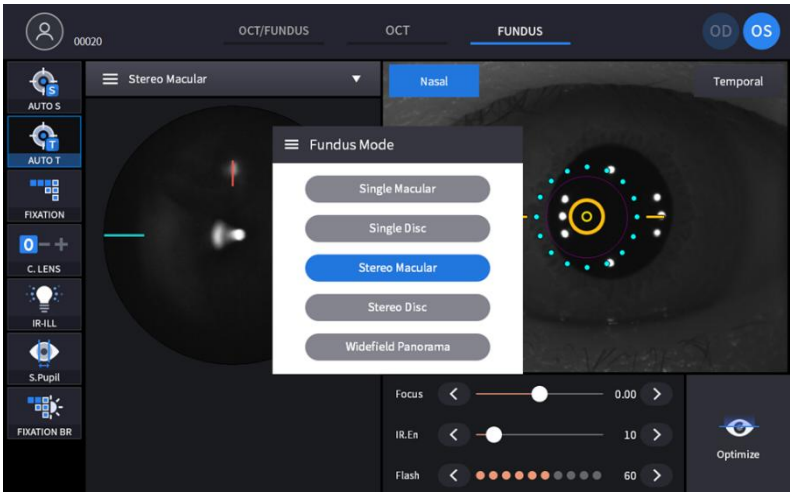
2. Align left/right index mark (B) and front index mark (A) of body and base with joystick.



3. Let the patient sit in front of instrument.



4. Set the mode and environment as following.



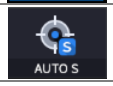
(1) Set capture region with the capture region combo box (

).

Single Macular	Shoot the only one Macular Fundus.
Single Disc	Shoot the only one Disc Fundus.
Stereo Macular	Shoot the twice Macular Fundus.

Stereo Disc	Shoot the twice Disc Fundus.
Widefield Panorama	Shoot the several retina Fundus.

(2) Set auto shooting mode.

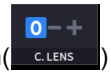
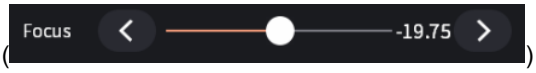
	Auto shooting is on.
	Auto shooting is off.

- 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.

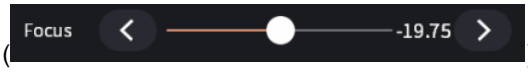
(3) Set auto tracking mode.

	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) 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.

(5) Set the diopter of patient by Focus icon
() if needed.

(6) Change brightness of IR fundus image with IR.En icon () if needed.

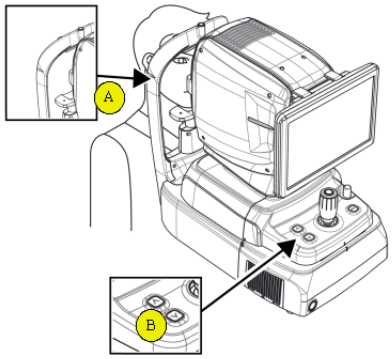
(7) If needed, Change the brightness level of white light for capturing fundus image with Flash icon
()

5. Align patient's eye to eye level mark on headrest.

(1) Let the patient's chin put on the chinrest.

(2) Let the patient's forehead adhere to headrest.

(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.

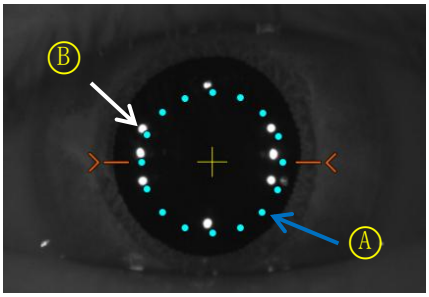


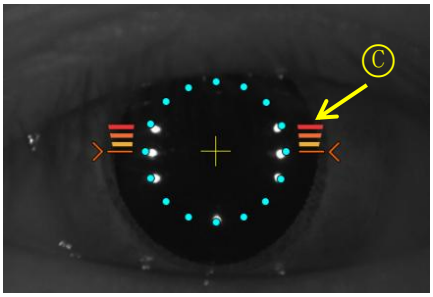
6. Instruct patient to watch internal fixation LED to fix patient eyes. Also, instruct patient to open eye widely, not to blink.

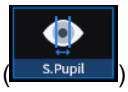
7. Move body with joystick until patient's eye appears on the screen.

8. Set the alignment and focus.

(1) Move the body up/down and left/right with joystick until ring of 16 blue align dots (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.

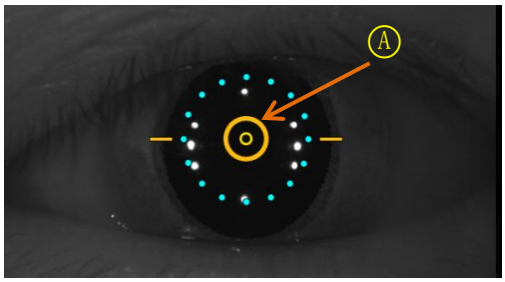




(2) If the pupil of patient is smaller than 16 blue align dot, press S-pupil icon (

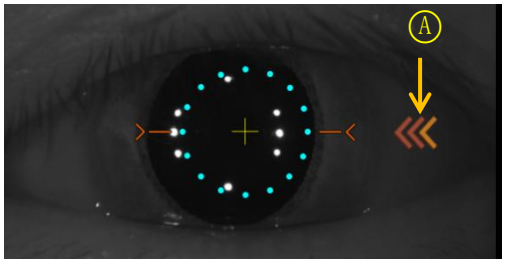
) to capture in small pupil mode. If you have set the Small Pupil Guide option to ON, small pupil icon is displayed in the upper left corner of the screen when small Pupil mode is required.

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



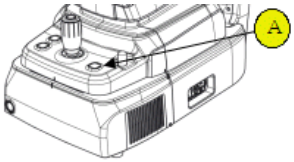
(4) If auto tracking is on, alignment and focus is automatically accomplished in tracking region.

(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 arrow direction with joystick.



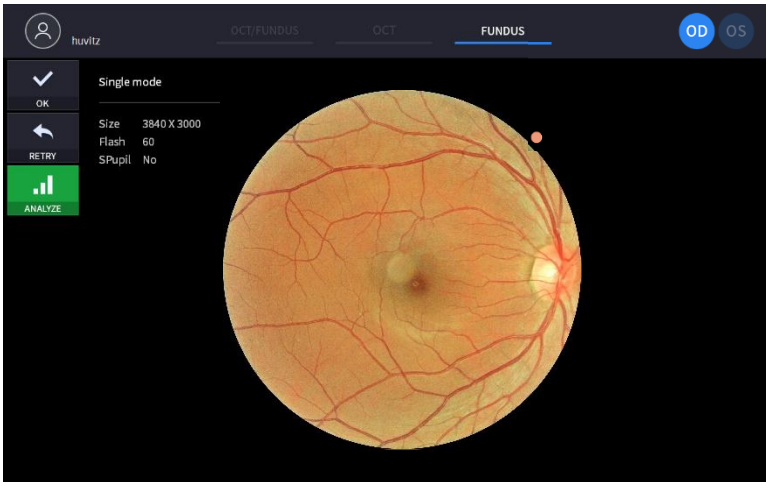
9. Capture image and check image quality.

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



(2) Press the button on joystick to capture image.
If auto shooting is on, ‘Optimize’ and ‘Capture’ is accomplished automatically.

(3) Check the result and decide to store or discard and retry.



① If the image is satisfactory, press OK icon (

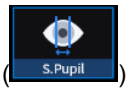
) to save image.

② 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.

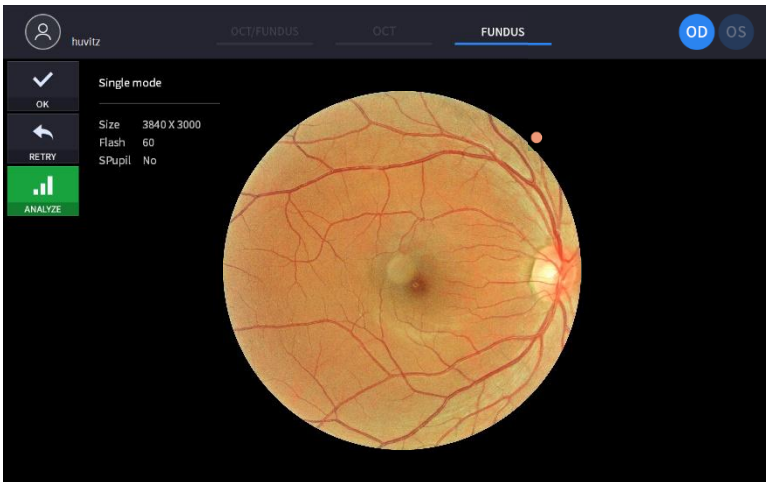
6.5. Analyze

6.5.1. Entering Analysis screen

1. Analysis immediately after scanning.

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

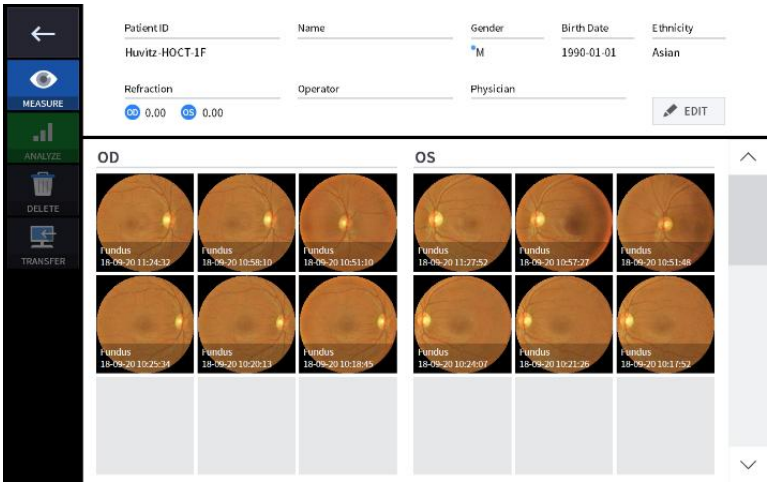
) from the captured image screen.



2. Analysis from measurement list.

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

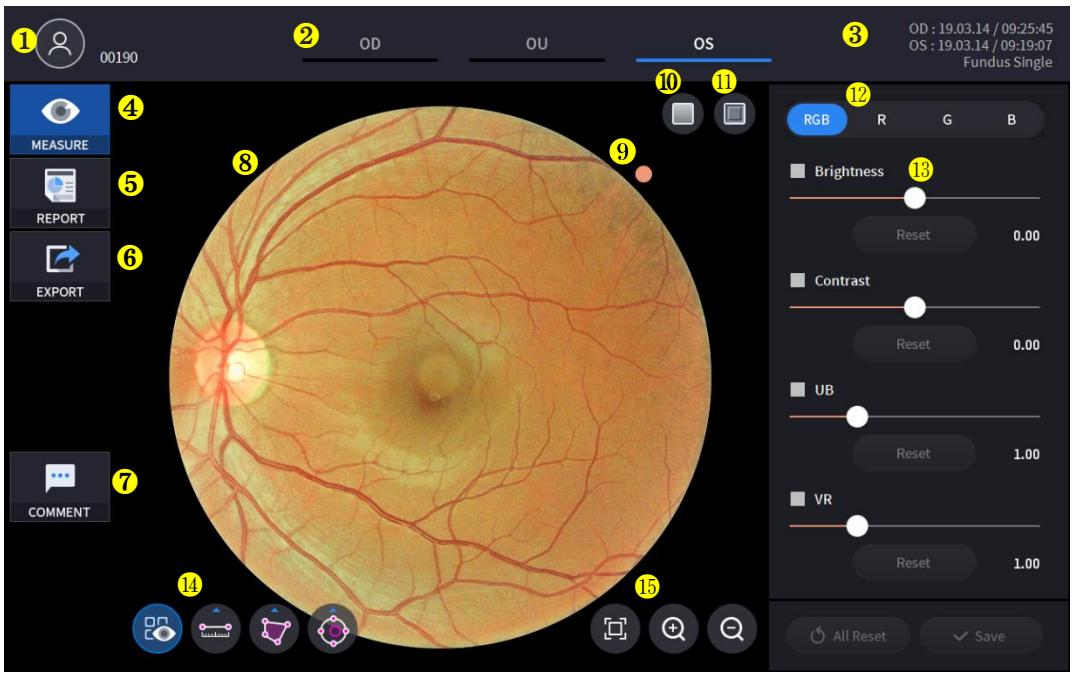
).



6.5.2. Fundus Analysis screen

- On the analysis screen, single and stereo are the same.

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 and information that 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	COMMENT	Leave a brief comment on the patient or measurement.
8	Fundus Image	Shows captured Fundus Image.
9	Direction Indication Mark	Indicates the orientation of the Fundus image. Mark always locates on the right upper side of the image.
10	Red Free	Apply a Red Free effect to the Fundus image.
11	Embossing	Apply a Embossing effect to the Fundus image.
12	RGB Channel	Selection of RGB Channel.
13	Adjustment control	Adjusting function of Brightness, Contrast, UB, VR.
14	Measurement tool	Length, Area, C/D Ratio measurement function on Fundus Image.
15	Magnification tool	Magnifying and Analyzing function of Fundus Image.

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

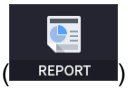
).

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

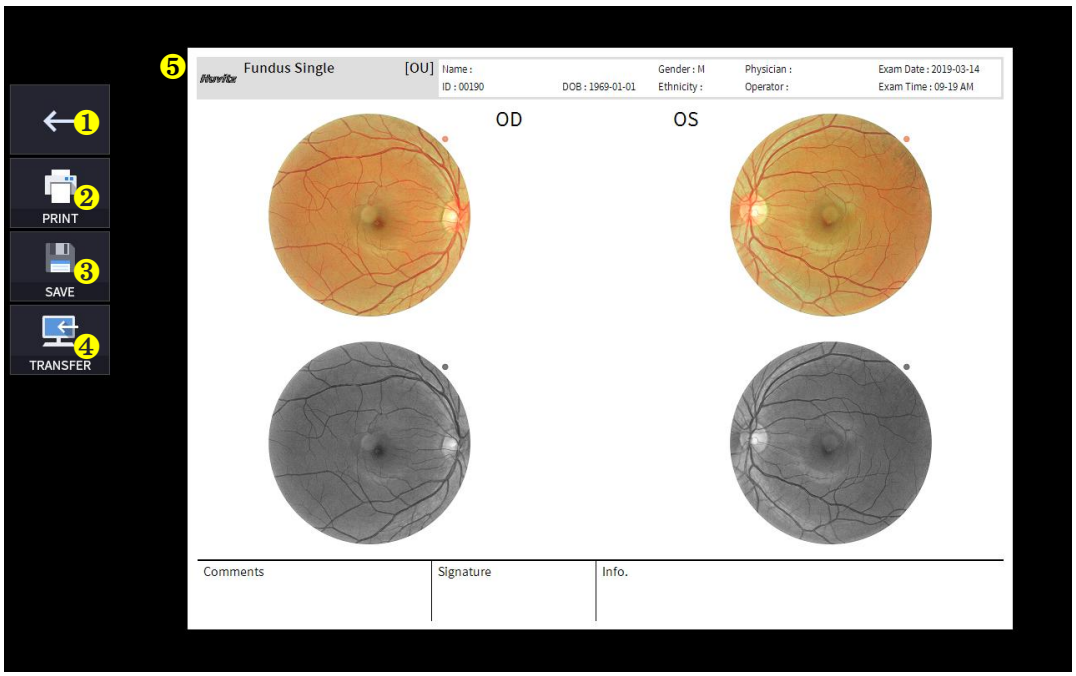
When selecting OU (

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

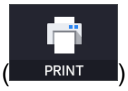


3. Select REPORT icon (

) shows REPORT screen shown below.

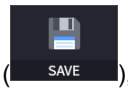


No	Name	Function
1	Previous screen	Go back to analysis screen.
2	PRINT	Save the current report showing as PDF file or print to a connected printer.
3	SAVE	Save the report as a JPG image if you have an external storage device connected to it.
4	TRANSFER	Sends the report to the DICOM Server if you are using the DICOM feature.
5	Report Preview	Preview of generated report.

(1) Selecting PRINT icon (

) shows printer option window.

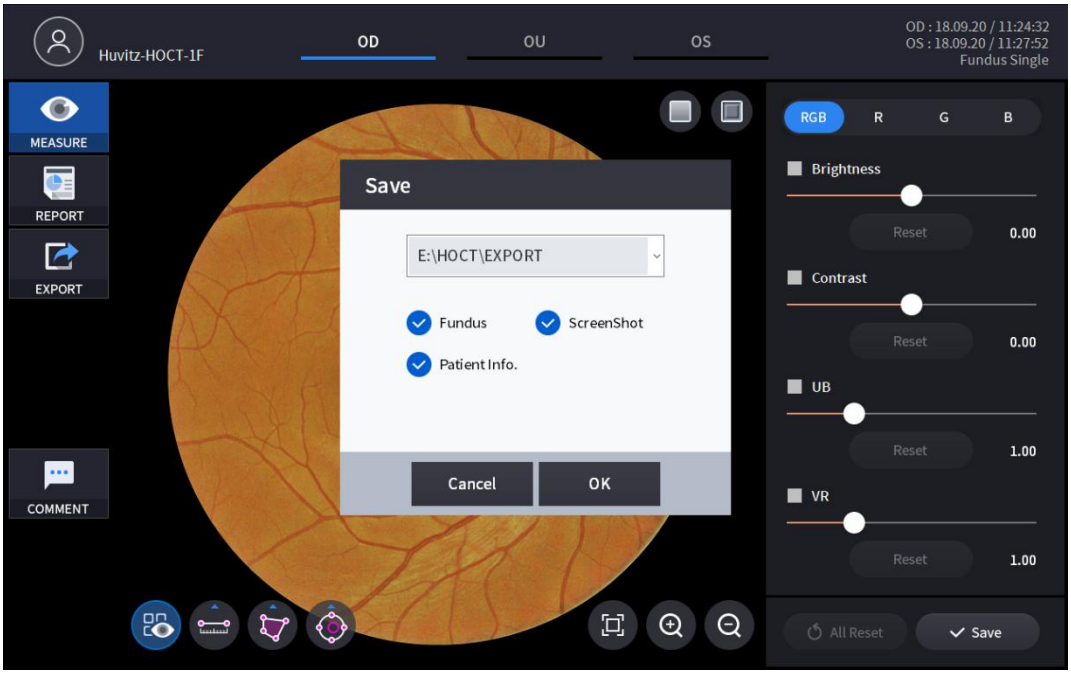


(2) Select the Save icon (

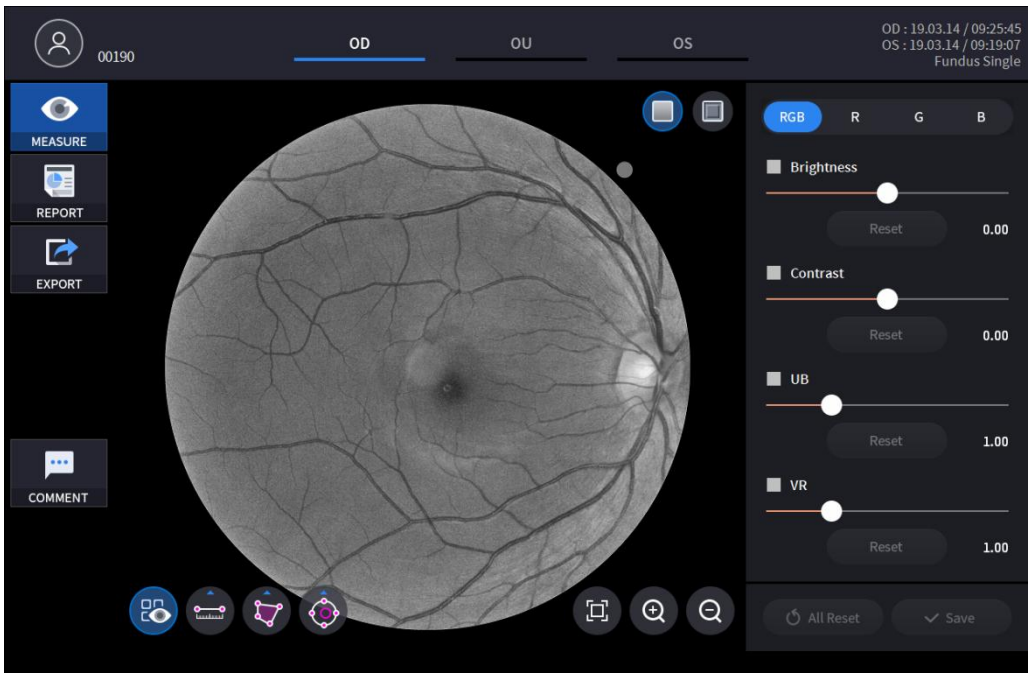
), the Select Storage Location window appears.



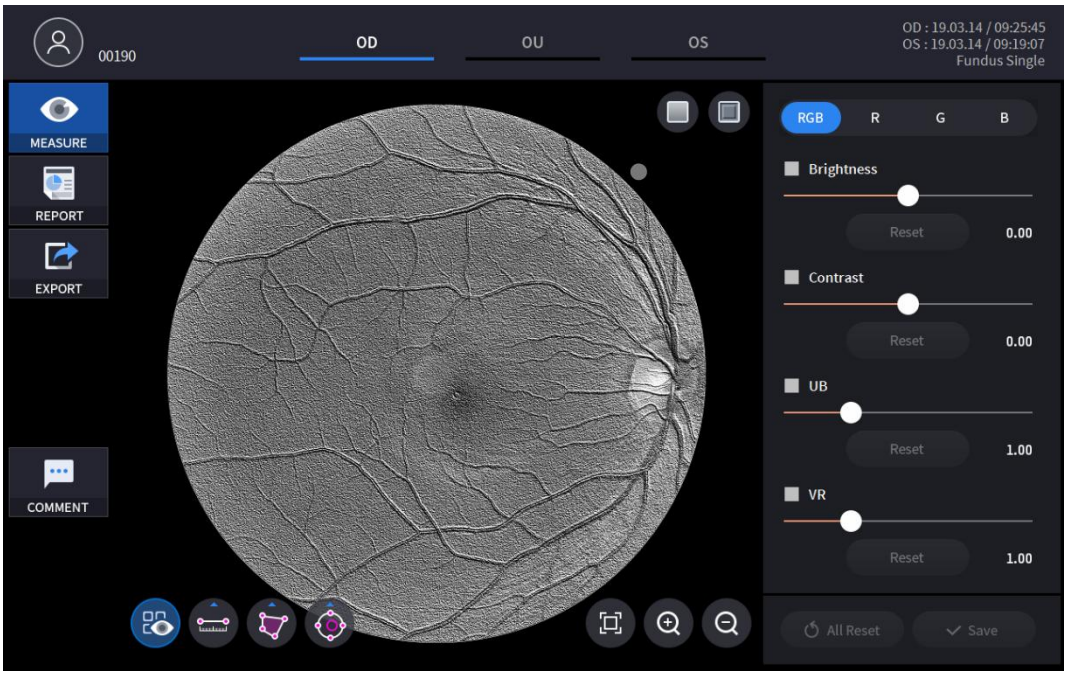
4. External storage device is connected, you can select TRANSFER icon (EXPORT) to save the desired data to the external storage device.



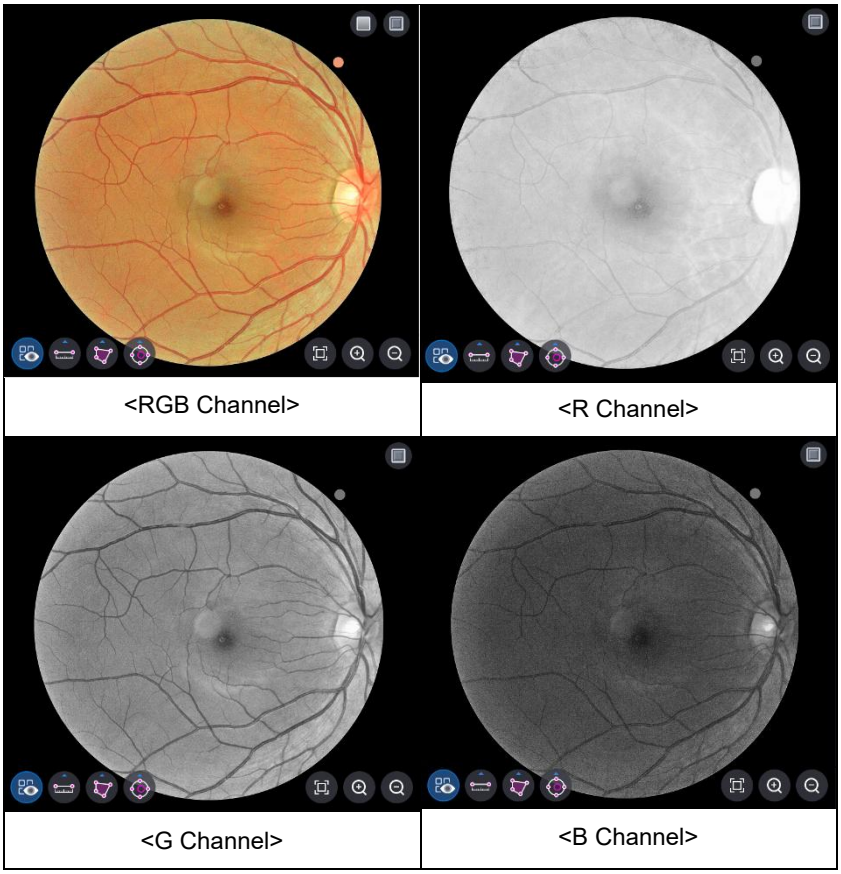
5. Use Red Free ON / OFF icon (,) to analyze Fundus Image with Red free Screen.



6. Use Embossing ON / OFF icon (,) to analyze Fundus Image with Embossing Mode..



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



<RGB Channel>

<R Channel>

<G Channel>

<B Channel>

8. Images can be adjusted using Slide Bar (

, 

, 

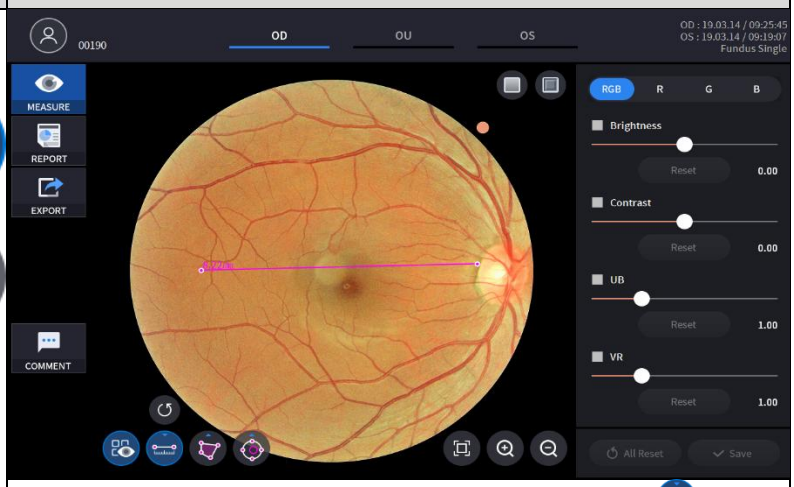
, 

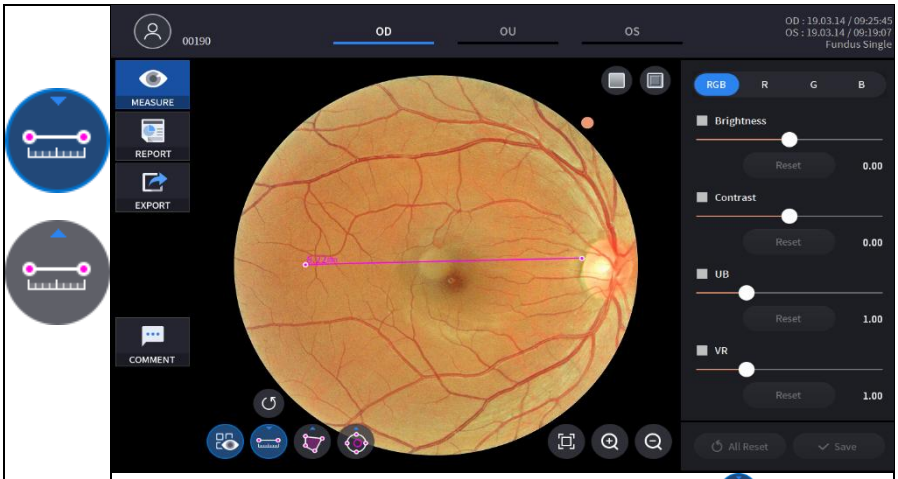
) of Adjustment Control.

	Adjustment of Brightness.
	Adjustment of Contrast.
	Adjustment of UB.
	Adjustment of VR.
	Resetting of individual Adjustment.
	Resetting of all Adjustment.
	Save all adjustments.

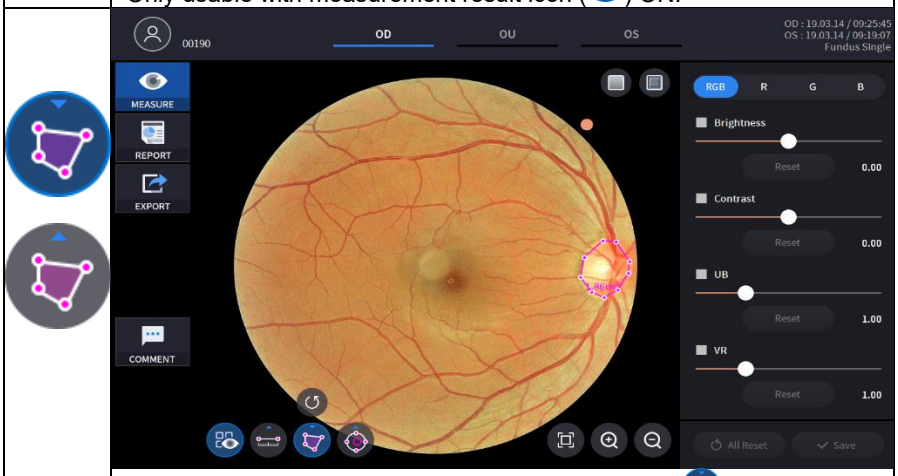
9. Length, Area, C/D Ration can be measured using Measurement Tool icon.

( ,  ,  , )

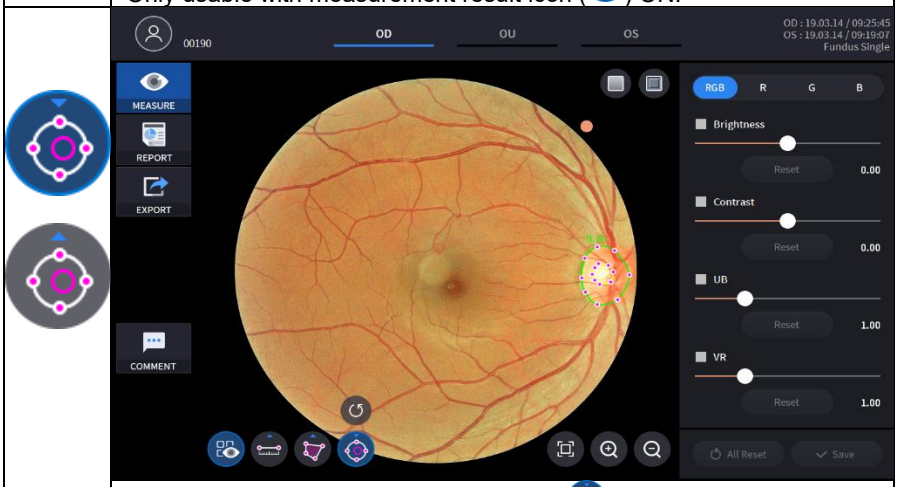
Icon ON / OFF	Screen and Function
 	 - ON: Shows results measured by length measurement icon (), area measurement icon (), C/D ration measurement icon () on Fundus Image. - OFF: Hides the measurements.



- 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.

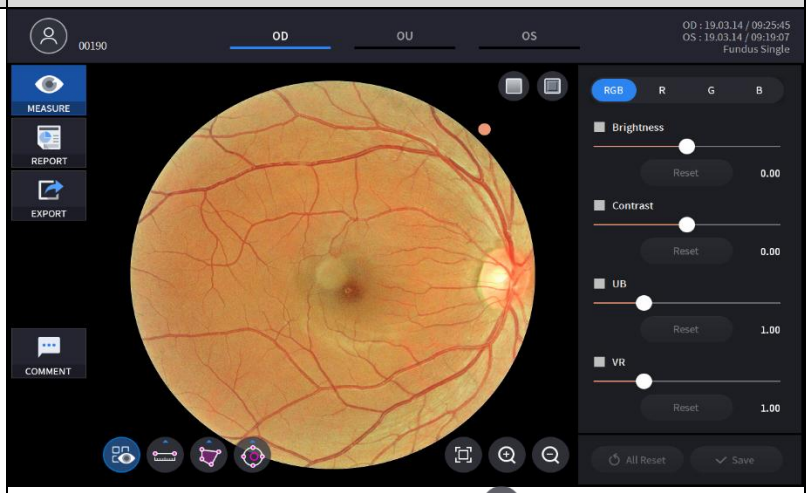
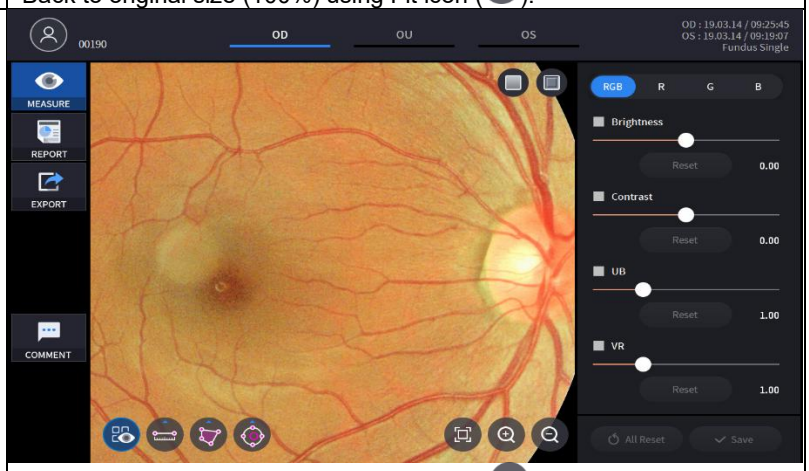


- Selecting a region with the Area measurement icon ( )shows the area of the region.
- Latest data can be deleted using Undo icon ( ).
- Only usable with measurement result icon ( ) ON.



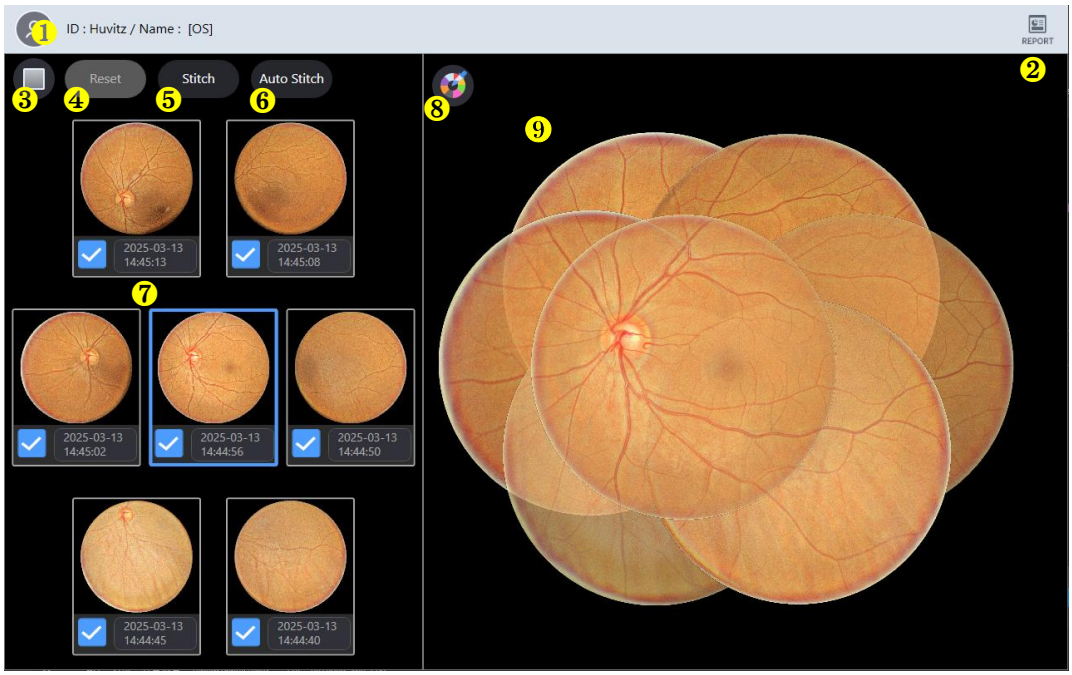
- With C/D ratio measurement switch icon ( ), clicking a point on the fundus image produces two concentric circles at the point. C/D ratio is calculated as the ratio of area of the two circles. The shape and size of each circles are adjusted by dragging the marks on the circles.
- Latest data can be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

10. 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.
	 - Reduce the magnified image using zoom out icon ( ). - Image will not be reduced to smaller than the original size.

6.5.3. Panorama 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	REPORT	Moves to report screen of the current measurement.
3	Red Free	Apply a Red Free effect to the Fundus image.
4	Reset	To reposition the fundus image, disable the stitch function.
5	Stitch	Run fundus image stitching at the currently specified position.
6	Auto Stitch	Automatically determine the position and run fundus image stitching.
7	Fundus panorama	Display all 7 measured fundus images, Select or deselect each image to include or exclude it from the stitched image.
8	Background Color	Change the background color of the stitched image.
9	Fundus Image	Display the stitched result image.

2. Select REPORT icon (

) shows REPORT screen shown below.

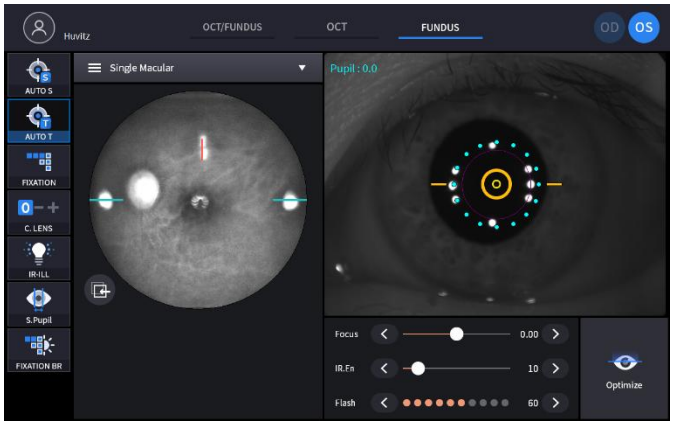
No	Name	Function
1	Previous screen	Go back to analysis screen.
2	PRINT	Save the current report showing as PDF file or print to a connected printer.
3	TRANSFER	Sends the report to the DICOM Server if you are using the DICOM feature.

6.6. Maintenance

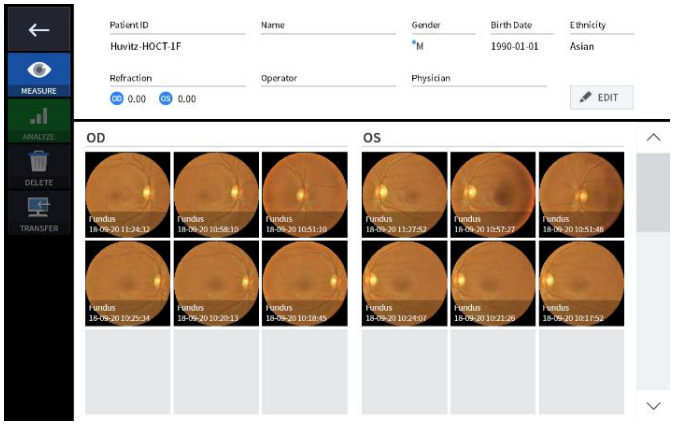
6.6.1. After operation

1. Exit software and Power off.

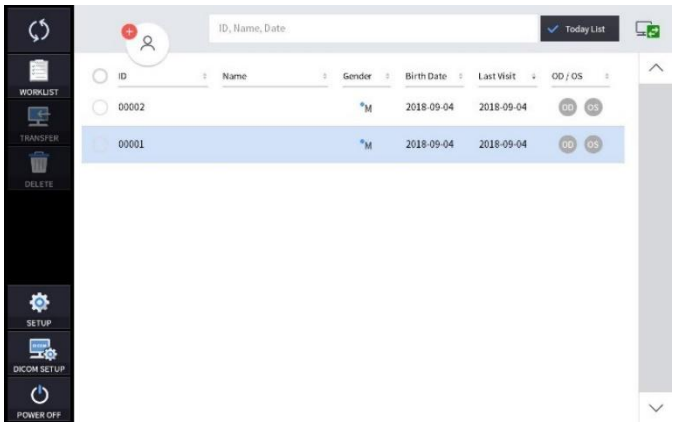
(1) Select the Patient information icon ( ) in the upper left corner of the screen.



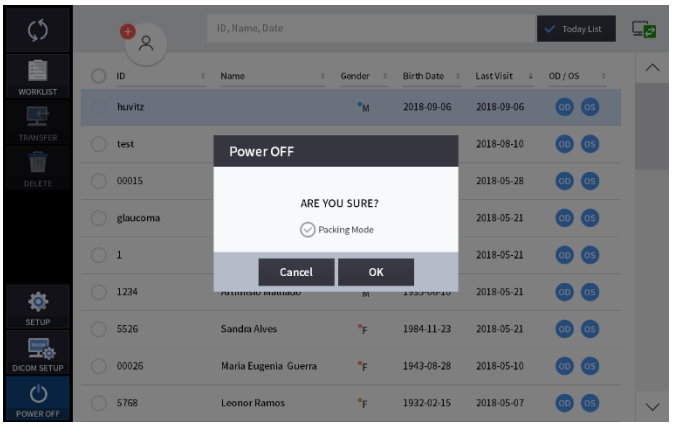
(2) Select the Previous screen icon ( ) in the upper left corner of the screen.



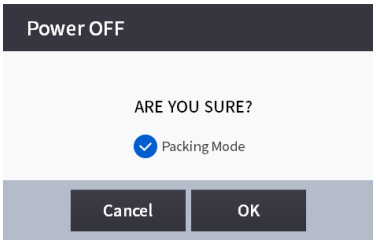
(3) Select the Power Off icon (POWER OFF) from the bottom left corner of the screen.



(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 HFC to the lowest position before Power off (This is for packaging).

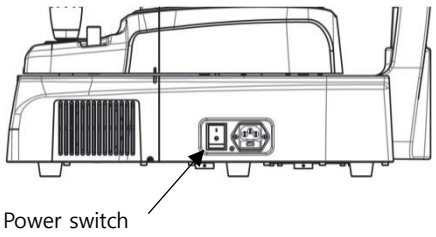


NOTE

To put the equipment in the packing box, select Packing Mode and then press OK to finish.

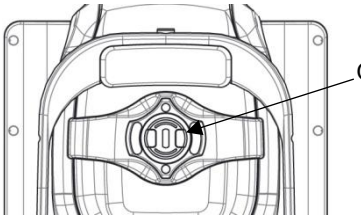
2. Turn off external devices (monitor, etc.) if any external device is connected.

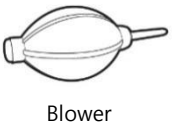
3. Turn the power switch off(O) on the base plate.



6.6.2. Cleaning

1. Cleaning objective lens
   (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.



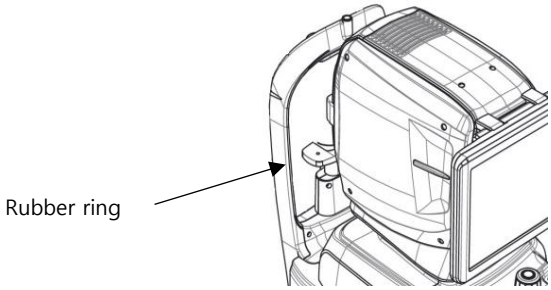


   (3) Any contaminants on the objective lens will affect the measurement. Wipe them using soft cotton swab or lens cleaning paper moistened with alcohol.
   (4) Be careful not to use the wrong tools, so as not to damage the surface of the lens.
   (5) When the Objective Lens Clean option in Setup mode is ON, the light is turned on to facilitate cleaning of the Objective Lens.

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.



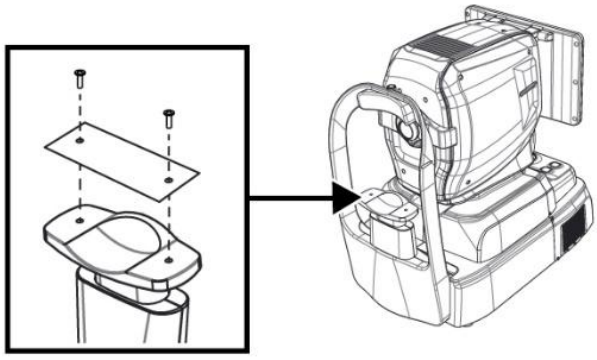
⚠ CAUTION

Do not use the solvents such as strongly volatile substance, thinner, benzene, etc
Do not use a sponge or cloth soaked in water because the water might leak into the equipment.
Clean headrest rubber and chinrest with an alcohol before sending device to authorized agent or Huvitz for maintenance.

N'utilisez pas de solvants tels que des substances fortement volatiles, des diluants, du benzène, etc.
N'utilisez pas d'éponge ou de chiffon imbibé d'eau car l'eau pourrait s'infiltrer dans l'équipement.
Nettoyez le caoutchouc de l'appuie-tête et la mentonnière avec de l'alcool avant d'envoyer l'appareil à un agent autorisé ou à Huvitz pour l'entretien.

6.6.3. Replacement of consumables and fuse

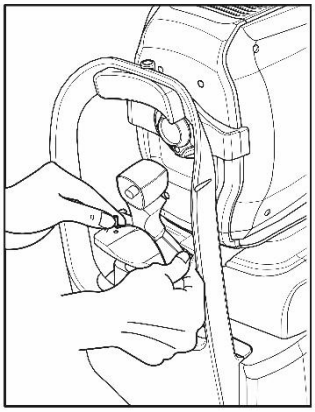
1. Replacing chinrest paper
   (1) Pull out two fixing pins from chinrest.
   (2) Put a new chinrest paper on the chinrest.
   (3) Insert two fixing pins into the chinrest paper hole.
   (4) Attach the chinrest paper to the chinrest.



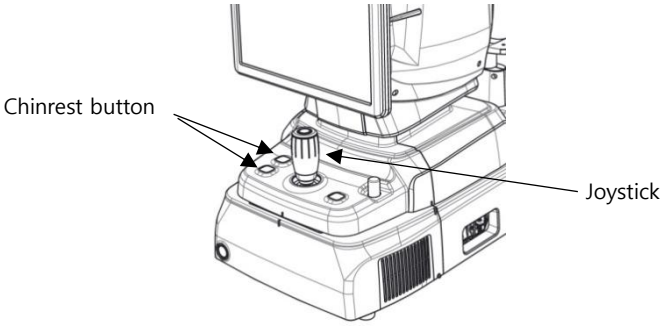
2. Replacing fuse
   (1) Ensure the power switch of device off (O).
   (2) Remove power cable from inlet.
   (3) Pull out fuse holder in the inlet with tweezers.
   (4) Replace two new fuses in the fuse holder. Be sure to check the fuse specification for the replacement (250V T 3.15AL).
   (5) Insert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

6.6.4. Self-diagnosis using Model eye

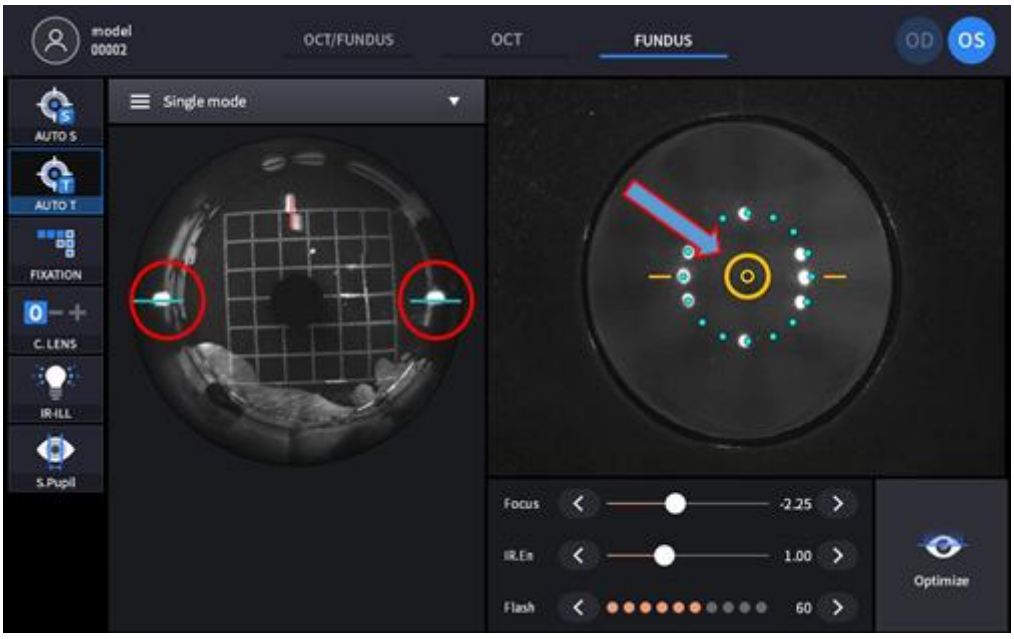
1. How to mount Model eye
   (1) Remove chinrest paper.
   (2) Mount Model eye as shown below and then fix it using two paper pins.



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



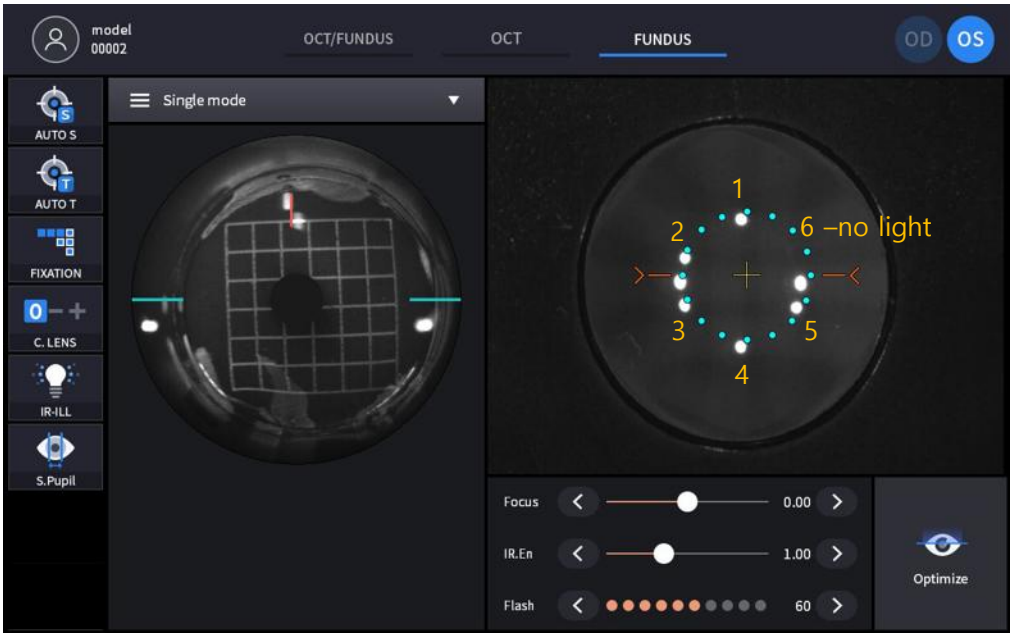
2. Checking working distance
   (1) Select FUNDUS measurement in MEASURE mode.



- 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

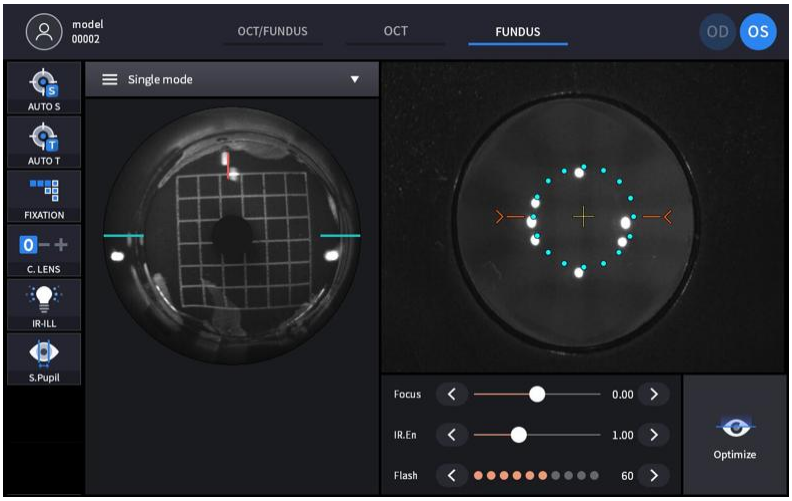
(1) Select FUNDUS measurement in MEASURE MODE.



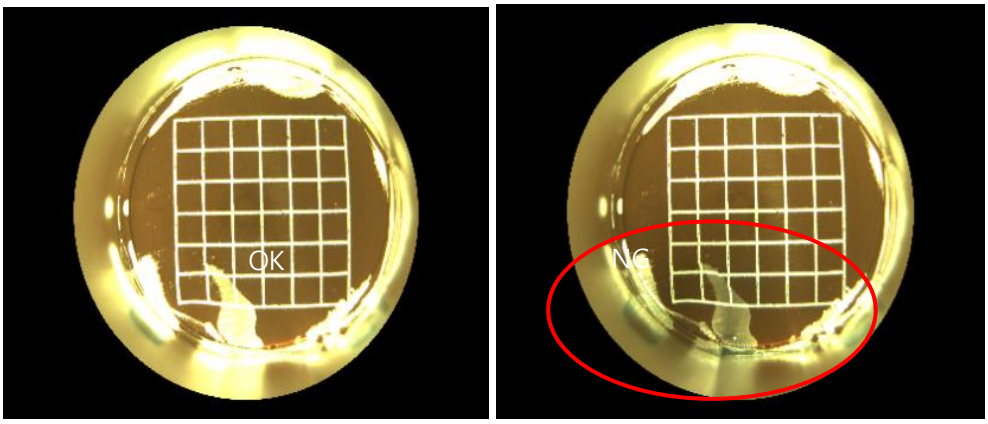
- Check anterior lighting LED. They consist of six dots except two center dots out of eight dots at anterior screen.
- KERATO SETUP shall be performed after changing LED when there is a problem with the LED and the LED shows OFF as number six shown in the picture.

4. Check Fundus Camera

(1) Select FUNDUS Mode and measure Fundus.

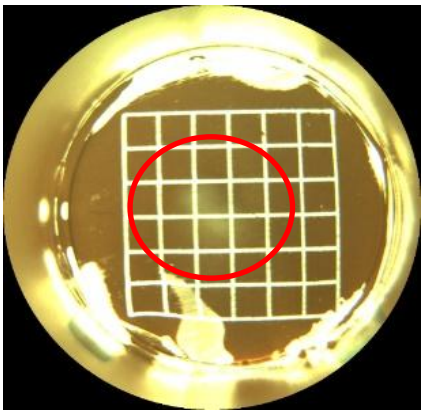


(2) Check if there are asymmetric areas as right picture from the measured images.



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

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



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

7

Troubleshooting Guide

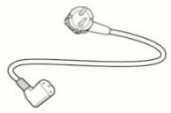
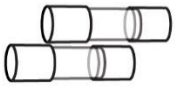
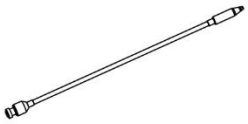
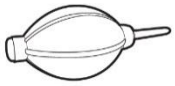
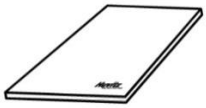
Should the device function improperly, attempt to correct the problem according to the following table before contacting sales distributors.
Contact a sales distributor after turning off the power when the device does not resume normal operation even after taking the following measures.

Problem	Cause	Solution
The screen does not turn on.	The power cable may not be 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 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

Specifications and Accessories

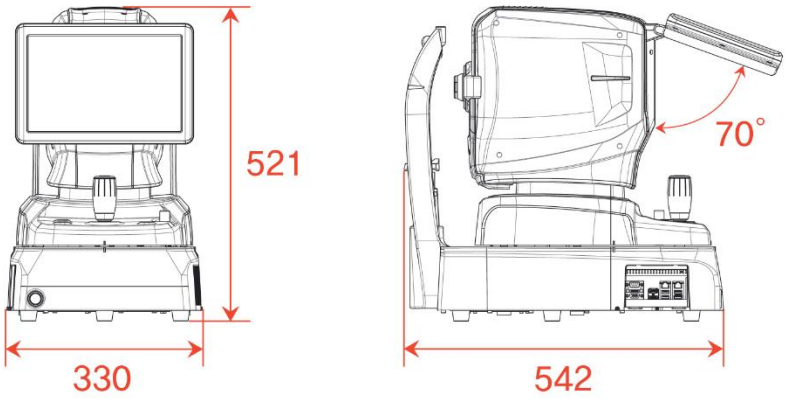
8.1. Standard Accessories

 Chinrest paper	 Touch pen	 Power cable
 Fuse (250V T 3.15A)	 Dust cover	 External LED
 Blower	 User manual	 Packing lock cap
 Model Eye		

8.2. Specifications

Device specifications	
Type	Non-mydriatic fundus camera
Resolution	Center :60 lines/mm or more Middle(r/2) :40 lines/mm or more Periphery(r) :25 lines/mm or more
Angle of view	45˚
Camera	Color Image Sensor
Minimum pupil diameter	4.0 mm (Normal mode), 3.3 mm (Small pupil mode)
Flash light	White light
Working distance	33 mm
Display	12.1 inch, 1280x800 pixel, Touch panel color LCD
Dioptric compensation for patient's eye	-33D ~ +33D total -33D ~ -7D with minus compensation lens -13D ~ +13D with no compensation lens +7D ~ +33D with plus compensation lens
Fixation target	LCD (internal), White LED (external)
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	X,Y for positioning, Z for working distance
Power supply	AC 100 - 240 V, 50/60 Hz, 1.6 - 0.7 A
PC	Built in computer
Dimensions	330(W) x 542(D) x 521(H) mm
Mass	28 kg

8.3. Drawings of System



9

EMC INFORMATION

Manufacturer announcement – electromagnetic waves trouble

- **Electromagnetic waves trouble**

  HFC-1 should be used in the below mentioned electromagnetic wave environment. HFC-1 purchaser or user needs to confirm whether HFC-1 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**

  HFC-1 is to be used in the below designated electromagnetic wave environment. HFC-1 customer and user need to guarantee that the HFC-1 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**

  HFC-1 is to be used in the below mentioned electromagnetic wave environment. HFC-1 purchaser or user needs to confirm whether HFC-1 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

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: Fundus Camera HFC-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.

11

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This Agreement will commence when you open this package or start the use of the Software and continue in effect until terminated by either party. You may terminate this Agreement at any time for convenience and HUVITZ may terminate this Agreement at any time for convenience. This Agreement will be immediately terminated if you fail to comply with any term or condition in this Agreement. Your payment will not be refunded in any event of termination. When this Agreement is terminated, you will cease your use of Software, and destroy and erase all the Software and Documentation. Section *4, 5, 6,* 7, 8, 13 and 14 will be unaffected and survive the termination of this Agreement.

10. NO ASSIGNMENT

This Agreement or any part of this Agreement may not be assigned or transferred by you without the prior written consent of HUVITZ. Any assignment or transfer without such consent will be null and void.

11. NO THIRD PARTY RIGHTS

This Agreement is intended to be solely for the benefit of the parties and is not intended to confer any benefits upon or create any rights in favor of, any person other than the parties in this Agreement.

12. EXPORT REGULATIONS

Software is subject to Japanese export security laws and regulations and may be subject to export laws and regulations in other countries. You agree to comply strictly with such export laws and regulations.

13. SEVER ABILITY

If any Section in this Agreement is found to be void or unenforceable by applicable law, such Section will be deleted automatically and the remaining Sections of this Agreement will remain in full force and effect.

14. NO WAIVER

The delay, omission or failure of HUVITZ to enforce any right or remedy in this Agreement will not be construed to be a waiver of such right or remedy of HUVITZ.

15. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement between the parties and supersedes any prior written or oral agreement between the parties concerning the Software.