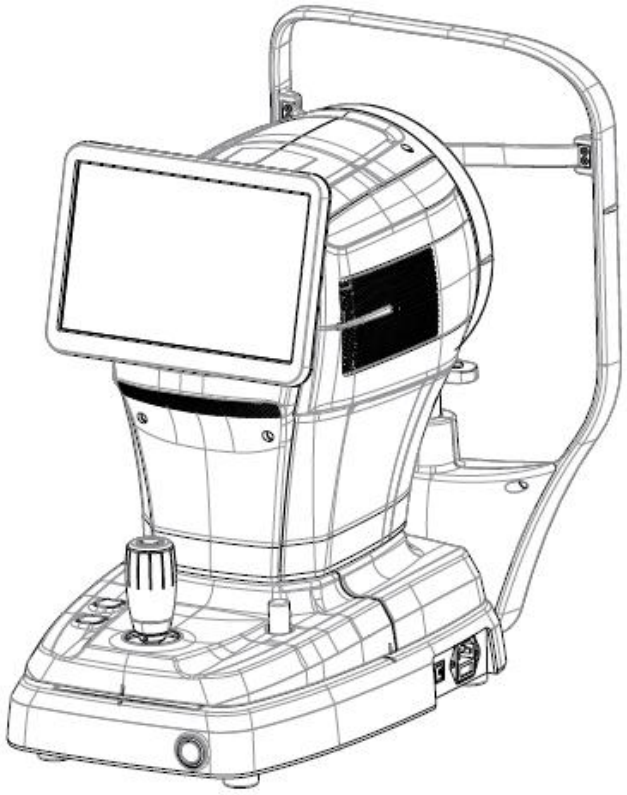
ENG

OPTICAL BIOMETER

HBM-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.

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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	2021.05.27	박 상 전	First issued
B	2023.04.21	박 상 전	Added new SW functions - Contact Lens Fitting - Myopia Management Added NOTE regarding errors in measurement
C	2023.09.08	박 상 전	Change screenshot for new GUI
D	2024.11.25	박 상 전	Updated the information of brazil representative
E	2025.11.17	김 재 민	Change appearance , Update GUI Screenshots 3.2. Delete dryeye content from Intended USE

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(2025/11/17)

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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

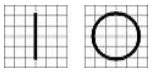
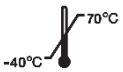
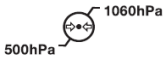
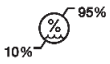
This is used to emphasize essential information.

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.)



Class I Laser Product
(Produit au laser de classe I)



CE for RoHS
RoHS Directive Compliance 2011/65/EU
(CE pour les RoHS Respect de la directive en matière de conformité 2011 / 65 / CE)



Medical Device
(dispositif medical)



Authorized representative in Switzerland
(Représentant autorisé dans la Suisse)

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.

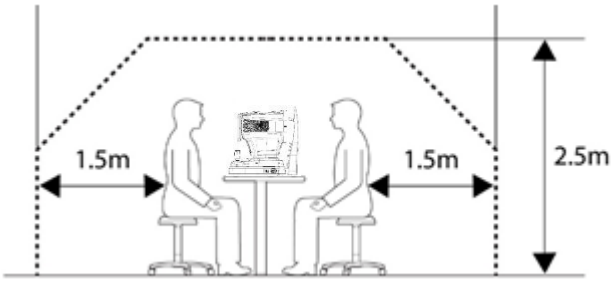
⚠ CAUTION

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.

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

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

- Do not direct Laser beams to human eyes when unncecessary.
- Do not look into the objective lens for a prolonged time.

L'équipement est un produit laser de classe I. Le laser utilisé pour l'équipement est sûr dans les conditions d'utilisation prévues, y compris dans des situations telles que l'examen de la LED à l'aide d'un équipement optique. Cependant, observez les précautions suivantes lors de l'utilisation de l'équipement.

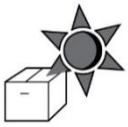
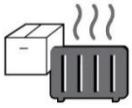
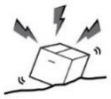
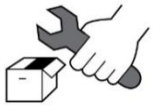
- Ne dirigez pas les faisceaux laser vers les yeux humains lorsque cela n'est pas nécessaire.
- Ne regardez pas dans l'objectif pendant une période prolongée.

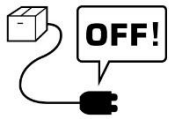
Intended User Profile

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: Doctor, ophthalmologist
c. Level of training: Recommend completing training how to use it is.
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.)

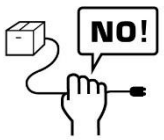
2.2. Environmental Considerations

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.

This instrument can withstand the following conditions:

1. Operation

- An ambient temperature range of 10℃ ~ 35℃ (50°F ~ 95°F)
- A relative humidity range of 30% ~ 90% (with non-condensing)
- An atmospheric pressure range of 800 ~ 1060hpa
- An illuminance of the measuring room at 10~100 lux

2. Transportation

- An ambient temperature range of -40℃ ~ 70℃ (-40F ~ 158°F)
- A relative humidity range of 10% ~ 95%
- An atmosphere pressure range of 500 ~ 1060hpa

3. Storage

- An ambient temperature range of -10℃ ~ 55℃ (14°F ~ 131°F)
- A relative humidity range of 10% ~ 95% (with non-condensing)
- An atmosphere pressure range of 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

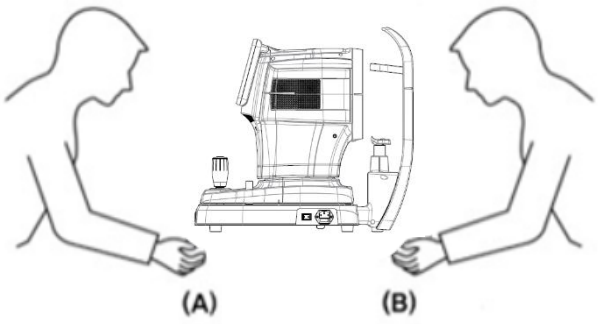
⚠ WARNING

1. This is an electric medical device. Use is limited to doctors or persons qualified by the law of each country.
2. The IOL calculator is an additional tool to help physicians selecting the appropriate IOL for particular patient. The result from our IOL calculator cannot serve as an only indicator of cataract surgery without additional comprehensive ophthalmic examination and specific diagnostic tests.
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., IEC62368 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 directley if an operator has a hand injury or a significant allergic reaction to the material used in the operaton 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 HBM-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 HBM-1. The manufacturer isn't responsible for the problem.

25. Immediately after the test, you may not be able to see clearly due to glare. It is recommended to sit back, relax and move around.

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. Install and operate software within secure operating environment that allows only authorized users to access and that the system network is equipped with Window firewall built-in Windows system, windows Defender antispyware tools and other common security tools /application systems

29. Avoid resetting or turning off the PC when the HBM-1 running.

30. 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

31. 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. Identify, analyze, evaluate and control these RISKS.

32. 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. Le calculateur de la LI est un outil supplémentaire pour aider les médecins à choisir la LI appropriée pour un patient particulier. Le résultat de notre calculateur de LI ne peut servir d'indicateur unique de la chirurgie de la cataracte sans un examen ophtalmique approfondi supplémentaire et des tests diagnostiques spécifiques.

3. 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.

4. 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.

5. 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.

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

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

8. 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

9. 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.

10. 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.

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

12. 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.

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

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

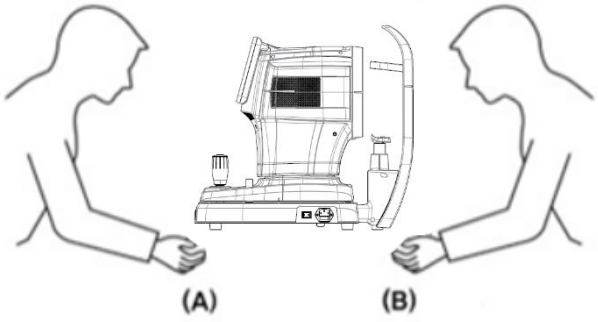
15. Si de la fumée, des étincelles ou un bruit ou une odeur anormale est remarqué provenant de l'instrument, veuillez éteindre immédiatement et débrancher la prise.

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

17. Ne placez pas l'instrument là où il est difficile de faire fonctionner le dispositif de déconnexion. (dispositif de déconnexion: câble d'alimentation)

18. 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, IEC62368 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.

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



20. 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

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

22. 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.

23. 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.

24. 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 HBM-1. Le fabricant n'est pas responsable du problème.

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

26. Immédiatement après le test, il se peut que vous ne puissiez pas voir clairement en raison de l'éblouissement. Il est recommandé de s'asseoir, de se détendre et de se déplacer.

27. Lorsque la boîte d'emballage est ouverte par inadvertance avant utilisation ou endommagée, veuillez appeler le centre A/S.
28. Assurez-vous que vous disposez toujours d'un antivirus et d'un pare-feu à jour installés sur votre système.

29. Évitez de réinitialiser ou d'éteindre le PC lorsque le HBM-1 est en marche.

30. 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.

31. 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. Il est conseillé à l'ORGANISME RESPONSABLE d'identifier, d'analyser, d'évaluer et de contrôler ces RISQUES.

32. Des modifications ultérieures du RÉSEAU INFORMATIQUE pourraient introduire de nouveaux RISQUES et nécessiter une analyse supplémentaire. Les modifications apportées au RÉSEAU INFORMATIQUE incluent :
    1) modifications de la configuration IT-NETWORK
    2) ajout d'éléments (plateformes 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.

6. After the examination, the patient may be slightly dazed. It is recommended to advise the patient to wait a few minutes before driving or performing actions that require perfect vision.

7. Contact lenses must not be worn by the patient during data acquisition.

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.

6. Après l'examen, le patient peut être légèrement étourdi. Il est recommandé de conseiller au patient d'attendre quelques minutes avant de conduire ou d'effectuer des actions nécessitant une vision parfaite.

7. Les lentilles de contact ne doivent pas être portées par le patient pendant l'acquisition des données.

3

INTRODUCTION

3.1. System Outline

The Huvitz Optical Biometer HBM-1 is a device for the biometric measurements of ocular structures.
The HBM-1's functions are combined with optical biometry and corneal topography.
HBM-1 contains all the basic functions of corneal topography for recording keratorefractive parameters.

HBM-1 Software uses Window 10 Operating System. Recognized formulae such as Holladay 1, Haigis, Hoffer Q, SRK/T, SRK II, Camellin-Calossi, Shammas No history are executed in the software and the information derived from the measurement can be used for various applications such as IOL calculation, IOL toric calculation, post lasik calculation and cataract operations.

3.2. Intended Use

The Optical Biometer HBM-1 is a medical device that optically measures eye components such as:

*Axial length
*Corneal curvature radii
*Corneal cylinder axis
*Anterior chamber depth
*Central corneal thickness
*Crystalline lens thickness
*White-to-white
*Pupil diameter
*Dry eye Analysis
The Optical Biometer HBM-1 also measures corneal topography.

3.3. Classification

- Classification of product: Class IIa according to Medical Device Regulation 2017/745 Annex VIII Rule 10
- 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)
- Classification of Laser Product: Class 1 (laser based on IEC 60825-1:2014 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

Optical Biometry measures ocular structures by analyzing of the interferometry signal. The signal is higher when some structure is found. From the signal, ocular structures are detected and calculated by signal processing. Corneal Topography is that show major refractive element of corneal surface. The Placido disc pattern is reflected by a 50% beam splitter attached to the body of the microscope. Algorithms based on image processing techniques were implemented for edge detection of pattern.

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 19980: Ophthalmic instruments – Corneal topographers

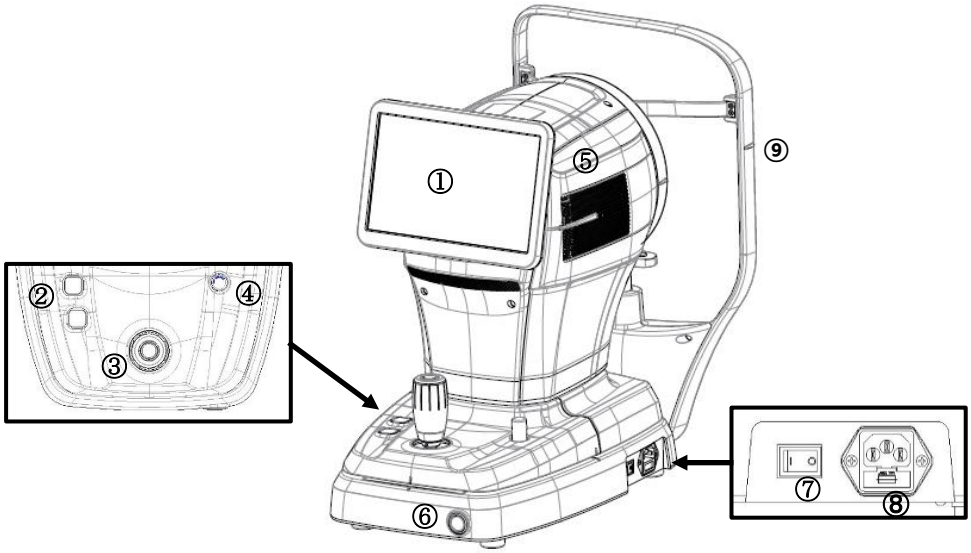
- IEC 60825-1: Safety of laser products – Part1: Equipment classification and requirements

4

System Overview

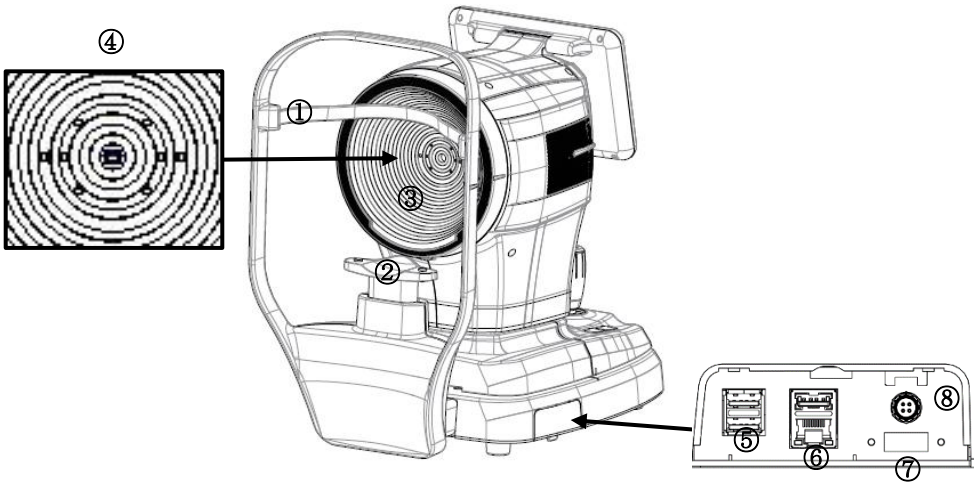
4.1. Configuration and Functions

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. Measurement button.
4		User Lock	Lock for fixing body to base frame.
5		Heat vent	Window for emitting internal heat.
6	Base	Power button	Button for turning power of internal PC on/off. When the power is on, white light is lit.
7		Power switch	Switch for power on/off.
8		Power inlet	Inlet for connecting power cable.
9	Headrest	Eye level mark	Mark for indicating base height of patient's eye.

Rear View

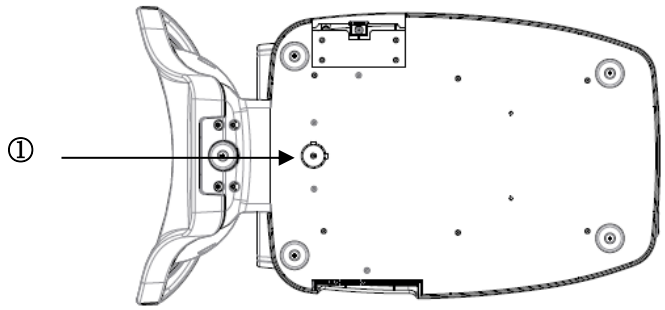


No	Part	Name	Description
1	Headrest	Headrest	The part that holds the patient's head
2		Chinrest	For fixing patient’s chin.
3	Body	Placido disk	Check the curvature of the cornea.
4		Focus LED	LEDs for checking patient’s eye.
5	Base	LAN port	Port for external network (1 ports)
6		USB port	Port for internal or external USB device (2 ports)
7		HDMI port	A port for connecting an external display device (1 port)
8		Foot switch port	A port for connecting a foot switch (1 port)

NOTE

Interference between USB 3.0 and 2.4GHz wireless signals may cause connectivity and data transfer speed issues. To avoid interference, consider using an extension cable, changing the wireless channel on Wi-Fi devices, or using only USB 2.0 devices. If the problem persists, consider using a wired connection or upgrading to a 5GHz wireless network.

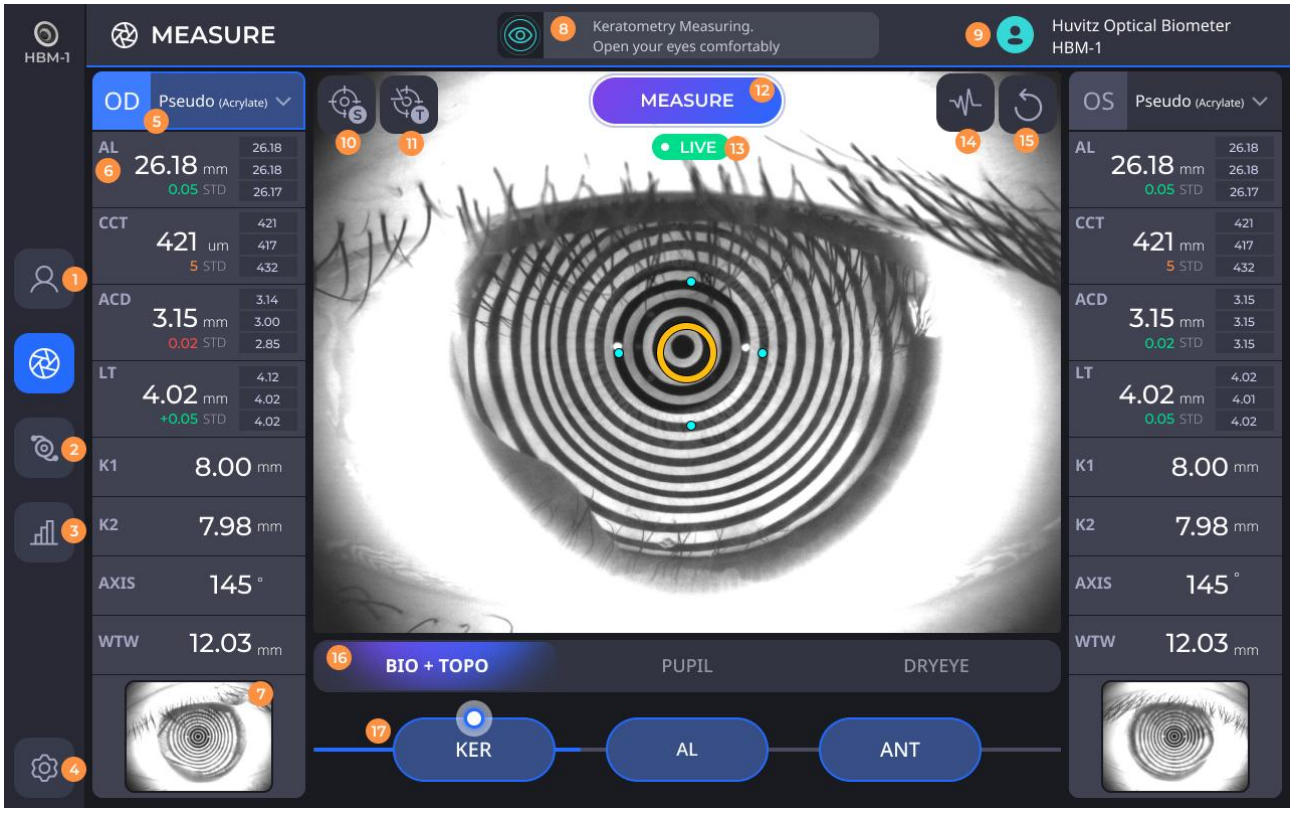
Bottom View

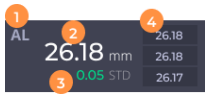


No	Part	Name	Description
1	Base	Packing lock	Lock for fixing body and base during transportation.

4.2. Main Body Screen Description

MEASURE screen



No	Name	Function
1	Patient	End the measurement and move to the patient list screen.
2	IOL Calculation	Use the measured data to move to the IOL Calculation screen.
3	Result	Use the measured data to move to the Result screen.
4	Setting	Open the settings popup.
5	Eye Status	Display the left/right eye indicator and the condition of the lens and vitreous of the examinee.
6	Measurement Data	Display the measured data.  1) Measurement data name 2) Average value of the measurement data 3) Standard deviation of the measurement data 4) List of measured data
7	Kerato Preview	Show the eye used for analysis after Keratometry measurement.
8	Message	Display messages required for measurement.
9	Patient Information	Display the patient's name and Patient ID.
10	Auto shot	Turn automatic measurement ON/OFF when focus is achieved.

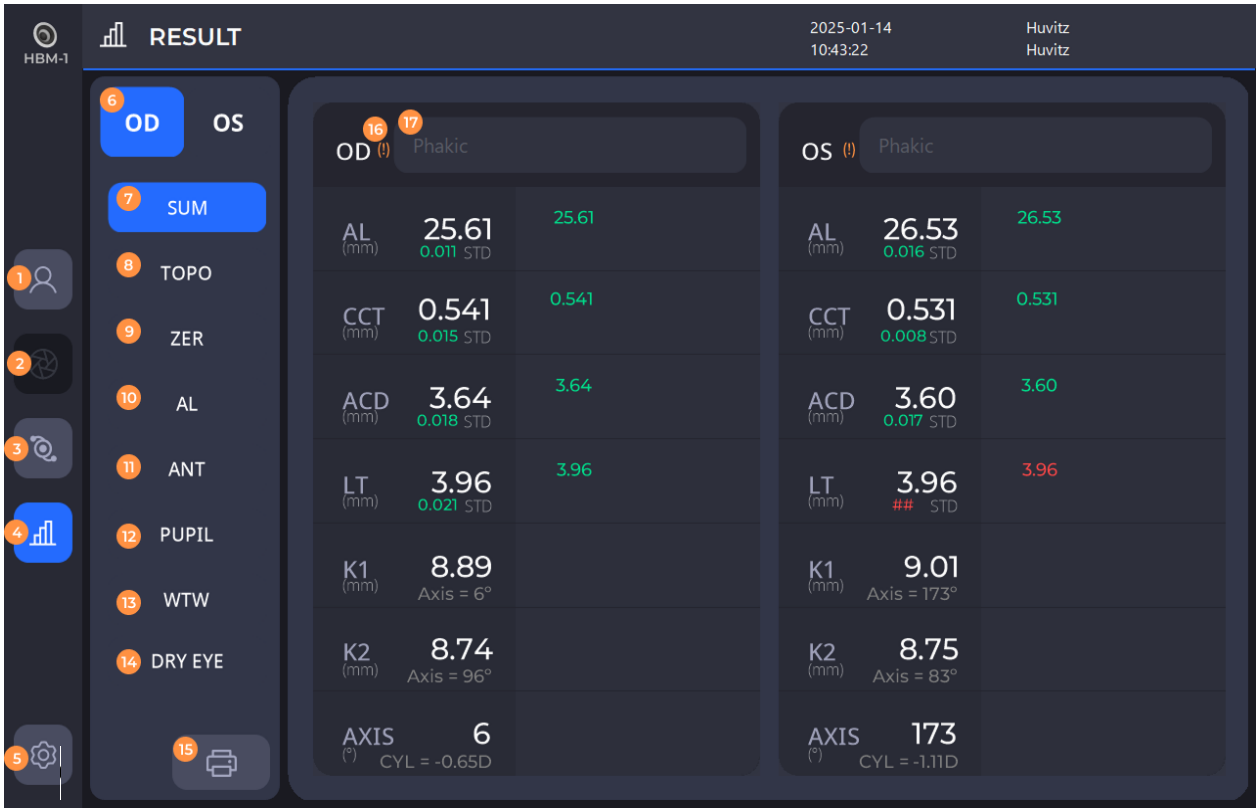
11	Auto Tracking	Turn the auto-focus function ON/OFF.
12	Measure Button	Start measurement when clicked.
13	Camera Status	Display the camera status. LIVE : The camera is playing in real time. PREV : Showing measured data in preview mode. REC : Measuring in REC mode such as Pupillometry, NIKBUT, and BLINK.
14	Live Signal	Display real-time A-scan signals during Biometry measurements (AL, CCT, ACD, LT). (Available only for Biometry measurement.)
15	Measurement Mode	Bio + Topo: Measurement mode providing Biometry and Keratometry usable for IOL Calculation. PUPIL: Mode for observing pupil changes such as daytime and nighttime conditions. DRY EYE: Mode for dry eye examination.

* During Dry Eye (Meibography) measurement, a wide field of view may be difficult to obtain depending on the distance between the patient and the device. Attaching the Wide Lens included with the device to the front of the unit increases the field of view and facilitates measurement.

* For measurements other than Dry Eye (Meibography), using the device with the Wide Lens attached may result in measurement errors.

RESULT screen

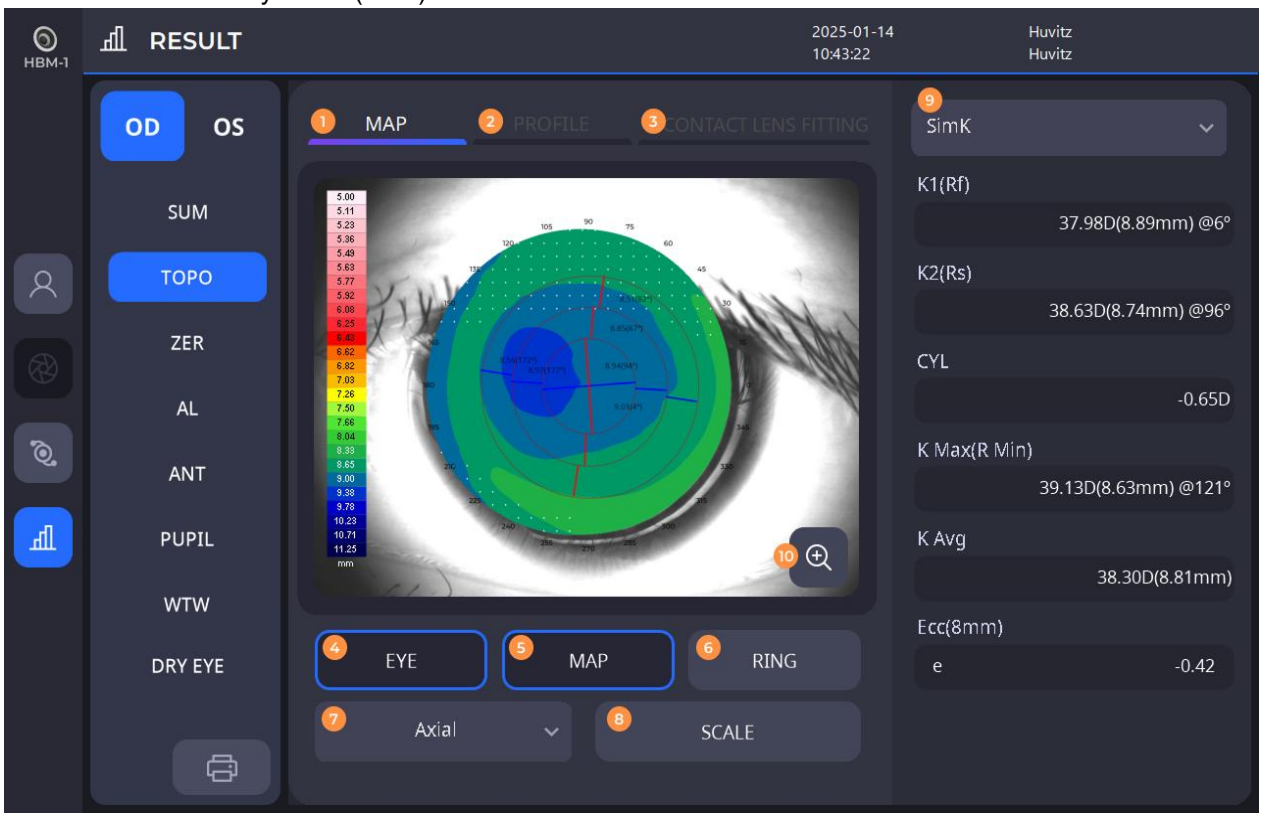
1. Summary result (SUM)



No	Name	Function
1	Patient	Move to the patient list screen.

2	Measure	Move to the measurement screen. * This action is only available during an active measurement.
3	IOL Calculation	Move to the IOL Calculation screen using the current data.
4	Result	Move to the result screen (current screen).
5	Setting	Open the settings popup.
6	Eyeside	Select the eye for which you want to view the results.
7	Summary	Move to the Summary screen to review all data at once.
8	Topography	Move to the screen for reviewing corneal topography such as Keratometry, Meridian, and Keratoconus.
9	Zernike	Move to the screen for analyzing aberrations using corneal topography.
10	Axial Length	Move to the screen for analyzing Axial Length data.
11	Anterior	Move to the screen for analyzing CCT, ACD, and LT data.
12	Pupillometry	Move to the screen for analyzing daytime vision, nighttime vision, Angle Kappa, and Chord Mu.
13	White To White	Move to the screen for analyzing White-to-White data.
14	Dry eye	Move to the screen for analyzing dry eye examination data.
15	Export	Move to the screen for generating HIIS-1, DICOM, or reports.
16	Warning Mark	Appears when there is a data issue or an informational message requiring attention. Clicking it opens a message popup like the one shown below. 
17	Eye Status	Indicates the condition of the examinee's lens and vitreous.

2. Keratometry result (KER)

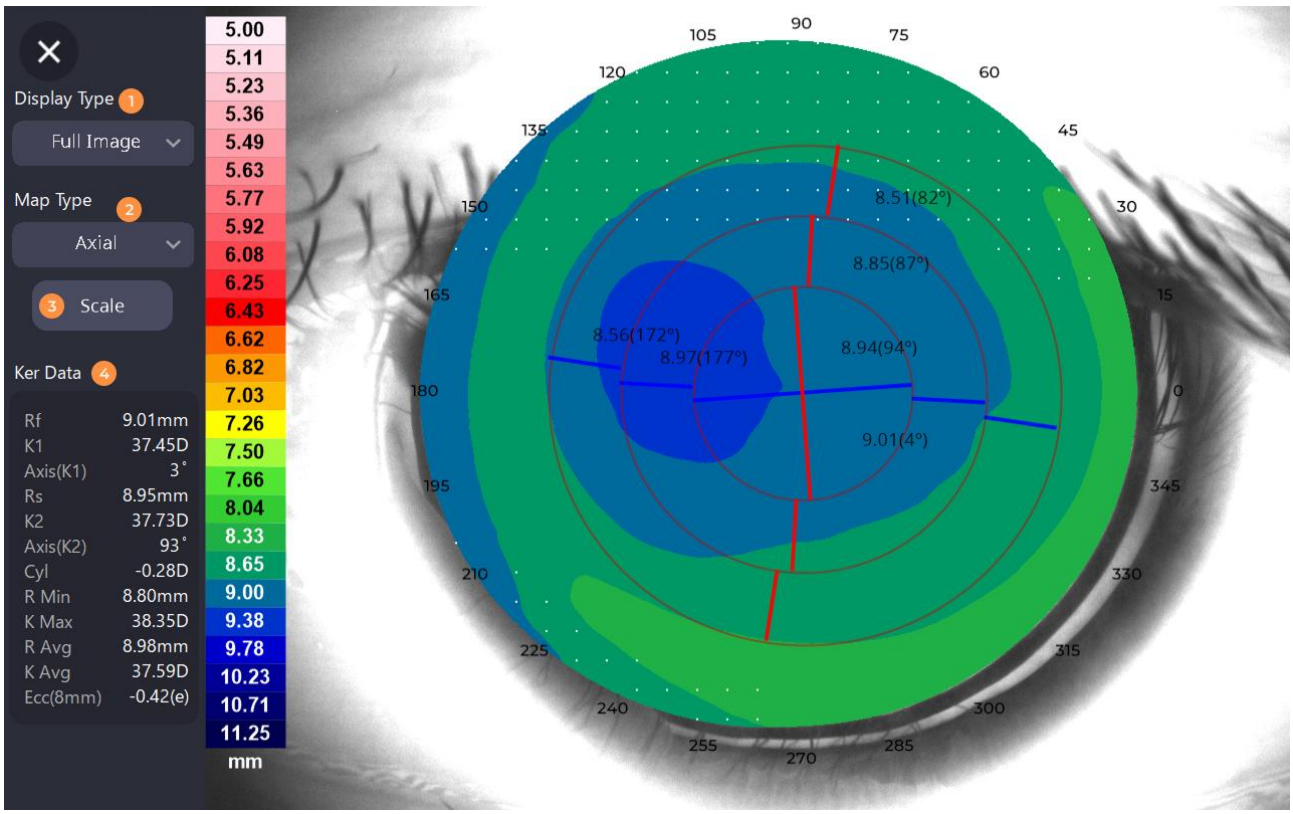


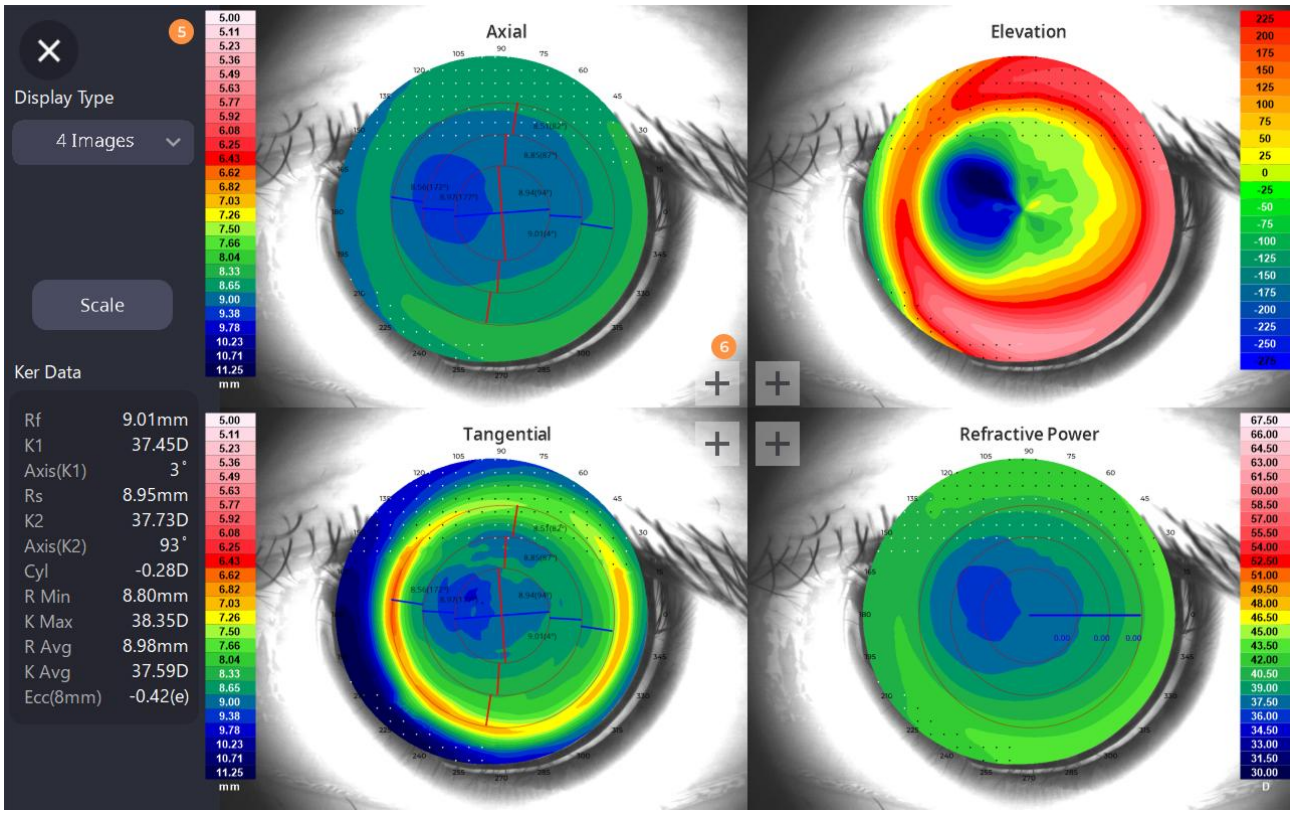


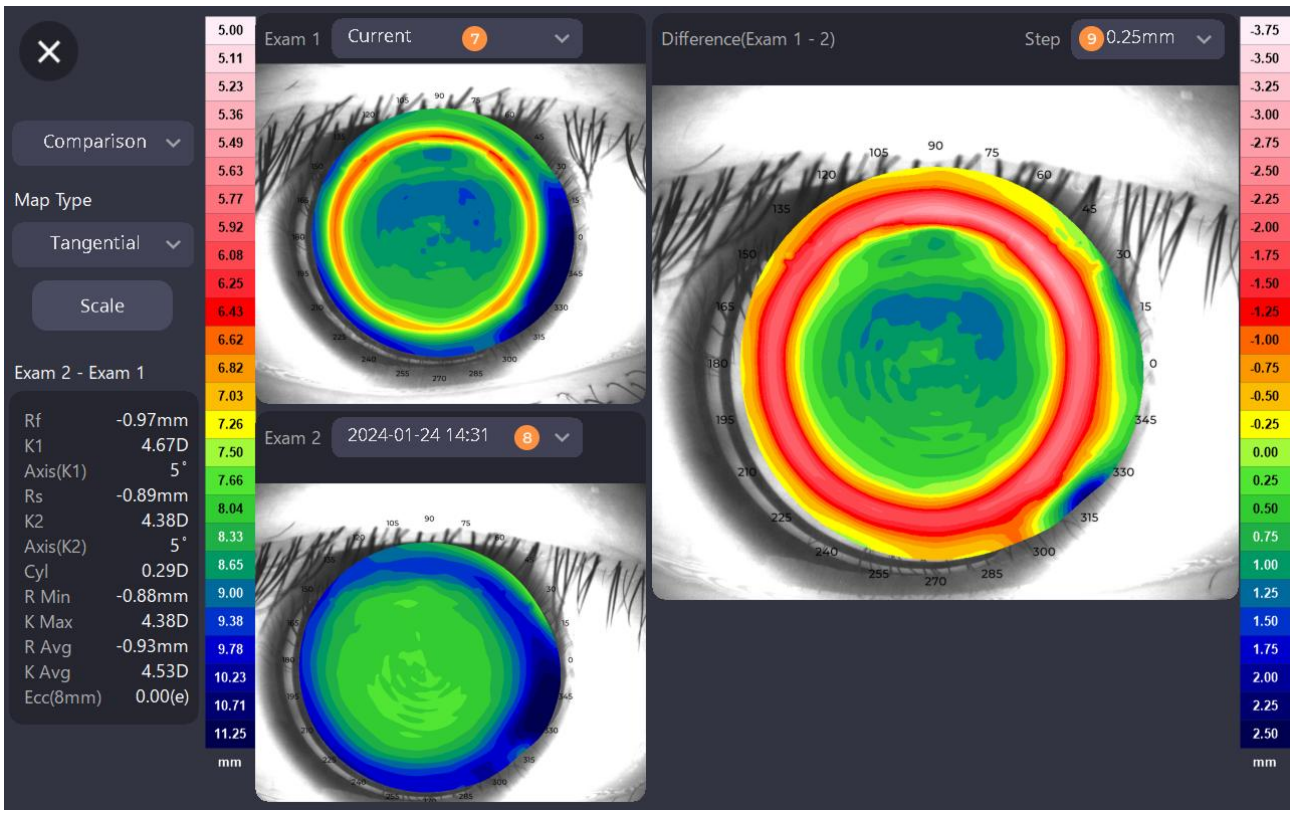


No	Name	Function
1	Map	Move to the Topography Map screen.
2	Profile	Move to the screen that compares the curvature of the steepest and flattest meridians.
3	Contact Lens Fitting	Move to the screen for lens fitting based on the measured corneal topography.
4	Eye	Turn ON/OFF the function that displays the examinee's eye as a background on the Topography Map screen.
5	Map	Turn ON/OFF the function that displays the map on the Topography Map screen.
6	Ring	Turn ON/OFF the function that checks the accuracy of Placido ring detection.
7	Topography Map Type	Select the type of Topography Map.
8	Scale	Select the map's color scale and overlay.
9	Simulated Keratometry	Analyze the corneal curvature of the simulated keratometry zone.
10	Zoom	Display the map in full screen and move to the 4-Maps or Comparison screen.
11	Meridian Keratometry	Analyze the corneal curvature from 2 to 7 mm.
12	Keratoconus	(Configurable in Setup: 2-4-6 mm or 3-5-7 mm)

2.1. Topography Zoom

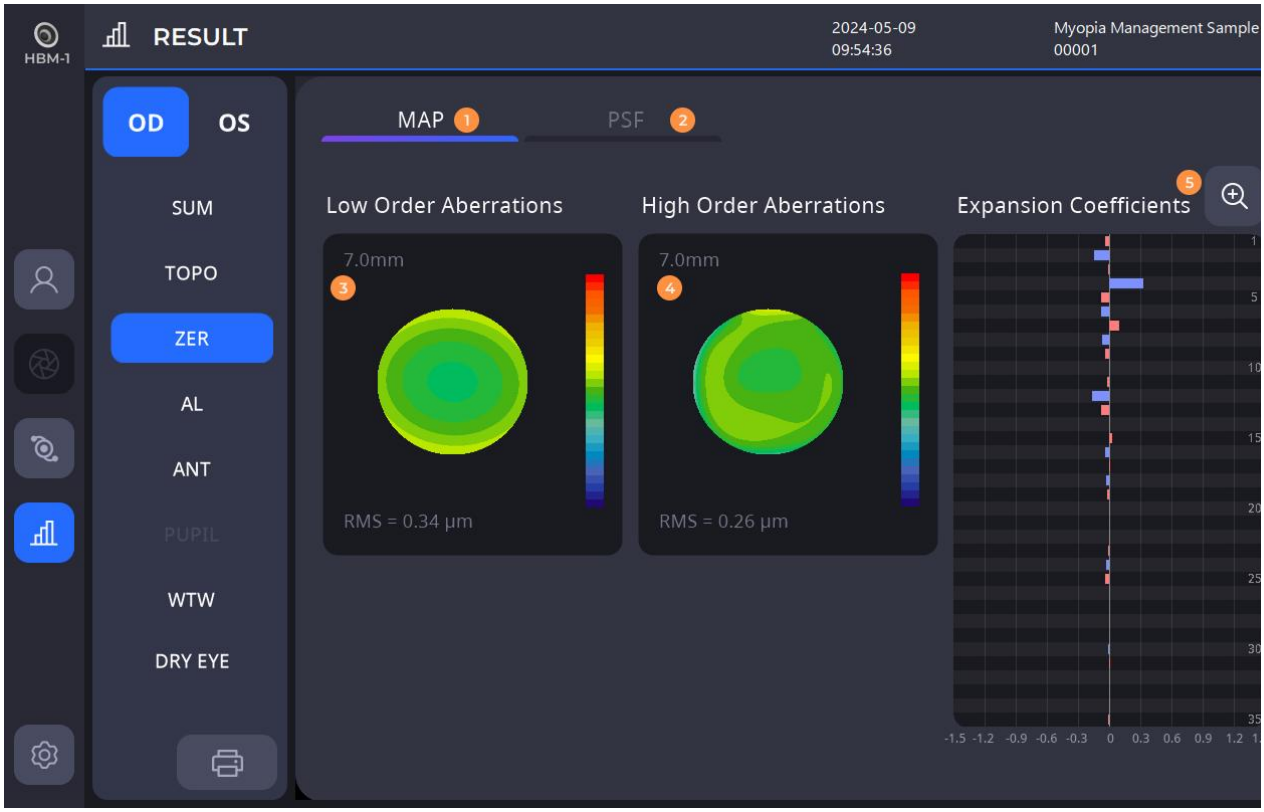

Display Type 1
Full Image
Map Type 2
Axial
3 Scale
Ker Data 4
Rf 9.01mm
K1 37.45D
Axis(K1) 3°
Rs 8.95mm
K2 37.73D
Axis(K2) 93°
Cyl -0.28D
R Min 8.80mm
K Max 38.35D
R Avg 8.98mm
K Avg 37.59D
Ecc(8mm) -0.42(e)
5.00
5.11
5.23
5.36
5.49
5.63
5.77
5.92
6.08
6.25
6.43
6.62
6.82
7.03
7.26
7.50
7.66
8.04
8.33
8.65
9.00
9.38
9.78
10.23
10.71
11.25
mm
8.51(82°)
8.85(87°)
8.56(172°)
8.97(177°)
8.94(94°)
9.01(4°)

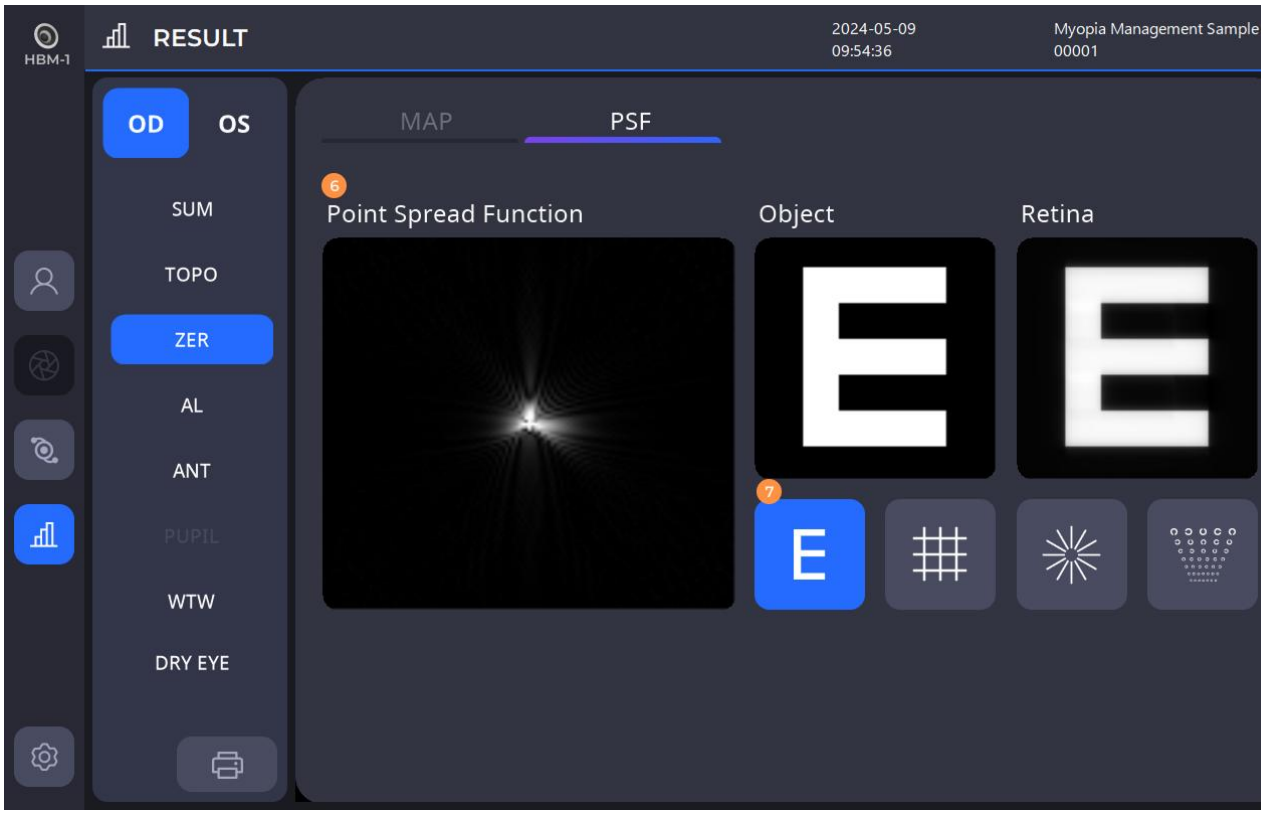

5
Display Type
4 Images
Scale
Ker Data
Rf 9.01mm
K1 37.45D
Axis(K1) 3°
Rs 8.95mm
K2 37.73D
Axis(K2) 93°
Cyl -0.28D
R Min 8.80mm
K Max 38.35D
R Avg 8.98mm
K Avg 37.59D
Ecc(8mm) -0.42(e)
Axial
Elevation
Tangential
Refractive Power
6



No	Name	Function
1	Display Type	Set the output type. (Full Image / Comparison / 4 Maps)
2	Map Type	Select the map to output.
3	Scale	Change the colorbar scale and overlay.
4	Simulated Keratometry	Display the screen that provides SimK data information.
5	4 Images	Display the screen that provides the 4-Map view.
6	Zoom	Enlarge the selected map within the 4-Map view.
7	Exam 1 선택	Select Comparison Target 1 in the Comparison screen.
8	Exam 2 선택	Select Comparison Target 2 in the Comparison screen.
9	Step	Select the step of the color scale in the Difference Map.

3. Zernike result (ZER)

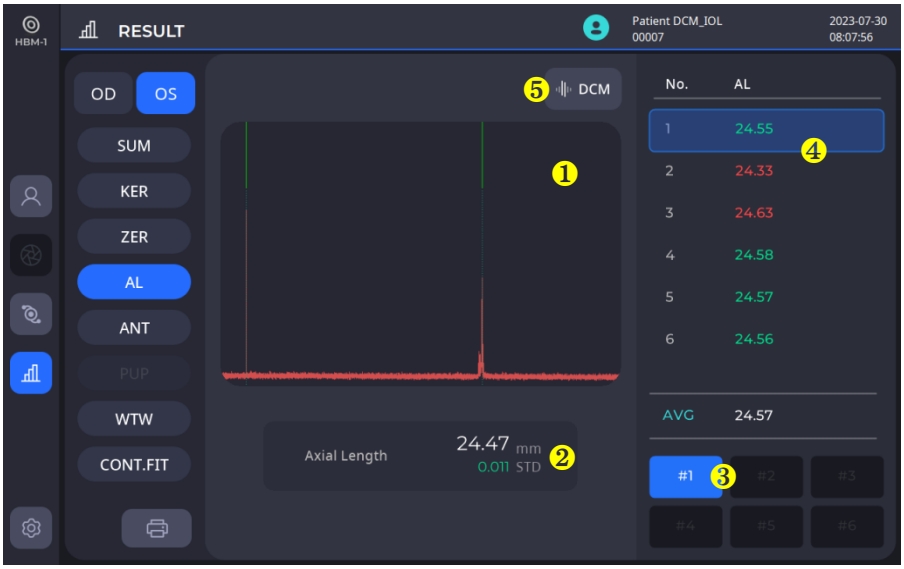






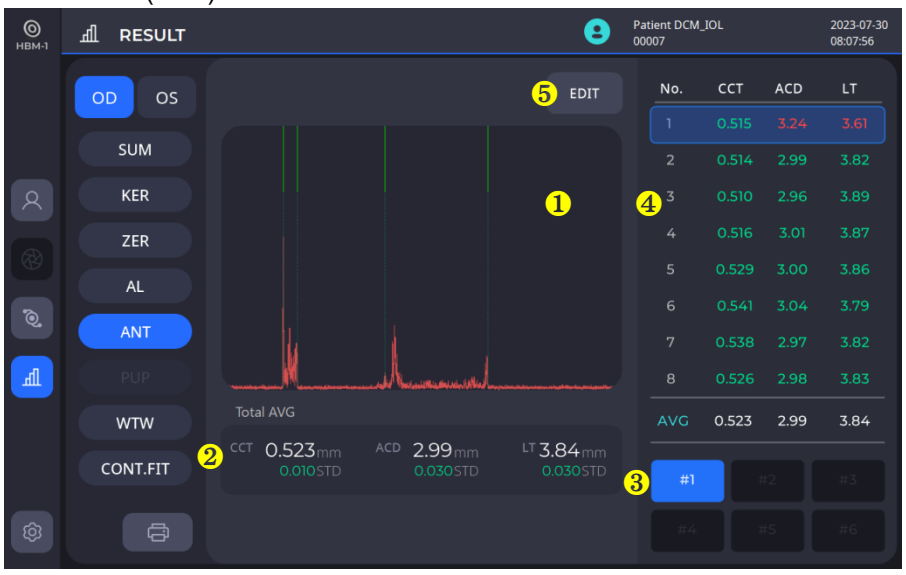
No	Name	Function
1	Map	Move to the aberration map and coefficient graph screen.
2	PSF	Move to the point spread screen.
3	Low Order Abbrrations	Display the low-order aberration map.
4	High Order Abbrrations	Display the high-order aberration map.
5	Detail	Display detailed data for each aberration.
6	PSF	Display the point spread image.
7	Echart/Grid/Radial/ETDRS	Echart: Display the E chart. Grid: Display the grid chart. Radial: Display the radial chart. ETDRS: Display the ETDRS chart.
8	Expansion Coefficients	Display detailed data for each aberration.

4. AL result (AL)



No	Name	Function
1	Signal graph	Show the measured signal image.
2	Average value	Show the average measured axial length value.
3	Each values	Select measurement to see in detail.
4	Detail values	6 measured values are grouped one single measurement. Show detail data of each measurement group. Detail value is evaluated by STD value. Detail value color indicates evaluation result, green means that value is reliable, red means that value is hard to reliable. Only reliable values(green color values) are included in the average value calculation(Each measurement values).
5	DCM	Find signal more precisely for dense cataract(On/Off) In case of dense cataract, this function can help to find weakness corneal signal.

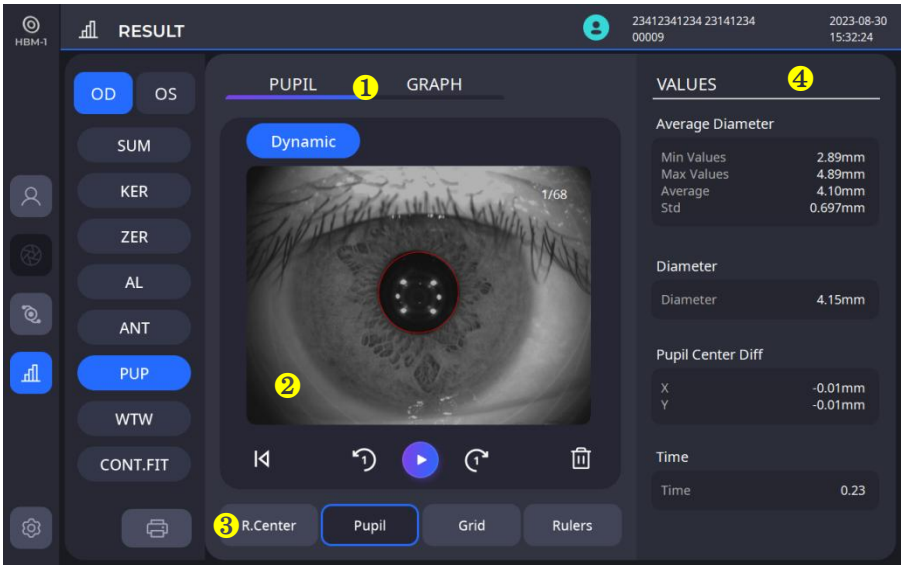
5. Anterior result (ANT)

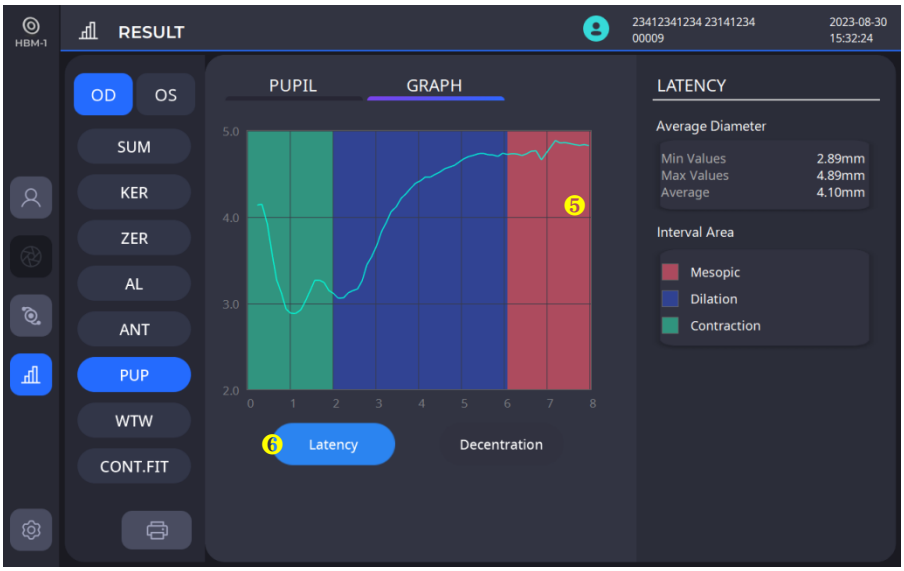


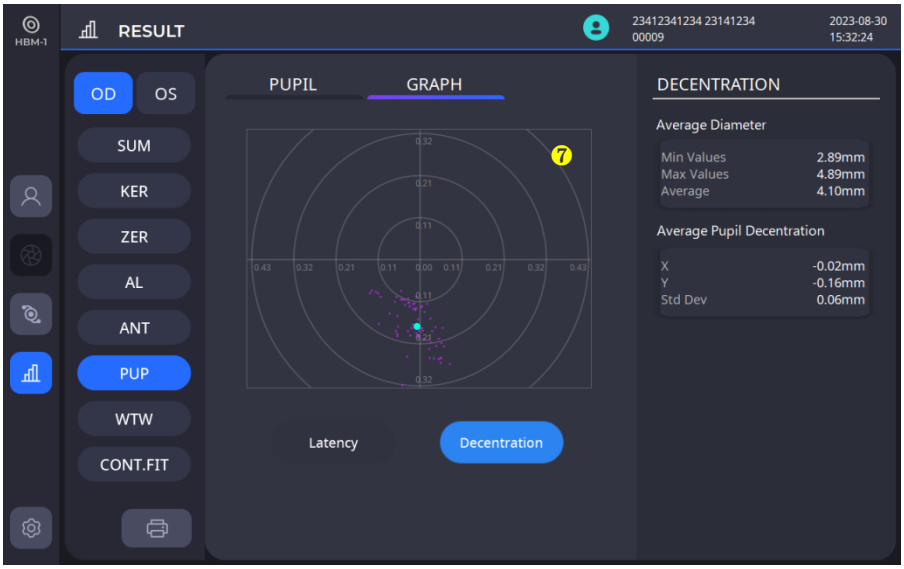
No	Name	Function

1	Signal graph	Show the measured signal image.
2	Average value	Show the average measured Anterior values(CCT: Central Corneal Thickness, ACD: Anterior Chamber Depth, LT: Lens Thickness)
3	Each values	Select measurement to see in detail.
4	Detail values	Show the each measurement Anterior values. Each value is evaluated by STD value. Each value color indicates evaluation result, green means that value is reliable, red means that value is hard to reliable. Only reliable values(green color values) are included in the average value calculation(Each measurement values).
5	Edit	Edit detection position for bad detection.

6. Pupilometry result (PUP)

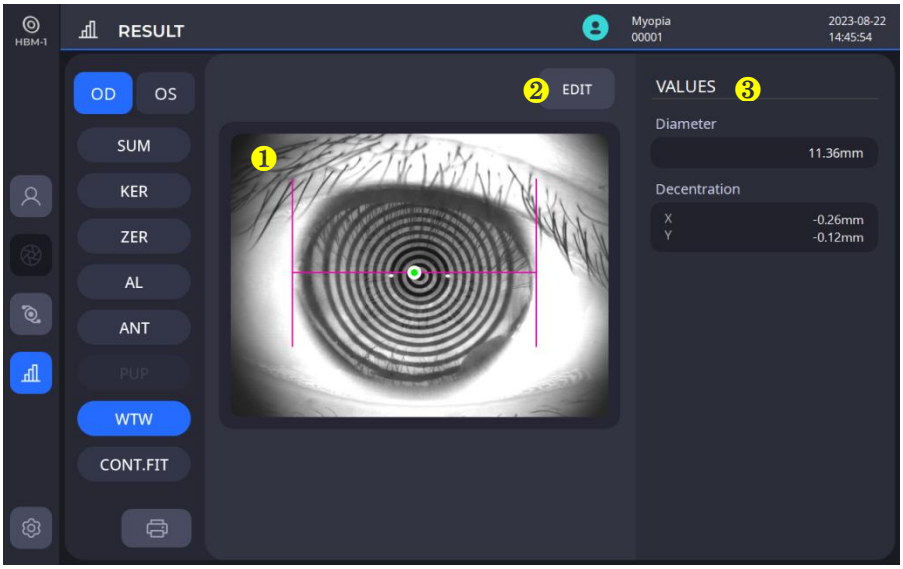


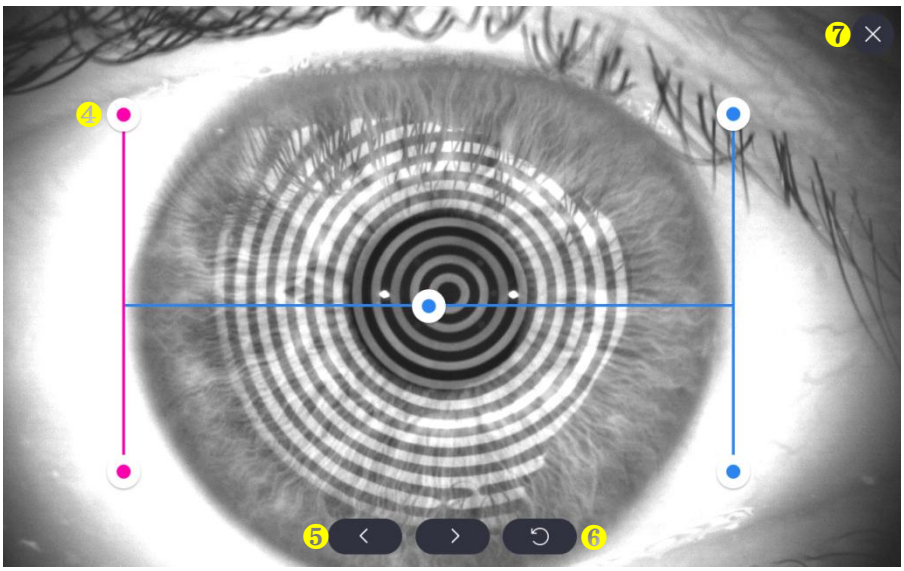




No	Name	Function
1	Pupil/Graphs	Pupil: Show the continuous image of pupil, and check the pupil changes. Graph: Show the Latency and Decentration graph.
2	Captured image	Show captured images during the measurement.
3	Display options	Select display options among Center, Pupil, Grid, Rulers
4	Measurement values	Show analyzed measurement result.
5	Latency	Show the variation of pupil during the measurement as graph.
6	Latency/Decentration Selection	Select page between Latency and Decentration
7	Decentration	Show the variation of pupil center.

7. White to White result (WTW)

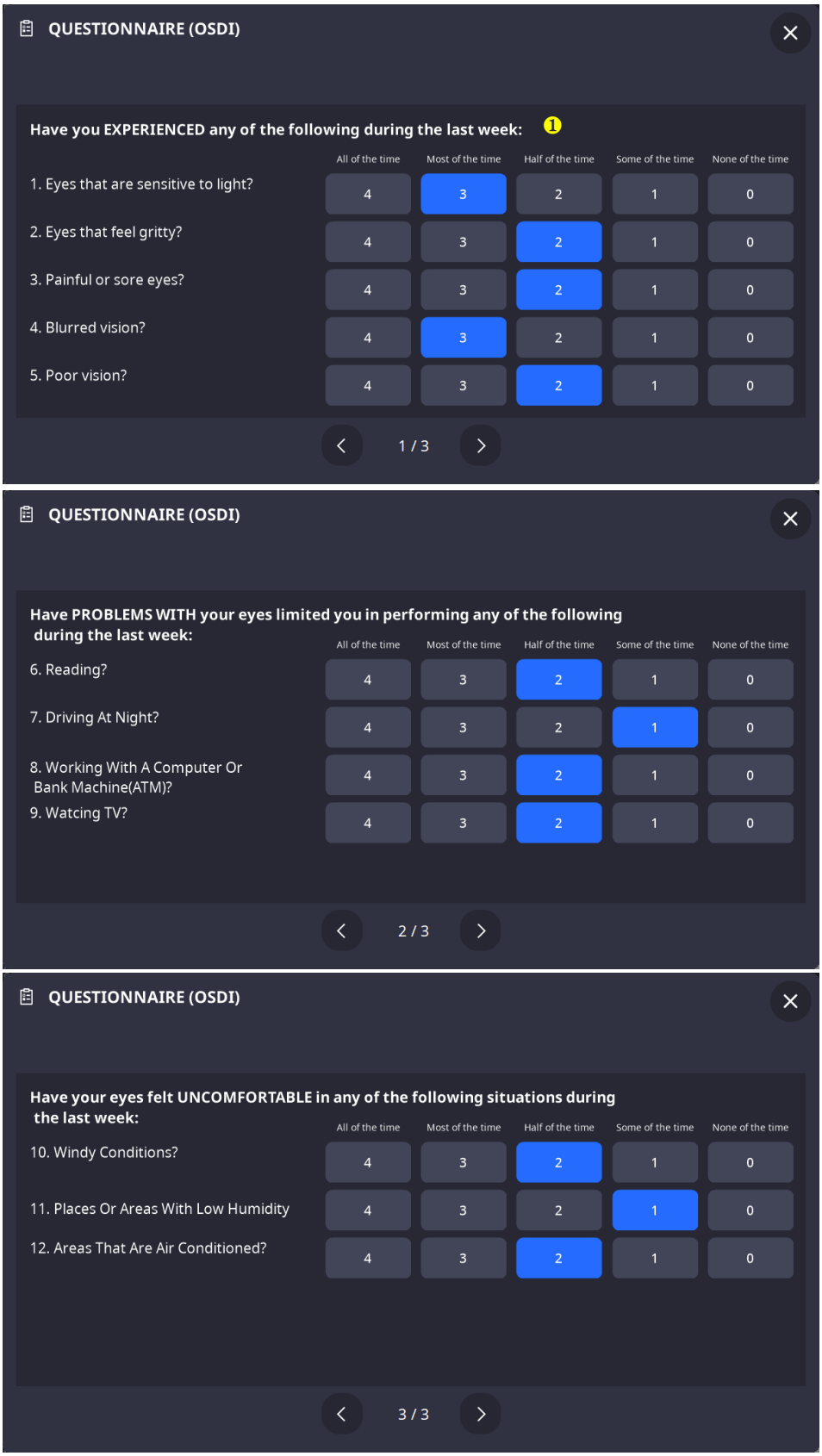




No	Name	Function
1	WTW bar	Calculate the WTW with the both bar distance.
2	Edit	Edit WTW bar states on the edit window.
3	Values	Show the White To White values.
4	edit window -Edit bar	Click the bar makes it active (pink color expressed the active state). In the active state, move the bar to set the WTW position.
5	edit window -detail move button	If you need small movement, using button supports it
6	edit window -reset	Reset the bar to original location.
7	edit window -save and close	Finished editing, save and close the edit window.

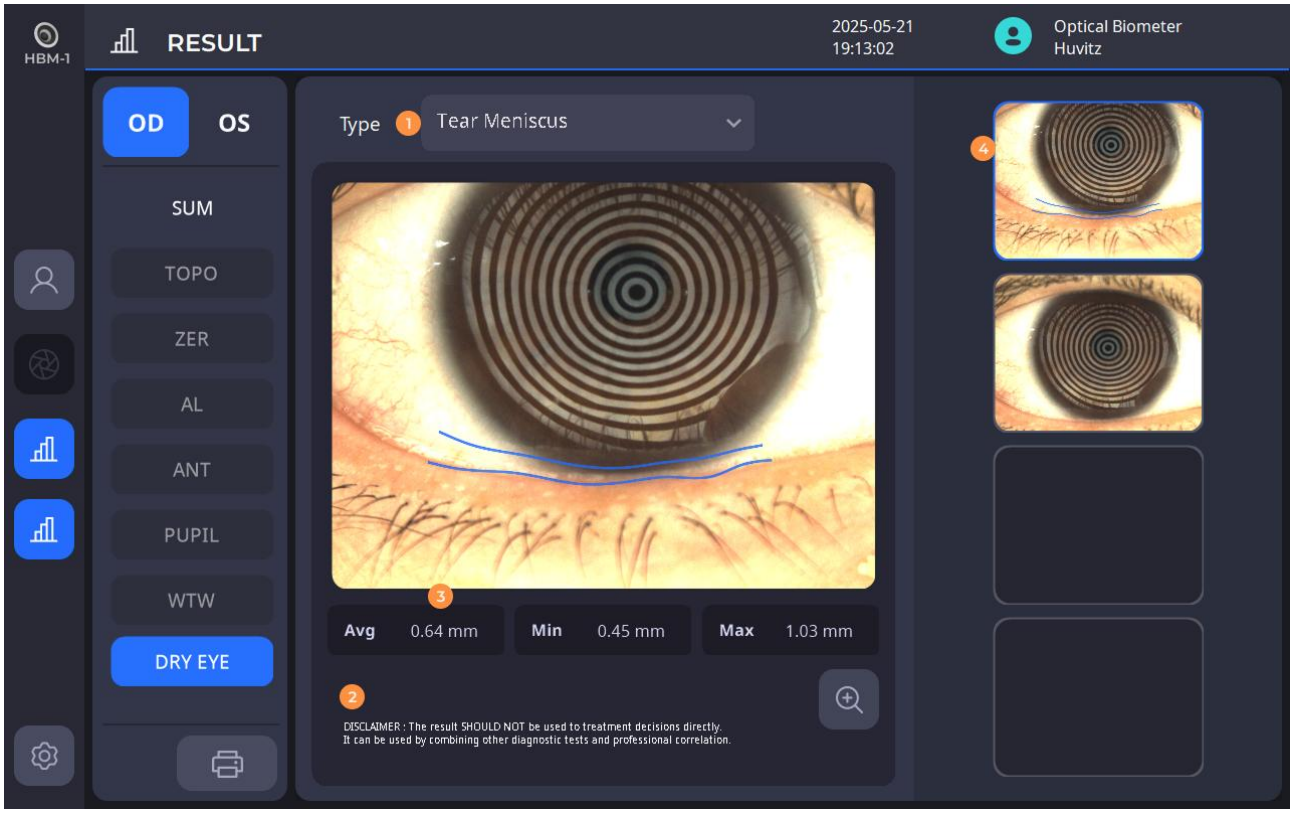
8. Dry Eye Analysis

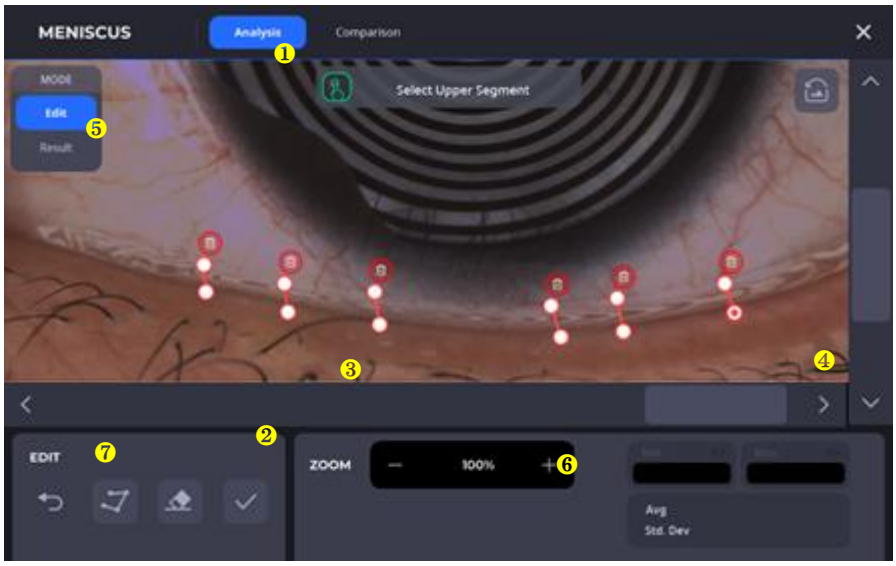
8.1. Questionnaire

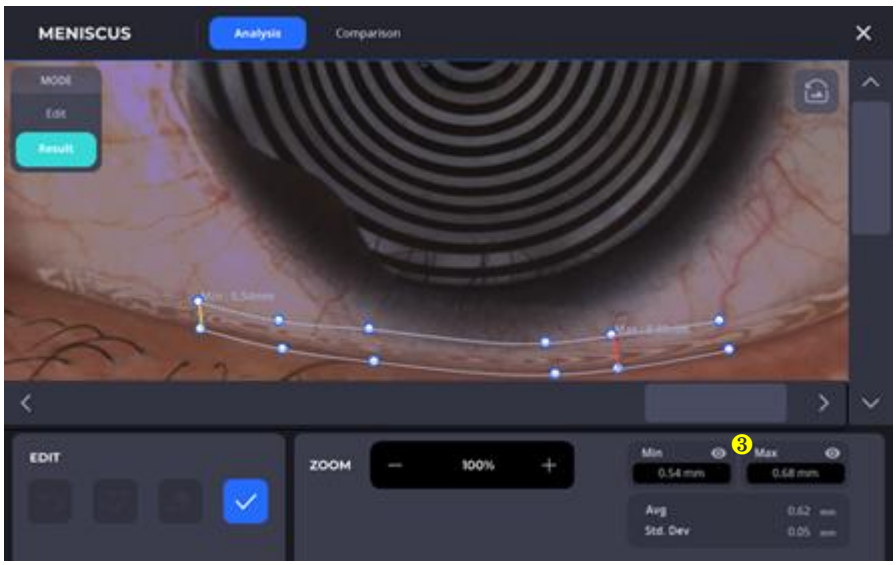


No	Name	Function
1	Survey Content	Write the survey content.

8.2. Tear Meniscus Height



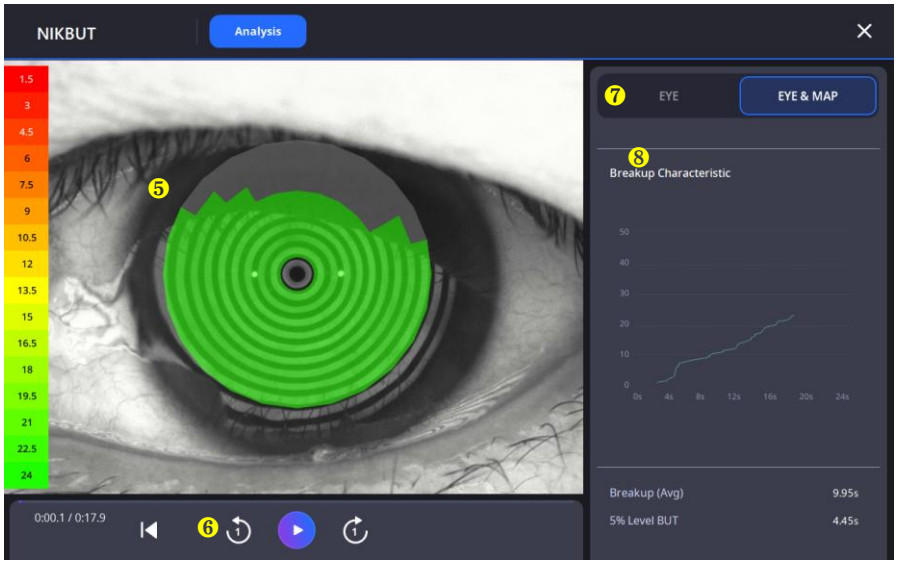




No	Name	Function
1	Type	You can select the desired dry eye examination result.
2	Image Selection	You can select a captured image to proceed with analysis.
3	Analysis Result	Displays the analysis result.
4	Detail Analysis	Allows detailed review and editing of the selected image.
5	Mode	Select the mode for choosing the tear film layer and viewing the results afterward.
6	Zoom	Zoom in or out on the image for analysis.
7	Edit	Configure and edit the selection area for analysis.

8.3. NIKBUT

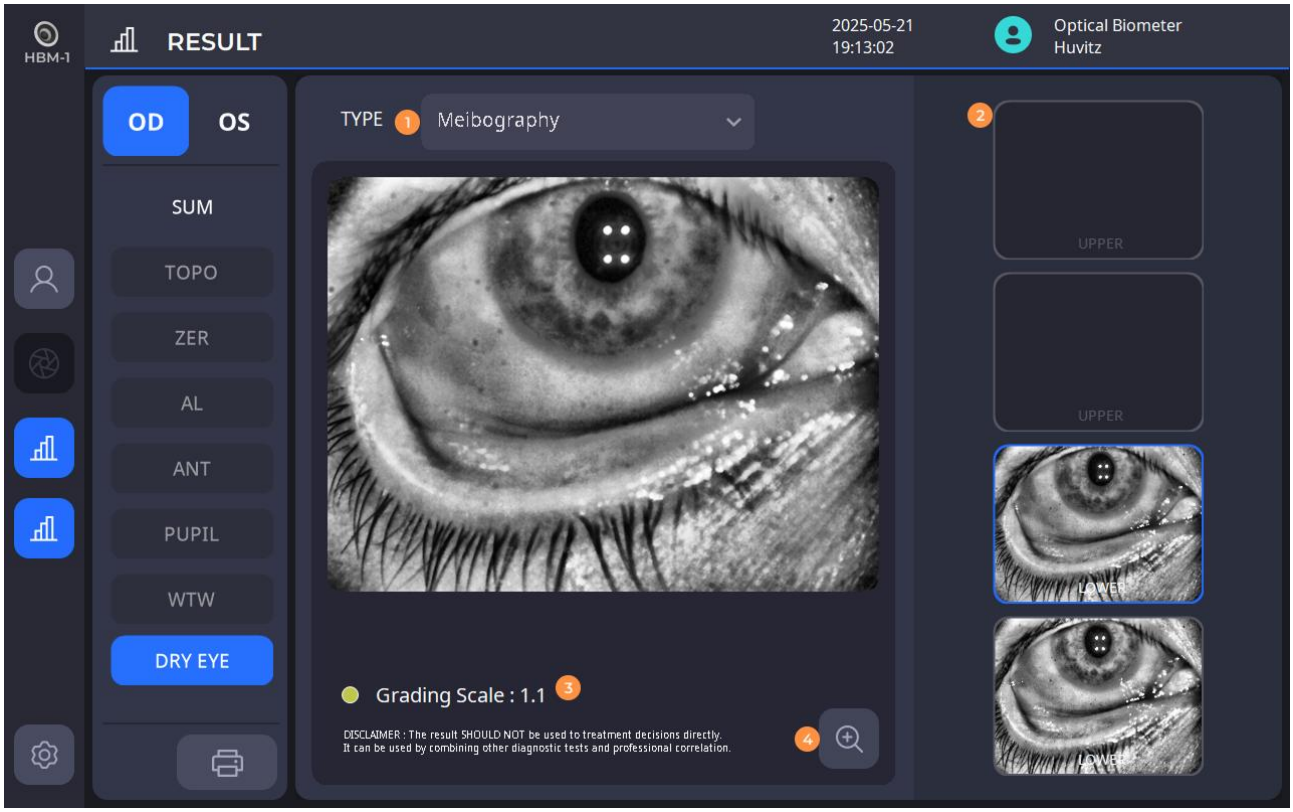


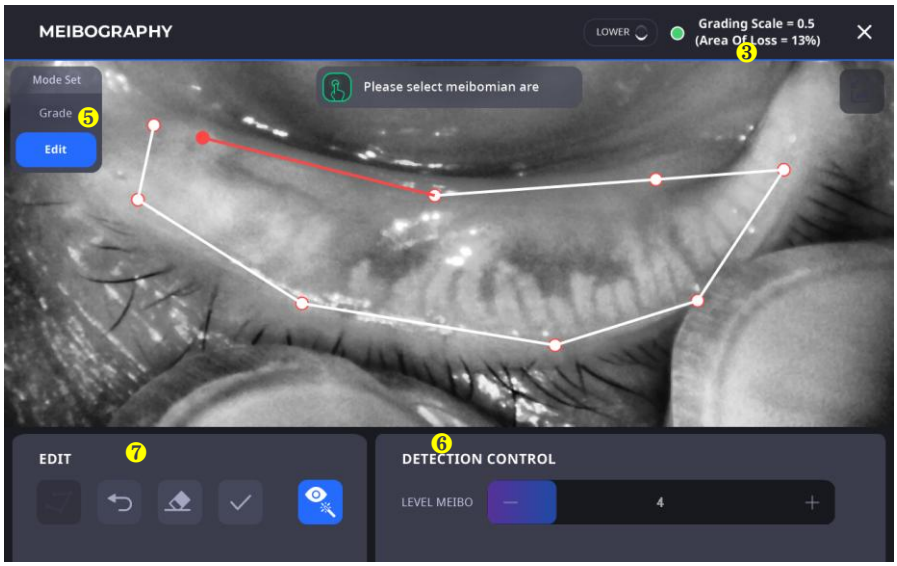


No	Name	Function
1	Type	You can select the desired dry eye examination result.
2	Image Selection	You can select a recorded video to review the results.
3	Analysis Result	Displays the analysis result.
4	Detail Analysis	Allows detailed review of the selected image.
5	Color Map	Displays the tear film breakup regions on a map along with the degree of breakup.
6	Play	Play the video or move frame by frame.

7	Eye & Map	Shows either the eye image or the map image depending on the selection.
8	Breakup Graph	Displays the breakup progression over time as a graph.

8.4. Meibography

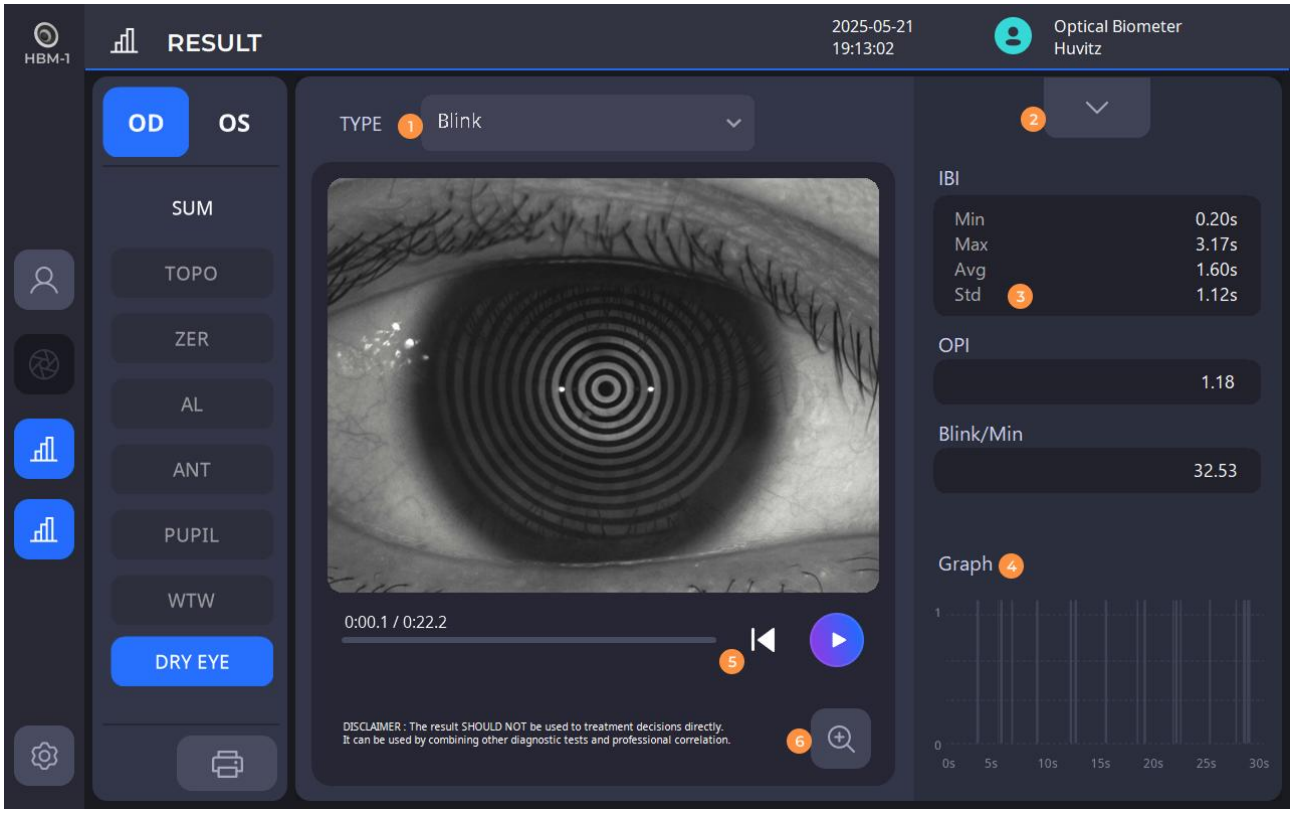




No	Name	Function
1	Type	You can select the desired dry eye examination result.
2	Image Selection	You can select a captured image to perform Meibo analysis.
3	Analysis Result	Displays the analysis result.

4	Detail Analysis	Allows detailed review and editing of the selected image.
5	Area Mode	Select either Grade mode or Edit mode for Meibo analysis.
6	Detection Control	Set the configuration values used for Meibo analysis.
7	Edit	Configure and edit the selection area for Meibo analysis.

8.5. Blink



No	Name	Function
1	Type	You can select the desired dry eye examination result.
2	Image List	Displays the list of recorded videos.
3	Analysis Result	Displays the analysis result.
4	Blink Graph	Shows a graph of blink timing over the recording period.
5	Play	Play the video.
6	Zoom	View the result screen in a larger display.

▌IOL screen

NOTE

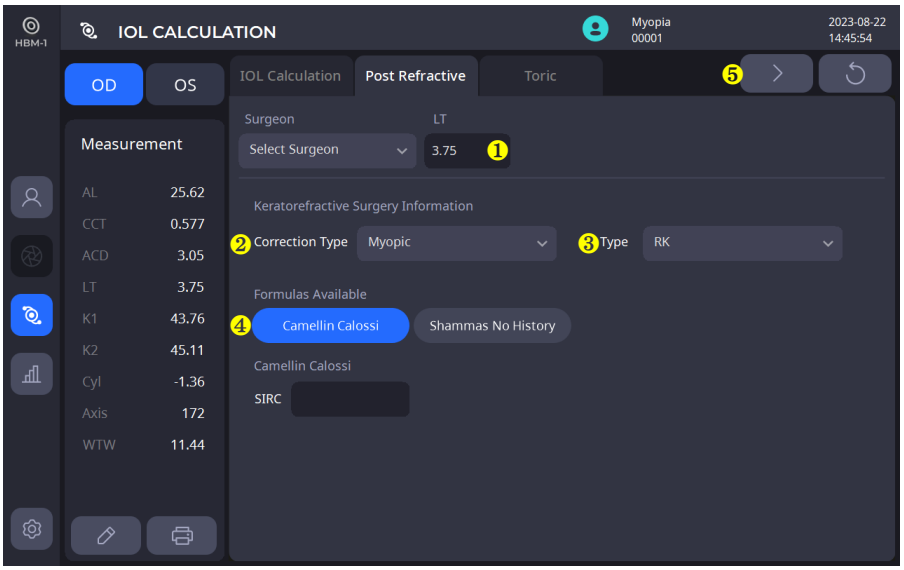
The results of the IOL calculator are not intended to serve medical or surgical decisions.
Huvitz does not guarantee that the calculated results will always be accurate.
Physicians who use this tool must make their own decisions regarding their patients and are responsible for outcomes.

1. IOL CALCULATION



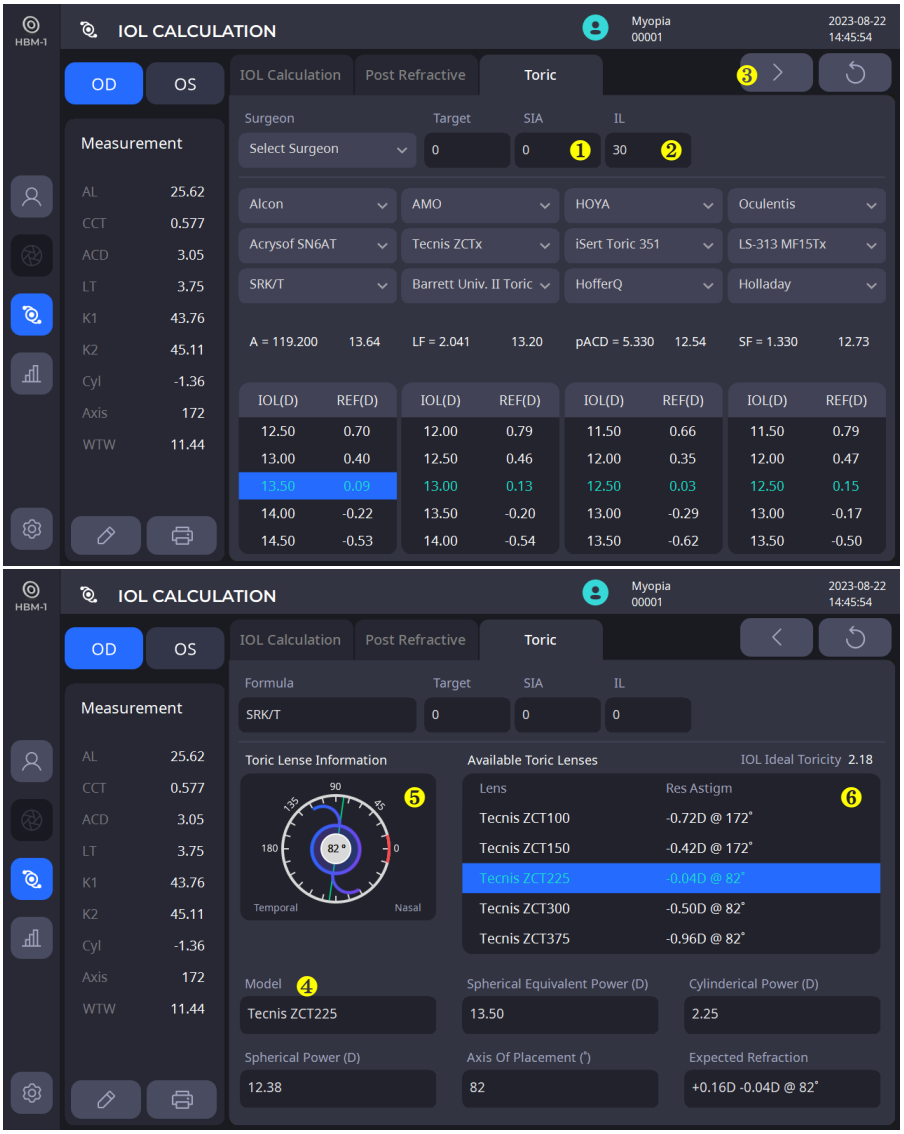
No	Name	Function
1	Result	Go to Result page. Check the measurement data detail.
2	Data Edit	Open the data editable window
3	Measurement Value	Show the values used for IOL calculation.
4	IOL Calculation/ Post Refractive IOL /Toric	IOL Calculation : It informs general IOL calculation with several formula Post Refractive IOL : It calculate IOL for patient who already had the surgery Toric : It informs general Toric IOL calculation with several formula
5	Surgeon	Select the Surgeon from the physician list.
6	Target	Put in the target refractive value that is expected after surgery.
7	Manufacturer	Select the IOL Manufacturer.
8	Model	Select the IOL Model.
9	Formula	Select the Formula.
10	Lens index	It shows intrinsic constant of IOL lens model. It is necessary when calculating IOL formula.
11	Ideal IOL Power	It shows ideal IOL power given target value
12	IOL calculation result	It informs 5 IOL power lists that are close to the target refractive value.
13	Reset	Reset the calculation result.

2. Post Refractive



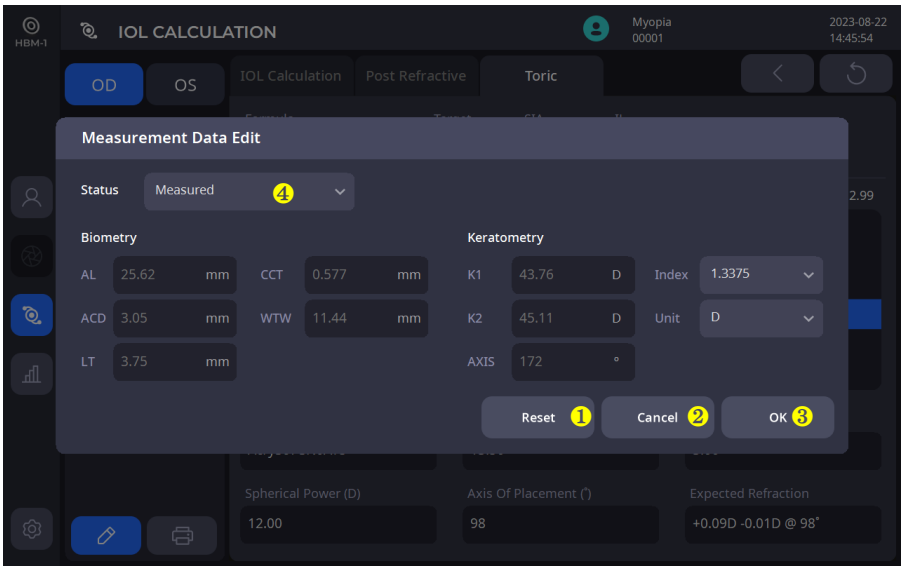
No	Name	Function
1	LT	LT value can be input before enter the Post IOL calculation mode.
2	Correction Type	Select the correction type.
3	Type	Select the prior refractive surgery type.
4	Formulas	Select the formulas, and check the input data.
5	Next	Go to next page for IOL calculation

3. Toric



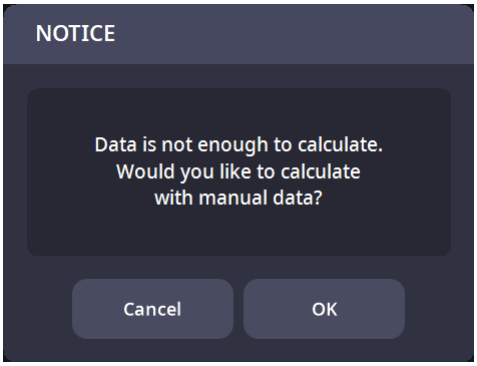
No	Name	Function
1	SIA	Put in the SIA(Surgical induced Astigmatism) value.
2	IL	Put in the IL(Incision Location) value
3	Next	Move to toric detail page based on input data
4	Model	Show selected lens information in detail.
5	Toric Lense Info	Show axis of toric lens and IL angle(red) on the picture
6	Available Toric Lenses	It shows 5 toric IOL lens lists that are close to the target value.

4. Data Edit



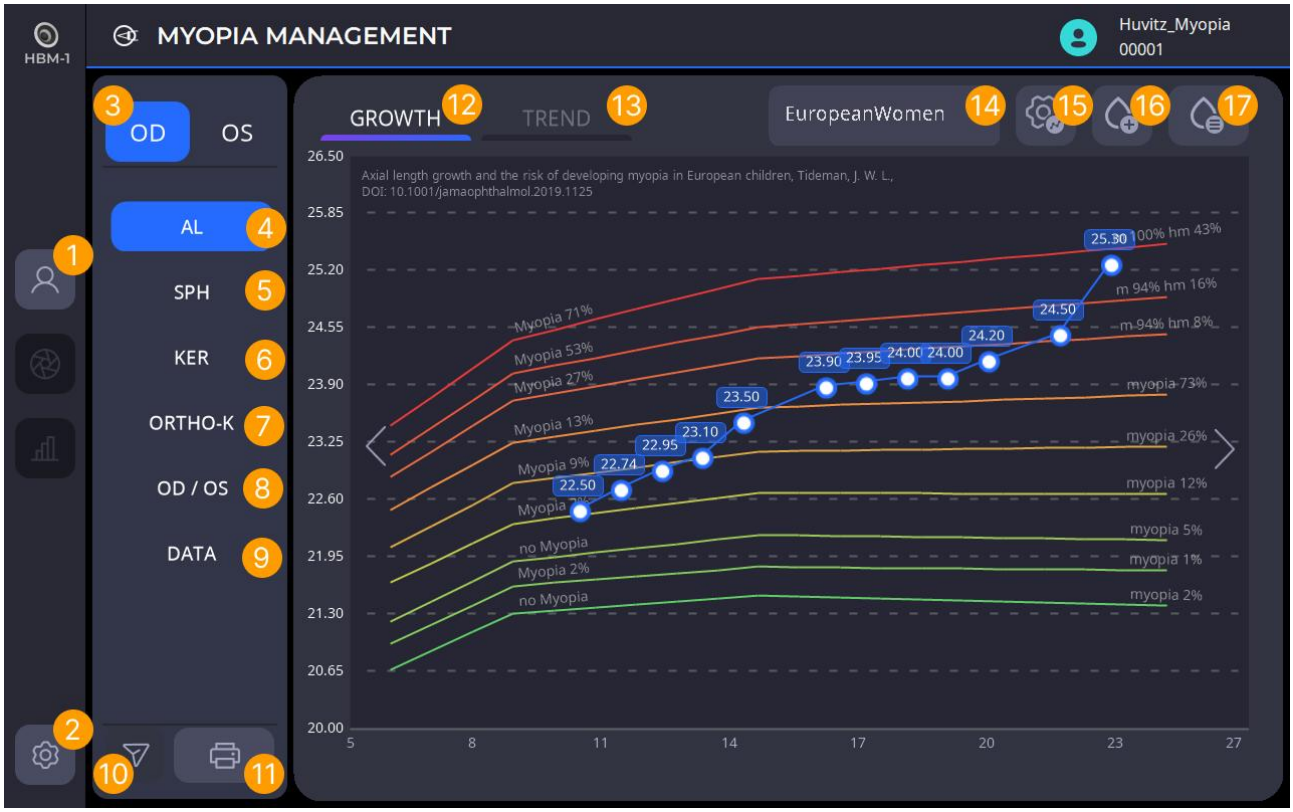
No	Name	Function
1	Reset	Reset values as measured data
2	Cancel	Close the window without saving.
3	OK	Save the data with modifications.
4	Status	Select manual which can enter the changeable input data or measured data

If there is not enough measurement data to calculate IOL lens, directly show up the 'Measurement Data Edit pop-up' window as following.



Myopia Management

1. AL (Axial Length Growth)



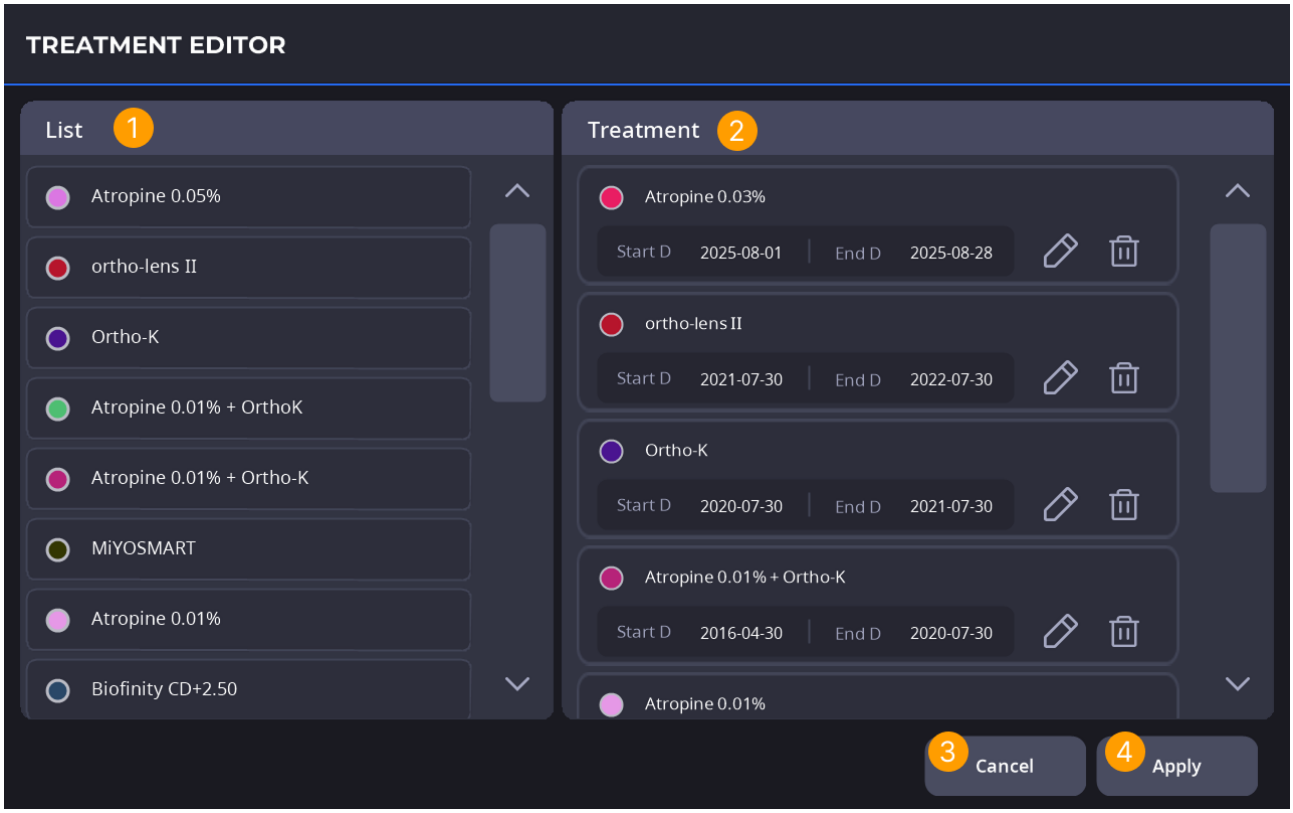
Through accumulated axial length data and normative data, the growth trend can be analyzed.

No	Name	Function
1	Patient	Returns to the measurement list screen.
2	Setting	Opens the HBM-1 Setting screen.
3	OD/OS	Allows selection between left eye (OS) and right eye (OD).
4	AL	Displays the trend or variation in axial length.
5	SPH	Shows the stored refractive error data of the examined eye.
6	KER	Displays the stored corneal mean curvature data of the examined eye.
7	ORTHO-K	Compares pre- and post-wear topography maps of orthokeratology lenses.
8	OD/OS	Displays data from both eyes simultaneously.
9	DATA	Manages data such as adding or deleting entries.
10	Transfer	Transfers myopia management data to HIIS-1.
11	Report	Opens the screen for printing myopia management data.
12	GROWTH	Displays the growth curve of axial length.

13	TREND	Displays a screen that calculates the annual change in axial length growth and assesses the associated risk level.
14	Normative data	Shows the growth trend curves for Asian and European populations.
15	Graph Setting	Allows configuration of the graph's X-axis, Y-axis, and value overlays.
16	Treatment Setting	Enables adding, deleting, or modifying the treatments being prescribed.
17	Treatment overlay	Overlays the currently prescribed treatment information on the graph.

Normative data Sources
Asia: Normative data and percentile curves for axial length and axial length/corneal \r\ncurvature in Chinese children and adolescents aged 4–18 years, He, X., DOI: 10.1136/bjophthalmol-2019-315580
Europe : Axial length growth and the risk of developing myopia in European children, Tideman, J. W. L., \r\nDOI: 10.1001/jamaophthalmol.2019.1125.

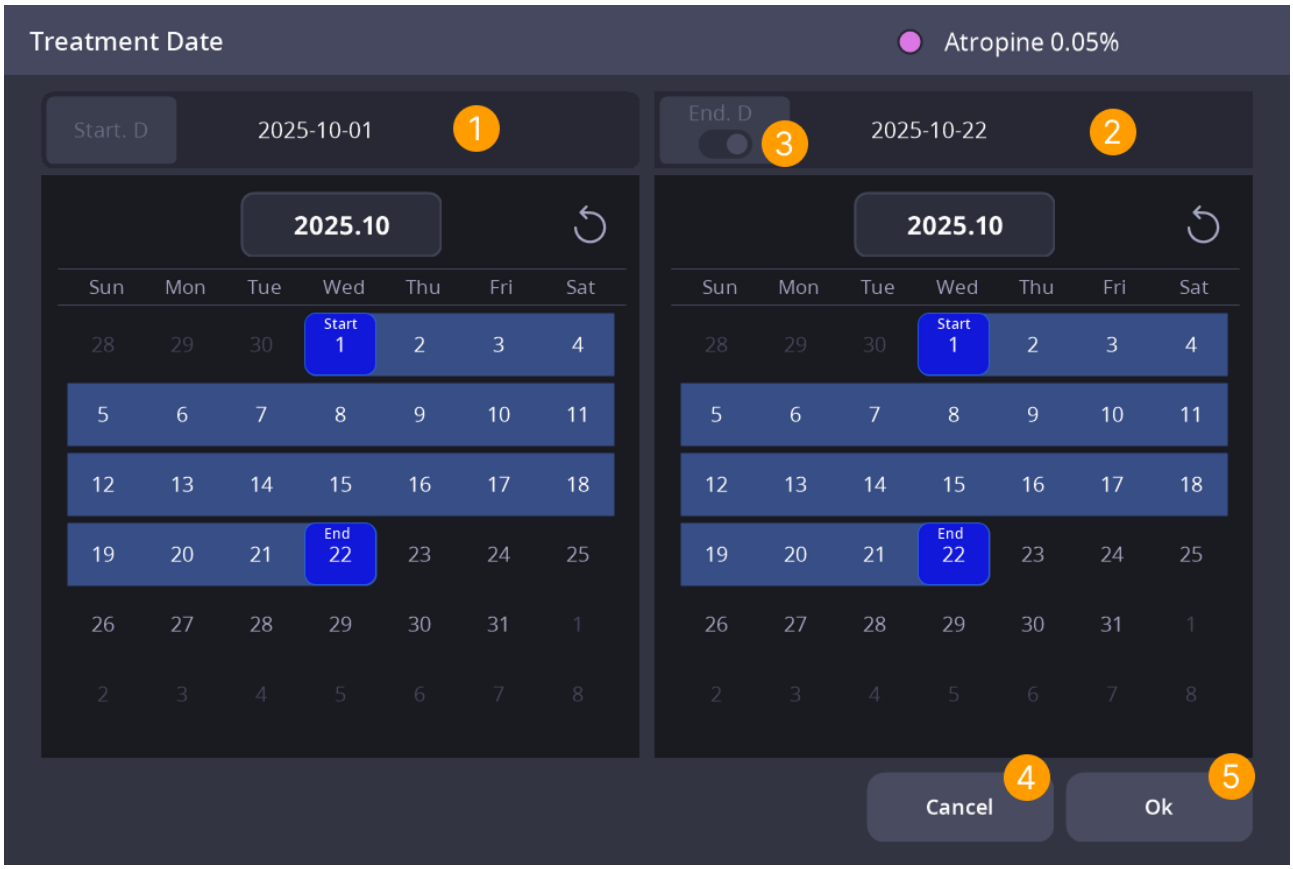
1.1. Treatment Editor



You can add, delete, or modify the patient's Treatment List.

No	명칭	기능
1	Treatment List	Displays the complete list of available treatments.
2	Treatment	Shows the current patient's Treatment List.
3	Cancel	Cancels the modifications and closes the window.
4	Apply	Applies the modifications and closes the window.

1.2. Add/Edit Treatment



You can set the start and end dates of the treatment.

No	명칭	기능
1	Treatment List	Displays the complete list of available treatments.
2	Treatment	Shows the current patient's Treatment List.
3	Cancel	Cancels the modifications and closes the window.
4	Apply	Applies the modifications and closes the window.

2. AL(Axial Length Trend)



Displays the annual growth rate of the subject's axial length, allowing evaluation of the rate of axial length growth.

No	명칭	기능
1	Legend	A legend that indicates whether the axial length growth rate is fast, moderate, or slow according to the graph's background color.

3. SPH(Spherical)



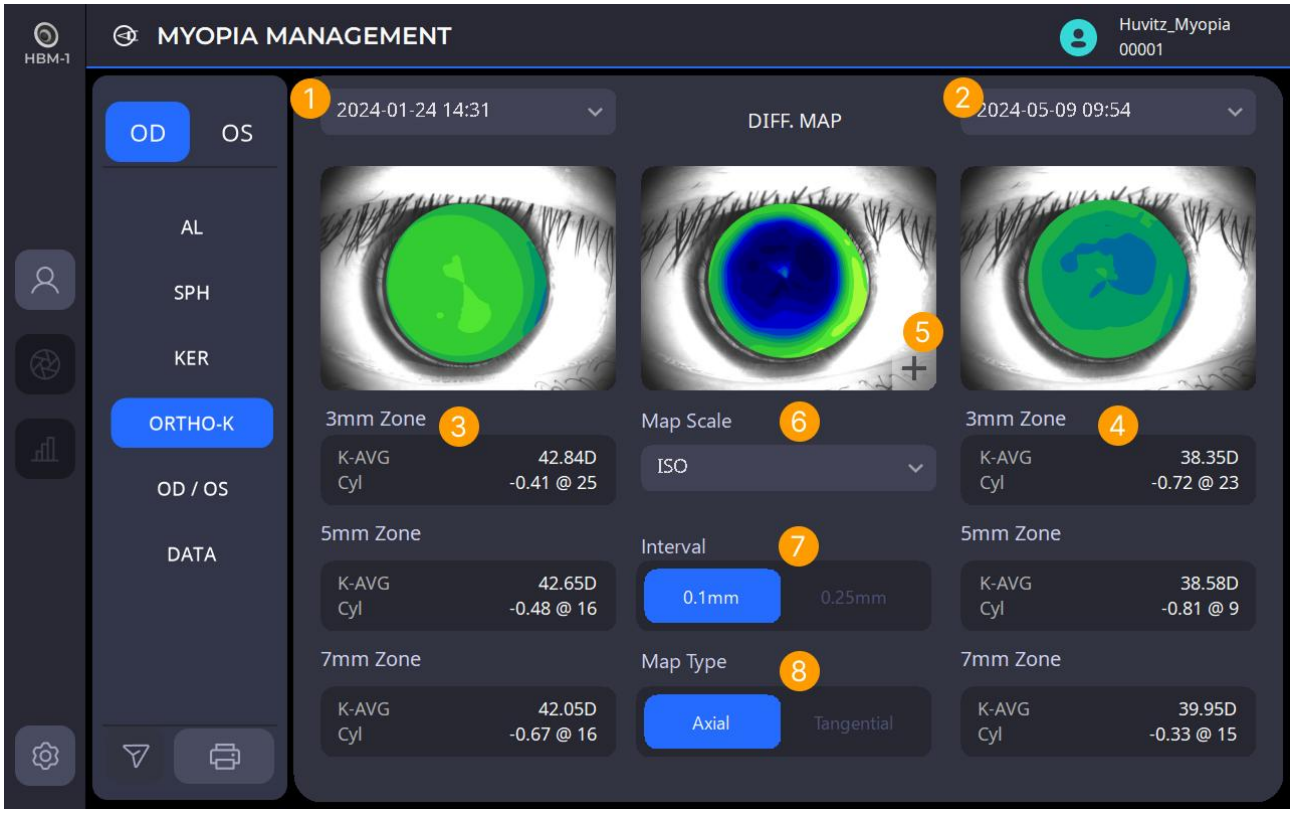
Displays the subject's refractive error data.

4. KER(Keratometry)



Displays the subject's corneal curvature data.

5. Ortho-K(Orthokeratology)



Displays a screen for comparing pre- and post-orthokeratology lens data.

No	명칭	기능
1	Before data	Selects the data recorded before lens wear.
2	After data	Selects the data recorded after lens wear.
3	Meridian data (Before)	Displays corneal curvature values (3-5-7 mm / 2-4-6 mm) before lens wear.
4	Meridian data (After)	Displays corneal curvature values (3-5-7 mm / 2-4-6 mm) after lens wear.
5	Diff Map Zoom	Enlarges the difference map to review pre- and post-lens changes in detail.
6	Map Scale	Adjusts the color scale of the topography map.
7	Interval	Modifies the color interval of the topography data.
8	Map Type	Switches the map type between Axial and Tangential modes.

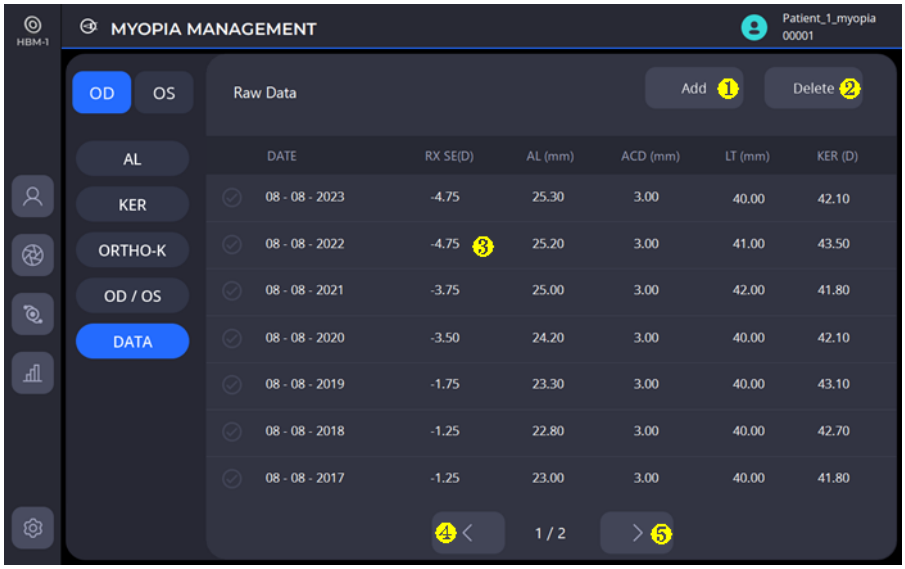
6. OD/OS (Comparison OU)



Show selected OD and OS data as graph.

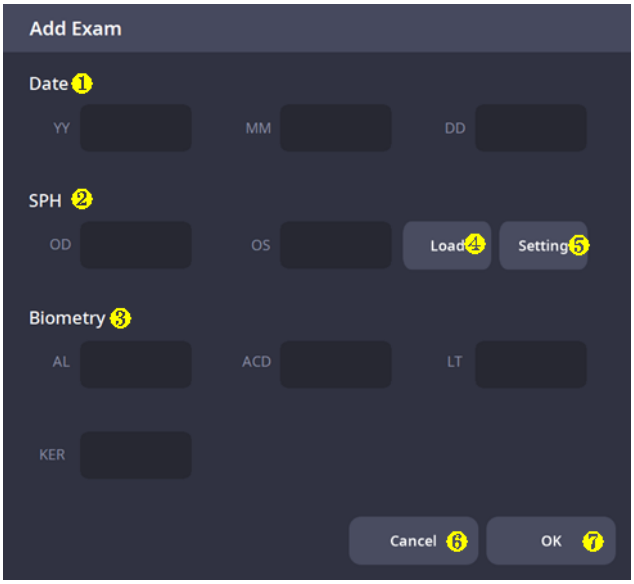
No	Name	Function
1	Select OD Data	Select the date of the Right eye of the subject to show the Axial Length, Corneal Curvature, and Refractive Error data.
2	Select OS Data	Select the date of the Left eye of the subject to show the Axial Length, Corneal Curvature, and Refractive Error data.
3	OD Data	Display data from the subject's Right eye. (Refractive Error, Corneal Curvature, and Axial Length from the left)
4	OS Data	Display data from the subject's Left eye. (Refractive Error, Corneal Curvature, and Axial Length from the left)
5	Compare Axial Length	It shows the length of the Axial Length of the right eye and the left eye of the subject.
6	Compare Corneal Curvature	It shows the length of the Corneal Curvature of the right eye and the left eye of the subject.
7	Compare Refractive Error	It shows the length of the Refractive Error of the right eye and the left eye of the subject.

7. Data (Managing Data) Screen



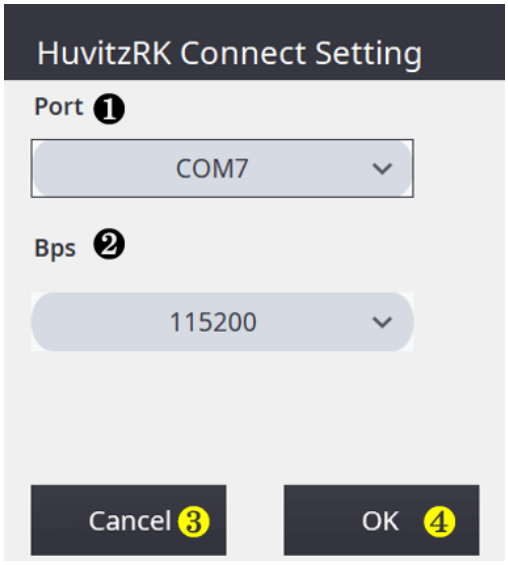
No	Name	Function
1	Add Data	Open the ‘Add Data’ screen.
2	Delete Data	Delete selected data.
3	Edit Data	Open the ‘Edit Data’ screen by double clicking
4	Move Data Table (Left)	Move the data table to the left.
5	Move Data Table (Right)	Move the data table to the Right.

7.1. Data Edit / Data Add Screen



No	Name	Function
1	Measurement Date	Enter the date on which you want to generate data.
2	SPH	Enter or load the refractive error.
3	Biometry Data	Enter AL, ACD, LT, and APP data.
4	Load Refractive Error Data	Load data from the Huvitz Refractometer
5	Connection Setting	Set up communication setting to connect with the Huvitz Refractometer.
6	Cancel	Close the screen without saving data.
7	Save	Save the data and close screen.

7.2. Refractometer Connection Setting Screen



No	Name	Function
1	Setup Connection Port	Set up the communication port that connects to the Refractometer by USB to RS232.
2	Setup Connection Bps	Set up the communication bps that connects to the Refractometer and USB to RS232.
3	Cancel	Close screen without saving settings.
4	Save	Save the settings and close screen.

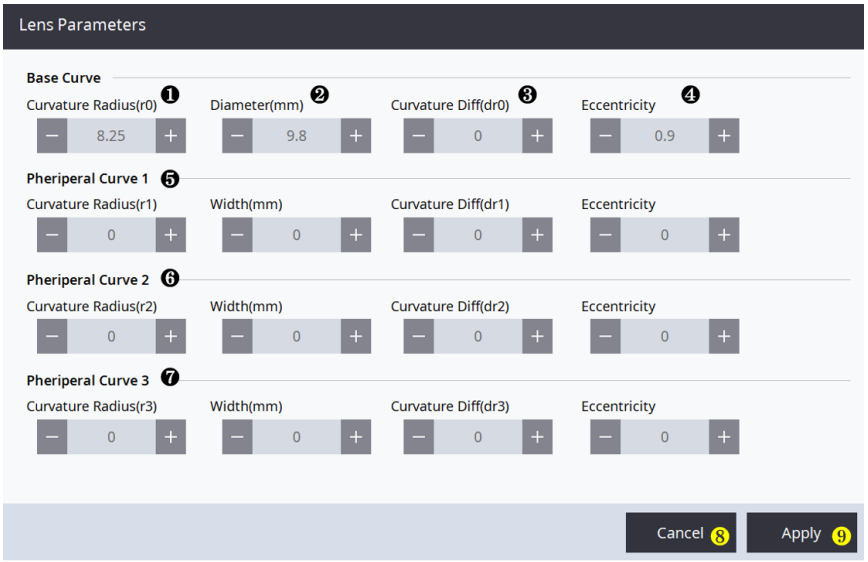
Contact Lens Fitting Simulation Screen

1. Contact Lens Fitting Main Screen



No	Name	Function
1	Simulation / Gallery	Select one of mode between showing fitting data and showing saved data.
2	Map display	Show the fitting map or corneal curvature map of the selected lens.
3	Curvature map / fitting map	Select showing map between curvature map and fitting map.
4	Kf / Ks Lens fitting graph	Show the distance between the cornea and the lens of each flatness and steepness.
5	Select lens manufacturer	Select the manufacturer of the lens.
6	Select a lens	If you selected a manufacturer, select a list of lenses for the manufacturer.
7	Modifying lens parameter	Modify the parameter for the selected lens.
8	Information Corneal Curvature	Show corneal curvature information for the subject.
9	Lens information	Show selected lens parameter.
10	Save	You can save current lens fitting data and see them in ‘Gallery’.

1.1. Lens Parameter Modification Screen



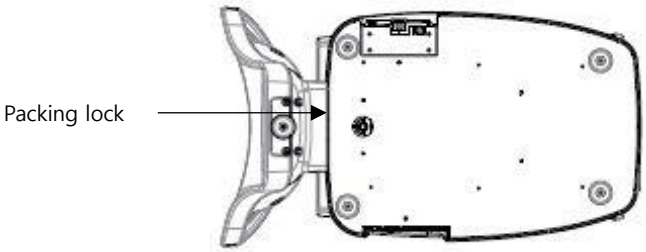
No	Name	Function
1	Set lens curvature	Sets the curvature of the lens.
2	Lens diameter Settings	Sets the diameter of the lens. Base Curve Diameter (mm): This means the full diameter Peripheral Curve Width (mm): The diameter of the corresponding peripheral curve.
3	setting the curvature difference	Sets the difference in curvature of the lens.
4	Set Eccentricity	Sets the eccentricity of the lens.
5	Lens primary curve setting	Sets the curvature / diameter / curvature difference / eccentricity of the primary curve.
6	Lens secondary curve setting	Sets the curvature / diameter / curvature difference / eccentricity of the lens secondary curve.
7	Lens 3rd Curve Settings	Sets the curvature / diameter / curvature difference / eccentricity of the lens tertiary curve.
8	Unsetting	Cancels the current setting and returns to the lens fitting screen.
9	Apply Settings	Saves the current settings and returns to the lens fitting screen.

5

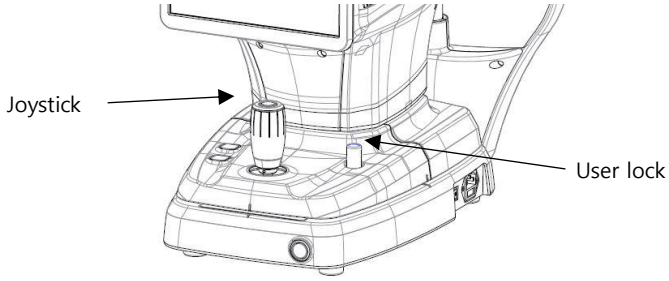
Installation Procedure

5.1. System installation

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



3. Unscrew the user lock lever on the body.



4. Attach the chinrest paper to the chinrest.
5. If needed, connect external devices.
   (1) 'PORT CAP' is opened by pushing the end of the bottom surface by hand.
   (2) If needed, connect mouse or keyboard
   (3) Connect communication cable of external device.
   (4) Close 'PORT CAP' with screw driver.
   (5) The PORT CAP can be separated from the product and reassembled when connecting the cable. (Figure "A" below)

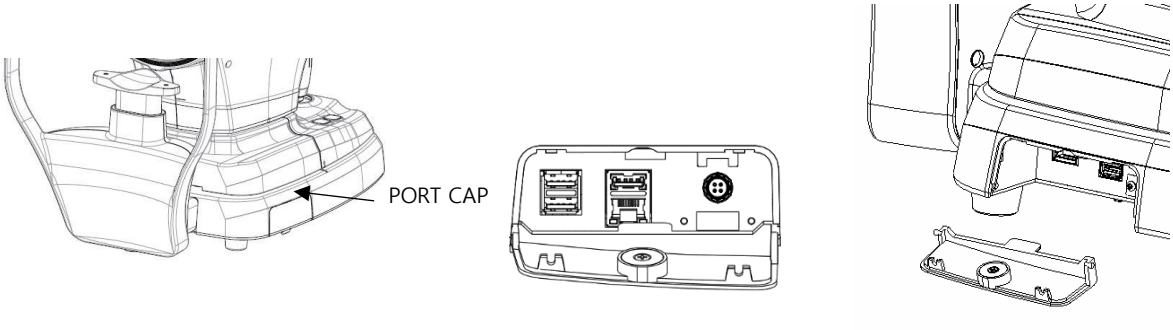
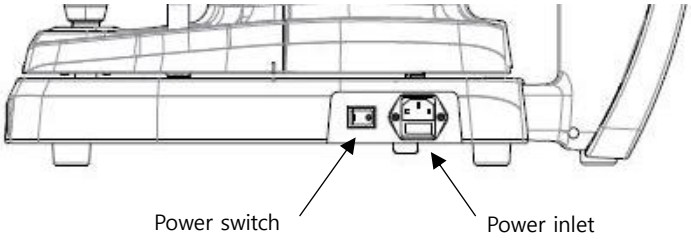
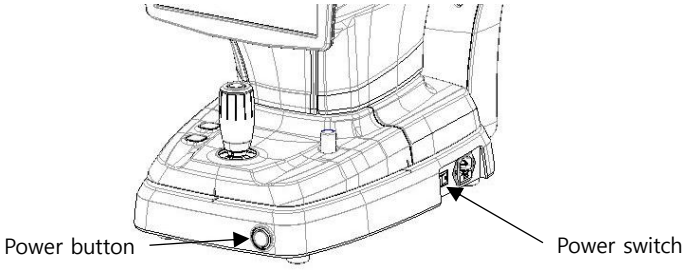


Figure "A"

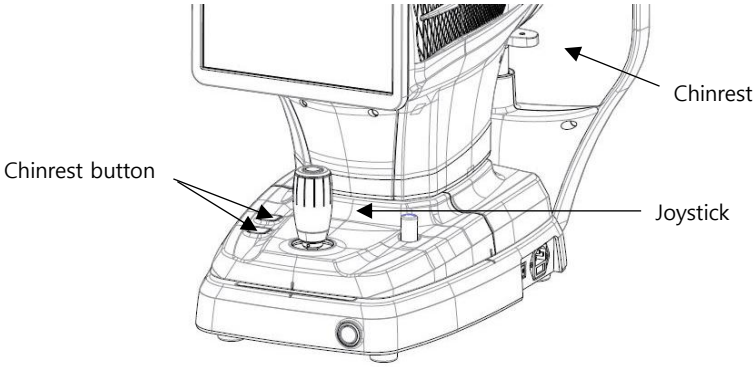
6. Check the power switch on the bottom right of base is off. (O position).
7. Connect power cable to power inlet. Also, connect the other side of power cable to electric outlet.



8. If external devices are connected, turn on external devices first.
9. Turn on the main body by pressing power switch (I position)
10. Turn on the internal PC by pressing power button.



11. Check there is no error during initialize process.
    Wait for until the initialization is complete.
12. Check the movement of body with joystick. Also, check the movement of motorized chinrest with chinrest button.

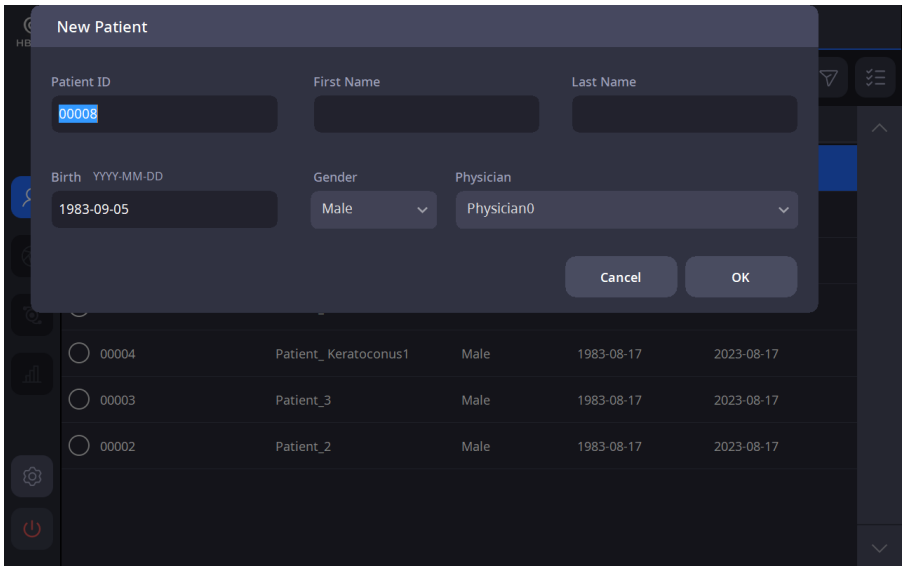


6

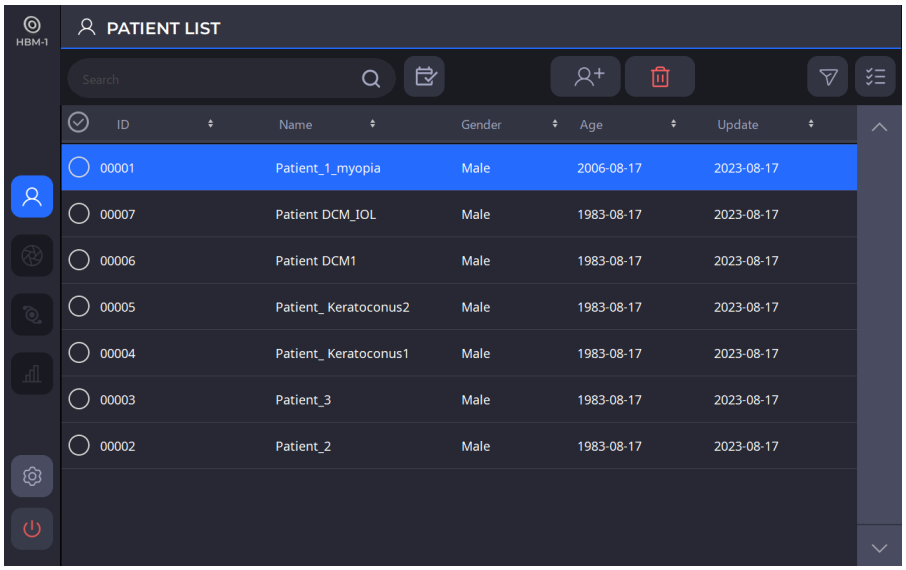
Operation

6.1. Software

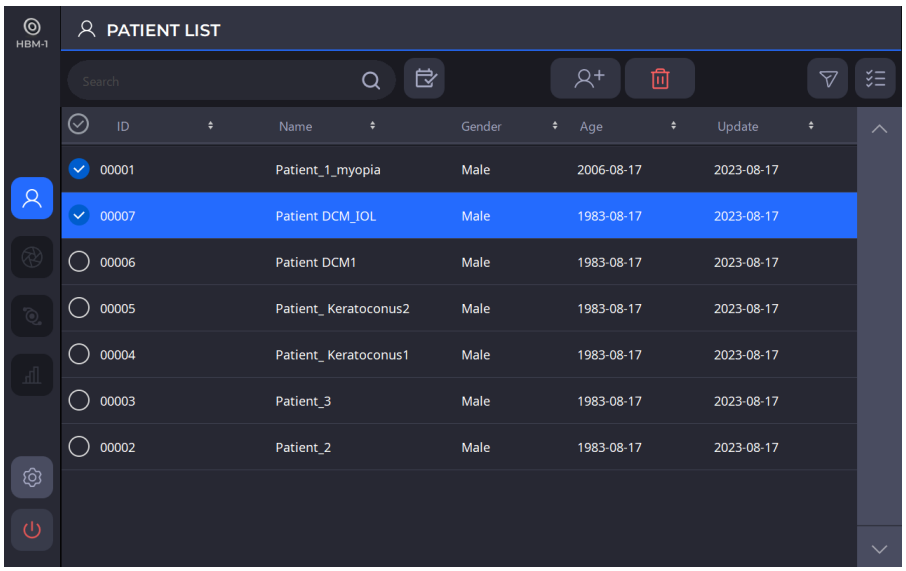
1. Execute HBM program from desktop screen.
2. Enter the ID and PW if login set in.
3. Press register patient icon ( ) and input patient information. If patient is existed already, skip this step.



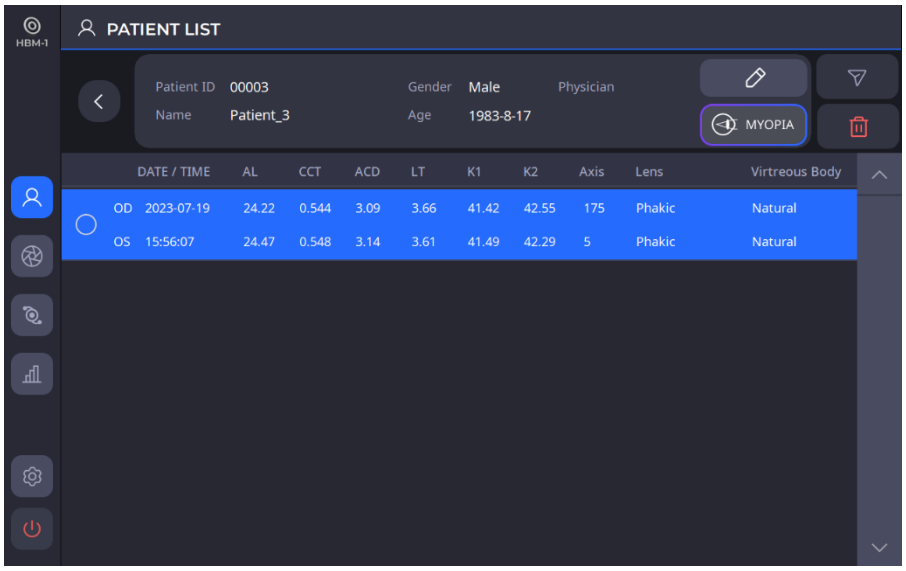
4. Select patient and check patient information is correct.



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



6. You can select a patient then it move to measurement lists page



7. Enter measurement mode by pressing measure icon ( ).

6.2. SETUP Mode

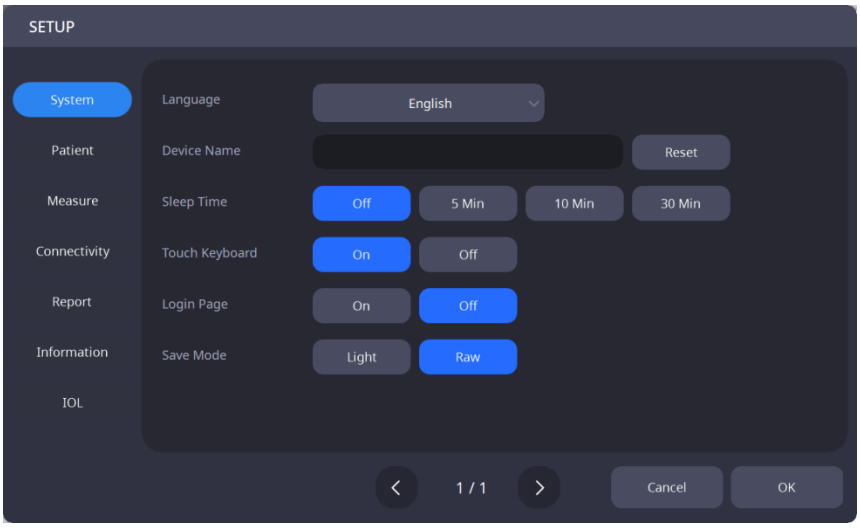
[To choose the section of setup]

- Enter setup mode by pressing icon [ ] on left down.
- You can select the section to setup from the left side.
- You can navigate the setup items with the page move buttons [,] at the bottom.

[To change settings]

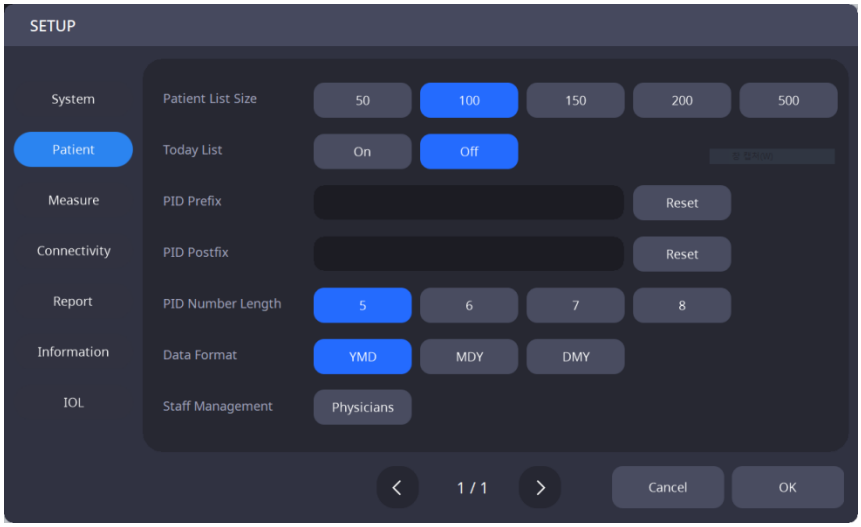
- Select the item to change.
- To press OK button will save all the changes made and exit the setup screen.
- To press CANCEL button will discard the changes and exit the setup screen.

1) System Settings



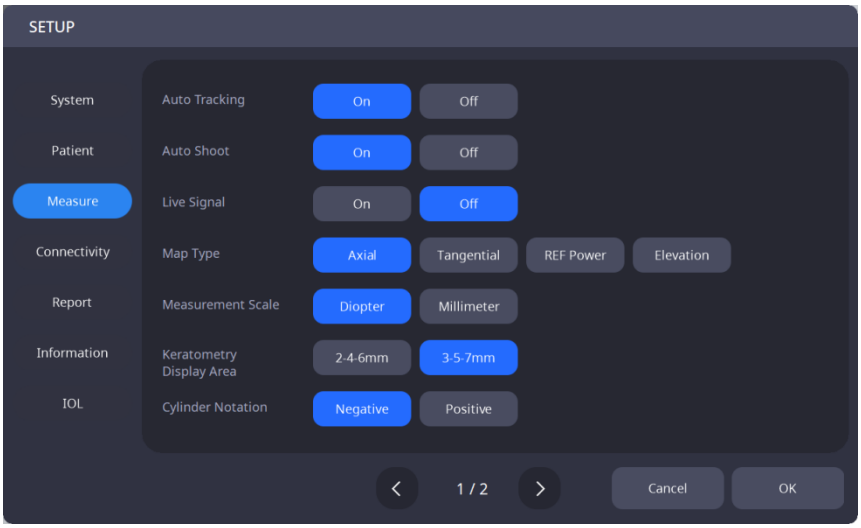
Language	Select language
Device Name	Set Device Name.
Sleep Time	Sleep mode time setting.
Touch Keyboard	Touch Keyboard ON/OFF setting.
Login Page	Set login mode use .
Save Mode	Set save data statue for biometry. Light : save result data only for biometry. Raw : save whole biometry data.

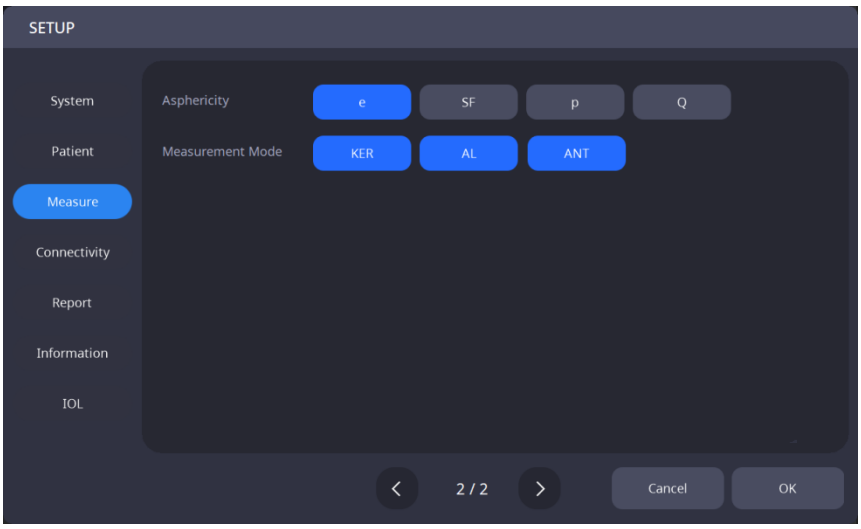
2) Patient Settings



Patient List Size	Set the number of patients to be displayed on the patient list.
Today List	Today List (List of patients visited today) settings.
PID Prefix	The function to set the prefix of the patient ID when make a new patient.
PID Postfix	The function to set the postfix of the patient ID when make a new patient.
PID Number Length	The function to set the length of patient ID.
Date Format	Format of the date (Year, Month, Day).
Staff Management	Register physician

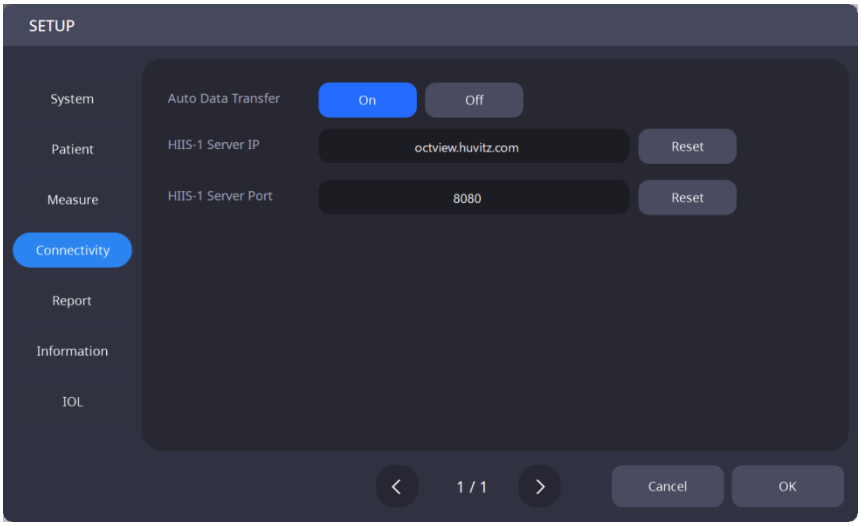
3) Measure Settings.





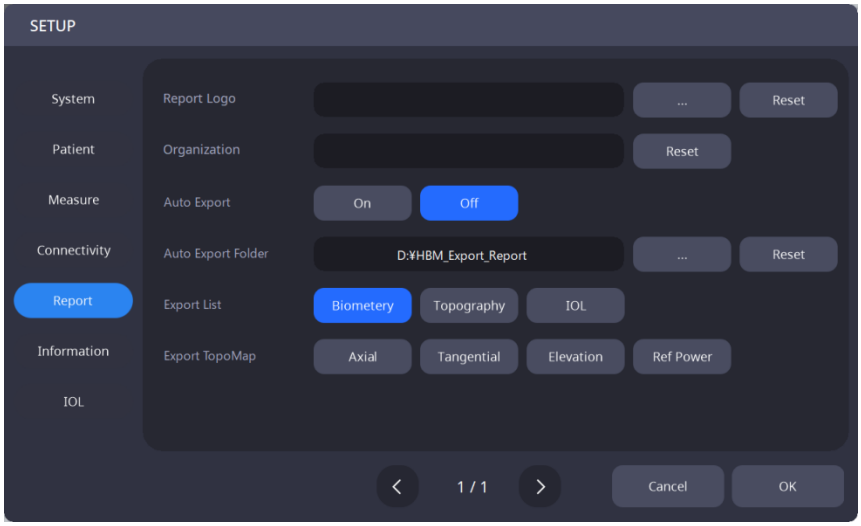
Auto Tracking	Auto Tracking ON/OFF setting.
Auto Shoot	Auto Shoot ON/OFF setting.
Live Signal	Live Signal ON/OFF setting.
Map Type	Select default map(Axial / Tangential)
Map Scales Measurement	Select default scale measurement (Diopter / Millimeters)
Keratometry Display Area	3-5-7 mm / 2-4-6 mm
Cylinder Notation	Positive / Negative
Asphericity	e / SF / p / Q
Measurement Mode	Set default measurement mode(Ker, AL, ANT Mode)

4) Connectivity Settings



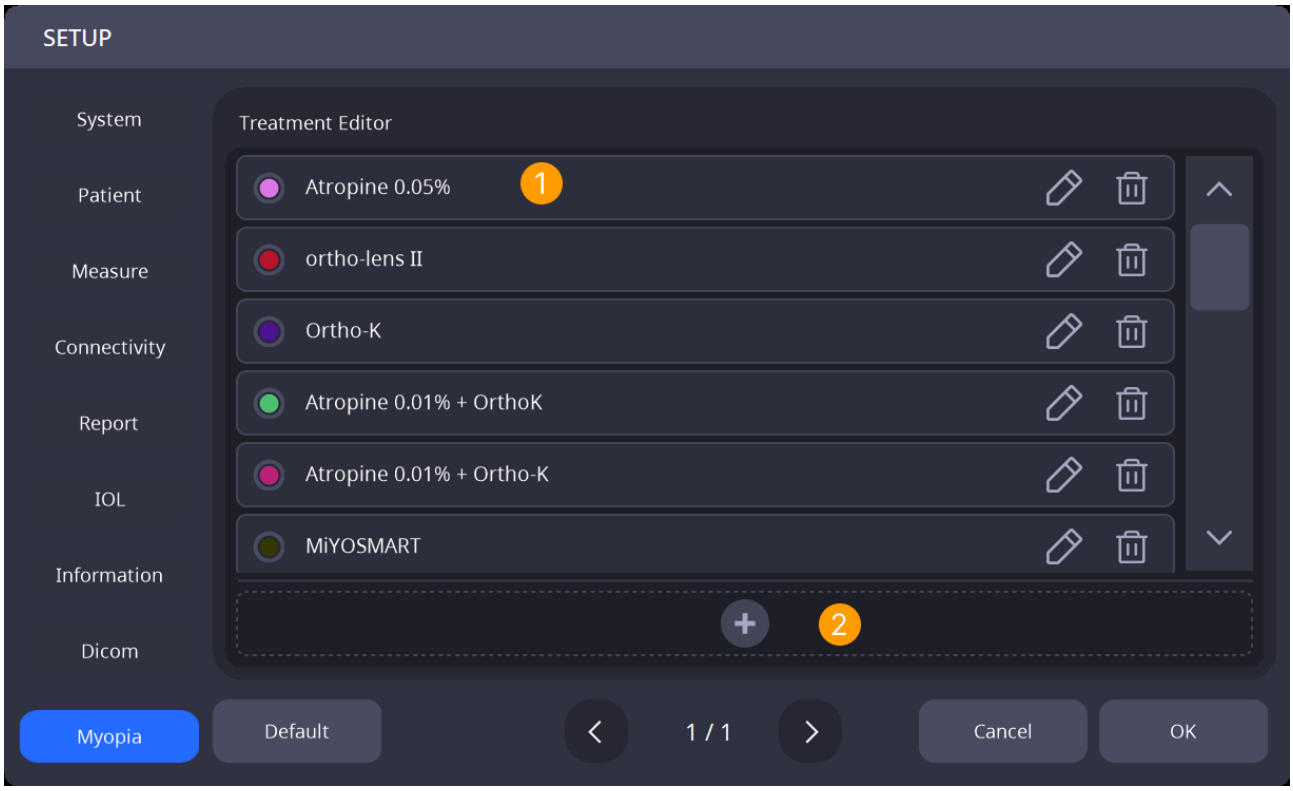
Network Folder	Network folder path.
Username	Network folder user name
Password	Network folder user password
Web Viewer Server IP	Web Viewer Server IP address setting.
Web Viewer Sever Port	Web Viewer Server port setting.
Auto Data Trans	Set the function to transfer the measured data to Web Viewer automatically.
Auto Export	Auto export setting

5) Report Settings



Report Logo	Set the report logo image.
Header	Assign the organization name.
Auto Export	Set auto export use
Auto Export Folder	Set auto export saving path
Export List	Select export report items
Export TopoMap	Select topo map for Topography report

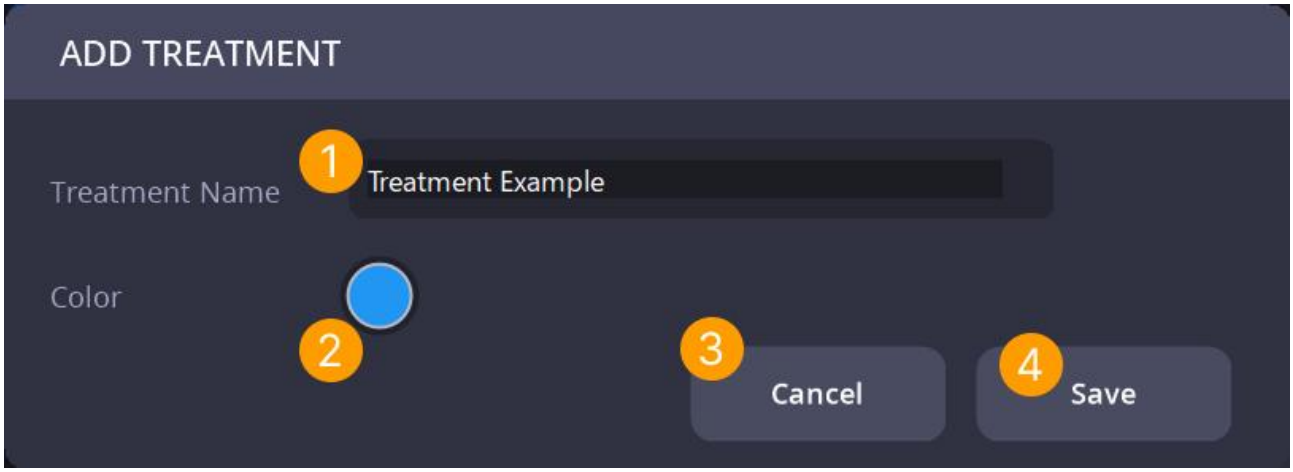
6) Myopia



Allows configuration of treatments used for Myopia Management.

No	Name	Function
1	Treatment data	Enables modification or removal of already added treatment data.
2	Add Treatment	Allows addition of a new treatment.

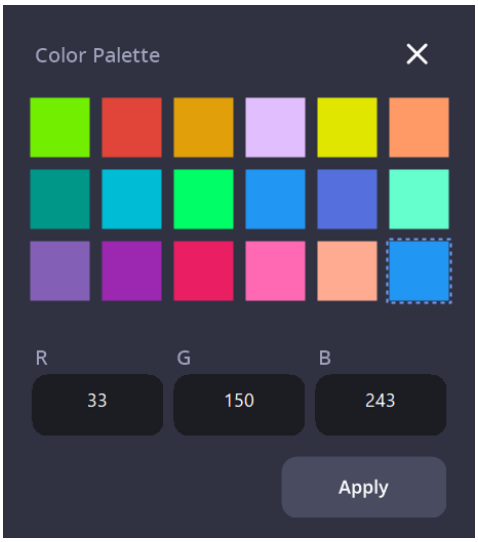
6.1. Add/Edit Treatment



Screen for adding or editing treatments.

No	Name	Function
1	Treatment Name	Sets the name of the treatment.
2	Color	Sets the color used for graph overlay.
3	Cancel	Closes the window without saving any changes.
4	Save	Saves and applies the modified or newly added settings, then closes the window.

6.2. Myopia Treatment Color Palette

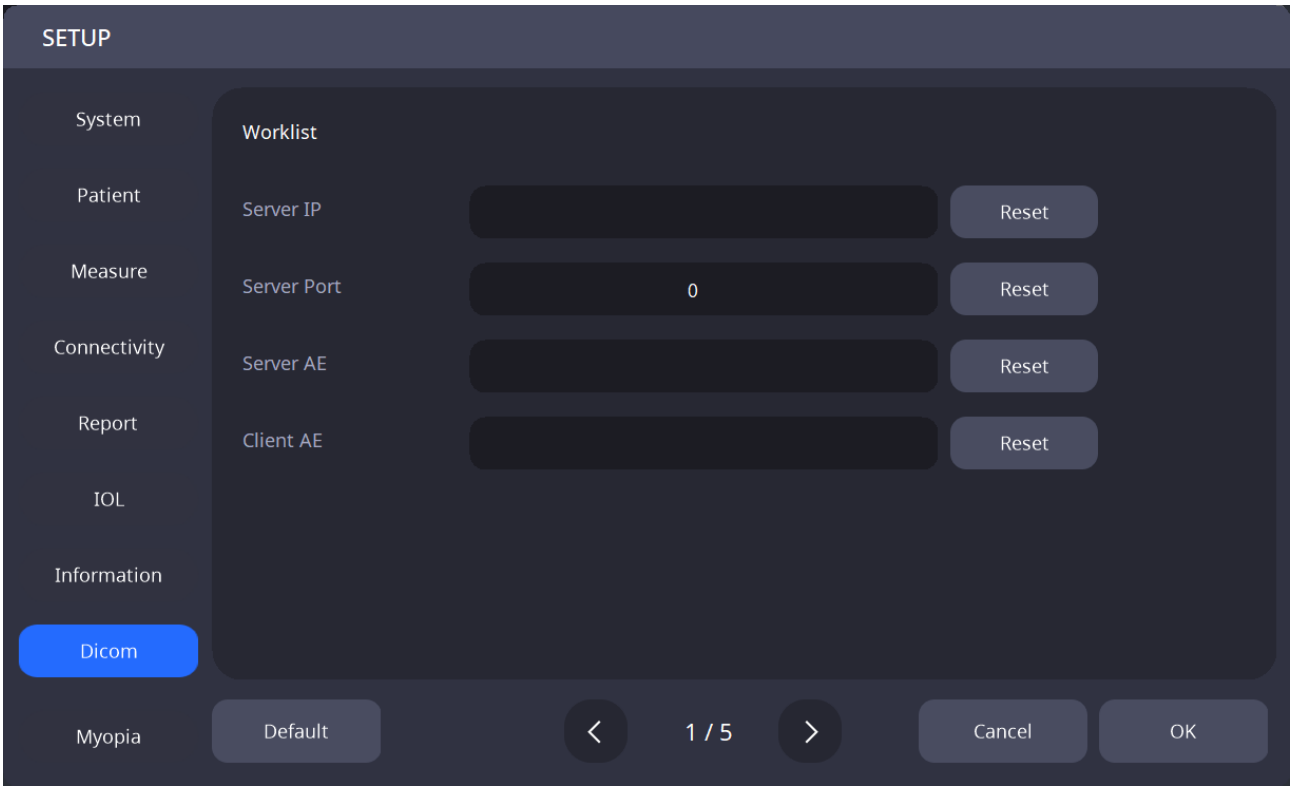


You can set the Treatment Color.

You can apply one of the preset example colors or manually adjust and apply a custom color.

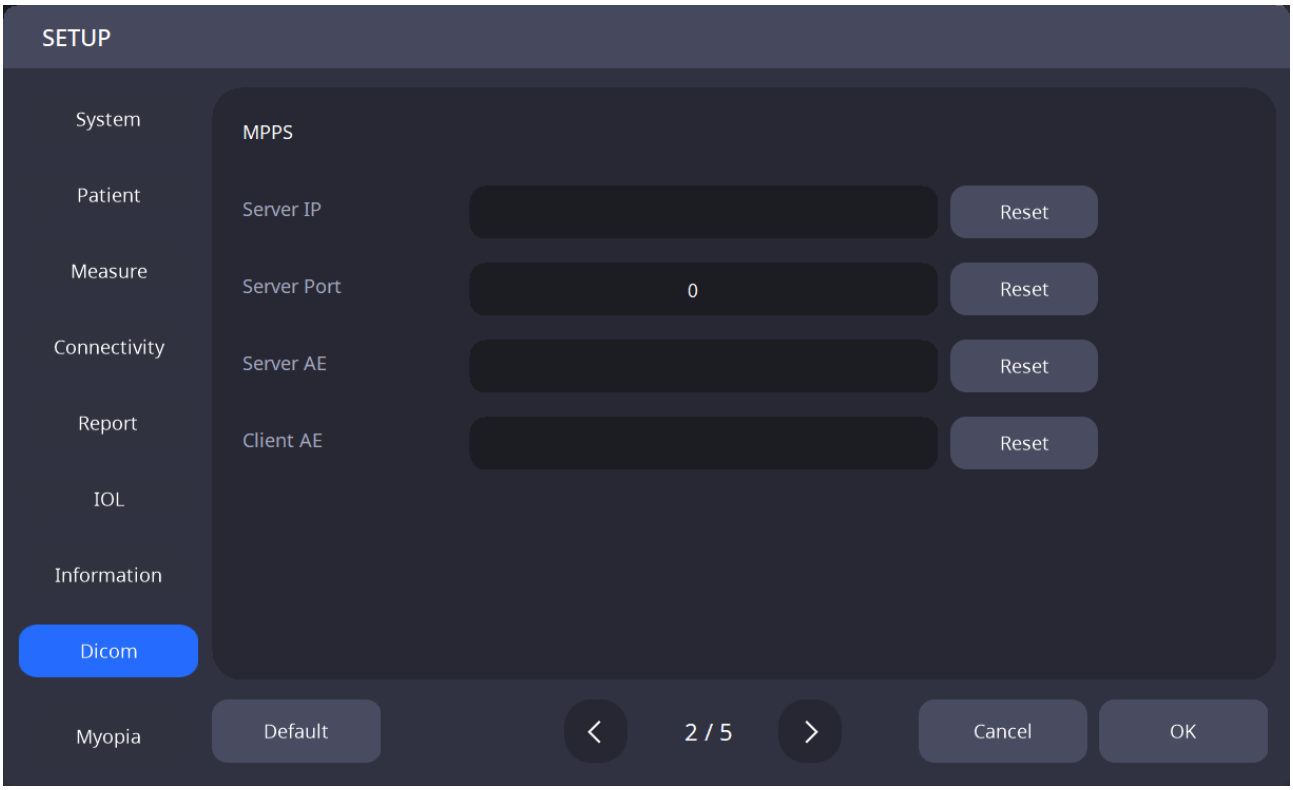
6.3. DICOM SETUP Mode

1. Worklist



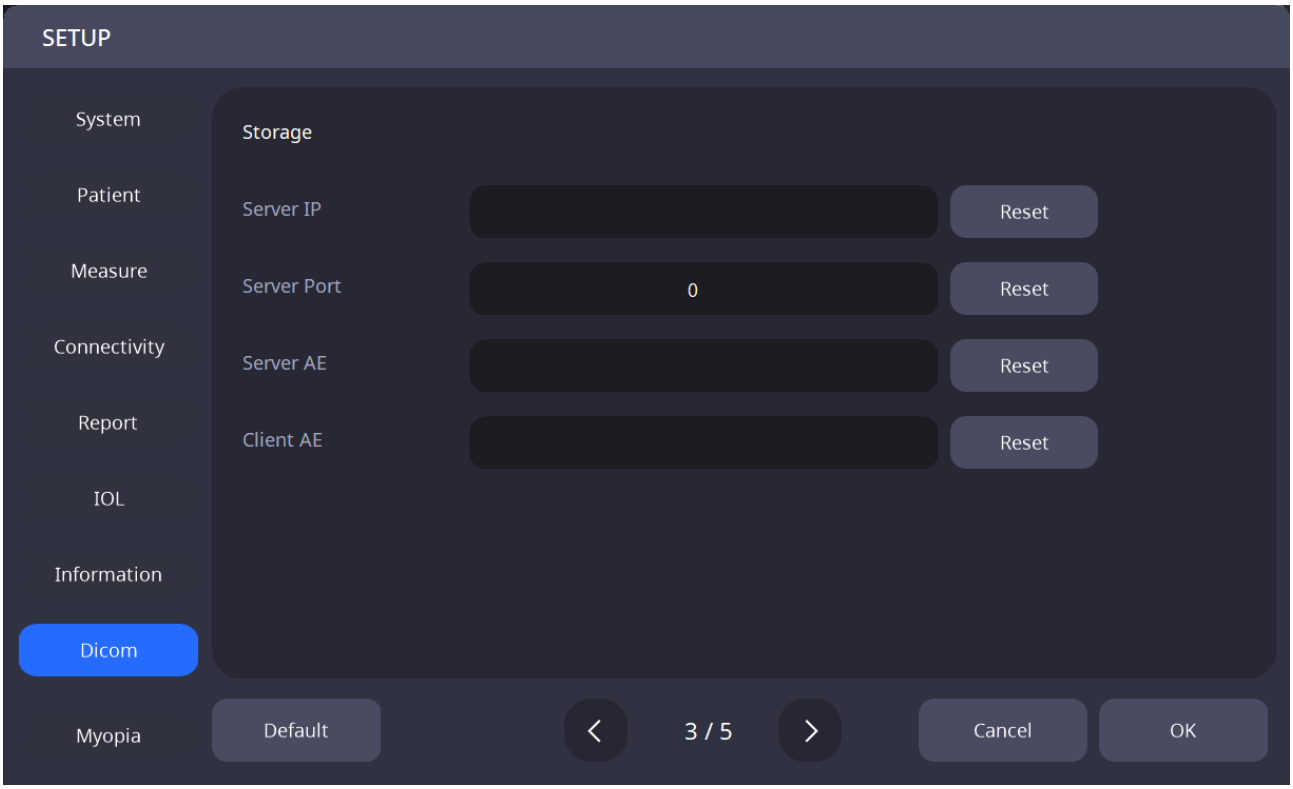
IP Address	Configure the IP address of the PC where the server program is installed.
Server Port	Configure the server port number.
Server AE	Configure the server AE.
Client AE	Configure the client AE.

2. MPPS



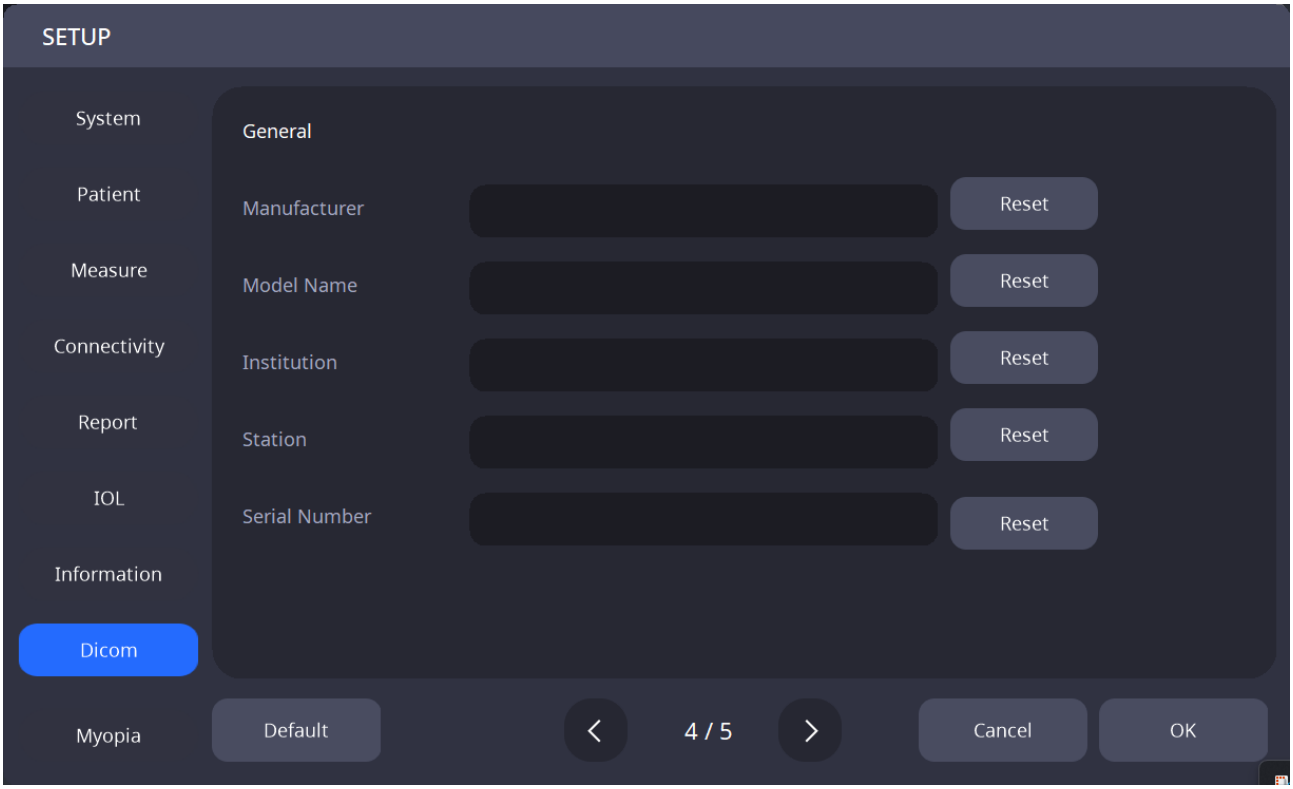
Server IP	Configure the IP address of the PC where the server program is installed.
Server Port	Configure the server port number.
Server AE	Configure the server AE.
Client AE	Configure the client AE.

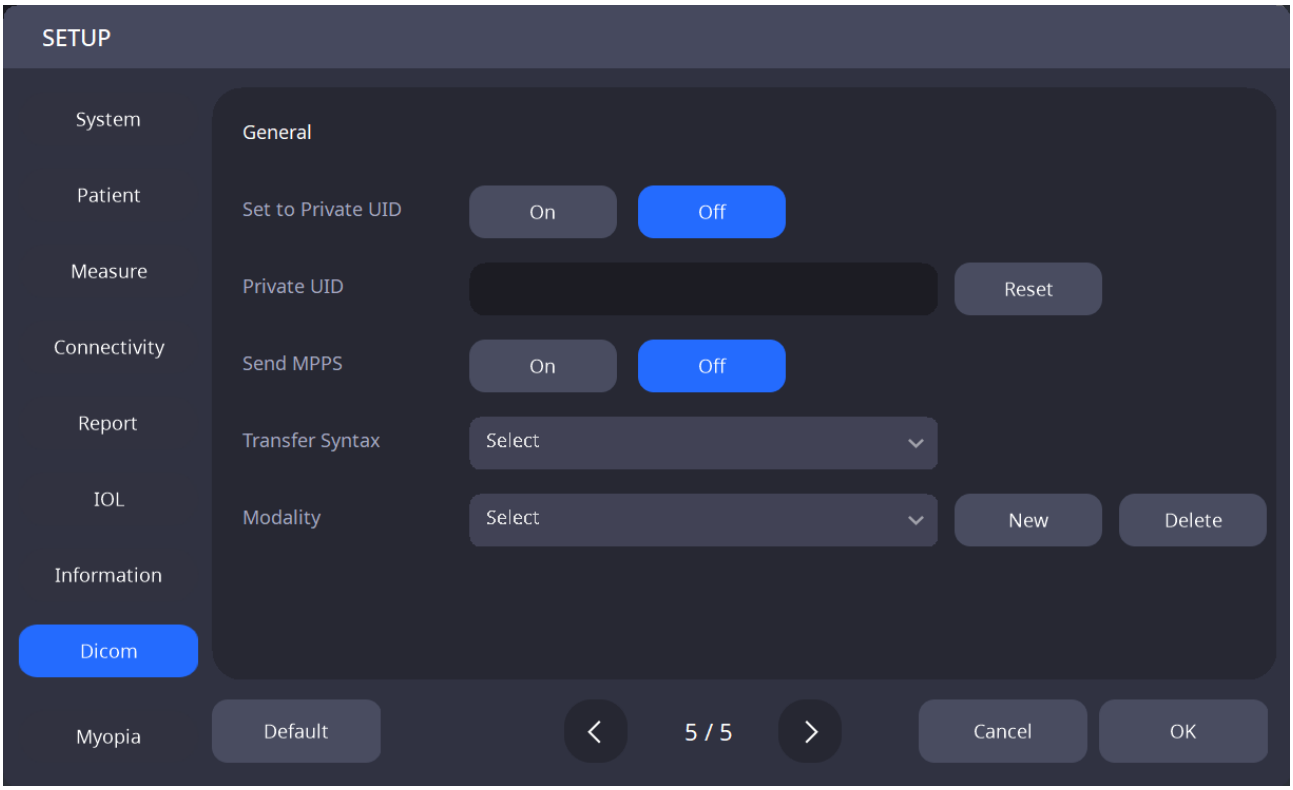
3. Storage



Server IP	Configure the IP address of the PC where the server program is installed.
Server Port	Configure the server port number.
Server AE	Configure the server AE.
Client AE	Configure the client AE.

4. General





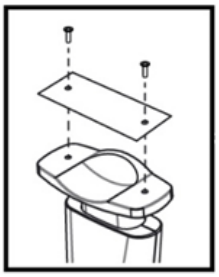
Manufacturer	Set the manufacturer.
Model Name	Set the product name.
Institution	Set the institution name.

Station	Set the station.
Serial Number	Set the product serial number.
Transfer Syntax	Set the transfer syntax.
Modality	Set the modality.
Set to Private UID	Turn the Private UID function ON/OFF.
Private UID	Set the Private UID.
Send MPPS	Turn MPPS transmission ON/OFF.

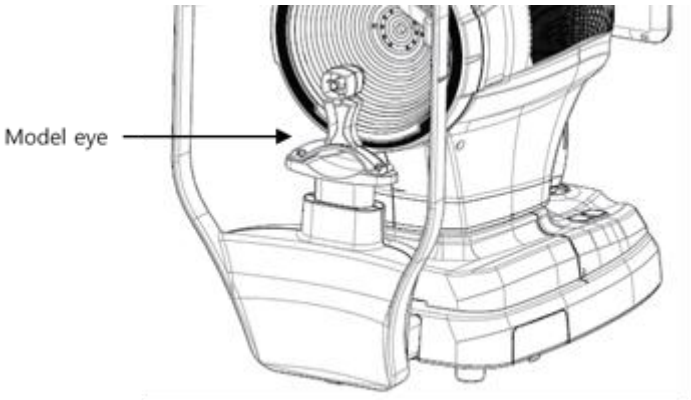
6.4. Device Check

1. Measuring Model Eye.

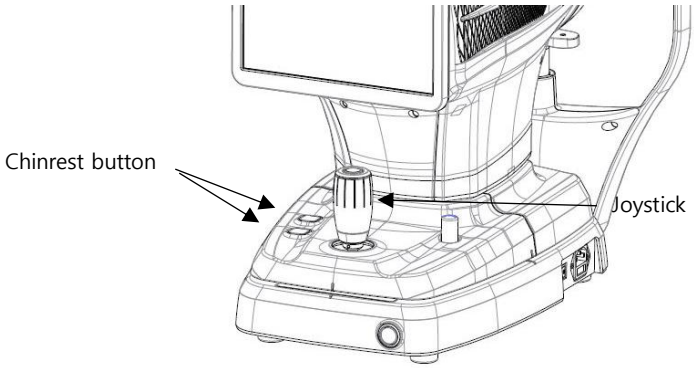
(1) Remove chinrest paper.



(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 placido disk using joystick and chinrest button.

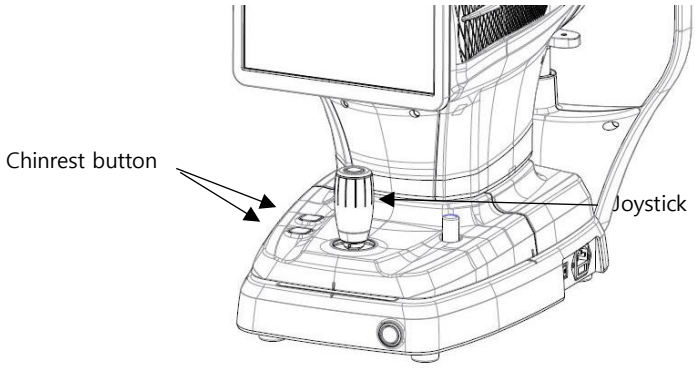


(4) After focusing, press the Joystick button.

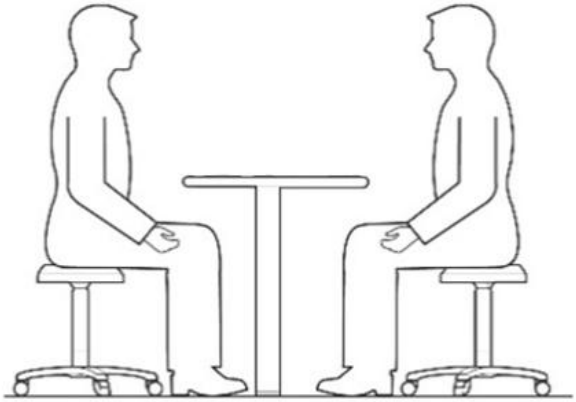
6.5. General Operation

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.

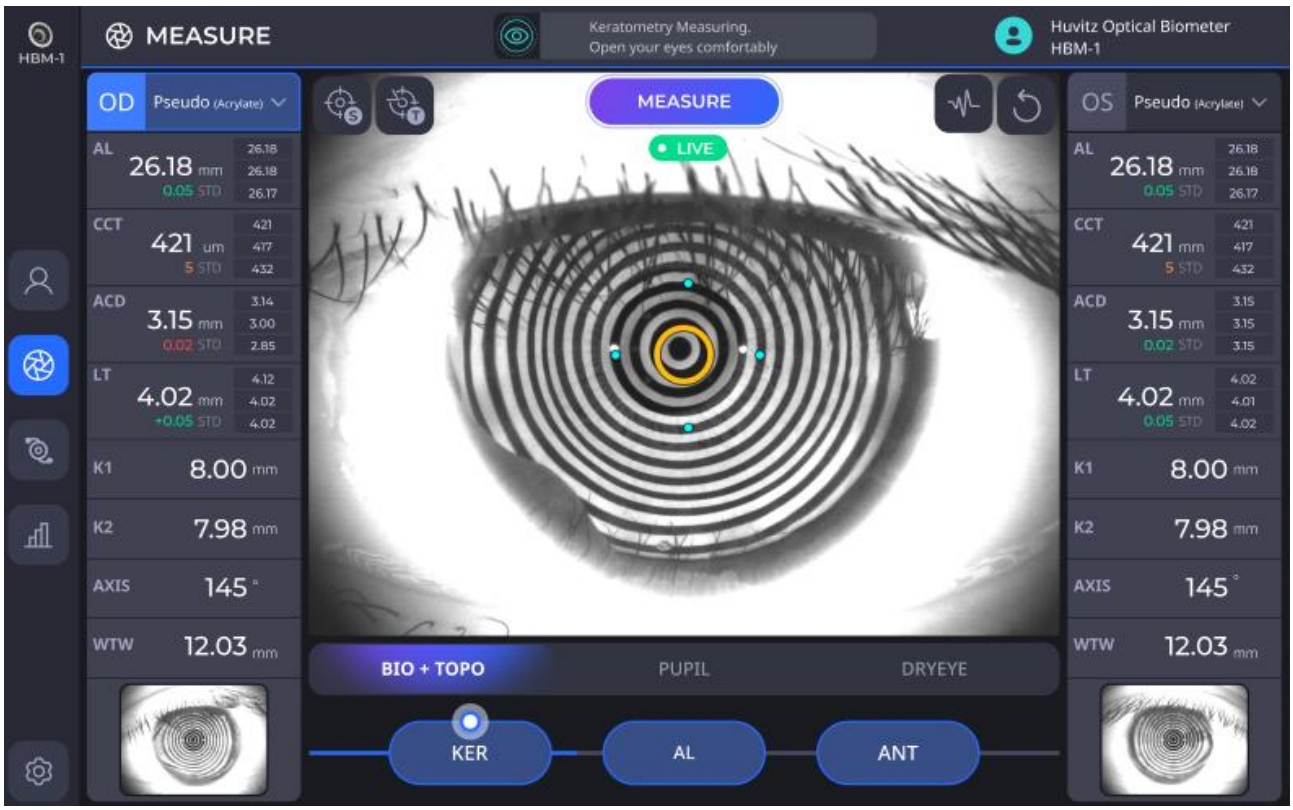


3. Let the patient sit in front of instrument.



4. Set the measurement mode.

You must select at least one among Bio + Topo, PUPIL, and DRYEYE.



BIO + TOPO	Biometer + Topographer measurement is on.
PUPIL	Pupillometry measurement is on.
DRYEYE	Dry eye measurement is on.

- If Biometry mode is on, user can choose the Keratometry, AxialLength, CCT, ACD, LT measurement.
- If Keratometry measurement is on, Keratometer image is taken with pressing the button on joystick and topography map, kerato values are calculated.
- If Axial Length measurement is on, Axial length signal is taken with pressing the button on joystick.
- If CCT, ACD, LT measurement (Anterior measurement) is on, CCT, ACD, LT signal is taken with pressing the button joystick.
- If Pupillometry mode is on, Pupil image is taken with pressing the button on joystick and pupil data is calculated.

5. Set the environment as following.

(1) Set auto shooting.

	Auto shooting is on.
	Auto shooting is off.

- If auto shooting is on, measurement conducted automatically when focused on the patient's eye properly.

(2) Set auto tracking.

	Auto tracking is on.
	Auto tracking is off.

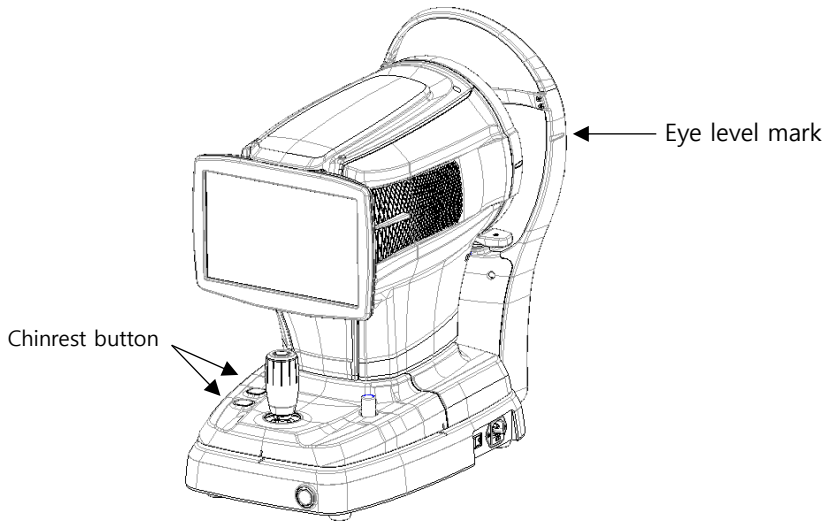
- If auto tracking is on, patient's eye is automatically focused on the center position when patient's eye is inside tracking region.

(3) Set Live Signal.

	Live Signal is on.
	Live Signal is off.

6. 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 on the body to fit the level of patient's eye to the eye level mark on the headrest.

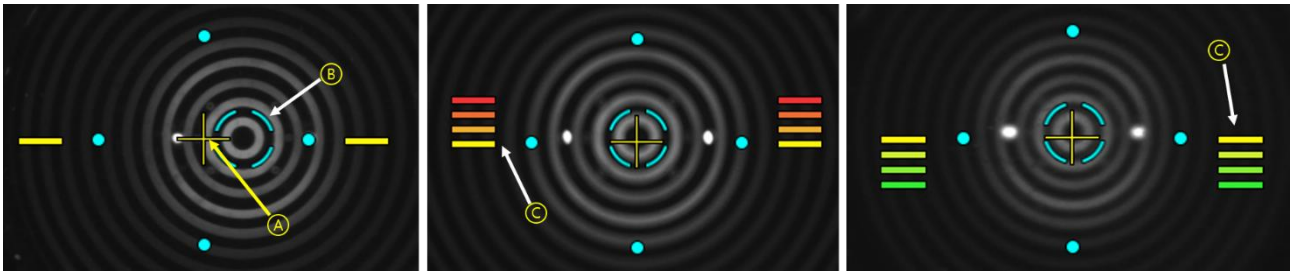


7. Instruct patient to watch internal fixation LED to fix patient eyes. Also, instruct patient to open eye widely, not to blink.

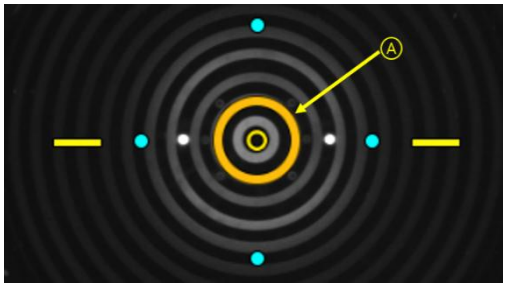
8. Move body with joystick until patient's eye appears on the screen.

9. Set the alignment and focus.

(1) Move the body up/down and left/right with joystick until center of placido-ring (A) and center of cross (B) are concentric. When two center dot are concentric, check the focus indicator bar (C). Move the body back and forth with joystick until it remain only yellow indicator bar.

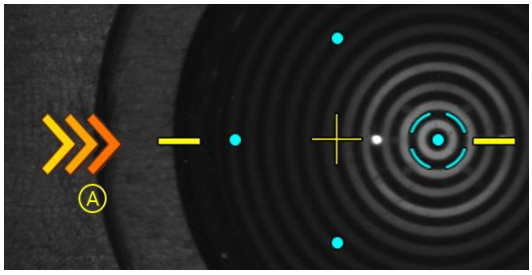


(2) Move joystick little by little until orange target mark (A) appears.



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

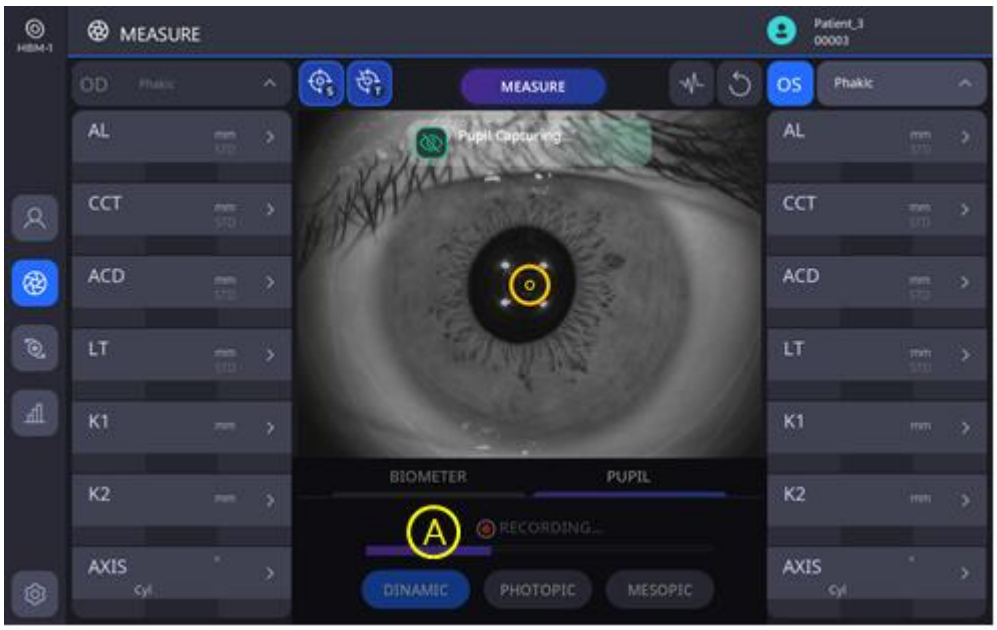
(4) If orange arrow (A) appears during auto tracking, it means auto tracking module go to the limit of tracking region. In that case, move body to the arrow direction with joystick.



(5) After confirming the alignment of the target mark during Axial Length / Anterior Chamber Depth measurement, press the button to start the measurement.

10. Press the button on joystick to capture image.

11. If pupillometry mode is on, wait until the progress bar are full, then press the joystick to stop measurement.



NOTE

While tracking and examination, patient should stay eye open widely. Otherwise, they are not working properly.

NOTE

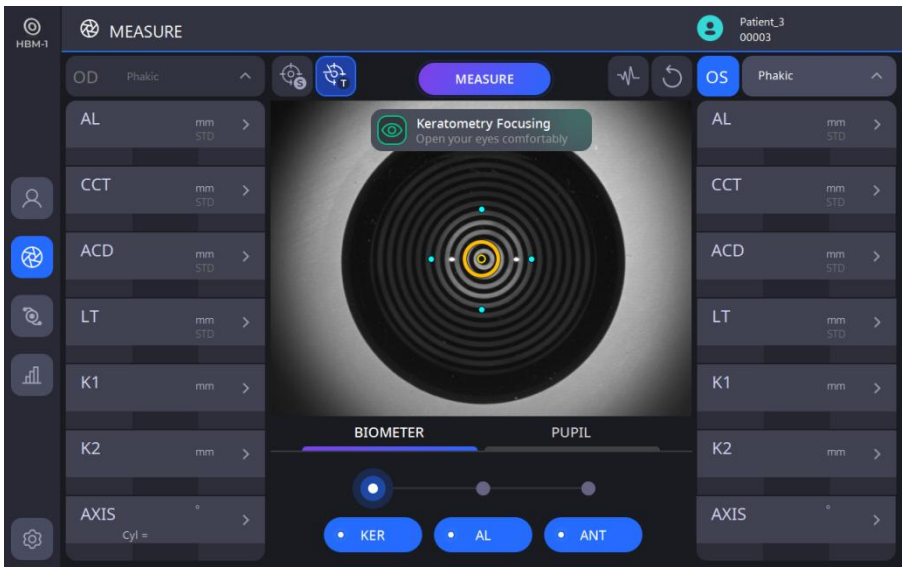
Errors in measurements can occur under one of these conditions: bad focus, closed eyelid, tear film irregularity, high standard deviation in multiple measurements, movement, measurement not in range.

6.6. Maintenance

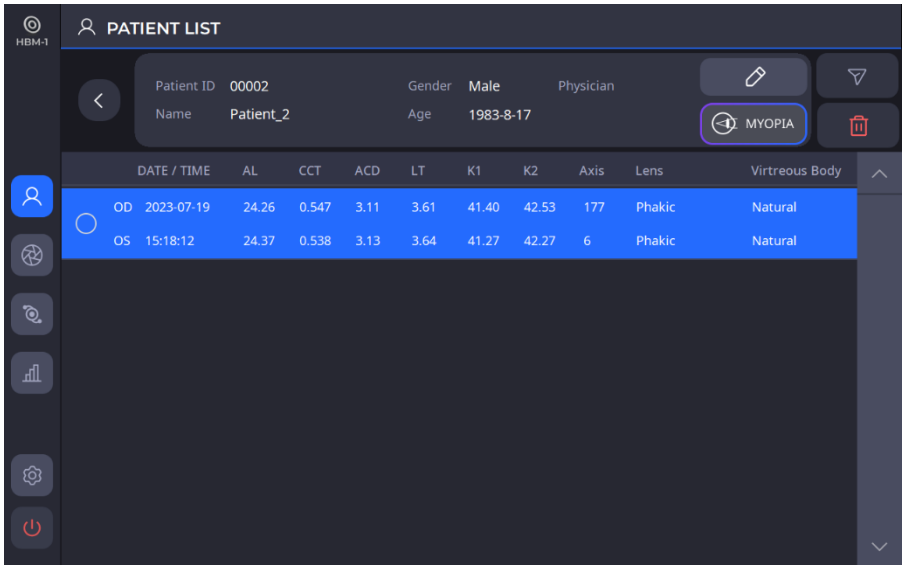
6.6.1. After operation

1. Exit software and Power off.

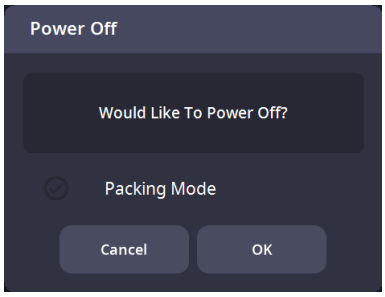
(1) Select the Patient information icon ( ) in the upper left corner of the screen.



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



(3) Selecting POWER OFF icon ( ) shows a pop-up window, Checking the Packing Mode will move chinrest and the body of HBM-1 to the lowest position before Power off (This is for packaging).



NOTE

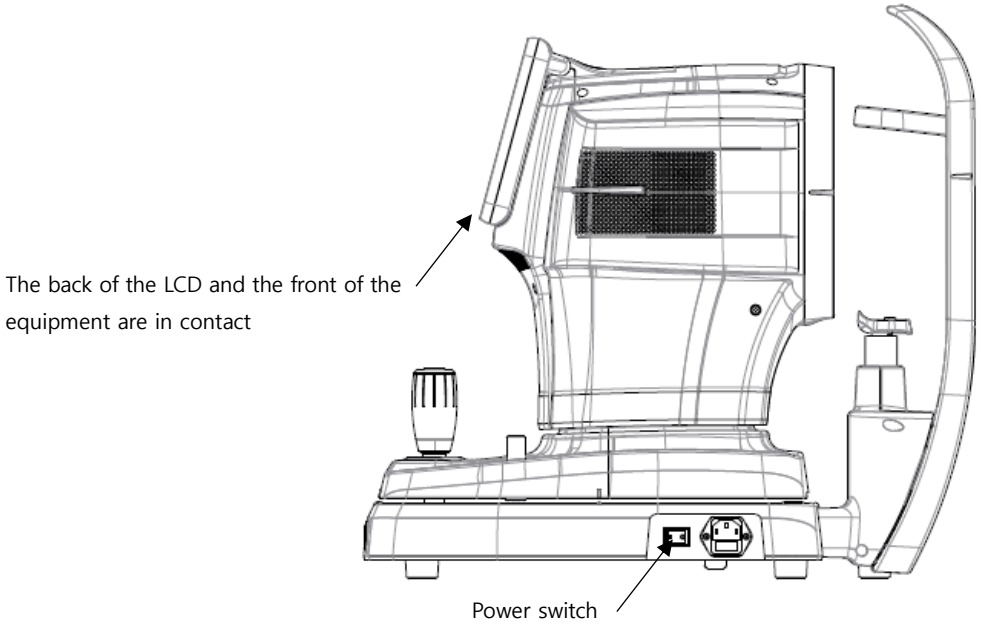
To put the equipment in the packing box, select Packing Mode and then press OK to finish.

NOTE

To put the equipment in the packing box, the back of the LCD must be placed in contact with the front of the equipment.
Failure to do so may damage the stay on the back of the LCD during transport.

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

Risk of electric shock if the HBM-1 is not completely disconnected from the mains for these jobs.
Pull the power plug before cleaning.

1. 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.

2. 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.

3. Placido disk
   (1) Placido disk is a precision component and is pressure-sensitive. The surfaces of these components are susceptible to scratching.
   (2) Take special care when cleaning the surface of the Placido disk. Use a lint-free, dry cloth.
   (3) If necessary, carefully clean the Placido disk with a barely damp cloth.
   (4) Make sure that no dust gets into the little holes.

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.

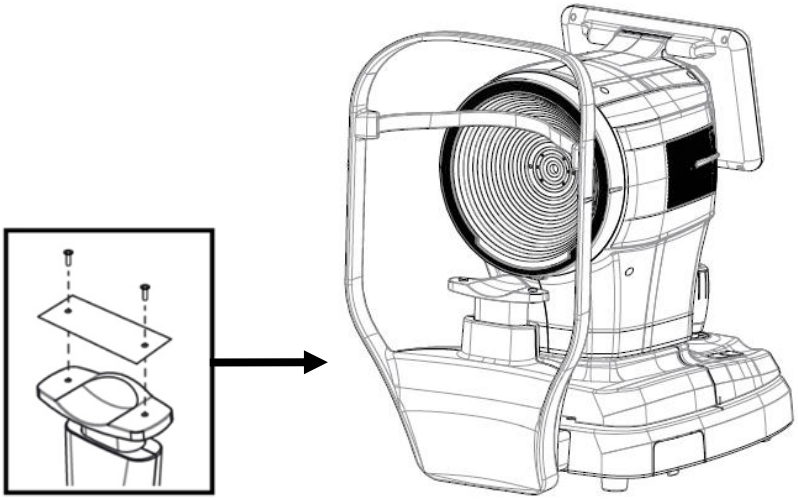
⚠ CAUTION

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

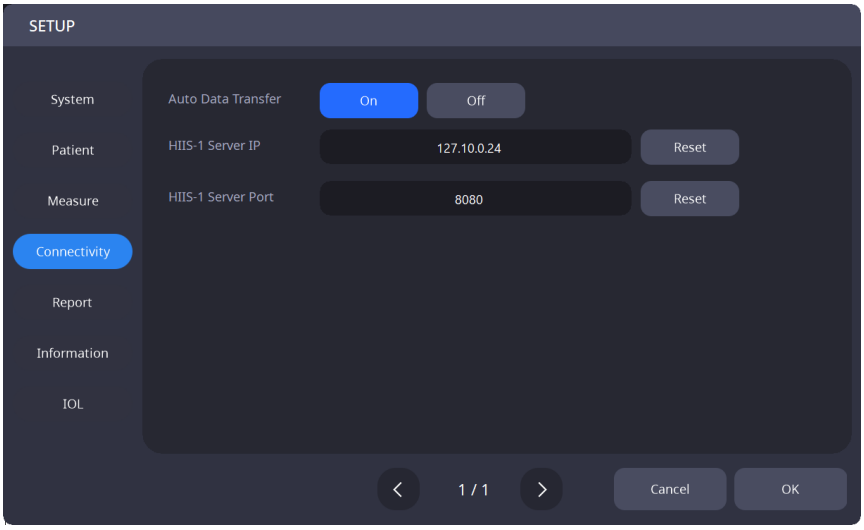
1. Replacing chinrest paper
   (1) Pull out two fixing pins from chinrest.
   (2) Put a new chinrest paper on the chinrest.
   (3) Insert two fixing pins into the chinrest paper hole.
   (4) Attach the chinrest paper to the chinrest.



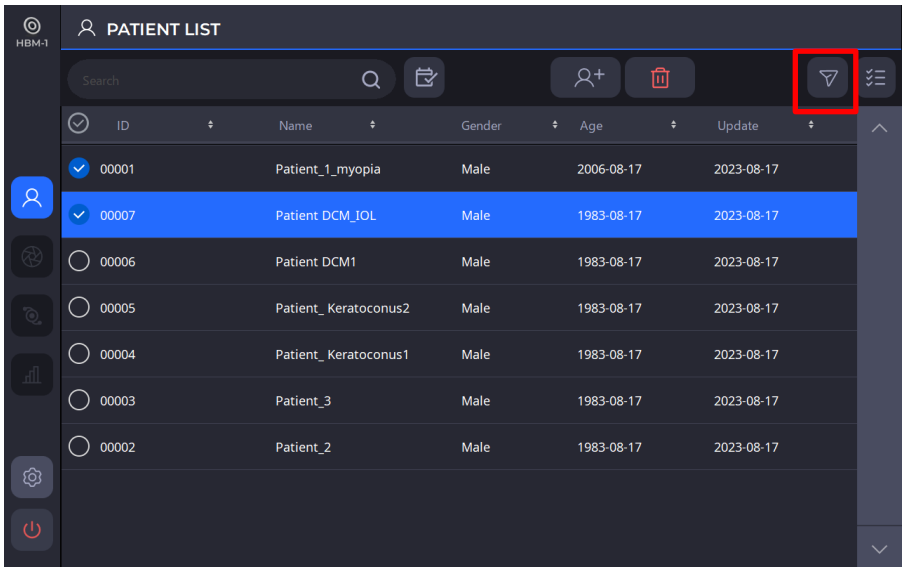
2. Replacing fuse
   (1) Ensure the power switch of device off (O).
   (2) Remove power cable from inlet.
   (3) Pull out fuse holder in the inlet with tweezers.
   (4) Replace two new fuses in the fuse holder. Be sure to check the fuse specification for the replacement (250V T 3.15AL).
   (5) Insert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

6.7. Send Data to Web-Viewer(HIIS)

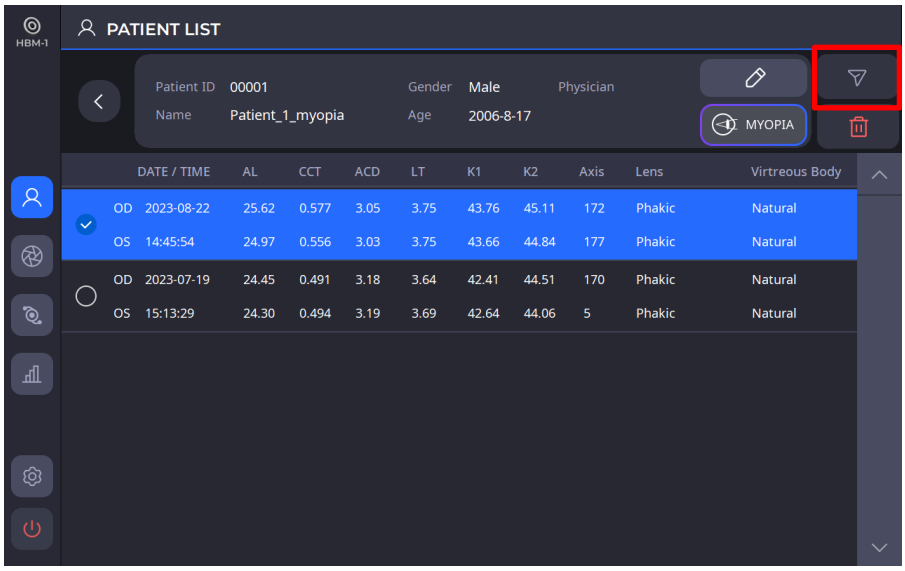
1. Fill in Server IP and Server Port information.
   (Server IP, it means local IP address, where HIIS S/W program is installed. Server Port is fixed with 8080.)



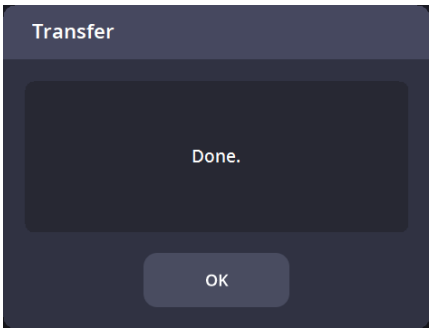
2. Select patients on the Patients List. And clicking 'TRANSFER' button[ ], send all of the selected patient data.



3. Select data in Data List. And clicking 'TRANSFER' button[ ], send the selected data.



4. When it succeeded to send data, the following message box popped up on the window.



7

Troubleshooting Guide

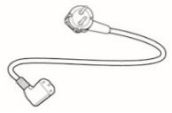
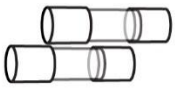
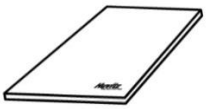
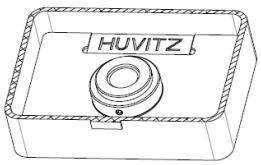
Should the device function improperly, attempt to correct the problem according to the following table before contacting sales distributors.
Contact a sales distributor after turning off the power when the device does not resume normal operation even after taking the following measures.

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.
Measurement data was not available.	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.

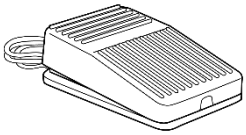
8

Specifications and Accessories

8.1. Standard Accessories

 Chinrest paper	 Touch pen	 Power cable
 Fuse (250V T 3.15A)	 Dust cover	 User manual
 Model Eye	 Wide lens pack	

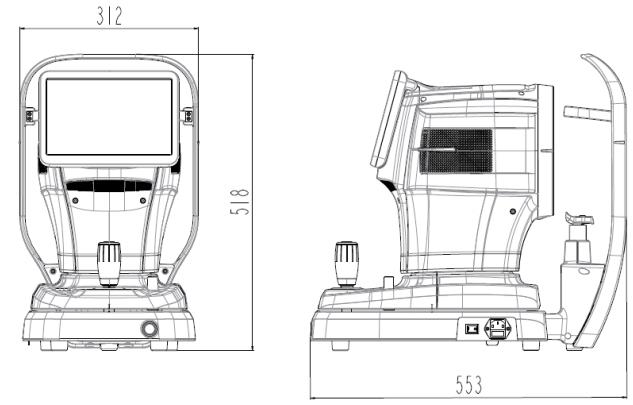
8.2. Optional Accessories

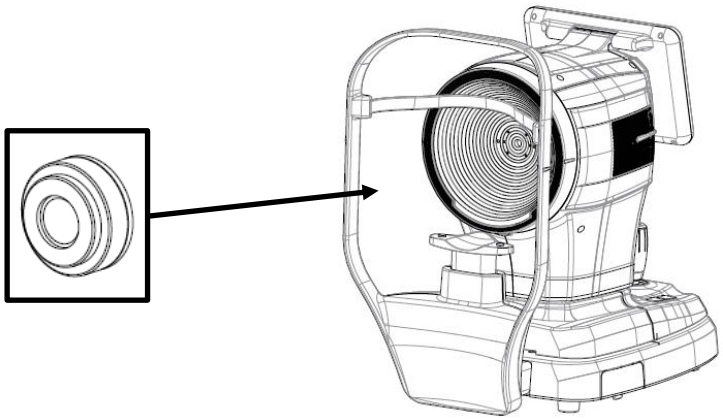
 Foot switch		

8.3. Specifications

Biometry		
Parameter	Measuring range	SD of Repeatability
Axial Length	14 – 40mm	±0.025 mm
Keratometry		
Parameter	Measuring range	SD of Repeatability
Corneal curvature radius	5 – 13mm	±0.03 mm
Corneal refractive power	25.96D~67.50D(refractive index:1.3375)	-
Direction of principal meridians	Measuring range: 1° – 180° Accuracy: according to the ISO 10343:2014 R1-R2≤0.3mm: ±4° R1-R2>0.3mm: ±2°	-
White-to-white distance	7 – 14mm	±0.05 mm
Pupil diameter	0.5 – 10mm	±0.05 mm
Corneal Topography		
Working distance	80 mm (100mm: when mounted wide lens)	
Placido disc	24 rings	
Points Analyzed	Over 100,000	
Biometry (Anterior) - Optional		
Parameter	Measuring range	SD of Repeatability
Anterior chamber depth	1.5 – 6.5mm	±0.04 mm
Central corneal thickness	0.25 – 1.3mm	±0.02 mm
Crystalline lens thickness	1.5-6.5mm(phakic) 0.5-3.5mm(pseudo-phakic)	±0.06 mm
Additional Function - Optional		
Dry eye function	Tear Meniscus, NIBUT, Meibomian, Blink Analysis, Questionnaire	
IOL calculator	General , Post Refractive, Toric	
Common		
Horizontal movement	55 mm (back and forth), 100 mm (left and right)	
Vertical movement	30 mm	
Chinrest movement	62 mm (up and down), motorized	
Auto tracking movement	X,Y for positioning, Z for working distance	
Power consumption	AC 100 - 240 V, 50/60 Hz, 1.6 - 0.7 A	
Dimensions	312(W) x 553(D) x 518(H) mm	
Weight	22 kg	

8.4. Drawings of System





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EMC INFORMATION

Manufacturer announcement – electromagnetic waves trouble

- **Electromagnetic waves trouble**

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

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

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

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SERVICE INFORMATION

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

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

Supply of parts required for repair:

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

Parts to be repaired by qualified service manpower:

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

1.6 Back up battery for clock and data.

■ How to Contact Huvitz Co., Ltd.

■ Huvitz Co., Ltd.

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

Tel: +82-31-428-9100 Fax: +82-31-477-9022(F/A)

E-mail : svc@huvitz.com website : www.huvitz.com

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