

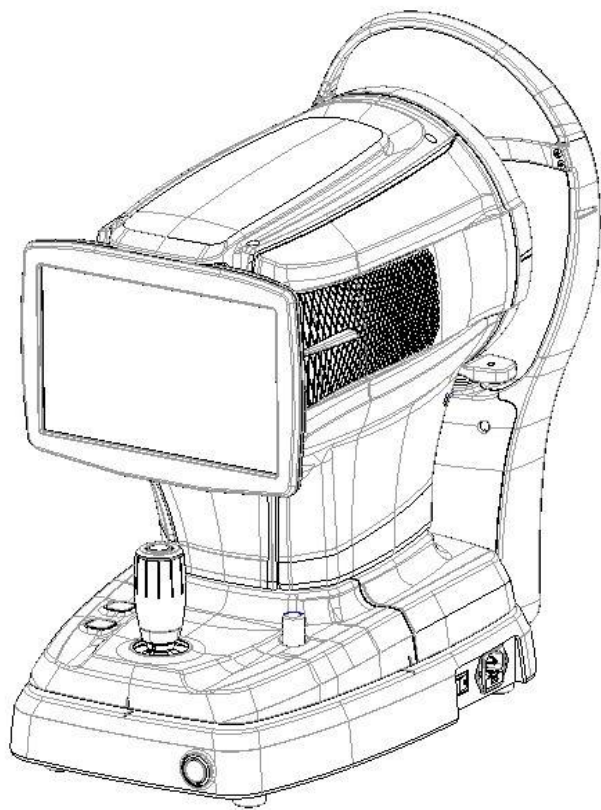


---

# 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.

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

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

### ■ Revision History

| Revision | Date       | Approval                                                                                   | Description                                                                                                           |
|----------|------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| A        | 2021.05.27 | <br>박 상 준 | First issued                                                                                                          |
| B        | 2023.04.21 | <br>박 상 준 | Added new SW functions<br>- Contact Lens Fitting<br>- Myopia Management<br>Added NOTE regarding errors in measurement |

**9000ENG0091-B**  
**(2023/04/21)**

©2021 HUVITZ Co., Ltd.

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

All rights reserved.

Under copyright laws, this manual may not be copied, in whole or in part, without the prior written consent of HUVITZ Co., Ltd.

## CONTENTS

|                                                  |           |
|--------------------------------------------------|-----------|
| <b>SAFETY PRECAUTIONS .....</b>                  | <b>4</b>  |
| 1.1. Overview .....                              | 4         |
| <b>Symbol Information .....</b>                  | <b>5</b>  |
| 2.1. Usage Precautions .....                     | 8         |
| 2.2. Environmental Considerations .....          | 10        |
| 2.3. Safety Warnings .....                       | 12        |
| 2.4. Safety Cautions .....                       | 17        |
| <b>INTRODUCTION .....</b>                        | <b>18</b> |
| 3.1. System Outline .....                        | 18        |
| 3.2. Intended Use .....                          | 18        |
| 3.3. Classification .....                        | 18        |
| 3.4. Contraindications .....                     | 18        |
| 3.5. Patient requirements .....                  | 19        |
| 3.6. Operating Principles .....                  | 19        |
| 3.7. Applied Standard List .....                 | 19        |
| <b>System Overview .....</b>                     | <b>20</b> |
| 4.1. Configuration and Functions .....           | 20        |
| 4.2. Main Body Screen Description .....          | 22        |
| <b>Installation Procedure .....</b>              | <b>41</b> |
| 5.1. System installation .....                   | 41        |
| <b>Operation .....</b>                           | <b>43</b> |
| 6.1. Software .....                              | 43        |
| 6.2. SETUP Mode .....                            | 45        |
| 6.3. DICOM SETUP Mode .....                      | 48        |
| 6.4. Device Check .....                          | 50        |
| 6.5. General Operation .....                     | 51        |
| 6.6. Maintenance .....                           | 56        |
| 6.6.1. After operation .....                     | 56        |
| 6.6.2. Cleaning .....                            | 58        |
| 6.6.3. Replacement of consumables and fuse ..... | 59        |
| 6.7. Send Data to Web-Viewer .....               | 60        |
| <b>Troubleshooting Guide .....</b>               | <b>62</b> |
| <b>Specifications and Accessories .....</b>      | <b>63</b> |
| 8.1. Standard Accessories .....                  | 63        |
| 8.2. Specifications .....                        | 64        |
| 8.3. Drawings of System .....                    | 64        |
| <b>EMC INFORMATION .....</b>                     | <b>65</b> |
| <b>SERVICE INFORMATION .....</b>                 | <b>67</b> |
| <b>SOFTWARE LICENSE AGREEMENTS .....</b>         | <b>69</b> |

# 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.

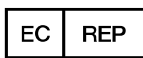
| Symbol                                                                              | Indication                                                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | 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.<br>(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.<br>(O sur l'interrupteur d'alimentation représentent respectivement ON et OFF.)                                                                                                                                                                                                                                                                      |
|    | Temperature Limitation<br>(Limitation de température)                                                                                                                                                                                                                                                                                                                                                           |
|   | Atmospheric pressure limitation<br>(Limitation de pression atmosphérique)                                                                                                                                                                                                                                                                                                                                       |
|  | Humidity limitation<br>(Limite d'humidité)                                                                                                                                                                                                                                                                                                                                                                      |
|  | Stack direction<br>(Direction de la pile)                                                                                                                                                                                                                                                                                                                                                                       |
|  | Keep DRY<br>(Garder au sec)                                                                                                                                                                                                                                                                                                                                                                                     |
|  | Fragile , handle with care<br>(Fragile, manipuler avec soin)                                                                                                                                                                                                                                                                                                                                                    |
|  | Keep away from sunlight<br>(Tenir à l'écart de la lumière du soleil)                                                                                                                                                                                                                                                                                                                                            |
|  | Stack layer limit<br>(Limiter la couche de pile)                                                                                                                                                                                                                                                                                                                                                                |
|  | Use no hook<br>(N'utilisez aucun crochet)                                                                                                                                                                                                                                                                                                                                                                       |
|  | WEEE Symbol – EU only<br><u>Disposal of your old appliance</u><br>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.<br>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 ou les autorités locales. L'élimination correcte de votre ancien appareil aidera à prévenir les conséquences négatives potentielles sur l'environnement et la santé humaine. Pour plus d'informations sur l'élimination de votre ancien 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 alternatif)



Consult instructions for use  
(Consulter les instructions d'utilisation)



MEDICAL – XXXXXXXX EQUIPMENT  
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE  
WITH ANSI/AAMI ES60601-1:2005/A2:2021, CAN/CSA-C22.2 No. 60601-1 (Amendment  
2:2022)

(MÉDICAL – ÉQUIPEMENT XXXXXXXX  
QUANT AUX RISQUES DE CHOC ÉLECTRIQUE, D'INCENDIE ET MÉCANIQUES  
UNIQUEMENT CONFORMÉMENT À ANSI/AAMI ES60601-1:2005/A2:2021, CAN/CSA-C22.2  
No. 60601-1 (Amendment 2:2022))



CLASS 1  
LASER PRODUCT

**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 médical)



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.

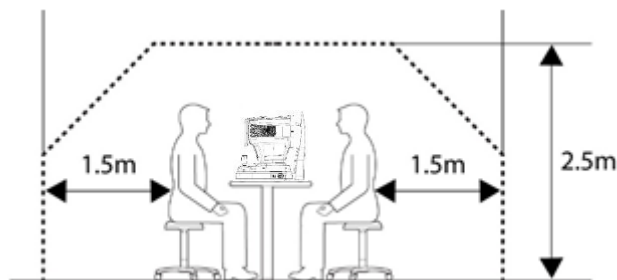
Pour l'utilisation d'équipements à une tension nominale inférieure à 125 Vca, minimum 6 A, type SJT ou SVT, 18 / 3AWG, 10 A, max 3,0 m de long: une extrémité avec type hospitalier, NEMA 5-15P Autre extrémité avec coupleur d'appareil.

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 an 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 unnecessary.
- 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.

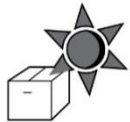
(Obtains a certificate of qualification such as optics, medical school, etc., after completing a certain amount of education.)

## 2.2. Environmental Considerations

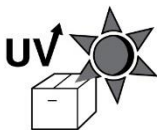
Avoid the following environments for operation or storage:



Where the instrument is exposed to water vapor.  
Don't operate the instrument with wet hands Indoor use only.



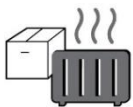
Where the instrument is exposed to direct sunlight.



A place where the equipment can be exposed to direct ultraviolet.



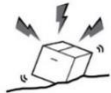
Where there are big changes in temperature.  
Optimal temperature range for normal operation is from 10°C to 35°C (Humidity : 30 ~ 90%).



Where there is hot equipment nearby.



Where the humidity is extremely high or there is a ventilation problem.



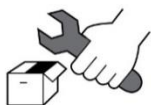
Where the instrument is exposed to excessive shocks or vibrations.



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°C ~ 35°C (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°C ~ 70°C (-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°C ~ 55°C (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.

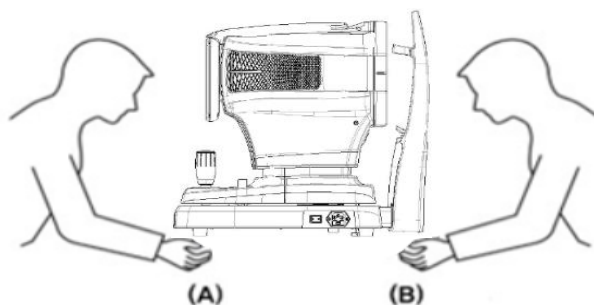
## 2.3. Safety Warnings



### WARNING

1. This is an electric medical device. Use is limited to doctors or persons qualified by the law of each country.
2. Do not make a diagnosis base on a single captured image. Doctors are responsible for making the final diagnosis based on the present and past medical records of the patient such as captured images. Without sufficient information, proper diagnosis may not be made.
3. This equipment must not be used in an area that is in danger of explosions and in the presence of flammable, explosive, or volatile solvent such as alcohol, benzene or similar chemicals.
4. Do not place or store this instrument in humid area. Do not expose the device to water splashes, dripping water, or sprayed water. Do not place containers with fluids, liquids, or gases on top of this instrument.
5. The device must be operated by a trained and qualified person or under his or her supervision.
6. Repair of this instrument must be conducted by HUVITZ's service technicians or other authorized persons.
7. Maintenance by users must observe the User's Manual and Service Manual. Any additional maintenance may only be performed by HUVITZ's service technicians or other authorized persons.
8. Manufacturers are not responsible for the damages caused by unauthorized alterations. Such tampering will forfeit any rights to receive services during the term of guarantee.
9. This instrument must be connected with the accessories supplied by HUVITZ. If you are to use other accessories, their safety or usability must be checked and proved by their manufacturers or HUVITZ.
10. Only those who have undergone proper training and instructions are authorized to install, use, operate, and maintain this instrument.
11. Do not apply excessive force to cable connections. If the cable does not connect easily, make sure that the connector (plug) is appropriate for the receptacle (socket). If you caused any damage to a cable connector(s) or receptacle(s), let the damage(s) be repaired by an authorized service technician.
12. Please do not pull on any cable. Always grab the plug when disconnecting cables.
13. Do not block any ventilation outlet necessary for proper heat dissipation.
14. If smoke, sparks or any abnormal noise or smell is noticed coming from the instrument, please switch the power off immediately and pull out the plug.
15. To avoid the risk of electric shock, this instrument must only be connected to protective earth.

16. Do not place the instrument where it is difficult to operate the disconnecting device. (disconnecting device: power cable)
17. External equipment intended for connection to signal input, signal output or other connectors of this instrument, shall comply with relevant IEC Standard (e.g., IEC60950 for IT equipment and IEC60601-1 series for medical electrical equipment). In addition, all such combination-system shall comply with the standard IEC60601-1 harmonized national standard or the combination. If, in doubt, contact qualified technician or your local representative. The operator should not touch the patient and accessible male parts of the SIP/SOP connectors simultaneously.
18. When you carry this product, please hold on left(A) and right(B) bottom of the product.



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

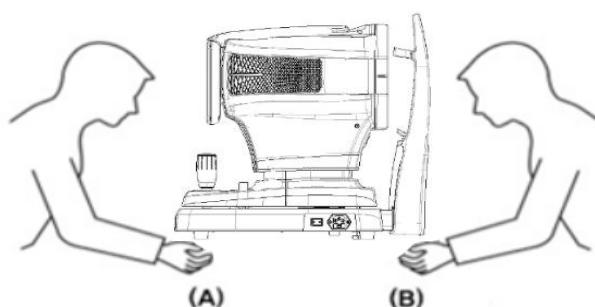
| Part Name         | Material                                         |
|-------------------|--------------------------------------------------|
| LCD Touch panel   | Glass                                            |
| Joystick / button | ABS + Silicon,<br>Aluminum(A6061 T6) + Anodizing |
| Power switch      | PC + PA66                                        |
| Cover             | ABS                                              |
| Chin Rest         | ABS                                              |

20. Do not measure to patients who are sensitive to light. (ex> photophobia)
21. When instrument is sent 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. Ne faites pas de diagnostic de base sur une seule image capturée. Les médecins sont chargés d'établir le diagnostic final sur la base des dossiers médicaux actuels et passés du patient, tels que les images capturées. Sans informations suffisantes, un diagnostic approprié ne peut être établi.
  3. Cet équipement ne doit pas être utilisé dans une zone à risque d'explosion et en présence de solvants inflammables, explosifs ou volatils tels que l'alcool, le benzène ou des produits chimiques similaires.
  4. Ne placez pas et ne stockez pas cet instrument dans un endroit humide. N'exposez pas l'appareil à des projections d'eau, à des gouttes d'eau ou à de l'eau pulvérisée. Ne placez pas de récipients contenant des fluides, des liquides ou des gaz sur le dessus de cet instrument.
  5. L'appareil doit être utilisé par une personne formée et qualifiée ou sous sa supervision
  6. La réparation de cet instrument doit être effectuée par les techniciens de service HUVITZ ou d'autres personnes autorisées
  7. La maintenance par les utilisateurs doit respecter le manuel de l'utilisateur et le manuel de service. Toute maintenance supplémentaire ne peut être effectuée que par les techniciens de service HUVITZ ou d'autres personnes autorisées
  8. Les fabricants ne sont pas responsables des dommages causés par des modifications non autorisées. Une telle altération perdra tout droit de recevoir des services pendant la durée de la garantie.
  9. Cet instrument doit être connecté aux accessoires fournis par HUVITZ. Si vous devez utiliser d'autres accessoires, leur sécurité ou leur utilisation doit être vérifiée et prouvée par leurs fabricants ou HUVITZ.
  10. Seuls ceux qui ont suivi une formation et des instructions appropriées sont autorisés à installer, utiliser, utiliser et entretenir cet instrument.
  11. N'appliquez pas de force excessive sur les connexions des câbles. Si le câble ne se connecte pas facilement, assurez-vous que le connecteur (fiche) est adapté à la prise (prise). Si vous avez causé des dommages à un ou plusieurs connecteurs ou prises de câbles, faites réparer les dommages par un technicien de maintenance agréé.
  12. Veuillez ne tirer sur aucun câble. Saisissez toujours la fiche lorsque vous débranchez les câbles.
  13. Ne bloquez aucune sortie de ventilation nécessaire à une bonne dissipation de la chaleur.
  14. Si de la fumée, des étincelles ou un bruit ou une odeur anormale est remarqué provenant de l'instrument, veuillez éteindre immédiatement et débrancher la prise.
  15. Pour éviter tout risque de choc électrique, cet instrument doit uniquement être connecté à la terre de

protection.

16. Ne placez pas l'instrument là où il est difficile de faire fonctionner le dispositif de déconnexion. (dispositif de déconnexion: câble d'alimentation)
17. Les équipements externes destinés à la connexion à l'entrée, à la sortie de signaux ou à d'autres connecteurs de cet instrument doivent être conformes à la norme CEI pertinente (par exemple, IEC60950 pour les équipements informatiques et IEC60601-1 pour les équipements électromédicaux). De plus, tous ces systèmes combinés doivent être conformes à la norme nationale harmonisée IEC60601-1 ou à la combinaison. En cas de doute, contactez un technicien qualifié ou votre représentant local. L'opérateur ne doit pas toucher simultanément le patient et les parties mâles accessibles des connecteurs SIP / SOP.
18. Lorsque vous transportez ce produit, veuillez tenir en bas gauche (A) et à droite (B) du produit.



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

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

20. Ne mesurez pas les patients sensibles à la lumière. (ex> photophobie)
21. Lorsque l'instrument est renvoyé au centre A / S pour réparation ou maintenance, ou avant que le technicien agréé ne soit arrivé sur place pour réparation ou maintenance, essuyez les surfaces de l'instrument (en particulier, les pièces qui entrent en contact avec le patient) avec un chiffon propre imbibé d'alcool à friction.
22. En cas d'incident grave impliquant le dispositif, l'utilisateur le signale au fabricant et à l'autorité compétente de l'État membre dans lequel l'utilisateur et / ou le patient sont établis.
23. Si un utilisateur utilise l'économie d'énergie prise en charge par Windows 10, à l'exception de l'économie d'énergie dans le paramètre Utilisateur, cela provoque des problèmes dans HBM-1. Le fabricant n'est pas responsable du problème.
24. L'utilisateur ne doit pas modifier le paramètre pris en charge par le fabricant. Cette modification peut entraîner des problèmes dans le HBM-1. Le fabricant n'est pas responsable du problème.
25. 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.

26. Lorsque la boîte d'emballage est ouverte par inadvertance avant utilisation ou endommagée, veuillez appeler le centre A/S.
27. Assurez-vous que vous disposez toujours d'un antivirus et d'un pare-feu à jour installés sur votre système.
28. Évitez de réinitialiser ou d'éteindre le PC lorsque le HBM-1 est en marche.
29. Même si la sauvegarde est configurée pour être effectuée, si l'alimentation n'est pas allumée ou si l'emplacement de sauvegarde est introuvable, la sauvegarde n'est pas effectuée.
30. La connexion de l'interface électronique à un réseau informatique comprenant d'autres équipements pourrait entraîner des risques non identifiés auparavant pour les patients, les utilisateurs ou des tiers. Il est conseillé à l'ORGANISME RESPONSABLE d'identifier, d'analyser, d'évaluer et de contrôler ces RISQUES.
31. Des modifications ultérieures du RÉSEAU INFORMATIQUE pourraient introduire de nouveaux RISQUES et nécessiter une analyse supplémentaire. Les modifications apportées au RÉSEAU INFORMATIQUE 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.

## **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

The Optical Biometer HBM-1 also measures corneal topography. The Optical Biometer HBM-1 also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.

### **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 an examination by this instrument must maintain concentration for a few minutes and adhere to the following instructions;

- After his/her face to the chinrest, 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**

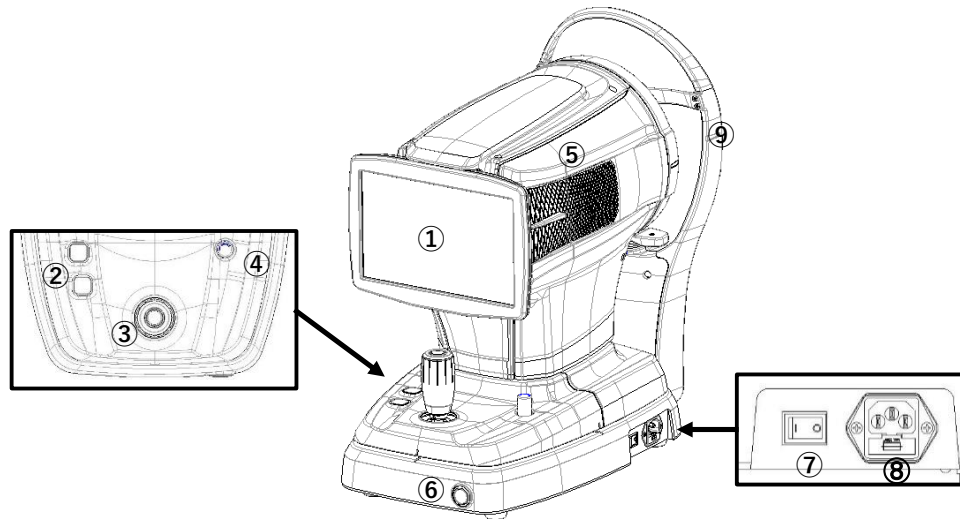
- IEC/EN 60601-1: MEDICAL ELECTRICAL EQUIPMENT
  - Part 1: General requirements for safety
- IEC/EN 60601-1-2: Medical electrical equipment Part1: General requirements for safety
  - Collateral Standard: Electromagnetic Compatibility-Requirements and tests
- ISO15004-1: Ophthalmic instruments
  - Fundamental 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: 2014: Safety of laser products – Part1: Equipment classification and requirements

# 4

## System Overview

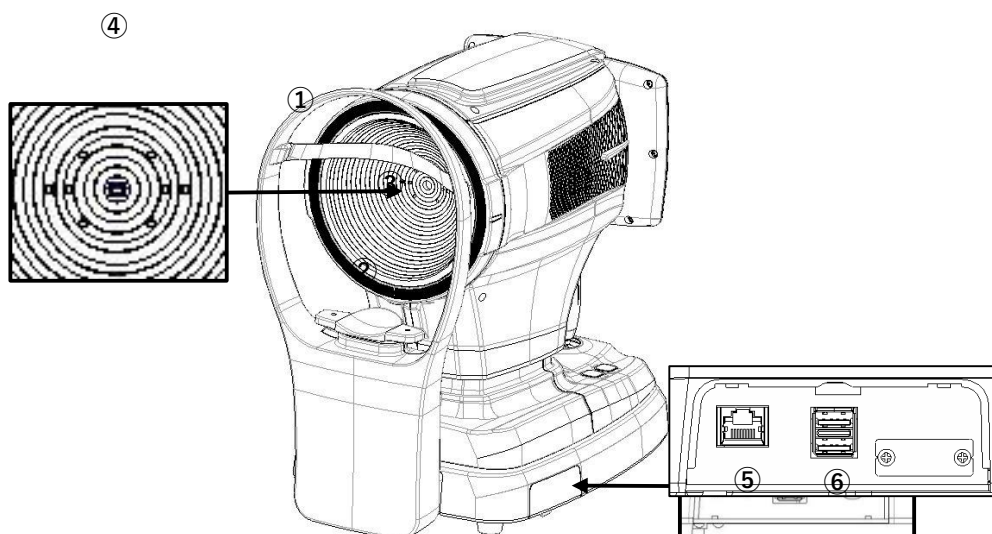
### 4.1. Configuration and Functions

#### ■ 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.<br>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.<br>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

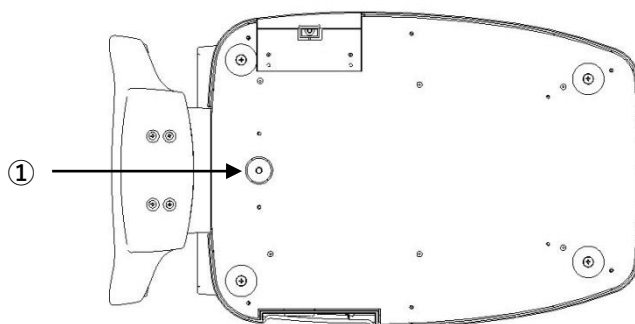


| No | Part     | Name         | Description                                        |
|----|----------|--------------|----------------------------------------------------|
| 1  | Headrest | Headrest     | The part that holds the patient's head             |
| 2  |          | Chinrest     | For fixing 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) |

**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.

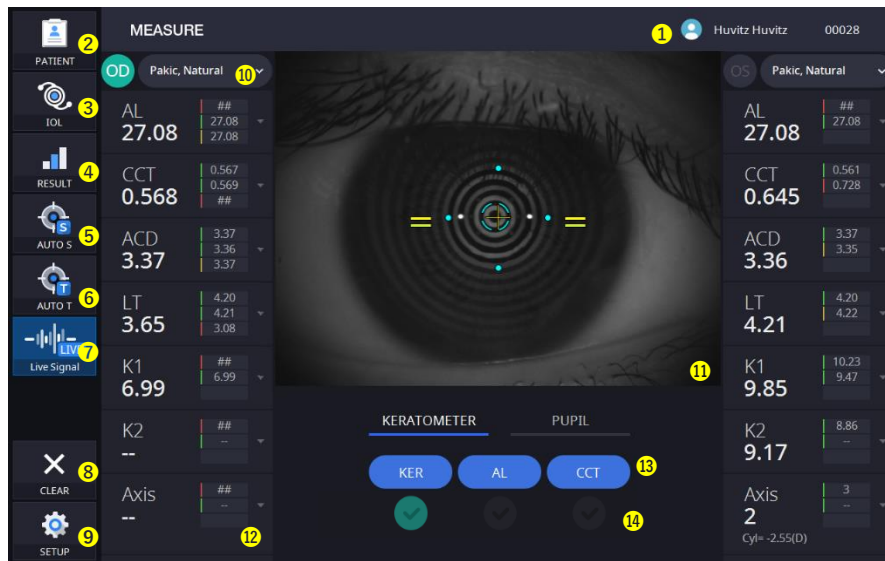
### ■ Bottom View



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

## 4.2. Main Body Screen Description

### MEASURE screen

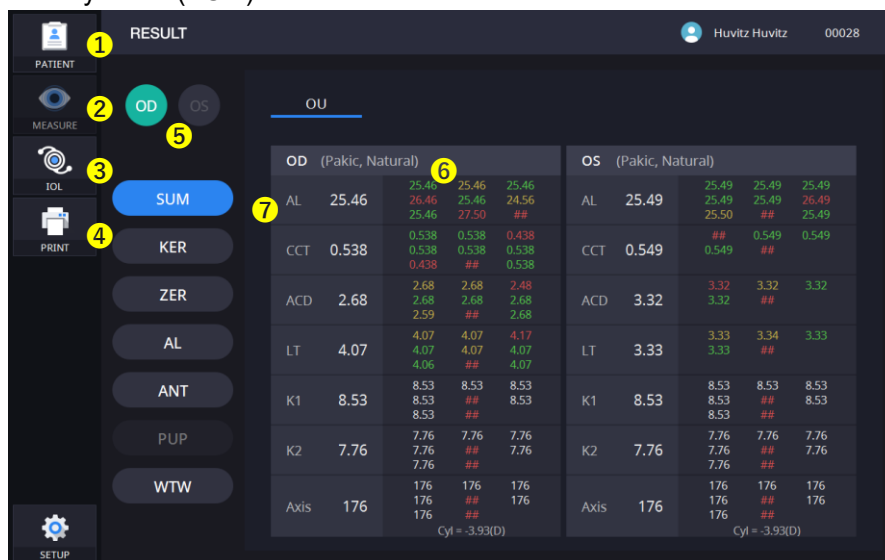


| No | Name                | Function                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Patient information | Shows the information of patient ID and name.                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 2  | Patient             | Go back to patient detail page.                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 3  | IOL                 | Go to IOL calculation page.<br>Simulate the IOL lens with measured data.                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 4  | Result              | Go to Result page.<br>Result page shows the detail information about the patient measurement.                                                                                                                                                                                                                                                                                                                                                                                                       |
| 5  | AUTO S              | Show auto shooting selection status.                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 6  | AUTO T              | Show auto tracking selection status.                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 7  | Live Signal         | Show live signal selection status.                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 8  | Clear               | Clear all of the measurement data.                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 9  | SETUP               | Change the measurement settings.                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 10 | Lens&Vitreous Info. | Shows the patient's Lens and Vitreous body information.<br>(If clicking, selection box will be slide down. And, User can change the options.)                                                                                                                                                                                                                                                                                                                                                       |
| 11 | Camera Image        | It shows the live camera images.                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 12 | Measurement Value   | It shows latest measured values.<br>So, user can check the measurement.<br>Each value color indicates evaluation result, green means that value is very reliable, yellow means that value is reliable a bit, red means that value is hard to reliable. ("##" value is perfectly error value.)<br>-AL: Axial Length.<br>-CCT: Central Corneal Thickness.<br>-ACD: Anterior Chamber Depth.<br>-LT: Lens Thickness.<br>-K1: Flat Keratometry.<br>-K2: Steep Keratometry.<br>-Axis: Angle degree of K1. |
| 13 | Measurement Mode    | Select the measurement mode before the measurement.                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

|    |               |                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 14 | Process Check | <p>It informs user to check the measurement status according to the measurement process.</p> <p> : waiting the process.</p> <p> : this turn.</p> <p> : already measured.</p> |
|----|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## ■ RESULT screen

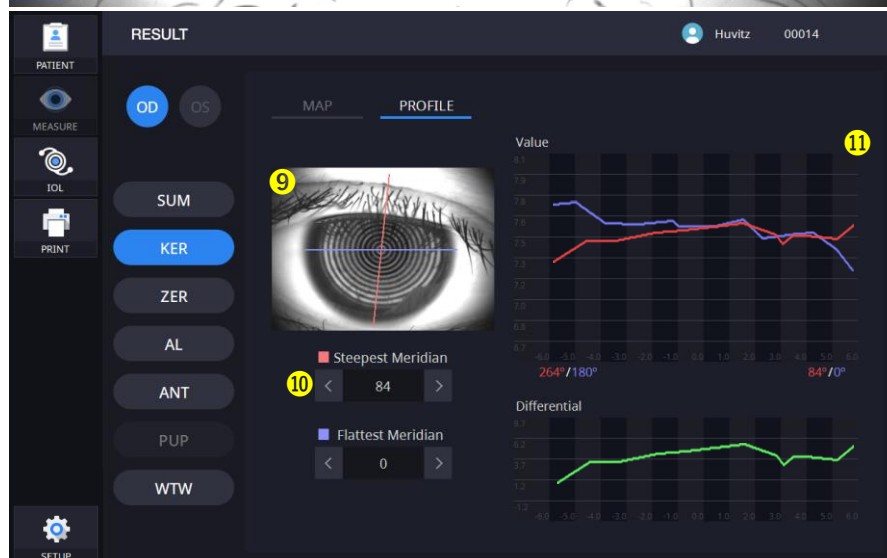
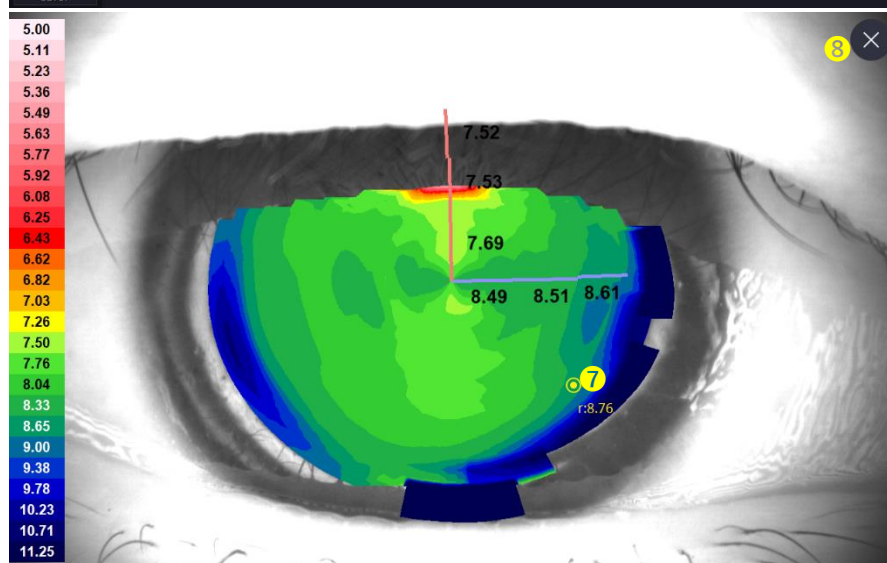
### 1. Summary result (SUM)



| OD (Pakic, Natural) |       | OS (Pakic, Natural) |       |
|---------------------|-------|---------------------|-------|
| AL                  | 25.46 | 25.46               | 25.46 |
| CCT                 | 0.538 | 0.538               | 0.538 |
| ACD                 | 2.68  | 2.68                | 2.68  |
| LT                  | 4.07  | 4.07                | 4.07  |
| K1                  | 8.53  | 8.53                | 8.53  |
| K2                  | 7.76  | 7.76                | 7.76  |
| Axis                | 176   | 176                 | 176   |

| No | Name                               | Function                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----|------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Patient                            | Go back to patient detail page.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2  | Measure                            | Measure patient and get new data.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3  | IOL                                | Go to IOL calculation page.<br>Simulate the IOL lens and formula with measured data.                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 4  | Print                              | Print report.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 5  | OD/OS                              | Show eye position. Select eye and Check the result.<br>- OD: right eye<br>- OS: left eye                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 6  | Eye&Lens&Vitreous body Information | Show the patient's Lens and Vitreous body.<br>Lens: Phakic, Aphakic, Pseudophakic(Unknown), Pseudophakic(silicone), Pseudophakic(PMMA), Pseudophakic(Acrylate), Pseudophakic(Memory)<br>Vitreous body: Natural, Silicone Oil                                                                                                                                                                                                                                                                                                 |
| 7  | Measured Value                     | Show the value name, average value, and each value.<br>Each value is evaluated by some standard.<br>Each value color indicates evaluation result, green means that value is very reliable, yellow means that value is reliable a bit, red means that value is hard to reliable. ("##" value is perfectly error value.)<br>-AL: Axial Length.<br>-CCT: Central Corneal Thickness.<br>-ACD: Anterior Chamber Depth.<br>-LT: Lens Thickness.<br>-K1: Flat Keratometry.<br>-K2: Steep Keratometry.<br>-Axis: Angle degree of K1. |

### 2. Keratometry result (KER)

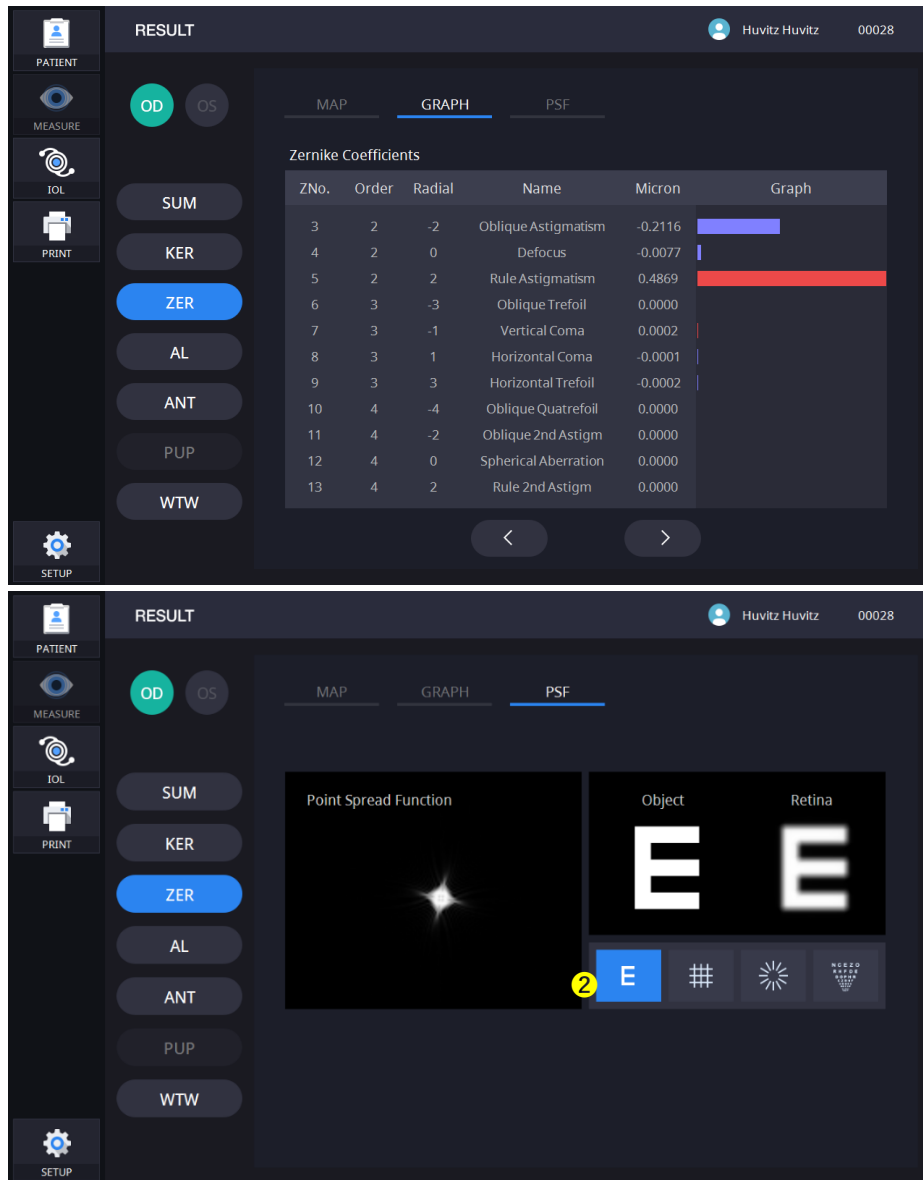


| No | Name        | Function                                                                                      |
|----|-------------|-----------------------------------------------------------------------------------------------|
| 1  | Map/Profile | Map: Show Topography map with various options.<br>Profile: Show curvature along the meridian. |

|    |                                  |                                                                                                                                                                                                                                                                                                                                                   |
|----|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2  | Data image                       | Show data image with the options.                                                                                                                                                                                                                                                                                                                 |
| 3  | Eye/Map/Ring                     | Display the image of the eye, topo map, topo rings.                                                                                                                                                                                                                                                                                               |
| 4  | Axial/Tangential                 | Select the topo map.                                                                                                                                                                                                                                                                                                                              |
| 5  | Zoom                             | Show the enlarged map.<br>If you want to check the data point by point, check it on the enlarged screen.                                                                                                                                                                                                                                          |
| 6  | Data values                      | Show the detail value (several zones value, keratoconus indice etc) about the topography.<br>Several zones value: The keratometry information at the point 3~7mm away from the center point is displayed.<br>(K1: Flat Keratometry, K2: Steep Keratometry, Avg: Average of Keratometry value in the zones, Cyl: Cylinder and Angle degree of K1.) |
| 7  | Point data                       | If you pick a point, you can see the data of that point.                                                                                                                                                                                                                                                                                          |
| 8  | Close Zoom                       | Close the enlarged map.                                                                                                                                                                                                                                                                                                                           |
| 9  | Eye Image&Meridian               | Eye image marked with steepest meridian and flattest meridian.                                                                                                                                                                                                                                                                                    |
| 10 | Control Meridian                 | If changing the angle of Meridian, the corresponding graph updated.                                                                                                                                                                                                                                                                               |
| 11 | Value Graph & Differential Graph | Shows the radius/diopter along the meridian line.<br>And Differential graph can be used to checking the difference with steepest meridian and flattest meridian.                                                                                                                                                                                  |

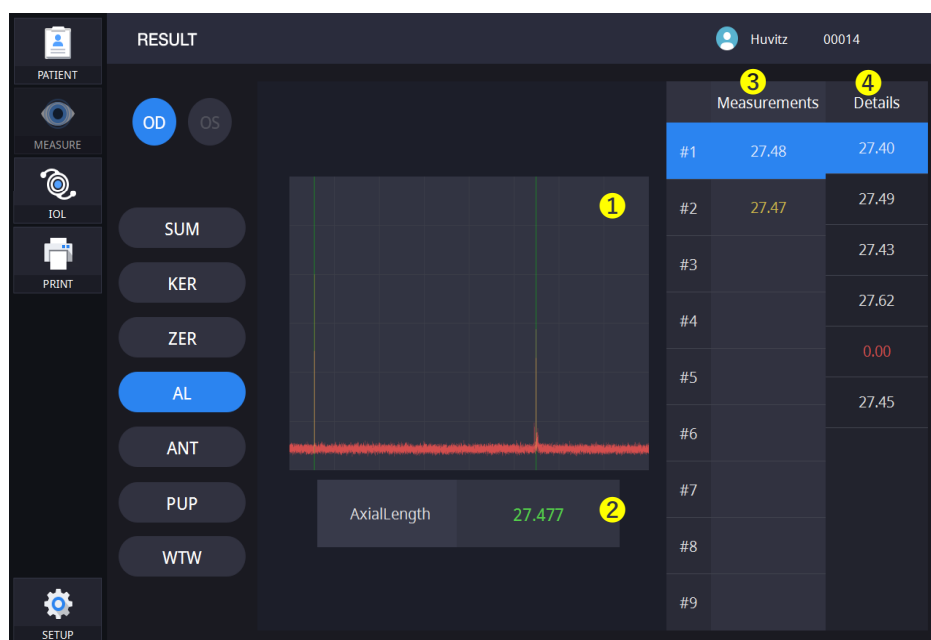
### 3. Zernike result (ZER)





| No | Name                     | Function                                                                                                                      |
|----|--------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| 1  | Map/Graph/PSF            | Map: Show the aberration map.<br>Graph: Show the coefficients graph.<br>PSF: Show the point spread function image.            |
| 2  | Echart/Grid/Radial/ETDRS | Echart : Show the E chart.<br>Grid : Show the Grid chart.<br>Radial : Show the Radial chart.<br>ETDRS : Show the ETDRS chart. |

#### 4. AL result (AL)



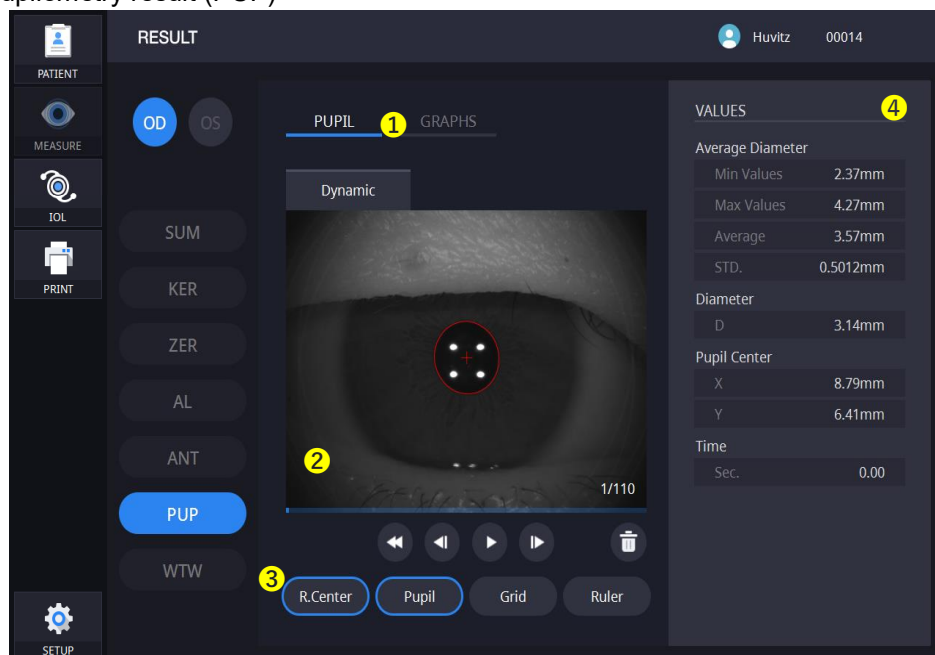
| No | Name          | Function                                                                                                                                                                                                                                                                                                                                                                                                  |
|----|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Signal graph  | Show the measured signal image.                                                                                                                                                                                                                                                                                                                                                                           |
| 2  | Average value | Show the average measured axial length value.                                                                                                                                                                                                                                                                                                                                                             |
| 3  | Each values   | Show each measurement axial length values. (it is the average of detail values.)<br>Each value is evaluated by some standard.<br>Each value color indicates evaluation result, green means that value is very reliable, yellow means that value is reliable a bit, red means that value is hard to reliable.                                                                                              |
| 4  | Detail values | 6 measured values are grouped one single measurement.<br>Show detail data of each measurement group.<br>Detail value is evaluated by some standard.<br>Detail value color indicates evaluation result, White means that value is reliable, red means that value is hard to reliable.<br>Only reliable values(=White color values) are included in the average value calculation(Each measurement values). |

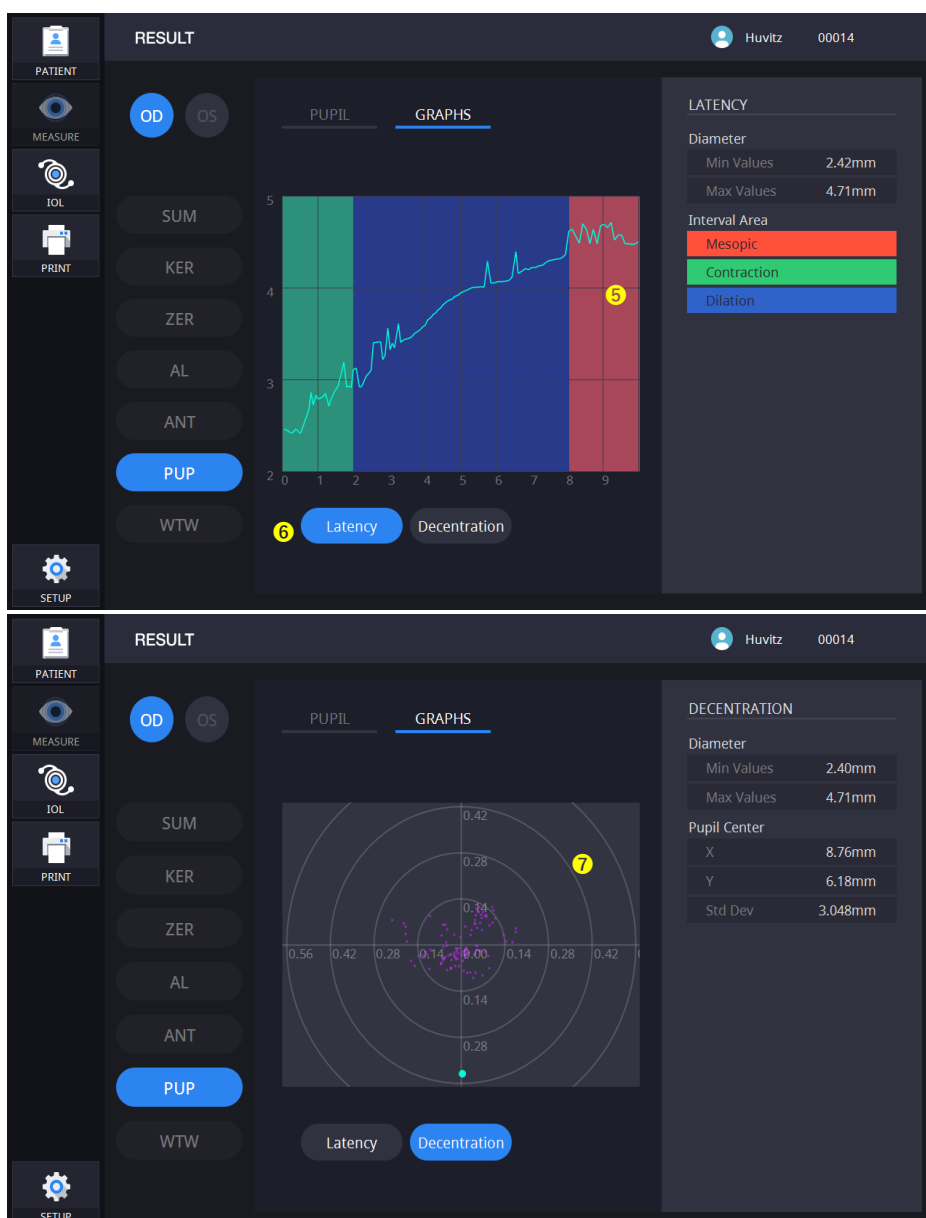
## 5. Anterior result (ANT)



| 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   | Show the each measurement Anterior values.<br>Each value is evaluated by some standard.<br>Each value color indicates evaluation result, green means that value is very reliable, yellow means that value is reliable a bit, red means that value is hard to reliable. |

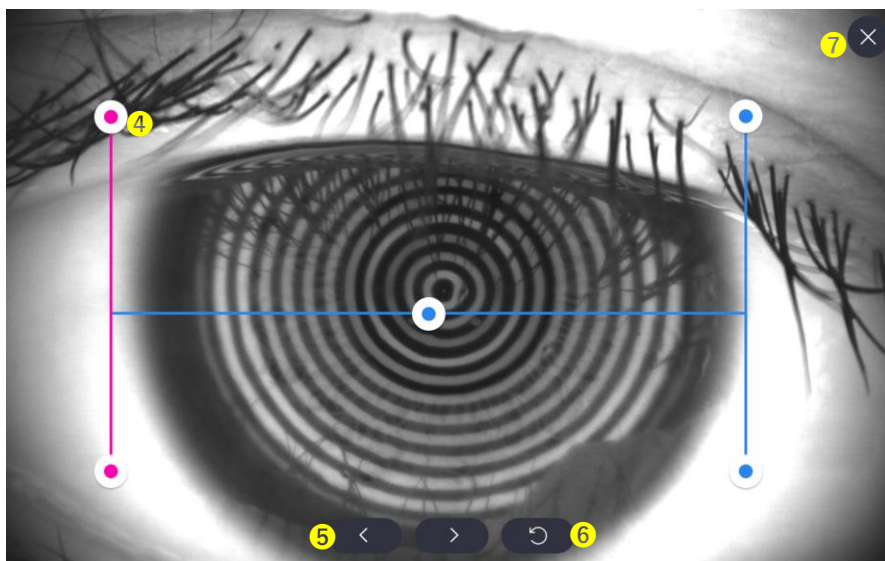
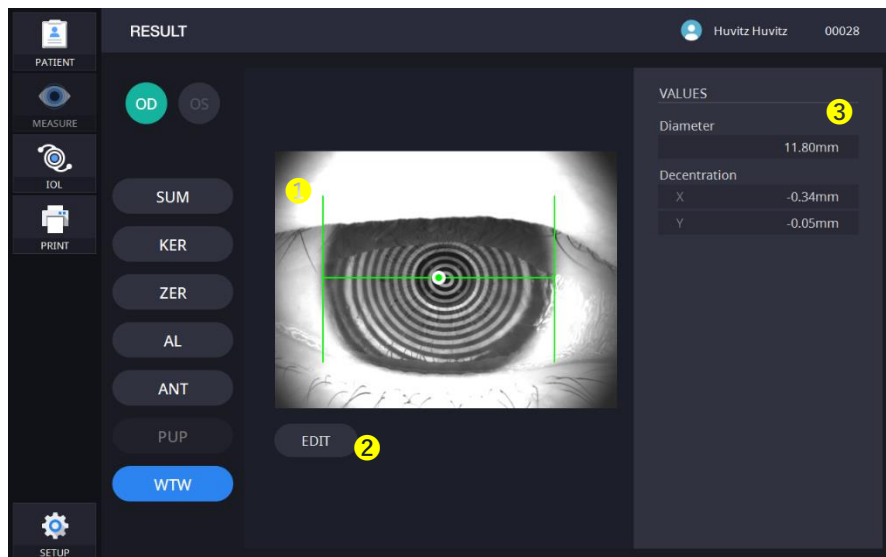
## 6. Pupilometry result (PUP)





| No | Name                 | Function                                                                                                                                                                 |
|----|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Pupil/Graphs         | Pupil: Show the continuous image of pupil, and check the pupil changes.<br>Graph: Show the Latency and Decentration graph.                                               |
| 2  | Captured image       | Show captured images during the measurement.                                                                                                                             |
| 3  | Display options      | Select display options.                                                                                                                                                  |
| 4  | Measurement values   | Show measurement data.                                                                                                                                                   |
| 5  | Graph                | Show the light latency with graph.                                                                                                                                       |
| 6  | Latency/Decentration | Select page.                                                                                                                                                             |
| 7  | Decentration         | Show the variance of pupil center and fixation.<br>Blue circle is decentration from center to fixation.<br>Purple rectangle is decentration from center to 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<br>-Edit bar           | Click the bar makes it active (pink color express the active state).<br>In the active state, move the bar to set the WTW position. |
| 5  | edit window<br>-detail move button | It is difficult to move the bar finely on a small screen, so it is used for fine adjustment.                                       |
| 6  | edit window<br>-reset              | Reset the bar to original location.                                                                                                |
| 7  | edit window<br>-save and close     | Finished editing, save and close the edit window.                                                                                  |

## **IOL screen**

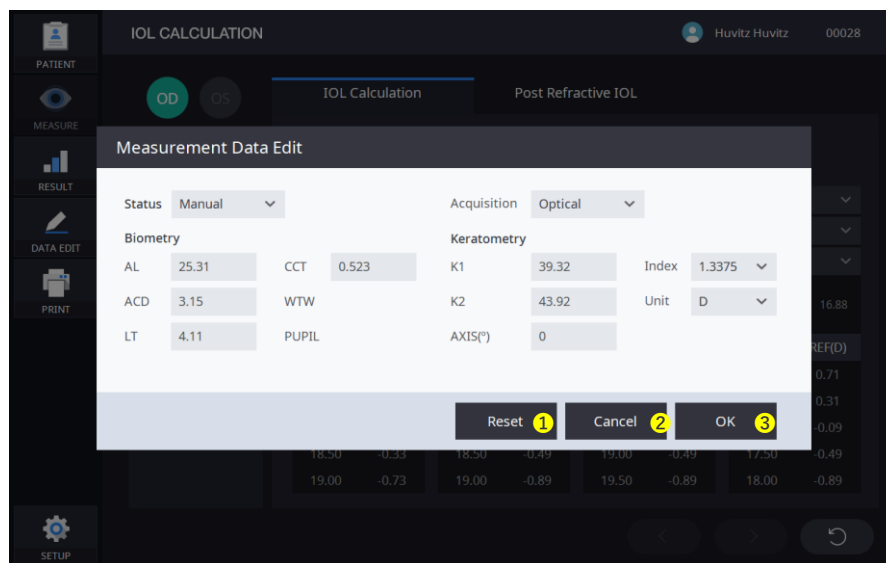
### **1. IOL CALCULATION**

The top screenshot shows the 'IOL Calculation' screen. It has a sidebar with buttons for PATIENT, MEASURE, RESULT (1), DATA EDIT (2), and PRINT. The main area has tabs for OD and OS. Under the 'Measurement' tab (3), there are fields for AL (25.31), CCT (0.523), ACD (3.15), LT (4.11), K1 (39.32), K2 (43.92), Axis (0), PUPIL, WTW, and Index (1.3375). The 'IOL Calculation' tab (4) has fields for Surgeon (Physician0 (5)) and Target (0 (6)). Below these are four columns of IOL data, each with a manufacturer (Alcon, SN60WF, SRK2), a model (SA60AT, SRK2), a formula (A=119.200, A=119.000, A=119.500, A=118.000), and a table of IOL(D) and REF(D) values. The bottom screenshot shows the 'Post Refractive IOL' screen. It has the same sidebar. The 'Post Refractive IOL' tab has fields for Surgeon (Select Surgeon), LT (0 (14)), Correction Type (Myopic (15)), and Type (RK (16)). Below these are 'Formulas Available' (Camellin-Calossi (17), Shamas No History) and a 'Camellin-Calossi' section with a 'SIRC' field. The bottom of the screen has navigation buttons (18).

| No | Name                                    | Function                                                                                                                                                                                                              |
|----|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Result                                  | Go to Result page.<br>Check the measurement data detail.                                                                                                                                                              |
| 2  | Data Edit                               | Go to the Measurement Data Edit pop-up window, edit data to calculate IOL exactly.                                                                                                                                    |
| 3  | Measurement Value                       | Show the values required for IOL calculation.                                                                                                                                                                         |
| 4  | IOL Calculation/<br>Post Refractive IOL | IOL Calculation : It informs general IOL calculation with several formula, that are SRK2, SRK/T, HofferQ, Haigis, Holladay.<br>Post Refractive IOL : It calculate IOL for patient who have already had the operation. |
| 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 is an intrinsic constant of IOL lens model. It is necessary when calculating IOL formula.                                                                                                                          |
| 11 | Ideal IOL Power                         | It is an ideal IOL power that expects the target refractive value.                                                                                                                                                    |

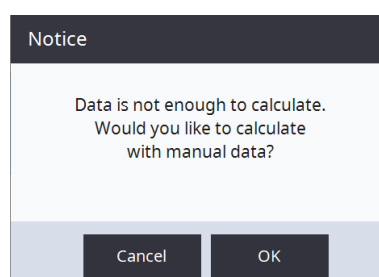
|    |                        |                                                                                                           |
|----|------------------------|-----------------------------------------------------------------------------------------------------------|
| 12 | IOL calculation result | It informs 5 IOL power lists that are close to the target refractive value.                               |
| 13 | Reset                  | Reset the calculation result.                                                                             |
| 14 | LT                     | LT value is important to Post-Operation IOL calculation. So, it is input to check the LT value once more. |
| 15 | Correction Type        | Select the correction type.                                                                               |
| 16 | Type                   | Select the prior refractive surgery type.                                                                 |
| 17 | Formulas               | Select the formulas, and check the input data.                                                            |
| 18 | Next                   | Go to next calculation page.                                                                              |

## 2. Data Edit



| No | Name   | Function                                                      |
|----|--------|---------------------------------------------------------------|
| 1  | Reset  | Reset values to measured data, return to the status:Measured. |
| 2  | Cancel | Cancel the window.                                            |
| 3  | OK     | Save the data with modifications.                             |

If there is not enough data to calculate IOL, directly show the 'Measurement Data Edit pop-up' with the following message.



## Myopia Management

### 1. RX / AL (Refractive Error / Axial Length ) Screen



| No | Name              | Function                                                                                                                  |
|----|-------------------|---------------------------------------------------------------------------------------------------------------------------|
| 1  | Patient           | Returns to Measurement List Screen.                                                                                       |
| 2  | OD/OS Select      | Select OD / OS.                                                                                                           |
| 3  | RX / AL           | Graphs the Refractive Error and the Axial Length.                                                                         |
| 4  | RX                | Graphs the Refractive Error.                                                                                              |
| 5  | AL                | Graphs the Axial Length.                                                                                                  |
| 6  | A.P.P             | Graphs the Average Pupillary Power.                                                                                       |
| 7  | Ortho-K           | Compare and Show Corneal Curvature Map Before And After Prescription Of Orthokeratology.                                  |
| 8  | OD/OS             | Compares the Refractive Error of the right/left eye , Axial Length, and the Cornea Curvature.                             |
| 9  | Data              | Manages The Subject's Data.                                                                                               |
| 10 | Average Graph     | Shows all the data of the refractive Error and the Axial Length in a single graph.                                        |
| 11 | Graph Move(Left)  | (When Average Graph is disabled) Moves the graph of refraction Error and Axial Length that is older than the current one. |
| 12 | Graph Move(Right) | (When Average Graph is disabled) Moves the graph of refraction Error and Axial Length that is older than the further one. |

## 2. RX (Refractive Error) Screen



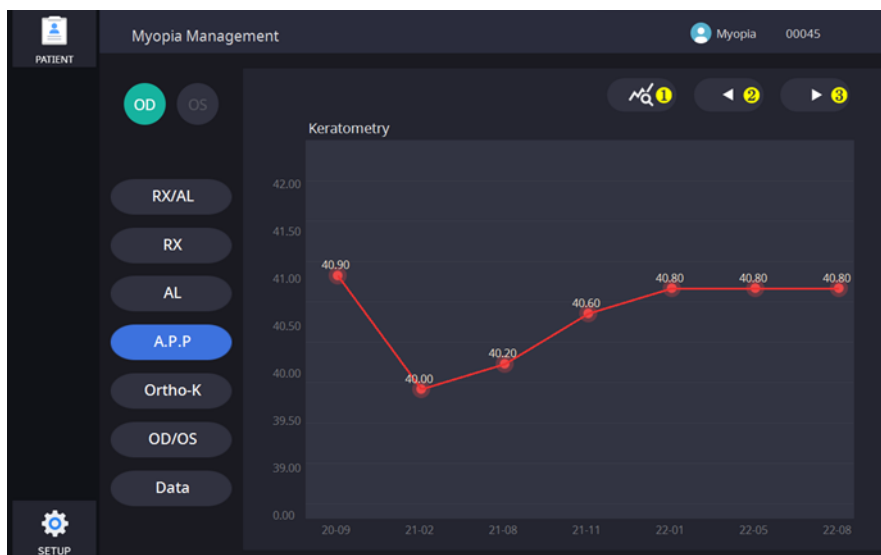
| No | Name              | Function                                                                                                 |
|----|-------------------|----------------------------------------------------------------------------------------------------------|
| 1  | Average Graph     | Shows all the data of the Refractive Error in a single graph.                                            |
| 2  | Graph Move(Left)  | (When Average Graph is disabled) Moves the graph of Refractive Error that is older than the current one. |
| 3  | Graph Move(Right) | (When Average Graph is disabled) Moves the graph of Refractive Error that is older than the further one. |

## 3. AL (Axial Length) Screen



| No | Name              | Function                                                                                             |
|----|-------------------|------------------------------------------------------------------------------------------------------|
| 1  | Average Graph     | Shows all the data of the Refractive Error in a single graph.                                        |
| 2  | Graph Move(Left)  | (When Average Graph is disabled) Moves the graph of Axial Length that is older than the current one. |
| 3  | Graph Move(Right) | (When Average Graph is disabled) Moves the graph of Axial Length that is older than the further one. |

## 4. A.P.P(Average Pupillary Power) Screen



| No | Name              | Function                                                                                                  |
|----|-------------------|-----------------------------------------------------------------------------------------------------------|
| 1  | Average Graph     | Shows all the data of the Corneal Curvature in a single graph.                                            |
| 2  | Graph Move(Left)  | (When Average Graph is disabled) Moves the graph of Corneal Curvature that is older than the current one. |
| 3  | Graph Move(Right) | (When Average Graph is disabled) Moves the graph of Corneal Curvature that is older than the further one. |

#### 5. Ortho-K(Orthokeratology) Screen



| No | Name            | Function                                                                                                                                       |
|----|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Before Map      | Select the date you want to be the reference for the subject to display the corneal curvature map.                                             |
| 2  | After Map       | Select the date you want to compare the subjects to show the corneal curvature map.                                                            |
| 3  | Before Meridian | Shows the 2mm/4mm/6mm (3mm/5mm/7mm option) average corneal curvature that you want to be the reference for the subject.                        |
| 4  | After Meridian  | Shows the 2mm/4mm/6mm (3mm/5mm/7mm option) average corneal curvature that you want to be the compared for the subject.                         |
| 5  | Diff Map        | Map the difference between reference corneal curvature and comparative corneal curvature. Click the '+' button in the bottom right to zoom in. |

|   |          |                                                                     |
|---|----------|---------------------------------------------------------------------|
| 6 | Scale    | Select Scale for the corneal curvature map. (Absolute / Normalized) |
| 7 | Map Type | Select the type of corneal curvature map. (Axial / Tangential)      |

## 6. OD/OS ( Comparison OU)



| 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                   | Displays data from the subject's Right eye.<br>(Refractive Error, Corneal Curvature, and Axial Length from the left)    |
| 4  | OS Data                   | Displays data from the subject's Left eye.<br>(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

Myopia Management

Myopia 00045

OD OS

RX/AL

RX

AL

A.P.P

Ortho-K

OD/OS

Data

Setup

Edit Del ADD

|                                  | DATE           | RX SE (D) | AL (mm) | ACD (mm) | LT (mm) | A.P.P (D) |
|----------------------------------|----------------|-----------|---------|----------|---------|-----------|
| <input type="radio"/>            | 31 - 03 - 2023 | -3.00     | 25.67   | 3.30     | 3.79    | 41.39     |
| <input checked="" type="radio"/> | 29 - 01 - 2023 | -3.00     | 25.50   | 3.30     | 3.50    | 41.20     |
| <input type="radio"/>            | 20 - 08 - 2022 | -2.50     | 25.30   | 3.30     | 3.30    | 40.80     |
| <input checked="" type="radio"/> | 25 - 05 - 2022 | -2.50     | 25.20   | 3.30     | 3.50    | 40.80     |
| <input type="radio"/>            | 05 - 01 - 2022 | -2.30     | 24.90   | 3.50     | 3.00    | 40.80     |
| <input type="radio"/>            | 20 - 11 - 2021 | -2.25     | 24.80   | 3.30     | 3.00    | 40.60     |
| <input checked="" type="radio"/> | 30 - 08 - 2021 | -2.00     | 24.00   | 3.00     | 3.30    | 40.20     |
| <input type="radio"/>            | 02 - 02 - 2021 | -1.80     | 23.80   | 2.20     | 3.50    | 40.00     |

1 2 3 4 5 6

1 / 2

| No | Name                    | Function                                                            |
|----|-------------------------|---------------------------------------------------------------------|
| 1  | Select all data         | Select/unselect all data.                                           |
| 2  | Edit Data               | Move to the screen where you want to modify the last selected data. |
| 3  | Delete Data             | Deletes the selected data.                                          |
| 4  | Add Data                | Move to the Add Data screen.                                        |
| 5  | Move Data Table (Left)  | Move the data table to the left.                                    |
| 6  | Move Data Table (Right) | Move the data table to the Right.                                   |

## 7.1. Data Edit / Data Add Screen

Edit Exam

Date

YY 2023 MM 03 DD 31

Refractive Error

OD -3 OS Load SET

Biometry

AL 25.67 ACD 3.3

LT 3.79 APP 41.39

Cancel OK

| No | Name                       | Function                                                           |
|----|----------------------------|--------------------------------------------------------------------|
| 1  | Measure Date               | Enter the date on which you want to generate data.                 |
| 2  | Refractive Error           | 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 Refractometry                            |
| 5  | Connection Setting         | Set up communication to communicate with the Huvitz Refractometry. |
| 6  | Cancel                     | Move to (7.) Data screen without saving data.                      |
| 7  | Save                       | Save the data and move to the (7.) Data screen.                    |

## 7.2. Refractometry Connection Setting Screen

**HuvitzRK Connect Setting**

Port **1**

COM7

Bps **2**

115200

Cancel **3**      OK **4**

| No | Name                  | Function                                                                              |
|----|-----------------------|---------------------------------------------------------------------------------------|
| 1  | Setup Connection Port | Set up the communication port that is connected to the Refractometry by USB to RS232. |
| 2  | Setup Connection Bps  | Set up the communication bps that is connected to the Refractometry and USB to RS232. |
| 3  | Cancel                | Move to (7.1.) screen without saving settings.                                        |
| 4  | Save                  | Save the settings and Move to the 7.1. screen.                                        |

## ■ Contact Lens Fitting Simulation Screen

### 1. Contact Lens Fitting Main Screen



| No | Name                                     | Function                                                                                               |
|----|------------------------------------------|--------------------------------------------------------------------------------------------------------|
| 1  | Return to Results Screen                 | Exit the contact lens fitting simulation and return to the Measurement Results screen.                 |
| 2  | Move Lens Fitting Data List (Previous)   | Moves from the list of stored lens fitting data to the previous list.                                  |
| 3  | Select lens fitting data list            | Gets the stored lens fitting data.                                                                     |
| 4  | Delete lens fitting data                 | Deletes the selected lens fitting data from the list.                                                  |
| 5  | Move Lens Fitting Data List (Next)       | Moves from the list of stored lens fitting data to the next list.                                      |
| 6  | Select OD/OS                             | Select the eyes to simulate the lens fitting.                                                          |
| 7  | Lens Fitting Map / corneal curvature map | Shows the fitting map or corneal curvature map of the selected lens of the subject.                    |
| 8  | Select corneal curvature map             | You can select a corneal curvature map. (Axial / Tangential Map support)                               |
| 9  | Select Lens Fitting Map                  | If Completed Selecting Lens, Displays the lens fitting map                                             |
| 10 | kf /ks Lens fitting graph                | Shows the distance between the cornea and the lens for the long axis/shortening for the selected lens. |
| 11 | Select lens manufacturer                 | Select the manufacturer of the lens.                                                                   |
| 12 | Select a lens                            | If you selected a manufacturer, select a list of lenses for the manufacturer.                          |
| 13 | Modifying lens parameter                 | Modify the parameter for the selected lens.                                                            |
| 14 | Information Corneal Curvature            | Shows corneal curvature information for the subject.                                                   |
| 15 | Save                                     | If there are selected lenses, they can be saved in the list window at (3).                             |

## 1.1. Lens Parameter Modification Screen

Lens Parameters

**Base Curve**

**Curvature Radius(r0) ①**  
 8.25

**Diameter(mm) ②**  
 9.8

**Curvature Diff(dr0) ③**  
 0

**Eccentricity ④**  
 0.9

---

**Peripheral Curve 1 ⑤**

**Curvature Radius(r1)**  
 0

**Width(mm)**  
 0

**Curvature Diff(dr1)**  
 0

**Eccentricity**  
 0

---

**Peripheral Curve 2 ⑥**

**Curvature Radius(r2)**  
 0

**Width(mm)**  
 0

**Curvature Diff(dr2)**  
 0

**Eccentricity**  
 0

---

**Peripheral Curve 3 ⑦**

**Curvature Radius(r3)**  
 0

**Width(mm)**  
 0

**Curvature Diff(dr3)**  
 0

**Eccentricity**  
 0

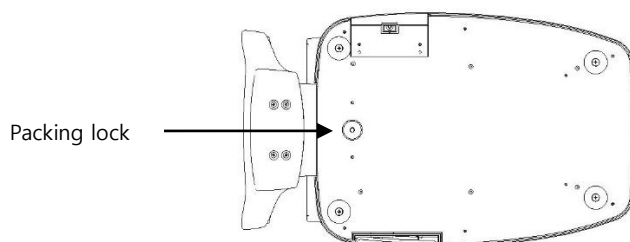
| No | Name                             | Function                                                                                                                                                                     |
|----|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Set lens curvature               | Sets the curvature of the lens.                                                                                                                                              |
| 2  | Lens diameter Settings           | Sets the diameter of the lens.<br>Base Curve Diameter (mm): This means the full diameter<br>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

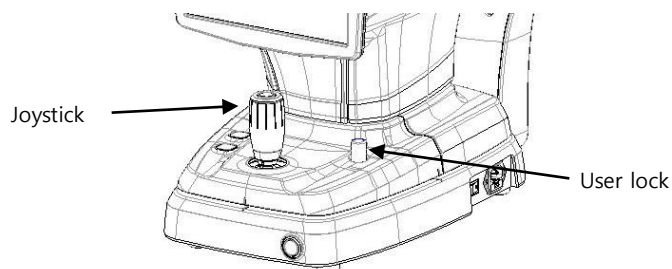
## Installation Procedure

### 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)

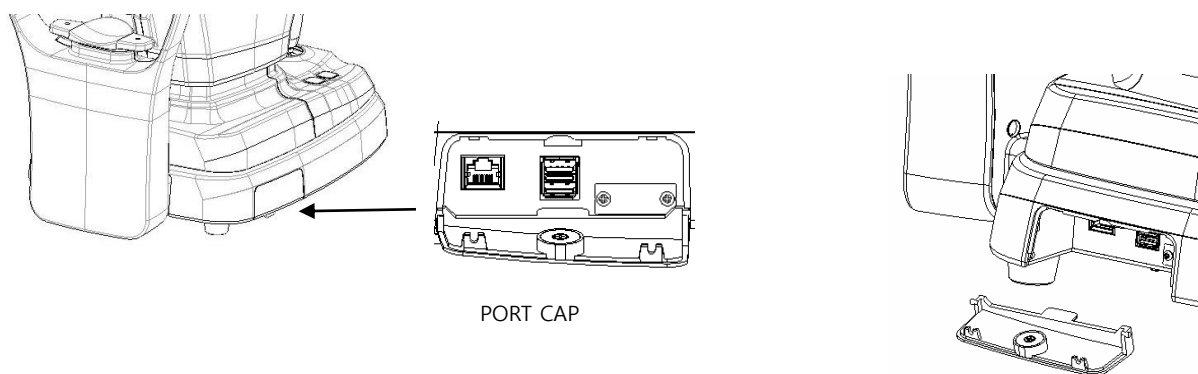
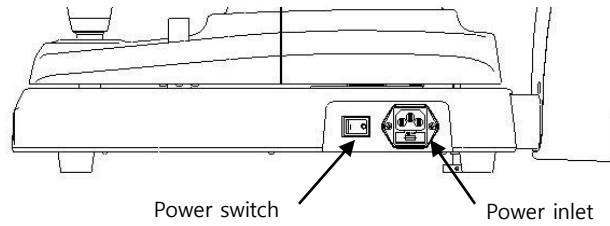
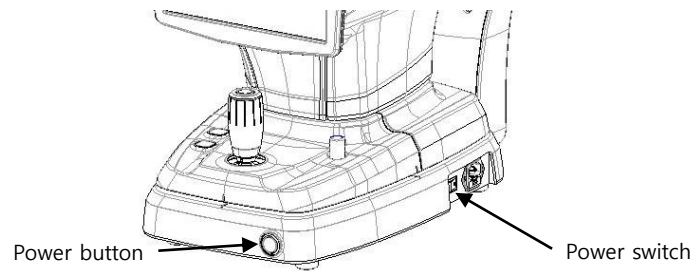


Figure "A"

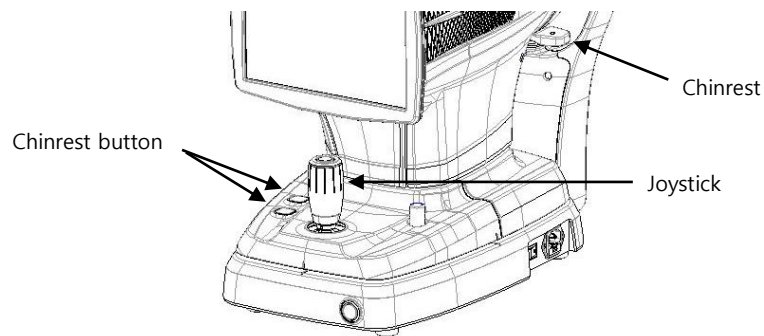
6. Check the power switch on the bottom right of base is off. (O position).
7. Connect power cable to power inlet. Also, connect the other side of power cable to electric outlet.



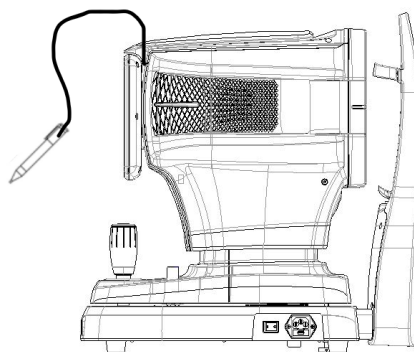
8. If external devices are connected, turn on external devices first.
9. Turn on the main body by pressing power switch (I position)
10. Turn on the internal PC by pressing power button.



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.



13. It is convenient to connect the touch pen to the hook on the back of the LCD with a string.

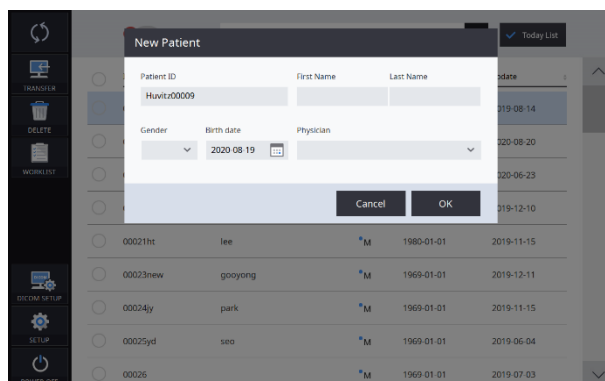


# 6

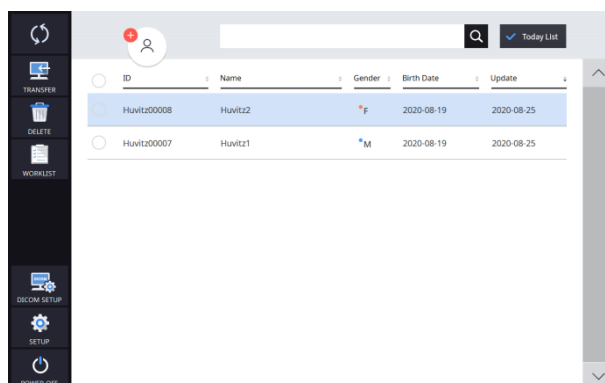
## Operation

### 6.1. Software

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

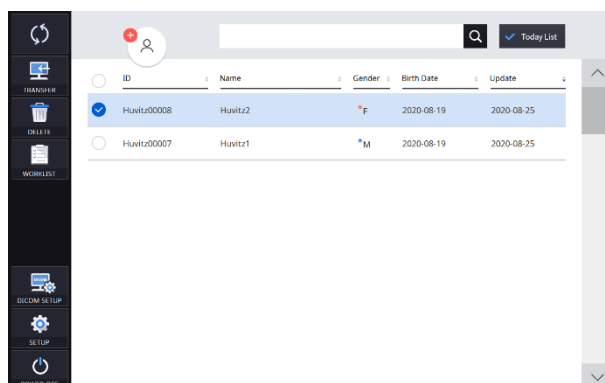


2. Select patient and check patient information is correct.



| ID                                           | Name    | Gender | Birth Date | Update     |
|----------------------------------------------|---------|--------|------------|------------|
| <input checked="" type="radio"/> Huvitz00008 | Huvitz2 | F      | 2020-08-19 | 2020-08-25 |
| <input type="radio"/> Huvitz00007            | Huvitz1 | M      | 2020-08-19 | 2020-08-25 |

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



| ID                                           | Name    | Gender | Birth Date | Update     |
|----------------------------------------------|---------|--------|------------|------------|
| <input checked="" type="radio"/> Huvitz00008 | Huvitz2 | F      | 2020-08-19 | 2020-08-25 |
| <input type="radio"/> Huvitz00007            | Huvitz1 | M      | 2020-08-19 | 2020-08-25 |

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



PATIENT LIST



RESULT



MEASURE



RISK



REPORT



PRINT



DELETE



Patient ID \_\_\_\_\_  
Huvitz00008

\_\_\_\_\_

Name  
Huvitz 2

\_\_\_\_\_

Gender  
F

\_\_\_\_\_

Birth Date  
2020-08-19

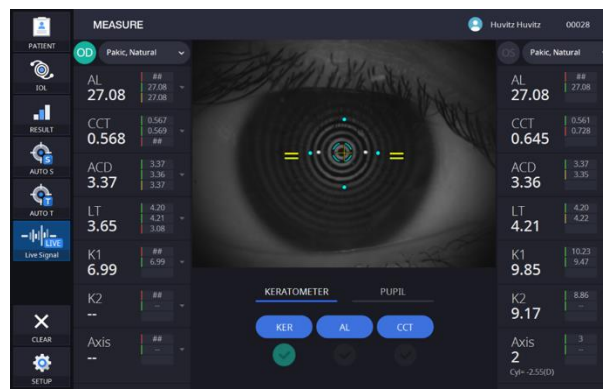
\_\_\_\_\_

Physician  
\_\_\_\_\_

| DATE / TIME            | AL                                                                                | CCT   | ACD   | LT   | K1   | K2   | Axis | Lens | Vitreous Body |         |
|------------------------|-----------------------------------------------------------------------------------|-------|-------|------|------|------|------|------|---------------|---------|
| 2020-08-18<br>21:15:25 |  | 23.03 | 0.558 | 3.14 | 3.50 | 7.67 | 7.64 | 0    | Phakic        | Natural |
|                        |  | 23.13 | 0.538 | 3.13 | 3.14 | 7.67 | 7.64 | 0    | Phakic        | Natural |
| 2020-08-14<br>15:01:12 |  | 23.40 | 0.555 | 3.45 | 3.21 | 7.11 | 7.40 | 30   | Phakic        | Natural |
|                        |  | 22.40 | 0.532 | 3.45 | 3.22 | 7.84 | 7.67 | 20   | Phakic        | Natural |

5. Enter observation mode by pressing measure icon (MEASURE).

The screen of observation mode is as follow.



## 6.2. SETUP Mode

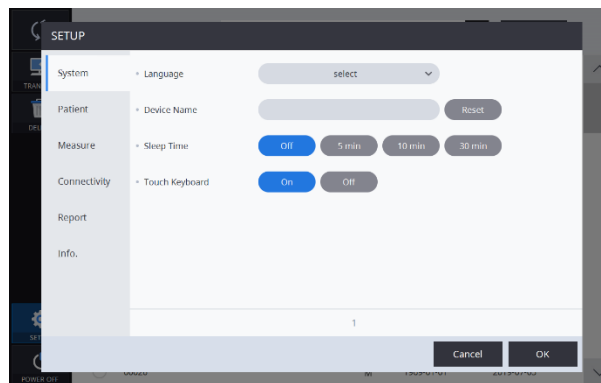
[To choose the section to setup]

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

[To change settings]

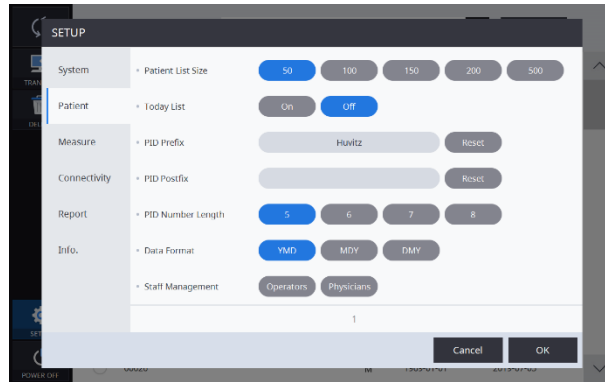
- Select the item to change.
- To press OK button will save all the changes made and exit the setup screen.
- To press CANCEL button will discard the changes and exit the setup screen.

### 1) System Settings



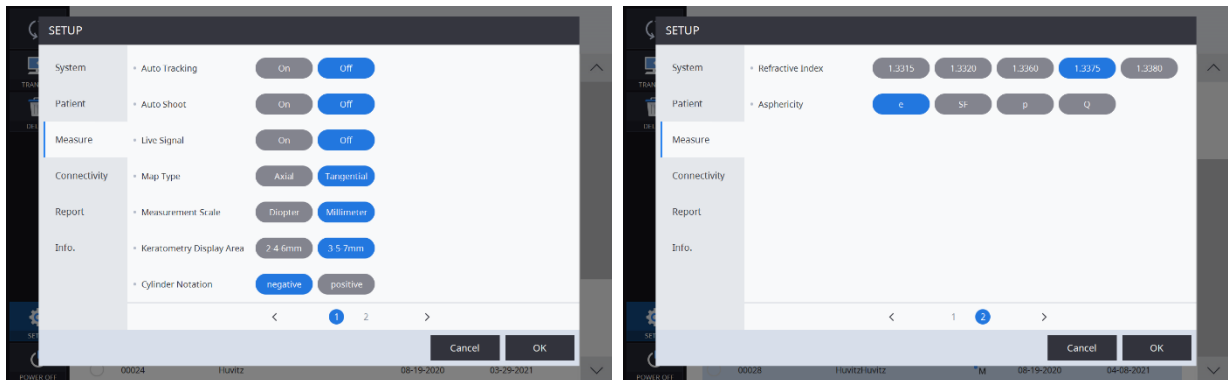
|                |                                |
|----------------|--------------------------------|
| Language       | Select language                |
| Device Name    | Set Device Name.               |
| Sleep Time     | Sleep mode time setting.       |
| Touch Keyboard | Touch Keyboard ON/OFF setting. |

## 2) Patient Settings



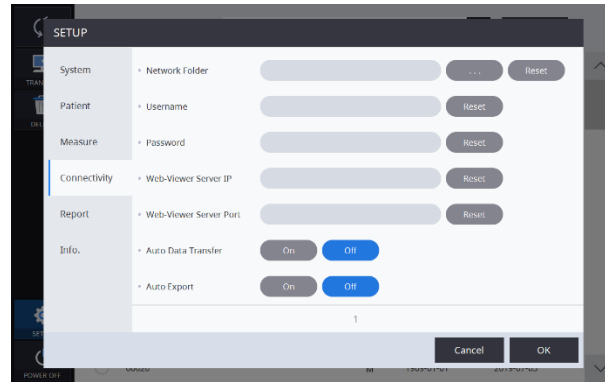
|                   |                                                       |
|-------------------|-------------------------------------------------------|
| Patient List Size | Number of patients to be displayed per pages.         |
| Today List        | Today List (List of patients visited today) settings. |
| PID Prefix        | The function to set the prefix of the patient ID.     |
| PID Postfix       | The function to set the postfix of the patient ID.    |
| PID Number Length | The function to set the length of patient ID.         |
| Date Format       | Format of the date (Year, Month, Day).                |
| Staff Management  | Register staffs                                       |

## 3) Measure Settings.



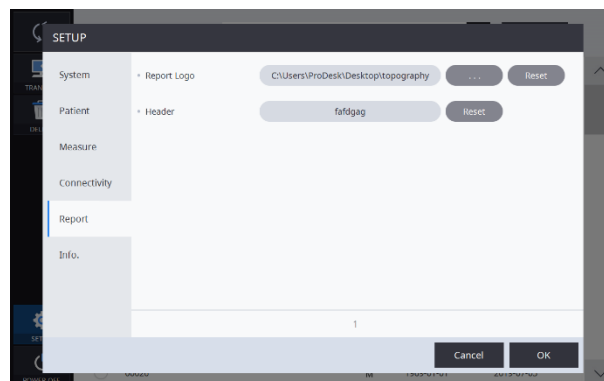
|                          |                                                             |
|--------------------------|-------------------------------------------------------------|
| Auto Tracking            | Auto Tracking ON/OFF setting.                               |
| Auto Shoot               | 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<br>(Diopter / Millimeters) |
| Keratometry Display Area | 3-5-7 mm / 2-4-6 mm                                         |
| Cylinder Notation        | Positive / Negative                                         |
| Refractive index         | 1.3315 / 1.3320 / 1.3360 / 1.3375 / 1.3380                  |
| Asphericity              | e / SF / p / Q                                              |

## 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                                                         |

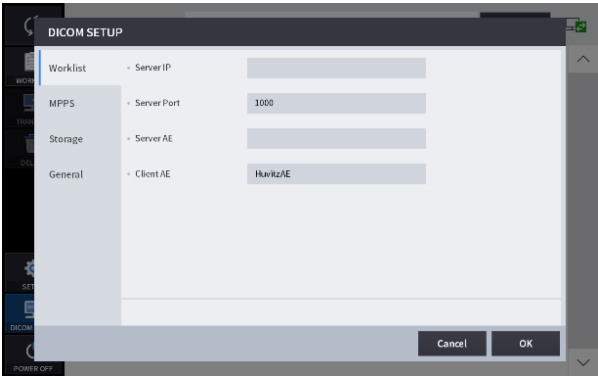
## 5) Report Settings



|             |                               |
|-------------|-------------------------------|
| Report Logo | Set the report logo image.    |
| Header      | Assign the organization name. |

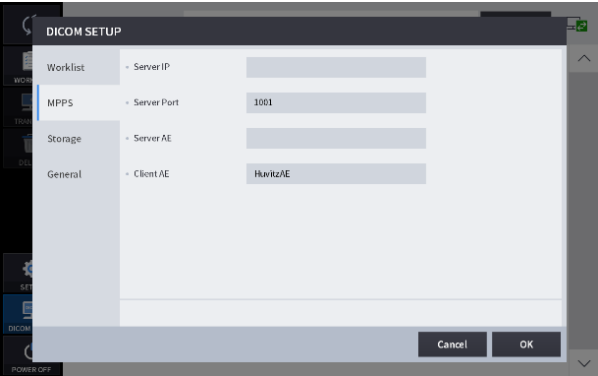
**6.3. DICOM SETUP Mode**

1. Worklist Setting



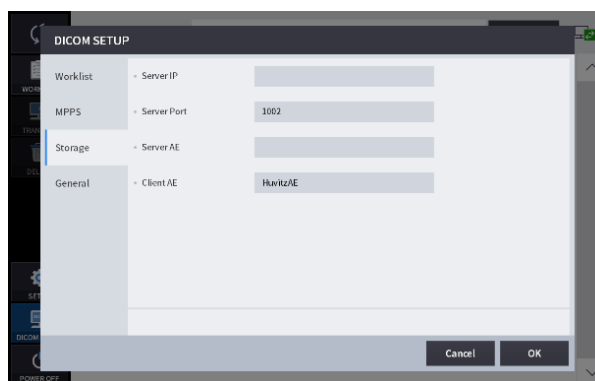
|                    |                                                             |
|--------------------|-------------------------------------------------------------|
| <b>Server IP</b>   | IP Address of the PC where the server program is installed. |
| <b>Server Port</b> | Set Port Number.                                            |
| <b>Server AE</b>   | Set Server AE.                                              |
| <b>Client AE</b>   | Set Client AE.                                              |

2. MPPS Setting



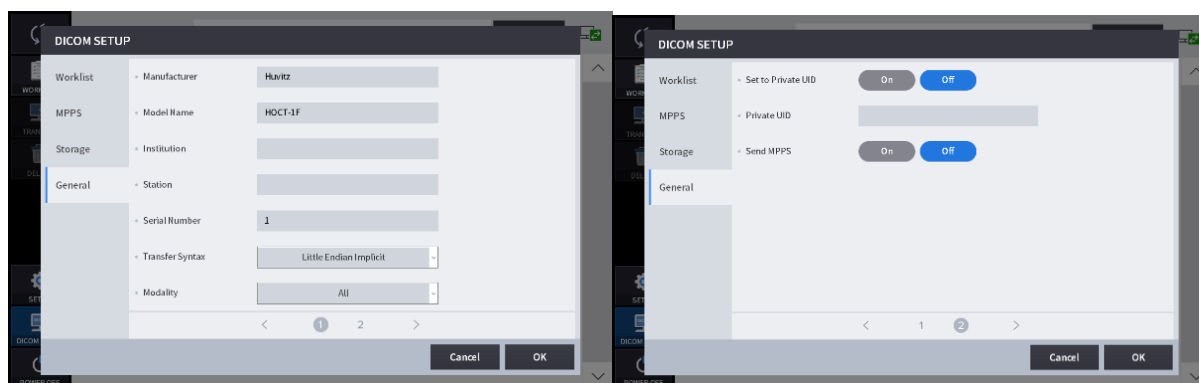
|                    |                                                             |
|--------------------|-------------------------------------------------------------|
| <b>Server IP</b>   | IP Address of the PC where the server program is installed. |
| <b>Server Port</b> | Set Port Number.                                            |
| <b>Server AE</b>   | Set Server AE.                                              |
| <b>Client AE</b>   | Set Client AE.                                              |

## 3. Storage Setting



|                    |                                                             |
|--------------------|-------------------------------------------------------------|
| <b>Server IP</b>   | IP Address of the PC where the server program is installed. |
| <b>Server Port</b> | Set Port Number.                                            |
| <b>Server AE</b>   | Set Server AE.                                              |
| <b>Client AE</b>   | Set Client AE.                                              |

## 4. General Setting

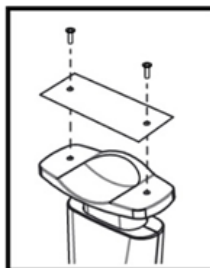


|                           |                                   |
|---------------------------|-----------------------------------|
| <b>Manufacturer</b>       | Set the name of the manufacturer. |
| <b>Model Name</b>         | Set the Model Name.               |
| <b>Institution</b>        | Set the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

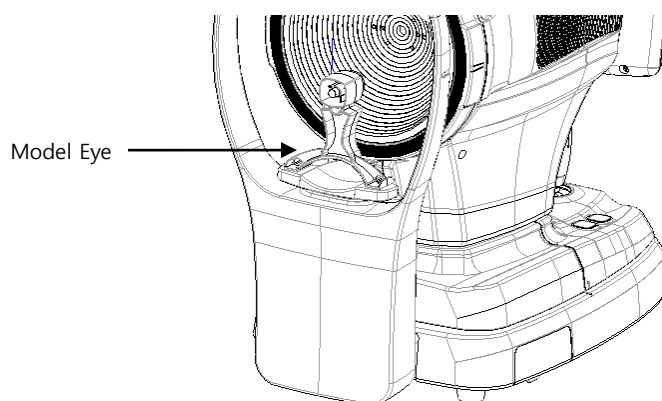
## 6.4. Device Check

### 1. Measuring Model Eye.

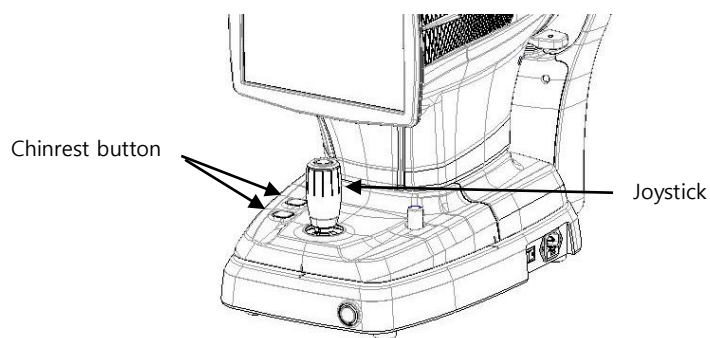
- (1) Remove chinrest paper.



- (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.

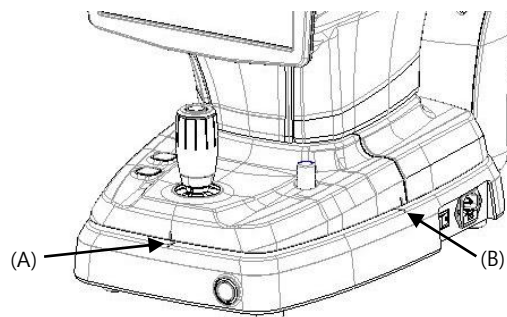


- (4) After focusing, press the Joystick button.

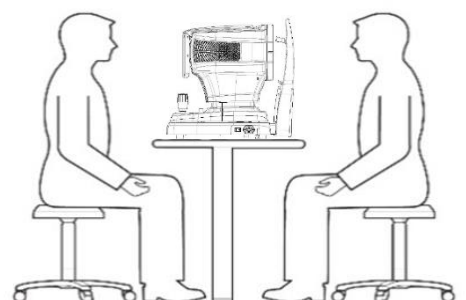
## 6.5. General Operation

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.

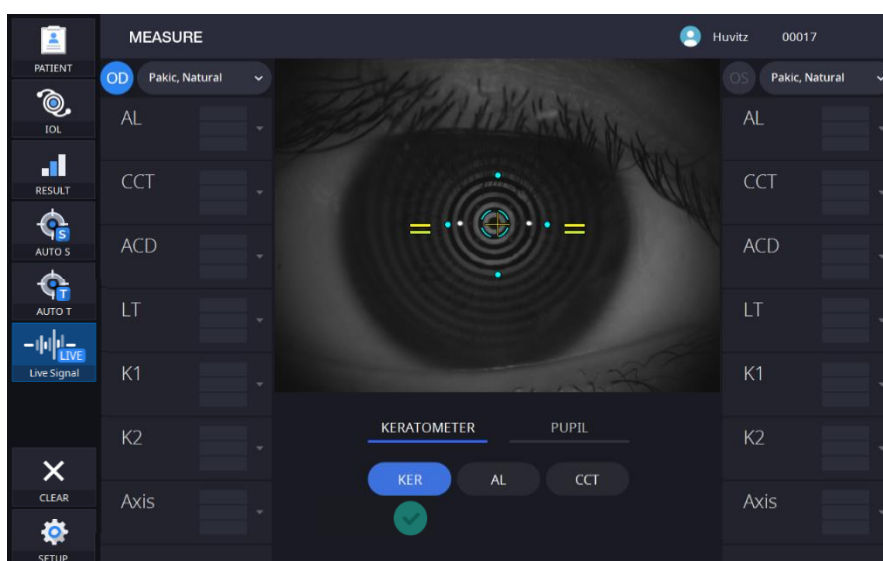


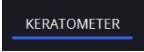
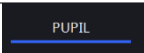
3. Let the patient sit in front of instrument.



4. Set the measurement mode.

Set Keratometer measurement or Pupil measurement.



|                                                                                   |                                                        |
|-----------------------------------------------------------------------------------|--------------------------------------------------------|
|  | Keratometer mode is on.                                |
|  | Keratometry measurement is on.                         |
|  | Axial Length measurement is on.                        |
|  | CCT, ACD, LT measurement (Anterior measurement) is on. |
|  | Pupillometry mode is on.                               |

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

##### (2) Set auto tracking.

|                                                                                     |                       |
|-------------------------------------------------------------------------------------|-----------------------|
|  | Auto tracking is on.  |
|  | Auto tracking is off. |

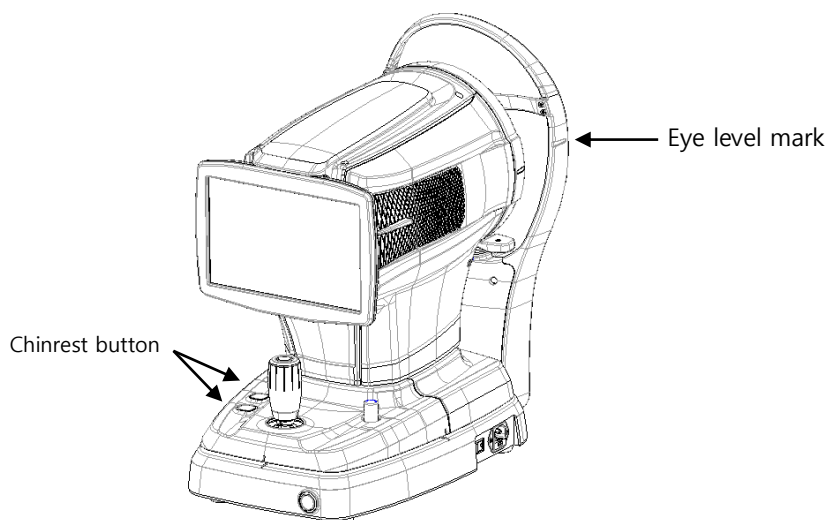
- If auto tracking is on, patient's eye is automatically tracked to center and focused when patient's eye is inside tracking region.
- Auto tracking is not supported for anterior capture mode.

##### (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.

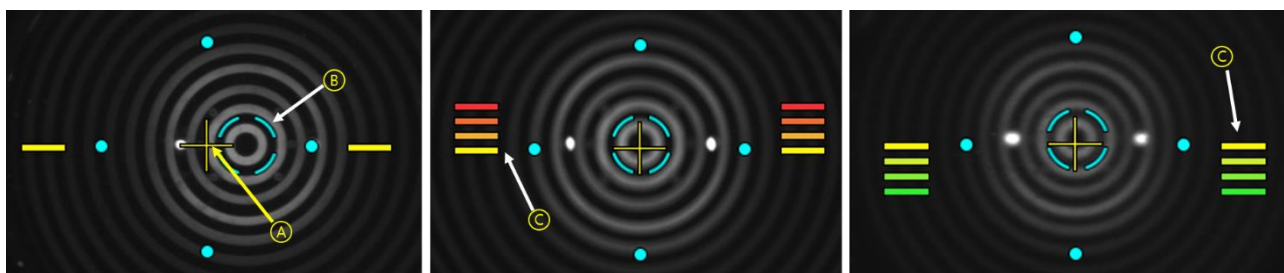


7. Instruct patient to watch internal fixation LED to fix patient eyes. Also, instruct patient to open eye widely, not to blink.

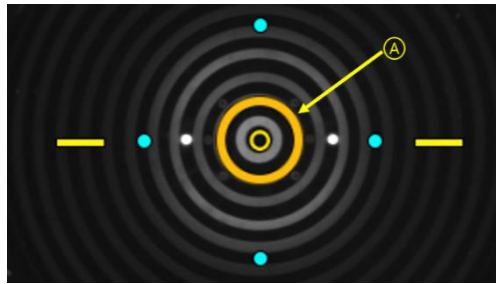
8. Move body with joystick until patient's eye appears on the screen.

9. Set the alignment and focus.

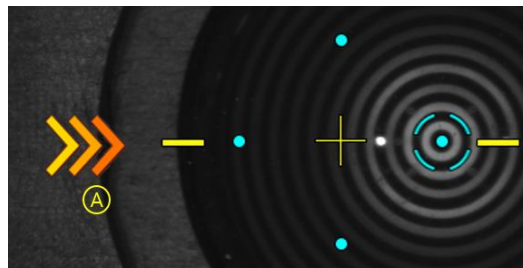
- (1) Move the body up/down and left/right with joystick until center of placido-ring (A) and center of cross (B) are concentric. When two center dot are concentric, check the focus indicator bar (C). Move the body back and forth with joystick until it remain only yellow indicator bar.



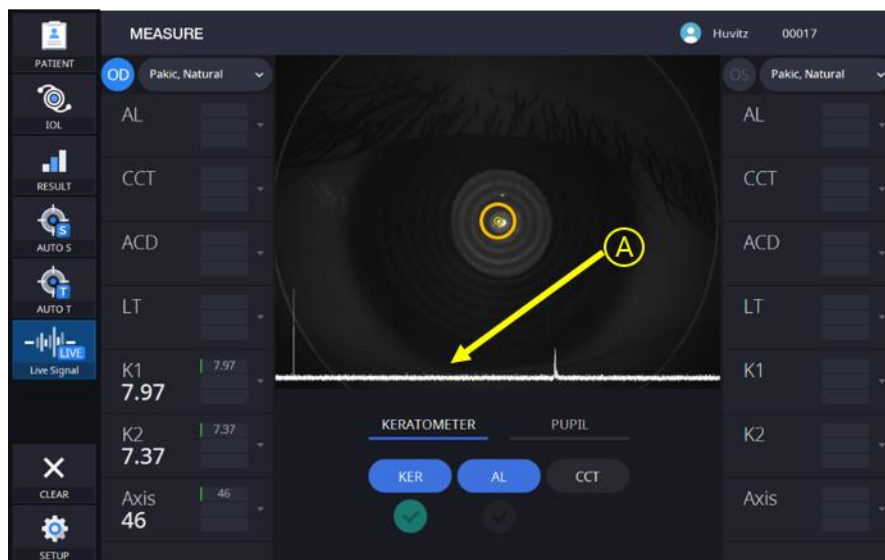
- (2) Move joystick little by little until orange target mark (A) appears.



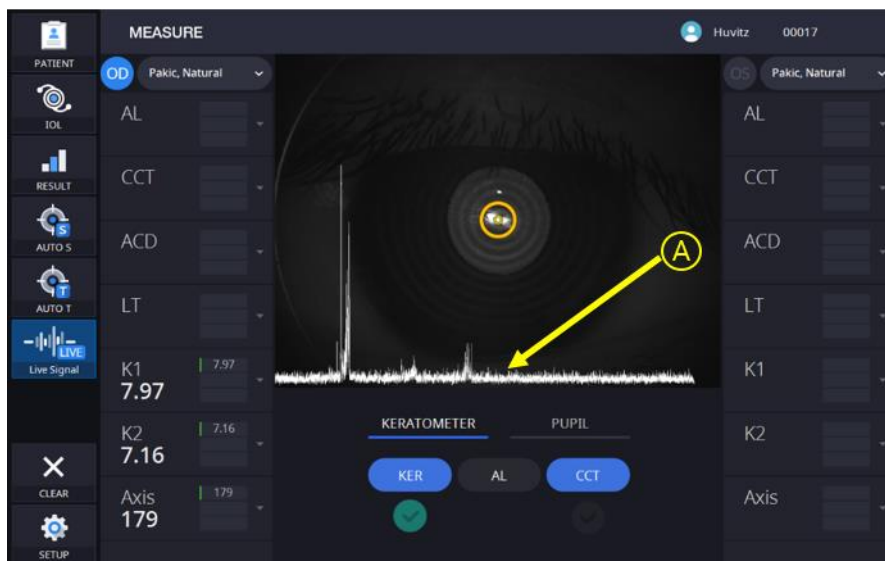
- (3) If auto tracking is on, alignment and focus is automatically accomplished in tracking region.
- (4) If orange arrow (A) appears during auto tracking, it means auto tracking module go to the limit of tracking region. In that case, move body to the arrow direction with joystick.



- (5) If the Axial Length measurement is on, check the real-time signal to see if the axial length signal (A) comes out well and capture.

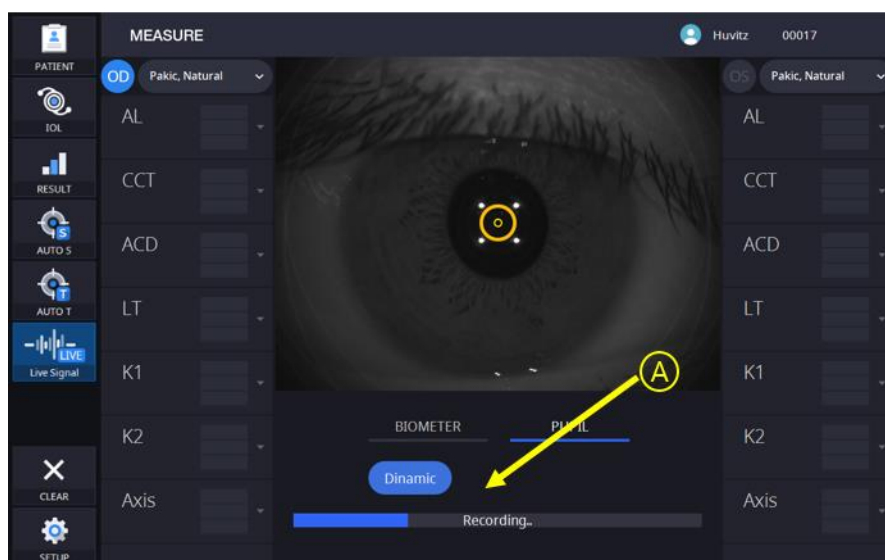


- (6) If CCT, ACD, LT measurement (Anterior measurement) is on, check the real-time signal to see if the anterior signal (A) comes out well and capture.



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

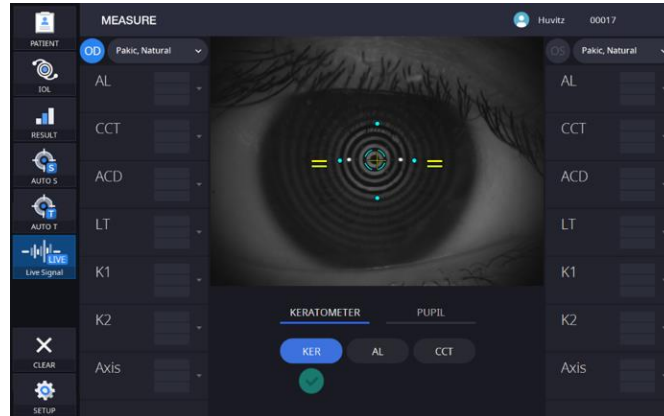
Errors in measurements can occur under one of these conditions: bad focus, closed eyelid, tear film irregularity, high standard deviation in multiple measurements, movement, measurement not in range.

## 6.6. Maintenance

### 6.6.1. After operation

- Exit software and Power off.

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



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

| Patient ID  | Name     | Gender | Birth Date | Physician |
|-------------|----------|--------|------------|-----------|
| Huvitz00008 | Huvitz 2 | F      | 2020-08-19 |           |

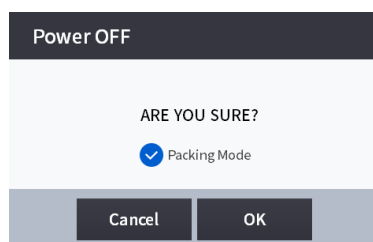
  

| DATE / TIME         | AL    | CCT   | ACD  | LT   | K1   | K2   | Axis | Lens   | Vitreous Body |
|---------------------|-------|-------|------|------|------|------|------|--------|---------------|
| 2020-08-18 21:15:25 | 23.03 | 0.558 | 3.14 | 3.50 | 7.67 | 7.64 | 0    | Phakic | Natural       |
| 2020-08-14 15:01:12 | 23.40 | 0.555 | 3.45 | 3.21 | 7.11 | 7.40 | 30   | Phakic | Natural       |

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

| ID          | Name    | Gender | Birth Date | Update     |
|-------------|---------|--------|------------|------------|
| Huvitz00008 | Huvitz2 | F      | 2020-08-19 | 2020-08-25 |
| Huvitz00007 | Huvitz1 | M      | 2020-08-19 | 2020-08-25 |

- (4) 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.

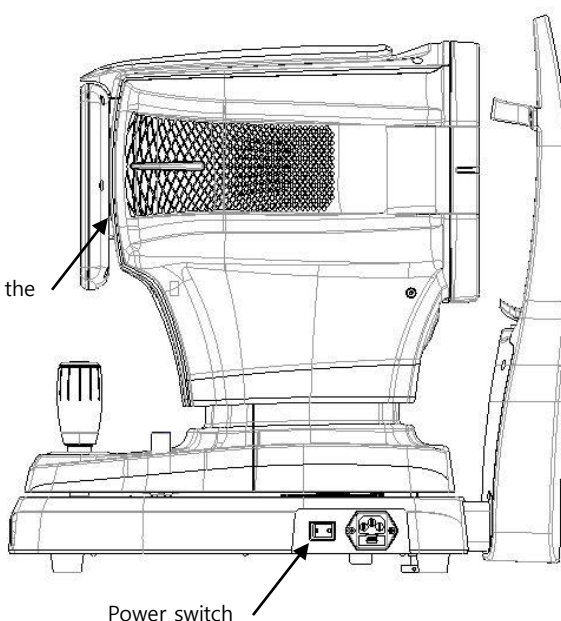
### NOTE

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.

The back of the LCD and the front of the equipment are in contact



### 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.*

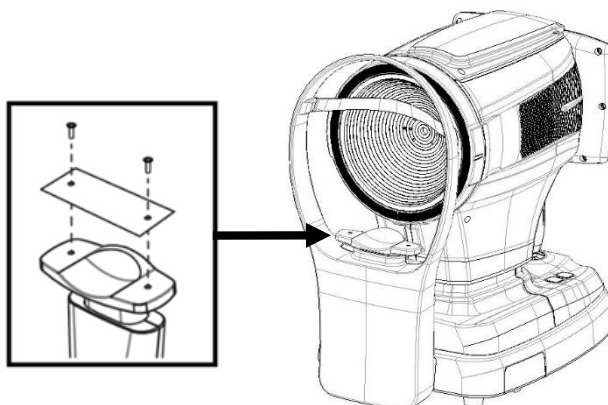
*N'utilisez pas d'éponge ou de chiffon imbibé d'eau car l'eau pourrait s'infiltrer dans l'équipement.*

*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.



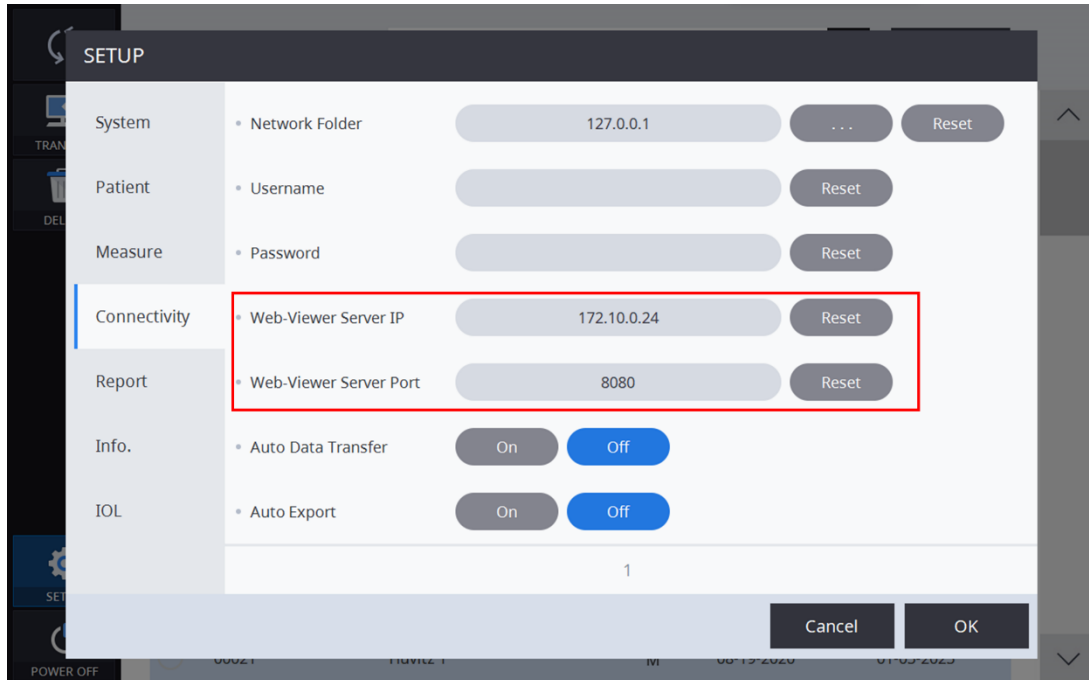
#### 2. Replacing fuse

- (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.

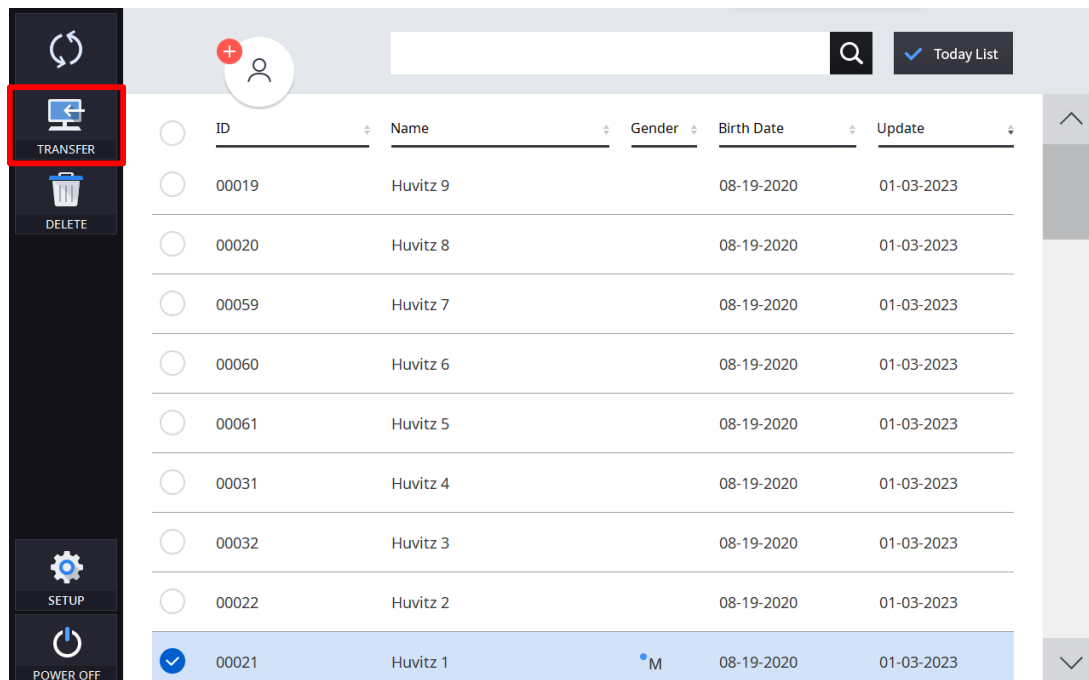
## 6.7. Send Data to Web-Viewer

1. Fill in Server IP and Server Port information.

(Server IP, it means local IP address, where HIS S/W program is installed. And Server Port is fixed with 8080.)



2. Select patients in the Patients List. And Clicking 'TRANSFER' button, send all of the patient data.



3. Select data in Data List. And Clicking 'TRANSFER' button, send the data.

PATIENT LIST

MEASURE

IOL

RESULT

DELETE

TRANSFER

SETUP

Pencil icon

Patient ID

00021

Name

Huvitz 1

Gender

M

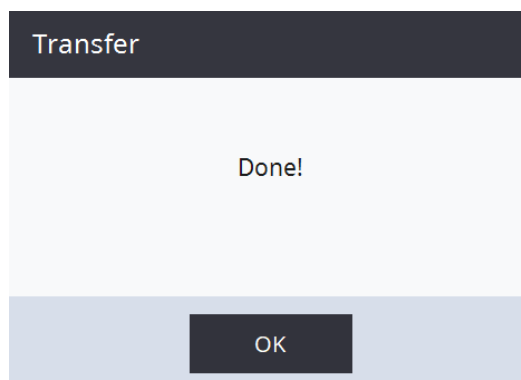
Birth Date

08-19-2020

Physician

|   | DATE / TIME            |    | AL    | CCT   | ACD  | LT   | K1    | K2    | Axis | Lens   | Vitreous Body |
|---|------------------------|----|-------|-------|------|------|-------|-------|------|--------|---------------|
| ✓ | 12-09-2022<br>13:54:16 | OD | 26.02 | 0.565 | 2.99 | 3.93 | 42.97 | 44.29 | 172  | Phakic | Natural       |
|   |                        | OS | 25.29 | 0.570 | 3.01 | 3.87 | 43.23 | 44.41 | 4    | Phakic | Natural       |
| ✓ | 11-23-2022<br>13:41:45 | OD |       | 0.514 | 2.97 | 3.96 |       |       |      | Phakic | Natural       |
|   |                        | OS |       | 0.512 | 2.97 | 3.94 |       |       |      | Phakic | Natural       |
| ○ | 11-23-2022<br>09:23:05 | OD | 26.00 | 0.519 | 3.02 | 3.91 | 43.44 | 44.96 | 174  | Phakic | Natural       |
|   |                        | OS | 25.28 | 0.517 | 2.96 | 3.92 | 43.16 | 44.21 | 179  | Phakic | Natural       |
| ✓ | 11-08-2022<br>09:03:00 | OD | 26.01 | 0.527 | 3.06 | 3.89 | 43.91 | 45.46 | 173  | Phakic | Natural       |
|   |                        | OS | 25.31 | 0.522 | 2.99 | 3.92 | 43.61 | 44.80 | 1    | Phakic | Natural       |
| ○ | 11-03-2022<br>14:52:35 | OD |       |       |      |      | 43.61 | 44.96 | 173  | Phakic | Natural       |
|   |                        | OS |       |       |      |      | 43.53 | 44.44 | 179  | Phakic | Natural       |

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.

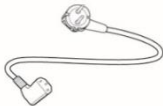
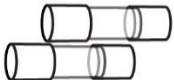
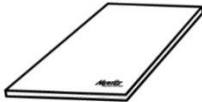
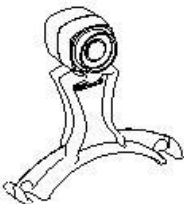
Contact a sales distributor after turning off the power when the device does not resume normal operation even after taking the following measures.

| 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

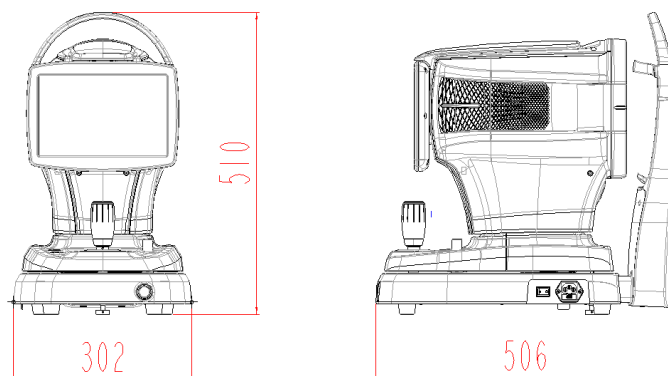
### 8.1. Standard Accessories

|                                                                                                          |                                                                                                 |                                                                                                    |
|----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <br>Chinrest paper      | <br>Touch pen  | <br>Power cable |
| <br>Fuse (250V T 3.15A) | <br>Dust cover | <br>User manual |
| <br>Model Eye          |                                                                                                 |                                                                                                    |

## 8.2. Specifications

| Biometry                         |                                                                                                                 |                     |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------|---------------------|
| Parameter                        | Measuring range                                                                                                 | SD of Repeatability |
| Axial length                     | 14 – 40mm                                                                                                       | ±0.025 mm           |
| 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)<br>0.5-3.5mm(pseudo-phakic)                                                                   | ±0.06 mm            |
| White-to-white distance          | 7 – 14mm                                                                                                        | ±0.05 mm            |
| Pupil diameter                   | 0.5 – 10mm                                                                                                      | ±0.05 mm            |
| Keratometry                      |                                                                                                                 |                     |
| Parameter                        | Measuring range                                                                                                 | SD of Repeatability |
| Corneal curvature radius         | 5 – 13mm                                                                                                        | ±0.03 mm            |
| Cornea refractive power          | 25.96D~67.50D<br>(Cornea equivalence's refractive power: 1.3375)                                                | -                   |
| Direction of principal meridians | Measuring range: 1° – 180°<br>Accuracy: according to the ISO 10343:2014<br>R1-R2≤0.3mm: ±4°<br>R1-R2>0.3mm: ±2° | -                   |
| Corneal Topography               |                                                                                                                 |                     |
| Working distance                 | 80mm                                                                                                            |                     |
| Placido disc                     | 24 rings                                                                                                        |                     |
| Points Analyzed                  | Over 100,000                                                                                                    |                     |
| Measuring accuracy               | Type A according to the ISO 19980:2012                                                                          |                     |
| Common                           |                                                                                                                 |                     |
| Display                          | Tiltable 10.1 inch, Touch panel color LCD                                                                       |                     |
| Horizontal movement              | 45 mm (back and forth), 100 mm (left and right)                                                                 |                     |
| Vertical movement                | 30 mm                                                                                                           |                     |
| Chinrest movement                | 62 mm (up and down), motorized                                                                                  |                     |
| Auto tracking                    | X,Y for positioning, Z for working distance                                                                     |                     |
| Power supply                     | AC 100 - 240 V, 50/60 Hz, 1.6 - 0.7 A                                                                           |                     |
| PC                               | Built in computer                                                                                               |                     |
| Dimensions                       | 302(W) x 506(D) x 510(H) mm                                                                                     |                     |
| Mass                             | 22 kg                                                                                                           |                     |

## 8.3. Drawings of System



## 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)<br>IEC 61000 – 4 – 2                                                                       | contact $\pm 8$ kV<br>in the air $\pm 15$ kV                                                                                                                                                       | contact $\pm 8$ kV<br>in the air $\pm 15$ kV                                                                                                                                                       |
| Electric rapid transients/burst<br>IEC 61000 – 4 – 4                                                                    | power supplying line $\pm 2$ kV<br>input/output line $\pm 1$ kV                                                                                                                                    | power supplying line $\pm 2$ kV<br>input/output line $\pm 1$ kV                                                                                                                                    |
| Surge<br>IEC 61000 – 4 – 5                                                                                              | between lines $\pm 1$ kV<br>between line and grounding<br>$\pm 2$ kV                                                                                                                               | differential mode $\pm 1$ kV<br>common mode $\pm 2$ kV                                                                                                                                             |
| Voltage dip,<br>instantaneous interruption,<br>voltage fluctuation at the<br>power input line<br><br>IEC 61000 – 4 – 11 | For 0.5 cycle<br>< 5 %UT (UT's > 95 % decrease)<br>For 5 cycle, 40 %<br>UT (UT's 60 % decrease)<br>For 25 cycle,<br>70 %UT (UT's 30 % decrease)<br>For 5 seconds < 5 %<br>UT(UT's > 95 % decrease) | For 0.5 cycle<br>< 5 %UT (UT's > 95 % decrease)<br>For 5 cycle, 40 %<br>UT (UT's 60 % decrease)<br>For 25 cycle,<br>70 %UT (UT's 30 % decrease)<br>For 5 seconds,<br>< 5 %UT(UT's > 95 % decrease) |
| Power frequency magnetic field<br>(50/60 Hz)<br>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 used at this environment.

| Tolerance test | IEC 60601 test conditions | Appropriateness level |
|----------------|---------------------------|-----------------------|
|----------------|---------------------------|-----------------------|

|                                                                          |                                   |        |
|--------------------------------------------------------------------------|-----------------------------------|--------|
| Conductivity RF electromagnetic field<br>IEC 61000 –<br>4 – 6            | 3 Vrms<br>150 kHz~80 MHz          | 3 Vrms |
| Radioactivity RF electromagnetic field<br>tolerance<br>IEC 61000 – 4 – 3 | 10 V/m<br>80 MHz~2.7 GHz<br>scope | 10 V/m |

# 10

---

## SERVICE INFORMATION

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

- 1.1 Name of Equipment Type: 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](mailto:svc@huvitz.com)

<http://www.huvitz.com>

### ■ EU Representative

---

Medical Device Safety Service GmbH (MDSS)

Schiffgraben 41, 30175 Hannover, Germany

Tel: +49-511-62628630

Fax: +49-511-62628633

### ■ CANADA Representative – CANADA ONLY

---

AXIS Medical Canada Inc.,

9820 Boulevard Du Golf, Anjou, QC

H1J 2Y7

Tel: 1 877 388-1515

**■ U.S.A Representative**

COBURN TECHNOLOGIES

55 Gerber road, South Windsor, Connecticut, 06074, United states

Tel: +1-860-648-4906

**■ Brazil Representative**

VR Medical

R. BATATAES 391, CEP 01423, SÃO PAULO

Tel: +55-11-3889-0875

**■ Australia Representative**

OPTICARE

118 Adderley St, Auburn NSW 2144

PHONE: 02 9748 8777

FAX: 02 9748 8666

**■ Australia Representative**

OPTICARE

118 Adderley St, Auburn NSW 2144

PHONE: 02 9748 8777

FAX: 02 9748 8666

**■ Australia Representative**

OPTICARE

118 Adderley St, Auburn NSW 2144

PHONE: 02 9748 8777

FAX: 02 9748 8666

## SOFTWARE LICENSE AGREEMENTS

### CAUTION

The software including all the contents of files, disk or other media may be used only when you agree with the "SOFTWARE LICENSE AGREEMENT" below.

Before using the Software, thoroughly read "SOFTWARE LICENSE AGREEMENT"

Le logiciel, y compris tout le contenu des fichiers, du disque ou d'autres supports, ne peut être utilisé que si vous êtes d'accord avec le "SOFTWARE LICENSE AGREEMENT" ci-dessous.

Avant d'utiliser le logiciel, lisez attentivement "SOFTWARE LICENSE AGREEMENT"

## SOFTWARE LICENSE AGREEMENT

This SOFTWARE LICENSE AGREEMENT (hereafter referred to as Agreement) is a legal contract between you (regardless of private users or corporate users) and HUVITZ CO., LTD. (hereafter referred to as HUVITZ).

By installing, copying, downloading or in any way starting to use the Software, you accept and agree to all the terms and conditions of this Agreement. If you don't agree with the terms and conditions of this Agreement, return the disc package and the instruction manual to the location where you obtained them.

### 1. GRANT OF LICENSE

HUVITZ grants to you a non-exclusive, non-transferable limited license to use the Software under the terms and conditions of this Agreement.

- You may use the Software in a single location on a hard disk of a computer
- "Use" of the Software means reading the Software to a temporary memory such as RAM of a computer, or installing the Software on a fixed memory such as a hard disk.
- When the Software is used on multiple computers, you must obtain the same number of the licenses as the number of computers where the Software will be used even if the Software will not be used concurrently on multiple computers.
- Installing the Software into a fixed memory such as a hard disk of a computer from the server doesn't mean, "Using" the Software as long as the network server runs only for installing the Software into another computer. In such cases, once another computer has the software installed from the server, that computer needs the license.

### 2. INTELLECTUAL PROPERTY OWNERSHIP

You acknowledge that the Software and the Documentation and all the duplications are the intellectual property of HUVITZ and that HUVITZ owns any and all source codes, copyrights, trademarks, patents, trade secrets, confidential information and any other proprietary rights of the Software and the Documentation. The Software and the Documentation are protected by copyright laws and international copyright treaties, as well as other intellectual property laws and treaties.

### 3. SOFTWARE VERSION

The Software and the Documentation may be updated or modified at HUVITZ's own discretion from time to time without any prior notice.

#### 4. RESTRICTIONS

- You may not use any HUVITZ trademarks, trade names or logos without the prior written consent of HUVITZ.
- You may not copy, duplicate, divert, modify, distribute, reverse engineer, decompose, disassemble or otherwise attempt to discover the source code of the Software and the Documentation without the prior written consent of HUVITZ.
- You may not use any HUVITZ trademarks, trade names or logos without the prior written consent of HUVITZ.
- You may not license or sublicense the Software, or assign, transfer or convey in any manner the Software to any third person without the prior written consent of HUVITZ. Any attempt to grant the Software to any third person will terminate this Agreement and relieve all obligations which may be undertaken on HUVITZ, regardless of whether the Software is paid for or not.

#### 5. WARRANTY

- You may receive a replacement when you find any physical damage to the CD-ROM or printed materials within 30 days from the receipt of the Software.
- Unless otherwise provided herein, the Software is being delivered to you on an "AS IS" basis. ALL EXPRESS OR IMPLIED CONDITIONS, REPRESENTATIONS AND WARRANTIES, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OF THIRD PARTY RIGHTS ARE DISCLAIMED. HUVITZ WILL NOT WARRANT THAT THE OPERATION OF THE SOFTWARE IS UNINTERRUPTED, OR ERROR-FREE.

#### 6. LIMITATION OF LIABILITY

IN NO EVENT WILL HUVITZ BE LIABLE TO YOU FOR ANY DAMAGES, LOSS, CLAIMS OR COSTS WHATSOEVER INCLUDING BUT NOT LIMITED TO ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES, OR ANY LOST REVENUES, PROFITS, DATA OR INFORMATION, ARISING OUT OF OR RELATED TO THE USE OF OR INABILITY TO USE SOFTWARE, EVEN IF HUVITZ IS NOTIFIED OF THE POSSIBILITY OF SUCH DAMAGES, LOSS, CLAIMS OR COSTS.

#### 7. FORCE MAJEURE

In no event HUVITZ will be liable to you for any delay or failure in the performance of its obligations under this Agreement if and to the extent such delay or failure in performance arise from any cause or causes beyond the reasonable control of HUVITZ, including, but not limited to, fire, explosion, flood, earthquake, war, rebellion or riots.

#### 8. INDEMNIFICATION

You agree to defend, indemnify and hold harmless HUVITZ, its affiliates and their directors, employees and agents from any damages, loss, liabilities or expenses (including attorneys fee) resulting from, or incurred in connection with or based upon (a) your breach or non-compliance of this Agreement or (b) installation or other operations to set up the Software by persons other than HUVITZ personnel or those specified by HUVITZ.

#### 9. TERM AND TERMINATION

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

#### 10. NO ASSIGNMENT

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

#### 11. NO THIRD PARTY RIGHTS

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

**12. EXPORT REGULATIONS**

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

**13. SEVERABILITY**

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

**14. NO WAIVER**

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

**15. ENTIRE AGREEMENT**

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