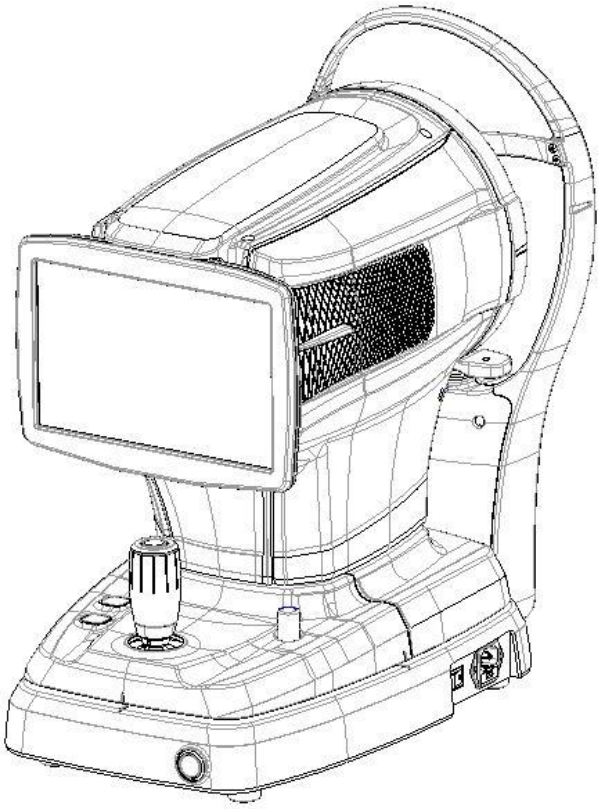
Huvitz

CORNEAL TOPOGRAPHER
HTG-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	박 상 전	First issued
B	2023.04.21	박 상 전	Updated NOTE for automatic tracking function Added NOTE regarding error in measurement

9000ENG0095-B
(2023/04/21)

©2021 HUVITZ Co., Ltd.
38, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea

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1

SAFETY PRECAUTIONS

1.1. Overview

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

⚠ WARNING

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

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

⚠ CAUTION

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

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

⚠ NOTE

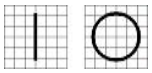
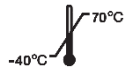
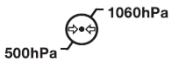
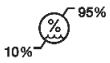
This is used to emphasize essential information.
Be sure to read this information to avoid operating the device incorrectly.

Ceci est utilisé pour souligner les informations essentielles.
Assurez-vous de lire ces informations pour éviter d'utiliser l'appareil de manière incorrecte.

2

Symbol Information

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

Symbol	Indication
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the appropriate User's or Service Manual. (Ce symbole identifie une note de sécurité. Assurez-vous de comprendre la fonction de ce contrôle avant de l'utiliser. La fonction de contrôle est décrite dans le manuel d'utilisation ou d'entretien approprié.)
	I and O on power switch represent ON and OFF respectively. (O sur l'interrupteur d'alimentation représentent respectivement ON et OFF.)
	Temperature Limitation (Limitation de température)
	Atmospheric pressure limitation (Limitation de pression atmosphérique)
	Humidity limitation (Limite d'humidité)
	Stack direction (Direction de la pile)
	Keep DRY (Garder au sec)
	Fragile , handle with care (Fragile, manipuler avec soin)
	Keep away from sunlight (Tenir à l'écart de la lumière du soleil)
	Stack layer limit (Limiter la couche de pile)
	Use no hook (N'utilisez aucun crochet)
	WEEE Symbol – EU only <u>Disposal of your old appliance</u> When this crossed-out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC. All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities. The correct disposal of your old appliance will help prevent

	potential negative consequences for the environment and human health. For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the product. (Symbole WEEE- EU seulement Mise au rebut de votre ancien appareil Lorsque ce symbole de poubelle barrée est joint à un produit, cela signifie que le produit est couvert par la directive européenne 2002/96 / CE. Tous les produits électriques et électroniques doivent être éliminés séparément du flux des déchets municipaux via des installations de collecte désignées par le gouvernement oules autorités locales. L'élimination correcte de votre ancient appareil aidera à prévenir les conséquences negatives potentielles sur l'environnement et la santé humaine. Pour plus d'informations sur l'élimination de votre ancient appareil, veuillez contacter votre mairie, le service d'élimination des déchets ou le magasin où vous avez acheté le produit.)
	Authorized representative in the European Community – EU ONLY (Représentant autorisé dans la Communauté européenne- EU seulement)
	Manufacturer (Fabricant)
	Date of manufacture (Il indique l'année de fabrication et le fabricant.)
	Refer to instruction manual/booklet (Se reporter au manuel d'instructions / brochure)
	Type B Isolated patient connection (Type B Connexion patient isolée.)
	Warning: Crushing or insert of hand (Attention: écrasement ou insertion de la main)
	QR code (QR code)
	Alternating Current (Courant alternative)
	Consult instructions for use (Consulter les instructions d'utilisation)

MEDICAL – XXXXXXX 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 XXXXXXX
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)

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

Medical Device
(dispositif medical)

Authorized representative in Switzerland
(Représentant autorisé dans la Suisse)

2.1. Usage Precautions

This device 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 device is imperative for its safe operation. Therefore, please read carefully all instructions before switching on this device. For more detailed information, please contact our Customer Service Department or one of our authorized representatives.

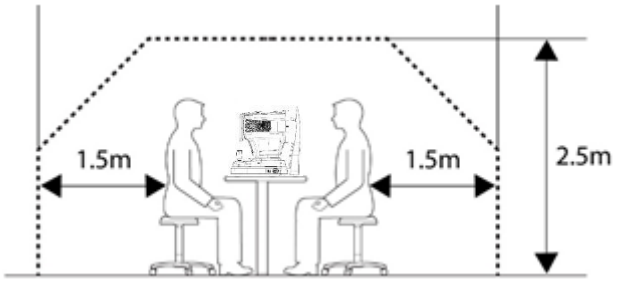
⚠ CAUTION

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

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

⚠ WARNING

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



If and instrument that does not comply with IEC 60601-1 is to be used, use an isolation transformer.
If a person handling a conductive part of the system comes into contact with a patient at the same time, hazard may occur due to leakage current exceeding the value specified in the applicable standard. Be careful not to touch patients when connecting or removing the power plug or cable connectors.

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

⚠ CAUTION

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

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

⚠ CAUTION

Do not install any software on device 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

1 Light Hazard Group I (according to the ISO15004-2)
This device is classified as a Group I. The LED used for the device is safe under expected use.
However, observe the following precautions when using the device.
- 1.1 Do not direct LED beams to human eyes when unnecessary.
- 1.2 Do not look into the objective lens for a prolonged time.
- 1.3 If the device cannot be used appropriately or any problem cannot be solved, Stop using the devcie immediately, and contact Huvitz or your authoirzed distributor.

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

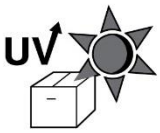
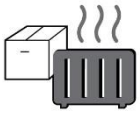
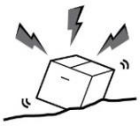
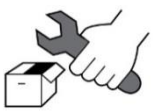
c. Level of training: Recommend completing training how to use it is.

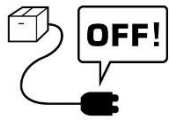
d. Education: Basic training is required for the use of equipment.

(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 device 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 device must only be connected to a supply mains with protective earth.

This instrument can withstand the following conditions:

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

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

3. Storage
- An ambient temperature range of -10℃ ~ 55℃ (14°F ~ 131°F)
- A relative humidity range of 10% ~ 95% (with non-condensing)
- An atmosphere pressure range of 700 ~ 1060hpa

Avoid environments where the device 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

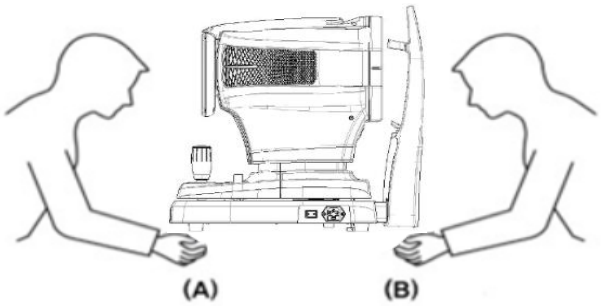
⚠ WARNING

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 device 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 directley if an operator has a hand injury or a significant allergic reaction to the material used in the operaton contact part.

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

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

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

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

23. If a user uses power save supported by Windows 10 except for the power save in User setting, it causes some trouble in HTG-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 HTG-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 HTG-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.

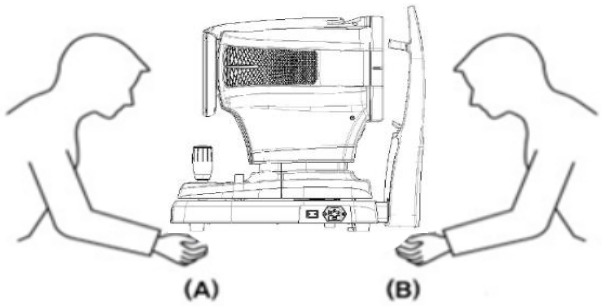
14. Si de la fumée, des étincelles ou un bruit ou une odeur anormale est remarqué provenant de l'instrument, veuillez éteindre immédiatement et débrancher la prise.

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 à gauche (A) et à droite (B) du produit.



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

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

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

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

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

23. Si un utilisateur utilise l'économie d'énergie prise en charge par Windows 10, à l'exception de l'économie d'énergie dans le paramètre Utilisateur, cela provoque des problèmes dans HTG-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 HTG-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 avez toujours un antivirus et un pare-feu à jour installés sur votre système

28. Installer et utiliser des logiciels dans un environnement d'exploitation sécurisé qui permet uniquement

aux utilisateurs autorisés d'accéder et que le réseau du système est équipé d'un pare-feu Windows intégré au système Windows, d'outils anti-logiciels espions Windows Defender et d'autres outils/systèmes d'application de sécurité courants

29. Évitez de réinitialiser ou d'éteindre le PC lorsque le HTG-1 fonctionne.

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

31. La connexion de l'interface électronique à un réseau informatique comprenant d'autres équipements pourrait entraîner des risques non identifiés pour les patients, les utilisateurs ou des tiers. Identifier, analyser, évaluer et contrôler ces RISQUES.

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

2.4. Safety Cautions

⚠ CAUTION

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

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

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

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

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

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

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

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

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

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

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

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

3

INTRODUCTION

3.1. System Outline

The Huvitz Corneal Topographer HTG-1 is a device for measuring and analyzing the cornea topography.
The Corneal Topographer HTG-1 optically measures eye components such as Corneal curvature radius, Corneal cylinder axis, White to White and Pupil diameter.

HTG-1 software based on Windows 10 operating system provides various tests of the anterior corneal surface.
Along with mapping of the corneal surface, HTG-1 provides various analyses of the patient's corneal surface.

HTG-1 Software Specifications:
Database management
Corneal wavefront analysis (Zernike)
Contact lens fitting software
On-board fluorescein acquisition
Auto-focus system
Corneal analysis
Integrated pupillometer
Keratoconus screening
Report management
Reviewing previous patient examinations

3.2. Intended Use

The Corneal Topographer HTG-1 is corneal analyzer as acquiring images of the cornea and measuring corneal topography. The rings of the placido reflected by the illuminated cone are used to geometrically calculate the topographic map of the cornea in the image.

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)

3.4. Contraindications

This device should not be used for:

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

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

3.5. Patient requirements

The patient who undergoes and examination by this instrument must maintain concentration for a few minutes and adhere to the following instructions;

- After his/her face to the chinrest, headrest.
- Keep the eye open

- Understand and follow instructions when undergoing an examination.

If the patient does not conform to these conditions, it is not possible to take a picture correctly

3.6. Operating Principles

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

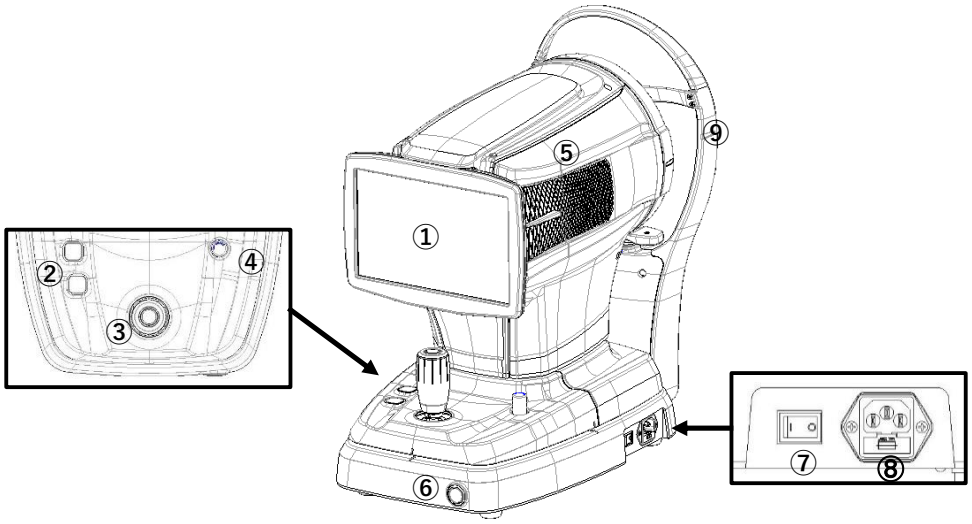
- IEC/EN 60601-1: MEDICAL ELECTRICAL EQUIPMENT
  - Part 1: General requirements for safety
- IEC/EN 60601-1-2: Medical electrical equipment Part1: General requirements for safety
  - Collateral Standard: Electromagnetic Compatibility-Requirements and tests
- ISO15004-1: Ophthalmic instruments
  - Fundamental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

4

System Overview

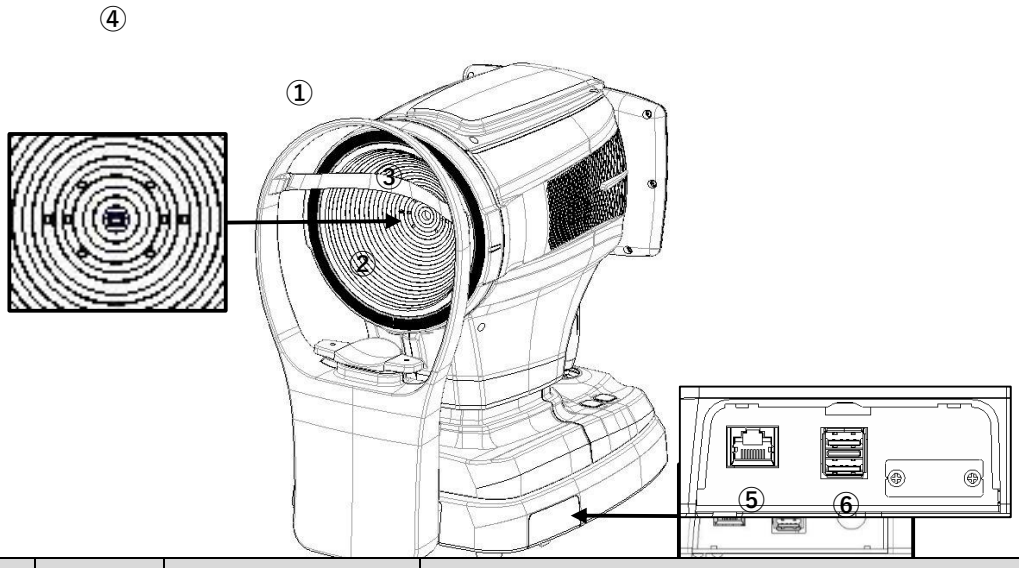
4.1. Configuration and Functions

Front View



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

Rear View

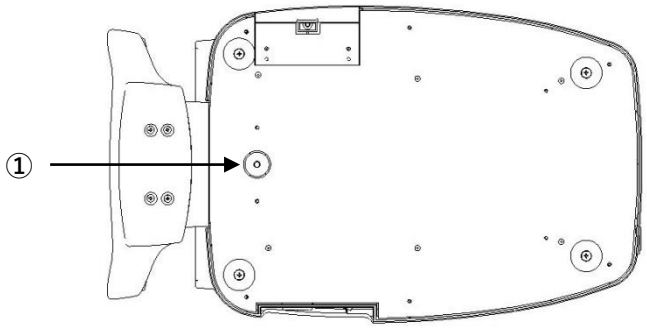


No	Part	Name	Description
1	Headrest	Headrest	The part that holds the patient's head
2		Chinrest	For fixing patient’s chin.
3	Body	Placido disk	Check the curvature of the cornea.
4		Focus LED	LEDs for checking patient’s eye.
5	Base	LAN port	Port for external network (1 ports)
6		USB port	Port for internal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

NOTE

Interference between USB 3.0 and 2.4GHz wireless signals may cause connectivity a
issues. To avoid interference, consider using an extension cable, changing the wireles
devices, or using only USB 2.0 devices. If the problem persists, consider using a wired
to a 5GHz wireless network.

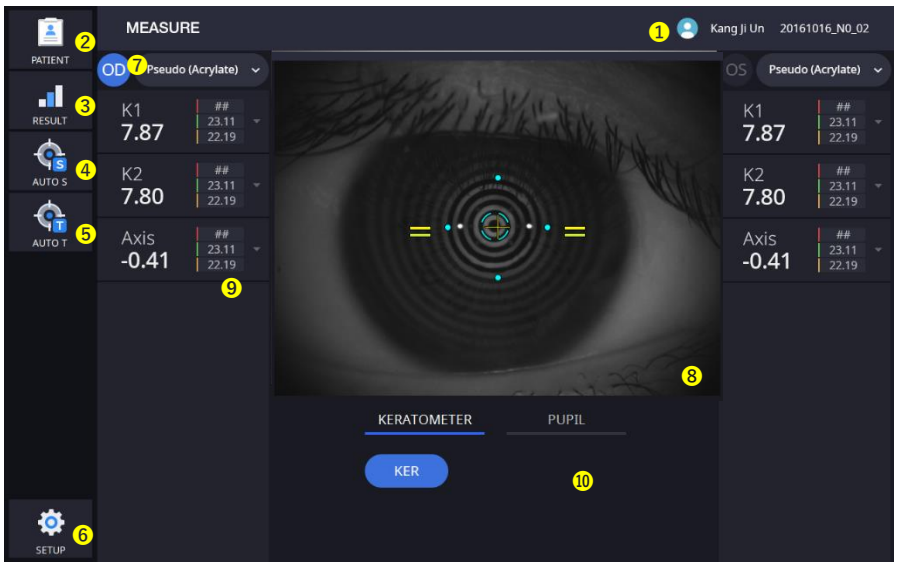
Bottom View



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

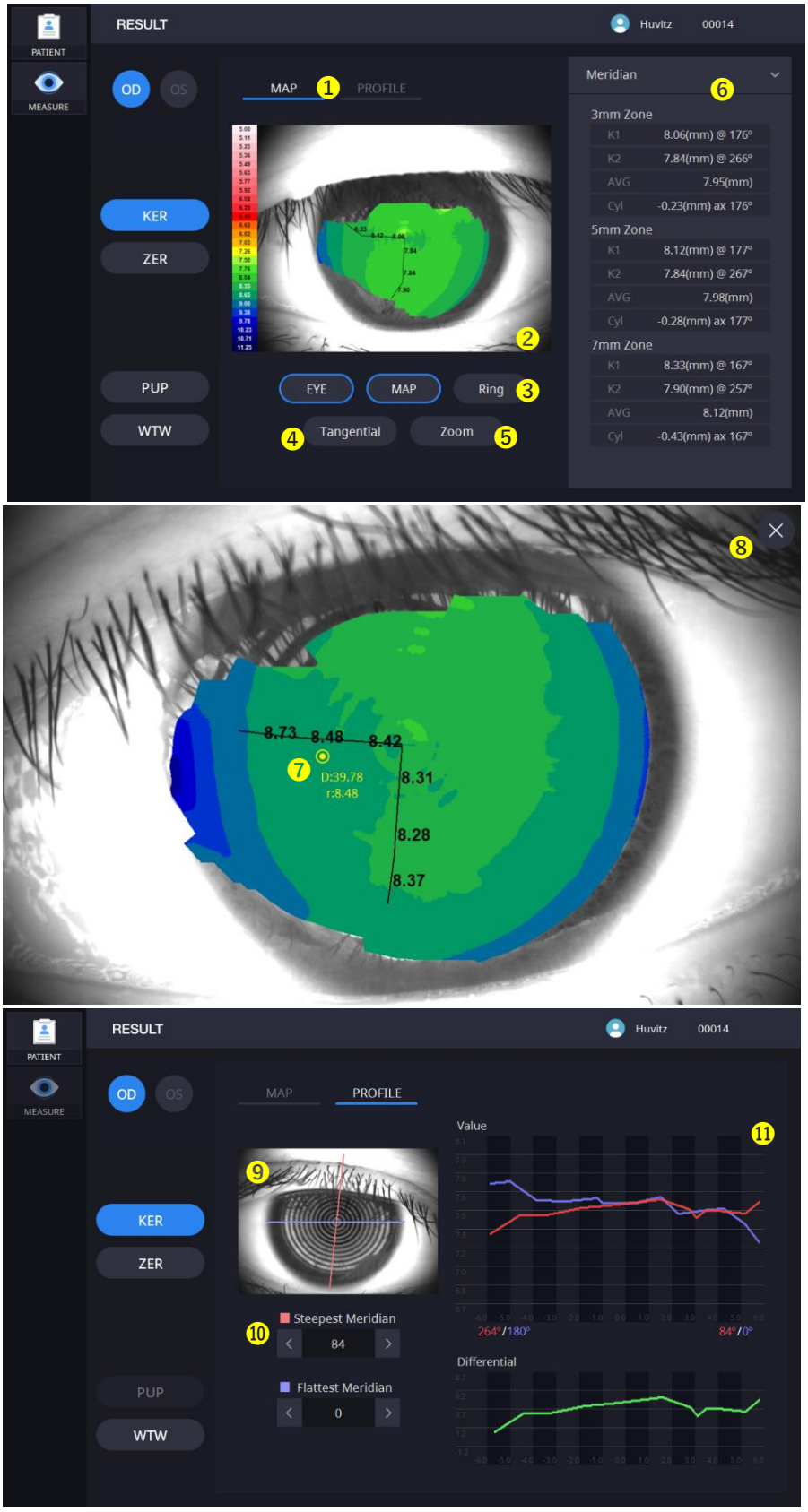
4.2. Main Body Screen Description

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	Result	Go to Result page. Result page shows the detail information about the patient measurement.
4	AUTO S	Show auto shooting selection status.
5	AUTO T	Show auto tracking selection status.
6	Set up	Change the measurement settings.
7	OD&OS info.	Shows the eye position.
8	Camera Image	It shows the live camera images.
9	Measurement Value	It shows latest measured values. So, user can check the measurement. 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. -K1: Flat Keratometry. -K2: Steep Keratometry. -Axis: Angle degree of K1.
10	Measurement Mode	Select the measurement mode before the measurement.

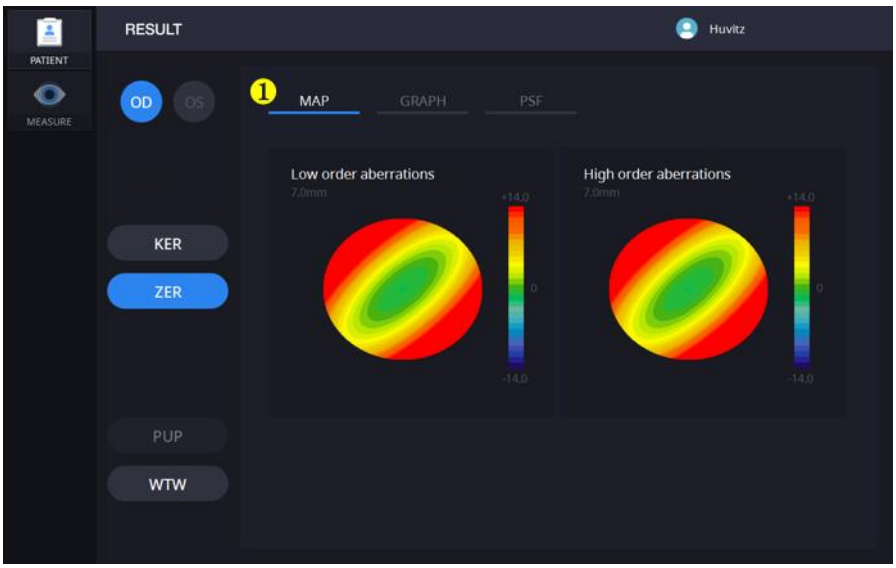
1. Keratometry result (KER)

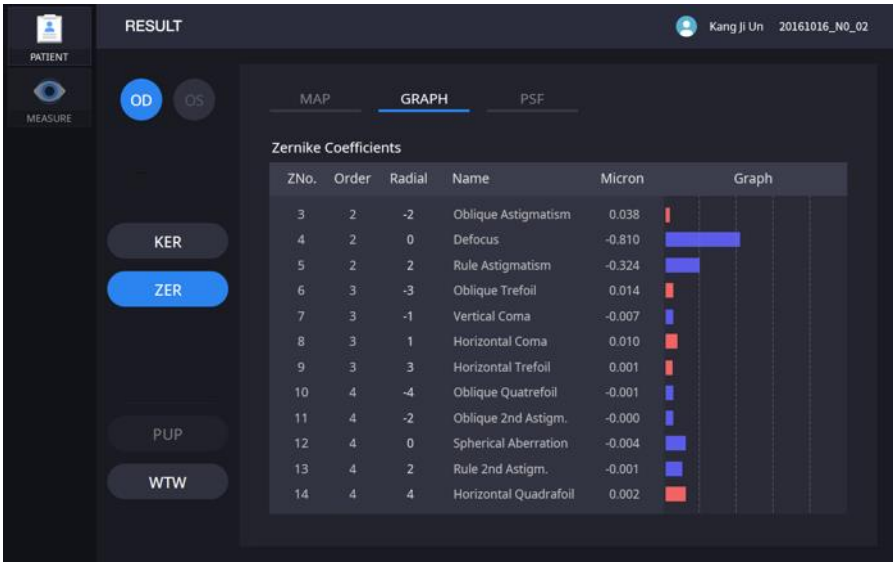


No	Name	Function
1	Map/Profile	Map: Show Topography map with various options. Profile: Show curvature along the meridian.

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. 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. Several zones value: The keratometry information at the point 3~7mm away from the center point is displayed. (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. And Differential graph can be used to checking the difference with steepest meridian and flattest meridian.

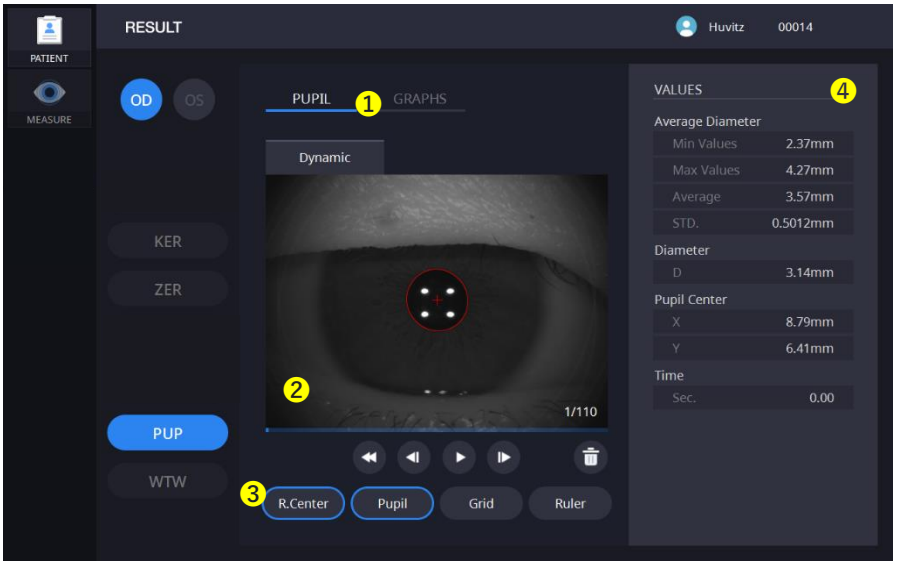
2. Zernike result (ZER)





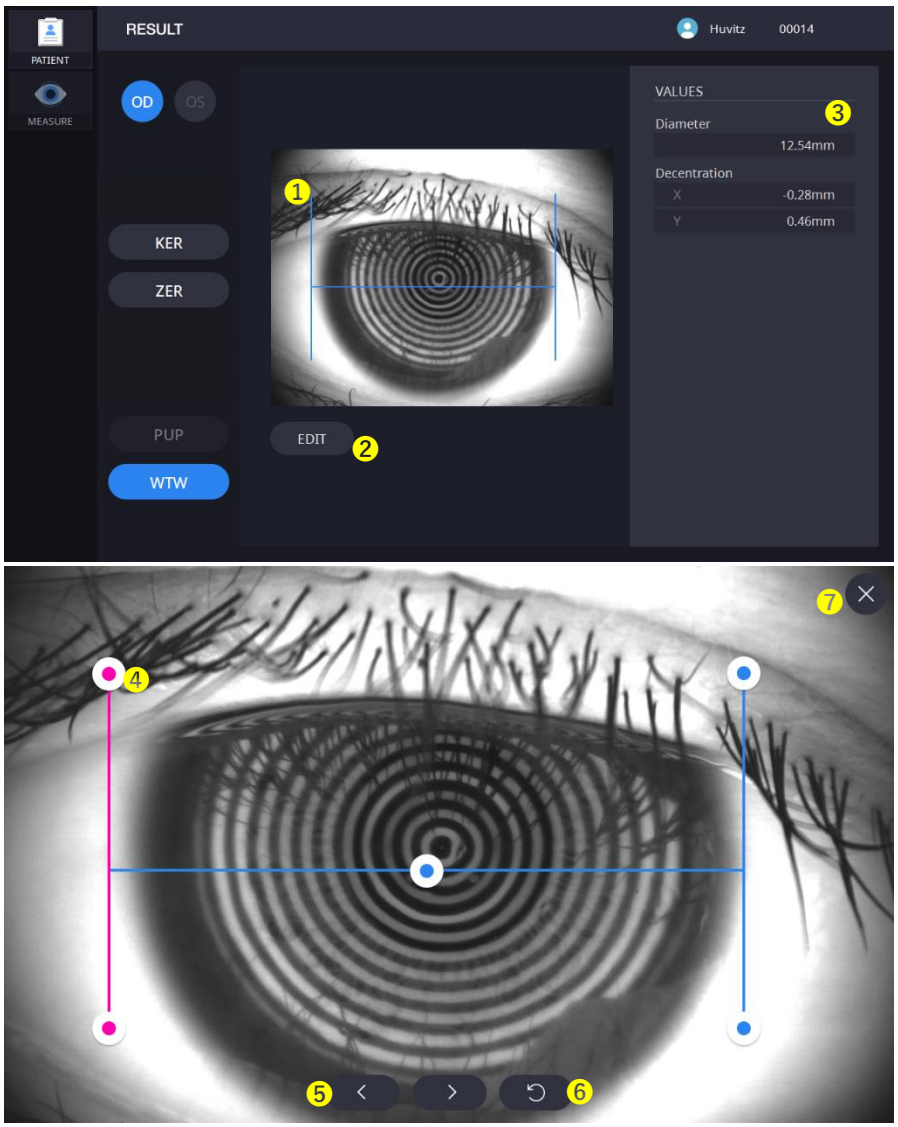
No	Name	Function
1	Map/Graph	Map: Show the aberration map. Graph: Show the coefficients graph. PSF: Show the point spread function image.

3. Pupilometry result (PUP)



No	Name	Function
1	Pupil/Graphs	Pupil: Show the continuous image of pupil, and check the pupil changes. Graph: Show the Latency 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.

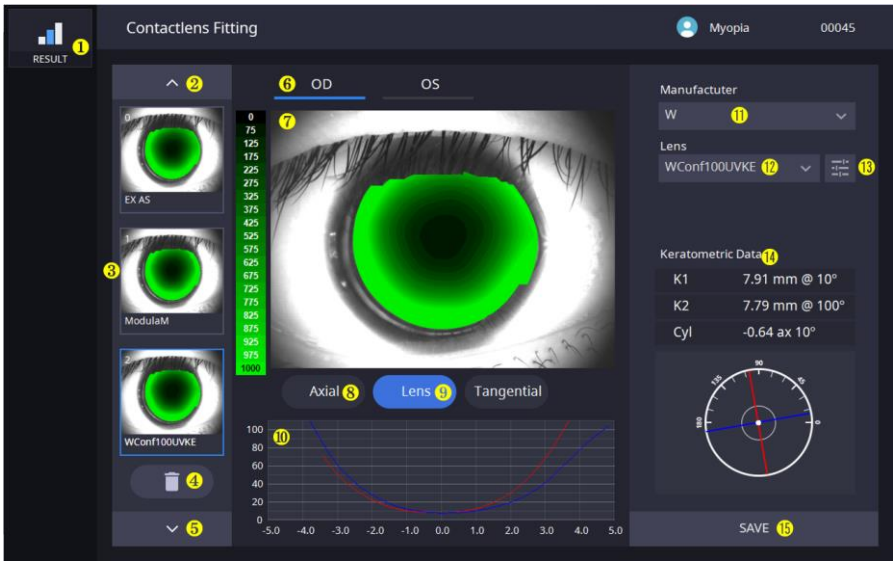
4. White to White result (WTW)



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 pupil values.
4	edit window -Edit bar	Click the bar makes it active (pink color express the active state). In the active state, move the bar to set the WTW position.
5	edit window -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 -reset	Reset the bar to original location.
7	edit window -save and close	Finished editing, save and close the edit window.

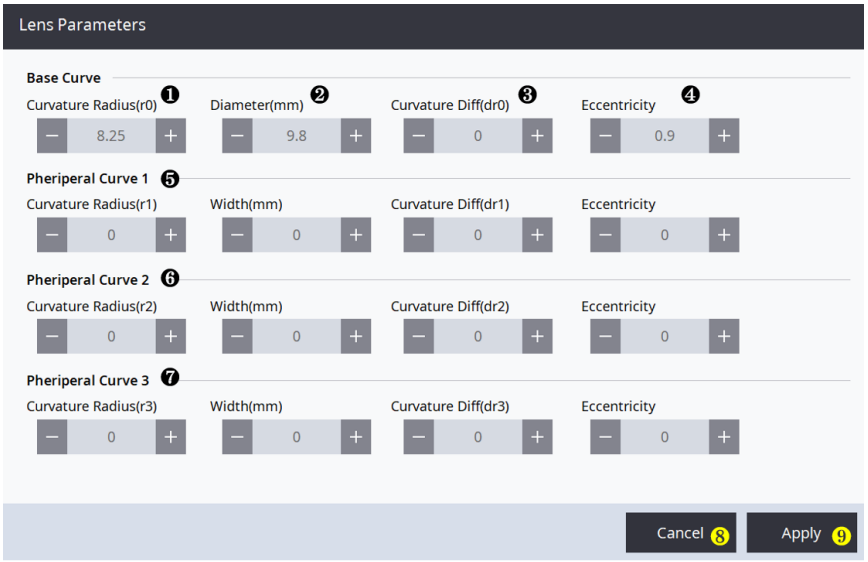
Contact Lens Fitting Simulation Screen

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



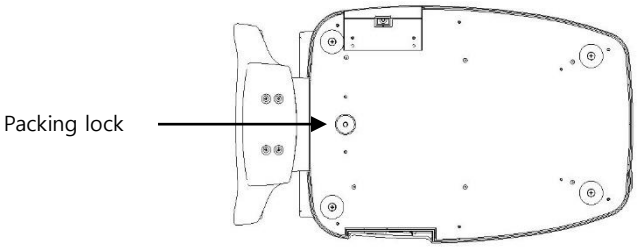
No	Name	Function
1	Set lens curvature	Sets the curvature of the lens.
2	Lens diameter Settings	Sets the diameter of the lens. Base Curve Diameter (mm): This means the full diameter Peripheral Curve Width (mm): The diameter of the corresponding peripheral curve.
3	setting the curvature difference	Sets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

5

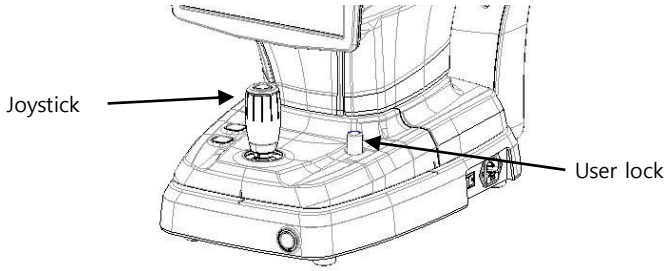
Installation Procedure

5.1. System installation

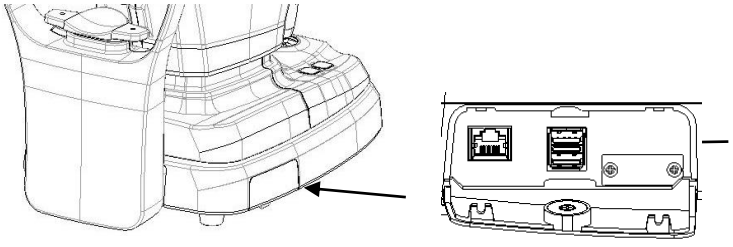
1. Place the main body unit on a stable table.
2. Loosen the two packing lock screw under the main body.



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)



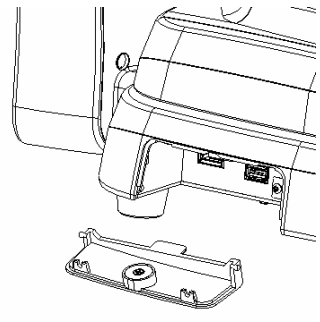
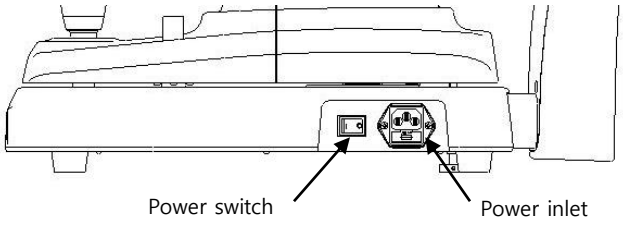


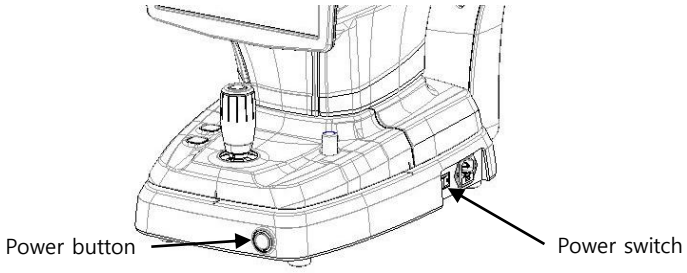
Figure "A"

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

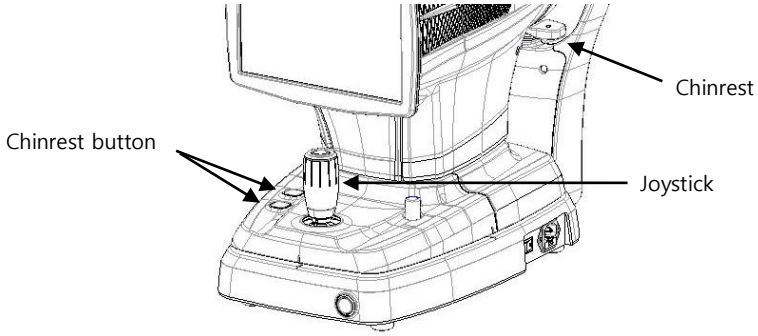
7. Connect power cable to power inlet. Also, connect the other side of power cable to electric outlet.



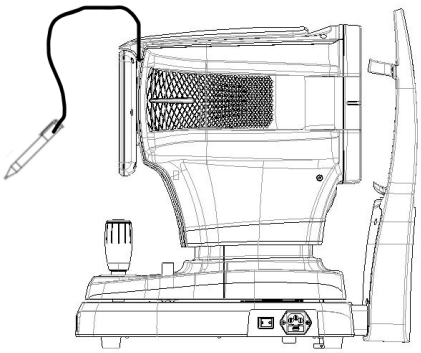
8. If external devices are connected, turn on external devices first.
9. Turn on the main body by pressing power switch (I position)
10. Turn on the internal PC by pressing power button.



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.

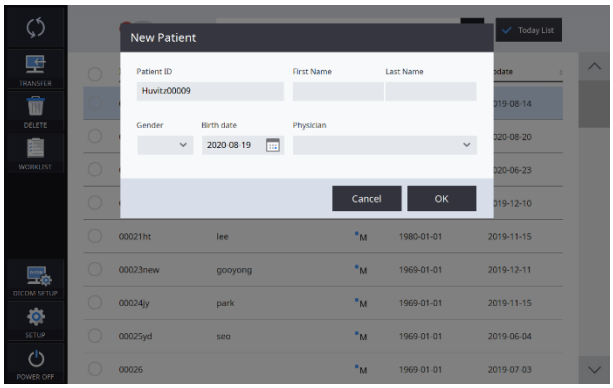


6

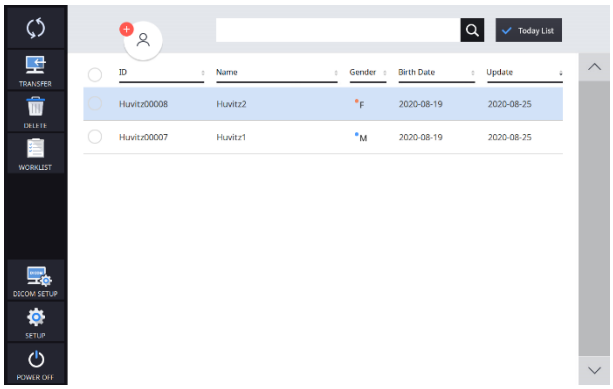
Operation

6.1. Software

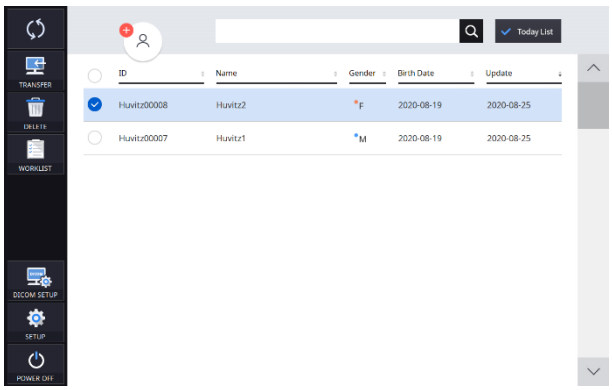
1. Press register patient icon ( ) and input patient information. If patient is resisted already, skip this step.



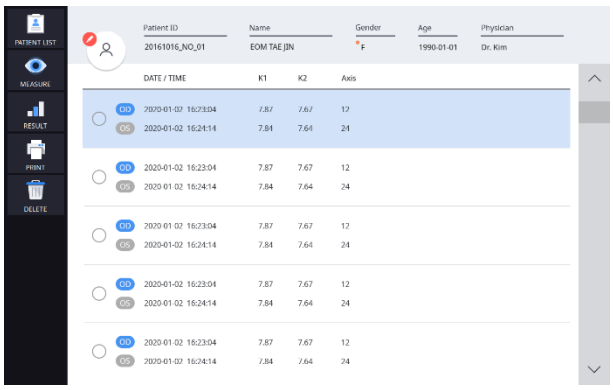
2. Select patient and check patient information is correct.



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.

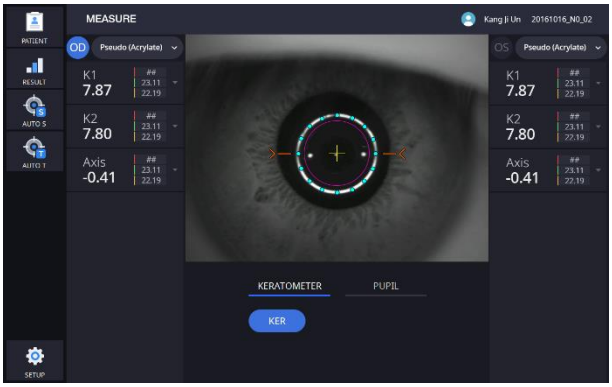


4. When you select a patient, the screen changes.



5. Enter observation mode by pressing measure icon (

).
The screen of observation mode is as follow.



6.2. SETUP Mode

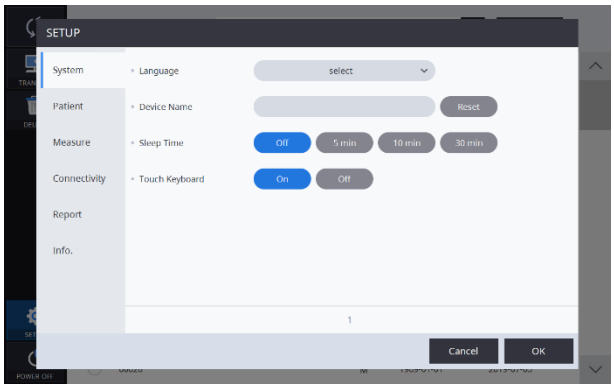
[To choose the section to setup]

- Setup mode consists of 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]

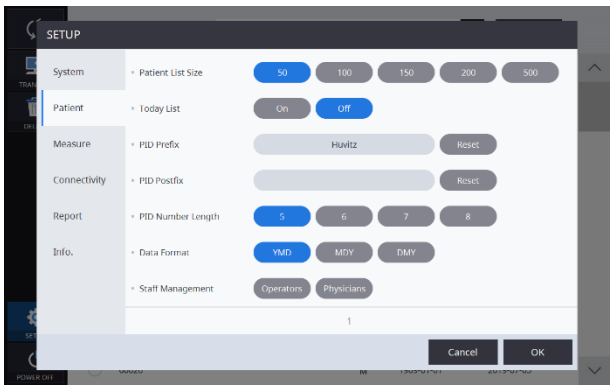
- Select the item to change.
- To press OK button will save all the changes made and exit the setup screen.
- To press CANCEL button will discard the changes and exit the setup screen.

1) System Settings



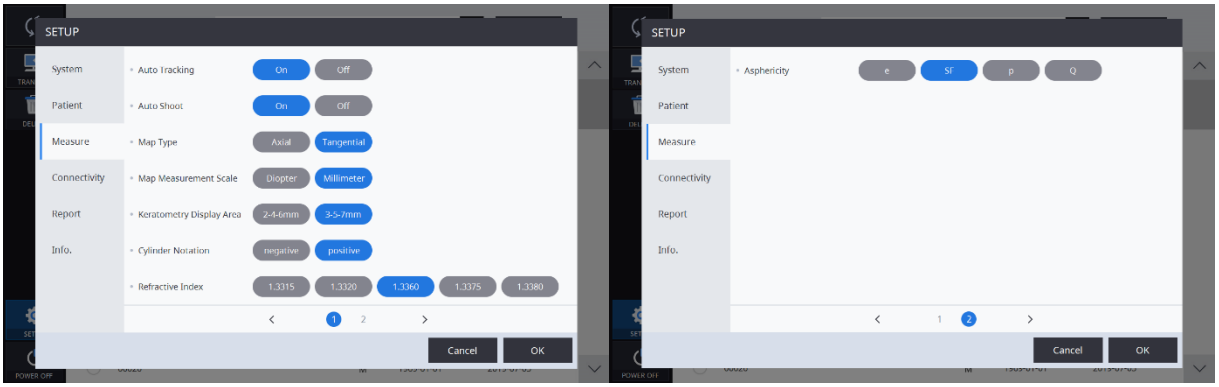
Language	Select language
Device Name	Set Device Name.
Sleep Time	Sleep mode time setting.
Touch Keyboard	Touch Keyboard ON/OFF setting.

2) Patient Settings



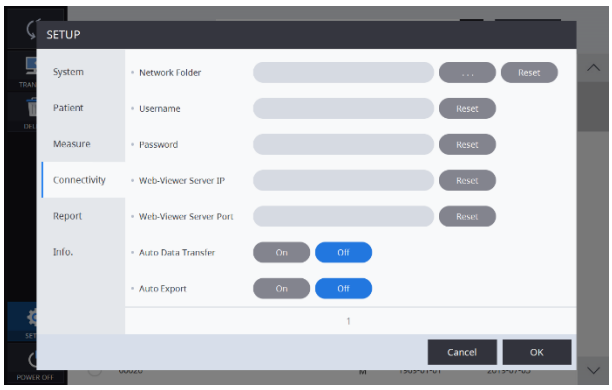
Patient List Size	Number of patients to be displayed per pages.
Today List	Today List (List of patients visited today) settings.
PID Prefix	The function to set the prefix of the patient ID.
PID Postfix	The function to set the postfix of the patient ID.
PID Number Length	The function to set the length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

3) Measure Settings.



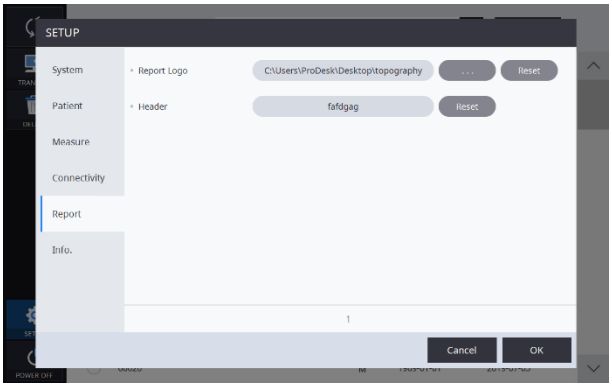
Auto Tracking	Auto Tracking ON/OFF setting.
Auto Shoot	Auto Shoot ON/OFF setting.
Map Type	Select default map(Axial / Tangential)
Map Scales Measurement	Select default scale measurement (Diopter / Millimeters)
Keratometry Display Area	3-5-7 mm / 2-4-6 mm
Cylinder Notation	Positive / Negative
Refractive 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

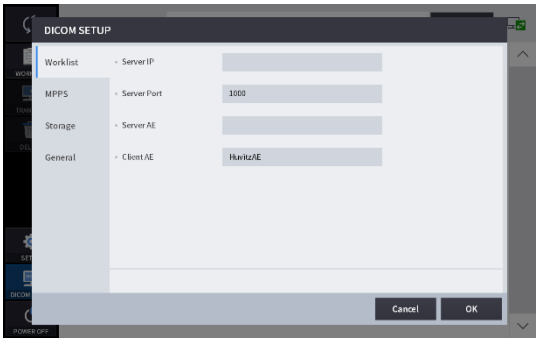
5) Report Settings



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

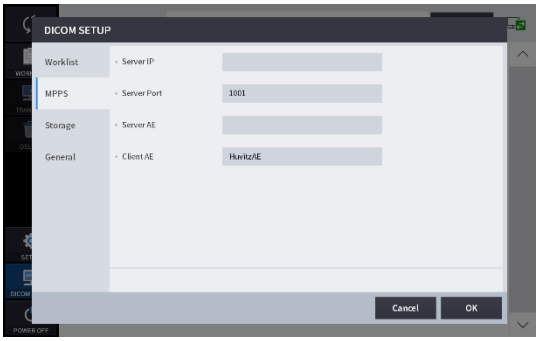
6.3. DICOM SETUP Mode

1. Worklist Setting



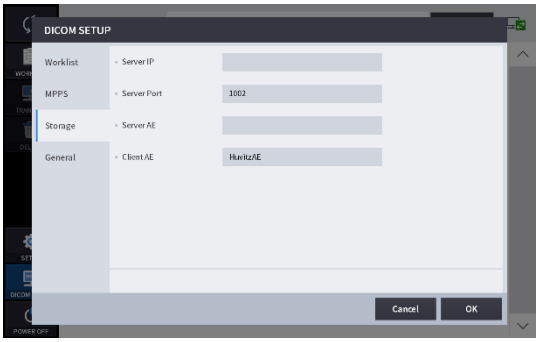
Server IP	IP Address of the PC where the server program is installed.
Server Port	Set Port Number.
Server AE	Set Server AE.
Client AE	Set Client AE.

2. MPPS Setting



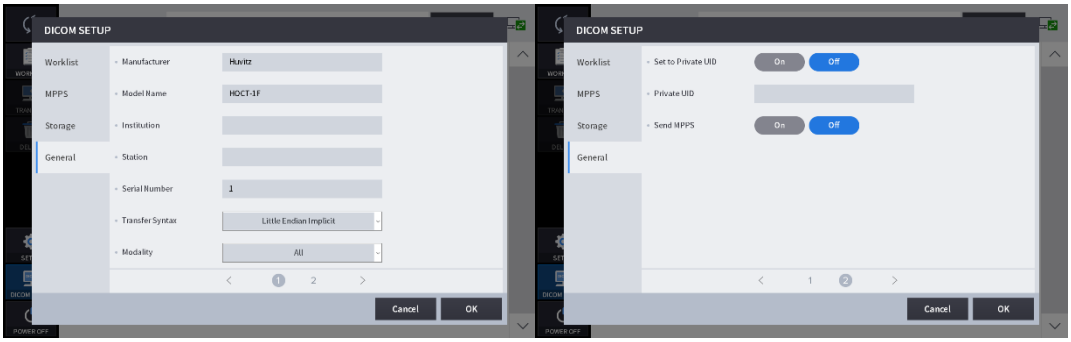
Server IP	IP Address of the PC where the server program is installed.
Server Port	Set Port Number.
Server AE	Set Server AE.
Client AE	Set Client AE.

3. Storage Setting



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

4. General Setting

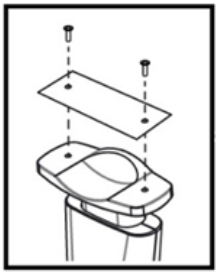


Manufacturer	Set the name of the manufacturer.
Model Name	Set the Model Name.
Institution	Set the name of the institution.
Station	Set the name of the Station.
Serial Number	Set the Serial Number.
Transfer Syntax	Set the Transfer Syntax.
Modality	Set the Modality.
Set to Private UID	Set Private UID ON/OFF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

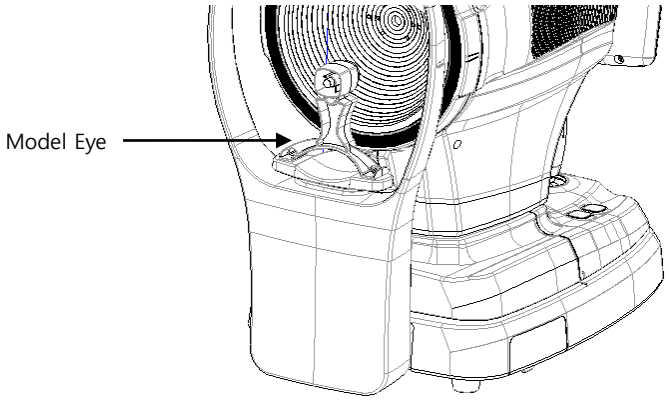
6.4. Device Check

1. Measuring Model Eye.

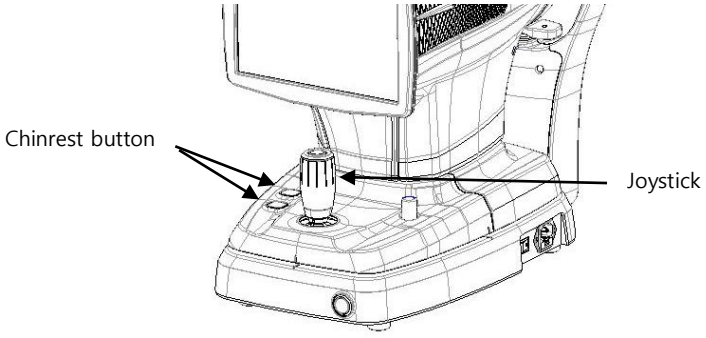
(1) Remove chinrest paper.



(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.

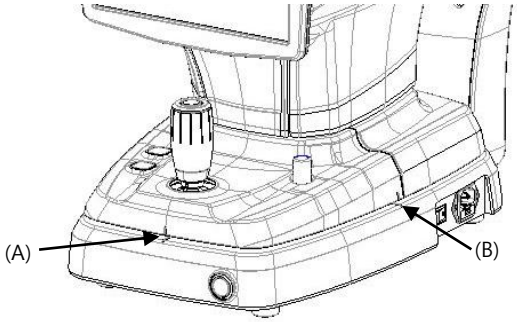


(4) After focusing, press the Joystick button.

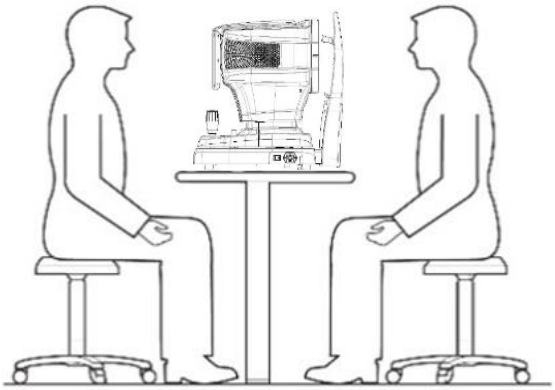
6.5. General Operation

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.

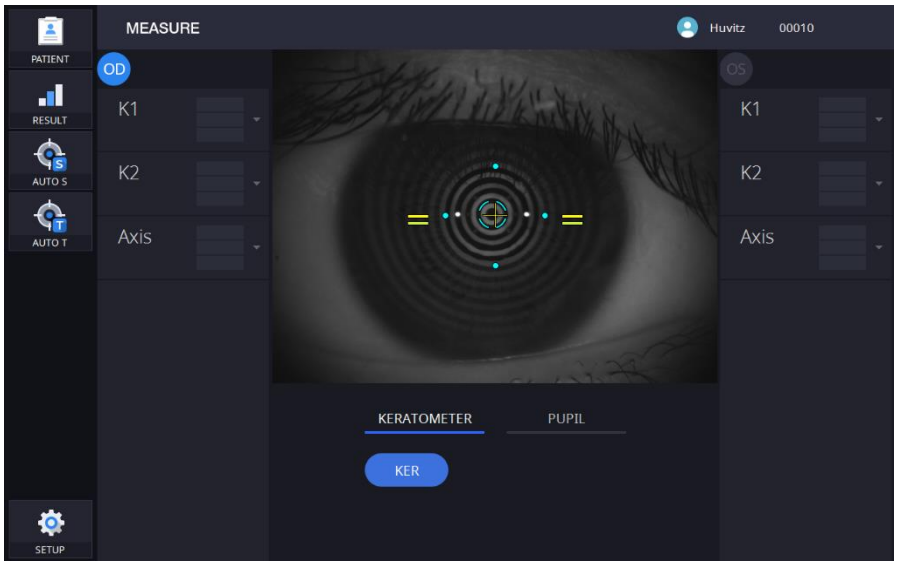
2. Align left/right index mark (B) and front index mark (A) of body and base with joystick.

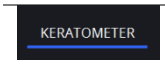


3. Let the patient sit in front of instrument.



4. Set the measurement mode.
   Set Keratometer measurement or Pupil measurement.

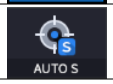


	Keratometer mode is on.
	Pupillometry mode is on.

- If Keratometer mode is on, Keratometer image is taken with pressing the button on joystick and topography map, kerato value is calculated.
- 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.

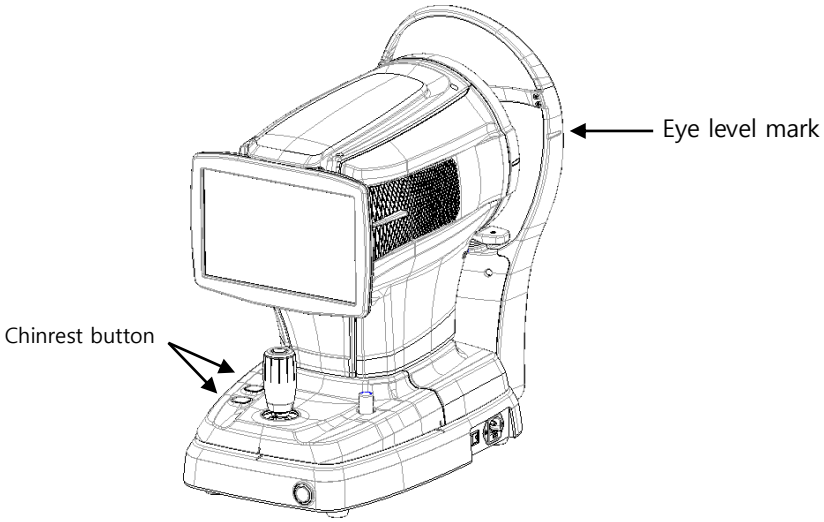
(2) Set auto tracking.

	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.

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.

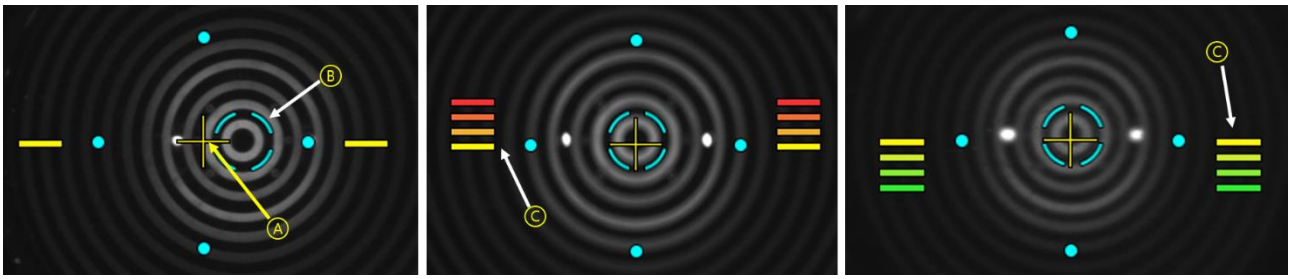


7. Instruct patient to watch internal fixation LED to fix patient eyes. Also, instruct patient to open eye widely, not to blink.

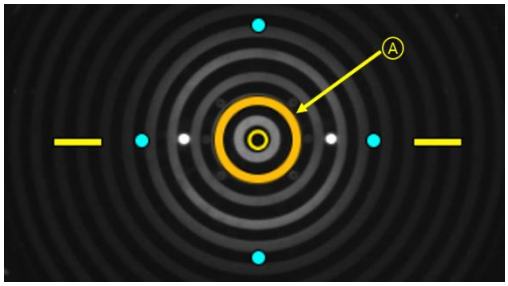
8. Move body with joystick until patient's eye appears on the screen.

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.

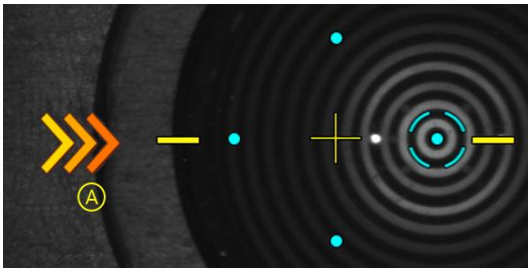


(2) Move joystick little by little until orange target mark (A) appears.



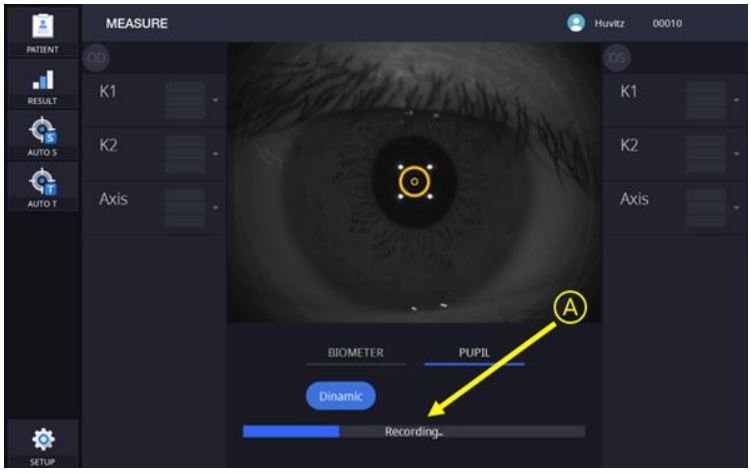
(3) If auto tracking is on, alignment and focus is automatically accomplished in tracking region.

(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.



11. Press the button on joystick to capture image.

12. 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

The automatic tracking function does not work at 3R and 38R, which are the boundaries of the corneal curvature radius measurement range. The measurement range boundary was measured manually using a model eye manufactured by HUVITZ.

NOTE

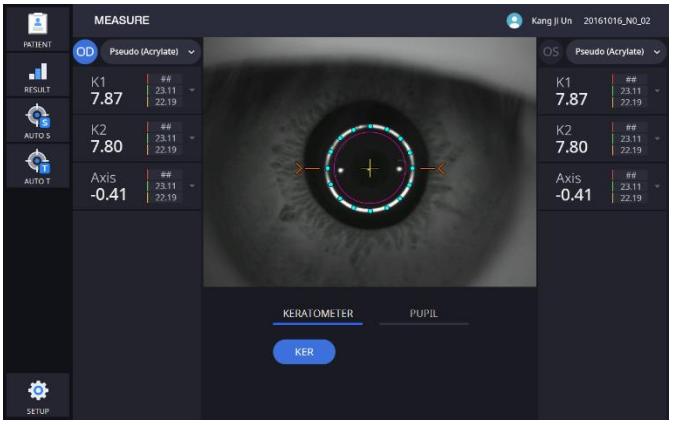
Errors in measurements can occur under one of these conditions: bad focus, closed eyelid, tear film irregularity, high standard deviation in multiple measurements, movement, measurement not in range.

6.6. Maintenance

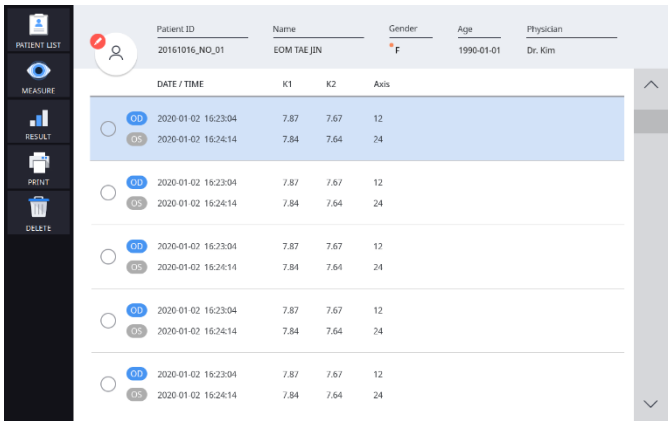
6.6.1. After operation

1. Exit software and Power off.

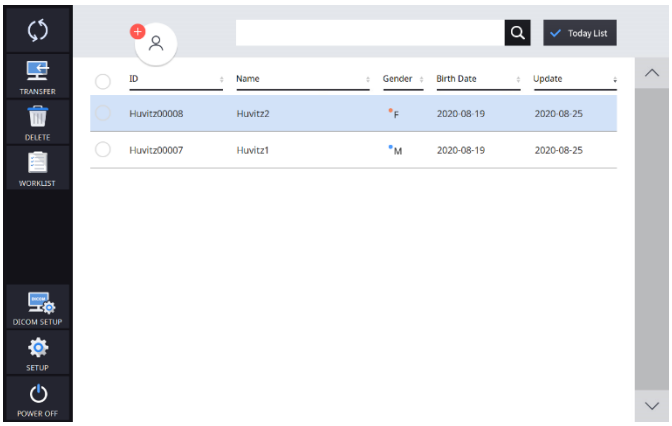
(1) Select the Patient information icon (PATIENT) in the upper left corner of the screen.



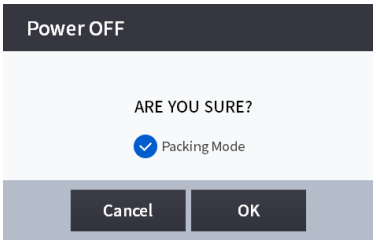
(2) Select the Previous screen icon (PATIENT LIST) in the upper left corner of the screen.



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



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



NOTE

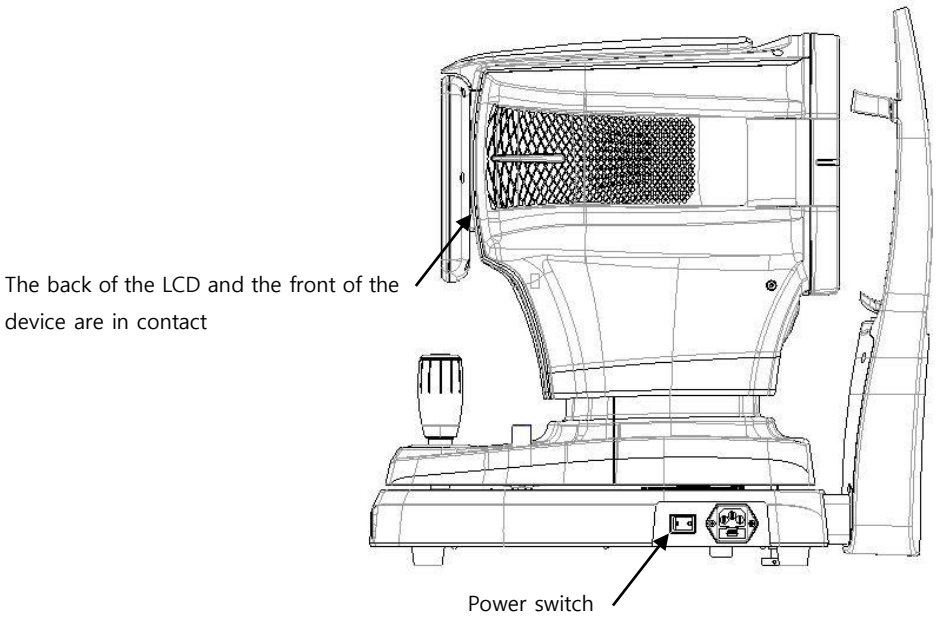
To put the device in the packing box, select Packing Mode and then press OK to finish.

NOTE

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

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

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



6.6.2. Cleaning

Risk of electric shock if the HTG-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.

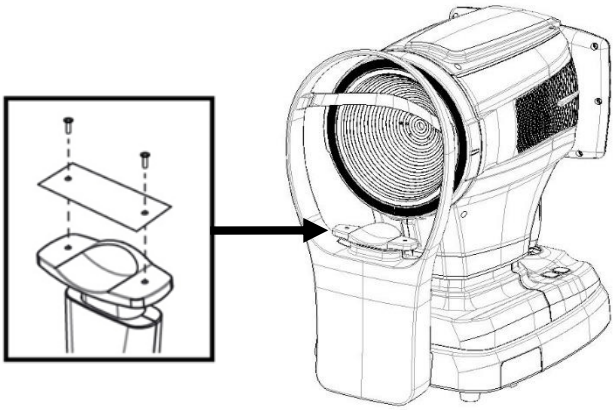
⚠ CAUTION

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 device.
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

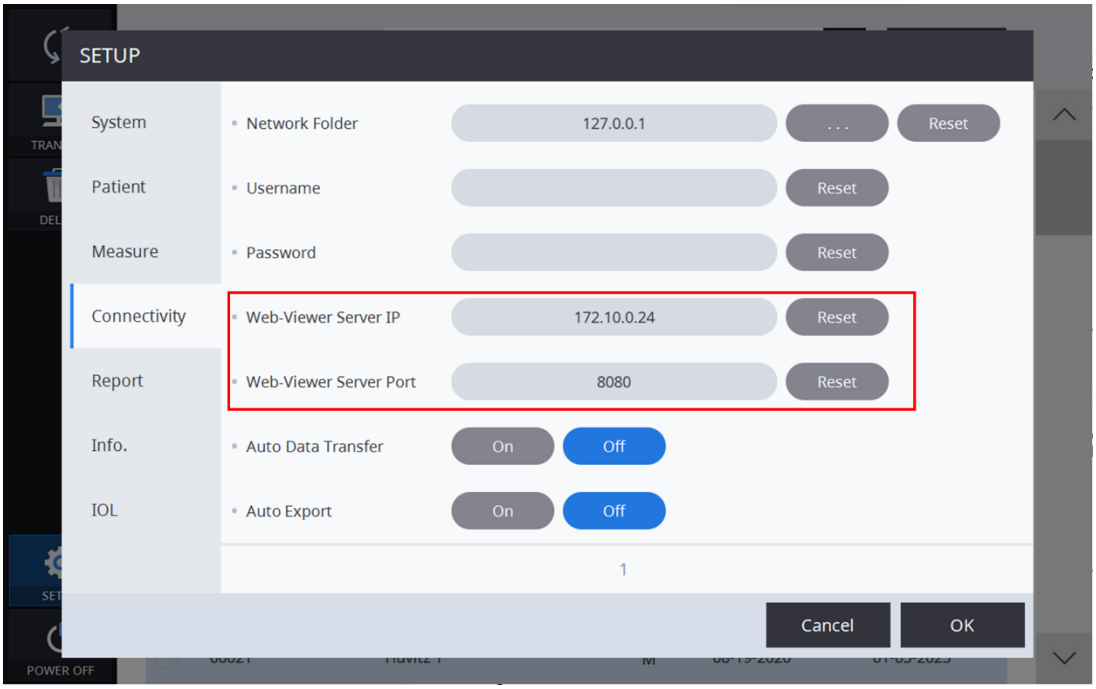
1. Replacing chinrest paper
   (1) Pull out two fixing pins from chinrest.
   (2) Put a new chinrest paper on the chinrest.
   (3) Insert two fixing pins into the chinrest paper hole.
   (4) Attach the chinrest paper to the chinrest.



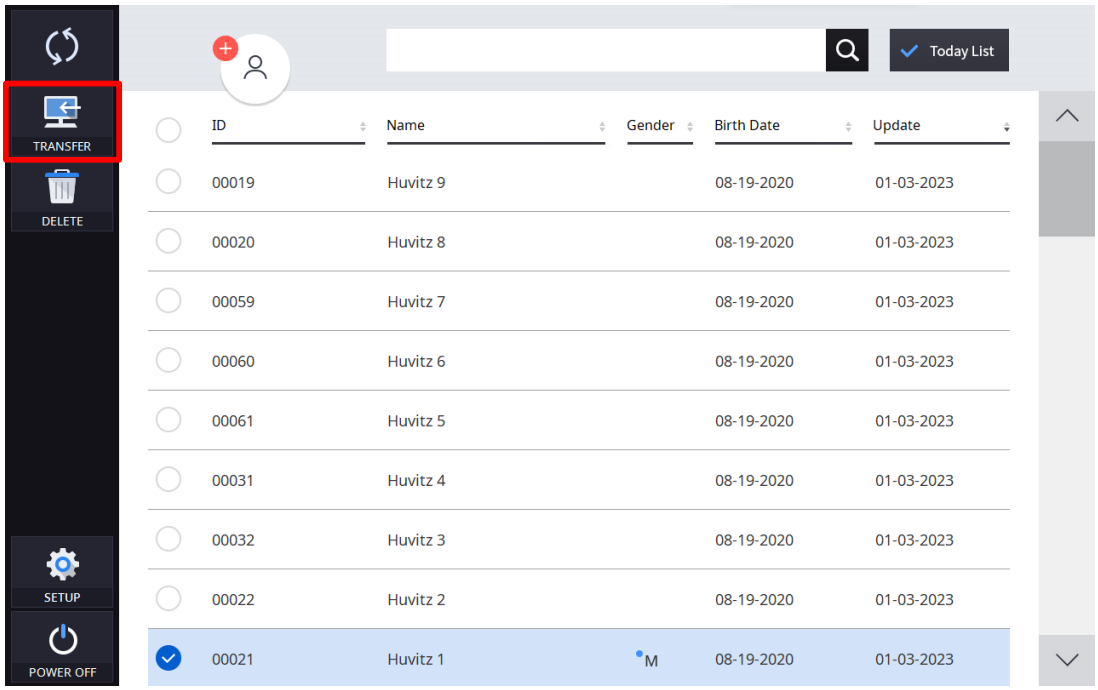
2. Replacing fuse
   (1) Ensure the power switch of device off (O).
   (2) Remove power cable from inlet.
   (3) Pull out fuse holder in the inlet with tweezers.
   (4) Replace two new fuses in the fuse holder. Be sure to check the fuse specification for the replacement (250V T 3.15AL).
   (5) Insert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

6.7. Send Data to Web-Viewer

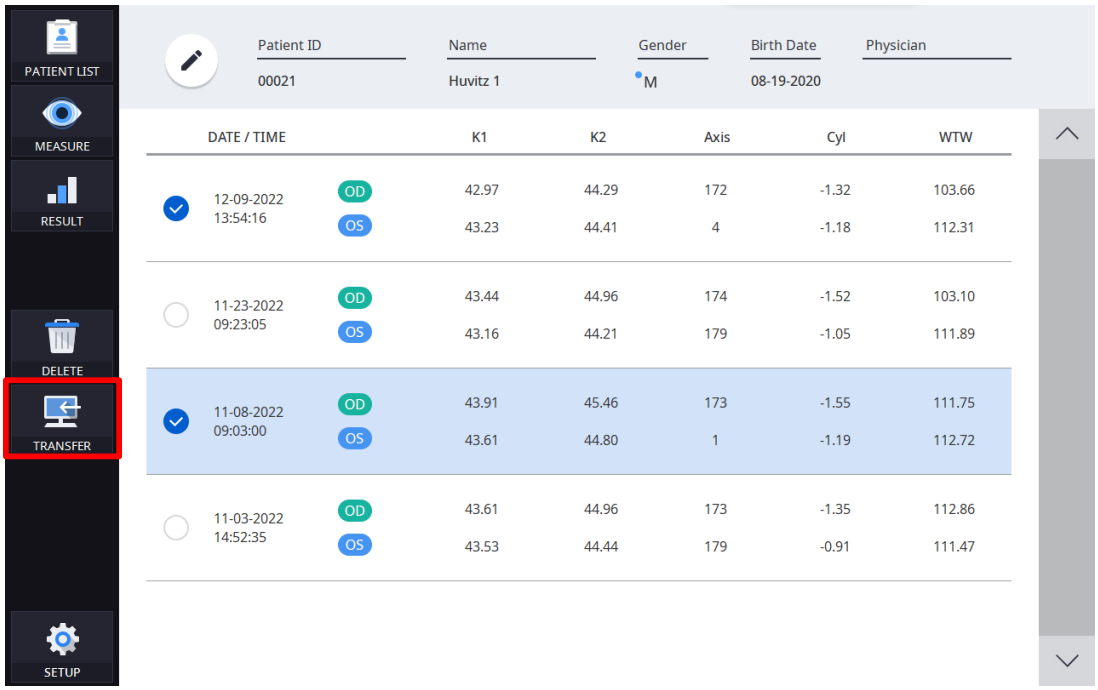
1. Fill in Server IP and Server Port information.
   (Server IP, it means local IP address, where HIS S/W program is installed. And Server Port is fixed with 8080.)



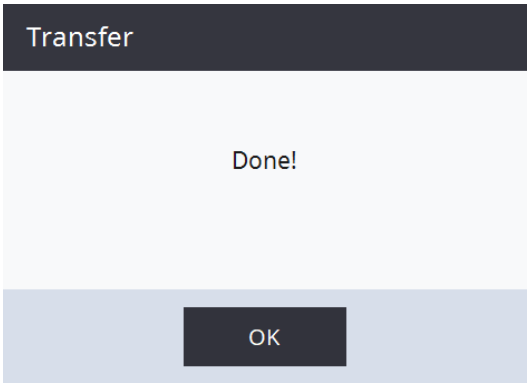
2. Select patients in the Patients List. And Clicking 'TRANSFER' button, send all of the patient data.



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



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



7

Troubleshooting Guide

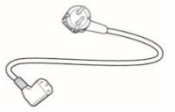
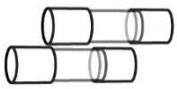
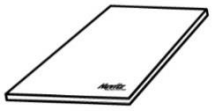
Should the device function improperly, attempt to correct the problem according to the following table before contacting sales distributors.
Contact a sales distributor after turning off the power when the device does not resume normal operation even after taking the following measures.

Problem	Cause	Solution
The screen does not turn on.	The power cable may not be connected.	Check the connection of the power cable.
	The power switch may not be turned on.	Check whether the power switch is turned on.
The screen does not turn on even though the system power is on	The system may be in sleep mode.	Restore the system from sleep mode by touching the screen.
The screen suddenly turns off		
The image of the intended part cannot be captured.	The patient may not be looking at the fixation target at the time of image capture	Instruct the patient to focus on the fixation target.
Measurement data was not available.	The patient's eyelid or eyelashes may be interfering with image capture.	Ask the patient to open their eyes wider. If the patient cannot open their eyes wider, lift the patient's lid, paying attention not to press against eyeballs.

8

Specifications and Accessories

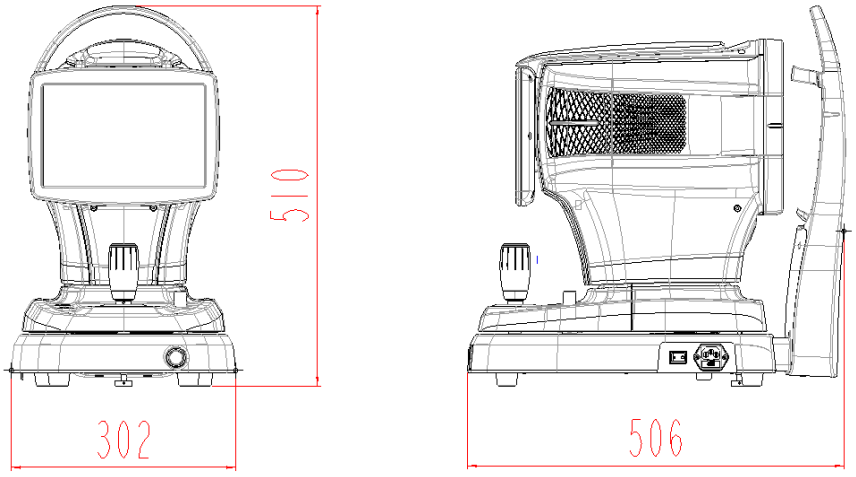
8.1. Standard Accessories

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

8.2. Specifications

Corneal Topography		
Working distance	80mm	
Placido disc	24 rings	
Keratometry		
Parameter	Measuring range	Accuracy
Corneal measurement range	Up to 9.8 mm (R = 8.0 mm, 42.2 D, n = 1.3375)	-
Corneal curvature radius	3.00 ~ 38.00 mm (9.00~ 112.5 Diopter, n = 1.3375)	±0.02mm (± 0.1D)
Direction of principal meridians	1° – 180°	According to the ISO 10343:2014 R1-R2≤0.3mm: ±4° R1-R2>0.3mm: ±2°
The accuracy and repeatability is in accordance with Type A, ISO 19980		
White-to-white distance	7 – 14mm	±0.05 mm
Pupil diameter	0.5 – 10mm	±0.05 mm
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	
Weight	21 kg	

8.3. Drawings of System



9

EMC INFORMATION

Manufacturer announcement – electromagnetic waves trouble

- **Electromagnetic waves trouble**

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

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

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

- **Electromagnetic waves tolerance**

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

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

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SERVICE INFORMATION

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

1.4 Name of Equipment Type: Corneal Topographer HTG-1
1.5 Typical No. of Equipment: Typical number consisted of 8 digits and characters written on its name plate.
1.6 Explanation on its symptom: Description in detail.

Supply of parts required for repair:

1.7 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:

1.8 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
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

■ UK Representative

Mainline Instruments

Unit 2, The Cyclo Works, Lifford Lane, Kings Norton

Birmingham, UK, B30 3DY

Tel: +44 (0)121 458 6800

Fax: +44 (0)121 458 6844

■ Switzerland Authorized Representative

MDSS CH GmbH

Laurenzenvorstadt 61

5000 Aarau

Switzerland

Email: info@mdssch.com

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