Huvitz

ENG

Auto Tono/Refracto/Kerato/Pachymeter

HTR-1A

USER MANUAL



IMPORTANT NOTICE

This product may malfunction due to electromagnetic waves caused by portable personal telephones, transceivers, radio-controlled toys, etc. Be sure to avoid having objects such as, which affect this product, brought near the product.

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

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

■ Revision History

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A	2020.01.02	이 중 재	First issued
B	21.04.16	이 중 재	Australia Representative Information Updated
C	21.09.17	이 중 재	Canada Representative Address updated, UK Representative Information Added.
D	22.06.20	이 중 재	Switzerland Representative Information Added Telephone number for all authorized representative deleted
E	22.08.08	이 중 재	Information regarding reference wavelength added Revised based on Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)
F	23.11.07	이 중 재	Added option parts : Light Shield
G	24.11.13	모 재 홍	Added the method of cleaning the nozzle window
H	25.06.23	박 준 형	Added 5GHz in the specification
I	26.02.24	이 중 재	Time limitation information was added to Section 2.1 following the Light Hazard evaluation

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1

1. SAFETY PRECAUTIONS

1.1. Overview

Safety is everyone's responsibility. The safe use of this device 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 mate riels en cas d'ignorance.

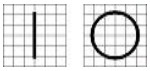
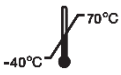
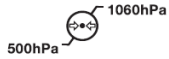
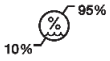
⚠ NOTE

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

2

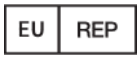
2. Symbol Information

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

Symbol	Indication
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the appropriate User's or Service Manual. (Ce symbole identifie une note de sécurité. Assurez-vous de comprendre la fonction de ce contrôle avant de l'utiliser. La fonction de contrôle est décrite dans le manuel d'utilisation ou d'entretien approprié.)
	I and O on power switch represent ON and OFF respectively. (O sur l'interrupteur d'alimentation représentent respectivement ON et OFF.)
	Temperature Limitation (Limitation de température)
	Atmospheric pressure limitation (Limitation de pression atmosphérique)
	Humidity limitation (Limite d'humidité)
	Stack direction (Direction de la pile)
	Keep DRY (Garder au sec)
	Fragile, handle with care (Fragile, manipuler avec soin)
	Keep away from sunlight (Tenir à l'écart de la lumière du soleil)
	Stack layer limit (Limiter la couche de pile)
	CE Mark (Marque CE)
	Use no hook (N'utilisez aucun crochet)



WEEE Symbol – EU only
Disposal of your old appliance
When this crossed-out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC.
All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.
The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health. For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the product.
(Symbole WEEE- EU seulement
Mise au rebut de votre ancien appareil
Lorsque ce symbole de poubelle barrée est joint à un produit, cela signifie que le produit est couvert par la directive européenne 2002/96 / CE.
Tous les produits électriques et électroniques doivent être éliminés séparément du flux des déchets municipaux via des installations de collecte désignées par le gouvernement oules autorités locales. L'élimination correcte de votre ancient appareil aidera à prévenir les conséquences negatives potentielles sur l'environnement et la santé humaine.
Pour plus d'informations sur l'élimination de votre ancient appareil, veuillez contacter votre mairie, le service d'élimination des déchets ou le magasin où vous avez acheté le produit.)



Authorized representative in the European Community – EU ONLY
(Représentant autorisé dans la Communauté européenne-EU seulement)



Manufacturer
(Fabricant)



Date of manufacture
(Il indique l'année de fabrication et le fabricant.)



Refer to instruction manual/booklet
(Se reporter au manuel d’instructions / brochure)



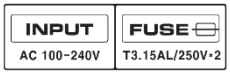
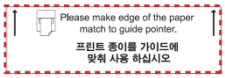
Type B Isolated patient connection
(Type B Connexion patient isolée.)



Warning: Crushing or insert of hand
(Attention: écrasement ou insertion de la main)



QR code
(QR code)

	Alternating Current (Courant alternative)
	The United States and Canada have mutual-recognition agreements. Therefore, if certified using a Canadian specification (CSA) for UL, the certification mark for the product will be a C-UL certification mark which means CSA specification compliance as follows. (Les États-Unis et le Canada ont conclu des accords de libre-échange. Par conséquent, si l'on obtient une certification au moyen d'une spécification canadienne (CSA) pour l'AMT, la marque de certification pour le produit sera une marque de certification C-UL, ce qui signifie la conformité de la spécification CSA comme suit.)
	CE for RoHS RoHS Directive Compliance 2011/65/EU (CE pour les RoHS Respect de la directive en matière de conformité 2011 / 65 / CE)
	Identifies the point where the system safety ground is fastened to the chassis. Protective earth connected to conductive parts of Class I equipment for safety purposes. (Identifie le point où la terre de sécurité du système est fixée au châssis. Terre de pro-tection connectée aux parties conductrices des équipements de classe I à des fins de sécurité.)
	COM Connector cable (COM Connector cable)
	VGA port Symbol (VGA port Symbole)
	INPUT, FUSE sticker (ENTRÉE, FUSE autocollant)
	Wi-Fi sticker (Wi-Fi autocollant)
	Print Jam Caution Sticker (Autocollant Attention Print Confiture)
	USB Sticker (USB Autocollant)
	Class I Laser Product (Produit au laser de classe I)

CH REP	Authorized representative in Switzerland (Représentant autorisé dans la Suisse)

MD	To indicate this product is Medical device (Pour indiquer que ce produit est un dispositif medical)

2.1. Usage Precautions

This equipment has been developed and tested in conformity with domestic & international safety standards and regulations, which guarantees the high stability of this product. This guarantees a very high degree of safety for this device. The legislator expects us to inform the user expressively about the safety aspects in dealing with the device. The correct handling of this equipment is imperative for its safe operation. Therefore, please read carefully all instructions before switching on this device. For more detailed information, please contact our Customer Service Department or one of our authorized representatives.

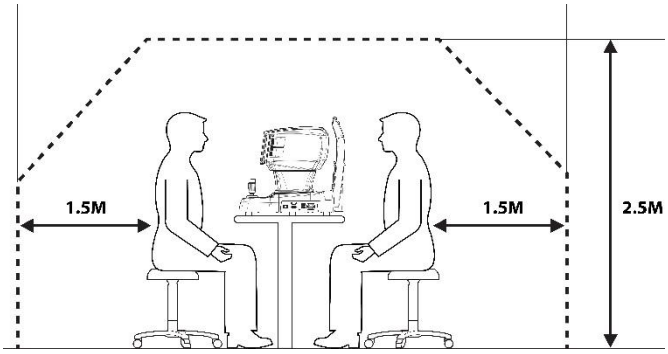
⚠ WARNING

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

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

⚠ WARNING

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



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

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

⚠ CAUTION

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

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

⚠ CAUTION

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

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

⚠ CAUTION

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

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

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

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

⚠ CAUTION

This device has been evaluated in accordance with ISO 15004-2 and is classified as Group 1 Dose Limit and Time Limit.
When used under the normal use conditions, including the specified working distance, exposure duration, and operating mode procedures as described in the instruction for use, the optical radiation exposure to the patient and the user does not pose a hazardous photobiological risk.
For the White LEDs and Blue LED light sources, the device is designed with time-limiting controls to ensure that the cumulative radiant exposure does not exceed 2.2 J/cm², which corresponds to the Group 1 dose limit.
Upon reaching 2.2 J/cm², a CAUTION notification is displayed and the LEDs are automatically power off.

- White: 300 seconds (when duty 100, single source)
- Blue: 550 seconds (when duty 100, single source)

Cet instrument a été évalué conformément à la norme ISO 15004-2 et est classé comme limite de dose et limite de temps du groupe 1.
Lorsqu'elle est utilisée dans les conditions normales d'utilisation, y compris la distance de travail, la durée d'exposition et le mode d'exploitation spécifiés dans le mode d'emploi, l'exposition optique au patient et à l'utilisateur ne présente pas de risque photobiologique.
Pour les DEL blanches et les sources lumineuses à DEL bleues, l'appareil est conçu avec des contrôles de limitation du temps pour s'assurer que l'exposition cumulative rayonnante ne dépasse pas 2,2 J/cm², ce qui correspond à la limite de dose du groupe 1.
Lorsqu'une énergie de 2,2 J/cm² est atteinte, une notification de type CAUTION s'affiche et les LED s'éteignent automatiquement.

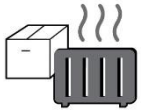
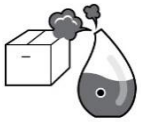
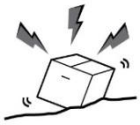
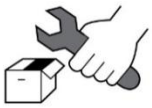
- White : 300 seconds (duty 100 %, source unique)
- Blue : 550 seconds (duty 100 %, source unique)

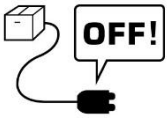
Intended User

The device must be operated by a trained and qualified person or under his or her supervision.
(e.g., doctor, ophthalmologist)

2.2. Environmental Considerations

Avoid the following environments for operation or storage**:**

	Where the instrument is exposed to water vapor. Don’t operate the instrument with wet hands Indoor use only.
	Where the instrument is exposed to direct sunlight.
	A place where the equipment can be exposed to direct ultraviolet.
	Where there are big changes in temperature. Optimal temperature range for normal operation is from 10°C to 35°C (Humidity : 30 ~ 90%).
	Where there is hot equipment nearby.
	Where the humidity is extremely high or there is a ventilation problem.
	Where the instrument is exposed to excessive shocks or vibrations.
	Where the instrument is exposed to chemical material or explosive gas.
	Be cautious so that things like dust and metal do not fall inside the instrument.
	Don’t disassemble or open the product. HUVITZ does not take responsibility for the possible problems
	Be careful not to block the fan of the instrument.



Don’t plug the AC power cable into the outlet unless all parts of the instrument are completely connected. Otherwise, it will cause severe damage on the instrument.



Pull out the power cable with holding the plug, not the cord.
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

For the normal operation of the instrument, please keep the ambient temperature is 10℃ ~ 35℃, humidity is 30% ~ 90% (with non-condensing) and atmospheric pressure is 800 ~ 1060hpa.

For the Transportation of the instrument, please keep the ambient temperature is -40℃ ~ 70℃, humidity is 10% ~ 95% and atmospheric pressure is 500 ~ 1060hpa.

For the Storage of the instrument, please keep the ambient temperature is -10℃ ~ 55℃, humidity is 10% ~ 95% (with non-condensing) and atmospheric pressure is 700 ~ 1060hpa.

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

2.3. Safety Warnings

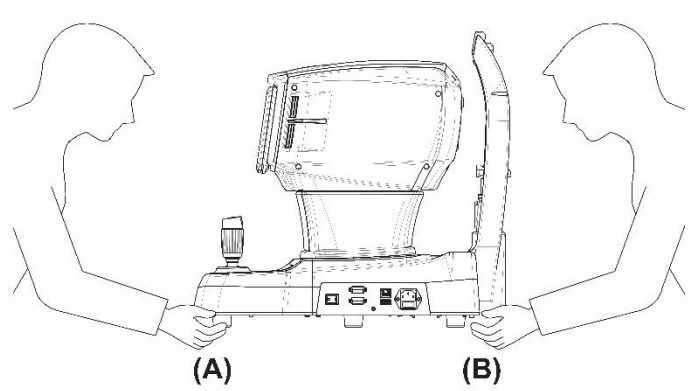
⚠ WARNING

The safety precautions and operating procedures must be thoroughly understood prior to operation of the device. The device complies with ISO 10342 subclause 4 (Ophthalmic instruments – Eye Refractometers) and ISO 10343 subclause 4 (Ophthalmic instruments - Ophthalmometers). The dioptric powers are indicated with reference wavelength λd = 546.07 nm or λd = 587.56 nm

Les précautions de sécurité et les procédures d'utilisation doivent être bien comprises avant d'utiliser l'appareil. Le dispositif est conforme au paragraphe 4 de l'ISO 10342 (Instruments ophtalmiques - Réfractomètres oculaires) et au paragraphe 4 de l'ISO 10343 (Instruments ophtalmiques - Ophtalmomètres). Les puissances dioptriques sont indiquées avec une longueur d'onde de référence λd = 546,07 nm ou λd = 587,56 nm

1. This is an electric medical device. Use is limited to doctors or persons qualified by the law of each country.
2. Do not make a diagnosis base on a single captured image. Doctors are responsible for making the final diagnosis based on the present and past medical records of the patient such as captured images. Without sufficient information, proper diagnosis may not be made.
3. This equipment must not be used in an area that is in danger of explosions and in the presence of flammable, explosive, or volatile solvent such as alcohol, benzene or similar chemicals.
4. Do not place or store this instrument in humid area. Do not expose the device to water splashes, dripping water, or sprayed water. Do not place containers with fluids, liquids, or gases on top of this instrument.
5. The device must be operated by a trained and qualified person or under his or her supervision.
6. Repair of this instrument must be conducted by HUVITZ's service technicians or other authorized persons.
7. Maintenance by users must observe the User's Manual and Service Manual. Any additional maintenance may only be performed by HUVITZ's service technicians or other authorized persons.
8. Manufacturers are not responsible for the damages caused by unauthorized alterations. Such tampering will forfeit any rights to receive services during the term of guarantee.
9. This instrument must be connected with the accessories supplied by HUVITZ. If you are to use other accessories, their safety or usability must be checked and proved by their manufacturers or HUVITZ.
10. Only those who have undergone proper training and instructions are authorized to install, use, operate, and maintain this instrument.
11. Do not apply excessive force to cable connections. If the cable does not connect easily, make sure that the connector (plug) is appropriate for the receptacle (socket). If you caused any damage to a cable connector(s) or receptacle(s), let the damage(s) be repaired by an authorized service technician.
12. Please do not pull on any cable. Always grab the plug when disconnecting cables.
13. Do not block any ventilation outlet necessary for proper heat dissipation.
14. If smoke, sparks or any abnormal noise or smell is noticed coming from the instrument, please switch the power off immediately and pull out the plug.
15. To avoid the risk of electric shock, this instrument must only be connected to protective earth.
16. Do not place the instrument where it is difficult to operate the disconnecting device. (disconnecting device: power cable)
17. External equipment intended for connection to signal input, signal output or other connectors of this instrument, shall comply with relevant IEC Standard (e.g., IEC60950 for IT equipment and IEC60601-1 series for medical electrical equipment). In addition, all such combination-system-shall comply with the standard IEC60601-1 harmonized national standard or the combination. If, in doubt, contact qualified technician or your local representative. The operator should not touch the patient and accessible male parts of the SIP/SOP connectors simultaneously.

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



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

Part Name	Material
LCD Touch pannel	Glass
Joystick / button	ABS + Silicon, Aluminum(A6061 T6)
Power switch	PC + PA66
Cover	ABS
Chin Rest	PC + 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. When using the automatic measurement mode, care should be taken to prevent the hands of the operator and the patient from touching the moving parts.

24. 



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.

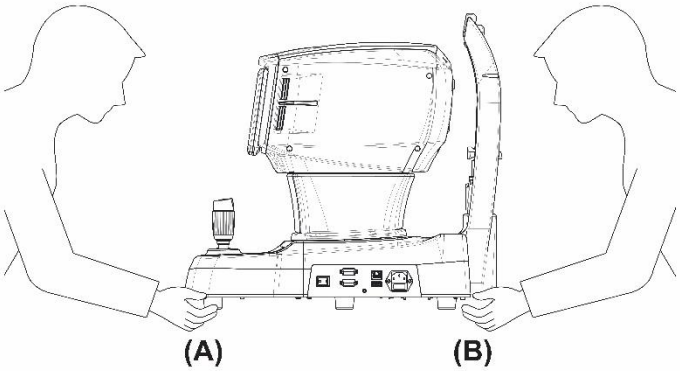
14. Si de la fumée, des étincelles ou un bruit ou une odeur anormale est remarqué provenant de l'instrument, veuillez éteindre immédiatement et débrancher la prise.

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)
Power switch	PC + PA66
Cover	ABS
Chin Rest	PC+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. Lors de l'utilisation du mode de mesure automatique, des précautions doivent être prises pour éviter que les mains de l'opérateur et du patient ne touchent les pièces mobiles.

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

7. Don't transmit data to other device or connect to other device when you find viruses in other device.

8. When this equipment is connected to the Wireless Network AP, set the wireless security type to WPA2-PSK.
   A. Access with applicable AP is not possible when other securities such as OPEN / WEP are set.
   B. The Company is not responsible for the problem that may result when accessing with the wireless network that is not secured.

9. Secure open space within 10m when it comes to the location of the wireless AP (HUB) where this equipment is to be connected.
   A. When the distance between this equipment and AP is over that of a specific distance, remove obstacle if there is obstacle, use Wireless Repeater or install additional AP (Wireless Hub) at nearby place.
   B. If there is a wireless connection, contact local technician or distributor to receive help.

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

11. 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 ITNETWORK
    5) upgrade of hardware and/or software platforms or software applications on the IT NETWORK.

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

7. Ne transmettez pas de données à un autre appareil ou ne vous connectez pas à un autre appareil lorsque vous trouvez des virus sur un autre appareil.

8. Lorsque cet équipement est connecté au point d'accès du réseau sans fil, définissez le type de sécurité sans fil sur WPA2-PSK.

A. L'accès avec le point d'accès applicable n'est pas possible lorsque d'autres sécurités telles que OPEN / WEP sont définies.
B. La Société n'est pas responsable du problème qui peut survenir lors de l'accès avec le réseau sans fil qui n'est pas sécurisé.

9. Sécurisez un espace ouvert à moins de 10 m en ce qui concerne l'emplacement du point d'accès sans fil (HUB) où cet équipement doit être connecté.

A. Lorsque la distance entre cet équipement et le point d'accès est supérieure à une distance spécifique, retirez l'obstacle s'il y a un obstacle, utilisez un répéteur sans fil ou installez un point d'accès (concentrateur sans fil) supplémentaire à proximité.
B. S'il y a une connexion sans fil, contactez un technicien ou un distributeur local pour recevoir de l'aide.

10. 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.

11. 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.

3

3. INTRODUCTION

3.1. System Outline

HTR-1A is an Auto Tono/Refracto/Kerato/Pachymeter that is intended use to measure the intraocular pressure of the patient's eye with less than 3 diopters of corneal astigmatism. Also, It is intended use to measure the refractive power, corneal curvature radius and central cornea thickness of the patient's eye.

Automatic eye examination refractive power, intra ocular pressure and central corneal thickness measurement device, HTR-1A is the equipment that measures refractive power of the test subject's eyeball to show Sphere (SPH), Cylinder (CYL) and Axis (AXS) information. Moreover, it can measure test subject's corneal curvature and PD (Purpillary Distance, distance between pupils) and pupil's size. In particular, it is possible to measure Peripheral Corneal Curvature separately when measuring corneal curvature, and it enables accurate prescription since it is possible to know the information of the cornea's center and periphery curvature individually. And also the HTR-1A can measure the intra ocular pressure(mmHg/hPa) and the corneal thickness of the human eye(μm).
Moreover, optimal eye examination information is provided depending on the state of test subject's eyes with the fol lowing other functions that are provided additionally.

- Color image observation
- Light observation with Retro-Illumination
- Abnormal curve state output via Zernike graph
- Tear film destruction time measurement
- Meibomian gland filming function

Automatic eye examination refractive power measurement device, HTR-1A carries out full automatic arrangement to the X-Y-Z axes (left and right/up and down/front and back) direction according to pupil to the location optimized for filming including pupil's automatic tracking function.

3.2. Intended Use

Auto Tono/Refracto/Kerato/Pachymeter, HTR-1A is a medical device which measures refractive power, corneal curva ture radius, intraocular pressure and corneal thickness of the patient's eye

3.3. Classification

- Classification of Product: Class IIa according to Medical Device Regulation 2017/745 (MDR) Annex VIII Rule 10
- Resistance against electric shock: Class I (earthed)
- Protection class against electric: Type B(headrest, chinrest paper)
- Classification of Laser Product: Class 1 (laser based on IEC 60825-1 Standard)
- Classification of Light hazard: Group I (EN/ISO15004-2 Standard)
- Protection against harmful ingress of water: Ordinary, IPX0
- Degree of safety in the presence of a flammable anesthetics mixture with air or with oxygen or with nitrous oxide: Not suitable for use in the presence of a flammable anesthetics mixture with air or with oxygen or with nitrous oxide.
- Mode of operation: Continuous

3.4. Contraindications

This device should not be used for:
- Patients who cannot maintain a relaxed position.
- Patients who had corneal surgery including corneal laser surgery and subjects with corneal scarring
- Do not measure to patients who are sensitive to light. (ex> photophobia)

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 Autheorized 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

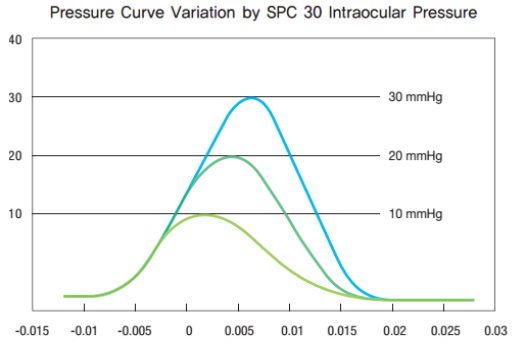
3.6.1 Tonometry

Based on the Imbert-Fick principle (W = Pt × A), the intraocular pressure is calculated by dividing the amount of air pressure into the area of applanated surface.

The device increases the air pressure puffed onto the cornea in proportion to time. The shape of the cornea changes gradually in the order of convex surface ⟶ applanated surface ⟶concave surface. This change is optically detected and the device calculates the time required to make the pressed area flat after air is puffed on it. The air pressure used to make the cornea flat is calculated by time, and finally the intraocular pressure is obtained.

3.6.2 SPC (Smart Puffing Control) function

The intraocular pressure measurement is performed with the air pressure as low as possible. When the measurement range is set to “SPC 30” or “SPC 60”, in the first measurement, the Auto Complete function, which stops puffing air as soon as the light reflected from the cornea is detected, activates in order to eliminate excessive puffing. This function contols the intensity of the air puffing according to the patient’s intraocular pressure, so the patient feels more soft and comfotable.



3.6.3 Pachymetry

The corneal thickness is optically measured in a non-contact method. The corneal thickness measuring beam(Infrared light) projected diagonally on the cornea is reflected from both the epithelial surface and endothelial surface. The different paths of reflected light are detected by the Camera. The corneal thickness is calculated from the distance between the paths of the epithelial reflection and endothelial reflection on the Camera.

3.6.4 Refractive power measurement

1) Light beam from the source is incident on the examinee’s eye and reflected from it’s retina.
2) According to the refraction condition of the examinee’s eye, that is, if the examinee’s eye is emmetropia, hyperopia or myopia, the reflected light from the retina is parallel to the optic axis of the eye, diverge or converge, respectively.
3) The light beam reflected from the examinee’s eye will be relayed by the lens and mirror, divided by the prism with aperture and then imaged on the TV camera as lens array bright spots.
4) From the Ellipsoidal Fitting of the coordinates of lens array bright spots captured by TV camera, the values of SPH, CYL and AX of eye can be derived.

3.6.5 Corneal curvature radius measurement

1) Corneal curvature radius measurement

The image of the mire ring projected on the patient’s cornea is captured and used for computation to determine the corneal curvature radius(refractive power) and the principle meridian direction.

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

- IEC/EN 60825-1: Safety of laser products- Part 1: Equipment classification and requirements

- 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 8612: Ophthalmic instruments - Tonometers

- ISO 10342: Ophthalmic instruments - Eye refractometers

- ISO 10343: Ophthalmic instruments - Ophthalmometer

4

4. System Overview

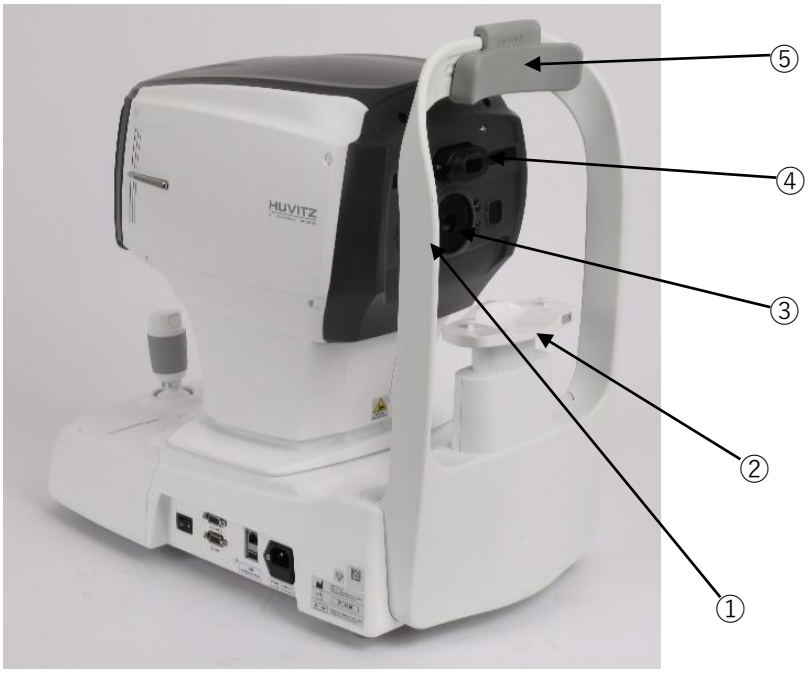
4.1. Configuration and Functions

External appearance



[Front part]

① **LCD Touch Screen:** display user interface and the result of measurement
② **Measurement Button:** A button pressed on to measure
③ **Joystick Lever (Operation Lever):** A lever for moving object to the front and back, left and right, and up and down
④ **Printer Open Button:** A button pressed on to open printer
⑤ **Printer:** Printing the measured results
⑥ **Operation Lamp:** Indicates whether or not the electric power is on



[Back part]

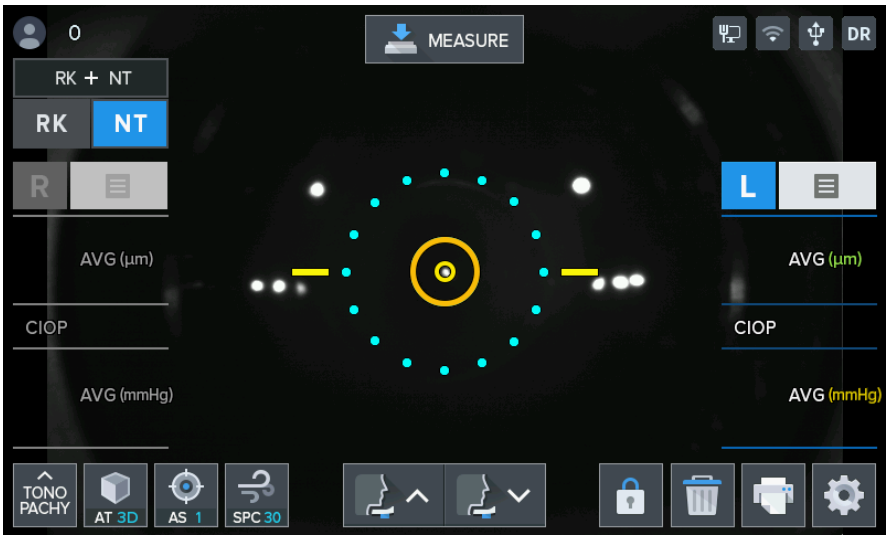
① **Height Adjustment Mark:** Adjusts the eyes` height of examinees.
② **Chinrest:** Preventing the vibration by fixing the chin.
③ **Measuring window:** Measuring the Refractive power and Corneal radius
④ **Air Nozzle:** Measuring the intraocular pressure on eyes**.**
⑤ **Forehead Rest:** Preventing the vibration by fixing the forehead.

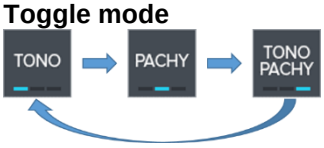
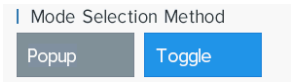
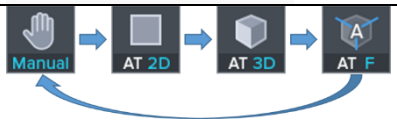


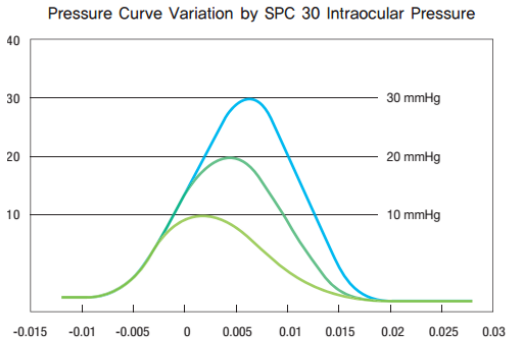
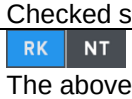
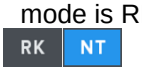
① **Power Switch:** Switch for power on/off.
② **RS-232C port:** Port for communicating external device.
③ **RGB port:** Port for external display device.
④ **LAN port:** Port for external network**.**
⑤ **USB port:** Port for Engineer only.

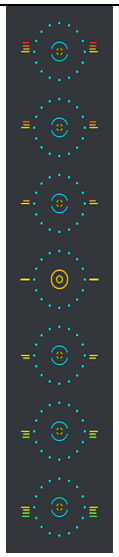
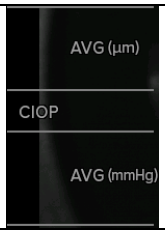
4.2. GUI interface

4.2.1. NT measurement screen



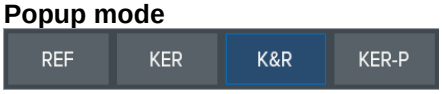
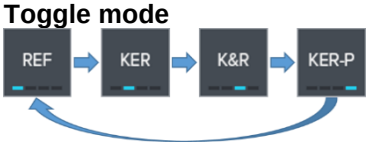
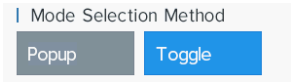
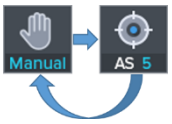
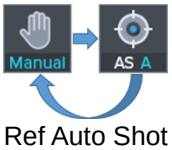
#	Symbol	Name	Function	Mode change
①		NT measurement mode	A popup button(or a toggle button according to the user setting) that enables to select tono, pachy and tono/pachy mode.	**Popup mode**  This popup menu appears after pressing the NT measurement mode button. Then the user is able to select mode. **Toggle mode**  ※ **Popup/toggle setting** User setup→MSR COMMON→Mode Selection Method 
②		Tracking mode	A toggle button that changes the Tracking mode for a measurement (MT/AT2D/AT3D/ATF)	 *Manual: Manual Tracking *AT2D: Auto tracking in the right and left, up and down directions are active *AT3D: Auto tracking in the forward and backward, right and left, up and down directions are activated *ATF: Full tracking. AT3D tracking features are activated plus support auto movement to the OD/OS and NT/RK measurement mode
③		Shot mode	A toggle button that changes the Shot mode for a measurement	 *AS1: Auto shooting 1time *AS3: Auto shooting 3times

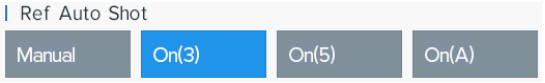
④		SPC mode (Smart Puffing Control)	A toggle button that changes the SPC mode for measurement range (SPC30/SPC60/30/60) The intraocular pressure measurement is performed with the air pressure as low as possible. When the measurement range is set to “SPC 30 or SPC 60”, in the first measurement, the automatic shutoff function, which stops puffing air as soon as the light reflected from the cornea is detected. Activates in order to eliminate excessive puffing.	 *30: The peak of the air pressure is fixed within the range of 1 to 30 mmHg *60: The peak of the air pressure is fixed within the range of 1 to 60 mmHg *SPC30: The peak of the air pressure is automatically controlled within the range of 1 to 30 mmHg *SPC60: 60mmHg or more of intraocular pressure. 
⑤		Chinrest Up/Down button	Move up or down the chinrest	
⑥		Safety lock button	A button that enables to set the z-axis position for safety of a patient to prevent the nozzle touching the eye	
⑦		Clear Button	A button that clears the measurement data	
⑧		Print Button	A button that prints the measurement data	
⑨		Setting Button	A button that allows to move to the User Set-up mode	
⑩		RK/NT mode Button	A toggle button that selects the RK/NT mode	 Normal state indicates not RK/NT mode  Checked state indicates RK/NT mode
⑪		RK/NT mode Buttons	Toggle buttons that select the current mode exclusively	 The above image indicates the current mode is RK mode  And This image indicates the current mode is NT mode
⑫		R/L side Buttons	Buttons allows to move the head to the left and right side	

⑬		Result Buttons	These buttons that allows to move to the result page and display all measurement data on the screen	
⑭		Measure Button	A button that measures the current mode	If the tracking mode is ATF(full tracking), this button is displayed with following image  And it works as a trigger for the full tracking mode
⑮		Patient Number (Counter)	This shows the patient measurement number	
⑯		Connection Status	These show the connection status of Ethernet, wifi, usb and phoropter(HDR series)	
⑰		Focus Indicator	Optimal measurement state. - It indicate 7 steps	
⑱		Measurement Data	Display the IOP data, CIOP, IOP average and CCT	*IOP: Intra Ocular Pressure *CIOP: Compensated Intra Ocular Pressure *CCT: Central Cornea Thickness

4.2.2. RK measurement screen



#	Symbol	Name	Function	Mode change	HAZARD ID
①		RK measurement mode	A popup button(or a toggle button according to the user setting) that enables to select REF, KER, K&R and KER-P mode.	**Popup mode**  This popup menu appears after pressing the RK measurement mode button. Then the user is able to select mode. **Toggle mode**  **※ Popup/toggle setting** User setup→MSR COMMON→Mode Selection Method 	
②		RK measurement mode	A toggle button that changes the Shot mode for a measurement	 Ref Auto Shot On(3)  Ref Auto Shot On(5)  Ref Auto Shot On(A) **※Ref Auto Shot setting** User Setup→MSR COMMON→Ref Auto	

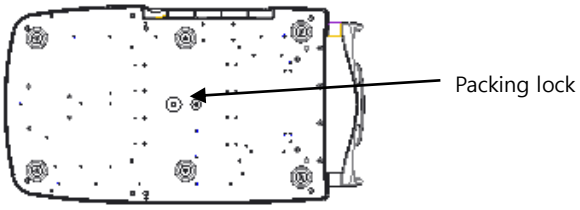
				Shot 	
③		Menu Button	A button that displays the menu for the extra features	 The menu for the extra features are displayed in the center of the screen	
④		Cylinder Button	A button that reverses the sign of cylinder values(+ → -, - → +)		
⑤		VD Button	A button that changes VD to one of the following set-up value	**※VD setting** User Setup→REF→VD 	

5

5. Installation Procedure

5.1. System installation

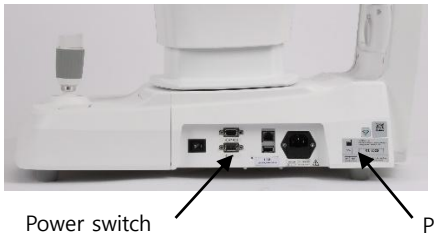
1. Place the main body unit on a stable table.
2. Loosen the packing lock screw under the main body.



3. Attach the chinrest paper to the chinrest.



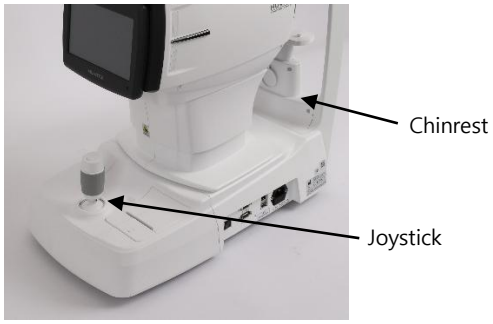
4. Check the power switch on the bottom right of base is off. (O position).
5. Connect power cable to power inlet. Also, connect the other side of power cable to electric outlet.



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



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



6

6. Practical training via Model Eye

1. Turning the main body's power ON

- Connect the power code appropriately as shown on the diagram on the side.



[Figure 6-1. Connect power cable]

- Turn on the power switch.
- Axis measurement screen appears when system check is completed.

2. Model Eye installation

Remove chin rest page, and fit in the pressing pin after aligning the hole at the Model Eye's lower part with chin rest's hole.



[Figure 6-2. Model Eye installation]

3. Convert to REF/KER mode or TONO/PACHY mode

Decide which measurement to perform whether REF/KER or TONO/PACHY by pressing 

buttons.

The current selected mode is displayed with blue painted button 

.

4. Convert to K&R, REF mode

If the current measurement mode is not set as “K&R” or “REF” on the monitor, change the mode setting so that the device can operate with one of the two.

5. Measurement location and focusing

A. REF/KER mode location and focusing

- Lean the operation lever towards the Model Eye until Mire Ring appears near the outer side arrangement ring.
- Focus so that the Mire Ring and outer side arrangement ring become the concentric circle while watching the monitor.
- Adjust the Mire Ring’s focus so that the inner side arrangement ring gets focused with the symbol for focusing.

1. Height adjustment: Turn the operation lever or adjust the chin rest’s height adjustment button.

2. Left and right adjustment: Lean the operation lever to the left and right and fit so that the outer side arrangement ring and Mire Ring become the concentric circle.

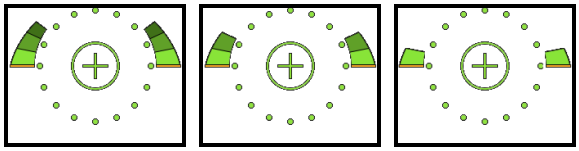
3. Focus adjustment: Adjust the focus so that the inner side arrangement ring becomes the symbol for focusing with the operation lever as the front and back.

- Automatic tracking function

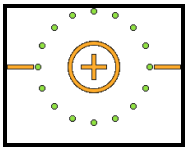
  Set the AF mode as AF to use the automatic tracking function.

  1. Use joystick to operate automatic tracking function, and move the main body so that the pupil is placed within the automatic tracking scope.
  2. When the pupil is placed within the automatic tracking scope, adjust the measurement location and focus by arranging automatically so that the proper measurement can take place by tracking the pupil’s center automatically.

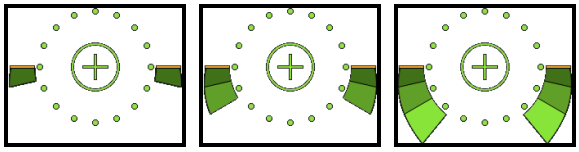
State that is too close to the eyes



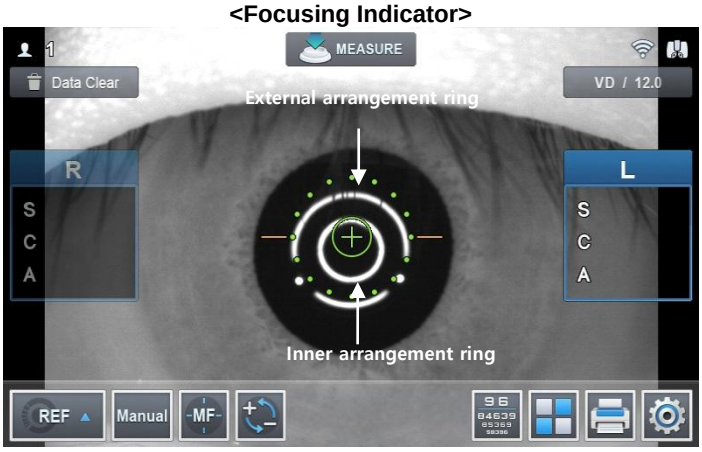
Location of accurate focus



State that is too far from the



<Focusing Indicator>



[Figure 6-4. Measurement location and focusing in REF/KER mode]

B. TONO/PACHY mode location and focusing

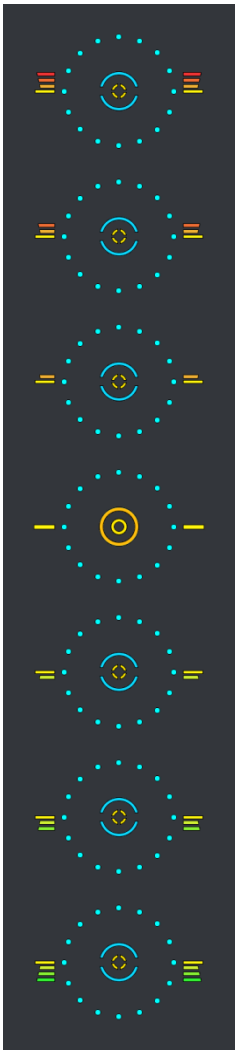
- Lean the operation lever towards the Model Eye until the external leds appear near the Eye.
- Focus so that the aim led and external leds are on position.

1. Height adjustment: Turn the operation lever or adjust the chin rest's height adjustment button.

2. Left and right adjustment: Lean the operation lever to the left and right and fit so that the aim led and external leds are on position.

3. Focus adjustment: Adjust the focus so that the focus indicator becomes the symbol for focusing with the operation lever as the front and back.

4. Focus indicator is divided into 7 steps by focus position.



→ Too close to the patient`s eye

→ Move the joystick lever to the operator side to move the main body away from the patient`s eye.

→ Optimal state

→ Move the joystick lever to the patient side to move the main body close to the patient`s eye.

→ Too far from the patient`s eye

NOTE

Model eye check shall be performed every 6 months. If you find maintenance of accuracy, please refer to 100 page, Section 10.3 Accuracy.

For maintenance details, contact Huvitz or your distributor. If maintenance cannot be performed by the user, request assistance from Huvitz or your distributor.

6. Measurement

① Manual measurement

① Carries out measurement location and focusing process for Model Eye.
② Press on the measurement switch. If measurement does not take place while the TRY AGAIN message gets output on the screen's lower part once again, repeat the process of 1 and press on the measurement switch once again.
③ Check whether proper measurement is taking place after comparing the diopter value and actual value measured that are recorded on the Model Eye's left side or right side. If the measurement value is not satisfactory, measure and re-check using the same method.

② Automatic measurement

①Set as AUTO mode by pressing on the MANUAL button located at the monitor's lower part.
②Carry out measurement location and focusing process for Model Eye.
③Outer side arrangement ring and Mire Ring become the concentric circle, and measurement starts when the Mire Ring is clear, and when the inner side arrangement ring changes into symbol for focusing.

7

7. Measurement

1. Turn on the power switch.
   When system check is over, the following figure type of measurement screen appears on the monitor screen.

2. Check the measurement screen that appears on the monitor.

NOTE

If the measurement screen that is shown below does not appear on the monitor screen, turn off the power and turn on the power switch on again after 10 seconds. If the measurement screen does not appear, contact the Huvitz's distributor.

3. Check the user Setup mode.
   Check and select various functions related to measurement including VD value or printer conditions. Print any message that you want to print along with the measurement data (refer to "user Setup mode" part).

WARNING

When the following type of situation results, turn off the power switch immediately. Then, contact the Huvitz's distributor after pulling out the power code from the AC power connection part.

- When smoke is detected from the equipment or when strange smell or sound is heard.
- When liquid was accidentally poured on the equipment or when a metallic material was dropped into the equipment
- When equipment was dropped or when external appearance was damaged.

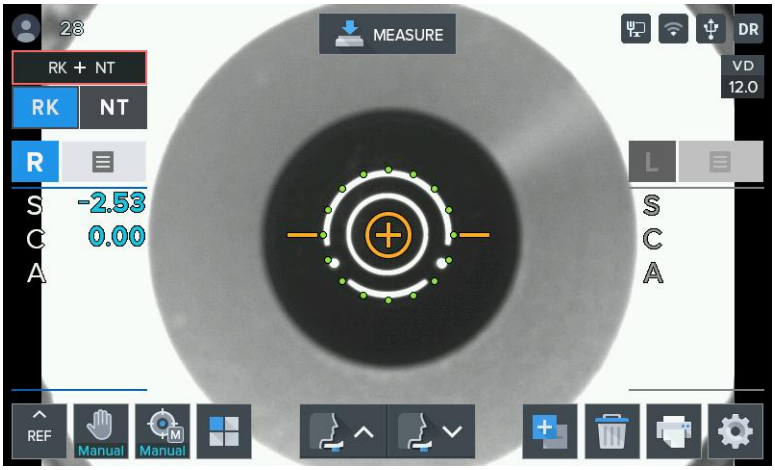
Lorsque le type de situation suivant se produit, coupez immédiatement l'interrupteur d'alimentation. Ensuite, contactez le distributeur du Hu-vitz après avoir retiré le code d'alimentation de la partie de connexion d'al mentation CA.

- Lorsque de la fumée est détectée dans l'équipement ou lorsqu'une odeur ou un son étrange se fait entendre.
- Lorsque du liquide a été accidentellement versé sur l'équipement ou lorsqu'un matériau métallique a été déposé dans l'équipement
- Lorsque l'équipement est tombé ou lorsque l'apparence extérieure a été endommagée.

7.1. Refractive power measurement mode (REF mode)

This is the mode that measures refractive power by itself.

- REF mode selection: Set in a way that the measurement mode indicator section on the screen turns into “REF” mode.



[Figure 7-1. REF mode screen]

7.1.1. Manual measurement mode

The mode gets converted to manual measurement mode when you press on the Auto button while in the automatic measurement mode. It is possible to stop automatic measurement function when “Auto Measurement” category is selected as “OFF” while in the user Setup mode. (Refer to “user SETUP mode” part)

① Eye height adjustment.
-. Have the test subject sit at the front part of the device

⚠ CAUTION

Do not have the test subject place his or her hand or finger on top of the chin rest’s lower part. Hand or finger may get injured.

Cleanse forehead rest with solvent such as ethanol every time the test subject changes to prevent infection.

Replace chin rest paper every time the test subject changes to maintain cleanness.

Ne laissez pas le sujet du test placer sa main ou son doigt sur la partie inférieure de la mentonnière. Une main ou un doigt peut se blesser.

Nettoyez le repose-front avec un solvant tel que l'éthanol à chaque fois que le sujet testé change pour éviter les infections.

Remplacez le papier de la mentonnière à chaque changement de sujet pour maintenir la propreté.

-. Adjust device’s electric table or chair’s height so that the patients can sit comfortably.



[Figure 7-1-1. eye height adjustment]

-. Have the test subject place his or her face on the chin rest and have the front of the forehead attached close to the forehead rest.

-. Turn the height adjustment lever so that the height of the test subject's eyes will be aligned with the height arrangement cover as shown on the figure.

② Measurement location and focusing

⚠ CAUTION

Do not place your hand or finger in between stage and Base. Moreover, avoid having the test subject place his or her hand or finger either. Hand or finger may get injured.

Ne placez pas votre main ou votre doigt entre la scène et la base. De plus, évitez de faire placer le sujet ou la main ou le doigt. La main ou le doigt peuvent se blesser.

-. Use the operation lever to pull up the main body to the front of the user.

-. Adjust to the left and right while pulling the operation lever to the front slowly so that the test subject's right eyes appear at the monitor screen's center. At this time, ensure that the shining Mire Ring and outer side arrangement ring becomes concentric circle.

-. Ask the test subject to watch the fixating target at the inside.

-. Adjust the focus so that the Mire Ring's outline becomes clear. When the focus is adequate, Circle symbol appears at the inner side arrangement ring.

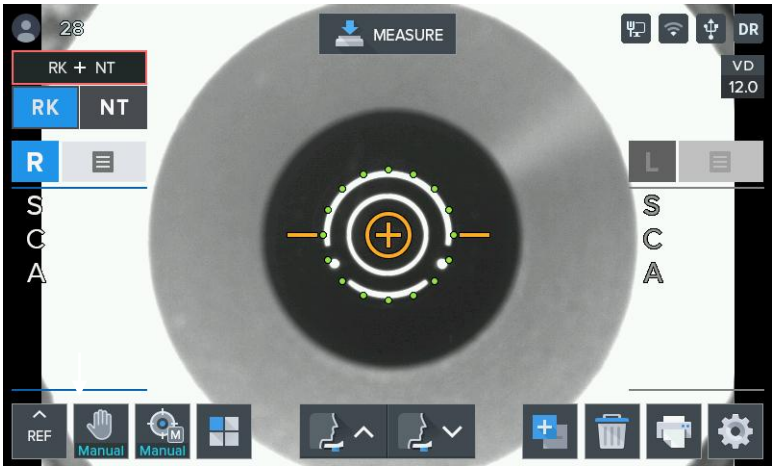
-. Height adjustment: Adjust by turning the operation lever or by pressing on the chin rest adjustment button.



[Figure 7-1-2. Height adjustment]

-. Left and right adjustment: Lean the operation lever to the left and right to adjust so that the outer side arrangement ring gets aligned to the Mire Ring's location.

-. Focus adjustment: Lean the operation lever, front and back to adjust the focus so that the Mire Ring becomes clear.



[Figure 7-1-3. REF manual measurement mode screen]

NOTE

If trying to adjust by leaning the operation lever is not sufficient, adjust by pushing the stage to the front, back, left and right.
When carrying out refractive power measurement continuously, then there may be margin of error when it comes to measurement in case of the test subject that finds intervention of accommodation force easy.
Measurement margin of error may result when the Mire Ring and outer side arrangement ring fails to maintain same axle during continuous measurement.

③ Measurement

-. Press on the measurement button.

-. Measurement is carried out continuously when measurement button is pressed on continually.

-. Measurement result is indicated on the monitor when measurement is completed.

-. Previous measurement result is indicated when carrying out continuous measurement.

④ Repetitive measurement

-. Measure repeatedly according to need.

-. The latest measurement value is indicated every time measurement takes place.

-. Up to 10 measurement frequencies (excluding measurement failure) are indicated for each of the eyes on the left and right. It is possible to see up to the 10 latest measurement values on the DISPLAY mode's screen.

⑤ Measurement of the opposite eyes.

-. Measures the left eyes while pushing the stage to the right side while holding the operation lever.

-. PD value (distance between pupils, Pupillary Distance) gets indicated on the monitor when the left and right eyes are measured.



[Figure 7-1-4. Screen indicating distance between pupils]

⑥ Printing

-. Print measurement result by pressing on the print button.

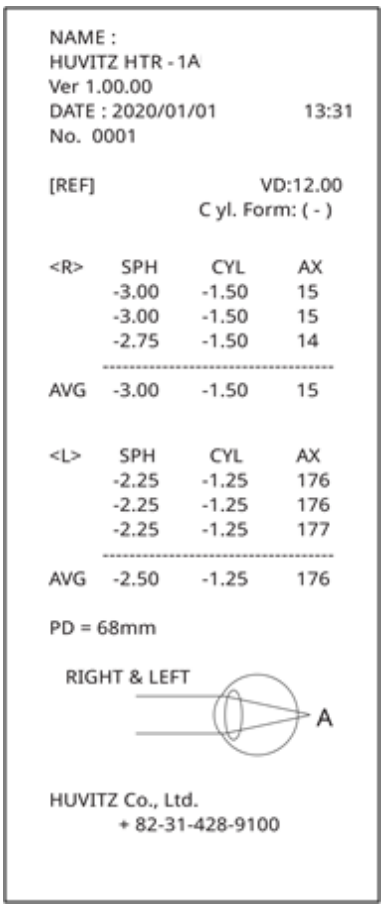
-. Contents selected from the user Setup mode get printed. (Refer to “user Setup mode” part)

-. Cut out the printing page.

-. Input the test subject’s name in the name space according to need.

NOTE

Value measured until now is removed when printing is carried out.
Printed text changes in a light manner since print is a thermal record. Copy when you want to keep measurement data for a long time.



[Figure 7-1-5. Example of a printed page]

7.1.2. Automatic measurement mode

The mode gets converted to automatic measurement mode when MANUAL button is pressed on while in the manual measurement mode.
While in the automatic measurement mode, measurement is carried out automatically even when the measurement button is not pressed on when the state reaches a state in which arrangement in the device and measurement is realized effectively.

① (Eye height adjustment), (measurement location and focusing) process is carried out just like the manual measurement mode.

② Measurement
-. Measurement is carried out automatically when the location arrangement and focusing are completed.

-. Value for new measurement result appears on the monitor screen after measurement takes place up to the frequency (possible to select among three, five and continuous) designated on the user Setup mode.

-. Up to 99 measurement frequencies are indicated and it is possible to check the measurement values up to the latest 10 times once again in the Display mode.



[Figure 7-1-6. REF automatic measurement mode indicator screen]

③ Measurement of the other eye.

-. Move the stage to the right side to measure the left eye using the same procedure.

-. When the measurement of the two eyes is complete, PD value is indicated on the monitor screen automatically.

④ Printing

-. Measurement result gets printed automatically when the measurement of the two eyes gets completed when the A-PRT category was selected as “ON” while in the user Setup mode.

-. Print by pressing on the print button when only one eye was measured or when the A-PRT category was selected as “OFF”.

-. Gets printed along with the message input while in the user Setup mode with the measurement data.

Refer to the following explanation when you see TRY AGAIN.

When TRY AGAIN message appears	Measures
Defective location fitting	Arrange the pupil's location more accurately, and measure
When eyelids or inner eyelashes block the pupil	Measure by asking the test subject to open the eyes wide, or by pushing up the upper eyelids.
When the pupil is smaller than the Alignment Ring	minimum pupil diameter that this device can measure is 2.0 ㎜. It is possible to measure at a bright place as well, but ensure that the eyes for testing are not exposed directly to the bright illumination or solar light to prevent pupil's contraction.
When you have complication such as cataract	Some cataracts can be measured in the Retro-Illum mode. Measure in the Retro-Illum mode when you are concerned that the measurement error may result due to the cornea's scratch or eye lens's turbidity. Measure cataract patients' corneal curvature while at the KER measurement mode instead of the K&R measurement mode.
When the Mire Image is visible as tears	Measure after having the eyes flicker a number of times.
When mire Image is not clear since cornea is dry	
When Mire Image was modified in an irregular manner due to the strong irregular astigmatism or cornea complication	Cannot measure.
When measurement range is deviated from	

7.2. Corneal curvature measurement mode (KER mode)

This is the mode for measuring the radius of cornea's curvature on its own.

-. KER mode selection: Set so that the measurement mode indicator section on the screen becomes "KER" mode.

7.2.1. Manual measurement mode

① Carry out the (eye height adjustment), (measurement location and focusing) process using the same method as that of the 7.1.1 refractive power measurement mode.

② Measurement

-. Press on the measurement button.

-. Measurement is carried out continuously when measurement button is pressed on continually.

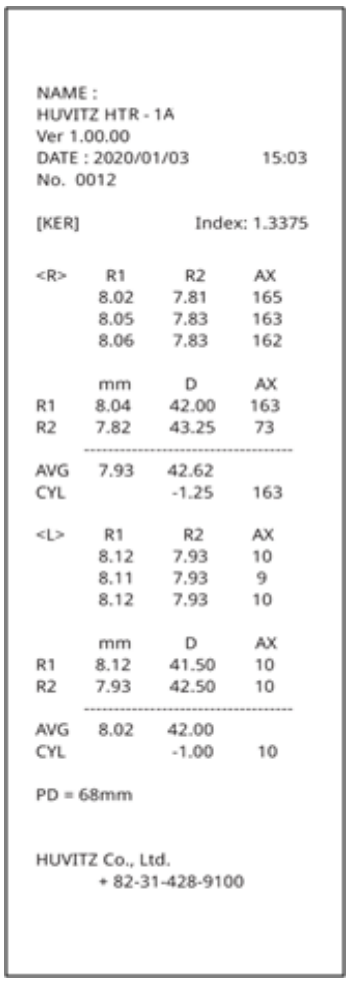
-. Measurement result is indicated on the monitor when measurement is completed. The most recent measurement result is indicated when continuous measurement is taking place.



[Figure 7-2-1. KER mode indicator screen]

③ Carry out the process using the same process as that of the (repetitive measurement), (measurement of the opposite eyes) in the 7.1.1 refractive power measurement mode.

④ Print the measurement result using the process that is like the (printing) process while at the 7.1.2 refractive power measurement mode.



NAME :
HUVITZ HTR - 1A
Ver 1.00.00
DATE : 2020/01/03 15:03
No. 0012

[KER] Index: 1.3375

<R>	R1	R2	AX
	8.02	7.81	165
	8.05	7.83	163
	8.06	7.83	162

	mm	D	AX
R1	8.04	42.00	163
R2	7.82	43.25	73
AVG	7.93	42.62	
CYL		-1.25	163

<L>	R1	R2	AX
	8.12	7.93	10
	8.11	7.93	9
	8.12	7.93	10

	mm	D	AX
R1	8.12	41.50	10
R2	7.93	42.50	10
AVG	8.02	42.00	
CYL		-1.00	10

PD = 68mm

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[Figure 7-2-2. Example of a printed page]

7.2.2. Automatic measurement mode

The mode gets converted to automatic measurement mode when MANUAL button is pressed on while in the manual measurement mode. In case of automatic measurement mode, when the state reaches a state in which the arrangement in the device and measurement is realized effectively, measurement takes place automatically even when the measurement button is not pressed on.

① Location arrangement and focus are adjusted just like the (measurement location and focusing) while in the 7.1.2 refractive power measurement mode.

② Measurement takes place automatically using the same method as that of the (measurement) process while in the 7.1.2 refractive power measurement mode.

③ Measurement result is printed using a method that is same as that of the (printing) process while in the 7.1.2 refractive power measurement mode.

7.3. Continuous corneal curvature / refractive power measurement mode (K&R mode)

This is the mode for carrying out the corneal curvature measurement and refractive power measurement continuously.

K&R mode selection: Set so that the measurement mode indicator section on the screen becomes “K&R” mode.

7.3.1. Manual measurement mode

① (Eye height adjustment), (measurement location and focusing) process is carried out just like the 7.1.1 refractive power measurement mode.

② Measurement

-. Press on the measurement button.

-. Measurement is carried out continuously when measurement button is pressed on continually.

-. Measurement result is indicated on the monitor when measurement is completed.

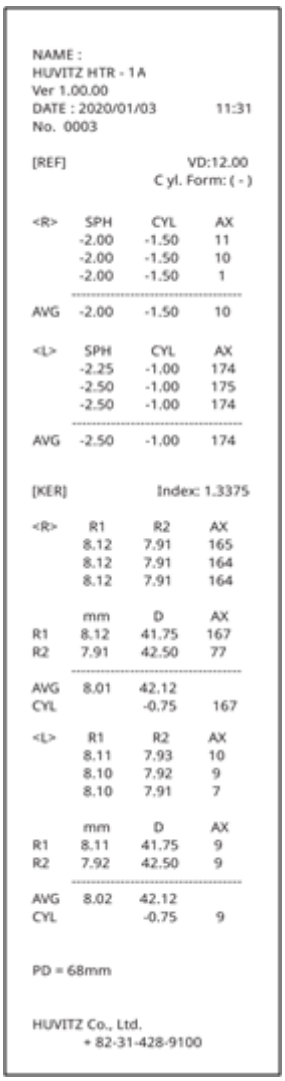
-. The most recent measurement result is indicated when continuous measurement is taking place.



[Figure 7-3-1. K&R mode indicator screen]

③ Operation process that is the same as that of the (repetitive measurement), (measurement of the opposite eyes) was executed in the 7.1.1 refractive power measurement mode.

④ Prints measurement result through the process that is the same as that of the (printing) in the 7.1.1 refractive power measurement mode.



NAME :
HUVITZ HTR - 1A
Ver 1.00.00
DATE : 2020/01/03 11:31
No. 0003

[REF] VD:12.00
Cyl. Form: (-)

<R>	SPH	CYL	AX
	-2.00	-1.50	11
	-2.00	-1.50	10
	-2.00	-1.50	1
AVG	-2.00	-1.50	10

<L>	SPH	CYL	AX
	-2.25	-1.00	174
	-2.50	-1.00	175
	-2.50	-1.00	174
AVG	-2.50	-1.00	174

[KER] Index: 1.3375

<R>	R1	R2	AX
	8.12	7.91	165
	8.12	7.91	164
	8.12	7.91	164

	mm	D	AX
R1	8.12	41.75	167
R2	7.91	42.50	77
AVG	8.01	42.12	
CYL		-0.75	167

<L>	R1	R2	AX
	8.11	7.93	10
	8.10	7.92	9
	8.10	7.91	7

	mm	D	AX
R1	8.11	41.75	9
R2	7.92	42.50	9
AVG	8.02	42.12	
CYL		-0.75	9

PD = 68mm

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[Figure 7-3-2. Example of a printed page]

⑤ Screen indication format selection

-. It is possible to designate symbol of astigmatism refractive power in the measurement mode that includes refractive power measurement. It is possible to designate in the user Setup mode. Moreover, it is possible to indicate Refractive power's measurement data following VD value in the measurement mode that includes refractive power measurement. It is possible to designate the desired VD value when VD button is pressed on continuously, and the ensuing measurement value gets indicated on the screen.

-. It is possible to designate screen indication format (R1/R2/AX → K1/K2/AX → AR/CY/AX) in the user Setup mode when it comes to the measurement mode that includes corneal curvature measurement.

7.3.2. Automatic measurement mode

The mode gets converted to automatic measurement mode when MANUAL button is pressed on while in the manual measurement mode.
While in the automatic measurement mode, measurement is carried out automatically even when the measurement button is not pressed on when the state reaches a state in which arrangement in the device and measurement is realized effectively.

① Location arrangement and focus are aligned with the process that is the same as that of the (measurement location and focusing) of the 7.1.2 refractive power measurement mode.

② Measurement takes place automatically using the same process as that of the (measurement) of 7.1.2 refractive power measurement mode.

③ Prints measurement result value by carrying out the (printing) process of the 7.1.2 refractive power measurement mode.

7.3.3. All kinds of markings

	Type	Denomination	Symbol's meaning	Coping method
Curve measurement	#	indicates low reliability	low reliability measurement value	re-measurement
	+ OUT	measurement range exceeded	spherical prescription exceeds +25 D	impossible to measure
	- OUT	measurement range exceeded	spherical prescription exceeds –30 D	
	C OUT	measurement range exceeded	astigmatism prescription exceeds ± 12 D	
Curvature measurement	#	indicates low reliability	low reliability measurement value	re-measurement
	+ OUT	measurement range exceeded	curvature radius exceeds 13.0 mm	impossible to measure
	- OUT	measurement range exceeded	curvature radius is 5.0 mm or less	
	C OUT	measurement range exceeded	cornea astigmatism exceeds 15.00 D	

7.4. Peripheral Corneal measurement (KER-P mode)

This is the mode that measures cornea's center and periphery curvature separately. Periphery curvature is measured at the locations toward the up and down left and right direction using the cornea's center as the standard. Relative eccentricity is shown by comparing periphery curvature with the cornea center's curvature.

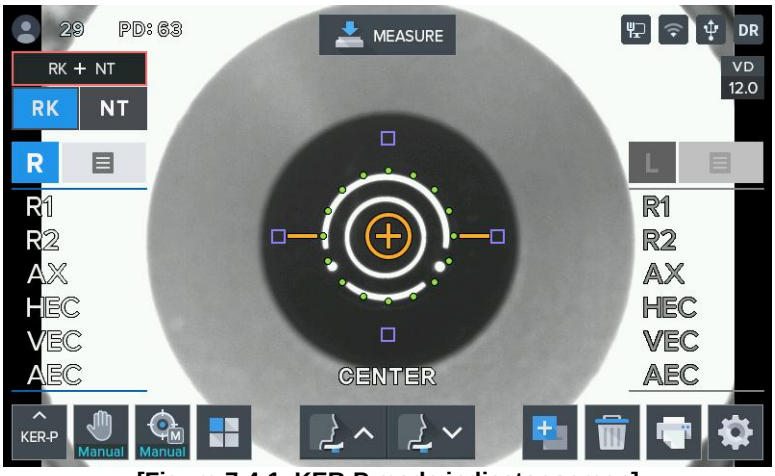
- KER-P mode selection: Set so that the measurement mode indicator section on the screen becomes "KER-P" mode.

NOTE

Eccentricity indicates how flatter Peripheral Corneal is when it comes to the cornea center. In general, curvature is the highest at the center when it comes to the human cornea while it flattens as it approaches the periphery. Accordingly, people may feel discomfort when lens such as RGP are prescribed merely by factoring in the cornea's center curvature. It is possible to select adequate lens by factoring in the patients' characteristics by utilizing the value of Peripheral Corneal's eccentricity obtained from KER-P mode.

① Cornea center measurement

-. Cornea's center is the location for the first measurement, and it is indicated as CENTER at the lower part of the screen's midpoint. Curvature that is measured from the cornea center is the same as the curvature that is measured in the KER mode.



[Figure 7-4-1. KER-P mode indicator screen]

Contents indicated on the screen when measuring cornea's center

-. R1: Curvature (major axis) at the cornea center
-. R2: Curvature (minor axis) at the cornea center
-. AX: Axis direction of the cornea center curved surface
-. HEC: Eccentricity of the overall eyeball's horizontal direction
-. VEC: Eccentricity of the overall eyeball's vertical direction
-. AEC: Overall eyeball's average eccentricity

② Peripheral Corneal measurement

Periphery direction that is measured currently is indicated in the screen's lower part. Moreover, four boxes are indicated to the up and down, and left and right of the Mire Ring. Each box indicates the measurement progress status of the Peripheral Corneal that applies. Inside of the box is filled with color when there is a result measured at the periphery towards the direction where box is located. If there is no measured result, the box is indicated as an empty box. Box that applies to the periphery location that is measured currently gets flickered.

Periphery direction

-. Superior (SUP): Upper side from the cornea's center
-. Inferior (INF): Lower side from the cornea's center
-. Temple (TEM): Towards the temple of the person subjected to measurement from the cornea's center
-. Nasal (NAS): Towards the nose of the person subjected to measurement from the cornea's center

③ Periphery measurement sequence

Measurement is carried out in the following order; TEM → SUP → NAS → INF.

When measurement takes place from the Peripheral Corneal direction, indicator light (Guidance LED light) for catching test subject's attention gets emitted at the area near the Mire Ring in actuality. Measurement is carried out in line with the Mire Ring's focus after eye examiner requests that the test subject watch the light of the indicator light.



[Figure 7-4-2. KER-P mode measurement screen]

Contents indicated on the screen when measuring Peripheral Corneal
(SUP, INF, TEM, and NAS)

-. R1: Curvature (major axis) at the Peripheral Corneal
-. R2: Curvature (minor axis) at the Peripheral Corneal
-. AX: Axis direction of the Peripheral Corneal curved surface
-. RM: Average curvature at the Peripheral Corneal
-. EQ: Difference between cornea center and diopter
-. EC: Peripheral Corneal's eccentricity

7.5. NT measurement: Tonometry and Pachymetry

This is the mode that measures intra ocular pressure and pachymetry.

- Mode selection: Set in a way that the measurement mode indicator section on the screen turns into “Tono” and “Pachy” , “TonoPachy” mode.

⚠ WARNING

Be careful not to touch the patient’s eye with the nozzle.

Be sure to check the safety distance before the measurement.

Set the safety lock with care before the measurement of the NT mode measurement.

Veillez à ne pas toucher l'œil du patient avec la buse.

Assurez-vous de vérifier la distance de sécurité avant la mesure.

Réglez le verrou de sécurité avec soin avant de mesurer la mesure en mode NT.

⚠ WARNING

Be careful not to touch the moving parts of the user and patient's hands when switching to RK to NT mode.

Before starting the measurement, make sure that the hand can come into contact with the moving part.

Veillez à ne pas toucher les parties mobiles de l'utilisateur et des mains du patient lorsque vous passez du mode RK au mode NT.

Avant de commencer la mesure, assurez-vous que la main peut entrer en contact avec la partie mobile.

7.5.1. Manual Measurement Mode

① Carry out the (eye height adjustment) process using the same method as that of the 7.1.1 refractive power measurement mode.

② Measurement location and focusing

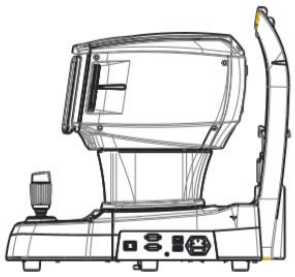
-. Use the operation lever to pull up the main body to the front of the user.

-. Adjust to the left and right while pulling the operation lever to the front slowly so that the test subject’s right eyes appear at the monitor screen’s center. At this time, ensure that the aim led and external leds are on position.

-. Ask the test subject to watch the fixating target at the inside.

-. Adjust the focus so that the aim led and external leds become clear. When the focus is adequate, yellow circle symbol appears at the focus indicator.

-. Height adjustment: Adjust by turning the operation lever or by pressing on the chin rest adjustment button.



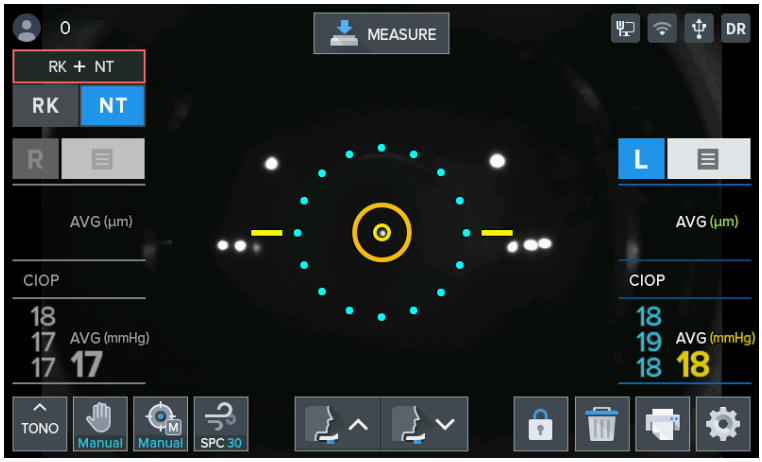
[Figure 7-5-1. Height adjustment]

-. Left and right adjustment: Lean the operation lever to the left and right to adjust so that the aim led is at the center of the eye.

③ Measurement

-. Press on the measurement button/Joystick shot button.

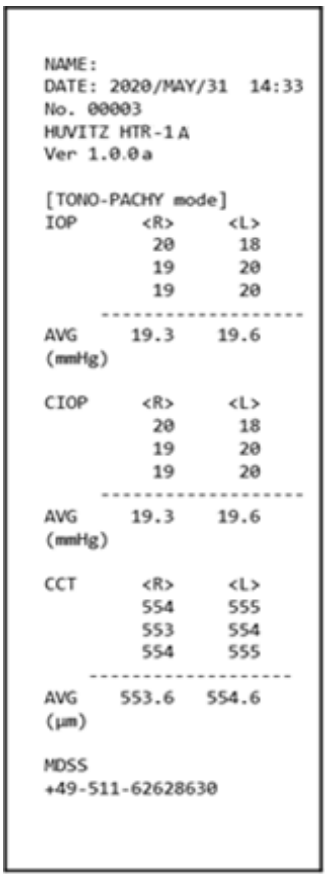
-. Measurement result is indicated on the monitor when measurement is completed. The most recent measurement result is indicated when continuous measurement is taking place.



[Figure 7-5-2. Tono mode indicator screen]

④ Carry out the process using the same process as that of the (repetitive measurement), (measurement of the opposite eyes) in the 7.1.1 refractive power measurement mode.

⑤ Print the measurement result using the process that is like the (printing) process while at the 7.1.2 refractive power measurement mode.



NAME:
DATE: 2020/MAY/31 14:33
No. 00003
HUVITZ HTR-1A
Ver 1.0.0a

[TONO-PACHY mode]

IOP	<R>	<L>
	20	18
	19	20
	19	20
AVG	19.3	19.6
(mmHg)		

CIOP	<R>	<L>
	20	18
	19	20
	19	20
AVG	19.3	19.6
(mmHg)		

CCT	<R>	<L>
	554	555
	553	554
	554	555
AVG	553.6	554.6
(μm)		

MDSS
+49-511-62628630

[Figure 7-5-3. Example of a printed page]

7.5.2. Automatic Measurement Mode

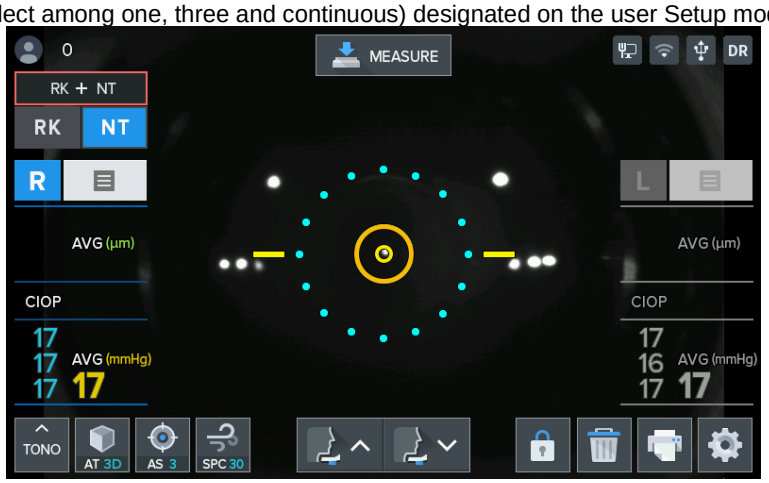
The mode gets converted to automatic measurement mode when MANUAL button is pressed on while in the manual measurement mode. In case of automatic measurement mode, when the state reaches a state in which the arrangement in the device and measurement is realized effectively, measurement takes place automatically even when the measurement button is not pressed on.

① Location arrangement and focus are adjusted just like the (measurement location and focusing) while in the 7.5.1 Manual Measurement Mode.

② Measurement

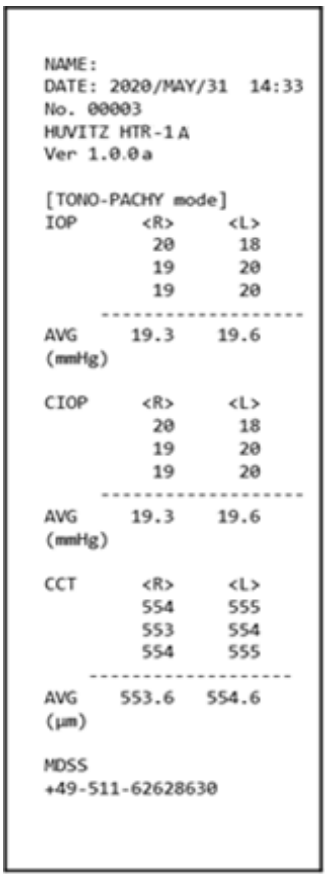
-. Measurement is carried out automatically when the location arrangement and focusing are completed.

-. Value for new measurement result appears on the monitor screen after measurement takes place up to the frequency (possible to select among one, three and continuous) designated on the user Setup mode.



[Figure 7-5-4. Tono mode indicator screen]

③ Measurement result is printed using a method that is same as that of the (printing) process while in the 7.1.2 refractive power measurement mode.



NAME:
DATE: 2020/MAY/31 14:33
No. 00003
HUVITZ HTR-1A
Ver 1.0.0a

[TONO-PACHY mode]

IOP	<R>	<L>
	20	18
	19	20
	19	20
AVG	19.3	19.6
(mmHg)		

CIOP	<R>	<L>
	20	18
	19	20
	19	20
AVG	19.3	19.6
(mmHg)		

CCT	<R>	<L>
	554	555
	553	554
	554	555
AVG	553.6	554.6
(μm)		

MDSS
+49-511-62628630

[Figure 7-5-5. Example of a printed page]

8

8. Other mode

8.1. Other menu mode

It is possible to convert to other mode by pressing on the  button in the main measurement mode

Press on the  button in all other modes to end the current mode and to return to the main measurement mode.

8.1.1. COLOR VIEW mode

This is the mode for observing with color screen by using Yellow Filter / White LED / Blue LED when it comes to the state when contact lens are worn by measuring cornea's curvature radius.



[Figure 8-1-1. Color View mode indicator screen]

Categories for the buttons that are indicated on the screen are as follows.

 : Select Yellow Filter mode ON/OFF.

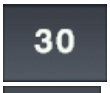
 : Select White LED mode ON/OFF.

 : Select Blue LED mode ON/OFF.

 : Output filmed image on the screen (maximum LEFT 2, RIGHT 2)

 : Indicates measurement DATA on the screen.

 : Button that lowers stage of LED's brightness by one step

 : Indicates current LED's brightness.

 : Button that increases stage of LED's brightness by one step.

 : Button that trasfer image data.

① Base value and OnK value are calculated automatically by using measurement value if the corneal curvature was measured in the KER mode.

② Eyes' location and focus are adjusted by using operation lever to see the image of the subject of eye examination clearly.

③  and  are used to adjust the White LED to an adequate brightness.

Categories of the data indicated on the screen are follows.

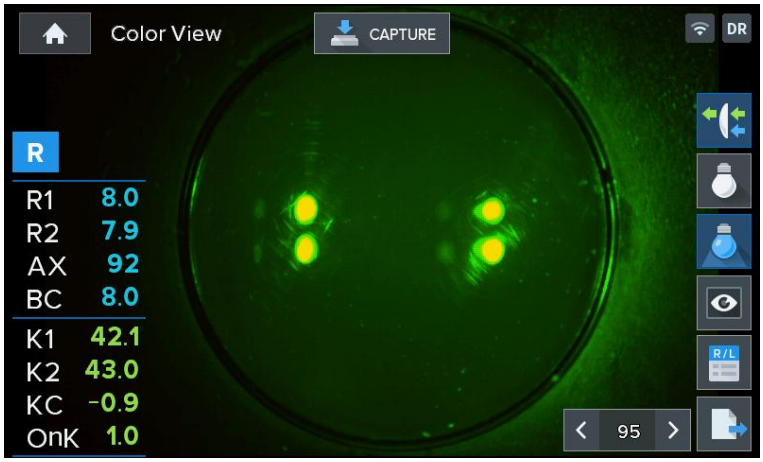
R1: Indicates corneal curvature's major axis
R2: Indicates corneal curvature's minor axis
AX: Indicates corneal curvature's axis
Base: Indicates contact lens' Base curve value
K1: Indicates corneal curvature's major axis as diopter
K2: Indicates corneal curvature's minor axis as diopter
CYL: Indicates astigmatism power value
Onk: Indicates contact lens' Onk prescription value

8.1.1.1. Yellow Filter

This is the function for observing the contact lens Fitting degree more clearly.

① Press on the  button in the Color view mode.

② Use  button and  button to adjust LED's brightness. Then, observe contact lens Fitting degree.



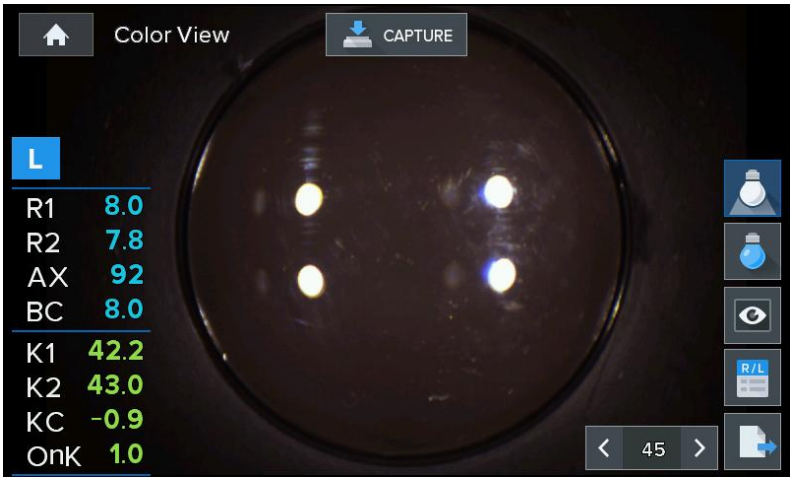
[Figure 8-1-2. Color View mode indicator screen (Yellow Filter)]

NOTE

Yellow Filter function is the function that uses S/W.

8.1.1.2. White LED

This is the function that uses White LED illumination to observe with color image.



[Figure 8-1-3. Color View mode indicator screen (White LED)]

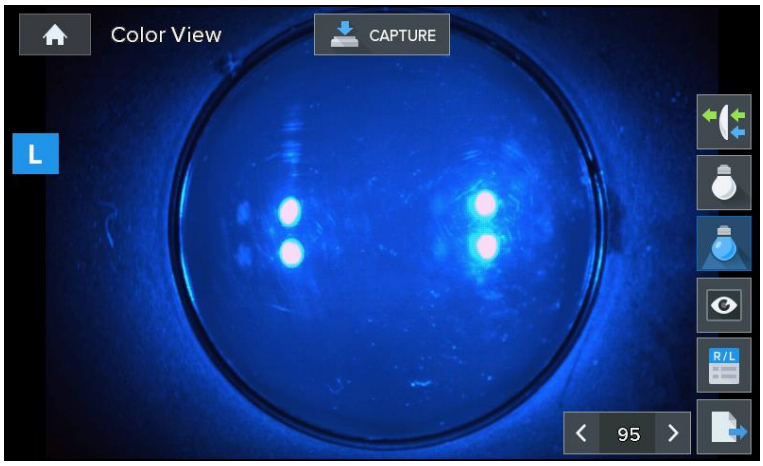
8.1.1.3. Blue LED

This is the function that observes cornea and contact lens Fitting degree by using fluorescence solution and Blue LED.

① Wear contact lens after dyeing the eyes using fluorescence solution.

② Press on the  button in the Color view mode, and use the operation lever to adjust eyes' location and focus.

③ Use  button and  button to adjust the Blue LED's brightness, and observe contact lens Fitting degree.



[Figure 8-1-4. Color View mode indicator screen (Blue LED)]

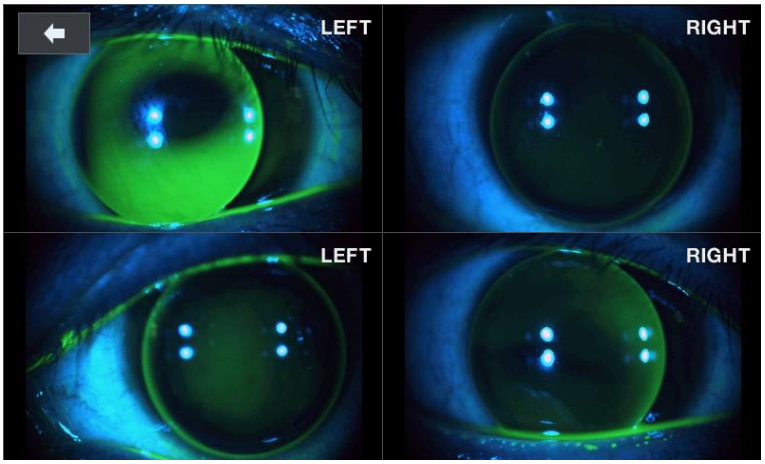
8.1.1.4. Returning to the measurement mode

Press on the  button in the Color View mode to return to the main measurement mode.

8.1.1.5. Capture screen

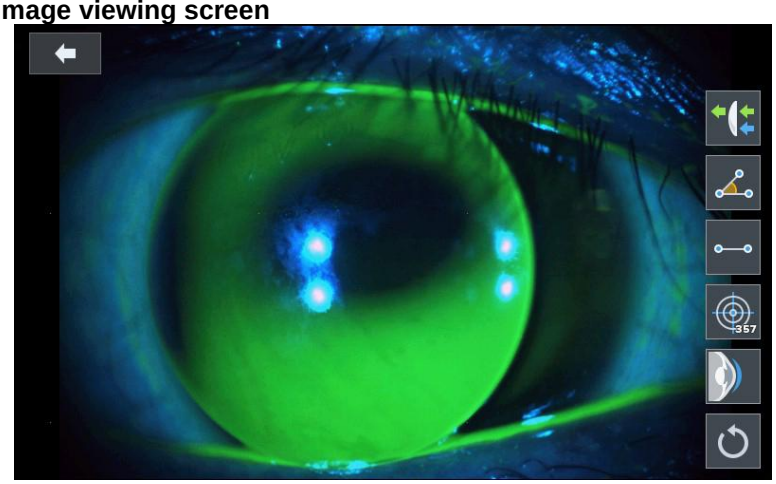
① Captures the image of subject of eye examination by pressing on the measurement button (joystick) in the Color View mode.

② Press on the  button to output filmed images on up to four screens on the DISPLAY screen.



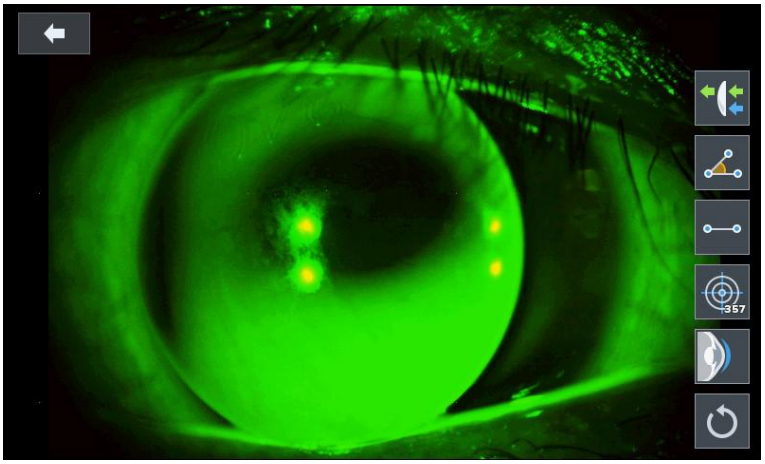
[Figure 8-1-5. Color View mode - capture screen]

8.1.1.6. Capture image viewing screen

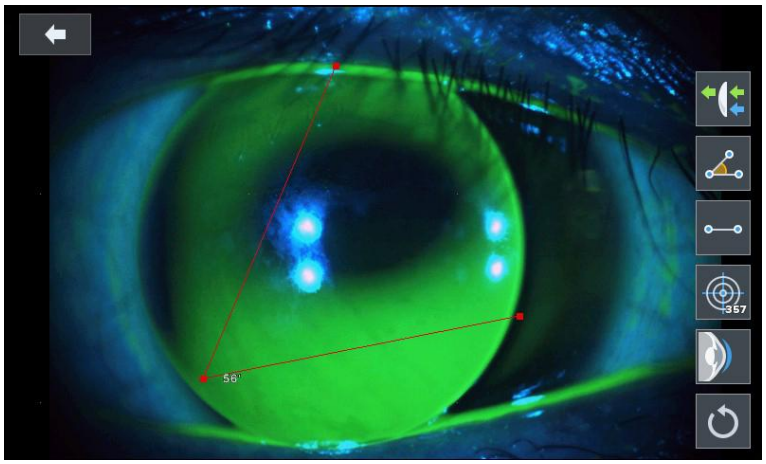


[Figure 8-1-6. Color View mode – captured image selection screen]

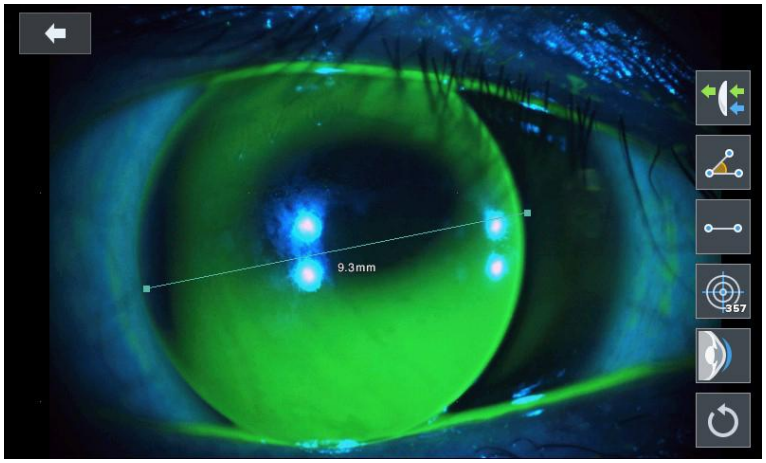
 : Emphasizes the green of the measurement image. (It is possible to check the distribution state of the fluorescence solution easily by indicating after emphasizing the green color of the measured image.)




: Measures angle. (Measures angle by touching the screen with three points of the angle to be measured.)

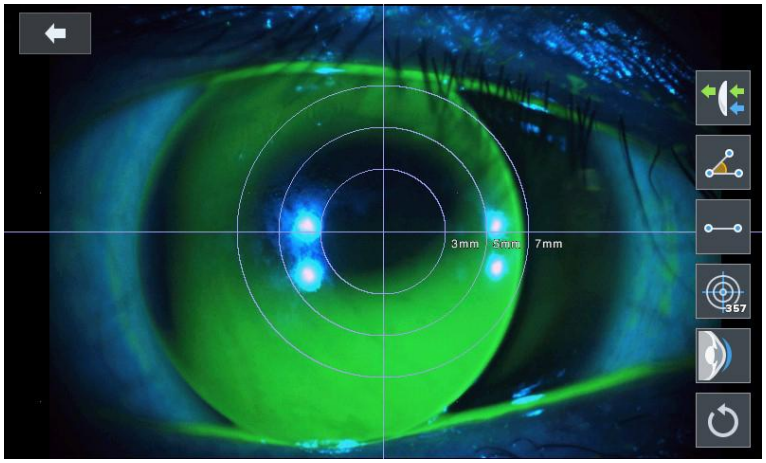



: Measures length. (Measures length by touching the screen with two points at the ends of the two sides when it comes to the length to be measured.)

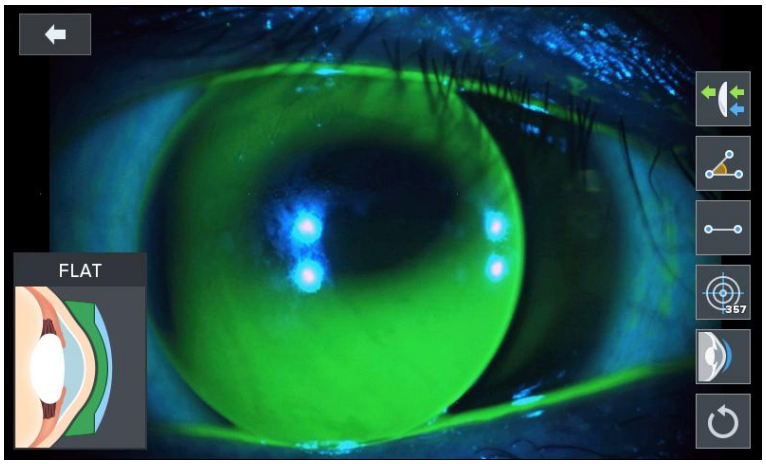


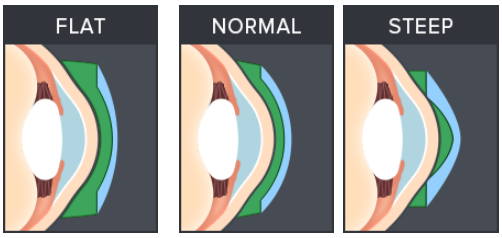


: Indicates guideline (3 mm, 5 mm, 7 mm).



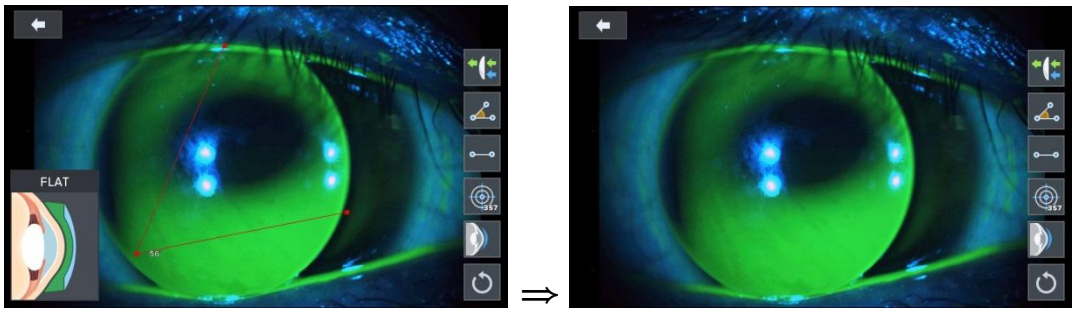

: Indicates contact lens fitting state. (Automatically discerns out in stages whether cornea's curvature and contact lens' curvature is flat, normal or steep to indicate on the screen.)





[Figure 8-1-7. Flat, Normal, Steep icon screen]


: Returning to the original state.
(Returns all that was indicated to the original state.)



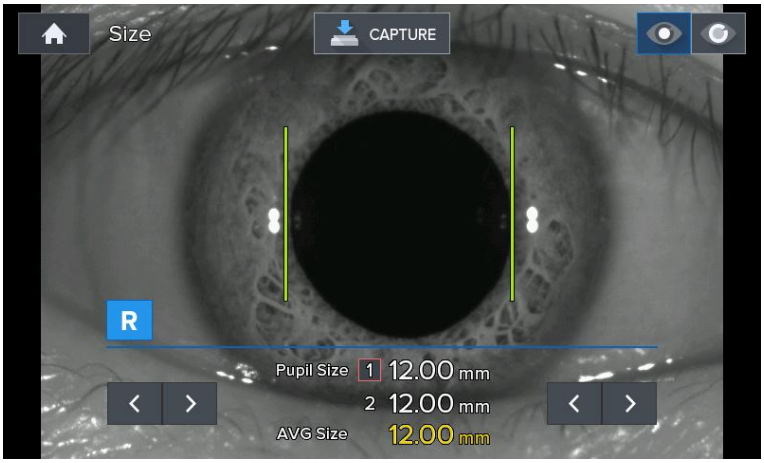
8.1.2. SIZE mode (pupil diameter measurement)

This is the mode that measures pupil's diameter.

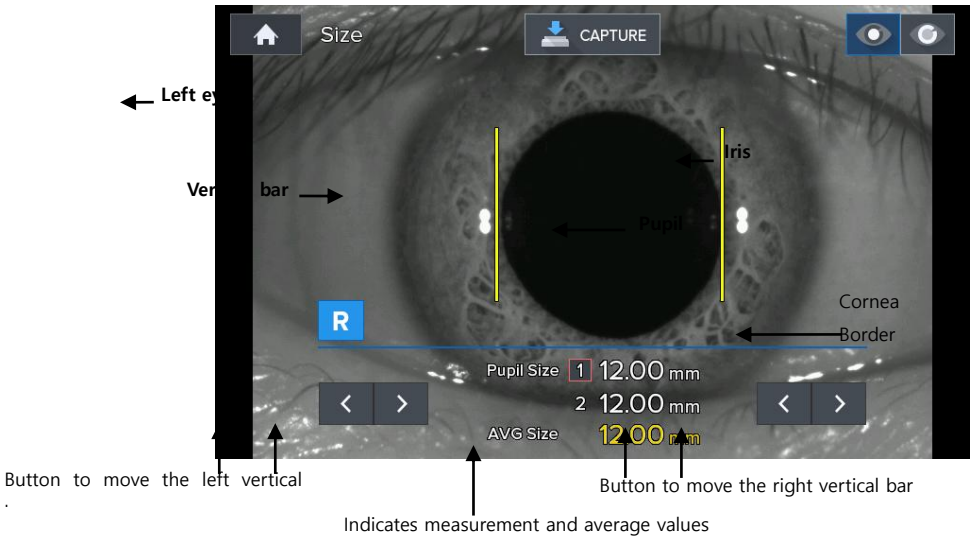
① Press on the 

button in the main measurement mode. Then, SIZE mode gets selected when the SIZE button is pressed on.

② Adjusts location and focus so that the image of the eyes to be measured can be clear.



[Figure 8-1-8. Size mode indicator screen (1)]



[Figure 8-1-9. Size mode indication screen (2)]

③ Measurement location and focusing
-. Ask the test subject to watch fixating target at the inside.
-. Move the operation lever to adjust the location so that the pupil is in between two vertical bars.
-. Focus is adjusted so that the cornea's corners are clearly visible.

NOTE

It is not possible to measure the pupil diameter accurately when focus is adjusted to the iris.

④ Measurement

-. When the measurement button is pressed on, current state gets filmed and the screen is shown as a paused screen.

-. Left  button and  button adjust the movement of the left bar while button of the right side  and  button adjust the movement of the right side bar.

⑤ Measurement value is indicated on the monitor.

-. Measurement value is saved automatically.

-. Measured value gets indicated at the Pupil Size at the screen's center lower part. Average of the recent two measure--. ment values is indicated in the "Avg Size" below.

-. Stopped screen is undone when you press on the measurement button.

⑥ Measurement repetition

-. It is possible to measure up to two measurement values when the measurement is repeated. Repeat the operation of 2 ~ 5 when measuring again.

⑦ Measurement of the eye on the opposite side

-. Measure the eye on the opposite side using the same method after moving the stage to the opposite side.

⑧ Measurement result output

-. Cornea diameter measurement result is output as the "[PUPIL SIZE]" category by the built-in printer.

8.1.3. ZERNIKE mode

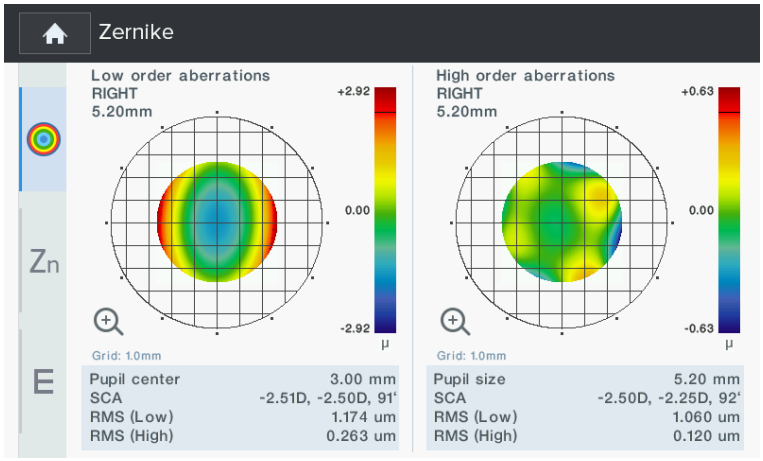
Zernike mode shows pupil domain's Wave-front information. Some kind of landform is drawn that assumes leveling according to actual Wave-front's distortion degree (aberrations) that is measured from the test subject with myopia or hyperopia using the Wave-front as the standard when it is at the emmetropia.

After measuring the refractive power in the REF or K&R mode, press on the ZMODE button of the  button to convert to Zernike mode. Guidance message gets indicated as "Calculating…" during a few standby time in order to calculate the information.

8.1.3.1. Screen composition

It is possible to convert the information that is indicated through the three buttons on the screen's left side.

 **: Map**

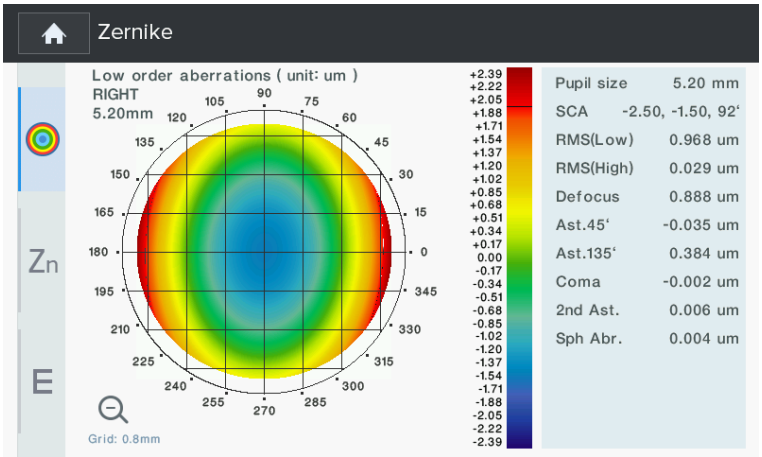


[Figure 8-1-10. Zernike mode screen (Map)]

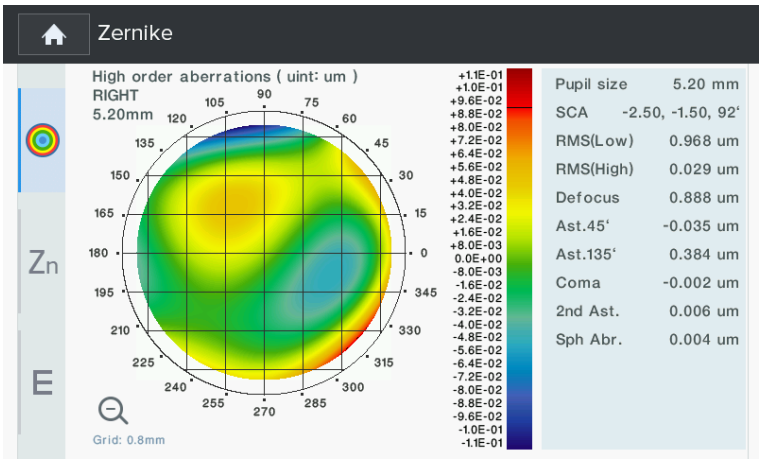
Pupil domain indicated on the left and right of the screen is manifested as graph format in which Wave-front's Low order aberrations and High order aberrations are expressed with colors. Information on the measurement domain is indicated on the screen's lower part. Result calculated on the pupil's narrow domain, wide domain is indicated separately on the left and right sides.

Pupil:	measurement domain. (example: 3.60 mm radius from the pupil's center)
SCA:	S=Spherical Aberration, C=Cylinder Aberration, A=Cylinder Axis
RMS (Low):	aberrations (Low order aberrations' average)
RMS (High):	aberrations (High order aberrations' average)

It is possible to see more detailed information when you touch the Wave-front aberrations graph.



[Figure 8-1-11. Zernike mode screen (Map) – Low order]



[Figure 8-1-12. Zernike mode screen (Map) – High order]

Graph on the left side of the screen indicated degree of Wave-front aberrations in the pupil domain in colors. Emmetropia, hyperopia and myopia are expressed in green, blue and red, respectively. Darker color is used when the eyes' abnormality is severe. When astigmatism is included, refractive power landform of the oval format is drawn towards the axis direction of astigmatism.

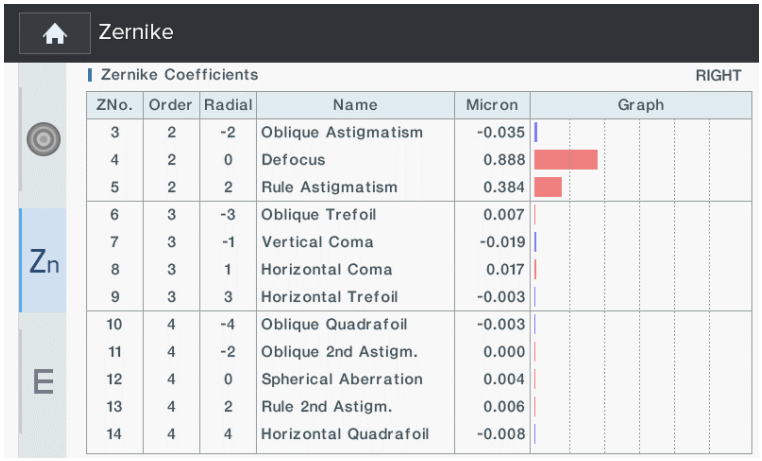
Map Level of the bar format on the graph's right side is the chart that show which color is used for certain value of Wave-front aberrations. Measured Wave-front aberrations' maximum and minimum values are indicated in micro meter (μm) unit. Wave-front aberrations in case of emmetropia is 0 and high Wave-front aberrations are assumed with the symbols of positive (+) and negative (-) each as the hyperopia and myopia are severe.

Information that is indicated additionally on the right side of the screen is as follows.

Defocus:	Defocus value
Ast 45˚:	45˚ astigmatism
Ast 135˚:	135˚ astigmatism
Coma:	Coma value
2nd Ast.:	Definition of representative aberrations (secondary astigmatism)
Sph Abr.:	Definition of representative aberrations (spherical aberrations)
RMS (Low):	Low order aberrations' average
RMS (High):	High order aberrations' average

Graph gets amplified into the entire screen when you press on the "+" button at the lower part of the graph's right side, and the image returns to the original image when you press on the "-" button at the amplified image's lower part of the right side.

Zn **: Graph**

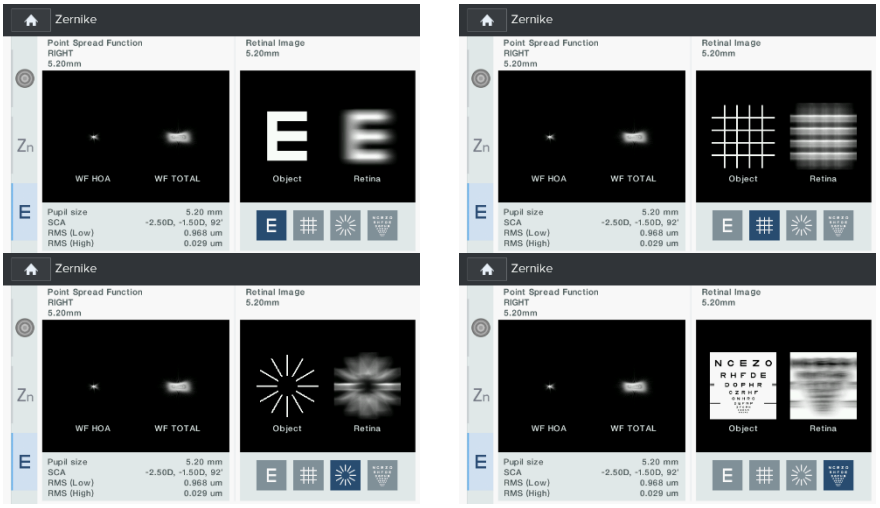


[Figure 8-1-13. Zernike mode screen (Graph)]

Graph information that is indicated on the screen indicates categories of the measured Zernike coefficient by type such as Coma, Defocus and others. Distribution graph of coefficient values is shown by using percentage for the size of each value and the sum of the total coefficients. Zernike coefficient value is indicated as the micro meter (μm) unit.

E **: PSF image**

PSF Image is indicated on the screen's left side to make it easy to know how light of the point shape forms at the retina based on the measured refractive power, and it is indicated on the right side how visual target for testing gets twisted in order to help understand.



[Figure 8-1-14. Zernike mode screen (PSF image)]

It is possible to modify the visual target for testing that is indicated on the screen using the following buttons.

1.1  : E chart

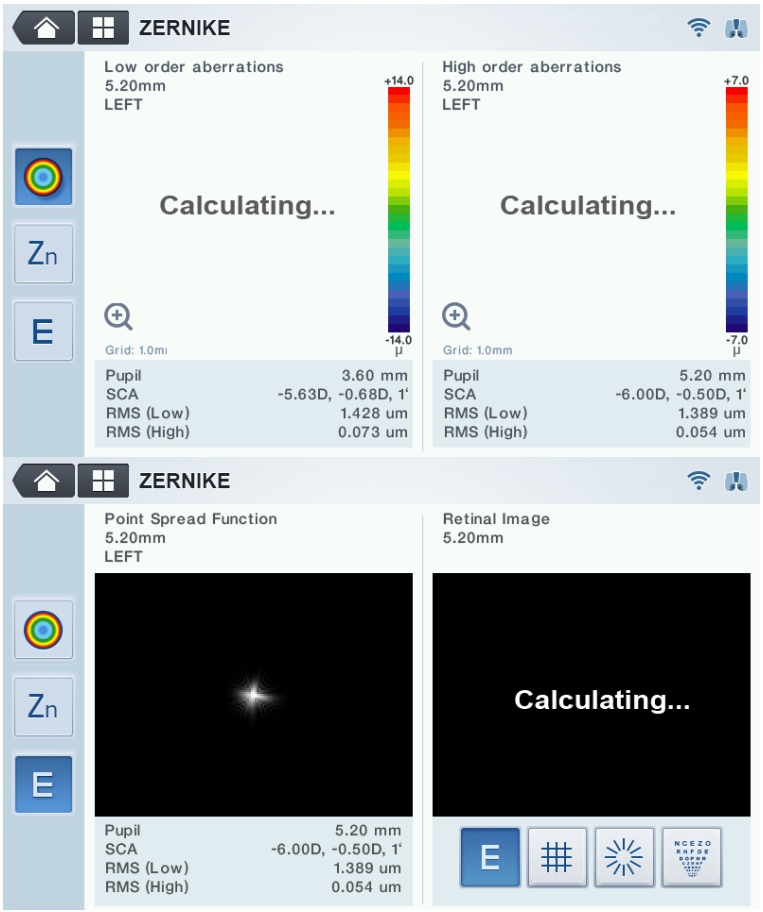
1.2  : Lattice type of chart

1.3  : Radiation type of chart

1.4  : ETDRS chart

8.1.3.2. Screen conversion

When the stage is moved to the left and right using operation lever, graph, Zernike coefficients and PSF image get converted to the results that are gained from the applicable stage location.



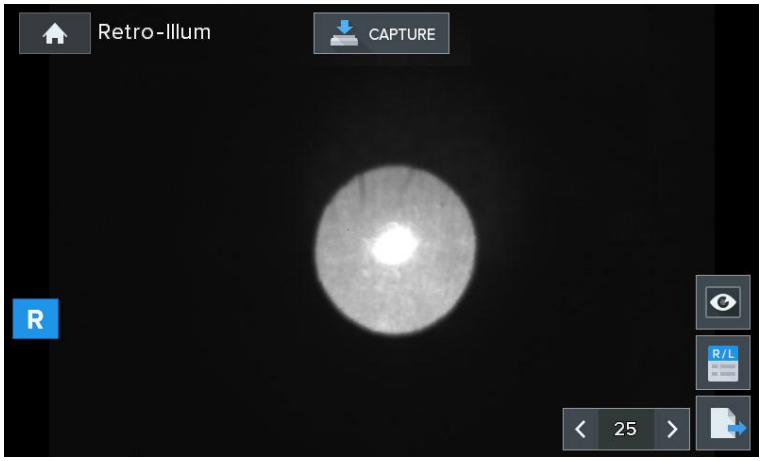
[Figure 8-1-15. Zernike mode (Map, PSF image) screen conversion]

8.1.4. RETRO-ILLUMINATION mode

Retro-Illumination mode is the mode that can observe eye lens by using Retro-illumination method. It is possible to observe eye lens' state by observing the shape of the light that is reflected from the retina while changing the brightness of the light that is radiated onto the eyes through illumination.

It is possible to observe the human beings' eye lens with severe cataract symptom or that is being affected by the symptom or to measure the refractive power. Moreover, it is possible to test the eye lens' turbidity. When the eye lens are not very turbid, then it is possible to measure the eyes' refractive power at the same time while observing the shape that is reflected from the retina at the same time. Moreover, if there is a scratch on the cornea, it is possible to observe the light penetration and uniformity of the artificial eye lens after observing the scratch or after administering artificial eye lens (IOL) surgery.

8.1.4.1. Arrangement and focusing



[Figure 8-1-16. Retro-Illumination screen]

① The mode turns into the Retro-Illumination mode when the RETRO-ILL button is pressed on after pressing on the 

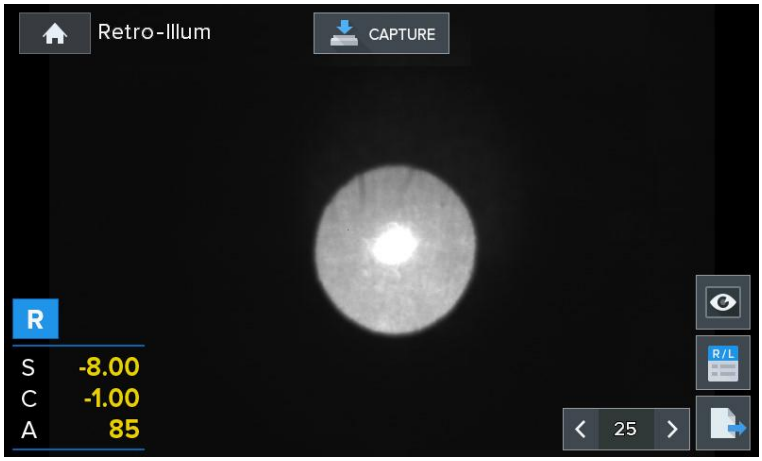
button.

② (Eye height adjustment), (measurement location and focusing) process is carried out using the method that is the same as that of the 8.1.1 refractive power measurement mode.

③ Retro-illumination image appears on the screen after the illumination is turned on and after the radiated light gets reflected on the retina. It is possible to observe eye lens, cornea's turbidity and cornea's scratch information by observing this Retro-illumination image.

④ Measurement screen appears when 

button is pressed on while on the screen. Measurement screen show on the screen along with the Retro-illumination image by measuring eyes' refractive power, astigmatism and astigmatism continually at the current location.



[Figure 8-1-17. Retro-Illumination measurement screen]

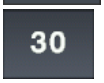
Buttons of the Retro-Illumination mode that are indicated on the screen are as follows.



: Button that converts to indicate on the measurement screen.


: This is the button for seeing the Retro-Illumination image saved once again by using measurement button.

 : Button for decreasing illumination's brightness

 : Indicates current illumination's brightness

 : Button for increasing illumination's brightness

8.1.4.2. Retro-Illumination observation

① Adjusts brightness of the LED for refractive power measurement

To see the image clearly, use  button and  button to change the LED brightness for refractive power measurement to an appropriate brightness.

② Observation of Retro-Illumination image

Use the operation lever to incidence by avoiding the unclear part of the eye lens when it comes to the illumination that is indented with the eyes. Ensuring that the light gets indented near the pupil is effective for observing Retro-illumination image.

NOTE

Avoid eye examination that lasts over 30 seconds to protect the test subject's eyes.

③ Saving the image

Use operation lever to adjust the focus on the image, and save the image by pressing on the measurement button.

NOTE

Turbidity of the eye lens caused by cataract can lead to margin of error when it comes to the measurement value by causing aberrations due to the eccentricity.

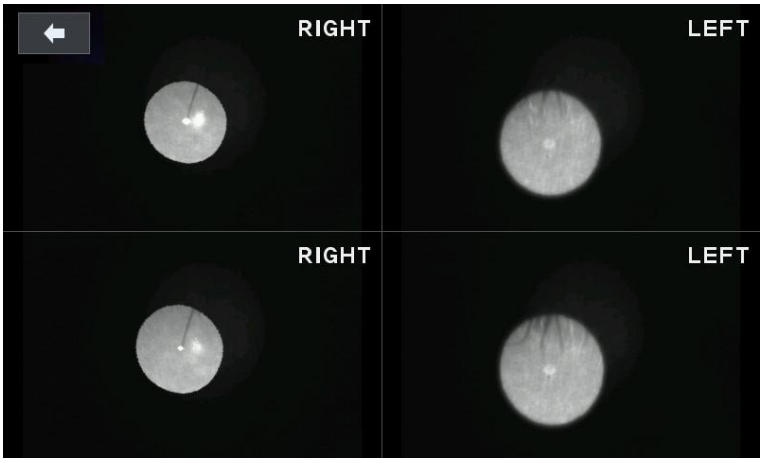
8.1.4.3. Saving

It is possible to save up to two images for the left and right eyes when it comes to the images saved by using measurement button.

8.1.4.4. Test for other eye

Saves the desired image for other eye as well.

8.1.4.5. Importing saved image



[Figure 8-1-18. Screen indicating saved image]

① Press on the  button to go into the Display mode in order to indicate the saved Retro-illumination image for the two eyes on the monitor screen once again.

② In the Display mode, each saved image is indicated on the screen and it is possible to indicate by amplifying the image when you touch a desired image.

③ The mode returns to the Display mode when the  button is pressed on while at the amplified screen.

④ The screen returns to the observation screen when the  button is pressed on in the Display mode.



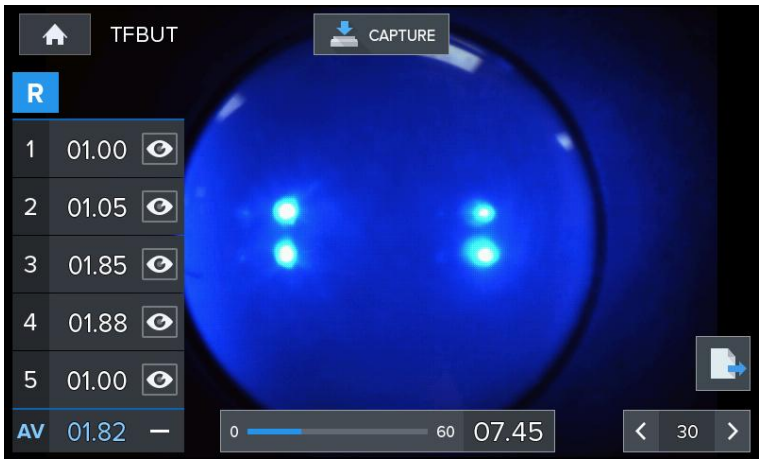
[Figure 8-1-19. screen indicating saved image (amplification)]

8.1.4.6. Returning to the main measurement mode

It is possible to return to the main measurement mode if you press on the  button while at the observation screen.

8.1.5. TFBUT measurement mode (Tear film break-up time)

This is the mode for measuring the time required until the dry part of the cornea's surface appears (tear film destruction time) after blinking the eyes.
The dry part is the normal phenomenon that results due to the evaporation and spread of the tears. Dry part starts to appear within 10 to 12 seconds in healthy eyes after blinking the eyes.



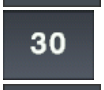
[Figure 8-1-20. TFBUT measurement screen]

Button information on the screen are as the following.

 : Button that indicates the filmed image on the view all screen.

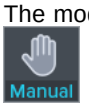
 : Button for deleting measured data

 : Button that lowers stage of LED's brightness by one step

 : Indicates current LED's brightness.

 : Button that increases stage of LED's brightness by one step

9.1.5.1. Tear film break-up time measurement

① The mode turns into TFBUT measurement mode when TFBUT mode button is pressed on after pressing on the 

button in the measurement mode.

② Use fluorescence solution to dye test subject's eyes.

③ Adjusts eye height and focus to facilitate observation.

④ Have a test subject blink the eyes two or three times and have the subject stop blinking in order to observe dry part.

⑤ Start measuring time by pressing on the measurement button the moment test subject blinks the eyes for the last time.

⑥ Stop the time by pressing on the measurement button when the dry part starts the device while observing tear film of the cornea, dyed with fluorescence solution.

⑦ Measured time gets indicated on the screen, and up to five measurements are enabled. When measured a number of times, average time gets output together.

-. When measured wrongly, it is possible to exclude wrongly measured measurement time from the average time. When the wrongly measured time is touched, red line is indicated on top of the measurement time. This time is excluded from the average time

.



8.1.5.2. Importing saved image

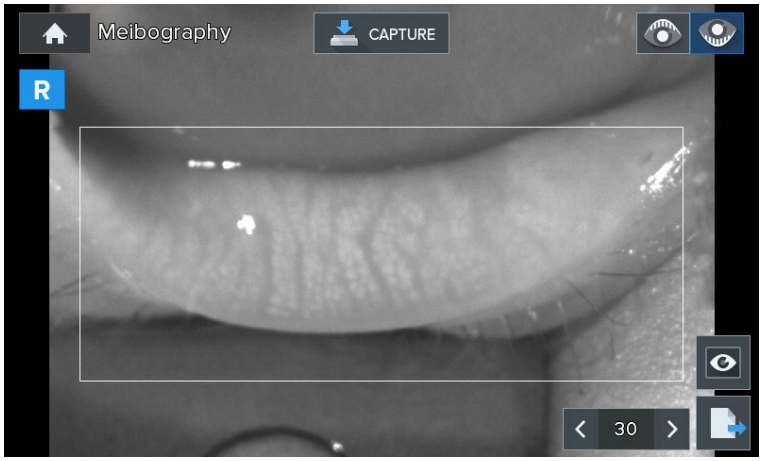
① Measurement time list is activated when measurement is completed.

② Press on the activated  button to indicate by amplifying the image.

③ Press on the  button on the amplified screen to return to the measurement screen.

8.1.6. Meibography mode

This is the mode that films the meibomian gland that is useful for the diagnosis of the xerophthalmia and that shows by emphasizing it.



[Figure 8-1-21. Meibography mode indicator screen]

Categories of the buttons that are indicated on the screen are as follows.

 : Button for modifying to the upper eyelid filming mode

 : Button for modifying to the lower eyelid filming mode

 : Button for indicating and analyzing filmed image

8.1.6.1. Meibogryphy measurement

① The following MEIBOGRYPHY MODE screen appears when Meibo button is pressed on after pressing on the 

button in the measurement mode.

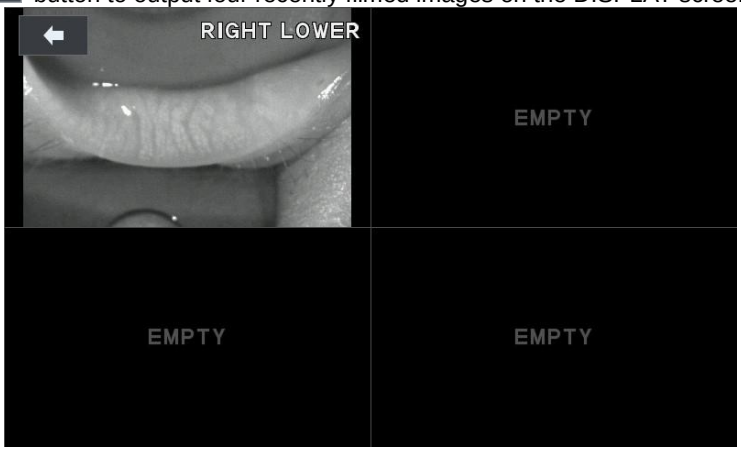
② Select the direction (up or down) of the eyelids where the meibomian gland to be measured is located.

③ Use joystick button to film meibomian gland. (Possible to film up to four pages)

8.1.6.2. Filming result selection screen

① Press on the joystick button at the Meibography mode to film test subject's meibomian gland.

② Press on the  button to output four recently filmed images on the DISPLAY screen.



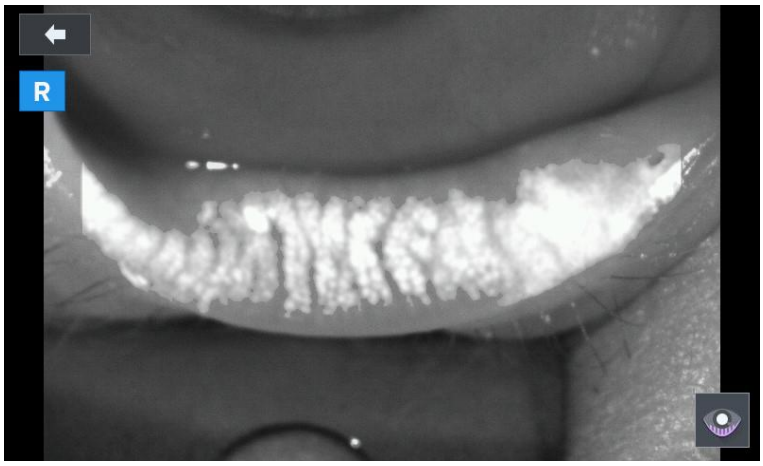
[Figure 8-1-22. Meibography filming result selection screen]

Categories of the buttons that are indicated on the screen are as follows.

UPPER/LOWER: Indicates the direction of the eyelids where filmed meibomian gland is located.

③ Press on the  button on the screen that filmed meibomian gland and the four images filmed recently are output on the DISPLAY screen.

8.1.6.3. Meibomian gland emphasis and analysis result screen



[Figure 8-1-23. Meibography View mode – emphasis and analysis result screen]

Categories of the buttons that are indicated on the screen are as follows.

 : This is the screen that shows the filmed image on the screen by amplifying.

 : This is the screen that emphasizes and indicates only the part that applies to the meibomian gland among the eyelid domain.

① Pressing on the  button analyses filmed image, and only part that applies to the meibomian gland among the eyelid domain is emphasized brightly and indicated on the screen.

② Pressing on the  button indicates the original copy image on the screen.

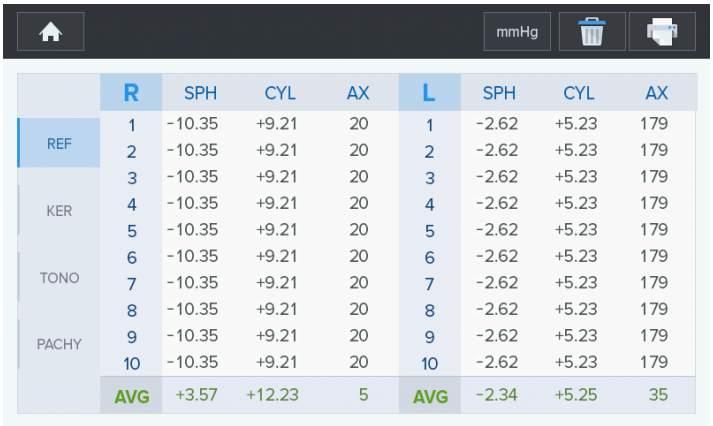
8.1.7. DISPLAY mode

It is possible to see the measurement results that are saved in the memory (up to 10 for the left and right eyes).

The mode changes into the DISPLAY mode when the DISP button is pressed on after pressing on the  button at the main measurement mode. It is possible to convert even when the measured value indicated on the screen's left and right sides is touched after measuring refractive power.

NOTE

Page changes when the REF button or KER button is pressed on in case of the K&R mode.
Measurement result that is saved in the memory when pressing on the PRINT button is printed out via built-in printer, and the result is deleted completely for the new measurement.



	R	SPH	CYL	AX	L	SPH	CYL	AX
REF	1	-10.35	+9.21	20	1	-2.62	+5.23	179
	2	-10.35	+9.21	20	2	-2.62	+5.23	179
KER	3	-10.35	+9.21	20	3	-2.62	+5.23	179
	4	-10.35	+9.21	20	4	-2.62	+5.23	179
TONO	5	-10.35	+9.21	20	5	-2.62	+5.23	179
	6	-10.35	+9.21	20	6	-2.62	+5.23	179
PACHY	7	-10.35	+9.21	20	7	-2.62	+5.23	179
	8	-10.35	+9.21	20	8	-2.62	+5.23	179
	9	-10.35	+9.21	20	9	-2.62	+5.23	179
	10	-10.35	+9.21	20	10	-2.62	+5.23	179
	AVG	+3.57	+12.23	5	AVG	-2.34	+5.25	35

[Figure 8-1-24. data measurement result]

Categories of the buttons that are indicated on the screen are as follows.

REF / REF : This is the screen that shows Refractometry measurement result.

KER / KER : This is the screen that shows Keratometry measurement result.

KER-P / KER-P : This is the screen that shows Ker-p measurement result.


: Button for deleting saved DATA and that returns to the measurement mode.


: Button for printing saved DATA.

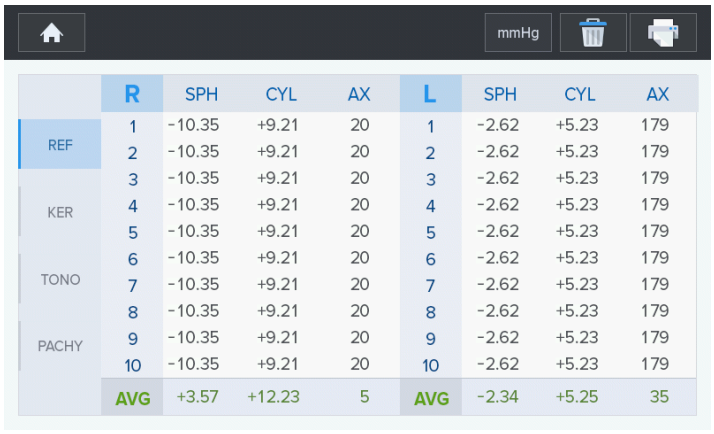
① Refractometry measurement result
-. Indicates the latest 10 measurement results (refractive power).

② Keratometry, Keratometry-p measurement result
-. Indicates the latest 10 measurement results (cornea curvature value).

8.2. Display of Result

You can see the measured results (Max ten(10) units of data) stored in memory in this mode.

As pushing R/L  button in the measurement mode, it can see measurement data.



	R	SPH	CYL	AX	L	SPH	CYL	AX
REF	1	-10.35	+9.21	20	1	-2.62	+5.23	179
	2	-10.35	+9.21	20	2	-2.62	+5.23	179
	3	-10.35	+9.21	20	3	-2.62	+5.23	179
KER	4	-10.35	+9.21	20	4	-2.62	+5.23	179
	5	-10.35	+9.21	20	5	-2.62	+5.23	179
TONO	6	-10.35	+9.21	20	6	-2.62	+5.23	179
	7	-10.35	+9.21	20	7	-2.62	+5.23	179
	8	-10.35	+9.21	20	8	-2.62	+5.23	179
PACHY	9	-10.35	+9.21	20	9	-2.62	+5.23	179
	10	-10.35	+9.21	20	10	-2.62	+5.23	179
	AVG	+3.57	+12.23	5	AVG	-2.34	+5.25	35

[Result mode Screen]

 **[Exit Button]**

As pushing Exit button, return to the main measurement screen.



[Unit Button]

As pushing Unit button, change to value of measured IOP data (mmHg <->hPa)

 **[Clear Button]**

As pushing Clear button, clear the all measurement data.

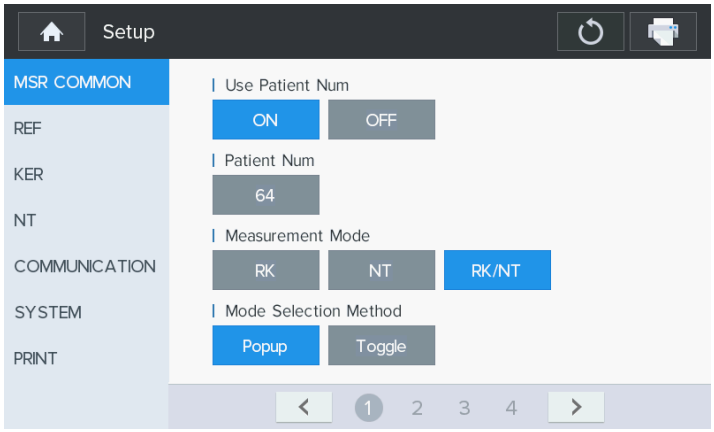
 **[Print Button]**

As pushing Print button, print the all over measurement data.

8.3. Setup Menu

It is to perform many setups relating to measurement, print-out, etc. As pushing Set up Button on the measurement screen, it entered SETUP mode.

8.3.1. MSR COMMON Page



[Setup mode Information (MSR COMMON – 1 Page)]

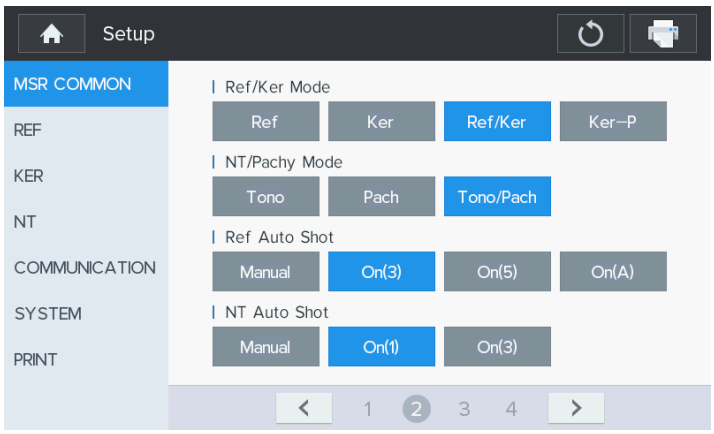
[How to Change Tab]
As pushing left side`s tab button, it is to enter the tab items.
[How to Change Page]
As pushing bottom side`s arrow button < > or page button 1,2,3,4 it is to enter the next page.
[How to change item and content]
Select the wanted item on the Screen, and to change the setting by touching on the category to be modified.

[Exit Button]
As pushing Exit button, return to the main measurement screen.

[Reload Button]
As pushing Reload button, revert to original values of all over the pages.

[Print Button]
As pushing Print button, print the all over setup values.

- **User Patient Num**: Patient measurement count On/Off
- **Patient Num:** Measurement patient number
- **Measurement Mode**: Current measurement mode for the overall
- **Mode Selection Method**: Selection method for the NT/RK measurement mode



[Setup mode Information (MSR COMMON – 2 Page)]

- **Ref/Ker Mode**: RK measurement mode

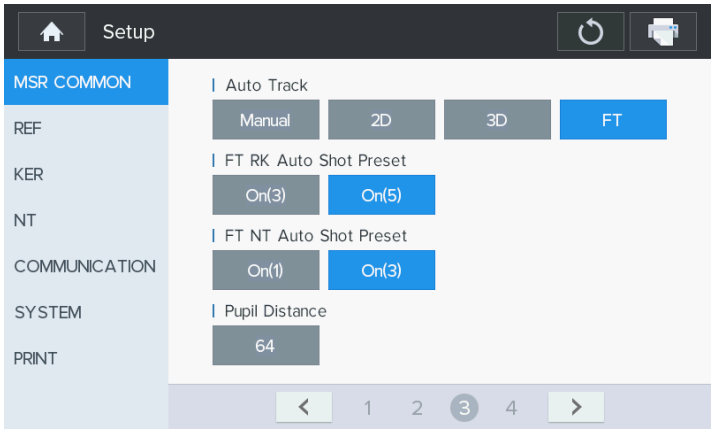
- **NT/Pachy Mode**: NT measurement mode

- **Ref Auto Shot**: Auto shot setting for the RK measurement mode

  Manual - Manual shot by measurement button
  On(3) - 3 times auto shot
  On(5) - 5 times auto shot
  On(A) - Auto shot continuously

- **NT Auto Shot**: Auto shot setting for the NT measurement mode

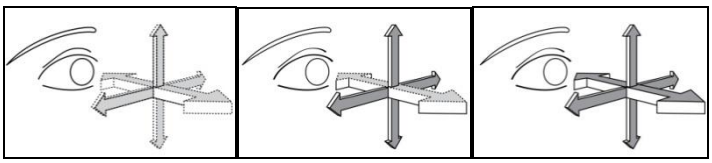
  Manual - Manual shot by measurement button
  On(1) - 1 times auto shot
  On(3) - 3 times auto shot



[Setup mode Information (MSR COMMON – 3 Page)]

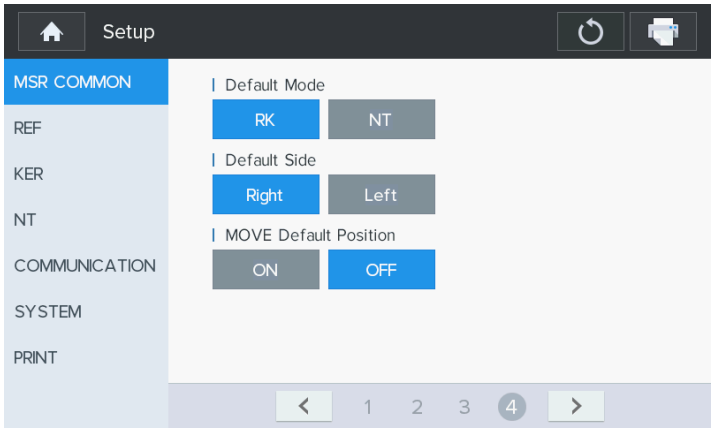
- **Auto Track**:

  Manual - Manually align the device and bring the eye into focus.
  2D (X, Y) - Right and left, up and down direction (Auto)
  3D (X, Y, Z) - Forward and backward, right and left, up and down direction on one side.
  FT - 3D features + OD, OS movement and NT, RK mode changes automatically



[Auto Tracking (MT, AT2D, AT3D)]

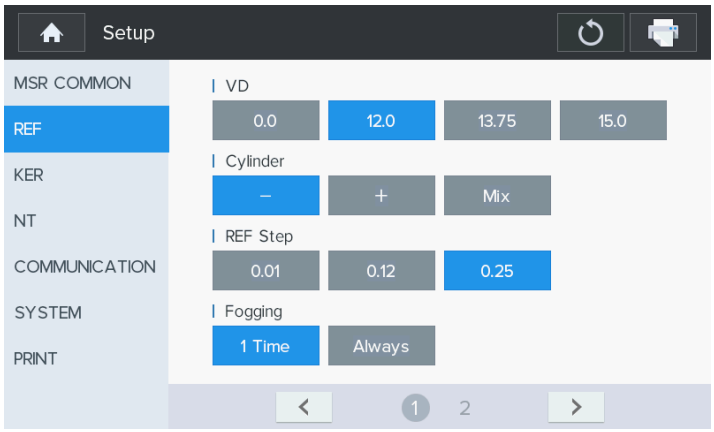
- **FT RK Auto Shot Preset**: the preset auto shot setting for the RK measurement when the user sets the tracking option FT
- **FT NT Auto Shot Preset**: the preset auto shot setting for the NT measurement when the user sets the tracking option FT
- **Pupil Distance**: the pupil distance setting for move to the other eye



[Setup mode Information (MSR COMMON – 4 Page)]

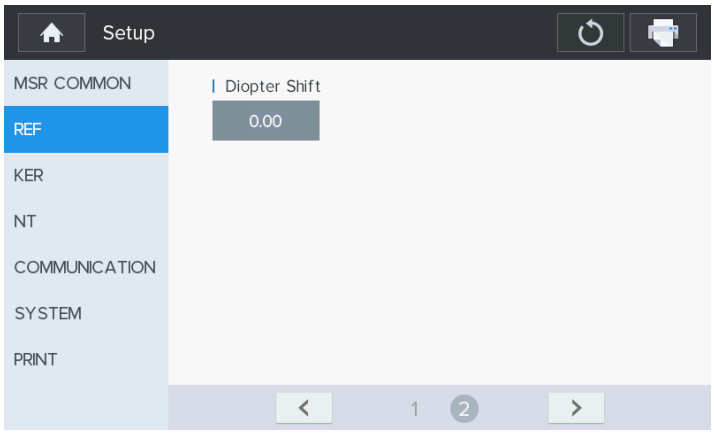
- **Default Mode**: Select the first head position of the FT measurement
- **Default Side**: Select the first eye side of the FT measurement
- **MOVE Default Position**: Set whether to return to the default mode after FT measurement

8.3.2. REF Page



[Setup mode Information (REF – 1 Page)]

- **VD**: A setting for the Vertex Distance
- **Cylinder:** Astigmatism marking form
- **REF Step:** Unit for indicating spherical prescription and astigmatism prescription
- **Fogging:** Select whether to carry out the mist execution frequency once or every time when carrying out continuous measurement



[Setup mode Information (REF – 2 Page)]

- **Diopter Shift:** Set up the applicable value to correct the diopter measurement value(Scope: -5.00~+5.00)

8.3.3. KER Page



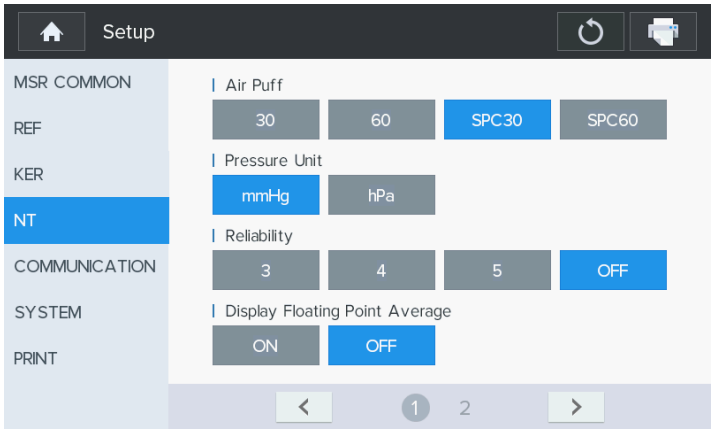
[Setup mode Information (KER)]

- **mm/D:** Marking form of cornea measurement

mm	R1	major axis radius
	R2	minor axis radius
	AX	major axis's angle
D	K1	minimum cornea refractive power
	K2	maximum cornea refractive power
	AX	minimum cornea refractive power's angle
AVG	AR	average curvature radius
	CY	cornea astigmatism prescription
	AX	cornea astigmatism's angle

- **KER Step:** Unit for indicating cornea refractive power and cornea astigmatism prescription
- **Index:** Selection of cornea equivalence's refractive power

8.3.4. NT Page



[Setup mode Information (NT – 1 Page)]

- **Air Puff:** Air Pressure automatic measurement by patient`s intraocular pressure.

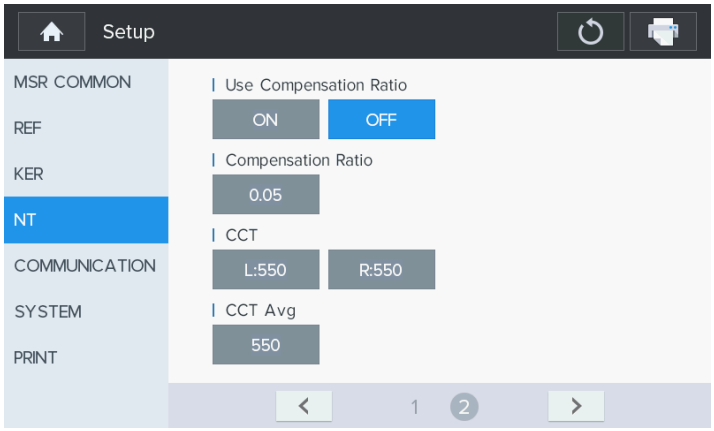
30: The peak of the air pressure is fixed within the range of 1 to 30 mmHg
60: The peak of the air pressure is fixed within the range of 1 to 60 mmHg
SPC 30: The peak of the air pressue is automatically controlled within the range of 1 to 30 mmHg
SPC 60: 30 mmHg or more of intraocular pressure.

- **Pressure Unit:** Selection of pressure unit (mmHg, hPa)

- **Reliability:** Set the reliable offset to remove unreliable IOP measured data. If any IOP measured data is out of reliable range (IOP measured average - reliable offset, IOP measured average + reliable offset), then it is considered unreliable.

Unreliable data are marked with an '*' on the printed result, and they are excluded from calculating IOP average.
If OFF is selected, checking reliability of IOP measured data is disabled.

- **Display Floating Point Average:** Set the floating point display of average value. If you select 'On', display the floating point.



[Setup mode Information (NT – 2 Page)]

- **Use Compensation Ratio:** Set whether Corneal Thickness compensation should be applied or not.

- **Compensation Ratio:** Setup of Compensation ratio (0.0001~1.0000)

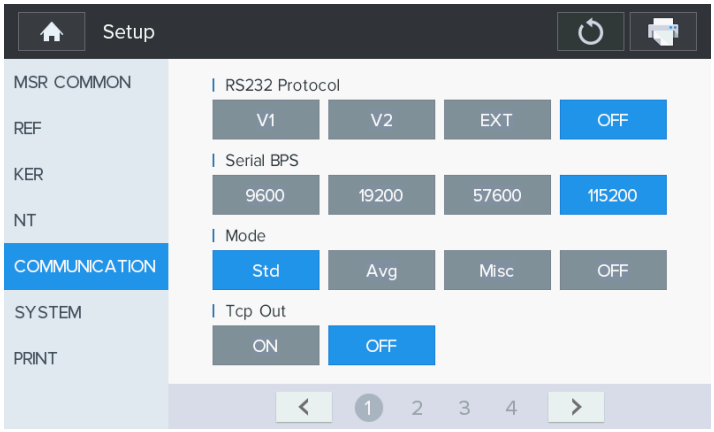
- **CCT:** Input data of Cornea Thickness (Left/Right)



[Input data of Cornea Thickness]

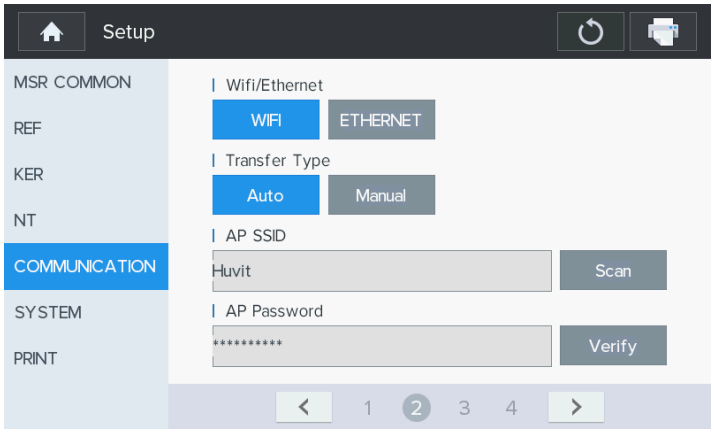
- **CCT Average:** Setup of average value for Cornea Thickness(as reference)

8.3.5. COMMUNICATION Page



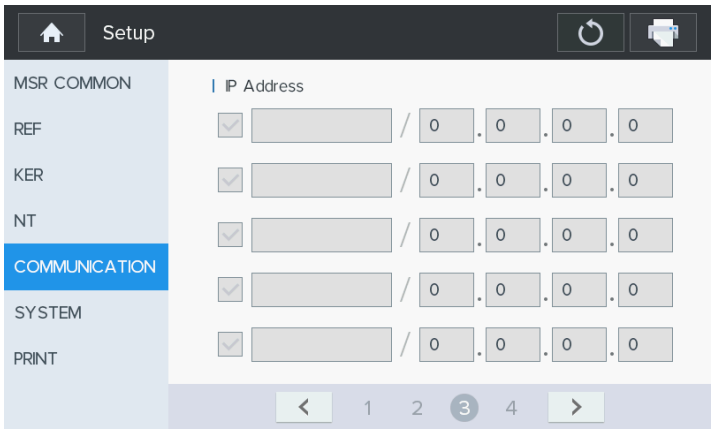
[Setup mode Information (COMMUNICATION – 1 Page)]

- **RS232 Protocol:** Setting up the transmission method(other equipment method and Version)
- **Serial BPS:** Select data transmission speed with other device
- **Mode:** Data format setting for transmission method
- **Tcp Out:** Data transmission on/off via Ethernet after printing result



[Setup mode Information (COMMUNICATION – 2 Page)]

- **Wifi Out:** Data transmission on/off via wifi after printing result
- **AP SSID:** Set access point service set identifier
- **AP Password:** Set access point password

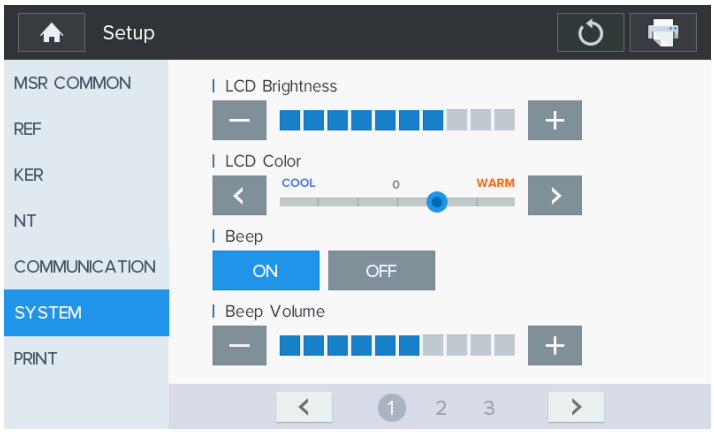


[Setup mode Information (COMMUNICATION – 3, 4 Page)]

- **IP Address:**

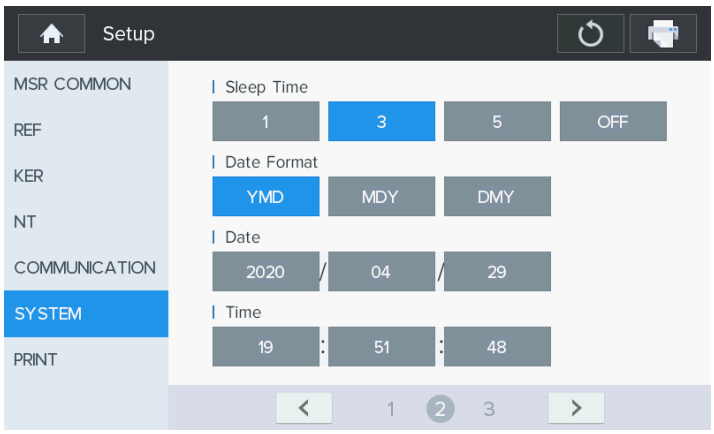
Each IP Address settings are consist of check [use or not], IP name and IP address

8.3.6. SYSTEM Page



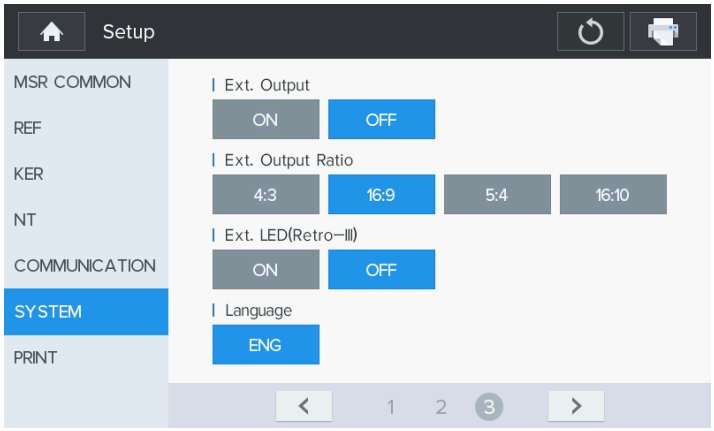
[Setup mode Information (SYSTEM – 1 Page)]

- **LCD Brightness:** Adjust brightness of LCD display(10~100%)
- **LCD Color:** Adjust color temperature of LCD display(COOL~WARM)
- **Beep:** Set beep sound on/off
- **Beep Volume:** Adjust beep sound volume



[Setup mode Information (SYSTEM – 2 Page)]

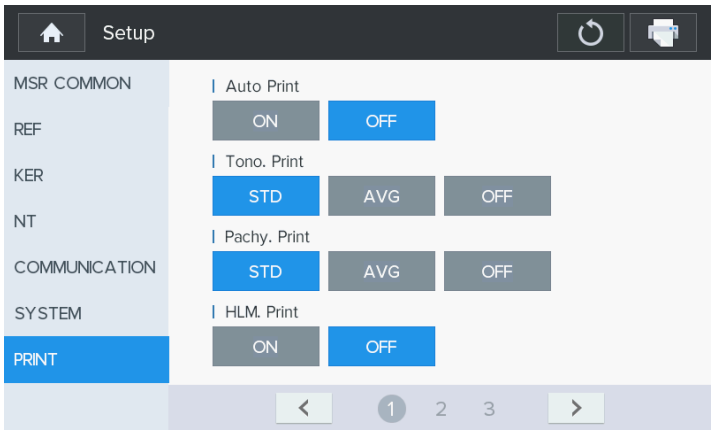
- **Sleep Time:** Setup the time required for entering into the power-saving mode
- **Date Format:** Set up of indication sequence of year/month/date
- **Date:** Set of year/month/day
- **Time:** Set of hour/minutes/second



[Setup mode Information (SYSTEM – 3 Page)]

- **Ext. Output:** Select whether to use external display output
- **Ext. Output Ratio:** Select resolution of external display output
- **Ext. LED(Retro-III):** Select whether to use external LED
- **Language:** Multi language setting

8.3.7. PRINT Page



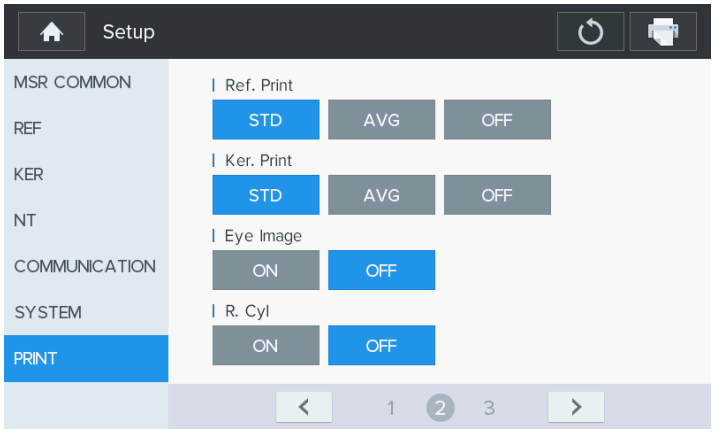
[Setup mode Information (PRINT– 1 Page)]

- **Auto Print:** In case of measuring in Auto mode, it is to print out the measured result automatically as the each measurement to left / right eyes is completed one after the other

- **Tono. Print:**
  STD: The measured Tonometry result & built-in printer of max ten (10) times are to be printed out
  AVG: Only average value is to be outputted printed out
  OFF: It is not to be printed out

- **Pachy. Print:**
  STD: The measured Pachymetry result & built-in printer of max ten (10) times are to be printed out
  AVG: Only average value is to be outputted printed out
  OFF: It is not to be printed out

- **HLM. Print:**
  ON: It is to print out the measured data from HLM-1.
  OFF: It is not to be printed out from HLM-1



[Setup mode Information (PRINT– 2 Page)]

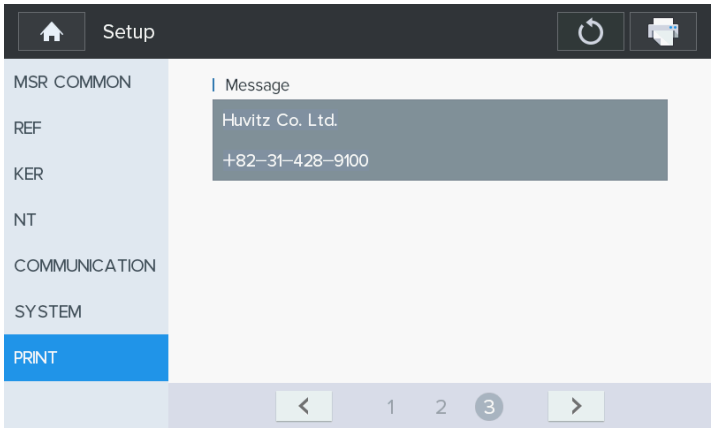
- **Ref. Print:**
  STD: The measured Refractometry result & built-in printer of max ten (10) times are to be printed out
  AVG: Only average value is to be outputted printed out
  OFF: It is not to be printed out

- **Ker. Print:**
  STD: The measured Keratometry result & built-in printer of max ten (10) times are to be printed out
  AVG: Only average value is to be outputted printed out
  OFF: It is not to be printed out

- **Eye Image:**
  : Selects output of the eyeball and curve figures following REF measurement result.

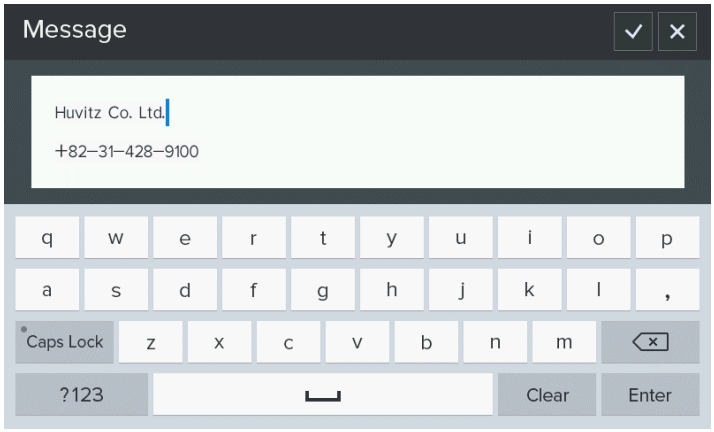
  ON: Selects output of the eyeball and curve figures following Refractometry measurement result.
  OFF: Did not get output.

- **R. Cyl (ON/OFF):**
  : : Selects remaining astigmatism output.



[Setup mode Information (PRINT– 3 Page)]

- **Message:** Input message to be output along with measurement data at the time of printing



[Virtual Keyboard]

[Character Input]

Clear : Erase of all input.

: Erase of text.

Enter : Change of line.

Caps Lock : Change of uppercase page.

?123 : Change of number and special character page.

: Save of information.

: Exit without save.

8.4. Measurement Data Transmission using WiFi

Measurement data can be transmitted to Huvitz Co. Ltd, phoropter using a WiFi network. Data can be transmitted without direct data cable connection using this function. Thus, it does not require any additional installations or take up installation spaces as it uses wireless network. Therefore, operations such as to install two equipment in different rooms on different floors are possible.

Maximum 10 phoropters can be registered, and up to four phoropters can be selected and used concurrently. Refraction data can be transmitted to all connected phoropters or to selected phoropters according to user settings.

Transmittable data are as the following.

-. Serial number of examinee.
-. Refractometry data on both eyes
-. Keratometry data on both eyes
-. Pupillary distance (PD)

8.4.1. WiFi Environment Setting

① Set the Access Point (AP) to provide WiFi network.
AP setting can vary in different manufacturers. Thus, set as the below referring to manual of each product.
-. Use Protocol: IEEE802.11b 2.4GHz WiFi
-. IP Assignment Mode: DHCP
-. Encryption Method: WPA2-PSK
-. AP SSID: A name to distinguish AP. Set as you like.
-. AP PASSWORD: Password. Set as you like.
-. After setting, please remember the AP SSID and AP PASSWORD to connect to WiFi network.

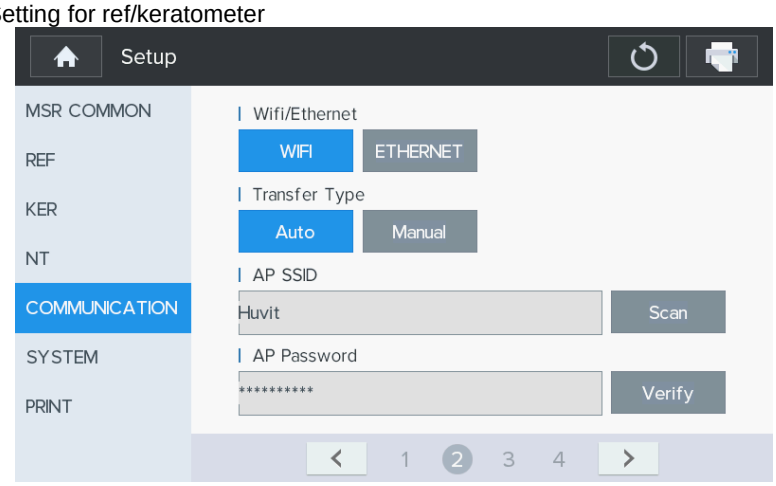
② WiFi Network Setting for Phoropter
Set up environment to connect to AP set on ① by referring to the manual of a phoropter. After setting up the environment, please remember the assigned IP address.

CAUTION

Use the static allocation IP Address that does not use the IP of the HDR that this device wants to access. When trying to access the device that uses the allocated IP by using DHCP function, access may not take place.

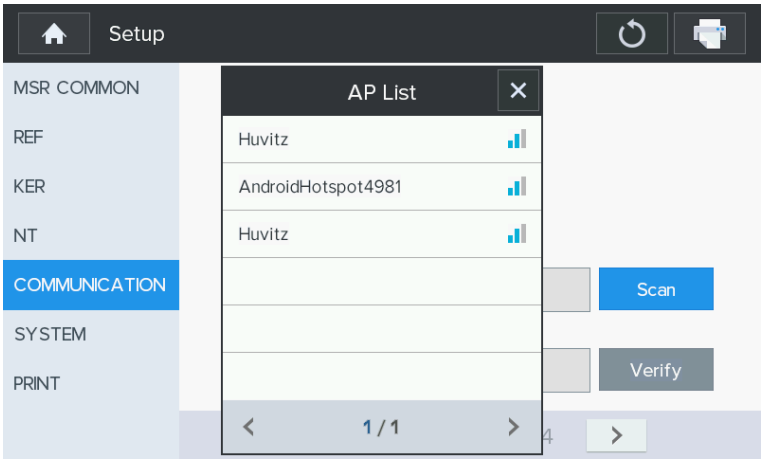
Utilisez l'adresse IP d'allocation statique qui n'utilise pas l'IP du HDR auquel cet appareil veut accéder. Lorsque vous essayez d'accéder au périphérique qui utilise l'IP allouée à l'aide de la fonction DHCP, l'accès peut ne pas avoir lieu.

③ WiFi Network Setting for ref/keratometer



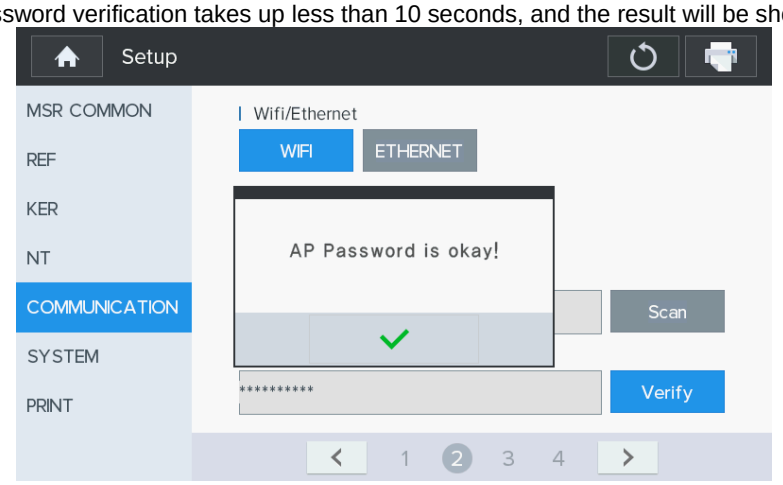
[Figure 8-4-1. WiFi Network Setting Screen]

-. Convert to User SETUP Mode, and select WIFI on page 2.
-. Turn on WiFi to use transmission function.
-. Set TRANSFER TYPE to set up data transmission method. (Refer to 9.4.3)
-. Press on the AP SSID entry window to enter SSID. When SSID is not known, press SCAN button on the right to select from available AP SSID.



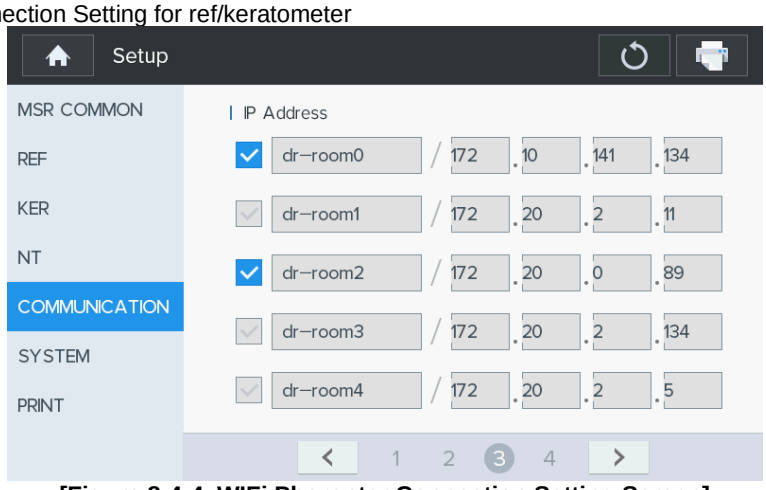
[Figure 8-4-2. WiFi AP Scan Result Screen]

-. Press on the AP PASSWORD entry window to enter password. Press VERIFY button on the right to confirm the password. Password verification takes up less than 10 seconds, and the result will be shown on the screen.



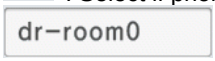
[Figure 8-4-3. WiFi AP Password Verification Result Screen]

④ Phoropter Connection Setting for ref/keratometer



[Figure 8-4-4. WIFi Phoropter Connection Setting Screen]

-. Convert to User SETUP Mode, ad select HDR IP 1 on page 2.
-. Enter information for phoropter to connect on each field.

-  : Select if phoropter will use the data transmission function.
- 

: Enter a name for the phoropter.
- 

: Enter the IP address of the phoropter. (Refer to ②.)

If there are more than six phoropters to enter, additional phoropters can be entered under HDR IP 2 Menu. Maximum 10 of phoropters can be registered. Up to four phoropters can be selected to use the transmission function concurrently.

8.4.2. Check WiFi Network Status

Current WiFi network status can be checked through the icons on the upper right of the screen.

 : Connected to AP normally.

 : Not connected to AP.

 : AP connection process is in progress.



: Connected to all selected phoropters normally.

 : Connection failure to one or more selected phoropters.

 : Phoropter connection process is in progress.

For user convenience, the machine will operate to make attempts to connect to AP automatically while the power is on if it is not connected to AP. Thus, user does not have to go through the AP connection process.

Also, the machine is set to make attempts to connect to all selected phoropters one by one automatically after connecting to AP.

CAUTION

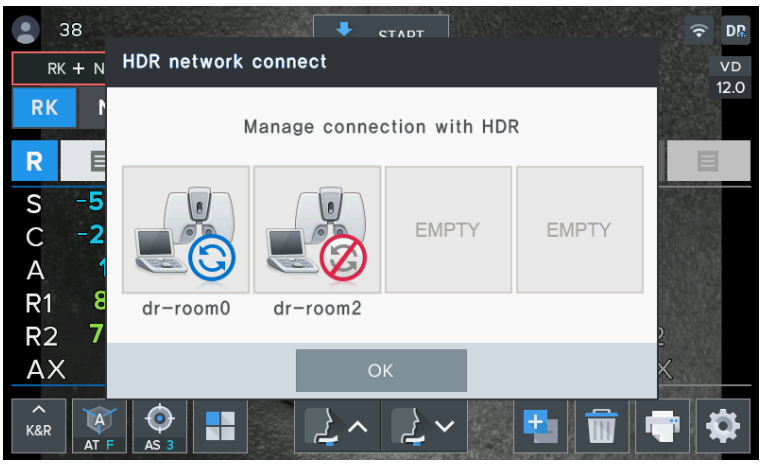
When the distance with the wireless AP is far, or if there is an obstacle between AP and this device, access may be unstable.
Increasingly effective communication is enabled when the AP is installed additionally at a near place or when the AP is moved to a closer place.

Lorsque la distance avec le point d'accès sans fil est éloignée, ou s'il y a un obstacle entre le point d'accès et cet appareil, l'accès peut être instable.
Une communication de plus en plus efficace est activée lorsque l'AP est installé en plus à un endroit proche ou lorsque l'AP est déplacé vers un endroit plus proche.

CAUTION

When the upper network's DHCP function is used due to the nature of the AP's DHCP movement, AP's IP reallocation movement may result, and thus network connection may be unstable during random period.

Lorsque la fonction DHCP du réseau supérieur est utilisée en raison de la nature du mouvement DHCP du point d'accès, le mouvement de réallocation IP du point d'accès peut en résulter et la connexion réseau peut donc être instable pendant une période aléatoire.



[Figure 8-4-6. Phoropter Connection Status Screen]

Status of each phoropter will be shown graphically on the four windows. Under the windows are the names of phoropters set by user. Graphic indications are described below.

(1)  : Connected to phoropter normally.

(2)  : Not connected to phoropter.

(3)  : Data transmission is complete. (At times of data transmission)

(4)  : Data transmission was unsuccessful. (At times of data transmission)

(5)

: There is not a phoropter selected.

If there is a connection error and the current status is on (2), try connecting again by pressing on the phoropter window. Connection takes up to 10 seconds depending on the environment, and the icon will change to (1) if the connection attempt was successful.

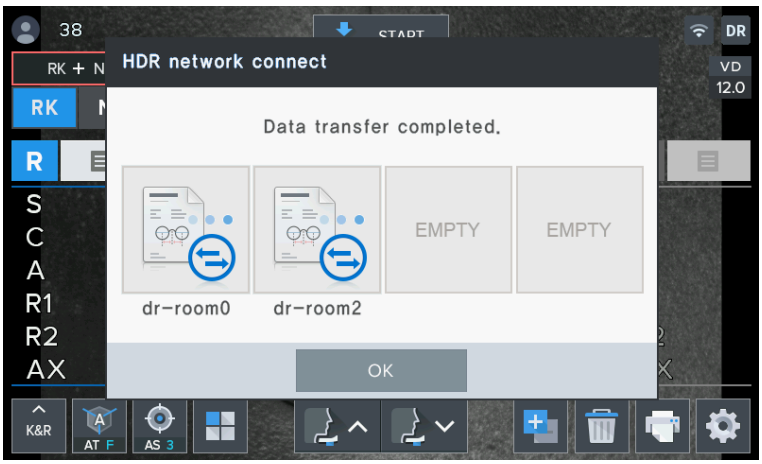
Turn off the status screen by pressing OK button on the bottom.

8.4.3. Measurement Data Transmission

After measuring refraction data of an examinee, the data can be transmitted to a phoropter through WiFi by pressing Print button on the front. Operations can vary depending on the TRANSFER TYPE set on the User SETUP.

① If it was set to AUTO

The data will be transmitted to all phoropters selected currently. After transmission, status screen (refer to 9.4.2) will appear, and user can confirm the transmission result through the graphical indications of phoropters (refer to 9.4.2).



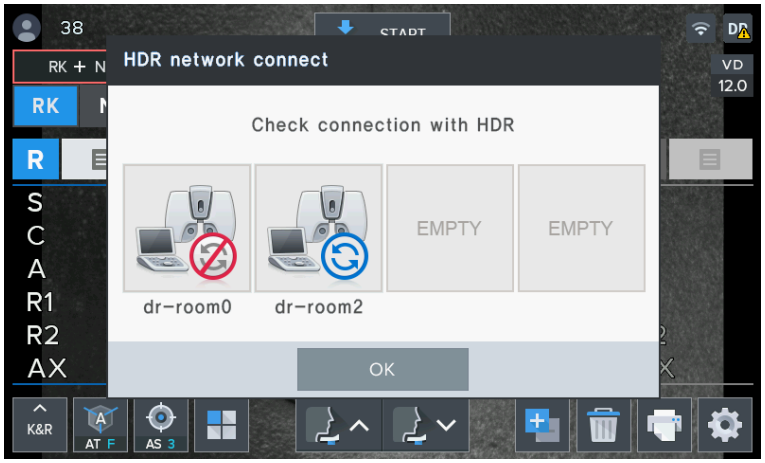
[Figure 8-4-7. Transmission Complete on AUTO Mode]

After confirming the result, press OK to turn off the status screen.

If there are connection errors on one or more phoropters, the setting will be converted to MANUAL without transmitting the data.

② If it was set to MANUAL

The data will not be transmitted immediately, and current phoropter connection status screen will appear.

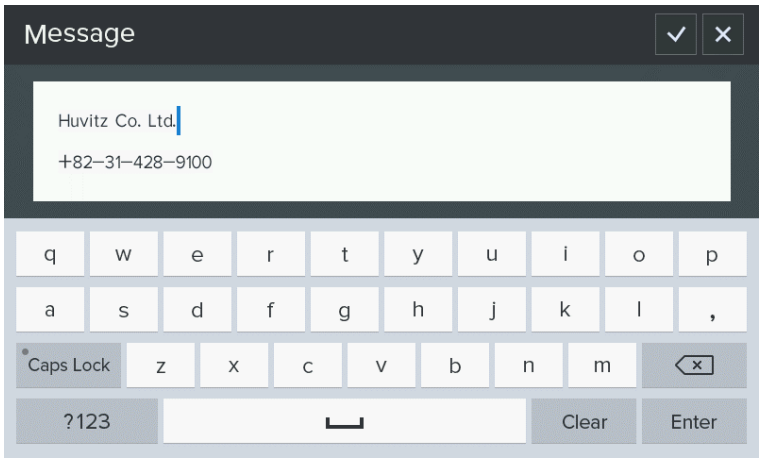


[Figure 8-4-8. Current Phoropter Connection Status Screen on MANUAL Mode]

Transmit data to a phoropter of user's choice by pressing on the phoropter window. If the phoropter is not connected, try to reconnect by pressing the window as shown in 9.4.2. After connecting to the phoropter, press on the window once again to transmit the data.

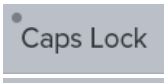
After completing the data transmission to the phoropter of user's choice, turn off the status screen by pressing OK button.

8.5. Input method

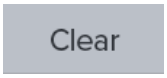


[Figure 8-5-1. other (text) input]

[Text input]

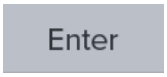


: Converts capital letter/small letter input mode.



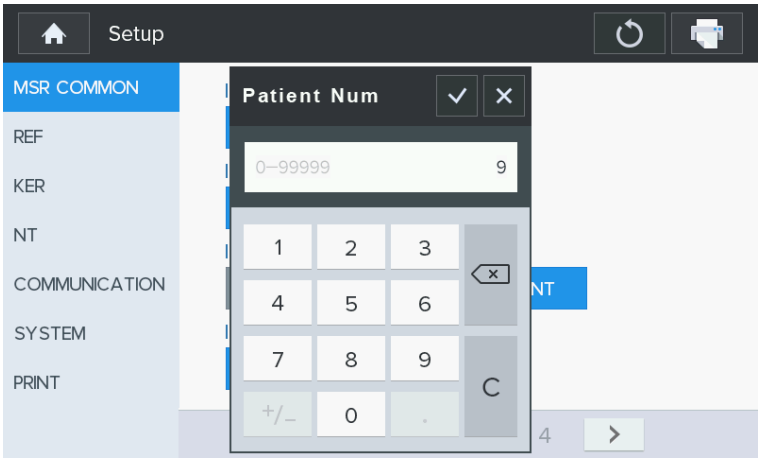
: Deletes all the input texts.


: (Back Space) deletes only one letter in front of the cursor.



: Converts the space in between the first and second lines.

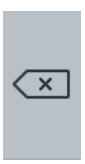

: Saves input text.



[Figure 8-5-2. other (number) input]

[Number input]

Range: Minimum ~ maximum scope that can be input
(Does not get saved when the scope is deviated from, and the warning message, “Out of Range!” appears.)


: Deletes the last number.



: Deletes all the numbers.


: Saves number and exists number input mode.

8.6. Power saving function

Power-saving function gets activated when you do not operate any function during three minutes (default). The mode returns to the measurement mode when you press on any button or touch the screen during the power-saving mode. It is possible to modify the power-saving time when you select the “SLEEP MODE” on the user SETUP mode.

9

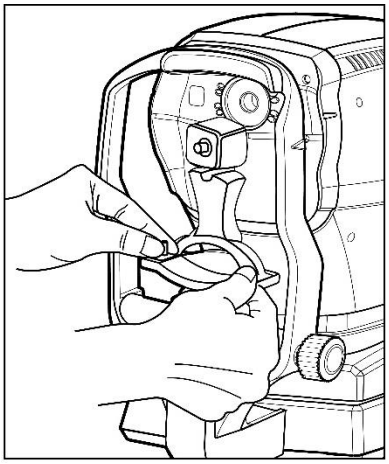
9. Self-diagnosis and maintenance/repair

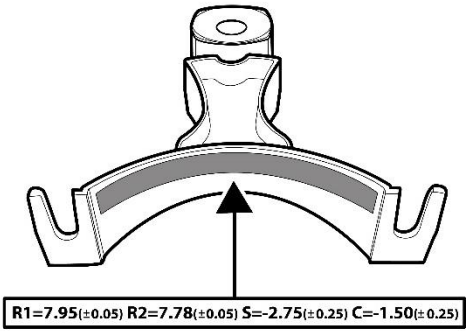
9.1. REF / KER Accuracy Check

Remove chin rest page, and fit in the pressing pin after aligning the hole at the Model Eye's lower part with chin rest's hole.

Perform the measurement and compare with the display value at the bottom of the model eye. (STEP 0.01)

Perform the accuracy check at regular intervals. (Daily checkup)





CAUTION

If the measurement result is widely different from the value shown on the model eye, call your dealer

Si le résultat de la mesure est très différent de la valeur indiquée sur l'œil du modèle, contactez votre revendeur.

9.2. IOP Calibration

We recommend that calibrate the HTR-1A periodically.
If the difference between HTR-1A and goldmann contact tonometer(is known as a gold standard) is more than 5mmHg frequently, we recommend that calibrate the HTR-1A.
Calibration is not allowed by a user because of the technical issues.
Contact to the Huvitz's authorized distributor or Huvitz Co.,Ltd.
If the period of calibration is resticted by the local law, follow up the local law.

9.3. Prior to calling a serviceman

Warning appears on the screen when there is a problem or when this device malfunctions. Take the following measures in case of the following.
Contact a sales distributor after turning off the power when the device does not resume normal operation even after taking the following measures.

9.3.1. REF / KER Mode Error Message

When power switch is turned on

Message	Root causes	Measures
Motor Error	Abnormality at the inside of the device	Turn off the power and turn the power on after 10 seconds. Contact a sales distributor when the warning message appears again
EEPROM Error		
EEPROM Data Error		
System Error		
Clock Error		
INVALID SETUP DATA – REF	Abnormality of the internal data for Refractometry	Contact a sales distributor
INVALID SETUP DATA - KER	Abnormality of the internal data for Keratometry	Contact a sales distributor

Message during measurement

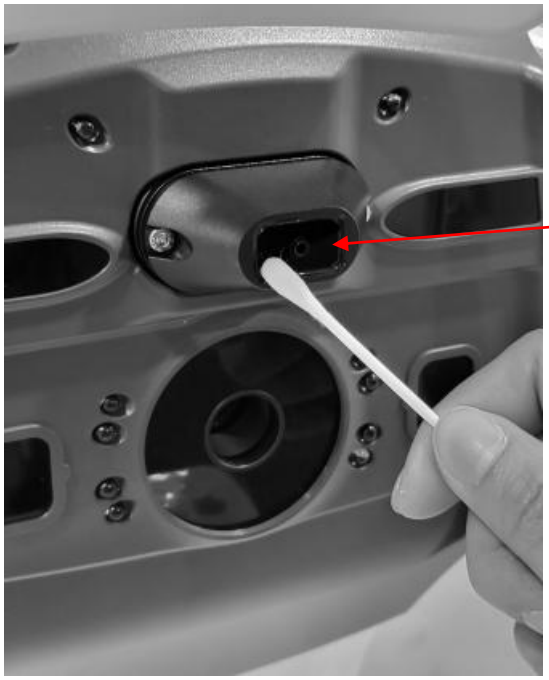
Message	Root causes	Measures
TRY AGAIN	Refer to Page 15	Refer to Page 15
	Contamination of the object lens on the measurement screen	Clean the object lens
+ OUT	Spherical prescription of the eye for testing exceeds +25 D	Impossible to carry out measurement
	Curvature radius of the eye for testing exceeds 13.0 mm	
	Contamination of the object lens on the measurement screen	Clean the object lens
- OUT	Spherical prescription for the eye for testing exceeds –30 D	Impossible to carry out measurement
	Curvature radius of the eye for testing is less than 5.0 mm	
	Contamination of the object lens on the measurement screen	Clean the object lens
C OUT	Astigmatism of the eye for testing exceeds 12 D	Impossible to carry out measurement
	Cornea astigmatism of the eye for testing exceeds 15 D	
	Contamination of the object lens on the measurement screen	Clean the object lens

Message when printing

Message	Root causes	Measures
CHECK PAPER	There is no printer page or the lever is not shut.	Add on printer page or close the lever.

9.3.2. NT Mode Error Message and Solution

Stage	Error message	Cause	solution
Self – test	LOAD SYSTEM DATA ... FAILED	failed to load system configuration data	1. Touch the screen or press joystick button 2. Load and Save default settings. 3. Setup setting and turn off the device 4. If same error message is displayed again, turn off the device and contact Huvitz or your authorized distributor
Tono mode	EYE NOT FOUND	Eye position is not align clearly	1. Clean the glass part around air nozzle and try again. 2. If same error message is displayed again, turn off the device and co ntact Huvitz or your authorized distributor.
	EYELID COV-ERED	Eye closed.	1. Try again. 2. If same error message is displayed again, turn off the device and contact Huvitz or your authorized distributor
	APPL WEAK	Applanation signal is weak.	
	APPL OVER	Applanation signal is strong	
	IOP OVER	the result of calculated data is over the meas-urement range	1. Change the measurement range (60, SPC 60) and retry 2. If same error message is displayed again, turn off the device and contact Huvitz or your authorized distributor.
	WEAK PRESS	Pressure of solenoid is weak.	
	SETUP INVALID	IOP Setup data is not valid.	1. Turn off the device and contact Huvitz or your authorized distributor
Pachy mode	IMAGE NOT FOUND	The detection of the corneal thickness area is not available	1. Reduce the brightness of circumstance and try again. 2. If same error message is displayed again, turn off the device and contact Huvitz or your authorized distributor.
	PACHY INVALID	the result of calculated pachy data is not valid.	1. Try again. 2. If same error message is displayed again, turn off the device and contact Huvitz or your authorized distributor
	P-SETUP INVA-LID	Pachy Setup data is not valid.	
	RANGE OVER	the result of calculated data is over the meas-urement range	
	TOO NEAR	the CCT area of cap-tured image is located in above	1.Try again 2. If same error message is displayed again, turn off the device and contact Huvitz or your authorized distributor
	TOO FAR	the CCT area of cap-tured image is located in below	
	[P]P-TR FAILED	The nozzle window is dirty and contaminat-ed.(Because of tears, fingerprints, cosmetics, etc.)	Clean the nozzle window with soapy water and soft cotton swab. (See the figure 9-3-2)
	[P]P-TR TIMEOUT		
	[P]SIG NOISE		
	[P]NO ANTERI-OR SIG		



[Figure 9-3-2.
Cleaning Nozzle Window]

9.4. Replacing

9.4.1. Printer page

Replace the paper for the printer immediately when red line appears on the paper.

① Open the cover by pressing on the button located next to the printer.

② Cut the paper that is stuck in the printer and take out the paper roll to the outside.

③ Put in new paper roll into the printer case.

④ Fixate the paper by pushing it into the printer. At this time, adjust the length to a degree that can be discharged as the paper gets fit into the paper discharge hole of the cover.

⑤ Close the cover after fitting in the ends of the paper to the hole that lies in between the covers.



[Figure 9-3-1. Printer paper replacing]

⚠ CAUTION

Be sure to use only the printer paper (9010A000001-A, W 57mm, D 50mm) specified by HUVITZ.

If printer paper other than those specified is used, the printer head may be damaged due to printing failure or paper jam.

Veillez à utiliser uniquement le papier d'imprimante (9010A000001-A, L 57 mm, P 50 mm) spécifié par HUVITZ.

Si du papier d'imprimante autre que ceux spécifiés est utilisé, la tête d'impression peut être endommagée en raison d'un échec d'impression ou d'un bourrage papier.

⚠ NOTE

Be sure that printer paper is not loaded in a tilted angle and that the core of the roll is properly placed. Printer paper may not be fed properly.

9.4.2. Chin rest paper

① Take out two pins from the chin rest.

② Push in the pin into the hole that is found on the chin rest paper. It is possible to mount over 50 pages.

③ Fit in a pin in each of the two holes of the chin rest.

9.5. Cleaning Equipment

① The equipment should be kept as clean basically. Do not use the solvents such as strongly volatile substance, thinner, benzene, etc.

② Put some soapy water to the soft cloth, and twist the water out of the cloth.
Then, polish each part of the equipment.

③ As polishing the parts of lens or glass, get rid of dusts on the surface of lens with wind-blower and use a dry cloth.

④ Always keep it clean for a patient to use chinrest paper in chin rest, to clean it often in head rest.

⑤ Always clean the patient contact parts (such as chin rest and head rest) and Hand-washing (Operator: such as an iodophor or chlorhexidine gluconate) prior to disinfection.

⑥ When using an FDA or CE-cleared (as appropriate) disinfecting agent, carefully follow the instructions provided the manufacturer of the product.

⑦ For low-level disinfection(normally), the patient contact parts may be wiped with any of the following low level disinfectants. Methods to disinfect to HTR-1A are as below:
-. Dry heat
-. Mechanical cleaning with disposable wipe / sterile gauze
-. Wipe with gauze soaked in alcohol or chemicals like hydrogen peroxide and Merthiolate
-. Soaking in chnicals like 70% isopropyl alcohol, 1:1000 Merthiolate, 3% hydrogen peroxide and 1:10 diluted house hold bleach (sodium hypochlorite)

Solution	Manufacturer	Cleaner/ Disinfectant	Active ingredient	Cleared/Approved for use in
Alkazyme	Alkapharm	Cleaner	Proteolyticenzyme, Quat, Ammonia	Europe
Klenzyme	Steis/Calgon Corp.	Cleaner	Enzymes	USA & Europe

⑧ For high-level disinfection(if needed), the patient contact parts may be wipe using one of the following disinfection agents:

Solution	Manufacturer	Cleaner/ Disinfectant	Active ingredient	Cleared/Approved for use in
Cidex OPA	Adavaced Steriliza-tion Product	Disinfectant	Orthophtalade-hyde	USA & Europe

9.6. When moving equipment installation place

① Turn off the main body's power switch.

② Separate power connection cable.

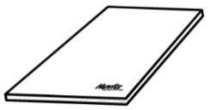
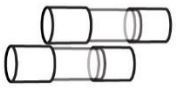
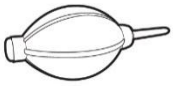
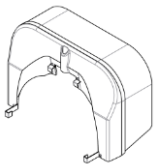
③ Lock by turning the Clamping bolt into the clockwise direction.

④ Move while maintaining horizontal balance while holding the lower part of the main body.

10

10. Specifications and Accessories

10.1. Standard Accessories

 1. Power cable	 2. Chinrest paper	 3. Printer Paper
 4. Dust cover	 5. Operation's manual	 6. Spare Fuse (250V T 3.15A)
 7. Wind Blower	 8. Model Eye	 9. Light Shield

No.	Accessory name	Function	Specification	Quantity
1	Power cable	Connect the device to power line	(Detachable) Rated 10 A, 250V. Plug type CEE7, Connector type IEC 60320/C13, and Cord type H05VV-F3G, min. 0.75 mm2, 3-conductor terminating in molded-on grounding type attachment plug. <HAR> marked on the cord. Maximum 2.5 m long.	1 unit
	Power cable (For use only 110V)		Detachable) Listed, Type SJT, min. No.18 AWG, 3-conductor terminating in molded-on Listed "Hospital Grade", parallel blade, NEMA 5-15P, grounding type attachment plug rated minimum 10 A,125 V. Maximum 2.5 m long.	1 unit
2	Chin rest paper	Spare parts	Material: paper, Finish: natural Size: 130 x 40 x 0.05mm,	100 sheet
3	Print paper	Spare parts	width: 57mm	2 rolls

4	Dust cover	Covering the device when is unused	Size: 320 * 590 * 600 Material: Natural Nonwoven Spunbond	1 piece
5	Operation's Manual	Instruction for use	B5	1volume
6	Spare Fuse	Spare parts	250V, T 3.15AL	2 units
7	Wind Blower	Remove dust of measure lens	-	1 unit
8	Model Eye	Self-diagnosis	SPH: –2.50D~-2.75D CYL: -1.25D~-1.50D R1: 7.95~8.00 R2: 7.78~7.83	1 unit
9	Light Shield	Blocks light around the eyes.	Size: 320 * 215 * 154 Color: Black	1 unit

10.2. Specification

Measurement mode	
Cornea curvature radius/Refractive power continuous measurement (K/R mode)	
Refractive power measurement (REF mode), Cornea curvature radius measurement (KER mode)	
Cornea peripheral radius measurement (KER-P mode)	
Central corneal thickness/Intra ocular pressure continuous measurement (TONO /PACHY mode)	
Intra ocular pressure measurement (TONO mode), central corneal thickness (PACHY mode)	
Refractive power measurement	
Distance between vertex of cornea (VD)	0.0, 12.0, 13.75, 15.0
Spherical prescription (SPH)	-30.00 ~ +25.00 D (in case of VD = 12 mm)
Astigmatism prescription (CYL)	0.00 ~ ±12.00D (0.01/0.12/0.25 D unit)
Astigmatism axis angle (AX)	0 ~ 180˚ (1˚ unit)
Astigmatism indication	-, +, MIX
Pupil distance (PD)	10 ~ 85 mm
Minimum pupil diameter that can be measured	Ø2.0 mm
Working Distance	45 mm
The accuracy specifications are based on the results of eye model testing preformed in accordance with ISO10342	
Cornea curvature radius measurement	
Corneal curvature radius	5.0 ~ 13.0 mm (0.01 mm unit)
Cornea refractive power	measurement unit: 25.96D~67.50D (cornea equivalence's refractive power: 1.3375) indication unit: 0.05/0.12/0.25D unit
Cornea astigmatism prescription	0.0 ~ -15.00 D (Increments: 0.05/0.12/0.25 D)
Cornea astigmatism axis angle	0 ~ 180˚ (1˚/ 5˚ unit)
Cornea diameter measurement	2.0 ~ 14.0 mm (0.1 mm unit)
The measuring range is in accordance with Code A, ISO 10343 and the measuring accuracy in accordance with Code 2, ISO 10343.)	
IOP measurement	
IOP range	1 ~ 60 mmHg SPC 30 / SPC 60, 30 / 60
Measurement increment	1 mmHg (Average : 0.1 mmHg)
Accuracy	±5.0 mmHg
Corneal thickness measurement	
CCT measurement range	300 ~ 800 μm

Measurement increment	1 μm		
Accuracy	±10.0 μm		
Wireless I/F			
Protocol	IEEE802.11b 2.4GHz WiFi / 802.11 a,n 5GHz WiFi		
Security mode	WPA2-PSK		
IP configuration	DHCP mode		
Auto travel distance			
Up and down	83 mm (±3mm) : Total	RK Mode	40 mm (±5mm)
		NT Mode	40 mm (±5mm)
Left and right	90 mm (±2mm)		
Front and back	40 mm (±2mm)		
Automatic tracking scope			
Up and down	± 5 mm		
Left and right	± 5 mm		
Front and back	± 5 mm		
Chin rest travel distance			
Up and down	65 mm (±3mm)		
Data memory			
10 session worth of measurement values for each of the eyes on the left and right			
Interface			
RS-232C	TONO/REF/KER/PACHY measure Data transfer to PC / HDR Capture Image transfer to PC Internal Software Update from PC(Engineer Only)		
USB	Internal Software Update from PC(Engineer Only)		
Ethernet	TONO/REF/KER/PACHY measure Data transfer to PC / HDR Capture Image transfer to PC		
WiFi	For communication with HDR-9000		
Ext. VIDEO	Analog RGB		
Hardware specs			
Built-in printer	Thermoelectric line printer/Auto Cutting		
power-saving function	Key power is blocked when the measurement is stopped up the set time. Recovered when pressing on the button or when the screen is touched.		
Monitor	85˚ Tiltable 7” Color LCD IPS Panel (800*480) Resistive Touch panel		
Dimensions	301(W) x 535(D) x 506(H) (mm)		
Weight	23.8Kg		
Power consumption	100-240 Vac 0.9-0.6A 50/60Hz		

10.3. Accuracy

- The accuracy specifications are based on the results of model eye testing performed in accordance with ISO10342 Ophthalmic instruments- Eye Refractometers, ISO10343 Ophthalmometers.

1) Refractometry

Criterion	Measuring range	Maximum scale interval	Test device	Tolerance
SPH	-15D ~ +15D (Maximum meridional vertex power)	0.25D	0D, ±5D, ±10D	±0.25D
			±15D	±0.50D
CYL	0D ~ 6D	0.25D	Sphere: approx. 0D Cylinder: -3D Axis: 0°, 90°	±0.25D
Axis	0° ~ 180°	1°		±5°
a The refractive error of the test device shall not differ by more than 1,0 D from the nominal value above. b Cylinder axis shall be indicated as specified in ISO 8429.				

2) Keratometry

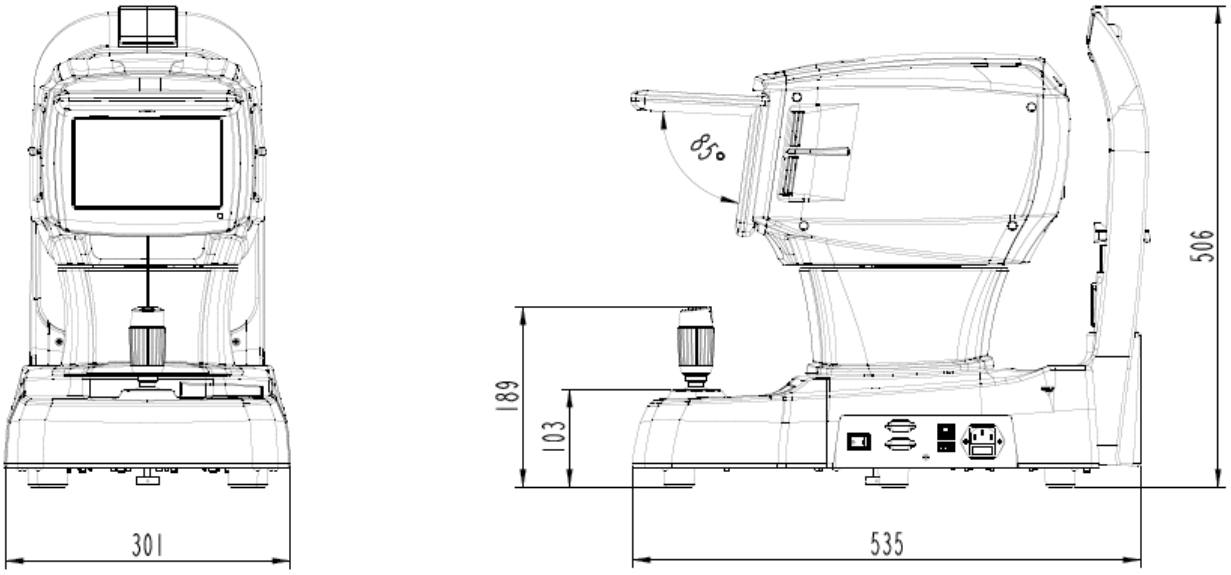
NO	Criterion		Requirement
1	Measuring range		6.5㎜ to 9.4㎜
2	Radii readings for	Continuously indicating instruments	Scale interval of 0.1㎜
		Digitally indicating instruments	Increment 0.02㎜
3	Measurement accuracy (twice the standard deviation, i.e. 2σ)		±0.05㎜

3) Measurement of direction of principal meridians

NO	Criterion		Requirement
1	Measuring range		0° to 180°
2	Meridian direction reading	continuously indicating scales	scale interval 5°
		digitally indicating scales	increment 1°
3	Measurement accuracy using test device (twice the standard deviation, i.e. 2σ)	for principal meridional differences in radii of curvature < 0,3 mm	±4°
		for principal meridional differences in radii of curvature ≥0,3 mm	±2°
Angular indications shall be in accordance with ISO 8429.			

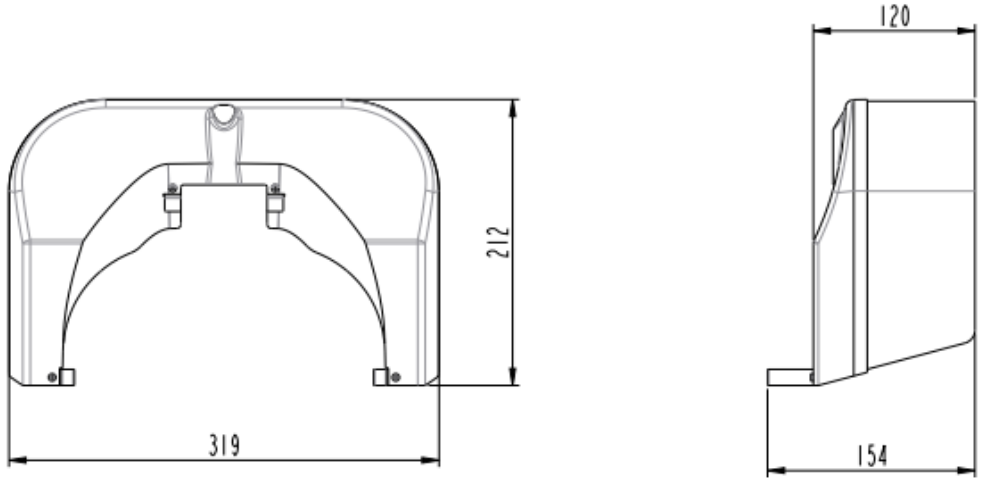
10.4. Drawings of System

1. HTR-1A



Weight: 23.8 Kg

2. LIGHT SHIELD



Weight: 0.35 Kg

10.5. Install of Light Shield

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③



④



⑤



11

11. EMC INFORMATION

Manufacturer announcement – electromagnetic waves trouble

- **Electromagnetic waves trouble**

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

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

HTR-1A is to be used in the below mentioned electromagnetic wave environment. HTR-1A purchaser or user needs to confirm whether HTR-1A 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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12. 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.

-. Name of Equipment Type: Auto Tono/Refracto/Kerato/Pachymeter HTR-1A
-. Typical No. of Equipment: Typical number consisted of 8 digits and characters written on its name plate.
-. Explanation on its symptom: Description in detail.

Supply of parts required for repair:

-. 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:

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

-. Back up battery for clock and data.