Huvitz

VISION SCREENER
Operation description
HVS-1

■ Revision History

Revision	Date	Approval	Description
A	2023.12.11		First issued
B	2025.01.08		Updated the representative of Brazil information
C	2025.03.24		Added the using method of web-viewer including the measurement results

9000ENG0133-C
(2025/03/24)

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

CONTENT

1. Introduction

1.1 Intended Use

The HVS-1 Vision Screener is intended to measure the refractive power of the eye.

1.2 Device overview

The Vision Screener, HVS-1 is a device that measures the refractive power of the human eye. The following parameters are measured:

- Spherical power(SPH)
- Cylinder power(CYL)
- Axis (AXS)
- Pupil Distance(PD)
- Pupil size

The HVS-1 can measure both eyes simultaneously from a distance of approximately one meter.
The measuring distance is calculated by the software using ultrasound, and the results are shown on the screen. When the measuring distance is deemed suitable for accurate measurement, the HVS-1 automatically captures the measurement of the eyes. This process involves sequentially irradiating the pupil with the IR LED along six axes, and capturing the reflected LED from the pupil through the camera. The pupil is detected from the acquired images, and analyzed to calculate refractive power. The results which include the measured refractive power and pupil information, are displayed on the screen and can be externally transmitted via WiFi or USB interface.

The HVS-1 displays the image of the human eye on the LCD screen at a suitable distance, which is aligned and determined using ultrasound. Additionally, the device offers visual and audible sounds to help the children focus during the measurement.

This equipment is not intended to replace a comprehensive examination performed by an ophthalmologist or to be directly used for prescribing purposes. The measured data is solely used for screening purposes.

1.3 Device classification

1. Classification of product :
   -. EU - Class I with a measuring function according to Annex IX (Rule 12) of the Medical Device regulation 2017/745
   -. MFDS – Class II
2. Resistance against electric shock : Class II (Adapter)
3. Protection against harmful ingress of water : Ordinary, IPX0
4. 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.
5. Mode of operation : Continuous

1.4 Contraindication

This device should not be used for:
- Patients who are hypersensitive to light.
- Patients who recently underwent photodynamic therapy
- Patients taking medication that causes photosensitivity

There are no known residual risks apart from those associated with the contraindications. However, in the event of unexpected occurrences or encountering various issues, please reach out to your local distributor or Authorized Representatives for assistance.

1.5 Patient requirements

Patients undergoing examination with this device must maintain concentration for a few minutes and adhere to the following instructions:

- Keep the eye open and focus on the LED
- Understand and follow instructions during the examination.

Failure to adhere to these conditions may result in incorrect imaging.

1.6 Applied Standard List

1) IEC/EN 60601-1: Medical electrical equipment Part 1: General requirements for safety

2) IEC/EN 60601-1-2: Medical electrical equipment Part1: General requirements for safety
 - Collateral Standard: Electromagnetic Compatibility-Requirements and tests

3) ISO15004-1: Ophthalmic instruments
 - Fundamental requirements and test methods
 General Requirements applicable to all Ophthalmic instrument

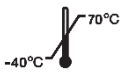
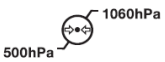
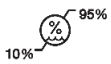
4) IEC 62471: Photobiological safety of lamps and lamp systems

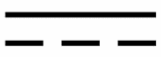
2. Safety information

2.1 Introduction

Safety is the obligation and responsibility of everyone. Ensuring the safe use of this device is crucial for all individuals involved, including installers, users, operators, and device managers. It is important to thoroughly read and understand this manual before installing, operating cleaning, repairing, or controlling this device and its accessories. All users or managers must pay special attention to the "WARNING" or "CAUTION" messages in the manual in addition to thoroughly mastering the contents of the manual.

2.2 Symbol explanation

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 'entretien approprié.)
	This symbol identifies a "Warning" caution against the existence of calamity that can cause severe personal injury, death or property loss in case of negligence. (Ce symbole identifie un « Avertissement » contre l'existence d'une calamité pouvant entraîner de graves blessures corporelles, la mort ou une perte de propriété en cas de négligence.)
	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 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. please contact your city office, waste disposal service or the shop where you purchased the product. Symbole WEEE- EU seulement 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. 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)
	QR code (QR code)
	Direct current (Courant direct)
	Alternating Current (Courant alternative)
	Consult instructions for use (Consulter les instructions d'utilisation)

	The United States and Canada have mutual-recognition agreements. Therefore, if certified using a Canadian specification (CSA) for UL, the certification mark for the product will be a C-UL certification mark which means CSA specification compliance as follows. (Les États-Unis et le Canada ont conclu des accords de libre-échange. Par conséquent, si l'on obtient une certification au moyen d'une spécification canadienne (CSA) pour l'AMT, la marque de certification pour le produit sera une marque de certification C-UL, ce qui signifie la conformité de la spécification CSA comme suit.)
CE RoHS	CE for RoHS RoHS Directive Compliance 2011/65/EU (CE pour les RoHS Respect de la directive en matière de conformité 2011 / 65 / CE)
MD	Medical Device (dispositif medical)
CH REP	Authorized representative in Switzerland (Représentant autorisé dans la Suisse)

2.3 Safety Precautions

1. Do not store or install this device at the following places;
   (a) Places containing volatile chemical substances such as alcohol, benzene, or inflammable and explosive materials.
   (b) Humid environments where there is significant water splashing or dripping.
   (c) Locations experiencing severe temperature changes.
   (d) Place with severe temperature change
   (e) Avoid placing the device near hot equipment.
   (f) Areas where the machine is exposed to excessive shocks or vibrations.
   (g) Take caution to prevent dust and metal from entering the machine.
   (h) Exercise caution when handling cables during device placement.
   (i) Placing where it is difficult to operate the disconnecting device. (Disconnecting device: Power Cable)

2. Do not place containers with liquid or gas on top of the device.

3. Only plug the AC power cord into the outlet when all parts of the machine are completely connected. Otherwise, severe damage to the machine may occur.

4. This device should be operated by qualified personnel with sufficient training or under such personnel's supervision.

5. This device can be modified only by Huvitz's service technician or a person with comparable qualifications.

6. Device management by customer should be carried out as explained in the user or service manual. Management that requires more sophisticated skill set should only be carried out by Huvitz's service technician or a person with comparable qualifications.

7. Manufacturer assumes responsibility for this device's safety, reliability and performance only when the following conditions are satisfied: (1) When this device was installed at a viable space in accordance to this manual's regulations, and (2) when this device was used and maintained according to the procedure regulated in this manual or service manual.

8. Manufacturer does not take responsibility for the damage resulting from this device's unlawful modification. Unlawful modification may void the warranty during the warranty period.

9. This device is utilized with the accessories provided by Huvitz. If consumer wants to use other manufacturers' accessories, safety of use must be proven and confirmed by Huvitz or by the accessories' manufacturer.

10. Only a person who completed adequate training or education program can install, operate and maintain this device.

11. Store the user or service manual in a readily accessible location for the person managing and using this device.

12. Do not apply excessive force to the cable connection. If the cable does not connect easily, check if the connector (plug) is suitable for the socket. If the connector or socket is damaged, a qualified service technician should repair it.

13. Do not pull on the device's cable. Hold the plug to take remove it and open the cable

14. This device should be used according to the purposes stated in the manual.

15. Always inspect the device's external appearance and check its functionality before use.

16. Turn off the power immediately and unplug the device if smoke, sparks, abnormal noise, or smells are detected.

17. IEC standard needs to be satisfied with in order to connect an outside device with input/output signal or other connector. (IT equipment is IEC 62368-1, and electric equipment for medical use is IEC 60601). Moreover, all the systems need to satisfy the safety requirement, IEC 60601-1 when it comes to the electric system for medical use. Person who connects outside device with input/output signal or other connector has the obligation to take responsibility in accordance to the IEC60601-1. Contact local technician or distributor if you have doubts.

18. This equipment may cause edge which is hazardous for other devices at the periphery. Wireless frequency may be generated or used, and energy may be released when the device is not installed or used according to the guideline. However, there is no guarantee that edge does not result when carrying out specific installation. If this device leads to hazardous interception on other device when the equipment is turned on/off, user needs to solve the interception issue by using one of the following measures.
    - Change direction or relocate the receiver
    - Distance between equipment is increased
    - Connect the equipment with the socket of the circuit connected with other device and other circuit
    - Ask manufacturing business or field service technician for help

19. This equipment must be connected to a supply mains with protective earth.
20. Must be used, stored and transported in the below environments.
    - Usage: temperature 10℃ ~ 40℃, relative humidity 30 ~ 90%, atmospheric pressure 800 ~ 1060hpa
    - Storage: temperature –10℃ ~ 55℃, relative humidity 10 ~ 95%, atmospheric pressure 700 ~ 1060hpa.
    - Transportation: temperature -40℃ ~ 70℃, relative humidity 10 ~ 95%, atmospheric pressure 500 ~ 1060hpa

21. 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.

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

23. 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.

24. Subsequent changes to the IT-NETWORK which is connected from external device 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

2.4 Precautions during use

1. Handle with care as shock can cause damage to both the exterior and interior components.

2. Precision measurement may be affected when the product is exposed to direct sunlight or too bright indoor illumination. It is advisable to conduct measurements in a darkened eye examination room for optimal accuracy.

3. Seek guidance at the place of purchase when connecting the device with other equipment.

4. If the inside of the device heats up suddenly in a cold area, vapor may form on the objective lens from the customer's side and on the optical parts inside the device. In such cases, wait for the vapor to dissipate before taking measurements.

5. Ensure that the objective lens from the customer's side, which is used for testing, remains clean at all times. Errors or compromised precision measurements may occur if it is contaminated with dust or foreign substances.

6. In the event of smoke, odors, or unusual noises during use, disconnect the power plug immediately. Then, follow the instructions provided by the place of purchase.

7. Do not use alcohol, thinner, benzene and organic solvent to clean this equipment’s surface, as they may cause damage.

8. When moving the HVS-1, always turn off the power switch, and fixate the stage. Then, move by lifting up with lower part of the body with both hands.

9. If the HVS-1 will not be used for an extended period, disconnect the power and cover it with the dust cover.

10. When using this equipment under normal conditions, the proper location is as shown below..

11. When accessing the device's data using a PC, it should only be used within an internal closed network as encryption communication for the data is not performed. Additionally, it is recommended to use a PC equipped with firewall and antivirus software.

12. Change the device's password regularly to prevent unauthorized access. (The password should be a combination of alphanumeric characters with a minimum length of 10 characters)

13. If the entered password is incorrect three times or more, usage will be suspended for 10 minutes.

14. To prevent unauthorized access and use when the user is away, activate the "Screen Auto-Off" function.

15. Only connect to the internal closed communication network (WiFi) with a set ID and password to prevent unauthorized access.

16. If there are symptoms indicating that the device may be controlled by a cyberattack or if there are suspicions of a DDoS attack, immediately turn off the device and contact the seller or Huvitz via messenger, email, or phone

17. The measurement results of the HVS-1 may vary depending on the surrounding environment, the patient's

health status during measurement, the measurement time, and the capabilities of the operator. Additional tests and examinations by an ophthalmologist are necessary to determine eyeglass prescriptions and treatments for the patient.

2.5 FCC Warning

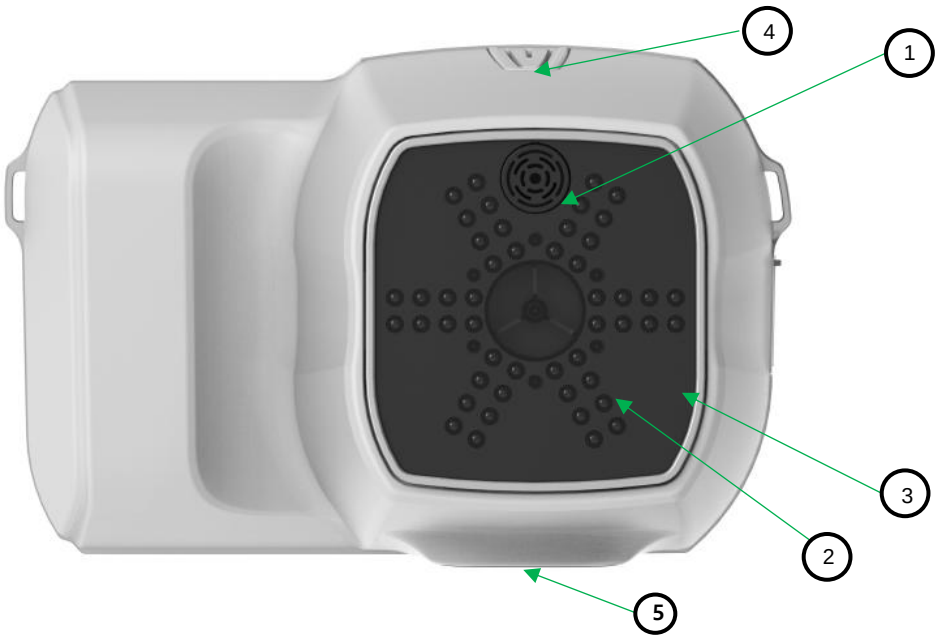
Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

3. Name and function of each part

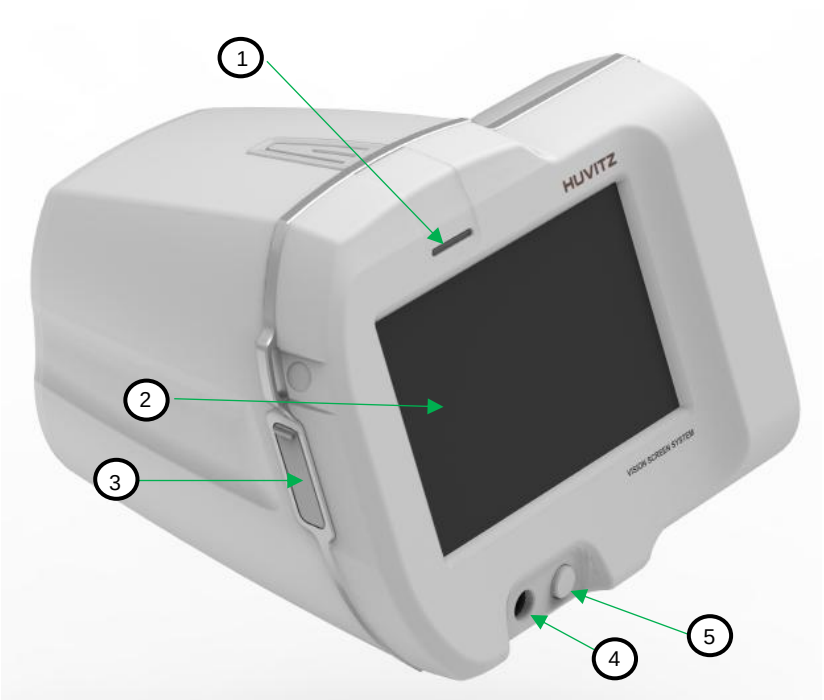
3.1 Front



[Front part]

1. **Distance sensor**: A sensor that measures distance.
2. **Focus LED**: LED to focus the patient.
3. **Front Glass**: Glass to protect LEDs.
4. **Speaker**: Audible sound for child.
5. **Camera mount :** 1/4 Inch

3.2 Rear



[Rear view]

1. Charge LED: Displays the charging status of the device. When charging, the LED emits a blue light, and once charging is complete, it turns green.
2. LCD Screen: This is a LCD for display.
3. USB port: Port that supports USB 2.0.
4. Charging port: This is the component where the charging cable is inserted.
5. Power on/off button: This button turns the power on/off. When the application is turned on, press for 2 seconds to open the exit window and hold for 5 seconds to force the shutdown.

⚠ NOTE: Due to the electrostatic discharge-sealed enclosure around the USB port, only USB types without USB bodies can be inserted correctly

The type of applicable :

The type of not applicable :

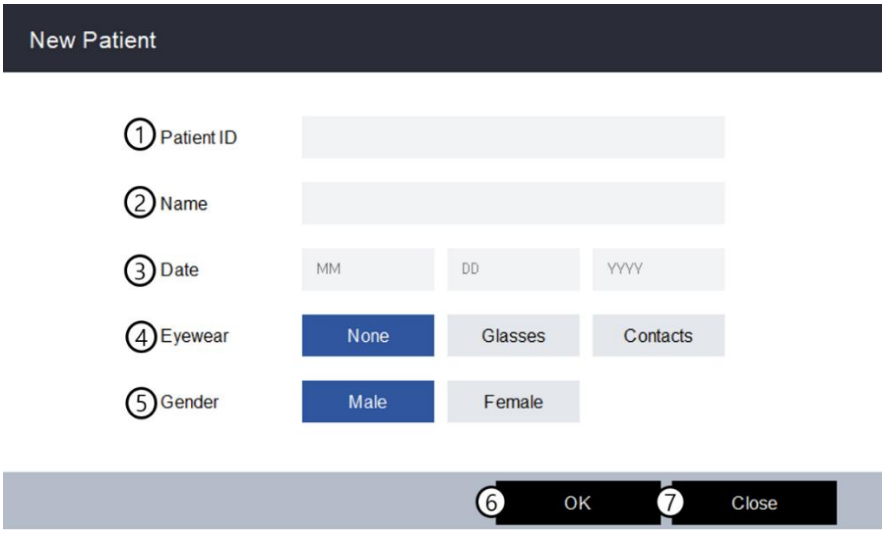
3.3 LCD Screen

3.3.1 Main Screen

[Main screen]

NO	Name	Function
1	New Patient	Moves to patient's information input screen.
2	Queue	Moves to Queue screen[Patients list to be measured].
3	6-12 Months	Moves to measurement screen for subjects aged 6-12 months
4	12-36 Months	Moves to measurement screen for subjects aged 12-36 months
5	3-6 Years	Moves to measurement screen for subjects aged 3-6 years
6	6-20 Years	Moves to measurement screen for subjects aged 6-20 years
7	20-100 Years	Moves to measurement screen for subjects aged 20-100 years
8	History	Moves to History screen [Patients list of completion].
9	Setup	Moves to setup screen

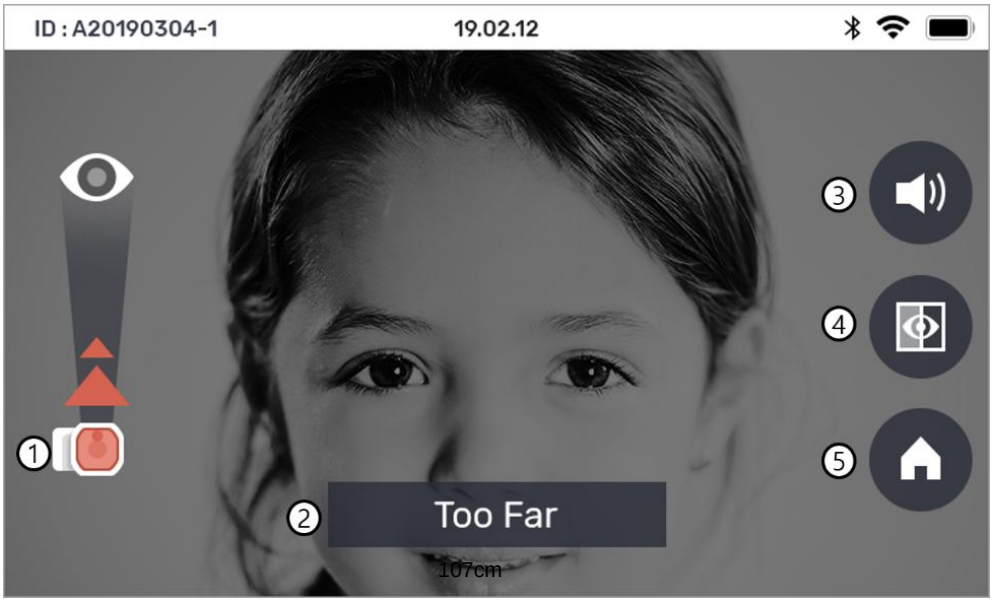
3.3.2 New Patient Screen



[New Patient Screen]

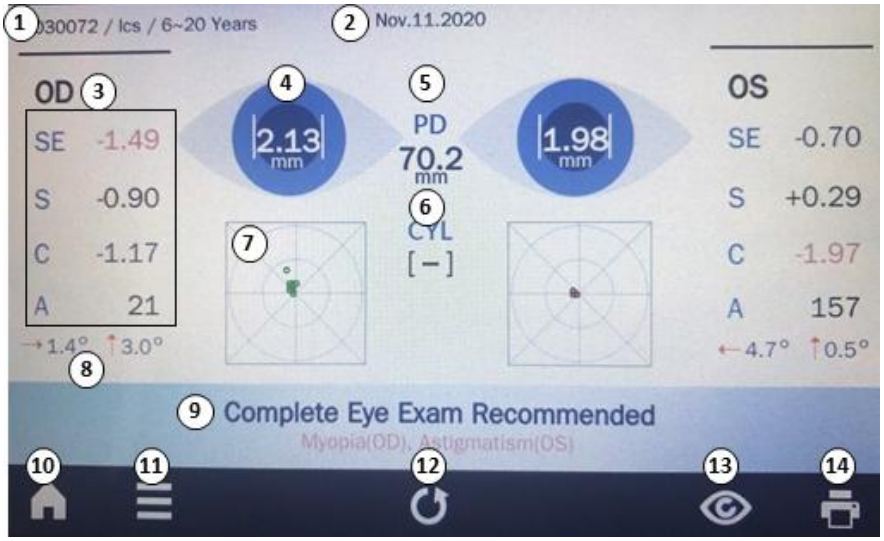
NO	Name	Function
1	Patient ID	Inputs the patient's ID
2	Name	Input patient's name
3	Date	Inputs patient's birth date
4	Eyewear	Selects the patient's eyewear status(None, Glasses, Contact lens)
5	Gender	Selects patient's gender
6	Ok	Saves the patient's information and moves to measurement screen.
7	Close	Moves to main screen

3.3.3 Measurement Screen



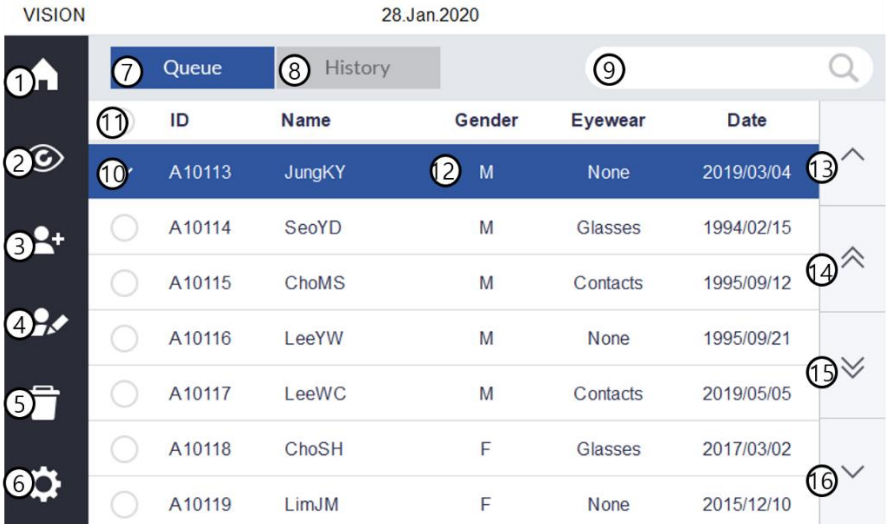
NO	Name	Function
1	 Indicator	Displays the direction where device should move
2	 Text indicator	Displays the distance between subject and operator
3	 Sound	Sound On/Off
4	 Mono mode	Selects the eye to be measured(left, right or both)
5	 Home	Moves to main screen

3.3.4 Result Screen



NO	Name	function
1	Patient's information	Displays patient's ID, name and age range
2	measurement date	Displays the date of measurement
3	SE, S, C, A	Displays the measured value - SE: Spherical Equivalent - S: Spherical Power - C: Cylinderical Power - A: Axis
4	Pupil size	Displays the pupil size
5	PD	Displays the pupil distance
6	CYL [-]	Displays the cylinder sign
7	Gaze	Plots the direction of gaze
8	Degree	Displays the direction of gaze as an angle
9	Complete Eye Exam Recommended	Displays the corresponding category in the criteria screen.
10	Home	Moves to main screen
11	Queue	Moves to queue screen
12	Retry	Moves to measurement screen
13	New Patient	Moves to new patient screen
14	Print	Prints the result

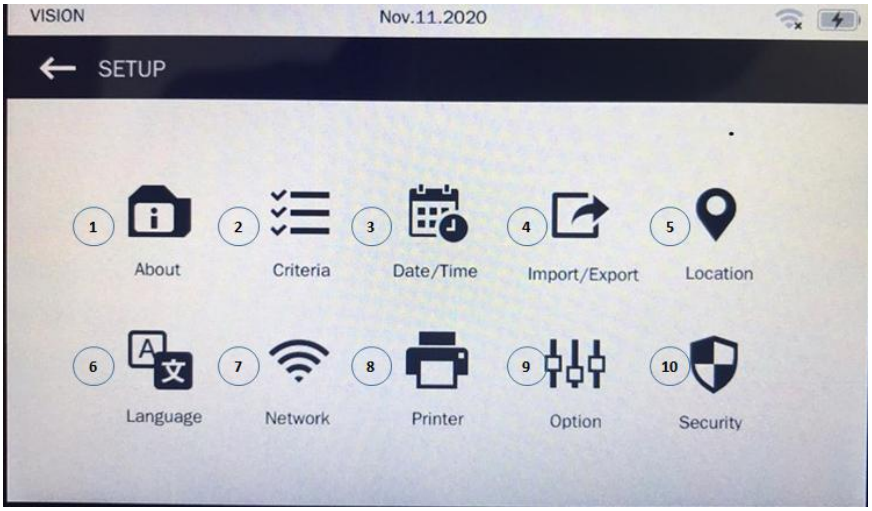
3.3.5 Queue screen



[Queue Screen]

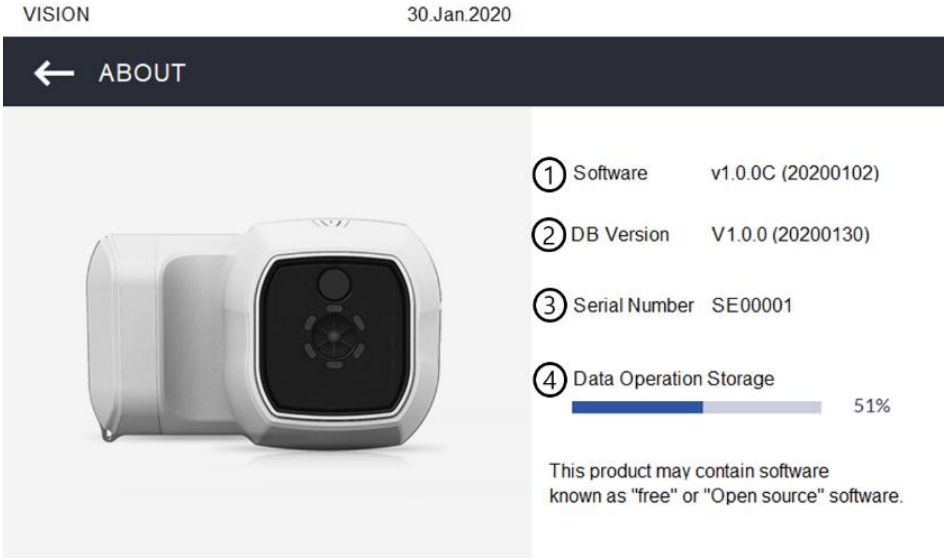
NO	Name	Function
1	Home	Moves to main screen
2	Measure	When a patient is selected, moves to measurement screen
3	New patient	Moves to new patient screen
4	Edit	When patient is selected, moves to edit screen
5	Delete	Removes the patient information
6	Setup	Moves to setup screen
7	Queue	Displays patients waiting for measurement
8	History	Displays patients whom measurement was completed
9	Search	Searches patients
10	One selection	Selects a patient
11	Full selection	Selects all patients
12	Selection Row	Displays a selected patient with a shadow
13	Up button	Page up
14	Quick Move up button	Move up 10% of the total pages at once.
15	Quick Move down button	Moves down 10% of the total pages at once.
16	Down button	Page down

3.3.6 Setup Screen



NO	name	function
1	About	Displays device information(software version, memory)
2	Criteria	View or modify age-specific criteria. The device's measurement results are compared to these criteria to display the judgment outcome.
3	Date/Time	Setup the date/time
4	Import / Export	Data import / export
5	Location	Inputs user's information
6	Language	Language settings
7	Network	Network settings (Wifi, TCP/IP, Webserver)
8	Printer	Setups printer setting
9	Option	Setup QR Code Displays, Report save, Data format, Cylinder sign, LCD brightness, Sound volume, Screen time out, power saving time, measurement screen off time.
10	Security	Enter the password

1) About( )



① Software Version : Displays the software Version
② DB Version: Displays the Database Version.
③ Serial Number: Displays the Serial Number.
④ Data Storage: Indicates the available storage of HVS-1.

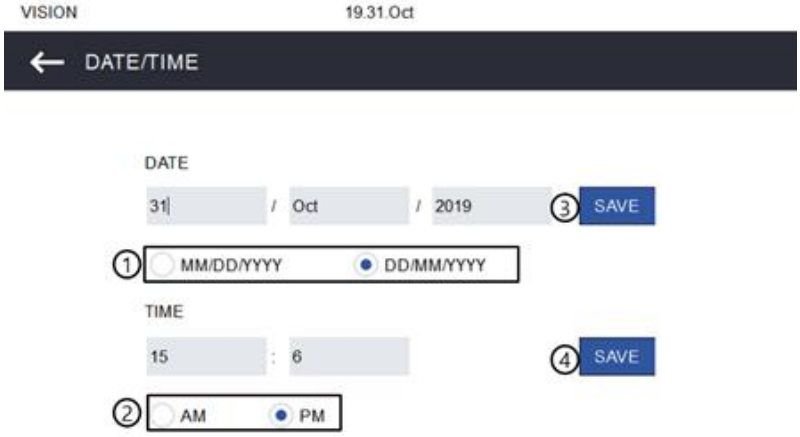
2) Criteria setup( )

The criterion of different categories are set according to the different age groups. This criteria screen will be displayed on the result screen with the measured results.

AGE(Months)	6-12	12-36	36-72	72-240	240-1200
Anisometropia	1.5	1	1	1	1
Astigmatism	2.25	2	1.75	1.5	1.5
Myopia	2	2	3 5	1	0.75
Hyperopia	3.5	3	2.5	2.5	1.5
Anisocoria	1	1	1	1	1
Gaze Vertical	8	8	8	8	8
Gaze Nasal	5	5	5	5	5

① Default: Resets the device to default settings configured by the manufacturer.
② Save: Saves the adjusted settings.

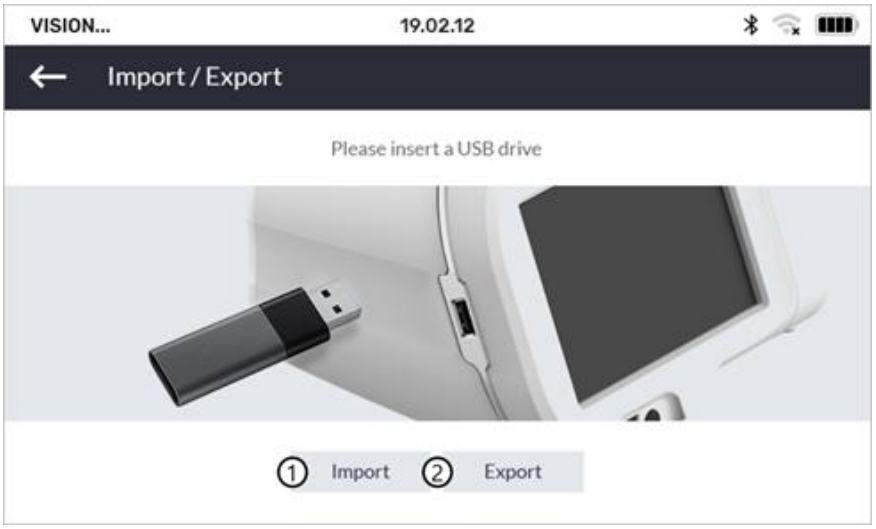
3) Date/Time setting( ) screen



① Date format: Choose the preferred date format.
② AM, PM: Select the time
③ Date Save: Save the date
④ Time Save: Save the time

4) Import / Export setting( )

> ⚠ NOTE
> The Import/Export button will become visible upon inserting the USB drive. When the USB drive is removed, the button will become invisible.



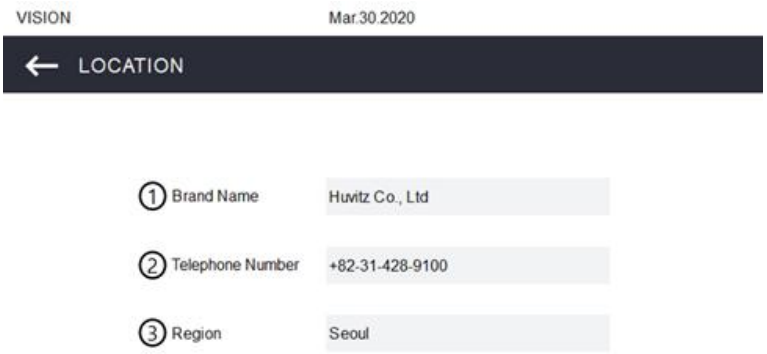
① Import: Data from the USB memory is imported.
The file name, header names, and order within the file must adhere to the following guidelines.
Import file name: PatientQueue.csv

- header name and order within PatientQueue.csv:

patientID	firstName	lastName	gender	birthDate	usingGlasses
syd9538	YoungDuk	Seo	M	19940215	None
Hong123	gildong	hong	M	19880215	None
Hi	Here	Seo	F	19990215	None

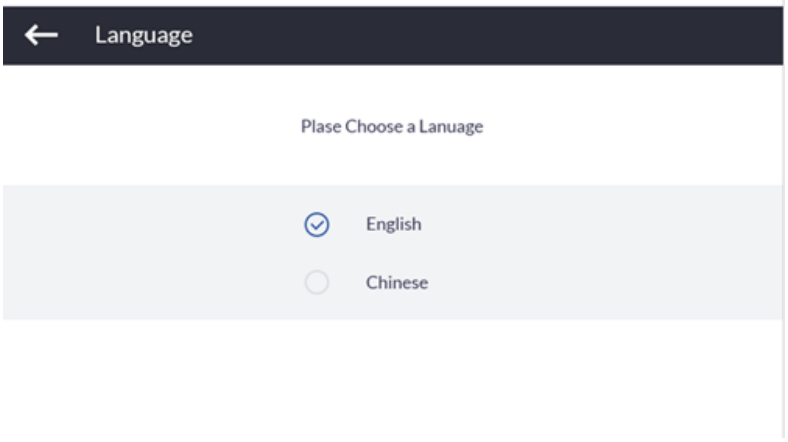
② export: Saves the completed measurements data to the USB memory.

5) Location setting( ) display screen

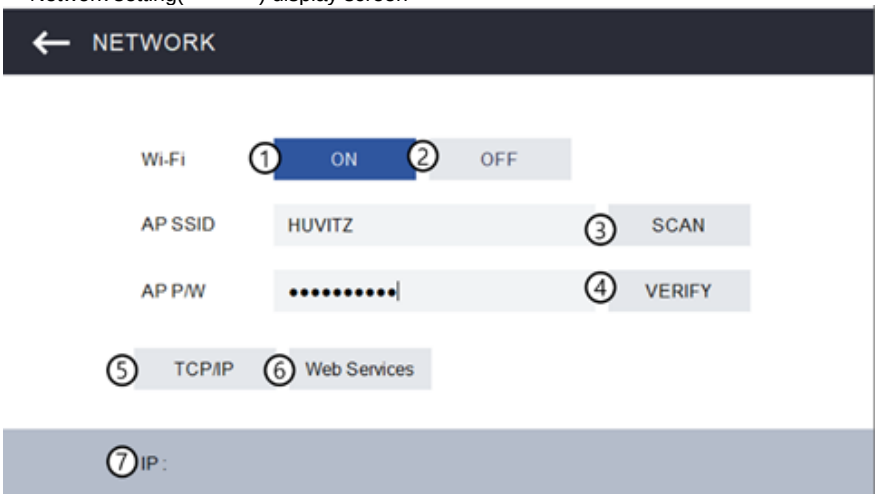


① Brand Name: Enter the business or institution name. This information will be visible when printed using a printer.
② Telephone Number: Enter the telephone number. This information will be visible when printed using a printer.
③ Region: Enter the region

6) Language setting( ) display screen:
select the language

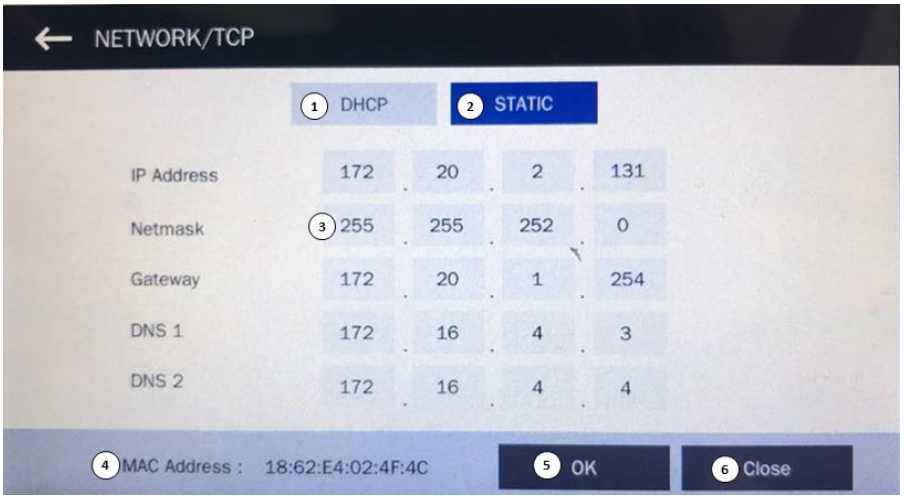


7) Network setting( ) display screen



① Wi-Fi ON : Turns on Wi-Fi.
② Wi-Fi OFF : Turns off Wi-Fi.
③ SCAN : Searches for Wi-Fi access points(AP).
④ VERIFY : Enter the Wi-Fi password
⑤ TCP / IP : moves to NETWORK/TCP screen(Static / DHCP setting).
⑥ Web Service : moves to Web Server setting screen.
⑦ IP : displays currently connected IP address.

7-1) NETWROK/TCP Screen

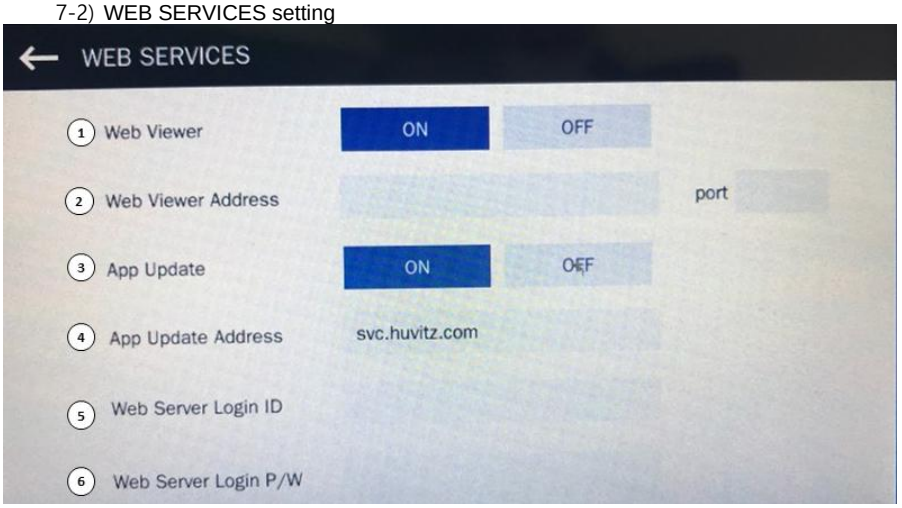


① DHCP : Displays the IP address assigned by the DHCP server.
② STATIC : Allow you to specify IP addresses.

> ⚠ NOTE
> When configuring a Static IP, you must first verify the bandwidth of the IP in DHCP mode.

③ Click on the corresponding cell to change the value.MAC Address : displays the MAC address
④ OK : Saves the values and returns to the previous screen.
⑤ Close : Returns to the previous screen.

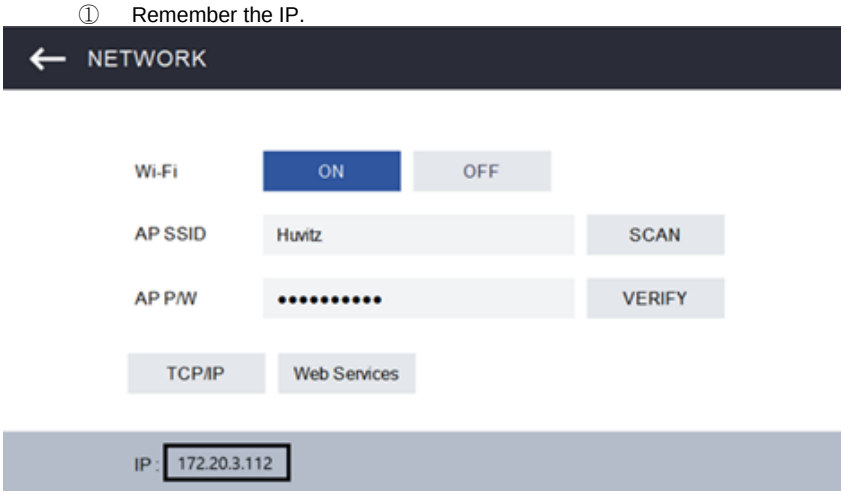
7-2) WEB SERVICES setting



① Web Viewer ON/OFF: Select to either enable or disable data transmission to the Web Viewer server.
② Web Viewer Address : Specifies the IP address and port number to access when the Web viewer feature is enabled
③ App Update ON/OFF: Enables or disables the function to remotely update the software.
④ APP Update Address : Specifies the address of the server where the software is located.
⑤ Web Server Login ID : Enter the ID to access the device from the web browser.
⑥ Web Server Login P/W : Enter the password to access to Web server.

7-3) How to view measurement results on the web

① Remember the IP.



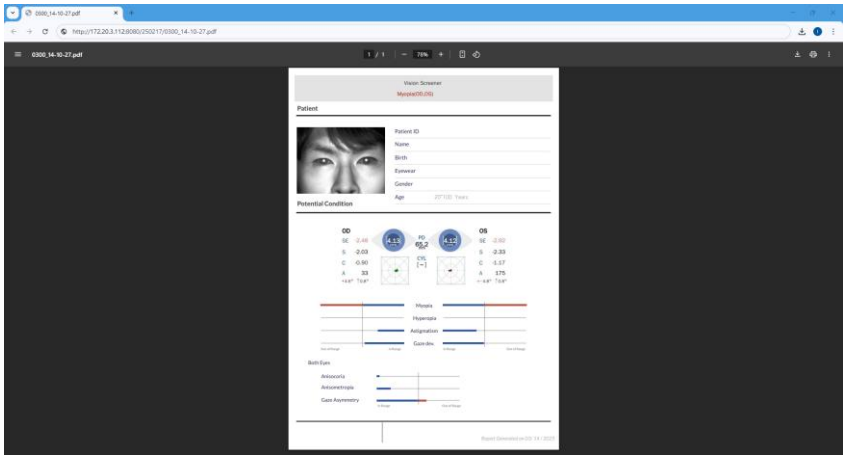
② Go to browser and type IP(you remembered before) :8080.

Report /

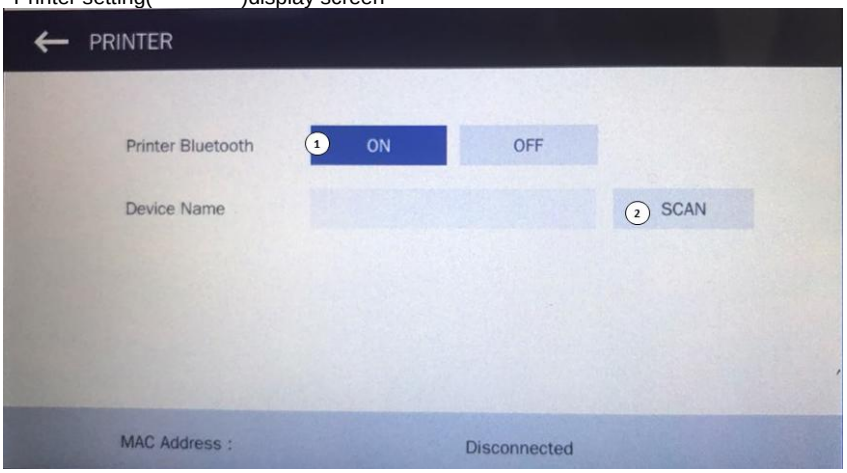
Name	Modified	Size
250224/	24-Feb-2025 10:02	[DIRECTORY]
250218/	18-Feb-2025 08:18	[DIRECTORY]
250217/	17-Feb-2025 18:47	[DIRECTORY]
250120/	20-Jan-2025 13:31	[DIRECTORY]
250117/	17-Jan-2025 15:24	[DIRECTORY]
250113/	13-Jan-2025 16:33	[DIRECTORY]
250109/	09-Jan-2025 16:45	[DIRECTORY]
250108/	08-Jan-2025 10:32	[DIRECTORY]
250106/	06-Jan-2025 19:37	[DIRECTORY]
241205/	05-Dec-2024 08:01	[DIRECTORY]
241128/	28-Nov-2024 16:24	[DIRECTORY]

Mongoose/6.11

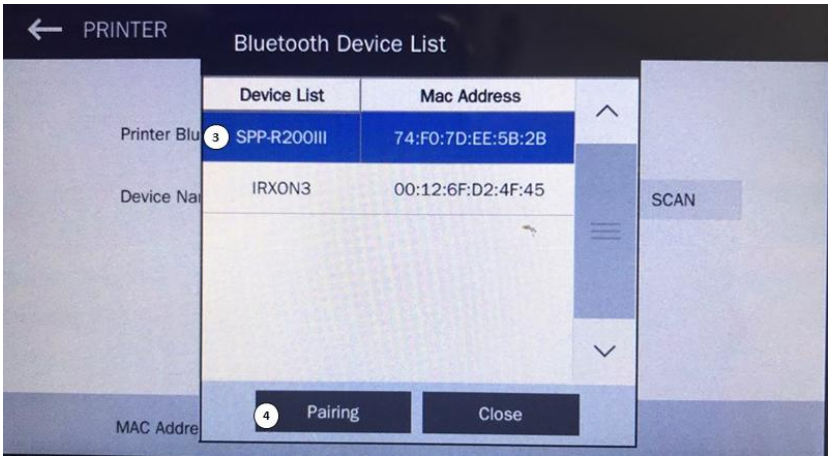
③ You can show measurement picture, measurement result report



8) Printer setting( )display screen

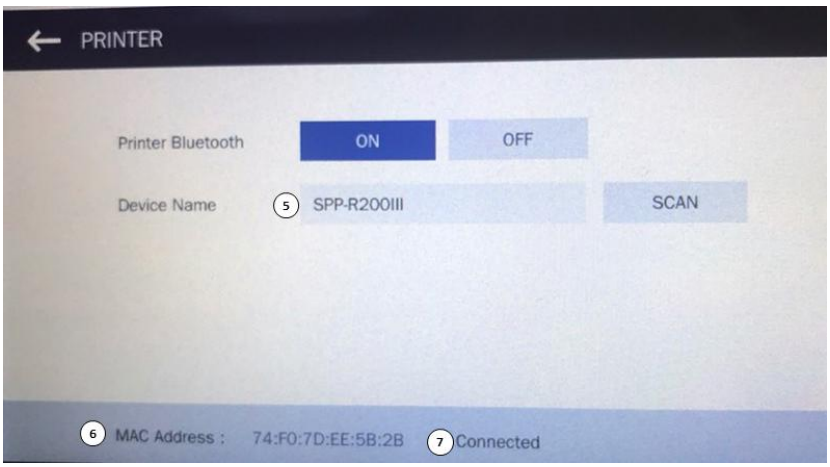


① Printer Bluetooth ON/OFF: Enables or disables Bluetooth function.
② SCAN: Searches for nearby Bluetooth devices.



③ SPR-R200III : Selects Bluetooth printer.

④ Pairing : Connects to a Bluetooth printer.



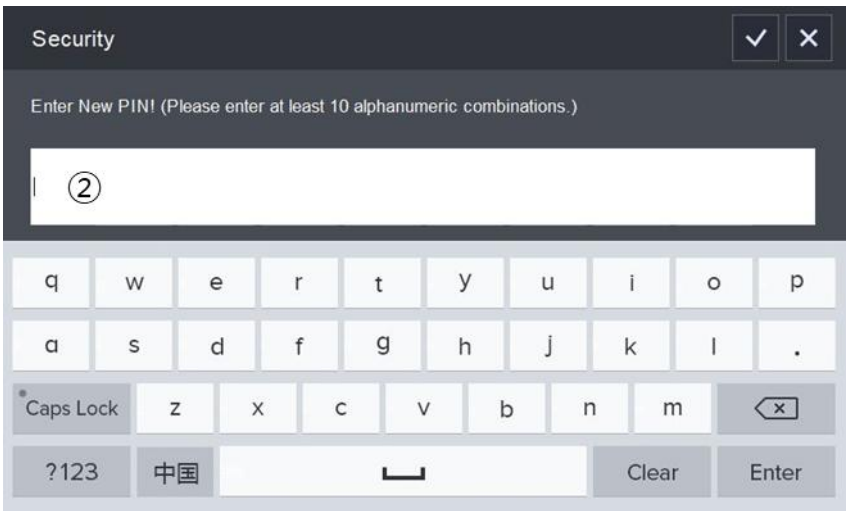
⑤ Confirms the connected Bluetooth printer.
⑥ MAC Address: Verifies the MAC address of the connected Bluetooth printer.
⑦ Connected: Displays the status of connection with Bluetooth printer.
(Connected – Connected, Disconnected – Connection lost)

9) Option setting( )Display Screen

① QR Code Display: Select to either enable or disable QR codes when printing by choosing ON/OFF.
② Report Save: Select the option to save patient's report.
③ Data Format: Select the preferred format to display data.
④ Cylinder Convention: Configure the display unit for cylindrical refractive power.
⑤ LCD Brightness: Adjust the brightness of the LCD screen.

⑥ Sound: Adjust the sound volume.
⑦ Screen Time out: Select the time for the automatic screen time out.
⑧ Auto Power Off Time: Set the time for the automatic power off.
⑨ Measure Screen Off time: Set the time for the measurement screen to turn off. If no measurement is taken during this time, it will return to the main screen.
⑩ Default: Select to reset into default settings set by the manufacturer.

10) Security ( ) setting display screen



① Use Security PIN Code : Enable (Yes) or disable (No) password protection on the device.
② If you enable the use of a PIN Code, enter the password and click the 'OK' button. Once a password is set, it will be required when powering on the device or waking up the LCD screen.

> ⚠ NOTE
> If you have set a PIN code, you must input it when a device wakes up from screen saver or during booting

4. Accessories

1. AC/DC Adapter 1EA
2. Hand Strip 1EA
3. Bag 1EA
4. User Manual 1EA
5. Bluetooth printer-option (Adapter, Manual, Printer paper) 1EA

5. Operating Procedure

5.1 Preparation before use

(1) After When the device is connected to a mains supply using the provided AC/DC Adapter, it charges. When the charging is completed with the device off, the charging LED turns green. However, when the device is on and charging, the charging LED does not turn green, even when the battery is fully charged.

⚠ WARNING: You must use the provided AC/DC Adapter.
Avoid using additional extension cables or portable multiple sockets.
To prevent the risk of electric shock, this device should only be connected to a power supply with a protective ground conductor. The device must be unplugged to completely disconnect it from the power supply.

(2) Turn on the device. The main screen will appear once the device is turned on.

⚠ NOTE: You must use a provided AC/DC Adapter.
Avoid using additional extension cables or portable multiple sockets.
To prevent the risk of electric shock, this device should only be connected to a power supply with a protective ground conductor. The device must be unplugged to completely disconnect it from the power supply.

(3) If necessary, select the 'SETUP' icon on the main screen to input/change device settings.

5.2 Operating procedure

1. On the main screen, choose either the [New Patient] icon or the [Age Range] icon.
   (1) If you select the [New Patient] icon, input the patient's information. Press the [OK] button to proceed to the measurement screen.
   (2) If you select the [Age Range] icon, you will be directed to the measurement screen. You can input the patient's information after the measurement.

2. Set the measurement conditions on measurement screen.

3. Position the patient.
   (1) Instruct the patient to stand at a distance of 1m from the device.
   (2) Ask the patient to face the front of the device with their knees positioned forward. Ensure that the device is at the same level as the patient's eyes.
   (3) Instruct the patient to focus on the fixation LED on the device. Hold the device with both hands and align it with the patient's eyes.

⚠ CAUTION – Hazard distance

Output of LED power was tested at a distance of 200mm.

Minimum safe distance for IR LED(Side RED LED) is 0.65m. Within the distance of risk(0.65m), IR LED(Side RED LED) is classified as “Risk Group 1”.

There is risk of retinal thermal or weak visual stimulus.

⚠ CAUTION

La distance de sécurité minimale pour la LED IR (LED ROUGE latérale) est de 0,65 m. Dans la distance de risque (0,65 m), la LED IR (LED ROUGE latérale) est classée comme « Groupe de risque 1 ».
Il existe un risque de thermique rétinien ou de faible stimulus visuel.

⚠ CAUTION – Hazard distance

Output of LED power was tested at a distance of 200mm

Minimum safe distance for IR LED(Center RED LED) is 0.65m. Within the distance of risk(0.65m), IR LED(Center RED LED) is classified as “Risk Group 1”.

There is risk of IR radiation for eye.

⚠ CAUTION

La distance de sécurité minimale pour la LED IR (LED ROUGE centrale) est de 0,65 m. Dans la distance de risque (0,65 m), la LED IR (LED ROUGE centrale) est classée comme « Groupe de risque 1 ».
Il existe un risque de rayonnement IR pour les yeux.

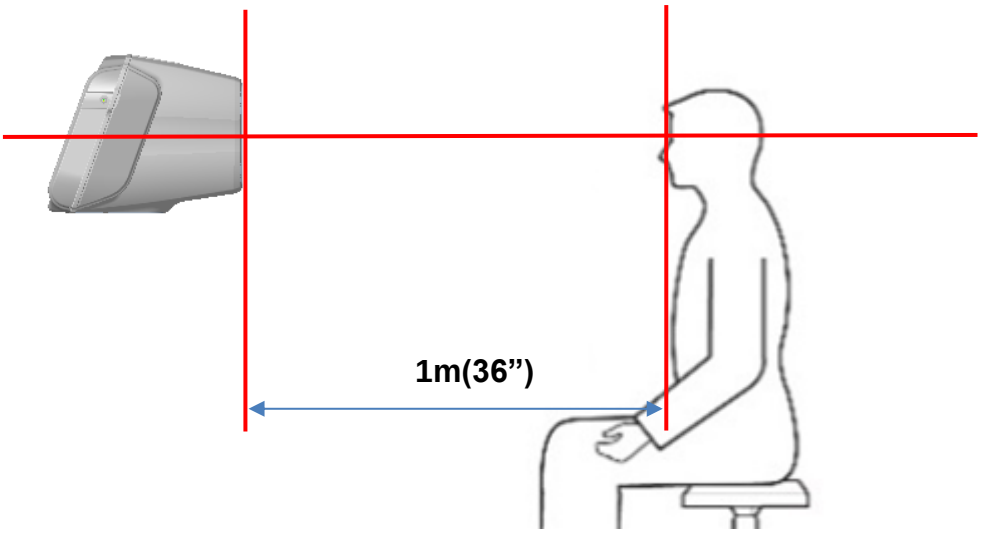
⚠ NOTE

The vision screener should be placed approximately 36 inches (1 meter) away from the subject and used.

We recommend measuring while sitting to reduce hand tremor.

⚠ NOTE

L'écran de vision doit être placé à environ 36 pouces (1 mètre) du sujet et utilisé.
Nous vous recommandons de mesurer en position assise pour réduire les tremblements des mains.



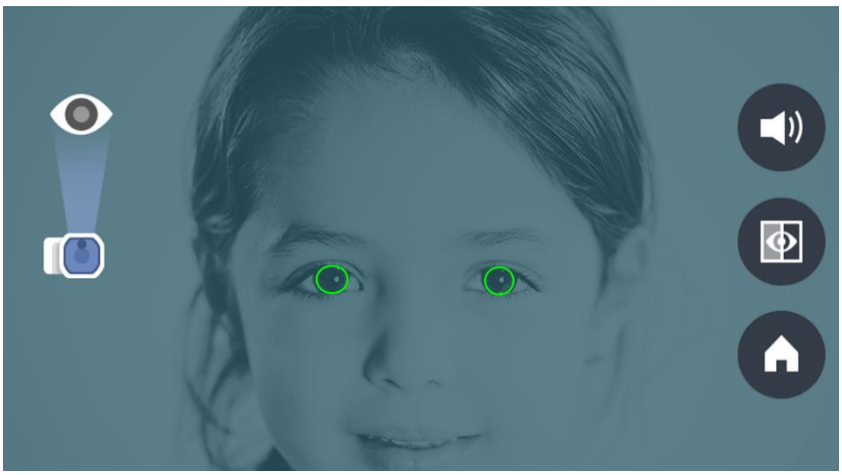
4. Align and measure

> ⚠ NOTE:
> A minimum of 4mm pupil size is required for measurements. Occasionally, measurement difficulties may arise due to room lighting. If the pupil size is too small, adjust the lighting in the room accordingly. Ideally, the pupil size should be larger than 5mm for optimal results.

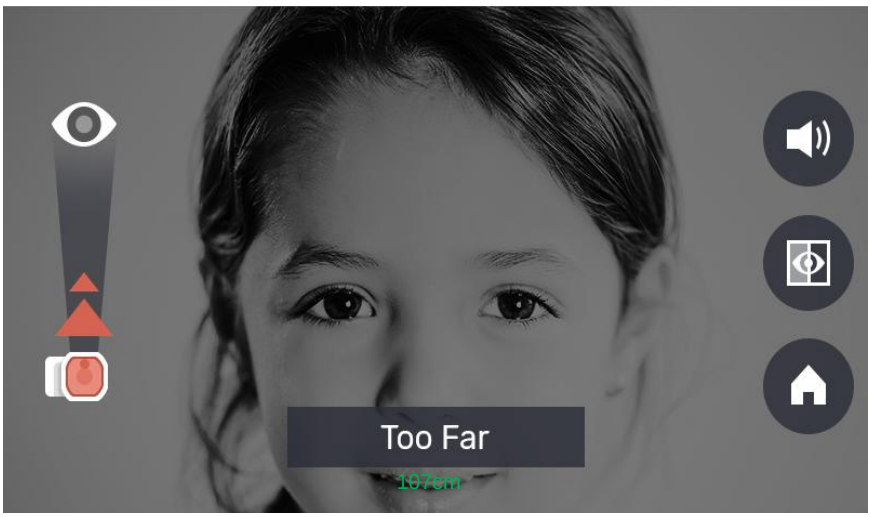
(1) Instruct the patient to look at the front of the device without moving their body or blinking.

(2) Align the device with the patient's eyes. Once alignment is achieved, a green ring will appear around the patient's eye.

1) Indication that alignment has been successfully completed:

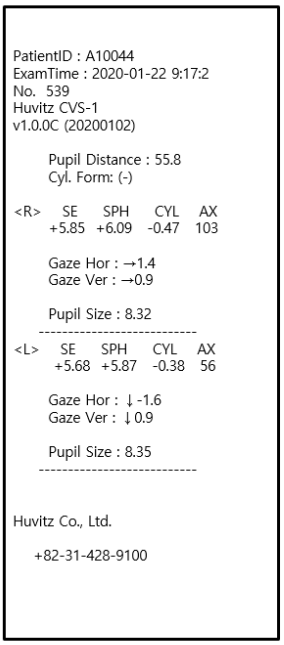


2) Indication that the device is positioned too far from the patient:
- In this situation, move the device closer to the patient..



(3) When alignment is successful, measurement is automatically taken.

5. Check the measurement results.
   (1) Check the result of the measurement.
   (2) If required, Select the [Print] icon to print out the results.
   If the patient information has not be entered, Select the [QUEUE] icon to enter the patient's information.
   If required, Select the other icons[HOME, QUEUE, RETRY, NEW PATIENT].



PatientID : A10044
ExamTime : 2020-01-22 9:17:2
No. 539
Huvitz CVS-1
v1.0.0C (20200102)

Pupil Distance : 55.8
Cyl. Form: (-)

<R>	SE	SPH	CYL	AX
	+5.85	+6.09	-0.47	103

Gaze Hor : →1.4
Gaze Ver : →0.9

Pupil Size : 8.32

<L>	SE	SPH	CYL	AX
	+5.68	+5.87	-0.38	56

Gaze Hor : ↓ -1.6
Gaze Ver : ↓ 0.9

Pupil Size : 8.35

Huvitz Co., Ltd.

+82-31-428-9100

[Example of a printout]

6. Maintenance

6.1 Cleaning Equipment

1. The device should always be kept clean. When cleaning, do not use volatile substances such as thinner, acetone, or benzene.

2. If the device is contaminated, dampen a soft cloth slightly with detergent, wring it out, and gently wipe the exterior of the device.

3. For the front of devices emitting signals and receiving reflective light, gently wipe with a soft cloth (e.g., microfiber).

4. When the device is not in use for an extended period, store the device in a dedicated bag or a clean place to protect it from external contaminants such as dust.

6.2 Disposal

To avoid potential negative consequences for the environment and possibly human health, this device should be disposed of as follows:

1. You should keep the packaging materials for relocation or repair. if you want to dispose the packaging material, it should be disposed of in accordance with national regulations.

2. The device contains a lithium battery and electrical parts. It should be disposed of in accordance with national regulations.

3. In the EU, the device should be disposed of in accordance with EU guidelines or national requirements.

7. Specifications

Spherical	Range	-8.0D to +8.0D
	Increment step	0.01D, 0.25D
	Accuracy	± 0.5D (-3.50D to +3.50D)
		± 1.0D (-8.0D to < -3.50D)
		± 1.0D (> +3.50D to +8.0D)
Cylindrical	Range	-3.0D to +3.0D
	Increment step	0.01D, 0.25D
	Accuracy	± 0.5D (-1.50D to +1.50D)
		± 1.0D (-3.00D to < -1.50D)
		± 1.0D (> +1.50D to +3.00D)
Axis	Range	0 - 180°
	Increment step	1°
	Accuracy	± 10° (For CYL's values > 0.50D)
Pupil size	Range	4.0 - 9.0mm
	Increment step	0.1mm
	Accuracy	± 0.4mm
Pupil distance	Range	35 - 80mm
	Increment step	1mm
	Accuracy	± 1.5mm
Measurement time	Accuracy	≤ 1s (After focusing)
Measuring distance	Range	100cm ± 5cm
Fixation target	visual pattern audible sound	
wireless network	802.11 b/g/n	
interface	USB 2.0	
AC/DC Adapter	Model Name : MDS-030AAC15 Input Voltage : 100-240 VAC Output Rating : 15Vdc, 2.0A	
Device Input	DC 15V, 2.0A	

8. EMC Information

Electromagnetic waves trouble

The device should be used in the below mentioned electromagnetic wave environment. The device purchaser or user needs to confirm whether a device is used in this type of environment.

Test standard	Compliance
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

Test standard	Test level	Compliance level
Electrostatic discharge(ESD) IEC 61000 - 4 - 2	contact ±8 kV in the air ±15 kV	Note1)* 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 %*U*T(*UT's* > 95 % decrease) For 5 cycle 40 %*U*T(*UT's* 60 % decrease) For 25 cycle 70 %*U*T(*UT's* 30 % decrease) For 5 seconds < 5 % *U*T(*UT's* > 95 % decrease)	For 0.5 cycle < 5 %*U*T(*UT's* > 95 % decrease) For 5 cycle, 40 % *U*T(*UT's* 60 % decrease) For 25 cycle, 70 %*U*T(*UT's* 30 % decrease) For 5 seconds, < 5 % *U*T(*UT's* > 95 % decrease)
Power frequency magnetic field (50/60 Hz) IEC 61000 - 4 - 8	30 A/m	30 A/m

Other *U*T is the a.c. power voltage for before approving the test level.

Note1)* ESD Test will be conducted with screw, lever, signal ports, enclosure, display, measurement button and power switch including VCP/HCP as criteria 'A'. But, criteria of connecting external monitor will be applied 'B' because flickering phenomenon of connecting external monitor during interference of electrostatic discharge doesn't affect essential requirement.

Electromagnetic waves		
Test standard	Test level	Compliance 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

9. Service Information

If you need a repair, service or any questions concerning the device, please contact Huvitz's distributor or your dealer.

Distributor or dealer's information

Name: _____

Address: _____

Telephone: _____

Email: _____

Device model: _____

Serial number: _____

if you cannot contact the distributor, contact huvitz