Huvitz

Vision Screener
HVS-1

USER MANUAL

Precautions

This product may malfunction due to the electromagnetic wave that is generated from mobile phone, two-way radio, machinery controlled wireless and others. Do not place any device that may affect this product nearby.

We believe that the contents of this user manual are accurate in overall since they were reviewed carefully. However, Huvitz does not assume any kind of responsibility for the latent mistake or omission that results from the use of information included in this user manual.

Huvitz has the right to make any kind of modification to this product or product specs anytime without prior notice and modification may not be renewed on this document.

Revision History

Revision	Date	Approval	Description
A	2023.12.11		First issued

CE 0197

9000ENG0133-A
(2023.09)

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 be used to measure the refractive power of the eye. It can measure refractive errors by detecting each eye from the eccentric lights. It is possible to measure in either binocular or monocular. The values from the measurements are compared with age based referral criteria. So, for some patient who need to visit a hospital, recommend as screening result. It is intended for use on subjects from 6 months to adults.

1.2. Equipment overview

The Vision Screener, HVS-1 is the equipment that measures refractive power of patient's eyeball to show Sphere (SPH), Cylinder (CYL) and Axis (AXS) information. It can also measure test subject's PD(Pupillary Distance, distance between pupils) and pupil's size. In particular, it is a hand-held instrument and is easy to measure. It can visualize the patient's eye image on the LCD screen at the distance from the subject and align the measurement distance by ultrasonic. It also provides visual and audible sound for the child to focus on the measurement. This equipment provides a fast data for easy evaluation of the most pediatric subjects of limited compliance. On the LCD display shows user interface functionality for data input and result. Each result screening provides binocular or monocular assessment of the subject's refraction data, pupil information.

However, This equipment is not intended to replace a full eye care examination by an ophthalmologist. The measured data is used for screening only, it must not be used directly to prescribe.

1.3. Grade classification and mentioned items

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. Contra Indication

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

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

1.5 Patient requirements

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

- Keep the eye open and see an focus LED
- 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

1.6 Operating Principle

The model HVS-1 can measure both eyes simultaneously in a short time at a distance of about one meter.
A measuring distance is calculated by software with using ultrasound, and displays the status on the screen.
After the distance value is checked, pressing the measurement button, the IR LED is sequentially irradiated to the pupil in each of the six axes, and the LED reflected from the pupil in each axis is imaged through the camera.
Pupil is detected using acquired images from a camera, and the detected pupil image is analyzed to calculate refractive power such as Sphere (SPH), Cylinder (CYL) and Axis (AXS).
The measured refractive power and pupil information are displayed on the screen, it can be output to the printer and it sent to the outside via WiFi or USB interface.

1.7 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 62471:2006: Photobiological safety of lamps and lamp systems

2

Information regarding safety

2.1. Introduction

Safety is everyone's obligation and responsibility. Safe use of this device is important for everyone involved - installers, users, operators and device managers. It is a must to study and to master this user manual individually prior to installing, using, cleaning, repairing or controlling this device and its accessories. It does not suffice to emphasize the importance of understanding the instructions found in this manual repeatedly in order to increase safety of patient or users. For this reason, the following safety warning chart is included at the adequate place on this manual in order to highlight information that requires special precaution or safety related information in particular. All the users or managers need to pay special attention in addition to mastering "WARNING" or "CAUTION" in the manual.

⚠ WARNING

"Warning" cautions against the existence of calamity that can cause severe personal injury, death or property loss in case of negligence.

⚠ CAUTION

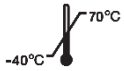
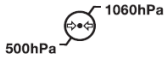
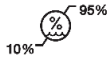
"Caution" informs of the matters related to calamity that can cause minor injury or property loss in case of negligence.

⚠ NOTE

"Note" explains important information related to installation, operation and management, and failure to comply may lead to calamity in case of negligence.

2.2. Safety indication

The International Electro technical Commission (IEC) announced the symbols that warn when connecting electric medical device's power or that warn against calamity that may occur. Classification and symbol are as follows.

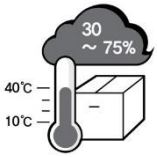
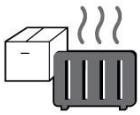
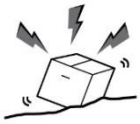
Symbol	Indication
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the appropriate User's or Service Manual. (Ce symbole identifie une note de sécurité. Assurez-vous de comprendre la fonction de ce contrôle avant 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)

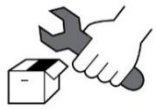
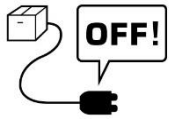
CE 0197	CE Mark (Marque CE)
	Use no hook (N'utilisez aucun crochet)
	WEEE Symbol – EU only Disposal of your old appliance When this crossed-out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC. All electrical and electronic products should 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.)
EC REP	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)
	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 for RoHS RoHS Directive Compliance 2011/65/EU (CE pour les RoHS Respect de la directive en matière de conformité 2011 / 65 / CE)
	Medical Device (dispositif medical)
	Authorized representative in Switzerland (Représentant autorisé dans la Suisse)

2.3. Environment related matters

The environment to avoid in operation and storage:

	Place where device comes directly into contact with moisture (do not operate the device with wet hand)
	Place where device is exposed directly to sunlight.
	A place where the equipment can be exposed to direct ultraviolet.
	Place with severe temperature change(The ideal operating temperature is 10℃ to 35℃ while the relative humidity is 30% to 75%.)
	Where there is a hot equipment nearby.
	Where the humidity is extremely high or there is a ventilation problem.
	Where the machine is exposed to excessive shocks or vibrations.
	Where the machine is exposed to chemical material or explosive gas.
	Be cautious so that things like dust and metal do not fall inside the machine.

	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 machine.
	Don’t plug the AC power cord into the outlet unless all parts of the machine are completely connected. Otherwise, it will cause severe damage on the machine.
	Pull out the power cord with holding the plug, not the cord. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

This instrument must be followed by these following conditions:

As for the environment when using the device, maintain temperature of 10 ~ 40 ℃, relative humidity level of 30 ~ 90 % and atmospheric pressure of 800 ~ 1060 hPa.

As for the environment when transporting the device, maintain temperature of -40 ~ 70 ℃, relative humidity level of 10 ~ 95 % (with non-condensing), and atmospheric pressure of 500 ~ 1060 hPa.

As for the environment when storing the device, maintain temperature of –10 ~ 55 ℃, relative humidity level of 10 ~ 95 % (with non-condensing), and atmospheric pressure of 700 ~ 1060 hPa.

Take precaution so that the device won’t be subjected to excessive shock or vibration.

2.4. Safety Precautions

This device was developed and proven according to the domestic and international safety specs. This guarantees this device's high safety level. By law, a manufacturer is obligated to provide sufficient explanation of the matters pertaining to the device safety to device users. Likewise, compliance with the contents of this device's manual is mandatory for safety sake. Thus, read the instructions in the manual sufficiently and understand prior to turning on the power. For many more information, inquire the distributor where you purchased the device.

1. Do not store or install this device at the following places; (a) place that runs the risk of exploding, or (b) place that has volatile chemical substance such as alcohol benzene or inflammable and explosive material.

2. Do not store or install at a humid place. To ensure normal operation, humidity level should range between 30 and 90%. The device should not be exposed to a place where water splashes significantly, water falls off, or gets sprayed. Do not place the container with liquid or gas on top of the device.

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

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

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

6. 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.

7. Manufacturer does not take responsibility for the damage resulting from this device's unlawful modification. However, device's unlawful modification becomes a factor for losing the right to get warranty during the warranty period.

8. 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.

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

10. Store user or service manual at a place that is readily accessible by the person who manages and uses this device.

11. Do not exert force on the cable connection. If cable does not get connected easily, then check whether connector (plug) is suitable for the socket. When connector or socket is damaged, qualified service technician needs to repair it.

12. Do not pull on the device's cable. Hold on the plug to take out to open up the cable.

13. This device can be used according to this manual in relation to the refractive power and their application.

14. Always test the state of the device's external appearance and check whether it is functioning well before using the device.

15. Turn off the power immediately and take out the plug when there is smoke, spark, abnormal noise or smell.

16. 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.

17. 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

18. Do not place at a difficult location when separating cable when it comes to the device's placement.

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
Characteristics

1. It is possible to carry out both refractive power measurement as well as pupil information with one machine.
2. It is possible to measure the refractive power ranging from –8.0 D to +8.0 D.
3. When measuring refractive power, it is possible to measure up to a minimum pupil diameter Ø4.0 mm.
4. It is hand held machine that can measure both eyes simultaneously in a short time at a distance of about one meter.
5. It can measure at the distance from the subject and align the measurement distance by ultrasonic.
6. It provides visual and audible sound for the child to focus on the measurement.
7. This machine provides a fast data for easy evaluation of the most pediatric subjects of limited compliance.
8. It uses infrared light for eye measurement. This infrared light is invisible to the human eye and nonhazardous.
9. Because this machine uses infrared light to preform measurements, to accurate measurements it is important to avoid interfering infrared ambient light in the examination room. It is better to darken the examination room.

4

Precautions during use

1. Handle with care since shock can damage the outside or the inside.

2. Precision measurement may be affected when the product is exposed to direct sunlight or too bright indoor illumination. It is recommended to measure at a dark eye examination room.

3. Get guidance at the place of purchase when using the device by connecting with other equipment.

4. When heating up the inside at a cold area all of the sudden, vapor may result on the object lens of the customer side and on the optical parts at the inside of the device. In this case, measure after waiting for the vapor to disappear.

5. Main the object lens from the customer side that is subjected to the test clean at all times. Error may result or precision measurement may be affected if tainted with dust or alien substance.

6. Take out the power plug to separate the power when there is smoke, smell or noise during use. Then, follow the instructions of the place of purchase.

7. Do not use alcohol, thinner, benzene and organic solvent to clean this equipment's surface since these may damage the equipment.

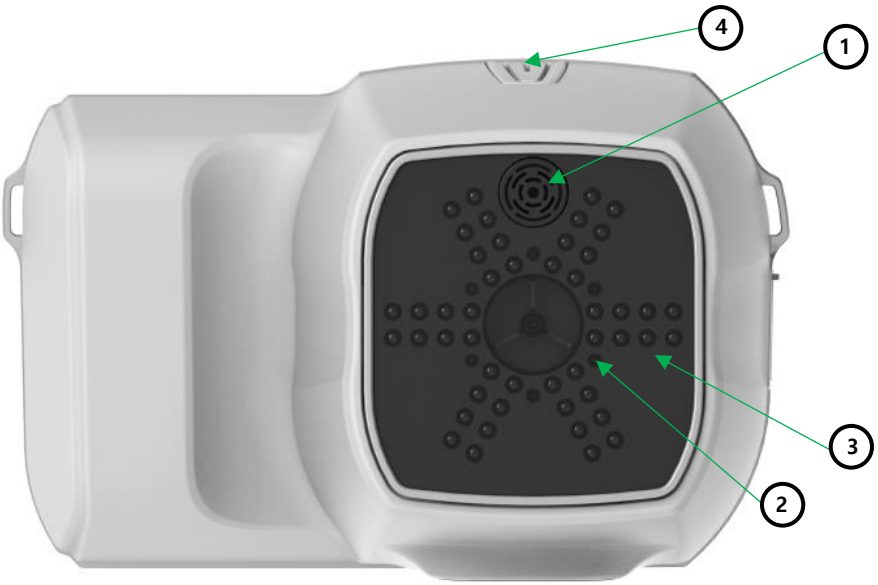
8. When moving the HVS-1, turn off the power switch always, and fixate the stage. Then, move by lifting up with lower part of the body with both hands.

9. When HVS-1 is not used for a long time, separate the power and cover it with the dust cover.

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

5
Name and function of each part

5.1. Key part



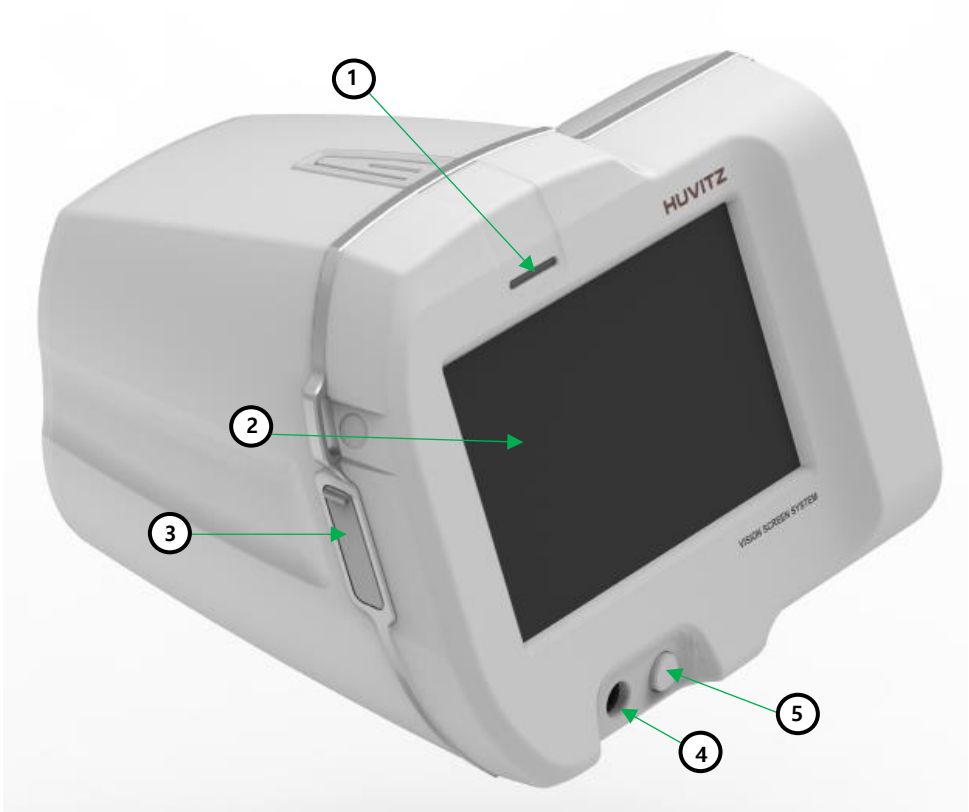
[Front part]

1. Ultrasonic sensor: It's 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.



[Back part]

1. Charge LED: Display the LED Status when charging. When you are charging, the led is red and charging complete is green.

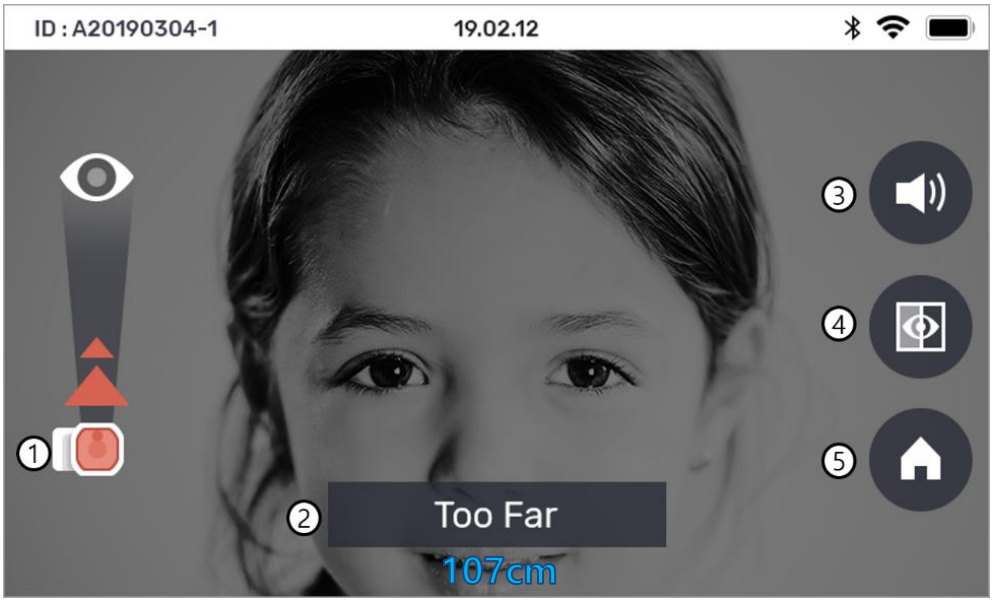
2. LCD Screen: This is a LCD for display.

3. USB port: Port that supports USB 2.0.

4. Charging port: This is the part where you plug in the charging line.

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.

5.2. Main measurement screen button explanation



[Measurement Screen]

1.  **(Indicator) :** Indicates the relative position of the equipment and eyes.

2. 

(Text Indicator) : Text informs the user if they need to get close or far.
The standard measurement distance is 100cm.

3.  **(Sound) button:** Button turns the sound on or off so that Patient 's focus on measurement.

4.  **(Mono mode) Button:** Button for measuring only one eye

5.  **(Home) button:** Button for going to Main Screen.

6

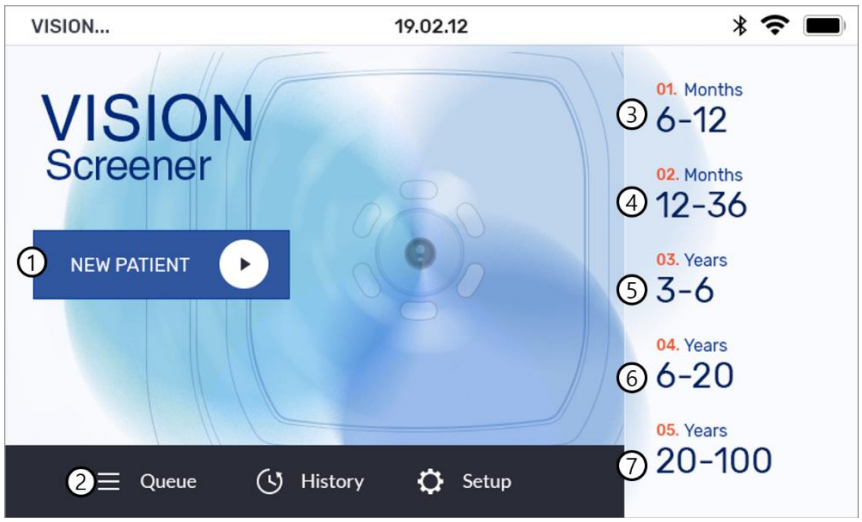
Measurement Method

1. Turning the main body's power ON

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

NOTE

If the Main 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 30 seconds. If the measurement screen does not appear, contact the Huvitz's distributor.



[Main screen]

1. New Patient Button: Go to where you enter information for measuring new patients. Enter the patient's information and Press OK button to enter the measurement.

2. Queue Button: Go to the list of patients waiting. There are two ways to measure.

3. Measure 6-12 months Button: Quickly measure patients between 6 and 12 months.

4. Measure 12-36 months Button: Quickly measure patients between 12 and 36 months.

5. Measure 3-6 years Button: Quickly measure patients between 3 and 6 years.

6. Measure 6-20 years Button: Quickly measure patients between 6 and 20 years.

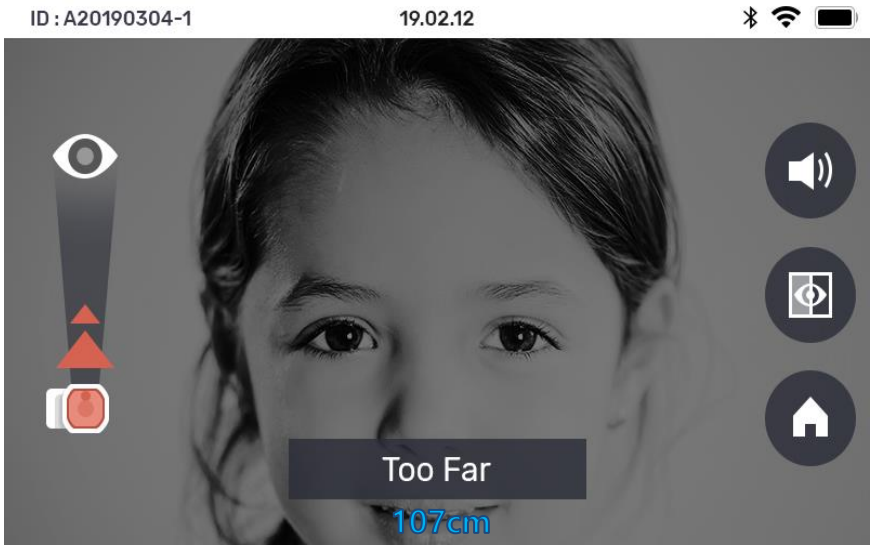
7. Measure 20-100 years Button: Quickly measure patients between 20 and 100 year

2. Selecting the Measurement mode

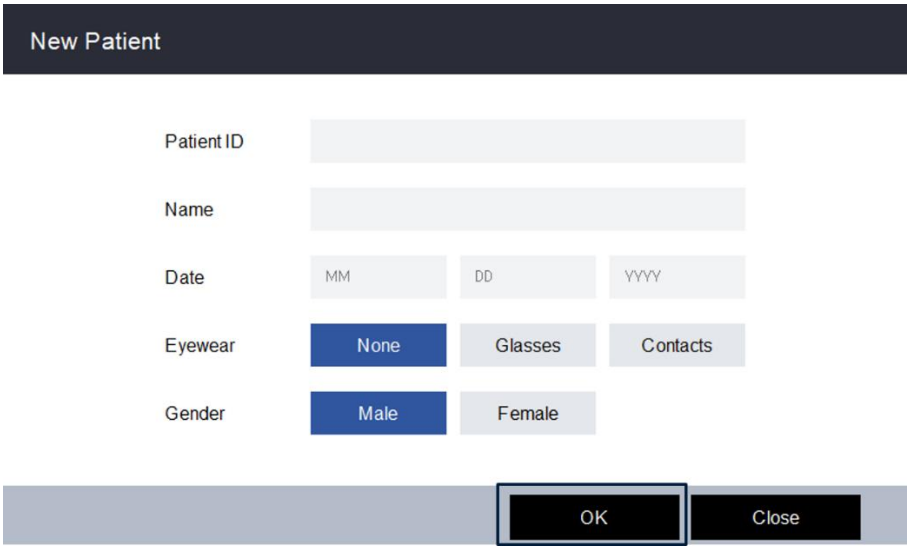
- New Patient Button: Enter the patient's information and press OK button to enter the measurement.

- Queue Patient Button: Select one check box or click a cell or press the measurement button to enter measurement mode.

- Measure 6-12 months Button: Quickly measure patients between 6 and 12 months.
- Measure 12-36 months Button: Quickly measure patients between 12 and 36 months.
- Measure 3-6 years Button: Quickly measure patients between 3 and 6 years.
- Measure 6-20 years Button: Quickly measure patients between 6 and 20 years.
- Measure 20-100 years Button: Quickly measure patients between 20 and 100 years



[Measurement Screen]

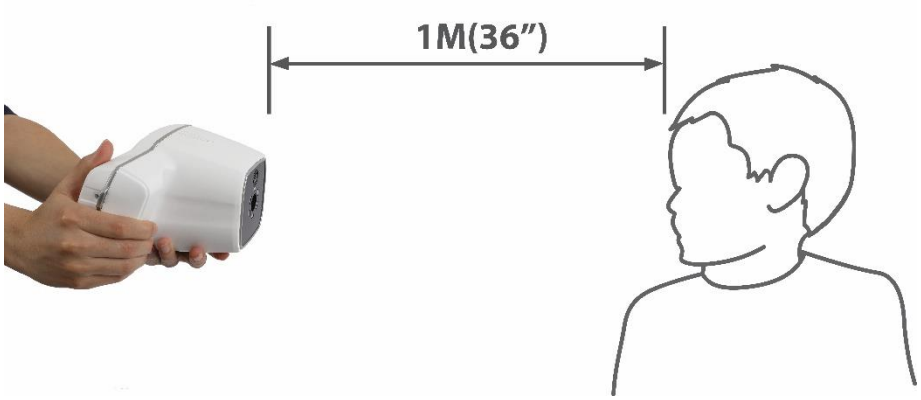


[New Patient measure select]

[Queue Screen measure select]

3. How to Focus the Vision Screener to patient

- Position vision screener approximately 36 inches (1meter) away from patient.
- Hold vision screener close to body and lean forward and backward until the screen becomes gray.
- Make small movements(move forward and back) until the yellows circle of the eye turns green.



[How to Focus the Vision Screener]

⚠ CAUTION

Eyes should be wide open and kept on the center of the frame for best results.

4. Measurement Environment

- For optimal screening results, screen in an environment with lower level subdued lighting. Be sure to eliminate or block any sources of sunlight and/or incandescent light from reflecting on the subject’s eyes.
  Florescent light is acceptable but note that the subject’s pupil size can be affected and can decrease your chances of a successful screening.

⚠ CAUTION

A minimum of 4mm pupil size is required for measurements. Sometimes it is difficult to measure because of room or light. If the pupil is too small, the user must adjust the light in the space.

The best result is bigger than 5mm.

7 Measurement

1. Position yourself approximately 1 meter from the patient. If using a tripod, place the tripod approximately 1 meter from patient.

2. Start screening and slowly rotate the device upward to meet both of the subject's eyes. Adjust your distance from the subject until both eyes are clear on the screen. You can focus the patient by pressing the sound button.
   With a tripod, adjust the tripods position up or down and side to side until the patient eyes are in focus on the screen.

   A blue indicator tells you if you are too close or too far from the subject.

⚠ NOTE

Keeping the vision screener even (on axis) with the subject's eyes will promote quicker results and help ensure you are not capturing other objects.

Position yourself with one foot in front of the other, slowly rock forward and back until the screen turns grey, indicating you are in the capture range. When using a tripod, move the tripod as needed to ensure focus on the subject's pupils until the screen turns grey.

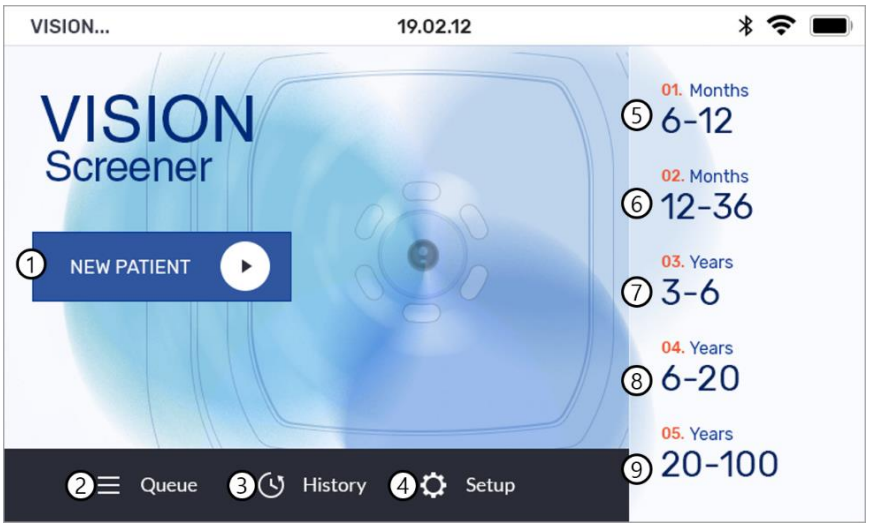
3. Keep the vision screener device steady until the screening wheel appears, indicating the capture process is underway.

4. If you were unable to capture the subject's pupils with a successful screening, the screening cycle will be stopped. You can retry the screening, flag the record, try monocular mode, or return to the Home screen.

5. If the pupils are too small, the device will notify you on screen to adjust the lighting in the room to promote larger pupil size.

8
Other Display

8.1. Main Screen



[Main Screen]

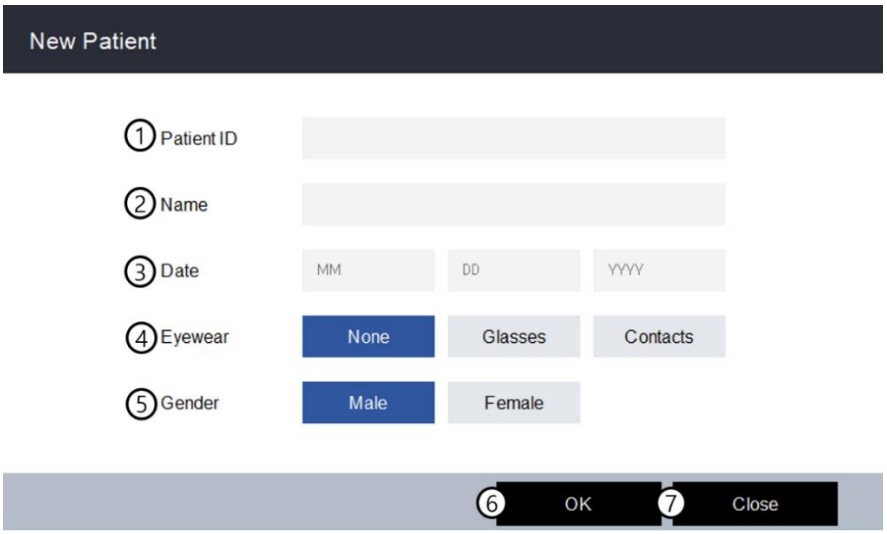
1. New Patient Button: Go to where you enter information for measuring new patients.
2. Queue Button: Go to the list of patients waiting.
3. History Button: Go to the list of patients whose measurements have been completed.
4. Setup Button: Go to Setup with Network, Multilingual Support, Options, Printers, and more.
5. Measure 6-12 months Button: Quickly measure patients between 6 and 12 months.
6. Measure 12-36 months Button: Quickly measure patients between 12 and 36 months.
7. Measure 3-6 years Button: Quickly measure patients between 3 and 6 years.
8. Measure 6-20 years Button: Quickly measure patients between 6 and 20 years.
9. Measure 20-100 years Button: Quickly measure patients between 20 and 100 years.

8.2. New Patient Screen

This is where you enter information about new patients to be measured.

You can go into the New Patient Screen by pressing on the 

(New Patient) button in the Main Screen.



[New Patient Screen]

1. Patient ID: This part is where patient's ID is written.
2. Name: This part is where patient's name is written.
3. Date: This is part where you write down birth date.
4. Eyewear: If the patient is not wearing glasses, Select None, Glasses if wearing glasses, or Contacts if using contact lenses.
5. Gender: If the patient's gender is male Select male and if the patient is female if gender select female.
6. Ok: Press the OK button to enter the measurement screen.
7. Close: Press the Close button to return Main.

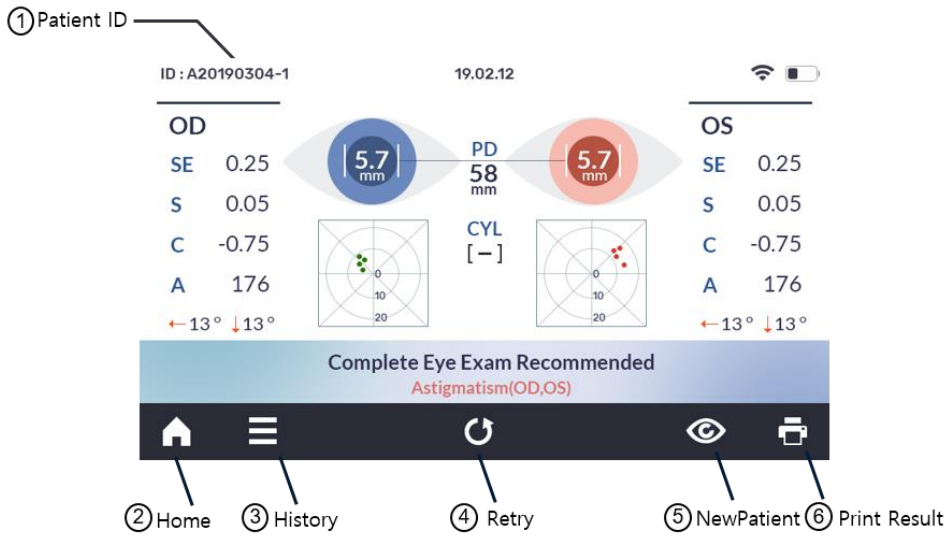
NOTE

The part where you write Date must be written down. This is because we calculate the reference table with Age. Patients younger than six months are replaced at the age of 0.5

8.3. Result Screen

It is possible to view information about patient measurements.

You can go into the Result Screen by completing measurement or when you press cell in History Screen.



[Result Screen(1)]

1. Patient ID: Show patient's ID.
2. Home: Press the Home button to go to the Main Screen.
3. History: Go to the list of patients whose measurements have been completed.
4. Retry: Re-Measure the patient you measured
5. New Patient: Go to the new patient Screen to register a new patient.
6. Print Result : 1) You can use the printer to view measurement data.
   2) You can view the QR Code for measurement data.
   3) You can send measurement data to Web Viewer.

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

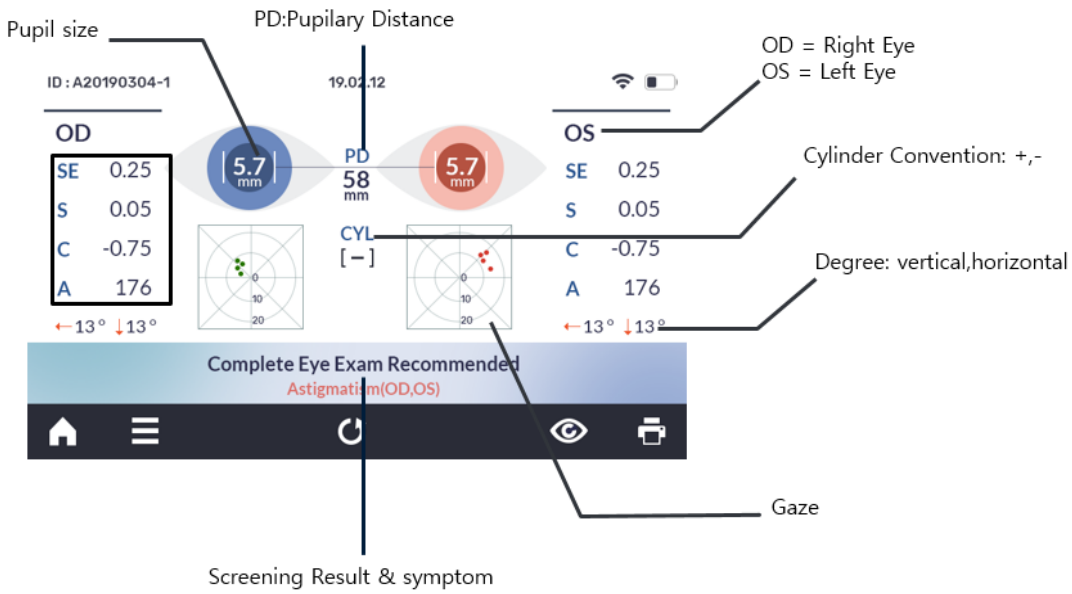
Gaze Hor : ↓-1.6
Gaze Ver : ↓0.9

Pupil Size : 8.35

Huvitz Co., Ltd.

+82-31-428-9100

[Example of a printed page]



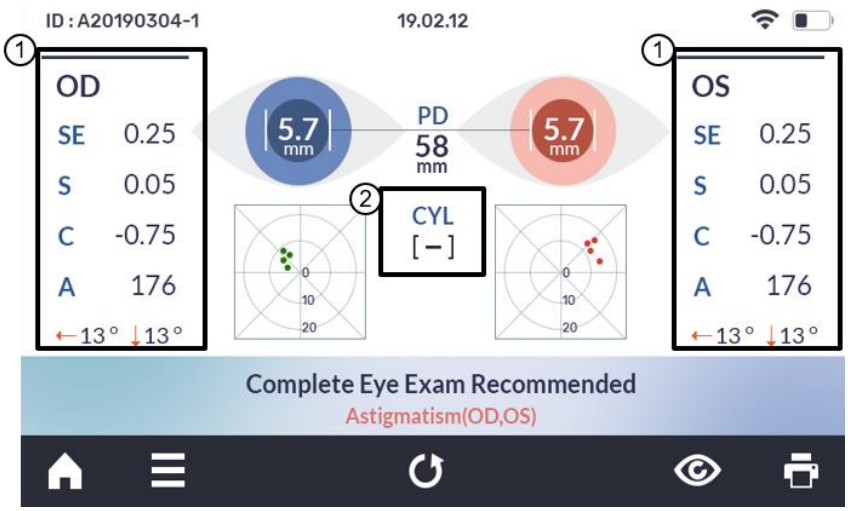
[Result Screen(2)]

SE: Spherical Equivalent
S: Spherical power
C: Cylinder power
A: Cylinder axis
Gaze: Gaze is where you're looking. When you are looking at the center of the red light on the camera, the value of the gaze is where you are looking.

Degree: When you are looking at the center of the red light, Degree displays how far it is from the center in which direction.

NOTE

Results shows “Screening Complete” or “Complete Eye Exam Recommended”. This message mean that the patient need to be examined by an eye specialist.



1. Data Format(Step) Conversion : When you click on this area, the result values change to 0.01 or 0.25.

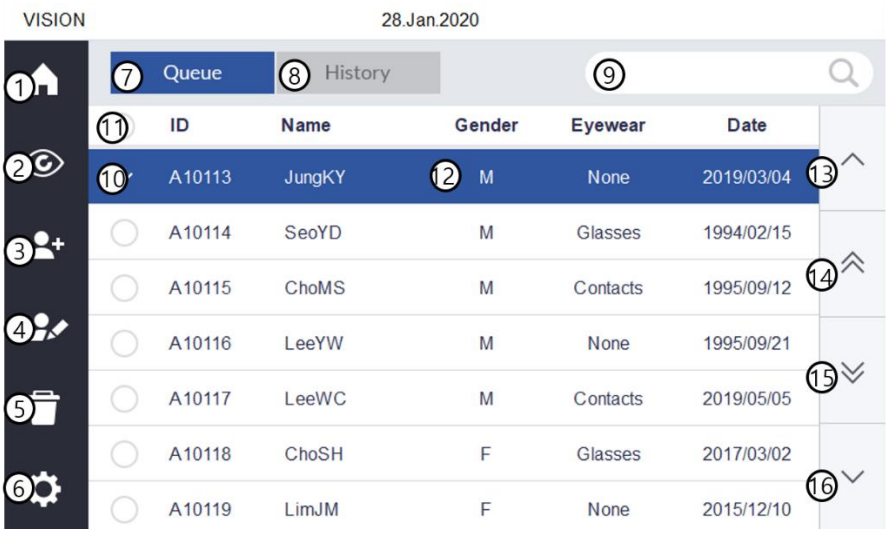
2. Step Conversion : If you click on this area, the Cylinder Sign change to + or -.

8.4. Queue Screen

This is a queue of patients to be measured. It is possible to measure, add, modify, or delete patients in the Queue.

You can go into the Queue Screen by pressing on the 

(Queue) button in the Main Screen



[Queue Screen]

1. Home: Press the Home button to go to the Main screen.
2. Measure: When only one check box is selected, the measurement button is activated and the selected patient enters the measurement mode. If no check box is selected, it is disabled.
3. New Patient: Button to add a new patient to the Queue Screen.
4. Edit: When only one check box is selected, the Edit button is activated and the selected patient enters the Edit mode. So change the patient's information. If no check box is selected, it is disabled.
5. Delete: Deletes one or all of selected rows. If no check box is selected, it is disabled.
6. Setup: Press the Setup button to go Setup screen.
7. Queue: Tap button to go to Queue screen.
8. History: Tap button to go to History screen.
9. Search: If press the Search button, Activated Virtual Keyboard and A row with typed words is searched.

10. Full Selection: Click this check box to select the check box for all rows.
11. One Selection: Click this check box to select the one corresponding rows.
12. Select Row: Selecting a row activates the row and enters the measurement with the patient's information that it has.
13. Up button : Move up the 1 page .
14. Quick Move Up Button: Move up to 10% of the entire page at a time.
15. Quick Move Down Button: Move down to 10% of the entire page at a time.
16. Down button: Move down the 1 page.

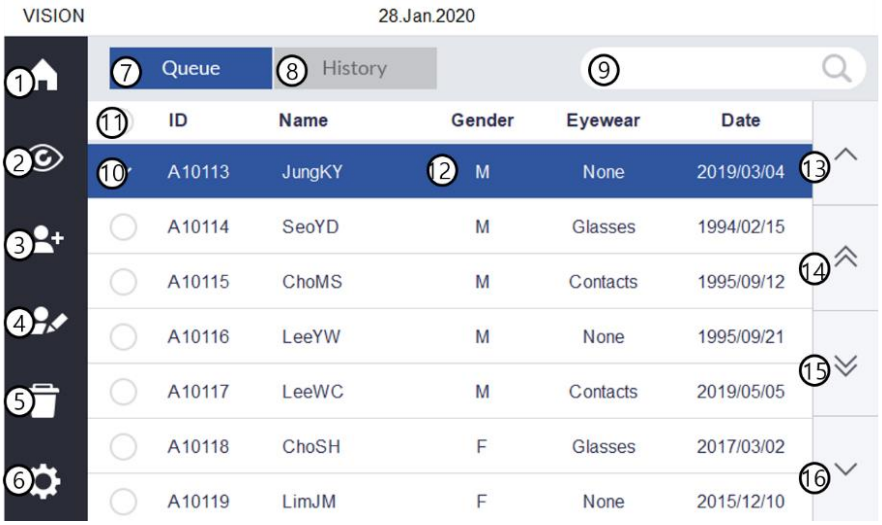
NOTE

The Home button and New Patient button, Setup button are always active, and the measurement and edit button are active only when one check box is clicked. And the delete button is only active when more than one check is clicked.

8.5. History Screen

This is a list of patients whose measurements have been completed. You can add, modify, or delete a patient form the history.

You can go into the History Screen by pressing on the History (History) button in the Main Screen



[History Screen]

1. Home: Press the Home button to go to the Main screen.
2. Measure: On the History Screen, this button is not active.
3. New Patient: Button to add a new patient to the Queue Screen.
4. Edit: When only one check box is selected, the Edit button is activated and the selected patient enters the Edit mode. So change the measure completed patient's information. If no check box is selected, it is disabled.
5. Delete: Deletes one or all of selected rows. If no check box is selected, it is disabled.
6. Setup: Press the Setup button to go Setup screen.
7. Queue: Tap button to go to Queue screen.
8. History: Tap button to go to History screen.

9. Search: If press the Search button, Activated Virtual Keyboard and A row with typed words is searched.

10. Full Selection: Click this check box to select the check box for all rows.

11. One Selection: Click this check box to select the one corresponding rows.

12. Select Row: Selecting a row activates the row and enters the Result Screen with the patient's information that it has.

13. Up button : Move up the 1 page .

14. Quick Move Up Button: Move up to 10% of the entire page at a time.

15. Quick Move Down Button: Move down to 10% of the entire page at a time.

16. Down button: Move down the 1 page.

NOTE

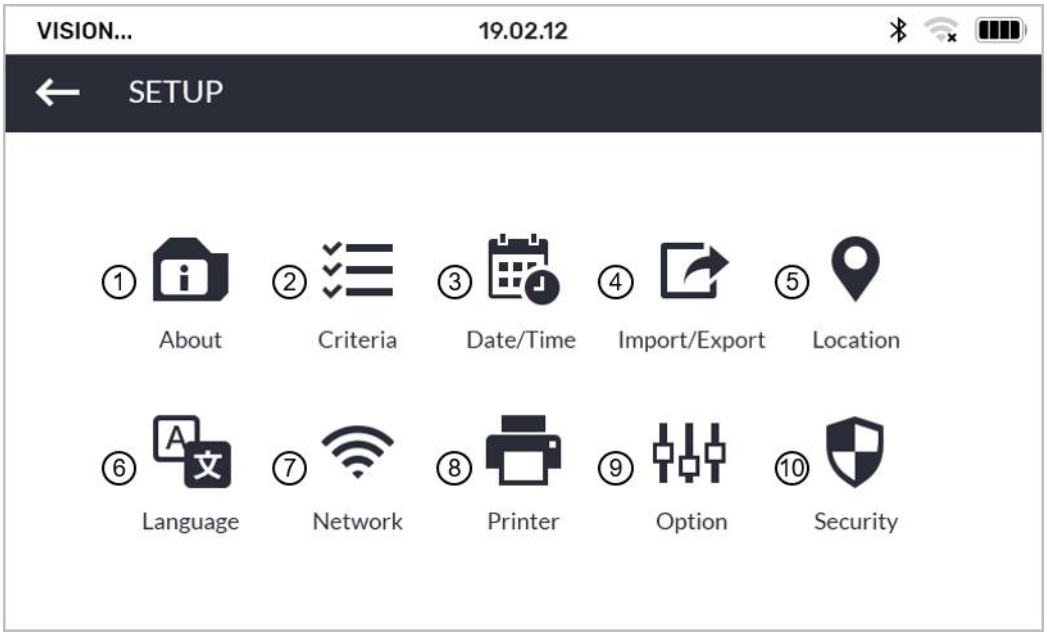
The Home button and New Patient button, Setup button are always active, and the measurement button is not active and edit button are active only when one check box is clicked. And the delete button is only active when more than one check is clicked.

8.6. User SETUP mode

This screen sets functions such as capacity of vision screener, criteria about symptom, time and date change, data extraction, regional settings, language settings, Wifi and Printer Connection, user options(sound, LCD brightness), password setting, etc. .

You can go into the Setup Screen by pressing on the 

(Setup) button in the Main Screen.



1. About: This screen shows information about the capacity or version of vision screener.
2. Criteria: This screen can modify or view the Criteria by age, which is the basis for the calculation of the disease associated with the result value of the Vision Screener.
3. Date/Time: This screen can modify Date or Time of Vision Screener
4. Import/Export: This screen can export measure data and Import queue list of patient.
5. Location: This Screen allows you to set the region.
6. Language: Multilanguage is supported.
7. Network: This screen can connect Wifi and set the DHCP/Static mode and can be changed webserver setting.
8. Printer : This screen can connect Bluetooth printer.
9. Option: This screen sets values such as how the resulting displays data, the screening time, the power saving mode time, sound and the screen brightness control.
10. Security: This screen can set the password for the Vision Screener and set the lock mode.

8.7. About Screen

This screen shows information about the capacity or version of vision screener. .

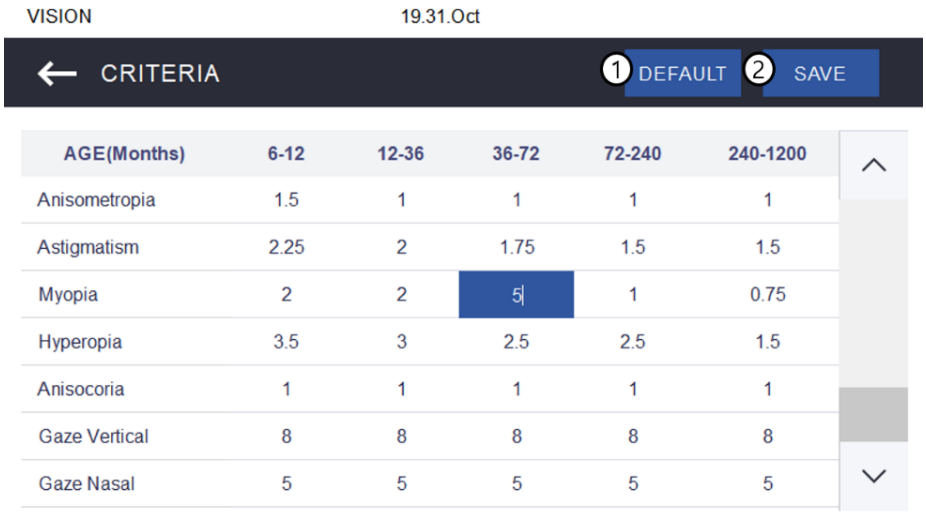
You can go into the About Screen by pressing on the  (About) button in the Setup Screen.

1. Software Version: Displays the software Version.
2. DB Version: Displays the Database Version.
3. Serial Number: Displays the Serial Number.
4. Data Storage: Displays the capacity of the storage inside the instrument.

8.8. Criteria Screen

This screen can modify or view the Criteria by age, which is the basis for the calculation of the disease associated with the result value of the Vision Screener.

You can go into the Criteria Screen by pressing on the (Criteria) button in the Setup Screen.



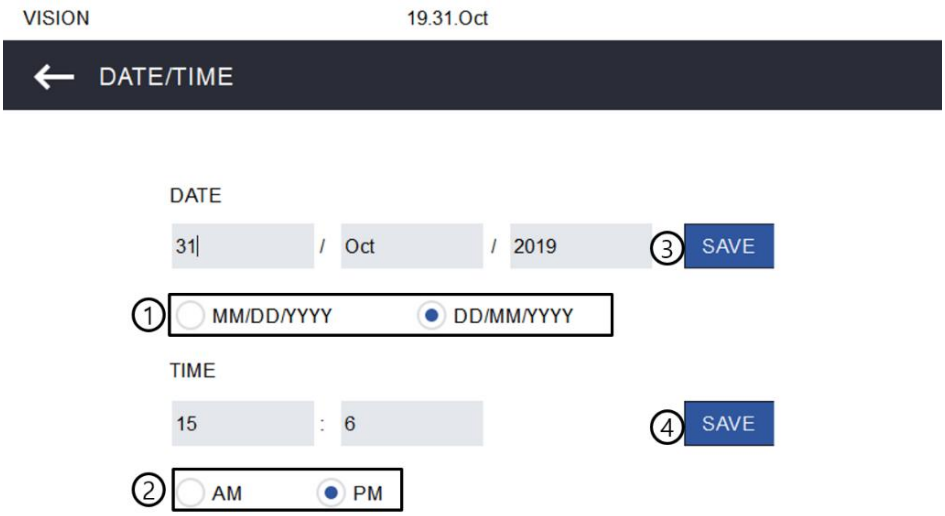
AGE(Months)	6-12	12-36	36-72	72-240	240-1200
Anisometropia	1.5	1	1	1	1
Astigmatism	2.25	2	1.75	1.5	1.5
Myopia	2	2	5	1	0.75
Hyperopia	3.5	3	2.5	2.5	1.5
Anisocoria	1	1	1	1	1
Gaze Vertical	8	8	8	8	8
Gaze Nasal	5	5	5	5	5

1. Default: If you change the Criteria table at any one time, the Default button is activated and the button is pressed to the initial value.
2. Save: Press the save button after completing the change to save the changed value.

8.9. Date/Time Screen

This screen can modify or view the Criteria by age, which is the basis for the calculation of the disease associated with the result value of the Vision Screener.

You can go into the Date/Time Screen by pressing on the  (Date/Time) button in the Setup Screen.



1. MM/DD/YYYY , DD/MM/YYYY: Selecting MM/DD/YYYY allows the month to be displayed first, DD/MM/YYYY may cause the date display format to be displayed first and also applies to the status display.
2. AM, PM: Apply time to AM or PM
3. Date Save The Date change is applied to the format currently selected during MM/DD/YYYY or DD/MM/YYYY.
4. Time Save: The time change is applied to the format currently selected during AM or PM.

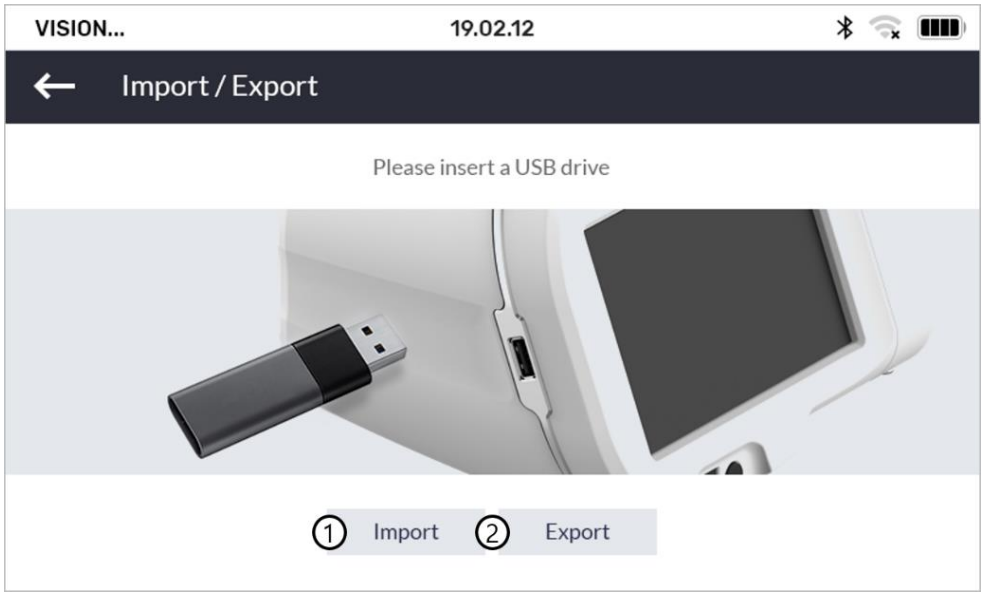
NOTE

Even if the time is less than 12 when selecting PM, the time is applied. ex) 5->17

8.10. Import/Export Screen

This screen can export measure Data(pdf, db, csv) and import queue list of patient.

You can go into the Import/Export Screen by pressing on the (Import/Export) button in the Setup Screen.



1. Import: If the PatientQueue.csv file is inside the USB, patient waiting lists are added to the Queue Screen. And the Banner.png is inside the USB, the banner applies to the report.

2. Export: When USB is connected, DB files, csv files are extracted for the measurement results.

NOTE

The Import/Export button will be visible after inserting the USB drive, When the USB drive removed, the button will be invisible

※ To put patient waiting list, you must name the file PatientQueue.csv and insert it into USB.
※ Example PatientQueue.csv.(You must write down the field(patientID, firstName, lastName, gender, birthDate, age, regDate, usingAge, usingGlasses, location)

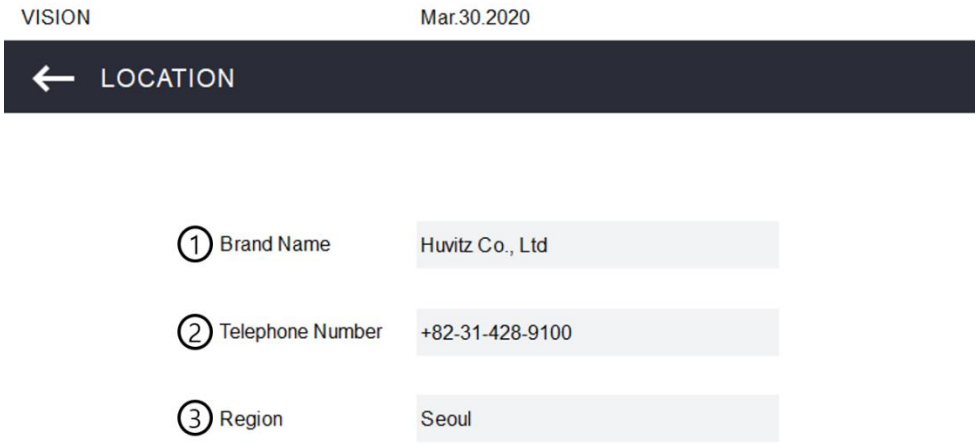
A	B	C	D	E	F	G	H	I	J
patientID	firstName	lastName	gender	birthDate	age	regDate	usingAge	usingGlasses	location
Hong123	GilDong	Hong	M	19921031	28		1	Glasses	Seoul
ESD111	Emma	Watson	F	19900415	30		10	Contacts	London
EMC404	Daniel	Radcliffe	M	19890723	31		0	None	China

※The name of Banner File must be Banner.png. And the size of the image must be 200*53.

8.11. Location Screen

This screen allows you to set the region.

You can go into the Location Screen by pressing on the (Location) button in the Setup Screen.



1. Brand Name : Type a name for the store.
2. Telephone Number : Type a name of the store number.
3. Region : Type a Region.

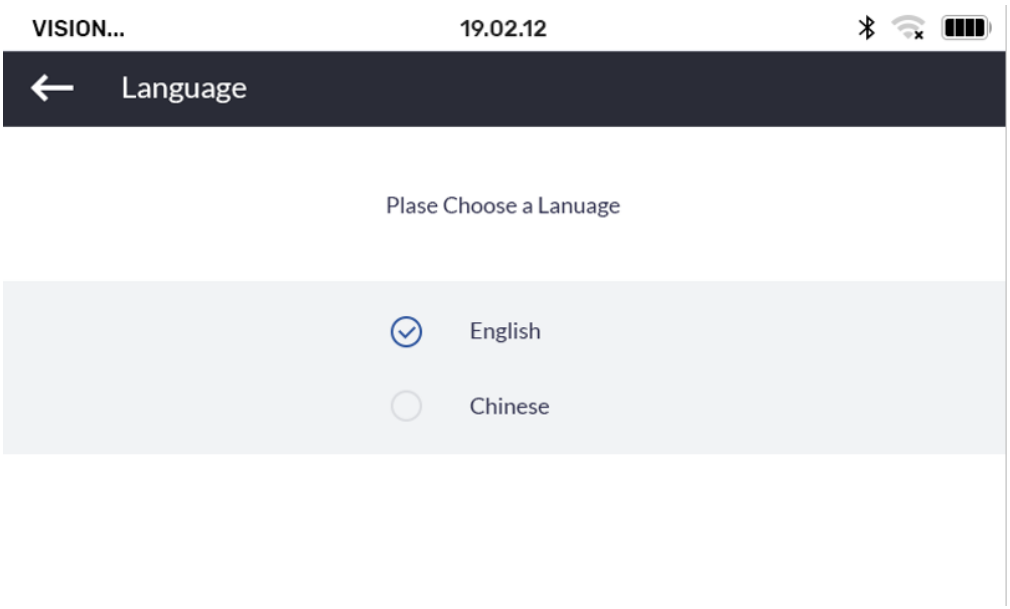
NOTE

What you type on this screen will reflected in the printout.

8.12. Language Screen

This screen can change language to Vision Screener.

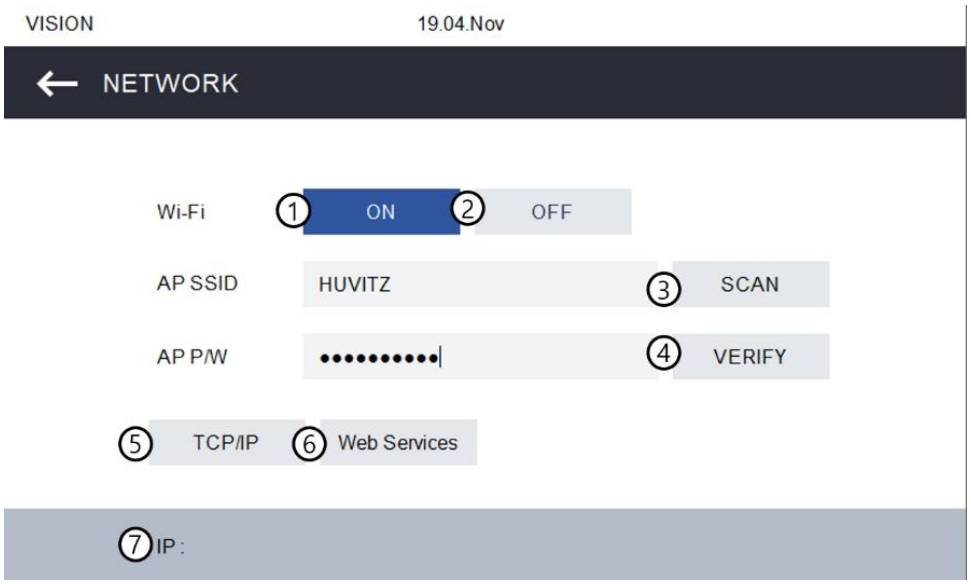
You can go into the Language Screen by pressing on the (Language) button in the Setup Screen.



8.13. Network Screen

This screen can connect wifi and set the DHCP/Static mode and can be changed webserver setting.

You can go into the Network Screen by pressing on the (Network) button in the Setup Screen.

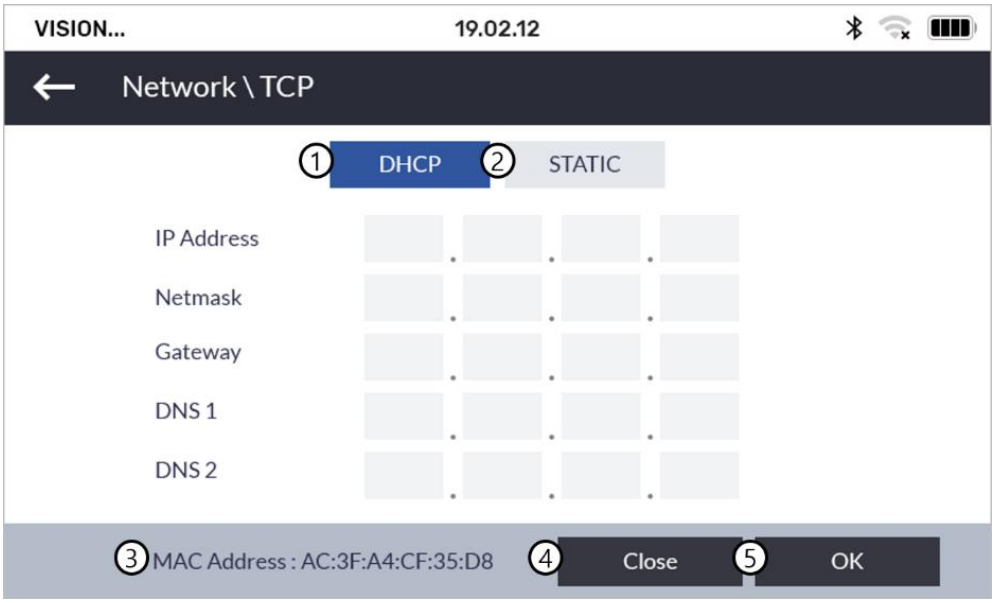


1. On: Turn on the Wifi. If you have an AP that was already connected, it will automatically connect.
2. OFF: Turn off the Wifi.
3. Scan: Search the surrounding the AP.
4. Verify: Try to connect entered the SSID AP and password AP.
5. TCP/IP: Go to Screen where you can convert to Static or DHCP mode.
6. Web Services: Go to Screen Where you modify Web server setting.
7. IP: Shows the IP of the currently connected AP.

8.14. TCP/IP Screen

This screen can connect set the DHCP/Static mode.

You can go into the TCP/IP Screen by pressing on the TCP/IP (TCP/IP) button in the Network Screen.



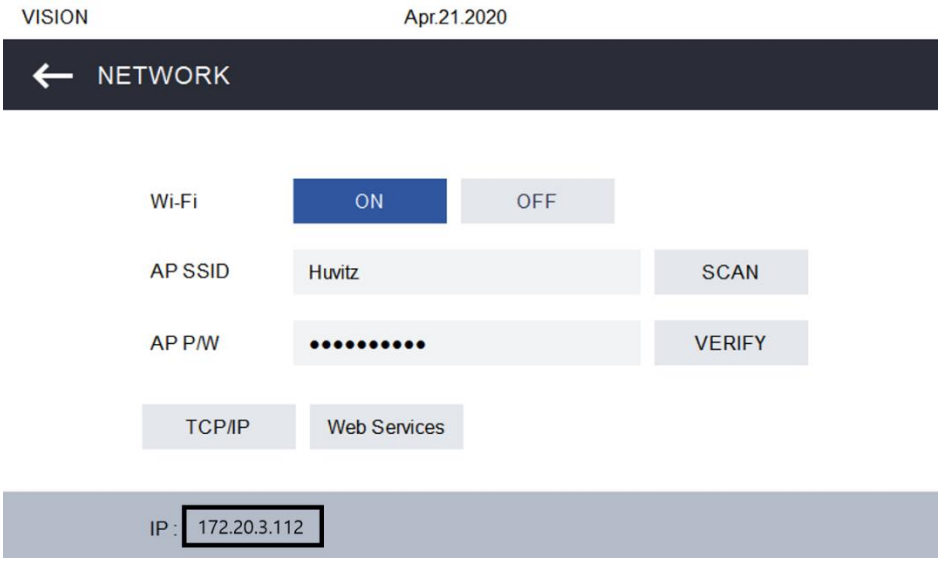
1. DHCP: DHCP mode.
2. Static: Static mode.
3. MAC Address: Show mac address of connected AP.
4. Close : Back to Network Screen.
5. OK: Applies the set Static or DHCP mode and go to Network Screen.

NOTE

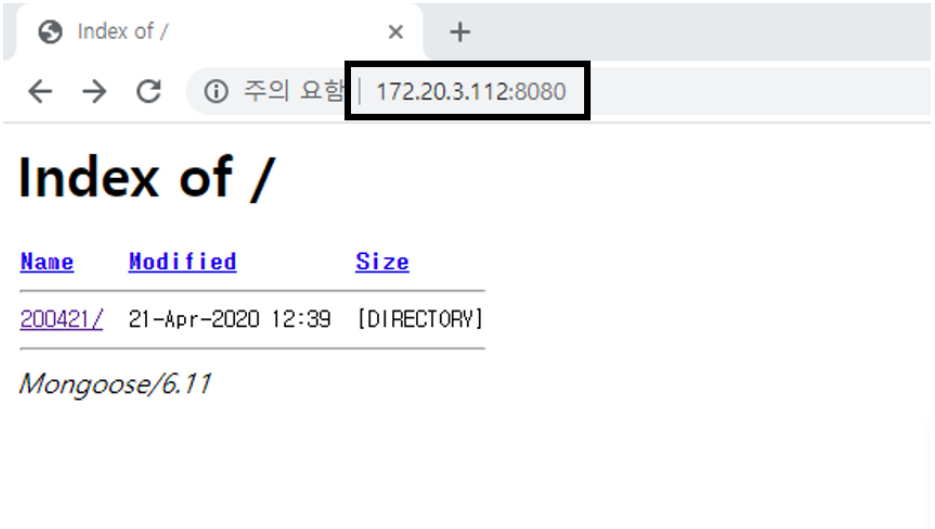
When setting up Static IP, you must first check the bandwidth of the IP in DHCP mode.

※ You can see measurement picture, measurement result report with a web browser.

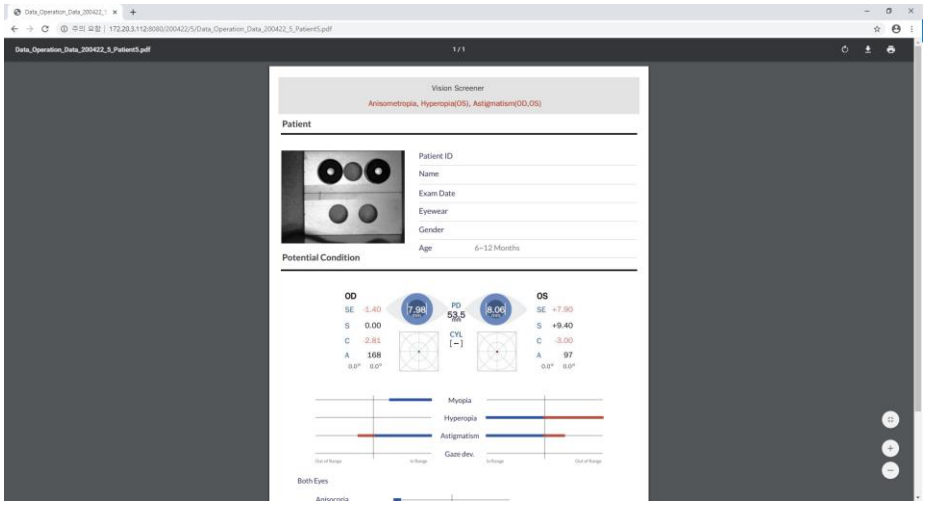
1. Remember the IP



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



3. You can show measurement picture, measurement result report.



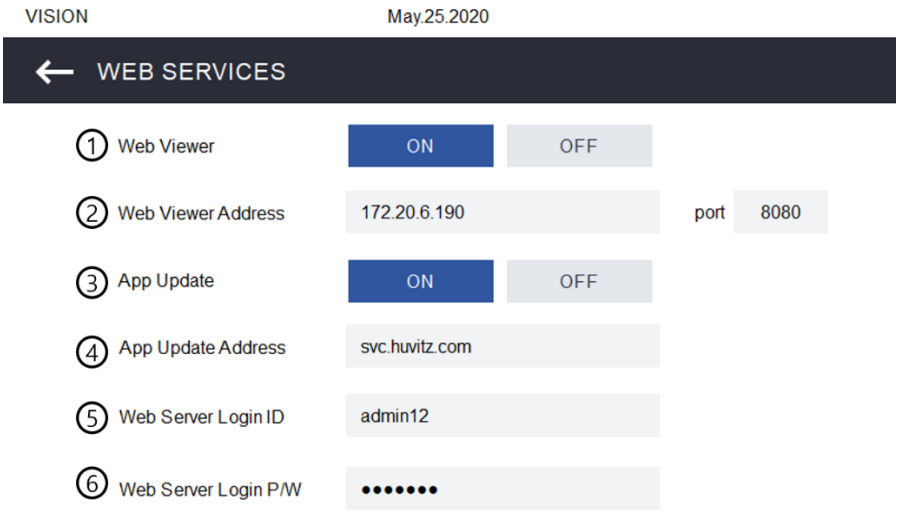
NOTE

You can set the ID and password you need to access the web server In the Web services Screen.

8.15. Web Services Screen

This screen can set the Web Viewer mode and App Remote Update.

You can go into the Web Services Screen by pressing on the Web Services (Web Services) button in the Network Screen.



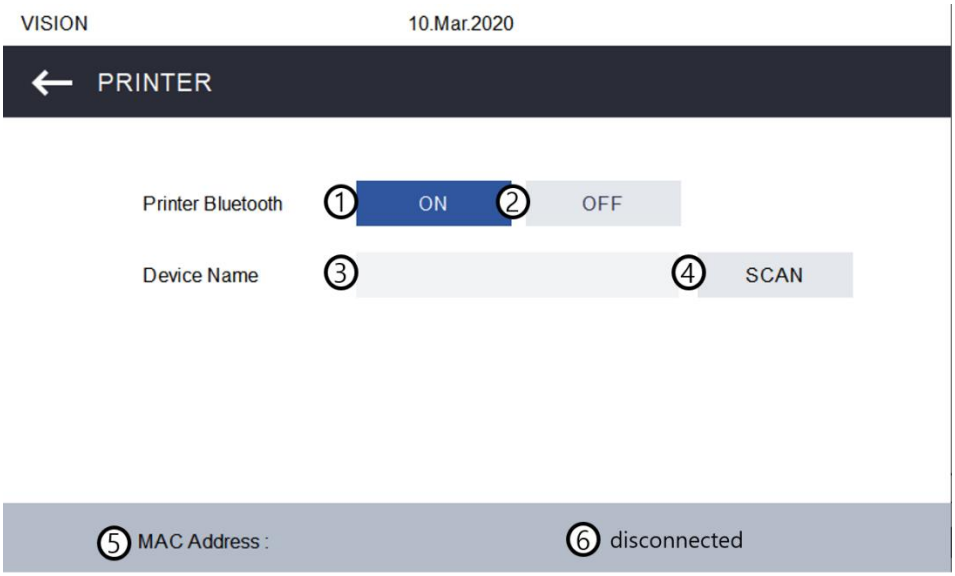
1. Web Viewer ON/OFF : The ability to receive data from HVS-1 with a web browser can be set to ON/OFF.

2. Web Viewer IP : When the ON button is pressed, the keyboard is activated when selected. Enter the IP and Port of the Web Viewer.
3. App Update: This button turns the remote App update on and Off
4. App update IP: Enter the IP or address of the remote App update server.
5. Web Server Login ID : You can set the ID for the web server.
6. Web Server Password ID : You can set the Password for the web server.

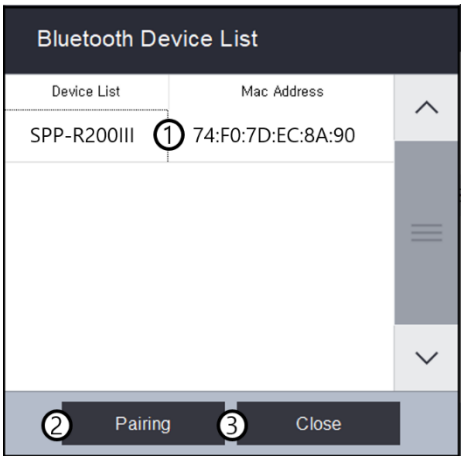
8.16. Printer Screen

This screen can scan, pairing and connect the Bluetooth printer.

You can go into the Printer Screen by pressing on the  (Printer) button in the Setup Screen.



1. Bluetooth On : Turn on the Bluetooth.
2. Bluetooth Off : Turn off the Bluetooth.
3. Device Name : Displays the name of device that paired and connected.
4. Scan : Search the Bluetooth devices around HVS-1.
5. Mac Address: Displays the Mac address of the connected device.
6. Connect state: Indicates the connection status with the Bluetooth devices.



[Bluetooth Scan Dialog]

1. Detected Bluetooth devices : Select the Bluetooth devices to pair
2. Pairing : Attempt to pair selected device. It takes about 30 seconds.
3. Close : Close the dialog and return to the printer screen.

NOTE

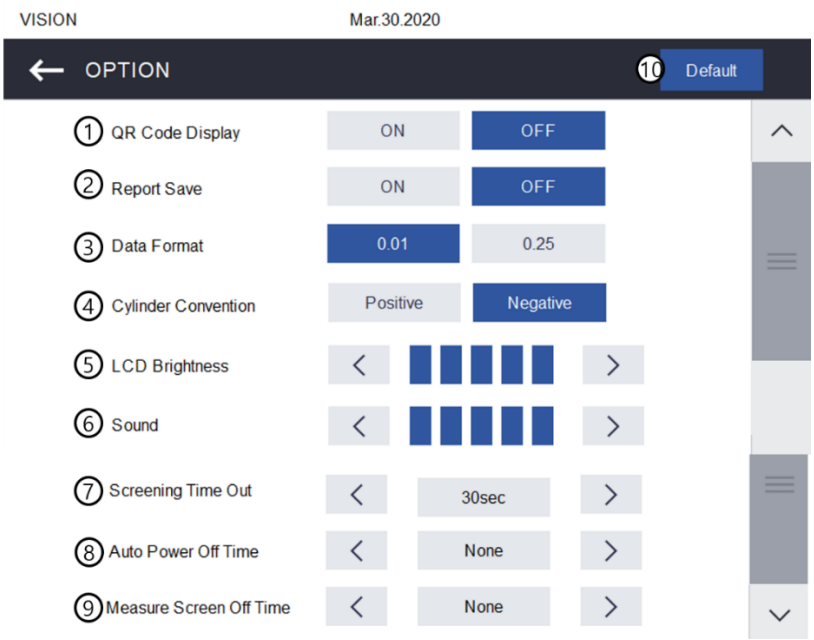
Once pairing is done, the connection is automatic from next time.

※ Recommended Bluetooth printer for **SPP-R200III of Bixolon**.

8.17. Option Screen

This screen sets values such as how the resulting displays data, the screening time, the power saving mode time, sound and the screen brightness control

You can go into the Option Screen by pressing on the (Option) button in the Setup Screen.

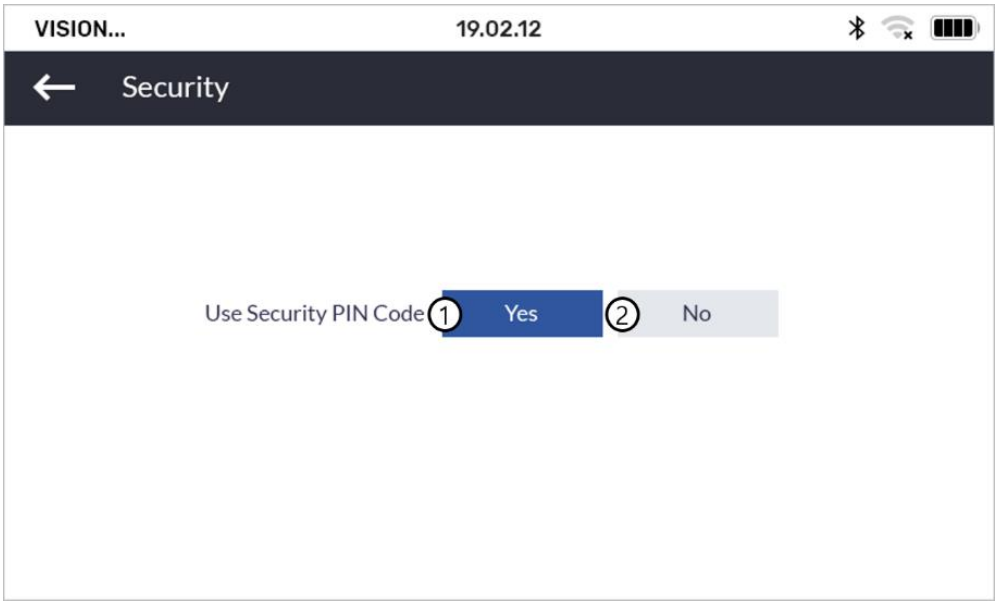


1. QR Code Display : select whether to use or disable the QR code when printing.
2. Report Save: select whether the report of the patient whose measurements have been completed is saved or not
3. Data Format: In the result screen, display the data 0.01 or 0.25 step.
4. Cylinder Convention: In the result screen, change the cylinder sign.
5. LCD Brightness: Adjust the LCD Brightness.
6. Sound: Adjust the sound
7. Screening Time out: Set the time when screen will turn off.
8. Auto Power Off Time: Set the time until you enter sleep mode after the screen turns off.
9. Measure Screen Off Time: Set the time
10. Default: Set all options to initial value.

8.18. Security Screen

This screen sets the password for the Vision Screener and set the lock mode.

You can go into the Security Screen by pressing on the (Security) button in the Setup Screen.



1. Yes: Press Yes and set the password to enter Lock mode at boot time, and then the screen is turned off according to the screening time, and then lock mode is executed.
2. No: Press No and enter the password you set to unlock the lock mode.

NOTE

Sleep mode and Lock mode(Input the password) are started according to the time set by the option and the user input is not available at the start of the Application.

9

Self-diagnosis and maintenance/repair

9.1. 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 HVS-1 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

- 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 Sterilization Product	Disinfectant	Orthophtalade-hyde	USA & Europe

9.2. 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.

⚠ CAUTION

Environment pollution may result when the device or lithium battery is discarded recklessly since this device uses lithium battery. To discard, outsource to a specialized waste disposal company.

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Information needed for servicing

Repair: Contact the Huvitz's distributor after preparing the information on the following matters when the problem is not resolved even after taking the measures described on 10.5 Phase.

- equipment name: HVS-1
- equipment's serial number: number on the name plate that is comprised of numbers and letters(SN)
- explanation of the symptom: detailed explanation

Year/month/day purchased: _____

Client name: _____

Client address: _____

Client contact number: _____

Model number: _____

Serial number: _____

- .

Parts that the service personnel need to repair:
- The following parts are consumables by nature and quality tends to decrease after using for a long time. But the user must not replace it in person. When the parts are consumed or deteriorated due to long time use, contact the Huvitz's distributor for replacement.
- Back-up battery for clock and data

Contact the Huvitz's service department directly by referring to the address and telephone numbers below if you cannot contact the distributor where you purchased the product.

Huvitz Co., Ltd. contact numbers

Address:

Huvitz Co., Ltd.

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

Tel: 031-428-9100 (main)

Fax: 031-477-9022 (FA Team: Field Application Team)

e-mail: svc@huvitz.com

www.huvitz.com

EU Representative

Medical Device Safety Service GmbH (MDSS)

Schiffgraben 41, 30175 Hannover, Germany

Tel: +49-511-62628630
Fax: +49-511-62628633

CANADA Representative – CANADA ONLY

AXIS Medical Canada Inc.,

9820 Boulevard Du Golf, Anjou, QC
H1J 2Y7
Tel: 1 877 388-1515

U.S.A Representative

COBURN TECHNOLOGIES

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

Tel: +1-860-648-4906

Switzerland Authorized Representative

MDSS CH GmbH

Laurenzenvorstadt 61

5000 Aarau

Switzerland

Email: info@mdssch.com

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Key specs

Spherical	range	-8.0D to +8.0D	
	Increment step	0.01D, 0.25D	
	accuracy	-3.50D to +3.50D	± 0.5D
		-8.0D to < -3.50D	± 1.0D
		> +3.50D to +8.0D	± 1.0D
Cylindrical	range	-3.0D to +3.0D	
	Increment step	0.01D, 0.25D	
	accuracy	-1.50D to +1.50D	± 0.5D
		-3.00D to < -1.50D	± 1.0D
		> +1.50D to +3.00D	± 1.0D
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	
Measuring distance	range	100cm± 5cm	
Fixation target	visual pattern audible sound		
wireless network	802.11 b/g/n		
interface	USB 2.0		

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Accessories

1. AC/DC Adapter 1EA
2. Hand Strip 1EA
3. Bag 1EA
4. Wind-Blower 1EA
5. User Manual 1EA
6. USB-C Type Cable-option 1EA.
7. Bluetooth printer-option (Adapter, Manual, Printer paper) 1EA

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EMC Information

Manufacturer announcement – electromagnetic waves trouble

Electromagnetic waves trouble	
HVS-1 should be used in the below mentioned electromagnetic wave environment. HVS-1 purchaser or user needs to confirm whether HVS-1 is used in this type of environment.	
Trouble test	**Question of appropriateness**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker IEC 61000-3-3	Complies

Manufacturer announcement – electromagnetic waves tolerance

electromagnetic waves tolerance		
HVS-1 is to be used in the below designated electromagnetic wave environment. HVS-1 customer and user need to guarantee that the HVS-1 will be used in this type of environment.		
Tolerance test	**IEC 60601 test level**	**Appropriateness level**
Electrostatic discharge(ESD) IEC 61000 - 4 - 2	contact ±8 kV in the air ±15 kV	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 tolerance		
HVS-1 is to be used in the below mentioned electromagnetic wave environment. HVS-1 purchaser or user needs to confirm whether HVS-1 issued 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