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# 1 General information

## 1.1 Device Outline

The Visual Acuity Chart System Model HDC-100 is a chart presenting device that displays the charts on the LED display panel. This medical device is controlled by a remote-control and external devices such as digital refractor, tablet and personal computer.

- Test distance can be set in the range of 1.5 to 8 meters in 0.1 meters increments (4.75 to 26 ft in 0.25 ft increments). The chart size is reduced or enlarged corresponding the set test distance to maintain the same visual angle.
- Charts of same visual acuity can be changed at random. This prevents erroneous test results caused by patients memorizing the charts.
- The 24 inches large and wide screen allows 0.03 VA (20/600, 6/200) visual acuity to be displayed.
- Images or slides can be displayed alternative to the charts.
- The charts can be displayed while the contrast is decreased to test the visual acuity under low-contrast conditions.

## 1.2 Device name and model

- Device name: Visual Acuity Chart System
- Model: HDC-100
- Rating: 100-240 V~, 50/60 Hz, 50 VA
- Software: Android 9.0.0
- Serial Number: See Marking plate. (Refer to 6.1 Main body)

## 1.3 Manufacturer

Huvitz Co., Ltd.

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

## 1.4 Qualification of the product as a medical device

***– in accordance with MDR Annex II Section 1.1 (e)***

### 1.4.1 Rational for qualification

The Visual Acuity Chart System is qualified as a medical device under Regulation (EU) 2017/745, Article 2 (1), which defines a medical device as:

> ‘medical device’ means any instrument, apparatus, appliance, software implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
> - diagnosis, prevent, monitoring, prediction, prognosis, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
> - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
> - providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
> and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
>
> The following products shall also be deemed to be medical devices:
> - devices for the control or support of conception;
> - product specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1 (4) and of those referred to in the first paragraph of this point.

The device is intended to be used by ophthalmologists, optometrists, and other eye-care professionals to display standardized optotypes and test charts for diagnosis and monitoring of visual acuity, which is a key parameter in the evaluation of eye diseases and vision disorders.

Therefore, its intended purpose directly supports a diagnostic medical function, even though the device itself is non-invasive and does not act on the human body.

#### 1.4.2 Not an accessory

The device is not merely an accessory under Article 2 (2) of the MDR, as it is not designed to enable another medical device to be used in accordance with its intended purpose, nor to specifically and directly assist a medical device in its medical function. It performs an independent diagnostic role by providing optotypes for vision testing.

#### 1.4.3 Classification and regulatory implication

Based on its intended purpose and non-invasive nature, the device is classified as:

| |
|---|
| Medical device, Class I (non-invasive)<br>according to MDR Annex VIII, Chapter III, Rule 13 |

## 1.5 Device classification and justification

– in accordance with MDR Annex II Section 1.1 (f)

#### 1.5.1 Risk class

The Visual Acuity Chart System is a non-invasive active medical device intended to be used by ophthalmologists, optometrists, and other eye-care professionals for the diagnosis and assessment of visual function. Accordingly, the device classified as Class I, in accordance with MDR Annex VIII, Chapter III, Rule 13.

#### 1.5.2 Justification for classification

##### 1.5.2.1 Applicable rule

| |
|---|
| MDR Annex VIII, Chapter III Classification Rules<br>6. ACTIVE DEVICES<br>6.5. Rule 13<br>Other active devices are classified as class I |

##### 1.5.2.2 Rationale

a) The device is an active device, since it uses electrical energy to display optotypes on an electronic screen.

b) It does not transfer energy to the human body, nor does it measure or monitor any physiological parameters.

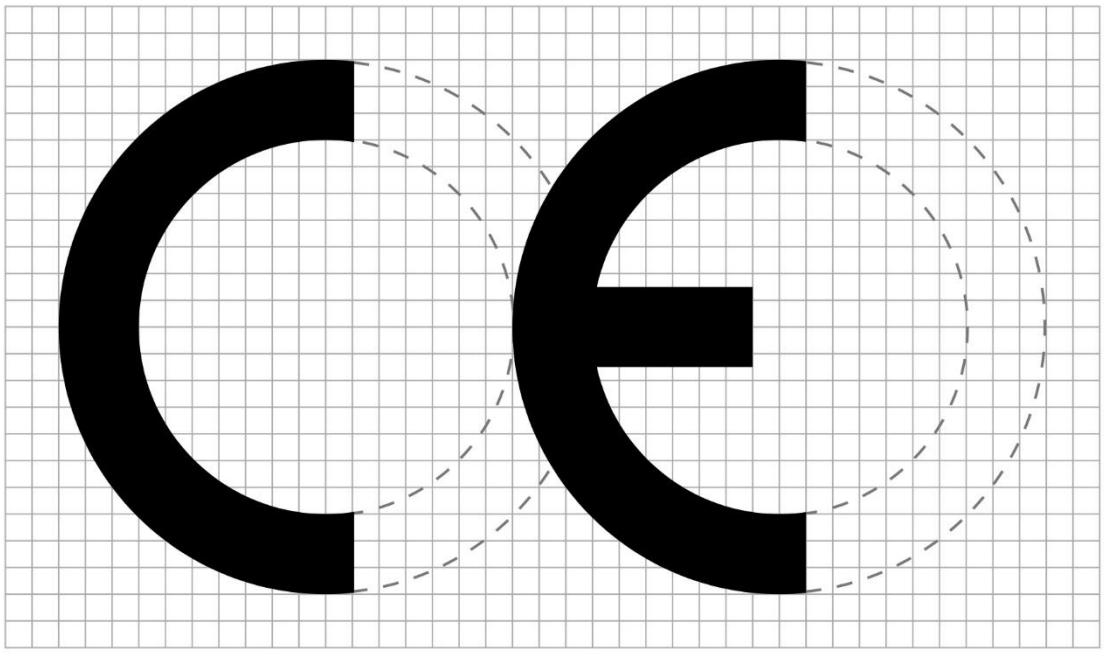
c) The device merely provides optical visual stimuli for vision testing and does not interact with the human body in any hazardous way.

d) As it does not meet the conditions described in Rules 9 to 12 and poses a very low risk to patients, it falls into the residual category under Rule 13 and is therefore classified as Class I.

### 1.5.3 Non applicability of other rules

| No. | Rule summary | A or N/A | Reason for non-applicability |
|---|---|---|---|
| **Rule 9** | Active devices intended to deliver energy to or exchange energy with the human body for diagnosis or therapy | N/A | The device does not deliver or exchange energy with the body |
| **Rule 10** | Active devices intended for monitoring or measurement of vital physiological parameters | N/A | The device performs no measurement or monitoring |
| **Rule 11** | Software intended for processing or interpretation of medical data | N/A | Built-in software only controls visual display; no diagnostic data processing |
| **Rule 12** | Active devices intended to emit or exchange energy absorbed by the body | N/A | The device emits only visible light for visual perception, not for absorption or treatment |
| **Rule 13** | All other active devices not covered by the above rules | A | Non-invasive, non-measuring, active visual display device |

## 1.6 Regulatory mark



[REGULATION (EU) 2017/745 – ANNEX V CE MARKING OF CONFORMITY]

## 1.7 Authorized Representative in EU

**Medical Device Safety Service GmbH**

Schiffgraben 41, 30175 Hannover, Germany

# 2 Information

## 2.1 Intended purpose

To display visual acuity test images on a screen for the purpose of patient's eyesight test.

## 2.2 Intended environment

| Item | Description |
|---|---|
| Location | Specialized medical institutions such as medical offices, refraction room, etc. in hospitals |
| Lighting | Indoor lighting 80 to 320 cd/$m^2$<br>200 cd/$m^2$ recommended |
| Noise | Used in relatively quiet conditions to allow conversation with the patients |
| Space | A certain distance from the patient must be ensured – at least 1.5m |
| Power supply | AC 100-240V 50/60Hz fixed outlet required |
| Buildings or infrastructures | Professional healthcare facility environment<br>Hospitals, medical institutions, and treatment facilities;<br>Hospitals except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging |
| Operating environment | Temperature: -10 °C to +40 °C<br>Humidity: 10 to 90 % (non-condensing)<br>Atmospheric pressure: 80 kPa to 106 kPa |

| | |
|---|---|
|  | This device is intended for use only in professional healthcare facility environments, such as hospitals, clinics, and optometry offices. Do not use in non-clinical or home environments. |
|  | Do not operate this device in close proximity to active high-frequency (HF) surgical equipment, as excessive electromagnetic interference (EMI) may cause malfunction or incorrect chart display. |
|  | This device must not be used inside or adjacent to the RF shielded room of an ME system for magnetic resonance imaging (MRI). Strong electromagnetic fields in such environments can lead to device failure and potential hazards. |

## 2.3 Intended user

### 2.3.1 Segmentation of occupation

| User group | Description |
|---|---|
| Doctor | A doctor who tests, diagnoses and prescribes a patient's vision in hospital |
| Optometrist | Specialized medical technician who specializes in eyesight test in hospitals, etc. |
| Optician | A medical technician who performs an eyesight test for prescription of eyeglasses or contact lenses |
| medical professional, technician or relevant qualifying holder | A person who assists the test according to the doctor's instructions |

### 2.3.2 User characteristics

- healthcare qualified professionals with relevant qualifications
- a secondary level of education, at least
- receive minimal training or instruction before using the product
- possibility of elderly users or user unfamiliar with digital devices

## 2.4 Residual risks

- Temporary eye fatigue or discomfort due to prolonged viewing of digital visual acuity charts.
- Possible discomfort for individuals who are sensitive to bright or high-contrast displays.

## 2.5 Indications

The device is indicated for patients requiring:

- Assessment of visual acuity due to refractive errors (myopia, hyperopia, astigmatism)
- Monitoring visual function in conditions affecting central vision
- Pre- and post-examination assessment during refraction procedures
- Evaluation of binocular vision, phoria, stereopsis, and contrast sensitivity (when applicable charts are selected)

It is intended for use in clinical environments such as ophthalmology clinics, optometry offices, optical shop, and hospital refraction rooms.

## 2.6 Contra-indications

There are no known absolute contraindications for the use of this device. However, use should be avoided or performed with caution in the following cases:

- Patients with photosensitive epilepsy or a history of light-induced seizures
- Patients who cannot maintain stable fixation or cannot understand displayed optotypes
- Patients with severe cognitive impairment preventing meaningful response
- Patients who experience discomfort due to bright digital displays

If any unusual symptoms (e.g., dizziness, visual discomfort) occur, testing shall be discontinued.

## 2.7 Patient target groups

The device is intended for:

- Adults and children capable of recognizing visual test symbols
- Patients with refractive errors or general ophthalmic conditions requiring visual acuity assessment
- Patients capable of following simple instructions and responding to visual stimuli

The device is not intended for unconscious patients, infants unable to respond, or patients requiring objective automated vision assessment.

## 2.8 Undesirable side-effects

No undesired physiological side effects are known or expected from the use of this device. Information regarding these considerations should be conveyed to the patient when necessary.

## 2.9 Operating principle

The Visual Acuity Chart System operates by displaying optotypes (letters, numbers, symbols, or figures) on an electronic display to assess a patient's visual acuity at defined distance. The device uses an Android-based software application running on an integrated display module that generates calibrated visual stimuli in accordance with standard visual-acuity testing method (e.g., Tumbling E, Landolt ring, Numbers). The optotypes are scaled according to the testing distance (1.5m to 8 m) to correspond to specific visual-acuity levels (e.g., 1.0, 0.8, 0.5, etc.).

### 2.9.1 Mode of action

The system does not act on or interact with the human body. Its mode of action is purely visual presentation of stimuli for subjective assessment of vision. It provides optical images on a display; the human eye perceives these images, and the examiner interprets the patient's response. There is no energy transfer, no diagnostic measurement, and no physiological effect generated by the device itself.

### 2.9.2 Scientific basis

The principle is based on established ophthalmic science for visual-acuity determination, as standardized in:

- ISO 8596:2017 – Ophthalmic optics – Visual acuity testing – standard and clinical optotypes and their presentation
- ISO 10938:2016 – Ophthalmic optics – Chart displays for visual acuity measurement – Printed, projected and electronic

| | |
|---|---|
|  | This device shall be operated only by quality healthcare professionals with appropriate training in visual acuity testing procedures. |
|  | Elderly users or those unfamiliar with digital devices may require additional instruction or supervised use to avoid operational errors. |
|  | The device is not intended for patient self-testing or layperson use. Any use outside the defined professional user group may compromise patient safety and test reliability. |

# 3 Safety information

| | |
|---|---|
|  | Use only with IEC 60601-1 compliant power supply – adapter. |
|  | Do not expose the device to moisture or liquids – risk of electric shock or fire |
|  | Ensure proper test distance (e.g., 5 m / 13 ft) between screen and patient's eye. |
|  | Not for home use or self-diagnosis by patients. |
|  | Do not operate in the presence of flammable anesthetic gases. |
|  | This device is intended for use only in professional healthcare facility environments, such as hospitals, clinics, and optometry offices. Do not use in non-clinical or home environments |
|  | Do not operate this device in close proximity to active high-frequency (HF) surgical equipment, as excessive electromagnetic interference (EMI) may cause malfunction or incorrect chart display. |
|  | This device must not be used inside or adjacent to the RF shielded room of an ME system for magnetic resonance imaging (MRI). Strong electromagnetic fields in such environments can lead to device failure and potential hazards. |
|  | This device shall be operated only by quality healthcare professionals with appropriate training in visual acuity testing procedures. |
|  | Elderly users or those unfamiliar with digital devices may require additional instruction or supervised use to avoid operational errors. |
|  | The device is not intended for patient self-testing or layperson use. Any use outside the defined professional user group may compromise patient safety and test reliability. |
|  | Malfunction may occur if this part becomes dusty or dirty. |
|  | The reliability of each chart can be different depending on user's ability and experience.<br>Prior to use, the operator must be sufficiently familiar with each chart type. |

| | |
|---|---|
|  | Use only the power supply adapter and power cord specified by the manufacturer. Use of other adapters may cause malfunction or damage. |
|  | Do not install the product using a wall mount bracket not specified by the manufacturer. Improper installation may cause the device to fall, resulting in product damage or personal injury. |
|  | - Install the device on a wall that is sturdy enough to support the weight (5kg).<br>- Use the wall mount bracket verified and supplied by manufacturer.<br>- Request for specialist's help as needed.<br>- Contact manufacturer or authorized local distributor when any problem is occurred during installation |
|  | - Never operate the device while installation.<br>- Do not touch the device with wet hands in order to avoid electric shock. |
|  | Use the wall mount bracket verified and supplied by manufacturer. |
|  | - Never install the wall mount bracket on a flimsy wall.<br>- Do not drill excessively big holes. |
|  | - The device shall be held by two persons.<br>- After hanging the instrument into the wall mount bracket, check the safety of connection. |
|  | All electric wires shall be connected firmly. |
|  | - Never plug the power cord in a socket outlet which does not have any PROTECTIVE EARTH Terminal.<br>- Do not touch any electrical parts with wet hands in order to avoid electric shock. |
|  | Be cautious about the polarity of battery. |
|  | Never use other electric source except applicable battery. |
|  | Do not disconnect power source in the progress of booting. |

| | |
|---|---|
|  | If test distance set improperly, the result may be inaccurate. |
|  | In correct configuration of type of VA Notation may result in erroneous test result. |
|  | Change the channel of MENU function in main body prior to change one of remote-control. |
|  | An invalid remote-control channel setting may affect other visual acuity chart systems located in the same room. |
|  | - In correct configuration of mirror function may result in erroneous test result. |
|  | For more accurate test, adjust the red color value corresponding with the condition of Red/Green glasses. |
|  | For more accurate test, adjust green color value corresponding with the condition of Red/Green glasses. |
|  | For more accurate test, adjust brightness value harmoniously with surrounding environment. |
|  | If a baud-rate sets improperly, serial communication cannot work well. Consult with specialist for this part. |
|  | Some of images cannot be displayed due to not-supported image format. |
|  | Some of videos cannot be played due to not-supported video format. |
|  | For detailed function of slide, consult with manufacturer or authorized local distributor. |
|  | Turn the power off and unplug the power cord from a socket outlet before cleaning. |
|  | Wiping with tissue paper by damage the screen seriously. |
|  | In case of cleaning, excessive force or loading may result in failure. |
|  | Do not leave water drops on the device. If the device is splashed with water, immediately wipe with absorbent cotton or a soft cloth. |
|  | Never use an organic solvent such as paint thinner. |

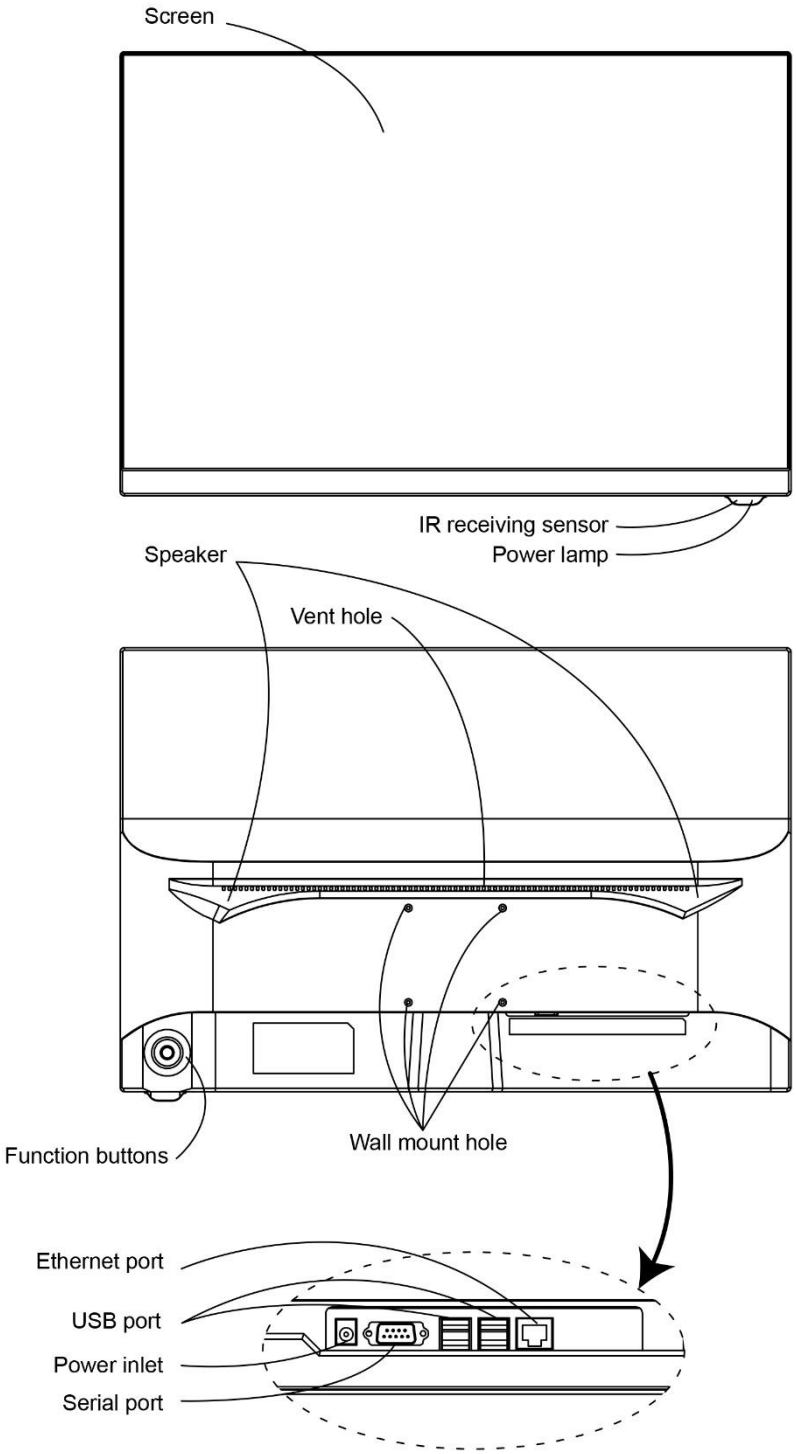
| | |
|---|---|
|  | Do not store or use in place with the following conditions:<br>- harmful gases or polluted air;<br>- blowing dust or sand;<br>- easy exposure to oil residue or fuel elements;<br>- atmosphere that has above standard levels of salt;<br>- prone to dust collecting;<br>- floor surface with a slope greater than 10°;<br>- voltage from wall sockets is changing severely;<br>- exposure to direct sunlight. |
|  | No modification of this equipment is allowed. |
|  | Do not modify this equipment without authorization of the manufacture. |
|  | If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment. |

## 3.1 Reporting of Serious Incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is located.

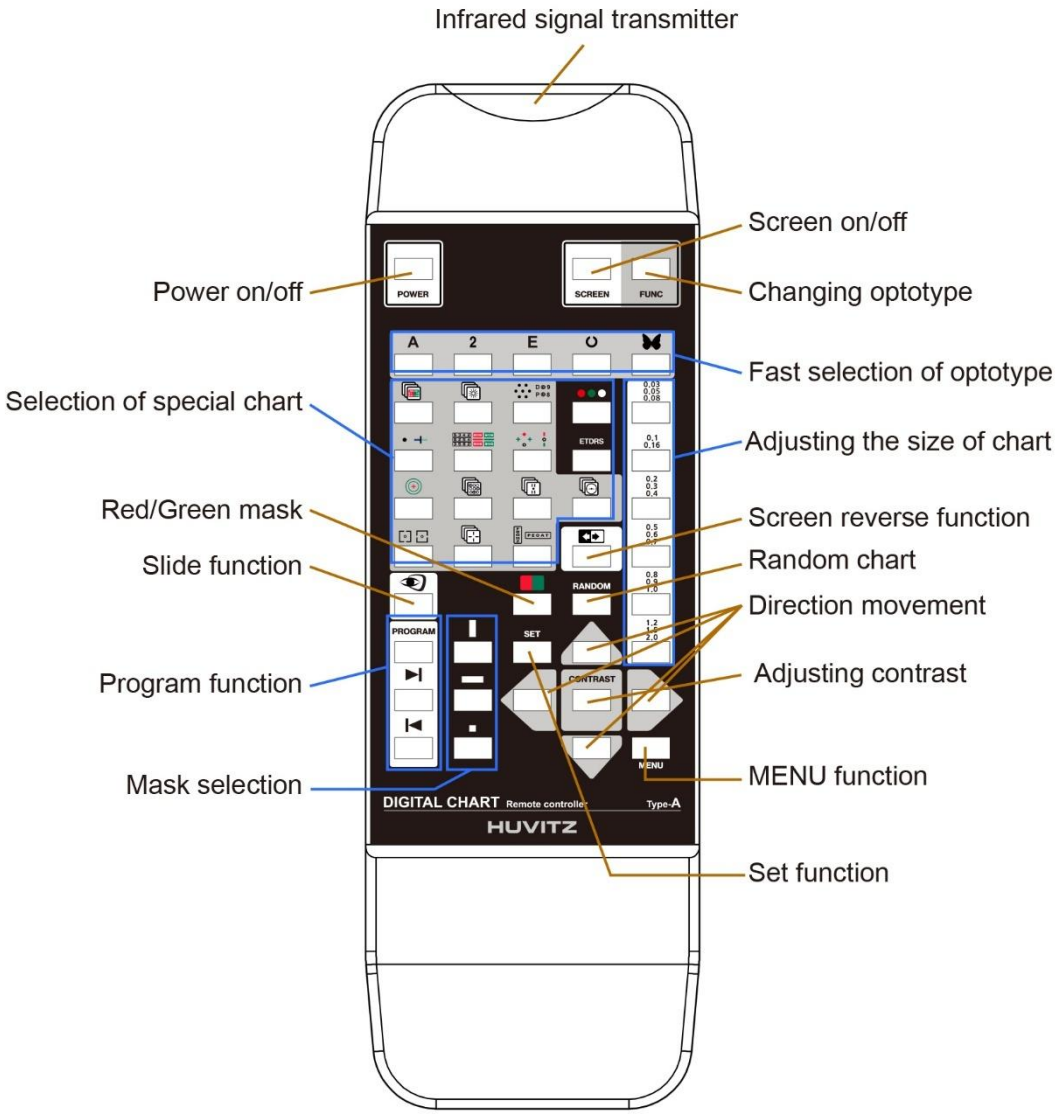
# 4 Device description

## 4.1 Main body



| Description | Function |
|---|---|
| Screen | Displaying the charts or functional information |
| IR receiving sensor | Receiving IR signal from the remote-control |
| Power lamp | Showing power on or off |
| Wall mount hole | Connecting parts to be mounted for wall mount bracket |
| Vent hole | Discharging heat of internal parts |
| Ethernet port | Connecting for using communication with RJ45 |
| USB port | Connecting with USB device |
| Power inlet | Connecting with power source |
| Speaker | Making a sound functional alarm |
| Function buttons | Executing internal functions such as power switch |

## 4.2 Remote-control



**[Infrared signal transmitter]**

This part is for transmitting infrared signal to main body.

| | |
|---|---|
|  | Malfunction or error can be occurred in case of dust or stain onto infrared signal transmitter. |

**[Power on/off]**

It turns on or off.

**[Screen on/off]**

Without power supplying, it switches screen on or off only.

**[Changing chart]**

It enables to choose one of 5 types in VA charts stored basically in the flash-memory sequentially.

**[Fast selection of chart]**

It enables to select one of 5 types in VA charts stored basically in the flash-memory directly.

| Buttons | Functions |
|---|---|
| A | Alphabet |
| 2 | Numbers |
| E | Tumbling E |
|  | Landolt ring |
|  | Pediatric |

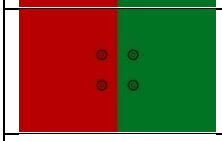
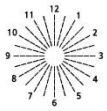
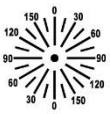
**[Adjusting size of chart]**

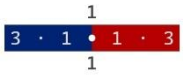
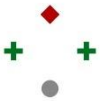
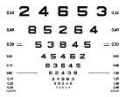
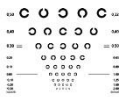
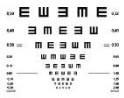
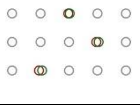
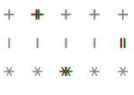
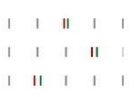
It can adjust the size of chart from VA 0.03 to VA 2.0 for each type of VA chart. [Type-A]

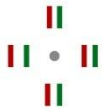
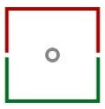
| **Type-A**<br>**Type-R**<br>**Type-U**<br>**Type-E** | **Type-D** | **Type-CN** |
|---|---|---|
| 0.03 | 6/200 | 20/600 |
| 0.05 | 6/120 | 20/400 |
| 0.08 | 6/75 | 20/250 |
| 0.1 | 6/60 | 20/200 |
| 0.16 | 6/45 | 20/150 |
| 0.2 | 6/30 | 20/100 |
| 0.3 | 6/24 | 20/80 |
| 0.4 | 6/21 | 20/70 |
| 0.5 | 6/18 | 20/60 |
| 0.6 | 6/15 | 20/50 |
| 0.7 | 6/12 | 20/40 |
| 0.8 | 6/9 | 20/30 |
| 0.9 | 6/7.5 | 20/25 |
| 1.0 | 6/6 | 20/20 |
| 1.2 | 6/6 | 20/20 |
| 1.5 | 6/4.5 | 20/15 |
| 2.0 | 6/3 | 20/10 |

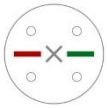
**[Selection of special chart]**

It shows a lot of special charts on the screen.

| Buttons | Displays | Functions |
|---|---|---|
|  |  | Duo-chrome #1 |
| |  | Duo-chrome #2 |
| |  | Cross-grid test |
|  |  | Astigmatism #1 – Clock dial |
| |  | Astigmatism #2 - Fan & block |
| |  | Astigmatism #3 – Axis |
| |  | Astigmatism #4 – Dug-chrome |
| |  | Astigmatism #5 – Axis |
|  |  | Dots |
| |  | Blur, distortion for cross cylinder |
|  |  | Color anomaly charts |
| |  | Color anomaly charts for three colors |
|  |  | Fixation dot / Maddox rod test |

| Buttons | Displays | Functions |
|---|---|---|
| |  | Thorington |
|  |  | Binocular vision #1 |
| |  | Binocular vision #2 |
|  |  | Worth 4 dots |
| |  | Dominant eye test |
| **ETDRS** |  | ETDRS: Early Treatment Diabetic Retinopathy Study (Alphabet) |
| |  | ETDRS: Early Treatment Diabetic Retinopathy Study (Number) |
| |  | ETDRS: Early Treatment Diabetic Retinopathy Study (Landolt ring) |
| |  | ETDRS: Early Treatment Diabetic Retinopathy Study (Tumbling E) |
|  |  | Schober test |
|  |  | Minutes stereo #1 (excluding Type-E) |
| |  | Minutes stereo #2 (excluding Type-E) |
| |  | Minutes stereo #3 (excluding Type-E) |
| |  | Minutes stereo #4 (Type-E only) |

| Buttons | Displays | Functions |
|---|---|---|
| |  | Minutes stereo #5 (Type-E only) |
| |  | Minutes stereo #6 (Type-E only) |
|  |  | Stereo test #1 |
| |  | Stereo test #2 |
| |  | Stereo test #3 |
| |  | Stereo test #4 |
| |  | Stereo test #5 |
|  |  | Stereo test #6 |
| |  | Stereo test #7 |
| |  | Stereo test #8 |
|  |  | Vertical coincidence test |
| |  | Horizontal coincidence test |
|  |  | Phoria test #1 (excluding Type-E) |
| |  | Phoria test #2 (excluding Type-E) |

| Buttons | Displays | Functions |
|---|---|---|
| |  | Phoria test #3 (Type-E only) |
| |  | Phoria test #4 (Type-E only) |
| |  | Phoria test #5 |
| |  | Phoria test #6 |
| |  | Phoria test #7 |
| |  | Phoria test #8 |
|  |  | Vertical von Graefe test |
| |  | Horizontal Graefe test |

| | |
|---|---|
| ⚠ | The reliability of each chart can be different depending on user's ability and experience.<br>Prior to use, it needs enough understanding for each chart. |

**[Red/Green mask]**

Red/Green color background put behind VA charts.

**[Slide function]**

It shows various images and video such as anatomy chart and advertisement to patients.

**[Screen reverse function]**

It reverses the color between black and white for special measurement.



**[Random chart]**

It displays random chart in the same VA charts.




**[Program function]**

It memorizes the chart and order before use. And, it displays memorized chart.

**[Direction movement]**

Where it needs, it carries out movement of direction for insertion of masks, change of setup, change of special chart and so on.

**[Adjusting the contrast]**

It increases or decreases the contrast of chart.

**[Mask selection]**

| | |
|---|---|
|  | It displays vertical one line of the chart. |
|  | It displays horizontal one line of the chart. |
|  | It displays one character of the chart. |

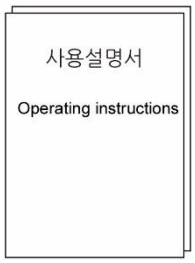
**[MENU function]**

It enters in MENU screen to preset all environmental variables such as test distance, brightness and so on.

**[Set function]**

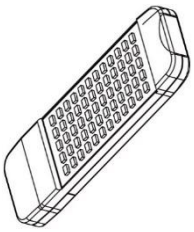
In program function or MENU function, it stores current set values or variables.

## 4.3 Accessories



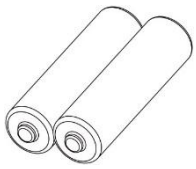

Operating instructions

UM-101



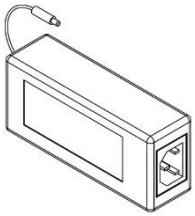
Remote-control

R1-A01



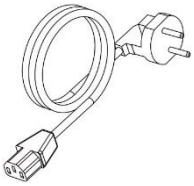
Two pieces of batteries

(IEC R6)



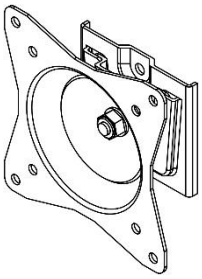
Power supply

GSM60A12



Power cord

KKP/30/KKS-16A



Wall mount bracket

Y-620

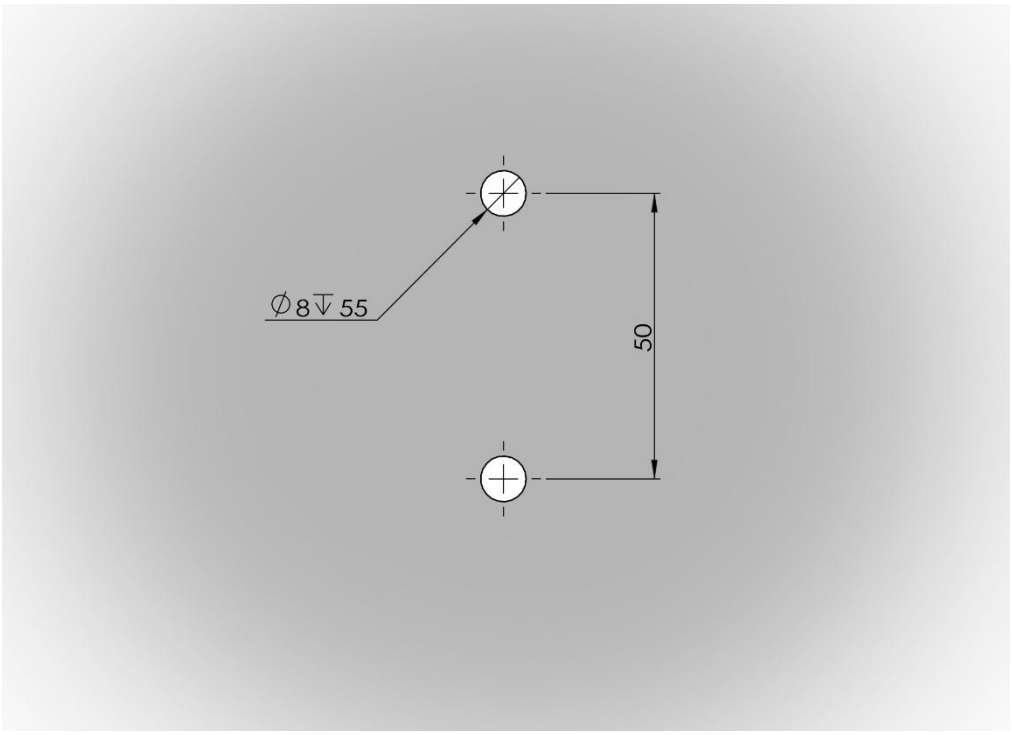
| | |
|---|---|
| **NOTE** | The Operating instructions are provided in English or Korean as standard.<br>For other languages, please contact your local distributor upon request. |
| **NOTE** | According to International Civil Aviation Organization – ICAO and IATA Dangerous Good Regulations – DGR, the transport of batteries may be restricted or prohibited on certain airlines or in specific countries. Therefore, some accessories of this product may be shipped without batteries included. |
| ⚠ | Use only the power supply adapter and power cord specified by the manufacturer. Use of other adapters may cause malfunction or damage. |
| ⚠ | Do not install the product using a wall mount bracket not specified by the manufacturer.<br>Improper installation may cause the device to fall, resulting in product damage or personal injury. |

# 5 Installation

| | |
|---|---|
| ⚠ | - Install the device on a wall that is sturdy enough to support the weight (5kg).<br>- Use the wall mount bracket verified and supplied by manufacturer.<br>- Request for specialist's help as needed.<br>- Contact manufacturer or authorized local distributor when any problem is occurred during installation |
| 🚫 | - Never operate the device while installation.<br>- Do not touch the device with wet hands in order to avoid electric shock. |

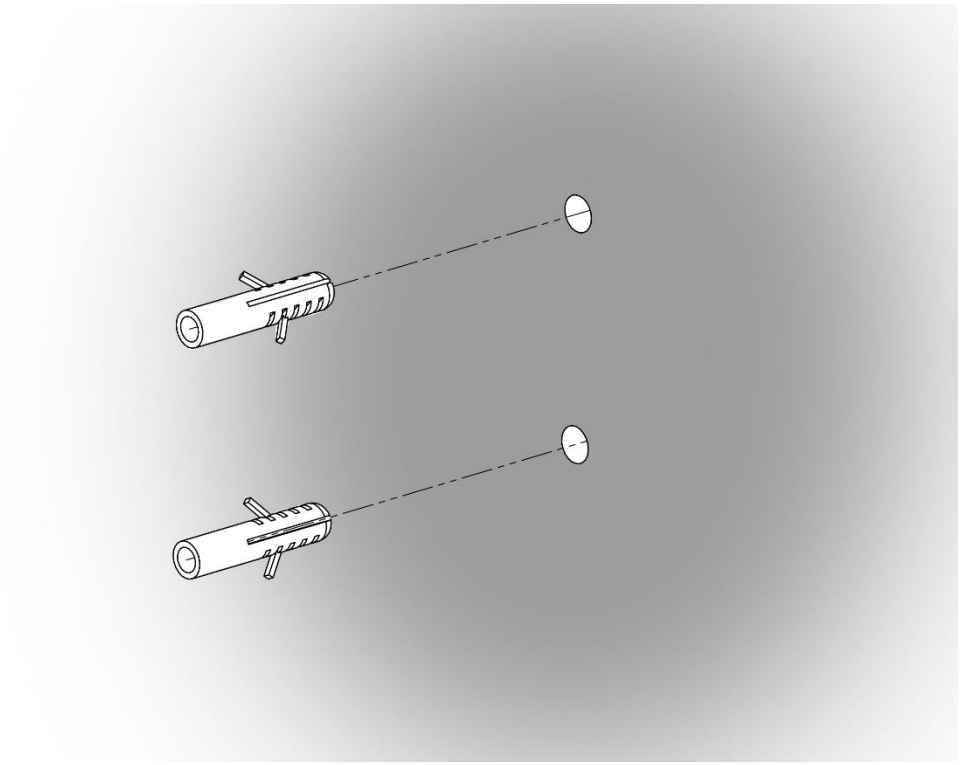
## 5.1 Installation of wall mount bracket

(1) With an electric power drill, drill two holes - 8mm diameter in sturdy and safe wall as follow.

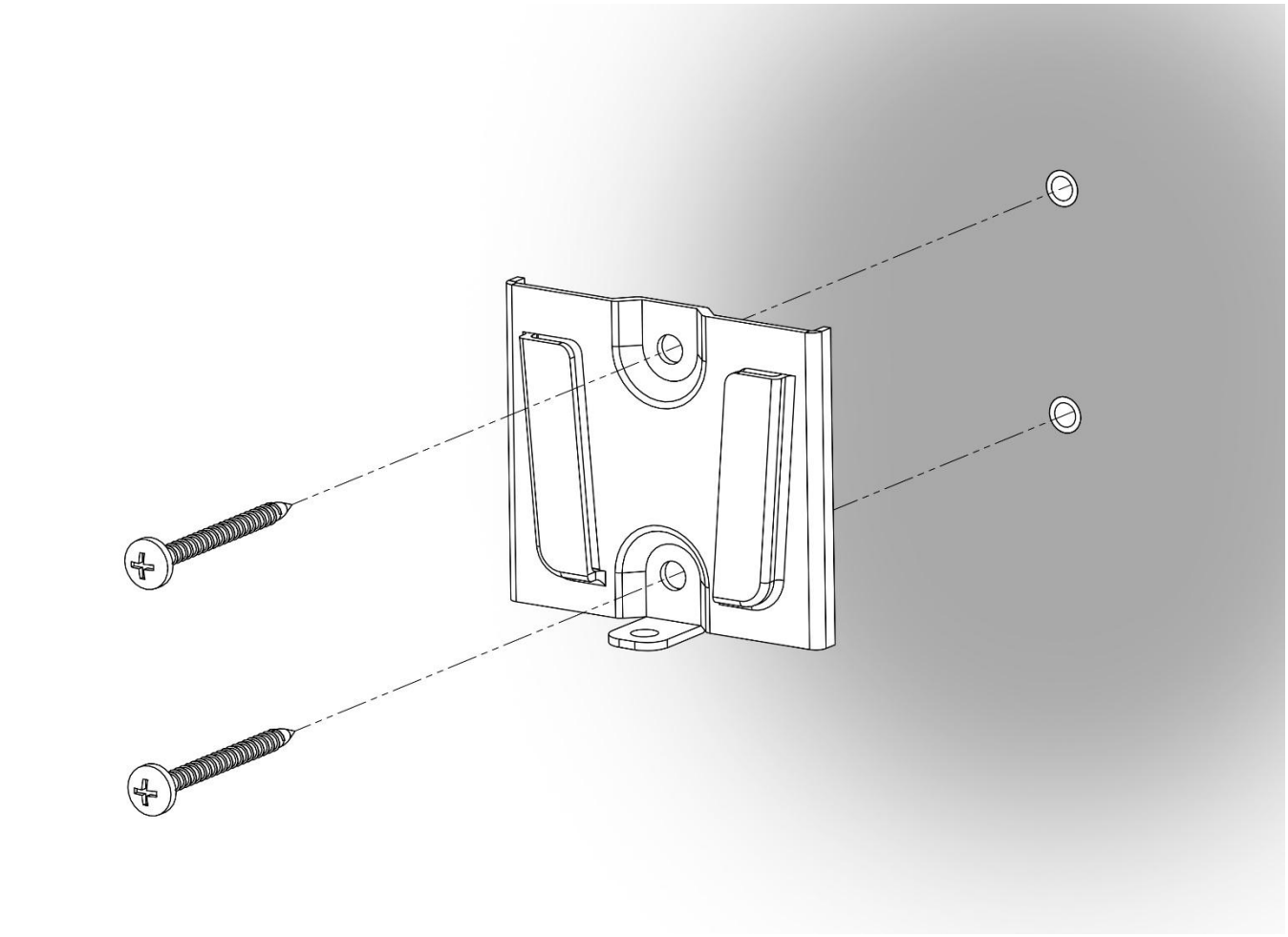



| | |
|---|---|
| ⚠ | Use the wall mount bracket verified and supplied by manufacturer. |
| 🚫 | - Never install the wall mount bracket on a flimsy wall.<br>- Do not drill excessively big holes. |

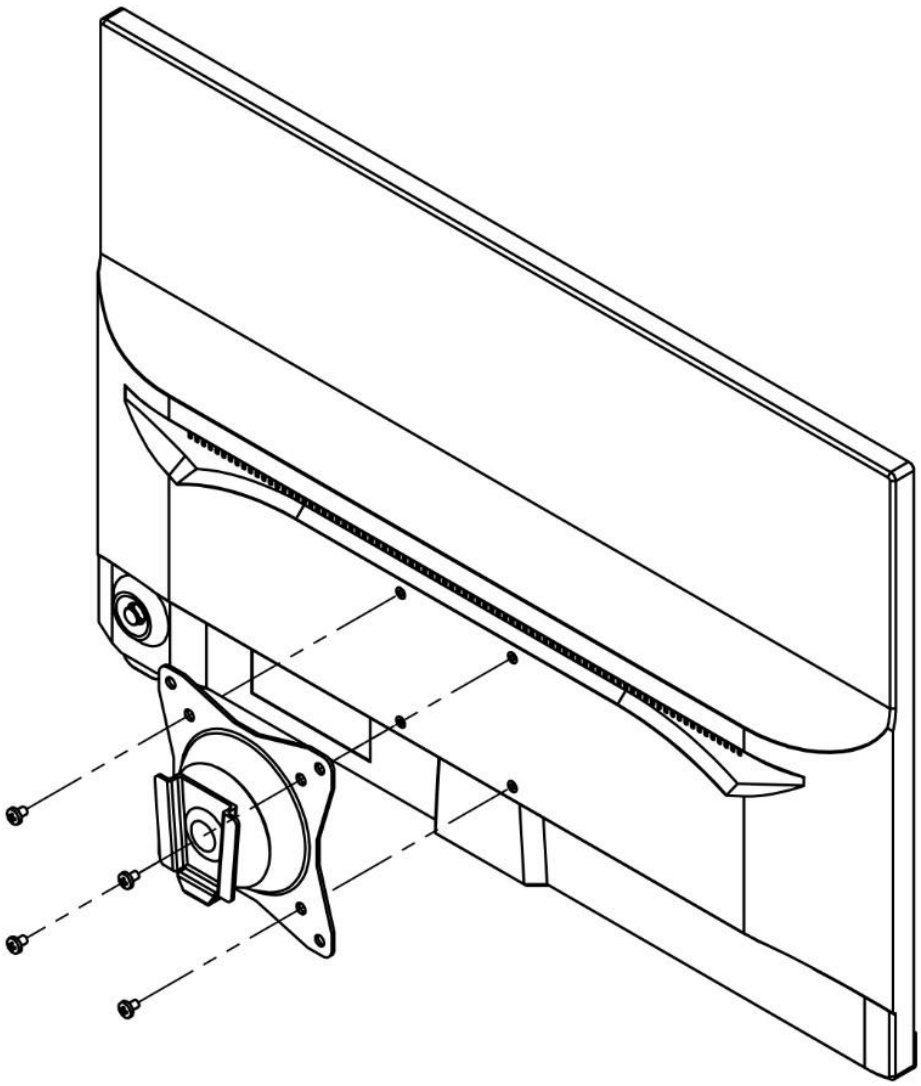
(2) If the material of wall to be attached is stone, put the plastic anchors into the drilling holes.



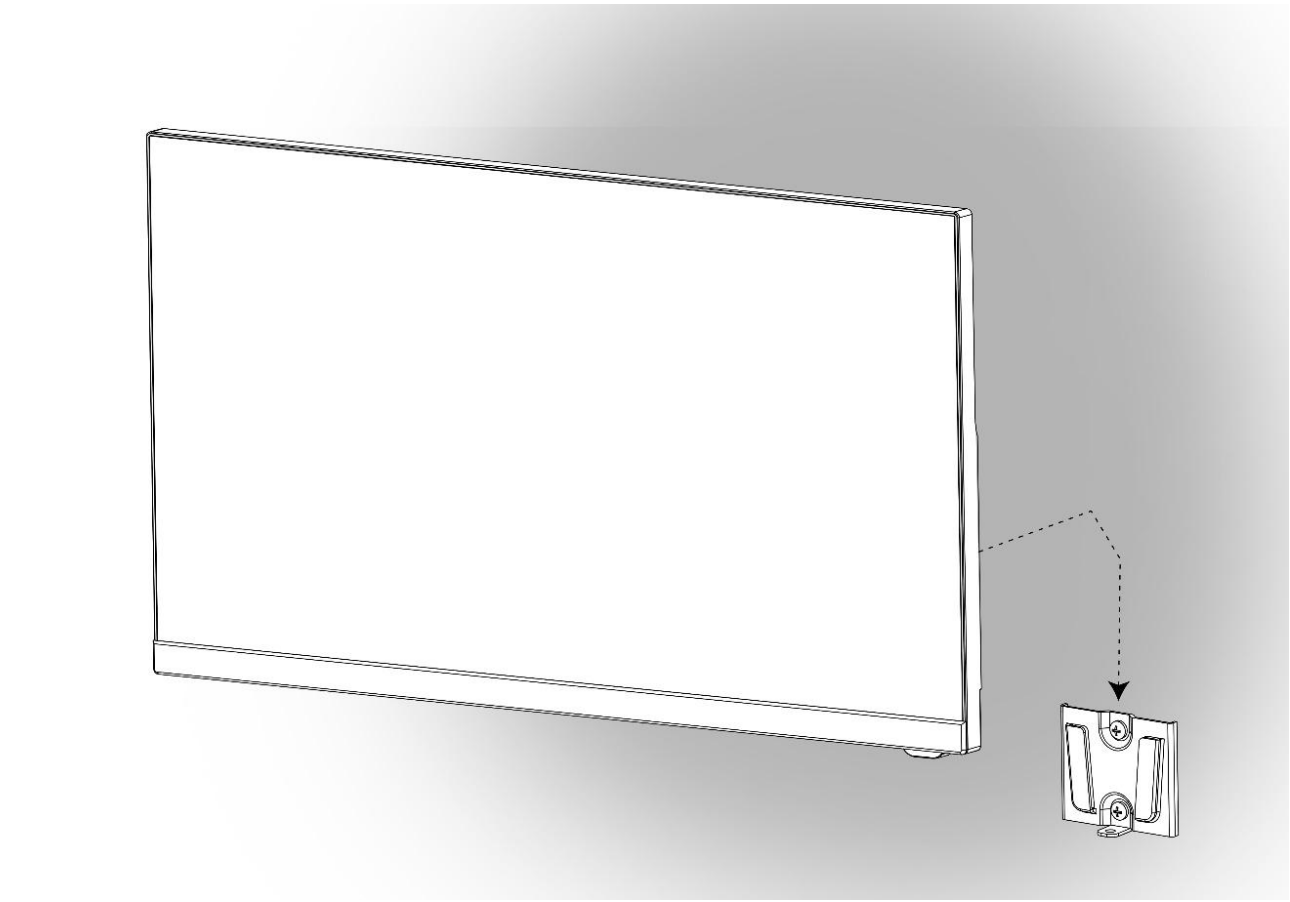
(3) Place wall mount bracket (Female) on the place corresponding with drilled holes, and then tighten round tapping bolts (M5 x 55L). As needed, put anchor blocks (M5) prior to tightening four round tapping bolts (M5 x 55L).



(4) Place wall mount bracket (Male) on the place corresponding with wall mount holes, and then tighten four screw bolts (M4 x 5L).

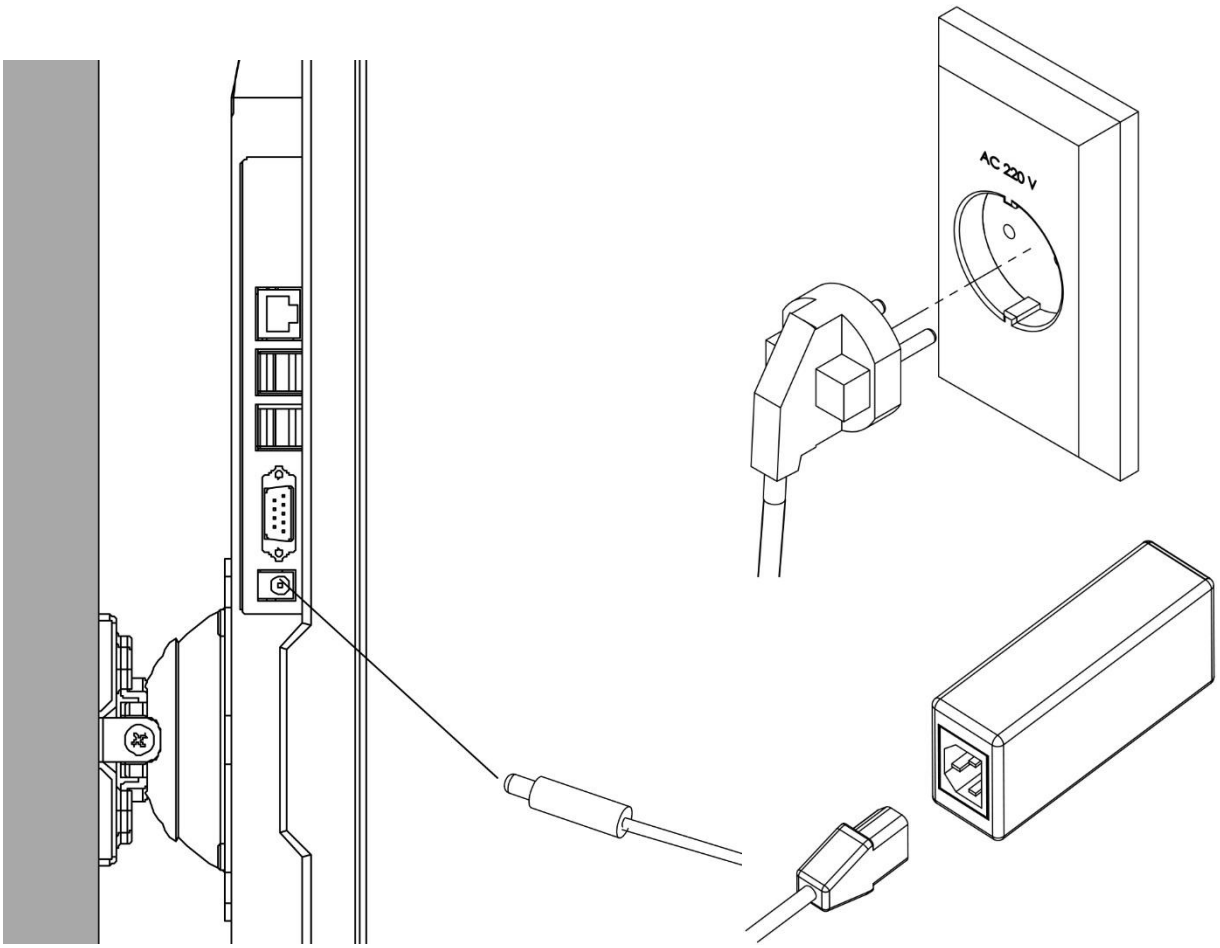


(5) CAREFULLY, hang the wall mount bracket (Male) into the wall mount bracket (Female) located on the wall.



| | |
|---|---|
| ⚠ | - The device shall be held by two persons.<br>- After hanging the instrument into the wall mount bracket, check the safety of connection. |

## 5.2 Wiring




(1) Plug the output connector of power supply in a power inlet of main body.

(2) Plug the power cord in a socket outlet located on the wall, and then insert opposite part of power cord in a socket located on power supply.

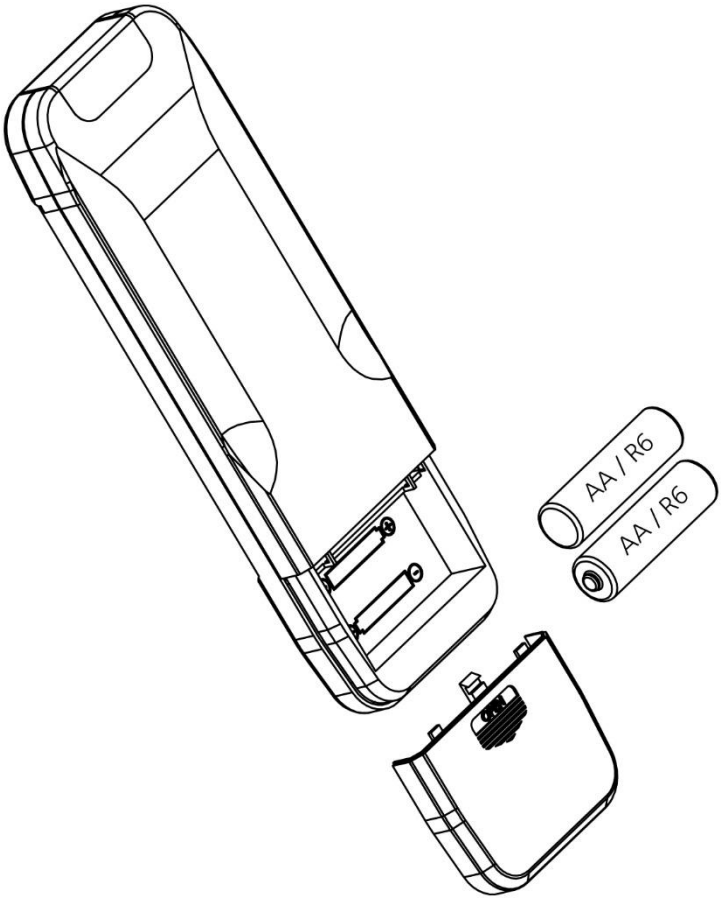
| | |
|---|---|
| ⚠ | All electric wires shall be connected firmly. |
| 🚫 | - Never plug the power cord in a socket outlet which does not have any PROTECTIVE EARTH Terminal.<br>- Do not touch any electrical parts with wet hands in order to avoid electric shock. |

## 5.3 Preparation of remote-control

(1) Open a battery cover of remote-control.

(2) Put two batteries corresponding with polarity in to battery holes.

(3) Close a battery cover firmly.

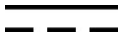
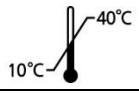
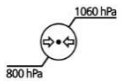



| **Applicable battery type** | |
|---|---|
| International Standard | R6 or LR6 |
| U.S. and Korea | AA |
| Japan | UM3 or AM3 |

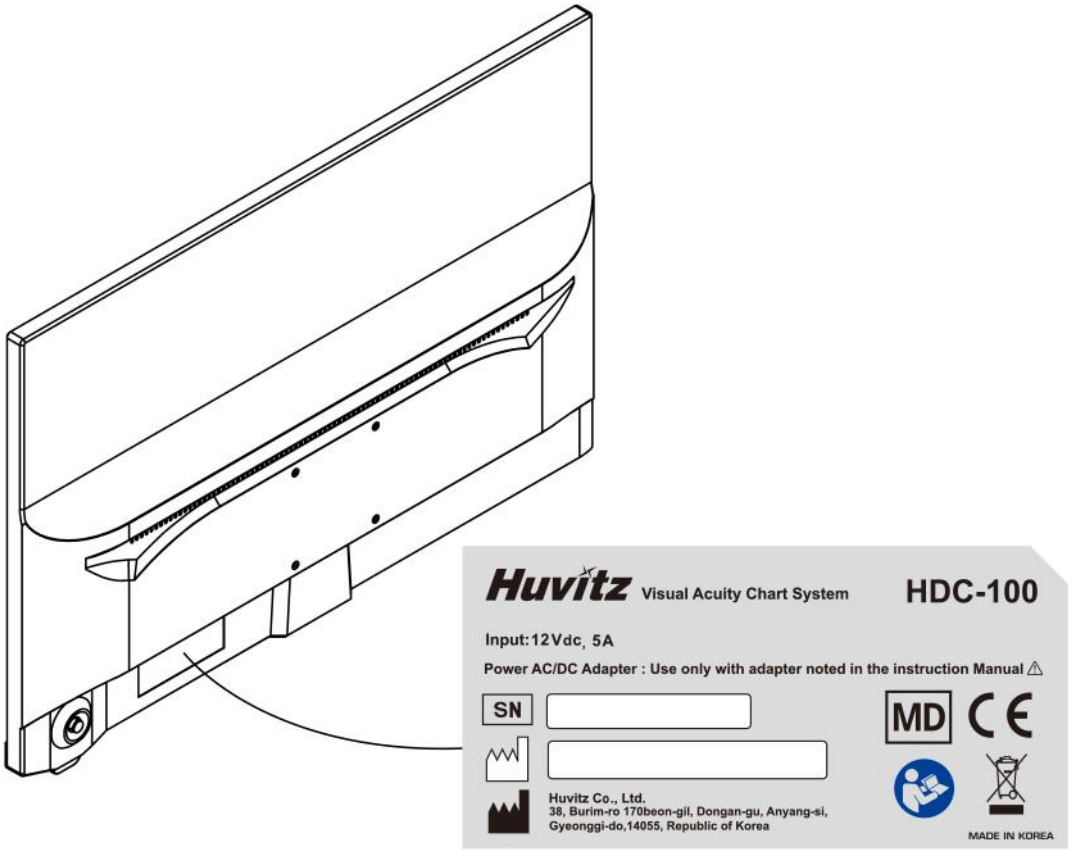
| | |
|---|---|
|  | Be cautious about the polarity of battery. |
|  | Never use other electric source except applicable battery. |

# 6 Label and symbols

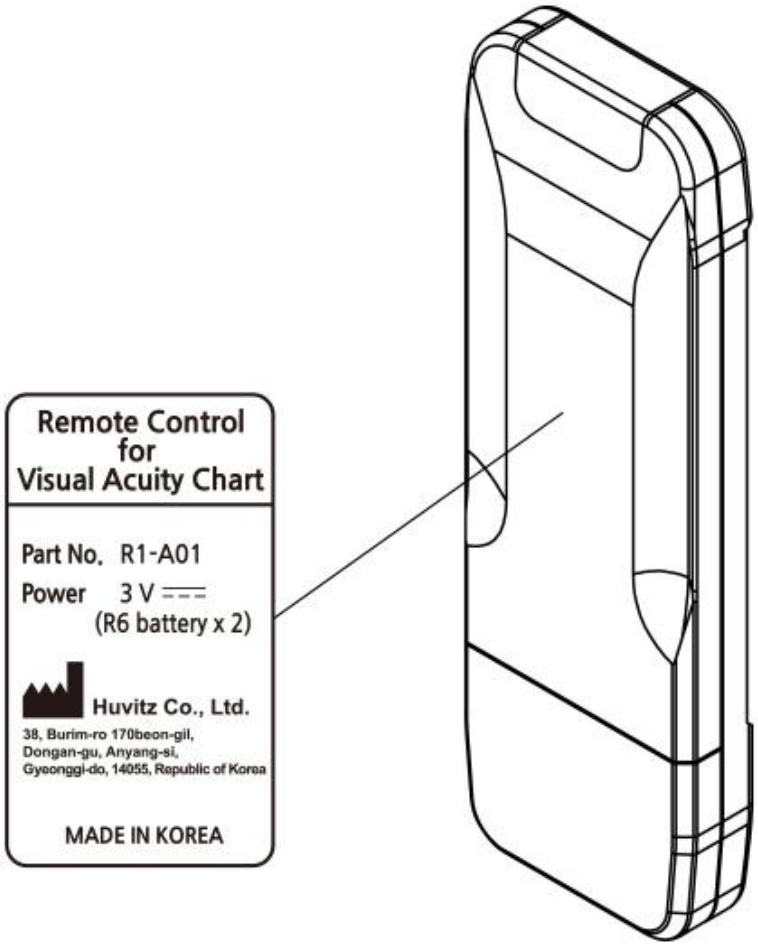
To call attention to operators, some labels and indications are provided on the device. If labels are curling up or characters are fading and becoming barely legible, contact manufacturer or authorized local distributor.

| Symbols | Description | Reference |
|---|---|---|
|  | Operating instructions | ISO 7000:2019-1641 |
|  | Caution | ISO 7000:2019-0434A |
|  | General prohibition sign and template for constructing a prohibition sign | ISO 7010:2019-P001 |
|  | Direct current | IEC 60417:2025-5031 |
|  | Alternating current | IEC 60417:2025-5032 |
|  | Refer to instruction manual/ booklet | ISO 7010:2019-M002 |
|  | Date of manufacture | ISO 7000:2019-2497 |
|  | Manufacturer | ISO 7000:2019-3082 |
|  | Serial number | ISO 7000:2019-2498 |
|  | Keep away from rain | ISO 7000:2019-0626 |
|  | Use no hook | ISO 7000:2019-0622 |
|  | Temperature limit | ISO 7000:2019-0632 |
|  | Humidity limitation | ISO 7000:2019-2620 |
|  | Atmospheric pressure limitation | ISO 7000:2019-2621 |
|  | Waste electrical and electronic equipment | Directive 2012/19/EU<br>ANNEX IX |

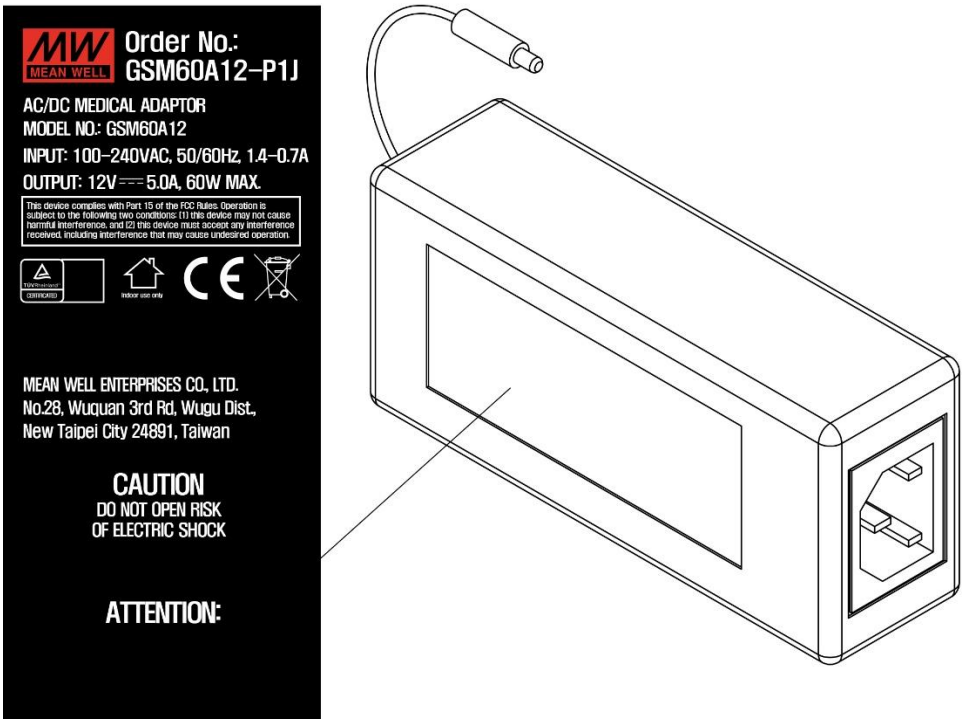
## 6.1 Main body


Huvitz Visual Acuity Chart System
HDC-100
Input: 12Vdc, 5A
Power AC/DC Adapter : Use only with adapter noted in the instruction Manual
SN
MD
CE
Huvitz Co., Ltd.
38, Burim-ro 170beon-gil, Dongan-gu, Anyang-si,
Gyeonggi-do,14055, Republic of Korea
MADE IN KOREA

## 6.2 Remote-control



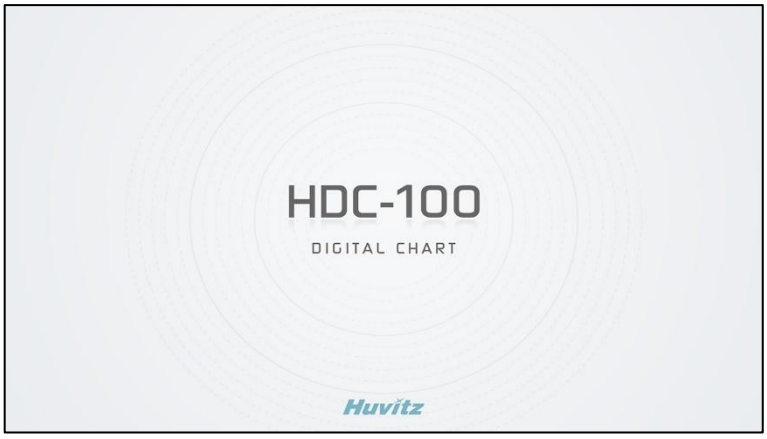
## 6.3 Power supply - Adapter



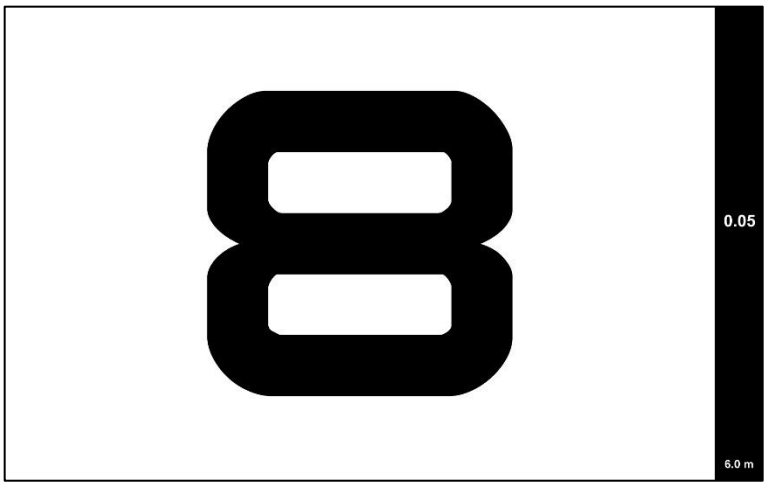
# 7 Preparation

## 7.1 Booting

(1) When you plug power cord in socket outlet, the booting is carried out with showing following image on the screen.



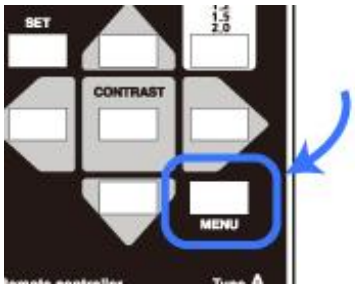

(2) After few seconds, visual acuity chart system displays on the screen as follow.

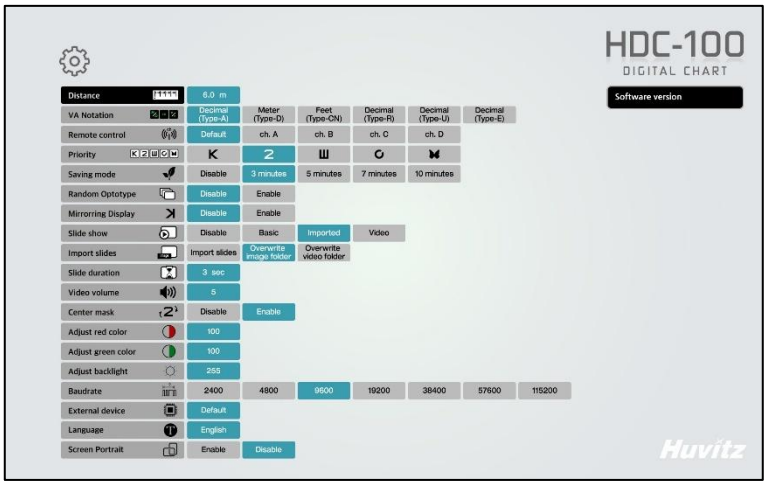



| | |
|---|---|
|  | Do not disconnect power source in the progress of booting. |

## 7.2 Preset function in MENU screen

(1) In order to enter the preset function, press MENU button on remote-control.




**How to navigate in MENU function.**




(2) **[Distance]** Selects test distance correctly according to the environment of refraction room. It is adjustable from 1.5 to 8 meters. ((4.75 to 26 ft)

| | |
|---|---|
| ⚠ | If test distance set improperly, the result may be inaccurate. |

(3) **[VA Notation]** Selects the type of VA Notation.

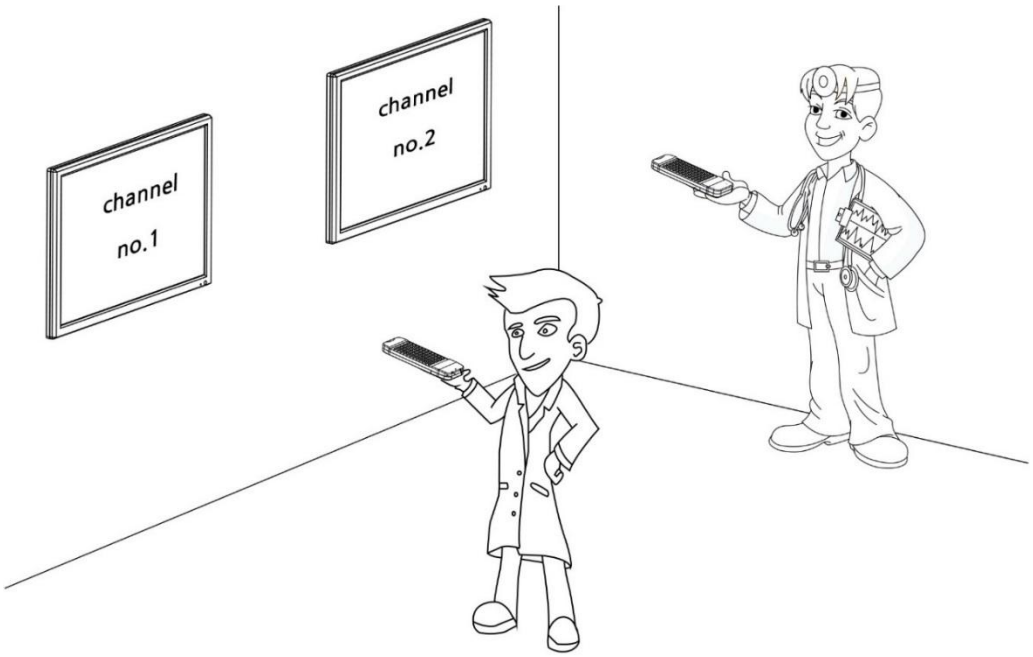
| **Type-A**<br>**Type-R**<br>**Type-U**<br>**Type-E** | **Type-D** | **Type-CN** |
|---|---|---|
| 0.03 | 6/200 | 20/600 |
| 0.05 | 6/120 | 20/400 |
| 0.08 | 6/75 | 20/250 |
| 0.1 | 6/60 | 20/200 |
| 0.16 | 6/45 | 20/150 |
| 0.2 | 6/30 | 20/100 |
| 0.3 | 6/24 | 20/80 |
| 0.4 | 6/21 | 20/70 |
| 0.5 | 6/18 | 20/60 |
| 0.6 | 6/15 | 20/50 |
| 0.7 | 6/12 | 20/40 |
| 0.8 | 6/9 | 20/30 |
| 0.9 | 6/7.5 | 20/25 |
| 1.0 | 6/6 | 20/20 |
| 1.2 | 6/6 | 20/20 |
| 1.5 | 6/4.5 | 20/15 |
| 2.0 | 6/3 | 20/10 |



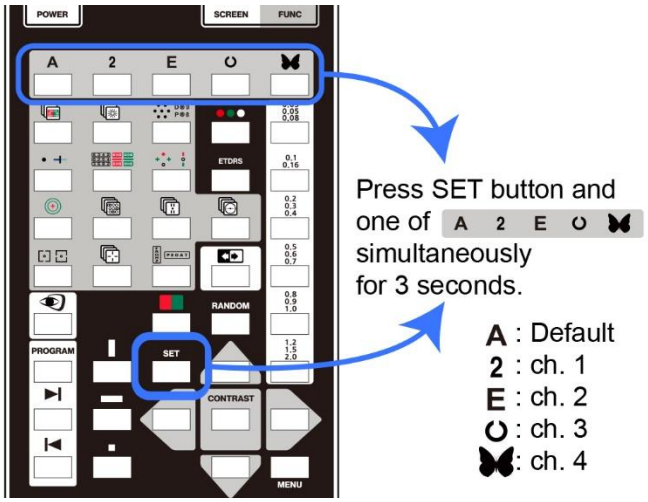
In correct configuration of type of VA Notation may result in erroneous test result.

(4) **[Remote-control]** Selects applicable the channel of remote-control.

This product can be used maximum four devices in the adjacent places without interference of remote-control's signals. If more than two devices are used in the room, it shall be selected.




**How to set the channel of remote-control.**




| | |
|---|---|
| ⚠ | Change the channel of MENU function in main body prior to change one of remote-control. |
| ⚠ | An invalid remote-control channel setting may affect other visual acuity chart systems located in the same room. |

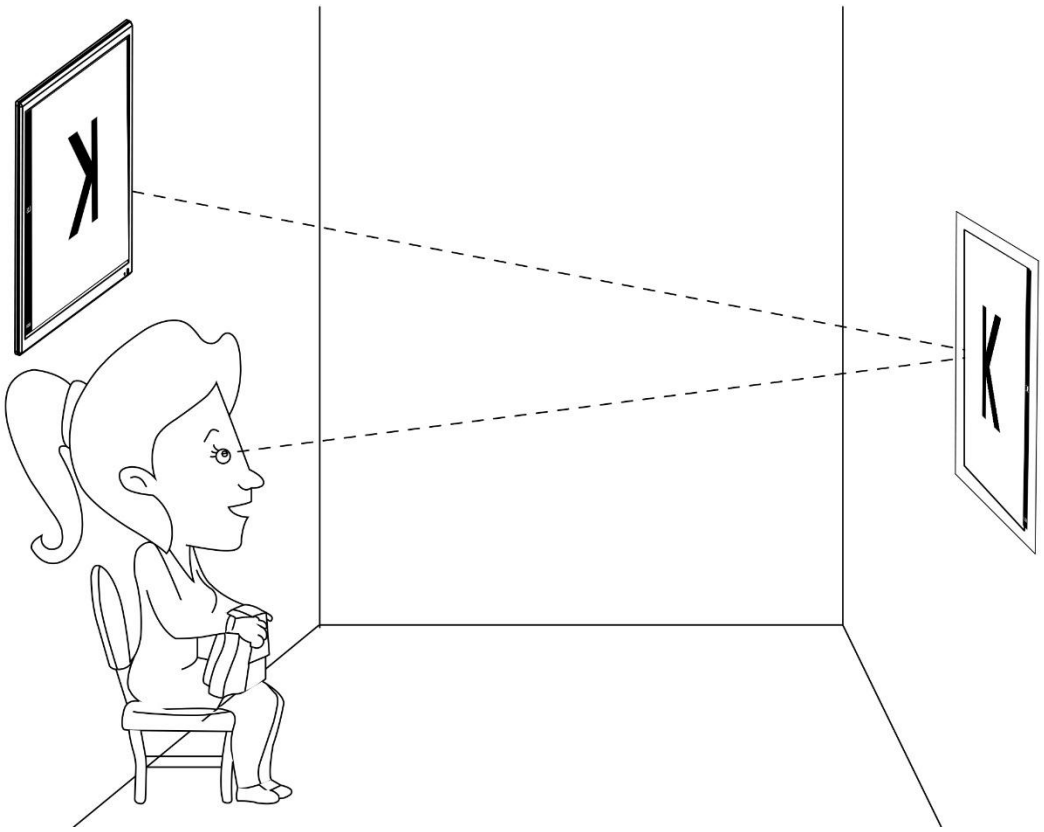
(5) **[Priority]** Selects a type of visual acuity chart to be shown firstly on the screen when the power on.

| Alphabet | Number | Tumbling E | Landolt ring | Pediatric |
|---|---|---|---|---|
| A | 2 | E |  |  |

(6) **[Saving mode]** Selects the duration for entering power saving function.

(7) **[Random Optotype]** Enables to display VA chart in random order, pressing the adjust the size of chart button.

(8) **[Mirroring Display]** In case of usage in the short distance less than 1.5 meters, the chart to be reflected on the mirror can be displayed on the screen.



| | |
|---|---|
| ⚠ | Incorrect configuration of mirror function may result in erroneous test result. |

(9) **[Slide show]** Select the images or videos to be shown on the screen in case of executing image slide function.

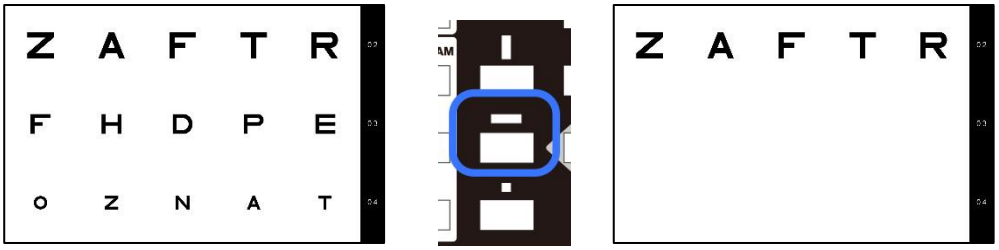
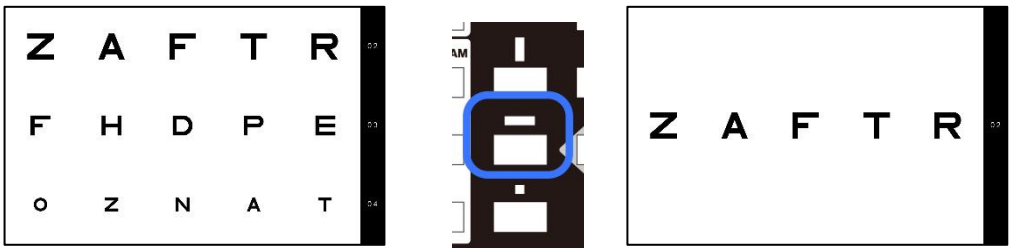
| | |
|---|---|
| **Disable** | Nothing to show |
| **Basic** | Display basic images stored in internal flash memory by manufacturer. |
| **Imported** | Display images stored in internal flash memory by operator. |
| **Video** | Display video stored in internal flash memory by operator. |

(10) **[Import slides]** Enables to import new image and video files from external USB Drive or to over-write all image or video files in the internal flash memory.

(11) **[Slide duration]** Selects a duration of slide function. It means that the delay time between image slides.

(12) **[Video volume]** Adjusts sound volume from 0 to 15 points.

(13) **[Center mask]** Select the position to display visual acuity chart on the screen in case of activating mask function.

| | |
|---|---|
| **Disable** |  |
| **Enable** |  |

(14) **[Adjust red color]** Adjust the brightness of red color for all charts.

| | |
|---|---|
| ⚠ | For more accurate test, adjust brightness value of red color corresponding with the condition of Red/Green glasses. |

(15) **[Adjust green color]** Adjust the brightness of green color for all charts.

| | |
|---|---|
| ⚠ | For more accurate test, adjust brightness value of green color corresponding with the condition of Red/Green glasses. |

(16) **[Adjust backlight]** Adjust the brightness of backlight on the screen.

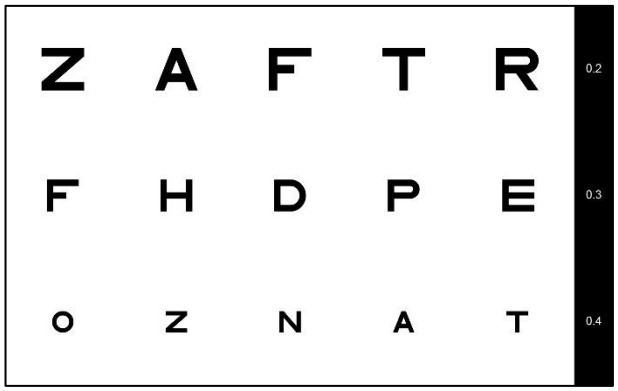
| | |
|---|---|
| ⚠ | For more accurate test, adjust brightness value harmoniously with surrounding environment. |

(17) **[Baudrate]** Select a baud-rate for serial communication with external device such as digital refractor, desktop and so on. For this, consult with manufacturer or authorized local distributor.

| | |
|---|---|
| ⚠ | If a baud-rate sets improperly, serial communication cannot work well. Consult with specialist for this part. |

(18) **[External device]** Select a device type using serial communication to connect with external device. For this, consult with manufacturer or authorized local distributor.

(19) **[Screen Portrait]** All information to be displayed on the screen is rotated through 90 degrees in order to use this instrument vertically.

| Disable | Enable |
|---|---|
|  |  |

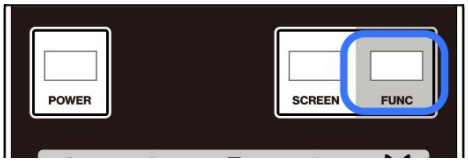


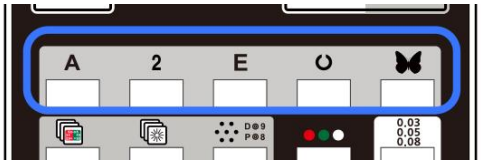
(20) After presetting all parameters, press SET button on remote-control. And then, press MENU button.

# 8 Operation

## 8.1 General visual acuity test

(1) In order to select a chart type to be used, press “OPTOTYPE” button or one of “Fast selection of chart” on the remote-control.



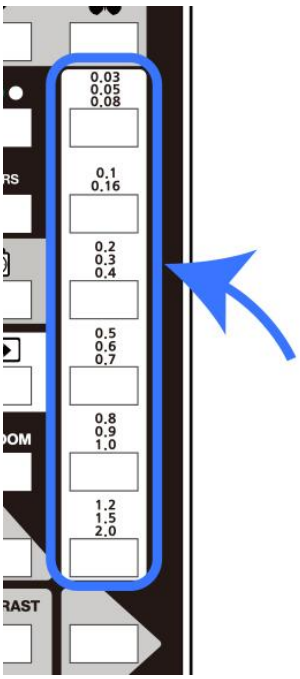

If “OPTOTYPE” button is pressed, a chart type is changed sequentially following order.

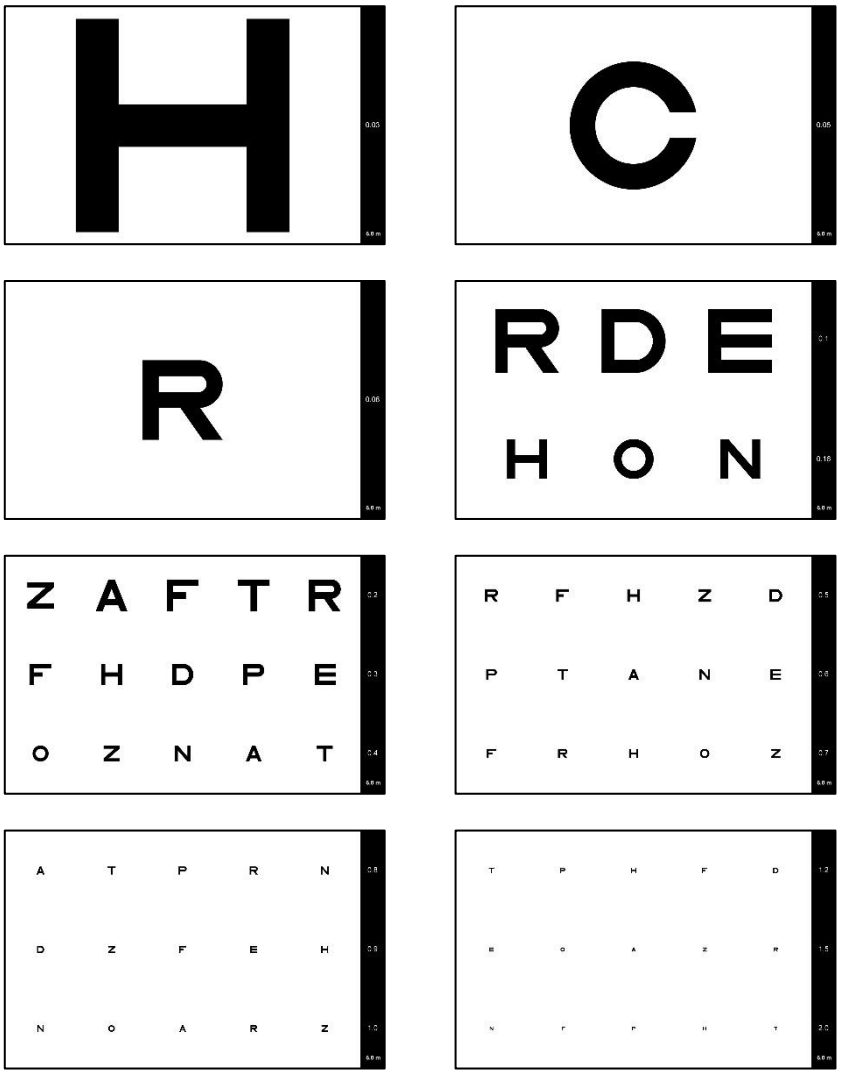
| A | 2 | E | O | | *User chart |
|---|---|---|---|---|---|
| Alphabet | Number | Tumbling E | Landolt ring | Pediatric | |

*** User chart**

This device can have a specialized chart made by operator or other specialists. For this, consult with manufacturer or authorized local distributor.

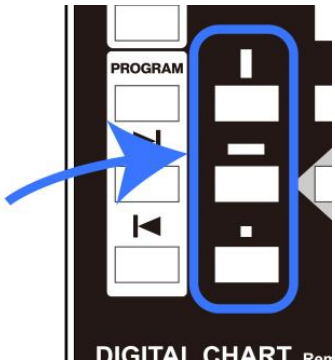
(2) Press “Adjusting the size of chart” button to change desired size.



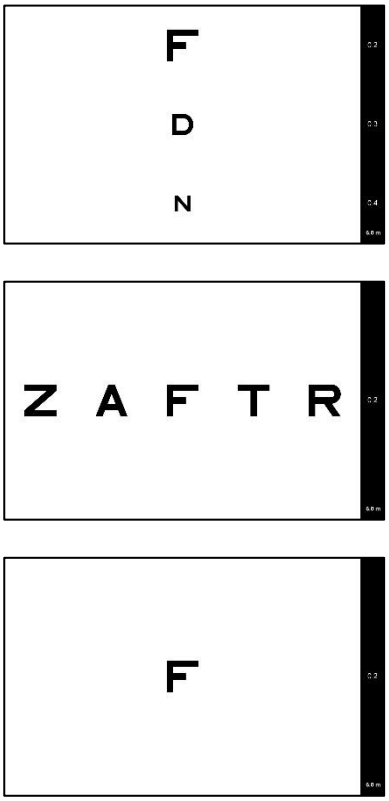



(3) As needed, mask function enables to do comfortable testing visually for patient.

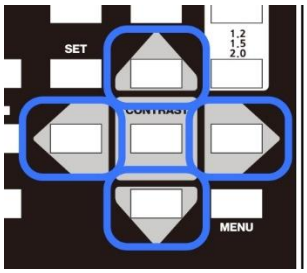
Press one of “Mask selection” buttons on the remote-control.





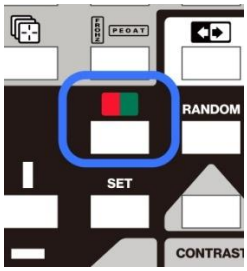

**How to use mask function**

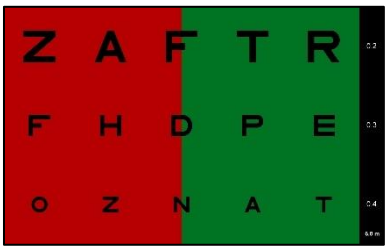



◀ or ▶ Move left or right

▲ or ▼ Move up or down

(3) As needed, red/green mask function can put behind Visual Acuity chart as background.



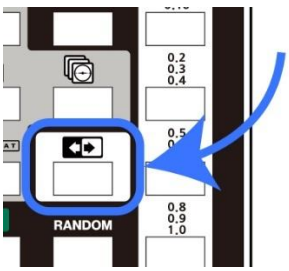

(4) As needed, random chart can be displayed on the screen by pressing “Random chart” button.

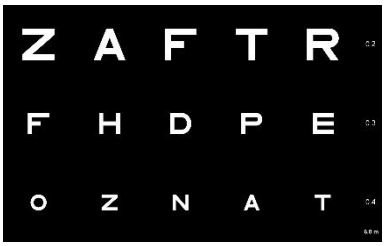
**What is RANDOM Chart?**

Randomly rearranges letter order at the same VA. This prevents erroneous test result from the patient memorizing the charts.

**Tips!**

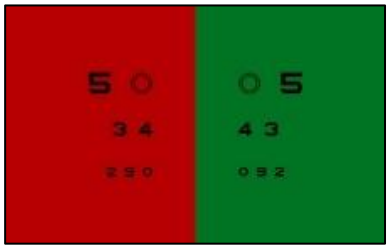
By pressing “Screen reverse function” button on the remote-control, the color between charts and background is changed. Make the best use of this function according to refraction environment.

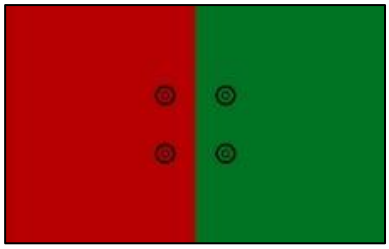


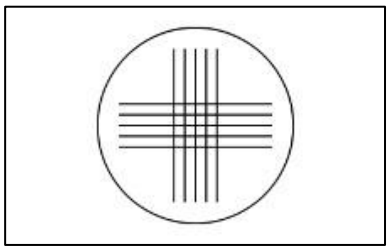



## 8.2 Duo-chrome test



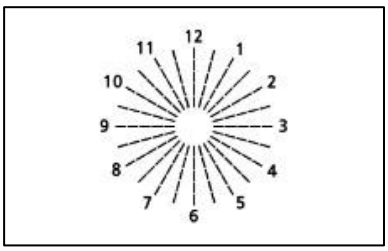




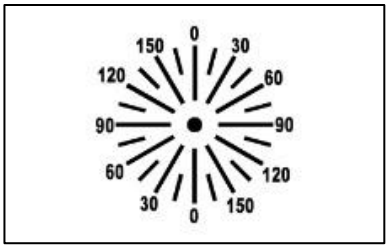


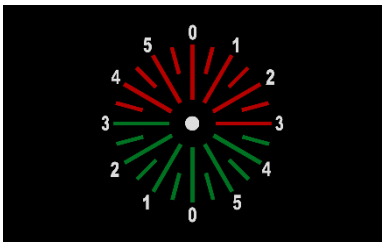
## 8.3 Astigmatic test

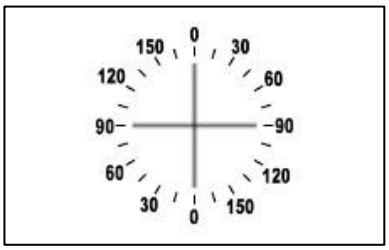


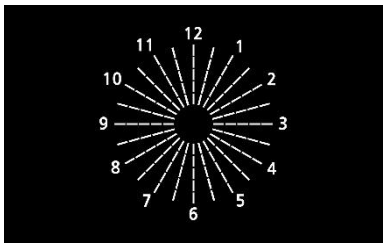




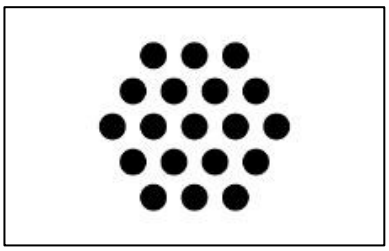



| | |
|---|---|
| **Tips!** | By pressing “Screen reverse function” button on the remote-control, the color between charts and background is changed. Make the best use of this function according to refraction environment.     |

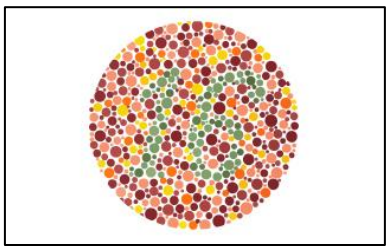
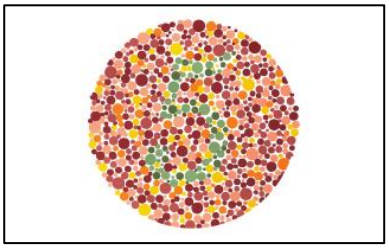
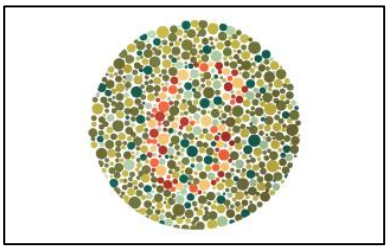
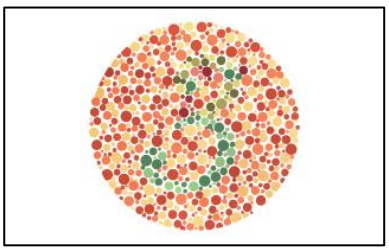
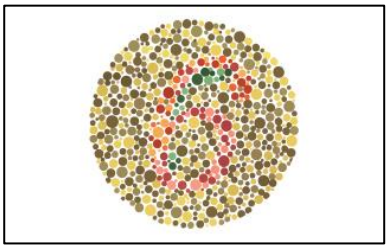
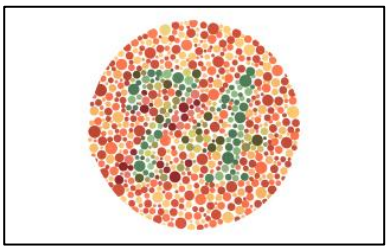
## 8.4 Cross-cylinder test

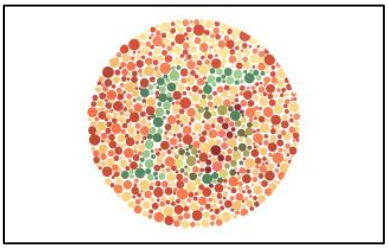
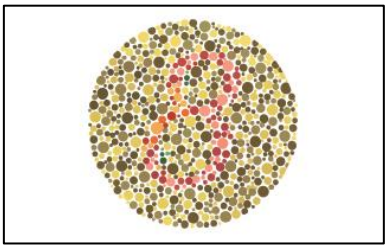
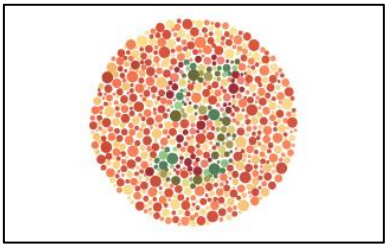
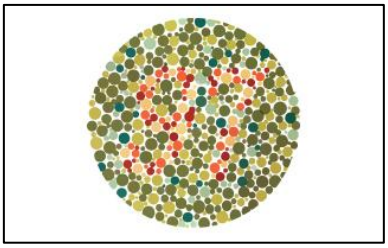
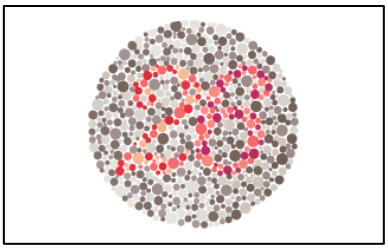
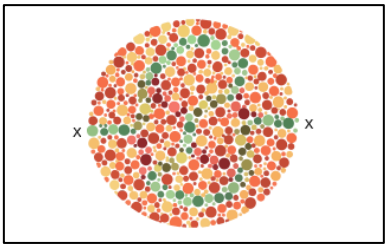


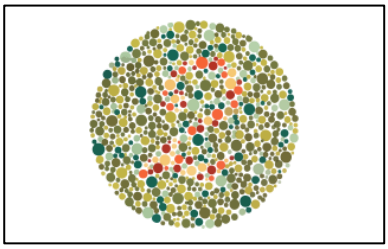
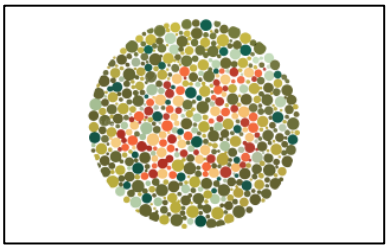
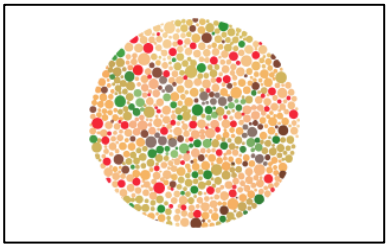
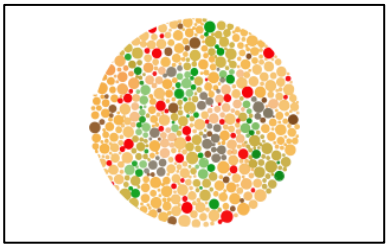
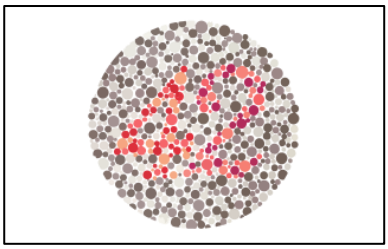
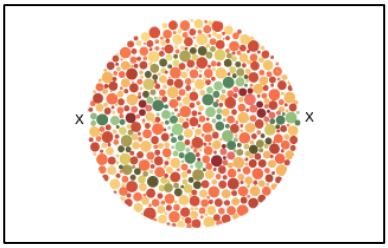



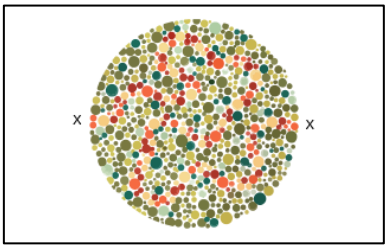
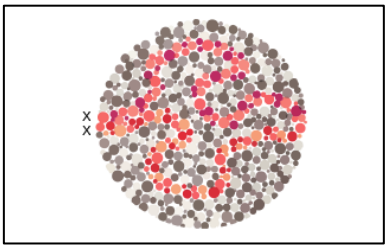
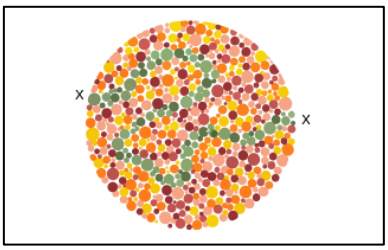
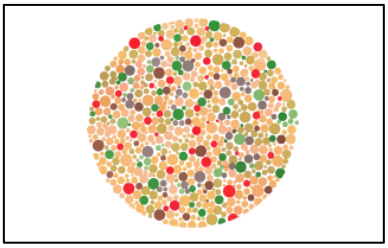
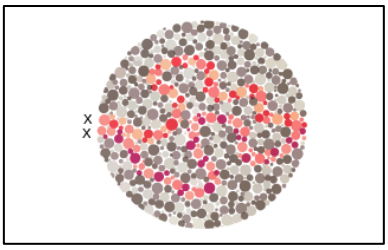
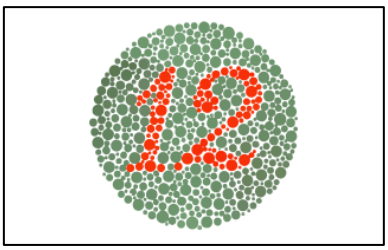


## 8.5 Color blindness test

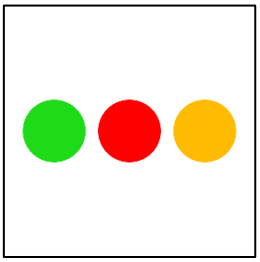
| | | |
|---|---|---|
| |  | Normal: 16<br>R/G deficiencies: unreadable |
| |  | Normal: 5<br>R/G deficiencies: unreadable |
|  |  | Normal: 6<br>R/G deficiencies: 5 |
| |  | Normal: 3<br>R/G deficiencies: 5 |
| |  | Normal: 6<br>R/G deficiencies: unreadable |
| |  | Normal: 74<br>R/G deficiencies: 21 |

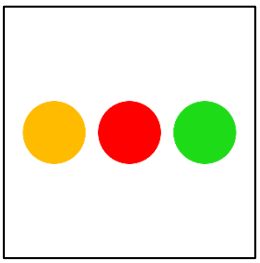
| | | |
|---|---|---|
| |  | Normal: 15<br>R/G deficiencies: 17 |
| |  | Normal: 8<br>R/G deficiencies: 3 |
| |  | Normal: 5<br>R/G deficiencies: 2 |
| |  | Normal: 97<br>R/G deficiencies: unreadable |
| |  | Normal: 26<br>Protanopia: 6<br>Protanomaly: 6 or 2<br>Deuteranopia: 2<br>Deuteranomaly: 2 or 6 |
| |  | Normal: following green line<br>R/G deficiencies: unrecognized |

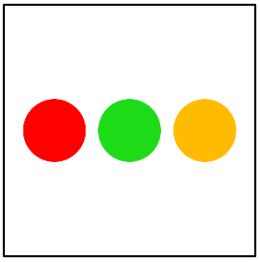
| | | |
|---|---|---|
| |  | Normal: 2<br>R/G deficiencies: unreadable |
| |  | Normal: 45<br>R/G deficiencies: unreadable |
| |  | Normal: unreadable<br>R/G deficiencies: any number |
| |  | Normal: unreadable<br>R/G deficiencies: following green and purple lines |
| |  | Normal: 42<br>Protanopia: 2<br>Protanomaly: 2 or 4<br>Deuteranopia: 4<br>Deuteranomaly: 4 or 2 |
| |  | Normal: following green line<br>R/G deficiencies: following green and purple lines |

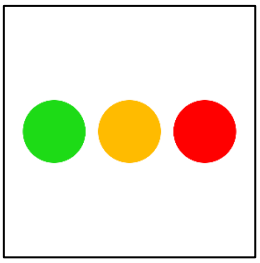
| | | |
|---|---|---|
| |  | Normal: unrecognized<br>R/G deficiencies: following line |
| |  | Normal: following purple and red lines<br>Protanopia: following purple line only<br>Protanomaly: following purple line only<br>Deuteranopia: following red line only<br>Deuteranomaly: following red line only |
| |  | Normal: following green line<br>R/G deficiencies: unrecognized |
| |  | Normal: unrecognized<br>R/G deficiencies: following line |
| |  | Normal: following purple and red lines<br>Protanopia: following purple line only<br>Protanomaly: following purple line only<br>Deuteranopia: following red line only<br>Deuteranomaly: following red line only |
| |  | Normal: 12<br>R/G deficiencies: 12 |





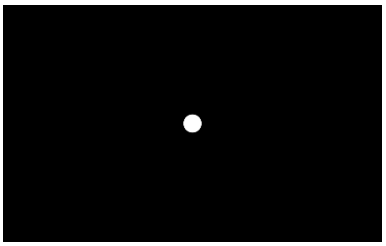


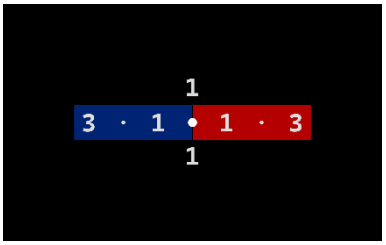




## 8.6 Maddox rod and Thorington test

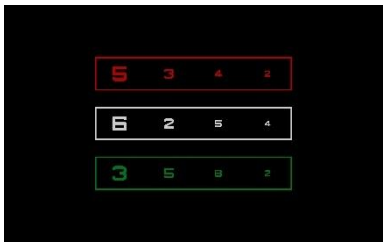


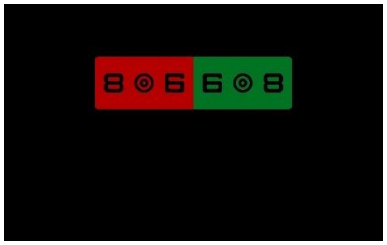




## 8.7 Binocular vision test

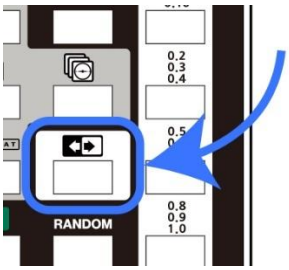


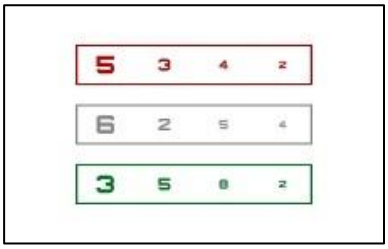


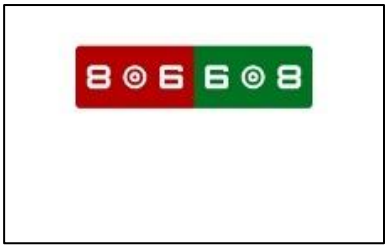


**Tips!**

By pressing “Screen reverse function” button on the remote-control, the color between charts and background is changed. Make the best use of this function according to refraction environment.

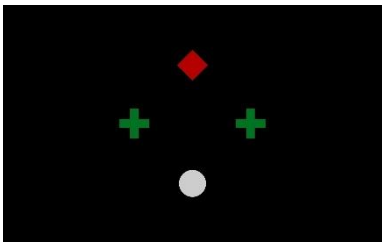


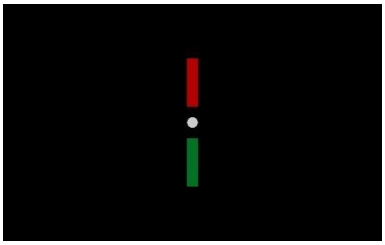





## 8.8 Worth-4-dots and dominant eye test

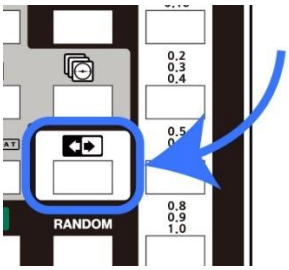


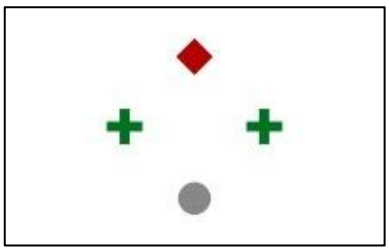


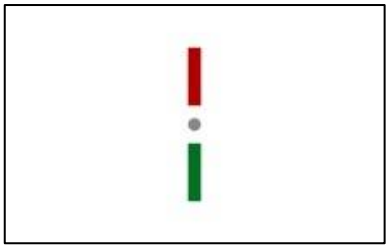


**Tips!**

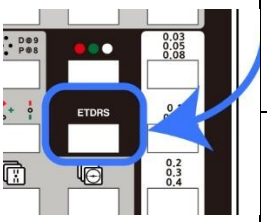
By pressing “Screen reverse function” button on the remote-control, the color between charts and background is changed. Make the best use of this function according to refraction environment.



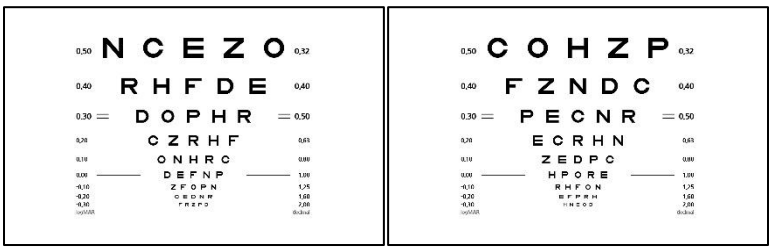


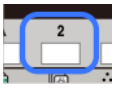
## 8.9 ETDRS

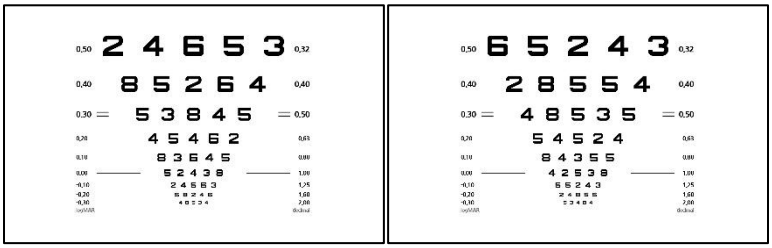






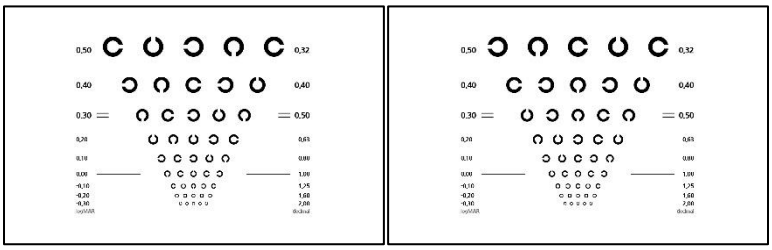


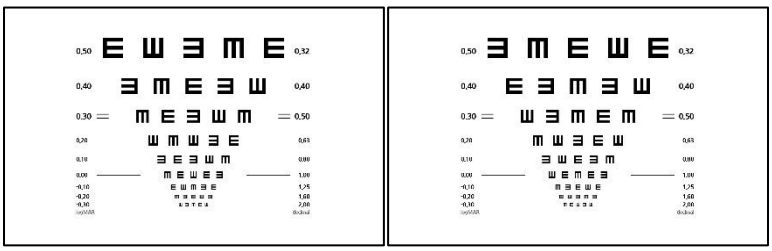












After pressing the ETDRS button, press the corresponding optotype button to display an ETDRS chart composed of the selected type of optotype. If you press a specific optotype button repeatedly, different ETDRS charts consisting of the same type of optotype will be displayed sequentially on the screen.

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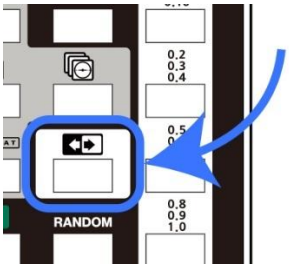
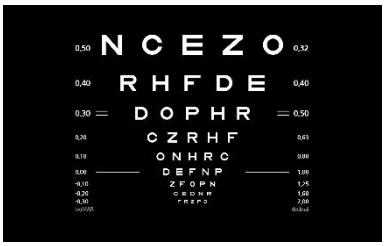
| **Tips!** | By pressing “Screen reverse function” button on the remote-control, the color between charts and background is changed. Make the best use of this function according to refraction environment.<br><br> |

## 8.10 Schober test

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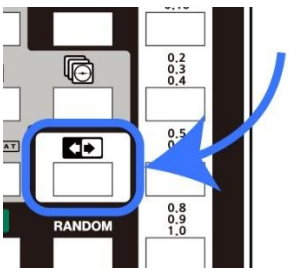
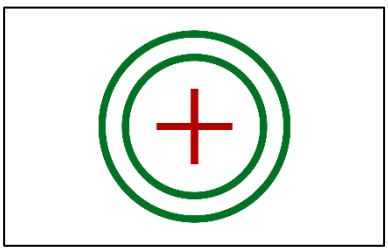
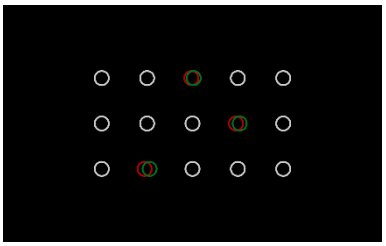
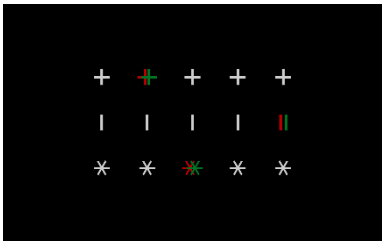
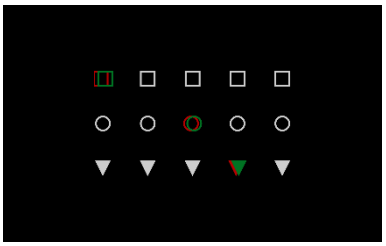
| **Tips!** | By pressing “Screen reverse function” button on the remote-control, the color between charts and background is changed. Make the best use of this function according to refraction environment.<br><br> |

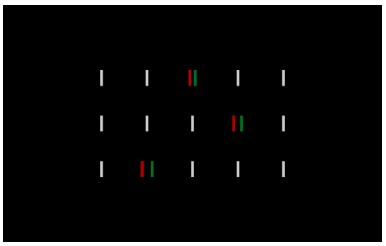
## 8.11 Minutes stereo test

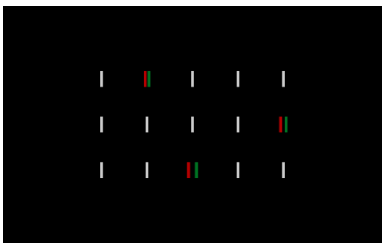


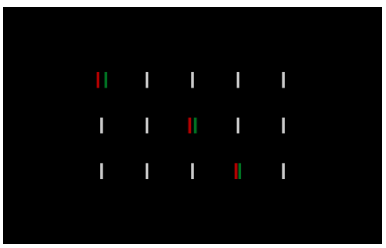












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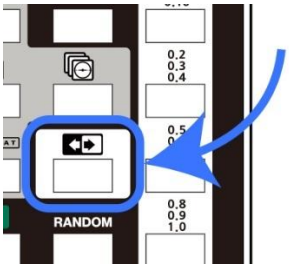
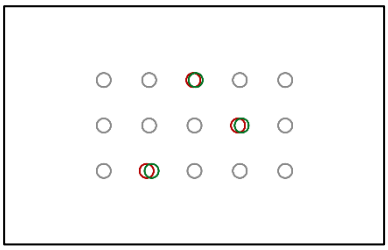
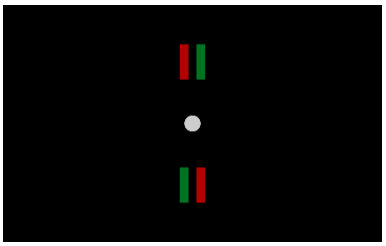
|---|---|
| **Tips!** | By pressing “Screen reverse function” button on the remote-control, the color between charts and background is changed. Make the best use of this function according to refraction environment. |

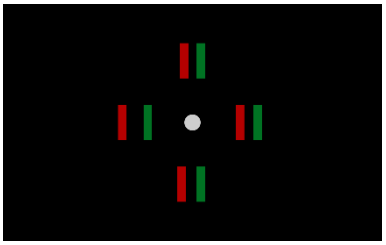


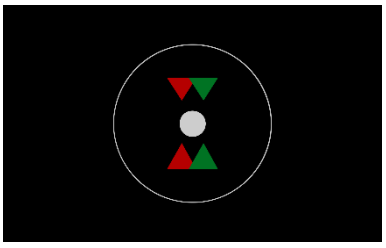



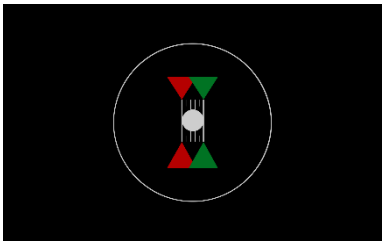
## 8.12 Stereo test

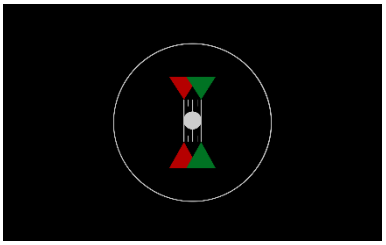




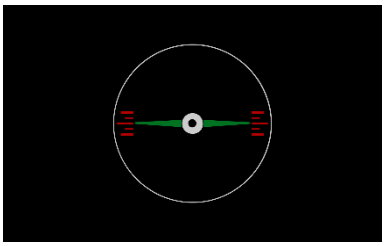












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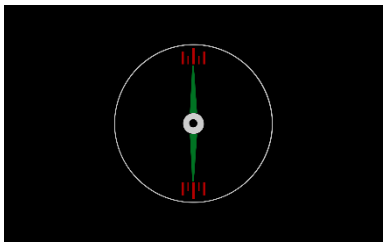
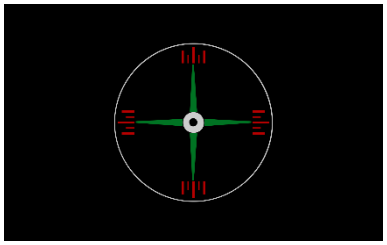
| |  |
| |  |

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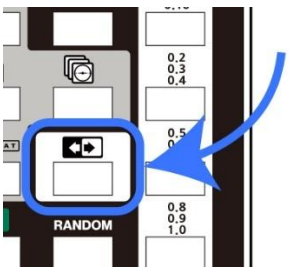
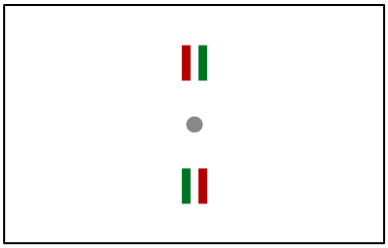
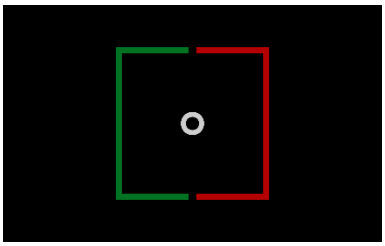
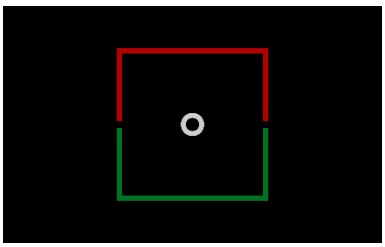
|---|---|
| **Tips!** | By pressing “Screen reverse function” button on the remote-control, the color between charts and background is changed. Make the best use of this function according to refraction environment.    |

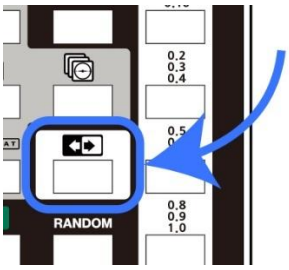
## 8.13 Coincidence test

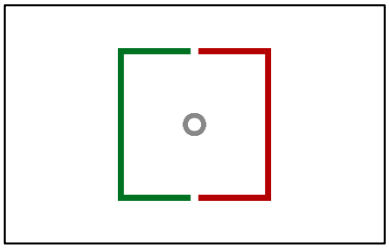






| | |
|---|---|
| **Tips!** | By pressing “Screen reverse function” button on the remote-control, the color between charts and background is changed. Make the best use of this function according to refraction environment. |

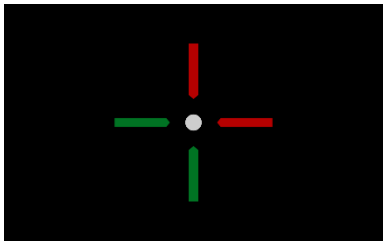


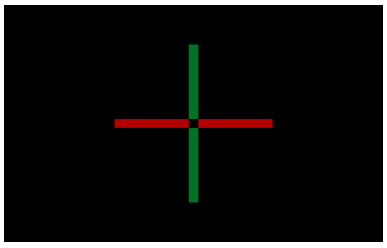



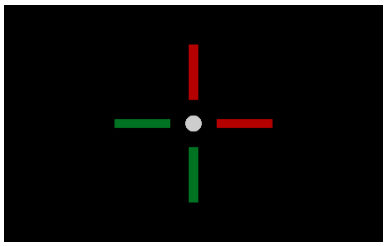
## 8.14 Phoria test



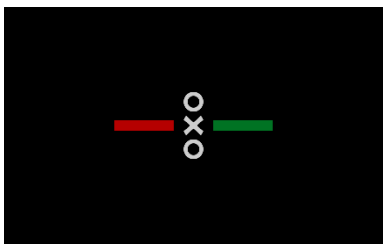












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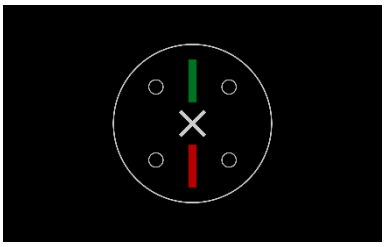
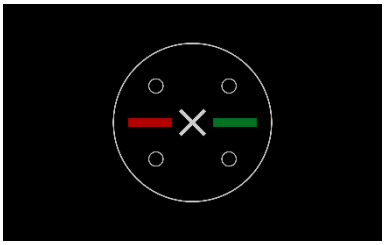
| |  |
| |  |

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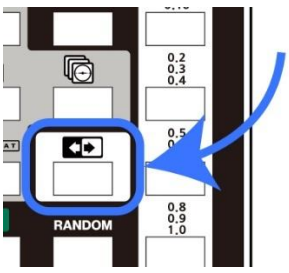
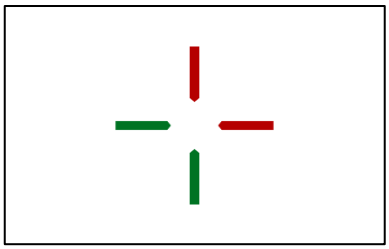
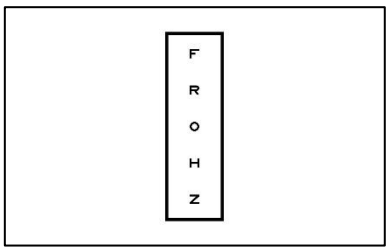
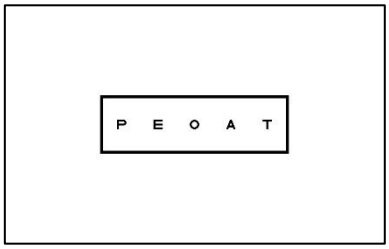
|---|---|
| **Tips!** | By pressing “Screen reverse function” button on the remote-control, the color between charts and background is changed. Make the best use of this function according to refraction environment.    |

## 8.15 Von Graefe test

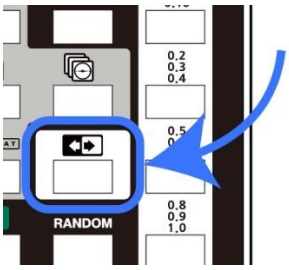



**Tips!**

By pressing “Screen reverse function” button on the remote-control, the color between charts and background is changed. Make the best use of this function according to refraction environment.



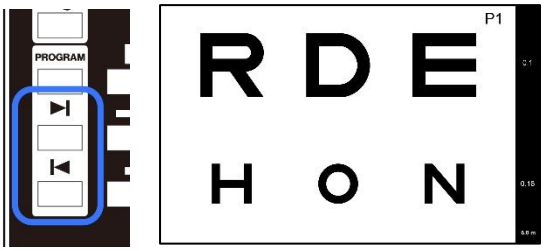



# 9 Program function

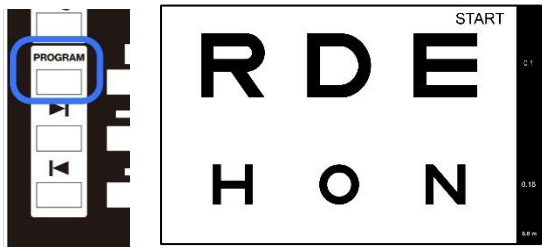
## 9.1 Set

(1) Press ▶| button on the remote-control. Program number (from P1 to P5) will be displayed on the top of screen.

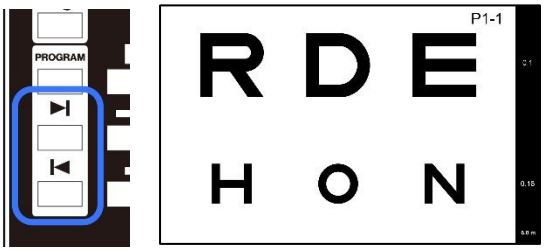
By pressing |◀ or ▶| button, choose program number.



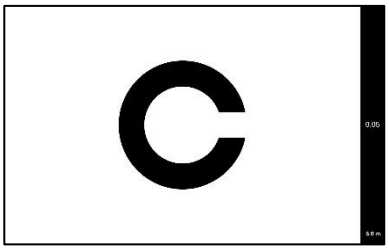

(2) Press PROGRAM button. “START” message will be displayed on the top of screen.



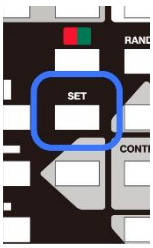

(3) Press |◀ or ▶| button. Chart number will be displayed on the top of screen. By pressing |◀ or ▶| button, choose chart number.

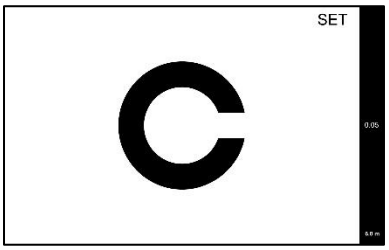



(4) Using the remote-control, display any chart to be stored by program.

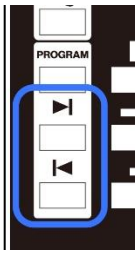


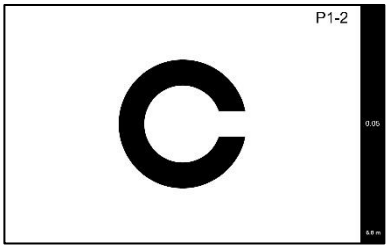
(5) Press SET button to store into program.



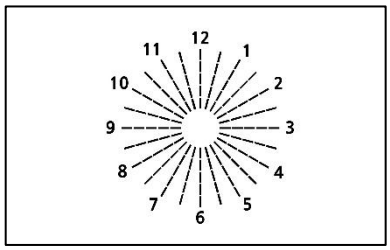




(6) Press ▶| button to change the chart number.

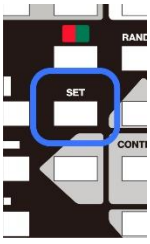


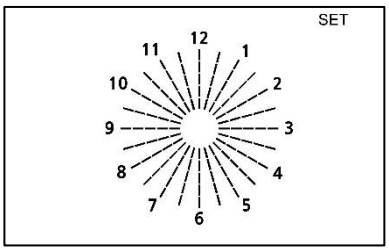




(7) Using the remote-control, display any chart to be stored by program.




(8) Press SET button to store into program.



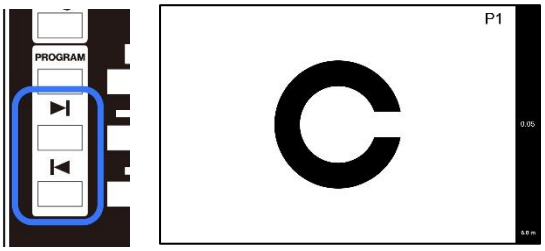




(9) Carry out the process as above description from (5) to (7) repeatedly until chart number 10.

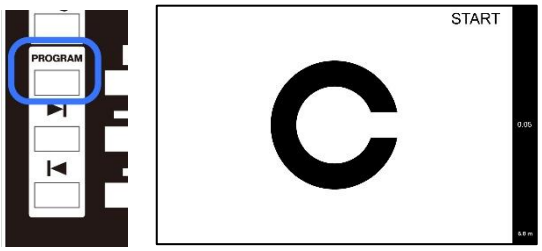
(10) Press PROGRAM button to escape.

## 9.2 Use

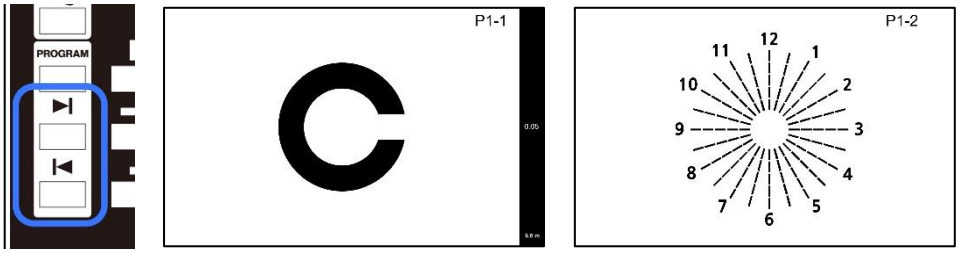
(1) Press ▶| button on the remote-control. Program number (from P1 to P5) will be displayed on the top of screen. By pressing |◀ or ▶| button, choose program number.




(2) Press PROGRAM button. “START” message will be displayed on the top of screen.



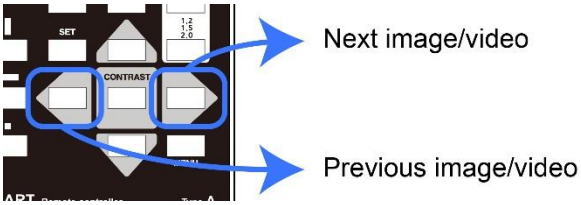

(3) Press |◀ or ▶| button. Chart number will be displayed on the top of screen. By pressing |◀ or ▶| button, choose chart number.




(4) If |◀ or ▶| button is pressed, charts stored in program are displayed sequentially with chart number on the screen.

# 10 Slide function

(1) Press “Image slide function” button on the remote-control. By pressing “Direction movement” buttons, images can be changed and displayed on the screen.




(2) If “Image slide function” button is pressed again, other type of slide image or video will be displayed on the screen.

| Basic | Imported image | Imported video |
|---|---|---|
| Display basic images stored in internal flash memory by manufacturer. | Display images stored in internal flash memory by operator. | Play videos stored in internal flash memory by operator. |

| | |
|---|---|
| ⚠ | Some of images cannot be displayed due to not-supported image format. |
| ⚠ | Some of videos cannot be played due to not-supported video format. |
| ⚠ | For detailed function of slide, consult with manufacturer or authorized local distributor. |

# 11 Maintenance

## 11.1 Malfunction warnings

| | |
|---|---|
|  | If the screen shows abnormal flickering, distorted optotypes, or unexpected brightness changes, stop using the device immediately and restart the system. If the issue persists, contact service personnel. |
|  | If the device emits unusual smell, heat, or noise, turn off the power and unplug the unit. |
|  | If the remote control becomes completely unresponsive after battery replacement, do not continue the examination until the cause is identified. |
|  | If the displayed chart does not correspond to the remote-control image, discontinue operation until synchronization is restored. |
|  | Do not attempt to open, modify, or repair the device on your own. |

## 11.2 Troubleshooting

In the event that the device does not work correctly, please check the problem according to the following table before contact manufacturer or authorized local distributor.

| Event | Recommended action |
|---|---|
| The screen does not light up even though the power on. | Check that the power cord is connected to a socket outlet firmly. |
| The chart is displayed improperly on the screen. | Switch off the device. After 3 minutes, turn it on again. |
| The remote-control does not work. | Replace batteries in the remote-control. |
| The remote-control does not work even though batteries are replaced. | Set a channel of the remote-control. |
| The image on the remote-control does not match the display | Unplug the power cord, wait for 10 seconds, and then plug it in again. |

| | |
|---|---|
| screen. | |
| The chart is blurry. | Adjust the brightness of backlight properly. |
| The screen is unclear. | Clean the display surface with a soft, dry cloth. |

## 11.3 Environmental & external influence precautions

*- MDR 23.4 (s) compliance*

| | |
|---|---|
|  | Avoid using the device in environments with excessive electromagnetic fields (e.g., MRI rooms, high-powered radio equipment). |
|  | The device may be sensitive to electrostatic discharge (ESD). Avoid touching the IR sensor or screen after building up static electricity. |
|  | Operate the device only within the specified temperature and humidity ranges. |
|  | Avoid strong reflections or glare from external light sources. |

## 11.4 Contra-indications & limitations of use

- No absolute contraindications are known.

- Use with caution in:

  - individuals with photosensitive epilepsy

  - individuals who experience discomfort from bright digital displays

- The device is intended only for displaying visual acuity charts.

It is not intended for diagnosis, treatment, or physiological measurement.

## 11.5 Biological, radiation, and material safety

- This device contains no medicinal substances, no tissues or cells, and no biological materials.

- This device emits only visible light, not radiation requiring protective measures.

- No CMR substances, endocrine-disrupting materials, or sensitizing materials are present.

## 11.6 Safe disposal information

- This device contains no sharp components, biological materials, or potentially infectious parts.

- Dispose of the device and its accessories in accordance with local regulations for electrical and electronic equipment waste – WEEE.

- Do not dispose of the device as unsorted municipal waste

- No special biomedical waste precautions are required.

## 11.7 Cleaning

Do not touch the screen as much as possible because its surface is specially coated. If the screen becomes dirty, the chart may become difficult to read and see. In such an occurrence, clean the panel.

| | |
|---|---|
|  | Turn the power off and unplug the power cord from a socket outlet before cleaning. |
|  | Wiping with tissue paper by damage the screen seriously. |
|  | In case of cleaning, excessive force or loading may result in failure. |
|  | Do not leave water drops on the device. If the device is splashed with water, immediately wipe with absorbent cotton or a soft cloth. |
|  | Never use an organic solvent such as paint thinner. |

(1) Turn the power off.

(2) Unplug the power cord from a socket outlet.

(3) Lightly wipe the screen with a soft and clean cloth or absorbent cotton.

## 11.8 Minimum hardware, network, and IT security requirements

This device incorporates an electronic programmable system and embedded software. To ensure proper operation and maintain the intended performance of the device, the following minimum requirements and IT security measures shall be observed:

### 11.8.1 Hardware requirements

- Use only the hardware supplied or approved by the manufacturer.
- Do not modify or replace internal components, firmware, or the operating system.
- Ensure stable power supply (100-240 Vac, 50/60 Hz) and avoid the use of unregulated power adapters.

### 11.8.2 IT Network requirements

- The device is designed for stand-alone operation and does not require network connectivity for normal clinical use.
- When network access is used (e.g., software update, service diagnostics), the network must comply with standard clinical IT infrastructure requirements:
    - Use of secured networks (e.g., WPA2/WPA3)
    - Restriction of unauthorized devices and public networks
    - Controlled access by authorized persons only

### 11.8.3 IT security measures

- The device must be protected against unauthorized access, modification, or installation of unverified software.
- Only manufacturer-approved software updates shall be installed.
- Do not connect the device to unsecured network environments.
- Access to system settings should be limited to authorized personnel.
- Maintain physical security to prevent tampering.

# 12 Transport and storage conditions

| | |
|---|---|
| **Temperature** | -10 °C to +40 °C |
| **Relative Humidity** | 10 % to 90 % (non-condensing) |
| **Atmospheric pressure** | 80 kPa to 106 kPa |

When storing the product, ensure that the following conditions:

- It shall not be splashed with water.

- Store the product away from environments where air pressure, temperature, humidity ventilation sunlight, dust, salty/sulfurous air, etc. could cause damage.

- Do not store or transport the instrument on a slanted or uneven surface or in an area where it is subject to vibrations or instability.

- Do not store the instrument where chemicals are stored or gas is generated.

| | |
|---|---|
|  | Do not store or use in place with the following conditions:<br>- harmful gases or polluted air;<br>- blowing dust or sand;<br>- easy exposure to oil residue or fuel elements;<br>- atmosphere that has above standard levels of salt;<br>- prone to dust collecting;<br>- floor surface with a slope greater than 10°;<br>- voltage from wall sockets is changing severely;<br>- exposure to direct sunlight. |

# 13 Detailed specifications

## 13.1 General

| | |
|---|---|
| **Display** | 24inch WUXGA TFT LCD (1920 x 1200 pixels) |
| **Active display area** | (W)518.4 x (H)324.0 mm<br>(W)20.4 x (H)12.8 inches |
| **Brightness** | Maximum 300cd/$m^2$ |
| **Measuring distance** | 1.5 - 8.0m (0.1m step)<br>4.75 – 26 feet (0.25 feet step) |
| **CPU** | Amlogic S905 SoC 4 x ARM Cortex-A53 1.5GHz<br>64bit ARMv8 Architecture @28nm |
| **GPU** | 3 x ARM Mali-450 MP 700MHz |
| **Memory** | SD Memory 32GB 90MB/s |
| **Operating system** | Google's Android Embedded system |
| **Power supply** | AC 100-240V, 50/60Hz, 50VA |
| **Control** | Infrared remote-control or serial communication |
| **Multi-control channel** | Max 4 channels |
| **External interface** | 4x USB, 1x RS-232, 1x Ethernet (10/100) |
| **Standard Accessory** | Wall mount bracket |
| **Dimension & weight** | (W)21 x (H)14 x (D) 1.6 inch / (W)534 x (H)361 x (D)41mm<br>Approximately 8.8 lbs (4 kg) |

## 13.2 Display pixel defect acceptance criteria

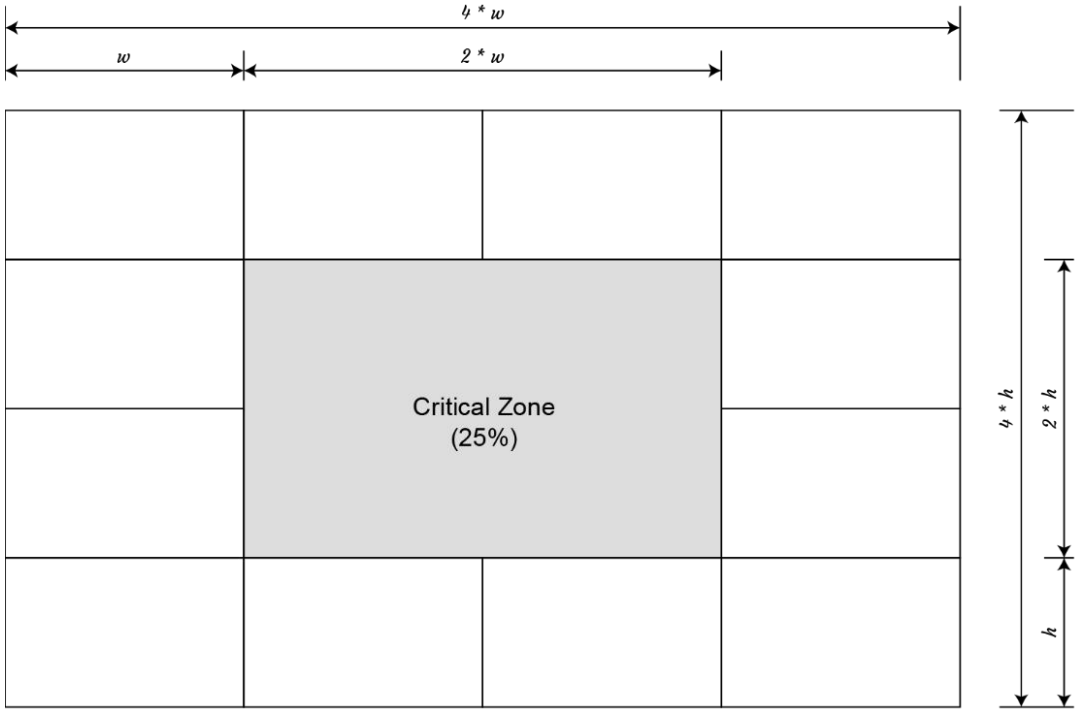
This device uses a high-resolution LCD display to present optotypes. To ensure consistent clinical performance, the display panel must meet the following pixel defect acceptance criteria at the time of shipment and during field service evaluation.

The criteria are defined based on:

- ISO 9241-307:2008 (Visual display requirements) – reference standard
- ISO 14971:2019 (Risk management – clinical impact evaluation)
- Manufacturer’s internal specification TSC-DMR-001
- MDR Annex I (GSPR 1, 5, 9, 10 – safety & performance)

### 13.2.1 Definitions

- Pixel: The smallest addressable element on the display, consisting of red, green and blue sub-pixels.
- Sub-pixel: A single color component within a pixel.
- Bright pixel defect: A pixel that remains permanently “on” (visible as a bright dot on a dark background).
- Dark pixel defect: A pixel that remains permanently “off” (visible as a dark dot on a bright background).
- Sub-pixel defect: Only one sub-pixel is stuck on/off while others operate normally.
- Cluster defect: Two or more defective pixels/sub-pixels adjacent in any direction.
- Critical (central) area: The central 25% of the active display area, defined by a 4 × 4 grid.
- Defects in this region are not allowed due to potential impact on visual acuity scoring.




[Critical zone of active display area]

### 13.2.2 Acceptance criteria

The display shall meet the following defect limits:

| No. | Type of defect | Acceptance criteria (per panel) |
|---|---|---|
| 1 | Bright pixel defects | ≤ 1 |
| 2 | Dark pixel defects | ≤ 2 |
| 3 | Sub-pixel defects (isolated) | ≤ 3 |
| 4 | Cluster defects (any type) | Not allowed |
| 5 | Any defect in the central 25% area | Not allowed |
| 6 | Total number of pixel-related defects | ≤ 3 (sum of items 1-3) |

Any display exceeding these limits is not accepted for delivery or field use.

### 13.2.3 Test Conditions

a) Test patterns:

- Full white / full black / full red / full green / full blue / checkerboard.

b) Viewing conditions:

- Ambient illumination: approx. 100 – 300 lux

- Viewing distance: 50 – 70 cm

- Viewing angle: perpendicular to screen center

c) Method:

- Visual inspection by trained personnel in accordance with manufacturer specification TSC-DMR-001.

**13.2.4 Rationale for criteria**

- The central region of the display is used for optotype presentation; defects in this zone may interfere with accurate visual acuity scoring.

- The allowed defect quantity outside the central area is clinically insignificant and validated through risk management.

- Criteria are stricter than general consumer-grade displays (ISO 9241-307), ensuring compliance with:

| |
|---|
| MDR Annex I GSPR 1 (safety & performance) |
| GSPR 5 & 9 (risk reduction as far as possible) |
| GSPR 10 (protection from physical hazards) |

**13.2.5 Field service / Post-Market handling**

- Customer complaints regarding visual artifacts are evaluated using the same criteria.

- Units exceeding the acceptance limits shall be repaired or replaced per the manufacturer’s PMS and vigilance procedures.

# 14 Regulatory and compliance information

| Category | Applicable standard / regulation | Scope | Test / Certification Reference | Status |
|---|---|---|---|---|
| Safety | IEC 60601-1:2005 +A1:2012 +A2:2020 | Medical electrical equipment – General requirements for basic safety and essential performance | Test Report No. M25WD-033 | Compliant (Pass) |
| | | | | |
| EMC | IEC 60601-1-2:2014 +A1:2020 | Electromagnetic compatibility (emissions / immunity) | Test Report No. SB25-G3074-EM2775 | Compliant (Pass) |
| Usability engineering | IEC 62366-1:2015 +A1:2020 | Usability engineering process | Usability Engineering File TSC-UE-001 | Compliant |
| Software validation | IEC 62304:2006 +A1:2015 (Class A) | Medical device software life cycle processes | Software Validation Report TSC-SVVP-001 | Compliant |
| Risk management | ISO 14971:2019 | Risk management for medical devices | Risk Management File TSC-RMF-001 | Compliant |
| Ophthalmic instruments | ISO 15004-1:2006 | Fundamental requirements and test methods for ophthalmic instruments | Test Report No. M25WD-033 | Compliant |
| Quality Management system | ISO 13485:2016 | Quality management systems for medical devices | QMS Certificate No. 25-b-1983 Rev.0 | Certified |
| EU regulation | [MDR] Regulation (EU) | Class I medical device | Declaration of Conformity | CE Marking |

| | | | | |
|---|---|---|---|---|
| | 2017/745 | | | |
| Korean regulation | Medical Device Act | Medical device approval | Registry No. 15-407 | Approved |
| Environmental directives | [WEEE] Directive 2012/19/EU | Waste electrical and electronic equipment | WEEE Symbol applied | Compliant |
| | [ROHS] Directive 2011/65/EU | Restriction of hazardous substances | Material Declaration | Compliant |
| Power supply | IEC 60601-1, IEC 60601-1-11 | GSM60A12 (MEAN WELL) medical power adapter | TÜV Rheinland, CB Certificate | Compliant |