

Handheld Auto Refractometer

easyRef Pro, R2X, R3X

User Manual



Shenzhen CERTAINN Technology Co., Ltd

Please read the manual carefully before using the device

Handheld Auto Refractometer

User Manual

Revision Control Copyright

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| | | | | |

Preface

We appreciate your purchase of our product easyRef Pro, R2X and R3X Handheld Auto Refractometer. easyRef Pro, R2X and R3X Handheld Auto Refractometer mainly used for the preliminary measurement and screening of diopter, and compared with other Handheld Auto Refractometer, its biggest advantage is portability and unique inspection method.

This user manual is designed by Certainn and only applies to easyRef Pro, R2X and R3X Handheld Auto Refractometer. It may cause damage or inaccurate inspection results if it is used in an inappropriate way. This user manual is recommended to be used as reference material for operation and training. The user is supposed to be medical workers or technicians who have received professional training. In addition, the results of easyRef Pro, R2X and R3X Handheld Auto Refractometer are not the prescription for buying glasses, the final decision shall be made by optometrist or opticians.

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1. Important Representation

1.1 Important Representation

Before using, please read this manual carefully. And please pay more attention to the security guidance. Other uses of this instrument are illegal.

- Only be used and operated strictly according to this user manual.
- Only the person authorized by Certainn can maintain the instrument.
- Since we will constantly improve our production, Certainn reserves the right to change the technical specifications without the prior notice.
- The model number, manufacturing number, accession designation number, registered standard, manufacturing year are indicated on nameplate of the instrument.

❖ Please read the manual thoroughly before any operation.

❖ This manual is only applicable to easyRef Pro, R2X and R3X produced by our company.

❖ All the information related to operating easyRef Pro, R2X and R3X is in this manual, including operating procedures, safety precautions, specifications, etc.

❖ Before the operation, it is important to understand safety precautions and procedures. Please keep this manual properly just in case.

❖ The equipment can only be operated by professional personnel, and all operations must strictly follow the manual.

❖ The instrument can only be repaired by qualified service personnel authorized by Shenzhen CERTAINN Technology Co., Ltd.

❖ Due to the continuous improvement of our products, Shenzhen CERTAINN Technology Co., Ltd. will reserve the right to change the technical specifications without notice.

❖ The final interpretation of this manual belongs to the Shenzhen CERTAINN Technology Co., Ltd.

1.2 Symbol Description

1.2.1 Explanation of warning symbols on the instrument



Caution: consult accompanying documents.

Note: There are important operating and maintenance instructions found in the manual.



Type B Applied parts.



Medical device



Serial number



Batch number



Non-ionizing electromagnetic radiation



Class 1 laser product

Note: This label indicates that there is a laser nearby, please pay attention to safety



Class II equipment



Manufacturing Date



Please read the manual prior to any operation.



No Sitting



No Pushing.



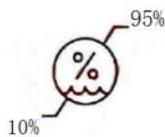
Fragile, Handle with care



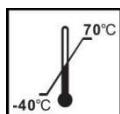
Keep Dry



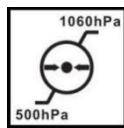
This way up



Humidity limitation (10% to 95%, including condensation)



Temperature limit (-40deg. C to 70 deg. C)



Atmospheric pressure limitation (500 hPa to 1060 hPa)



Note: No Roll over



Manufacturer



1. The device will be put on the European market after December,2020.
2. The device is not to be disposed of via the municipal waste collection system of any member state of the European Union. It is very important that customers understand and follow all laws regarding the proper decontamination and safe disposal of electrical equipment.

Waste Electrical and Electronic Equipment (WEEE) Recycling Instructions

When determined that the device is ready for disposal, it is to be recycled following the policies and procedures reflecting respective country's requirements. Do not dispose of device as general waste.

1.2.2 Position of the product label and serial number

The product label is attached on back cover of the equipment:



1.2.3 Explanation of symbols in the user manual

 The symbol warns that violation of operating procedures may cause malfunctions and personal injury. Violation of the handling procedures will damage the instrument or accessory equipment!

 The part that identifies this symbol in the manual must be executed!

1.3 Security Requirements

1.3.1 Safety Notes.

This product complies with the requirements of EU medical device regulations

According to IEC 60601-1-2:2014+AMD1:2020 EMC classification , this instrument is categorized as following:

Class II devices (Internal power supply equipment), Handheld ordinary equipment

B type –Degree of protection against electric shock of applicable parts (Forehead pad)

Degree of protection against liquid immersion: IPX0.

Class of operation: Continuous.

1.3.2 Light radiation safety

According to IEC 60825-1: 2014, this instrument is a class 1 laser product.

Operation of the product must be carried out in accordance with the user manual, unauthorized or disassembly of the instrument may lead to radiation hazards.



Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

When using this product, we should avoid long direct light exposure window which may cause retinal injury.

Please do not open the instrument enclosure without permission, which may cause accidental light radiation hazard.

The light source used in this product is the specified accessories. If it needs to be replaced and returned to the factory for processing, any unauthorized customer service personnel or agents shall not disassemble the equipment without permission to replace

and repair the light source, otherwise it may cause damage to the instrument and/or light radiation hazard.

1.3.3 Electromagnetic Compatibility



Note: easyRef Pro, R2X and R3X Handheld Auto Refractometer conforms to IEC 60601-1-2:2014+AMD1:2020 EMC requirements.

User must install and operate the device based on the provided EMC information.

Portable or mobile RF communication device might influence the performances of easyRef Pro, R2X, R3X Handheld Auto Refractometer, please avoid strong electromagnetic disturbance.

Instructions for use:

The ME EQUIPMENT or ME SYSTEM is suitable for healthcare environments and so on.



Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.



Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



Warning: NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals

(CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.



Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."



Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of

the Handheld Auto Refractometer (easyRef Pro, R2X, R3X), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

! **Warning:** Only the power adapter and battery approved by Certainn can be used. In order to avoid damage to the instrument, please do not change the charging parts

Even if other devices meet the emission requirements of the corresponding national standards, the easyRef Pro, R2X, R3X Handheld Auto Refractometer may still be interfered by other devices.

! **Warning:** Do not approach active high-frequency surgical equipment and magnetic resonance imaging systems in radio-frequency shielded rooms, where the intensity of EMI disturbances is high.

! **Warning:** Make sure that all electrical accessories connected to the easyRef Pro, R2X, R3X Handheld Auto Refractometer must comply with IEC 60601-1, if in doubt, consult the technical service department or your local representative

! **Warning:** No unauthorized modification allowed of the ME EQUIPMENT

! **Caution:** Please do not connect a removable storage device to the equipment without permission, in order to avoid potential computer virus. Computer virus may affect equipment performance, damage patient database, even void the warranty.

! **Warning:** Any non-medical peripheral devices equipment connected to the interface ports must be certified according to the respective IEC standards (for example, IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment) Also, all configurations shall comply with the system standard IEC 60601-1. Any person who connects or installs accessories to the system has the responsibility to verify the compliance.

! **Caution:** Federal law restricts this device to sale by or on the order of a doctor.

If any: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES

may be specified either generically (e.g., shielded cable, load impedance) or specifically (e.g., by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL

PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSE

NTIAL PERFORMANCE” need not be used).

The following cables should be used to meet the requirements of electromagnetic emission and anti-interference:

| No | Cable name | Manufacturers | INPUT | Output |
|----|-------------------------|---------------------------------------|----------------------------|---|
| 1 | switching power adaptor | Shenzhen Longxc Power Supply CO.,LTD. | 100-240V~ 50/60Hz, 0.5A | 5.0V  2.0A |

RF transmitter equipment and system requirements:

| No | Types | Launch frequency | Modulation type | Frequency characteristics | Radiated power | Remark |
|----|--------------|--------------------|-----------------|---------------------------|----------------|--------|
| 1 | Bluetooth LE | 2400MHz-2483.5 MHz | GFSK | 2.4G | ≤20dBm | |

Battery information

| No | Types | Model | Ratings | Remark |
|----|-----------------------------|----------|--------------|--------|
| 1 | Rechargeable Li-ion Battery | PL903565 | 3.8V,5600mAh | |

EMC (IEC 60601-1-2:2014+AMD1:2020)

The ME EQUIPMENT or ME SYSTEM is suitable for professional healthcare environment and so on.

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

Table 1

| Guidance and manufacturer's declaration - electromagnetic emissions | |
|---|------------|
| Emissions test | Compliance |
| RF emissions CISPR 11 | Group 1 |
| RF emissions CISPR 11 | Class A |
| Harmonic emissions IEC 61000-3-2 | Class A |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies |

Table 2

| Guidance and manufacturer's declaration - electromagnetic Immunity | | |
|--|---|---|
| Immunity Test | IEC 60601-1-2 Test level | Compliance level |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air |
| Electrical fast transient/burst IEC 61000-4-4 | Power supply lines: ±2 kV input/output lines: ±1 kV 100 kHz repetition frequency | Power supply lines: ±2 kV 100 kHz repetition frequency |
| Surge IEC 61000-4-5 | line(s) to line(s): ±0.5, ±1 kV line(s) to earth: ±0.5, ±1, ±2 kV | line(s) to line(s): ±0.5, ±1 kV |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle | 0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle |
| Power frequency magnetic field IEC 61000-4-8 | 30 A/m 50Hz/60Hz | 30 A/m 50Hz/60Hz |
| Conduced RF IEC61000-4-6 | 150KHz to 80MHz: 3Vrms 6Vrms (in ISM bands) 80% Am at 1kHz | 150KHz to 80MHz: 3Vrms 6Vrms (in ISM bands) 80% Am at 1kHz |
| Radiated RF IEC61000-4-3 | 3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz | 3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz |
| NOTE U _T is the a.c. mains voltage prior to application of the test level. | | |

Table 3

| Guidance and manufacturer's declaration - electromagnetic Immunity | | | | | | | |
|---|--------------------------------|---------------|---|--|-----------------------|---------------------|--|
| Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment) | Test Frequen cy (MHz) | Band (MHz) | Service | Modulation | Modul ation (W) | Distan ce (m) | IMMUNI TY TEST LEVEL (V/m) |
| | 385 | 380 –390 | TETRA 400 | Pulse modulation 18 Hz | 1,8 | 0.3 | 27 |
| | 450 | 380 –390 | GMRS 460, FRS 460 | FM ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| | 710 | 704 – 787 | LTE Band 13, 17 | Pulse modulation 217 Hz | 0,2 | 0.3 | 9 |
| | 745 | | | | | | |
| | 780 | 800 – 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation 18 Hz | 2 | 0.3 | 28 |
| | 810 | | | | | | |
| | 870 | | | | | | |
| | 930 | | | | | | |
| | 1720 | 1700 –1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| | 1845 | | | | | | |
| | 1970 | | | | | | |
| | 2450 | 2400 –2570 | Bluetooth WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| | 5240 | 5100 –5800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 0,2 | 0.3 | 9 |
| | 5500 | | | | | | |
| | 5785 | | | | | | |

Recommended separation distances between portable and mobile RF communications equipment and the easyRef Pro, R2X, R3X handheld auto refractometer

The easyRef Pro, R2X, R3X handheld auto refractometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the easyRef Pro, R2X, R3X handheld auto refractometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the easyRef Pro, R2X, R3X handheld auto refractometer as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter | | |
|--|---|--------------------|--------------------|
| | 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2,5 GHz |
| | $d = 1.17\sqrt{P}$ | $d = 1.17\sqrt{P}$ | $d = 2.33\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1.3.4 Transport and Installation

- Keep the product upward during transportation.
- ⚠ ● Caution: The instrument is allowed to be transported by general means of transportation, but the severe impact, vibration, rain and snow splashing during transportation shall be prevented. The transportation requirements shall be specified in the order contract
- Do not work in inflammable, explosive and strong electromagnetic interference place!
- Only the power adapter and battery recognized by Certainn can be used. In order to avoid any damage, please do not change the charging parts.

1.3.5 Operation Forbiddance

- The operation of easyRef Pro, R2X, R3X must follow the operating instructions, or it may cause stoppage and damage.
- This instrument may ignite combustible gas or steam. Do not use this instrument in the environment with combustible and anesthetic gas (for example: nitrous oxide) or pure oxygen.
- Do not disassemble optical system and components unless the operating instructions indicated.
- It is forbidden to refit or add accessories! Only the accessory produced or recognized by Certainn can be used in this instrument.
- If there are any errors, it must be repaired by professionals trained by Certainn Technology Co., Ltd. In order to avoid damage, it is forbidden to tear down by oneself.
- Do not use chemical reagent wiping the instrument surface and accessories.
- If there is damage or destroy caused by inobservance to the user manual, improper maintenance, incorrect use and violent collisions reasons beyond we can guarantee, the user will responsible for these. Please reference the details in the quality guarantee terms about maintenance, calibration and warranty.
- These are not included in the warranty scope: artificial damage, break, thump, bump, inundation, teardown without authorization or other force majeure reasons.
- Please do not put the instrument or battery into water or fire.
- The battery is an explosive product, please do not try to open the battery, hit or drop

the battery, the internal structure of the battery is not covered by the warranty

- Do not attempt to short-circuit the positive (+) and negative (-) batteries. Do not use the battery on other devices.
- Do not use batteries that have leaked, discolored, or have changed appearance
- It is forbidden to directly solder anything on the battery
- If the battery fluid leaks into your skin, clothing or even your eyes, immediately wash with plenty of water and then seek medical attention.
- Please do not storage the battery in high temperature, inflammable and explosive environment.
- When the equipment reaches the expected life and is scrapped, it should be disposed of in accordance with local laws and regulations, and it is forbidden to discard it at will.
- To completely disconnect the power, unplug the adapter
- The equipment can be disconnected from the power supply network only by separating the power adapter plug from the power grid socket. To prevent the patient from electric shock, it is prohibited to touch the patient and the signal input and output interfaces of this device at the same time.



Warning: The host must be charged by the matching power adapter. It is prohibited to use other adapters to charge, and it is also prohibited to use this matching power adapter to charge other devices.

1.3.6 Instructions

- When you need to move the instrument elsewhere, please refer to the installation instructions in the previous section.
- Please ensure the battery power of the instrument, so as not to exhaust the battery during use and delay the inspection
- When the instrument needs to charge, please follow the safety instructions and operating methods of this user manual.
- When the patient is next to the instrument, do not perform maintenance or replace parts, otherwise they may be injured.

1.4 FCC Requirement

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

2. System structures and functions

2.1 Fundamental principle

The Handheld Auto Refractometer uses the infrared fundus reflection phase method to emit a beam of infrared light with a specific wavelength, through the subject's cornea, lens, etc., and finally projected to the eye retina, and then reflected back to the corresponding optical system of the instrument. The image is taken through the image sensor, and the spherical refraction power, cylindrical refraction power and astigmatism axis are calculated after image processing and signal processing, which is used to determine the refractive state of human eyes.

2.2 Product structure and constitution

The product mainly consists of [a host and software](#).

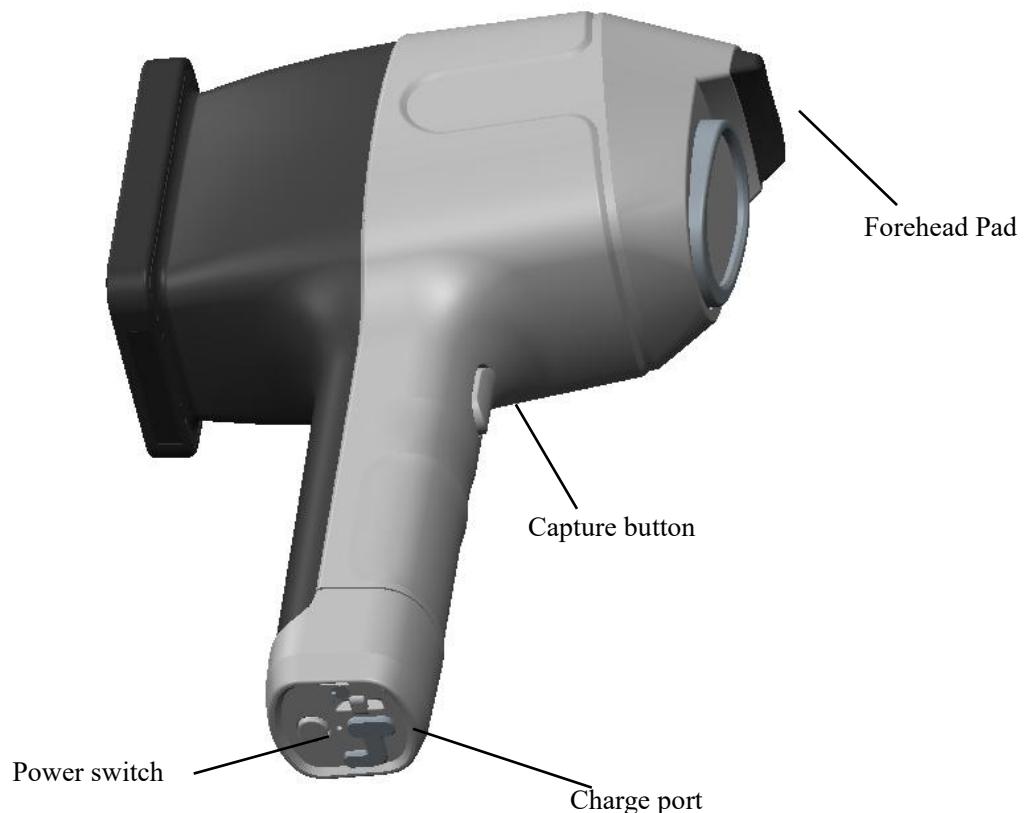


Figure 2.1 Device

2.3 Runtime environment

Operating environment: Android 11

Host configuration: RK3568、4G+16G

Display screens: 2.8" touch screen

Resolution :480*640

2.4 Function

As an effective instrument for detecting the refractive power of the human eye, the easyRef Pro, R2X, R3X Handheld Auto Refractometer can quickly perform the refractive power detection, which solves the influence of the medical staff's command and judgment on the test results, making the test results more objective and reasonable.

2.5 Intended use

It is suitable for the preliminary measurement of human eye refraction, including spherical refraction power, cylindrical refraction power and astigmatism axis.

2.6 Contraindications

There are no absolute contraindications.

3. Specifications

| | | |
|---|---|--------------------------------|
| Spherical power range | | easyRef Pro: -25.0D~+25.0D |
| | | R2X: -20.0D~+15.0D |
| | | R3X: -20.0D~+20.0D |
| Spherical power interval (Cell value) | | 0.01D, 0.12D, 0.25D selectable |
| Spherical power tolerance | -10D~10D | ±0.25D |
| | <-10D or >10D | ±0.5D |
| Spherical power measurement repeatability | | ≤0.13D |
| Cylindrical power range | | -12.0D ~+12.0D |
| Cylindrical power interval (Cell value) | | 0.01D, 0.12D, 0.25D selectable |
| Cylindrical power tolerance | | ±0.25D |
| Axial range | | 0°~180° |
| Axial interval | | 1° |
| Axial view tolerance | -3D≤DC≤3D | ±5° |
| | DC>3D or DC<-3D | ±3° |
| | Note: DC represents the column mirror degree. | |

Other parameters

- Dimensions (instrument only): 224 × 165 × 77.2 (mm);
- Weight: 705g;
- Power adapter input: 100-240V~, 50/60Hz, 500mA;
- Internal battery : 3.8V, 5600mAh, 21.28Wh;
- service life: 6 years.

The laser module information is as follows:

| | |
|----------------------|-------------------------|
| Central Wavelength | 850nm±20nm |
| Maximum output power | 5 mW |
| Beam divergence | θ _{II} : 9 deg |
| | θ _⊥ : 32 deg |
| Laser safety level | class 1 laser product |

4. Installation and maintenance

4.1 Installation



- Before unpacking, please check carefully whether the external package is complete. If there is obvious damage, please don't open and contact the forwarding agent.
- Installation by professional personnel of our company or professional personnel authorized by our company;
- If the power of the instrument is insufficient, please use the original charger to charge the instrument;
- For transportation safety, we may remove the battery from the instrument before leaving the factory. Before use, please install the original battery of the easyRef Pro, R2X / R3X Handheld Auto Refractometer.
- If the instrument is still to be transported in the future, in case unnecessary losses, we recommend that you keep the original packing material or adopt another proper transport packaging way.

4.2 Cleaning

- Before cleaning, please turn off the power. It is forbidden to clean the instrument while using.



- While cleaning the mainframe, do not use the solvents containing acetone or xylene, and never use abrasive cleaners. Only use common detergent.
- While cleaning, it is forbidden to let any liquid enter the interior of the device
- Clean with a soft clean wet cloth to the surface of the instrument.
- Keep the optical components clean. If the lens is dusty or smudged, use Ear blowing ball to blow it, and then wipe it gently with degreased gauze dipped in absolute alcohol or lens cleaning paper.
- The forehead rest is where the instrument often contacts the patient. After the inspection is completed, the patient's sweat or cosmetics may remain on the forehead rest , Therefore, the forehead rest needs to be cleaned after each inspection.



Note: Before examining each patient, use a clean gauze or cloth moistened with disinfectant alcohol to clean the forehead rest. For stubborn stains, use a cloth dampened with disinfectant alcohol to wipe, instead of repeatedly wiping the forehead rest with a dry cloth.

4.3 Maintenance and environment conditions

4.3.1 Maintenance



If the instrument needs to be opened for maintenance or repair purposes, this work can only be performed by qualified professionals authorized by Certainn or under the guidance of professionals.

- If it exceeds warranty period, we suggest that you buy a service contract from Certainn, please contact Certainn for service details.
- It is forbidden for any solution to enter the instrument to avoid damage to the components, and no internal components of the instrument can be disinfected

4.3.2 Environmental Conditions

Transport

Temperature: -40°C to $+70^{\circ}\text{C}$

Relative Humidity: 10% to 95%

Atmospheric Pressure: 500hPa to 1060hPa

Storage

Temperature: -10°C to $+55^{\circ}\text{C}$

Relative Humidity: 10% to 95%

Atmospheric Pressure: 700hPa to 1060hPa

Non-corrosive Gases, Ventilated Room

Operation

Temperature: $+10^{\circ}\text{C}$ to $+40^{\circ}\text{C}$

Relative Humidity: $\leq 80\%$

Atmospheric Pressure: 86kPa to 106kPa

5. The Function and Operation

5.1 Preparation before inspection

1. Fully charge the battery
2. Prepare sufficient thermal paper and turn on the Bluetooth printer.
3. Check the environment

Strong sunlight will affect the normal operation of the instrument, so it is best to check in a dark room. You can take the following measures to adjust the ambient light.

Close curtains: do not operate near windows without curtains;

Turn off the light: The darker light helps to check the small pupils of adults (without mydriatics) However, when the light is too dim and the iris of the subject is dark, the operator will not be able to see clearly, resulting in the cross target cannot be aimed at the pupil

Prepare the seats of the operator and the examinee, and adjust the height of the seats so that the eyes of both sides are basically on the same horizontal line.

5.2 Inspection steps

1. Starting up

Long press the power button to switch on the device and enter the main interface, as shown in the Figure 5.1.

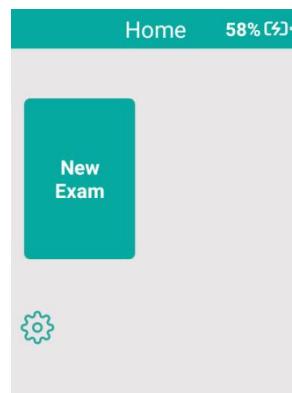


Figure 5.1 Main interface

2. Create a new patient

Touch <New Exam> to Create a new patient, the system will go to Display interface automatically.

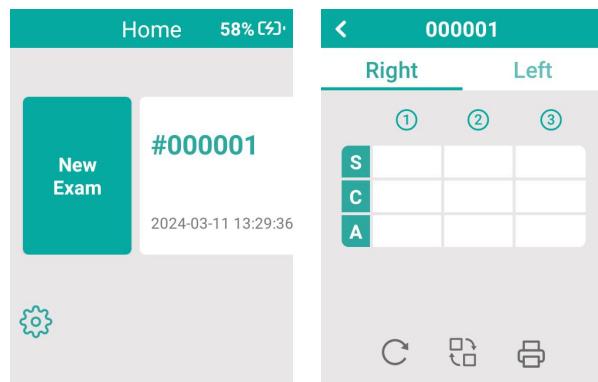


Figure 5.2 Create a new patient

3. Adjust the posture

Fix the position of the subject so that their eyes and the instrument are at the same level (it is recommended that the operator sits opposite the subject).

4. Choose left eye or right eye

In the Display interface shown in Figure 5.2, tap the screen to switch between the left and right eyes.

5. Start the examination

Press the Capture button on the device front shown in Figure 2.1 to enter the pre-capture interface, as shown in Figure 5.3 below:

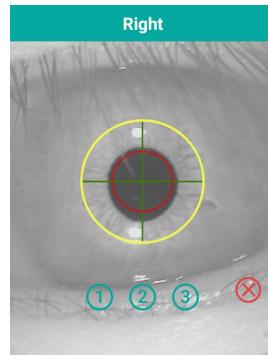


Figure 5.3 Pre-capture interface

6. Aim at the pupil

The operator holds the instrument and gently put it against the subject's forehead; the operator can observe the cross-shaped target in the alignment interface of the software. During operation, move the instrument up, down, left, and right until the cross-hair is aimed at the pupil of the eye to be measured as shown in Figure 5.4.

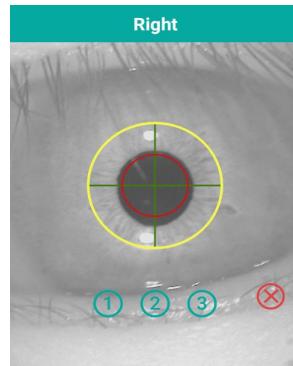


Figure 5.4 Aiming reference

2) guide the subject to gaze at the target, as shown in the figure.



Figure 5.5

7. Capture

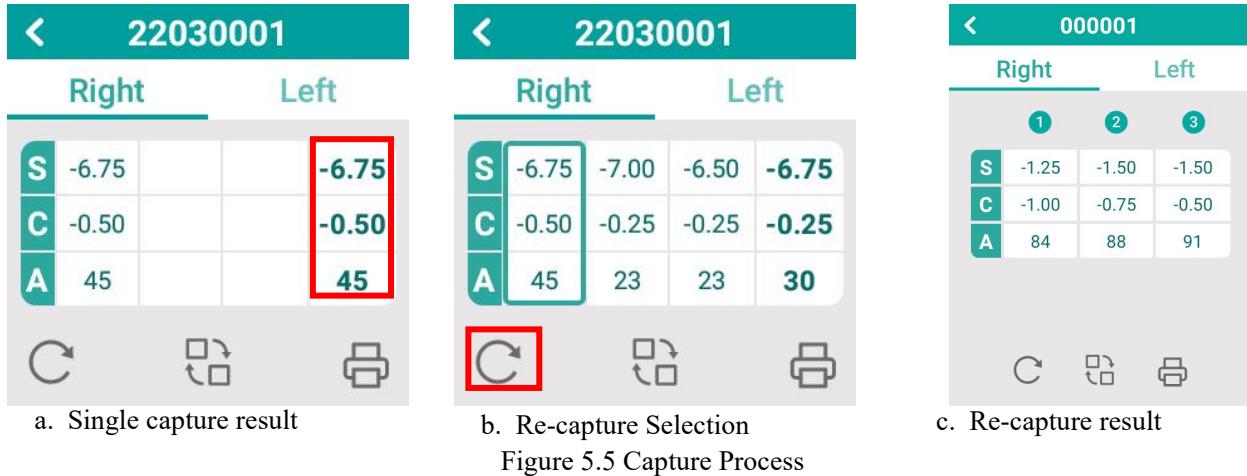
When the cross-hair is aimed at the pupil of the eye under test, press the Capture button to execute the acquisition. At this time, the instrument emits a "beep" sound. When the sound stops, the test is completed, and the software displays "S (spherical degree)" "C (Cylindrical degree)" "A (axis position)" results and the last column shows the final result, as shown in Figure 5.5 a. The final result has two ways of calculation and please see Chapter 5.6 for details.

Multiple capture: easyRef Pro, R2X, R3X supports up to 3 sub-captures and press the capture button to continue the next sub-scan.

Exit the capture: Touch the backspace icon on the interface to return to the main interface. (During the capture in the pre-capture interface, press the capture button or the backspace icon on the interface to exit and return to the Display interface.)

Inspection eye switch: Touch the <Right> or <Left> icon in the Display interface to switch the inspection eye.

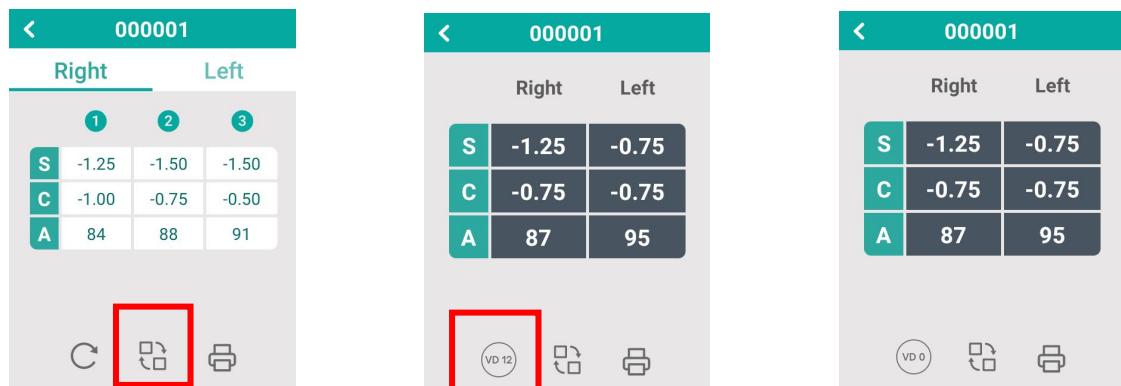
Re-capture: Select the captured results and touch the retry icon as shown in Figure 5.5 b (marked in red) to re-capture for this result and the retry icon is by default set to re-capture the last result.



Operation tips: When the cross target has been correctly aligned with the pupil, but the instrument does not capture, it is recommended to take the procedures below:

- Take the operation at dark room
- Make sure the instrument is facing the subject and aligns with the patient eye.
- Make sure that the eyelid of the subject does not cover the pupil.

8. Review the result.



Touch the switch icon to switch the view mode. Detailed view is for the detailed results of the single eye and OU view is for the final results of both eyes.

Touch the switch icon or to switch the view mode (figure 5.7). The values will be different, and report will be also a little different, please see Chapter 5.4 for details.

Note: The default setting is VD12 mode.

VD12: The result is calculated under the condition that the Vertex distance is 12 mm

VD0: The result is calculated under the condition that the Vertex distance is 0 mm

5.3 Query the records

Swipe left on the main interface to view recent inspection records or touch the bottom page number to input the specific record.

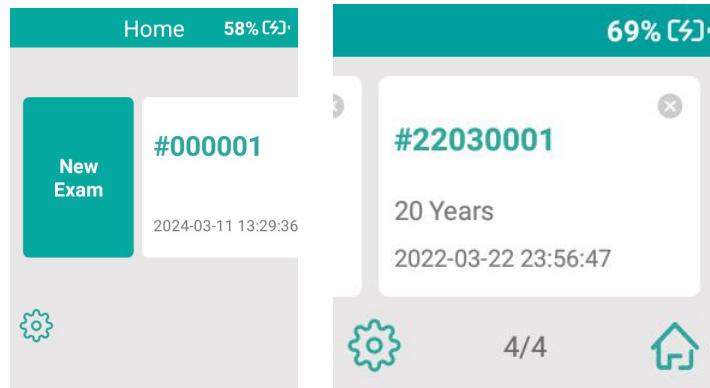
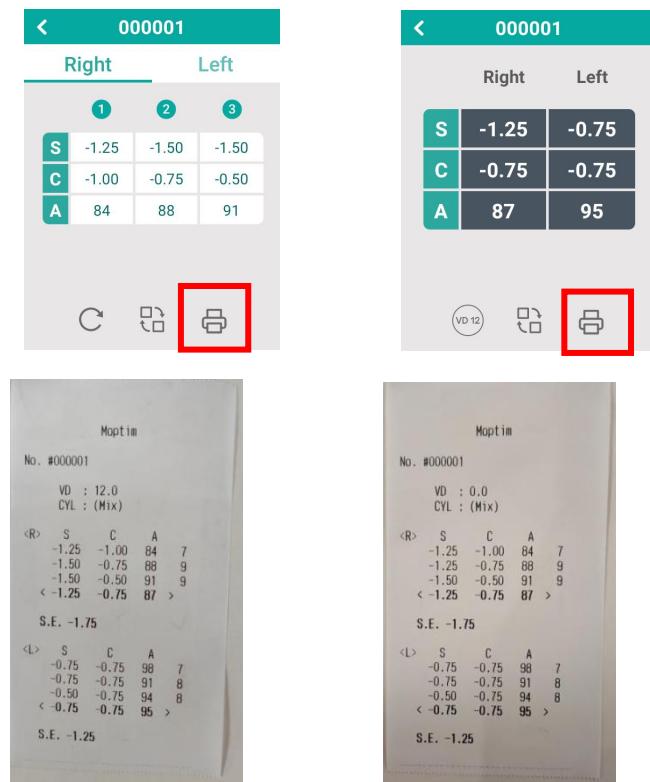


Figure 5.8 Query the records

5.4 Print

Touch the print icon on the main interface to print the current result as shown in Figure 5.9. (Please connect the Bluetooth printer first, see Chapter 5.6 for details.)



VD12 report

VD0 report

Figure 5.9 Report

5.5 Delete the data

Touch the delete icon on the main interface as shown in Figure 5.10 to delete the record.

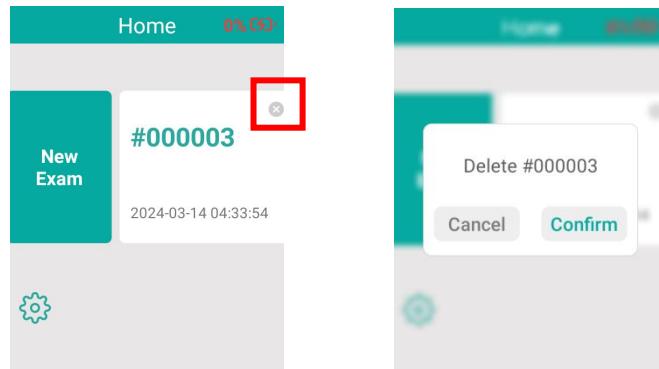


Figure 5.10 Delete data

5.6 Settings

1. Printer connection settings

Touch settings icon in the main interface and select Bluetooth option to connect the Bluetooth printer. the print icon on the main interface to print the inspection results displayed .

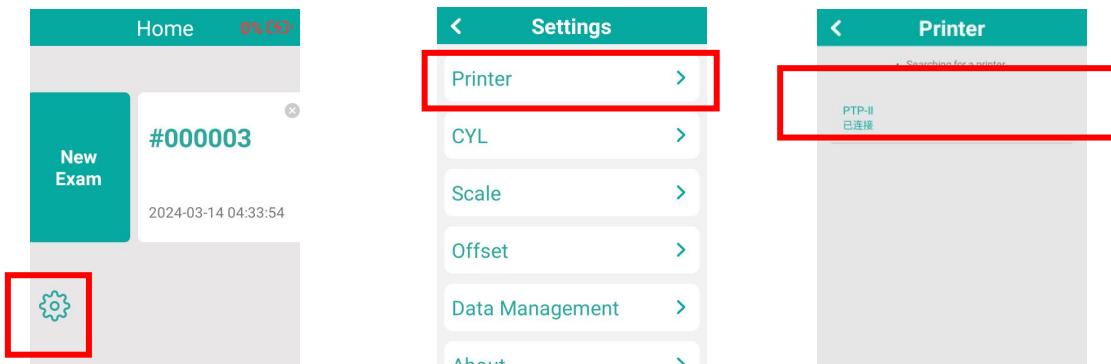


Figure 5.11 Bluetooth printer connection

Note: Please use the Bluetooth printer recommended by Shenzhen Certainn Technology Co., Ltd.

2. CYL settings.

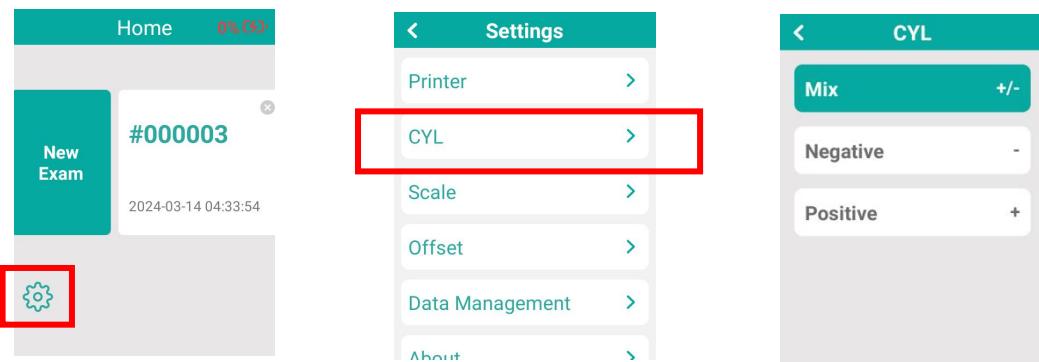


Figure 5.12 CYL Settings

It supports two ways of calculating the cylinder power. Default value means the value can be positive or negative while Negative Value means it is calculated in negative way and the value can only be negative.

5.7 System Troubleshooting

1. If the system starts up abnormally (system crash or pending on the boot screen) and it cannot be resolved after resetting, please contact the after-sales department of the local authorized distributor.
2. If the system keeps rebooting, please contact the after-sales department of the local authorized distributor.
3. If Bluetooth works abnormally, please switch off the Bluetooth and restart it and if it still cannot work, please reboot the system.
4. If the Touch screen does not work, please reboot the system.
5. If APP does not respond, please wait for the App self-recovery or reboot the system.

6. Battery and charger

The easyRef Pro, R2X, R3X Handheld Auto Refractometer is powered by a rechargeable battery. The battery and charger are part of the instrument. When the standby time and test time of the instrument are significantly shortened, please contact Certainn to replace the battery and recycle the old battery.

Only the batteries and chargers approved by Certainn can be used. For approved batteries and chargers, please consult your local distributor.

If the instrument is not used for a long time, the battery of the instrument should be fully charged every three months during storage (the battery must be fully charged before storage)

Permanent failure of the battery will be caused if the battery is in 0 power state for a long time.

When the charger is not in use, please disconnect it from the easyRef Pro, R2X, R3X Handheld Auto Refractometer and unplug the charger wire from the power socket. Do not connect the fully charged battery to the charger for a long time, as overcharging can shorten the battery life.

The instrument in the charging process should pay attention to the charger wire to prevent tripping caused accidental injury.

If it is not in use for a long time, please take off the battery to prevent battery leakage.

7. Packing List

| Item | Name | Qty |
|------|---------------|-----|
| 1 | Device | 1 |
| 2 | Power Adapter | 1 |
| 3 | Warranty Card | 1 |
| 4 | Certification | 1 |
| 5 | User Manual | 1 |

LEGAL NOTICES

Limited Warranty

This Warranty gives you specific legal rights, and you may have other rights, which vary from state to state. For one year from the date of delivery (the "Warranty Period") to the original purchaser ("You," "Your," "Purchaser"), Shenzhen Certainn Technology Co., Ltd. ("CERTAINN," "Seller," "We," "Our," "Us") warrants its easyRef Pro, R2X, R3X, excluding components and software as stated below (the "easyRef Pro, R2X, R3X") to be free from defects in material or workmanship. In the event of failure, seller's obligation is limited to repairing or replacing on an exchange basis the parts that have been promptly reported as defective by Purchaser during the Warranty Period and are confirmed as defective by Seller upon inspection. This Warranty covers all parts, labor, travel and expenses for the Warranty Period, except as otherwise stated herein. This Warranty only applies to the original Purchaser and shall not, in any way, be transferable or assignable.

The procedure for warranty claims shall be as follows: when you believe the easyRef Pro, R2X, R3X is defective, promptly report the defect to CERTAINN. Whenever possible, we will provide "in the customer's office" service to repair your easyRef Pro, R2X, R3X. However, at our discretion, repairs may be made in our repair department. In this case, we will pay all shipping costs unless your easyRef Pro, R2X, R3X is found upon inspection not to be eligible for repair under this Warranty, in which case you will be responsible for one-half the shipping costs. If your easyRef Pro, R2X, R3X is ineligible for repair under Warranty, we will notify you, and any repairs you authorize will be performed at our normal rates. All replaced parts will become the property of CERTAINN.

This Warranty specifically covers the easyRef Pro, R2X, R3X, including the instrument table. This Warranty does NOT cover: consumable items such as operating supplies, paper or storage media, or the servicing of any external printer. Those items will be covered by their manufacturer's warranty and arrangement for service must be made through that manufacturer. This Warranty will NOT apply if repair or parts replacement is required because of accident, neglect, misuse, acts of God, transportation or causes other than ordinary use, or supplies or accessories that do not meet the proper operating specifications of CERTAINN. This Warranty does NOT apply to any articles that have been repaired or altered except by CERTAINN.

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You acknowledge that you have read all the provisions in this Chapter, including this License and Limited Warranty, understand them, and agree to be bound by their terms and conditions.

SERVICE COMMITMENT

Thank you very much again for purchasing our easyRef Pro, R2X, R3X.

CERTAINN has established a set of strict quality control system, to engineer excellent quality of products, but because it is a complex high-tech equipment, fail to follow operating procedures may cause errors, even damage to instrument. Therefore, we have to remind you: please read and comprehend this manual before use, and operate strictly in accordance with our rules.

If you have any questions while using our equipment, please contact us.

If you feel that our instruments have any room for improvement, please contact us.

If our instrument has any trouble, please call us.

If you have good suggestions or criticism for our products or work, please feel free to tell us.

If you no longer use our instruments, dispose them according to the local and national laws.

Our staff will welcome your call with full enthusiasm, and answer your questions in the most sincere attitude, solve your problem as soon as possible, and sincerely accept your criticisms and suggestions.

Manufacturer: Shenzhen Certainn Technology Co., Ltd.

Address: L302, Bldg.2, No.8 Tangtou 1st Road, Shenzhen, Guangdong, 518108, China

Tel: +86-755-84084505 or 84084519

Website: www.moptim.com

(This manual is subject to update without notice)