

# **Auto Refracto-Keratometer**

## **RM-600 /RK-600 User's Manual**



Please be sure to read this manual carefully before using the instrument and keep it handy for ready reference.

Thank you for choosing and using our products. This keratometer is a precision instrument which uses Shack-Hartmann wave front sensing principle combined with accurate image analysis and processing technology to measure human eyes objectively.

The diopter number measured by the keratometer can not be used as the sole basis for optometry. The keratometer can not replace the optometry of the cinematographer and lens correction technology, but can only provide a certain reference for manual optometry. This type of keratometer does not contain the contact lens measurement function.

### **Product performance:**

1. The measurement range of spheroscope is  $-35\text{m}^{-1} \sim +25\text{m}^{-1}$  (minimum resolution is  $0.01\text{m}^{-1}$ )
2. The measurement range of cylindrical mirror is  $0 \sim 12\text{m}^{-1}$  (minimum resolution is  $0.01\text{m}^{-1}$ )
3. The measurement range of curvature radius is  $6.5 \sim 10\text{mm}$  (minimum resolution is  $0.01\text{mm}$ )
4. The measurement range of the main meridian axis is  $0 \sim 180^\circ$  (the minimum resolution is  $1^\circ$ )
5. The error of pupil distance indicating value shall not be greater than  $\pm 1\text{mm}$

### **The main structure and composition of the product:**

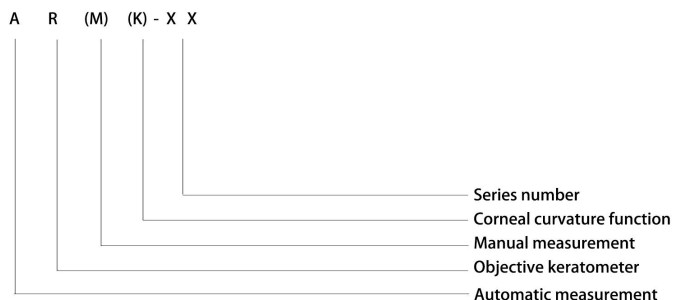
The optical part, the mechanical transmission part, the software control part (release version ver1.0.0), the display part and the printer.

### **Scope of application:**

It is used to measure the refractive state of the human eye (including spherical, cylindrical and optical axis, as well as pupil distance) and corneal curvature (RK-600 only).

**Contraindications:** Not for neonatal measurement.

### **Type naming rules**



### Model/specification

Product model	Specification(L×W×H) (mm)	Input power(VA)	Display mode	Remarks
RM-600	491×304×458	60	Liquid crystal	Wavefront aberration
RK-600	491×304×458	60	Liquid crystal	Wavefront aberration, corneal curvature

### Software version

Software model of this product: RM (K) -600;

Release version number;ver1.0.0.

### Disclaimer

1. This manual is written in strict accordance with relevant national laws and regulations and the technical specifications of the company. The accuracy and completeness of the content have been tried in the preparation process, but there is no guarantee that this manual is free from any omissions or errors in interpretation.
2. The Company reserves the right to modify the software and hardware of the product without notice.
3. The Company shall not be responsible for any consequences caused by improper use.
4. The Company reserves the right of final interpretation of the specification.

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# **1 ELECTROMAGNETIC COMPATIBILITY GUIDE AND MANUFACTURER STATEMENT**

This product is in compliance with the electromagnetic compatibility regulations in this manual. To ensure compliance with these regulations, the user needs to install and use the information provided in this manual. Such as the use of non - manufacturers to provide the cable may cause the increase or decrease in the immunity of the product launch.

## **Warning!**

1. The use of non - manufacturer supplied cables may cause an increase in the electromagnetic radiation of this product or decrease the immunity.
2. Portable or mobile radio frequency communication equipment should not be used closer to any part of the auto refractometer than the recommended isolation by distance, including the cable.
3. In addition to the transducer and cable in sale as spare parts of components from the original equipment or system manufacturer, the use of other accessories, transducers and cables may cause an increase in the device or system to launch or decrease in immunity.
4. The device or systems should not be close to or stacked up with other devices, and if you have to approach or stack, it should be observed to verify the normal operation of its use.
5. The other accessories, transducer or cable to be used together with the device and system, it may cause an increase in the device or system to launch or decrease in immunity.

## 1.1 Electromagnetic Emission Guide and Manufacturer Statement(Form1)


Guide and manufacturer's statement—Electromagnetic emission		
[ <b>Prototype ARK-1PLUS</b> ] expected to be used in the electromagnetic environment of the following requirements, buyers and users should ensure that it is used in this electromagnetic environment		
Launching Test	Conformity	Electromagnetic Environment—Guide
Radio frequency emission GB 4824	Group 1	[ <b>Prototype ARK-1PLUS</b> ] Radio frequency energy to be used for internal function only. Therefore, its RF emission very low, and the possibility of interference in the electronic device is very small.
Radio frequency emission GB 4824	Class B	
Harmonic emission GB 17625.1	Not applicable	
Voltage fluctuation/Flicker emission GB 17625.2	Not applicable	[ <b>Prototype ARK-1PLUS</b> ] Applicable for all of the facilities in use, including the home and the direct connection of residential public low voltage power supply network.

## 1.2 Electromagnetic Immunity Guide and Manufacturer Statement (Form2)

Guide and manufacturer's statement—Electromagnetic immunity			
<p><b>[Prototype ARK-1PLUS]</b> expected to be used in the electromagnetic environment of the following requirements, buyers and users should ensure that it is used in this electromagnetic environment</p>			
Immunity Test	IEC60601 Test Level	Meet Level	Electromagnetic Environment—Guide
Electrostatic discharge GB/T 17626.2	±6kV contact discharge  ±8kV air discharge	±6kV contact discharge  ±8kV air discharge	The ground should be wood, concrete or ceramic tile, if the ground is covered with synthetic material, the relative humidity should be at least 30%
Electric fast transient pulse group GB/T 17626.4	±2kV power line  ±1kV input/output line	±2kV power line	Network power supply should have a typical commercial or hospital environment in the use of quality
Surge GB/T 17626.5	±1kV line to line  ±2kV line to ground	±1kV line to line  ±2kV line to ground	Network power supply should have a typical commercial or hospital environment in the use of quality

Power input line voltage dips, short interruptions and voltage variations GB/T 17626.11	$<5\%U_t$ , last 0.5 cycle (Above $U_t$ , $>95\%$ sag) $40\% U_t$ , last 5 cycle (Above $U_t$ , $60\%$ sag) $70\% U_t$ , last 25 cycle (Above $U_t$ , $30\%$ sag) $<5\% U_t$ , last 5s (Above $U_t$ , $>95\%$ sag)	$<5\%U_t$ , last 0.5 cycle (Above $U_t$ , $>95\%$ sag) $40\% U_t$ , last 5 cycle (Above $U_t$ , $60\%$ sag) $70\% U_t$ , last 25 cycle (Above $U_t$ , $30\%$ sag) $<5\% U_t$ , last 5s (Above $U_t$ , $>95\%$ sag)	Network power supply should have a typical commercial or hospital environment in the use of quality. If the users need [ <b>Prototype ARK-1PLUS</b> ] to continuously run during power supply interruption, then it's recommended the [ <b>Prototype ARK-1PLUS</b> ] is powered by a constant power supply or battery
Power frequency magnetic field (50Hz) GB/T 17626.8	3A/m	3A/m	The power frequency magnetic field should have the characteristics of the power frequency magnetic level in a typical commercial or hospital environment
<b>Note:</b> $U_t$ refers to the AC network voltage before applying the test voltage.			

1.3 Electromagnetic Immunity Guide and Manufacturer Statement (Form3)

Guide and manufacturer's statement—Electromagnetic immunity			
[ <b>Prototype ARK-1PLUS</b> ] expected to be used in the electromagnetic environment of the following requirements, buyers and users should ensure that it is used in this electromagnetic environment			
Immunity Test	IEC60601 Test Level	Meet Level	Electromagnetic Environment—Guide
Radio frequency transmission GB/T 17626.6	3 V (effective value) 150 kHz ~ 80 MHz	3V (effective value)	Portable or mobile radio frequency communication equipment should not be used closer to any part of [ <b>Prototype ARK-1PLUS</b> ] refractometer than the recommended isolation by distance, including the cable. The distance should be calculated with the corresponding formula of the transmitter frequency. The recommended isolation distance: $d=1.2\sqrt{P}$  $d=1.2\sqrt{P}$ 80MHz~800MHz $d=2.3\sqrt{P}$ 800MHz~2.5GHz
Radio frequency radiation GB/T 17626.3	3 V/m 80 MHz ~ 2.5 GHz	3 V/m	In formula: P — Maximum output rated power of the transmitter provided by the manufacturer, unit for Watt(W) d—Recommended isolation distance, unit for meter(m). The electric field intensity of fixed radio frequency transmitter is determined by the investigation <sup>a</sup> of electromagnetic field, in each frequency range <sup>b</sup> should be lower than Meet Level. Interference may occur near the devices marked with the following items.

**Note 1:** at 80MHz and 800MHz frequency point, use the formula for higher frequency bands

**Note 2:** these guidelines may not be suitable for all cases, because the electromagnetic propagation is influenced by the absorption and reflection of buildings, objects and human bodies.


<sup>a</sup> fixed transmitter, such as wireless (cellular/cordless) telephone and ground mobile radio base station, amateur radio, AM and FM radio and television broadcasting, etc. the electric field intensity can not be accurately predicted in theory. In order to evaluate the electromagnetic environment of a fixed RF transmitter, the survey of electromagnetic field should be considered. If the electric field intensity measured where [**Prototype ARK-1PLUS**] place is higher than above applicable RF Meet Level, [**Prototype ARK-1PLUS**] should be observed to verify whether it can work normally. If abnormal performances happen, the supplementary measures may be necessary, such as re-adjust the direction or position of [**Prototype ARK-1PLUS**]

<sup>b</sup> in the entire frequency range of 150 kHz ~ 80 MHz, the electric field intensity should be less than 3V/m.

# 1.4 The Recommended Isolation Distance Between Portable and Mobile Radio Frequency Communication Equipments and [Prototype ARK-1PLUS] (Form 4)

The recommended isolation distance between portable and mobile radio frequency communication equipments and [Prototype ARK-1PLUS]			
[Prototype ARK-1PLUS] expected to be used in the electromagnetic environment of the radio frequency radiation disturbance controlled. According to the maximum output rated power of communication equipment, the buyer or user may prevent the electromagnetic interference by maintaining a minimum distance to be recommended as following items between the portable and mobile radio frequency communication equipment(transmitter) and [Prototype ARK-1PLUS]			
Maximum output rated power of transmitter: W	Isolation distance of different frequency of transmitter/m		
	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz~800MHz $d=1.2\sqrt{P}$	800MHz~2.5GHz $d=2.3\sqrt{P}$
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
<p>To the maximum output rated power of transmitter that not listed in the above forms,</p> <p><b>d</b> is recommended as isolation distance, unit for meter(m), the formula in the frequency column of the corresponding transmitter is available, here <b>p</b> is the maximum output rated power of transmitter provided by the manufacturer, unit for Watt(W).</p> <p><b>Note 1:</b> at 80MHz and 800MHz frequency point, use the formula for higher frequency bands</p> <p><b>Note 2:</b> these guidelines may not be suitable for all cases, because the electromagnetic propagation is influenced by the absorption and reflection of buildings, objects and human bodies.</p>			

## **2 SAFETY PRECAUTIONS**

**Safety Signs and Instructions**  Be Careful, remove the screw before installation

**This manual is intended for the following readers:**

Medical personnel carrying out routine operation of instruments;

Personnel involved in instrument maintenance and troubleshooting.

Please use the instrument in accordance with the method specified by the manufacturer. Before using the instrument, please read and understand all the contents in the manual carefully. Otherwise, the instrument will be damaged.

### **Operating environment description**

This product belongs to the continuous operation of common equipment (closed equipment without anti-fluid), can not be used in the presence of flammable anesthetic gas and air mixture or oxygen or nitrous oxide mixture.

This product may fail due to interference from electromagnetic waves emitted by portable TV, radio transceiver, electric toys, etc. Please ensure that you stay away from these products.

Electromagnetic compatibility: Keep the product away from objects that produce strong electromagnetic waves or noise. Such as: nuclear magnetic resonance equipment, microwave generating equipment, radiation equipment (X-ray machine, CT machine, etc.).

Keep this product away from high frequency surgical instruments. Such as: high-frequency electric knife, mobile phone, etc.









### **Intellectual property rights**

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Without the written consent of the Company, no person or organization may copy, modify, translate or distribute this instruction manual in any form.








**Symbol description (Table 5)**

Symbol	description	Symbol	Description
	On/off		Fear of rain
	Danger warning		Fear of sun
	Fragile article		Fear of radiation
	Upward		Please refer to the attached document

**Warnings and Precautions (Table 6)**

Mark	Description
 Danger	Please follow the normal steps to plug and unplug the power!This could result in serious injury or death!
 Danger	Please don't plug and unplug with wet hands!This could result in serious injury or death!
 Danger	Use the prescribed power supply, otherwise it will cause fire or electric shock!
 Danger	Do not disassemble or repair the machine without permission, or it will lead to fire or electric shock!
 Danger	Before opening the host cover, remove the power supply. When the cover is open, the device cannot be used.
 Danger	The power supply of the device is 220V50Hz, and the socket must be grounded. Before using the device, verify that the power supply voltage matches the voltage of the adapter, and the power supply must be grounded.
 Warning	The optical part of the device is equipped with a class 1 laser product (according to GB7247.1-2012), which is emitted from the exit pupil.In order to avoid exposure to harmful laser radiation, please consult the local distributor or manufacturer during assembly, maintenance and replacement. If you do not use the control or adjustment device or perform the steps in accordance with this regulation, it may cause harmful radiation exposure risk.
 Warning	Static electricity may damage the device. Therefore, pay attention to ESD prevention when using the device.
 Warning	If the device is not used for a long time, remove the adapter and power supply.

 Warning	To ensure safety, all parts and components of this instrument are only available from the manufacturer or authorized supplier.
 Warning	To ensure safety, all parts and components of this instrument are only available from the manufacturer or authorized supplier.
 Warning	To prevent the measurement accuracy from being affected by electromagnetic interference from other devices, keep away from strong interference sources such as short-wave and high-frequency devices when using the product.
 Warning	No maintenance or maintenance should be performed while the product is being used by patients.
 Attention	In accordance with the instructions and precautions in this manual, the company promises that all operations are safe and reliable.

## 2.1 Operation

- 2.1.1 Please do not open or touch the inside of the instrument at will in case of electric shock or instrument failure.
- 2.1.2 Keep the instrument well grounded to avoid personal safety or instrument damage.
- 2.1.3 When using the touch screen (resistive screen, please touch and hold for about 0.1 seconds), do not press the button too hard to avoid damage to the display.
- 2.1.4 When the machine is placed in direct sunlight or the indoor light is too strong, the measurement accuracy will be affected. Darkroom measurements are recommended.
- 2.1.5 Please do not use it in an environment with too much humidity and heat or dust, which will have adverse effects on the instrument.
- 2.1.6 If you want to connect this instrument to other instrument, please follow our local agent's instructions.
- 2.1.7 In cold room, when temperature suddenly rise, dew maybe appear on the protection glass of measuring window or internal optical parts. In case this happen, it can be used till the dew disappear.
- 2.1.8 Keep the measuring window lens clean at all time. The dust and other substances may cause error in measuring or affect the measuring precision.
- 2.1.9 If you encounter any abnormal conditions, such as smoking or strange smells, turn off the instrument and pull out the power cord immediately. Contact the local experts/agent or original manufacturer

to check and repair, you can use till the trouble is absolutely removed.

- 2.1.10 The use of materials that directly contact with the skin part: During operating the instrument, it should be used to separate the instrument from the patient's touch part with medical non-woven fabric(size for 8cm x 8cm), to avoid the direct contact with the surface of the instrument.

## 2.2 In Storage

- 2.2.1 Don't store the instrument in a place where it may get wet or where poisonous gas or liquid is stored.
- 2.2.2 Be sure to store the instrument in a place away from direct sunlight and with the specified temperature and humidity.

## 2.3 In Transference

- 2.3.1 During carrying the instrument, please take great care to avoid colliding and falling. Sudden or strong impact may damage the instrument or performances.
- 2.3.2 Before carrying, please turn off the machine and lock tightly the sliding body. During carrying, please catch the bottom tightly by two hands.

## 2.4 After Using

- 2.4.1 If the instrument won't be used for a long time, disconnect the power cable from the wall-outlet. It may cause a fire.
- 2.4.2 When the instrument is not used, turn the power off and put the dust cover on. Keeping the machine in electricity supplying will reduce the use life of the instrument. If the instrument is not covered for a long time, dust may affect the measuring accuracy.



## 2.5 In Maintenance










- 2.5.1 This instrument is a precision optical instrument, which needs regular calibration and regular filling of lubricating oil in the moving part.
- 2.5.2 When replacing a fuse, you must remove the power plug and replace the fuse with the correct size to avoid fire.



- 2.5.3 In case of instrument failure, if it needs to be disassembled and repaired, it must be completed by professional maintenance personnel after obtaining the manufacturer's permission or contacting local dealers. After disassembly, the manufacturer has the right to take no responsibility for maintenance.
- 2.5.4 The product is a non-sterile medical device. Daily cleaning and disinfection of the product is carried out by the end user using a soft wet cloth and sponge dipped in dish washing detergent. Please do not use alcohol, sodium, benzene and other organic compounds to clean the surface of the machine to avoid damage to the instrument. The measuring window is often cleaned with a soft cloth to maintain the measuring accuracy;
- 2.5.5 Determination of Disinfection method According to the requirements of "Disinfection of environment and object surface" in Hygienic Standard for Hospital Disinfection GB15982-2012, general parts of the product shall be cleaned in time, jaw rest, forehead rest and handle shall be disinfected at medium level. Alcohol-based disinfectants should be used for jaw rest, forehead rest and handle in accordance with WS/T367-2012 Technical specification for disinfection of medical institutions. Wipe the surface with a 75% (by volume) ethanol solution.

## 2.6 Safety Symbol

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

	I and O on power switch represent ON and OFF respectively
	Type B Isolated patient connection

	<p>This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the appropriate User's or Service Manual.</p>
	<p>It indicates the year of manufacture and the manufacturer.</p>
	<p>Manufacturer</p>
	<p>Authorised Representative in the European Community</p>
	<p>Identifies the point where the system safety ground is fastened to the chassis. Protective earth connected to conductive parts of Class I equipment for safety purposes.</p>
	<p>Temperature Limitation</p>
	<p>Keep DRY</p>
 UL60601-1 CAN/CSA C22.2 NO.601.1	 MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK FIRE AND MECHANICAL HAZARDS ONL ACCORDANCE WITH UL 60601-1,AND CAN/CSA C22.2 NO.601.1

	<p>Disposal of your old appliance</p> <p>When this crossed-out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC.</p> <p>All electrical and electronic product should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or local authorities. The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health. For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the product.</p>
	<p>Alternating Current</p>

### 3 UNPACKING AND INSTALLATION

#### 3.1 Notices and Procedures of Taking out the Instrument

Catching the bottom and chin rest frame separately by two hands, don't catch the screen or operation lever (Figure 1)



(Figure 1)

#### 3.2 Power Line Inlet and USB Interface 、RS232 Interface (Figure2、 3)

3.2.1 Power socket AC power access (fuse included) Fuse: F5AL 250V Use the power cord provided with the instrument to plug it firmly into the AC power socket (as shown below on the bottom of the instrument)



Figure2

### 3.2.2 Data interface USB\RS232 interface

Press the data interface compartment cover to open the data interface compartment and connect external equipment (this Keratometer and the connected automatic Keratometer head system should comply with the relevant electrical requirements in GB9706.1-2020. If you need to connect 232 interface, please contact the manufacturer or local dealer)



Figure3

### 3.3 Chin rest Paper Installation

Use the specified chin rest paper (Figure 4)



Figure 4



## 4 FUNCTIONS OF THE MAJOR COMPONENTS

### Front (Figure 5)



(Figure 5)

**LCD Screen:** Monitor for measurement display

**Height Adjustment Mark:** The eyes' height position of the patients

**Printer Cover:** Press the cover to open or close

**Jaw Rest:**Support jaw

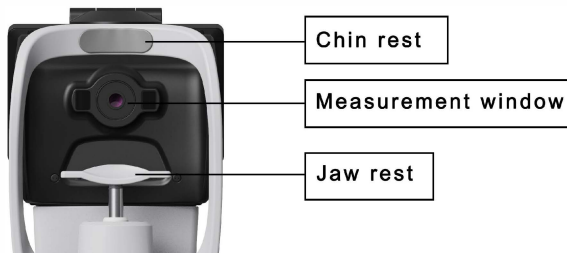
**Measure Switch:** Performing the measurement by pressing after focusing

**Joystick:** Adjust the focus by moving it left/right, up/down, forward/backward

**Chin rest lift Switch:** Adjust the height of the chin rest

**Stop Switch:** Control machine start and stop

### Back (Figure 6)



(Figure 6)

Chin Rest: The platform for placing the patients' chin

Jaw Rest: Support jaw

Measuring Window: Imaging on the retina of the patients' eyes

## **5 MAIN TECHNICAL INDEXES**

### **5.1 Measurement Performance Parameters**

5.1.1 The measurement range of spherical lens is  $-35\text{m}^{-1}\sim+25\text{m}^{-1}$  (minimum resolution  $0.01\text{m}^{-1}$ )

5.1.2 The measurement range of cylindrical lens is  $0\sim 12\text{m}^{-1}$  (minimum resolution  $0.01\text{m}^{-1}$ )

5.1.3 The measurement range of curvature radius is  $6.5\sim 10\text{mm}$  (minimum resolution  $0.01\text{mm}$ )

5.1.4 The measurement range of the main meridian axis is  $0\sim 180^\circ$  (the minimum resolution is  $1^\circ$ )

5.1.5 The measurement range of the cylindrical lens axis is  $0\sim 180^\circ$  (the minimum resolution is  $1^\circ$ )

### **5.2 Other Performance Parameters**

5.2.1 9-inch TFT touch screen (adjustable viewing Angle).

5.2.2 Printer: 57mm thermal printer

5.2.3 Visible illumination at exit pupil:  $< 3\text{Lx}$

5.2.4 Power supply voltage: AC100-240V

5.2.5 Power Supply Frequency: 50-60Hz

5.2.6 Power Consumption: 60VA

5.2.7 Net Weight: 22Kg

5.2.8 The service life of this keratometer is 10 years. In order to ensure the accuracy of measurement, please carry out measurement verification every year.

5.2.9 Production date: See the device nameplate.

### **5.3 Protection Level**

5.3.1 Product grade: Medical Device Level 2

5.3.2 Electrical Shock: Level I (Grounded)

5.3.3 Electrical Shock Protection Grade: Class B

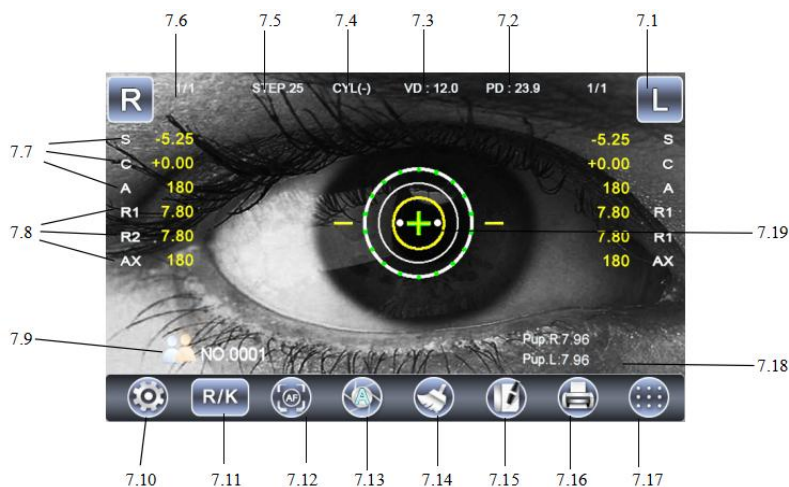
### **5.4 Device Type**

- 5.4.1 Anti-shock Type: Class I device;
- 5.4.2 Shock protection degree: Type B application part;
- 5.4.3 Non-AP Devices and non-APG devices;
- 5.4.4 Operation mode: continuous operation;
- 5.4.5 The device shall not be used in the environment of flammable anesthetic gas.

## 6. ENVIRONMENT TERMS

- 6.1 Ambient Temperature: 10℃~30℃
- 6.2 Ambient relative humidity: (30~75) % RH
- 6.3 Air Pressure: 86kPa~106 kPa
- 6.4 Altitude: Less than 2000m
- 6.5 No strong vibration or corrosive gas exists around the keratometer
- 6.6 No strong electromagnetic interference exists around the keratometer
- 6.7 The ambient illumination of the keratometer should be less than 150Lx
- 6.8 The keratometer should be placed on a level and adjustable working surface

## 7 LCD SCREEN DISPLAY (Figure 7)



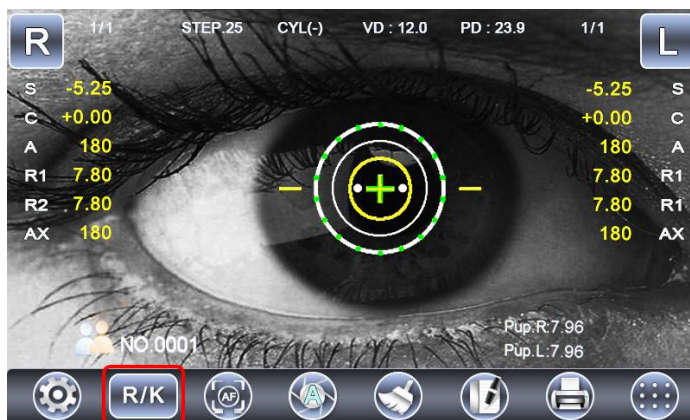
(Figure 7)

- 7.1 L/R Sign: Flashing sign indicates the current measured eye
- 7.2 Pupil distance
- 7.3 VD selection (shortcut key)
- 7.4 Astigmatism symbol selection (shortcut key)
- 7.5 Step selection (shortcut key)
- 7.6 The number of power/corneal parameters measured
- 7.7 Power display
- 7.8 Corneal value display
- 7.9 Adult//child mode selection
- 7.10 Menu set
- 7.11 Measurement mode selection
- 7.12 Auto/manual measurement selection (partial model)
- 7.13 Auto/manual tracking and focusing selection (partial model)
- 7.14 Data clear key
- 7.15 Data record check
- 7.16 Printer
- 7.17 Lattice display
- 7.18 Left/right eye pupil diameter
- 7.19 Pupil alignment target

## 8 MENU (Figure 8)



### 8.1 Measurement Mode Selection

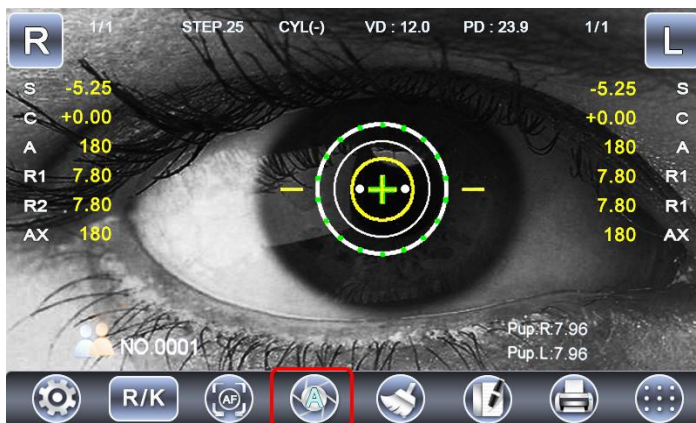
Touch this key to pop up three measurement mode menu (as shown in Figure 8), the user can choose to touch any measurement mode menu under need (KER for Keratometry mode, R/K for RefracKeratometry mode, REF for Refractometry mode).



(Figure 8)



## 8.2 Auto/Manual Measurement Selection (partial model)

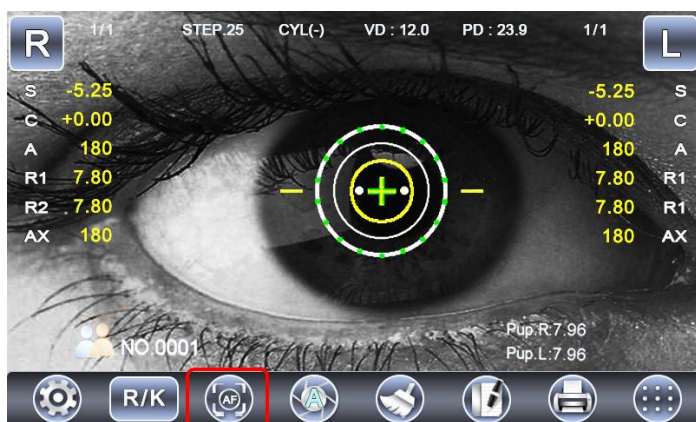
Touch (  or  ) key (as shown in Figure 9) to select auto measurement mode (A) or manual measurement mode (M)



(Figure 9)


## 8.3 Auto/Manual Tracking and Focusing Selection (partial model)

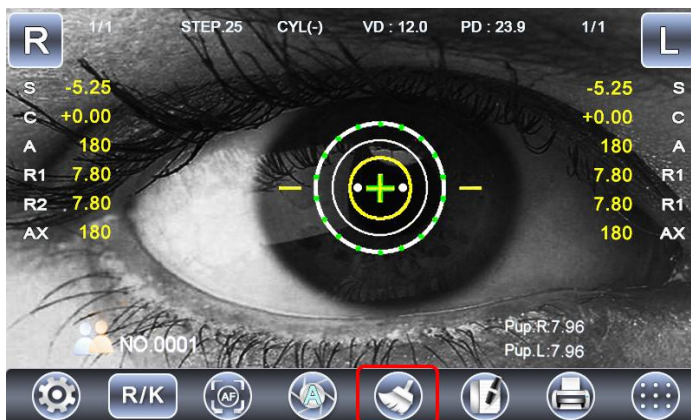
Touch(  or  ) key (as shown in Figure 10) to select auto tracking and focusing mode (AF) or manual tracking and focusing mode (MF)



(Figure 10)


#### 8.4 Data Clear Key (Figure 11)

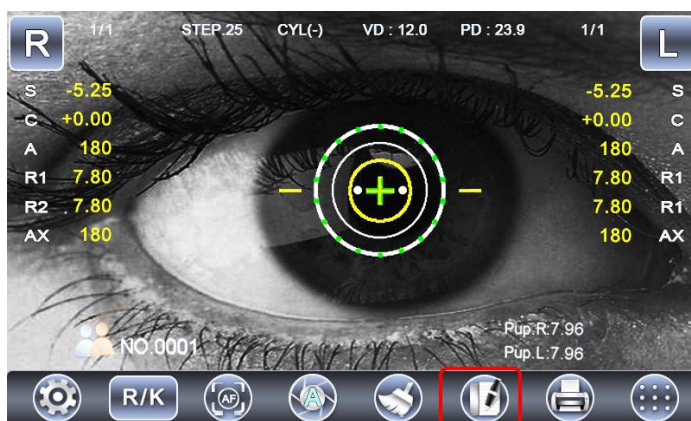
Touch  key to clear the measurement data



(Figure 11)

#### 8.5 Data Record Check(Figure 12)


Touch (  key to check the measurement data (directly print out the data, the measurement data won't be recorded)

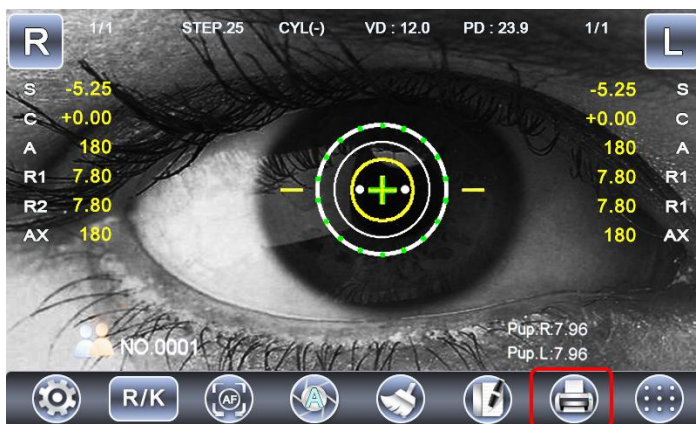


( Figure 12)

Left/right eyes data can be recorded max.10 items separately. Touch REF to display the recorded refractometry data only, touch KER to display the recorded keratometry data only, touch CLEAR key to clear the recorded data, touch RETURN key to return to the measurement interface.


## 8.6 Printer Set

Touch (  ) key to print current data ( Figure 13)

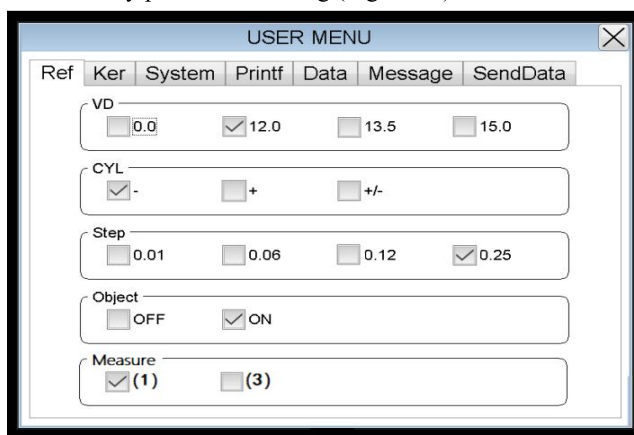


( Figure 13)

## 8.7 Menu Set

Touch (  ) key to enter the subsidiary menu setting (Current selection for blue)

### 8.7.1 Refractometry parameters setting (Figure 14)



(Figure 14)

VD: Distance between corneal and back top focus of lens, 0.0mm (contact lens), 12.0mm (Asian), 13.5mm (Middle East), 15.0mm (European)

CYL: Astigmatism symbol selection,  $-$ 、 $+$ 、 $\pm$ (Mix)

STEP: Measurement data precision selection

Object: Visual guide target atomization function switch (position of guiding target atomization)

Measure: The number of times the measurement results are displayed

### 8.7.2 Keratometry parameters setting (Figure 15)

USER MENU

Ref Ker System Printf Data Message SendData

mm/D ☒ mm ☐ D ☐ AVG

Step ☒ 0.05 ☐ 0.12 ☐ 0.25

Index ☐ 1.332 ☐ 1.336 ☒ 1.3375

Target range ☒ OFF ☐ STD1 ☐ STD2

(Figure 15)

MODE : Keratometry radius measurement (mm), keratometry power measurement ( $m^{-1}$ ) and average value display (AVG) optional

STEP: Keratometry power precision display

REFRACTIVE INDEX: Factory defaults to 1.3375

Target range: select the size of the target range

### 8.7.3 Mode setting (Figure 16)

USER MENU

Ref Ker System Printf Data Message SendData

Measure ☒ AUTO ☐ MANUAL Focus ☒ AUTO ☐ MANUAL

Beep ☐ OFF ☐ LOW ☒ MID ☐ HIGH

Init Mode ☐ REF ☐ KER ☒ K&R

Screen Off ☐ OFF ☐ 5MIN ☐ 10MIN ☒ 30MIN

Screen light Bright:

(Figure 16)



Mode: Manual measurement mode and auto measurement mode optional  
 (Auto measurement icon for grey said this model without this feature)  
 Beep: Sound prompt when operating. If set off, operation will keep silent  
 INT-Mode: Measurement mode selection (same as the main interface function), default startup mode for each starting  
 Screen Off: Instrument standby time setting (5 minutes, 10 minutes, 30 minutes and 60 minutes optical) (touch any key to wake up)  
 Screen light: LCD screen brightness setting

#### 8.7.4 Printing setting and printing paper replacement (Figure 17)

The screenshot shows a 'USER MENU' window with a close button (X) in the top right corner. Below the title bar are several tabs: 'Ref', 'Ker', 'System', 'Printf', 'Data', 'Message', and 'SendData'. The 'Printf' tab is currently selected. The settings are organized into two columns of rounded rectangular boxes, each containing a label and several radio button options.

Setting	Options	Selected
Grade Print	70%, 80%, 90%, 100%	100%
Ref Printf	OFF, STD, AVG	STD
Ker Printf	OFF, STD, AVG	STD
Auto Printf	OFF, ON	OFF
Eye Printf	OFF, ON	OFF
Clear Printf	OFF, ON	OFF
SE	OFF, ON	OFF
Pup Dia.	OFF, ON	OFF
BC	OFF, ON	OFF
Print	OFF, ON	ON
Print Language	Chinese, English	English

(Figure 17)

**PRINT CONGCENTRATION** :Set the appropriate print concentration according to different thermal printing paper  
**REFRACTOMETRY**: When OFF selected, the refractometry power won't be printed out. When STD selected, all refractometry power will be printed out. When AVG selected, only print the average value of the refractometry power.

**KERATOMETRY:** When OFF selected, the keratometry power won't be printed out. When STD selected, all keratometry power will be printed out. When AVG selected, only print the average value of the keratometry power.

**AUTO:** When ON selected, the measurement results will be printed out automatically after the both eyes measurement finished (in this case, the data is cleared automatically) When OFF selected, press the print key on panel to print out the measurement results.

**EYE:** When ON or OFF selected, the refractometry state diagram will be printed or not.

**CLEAR PRINT DATA:** Automatically erase data after printing

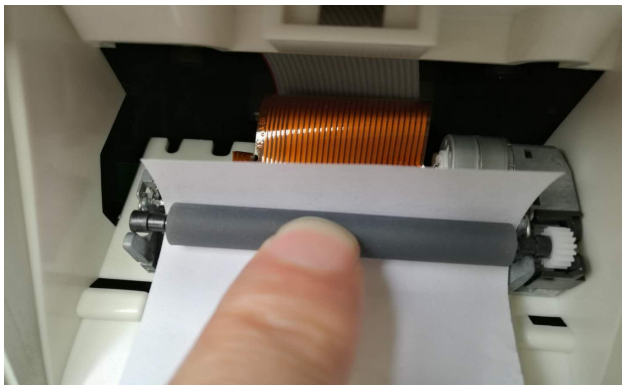
**SE:** When ON or OFF selected, SE data (the approximate value of cylinder power converted into sphere power) will be printed or not.

**PUPIL:** When ON or OFF selected, the pupil diameter will be printed or not.

**BC:** When ON or OFF selected, BC(base curve of corneal contact lens) will be printed or not.

### **How to install the printing paper (Figure 18)**

- 1.) Pull outwards the printer cover, open the cover
- 2.) Place the new printer paper in the box, keep the paper head upwards
- 3.) Draw the paper outwards and directly ride on the printer wheel
- 4.) Push the cover back and close the cover



(Figure 18)

### 8.7.5 Data setting (Figure 19)

USER MENU

Ref Ker System Printf Data Message SendData

Year: 2018 Month: 1 Day: 1

Hour: 1 Minute: 1 Second: 1

No.: 1

Date Format: ☒ YMD ☐ MDY ☐ DMY

Auto Count: ☒ OFF ☐ ON

(Figure 19)

DISP: Date, month and year display mode

DATE: Edit or modify the exact time of date and month and year

TIME: Edit or modify the exact time of second and minute and hour

COUNT: When ON or OFF selected, recording the number of patients in main interface will be refreshed or not

No.: Patient number setting, patient measuring number setting

Touch DATE, TIME and NUMBER options, enter the sub menu as shown below, select the appropriate number.

### 8.7.6 Printing message setting (Figure 20)

MSG1 for company name or product model number setting

MSG2 for company address or brand name setting. Users can edit this information freely according to the exact requires. After setting, press ENTER key to preserve and quit.

The screenshot shows a 'USER MENU' window with a close button (X) in the top right. Below the title bar is a tabbed interface with tabs: 'Ref', 'Ker', 'System', 'Printf', 'Data', 'Message', and 'SendData'. The 'Message' tab is selected. Inside the 'Message' tab, there are three text input fields labeled 'Mesaage1', 'Mesaage2', and 'Bluetooth:'. Below these fields is a numeric keypad with buttons for digits 1-0, letters A-J, K-T, U-Z, and punctuation. At the bottom of the keypad are function keys: '-', '+', '|', '!', 'spa', 'A/a', 'BS', 'CLR', and 'ENT'.

(Figure 20)

ENTER key for confirming and preserving

A/a for capital/small letter conversion

BS for deleting single letter

SPA key for space bar

CRL key for clearing all letters


#### 8.7.7 Data transfer setting (Figure21)

The screenshot shows the 'USER MENU' window with the 'Data' tab selected. The 'Data' tab contains two sections. The first section is 'Baut Rate' (note the typo) with four radio button options: 9600, 19200, 57600, and 115200. The 115200 option is selected. The second section is 'Auto Send' with two radio button options: OFF and ON. The OFF option is selected.

(Figure21)

According to the requires of the connected devices, customers choose the corresponding baud rate, and open the auto option, the measurement data will be automatically transferred to the connected devices, meanwhile the refractometer data will be automatically cleared.

#### 8.8 Array display

Touch (  ) key to display the patient's fundus array distribution (indirect evaluation of fundus imaging quality). (Figure.22)



(Figure.22)

## 8.9 Shortcut Key

8.9.1 Step set: successively touch STEP key to quickly switch 0.01、0.06、0.12、0.25

8.9.2 CYL axis set: successively touch CYL key to quickly switch —、+、±

8.9.3 VD set: successively touch VD key to quickly switch 0、12、13.5、15

## 9 MEASUREMENT

Suitable crowd and contraindication

Target patients for adults and children, and crowd of eye power range (  $-35\text{m}^{-1} \sim +25\text{m}^{-1}$  ). This product is not suitable for newborn eye measurement.

### 9.1 Preparations before Measurement

9.1.1 Place the device on the specified instrument table, loose the stage fixing lever and keep the device in free sliding state, adjust the four rubber feet to keep the device in horizontal.

9.1.2 Fix and install the specified chin rest paper and printing paper separately

9.1.3 Connect the spare power line to the instrument socket tightly (ensure the local voltage fit to the instrument specification)

9.1.4 Turn on the left side power switch (green indicator light show right in electricity connection), the instrument goes into self-check procedures. After self-check over, it automatically switches to main interface for measurement.

## 9.2 Notes for Operator and Patient

### 9.2.1 Adjust the chair height and screen angle in right position

### 9.2.2 Ensure the patient in comfortable and relaxed posture before measurement

### 9.2.3 By adjusting the instrument tabletop, keep the instrument height same to the patient natural sitting posture

### 9.2.4 Settle patient's chin touch the chin rest front and forehead touch the rubber forehead rest in level (keep face parallel with the measurement window)

### 9.2.5 By observing the patient eyes position and height adjustment mark, press the chin rest up/down key on panel to adjust the patient's eyes same height to the measurement window

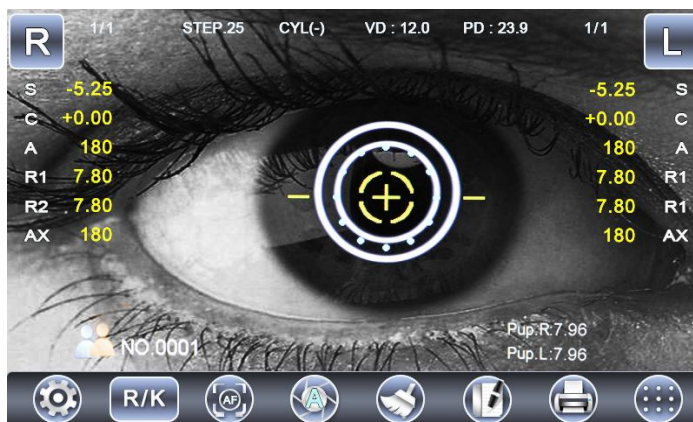
### 9.2.6 By the operation lever, move the sliding body left and right to move the patient's eyes in the measurement range (if the distance of two sides asymmetrical, adjust it by fixing the patient's head deviation)

## 9.3 Measurement

The measurement alignment method of this device for pupil and center measurement cross target in coincidence

### 9.3.1 Normal Measurement Mode

Holding the operation lever, quickly shift the sliding body to left side, keeping the measurement window roughly aligning with the patient's right eye socket (Figure.23)



(Figure.23)

Observing the patient's eye location on screen, rotate the operation

lever (up and down adjustment), meanwhile swing the operation lever left and right, till the yellow cross-ring target aligning at the patient's corneal vertex, then shift the operation lever front and back, till the patient's eye is clearly focused in the center measurement socket (the accuracy of focusing can be confirmed by observing whether level between the two points of split focusing and cross-ring target) (Figure.24,25)



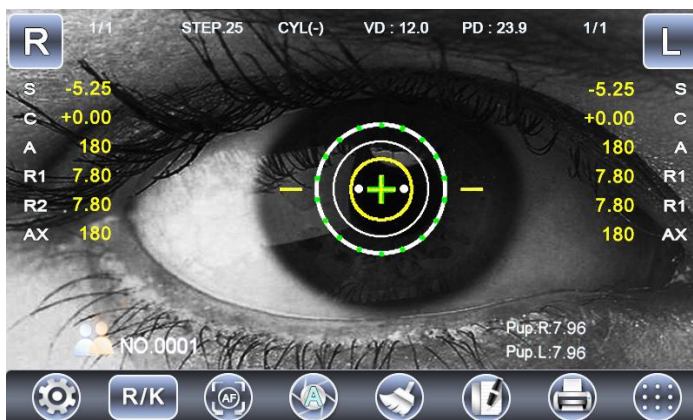
(Figure.24 away from patient's eye)



(Figure.25 close to patient's eye)

Prompt the patient to open eyes wide (eyelid and eyelash covering eyeball will affect the measurement accuracy), both eyes look right ahead.

Slightly adjust the operation lever, till the two points of slit focusing level with the cross-ring target, and yellow cross measurement target becomes thick and green, press the measurement button, when the measuring light flashing (the screen refreshed in black in moment), it shows the measurement over (the patient no need to see clearly the object-image during measuring, the measurement result same accuracy). The measurement result will be displayed on screen. (Figure.26) .



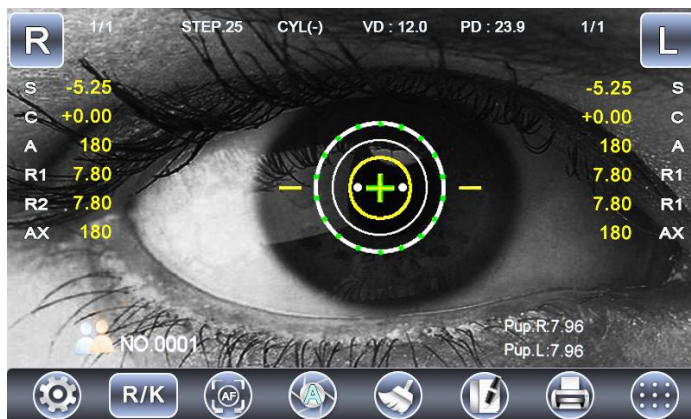
(Figure.26)

Shift the sliding body to right side, repeat the above steps, measure the patient's left eye.

Both eyes measurement over, pupil distance will be displayed automatically on the corresponding position. Choose whether or not to print the measurement results according to settings (auto printing or data output transmission over, the data on screen will be automatically cleared).

### 9.3.2 Child measurement mode

To measure children or the patients with pupil fibrillation, select child mode (Touch 7.9 key, the right small humanoid icon becomes green). (Figure 27)

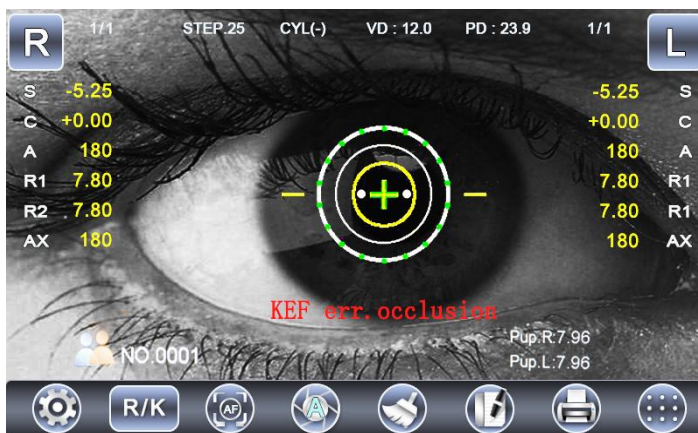


(Figure 27)

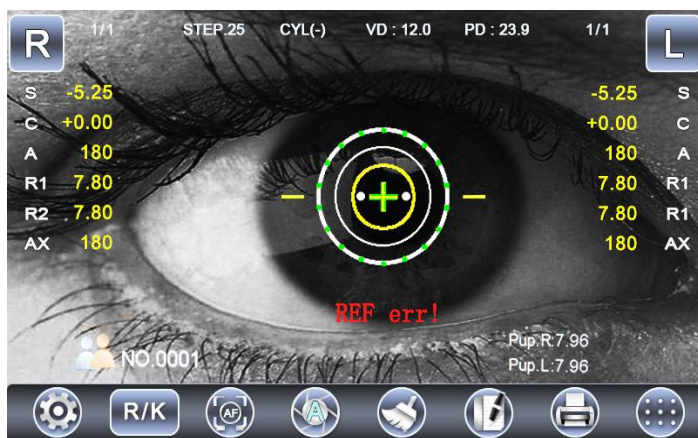
### 9.3.3 Measurement error prompt

During measurement, if the patients found having eyelid ptosis, eyelash disturbance, cataract, microcoria, keratopathy, corneal vertex and pupil center non coincidence, the error prompt will appear on screen when the instrument can't measure normally, please select the manual measurement mode or force measurement mode (long press the measurement button). (Figure 28 29).





(Figure 28 )



(Figure 29)

## 10 COMMON TROUBLE SHOOTING

### 10.1 Power indicator light not work

Check and confirm whether the local power fits to the instrument, whether the power plug loose, or whether the fuse damaged (in case this happen, please replace the same specified fuse)

#### 10.2 Chin rest not lift

Check whether the chin rest lift to limit position

#### 10.3 Printer can't work regularly

Check whether the printing paper is finished (in case this happen, red indicator light on panel will flash). Or whether the print setting is correct, and whether there is the measurement data (no data, not print)

#### 10.4 Sliding body not flexible

Check whether the stage fixing lever placed at right position, or whether other sundries go into the slide slot

#### 10.5 Press measurement button, but no data appear

Check whether the patient pupil smaller than 2mm, whether the eye position seriously incorrect, whether the cross measurement target aligns with the patient pupil (the target becomes thick and green), or whether the patient eyeground seriously diseased

#### 10.6 Measurement light not work

When the measurement over, the measurement light will automatically turn off. Sway the sliding body, it will turn on automatically

10.7 If other problems appear, please contact the local agent or original manufacturer

- If the fault phenomenon listed in the common trouble shooting can't be resolved, please contact the original manufacturer or local agent to repair.
- Please provide us with the following information:
  - Instrument name and model number
  - Instrument serial number
  - Fault phenomenon (detailed as possible)

#### (1.) Accessory maintenance limitation

Providing maintenance accessories to maintain the instrument functions during the instrument lifetime

#### (2.) Processing of instrument

- To be disposed carelessly of the instrument and accessories will pollute the environment
- Please contact the professional waste disposal company or local dealer before disposing this instrument

## 11 PACKAGING, TRANSPORTATION, STORAGE

Storage condition between -25°C and +40°C, transportation condition between -40°C and 70°C, relative humidity between 30% and 75%, air pressure between 86kpa and 106kpa

- (1.)Packing list, certificate and manual are included in the packing box
- (2.)The product packaging is not allowed to be shipped with flammable, explosive, corrosive products. Loading should be neat, stable and firm, super high and overweight is not allowed. In transit, rain and snow prevention, anti sun, anti impact, drop prevention should be noted carefully.
- (3.)The product packaging should be stored in a room temperature, dry and well ventilated warehouse, and can't be stored with chemical agents, acid and alkali substances, and other harmful substances.

## 12 ENVIRONMENTAL PROTECTION

Instruments that have been scrapped and have ceased to be used shall be disposed of in accordance with relevant local laws and regulations.

## 13 ENCLOSURE ACCESSORIES

Number	Specification	Quantity
1	User's Manual	1
2	Dustproof Cover	1
3	Lens Dustproof Piston	1
4	Model Eye	1
5	Power Line	1
6	Cleaning Cloth	1
7	Printing Paper	1
8	Fuse	2
9	Chinrest Pin	2