

# Auto Refracto-Keratometer



Adjustable touch  
screen LCD

Electric forehead

Automatic Paper  
Cutting Printer

Power on/off button

## RK-8000/RM-8000

### More Details



Power Line Inlet  
and RS232 interface



Electric forehead  
Running smoothly  
Flexible operation  
Experience is good



Electric lift  
Sensitive operation  
Running smoothly



Automatic cutting

Built-in thermal printer  
to replace  
paper easy to print  
automatically cut paper



## Main Technical Indexes



- ▶ Corneal Vertical Distance(VD): 0.00mm、12mm、13.75mm、15mm
- ▶ SPH: -20.00 m<sup>-1</sup> ~ +20.00 m<sup>-1</sup> ( VD=12mm, 0.01 m<sup>-1</sup>、0.06 m<sup>-1</sup>、0.12 m<sup>-1</sup>、0.25 m<sup>-1</sup> unit ), deep myopia measurement available
- ▶ CYL: 0.00 m<sup>-1</sup> ~ ±6.00 m<sup>-1</sup> (0.25 m<sup>-1</sup> unit)
- ▶ Cylinder Form: -、+、±
- ▶ Axis(AX): 1° ~ 180° (1° unit)
- ▶ Pupil Distance(PD): 10mm ~ 85mm(0.1mm unit)
- ▶ Radius of Corneal Curvature: 5.0 ~ 10.0mm (0.01mm unit)
- ▶ Corneal Power: 33.00 m<sup>-1</sup> ~ 67.00 m<sup>-1</sup> (in case that the corneal equivalent refractive power is 1.3375)
- ▶ Corneal Astigmatism: 0.00 m<sup>-1</sup> ~ 15.00 m<sup>-1</sup> (0.06 m<sup>-1</sup>/0.12 m<sup>-1</sup>/0.25 m<sup>-1</sup> unit)
- ▶ 9" TFT touch screen (angle adjustable)
- ▶ Printer: 57mm thermal printer
- ▶ Measuring Light Energy: <30uW (prevent injury to eyes during measuring)
- ▶ Measuring Time: <0.5s
- ▶ Minimum 2.0mm pupil can be measured. The application of cloud and mist chart technology allows the patients' eyes to look at the internal targets in a natural and comfortable situation and make the measurement more accurate
- ▶ Auto tracking, auto focusing and auto measuring of end of measurement (partial model)
- ▶ Electrical Power: AC100 ~ 240V, 50/60Hz
- ▶ Consumption: 60AV
- ▶ N.W.: 24kgs
- ▶ G.W.: 29kgs
- ▶ Dimensions: L510mm × W328mm × H450mm



# **Auto Refracto-Keratometer User's Manual**



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

The Auto Refracto-Keratometer is one high precision instrument of objective measuring the patient's eyes with unique optical system inside and accurate imaging analyzing and processing in Hartman technology. It's mainly used to measure the patient's diopter, including sphere power, cylinder power, optical axis, pupil distance and corneal curvature, to provide reference datas for eyes' treating and eyeglasses choice. The measurement result can be displayed on screen or printed out on paper, and can also be transferred to auto phoropter (fit to RS232 interface)). If the auto phoropter can output data, this Auto Refracto-Keratometer can directly print out the measured optometry data by auto photoptor.

## SPECIFICATIONS

Differences	Auto Refracto-Keratometer	Auto Refractometer
<b>Production</b>	Edit and embed software of refractometer and keratometer, use objective standard tool、corneal curvature standard device to adjust and calibrate	Edit and embed software of refractometer only, use objective standard device to adjust and calibrate
<b>mode</b>	REF 、 KER 、 and REF\KER three measurement modes optional	Default REF measurement mode
<b>Imaging principle design</b>	A standard ring is projected onto the patient's cornea with a group of 760nm infrared light, the corneal astigmatism and axis are calculated according to the different curvature parameters in each direction of the corneal reflex ring. Use 850nm infrared light to project the Hartmann lenslet array into the fundus of the patient's eyes, and separately calculate the parameters such as sphere, cylinder and axis according to the fundus reflection array.	Use 850nm infrared light to project the Hartmann lenslet array into the fundus of the patient's eyes, and separately calculate the parameters such as sphere , cylinder and axis according to the fundus reflection array.
<b>Purpose</b>	The instrument can be used to measure the curvature of the meridians of the center area about 3mm on the anterior corneal surface, that is the radius of curvature and curvature, so as to determine whether or not the cornea has astigmatism, astigmatism power and axial direction. It can also be used to measure the power of the patient, such as sphere, cylinder and axis.	used to measure the power of the patient, such as sphere, cylinder and axis.
<b>Measureme</b>	Manual measurement and automatic measurement. Aligning the measurement target at the corneal vertex, manual or automatic focus to clear state, the	Manual measurement and automatic measurement. Aligning the measurement target at the corneal



<b>nt mode</b>	instrument will automatically measure the corneal curvature power. Use the same measuring method to automatically measure the powers of sphere, cylinder and axis.	vertex, manual or automatic focus to clear state, the instrument will automatically measure the powers of sphere, cylinder and axis.
<b>Patient</b>	Non-contact measurement, the patient opens his eyes and looks right ahead, and move the target to complete the measurement(note the replacement of the chinrest paper and the forehead rubber cleaning )	Non-contact measurement, the patient opens his eyes and looks right ahead, and move the target to complete the measurement(note the replacement of the chinrest paper and the forehead rubber cleaning )

The serial Auto Refracto-Keratometer consist of optical system, mechanical transmission system, COMS image sensing system, microcomputer control system, and printer etc., are the professional instruments of providing reference data for glasses and eye diagnosis and treatment. According to measurement function, it's divided into refractive parameters measurement and refractive parameters measurement/corneal curvature measurement. According to measurement mode, it's divided into manual measurement and automatic measurement.

#### **DISCLAIMER**

1. This manual has been carefully checked to insure the contents' accuracy and perfect during compiling, however, for possible errors or omissions contained herein.
2. The company reserves the right to make changes to this product or the specifications at any time without prior notice.
3. The company own the final interpretation to this manual.

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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-B</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-B</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.  [ <b>Prototype ARK-B</b> ] Applicable for all of the facilities in use, including the home and the direct connection of residential public low voltage power supply network.
Radio frequency emission GB 4824	Class B	
Harmonic emission GB 17625.1	Not applicable	
Voltage fluctuation/Flicker emission GB 17625.2	Not applicable	


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

Guide and manufacturer's statement—Electromagnetic immunity			
[ <b>Prototype ARK-B</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
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	$\pm 2\text{kV}$ power line  $\pm 1\text{kV}$ input/output line	$\pm 2\text{kV}$ power line	Network power supply should have a typical commercial or hospital environment in the use of quality
Surge GB/T 17626.5	$\pm 1\text{kV}$ line to line  $\pm 2\text{kV}$ line to ground	$\pm 1\text{kV}$ line to line  $\pm 2\text{kV}$ 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-B</b> ] to continuously run during power supply interruption, then it's recommended the [ <b>Prototype ARK-B</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			
[Prototype ARK-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)	<p>Portable or mobile radio frequency communication equipment should not be used closer to any part of [Prototype ARK-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:</p> $d=1.2\sqrt{P}$  <p><math>d=1.2\sqrt{P}</math>      80MHz~800MHz</p> <p><math>d=2.3\sqrt{P}</math>      800MHz~2.5GHz</p>
Radio frequency radiation GB/T 17626.3	3 V/m 80 MHz ~ 2.5 GHz	3 V/m	<p>In formula: P — Maximum output rated power of the transmitter provided by the manufacturer, unit for Watt(W)</p> <p>d—Recommended isolation distance, unit for meter(m).</p> <p>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.</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>
<p><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 [<b>Prototype ARK-B</b>] place is higher than above applicable RF Meet Level, [<b>Prototype ARK-B</b>] 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[<b>Prototype ARK-B</b>]</p> <p><sup>b</sup> in the entire frequency range of 150 kHz~80 MHz, the electric field intensity should be less than 3V/m.</p>

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

The recommended isolation distance between portable and mobile radio frequency communication equipments and [ <b>Prototype ARK-B</b> ]			
[ <b>Prototype ARK-B</b> ] 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 [ <b>Prototype ARK-B</b> ]			
Maximum output rated power of transmitter: W	Isolation distance of different frequency of transmitter/m		
	150kHz~ 80MHz	80MHz~ 800MHz	800MHz~2.5GHz

	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
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


To the maximum output rated power of transmitter that not listed in the above forms, **d** is recommended as isolation distance, unit for meter(m), the formula in the frequency column of the corresponding transmitter is available, here **p** is the maximum output rated power of transmitter provided by the manufacturer, unit for Watt(W).

**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.



## 2. SAFETY PRECAUTIONS

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

### 2.1 Operation

- 2.1.1 Don't optionally open and touch the inside parts of the instrument, it may cause an electric shock or the system may malfunction.
- 2.1.2 Please keep this instrument ground connection well to avoid possible injury to people or the instrument damaged.
- 2.1.3 Don't touch the screen(resistance touch-screen, contact and hold it for about 0.1 second) in too strong strength, it may damage the screen.
- 2.1.4 Don't put the instrument at the place of direct sunlight or too strong illumination, it may affect the measuring precision. It's strongly suggested to be used indoors or in darkroom.
- 2.1.5 Don't use the instrument in a hot, humid or dusty environment. Such environments cause bad influences to 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.

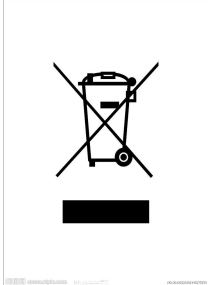

## 2.5 In Maintenance

- 2.5.1 It's one high precision optical instrument and need to be calibrated regularly.
- 2.5.2 Please fill the lube to the sliding parts regularly at the experts' guide.
- 2.5.3 Be sure to replace the fuse after disconnecting the power cord from the power inlet and use the specified fuse for replacement. Otherwise, it may cause a fire.
- 2.5.4 In case the instrument breaks down, it must be checked and repaired by the specified experts who know this instrument very well, or contacting the local authorized agent or original manufacturer. Open and repair the instrument by oneself, the agent or manufacturer don't be in charge of the consequence.
- 2.5.5 This instrument for non sterile medical device. Daily cleaning and disinfection of device by end user. Please use a soft cloth or sponge, wet cloth or detergent to clean the device. Don't use alcohol, water, benzene and other organic compounds to clean the surface of the instrument, to avoid damage to the device. The measuring window is often cleaned by a soft cloth to remove dust to maintain the accuracy of the measurement.
- 2.5.6 Determination of disinfection method:  
According to the requirements of "environmental and object surface disinfection" in the hospital disinfection and sanitation standard of GB 15982-2012, the general components of the device are cleaned in time, the chin-rest and forehead rest and operation lever are demanded to be disinfected in middle level disinfection.  
In accordance with the regulations of the WS/T 367-2012 medical institutions disinfection technical specifications, the chin-rest and forehead rest and operation lever are demanded to be disinfected by using alcohol disinfectant, and use 75% (volume ratio) ethanol solution to wipe the surface of the object.

## 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
	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.
	It indicates the year of manufacture and the manufacturer.
	Manufacturer
	Authorised Representative in the European Community
	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.
	Temperature Limitation
	Keep DRY
 UL60601-1 CAN/CSA C22.2 NO.601.1	 MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK FIRE AND MECHANICAL HAZARDS ONLY

	<p>ACCORDANCE WITH UL 60601-1, AND CAN/CSA C22.2 NO.601.1</p>
	<p><b>Disposal of your old appliance</b></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 chinrest frame separately by two hands, don't catch the screen or operation lever (Figure 1)



(Figure 1)

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

Connect the spare power line with the power supply socket (RS232\USB interface connection demanded, please contact the original manufacturer or local agent)



Figure2



Figure3

Power Supply Socket: Power Switch/Socket: AC power on/off with indicator light / AC power inlet (fuse F5AL 250V inside)

Data Interface: Data Interface: USB\RS232 interface to be connected with other equipments (This refractometer and the automatic phoropter serials connected should comply with the related electrical requirements in IEC60601-1-1-2000)

### 3.3 Chinrest Paper Installation

Use the specified chinrest paper (Figure 4)

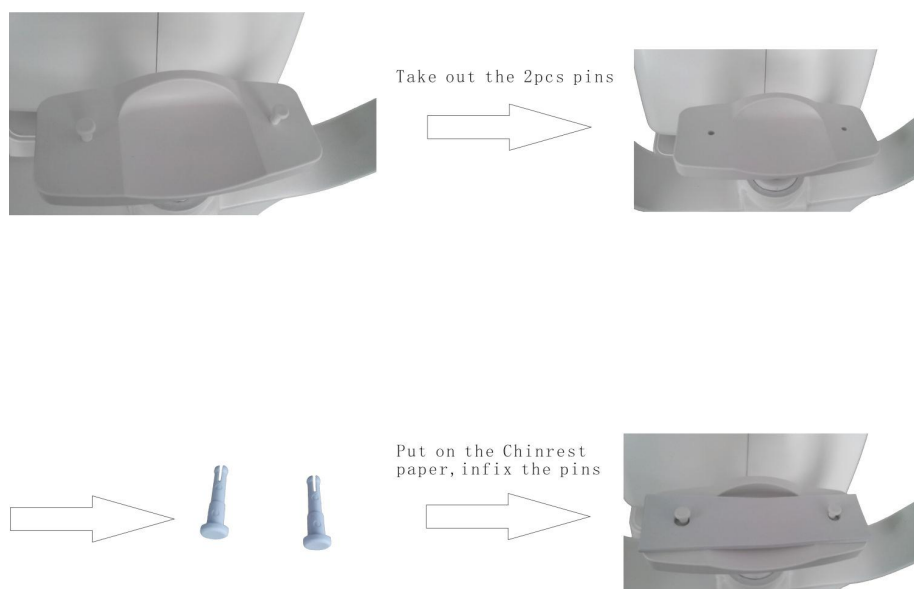


Figure 4

## 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

Measure Button: Performing the measurement by pressing after focusing

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

Stage Fixing Lever: Lock the sliding body

Rubber Feet: Support and adjust the instrument horizontal

Chinrest Up/Down Button: Adjust the height of the chinrest

Back (Figure 6)



(Figure 6)

Chinrest: The platform for placing the patients' chin

Forehead Rest: The place against the patients' forehead

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

## 5. MAIN TECHNICAL INDEXES

### 5.1 Measurement Performance Parameters

- 5.1.1 Corneal Vertical Distance(VD): 0.00mm、12mm、13.75mm、15mm
- 5.1.2 SPH: -20.00 m<sup>-1</sup>~ +20.00 m<sup>-1</sup>( VD=12mm, 0.01 m<sup>-1</sup>、0.06 m<sup>-1</sup>、0.12 m<sup>-1</sup>、0.25 m<sup>-1</sup> unit ), deep myopia measurement available
- 5.1.3 CYL: 0.00 m<sup>-1</sup> ~ ±6.00 m<sup>-1</sup> (0.25 m<sup>-1</sup> unit)
- 5.1.4 Cylinder Form: —、+、±
- 5.1.5 Axis(AX): 1°~ 180° (1° unit)
- 5.1.6 Pupil Distance(PD): 10mm ~ 85mm(0.1mm unit)
- 5.1.7 Radius of Corneal Curvature: 5.0 ~ 10.0mm (0.01mm unit)
- 5.1.8 Corneal Power: 33.00 m<sup>-1</sup>~ 67.00 m<sup>-1</sup> (in case that the corneal equivalent refractive power is 1.3375)
- 5.1.9 Corneal Astigmatism: 0.00 m<sup>-1</sup> ~ 15.00 m<sup>-1</sup> (0.06 m<sup>-1</sup>/0.12 m<sup>-1</sup>/0.25 m<sup>-1</sup> unit)

### 5.2 Other Performance Parameters

- 5.2.1 9" TFT touch screen (angle adjustable)
- 5.2.2 Printer: 57mm thermal printer
- 5.2.3 Measuring Light Energy: <30uW (prevent injury to eyes during measuring)
- 5.2.4 Measuring Time: <0.5s
- 5.2.5 Minimum 2.0mm pupil can be measured. The application of cloud and mist chart technology allows the patients' eyes to look at the internal targets in a natural and comfortable situation and make the measurement more accurate
- 5.2.6 Auto tracking, auto focusing and auto measuring of end of measurement (partial model)
- 5.2.7 Electrical Power: AC100 ~ 240V, 50/60Hz
- 5.2.8 Consumption: 60AV
- 5.2.9 N.W.: 24kgs
- 5.2.10 G.W.: 26.5kgs
- 5.2.11 Dimensions: L510mm×W328mm×H450mm
- 5.2.12 The refractometer service life for 10 years, to ensure accurate measurement, please make the metrological verification every year

### 5.3 Protection Level

- 5.3.1 Product Grade: Medical apparatus and instruments grade II
- 5.3.2 Electric Shock: Level I (ground)
- 5.3.3 Electric Shock Protection Class: Class B

### 5.4 Device Type

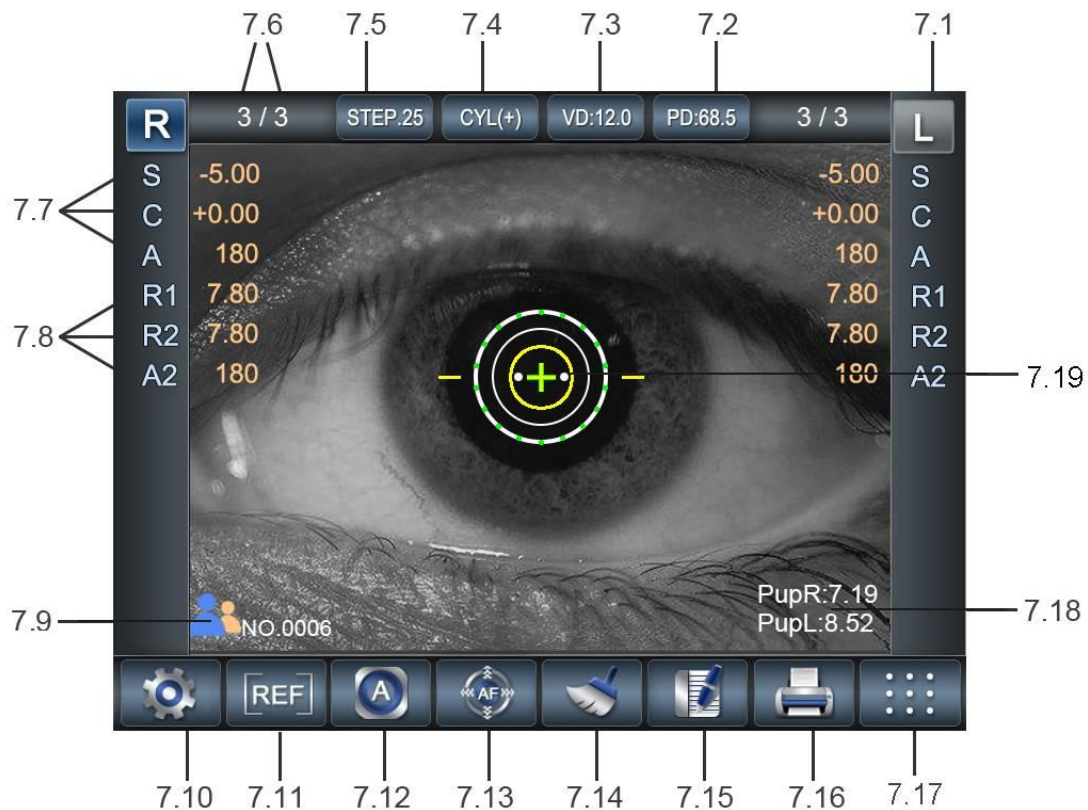
- 5.4.1 Anti Electric Shock Type: Class I
- 5.4.2 Anti Electric Shock Degree: Applicable type B
- 5.4.3 Non AP device, non APG device
- 5.4.4 Running Mode: Continuous duty



## 6. ENVIRONMENT TERMS

- 6.1 Temperature: 10°C ~ 30°C
- 6.2 Relative Humidity: (30~75) %RH
- 6.3 Atmospheric Pressure: 86kPa ~ 106kPa
- 6.4 Altitude: <2000m
- 6.5 No strong vibration and corrosive gas around
- 6.6 No strong electromagnetic interference around
- 6.7 Brightness: <150Lx
- 6.8 The device should be placed at the specified instrument table that can rise and fall vertically
- 6.9 The device can't be used in the environment of flammable and anesthetic gas

## 7. LCD SCREEN DISPLAY (Figure 7)



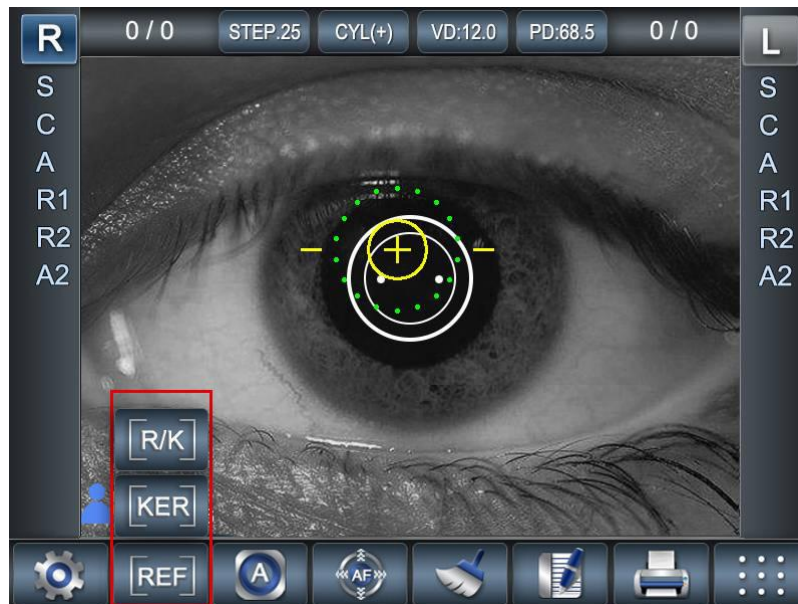
(Figure 7)

- 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

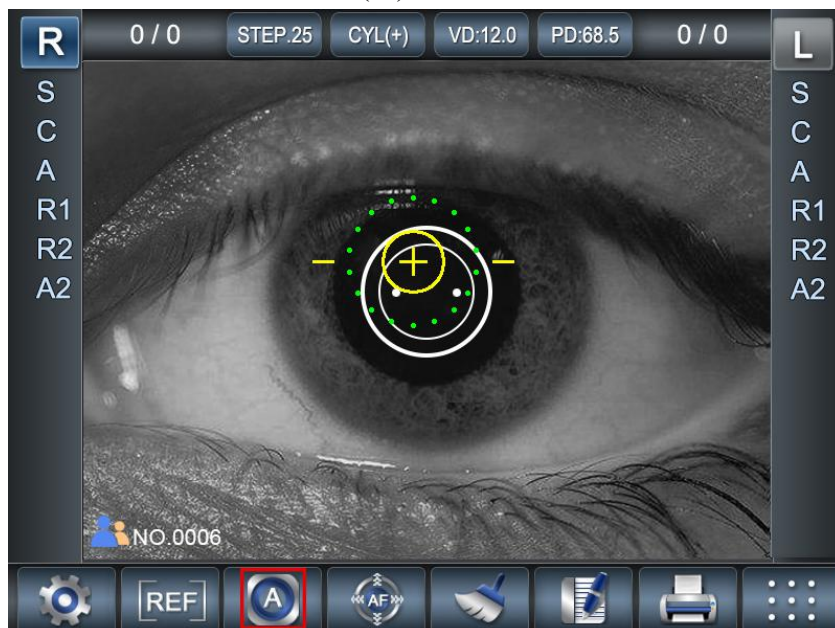
Touch this key to pop up three measurement mode menu (as shown in Figure 8), the user can choose to touch any measurement mode menu under need (KER for Keratometry mode, R/K for RefracKeratometry mode, REF for Refractometry mode)



(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)




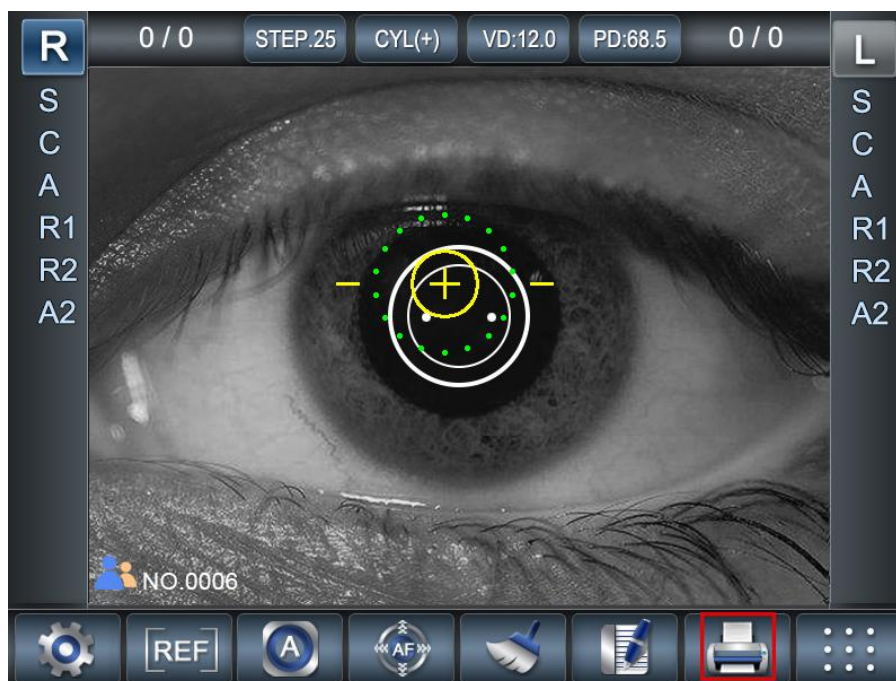


( Figure 12)

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)

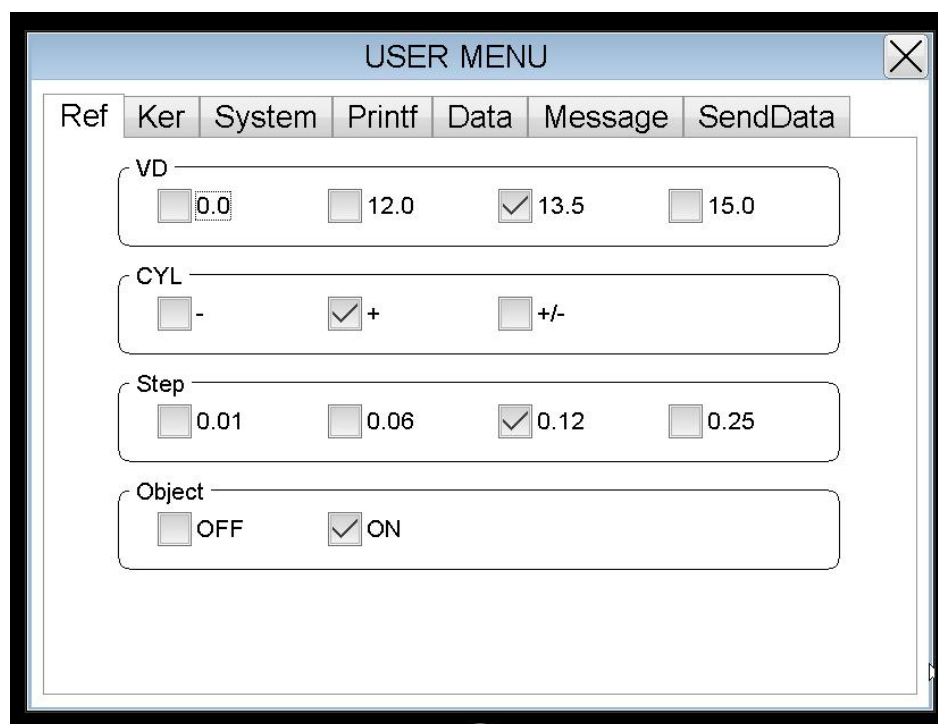


( Figure 13)

#### 8.7 Menu Set

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

### 8.7.1 Refractometry parameters setting (Figure 14)



USER MENU

Ref Ker System Printf Data Message SendData

VD

☐ 0.0 ☐ 12.0 ☒ 13.5 ☐ 15.0

CYL

☐ - ☒ + ☐ +/-

Step

☐ 0.01 ☐ 0.06 ☒ 0.12 ☐ 0.25

Object

☐ OFF ☒ ON

(Figure 14)

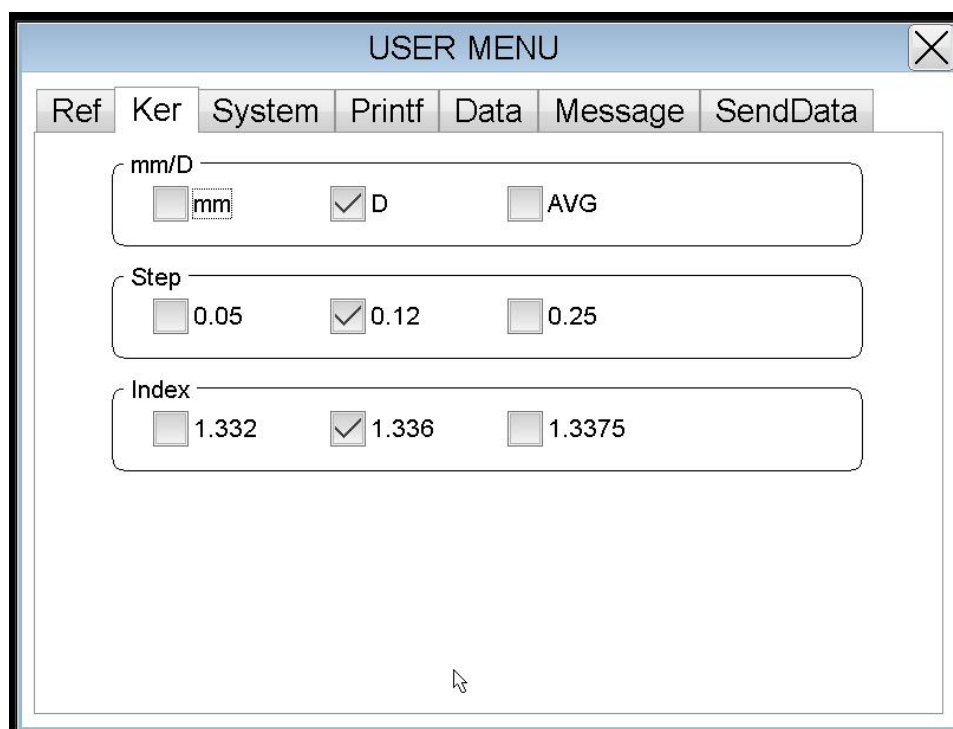
VD: Distance between corneal and back top focus of lens, 0.0mm (contact lens), 12.0mm (Asian), 13.5mm (Middle East), 15.0mm (European)

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

STEP: Measurement data precision selection

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

### 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

(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

#### 8.7.3 Mode setting (Figure 16)

The screenshot shows a 'USER MENU' window with a title bar and a close button. Below the title bar are seven tabs: 'Ref', 'Ker', 'System', 'Printf', 'Data', 'Message', and 'SendData'. The 'System' tab is selected. The main content area contains four settings sections, each with a title and a group of checkboxes:

- Measure**: ☐ MANUAL, ☒ AUTO
- Beep**: ☐ OFF, ☒ LOW, ☐ MID, ☐ HIGH
- Init Mode**: ☐ REF, ☒ KER, ☐ K&R
- Screen Off**: ☒ 5MIN, ☐ 10MIN, ☐ 30MIN, ☐ 60MIN

(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-M: Measurement mode selection (same as the main interface function), default startup mode for each starting

STAND BY: Instrument standby time setting (5 minutes, 10 minutes, 30 minutes and 60 minutes optional) (touch any key to wake up)

BRIGHTNESS: 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 is a tabbed interface with tabs for 'Ref', 'Ker', 'System', 'Printf', 'Data', 'Message', and 'SendData'. The 'Printf' tab is currently selected. Inside the 'Printf' tab, there are seven groups of settings, each with a label and a set of radio buttons:

- Grade Print**: ☐ 100%, ☐ 90%, ☒ 80%, ☐ 70%
- Ref Printf**: ☒ OFF, ☐ STD, ☐ AVG
- Ker Printf**: ☒ OFF, ☐ STD, ☐ AVG
- Auto Printf**: ☒ OFF, ☐ ON
- Eye Printf**: ☒ OFF, ☐ ON
- Clear Printf**: ☒ OFF, ☐ ON
- SE Printf**: ☒ OFF, ☐ ON

(Figure 17)

**PRINT CONCENTRATION** :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)**

Press the print engine room panel button to open the print engine room, pull out the print paper head and close the printer door. ( figures 18)





(Figure 18)

#### 8.7.5 Data setting (Figure 19)

(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 window titled "USER MENU" with a close button (X) in the top right corner. Below the title bar, there are several tabs: "Ref", "Ker", "System", "Printf", "Data", "Message", and "SendData". The "Message" tab is currently selected. Inside the "Message" tab, there are two sections: "Mesaage1" and "Mesaage2". Each section has a text input field. The "Mesaage1" field contains the text "12345". The "Mesaage2" field contains the text "67890". Below these input fields is a numeric keypad with buttons for digits 1-0, a row of letters A-J, a row of letters K-T, a row of letters U-Z, comma, period, colon, and at-sign, and a final row with hyphen/underscore, equals/asterisk, pipe/ampersand, exclamation mark, space bar, A/a, BS, CLR, and ENT. A mouse cursor is visible near the bottom right of the window.

(Figure 20)

ENTER key for confirming and preserving

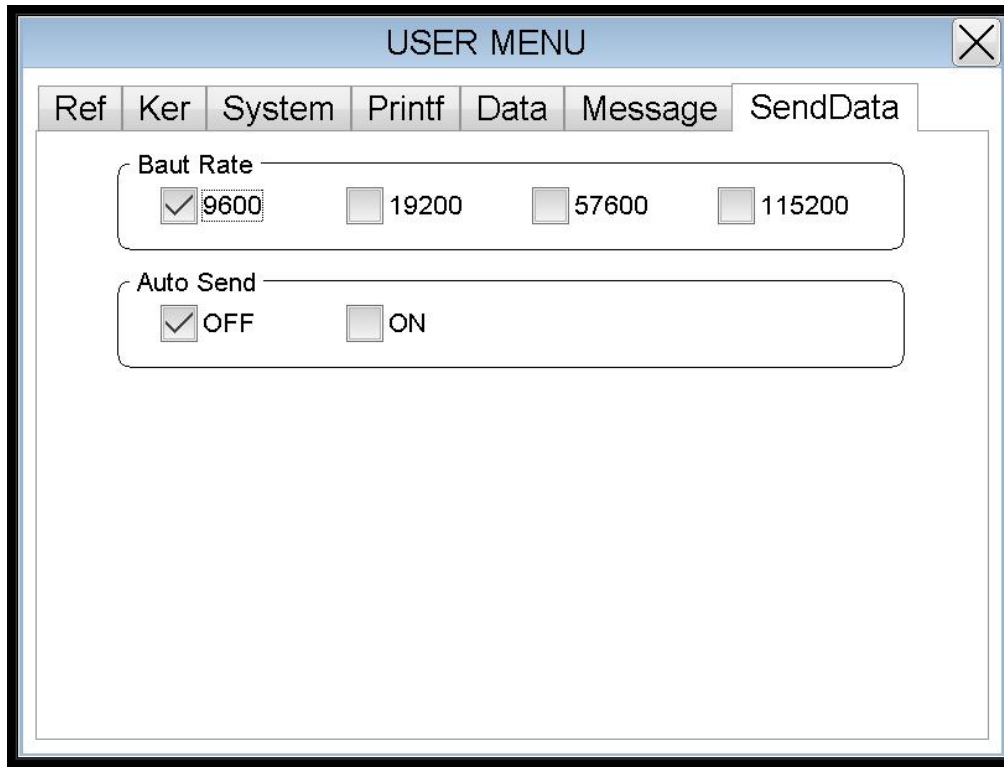
A/a for capital/small letter conversion

BS for deleting single letter

SPA key for space bar

CRL key for clearing all letters


### 8.7.7 Data transfer setting (Figure21)



(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 —、+、 $\pm$

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 ( $-20\text{ m}^{-1} \sim +20\text{ m}^{-1}$ ). 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 chinrest 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

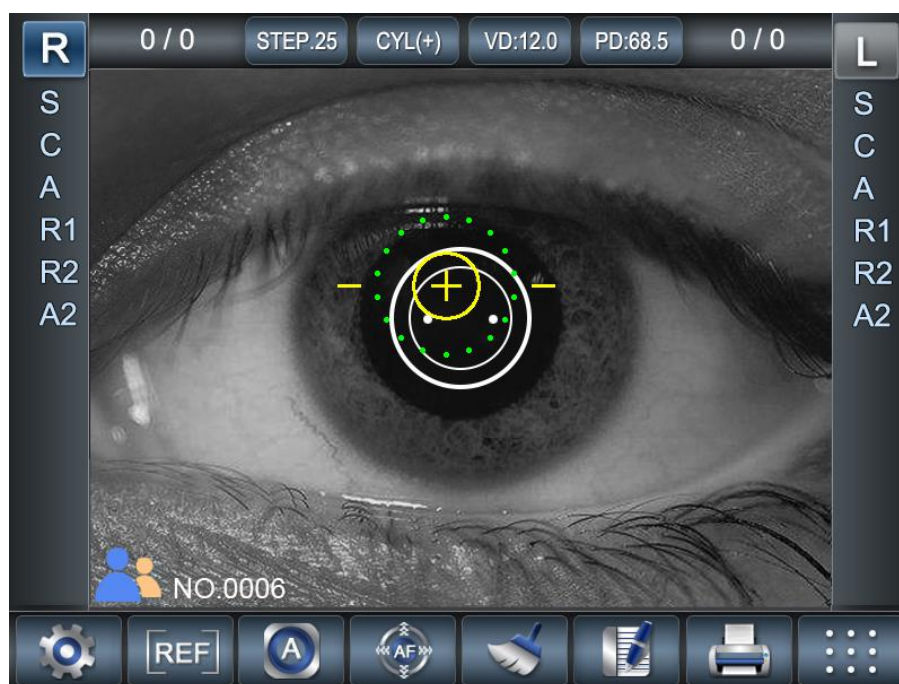
- 9.2.1 Adjust the chair height and screen angle in right position
- 9.2.2 Ensure the patient in comfortable and relaxed posture before measurement
- 9.2.3 By adjusting the instrument tabletop, keep the instrument height same to the patient natural sitting posture
- 9.2.4 Settle patient's chin touch the chinrest 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 chinrest 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)

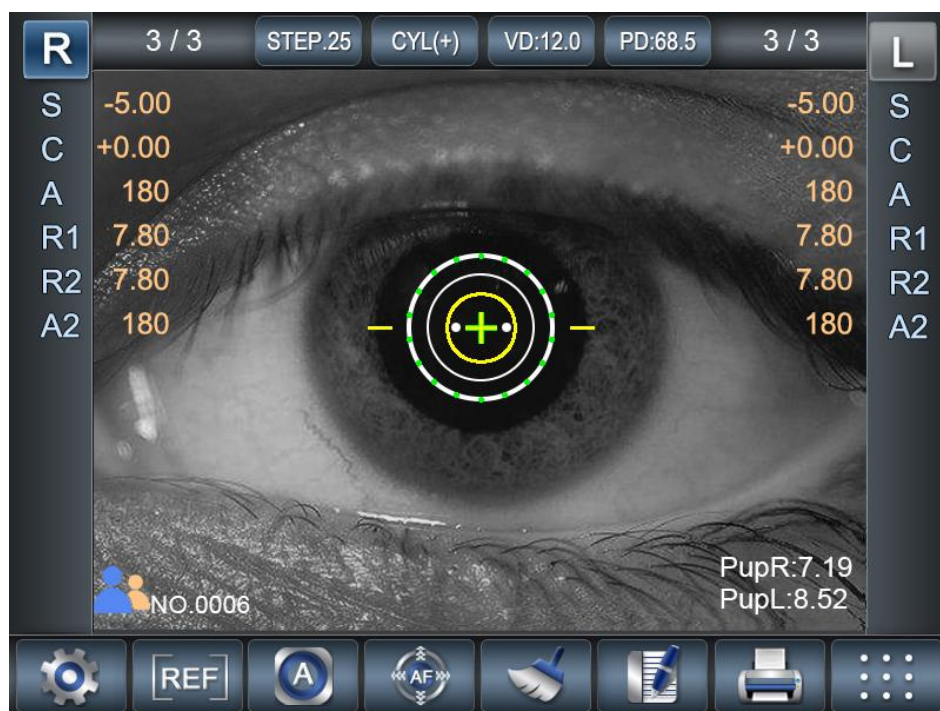


(Figure.25 close to patient's eye)

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)。





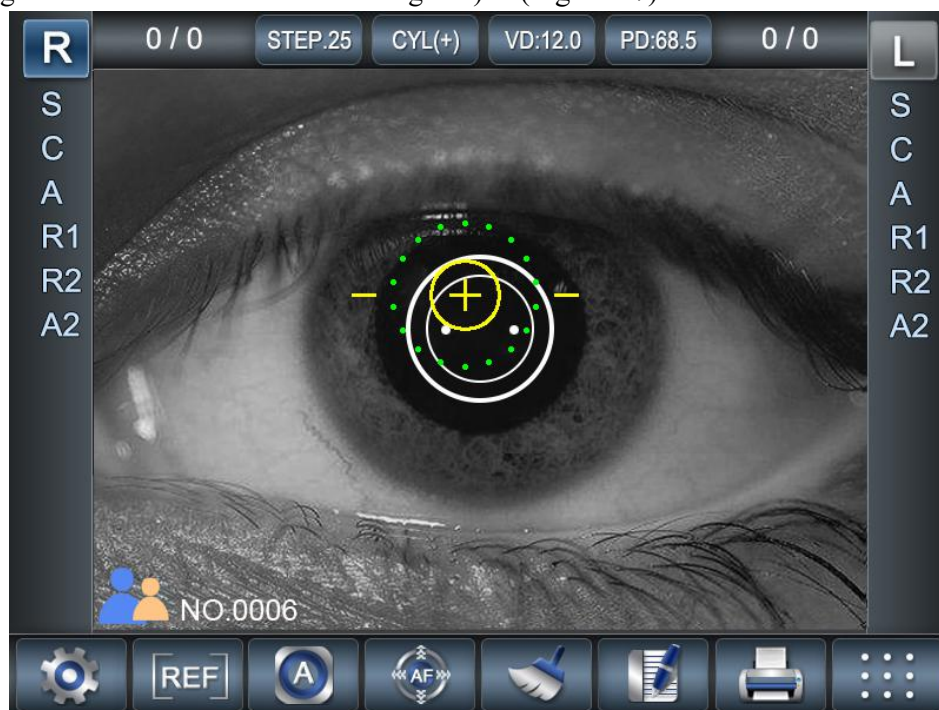
(Figure.26)

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)



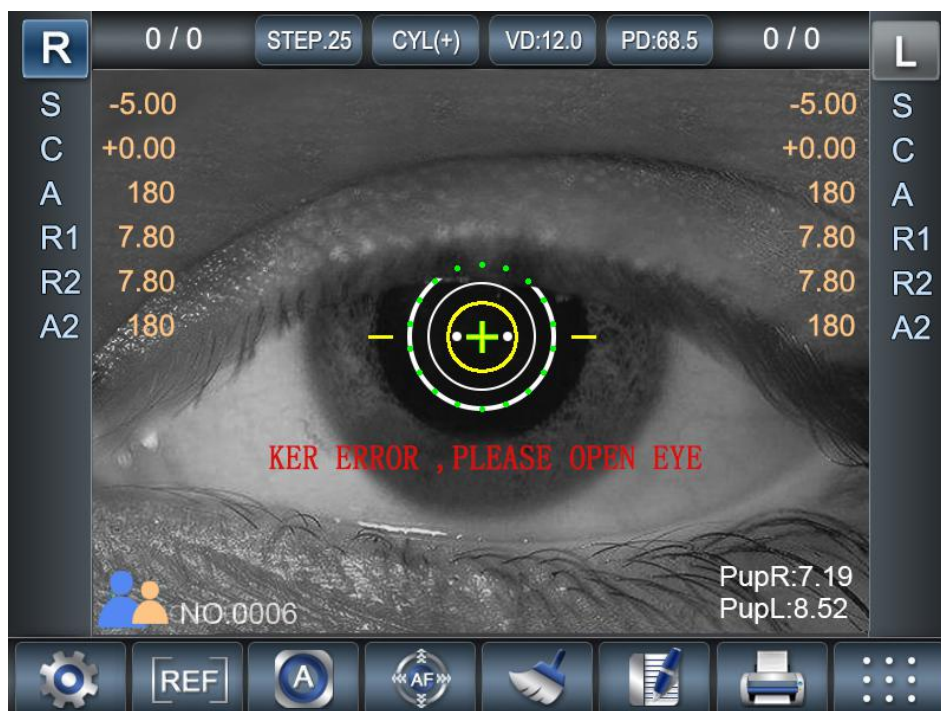
(Figure 27)

### 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 noncoincidence, 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 Chinrest not lift

Check whether the chinrest 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

The instruments that have been scrapped, should be strictly deposited in accordance with the requirements of 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	Chinrest Paper	1
7	Cleaning Cloth	1
8	Printing Paper	1
9	Fuse	2
10	Chinrest Pin	2



**Fiscal Year 2021**

## **FDA Registration Confirmation**

**Manufacturer:** SHANGHAI TOP VIEW INDUSTRIAL CO.,LTD

**Address:** No.3388 GongHeXin Road,JingAn Shanghai , CN 200436

**US Agent:** Regrek LLC

**Address:** 19 Holly Cove Ln.,Dover, Delaware, 19901, UNITED STATES

**The facility registration and device listing information:**

**Registration Number:**3012707847 **Owner/Operator Number:** 10059986

**Device Listing#:** See annex

This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a attestation of registration, nor does the U.S. Food and Drug Administration recognize a attestation of registration.

  
Authorized Signature(s)

Signature:

Place: China/ Shanghai

Expiration Date: Dec. 31. 2021





# FDA Registration Confirmation

## ANNEX:

Listing No	Code	Device Name
D345115	HKO	Refractometer, ophthalmic (TPV800 handheld refractor; TPV series auto refractometer)
D345116	HKN	Refractor, manual, non-powered, including phoropter (phoropter)
D345117	HKZ	Sterilizer, tonometer (TPV500 tonometer)
D345118	PJZ	Camera, ophthalmic, general-use (Hand-held Fundus Camera; TPV series Digital Fundus Camera)
D345119	PUE	Biomicroscope, slit-lamp, AC-powered, exempt (TPV series slit lamp)
D345120	HRJ	Table, instrument, powered, ophthalmic (Ophthalmic unit)
D345121	HLM	Instrument, measuring, lens, ac-powered (TPV series lens meter)
D345122	HPA	Frame, trial, ophthalmic (trial frame)
D345123	HPC	Set, lens, trial, ophthalmic (trial lens set)
D345124	HOX	Chart, visual acuity (visual charter)
D345125	HPT	Perimeter, automatic, ac-powered (perimeter)
D345341	HOS	Projector, ophthalmic (projector charter)
D345342	HLH	Pupillometer, manual (pupillometer)
D345343	HRM	MICROSCOPE, OPERATING & ACCESSORIES, AC-POWERED, OPHTHALMIC (operating microscope)



D345344	KZA	DEVICE, VEIN LOCATION, LIQUID CRYSTAL (vein finder)
D366893	HLJ	Ophthalmoscope, battery-powered (ophthalmoscope retinoscope)
D366894	MDM	INSTRUMENT, MANUAL, SURGICAL, GENERAL USE (ophthalmic surgical instrument)
D366895	MMQ	Topographer, corneal, ac-powered (cornealtopographer)

END OF THE ANNEX

  
Authorized Signature(s)

Signature:

Place: China/ Shanghai

Expiration Date: Dec. 31. 2021



# Alibaba.com verified Supplier



## Assessment Report

*Presented to*

**Shanghai Top View Industrial Co., Ltd.**

**上海拓扑威实业有限公司**

Gold Supplier & Assessed Company Relationship:	<input checked="" type="checkbox"/> Self-owned <input type="checkbox"/> Wholly Owned <input type="checkbox"/> Shareholder/Partner <input type="checkbox"/> Cooperation Partner
Company Address	Room 906, Yongding Plaza, No. 3388, Gonghe New Road, Jingan District, Shanghai, China
City / Country:	Shanghai / China
Consigner of Assessment:	Alibaba
Gold Supplier Member ID:	shtopview
Gold Supplier Company Name:	Shanghai Top View Industrial Co., Ltd.
Contact Person:	Mr. Tao Shangguan
Phone Number:	0086-21-61178155
Fax Number:	N/A
Email:	info@shtopview.com
Website Address (URL):	<a href="https://shtopview.en.alibaba.com">https://shtopview.en.alibaba.com</a>

*Service Provided by Intertek*

*Report No.: 22069995\_T*





Alibaba.com Verified Supplier  
Assessment Report

Report No.: 22069995\_T

Report Number:	22069995_T	Assessment Type	Trading Assessment
Date of Assessment:	31/Aug./2021	Report Date:	31/Aug./2021
Assessor's Name:	Zad Zhang	Validity Period:	01/Sep./2021 - 31/Aug./2022
Reviewed By:	Mack Long	Online Verification:	<a href="https://www.intertek.com.cn/ASVService/Home/IndexCN">https://www.intertek.com.cn/ASVService/Home/IndexCN</a>

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## Section 1: Company Overview

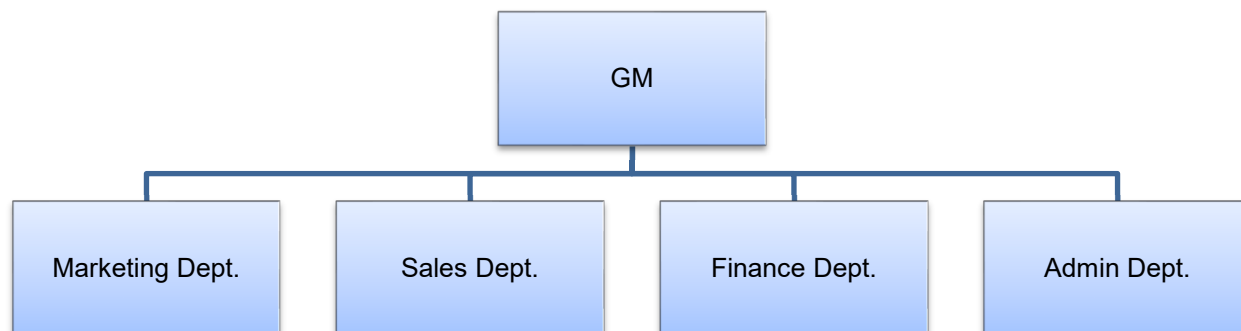
Company Overview			
1.1 Legal Validity			
Does the company have a valid business license?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Business License Number:	9131011506602810 2F
Year Established:	18/Apr./2013	Validity Period:	18/Apr./2013-17/Apr./2033
Export Experience:	8 Years	Industry Experience:	8 Years
Registered Address:	Room 150, Building 3, No. 2558, Zhouzhu Road, Pudong New Area, Shanghai, China		
Company Address:	Room 906, Yongding Plaza, No. 3388, Gonghe New Road, Jingan District, Shanghai, China		
Is It Listed Company?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Company Stock Code:	N/A
Annual review conducted by the Industrial & Commercial Bureau?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed By:	Market Supervision Administration Bureau of Pudong New Area, Shanghai
Registered Capital:	RMB 2,000,000		
Corporate Representative:	Mr. Tao Shangguan		
Industry:	Optical Instrument		
Business Type:	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Trading Company <input type="checkbox"/> Manufacturer & Trading Company		
Type of Ownership:	<input checked="" type="checkbox"/> Private Owner <input type="checkbox"/> Public Company <input type="checkbox"/> Joint Venture <input type="checkbox"/> Stated Owned <input type="checkbox"/> Sole Proprietorship <input type="checkbox"/> Other		
Products /Service:	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer		
1.2 Company Building Information			
Certification Type: <input type="checkbox"/> Land Certification <input type="checkbox"/> Real Estate Certification <input checked="" type="checkbox"/> Lease Agreement <input type="checkbox"/> Factory Officer Claimed			
Total Building Size:	326 m2		
Office Size:	326 m2		



## Section 2: Human Resources

### Human Resources

#### 2.1 Company Chart



#### 2.2 Employee Headcount

Department Name	Full Time Employee(s)	Part-Time Employee(s)	Total
GM	1	0	1
Marketing Dept.	4	0	4
Sales Dept.	8	0	8
Finance Dept.	1	0	1
Admin Dept.	1	0	1
<b>Total Number:</b>	15	0	15

#### 2.3 Management

Department	Name	Title	Education	Year(s) in Current Company
Confidential	Confidential	Confidential	Confidential	Confidential



## Section 3: Current Export Situation

Current Export Situation						
There are <u>8</u> foreign trading employee(s) in the company.						
<b>Working Experience</b>	<b>Headcount</b>		<b>Accepted Language</b>	<b>Listening &amp; Speaking</b>	<b>Reading &amp; Writing</b>	
	Over 30 Years	0	English	Yes	Yes	
	21-30Years	0	N/A	N/A	N/A	
	11-20 Years	0	N/A	N/A	N/A	
	6-10 Years	0	N/A	N/A	N/A	
	2-5 Years	8	N/A	N/A	N/A	
	Less than 2 years	0	N/A	N/A	N/A	
Does the company have a valid export license?			<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
Export License Registration No.:			01314518			
Total Revenue (Previous Year, USD):			Confidential			
Total Export Revenue (Previous Year, USD):			c			
Estimated Export Revenue (Current Year, USD):			Confidential			
Trade Agents Employed Overseas:			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
Nearest Port:			Shanghai Port			
Accepted Payment Terms			<input checked="" type="checkbox"/> FOB <input checked="" type="checkbox"/> CIF <input checked="" type="checkbox"/> EXW <input checked="" type="checkbox"/> CFR			
Accepted Payment Type:			<input checked="" type="checkbox"/> L/C <input checked="" type="checkbox"/> T/T <input checked="" type="checkbox"/> Credit Card <input checked="" type="checkbox"/> Cash <input checked="" type="checkbox"/> West Union <input checked="" type="checkbox"/> Money Gram <input checked="" type="checkbox"/> Paypal <input checked="" type="checkbox"/> Moneybookers			
Average lead time from product order confirmation to production delivery (products exiting the factory):						
Product Category			Num	Unit		
Auto Lens Meter			3	Days		
Slit Lamp			3	Days		
3D Auto Lens Edger			3	Days		
Rebound Tonometer			3	Days		
Auto Refractometer			3	Days		
Average Sampling Time						
Product Category			Lead Time			
Auto Lens Meter			3 Days			
Slit Lamp			3 Days			
3D Auto Lens Edger			3 Days			



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Rebound Tonometer	3 Days
Auto Refractometer	3 Days
The Shortest Sampling Time	
Product Category	Shortest Lead Time
Auto Lens Meter	3 Days
Slit Lamp	3 Days
3D Auto Lens Edger	3 Days
Rebound Tonometer	3 Days
Auto Refractometer	3 Days



## Section 4: Export Business Capacity

Export Business Capacity			
4.1 Market Distribution (Previous 12 Months)			
Market	Main Product(s)	Revenue (USD)	Total Revenue (%)
North America	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	5
South America	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	50
Eastern Europe	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	2
Southeast Asia	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	5
Africa	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	5
Oceania	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	2
Mid East	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	5
Eastern Asia	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	5
Western Europe	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	10
Central America	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	2



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Northern Europe	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	2
Southern Europe	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	2
South Asia	Auto Lens Meter, Slit Lamp, 3D Auto Lens Edger, Rebound Tonometer, Auto Refractometer	Confidential	5

**4.2 Main Clients**

Client Name	Main Product(s)	Total Revenue (%)
Confidential	Confidential	Confidential



## Section 5: Quality Assurance

Quality Assurance						
5.1.1 Quality Management System Certification						
Certification	Certified By	Certificate No.	Business Scope	Validity Date		
N/A	N/A	N/A	N/A	N/A		
5.1.2 Product Certification						
Certification	Certified By	Certificate No.	Product Name & Model No.	Validity Date		
N/A	N/A	N/A	N/A	N/A		
5.2 Supplier Management						
Item	Content	Observations /Comments				
5.2.1	Does the company have a supplier assessment procedure?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No				
5.2.2	Does the company have an updated list of approved suppliers?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No				
5.2.3	Has the company established and implemented a standard procedure for purchasing contract review and approval?	<input checked="" type="checkbox"/> Yes, with written standard procedures <input type="checkbox"/> Yes, with written procedure but lack of consistent standard <input type="checkbox"/> No				
5.2.4	Does the company keep its supplier assessment reports?	<input checked="" type="checkbox"/> Yes, assessment reports are available for more than 3 years <input type="checkbox"/> Yes, assessment reports are available for the last 1-3 years <input type="checkbox"/> Yes, assessment reports are available for the previous 12 months <input type="checkbox"/> No				
5.2.5	Are the company's purchasing documents sufficient to ensure product safety control and their customers' requirements?	<input checked="" type="checkbox"/> Yes, the purchasing document includes all the information required <input type="checkbox"/> Yes, however the purchasing document includes incomplete information <input type="checkbox"/> No				
5.2.6	Is there a procedure to conduct random product inspections after final packaging?	<input checked="" type="checkbox"/> Yes, with clear standard and written inspection records <input type="checkbox"/> Yes, with inspection records but no procedures <input type="checkbox"/> Yes, with procedures but no inspection records <input type="checkbox"/> No, inspections are not necessary				
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5.3 After Sales Service		
Item	Content	Observations /Comments
5.3.1	Is customer feedback, including complaints, clearly recorded and maintained?	<input checked="" type="checkbox"/> Yes, with a standard feedback form and records <input type="checkbox"/> Yes, with a standard feedback form but no records <input type="checkbox"/> Yes, with records but no standard feedback form <input type="checkbox"/> No
5.3.2	Are there any clear procedures for handling customer complaints?	<input checked="" type="checkbox"/> Yes, with clear procedures and written records <input type="checkbox"/> Yes, with clear procedures but no written records <input type="checkbox"/> Yes, with written records but no clear procedures <input type="checkbox"/> No
5.3.3	Is there a closed-loop corrective action system in place?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.3.4	Can finished/package products be traced by lot identification to the appropriate raw material test reports?	<input checked="" type="checkbox"/> Yes, with procedures to trace raw materials <input type="checkbox"/> Yes, main raw material can be traced <input type="checkbox"/> No, only the production date can be traced <input type="checkbox"/> No
5.3.5	Is there a product alert and recall procedure?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.3.6	Do you have a complete after sales service capability?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.4 Overseas After Sales Service		
5.4.1	Is it possible to provide expatriate engineer services?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.4.2	If possible provide expatriate engineer,what kind of onsite after-sales services are included?	<input checked="" type="checkbox"/> Debugging <input checked="" type="checkbox"/> Maintain <input checked="" type="checkbox"/> Repair <input type="checkbox"/> Other



## Section 6: R & D Capacity

R&D Capacity						
6.1 Current Situation						
There is <u>0</u> R&D engineer(s) in the company.						
Education Level	Headcount		Work Experience	Headcount		
Doctorate	0		Over 30 Years	0		
Post-Graduate	0		21-30 Years	0		
Graduate	0		11-20 Years	0		
Junior College	0		6-10 Years	0		
Technical School	0		2-5 Years	0		
High School	0		Less than 2 years	0		
Patent Situation						
Patent No.	The Name of the Patent	The Patent Type		Available Date		
N/A	N/A	N/A		N/A		
Brand Situation						
Registration/ap plication No.	Brand Name	For Approval to Use Goods	Validity Date	Ref.		
27928760	Refer to Photo	Category: 9	14/Nov./2018- 13/Nov./2028	Photo in Section 8 (Trademark Photos)		
The Average Time For New Products Launched						
Product Category		Num	Unit			
N/A		N/A	N/A			
The Shortest Time For A New Item Launched						
Product Category		Num	Unit			
N/A		N/A	N/A			
Does the company provide ODM service for others?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				
Are there relevant design input/output, review, and verification documents available for the assessment company?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				
Based on inspection, are R & D employees equipped with adequate specialized equipment?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				
If yes, please list all key equipment used:		N/A				



Do R& D employees use any specific software for designing new products?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, please list the main software used:	N/A
Please list all certifications and/or qualifications of the R & D department:	N/A
Has the company established standard design procedures for new products?	<input type="checkbox"/> Yes, with clear written instructions <input type="checkbox"/> Yes, without written instructions <input checked="" type="checkbox"/> No
Have the designed products been internal verified or validated?	<input type="checkbox"/> Yes, with clear written records <input type="checkbox"/> Yes, only part written records <input type="checkbox"/> Yes, without written records <input checked="" type="checkbox"/> No
Have the designed products been tested by a third-party inspection body?	<input type="checkbox"/> Yes, all designed products have been tested <input type="checkbox"/> Yes, only part of designed products have been tested <input checked="" type="checkbox"/> No
Are the designed products confirmed by the customers?	<input type="checkbox"/> Yes, all designed products have been confirmed <input type="checkbox"/> Yes, part of designed products have been confirmed according to client's requirements <input checked="" type="checkbox"/> No
Does the company has qualification requirements for designers?	<input type="checkbox"/> Yes, with written job description <input type="checkbox"/> Yes, without written job description <input type="checkbox"/> No, but at least two years design experience is needed <input checked="" type="checkbox"/> No
Are the designers' qualifications recognized by the company?	<input type="checkbox"/> Yes, with written records <input type="checkbox"/> Yes, without written records <input checked="" type="checkbox"/> No
What level of design services are provided?	<input checked="" type="checkbox"/> Only add logo/change color/material <input type="checkbox"/> Sample processing <input type="checkbox"/> Graphic processing <input type="checkbox"/> Create an entirely new product

**New Products Launched quantity for each year**

Product Category	Num	Unit
N/A	N/A	N/A

**6.2 R&D Real Case Description**

<b>Customer's Name</b>	N/A
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Customer's Location	N/A	
Customer's Industry:	N/A	
Order's Requirement Description:	N/A	
6.3 Design Process		
Process 1	Process 2	Process 3
N/A	N/A	N/A
Description: N/A	Description: N/A	Description: N/A
6.4 Design Devices		
Device 1	Device 2	Device 3
N/A	N/A	N/A



## Section 7: Company Development / Expansion Plans

Company Development / Expansion Plans		
Item	Company Development Action	Timeframe
1	The organization is going to develop more markets.	1 Year



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## Section 8: Certification & Photos

### Certification & Photos

#### Certification & Photos -- Business License (Original)



#### Certification & Photos -- Business License

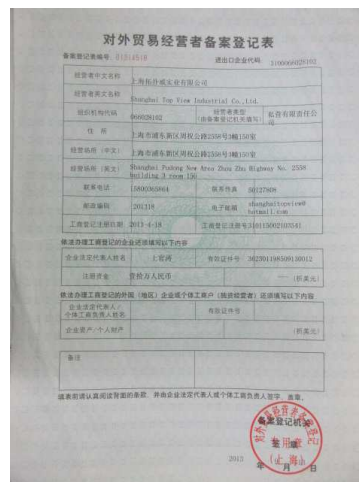
#### (Duplicate) with Certificate / Records of Annual Inspection



#### Certification & Photos -- Permit for Opening Bank Account



#### Certification & Photos -- Import and Export Enterprise Registration



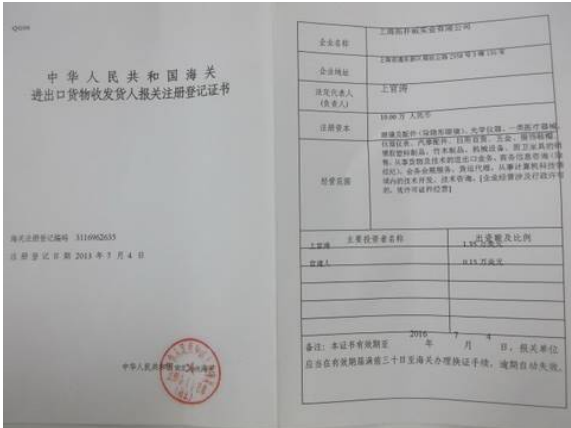

#### Certification & Photos -- Custom Clearance Registration Form

#### Certification & Photos -- N/A







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		N/A	
<b>Patent Photos</b>			
<b>Certification &amp; Photos –N/A</b>		<b>Certification &amp; Photos –N/A</b>	
N/A		N/A	
<b>Product Certification Photos</b>			
<b>Certification &amp; Photos --</b>		<b>Certification &amp; Photos --</b>	
N/A		N/A	
<b>Quality Management System Certification Photos</b>			
<b>Certification &amp; Photos --</b>		<b>Certification &amp; Photos --</b>	
N/A		N/A	
<b>Trademark Photos</b>			
<b>Certification &amp; Photos -- Tardemark</b>		<b>Certification &amp; Photos -- N/A</b>	
		N/A	

## Section 9: Company and Product Samples

Company and Product Samples	
<b>Company Gate</b> 	<b>Office</b> 
<b>Product Sample- Auto Lens Meter</b> 	<b>Product Sample- Slit Lamp</b> 
<b>Product Sample-3D Auto Lens Edger</b>	<b>Product Sample- Rebound Tonometer</b>





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Product Sample- Auto Refractometer



N/A



N/A



## Section 10: Competitive Advantages

<b>10.1 Product Group Capacity</b>		
<b>10.1.1 Products Sold (Within 12 Months)</b>		
<b>Products Name</b>	<b>Quantity</b>	<b>Revenue (USD)</b>
Auto Lens Meter	400 Sets	Confidential
Slit Lamp	150 Sets	Confidential
3D Auto Lens Edger	70 Sets	Confidential
Rebound Tonometer	300 Sets	Confidential
Auto Refractometer	500 Sets	Confidential
<b>10.1.2 Suppliers Cooperated With (Within 12 Months)</b>		
No. of cooperation suppliers (total)	Confidential	
No. of suppliers (which cooperated over 2 times)	Confidential	
No. of provinces which cooperation suppliers belong to	Confidential	
Would the company like to provide design solution service for integration project?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, these projects include	According to client requirement	
Would the company like to provide a total solution for purchasing?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Part, _____ <input type="checkbox"/> No	
If yes, please describe it	According to client requirement	
<b>10.1.3 Real Case Description:</b>		
Customer Name	Confidential	
Customer Country	Confidential	
Customer Region	Confidential	
Products Category	Confidential	
Order Value (USD)	Confidential	
Order Processing Process	Confidential	
Customer's Feedback	Confidential	
<b>10.2 Real Case for Lower MOQ &amp; Lead Time</b>		
<b>Products Name</b>	<b>MOQ (In the last 12 Months)</b>	<b>Shortest Lead Time</b>
Auto Lens Meter	Confidential	Confidential
Slit Lamp	Confidential	Confidential
3D Auto Lens Edger	Confidential	Confidential
Rebound Tonometer	Confidential	Confidential



Auto Refractometer	Confidential	Confidential			
MOQ (In the last 12months)	<input checked="" type="checkbox"/> Less than 10 <input type="checkbox"/> 10-20 <input type="checkbox"/> 20-50 <input type="checkbox"/> 50-100 <input type="checkbox"/> 100-300 <input type="checkbox"/> More than 300				
10.3 Real Case for Large Contract					
Products Name	Order (In the past 12 Months)	Shortest Lead Time			
Auto Lens Meter	Confidential	Confidential			
Slit Lamp	Confidential	Confidential			
3D Auto Lens Edger	Confidential	Confidential			
Rebound Tonometer	Confidential	Confidential			
Auto Refractometer	Confidential	Confidential			
10.4 Overseas after-sales service capacity					
If yes, what onsite after-sales services are included	N/A				
Equipment -installation, maintenance and other services	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				
Technical advice	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				
Personnel training	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				
Other:	N/A				
Average response time:					
Num	Unit				
N/A	N/A				
10.5 After-sales service capacity					
Average Guarantee Time					
Product Category	Num	Unit			
Auto Lens Meter	1	Year			
Slit Lamp	1	Year			
3D Auto Lens Edger	1	Year			
Rebound Tonometer	1	Year			
Auto Refractometer	1	Year			
The Longest Guarantee Time					
Product Category	Num	Unit			
Auto Lens Meter	1	Year			
Slit Lamp	1	Year			
3D Auto Lens Edger	1	Year			
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Rebound Tonometer	1	Year
Auto Refractometer	1	Year
Does the company accept small order?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	



## Section 11: Service Capabilities

<b>11.1 Experience with Large-scale Procurement Contracts</b>		
Have you had a procurement contract with a Fortune 500 company?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Do you have an overseas onsite service center?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
The country/region of your overseas service center		N/A
<b>11.2 Overseas Showroom</b>		
Do you have an overseas showroom?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Country/Region		N/A
<b>11.3 Offline Trade Show</b>		
Have you participated in offline trade shows?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Tradeshow name	CHINA (SHANGHAI) INTERNATIONAL OPTICS FAIR	Official images from the trade show
Date attended	11/Feb./2020	Confidential
Host Country/Region	Other China	



## Section 12: Supply Chain Capability

<b>12.1 Centralized Procurement</b>	
In the past 12 months, have you sold products from at least three sub-categories?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>12.2 Overseas Warehouse</b>	
Do you have an overseas warehouse?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Country/Region	N/A

-- End of Report --