Auto Refractometer

AR-7610 Auto Refractometer ARK-7610 Auto Ref/Keratometer

Feature:

- New optical system, unique imaging impression
- Hartman imaging analyzing and processing technology, accurate measurement result
- TFT touch screen, can move front and back freely Motorized chin rest
- Manual focusing, auto measuring ٠
- The most cost-effective Hartmann refrac(kera)tometer in the world. •

Adjustable LCD Touch Screen



High brightness and contrast 7" wide color TFT LCD screen, smooth touch mode, different angle can be adjusted

Hartmann imaging processing technology





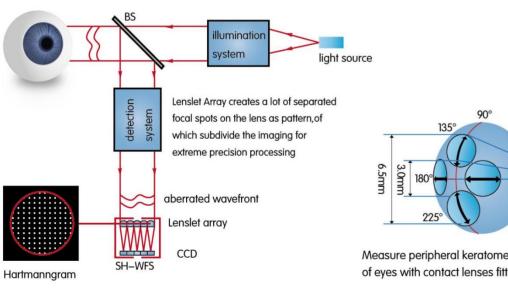
By pressing the Up & Down buttons, the users can set and adjust the height of the patient's chin freely and quickly

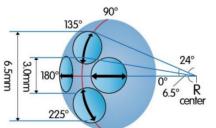


Data Record



3 groups of data stored each measurement, maximum 10 groups of data can be stored





Measure peripheral keratometry precision of eyes with contact lenses fitting

Departion interface function



Intuitive icons provide the user an easier operating circumstances, and make the measurement become more convenient and the data to be measured more accurate and fast

Technical Data	
Vertex Distance(VD)	0.0, 12.0, 13.75, 15.0
SPH	30.00D~+25.00D (VD=12mm
CYL	0.00D~t 10.00D (0.06, 0.12,
Axis(AX)	10 ~180 (10 Unit)
Cylinder Form	—, +, ±
Puiple Distance(PD)	10~86mm
Minimum Pupil Diameter	2.0mm
Measuring Time	< 0.5s
Pupil Diameter	2.008.00mm
Measuring Light Energy	< 30uw (Insure measuring sa
Radius of Curvature	5.0~ 10.0mm (0.01mm Unit)
Corneal Power	33.00D~67 00D(In case that t
Corneal Astigmatism	0.00D~-15.00D(0.06D/0.12
Data Storing	Each 10 measured values of le
Axis	1°~180°
Chart	Auto fog
Monitor	7" TFT LCD touch screen (Ang
Built-in Printer	57mm thermal printer



n, 0.01, 0.06, 0.12, 0.25 Unit) 0.25 Unit)

fety) the comneal equivalent refractive power is 1.3375) 2D/0.25D Unit) left eyes and right eyes

gle of view adjustable)

NANJING REDSUN OPTICAL CO., LTD.



ADD: 18-304 South of XishangQiao Road of Yuhua Nanjing,China

TEL:0086-25-58575880

DECLARATION OF CONFORMITY (F

We, the manufacturer:

Nanjing Redsun Optical Co.,Ltd. NO.18 South of Xishangqiao Road of Nanjing, China. Tel: 0086-25-58575880

EU Representative: LUXUS LEBENSWELT GMB

Address: KOchstr.1, 47877, Willich, Germany

Declare under our sole responsibility that:

Product: Auto Refractometer Model Name: AR7610 Product Group: Ophthalmic Equipment Classification: Class I (in compliance with Annex VIII, RULE 1,, Medical Device

Regulation) Are in conformity with:

Essential Requirements of European Directive(s):

Medical Device Regulation (EU) 2017/745

.......................

Standard(s):EN60601-1:2006+A1:2013 ISO9001:2008

Test report(s):TRS15060065 ISO13485:2003

The compliance with the European Directive (2017/745C) is under the monitoring of the Notified Body: For and behalf of

NANJING REDSUN OPTIC Signature: Helen He

anager 2022-5-5

Sale

Authorized Signature



REGISTRATION NO. 04717Q10000369

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Nanjing Redsun Optical Co., Ltd.

Registered Address: No.18 South of Xishangqiao Road of Nanjing City, Jiangsu ,China. Manufacturing Address: No.18 South of Xishangqiao Road of Nanjing City, Jiangsu,China

Has been assessed and conformed to the following standard(s) YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, Development, Production and Service of Slit Lamp, Perimeter, Ophthalmic Ultrasound A/B Scan, Automatic computer perimeter, Fundus Camera, Handheld Slit Lamp. Phaco Emulsification, Operation Microscope, Auto Refractometer, Phoropter, Ophthalmic Laser and other machines.

> Date of issue: October 20, 2021 Date of expiry: October 19, 2024

General Manager:

ger: Sal

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (munu and a core ditation administration of the People's Republic of



AR(K)7610 Auto Refracto-Keratometer User's Manual



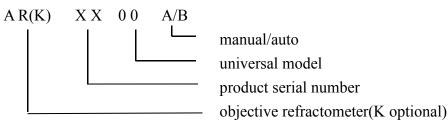
Please be sure to read this manual carefully before using the instrument and keep it handy for ready reference.

Thanks for your choice and use of this instrument. **ARK7610**Auto RefracKeratometer 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 phoroptor (fit to RS232 interface)). If the auto phoroptor can output data, this instrument**ARK7610** can directly print out the measured optometry data by auto photoptor.

Model No./Specifications

Item No.	Spec.(L x W x H)	Input Power	Display	Remarks
	(mm x mm x mm)	(VA)		
AR7610	750×400×580	60	TFT Color	Wavefront
			LCD	Aberration(Manual)
ARK7610	750×400×580	60	TFT Color	Wavefront Aberration
			LCD	Corneal Curvature(Manual)

Refractometer Named



Refractometer Division Description

The serial refractometers 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 MANUFA-

CTUTER 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 ARK7610 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.
- 6. The ME EQUIPMENT are not serviced or maintained while in use with the patient

7. Do not posit the equipment to make it difficult to operate the power plug which uses to isolate 8.the equipment circuits electrically form the supply mains.

8. No modification of this equipment is allowed.

1.1 Electromagnetic Emission Guide and Manufacturer Statement(Form1)

Guide and manufacturer's statement—Electromagnetic emission

[**Prototype ARK7610**] 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 CISPR11	Group 1	[Prototype ARK7610] 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 CISPR11	Class B	[Prototype ARK7610] Applicable for all of the facilities in use, including the
Harmonic emission IEC61000-3-2	Not applicable	home and the direct connection of residential public low voltage power
Voltage fluctuation/Flicker emission IEC61000-3-3	Not applicable	supply network.

1.2 Electromagnetic Immunity Guide and Manufacturer Statement (Form2)

Guide and manufacturer's statement—Electromagnetic immunity [Prototype ARK7610] 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 IEC60601 Test Electromagnetic Immunity Meet Level Test Environment—Guide Level The ground should be wood, ±6kV $\pm 6 kV$ Electrostatic concrete or ceramic tile, if the contact discharge contact discharge ground is covered with discharge IEC61000-4 synthetic material, the relative $\pm 8 kV$ $\pm 8 kV$ humidity should be at least -2 air dischange air dischange 30%

Electric fast transient pulse group IEC61000-4 -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 IEC61000-4 -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 IEC61000-4 -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 [Prototype ARK7610] to continuously run during power supply interruption, then it's recommended the [Prototype ARK7610] is powered by a constant power supply or battery
Power frequency magnetic field (50Hz) IEC61000-4 -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

Note : Ut 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 ARK7610**] 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 IEC61000-4-6 Radio frequency radiation IEC61000-4-3	3 V (effective value) 150 kHz ~ 80 MHz 3 V/m 80 MHz ~ 2.5 GHz	3V (effective value) 3 V/m	Portable or mobile radio frequency communication equipment should not be used closer to any part of [Prototype ARK7610] 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 In formula : P — Maximum output rated power of the transmitter provided by th (())) ufacturer, 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 ^a of electromagnetic field, in each frequency range ^b should be lower than Meet Level. Interference may occur near the devices marked with

- 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.

^a 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

ARK7610] place is higher than above applicable RF Meet Level, [**Prototype** ARK7610] 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** ARK7610]

^b in the entire frequency range of 150 kHz \sim 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** ARK7610] (Form 4)

The recommended isolation distance between portable and mobile radio frequency communication equipments and [**Prototype ARK7610**]

[Prototype ARK7610] 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** ARK7610]

	Isolation distanc	e of different freque	ncy of transmitter/m
Maximum output rated power of transmitter: W	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

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

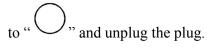
frequency bands

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

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.
- 2.1.11 Once finish the measurement, turn off the ME equipment by switching the switch



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 WS310-2, 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.

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)





3.2 Power Line Inlet and RS232 Interface (Figure 2, 3)

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





Figure3

Power Supply Socket: AC power inlet (fuse F5AL 250V inside)

Data Interface: RS232\USB interface to be connected with other equipments (This refractometer and the automatic phoroptor serials connected should comply with the related electrical requirements inIEC60601-1-1-2000)

3.3 Chinrest Paper Installation

Use the specified chinrest paper (Figure 4)

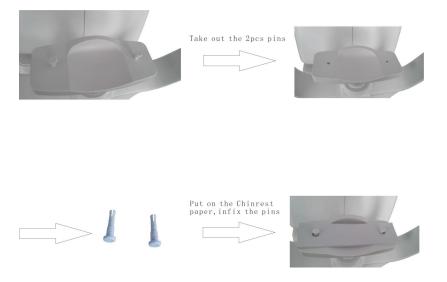
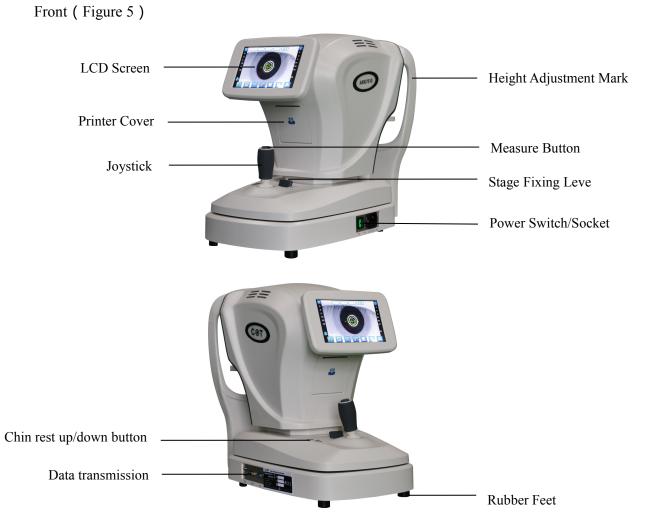


Figure 4

4. FUNCTIONS OF THE MAJOR COMPONENTS



(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 Power Switch/Socket: AC power on/off with indicator light / AC power inlet (fuse F5AL 250V inside) Rubber Feet: Support and adjust the instrument horizontal Chinrest Up/Down Button: Adjust the height of the chinrest

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

Back (Figure 6)



(Figure 6)

Chinrest: The platform for placing the patients' chin, Chin support is the applied part, Adjustable eye position, The maximum weight of jaw support is 6kg 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、13.5mm、15mm

5.1.2 SPH: -20.00 m⁻¹~ +20.00 m⁻¹(VD=12mm , 0.01 m⁻¹ $, 0.06 m^{-1} , 0.12 m^{-1} ,$

 $0.25~m^{-1}$ unit), deep myopia measurement available 5.1.3 CYL: 0.00 m^{-1} \sim ±6.00 m^{-1} (0.25 m^{-1} unit)

- 5.1.4 Cylinder Form: $-, +, \pm$
- 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⁻¹ \sim 67.00 m⁻¹ (in case that the corneal equivalent refractive power is 1.3375)
- 5.1.9 Corneal Astigmatism: $0.00 \text{ m}^{-1} \sim 15.00 \text{ m}^{-1} (0.06 \text{ m}^{-1}/0.12 \text{ m}^{-1}/0.25 \text{ m}^{-1} \text{ unit})$
- 5.2 Other Performance Parameters
- 5.2.1 7"TFT touch screen (angle adjustable)
- 5.2.2 Printer: 57mm thermal printer, auto paper cutting
- 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.: 17.5kgs
- 5.2.10 G.W.: 24kgs
- 5.2.11 Dimensions: L750mm×W400mm×H580mm
- 5.2.12 The refractometer service life for 6 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 The number of power/corneal parameters measured
- 7.3 Step selection (shortcut key)
- 7.4 Astigmatism symbol selection (shortcut key)
- 7.5 VD selection (shortcut key)
- 7.6 Lattice display
- 7.7 Power display
- 7.8 Corneal value display
- 7.9 Adult//child mode selection
- 7.10 Measurement mode selection
- 7.11 Auto/manual measurement selection (partial model)
- 7.12 Auto/manual tracking and focusing selection (partial model)
- 7.13 Data clear key
- 7.14 Data record check

- 7.15 Menu set
- 7.16 Pupil alignment target
- 7.17 Left/right eye pupil diameter

8. MENU (Figure 8)



(Figure 8)

8.1 Measurement Mode Selection

Touch this key to pop up three measurement mode menu (as shown in Figure 10), 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)

8.2 Auto/Manual Measurement Selection (partial model)

Touch this key to select auto measurement mode (A) or manual measurement mode (M)

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

Touch this key to select auto tracking and focusing mode (AF) or manual tracking and focusing mode (MF)

8.4 Data Clear Key

Touch this key to clear the measurement data

8.5 Data Record Check

Touch this key to check the measurement data (directly print out the data, the measurement data won't be recorded)(Figure 9)

AX 180
180
180
180

(Figure 9)

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 Menu Set

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

- 8.6.1 Refractometry parameters setting (Figure 10)
 - 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)



- (Figure 10)
- 8.6.2 Keratometry parameters setting (Figure 11)



(Figure 11)

- MODE : Keratometry radius measurement (mm), keratometry power measurement (m⁻¹) and average value display (AVG) optional
- STEP: Keratometry power precision display

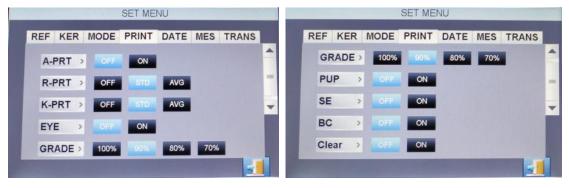
REFRACTIVE INDEX : Factory defaults to 1.3375

REF KER	MODE	PRINT	DATE	MES	TRANS
MODE	> Manual	AUTO			
BEEP	OFF	LOW	MID	н	
INT-M	REF	KER			
SHUT	5 MIN	10 MIN		60 MIN	4
BRIGHT					100

8.6.3 Mode setting (Figure 12)

- (Figure 12)
- 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 optical) (touch any key to wake up)
- 8.6.4 Printing setting and printing paper replacement (Figure 13 14)





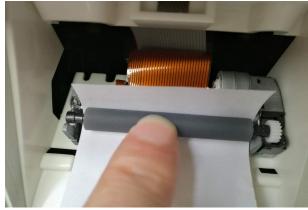


- AUTO: When ON selected, the measurement results will be printed out automatically after the both eyes measurement finished (in this case, the data is cleared automatically) When OFF selected, press the print key on panel to print out the measurement results.
- REFRACTOMETRY: When OFF selected, the 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.
- EYE: When ON or OFF selected, the refractometry state diagram will be printed or not.
- CONCENTRATION: Set the appropriate print concentration according to different thermal printing paper.
- PUPIL: When ON or OFF selected, the pupil diameter will be printed or not.
- SE: When ON or OFF selected, SE data (the approximate value of cylinder power converted into sphere power) 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 15)

- 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 15)

```
8.6.5 Data setting (Figure 16)
```

			SET ME	NU		
REF	KER	MODE	PRINT	DATE	MES	TRANS
DI	SP >	YMD	MDY	DMY		
DA	TE		M:08	D:17		
TIN	/IE >		M:44	S:36		
co	UNT >		ON			
No	. >					
		1000			1000	

(Figure 16)

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, press ENT key to confirm and preserve, press RETURN key to quit. Press BS key to delete one by one, press C key to clear all. (Figure17)

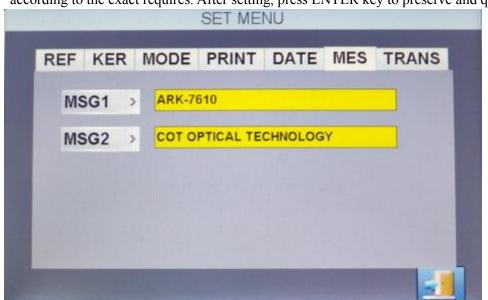
REF KEF	2	MODE	PRINT	DAT	IN	PUT	DATA	
DISP	>		MDY	DM	2021			
DATE	>		M:08	D:1	-7	18	.9	
TIME	>		M:44	S:3		5	6	13
COUNT	>		ON		1	2	-	be
No.	>	0001			1	a.	-	

(Figure17)

8.6.6 Printing message setting (Figure 18)

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.



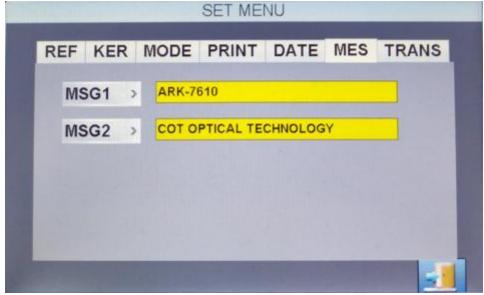
(Figure 18) Touch the yellow blank space to enter the message editing menu (Figure 19)

REF	K	ER	MOI	DE	PRIN	Т	DATE	M	ES	TRA	NS
ARK-	7610										
1	2	3	4	5	6	7	8	9	0		+
Q	w	E	R	T	Y	U	1	0	P	SPA	CR
A	S	D	F	G	H	J	к	L		@	BS
z	x	С	V	в	N	М			A/a	EN	TER

(Figure 19)

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

8.6.7 Data transfer setting (Figure 20)



(Figure20)

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. 8.7 Shortcut Key

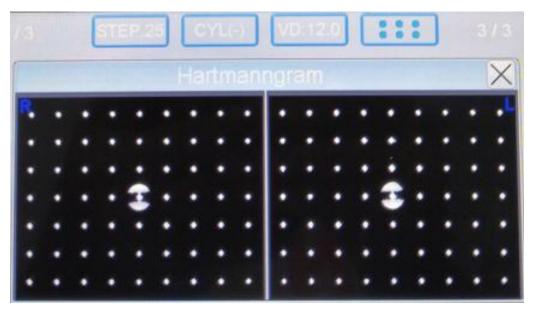
8.7.1 Step set: successively touch STEP key to quickly switch 0.01, 0.06, 0.12, 0.25 steps

8.7.2 CYL axis set: successively touch CYL key to quickly switch —, +, \pm

8.7.3 VD set: successively touch VD key to quickly switch 0, 12, 13.5, 15

8.7.4 Array display: touch array key to display the patient's fundus array distribution (indirect

evaluation of fundus imaging quality). (Figure.21)



(Figure.21)

9. MEASUREMENT

Suitable crowd and contraindication

Target patients for adults and children, and crowd of eye power range (-20 m⁻¹ \sim +20 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.22)



(Figure.22)

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.23,24)

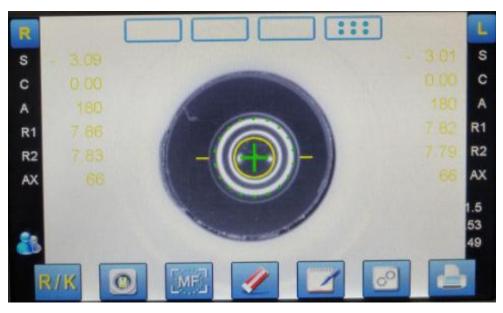


(Figure.23 away from patient's eye)

(Figure.24 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 split 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.25) 。

(Figure.25)

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 26)



(图26)

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 27 28).



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 deseased

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 be scrapped, should be strictly deposed in accordance with the requirements of local laws and regulations

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

13. ENCLOSURE ACCESSORIES

14. SUPPLEMENTARY NOTES

Operator's safe termination of equipment operation steps, After closing the switch, pull out the plug and put on the dust cover

The disposable CR2032 battery in the refractometer shall be replaced by the manufacturer's engineer