

ophthalmic optical biometer

manual



Chongqing Bio New Vision Medical Equipment Co., Ltd.

foreword

Thanks for choosing our products, and I would like to express my gratitude. In order to use this device reasonably, please read the manual carefully before use.

If you have any ambiguity or disagreement with any content or terms of this manual, or if you encounter technical problems during use, please contact our company or authorized dealers.

【Medical device registration certificate number】

【Production license number】 Chongqing Food and Drug Administration Production No.

【Registrant name】 Chongqing Bio New Vision Medical Equipment Co., Ltd.

【 R e s i d e n c e 】 2nd floor of building #5, 27 Fengsheng Road, Jinfeng Town, High-Tech Industrial Development Zone, 401329 Chongqing, People' s Republic of China.

【Production address】 2nd floor of building #5, 27 Fengsheng Road, Jinfeng Town, High-Tech Industrial Development Zone, 401329 Chongqing, People' s Republic of China.

【After-sales service company】 Chongqing Bio New Vision Medical Equipment Co., Ltd.

【 C o n t a c t 】 phone number: 023-65456668 zip code:401329

【production date】 see nameplate

【Period of use】 5 years
【Authorized date】 2021.01
【Revision date】 -
【 v e r s i o n 】 01

 warning

please read this manual carefully before use;

AC power must be disconnected while equipment is being cleaned;

Do not open the device without permission;

Indoor use only.

catalogue

1 product introduction	1
2 product structure	9
3 basic operation	12
4 cleaning, maintenance and preventive inspections	22
5 precautions	24
6 common faults and causes	25
7 transport and storage	26
8 environmental protection	28
9 electromagnetic compatibility	29
10 manufacturer's responsibility	36

1 Product introduction

1.1 product name

ophthalmic optical biometer

1.2 model

1.3 range of application/intended use

Used to measure corneal diopter, astigmatism axis, eye axis length, central corneal thickness, anterior chamber depth, white-to-white distance, pupil diameter and calculate intraocular lens power.

1.4 contraindications

no

1.5 working principle

The ophthalmic optical biometer is based on the principle of optical low coherence reflection (OLCR). It used a beam emitted by an ultra-bright diode and is divided into two beams. One beam passes through the eye to obtain backscattered light signals of different depths of tissue, and the other beam passing through the reference arm, it is reflected into the optical receptor at the same time. When the two beams of light meet, if the difference in the path distance between the two beams of light is less than the interface length, the optical receptor can measure the interference signal, according to the measured distance of the position of the mirror in the interferometer is equivalent to the optical path from the cornea to the retina.

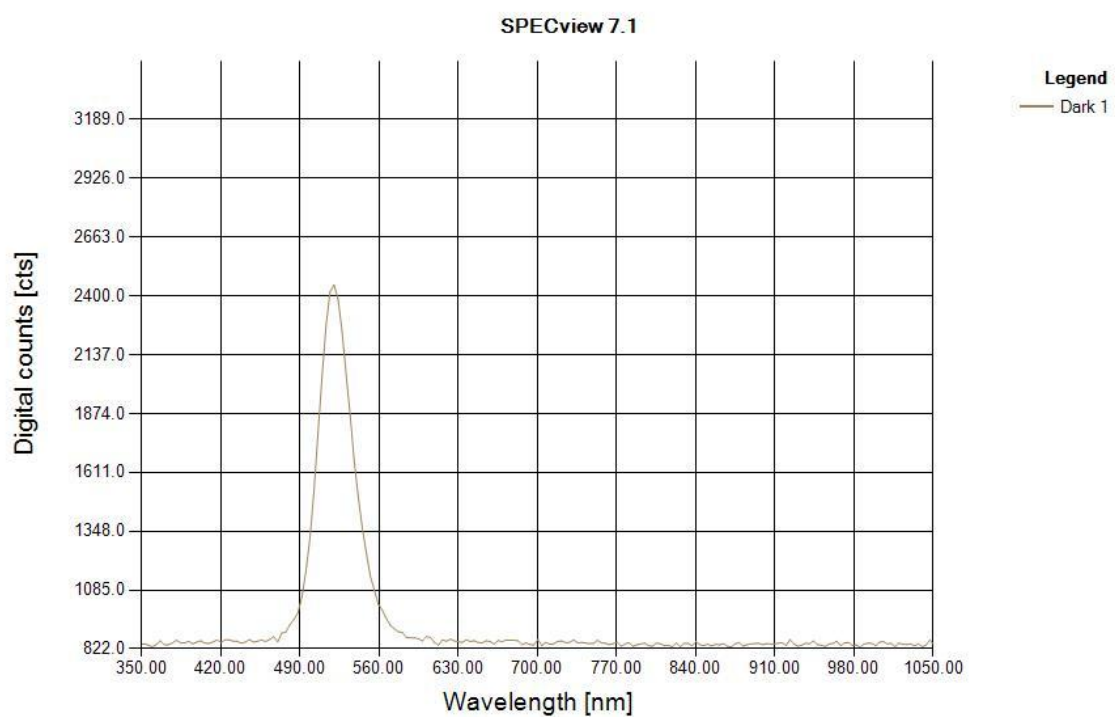
1.6 technical parameters

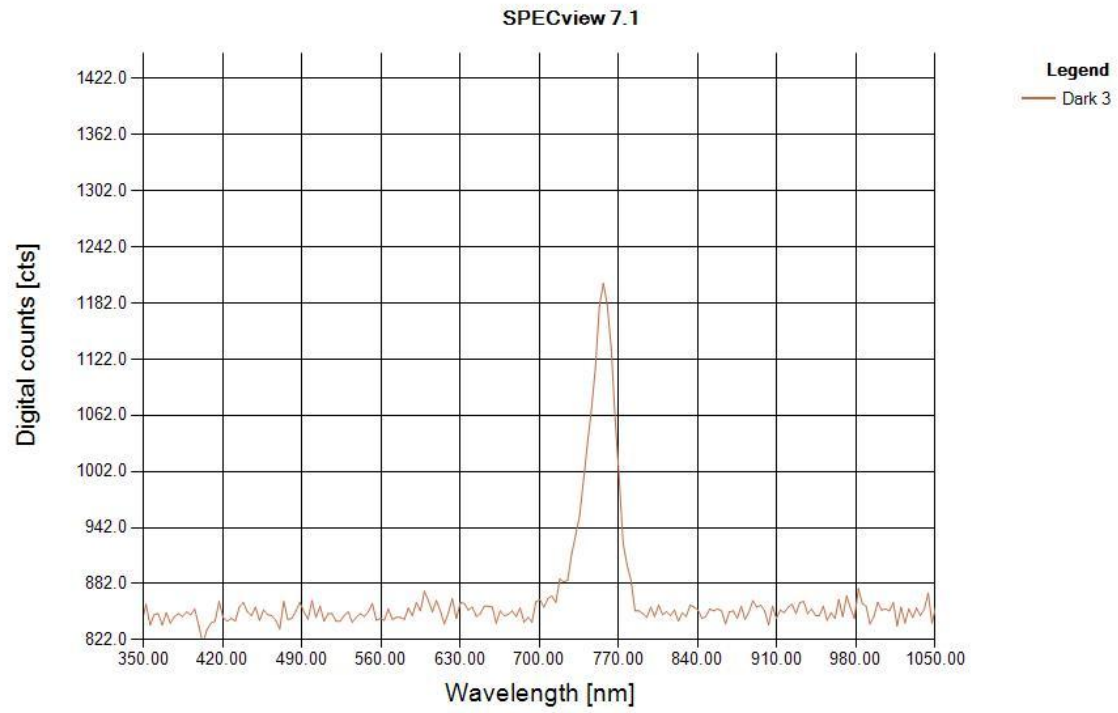
1.6.1 performance parameters

no.	measured items	Measurement range	Measurement error	repeatability
1	corneal diopter (K)	36.21D~50.60 D	± 0.25 D	≤ 0.13 D
2	astigmatism axis (AST)	$0^{\circ} \sim 180^{\circ}$	$\pm 4^{\circ}$	$\leq 2^{\circ}$
3	axis length (AL)	14 mm~33mm	± 0.1 mm	≤ 0.025 mm

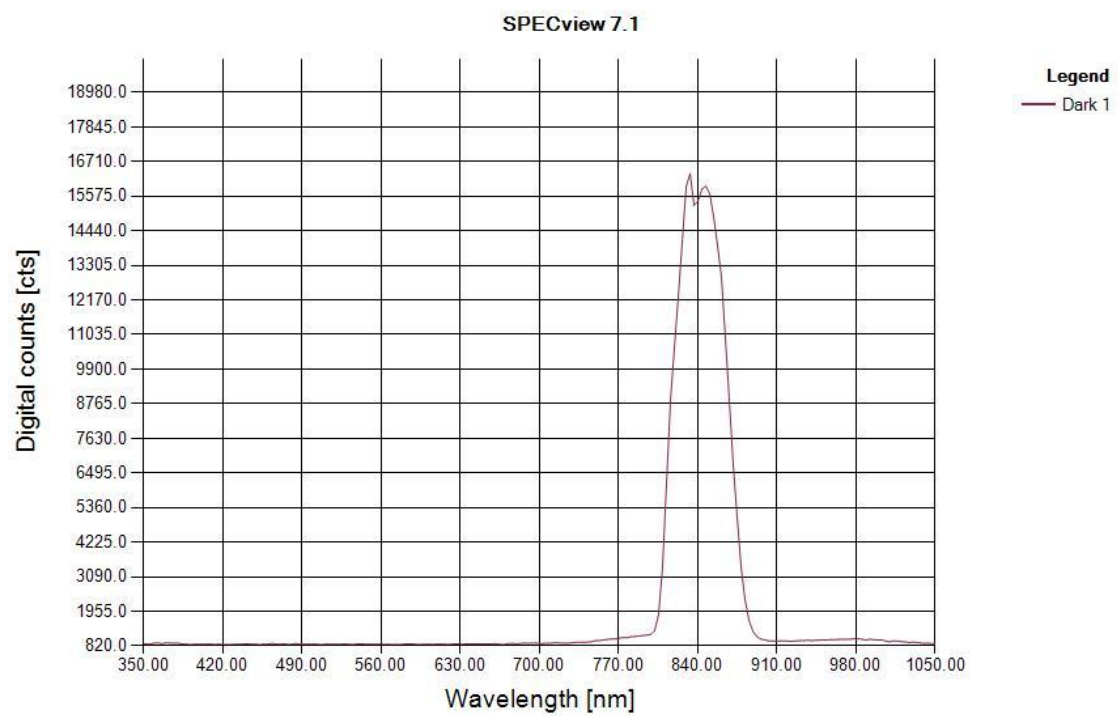
4	central corneal thickness (CCT)	200 μm ~1200 μm	$\pm 15 \text{ } \mu\text{m}$	$\leq 10 \text{ } \mu\text{m}$
5	anterior chamber depth (ACD)	0.7 mm~11 mm	$\pm 0.3 \text{ mm}$	$\leq 0.02 \text{ mm}$
6	white-to-white distance (WTW)	7 mm~16 mm	$\pm 0.5 \text{ mm}$	$\leq 0.3 \text{ mm}$
7	pupil diameter (PD)	2 mm~13 mm	$\pm 0.5 \text{ mm}$	$\leq 0.3 \text{ mm}$

1.6.2 When the device is in the state of maximum light intensity and maximum aperture, the relative spectrum output between the spectral wavelengths of 305~1100 nm is shown in the figure below.

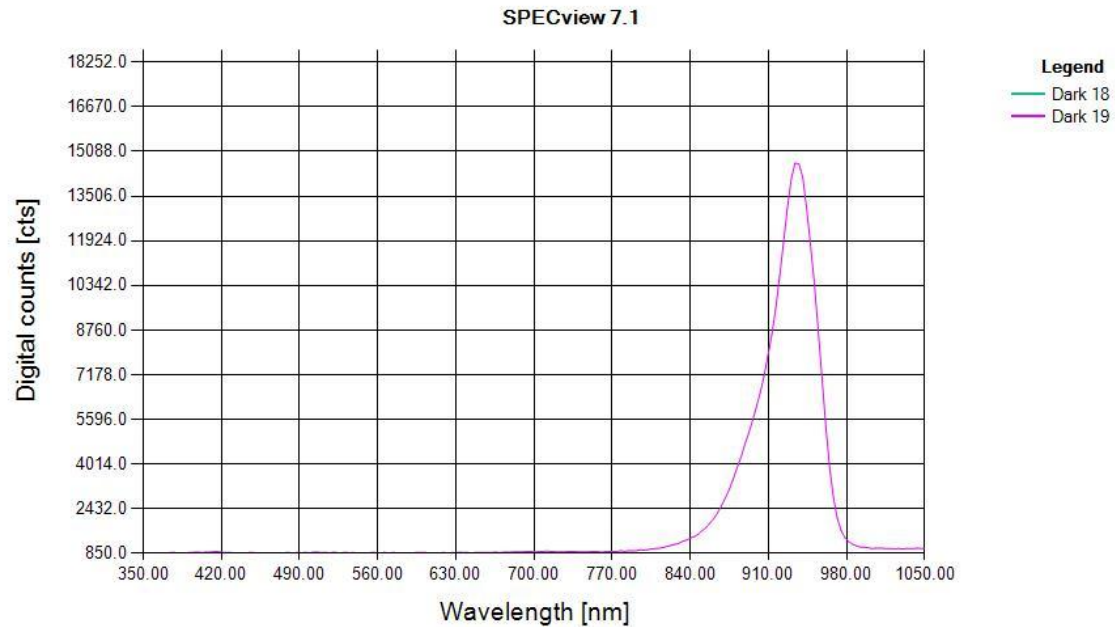




curvature measurement light source (765nm)



axial length measurement and central fixation light source (845nm)



infrared lighting source (940nm)

1.7 normal working environment

- 1) environmental temperature: $+5^{\circ}\text{C} \sim +40^{\circ}\text{C}$ 。
- 2) relative humidity: 40%~80%。
- 3) atmospheric pressure: 760 hPa~1060 hPa。
- 4) power conditions: a.c.220 V, 50 Hz。

1.8 product electrical safety features

- 1) Classify by type of protection against electric shock: class I equipment
- 2) Classify by degree of protection against electric shock: type B applied part.
- 3) Classify according to the degree of protection against liquid ingress in GB/T 4208: common type
- 4) Classify according to the degree of safety when used in the case of flammable anesthetic gas mixed with air or mixed with oxygen or nitrous oxide: cannot be used in flammable anesthetic gas mixed with air or mixed with oxygen or nitrous oxide.
- 5) Classify by operation mode: continuous operation
- 6) Rated voltage and frequency of equipment: a.c.220V, 50Hz

7) Input power of medical electrical equipment: 200VA

8) Does the device have an applied part that can be protected against the effects of defibrillation discharges: none

9) Whether the device has a signal input or output section: yes

10) Permanently installed equipment or non-permanently installed equipment: non-removable equipment

1.9 optical radiation safety

Ophthalmic optical biometer shall meet the requirements specified in the optical radiation safety standard ISO 15004-2:2007

1.10 network security instructions

1) operating environment

Requirement name	detail
Hardware configuration requirements	a)CPU is not less than 1.6 GHz b)memory not less than 4GB c)hard disk not less than 120GB d)Display not smaller than 10 inches
software environment 1 requirements	Windows 7 32-bit and above operating system, no other support software and application software required. The system comes with its own firewall and does not need to be updated.

2) network security

data interface

a)The software performs two-way data transmission with the U disk through the USB data interface, and the transmission protocol is the USB2.0 communication protocol

b)The software uses U disk for electronic data exchange, and the storage format is jpg.

user types and permissions

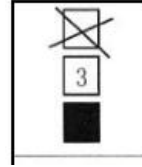
The software should have an account number and password to identify user identity, user type and authority. User types include administrator, repair (maintenance personnel), and user (doctor). User authority is administrator authority, maintenance personnel authority and doctor authority.

1.11 Symbols and logos

	Notice! Consult random files		Type B application part
	computer switch		alternating current
	on (main power)		off (main power)
	network interface		USB interface
	indicates that the transport package is afraid of rain		indicates that the shipping package should be transported upright



indicates that the shipping package contains fragile items and should be handle with care



indicates that the maximum number of stacking layers that can be stacked for the same package is 3 layers

1.12 device installation

1.12.1 hardware installation

In order to ensure the safe and stable operation of the device, please ensure a good installation environment

- 1)This device must be installed in a clean, quiet, dry environment on a flat, non-sloping table
- 2)This device needs to install a dedicated ground wire
- 3) Open the box, remove the foam inside, and two persons together lift it out.

1.12.2 software installation

software name: biometer software

Software release version: V 1.0

Software provider name: Chongqing Bio New Vision Medical Equipment Co., Ltd.

Software provider address: 2nd floor of building #5,27 Fengsheng Road, Jinfeng Town, High-Tech Industrial Development Zone, 401329 Chongqing, People' s Republic of China

1.12.2.1 software installation,configuration,maintenance

This software is a green version without installation and you can use it by decompressing the file to the D disk. The software requires no configuration and basically no maintenance. When new software needs to be upgraded, just

reinstall the new software; virus, serious misoperation or hardware system failure may damage the software system of the device. If the software system is seriously damaged, please decompress the software again.

1.12.2.2 software backup

After the software inspection is completed, the data files are stored in the software installation folder in .DB format, and the contents of the entire installation folder can be backed up. The default directory of system software is “D:\ albio\dbfs” .

1.12.2.3 software uninstall

After opening the “D:\ albio” directory, delete this folder and the uninstallation is complete.

1.13 period of use

The use period of this product is 5 years

1.14 supplier' s name and address

The supplier of this product is: Chongqing Bio New Vision Medical Equipment Co., Ltd.

The address of supplier is: 2nd floor of building #5, 27 Fengsheng Road, Jinfeng Town, High-Tech Industrial Development Zone, 401329 Chongqing, People' s Republic of China

2 product structure

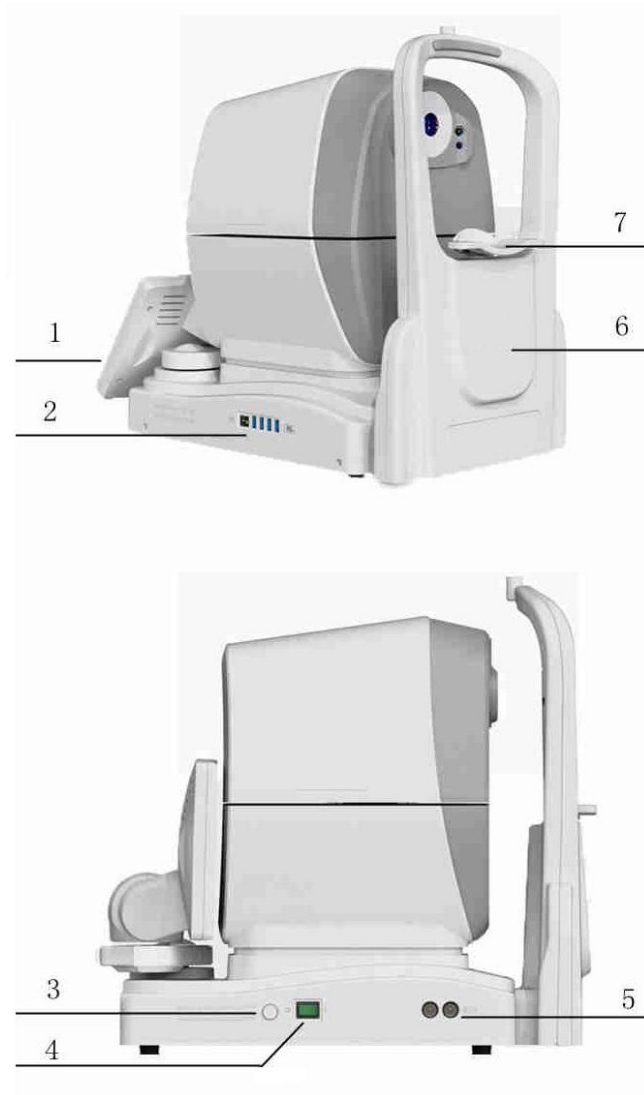
2.1 product structure composition

The ophthalmic optical biometer consists of a host, power cord and software.

The software is the control software component

2.2 product parts picture

- 1 display screen
- 2 external interface
- 3 computer switch
- 4 power switch
- 5 fuse holder
- 6 chin rest shelf
- 7 chin rest



2.3 product parts description

➤ computer switch

The computer switch controls the startup and shutdown of the computer inside the device. The computer switch will not cut off the total power of the device. If the device will not be used for a long time, it is recommended to turn off the power switch.

➤ power switch

The power switch controls the connection and disconnection of the power supply of the equipment, “|” means connection, “○” means disconnection. The power cord interface is the connection port of the external power cord. Next to the power cord connector is a fuse.

➤ display screen

The display screen provides an interactive interface for equipment operation. Users can preview the inspection results and manage medical record data through the display screen.

➤ external interface

Network interface: RJ-45 Ethernet interface, following IEEE802.3 standard.

USB interface: total 4 interfaces, using the USB 2.0 standard, the device that supports the protocol above USB 2.0 can be used, and an external keyboard, mouse or printer can be used.

Note: the printer user purchases it by himself. When used together, it should meet the requirements of GB 9706.1、GB 9706.15、YY 0505 and GB 4824.

3 basic operation

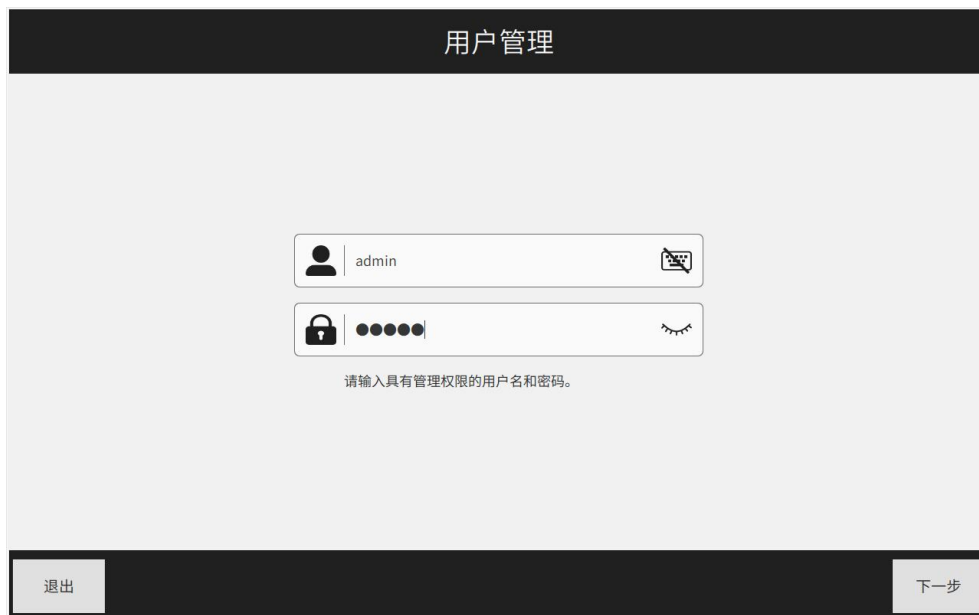
This chapter introduces the basic operation flow of the inspection procedure of the ophthalmic optical biometer.

3.1 user login

User login, enter username and password, click “Login”

A dark-themed user login window with a close button (X) in the top right corner. The title "用户登录" (User Login) is centered. Below the title are two input fields: the first is for the username with the placeholder "请输入用户名" (Please enter username) and a user icon; the second is for the password with the placeholder "请输入密码" (Please enter password) and a lock icon. A "登录" (Login) button is centered below the input fields. At the bottom, there are two links: "重置密码" (Reset Password) on the left and "用户管理" (User Management) on the right.

In this interface, you can create, delete or browse user information. To create new user, delete or view all user information, you need to login with an administrator account. Default administrator: administrator, password:0

A light-themed user management window with a title bar "用户管理" (User Management). It contains two input fields: the first is for the username with the placeholder "admin" and a user icon; the second is for the password with a series of dots and a lock icon. Below the input fields is a prompt: "请输入具有管理权限的用户名和密码。" (Please enter the username and password with management rights). At the bottom, there are two buttons: "退出" (Exit) on the left and "下一步" (Next Step) on the right.

The software should have an account number and password to identify user

identity, user type and authority. User types include Administrator, Repair (maintenance personnel), and User (doctor). User authority is administrator authority, maintenance personnel authority and doctor authority.

Administrator: can creat other users, collect data, analyze data, export data functions.

Repair (maintenance personnel): has all permissions and can operate all functions

User (doctor): collect data, analyze data, export data functions.

After successful login, enter the operation interface home page.



3.2 entry information

3.2.1new patient

Click the icon  to enter the new patient interface, enter the relevant information and click .

新建患者

基本信息

屈光手术眼数据

* 患者ID

生产PID

WorkList

* 姓名

* 性别

男性

女性

其他

* 出生日期

1980-01-01

41

...

备注

返回

保存

开始测量

icon meaning description	
产生PID	No need to enter patient information, ID is randomly generated
WorkList	setup with DICOM3

Enter the interface **新建患者**, click **屈光手术眼数据**, the doctor can input K1 (horizontal curvature), K2(vertical curvature), preoperative refraction, postoperative refraction, contact lens curvature, and contact lens curvature according to the actual situation of the patient and click save. Adjust the machine to a suitable height and go to the next step **开始测量**.

新建患者

基本信息

屈光手术眼数据

OD

OS

K1[D]

0

K2[D]

0

K1[D]

0

K2[D]

0

眼球

角膜

眼球

角膜

术前屈光[D]

0

0

0

0

术后屈光[D]

0

0

0

0

接触镜曲率[D]

0

0

戴接触镜后曲率[D]

0

0

0

0

返回

保存

开始测量

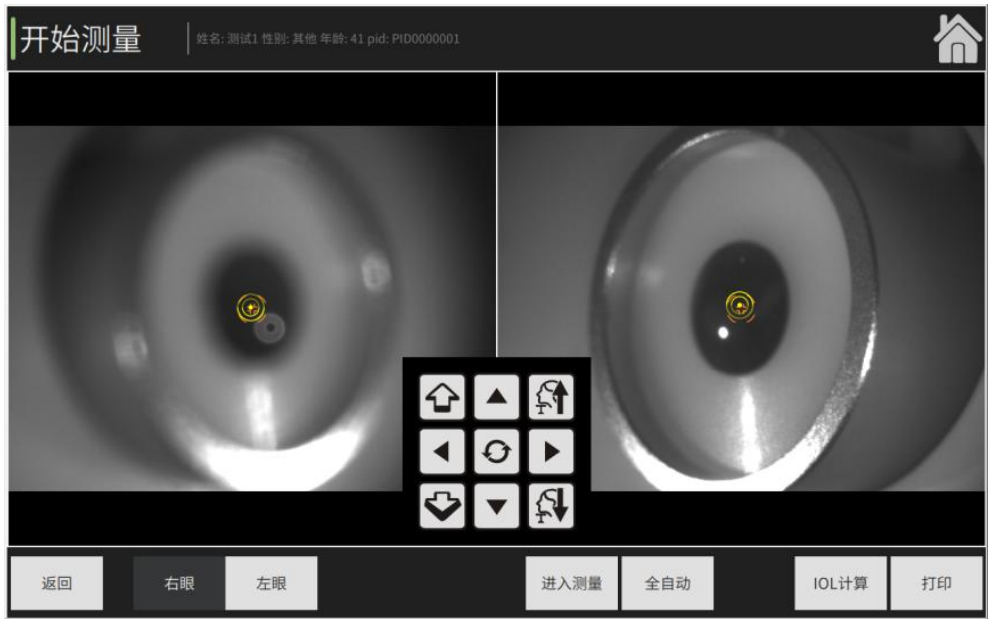
icon meaning description	
OD	right eye
OS	left eye
K1[D]	horizontal curvature
K2[D]	vertical curvature

3.3 data measurement

3.3.1preparation before measurement



Click the icon to enter the start measurement interface to collect data.



icon meaning description			
	back to main menu		reset
	up (3D motion system)		raise (chin rest)
	down (3D motion system)		drop (chin rest)
	left (3D motion system)		front(3D motion system)
	right(3D motion system)		back(3D motion system)

3.3.2 patient' s position adjustment

1) The patient' s chin is placed on the chin rest, the forehead is close to the forehead rest, and the eyes are fixed on the front.

2) Eye' s choose: 

3)Chin rest adjustment: click   to align the patient' s eyes parallel to the chin rest eye line.

3.3.3manual alignment

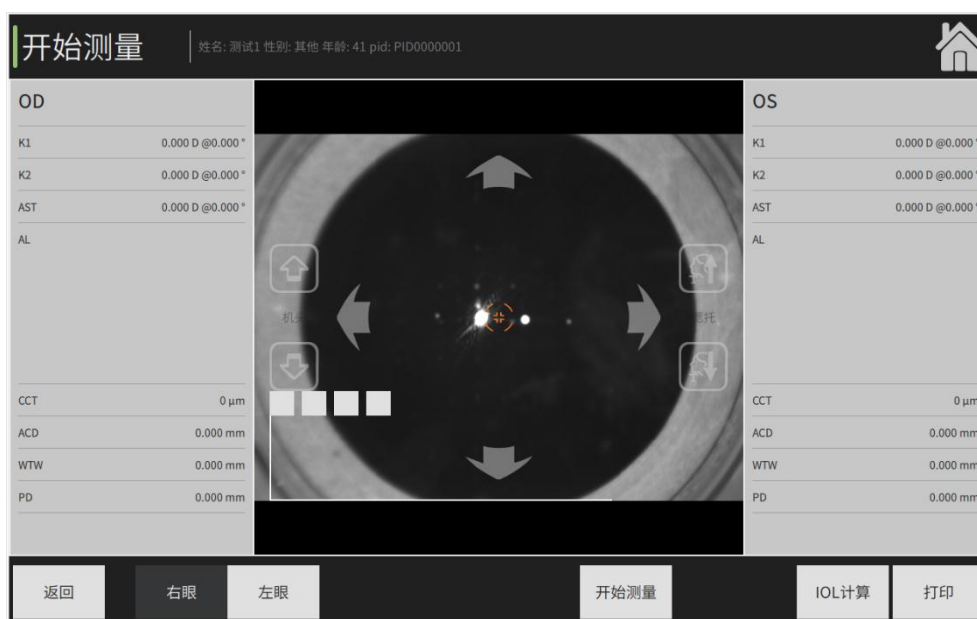
1) Click  to adjust the alignment, basically move the patient' s eyes to the center of the screen, so that the two alignment orange marks are placed in the middle of the pupil.

2) Adjust   the front/ back arrows to align the alignment point with the pupil.

icon meaning description			
	show right eye		show left eye
	up (3D motion system)		chin rest up
	down (3D motion system)		chin rest down
	left (3D motion system)		machine head up
	right (3D motion system)		machine head down

3.3.4start to measure

Click , enter the start measurement interface.



icon meaning description			
K1	Corneal dioptr-horizontal curvature	K2	Corneal dioptr-vertical curvature
AST	astigmatism axis	AL	eye axis length
CCT	central corneal thickness	ACD	anterior chamber depth
WTW	White-to-white distance/ corneal diameter	PD	pupil diameter

When the center of the pupil of the eye to be inspected is fixed in the center of the ring, focus the center focus; click the button 开始测量 to start measurement.

To capture another eye 左眼, repeat the above steps.

3.3.5 fully automatic alignment

Click 全自动, the ophthalmic optical biometer will automatically align and measure the data. To capture another eye, repeat the above steps.

3.3.6 calculate intraocular lens degree

3.3.6.1 calculate IOL



Enter the interface 开始测量, if all the measured values have been determined,

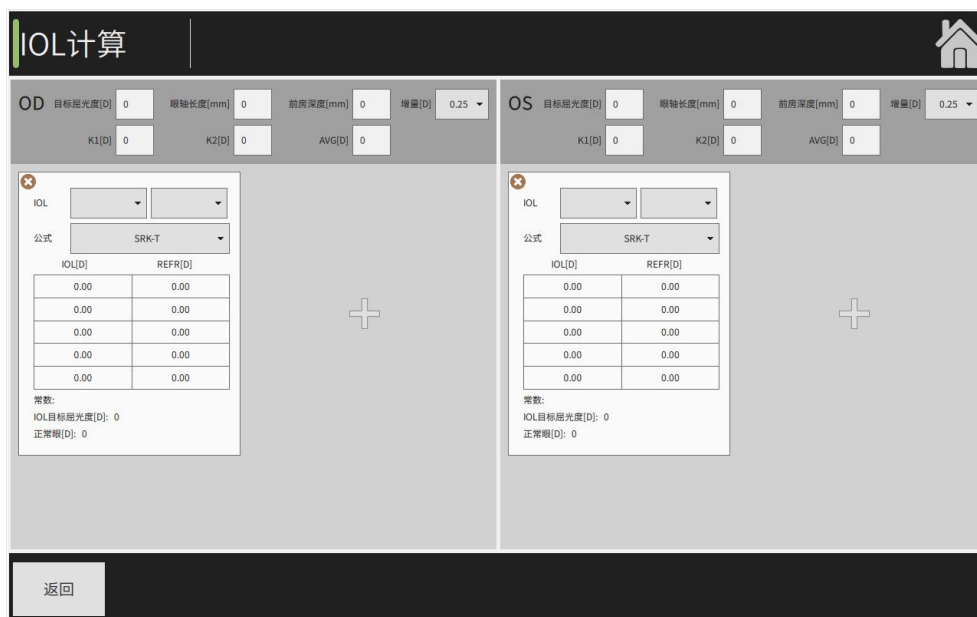
perform various IOL degree calculation operations according to the different needs of the patient's surgery or after surgery, click the icon  to enter the IOL calculation interface.



The screenshot shows the 'IOL计算' (IOL Calculation) interface. It has a dark header with a home icon on the right. Below the header, there are two main sections for 'OD' (Right Eye) and 'OS' (Left Eye). Each section contains input fields for '目标屈光度[D]' (Target Refractive Power [D]), 'AL[mm]' (Axial Length [mm]), 'ACD[mm]' (Anterior Chamber Depth [mm]), '增量[D]' (Increment [D]), 'K1[D]', 'K2[D]', and 'AVG[D]'. The 'OD' section also has a 'K1[D]' field. Below these fields are two large gray areas with a white plus sign, intended for displaying results or additional data. At the bottom left, there is a '返回' (Return) button.

3.6.2 IOL parameter settings

Enter the interface , click , enter the list parameters target diopter, axial length, anterior chamber, cornea, eyeball; select the corresponding lens type and formula for calculation according to your needs. The degree of the corresponding implanted intraocular lens is automatically calculated and a list of IOL calculation results is displayed.



This screenshot shows the 'IOL计算' interface with parameter settings and calculation results. The 'OD' and 'OS' sections now have dropdown menus for 'IOL' and '公式' (Formula). Below these, there are tables for 'IOL[D]' and 'REFR[D]' results. The 'OD' section shows a table with 5 rows of 0.00 values. The 'OS' section shows a table with 5 rows of 0.00 values. Below the tables, there are '常数' (Constants) fields for 'IOL目标屈光度[D]' and '正常眼[D]'. At the bottom left, there is a '返回' (Return) button.

3.4 data management

3.4.2 inspection records



Click the icon to enter the information management interface, click

查询

, select a patient in the results, and then click the button 检查记录 at the right bottom to view the patient's medical record. You can also choose other retrieval methods according to your needs: such as recent checks.

信息管理

查询

最近检查

检查日期

1970-01-01

...

到

2021-06-21

...

患者ID	姓名	性别	出生日期	备注
PID0000001	测试1	其他	1980-01-01	

最近检查时间排序

第 1/1 页, 共计 1 条记录

<<

<

1

Goto

>

>>

返回

检查记录

删除

修改

复查

打印预览

3.4.3 inspection result



Enter and click 检查记录 to enter the inspection result page. The

system provides a variety of indicators to help the examiner evaluate the reliability of the inspected eyes examination results. Indicators includes :K1(corneal diopter-horizontal curvature), K2 (corneal diopter-vertical curvature), AST (axial astigmatism), AL (axial length), CCT(central corneal thickness), ACD (anterior chamber depth), WTW (white-to white distance), PD(pupil diameter).

检查结果									
检查日期	眼别	K1 [D]	K2 [D]	AST [D]	AL [mm]	CCT [μ m]	ACD [mm]	WTW [mm]	PD [mm]
2021-06-21...	左眼	0	0	0	0	0	0	0	0
	右眼	0	0	0	0	0	0	0	1027.0666910...
2021-06-21...	左眼	0	0	0	0	0	0	0	0
	右眼	0	0	0	0	0	0	0	1041.8999938...
2021-06-21...	左眼	0	0	0	0	0	0	0	0
	右眼	0	0	0	0	0	0	0	1045.0666503...
2021-06-21...	左眼	0	0	0	0	0	0	0	0
	右眼	0	0	0	0	0	0	0	1039.5999755...
2021-06-21...	左眼	0	0	0	0	0	0	0	0
	右眼	0	0	0	0	0	0	0	0
2021-06-21...	左眼	0	0	0	0	0	0	0	0
	右眼	0	0	0	0	0	0	0	0
2021-06-21...	左眼	0	0	0	0	0	0	0	0
	右眼	0	0	0	0	0	0	0	118
2021-06-21...	左眼	0	0	0	0	0	0	0	0

返回
删除
修改
复查
打印预览

3.5 printout

Click the icon  to view the inspection record, click 打印预览 to browse the report of the inspection result, and click  to choose to print the report in the print preview interface.







AL			
<右眼>	mm	类型	
Add	23.88	Phakic	
<左眼>	mm	类型	
Add	23.44	Phakic	
K (Phi=2.4) Index=1.3375			
<右眼>	mm	D	deg
<K1	7.55	44.70	2>
<K2	7.48	44.12	92>
<AVG	7.52	44.88	>
<Axis		-0.42	2>
<左眼>	mm	D	deg
<K1	7.55	44.70	171>
<K2	7.50	4500	81>
<AVG	7.53	44.82	>
<Axis		-0.30	171>
ACD			
<右眼>	mm	CCT	
AVG	ERR	518	
<左眼>	mm		
AVG	3.95	514	
WTW			
<右眼>	mm	PS	mm
	11.4	5.3	
<左眼>	mm	mm	mm
	11.5	5.3	

3.6 parameter settings

The system can modify various parameters, set the starting eye position to select the left eye or the right eye during the examination, and set the number of measurements of the axial length of the eye.

设置

系统

传输速率

返回

检查时开始眼位

左眼

右眼

眼轴长测量次数

To set the transmission rate, you can manually enter the anterior chamber rate, lens rate, vitreous rate, and corneal rate.

设置

系统

传输速率

返回

速率

前房速率

晶状体速率

玻璃体速率

角膜速率

晶状体速率列表

名称	速率(m/s)

玻璃体速率列表

名称	速率(m/s)

3.7 shutdown

After checking, click the main interface

关闭电源

 to close the software and computer. After shutdown, turn off the power and cover the objective lens to prevent the lens from sticking to dust or scratching.

4 cleaning, maintenance and preventive inspections

is an all-in-one ophthalmic outpatient diagnostic device that does not require a lot of routine maintenance. Before cleaning and maintenance, please cut off the power supply of the equipment.

4.1 cleaning and disinfection

1) chin rest, forehead rest

Disposable chin rest paper is provided at the contact part of the patient; please replace it for next use after the examination. Replacement method: first remove the clips on both ends of the chin rest paper, install the disposable chin rest paper, and then install the clips.

2) display screen

Dampen a soft cloth with a little water, then dry the surface with a soft, lint-free cloth.

3) other external surfaces

Other exterior surfaces of the device can be cleaned with a soft, lint-free cloth dampened with a little water.

4) handling of reuse

Disinfection of chin rest and forehead rest: use absorbent cotton and wipe with 75% medical disinfectant alcohol for disinfection. The action time is not less than 3 minutes. Number of reuses: unlimited.

5) cleaning and disinfection cycle

It is recommended to disinfect the whole machine every time it is used, and clean once a month.

☞note:

Pay attention to waterproofing when cleaning, the lint-free cloth can be wet but not dripping, preventing any liquid from entering the device.

4.2 replacement repair

1) Turn off the power and unplug the power cord.

2) Remove the fuse holder with a tool

3) After replacing the new fuse tubes, install the fuse holder

Note: please use fuse tubes of the same model, specification and rating.

4.3 preventive check

1) safety check

Check whether the chin rest, forehead rest and the assembled parts are firm and running normally; whether the connecting parts are loose, fall off or cracked, etc. if so, please contact our company or an authorized dealer. Recommended monthly.

2) function check

Check whether the power switch and button are normal; check whether each indicator light is normal after power on; if so, please replace it in time. Enter the software to check whether the basic functions are normal. If the software is abnormal, please contact our company or an authorized dealer to obtain the latest software upgrade. Recommended monthly.

5 precautions

- 1) Do not use this device in flammable, explosive, high temperature and dusty environments.
- 2) The equipment should be used indoor and kept clean and dry.
- 3) The equipment should be installed on a flat surface to avoid tipping. Other medical equipment that must be installed and used in the same environment must comply with the same electromagnetic compatibility principles. Non-compliant or poorly EMC-compliant equipment must be installed at least 2 meters away from the equipment and must be powered by a different power cord.
- 4) Please use the special power cord configured with this equipment and ensure that the equipment is well grounded.
- 5) Please use fuse tube T2AL250V of the specified type and rating. When replacing the fuse tube , cut off the power first.
- 6) Do not place body parts such as fingers, hair, etc. on the moving parts of the device, otherwise there is a risk of pinching.
- 7) When the device is not in use, cut off the power first, and then cover it

with a dust cover.

8) If there is malfunction, please contact our company or an authorized dealer.

6 common faults and causes

If the problem occurs, please check it according to the following table to try to troubleshoot the cause of the problem. If the problem is still not resolved, please contact our company or an authorized dealer.

problems	Possible causes	solution
Can' t start normally	the power cord is not properly connected	check connections for looseness

	the power switch is in the “○” position	Put the switch in the “ ” position
	fusing fuse	replace the fuse of the same specification
display not show	the cable is loose and the display is broken	Tighten the loose connection and replace the display
Open the software, image not show	computer system failure, computer poisoning, loose wiring	Reinstall the operating system, antivirus, check the wiring, and replug the cable

7 transportation and storage

- 1、When transporting the equipment, it should be protected from moisture,

stored upside down, and avoid severe vibration.

2、The equipment should be stored in an ambient temperature range of $-40^{\circ}\text{C} \sim 55^{\circ}\text{C}$, relative humidity range $\leq 85\%$, atmospheric pressure range: $760\text{hPa} \sim 1060\text{hPa}$, no corrosive gas and well-ventilated room.

3、If the equipment needs to be moved for a short distance, please carefully lift it with your hands; if the equipment needs to be transported for a long distance, it should be re-packed in the original packaging and then transported.

8 environmental protection

During the normal use and maintenance of this equipment, the replaced components or other wastes should be properly disposed according to the requirements of local laws and regulations, and can't be discarded at will. When the equipment reaches the end of its life, it should be recycled according to the requirements of local laws and regulations, so as not to cause pollution to the environment.

9 electromagnetic compatibility

1、equipment grouping and classification

The ophthalmic optical biometer belongs to Group 1 Class A equipment according to the national standard GB4824

2、basic performance

The ophthalmic optical biometer shall meet the following requirements under the test conditions specified in 36.202 of YY 0505

- 1) The parameters can be set as expected and displayed normally, and the normal functions of each button should not fail.

3、electromagnetic emission

Guidelines and Manufacturer' s declaration- Electromagnetic Emissions		
The ophthalmic optical biometer is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment.		
emission test	compliance	Electromagnetic environment - guidelines
RF emission GB 4824	Group 1	The ophthalmic optical biometer uses RF energy only for its internal functions. Therefore, it has low RF emissions and is less likely to cause interference to nearby electronic equipment
RF emission GB 4824	Class A	The ophthalmic optical biometer is suitable for use in non-domestic and domestic residential public low-voltage power supply networks that are not directly connected to
Harmonic emission GB 17625.1	Not applicable	

GB 17625.2	Not applicable	the AL- VIEW ophthalmic optical biometer.
------------	----------------	---

4、electromagnetic immunity

Guidelines and manufacturer' s statement- electromagnetic immunity			
The ophthalmic optical biometer is intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment			
Immunity test	IEC 60601 Test level	Match level	Electromagnetic environment- guidelines
Electrostatic discharge GB/T 17626.2	$\pm 6\text{ kV}$ contact discharge $\pm 8\text{ kV}$ air discharge	$\pm 6\text{ kV}$ contact discharge $\pm 8\text{ kV}$ air discharge	Floors should be wood, concrete or tile, and if covered with synthetic materials, the relative humidity should be at least 30%
Electrical fast transient burst GB/T 17626.4	$\pm 2\text{ kV}$ to the power cord	$\pm 2\text{ kV}$ to the power cord	Mains power should be of typical quality used in a commercial or hospital environment
surge GB/T 17626.5	$\pm 1\text{ kV}$ line to line $\pm 2\text{ kV}$ line to line	$\pm 1\text{ kV}$ line to line $\pm 2\text{ kV}$ line to line	Mains power should be of typical quality used in a commercial or hospital environment

Voltage dips, short interruptions, and voltage variation on power input lines GB/T 17626.11	$<5\%U_T$, for 0.5 cycle (on U_T, $>95\%$ dip) $40\% U_T$, for 5 cycle (on U_T, 60% dip) $70\% U_T$, for 25 cycle (on U_T, 30% dip) $<5\% U_T$, for 5s (on U_T, $>95\%$ dip) Note: U_T is the AC network voltage 220V before applying the test voltage.	$<5\%U_T$, for 0.5 cycle (on U_T, $>95\%$ dip) $40\% U_T$, for 5 cycle (on U_T, 60% dip) $70\% U_T$, for 25 cycle (on U_T, 30% dip) $<5\% U_T$, for 5s (on U_T, $>95\%$ dip) Note: U_T is the AC network voltage 220V before applying the test voltage.	Mains power should be of the quality used in a typical commercial or hospital environment. If users of the ophthalmic optical biometer require continuous operation during the ophthalmic optical biometer be powered by an uninterruptible power supply.
Power frequency magnetic field (50 Hz /60 Hz) GB/T 17626.8	3 A/m	3 A/m	The power frequency magnetic field should have the power frequency magnetic field level characteristics of a typical location in a commercial or hospital environment

5、electromagnetic immunity- for non-life support equipment and systems

Guidelines and manufacturer' s declaration- electromagnetic immunity
The ophthalmic optical biometer is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment

Immunity test	IEC 60601 Test level	Match level	Electromagnetic environment-guidelines
RF conduction GB/T 17626.6 RF radiation GB/T 17626.3	3 V (valid value) 150 kHz~80 MHz 3 V/m 80 MHz~2.5 GHz	3 V (valid value) 3 V/m	Portable and mobile RF communication equipment should not be used closer to any part of the ophthalmic optical biometer, including cables, than the recommended isolation distance. The distance should not be calculated by the formula corresponding to the frequency of the transmitter recommended isolation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d=2.3\sqrt{P} \quad 800 \text{ MHz} \sim 2.5 \text{ GHz}$ in the formula: P- according to the transmitter manufacturer's maximum output power rating of the transmitter, the unit is watts (W) d- recommended isolation distance, the unit is meter (M) Field strengths from fixed RF transmitters are determined by surveying the electromagnetic site and should be lower than the compliance level in each frequency range.

			Interference may occur near equipment marked with the following symbols. 
Note 1: at 80MHz and 800 MHz, the formula for the higher frequency band is used Note 2: these guidelines may not be suitable for all situations, electromagnetic propagation is affected by absorption and reflection from buildings, objects and people			
a. Stationary transmitters, such as base stations for wireless (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasting, and television broadcasting, have field strengths that cannot be predicted theoretically with accuracy. To assess the electromagnetic environment of fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the ophthalmic optical biometer is located is higher than the above RF compliance level, the ophthalmic optical biometer should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorienting or repositioning the ophthalmic optical biometer b. In the entire frequency range of 150kHz– 80 MHz, the field strength should be less than 3V/m			

6、Recommended separation distance between portable and mobile RF communication equipment

and ophthalmic optical biometer —for non-life support equipment and systems

Recommended separation distance between portable and mobile RF communication equipment and ophthalmic optical biometer			
The ophthalmic optical biometer is intended for use in electromagnetic environments where RF radiation disturbances are controlled. Depending on the maximum output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining an minimum distance between portable and mobile RF communication equipment (transmitters) and the ophthalmic optical biometer as recommended below.			
Maximum rated output power of the transmitter W	Corresponding to the isolation distance of different frequencies of the transmitter/m		
	150 kHz~80 MHz $d=1.2\sqrt{P}$	80 MHz~800 MHz $d=1.2\sqrt{P}$	800 MHz~2.5 GHz $d=2.3\sqrt{P}$
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
For the maximum rated output power of transmitters not listed in the table above, the recommended isolation distance d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is the transmitter maximum output power rating provided by the transmitter manufacturer, the unit is watts (W) Note 1: at 80MHz and 800 MHz, the formula for the higher frequency band is used Note 2: these guidelines may not be suitable for all situations, electromagnetic propagation is affected by absorption and reflection from buildings, objects and people			

7、 installation environment

The ophthalmic optical biometer is used in non-household and not directly connected to the public low-voltage power supply network of domestic residential buildings. The

power socket should have reliable protective grounding measures, and use the power cords, parts and accessories provided with it. Floors should be wood, concrete or tile, and if covered with synthetic materials, the relative humidity should be at least 30%. Other equipment used at the same time in the vicinity of this equipment shall comply with the relevant requirements for electromagnetic compatibility

The possible influence of portable and mobile RF communication equipment on the ophthalmic optical biometer can see “ 6 recommended isolation distance between portable and mobile RF communication equipment and the ophthalmic optical biometer .

The ophthalmic optical biometer can only use the power cord, parts and accessories supplied by the manufacturer (see 8 accessories list for details). When using these power cords, parts and accessories meet the requirements of 36.201 and 36.202 of YY 0505.

 Caution: the use of accessories and cables other than those sold by the manufacturer of the equipment as spare parts for internal components may result in increased emissions or reduced immunity of the equipment.

 Caution: use of accessories or cables other than those specified with the device may result in increased emissions or decreased immunity from the device.

 Caution: the equipment should not be used close to or stacked with other equipment, if it must be used close to or stacked, it should be observed to verify that it operates normally in the configuration it is used in.

 Caution: equipment may be interfered with and/or suffer from reduced performance related to essential performance and safety when used near equipment marked with .

8、list of accessories

no.	Accessories names	model	parameters
-----	----------------------	-------	------------

1	power cable	D1-3	10A, 250V~, 0.75 square wire length 1.8m, unshielded wire.
---	-------------	------	---

10 manufacturer' s responsibility

The company is only responsible for the impact on the safety of the equipment in the following cases

- assembly, additions, commissioning, alterations for repairs are carried out by approved personnel;

- the electrical facilities in the room are in compliance with the relevant requirements

- for the correct operation of the instrument, it is used in accordance with the requirements of the instruction manual.

When using this product, users need relevant maintenance material, such as circuit diagrams, component lists, legends, calibration rules, etc., please contact our company or authorized dealers.

All replacement parts for this equipment can only be provided by our company. If the user uses parts not provided by the company, the minimum safety level will be reduced, resulting in adverse consequences, and the responsibility shall be borne by the user.

warranty statement

Commitment: the company can provide the necessary information for the designated repairable equipment parts.

1. The company provides equipment maintenance and free consultation for life.
2. From the date of purchase, the equipment is guaranteed for one year free of charge under the premise of complying with the instruction manual.
3. During the warranty period, the following conditions will be charged for maintenance

● Damaged caused by the use, maintenance and storage not in accordance with the instruction manual

● Damage to the equipment caused by unauthorized disassembly/ modification by personnel not authorized by the company.

● Damage to equipment caused by accident, misuse, or irresistible natural factors.



China Care Medical Equipment Co., Ltd.
Address: Room B101, Zhongbang Business Building, No. 87
Puxing Road, Tianhe, Guangzhou, China Web: www.chinacaremedical.com