

Corneal Topography

Instruction Manual

CHONGQING SUNKINGDOM MEDICAL INSTRUMENTS CO., LTD.

Preface	.IV
Chapter 1 General Description	1
1.1 Product Introduction	1
1.2 Instructions for Use	1
1.3 Product Configuration	3
1.4 Scope of application	4
1.5 Contraindications	5
1.6 Scope of application	5
1.7 Product Characteristics	5
1.8 Transport and Storage	5
1.9 Relative Spectra of Outgoing Beam in Instrument	6
1.10 Optical radiation safety	6
Chapter 2 Product Profile	7
2.1 Primary Performance Indicators	7
2.2 Technical Parameters	7
2.3 Product Structure Diagram	7
2.4 Dimensions. Overall weight	8
Chapter 3 Installment	9
3.1 Environment of use	9
3.2 Out of Box Inspection	9
3.3 Installation Environment	9
3.4 Installation Step	.10
Chapter 4 Operating Procedure	. 11
4.1 Replace disposable gauze	. 11
4.2 Startup	. 11
4.3 New Patient	11
4.4 Patient Position Correction	11
4.5 Test Process	12
4.6 Analyze Functions	12
4.7 Print	12
4.8 Shutdown	.12
Chapter 5 Software Usage	13
5.1 Login Screen	13
5.2 Main Screen	13
5.3 Corneal topography	.14
5.3.1 Acquisition interface	.14
5.3.2 Overall view	.15
5.4 Single Map	.17
5.5 Four View	18
5.6 3D View	19
5.7 Fourier Analysis	.20
5.8 Zernike Analysis	21
5.9 Keratoconus analysis	22

Catalogue

5.10 Contact Lens Fit	23
5.11 Two maps compare	25
5.12 Two maps subtract	25
5.13 Dry Eye Collection (SK-7000B)	26
5.14 Dry Eye Item Analysis Interface (SK-7000B)	27
5.14.1 TMH Analysis Interface	27
5.14.2 NIBUT analysis interface	28
5.14.3 Lipid layer analysis interface	29
5.14.4 Red eye Analysis Screen	29
5.14.5 Gland Opening Analysis Screen	30
5.14.6 Meibomian gland analysis interface	31
5.14.7 Corneal Staining Analysis Interface	32
5.15 Dry Eye Analysis (SK-7000B)	32
5.16 Patient database	33
5.17 Hospital Information Setting	34
5.18 System Setting	35
5.19 User Management Settings	36
5.20 Dicom Setting	36
5.21 Printing and Preview	37
Chapter 6 Software Description	39
6.1 Software name and model	39
6.2 Software Version Number	39
6.3 Software Provider	39
6.4 Software Support	39
6.5 Software Application Backup & Restore	39
6.6 Software Maintenance	39
6.7 Software installation	40
Chapter 7 Maintenance and care	41
7.1 General Precautions	41
7.2 Cleaning and maintenance of equipment (disinfection)	41
7.3 Preventive inspection and maintenance (if any)	42
7.4 Component Replacement (if applicable)	42
7.5 Common Troubleshooting (if applicable)	42
7.6 Waste Handling	43
7.7 Jaw rest safety factor description	43
Chapter 8 Symbol Explanation	44
8.1 Device symbol explanation	44
8.2 Explanation of Packaging Symbols	44
Chapter 9 Warranty Statement	45
Chapter 10 Electromagnetic compatibility	46
10.1 Equipment Group Classification	46
10.2 Essential Performance	46
10.3 Electromagnetic Emissions	46
10.4 Electromagnetic Immunity	46
10.5 Electromagnetic Immunity – For Equipment and Systems that are Not I	∟ife-

Supporting	.48
10.6 Recommended separation distances between portable and mobile	RF
communications equipment and XXXX (Model: Table 1)	.49
10.7 Installation Environment	49
10.8 List of attachments	50
10.9 List of equipment used in coordination test	51

Preface

Dear User:

Thank you for choosing to use the corneal topography manufactured by Chongqing Sunkingdom Medical Instrument Co., Ltd. (hereinafter referred to as"Sunkingdom"). "Sunkingdom" corneal topography instrument can be trusted by you, we are deeply honored. In order to give you a general understanding of the "Sunkingdom" corneal topography, we have configured this instructions for use for you, including the installation, method of use, instructions for use, maintenance, transportation, storage, etc., which are essential guidelines for your use of this instrument.

In order to enable you to better understand the relevant knowledge of the instrument, please carefully read the instructions for use before use, and believe that it will be of great help to you in the effective use of this instrument.

It is recommended that you carefully perform the following prior to use:

1 . Carefully check that the instrument is consistent with the packing list, and that the instructions for use and accessories are complete.

2. Please read the accompanying documents carefully and keep them properly.

Manufacturer Responsibility:

Company shall only assume responsibility for the safety, reliability and performance of the Instrument if:

• Assembly operations, extensions, readjustments, improvements and repairs are performed by persons authorized by the Company.

• Associated electrical Instrument complies with national standards.

◆ Instrument is used in accordance with conditions and requirements listed in the instructions for use.

Product registration information:

Manufacturing License No .:

Registration certificate No.:

Serial number of technical requirements for this product:

The pictures provided in this manual are effect drawings. Please consult Sunkingdom Company if there is any unknown. **Consulting Phone:** 023-681028055

Chapter 1 General Description

1.1 Product Introduction

Corneal Topography use optical imaging techniques to obtain topographic data on the corneal surface of the eye. It measures the curvature, height, shape of the cornea and any irregularities or abnormalities etc. This information has important roles in the diagnosis of corneal diseases, planning and monitoring of corneal surgery , customization of contact lenses.

SK-7000A: Can be used to measure corneal curvature distribution.

SK-7000B: Can be used to measure corneal curvature distribution and dry eye examination.

1.2 Instructions for Use



- 1.2.1 For your safety and benefit, please read this product instruction manual and all information supplied with it carefully before you use the equipment. We shall not be liable for any personal injury, property or other damage resulting from your failure to use and operate the equipment in accordance with the product manual.
- 1.2.2 This device can only be installed in a darkroom and is intended for use by trained ophthalmic clinicians and technicians only.
- 1.2.3 The voltage at the location of the device must reach the required voltage of the company, if the voltage is unstable, please equip yourself with voltage regulating equipment. If the voltage is not stable, please equip yourself with voltage regulating equipment. The company will not be responsible for any problems caused by the voltage of this equipment.
- 1.2.4 In order to avoid the equipment from the environment (moisture, dust, liquid, direct exposure to sunlight, etc.), the product should be kept clean and dry, do not use in flammable, high heat, dusty environment. Please be careful not to allow liquids or other debris to enter the equipment, otherwise it may cause short-circuiting of the internal components of the equipment and thus cause electric shock or fire.

- 1.2.5 Without the company's permission, you can not open the equipment shell, or the consequences of the company will not be responsible.
- 1.2.6 The operator should wear disposable medical surgical gloves when using the equipment.
- 1.2.7 In order to better maintain the equipment, if you need to turn on the equipment again after switching off the power, you need to wait for 5 seconds, and for computers, you need to wait for 15 seconds.
- 1.2.8 All parameters (hardware and software) of the device cannot be changed at will.
- 1.2.9 Do not touch the surface of the lens with your hands or hard objects.
- 1.2.10 The instrument should be installed on the ground at an angle of inclination of less than 2° to avoid the instrument tipping over.
- 1.2.11 Take care to select fuses of the type and rating specified for this product.
- 1.2.12 When the instrument is not in use, disconnect the power supply and put on the dust cover; if the equipment is left unused for a long period of time, make sure that the equipment is energised for more than 4 hours every 3 weeks.
- 1.2.13 When using, please check all cables should be correctly and firmly connected, and ensure good grounding.
- 1.2.14 Environmental protection clause: When equipment or components in the system are damaged or reach the end of their service life, they may cause pollution to the environment if they are thrown away, so they should be recycled or scrapped in accordance with local laws and regulations.
- WARNING: To avoid the risk of electric shock, this equipment must always be connected to a power supply network with protective earthing.

WARNING: Do not modify this equipment without the manufacturer's authorisation.

About this product instruction (hereinafter referred to as "manual")

- (1) The pictures in this manual are effect diagrams, please refer to the actual content.
- (2) If you have any content or terms of the manual is unclear or objection, or the use of the instrument, you encounter technical problems, you are welcome to call: 023-68102805.
- (3) The company reserves the right to interpret and modify the manual.

1.3 Product Configuration

1.3.1 Structural composition

Corneal Topography is composed of host, power box and software, and the details are as follows:

Model	Hardware	Functi structural	onal and differences	Ex	ternal Softwa	re Compon	ents
specificatio n	compositio n	Collecto r	Light source	Name	Model specificati on	Release Version	Software Differences
SK-7000A	Optics, mobile mechanism	Monitor CCD	Placio ring white lamp, alignment illuminatio n infrared, fixation lamp	Corneal Topograph y system software	SK- 7000PA	V1.0	Overall view, single figure optional, quadruple figure optional, 3D image, Fourier analysis, Zernike Analysis, keratoconus analysis, contact lens fitting, two- figure display, two- figure comparison
SK-7000B	illumination system, power supply box	Monitor CCD	Placio ring white lamp, Placido ring infrared, meibomia n gland infrared, corneal staining blue lamp, alignment illuminatio n infrared,	Corneal Topograph y system software	SK- 7000PB	V1.0	Overall view, single figure optional, quadruple figure optional, 3D image, Fourier analysis, Zernike Analysis, keratoconus analysis, contact lens fitting, two- figure display, two- figure

Table 1 List of product models

fixation lamp, gland opening white lamp	comparison, seven dry eyes (tear meniscus height, tear breakup time, lipid layer, Red eyes, Gland opening, meibomian
	opening, meibomian
	giand, corneal staining)

- 1.3.2 Typical operating environment of software
- 1.3.2.1 Hardware configuration

CPU: Intel Core i5-12450 and above

Memory: 16G

Hard disk: 1TB free space

1.3.2.2 Software environment

System software: Windows10 64-bit Chinese operating system and compatible version.

1.3.2.3 Network conditions

Local area network, bandwidth 100 Mb/s .

Security Software

WINDOWS system firewall (firewall version is same as operating system version:).

Requirements for Software Environment and Security Software Updates

The system software, application software and security software do not need to be updated.

The computer running the system software of corneal topographer should meet the requirements of GB 4943.1 standard in addition to 1.3.2 typical environment of external control type software. Computer and corneal topographer with the use of medical electrical systems, should meet the requirements of GB 9706.1 in Chapter 16.

1.4 Scope of application

This product is used in medical institutions for corneal curvature distribution and dry eye examination.

1.5 Contraindications

None.

1.6 Scope of application

This manual applies to Corneal Topography SK-7000A, SK-7000B.

1.7 Product Characteristics

- Classification according to protection against electric shock: Class I
- ◆ Applied part type: Type B applied part
- Classification according to the degree of protection against liquid ingress and particulate matter: IPX0.
- Classification according to sterilization method: Not applicable.
- Classification according to the applicability to oxygen-rich environment: Not applicable to oxygen-rich environment.
- Classification according to operation mode: Continuous operation.
- ◆ Rated voltage and frequency of equipment: a.c. 220 V, 50 Hz.
- Equipment input power: 120 VA.
- ♦ Altitude: no more than 3000m.
- Pollution degree: Level 2.
- ♦ Has a signal input/output part: Yes.

1.8 Transport and Storage

1.8.1 Shipping Conditions

This instrument should be transported with moisture-proof, anti-inversion, and avoiding violent vibration.

Transport conditions: transport according to the requirements of the ordering contract, in the process of transport should avoid rain and snow splash and mechanical collision, can not be inverted, can not be exposed to the sun.

If the installed instruments need to be transported and moved for a short distance, the connecting wires between the instruments should be removed and transported separately. If the instrument needs to be transported for a long distance, it should be reloaded into the original package and then transported.

1.8.2 Storage environment

The Corneal Topography with integral package shall be stored in a clean room with

environment temperature of 0° C ~ 55° C , relative humidity of $\leq 85\%$, atmospheric pressure of 700 hPa ~ 1060 hPa , ventilated, dry and non-corrosive gas .

1.9 Relative Spectra of Outgoing Beam in Instrument

XXXXXX.

1.10 Optical radiation safety

XXXXXX.

Chapter 2 Product Profile

2.1 Primary Performance Indicators

2.2 Technical Parameters

Serial	Technical indicator	Parameter
Number		
1	Working distance	75 mm
2	Corneal topography ring number	24 Ring

2.3 Product Structure Diagram



- 1) Chin Bracket
- 2) Frontal Brace Strap. Used to place and secure the patient's forehead
- 3) Jaw rest. Used to place and fix the patient's jaw
- 4) Base mobile platform
- 5) Placido Disc

6) Chin rest height adjustment knob

7) Manipulate the handle to move the instrument in the horizontal plane, and rotate the handle to adjust the height of instrument.

8) Shoot button for acquiring images.

- 9) Host switch turns off power to Corneal Topography.
- 10) Data wire hole, electronic control wire hole
- 11) Base locking knob, base does not move after locking.

2.4 Dimensions, Overall weight

L: 335 W: 380 H: 565

2.4.1 Light source

Placido disk white ring light source: white LED

Placido disk infrared ring light source: infrared LED 855 nm Tolerance: ± 5 nm

Opposing light source: infrared LED 855 nm Tolerance: ± 5 nm

Fixation light source: Green LED 525 nm Tolerance: ± 5 nm

Visible supplementary light: white LED (SK-7000B)

Corneal staining light source: blue LED 467 nm; tolerance: ± 7 nm (SK-7000B)

Lamina ray source: infrared LED 855 nm Tolerance: ± 5 nm (SK-7000B)

Item	Range	Repeatability P	
Radius of curvature	3 mm-38 mm	± 0.03 mm	0.03 mm
Pupil size	1-13 mm	± 0.1 mm	0.1 mm
White to White	6-17 mm	± 0. 1 mm	0.1 mm
Axial angle	0-180°	± 2°	2°

2.4.2 Performance Indicators

2.4.3 Functional indicators

Measuring range of corneal topography: 9.2mm Error: ±1mm (Placido ring)

Number of measurement points: ≥34560 points

Alignment mode: Fixed focus, manual alignment

Measurement mode: automatic/manual shooting

Examination items: corneal topography, dry eye

Measurement data: corneal curvature, astigmatism axis position, pupil diameter, white-to-white distance, etc.

Data output: external printer output

Data interface: USB, support DICOM uploading

Chapter 3 Installment

3.1 Environment of use

- Ambient temperature: 10° C ~ 35° C.
- ◆ Relative humidity: 30% ~ 75%.
- ♦ Atmosphere pressure: 700 hPa ~ 1060 hPa.
- Supply voltage: a.c.220V 50 Hz.
- Input power:
- Other: No strong electromagnetic field interference.

3.2 Out of Box Inspection

Carefully open the unit package and check against the following packing slip before discarding the packaging material.

Name	Quantity
Corneal Topography host	1 set
Power box	1 piece
Power cord	1 piece
Simulating eye	3 pieces
Corneal Topography system	1 piece
software	
Directions	1 piece
Certificate of Compliance	1 sheet
Qualification Documents	1 set

Table 2 Boxing List for SK-7000A, SK-7000B Corneal Topography

3.3 Installation Environment

To ensure safe and stable operation of the device, ensure a good installation environment:

(1) The device must be mounted on a flat, non-beveled table in a position which is easy for the operator to operate .

(2) The device should not be placed in a position where it is difficult to operate the power switch.

(3) The device must be installed in a clean, quiet, dry environment.

(4) The device must be installed in an absolute dark room with no visible matter 1 meter away.

(5) This device shall be installed by the personnel who have received professional technical training, and shall not be disassembled without permission after installation.

3.4 Installation Step

3.4.1 Host Placement

Take out the main frame of measuring instrument and place it on the table; pay attention to it being horizontal and not inclined, as shown in the figure below.



3.4.2 Connect Power Line, Data Line

Connect the power port of the Corneal Topography System host to the power box and the data cable to the computer USB3.0Interface.

Chapter 4 Operating Procedure

4.1 Replace disposable gauze

When changing a patient for examination, it must be changed Disposable medical gauze pieces in contact with the patient as follows.

Disposable medical gauze replacement method:

A. unfold the gauze piece;

B. wrap the gauze piece around the jaw support and forehead support, and press the self-wrap tight cloth on the gauze piece to prevent loosening;

C. Removal method: The gauze piece can be removed by pulling it apart from the wrapping cloth.

4.2 Startup

After the power cord and data cable have been connected according to the procedures in 3.4.2, connect the power plug of power cord to the socket with good protective earthing, and then turn on the power supply of host and computer system.

Double-click the Corneal Topography System Software Desktop icon on the computer system to display the login interface. After the user selects the account and enters the password (the default user name of the system is admin; the password is empty), it can enter the software main interface.

4.3 New Patient

After entering the main interface, click to enter the new patient interface. After entering the patient information in turn, click the corneal topography acquisition button (select the acquisition mode after entering) or dry eye acquisition button to enter the acquisition interface.

4.4 Patient Position Correction

Instruct the patient to place the lower jaw on the jaw rest, the upper forehead must be close to the anterior forehead band, use the jaw rest adjustment knob to adjust the jaw rest height, so that the patient 's eye angle is parallel to the eye position line.

4.5 Test Process

- Enter the acquisition interface;
- Set shooting mode: automatic/manual;
- Click the on-screen shooting button or handle shooting button to start the acquisition; (If automatic shooting mode is selected, the shooting will be automatically performed after X, Y and Z axes meet the requirements)
- After acquisition, the software automatically jumps to the analysis function interface.

4.6 Analyze Functions

In the right side of main interface, click any analysis function option in the function overview to enter the corresponding analysis function interface to view the detailed results.

4.7 Print

Click the Print/Print Preview button in any analysis function screen to print or preview the current analysis results.

4.8 Shutdown

Turn off the power switch and turn off the computer power after the check is completed on the same day, or when not in use for a long time.

Chapter 5 Software Usage

5.1 Login Screen

In the login window, enter the username and password (System default username: admin, password: empty) and then click Login to enter the main interface.

Following is an example of SK-7000B, SK-7000A has no dry eye inspection function compared to SK-7000B. That is, there is no ocular surface analysis acquisition button in the main interface of SK-7000A, and there is no dry eye overview of SK-7000A in the functional overview.

5.2 Main Screen



☐ Corneal topography acquisition, click to enter the corneal topography acquisition interface.

② Dry eye data acquisition, click to enter the dry eye acquisition screen (SK-7000A does not have this icon).

BDocument management, access to patient database.

Dicom Upload

b Print and click to print the report.

BPrint Preview and enter the Preview screen

7 System Settings

Minimize button, click to minimize the software

Restore button, click
Close button: click to exit the software
Patient information bar displays patient basic information (ID, name, gender, date of birth, name of examining physician).
Add new patient
Delete Patient Information
Modify patient information
Explanted: Delete this patient
Enter: move patient from patient encounter area to waiting area
Activity display area : When the functions of acquisition, analysis, creating new patient and database are opened, the corresponding function information is

displayed in this area.

5.3 Corneal topography

5.3.1 Acquisition interface



 ☐ Patient Information Bar , which displays the patient 's basic information (I D , name, gender, date of birth, operating physician).

 ②Indicator box showing alignment status.

B Corrected value of X, Y and Z : auxiliary display of position deviation between

positioning lamp center and monitoring center.

▲Eye specific instruction, OD : right eye; OS : left eye.

⑤Shooting mode, contestants can move and automatically shoot.

⑥Shoot button, click to shoot images.

5.3.2 Overall view



☐Select the original map and click to view the original map or replace the analyzed image.

Analytical Results: Results are shown for each parameter after analysis.

③Simplified diagram: Analyzed images are shown with blue lines marking the inner ring of the ring; red lines marking the outer ring; white dashed lines marking the iris margin (white to white); "white +" marking the center of the pupil margin; and "white ⋅" marking the center of the image (pupil center).

▲ Visible/Infrared toggle button: click to switch the simplified graph from visible to infrared.

⑤ Corneal Topography Type: selectable in Axial/Radial Curvature (default), Tangential Curvature, Height, and Refractive Maps.

Display Infos
✓ Apex
✓ Rmin
Pupil Center
Pupil Border
SI-NT
✓ OS/OD
✓ Grid
✓ 9mm Border
✓ Background
✓ Value
Numeric Value
O Hemimeridians
O Meridians
3, 5, 7mm meridians
Tools
Oursor
○ Distance
○ Gradient
⊖ Chart

^(B) Curvature data on main meridian: it is feasible to point any point of topography map to move the meridian. After stopping the movement, a pop-up window will be displayed. The data coordinate graph of current meridian is not saved. That is to say, the distance disappears after clicking the mark/toggle other functional interface again. Display the radius of curvature rectangular coordinates on the main meridian throughout the corneal topography range.

9Feature Overview

SK-7000A	SK-7000B
Overall view	Overall view
Single Selection	Single Selection
FourView	FourView
3D View	3D View
Two maps compare	Two maps compare
Two maps subtract	Two maps subtract
Fourier analysis	Fourier analysis
Zernike analysis	Zernike analysis
Keratoconus analysis	Keratoconus analysis
Contact Lens fitting	Contact Lens fitting
	Dry eye analysis

5.4 Single Map

It is convenient for the physician to view the single type topography more carefully, and its detailed function is consistent with the color topography function in the overview map.



Mouse (cursor) in the topography map, pointing to the location, showing the point coordinates/polar coordinates (coordinate type can be switched in the setting interface), the corresponding value. Following figure:



5.5 Four View

4 types of topographic maps can be selected for display, and the rest of the functions are the same as the single colour map operation function, which is the basic type commonly used by doctors and often prints topographic maps with this function. The default placement order of the 4 maps is, refractive force map, height map, axial/radial curvature map, tangential curvature map.



In addition, the quadmap can realise the linkage of multiple maps. When the mouse (cursor) is on a topographic map, the other topographic maps on the linkage map will display the value of the point at the same time (the topographic map where the mouse is located is marked with a big "10" cursor, and the rest of the linkage maps are marked with a small "10" cursor), as shown in the figure below.



5.6 3D View



[†]Zoom in/out Display Settings: Overall zoom in and out of 3D color maps.

② 3D color map shows: 3D image effect of corneal anterior curvature topography is shown , and the color of attached ruler is in 3D color map.

③ Move button : Click button to control the specific direction observed in 3D color map, or hold the left mouse button to drag and view in the image.

5.7 Fourier Analysis



5.7.1 Original Map

Operation, function, and display are consistent with the axial curvature map in corneal topography.

5.7.2 Equivalent Spherical Lens

Identified by the arithmetic mean of all radii of curvature for each ring, the spherical component allows an approximate calculation of corneal eccentricity.

5.7.3 Off-centre

The minimum value on each ring is indicated by a white ring and the position of the maximum value is indicated by a black ring, reflecting the degree of corneal eccentricity.

5.7.4 Regular Astigmatism

The second-order wave component corresponds to a two-frequency sine wave that transmits two minima with two maxima on each ring within a given radius, reflecting the degree of regular astigmatism of the cornea.

5.7.5 Irregularity

The remaining wave components taken together give the irregularity of the corneal rings, responding to the degree of irregularity of the corneal surface.

5.7.6 Fourier coefficient

The coefficients based on the calculation of individual components allow a quick digital description of the corneal surface;

 $(\ensuremath{\mathbbm 1}$) Spherical Rmin (spherical minimum radius): the smallest radius of curvature in the spherical component.

2 Spher. Eccentricity: Corneal eccentricity calculated from the spherical component. Do not confuse with 30 ° eccentricity, which is determined by the method of vector radius.

③ Max. Decentration: maximum value and its location in the Eccentricity plot.

④ Astigma. Central (central astigmatism): regular mid-astigmatism curvature difference and axial position.

⑤ Astigma. Peripheral: regular curvature difference of peripheral astigmatism and axial position.

		Axial/Radial Plot	Curvature	Tangential Plot	Curvature
Sphere	Minimum	< 6 .87		< 6 .93	
Radius					
Spherical ecce	entricity	> 0 .84 < 0 .1	8	> 0 .84 < 0 .1	8
Maximum eccentricity		> 0.43		> 0 .84	
Peripheral astigmatism		> 0 .032		> 0 .141	

If the value is sick, the value is highlighted in red

5.8 Zernike Analysis

Zernike Analysis is a Zernike analysis of corneal topographic height data, which calculates a coefficient for each Zernike polynomial.



1 Zernike Polynomial overview: corresponds to the Zernike coefficients shown separately on the left side, a few items are checked on the left side and the corresponding tick options are shown in its area.

② Zernike Matching Parameters: Before performing Zernike analysis, set the analysis range, analysis order and subtracted reference shape, and the detailed window is as follows.

Mo	dify Zernike Fit	Parameters
Zern	ike analysis scope	
٥	Diameter: 8.0 🔻	mm
0	All topography	
Orde	rs	
n =	6 -	

- Order: Maximum order used to set the Zernike polynomial calculation.
- Zernike Analytical Range: Setting the fixed diameter of the analysis, or the topographic map range

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mojin… 2024040100…	Kmax	43.3D	Kerato	onus Analysis(Ol	D)		Kerato	conus Analysis(OS)					
李鑫 2024040100…	Kmax pos. 1.49r	nm @ 280"	Date	2024-04-08 2024-0 09:27:20 09:31	4-08 :02		Date	2024-04-08 2024-04-08 09:27:20 09:31:02					
test afta 2024032800…	PS nos 0.24	2.4/11111 mm @ 45°	ISV	0.92 0.9	2		ISV	0.92 0.92					Analysis
Waiting area	WTW	11.86mm											Keratoconus
	Corneal pos. 0.28r	nm @ 198°	IVA	1.01 1.0	·		IVA	1.01 1.01					Analysis
<i>—</i> 6 <i>—</i> 6	AA	93%	СКІ	1.03 1.0	3		скі	1.03 1.03					Fitting
	I-S	-0.38	RMin	7.72 7.8	D		RMin	7.75 7.83					
	1KC	0.29	111.0	44 33			1114	44 22					Analysis
	Calculation Zone:	5.0 mm 🗶	IHA	4.4 2.2			IHA	4.4 2.2					
	Q.h	-0.25	IHD	0.011 0.01	0		IHD	0.011 0.010					
	Q.v	0.05	Z40	0.14 0.1-	4		Z40	0.32 -0.04					
	740	-0.22	TVC	0.30 0.3			TYC	0.20 0.50					
	MPP	42.71D	INC	0.59 0.2			INC	0.50					
	HOA RMS	0.39µm		92% 93%	6		M	94% 88%					
		- 19 C	ϵ										

5.9 Keratoconus analysis

5.9.1 Vertical Decentration Diagram

Vertical decentration is presented at the patient and examination interfaces by height data Fourier analysis.

Mouse (cursor) On a certain topography map, other topographies on the joint map simultaneously display the value of this point (the topography map where the mouse is located is marked with a large"ten"cursor, and the other linkage is marked with a small"ten"cursor)

5.9.2 Index Progression

Shows indices recorded from historical exams of different eyes of the same patient.

(1) ISV : Index of Surface Variance gives the deviation of each corneal radius

from the mean. Enhancement of various types of irregular corneal surfaces (scarring, astigmatism, distortion, keratoconus, etc. caused by contact lenses).

② IVA : Index of Vertical Asymmetry gives the degree of symmetry of the horizontal vertex corneal radius relative to the reflection axis. True improvement for tilted astigmatic axis, keratoconus, or marginal distortion.

3Rmin: minimum radius of corneal curvature in topography.

④ IHA : Index of Height Asymmetry (horizontal asymmetry index) gives the degree of symmetry of horizontal apex height data relative to the reflection axis.

⑤ IHD : Index of Height Decentration (vertical decentration index) This index is calculated based on height Fourier analysis and gives the degree of vertical axis deviation. Steeper in keratoconus.

6 Z40 : Zernick aberration coefficient

⑦ TKC : keratoconus grade

8 AA : Percentage of actual analytical range and theoretical analytical range in corneal topography.

examinations on the same eye of the patient.

5.10 Contact Lens Fit



5.10.1 Lens Fluorescence Image Simulation

- (1) Fluorescent color bar, default color scale is 7 5 μm , right mouse click on the color bar, pop-up setting, and select 7 5 μm , 100 μm , 1 50 μm , 2 00 μm , 3 00 μm range
- 2 Image simulation display area, with the captured ocular surface as background color, red coil as corneal diameter and fluorescent green as simulated lens, click button to select operation mode, as follows:

Cursor, which can be arbitrarily clicked and pressed on the fluorescent green lens, the coordinates and values of this point will appear in the upper left corner of the image

Drag to drag a fluorescent green lens anywhere in the red area and reset the analog data each time the drag stops

Mark length, any area in the red coil can be marked for length, and length marks are not saved.

Rotation, can rotate the lens, long press the up and down buttons, drag to rotate the lens, when the rotation ends, can generate thumbnails

Save, the currently fitted lens can be saved in the right thumbnail

5.10.2 Main Meridian Contact Lens Distance

This display allows a better estimate of adjustment as the profile of the curve readily indicates whether adjustment is flat, steep or parallel. If the adjustment is flat, the curve bends upward, if steep, bends downward, and for parallel adjustment, Horizontal abscissa represents diameter (0, 2, 4, 6, 8 mm), ordinate represents height of contact lens to cornea (10, 20, 30, 40, 50, 60, 70, 80, 90, 100 μ m)

5.10.3 Anterior Surface Corneal Data, Meridian Graphs, and Eccentricity Values

1) 3 mm Anterior Surface Corneal Data

2 3 mm meridian view

③ 6-10 mm Main meridian heart rate value

5.10.4 Select Lenses

With the commonly used manufacturer model parameters of contact lens, it is feasible to select the suitable manufacturer and model contact lens through the pull-down bar to perform the simulated fluorogram. When the manufacturer is selected well, it is automatically allowed to select the most suitable contact lens by default

5.10.5 Custom Lenses

Simulated fluorograms can be performed in custom lens regions with custom lens parameters

5.11 Two maps compare

i 💿 📰 🗇						ê	@ O	Û	- • ×
Name: 焼芹0408 Sex: Female ID: 20240408000001 Birthday: 1990-01-01	Corneal Indices 2024-04-10 16:21 * SimK I	OD images(QS)	50.0 80.0 79.0 8- 10 8- 10 8- 10 8- 10 70.0	Refractive Power Map 90'(5) 508	OD .	Corneal Indices 2024-04-10 16:21 SimK		OS Imagos(QS)	Features Topography ^ Overview
Doctor: Patient info	K1 K2 Rv 8.	37.7D 37.9D 95mm	50.0 4 46.0 4 44.0 2	410 412 408 401 355 39.9 38.5 38.2		К1 К2 Rh		37.9D 38.0D 8.91mm	Single Selection
🌲 🌲 🏯	Rh 8. Km Rm 8.	90mm 37.8D 92mm	42.8 40.0 38.0 2	39.9 33.9 37.9 37.9 19.1 - 36.6 37.4 37.9 39.9 37.6 37.9 38.8	or (M)	Rv Km Rm		8.87mm 37.9D 8.89mm	FourView
1 2024041600···· 123 2024041500····	Axis.h Axis.v Astig	152° 62° 0.2D	36.0 34.0 32.0	38.5 38.4 40.2 38.6 39.2 40.5 40.5		Axis.h Axis.v Astig		138° 48° 0.2D	3D View Two Maps
zeh 2024041100… 姚芹0408 2024040800… 姚芹20… 2024032600… 过于其… 2024040800…	a d d d d d d d d d d d d d d d d d d d	0.20	36.6 8- 28.8 8- 10.0 10- Abs D 10-	270'00		ë(94 710	0.20	Compare Two Maps Subtract
mojin… 2024040100…	Kmax	43.0D		Refractive Power Map	- 10 -	Kmax		42.4D	Fourier Analysis
李嘉 2024040100… test afta 2024032800…	Kmax pos. 4.36mm (PS 2.	@ 265° 14mm	90.0 80.0	901(S) 595	OS	Kmax pos. PS	4.40mn	n @ 263° 2.39mm	Zernike Analysis
Waiting area	PS pos. 0.19mm (WTW 11. Corneal pos. 0.34mm (@ 238° 94mm @ 216°	70.0 8 0-338 60.0 6 50.0 6	402 411 412	18	PS pos. WTW Corneal pos.	0.26mn 1 0.16mn	n @ 235° 1.94mm n @ 332°	Keratoconus Analysis Contact Lens
~ 0 ~ 0	AA I-S TKC	92% 0.33 0.14	44.8 42.9 40.0	38.0 38.7 38.0 37.7 38.2 40.4 37.8 37.8 38.0		AA I-S TKC		92% 0.33 0.21	Fitting Dry Eye Analysis
	Calculation Zone: Ø=5.0 m	m ¥	38.0 2	38.2 38.2 38.2 40.6		Calculation Z	one: Ø=5.0	mm 💌	FUIDIYSIS
	Q.h Q.v	0.06 0.40	36.0 34.0 32.0	38.3 3900 39.0 38.9 40.7 40.1 40.9		Q.h Q.v		-0.08 0.42	
	Z40 MPP 3	-0.07 38.39D	30.0 8-	26. 55		Z40 MPP		-0.01 38.39D	
	HOA RMS 0	.51µm	16.6 IC-	270'(1)	A	HOA RMS		0.57µm	

Binocular control refers to the comparison of parameters and topography of the same eye at different stages, which is commonly used for preoperative and postoperative visits. This functional interface can freely select the eyes and examination time to be compared according to the pull-down historical time bar, as well as change the types of topography to be compared.



5.12 Two maps subtract

Corneal data and topography of patients in different eyes/at different times of the same patient were selected for difference comparison, and A-B the difference values and difference maps between the two maps were obtained.

5.13 Dry Eye Collection (SK-7000B)



Home screen click is to enter Dry Eye acquisition screen

2 Default Automated/Manual

③ Check the light source switch: switch between infrared and visible light items (applicable to TMH)

A Software Photograph Eye Selection: Use O not need to manually select eyes when taking photos or videos, point O D/OS Select.

句Dry Eye Analysis button.

Software photography function: click on software Take photos or videos with functional equivalent handle photo button.

Print Button

B Thumbnail holding are a with video files

Patient information status

5.14 Dry Eye Item Analysis Interface (SK-7000B)

After acquisition, automatically enter the analysis interface/main interface browsing interface, double-click the dry eye image to enter the analysis interface for browsing.



5.14.1 TMH Analysis Interface

After acquisition, directly enter the acquisition analysis interface

1 TMH Analysis Button, Re-analyze TMH

2 Print button, enter the TMH print preview screen

3TMH Results

4 TMH Reference

5.14.2 NIBUT analysis interface



①NIBUT Analysis Button ②Enter NIBUT print preview screen ③Preview Video Window ④Breakdown Block Location Diagram ⑤Break Time/Break degree Line Diagram ⑥NIBUT TEST RESULTS ⑦NIBUTdown Reference

5.14.3 Lipid layer analysis interface



1 Enter the lipid layer print preview screen

- ☑Lipid Layer Thickness Profile
- යුLipid Layer Thickness Results
- Abbreviated Lipid Layer
- 句Reference Plot for Lipid Layer Thickness
- 5.14.4 Red eye Analysis Screen



☐Red eyes Analysis Button

2 Enter the eye-red print preview screen

③Artwork /Enhancement 1/Enhancement 2 toggle button, click button to switch the

preview image

Areas of conjunctival enhancement

5Ciliary Enhancement Area

⁶ Conjunctiva /Ciliary Score toggle button which toggles the eye red reference graph to score conjunctiva/nodular individually.

7 Abbreviated Red eyes.

BRed eyes Reference Plot

5.14.5 Gland Opening Analysis Screen



1 UP/DOWN Upper and Lower Eyelid Switching

යුGland Opening Obstruction Reference

5.14.6 Meibomian gland analysis interface



1 Auto /Manual: Automatic is local enhancement or coloring, manual is image augmentation, and manual analysis requires dragging the thumbnail left and right to score.



Global Enhancement

自Meibomian Gland Analysis Button

BEnter the Meibomian Gland Print Preview screen

Analysis area selection box allows manual adjustment of the analysis box range

to make the analysis of the meibomian gland area more accurate.

句Staining, absence of staining of meibomian glands



[®] Meibomian gland absence reference map, refers to the degree of meibomian gland loss, and evaluates the quality.

Imm meet year immed dynamicy immed dynamicy

5.14.7 Corneal Staining Analysis Interface

1 Corneal Staining Print Preview Button

Analysis area, analysis area can be arbitrarily adjusted to make analysis results more accurate.

③ Corneal staining refers to the chart, refers to the degree and extent of corneal staining, and evaluates the quality.

5.15 Dry Eye Analysis (SK-7000B)

Click "Dry Eye Analysis" in the main screen functional area to display the following screen:



This screen displays all dry eye item exam thumbnails taken for this patient on a specified date, and double-clicks to re-enter the analysis screen to view/modify the analysis results

5.16 Patient database

🖸 🔘 🗮 🏟											G	ଜି 🔅	í	-	ĵ ×
Name: guoyuq	Stu	dies													
Sex: Male		-		From :		H								_	
ID: 20240323000003		Export	P Import												收站
Birthday: 1990-01-01							1								
Doctor:	Sel.	ID		Name	Sex	Birthday	Age	Doctor	Exam time	Topography	Оре	rate			
Patient info		2024041600	0002	1	Male	1990-01-01	34		2024-04-16 15:56	Yes	Details	Delete			
		2024041500	0001	123	Male	1990-01-01	34		2024-04-15 11:28	Yes	Details	Delete			
🛋 🛋 🎽		2024041100	0002	zeh	Male	1990-01-01	34		2024-04-17 15:44	Yes	Details	Delete			
吴总 2024032300…		2024040800		[−] 第1/〒0408	Female	1990-01-01	34		2024-04-17 15:37	Yes	Details	Delete			
guoyuq 2024032300…		2024032600	0003 \$	野牛20240326	Female	1774-01-01	250		2024-04-10 16:54	Yes	Details	Delete			
刘森林 2024032300…		2024040800	0002	过于其0408	Male	1990-01-01	34		2024-04-08 15:40	Yes	Details	Delete			
陈老师 2024032200…		2024040100	0002	mojinming	Male	1990-01-01	34		2024-04-01 15:24	Yes	Details	Delete			
测试3 2024031500…		2024040100	0001	李矗	Male	1990-01-01	34		2024-04-01 15:12	Yes	Details	Delete			
test 2024031800…		2024032800	0007	test afta	Male	1990-01-01	34		2024-03-29 18:00	Yes	Details	Delete			
CS2 2024031500…		2024032800	0008	ces	Male	1990-01-01	34		2024-03-28 17:28	Yes	Details	Delete			
測试 2024031500…		2024032800	0001	11	Female	1990-01-01	34		2024-03-28 15:47	Yes	Details	Delete			
780a,2 2024031500···								Study histo	ry						
Waiting area						Birthday	Age			Topography	Оре				
2 th 2 th															
								Result previ	ew						
			K1: D	К	E D	•	lm: D								
		OD	ECC:	As	tig: D		upil: mm								
			ФНН: mm	TP	«C:	,	A:								

5.16.1 Search Field

You can quickly locate the patient information you need to find by pulling down the bar and selecting one of the following: ID, Patient Name, Doctor, Operating Doctor, Date of Birth, Test Time Range. The patient details are displayed in the Patient Details column below.

5.16.2 Patient Information Column

Patient details include ID, name, gender, date of birth, age, doctor's information, query collection completion (if the patient has already had a corneal topography, "Yes" is displayed under Corneal Topography, and if dry eye is completed, "Yes" is

displayed under Dry Eye). "

5.16.3 Corneal Topography Results Preview

Display the patient's monocular partial examination result data: K1, K2, Km, ECC, Asting, Pupil, ΦHH, TCK, AA.

Image information: axial map, height map.

Clear: Select patient information arbitrarily, without selecting the history, all history records of the patient will be cleared, if the patient's specific history is selected, only the specific history data under the patient will be cleared.

Restore: Any selection of patient information, without selecting history, restores all history records for that patient, if patient specific history is selected, only the specific history data under that patient is restored.

Return: Click to return to the patient database.

Regular purge setting: 50/100/150 can be set, when the set number of entries is reached, the 25 earliest deleted data will be automatically purged.

🏟 🖺 🍥			66	O	- • ×
Name: guoyuq		Cutore DICON			
Sex: Male	Hospital info	System Users DICOM			
ID: 20240323000003					
Birthday: 1990-01-01	Hospital name:				
Doctor:					
Patient info	Doctor:	👻 + 🗉 Set default			
	Hospital icon:				
吴总 2024032300…					
guoyuq 2024032300…					
刘森林 2024032300…					
陈老师 2024032200…					
海馬马 2024031300····					
CS2 2024031500···					
测试 2024031500…					
测试2 2024031500…					
Waiting area	Service provider:				
2 0 2 0					
		i i i i i i i i i i i i i i i i i i i			

5.17 Hospital Information Setting

5.18.1 Hospital name

As one of the contents shown on the printed report , \blacksquare : font color can be selected for this icon.

5.18.2 Physician

As one of the patient information contents, input the doctor 's name to add/delete the doctor' s name in the list, default button, select the doctor 's name, the name will appear after the name *; the name will be shown in the new patient information doctor' s column and the printed report doctor 's column.

5.18.3 Print icon

Pictures can be added in png format, up to 1 MB in size, with resolution adaptive settings shown as Print Report icon.

5.18.4 Service Unit Display as one of the printed reports

5.18 System Setting

	💿 🗄 🏟			ē	ଜ	۲	(j)	-	•
Name: Sex: M ID: 202	guoyuq ale 40323000003	Hospital info	System Users DICOM						
Birthd	ay: 1990-01-01	Dispały language	English						
Doctor		Hot Key Setings							
Patier	nt info	Add New Patient	ณ						
2.	2. 2	Capture Topography Imaj	es F2						
98	2024022200	Print	F3						
guoyuq	2024032300	Date Format							
刘森林	2024032300…	Year-Month-Day	O Day-Month-Year O Month-Day-Year						
陈老师	2024032200…	Default Printer	导出为WPS PDF *						
测试3	2024031500	Color bar style	American Style 👻						
CS2	2024031500	Map Display	Only reconginzed area Include interpolated area	Ø = 10.0	mm Ŧ				
测试	2024031500…	Coordinate system	Cartesian Polar						
测试2	2024031500…	Asohericity							
Waiti	ng area	Discide Calibration	op othe of og						
_									

It can set the software language, which includes Chinese language, English language and French language. It is required to restart after successful selection, and all words on the software interface are changed to the corresponding language; shortcut key setting (customizable modification), such as F1 main interface enters the new patient, F2 main interface enters the corneal topography acquisition interface, F3 main interface enters the ocular surface comprehensive analysis and acquisition, click A/t + P in the analysis interface enters the print preview interface, the format is displayed on the day and year, the printer is selected and set, and the Placido ring is calibrated regularly

5.19 User Management Settings

Name: guoyuq Ser: Male Hospital info System Users DICOM				
1: 20240732000003				
Doctor: admin admin				
Patient info				
栗島 2024932300				
guoyuq 2024032300···				
对森林 2024032300…				
陈老师 2024032200…				
#it3 2024031500···				
test 2024031800···				
CS2 2024031500··· E Enable login when startup				
湯は 2024031500… Add Modify Chiefs				
#i#2 2024031500···				
Waiting area				

5.19.1 Manage login user interface

Display software login account setup information. User name and password can be changed, and user name and password can be added, where the default user name admin cannot be deleted and changed, but admin 's password can be changed

5.19.2 Enable login interface

When selected, the software needs to go through the login interface to open, and when not selected, the software opens directly to the main interface.

5.20 Dicom Setting

🙆 🔘 🗮 🍕
Name: guoyuq
Sex: Male
ID: 20240323000003
Birthday: 1990-01-01
Doctor:
Patient info
2. 2. 2
吴总 2024032300…
alati 2024032300
防老師 2024032300…
测试3 2024031500…
test 2024031800
CS2 2024031500····
测试 2024031500…
测试2 2024031500…
Waiting area
2. 2.

Dicom refers to digital medical imaging and transmission protocol. According to I P

ground, Mask, Gate and other information input for upload, Dicom can click the patient to be uploaded after the setup is completed, and click to upload the patient information and picture information to Dicom server.



5.21 Printing and Preview

Corneal Topography Printing

In the dry eye analysis screen/acquisition screen/dry eye overview screen, click the print button and the following dialog box will appear:



Following print screen pops up after selecting dry eye item to print

	Zoom in	Zoom out	JPG	PDF			
r of copies					Comp	rehensive Report	
					ID: 20240408000001 Name: 96740 Gender: Female Age: 34	408	Vision R: 0 L: 0
Print					OD	os	OD OS
					N 18 U 7		Pirst:11.80s Class:Nor Average :11.80s Class:Critical
					Normal: fints-10x, averages-14x; Critical: finta-6-fx, averages T M H	7-13s; Dry eye: first <ss, average<7s<="" td=""><td>Central0.31mm Class.Nor</td></ss,>	Central0.31mm Class.Nor
					infrared(mm): Nor: TMH±0.2; Mid: 0.1±TMH<0.2; Mor	ferate: 0 <tmh<0.1; severe:="" td="" unme<=""><td>asurable</td></tmh<0.1;>	asurable
					L L A Reference pitters 60-tion tober	245 325 6	Avg: 10–60nn High: > 100nn Lou: <15nm
					1	\bigcirc	Nasalt0.8 Class.Mild Bitamporat0.3 Class.Mild
					Red eyes Grade Index: 0: No hyperemia; >0-1: Mild; 21-2: N	oderate: 22-3: Severe: 23: Serious	-
					М Е В В О	Mine	Score2 Class.Moderate Def Rated6%
					Score: O-No deficiency: 1-Deficiency:5395; 2-Deficiency:3495	-66%; 3-Deficiency;67%.	

Dry Eye Print Interface

5.21.1 Toolbar

Zoom in the print preview report and place it up to 2 00% , when placed to maximum,

EXPOSE: Export the report to JPEG format, pop up the path selection box, and select the appropriate path to export the report.

PDF : Report everywhere in PDF format, pop up the path selection box and select the appropriate path to export the report.

EVALUATE: Print the specified report form for the selected printer according to the printer settings selection in System Settings.

5.21.2 Information Bar

① Display hospital name: it is displayed according to the hospital name set in the hospital information in the setting.

② Display the name type of printing report: Select printing in the analysis interface, enter the printing preview interface of corresponding analysis function. If you click preview printing in the overview figure analysis interface, enter the printing preview interface of overview figure.

③ Display the basic information of patients: ID, name, gender, date of birth, age and binocular vision.

④ Display operation information: examination time and operating physician.

(5) Display service unit: display according to the unit name set in the service unit within the setting.

5.21.3 Preview Report

Display is all information shown in the function interface, such as: all data, all images.

Chapter 6 Software Description

6.1 Software name and model

Name: Sunkingdom Corneal Topography System Software

6.2 Software Version Number

SK-7000PA Software Release Version: V1.0 SK-7000PB Software Release Version: V1.0

6.3 Software Provider

Operational Soft Parts provided by Name : Chongqing Sunkingdom Medical Instrument Co., Ltd.

Operating Software Provided by: 35-2 Yingtian Guangdian Valley, Caijiagang Town, Beibei District, Chongqing, China

6.4 Software Support

Chongqing Sunkingdom Medical Instrument Co., Ltd. provides technical support, provides software operation training for software users, and continuously upgrades and optimizes the operation software.

6.5 Software Application Backup & Restore

Backup: upper computer software, back up software is required. Patient data recommends that users perform regular data backups. If backup is required, insert USB flash disk first, check all patients in document management interface, click Export to select the designated USB flash disk path to back up the data to USB flash disk;

Restore: Select export in the database interface, select the specified path, click export to restore the backup data.

6.6 Software Maintenance

After the completion of software configuration, maintenance is basically

unnecessary. When there is new software to be upgraded, the software can be upgraded; serious misoperation or hardware system failure may damage the software system of the device.

6.7 Software installation

③ Double-click the Desktop Topography System Software Installation Package



选择安装	走语言	×
٢	选择安装时要使用的语言:	
	简体中文	~
	确定 取	消

- (4) Select Installation Language
- \bigcirc Select Next
- 6 Select the installation path, which can be customized by the operator in the default C drive S KEye folder.
- \bigcirc Click Install to finish the installation and the desktop will generate



Chapter 7 Maintenance and care

In order to obtain better use effect and longer service life, it is necessary to have good use environment without interference and correct maintenance method.

7.1 General Precautions

◆ This equipment should be pushed and pulled carefully, away from the source of vibration, and should be placed in a cool, dry and ventilated place.

• Do not mix with toxic, corrosive, flammable and explosive items when storing.

• Check the appearance of the equipment for damage before use.

- Check the power cord for damage, if so, please replace it before use.
- The power cord should be plugged into a well-grounded outlet.

 Please do not load or unload any parts of the equipment after it is powered on.

◆ When the machine is not used for a long time, unplug it from the power supply. Store the main unit in a dry and ventilated environment.

◆ Prohibit the use of USB memory sticks on the instrument.

◆ If the instrument is returned to the factory for repair, please sterilise the cheek rests, forehead strap, etc. with 75% medical alcohol.

7.2 Cleaning and maintenance of equipment (disinfection)

◆ After the equipment inspection is completed, surface dust should be removed daily with a cleaning cloth and covered with a dust cover.

◆ Weekly wipe the stains on the outer surface of the equipment with a wet rag with a little centre cleaner and then dry it with a dry rag. And sterilise the cheek rest, forehead strap and operating handle with 75% medical alcohol.

◆ Normal use before the recommended ten minutes in advance of the boot warm-up to ensure that the equipment works properly.

◆ Touch screen maintenance: touch screen easy to damage. Only use a wet cloth to wipe. Can not use solvents or alcohol.

7.3 Preventive inspection and maintenance (if any)

When this equipment is not used, it is necessary to turn off the power switch and unplug the power plug; when it is not used for a long time, it is best to power on once a month, about 10 minutes each time.

Equipment accuracy can be verified using random incidental eye measurements over long periods of time

Note: Disconnect power from the control unit during inspection.

7.4 Component Replacement (if applicable)

User can repair or replace parts information at his/her discretion (parts of our designated model must be used)

7.4.1 Type and rated value of safety tube: T2AL250V (the fuse shall meet the requirements of national standard GB 9364)

Note: When replacing the fuse, disconnect the power supply and open the fuse box for replacement.

7.5 Common Troubleshooting (if applicable)

Fault	Situation	Exam				
		Verify that the power plug is plugged in				
No display on		Confirm that the device is connected to the power				
control panel		cable				
	Bad fuse after	Contact our service personnel				
Control panel	Image dim	Adjust brightness				
Moving parts		Please do not move it by force, contact our after-				
failure		sales service staff.				
	Print paper output	Confirm Paper Polls are Directed Correctly				
I Inable to Print	is not printed					
	No Print Paper	Confirm whether the printer is out of paper, such				
	Output	as out of paper need to be replaced with new				
	Calput	printing paper				

Service drawings are available upon customer request.

7.6 Waste Handling

During the normal use and maintenance of this equipment, the replaced components or other wastes shall be properly handled according to the requirements of local laws and regulations and may not be discarded at will. Equipment shall be recycled at the end of its life in accordance with local laws and regulations to avoid environmental contamination.

7.7 Jaw rest safety factor description

Jaw rest rated load: 5 kg Jaw rest safe load: 5 kg Jaw Tray Break Load: > 20 kg Metal Member Break Load: > 20 kg

Chapter 8 Symbol Explanation

8.1 Device symbol explanation

Power On	O Power disconnected					
DC	\sim Communication					
★ Type B Applied Parts	Caution! Consult accompanying					
	documents					
Protective earthing	a.c. alternating current					
ON means power on	OFF means power off					
Quick key: adjust chin rest height	Quick Key: Eye Switch/Measure					
T2AL250V Power fuse marking	POWER Power On Indicator					

Table 5 Explanation of device symbols

8.2 Explanation of Packaging Symbols

易碎物品	11 向上	協商	3 4 4 4 4 5 2 5 4 5 4 5 4 5 4 5 4 5 4 5 4
Fragile articles are	The package	This package	This package
contained in the	shipping unit shall be	shipping unit is	shipping unit is
transport package	shipped upright.	protected from	stacked up to 3
and shall be handled		rain.	layers.
with care.			-

Chapter 9 Warranty Statement

Commitment: The factory can provide the information necessary for the equipment parts which are designated as repairable by the factory.

1. Our company will provide lifetime equipment maintenance and free consultation.

2. This equipment is warranted free of charge for one year from the date of purchase under the premise of complying with this instruction manual.

3. During the warranty period, the following cases will be charged for maintenance:

• Damage caused by the use, maintenance and storage without following the instruction manual;

• Without the authorisation of Chongqing Shangbang Medical Equipment Co., Ltd. personnel, private dismantling / modification caused by damage to the equipment;

• Damage caused by accidents, misuse, or irresistible natural factors.

If you have any objection to the instruction manual or do not understand any part of it, please call: 023-68102805.

Chapter 10 Electromagnetic compatibility

10.1 Equipment Group Classification

Corneal Topography belongs to Group 1 Class A equipment according to the grouping classification in GB 4824.

10.2 Essential Performance

Under the test conditions specified in 36.202 of YY 0505, Corneal Topography shall meet the following requirements:

1) Normal display of parameters can be set as expected, normal function of each key shall not be invalidated, the software operates normally, the monitoring window displays normally, and clear images can be taken.

10.3 Electromagnetic Emissions

Guidance and Manufacturer 's Declaration – Electromagnetic Emissions			
Corneal Topography is intended for use in the electromagnetic environment specified below. The customer or the user shall assure that it is used in such an environment:			
Emission test	Compliance	Electromagnetic environment – guidance	
RF Emissions GB 4824	Group 1	Corneal Topography use RF energy only for their internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.	
RF Emissions GB 4824	Class A	The Corneal Tonography is intended	
Harmonic emissions GB 17625.1	Not applicable	for use in hospital-specific low-voltage power grids that are not directly connected	
Voltage fluctuations/flicker emissions GB 17625.2	Not applicable	to the public low-voltage power grid domestic use and residences.	

10.4 Electromagnetic Immunity

Guidance and manufacturer 's declaration – electromagnetic immunity

Corneal Topography is intended for use in the electromagnetic environment specified below. The customer or the user shall assure that it is used in such an environment:

			Electromagnetic
Immunity test	IEC 60601 test level	Coincidence level	environment –
			guidance
Electrostatic discharge GB/T 17626.2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient Burst GB/T 17626.4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge GB/T 17626.5	± 1 kV line to line ± 2 kV line (s) to earth	± 1 kV line to line ± 2 kV line (s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines GB/T 17626.11	< 5% U $_{\rm T}$ for 0.5 cycle (> 95% dip in U $_{\rm T}$) 40% U $_{\rm T}$ for 5 cycles (60% dip on U $_{\rm T}$) 70% U $_{\rm T}$ for 25 cycles (30% dip on U $_{\rm T}$) < 5% U $_{\rm T}$ for 5 sec (> 95% dip in U $_{\rm T}$) Note: U $_{\rm T}$ refers to AC mains voltage 220 V prior to application of test voltage.	< 5% U $_{T}$ for 0.5 cycle (> 95% dip in U $_{T}$) 40% U $_{T}$ for 5 cycles (60% dip on U $_{T}$) 70% U $_{T}$ for 25 cycles (30% dip on U $_{T}$) < 5% U $_{T}$ for 5 sec (> 95% dip in U $_{T}$) Note: U $_{T}$ refers to AC mains voltage 220 V prior to application of test voltage.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Corneal Topography requires continuous operation during power interruption, it is recommended that the Corneal Topography be powered from an uninterruptible power supply.
Power Frequency Magnetic Field (50 Hz) GB/T 17626.8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

10.5 Electromagnetic Immunity – For Equipment and Systems that are

Not Life-Supporting

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, electromagnetic site survey should be considered. If the measured field strength in the location where the topographer is located is above the RF compliance level above, the topographer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the topographer .

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

10.6 Recommended separation distances between portable and

mobile RF communications equipment and XXXX (Model: Table 1)

For equipment and systems that are not life-supporting
 Recommended separation distances between portable and mobile RF
 communications equipment and a Corneal Topography

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

Maximum	Separation distance according to frequency of transmitter/m		
rated output	150 kHz to 80	80 MHz to 800 MHz	800 MHz to 2.5 GHz
power of	MHz	$D = 1.2\sqrt{P}$	$D = 2.3\sqrt{P}$
transmitter	$D = 1.2\sqrt{P}$		
W			
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

10.7 Installation Environment

The corneal topographer is to be used in non-domestic and hospital-specific low-voltage power supply grids not directly connected to the public low-voltage power

supply grid of domestic dwellings. The power socket should have a reliable protective earthing and use the supplied matching power cord, components and accessories. The floor should be wooden, concrete or tiled, or if the floor is covered with a synthetic material, the relative humidity should be at least 30%. Other equipment used simultaneously in the vicinity of this equipment should comply with the requirements related to electromagnetic compatibility.

The possible effects of portable and mobile RF communication equipment on the corneal topographer are described in detail in "6 Recommended isolation distances between portable and mobile RF communication equipment and the corneal topographer".

The corneal topographer is restricted to the use of power cords, components, and accessories that are shipped with the device by the manufacturer (see Table 6 for a list of accessories). When using these power cords, components, and accessories comply with the requirements of 36.201 and 36.202 of YY 0505.

WARNING: Except for accessories and cables sold by the manufacturer of the system as spare parts for internal components, the use of accessories and cables other than those specified may result in an increase in system emissions or a decrease in immunity.

WARNING: The use of unspecified accessories or cables with the system may result in increased system emissions or reduced immunity.

WARNING: The system should not be used in close proximity to or stacked on top of other equipment, and if it must be used in close proximity or stacked on top of each other, it should be observed to verify that it will function properly in the configuration in which it is used.

WARNING: The system may be used in the vicinity of tagged equipment and may be subject to interference and/or degradation of performance related to basic performance and safety.

10.8 List of attachments

No.	Attachment Name	Model	Parameter
1	Power cord	3 x 0.75 mm ²	1.8 m long Unshielded Line
2	Switching Power Supply	RPS-200-24-C	INPUT: 80-264VAC OUTPUT: + 24VDC

Table 6 List of attachments

3	Magnetic ring	ZCAT3035-1330	Ф13
4	Magnetic ring	ZCAT2035-0930A	Ф9
5	Magnetic ring	ZCAT2132-1130	Ф11

10.9 List of equipment used in coordination test

XXXXXX.

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Telephone: 023-68102805
Postcode: 400707
Company website: www.cqsunkingdom.com

Production date: see nameplate
Use term: 8 years
Note: The use term is derived in accordance with XXXXXXXXX.
Date of preparation of instructions:
Date of instruction manual revision:
Instruction manual version:

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