

Anexa 12 Refractometru automat

KR9600, RedSun Optical, China

Parametri solicitati	Parametri oferiti
Specificații	Specificații
Mod de masurare: K/R - masurarea refracției/ keratometrieda	Mod de masurare: K/R - masurarea refracției/ keratometrieda
REF măsurarea refracției da	REF măsurarea refracției da
KER măsurarea keratometrică da	KER măsurarea keratometrică da
Măsurarea refracției: Axa: 0 - 180 (pas 1)	Măsurarea refracției: Axa: 1 - 180° (pas 1°)
Distanța pupilară: 10 - 85mm	Distanța pupilară: 10 - 85mm
Diametrul minim al pupilei ± 2.0mm	Diametrul minim al pupilei - 2.0mm
Ținta: Ținta automată de ceață	Ținta: Ținta automată de ceață
Masurare cheratotermica:	Masurare cheratotermica:
Raza de curbura: 5*10mm (cu un pas de 0.01mm)	Raza de curbura: 5*10mm (cu un pas de 0.01mm)
Forta de refractive: 33.75D - 67.50D (pas 0.12/0.25D)	Forta de refractive: 33.75D - 67.50D (pas 0.12/0.25D)
Puterea cilindrică: 0.00 ±15.00D (pas 0.12/0.25D)	Puterea cilindrică: 0.00 ±15.00D (pas 0.12/0.25D)
Axa: 0 - 180 (pas 1)	Axa: 1 - 180° (pas 1°)
Diametrul corneei: 2.0 - 12.0 mm	Diametrul corneei: 2.0 - 12.0 mm
Specificații hardware	Specificații hardware
Monitor LCD color min. 7 inch	Monitor LCD color - 7 inch
Imprimanta "Imprimanta termică cu încărcare ușoară și tăietor automat" da	Imprimanta "Imprimanta termică cu încărcare ușoară și tăietor automat" da
Economie de energie 5/15 minute da	Economie de energie 5/15 minute da
Iesire date RS/232 / Bluetooh da	Iesire date RS 232 / Bluetooh da
Alimentare 240V da	Alimentare 110~240V da

Anexa 13 Scanner oftalmic si pasimetru

SW—1000AP, RedSun Optical, China

Parametri solicitati	Parametri oferiti
Specificații	Specificații
Opțiunea de scanare	Opțiunea de scanare
Frecvența 10 MHz	Frecvența 10 MHz
Precizia măsurării lungimii axiale ≤ 0.05 mm	Precizia măsurării lungimii axiale ± 0.05 mm
Adâncime ≥ 40 mm	Adâncime: 15-35 mm
Viteza de propagare 1641.1532	Viteza de propagare 1641.1532
Date de iesire :Cornea, camera anterioara, lentil, umorul vitros, lungimea axială	Date de iesire :Cornea, camera anterioara, lentil, umorul vitros, lungimea axială
Calcul IOL: "6 metode generale, Srk2, Srk/t, Binkhort II, Hoffer Q, Hollady, Haigis"	Calcul IOL: "6 metode generale, SRK-II, SRK-T, BINKHORST II, HOFFER- Q, HOLLADAY, HAIGIS"
Mod implicit pentru ochi: Normal, dens, afhacic, PMMA, silicon, acrylic, cataracta și 2 moduri personalizate	Mod implicit pentru ochi: Normal, dens, afhacic, PMMA, silicon, acrylic, cataracta și 2 moduri personalizate
Modulul Pasimetru	Modulul Pasimetru
Frecvența 20 MHz	Frecvența 20 MHz
Precizie de măsurare a corneei: $<0,01$ mm	Precizie de măsurare a corneei: $<0,01$ mm
Adâncime: 0,15 mm-1,5 mm	Adâncime: 0,3 mm-1,5 mm
Viteza de propagare: 1640	Viteza de propagare: 1640
Ieșirea datelor: Grosimea corneei	Ieșirea datelor: Grosimea corneei
Metoda de măsurare: Modul de măsurare a contractului	Metoda de măsurare: Modul de măsurare a contractului
Alți parametri:	Alți parametri:
Cistiga: 99 dB	Cistiga: 99 dB
Ecran tactil colorat: ≥ 6 inch	Ecran tactil colorat: ≥ 6 inch
Rezoluția ecranului: $\leq 0,1$ mm	Rezoluția ecranului: $\leq 0,1$ mm
Informații de ieșire: Date din 10 grupuri, calculul mediei și deviației standard	Informații de ieșire: Date din 10 grupuri, calculul mediei și deviației standard
Locație de stocare: ≥ 200 de copii ale datelor examinilor	Locație de stocare: ≥ 200 de copii ale datelor examinilor
Imprimare: Imprimantă termică rapidă incorporată	Imprimare: Imprimantă termică rapidă incorporată

KR9600 /RM9600 Auto Refractometer



KR9600 With keratometer .

RM9600 Without keratometer , others same

This model can connect to the, CV7200 ,CV7600 Auto phoropter, RS1000/1001/1500/1501 Auto chart projector, TL6500 TL6800 Auto lensmeter, , CM1800 ,CM1900C LCD vision chart .

Feature

- 1.7" tiltable color and touch screen.with keratometer function
- 2.auto detachment printer
- 3.auto tracking on Y Axis
- 4.motorized chinrest
- 5.Motorized joystick
6. One key lock
- 7.IOL function, can measure the eye whose eye with cataract or other eye surgical before.

Specifications

Measurement mode	K/R mode	Refractive and Keratometer measurement.
	REF mode	Refractive measurement
	KEF mode	Corneal curvature measurement
Refractive measurement	Vertex Distance	0.0,12.0,13.75,15.0 mm
	Sphere	-25.00~+22.00D
	Cylinder	(0.12/0.25D step)(VD=12mm)
		0.00~±10.00D (0.12/0.25D step)
	Axis	1°~180°(1° step)
	Pupil Distance	10~85 mm
	Min. pupil diameter measurable	2.0mm
Corneal curvature measurement	Target	Automatic fogging target
	Radius of curvature	5~10mm(0.01mmstep)
	Corneal Refraction	33.75~67.50D(0.12/0.25Dstep)
	Corneal Astigmatism	0.00~-15.00D(0.12/0.25Dstep)
	Angle of corneal	1°~180°(1°step)
Hardware specification	Corneal diameter	2.0~12.00mm
	Monitor	7 inch Color touch LCD
	Printer	Auto detachment printer
	Power saving function	OFF, 5, 15 mins (selectable)
	Date output	RS232/Bluetooth
	Power supply	AC110~220 V,50/60HZ
	Dimensions/weight	288(W)*500(D)*480(H)mm/14kg

SW-1000AP A Scan & Pachymeter

Models:

SW-1000A A scan only

SW-1000P Pachymeter only

SW-1000AP A scan and Pachymeter

You can buy separately



Technical Specifications

A SCAN

A scan probe: 10MHz with LED

Depth:15-35mm

Measurement precision: $\pm 0.05\text{mm}$;

Method of measurement: immersion and contact

Eye mode: Phakic/ Aphakic/Dense/ various IOL

IOL formula: SRK-II, SRK-T, BINKHORST- II, HOLLADAY, HOFFER-Q, HAIGIS

Curve Freeze:control by foot switch,quto freeze and manual freeze

Storage: 10 cases, 5 readings each case

Output: A scan table and calculation and thermal printer

PACHYMETER

P scan probe: 20MHZ, angle of 45 degrees makes easier operation

Resolution: 5um

Measuring range: 300um~1500um

Display: SINGLE mode and MAP mode

CDisplay:Large color liquid -crystal screen.

Each group is the average of 10 measurements

Output:LCD display and thermal print

Single mode and MAP mode

Others:

Large color liquid-crystal screen

Touch screen input, easy operation

Curve freezing: Manual/Auto mode, controlled by pedal

Built-in speed thermal printer



REGISTRATION NO. 04717Q10000369

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Nanjing Redsun Optical Co., Ltd.

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

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

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

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

Date of issue: October 20, 2019

Date of expiry: October 19, 2022

General Manager:

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

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. Jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993

DECLARATION OF CONFORMITY



We, the manufacturer:

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

EU Representative: LUXUS LEBENSWELT GMB

Address: KOchstr.1, 47877, Willich, Germany

Declare under our sole responsibility that:

Product:Auto refractometer
Model Name:KR9600

Product Group: Ophthalmic Equipment
Classification: Class I (in compliance with Annex I&VII, Medical Device Directive)

Are in conformity with:

Essential Requirements of European Directive(s):
93/42/EEC Medical Device Directive (including 2007/47/EC)

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

Test report(s):TRS15060065
ISO13485:2003

The compliance with the European Directive (93/42/EEC) is under the monitoring of the Notified Body:

For and behalf of
NANJING REDSUN OPTICAL CO.,LTD.

Signature:Helen He

Export Sale
Manager 2022-08-16

Authorized Signature

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Product:A Scan & Pachymeter
Model Name: SW-1000AP

Product Group: Ophthalmic Equipment
Classification: Class I (in compliance with Annex I&VII, Medical Device Directive)

Are in conformity with:

Essential Requirements of European Directive(s):
93/42/EEC Medical Device Directive (including 2007/47/EC)

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

Test report(s):TRS15060065
ISO13485:2003

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