

Anexa 5 Autokeratorefractometru

FKR8900, RedsunOptical, China

Parametri solicitati	Parametri oferiti
Denumirea dispozitivului : Autokeratorefractometru Specificatie tehnica: "Puterea de refracție Măsurare:" Puterea de refracție sferică < 25D la + 22D (pași 0,12D / 0,25D) Puterea de refracție cilindrică de la ± 10D (pași 0,12D / 0,25D) Unghiul axial astigmatic ± 0° până la 180° (în trepte de 1° sau 5°) Diametru minim pupilar măsurabil ± 2 mm "Curbura corneei Măsurare:" Raza de curbura a corneei ±5,00-10,00 mm (pas 0,01 mm) Puterea de refracție a corneei ± 67.50D la 33.75D (pași 0.12D / 0.25D) (unde, puterea de refracție a corneei = 1,3375) Puterea de refracție astigmatică a corneei < ± 10D (pași 0,12D / 0,25 D) Unghiul axial astigmatic cornean ± 0° până la 180° (pași de 1° / 5°) Gama de verificare a refracției subiective: Putere de refracție sferică: Puterea de refracție sferică: < - 18D la + 18D (pași 0,25D) Diagrama de testare: Diagrama de testare a vederii de la ± 0,1 la 1,2 sau de la 20/200 la 20/15, afișare grilă Afișarea diagramei: Per ansamblu, seria orizontală, schimbarea contrastului Elemente de testare: Miopie, miopie, test de orbire Gama de măsurare PD < 20mm la 85mm (pas de 0,5mm) Terminal de transport date USB (Import) / LAN (Export) Alimentare electrică 240V c.a., 50Hz Accesorii Printarea rezultatului Da Suport trofeu (automatizat) electric Da Certificat CE Da Manual de utilizare Da Manual de service Da Ghid rapid al utilizatorului Da	Denumirea dispozitivului : Autokeratorefractometru Specificatie tehnica: "Puterea de refracție Măsurare:" Puterea de refracție sferică - 25D la + 22D (pași 0,12D / 0,25D) Puterea de refracție cilindrică de la - 10D pina la +10D (pași 0,12D / 0,25D) Unghiul axial astigmatic ± 0° până la 180° (în trepte de 1°) Diametru minim pupilar măsurabil - 2 mm "Curbura corneei Măsurare:" Raza de curbura a corneei 5 ~10 mm (pas 0,01 mm) Puterea de refracție a corneei de la 33.00D ~ 67.00D (pași 0.12D / 0.25D) (unde, puterea de refracție a corneei = 1,3375) Puterea de refracție astigmatică a corneei 0~15.00D (pași 0,12D / 0,25 D) Unghiul axial astigmatic cornean 1° până la 180° (pași de 1° / 5°) Gama de verificare a refracției subiective: Putere de refracție sferică: Puterea de refracție sferică: - 25D la + 25D (pași 0,25D) Terminal de transport date RS-232 Alimentare electrică 240V c.a., 50Hz Accesorii Printarea rezultatului Da Suport trofeu (automatizat) electric Da Certificat CE Da Manual de utilizare Da Manual de service Da Ghid rapid al utilizatorului Da

FR8900/KR-8900 Auto Refractometer



FR8900 without keratometer function.

KR8900, with keratometer function, others same.

1. Combine measurement to diopter and corneal curvature
2. The precedent optical technique, consistent measurement and accurate figure.
3. The most advanced technique of a graph edition, make the graph measured quickly and clear.
4. Humanized focusing design to make grasp focus more quickly.

KR-8900 AUTO KER/REFRACTOR

Measurement mode	K/R	Measure diopter and corneal curvature
	REF	Measure diopter
	KER	Measure corneal curvature
Diopter measurement	Vertical distance	0mm, 12.0mm, 13.75mm
	Sphere	-25.00 ~ +22.00D(0.12/0.25D steps)(VD=12mm)
	Cylinder	-10D to +10D(0.12/0.25D steps)
	Axis	1° ~ 180°(steps 1°)
	Pupil distance	45 ~ 85mm(accuracy 0.5mm)
Corneal measurement	Minimum pupil diameter	Φ2.0mm
	Charter	Auto fogging method
	Corneal curvature radius	5 ~ 10mm(0.01mm steps)
	Corneal diopter	33.00 ~ 67.00D(0.12/0.25D steps)
	Corneal Astigmatism	0.00 ~ -15.00D(0.12/0.25D steps)
	Axis	1° ~ 180°(steps 1°)
	Corneal diameter	2.0 ~ 12.00mm
Product specification	Data output	Rs-232 interface, Video output
	Display	5.7" TFT color LCD screen
	Printer	Import thermal printer
	Energy save	Auto monitor energy save, no operation for 5 minutes
	Power supply	AC100 ~ 240V, 50/60HZ
	Dimension/Weight	275 (W)*475(D)*435-465(H)mm/18kg

FA6500K /FA6500 Auto Refractometer



FA6500 without keratometer

FA6500K, with keratometer function, others same.

Feature :

7" color and touch screen, more easy operate.

Tilt screen.

Motorized chinrest.

With keratometer, auto tracking function.

Specifications

Sphere	-20~+20D(VD=12)0.125D step
Cylinder	-8~+8D, 0.125D Step
Axis	0~180°1°step
PD	45~88mm, 1mm step
VD	0mm, 12mm, 13.75mm
Min.Pupil Size	2mm
Radius of curvature	5.0~10mm(increment:0.01mm)
Corneal Power	33.75-67.50D (when corner equivalent refractive index is 1.337) (increment selectable from 0.12, 0.25D)
Corneal astigmatism	0~8D(increment selectable from 0.12, 0.25D)
Axis	1~180°(increment:1°)
Corneal diameter	2.0~14 mm(increment:0.1mm)
Memory of data	10 measure vature for each right and left eye
Chart	Follow up colorful fogging chart system
display	7" TFT LCD
print	Thermal printer
Power supply	220V/110V, 50/60Hz
Dimension	478*268*472mm
Weight	-20kg(44lb)



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

EC Certificate Production Quality Assurance System: Certificate CN20/608238
The management system of

NINGBO FLO OPTICAL TECHNOLOGY DEVELOPMENT CO., LTD.

Floor 4, Block 6, No.1177, Lingyun Road, National High-tech Zone,
Ningbo, Zhejiang, 315040, China
has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

**Restricted to the aspects of manufacture concerned with the conformity of
the devices with metrological requirements**

For the following products

Class I Measuring:

**Auto Refractor (Model: FKR-8900, FR-8900,
Auto Kerato/Refractometer (Model: FKR-710, FR-710)**

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination
Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate
to place that device on the market.

This certificate is valid from 11 August 2020 until 06 August 2023
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 07 August 2015
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered CN/NGB/ 5879

Authorised by



SGS Belgium NV, Notified Body 1639

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LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

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