



AUTO REFKERATO ARKM-200

A i m i n g a t n e w l e v e l s i n q u a l i t y



AUTO REFKERATO ARKM-200

New Generation of Multi-Functional Instrument

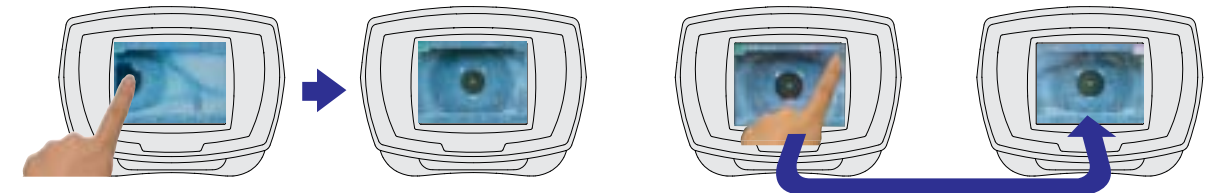


Highly accurate measurement combined with short examination time and ease of use makes working with the ARKM-200 both professional and quick. The advanced touch-screen display allows you to perform both refraction and keratometry automatically with one simple movement. Capture one eye on the display and the ARKM-200 will do both eyes automatically. With the new features, the ARKM-200 will surely make your office more efficient

- Various settings like changing modes can be done on the touch panel display.
- The wide viewed fixation target assures natural fixation to avoid accommodation of a patient's eye.
- The quick thermal printer has shortened the total measurement time.

1 Automatic Measurement

1. Use power assist joystick for rough alignment.
2. Touch the center of the pupil on the display with your fingertip and ARKM-200 will automatically align and begin measurement.
3. Press the R/L Icon on the display and the instrument will automatically move to and measure the other eye.
4. Printing is automatic.



2 Power Joystick

- Move the joystick ring up/down and the instrument head moves up/down quickly.
- Move the joystick hand rest to the right/left or backward/forward and the instrument head moves to the right/left or backward/forward quickly.
- Rotate the joystick ring and the instrument head moves up/down slowly.
- Tilt the joystick and the instrument head moves in each direction slowly.



3 Power Chinrest

The chin rest can be moved by pushing the buttons on the front panel. No need to reach out to the chin rest for manual adjustment.



4 Refractometry

- Normal Mode:**
Fogging is applied automatically for each measurement for more accurate results.
- Quick Mode:**
Fogging is applied as needed for consecutive measurements.
- IOL/CAT Mode:**
The mode is used to measure cataract or pseudophakic eyes.



5 Keratometry

- Short consecutive measurements and provide reliable data.
- Measurements at $\Phi 6.0\text{mm}$ ($R=8.0\text{mm}$) as well as at $\Phi 3.0\text{mm}$ give you enough information for contact lens fitting.
- Base curves of contact lenses are stored, categorized and suggested manufactures are automatically printed.



6 Diameter Measurement of Cornea and Pupil

Measurement can be done easily by moving the two cursors on the display to the boundary of Cornea or Pupil. This is useful for deciding the diameter of a contact lens and for other contact lens fitting practices.





Specifications

Measurement Ranges		
Refractometry	Sphere	-25.00 to +22.00D (VD=12.00mm)
	Cylinder	-10.00 to +10.00D (VD=12.00mm)
	Axis	0 to 180 degrees
	Minimum Pupil Dia.	φ 3.00mm / φ 6.00mm
	Measurement Time	0.2 sec.
Keratometry	Range	5.00mm to 11.00mm
	Corneal Refraction	30.68D to 67.50D (n=1.3375)
	Corneal Astigmatism	0 to 10D (n=1.3375)
	Axis	0 to 180 degrees
	Measured Area	φ 3.00mm / φ 6.00mm (at 8.0mm of Corneal Radius)
	Measurement Time	0.1 sec.
PD measurement		50mm to 86mm
Diameter Measurement of Cornea and Pupil		1.0mm to 14mm
Chinrest		Power Chinrest
Printer		High Speed Thermal Line Printer
Output port		RS-232C
Power Requirement		AC-100 to 240V 50/60Hz 130VA
Size		466mmH x 300mmW x 493mmD
Weight		19kgs

● Design and specifications are subject to change as improvements are made to the product.

TAKAGI SEIKO CO.,LTD.

330-2 IWAFUNE, NAKANO-SHI, NAGANO-KEN, 383-8585, JAPAN
 TEL.+81-269-22-4512 FAX.+81-269-26-6321
 URL:<http://www.takagi-j.com> E-mail:info@takagi-j.com

CE
 0123

B06002 Rev.1 Printed in Japan 2011.9 KY



AUTO REFKERATO ARKM-200

Aiming at new levels in quality



AUTO REFKERATO

ARKM-200

New Generation of Multi-Functional Instrument



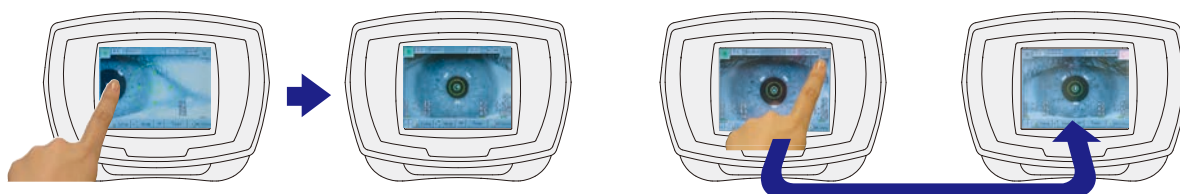
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Automatic Measurement

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B06002 Rev.1 Printed in Japan 2011.9 KY

The management system of

Takagi Seiko Co., Ltd.

330-2 Iwafune, Nakano-shi, Nagano-ken, 383-8585, Japan

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on Medical Devices, Annex II (excluding section IV)

For the following products

**Refkeratometer (Model; ARKM-200), Pachymeter
(Model; P-1), Tonometer (Model; SNT-700),
AutoRefkeratometer (ARKM-150)**

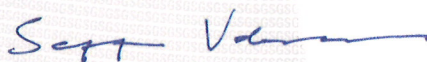
Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 30 October 2019 until 31 March 2024
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 20 February 2013

This certification is based on decision: F119/07013P0

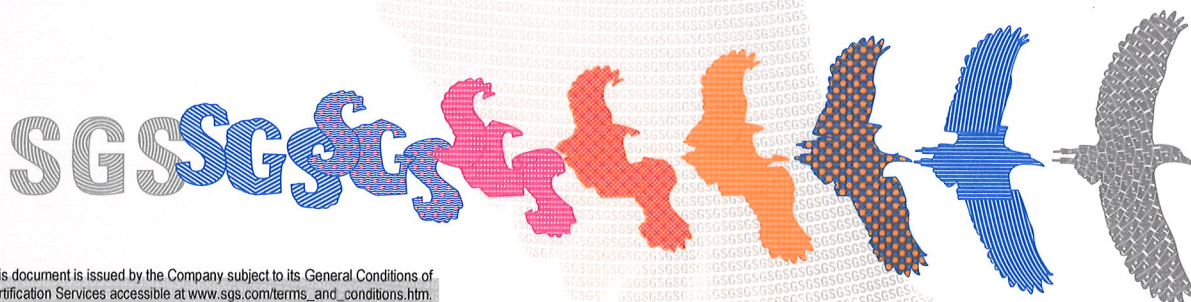
Authorised by



Seppo Vahasalo
Notified Body Manager

SGS Fimko Ltd., Notified Body 0598
Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

Page 1 of 2



Attachment 1 to SGS Fimko Ltd. EC certificate FI19/07010 Issue 1

Manufacturer	Takagi Seiko Co., Ltd.
Address	330-2 Iwafune, Nakano-shi, Nagano-ken, 383-8585, Japan
Activity and Medical Device Product Category	93/42/EEC Annex II (excluding Section 4) Refkeratometer (Model; ARKM-200), Pachymeter (Model; P-1), Tonometer (Model; SNT-700), AutoRefkeratometer (ARKM-150)

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

Medical Device	Class	Trademark(s) and Model(s)/type(s)
Refkeratometer	Ila	ARKM-200
Pachymeter	Ila	P-1
Tonometer	Ila	SNT-700
AutoRefkeratometer	Ila	ARKM-150

Certificate JP12/040328

The management system of

Takagi Seiko Co., Ltd.

330-2 Iwafune, Nakano-shi, Nagano-ken, 383-8585 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

1. Design, development, manufacture, service and distribution of Slit Lamp microscopes, Operating microscopes, Phoroptors, Projection perimeters, Contrast glare testers, Chart projectors, Ophthalmic tables, Ophthalmic chairs, Ophthalmic stands, Tonometers and Refkeratometers
2. Service of Keratometers, Pachymeters and Synoptophores

This certificate is valid from 31 March 2022 until 31 March 2025 and remains valid subject to satisfactory surveillance audits.

Issue 7. Certified since 01 April 2010.

Authorised by



SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com



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DECLARATION OF CONFORMITY

We,

Manufacturer's name:	Takagi Seiko Co., Ltd.
Address:	330-2 Iwafune, Nakano-shi, Nagano-ken, 383-8585, Japan
European Representative:	Emergo Europe B.V.
Address:	Prinsessegracht 20 2514 AP The Hague The Netherlands

declare under our sole responsibility that the product:

Product Name:	Auto Refkerato
Model No.:	ARKM-200
MDD Classification:	Class II a (by 93/42/EEC Annex IX rule 10)
Accessories (Optional)	No any accessories with ARKM-200
Serial No.(sn)/Lot No.(Lot):	SN. 2031909~2031912

following the provisions of EC Council Directive(s):

93/42/EEC Annex II excluding section 4 (MDD)、2011/65/EU (RoHS)

Notified Body:

Notified Body:	SGS Fimko Ltd, Notified Body 0598
	Takomotie 8, FI-00380 Helsinki, Finland
Certificate:	FI/1907010

to which this declaration relates is in conformity with the following standard(s) or other normative document(s):

93/42/EEC Annex II excluding section 4 (MDD)、EN ISO 13485:2016、EN ISO 14971:2012
EN 60601-1:2006/A1:2013、EN 60601-1-2:2015、EN 60601-1-6:2010、EN ISO 15004-1:2009
EN ISO 10993-1:2009、EN 62304:2006、EN 62366:2008、EN 15223-1:2016、EN 1041:2008
2011/65/EU (RoHS)、EN 50581:2012

Date of Issue: 2021/2/23

Signature:



Printed Name: Kenji Takeuchi

Title: Manager, Quality Assurance Department

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 11.07.2023

Solicitantul FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6, tel./fax: 022-273712, e-mail: contact@datacontrol.md solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- 1) AutoRefkeratometru, Ref.: ARKM-200, ARKM-150

Se anexează următoarele acte:

- 1) Declarație de Conformitate, din 23.02.2021;
- 2) Certificat ISO 13485, No. JP12/040328 din 31.03.2022 ;
- 3) Certificarte CE NR. FI19/07010 din 30.10.2019.

Data 11.07.2023

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu
17/6

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- 1) Declarație de Conformitate, din 23.02.2021;
- 2) Certificat ISO 13485, No. JP12/040328 din 31.03.2022 ;
- 3) Certificarte CE NR. FI19/07010 din 30.10.2019.

Sunt autentice și corespund realității.

Numele, prenumele și funcția

Semnătura _____

Grabazei Alexandru, director general.

Data 11.07.2023

The management system of

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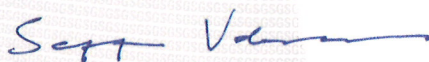
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This certification is based on decision: F119/07013P0

Authorised by



Seppo Vahasalo
Notified Body Manager

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2011/65/EU (RoHS)、EN 50581:2012

Date of Issue: 2021/2/23

Signature:



Printed Name: Kenji Takeuchi

Title: Manager, Quality Assurance Department