



AUTO REFKERATO ARKM-150

S e r v i n g y o u r v i s i o n

- Highly Accurate
- Simple to Use
- Diameter Measurement of Cornea and Pupil
- High Speed Printer
- Auto Shot
- Color Touch Screen



AUTO REFKERATO ARKM-150

Realization of Simple and Highly Cost-effective Refkerato Functions

Refractometry

Simple handling of the fine adjustment and measurement by yourself.
Fogging is applied automatically for each measurement for more accurate results.

Keratometry

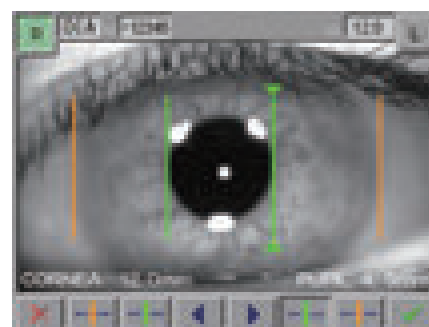
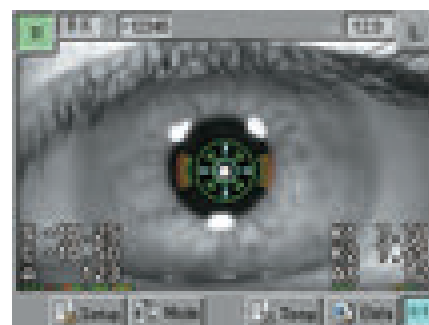
Short consecutive measurements and time provide reliable data.
Measurements at $\phi 3.0\text{mm}$ (R = 8.0mm) give you enough information for contact lens fitting.

Diameter Measurement of Cornea and Pupil

Easy measurement by moving the two cursors on the display to the boundaries of Cornea or Pupil.

Language Selection

ARKM-150 has a Multi-language function. You can select your required language from "English", "Japanese", "German", "Chinese", "Spanish", "Spanish Latin America", "Italian", "Portuguese", "French" and "Russian".



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.		$\phi 2.00\text{mm}$
	Measurement Time		0.2 second/single eye (data taking time)
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		$\phi 3\text{mm}$ (at 8.00mm corneal curvature)
	Measurement Time		0.1 second/single eye (data taking time)
PD measurement			50mm to 86mm
Corneal diameter and pupillary diameter measurement	Measurement range		1.0mm to 14.0mm
	Display unit		0.1mm
Built-in Printer			Thermal printer
Data output type			RS232C / USB-D
Display			5.7 inch color liquid crystal display
Dimensions and weight			297(W)x500(D)x448(H)mm
Approx.			17kg
Power Requirements			AC 100V to 240V
			50 / 60 Hz
			80VA to 100VA

● 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

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B16003 Rev.0 Printed in Japan 2016.8 KY



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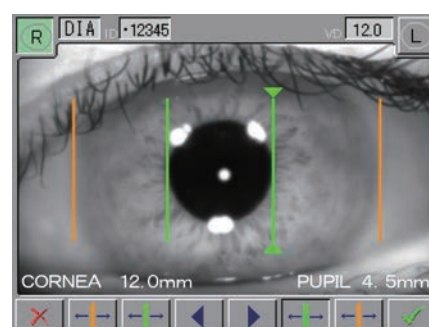
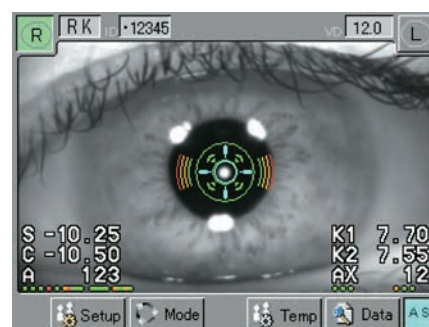
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CE
0120

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)**

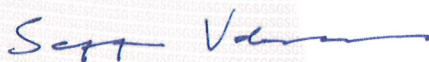
Products covered are listed in Attachment 1 of this certificate

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

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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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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 ;
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Sunt autentice și corespund realității.

Numele, prenumele și funcția

Grabazei Alexandru, director general.

Semnătura _____

Data 11.07.2023

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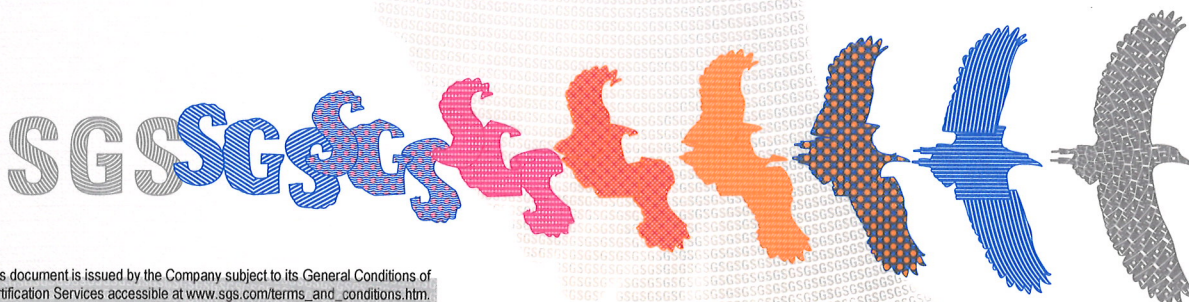
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DECLARATION OF CONFORMITY

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