

INSTRUCTION MANUAL WAVE-FRONT ANALYZER

KR-1W

## INTRODUCTION

Thank you for purchasing the TOPCON Wave-front Analyzer KR-1W.

### INTENDED USE / INDICATIONS FOR USE

To measure the refractive power of the eye with a function of cornea topography, and to present the measurement data to the eye care professional.

### **FEATURES**

This instrument has the following features:

- The refractive power of the eye, the curvature radius of the cornea and the pupil diameter can be determined by simple operations.
- By displaying the Shack-Hartmann image and Placido ring image, wavefront aberration measurement of the eye can be done.
- · Auto alignment and auto start functions enabling quick measurement under best conditions.

## **PURPOSE OF THIS MANUAL**

This text outlines the TOPCON Wave-front Analyzer KR-1W and describes basic operations, troubleshooting, checking, maintenance and cleaning.

To encourage the safe, efficient use of this instrument, carefully read "DISPLAYS AND SYMBOLS FOR SAFE USE" and "GENERAL SAFETY INFORMATION."

Also, keep this User Manual in a convenient location for your future reference.

## **PRECAUTIONS**

- To ensure smooth operation, install the instrument on a leveled stand free of vibrations. Also, do not place any objects on the instrument.
- Connect all cables according to Preparation instructions on page 30.
- · Use the specified source voltage.
- When not in use, turn off the power and put the measuring window cap and dust cover on.
- · To ensure the correct reading, do not mar the measuring window with finger prints, dust, etc.
- · Use this machine in a darkroom.



- 1. No part of this manual may be copied or reprinted, in whole or in part, without prior written permission.
- 2. The contents of this manual are correct to the best of our knowledge. Please inform us of any ambiguous or erroneous descriptions, missing information, etc.
- 3. This manual is original instructions.

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## **DISPLAYS AND SYMBOLS FOR SAFE USE**

To encourage safe and proper use and to prevent danger to the operator and others or potential damage to property, warnings and cautions are placed on the instrument body and inserted in the manual.

We suggest that everyone understand the meaning of the following displays, icons and text before reading the "GENERAL SAFETY INFORMATION" and observe all listed instructions.

### **DISPLAY**

Display	Meaning	
<b>⚠</b> WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.	
<b>⚠</b> CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.	
<b>F</b> NOTE	Useful functions to know and attentions to prevent troubles are noted.	

## **SYMBOL**

Symbol	Description		
$\sim$	Alternating Current		
	Off (power: disconnection from the main power supply)		
	On (power: connection to the main power supply)		
*	Type B applied part		
$\triangle$	General warning sign		
	Refer to instruction manual/booklet		
سا	Date of manufacture		
SN	Serial number		
	Manufacturer		
EC REP	Authorised Representative in the European Community		

## **GENERAL SAFETY INFORMATION**



## **Ensuring the Safety of Patients and Operators**

When operating the instrument, be not touch the patient's eye or nose. [Inform the patient accordingly]

The safety and effectiveness of the Wave-front Analyzer KR-1W has not been established for use of the device as an accessory interfaced to the refractive laser for the treatments of the higher order aberrations of the eye by photorefractive keratectomy (PRK), phototherapeutic keratectomy (PTK), or laser assisted in situ keratomileusis (LASIK).

## **Preventing Electric Shocks and Fires.**

To avoid fire and electric shock, install the instrument in a dry place free of water and other liquids.

To avoid fire and electric shock, do not put cups or other containers with liquids near the instrument.

To avoid electric shocks, do not insert metal objects into the instrument body through the vent holes or gaps.

To avoid fire in the event of an instrument malfunction, immediately turn OFF the power switch "O" and disconnect the power cord from the instrument if you see smoke coming from the instrument, etc. Don't install the instrument where it is difficult to disconnect the power cord from the instrument. Ask your dealer for service.

Modification of this instrument is not permitted.



## **Ensuring the Safety of Patients and Operators**

To avoid injury when operating the chinrest up/down button, be careful not to catch the patient's fingers.

To avoid injury when operating the measuring head up or down, be careful not to catch the patient's/operator's fingers.

## Preventing Electric Shocks and burn.

To avoid electric shock, do not open cover. For repair, ask a certified Topcon Service Engineer.

When changing the fuse, turn off the power, and disconnect the power cord. Use the properly rated fuse.

## **Ensuring Security**

- When connecting this instrument to an external device through LAN, apply the security update to the external device, make use of anti-virus software and take other countermeasures against computer virus properly.
- Do not connect any USB storage device that is not checked with the anti-virus software to the USB port of this instrument.
- When connecting this instrument to an external device through LAN, set the ID and password of the user to the external device.
- When outputting data to the shared folder on an external device from this instrument, set a proper user ID and password to the shared folder. To enable encrypted communication, set an encryption option on the shared folder.

## **Electromagnetic Compatibility (EMC)**

This instrument has been tested (with 100/120/230V) and found to comply with IEC 60601-1-2:2014+AMD1:2020 (Ed.4.1).

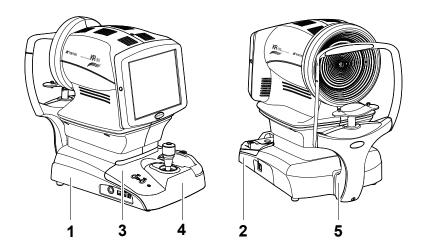
This instrument may emit a radio frequency energy (within the standard) and cause an adverse effect on the devices located nearby.

When such effect is confirmed by the ON/OFF operation, a proper treatment as to change the direction, use another outlet, etc. is recommended. If the problem remains unsolved, call your dealer.

## **WARNING INDICATIONS AND POSITIONS**

To ensure safety, this machine provides warning displays.

Use the instrument correctly by observing the display instructions. If any of the following display labels are missing, contact your TOPCON dealer at the address listed on the back cover.



No.	Label	Meaning	
1	<b>A</b>	WARNING To avoid injury caused by electric shock, do not open the cover. Ask your dealer for service.	
2	<b>A</b>	WARNING Electric shock may cause burns or a possible fire. Turn the power switch OFF and unplug the power cord before replacing the fuses. Replace only with fuses of the correct rating.	
3	<b>A</b>	CAUTION  When operating the chinrest up/ down switch, be careful not to pinch the patient's hand.  The patient may be injured.	
4	<b>A</b>	CAUTION  Be careful not to hit the patient's eyes or nose with the instrument during operation	
5	*	Degree of protection against electric shock : TYPE B APPLIED PART	

## **CHECKPOINTS FOR MAINTENANCE**

Checkpoints by the user

- (1) Periodically measure the supplied model eye ball to check the precision.
- (2) Clean the measurement window if it is dirty.
- (3) Clean the facerest or chin-rest if they are dirty.
- (4) Apply a dust cover when the instrument is not in use.

See "MAINTENANCE AND CHECKING" and "DAILY MAINTENANCE" in the "User Manual" for more information.

## **SPECIFICATIONS**

## **SPECIFICATION AND PERFORMANCE**

Range of Refractory	
Measurement	Spherical refractive power: -25 - +22D (0.01D/0.12D/0.25D steps) Cylindrical refractive power: 0D - ±10D (0.01D/0.12D/0.25D steps) Direction of astigmatic axis: 0 - 180° (1°/5° steps)
	(where, spherical refractive power + cylindrical refractive power ≤ +22D, or spherical refractive power + cylindrical refractive power ≥ -25D)
Range of Cornea Curvature	Measurement range: $\phi$ 8mm (max.)
Measurement	Measured minimum pupil diameter: $\phi$ 2mm
	Cornea curvature radius: 5.00 - 10.00mm (0.01mm steps) Corneal refractive power: 67.50 - 33.75D (0.01D/0.12D/0.25D steps)
	(where, corneal refractive power = 1.3375)
	Corneal astigmatic power: 0D - ±10D (0.01D/0.12D/0.25D steps) Direction of corneal astigmatic axis: 0 - 180° (1°/5° steps)
	Cornea shape measurement range: $\phi$ 0.8mm - $\phi$ 9.2mm (where, cornea curvature radius = 8mm)
Range of PD Measurement	20-85mm (1mm display units)
External connection terminal	USB (input/output, output), RS-232C (output), LAN (input/output)

<sup>\*</sup> For product improvements, these specifications are subject change without notice.

## GENERAL INFORMATION ON USAGE AND MAINTE-NANCE

## INTENDED PATIENT POPULATION

The patient who undergoes an examination by this instrument must maintain concentration for a few minutes and keep to the following instructions:

- To fix the face to the chinrest, forehead rest.
- To keep the eye open.
- To understand and follow instructions when undergoing an examination.

#### INTENDED USER PROFILE

The Wave-front Analyzer KR-1W is a precision electrical instrument for medical use which must be used under the guidance and instructions of a doctor.

## **ENVIRONMENTAL CONDITIONS OF USE**

Temperature: 10°C to 40°C

Humidity: 30% to 90% RH (without condensation)

Pressure: 800hPa to 1060hPa

## STORAGE, USAGE PERIOD

1. Environmental conditions (without package)

\*Temperature: 10°C to 40°C

Humidity: 10% to 95% (without condensation)

Pressure: 700hPa to 1060hPa

- \* THIS INSTRUMENT DOES NOT MEET THE TEMPERATURE REQUIREMENTS OF ISO 15004-1 FOR STORAGE. DO NOT STORE THIS INSTRUMENT IN CONDITIONS WHERE THE TEMPERATURE MAY RISE ABOVE 40°C OR FALL BELOW 10°C.
- 2. When storing the instrument, ensure that the following conditions are met:
  - (1)The instrument must not be splashed with water.
  - (2)Store the instrument away from environments where air pressure, temperature, humidity, ventilation, sunlight, dust, salty/sulfurous air, etc. could cause damage.
  - (3)Do not store or transport the instrument on a slanted or uneven surface or in an area where it is subject to vibrations or instability.
  - (4)Do not store the instrument where chemicals are stored or gas is generated.
- 3. Normal life span of the instrument:

8 years from delivery providing regular maintenance is performed [TOPCON data]

### **ENVIRONMENTAL CONDITIONS FOR PACKAGING IN STORAGE**

(Product in its normal transport and storage container as provided by manufacturer)

Temperature: -20°C to 50°C Humidity: 10% to 95%

Pressure: 700hPa to 1060hPa

# ENVIRONMENTAL CONDITIONS FOR PACKAGING IN TRANSPORTATION

(Product in its normal transport and storage container as provided by manufacturer)

Temperature: -40°C to 70°C Humidity: 10% to 95%

Pressure: 700hPa to 1060hPa

## **ELECTRIC RATING**

Supply voltage: 100-240VAC, 50-60Hz

Power input: 160VA

## **DIMENSIONS AND WEIGHT**

Dimensions: 304(W)x521(D)x474-504(H)mm

Weight: 23kg

## **OPERATION PRINCIPLE**

To receive light flux from a secondary light source, projected from a light source (point light source) placed at a position conjugate to the eyeground and formed on the retina, by a CMOS sensor through a Shack-Hartmann board (formed with a two-dimensionally lined small lens array), and determine the spherical refractive power, cylindrical refractive power, direction of astigmatic axis and refractive wavefront aberration through computation.

To project a Placido ring to the cornea, receive the reflected image from the cornea surface using a CCD camera, and determine the curvature radius, corneal refractive power, direction of corneal astigmatic axis and corneal wavefront aberration through computation, and, to display the distribution of curvature radius by mapping.

## **DISPOSAL**

When disposing the instrument and/or parts, follow the local regulations for disposal and recycling.



This symbol is applicable for EU member countries only. To avoid potential damage to the environment and possibly human health, this instrument should be disposed of (i) for EU member countries - in accordance with WEEE (Directive on Waste Electrical and Electronic Equipment), or (ii) for all other countries, in accordance with local disposal and recycling laws.

This Product Contains a coin cell.

You cannot replace batteries by yourself. When you need to replace and/or dispose batteries, contact your dealer or TOP-CON listed on the back cover.



**EU Battery Directive** 

This symbol is applicable for EU members states only.

Battery users must not dispose of batteries as unsorted general waste, but treat properly.

If a chemical symbol is printed beneath the symbol shown above, this chemical symbol means that the battery or accumulator contains a heavy metal at a certain concentration.

This will be indicated as follows:

Hg: mercury(0.0005%), Cd: cadmium(0.002%), Pb: lead(0.004%) These ingredients may be seriously hazardous to human and the global environment.

This product contains a CR Lithium Battery which contains Perchlorate Material-special handling may apply.

See http://www.dtsc.ca.gov/hazardouswaste/perchlorate/ Note: This is applicable to California,U.S.A.only

## REFERENCE MATERIAL

## ABOUT THE BARCODE AND THE QR CODE OF THE BACK COVER

The barcode and the QR code of the back cover indicates the parts management.



## OPERATING AND USAGE METHOD

## Usage method

- **1** Connect the power supply cord to a commercial power source.
- **2** When externally connected devices are used, connect them and turn ON the power source (if it has a power switch).
- **3** Turn ON the power switch.
- **4** Set measurement mode (ref/kerato, ref, kerato) if required.
- **5** Rest the patient's chin on the chin-rest, align their face with the facerest and adjust the height of the chin-rest with the chin-rest up/down button to adjust the height of the patient's eye.
- **6** Operate the control lever to move the main unit up, down, left or down so that the patient's eye is displayed within the centre of the touch panel colour LCD monitor (hereinafter referred to as "touch panel monitor") screen.
- **7** Press the measurement switch when the alignment settings are set to full auto alignment. After alignment is adjusted automatically, the number of measurements will be made with the new settings. Alignment of the other eye is conducted automatically, and the number of measurements will be made with the new settings. (if alignment settings are auto tracking, alignment will be adjusted automatically only for the preset eye. If the alignment settings are set manually, operate the control lever to align the instrument with the patient's eye, and press the measurement switch to conduct measurements.)
- **8** Operate the touch panel monitor after measurements if required to print out the measurement results to the printer built into the instrument. (operate the touch panel monitor even when forwarding data to externally connected devices.)
- **9** When other patients are to be measured soon after and the previous measurement results have not been printed out, operate the touch panel to delete the data and start measurements.
- **10**Turn OFF the power supply switch after usage is complete.
- **11** Turn OFF the power switch of externally connected devices or computers that have been connected (if the externally connected devices or computers have a power switch).
- **12**Remove the power plug from the power outlet.

See "PREPARATIONS", "BASIC OPERATIONS", "INDIVIDUAL OPERATIONS" and "MAINTENANCE AND CHECKING" in the "User Manual" for more information.

Please provide the following information when contacting us regarding questions about this instrument:

Model name: KR-1W

• Manufacturing No. Shown on the rating plate on the backof the instrument.

• Period of use: Please inform us of the date of purchase.

• Defective condition: Please provide us with as much detail as possible on the

problem.

WAVE-FRONT ANALYZER KR-1W

**INSTRUCTION MANUAL** 

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## KR-1W

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