



INSTRUCTION MANUAL REFRACTION SYSTEM

Chronos

INTRODUCTION

Thank you for purchasing the TOPCON REFRACTION SYSTEM Chronos.

INTENDED USE / INDICATIONS FOR USE

The Chronos measures the spherical refractive power, cylindrical refractive power, and astigmatism axis direction of the eyeball. The curvature radius of the corneal surface is measured. In addition, various subjective refraction acuity examinations are performed.

FEATURES

This instrument has the following features:

- It is possible to measure the refractive power and the curvature radius of the corneal surface and perform subjective measurement for both eyes at the same time.
- Simultaneous auto-alignment for both eyes enables the operator to carry out measurement.
- It is possible to perform subjective measurement as keeping the binocular vision.

PURPOSE OF THIS MANUAL

This manual outlines the Chronos, including operating procedures, troubleshooting, maintenance and cleaning.

Before using the instrument, carefully read the "DISPLAYS AND SYMBOLS FOR SAFE USE" and the "GENERAL SAFETY INFORMATION" to familiarize yourself with the features of the Chronos and use it efficiently and safely.

Always keep this manual at hand.

This manual does not explain how to operate a personal computer (PC), Microsoft Windows and iPad/iOS. It is made on the assumption that the customers have knowledge enough about a personal computer, Microsoft Windows and iPad/iOS.

For operating a personal computer, Microsoft Windows and iPad/iOS, refer to the manual of each equipment.



TRADEMARKS

Chronos is a trademark of TOPCON CORPORATION.

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iPad is a registered trademark of Apple Inc. in U.S. and other countries.

 Original Instructions This manual was originally written in English.

^{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.

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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 properties, warnings and cautions are placed on the instrument body and inserted in the Instruction 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
	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or physical damage.
Ê NOTE	Useful functions to know. Paying attention to these will prevent the noted problems.

SYMBOL

Symbol	Description
\sim	Alternating Current
\bigcirc	Off (power: disconnection from the mains)
	On (power: connection to the mains)
τ	Type B applied part
\triangle	General warning sign
<pre></pre>	Refer to instruction manual/ booklet
M	Date of manufacture
SN	Serial number
	Manufacturer

GENERAL SAFETY INFORMATION

Ensuring the Safety of Patients and Operators

Be careful not to hit the patient's eyes or nose with the instrument during operation. [If the instrument hits the patient's eye or the patient's nose is caught by it, he/she may be injured.]

Preventing Electric Shocks and Fire.

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

Do not attempt disassembling, rebuilding and/or repairs on your own.

[To avoid electric shock and fire]

[Your eyes may be exposed to Class 3B invisible laser radiation.]

Ask your dealer for repairs.

Do not use the instrument under the condition that there is build-up of dust and liquid on power inlet, power connector and power plug.

[If you use the instrument with dust, fire may occur.]

Ensuring the Safety of Patients and Operators

When operating the instrument, make sure that the patient's finger or nose is not put between the measuring head and drive base unit and between the right and left measuring windows. [The patient's finger or nose may be caught by these units to injure the patient.]

When installing this instrument on the adjustable instrument table, be careful to prevent your fingers from being caught by these units.

[Your fingers may be caught between the instrument and the adjustable instrument table to cause injury.]

This instrument must be installed by two workers.

[If one worker tries to install the instrument, it may turn over or fall off to cause injury.]

Do not perform any operation and adjustment by other procedures except those described in this manual.

Your eyes may be exposed to dangerous ray radiation.

- Use this instrument in the environment where the operator can check directly the patient.
- When wireless communication is used, use this instrument in the environment without obstacles and wireless interference.

Preventing Electric Shock and Burn

To avoid electric shock, do not handle the power supply plug with wet hand.

To avoid fire in the event of an instrument malfunction, immediately turn OFF the power switch of the adjustable instrument table and disconnect the power plug 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 plug from the instrument. Ask your dealer for service.

[If the instrument is being used without taking remedial measures, electric shock or burn may occur.]

Install this instrument under the condition that it is mounted inside the adjustable instrument table. Do not use the single unit of only the main unit or power supply unit. [To avoid electric shock]

To avoid the danger of electric shocks, connect this instrument to only the power supply (for commercial use) equipped with a protective earth system.

[To avoid electric shocks]

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.

The devices connected to digital or analog interface must comply with the international safety standards such as IEC and ISO standards (for example, IEC 60950-1 or IEC 62368-1 for information devices and IEC 60601-1 for medical devices).

When an external device is additionally connected to the medical electric devices that configure a medical electric system, the whole system (including the connected external device) must comply with the standards of the medical electric system.

If you have any question, consult the dealer from whom you purchased the instrument or the offices listed on the back cover.

Electromagnetic Compatibility (EMC)

This instrument has been tested (with 100V/120V/230V) and found to comply with IEC 60601-1-2 Ed.4.0:2014. This instrument radiates radio frequency energy within standard and may affect other devices in thevicinity. If you have discovered that turning on/off the instrument affects other devices, we recommend you change its position, keep a proper distance from other devices, or plug it into a different outlet. Please consult the dealer from whom you purchased the instrument if you have any additional questions.

DISCLAIMERS

- TOPCON shall not take any responsibility for damage due to fire, earthquakes, actions by third persons and other accidents, or damage due to negligence and misuse by the user and any use under unusual conditions.
- TOPCON shall not take any responsibility for damage derived from inability to properly use this instrument, such as loss of business profit and suspension of business.
- TOPCON shall not take any responsibility for damage caused from using this instrument in a manner other than that described in this Instruction manual.
- Diagnoses made shall be the responsibility of the user and TOPCON shall not take any responsibility for the results of such diagnoses.

POSITIONS OF WARNING AND CAUTION INDICATIONS

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	<u>A</u> 🚱	CAUTION When operating the instrument, make sure that the patient's finger or nose is not put between the measuring head and drive base unit and between the right and left measuring windows. [The patient's finger or nose may be caught by these units to injure the patient.]	
2	π	Degree of protection against electric shock : TYPE B APPLIED PART	

STANDARD ACCESSORIES

Upon unpacking, make sure that all the following standard accessories are included. Figures in () are the quantities.



MAINTENANCE



During the service/maintenance work, turn off the start switch of the power supply unit and the power switch of the adjustable instrument table and do not use this instrument for the patient.

DAILY CHECKUPS

User maintenance items

Item	Inspection time	Contents
Inspection	Before using	 The instrument must operate correctly. Measuring window (measuring lens, measuring mirror, KERATO ring and anterior segment filter) must be free of dirt or flow. The power inlet, power connector and power plug must be free of dirt.
Cleaning	When the part is stained	Measuring windowAnterior segment filterCover, etc.
Replacement	As required	Printer paper

Manufacturer maintenance items

Item	Inspection time	Contents
Cleaning each part	At least every 12 months	Cleaning the external partsCleaning the optical systemCleaning the power supply unit
Safety check	At least every 12 months	 Checking the looseness of the nut fixing the measuring heads on the drive base units (right and left) Checking the six screws fixing the main unit on the adjustable instrument table
Operation check	At least every 12 months	 Operation of the instrument Operation of switches
Accuracy check	At least every 12 months	 Checking the measuring function (by special tool)

SPECIFICATIONS & PERFORMANCE

Objective measurement				
	Spherical refractive power	-25D - +22D(*1, 2)		
measurement range	Cylindrical refractive power	0D – -10D(*1, 2))		
mododromontrango	Cylinder axial angle	1° – 180°		
	Corneal curvature radius	5.00mm – 10.00mm		
Corneal curvature	Corneal refractive power	67.50D – 33.75D (Conversion value when the corneal refractive ratio is 1.3375)		
measurement range	Corneal principal meridian direction	1°–180°		
	Spherical/cylindrical refractive power	0.12D		
	Cylinder axial angle	1°		
Minimum measurement	Corneal curvature radius	0.01mm		
	Corneal refractive power	0.12D		
	Corneal principal meridian direction	1°		
Display of measured value	Displayed on the screen of t	he operation controller.		
Minimum measurable pupil diameter	φ2.0mm			
PD measurement range	50mm – 80mm			
Minimum PD measurement unit	0.5mm			
Subjective measurement				
Subjective measurement				
Subjective measurement	Spherical power/ADD/ Cylindrical power	-18.00D \leq Equivalent spherical power \leq +18.00D (*3)		
Subjective measurement	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5)	$\begin{array}{l} -18.00D \leq Equivalent \ spherical \ power \leq +18.00D \\ (*3) \\ -8.00D \leq Cylindrical \ power \leq 0.00D \ (*4) \end{array}$		
Subjective measurement Refraction measurement	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle	-18.00D \leq Equivalent spherical power \leq +18.00D (*3) -8.00D \leq Cylindrical power \leq 0.00D (*4) 1° – 180°		
Subjective measurement Refraction measurement range	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle Horizontal prism (One eye movable range)	-18.00D \leq Equivalent spherical power \leq +18.00D (*3) -8.00D \leq Cylindrical power \leq 0.00D (*4) 1° - 180° ±15.0 \varDelta (*6)		
Subjective measurement Refraction measurement range	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle Horizontal prism (One eye movable range) Vertical prism (One eye movable range)	-18.00D \leq Equivalent spherical power \leq +18.00D (*3) -8.00D \leq Cylindrical power \leq 0.00D (*4) 1° - 180° ±15.0 \varDelta (*6) ±2.5 \varDelta		
Subjective measurement Refraction measurement range	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle Horizontal prism (One eye movable range) Vertical prism (One eye movable range) Spherical/ADD refractive power	-18.00D \leq Equivalent spherical power \leq +18.00D (*3) -8.00D \leq Cylindrical power \leq 0.00D (*4) 1° - 180° ±15.0 Δ (*6) ±2.5 Δ 0.25D		
Subjective measurement Refraction measurement range	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle Horizontal prism (One eye movable range) Vertical prism (One eye movable range) Spherical/ADD refractive power Cylindrical refractive power	-18.00D \leq Equivalent spherical power \leq +18.00D (*3) -8.00D \leq Cylindrical power \leq 0.00D (*4) 1° - 180° ±15.0 Δ (*6) ±2.5 Δ 0.25D 0.25D		
Subjective measurement Refraction measurement range Minimum measurement unit	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle Horizontal prism (One eye movable range) Vertical prism (One eye movable range) Spherical/ADD refractive power Cylindrical refractive power Cylinder axial angle	$-18.00D \le$ Equivalent spherical power $\le +18.00D$ (*3) $-8.00D \le$ Cylindrical power $\le 0.00D$ (*4) $1^{\circ} - 180^{\circ}$ $\pm 15.0 \ \Delta$ (*6) $\pm 2.5 \ \Delta$ $0.25D$ 1°		
Subjective measurement Refraction measurement range Minimum measurement unit	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle Horizontal prism (One eye movable range) Vertical prism (One eye movable range) Spherical/ADD refractive power Cylindrical refractive power Cylinder axial angle Prism refractive power	$-18.00D \le Equivalent spherical power \le +18.00D$ (*3) $-8.00D \le Cylindrical power \le 0.00D$ (*4) $1^{\circ} - 180^{\circ}$ $\pm 15.0 \ \Delta$ (*6) $\pm 2.5 \ \Delta$ $0.25D$ 1° $0.1 \ \Delta$		
Subjective measurement Refraction measurement range Minimum measurement unit	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle Horizontal prism (One eye movable range) Vertical prism (One eye movable range) Spherical/ADD refractive power Cylindrical refractive power Cylinder axial angle Prism refractive power Far-/Near-point test distance	-18.00D \leq Equivalent spherical power \leq +18.00D (*3) -8.00D \leq Cylindrical power \leq 0.00D (*4) 1° - 180° ±15.0 Δ (*6) ±2.5 Δ 0.25D 0.25D 1° 0.1 Δ e can be set between 25cm and 6.096m.		
Subjective measurement Refraction measurement range Minimum measurement unit Test distance Visual acuity measure- ment range(*7)	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle Horizontal prism (One eye movable range) Vertical prism (One eye movable range) Spherical/ADD refractive power Cylindrical refractive power Cylinder axial angle Prism refractive power Far-/Near-point test distance 0.05 – 1.6	-18.00D \leq Equivalent spherical power \leq +18.00D (*3) -8.00D \leq Cylindrical power \leq 0.00D (*4) 1° - 180° ±15.0 Δ (*6) ±2.5 Δ 0.25D 0.25D 1° 0.1 Δ e can be set between 25cm and 6.096m.		
Subjective measurement Refraction measurement range Minimum measurement unit Test distance Visual acuity measurement range(*7) Chart	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle Horizontal prism (One eye movable range) Vertical prism (One eye movable range) Spherical/ADD refractive power Cylindrical refractive power Cylinder axial angle Prism refractive power Far-/Near-point test distance 0.05 – 1.6 Visual acuity test chart, sphe astigmatism correction test of	-18.00D \leq Equivalent spherical power \leq +18.00D (*3) -8.00D \leq Cylindrical power \leq 0.00D (*4) 1° - 180° ±15.0 Δ (*6) ±2.5 Δ 0.25D 0.25D 1° 0.1 Δ e can be set between 25cm and 6.096m.		
Subjective measurement Refraction measurement range Minimum measurement unit Test distance Visual acuity measure- ment range(*7) Chart Background luminance	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle Horizontal prism (One eye movable range) Vertical prism (One eye movable range) Spherical/ADD refractive power Cylindrical refractive power Cylinder axial angle Prism refractive power Far-/Near-point test distance 0.05 – 1.6 Visual acuity test chart, sphe astigmatism correction test of 155±15cd/m2	-18.00D \leq Equivalent spherical power \leq +18.00D (*3) -8.00D \leq Cylindrical power \leq 0.00D (*4) 1° - 180° ±15.0 Δ (*6) ±2.5 Δ 0.25D 0.25D 1° 0.1 Δ e can be set between 25cm and 6.096m. erical power correction test chart, chart and binocular function test chart		
Subjective measurement Refraction measurement range Minimum measurement unit Test distance Visual acuity measurement range(*7) Chart Background luminance Display of measured value	Spherical power/ADD/ Cylindrical power These must meet all the condi- tions mentioned at the right.(*5) Cylinder axial angle Horizontal prism (One eye movable range) Vertical prism (One eye movable range) Spherical/ADD refractive power Cylindrical refractive power Cylinder axial angle Prism refractive power Far-/Near-point test distance 0.05 – 1.6 Visual acuity test chart, sphe astigmatism correction test of 155±15cd/m2 Displayed on the screen of t	$-18.00D \le$ Equivalent spherical power $\le +18.00D$ (*3) $-8.00D \le$ Cylindrical power $\le 0.00D$ (*4) $1^{\circ} - 180^{\circ}$ $\pm 15.0 \ Δ (*6)$ $\pm 2.5 \ $\Delta$$ $0.25D$ $0.25D$ 1° $0.1 \ $\Delta$$ $0.1 \ $\Delta$$ e can be set between 25cm and 6.096m.erical power correction test chart, chart and binocular function test charthe operation controller.		

Measuring head move- ment	Right-and-left direction	Inside -9mm to Outside +12.5mm	
	Up-and-down direction	Down 15mm to Up 15mm	
	Back-and-forth direction	Forward: 20mm - Backward: 20mm	
Measuring head rotary angle	Convergence 17.5° to Divergence 8.5° (Eyeball torsion axis center)		

- (*1) The dioptric powers are indicated with reference wavelength λ_d =587.56 nm
- (*2) Spherical refractive power + Cylindrical refractive power \leq +22D or Spherical refractive power + Cylindrical refractive power \geq -25D
- (*3) The conversion value with "VD=12mm" is described here.
- (*4) The conversion value with the pupil power (VD=-3mm) is described here.
- (*5) The value described here is the maximum value. The measurement range is smaller according to the test distance setting for executing a test or the setting conditions of VD during measurement.
- (*6) The value described here is the maximum value. The measurable range is smaller according to the combination of the patient's PD and the test distance.
- (*7) 0.1 1.6 complies with ISO 10938. ETDRS chart using Landolt Ring (visual acuity 0.25 1.6) complies with ANSI Z80.21.

Conformity standards

- ISO 10938:2016 Ophthalmic optics Chart displays for visual acuity measurement Printed, projected and electronic
- ISO 8596:2017+Amd.1 Ophthalmic optics Visual acuity testing Standard and clinical optotypes and their presentation Verification Result of Conformity
- ISO 10343:2014 Ophthalmic instruments Ophthalmometers: Type B
- ISO 10342:2010 Ophthalmic instruments Eye refractometers
- ANSI Z80.21:2010 for Ophthalmics Instruments General-Purpose Clinical Visual Acuity Charts

GENERAL INFORMATION ON USAGE AND MAINTE-NANCE

INTENDED PATIENT POPULATION

Patients undergoing examination with this instrument must be able to follow instructions including:

- Being able to position their face appropriately in the forehead rest.
- Keep the eye open as instructed by the examiner.
- Understand and follow instructions when undergoing examination.

INTENDED USER PROFILE

Ophthalmologists/optometrists/orthoptists/other certified health professionals

ENVIRONMENTAL CONDITIONS FOR USE

Temperature: 10°C - 35°CHumidity: 30% - 90% (without dew condensation)Pressure: 800hPa - 1060hPa

STORAGE, USAGE PERIOD

- 1. Environmental conditions (without package)
 - *Temperature : 10°C 40°C
 - Humidity : 10% 95% (without dew condensation)

Pressure : 700hPa - 1060hPa

- * THIS INSTRUMENT DOES NOT MEET THE TEMPERATURE REQUIREMENTS OF ISO 15004-1 FOR STORAGE. DO NOT STORE THIS INSTRUMENT IN CONDITIONS WHERE THE TEM-PERATURE 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.
- Normal life span of the instrument:
 8 years from delivery providing regular maintenance is performed [TOPCON data]

ENVIRONMENTAL CONDITIONS FOR PACKAGING IN STORAGE

 Temperature
 : -20°C - 50°C

 Humidity
 : 10% - 95%

 Pressure
 : 700hPa - 1060hPa

ENVIRONMENTAL CONDITIONS FOR PACKAGING IN TRANSPORTATION

Temperature	: -40°C - 70°C
Humidity	: 10% - 95%
Pressure	: 700hPa - 1060hPa

ELECTRIC RATING

Source voltage : AC100-240V Frequency : 50-60Hz Power input : 160VA

DIMENSIONS AND WEIGHT

Main unit

Dimensions : 510-540mm (H) × 671-766mm (W) × 278-357mm (D) Weight : 31.2kg

Power supply unit

Dimensions : 276mm (H) × 117mm (W) × 197mm (D) Weight : 3.5kg

SYSTEM CLASSIFICATION

Types of protection against electric shocks: This instrument is classified as Class I equipment.

Class I equipment does not depend only on basic insulation for protection against electric shocks, but also provides a means of connection to a protective earth system of facilities so that metal parts that come into contact do not become conductive while the basic insulation is in failure.

Degree of protection against electric shocks: Type B applied part

Type B applied part is the applied part complying with the specified requirements of the Standard IEC 60601-1 to provide protection against electric shock, particularly regarding allowable LEAKAGE CUR-RENT.

Degree of protection against harmful ingress of water: IPX0

The Chronos has no protection against ingress of water. (The degree of protection against harmful ingress of water defined in IEC 60529 is IPX0.)

Classification according to the method(s) of sterilization or disinfection recommended by the manufacturer: not applicable.

The Chronos has no part to be sterilized or to be disinfected.

Classification according to the degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The Chronos should be used in environments where no flammable anesthetics and/or flammable gases are present.

Classification according to the mode of operation: Continuous operation.

Continuous operation is the operation under normal load for an unlimited period, without the specified limits of temperature being exceeded.



BASIC OPERATION PRINCIPLE

The right and left measuring heads project the refraction measuring ring of the near infrared light to the patient's eye retina and the image reflected by the retina is received by the camera. Arithmetic processing is performed for the received image to calculate the spherical/cylindrical power and axial angle. The anterior segment image received by the camera is displayed on the controller.

KERATO ring is projected to the cornea and the image reflected by the cornea surface is received by the camera. Arithmetic processing is performed for the received image to calculate the corneal curvature radius and corneal refractive power.

By detecting the pupil center and a Purkinje image, the measuring heads are automatically aligned with the patient's eye.

The test charts, which are displayed on the electronic panel (LCOS) built in the measuring heads, are presented through the subjective test optical system.

According to the patient's response when seeing the test charts, the inspector operates the controller to change the lens position in the optical system and consequently the subjective refraction test is performed.

DISPOSAL

When disposing of Chronos 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.
	You cannot replace batteries by yourself. When you need to replace and/or dispose batteries, contact your dealer or TOPCON listed on the back cover.
ெ டி NOTE	
	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 chemi- cal 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%)
	ronment.

PATIENT'S ENVIRONMENT

When the patient or inspector may touch the devices (including the connecting devices) or when the patient or inspector may touch the person that comes into contact with the devices (including the connecting devices), the patient's environment is shown below.

In the patient's environment, use the device conforming to IEC 60601-1. If you are compelled to use any device not conforming to IEC 60601-1, use an insulation transformer or the common protective earth system.



	 Don't connect an additional power strip or an extension cord to the system. Don't connect any device which is not recognized as one component of the system. The personal computer, the Wifi router and the operation controller must be installed out of the patient's environment.
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ELECTROMAGNETIC COMPATIBILITY

This product conforms to the EMC Standard (IEC 60601-1-2: 2014). The electromagnetic environment assumed for the whole life cycle is home medical treatment environment.

If there is electromagnetic jamming that is higher than IEC 60601-1 test level, the following troubles may occur as loss/deterioration of basic performance caused by electromagnetic jamming:

- Measured value reliability is lowered or measurement cannot be performed;
- Alignment is not correctly completed;
- The values in the output data are not correct;
- Patient ID is not correctly displayed.
- a) MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.
- b) Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIP-MENT.
- c) The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or SYSTEM as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or SYSTEM.
- d) The EQUIPMENT or SYSTEM should not be used adjacent to or stacked with other equipment. IF adjacent or stacked use is necessary, the EQUIPMENT or SYSTEM should be observed to verify normal operation in the configuration in which it will be used.
- e) The use of the ACCESSORY, transducer or cable with EQUIPMENT and SYSTEMS other than those specified may result in increased EMISSION or decreased IMMUNITY of the EQUIPMENT or SYSTEM.
- f) Do not use the devices generating electromagnetic waves within 30cm from all the parts of the instrument and system. Those devices may have influence on this instrument.

Item	Cable Shielded	Ferite Core	Length (m)
AC power cord (for the instrument)	No	No	1.9
LAN cable	Yes	Yes	3
USB-LAN conversion adapter	-	-	-
Personal computer	-	-	-
AC power cord (for personal computer)	No	No	1.5
Wifi router	-	-	-
AC adapter (for Wifi router)	No	No	1.5
Tablet	-	-	-

Guidance and manufacturer's declaration - electromagnetic emissions				
The Chronos is intended for use in the electromagnetic environment specified below. The customer or the user of the Chronos should assure that it is used in such an environment.				
Emissions test	Compliance	Electromagnetic environment - guidance		
RF emissions CISPR 11	Group 1	The Chronos uses RF energy only for its internal function. There- fore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.		
RF emissions CISPR 11	Class B	The Chronos is suitable for use in all establishments excluding domestic and those directly connected to the public low-voltage		
Harmonic emissions IEC 61000-3-2	Class A	power supply network that supplies buildings used for domestic purposes.		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies			

Guidance and manufacturer's declaration - electromagnetic immunity				
The Chronos is intended for use in the electromagnetic environment specified below. The customer or the user of the Chronos should assure that it is used in such an environment.				
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humid- ity should be at least 30%.	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines Cyclic frequency 100kHz	±2 kV for power supply lines ±1 kV for input/output lines Cyclic frequency 100kHz	Mains power quality should be that of a typical commercial or hospital envi- ronment.	
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital envi- ronment.	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% <i>U</i> _T for 0.5 cycle (with phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% <i>U</i> _T for 1 cycle 0° 70% <i>U</i> _T for 25/30 cycles 0% <i>U</i> _T for 250/300 cycles	0% $U_{\rm T}$ for 0.5 cycle (with phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% $U_{\rm T}$ for 1 cycle 0° 70% $U_{\rm T}$ for 25/30 cycles 0° 0% $U_{\rm T}$ for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital envi- ronment. If the user or the Chronos requires continued operation during power mains interruptions, it is rec- ommended that the Chronos be pow- ered from an uninterruptible power supply or battery.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commer- cial or hospital environment.	
NOTE $U_{\rm T}$ is the a.c. mains voltage prior to application of the test level.				

(Guidance and manufacturer's declaration - electromagnetic immunity							
The Chronos is intended for use in the electromagnetic environment specified below.								
The customer or the	user of the	e Chronos shou	ld assu	ire that it is used ir	n such an envi	ronment.		
Immunity test	IEC 60601 test level Con		mpliance level	Electromagnetic environment- guidance				
					Portable and	mobile R	F communication	ns
	2 Vrmc		2 Vrm	6	equipment sh	nould be	used no closer	to
	150kHz t	3 vrms 150kHz to 80MHz		s Iz to 80MHz	any part of the Chronos, including cables, than the recommended separation dis-			
					tance calcula	ted from	the equation app	oli-
	6Vrms		6Vrms		cable to the fr	equency of	of the transmitter.	
Conducted RF	Within Is	SM band and radio band of	Within	ISM band and	Bacommond	od conor	ation distance	
IEC 61000-4-6	150kHz 1	to 80MHz	150kF	Iz to 80MHz	$d = \frac{6}{F}\sqrt{P}$	eu separa		
Radiated RF	10V/m		10V/m	ı	E			
IEC 01000-4-3	80MHz te	o 2.7GHz	80MH	z to 2.7GHz	In the above	equation,	P is the maximu	ım
	Proximity	y electromag-	Proxin	nity electromag-	output power rating of the transmitter in		IN ter	
	commun	ication equip-	comm	unication equip-	manufacturer, d is the recommended sep-		p-	
	ment ^{a)}		ment ^{a)}		aration distance in meters (m), and E is		is	
					the radiation electromagnetic site level in			in
						//m).		
NOTE 1 These guid	lelines may	y not apply in a	all situa s and r	tions. Electromagi	netic propagat	ion is affe	cted by absorptio	on
^a The provimity elec		ic site of radio (nications equipme	nt is shown in	the table	helow	
	lionagnet		Johnnu					
[MHz]	Band [MHz]	Equipmen	t	Modulation	Maximum output (W)	Distance (m)	Immunity test value [V/m]	
385	380-390	TETRA 400	0	Pulse modulation 18F	Iz 1.8	0.3	27	
450	430-470	GMRS 460 FRS 460)	FM ±5kHz 1kHz sine	2	0.3	28	
710	704-787	LTE Band 13, 17		Pulse modulation	0.2	0.3	9	
780	101101	ETE Band To	217Hz		0.2	0.0	Ū	
810		GSM 800/90	00					
870	800-960	iDEN820	J	Pulse modulation 18F	Iz 2	0.3	28	
930	930 CDMA850		5					
1720		GSM 1800)					
1845	CDMA1 GSM 1		D)	Pulse modulation				
1070	1700-1990	DECT	,	217Hz	2	0.3	28	
1970		LTE Band 1,3,4,25 UMTS						
2.172		Bluetooth WLAN 802.11 b/a		Pulse modulation				
2450	2400-2570 RFID 2450	217Hz		2	0.3	28		
5240				Pulse modulation				
5500	5100-5800	WLAN 802.11	a/n	217Hz	0.2	0.3	9	
5705						<u> </u>		

SAFETY OF LASER PRODUCTS

SLD products	SLD for refractometry				
	LED emitting port	0.031cm	cm ²		
	Output	5161µW/cm ²			
	Wavelength (Centroid)	875nm			
	Beam divergence (20)	5.64deg (0.098rad)			
	Laser type	CW			
	Pulse	Light emitting time	1768 ms		
		Pulse	Frequency	10 kHz	
			Pulse width	6.25 µs - 0.1 ms	
SLD light source	SLD for refractometry				
	Class of laser products Class 3B				
	Output	14.6mW (CW)			
	Wavelength (Centroid)	875nm			
	Beam divergence (20)	H:11deg (0.19rad) V:36deg (0.63rad)			

* LED light and laser beam are emitted from the measuring window.



IT NETWORK ENVIRONMENT

- Chronos can be connected with a lens meter and NAS in order to be connected with an external personal computer (PC), input the lens data, Ref data and other data, and output the measurement data by operating the main unit.
- Refer to the Fig. A below for the characteristics, configuration, technical specification, intended information flow and route when connected with an IT network. For remote operation, refer to the Fig. B below.
- When connected with an IT network, ensure the appropriate and sufficient security to prevent the infection with a computer virus, the leak of information, etc.
- When any failure occurs in IT systems, some troubles may be caused by it. For example, the input data/output data cannot be sent/received to/from the devices connected with network, or the operator cannot operate the main unit.
- When connected with an IT network with which a device other than Chronos is connected, the patient, the operator or the third party may suffer unexpected and unacceptable risks. Before using Chronos, it is recommended to identify, analyze, evaluate and manage these risks.
- When the IT network has been changed after the connection, a new risk may occur. So an additional analysis is necessary.

The devices that will be connected with Chronos

- The change of IT network includes the following items:
 - Change in the IT network configuration;
 - Connection of additional items to IT network;
 - Removal of items from IT network;
 - Update of the device connected with IT network;
 - Upgrade of the device connected with IT network.



*1: Main connection should be done by "PC with the specified specification + USB-LAN conversion adapter". As an auxiliary method, it is also allowed to connect by "a commercial tablet computer + wifi router".

Fig. A: Configuration of a typical IT network connection

For remote operation

- Remote operation means that the operator operates Chronos from a location remote from the Chronos main unit and the patient.
- Refer to Figure B below for characteristics, configuration, technical specifications, intended information flow and route when connected with IT network.

Preparation for remote operation

- Place the support staff member near the patient to support the inspection.
- Prepare the support device for voice communication between the support staff member and the operator.
- Install the online conferencing software for voice communication during the inspection on the operating device used by the operator and the support device used by the support staff member.

Operation Flow

- 1) Support staff member should connect their support device to the facility network and launch the online conferencing software.
- 2) The examiner should connect the control device to the facility network and launch the operating software and online conference software.
- 3) Before the inspection, make sure that the operator, support staff member, and the patient can communicate via voice through the online conferencing software.
- 4) The operator should start the inspection after confirming that the patient and the support staff member are near the main unit.
- 5) The support staff member should monitor the patient and the main unit during the inspection so that the patient can perform the inspection properly.

Cautions for remote operation

- When connecting to an IT network, check the precautions described on the previous page.
- When the operator uses Chronos from outside the facility, the control device should be connected to the facility network via VPN or other means to ensure security.
- The operator should be aware of his/her surroundings to prevent a third party from viewing the screen of the operating device.
- If voice communication cannot be established due to communication failure, etc., wait until communication is restored or interrupt the inspection.
- Support staff member should always stay close by the patient and the main unit so that the operator can give appropriate instructions to the patient and support staff member can directly check the condition of the patient and the main unit.
- The location of the main unit, the operator, and the data storage device should be in the same country or in a region where the same laws and regulations apply.



*1, *2: The connection should be PC or tablet with specified specifications, it is also allowed to connect by wifi.

Fig. B: Configuration of IT network connection for remote control

SPECIFICATIONS OF THE CONNECTED DEVICES

The specifications and performance of the devices that should be connected to Chronos are shown below.

• Operation controller and Wifi router

These devices must conform to EMC standard (CISPR 22/CISPR 24, CISPR 32/CISPR 35 or VCCI; Emission standard: Class B).

Specifications of PC/tablet to be used as the operation controller				
	Surface Go2	iPad Air (Third	iPad	iPad Pro
OS		generation)	(9th generation)	(6th generation)
	Windows 10	iPad OS 13	iPadOS 15	iPadOS 16
Screen size	10.5 inches	10.5 inches	10.2 inches	12.9 inches
Resolution/aspect ratio	1,920×1,280 /	2,224×1,668 /	2,160×1,620 /	2,732×2,048 /
(*1)	3:2	4:3	4:3	4:3
Wireless	IEEE802.11 (When the wireless system is built in)			
communication standard				
Browser software	Main application : Google Chrome (*2)			
DIOWSEI SOliware	SightPilot	: Google Chrome	(*2)	
Others	IEC 60950-1 or IEC 62368-1 (CE marking)			
	SightPilot is only	operable in portra	it mode.	

(*1) If you use others except the above-mentioned resolution, the screen layout may be sharply destroyed.

(*2) Refer to the User Manual about the compliant version.

Specifications of Wifi router				
Wireless communication standard	IEEE802.11 (*3)			
Others	IEC 60950-1 or IEC 62368-1 (CE marking)			

(*3) The standard must be fit to the tablet that is to be connected to Chronos. Unless the standard is fit to the tablet, wireless connection cannot be executed.

 Adjustable instrument table exclusively for Chronos (CGS-1000) By using this table, you can change the instrument height freely. So you can perform measurement easily.

Specifications

- Weight75kg
- Power supply input (rated voltage)....430VA,100-240V



NOTE

When you want to ask a question/make inquiries about the Chronos adjustable instrument table or when you request for repair or any other service about it, contact the dealer whom you purchased the product or the offices described on the back cover.

OPTIONAL ACCESSORIES

Chinrest CRX-1000

FEATURES

This device is an optional accessory of Chronos. This device is intended to be used to fix patient's head.



Please ask your local dealer or TOPCON subsidiary office (see the back cover)

REFERENCE DATA

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 (Main application)

- **1** Connect the adjustable instrument table to the commercial power supply. If necessary, connect the operation controller and the Wi-Fi router to the commercial power supply.
- **2** Turn ON the power switch of the adjustable instrument table.
- **3** Turn ON the start switch of the power supply unit.
- **4** Turn ON the operation controller and check the connection with the Wi-Fi router.
- **5** Make sure that the lamp of the main unit is lit in green. Then, start the browser software of the operation controller and input the following address to the address bar of the browser. http://10.1.2.3/topcon/sub/patient.php
- **6** Input the user name and password on the login screen.
- **7** Input the patient's data on the patient information input screen.
- **8** Support the patient's face with the forehead rest and Cheek rest. If necessary, adjust the height of the main unit with the elevation lever of the adjustable instrument table.
- **9** Refer to the instruction of the alignment guide and operate the pupil distance (PD) so that the pupil may be within the patient's eye display area.
- **10** Tap the [Start] button, and the position is automatically adjusted. After the adjustment is completed, refractometry and keratometry are performed.
- **11** Tapping the [Start] button enables the operator to perform measurement again. If necessary, carry out this operation.
- **12** When there is no problem in the results of the objective refraction measurement, tap the task shift button to shift to the subjective tests. Make sure that the measured values of the objective measurement are set on the main data.
- **13** Select a chart icon of the test which is to be executed from the chart page. Only by selecting a chart icon, the test parameters are automatically changed to those related to the selected icon. If necessary, change the patient's eye.
- **14** Referring to the navigation icon displayed on the operation button, perform the test as changing the correction value by tapping the operation button. If the optometry window frame flashes in pink during the test, the patient's eye is not at the correct position. If flashing continues, select "Auto-alignment" from the hamburger menu at the lower right of the screen and perform alignment again.
- **15** After the subjective test has been completed, tap the task shift button to shift to the output screen.
- **16** Tap the [BINO & US-21] button. You can check the results of the binocular function test and the US-21 test. Tap the [Obj. Ref] button. You can check all the measured values of refractometry and keratometry.

- **17** Tap the [Print/Data Export] button. According to the setting, the data are printed by the printer built-in the power supply unit/the external printer or the data are output.
- **18** Tap the task shift button. The measurement data are cleared, the main unit is reset and the patient information input screen appears again.
- **19** Finish the browser of the operation controller.
- **20** Turn OFF the operation controller.
- **21** Turn OFF the start switch of the power supply unit.
- **22** Turn OFF the power switch of the adjustable instrument table.

Usage method (Sight Pilot)

1 Start

Launch Chronos Sight Pilot. (If you use Sight Pilot, consult the dealer from whom you purchased the instrument or the offices listed on the back cover.)

Press "START EXAM" button, and you will continue to the PATIENT DETAILS screen.

2 Patient Details

Enter patient information (patient ID, first name, last name and birthday). If the patient has glasses, enter the details of those glasses.

3 Guiding the patient

Wipe the forehead and Face shield clean and explain the examination to the patient. Instruct the patient to sit in the correct position for the chronos.

Ensure that patient sees the targeting picture (a house far behind the meadows) in Chronos and press the "Next" button to continue to the OBJECTIVE REFRACTION screen.

4 OBJECTIVE REFRACTION

Ensure that both eyes of the patient are correctly positioned in the Live camera windows and press the "Start" button.

Press the "Start" button and the REF and KERATO measurements start after the adjustment is completed.

If necessary, you can press the "Start" button to start the measurement again.

If there is no problem with the results of the measurement, press the "Next" button to continue to the SUBJECTIVE REFRACTION screen.

5 SUBJECTIVE REFRACTION

Follow the instructions on the screen to perform the SUBJECTIVE REFRACTION. When all SUBJECTIVE REFRACTION are completed or the patient is judged to be unsuitable for the Chronos, it will continue to the RESULTS screen.

6 RESULTS

Press the "Print" button to print the results from the Chronos printer. Press "Send" button to send the result and all examination data to XXX. Press "Finish" button to delete all examination data, finish the examination and reset Chronos.

Please refer to the User Manual.

When calling please give us the following information about your unit:

- Model name: REFRACTION SYSTEM Chronos
- Serial No.: Shown on the rating plate on the rear side of the main unit
- 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.

REFRACTION SYSTEM Chronos

INSTRUCTION MANUAL

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