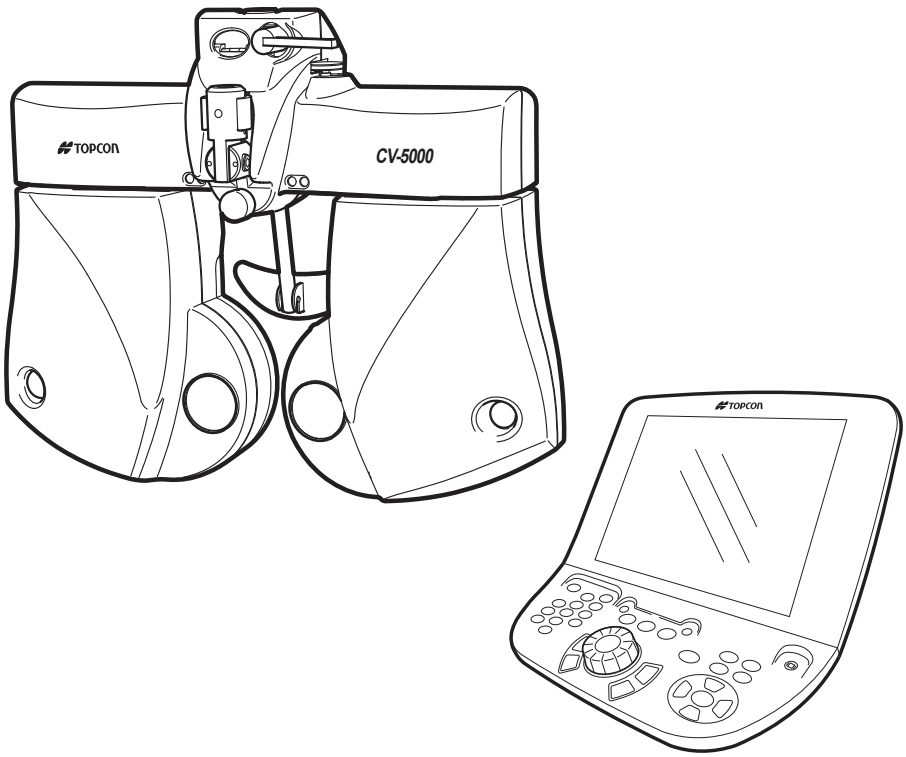
TOPCON



INSTRUCTION MANUAL

COMPU VISION

CV-5000

[en]	Instruction manuals in official languages of the Member States of the European Union are available on the following website:
[de]	Bedienungsanleitungen in den Amtssprachen der Mitgliedstaaten der Europäischen Union sind auf der folgenden Website verfügbar:
[fr]	Les manuels d'instructions dans les langues officielles des États membres de l'Union européenne sont disponibles sur le site web suivant:
[es]	Los manuales de instrucciones en las lenguas oficiales de los Estado miembros de la Unión Europea están disponibles en el siguiente sitio web:
[it]	I manuali di istruzioni nelle lingue ufficiali degli Stati membri dell'Unione Europea sono disponibili sul seguente sito web:
[sv]	Instruktionsmanualer på officiella språk för EU:s medlemsstater finns på följande webbplats:
[da]	Brugsanvisninger på officielle sprog i Den Europæiske Unions medlems-stater er tilgængelige på følgende websted:
[pt]	Os manuais de instruções nos idiomas oficiais dos estados-membros da União Europeia estão disponíveis no seguinte site:
[pl]	Instrukcje obsługi w językach urzędowych państw członkowskich Unii Europejskiej są dostępne na następującej stronie internetowej:
[nl]	Instructiehandleidingen in de officiële talen van de lidstaten van de Europese Unie zijn beschikbaar op de volgende website:
[fi]	Euroopan unionin jäsenvaltioiden virallisilla kielillä olevat käyttöohjeet ovat saatavilla seuraavalla verkko-sivustolla:
[el]	Τα εγχειρίδια οδηγιών στις επίσημες γλώσσες των κρατών μελών της Ευρωπαϊκής Ένωσης διατίθενται στον ακόλουθο δικτυακό τόπο:
[sk]	Inštrukčné manuály v úradných jazykoch členských štátov Európskej únie sú k dispozícii na tejto webovej stránke:
[cs]	Instrukční příručky v úředních jazycích členských států Evropské unie jsou k dispozici na této webové stránce:
[sl]	Navodila za uporabo v uradnih jezikih držav članic Evropske unije so na voljo na naslednjem spletnem mestu:
[et]	Euroopa Liidu liikmesriikide ametlikes keeltes kasutusjuhendid on saadaval järgmisel veebisaidil:
[hu]	Az Európai Unió tagállamainak hivatalos nyelvein található használati utasítások a következő weboldalon érhetők el:
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[lt]	Naudojimo instrukcijas oficialiomis Europos Sąjungos valstybių narių kalbomis rasite šioje svetainėj:
[ro]	Manuale de instrucțiuni în limbile oficiale ale statelor membre ale Uniunii Europene sunt disponibile pe următorul site web:
[bg]	Наръчниците за инструкции на официалните езици на държавите-членки на Европейския съюз са достъпни на следния уебсайт:
[hr]	Priručnici s uputama na službenim jezicima država članica Europske unije dostupni su na sljedećoj web stranici:
[no]	Instruksjonshåndbøker på offisielle språk i EUs land er tilgjengelige på følgende nettsted:

https://global.topcon.com/Manuals_IFUs/

INTRODUCTION

Thank you for purchasing the TOPCON COMPU VISION CV-5000.

INTENDED USE / INDICATIONS FOR USE

This instrument is used to measure the refractive power of the eye and to test binocular functionality.

CLINICAL BENEFITS

Target all patient's eyes to be determined for prescription value.

FEATURES

This instrument has the following features:

- The compact design lens chamber enables you to see the patient's face.
- The distance acuity chart can be controlled by the 1Dial Controller.
- The PD (pupil distance) and the anterior eye alignment can be checked even in a dark optometry room.
- The large 10.4-inch touch panel liquid crystal display unit is used to easily conduct an examination or patient education.
- "Help", "Dial Navigation" and other functions support the optometrist.

PURPOSE OF THIS MANUAL

To ensure safe and effective use of the instrument, carefully read "DISPLAY AND SYMBOLS FOR SAFE USE" and "GENERAL SAFETY INFORMATION" and then use the instrument as instructed.
Keep the manual at hand for future reference.

SERIOUS INCIDENT REPORTING

In case any serious incident occurs in relation to the device, please report it to the manufacturer, authorized representative and the competent authority in which the user and/or patient is established.

CE UK CA

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 translation of the original instructions.This manual was originally written in English.

CONTENTS

6.OPERATING AND USAGE METHOD

DISPLAY 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, important cautionary messages are placed on the instrument body and inserted in the manual.
We suggest that everyone using the instrument understand the meaning of the following displays, icons and text before reading the "SAFETY CAUTIONS" and observe all listed instructions.

DISPLAYS

Display	Meaning
⚠ **WARNING**	Incorrect handling by ignoring this display may lead to a risk of death or serious injury.
⚠ **CAUTION**	Incorrect handling by ignoring this display may lead to personal injury or physical damage.

- Injury refers to cuts, bruises, burns, electric shock, etc. which do not require hospitalization or extended medical treatment.
- Physical damage refers to extensive damage to the building, nearby equipment and/or surrounding furniture.

SYMBOL

Symbol	Description
	Alternating Current
	Off (power: disconnection from the mains)
	On (power: connection to the mains)
	Type B applied part
	General warning sign
	Refer to instruction manual/ booklet
	Date of manufacture
	Serial number
	Manufacturer

Symbol	Description
	Authorised Representative in the European Community
	Authorised Representative (Responsible Person) in the United Kingdom.
	Medical Devices
	Unique Device Identification (UDI)
	Humidity limitation
	Atmospheric pressure limitation
	Temperature limit
	Keep away from sunlight
	Fragile, handle with care
	Keep dry
	This way up
	Maximum number of identical packages which may be stacked on one another.
	General symbol for recovery/recyclable. (for the package)
	Recycling symbol for plastic in the package. Low density polyethylene
	
	Indicates that the product conforms to the requirements of the Medical Device Regulation(EU)2017/745 and of the other applicable Union legislation
	Indicates that the product conforms to the requirements of the Part II of UK Medical Devices Regulation 2002, and of the other applicable legislations.
	CSA listing mark

GENERAL SAFETY INFORMATION

⚠ WARNING

Ensuring the Safety of Patients and Operators
Be careful not to bump the patient's eyes or nose with the instrument during operation. The patient may be injured.

Preventing Electric Shocks and Fires.
To avoid fire and electric shock, install the instrument in a 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 shock, do not insert metal objects into any openings, etc.
To avoid fire in the event of an instrument malfunction, immediately turn off the power switch and unplug the cable if you see smoke coming from the instrument or if you detect other problems. Don't install the instrument where it is difficult to disconnect the power plug from the outlet. Ask your dealer for repairs.
Modification of this instrument is not permitted.
To avoid electric shock and fire, do not disassemble, modify or repair the equipment. Ask your dealer for repairs.
Electoric shock may cause bums 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.
To avoid injury caused by electric shock, do not open the cover. Ask your dealer for service.
To avoid fire and electric shock in case of leakage, be sure to use a grounded outlet. Do not connect to outlets that are not grounded.
To avoid electric shock, be sure to remove the power cable from the instrument body before removing the fuse cover for replacement. Also, do not connect the power cable to the instrument body with the fuse cover left unfixed.
To avoid fire in the event of an instrument malfunction, use a properly rated fuse.

⚠ CAUTION

Ensuring the Safety of Patients and Operators
When moving the instrument body up and down, be careful not to bump it against the patient's face. The patient may be injured. This instrument should only be used by skilled operators.
To prevent the instrument from tipping over or falling and to avoid injury, do not install the instrument on an uneven, unsteady or sloping surface.
Do not put your hand between the mounting arm and the instrument. Your hand may be pinched.
To avoid injury due to contact, do not bring the patient's face close to the near-point rod.
To avoid injury caused by pinching when moving the monitor unit, do not place your hand between the monitor unit and the main unit.
Install the devices (RM, CL and others), which will be connected with the optional accessories, out of the CV-5000 patient's environment.
Do not to connect additional a power strip (it shall be not only in patient environment also in outside of patient environment).
Install the visual acuity chart out of the CV-5000 patient's environment.
Install the devices (RM, CL and others) to be connected out of the CV-5000 patient's environment.
When tilting the instrument downward, place the measuring head away from the patient to prevent him/her from being injured by colliding against it.
Do not tilt the instrument downward while the near-point rod is pulled down. The near-point rod may hit the instrument or desk and damage the instrument.
To avoid injury caused by pinching when moving the monitor unit of the 1Dial Controller , do not place your hand between the monitor unit and the controller unit.
• When you connect this instrument on the personal computer connected to a network, ensure security properly in order to prevent the infection with computer virus, leak of information and other troubles. • When connected this instrument on the client server system, it is assumed that the data and database files will be placed on the network. Manage the folders which save these files and the access right to the files correctly. • Manage the personal computer and media (recording media), which save the data obtained and backed up by this instrument, in order to prevent the computer and media from being wrongly used or taken out by the third party.

Preventing Electric Shocks.
To avoid damage to the instrument or an injury caused by electric shock, turn off the power switch and unplug the power cord before cleaning the instrument.
To avoid electric shock, do not touch the external connection terminal and the patient at the same time.

Preventing Electric Shocks.
To avoid electric shock, do not handle the plugs with wet fingers.

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.

Electromagnetic Compatibility (EMC)
This instrument has been tested (with 100V/120V/230V) and found to comply with IEC60601-1-2:2014(Ed.4.0). This instrument radiates radio frequency energy within standard and may affect other devices in the vicinity. 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.

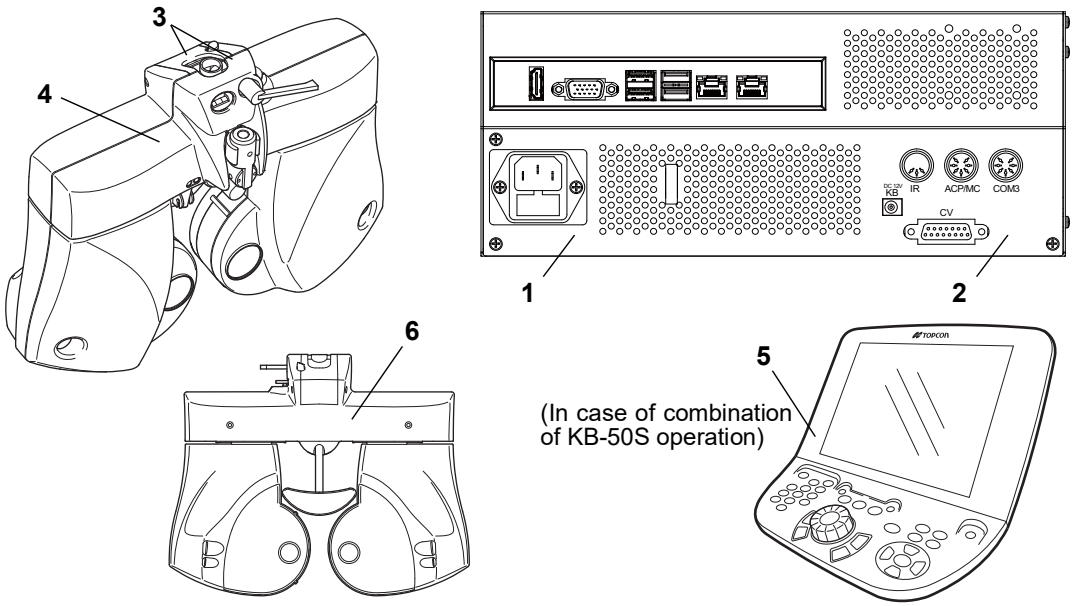
DISCLAIMERS

- 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 manual.
- TOPCON is not responsible for any damage caused by unauthorized access from outside, malware or viruses.
- Diagnoses made shall be the responsibility of the user and TOPCON shall not take any responsibility for the results of such diagnoses.

WARNING DISPLAYS AND POSITIONS

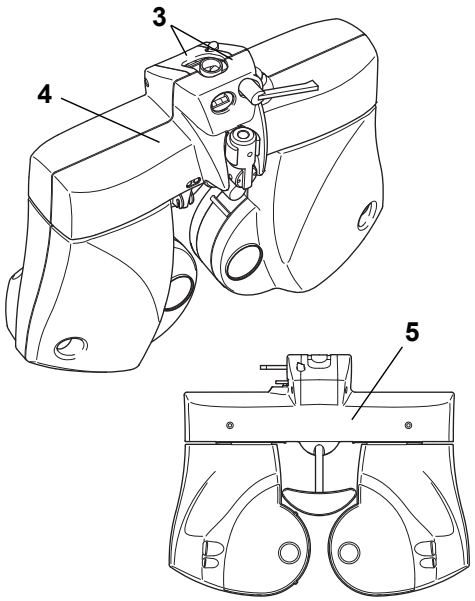
To ensure safety, the machine provides warning displays.
Use the instrument correctly by observing the display instructions. If any of the following display labels are missing, contact your TOPCON dealer or your local Topcon office listed on the back cover of this manual.

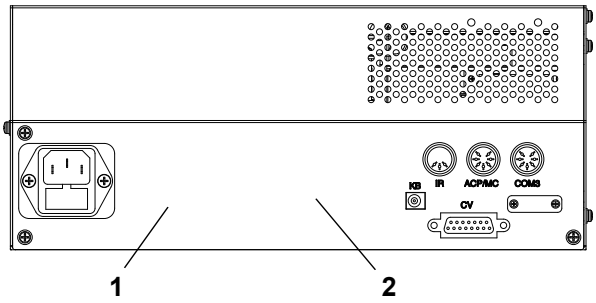
In case of combination of KB-50S or mouse operation.



No.	Label	Meaning
1		**WARNING** Electoric shock may cause bums 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.
2		**WARNING** To avoid injury caused by electric shock, do not open the cover. Ask your dealer for service.
3		**CAUTION** Do not put your hand between the mounting arm and the instrument. Your hand may be pinched.
4		**CAUTION** To avoid injury due to contact, do not bring the patient's face close to the near-point rod.
5		**CAUTION** To avoid injury caused by pinching when moving the monitor unit, do not place your hand between the monitor unit and the main unit.
6		Degree of protection against electric shock : TYPE B APPLIED PART

In case of combination of PC operation.





No.	Label	Meaning
1		**WARNING** Electoric shock may cause bums 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.
2		**WARNING** To avoid injury caused by electric shock, do not open the cover. Ask your dealer for service.
3		**CAUTION** Do not put your hand between the mounting arm and the instrument. Your hand may be pinched.
4		**CAUTION** To avoid injury due to contact, do not bring the patient's face close to the near-point rod.
5		Degree of protection against electric shock : TYPE B APPLIED PART

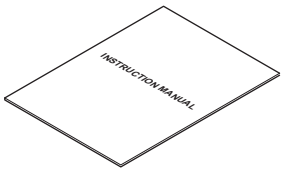
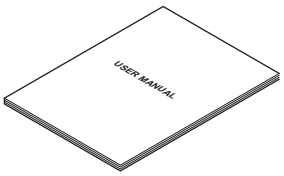
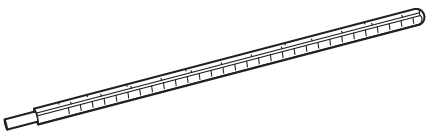
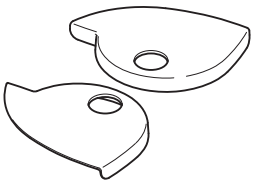
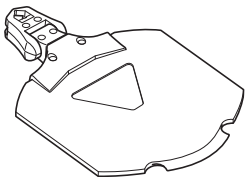
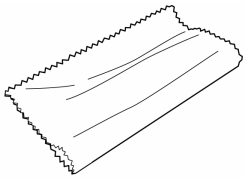
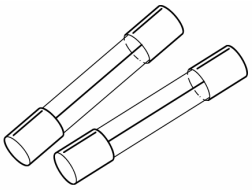
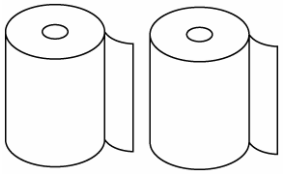
1. BEFORE USE

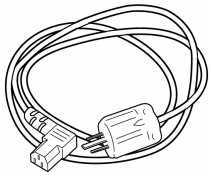
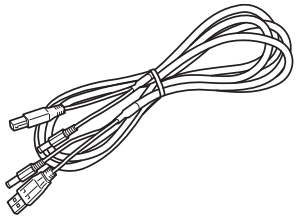
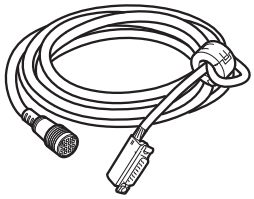
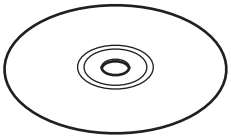
1.1 CHECKING THE ACCESSORIES

⚠CAUTION	Install the devices (RM, CL and others), which will be connected with the optional accessories, out of the CV-5000 patient's environment.

STANDARD ACCESSORIES

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

Instruction Manual *1 	User manual (1)*1 
Dust cover (1) 	Near-point rod (1) 
Forehead rest (1) 	Face shield (2) 
Near-point card and card holder (1 each) 	Silicone cloth (1) 
Fuses (2) 	Printer paper (2)*2 

Power cord (1)  The shape is different according to the destination.	1Dial Controller connection cable (1) 
Measuring head connection cable (1) 	Install CD (1)*3 

*1 Depending on the destination, this is not attached.

*2 For combination of KB-50S or mouse operation only.

*3 For combination of PC operation only.

Use the standard accessories except the following units in the patient's environment.
- User manual
- Dust cover
- Silicone cloth

OPTIONAL ACCESSORIES

The optional accessories must be connected by a service engineer. If you have purchased any optional accessories, contact a service engineer.

- Communication cable (DIN/DIN)
  This cable is used to connect KR, CL and the visual acuity chart.
  Both ends of the cable are the DIN connector type.
- Communication cable (DIN/D-sub)
  This cable is used to connect KR, CL, etc.
  One end of the cable is the DIN connector type and the other is the D-SUB 9-pin type.
- Infrared communication unit
  This unit is used to perform infrared communication with the visual acuity chart.
- PIXELCHART (PC-50S)
  This visual acuity chart operates in linkage with the CV system.
- PIXELCHART (PC-50SB)
  This visual acuity chart operates in linkage with the CV system.
- Mirror Chart (MC-4S)
  This visual acuity chart operates in linkage with the CV system.
- 1 DIAL CONTROLLER KB-50S (for combination of KB-50S operation)

- POWER SUPPLY UNIT for CV-5000 (BUILT-IN PC TYPE) (for combination of KB-50S or mouse operation)
- POWER SUPPLY UNIT for CV-5000 (PC EXTERNAL TYPE) (for combination of PC operation)

* The PC and Mouse are commercial products. For usable external devices and connection cables, please contact your local distributor or contact address on the back cover.

PRODUCTS SOLD SEPARATELY

In case of combination of Mouse operation

The commercial products sold separately are necessary to use the CV system. Use the device complying with IEC 62368-1.

- Display
  Your display must meet the following specifications.
  Resolution: XGA (1024 x 768) is possible.
  Connection: Analog VGA (Mini D-Sub 15) can be connected.
- Mouse (USB connection)

In case of combination of PC operation

The commercial products sold separately are necessary to use the CV system. Use the device complying with IEC 62368-1.

- Personal computer (including the main unit, display, keyboard and mouse)
  Your personal computer must meet the following specifications.
  OS: Windows XP Professional (32 bits)/Windows 7 Professional (32 bits/64 bits)
  /Windows 10 (32 bits/64 bits)
  CPU: Clock frequency is 1GHz or more.
  Memory: 1GB or more (32-bit OS)/2GB or more (64-bit OS)
  HDD: Free capacity of 500MB or more
  Serial port: 1 or more
  Display: Resolution of SXGA (1280 x 1024) or more

- At least one serial port is necessary to connect to the power supply unit.
  To connect to RM/CL, more serial ports for the connected devices are necessary.
- To connect PIXELCHART or Mirror Chart (optional) as a visual acuity chart, a free DVI connector is necessary.
- To connect another CV-5000 system, the LAN connecter is needed.

2. MAINTENANCE

USER MAINTENANCE ITEMS

Item	Inspection time	Contents
Inspection	Before using	• The instrument must operate correctly. • The examination window and corneal aligning window must be free of stain or flaw.
Cleaning	When the part is stained	• Examination window and corneal aligning window • Cover, switch and others
Replacement	As required	• Fuse

3. APPENDICES

3.1 SHAPE OF PLUG

Country	Voltage/frequency	Shape of plug
Mexico	110V/50Hz	Type C&E
Argentina	220V/60Hz	Type A
Peru	220V/60Hz	Type A
Venezuela	110V/50Hz	Type C&E
Bolivia & Paraguay	220V/60Hz	Type A (Most common) Type H (Infrequently)
Chile	220V/60Hz	Type A
Colombia	110V/50Hz	Type C
Brazil	220V/60Hz 127V/60Hz	Type A Type C
Ecuador	110V/50Hz	Type C&E
United States	120V/60Hz	Type A (Hospital Grade)
Canada	120V/60Hz	Type A (Hospital Grade)

Mains Plugs Used in Europe Member states

Country	Voltage/frequency	Type of plug
Austria	230V/50Hz	Type C / F
Belgium	230V/50Hz	Type C / E
Bulgaria	230V/50Hz	Type C / F
Croatia	230V/50Hz	Type C / F
Cyprus	230V/50Hz	Type G
Czech Republic	230V/50Hz	Type C / E
Denmark	230V/50Hz	Type C / E / F / K
Estonia	230V/50Hz	Type C / F
Finland	230V/50Hz	Type C / F
France	230V/50Hz	Type C / E
Germany	230V/50Hz	Type C / F
Greece	230V/50Hz	Type C / F
Hungary	230V/50Hz	Type C / F
Ireland	230V/50Hz	Type G

Country	Voltage/frequency	Type of plug
Italy	230V/50Hz	Type C / F / L
Latvia	230V/50Hz	Type C / F
Lithuania	230V/50Hz	Type C / F
Luxembourg	230V/50Hz	Type C / F
Malta	230V/50Hz	Type G
Netherlands	230V/50Hz	Type C / F
Poland	230V/50Hz	Type C / E
Portugal	230V/50Hz	Type C / F
Romania	230V/50Hz	Type C / F
Slovakia	230V/50Hz	Type C / E
Slovenia	230V/50Hz	Type C / F
Spain	230V/50Hz	Type C / F
Sweden	230V/50Hz	Type C / F
United Kingdom	230V/50Hz	Type G

4. SPECIFICATIONS AND PERFORMANCE

MEASURING HEAD

Spherical power	Measuring range	+27.00 to -27.00D
	Measuring step	0.25D/1.00D/2.00D/3.00D
Cylinder power	Measuring range	+8.00 to -8.00D
	Measuring step	0.25D/1.00D
Cylinder axis	Measuring range	0 to 180°
	Measuring step	1°/5°/15°
Prism	Measuring range	0 to 20Δ (all direction)
	Measuring step	0.1Δ /0.2Δ /0.5Δ /1.0Δ
Pupillary distance	Adjustment range	48 to 80mm
	Adjustment step	0.5mm/1.0mm
Cross cylinder	Jackson Cross cylinder	±0.25D/±0.50D
	Auto Cross cylinder	±0.25D
Test lens (Aux lens)	Red-Green filter, Polarizing filter (45°/135°, Circular Polarizing filter[1)]), Prism (6Δ /10Δ), Red Maddox (horizontal/vertical), Lens for retinoscopy (+1.5D/ +2.0D), Cross cylinder for measuring presbyopia (±0.50D), Occluding plate, Pinhole, and Cross hairs glass.	
Reference eyeglass wearing distance	12mm, 13.75mm, 16mm, 18mm, 20mm	
Convergence	Near-point distance 40/67cm (Minimum papillary distance at near-point 40cm convergence : 53mm)	
Forehead rest adjustment range	15mm	

1) The combination of the polarizing filter must be one of the following: 45°/135° and 135°/45° or 45°/135° and circular polarizing filter.

POWER SUPPLY UNIT

OS	Windows 10 IoT Enterprise 2019 LTSC(OS Build 17763.2366)

1Dial Controller (In case of combination of KB-50S operation)

Monitor	10.4 color touch panel display
Adjustment angle of monitor unit	113° to 223°

5. GENERAL INFORMATION ON USAGE AND MAINTENANCE

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 forehead rest.
  To understand and follow instructions when undergoing an examination.

INTENDED USER PROFILE

The CV-5000 is an electric instrument for medical use.
Use this instrument under a doctor's guidance.

ENVIRONMENTAL CONDITIONS FOR USE

Temperature : 10°C - 40°C
Humidity : 30% - 90% (non-condensing)
Pressure : 700hPa - 1060hPa

STORAGE, USAGE PERIOD

1. Storage (without wrapping (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 TEMPERATURE MAY RISE ABOVE 40°C OR FALL BELOW 10°C.**

2. Storage (with wrapping (with package))

   Temperature: -20°C - 50°C
   Humidity: 10% - 95%
   Pressure: 700hPa - 1060hPa

3. Transportation (with wrapping (with package))

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

4. When storing the instrument, ensure that the following conditions are met:
   (1) The instrument should not be splashed with water.
   (2) Store the instrument away from the environment 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 slope 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.
5. Usage period
   8 years from delivery providing regular maintenance is performed (according to the self-certification [Topcon data])

ELECTRIC RATING

Power supply voltage : AC100-240V, 50-60Hz
Frequency : 50-60Hz
Power supply input : 150VA

DIMENSIONS AND WEIGHT

Measuring head(Non-arm mounted type)

Dimensions : 309 - 341mm (W) x 114mm (D) x 261mm (H)
Weight : 4kg

Measuring head(Arm-mounted type)

Dimensions : 309 - 341mm (W) x 114mm (D) x 324mm (H)
Weight : 4.6kg

Power supply unit (In case of combination of KB-50S or mouse operation)

Dimensions: 276mm (W) x 197mm (D) x 117mm (H)
Weight: 3.9kg

Power supply unit (In case of combination of PC operation)

Dimensions: 276mm (W) x 197mm (D) x 117mm (H)
Weight: 2.7kg

1Dial Controller (In case of combination of KB-50S operation)

Dimensions: 300mm (W) x 250mm (D) (MAX) x 200mm (H) (MAX)
Weight: 2.3kg

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 CURRENT.
The forehead rest of this instruments is "Type B applied part".

Degree of protection against harmful ingress of water: IPX0

CV-5000 has no protection against ingress of water. (The degree of protection against harmful ingress of water defined in IEC60529 is IPX0.)

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

CV-5000 has no part to be sterilized or 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.

CV-5000 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.

OPERATING PRINCIPLE

There are two or more automated lens banks that operate independently of each other and depending on the lens requirement will align to provide the correct value and/or task.

DISPOSAL

1. Please follow your national or regional law for environmentally safe disposal of electrical and electronic equipment.
2. For the European Union please comply with the requirements of WEEE:
   - Do not dispose this device or any part of it as unsorted municipal waste;
   - Dispose the device at the municipal collection centers or using the available alternative collection schemes and keep a proof of evidence of the disposal; or
   - Contact your dealer or Topcon European Representative (if you are in EU members).

This symbol is applicable for EU member countries only.
To avoid potential negative consequences for 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 TOPCON listed on the back cover.

EU Battery Directive

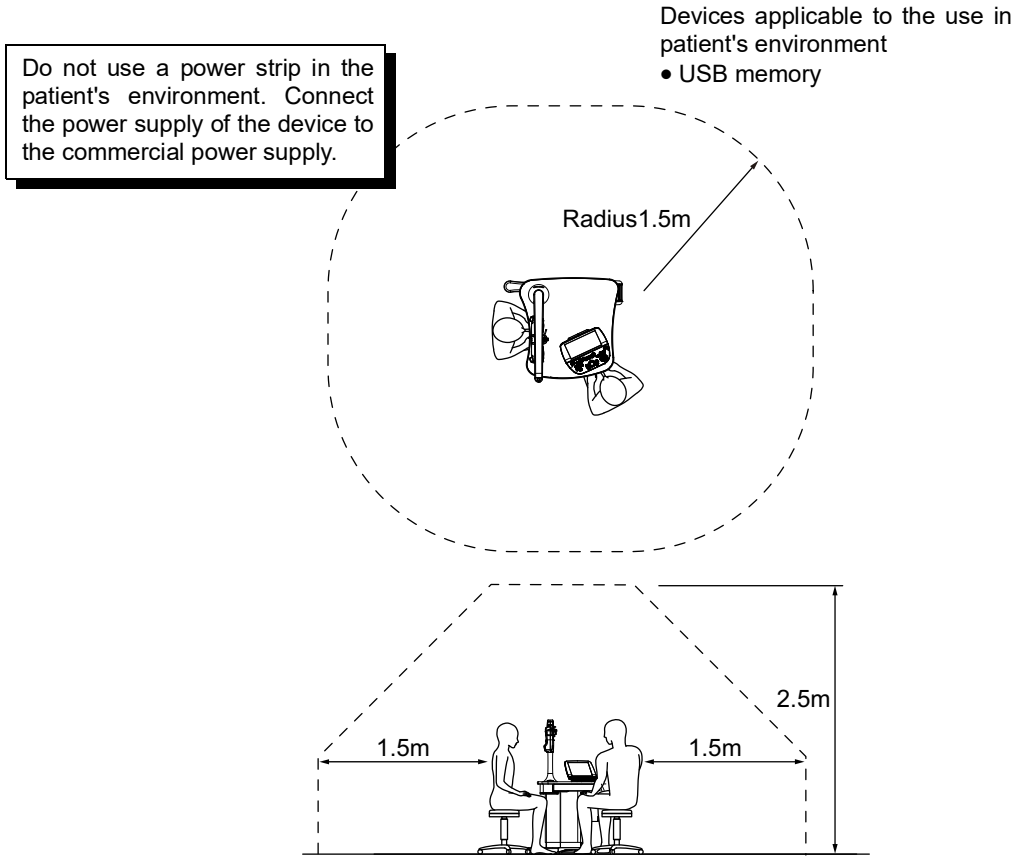
This symbol is applicable for EU members states only.

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 beseriously hazardous to human and the global environment.

PATIENT'S ENVIRONMENT

When the patient or operator may touch the devices (including the connected devices) or when the patient or operator may touch the person contacting the devices (including the connecting devices), the patient's environment is shown below.

In the patient's environment, use the device conforming to IEC60601-1. If you are compelled to use any device not conforming to IEC60601-1, use an insulation transformer.



For the units to be used in the patient's environment, refer to "STANDARD ACCESSORIES" (P. 12) and "OPTIONAL ACCESSORIES" (P. 13).

ELECTROMAGNETIC COMPATIBILITY

This product conforms to the EMC standard IEC 60601-1-2:2014(Ed.4.0).

The expected electromagnetic environment for the whole life cycle is home medical treatment environment.

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 EQUIPMENT.
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	Length (m)	Shield	Ferrite Core
RS-232C & 24V cable	0.5	Yes	Yes
RS-232C & 24V cable	8.0	Yes	Yes
USB & DC cable	5.0	Yes	Yes
DVI cable + DVI/HDMI change cable	13.0 + 0.2	Yes	Yes
AC power cord for POWER SUPPLY UNIT	1.5	No	No
	3.0		
DC cable	1.5	No	Yes
AC power cord for AC adapter (MIRROR CHART, PixelChart)	1.5	No	No
	3.0		
Measuring head	—	—	—
1DIAL CONTROLLER	—	—	—
POWER SUPPLY UNIT	—	—	—
MIRROR CHART	—	—	—
PixelChart	—	—	—
AC adapter	—	—	—
Alignment emitter	—	—	—

Guidance and manufacturer's declaration - electromagnetic emissions		
The CV-5000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CV-5000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The CV-5000 uses RF energy only for its internal function. Therefore, 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 CV-5000 is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The CV-5000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CV-5000 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 humidity 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 Repetition frequency 100kHz	± 2 kV for power supply lines ± 1 kV for input/output lines Repetition frequency 100kHz	Main power quality should be that of a typical commercial or hospital environment.
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) ± 2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and Voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle (with phase angle 0°, 45°, 90°, 135°, 180°,225°, 270° and 315°) 0% U_T for 1 cycle 0° 70% U_T for 25/30 cycles 0° 0% U_T for 250/300 cycles	0% U_T for 0.5 cycle (with phase angle 0°, 45°, 90°, 135°, 180°,225°, 270° and 315°) 0% U_T for 1 cycle 0° 70% U_T for 25/30 cycles 0° 0% U_T for 250/300 cycles	Main power quality should be that of a typical commercial or hospital environment. If the user or the CV-5000 requires continued operation during main power interruptions, it is recommended that the CV-5000 be powered 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 commercial or hospital environment.
NOTE U_T is the a.c. main voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The CV-5000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CV-5000 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80MHz 6 Vrms Within ISM band and amateur radio band of 150kHz to 80MHz 10 V/m 80MHz to 2.7GHz Proximity electromagnetic field from radio communication equipment a)	3 Vrms 150kHz to 80MHz 6 Vrms Within ISM band and amateur radio band of 150kHz to 80MHz 10 V/m 80MHz to 2.7GHz Proximity electromagnetic field from radio communication equipment a)	Portable and mobile RF communications equipment should be used no closer to any part of the CV-5000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the radiation electromagnetic field level in volt/meter (V/m).
NOTE	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

a) The table below shows the proximity electromagnetic field from radio communication equipment.

Test frequency [MHz]	Band [MHz]	Equipment	Modulation	Maximum output (W)	Distance (m)	Immunity test value [V/m]
385	380-390	TETRA 400	Pulse modulation 18Hz	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 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN820 CDMA850 LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800 CDMA1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

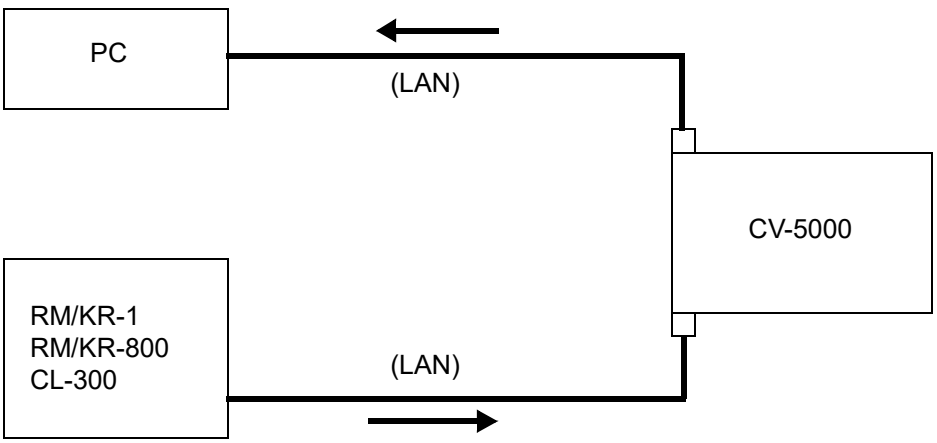
REQUIREMENT TO THE EXTERNAL CONNECTION DEVICES

The accessory devices that are connected to the analog and digital interface must comply with the relevant IEC standard.
(Example: IEC 62368-1 for the data processing devices and IEC60601-1 for the medical devices)
All of configuration must comply with IEC60601-1.
Those who connect the additional device to the signal input/output units should make a medical system and therefore take total responsibility to obey the requirements of IEC60601-1 about their system. If someone has a question, he/she must contact the TOPCON authorized dealer or TOPCON office at the address on the back cover.

IT NETWORK ENVIRONMENT

- CV-5000 can be connected with personal computer (PC), output the measurement data by operating the main unit.
- Refer to the figure below for the characteristics, configuration, technical specification, intended information flow and route when connected with an IT network.
- 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 output data cannot be sent to the devices connected with network.
- When connected with an IT network with which a device other than CV-5000 is connected, the patient, the operator or the third party may suffer unexpected and unacceptable risks. Before using CV-5000, 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 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

Output of measured data, patient information and device information.



Output of measured data, patient information.

SPECIFICATIONS OF PERSONAL COMPUTER (COMMERCIAL PRODUCT) TO BE CONNECTED

⚠ **CAUTION**	• When you connect this instrument on the personal computer connected to a network, ensure security properly in order to prevent the infection with computer virus, leak of information and other troubles. • When connected this instrument on the client server system, it is assumed that the data and database files will be placed on the network. Manage the folders which save these files and the access right to the files correctly. • Manage the personal computer and media (recording media), which save the data obtained and backed up by this instrument, in order to prevent the computer and media from being wrongly used or taken out by the third party.

Please refer to the user manual of the exclusive software.

6. OPERATING AND USAGE METHOD

Usage method

With KB-50S or a commercially available mouse and monitor connected

1. Connect the main unit, POWER SUPPLY UNIT for CV-5000 (BUILT-IN PC TYPE), KB-50S or a commercially available mouse and monitor.
2. Connect the power supply cord to a commercial power source.
3. Adjust the instrument distance between the patient's pupils and the distance between instrument's pupils.
4. Set the main unit in front of the patient's face.
5. Adjust to a horizontal level by rotating the horizontal adjustment knob while observing the level.
6. Turn ON the POWER SUPPLY UNIT for CV-5000 (BUILT-IN PC TYPE).
7. Measure the distance from the corneal vertex to the main unit.
8. Operate the KB-50S or commercially available mouse and use each lens installed within the main unit to conduct a subjective refraction test.
9. After use, turn OFF the POWER SUPPLY UNIT for CV-5000 (BUILT-IN PC TYPE) switch, and remove the instrument from the power source.

With a commercially available PC connected

1. Connect the main unit, POWER SUPPLY UNIT for CV-5000 (PC EXTERNAL TYPE) and commercially available PC with special software installed.
2. Connect the main unit and PC power supply cord to a commercial power source.
3. Turn ON the power switch of the commercially available PC.
4. Turn ON the POWER SUPPLY UNIT for CV-5000 (PC EXTERNAL TYPE).
5. Set the main unit in front of the patient's face.
6. Adjust to a horizontal level by rotating the horizontal adjustment knob while observing the level.
7. Adjust the instrument distance between the patient's pupils and the distance between instrument's pupils.

8 Measure the distance from the corneal vertex to the main unit.

9 Operate the PC and use each lens installed within the main unit to conduct a subjective refraction test.

10 After use, turn OFF the PC power supply switch.

11 After use, turn OFF the POWER SUPPLY UNIT for CV-5000 (PC EXTERNAL TYPE) switch and remove the instrument from the power source.

See "BASIC OPERATIONS" in the "User Manual" for more information.

Please refer to the User Manual.

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

- Model name: CV-5000, KB-50S
- Serial No.: This is described on the rating nameplate on the top surface of 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.

COMPU VISION CV-5000

INSTRUCTION MANUAL

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COMPU VISION

CV-5000

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