

SOLOS

Automatic Lens Analyzer

Instruction For Use

Cod. 42-0001417 SOLOS

CE

Rev. 05 – 2022

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<i>Manufacturer</i>	<i>Distributor</i>
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1

INTRODUCTION

Thank you for purchasing SOLOS. 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 INSTRUCTION MANUAL at hand for future reference.

1.1 INTENDED USE

SOLOS is an instrument intended for use by an optometric/ ophthalmic professional to monitor the visual defects through the measurements of spectacles and single lens optical properties.

1.2 INTENDED USERS

The device must be used by qualified personnel: eye specialists, ophthalmologists, opticians and optometrists.

1.3 PLACE OF USE

Health centers, optician shops, eye hospitals and other eye-care related facilities.

1.4 SERIOUS INCIDENT REPORTING

In case any serious incident occurs in relation to the device, please report it to the manufacturer. If you are in the EU area, please report the incident to the manufacturer, and the competent authority of the Member State.

2 | PRECAUTIONS AND SAFETY

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 INSTRUCTION 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.

2.1 DISPLAY AND SYMBOLS FOR SAFE USE

Table 1: Symbol

Symbols	Standard Reference	Description
		Class I Product compliant with Regulation (EU) 2017/745
	IEC 60417-5032	Alternate current
	ISO 7010-M002	Read the instructions for use before usage
	ISO 7010-W001	Warning Sign <i>Symbol used to alert users to potential hazards</i>
	ISO 7000-3082	Manufacturer
	ISO 7000-2497	Date of Manufacture
	ISO 7000-2493	Catalogue number
Group 0	IEC 62471	Product classifiable as Group 0 (risk exempt) in accordance with IEC 62471

Table 1: Symbols (continue)

Symbols	Standard Reference	Description
	ISO 15223-1	Medical device
	ISO 7000-0632	Temperature limitation <i>Indicates the temperature limits to which the medical device can be safely exposed</i>
	ISO 7000-0224	Humidity limitation <i>Indicates the range of humidity to which the medical device can be safely exposed</i>
	ISO 7000-2621	Atmospheric pressure limitation <i>Indicates the range of atmospheric pressure to which the medical device can be safely exposed</i>
	ISO 7000-0626	Keep dry <i>Indicates a medical device that needs to be protected from moisture</i>
	ISO 7000-0621	Fragile, Handle with care
	ISO 7000 - 0623	This way up <i>Indicates correct upright position of the transport package</i>
		Wifi
	ISO 7000-2498	Serial Number
	IEC 60417-5016	Fuses

Table 1: Symbols (continue)

Symbols	Standard Reference	Description
		This symbol is solely applicable in EU countries. In order to avoid any negative consequences on the environment and possibly also on human health, this instrument must be disposed of according to the current provisions (i) in EU countries in compliance with the WEEE provision (Directive for waste consisting of electrical and electronic devices), or (ii) for all the other countries, in compliance with the local provisions and laws on recycling.

2.2 SAFETY GUIDELINES

- SOLOS device can only be used for the design purposes described in this manual.
- The device must be used in the environmental conditions as specified in this document.
- The least favorable environment is defined as the maximum values of temperature for the unit to be operating in, while the unit is consuming the maximum current. The environmental value is stated as +40 °C.
- The device must be connected to an appropriate power source, otherwise its performance may be reduced.
-  Position the unit so that it is not difficult to disconnect the plug for connection to the main supply.
- Keep this manual at hand and close to the device at all times.
- Turn off the device if it is not going to be used for a long period of time.
- Only use original SOLOS Series accessories and spare parts.
- Do not use the device in the vicinity of highly flammable materials or in areas with an explosion risk.
- Unauthorized software installation in the device is not permitted.

2.3 ELECTRICAL SAFETY

-  To avoid the risk of electric shocks, this equipment must only be connected to supply mains with protective ground.
- The device has an onboard power supply unit installed. For connection to the mains, use only the manufacturer-approved cables provided with the device.
- Before performing maintenance on the device, turn it off and disconnect the power cable.

-  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.
-  Electric shock may cause burns or a possible fire. Turn the power switch OFF and unplug the power cord before replacing the fuses. Replace only with fuses of the correct rating.
-  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.

2.4 LED EMISSION SAFETY

SOLOS has a series of LEDs of various types and powers installed.

The device is classified as group 0 (risk exempt) according to IEC 62471:2006.

2.5 INTERACTIONS WITH EXTERNAL DEVICES

SOLOS complies with the CE marking requirements.

-  Before connecting an external device, such as a computer, printer, monitor, keyboard, mouse or other devices, make sure that they comply with the EN 60950-1 standard and have the CE marking.
-  Connecting electrical equipment to the device actually results in the creation of medical equipment, and may jeopardize safety.
- When SOLOS is installed in rooms for medical use, the PC and the connected printer must be powered using an IEC 60601-1 compliant insulating transformer.
- If SOLOS is installed in rooms for medical use without a computer, it is not necessary to use an insulating transformer.
- Do not use mobile phones or other devices not compliant with the requirements of class B EMC in the vicinity of SOLOS.
-  Every external device that has to be connected to SOLOS must have a connection cable (USB or LAN) with a maximum length of 3 m.

The purpose of SOLOS connection to an IT network is data export and remote technical assistance.

The SOLOS USB port must be connected to printer with USB or LAN interface. Ask Topcon technical assistance for printer driver installation.

The SOLOS can be connected to a Local Area Network (LAN) through the LAN connector. The network must have Ethernet protocol (IEEE 802.3). Ask Topcon technical assistance and the system administrator for SOLOS and network settings.

Connection of SOLOS to a computer network that includes other equipment could result in previously unidentified RISKS; identify, analyze, and control such RISKS (refer to IEC 60601-1:2005).

Subsequent changes to a computer network could introduce new RISKS and require new analysis.

Changes to the computer network include:

- changes in computer or data network configuration;
- connection of additional items to computer network;
- disconnecting items from computer network;
- update of equipment connected to computer network;
- upgrade of equipment connected to computer network.

The term computer network used here corresponds to the term network/data coupling in IEC 60601-1:2005.

2.6 TRANSPORT AND PACKAGING

- The device must be transported and stored in its original packaging.
- For the storage and transport conditions please refer to the specifications contained in this document.
- Keep the original packaging with care in case the device needs to be transported again.

2.7 CLEANING

- Regularly clean the device removing dust using a soft cloth. In the case of more persistent surface dirt, use a soft cloth soaked with water or alcohol (70% max).
-  Be careful not to wet the device and clean it only as indicated to prevent damaging it. Never use solvents or other abrasive agents.

3 | INSTALLATION

3.1 UNPACKING AND PACKING OF THE SYSTEM

⚠️ Keep the original packaging for future use. The system must always be handled/-shipped in its original packaging, which is specifically designed to protect it against damages. Before installing the system, read [chapter 2](#) in this manual.

The steps are illustrated in the following pictures:



(1)



(2)



(3)



(4)



(5)

4

ACCESSORIES

Check Calibration Tool



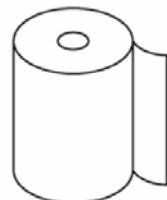
Power cable (country specific)



Instruction for Use



Printer Paper



Cartridge



5 | TECHNICAL SPECIFICATIONS

General information

Lens analysis	Focimeter, Lens Mapper, Spectrometer
Operating mode	Total automatic
Light Source	Green Led 535 nm ± 10 nm
Acquisition type	Single Lens, Spectacles
Lens type	Monofocal, Bifocal, Progressive and Degressive lens
Lens Detection	Automatic
Marking	Single Lens, Spectacles
Spectrometer	Transmittance and Chromaticity analysis

Measurement range

Sphere power	from -20 D to 20 D (step 0.01, 0.0625, 0.125, 0.25 D)
Cylinder power	from -10 D to 10 D (step 0.01, 0.0625, 0.125, 0.25 D)
Cylinder axis	from 0° to 180° (step 1°)
Addition power	from -4 D to 4 D (step 0.01, 0.0625, 0.125, 0.25 D)
Prism power	from 0 D to 20 D (step 0.01, 0.0625, 0.125, 0.25 D)
Prism base	from 0° to 360° (step 1°)
PD Measurement	Mono/Bino
Spectrometer range	from 315 nm to 800 nm

Electrical specifications

Power supply	AC 100 - 240 V — 50 / 60 Hz
Power input	50 VA
Fuse	2.5 A L 250 V (dimensions 20x5 mm)

Environmental conditions	Operation	Storage	Transport
Temperature	from 10 °C to 40 °C	from -20 °C to 70 °C	from -20 °C to 70 °C
Relative humidity	from 8% to 75% (no condensate)	from 8% to 75% (no condensate)	from 8% to 75% (no condensate)
Atmospheric pressure	from 700 hPa to 1060 hPa	from 700 hPa to 1060 hPa	from 700 hPa to 1060 hPa

Onboard components

Operating system	Linux Custom Image
Processor	Icore MX8 Mini
RAM	1 GB
Hard Disk	4 GB eMMC
External connections	2 USB, 1 Ethernet, 1 RS-232
Connectivity	802.11 b/g/n Wifi, LAN

Mechanical specifications

Width	245 mm
Height	437 mm
Depth	354 mm
Net Weight	11 kg

6 MAINTENANCE

No special scheduled maintenance is necessary for the product.

6.1 CHANGING THE FUSES OF SOLOS DEVICE

 Make sure that the power switch of the main body is off and the power cable is unplugged.

 It is mandatory to use fuses only with the indicated characteristics.

 The use of undersized fuses can cause the interruption of power to the device during normal working conditions. In this case there is no risk to the user, nor for the patient, but the device turns off at inopportune moments, and this can cause data loss.

 The use of oversized fuses can lead to damage to the internal electronics of the device due to current overload for non-interruption by fuses. In this case you do not identify risks to the patient, but on the user or damage to the device and then stop working and possible data loss.

Remove the blown fuse from its seat and replace it with an identical as indicated in technical specifications.

 Make sure that the power switch of the main body is off and the power cable is unplugged.

The procedure to change the fuse is the following (see [figure 1](#)):

- 1 open the fuse box cover using a screwdriver;
- 2 take out the fuse box (use a screwdriver to release it);
- 3 substitute the fuses and make sure they stay in the correct position;
- 4 push the fuse box carefully back into position;
- 5 close the black cover again and check if correct voltage is displayed in the opening.

Table 3: Fuse Types

Power supply voltage	Fuse type	Fuse value
220 - 240 V	20x5 mm	T 2.5 A L antisurge



(6)



(7)

Figure 1: Fuse changing procedure

7 | OPERATING AND USAGE METHOD



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