

OST™



100C • 100 • 150 • 250C • 250 • 250H • 350



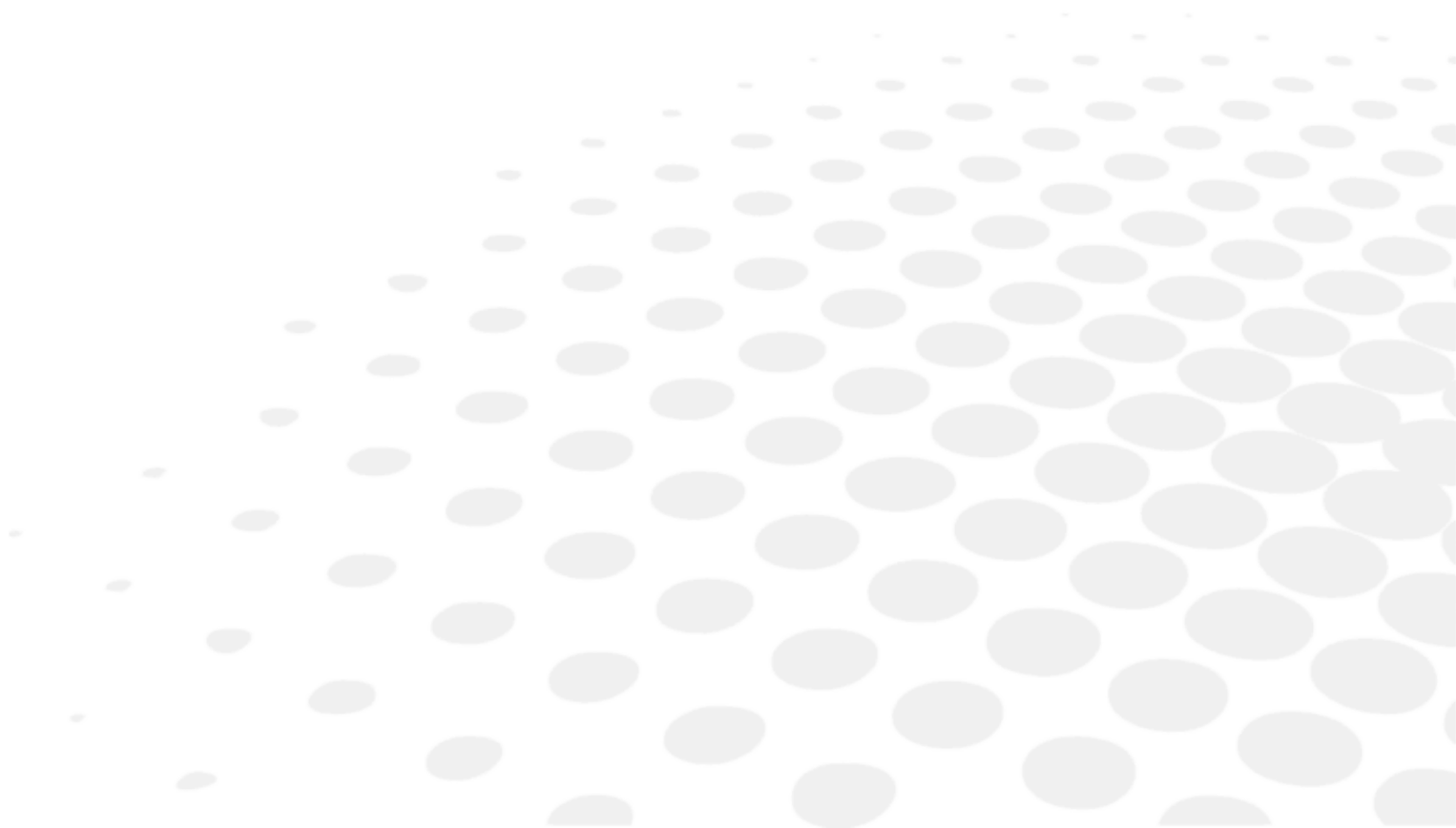
USER MANUAL


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I. INTRODUCTION



 The latest version of this user manual is available on a web space.
To access other available languages, please scan the QR code available at the end of this user manual > QR Code Chapter (p.39).

For a safer, more effective use, follow the instructions outlined in this manual.

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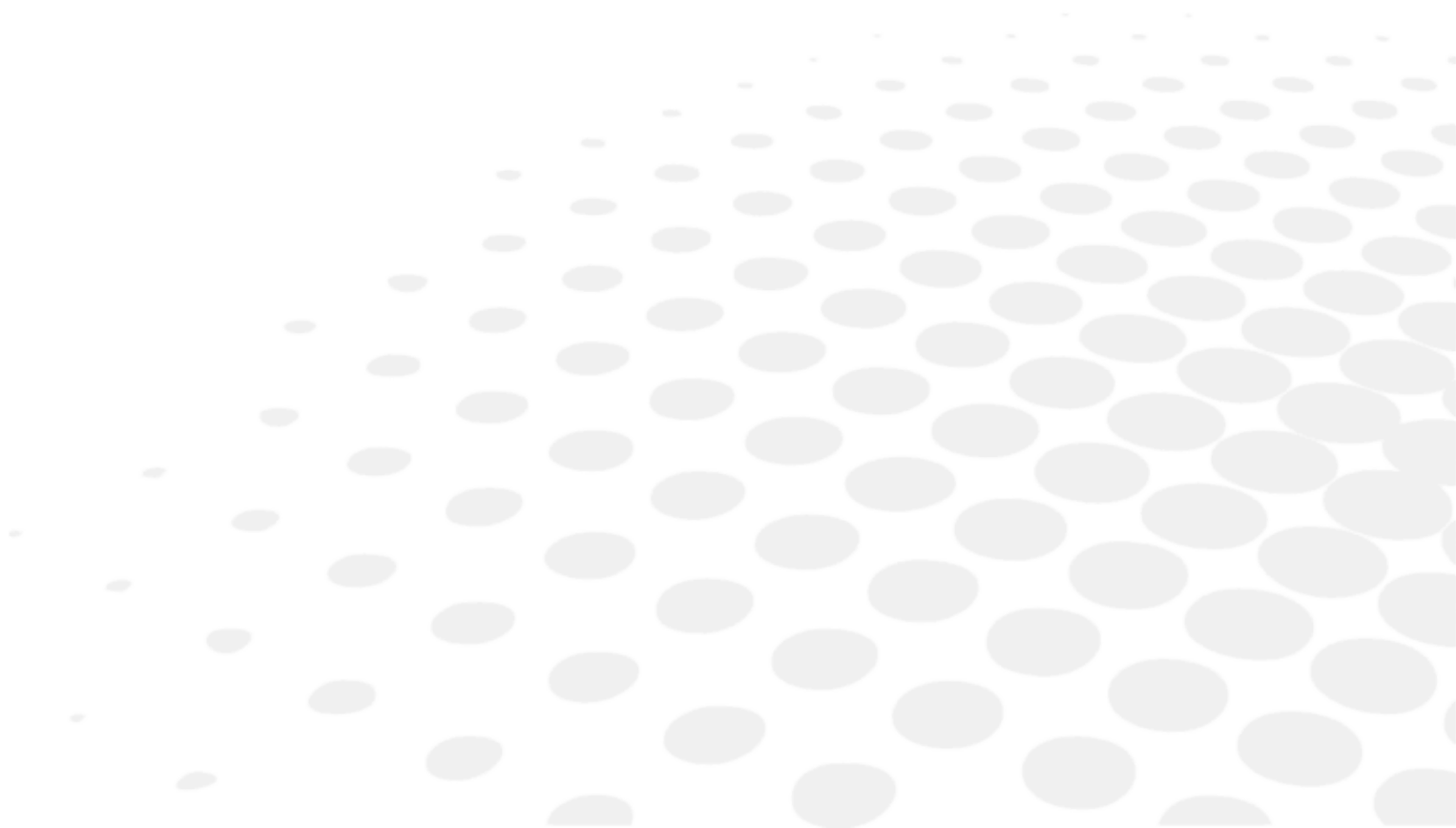
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II. DIRECTION FOR USE



1. Intended use

a. Intended purpose

Refraction units are intended for use by eye care professionals during ophthalmic examinations in conjunction with ophthalmic instruments (phoropter, refractometer, keratometer, slit lamp).

b. Indications for use

These refraction units provide several patient and instruments adjustments for the examination to be performed ergonomically.

2. Expected clinical benefit

These refraction units provide support and position control to ophthalmic instruments by eye care professionals and patients during ophthalmic examination or treatment.

3. Contraindications

There are no known contraindications.

These units are designed to accommodate patients up to 150 kg.

4. Side effects

There are no known side-effects.

Please report any serious incident that occurred in relation to the device to essilor-instruments-vigilance@essilor.com and to the local competent authority for medical devices.

5. Intended population

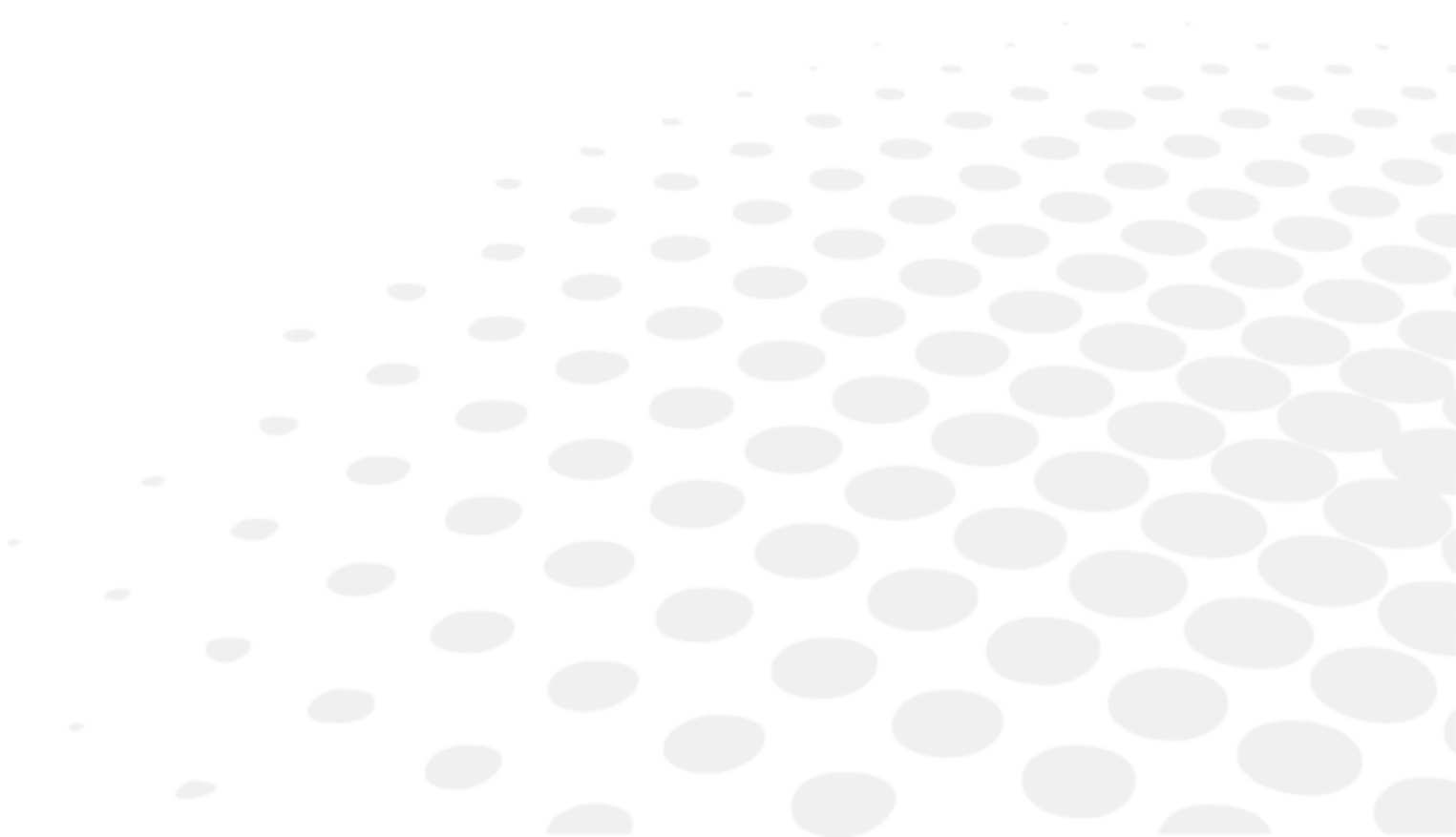
These refraction units are adapted to patients that can be seated on the chair, according to the units' maximum patient weight capacity.

The refraction units OST 250 H and OST 350 are designed to accommodate wheelchair patients.




6. Intended users

These devices are intended for eye care professionals use only.

III. CAUTIONS AND WARNINGS



1. Definitions

SYMBOL	DESCRIPTION
	Caution: a hazardous situation that, if not avoided, could result in minor or moderate injury.
	Warning: a hazardous situation that, if not avoided, could result in death or serious injury.
	Important and/or useful additional information to learn relating to the text in this manual.

2. Product safety

- Please do not use the refraction unit other than explained in this manual.
- Please use the refraction unit at 220-230 VAC, 50/60 Hz (the tolerance range for these values has been determined as 10%). Otherwise, severe damage to the unit and the user may occur.

a. Precautions for use



- Never attempt to dismantle the instrument. This may cause a malfunction or fire.
- If the instrument does not work properly, do not touch the inside. Disconnect the plug from the outlet and consult your dealer.
- If liquid spills onto the instrument or foreign objects get inside, disconnect the plug from the outlet and consult your dealer.
- If any abnormalities occur (noise, smoke, etc.), disconnect the plug from the outlet and consult your dealer. Continued use may result in fire or personal injury.
- The covers are fragile, handling them while wearing jewelry or having long nails can lead to scratches.
- The white covers may yellow over time when exposed to ultraviolet light for an extended period.
- Do not set up the refraction unit in places where it may be leaking water or on a wet ground.
- After the installation, do not try to move the instrument table. Do not pull the console and column stand, otherwise damage to the unit may occur.
- Technical installation and set-up of the instrument should be made by authorized service personnel. Any interventions made to the refraction unit other than made by authorized service personnel shall put the unit out of warranty.
- During examinations, the unit's movements must be controlled under constant supervision by the healthcare professional. The healthcare professional must ensure that there are no obstructions during movement that could cause collisions leading to injury or equipment damage. The patient should be warned by the healthcare professional that the patient's hands should not come into contact with the table when the table is moved to the zero position.
- The healthcare professional must ensure that the space between the patient in the chair and the table of the unit to be moved is wide enough to prevent contact between the patient and the table. The healthcare professional must lower the patient chair and/or increase the table height before starting the examination.
- To handle the manual arm, always release the black handle **BEFORE** rotating the arm and then lock it to keep it in place.



- Do not try to repair or modify the instrument.
- Never try to perform any repairs inside the instrument yourself. In the event of malfunctions, consult your dealer.
- Children under the age of 6 should not use refraction unit without their parents.
- The refraction unit is not suited for use in air/flammable anesthetic gas, oxygen or nitrous oxide/flammable anesthetic gas atmosphere.
- This product should be used in an environment free of flammable anesthetic gas and other flammable gases.

b. Power source



- Do not use multi-socket power strips, adapters or extension cords to connect the instrument to the mains.
- Make sure the power cord is fully inserted into both the outlet and the instrument. Failure to insert it properly may result in a fire or electric shock.
- Clean the power cord regularly to avoid dust build up. If the cord is dirty, it may cause a malfunction or fire.
- If the power cord becomes hot after using the instrument, check that it is not dirty. If it is not, replace the power cord with a new one. Continued use may cause malfunction or personal injury.
- Use the instrument with the appropriate supply voltage. Continued use with a supply voltage greater than the rated power may cause malfunction or fire.
- Hold the plug when you insert or remove the power cord.
- Use only the power cord provided with the device.



- To avoid the risk of electric shock, this device must only be connected to a supply mains with an earth connection.
- Take care to use the power cord grounding cable when connecting to the ground terminal.
- Do not damage the power cord (by bending it, pulling it or placing heavy objects on top of it, etc.). Do not modify it either. If the cord is damaged (loose contact, damaged sheath, etc.), replace it with a new cord. Continued use may result in an electric shock or fire.
- Do not touch the power plug with wet hands. This may cause an electric shock.
- If you do not use the instrument for an extended period, disconnect the power cord from the outlet.

c. Electromagnetic compatibility

This device generates, uses and can radiate radio frequency (RF) energy. If this equipment is not used as specified in this manual, it may cause electromagnetic interference.

This device has been tested in accordance with the EN 60601-1-2 Standard for Medical Products and its compliance with acceptable limits has been determined. These limits indicate that the device provides acceptable protection against electromagnetic interference (EMC) when used as directed in the manual.

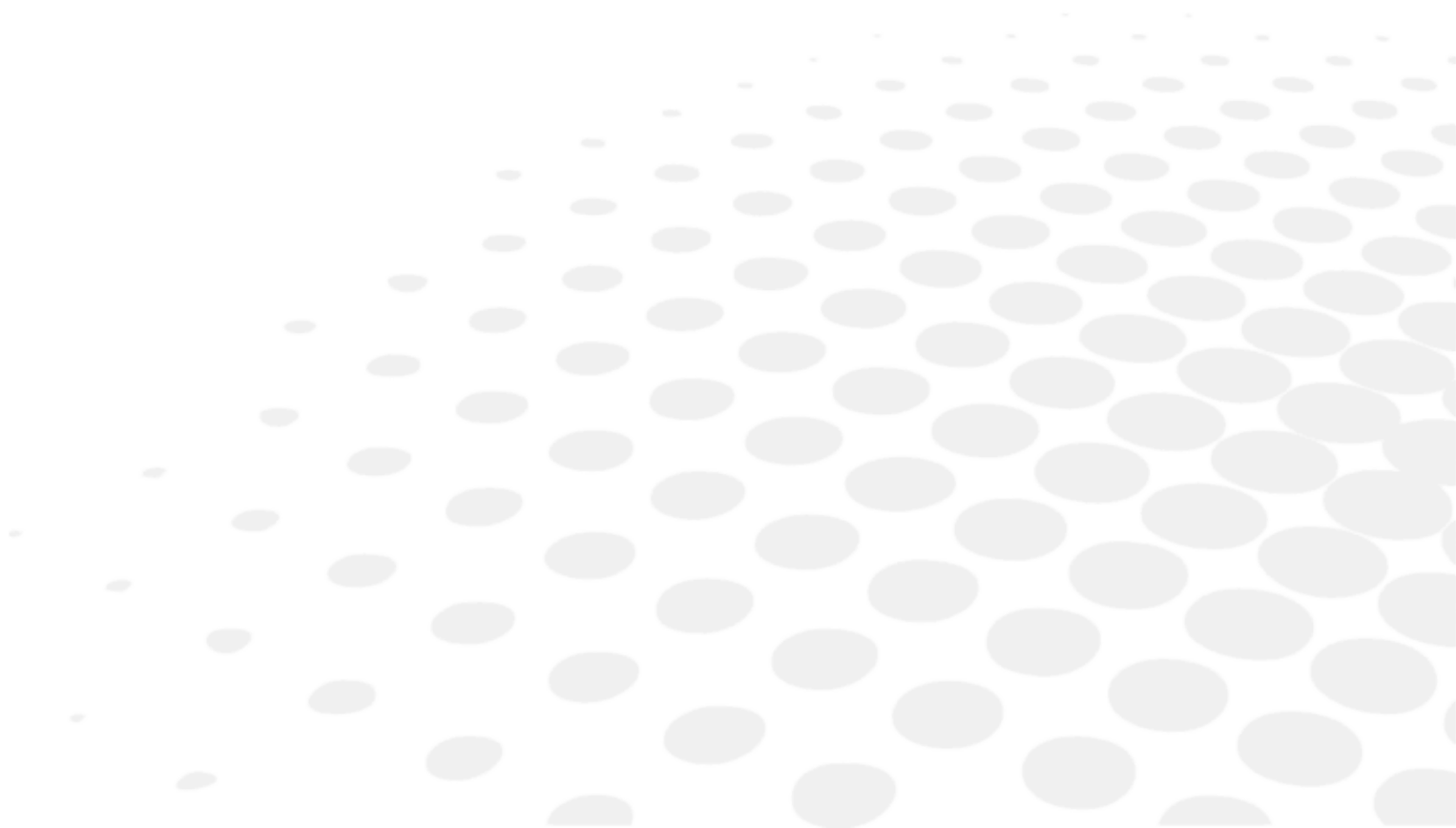
This device has been designed and manufactured in accordance with the requirements of the EN 60601-1-2 standard. It may be affected by portable and mobile RF communications devices. It should therefore not be stored with other equipment.

For more information on this device and EMC, see part IX.2 of this manual.

d. Others

- The metal chassis of the refraction unit is protectively grounded. However, the reliability of the grounding depends on the electrical supply of the place where the unit is used. The unit should be used by plugging into an earthed socket.
- Please unplug the main power cable when working place lamp and socket power inlets on refraction unit are being plugged on and off.
- Check the refraction unit and accessories carefully and be sure they have not been damaged during dispatch. About the refraction unit and/or accessories that are damaged during dispatch, please get in touch with your dealer.
- Prior to first use of the refraction unit, please carefully read and understand the user manual thoroughly.
- Please keep the user manual at a distance where the user can reach quickly.

IV. PRODUCT DESCRIPTION



1. Product plan with description

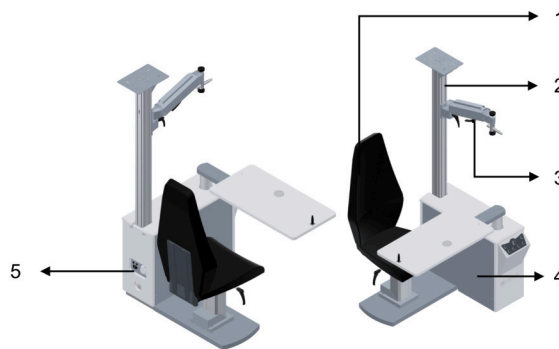
a. OST 100 C



With:

1. **Chair:** Chair where the patient is seated during examination.
2. **Stand column:** Column where the head lamp, chart projector, manual phoptor arm and other instruments are installed.
3. **Main body:** Main body of the refraction unit.
4. **Plug outlet:** Plug outlet for an extra instrument 220-230 VAC, 50/60 Hz.

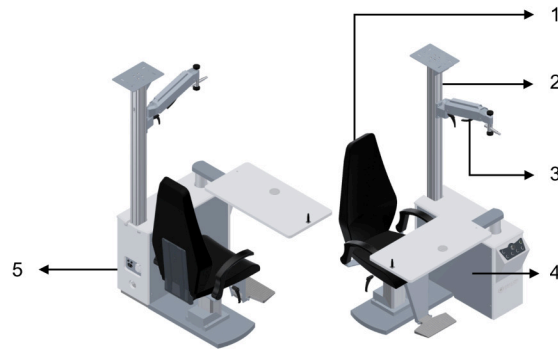
b. OST 100



With:

1. **Chair:** Chair where the patient is seated during examination.
2. **Stand column:** Column where the head lamp, chart projector, manual phoptor arm and other instruments are installed.
3. **Manual phoptor arm:** Arm where the phoptor is installed.
4. **Main body:** Main body of the refraction unit.
5. **Plug outlet:** Plug outlet for an extra instrument 220-230 VAC, 50/60 Hz.

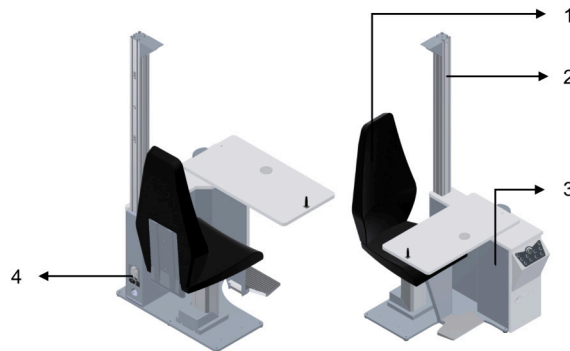
c. OST 150



With:

1. **Chair:** Chair where the patient is seated during examination.
2. **Stand column:** Column where the head lamp, chart projector, manual phoropter arm and other instruments are installed.
3. **Manual phoropter arm:** Arm where the phoropter is installed.
4. **Main body:** Main body of the refraction unit.
5. **Plug outlet:** Plug outlet for an extra instrument 220-230 VAC, 50/60 Hz.

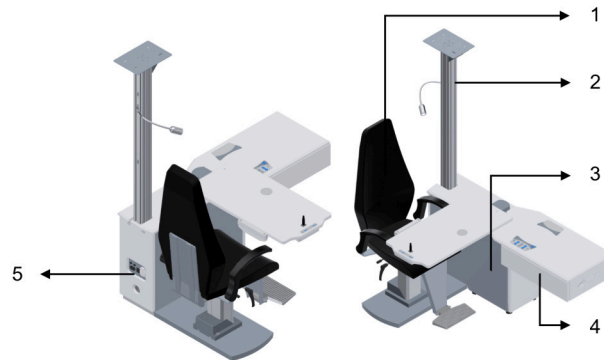
d. OST 250 C



With:

1. **Chair:** Chair where the patient is seated during examination.
2. **Stand column:** Column where the head lamp, chart projector, manual phoropter arm and other instruments are installed.
3. **Main body:** Main body of the refraction unit.
4. **Plug outlet:** Plug outlet for an extra instrument 220-230 VAC, 50/60 Hz.

e. OST 250



With:

1. **Chair:** Chair where the patient is seated during examination.
2. **Stand column:** Column where the head lamp, chart projector, manual phoptopter arm and other instruments are installed.
3. **Main body:** Main body of the refraction unit.
4. **Drawer:** Drawer to put the trial lens set or accessories in.
5. **Plug outlet:** Plug outlet for an extra instrument 220-230 VAC, 50/60 Hz.

f. OST 250 H



With:

1. **Chair:** Chair where the patient is seated during examination.
2. **Stand column:** Column where the head lamp, chart projector, manual phoptopter arm and other instruments are installed.
3. **Main body:** Main body of the refraction unit.
4. **Drawer:** Drawer to store the trial lens set or accessories.
5. **Plug outlet:** Plug outlet for an extra instrument 220-230 VAC, 50/60 Hz.

g. OST 350



With:

1. **Chair:** Chair where the patient is seated during examination.
2. **Stand column:** Column where the head lamp, chart projector, manual photopter arm and other instruments are installed.
3. **Triple table:** Triple table that rotates, which can carry three ophthalmology instruments together.
4. **Drawer:** Drawer to store the trial lens set or accessories in.
5. **Main body:** Main body of the refraction unit.
6. **Plug outlet:** Plug outlet for an extra instrument 220-230 VAC, 50/60 Hz.

h. Standard features

Standard features	OST 100 C	OST 100	OST 150	OST 250 C	OST 250	OST 250 H	OST 350
Fixed chair backrest	✓	✓	✓	✓	NA	NA	NA
Fully reclinable chair backrest	NA	NA	NA	NA	✓	✓	✓
360° chair rotation	✓	✓	✓	NA	✓	✓	✓
Height-Adjustable motorized chair	✓	✓	✓	✓	✓	✓	✓
Separated baseplate	✓	NA	NA	NA	NA	NA	NA
Suitable for wheelchair	NA	NA	NA	NA	NA	✓	✓
5 W LED head lamp	✓	✓	✓	✓	✓	✓	✓
Flexible near vision lamp	Optional	Optional	Optional	Optional	✓	✓	✓
Chair footrest	✓	Optional	✓	✓	✓	✓	✓
Chair armrest	Optional	Optional	✓	Optional	✓	✓	✓
Manual arm	Optional	✓	✓	Optional	Optional	Optional	Optional
Sliding table	NA	✓	✓	✓	✓	✓	Rotating
Mini keypad on sliding table	NA	NA	NA	NA	✓	✓	NA
Mini keypad on rotating table	NA	NA	NA	NA	NA	NA	✓
Height adjustable electrical table	NA	NA	NA	✓	✓	✓	✓
Chart projector plate on profile	Optional	✓	✓	Optional	✓	✓	Optional
Projector arm plate	Optional	Optional	Optional	Optional	Optional	Optional	✓
Column accessory holder	Optional	Optional	Optional	Optional	Optional	✓	✓

Mechanical brake	NA	✓	✓	NA	✓	NA	NA
Electromagnetic brake	NA	NA	NA	✓	NA	✓	✓
Foot pedal for chair lift	NA	NA	NA	Optional	Optional	Optional	✓
Common chinrest	NA	Optional	Optional	Optional	✓	✓	Optional
Single drawer	NA	NA	NA	NA	✓	✓	✓

2. List of accessories

a. Standard

- User manual

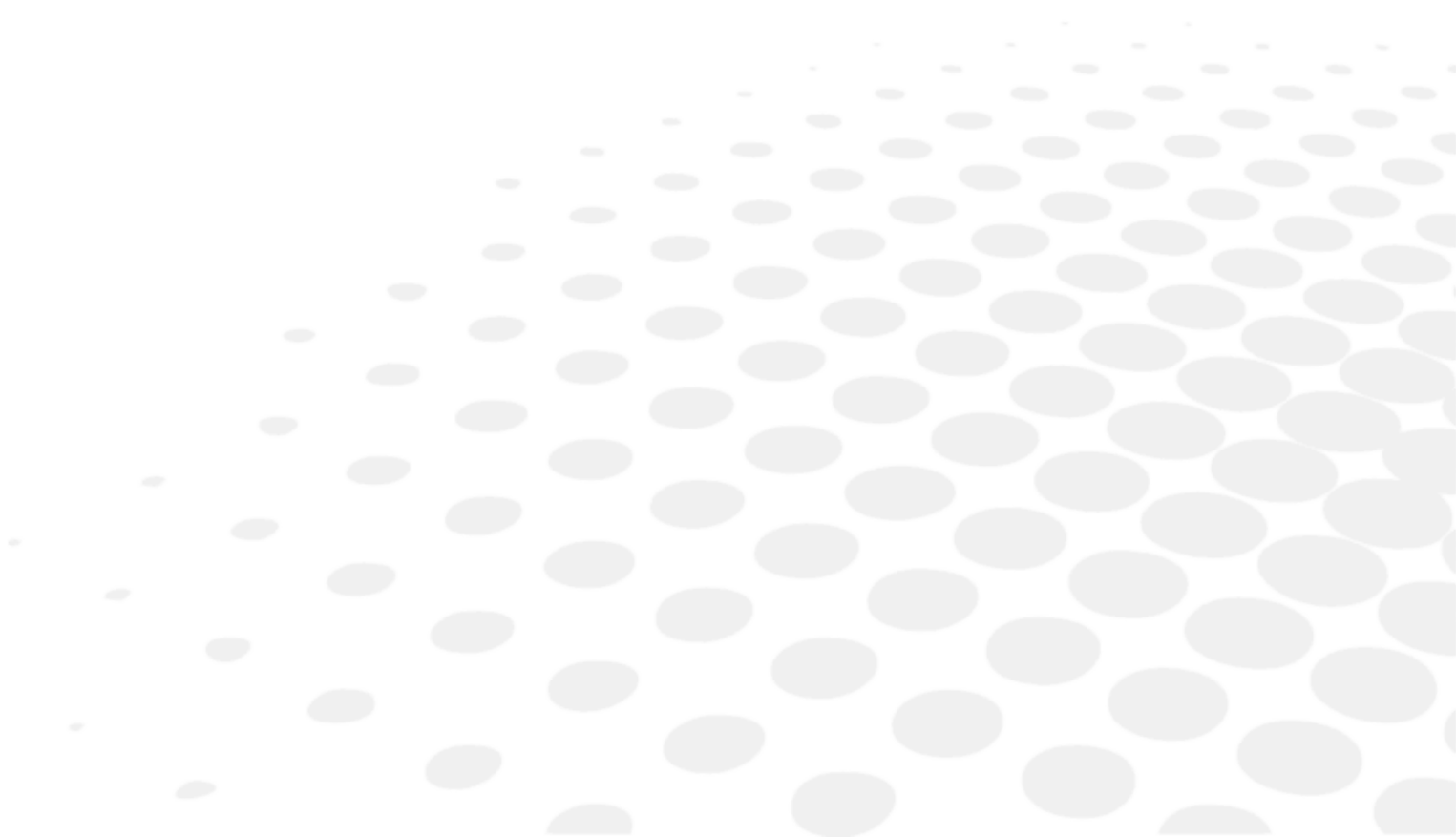
b. Optional

Optional accessories	References	OST 100 C	OST 100	OST 150	OST 250 C	OST 250	OST 250 H	OST 350
Manual arm	OST012	✓	✓	✓	✓	✓	✓	✓
Spacer	OST046	✓	✓	✓	✓	✓	✓	✓
OST Column accessory holder	OST047	✓	✓	✓	✓	✓	✓	✓
Monitor support arm	OST048	✓	✓	✓	✓	✓	✓	✓
Chair footrest	OST109	✓	✓	✓	✓	✓	✓	✓
Chair armrest	OST110	✓	✓	✓	✓	✓	✓	✓
Flexible near vision lamp	OST127	✓	✓	✓	✓	NA	NA	NA
Projector arm plate	OST202	✓	✓	✓	✓	✓	✓	✓
Flexible near vision lamp	OST208	NA	NA	NA	NA	✓	✓	✓
Common chinrest	OST210	NA	✓	✓	✓	✓	✓	NA
Double column	OST254	NA	NA	NA	NA	✓	✓	NA
Chair foot pedal	OST371	NA	NA	NA	NA	✓	✓	✓
Double drawer with shelf	OST376	✓	✓	✓	✓	✓	✓	✓
Motorized arm	OST380	✓	NA	NA	NA	✓	✓	✓
Mini motorized arm	OST380C	NA	NA	NA	✓	NA	NA	NA
Triple drawer mobile	OST381	✓	✓	✓	✓	✓	✓	✓
Double drawer mobile	OST382	✓	✓	✓	✓	✓	✓	✓

c. Detachable parts

- Power cable (2.5 m)

V. OPERATING INFORMATION





- This instrument must be installed by authorized service personnel. To install the instrument or to change its connection, please contact your Essilor dealer.
- Respect the precautions below:
 - Do not install the instrument in a location:
 - Where dust or dirt accumulates,
 - Directly exposed to sun light,
 - Oxygen rich,
 - Displaying extreme temperatures and humidity levels,
 - Likely to undergo strong oscillations or sudden shocks.
- Do not use the instrument with flammable anaesthetics or in conjunction with flammable agents

1. Installation of the device

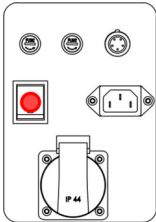
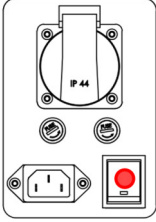
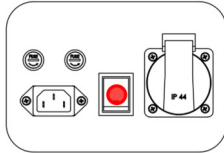


Installation manuals can be provided on request to your local Essilor technical team.



Essilor declines all responsibility in the event of incorrect installation of the product by anyone other than a authorized service personnel trained by Essilor.

2. Turning [On/Off] the device

OST 100 C	OST 250 C	OST 100 / OST 150 / OST250 / OST250 H / OST 350
		



Make sure that you plug in the device.

[On/Off] operation is performed by pressing the power button indicated in red above.

3. Connection to other instruments

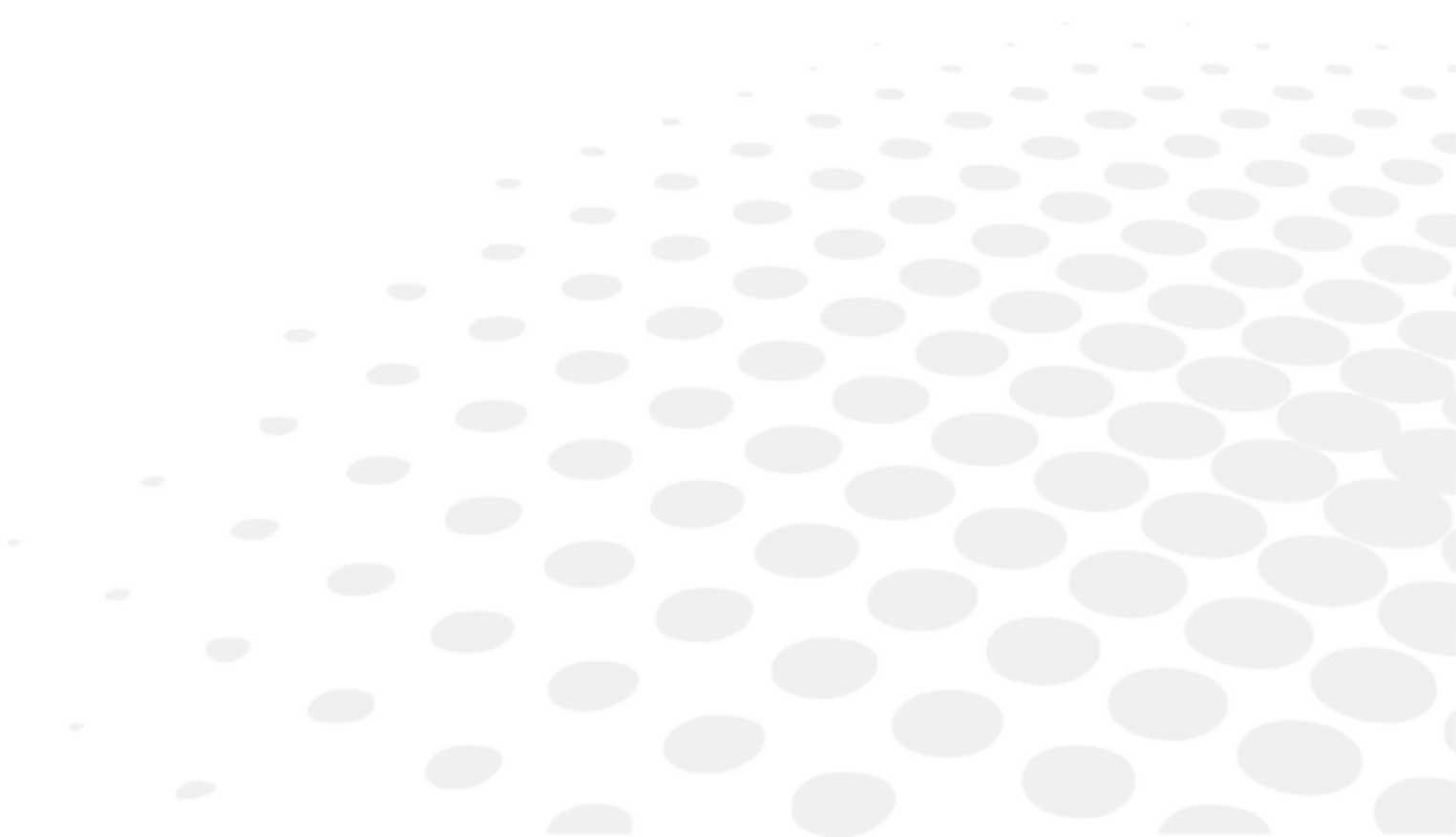
The OST can be connected to accessories, such as:

- Manual arm
- Spacer
- Column accessory holder
- Monitor support arm
- Chair footrest
- Chair armrest
- Flexible near vision lamp
- Projector arm plate
- Common chinrest
- Double column
- Chair foot pedal
- Double drawer with shelf
- Motorized arm
- Mini motorized arm






- Triple drawer mobile
- Double drawer mobile

For the other instruments, technical installation and set-up must be made by authorized service personnel.
For details, please ask your local dealer.








VI. USE OF THE DEVICE













1. OST 100C

Keypad	Control	Description
		Power On-Off control
		Chair Up-Down control
		(Optional) motorized arm control
		Near vision lamp control

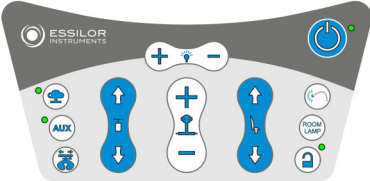










2. OST 100, OST 150



Keypad	Control	Description
		Power On-Off control
		Lamp light control
		Projector power control
		Auxiliary power control
		Chair Up-Down control
		Slit lamp light control

3. OST 250 C

Keypad	Control	Description
		Power On-Off control
		Lamp light control
		Projector power control
		Auxiliary power control
		Chair Up-Down control
		Slit lamp light control
		Electro magnet control
		Table Up-Down control
		(Optional) Motorized arm control

4. OST 250, OST 250 H, OST 350

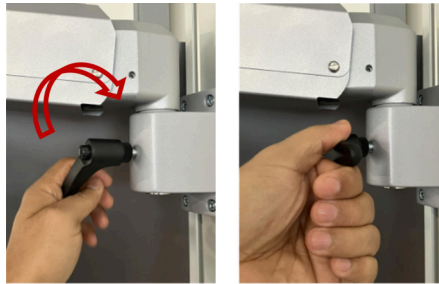
Keypad	Control	Description	
		Power On-Off control	
		Dimmable head lamp control	
		Projector power control	
		Auxiliary power control	
		(Optional) Motorized arm control	
		Near vision lamp control	
			Room lamp control
			Electro magnet control
			Chair Up-Down control

		Table Up-Down control
		Slit lamp light control



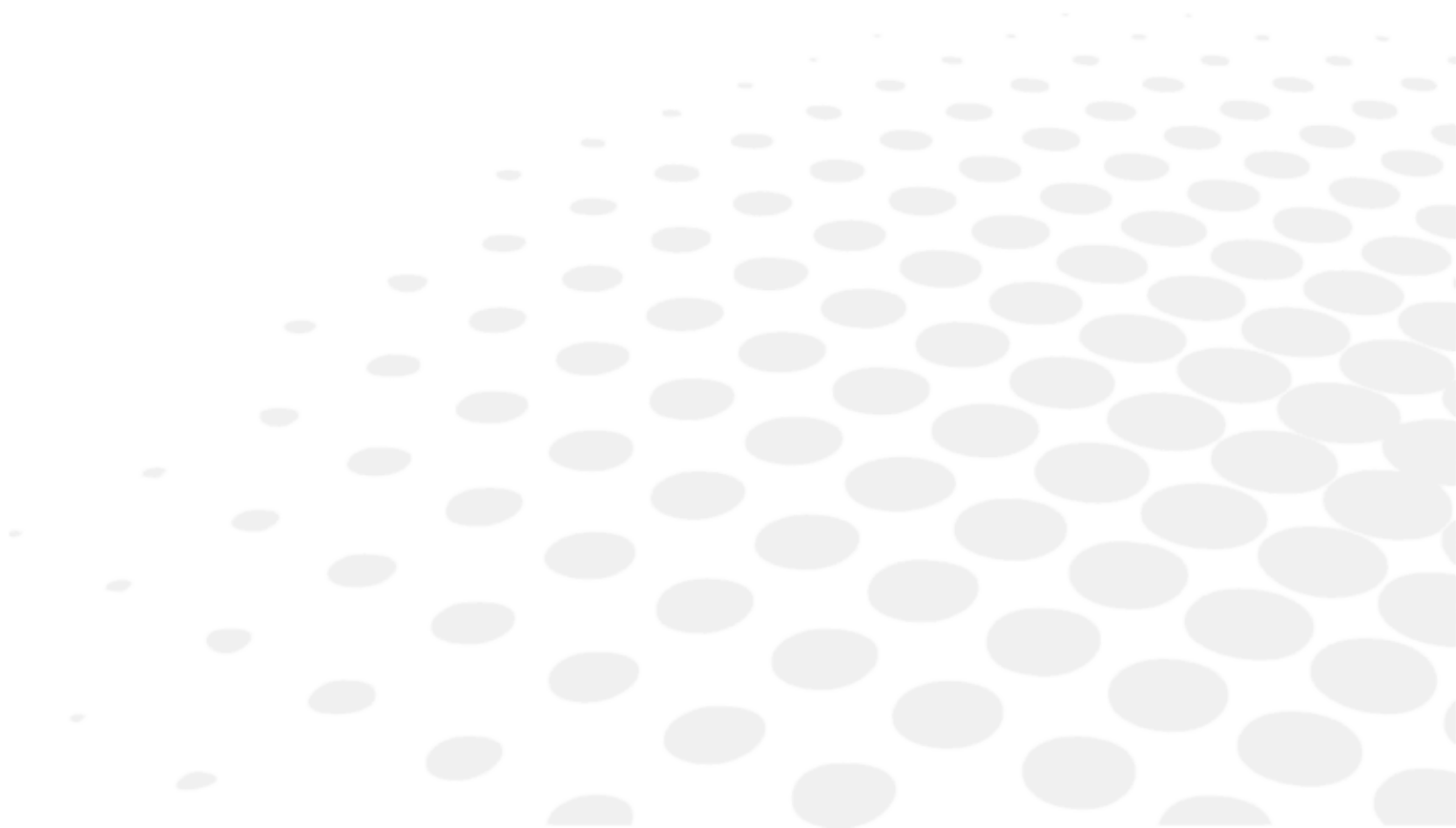
Reminder & Best practices

To handle the manual arm, always release the black handle BEFORE rotating the arm and then lock it to keep it in place.



The handle is screwed into the arm holder. When locked, the threaded end of the screw blocks the arm rotation.
If the handle is not released before the arm is rotated, the screw will wear out.

VII. MAINTENANCE





- In order to ensure safety and the performance of the instrument, all maintenance operations, unless otherwise specified in this manual, must be carried out by qualified maintenance technicians.
- If you find that this device is dirty, you can clean it as often as you want (see after the specific cleaning methods).

1. Storage and handling condition



Respect the operating, storage and transport conditions noted below.

Avoid condensation conditions.

	Temperature	Humidity	Atmospheric pressure
Use	[+20°C; +30°C]	[30 %; 70%]	[0.49 atm; 1 atm]
Storage	[0°C; +40°C]	[30 %; 70%]	[0.49 atm; 1 atm]
Transport	[-10°C; +50°C]	[30 %; 70%]	[0.49 atm; 1 atm]

2. Cleaning instructions



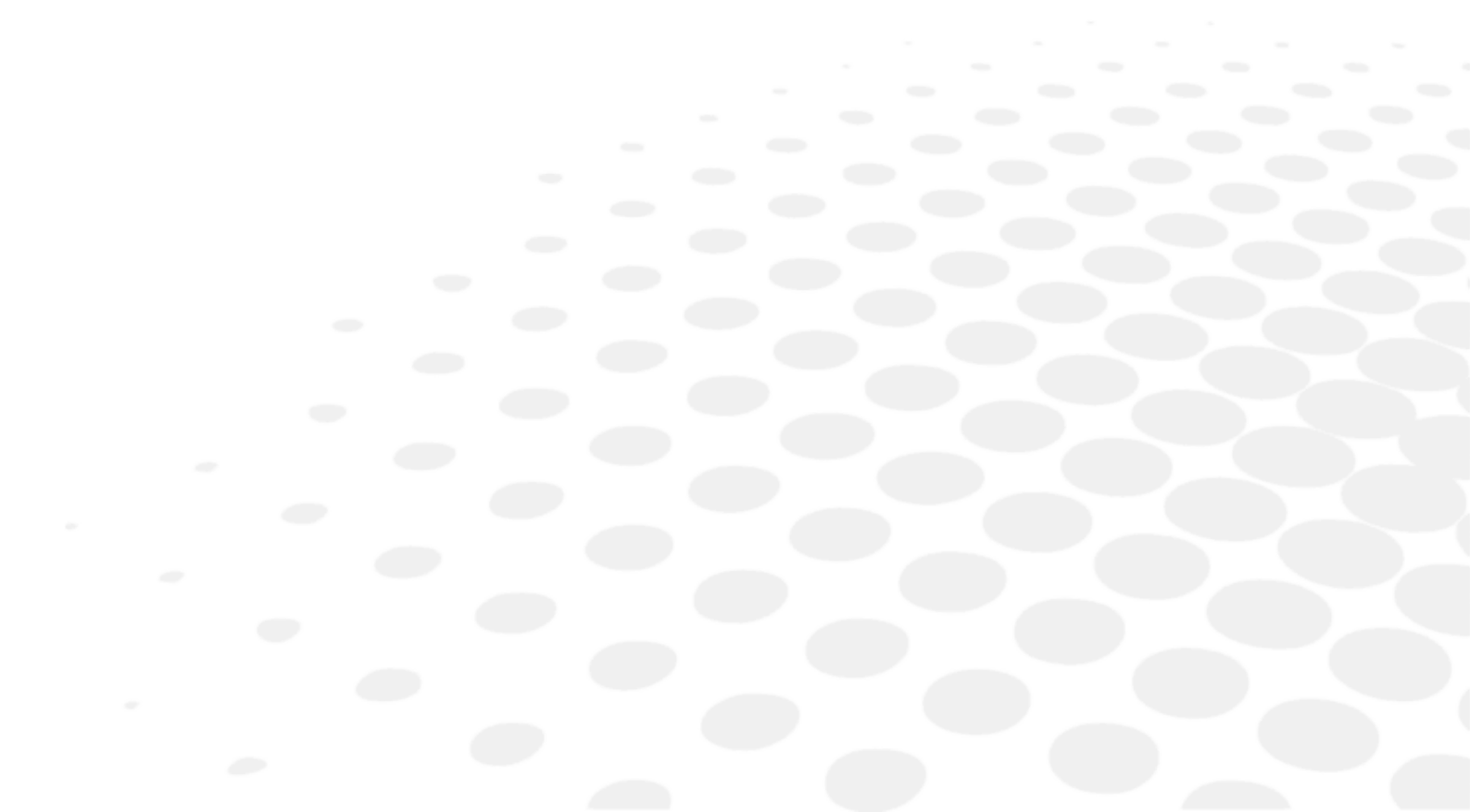
Never use alcohol-xylo and similar liquid cleaner for the cleaning of the refraction unit chair and wooden part. These cleaning materials may cause damage on the plastic and wooden surfaces.



To avoid any incident, unplug the instrument before cleaning.

- Prior to cleaning, please be sure to turn off the device by pressing the power button and to unplug the power cable.
- You can clean both the wooden and metal parts of the refraction unit with a clean damp cloth.

VIII. ERROR AND TROUBLESHOOTING



If a problem is detected, refer to the table below in order to take the appropriate measures.

Symptoms	Causes and Measurements
Refraction unit does not work. Power keypad led does not turn on.	No electricity on the unit <ul style="list-style-type: none"> • The outlet where the instrument is connected has a breakdown. Call an authorized electrician to check the outlet. • Power cable of the table is damaged (signs of being smashed or cracked can be seen). Spare power cable can be provided by your authorized dealer. • Check the glass fuse at the back of the instrument. Replace with fuses with same value. Spare fuses can be provided by your authorized dealer. Keypad panel does not work <ul style="list-style-type: none"> • Contact authorized service.
Head lamp does not work	Head lamp bulb has blown <ul style="list-style-type: none"> • Turn off power, unplug the cable and change the bulb. Spare bulbs can be provided by your authorized dealer.

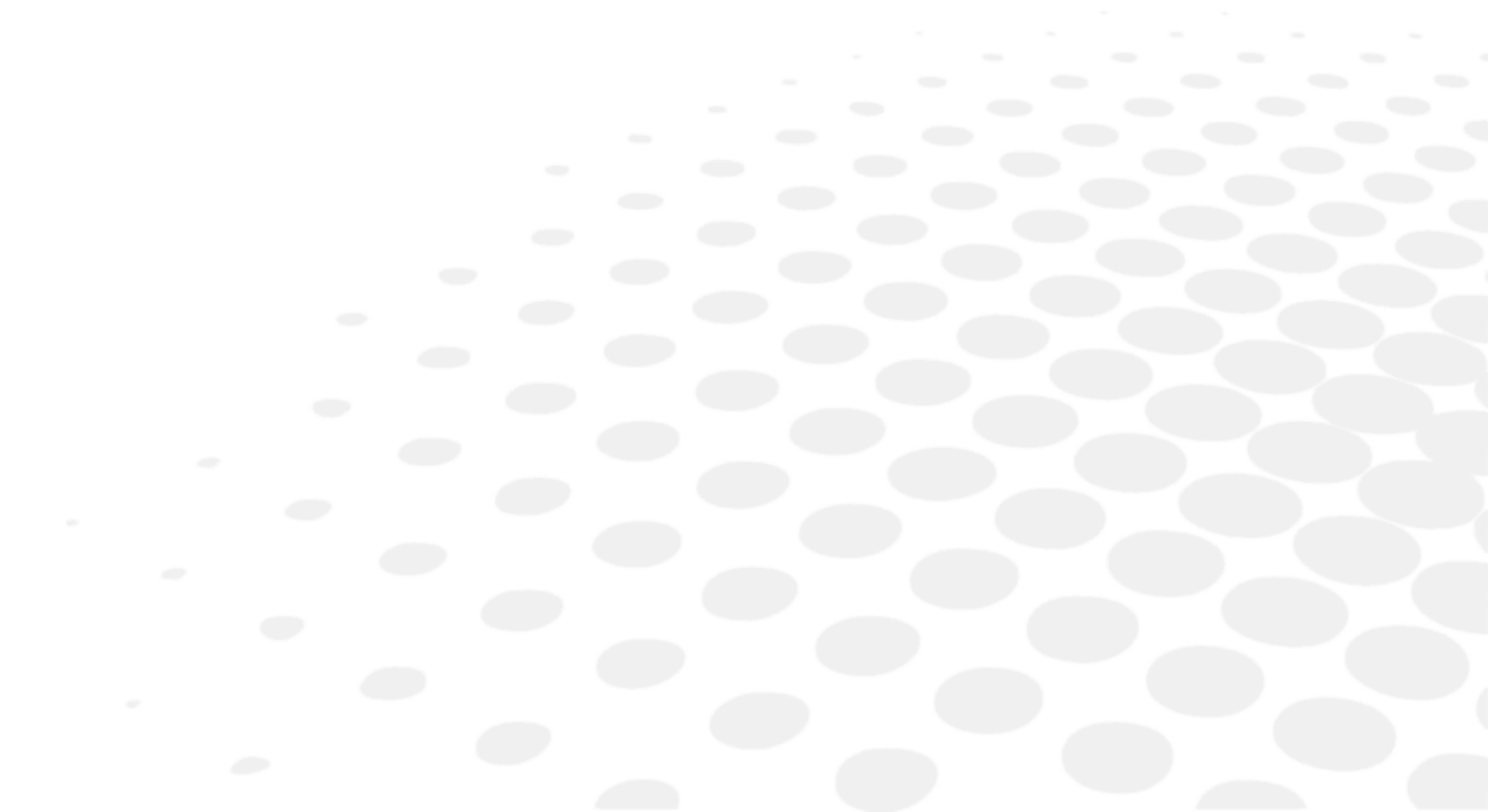
If the problem has not been resolved after taking the measures listed above, contact your local distributor immediately. Your dealer has been trained by Essilor.



Please refer to the name plate and let us have the following information:

- Name of the instrument: OST XXX
- Serial number: 7 digit-characters indicated on the name plate
- Detailed defects

IX. TECHNICAL DESCRIPTION



OST is a class I medical device (Regulation (EU) 2017/745).

Basic UDI of the device: 361502000000I0ST0000000DX.

1. Technical data

a. Product lifespan

The expected life of the device and its components is 10 years.

b. Product dimensions and weight

Dimensions

Dimensions	OST 100 C	OST 100	OST 150	OST 250 C	OST 250	OST 250 H	OST 350
Height	195 cm	185 cm	185 cm	185 cm	185 cm	185 cm	180 cm
Width	Body: 50 cm Chair: 50 cm	160 cm	160 cm	140 cm	175 cm	180 cm	175 cm
Depth	Body: 67.5 cm Chair: 89 cm	130 cm	130 cm	118.5 cm	142 cm	160 cm	185 cm

Weight

Weight	OST 100 C	OST 100	OST 150	OST 250 C	OST 250	OST 250 H	OST 350
Total weight	160 kg	190 kg	200 kg	245 kg	235 kg	375 kg	360 kg

c. LED specifications

For OST 100 C, OST 100, OST 150, OST 250 C

- W: 4.5 W
- Im: 350 lm
- T[Kelvin]: 2700 K = warm white
- V . Hz: 220-240 V~ . 50/60 Hz
- Type: GU10

For OST 250, OST 250 H, OST 350

- W: 4.5 W Dimmable
- Im: 350 lm
- T[Kelvin]: 2700 K = warm white
- V . Hz: 220-240 V~ . 50/60 Hz
- Type: GU10

d. Acoustic levels

For OST 100 C, OST 100, OST 150, OST 250 C

- Ambient: 45 dB
- Maximum exposure: 53 dB

For OST 250, OST 250 H, OST 350

- Ambient: 48.2 dB
- Maximum exposure: 58.2 dB

e. Product electrical data

For OST 100C

- Power: 220-230 VAC, 50/60 Hz
- Fuse: 8 Amper
- Electrical classification: Class 1, Type B

For OST 100, OST 150, OST 250 C, OST 250, OST 250 H

- Power: 220-230 VAC, 50/60 Hz
- Fuse: 8 Amper
- Table electricity outlet: 0-6-12 VAC Dimmable and 220-230 VAC, 50/60 Hz
- Electrical classification: Class 1, Type B

For OST 350

- Power: 220-230 VAC, 50/60 Hz
- Fuse: 10Amper
- Table electricity outlet: 0-6-12 VAC Dimmable and 220-230 VAC, 50/60 Hz
- Electrical classification: Class 1, Type B

f. Power consumption

Model	Volt	Amper	Volt Amper	Watt	Kilowatt
OST 100 C	220 V	0,90 A	140 VA	200 W	1,58 KWH
OST 100/OST 150	220 V	0,90 A	140 VA	200 W	1,58 KWH
OST 250 C	220 V	1,00 A	200 VA	220 W	1,55 KWH
OST 250	220 V	0,6 A	120 VA	135 W	1,45 KWH
OST 250 H	220 V	0,7 A	130 VA	160 W	1,50 KWH
OST 350	220 V	1,05 A	210 VA	225 W	1,60 KWH

g. IP Classification

IP20

h. Technical Information

	OST 100 C	OST 100	OST 150	OST 250 C	OST 250	OST 250 H	OST 350
Sliding table Capacity	NA	20+20 kg	20+20 kg	20+20 kg	20+20 kg	20+20 kg	20+20+20 kg
Chair load capacity	150 kg	150 kg	150 kg	150 kg	150 kg	150 kg	150 kg
Chair fixed by hand	360° rotation	360° rotation	360° rotation	Fixed	360° rotation	360° rotation	360° rotation
Chair stroke	18 cm	18 cm	18 cm	18 cm	18 cm	18 cm	18 cm
Chair motor	24 V DC	24 V DC	24 V DC	24 V DC	24 V DC	24 V DC	24 V DC
Table stroke	NA	NA	NA	18 cm	18 cm	18 cm	18 cm
Table motor	NA	NA	NA	24 V DC	24 V DC	24 V DC	24 V DC

2. Electromagnetic compatibility

In this chapter, you will find the information necessary to ensure that your device is installed and put into service in the best conditions in terms of electromagnetic compatibility.



- All of the information listed below is based on normative requirements to which manufacturers of electro-medical devices are subject, as defined in the IEC60601-1-2 Ed4 standard.
- The device complies with the applicable electromagnetic compatibility standards, however, the user must ensure that any electromagnetic interference does not create an additional risk, such as radio frequency transmitters or other electronic devices.
- The different device's cords must be separated from each other.
- Certain types of mobile telecommunication devices, such as mobile phones, may interfere with the device. Recommended separation distances must therefore be respected.
- The device shall not be used in the vicinity of or placed on another device. If this cannot be avoided, it is necessary to check its proper functioning under the conditions of use before using it. The use of accessories other than those specified or sold by the manufacturer as replacement parts may result in an emissions increase or a decrease in the immunity of the device.
- In case the device stops working, reset the device and restart test from the beginning. Do not use the previous data to make prescription.

Guidance and manufacturer's declaration - electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. The user or customer of this device should ensure use in such environments.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal functions. Therefore, their RF emissions are very low and are unlikely to cause interference to nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	This device is suitable for use in all installations, including local installations and those directly connected to the Low Voltage power supply network supplying buildings used for local purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compatible	

Guidance and manufacturer's declaration - electromagnetic immunity


This device is intended for use in the electromagnetic environment specified below. The user or customer of this device should ensure that it is used in such environments.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (EB) IEC 61000-4-2	+ 8 kV contact + 15 kV air	+ 8 kV contact + 15 kV air	Floors must be wood, concrete or ceramic tiled. If the floors are covered with synthetic material, the relative humidity is at least 30%. It should be 30.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz	± 2 kV 100 kHz	City utility power quality should be typical hospital environment.
Pulse Immunity IEC 61000-4-5	0.5-1 kV phase(s) to phase(s) 0.5-1-2 kV phase(s) to earth	+0.5-1 kV phase(s) to phase(s) 0.5-1-2 kV phase(s) to earth	City utility power quality should be typical hospital environment.
Voltage dips, short interruptions and voltage fluctuations in power supply input lines IEC 61000-4-11	%0 U _T ; 0.5 per at 0° 45°, 90°, 135°, 180°, 225°, 270°, and 335°, %70 U _T ; 25 per %0 U _T ; 1 per %0 U _T ; 250 per	%0 U _T ; 0.5 per at 0° 45°, 90°, 135°, 180°, 225°, 270°, and 335°, %70 U _T ; 25 per %0 U _T ; 1 per %0 U _T ; 250 per	City utility power quality should be typical hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m, 50Hz	30 A/m, 50Hz	The magnetic fields of the power frequency should be typical location-specific levels in a hospital environment.

NOTE: U_T value is the AC mains voltage before the test level is applied.

Recommended separation distances between portable and mobile RF communications equipment and the product

This device is intended for use in the electromagnetic environment specified below. The user or customer of this device should ensure use in such an electromagnetic environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	150kHz-80MHz, 3V rms, 80% AM (1kHz) (6Vrms for ISM bands)	3 V _{efficiency}	Portable and mobile RF communications equipment should be used no closer to any part of the Model 005, including cables, than the separation distance calculated by the equation appropriate for the transmitter frequency. Recommended separation distance $d = 1.16 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 0,15 MHz to 80 MHz $d = 2.3 \sqrt{P}$ 80 MHz ila 2.7 GHz Here, P is the highest output power rating of the transmitter specified by the transmitter manufacturer in watts (W), and d is the recommended separation distance in meters (m).
Radiant RF IEC 61000-4-3	80MHz - 2700MHz, 3V/m, 80% AM (1kHz)	3 V/m	The radiated field strength from fixed RF transmitters determined by an electromagnetic site discovery should be less than the Compliance Level in each frequency range. Interference may occur due to proximity to equipment marked with the following symbol. 

NOTE 1: For frequencies of 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guides may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

^a ISM (Industrial, scientific and medical) bands between 150 KHz and 80 MHz, 6.765 to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.

^b Compliance levels in the ISM frequency band in the 150 KHz and 80 MHz frequency range and in the 80 MHz to 2.5 GHz frequency range are intended to reduce the possibility of interference caused by the unintentional transport of mobile/portable communication equipment to the patient area. Therefore, an additional factor of 10/3 is taken into account in the formula used to calculate the recommended separation distance for transmitters in these frequency ranges.

^c The intensity of the radiated field from fixed transmitters such as base stations of radiotelephones (cellular/cordless) and mobile ground radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. Electromagnetic site exploration should be considered for the assessment of the electromagnetic environment from fixed RF transmitters. Normal operation of the ET Equipment (or ET System) should be observed if the measured field strength where the Model 005 is used exceeds the applicable RF compliance level specified above. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning the Model 005.

^d Over the frequency range 150 kHz to 80 MHz, the field strength should be less than 1 V/m.

3. Disposal



Instructions for the disposal of the instrument in accordance with Directives 2012/19/EU and 2011/65/EU regarding the limitation of dangerous substances in electrical and electronic equipment and the disposal of electrical and electronic waste.

When it reaches the end of its lifetime, the instrument should not be thrown out with the household refuse. It can be disposed of at a waste management center operated by the municipality or the retailers who offer this service.

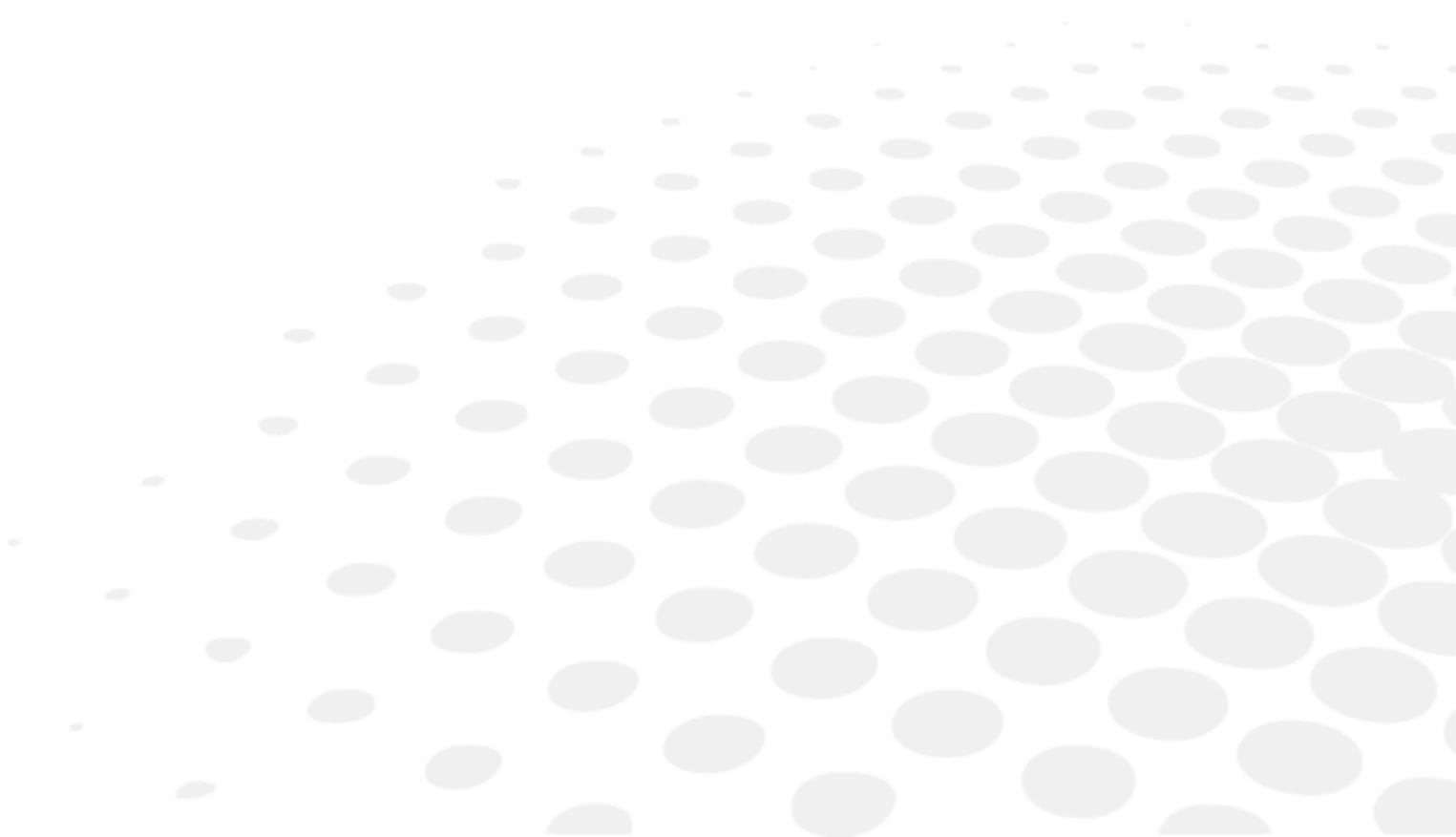
The separate disposal of an electrical device avoids any damage to the environment or health that could result from a non-compliant disposal, and also allows the materials it is composed of to be recycled in order to save energy and resources.

The pictogram of the wheeled container appears on the label of the instrument. It indicates the obligation for separate collection and disposal of end-of-life/out-of-use electrical and electronic equipment.







- The user must take into account the potentially harmful effects on the environment and human health that could result from the non-compliant disposal of the instrument in its entirety or some of its components.
- To avoid the release of dangerous substances into the environment and to encourage the preservation of natural resources, the manufacturer facilitates, in the event that the user wishes to dispose of the instrument at the end of its lifespan, the reuse, recovery and recycling of the instrument and its components. Before disposing of the instrument, the requirements of European and national regulations must be taken into consideration.
- Do not dispose of the instrument with household waste, but dispose of it separately by giving it in a company specialized in the disposal of electrical and electronic equipment or at the local administrative services in charge of waste collection.
- The supplier or manufacturer is required to recover the old equipment.
- By joining a consortium for the waste of technological equipment, the manufacturer covers the treatment and recycling costs of the used instrument.
- The manufacturer undertakes to provide the user with all the information relating to the dangerous substances contained in the device and the methods of recycling these substances, and to inform them of the existence of recycling of the used equipment. The law provides for severe penalties in case of infringement.















X. SYMBOL EXPLANATION



1. On the document















SYMBOL	DESCRIPTION
	Caution: a hazardous situation that, if not avoided, could result in minor or moderate injury.
	Warning: a hazardous situation that, if not avoided, could result in death or serious injury.
	Important and/or useful additional information to learn relating to the text in this manual.
	Tips: practical advice.

2. On the device

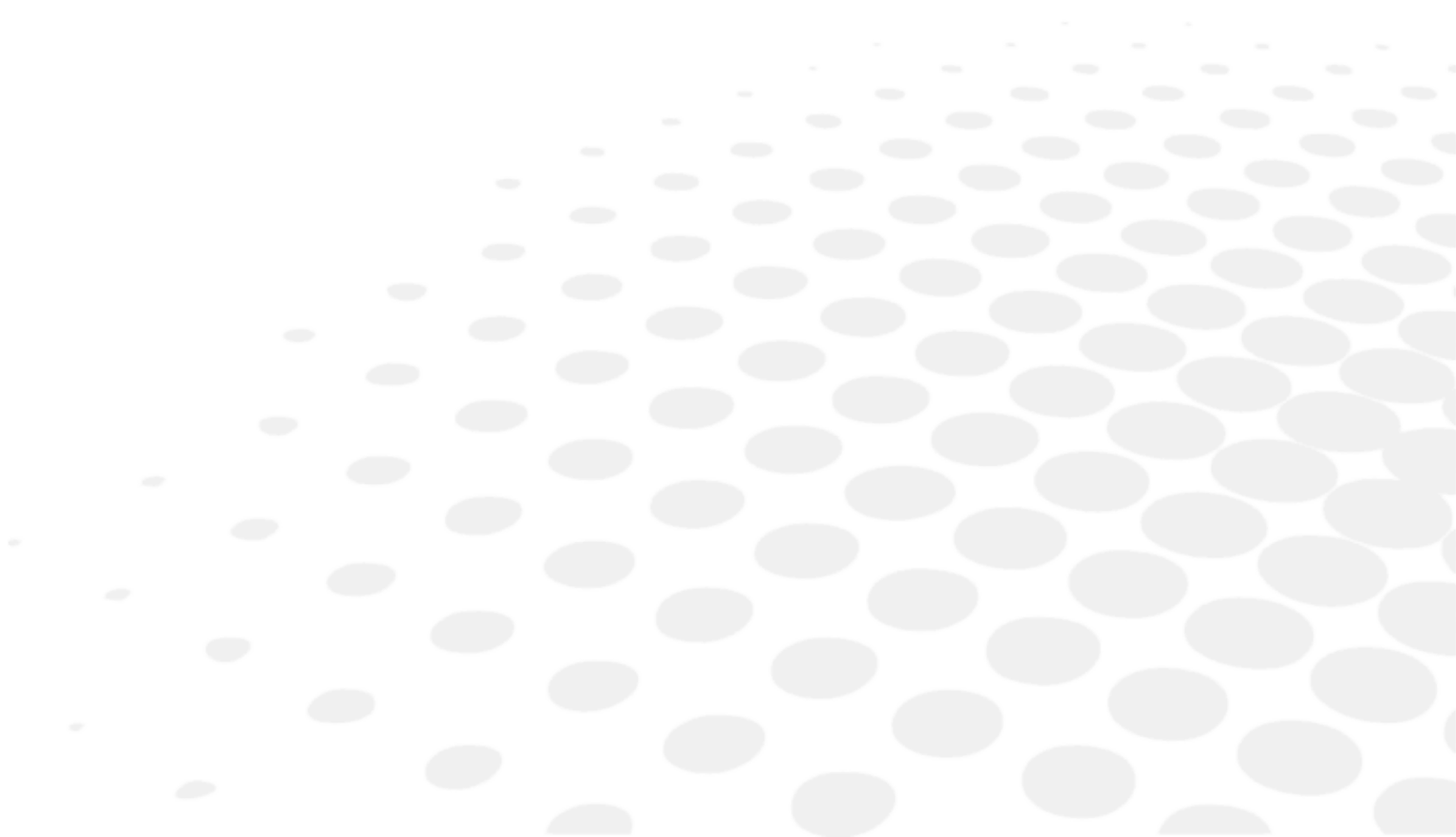
SYMBOL	DESCRIPTION
	Manufacturer
	Country of manufacture and Manufacturing date (Year-Month)
	Medical device
	CE Marking (European regulation relating to medical devices)
	Product reference
	Product serial number
	Unique device identifier
	Refer to instruction manual/ booklet
	General warning sign
	Alternating current
	Protective earth (ground)
	Type B applied part
	IP classification
	Waste disposal symbol in accordance with Directives 2012/19/EU and 2011/65/EU

3. On the packaging

For proper handling, storage and transport requirement.

SYMBOL	DESCRIPTION
	This way up
	Maximum stacking of products above market product
	Fragile; handle with care
	Keep dry
	Indicate the thermal limits to which the medical device can be exposed in complete safety
	Indicate the humidity limits to which the medical device can be exposed in complete safety
	Indicate the limits of atmospheric pressure to which the medical device can be exposed in complete safety
	Medical device
	CE Marking (European regulation relating to medical devices)
	Product reference
	Product serial number
	Unique device identifier
	Waste disposal symbol in accordance with Directives 2012/19/EU and 2011/65/EU
	Indicates that the packaging is recyclable

XI. EXCLUSION OF LIABILITY



The product shall be used in compliance with the applicable laws and regulations, by qualified, professional users. The product must be installed and used according to the instructions provided in the present user manual and to any written direction or recommendation provided by Essilor (the “documentation”).

Essilor reserves the right to revise the documentation and to make changes in its content from time to time. Preventive and corrective maintenance (including regular calibration if necessary, according to the documentation) shall be performed in accordance with the documentation.

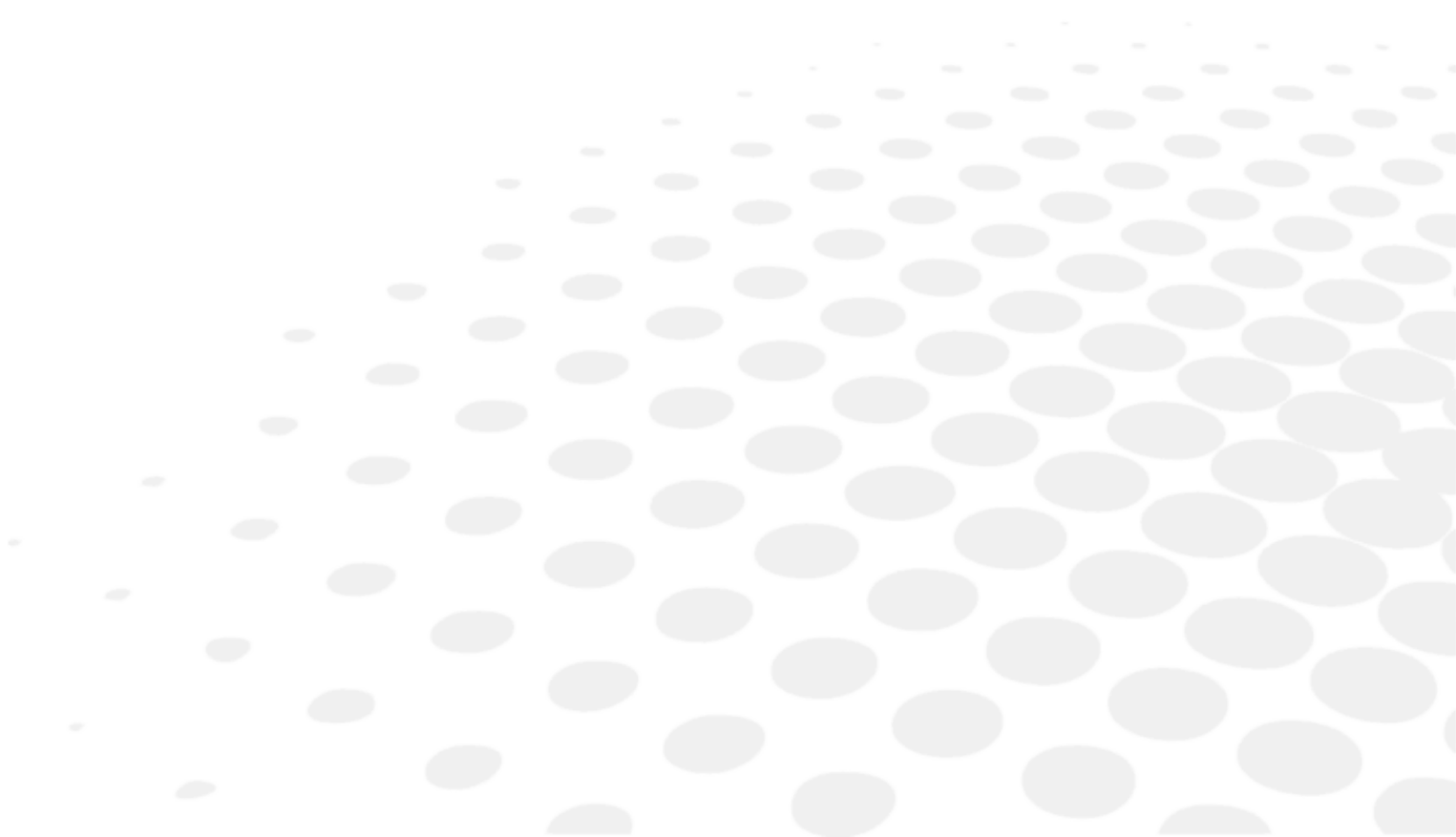
Any product warranty offered by Essilor is contingent upon use of the product in accordance with the documentation and with the product’s intended use and does not cover products that were modified without Essilor’s prior written approval or repaired by a third party not approved by Essilor, nor to products that were subjected to physical, chemical or electrical stress that the products were not originally designed for.

Essilor shall not be held liable for any damages suffered by the user of the product, the product, or any third party, resulting from any user’s non-compliance to the present section.

If the product offers a connectivity function, the user shall be sole responsible for:

- selecting, obtaining and maintaining all required internet access and telecommunications at its own costs; and
- adopting and maintaining procedures and measures to protect its workstations, hardware and software, other than the Product, including against any virus or intrusion

XII. QR CODE



The latest version of the user manual in the appropriate language is available on a web space. Upon request, a paper version can be provided for free.

en The complete user manual is available on a web space in PDF format. To access it, please scan the QR code below using a dedicated tool or application. Please make sure that your device is suitable and has an appropriate software to display the electronic Instructions for use.

fr Le manuel utilisateur complet est disponible sur un espace web au format PDF. Pour y accéder, veuillez scanner le QR code ci-dessous à l'aide d'un outil ou d'une application dédié(e). Veuillez vous assurer que votre appareil est compatible et dispose d'un logiciel approprié pour afficher le manuel électronique.

ar لتمكن من الوصول إليه، يُرجى مسح رمز الاستجابة السريعة PDF دليل المستخدم الكامل متوفر من خلال موقع الويب بصيغة أدناه باستخدام أداة أو تطبيق مخصص لذلك. يُرجى التأكد من أن جهازك مناسب ويحتوي على برنامج مناسب لعرض التعليمات الإلكترونية الخاصة بالاستخدام.

be Поўная інструкцыя карыстальніка даступна ў інтэрнэт-прасторы у фармаце PDF. Каб атрымаць да яе доступ, адсканіруйце QR-код ніжэй пры дапамозе спецыяльнага сродку або праграмы. Калі ласка, упэўніцеся, што ваша прылада прыдатная для паказу электроннай Інструкцыі па карыстанню і што на ёй усталявана адпаведнае праграмае забеспячэнне.

bg Пълното ръководство за потребителя е достъпно в уеб пространството. За да получите достъп до него, моля, сканирайте QR кода по-долу, като използвате специален инструмент или приложение. Моля, уверете се, че вашето устройство е подходящо и разполага с подходящ софтуер за преглед на електронните Инструкции за употреба.

cs Kompletní uživatelský návod je k dispozici na webovém prostoru ve formátu PDF. Chcete-li k němu získat přístup, naskenujte prosím níže uvedený QR kód pomocí speciálního nástroje nebo aplikace. Ujistěte se prosím, že používáte vhodné zařízení, které má vhodný software pro zobrazení elektronického uživatelského návodu.

da Den komplette brugervejledning er tilgængelig på et webområde i PDF-format. For at få adgang til den skal du scanne QR-koden nedenfor ved hjælp af et dedikeret værktøj eller program. Sørg for, at din enhed er egnet og har en passende software til at vise de elektroniske brugsanvisninger.

de Die vollständige Bedienungsanleitung ist auf einem Webspace im PDF-Format verfügbar. Für den Zugriff scannen Sie bitte den untenstehenden QR-Code mit einem speziellen Tool oder einer Anwendung. Bitte vergewissern Sie sich, dass Ihr Gerät für die Anzeige der elektronischen Gebrauchsanweisungen geeignet ist und über eine entsprechende Software verfügt.

el Το πλήρες εγχειρίδιο χρήσης είναι διαθέσιμο σε έναν ιστοχώρο σε μορφή PDF. Για να αποκτήσετε πρόσβαση σε αυτό, σκανάρετε τον κωδικό QR παρακάτω χρησιμοποιώντας ένα ειδικό εργαλείο ή εφαρμογή. Βεβαιωθείτε ότι η συσκευή σας είναι κατάλληλη και έχει το κατάλληλο λογισμικό για την προβολή των ηλεκτρονικών οδηγιών χρήσης.

es El manual de uso completo está disponible en un espacio web. en formato PDF. Para acceder a él, escanee el código QR debajo utilizando una herramienta o aplicación dedicada. Asegúrese de que su dispositivo sea adecuado y tenga el software apropiado para mostrar las Instrucciones de uso electrónicas.

et Täielik kasutusjuhend on saadaval veebis PDF-vormingus. Juurdepääsuks palun skannige allolevat QR-koodi, kasutades selleks vastavat tööriista või rakendust. Veenduge, et teie seade sobib ja et selles on elektroonilise kasutusjuhendi kuvamiseks sobiv tarkvara.

fi Täysi käyttöopas on saatavana verkosta PDF-muodossa. Saat pääsyn siihen skannaamalla alla olevan QR-koodin käyttäen siihen tarkoitettu työkalua tai sovellusta. Varmista, että laitteesi on sopiva ja sisältää asianmukaisen ohjelmiston sähköisten käyttöohjeiden esittämiseen.

he למטה באמצעות כלי או QR-כדי לגשת אליו, יש לסרוק את קוד ה PDF המדריך המלא למשתמש זמין באתר אינטרנט בפורמט אפליקציה ייעודיים. חשוב לוודא שהמכשיר שלך מתאים ובעל תוכנה מתאימה להצגת הוראות השימוש האלקטרוניות.

hr Potpun korisnički priručnik dostupan je na mrežnom prostoru u PDF formatu. Da biste mu pristupili, skenirajte QR kôd u nastavku pomoću odgovarajućeg alata ili aplikacije. Provjerite je li vaš uređaj prikladan i ima li odgovarajući softver za prikaz elektroničkih uputa za upotrebu.

- hu A teljes felhasználói kézikönyv elérhető az interneten PDF formátumban. Eléréséhez olvassa be az alábbi QR-kódot egy erre szolgáló eszközzel vagy alkalmazással. Ellenőrizze, hogy eszköze képes és rendelkezik a megfelelő szoftverrel az elektronikus használati útmutató megjelenítésére.
- id Panduan pengguna lengkap tersedia di ruang web dalam format PDF. Untuk mengaksesnya, silakan pindai kode QR di bawah ini menggunakan alat atau aplikasi khusus. Pastikan peranti Anda sesuai dan memiliki perangkat lunak yang layak untuk menampilkan petunjuk penggunaan elektronik.
- it Il manuale utente completo è disponibile in formato PDF su uno spazio Web. Per accedervi, leggere il codice QR sottostante mediante un apposito strumento o un'applicazione dedicata. Assicurarsi che il dispositivo sia adatto e che disponga di un software appropriato per visualizzare le istruzioni per l'uso in formato elettronico.
- ja 完全なユーザーマニュアルは、PDF形式でウェブスペースから入手できます。アクセスするには、専用のツールまたはアプリケーションを使用して、以下のQRコードをスキャンしてください。お使いのデバイスが適切であり、電子説明書を表示する適切なソフトウェアがインストールされていることを確認してください。
- ko 전체 사용 설명서는 웹 공간에 PDF 형식으로 있습니다. 이 설명서에 액세스하려면, 전용 도구 또는 앱을 사용하여 아래 QR 코드를 스캔하십시오. 사용자의 기기가 적합하고 전자적인 사용 설명서를 표시할 수 있는 적절한 소프트웨어가 있는지 확인하시기 바랍니다.
- lt Išsamaus naudotojo vadovo PDF formatu ieškokite interneto svetainėje. Kad jį atvertumėte, specialiu įrankiu arba programėle nuskaitykite toliau pateiktą QR kodą. Įsitinkite, kad jūsų įrenginys yra tinkamas ir turi tinkamą programinę įrangą elektroninems naudojimo instrukcijoms rodyti.
- lv Pilnā lietotāja instrukcija ir pieejama tīmeklī PDF formātā. Lai tai piekļūtu, lūdzu, noskenējiet tālāk redzamo kvadrātkodu, izmantojot tam paredzētu rīku vai lietojumprogrammu. Lūdzu, pārlicinieties, vai jūsu ierīce ir piemērota un vai tai ir atbilstoša programmatūra elektroniskās lietotāja instrukcijas attēlošanai.
- ms Manual pengguna yang lengkap boleh didapati di ruang laman dalam format PDF. Untuk mengaksesnya, sila imbas kod QR di bawah menggunakan alat atau aplikasi khusus. Sila pastikan yang peranti anda adalah serasi dan mempunyai perisian yang sesuai untuk memaparkan Arahan elektronik untuk tujuan penggunaan.
- mt Il-manwal tal-utent shiĥ huwa disponibbli fuq il-web f'format PDF. Biex taċċessah, jekk jogħġbok skennja l-kodiċi QR t'hawn taħt permezz ta' għodda jew applikazzjoni apposta. Jekk jogħġbok żgura li l-apparat huwa xieraq u għandu s-software adattat biex juri l-Istruzzjonijiet għall-Użu elettronici.
- nl De volledige gebruikershandleiding is in PDF-formaat beschikbaar op een website. U kunt de handleiding bereiken door de QR-code hiernaast te scannen met een geschikte applicatie. Uw apparaat moet geschikt zijn en over de juiste software beschikken om de elektronische gebruiksaanwijzing weer te geven.
- no Den komplette brukerhåndboken er tilgjengelig på et webhotell i PDF-format. For å få tilgang til den, skann QR-koden nedenfor ved hjelp av et dedikert verktøy eller applikasjon. Sørg for at enheten din er egnet og har en passende programvare for å vise den elektroniske bruksanvisningen.
- pl Kompletna instrukcja użytkownika jest dostępna na stronie internetowej w formacie PDF. Aby uzyskać dostęp, zeskanuj poniższy kod QR przy użyciu dedykowanego narzędzia lub aplikacji. Upewnij się, że urządzenie jest zgodne i wyposażone w odpowiednie oprogramowanie pozwalające wyświetlać elektroniczną Instrukcję obsługi.
- pt O manual do utilizador completo está disponível num espaço online no formato PDF. Para aceder a este, queira digitalizar o QR Code abaixo usando uma ferramenta ou uma aplicação dedicada. Certifique-se de que o seu dispositivo é compatível e possui um software apropriado para exibir as instruções eletrónicas de utilização.
- pt (brazil) O manual do usuário completo está disponível em um espaço online no formato PDF. Para acessar a este, por favor, digitalizar o QR Code abaixo usando uma ferramenta ou um aplicativo dedicado. Seu dispositivo deve ser compatível e possuir um software apropriado para exibir as instruções eletrônicas de utilização.
- ro Manualul de utilizare complet este disponibil online în format PDF. Pentru a-l accesa, scanați codul QR de mai jos folosind un instrument sau o aplicație dedicată. Asigurați-vă că dispozitivul dumneavoastră este potrivit și are un software adecvat pentru afișarea Instrucțiunilor de utilizare în format electronic.
- ru Полное руководство пользователя доступно в интернет-пространстве в формате PDF. Чтобы получить к нему доступ, отсканируйте QR-код ниже с помощью специального инструмента или приложения. Убедитесь, что

ваше устройство подходит и имеет соответствующее программное обеспечение для отображения электронных инструкций по эксплуатации.

sk Celý používateľský manuál je dostupný vo webovom priestore vo formáte PDF. Ak chcete získať prístup, naskenujte nižšie uvedený QR kód pomocou špeciálneho nástroja alebo aplikácie. Uistite sa, že máte vhodné zariadenie s vhodným softvérom na zobrazenie elektronického návodu na použitie.

sl Celoten uporabniški priročnik je na voljo kot dokument PDF na spletnem mestu. Za dostop optično preberite spodnjo kodo QR z namenskim orodjem ali aplikacijo. Prepričajte se, da je vaša naprava primerna in ima ustrezno programsko opremo za prikaz elektronskih navodil za uporabo.

sr Kompletno uputstvo za korisnike je dostupno na veb prostoru u PDF formatu. Da biste mu pristupili, skenirajte QR kôd u nastavku pomoću namenske alatke ili aplikacije. Proverite da je vaš uređaj odgovarajući i da li ima potreban softver za prikaz elektronskog Uputstva za upotrebu.

sv Den fullständiga bruksanvisningen finns tillgänglig på ett webbutrymme i PDF-format. För att komma åt den, vänligen skanna QR-koden nedan med ett dedikerat verktyg eller program. Se till att din enhet är lämplig och har en passande programvara för att visa de elektroniska användningsinstruktionerna.

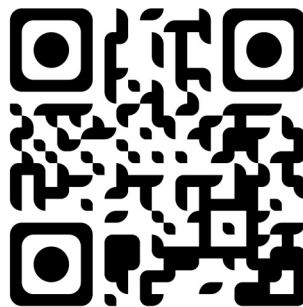
th สามารถรับคู่มือผู้ใช้ฉบับสมบูรณ์ในรูปแบบ PDF ได้จากบนเว็บไซต์ โดยในการเข้าถึง โปรดสแกนคิวอาร์โค้ดด้านล่างด้วยเครื่องมือหรือแอปพลิเคชันเฉพาะ โปรดตรวจสอบให้แน่ใจว่าอุปกรณ์ของคุณนั้นเหมาะสม และมีซอฟต์แวร์ที่สามารถใช้ในการแสดงคำแนะนำการใช้งานอิเล็กทรอนิกส์ได้อย่างถูกต้อง

tr Kullanım kılavuzunun tamamı web alanında, PDF formatında mevcuttur. Buna erişmek için lütfen uygun bir araç veya uygulama kullanarak aşağıdaki QR kodunu okutun. Lütfen cihazınızın uyumlu ve elektronik kullanım talimatlarını görüntülemek için uygun bir yazılıma sahip olduğundan emin olun.

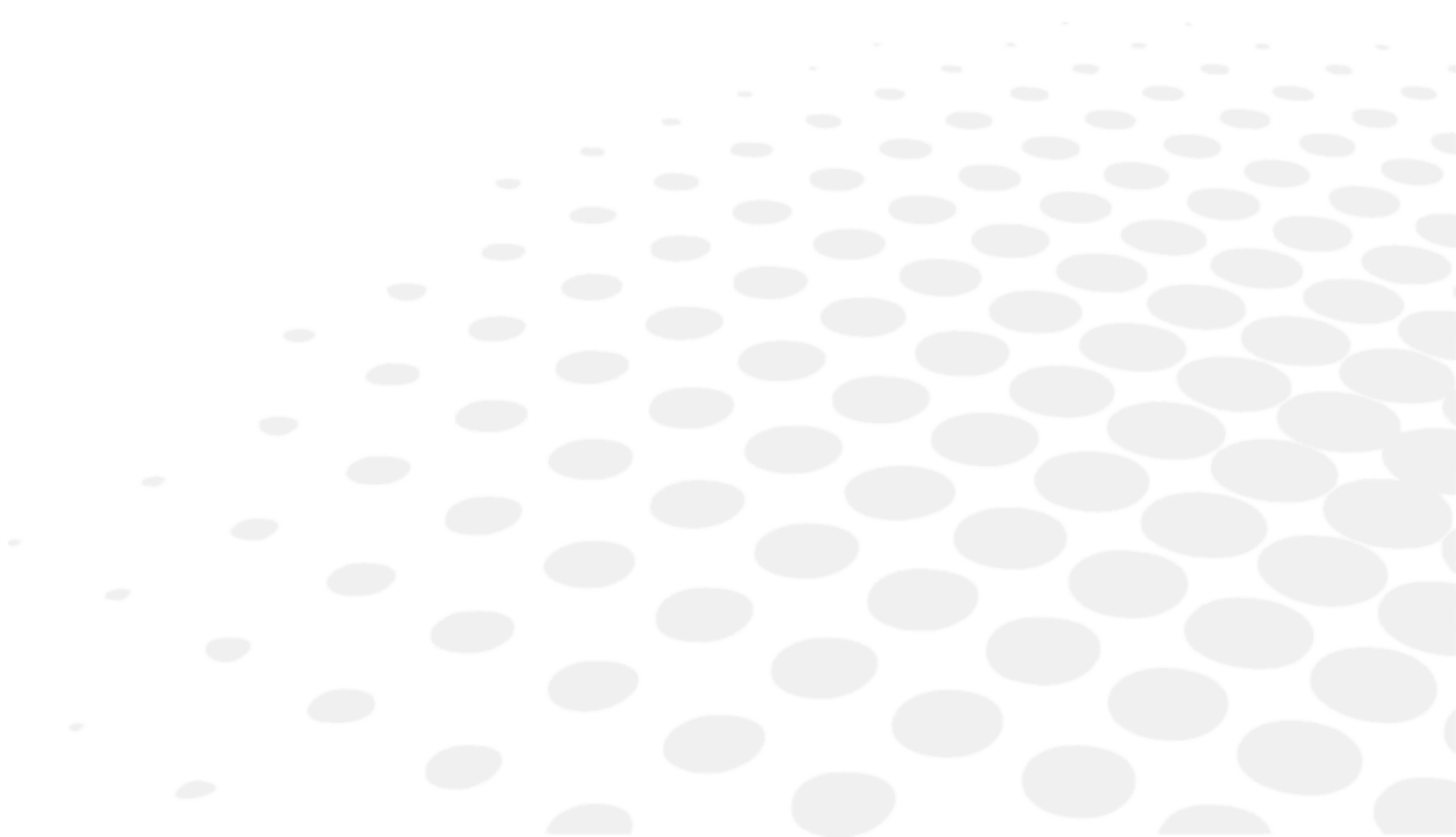
uk Повна версія посібника користувача доступна в інтернеті в форматі PDF. Щоб отримати до нього доступ, скануйте QR-код нижче за допомогою спеціального додатку. Для перегляду електронного посібника користувача на вашому пристрої він повинен мати відповідні характеристики та програмне забезпечення.

vi Hướng dẫn sử dụng đầy đủ có sẵn trên không gian web ở định dạng PDF. Để truy cập, vui lòng quét mã QR bên dưới bằng công cụ chuyên dụng hoặc bằng ứng dụng. Vui lòng đảm bảo rằng thiết bị của bạn phù hợp và có phần mềm phù hợp để hiển thị Hướng dẫn sử dụng điện tử

zh 完整的操作手册以 PDF 格式在网络上提供。如需获取，请使用专门的工具或应用程序扫描下方二维码。请确保您的设备适用并安装有相应的软件，能够显示电子版使用说明。



XIII. CONTACT INFORMATION



If the instrument appears malfunctioning, it is highly recommended to check the instrument according to the troubleshooting procedure of this manual.

If any problem persists or the instrument is damaged or malfunctioning or it is mentioned to contact your local distributor, please follow the steps below.

- Please contact the local distributor in your province or country at first. All information is available on www.essilor-instruments.com in the “Contact” section.
- If the product has been provided with electronic instruction and you need a paper format, please contact your local distributor.
- If any serious incident occurred in relation to the device, report it to essilor-instruments-vigilance@essilor.com and to the local competent authority for medical devices.
- Before calling to the local distributor, please be sure to check Model and Serial Numbers.
- The serial number is unique to this unit and is accessible on the product. It is recommended to fill up the following table as soon as you purchase our product.
- Please keep this manual as a permanent record of your purchase and keep your purchase receipt as your proof of purchase.

Date of Purchase:

Dealer’s Name:

Dealer address:

Dealer Phone No.:

Model No.:

Serial No.:



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