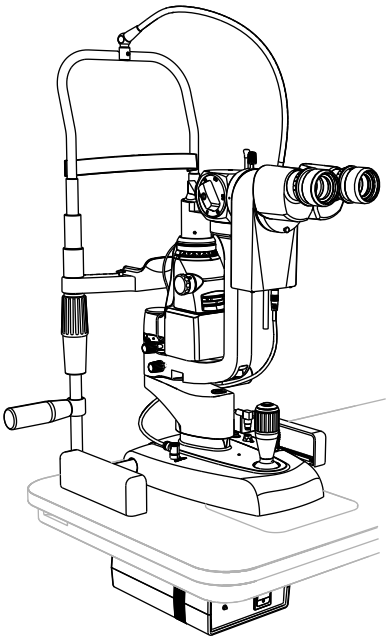
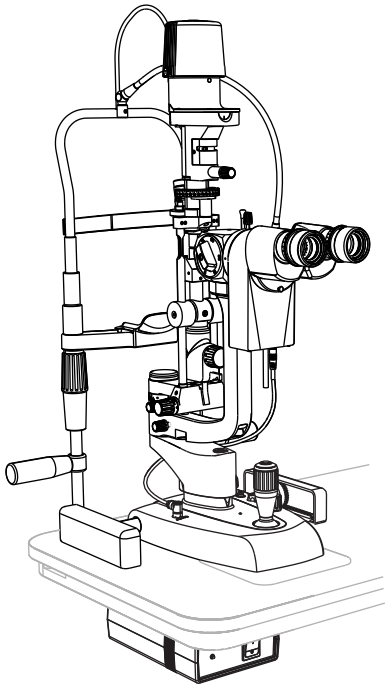
COSTRUZIONE STRUMENTI OFTALMICI





SLIT LAMP

INSTRUCTIONS FOR USE

SL9800 / SL9900 / SL9900 ELITE

COSTRUZIONE STRUMENTI OFTALMICI

Via degli Stagnacci 12/E | 50018 Scandicci (FI) | ITALY
Phone: +39 055 722191 | Fax: +39 055 721557

cso@csoitalia.it | www.csoitalia.it

SL9800SL9900IFUENGCSO0208032024

ENG

1 INTRODUCTION

The slit lamp is the result of extensive research, conducted with experts to ensure the product's technical innovation, quality and design.

1.1 SYMBOLS

The following symbols may be displayed in the instructions for use, on the package or on the device:

Symbol	Meaning
	Caution
	Danger of electric shock
	Read the instructions for use
	General obligation
	Note. Useful information for the user
	General prohibition sign
	Manufacturer
	CE Marking (EU Regulation 2017/745)
	Medical device
	Waste disposal in compliance with Directives 2012/19/EU (WEEE) and 2011/65/EU (RoHS II)

1.1.1 DEVICE SYMBOLS

Symbol	Meaning
	Type B applied part
	Class II device

1.2 GENERAL WARNINGS

THESE INSTRUCTIONS FOR USE REFER TO SLIT LAMPS SL9800, SL9900 AND SL9900 ELITE (HEREINAFTER "DEVICE").
THE SL9800 DEVICE HAS BOTTOM ILLUMINATION. THE SL9900 AND SL9900 ELITE DEVICES HAVE TOP ILLUMINATION, WITH THE POSSIBILITY OF TILTING THE LIGHTING ASSEMBLY. THE SL9900 ELITE DEVICE IS ALSO EQUIPPED WITH ILLUMINATOR.
THE SL9800 AND SL9900 DEVICES ARE AVAILABLE IN THE XX AND XX-D MODELS. THE SL9900 ELITE DEVICE IS AVAILABLE IN THE XX-D MODEL.
THE "XX" CODING IDENTIFIES THE TYPE OF MICROSCOPE SUPPLIED WITH THE DEVICE AND INSTALLED ON THE OBSERVATION UNIT. THE "-D" CODING IDENTIFIES THE DIGITAL DEVICE MODELS, WHICH HAVE DIGITAL SET-UP.

The indications on the available devices and models provided in this paragraph refer to the basic supply. If you have chosen optional components or accessories, the actual setup of the device may differ from the basic supply.

In the instructions for use, the paragraphs dedicated to a specific device are marked with SL9800, SL9900 or SL9900 ELITE.
Some paragraphs are dedicated to specific device models only and are marked with the "Xx" or "Xx-D" coding.
When nothing is specified, the paragraph applies to all the devices and models.

THE ORIGINAL TEXT IS IN ITALIAN.

Before using the device or after a long period of non-use, carefully read these instructions for use. Follow the directions provided in the instructions for use and on the device.

Always keep these instructions for use in an accessible and nearby place. If you decide to sell this device to a new user, remember to include these instructions for use, complete and readable.

Keep the original box and packaging, as the free-of-charge support service does not cover damage resulting from inadequate packaging of the device when sent back to an authorised Service Centre.

Before using the device, check that there is no sign of damage due to transport or incorrect storage, which could compromise the correct operation of the device.

It is forbidden to reproduce, in full or in part, texts or images contained in these instructions for use without the written authorization of the Manufacturer.

The Manufacturer reserves the right to modify the contents of the instructions for use without prior notice.

1.3 REFERENCE REGULATIONS

1.3.1 EU DIRECTIVES

- Regulation (EU) 2017/745 of the European Parliament and Council of 5 April 2017 on medical devices
- Directive 2012/19/EU on waste of electric and electronic equipment (WEEE)

1.3.2 TECHNICAL STANDARDS

- IEC 60601-1 - "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- CEI IEC 60601-1-2 - "Medical Electrical Equipment – Collateral Standard: Electromagnetic Compatibility"
- UNI EN ISO 15004-1 - Ophthalmic Instruments. Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic devices
- UNI EN ISO 15004-2 - Ophthalmic Instruments. Fundamental requirements and test methods - Part 2: Light hazard protection.
- UNI CEI EN ISO 14971 - Medical devices. Application of risk management to medical devices

1.3.3 QUALITY MANAGEMENT SYSTEM STANDARDS

- UNI CEI EN ISO 13485 - Medical devices. Quality management systems - Requirements for regulatory purposes"

1.4 WARRANTY

The Manufacturer is responsible for the device conformity to Regulation (EU) 2017/745 of 5 April 2017 for:

- performance
- safety and reliability
- CE marking

The Manufacturer rejects all responsibility for:

- installation and start-up that is not carried out in compliance with the directions and precautions reported in the instructions for use

- use of the device that fails to comply with the instructions for use or precautions reported in the instructions for use
- use of non-original accessories or spare parts
- repairs and safety checks not carried out by expert, qualified and trained personnel authorised by the Manufacturer
- failure of the electrical system of the premises where the device is installed to comply with the technical standards, laws and regulations in force in the country where the device is installed
- direct or indirect consequences or damage to objects or persons caused by the misuse of the device or erroneous clinical analysis obtained from its use

The Manufacturer guarantees the device for 24 months after the invoice date. The warranty covers the replacement by the Manufacturer or an authorised Service Centre of components and materials and the corresponding labour. Shipping and transport costs are to be paid by the customer.

The warranty does not cover:

- repairs of malfunctions caused by natural disasters, mechanical shocks (falls, collisions, etc.), electrical system defects, negligence, misuse, maintenance or repairs carried out with non-original materials
- any other misuse or use not intended by the Manufacturer
- damage caused by service failings or inefficiencies due to causes or circumstances out of the Manufacturer's control
- wear and/or deterioration of parts caused by normal use of the device and failures caused by misuse of the device or by maintenance carried out by personnel not authorized by the Manufacturer

To request maintenance interventions or obtain technical information about the device, contact an authorised Service Centre or the device Manufacturer directly.

The customer will not be refunded for damage caused by device downtime.

1.5 MANUFACTURER IDENTIFICATION

C.S.O. SRL
Costruzione Strumenti Oftalmici
Via degli Stagnacci, 12/E
50018 - Scandicci (FI) - ITALY
phone: +39-055-722191 - fax +39-055-721557
cso@csoitalia.it
www.csoitalia.it

2 SAFETY

2.1 SAFETY WARNINGS

DANGER
Danger of electric shock. Do not let water fall on the device. Do not immerse the device in water or other liquids.

DANGER
Danger of electric shock. If the power supply cables are damaged, they must be replaced by an authorised Service Centre to prevent any risk.

DANGER
Danger of electric shock. Unplug the power supply cable from the power socket before disinfecting or cleaning the device and before any maintenance operation.

DANGER
Danger of electric shock. Do not touch the power supply cables with wet hands.

DANGER
Danger of electric shock. Do not allow the power supply cables to come into contact with sharp edges or cutting parts. Always fix the power supply cables in place with ties.

CAUTION
Do not use the device if visibly damaged. Periodically inspect the device and connection cables to check for signs of damage.

CAUTION
Always keep the device out of the reach of children.

CAUTION
Danger of falling device. Do not leave loose cables in places where people may walk.

CAUTION
Danger of tripping and falling. Do not leave loose cables, as they might be of obstacle or danger for the patient or operator.

CAUTION
If you notice a strange odour or smoke coming out of the device or if it becomes hot, turn it off immediately. Do not continue to use a damaged device or damaged component. Danger of injuries.

CAUTION

The electric network must have a residual-current device (IΔn=30mA) and circuit breaker (Vn=230V) to protect the device. Place the device in such a way that the power socket is easily accessible.

It is forbidden to carry out any maintenance operation on the device not indicated in the instructions for use.

It is forbidden to place the device in humid, dusty places or environments subject to sudden variations in temperature and humidity.

It is forbidden to use any extension cables not authorised by the device Manufacturer.

It is forbidden to use the device outdoors.

The device is classified in accordance with technical standard IEC 60601-1 as an electro-medical device, and is therefore suitable for installation in the patient area.

Patient area: any volume in which a patient with applied parts may intentionally or unintentionally come into contact with other electromedical devices or electromedical systems, masses or foreign masses, or other people in contact with these elements.

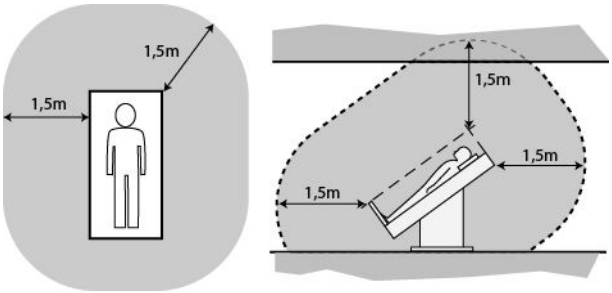


Fig. 1 - Patient area

2.2 DEVICE IDENTIFICATION

2.2.1 REGISTRATION DATA IN THE LIST OF MEDICAL DEVICES

The device registration data can be verified on this page of the website of the Ministry of Health:
Ministero della Salute - Ricerca dispositivi

2.2.2 DEVICE DATA PLATE

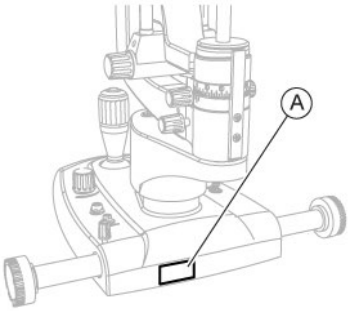


Fig. 2 - Data plate position

Pos	Description
A	Device data plate

SL9800 device, Xx and Xx-D model

Fig. 3 - Data plate for the Xx model

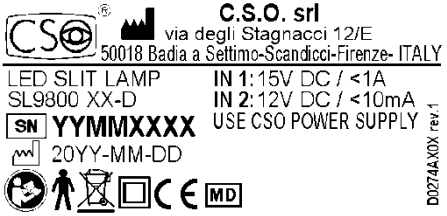


Fig. 4 - Data plate for the Xx-D model

SL9900 device, Xx and Xx-D model

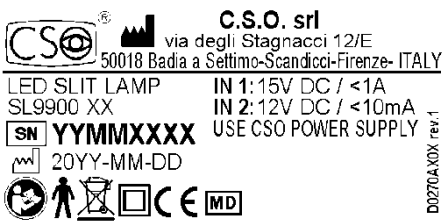


Fig. 5 - Data plate for the Xx model

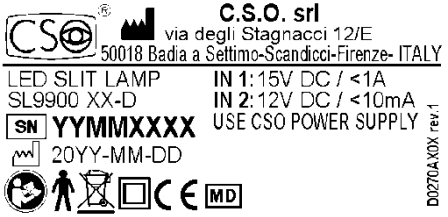


Fig. 6 - Data plate for the Xx-D model

SL9900 ELITE device, Xx-D model

Fig. 7 - Data plate for the Xx-D model

2.2.3 DATA PLATE OF THE VIDEOCAMERA

Fig. 8 - Data plate of the video camera for Xx-D models

2.2.4 POWER SUPPLY UNIT DATA PLATE

Fig. 9 - Power supply unit data plate

2.3 INTENDED USE

The device is characterized by an innovative design of the optical observation unit which has a multilayer anti-reflective treatment system. This system spreads the light in a more effective way and increases the optical resolution and the contrast by up to the 20% compared with those typical for this kind of device.
The devices are used by ophthalmologist and the opticians (within the scopes of their respective professional competences) to carry out specific ophthalmic diagnostic investigations (biomicroscopic examination of the eye).

The device is dedicated to:

- Stereo-microscopic observation of the eye exposed to the slit light
- Microscopy of the fundus and the posterior vitreous body (with Hruby lens)
- Eye observation and evaluation of the contact lenses positioning

The device, with the application software Phoenix allows for:

- Guided manual acquisition
- Management of patient data and the possibility of personalizing research and statistics
- Dry Eye Report, in combination with other C.S.O. devices. SRL

The device has no known contraindications.

Dry Eye Report

The Dry Eye Report provides an overall evaluation of the patient's clinical conditions, aimed at diagnosing tear film dysfunctions. The evaluation is based on:

- Ocular Surface Disease Index (OSDI)
- Eye redness analysis
- Meibomian glands analysis (acquired from other C.S.O. SRL devices)
- Tear meniscus analysis
- NI-BUT (acquired from other C.S.O. SRL devices)

Illumination (SL9800 device)

The device is equipped with professional LED illumination positioned on the lower part of the device. The LED illumination allows high-quality observation and a perfect comfort for the patient.

The maximum light intensity is 284,000 LUX with a life of 50,000 hours approximately.

Illumination (device SL9900 and SL9900 ELITE)

The device is equipped with professional LED illumination positioned on the top part of the device. The LED illumination allows high-quality observation and a perfect comfort for the patient.

The maximum light intensity is 284,000 LUX with a life of 50,000 hours approximately.

The tilting support allows to project the light vertically tilted by up to 20°, in steps of 5°. This is very useful during horizontal optical observation, in gonioscopy and in eye fundus examination.

Illuminator

During the observation, the illuminator allows to illuminate, with diffused light, those parts of the eye which, otherwise, would be left dark.

CAUTION

The light emanated by the device is potentially dangerous. The risk of eye damages is directly proportional to the exposure time. The exposure to the light emitted by the device while the device is operating at the maximum intensity exceeds the limit established by the EN 15004-2 standard. The maximum time of exposure to the light at maximum intensity must not exceed 160 seconds.

Microscope

Microscope with convergent optic and yellow filter (for fluorescein examination): this filter allows fast examination and better image quality. Magnifications from 6x up to 40x. Bright images, clear and with good contrast, thanks to the multi-layer anti-reflection treatment.

Video camera

The new digital video camera has been designed for ophthalmological purposes. The video camera is based on a high performance CCD sensor, characterized by excellent colour rendering. The increased resolution and speed (doubled in progressive live mode) make tiny details really sharp and the display is very smooth. The digital video camera is perfectly integrated with the new Phoenix application software, and perfectly suitable for acquiring and processing images (DICOM compatible). The application software allows to acquire images and videos of the eye. The video camera is connected to the PC through a USB 3.0 cable.

Sensor	1/1.8" progressive scan colour CCD
Image resolution	up to 1624 (h) x 1232 (v)
Resolution depth	14 bits
Connection interface	USB 3.0
Frame rate	15 fps
Video modes	1280x960

If the video camera is installed on the device, the device must be used in conjunction with a PC and the Phoenix application software.

For the system requirements, read paragraph **"Personal Computer" on page 37.**

The device must only be used by specialist practitioners and sector operators (such as optometrists), within the limits of the laws and regulations for the exercise of the profession.

2.4 MEDICAL DEVICE CLASSIFICATION

Technical data	Value
Classification in compliance with annexe VIII of Regulation (EU) 2017/745	Class I

2.5 ELECTROMEDICAL DEVICE CLASSIFICATION

Classification in compliance with technical specification IEC 60601-1

Technical data	Value
Type of protection against direct and indirect contacts	Class II
Applied parts	Type B
Protection degree against humidity	IP20 (no protection against infiltration by liquids)
Sterilisation or disinfection method	This device can be disinfected
Degree of protection in the presence of anaesthetics or flammable detergents	No protection
Degree of electrical connection between device and patient	Devices with part applied to the patient
Use conditions	Continuous operation

2.6 CLASSIFICATION FOR PHOTOBIOLOGICAL SAFETY

Technical data	Value
Device classification in accordance with EN 15004-2	Risk group 2

2.7 ENVIRONMENTAL CONDITIONS

Phase	Technical data	Min	Max
Transport	Temperature	-40°C	+70°C
	Atmospheric pressure	500 hPa	1060 hPa
	Relative humidity	10%	95%
Storage	Temperature	-10°C	+55°C
	Atmospheric pressure	700 hPa	1060 hPa
	Relative humidity	10%	95%
Use	Temperature	+10°C	+35°C
	Atmospheric pressure	800 hPa	1060 hPa
	Relative humidity	30%	90%

CAUTION
Danger of damage to the device. During transport and storage, the device may be exposed to the environmental conditions described, only if kept in the original package.

2.8 DISPOSAL AT THE END OF THE USEFUL LIFE

Instructions for the correct disposal of the device pursuant to European Directives 2012/19/EU and 2011/65/EU regarding the reduction of the use of dangerous substances in electrical and electronic equipment, as well as waste disposal.
At the end of its useful life, the device must not be disposed of with urban waste. The device may be delivered to designated separate collection centres set up by the municipal administration or to dealers that offer this service. Separately disposing of an electrical device prevents potential negative consequences for the environment and health caused by improper disposal and allows the materials it is made of to be recycled so as to attain significant savings in energy and resources. The data plate of the device displays the symbol of the crossed-out wheeled bin. The crossed-out wheeled bin symbol indicates the obligation to collect and dispose of electrical and electronic equipment separately at the end of their useful life.

The user must consider the potentially dangerous effects for the environment and human health arising from the improper disposal of the whole device or its parts.

Should the user wish to dispose of the device at the end of its useful life, the Manufacturer facilitates its potential reuse and recovery and the recycling of the materials contained therein. This prevents the release of hazardous substances into the environment and promotes the conservation of natural resources. Before disposing of the device, it is crucial to take into consideration European and national regulations, which prescribe the following:

- not to dispose of it as urban waste, but separate its parts, seeking advice from a firm specialised in the disposal of electrical/electronic equipment or the local administration in charge of waste collection
- in the event that a new device is purchased from the same Manufacturer to replace an old one placed on the market before 13 August 2005, equivalent and with the same functions as the new device, the Distributor or Manufacturer is legally required to collect the old device
- if the user decides to dispose of a used device placed on the market after 13 August 2005, the Distributor or Manufacturer is legally required to collect it
- the Manufacturer takes care, by joining the appropriate technological waste disposal consortium, of the treatment and recycling of the used device collected, bearing any costs

The Manufacturer is available to provide the user with information regarding the dangerous substances contained in the device, the recycling of these substances and the potential reuse of the used device.
Strict administrative sanctions for those failing to comply are provided for by law.
For specific information about disposal in countries other than Italy, contact your local Dealer.

2.9 MANUFACTURER DECLARATIONS

2.9.1 ELECTROMAGNETIC COMPATIBILITY

The device is subject to specific requirements regarding electromagnetic compatibility (EMC). The following factors may cause electromagnetic interference:

- Portable and mobile radio frequency (RF) communication devices located in the vicinity of the device.
- Other products installed near or connected to the device.
- Accessories, cables and spare parts not specified in the instructions for use and not sold by CSO as spare parts.

When using the device, certain precautions must be taken to respect EMC, including:

- Observe the instructions for use.
- Follow the restrictions and instructions in this section.

Essential performance restrictions
The device has the following essential performance: acquisition quality.

Danger from electromagnetic radiation

CAUTION
Using the device in the vicinity of other devices or connected to other devices not described in the instructions for use (e.g. in combination with an ophthalmic table) may cause interference with the functioning of the device.
Should it be necessary to use the device with other devices not described in the instructions for use, all devices must be monitored to ensure correct functioning.

CAUTION
Do not use portable high-frequency (HF) communication equipment (such as antenna cable and external antennas) and do not place equipment cables within a 30 cm (12 inches) radius around the device. Otherwise, a deterioration in the performance of the device can be expected.

CAUTION
The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this equipment could lead to increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

CAUTION
Portable radio frequency (RF) communication equipment (including peripherals such as antenna cables and external antennas) must be used at a distance of no less than 30 cm (12 inches) from any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may occur.

Environmental conditions for intended use

The device is intended for use in professional healthcare facilities as regards electromagnetic compatibility. These are in particular hospitals and doctors' surgeries, including those connected to the public electricity network (e.g. in residential areas), and opticians' and optometrists' premises.

The device is not intended for operation in the following environments:

- Home healthcare (e.g. residential accommodation, nursing homes)
- Outdoor environments
- In vehicles (for example, cars, trains, ships, planes)
- Other special environments (for example military facilities, heavy industry, medical treatment or diagnostic facilities with high-powered devices. These include in particular high-frequency surgical devices, short-wave therapy equipment and magnetic resonance devices)

The device is designed to be used in a room with the following electromagnetic characteristics:

Emission test	Compliance	Electromagnetic environment
Radio frequency emission. CISPR 11	Assembly 1	The device uses radio frequency energy only for its internal functioning. The device's electromagnetic emissions are very low and should not cause interference with nearby electronic devices.
Radio frequency emission. CISPR 11	Class B	The device may be used in all environments, including domestic ones. The device can be connected directly to a low-voltage electric network like that of residential buildings.
Harmonic emissions. IEC 61000-3-2	Class A	The device may be used in all environments, including domestic ones. The device can be connected directly to a low-voltage electric network like that of residential buildings.
Limitation of voltage changes, voltage fluctuations and flicker. IEC 61000-3-3	Compliant	The device may be used in all environments, including domestic ones. The device can be connected directly to a low-voltage electric network like that of residential buildings.

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment
Electrostatic discharge. IEC 61000-4-2	±6 kV in contact ±8 kV in air	±6 kV in contact ±8 kV in air	The floors must be made of wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity must be at least 30%.
Temporary/rapid sequences of electrical pulses. IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	The network power supply must be that of a typical commercial or hospital environment.
Impulse. IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	The network power supply must be that of a typical commercial or hospital environment.
Voltage dips. Brief disruptions and variations in voltage on power supply input lines. IEC 61000-4-11	<5% Un for 0.5 cycles 40% Un for 5 cycles 70% Un for 25 cycles <5% Un for 5 s	<5% Un for 0.5 cycles 40% Un for 5 cycles 70% Un for 25 cycles <5% Un for 5 s	The network power supply must be that of a typical commercial or hospital environment. If the device user requires continued operation during power outages and voltage dips, the device must be powered by an uninterrupted power supply or battery.
Magnetic field at mains frequency (50/60Hz). IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at mains frequency must have the same levels as a typical commercial or hospital environment.
RF conducted IEC 61000-4-6 **RF radiated IEC 61000-4-3**	3 Vrms From 150 kHz to 80 MHz 3 V/m From 80 MHz to 2.5 GHz	3 Vrms 3 V/m	(1)

(1) Portable and mobile RF communication equipment must be used no closer to any part of the device, including cables, than the recommended separation distance (d) calculated from the equation applicable to the frequency of the transmitter.

d=1.167*sqrt (P)

d=1.167*sqrt (P) 80 MHz to 800 MHz

d=2.333*sqrt (P) 800 MHz to 2.5 GHz

P: maximum output power rating of the transmitter in watts (W), according to the transmitter Manufacturer.

d: recommended distance in metres (m) at which portable radio frequency (RF) devices can be used.

The field strength emitted by fixed RF transmitters, as determined by an electromagnetic site survey, must be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

(Un) is the AC mains voltage prior to application of the test level.

At 80 MHz and 800 MHz, the higher frequency range applies. The exposed electromagnetic environment may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3 DEVICE DESCRIPTION

3.1 SUPPLY DESCRIPTION

SL9800 device

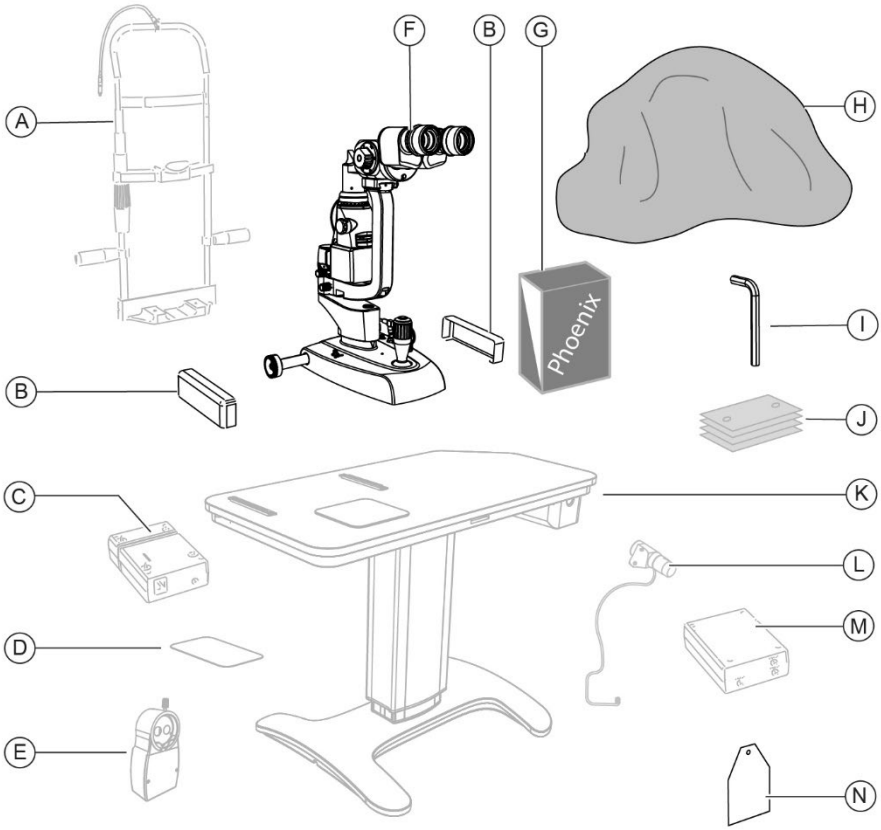


Fig. 10 - Supply description

Pos	Name		Description
A	Chin rest	Optional (*)	Adjustable height. Adjustable distance between chin and forehead. Fixation point included.
B	Wheel cover		Protection against accidental crushing of fingers.
C	Power supply unit	Optional (*)	A cable is provided with the power supply unit.
D	Sticker pad	Optional (*)	Sticker for right/left identification.
E	Video camera	Optional	Digital video camera with connection cables. Only compatible with 3x, 5x and zoom microscopes.
F	Device		Consisting of an observation unit with microscope and a lighting assembly with LED illumination installed at the bottom.
G	Application software	Optional	Application software for image acquisition and device management. If the video camera is installed on the device, the device must be used in conjunction with the Phoenix application software.
H	Dust cover		Place on the device when not in use to protect it from dust.
I	Hexagon wrench with screws		
J	Chin cup papers	Optional	Papers to be placed on the chin cup of the chin rest.
K	Ophthalmic table	Optional	Table top with support base with one or two columns and electric height adjustment. Drawer and auxiliary power sockets with cable guides.
L	Illuminator	Optional	LED illuminator
M	Isolation transformer	Optional	230V/230V for the use of non-electromedical devices in the patient area.
N	Breathing shield		

Optional: accessory not provided with the basic supply.
Accessories marked with (*) are essential for the proper operation of the device.

For the list of available accessories and models, contact the Manufacturer or the local Distributor.

SL9900 device

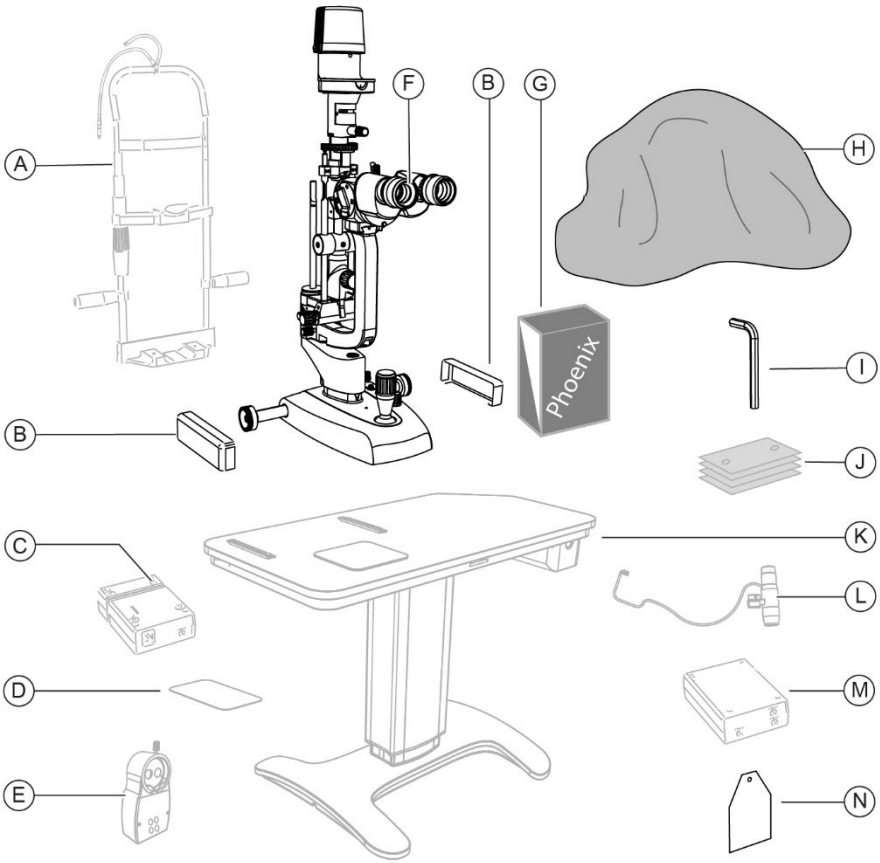


Fig. 11 - Supply description

Pos	Name		Description
A	Chin rest	Optional (*)	Adjustable height. Adjustable distance between chin and forehead. Fixation point included.
B	Wheel cover		Protection against accidental crushing of fingers.
C	Power supply unit	Optional (*)	A cable is provided with the power supply unit.
D	Sticker pad	Optional (*)	Sticker for right/left identification.
E	Video camera	Optional	Digital video camera with connection cables. Only compatible with 3x, 5x and zoom microscopes.
F	Device		Consisting of an observation unit with microscope and a lighting assembly with LED illumination installed at the top. The device is equipped with a lighting assembly tilting system.
G	Application software	Optional	Application software for image acquisition and device management. If the video camera is installed on the device, the device must be used in conjunction with the Phoenix application software.
H	Dust cover		Place on the device when not in use to protect it from dust.
I	Hexagon wrench with screws		
J	Chin cup papers	Optional	Papers to be placed on the chin cup of the chin rest.
K	Ophthalmic table	Optional	Table top with support base with one or two columns and electric height adjustment. Drawer and auxiliary power sockets with cable guides.
L	Illuminator	Optional	LED illuminator
M	Isolation transformer	Optional	230V/230V for the use of non-electromedical devices in the patient area.
N	Breathing shield		

Optional: accessory not provided with the basic supply.
Accessories marked with (*) are essential for the proper operation of the device.

For the list of available accessories and models, contact the Manufacturer or the local Distributor.

SL9900 ELITE device

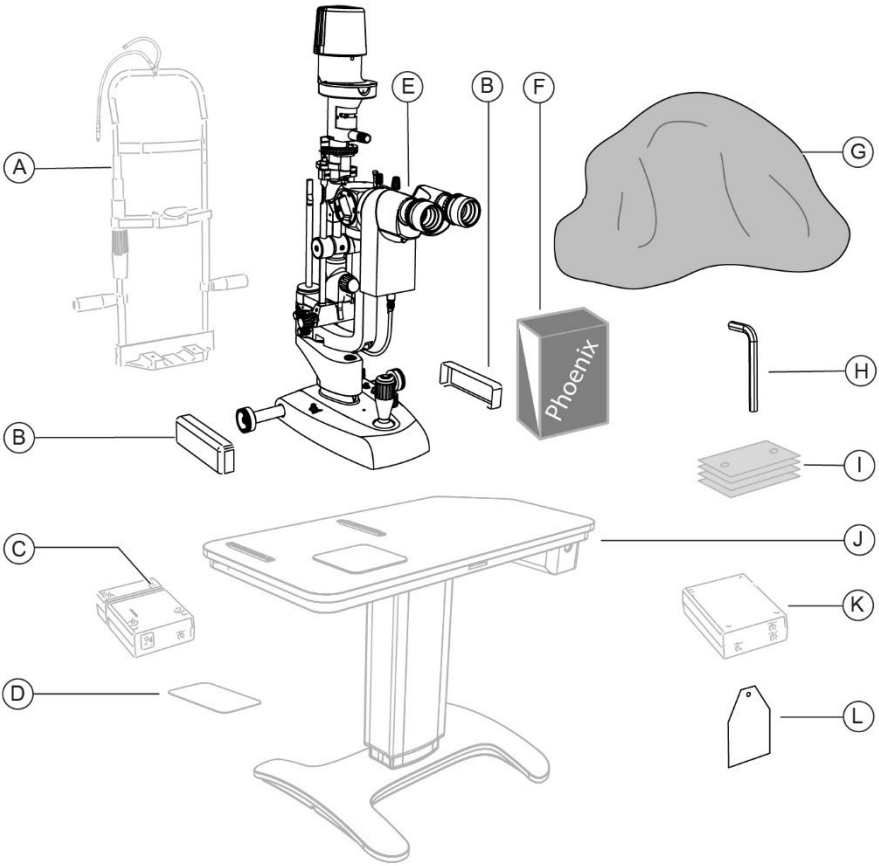


Fig. 12 - Supply description

Pos	Name		Description
A	Chin rest	Optional (*)	Adjustable height. Adjustable distance between chin and forehead. Fixation point included.
B	Wheel cover		Protection against accidental crushing of fingers.
C	Power supply unit	Optional (*)	A cable is provided with the power supply unit.
D	Sticker pad	Optional (*)	Sticker for right/left identification.
E	Device		The device consists of an observation unit with microscope and a lighting assembly with LED illumination installed at the top. The device is equipped with a lighting assembly tilting system. A digital video camera with connection cables is installed on the device.
F	Application software	Optional	Application software for image acquisition and device management. If the video camera is installed on the device, the device must be used in conjunction with the Phoenix application software.
G	Dust cover		Place on the device when not in use to protect it from dust.
H	Hexagon wrench with screws		
I	Chin cup papers	Optional	Papers to be placed on the chin cup of the chin rest.
J	Ophthalmic table	Optional	Table top with support base with one or two columns and electric height adjustment. Drawer and auxiliary power sockets with cable guides.
K	Isolation transformer	Optional	230V/230V for the use of non-electromedical devices in the patient area.
L	Breathing shield		

Optional: accessory not provided with the basic supply.
Accessories marked with (*) are essential for the proper operation of the device.

For the list of available accessories and models, contact the Manufacturer or the local Distributor.

3.1.1 SL9800 DEVICE

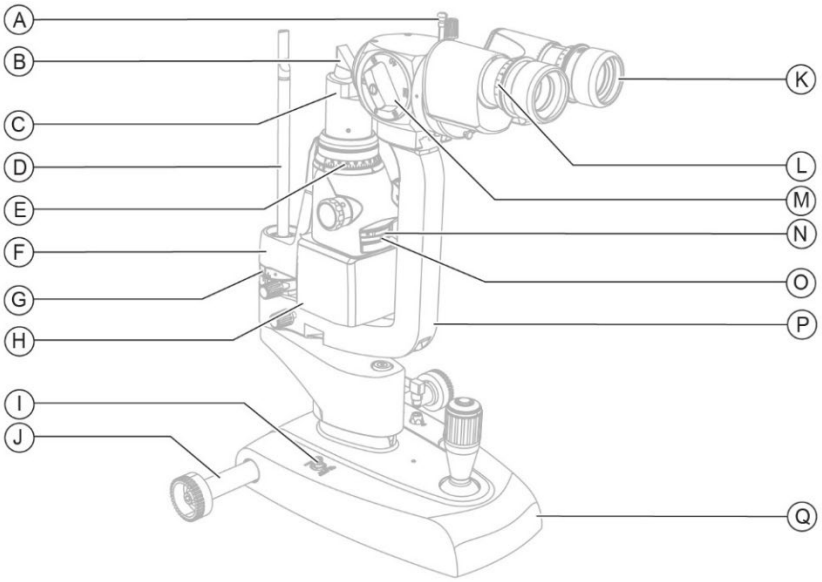


Fig. 13 - SL9800 device - left side

Pos	Name	Description
A	Yellow filter insertion rod	
B	Light diffusing filter	
C	Prism-holder head	
D	Calibration testing tool	
E	Dial with rotation indicator	To adjust the slit rotation
F	Lighting assembly arm	
G	Graduated scale	To indicate the lighting assembly position
H	Lighting unit	
I	Connector	To connect the device with the video camera (Optional)
J	Sliding rod	
K	Eyepieces	
L	Graduated scale	To correct refractive errors
M	Microscope	
N	Slit height adjustment dial	Equipped with graduated scale
O	Filter selector	
P	Microscope arm	
Q	Base	

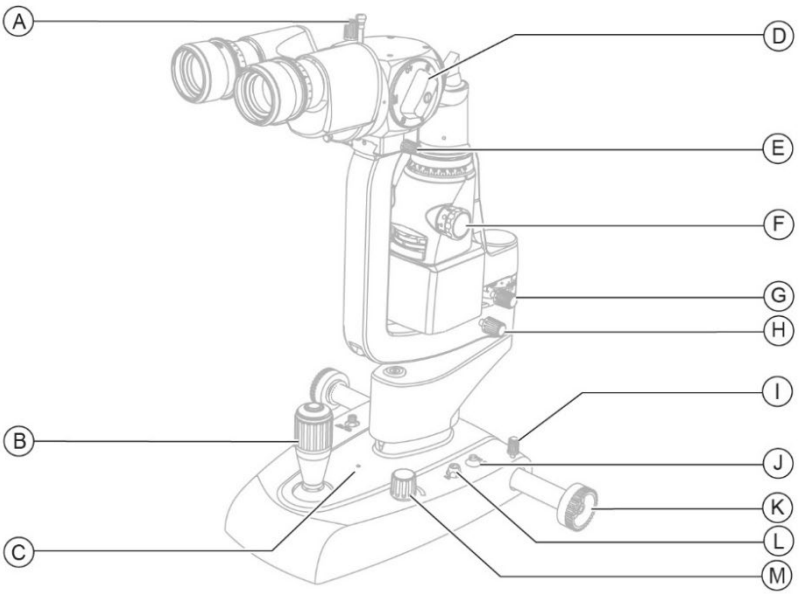


Fig. 14 - SL9800 device - right side

Pos	Name	Description
A	Binoculars or video camera (Optional) locking/unlocking knob	
B	Joystick	
C	Operation indicator	To select the magnification
D	Microscope selector	
E	Microscope locking/unlocking knob	
F	Slit width adjustment knob	
G	Lighting assembly arm locking/unlocking knob	To adjust the arm rotation
H	Microscope arm locking/unlocking knob	To adjust the arm rotation
I	Base locking/unlocking knob	
J	Connector	To connect the device with the power supply unit
K	Cogwheels	
L	Connector	To connect the base with the lighting assembly
M	Light intensity adjustment knob	

3.1.2 SL9900 DEVICE

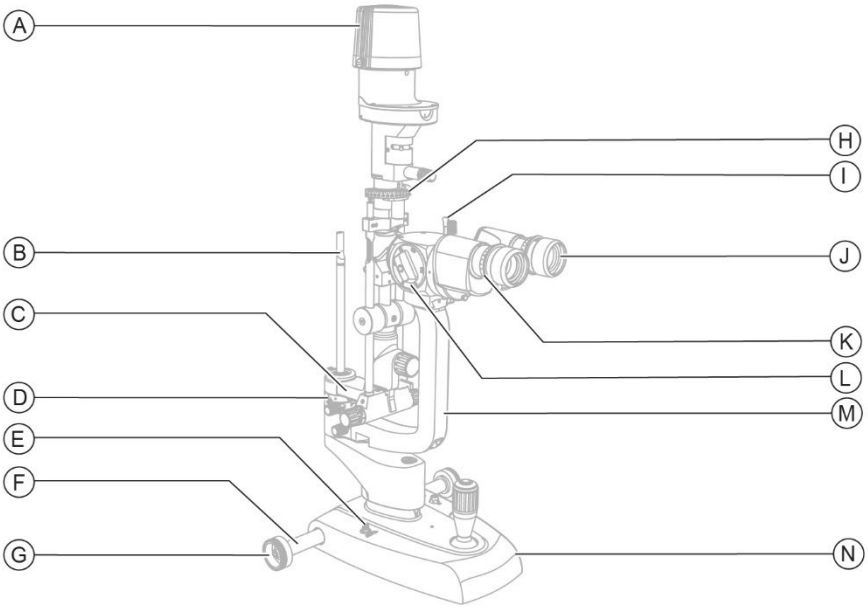


Fig. 15 - SL9900 device - left side

Pos	Name	Description
A	Lighting unit	LED illumination
B	Calibration testing tool	
C	Lighting assembly arm	
D	Graduated scale	To indicate the lighting assembly position
E	Connector	To connect the device with the video camera
F	Sliding rod	
G	Cogwheels	
H	Graduated scale	To indicate the slit tilting
I	Yellow filter insertion rod	
J	Eyepieces	
K	Graduated scale	To correct refractive errors
L	Microscope	
M	Microscope arm	
N	Base	

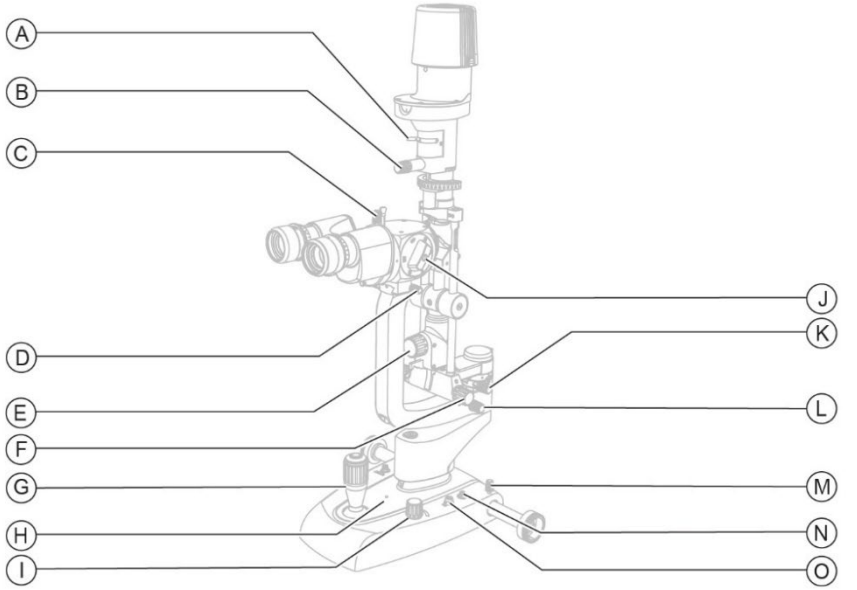


Fig. 16 - SL9900 device - right side

Pos	Name	Description
A	Filter selector	
B	Slit height adjustment knob	
C	Binoculars or video camera (Optional) locking/unlocking knob	
D	Microscope locking/unlocking knob	
E	Horizontal tilting setting knob	
F	Slit width adjustment knob	
G	Joystick	
H	Operation indicator	
I	Light intensity adjustment knob	
J	Microscope selector	To select the magnification
K	Lighting assembly arm locking/unlocking knob	To adjust the arm rotation
L	Microscope arm locking/unlocking knob	To adjust the arm rotation
M	Base locking/unlocking knob	
N	Connector	To connect the device with the power supply unit
O	Connector	To connect the base with the lighting assembly

3.1.3 SL9900 ELITE DEVICE

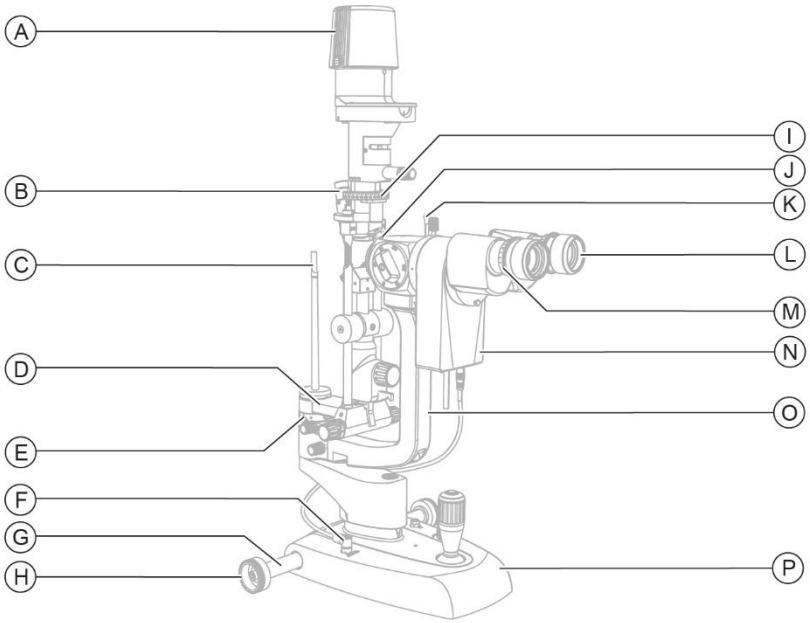


Fig. 17 - SL9900 ELITE device - left side

Pos	Name	Description
A	Lighting unit	LED illumination
B	Illuminator	LED illuminator
C	Calibration testing tool	
D	Lighting assembly arm	
E	Graduated scale	To indicate the lighting assembly position
F	Connector	To connect the device with the video camera
G	Sliding rod	
H	Cogwheels	
I	Graduated scale	To indicate the slit tilting
J	Microscope	
K	Yellow filter insertion rod	
L	Eyepieces	
M	Graduated scale	To correct refractive errors
N	Video camera	Digital video camera
O	Microscope arm	
P	Base	

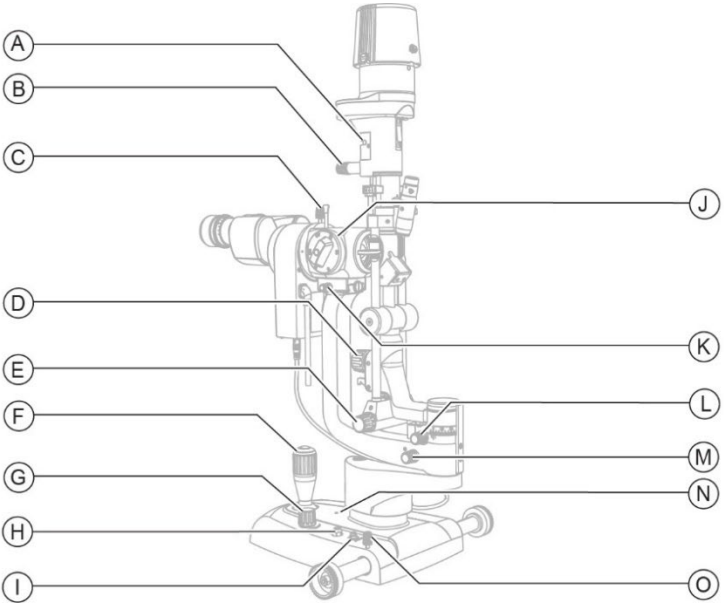


Fig. 18 - SL9900 ELITE device - right side

Pos	Name	Description
A	Filter selector	
B	Slit height adjustment knob	
C	Binoculars or video camera locking/unlocking knob	
D	Horizontal tilting setting knob	
E	Slit width adjustment knob	
F	Joystick	
G	Light intensity adjustment knob	
H	Connector	To connect the base with the lighting assembly
I	Connector	To connect the device with the power supply unit
J	Microscope selector	To select the magnification
K	Microscope locking/unlocking knob	
L	Lighting assembly arm locking/unlocking knob	To adjust the arm rotation
M	Microscope arm locking/unlocking knob	To adjust the arm rotation
N	Operation indicator	
O	Base locking/unlocking knob	

3.1.4 POWER SUPPLY UNIT

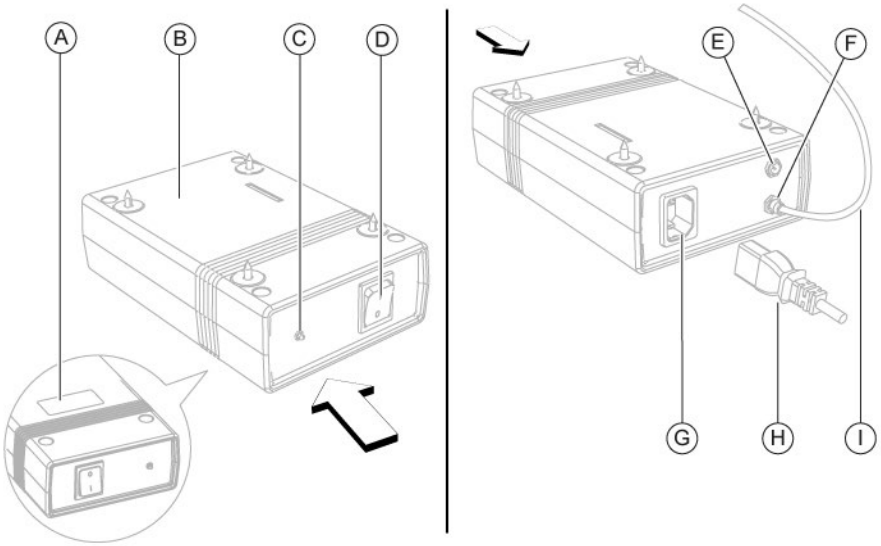


Fig. 19 - Power supply unit

Pos	Description
A	Data plate
B	Power supply unit
C	Power indicator light
D	Power switch
E	Fixation point power supply cable connector
F	Device power supply cable connector
G	Power supply unit power supply cable connector
H	Power supply cable of the power supply unit
I	Device power supply cable

3.1.5 CHIN REST

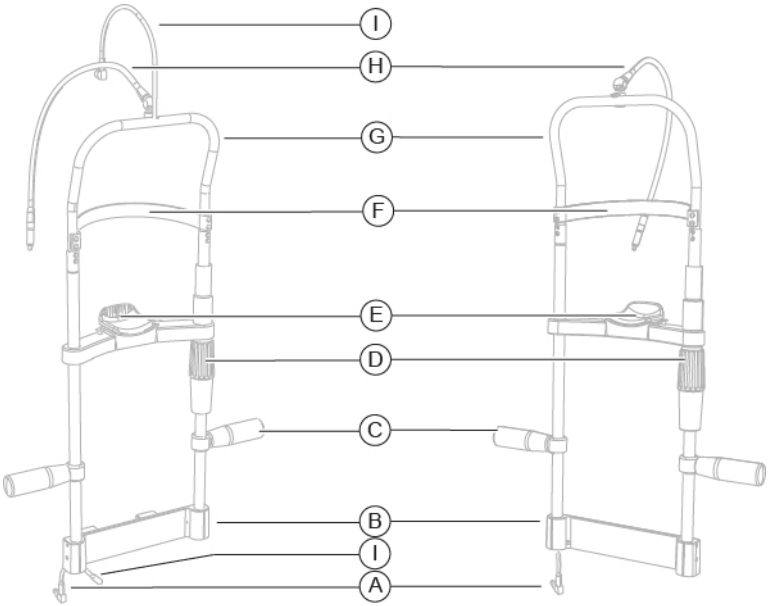


Fig. 20 - Chin rest for SL9900 and SL9900 ELITE device (left) and for SL9800 device (right)

Pos	Description
A	Fixation point power supply cable
B	Chin rest support
C	Chin rest handle
D	Chin cup adjustment knob
E	Chin cup
F	Forehead rest
G	Chin rest structure
H	Fixation point
I	Connection cable between the base and the lighting unit

3.1.6 OPHTHALMIC TABLE

Different table models are available based on the customer's choice. The table is composed of a table top on which the cogged wheels for the device compartment are installed. The table has one or two motorised telescopic columns that permit the height adjustment of the table top.

Fig. 21 - Ophthalmic table

For information on ophthalmic tables, please read the instructions for use of the ophthalmic table.

3.1.7 PERSONAL COMPUTER

If the video camera is installed on the device, the device must be used in conjunction with a PC and the Phoenix application software.
Minimum system requirements:

- CPU: i5 quad core (2,5 GHz)
- RAM: 8 GB
- Video Card: 1 GB RAM (not-shared) resolution 1920 x 1080 pixels
- Operating system: Windows 11 (64 bit)

Fig. 22 - Personal Computer

The PC must comply with Directive IEC 62368-1 Information technology equipment - Safety - Part 1: General requirements.
If the PC is installed in the patient area, it is also necessary to install an isolation transformer compliant with Directive IEC 60601-1:2005 + A1:2012 - "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance".

It is possible to connect other accessories to the PC (printer, modem, scanner, etc.) through the port interfaces. The accessories (printer, modem, scanner, etc.) must be installed outside the patient area.

The accessories must comply with Directive IEC 62368-1 Information technology equipment - Safety - Part 1: General requirements.
If the accessories are installed in the patient area, it is also necessary to install an isolation transformer compliant with Directive IEC 60601-1:2005 + A1:2012 - "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance".

3.2 TECHNICAL DATA

3.2.1 SL9800 DEVICE

Technical data	Value
Supply voltage	120-230 V ±10% 50/60 Hz 1 A
Size (HxWxD)	440 x 313 x 335 mm
Device weight	7.4 kg
Base movement (x, y, z)	105 x 110 x 30 mm
Precise movement (x, y)	14 ± 0,5 mm
Main unit package size	525 x 770 x 380 mm
Table top package size	680 x 530 x 195 mm
Accessories package size	355 x 245 x 240 mm
Consumables	Package of chin cup papers

Illumination

Technical data	With prism-holder head	With split head
Slit projection index	1.33X	1.33X
Slit width (continuous setting)	0 - 15 mm	0 - 15 mm
Slit length (continuous setting)	1 - 15 mm	1 - 15 mm
Maximal length of the slit	15 millimetres	15 millimetres
Aperture diaphragms	15, 9, 5.5, 0.3 mm	15, 9, 5.5, 0.3 mm
Filters	Blue, red, green (red free)	Blue, red, green (red free)

Technical data	With prism-holder head	With split head
Illuminator	White LED	White LED
Slit rotation	± 90° continuous on Tabo scale	± 90° continuous on Tabo scale
Incidence angle	0° horizontal	Total angle 10.2°
Rotation interval of the slit projector	+/-90°, angular scale, reference on 0°	+/-90°, angular scale, reference on 0°
Working distance (prism outlet/patient's eye distance)	69.5 millimetres	80 millimetres
Device operating voltage	15V DC 1A	15V DC 1A
Light source type	White LED	White LED
Luminosity adjustment	Continuous adjustment	Continuous adjustment
Light intensity	284000 Lux	284000 Lux
Colour temperature	3100K	3100K

Chin rest

Technical data	Value
Fixation point	Red light adjustable
Chin rest stroke	70 mm ±1

3.2.2 SL9900 AND SL9900 ELITE DEVICE

Technical data	Value
Supply voltage	120-230 V ±10% 50/60 Hz 1 A
Size (HxWxD)	675 x 313 x 335 mm
Device weight (Xx, Xx-D)	7.8 kg
Device weight (ELITE Xx-D)	7.8 kg
Base movement (x, y, z)	105 x 110 x 30 mm
Precise movement (x, y)	14 ± 0,5 mm
Main unit package size	525 x 770 x 380 mm
Table top package size	680 x 530 x 195 mm
Accessories package size	355 x 245 x 240 mm
Consumables	Package of chin cup papers

Illumination

Technical data	Value
Slit projection index	1X
Slit length (continuous setting)	1 - 12 mm
Slit width (continuous setting)	0 - 12 mm
Maximal length of the slit	12 millimetres
Aperture diaphragms	12, 9, 5, 3, 1, 0.2 mm
Filters	Blue, red, green (red free), ND50%
Illuminator	White LED
Slit rotation	±90° continuous on Tabo scale
Incidence angle	variable 0° / 5° / 10° / 15° / 20°
Rotation interval of the slit projector	±90°, angular scale, reference on 0° and ±10°
Working distance (prism outlet/patient's eye distance)	80 millimetres
Horizontal offset	± 4° with reference on 0°
Device operating voltage	15V DC 1A
Light source type	White LED
Luminosity adjustment	Continuous adjustment
Light intensity	284000 Lux

Chin rest

Technical data	Value
Fixation point	Red light adjustable
Chin rest stroke	70 mm ±1

To request spare parts, specify the code given in paragraph **"List of spare parts and accessories" on page 76.**

3.2.3 MICROSCOPE

The microscope features differ depending on the chosen setup: 2x, 3x, 5x and zoom.

Microscope 2x

The 2x microscope does not support video camera installation.

Technical data	Value
Type	Convergent - 2 positions
Ocular convergence angle	13°
Eyepieces	10x
Refractive error compensation	±8 D
Declared magnifications	10x / 16x
Visual field	18.5mm / 12mm
Interpupillary distance	From 51.5 mm to 87 mm

Microscope 3x

Technical data	Value
Type	Galilean convergent with magnification change system - 3 positions
Ocular convergence angle	6°
Eyepieces	12,5x
Refractive error compensation	±8 D
Declared magnifications	10x / 16x / 25x (3 levels)
Real corresponding magnifications	8.5x / 14.8x / 25.6x (3 levels)
Visual field	From 26 mm to 8.5 mm (3 levels)
Interpupillary distance	From 50 mm to 80 mm
Barrier filter	Yellow

Microscope 5x

Technical data	Value
Type	Galilean convergent with magnification change system - 5 positions
Ocular convergence angle	6°
Eyepieces	12,5x
Refractive error compensation	±8 D
Declared magnifications	6x / 10x / 16x / 25x / 40x (5 levels)
Real corresponding magnifications	5.6x / 8.5x / 14.8x / 25.6x / 39.3x (5 levels)
Visual field	From 41 mm to 5.7 mm
Interpupillary distance	From 50 mm to 80 mm
Barrier filter	Yellow

Zoom microscope

Technical data	Value
Type	Galilean convergent with continuous variable magnification change system
Ocular convergence angle	6°
Eyepieces	12,5x
Refractive error compensation	±8 D
Declared magnifications	7x / 30x
Visual field	From 30 mm to 7.4 mm
Interpupillary distance	From 50 mm to 80 mm
Barrier filter	Yellow

3.2.4 VIDEO CAMERA

Technical data	Value
Resolution	5 Mpx
Pixel resolution	2448x2048
Frame rate	35 fps
Communication port	USB 3.0

4 DEVICE USE

4.1 HOW TO INSTALL THE DEVICE

CAUTION
Danger of falling device. The device must be installed on a horizontal and stable surface.

1 Place the ophthalmic table in the room. The table must be lifted by two people.
2 If present, lock the table wheels. Lower the brake lever.
3 Place the power supply unit under the table top. Screw the screws into the four holes.

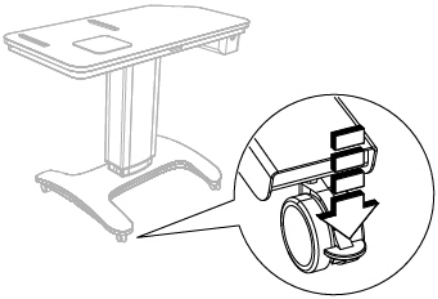


Fig. 23 - Position the ophthalmic table

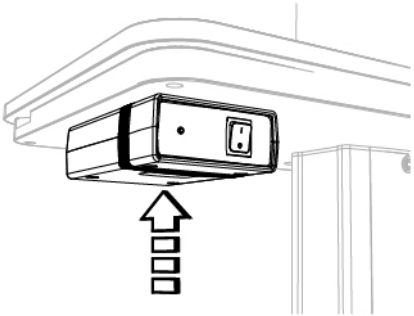


Fig. 24 - Position the power supply unit

4 Check the position of the sticker with respect to the central axis (A).
5 Remove the protective film. Place the sticker pad between the two guide rails and the sliding plate.

Respect the indicated distances while placing the sticker pad on the table top.

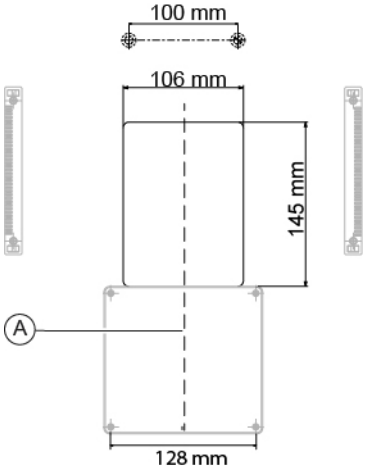


Fig. 25 - Distances for the installation of the sticker pad

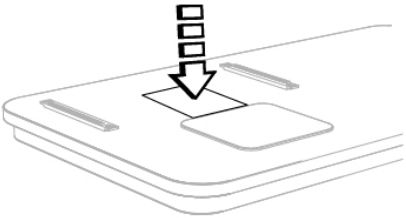


Fig. 26 - Position the sticker pad

6 Remove the joystick protection (B) under the device base.

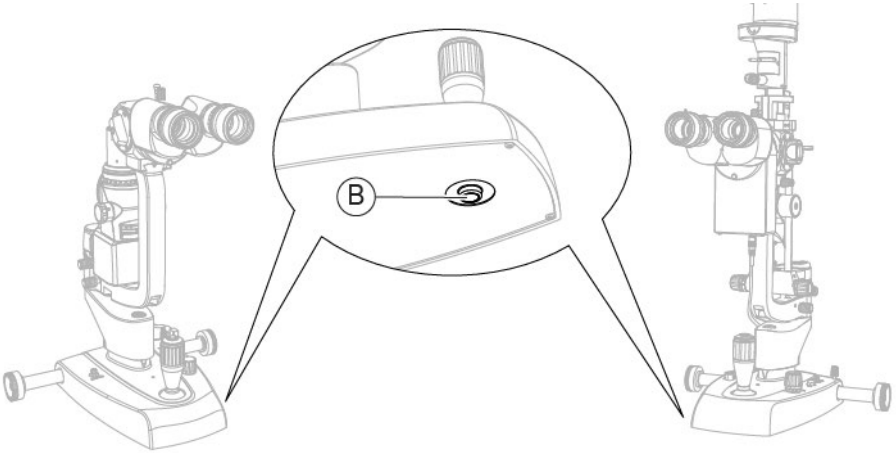


Fig. 27 - Remove the joystick protection

7 Position the device on the table top and align the cogwheels on the guide rails.

8 Install the two wheel covers on the guide rails on the table top.

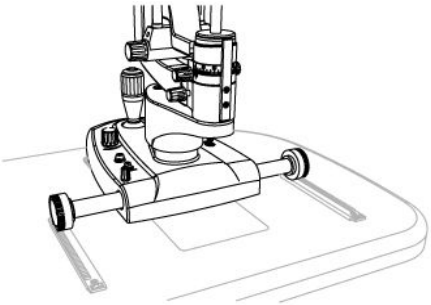


Fig. 28 - Position the device

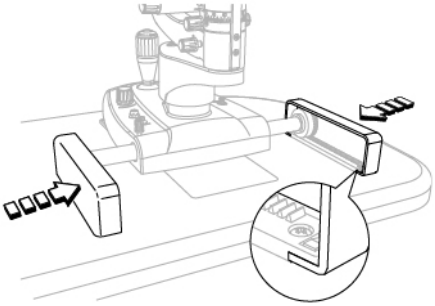


Fig. 29 - Install the wheel covers

9 Install the chin rest. Under the table top there are two inserts to fasten the chin rest support to the table top.

The chin rest must be installed so that the eye level indicator (1) is at a height of 380 mm with respect to the table top.

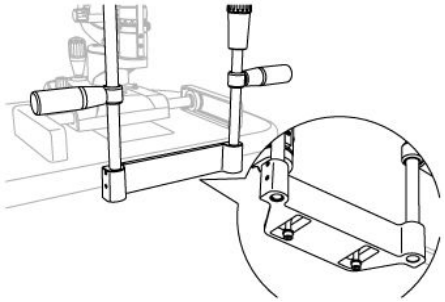


Fig. 30 - Position the chin rest

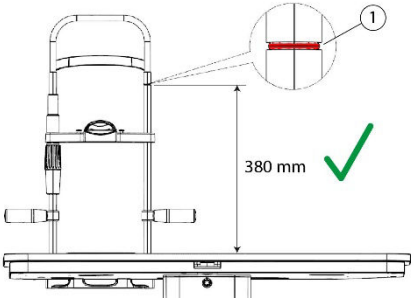


Fig. 31 - Correct height of the eye level indicator

10 If the eye level indicator does not reach the required height, adjust the chin rest.

11 Loosen the 4 locking grub screws placed on the chin rest support.

12 Slide the chin rest rods until the required height of 380 mm is reached. Tighten the previously loosened locking grub screws.

The chin rest rods must be adjusted upwards no more than 18 mm.

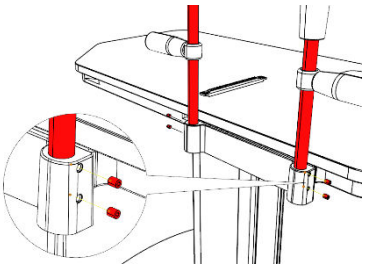


Fig. 32 - Loosen the grub screws of the chin rest

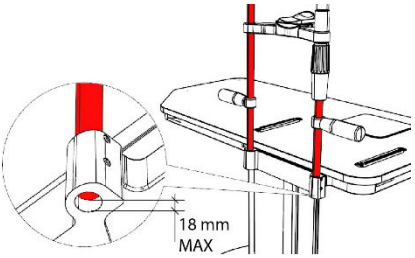


Fig. 33 - Maximum adjustment height of the rods

13 Carry out the electrical connections between the components.

4.2 HOW TO CONNECT THE DEVICE

SL9800 device

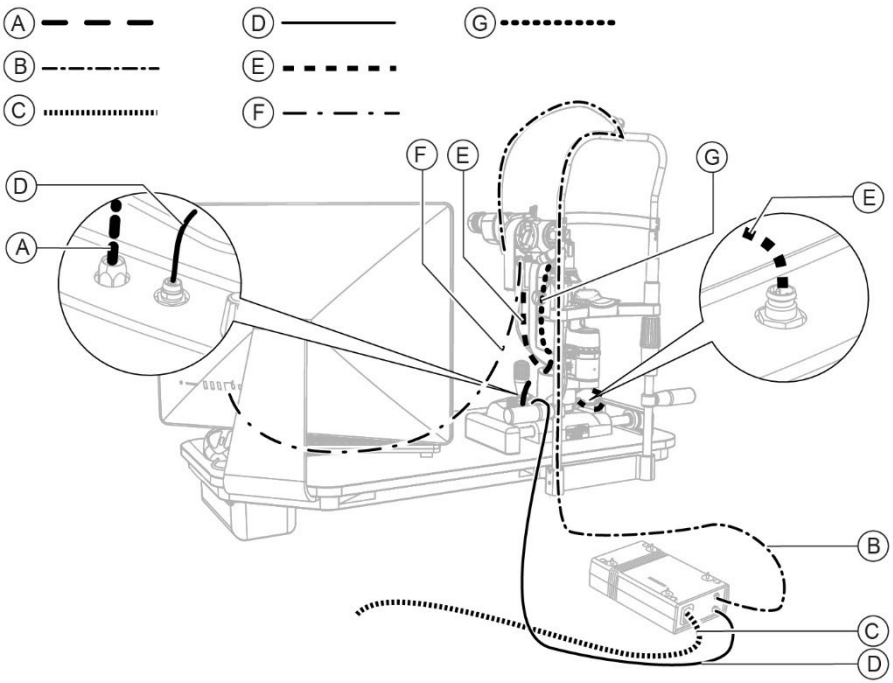


Fig. 34 - SL9800 device connection

Pos	Name
A	Connection cable between the base and the lighting unit
B	Fixation point power supply cable
C	Power supply cable of the power supply unit
D	Device power supply cable
E	Connection cable between the base and the video camera (*)
F	Connection cable between the video camera and the PC (*)
G	Connection cable between the lighting unit and the illuminator (*)

The parts marked with (*) are optional.

To connect the table base to the electric network, read instructions for use of the table or the ophthalmic unit.

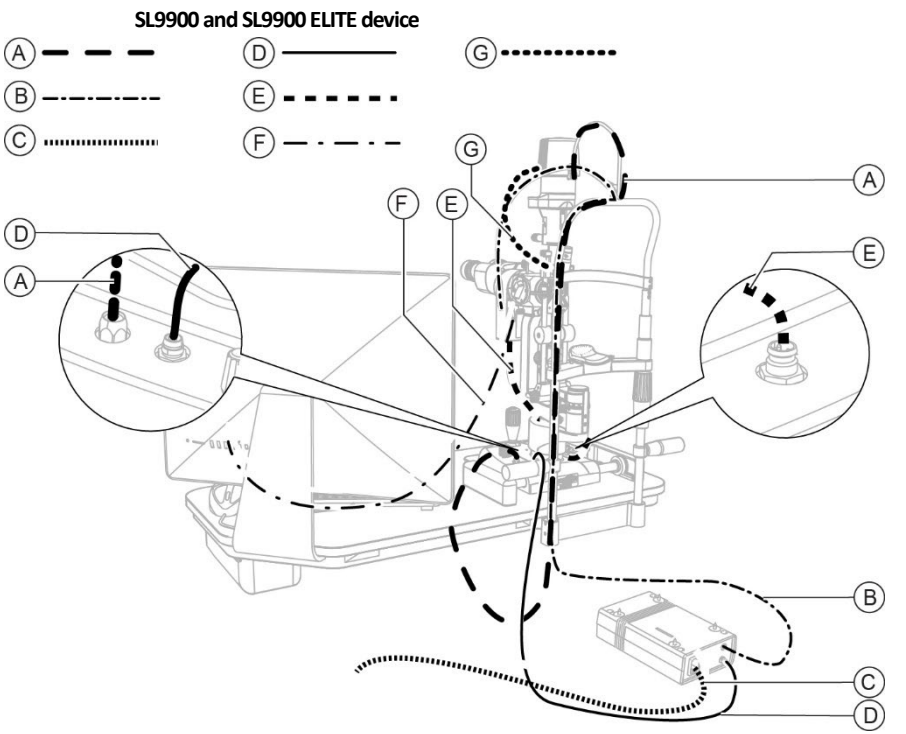


Fig. 35 - Connection of the SL9900 and SL9900 ELITE device

Pos	Name
A	Connection cable between the base and the lighting unit
B	Fixation point power supply cable
C	Power supply cable of the power supply unit
D	Device power supply cable
E	Connection cable between the base and the video camera (*)
F	Connection cable between the video camera and the PC (*)
G	Connection cable between the lighting unit and the illuminator (*)

The parts marked with (*) are optional.

To connect the table base to the electric network, read instructions for use of the table or the ophthalmic unit.

4.3 HOW TO ARRANGE THE ELECTRIC CABLES

CAUTION
Danger of falling device. Do not leave loose cables in places where people may walk.

CAUTION
Danger of tripping and falling. Do not leave loose cables, as they might be of obstacle or danger for the patient or operator.

DANGER
Danger of electric shock. Do not allow the power supply cables to come into contact with sharp edges or cutting parts. Always fix the power supply cables in place with ties.

It is forbidden to use any extension cables not authorised by the device Manufacturer.

For the proper positioning of electric cables and connection to the lifting column, read the instructions for use of ophthalmic tables or ophthalmic units. The instruction manual can also be downloaded from the website www.csoitalia.it.

The power socket located on the lower part of the column of the ophthalmic table is specific for the connection to the electric network. One of the power sockets at the top of the lifting column is dedicated to the power supply unit of the device.

4.4 HOW TO TURN ON THE DEVICE

1 Switch the power switch of the power supply unit to turn it ON. The operation indicator on the device base turns on.
2 It is now possible to proceed with the observation.

If the device is equipped with video camera (Xx-D):

Read the instructions for use before using the Phoenix application software.
The instruction manual can be downloaded from the website www.csoitalia.it.
Reference can also be made to the application software handbook.

1 Start the Phoenix application software.
2 Wait until the main screen of the application software is displayed.
3 Click NEW PATIENT and enter their personal data. If the patient is already present in the database, you can automatically search for their surname by typing it into the command prompt. A new examination will be created automatically.
4 Select the device to be used.
5 The image acquisition screen will open. It is now possible to acquire the image.

4.5 INDICATIONS GIVEN BY THE OPERATION INDICATORS

To monitor the operation of the device, check the status of the operation indicator on the device base.

Status of the operation indicator on the base	Meaning
Indicator on. Continuous. Green.	Correct operation.
Indicator on. Continuous. Red.	Turn off the device. Wait for the operation indicator on the base to turn off. Check the connection cable between the base and the lighting unit. Restore the connection and turn the device back on. If the problem persists, contact Technical Assistance.
Indicator on. Slow or rapid flashing. Red and green.	Turn off the device. Contact Technical Assistance.
Indicator on. Three rapid flashes (red-green-red light) alternating with continuous green light.	Turn off the device. Contact Technical Assistance.
Indicator on. Continuous. Orange.	Turn off the device. Contact Technical Assistance.

4.6 HOW TO ADJUST THE CHIN CUP

1 Ask the patient to sit down.
2 Show the patient how to position their face against the chin cup and forehead rest.
3 Check that the eye is correctly positioned in relation to the shooting channel.

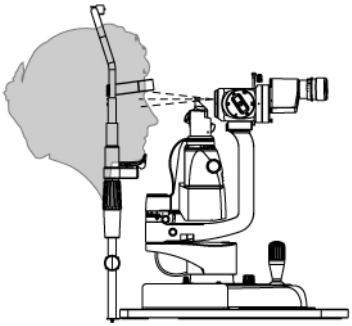


Fig. 36 - Patient position on chin rest SL9800

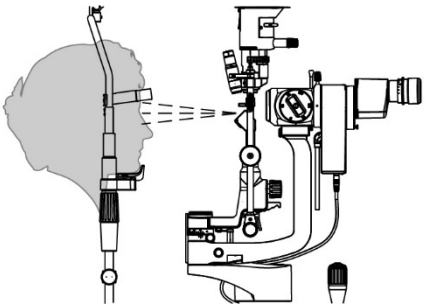


Fig. 37 - Patient position on chin rest SL9900 - SL9900 ELITE

4 Raise or lower the chin cup by rotating the knob.

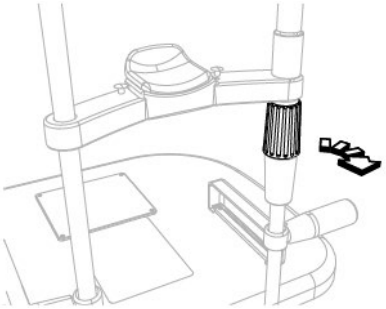


Fig. 38 - Knob rotation

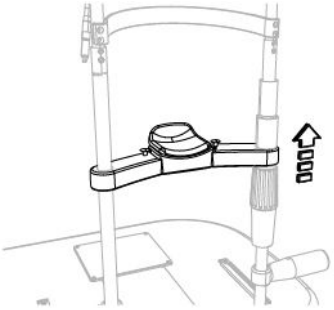


Fig. 39 - Chin cup positioning

4.7 HOW TO DISPLAY THE IMAGE (SL9800)

1 Move towards the patient's eye with the device.
Maintain a distance from the patient of d=68 mm with the prism holder head
Maintain a distance from the patient of d=80 mm with the split head

2 Move the joystick and place the device with the shooting channel near the patient's eye.

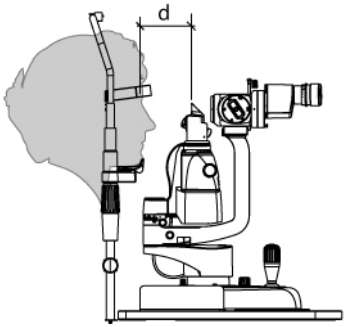


Fig. 40 - Distance from the patient

3 Adjust the eyepieces' interpupillary distance.

4 If necessary, pull out the sliding eyepiece covers. The eyepiece covers are suitable for spectacles wearers.

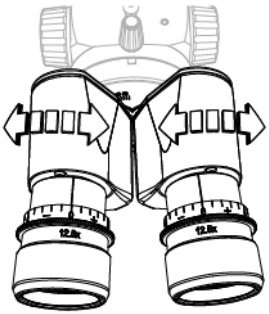


Fig. 41 - Interpupillary distance adjustment

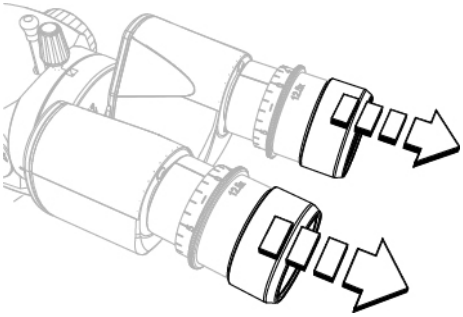


Fig. 42 - Eyepiece cover placement

5 Bring the image into focus by rotating the eyepieces to correct the refractive error.

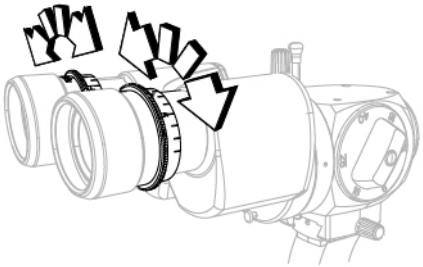


Fig. 43 - Refractive error correction

6 Turn the dial (A) to select the diaphragm diameter and slit height.
7 Turn the filter selector (B) to select the filters.
8 Insert the yellow filter by lifting the rod on the microscope.

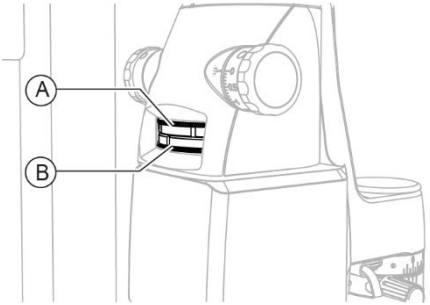


Fig. 44 - Select the diaphragm diameter, the slit height (A) and the filters (B)

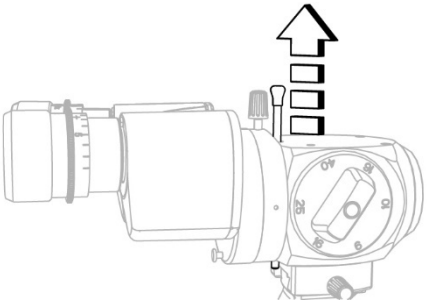


Fig. 45 - Insert the yellow filter

9 Perform some micro movements with the joystick to obtain the best image quality.
10 Use the locking/unlocking knob to change the microscope position.

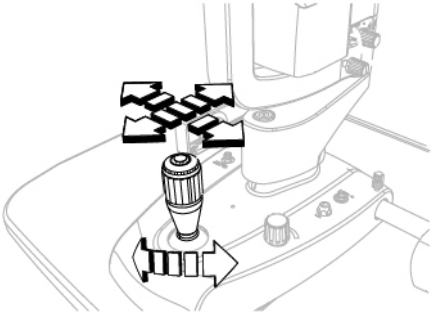


Fig. 46 - Device positioning

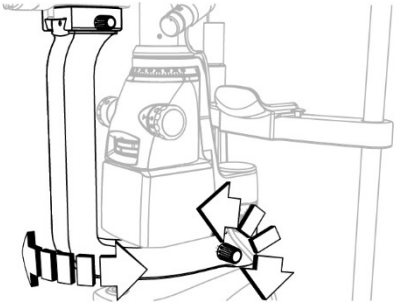


Fig. 47 - Microscope position adjustment

11 Use the locking/unlocking knob to change the lighting assembly position.
12 To adjust the intensity of the light, turn the knob on the device base.

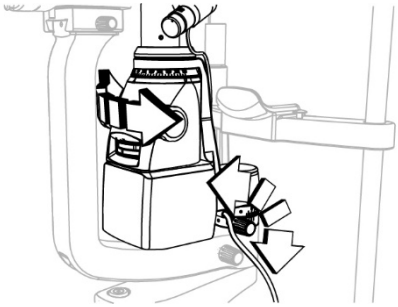


Fig. 48 - Lighting assembly locking knob

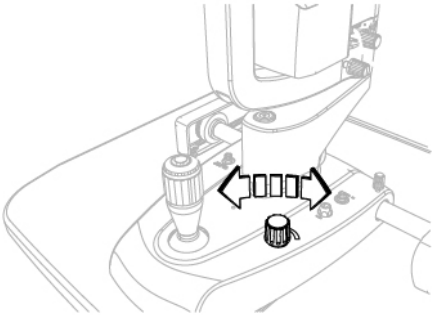


Fig. 49 - Light intensity adjustment

13 During the examination, adjust the slit width.
14 If necessary, change the image magnification.

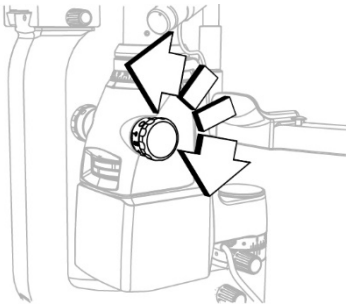


Fig. 50 - Slit width adjustment

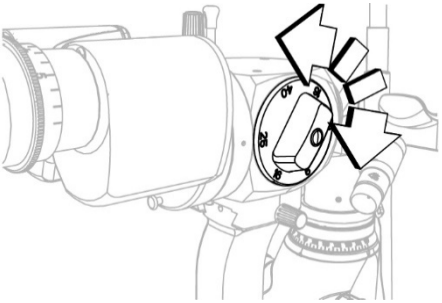


Fig. 51 - Microscope magnification change

15 If necessary, readjust the slit rotation again, checking the value on the dial with rotation indicator (A).

16 If necessary, readjust the position of the lighting assembly.

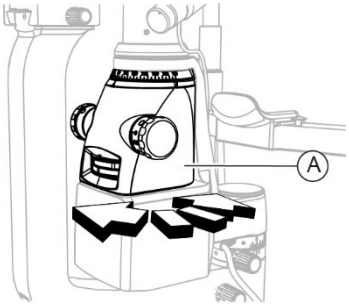


Fig. 52 - Slit rotation

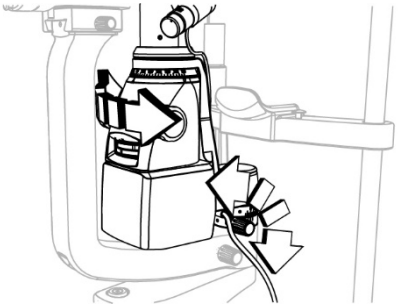


Fig. 53 - Adjusting the projection angle of the lighting assembly

4.8 HOW TO VIEW THE IMAGE (SL9900 AND SL9900 ELITE)

1 Move towards the patient's eye with the device.

2 Move the joystick and place the device with the shooting channel near the patient's eye.

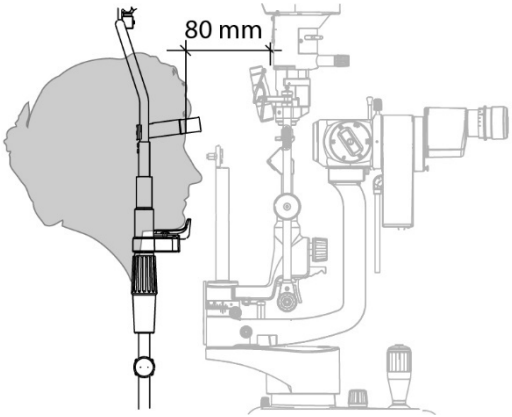


Fig. 54 - Distance from the patient

3 Adjust the eyepieces' interpupillary distance.

4 If necessary, pull out the sliding eyepiece covers. The eyepiece covers are suitable for spectacles wearers.

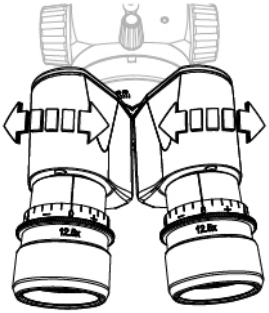


Fig. 55 - Interpupillary distance adjustment

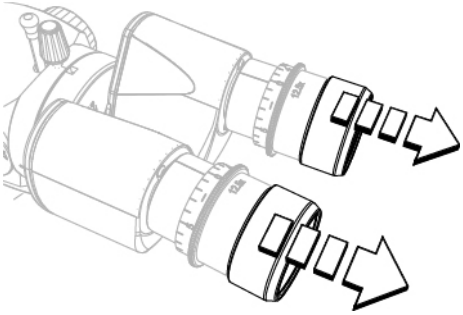


Fig. 56 - Eyepiece cover placement

5 Bring the image into focus by rotating the eyepieces to correct the refractive error.

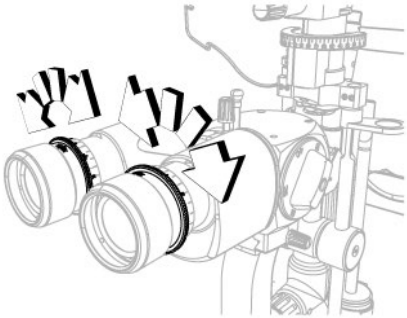


Fig. 57 - Refractive error correction

6 Adjust the slit width.

7 Insert the yellow filter by lifting the rod on the microscope.

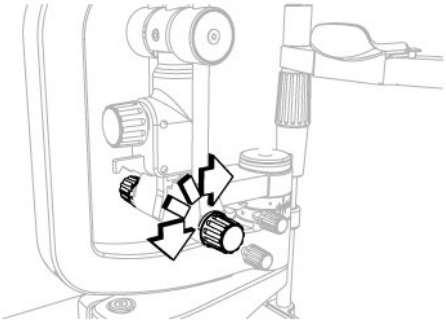


Fig. 58 - Slit width adjustment

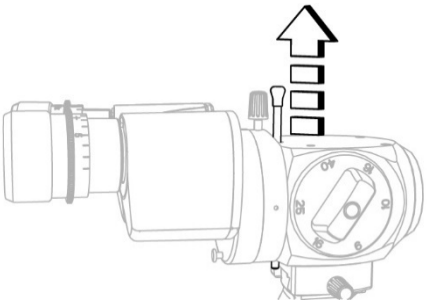


Fig. 59 - Insert the yellow filter

8 Perform some micro movements with the joystick to obtain the best image quality.

9 Use the locking/unlocking knob to change the microscope position.

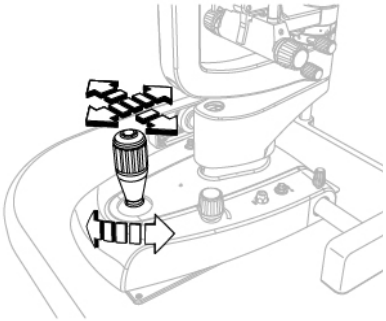


Fig. 60 - Device positioning

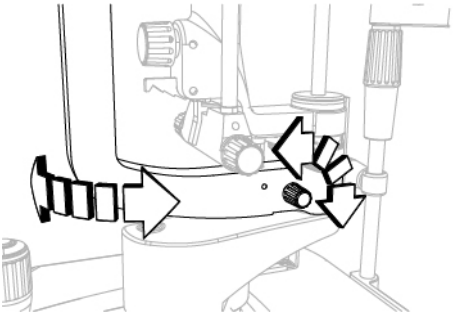


Fig. 61 - Microscope position adjustment

10 Use the locking/unlocking knob to change the lighting assembly position.

11 To adjust the intensity of the light, turn the knob on the device base.

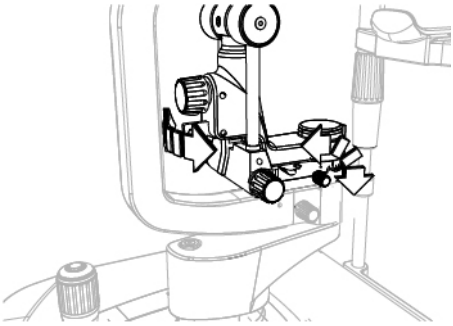


Fig. 62 - Adjusting the projection angle of the lighting assembly

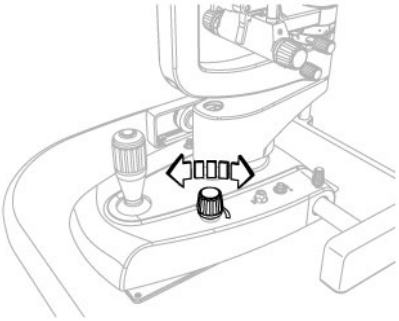


Fig. 63 - Light intensity adjustment

12 During the examination, adjust the slit height.

13 If necessary, change the microscope magnification.

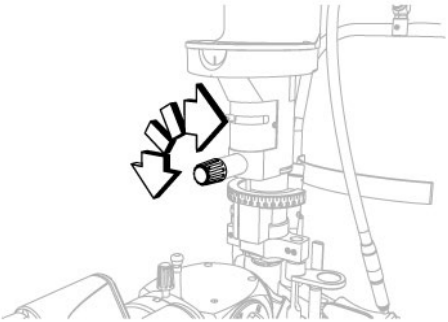


Fig. 64 - Adjust the slit height

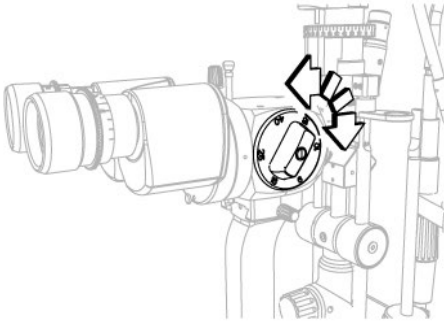


Fig. 65 - Microscope magnification change

14 Adjust the slit rotation by checking the value on the dial with rotation indicator (A) to correctly position the lighting unit.

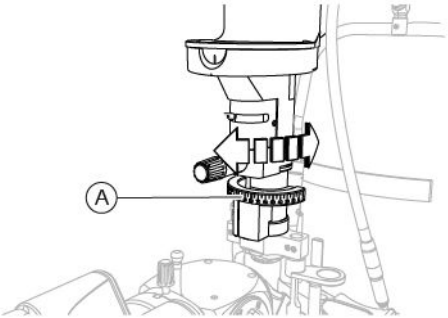


Fig. 66 - Slit rotation

15 To adjust the horizontal tilting loosen the knob (A). Tighten the knob to lock in position.

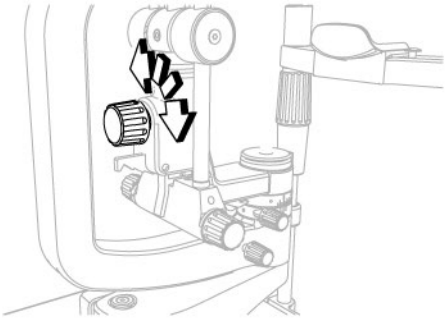


Fig. 67 - Locking/unlocking knob

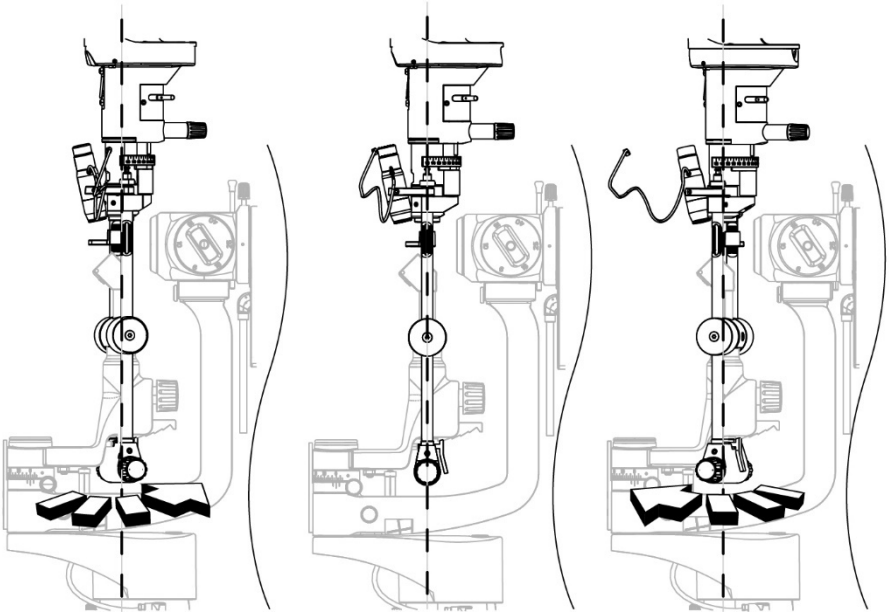


Fig. 68 - Horizontal tilting

16 To adjust the vertical tilting press the locking lever (C). The lamp can be tilted using the adjustment steps of the locking lever.

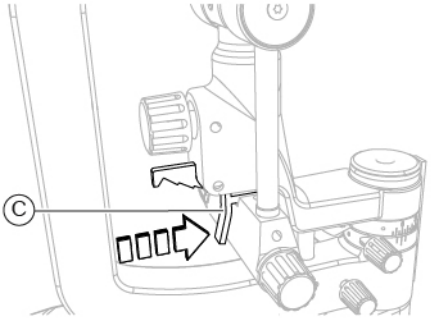


Fig. 69 - Locking lever for vertical tilting

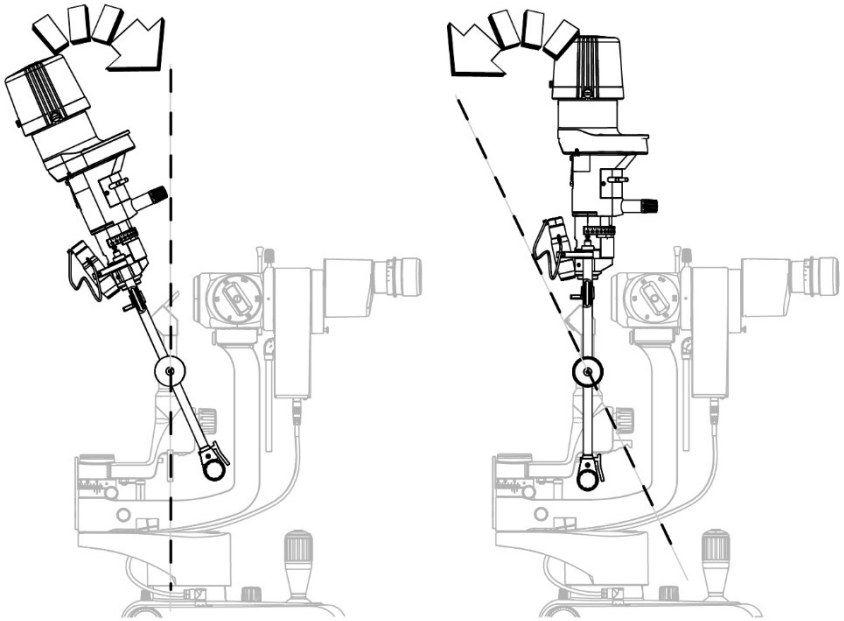


Fig. 70 - Vertical tilting

4.9 HOW TO ACQUIRE THE IMAGE (XX-D)

If the device is equipped with a video camera, it is possible to acquire images with the management application software and then analyse them.

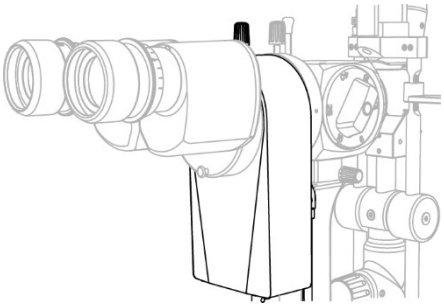


Fig. 71 - Mizar video camera

1 Focus the image by moving the joystick.
2 Press the joystick button to acquire the image. It is possible to capture multiple images at the same time. The image will be saved in the gallery.

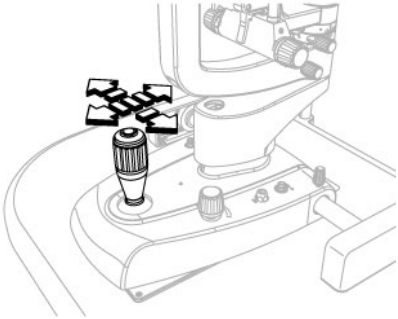


Fig. 72 - Image focusing

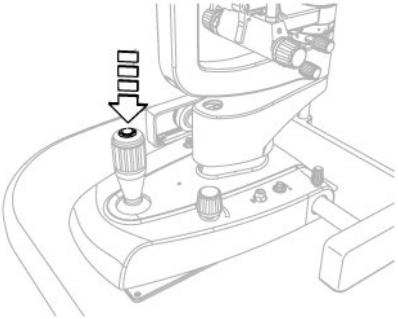


Fig. 73 - Image acquisition

4.10 HOW TO CHANGE CHIN CUP PAPERS

At the end of each examination, always remove the chin cup paper, so that there is always a new one, to ensure hygiene for the next patient.

The device is provided with a pack of chin cup papers. After using the last chin cup paper, replace the pack.

1 Clean the chin cup using a non-abrasive cloth to avoid damaging the material.
2 Extract the two plastic rivets.
3 Position the new pack of chin cup papers.
4 Replace the plastic rivets in the holes of the pack and in the holes of the chin cup.

Fig. 74 - Chin cup paper replacement

To request spare parts, specify the code given in paragraph **"List of spare parts and accessories" on page 76.**

4.11 HOW TO TURN OFF THE DEVICE

CAUTION
Do not turn off the computer and do not disconnect the connection cable between the computer and the device when the program is in use (Xx-D).

1 Lock the device. Turn the locking knob.

If the device is equipped with video camera (Xx-D):

Exit the application software.
Turn off the PC.

2 Switch the power switch of the power supply unit to turn it OFF.
3 Place the dust cover on the device to prevent dust accumulation.

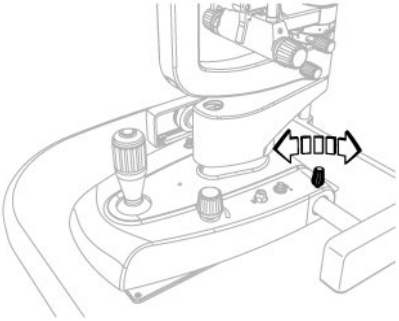


Fig. 75 - Device locking

4.12 HOW TO INSTALL THE ACCESSORIES

The accessories described may be optional and vary depending on the device model.

4.12.1 HOW TO INSTALL THE VIDEO CAMERA (XX-D)

The 2x microscope does not support video camera installation.

1 Support the binoculars (A).
2 Loosen the locking/unlocking knob on the microscope (B).
3 Remove the binoculars.
4 Bring the video camera (C) close to the microscope (D).
5 Loosen the locking/unlocking knob on the microscope.
6 Install the video camera.
7 Tighten the locking/unlocking knob on the microscope.

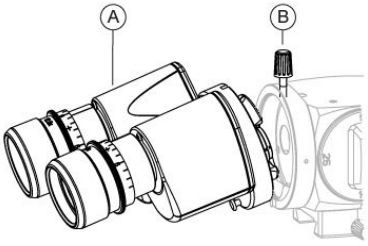


Fig. 76 - Binoculars removal

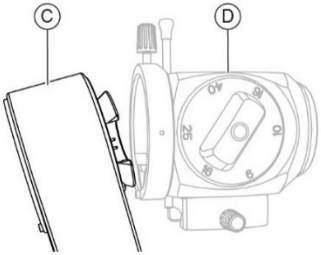


Fig. 77 - Installing the video camera

8 Loosen the locking/unlocking grub screw on the video camera.
9 Install the binoculars.
10 Tighten the locking/unlocking grub screw on the video camera.
11 Connect the connection cable (E) of the video camera to the connector on the device base.
12 Connect the USB 3.0 cable (F) of the video camera to the PC.

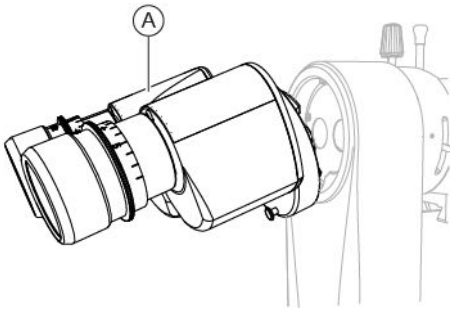


Fig. 78 - Binoculars installation

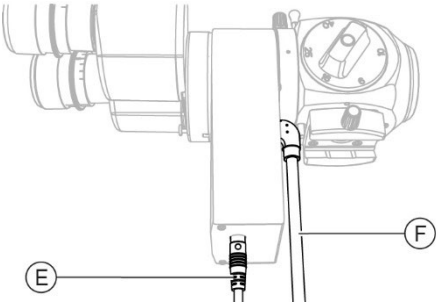


Fig. 79 - Connecting the video camera

4.12.2 HOW TO INSTALL THE ILLUMINATOR (SL9800)

1 Place the illuminator (A) next to the lighting assembly.
2 Tighten the screw (B) to fasten the illuminator.
3 Connect the connection cable (D) to the connector (E) on the circuit board of the lighting unit.
4 The LED (F) shows the operating status of the lighting unit.
5 To turn on the illuminator and adjust the light intensity; turn the knob (C).

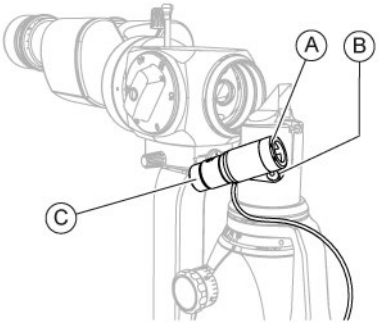


Fig. 80 - Illuminator installation

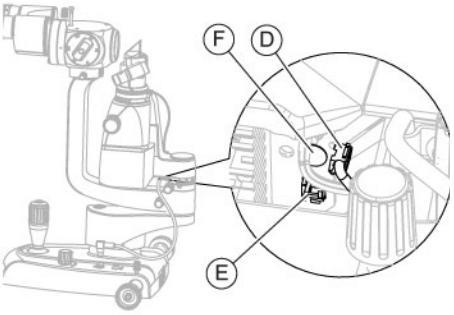


Fig. 81 - Connecting the illuminator

4.12.3 HOW INSTALL THE ILLUMINATOR (SL9900 AND SL9900 ELITE)

1 Turn the slit width adjustment knob in order to lower the rod (E).
2 Manually lift the component (D) and hold it up.
3 Insert the flat ring (I) on the rod (E). The ring has to lean on the part (J).
4 Insert the illuminator arm (C) on the rod.
5 Insert the round ring (H) on the rod.
6 Insert the locking ring (F) on the rod.
7 Screw in the screw (G) of the locking ring.
8 Manually lower the component (D).
9 Unscrew the screws (M) and lift the protection (K).
10 Connect the connection cable (L) to the connector on the illuminator.
11 Reassemble the protection (K) and tighten the screws (M).
12 Turn the knob (A) to turn on the illuminator and adjust the light intensity.

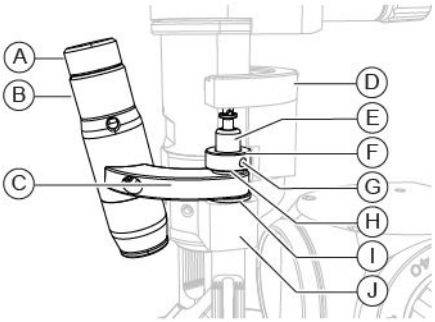


Fig. 82 - Illuminator installation

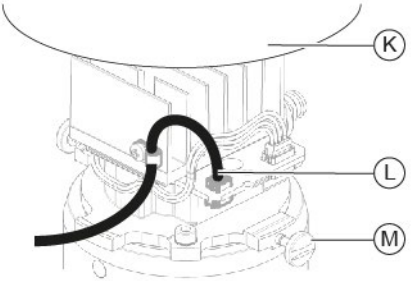


Fig. 83 - Connecting the illuminator

4.12.4 HOW TO INSTALL THE ADDITIONAL LIGHT DIFFUSION FILTER (SL9900 AND SL9900 ELITE)

To install the additional light diffusion filter:

1 Insert the light diffusion filter (B) on the rod (D). Use the opening (A) on the light diffusion filter and the profile (C) on the rod.

2 Lift the light diffusion filter upwards to fasten it on the rod.

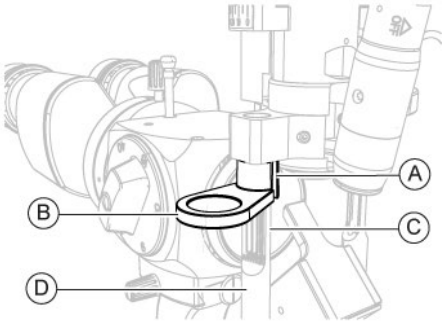


Fig. 84 - Installing the light diffusion filter

To use the additional light diffusion filter:

1 Turn the light diffusion filter horizontally on the rod.

2 Position the light diffusion filter in line with the illuminator.

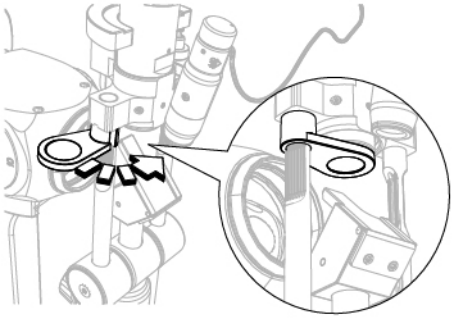


Fig. 85 - Positioning the light diffusion filter

4.12.5 HOW TO INSTALL THE SINGLE OR DOUBLE OUTPUT SPLITTER (XX-D)

The 2x microscope does not support video camera installation.

1 Support the binoculars (A).
2 Loosen the locking/unlocking knob on the microscope (B).
3 Remove the binoculars.
4 Position the separator (C) near the microscope (D).
5 Loosen the locking/unlocking knob on the microscope (B).
6 Install the separator.
7 Tighten the locking/unlocking knob on the microscope.

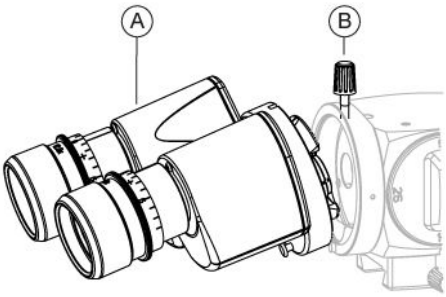


Fig. 86 - Binoculars removal

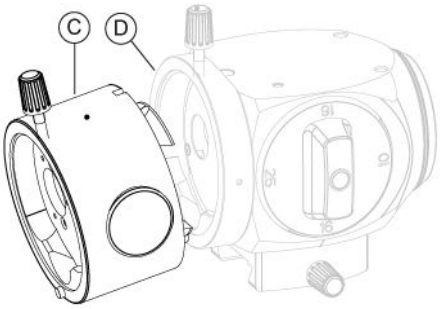


Fig. 87 - Installing the separator

8 Install the binoculars.
9 Tighten the locking/unlocking knob on the separator.

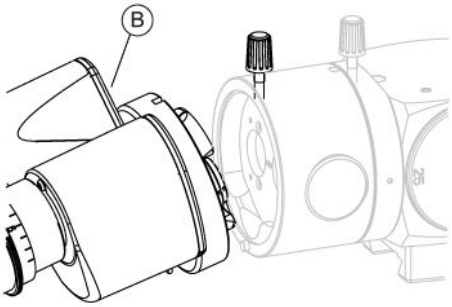


Fig. 88 - Binoculars installation

4.12.6 HOW TO INSTALL THE VIDEO CAMERA FITTING (XX-D)

Before installing the accessory, install the separator.

1 Remove the lid (C) installed on the separator (B).
2 Install the video camera fitting (A) on its seat on the separator. Align the plug (D) of the video camera fitting with the plug (E) on the separator.
3 Turn the dial (F) of the video camera fitting to fasten the fitting to the separator.

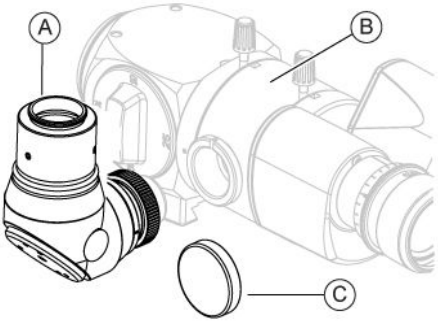


Fig. 89 - Video camera fitting

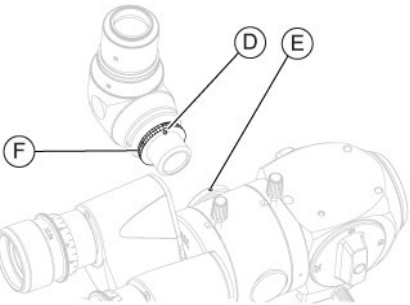


Fig. 90 - Fastening the video camera fitting

4.12.7 HOW TO INSTALL THE PHOTO CAMERA FITTING (XX-D)

Before installing the accessory, install the separator.

1 Remove the lid (C) installed on the separator (B).
2 Install the photo camera fitting (A) on its seat on the separator. Align the plug (D) of the photo camera fitting with the socket (E) on the seat of the separator.
3 Turn the dial (F) of the photo camera fitting to fasten the fitting to the separator.

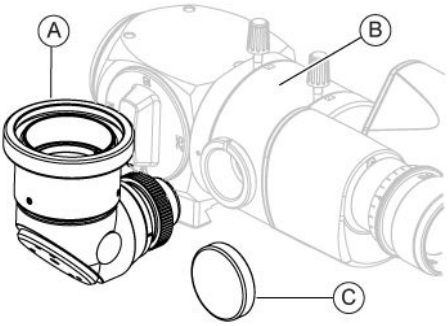


Fig. 91 - Photo camera fitting

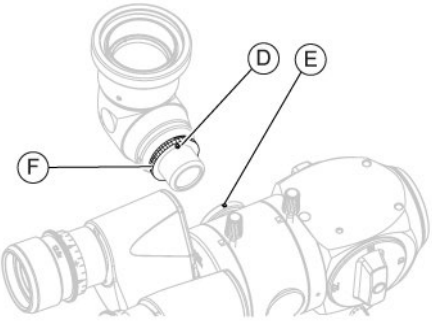


Fig. 92 - Fastening the photo camera fitting

4.12.8 HOW TO INSTALL THE EYEPIECE FOR THE SECOND OPERATOR

Before installing the accessory, install the separator.

1 Remove the lid (D) installed on the separator (B).
2 Lift the locking/unlocking knob (C) on the eyepiece for the second operator (A).
3 Install the eyepiece for the second operator on its seat on the separator. Align the plug (F) of the eyepiece for the second operator with the socket (G) on the seat of the separator.
4 Turn the dial (E) of the eyepiece for the second operator to fasten the eyepiece to the separator.

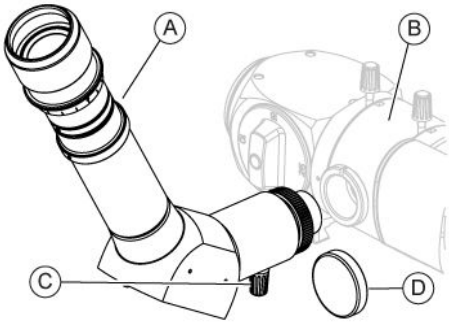


Fig. 93 - Eyepiece for the second operator

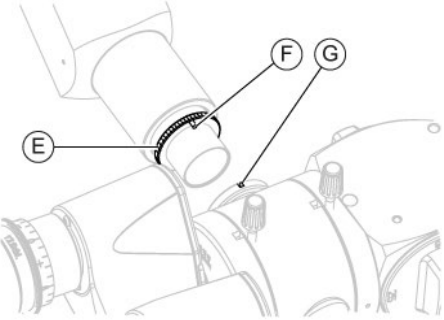


Fig. 94 - Locking the eyepiece for the second operator

4.12.9 HOW TO REPLACE THE EYEPIECES OF THE BINOCULARS

1 Remove the eyepieces installed on the binoculars.
2 Slightly press the new eyepieces on the binoculars to install them.
3 Check that the eyepieces are inserted correctly.

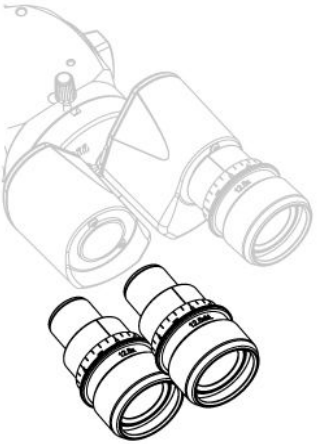


Fig. 95 - Eyepieces

5 ORDINARY MAINTENANCE

5.1 SAFETY WARNINGS

DANGER
Danger of electric shock. Unplug the power supply cable from the power socket before disinfecting or cleaning the device and before any maintenance operation.

CAUTION
The device does not contain any parts requiring user intervention. Do not remove any parts of the device.

It is forbidden to carry out any maintenance operation on the device not indicated in the instructions for use.

In the case of damage or malfunction or for any maintenance operations not indicated in the instructions for use, contact an authorised Service Centre or the device Manufacturer.

5.2 ELECTRICAL SAFETY CHECK

DANGER
Electrical danger due to age and wear.
The electrical safety of the device may decrease with age and wear.
Follow and comply with the regulations in force in the country of use regarding electrical tests on devices.
Otherwise, have an electrical safety test performed at least once a year in accordance with IEC 62353 by the manufacturer or a qualified technician. Follow the procedure indicated in the technical manual issued by the manufacturer.
Record and keep evidence of the tests and measurements taken during tests.
The test ends with a device operation test. This operation must be performed by a person familiar with the device application.

5.3 CLEANING AND DISINFECTION

CAUTION
Carefully follow the instructions for cleaning and disinfection described in this manual, in order to avoid any damage to the device and accessories.

CAUTION
A correct cleaning and disinfection procedure, together with appropriate operating procedures, is essential to preventing the spread of infections or cross contamination.

CAUTION
Danger of material damage. Do not use spray products.
Do not use excessively wet cloths, as they may drip.
If needed, use a damp and well wrung out cloth.
Make sure no liquid penetrates into the device.

Cleaning and disinfection procedures must be carried out regularly.

Device parts that do not come into direct contact with the patient must be cleaned at least once a day.
Device parts that do come into direct contact with the patient must be thoroughly cleaned and disinfected after each use.

This section describes the procedures to be carried out during use and maintenance in order to ensure proper cleaning and disinfection of the device and its accessories.

5.3.1 RECOMMENDED PRODUCTS FOR CLEANING AND DISINFECTION

CAUTION
Danger of material damage. Do not use solvents, acidic or basic solutions (pH <4,5 or >8,0), abrasive or caustic substances, chlorine-based and chlorine-derived products.
The Manufacturer is not liable for any damage caused by using disinfectant products not indicated in this manual.

The choice of the most suitable product and procedures for the cleaning and disinfection of the device must take into account both the sensitivity of the device to specific substances and the effectiveness of the product.
For the cleaning and disinfection procedures, use products approved by the FDA or EC for medical devices or medical-surgical devices.
Use the products as listed below, divided by category:

Detergents	Use polyenzymatic solutions or neutral surfactant-based solutions.
Disinfectants and decontaminating products	Use products for disinfecting surfaces (containing or not containing aldehyde) or formaldehyde-free surface disinfectants (i.e. Kohrsolin FF). Alternatively, you may use ethyl alcohol, 70% v/v alcohol or isopropyl alcohol.

For information about the use of the chosen product, follow the instructions provided by the manufacturer.

5.3.2 CLASSIFICATION OF THE CRITICALITY OF THE DEVICE

CAUTION
The device supplied is not sterile and must not be sterilised prior to use.

This device is classified as "non-critical" since it is only used on intact skin and therefore has a low infectious risk.
For devices classified as non-critical, regular cleaning or low-level disinfection is sufficient. However, when the patient's condition is transmissible by direct contact or in case of accidental exposure to body fluids, the device must be disinfected with a higher-level disinfectant after cleaning.

5.3.3 DEVICE CLEANING

CAUTION
Carefully follow the cleaning instructions described in this section in order to avoid damage to the device and its accessories.

CAUTION
Danger of material damage. Clean using a non-abrasive cloth to avoid damaging the surface.

The device must be regularly cleaned.

The device is provided with a cover for protection from dust, especially during periods of non-use.

Clean the outer parts of the device using a damp, non-abrasive cloth and a rinse-free cleaning solution.

For more information about suitable cleaning products, read paragraph **"Recommended products for cleaning and disinfection" on page 73.**

5.3.4 CLEANING THE APPLIED PARTS

CAUTION
Danger of material damage. Only use detergent and disinfectant products specifically approved for medical devices or medical-surgical devices.

The applied parts that come into direct contact with the patient during the examination must be thoroughly cleaned after each use with a disinfectant approved for the purpose.

1 Turn off the device and unplug it from the power socket.
2 Clean the applied parts using products suitable for surface disinfection (they may contain aldehyde).
Alternatively, use a non-abrasive cloth soaked in a solution of water, ethyl alcohol (70% maximum) or isopropyl alcohol.

For more information about suitable cleaning products, read paragraph **"Recommended products for cleaning and disinfection" on page 73.**

5.3.5 CLEANING THE OPTICAL COMPONENTS

CAUTION
Danger of material damage. The device is equipped with optical components. The optical components of the device are precision and pressure-sensitive parts. Clean using a non-abrasive cloth to avoid damaging the surface.

Clean the optical components carefully using a dry, non-abrasive, lint-free cloth.

5.4 DEVICE EXCURSION CHECK

Check that the base sliding rod is well cleaned. Move the device base all the way to the right and all the way to the left, back and forth. Check that the device performs all movements completely.

5.5 LIST OF SPARE PARTS AND ACCESSORIES

Code	Description
100257720	SL9900 LED table top chin rest
100258700	SL9800 LED table top chin rest
103301800	45x90 cm table top with cogged wheels and drawer
330259900	Power supply unit - lamp base connection cable, length 80 cm per LED
330259901	Power supply unit - lamp base connection cable, length 5 m per LED
3001007ID3F	Network power supply cable
3001007EI3P	Isolation transformer - electric table cable
330701090	Electric table - power supply unit cable 50 cm
960270-00	Installation kit accessories
4014010	Chin cup papers
960206C00	Dust cover for SL9900
960102-00	Dust cover for SL9800
960206021.O	Projection mirror for SL9900
100250250	Light diffusion filter for SL9900 and SL9900 ELITE
100226619	12.5x eyepiece with light shield
330274300	2 m long USB 3.0 cable for 5 MP video camera
330274310	5 m long USB 3.0 cable for 5 MP video camera
330274303	Connection cable between the device base and the 5 MP video camera
100226627	Eyepiece plastic covering
100250090	Calibration testing tool

For spare parts or accessories not included in the list, ask the Manufacturer or local Dealer.

5.6 TROUBLESHOOTING

Issue	Cause	Solution	Note
The device does not switch ON	Power cable not connected to the power supply unit.	Connect the power supply cable of the device to the power supply unit. Switch the power switch of the power supply unit to turn it ON.	If the device is powered through the table, check the connection of the table to the electric network. Check the operation of the table fuses.
The PC does not switch on	Power cable not connected to the power supply unit.	Connect the power supply cable to the power supply unit. Switch the power switch of the power supply unit to turn it ON. Replace the PC.	Ensure that the electric system of the room is working correctly.
The operating system of the PC does not start	Hard Disk failure. Corrupted operating system.	Replace the Hard Disk. Reinstall the operating system. Replace the PC.	Contact Technical Assistance. Ensure that the new PC meets to the minimum requirements of the device.
The Phoenix application software does not start	Hard Disk failure. The anti-virus software is preventing the start of the Phoenix application software. Corrupted operating system. The Phoenix application software does not work properly.	Replace the Hard Disk. Check the anti-virus software settings. Reinstall the operating system. Reinstall the Phoenix application software.	Contact Technical Assistance. The installation of the Phoenix application software requires administrator privileges.

Issue	Cause	Solution	Note
The Phoenix application software does not work properly	The connection cable between the device and PC does not work properly. The anti-virus software interferes with the drivers of the Phoenix application software. The Phoenix application software is installed as local user.	Unplug and then re-plug the connection cable between the device and the PC. Replace the connection cable between the device and the PC. Uninstall the anti-virus software. Reinstall the Phoenix application software.	The installation of the Phoenix application software requires administrator privileges.
The Phoenix application software does not install	The PC does not meet the minimum requirements for the installation.	Follow the Phoenix application software installation instructions.	Make sure the PC characteristics meet the requirements of the Phoenix application software.
The PC mouse does not work	Connection cable with the PC disconnected. The power switch of the mouse is OFF. The mouse batteries are exhausted (only for wireless mouse).	Check that the mouse connection cable is properly inserted into the USB port. Turn on the mouse by switching the power switch to ON. Replace the mouse batteries (only for wireless mouse).	Check that the PC control panel does not show conflicts between devices.
The PC keyboard does not work	Connection cable with the PC disconnected. The power switch of the keyboard is switched to OFF. The keyboard batteries are exhausted (only for wireless keyboard).	Check that the keyboard connection cable is properly inserted into the USB port. Turn on the keyboard by switching the power switch to ON. Replace the keyboard batteries (only for wireless keyboard).	Check that the PC control panel does not show conflicts between devices.

Issue	Cause	Solution	Note
The images can't be saved in the database (Xx-D)	The database is not connected to the Phoenix application software. No network connection. The USB cable is faulty.	Check that the correct path to the "database.db3" file is specified on the database setup screen. Refresh the connection to the database file. Check that the network connection is working. Replace the USB cable.	Regularly check the connection to the data network. Use USB 3.0 cables only.
Failed image acquisition (Xx-D)	The patient moved or closed the eyes during the acquisition.	Ask the patient to keep their eyes open, look at the fixation light and not move their eyes.	
Failed image focusing	Presence of dust or grease on the optical parts of the device.	Clean the optical parts of the device with a soft cloth.	Make sure the patient does not touch the optical parts.
No recognition of the left/right portion of the eye by the device	No installation of the sticker pad under the device base. The position detector does not work.	Install the sticker pad under the device base.	Some colours and materials of the table top do not reflect the infrared light. Move a white paper below the device base to check the operation of the position detector.
Device movement difficulties (forward, back, left, right)	The joystick's plastic protection was not removed from the base during installation. The device locking knob is tight. The sliding rod is dirty.	Remove the joystick's plastic protection from the base. Loosen the device locking knob. Clean the sliding rod.	Before starting the examination, check that the device locking knob is loose.
The operation indicator does not turn on	The device power supply cable does not work or is disconnected.	Replace the device power supply cable.	

Issue	Cause	Solution	Note
The device does not generate any light	The device power supply cable does not work or is disconnected. The light intensity adjustment knob is at minimum. The slit is completely closed. The LED illumination does not work.	Replace the device power supply cable. Open the slit. Increase the light intensity. Replace the light source.	

COSTRUZIONE STRUMENTI OFTALMICI

Via degli Stagnacci 12/E | 50018 Scandicci (FI) | ITALY
Phone: +39 055 722191 | Fax: +39 055 721557

cso@csoitalia.it | www.csoitalia.it

SL9800SL9900IFUENGCSO0208032024