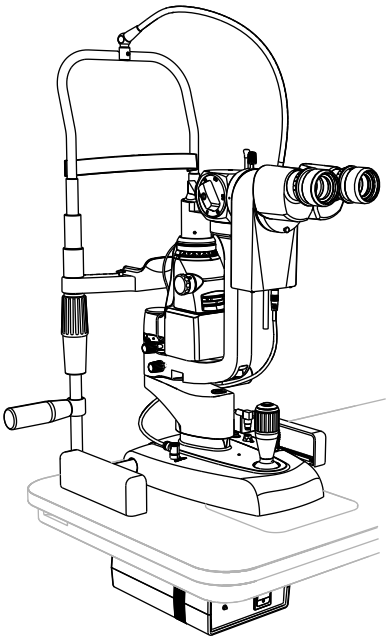
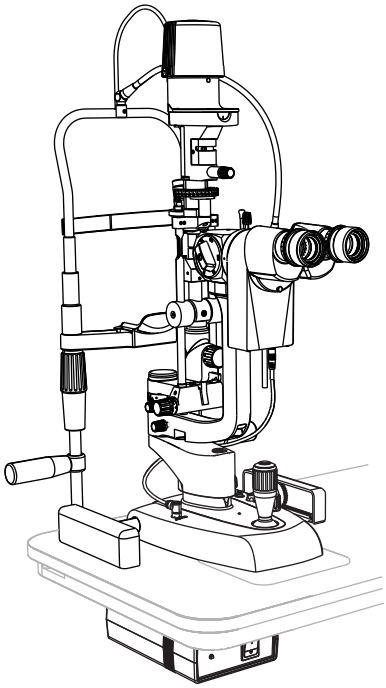
COSTRUZIONE STRUMENTI OFTALMICI





SLIT LAMP

INSTRUCTIONS FOR USE

SL9800 / SL9900 / SL9900 ELITE

COSTRUZIONE STRUMENTI OFTALMICI

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IFU305EN02.07 - 10/2023

EN

1 INTRODUCTION

The slit lamp is the result of a long research period, carried out by experts in the sector in order to give the product technical innovation, quality and design.

1.1 SYMBOLS

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

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 THE SLIT LAMPS SL9800, SL9900 AND SL9900 ELITE ("DEVICE" FROM NOW ON).
THE DEVICE SL9800 IS EQUIPPED WITH ILLUMINATION FROM BELOW. THE DEVICES SL9900 AND SL9900 ELITE ARE EQUIPPED WITH ILLUMINATION FROM ABOVE AND TILTING OF THE LIGHTING ASSEMBLY. THE DEVICE SL9900 ELITE IS ALSO EQUIPPED WITH ILLUMINATOR.
THE DEVICES SL9800 AND SL9900 ARE AVAILABLE IN THE XX AND XX-D MODELS. THE DEVICE SL9900 ELITE DEVICE IS AVAILABLE IN THE XX-D MODEL.
THE CODING "XX" IDENTIFIES THE TYPE OF MICROSCOPE SUPPLIED WITH THE DEVICE AND INSTALLED ON THE OBSERVATION UNIT. THE CODING "-D" IDENTIFIES THE DIGITAL MODELS OF THE DEVICES, PROVIDED WITH DIGITAL SET-UP.

The information 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 configuration of the device may differ from the basic supply.

Within the instructions for use, the paragraphs dedicated to one or another device are marked with SL9800, SL9900 or SL9900 ELITE.
Some paragraphs are dedicated to specific device models only and are marked with the coding "Xx" or "Xx-D".
When not specified the paragraph is valid for all the devices and models.

THE ORIGINAL TEXT IS IN ITALIAN.

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

Always keep these instructions for use in an accessible and nearby place. Should you decide to sell the device to third parties, the instructions for use shall be handed over intact and legible.

Keep the original packaging, as free assistance does not cover failures caused by improper packaging of the device when this is shipped to an authorized Service Centre.

Before using the device, check that there is no sign of damages due to transport or an incorrect storage, that could compromise the correct functioning of the device.

It is forbidden to reproduce, totally or partially, 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 advance notice.

1.3 NORMATIVE REFERENCES

1.3.1 EU DIRECTIVES

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

1.3.2 TECHNICAL STANDARDS

- IEC 60601-1: 2005 + A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EC 60601-1-2:2014 Edition 4 Collateral Standard: Electromagnetic disturbances - Requirements and tests
- UNI EN ISO 15004-1:2009 Ophthalmic Instruments. Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic devices
- UNI EN ISO 15004-2:2007 Ophthalmic Instruments. Fundamental requirements and test methods - Part 2: Protection against light hazards
- UNI CEI EN ISO 14971:2012 Medical devices. Application of risk management to medical devices

1.3.3 QUALITY MANAGEMENT SYSTEM STANDARDS

- UNI CEI EN ISO 13485:2016 "Medical devices. Quality management systems - Requirements for regulatory purposes"

1.4 WARRANTY

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

- features
- safety and reliability
- CE marking

The Manufacturer refuses any responsibility for:

- installation and start-up operations not carried out in compliance with the indications and precautions reported in the instructions for use
- use of the device not complying with the indications and precautions reported in the instructions for use
- use of non-original accessories or spare parts
- repairs and safety checks carried out by personnel not being competent, qualified, trained and authorized by the Manufacturer
- non-compliance of the electrical system of the room where the device is installed 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 people, deriving from improper use of the device or from incorrect clinical assessments obtained through the use of the device

The Manufacturer guarantees the device for 24 months after the invoice date. The Warranty includes the substitution, at the Manufacturer's or an Authorized Service Centre, of components and materials and the relative labour. Shipping and transport fees are to be paid by the client.

The warranty does not cover:

- repairs of faults originating from natural disasters, mechanical shocks (fall, hit, etc), electrical system faults, negligence, improper use, maintenance or reparations carried out with non-original materials
- any other method of improper use and/or not foreseen 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 improper use of the device or by maintenance carried out by personnel not being authorized by the Manufacturer

To request maintenance or technical information on the device, contact an authorized Service Centre or directly the Manufacturer of the device.

The client will not be refunded for damage caused by device stoppage.

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 cables are damaged, have them replaced at an authorized Service Centre, in order 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.

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

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

CAUTION
Danger of falling device. Do not leave free cables in a place where people could walk.

CAUTION
Danger of stumbling and falling. Do not leave loose cables which may represent an obstacle or danger for the patient or operator.

CAUTION
Risk of electric shock. Do not touch the power supply cables with wet hands.

CAUTION
Risk of electric shock. Do not leave the power supply cables in contact with sharp edges or cutting parts. Always collect and fasten the power supply cables.

CAUTION
If a strange smell comes from the device, if the device emits heat or smoke, turn off the device immediately. Do not continue to use a damaged device or damaged part. Danger of injuries.

CAUTION
The power grid shall have a residual-current device (IΔn=30mA) and circuit breaker (Vn=230V) to protect the device. Place the device so that the power socket is easily accessible.

It is forbidden to carry out any maintenance operation on the device not mentioned 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 cable not authorized by the device Manufacturer.

It is forbidden to use the device outdoors.

The device does not generate and does not receive any electromagnetic interference if placed near other electrical appliances. No preventive or corrective actions are required.

The device is classified following the technical standard IEC 60601-1: 2005 + A1: 2012 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.

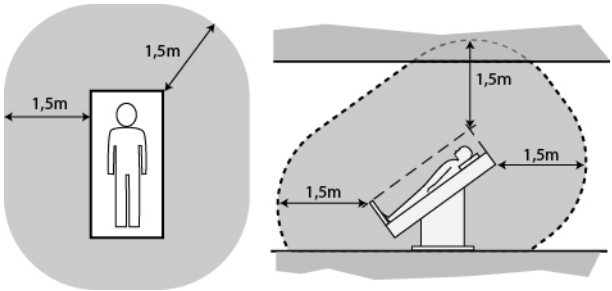

Fig. 1 - Patient area

2.2 DEVICE IDENTIFICATION

2.2.1 REGISTRATION DATA IN THE LIST OF MEDICAL DEVICES

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

2.2.2 DEVICE DATA PLATE

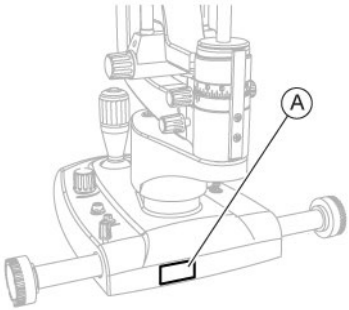

Fig. 2 - Data plate position

Pos	Description
A	Device data plate

SL9800 device, Xx and Xx-D model

Fig. 3 - Data plate for the Xx model

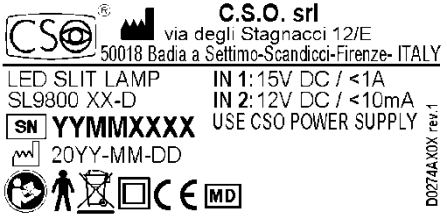

Fig. 4 - Data plate for the Xx-D model

SL9900 device, Xx and Xx-D model

Fig. 5 - Data plate for the Xx model

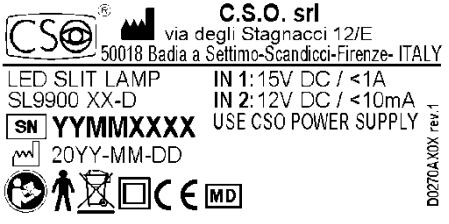

Fig. 6 - Data plate for the Xx-D model

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 the Xx-D models

2.2.4 POWER SUPPLY UNIT DATA PLATE

Fig. 9 - Data plate of the power supply unit

2.3 INTENDED USE

The device is characterized by an innovative design of the optical observation unit which adopts a multilayer anti-reflective treatment system. This system spreads the light in a more effective way and increases the optical resolution and the contrast up to the 20% compared with those typical for this kind of device.

The devices are useful for the ophthalmologist and the optician (in the environment of the 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. SRL devices

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
- NiBUT (acquired from other C.S.O. SRL devices)

Illumination (device SL9800)

The device is equipped with a professional LED illuminator placed in the lower part of the device. The LED illumination allows a 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 circa.

Illumination (device SL9900 and SL9900 ELITE)

The device is equipped with a professional LED illuminator placed in the upper part of the device. The LED illumination allows a 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 circa.

The tilting support allows to project the light vertically tilted up to 20°, with gaps of 5°. This is very useful in the horizontal optical observation, in the gonioscopy and in the 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 functioning at the maximum intensity exceeds the limit established by the Norm 15004-2. The maximum time of exposure to the light, when the light has the maximum intensity, doesn't have to exceed 160 seconds.

Microscope

Microscope with convergent optic, with yellow filter (for fluorescein examination): this filter allows a fast examination and a better images quality. Magnifications from 6x up to 40x. Bright images, clear and contrasted thanks to the multi strata antireflection 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 an excellent colour rendering. The increasing in resolution and in speed (doubled in the progressive live mode) make tiny details really sharp and displaying very flowing. The digital video camera is perfectly integrated with the new Phoenix application software, perfectly suitable for the needs of capturing and processing images (DICOM compatible). The application software allows to capture 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 rates	15 fps
Video modes	1280x960

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

For system requirements, read paragraph **"Personal Computer" on page 31.**

The device shall only be used by specialist practitioners and professionals (such as optometrists), within the limits of the law 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 based on the IEC 60601-1:2005 + A1:2012 technical standard

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 inflammable detergents	No protection
Degree of electrical connection between device and patient	Devices with part applied to the patient
Use conditions	Continuous functioning

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	-40°C	+70°C
	Atmospheric pressure	500 hPa	1060 hPa
	Relative humidity	10%	95%
Use	Temperature	+10°C	+35°C
	Atmospheric pressure	700 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 contained in its original packaging.

2.8 DISPOSAL AT THE END OF THE USEFUL LIFE

Warnings for the correct disposal of the device in accordance with Directive 2012/19/EU and Directive 2011/65/EU relating to the reduction of the use of hazardous substances in electrical and electronic equipment, as well as waste disposal.
At the end of its useful life, the device shall not be disposed of as urban waste. The device may be delivered to designated waste sorting centres set up by the municipal administration or to dealers that offer this service. Separately disposing of an electrical device prevents possible negative consequences for the environment and health, caused by its improper disposal, and lets the materials it is made of to be recycled so as to achieve significant savings of energy and resources. The symbol of the crossed-out wheeled bin is shown on the data plate of the device. The graphic symbol of the crossed-out wheeled bin indicates the obligation to separately collect and dispose of the electrical and electronic equipment at the end of their useful life.

The user has to consider the effects potentially dangerous for the environment and the human health originating from an improper disposal of the whole device or its parts.

In case the user wishes to dispose of the device used at the end of its useful life, the Manufacturer facilitates the possibility of its reuse and the recovery and recycling of the materials contained therein. This to prevent the release of hazardous substances into the environment and to promote conservation of natural resources. Before disposing of the device, it is necessary to take into consideration the European and national regulations that order what follows:

- not to dispose as urban waste but collect it separately and address to a firm specialized in the disposal of electrical and electronic equipment or to the local administration in charge for 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 of the new device, the Distributor or Manufacturer are legally required to collect the old device
- if the user decides to dispose a used device, put on the market after the 13th August 2005, the Distributor or the Manufacturer have to collect it
- the Manufacturer takes care, by joining a consortium for electronic waste, of the treatment and the recycling of the used device by paying its 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 transgressors are provided for by law.
For specific information about the disposal in countries other than Italy, contact the local Dealer.

2.9 MANUFACTURER DECLARATIONS

2.9.1 ELECTROMAGNETIC EMISSIONS

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 power grid 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 power grid 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 power grid like that of residential buildings.

Immunity test	IEC 60601-1-2 Proof level	Compliance level	Electromagnetic environment
Electrostatic discharge. IEC 61000-4-2	±6 kV on contact ±8 kV in air	±6 kV on contact ±8 kV in air	Floors shall be wood, concrete or ceramic tile. If the floors are covered with synthetic material the relative humidity should 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	Mains power quality shall 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	Mains power quality shall 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	Mains power quality shall be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterrupted power supply or battery.
Magnetic field at mains frequency (50/60Hz). IEC 61000-4-8	3 A/m	3 A/m	Power frequency of the magnetic fields should be that of 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 should 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: is the maximum output power rating of the transmitter in watts (W) according to the transmitter Manufacturer.

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

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should 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 electromagnetic environment exposed 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

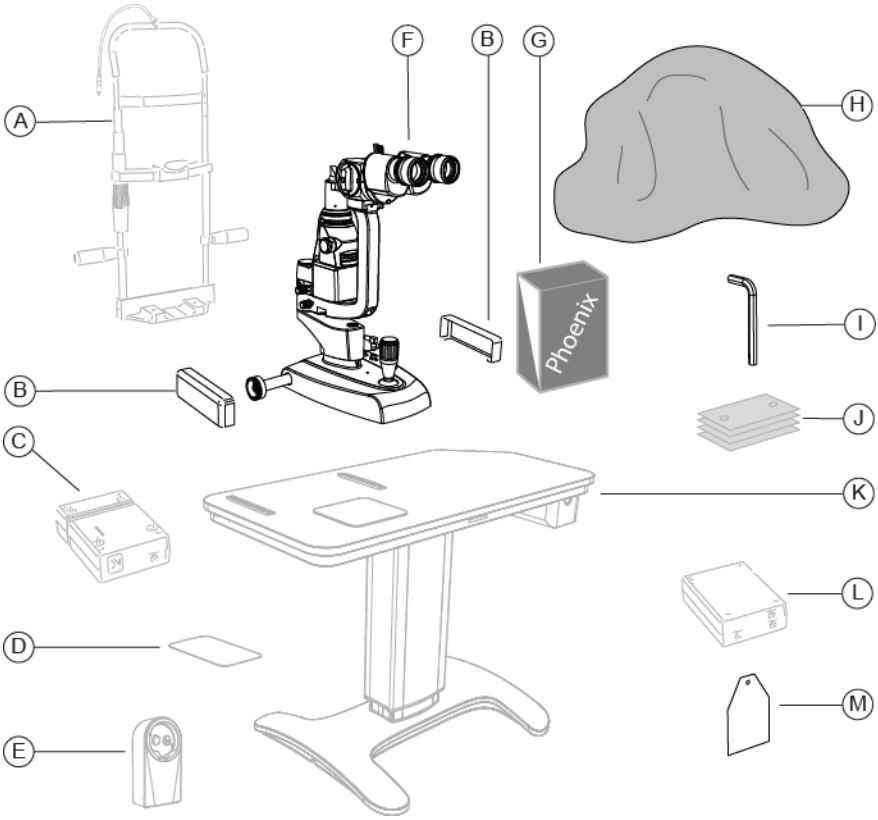

Fig. 10 - Supply description

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 shall be used in conjunction 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 equipped with one or two columns and electric height adjustment. Drawer and auxiliary power sockets with cable guides.
L	Isolation transformer	Optional	230V/230V for the use of the non-electromedical devices in the patient area.
M	Breathing shield		

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

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

Device SL9900 and SL9900 ELITE

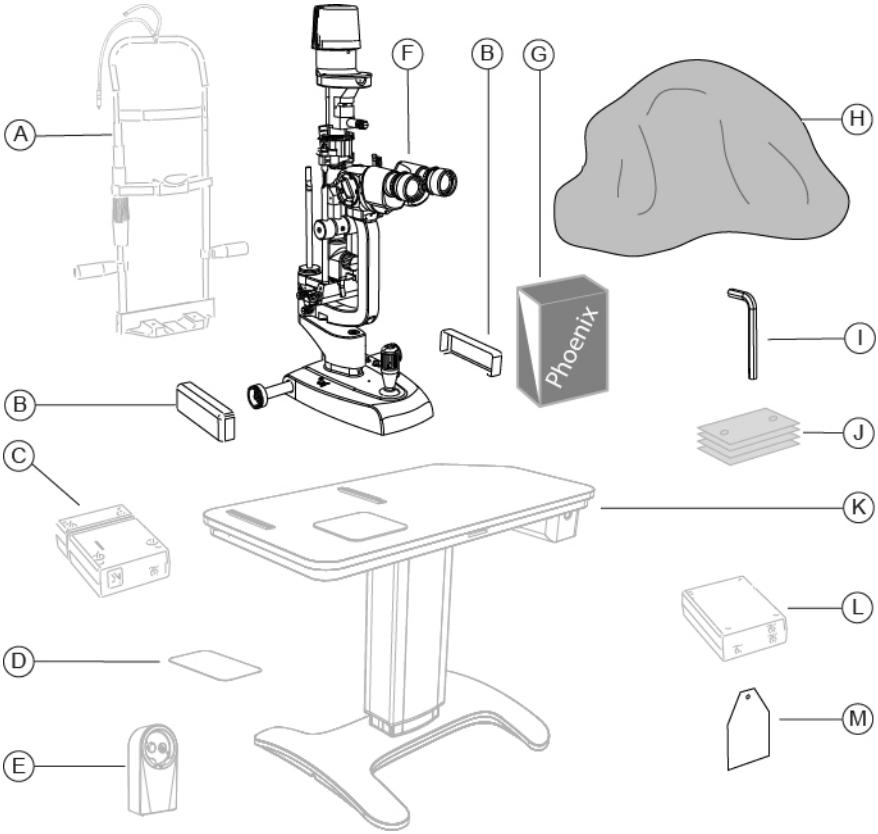

Fig. 11 - Supply description

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 tilting system of the lighting assembly.
G	Application software	Optional	Application software for image acquisition and device management. If the video camera is installed on the device, the device shall be used in conjunction 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 equipped with one or two columns and electric height adjustment. Drawer and auxiliary power sockets with cable guides.
L	Isolation transformer	Optional	230V/230V for the use of the non-electromedical devices in the patient area.
M	Breathing shield		

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

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

3.1.1 SL9800 DEVICE

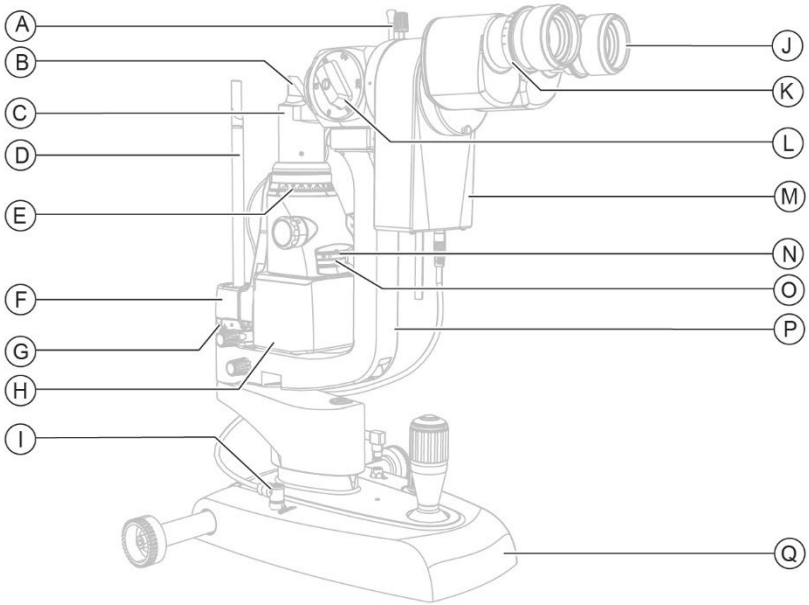

Fig. 12 - Device SL9800 - left side

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 reveal the lighting assembly position
H	Lighting unit	
I	Connector	To connect the device with the video camera
J	Eyepieces	
K	Graduated scale	To correct refractive errors
L	Microscope	
M	Video camera	Digital video camera (Optional)
N	Slit height adjustment dial	Equipped with graduated scale
O	Filter selector	
P	Microscope arm	
Q	Base	

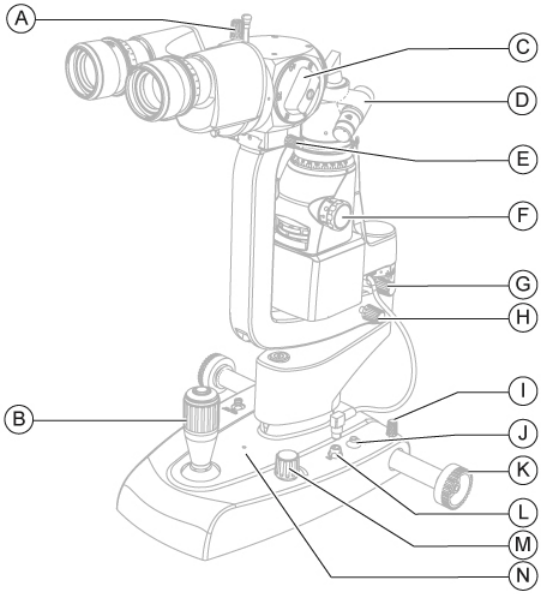

Fig. 13 - Device SL9800 - right side

Pos	Name	Description
A	Locking/unlocking knob for the binoculars or the video camera	
B	Joystick	
C	Microscope selector	To select magnifications
D	Illuminator	LED illuminator (Optional)
E	Microscope locking/unlocking knob	
F	Slit width adjustment knob	
G	Locking/unlocking knob of the lighting assembly arm	To adjust the arm rotation
H	Locking/unlocking knob of the microscope arm	To adjust the arm rotation
I	Locking/unlocking knob of the base	
J	Connector	To connect the device with the power supply unit
K	Cogged wheels	
L	Connector	To connect the base with the lighting assembly
M	Light intensity adjustment knob	
N	Operation indicator	

3.1.1 DEVICE SL9900 AND SL9900 ELITE

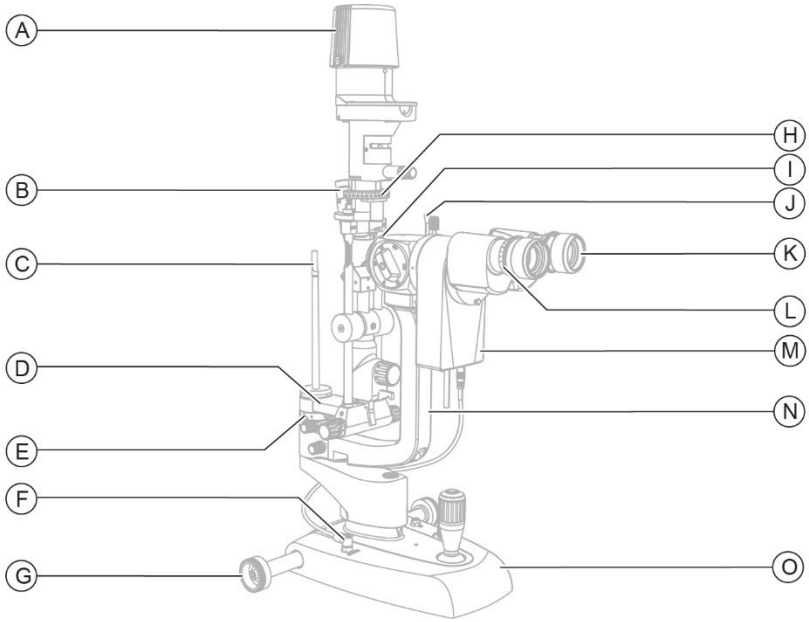

Fig. 14 - Device SL9900 and SL9900 ELITE - left side

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

The parts marked with (*) are optional for the device SL9900.

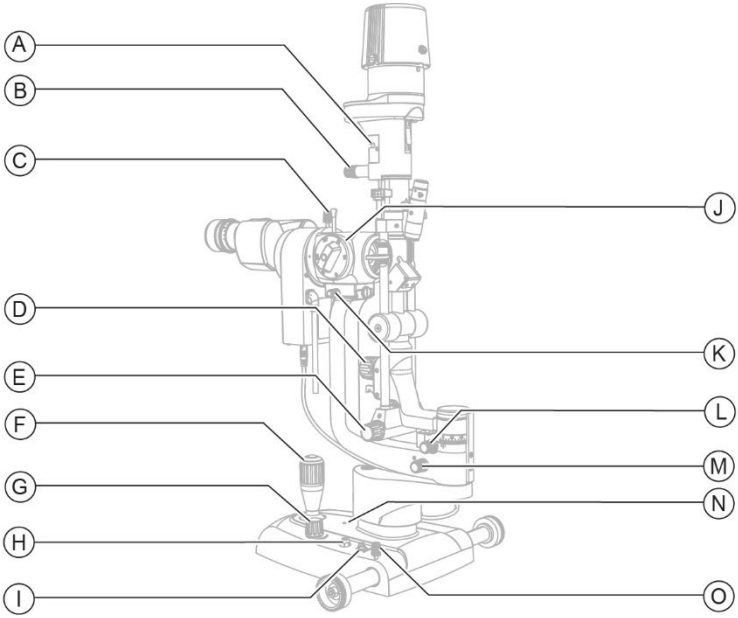

Fig. 15 - Device SL9900 and SL9900 ELITE - right side

Pos	Name	Description
A	Filter selector	
B	Slit height adjustment knob	
C	Locking/unlocking knob for the binoculars or the video camera	
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 magnifications
K	Microscope locking/unlocking knob	
L	Locking/unlocking knob of the lighting assembly arm	To adjust the arm rotation
M	Locking/unlocking knob of the microscope arm	To adjust the arm rotation
N	Operation indicator	
O	Locking knob of the base	

3.1.2 POWER SUPPLY UNIT

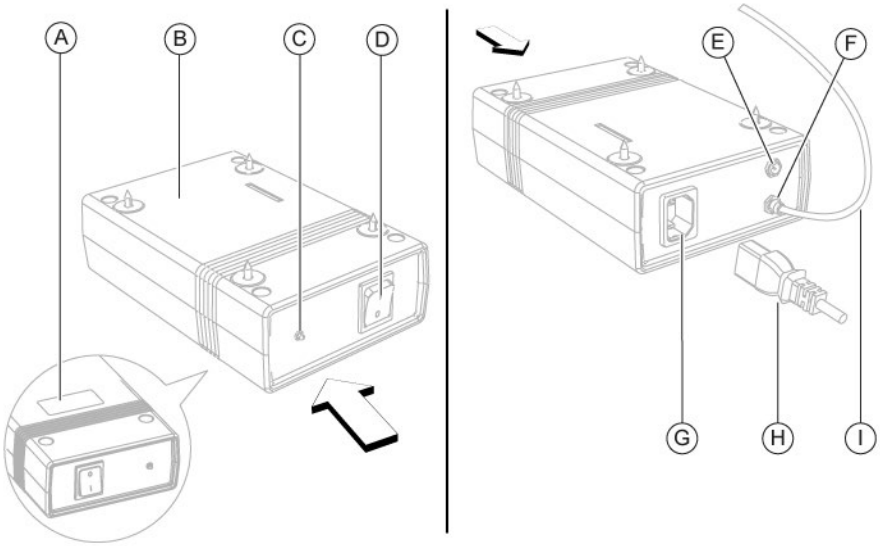

Fig. 16 - Power supply unit

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

3.1.3 CHIN REST

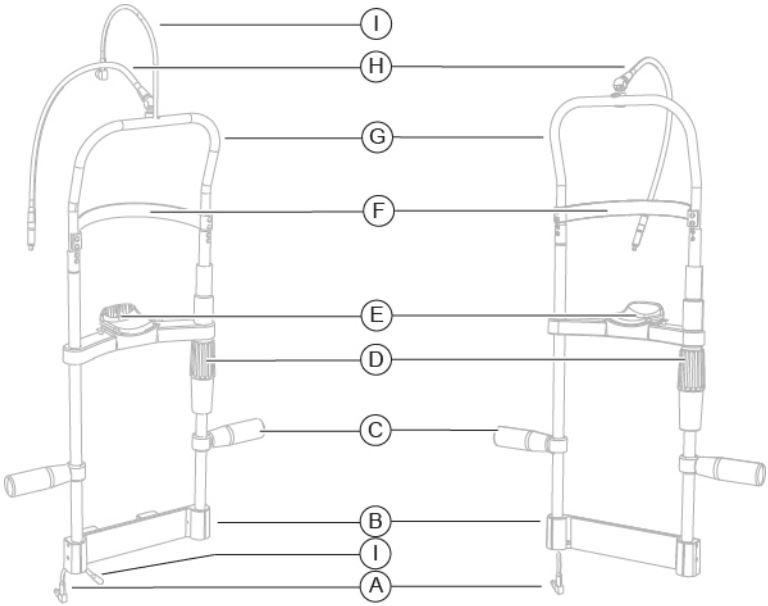

Fig. 17 - Chin rest for SL9900 and SL9900 ELITE device (left) and for SL9800 device (right)

Pos	Description
A	Power cable of the fixation point
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

3.1.4 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 guides 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. 18 - Ophthalmic table

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

3.1.5 PERSONAL COMPUTER

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

- PC: 4 GB RAM - 1 GB RAM Video Card (not shared) resolution 1280 x 960 pixels or higher
- Operating system: Windows 7 (32/64 bit), Windows 8 (64 bit) and Windows 10 (64 bit).

Read the document "Minimum PC requirements" which can be downloaded from the website www.csoitalia.it under the section "Documents - Software download" (registration required).
Read the instructions for use of the application software.

Fig. 19 - Personal Computer

The PC shall comply with standard IEC 60950-1 Information technology equipment - Safety - Part 1: General requirements.
If the PC is installed in the patient area it is necessary to install an isolation transformer compliant with the 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 ports interfaces. The accessories (printer, modem, scanner, etc) shall be installed outside the patient area.

The accessories shall comply with standard IEC 60950-1 Information technology equipment - Safety - Part 1: General requirements.
If the accessories are installed in the patient area it is necessary to install an isolation transformer compliant with the 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
Fine 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 mm	15 mm
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)
Illuminator	White LED	White LED
Slit rotation	± 90° continuous on Tabo system	± 90° continuous on Tabo system
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 mm	80 mm
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
Chinrest stroke	70 mm ±1

3.2.2 DEVICE SL9900 AND SL9900 ELITE

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
Fine 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 mm
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 system
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 mm
Horizontal decentration	± 4° reference on 0°
Device operating voltage	15V DC 1A
Light source type	White LED
Luminosity adjustment	Continuous adjustment

Technical data	Value
Light intensity	284000 Lux

Chin rest

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

To request spare parts, specify the code given in the paragraph **"Spare parts and accessories list" on page 73.**

3.2.3 MICROSCOPE

Microscope features differ depending on the chosen configuration: 2x, 3x, 5x and zoom.

Microscope 2x

The 2x microscope does not support the 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)

Technical data	Value
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
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 shall be lifted by two people.
2 If present, fasten the table wheels. Lower the brake lever.
3 Place the power supply unit under the table top. Screw the screws into the four holes.

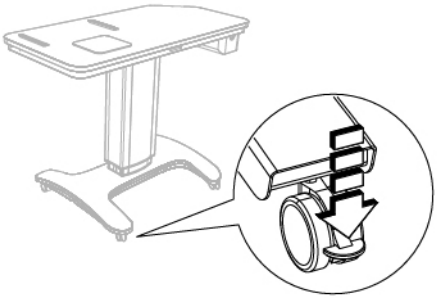

Fig. 20 - Place the ophthalmic table

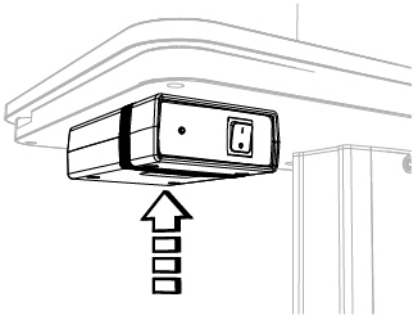

Fig. 21 - Place the power supply unit

4 Verify the position of the sticker relative to the central axis (A).

5 Remove the protective film. Place the sticker pad between the two guides and the sliding plate.

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

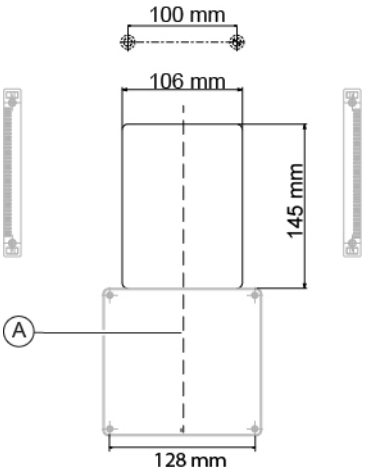

Fig. 22 - Distances for installing the sticker pad

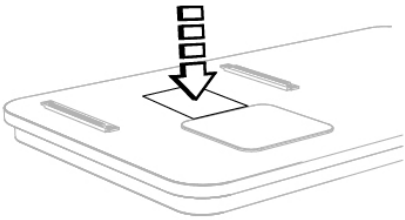

Fig. 23 - Place the sticker pad

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

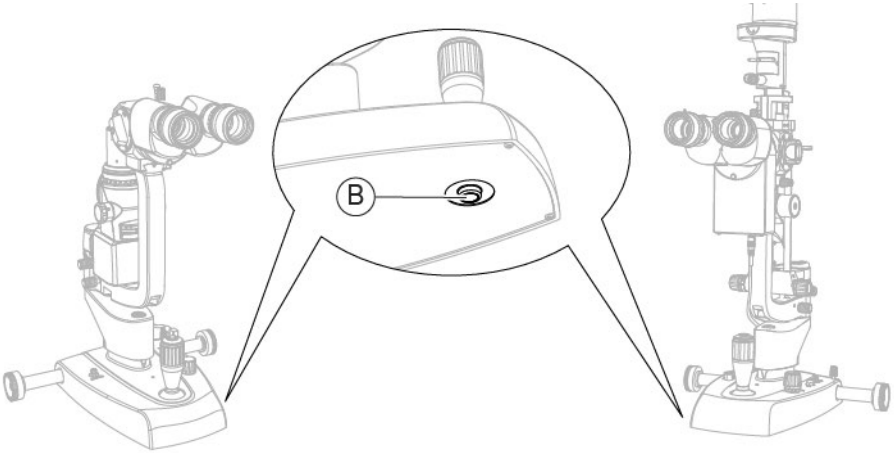

Fig. 24 - Remove the joystick protection

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

8 Install the two wheel covers on the guides on the table top.

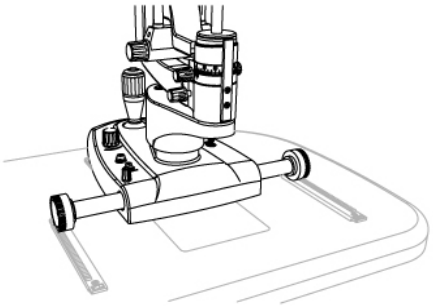

Fig. 25 - Place the device

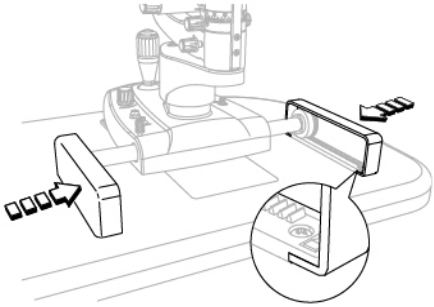

Fig. 26 - Install the wheel covers

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

The chin rest shall be installed so that the eye level indicator (1) is placed at a height of 380 mm from the table top.

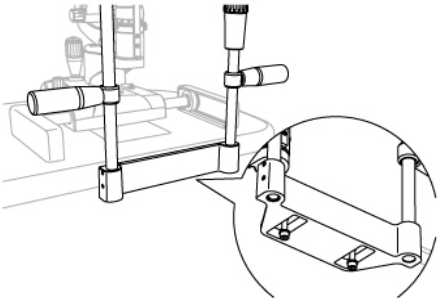

Fig. 27 - Place the chin rest

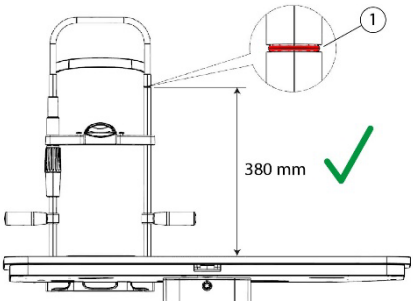

Fig. 28 - Correct height of the eye level indicator

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 reaching the required height of 380 mm. Tighten the previously loosened locking grub screws.

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

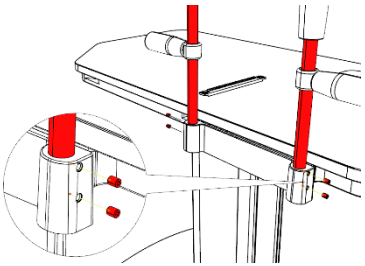

Fig. 29 - Loosen the grub screws of the chin rest

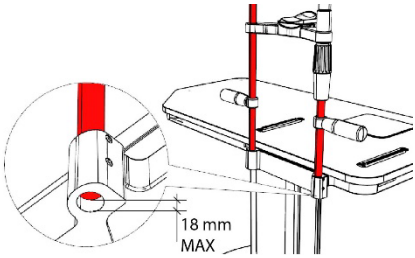

Fig. 30 - Maximum adjustment height of the rods

13 Carry out the electrical connections between the components.

4.2 HOW TO CONNECT THE DEVICE

SL9800 device

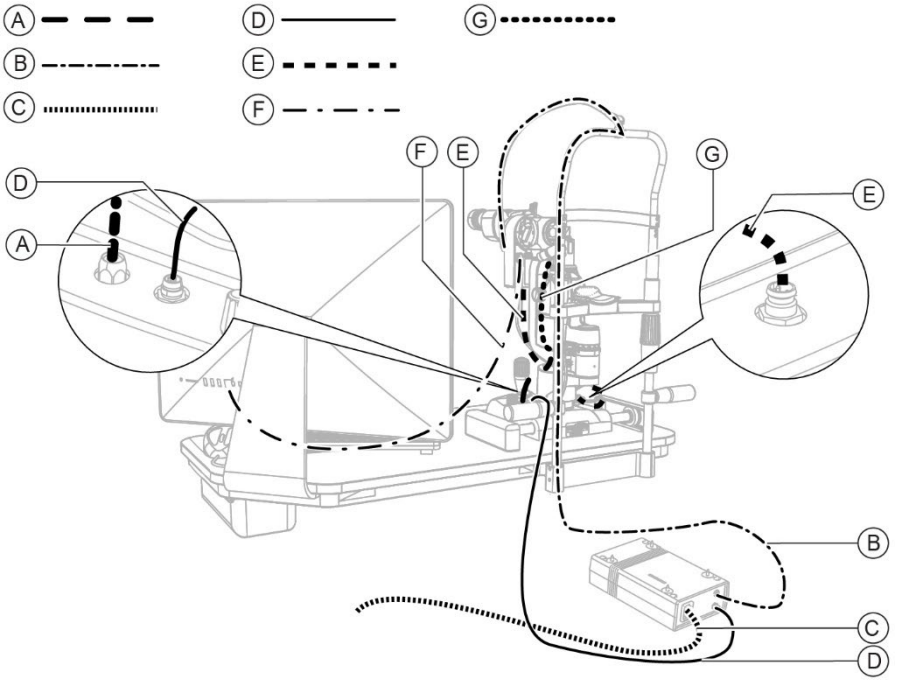

Fig. 31 - Connecting the device SL9800

Pos	Name
A	Connection cable between the base and the lighting unit
B	Power cable of the fixation point
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 power the table basement, read instructions for use of the table or of the ophthalmic unit.

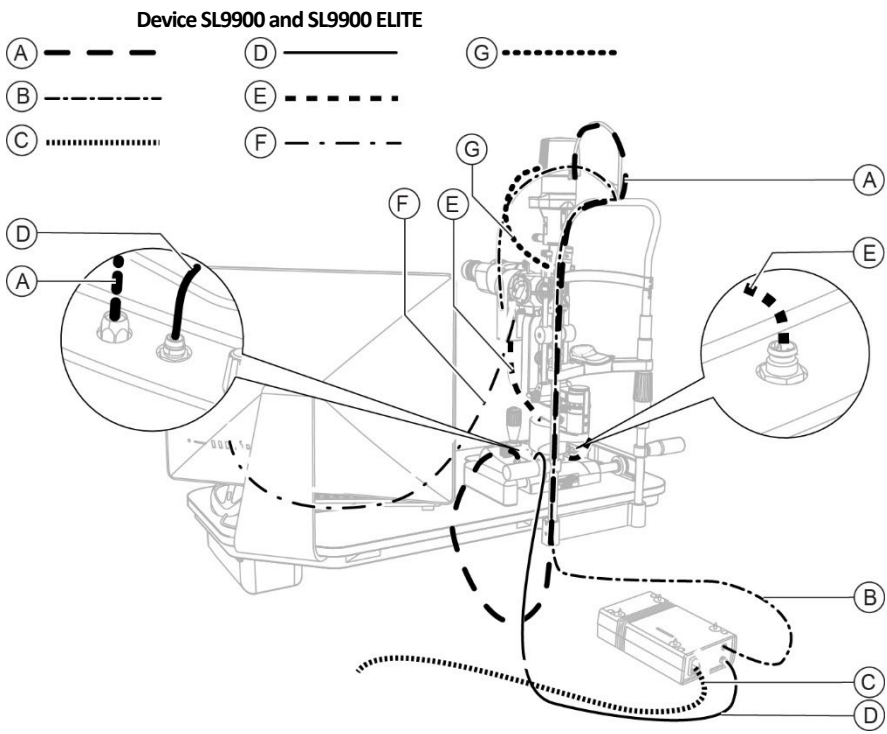

Fig. 32 - Connection of the device SL9900 and SL9900 ELITE

Pos	Name
A	Connection cable between the base and the lighting unit
B	Power cable of the fixation point
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 power the table basement, read instructions for use of the table or of the ophthalmic unit.

4.3 HOW TO PLACE THE ELECTRIC CABLES

CAUTION
Danger of falling device. Do not leave free cables in a place where people could walk.

CAUTION
Danger of stumbling and falling. Do not leave loose cables which may represent an obstacle or danger for the patient or operator.

CAUTION
Risk of electric shock. Do not leave the power supply cables in contact with sharp edges or cutting parts. Always collect and fasten the power supply cables.

It is forbidden to use any extension cable not authorized by the device Manufacturer.

For the proper placement of electrical cables and connection to the elevation column, read the instructions for use of ophthalmic tables or of 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 power grid. One of the power sockets placed 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 ON. The operation indicator on the device base turns on.
2 Now it is possible to go on 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 or you may read the application software guide.

1 Launch the Phoenix application software.
2 Wait until the main screen of the application software is displayed.
3 Click on NEW PATIENT and enter the 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. Image acquisition can be now carried out.

4.5 INDICATIONS GIVEN BY THE FUNCTIONING INDICATORS

For monitoring the device functioning it is necessary to verify the status of the operation indicator on the device base.

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

4.6 HOW TO ADJUST THE CHIN CUP

1 Ask the patient to take a seat.
2 Tell the patient how to take place on the chin cup and on the forehead rest.
3 Verify the correct eyes position respectively to the shooting channel.

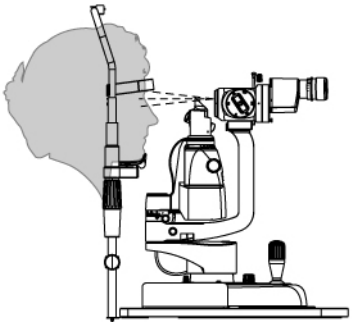

Fig. 33 - Patient position on the chin rest SL9800

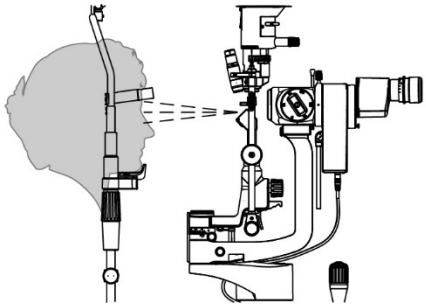

Fig. 34 - Patient position on the chin rest SL9900 - SL9900 ELITE

4 Turn the knob to lift or lower the chin cup.

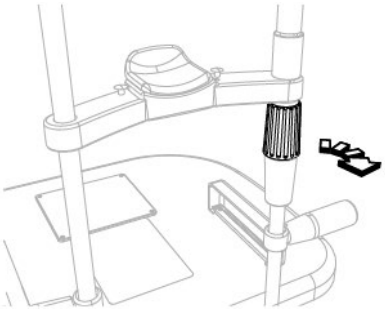

Fig. 35 - Knob rotation

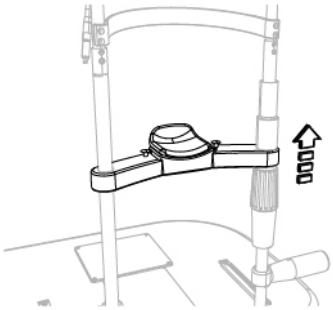

Fig. 36 - Placing the chin cup

4.7 HOW TO VISUALIZE THE IMAGE (SL9800)

1 Move towards the patient's eye with the device.
d=68 mm with prisma holder head
d=80 mm with split head

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

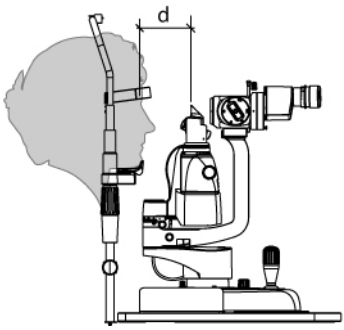

Fig. 37 - Distance from the patient

3 Adjust the eyepieces interpupillary distance.

4 If necessary, pull out the sliding eyecups. Eyepiece covers are suitable for spectacles wearers.

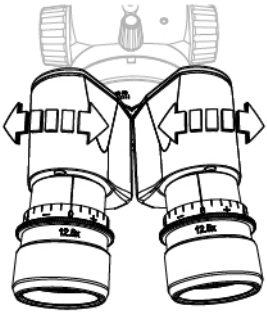

Fig. 38 - Interpupillary distance adjustment

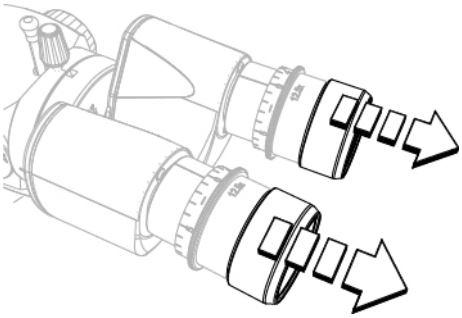

Fig. 39 - Placing the eyepiece covers

5 Bring the image into focus by rotating the eyepieces for the refractive error correction.

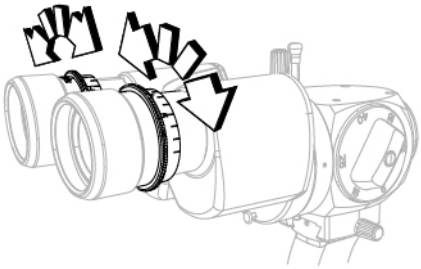

Fig. 40 - Refractive error correction

6 Turn the ferrule (A) to select 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.

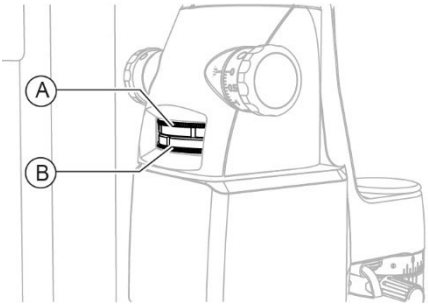

Fig. 41 - Select the diaphragm diameter, the slit height (A) and the filters (B)

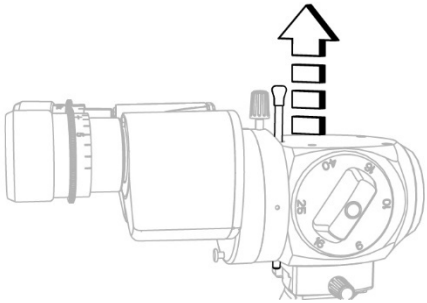

Fig. 42 - Insert the yellow filter

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

10 Use the turning locking/unlocking knob to change the microscope position.

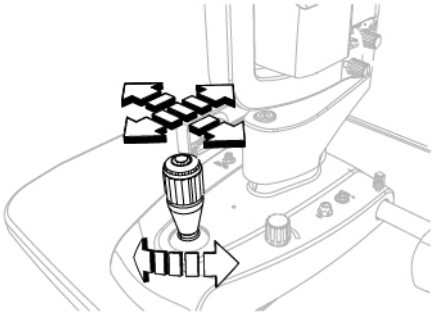

Fig. 43 - Placing the device

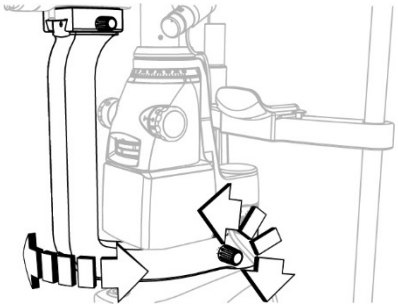

Fig. 44 - Microscope position adjustment

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

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

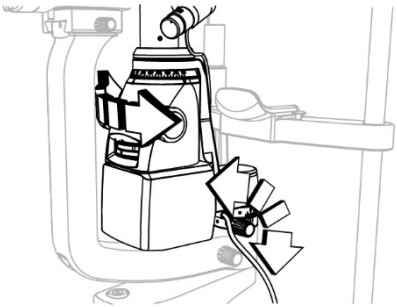

Fig. 45 - Locking knob of the lighting assembly

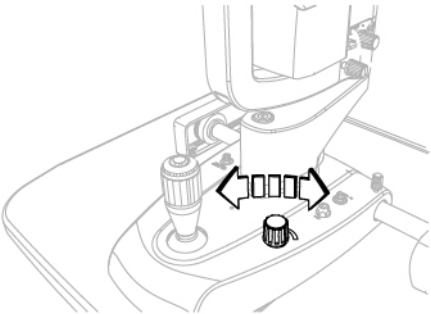

Fig. 46 - Light intensity adjustment

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

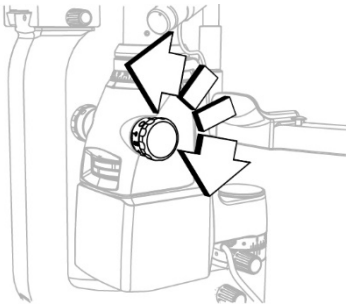

Fig. 47 - Slit width adjustment

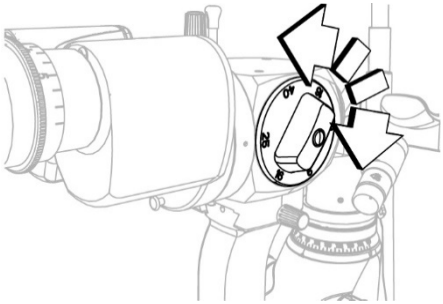

Fig. 48 - Microscope magnification change

15 If necessary, readjust the slit rotation by checking the value on the dial with rotation indicator (A).
16 If necessary, readjust the position of the lighting assembly.

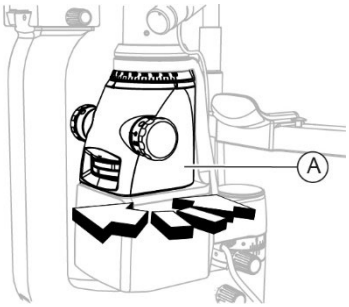

Fig. 49 - Slit rotation

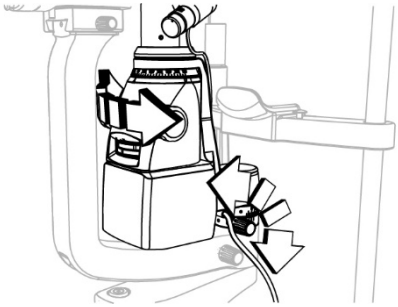

Fig. 50 - Adjusting the projection angle of the lighting assembly

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.

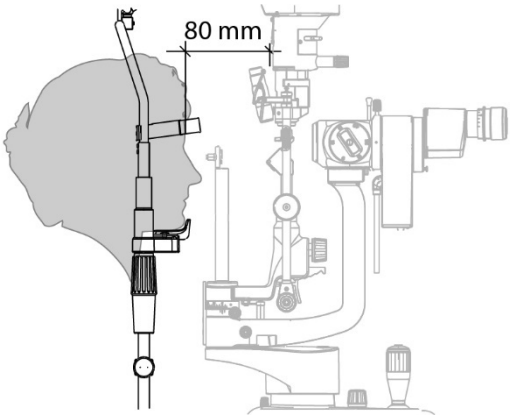

Fig. 51 - Distance from the patient

3 Adjust the eyepieces interpupillary distance.
4 If necessary, pull out the sliding eyecups. Eyepiece covers are suitable for spectacles wearers.

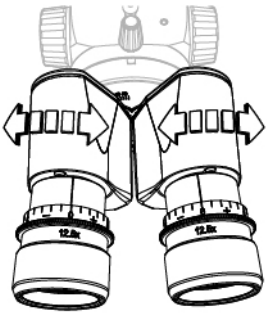

Fig. 52 - Interpupillary distance adjustment

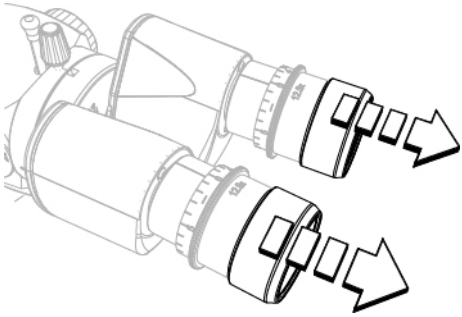

Fig. 53 - Placing the eyepiece covers

5 Bring the image into focus by rotating the eyepieces for the refractive error correction.

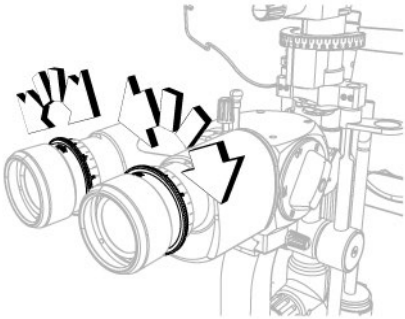

Fig. 54 - Refractive error correction

6 Adjust the slit width.

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

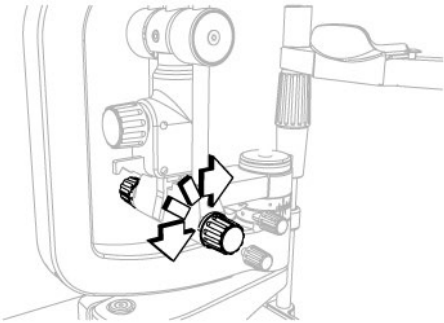

Fig. 55 - Slit width adjustment

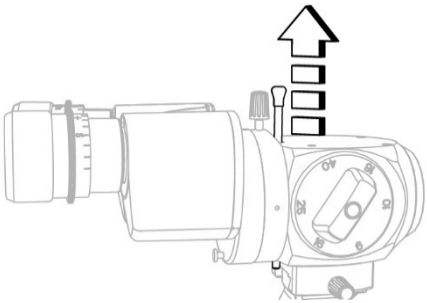

Fig. 56 - Insert the yellow filter

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

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

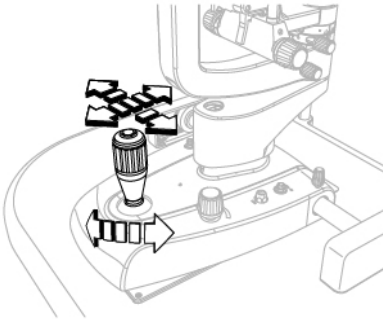

Fig. 57 - Placing the device

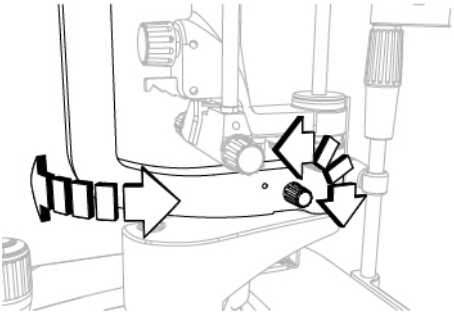

Fig. 58 - Microscope position adjustment

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

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

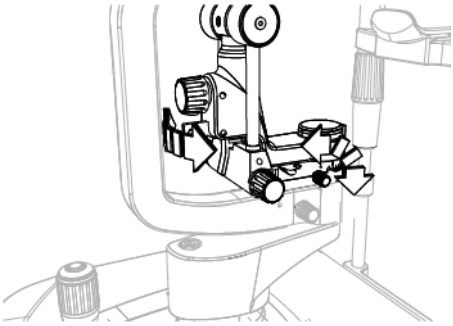

Fig. 59 - Adjusting the projection angle of the lighting assembly

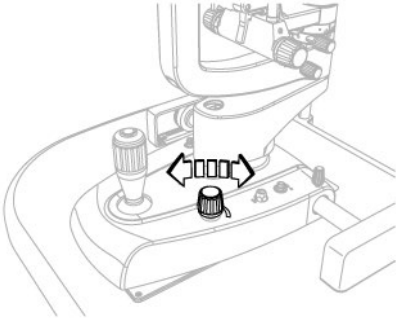

Fig. 60 - Light intensity adjustment

12 During the examination, adjust the slit height.

13 If necessary, change the microscope magnification.

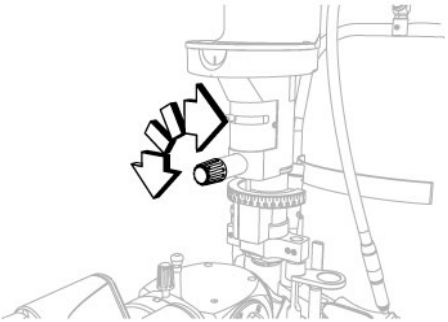

Fig. 61 - Adjust the slit height

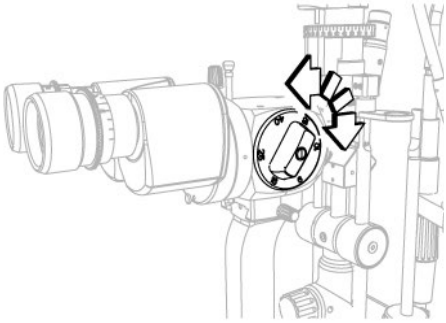

Fig. 62 - Microscope magnification change

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

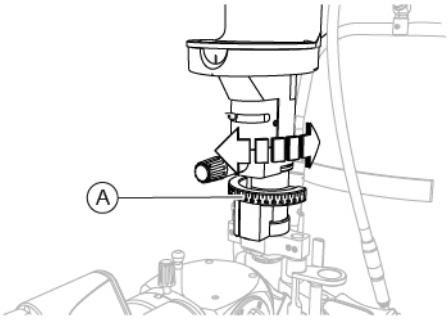

Fig. 63 - Slit rotation

15 Loosen the knob (A) to carry out horizontal tilting. Tighten the knob to lock.

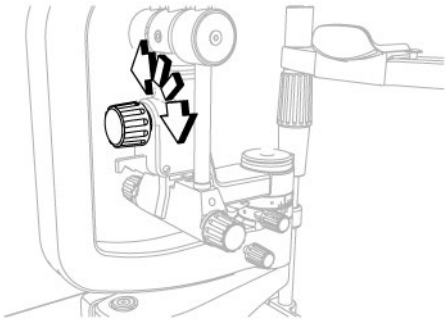

Fig. 64 - Locking/unlocking knob

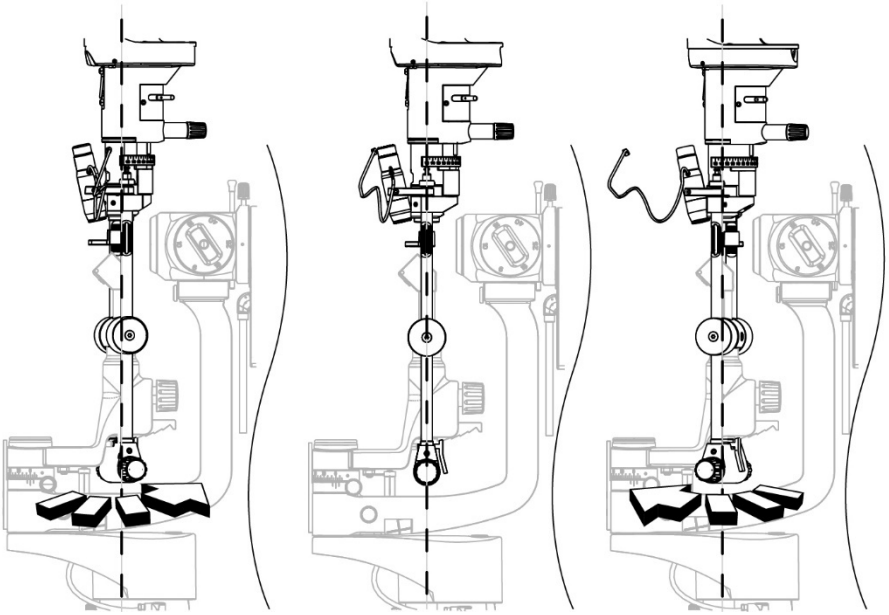

Fig. 65 - Horizontal tilting

16 To tilt vertically press the locking lever (C). The lamp can be inclined following the twitches of the blocking lever.

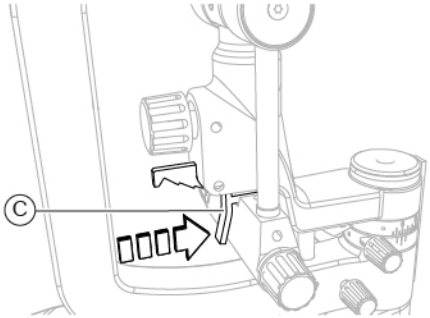

Fig. 66 - Locking lever for vertical tilting

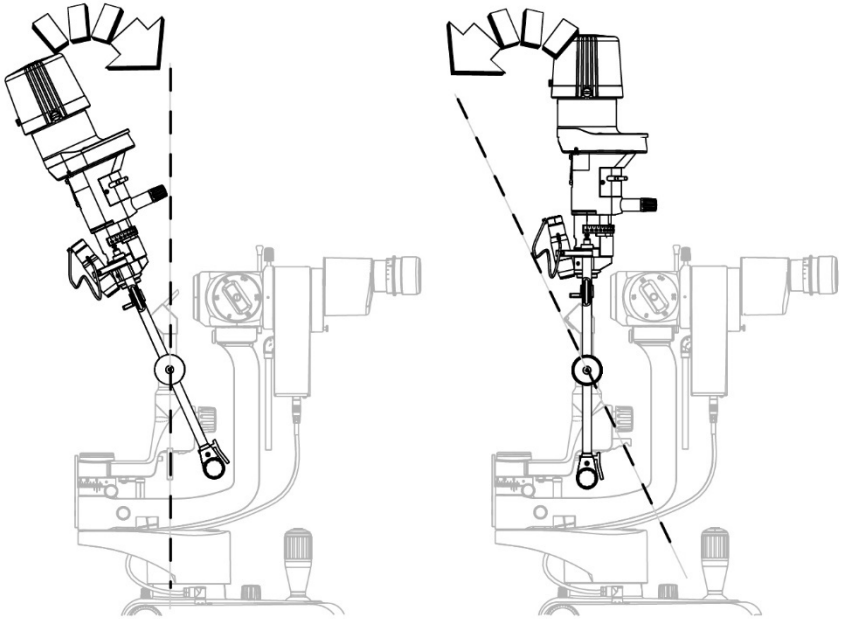

Fig. 67 - Vertical tilting

4.9 HOW TO ACQUIRE THE IMAGE (XX-D)

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

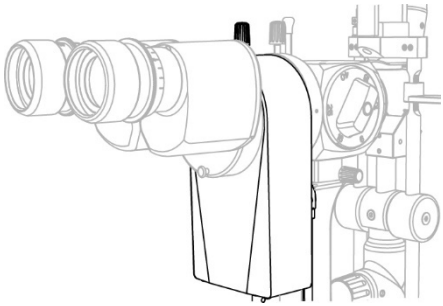

Fig. 68 - Mizar video camera

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.

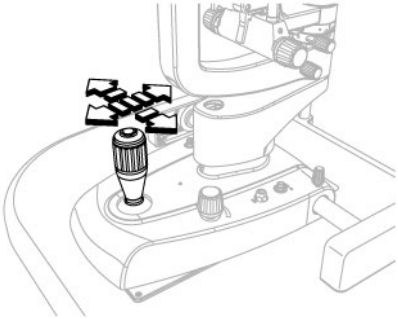

Fig. 69 - Image focusing

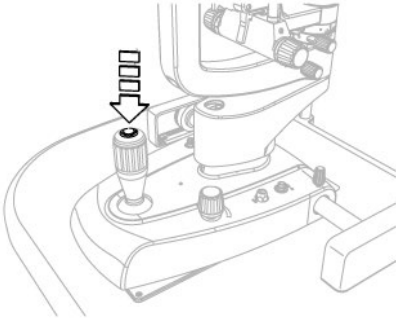

Fig. 70 - Image acquisition

4.10 HOW TO CHANGE CHIN CUP PAPERS

At the end of the examination, remove and replace the chin cup paper so that it is always new and hygienic for the next patient.

The device is provided with a package of chin cup papers. When you use the last paper change the package.

1 Clean the chin cup using a non-abrasive cloth to avoid damaging the material.
2 Extract the two plastic rivets.
3 Place the new package of chin cup papers.
4 Insert the plastic rivets into the holes of the package of chin cup papers and into the holes of the chin cup.

Fig. 71 - Changing chin cup papers

To request spare parts, specify the code given in the paragraph **"Spare parts and accessories list" on page 73.**

4.11 HOW TO TURN OFF THE DEVICE

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

1 Fasten 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 OFF.

3 Place the dust cover on the device to prevent dust from accumulating on the device.

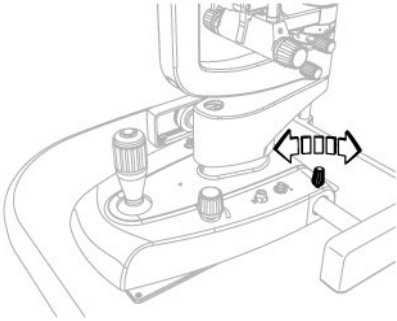

Fig. 72 - Fastening the device

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 the video camera installation.

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

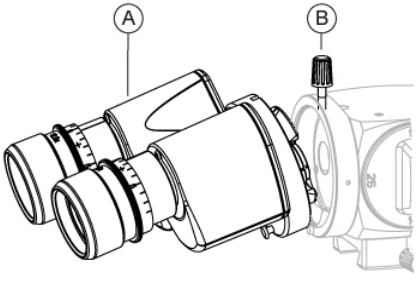

Fig. 73 - Removing the binoculars

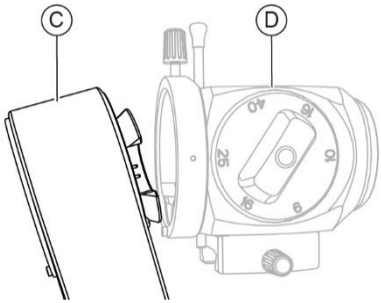

Fig. 74 - Installing the video camera

8 Loosen the locking/unlocking grub screw on the video camera.
9 Install the binocular.
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.

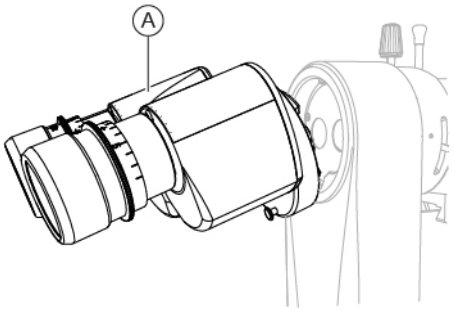

Fig. 75 - Installing the binoculars

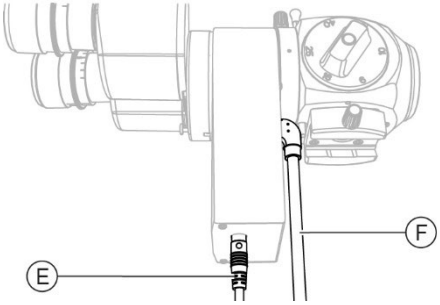

Fig. 76 - Connecting the video camera

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 luminous intensity, turn the knob (C).

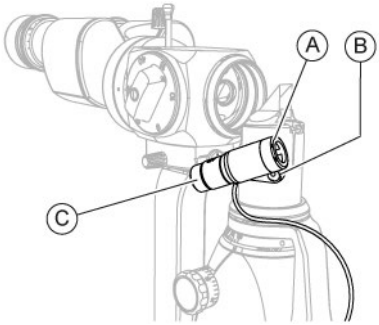

Fig. 77 - Installing the illuminator

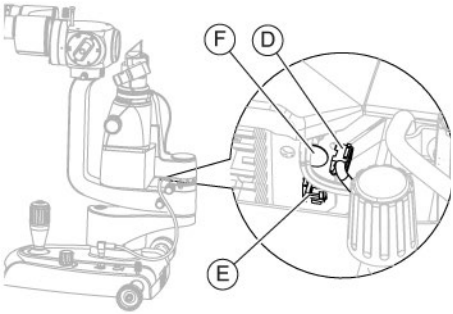

Fig. 78 - Connecting the illuminator

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 remove the protection (K).
10 Connect the connection cable (L) to the connector on the illuminator.
11 Reassemble the protection (K) and fasten the screws (M).
12 To turn on the illuminator and adjust the luminous intensity, turn the knob (A).

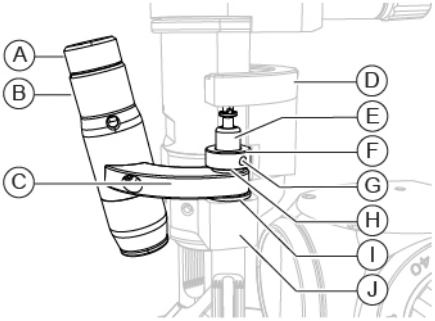

Fig. 79 - Installing the illuminator

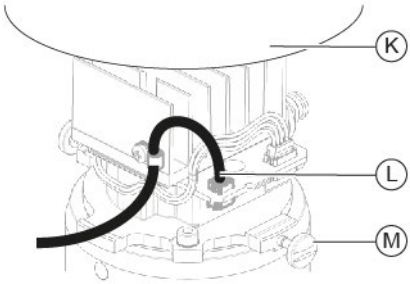

Fig. 80 - Connecting the illuminator

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 secure it on the rod.

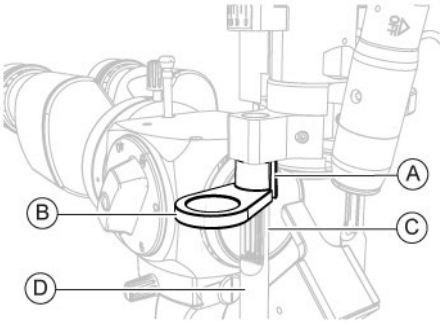

Fig. 81 - Installing the light diffusion filter

To use the additional light diffusion filter:

1 Turn the light diffusion filter horizontally on the rod.

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

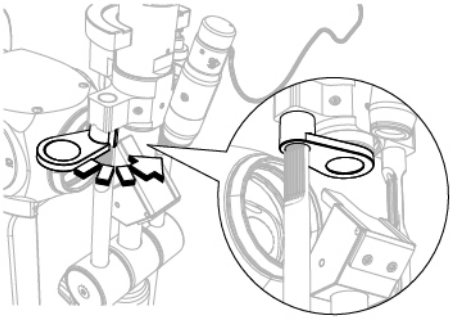

Fig. 82 - Placing the light diffusion filter

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

The 2x microscope does not support the video camera installation.

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

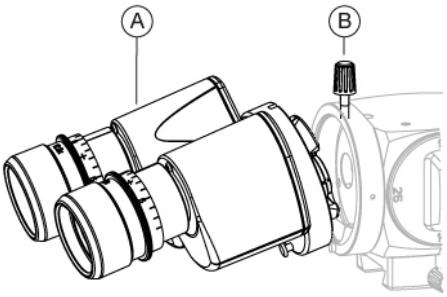

Fig. 83 - Removing the binoculars

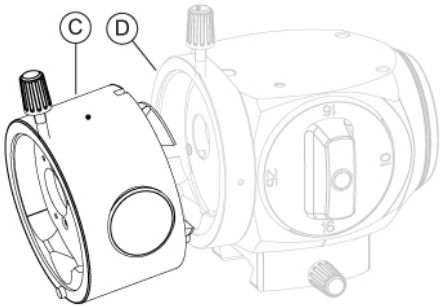

Fig. 84 - Installing the splitter

8 Install the binocular.
9 Fasten the locking/unlocking knob on the separator.

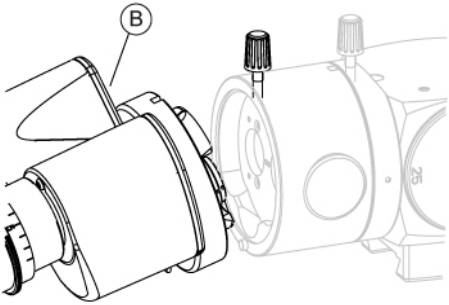

Fig. 85 - Installing the binoculars

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 splitter. Align the plug (D) of the video camera fitting with the plug (E) on the splitter.
3 Turn the dial (F) of the video camera fitting to fasten the fitting to the splitter.

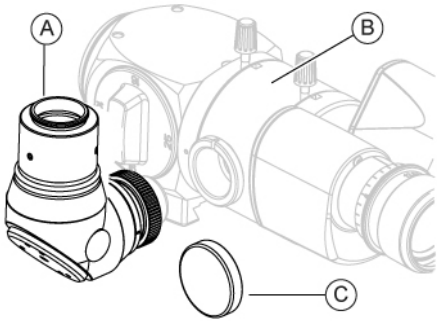

Fig. 86 - Video camera fitting

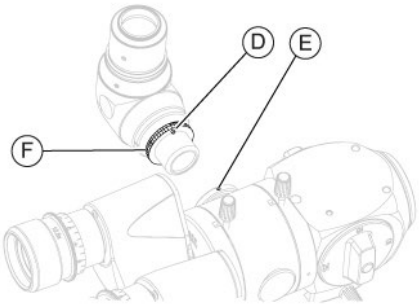

Fig. 87 - Fastening the video camera fitting

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

Before installing the accessory, install the separator.

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

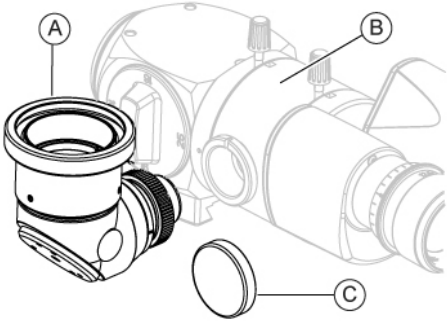

Fig. 88 - Camera joint

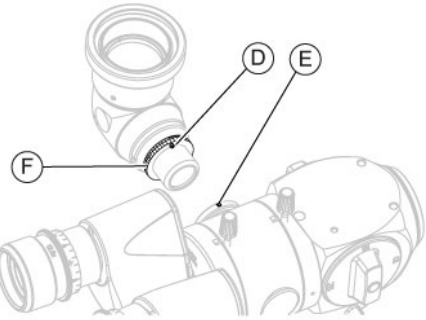

Fig. 89 - Camera connector blockage

4.12.8 HOW TO INSTALL THE OCULAR 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 on the microscope (C) on the ocular for the second operator (A).
3 Install the ocular for the second operator on its seat on the separator. Align the plug (F) of the ocular for the second operator with the socket (G) on seat of the separator.
4 Turn the dial (E) of the eyepiece for the second operator to fasten the eyepiece to the splitter.

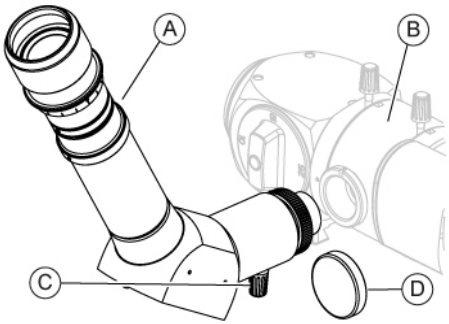

Fig. 90 - Ocular for the second operator

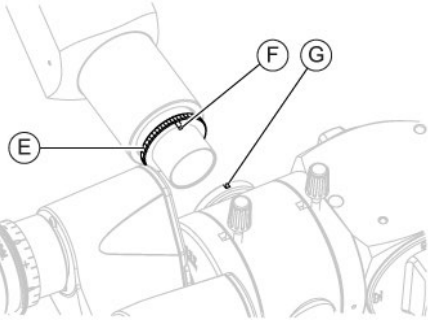

Fig. 91 - Ocular for the second operator blockage

4.12.9 HOW TO REPLACE EYEPIECES FOR THE BINOCULAR

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

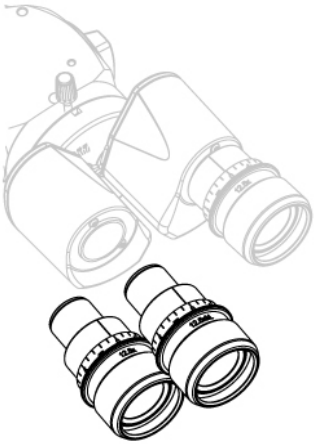

Fig. 92 - Eyepieces

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 part requiring user intervention. Do not remove any part of the device.

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

In case of operational faults or malfunctions or for every operation not mentioned in the instructions for use, there is the obligation to address an authorized technical assistance centre of the device Manufacturer.

5.2 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 shall be routinely carried out.

Device parts that do not come into direct contact with the patient shall be cleaned at least once a day.
Device parts that do come into direct contact with the patient shall 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.

5.2.1 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 takes into account both the sensitivity of the device to specific substances and the product's disinfecting effectiveness.
For cleaning and disinfection procedures, use products approved by the FDA or CE for medical devices or medical-surgical devices.
Abide by the products 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 using the chosen product, please comply with the instructions provided by the manufacturer.

5.2.2 CLASSIFICATION OF THE CRITICALITY OF THE DEVICE

CAUTION
The device is supplied non-sterile and it shall not be sterilized prior to use.

This device is classified as "non-critical" since it only comes into contact with 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 the case of accidental exposure to body fluids, the device shall be disinfected with a higher-level disinfectant after cleaning.

5.2.3 DEVICE CLEANING

CAUTION
Carefully follow the cleaning instructions described in this section in order to avoid any 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 shall be regularly cleaned.

The device is provided with a dust cover whose function is to protect it 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 cleansing products, read the paragraph **"Recommended products for cleaning and disinfection" on page 70.**

5.2.4 CLEANING THE APPLIED PARTS

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

Applied parts that come into direct contact with the patient during the examination shall 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 cleansing products, read the paragraph **"Recommended products for cleaning and disinfection" on page 70.**

5.2.5 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.

5.3 SPARE PARTS AND ACCESSORIES LIST

Code	Description
100257720	SL9900 LED table top chin rest
100258700	SL9800 LED table top chin rest
103301800	Table top 45x90 cm, with rails and drawer
330259900	Connecting power cable - lamp base, length 80 cm per LED
330259901	Connecting power cable - lamp base, length 5 m per LED
3001007ID3F	Power cord
3001007EI3P	Cable isolation transformer - electric table
330701090	Cable electric table - power supply unit 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 and SL9900 ELITE
100250250	Light diffusion filter for SL9900 and SL9900 ELITE
100226619	Eyepiece 12.5x with protection from light
330274300	USB 3.0 cable 2 m length for 5 MP video camera
330274310	USB 3.0 cable 5 m length for 5 MP video camera
330274303	Connection cable between the device base and the video camera 5 MP
100226627	Eyepiece plastic covering
100250090	Calibration testing tool

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

5.4 TROUBLESHOOTING

Issue	Cause	Solution	Note
The device does not switch ON	Power cable not connected to the power supply unit.	Connect the power cable of the device to the power supply unit. Switch the power switch of the power supply unit to ON.	If the device is powered trough the auxiliary power supply of the table, check the connection of the table to the power line. Check the functioning 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 ON. Replace the PC.	Ensure the room's electrical line works properly.
PC operating system does not start	Hard Disk failure. Corrupted operating system.	It is necessary to replace the Hard Disk. Reinstall the operating system. Replace the PC.	Contact the Technical Assistance. Ensure the new PC conforms to the minimum requirements of the device.
The application software does not start	Hard Disk failure. The anti-virus software impedes the starting of the application software Phoenix. Corrupted operating system. The Phoenix application software does not work properly.	It is necessary to replace the Hard Disk. Check the anti-virus software settings. Reinstall the operating system. Reinstall the Phoenix application software.	Contact the Technical Assistance. The installation of the application software Phoenix needs the administrator privileges.
The application software does not work properly	The connection cable between the device and the PC does not work properly. The anti-virus software interferes with the drivers of the application software Phoenix. The application software Phoenix is installed as local user.	Unplug and plug in again the connection cable between device and 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 application software Phoenix needs the administrator privileges.

Issue	Cause	Solution	Note
The application software does not install	The PC does not have the minimum features required for the installation.	Follow the application software installation instructions.	Make sure the PC features are equivalent to those required by the application software.
The PC mouse does not work	The connection cable between the device and the PC is not connected. Mouse switch in position OFF. The mouse batteries are down (only for wireless mouse).	Check that the mouse connection cable is properly inserted into the USB port. Switch the mouse button in position ON. Replace the mouse batteries (only for wireless mouse).	Check that there are no conflicts between devices from the PC control panel.
The PC keyboard does not work	The connection cable between the device and the PC is not connected. Keyboard switch in position OFF. The keyboard batteries are down (only for wireless keyboard).	Check that the keyboard connection cable is properly inserted into the USB port. Switch the keyboard button in position ON. Replace the keyboard batteries (only for wireless keyboard).	Check that there are no conflicts between devices from the PC control panel.
The images can't be saved in the database (Xx-D)	The database is not connected to the Phoenix application software. No internet connection. The USB cable does not work.	Verify that in the configuration screen of the database is specified the correct path to the "phoenix.mdb" file. Refresh the connection to the database file. Check whether the internet connection is functioning. Replace the USB cable.	Regularly check the connection to the data network. Use USB 3.0 cables only.
Failed image capture (Xx-D)	The patient moved or closed the eyes during the acquisition.	Ask the patient to keep their eyes open, to look at the fixation point and not to move their eyes.	
Failed image focusing	Presence of dust of 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.

Issue	Cause	Solution	Note
Missing acknowledgement of eye position left / right position by the device	Missing 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 may not reflect the infrared light. Move a white paper below the device base to check the functioning of the position detector.
Device movement difficulties (ahead, back, left, right)	The joystick plastic protection has not been removed from the base during the installation. The device blocking knob is fastened.	Remove the joystick's plastic protection from the base. Loosen the device blocking knob.	Before starting the examination, check that the device locking knob is loosened.
Functioning indicator does not turn on	The device connection cable does not work or is disconnected.	Check the connection.	
The device does not generate any light	The device connection cable does not work or is disconnected. Light intensity adjustment knob is at minimum. The slit is completely closed. The LED illumination does not work.	Check the connection. Open the slit. Increase the light intensity. Replace the luminous source.	

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