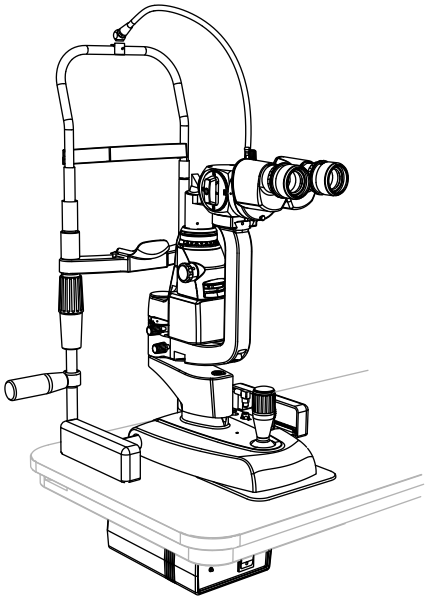
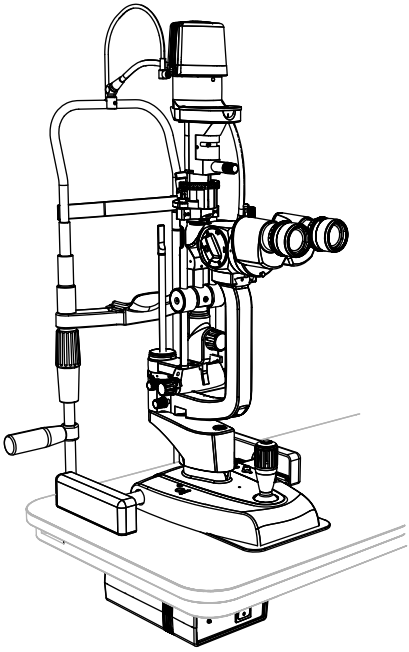
CSO® COSTRUZIONE STRUMENTI OFTALMICI





SLIT LAMP

INSTRUCTIONS FOR USE

SL9800 / SL9900 / SL9900 ELITE

CSO®

COSTRUZIONE STRUMENTI OFTALMICI

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IFU305EN00 - 06/2020

CE

EN

1 INTRODUCTION

The device is the result of a long research period, conducted by experts to give the product technical innovation, quality and design.
The device can be easily used thanks to the guided manual capture and the electronic control of all the functions of the device.

1.1 SYMBOLS

Within the instructions for use, on the package or on the device, there can be the following symbols:

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 (Directive 93/42/EEC). Identification number of the notified body (IMQ).
	Waste disposal in compliance with the Directive 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 ARE REFERRED TO THE DEVICES SL9800 AND SL9900.
THE DEVICE SL9800 HAS THE ILLUMINATION FROM BELOW. THE DEVICE SL9900 HAS THE ILLUMINATION FROM ABOVE THE OPTION OSCILLATION OF THE LAMP GROUP.
THE MODELS ARE IDENTIFIED WITH THE LETTERS Xx DEPENDING ON THE TYPE OF MICROSCOPE INSTALLED ON THE OBSERVATION GROUP.
THE MODELS ARE IDENTIFIED WITH THE LETTERS Xx-D IF THE DIGITAL VISION HR VIDEO CAMERA AND THE WHITE LED ILLUMINATOR KIT ARE INSTALLED ON THE OBSERVATION GROUP.
THE DEVICES SL9800 AND SL9900 IN THE MODELS Xx-D HAVE THE DIGITAL VISION HR VIDEO CAMERA WITHOUT THE FUNCTION BUTTONS.
THE DEVICE SL9900, MODEL ELITE Xx-D HAS THE DIGITAL VISION HR VIDEO CAMERA WITH THE FUNCTION BUTTONS AND THE WHITE LED ILLUMINATOR KIT.

Within the instructions for use, the paragraphs dedicated to one or another device are marked with SL9800 or SL9900.
The paragraphs dedicated to one or another model are marked with Xx, Xx-D or ELITE 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 if you don't use it since a long time, read these instructions carefully. Read the instructions given in the instruction manual and reported on the device.

Keep this manual close by for future consultation. If you should decide to sell this appliance to other people, remember to also include these instructions, complete and readable.

Keep the original box and packaging, as the free-of-charge service does not cover any damage resulting from inadequate packaging of the product when this is sent back 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 himself the right to modify the contents of the instructions for use, without notice.

1.3 NORMATIVE REFERENCES

1.3.1 COMMUNITY DIRECTIVES

- Directive 93/42/EEC and subsequent modifications and integrations concerning medical devices
- Directive 2012/19/EU on waste 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: Light hazard protection.
- UNI CEI EN ISO 14971:2012 Medical devices. Application of risk management to medical devices.

1.3.3 QUALITY MANAGEMENT SYSTEMS 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 Community directive 93/42/EEC as amended by the 2007/47/EC for:

- features
- safety and reliability
- CE marking

The Manufacturer refuses any responsibility for:

- installation and activation not activated in conformity to the indications and the precautions reported in the instructions for use
- use not in compliance with the instructions for use and precautions reported in the instructions for use
- use of accessories or spare parts not provided or suggested by the Manufacturer
- repairs and safety controls not effectuated by expert, qualified, trained and personnel authorized by the Manufacturer
- electrical system of the space where the device is installed not in compliance with the technical standards, the laws and regulations in effect in the country of installation of the device
- direct or indirect consequences or damages to objects or persons, originating from the improper use of the device or erroneous clinical analysis originating from its use

The Manufacturer guarantees the device for 24 months after invoicing. The Warranty includes the substitution, at the Manufacturer's or an Authorized Service Centre, of components and materials and the relative labour. The 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 improper use or not intended by the Manufacturer
- damages caused by service lack or inefficiency, originating by causes or circumstances out of the Manufacturers control
- the parts subject to usage and/or deterioration originating from the normal use and those that might be broken because of an improper use or maintenance carried out by personnel non-authorized by the Manufacturer.

To ask maintenance interventions or to have technical information about the device, address to an Authorized Service Centre or directly to the device Manufacturer.

The client will not be refunded for damages originating from the device halt.

1.5 MANUFACTURER IDENTIFICATION

CSO S.r.l.
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
Electric shock danger. Do not let water fall on the device. Do not immerse the device in water or other liquids.

DANGER
Electric shock danger. If the power cables are damaged, they must be replaced in an Authorized Service Centre to prevent any risk.

DANGER
Electric shock danger. Unplug the power cable from the mains socket before disinfecting the device and before any maintenance operation.

CAUTION
Do not use the device if visibly damaged. Periodically inspect the device and the connection cables to verify if there are damage signs.

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

CAUTION
Danger of device falling down. Do not leave free cables which can represent an obstacle or a danger for the patient or the operator.

CAUTION
Danger of stumbling and falling. Do not let the power cord or the connection cables free in a place where people could walk.

CAUTION
Electric shock risk. Do not touch the power supply cables with wet hands.

CAUTION
Electric shock risk. Do not leave the power supply cables in contact with sharp corners or objects. Collect and attach always the power supply cables.

CAUTION

If you notice a wired odour or smoke coming out of the device or if it emanates heat, turn it off immediately. Do not keep using a damaged product or a damaged part. Danger of injuries.

CAUTION

The electrical net must have a Residual-Current Circuit Breaker (IΔn=30mA) Thermal-Magnetic 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 technical operation on the device that is not recalled or described in these instructions for use.

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

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

It is forbidden to use the device outdoors.

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

2.2 DEVICE IDENTIFICATION

2.2.1 REGISTRATION DATA IN THE MEDICAL DEVICES LIST

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

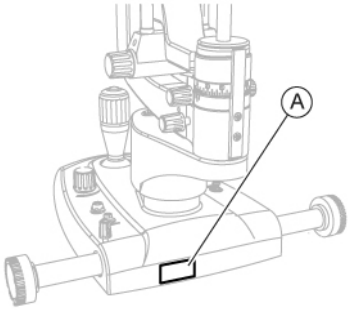

Fig 1 - Plates position

Pos	Description
A	Device data plate

Device SL9800 model Xx and Xx-D

Fig 2 - Data plate for the model Xx

Fig 3 - Data plate for the model Xx-D

Device SL9900 model Xx and Xx-D

Fig 4 - Data plate for the model Xx

Fig 5 - Data plate for the model Xx-D

Device SL9900 model ELITE Xx-D

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

2.2.3 POWER SUPPLY UNIT DATA PLATE

Fig 7 - Power supply unit data plate

2.3 INTENDED USE

The SLIT LAMPS, models SL9800/SL9900/SL9900ELITE, are characterized by a modern project of the optical parts which have an anti-reflection 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 capture
- management of the patients' data and possibility to personalize researches and statistics
- Dry Eye Report

Dry Eye Report

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

- Ocular Surface Disease Index (OSDI)
- analysis of the redness of the eye
- Analysis of Meibomian glands
- Tear meniscus analysis
- NiBUT.

Illumination source (device SL9800)

The device is equipped with a professional LED illuminator placed in the lower part of the device. The maximum luminous intensity is 284000 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 luminous intensity is 284000 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.

White LED illuminator kit

The white LED illuminator is an optional for the devices model Xx.
The white LED illuminator kit is standard equipment for the device models Xx-D and model ELITE Xx-D.

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 exam): this filter allows a fast exam and a better images quality. Magnifications from 6x up to 40x. Bright images, clear and contrasted thanks to the multi strata antireflection treatment. Only the microscopes 3x, 5x and zoom can support the video camera Digital Vision HR.

Video camera Digital Vision HR

The video camera Digital Vision HR is an optional for the models Xx-D and ELITE Xx-D.
For the device model ELITE Xx-D, the video camera Digital Vision HR has function buttons to allow a rapid access to the operator's personalized functioning settings.

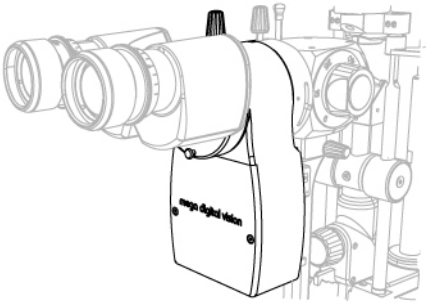

Fig 8 - Video camera Digital Vision HR (Xx-D)

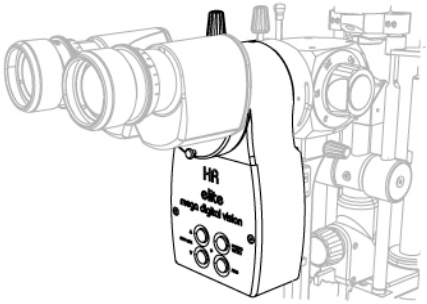

Fig 9 - Video camera Digital Vision HR (ELITE Xx-D)

The new digital video camera Digital Vision HR has been designed for ophthalmological purposes. The video camera is based on a 2 high performances 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 new digital camera Digital Vision HR is perfectly integrated with the new application software Phoenix, perfectly suitable for the needs of images capturing and processing (DICOM compatible). The application software allows to capture images and videos of the eye. The video camera is connected to the PC with 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

When the video camera Digital Vision HR is installed, the device must be used in combination with a PC and the application software denominated Phoenix.

For system requirements (digital HR version) read paragraph "**Personal Computer" at page 30**.

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

Patient area: any volume in which intentional or unintentional contact can occur between patient and parts of the system or between patient and other persons touching parts of the system.

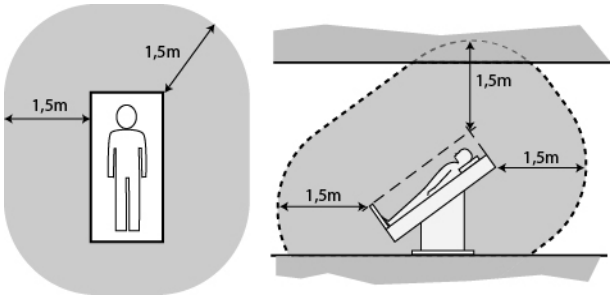

Fig 10 - Patient area

2.4 MEDICAL DEVICES CLASSIFICATION

Technical data	Value
Classification in compliance with the attached IX to the Directive 93/42/EEC and successive modifications	Class I

2.5 MEDICAL ELECTRICAL DEVICES CLASSIFICATION

Classification complying with the standard EN 60601-1:2005 + A1:2012

Technical data	Value
Type of protection against the direct and indirect contacts	Class II
Applied parts	Type B
Protection degree against humidity	IP20 (no protection against liquid infiltration)
Sterilization or disinfection method	This device can be disinfected

Technical data	Value
Protection degree in presence of anaesthetics or inflammable detergents	No protection
Electrical connection degree between device and patient	Appliances with applied part on 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	-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 device damages. During transport and storage, the device can be exposed to the environmental conditions for a maximum period of 15 weeks, only if kept in the original packaging.

2.8 DISPOSAL AT THE END OF THE USEFUL LIFE

Instruction for disposal of product correctly according to European Directive 2012/19/EU, and 2011/65/EU about the reduction of use of dangerous substances in the electrical and electronic equipment, as well as waste disposal.

At the end of its useful life, the device must not be disposed of as urban waste. The device can be delivered to the appropriate

separate waste collection centres set up by municipal administrations or to retailers 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. On the label of the device there is the symbol of the of the crossed-out wheeled bin. The graphic symbol of the crossed-out wheeled bin, indicates the obligation to collect and dispose separately 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 the technological devices waste, of the treatment and the recycling of the used device by paying its costs.

The Manufacturer is available to give the user all the information about the dangerous substances contained in the device, and on the recycling modalities of those substances and about the possibility of a reuse of the used device.
Strict sanctions for transgressors are provided for by law.
For specific information about the disposal in other countries 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	Group 1	The device uses radio frequency energy only for its inner functioning. The radio frequency emissions of the device are very low and should not cause interferences with the near appliances.
Radio frequency emission. CISPR 11	Class B	The device can be used in all the environments, included the domestic environment. The device can be connected directly to a low-voltage power supply net as there is in the housing units.
Harmonic emissions. IEC 61000-3-2	Class A	The device can be used in all the environments, included the domestic environment. The device can be connected directly to a low-voltage power supply net as there is in the housing units.
Limitation of voltage changes, voltage fluctuations and flicker. IEC 61000-3-3	Compliant	The device can be used in all the environments, included the domestic environment. The device can be connected directly to a low-voltage power supply net as there is in the housing units.

Immunity test	IEC 60601-1-2 test level	Conformity level	Electromagnetic environment
Electrostatic discharge. IEC 61000-4-2	±6 kV contact. ±8 kV air	±6 kV contact. ±8 kV air	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/burst. IEC 61000-4-4	±2 kV for power supply lines. ±1 kV for input/output lines	±2 kV for power supply lines. Non-applicable	Mains power quality shall be that of a typical commercial or hospital environment.
Surge 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.

Immunity test	IEC 60601-1-2 test level	Conformity level	Electromagnetic environment
Voltage dips. Short interruptions and voltage variations 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.
Power frequency (50/60Hz) magnetic fields. 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 conduced IEC 61000-4-6 RF conduced IEC 61000-4-3	3 Vrms from 150kHz 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 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: is the recommended distance in metres (m) at which the portable radio frequency (RF) appliances 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. These guidelines 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

Device SL9800

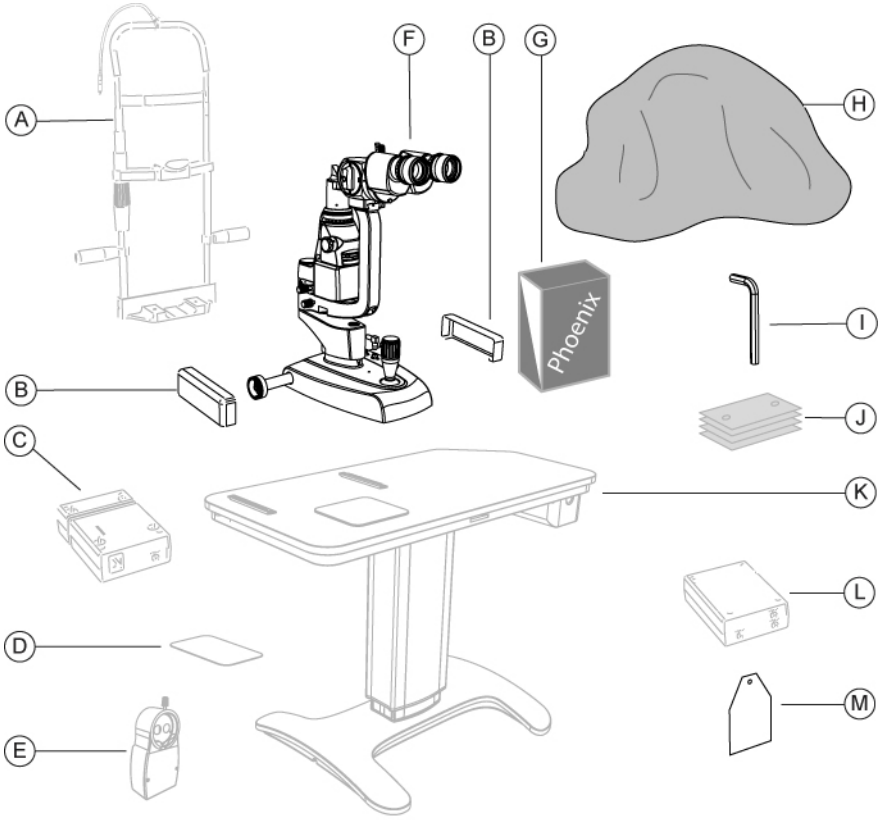

Fig 11 - Supply description

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

Pos	Denomination		Description
A	Chin rest	Optional (*)	Adjustable height. Adjustable distance between chin and forehead. Fixation point included.
B	Wheel-cover carter		Protection against accidental hand crushing.
C	Power supply unit	Optional (*)	A cable is provided with the power supply unit.
D	Sticker pad	Optional (*)	Sticker for right/left identification.
E	Image separator	Optional	Digital video camera with connection cables.
F	Device		Composed by an observation group with microscope and by a lamp group with LED illumination fixed above. The device has a system of oscillation of the lamp group.
G	Application software		Application software for image capture and device management.
H	Protective cover		Place on the device when it is not in use to protect it from dust.
I	Hex wrench with screws		
J	Package of chin cup papers	Optional	Papers to be placed on the chin cup of the chin rest.
K	Ophthalmic table	Optional	Adjustable electric support surface with one or two columns. Drawer and auxiliary sockets with fairlead.
L	Isolation transformer	Optional	230V/230V for the use of the non-electromedical appliances in the patient area.
M	Breathing shield		

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

Device SL9900 and SL9900 ELITE

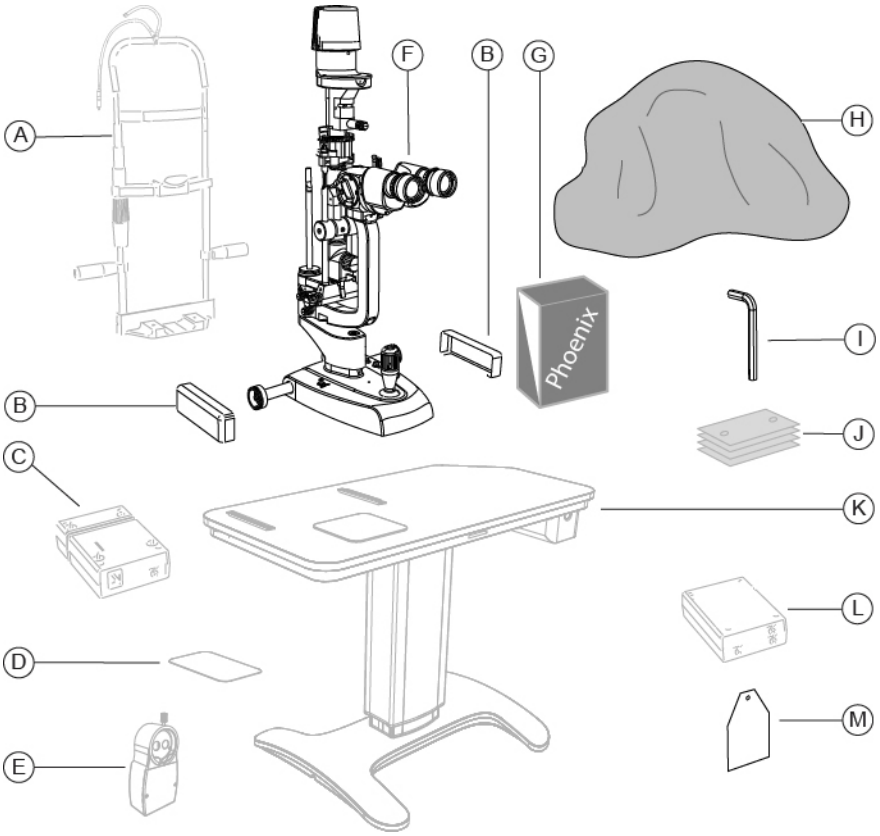

Fig 12 - Supply description

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

Pos	Denomination		Description
A	Chin rest	Optional (*)	Adjustable height. Adjustable distance between chin and forehead. Fixation point included.
B	Wheel-cover carter		Protection against accidental hand crushing.
C	Power supply unit	Optional (*)	A cable is provided with the power supply unit.
D	Sticker Pad	Optional (*)	Sticker for right/left identification.
E	Image separator	Optional (*)	Digital video camera with connection cables.
F	Device		Composed by an observation group with microscope and by a lamp group with LED illumination fixed above. The device has a system of oscillation of the lamp group.
G	Application software		Application software for image capture and device management.
H	Protective cover		Place on the device when it is not in use to protect it from dust.
I	Hex wrench with screws		
J	Package of chin cup papers	Optional	Papers to be placed on the chin cup of the chin rest.
K	Ophthalmic table	Optional	Adjustable electric support surface with one or two columns. Drawer and auxiliary sockets with fairlead.
L	Isolation transformer	Optional	230V/230V for the use of the non-electromedical appliances in the patient area.
M	Breathing shield		

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

3.1.1 DEVICE SL9800

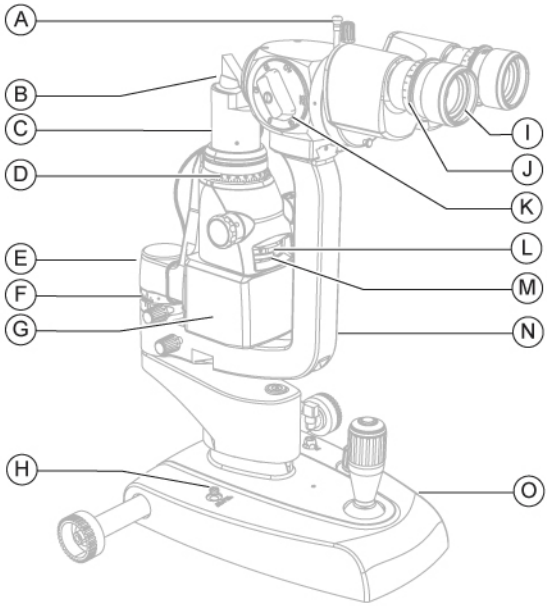

Fig 13 - Device SL9800 - left side

Pos	Description
A	Yellow filter insertion rod
B	Light diffuser
C	Prisma holder head
D	Slit rotation indicator ring
E	Lamp group arm
F	Graduated scale: indicates the position of the lamp group
G	LED illumination unit
H	Connection port for video camera Digital Vision HR
I	Eyepieces
J	Ametropia correction graduated scale
K	Microscope
L	Adjustment ferrule for the height of the slit with graduated scale
M	Filters insertion command ferrule
N	Microscope arm
O	Base

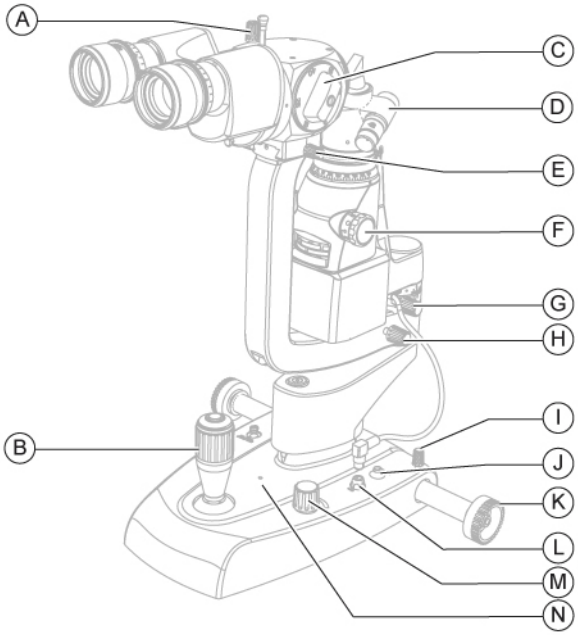

Fig 14 - Device SL9800 - right side

Pos	Description
A	Binocular locking/unlocking knob
B	Joystick
C	Microscope magnifications knob
D	Additional LED illuminator (optional)
E	Microscope locking/unlocking knob
F	Slit width adjustment knob
G	Lamp group arm turning locking/unlocking knob
H	Observation group with microscope arm turning locking/unlocking knob
I	Device blocking knob
J	Power port
K	Cogged wheels
L	Mains connector for lamp group supply
M	Light intensity adjustment knob
N	Functioning indicator

3.1.2 DEVICE SL9900

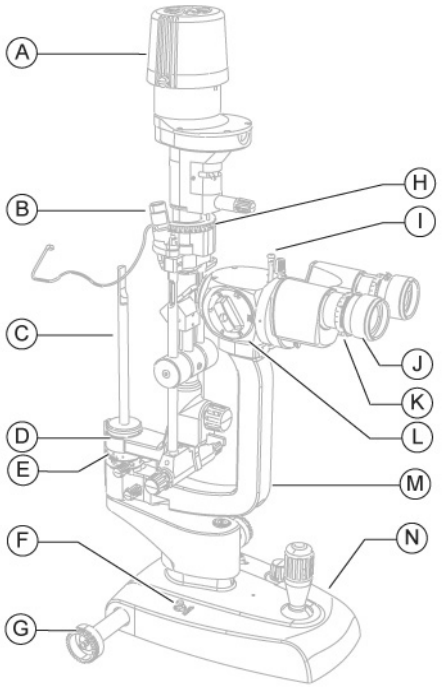

Fig 15 - Device SL9900 - left side

Pos	Description
A	LED illumination unit
B	Additional LED illuminator (optional)
C	Calibration rod
D	Lamp group arm
E	Graduated scale: indicates the position of the lamp group
F	Connection socket for video camera Digital Vision HR
G	Cogged wheels
H	Graduated scale indicating the slit inclination
I	Yellow filter insertion rod
J	Eyepieces
K	Ametropia correction graduated scale
L	Microscope
M	Microscope arm
N	Base

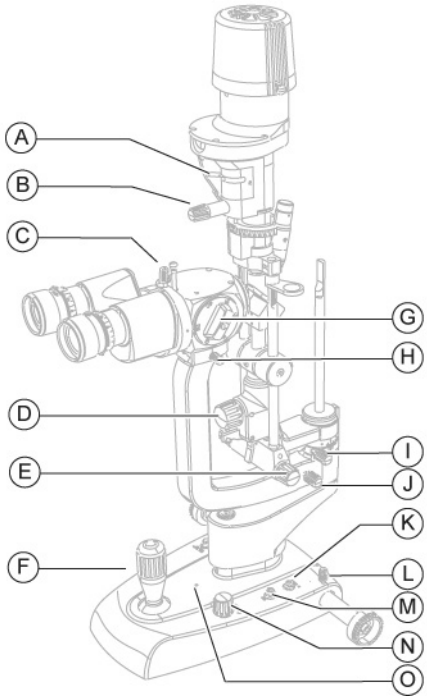

Fig 16 - Device SL9900 - right side

Pos	Description
A	Light filters insertion lever
B	Slit height adjustment knob
C	Binocular locking/unlocking knob
D	Horizontal tilting knob
E	Slit width adjustment knob
F	Joystick
G	Microscope magnifications knob
H	Microscope locking/unlocking knob
I	Lamp group arm turning locking/unlocking knob
J	Observation group with microscope arm turning locking/unlocking knob
K	Power supply outlet
L	Device blocking knob
M	Mains connector of the illumination unit
N	Light intensity adjustment knob
O	Functioning indicator

3.1.3 DEVICE SL9900 ELITE

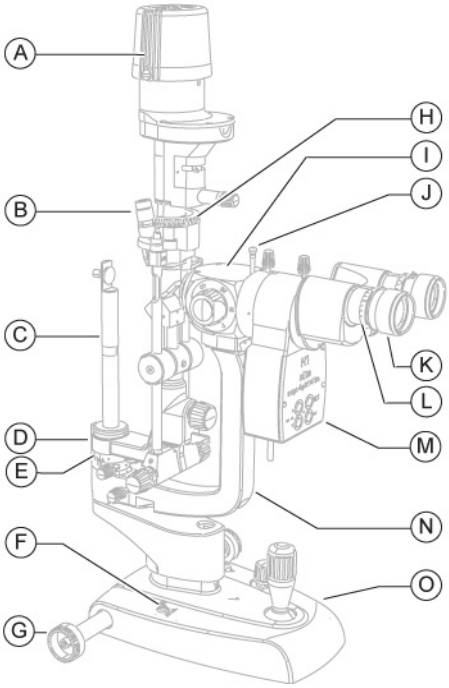

Fig 17 - Device SL9900 ELITE - left side

Pos	Description
A	LED illumination unit
B	Additional LED illuminator
C	Calibration rod with register
D	Lamp group arm
E	Graduated scale: indicates the position of illumination unit
F	Connection socket for video camera Digital Vision HR
G	Cogged wheels
H	Graduated scale indicating the slit inclination
I	Microscope
J	Yellow filter insertion rod
K	Eyepieces
L	Ametropia correction graduated scale
M	Video camera Digital Vision HR
N	Microscope arm
O	Base

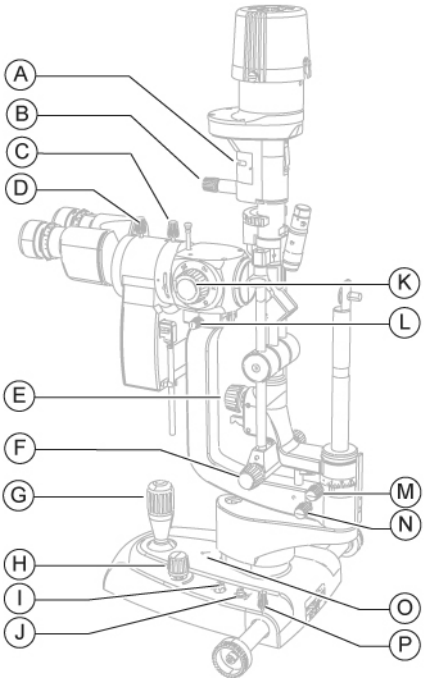

Fig 18 - Device SL9900 ELITE - right side

Pos	Description
A	Light filters insertion lever
B	Slit height adjustment knob
C	Video camera locking/unlocking knob
D	Binocular locking/unlocking knob
E	Horizontal tilting knob
F	Slit width adjustment knob
G	Joystick
H	Light intensity adjustment knob
I	Mains connector of the LED illumination unit
J	Power supply outlet
K	Change magnifications knob
L	Microscope locking/unlocking knob
M	Lamp group arm turning locking/unlocking knob
N	Observation group with microscope arm turning locking/unlocking knob
O	Functioning indicator
P	Device blocking knob

3.1.4 POWER SUPPLY UNIT

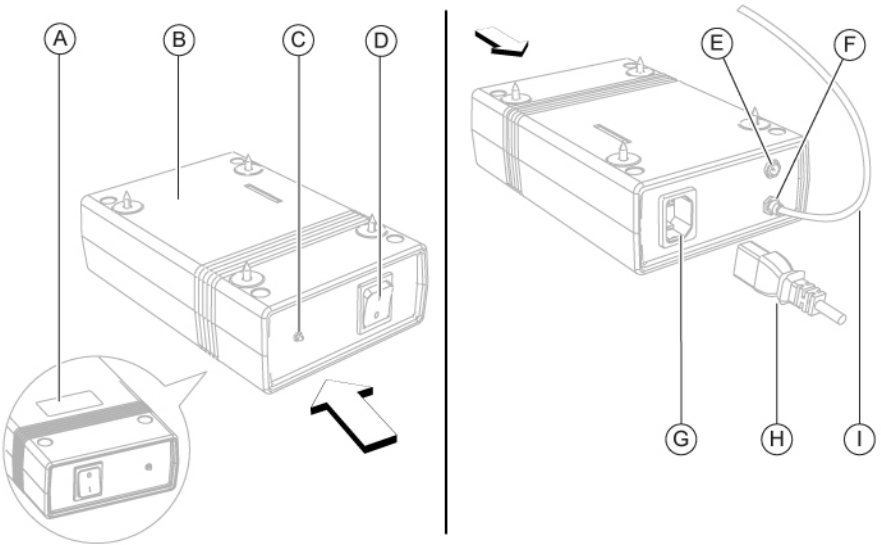

Fig 19 - Power supply unit

Pos	Description
A	Data plate
B	Power supply unit
C	Power supply status control light
D	ON/OFF switch
E	Mains connector for fixation point
F	Device mains connector
G	Power supply mains connector
H	Power supply cable
I	Device power cable

3.1.5 CHIN REST

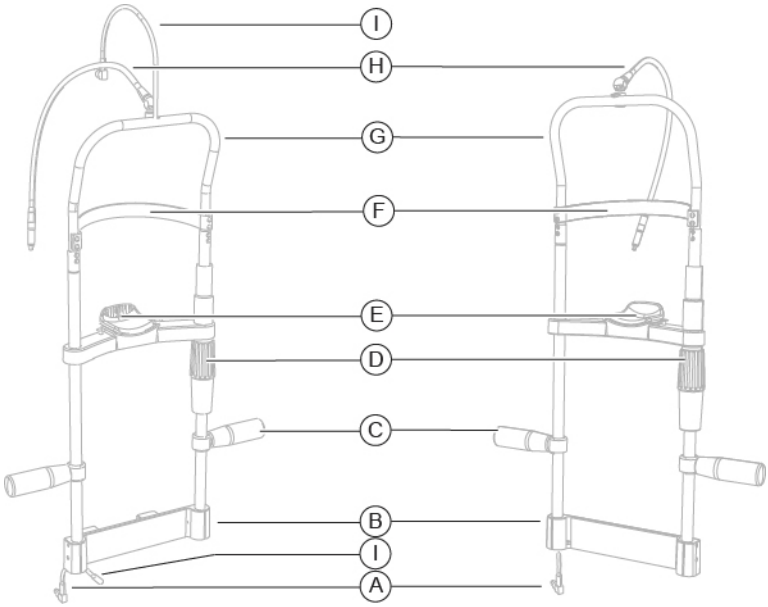

Fig 20 – Chin rest for SL9900 and SL9800

Pos	Description
A	Connection cable for fixation point
B	Chin rest support
C	Handle
D	Chin cup adjustment knob
E	Chin cup
F	Forehead rest
G	Chin rest structure
H	Fixation point
I	Lamp power supply cable (only included with chin rest for SL9900 and SL9900 ELITE)

3.1.6 OPHTHALMIC TABLE

Different table models are available accordingly to the client's choice. The electric table is composed by a support surface on which are installed the cogged guides for the device housing. The table has one or two telescopic columns, motorized, that allow to adjust the height of the support table top.

Fig 21 - Ophthalmic table

Read the instructions for use of the ophthalmic table.

3.1.7 PERSONAL COMPUTER

The device must be used in combination with a PC and the application software Phoenix. Minimum system requirements:

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

Read the instructions for use of the application software.

Fig 22 - Personal Computer

The PC must be compliant to the norm 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 insulating 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 analogical or digital interfaces. The accessories (printer, modem, scanner, etc) must be installed outside the patient area.

The accessories must be compliant to the norm 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 insulating transformer compliant with the directive IEC 60601-1:2005 + A1:2102 - "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance".

3.2 TECHNICAL DATA

3.2.1 DEVICE SL9800

Technical data	Value
Supply voltage	120-230V ±10% 50/60 Hz 1A
Size (HxLxP)	440 x 313 x 335 mm
Device weight	7 kg
Base movement (x, y, z)	105 x 110 x 30 mm
Fine movement (x, y)	14 ± 0,5 mm
Packaging size main unit	40x52x74(H) cm
Packaging size table top	60x65x22(H) cm
Consumables	Package of chin cup papers

Illumination

Technical data	With prisma holder head	With split head
Protection degree of the slit	1.16X	1.3X
Slit width (continuous setting)	0 – 14 mm	0 - 16 mm
Slit length (continuous setting)	1.8 – 13 mm	2 - 15 mm
Maximal length of the slit	14 mm	16 mm
Aperture diaphragms	14, 9, 5.5, 0.3 mm	16, 10.5, 6.5, 0.4 mm
Filters	Blue, red, green (red free)	Blue, red, green (red free)
Illuminator	LED illuminator	
Slit rotation	± 90° continuous on Tabo system	± 90° continuous on Tabo system

Technical data	With prisma holder head	With split head
Incidence angle	0° horizontal	Angular double +/-11°
Rotation interval of the slit projector	+/-90°, angular scale, reference on 0°	+/-90°, angular scale, reference on 0°
Operation distance (prisma outlet/patient's eye distance)	68 mm	80 mm
Device operating voltage	15V DC	15V DC
Luminous source type	LED	LED
Luminosity adjustment	Continuous adjustment	Continuous adjustment
Luminous intensity	284000 Lux	284000 Lux

Chin rest

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

3.2.2 DEVICE SL9900

Technical data	Value
Supply voltage	120-230V ±10% 50/60 Hz 1A
Size (HxLxP)	675 x 313 x 335 mm
Device weight (Xx, Xx-D)	8.7 kg
Device weight (ELITE Xx-D)	9.4 kg
Base movement (x, y, z)	105 x 110 x 30 mm
Fine movement (x, y)	14 ± 0,5 mm
Packaging size main unit	40x52x74(H) cm
Packaging size table top	60x65x22(H) cm
Consumables	Package of chin cup papers

Illumination	
Technical data	**Value**
Protection degree of the slit	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), grey
Illuminator	LED illuminator
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°
Operation distance (prisma outlet/patient's eye distance)	80 mm
Horizontal decentration	± 4° reference on 0°
Device operating voltage	15V DC
Luminous source type	LED
Luminosity adjustment	Continuous adjustment
Luminous intensity	284000 Lux

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

To order spare parts, read the appropriate code in the paragraph **"Spare parts list** at page **70**".

3.2.3 MICROSCOPE

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

2x microscope characteristics

The 2x microscope does not support the installation of the video camera Digital Vision HR.

Technical data	Value
Type	Convergent - 2 positions
Ocular convergence angle	13°
Eyepieces	10x
Ametropia compensation	+/- 8 D
Declared magnifications	10x / 16x
Visual field	18,5 mm / 12 mm
Interpupillary distance	from 51.5 mm to 87 mm

3x microscope characteristics

Technical data	Value
Type	Galilean convergent with magnification change system - 3 positions
Ocular convergence angle	6°
Eyepieces	12,5x
Ametropia compensation	+/- 8 D
Declared magnifications	10x / 16x / 25x / 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

5x microscope characteristics

Technical data	Value
Type	Galilean convergent with magnification change system - 5 positions
Ocular convergence angle	6°
Eyepieces	12,5x
Ametropia compensation	+/- 8 D
Declared magnifications	6x / 10x / 16x / 25x / 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 characteristics

Technical data	Value
Type	Galilean convergent with magnification variation continuous variable
Ocular convergence angle	6°
Eyepieces	12,5x
Ametropia 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

4 DEVICE USE

4.1 HOW TO INSTALL THE DEVICE

CAUTION

Danger of device falling down. The table 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, block the table wheels. Lower the lever of the brake.
3 Place the power supply unit under the table top. Fasten the screws to the four holes.

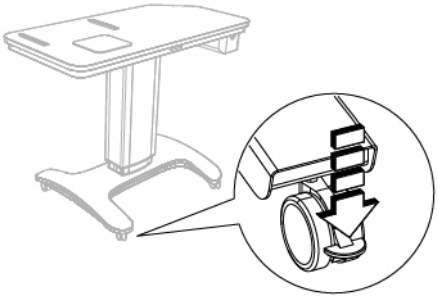

Fig 23 - Table placement

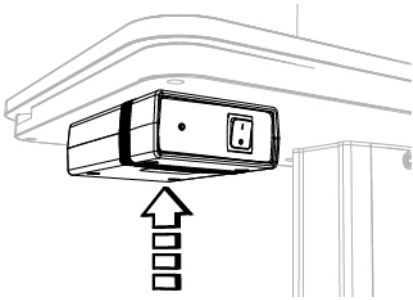

Fig 24 - Power supply unit placement

4 Verify the sticker position respectively to the central axis (A).
5 Remove the protection film. Place the sticker pad between the two cogged wheels and the scrolling plate.

Respect the indicated distances while placing the sticker pad (for right/left identification) on the table top.

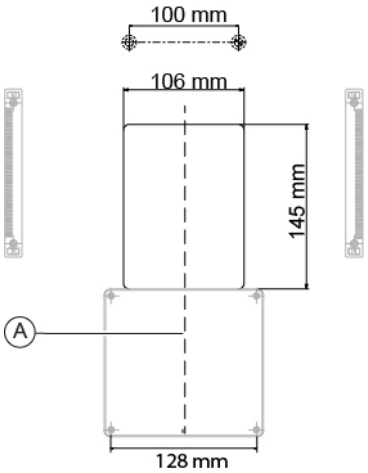

Fig 25 – Distances

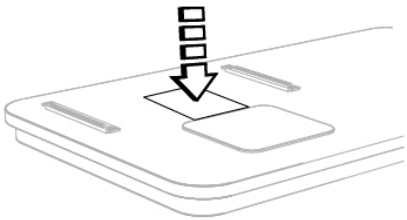

Fig 26 – Placement of the sticker pad

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

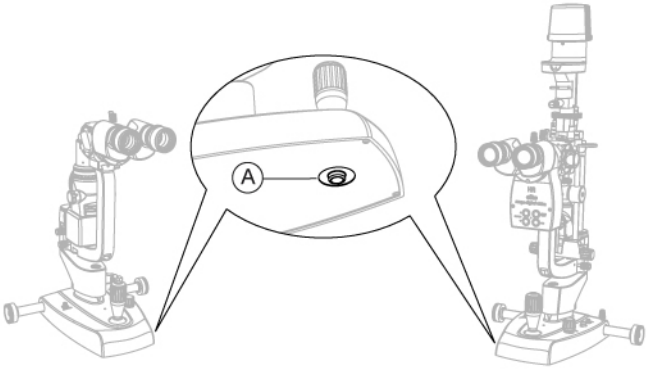

Fig 27 – Protection removal

7 Place the device on the table top and align the two wheels on the cogged guides.

8 Lock the two protection carters to the cogged wheels on the table top.

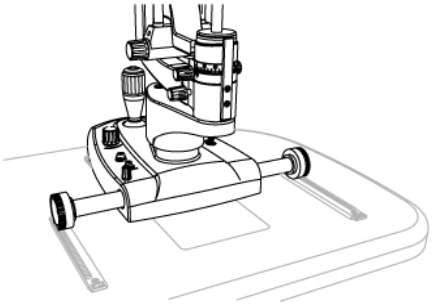

Fig 28 - Placement of the device

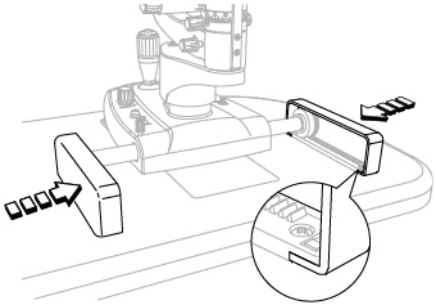

Fig 29 - Placing protection carters

9 Install the chin rest. Under the table top, there are two screws to block the chin rest support to the table top.

10 Electrical connection between the several components.

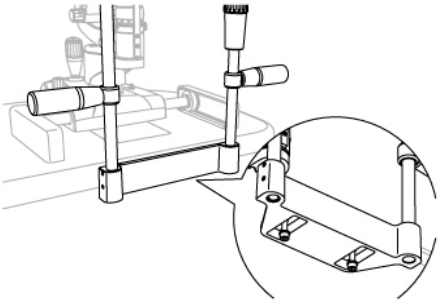

Fig 30 - Placement of the chin rest

4.2 HOW TO CONNECT THE DEVICE

Device SL9800

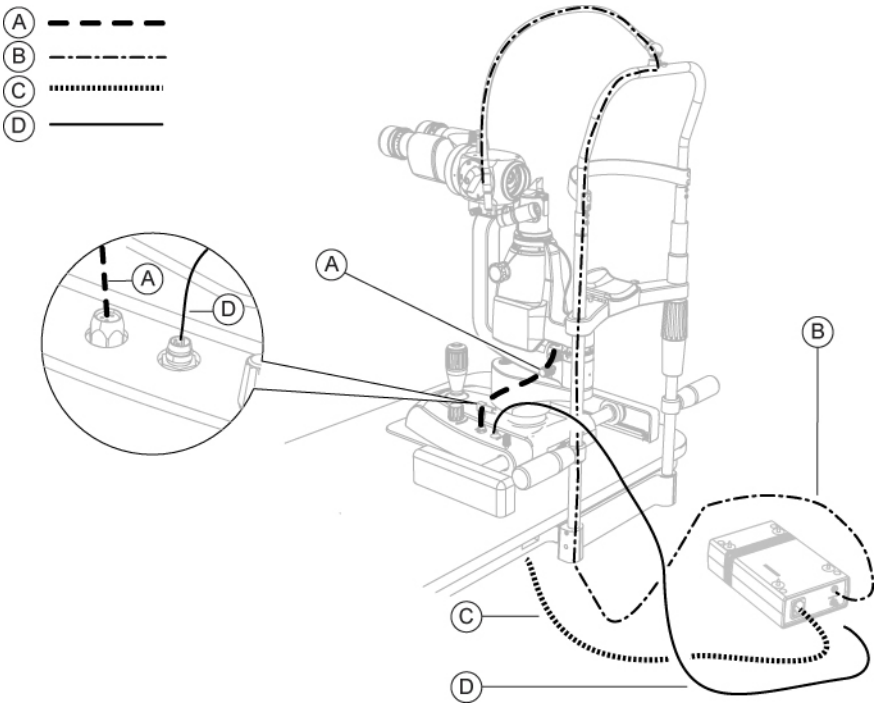

Fig 31 - Connecting the device SL9800

Pos	Denomination
A	Power cable for the connection between the lamp unit and the device base
B	Connection cable for fixation point on the chin rest
C	Power cable for the connection of the table with the power supply unit
D	Power cable for the connection between the power supply unit and the device

To power the table basement, read instructions for use of the table or of the ophthalmic unit.

SL9900

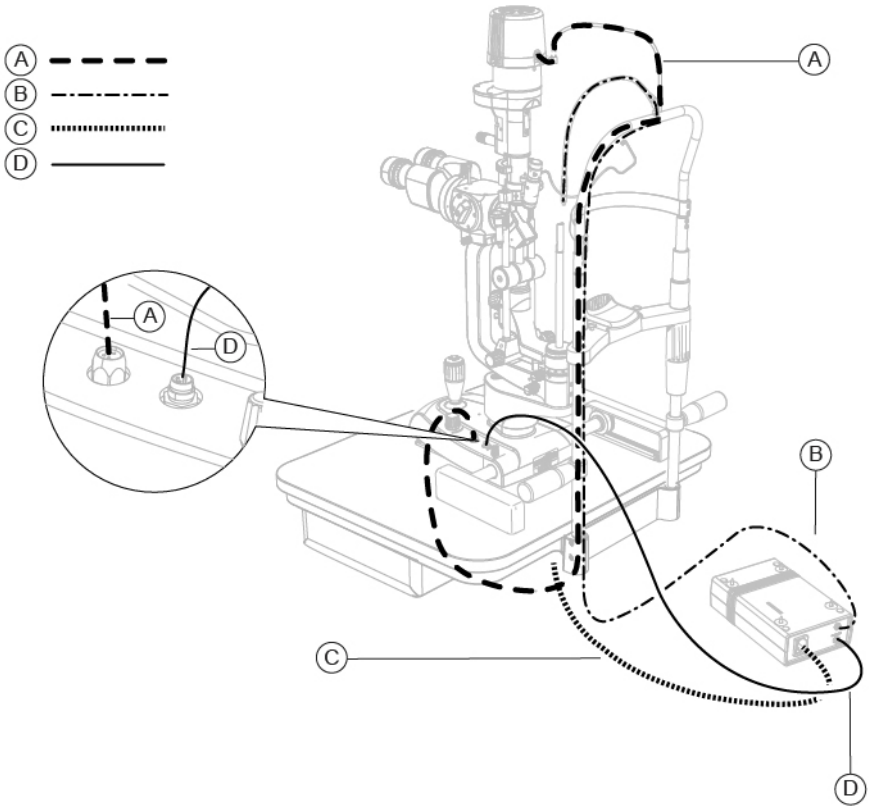

Fig 32 - Connecting the device SL9900

Pos	Denomination
A	Power cable for the connection between the lamp unit and the device base
B	Connection cable for fixation point on the chin rest
C	Power cable for the connection of the table with the power supply unit
D	Power cable for the connection between the power supply unit and the device

To power the table basement, read instructions for use of the table or of the ophthalmic unit.

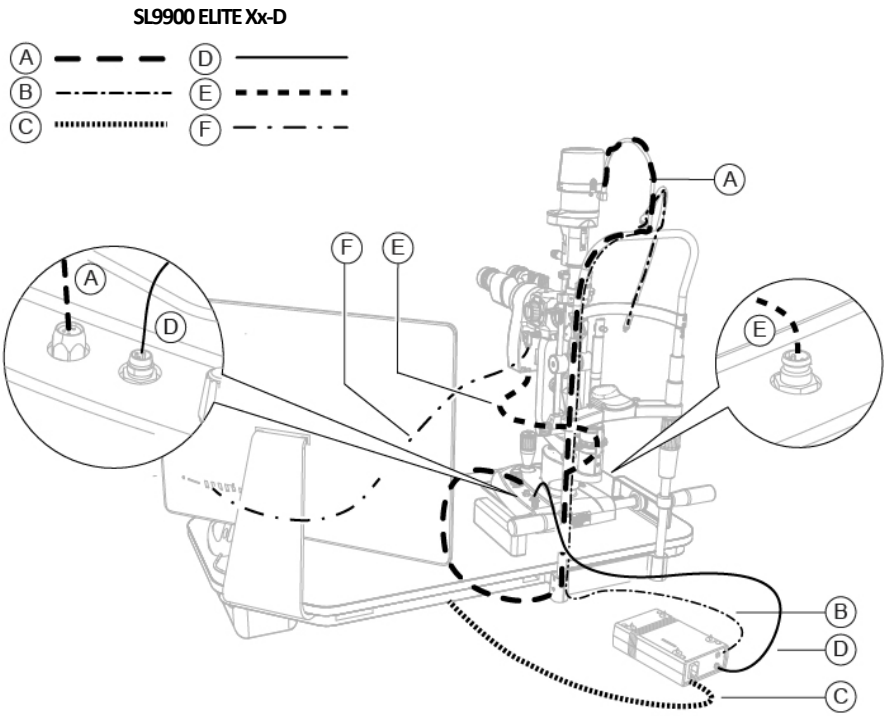

Fig 33 - Connecting the device SL9900 ELITE Xx-D

Pos	Denomination
A	Power cable for the connection between the lamp unit and the device base
B	Connection cable for fixation point on the chin rest
C	Power cable for the connection of the table with the power supply unit
D	Power cable for the connection between the power supply unit and the device
E	Power cable for the connection between the video camera Digital Vision HR and the device base
F	Connection cable between video camera Digital Vision HR and PC

To power the table basement, read instructions for use of the table or of the ophthalmic unit.

4.3 HOW TO PLACE ELECTRIC CABLES

CAUTION
Danger of device falling down. Do not leave free cables which can represent an obstacle or a danger for the patient or the operator.

CAUTION
Danger of stumbling and falling. Do not let the power cord or the connection cables free in a place where people could walk.

CAUTION
Electric shock risk. Do not leave the power supply cables in contact with sharp corners or objects. Collect and attach always the power supply cables.

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

For the proper placement of electrical cables and connection to the elevation column, read 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 is on the lower part of the column of the ophthalmic table and it has to be used for the connection to the mains power. One of the power sockets on the upper part of the elevation column is dedicated to the device power supply unit.

4.4 HOW TO TURN ON THE DEVICE

1 Press the activation switch of the power supply unit on ON. The device control light turns on. The supply control light on the base turns on.
2 Now it is possible to go on with the observation.

If the device is equipped with video camera Digital Vision HR (Xx-D, ELITE Xx-D):

1 Launch the program Phoenix on the PC.
2 Wait until the main screen of the application software is shown.

Read the instructions for use before using the application software.
The instruction manual can also be downloaded from the website www.csoitalia.it or you can read the application software guide.

3 Click on NEW PATIENT and enter his personal data. If the patient is already present in the database, you can automatically search the surname in the surname command line.
4 A new examination will be created automatically.

5 Select the device to be used.
6 The image capture screen will open. Now it is possible to acquire the image.

Creation of a new exam

- Click on the button NEW EXAMINATION.
- Select the device to be used.
- The image capture screen will open. Now it is possible to acquire the image.

4.5 INDICATIONS GIVEN BY THE FUNCTIONING INDICATORS

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

Functioning indicator on the base	Meaning
Indicator on. Continuous. Green.	Powered base. Powered lamp group. White light emission. 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 lamp holder. Restore the connection and switch back on. If the problem persists, contact the Assistance Centre.
Indicator on. Two pulses and one pause. Green and yellow.	Turn off the device. Contact the Assistance Centre.
Indicator on. Fast pulses (2 every second). Red and green.	Turn off the device. Contact the Assistance Centre.
Indicator on. Slow pulses (1 every 3 seconds). Red and green.	Turn off the device. Contact the Assistance Centre.
Indicator on. Two pulses and one pause. Red and green.	Turn off the device. Contact the Assistance Centre.
Indicator on. Continuous. Yellow.	Turn off the device. Contact the Assistance Centre.

4.6 HOW TO ADJUST THE CHIN REST

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

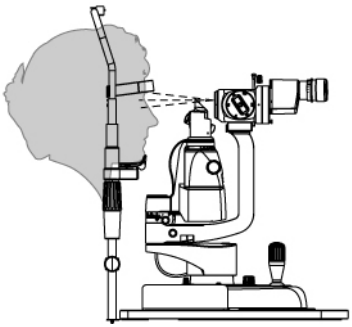

Fig 34 - Patient position on the chin rest SL9800

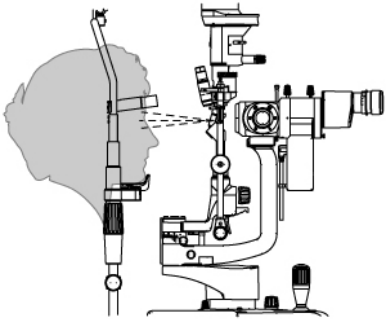

Fig 35 - Patient position on the chin rest SL9900 - SL9900 ELITE

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

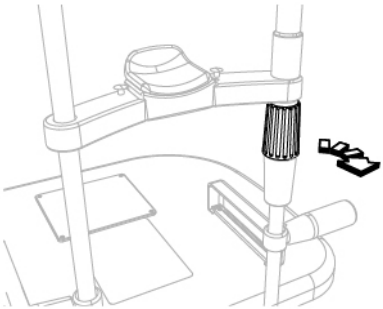

Fig 36 - Knob rotation

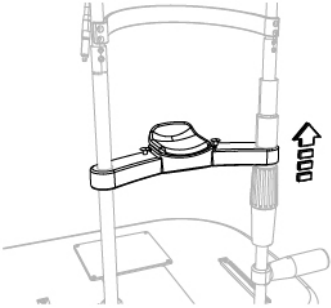

Fig 37 - Placing the chin cup

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.

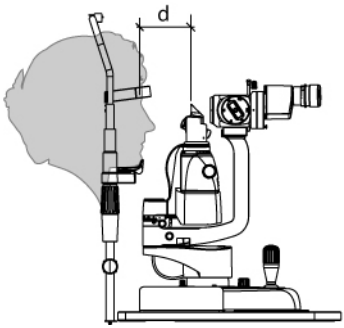

Fig 38 - Distance from the patient SL9800

3 Adjust the eyepieces interpupillary distance.

4 If necessary, pull out the sliding eyecups. Eyecups are suitable for spectacle wearers.

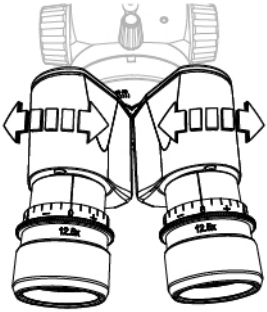

Fig 39 - Interpupillary distance adjustment

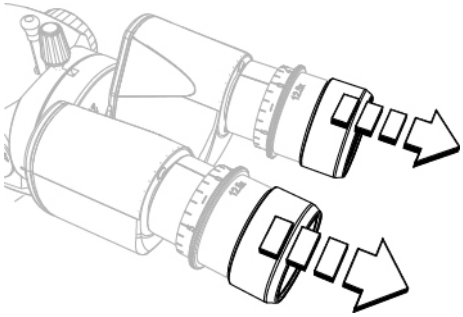

Fig 40 - Placing the eyepieces cover

4 Bring the image into focus by rotating the eyepieces for the ametropia correction.

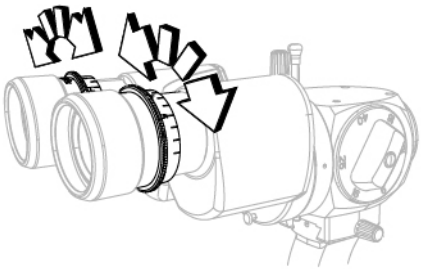

Fig 41 - Ametropia correction

5 Turn the ferrule (A) to select diaphragm diameter and slit height.
6 Turn the ferrule (B) to select the filters.
7 Insert the yellow filter by lowering the lever on the microscope group.

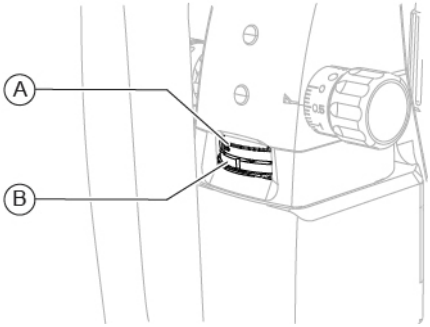

Fig 42 - Diaphragm diameter, slit height (A) and filters (B) selection

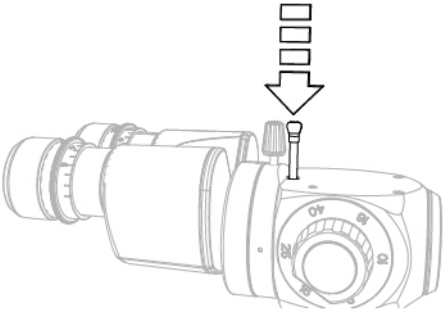

Fig 43 - Inserting the yellow filter

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.

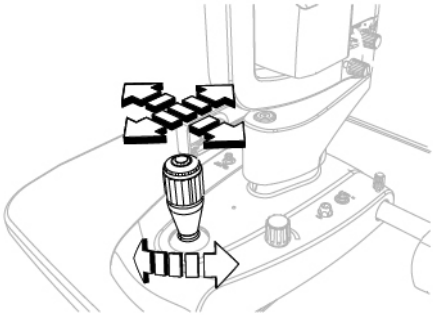

Fig 44 - Placing the device

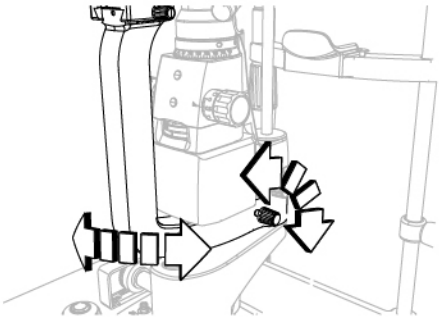

Fig 45 - Microscope position adjustment

10 Use the locking/unlocking knob to change the illumination source position.

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

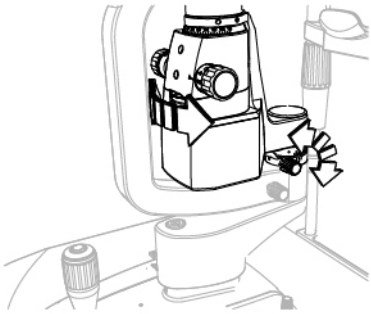

Fig 46 - Illumination source blocking knob

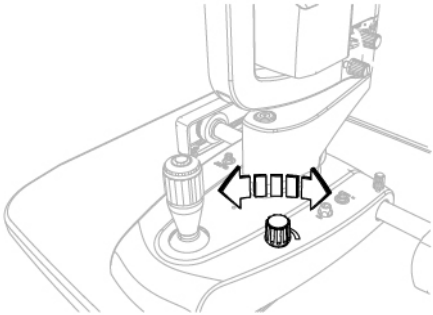

Fig 47 - Light intensity adjustment

12 During the exam, adjust the slit width

13 If necessary, change the image enlargement

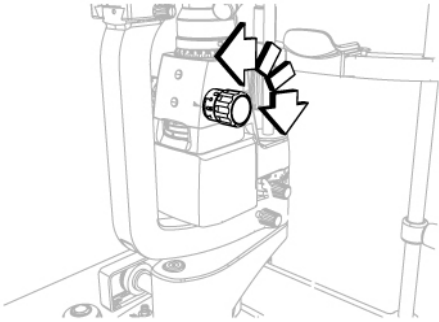

Fig 48 - Slit width adjustment

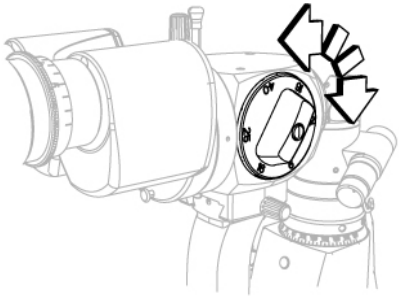

Fig 49 - Microscope magnification change

14 If necessary, adjust again the slit rotation verifying the value on the rotation indicator ring (A).

15 If necessary, adjust again the position of the illumination source.

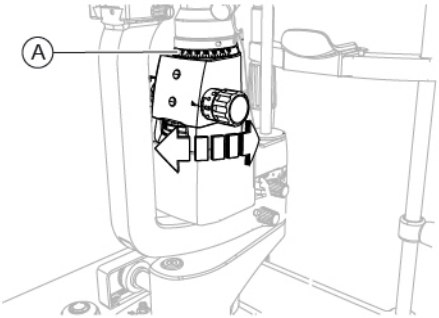

Fig 50 - Slit rotation

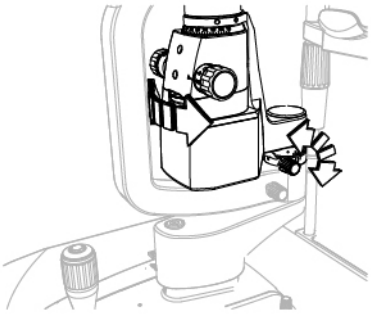

Fig 51 - Illumination source projection angle adjustment

4.8 HOW TO VISUALIZE THE IMAGE (SL9900)

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.

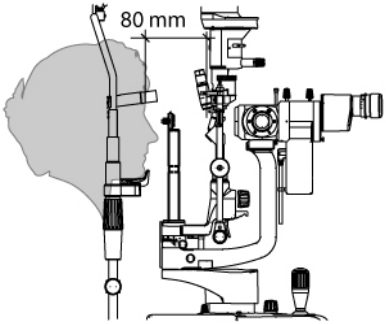

Fig 52 - Distance from the patient SL9900

3 Adjust the eyepieces interpupillary distance.

4 If necessary, pull out the sliding eyecups. Eyecups are suitable for spectacle wearers.

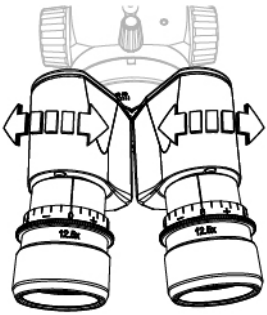

Fig 53 - Interpupillary distance adjustment

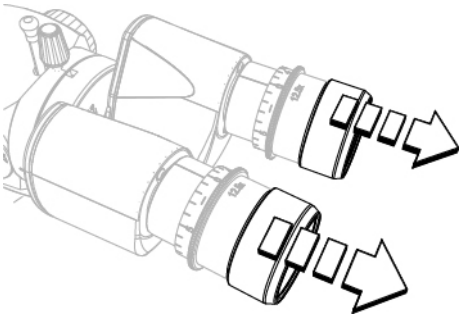

Fig 54 - Eyecups placement

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

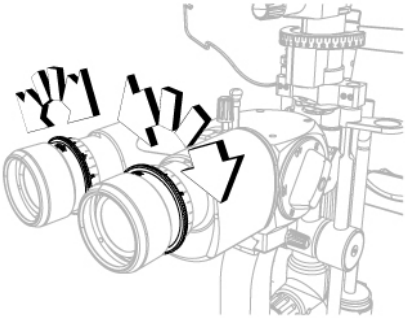

Fig 55 - Ametropia correction

6 Adjust the slit width.

7 Insert the yellow filter by lowering the lever on the microscope group.

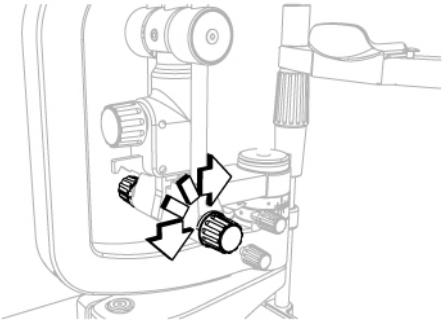

Fig 56 - Slit width adjustment

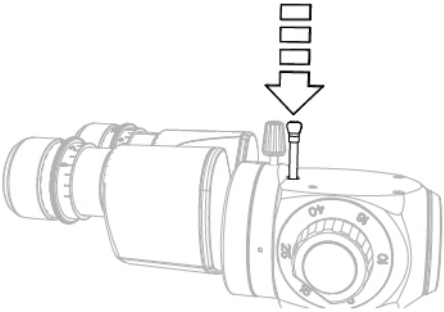

Fig 57 - Inserting the yellow filter

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.

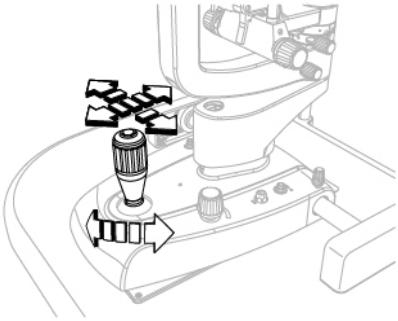

Fig 58 - Placement of the device

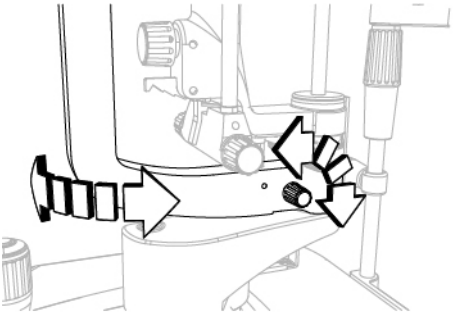

Fig 59 - Microscope position adjustment

10 Use the locking/unlocking knob to change the illumination source position.
11 To adjust the intensity of the light, turn the knob on the device base.

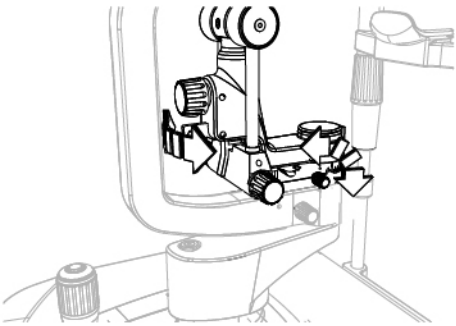

Fig 60 - Adjusting the illumination source projection angle

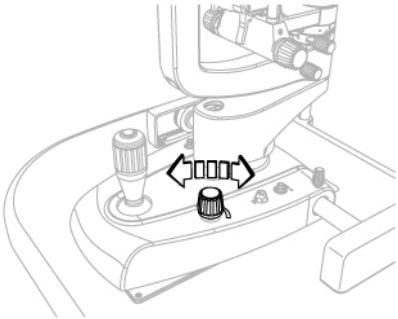

Fig 61 - Light intensity adjustment

12 During the exam adjust the slit height.
13 If necessary, change the microscope magnification.

Fig 62 - Diaphragm diameter selection

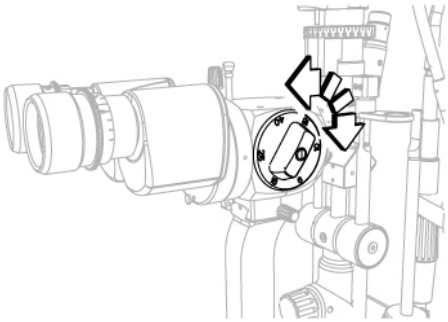

Fig 63 - Microscope magnification change

14 Adjust the slit rotation verifying the value on the rotation indicator ring (A) to place the illumination unit correctly.

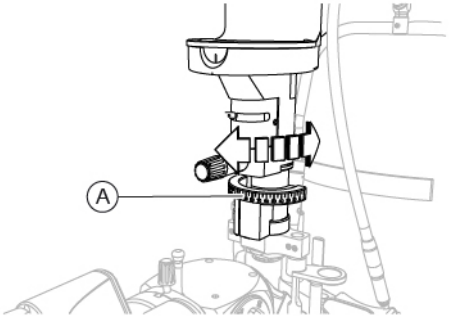

Fig 64 - Slit rotation

15 To tilt horizontally loosen the locking/unlocking knob (A). Tighten the knob to lock.

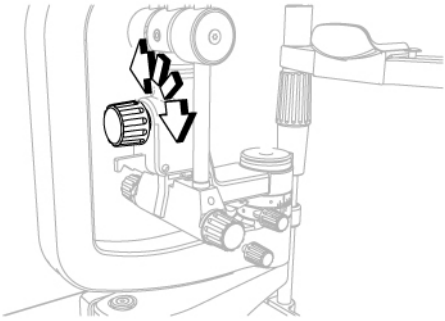

Fig 65 - Locking/unlocking knob

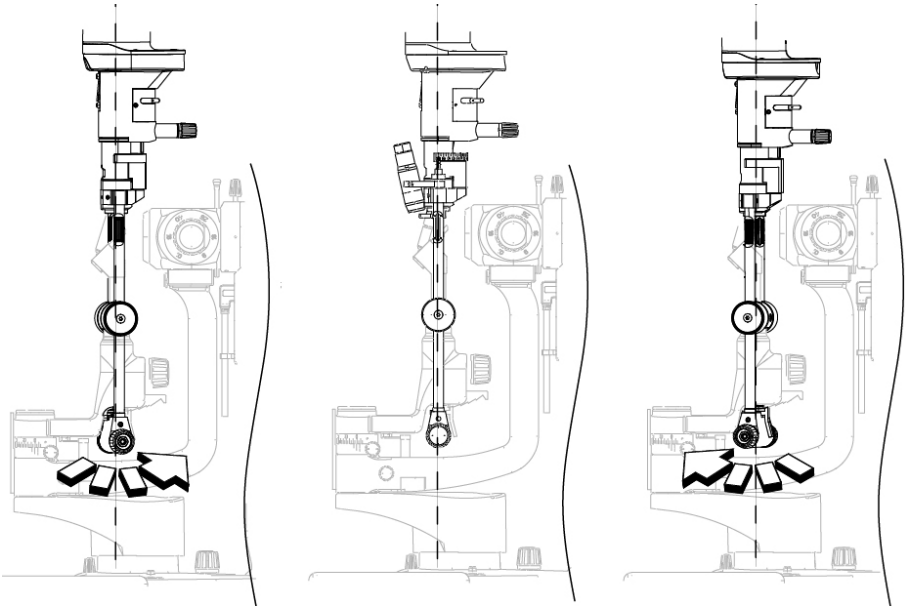

Fig 66 - Horizontal tilting

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

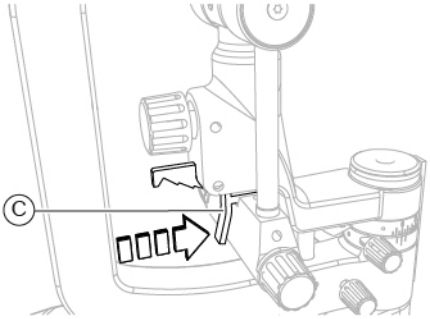

Fig 67 - Blocking lever for vertical tilting

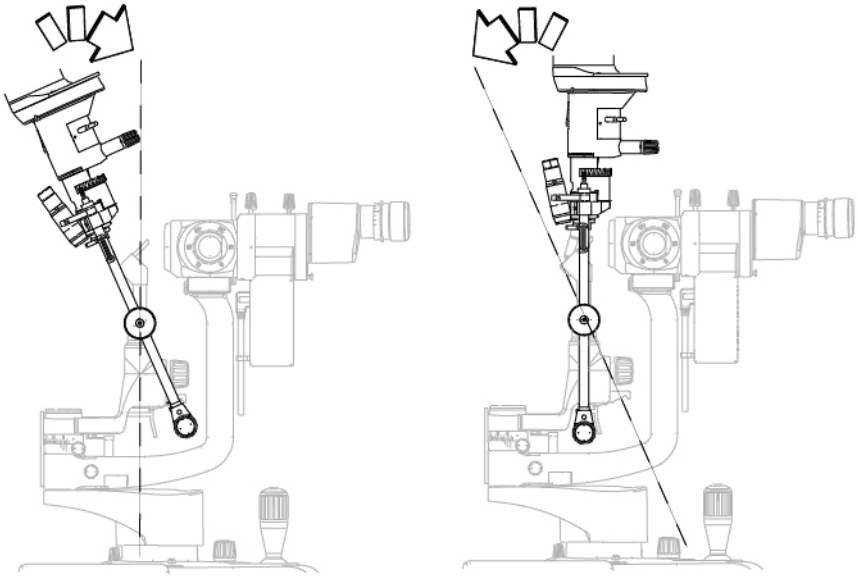

Fig 68 - Vertical tilting

4.9 HOW TO CAPTURE THE IMAGE

4.9.1 CAPTURING THE IMAGE WITH VIDEO CAMERA DIGITAL VISION HR (Xx-D)

If the device is equipped with video camera Digital Vision HR it is possible to capture the image with the analysis and management software and perform the analysis of the captured images.

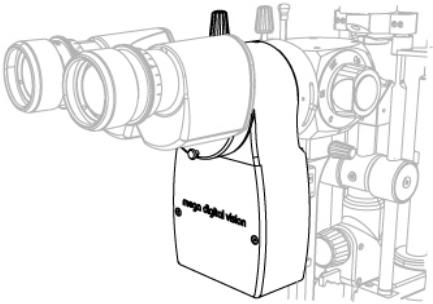

Fig 69 - Video camera Digital Vision HR

1 Bring the image into focus.
2 Push down the joystick to confirm and capture the image. It is possible to capture multiple images at the same time. The image will be saved in the gallery.

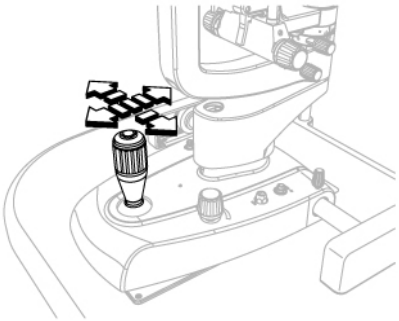

Fig 70 - Image focus

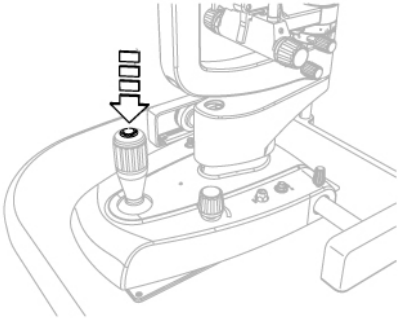

Fig 71 - Image capture

4.9.2 CAPTURING THE IMAGE WITH VIDEO CAMERA DIGITAL VISION HR (ELITE Xx-D)

If the device is equipped with video camera Digital Vision HR it is possible to capture the image and send it to the images' management and analysis software.
SHUTTER: press the buttons UP/DOWN to obtain the best image condition.
VIDEO/FOTO: button to switch from the PHOTO mode to the VIDEO mode

REG: button for image adjustment. Different settings are available.

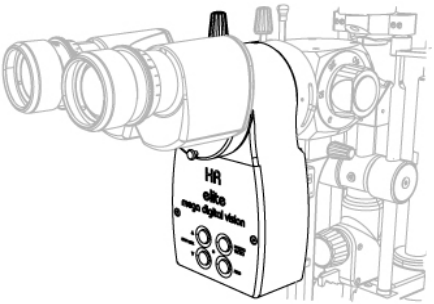

Fig 72 - Video camera Digital Vision HR

1 Bring the image into focus. Use the SHUTTER buttons to obtain the best image condition.
2 Use the REG buttons to adjust the image quality.
3 Push down the joystick to confirm and capture the image. It is possible to capture multiple images at the same time. The image will be saved in the gallery.

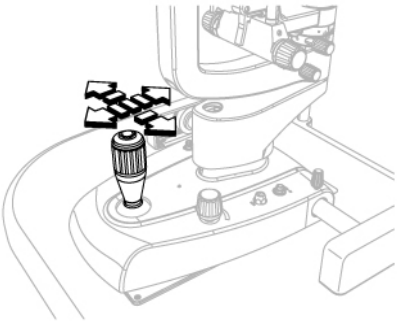

Fig 73 - Image focus

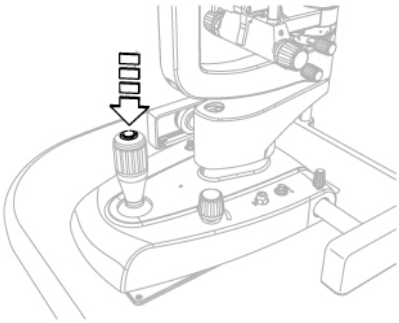

Fig 74 - Image acquisition

Refer to the application software instructions for the image managing in the database.

4.10 HOW TO REPLACE CHIN CUP PAPERS

At the end of each exam remove the paper for chin cup in order to always have a new and hygienic one for the next patient.

This 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 damp 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 in the holes of the package and in the holes of the chin cup.

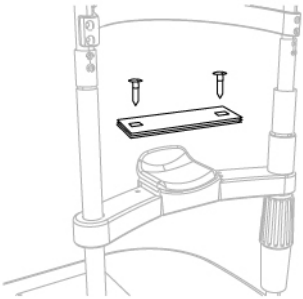

Fig 75 - Changing chin cup papers

To order a spare part read the code in the "**Spare parts list at page 70**"

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.

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, ELITE Xx-D).

1 Immobilize the device. Turn the locking knob.
2 Exit the application software.
3 Turn off the computer (Xx-D, ELITE Xx-D).
4 Press the activation switch of the power supply unit on OFF.
5 Place the protective cover on the device to prevent dust to fall on the device.

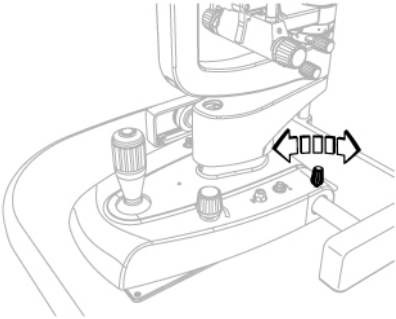

Fig 76 - Blocking the device

4.12 HOW TO INSTALL THE ACCESSORIES

4.12.1 HOW TO INSTALL THE VIDEO CAMERA DIGITAL VISION HR

The 2x microscope does not support the installation of the video camera Digital Vision HR.

1 Support the binocular (A).
2 Loosen the locking/unlocking knob on the microscope (B).
3 Remove the binocular.
4 Connect the USB 3.0 cable to the video camera.
5 Place the video camera (C) near the microscope (D).
6 Loosen the locking/unlocking knob on the microscope.
7 Install the video camera.
8 Fasten the locking/unlocking knob on the microscope.

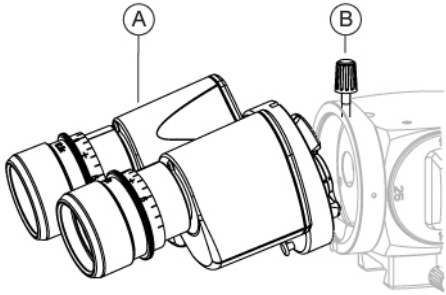

Fig 77 - Binocular removal

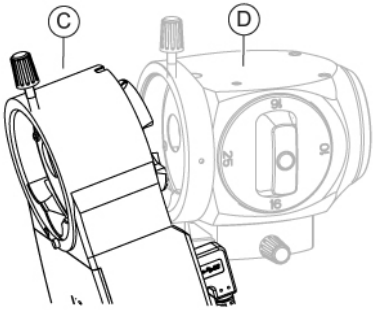

Fig 78 - Installing video camera Digital Vision HR

9 Loosen the locking/unlocking knob on the video camera.
10 Install the binocular.
11 Fasten the locking/unlocking knob on the video camera.
12 Connect the power cable of the video camera (E) with the mains connector on the device base.
13 Connect the USB 3.0 cable (F) of the video camera with the PC.

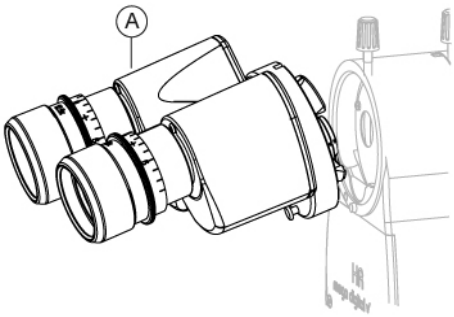

Fig 79 - Binocular installation

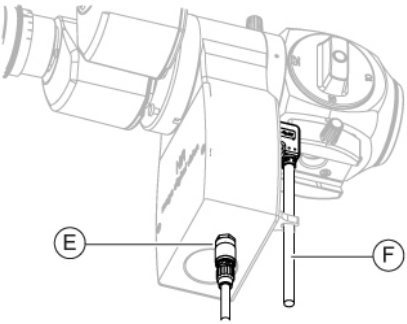

Fig 80 - Video camera Digital Vision HR connection

4.12.2 HOW TO INSTALL THE ADDITIONAL LED ILLUMINATOR (SL9800)

1 Place the illuminator (A) next to the illumination unit.
2 Fasten the screw (B) to block the device.
3 Connect the power cable (D) to the mains connector (E) on the illumination device card.
4 The led (F) indicates the functioning status of illumination device.
5 To turn on the illuminator and adjust the luminous intensity turn the knob (C).

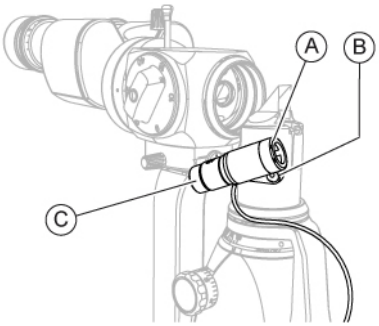

Fig 81 - Illuminator installation

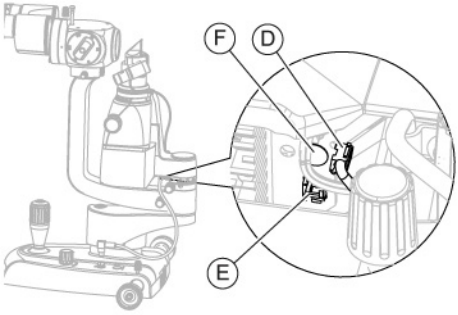

Fig 82 - Illuminator connection

4.12.3 HOW TO INSTALL THE ADDITIONAL LED ILLUMINATOR (SL9900)

1 Turn the slit width adjustment knob in order to lower the rod (E).
2 Lift the part (D).
3 Insert the flat ring (I) on the rod (E). The ring has to lean on the part (J).
4 Insert the white LED illuminator kit (C) arm in correspondence with the rod.
5 Insert the round ring (H) on the rod.
6 Insert the closing ring (F) on the rod.
7 Push down the closing ring (F). Fasten the STEI screw (G).
8 Unscrew the screws (M) and remove the protection (K).
9 Connect the power supply cable of the illumination device (I) with the mains connector on the LED illumination device.
10 Reassemble the protection (K) and fasten the screws (M).
11 To turn on the illuminator and adjust the luminous intensity turn the knob (A).

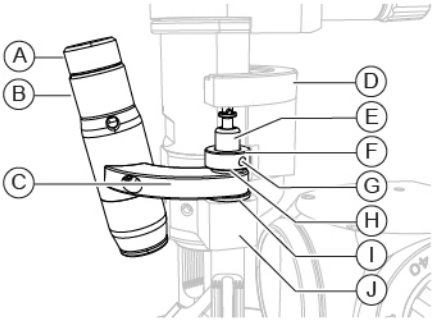

Fig 83 - Additional LED illuminator installation (optional)

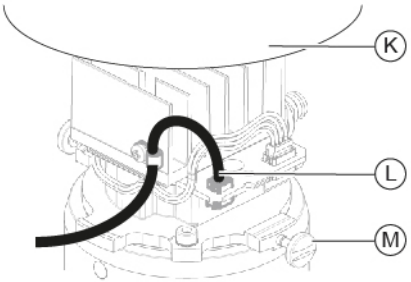

Fig 84 - Illumination device connection

How to install the light diffuser:

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

2 Lift the light diffuser filter to block it on the rod.

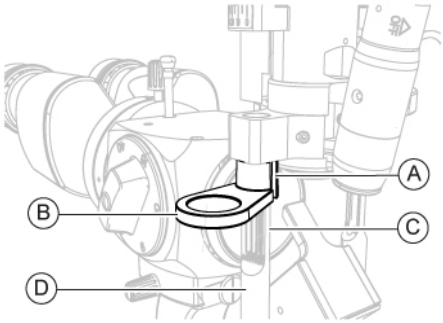

Fig 85 - Light diffuser installation

Using the light diffuser filter:

1 Turn the diffuser filter horizontally on the rod.

2 Place the filter next to the illumination unit.

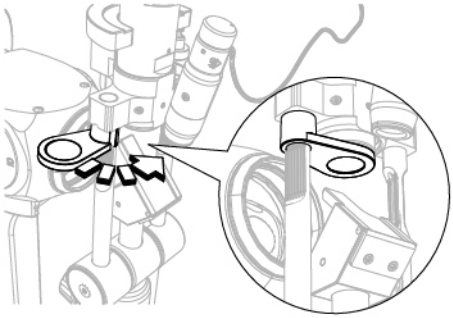

Fig 86 - Placing the light diffuser

4.12.4 HOW TO INSTALL THE SEPARATOR, SINGLE AND DOUBLE EXIT

The 2x microscope does not support the installation of the video camera Digital Vision HR.

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.

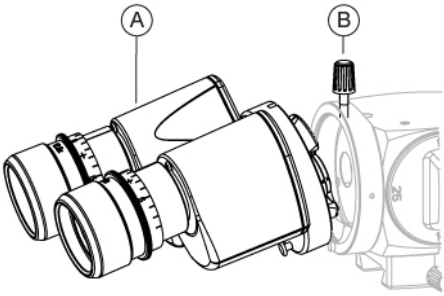

Fig 87 - Binocular removal

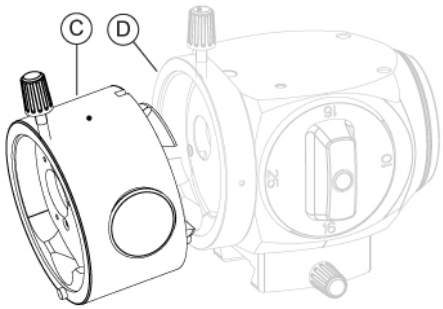

Fig 88 - Separator installation

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

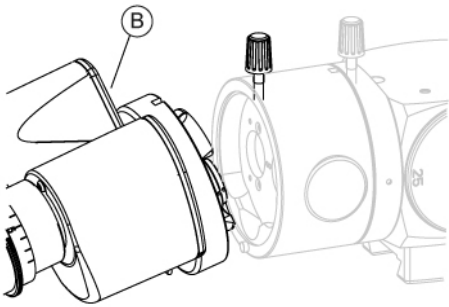

Fig 89 - Binocular installation

4.12.5 HOW TO INSTALL THE VIDEO CAMERA CONNECTOR

Before installing the accessory, install the separator.

1 Remove the lid (C) installed on the separator (B).
2 Install the video camera connector (A) on its seat on the separator. Align the plug (D) of the video camera connector with the socket (E) on seat of the separator.
3 Turn the ferrule (F) of the video camera connector to block the accessory of the separator.

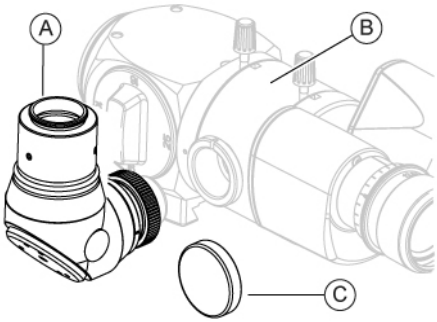

Fig 90 - Video camera connector

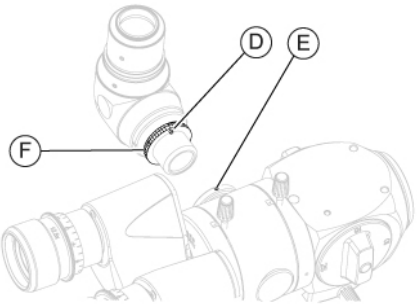

Fig 91 - Video camera connector blockage

4.12.6 HOW TO INSTALL THE CAMERA CONNECTOR

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 ferrule (F) of the camera connector to block the accessory of the separator.

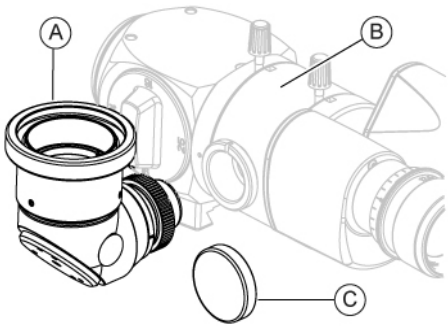

Fig 92 - Camera joint

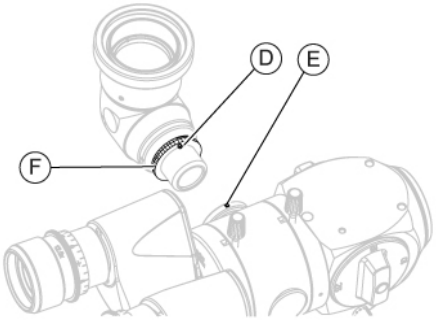

Fig 93 - Camera connector blockage

4.12.7 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 ferrule (E) of the ocular for the second operator to block the accessory of the separator.

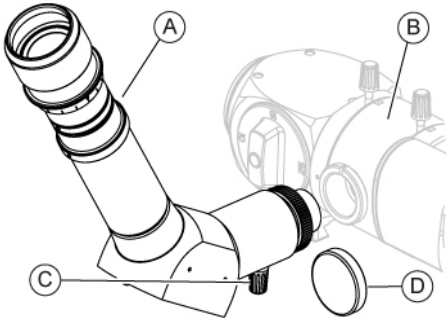

Fig 94 - Ocular for the second operator

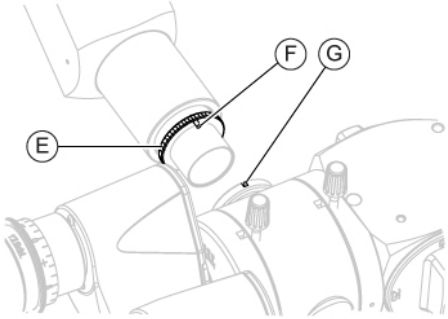

Fig 95 - Ocular blockage for the second operator

4.12.8 HOW TO REPLACE EYEPIECES FOR THE BINOCULAR

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

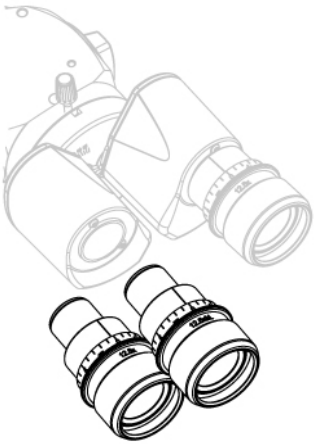

Fig 96 - Eyepieces

5 ORDINARY MAINTENANCE

5.1 SAFETY WARNINGS

DANGER
Electric shock danger. Unplug the power cable from the mains socket before disinfecting the device and before any maintenance operation.

CAUTION
The device does not contain any piece that requires the user's intervention. Do not dismantle any part of the device.

it is forbidden to carry out any maintenance operation on the device that is not recalled in 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 about cleaning and disinfection described in this manual, in order to avoid any damages to the device and the accessories.

CAUTION
A correct cleaning and disinfection procedure, together with appropriate operating procedures, are essential to prevent the spread of infections or cross-contaminations.

CAUTION
Danger of material damages. 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 regularly carried out.

Parts of the device that do not come into direct contact with the patient shall be cleaned at least once a day.
Parts of the device that do come into direct contact with the patient shall be thoroughly cleaned and disinfected after each application.

The current section described the procedures to be carried out during use and maintenance, in order ensure proper cleaning and disinfection of the device and its accessories.

5.2.1 RECOMMENDED PRODUCTS FOR CLEANING AND DISINFECTION

CAUTION
Danger of material damages. 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 damages caused by using disinfecting products which are 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 medical products FDA or CE approved for medical devices or medical-surgical devices.
Follow the products listed below, divided by category:

Detergents	Use polyenzymatic solutions or neutral surfactant-based solutions.
Disinfectants and decontaminating products	Use surface-friendly disinfectants (containing or not containing aldehyde) or formaldehyde-free surface disinfectants-cleaners (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 DEVICE FOR HYGIENE AND SAFETY

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 is only used on healthy skin and therefore has a low infectious risk**.**
For devices classified as non-critical, regular cleaning is sufficient, or low-level disinfection.

However, in cases where the patient's condition is transmissible by direct contact, or in 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 instructions about cleaning described in this paragraph, in order to avoid any damages to the device and the accessories.

CAUTION

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

The device shall be regularly cleaned.

The device is provided with a 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 cleansing solution.

For more information about suitable cleansing products, read the **"Recommended products for cleaning and disinfection" paragraph on page 68.**

5.2.4 CLEANING THE APPLIED PARTS

CAUTION

Danger of material damages. Only use detergent and disinfecting 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 electrical outlet.

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 **"Recommended products for cleaning and disinfection" paragraph on page 68.**

5.2.5 CLEANING THE OPTICAL COMPONENTS

CAUTION

Danger of material damages. 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	Paper for chin cup
960206C00	Dust cover for SL9900
960102-00	Dust cover for SL9800
960206021.O	SL9900 projecting mirror
100250250	Light diffuser for SL9900
100270210	External LED illuminator kit for SL9900
100272210	External LED illuminator kit for SL9800
100257300	Micrometrical eyepiece 12.5x with protection from light
30200815	USB 3.0 Cable 2 m length
330130100	USB 3.0 Cable 5 m length
330259900	Connection cable between table-instrument base
100226627	Eyepiece plastic covering

For spare parts or accessories not included in the list, ask the Manufacturer or the 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 Press the ON/OFF button on the device.	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 cable to the power supply unit. Press the button of the power supply unit on ON. Replace the PC.	Make sure the power outlet of the room works properly.
PC Operating system does not start	Hard Disk failure. Spoiled operating system.	It is necessary to replace the Hard Disk. Reinstall the operating system. Replace the PC.	Contact the Technical Service Centre. Make sure the New PC features are equivalent to those required by the device.
The application software does not start	Hard Disk failure. The anti-virus software impedes the starting of the application software Phoenix. Spoiled operating system The application software Phoenix does not work properly.	It is necessary to replace the Hard Disk. Check the settings of the anti-virus software. Reinstall the operating system. Reinstall the Phoenix application software.	Contact the Technical Service Centre. The installation of the application software Phoenix needs the administrator privileges.
The application software does not work properly	The connection cable between device and 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 device and 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 mouse of the PC does not work	Connection cable with the PC disconnected. Mouse switch in position OFF. The mouse batteries are down (only for wireless mouse)	Check that the mouse connection cable properly fit in USB port. Switch the mouse button in position ON. Replace mouse batteries (only for wireless mouse).	From the control panel of the PC, check that there are no devices conflicts.
The keyboard of the PC does not work	Connection cable with the PC disconnected. Keyboard switch in position OFF. The keyboard batteries are down (only for wireless keyboard)	Check that the keyboard connection cable properly fit in USB port. Switch the keyboard button in position ON. Replace keyboard batteries (only for wireless keyboard).	From the control panel of the PC, check that there are no devices conflicts.
The images can't be saved in the database (Xx-D).	The database is not connected to the application software Phoenix. Power connection absent. 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. Restore the connection to the database file. Check the functioning of the net connection. Replace the USB cable.	Regularly verify the connections with the data net. Use USB 3.0 cables only.
Failed image capture (Xx-D)	The patient moved or closed the eyes during the capture	Ask the patient to keep the eyes open, look the fixation light and not to move the eyes.	
Failed image focus	Presence of dust of grease on the optical parts of the device.	Clean the surface of optical parts with a soft cloth.	Make sure the patient does not touch the optical parts.

Issue	Cause	Solution	Note
Missing acknowledgment of eye position left / right position by the device	Missing installation of black sticker below the base of the device. Fault of positioning detector	Install the black sticker below the base of the device.	Some colours and material of the table top may not reflect the infrared light. Move a white paper below the base of the device to check the functioning of the positioning detector.
Device movement difficulties (ahead, back, left, right)	The joystick plastic protection has not been removed from the base during the installation. Device blocking knob is fastened	Remove the joystick plastic protection from the base. Loosen the device blocking knob.	Before starting the exam check that the device blocking knob is loosened.
Functioning indicator does not turn on.	The connection cable of device and PC does not work or is disconnected.	Replace the power cable from the power supply unit to the device.	
The device does not generate any light	The connection cable of device and PC does not work or is disconnected. Light intensity adjustment knob is at minimum. The slit is completely closed. The LED lamp does not work.	Replace the power cable from the power supply unit to the device. Open the slit. Increase the light intensity. Replace the luminous source.	

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