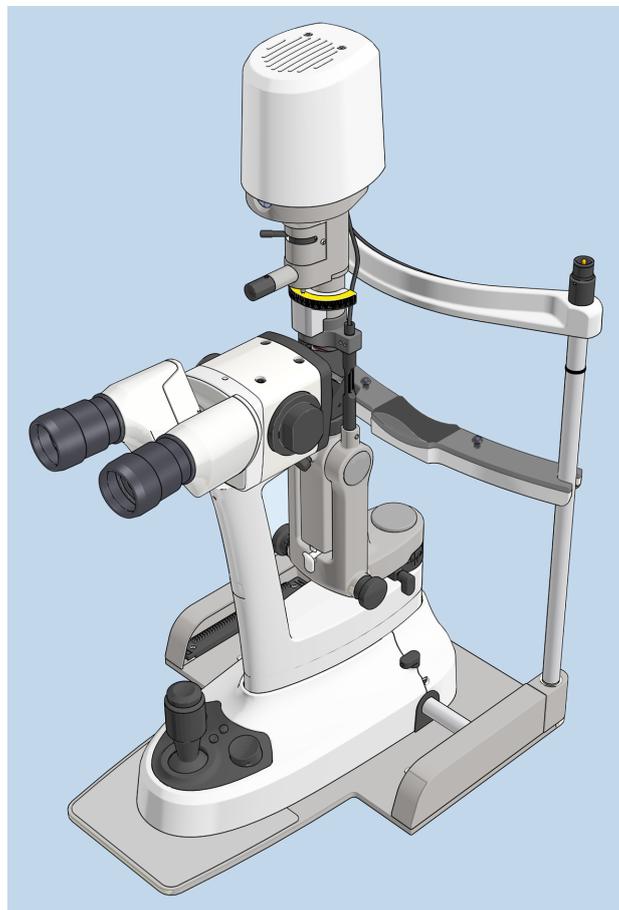


SL 800
Slit lamp

Documentation set



Copyright

© 2019, Carl Zeiss Meditec AG, Jena

Trademarks

All trademarks mentioned in this document are the property of their respective owners.

Table of contents

1	Notes on the instructions for use	7
1.1	Product name	7
1.2	Scope of application	7
1.3	Purpose and storage of the documentation	7
1.4	Questions and comments	7
1.5	Conventions in this document	7
1.5.1	Conventions in all text areas	7
1.5.2	Conventions in a course of action	8
1.6	Applicable documents	8
2	Safety notes	9
2.1	Intended user profile	9
2.2	Intended field of application.....	9
2.2.1	Intended use	9
2.2.2	Patient population.....	9
2.3	Responsibilities and duties of the responsible organization	10
2.3.1	Notification to manufacturers and authorities.....	11
2.4	Responsibilities and duties of the operator	11
2.5	Risk due to optical radiation.....	13
2.6	Maintenance measures	14
3	Description of the device.....	15
3.1	Package check list	15
3.2	Device marking.....	15
3.3	Structure of the device	17
3.4	Structure of the power supply unit.....	18
3.5	Control elements	19
3.6	Control buttons and indicator lamps on the power supply unit.....	24
3.6.1	Configuration switches on power supply unit.....	25
3.7	Functional description	26
4	Installation	27
4.1	Installation safety	27
4.2	Installing the device.....	28
4.3	Connecting the device	30
5	Before every use.....	33
5.1	Preparation safety	33

6	Daily startup.....	35
6.1	Switching on	35
7	Operation	37
7.1	Operation safety.....	37
7.2	Adjusting the eyepieces and interpupillary distance	37
7.3	Positioning the diffusor	38
7.4	Setting the brightness	39
7.5	Positioning the patient	39
7.6	General notes on device operation	39
7.7	Reading the angular difference between illumination and observation unit.....	40
7.8	Tonometry.....	41
7.9	Gonioscopy.....	42
7.10	Switching off the device	43
8	Cleaning and disinfection	45
8.1	Safety when cleaning and disinfecting the device	45
8.2	Cleaning	46
8.3	Disinfection	46
9	Maintenance	47
9.1	Testing electrical safety	47
9.2	Replacing the fuses.....	49
9.3	Installing software updates for the device.....	50
9.4	Creating a log file	50
9.5	Changing paper pads.....	51
10	Troubleshooting	53
10.1	Malfunctions	53
10.2	Service information	54
11	Technical specifications.....	55
11.1	Essential performance	55
11.2	Compliance.....	55
11.2.1	Directives with which the device is compliant	55
11.2.2	The device meets the following requirements and standards	55
11.2.3	Device classification.....	55
11.3	Illumination	56
11.4	Stereomicroscope	56
11.5	Instrument base.....	56

11.6	Headrest	57
11.7	Dimensions and weights	57
11.8	Ambient conditions	57
11.9	Electrical specifications	58
11.10	Electromagnetic compatibility	59
11.10.1	Ambient conditions for intended use	59
11.10.2	Restrictions on essential performance	60
12	Optional accessories	65
12.1	Adjust the counterweight for the height adjustment of the instrument base	66
12.2	SL cam compact	68
12.3	Wide-field illumination	69
12.4	10x eyepiece, cross-hairs	70
12.5	Focusing rod	71
12.6	AT 030 applanation tonometer	71
12.7	Fundus VarioView	72
12.8	Yellow filter aperture module	76
12.9	Tube adapter 20°	79
12.10	Beam splitter	81
12.11	Co-observation tube with eyepiece	84
12.12	Fixation lamp	85
12.13	Breathing shield	86
12.14	Paper pads	86
12.15	Instrument table	86
13	Disposal of the device	89
	Glossary	91
	Keyword index	93

Empty page, for your notes

1 Notes on the instructions for use

1.1 Product name

The SL 800 slit lamp is referred to as "device" in these instructions for use.

1.2 Scope of application

The present instructions for use apply to the SL 800 slit lamp carrying the following marking:

- Reference number: 2268-355

1.3 Purpose and storage of the documentation

These instructions for use explain the safety features, functions and performance parameters of the device. They contain instructions on the safe use of the device and identify measures for its care and maintenance.

Correct operation of the device is imperative for its safe and successful function.

- ▶ Read these Instructions for Use before setting up and using the device the first time.
- ▶ Keep the instructions for use accessible for all users at all times.
- ▶ Pass the instructions for use to future owners of the device.

1.4 Questions and comments

- ▶ If you have questions or comments concerning these instructions for use or the device itself, contact ZEISS Service.

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

1.5 Conventions in this document

Certain types of information are specially marked in this document for better recognition.

1.5.1 Conventions in all text areas

- This is a list.
 - This is a second level list.

This is a cross-reference: Questions and comments [▶ 7].

This is **bold type**.

This is `software code or program text`.

Names of software dialogs, fields or menus, and software messages are marked by quotation marks:

- "View" menu.
- "Do you want to save the settings?"

The steps in menu and file paths are separated by slashes:

- "File / Save as"
- "My documents / Documents"

Keys, buttons, knobs, levers and other operating controls are marked by square brackets:

- [START] key
- [Next] button

1.5.2 Conventions in a course of action

WARNING!

This is warning information about hazards that can cause death or severe injuries if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

CAUTION!

This is warning information about hazards that can cause injuries if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

NOTE

This is warning information about hazards that can cause property damages if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

- This is a requirement that must be met before the start of a sequence of actions.

1. This is a command.

2. **CAUTION! This is a warning message about hazards that can occur during a single action.** This is a command.

⇒ This is the result of a sequence of actions.

1.6 Applicable documents

Please observe also the instructions for use of any additional equipment used with this device.

2 Safety notes

2.1 Intended user profile

This device may only be installed, operated, used and maintained by persons who have been properly trained or who have the required knowledge and experience to do so. Please also adhere to the national qualification guidelines applicable in your country.

Persons who operate the device must have knowledge of basic ophthalmic examination and diagnosis methods as well as of ophthalmic optics. This includes, among others, persons belonging to the following occupational groups or their national equivalents:

- Ophthalmologist
- Optometrist
- Optician

2.2 Intended field of application

This device may only be set up, operated and used for the indication for use specified herein and according to national regulations, consistent with the applicable industry standards and occupational safety and accident prevention regulations.

2.2.1 Intended use

This slit lamp is intended for eye examinations. It is used as a universal device for observation, diagnosis, evaluation and documentation of diseases or traumata that influence the structural properties of the eye.

2.2.2 Patient population

The device was developed for a wide patient population. In principle, people of all age groups can be examined.

- ▶ However, do not use this device in patients with the following conditions:
 - Patients who are unable to follow the instructions of the user,
 - Patients who are unable to sit upright in front of the device,
 - Patients who have forehead or chin injuries that prevent the head from being supported on the forehead rest or chin rest.

2.3 Responsibilities and duties of the responsible organization

Operating personnel

The device may only be operated by instructed and trained personnel.

- ▶ Ensure that the operating personnel have been trained and instructed.
- ▶ Ensure that the operating personnel have read and understood the instructions for use.
- ▶ The instructions for use should be readily accessible to the operating personnel at all times.
- ▶ To facilitate access for the entire operating personnel: If necessary, request further copies of the instructions for use from ZEISS.
- ▶ Define the required skills for handling the device and provide information on who is authorized for which activities.
- ▶ Define rules for reporting errors and damage, and provide information on these (see Notification to manufacturers and authorities [▶ 11]).
- ▶ Regularly check compliance with the national laws and regulations concerning accident prevention and occupational health.

Complete the following checks before using the device:

- Visual inspection of the device and its accessories for damage, as well as legibility of markings and labels
- Check the ventilation slits of the device. They should not be covered or obstructed.
- Functional check of all switches, buttons, connectors and indicator lamps on the device

Service life

The development, production and maintenance of the device, together with associated risks, are based on an expected service life of eight years, assuming that the device is operated and maintained as prescribed in these instructions for use.

Changes to the product

Modifications to the product or failure to follow the manufacturer's instructions may substantially reduce the expected service life and significantly increase the risks associated with the use of this device and are thus not permitted.

Accessories and additional equipment

- ▶ If you want to connect accessories or additional equipment other than those described in these instructions for use to the device: Contact your ZEISS representative [▶ 7].

Additional equipment connected to medical electrical equipment must demonstrably comply with the applicable IEC or ISO standards (e.g. IEC 60950-1 for data processing equipment).

Furthermore all configurations must comply with the normative requirements for medical systems (see IEC 60601-1-1 or section 16 of IEC 60601-1).

If you connect additional devices to medical electrical systems, you are a system configurer and are thus responsible for ensuring that the system complies with the normative requirements for systems.

2.3.1 Notification to manufacturers and authorities

If an incident occurs in connection with this medical device which affects the responsible organization or another person, the responsible organization (or person responsible) must report this incident to the manufacturer or seller of the medical product. In some countries (e.g. the European Union) the responsible organization must report this incident to the responsible authorities in the applicable country.

2.4 Responsibilities and duties of the operator

Electrical safety

- ▶ Switch the device off every time before disconnecting it from the power supply, or if you are not going to use the device for any length of time.
- ▶ Also switch off the device and disconnect it from the power supply before cleaning surfaces or accessories with a damp cloth.
- ▶ Use only cables and plugs which are in perfect working condition.
- ▶ Connect the device only to a power supply that corresponds to the values specified on the rating plate.
- ▶ Never pull the cable to disconnect the plug.
- ▶ Do not use multiple sockets.
- ▶ Do not use extension cables.
- ▶ Observe the instructions regarding electromagnetic compatibility (EMC).
- ▶ Set the device up so that the power cable can be disconnected from the power supply quickly and without any supplementary means.

- ▶ Connect the device using the power cable intended for use with the device. If the device is mounted on an instrument table qualified by Carl Zeiss Meditec, it will be powered through this table.
- ▶ Perform the electrical installation in conformance to IEC 60364-7-710 or the applicable national regulations. This includes the integration of a ground fault circuit interrupter (GFCI).
- ▶ Do not touch the patient and the connections of the device simultaneously.

The SL 800 is a device of protection class II. The third wire in the power connection cable is only a functional earth wire.

Live parts are accessible inside the device. If you remove the housing, you are exposed to the risk of an electric shock.

- ▶ Never open the device!

Ambient conditions

- ▶ Make sure that the installation requirements and the operation of the device meet the following requirements:
 - Low vibration
 - Clean environment
 - Avoid extreme mechanical loads
- ▶ Do not operate or store the supplied devices in environmental conditions other than those prescribed.
- ▶ Do not operate the supplied devices, when powered by electricity,
 - on easily inflammable materials,
 - in explosion risk areas (e.g. combustible mixture of anesthetic, cleaning or disinfecting agents with air, oxygen or nitrous oxide).
- ▶ Do not store or use this device in damp areas. Do not expose the device to water splashes or dripping or sprayed water.
- ▶ Ensure that no liquids can enter the device.
- ▶ Protect all optical exits (e.g. projector mirror, front lens, binocular tube of stereomicroscope) against contamination and avoid touching optical exits.

Decommissioning

- ▶ If one of the following events should occur, disconnect the cable from the power supply, label the device clearly as being out of service and report the problem to the ZEISS Service:
 - Electric shock
 - Penetration of substances

- Frequently occurring error messages
- Faults that cannot be remedied based on the information provided in these instructions for use

If you use the device in combination with an accessory for image documentation, please note that if the sensor for laterality detection is defective, the right/left labeling of image data may be incorrect. In this case, inform ZEISS Service about the problem and check the right/left labeling of image data.

Symbols and labels

- ▶ Observe the symbols and labels attached to the device.

Transport

- ▶ Transport the device over long distances (e.g. move, return for repair, etc.) only in original packaging or special return packaging.
- ▶ Contact your dealer or ZEISS Service.

2.5 Risk due to optical radiation

This is a group 2 device according to ISO 15004-2:2007.

The light emitted by this device is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this device when operated at maximum intensity will exceed the safety guideline for the aphakic eye after 48 s.

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures.

Some groups of people will be at greater risk due to anatomical conditions (e.g. infants, aphakes and persons with diseased eyes). The risk may also be increased if the patient being examined has recently had any exposure to light (e.g. an eye examination or treatment).

The device allows to illuminate the eye with two different white tones using the VarioLight function.

The cold white VarioLight can offer an advantage when examining transparent media in the anterior segment of the eye, while the warm white VarioLight creates natural image effects when viewing circulated tissue e.g. in the posterior segment of the eye. The time required to exceed the ISO 15004-2:2007 guideline is reduced to 48 seconds if cold white VarioLight is used exclusively, compared with 88 seconds if warm white VarioLight is used exclusively.

Ratio for duration of exposure cold white [%] : warm white [%]	VarioLight	
	cold white [s]	warm white [s]
100 : 0	48	0
75 : 25	36	22
50 : 50	24	44
25 : 75	12	66
0 : 100	0	88

Table 1: Examples of exposure duration up to the safety guideline threshold when using warm and cold white light.

- ▶ Never look into the sun through the binocular tube and eyepieces.

2.6 Maintenance measures

Maintenance procedures (maintenance and repairs) which are not specified in these instructions for use may only be carried out by persons authorized by Carl Zeiss Meditec and solely according to the service instructions issued by Carl Zeiss Meditec. For planning and implementing these maintenance and care procedures please contact ZEISS Service or your local dealer.

3 Description of the device

3.1 Package check list

SL 800 version for installation on an instrument table

- SL 800 slit lamp
- Binocular tube (convergent or parallel)
- 2 eyepieces
- Headrest
- Power supply unit
- Power supply cable
- Documentation set
- Mounting accessories
- Dust cover

When using the device mounted on an examination unit, an optional cable extension set is available.

Depending on your order, additional optional components and accessories may also be included in the delivery package.

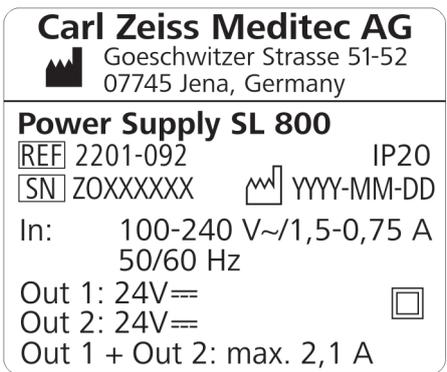
3.2 Device marking

Instrument base

Labels	Explanation
	SL 800 type label
	 Manufacturer
	 Date of manufacture
	 Applied part type B
	IP20 Ingress protection rating for housing (protected against solid foreign bodies of ≥ 12.5 mm in diameter, no protection against penetration of water)
	 EU conformity symbol
	 Disposal advice for EU

Labels	Explanation
	SL 800 identification label
	REF Catalogue number / part number
	SN Serial number
YYYY-MM-DD	Label with manufacturing date
	"Observe user manual" information label
Rx only	Label: According to Federal Law of the U.S.A. this device may only be purchased by a physician or by order of a physician.
	CSA approval for USA and Canada

Power supply unit

Labels	Explanation
	Power supply unit type label
	 Manufacturer
	 Date of manufacture
	IP20 Ingress protection rating for housing (protected against solid foreign bodies of ≥ 12.5 mm in diameter, no protection against penetration of water)
	REF Catalogue number / part number
	SN Serial number
	 Device of protection class II
	"Disconnect device from the power supply before opening" information label
	"Observe user manual" information label
	Fuse identification label

Labels	Explanation
	Unique device identification code (data matrix) for power supply unit

3.3 Structure of the device

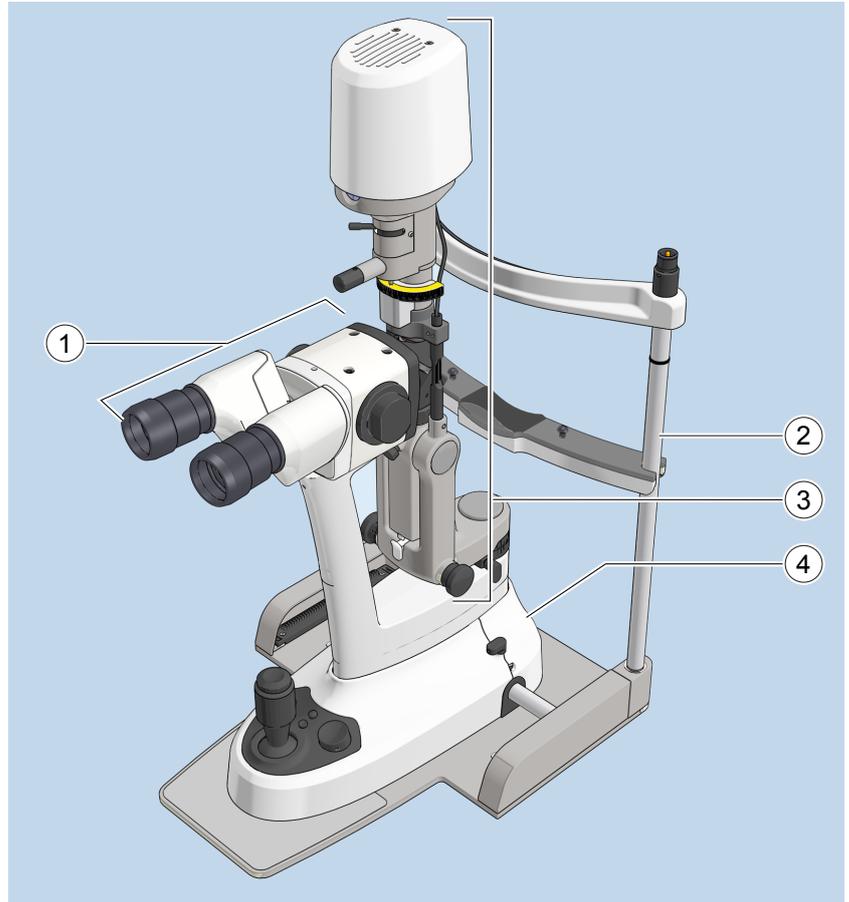


Figure 1: Structure of the SL 800

1	Observation unit (stereo-microscope): comprising front lens, magnification changer, convenience interface, binocular tube and eyepieces	2	Headrest with chinrest (applied part) and forehead rest (applied part)
3	Illumination unit (slit projector)	4	Instrument base

3.4 Structure of the power supply unit

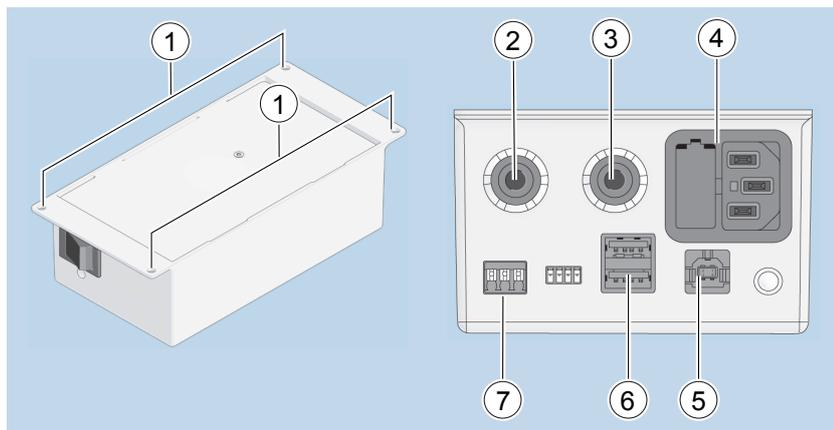


Figure 2: Connectors of the power supply unit

1	Housing with four mounting holes	2	Slit lamp connection
3	Slit lamp connection (alternative)	4	Power input with power input fuses
5	USB-B port for connection of SL Workstation or external PC	6	USB-A port for fixation lamp and wide-field illumination
7	EcoMode (external) for connection of an external switching device (sliding table switch) when the device is mounted on an examination unit		

3.5 Control elements

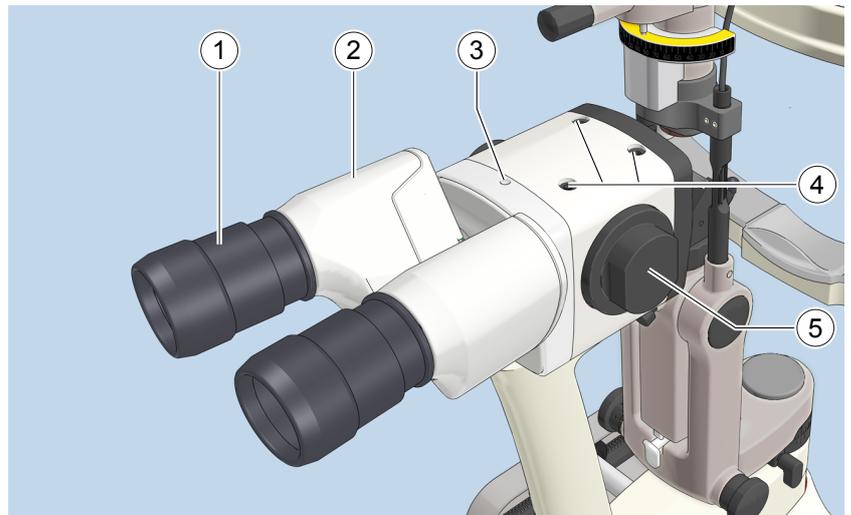


Figure 3: Controls of the stereomicroscope

Pos.	Name	Explanation
1	Eyepieces with eyecups	<p>The eyecups help to find the ideal working distance between user and eyepiece.</p> <ul style="list-style-type: none"> ■ Spectacle wearers should slide the eyecups onto the eyepiece towards the patient up to the stop. ■ Non spectacle wearers should pull out the eyecups up to the stop.
2	Binocular tube	Convergent or parallel tube (for adaptation to the interpupillary distance of the operator)
3	Convenience interface with threaded pin	For attaching the binocular tube. The convenience interface is already integrated in some optional components and accessories.
4	Mounting interface	For attaching accessories (e.g. applanation tonometer holder)
5	Magnification changer	Rotary knob for manual magnification change

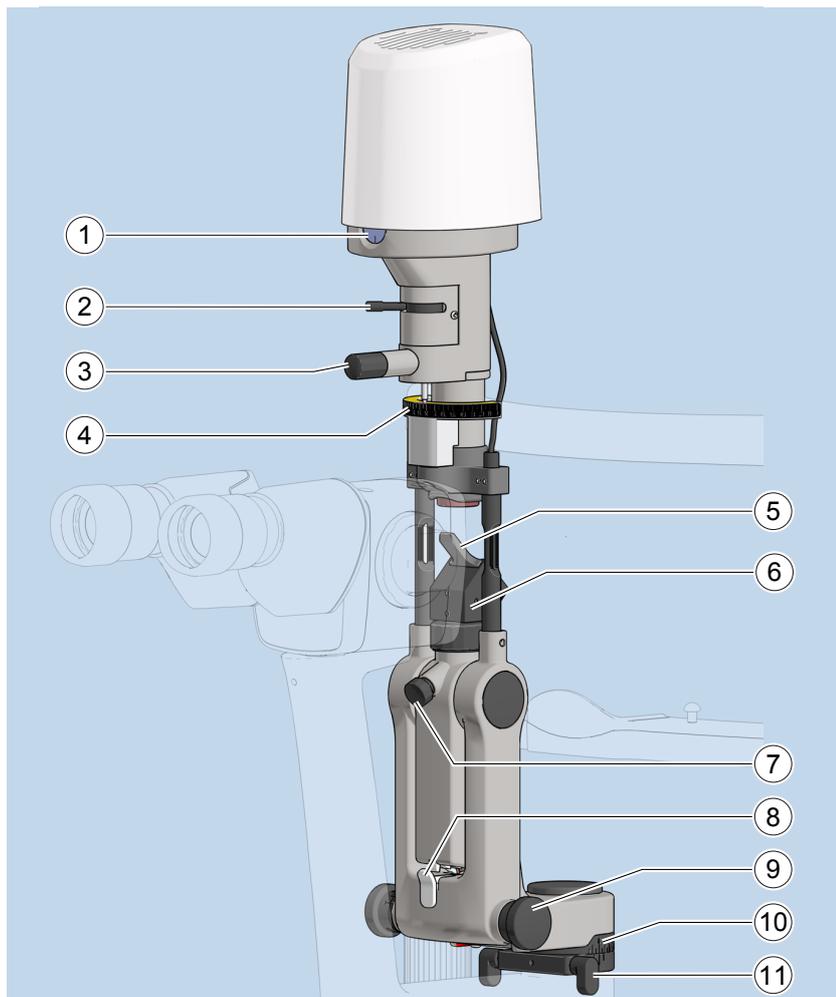


Figure 4: Display and control elements of the slit projector

Pos.	Name	Explanation
1	Scale for slit length setting	Display of the adjusted slit length
2	Filter insertion lever	Lever to set the examination illumination. Setting options: red, blue, VarioLight cold white, VarioLight warm white, green (red-free)
3	Rotary knob for slit length and blue filter setting and lever for slit rotation	Rotary knob for setting the slit length in variable steps of 0.2/1/3/5/9/12 mm and continuously from 1 mm to 12 mm, blue filter. Lever for setting the slit rotation continuously from 0° to 180° with stops at 45°/90°/135°
4	Scale to display the slit rotation	Display range: 0° to 180° with 5° scale gradation
5	Mirror	
6	Mirror base	Allows decentering of the slit illumination by pivoting

Pos.	Name	Explanation
7	Button to release decentration of slit image	Allows decoupling of observation and illumination unit when released. When fixed, the observation and illumination unit is coupled, i.e. centered.
8	Lever for vertical inclination angle	Allows setting of the angle of incidence from 0° to 20° in steps of 5°
9	Rotary knob for slit width adjustment	Setting range: continuously from 0 mm to 12 mm, with scale from 0 mm to 0.2 mm
10	Scale for angular difference	Scale indicating angular difference between illumination and observation with click stops at -60°/-45°/0°/+45°/+60°
11	Locking lever	Lever to fixate the angular difference between illumination and observation

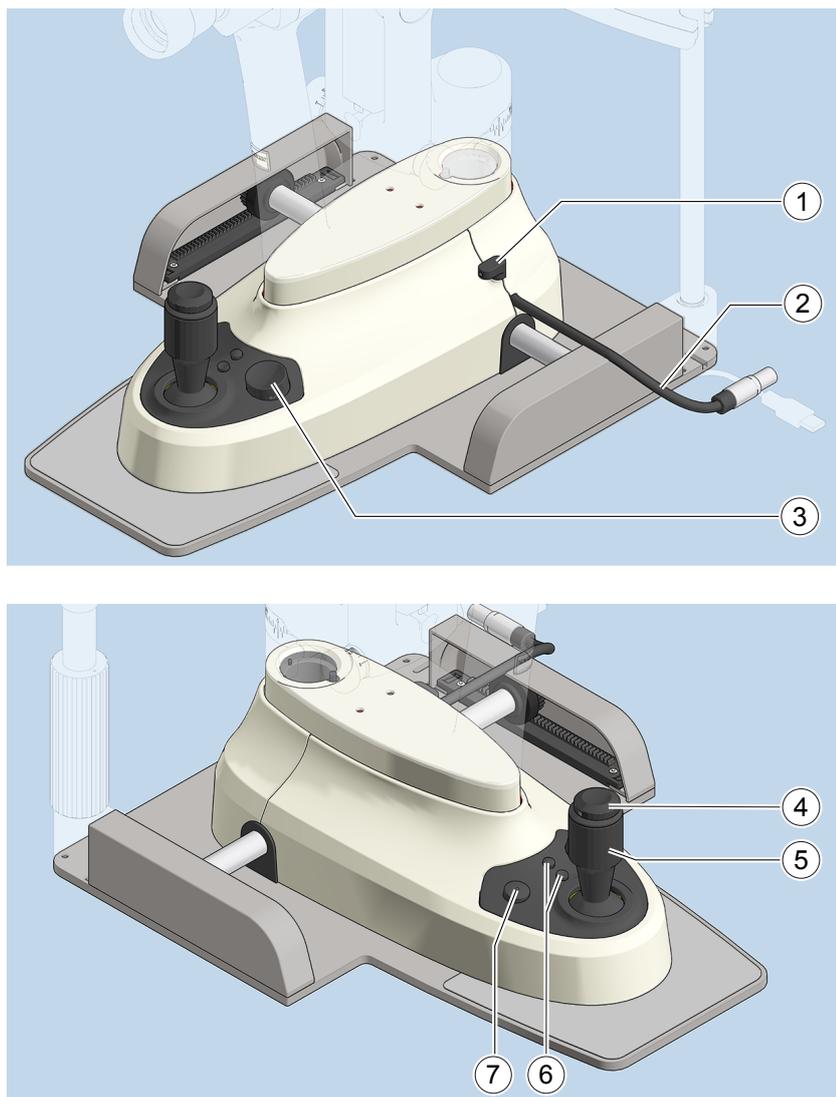


Figure 5: Controls of the instrument base

Pos.	Name	Explanation
1	Manual brake	Lever for manual brake
2	Power supply cable of slit lamp	
3	Brightness control	Brightness setting for slit projector illumination.
4	Joystick cover	Fixed version is without function. Optional version with push and turn function allowing image documentation combined with optional SL Imaging Solution
5	Joystick	Control for positioning the slit lamp relative to the patient's eye
6	AutoView control buttons (optional)	Control of the optional motorized magnification changer

Pos.	Name	Explanation
7	Control button of QuickStop (optional)	For fast locking the instrument base. Indicator LED in the control lights up when the quick-action brake is activated.

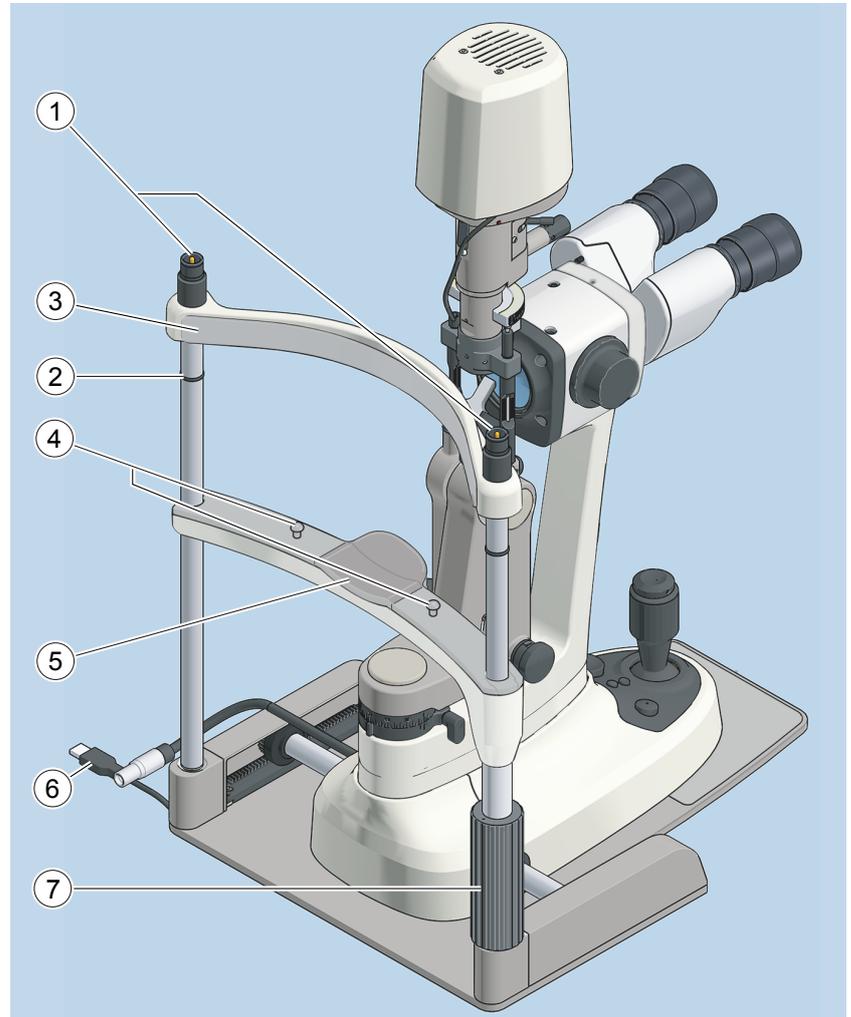


Figure 6: Control elements of the headrest

Pos.	Name	Explanation
1	Fixation lamp connectors (optional)	For connecting a fixation lamp (optional) to fixate the viewing direction of the patient's eye that is not being examined.
2	Canthus markings	Black eye level marks to identify the required patient eye level for optimum observation
3	Forehead rest (applied part)	
4	Fastening pins	Fastening pins for paper pads
5	Chinrest (applied part)	

Pos.	Name	Explanation
6	Supply cable for fixation lamp	Cable to connect the fixation lamp to the power supply unit
7	Vertical adjustment	Control elements for chinrest height adjustment

3.6 Control buttons and indicator lamps on the power supply unit

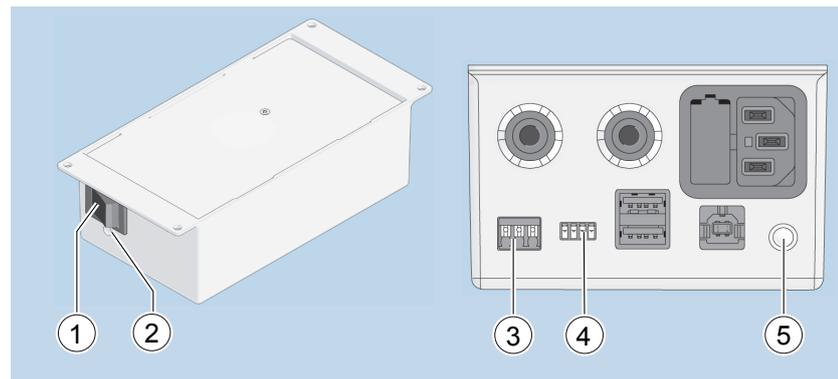


Figure 7: Control buttons and indicator lamps on the power supply unit

Pos.	Name	Explanation
1	Power switch	I - On, 0 - Off
2	Indicator lamp	Lights green when the device is switched on. Not illuminated when device is switched off.
3	EcoMode (external)	For connection of an external switching device (sliding table switch) when the device is mounted on an examination unit. For connection details please contact ZEISS Service.
4	Configuration switch	Allowing personalized settings of the device. See Configuration switches on power supply unit [▶ 25].
5	Indicator lamp	Not illuminated when device is switched off. Permanently lit green when the device is ready for operation. Flashes green when an error has occurred. Pulsates when EcoMode is activated.

3.6.1 Configuration switches on power supply unit

Some functions of the device can be individually configured by adjusting the four configuration switches on the power supply unit.

- To set the configuration switches, use an object with a rounded tip.

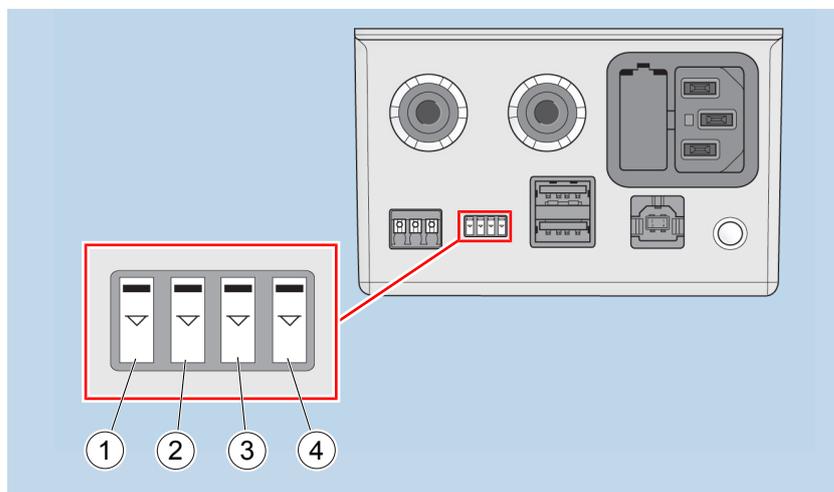


Figure 8: Configuration switches on power supply unit

No.	Configuration	Switch setting	Action
1	Not assigned	Not specified	Not specified
2	EcoMode	bottom (factory default): automatic	The illumination of the device switches off automatically if the user does not touch or move the joystick for approx. 3 minutes. The illumination of the device switches automatically back to the preset brightness as soon as the user touches the joystick again.
		top: disabled	EcoMode is disabled.
3	QuickStop	bottom (factory default): automatic	When the device changes to EcoMode, the QuickStop is automatically enabled so that the instrument base is fixed in the appropriate position. The manual enabling and disabling of QuickStop remains unaffected by the function described.
		top: manual	QuickStop is not enabled when the device changes to EcoMode. Quickstop can be enabled or disabled by pressing the corresponding key.

No.	Configuration	Switch setting	Action
4	Magnification changer with AutoView option	bottom (factory default): stopped	<p>Press the "+" or "-" button (see Control elements [▶ 19]) to set the magnification changer to the next higher or next lower magnification. Once the highest or lowest magnification is reached, pressing the "+" or "-" key has no further effect.</p> <ul style="list-style-type: none"> ■ "+" direction: 6x → 10x → 16x → 25x → 40x (stop) ■ "-" direction: 40x → 25x → 16x → 10x → 6x (stop)
		top: continuous	<p>Press the "+" or "-" button to set the magnification changer to the next higher or next lower magnification. Once the highest magnification is reached, press the "+" key again to jump to the lowest magnification. Once the lowest magnification is reached, press the "-" key again to jump to the highest magnification.</p> <ul style="list-style-type: none"> ■ "+" direction: 6x → 10x → 16x → 25x → 40x → 6x → 10x → ... ■ "-" direction: 40x → 25x → 16x → 10x → 6x → 40x → 25x → ...

3.7 Functional description

The slit lamp consists of an instrument base with joystick onto which a slit projector (serving as illumination unit) and a stereomicroscope with binocular tube and eyepieces (serving as observation unit) are mounted. The headrest is used to position the patient's head. The slit projector generates a slit image at a specified distance from the slit lamp (focus plane). The user can variably adjust the width, length, position and brightness of the slit image by means of appropriate control elements and filters. The observation unit allows the user to view the eye structure in various magnification steps. The user can position the slit lamp in all three axes using the joystick of the instrument base so that the eye structure is in focus. The slit lamp can be extended with optional components and accessories, e.g. for image documentation or for measuring intraocular pressure.

4 Installation

4.1 Installation safety

WARNING!

Electrical hazard

The use of unsuitable power cables could result in electric shock.

- ▶ Ensure that the power supply plug is suitable and certified for the local connection.
- ▶ Observe the following specifications when replacing the supplied power cable:
 - Protective earth conductor resistance maximum 0.1 Ohm
 - Local certification of the power cable for connection to medical devices
 - Device plug C13 conforming to IEC 60320
 - Cross-section at least 0.75 mm² / AWG 18 ; Hospital Grade design for specific countries (e.g. USA, Canada) (For cables > 2.5 m the cross-section must be increased to 1.5 mm²).

WARNING!

Electrical hazard due to connecting additional devices

If other system components are connected to the instrument table than those described in this manual, a non-medically-rated system is created in accordance with IEC 60601-1. There is a risk of electrical shock.

- ▶ No components other than the system components described should be connected.
- ▶ In case of system changes ensure that the safety requirements as per IEC 60601-1 are met.
- ▶ Always ensure that all external accessories are approved as a medical device or connected to a power isolation transformer.
- ▶ The power supply connections of the instrument table must only be used for supplying power to the device. Use of the power supply connections as a multiple socket is prohibited.
- ▶ Only use the USB ports on the power supply unit to power the optional accessories described or to write log files or import software updates (see Installing software updates for the device [▶ 50] and Creating a log file [▶ 50]). Any other use is prohibited.

WARNING!

Fire hazard from faulty electrical installation

Fire can occur due to faults in the electrical installation.

- ▶ Ensure that the electrical installation conforms to IEC 60364-7-710.
- ▶ Ensure that the power consumption data on the type plate are met when selecting overcurrent protection.

4.2 Installing the device

NOTE

Mechanical hazard

Incorrect installation may damage the device.

- ▶ Never use the headrest to lift or carry the device.
- ▶ To lift or carry the device, hold it only under the base plate of the instrument base.

Action

1. Open the transport box and familiarize yourself with the unpacking instructions.
2. Remove the upper part of the device packaging.
3. Remove the power supply unit and put it aside for later assembly.
4. Remove the device and place it on the selected instrument table or examination unit.
5. Use the screws supplied to secure the device in the corresponding holes on the table top of the selected instrument table or examination unit.

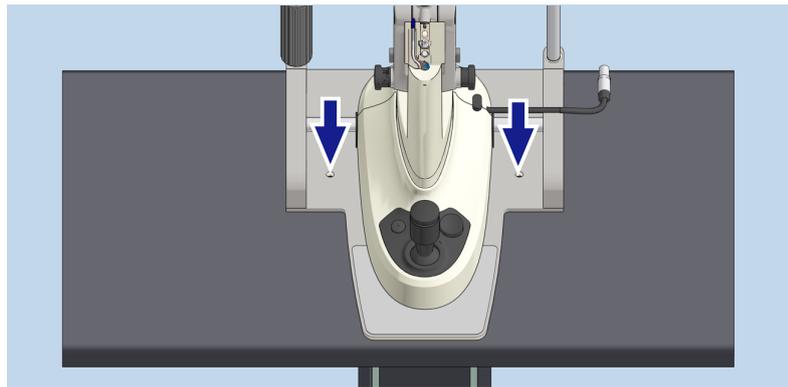


Figure 9: Installing the device

6. Cover the screws with the caps provided.
7. Carefully remove the red transport lock and keep it for future transport.
8. If applicable, remove the supplied headrest and attach it to the examination unit.
9. If the device is used on an examination unit with a separately mounted headrest to which the slit lamp moves laterally, the deflectors included in the optional cable extension kit must be installed. Position the deflectors laterally to the headrest feet. Fasten the deflectors to the table top using the appropriate countersunk screws with diameter 4 (not included in the

delivery package). Ensure that the deflectors do not protrude beyond the table top and that the cable of the fixation lamp is not pinched.

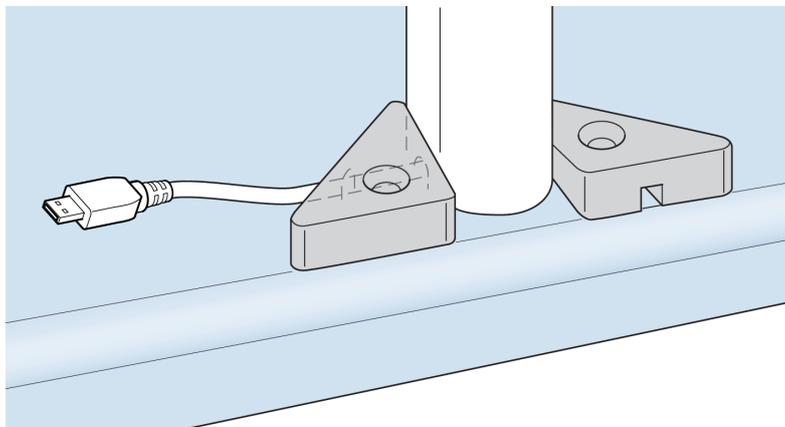


Figure 10: Position the deflectors laterally to the head rest feet on the patient's side of the examination unit.

10. If applicable, remove additional system components and attach them according to the instructions in the Optional accessories [▶ 65] chapter.
11. If the device is mounted on an instrument table qualified by ZEISS, attach the power supply unit to the intended position underneath the table top. Use the four screws provided.
12. When using the device on an examination unit, connection cables can be extended using the optional cable extension set. The technician of the manufacturer of the examination unit should perform the installation.
13. If necessary, change the factory settings of the device on the power supply unit to the switch allocation described in the Configuration switch on power supply unit [▶ 25] chapter by changing the respective configuration switch settings using an object with a rounded tip.

4.3 Connecting the device

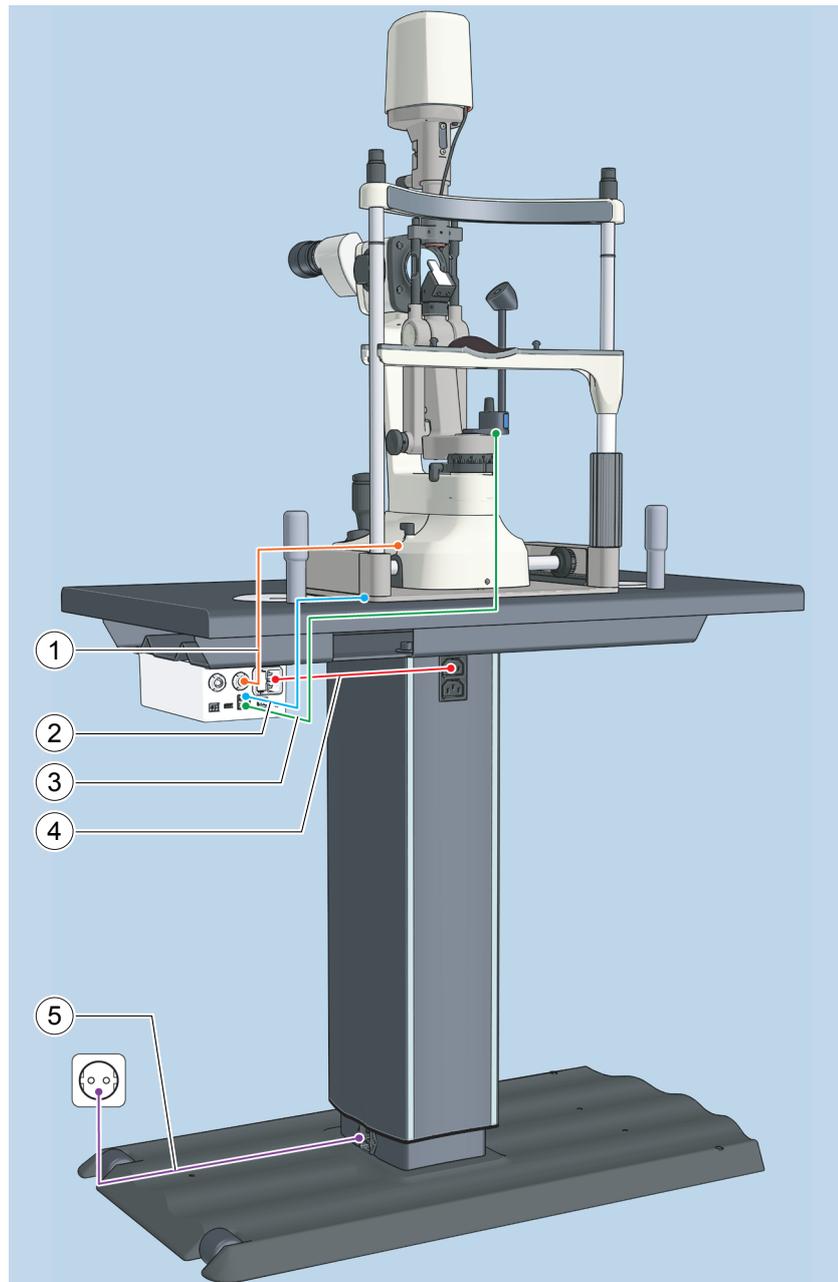


Figure 11: Connecting the device

1	Slit lamp cable (orange line)	2	Fixation lamp cable (blue line)
3	Wide-field illumination cable (green line)	4	Power supply cable for power supply unit (red line)
5	Power cable for instrument table (violet line)		

After unpacking and installing the device and after attaching the power supply unit, connect the device by performing the following steps:

Action

- ▶ Connect the round plug of the slit lamp cable to the corresponding socket on the power supply unit (1). Make sure that the plug is correctly oriented in relation to the socket.
- ▶ If applicable, connect the fixation lamp cable with one of the two USB-A ports (2).
- ▶ If applicable, connect the wide-field illumination cable with the other USB-A port (3).
- ▶ Connect the power supply unit via the power cable to one of the two sockets on the instrument table (4) or to a corresponding socket on the examination unit.
- ▶ Connect the power cable of the instrument table or examination unit to a socket on the wall (5). Please note that no multiple sockets or extension cables may be used.

If the optional cable extension set is used, use the cables with the respective sockets on the connection box of the cable extension set.

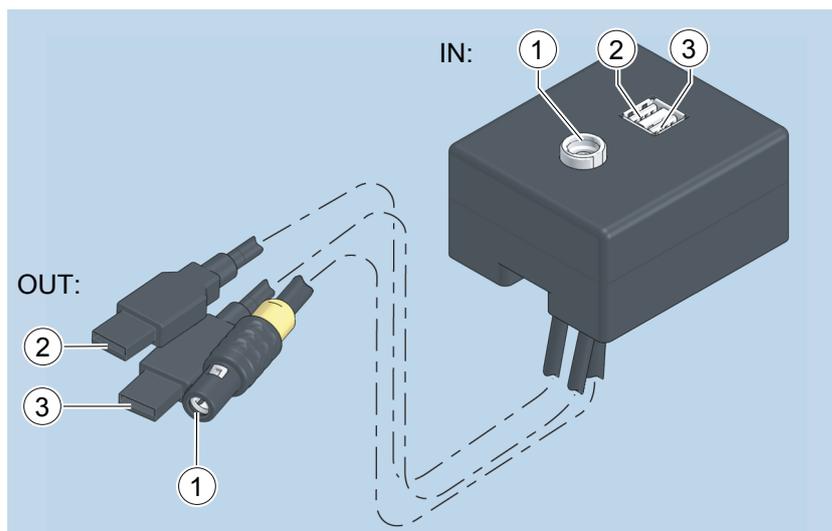


Figure 12: Optional cable extension set

1	Slit lamp connection	2	USB-A port for fixation lamp
3	USB-A port for wide-field illumination		

Please also observe the instructions for use of the selected instrument table or examination unit.

Empty page, for your notes

5 Before every use

5.1 Preparation safety

Prior to using the device, the user must ensure that it is in a good condition and fully functioning. Furthermore, the user must follow the instructions in the user manual. The following inspections must be carried out each working day prior to use:

- ▶ Visual inspection of the device, power cable and accessories to ensure that they are present and intact. If parts are missing or damage is visible, the device should not be used and should be taken out of service.
- ▶ Check the ventilation slits of the device. They should not be covered or obstructed.

Empty page, for your notes

6 Daily startup

6.1 Switching on

Action

- ▶ Switch on the device using the power switch on the power supply unit.

Result

- ✓ After a short initialization phase, the slit projector lights up if the brightness and slit width/height are set to a value greater than zero.

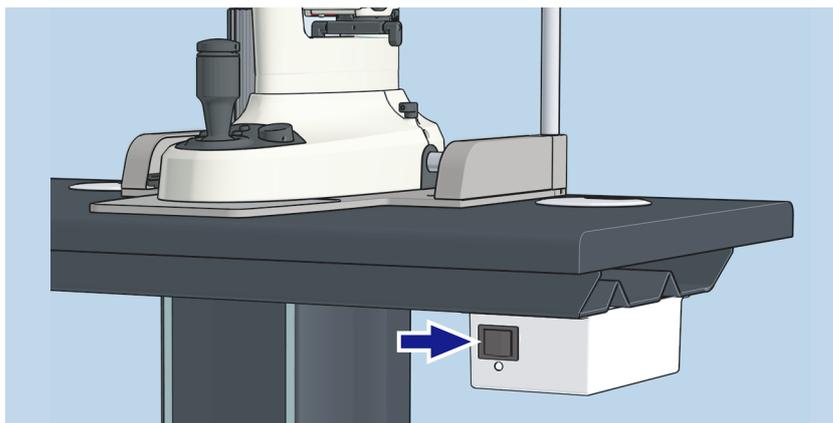


Figure 13: Switching the device on

Empty page, for your notes

7 Operation

7.1 Operation safety

CAUTION!

Mechanical risk from moving parts

Injuries may be caused by the instrument table lowering.

- ▶ When lowering the instrument table always ensure that no objects or body parts are within the movement range of the tabletop.
- ▶ Read the user manual of the instrument table and follow its warning instructions.

CAUTION!

Mechanical risk from falling parts

The patient may injure him/herself or the device may be damaged.

- ▶ Instruct the patient not to touch the device with his/her hands.
- ▶ Instruct the patient not to use the device as a support or an aid when standing up.

CAUTION!

Mechanical hazard from moving parts

Injuries may result from trapped fingers.

- ▶ When operating the device, be careful not to put your fingers between moving components.

7.2 Adjusting the eyepieces and interpupillary distance

Exact adjustment of the eyepieces is a prerequisite for optimum examination results and is necessary when using accessories for image documentation. Otherwise, the image may appear to be sharp during observation through the eyepiece, but a blurred image may be captured by the camera or displayed on the monitor.

Adjust the eyepieces to your corrected distance refraction values.

Action

1. Make sure the eyepieces are pushed up to the stop.
2. Pull out the eyecups if you do not wear spectacles. If you wear spectacles push the eyecups in.
3. Set the diopter setting ring on both eyepieces to 0 D if you do not need to compensate for ametropia.
4. If you need to compensate ametropia set your distance refractive values on the diopter scale of the eyepieces. Make a note of the eyepiece settings for future use.
5. If more than one user uses the device, prepare a table with the individual refractive powers and keep it in a handy location near the device.

Adjust the eyepieces to your individual correct refraction values or to a possible instrument myopia using the optional focusing rod. Mount the optional focusing rod and adjust the eyepieces as follows:

6. Remove the cover of the swivel joint and store it for further use in a safe place.
7. Insert the focusing rod into the swivel joint and rotate the black observation plane of the focusing rod to the front of the stereomicroscope.
8. Swivel the observation unit and illumination unit to the center position (0°).
9. Set the slit width to about 1 mm.
10. Select a medium magnification (i.e. 10x or 16x).

Perform the following steps for each eye individually:

11. Set the diopter scale to +8 D.
12. Rotate the diopter scale of the eyepiece towards -8 D until you see a focused slit projection.
13. Set the interpupillary distance on the binocular tube to your interpupillary distance.

7.3 Positioning the diffusor

If necessary, swivel out the diffusor. Swivel the diffusor in only if you need diffuse illumination for examination of the anterior eye segment. The diffusor can be attached to either the left or right arm of the projector, depending on user preference.

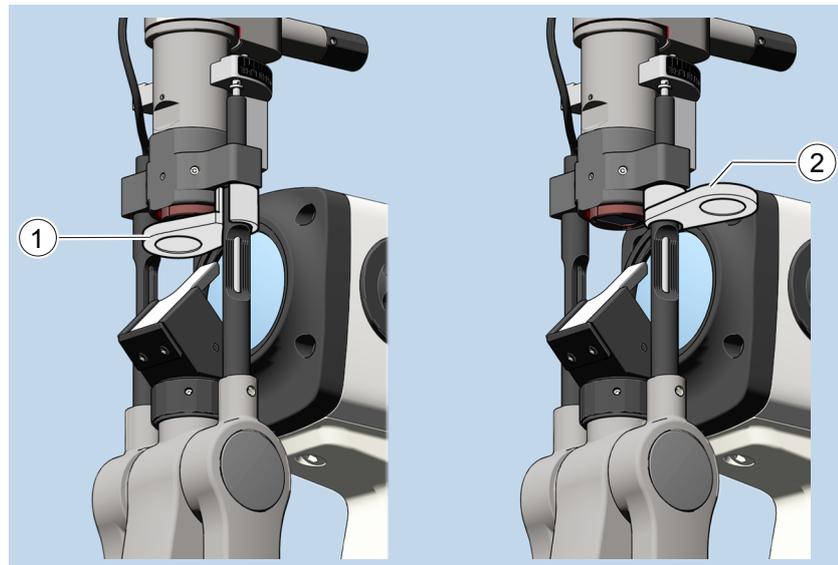


Figure 14: Possible positions of the diffusor on the mirror

1	Diffusor swiveled in	2	Diffusor swiveled out
---	----------------------	---	-----------------------

7.4 Setting the brightness

Action

- ▶ Set the brightness control on the instrument base to the desired brightness. In the final position of the control (left) the illumination is switched off. Turning the control allows continuous adjustment of brightness. If turned fully to the right stop, the brightness is set to maximum.

The illuminance on the fundus can be reduced as follows:

- ▶ Decrease the brightness level of the illumination.
- ▶ Do not set the slit width and length larger than necessary.
- ▶ Do not dilate the patient's pupil unless it is really necessary.

7.5 Positioning the patient

Action

- ▶ Position the patient so that his/her chin and forehead are pressed firmly against the headrest.
- ▶ Adjust the height of the chinrest until the patient's eyes are approximately level with the canthus marks.
- ▶ Make sure that the patient rests his/her hands in his/her lap. This also assists in obtaining the correct posture with regard to the headrest.

7.6 General notes on device operation

Action

- ▶ Choose a slit length and width that only illuminates the eye segment which is to be examined. Otherwise, sections of high reflectance (e.g. sclera) may be illuminated, thus causing disturbing glare.
- ▶ Select the filters with the filter lever according to the type of examination.
- ▶ For retroillumination, set the angle between observation and illumination as low as possible. If necessary, loosen the button for slit centering and slightly decenter the illumination by swiveling the mirror base.

7.7 Reading the angular difference between illumination and observation unit

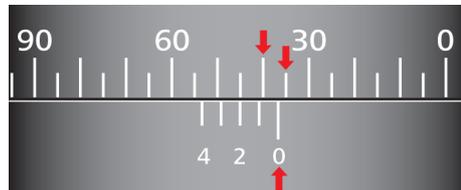
The scale on the swivel joint enables you to read or adjust the angular difference between the illumination and observation unit.

In order to increase the angular accuracy to the accuracy of 1° , a vernier is used. The scale is divided into two parts. The upper scale has a 5° graduation. On the lower index scale there is the scale index marked with 0 and four further graduation marks. Of these five graduation marks, exactly one always forms a line with a graduation mark on the upper scale.

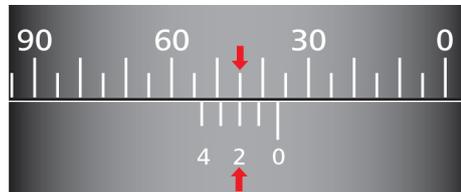
Action

- Read the value of the angle as follows:

If the scale index marked with 0, for example, stands between 35° and 40° , this limits the range of the deflection angle to a value between 35° and 40° . The smaller value is the first value of the angle to be determined (in the example: 35°).



The graduation mark on the index scale, which forms a line with a graduation mark on the upper scale, then gives the second value of the angle to be determined (in the example: 2°).



The angular difference between illumination and observation unit is the sum of the two single values (in the example: $35^\circ + 2^\circ = 37^\circ$).

7.8 Tonometry

Prerequisite

- ☑ The measuring prisms must be disinfected and undamaged. Therefore, we recommend the use of several measuring prisms.

Action

- ▶ Please refer to the instructions for use and disinfection of tonometer measuring prisms on our website and in the instructions for use of the AT 030 applanation tonometer.
- ▶ Make sure that the table top of the instrument table or examination unit is horizontal, thus avoiding movement of the slit lamp with attached tonometer towards the patient. This is of particular importance when taking tonometric measurements without locking the instrument base. We recommend that you always lock the instrument base using the QuickStop (if available) or the manual brake as soon as the measuring prism touches the cornea.
- ▶ When using the optional applanation tonometer, we recommend looking through the left eyepiece with the right eye while observing the patient with the left eye or looking through the right eyepiece with the left eye while observing the patient with the right eye.

7.9 Gonioscopy

Prerequisite

☑ Contact glasses must be disinfected and undamaged.

Action

► For the observation of different angular ranges, the illumination angle can be varied vertically between 0° and 20°. Use the control element to set the inclination angle (angle of incidence).

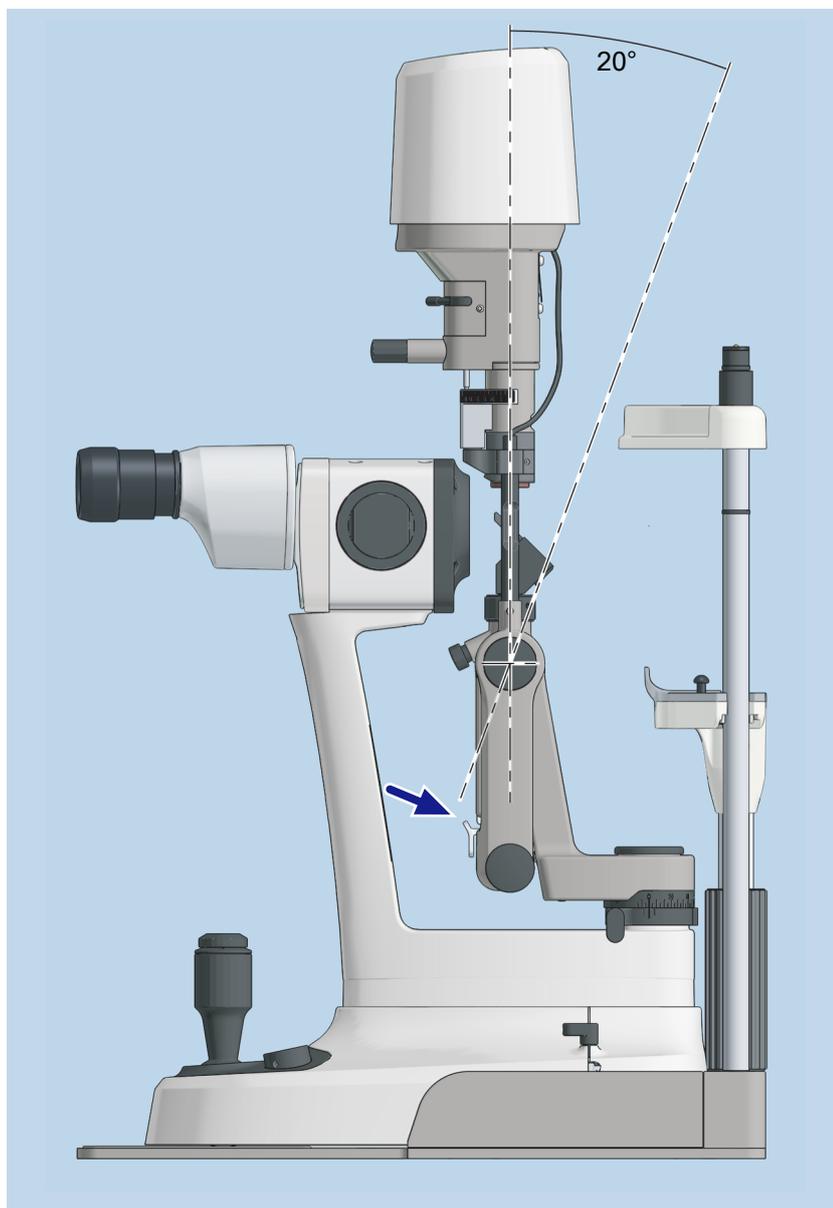


Figure 15: Adjusting the vertical inclination angle (angle of incidence)

7.10 Switching off the device

Action

1. Switch off the device using the power switch on the power supply unit. The light of the slit lamp remains lit for a short moment due to technical reasons.

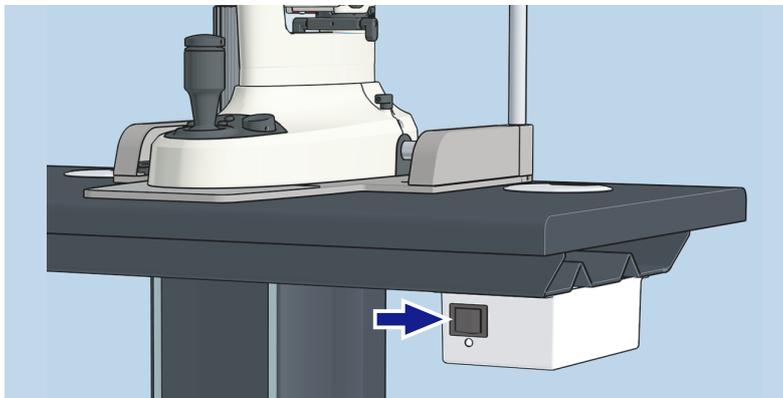


Figure 16: Switching off the device

2. Disconnect the power plug to separate the device from the mains supply.

Empty page, for your notes

8 Cleaning and disinfection

8.1 Safety when cleaning and disinfecting the device

WARNING!

Electrical hazard due to penetration of moisture

The penetration of moisture into the device may cause an electric shock.

- ▶ Prevent moisture from penetrating the device or the accessories.
- ▶ Disconnect the power cable from the power supply before cleaning or disinfecting the device.

CAUTION!

Biological hazard due to cross-contamination

In case of no or inadequate disinfection of the device, the patient may be infected with germs.

- ▶ Parts with which the patient has come into contact during the examination (chin rest, forehead rest) should be cleaned with a disinfectant approved for the purpose.
- ▶ Observe the exposure times prescribed by the disinfectant manufacturer.

NOTE

Damage due to improper cleaning and disinfection

Some cleaning agents and disinfectants may have an adverse effect on plastic components. Damage caused by such disinfectants is not covered by our warranty.

- ▶ Observe the national disinfection regulations.
- ▶ Use only disinfectants approved by the manufacturer for the treatment of plastics and painted surfaces. The surfaces of the device have been tested and are guaranteed to resist frequent treatment with alcoholic disinfectants and cleaning agents (e.g. isopropyl alcohol up to 99.5 % and ethanol up to 96 %) over a long period.
- ▶ Do not use aggressive (e.g. acetone) or abrasive cleaning agents.

8.2 Cleaning

The optical components (mirror, front lens and eyepieces) can be cleaned if necessary. To remove dust from surfaces accessible from the exterior, use a soft brush.

Action

- ▶ Use the following utensils for cleaning:
 - LensPen® cleaning pen (order number 000000-0483-896)
 - ZEISS optical cleaning set (order number 000000-1216-071)
- ▶ Clean the front lens by moving the swab or lens-cleaning instrument with a circular motion from the center of the lens to the edge. Then switch on the illumination of the device to check the cleaning effect.
- ▶ Clean very dirty paint surfaces with a cloth moistened (not dripping) with weak detergent.
- ▶ We recommend using paper pads for the chinrest. Replace the paper pads after each patient.
- ▶ Use the supplied cover to protect the device from dust when not in use.

8.3 Disinfection

Device parts with which the patient has come into contact, e.g. chinrest and forehead support, should be cleaned before each examination with a disinfectant approved for the purpose. These parts are not removable.

We recommend wipe disinfection, as optical components can be damaged by spraying with disinfectants. Please note that only the forehead support and chinrest are to be disinfected, but no optical components of the device.

Action

1. In case of coarse contamination (e.g. makeup or dirt stains) remove visible stains with a soft cloth, moistened with a mild detergent or 70% isopropyl alcohol solution.
2. Then use another soft cloth, moistened with 70% isopropyl alcohol solution, and wipe the surfaces of the forehead support and chinrest so that they are completely wetted.
3. Do not rub the surfaces dry, but allow the surfaces to dry completely, before the patient comes in contact with them.

9 Maintenance

9.1 Testing electrical safety

 **WARNING!**

Electrical hazard due to aging and wear

The electrical safety of the device may deteriorate due to aging and wear.

- ▶ Please obtain information on the relevant regulations in your country regarding electrical equipment inspections. These must be adhered to!
 - ▶ Unless legal requirements dictate otherwise, the operator is advised to carry out an annual inspection in which the electrical safety is tested in accordance with IEC 62353. When performing the inspection, observe the following instructions or the service instructions issued by ZEISS.
-

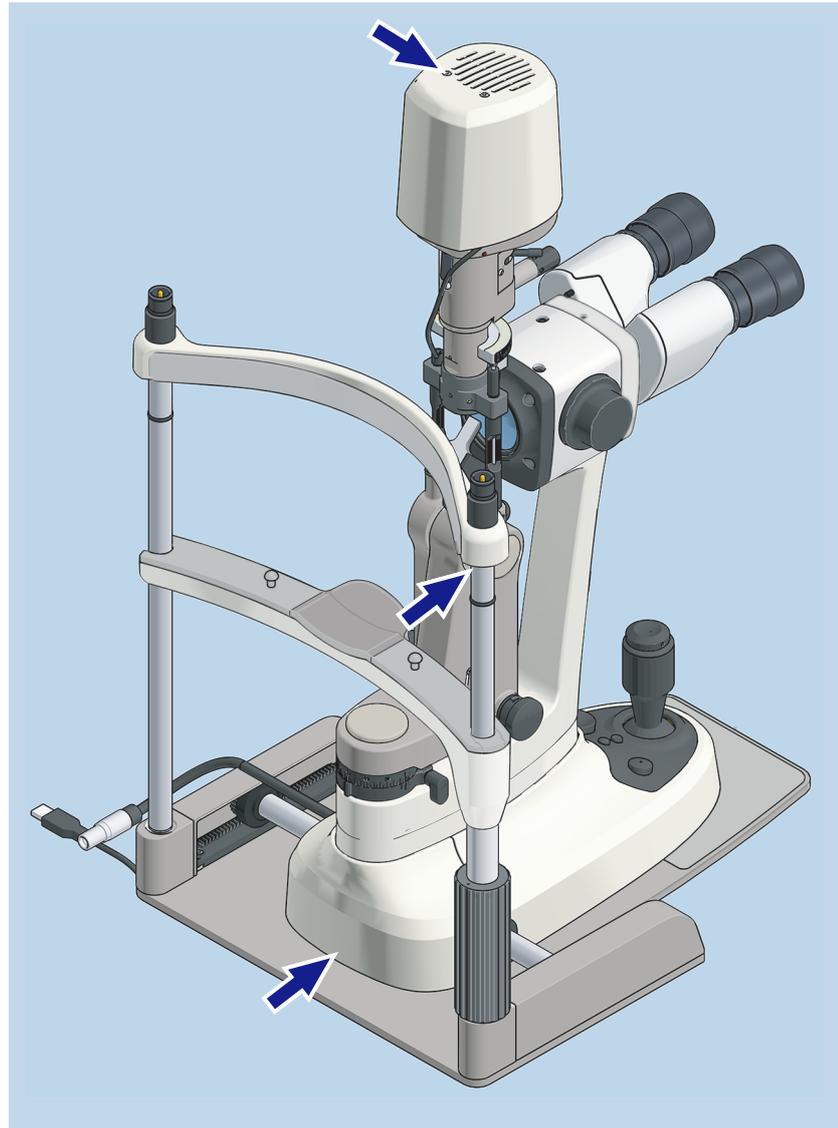


Figure 17: Measurement points on the device

Action

1. Perform a visual inspection of all components and cables to ensure they are in proper condition.
2. If there are doubts about the effectiveness of the insulation (such as multiple triggering of the fault circuit interrupter or other protective devices in the physician's practice, or traces of liquid on the device which suggest the penetration of liquid), measure the insulation resistance with a test voltage of 500 V.
⇒ The measured value may not be less than 7 MΩ.
3. After this, the device leakage current must be measured. The differential current method should be preferably used. The device should be in operation during measurement. Press the measuring tip onto the measurement points shown in the figure.
⇒ The measured value may not exceed 0.1 mA.

4. The inspection is concluded by a function check. This should be performed by a person who is familiar with the application.
5. Note down the measured values.

9.2 Replacing the fuses

NOTE

Electrical hazard due to incorrect fuse

Inserting an incorrect fuse may damage the system.

- ▶ Disconnect from the power supply before changing the fuse!
- ▶ Only use fuses which meet the specifications given on the sign for fuse labels.

The fuse compartment with the fuse cartridge and the two fuses is located at the left-hand side of the power input of the device.

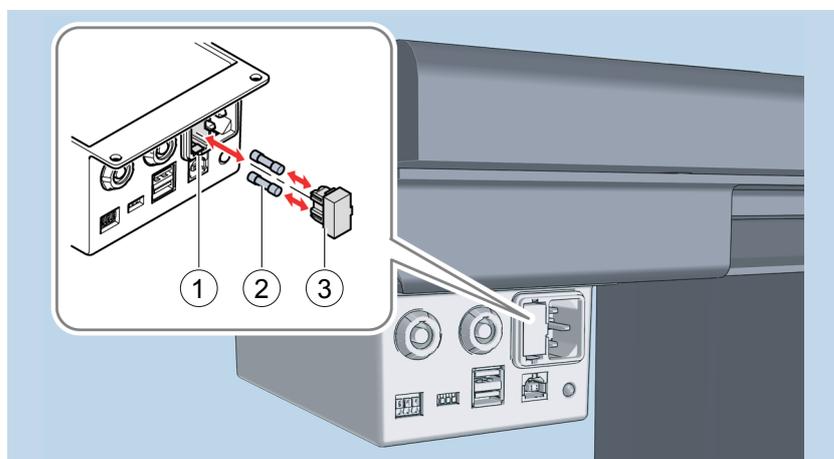


Figure 18: Replace the fuses

1	Fuse compartment	2	Fuse
3	Fuse carrier		

Action

1. Disconnect the power supply unit from the power supply.
2. Remove the fuse carrier with fuses by pressing gently on the snap-in clip. Use a small slotted screwdriver or a similar tool to loosen the clips at the top and bottom of the fuse carrier.
3. Replace the defective fuse.
4. Reinsert the fuse carrier with fuse. Ensure that the fuse carrier snap-in clip is correctly positioned.
5. Reconnect the power supply cable and start up the device as usual.

9.3 Installing software updates for the device

Action

1. Contact ZEISS Service to receive the latest software version of the device.
2. Switch off the device at the power supply unit.
3. Remove all USB cables from the power supply unit (any connections to a PC, fixation lamp, wide-field illumination).
4. Insert the USB drive with the latest software version into one of the USB-A ports.
5. Switch on the device at the power switch.
 - ⇒ The update starts automatically. The data of all modules connected to the device are now transmitted successively. Conclusion of each module update is confirmed by two beeps. Depending on the number of modules to be updated, this process can take up to 10 minutes. The end of the update is confirmed by five short beeps.
6. Switch off the device at the power supply unit after successful update.
7. Reconnect the removed USB cables to the corresponding USB ports of the power supply unit.
8. Switch the device on at the power supply unit to continue working with the device.

If you have any questions concerning the update, please contact ZEISS Service.

9.4 Creating a log file

The device allows you to create a log file if required. It contains information on configuration, status of individual modules or any errors that may have occurred. The log file is very helpful for preparing a ZEISS Service call in the event of a technical problem with the device. If you make a service call, send the log file to ZEISS Service.

Action

1. Use an empty USB drive. This must be formatted in FAT32 format.
2. Remove all USB cables from the power supply unit (any connections to a PC, fixation lamp, wide-field illumination).
3. Switch on the device at the power switch.
4. Insert the prepared USB drive into the lower of the two USB-A ports.
 - ⇒ Writing of the device log file starts automatically. After a few seconds, the device confirms completion of log file creation by three short beeps.
5. Switch off the device at the power supply unit after the log file has been stored.

6. Reconnect the removed USB cables to the corresponding USB ports of the power supply unit.
7. Send the log file "SL800_Log_97XXXXXXXXX_Y.....Y.txt" together with further information about the device (serial number, connected accessories) via e-mail to ZEISS Service. Describe the failure as precisely as possible: Which behavior was detected? When did you notice it the first time? How often does it occur? By which sequence can it be triggered? Add photos if necessary.

If you have any questions concerning the log file creation, please contact ZEISS Service.

9.5 Changing paper pads

Action

1. Pull out the two fastening pins attaching the paper pads to the headrest.
2. Place the paper pads onto the chinrest of the headrest.
3. Insert the two fastening pins through the holes in the paper pads and back into the holes provided on the headrest.
4. After each examination, tear off the top paper pad and dispose of it.

Empty page, for your notes

10 Troubleshooting

10.1 Malfunctions

Unexpected behavior	Cause	Remedy
Slit illumination is dark.	Power supply unit is not connected to the power supply.	▶ Connect the power supply unit to the power supply.
	The device is switched off (green light beside the power switch of the power supply unit is not illuminated).	▶ Switch on the device at the power switch.
	Cable between power supply unit and slit lamp is not correctly connected.	▶ Check the cable connection between slit lamp basis and the power supply unit.
	Brightness control is set to 0.	▶ Turn the brightness control clockwise (maximum at right stop).
	Slit width is set to 0.	▶ Enlarge the slit width.
	The red filter of the filter wheel and the blue filter of the slit length adjustment are positioned one above the other.	▶ Change either the position of the filter lever or the slit length.
	The device is in EcoMode (slowly pulsating green lamp on the power supply unit).	▶ Move the device from one side to the other using the joystick or change the magnification.
The indicator lamp on the rear of the power supply unit flashes green.	A fault has occurred in the electronic system of the device. The usability of the device is not necessarily restricted by this.	▶ Switch the device off and on again.
The slit image is not homogenous.	The setting of the slit length is between the click-stops.	▶ Turn the slit length control until you can feel the click-stop.
	The filter lever is positioned between click-stops.	▶ Turn the filter lever until you can feel the click-stop.
	The diffusor is swiveled in (partly).	▶ Swivel out the diffusor completely from the beam path.
The magnification is difficult to change.	Your device is provided with a motorized magnification changer. You can see this by the fact that the magnification changer only has a rotary knob labeled with magnification levels on one side.	▶ Use the AutoView buttons on the instrument base to change the magnification.

Contact ZEISS Service if you cannot solve the problems with the help of this table.

10.2 Service information

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

11 Technical specifications

11.1 Essential performance

The device does not have any essential performance features as defined in IEC 60601-1.

11.2 Compliance

If modifications not authorized by the manufacturer are made to the device, this declaration ceases to be valid.

11.2.1 Directives with which the device is compliant

The device complies with the 93/42/EEC Medical Devices Directive (MDD).

Device class in accordance with the MDD: I

It carries the CE mark.

The product is RoHS-compliant according to Directive 2011/65/EU.

11.2.2 The device meets the following requirements and standards

- IEC 60601-1
- IEC 60601-1-2
- ISO 10939
- ISO 15004-1
- ISO 15004-2

11.2.3 Device classification

The device is classified as follows:

- Protection class: II
- Ingress protection rating: IP 20
- Group 2 pursuant to ISO 15004-2
- UMDNS No.: 12-281
- Instrument type: B (IEC60601-1)

11.3 Illumination

	Value
Slit illumination	VarioLight cold white, VarioLight warm white
Illumination	Brightness continuously adjustable
Width of slit image	continuously 0 to 12 mm
Length of slit image	variable in steps of 0.2/1/3/5/9/12 mm continuously from 1 mm to 12 mm with scale display
Slit image diameter	0.2/1/3/5/9/12 mm
Slit image rotation	continuous 0° to 180°, click-stops at 45°/90°/135°
Slit image decentration (horizontal)	possible, can be fixed at 0°
Tilt angle (vertical)	0°/5°/10°/15°/20°
Illumination unit swivel range	180°, scale for angular difference click-stops at 0°/±45°/±60°
Filter	red, blue, green (red-free)
Diffusor	Swivel-in

11.4 Stereomicroscope

	Value
Magnifications	6x/10x/16x/25x/40x
Field of view diameter	37 mm to 5.2 mm
Eyepiece magnification	10x Compensation of ametropia ±8 D
Interpupillary distance	Convergent tube 50 mm to 84 mm Parallel tube 52 mm to 78 mm

11.5 Instrument base

	Value
Adjustment range	110 mm (side), 30 mm (height), 110 mm (depth)

11.6 Headrest

	Value
Adjustment range of chinrest	80 mm (vertical)

11.7 Dimensions and weights

	Value
Device mass	12 kg (with headrest)
Dimensions of device	315 mm x 655 mm ± 15 mm x 395 mm (width x height x depth)

11.8 Ambient conditions

	Value
Ambient conditions for the intended use	
Temperature	+10 °C to +35 °C
Relative humidity	30 % to 95 %
Atmospheric pressure	700 hPa to 1060 hPa
Ambient conditions for storage	
Temperature	-10 °C to +55 °C
Relative humidity	10 % to 95 %
Atmospheric pressure	700 hPa to 1060 hPa
Ambient conditions for transport in original packaging	
Temperature	-30 °C to +70 °C
Relative humidity	10 % to 95 %
Atmospheric pressure	500 hPa to 1060 hPa

11.9 Electrical specifications

	Value
Rated voltage	100 V to 240 V AC
Frequency	50 / 60 Hz
Current consumption	max. 0.75 A at 230 VAC max. 1.5 A at 120 VAC
Operating mode	Continuous operation
Fuses	2xT 2A H 250 V 5x20 mm
Fixation lamp (optional)	5 V / 0.3 W

11.10 Electromagnetic compatibility

The device is subject to specific requirements with regard to electromagnetic compatibility (EMC). The following factors can cause electromagnetic interference:

- Portable and mobile RF communication devices in the vicinity of the device.
- Other products which are set up in the vicinity or stacked with the device.
- Accessories, cables and spare parts that are not specified in these instructions for use and not sold by ZEISS as spare parts.

When using the device, you must comply with the following precautionary EMC measures:

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

NOTE

The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

11.10.1 Ambient conditions for intended use

The device is intended for use in professional healthcare facilities with regard to electromagnetic compatibility. These include in particular hospitals and medical practices, including those connected to the public power supply (e.g. in residential areas), and premises of opticians and optometrists.

It is not intended for operation in the following environments:

- Home health care (e.g. residential accommodation, nursing homes)
- Outdoor environments
- In vehicles (e.g. cars, trains, ships, aircraft)
- Other special environments (e.g. military facilities, heavy industry, facilities for medical treatment or diagnosis with high-power devices. These include in particular high-frequency surgical devices, short-wave therapy equipment and MRI devices.)

11.10.2 Restrictions on essential performance

The device does not have any essential performance features as defined in IEC 60601-1. Therefore, no impairment of the essential performance characteristics is expected due to electromagnetic interference.

CAUTION!

Hazard from electromagnetic radiation

Using SL 800 in direct proximity to other devices or stacked together with other devices can result in unforeseen interference with device operation.

- ▶ With the exception of the equipment combinations described in these instructions for use (e.g. combination with instrument table), use of SL 800 directly adjacent to or stacked with other devices should be avoided.
- ▶ If it is nonetheless necessary to operate SL 800 in the aforementioned manner, the device and the other devices should be observed to check for intended operation of the arrangement used.
- ▶ Do not use portable HF communications equipment (including peripheral devices such as antenna cable and external antennas) within a radius of 30 cm around the SL 800, including cables specified by the manufacturer. Otherwise, a deterioration of the performance of the device is to be anticipated.

CAUTION!

Hazard from electromagnetic radiation

The use of accessories, all types of transducers and cables not specified in this user manual or not sold by Carl Zeiss Meditec as replacement parts may result in higher electromagnetic emissions or reduced immunity of the device and thus in faulty operation.

- ▶ Purchase spare parts (including spare cables) solely from Carl Zeiss Meditec or dealers authorized by Carl Zeiss Meditec.
- ▶ Ensure that optional accessories in the field of information technology (e.g. PCs or printers) comply with the requirements of Class B conforming to CISPR 32.

Relevant accessories, cables and transducers:

- Power supply cable (2.5 m)
- Cable extension set (5.0 m)
- Wide-field illumination with connection cable (0.9 m)
- USB cable for accessories of photographic documentation
- SL cam compact
- SL Workstation
- Instrument table

No regular inspections and maintenance are required in order to maintain electromagnetic compatibility (EMC). If obvious damage to the device is detected (e.g. housing or cables), remove the device immediately from service, label it clearly as being out of service, and contact ZEISS Service. It may still be possible to operate SL 800, but there could be increased emissions and/or decreased immunity.

The following guideline applies only to the accessories specified for and delivered with the device from ZEISS.

Emission

Emitted interference	Standard	Compliance
Conducted emission	CISPR 11	Group 1, Class B
Radiated emission	CISPR 11	Group 1, Class A
Harmonic emissions	IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions	IEC 61000-3-3	Complies

Immunity

Phenomenon	Standard	Test level
Electrostatic discharge (ESD)	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air (housing, headrest)
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz (housing)
Electrical fast transient/burst	IEC 61000-4-4	± 2 kV, 100 kHz repetition rate (power cable) ± 1 kV, 100 kHz repetition rate (data cable*)
Surge voltage/surges line to line	IEC 61000-4-5	± 0.5 kV, ± 1 kV (power cable)
Surge voltage/surges line to earth		± 0.5 kV, ± 1 kV, ± 2 kV (power cable)
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM frequency bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz (power and data cable*)
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m, 60 Hz (housing)
Voltage dips	IEC 61000-4-11	0 % U _T ; 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U _T ; 1 cycle and 70 % U _T ; 25 cycles at 50 Hz/30 cycles at 60 Hz single-phase: at 0° (power cable)
Voltage interruptions		0 % U _T ; 250 cycles at 50 Hz/300 cycles at 60 Hz (power cable)

* including data cables with a maximum length of less than 3 m

Phenomenon	Standard	Frequency band [MHz]	Radio service	Test level [V/m]
Immunity to radiated radio frequencies, caused by wireless communications equipment in accordance with IEC 60601-1-2:2014, Table 9	IEC 61000-4-3	380-390	TETRA 400	27
		430-470	GMRS 460, FRS 460	28
		704-787	LTE Band 13,17	9
		800-960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	28
		1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28
		2400-2570	Bluetooth; WLAN 802.11b/g/n; RFID 2450; LTE Band 7	28
		5100-5800	WLAN 802.11 a/n	9

Empty page, for your notes

12 Optional accessories

Accessories for image documentation: SL Imaging Solution

- SL cam compact [▶ 68]
- Wide-field illumination [▶ 69]
- 10x eyepiece, cross-hairs [▶ 70]
- Focusing rod [▶ 71]

Accessories for measurement of intraocular pressure

- AT 030 applanation tonometer [▶ 71]

Accessories for fundus observation

- Fundus VarioView [▶ 72]

Additional accessories

- Yellow filter aperture module [▶ 76]
- Tube adapter 20° [▶ 79]
- Beam splitter [▶ 81]
- Co-observation tube with eyepiece [▶ 84]
- Fixation lamp [▶ 85]
- Breathing shield [▶ 86]
- Paper pads [▶ 86]
- Instrument table [▶ 86]

These instructions for use describe accessories that are not essential components of the individual deliveries. A current list of accessories can be obtained from your ZEISS contact person.

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

Use only accessories and spare parts which are approved by ZEISS for this device. When using accessories and spare parts that are not approved by ZEISS, safe operation of the device cannot be guaranteed.

12.1 Adjust the counterweight for the height adjustment of the instrument base

Depending on the optional components and accessories mounted on the device, it is possible to adjust the compensating spring force to the height adjustment of the instrument base. This is done by activating or deactivating up to two additional springs.

The weight compensation of the device is set at the factory so that the weight of the observation and illumination unit and the counterweight of the weight compensation are approximately equal in the middle range of the height adjustment. This enables easy height adjustment. If additional components or accessories are mounted on or removed from the device, the preset equilibrium will shift accordingly. The height adjustment of the device may then no longer be smooth enough. The adjustable weight compensation allows to compensate for the weight of additional components and accessories in defined steps.

Four weight compensation steps can be set by means of two springs. The interaction of the springs is shown in the following table:

Compensation step	Weight of additional components	Balance spring	
		Left	Right
1	Factory setting according to package check list	Fixed	Fixed
2	+	Fixed	Released
3	++	Released	Fixed
4	+++	Released	Released

A released spring means an additional spring force which counteracts the weight of the additional components. The smallest additional spring force (1) results when both springs are fixed. The highest additional spring force (4) results when both springs are released.

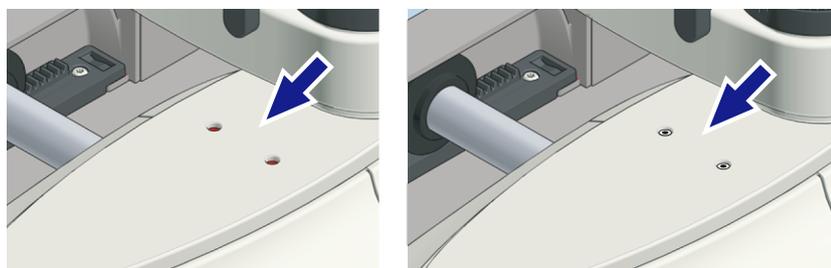
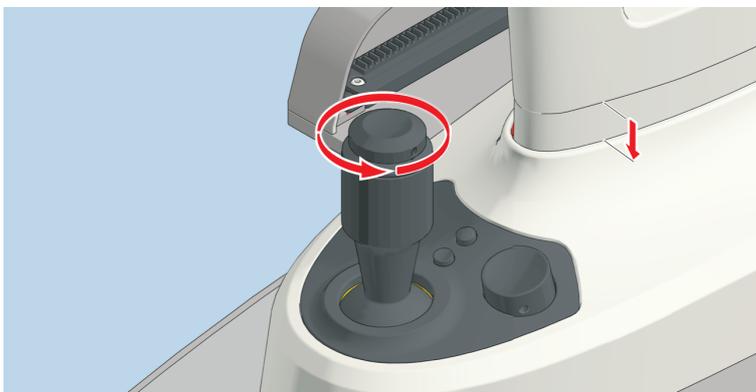


Figure 19: Instrument base with fixed (left) and released (right) springs

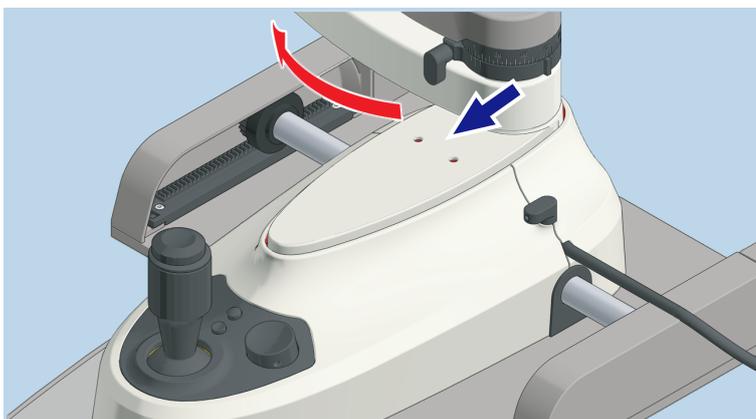
Adjust the counterweight

Action

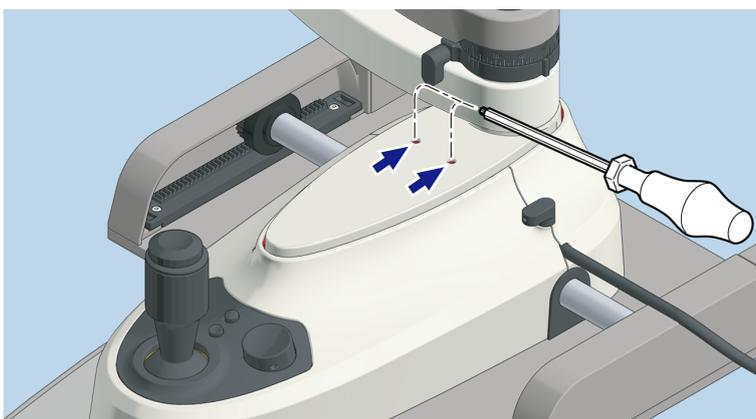
1. Turn the joystick counterclockwise until the instrument base is in its lowest position.



2. Swivel the observation and illumination unit to the side. As a result, two openings become visible, behind each of which there is a screw.



3. Loosen or attach the three screws with the size 3 screwdriver supplied.



Result

- ✓ The weight compensation is set correctly when the forces required for the upward and downward movements are balanced in the middle range of the height adjustment.

12.2 SL cam compact

SL cam compact is an image documentation accessory that allows you to capture high-resolution images and videos in combination with the SL Imaging Software and the joystick cover for image documentation.

In addition to the integrated camera, SL cam compact has an integrated yellow filter aperture module which allows you to observe and document fluorescein dyeings with improved contrast and to extend the range of depth of field during observation and documentation. You can insert and remove the yellow filter and the aperture from the observation beam path using the respective control element.

The joystick cover for image documentation has a control element for pushing and turning. Press the control element momentarily ($< 1\text{ s}$) to release the capture of one image at a time. Press and hold the control element ($> 1.0\text{ s}$) to start or stop recording a video. It is possible to capture additional images during a video recording by briefly pressing the control element. By turning the control element the parameter selected in the settings of the SL Imaging Software is changed.

The SL cam compact is mounted between the stereomicroscope and binocular tube. The joystick cover for image documentation is mounted instead of the cover of the standard joystick.

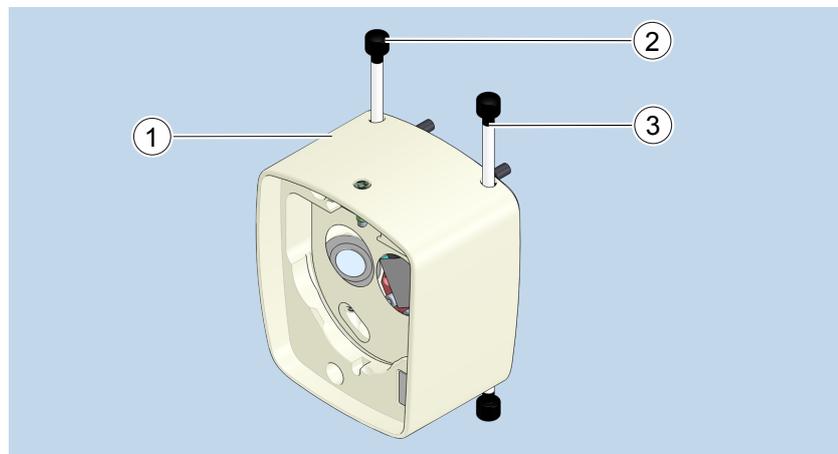


Figure 20: SL cam compact

1	SL cam compact	2	Yellow filter
3	Aperture		

Observe the instructions for use of the SL Imaging Solution.

12.3 Wide-field illumination

You can use the optional wide-field illumination to brighten the slit zone when recording image and video data.

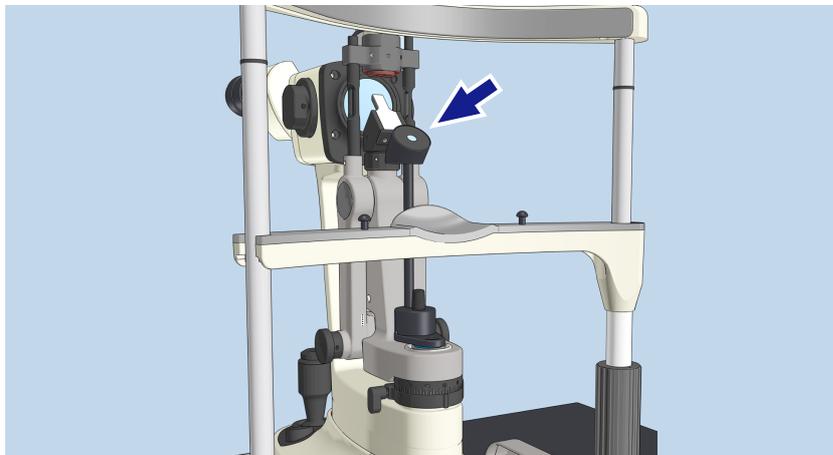


Figure 21: Device with wide-field illumination

Observe the instructions for use of the SL Imaging Solution.

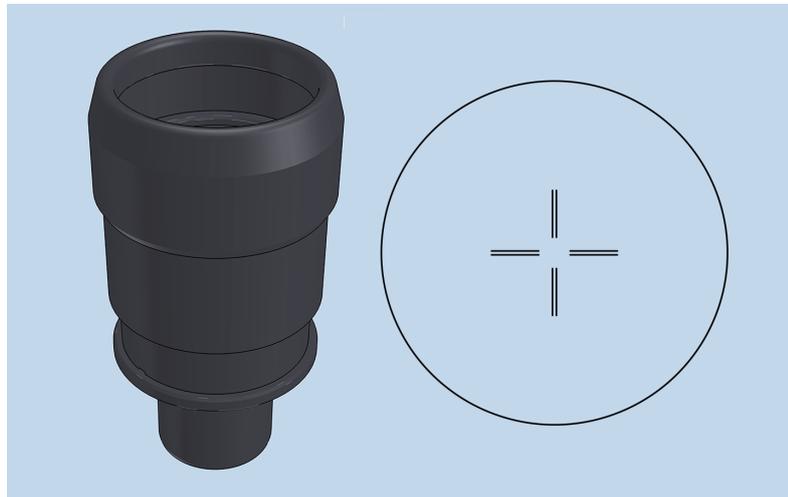
12.4 10x eyepiece, cross-hairs

The accommodation capability of the user's eye is normally not taken into account during slit lamp examination. However, it is important for image documentation to set the eyepieces correctly. Otherwise, the image may appear to be sharp during observation, but a blurred image may be captured by the camera. The 10x eyepiece with double cross-hair is used for exact diopter compensation by focusing the cross-hair. Only a sharp image of the cross-hairs and a focused image of the eye structure guarantee a sharply focused image or video for image documentation.

You can replace the standard eyepiece with the 10x eyepiece with cross-hairs:

Action

1. Pull the standard 10x eyepiece out of the binocular tube on the tube side of your leading eye.
2. Insert the 10x eyepiece with cross-hairs.



3. Make sure the eyepiece is pushed up to the stop.
4. Set the eyepiece as described in the instructions in the chapter Adjusting the eyepieces and interpupillary distance [▶ 37].

12.5 Focusing rod

The focusing rod can be used to compensate for individual ametropia of the user or any device ametropia by adjusting the diopter scale on the eyepieces. Exact adjustment of the eyepieces is a prerequisite for optimum examination results and is necessary when using accessories for image documentation. Otherwise, the image may appear to be sharp during observation, but a blurred image may be captured by the camera, see Adjusting the eyepieces and interpupillary distance [▶ 37].

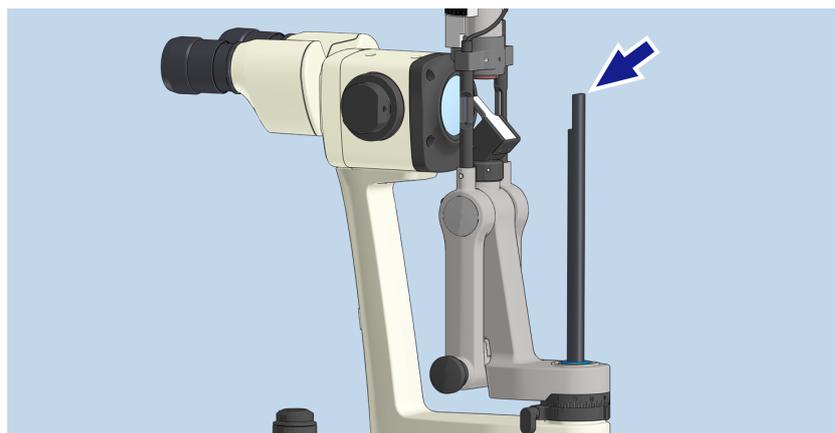


Figure 22: Focusing rod

12.6 AT 030 applanation tonometer

The applanation tonometer is for measuring the intraocular pressure of a seated patient. The correct tonometer holder should be used for mounting on the various ZEISS slit lamps.

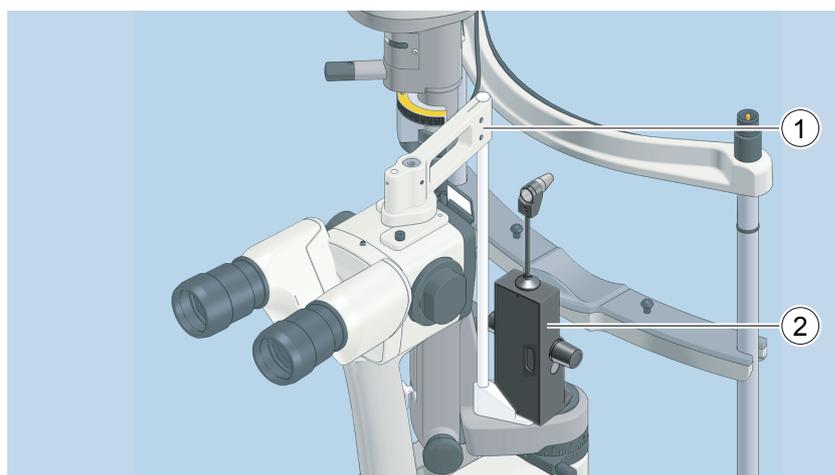


Figure 23: SL 800 with AT 030 applanation tonometer

1	Tonometer holder	2	AT 030 applanation tonometer
---	------------------	---	------------------------------

Observe the instructions for use of the applanation tonometer.

12.7 Fundus VarioView

Fundus VarioView is an accessory for improved fundus observation. The default stereo angle of the device allows stereoscopic observation of the anterior eye segment with a high aperture. When observing the posterior eye segment, the binocular field of view is severely restricted even with a dilated pupil, or may be not seen at all. This is especially the case when examining the fundus periphery using a Goldmann contact lens or when observing the chamber angle (gonioscopy). Using the Fundus VarioView the rotary knob allows the default stereo angle to be decreased. This leads to increased overlapping of the two observation beam paths, thereby increasing the binocular field of view and thus enabling stereoscopic observation of the fundus with a significantly improved view.

Fundus VarioView has two working positions. The following figure shows the observation beam path at a decreased stereo angle B compared to the standard setting A. The two positions can be alternated between using the rotary knob.

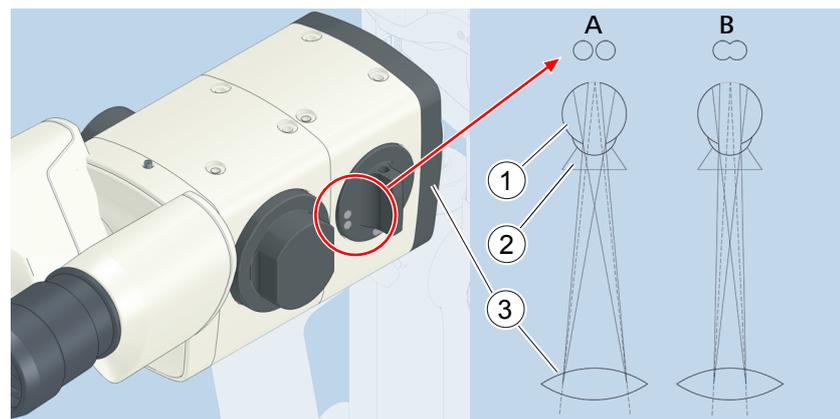


Figure 24: Beam path of Fundus VarioView switched off (A) / on (B)

1	Patient's eye	2	Contact lens
3	Front lens		

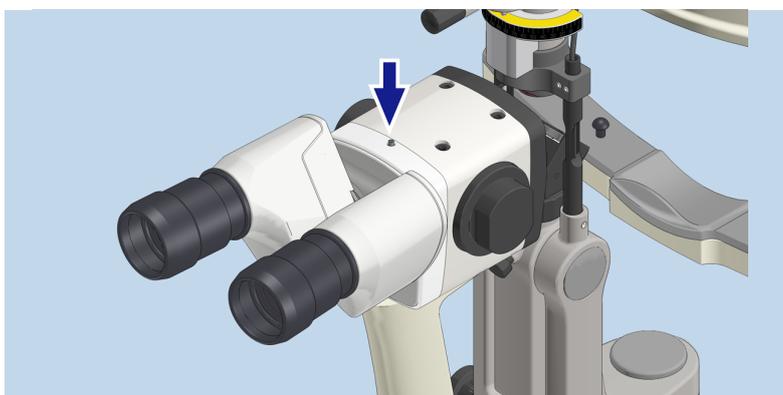
Mounting the Fundus VarioView (if not already factory-mounted):

NOTE! We recommend to carry out the assembly with the help of a second person.

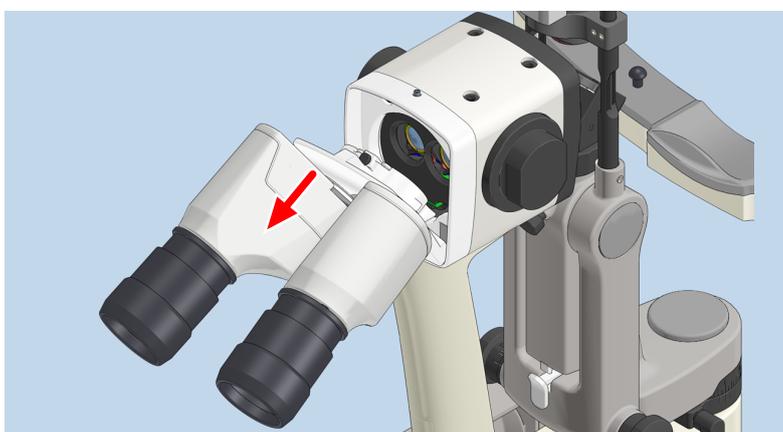
Action

1. Switch off the device at the power supply unit.
2. Lock the instrument base using the manual brake.

3. Hold the binocular tube while loosening the threaded pin at the top of the convenience interface with the size 1.5 screwdriver, supplied.



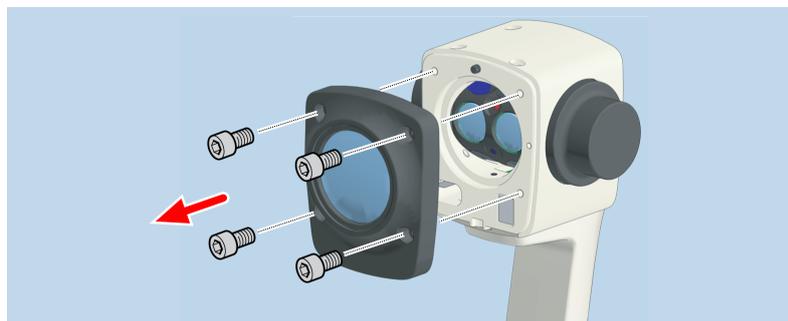
4. Tilt the binocular tube downwards out of the convenience interface.



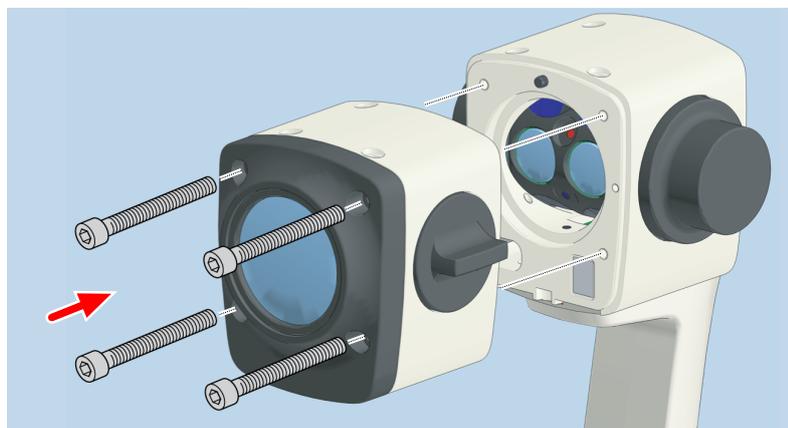
5. Put the binocular tube aside.
6. Remove any attached accessories from the device, e.g. photographic documentation accessories.
7. Swivel the illumination unit to one side and fix the position of the illumination unit.



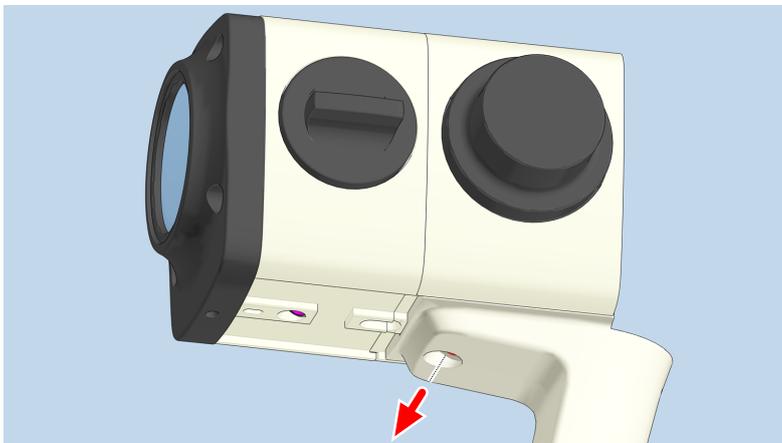
- 8. Swivel the observation unit to the other side.
- 9. Using the supplied size 3 screwdriver, loosen the four screws M4x10 on the front lens (patient's side).
- 10. Carefully remove the front lens from the stereomicroscope.



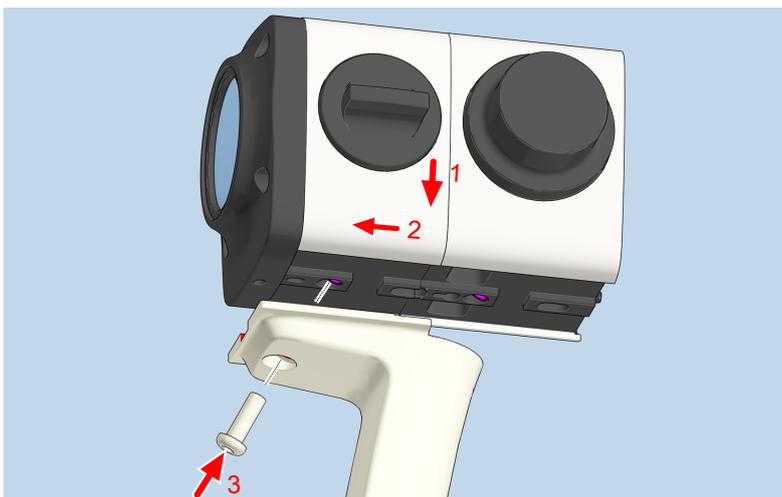
- 11. Attach the Fundus VarioView with the front lens in front of the stereomicroscope.
- 12. Using the size 3 screwdriver, tighten the supplied screws M4x60 to attach the Fundus VarioView to the front lens.



13. Hold the newly configured observation unit (stereomicroscope with front VarioView fundus) and loosen the screw on the carrier arm using the size 4 screwdriver, supplied.



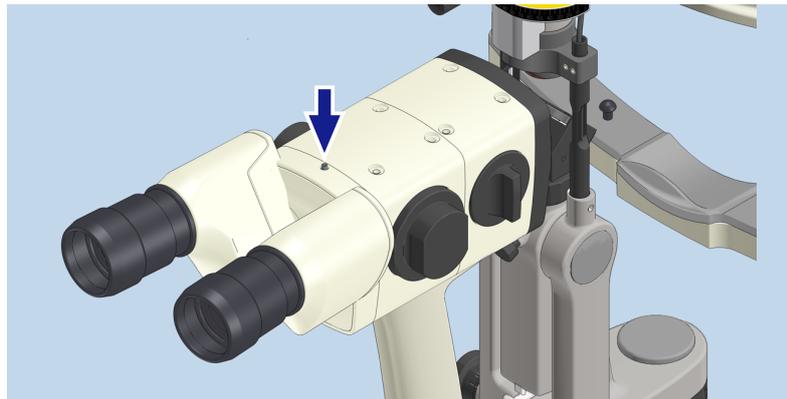
14. Lift the observation unit slightly and position it so that the screw is below the VarioView fundus. **NOTE! Make sure not to kink the cable of the stereomicroscope.**



15. Tighten the screws with the size 5 screwdriver, supplied.



16. Mount all accessories and the binocular tube to the device.



⇒ The binocular tube must be flush with the convenience interface or attached accessories.

12.8 Yellow filter aperture module

The yellow filter aperture module allows you to observe and document fluorescein stains with improved contrast and to extend the depth of field during observation.

The yellow filter serves as a barrier filter for examinations with fluorescein in combination with a blue filter which is swiveled into the observation beam path of the device. The yellow filter filters the blue excitation light coming from the slit lamp and transmits only the yellow-green fluorescence radiation.

You can insert and remove the yellow filter using the left push rod and the aperture using the right push rod from the observation path.

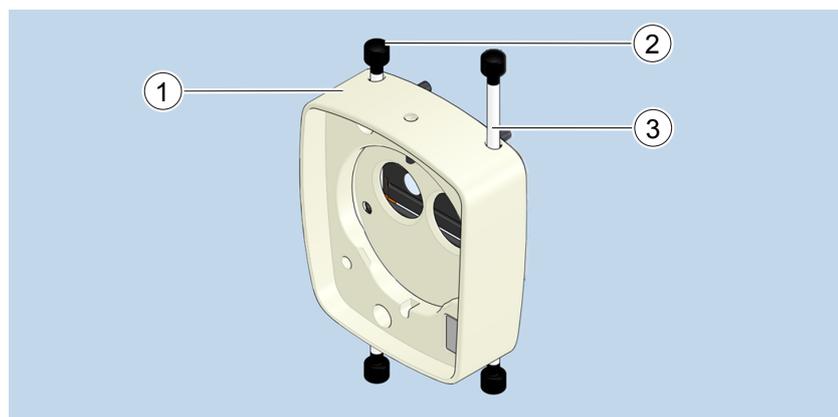


Figure 25: Yellow filter

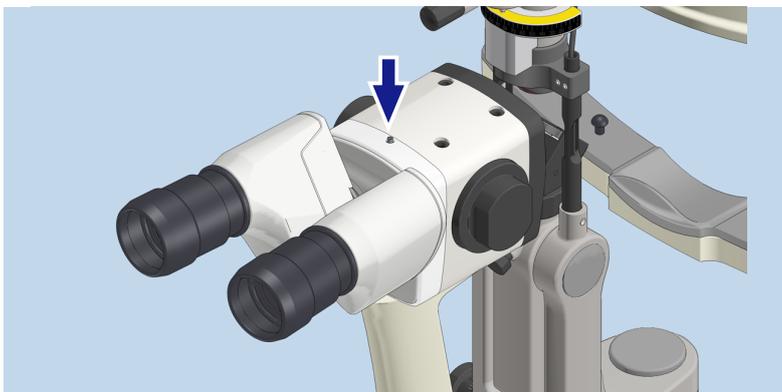
1	Yellow filter aperture module	2	Yellow filter
3	Aperture		

Mounting (if not already factory-mounted):

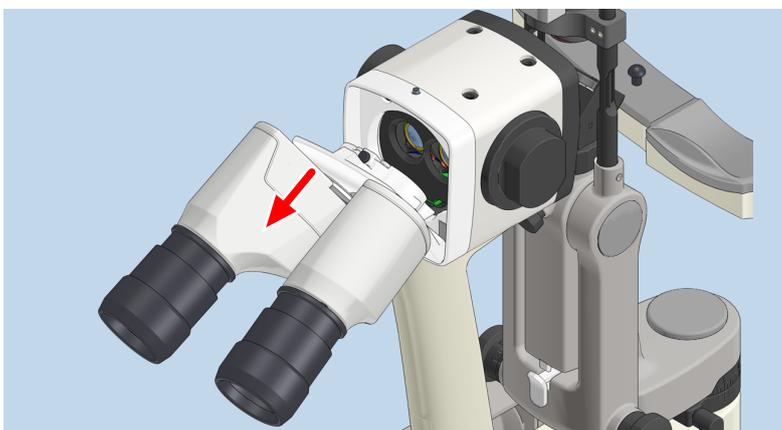
Action

1. Switch off the slit lamp at the power supply unit.
2. Lock the instrument base using the manual brake.

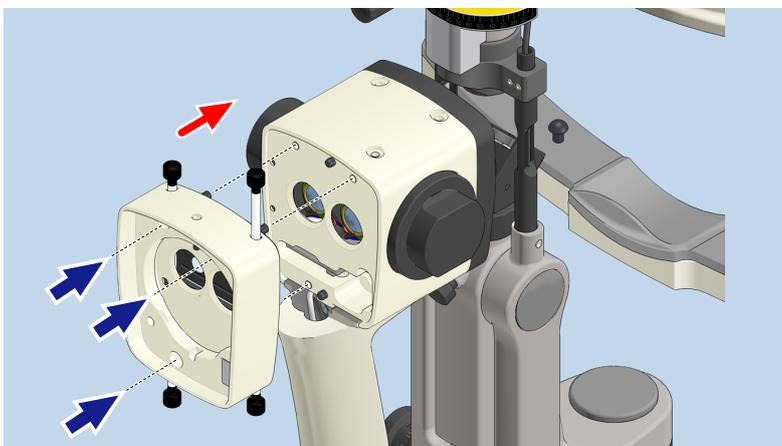
3. Hold the binocular tube firmly while loosening the threaded pin at the top of the convenience interface with the size 1.5 screwdriver, supplied.



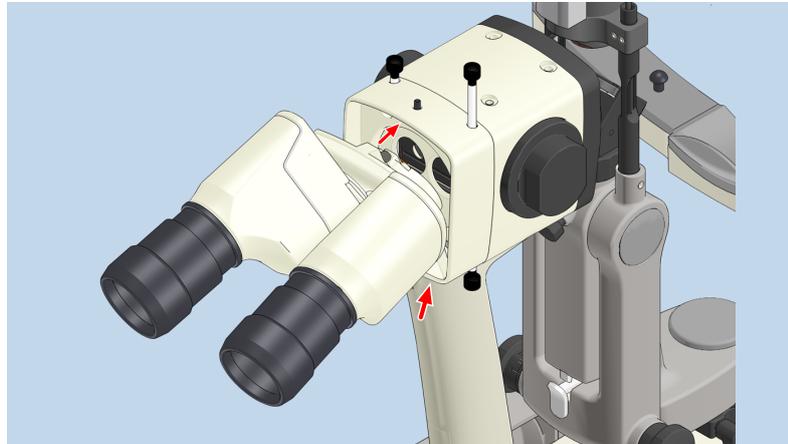
4. Tilt the binocular tube downwards out of the convenience interface.



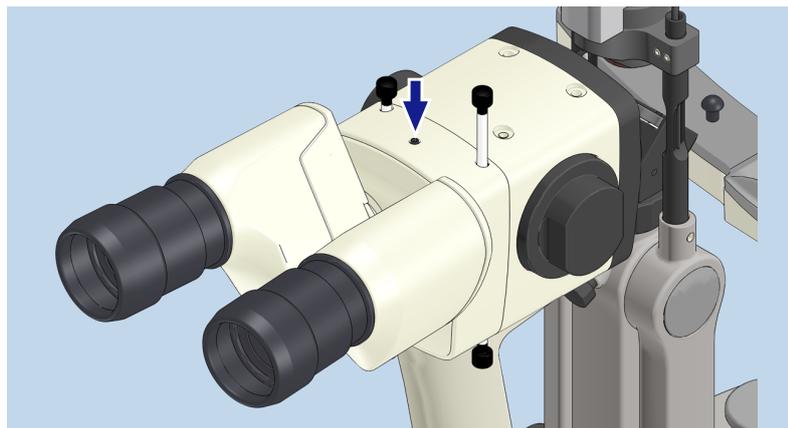
5. Put the binocular tube aside.
6. Remove the three screws of the convenience interface with the size 3 screwdriver, supplied.
7. Attach the yellow filter aperture module to the stereo-microscope. Ensure that the orientation pins are positioned correctly.



8. Hand-tighten the screws which are integrated into the yellow filter aperture module using the size 3 screwdriver, supplied.
9. Attach the binocular tube from the bottom to the yellow filter aperture module and tilt the binocular tube upwards.



10. Attach the binocular tube to the convenience interface of the yellow filter aperture module by tightening the threaded pin using the size 1.5 screwdriver.



⇒ After successful attachment, the binocular tube must be flush with the yellow filter aperture module.

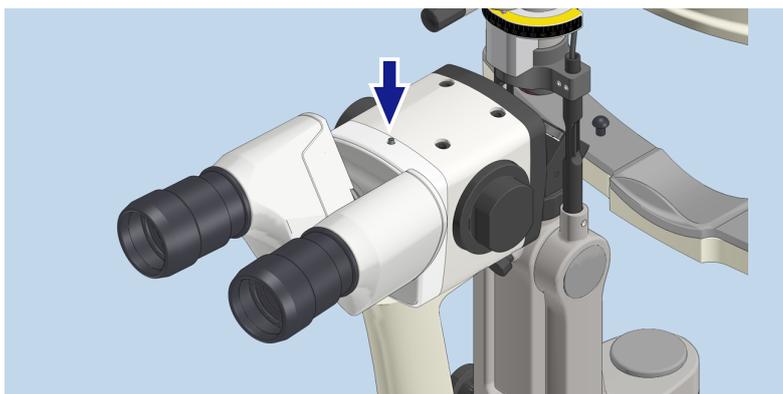
12.9 Tube adapter 20°

The tube adapter 20° causes the convergent or parallel tube to slant upwards by 20°, relieving strain on the neck when working.

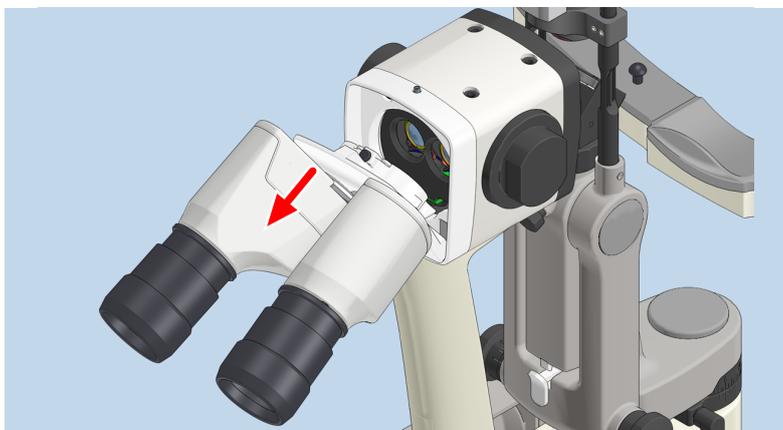
Assembly:

Action

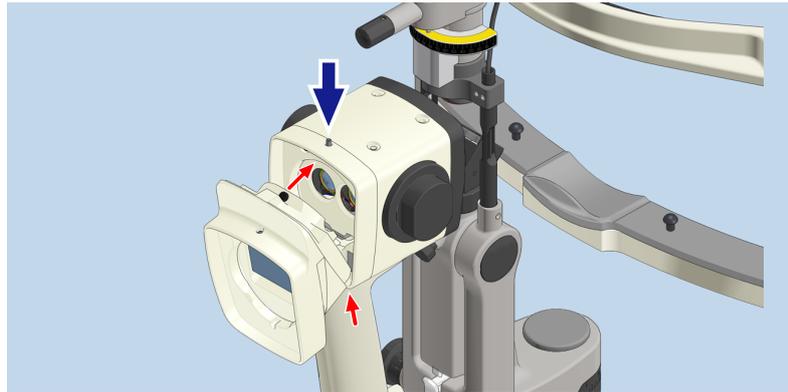
1. Switch off the device at the power supply unit.
2. Lock the instrument base using the manual brake.
3. Hold the binocular tube while loosening the threaded pin at the top of the convenience interface with the size 1.5 screwdriver, supplied.



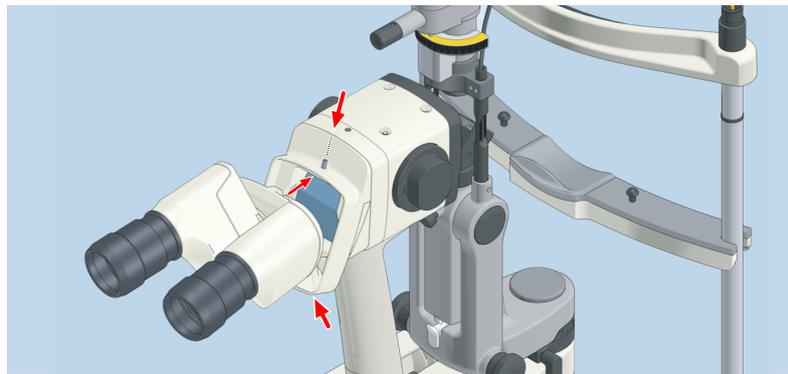
4. Tilt the binocular tube downwards out of the convenience interface.



5. Put the binocular tube aside.
6. Insert the tube adapter 20° into the convenience interface and tilt it upwards.



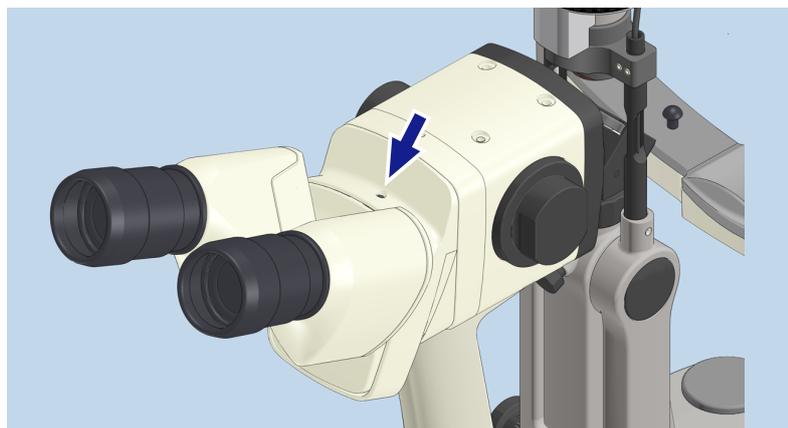
7. Attach the tube adapter 20° by tightening the threaded pin.



⇒ After successful attachment, the convenience interface must be flush with the tube adapter 20°.

8. Attach the binocular tube from the bottom to the convenience interface and tilt it upwards.

9. Attach the binocular tube by tightening the threaded pin.



⇒ After successful attachment, the binocular tube must be flush with the tube adapter 20°.

12.10 Beam splitter

Using the beam splitter, you can, for example, connect optional co-observation components to the device.

The prism slide is moved to send either 100 % of light to the binocular tube or to divide it into 50 % each to the binocular tube and the accessory attachments.

- Prism slide in bottom position: 100 % of light is sent to binocular tube or observer
- Prism slide in top position: 50 % of light is sent to binocular tube or observer and 50 % of light is sent to the accessory attachments of the beam splitter

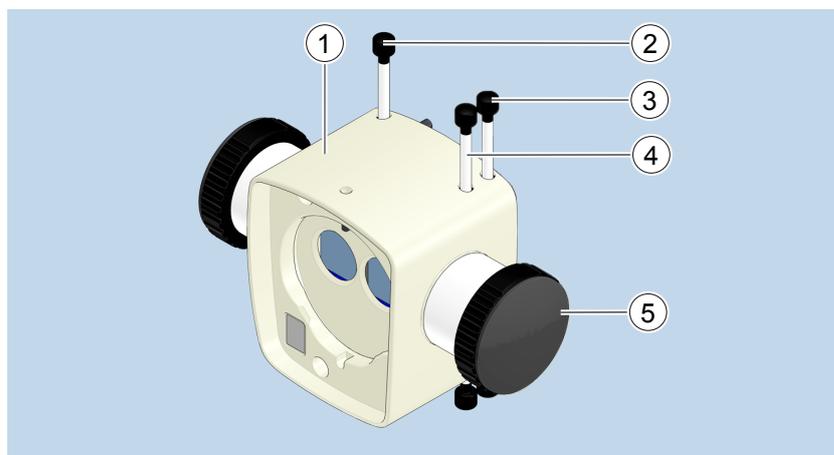


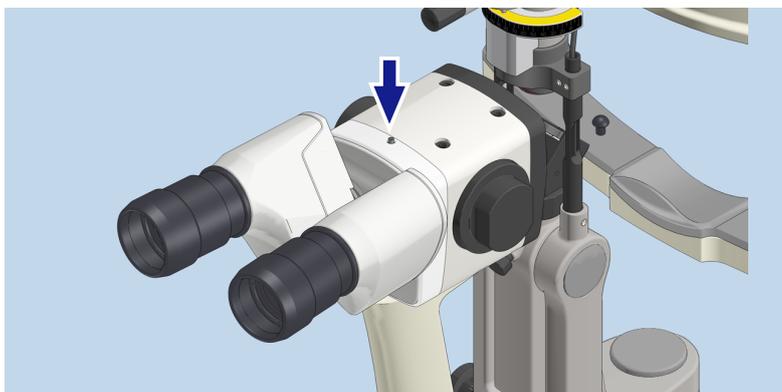
Figure 26: Beam splitter

1	Beam splitter	2	Yellow filter
3	Aperture	4	Prism slider
5	Accessory attachment		

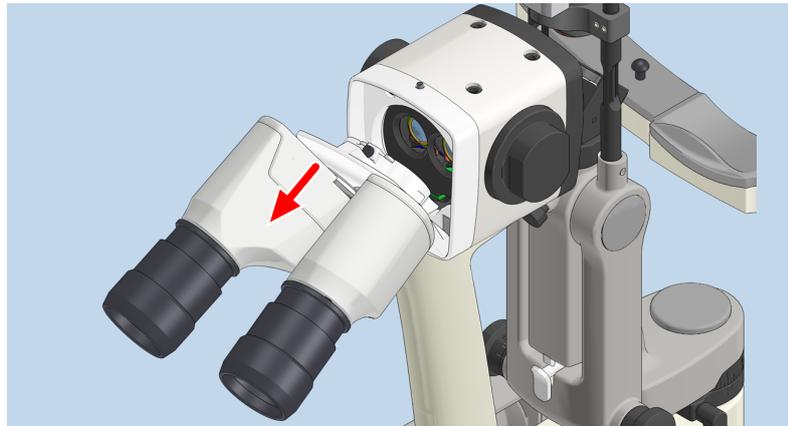
Mounting (if not already factory-mounted):

Action

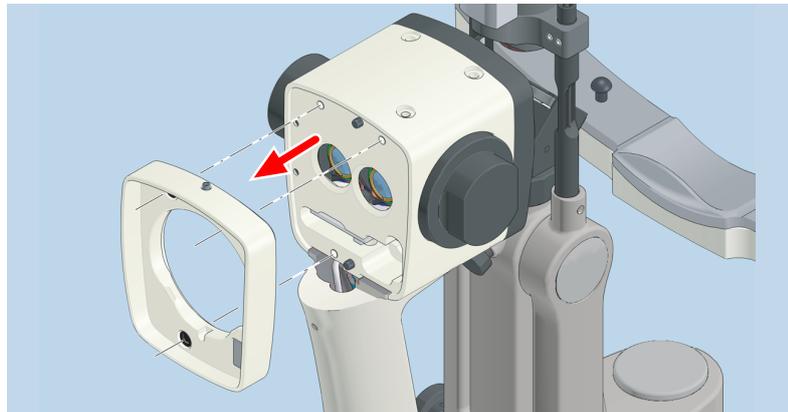
1. Switch off the device at the power supply unit.
2. Lock the instrument base using the manual brake.
3. Hold the binocular tube firmly while loosening the threaded pin at the top of the convenience interface with the size 1.5 screwdriver, supplied.



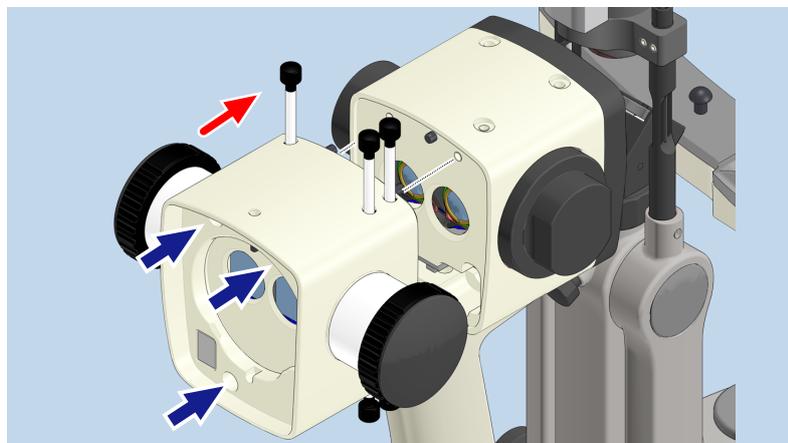
4. Tilt the binocular tube downwards out of the convenience interface.



5. Put the binocular tube aside.
6. Loosen the three screws of the convenience interface with the size 3 screwdriver, supplied.

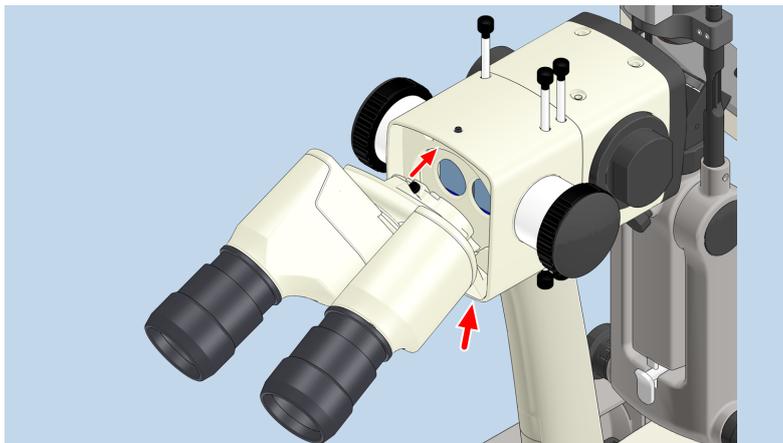


7. Ensure that the three control elements of the beam splitter module to be mounted are extended upwards.
8. Attach the beam splitter to the stereomicroscope.
NOTE! Ensure that the orientation pins are positioned correctly.

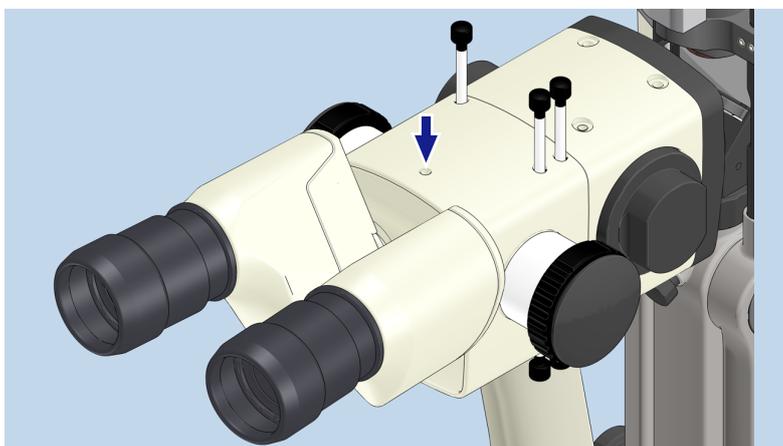


9. Tighten the integrated screws of the beam splitter handtight.

10. Attach the binocular tube from the bottom to the beam splitter and tilt the binocular tube upwards.



11. Attach the binocular tube to the beam splitter by tightening the threaded pin.



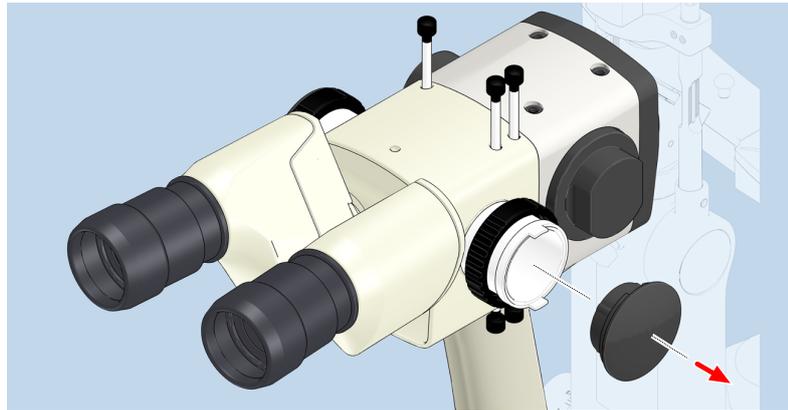
⇒ After successful attachment, the binocular tube must be flush with the beam splitter module.

12.11 Co-observation tube with eyepiece

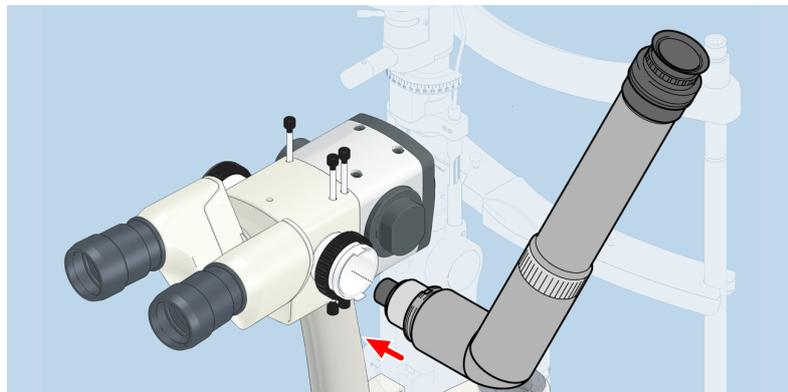
The co-observation tube permits monocular observation of the slit lamp examination. It is mounted on one of the two accessory attachments of the beam splitter.

Action

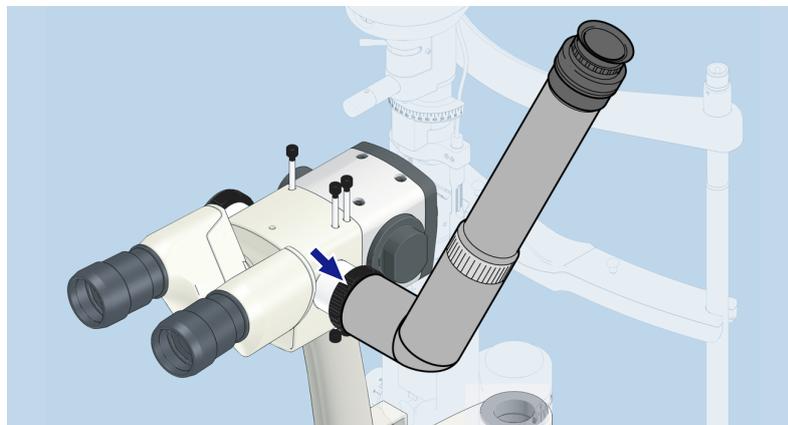
1. Insert the supplied eyepiece of the co-observation tube.
2. Loosen the sleeve nut on the selected attachment of the beam splitter in the "→ OPEN" direction.



3. Insert the co-observation tube into the attachment. Ensure the appropriate orientation of the co-observation tube is still correct.



4. Re-tighten the sleeve nut.



5. Swivel the co-observation tube into the desired position.

12.12 Fixation lamp

If the existing headrest has fixation lamp connections, you can mount the fixation lamp as described below.

The fixation lamp allows indirect control of the patient's eye by moving the unexamined eye in a defined viewing direction using the fixation lamp. By turning the cover accordingly, you can use two differently sized luminous points for fixation. The fixation lamp flashes permanently as soon as the power supply unit is switched on.

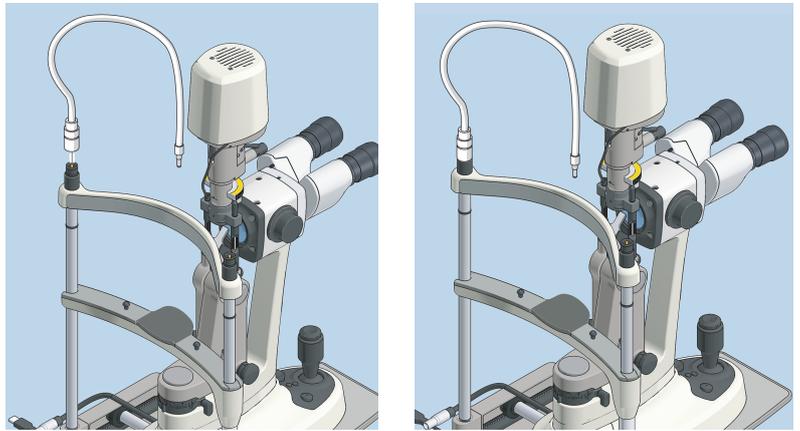
Assembly:

Prerequisite

- The headrest cable must be connected to the power supply unit.

Action

1. Carefully insert the fixation lamp from above onto the desired fixation lamp connection.



2. Hand-tighten the sleeve nut.
3. Position the fixation lamp and, if necessary, turn the cover to the desired position.
4. If not already done, connect the fixation lamp cable to one of the two USB-A ports on the power supply unit or the optional cable extension set.

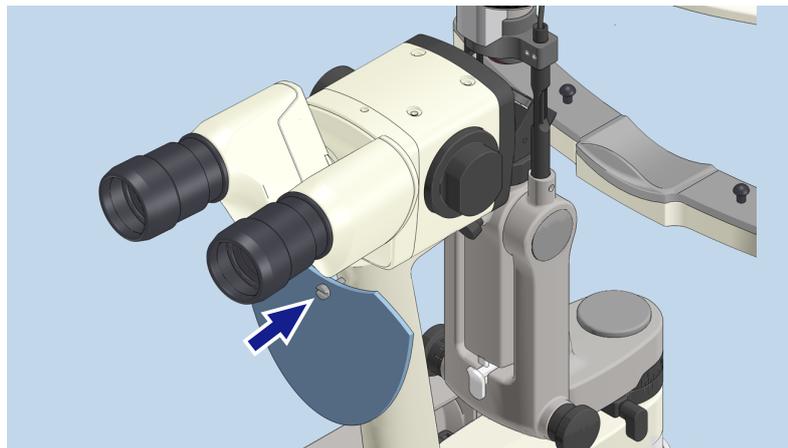
12.13 Breathing shield

A breathing shield may be mounted to the carrier arm of the stereomicroscope to shield the patient and physician from each other's breath.

Assembly:

Action

1. Attach the breathing shield to the carrier arm of the stereomicroscope using the integrated screw.



2. Remove the protective film, if necessary.

12.14 Paper pads

Paper pads for the chinrest of the headrest improve hygienic conditions.

Attaching the paper pads:

Action

- ▶ Place the paper pads onto the chinrest using the fastening pins supplied with the headrest.

12.15 Instrument table

WARNING!

Electrical hazard due to improper electrical connection

Improper electrical installation may cause an electric shock.

- ▶ Connect the device via an instrument table qualified by Carl Zeiss Meditec. If using another table, the user is solely responsible for ensuring the electrical safety of the device.

⚠ CAUTION!

Mechanical hazard due to instability

Injury may be caused by falling parts.

- ▶ When selecting a suitable table, ensure that the combination of table and device is stable up to a tilt angle of 10°. The table must be designed for 4 times the weight of the device configuration.
- ▶ When using a mobile table ensure that the casters have locking devices.

ZEISS offers two instrument tables for the device. If the device is mounted on an instrument table qualified by ZEISS, it will be powered through this table. Follow the instructions for use of the instrument table.

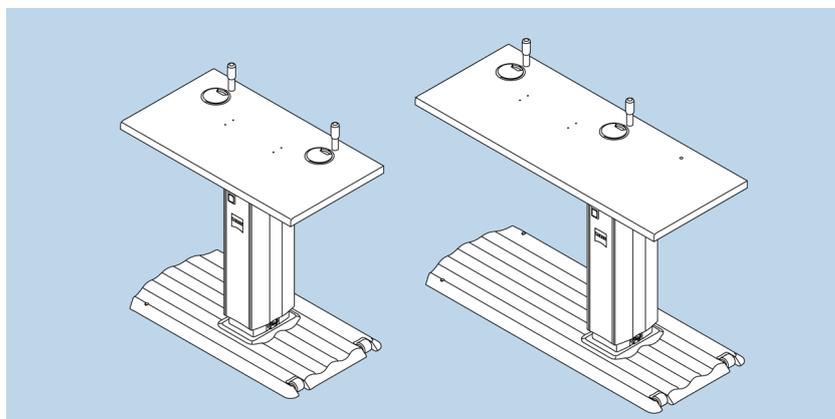


Figure 27: Instrument tables

Empty page, for your notes

13 Disposal of the device

- ▶ Retain packaging materials for future relocation or repair.
- ▶ If you wish to dispose of the packing material: Submit the packaging material to a recognized collection system for recycling.

The device contains electronic components.

- ▶ Dispose of the device properly and in accordance with national legislation.



In accordance with applicable EU guidelines and national regulations at the time at which the product was brought onto the market, the product specified on the consignment note is not to be disposed of via the domestic waste disposal system or communal waste disposal facilities.

- ▶ For more information about the disposal of the device, please contact the ZEISS contact partner in your country.

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

- ▶ If you resell the device or its components: Inform the buyer that the device is to be disposed of in accordance with the currently applicable regulations.

Empty page, for your notes

Glossary

D

D (diopter) is the unit of measurement of the refractive power of optical systems.

Electromagnetic compatibility (EMC)

EMC (electromagnetic compatibility) designates the usually desired state in which technical devices do not impede each other by undesired electric or electromagnetic effects (non-interference).

IEC

International Electrotechnical Commission

ISO

International Organization for Standardization

MDD

Medical Device Directive

SL

Slit lamp

USB

USB (universal serial bus) is a standard connector to connect peripheral devices.

Empty page, for your notes

Keyword index

A

Ambient conditions 12

C

Changes to the product 10

D

Decommissioning 12

Diffusor 38, 53, 56

Disposal

 Electronics 89

 Packaging material..... 89

Duration of exposure 13

E

EcoMode 24, 25, 53

Electrical safety 11

Electromagnetic compatibility 59

Essential performance..... 55

F

Filter 20, 26, 39, 53, 56, 68, 76, 77, 78

Fluorescein 68, 76

G

Ground fault circuit interrupter 12, 48

I

Instrument myopia 38, 71

Instrument table 12, 15, 28, 29, 30, 37, 41, 65,
86, 87

Intended user profile 9

O

Operating personnel..... 10

P

Package check list..... 12, 15, 29, 66, 86

Patient population 9

Q

QuickStop..... 23, 25, 41

S

Service life 10

U

User profile..... 9

V

VarioLight..... 13, 14, 20, 56



Carl Zeiss Meditec AG

Goeschwitzer Strasse 51-52

07745 Jena

Germany

Internet: www.zeiss.com/med

E-Mail: info.meditec@zeiss.com



000000-2268-355-DokS-GB-300719