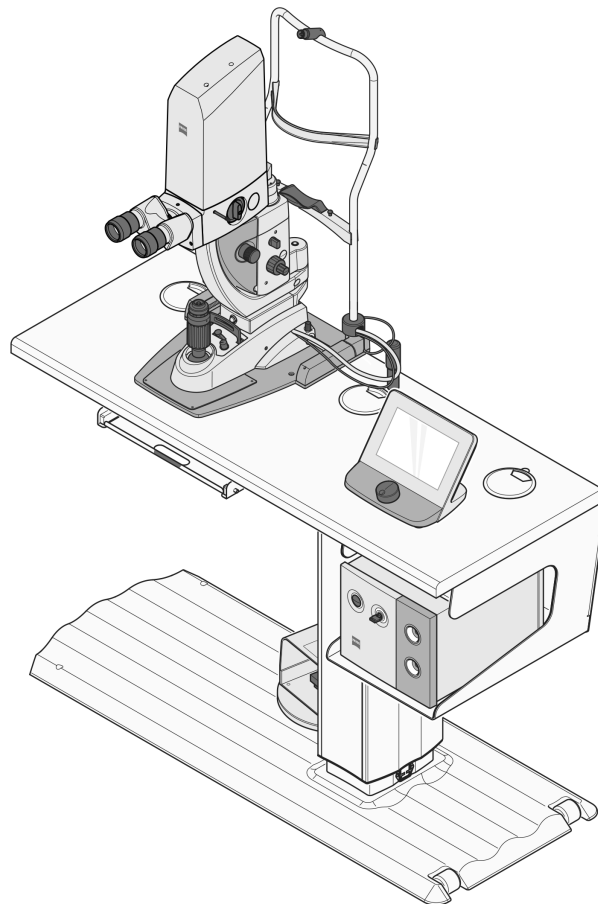


VISULAS

Documentation set



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1 Notes on the instructions for use

1.1 Product name

VISULAS green, VISULAS yag and VISULAS combi are referred to in these instructions for use as "system".

In the following, when statements or references apply equally to all models, we will refer simply to "VISULAS".

1.2 Scope of application

The present instructions for use apply to the VISULAS consoles and laser applicators with the following marking:

- Reference number: 2222-001 (Single Port, laser console with one optic fiber port)
- Reference number: 2222-002 (Dual Port, laser console with two optic fiber ports)
- Reference number: 2222-003 (Combi, laser console with two optic fiber ports)
- Reference number: 2222-004 (YAG, laser console without an optic fiber port)
- Reference number: 2039-606 (LSL green classic)
- Reference number: 2039-607 (LSL green comfort)
- Reference number: 2039-608 (LSL green combi)
- Reference number: 2039-609 (LSL yag)
- Reference number: 2222-000 (LIO VISULAS green)

and laser endoprobes which are approved for VISULAS.

NOTE! These instructions for use describe the maximum configuration and maximum functionality. You may find that some configurations or functionalities are not available in your country. Please contact our regional representatives for more information. Subject to changes in design and scope of delivery, and to ongoing technical development.

1.3 Purpose and storage of the documentation

These instructions for use explain the safety features, functions and the performance parameters of the system. They are a guide for safe operation and specify the measures for maintenance and repair of the system.

The correct operation of the system is vital for safe and successful operation.

Action

- ▶ Read these instructions for use before starting and using the system.
- ▶ Keep the instructions for use where they are accessible at all times for all users.
- ▶ Pass the instructions for use on to the next owner of the system.

1.4 Questions and comments

Action

- ▶ If you have any questions or comments concerning these instructions for use or the system, please contact ZEISS Service.

You can find the ZEISS representative for your country online 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 [▶ 10].

This is **highlighted text**.

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.

Prerequisite

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

Action

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 software descriptions and enclosed quick guides of the associated licenses as well as the instructions for use of other components and accessories used with this device. Please check at regular intervals whether a newer version of these instructions for use is available at <http://www.zeiss.com/ifu>.

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2 General safety instructions

2.1 Intended use

The intended use is contained in the software description supplied depending on the configuration.

2.2 Intended user profile

The intended user profile is contained in the software descriptions supplied depending on the configuration.

2.3 Clinical benefits

The clinical benefits for a treatment with the VISULAS depend on the clinical application and are therefore included in the software descriptions supplied depending on the configuration.

2.4 Patient population

If appropriate clinical Indications [► 13] are given and Contraindications [► 13] are excluded, therapeutic laser treatment can in principle be performed in patients of all age groups. You will find further information in the software descriptions supplied depending on the configuration.

2.5 Indications

The indications depend on the clinical application and are therefore included in the software descriptions supplied depending on the configuration.

2.6 Contraindications

The contraindications depend on the clinical application and are therefore included in the software descriptions supplied depending on the configuration.

2.7 Warnings

General and application-specific warnings are included in the respective software descriptions.

2.8 Precautions

2.8.1 General information

- ▶ The system may only be installed, operated, used and maintained by persons who have the appropriate training or knowledge and experience. Please also adhere to the national qualification guidelines applicable in your country.
- ▶ Report an incident or near incident to the medical device manufacturer or distributor in a timely manner. Observe local laws for additional reporting to competent authorities.
- ▶ Note the software descriptions and information accompanying the accessories, additional devices, optional parts and consumables.
- ▶ Make sure that persons who use the device or are in the laser area have been instructed on the behavior to be observed and the use of the system.
- ▶ Designate and authorize a laser safety officer to provide the necessary training and ensure that protective measures are maintained in the laser area.
- ▶ Instruct users once a year about the special hazards of laser radiation and about the safety equipment of the device which is not operated regularly (e.g. laser emergency stop device).
- ▶ Carry out daily inspection measures according to the information given in Daily inspection [▶ 101].
- ▶ USA only: United States national law prohibits the physician from selling this device directly or through a third party.
- ▶ Pay attention to the following safety notice for the head strap (material number: 306883-0000-000):
CAUTION! This product contains natural rubber latex which may cause allergic reactions.

2.8.2 Installation notes

2.8.2.1 General information

- ▶ Installation, instruction and commissioning shall only be performed by the manufacturer or by companies authorized by the manufacturer.

WARNING! Do not modify this equipment without authorization of the manufacturer.

- ▶ The instructions for use should be readily accessible to the operating personnel at all times.
- ▶ Only connect devices, accessories and detachable parts authorized by the manufacturer or designated in these instructions for use. Contact your ZEISS contact partner for an up-to-date list.

WARNING! Only use accessories, transformers and cables which are specified or provided by the manufacturer for this device. The use of alternative parts may result in higher electromagnetic emissions or reduced immunity of the device and thus in faulty operation.

2.8.2.2 Structural requirements and positioning of the device

- ▶ Install and operate the system in accordance with the ambient and connection conditions contained in the technical data (see Technical specifications [▶ 129]).
- ▶ Operate the device only in rooms suitable for class 4 lasers according to IEC 60825-1.
- ▶ Only operate the device in an environment where no conductive contamination can occur.
- ▶ Install a fire extinguisher in the vicinity of the device.
- ▶ Set the device up so that the power cable can be disconnected from the power supply quickly and without any supplementary means.
- ▶ Keep the laser area as small as possible in terms of space within the specified task.
- ▶ Ensure that the emitted laser beam passes outside the working and traffic area in as small an area as possible that is not easily accessible. In particular, the emitted laser beam must pass above or below eye level.
- ▶ Ensure that the laser hazard area is clearly demarcated and marked as such during laser operation. Laser operation must be indicated by laser warning lights at the access to laser areas.
- ▶ Only use third-party laser warning lights if the electrical connection is sufficiently insulated (at least 4 kV AC).

- ▶ In rooms intended for laser operation, ensure that the floors, ceiling, walls and other structural elements have diffusely reflecting surfaces. Suitable non-flammable covers should be provided for bare surfaces such as windows.
- ▶ Ensure by technical or organizational measures that exposure above the maximum permissible irradiation, also by reflected or scattered laser radiation, is prevented.
- ▶ Make sure that the laser beam - as far as possible - is limited by a diffusely reflecting target surface in such a way that a hazard due to direct or diffuse reflection is minimized. For example, align the system so that the laser exit aperture is not aimed at the entrance door of the treatment room.
- ▶ Ensure that optical devices used to observe the surgical field are equipped with suitable laser protection filters if the maximum permissible irradiation can be exceeded.
- ▶ Set up the device including components and accessories located in the laser beam path in such a way that an unintentional change of their position and the beam direction is avoided.
- ▶ Do not operate the electrical devices contained in the delivery package:
 - in explosive atmospheres,
 - on easily inflammable materials,
 - in the presence of inflammable anesthetics or volatile solvents, such as alcohol, benzene or similar,
 - in oxygen-enriched environments.

2.8.2.3 Electrical safety and electromagnetic compatibility

WARNING! To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- ▶ Ensure that a ground fault circuit interrupter (GFCI) and an adequate overcurrent protection are installed.
- ▶ Do not use multiple sockets and / or extension cables.
- ▶ Connect the device using the power cable intended for use with the device and matching the local wall connection.
- ▶ When the device is combined with other electrically powered devices, the requirements of IEC 60601-1 must be taken into account.
- ▶ Perform the electrical installation in conformance to IEC 60364-7-710 or the applicable national regulations.

- ▶ 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 VISULAS, including cables specified by the manufacturer. Otherwise, deterioration in the performance is to be anticipated.
- ▶ Do not use the device in locations where the electromagnetic interference level is higher than specified in the technical data, see Electromagnetic compatibility [▶ 138].
- ▶ Ensure that multimedia or IT equipment connected to the device via signal lines complies with the requirements of CISPR 32.

WARNING! Avoid using the device in direct proximity to other devices, or stacked together with other devices, as this could result in faulty operation. If it is nonetheless necessary to operate the device in the aforementioned manner, the device and the other devices should be monitored to ensure the safety of the arrangement used.

2.8.2.4 IT networks

- ▶ Note that if the system is integrated into an IT network and the patient treatment data are combined, undesired modification of the treatment data or unauthorized use of patient data with associated treatment data is possible.
- ▶ Perform risk management according to IEC 80001-1 when integrating the system into an IT network.
- ▶ Note that a reassessment of risks is required for the following changes in IT networks:
 - Changes to the IT network configuration
 - Connecting additional elements in the IT network
 - Removal of elements from the IT network
 - Updating or upgrading devices connected to the IT network

2.8.2.5 Data security

- ▶ Protect the system and patient data from unauthorized use. Please also observe the nationally applicable laws and regulations for the protection of sensitive data.

2.8.3 Instructions for daily startup

- ▶ Remove the dust cover when connecting the device to the supply mains.

CAUTION! When lowering the instrument table, always ensure that no body parts are within the movement range of the tabletop.

- ▶ Avoid the penetration of liquids. Except for the foot switch, the device does not provide protection against the ingress of liquids.

2.8.4 Instructions for shutting down

- ▶ Disconnect the system from the power supply if you are not going to use the system for any length of time.
- ▶ When not in use, remove the key switch from the system to prevent its use by unauthorized persons.
- ▶ Place the protective cap on the optical fiber if the device is not in use.
- ▶ Pull the dust cover over the device after disconnecting it from the power supply to reduce exposure to dust.
- ▶ In the following cases, take the system out of operation and notify ZEISS Service of any required repair measures:
 - Unexpected change of laser energy / power or laser position
 - Electric shock
 - Penetration of liquids
 - Occurrence of smoke, fire or burning odor
 - Disimprovement of the system performance
 - Recurring error messages
 - Response of the system in contradiction with the information in these instructions for use
 - Safety-relevant deviation as a result of inspection measures
 - System related incidents or near incidents that (may) have resulted in injury to the patient or physician (user).
- ▶ In case of obvious defects, take the laser safety goggles or other protective filters out of operation. Examples of such defects are clearly visible changes to the protective filter (cracks, color changes, changes in light transmission) or faults in the mount or holder that impair protection against incident radiation from the side.

2.8.5 Reprocessing instructions (cleaning and disinfection)

- ▶ Allow cleaning agents and disinfectants containing flammable solutions to evaporate completely before using the device or emitting laser radiation.
- ▶ Clean and disinfect the applied parts according to the specified procedure or according to another procedure recognized by professional associations before applying them on a patient.
- ▶ Do not use spray cleaning or disinfection.
- ▶ Clean accessible optics in case of contamination according to the specified procedure.

2.8.6 Instructions on maintenance

- ▶ No treatments may be performed on patients during the maintenance and repair work.
- ▶ Maintenance measures not contained in these instructions for use shall be performed only by persons authorized by Carl Zeiss Meditec. Maintenance measures may only be carried out according to the service instructions issued by Carl Zeiss Meditec.
- ▶ Perform safety checks at least every 2 years by the manufacturer or by personnel authorized by the manufacturer. If necessary, contact your ZEISS representative for an overview of the minimum content of the safety check.
- ▶ Do not open the device housing.
- ▶ Do not allow anyone to look into the laser exit aperture when the device is switched on, even if laser safety goggles have been put on. The radiation emitted at the laser exit aperture (including illumination of the applicators and aiming beam) exceeds the limits of the maximum permissible irradiation values for human eyes not being treated with laser radiation for therapy purposes.
- ▶ Do not look directly into the laser beam which is scattered back by bright, reflective surfaces.
- ▶ Do not point the laser beam at highly reflective surfaces (e.g. metal instruments).
- ▶ Disconnect from the power supply before changing the fuse!
- ▶ Only use fuses which meet the specifications given on the sign containing the fuse markings.
- ▶ Switch the illumination of LIO VISULAS green off and let the LED cool down before replacing the LED.

2.8.7 Notification to manufacturers and authorities

If a serious incident affecting the user, patient or another person occurs in connection with this medical device, the responsible organization or person responsible must report this incident to the manufacturer or seller of the medical product.

In member states of the European Union, the responsible organization or person must report serious incidents to their competent authority. In all other countries, comparable rules apply where national legislation so requires.

2.9 Side effects

The side effects during treatment with the VISULAS depend on the clinical application and are therefore included in the software descriptions supplied depending on the configuration.

3 Description of VISULAS green

3.1 Package check list

3.1.1 Software licenses, accessories and options

Depending on the selected configuration of the VISULAS green, only certain software licenses, accessories and options are clinically useful or technically possible. The following table shows the logical combination of laser applicators with usable licenses, accessories and options:

	LSL green classic Ref. no. 2039-606	LSL green comfort Ref. no. 2039-607	LIO VISULAS green	Endoprobes
Software licenses				
VERTE	X	X	X	X
VITE		X		
SLT		X		
YAG				
VOLANTE				
LASER REPORT	X	X	X	X
Accessories / options				
IT.i instrument tables	X	X		
SL Imaging Solution	X	X		
AT 030 tonometer	X	X		
Physician's safety filter for OPMI*				X
ACCENTO ergo tube	X	X		
Foot switch	X	X	X	X
Laser warning light	X	X	X	X
Panel PC	X	X		
Co-observation tube	X	X		
VISUCONNECT	X	X	X	X

Table 1: Overview of usable software licenses, accessories and options of the VISULAS green depending on the laser applicator used

*Active and passive physician's safety filters are available for popular surgical microscopes from the manufacturers ZEISS, Möller-Wedel, Leica and Wild. If you are using a surgical microscope from another manufacturer, it must be determined whether it provides a compatible interface. Please contact your ZEISS consultant for this.

3.1.2 Device configurations with laser slit lamps

3.1.2.1 VISULAS green with LSL green classic laser slit lamp

- VISULAS green (Laser console with single or dual port and control panel)
- LSL green classic laser slit lamp
- Fiber optic cable (2.0 m)
- Foot switch
- Parallel or convergent tube $f = 140$ mm
- 2 eyepieces 10x
- Armrest (height-adjustable)
- Dust cover
- Fixation lamp
- Power supply cable (2.5 m)
- Documentation set
- Laser safety goggles

3.1.2.2 VISULAS green with LSL green comfort laser slit lamp

- VISULAS green (Laser console with single or dual port and control panel)
- LSL green comfort laser slit lamp
- Fiber optic cable (2.0 m)
- Foot switch (1.6 m)
- Parallel or convergent tube $f = 140$ mm
- 2 eyepieces 10x
- Armrest (height-adjustable)
- Dust cover
- Fixation lamp
- Power supply cable (2.5 m)
- Documentation set
- Laser safety goggles

3.1.3 LIO VISULAS green

- LIO VISULAS green laser indirect ophthalmoscope
- Charging dock with power supply unit and connection cable
- Wall mount template for charging dock
- 3 screws and 3 plugs for wall mounting of charging dock
- Aspheric glass lens 20 D type OI-20 for laser applications
- Spare battery
- 2 plane lenses (0 D)
- Documentation set

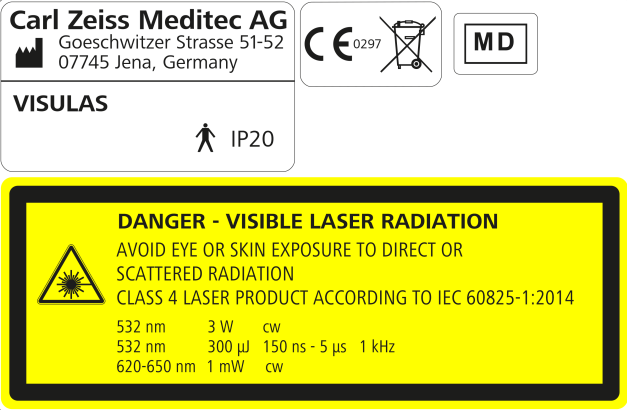






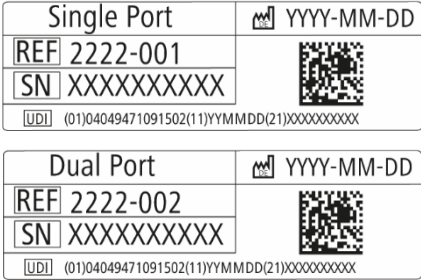




3.1.4 VISULAS green device configuration with endoprobes





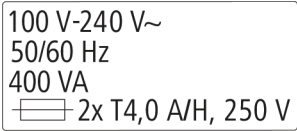


- VISULAS green (Laser console with single port and control panel)
- Foot switch (1.6 m)
- Extension cable for foot switch (3.4 m)
- Laser endoprobes
- Power supply cable (2.5 m)
- Physician's safety filter for co-observation tube on surgical microscope
- Documentation set
- Laser safety goggles

3.2 External labels





3.2.1 VISULAS green laser console (single port and dual port)

The label texts on the laser endoprobes, SL Imaging Solution, AT 030, VISUCONNECT 600 and the instrument tables are described in the corresponding instructions for use.













Labels	Explanation
	VISULAS type label
	 Manufacturer
	 Type B applied part
	IP20 Protected against harmful solid foreign objects of 12.5 mm in diameter and greater; Non-protected against harmful ingress of water
	CE approval label and disposal advice for EU
	 Indicates that the product is in compliance with European legislation for medical devices, with identification number of notified body
	 Separate collection for electrical and electronic equipment
	Marking the device as a medical device
	 Medical device
	Laser Class 4 warning label
	 Warning; Laser beam
	Identification label for laser consoles
	 Catalog number
	 Serial number
	 Date of manufacture / Country of manufacture
	 Unique device identifier

Labels	Explanation
	Information label with serial number and model name
	Disconnect mains plug from electrical outlet
	Follow instructions for use
	Warning; Laser aperture at the end of the optical fibre applicator
	Electrical specifications
	 Fuse
	 Alternating current






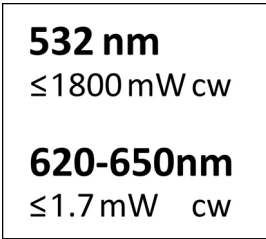

Control panel (TouchControl panel)






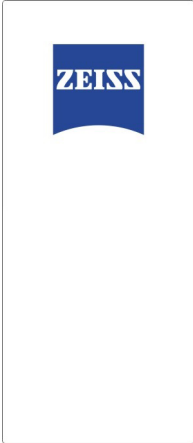
Labels	Explanation
	Identification label
	 Catalog number
	 Serial number
	 Identification code

3.2.2 LSL green comfort / classic laser slit lamp







Labels	Explanation
<div> <div> Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany </div> <div> LSL green classic   </div> </div> <p>classic</p> <div> <div> Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany </div> <div> LSL green comfort   </div> </div> <p>comfort</p>	<div>Type label</div> <div>  <div>Manufacturer</div> </div> <div>  <div>Type B applied part</div> </div> <div>  <div>Separate collection for electrical and electronic equipment</div> </div>
<div> <div> REF 2039-606 SN XXXXXXX </div>  </div> <p>classic</p> <div> <div> REF 2039-607 SN XXXXXXX </div>  </div> <p>comfort</p>	<div>Identification label</div> <div> <div>REF</div> <div>Catalog number</div> </div> <div> <div>SN</div> <div>Serial number</div> </div> <div>  <div>Identification code</div> </div>
	Warning; Optical radiation
	Laser aperture

3.2.3 LIO VISULAS green

Labels	Explanation
 <p>The label is rectangular with a notch on the left side. It contains the following information: 'Carl Zeiss Meditec AG' with a factory icon, 'Goeschwitzer Strasse 51-52', '07745 Jena, Germany', 'LIO VISULAS green', a person icon, a date icon 'YYYY-MM-DD', 'IP20' with a crossed-out water drop icon.</p>	LIO VISULAS green type label
	 Manufacturer
	 Date of manufacture
	 Type B applied part
	IP20 Protected against harmful solid foreign objects of 12.5 mm in diameter and greater; Non-protected against harmful ingress of water
	 Indicates that the product is in compliance with European legislation for medical devices, with identification number of notified body
 <p>The label is rectangular and contains the following information: '532 nm', '≤1800 mW cw', '620-650nm', '≤1.7 mW cw'.</p>	 Separate collection for electrical and electronic equipment
	Information label on permissible wavelengths and laser powers when operating LIO VISULAS green.

Labels	Explanation
	Identification label
	 Catalog number
	 Serial number
	 Follow instructions for use
	 Laser aperture
	ZEISS logo

3.2.4 Foot switch

Labels	Explanation
 <p>Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany</p>	Type label
<p>Standard foot switch</p> <p>REF 2209-639 SN XXXXX</p> <p> IPX8</p> <p>000000-2214-455-Vs07</p>	 Manufacturer
<p>Standard</p>	<p>IPX8 Protected against the effects of continuous immersion in water</p>
<p>TouchControl foot switch</p> <p>REF 2202-530 SN XXXXX</p> <p> IPX8</p> <p>000000-2214-456-Vs07</p>	 Separate collection for electrical and electronic equipment
<p>TouchControl</p>	<p>REF Catalog number</p>
	<p>SN Serial number</p>
	 Identification code

3.3 Device configuration

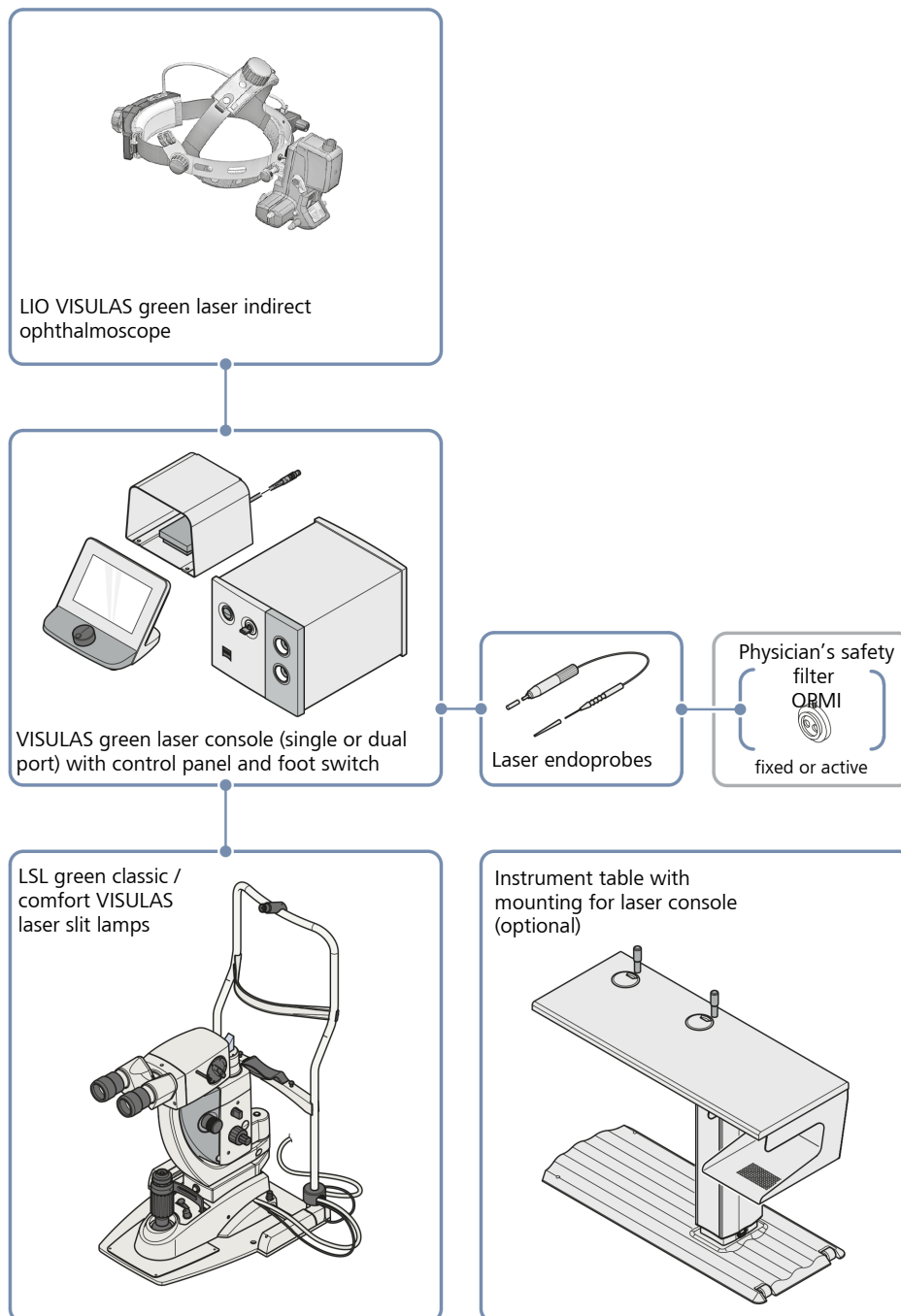


Figure 1: Device configuration

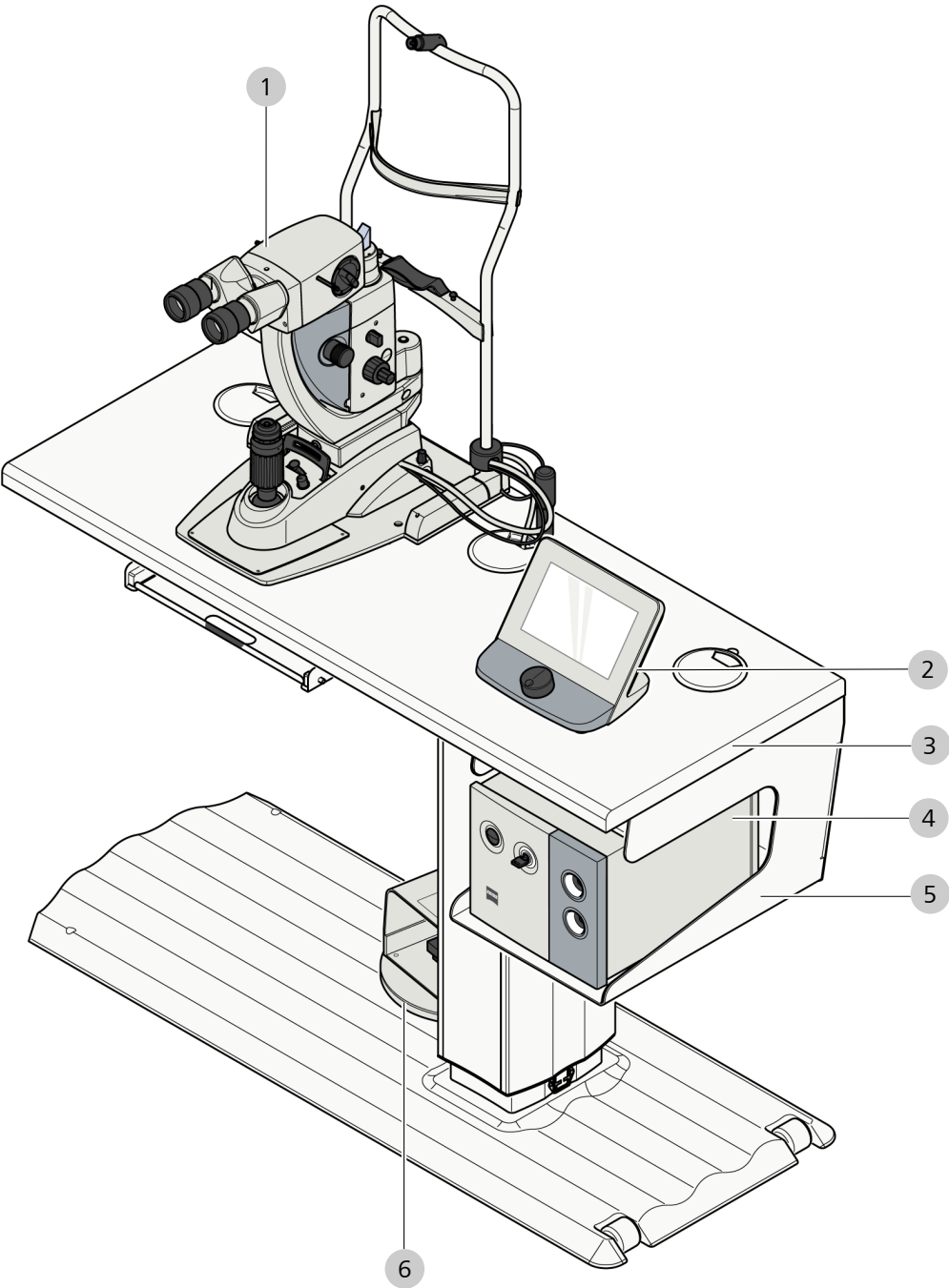


Figure 2: System overview VISULAS green

1	Laser slit lamp	2	Control panel
3	Instrument table	4	Laser console
5	Table mounting for laser console	6	Foot switch

3.3.1 LSL green laser slit lamp

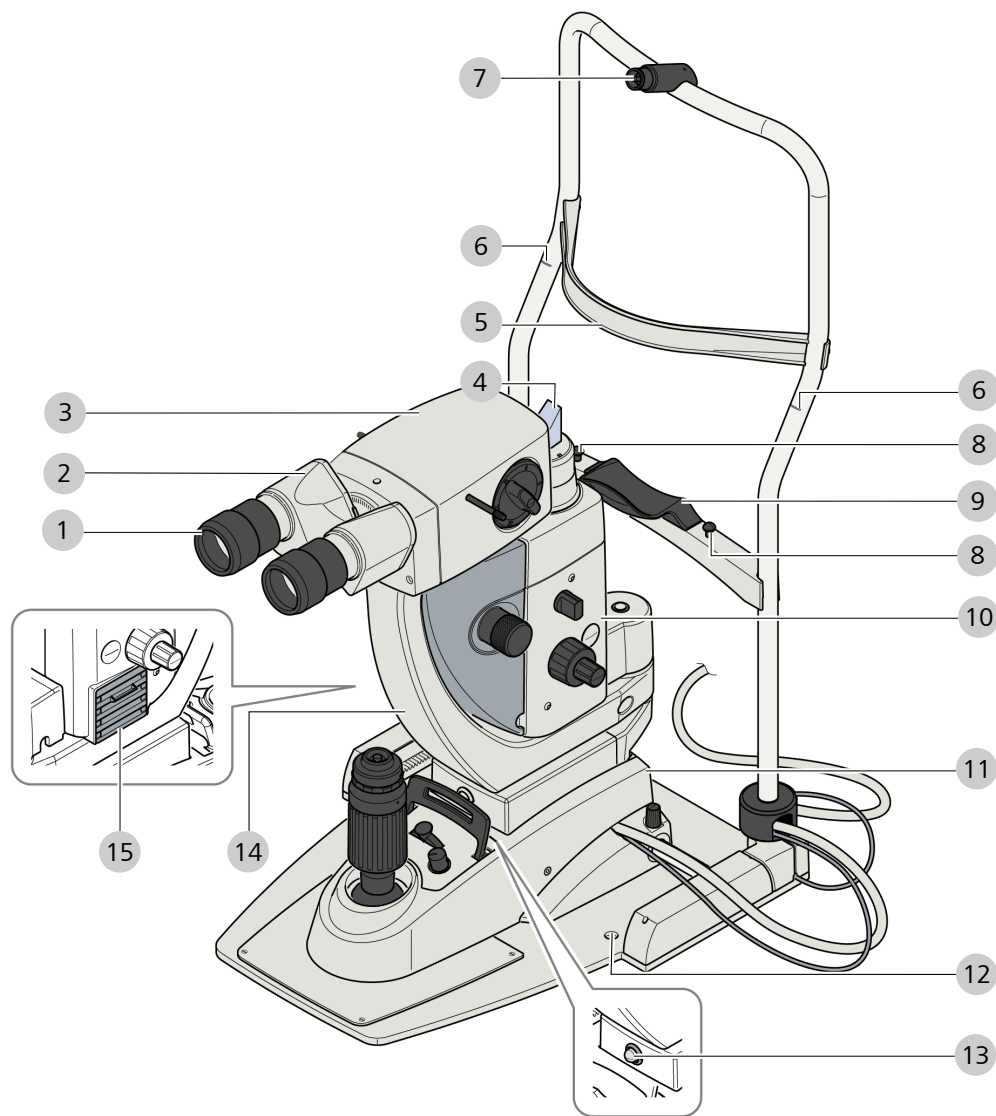


Figure 3: Laser slit lamp (version shown is the LSL green comfort)

1	Eyepiece with adjustable eye cup	2	Binocular tube
3	Microscope stand with fixed physician's safety filter	4	Prism head, illumination and laser exit aperture
5	Forehead rest (applied part)	6	Markings for setting the optimum eye level for the patient
7	Fixation lamp mounting	8	Fastening pins for paper pads
9	Chin rest (applied part)	10	Slit lamp housing
11	Instrument base	12	Mounting holes
13	Physician's detection sensor (infra-red movement sensor)	14	Slit lamp swivel arm
15	Cover for illumination unit		

3.3.1.1 Beam delivery in the laser slit lamp

The laser beam is interlaced into the illumination beam path, so that the slit image and the laser spot can move around the fundus in synchrony. This ensures that the area of the fundus which is to be coagulated is always illuminated, even in the peripheral fundus. This means of combining illumination and laser beams is particularly advantageous for small illumination fields.

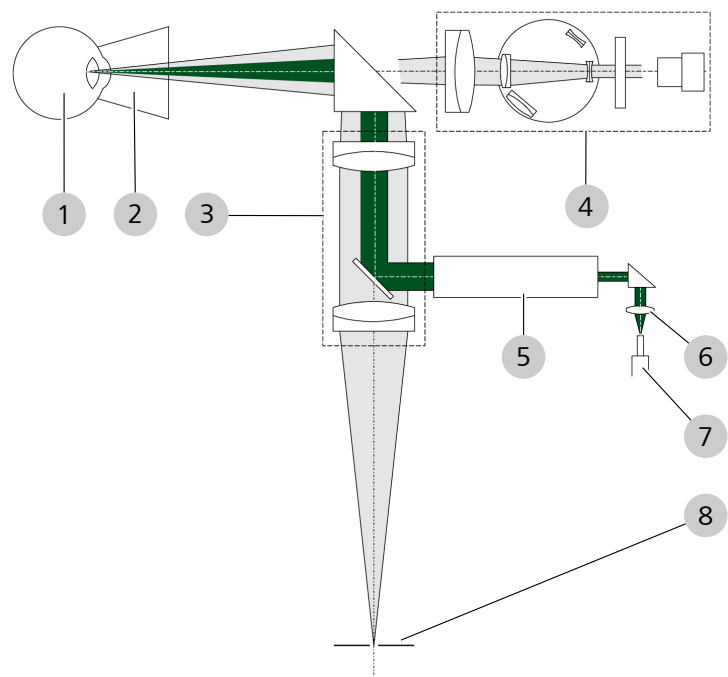


Figure 4: Beam delivery in the LSL green laser slit lamp

1	Patient's eye	2	Contact lens
3	Optical system for slit lamp and laser spot visualization	4	Corneal microscope with physician's safety filter
5	Laser beam expander	6	Coupling lens
7	Optical fiber	8	Slit illumination system

3.3.2 LIO VISULAS green

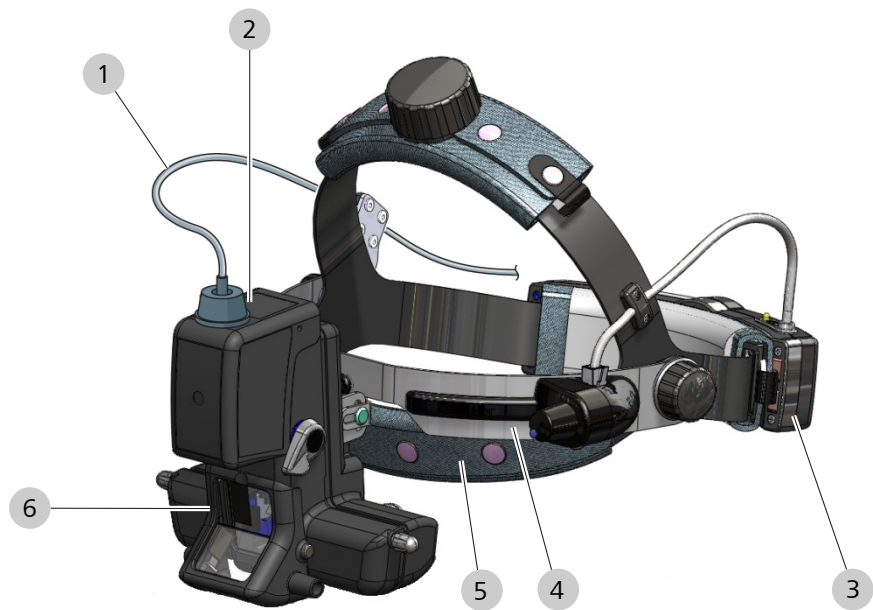


Figure 5: LIO VISULAS green from the physician's view (left) and patient's view (right)

1	Optical fiber	2	Binocular component
3	Battery	4	Support for binocular component
5	Head strap	6	Laser exit aperture



Figure 6: Binocular component from the physician's view (left) and patient's view (right)

1	Eyepieces	2	Window for LED illumination
3	Projection mirror for laser beam and aiming beam (laser exit aperture)		

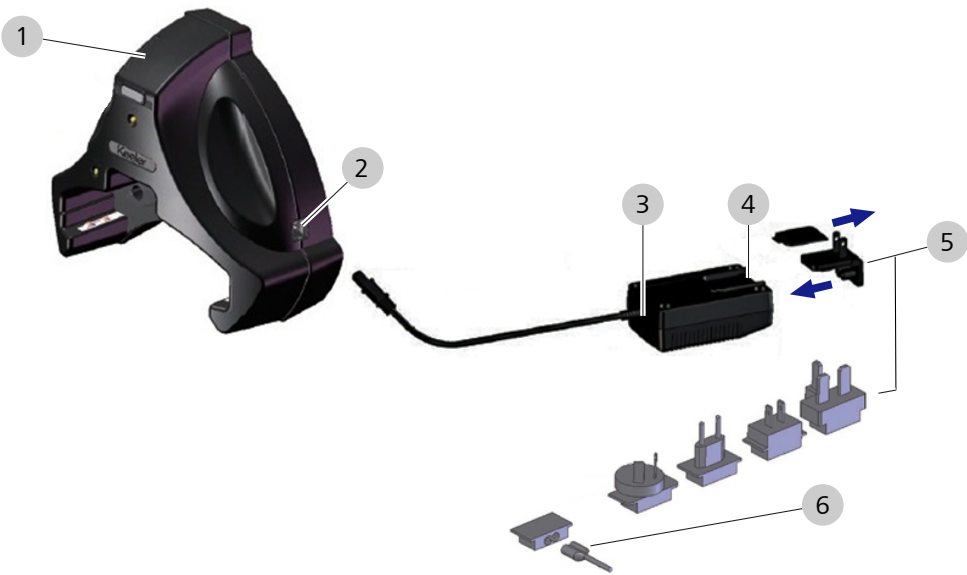


Figure 7: Charging station with power supply unit

1	Battery	2	Input socket for power supply connector cable
3	Power supply and connector cable	4	Cover plate
5	Power plug adapter	6	IEC 60320 type 7 plug (not included in the delivery package)

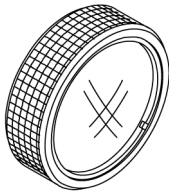


Figure 8: Aspheric lens 20 D

3.3.3 Endoprobes

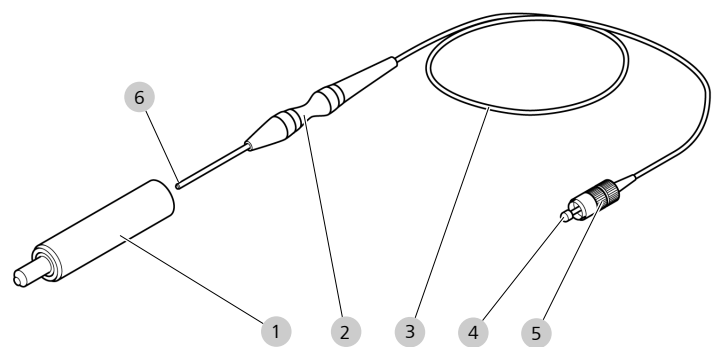


Figure 9: Laser endoprobe: example

1	Protective cap	2	Handpiece (applied part)
3	Optical fiber (3 m)	4	Protective cap
5	SMA connector	6	Laser exit aperture

3.4 Controls, display elements and connectors

3.4.1 Laser console

The laser console is the central power supply and control unit for the VISULAS green.

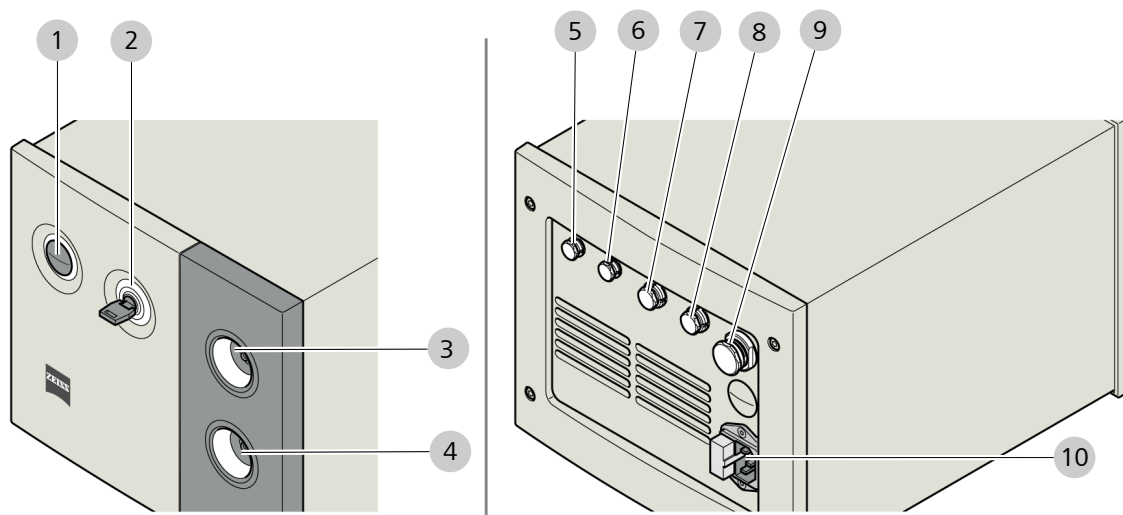






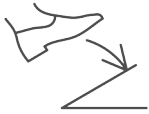




Figure 10: Control elements, displays and ports on the laser console of VISULAS green (version shown is the console version with dual optical fiber port)

Item	Icon / Name	Explanation
1	<p>STOP</p> 	Intended for immediate deactivation of the laser beam (lights up when laser stop switch is enabled). The laser stop switch interrupts the laser radiation to prevent hazards to persons. The laser stop switch is structurally independent of all of the other laser shutdown systems. When the laser stop switch is pressed, the system switches to the "Prepare" work step and all functions on the control unit are locked. To resume operation, press the laser stop switch again.
2	Key switch	The system features a key switch for the laser console. No laser radiation is emitted when the key is in the off position. The key can be removed.
3	<p>LSL / ENDO (only in case of dual port laser console)</p>  <p>LSL / ENDO / LIO (only in case of single port laser console)</p> 	<p>Optical fiber connection for</p> <ul style="list-style-type: none"> ■ Laser slit lamp ■ Laser endoprobe ■ LIO VISULAS green laser indirect ophthalmoscope <p>Illuminated ring on the corresponding fiber optic port lights up when selected:</p> <ul style="list-style-type: none"> ■ White in "Treat" work step ■ Red when therapy laser is triggered

Item	Icon / Name	Explanation
4	<p>LIO (only in case of dual port laser console)</p> 	<p>Optical fiber for LIO VISULAS green laser indirect ophthalmoscope</p> <p>Illuminated ring on the corresponding fiber optic port lights up when selected:</p> <ul style="list-style-type: none"> ■ White in "Treat" work step ■ Red when therapy laser is triggered
5	<p>Interlock</p> 	<p>Connector for door contact and external laser warning lamp. When the contacts of the plug connector are opened, laser emission is interrupted. As delivered, a short-circuit plug is plugged into the plug connector. Note that using the remote lock increases the probability of interrupting the laser treatment.</p>
6	<p>Services</p> 	<p>Interface for Services and VISUCONNECT 600 data transfer adapter</p>
7	<p>Foot switch</p> 	<p>Connection to foot switch</p>
8	<p>Display</p> 	<p>Connector for control panel</p>
9	<p>Slit lamp</p> 	<p>Connection socket for slit lamp and active external physician's safety filter for surgical microscopes</p>
10		<p>Power input with fuse compartment</p>

3.4.2 Control panel (TouchControl panel)

The laser console is operated via touch screen menus or using the combined rotary knob / button on the control panel.

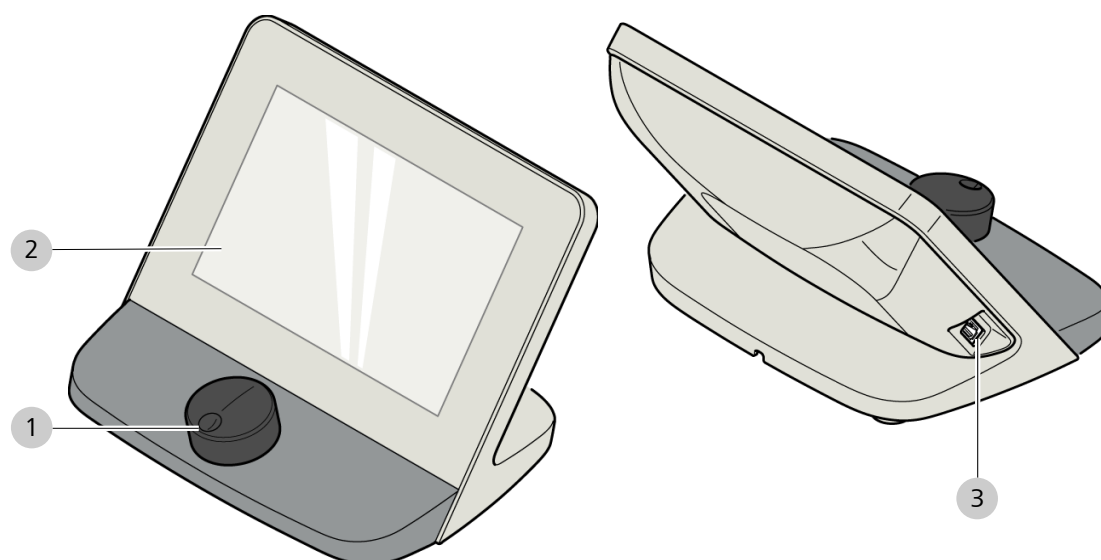


Figure 11: Control panel (TouchControl panel)



Item	Icon / Name	Explanation
1	Combined rotary knob / button	Alternatively to touch screen operation, the system can be controlled by turning / pressing the rotary knob / button. As long as no parameters have been activated, the knob can be rotated to switch between the parameters. Pressing the button on the rotary knob activates the selected parameter. Once a parameter has been activated, the parameter value can be decreased or increased by turning the knob to the left or right respectively. Pressing the button on the rotary knob will deactivate the selected parameter.
2	Touch screen	The system can be controlled via the touch screen. The parameters are activated by tapping. The parameter values can be adjusted by tapping the arrow keys or with circular movements (see Changing parameter values on the touch screen ► 41).
3	USB	USB port for software updates, pdf export of treatment reports and servicing; only for data storage media without external power supply

Parameter changes and transition to the next step in the navigation bar will be confirmed by an acoustic signal. A long acoustic signal will be emitted when changing from the "Treat" work step when the laser is active. The volume of the acoustic signals can be adjusted in the "Configure" work step.

Each time the laser is triggered, this will be confirmed by a short acoustic signal. This acoustic signal can be switched on and off in the "Configure" work step. In the "Treat" work step, the laser emission is also displayed on the touch screen as a red border.

3.4.2.1 Changing parameter values on the touch screen



Item	Icon/ Name	Explanation
1	Parameter	Parameter to be changed. The parameters are activated by tapping the touch screen.
2		Graphic representation of the set parameter value. The parameter value can be changed with circular movements on the touch screen.
3	Parameter value	Numerical display of the set parameter value.
4		Arrows for setting the parameter value. The parameter value can be changed by tapping on the touch screen.

Alternatively, the parameters can also be selected, changed and confirmed using the combined rotary knob/button.

3.4.2.2 Data input with on-screen keyboard

Data input on the control panel is done via the on-screen keyboard. It appears automatically as soon as the cursor is inserted into a text box.

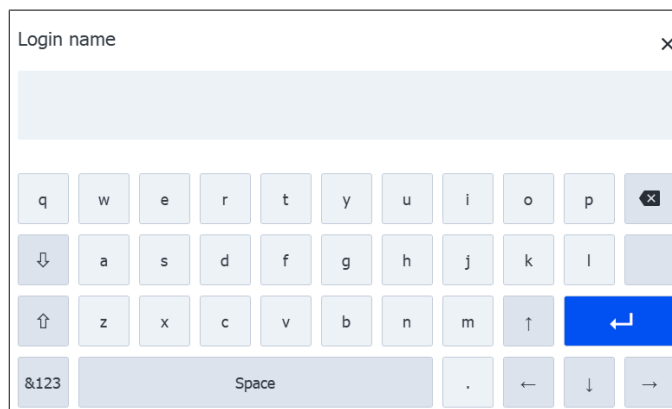


Figure 12: On-screen keyboard

3.4.3 LSL green comfort laser slit lamp

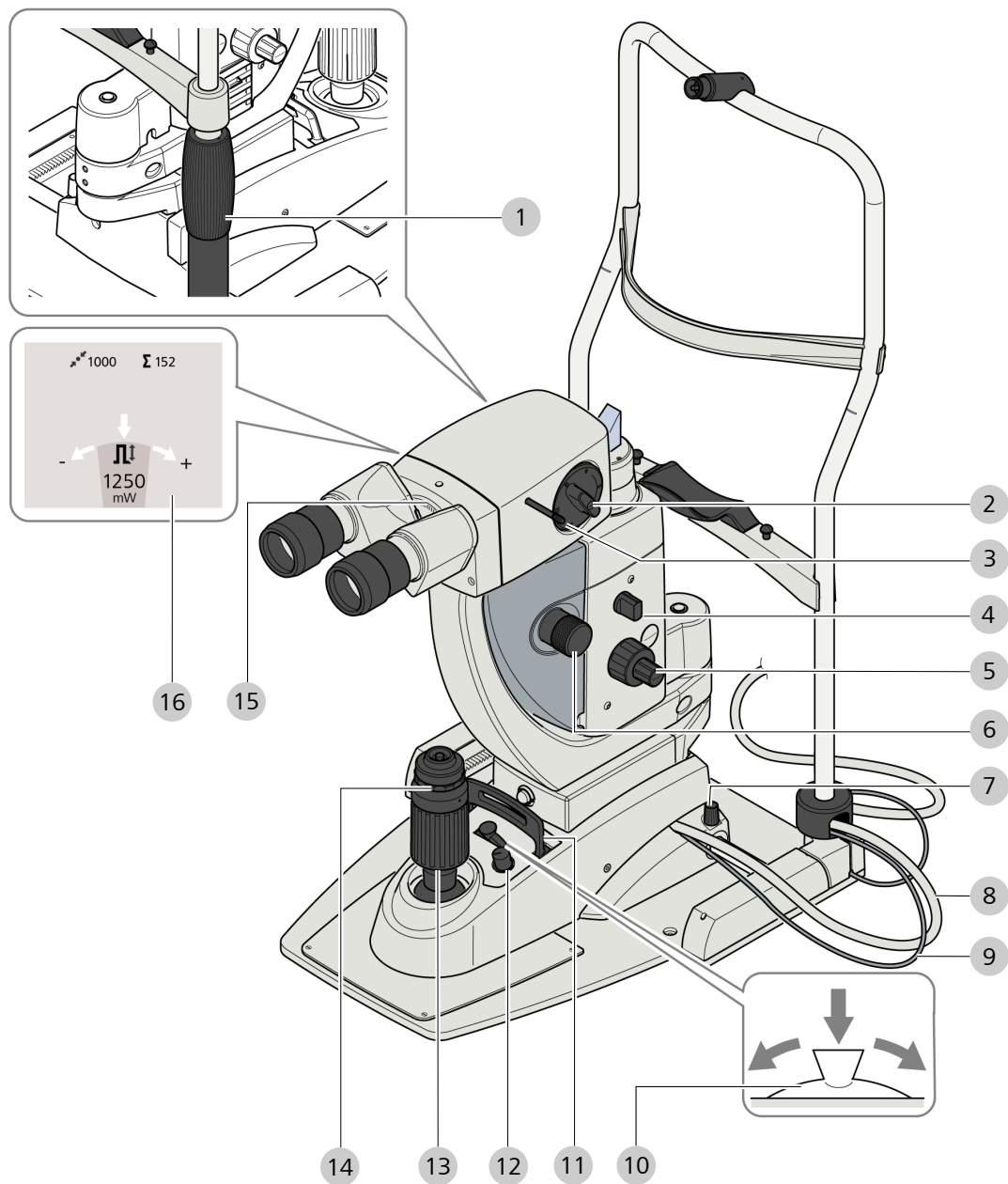


Figure 13: Control elements on the LSL green comfort laser slit lamp

Item	Name	Explanation
1	Height adjustment for chin rest	The optimum eye level for the patient can be set by turning the height adjustment of the chin rest.
2	Magnification changer	The magnification can be set in 5 stages using the magnification changer.
3	Left / right adjustment for LSL InsightView display	Slide bar for changing eyes for the LSL InsightView display.

Item	Name	Explanation
4	Filter selector	White line pointing up: Full aperture combined with a heat-absorbing filter. White line to the patient: Blue filter for tonometry and fluorescence observations. White line to the physician: Green filter for examining the fundus.
5	Adjustment knob for slit height / width	The slit height can be set to 1/3/5/9/14 mm and to special slit positions ($0^\circ/\pm 45^\circ/\pm 90^\circ$). The slit width can be continuously adjusted from 0 mm to 14 mm.
6	Laser spot size control knob	Control knob for setting the laser spot size
7	Locking screw for instrument base	Locking screw for securing the instrument base at the desired position
8	Laser slit lamp connecting cable	The plug on this cable is inserted into the fiber optic port for LSL on the laser console.
9	Fixation lamp connecting cable	This cable connects the fixation lamp with the instrument base.
10	TouchControl LSL center switch	Rocker for selection and adjustment of parameters (see LSL InsightView display and TouchControl LSL center switch [► 45]).
11	Fast-action base lock	Lever tilted towards the patient: The base is locked. Lever tilted towards the physician: The base can be moved freely. XY coarse adjustment is achieved by moving the complete instrument base.
12	Brightness control	Brightness control for slit illumination
13	Joystick with manual trigger	XY fine adjustment is performed by tilting the joystick. The Z adjustment is made by rotating the joystick. The system has a manual trigger for laser beam control. By operating the manual trigger, the laser radiation can be applied to the patient's eye. The treatment can be interrupted by releasing the manual trigger.
14	Electronic micromanipulator with locking ring	The electronic micromanipulator is used to make fine adjustments to the slit image and laser spot jointly while the locking ring is released.
15	Scale bar	Interpupillary distance scale
16	LSL InsightView display	Display for data projection of treatment parameters

3.4.3.1 LSL InsightView display and TouchControl LSL center switch

In the LSL green comfort laser slit lamp, the current parameter values can be seen on the integral LSL InsightView display in the observer's field of vision. The parameter values can thus be adjusted with the TouchControl LSL center switch during treatment.

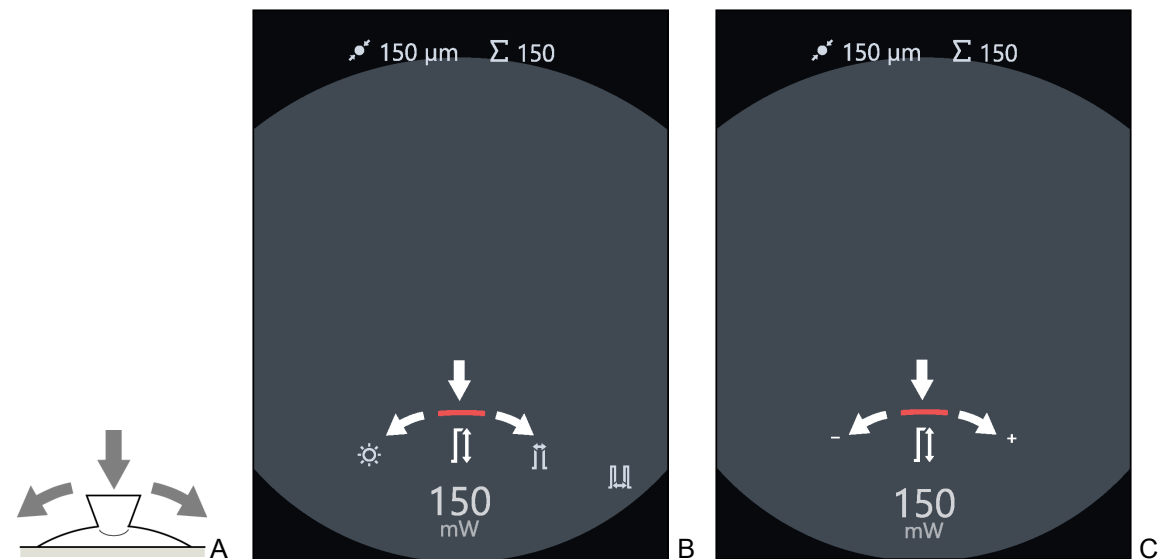












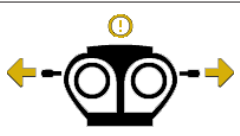



Figure 14: TouchControl LSL center switch (A), selection of a parameter (B) and modification of a parameter (C)

Icon/Name	Explanation	
	No parameter activated.	A parameter has been activated.
 Press towards the left	Switch to the next parameter anticlockwise.	Value of the activated parameter is reduced.
 Press towards the right	Switch to the next parameter clockwise.	Value of the activated parameter is increased.
 Press downwards	The selected parameter is activated.	The parameter is deactivated.
	Display of set laser spot size (only for photocoagulation)	
	Display of the number of hitherto triggered laser spots or number of lesions (depending on activated laser mode)	

Icon/Name	Explanation
Adjustable parameters	
	Laser power / laser energy (depending on activated laser mode)
	Pulse duration (only for photocoagulation)
	Pause between laser pulses (only for photocoagulation)
	YAG pulse mode (only with activated YAG and / or VOLANTE software licenses)
	Rotation of the multi-spot sequence (only with activated VITE license software)
	Brightness of the LSL InsightView display
	Brightness of the aiming beam
	The LSL InsightView display is being moved from one observation channel (e.g. for left eye) to the other observation channel (e.g. for right eye). Slide the display all the way to the stop.
	A message or error message is displayed on the TouchControl panel that requires confirmation or action by the user.

3.4.3.2 Brightness control

The laser slit lamp has a rotary knob controller that controls the brightness of the slit illumination. If the controller is turned clockwise, the brightness of the slit illumination increases (logarithmic control). If the control is turned counterclockwise, the brightness of the slit illumination is reduced. The brightness is represented by the thickness of the marking line of the rotary knob.

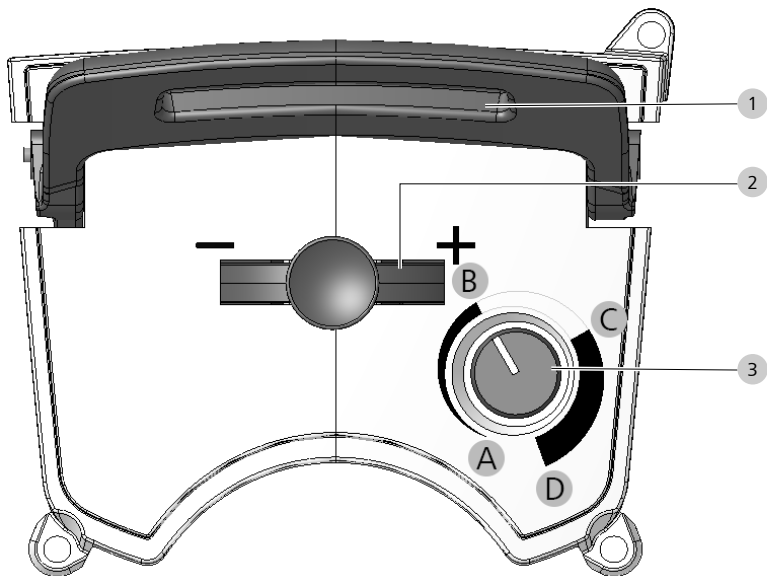


Figure 15: Quick-action lock, TouchControl center switch and brightness control for adjusting the slit lamp illumination

Item	Name	Explanation
1	Fast-action base lock	Lever tilted towards the patient: The base is locked. Lever tilted towards the physician: The base can be moved freely. X/Y coarse adjustment is achieved by moving the complete instrument base.
2	TouchControl LSL center switch	Rocker for selection and adjustment of parameters.

Item	Name	Explanation
3	Brightness control	<p>The marking of the rotary knob controller has several setting ranges:</p> <ul style="list-style-type: none">■ Controller position A: slit lamp illumination is switched off (dark position)■ Controller position B: maximum possible brightness level for slit lamp examination of the aphakic eye for more than 30 minutes (without filter swiveled in)■ Controller position C: 50 % position of maximum possible brightness level■ Controller position D: maximum brightness of slit lamp illumination

3.4.4 LSL green classic laser slit lamp

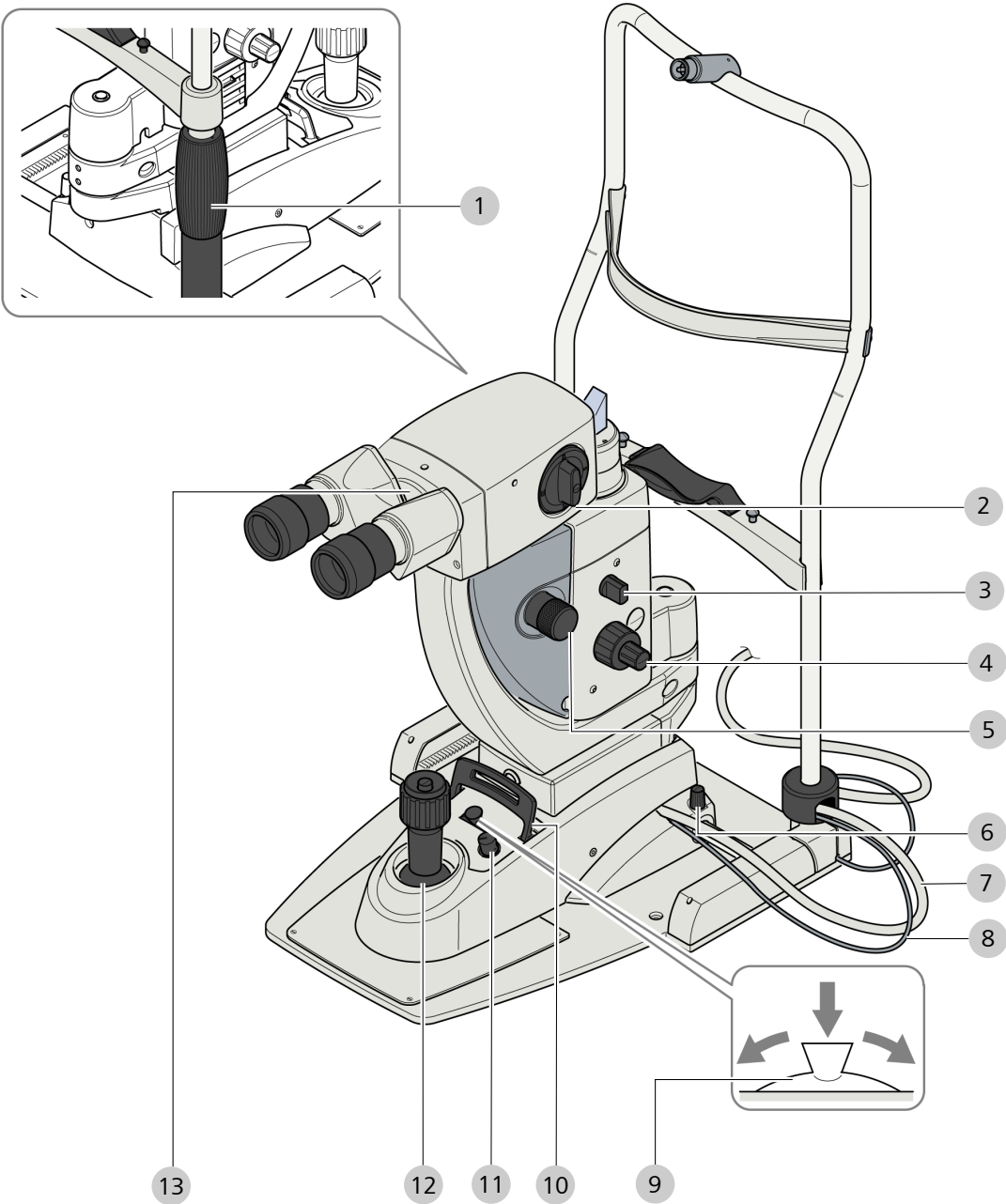


Figure 16: Control elements on the LSL green classic laser slit lamp

Item	Name	Explanation
1	Height adjustment for chin rest	The optimum eye level for the patient can be set by turning the height adjustment of the chin rest.
2	Magnification changer	The magnification can be set in 3 stages using the magnification changer.

Item	Name	Explanation
3	Filter selector	White line pointing up: full opening White line to the patient: Blue filter for tonometry and fluorescence observations. White line to the physician: Green filter for examining the fundus.
4	Adjustment knob for slit height / width	The slit height can be set to 1/3/5/9/14 mm and to special slit positions ($0^\circ/\pm 45^\circ/\pm 90^\circ$). The slit width can be continuously adjusted from 0 to 14 mm.
5	Laser spot size control knob	Control knob for setting the laser spot size
6	Locking screw for instrument base	Locking screw for securing the instrument base at the desired position
7	Laser slit lamp connecting cable	The plug on this cable is inserted into the fiber optic port for LSL on the laser console.
8	Fixation lamp connecting cable	This cable connects the fixation lamp with the instrument base.
9	TouchControl LSL center switch	Rocker for selection and adjustment of parameters (see LSL InsightView display and TouchControl LSL center switch [► 45]).
10	Fast-action base lock	Lever tilted towards the patient: The base is locked. Lever tilted towards the physician: The base can be moved freely. XY coarse adjustment is achieved by moving the complete instrument base.
11	Brightness control	Brightness control for slit illumination
12	Joystick with manual trigger	XY fine adjustment is performed by tilting the joystick. The Z adjustment is made by rotating the joystick. The system has a manual trigger for laser beam control. By operating the manual trigger, the laser radiation can be applied to the patient's eye. The treatment can be interrupted by releasing the manual trigger.
13	Scale bar	Interpupillary distance scale

3.4.4.1 LSL InsightView display and TouchControl LSL center switch

See LSL InsightView display and TouchControl LSL center switch [► 45].

3.4.4.2 Brightness control

See Brightness control [► 47].

3.4.5 LIO VISULAS green

3.4.5.1 Head strap

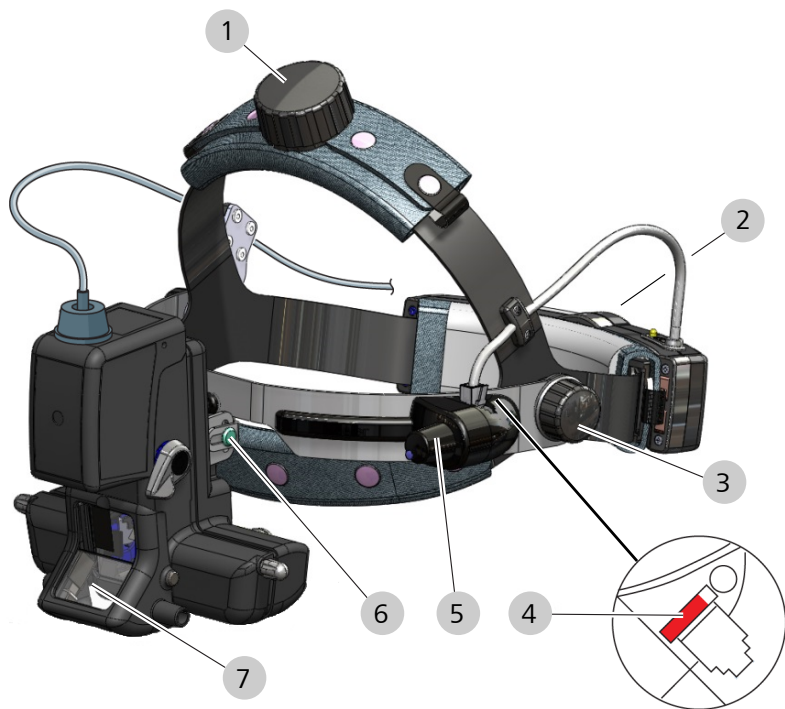


Figure 17: Control elements on the head strap

Item	Name	Explanation
1	Knob for adjusting the head strap height	Used to securely fix the device to the head
2	Knob for adjusting the head strap size	Used to securely fix the device to the head
3	Clamp for the binocular component support	With the clamp loosened, the height of the support for binocular component can be adjusted.
4	Red slider	Make sure that the slider is always in the indicated position.
5	Brightness setting knob for LED	Turning the knob clockwise switches on the LED illumination and sets the desired brightness.
6	Clamp for binocular component	With the clamp loosened, the height and tilt of the binocular component can be adjusted.
7	Laser decoupling mirror	Laser exit aperture and optical filter

3.4.5.2 Binocular body

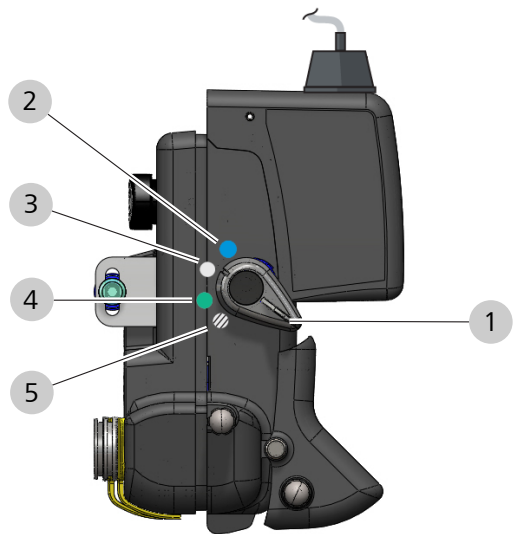






Figure 18: Binocular component - side view

Item	Icon	Name	Explanation
1		Filter selection lever	Filter selection lever to select a suitable filter
2		Cobalt blue filter	For fluorescein angiography
3		No filter	For observation in bright white illumination
4		Red-free filter	Reduces red light so that blood appears black and stands out against the dark background
5		Diffuser	The extra-wide diffuse light beam allows relaxed working during difficult fundus examinations. This setting is helpful for beginners because the alignment between the head strap, lens and pupil to produce a complete lens image is not as critical as with a normal light beam.

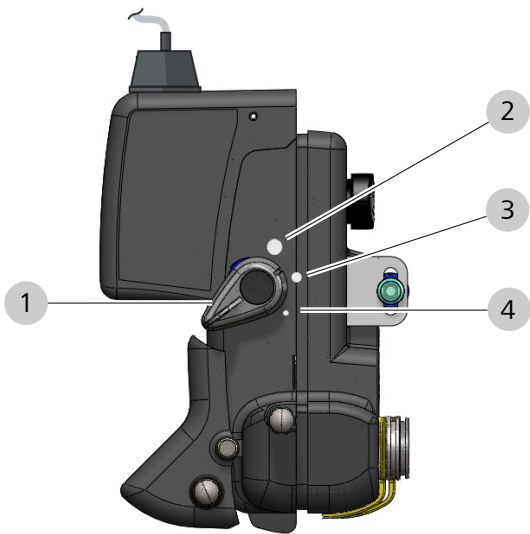





Figure 19: Binocular component - side view

Item	Icon	Name	Explanation
1		Aperture selection lever	Aperture selection lever to select the aperture
2		Large aperture	A large, round, and homogeneous spot for routine examination under complete mydriasis. In this position, the mirror remains in the anterior position and the optics diverge.
3		Intermediate aperture	The intermediate image reduces reflections when the pupil is only partially dilated or poorly dilated (3 mm). It is also particularly suitable for closer observation of certain fundus areas. The mirror and optics remain in the center position.
4		Small aperture	This light spot is ideal for small and undilated pupils. The mirror moves to the rear, the optics converge automatically.

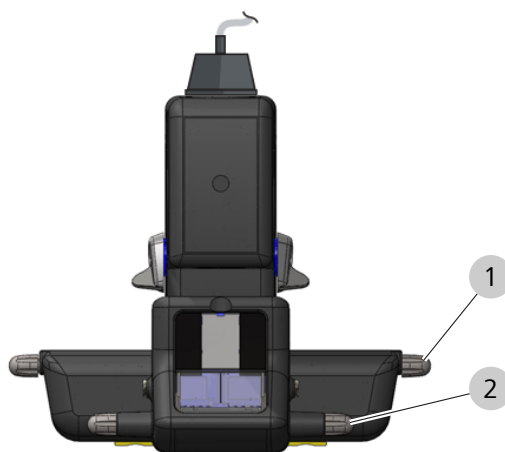


Figure 20: Binocular component - patient side

Item	Name	Explanation
1	Illumination setting	The brightness of the light spot can be raised or lowered using the illumination setting. The illumination setting has a wider adjustment range than the laser control, so the laser should be adjusted first and then the overlaying illumination.
2	Laser angle setting	The projection angle of the laser beam can be adjusted using the swiveling mirror on the front.

3.4.5.3 Charging status displays



Figure 21: Battery in head strap

Item	Icon	Name	Explanation
1		Status display for the battery in head strap	<ul style="list-style-type: none">■ Lights up yellow: Battery charged■ Flashing yellow: Battery must be charged.■ Does not light up: Battery is empty, or no battery inserted

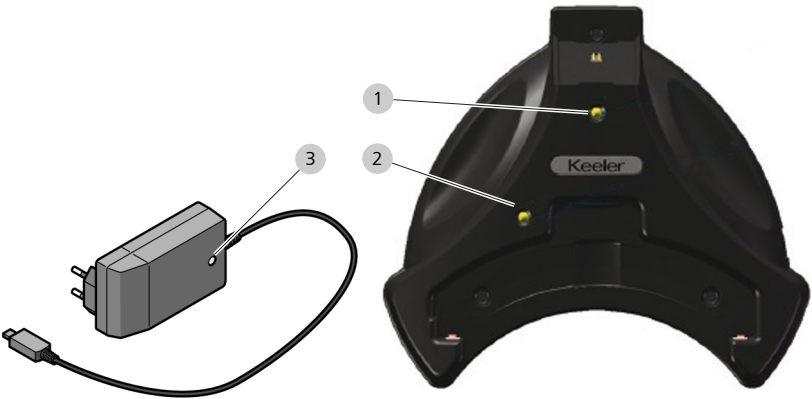


Figure 22: Charging station

Item	Name	Explanation
1	Charging status display (LED) for spare battery	<ul style="list-style-type: none">■ Lights up yellow: Battery is being charged■ Flashing yellow: Battery is nearly charged■ Does not light up: Battery is charged
2	Charging status display (LED) battery in head strap	
3	Status display (LED) for power supply unit	Lights up green if power supply unit is connected to power supply.

3.4.6 Standard foot switch

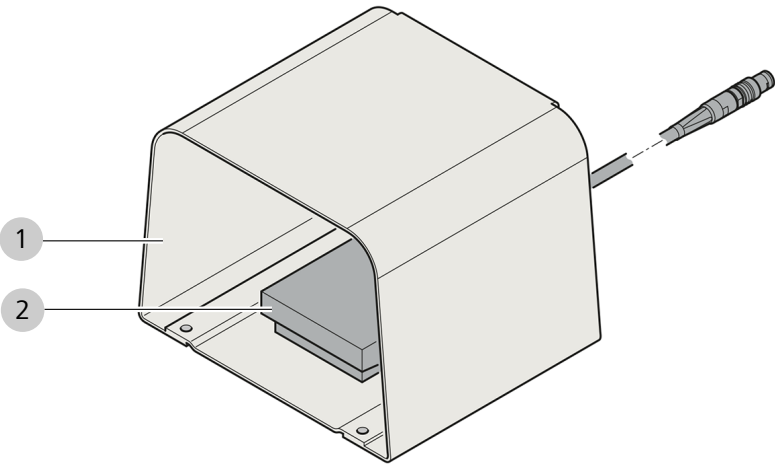


Figure 23: Standard foot switch

Item	Name	Explanation
1	Protective cover	
2	Trigger	Depending on the setting, pressing the trigger will emit one or more laser pulses which are applied to the patient's eye. The desired parameters must have been set previously using the control panel / TouchControl LSL center switch.

The standard foot switch can be placed separately on the floor next to the instrument table or attached to the foot of the instrument table.

3.4.7 TouchControl foot switch

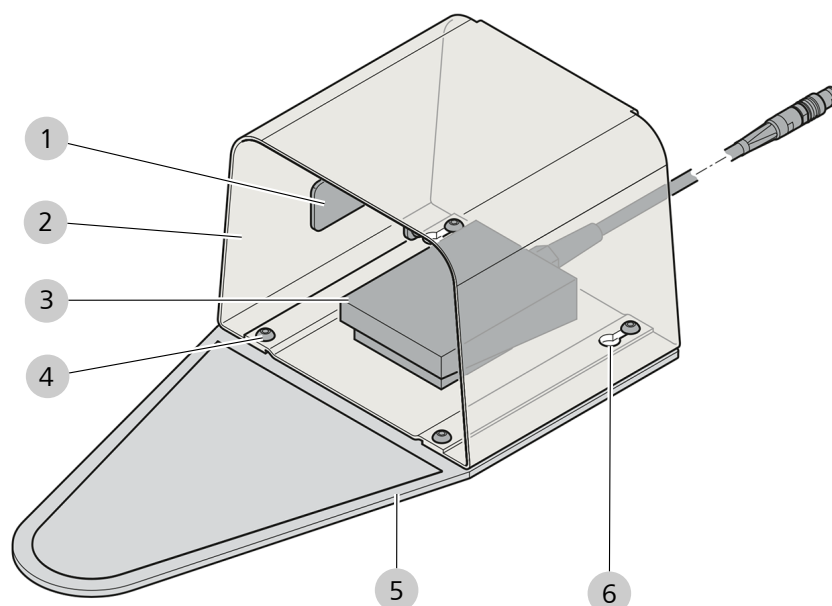


Figure 24: TouchControl foot switch

Item	Name	Explanation
1	Lever for changing parameters	This lever is used for changing the values of the selected parameter. Tapping the left side of the lever reduces the parameter value; tapping the right side of the lever increases the parameter value.
2	Protective cover	
3	Trigger	Depending on the setting, pressing the trigger will emit one or more laser pulses which are applied to the patient's eye. The desired parameters must have been previously set with the parameter changing lever or on the control panel / TouchControl LSL center switch.
4	Front screws	Front screws for fastening the foot switch to the base plate.
5	Non-slip base	The non-slip base prevents the foot switch from slipping while operated.
6	Rear screws to fix the foot switch on the base	Rear screws for fastening the foot switch to the base plate.

The TouchControl foot switch can be placed separately on the floor beside the instrument table or mounted on the foot of the instrument table.

3.5 Functional description

3.5.1 Green laser for photocoagulation

Pumped by a diode laser at 810 nm, a laser beam with a wavelength of 1064 nm, the frequency of which is doubled by means of a non-linear crystal, is produced in a Nd:YVO₄ solid state medium. The wavelength is thus halved to 532 nm. This green laser beam is coaxially superimposed with the red aiming beam and provided on the fiber output or on one of the two fiber outputs. With an optical fiber, the two laser beams are guided to the applicator (e.g. laser slit lamp or indirect ophthalmoscope).

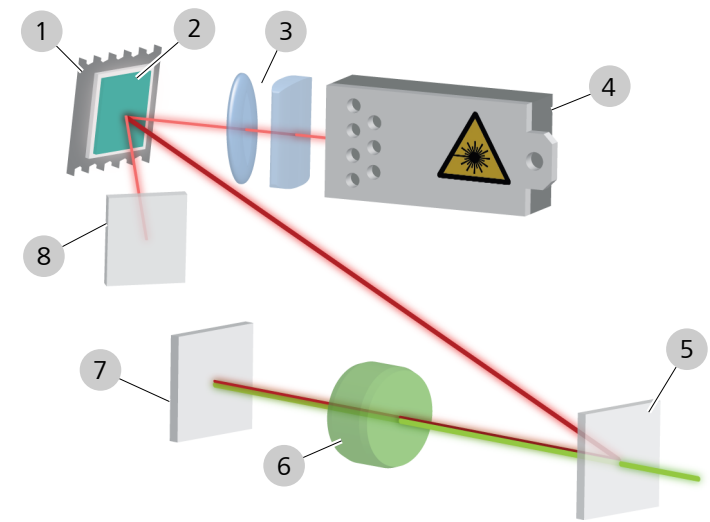


Figure 25: Generation of laser beam with a wavelength of $\lambda = 532\text{ nm}$ [1]
[► 153]

1	Heat sink	2	Laser medium: Nd:YVO ₄ disk
3	Coupling lens	4	Pump source: diode laser
5	Decoupling mirror	6	Frequency doubling: non-linear optical crystal
7	End mirror	8	End mirror of pump resonator

3.5.2 LSL green comfort / classic laser slit lamp

The laser beam is superimposed upon the slit illumination beam path so that the laser spot is coincident with the slit image on the fundus at all times. This ensures that the area of the fundus which is to be coagulated is always illuminated, even in the peripheral fundus. This means of combining illumination and laser beams is particularly advantageous for small illumination fields.

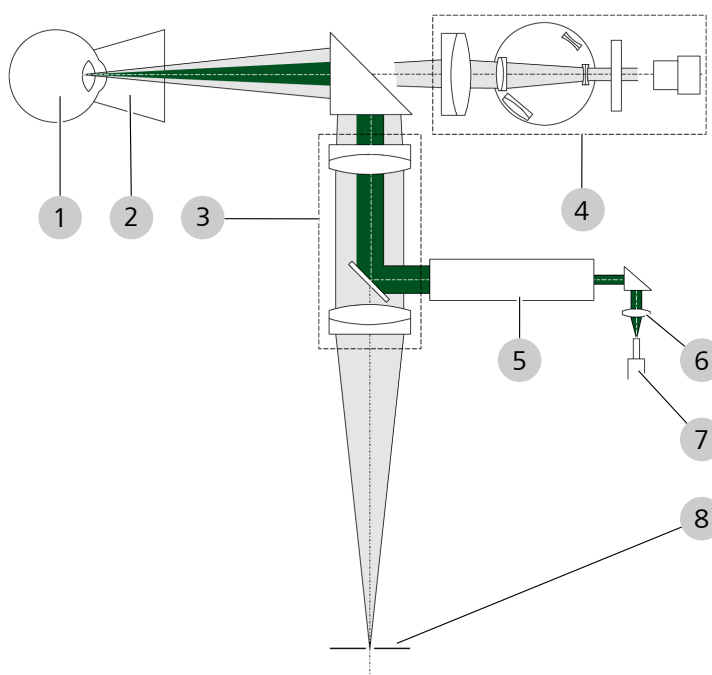


Figure 26: Beam delivery in the LSL green laser slit lamp

1	Patient's eye	2	Contact lens
3	Optical system for slit lamp and laser spot visualization	4	Microscope
5	Laser beam expander	6	Coupling lens
7	Optical fiber	8	Slit illumination system

3.5.3 LIO VISULAS green

The LIO VISULAS green laser indirect ophthalmoscope is intended for connection to the laser consoles of the VISULAS green and VISULAS combi. An optical system projects an aiming and treatment laser beam from the laser via an optical fiber cable. The user can set the projection angle of the laser by approx. ± 3 degrees. The illumination pattern can be set separately.

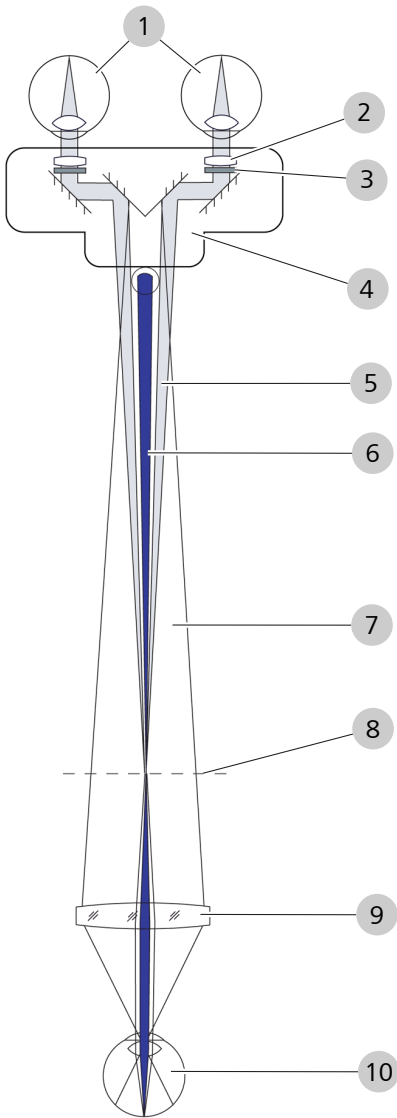


Figure 27: LIO VISULAS green beam delivery

1	Physician's eye	2	Lens +2 D
3	Physician's safety filter	4	Binocular component
5	Observation beam path	6	Laser beam path
7	Illumination beam path	8	Intermediate image plane and laser beam waist
9	Aspheric lens 20 D	10	Patient's eye

The binocular component allows stereoscopic observation of the fundus of the patient's eye. It is equipped with +2 D lenses to help physicians accommodate. These lenses can be replaced by glass lenses with a refractive power of 0 D.

The laser beam is transferred to the laser indirect ophthalmoscope using an optical fiber and will be coupled directly into the illumination beam path. The observation beam path, illumination beam path and laser beam path are coaxial.

The physician observes the reverse intermediate image generated by the aspheric lens 20 D through the eyepieces of the binocular component. The smallest laser spot diameter can be achieved by selecting a working distance at which the focus ("waist") of the laser beam is located on the intermediate image plane.

The aspheric lens 20 D focuses the light source of the illumination equipment onto the iris of the patient's eye. Using a 20 D aspheric lens produces an overall magnification of the system of approx. 2x.

3.5.4 Endoprobes

It is recommended to use VISULAS with ZEISS laser endoprobes as the efficacy and safety of this combination has been demonstrated. As a rule, VISULAS can also be used with commercial laser endoprobes which have been approved for intraocular treatment. Carl Zeiss Meditec accepts no liability for the use of third party laser endoprobes. When using the third-party endoprobes, please observe the specification in the technical data [► 129].

Light transmission of laser endoprobes may vary from supplier to supplier. If you change your laser endoprobe supplier, make sure that your local ZEISS service engineer measures and stores the transmission of the new laser endoprobe in the system. Only then will the proper output power be indicated on the graphical user interface of the control panel.

When using laser endoprobes, observe the user manual for the respective laser endoprobe.

4 Description of VISULAS yag

4.1 Package check list

4.1.1 Software licenses, accessories and options

Depending on the selected configuration of the VISULAS yag, only certain software licenses, accessories and options are clinically useful or technically possible. The following table shows the logical combination of laser applicators with usable licenses, accessories and options:

	LSL yag
Software licenses	
VERTE	
VITE	
SLT	
YAG	X
VOLANTE	X
LASER REPORT	X
Accessories / options	
IT.i instrument tables	X
SL Imaging Solution	X
AT 030 tonometer	X
Physician's safety filter for OPMI	
ACCENTO ergo tube	X
Foot switch	X
Laser warning light	X
Panel PC	X
Co-observation tube	X
VISUCONNECT	X

Table 2: Overview of usable software licenses, accessories and options with VISULAS yag








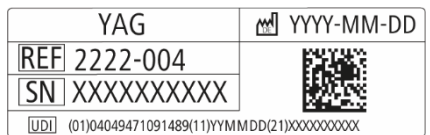




4.1.2 Device configuration for VISULAS yag with laser slit lamp




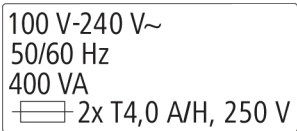


- VISULAS yag (laser console and control panel)
- LSL yag laser slit lamp
- Foot switch (optional)
- Parallel or convergent tube $f = 140 \text{ mm}$
- 2 eyepieces 10x
- Armrest (height-adjustable)
- Dust cover
- Fixation lamp
- Power supply cable (2.5 m)
- Documentation set
- Laser safety goggles

4.2 External labels





4.2.1 VISULAS yag laser console

The label texts on the SL Imaging Solution, AT 030 and instrument tables are described in the corresponding instructions for use.











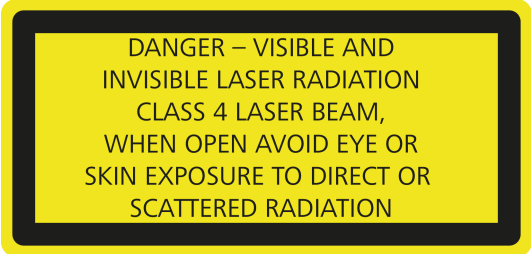
Labels	Explanation
	VISULAS type label
	 Manufacturer
	 Type B applied part
	IP20 Protected against harmful solid foreign objects of 12.5 mm in diameter and greater; Non-protected against harmful ingress of water
	CE approval label and disposal advice for EU
	 Indicates that the product is in compliance with European legislation for medical devices, with identification number of notified body
	 Separate collection for electrical and electronic equipment
	Marking the device as a medical device
	 Medical device
	Laser Class 4 warning label
	 Warning; Laser beam
	Laser console identification label
	 Catalog number
	 Serial number
	 Date of manufacture / Country of manufacture
	 Unique device identifier

Labels	Explanation
	Information label with serial number and model name
	Disconnect mains plug from electrical outlet
	Follow instructions for use
	Electrical specifications
	 Fuse
	 Alternating current







Control panel (TouchControl panel)

Labels	Explanation
	Identification label
	 Catalog number
	 Serial number
	 Identification code

4.2.2 LSL yag laser slit lamp

Icon	Name
	Type label
	 Manufacturer
	 Type B applied part
	 Separate collection for electrical and electronic equipment
	Identification label
	 Catalog number
	 Serial number
	 Identification code
	Warning; Optical radiation
	Laser aperture
	Laser Class 4 warning label

4.2.3 Foot switch

Labels	Explanation
 <p>Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany</p>	Type label
<p>Standard foot switch</p> <p>REF 2209-639 SN XXXXX</p> <p> IPX8</p> <p>000000-2214-455-Vs07</p>	 Manufacturer
<p>Standard</p>	<p>IPX8 Protected against the effects of continuous immersion in water</p>
<p>TouchControl foot switch</p> <p>REF 2202-530 SN XXXXX</p> <p> IPX8</p> <p>000000-2214-456-Vs07</p>	 Separate collection for electrical and electronic equipment
<p>TouchControl</p>	<p>REF Catalog number</p>
	<p>SN Serial number</p>
	 Identification code

4.3 Device configuration

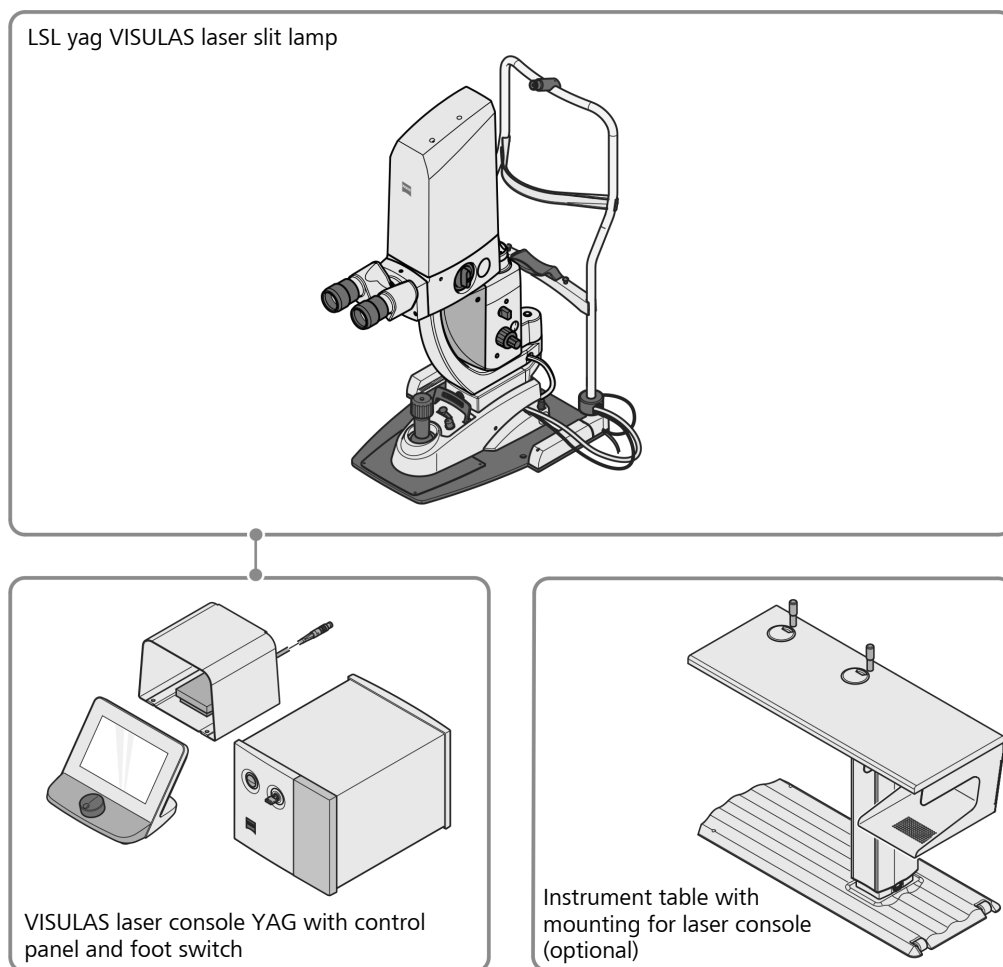


Figure 28: Device configuration

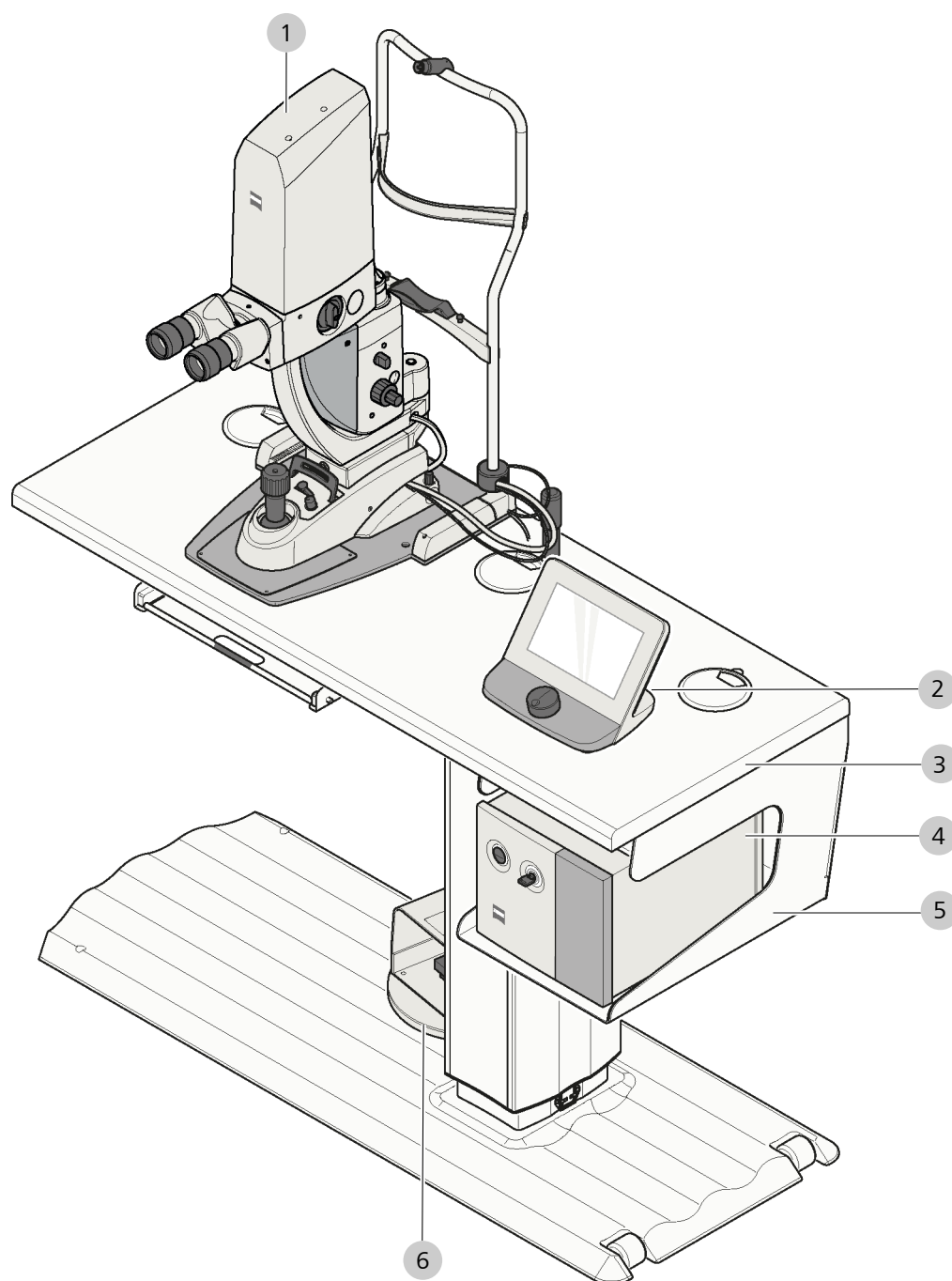


Figure 29: VISULAS yag system overview

1	Laser slit lamp	2	Control panel
3	Instrument table	4	Laser console
5	Table mounting for laser console	6	Foot switch

4.3.1 LSL yag laser slit lamp

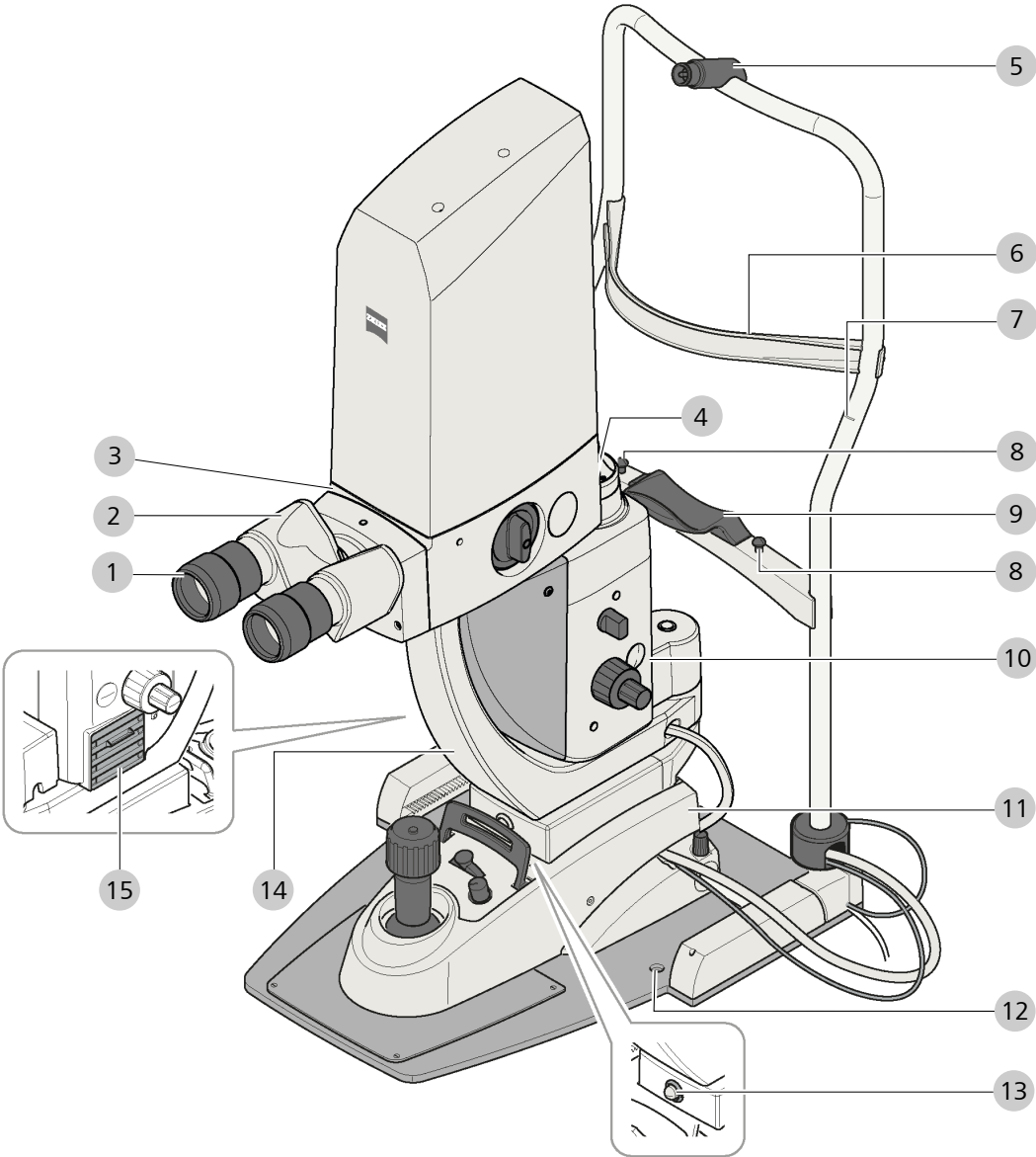


Figure 30: LSL yag laser slit lamp

1	Eyepiece with adjustable eye cup	2	Binocular tube
3	Microscope stand with fixed physician's safety filter	4	Prism head, illumination and laser exit aperture
5	Fixation lamp and YAG laser warning lamp mounting	6	Forehead rest (applied part)
7	Markings for setting the optimum eye level for the patient	8	Fastening pins for paper pads
9	Chin rest (applied part)	10	Slit lamp housing
11	Instrument base	12	Mounting holes

13	Physician's detection sensor (infra-red movement sensor)	14	Slit lamp swivel arm
15	Cover for illumination unit		

4.4 Controls, display elements and connectors

4.4.1 YAG laser console

The laser console is the central power supply and control unit for the VISULAS yag.

In contrast to the other VISULAS models, the VISULAS laser console YAG has no fiber optic connections and can therefore only be combined with the LSL yag laser slit lamp.

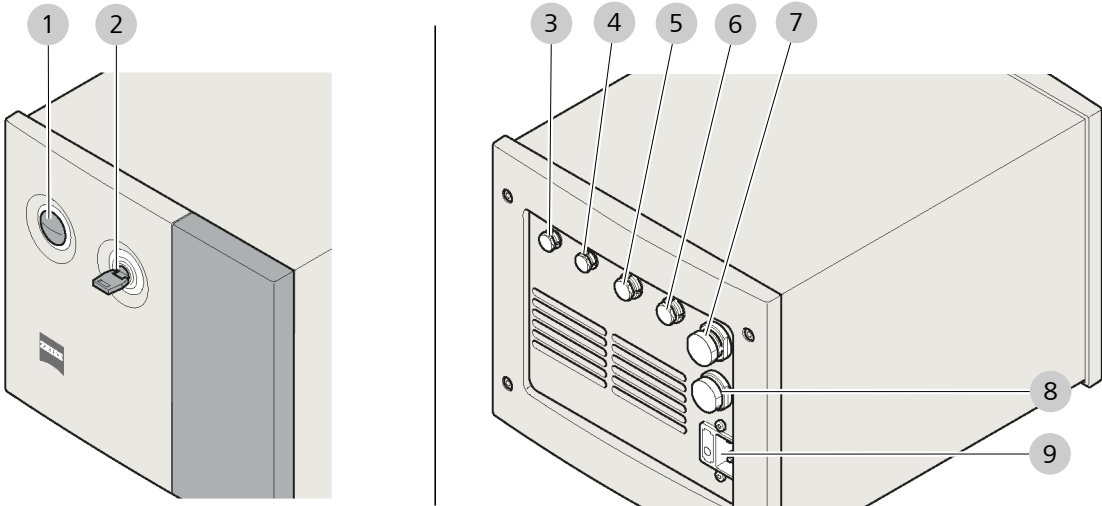



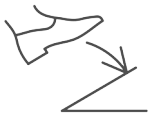




Figure 31: Controls, displays and connectors on the VISULAS yag laser console

Item	Icon / Name	Explanation
1	<div>STOP</div> 	Intended for immediate deactivation of the laser beam (lights up when laser stop switch is enabled). The laser stop switch interrupts the laser radiation to prevent hazards to persons. The laser stop switch is structurally independent of all of the other laser shutdown systems. When the laser stop switch is pressed, the system switches to the "Prepare" work step and all functions on the control unit are locked. To resume operation, press the laser stop switch again.
2	Key switch	The system features a key switch for the laser console. No laser radiation is emitted when the key is in the off position. The key can be removed.
3	<div>Interlock</div> 	Connector for door contact and external laser warning lamp. When the contacts of the plug connector are opened, laser emission is interrupted. As delivered, a short-circuit plug is plugged into the plug connector. Note that using the remote lock increases the probability of interrupting the laser treatment.

Item	Icon / Name	Explanation
4	<p>Services</p> 	Interface for Services and VISUCONNECT 600 data transfer adapter
5	<p>Foot switch</p> 	Connection to foot switch
6	<p>Display</p> 	Connector for control panel
7	<p>Slit lamp</p> 	Slit lamp connector
8	<p>YAG</p>	Connector for YAG HV power supply
9		Power input with fuse compartment

4.4.2 Control panel (TouchControl panel)

See Control panel (TouchControl panel) [► 40].

4.4.3 LSL yag laser slit lamp

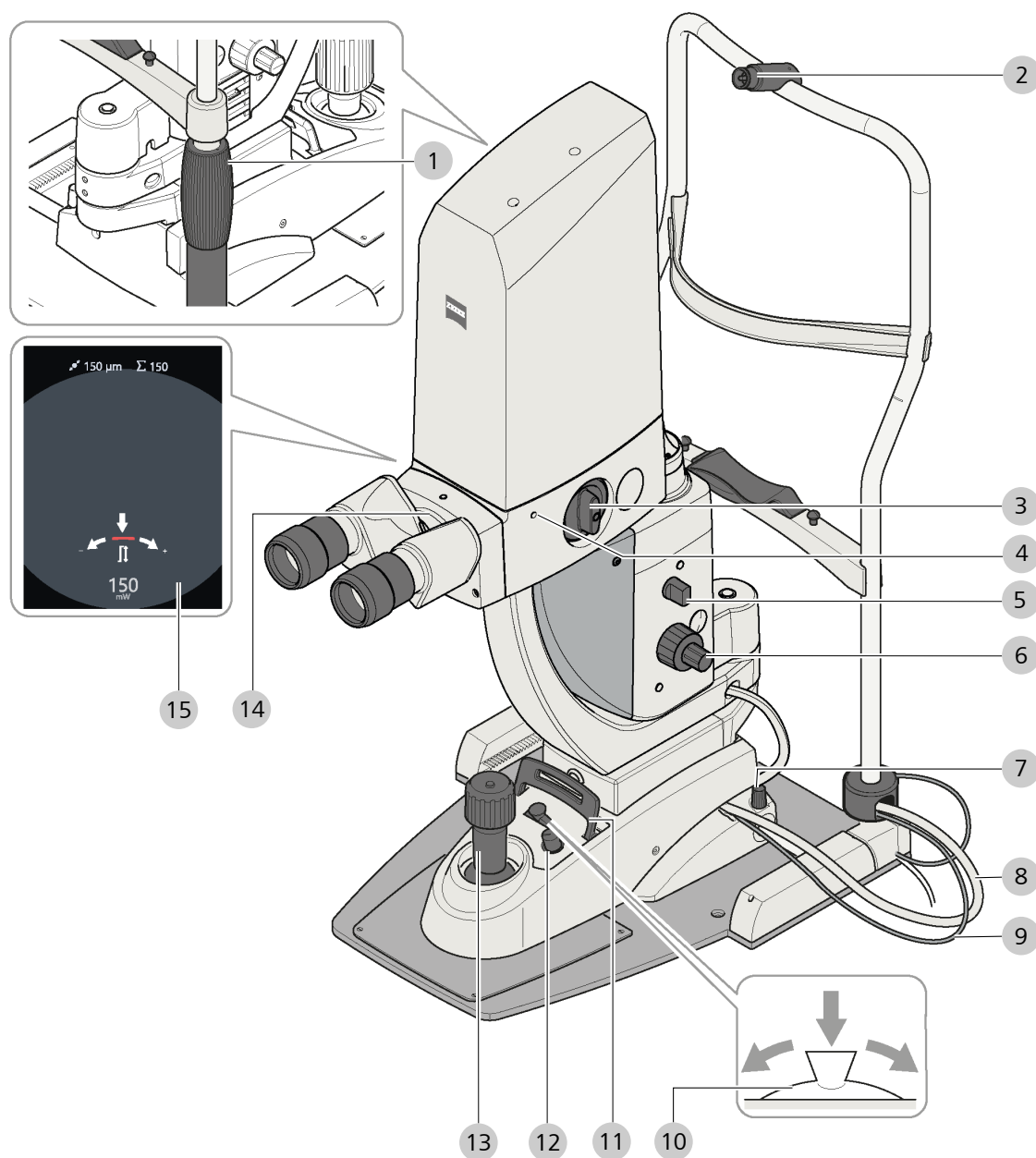


Figure 32: Control elements on the LSL yag laser slit lamp

Item	Name	Explanation
1	Height adjustment for chin rest	The optimum eye level for the patient can be set by turning the height adjustment of the chin rest.
2	Fixation lamp and YAG laser warning lamp mounting	The YAG laser warning lamp lights up red when the high-voltage supply to the YAG laser source is ready.
3	Magnification changer	The magnification can be set in 3 stages using the magnification changer.

Item	Name	Explanation
4	Left / right adjustment for LSL InsightView display (optional)	Slide bar for changing eyes for the LSL InsightView display.
5	Filter selector	White line pointing up: full opening White line to the patient: Blue filter for tonometry and fluorescence observations. White line to the physician: Green filter for examining the fundus.
6	Adjustment knob for slit height / width	The slit height can be set to 1/3/5/9/14 mm and to special slit positions ($0^\circ/\pm 45^\circ/\pm 90^\circ$). The slit width can be continuously adjusted from 0 to 14 mm.
7	Locking screw for instrument base	Locking screw for securing the instrument base at the desired position.
8	Laser slit lamp connecting cable	The plug on this cable is inserted into the fiber optic port for LSL on the laser console.
9	Fixation lamp connecting cable	This cable connects the fixation lamp with the instrument base.
10	TouchControl LSL center switch	Rocker for selection and adjustment of parameters (see LSL InsightView display and TouchControl LSL center switch [► 45]).
11	Fast-action base lock	Lever tilted towards the patient: The base is locked. Lever tilted towards the physician: The base can be moved freely. XY coarse adjustment is achieved by moving the complete instrument base.
12	Brightness control	Brightness control for slit illumination
13	Joystick with manual trigger	XY fine adjustment is performed by tilting the joystick. The Z adjustment is made by rotating the joystick. The system has a manual trigger for laser beam control. By operating the manual trigger, the laser radiation can be applied to the patient's eye.
14	Scale bar	Interpupillary distance scale
15	LSL InsightView display (optional)	Display for data projection of treatment parameters If your VISULAS yag system has been equipped with the LSL InsightView Display option (head-up display for the laser slit lamp), refer to LSL InsightView display and TouchControl LSL center switch [► 45] for more information on the icons shown in the display.

4.4.3.1 LSL InsightView display and TouchControl LSL center switch

See LSL InsightView display and TouchControl LSL center switch [► 45].

4.4.3.2 Brightness control

See Brightness control [► 47].

4.4.4 Standard foot switch

See Standard foot switch [► 57].

4.4.5 TouchControl foot switch

See TouchControl foot switch [► 58].

4.5 Functional description

4.5.1 Infrared laser for photodisruption

The VISULAS yag is an ophthalmic therapy laser system for non-contact incision of ocular tissue. The radiation is generated by a Q-switched Nd:YAG laser, which emits pulses of typically < 4 ns duration and a maximum energy of approximately 10 mJ at a wavelength of 1,064 nm. To effectively achieve higher laser energies, the laser must be switched from YAG pulse mode 1 to YAG pulse modes 2 or 3. In this case, 2 (YAG pulse mode 2) or 3 (YAG pulse mode 3) short pulses are emitted at very short intervals (in the range of 50 µs). The total duration of the pulse sequence is shorter than typical heat diffusion times in ocular tissue, allowing effective laser pulse energies of up to 45 mJ to be achieved.

At the focus of the laser beam, a plasma is created which is at a high pressure and temperature, but is spatially confined. This phenomenon is termed optical breakdown or photodisruption. The plasma expands, thereby cooling rapidly, resulting in no thermal effect on the tissue. However, the mechanical stress due to the shock wave accompanying the expansion of the plasma results in an incisional effect.

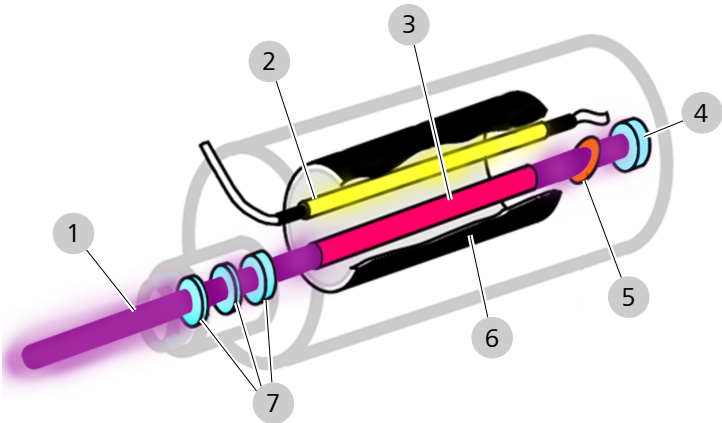


Figure 33: Structure of the Q-switched Nd:YAG laser for the generation of 1064 nm laser radiation

1	1064 nm YAG laser beam	2	Flash lamp (pumping source)
3	Nd:YAG laser crystal	4	Imaging optics
5	Saturating absorber for passive Q-switching	6	Laser cavity
7	Imaging optics		

4.5.2 LSL yag laser slit lamp

An Nd:YAG laser (1) generates the therapy beam. The beam passes through the energy attenuator (5), is then combined with the aiming beam (6) and coupled into the observation path of the microscope by means of a coupling mirror (11). The prism head of the slit illumination (13) is lowered by 10°. The optical components (2) can be used to adjust the axial offset between the aiming beam focus and the therapy beam focus.

NOTE! In the central illumination position, a small part of the therapy beam is clipped.

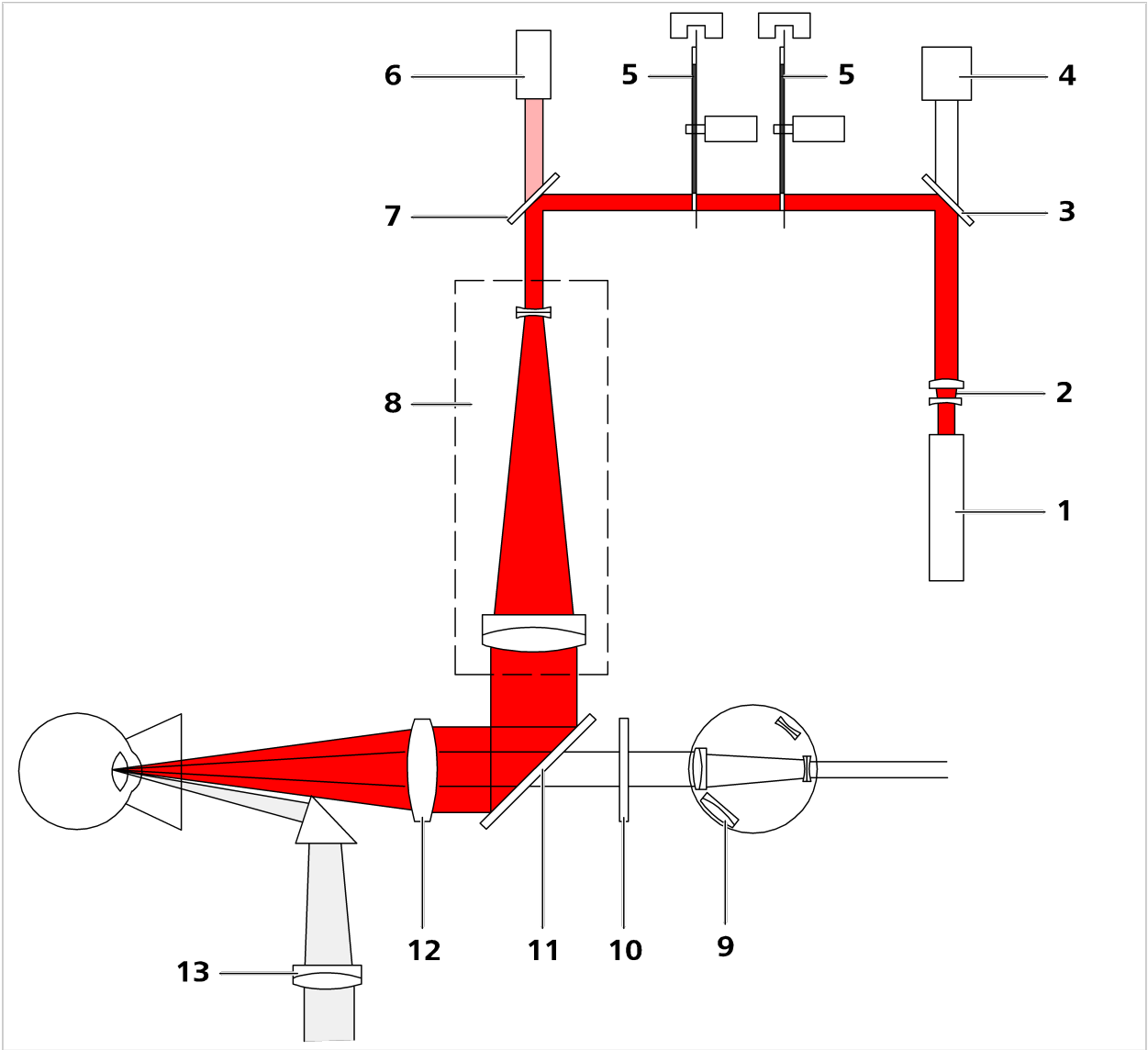


Figure 34: LSL yag beam delivery

1	Nd:YAG laser	2	Motorized focus shift
3	Partially transmitting mirror for energy meter	4	Energy meter and pulse counter
5	Energy attenuator	6	Aiming beam diode laser, switchable between 2-spot and 4-spot

7	Aiming beam coupling mirror	8	Beam expander
9	Galilean magnification changer	10	Physician's safety filter
11	Coupling mirror for coupling the laser beam into the viewing path	12	Slit lamp objective
13	Slit illumination system		

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5 Description of VISULAS combi

5.1 Package check list

5.1.1 Software licenses, accessories and options

Depending on the selected configuration of VISULAS combi, only certain software licenses, accessories and options are clinically useful or technically possible. The following table shows the logical combination of laser applicators with usable licenses, accessories and options:

	LSL green combi	LIO VISULAS green	Endoprobes
Software licenses			
VERTE	X	X	X
VITE	X		
SLT	X		
YAG	X		
VOLANTE	X		
LASER REPORT	X	X	X
Accessories / options			
IT.i instrument tables	X		
SL Imaging Solution	X		
AT 030 tonometer	X		
Physician's safety filter for OPMI*			X
ACCENTO ergo tube	X		
Foot switch	X	X	X
Laser warning light	X	X	X
Panel PC	X		
Co-observation tube	X		
VISUCONNECT	X	X	X

Table 3: Overview of usable software licenses, accessories and options of VISULAS combi depending on the laser applicator used

*Active and passive physician's safety filters are available for popular surgical microscopes from the manufacturers ZEISS, Möller-Wedel, Leica and Wild. If you are using a surgical microscope from another manufacturer, it must be determined whether it provides a compatible interface. Please contact your ZEISS consultant for this.

5.1.2 VISULAS combi device configuration with LSL green combi laser slit lamp

- VISULAS combi (laser console and control panel)
- LSL green combi laser slit lamp
- Fiber optic cable (2.0 m)
- Foot switch (optional for versions "yag / slt" and "yag / green")
- Parallel or convergent tube $f = 140$ mm
- 2 eyepieces 10x
- Arm rest
- Dust cover
- Fixation lamp
- Power supply cable (2.5 m)
- Documentation set
- Laser safety goggles

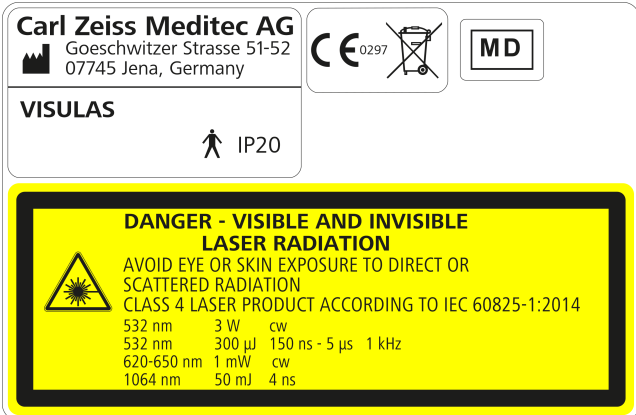






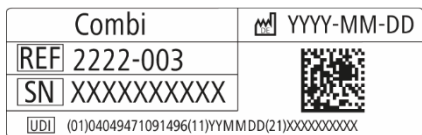




5.1.3 LIO VISULAS green







- LIO VISULAS green laser indirect ophthalmoscope
- Charging dock with power supply unit and connection cable
- Wall mount template for charging dock
- 3 screws and 3 plugs for wall mounting of charging dock
- Aspheric glass lens 20 D type OI-20 for laser applications
- Spare battery
- 2 plane lenses (0 D)
- Cap for fixation lamp mounting
- Documentation set

5.2 External labels






5.2.1 VISULAS combi laser console

The label texts on the SL Imaging Solution, AT 030 and instrument tables are described in the corresponding instructions for use.





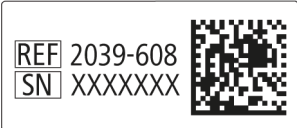





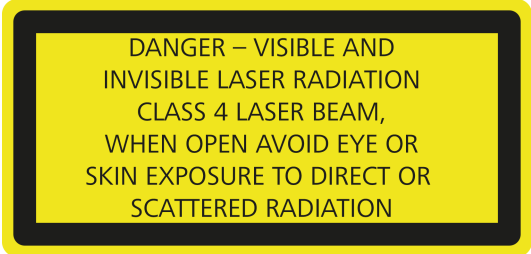
Labels	Explanation
	VISULAS type label
	 Manufacturer
	 Type B applied part
	IP20 Protected against harmful solid foreign objects of 12.5 mm in diameter and greater; Non-protected against harmful ingress of water
	CE approval label and disposal advice for EU
	 Indicates that the product is in compliance with European legislation for medical devices, with identification number of notified body
	 Separate collection for electrical and electronic equipment
	Marking the device as a medical device
	 Medical device
	Laser Class 4 warning label
	 Warning; Laser beam
	Laser console identification label
	 Catalog number
	 Serial number
	 Date of manufacture / Country of manufacture
	 Unique device identifier

Labels	Explanation
	Information label with serial number and model name
	Disconnect mains plug from electrical outlet
	Follow instructions for use
	Warning; Laser aperture at the end of the optical fibre applicator
<div>100 V-240 V~ 50/60 Hz 400 VA 2x T4,0 A/H, 250 V</div>	Electrical specifications
	 Fuse
	 Alternating current






Control panel (TouchControl panel)

Labels	Explanation
<div> Carl Zeiss Meditec AG  Goeschwitzer Strasse 51-52 07745 Jena, Germany TouchControl panel  REF 2039-605 SN XXXXX </div>	Identification label
	 Catalog number
	 Serial number
	 Identification code

5.2.2 LSL green combi laser slit lamp

Labels	Explanation
 <p>Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany LSL green combi</p>	Type label
	 Manufacturer
	 Type B applied part
	 Separate collection for electrical and electronic equipment
	Identification label
	 Catalog number
	 Serial number
	 Identification code
	Warning; Optical radiation
	Laser aperture
	Laser Class 4 warning label

5.2.3 Foot switch

Labels	Explanation
 <p>Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany</p> <p>Standard foot switch</p> <p>REF 2209-639 SN XXXXX</p> <p>000000-2214-455-Vs07</p> <p>IPX8</p>	Type label
	 Manufacturer
	IPX8 Protected against the effects of continuous immersion in water
	 Separate collection for electrical and electronic equipment
	REF Catalog number
	SN Serial number
	 Identification code
 <p>Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany</p> <p>TouchControl foot switch</p> <p>REF 2202-530 SN XXXXX</p> <p>000000-2214-456-Vs07</p> <p>IPX8</p>	
Standard	
TouchControl	

5.3 Device configuration

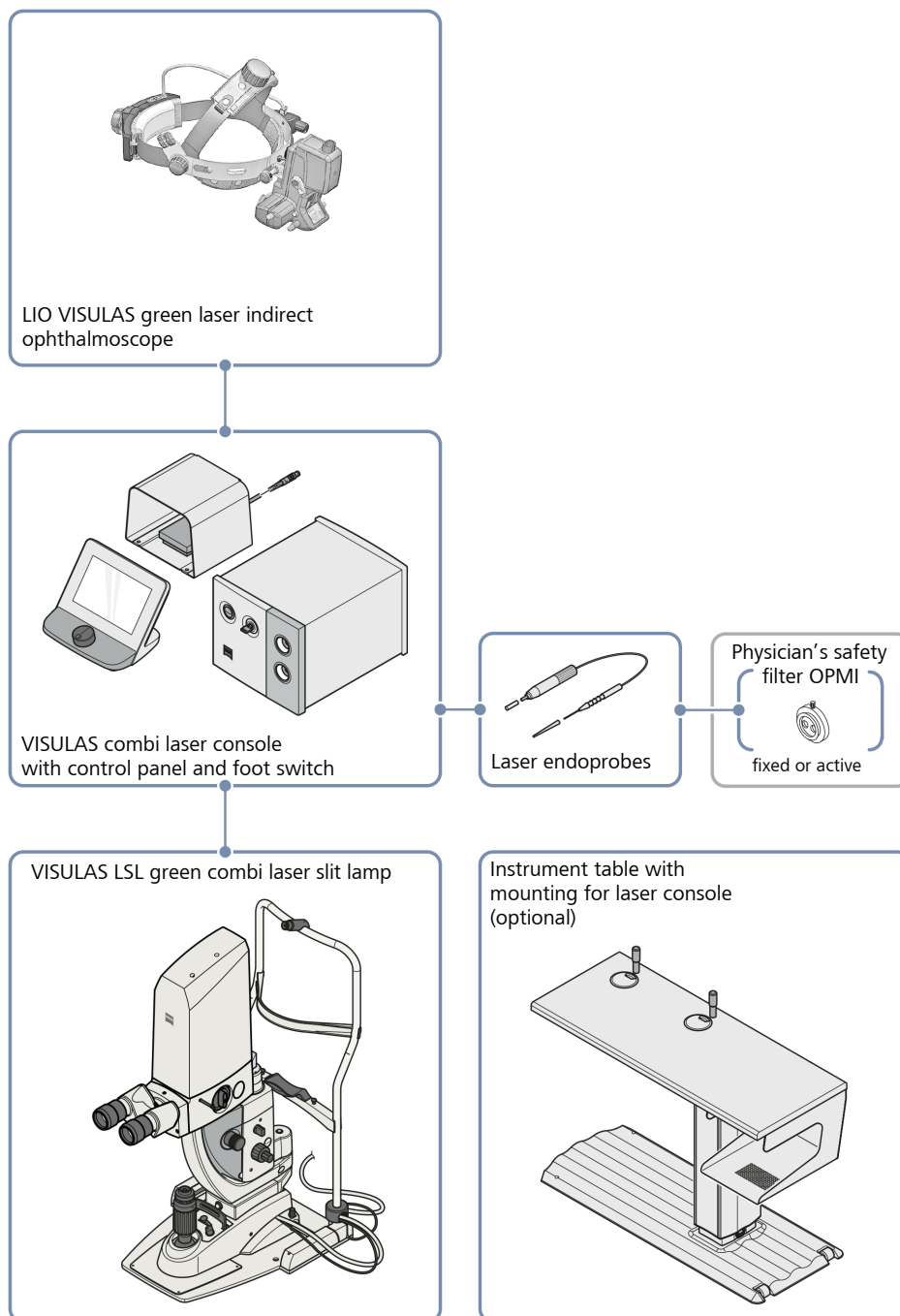


Figure 35: Device configuration

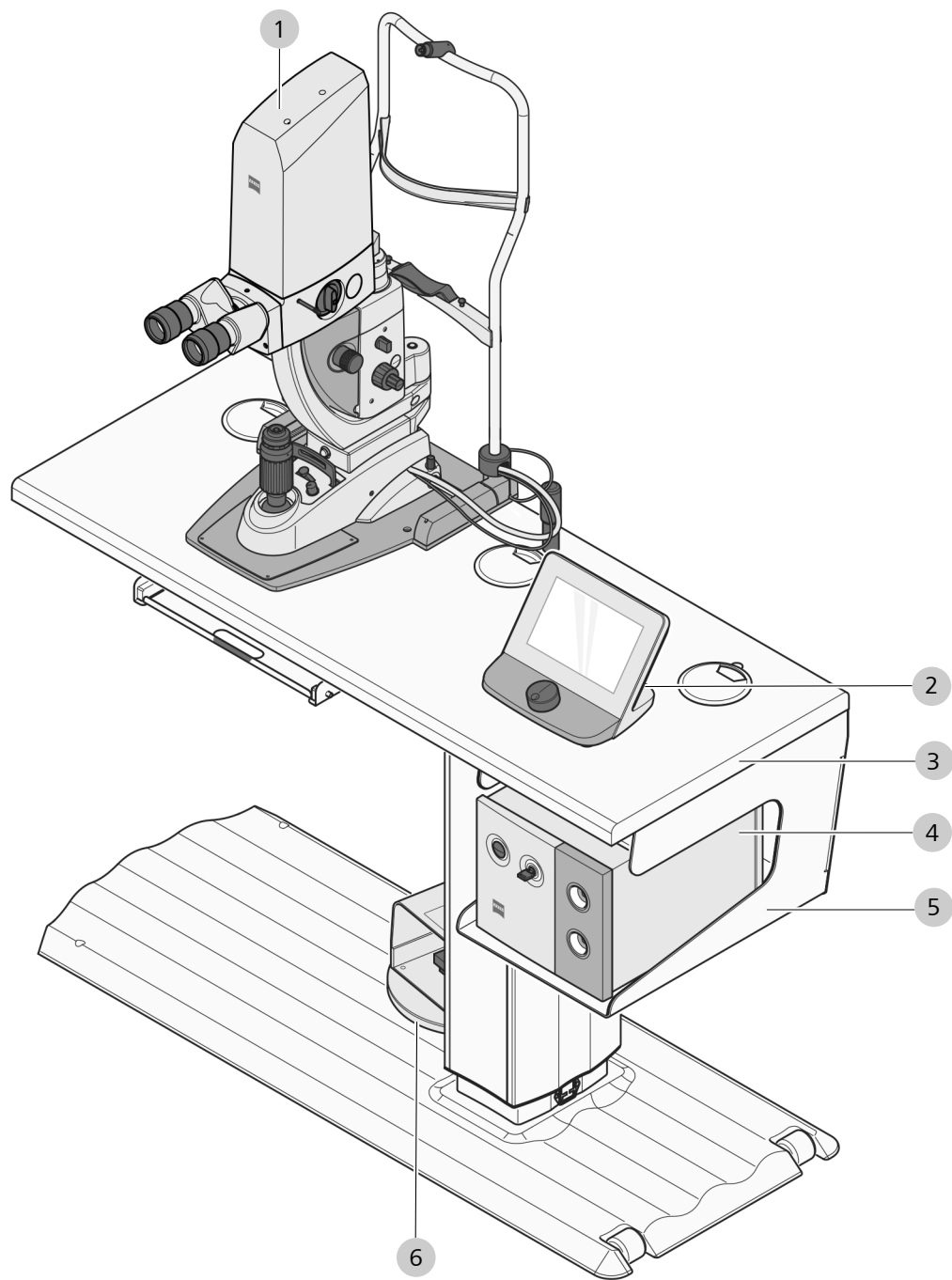


Figure 36: VISULAS combi system overview

1	Laser slit lamp	2	Control panel
3	Instrument table	4	Laser console
5	Table mounting for laser console	6	Foot switch

5.3.1 LSL green combi laser slit lamp

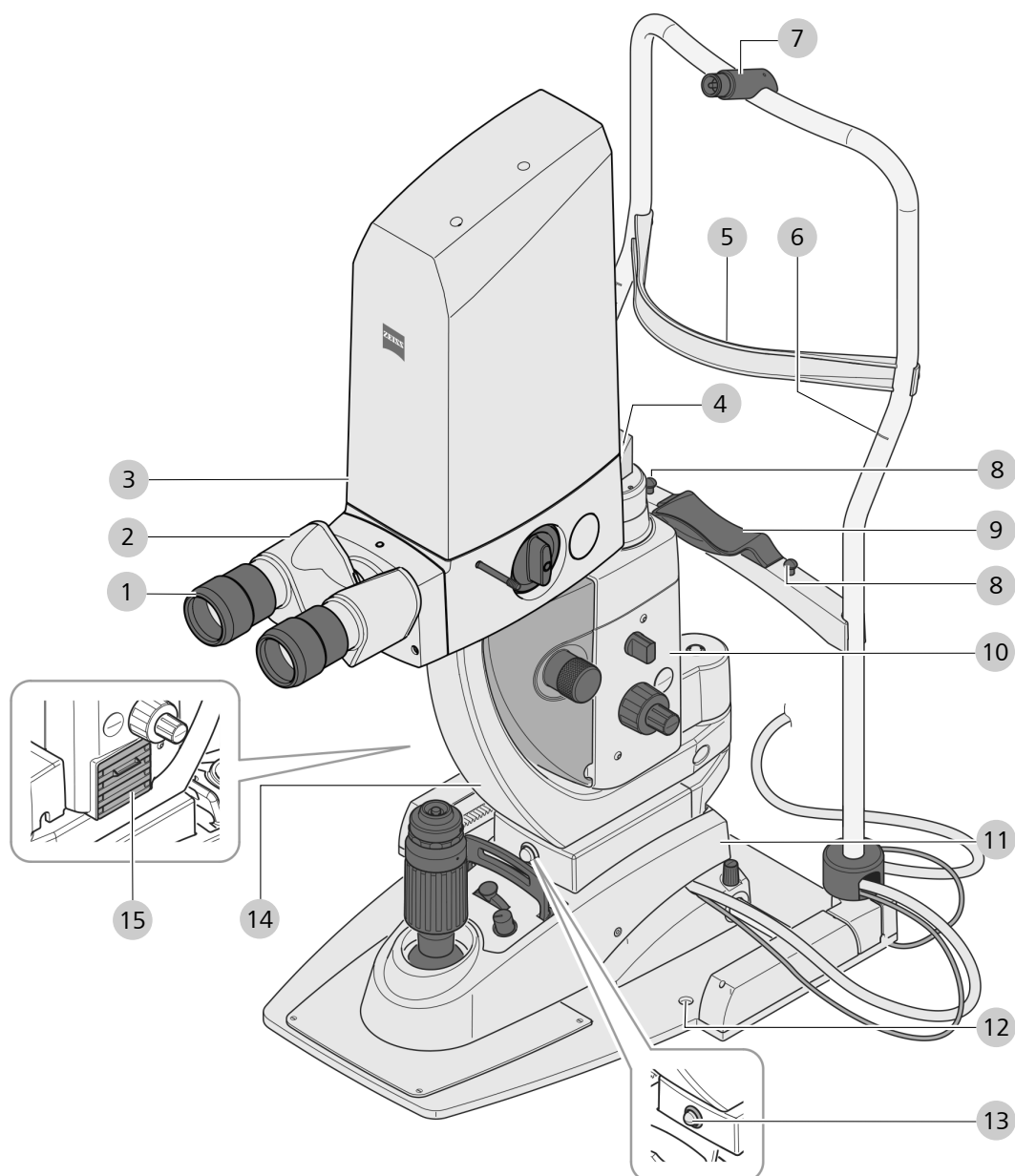


Figure 37: LSL green laser slit lamp

1	Eyepiece with adjustable eye cup	2	Binocular tube
3	Microscope stand with YAG laser mounting and fixed physician's safety filter	4	Prism head, illumination and laser exit aperture
5	Forehead rest (applied part)	6	Markings for setting the optimum eye level for the patient
7	Fixation lamp and YAG laser warning lamp mounting	8	Fastening pins for paper pads
9	Chin rest (applied part)	10	Slit lamp housing

11	Instrument base	12	Mounting holes
13	Physician's detection sensor (infra-red movement sensor)	14	Slit lamp swivel arm
15	Cover for illumination unit		

5.3.2 LIO VISULAS green

See LIO VISULAS green [► 35].

5.4 Controls, display elements and connectors

5.4.1 VISULAS combi laser console

The laser console is the central power supply and control unit for the VISULAS combi.

The laser console of VISULAS combi has two fiber optic ports and can only be combined with the LSL green combi laser slit lamp, the LIO VISULAS green and laser endoprobes.

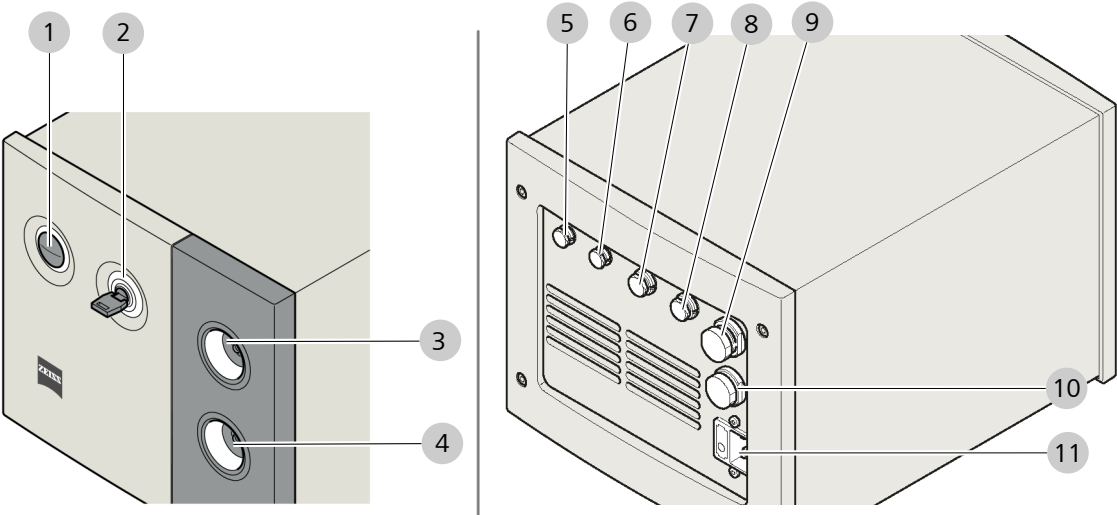

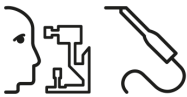



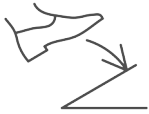




Figure 38: Controls, displays and connectors on the laser VISULAS combi console

Item	Icon / Name	Explanation
1	STOP 	Intended for immediate deactivation of the laser beam (lights up when laser stop switch is enabled). The laser stop switch interrupts the laser radiation to prevent hazards to persons. The laser stop switch is structurally independent of all of the other laser shutdown systems. When the laser stop switch is pressed, the system switches to the "Prepare" work step and all functions on the control unit are locked. To resume operation, press the laser stop switch again.
2	Key switch	The system features a key switch for the laser console. No laser radiation is emitted when the key is in the off position. The key can be removed.
3	LSL / ENDO 	Optical fiber connection for <ul style="list-style-type: none">■ Laser slit lamp■ Laser endoprobe■ LIO VISULAS green laser indirect ophthalmoscope Illumination ring on the corresponding fiber optic port lights up when selected: <ul style="list-style-type: none">■ White in "Treat" work step■ Red when therapy laser is triggered

Item	Icon / Name	Explanation
4	<p>LIO</p> 	<p>Optical fiber for LIO VISULAS green laser indirect ophthalmoscope</p> <p>Illumination ring on the corresponding fiber optic port lights up when selected:</p> <ul style="list-style-type: none"> ■ White in "Treat" work step ■ Red when therapy laser is triggered
5	<p>Interlock</p> 	<p>Connector for door contact and external laser warning lamp. When the contacts of the plug connector are opened, laser emission is interrupted. As delivered, a short-circuit plug is plugged into the plug connector. Note that using the remote lock increases the probability of interrupting the laser treatment.</p>
6	<p>Services</p> 	<p>Interface for Services and VISUCONNECT 600 data transfer adapter</p>
7	<p>Foot switch</p> 	<p>Connection to foot switch</p>
8	<p>Display</p> 	<p>Connector for control panel (TouchControl panel)</p>
9	<p>Slit lamp</p> 	<p>Connection socket for slit lamp and active external physician's safety filter for surgical microscopes</p>
10	<p>YAG</p>	<p>Connector for YAG HV power supply</p>
11		<p>Power input with fuse compartment</p>

5.4.2 Control panel (TouchControl panel)

See Control panel (TouchControl panel) [► 40].

5.4.3 LSL green combi laser slit lamp

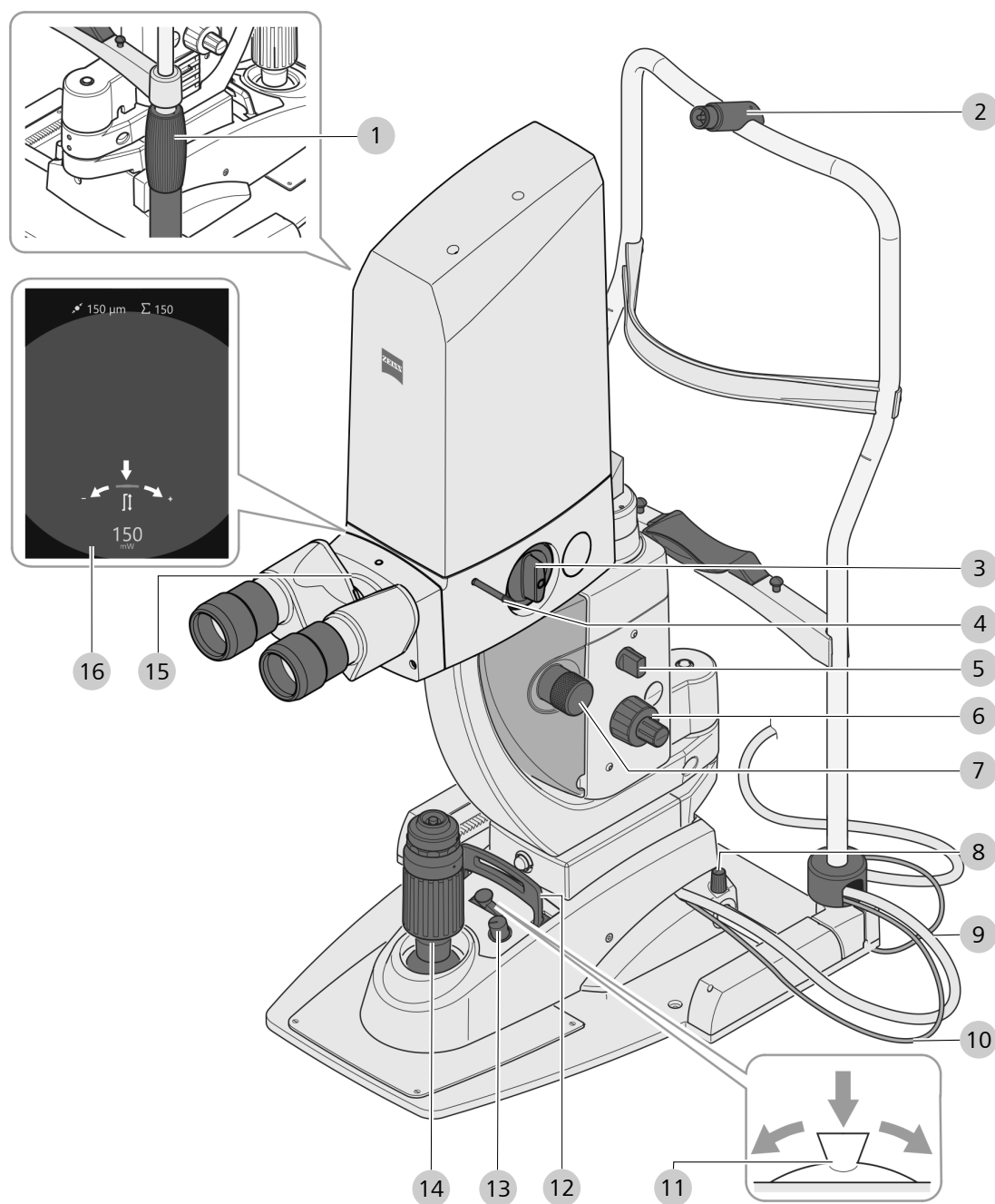


Figure 39: Control elements on the LSL green combi laser slit lamp

Item	Name	Explanation
1	Height adjustment for chin rest	The optimum eye level for the patient can be set by turning the height adjustment of the chin rest.
2	Fixation lamp and YAG laser warning lamp mounting	The YAG laser warning lamp lights up red when the high-voltage supply to the YAG laser source is ready.
3	Magnification changer	The magnification can be set in 5 stages using the magnification changer.

Item	Name	Explanation
4	Left / right adjustment for LSL InsightView display	Slide bar for changing eyes for the LSL InsightView display.
5	Filter selector	White line pointing up: White line to the patient: Blue filter for tonometry and fluorescence observations. White line to the physician: Green filter for examining the fundus.
6	Adjustment knob for slit height / width	The slit height can be set to 1/3/5/9/14 mm and to special slit positions ($0^\circ/\pm 45^\circ/\pm 90^\circ$). The slit width can be continuously adjusted from 0 to 14 mm.
7	Laser spot size control knob	Control knob for setting the laser spot size
8	Locking screw for instrument base	Locking screw for securing the instrument base at the desired position
9	Laser slit lamp connecting cable	The plug on this cable is inserted into the fiber optic port for LSL on the laser console.
10	Fixation lamp connecting cable	This cable connects the fixation lamp with the instrument base.
11	TouchControl LSL center switch	Rocker for selection and adjustment of parameters (see LSL InsightView display and TouchControl LSL center switch [► 45]).
12	Fast-action base lock	Lever tilted towards the patient: The base is locked. Lever tilted towards the physician: The base can be moved freely. XY coarse adjustment is achieved by moving the complete instrument base.
13	Brightness control	Brightness control for slit illumination
14	Joystick with manual trigger	XY fine adjustment is performed by tilting the joystick. The Z adjustment is made by rotating the joystick. The system has a manual trigger for laser beam control. By operating the manual trigger, the laser radiation can be applied to the patient's eye. The treatment can be interrupted by releasing the manual trigger.
	Electronic micromanipulator with locking ring	The electronic micromanipulator is used to make fine adjustments to the slit image and laser spot jointly while the locking ring is released.
15	Scale bar	Interpupillary distance scale
16	LSL InsightView display	Display for data projection of treatment parameters For more information on the icons displayed in the LSL InsightView display (head-up display of the laser slit lamp), refer to LSL InsightView display and TouchControl LSL center switch [► 45].

5.4.3.1 LSL InsightView display and TouchControl LSL center switch

See LSL InsightView display and TouchControl LSL center switch [► 45].

5.4.3.2 Brightness control

See Brightness control [► 47].

5.4.4 LIO VISULAS green

See LIO VISULAS green [► 35].

5.4.5 Endoprobes

See Endoprobes [► 37].

5.4.6 Standard foot switch

See Standard foot switch [► 57].

5.4.7 TouchControl foot switch

See TouchControl foot switch [► 58].

5.5 Functional description

The VISULAS combi is the maximum instrument configuration of the VISULAS model series. The system has both a photocoagulation and a photodisruption laser source and in principle allows all laser treatments related to these procedures. In order to use certain types of treatment, the corresponding software licenses must be installed on the system.

The functional description of the coagulation laser [► 59] and the functional description of the Nd:YAG laser [► 76] can be found on the specified pages in these instructions for use.

NOTE! Please note that laser treatment with the YAG laser in the central position of the illumination is not possible with the VISULAS combi. The illumination must be swiveled out by at least 17° before emission of the laser radiation. The system automatically detects the swiveling state of the slit lamp housing (see position 10 in LSL green combi laser slit lamp [► 90]) and releases the laser emission only in the swiveled-out state.

6 Installation

6.1 Installation safety

WARNING!

General hazards

Installation errors can lead to general hazards.

- ▶ Have installation, instruction and commissioning performed only by the manufacturer or by companies authorized by the manufacturer.

NOTE

Contamination and damage to the fiber optic cable

The functioning of the fiber optic cable may be impaired by contamination and damage.

- ▶ Do not touch the end of the fiber optic cable with your fingers.
- ▶ Protect the end of the fiber optic cable from contamination.
 - ⇒ Due to absorption effects at high laser power, any dirt may result in destruction of the end surface of the fibers.
- ▶ Carefully screw the optical fibers tight by hand. Do not use tools.
- ▶ Do not use optical fibers and application systems from other manufacturers.

6.2 Installation of LIO VISULAS green

6.2.1 Connecting

Action

1. Insert the optical fiber of the LIO VISULAS green indirect laser ophthalmoscope in the optical fiber port of the laser console. Carefully screw the optical fibers tight by hand.
2. Connect the power supply unit to the input socket of the charging station.
3. Replace the cover plate in the power supply unit with one of the supplied adapters that fits your power supply.
4. Connect the adapter to the mains supply.

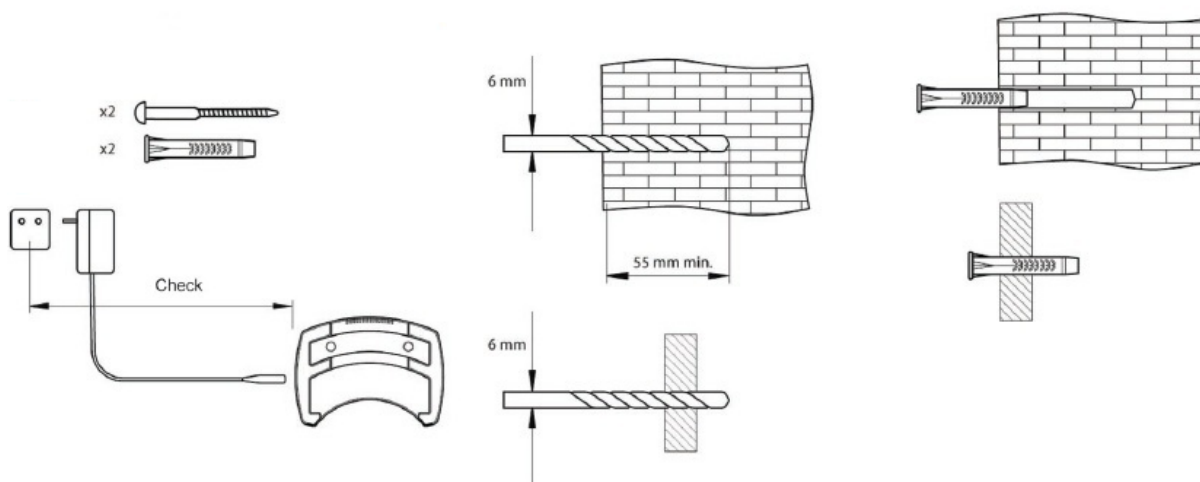
6.2.2 Mounting the charging dock to the wall (optional)

Action

1. Use the template provided to mark the position of the drill holes on the wall.



2. Drill the holes according to the dimensions in the drawing.



3. Attach the charging station to the wall using the screws and plugs supplied.

NOTE! When the charging station is attached to the wall, no devices other than the LIO VISULAS green indirect laser ophthalmoscope with its spare batteries may be attached to it. This is to prevent it from falling.

6.3 Moving the instrument table with the devices

CAUTION!

Mechanical hazard 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.

Action

1. Carefully lower the instrument table to the lowest position.
2. Slightly lift the table by the narrow side of the tabletop, on the slit lamp side, and move it by the castors. Use both hands to lift the table. Note the position of the castors on the table foot.

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7 Daily startup

7.1 Daily inspection

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 for use. The following inspections must be carried out each working day prior to use:

Action

- ▶ Visual inspection for presence of devices, detachable parts, components and accessories and for any damage
 - ▶ Checking that the ventilation slits are not covered or obstructed
 - ▶ Checking that laser safety goggles are present and do not show any damage.
 - ▶ Checking the laser exit ports or eyepieces for dirt or damage
 - ▶ Ensure that there are no snags or sharp bends in the fiber optic cable or other cables have no snags or sharp bends
 - ▶ Checking the presence and integrity of the instructions for use and external labeling
- ⇒ If parts are missing or damage is visible, proceed as described in Shutting down.

7.2 Switching on and routine tests

Action

- ▶ Plug the power cable into a power outlet.
- ▶ Switch on the system using the key switch on the laser console.
 - ⇒ The first "Configure" work step is displayed on the control panel screen.

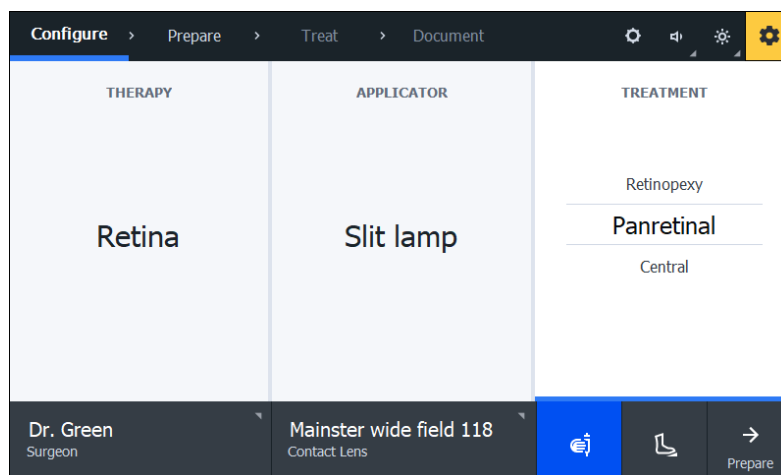


Figure 40: "Configure" work step

NOTE! When switching on the system, make sure that no USB storage device is plugged into the USB connector of the TouchControl panel (control unit).

8 Shutting down

WARNING!

General hazards

Certain hazardous situations can lead to injuries.

- ▶ In the following cases, take the system out of operation and notify ZEISS Service for repair measures:
 - Unexpected change in laser energy / laser power or position
 - Electric shock
 - Penetration of liquids
 - Occurrence of smoke, fire or burning odor
 - Disimprovement in performance of the system
 - Recurring error messages
 - Response of the system in contradiction with the information in these instructions for use
 - Safety-relevant deviation as a result of inspection measures
 - System related incidents or near incidents that (may) have resulted in injury to the patient or physician (user).

WARNING!

Hazard due to laser radiation

Defective laser safety equipment can cause injuries.

- ▶ Take the laser safety goggles or other protective filters out of operation in case of obvious defects, e.g. visible changes to the protective filter, cracks, color changes, changes in light transmission, or faults in the mount or holder that impair protection against incident radiation from the side.

8.1 VISULAS system with laser slit lamp

Action

- ▶ Switch off the system using the key switch on the laser console.
NOTE! Components of the system remain energized even after the system has been switched off with the key switch.
WARNING! When not in use, remove the key switch from the system to prevent its use by unauthorized persons.
- ▶ Disconnect the system from the mains supply if you are not going to use the system for any length of time.
- ▶ Use the supplied cover to protect the laser slit lamp from dust when not in use.
- ▶ In order to protect the internal optical elements of the laser slit lamp from dust, do not leave the laser slit lamp without the objective, binocular tube or eyepiece attached.
- ▶ Store objectives, eyepieces, accessories and other detachable parts in dust-free cases when they are not being used.

8.2 VISULAS system with LIO VISULAS green

Action

- ▶ After treatment, switch off the laser console using the key switch.
WARNING! When not in use, remove the key switch from the system to prevent its use by unauthorized persons.
- ▶ Switch off the LED illumination of the LIO VISULAS green by turning the brightness adjustment knob counterclockwise as far as it will go.
- ▶ Remove the batteries from the device if you are not going to use the device for any length of time.
- ▶ To completely disconnect the system from the mains supply, the charging station must be unplugged from the mains socket.

8.3 VISULAS system with laser endoprobe

Action

- ▶ Switch off the system using the key switch on the laser console.
WARNING! When not in use, remove the key switch from the system to prevent its use by unauthorized persons.
- ▶ Unscrew the SMA plug from the optical fiber port of the console by hand and pull off the optical fiber.
- ▶ Dispose of the endoprobe in accordance with applicable regulations and accompanying information.

9 Cleaning and disinfection

9.1 General information

NOTE

Damage due to improper cleaning, disinfection and sterilization

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

The system or its accessories are not suitable for sterilization procedures.

- ▶ 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 (e.g. isopropyl alcohol up to 99.5 % and ethanol up to 96 %) or peracetic acid-based (e.g. Gigasept PAA concentrate base) disinfectants and cleaning agents over a long period.
- ▶ Do not use aggressive (e.g. acetone) or abrasive cleaning agents.
- ▶ If you are unsure about damage, test the agent for damage in an inconspicuous place or contact Zeiss Service.

9.2 Cleaning of VISULAS

Action

- ▶ All parts of the devices, casing and the arm rest may be wiped off with a moist but not drip-wet cloth.
- ▶ Wipe off any marks or stains with distilled water, to which a drop of household detergent has been added.
- ▶ To clean the monitor, commercially available cleaning cloths for computers and monitors should be used.
- ▶ Use a commercial lens cleaning tissue (moist or dry) for cleaning the optical surfaces on the patient's side.
- ▶ Remove dust from optical surfaces by means of a fine brush.

9.3 Disinfection of VISULAS

Device parts that are routinely in contact with patients, i.e. the forehead rest and chin rest, should be disinfected before each examination. These parts are not removable.

Perform manual wipe disinfection according to the following procedure:

Action

1. Wear protective gloves when performing cleaning or disinfection procedures.
2. Use a lint-free microfiber cloth soaked in 70 % isopropanol solution to remove visible soiling.
3. Then dispose of the cloth used for cleaning.
4. Use another lint-free microfiber cloth soaked in 70 % isopropanol solution for disinfection. To prevent the spread of germs, avoid "back and forth" wiping, but wipe once under low pressure from one end to the other of the part to be disinfected until completely wetted.
5. Make sure that the surfaces remain completely wetted during the exposure time of one minute. If necessary, repeat the wetting with an unused area of the cloth or a new cloth.
6. Dispose of the used cloths as well as gloves.
7. Allow the surfaces to dry completely, before the patient comes in contact with them.

If you use a different cleaning and disinfection procedure, make sure that the procedure is effective for removing the micro-organisms that are present.

9.4 Cleaning of optical components of VISULAS

Action

1. Identify the soiled spot. Only clean if there is visible contamination.
2. Use a bellows to remove non-adherent dirt on the optical surface.
3. Disconnect the device from mains supply.
4. Use a polyester wiper moistened with distilled water to remove stubborn, water-soluble contamination or / and a polyester wiper moistened with pure n-hexane to remove greasy, water-insoluble contamination. As an alternative to n-hexane, a freshly prepared solution of 5 to 10 drops of a dishwashing detergent in 10 ml of distilled water can be used.
5. Remove excess solvent so that the agent cannot run into the edge areas of the optics.
6. Make spiral movements from the center to the edge to remove the impurities.
7. Repeat the procedure with a freshly moistened polyester wiper until the soiling is no longer visible.
8. If household detergent is used: If necessary, wipe away residues of the rinsing solution again in a spiral with polyester wipers soaked in distilled water.

9.5 Treating contact lenses

The following procedures and instructions for cleaning, disinfection and sterilization are applicable to all contact lenses supplied by ZEISS (except ophthalmoscope lenses such as OI-20). All information has been taken from the corresponding instructions for use from Ocular Instruments, Inc.

9.5.1 Cleaning

Action

1. Immediately after removing the product from the patient's eye, rinse thoroughly in cold or lukewarm water.
2. Apply a few drops of a mild liquid soap (i.e. neutral pH of 7.0) to a moistened cotton ball.
3. Gently wipe the cotton ball over the device in circular motions.
4. Rinse thoroughly in cold or lukewarm water and dry carefully with a lint-free cloth. Then perform disinfection or sterilization according to instructions.

9.5.2 Disinfection

Action

1. Soak the contact lens in glutaraldehyde (2 % or 3.4 % aqueous solution; temperature according to manufacturer's instructions; contact time at least 20 minutes) or bleach solution (10 % solution mixed from 1 part bleach and 9 parts cold or lukewarm water; recommended contact time 10 minutes).
2. Remove the disinfectant solution by rinsing the lens thoroughly. We recommend 3 cycles of 1 minute each with cold or lukewarm water.
3. Dry the contact lens thoroughly and place it in a dry container for storage to protect it from contamination.

NOTES:

- To avoid damage to the lens, do not exceed the recommended exposure time.
- Disinfectant solutions other than those listed above that are approved for use in your region (e.g., FDA, DGHM, VAH, CE Mark, etc.) may be used according to the disinfectant manufacturer's label instructions. Pay close attention to the disinfectant manufacturer's recommended concentrations and contact times. Make sure the disinfectant solution makes complete contact with all instrument surfaces and lumens.
- The lenses of the contact lenses are compatible with Asepti-Wipe, Cavi-cide, Cidex, Cidex OPA, DisCide Wipe, Enviro-cide, Tristel Wipes System, Steris Resert and Opti-Cide. They are also compatible with H₂O₂-3 %.

9.5.3 Sterilizing

When used on patients with ulcerative cornea, the lens must be sterilized before the next use.

Information on sterilization procedures:

- Autoclaving: not possible
- Sterrad: not possible (Attention: devices have a limited lifetime after 10 cycles)
- Steris System 1E: possible according to manufacturer's instructions
- 3M Optreoz 125-Z Low Temperature Sterilization System - Cycle 2: possible according to manufacturer's instructions (Attention: colored aluminum will bleach to a natural aluminum color within 25 cycles).
- ETO: possible with the following parameters:
 - Minimum duration: 1 hour
 - Temperature: 54 °C
 - Ventilation time: 12 hours

9.6 Treating ophthalmoscope lenses

The following procedures and instructions for cleaning, disinfection and sterilization are applicable to all ophthalmoscope lenses supplied by ZEISS (e.g. OI-20). All information has been taken from the corresponding instructions for use from Ocular Instruments, Inc.

9.6.1 Cleaning

Action

1. Wipe the lens with a cloth soaked in alcohol.
2. Now perform disinfection or sterilization according to instructions.

9.6.2 Disinfection

Action

1. Soak the contact lens in glutaraldehyde (2 % or 3.4 % aqueous solution; temperature according to manufacturer's instructions; contact time at least 20 minutes) or bleach solution (10 % solution mixed from 1 part bleach and 9 parts cold or lukewarm water; recommended contact time 10 minutes).
2. Remove the disinfectant solution by rinsing the contact lens thoroughly. We recommend 3 cycles of 1 minute each with cold or lukewarm water.
3. Dry the contact lens thoroughly and place it in a dry container for storage.

Notes

- To avoid damage to the contact lenses, do not exceed the recommended exposure time.
- The contact lenses are compatible with Asepti-Wipe, Cavi-cide, Cidex, Cidex OPA, DisCide Wipe, Tristel Wipes, H₂O₂-3 %, Enviro-cide and Opti-Cide.

9.6.3 Sterilizing

Information on sterilization procedures:

- Autoclaving: not possible
- Sterrad: not possible
- Steris System 1E: possible according to manufacturer's instructions
- ETO: possible with the following parameters:
 - Minimum duration: 1 hour
 - Temperature: 54 °C
 - Ventilation time: 12 hours

NOTE! The ophthalmoscope lenses must not be steam-autoclaved or boiled. They must not be soaked in alcohol, acetone or other solvents.

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10 Maintenance and care

10.1 Safety inspection

Independent of the regular safety inspections required in Instructions on maintenance [► 19], some countries require electrical safety tests. Use the following test procedures and test points to perform these tests.

- Perform a visual inspection of all components and cables to ensure they are in proper condition.
- Check the protective earth conductor resistance. For this purpose, connect the system to the measuring instrument using the power cable. To perform a measurement, press the measuring tip to the measurement points on the laser console, the laser slit lamp and the instrument table, as shown in the figures. If using other tables, measure at a suitable point connected to the protective conductor.

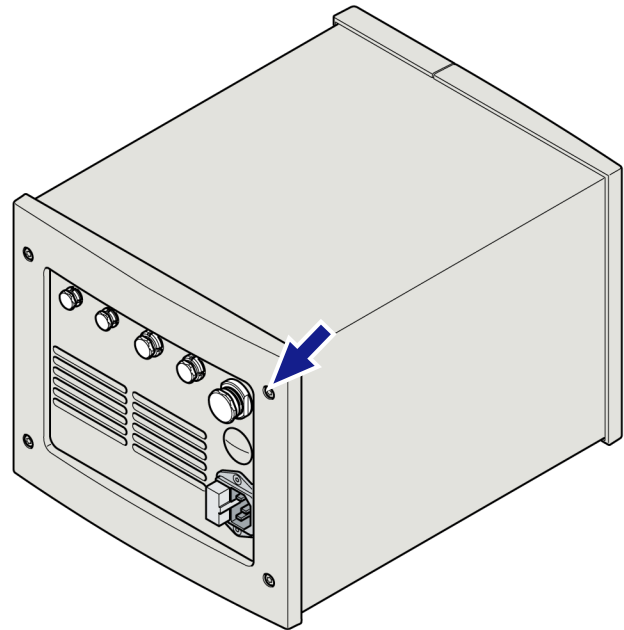


Figure 41: Measuring point on laser console (illustrated for VISULAS green console)

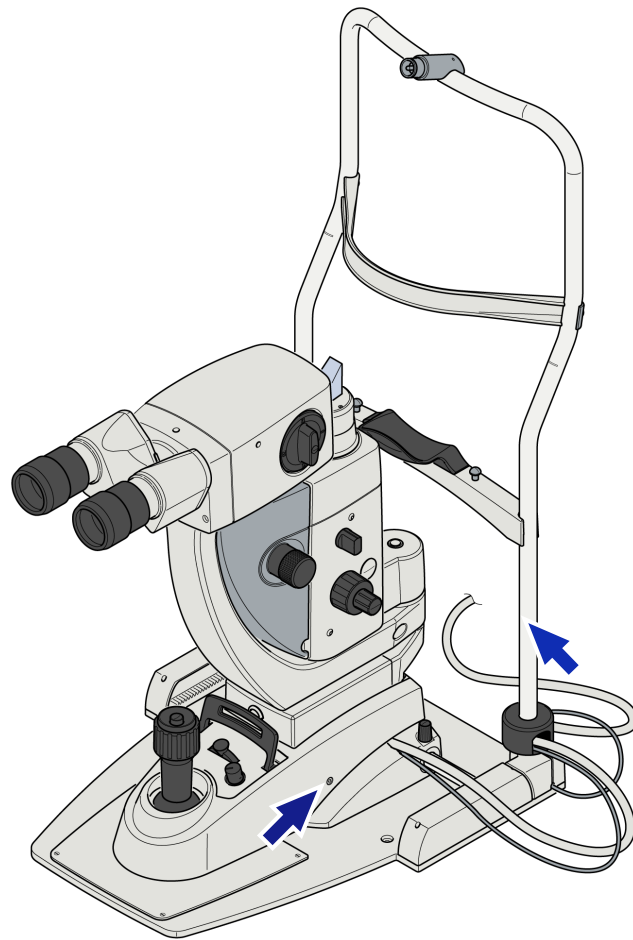


Figure 42: Measuring point on laser slit lamp (illustrated for LSL green classic)

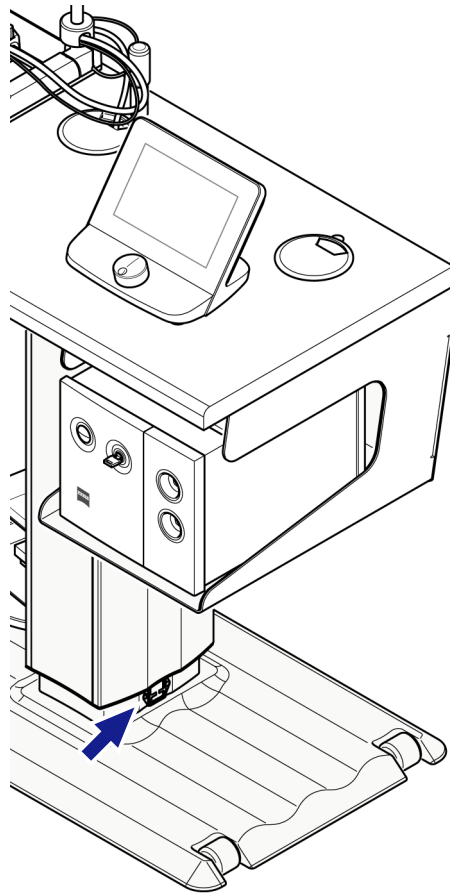


Figure 43: Measuring point on ZEISS instrument table

- ⇒ The measured value may not exceed $0.3\ \Omega$.
- ▶ If there are doubts about the efficacy of the insulation (such as multiple triggering of the fault circuit interrupter or other protective devices at the place of use, or traces of liquid on the system which suggest the penetration of liquid), measure the insulation resistance with a test voltage of 500 V.
 - ⇒ The measured value may not fall below $2\ \text{M}\Omega$.
- ▶ After successful measurement, the device leakage current must be measured. This is preferably done using the differential current method while the device is in its operating state. Press the measuring tip onto the measurement points again.
 - ⇒ The measured value may not exceed $0.5\ \text{mA}$.

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11 Troubleshooting

11.1 Faults (with messages)

Faults are indicated as system information on the control unit display. The user is also alerted by short audible signals.


Note: Follow the instructions given.

Warning message: Remedy the fault using the troubleshooting tables below.

Action

- ▶ If a fault occurs, which cannot be remedied by using the following tables, please contact ZEISS Service, citing the error number displayed.
- ▶ Label the system as being out of order, remove the key from the key switch and disconnect the power plug.

Error message	Cause	Remedy
Door interlock is activated. For your safety, the VISULAS cannot be used further when the door is open. Close the door of the treatment room to continue using the unit.	The door contact interlock is open.	▶ Shut the door and check that the shorting plug is correctly plugged into the yellow socket.
Laser stop button has been pressed. For your safety, the VISULAS cannot be used when the Laser stop switch is activated. Unlock the laser stop switch to be able to use the device again.	The laser stop switch is locked.	▶ For safety reasons, the device cannot be used. The laser stop switch is activated when lit. To resume operation, press the laser stop switch again.
Communication error with physician's safety filters / laser slit lamp. The connection to the slit lamp or the physician's safety filter was interrupted. Check the correct connection of the laser slit lamp or the physician's safety filter for the surgical microscope. Then restart VISULAS. If the error occurs repeatedly, please contact ZEISS Service.	The connection to the slit lamp or the physician's safety filter was interrupted.	▶ Check that the slit lamp and the external physician's safety filter for the surgical microscope are correctly connected and properly inserted.
Fiber not connected. There is no optical fiber connected to the VISULAS. Check if the optical fibers are properly connected.	No optical fiber detected.	▶ Check that the optical fiber is properly inserted and screwed in tightly.

Error message	Cause	Remedy
Connection error to laser trigger. No trigger for laser radiation connected to VISULAS. Check if the foot switch and laser slit lamp are properly connected.	No trigger for laser detected.	<ul style="list-style-type: none"> ► Check that the foot switch and the slit lamp are correctly connected and properly inserted.
Temperature control is active. VISULAS currently regulates to the working temperature. Please wait until the device is ready. Make sure that the vent slots on the laser console are not covered and that the room temperature is between 10 °C and 35 °C.	Temperature within the laser console is too high.	<ul style="list-style-type: none"> ► Make sure that the vent slots on the laser console are not covered. ► Ensure that the ambient temperature is between 10 °C and 35 °C.
Device temperature is too high. The working temperature of the VISULAS is too high. Make sure that the vent slots on the laser console are not covered and that the room temperature does not fall below 35 °C. Then restart VISULAS.	The temperature of the VISULAS is too high.	<ul style="list-style-type: none"> ► Make sure that the vent slots on the laser console are not covered. ► Ensure that the ambient temperature is below 35 °C. ► Then restart VISULAS.
Device temperature is too low. The working temperature of the VISULAS is too low. Make sure that the room temperature is above 10 °C. Then restart VISULAS.	Temperature of VISULAS is too low.	<ul style="list-style-type: none"> ► Make sure that the room temperature is above 10 °C. ► Then restart VISULAS.
Laser power. The laser power deviates from the preset values by more than 20 %. Two short consecutive tones are emitted from the device. When using the YAG laser, the following symbol is displayed on the right side of the screen for 10 s. 	The internal monitoring systems have identified that the actual laser power output deviates from the target power output selected on the control panel by more than 20 %.	<p>Note: For physical reasons, the 20 % deviation of the actual laser power from the set laser power occurs sporadically.</p> <ul style="list-style-type: none"> ► Contact ZEISS Service if the message occurs repeatedly.

Error message	Cause	Remedy
Error. The system has detected a technical error and has been shut down for your safety. Restart VISULAS. If the error persists, contact ZEISS Service. This message is accompanied by three long beeps.	The device has detected an internal error that can only be repaired by a ZEISS Service representative.	<ul style="list-style-type: none"> ▶ Restart VISULAS. ▶ Contact ZEISS Service if the error occurs repeatedly. ▶ Download the LOG file and provide it to ZEISS Service on request.
Wrong value for spot size. An inappropriate spot size was selected for the chosen treatment pattern. Set one of the available spot sizes.	A technically unavailable spot size was selected.	<ul style="list-style-type: none"> ▶ Please change the "Spot size" parameter according to the on-screen instruction.
Wrong value for spot size. An inappropriate spot size for the selected treatment type was selected. Set the spot size to 50 µm (or 100 µm).	A technically unavailable spot size was selected.	<ul style="list-style-type: none"> ▶ Please change the "Spot size" parameter according to the on-screen instruction.
Wrong value for spot size. In multi spot mode, only the following spot sizes are available: 50; 100; 200; 300. Set one of the available spot sizes.	For multi spot treatment, a technically unavailable spot size was selected.	<ul style="list-style-type: none"> ▶ Please change the "Spot size" parameter according to the on-screen instruction.
Error during laser emission. The YAG laser was not triggered properly. Reduce the release speed and ensure that the slit lamp housing has swung out sufficiently far.	The YAG laser radiation could not be triggered properly.	<ul style="list-style-type: none"> ▶ The YAG laser pulses can only be applied to the patient's eye at the specified maximum shot rate. Note that the maximum shot rate is reduced in YAG pulse modes 2 and 3. The corresponding specifications can be found in Technical data of VISULAS yag [▶ 133] and Technical data of VISULAS combi [▶ 135].
Foot switch or joystick trigger activated. It is not possible to change the treatment mode while the trigger is pressed. To be able to continue, release the trigger.	For safety reasons, it is not permitted to switch to treatment mode while the trigger is pressed.	<ul style="list-style-type: none"> ▶ To continue, release the trigger.
YAG laser self-test. The VISULAS performs a self-test. Please wait until the device is ready.	The self-test of the YAG laser has been started.	<ul style="list-style-type: none"> ▶ Wait until the process has been completed.

Error message	Cause	Remedy
Burst mode is activated. The VISULAS YAG pulse mode has been activated. At the next triggering, 2 or 3 short pulses are emitted, depending on the setting, in order to provide the set laser energy.	The VISULAS YAG pulse mode 2 has been activated.	This informs you that, from now on with each activation of the trigger, several shots will be applied to the patient's eye in order to provide the set laser energy.
The laser slit lamp blocks the laser radiation. The illumination unit of the laser slit lamp locks the YAG laser radiation. Swivel the slit lamp housing out of the beam path. The VISULAS releases the laser radiation as soon as the housing has been swiveled out at least 16° from the zero position.	The illumination unit of the laser slit lamp locks the YAG laser radiation.	<ul style="list-style-type: none"> ▶ Follow the instructions on the display of the TouchControl panel.
YAG control connection error. Communication to the YAG laser control is disrupted. If the problem persists, contact ZEISS Service.	Communication to the YAG laser control is disrupted.	<ul style="list-style-type: none"> ▶ Restart VISULAS. ▶ Contact ZEISS Service if the error occurs repeatedly.
Connection error to the laser slit lamp. Communication to the laser slit lamp is disrupted. Check if the plug at the laser slit lamp is properly connected. Then restart VISULAS. If the error occurs repeatedly, contact ZEISS Service.	Communication to the laser slit lamp is disrupted.	<ul style="list-style-type: none"> ▶ Check if the laser slit lamp is properly connected. ▶ Restart VISULAS. ▶ Contact ZEISS Service if the error occurs repeatedly.
Connection error to TouchControl panel. Communication to the TouchControl panel is disrupted. Check if TouchControl panel is properly connected. If the connection is correct, restart VISULAS. If the error occurs repeatedly, contact ZEISS Service.	Communication to the TouchControl panel is disrupted.	<ul style="list-style-type: none"> ▶ Check if TouchControl panel is properly connected. ▶ Restart VISULAS. ▶ Contact ZEISS Service if the error occurs repeatedly.

Error message	Cause	Remedy
<p>Connection error to InsightView display.</p> <p>VISULAS has detected a communication error to the InsightView display. The display is switched off. Restart VISULAS. If the error persists, contact ZEISS Service.</p>	<p>Communication with the LSL InsightView (head-up display of the laser slit lamp) is interrupted.</p>	<ul style="list-style-type: none"> ▶ Restart VISULAS. ▶ Contact ZEISS Service if the error occurs repeatedly.
<p>Error.</p> <p>The external physician's safety filter for the surgical microscope could not be detected. Make sure that the external physician protection filter is correctly connected and restart VISULAS. If the error persists, contact ZEISS Service.</p>	<p>The external physician's safety filter for the surgical microscope could not be detected.</p>	<ul style="list-style-type: none"> ▶ Check the correct connection of the external physician's safety filter for the surgical microscope, see Laser console [▶ 38], position 9. ▶ Restart VISULAS. ▶ Contact ZEISS Service if the error occurs repeatedly.

11.2 Faults (no messages)

Fault	Cause	Solution
Instead of the "Treat" work step, the "DEMO Treat" work step appears. The laser cannot be triggered.	DEMO mode is activated.	<ul style="list-style-type: none"> ▶ Press the [DEMO] button in "Settings / System / Information" to deactivate DEMO mode.
Device cannot be switched on.	<p>The device is not connected to the power supply.</p> <p>The fuse is blown or faulty.</p>	<ul style="list-style-type: none"> ▶ Make sure that the device is plugged into a mains socket. ▶ Make sure that the power switch on the instrument table is switched on. ▶ Replace the fuse as described in Replacing the fuse [▶ 121].
The LED of the fixation light cannot be switched on.	Light-emitting diode is defective.	<ul style="list-style-type: none"> ▶ Replace the light-emitting diode as described in Replacing the light-emitting diode [▶ 122].
Slit Illumination does not work.	<p>The device is not connected to the power supply.</p> <p>LED illumination is defective.</p>	<ul style="list-style-type: none"> ▶ Make sure that the device is plugged into a mains socket. ▶ Make sure that the power switch on the instrument table is switched on. ▶ Please contact ZEISS Service to replace the LED illumination unit.
The LED illumination of LIO VISULAS green does not work.	LED illumination or battery in LIO VISULAS green is defective.	<ul style="list-style-type: none"> ▶ Replace or charge the LIO VISULAS green battery as described in Change batteries in LIO VISULAS green [▶ 124] and Batteries in LIO VISULAS green are empty [▶ 125]. ▶ If the problem persists after replacing or charging the battery, replace the LED of LIO VISULAS green as described in Replacing the LED in LIO VISULAS green [▶ 123]. ▶ If the problem persists after replacement of the battery and LED, the defective battery must be replaced according to Batteries in LIO VISULAS green are defective [▶ 124].

11.2.1 Replacing the fuse

 **WARNING!**

Fire hazard

Inserting an incorrect fuse may cause a fire.

- ▶ Disconnect the device from the mains supply before replacing the fuse!
- ▶ Only use fuses which meet the specifications given on the sign containing the fuse markings.

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

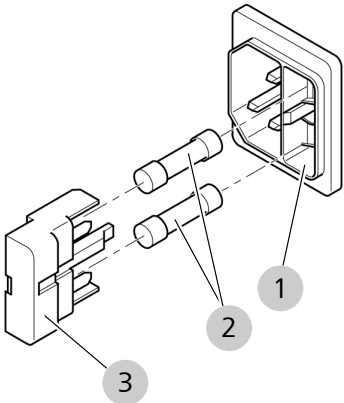


Figure 44: Replacing the fuses

1	Fuse compartment	2	Fuse
3	Fuse carrier		

Action

1. Remove the fuse carrier with fuse by pressing gently on the snap-in clip.
2. Replace the defective fuse.
3. Reinsert the fuse carrier with fuse. Ensure that the fuse carrier snap-in clip is correctly positioned.

11.2.2 Replacing the light-emitting diode

NOTE

Damage caused by unsuitable LED

Installing an unsuitable LED may cause the fixation lamp to overheat and be destroyed.

► Operate the optional fixation lamp of the laser slit lamp only with the standard red-flashing LED as supplied.

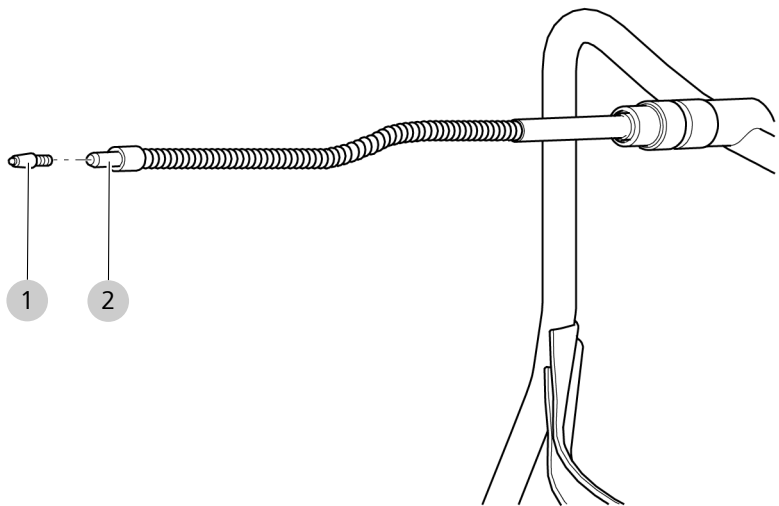


Figure 45: Replacing the light-emitting diode

1	Light-emitting diode flashing red	2	Light-emitting diode socket
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- Action
1. Unscrew the defective diode from the socket.
 2. Replace the light-emitting diode with a new one.

11.2.3 Replacing the LED in LIO VISULAS green

CAUTION!

Thermal hazard

Touching the hot LED may result in burn injuries.

- Switch the illumination of LIO VISULAS green off and let the LED cool down before replacing the LED.

NOTE! The LIO VISULAS green laser indirect ophthalmoscope may only be used with the corresponding LED (material number 000000-2222-088).

Action

1. Remove the LED carrier on the back of the device.
2. Slide the new LED carrier completely into the device. Make sure that the LED is facing downward.

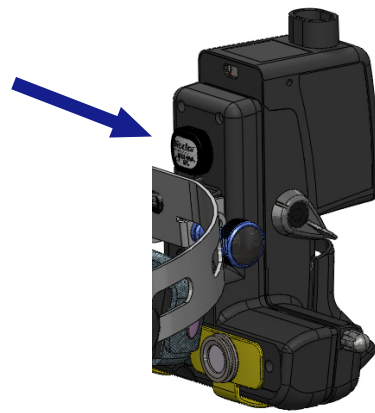


Figure 46: Replacing the LED

Result

- ✓ Make sure that the red slider on the illumination button is on the left side.

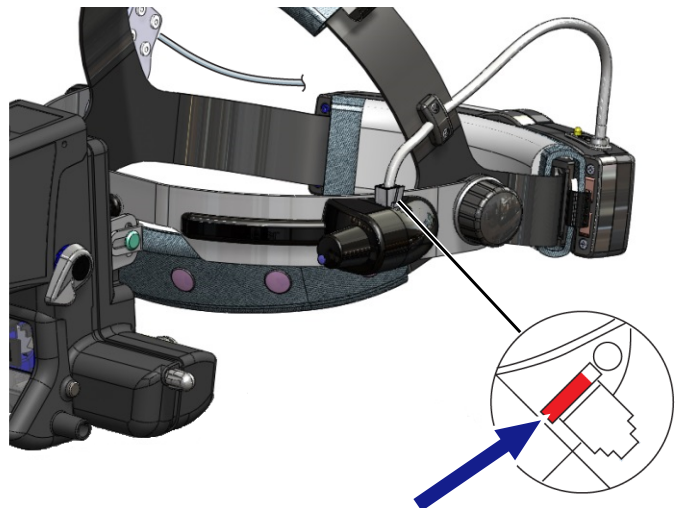


Figure 47: Switch setting in operating position

11.2.4 Change batteries in LIO VISULAS green or insert new battery

11.2.4.1 Change batteries in LIO VISULAS green

Action

1. Push the release knob of the battery.



Figure 48: Push release knob

2. Remove the battery upwards from the holder.
3. Insert the new battery and press down until it snaps in.



Figure 49: Inserting the battery

11.2.4.2 Batteries in LIO VISULAS green are defective

- Look for faulty and damaged spots on the batteries.
- A battery cannot be used anymore if
 - the casing is damaged or distorted.
 - the metal parts of the battery are discolored.
 - the battery is hot when not in use.
 - the battery leaks.

11.2.4.3 Batteries in LIO VISULAS green are empty

The device battery can be removed and charged in the charging station. The treatment can be resumed after inserting the spare battery.

Alternatively, the battery can also be charged when the device is placed in the charging station.



Figure 50: Charging the batteries

Action

1. If you want to charge the battery in the device, place the device in the charging station.
NOTE! Make sure that the device is firmly connected to the charging station and cannot fall down. The LIO VISULAS green laser indirect ophthalmoscope must be switched off during the charging process.
2. If you want to charge the spare battery, place it in the charging station.

A status LED on the charging station indicates which battery is being charged (battery in the device and / or spare battery).

Charging a battery in the head strap lasts about 2 hours.

Charging the spare battery lasts about 4 hours.

The charged battery has an operating time of 2 hours at full power.

The battery can be removed and used at any time during charging. The charging process continues when the battery is placed back in the charging station.

11.3 Service information

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

Empty page, for your notes

12 Disposal of the system

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

The system contains electronic components with built-in batteries.

- ▶ Dispose of the system and the built-in batteries properly and in accordance with national regulations.



In accordance with applicable EU guidelines and national regulations at the time at which the system 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 further information on disposing of the system, contact the ZEISS contact person for your country.

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

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

Empty page, for your notes

13 Technical specifications

13.1 Risk-relevant performance features of clinical functions

- No unexpected laser emission without actuation of the laser control switches
- No laser power or laser energy deviation of more than 20 % without warning message and no laser power or laser energy deviation of more than 50 % without error message during laser emission due to unintentional change of laser output parameters.
- No displaced laser fires due to unintended position change of therapy laser beam.

13.2 Technical data of VISULAS green

13.2.1 Single Port / Dual Port laser console

	Value
UMDNS No.	17-446
Operating mode	Continuous operation
Expected service life according to IEC 60601-1	12,000 h
Laser type	Frequency doubled Nd:YVO ₄ , diode-pumped, cw
Laser class of therapy beam	Class 4 (in accordance with IEC 60825-1)
Wavelength of therapy beam	532 nm ±1 nm
Maximum power on laser exit aperture of laser source	3 W
Maximum power at cornea in cw mode	1500 mW
Pulse duration (single pulse)	10 ms to 2500 ms, cw (max. 180 s)
Pulse duration (multi spot)	10/20/30/40/50 ms
Pulse interval	10 ms to 6000 ms
Max. laser energy at cornea in selective mode	65 µJ (this corresponds to a fluence of 2.6 J/cm ²)
Pulse duration (selective mode)	150 ns to 5 µs (1/e ²) 100 ns to 300 ns (FWHM)

	Value
Max. pulse repetition frequency	1 kHz
Aiming beam	Diode, 620 nm to 650 nm, max. 1 mW at the cornea (class 2 in accordance with IEC 60825-1)
Rated voltage, frequency	100 V to 240 V AC ($\pm 10\%$); 50/60 Hz
Power consumption	400 VA
Ingress protection rating	IP 20
Protection class	I
Applied parts type	B (in accordance with IEC 60601-1)
Fuses	2 x T 4.0 A; H; 250 V
Cooling of therapy laser source	Thermoelectric
Dimensions of laser console (H x W x D)	201 mm x 230 mm x 290 mm
Dimensions of control panel (H x W x D)	201 mm x 143 mm x 160 mm
Laser console weight	≤ 8 kg
Control panel weight	≤ 2 kg

13.2.2 LSL green comfort / classic laser slit lamp

	Value
Device group	2 in accordance with ISO 15004-2
Operating mode	Continuous operation
Laser beam guidance	Interlaced with slit illumination system
LED illumination	Continuously adjustable brightness
Slit width	0 mm to 14 mm (continuously)
Slit height	1/3/5/9/14 mm
Slit image rotation	$0^\circ/\pm 45^\circ/90^\circ$
LSL green comfort magnification	5x/8x/12x/20x/32x
LSL green classic magnification	8x/12x/20x
Pupil distance setting range	55 mm to 78 mm

	Value
Adjustment range for the observer's refractive error	-5 D to +5 D
Laser treatment spot size	Continuously adjustable from 50 µm to 1000 µm (without contact lens), parfocal, larger spot sizes depending on contact lens used
Laser beam divergence	$NA \leq 0.12$ / beam divergence $\leq 7^\circ$
NOHD (Nominal ocular hazard distance) (calculation see LSL green classic and comfort laser slit lamps ► 158))	16 m
Electrical power supply	Supplied by laser console
Ingress protection rating	IP 20
Weight	≤ 12.5 kg

13.2.3 LIO VISULAS green

13.2.3.1 Indirect ophthalmoscope

	Value
Device group	2 in accordance with ISO 15004-2
Operating mode	Continuous operation
Setting range of head strap length	Continuously adjustable
Ingress protection rating	IP 20
Weight	≤ 800 g (including optical fiber, without charging dock)
Illumination intensity	Continuously adjustable
Illumination patch sizes	20 / 40 / 60 mm ± 10 %*
Adjustable pupil distance	48 mm to 76 mm
Ophthalmoscope filters	Empty, red free, blue and diffuse
Laser beam divergence	$NA \leq 0.24$ / beam divergence $\leq 14^\circ$
Laser angle setting	$\pm 3^\circ$
NOHD (Nominal ocular hazard distance, calculation see LIO VISULAS green ► 161))	30 m

*Measurements taken at 440 mm from the front surface of the LIO VISULAS green

13.2.3.2 Charging dock with power supply unit

	Value
Rated voltage, frequency	100 V to 240 V AC (± 10 %); 50/60 Hz
Current consumption	≤ 700 mA
Output voltage / current	12 V DC / 2.5 A
Ingress protection rating	IP X0
Protection class	II

13.2.4 Endoprobes

	Value
Connection	SMA 905 socket
Protection against electric shock	minimum type B
Max. laser power output in the range from 500 nm to 820 nm	2.5 W
Numerical aperture	0.22
Fiber core diameter	200 μm
Transmission in the range from 500 nm to 715 nm and from 745 nm to 820 nm	> 80 %
Electrical insulation between connector and needle	> 100 M Ω
Laser beam divergence	NA ≤ 0.24 / beam divergence $\leq 14^\circ$
NOHD (Nominal ocular hazard distance) (calculation see Endoprobes [► 160])	3 m
Required approval	as medical device or as an accessory for a medical device

13.3 Technical data of VISULAS yag

	Value
UMDNS No.	17-446
Operating mode	Continuous operation
Expected service life according to IEC 60601-1	12,000 h
Laser type	Nd:YAG laser, flash lamp-pumped, Q-switched
Laser class	Class 4 (in accordance with IEC 60825-1)
Wavelength of therapy beam	1064 nm \pm 2 nm
Pulse duration	< 4 ns (typically 2 ns to 3 ns)
Laser beam guidance	Free beam arrangement in the head of the laser slit lamp
Laser energy in YAG pulse mode 1 (single pulse)	9.0 mJ to 13.0 mJ at max. 2.5 Hz
Laser energy in YAG pulse mode 2 (double pulse)	18.0 mJ to 28.0 mJ at max 1.0 Hz (33 kHz burst frequency)
Laser energy in YAG pulse mode 3 (triple pulse)	29.0 mJ to 45.0 mJ at max 1.0 Hz (33 kHz burst frequency)
Energy attenuation	2/4/6/8/10/12/14/16/20/24/28/32/36/40/42/48/56/60/64/70/80/100 %
Focus diameter	6.5 μ m \pm 20 % in air
Laser beam divergence	14° \pm 20 % round angle
Aiming beam	Diode, 4-point aiming beam (switchable to 2-point aiming beam), 660 nm to 680 nm, max. 150 μ W at the cornea (class 1 according to IEC 60825-1)
Focus shift between aiming and therapy beam	0/150/225/300 μ m, toggle between anterior and posterior
Device group	2 in accordance with ISO 15004-2
LED illumination	Continuously adjustable brightness
Slit width	0 mm to 14 mm (continuously)
Slit height	1/3/5/9/14 mm
Slit image rotation	0°/ \pm 45°/90°
Pupil distance setting range	55 mm to 78 mm

	Value
Adjustment range for the observer's refractive error	-5 D to +5 D
Magnification	8x/12x/20x
Rated voltage; frequency	100 V to 240 VAC ($\pm 10\%$); 50/60 Hz
Power consumption	400 VA
Electrical power supply of LSL yag	Supplied by laser console
Ingress protection rating of LSL yag and console	IP 20
Protection class	I
Device type	B (in accordance with IEC 60601-1)
Fuses	2 x T 4.0 A; H; 250 V
Cooling system	Thermoelectric
Laser console dimensions (H x W x D)	201 mm x 230 mm x 290 mm
Laser console weight	≤ 8 kg
Control panel weight	≤ 2 kg
Weight of laser slit lamp	≤ 16.0 kg
NOHD (Nominal ocular hazard distance) (calculation see LSL yag laser slit lamp and LSL green combi [► 156])	4 m

13.4 Technical data of VISULAS combi

13.4.1 Laser console combi

	Value
UMDNS No.	17-446
Operating mode	Continuous operation
Expected service life according to IEC 60601-1	12,000 h
Coagulation laser type	Frequency doubled Nd:YVO ₄ , diode-pumped, cw
Laser class of coagulation laser	Class 4 (in accordance with IEC 60825-1)
Wavelength of therapy beam for laser coagulation	532 nm ±1 nm
Maximum power on laser exit aperture of coagulation laser source	3 W
Max. power of coagulation laser at cornea in cw mode	1500 mW
Pulse duration of coagulation laser (single pulse):	10 ms to 2500 ms, cw (max. 180 s)
Pulse duration of coagulation laser (multi spot)	10/20/30/40/50 ms
Pulse interval of coagulation laser	10 ms to 6000 ms (adjustable)
Max. laser energy at cornea in selective mode	65 µJ (this corresponds to a fluence of 2.6 J/cm ²)
Pulse duration (selective mode)	150 ns to 5 µs (1/e ²) 100 ns to 300 ns (FWHM)
Max. pulse repetition frequency	1 kHz
Aiming beam of coagulation laser	Diode, 620 nm to 650 nm, max. 1 mW at the cornea (class 2 in accordance with IEC 60825-1)
Rated voltage; frequency	100 V to 240 V AC (±10 %); 50/60 Hz
Power consumption	400 VA
Ingress protection rating	IP 20
Protection class	I
Device type	B (in accordance with IEC 60601-1)

	Value
Fuses	2 x T 4.0 A; H; 250 V
Cooling system	Thermoelectric
Dimensions of laser console (H x W x D)	201 mm x 230 mm x 290 mm
Laser console weight	≤ 8 kg
Control panel weight	≤ 2 kg

13.4.2 LSL green combi laser slit lamp

	Value
Operating mode	Continuous operation
YAG laser type	Nd:YAG laser, flash lamp-pumped, Q-switched
YAG laser class	Class 4 (in accordance with IEC 60825-1)
Wavelength of YAG therapy beam	1064 nm ±2 nm
Pulse duration	< 4 ns (typically 2 ns to 3 ns)
Laser beam delivery of coagulation laser	Interlaced with slit illumination system
Nd:YAG laser beam guidance	Free beam arrangement in the head of the laser slit lamp
YAG pulse mode 1 (single pulse)	9.0 mJ to 13.0 mJ at max. 2.5 Hz
YAG pulse mode 2 (double pulse)	18.0 mJ to 28.0 mJ at max 1.0 Hz (33 kHz burst frequency)
YAG pulse mode 3 (triple pulse)	29.0 mJ to 45.0 mJ at max 1.0 Hz (33 kHz burst frequency)
YAG energy attenuation	22 levels: 2/4/6/8/10/12/14/16/20/24/28/32/36/40/42/48/56/60/64/70/80/100 %
YAG focus diameter	6.5 µm ±20 % in air
YAG laser beam divergence	14° ±20 % round angle
YAG aiming beam	Diode, 2-point / 4-point (switchable) 660 nm to 680 nm, max. 150 µW at the cornea (class 1 in accordance with IEC 60825-1)
Focus shift between aiming and therapy beam	0/150/225/300 µm, toggle between anterior and posterior

	Value
NOHD YAG laser (calculation see LSL yag laser slit lamp and LSL green combi [► 156])	4 m
Laser beam delivery of coagulation laser	Interlaced with slit illumination system
Size of coagulation laser spot	Continuously adjustable from 50 µm to 1000 µm (without contact lens), parfocal, larger spot sizes depending on contact lens used
Laser beam divergence of coagulation laser	$NA \leq 0.12$ / beam divergence $\leq 7^\circ$
NOHD coagulation laser (calculation see LSL green classic and comfort laser slit lamps [► 158])	16 m
Device group	2 in accordance with ISO 15004-2
LED illumination	Continuously adjustable brightness
Slit width	0 mm to 14 mm (continuously)
Slit height	1/3/5/9/14 mm
Slit image rotation	$0^\circ/\pm 45^\circ/90^\circ$
Magnification	5x/8x/12x/20x/32x
Pupil distance setting range	55 mm to 78 mm
Adjustment range for the observer's refractive error	-5 D to +5 D
Electrical power supply	Supplied by laser console
Ingress protection rating	IP 20
Weight	≤ 16.0 kg

13.4.3 LIO VISULAS green

See LIO VISULAS green [► 131].

13.4.4 Endoprobes

See Endoprobes [► 132].

13.5 Ambient conditions

	Value
Ambient conditions for operation	
Temperature	+15 °C to +30 °C
Relative humidity	Max. 90 % (non-condensing)
Altitude	up to 3000 m above sea level
Ambient conditions for storage and transport in original packaging	
Temperature	-40 °C to +70 °C
Relative humidity	≤ 95 % (non-condensing)
Air pressure	500 hPa to 1,060 hPa
Ambient conditions for storage and transport without original packaging	
Temperature	-10 °C to +55 °C
Relative humidity	≤ 85 % (non-condensing)
Air pressure	700 hPa to 1,060 hPa

13.6 Electromagnetic compatibility

13.6.1 Ambient conditions for intended use

With regard to electromagnetic compatibility, the VISULAS models are intended for use in the professional medical work environment (e.g. hospitals, surgical centers, operating rooms). They are not intended for use outside an HF shielded room of a magnetic resonance imaging medical device. Furthermore, the device should not be operated in private healthcare or in special environments with increased electromagnetic interference sensitivity or interference emission (e.g. in the vicinity of radar systems or short-wave therapy devices).

13.6.2 Restriction on clinical functions

The following characteristics have been demonstrated during electromagnetic interference:

- No unexpected laser emission without actuation of the laser control switches¹
- No laser power deviation of more than 20 % without warning message and no laser power deviation of more than 50 % without error message during laser emission due to unintended laser output parameter modification²
- No misplaced laser shots due to unintentional change of position of the therapy laser beam³

Restrictions of clinical functions due to electromagnetic interference are unlikely. Possible side effects and complications in case of failure of the above clinical functions are described in the software descriptions of the available licenses. The interfering radiation has no influence on other clinical functions.

¹ Unintentional triggering of the laser by electromagnetic interference is unlikely, due to suitable design measures. Should unintentional triggering nevertheless occur, operate the laser EMERGENCY STOP function. You will recognize the triggering by an acoustic and / or optical indication on the laser emission display.

² The unintentional increase of laser energy / power due to electromagnetic interference is unlikely, due to appropriate design measures. If an unintentional increase of the laser output parameters and the associated visible side effects should nevertheless occur, stop the treatment via the control switch for laser emission. You will recognize increased laser energy / power by increased bleeding into the treated tissue or spread of disruption or coagulation to adjacent tissue.

³ The unintentional change in position of the laser due to electromagnetic interference is unlikely, due to appropriate design measures. If an unintentional change in position nevertheless occurs, stop the treatment via the control switch for laser emission. You will recognize a change in position by the change in the aiming beam or the local effect in the treatment area.

CAUTION!

Hazard from electromagnetic radiation

Using the device in direct proximity to other devices or stacked together with other devices should be avoided as this could result in faulty operation. If it is nonetheless necessary to operate the device in the aforementioned manner, the device and the other devices should be monitored to ensure 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 VISULAS, including cables specified by the manufacturer. Otherwise, deterioration in the performance is to be anticipated.

Relevant accessories, optional components and cables:

- VISULAS laser consoles
- VISULAS control panel
- VISULAS laser slit lamps
- Standard foot switch (1.6 m)
- TouchControl foot switch (1.6 m)
- Extension cable for foot switch (3.4 m)
- Power supply cable (2.5 m, country-specific)
- LIO VISULAS green laser indirect ophthalmoscope (5 m)
- Fixation lamp
- Flashing diode (red) for fixation lamp
- IT 1060.i instrument table
- IT 760.i instrument table
- Laser warning light
- Doorlock isolator
- Panel PC
- SL Imaging Solution
- LSL InsightView display
- VISUCONNECT 600 (network adapter)

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

13.6.3 Guidelines and manufacturer's electromagnetic compatibility declaration

The following guideline applies exclusively to parts specified for and delivered with the device by the manufacturer or seller.

Guidance and manufacturer's declaration – electromagnetic emissions	
VISULAS is intended for use in the electromagnetic environment specified below. The customer or the user is responsible for ensuring that it is operated in such an environment.	
Emissions test	Compliance
HF emissions CISPR 11	Group 1
HF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies

NOTE! The properties of the device determined by emissions permit its use in industrial areas and in hospitals (CISPR 11, Class A). If used in a residential area (for which Class B usually is required as per CISPR 11), the device may not provide the necessary protection with regard to radio frequency communication services. The user may have to take corrective measures such as moving or realigning the device.

Guidance and manufacturer's declaration – electromagnetic immunity		
VISULAS is intended for use in the electromagnetic environment specified below. The customer or the user is responsible for ensuring that it is operated in such an environment.		
Electromagnetic immunity test	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst immunity IEC 61000-4-4	±2 kV; 100 kHz repetition rate for power supply lines ±1 kV; 100 kHz repetition rate for signal lines including lines with a maximum length of less than 3 m	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV for line(s) to line(s) ±2 kV for line(s) to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T ; 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; for 1 cycle and 70 % U_T for 25 / 30 cycles, single-phase: at 0° 0 % U_T ; 250 / 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VISULAS requires continued operation during power mains interruptions, it is recommended that the VISULAS be powered from an uninterruptible power supply or a battery.
Magnetic fields IEC 61000-4-8	30 A/m at 60 Hz	Magnetic fields in the power frequency should correspond to the typical values that are found in business and hospital environments.
Note: U_T is the AC voltage supply before application of the test level.		

Guidance and manufacturer's declaration – electromagnetic immunity	
The VISULAS is intended for use in the electromagnetic environment specified below. The customer or the user is responsible for ensuring that the device is operated in such an environment.	
Electromagnetic immunity test	Compliance level
Conducted HF disturbances pursuant to IEC 61000-4-6 including lines with a maximum length of less than 3 m	3 V _{rms} 150 kHz to 80 MHz
	6 V _{rms} ISM bands ^a
	80 % AM at 1 kHz
Radiated HF disturbances IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz
Radiated HF disturbances by near fields of wireless communication devices as per IEC 61000-4-3	27 V/m 385 MHz
	28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz
	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5500 MHz, 5785 MHz
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.	
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection by structures, objects and persons.	
^a The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.	

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14 Optional components and accessories

Please refer to the instructions of use of the relevant accessories and optional components.

- License for "VERTE" coagulation treatments
- License for "YAG" photodisruption treatments
- License for "VOLANTE" membranectomy treatment
- License for "SLT" selective laser trabeculoplasty treatment
- Multi-spot license "VITE"
- License for exporting treatment data "LASER REPORT"
- VISUCONNECT 600 for data transfer from VISULAS to FORUM (see instructions for use of VISUCONNECT 600 and Section VISUCONNECT 600 [► 147])
- Panel PC
- SL Imaging Solution (see instructions for use of SL Imaging Solution and Section SL Imaging Solution [► 150])
- LSL InsightView display
- Standard foot switch (1.6 m)
- TouchControl foot switch (1.6 m)
- IT 1060.i instrument table (see instructions for use of the instrument table and Section Instrument table [► 147])
- IT 760.i instrument table (see instructions for use of the instrument table and Section Instrument table [► 147])
- LSL breathing shield
- LIO breathing shield
- Table mounting for VISULAS green on IT 1060.i / IT 760.i
- Foot extension for IT 1060.i instrument table (see instructions for use of the instrument table and Section Instrument table [► 147])
- Adapter plate for foot switch on IT 1060.i / IT 760.i
- Extension cable for foot switch (3.4 m)
- Ergo tube
- Parallel or convergent tube $f = 140 \text{ nm}$
- 12.5 eyepiece for laser slit lamp
- Monocular assistant's scope with eye patch
- YAG laser safety goggles
- Argon / 532 laser safety goggles
- Laser safety goggles for combined protection against infrared and green laser radiation
- Laser warning lamp (see laser warning lamp addendum)
- LIO VISULAS green laser indirect ophthalmoscope

- Battery for LIO VISULAS green (1919-P-5338), ZEISS order number 000000-2222-038
- LED for LIO VISULAS green (1012-P-5305), ZEISS order number 000000-2222-088
- Transport case for LIO VISULAS green
- Doorlock isolator (only if third party laser warning lights are used)
- Laser training eye with holder (complete kit with 10 spare capsules, membranes, fundi and irises)
- Spare capsules for laser training eye (25 pc.)
- Spare membranes for laser training eye (25 pc.)
- Spare irises for laser training eye (25 pc.)
- Spare fundi for laser training eye (25 pc.)
- AT 030 applanation tonometer (see instructions for use of the AT 030 applanation tonometer and Section AT 030 [► 150])
- Physician's safety filter for surgical microscopes
 - Active physician's safety filter, single, for ZEISS /Möller-Wedel surgical microscope
 - Active physician's safety filter, double, for ZEISS / Möller-Wedel surgical microscope
 - Fixed physician's safety filter for ZEISS / Möller-Wedel surgical microscope
 - Active physician's safety filter, single, for Leica / Wild surgical microscope
 - Active physician's safety filter, double, for Leica / Wild surgical microscope
 - Fixed physician's safety filter, for Leica / Wild surgical microscope
- Contact lenses
- Laser endoprobes
- Head strap
- Arm rest

These instructions for use also describe configurations that are not necessarily included in the individual delivery scope. The differences in the configurations available to the user are due to the country-

specific registration status of the device. A current list of accessories which are approved in your country can be obtained from your ZEISS contact partner.

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

Use only accessories, detachable parts and spare parts which are approved by ZEISS for this system. The system safety during operation cannot be guaranteed if accessories and spare parts are used that are not approved by ZEISS.

14.1 Instrument table

ZEISS IT.i instrument tables can be used for the installation of VISULAS. If you are using other tables, they must meet the following requirements:

- Load-bearing capacity for the weight of the device configuration used
- Adjustable height to fit the size of the patient
- Possibility to screw the laser slit lamp into the two mounting holes
- Tilt stability with the configuration at 10° inclination
- Compliance with the limits specified in Safety inspections when using the power supply via the table
- Suitability of the instrument table power supply for the power consumption of the connected devices when supplying power to the devices via the table
- Certification mark of a nationally recognized test laboratory according to the IEC 60601-1 standard or equivalent for the motor-driven instrument table

If these requirements are not met, the safety of the configuration may be reduced.

14.2 VISUCONNECT 600

VISUCONNECT 600 converts or saves data in a data format that can be read and saved by patient management systems such as ZEISS FORUM.

VISULAS transmits the treatment data to VISUCONNECT 600 via serial connection. A specially configured serial cable is supplied for this electronic connection, which connects to the SERVICES port of the VISULAS console and the RS232 port of the VISUCONNECT 600.

Note that the serial cable also supplies power to VISUCONNECT 600. No additional power supply unit is needed. Please consult the VISUCONNECT 600 instructions for use.

14.3 Panel-PC (SL Workstation)

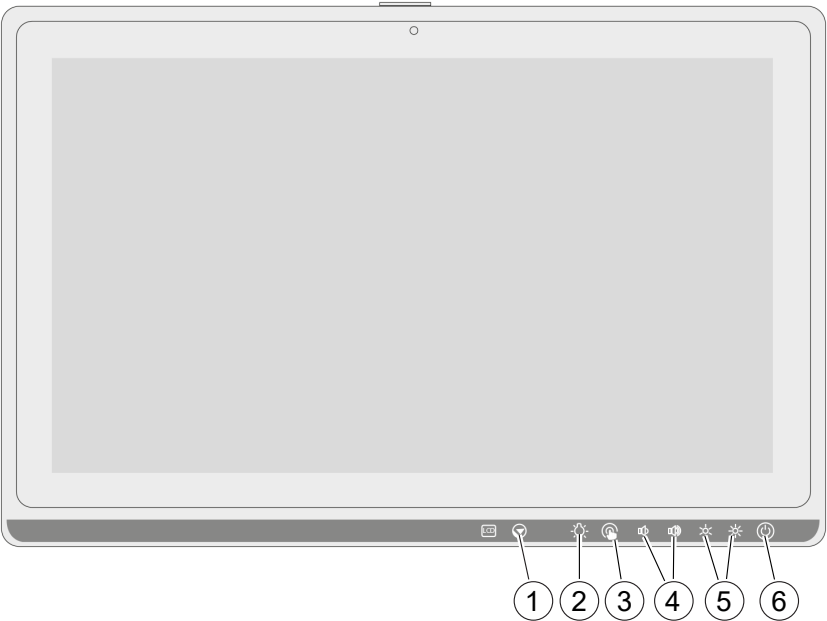


Figure 51: Front view of SL Workstation

1	LCD on / off	2	Reading light
3	Touch screen on / off	4	Volume
5	LCD brightness	6	Power switch

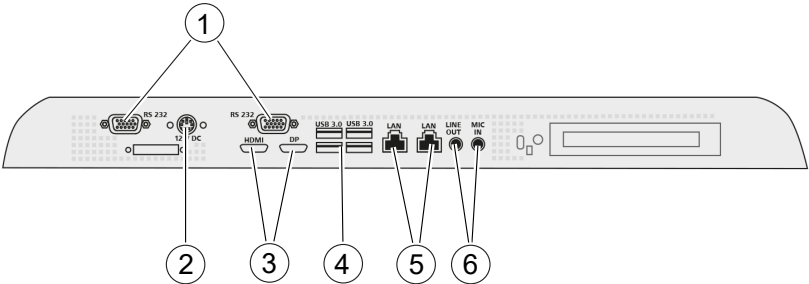


Figure 52: Plug-in connections on the underside of the SL Workstation

1	2 x RS 232 (Service plug)	2	Power supply connection 12 V DC
3	HDMI and DisplayPort	4	4x USB 3.0
5	2x 1.5 kV Isolated Gigabit Ethernet Port	6	Audio (mic-in / line-out) (service ports)

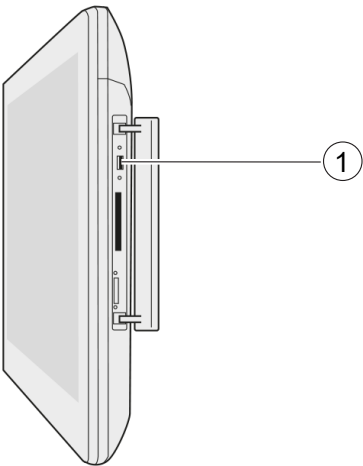


Figure 53: Lateral connections of the SL Workstation

1	USB 3.1 x 2		
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14.4 SL Imaging Solution

For the use of VISULAS in combination with SL Imaging Solution, the instructions for use of SL Imaging Solution and the Microsoft Software License Agreement apply with the following additional instructions:

- The VISULAS laser slit lamp offers a connection adapter which is designed in the same way as the adapters of the SL 120 and SL 130 slit lamps. Mounting is performed according to the corresponding instructions in "Mounting the SL cam compact on the SL 120 and SL 130 slit lamps" of the SL Imaging Solution instructions for use.
- Installation of system components:
 - SL Workstation will be connected according to the figure "Installation of system components – schematic overview - SL 115 Classic, SL 120, SL 220, SL 130 Variant A with SL Workstation" in the SL Imaging Solution instructions for use.
 - The VISULAS laser consoles are supplied either via the instrument table (if supplied) or via a direct power connection.
 - The VISULAS laser slit lamps are supplied via the corresponding VISULAS laser console. There is no need for a separate supply connection.

14.5 AT 030

For the use of the AT 030 in combination with VISULAS, the instructions for use of the AT 030 applanation tonometer and the instructions for use and disinfection of tonometer measuring prisms (applied part) apply with the following additional instructions:

- The AT 030 can be attached to the VISULAS laser slit lamps with a special fixed tonometer holder. The corresponding tonometer holder can be purchased separately.

14.6 Doorlock isolator

NOTE! The doorlock isolator may only be connected to the VISULAS laser consoles.

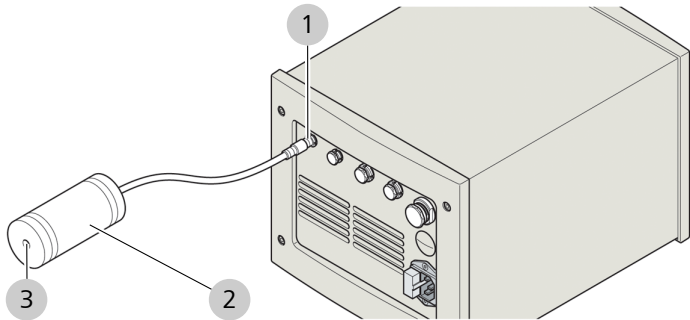


Figure 54: Connecting the doorlock isolator

1	Door contact interlock port	2	Doorlock isolator
3	Output socket for third party door interlock		

Action

1. Remove the connector from the interlock port of the laser console and connect the plug of the doorlock isolator with this port.
2. Connect the door contact interlock of your laser warning light with a 3.5 mm jack plug (mono) to the output socket of the doorlock isolator. The contact must be operated in floating mode (potential-free).

NOTE! The connection must be installed with strain relief so that the connector cannot be pulled inadvertently from the socket.

NOTE! The door contact of the ZEISS laser warning lamp can be connected to the interlock port of the door contact directly without a doorlock isolator.

14.7 Power cable

If the supplied power cable must be replaced, the following specifications must be adhered to as a minimum:

- Protective ground conductor for the overall configuration according to Safety inspection [► 111]
- Local certification of the power cable for connection to medical devices
- Device plug C13 conforming to IEC 60320
- Cross section and current capacity suitable for the overall configuration
- Hospital-grade version for certain countries (e.g. USA, Canada)

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15 References

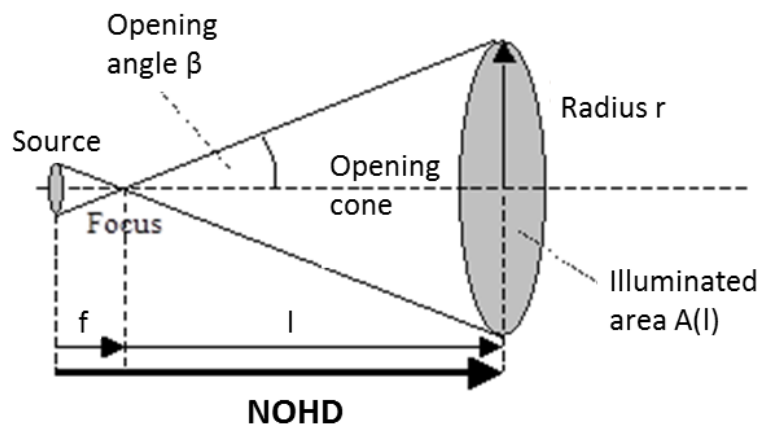
[1] Graph according to Kaschke M, Donnerhacke KH, Rill MS:
Optical Devices in Ophthalmology and Optometry. Wiley-VCH
2014, ISBN 978-3-527-41068-2.

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Appendix: NOHD calculation

According to applicable standards, a laser safety zone must be defined for all medical lasers of Class 3R or higher. In the following, the Nominal Ocular Hazard Distance (NOHD) is determined for all VISULAS laser models.

The following considerations are made for persons without special laser protection (e.g. assistants or persons accompanying patients) who are attending the laser treatment. Since both the attending physician and optional co-observers are protected by the internally installed filters, you can safely be inside the NOHD area. The same also applies to all persons wearing suitable laser safety goggles (532 DIR LB5 1064 D LB2 IR LB6 according to DIN EN 207).



Calculation of NOHD:

If E is the maximum pulse energy of the laser, r is the maximum pupil radius of the eye, l is the distance of the eye from the laser focus, β is half the divergence angle (angle of exit aperture) of the laser, and f is the distance between the laser aperture and the laser focus, then it follows:

$$\text{MPE} \times C_s < E / (\pi r^2)$$

$$\rightarrow \text{MPE} = E / (\pi l^2 \tan^2 \beta)$$

$$\rightarrow \text{NOHD} = f + l = f + 1 / \tan \beta [E / (\text{MPE} \times \pi)]^{1/2}$$

LSL yag laser slit lamp and LSL green combi

For the calculation of the maximum permissible exposure (MPE) and NOHD of the infrared Nd:YAG laser of VISULAS combi and VISULAS yag, the following assumptions were made:

- Since the aiming beam laser of the Nd:YAG laser is a class 1 laser, it is not considered below.
- The infrared radiation of the Nd:YAG laser is not visible. Nevertheless, when the laser radiation is emitted at high energies, an optical breakdown is produced which is clearly visible and audible. Therefore, a maximum exposure duration of 10 s is assumed in the following. This assumption is further supported by the fact that the Nd:YAG laser can only emit in single-shot mode due to the Q-switching.
- The maximum emittable laser energy of the VISULAS Nd:YAG laser is physically defined by the laser design and the absorbed light energy in the generated plasma. Studies have shown that the maximum emitted light energy from the focal area (location of the breakdown) does not exceed 2.6 mJ, regardless of whether the laser is operated in YAG pulse mode 1, 2, or 3.
- The laser source is assumed to be a point source.
- Compared to IEC 60825-1:2014, the calculations according to IEC 60825-1:2007 lead to lower results for the NOHD. For this reason, they will not be listed separately here.

Parameters for NOHD calculation:

Laser source	Q-switched Nd:YAG
Maximum energy per pulse	2.6 mJ (remaining energy is absorbed by plasma of optical breakdown)
Laser wavelength	1064 nm
Pulse duration of single pulse	4 ns
Maximum repetition rate	2.5 Hz (YAG pulse mode 1) 1.0 Hz (YAG pulse mode 2) 1.0 Hz (YAG pulse mode 3)
Number of possible shots during exposure as per IEC 60825-1:2014	25 (YAG pulse mode 1) 20 (YAG pulse mode 2) 30 (YAG pulse mode 3)
Number of possible shots during exposure as per IEC 60825-1:2007	25 (YAG pulse mode 1) 10 (YAG pulse mode 2; 2 pulses within 50 µs) 10 (YAG pulse mode 3; 3 pulses within 50 µs)

Minimum beam divergence angle	11.2 (195 mrad)
C5 parameters as per IEC 60825-1:2014	1 for all YAG pulse modes
C5 parameters as per IEC 60825-1:2007	0.4472 (YAG pulse mode 1) 0.5623 (YAG pulse mode 2) 0.5623 (YAG pulse mode 3)
Parameters C6 and C7 as per IEC 60825-1:2014 and IEC 60825-1:2007	1 for all YAG pulse modes
Focus distance f	0.11 m
MPE single pulse as per IEC 60825-1:2014	0.02 J/m ² for all YAG pulse modes
MPE single pulse as per IEC 60825-1:2007	0.05 J/m ² for all YAG pulse modes
MPE during exposure duration (10 s)	20.24 J/m ² (YAG pulse mode 1) 25.31 J/m ² (YAG pulse mode 2) 33.74 J/m ² (YAG pulse mode 3)
MPE mean pulses as per IEC 60825-1:2014 (T_i for 1064 nm = 13×10^{-6} s)	0.02 J/m ² for all YAG pulse modes
MPE mean pulses as per IEC 60825-1:2007 (T_i for 1064 nm = 50×10^{-6} s)	0.022 J/m ² (YAG pulse mode 1) 0.028 J/m ² (YAG pulse mode 2) 0.028 J/m ² (YAG pulse mode 3)
NOHD (highest value from IEC 60825-1:2007 and IEC 60825-1:2014)	2.18 m (YAG pulse mode 1) 2.58 m (YAG pulse mode 2) 3.14 m (YAG pulse mode 3)

Table 4: Parameters for NOHD calculation

LSL green classic and comfort laser slit lamps

For the calculation of the maximum permissible exposure (MPE) and NOHD of the green Nd:YVO₄ laser of VISULAS combi and VISULAS green, the following assumptions were made:

- Green laser light is clearly visible (maximum of the V(λ)-curve), therefore we assume a maximum exposure of 250 ms (eyelid closure reflex). Persons who are in the laser protection area but do not work directly with the laser and may not have laser protection goggles can close their eyes and turn away from the laser during this time.
- For the calculation of MPE and NOHD, the maximum laser power is defined by the maximum adjustable laser power + 50 % (according to IEC 60601-2-22).
- The laser source is assumed to be a point source.
- Since the MPE of the aiming beam laser is evaluated in the same parameter category of IEC 60825-1 and the emitted power is significantly below the power of the therapy laser, the aiming beam laser is not considered separately in the following.

Parameters for NOHD calculation:

Laser source	Nd:YVO ₄ (cw, short pulse)
Maximum power / energy per pulse	1.5 W + 50 % = 2.25 W (cw mode) 65 µJ + 50 % = 98 µJ (selective mode)
Laser wavelength	532 nm
Maximum pulse duration in selective mode	5 µs
Maximum number of emitted pulses during exposure (0.25 s)	52
Minimum beam divergence angle	1.6° (30 mrad)
C5 parameters as per IEC 60825-1:2014	1 for all YAG pulse modes
C7 parameters as per IEC 60825-1:2007	1 for cw mode 0.372 for selective mode
Focus distance f	0.11 m
MPE for single pulse	6.17 J/m ² (pulsed cw mode) 2 x 10 ⁻³ J/m ² (selective mode)

MPE during exposure duration (0.25 s)	<p>25.46 J/m² (cw mode)</p> <p>6.36 J/m² (pulsed cw mode)</p> <p>1.2 x 10⁻³ J/m² (selective mode as per IEC 60825-1:2014)</p> <p>6.36 J/m² (selective mode as per IEC 60825-1:2007)</p>
MPE for average pulses	<p>6.17 J/m² (pulsed cw mode)</p> <p>2.0 x 10⁻³ J/m² (selective mode as per IEC 60825-1:2014)</p> <p>1.0 x 10⁻³ J/m² (selective mode as per IEC 60825-1:2007)</p>
NOHD	<p>7.05 m (cw mode)</p> <p>12.06 m (pulsed cw mode)</p> <p>9.03 m (selective mode as per IEC 60825-1:2014)</p> <p>15.10 m (selective mode as per IEC 60825-1:2007)</p>

Table 5: Parameters for NOHD calculation

Endoprobes

For the calculation of the maximum permissible exposure (MPE) and NOHD of the green Nd:YVO₄ laser of VISULAS combi and VISULAS green, the following assumptions were made:

- Green laser light is clearly visible (maximum of the V(λ)-curve), therefore we assume a maximum exposure of 250 ms (eyelid closure reflex). Persons who are in the laser protection area but do not work directly with the laser and may not have laser protection goggles can close their eyes and turn away from the laser during this time.
- For the calculation of MPE and NOHD, the maximum laser power is defined by the maximum adjustable laser power + 50 % (according to IEC 60601-2-22).
- The laser source is assumed to be a point source.
- Since the MPE of the aiming beam laser is evaluated in the same parameter category of IEC 60825-1 and the emitted power is significantly below the power of the therapy laser, the aiming beam laser is not considered separately in the following.
- The calculation according to IEC 60825-1:2007 and IEC 60825-1:2014 lead to identical results and are therefore not listed separately.

Parameters for NOHD calculation:

Laser	Nd:YVO ₄ (cw)
Maximum power	1.5 W + 50 % = 2.25 W (cw mode)
Laser wavelength	532 nm
Minimum beam divergence angle	9° (157 mrad), pure divergent beam without focus
C5 parameters in accordance with IEC 60825-1:2014	1 for cw mode
Focus distance f	0 m
MPE for single pulse	6.17 J/m ² (pulsed cw mode)
MPE during exposure duration (0.25 s)	25.46 J/m ² (cw mode) 6.36 J/m ² (pulsed cw mode)
MPE for average pulses	6.17 J/m ² (pulsed cw mode)
NOHD	1.23 m (cw mode) 2.21 m (pulsed cw mode)

Table 6: Parameters for NOHD calculation

LIO VISULAS green

For the calculation of the maximum permissible exposure (MPE) and NOHD of the green Nd:YVO₄ laser of VISULAS combi and VISULAS green, the following assumptions were made:

- Green laser light is clearly visible (maximum of the $V(\lambda)$ -curve), therefore we assume a maximum exposure of 250 ms (eyelid closure reflex). Persons who are in the laser protection area but do not work directly with the laser and may not have laser protection goggles can close their eyes and turn away from the laser during this time.
- For the calculation of MPE and NOHD, the maximum laser power is defined by the maximum adjustable laser power + 50 % (according to IEC 60601-2-22).
- The laser source is assumed to be a point source.
- Since the MPE of the aiming beam laser is evaluated in the same parameter category of IEC 60825-1 and the emitted power is significantly below the power of the therapy laser, the aiming beam laser is not considered separately in the following.
- The calculations according to IEC 60825-1:2007 and IEC 60825-1:2014 lead to identical results and are therefore not listed separately.

Parameters for NOHD calculation:

Laser	Nd:YVO ₄ (cw)
Maximum power	1.5 W + 50 % = 2.25 W (cw mode)
Laser wavelength	532 nm
Minimum beam divergence angle	0.8° (10 mrad), pure divergent beam without focus
C5 parameters in accordance with IEC 60825-1:2014	1 for cw mode
Focus distance f	0.3 m
MPE for single pulse	6.17 J/m ² (pulsed cw mode)
MPE during exposure duration (0.25 s)	25.46 J/m ² (cw mode) 6.36 J/m ² (pulsed cw mode)
MPE for average pulses	6.17 J/m ² (pulsed cw mode)
NOHD	14.17 m (cw mode) 24.20 m (pulsed cw mode)

Table 7: Parameters for NOHD calculation

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Glossary

D

Diopter (unit of measurement of the refractive power of optical systems)

FWHM

Full width half maximum

HF

High frequency

LIO

Laser indirect ophthalmoscope

MPE

Maximum permissible exposure

NOHD

Nominal ocular hazard distance

YAG

Yttrium Aluminum Garnet (laser medium)

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