Software description of the SLT license

Documentation set

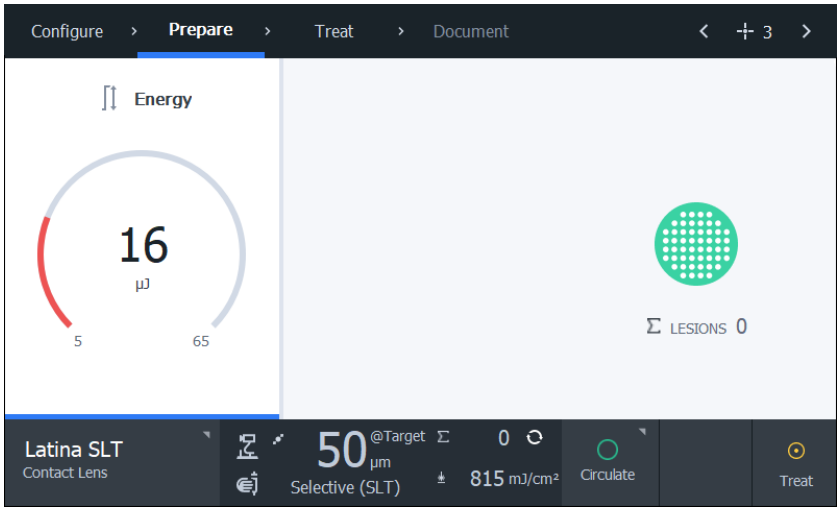

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Table of Contents

1 Notes on the instructions for use

1.1 Product name

VISULAS green, VISULAS yag or VISULAS combi are referred to in these instructions for use as "system". If statements or references apply equally to all models, the following will refer simply to "VISULAS".

The software license for configuring and controlling Selective Laser Trabeculoplasty (SLT) is referred to as "SLT" in these instructions for use.

1.2 Scope of application

The present instructions for use apply for the SLT license in combination with VISULAS models with the following marking:

- Reference number: 000000-2434-615 (SLT SW license)

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 [▶ 5].

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

These instructions for use apply only in combination with the VISULAS instructions for use. Please also refer to the enclosed quick reference guide and check at regular intervals whether a newer version of these instructions for use is available at http://www.zeiss.com/ifu.

Empty page, for your notes

2 General safety instructions

2.1 Intended use

VISULAS green is intended for use in photocoagulating ocular tissues in the treatment of diseases of the eye, including:

- Photocoagulation of the retina
- Trabeculoplasty
- Iridotomy

VISULAS green is intended for use in Selective Laser Trabeculoplasty (SLT).

VISULAS combi is intended for use in photocoagulating and photodisrupting ocular tissues in the treatment of diseases of the eye, including:

- Photocoagulation of the retina
- Trabeculoplasty
- Iridotomy
- Posterior capsulotomy
- Membranectomy

VISULAS combi is intended for use in Selective Laser Trabeculoplasty (SLT).

Within the scope of the software description of the SLT license, only the intended use "Selective Laser Trabeculoplasty" is covered. All other intended uses listed above are covered in the corresponding software descriptions of VISULAS.

2.2 Intended user profile

The operator of a therapeutic laser shall be an ophthalmologist who is trained in the use of therapeutic lasers, i.e., not an optometrist, technician or assistant. Please also adhere to the national qualification guidelines applicable in your country. ZEISS recommends that persons who are new to this treatment technique familiarize themselves thoroughly with the procedure. VISULAS laser systems may only be installed, operated, used and maintained by persons who have the necessary training, knowledge and experience. Furthermore, persons working or staying in the laser safety area must be instructed annually on the safety guidelines, precautions and operation of the laser system.

2.3 Clinical benefits

Treatment with the VISULAS, including all components and accessories, offers a clinical benefit in the treatment of various eye diseases with the aim of preventing disease progression or averting severe vision loss.

2.4 Patient population

If appropriate clinical Indications [▷ 10] are given and contraindications [▷ 10] are excluded, therapeutic laser treatment can in principle be performed in patients of all age groups. The safety and efficacy of the treatment method has not been established for children and adolescents.

2.5 Indications

- Primary open-angle glaucoma

2.6 Contraindications

The use of the device is contraindicated for the following indications:

- Acute angle-closure glaucoma if the trabecular meshwork is not sufficiently visible.
- Strong clouding of the anterior ocular media, such that the target area cannot be clearly identified
- Neovascular glaucoma
- Uveitic glaucoma

Contraindications are not limited to the above list. For a complete list of contraindications, please consult medical literature, associations and current legislation in your particular country.

2.7 Warnings

Objective evaluation of patients eligible for these procedures must be performed with consideration of the risks and contraindications, and weighing the potential desirable and undesirable effects.

▶ Avoid laser treatment with the VISULAS and laser slit lamp in the following patient groups:

- Patients who are unable to sit upright in front of the device
- Patients who have difficulty resting the head on the forehead and chin rest for several minutes, when sitting upright, e.g. patients with intervertebral disc problems, severely obese patients, pregnant women
- Patients who have forehead or chin injuries that prevent the head from being supported on the forehead rest or chin rest
- Patients who are unable to follow the instructions of the attending physician
- Patients who are not able to fixate adequately

- ▶ Be especially cautious about illuminance and illumination duration when examining premature infants, babies, toddlers, and aphakic patients.
- ▶ Treat patients with strong pigmentation of the chamber angle only with very low energy (typically 10 µJ), since the frequency of short-term increase in intraocular pressure correlates with the degree of pigmentation. Treat only in the range of 90° and repeat the treatment in several steps if required. Consult the literature for recommended treatment procedures and concomitant medications.
- ▶ Selective laser trabeculoplasty:
  The safety and efficacy of SLT has not been established for patients with:
  - post-traumatic glaucoma with angle recession and
  - angle dysgenesis.

2.8 Precautions

Please also observe the precautionary notes in the accompanying VISULAS instructions for use.

2.8.1 General information

- ▶ Keep these instructions for use where they are easily accessible at all times for the persons operating the device.

2.8.2 Instructions for treatment preparation

- ▶ Protect the laser area from being entered by unauthorized persons.
- ▶ Ensure that only persons whose presence is required are in the laser area.
- ▶ Keep reflective or shiny objects or surfaces away from the vicinity of the laser beam or cover the surfaces. Cover windows and reflecting walls with non-combustible cloths.
- ▶ Make sure that the dioptric correction on the slit lamp is set to your visual acuity.
- ▶ Notify the persons present in the laser area immediately before switching to laser ready mode. This gives those present in the laser area the opportunity to take all necessary protective measures in good time, in particular to put on the laser safety goggles.

2.8.3 General notes on handling the device

- If operating or adjustment devices different from those specified here are used or other procedures are carried out, this may lead to dangerous radiation exposure.
- Do not touch electrical contacts (e.g. electrical interfaces or lamp holders) and the patient at the same time.
- Switch the unit to laser standby mode if you are not planning an immediate treatment or if treatment preparation must be interrupted. The standby mode prevents unintentional exposure to laser radiation should the foot switch be accidentally actuated.

2.8.4 Notes on laser treatment

- The efficacy and safety of this combination has not been demonstrated in the following cases:
  - for children and adolescents,
  - for all forms of secondary open-angle glaucoma.
- Please refer to the instructions for the treatment of patients with a strongly pigmented chamber angle in Warnings [▶ 10].
- Ensure that all persons in the laser area (except physician and patient) can see the VISULAS laser emission display clearly.
- Check the integrity of the beam delivery system. Because the aiming beam follows the same optical path through the beam delivery system as the therapy beam, it represents a good method for checking that the beam delivery system is undamaged. If the aiming beam at the laser exit aperture is not visible, is weak or appears diffuse, it may indicate damage to or improper function of the laser beam delivery system.
- Always focus the slit lamp so that the trabecular tissue to be treated and aiming beam are both sharply in focus.
- Only use instruments for medical application in the laser beam path which are shaped or surface-finished to prevent hazardous reflection.
- Do not put flammable materials, solutions or gases into the beam path of the laser. Fire or explosion hazard exists if the laser exit aperture is used in the presence of flammable materials, solutions or gases or in an oxygen-enriched environment. Some materials saturated with oxygen, e.g. cotton, can be ignited at the high temperatures that occur when the laser device is used as intended.
- Avoid irradiation of eyes that are not intended to be treated and irradiation of skin surfaces by direct or scattered radiation.
- Do not apply the therapy beam to skin surfaces for demonstration purposes. Test eyes can be purchased from Carl Zeiss Meditec for demonstration purposes.

- When using a monocular co-observation tube during laser treatment, cover the second eye of the co-observer with the supplied eye patch.
- Avoid severe bending, kinking or incomplete attachment of fiber optic equipment. This can lead to unintentional leakage of laser radiation at the damaged areas.
- Ensure that the substances coming into contact with the laser radiation, e.g. silicone oils, gases, do not produce hazardous substances.
- Make sure that the substances coming between the target tissue and the laser exit aperture, e.g. silicone oils, gases, contact gel, anesthetics, do not restrict the view of the target tissue or create unwanted reflections. Transmission losses can lead to undesirable local effects and associated side effects.
- Use the supplied laser safety goggles (order number 000000-0619-616) or provide the following laser safety goggles for persons in the laser area during coagulation treatments: 532 DIR LB5.
- Ensure that the eye to be treated is stabilized by appropriate measures to avoid unwanted eye and head movements.
- Hold the contact lens surface as perpendicular as possible to the aiming and therapy beam for treatment.
- Use contact lenses that are suitable for the maximum laser power or energy and that have an anti-reflective coating to reduce back reflections.
- Only use contact lenses with a magnification factor of 1.0, as other magnification factors change the beam diameter and laser energy density.
- Do not use the "Selective Laser Trabeculoplasty" (SLT) option on the retina.
- Note that if there is no or reduced pigmentation of the tissue to be treated, the desired treatment effect cannot be achieved.
- Use the lowest possible power necessary to achieve the desired clinical effect.
- Never fire the laser if the aiming beam is not clearly visible in the area to be treated.
- Observe the treatment area during laser treatment and stop the treatment in case of hazardous situations.
  - ⇨ In individual cases, green laser light may be perceived at the eyepiece. This does not represent a malfunction, as the perception threshold of green laser light is far below the laser safety limit.
- Measure the patient's intraocular pressure after laser treatment and administer the necessary medication if there is a marked increase.

- Avoid vibrations during laser treatment.
- Examine the patient for adverse reactions in the area of skin that comes into contact with the device, such as redness (erythema), swelling (edema), irritation, sensitization (delayed type IV hypersensitivity), allergy, immune reaction, or other reactions. Report such side effects to the manufacturer.

2.8.5 Notes on illumination

- Limit the exposure intensity and the exposure time of the co-observation illumination. Please observe the relevant information in "Brightness control" of the VISULAS instructions for use.

ATTENTION - The light emitted by this device may be harmful. The longer the duration of exposure, the greater the risk of ocular damage. Exposure exceeding 54 minutes at maximum intensity level with LIO or exposure exceeding the specified durations in the following table for laser slit lamps will result in exceeding the reference value for hazard.

Maximum radiation exposure times per applicator / model in [min]:[s]				
Retina protection filter	Without retina protection filter		With retina protection filter	
Brightness level in [%]	100 % 	50 % 	100 % 	50 % 
Applicator (model)				
LSL (VISULAS green and combi)	08:30	20:30	198:00	Not applicable[1]
LSL (VISULAS yag)	03:24	11:00	42:00	Not applicable[1]

[1] The brightness value of 50 % with retinal protection filter is unsuitable for co-observation of a treatment due to insufficient brightness and is not specified for this reason.

Exposure times apply to cumulative retinal exposure. Exposure times are specified for clear media. Opaque media and / or blood extend these times. For the LIO optical radiation hazard check, the diameter of the ophthalmoscopy lens used was 48 mm and the refractive index was 20 m^{-1}

- When operating the system, avoid looking directly into the light emitting prism of the laser slit lamp.
- Never look into the sun or other intense light sources through the binocular tube and eyepieces.

2.8.6 Changing the laser applicator

- Never start treatment if a different applicator is shown in the display to the one required, and / or if no physician's safety filter is fitted.
- Deactivate the treatment beam and always switch the aiming beam off before changing the applicator or releasing the applicator fibers from the laser module for any other reason.
- After physically changing the applicator, e.g. from laser indirect ophthalmoscope to slit lamp, also select the desired new applicator in the main menu of the control unit.
- Please note that incorrect release of the fiber when the laser is in operation may result in a brief discharge of scattered radiation to the surroundings.
- When laying and using the fiber optics, please note that reducing the minimum bending radius below 20 mm can lead to lasting damage to the fiber.

2.9 Side effects

Selective laser trabeculoplasty:

- Ocular pain
- Visual disturbances, e.g. photophobia
- Ocular hypertension
- Disorders of cornea, e.g. inflammation, endothelial change
- Anterior chamber hemorrhage
- Iridocyclitis
- Disorders of iris and ciliary body, e.g. synechiae, pigment dispersion
- Disorders of conjunctiva, e.g. hyperemia, subconjunctival haemorrhage
- Disorders of retina, e.g. macula edema

Side effects are not limited to the list above. For further information on a comprehensive list of side effects, please consult the relevant medical literature, professional associations and the legislation applicable in your country.

2.10 Risk-relevant performance features of clinical functions

Please observe the risk-relevant performance features noted in the VISULAS instructions for use.

3 Preparation of the system for laser treatments

The Selective laser trabeculoplasty can only be used in combination with VISULAS green and VISULAS combi once the SLT treatment license has been activated. This treatment license is provided by Carl Zeiss Meditec or its authorized representatives on the basis of a commercial agreement.

3.1 Default software settings

Use the "Settings" button in the right upper corner to open the "Settings" dialog.

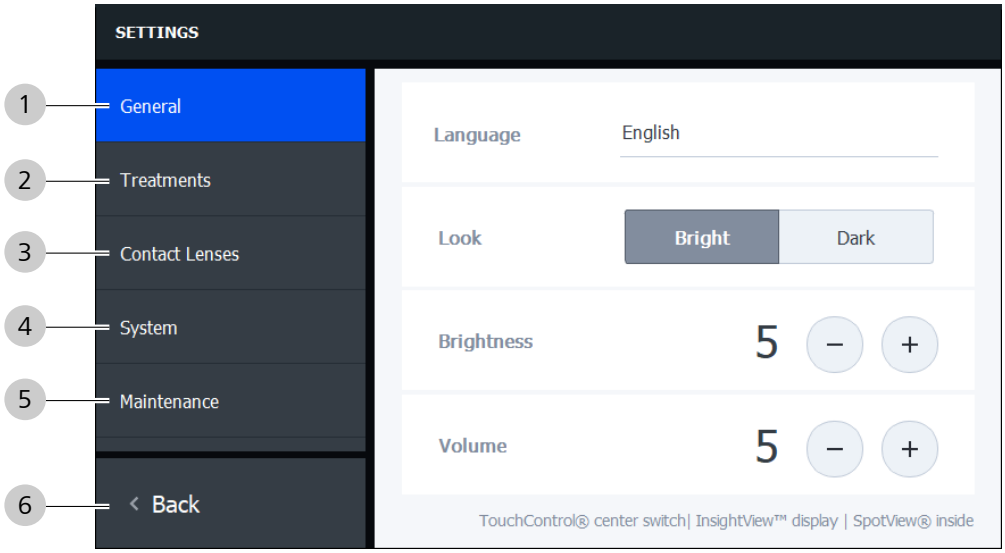


Figure 1: "Settings" dialog

Item	Icon / Name	Explanation
1	General	Access and customize the settings of the user interface.
2	Treatments	Access and customize treatment profiles.
3	Contact Lenses	Access and customize contact lens profiles.
4	System	Access system information and activate DEMO mode.
5	Maintenance	Access license options and maintenance information
6	Back	Close the "Settings" dialog. Return to the main dialog.

3.1.1 General

On this tab, general settings of the user interface can be set, such as language or look.

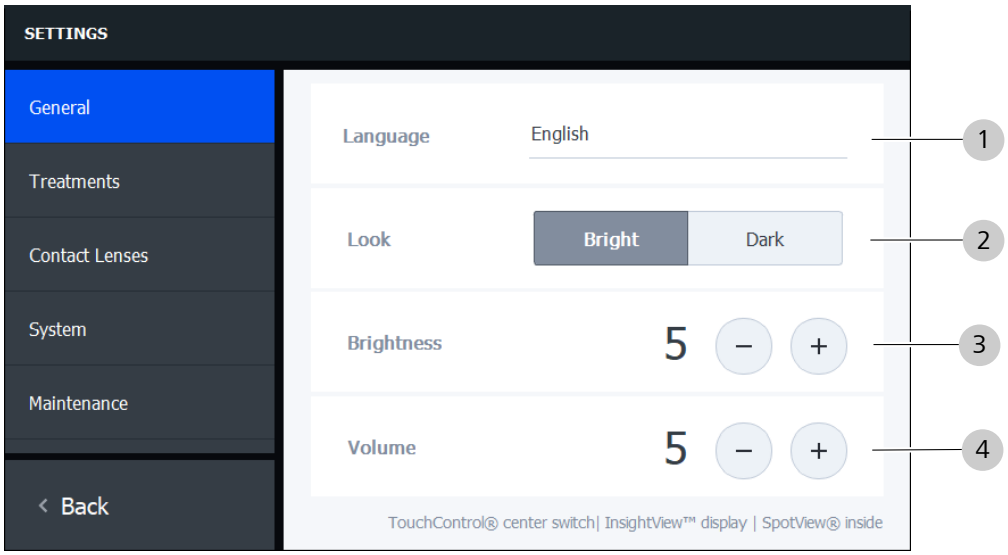


Figure 2: "General" tab

Item	Icon / Name	Explanation
1	Language	Use the drop-down list to select the display language.
2	Look	Select the dark or bright theme for the look of the user interface. ■ Bright: bright user interface ■ Dark: dark user interface
3	Brightness	Use [+] and [-] buttons to set the brightness of the control panel.
4	Volume	Use the [+] and [-] buttons to set the volume for warning and information alarms.

3.1.2 Treatments

On this tab, you can preset frequently required treatment configurations. These are assigned to user profiles and are available when the respective user is selected.

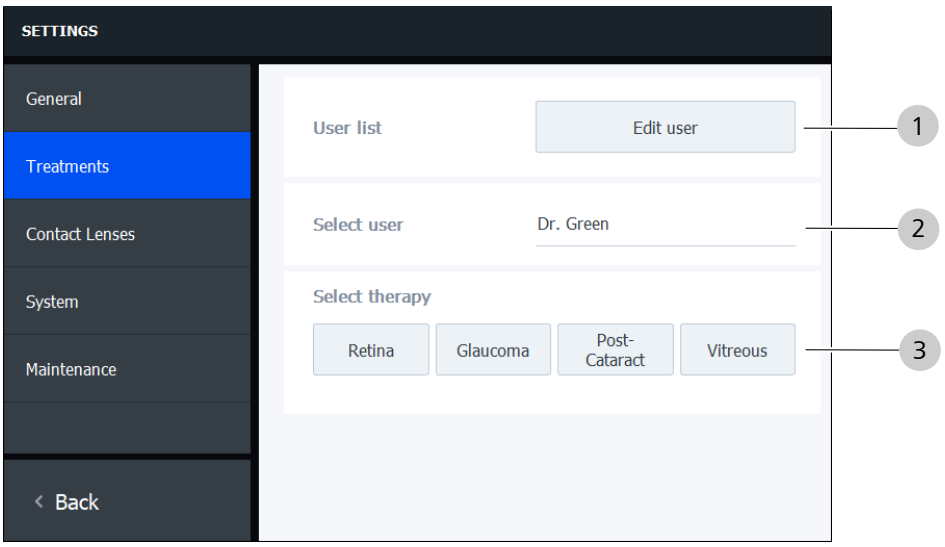


Figure 3: "Treatments" tab

Item	Icon / Name	Explanation
1	User list	Edit the data of the selected user name.
2	Select user	Use the drop-down list to select the user. The default profile name is "Standard"
3	Select therapy	Select a therapy for which the user-specific settings are to be made.
	Retina	Select retina treatment.
	Glaucoma	Select glaucoma treatment.
	Post-Cataract	Select post-cataract treatment.
	Vitreous	Select vitreous body treatment.

3.1.2.1 User management

In this dialog, you can manage users. Profiles may be added, edited or deleted.

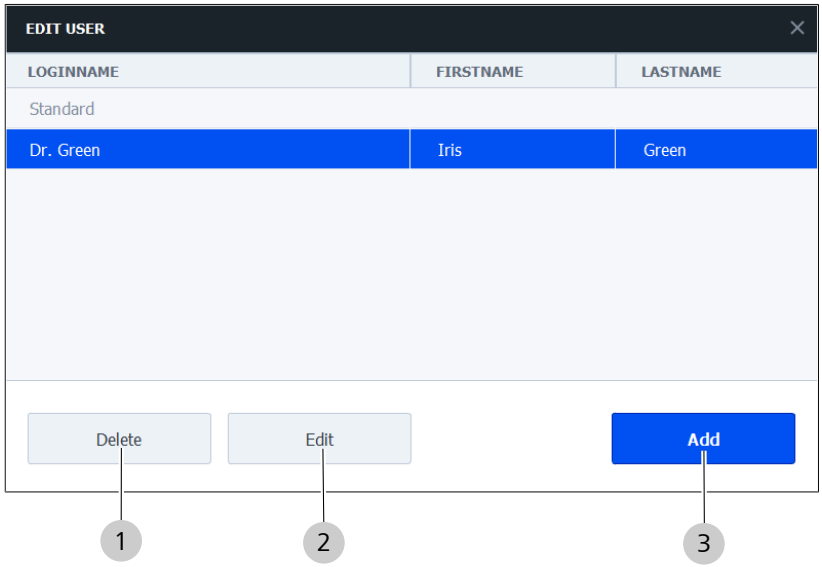


Figure 4: "EDIT USER" dialog with current user list

Item	Icon / Name	Explanation
1	Delete	Delete the selected user. The action must be confirmed in the following dialog.
2	Edit	Edit the select user.
3	Add	Add a user.

Add or edit a user

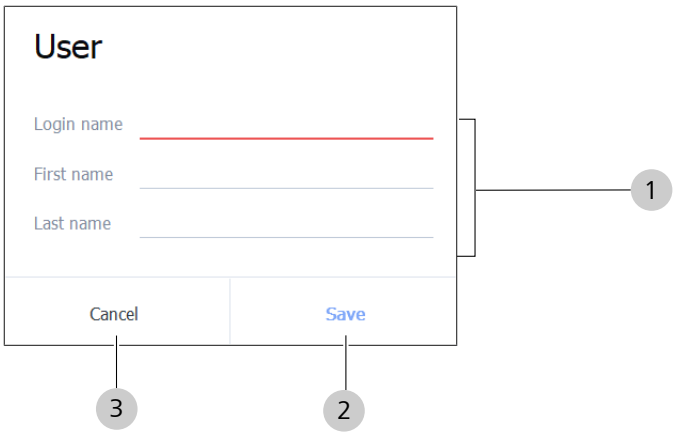


Figure 5: "User" dialog

Item	Icon / Name	Explanation
1	Input area	Enter user data.
2	Save	Save and close the dialog.
3	Cancel	Close the dialog without saving.

3.1.3 Selection and parameterization of contact lenses

On this tab, you can manage contact lens data. Contact lenses may be added, edited or deleted.
An overview of the default contact lenses can be found in the Default parameters [▶ 41].

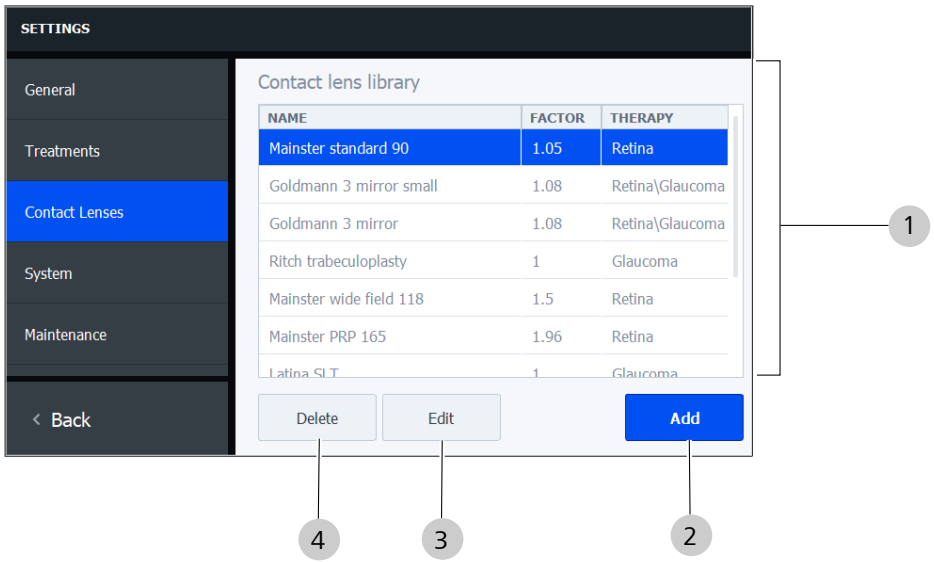


Figure 6: "Contact Lenses" tab

Item	Icon / Name	Explanation
1	Contact lens library	List of currently available contact lenses
2	Add	Add a contact lens.
3	Edit	Edit the selected contact lens.
4	Delete	Delete the selected contact lens. The action must be confirmed in the following dialog.

Add or edit a contact lens profile

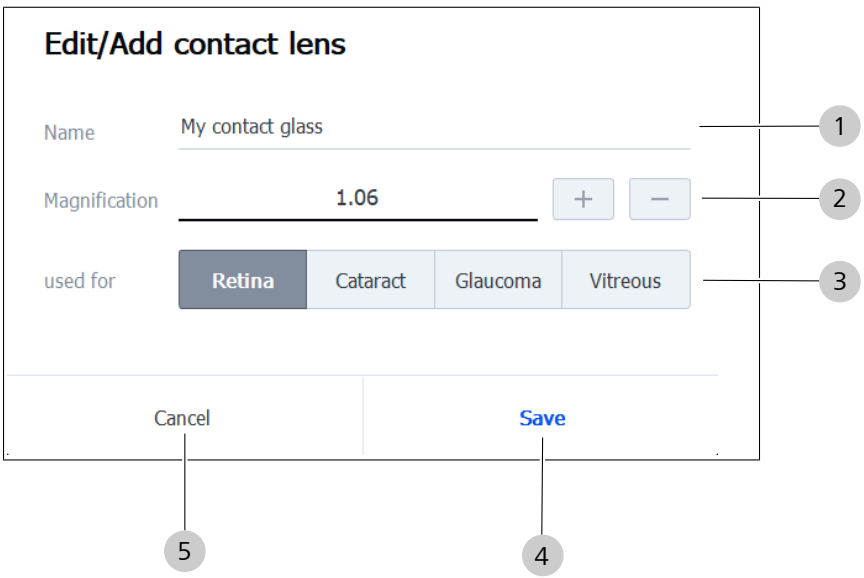


Figure 7: Dialog for adding or editing a contact lens

Item	Icon / Name	Explanation
1	Name	Enter or edit the name of a contact lens.
2	Magnification	Use [+] and [-] buttons to set the magnification factor. Please refer to the specifications or instructions for use of the contact lens.
3	used for	Select therapies for which the contact lens is to be used.
4	Save	Save the settings and close the dialog.
5	Cancel	Close the dialog without saving.

3.1.4 System information and DEMO mode

On this tab, you can view product version information and enable / disable DEMO mode.

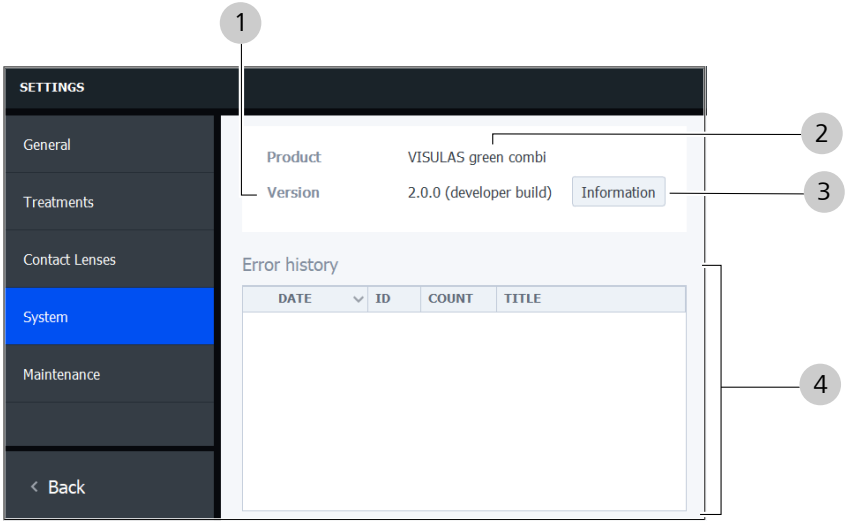


Figure 8: "System" tab

Item	Icon / Name	Explanation
1	Version	Display product version
2	Product	Display product name
3	Information	Access details or enable DEMO mode.
4	Error history	Display a list of all errors

Details and DEMO mode

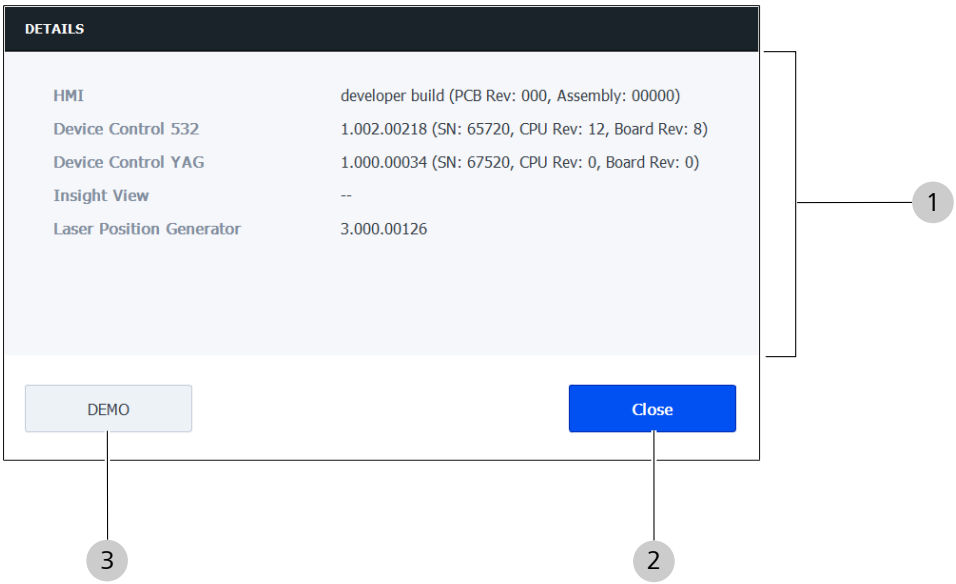


Figure 9: "Details" dialog

Item	Icon / Name	Explanation
1	Information area	Display details of product version
2	Close	Close the dialog.
3	DEMO	Enabling / disabling DEMO mode. The action must be confirmed in the following dialog. In DEMO mode the laser is deactivated, other functions can be accessed.

3.1.5 Maintenance of the software and license management

On this tab, you can find license information and trigger maintenance-related actions.

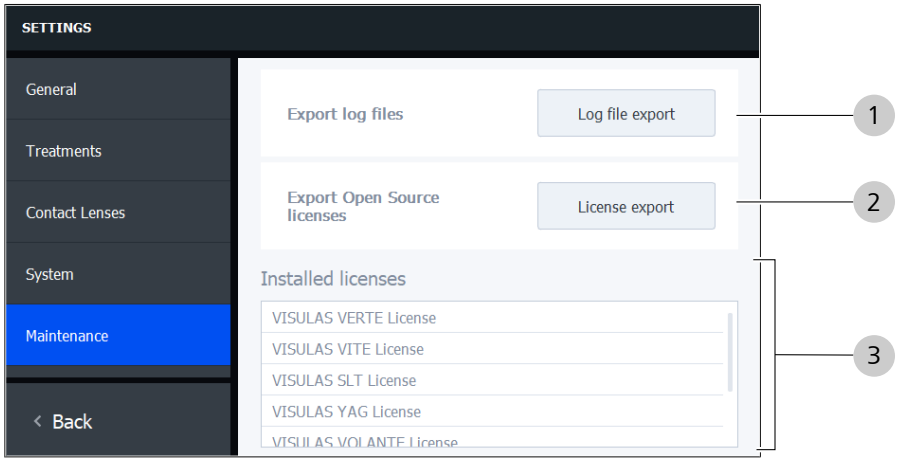


Figure 10: "Maintenance" tab

Item	Icon / Name	Explanation
1	Export log files	Use the [Log file export] button to open a browser window for selecting the export directory and confirming the export of the log files.
2	Export Open Source licenses	Use the [License export] button to open a browser window for selecting the export directory and confirming the export of the license files. If you have any questions about Open Source or its sources, please contact us at the following e-mail address: opensource.med@zeiss.com
3	Installed licenses	Displays all installed licenses

3.2 Software user interface

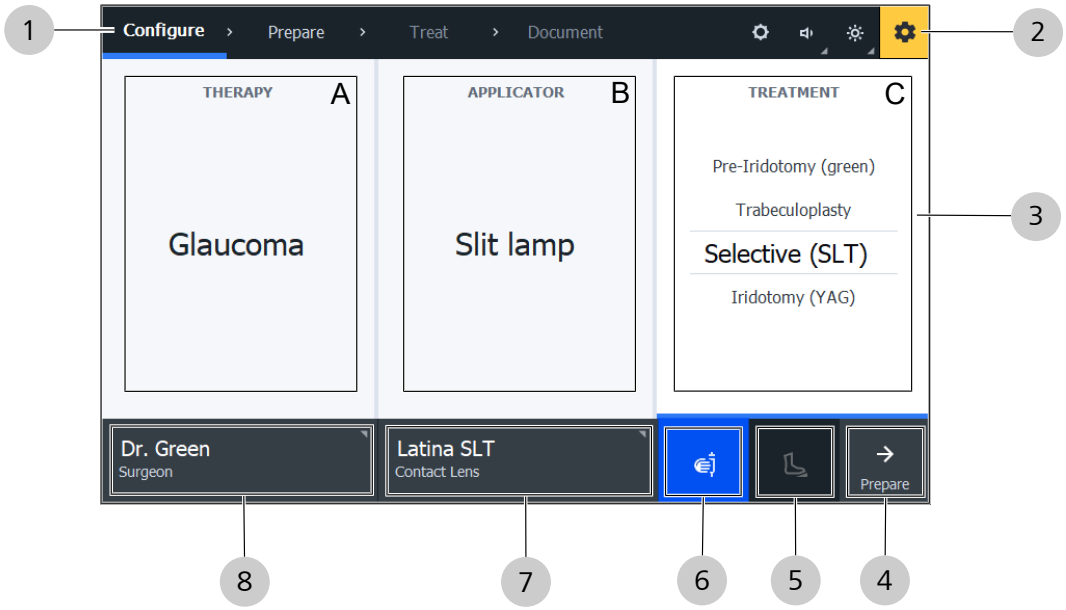


Figure 11: "Configure" work step in "Selective" mode.

Item	Icon / Name	Explanation
1	Navigation bar	Navigation bar in the "Configure" work step
2	System settings	Access to online help, alarm volume and system settings
3 A	THERAPY	The selected therapy is displayed.
3 B	APPLICATOR	The selected applicator is displayed.
3 C	TREATMENT	The selected treatment is displayed. Some treatment procedures are predefined by default. In the settings, you can adjust the treatment parameters and define additional treatment procedures.
4	Prepare	Direct access to the "Prepare" work step.
5		Foot trigger control element with which the laser pulse is triggered.
6		Manual trigger control element with which the laser pulse is triggered.
7	Contact lens	Select the contact lens using the drop-down list. Some contact lenses are already preconfigured by default. You may add other contact lenses under "Settings".
8	Surgeon	The selected user / surgeon will be displayed.

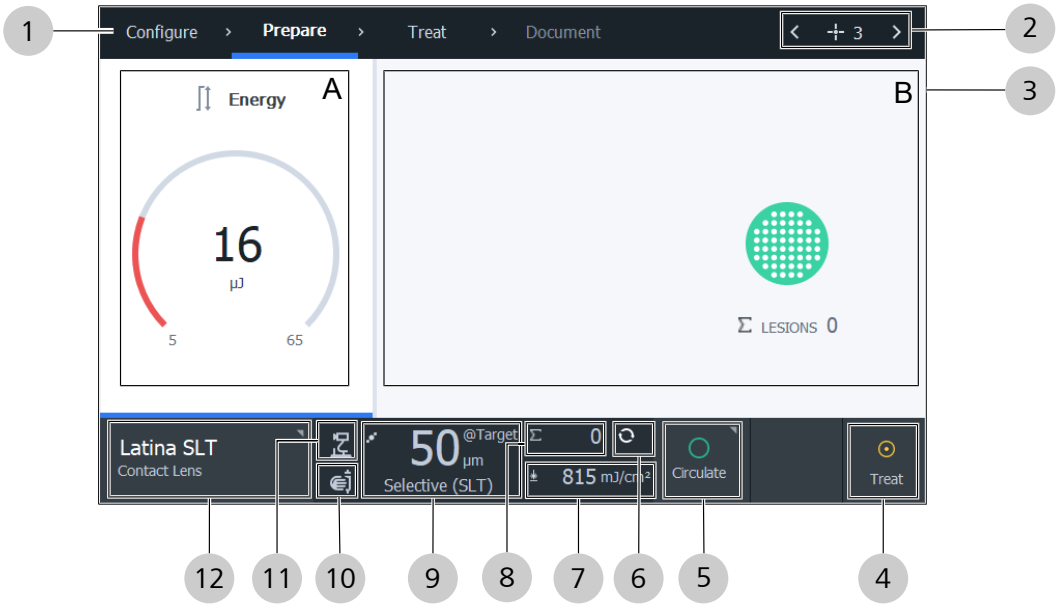


Figure 12: "Prepare" step for the Selective mode

Item	Icon / Name	Explanation
1	Navigation bar	Navigation bar in the "Prepare" work step
2		Set the brightness of the aiming beam using the [<] and [>] buttons.
3 A	Energy	Set the laser power. The laser power can be changed by using the rotary knob, by tapping the two arrow keys or by circular gestures on the displayed arc.
3 B	Σ LESIONS 0	Scheme of the treatment pattern and number of lesions
4	Treat	Direct access to "Treat" work step
5	Circulate (rotating) Point (fix spot)	Toggling between rotating or fixed aiming beam
6		Reset the laser spot counter to zero.

Item	Icon / Name	Explanation
7		Displays the energy density (laser fluence) of the laser beam at the area to be treated. The energy density is a measure of the therapeutic effect on the eye.
8		Shows the number of triggered laser pulses.
9		Displays the set laser spot size. The laser spot size at the treatment site is displayed depending on the selected contact lens (marked with "@ target").
10		Displays the selected trigger. In this example, the manual trigger is selected.
11		Displays the selected applicator. In this example, the laser slitlamp is selected.
12	Contact lens	Select the contact lens using the drop-down list. Some contact lenses are already preconfigured by default. You may add other contact lenses under "Settings".

The user interface of the "Treat" work step is described in Performing laser treatment [▶ 33].

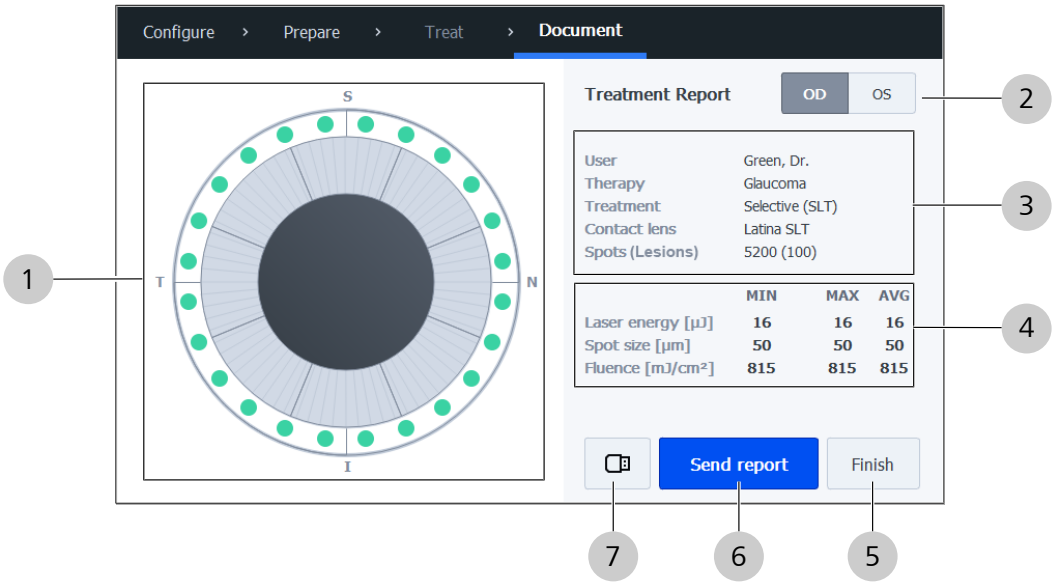
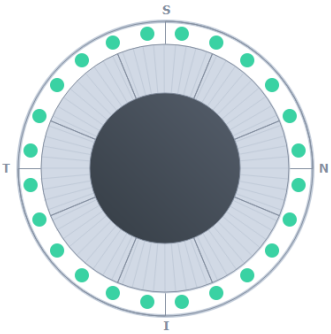


Figure 13: Treatment report - Selective mode

Item	Icon / Name	Explanation
1		Selection window with graphic presentation for the manual marking of the areas to be treated in the patient's eye
2		OD / OS selection (right eye / left eye)
3	Treatment data	Data of the performed treatment
4	Laser parameters	List of the used laser parameters
5	Finish	Finish the current treatment. Please note that all treatment data is deleted when this button is used.
6	Send report	Send report data to FORUM. This option is only available if the LASER REPORT license has been installed.
7		Exporting data as a pdf file to a USB flash drive.

3.3 Setting the eyepieces for operation with the laser slit lamp

Action

1. Make sure the eyepieces are plugged in correctly and the eyecups pulled out (for spectacle wearers: pushed in).
2. Turn the diopter setting ring on both eyepieces fully towards "+" (counter-clockwise) as far as it will go.
3. Look through each eyepiece with one eye in turn, rotating the diopter setting ring for the eyepiece through which you are looking towards "-" (clockwise) until the parameters displayed in InsightView are sharply in focus.
4. Repeat the process for the other eye.
5. Select the other magnification steps on the slit lamp. The image should remain sharply in focus at all magnifications. If not, the procedure should be repeated.
6. Make a note of the eyepiece settings in the table provided in the appendix, Notes [▷ 45]. In future you will need only to adjust the eyepieces to these values.

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4 Treatment sequence

The following chapters describe the intended use of the VISULAS on the basis of typical work sequences. In daily use, you can deviate from this rigid specification if you are familiar with the handling of the system and have your own experience regarding energy settings and the resulting effect. Please observe the steps described below to avoid risks for users, patients and third parties.

NOTE! Selective mode is only available if you have the appropriate SLT software license and a LSL green comfort or LSL green combi laser slit lamp model. In Selective mode, the laser is always triggered by the manual trigger. When switching to this mode, the system is automatically reconfigured and a corresponding message will be displayed.

4.1 Preparing the patient for treatment

Action

1. Explain to the patient the nature, scope, implementation, expected consequences and risks of the measure as well as its necessity, urgency, suitability and chances of success with regard to the therapy. When providing information, alternatives to the measure must also be pointed out if several medically equally indicated and common methods can lead to significantly different types of stress and risk or prospects of a cure. Please also observe the respective national regulations regarding the obligation to inform patients.
   To inform patients, use educational materials from providers that are approved in your country or certified to ISO 13485.
2. If the system is switched off, start the VISULAS.

4.2 Performing laser treatment

⚠ WARNING!

Hazard due to laser radiation

The eyes of all persons in the laser area can be injured by laser radiation.

- Use the supplied laser safety goggles (order number 000000-0619-616) or provide the following laser safety goggles for persons in the laser area during coagulation treatments: 532 DIR LB5.

⚠ WARNING!

Hazard due to incorrect dosage of laser radiation

Incorrect dosage of laser radiation leads to a reduction in the safety and efficacy of the treatment.

- Only use contact lenses with a magnification factor of 1.0, as other magnification factors change the beam diameter and laser energy density.

Patient's medical history

Action

1. Inquire about the patient's comfort level.
2. Review the patient's most recent diagnostic and treatment reports to get a complete picture of their eye status.

Preparing VISULAS for treatment

Action

1. Adjust the table height for the patient as required.
2. Set up the chin and forehead rest.
3. Adjust the eyepieces of the slit lamp according to individual requirements (see Setting the eyepieces for operation with the laser slit lamp [▷ 31]).

Preparing the patient for treatment

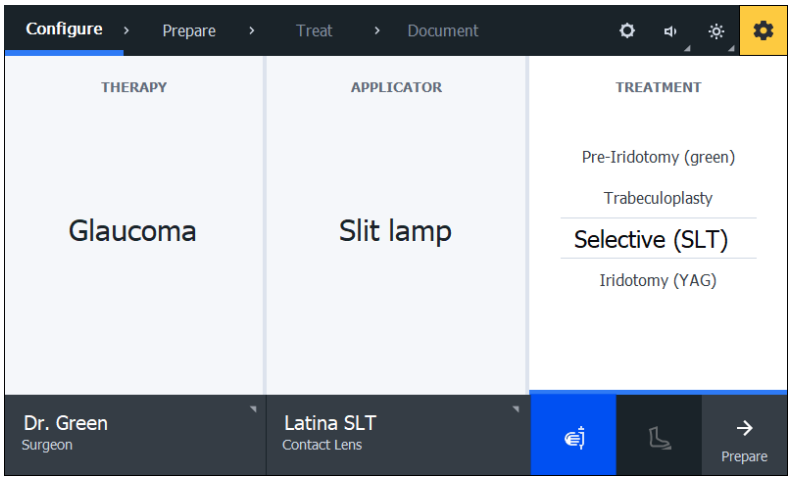
Action

1. Apply a local anesthetic and, if necessary, a miotic to the patient's eye to be treated according to the usual treatment standards.
2. Instruct the patient to assume the correct posture and head position.
3. Give the patient instructions about the course of treatment to follow.
4. Reassure the patient.
5. Make sure that the correct eye (OD / OS) will be treated.

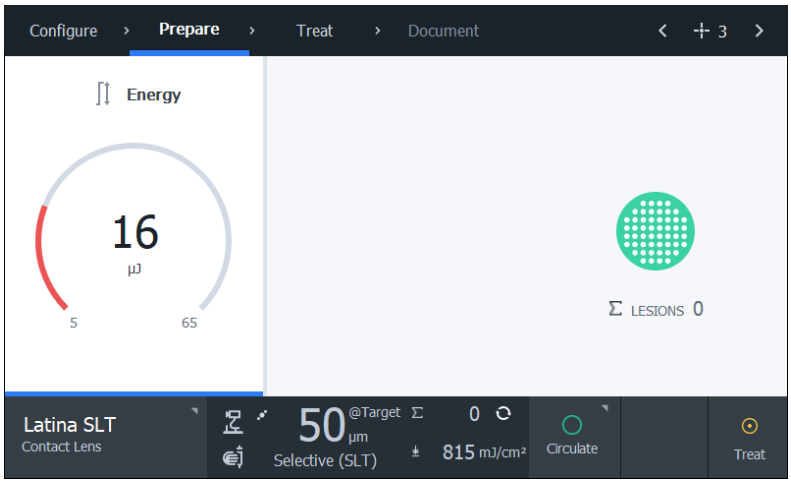
Prepare laser treatment

Action

1. Obtain an overview of the eye to be treated. To do this, perform a slit lamp examination.
   TIP: Start with a low magnification for an overview. Increase the magnification to see the details.
2. On the control panel, select the following items in the "Configure" work step:
   - Therapy: "Glaucoma"
   - Laser applicator: "Slit lamp"
   - Treatment type: "Selective (SLT)"
   - User
   - Contact lens: "Latina SLT" or one of the contact lenses you have defined
   - Trigger: "Manual"



3. On the navigation bar of the control panel, select the "Prepare" work step.



4. Set the individual treatment parameters.
   CAUTION! Set the initial individual treatment parameters depending on the pigmentation of the trabecular meshwork or the patient-specific parameters from past treatments.
   The following Scheie grading system and table show recommended starting values for treatment. The stronger the pigmentation of the patient's eye, the lower the energy should be set. Use the lowest possible power necessary to achieve the desired clinical effect.
   NOTE! A tissue reaction such as bleaching or the formation of cavitation bubbles is not expected. Titrating the energy until these reactions appear is therefore not possible and not necessary. If you see any of these reactions, decrease the energy until they disappear.
   WARNING! Treat patients with strong pigmentation of the chamber angle only with very low energy levels (typically 10 µJ), as the frequency of short-term increase in intraocular pressure correlates with the degree of pigmentation.
   In Conversion of laser energies to be set [▶ 43], you will find a conversion table of laser energies of VISULAS lesions consisting of 52 single spots to corresponding Nd:YAG single shot lesions at a diameter of 400 µm.

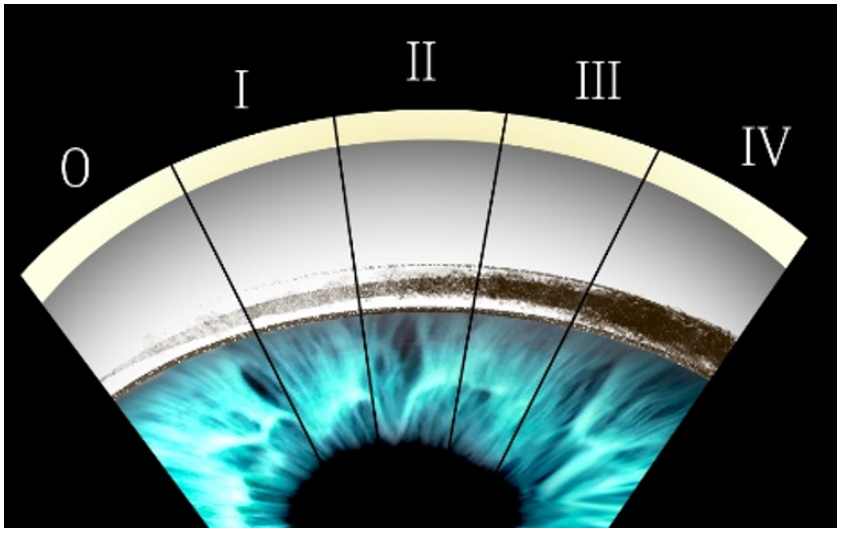
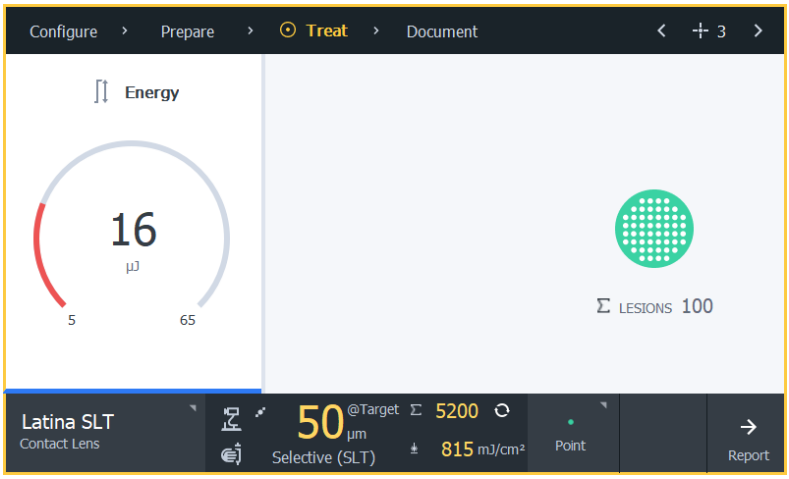


Figure 14: Scheie grading scheme for the determination of the pigmentation level of chamber angle

Pigmentation of trabecular meshwork	Scheie grading	Setting of laser pulse energy [µJ]
None to just visible	0	30 to 40
Mild to moderate	I + II	20 to 30
Marked to intense	III + IV	10 to 20

5. Set the laser spot diameter to 50 µm using the adjusting knob on the slit lamp.
6. Instruct persons in the laser protection area to put on laser safety goggles.
   WARNING! When using a monocular co-observation tube during laser treatment, cover the second eye of the co-observer with the supplied eye patch.
7. Position the contact lens:
   - Use a contact lens suitable for the selected treatment type.
   - Make sure that the contact lens is free of lint, grease and damage. If necessary, clean the contact lens according to the instructions on the package insert.
   - Apply contact gel to the contact lens.
   - Place the contact lens on the patient's eye.
   WARNING! - Hold the contact lens surface as perpendicular as possible to the aiming and therapy beam for treatment.
   NOTE! If you use a contact lens with deflection mirrors, be sure to keep the laser beam away from the mirrored edges. When the beam hits the black area around the mirror, it can be absorbed and burn the area. Contact lenses damaged in this way cannot be repaired.
8. Select the "Treat" work step in the navigation bar of the control panel. The aiming beam is now visible.



9. Using the slit lamp joystick control, carefully position the aiming beam until the light spot appears sharply delineated and the tissue to be treated is seen sharply in focus. Depending on the selected mode, the aiming beam rotates around the tissue to be treated or is visible in the center of the area to be treated.
   WARNING! Always focus the slit lamp so that the trabecular tissue to be treated and aiming beam are both sharply in focus.
   NOTE! In rare cases, you may perceive chain-like multiple reflections of the aiming beam. These are virtual reflections, i.e. they are artifacts of the microscope only and are not present on the eye structure. The actual aiming beam is easily distinguishable by its brightness.

Performing laser treatment with the set laser parameters

Action

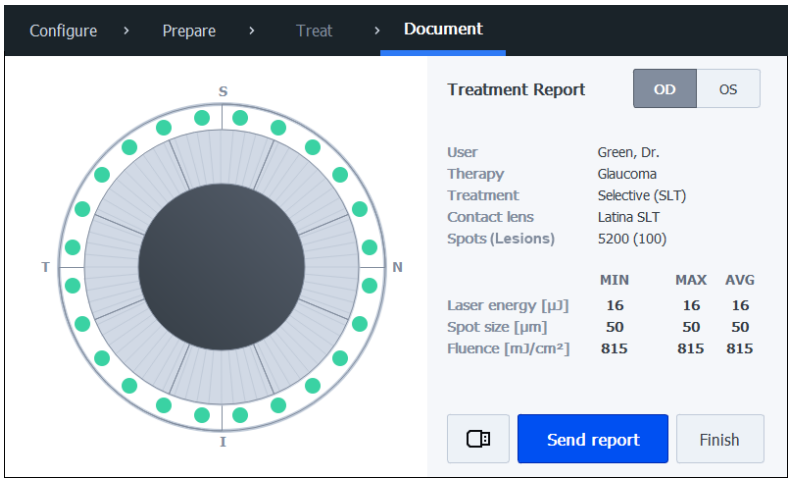
1. Focus the aiming beam as carefully as possible on the tissue to be treated.
   WARNING! Never fire the laser if the aiming beam is not clearly visible in the area to be treated.
2. Hold the trigger for approximately 0.5 seconds to fully apply the SLT lesion consisting of 52 single spots.
   WARNING! Observe the treatment area during laser treatment and stop the treatment in case of hazardous situations.
   NOTE! A tissue reaction such as bleaching or the formation of cavitation bubbles is not expected. Titrating the energy until these reactions appear is therefore not possible and not necessary. If you see any of these reactions, decrease the power until they disappear.
3. Apply approximately 100 non-overlapping lesions over 360° of trabecular meshwork (approximately 25 lesions per quadrant).
   WARNING! Treat patients with strong pigmentation of the chamber angle only with non-overlapping lesions over 90°, as the frequency of short-term increase in intraocular pressure correlates with the degree of pigmentation. Repeat the treatment in several steps if required.
4. Inspect the patient's treated eye tissue.
   WARNING! Measure the patient's intraocular pressure after laser treatment and administer the necessary medication if there is a marked increase.
5. Provide the patient with the usual standard of care and decide if another session is needed to complete the treatment.

4.3 Documentation of laser treatment

Complete the treatment data

Action

1. Select the "Document" work step in the navigation bar of the control panel.
   ⇨ The treatment parameters of the completed treatment are displayed.
2. Select the treated eye (OD - right eye, OS - left eye).
   ⇨ A schematic view of the treated eye will be displayed on the left-hand side of the window.



3. Tap on the different areas on the screen to mark the areas of the eye which have been treated.
4. Document the treatment according to the specified standards.
5. Schedule a follow-up appointment if necessary.

Exporting treatment data as a PDF report on a USB drive

Action

1. Insert a USB drive into the USB port provided for this purpose.
2. Press the button with the USB drive.
   ⇨ A prompt appears.
3. Enter the patient name or patient ID and confirm your entry with [OK].
   ⇨ The treatment report is available on the USB drive after saving.

Exporting treatment data to FORUM

Action

1. If you have the "LASER REPORT" license, you can export the treatment data to FORUM (from FORUM Vs. 4.2) by pressing the [Send report] button.
2. In FORUM you can create, save and export a treatment report.

NOTE! After exiting the "Document" step, the treatment parameters and the report are no longer available on the VISULAS.

4.4 Preparation of VISULAS for the next patient

Action

1. Clean and disinfect the applied parts.
   CAUTION! 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.
2. Remove the used paper from the chin rest.
3. Keep the contact lens in a safe place not accessible to unauthorized persons.

5 Default parameters

5.1 SLT treatments

Treatment	Laser energy in mJ 	Spot size in µm 
Selective laser trabeculoplasty (SLT)	10	50

Table 1: Default parameters for possible glaucoma treatments with SLT

5.2 Contact lenses

Contact lens model	Magnification factor of laser spot	Treatment area
Latina SLT	1.0	Selective laser trabeculoplasty (SLT)

Table 2: Contact lens parameters

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6 Conversion of laser energies to be set

VISULAS energy in µJ	Nd:YAG SLT laser: energy in mJ
6	0.2
8	0.3
10	0.4
12	0.5
14	0.6
16	0.6
18	0.7
20	0.8
22	0.9
24	1.0
26	1.0
28	1.1
30	1.2
32	1.3
34	1.4
36	1.4
38	1.5
40	1.6
42	1.7
44	1.8
46	1.8
48	1.9
50	2.0
52	2.1
54	2.2
56	2.3
58	2.3
60	2.4

VISULAS energy in µJ	Nd:YAG SLT laser: energy in mJ
62	2.5
64	2.6

Table 3: Conversion of laser energies to be set

7 Notes

User name	Refraction of left eye [D]	Refraction of right eye [D]	Eye distance [mm]

Table 4: Personal settings and values

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Glossary

D

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

OD

Oculus dexter (right eye)

OS

Oculus sinister (left eye)

SLT

Selective laser trabeculoplasty

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