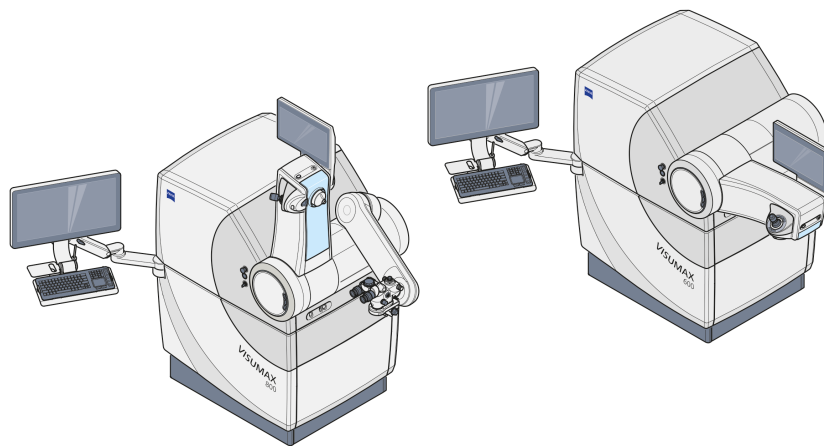


VISUMAX 600, VISUMAX 800

Flap option

Documentation set



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1 Notes on the instructions for use

1.1 Name of product

The VISUMAX device in the model versions 600 and 800 is referred to as "the device" in the following.

1.2 Scope of application

The present instructions for use apply to

VISUMAX 600 with the following marking:

- Reference number: REF 09510

and

VISUMAX 800 with the following marking:

- Reference number: REF 09511

1.3 Purpose and storage of the documentation

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

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

Action

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

1.4 Questions and comments

Action

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

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

1.5 Conventions in this document

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

1.5.1 Conventions in all text areas

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

This is a cross-reference: Conventions in this document [► 5].

This is **bold type**.

This is `software code or program text`.

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

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

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

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

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

- [START] key
- [Next] button

1.5.2 Conventions in a course of action

WARNING!

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

The warning message names the possible consequences.

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

CAUTION!

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

The warning message names the possible consequences.

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

NOTE

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

The warning message names the possible consequences.

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

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 are only valid in connection with the corresponding instructions for use:

Documents

- Instructions for use for VISUMAX 600 / VISUMAX 800
000000-2383-581-DokS-en-GB-DDMMYY
- Instructions for use for Treatment Pack

Please note that a patient supporting system is absolutely necessary for the use of this device. In particular, familiarize yourself with section Minimum requirements for patient supporting system in the instructions for use of VISUMAX 600 / VISUMAX 800 and with the instructions for use of the patient supporting system.

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2 Safety notes

2.1 Intended user profile

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

User profile: Releasing and performing treatments

The following training, knowledge and experience requirements must be fulfilled:

- Completed specialist medical training, ophthalmologist
- Experience in dealing with graphical user interfaces
- Knowledge of current ophthalmic diagnostic procedures and their measurement results for refractive surgery treatment planning
- Knowledge of current therapy methods in refractive surgery
- Knowledge of the effects of incorrect or inaccurate readings on the therapy
- Knowledge regarding the consistency check of data used for treatment planning
- Practical experience in corneal surgery

User profile: Treatment planning

The following training, knowledge and experience requirements must be fulfilled:

- Experience in dealing with graphical user interfaces
- Knowledge of current ophthalmic diagnostic procedures and their measurement results for refractive surgery treatment planning
- Knowledge of current therapy methods in refractive surgery
- Knowledge of the effects of incorrect or inaccurate readings on the therapy
- Knowledge regarding the consistency check of data used for treatment planning

2.2 Intended field of application

This device and its treatment options may be set up, operated and used only for the intended use and in accordance with local country-specific regulations, generally accepted engineering standards, and occupational safety and accident prevention regulations.

2.2.1 Intended use / Indication for use

This device is intended for use in creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

Any use of this treatment option of the device beyond the intended use described in this manual is off-label use.

2.2.2 Contraindications

The following **contraindications** do not permit treatment with the device for refractive surgery or surgical treatment requiring an initial corneal incision:

Patient population

- Patients under the age of 18
- Patients not able to understand and give informed consent
- Patients not able to lie flat in a horizontal position
- Patients not able to fixate on a light spot
- Patients not able to make themselves understood or react to instructions
- Patients who are pregnant or breastfeeding

Medication and anesthesia

- Treatment with medications with possible ocular side effects (e.g. Accutane®, Cordarone®)
- Treatment with medications which affect wound healing (e.g. steroids, antimetabolites, immunosuppressants)
- Known allergies or intolerance to medications used
- Intolerance of topical anesthesia

Previous eye treatments

- Existing corneal implant
- Previous ocular surgery of the eye to be treated (e.g. radial keratotomy)

Corneal thickness

- Preoperative corneal thickness < 480 µm
- Residual stromal thickness < 250 µm

Diseases of the eye and adnexa

- Existing or acute general infections of the eye
- Ocular herpesviral infections (herpes simplex, zoster ocular disease)

- Disorders of the eyelid (e.g. blepharitis, lagophthalmos, blepharophimosis)
- Disorders of lacrimal system (e.g. dry eye syndrome, or in the case of Sicca syndrome)
- Disorders of cornea (e.g. keratitis and extensive corneal neovascularization, corneal scars and opacities, corneal oedema, corneal dystrophies, keratoconus, corneal deformities, recurrent erosion of cornea)
- Disorders of iris (e.g. uveitis)
- Cataract
- Disorders of retina (e.g. degeneration of macula, diabetic retinopathy)
- Uncontrolled glaucoma
- Instable refraction
- Visual disturbances (e.g. diplopia, monocular blindness)

Other disorders

- Diabetes with or without complications
- Dermatological diseases that can affect the eye
- Rheumatic diseases which may affect the eye (e.g. rheumatoid arthritis, rheumatism)
- Active systemic connective tissue disorders or active autoimmune diseases
- Injury of eye and orbit (e.g. corneal abrasion, ocular trauma)
- Wound healing disturbances

With the following **relative contraindications**, treatment with the device is not recommended for refractive surgery or surgical treatments that require initial incisions of the cornea:

- Application of certain systemic medication (e.g. Sumatriptan, Levonorgestrel implants, colchicine)
- Conjunctivitis
- Scleritis
- Controlled glaucoma or glaucoma suspect (intraocular pressure > 21 mm Hg)
- Strabismus
- Visual disturbances such as severe amblyopia or functional monocularity
- Nystagmus
- Controlled systemic connective tissue disorders or controlled autoimmune diseases

2.2.3 Side effects

The following **side effects** may occur during or after making corneal incisions with the device:

Diseases of the eye and adnexa

- Disorders of eyelid (e.g. inflammation of the eyelid)
- Disorders of lacrimal system (e.g. dysfunction of the lacrimal gland including dry or watery eye)
- Disorders of conjunctiva (e.g. conjunctivitis, pterygium, conjunctival hemorrhage, conjunctival vascular disorders and cysts, deformation of the conjunctiva)
- Disorders of cornea (e.g. keratitis and corneal neovascularization, corneal scars and opacities, corneal deposits, bullous keratopathy, corneal edema, changes in corneal membranes, hereditary corneal dystrophies, keratoconus and other corneal deformities, hemorrhages of corneal incisions in case of vascularization)
- Disorders of iris (e.g. iridocyclitis)
- Disorders of the lens (e.g. cataract)
- Disorders of choroid (e.g. choroidal hemorrhage)
- Disorders of retina (e.g. retinal detachments and breaks, background retinopathies, macular hole, retinal hemorrhage, separation of retinal layers)
- Glaucoma
- Disorders of vitreous body (e.g. vitreous opacities, vitreous detachment)
- Disorders of globe (e.g. anterior chamber reaction)
- Disorders of optic nerve and visual pathways (e.g. neuropathy)
- Disorders of ocular muscles (e.g. strabismus)
- Disorders of refraction and accommodation
- Visual disturbances
- Visual impairment including blindness
- Other disorders of eye and adnexa (e.g. ocular pain)
- Injury of eye
- Foreign bodies or bubbles in the outer eye

Other side effects

- Ocular autoimmune reaction
- Mental and behavioral disorders (e.g. depression, phobia)
- Sleep disorders, myokymia
- Symptoms (e.g. tachycardia, nausea and vomiting, drowsiness, dizziness, suicide risk, headache, malaise and fatigue, allergic reaction)

Side effects when applying Treatment Pack

- Keratitis
- Temporary impressions of the suction ring on the eye
- Erosion of cornea or activation of existing basal membrane dystrophy

Side effects when applying the patient supporting system

- Injuries to the forehead or head

Temporary impediments

- Temporary impediment of the visual field during eye suction
- Temporary gas bubbles in the cornea
- Pressure and / or foreign body sensation

2.2.4 Complications

Complications related to the procedure

- Flap complications (e.g. striae or folds, flap rupture, flap dislocation, flap perforation, flap melt)
- Complications with the hinge (e.g. hinge rupture)

Problems with cuts and / or incisions and their separation / opening

- Interrupted cutting procedure (e.g. suction loss on the eye)
- Incomplete / omitted incisions
- Decentered incisions (e.g. centering difficulties)
- Unintended incisions
- Incorrectly positioned incisions / incorrect cutting geometry (e.g. due to docking difficulties)
- Difficult separation of incision surfaces / poor incision quality

In addition, please consult medical literature and recommendations of professional associations in your country.

2.3 Responsibilities and duties of the responsible organization

Operating personnel

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

- ▶ Restrict access to the device to authorized operating personnel.
- ▶ Ensure that the operating personnel have been trained and instructed.
- ▶ Make sure that the operating personnel have read and understood the instructions for use.
- ▶ Keep the instructions for use available at all times for the operating personnel.
- ▶ To facilitate access for the entire operating personnel: If necessary, request further copies of the instructions for use from ZEISS.
- ▶ Define the required skills for handling the device and provide information on who is authorized for which activities.
- ▶ Define rules for reporting errors and damage, and provide information on these (see Notification to manufacturers and authorities [▶ 15]).
- ▶ Regularly check compliance with the national laws and regulations concerning accident prevention and occupational health.

Accessories and additional equipment

- ▶ If you want to connect accessories or additional equipment to the device: contact your ZEISS contact [▶ 5].

Additional equipment connected to medical electrical devices must include documentation showing compliance with the corresponding IEC or ISO standards (e.g. IEC 62368-1 for data processing equipment).

Furthermore, all configurations must comply with the normative requirements for medical systems (see IEC 60601-1-1 or section 16 of the 3rd edition of IEC 60601-1, as applicable).

If you connect additional devices to medical electrical systems, you are a system configurer and are thus responsible for ensuring that the system complies with the normative requirements for medical electrical systems (see VISUMAX 600 / VISUMAX 800 documentation set, section ME system).

Local laws take precedence over the above normative requirements.

Combination with diagnostic devices

Incorrect alignment of the medical diagnostic device or the patient head during acquisition of the iris image will result in angular errors.

- Ensure correct alignment of the diagnostic device and patient head.

2.3.1 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.

2.4 Responsibilities and duties of the operator

Explain to the patient the benefits, contraindications, mode of operation and risks associated with the treatment.

Observe all contraindications cited in the literature of medical professional associations and the laws in force in your country.

Take special care to ensure exact alignment of the patient's eye. The device cannot correct manual alignment errors of the patient eye. These errors may have a negative impact on the treatment results. Encourage the patient to cooperate in achieving optimum results.

2.5 Safety in product use

The safety instructions for the use of the product can be found in section Operation [► 19]).

2.6 Package check list

The option is supplied with the following accessories

- License for the treatment option
- Documentation set

2.7 Activation of treatment option licenses

The device with the Flap treatment option can only be used for operations after the treatment option license for the Flap option has been activated.

This treatment option licence is provided by Carl Zeiss Meditec or its authorized representative on the basis of a commercial agreement.

Follow the instructions for use of VISUMAX 600 / VISUMAX 800, section Activation of treatment option licenses.

3 Functional description

VISUMAX 600 / VISUMAX 800 is used to create a corneal flap in patients undergoing LASIK or another treatment that initially requires a lamellar incision in the cornea. For this purpose, the femtosecond laser is used to create the flap cut (a circular planar cut parallel to the corneal surface) and to add a flap side cut to this. As the flap side cut does not cover the full 360°, a flap hinge with the corresponding dimension is created.

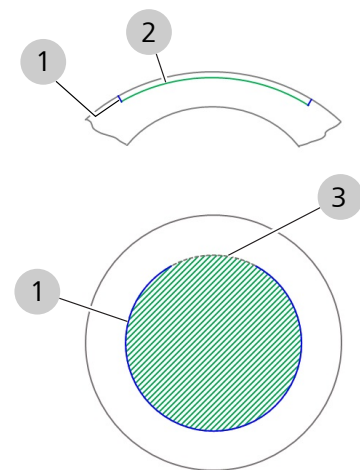


Figure 1: Incision geometry of the flap procedure

1	Flap side cut	2	Flap cut
3	Flap hinge		

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4 Operation

Detailed information on the general operation of the VISUMAX 600 / VISUMAX 800 as well as the planning and execution of treatments can be found in the instructions for use "VISUMAX 600 / VISUMAX 800".

RSTP - Standard treatment procedures for flap

The aim of this section is to present Recommended Standard Treatment Procedures (RSTP) for flap generation with the VISUMAX 600 and VISUMAX 800 laser systems.

General notes

There are various ways of achieving successful surgery. Nonetheless, Carl Zeiss Meditec has compiled a list of recommended treatment procedures (RSTP). This is the result of information from experienced surgeons and reflects the experience of many years of business in the field of refractive surgery. This list will enable you as the physician to perform treatments leading to high-quality results in the interest of your patients.

We therefore recommend using the standard treatment procedures. If alternative procedures are used, an exact comparison should be made with the determined clinical findings of the patient.

Together with our clinical researchers we constantly endeavor to further qualify these recommendations and regularly improve the recommended methods in line with new findings.

Your experience in using other lasers from Carl Zeiss Meditec or its competitors may be at variance with the recommendations given here which have been optimized for the device. Reading these recommendations is not a substitute for the need to carefully study the instructions for use or for the detailed training provided by Carl Zeiss Meditec, nor does it release you from the obligation to update your own expertise in keeping with the latest results of general research in the field of refractive surgery.

4.1 Safety during operation

During normal operation of the device no eye protection is required.

For further instructions on device operation refer to the onscreen help and the following sections of these instructions for use.

4.2 Preparing treatment

CAUTION!

Hazards caused by the treatment if the contraindications are ignored

If the contraindications associated with this treatment option are not taken into account, the patient may be exposed to danger.

- ▶ Observe all contraindications in section Contraindications [▶ 10] and the current information according to the literature of medical professional associations and according to the laws in force in your country.

Before you make the decision about the treatment of a patient and prepare the patient for surgery:

Action

- ▶ 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 and 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.
- ▶ Perform all relevant examinations in good time before the planned procedure, including the retina, and enquire about the working conditions of your patient, e.g. night driving.
- ▶ Check that sufficient treatment option licenses are saved for the desired treatment option and that the required Treatment Packs and supplies are ready.
- ▶ Make sure that the patient observes a waiting period of at least 3 to 4 weeks for hard contact lenses and 1 to 2 weeks for soft contact lenses before the preliminary examination and that he / she does not wear the contact lenses during this period.
- ▶ Repeat the examinations and check the decision for surgery again immediately prior to surgery.
- ▶ At least a week before surgery, remind your patient to observe the following rules for at least three days prior to the surgery:
 - Not to wear contact lenses at any time
 - Not to apply make-up or mascara
 - To take pre-operative topical antibiotics (optional)
- ▶ Observe all contraindications cited in the literature of professional medical associations and in the relevant laws in force in your country (e.g. keratoconus, irregular corneal topography etc.).

- ▶ Check the refraction of the eye to be treated and consider the individual corneal vertex distance. To determine the subjective refraction, "fogging" techniques and / or duochrome tests should be used to repress accommodation. In particular, we recommend determining the cycloplegic refraction for non-presbyopic, hyperopic patients. This also makes it possible to examine the fundus of the eye.
- ▶ Measure the pupil diameter using a recognized standard procedure, even in the dark. This serves to determine the treatment diameter and the associated amount of removed tissue.
- ▶ Measure the thickness of the cornea, even peripherally at its thinnest point, using a recognized standard procedure, and determine its curvature also using a recognized standard procedure.
- ▶ When measuring with a pachymeter or tomography unit, please always consider the accuracy specifications of the manufacturer, especially for further calculations such as the residual stromal thickness and cyclotorsion correction.

4.3 Planning the treatment

Selection of Treatment Pack size

Treatment Pack is available in sizes S, M and L. Each Treatment Pack is labeled with the according size.

The choice of Treatment Pack size for surgery depends on the following criteria:

- Diameter of suction ring < effective white-to-white diameter of the eye to be treated.
- Flap diameter ≤ maximum plannable flap diameter for the corresponding Treatment Pack size.

CAUTION!

Suction loss due to excessively large Treatment Pack size

If Treatment Pack is too large, this can lead to suction pressure on the conjunctiva, unstable eye fixation and suction loss, which can have a negative impact on the treatment outcome.

- ▶ Always select the smallest possible Treatment Pack for treatment.

We recommend the following Treatment Pack sizes for the specified minimum "white-to-white" diameters:

Size of Treatment Pack	S	M	L
Minimum "white-to-white" diameter (mm)	11.2	11.7	12.4

The maximum possible incision diameter for each Treatment Pack is specified in section Technical specifications [► 43] and will automatically be checked for the selected Treatment Pack.

CAUTION!

Residual stromal thickness

A residual stromal thickness that is too small can lead to the development of ectasia and thus to a deterioration of visual acuity.

- ▶ Pachymetry should be determined before treatment.
- ▶ It must be ensured in the treatment planning that the pachymetry does not exceed the minimum corneal thickness.
- ▶ The residual stromal residual thickness after treatment must not be less than 250 µm, otherwise treatment planning is not possible.

Prerequisite

- ☒ You have performed the surgical preparation for the patient.
- ☒ All information necessary for planning this treatment is available.

Action

- ▶ First enter all anatomical parameters (such as pachymetry, k values, etc.) and the manifest refraction of the patient. For safety reasons, these input fields do not have any initial values.

The displayed stromal thickness is a theoretical expected value. In the event of changes in the surgical procedure, the residual stromal thickness achieved may differ from the displayed value.

- ▶ Please also consider that the calculation of the residual stromal thickness is based on the entered pachymetry value, which has a measurement uncertainty.
- ▶ When measuring with a pachymeter, please always consider the accuracy specifications of the manufacturer, especially for further calculations.
- ▶ Select the Treatment Pack size (S, M, L) according to the information given above.
- ▶ Adjust the geometrical parameters.
- ▶ Check the flap diameter. Ideally, the flap diameter should be larger than the ablation zone of the LASIK procedure.
- ▶ Check the flap thickness. Note that the displayed residual corneal thickness is further reduced by the subsequent ablation process.
- ▶ Check the position of the flap hinge as this may be positioned differently for the right and left eye.
- ▶ Pay attention to the messages from the planning software to resolve inconsistencies in planning.
- ▶ Save the treatment planning when finished.

4.4 Performing treatment

- Prior to treating a patient, check the refraction of the eye to be treated.
- Check the result for consistency with prior treatment planning.

4.4.1 Preparing and positioning the patient

CAUTION!

Complications due to incorrect alignment of the patient head

Incorrect alignment of the patient supporting system in relation to the device can lead to incorrect alignment of the patient head in relation to the laser arm and thus to an unwanted surgical result.

- ▶ Check the correct alignment of the patient supporting system in relation to the device and the correct alignment of the patient head in relation to the laser arm before each docking of an eye (see instructions for use of VISUMAX 600 / VISUMAX 800 Adjusting the patient supporting system).

Prerequisite

- ☒ The device is in standby mode (device arm(s) folded up) as indicated in the instructions for use VISUMAX 600 / VISUMAX 800.

Action

1. Check the correct alignment of the patient supporting system relative to the device.
2. Bring the patient into the treatment room.
3. Lay the patient on the patient supporting system and position him for treatment in dorsal position.
4. Ensure that the patient is in a correct and comfortable position.
5. Check the patient data and start the treatment procedure on the planning screen of the device.
6. Check the identity of the patient again using the master data.
7. Use the side view camera video and the corresponding overlay on the planning screen to check the correct position of the patient head.
8. If necessary, correct the position of the head using the patient supporting system or by moving the device head via entries on the planning screen.

4.4.2 Preparing the eye

CAUTION!

Incomplete incisions and poor tissue separation due to foreign bodies, anesthetics, meibomian secretion, markings on the corneal surface or drying of the cornea

Drying of the cornea can adversely affect the focusing of the laser radiation and the position of the cornea. Certain substances or particles on the cornea, e.g. foreign bodies, anesthetics, meibomian secretion or markings on the corneal surface absorb the laser light, which may result in incomplete incisions and poor tissue separation.

- ▶ Attach the contact glass to the laser objective before rinsing the eye.
- ▶ Irrigate the corneal surface thoroughly to remove any residual meibomian secretions or other particles.
- ▶ Moisten the cornea regularly as long as the speculum is inserted.
- ▶ Clean the corneal surface and remove anesthetic fluid and other particles before docking.
- ▶ If you use corneal markers, use only IR-transparent marking ink.
- ▶ Check that the marking is not visible in IR illumination.

CAUTION!

Incomplete incisions and poor tissue separation due to use of contact agents or excessive exposure to anesthetics

The use of contact agents between cornea and contact glass or excessive exposure to anesthetics by a delayed workflow can have negative impact on the focusing of the laser radiation and the position of the cornea. This may result in incomplete incisions and poor tissue separation.

- ▶ Do not use a contact agent.
- ▶ Administer the local anesthetic only immediately before the laser treatment, taking into account the specified exposure time. Consider postponing surgery to another treatment day if workflow is interrupted.

Prerequisite

Action

- ☒ The patient has been prepared and correctly positioned.
 1. Give a topical anesthetic.
 2. Provide a suitable sterile environment for the eye and ensure that the lashes do not protrude into the operating area.
 3. Insert the lid speculum.
 4. Open the lid speculum so that you have good access to the treatment area, ideally with the iris in the center of the palpebral fissure.

5. Mark the cornea non-symmetrically and symmetrically on the opposite side using an appropriate marking ink, e.g. gentian violet.
6. Rinse the corneal surface thoroughly to remove any residual meibomian secretion or other particles.
7. Remove any excess of liquid on the cornea and the surrounding area where the suction of Treatment Pack is to be applied. The surface should be moist but not wet.

4.4.3 Activating the laser mode

CAUTION!

Incomplete incisions and poor tissue separation due to dirt on the optics of the laser exit aperture

Dirt on the optics of the laser exit aperture absorbs the laser light, resulting in incomplete incisions and poor tissue separation.

- ▶ Protect all optical exits (laser exit aperture and surgical microscope tube) against contamination and avoid touching optical exits.
- ▶ Never touch or clean the optics of the laser exit aperture. The laser exit aperture is checked for contamination during the regular safety inspection. Cleaning may only be performed by ZEISS Service.

Prerequisite

- ☒ The patient has been prepared and is aligned to the device.

Action

- ▶ Press the laser mode button [LM] on the device head.

Result

- ✓ The laser arm moves into the working position.

If the patient head is in the collision area of the laser arm, the automatic movement of the laser arm is stopped.

Remove the obstacle from the swivel range or reposition the patient head. If the collision sensor cannot be switched off by this method, bring the laser arm into the working position by holding down the laser mode button [LM]. Pay attention to possible collisions of the laser arm with the patient and stop the arm movement manually or by releasing the laser mode button [LM] if necessary.

4.4.4 Confirming treatment data

CAUTION!

Complications due to incorrect treatment parameters

The use of incorrect treatment parameters, mix-up of the patient, eye or treatment method can lead to unwanted treatment results.

- ▶ Make sure that you have chosen the right patient, the right treatment method and the correct eye.
- ▶ Check the treatment parameters carefully.
- ▶ Do not begin laser treatment until all parameters are correct.

Prerequisite

- ☒ The laser mode is active.

Action

1. Select the eye to be treated on the treatment screen (OD / OS).
2. Verify the personal data, the planned treatment parameters and the eye to be treated, e.g. by talking to the patient or by using the Surgical Safety Checklist on the treatment screen. Then confirm your verification.

Advanced treatment parameters

The optional "Advanced treatment parameters" function must be activated by the application specialist in the course of application training, depending on the range of use of the device and the level of training achieved.

 CAUTION!

Complications with impact on applicative characteristics and clinical results

Simultaneous changing of several parameters in large increments can have a significant effect on the applicative characteristics and clinical results.

- ▶ Adjust the pulse and track distance as well as energy treatment parameters only in small increments.
- ▶ Do not exceed step sizes of 0.1 µm for the pulse and track distance as well as two stages for the energy unless you have already gained experience with the effect achieved.
- ▶ Contact ZEISS Application Support for optimum settings.

Action

1. Tap the [Advanced] button to select and adjust advanced treatment parameters.

As a rule the following effect can be anticipated:

- When the spot and track distance are decreased, the incision time will be increased, and the energy can be slightly decreased.
- When the spot and track distance are enlarged, the incision time will be reduced and the energy can be slightly increased.
- Increasing the energy results in improved tissue separation, provided there is no excess gas formation in the tissue.
- Slight gas formation in the tissue has only a minor influence on tissue separation.
- If no gas formation is observed in the tissue, the energy can be slightly increased for improved tissue separation.
- If the direction of scanning is changed, it may be necessary to adjust the other parameters.

It is recommended to use the same energy level for the side and lamellar incisions of the different applications.

2. Check and confirm the treatment parameters for the eye to be treated after optimizing the advanced parameters. The modified parameters are immediately effective for the subsequent treatment.
The preferred settings can be saved as standard values for the device. This can be done by the ZEISS application specialist responsible.

4.4.5 Attaching Treatment Pack

CAUTION!

The light emitted by the VIS treatment illumination (white light LED) integrated in the VISUMAX 600 / VISUMAX 800 is potentially hazardous

The longer the duration of exposure, the greater the risk of ocular damage. With this illumination unit, an irradiation period at maximum intensity leads to exceeding the recommended hazard reference value of 2.2 J/cm^2 after 1.1 minutes.

At 2.2 J/cm^2 the risk of retinal injury is not high, but some patients are more vulnerable than others. Care should therefore be taken when exceeding this reference value. There is a significant risk of retinal injury if the reference value of 10 J/cm^2 is exceeded and the user should therefore avoid irradiation lasting more than 5 minutes. The light dosage from the illumination system is a product of light intensity and exposure time.

- ▶ Dock the patient as soon as possible after attaching the contact glass to avoid unnecessary irradiation of the eye.
- ▶ Switch to IR illumination to completely avoid the hazard.

 CAUTION!

Hazards due to contact of the eye with the device without using Treatment Pack

Contact of the laser exit aperture with the patient's eye can cause injury due to the edges of the contact glass mount. Furthermore, contamination of the eye with non-sterile parts of the device is possible.

Possible contamination of the laser exit aperture can lead to incomplete incisions in the eye.

- ▶ Always ensure that there is no contact with the patient when the objective lens is lowered.
- ▶ Check the cleanliness of the optics of the laser exit aperture prior to each treatment and prior to swiveling down the laser arm.
- ▶ Attach the contact glass to the laser objective before rinsing the eye.
- ▶ Never clean the optics at the laser exit aperture yourself, always contact ZEISS Service.

 CAUTION!

Incomplete incisions and poor tissue separation or incorrect incision geometry due to unsuitable Treatment Pack

The use of unsuitable Treatment Pack or Treatment Pack not approved for this device may result in incomplete incisions or incorrect incision geometry, which may have a negative impact on the treatment result.

- ▶ Use only Treatment Pack which is expressly approved by Carl Zeiss Meditec.

 CAUTION!

Incomplete incisions or poor tissue separation due to the use of a smaller Treatment Pack than selected in the planning

The device checks whether the size of the attached contact glass matches the selected size in the treatment planning and indicates any deviation. If Treatment Pack is smaller than specified in the treatment plan, this can lead to incomplete laser incisions, which can have a negative impact on the treatment result.

- ▶ Ensure that the size of the connected Treatment Pack corresponds to the planned treatment diameter size in the graphical user interface.

 CAUTION!

Incomplete incisions and poor tissue separation due to contamination of the contact glass

Unpacking or touching Treatment Pack can contaminate the optically effective surface of the contact glass. This leads to shading of the laser radiation and thus to incomplete incisions and poor tissue separation during laser treatment, which can have a negative impact on the treatment result.

- ▶ When unpacking and attaching Treatment Pack, be careful not to touch the contact glass.
- ▶ Before attaching Treatment Pack, check the contact glass for contamination.

 CAUTION!

Mechanical hazard and suction loss due to improper attachment of Treatment Pack

If the mechanical connection between Treatment Pack and the vacuum connection of the device is not tight, this can lead to underpressure and thus suction loss, which can have a negative impact on the treatment result. The attachment of Treatment Pack must be twisted tightly onto the vacuum connection so that the connection is sealed. The device allows treatments only if a sufficient underpressure has been reached.

- ▶ Ensure that the Treatment Pack connection is correctly attached to the vacuum connection of the device.
- ▶ Make sure that you do not overtighten the connection, otherwise it may break off with sharp corners and edges and can only be removed by a service call.

 CAUTION!

Biological hazard, risk of infection or cross-contamination due to non-sterile patient environment or improper handling of Treatment Pack

Improper handling of Treatment Pack in sterile packaging can have a negative impact on its sterility, which may result in a biological hazard to the patient's eye, infection or cross-contamination.

- ▶ Observe the current hygiene recommendations of the medical associations in all procedures on the patient's eye.
- ▶ Do not remove the sterile Treatment Pack from its wrappings until immediately before use and take precautions to ensure that it remains sterile.
- ▶ Use only originally wrapped Treatment Packs in a sterile environment. Do not use Treatment Pack if it has passed its use-by date (see wrapping), or if its wrapping is damaged. Do not use Treatment Pack if it was not stored correctly.
- ▶ Examine the wrappings of Treatment Pack to ensure there is no damage before removing it. Do not use Treatment Pack if you are not certain that it is sterile.
- ▶ Use each Treatment Pack only once.

Prerequisite

- ☒ The treatment data of the eye are confirmed.

Action

1. Move the laser objective in the laser arm to its working position by turning the joystick of the laser arm until you are prompted on the treatment screen to attach Treatment Pack.
2. Note the indication of the planned size of Treatment Pack.
3. Check the correct size / type of Treatment Pack before unpacking it.
4. Unpack Treatment Pack from its sterile packaging.
5. Then check the cleanliness of the contact glass surfaces.
6. Attach the contact glass to the device and connect the tube with the vacuum connection.
7. Hold the contact glass only by its holder and do not touch the optical parts of the contact glass.

4.4.6 Docking and suctioning the eye

CAUTION!

The light emitted by the fixation light integrated in VISUMAX 600 / VISUMAX 800 is potentially hazardous

The longer the duration of exposure, the greater the risk of ocular damage. Irradiation with this illumination unit leads to exceeding the recommended hazard reference value of 2.2 J/cm^2 after 2.2 minutes.

At 2.2 J/cm^2 the risk of retinal injury is not high, but some patients are more vulnerable than others. Care should therefore be taken when exceeding this reference value. There is a significant risk of retinal injury if the reference value of 10 J/cm^2 is exceeded and the user should therefore avoid irradiation lasting more than 10 minutes.

The light dosage from the illumination system is a product of light intensity and exposure time.

- ▶ Start the treatment promptly after docking the eye.

CAUTION!

Complications due to poor alignment and centering of the patient eye

Manual alignment errors of the patient's eye cannot be corrected by the device and can lead to a decentered position of the corneal incisions, which can have a negative impact on the treatment result.

- ▶ Encourage the patient to cooperate in achieving optimum results.
- ▶ Check the function of the fixation light on the live image.
- ▶ Remind the patient to stare at the fixation light.
- ▶ Do not disable the fixation light before docking.
- ▶ Use the IR illumination option if you cannot see the patient's pupil.
- ▶ Take special care to ensure exact alignment of the patient's eye after suctioning.

CAUTION!

Complications due to poor alignment and centering of the patient eye when using the pupil as reference

If the pupil is used as a reference measure for the centering of the patient's eye, this can lead to a decentered treatment under certain circumstances, which can have a negative impact on the treatment result.

Lateral movement of the contact glass after contact with the eye can interfere with the alignment of the eye, as the patient may then no longer look correctly at the fixation light. In this case the desired corneal position on the contact glass no longer matches the pupil image. The device cannot detect this.

- ▶ If possible, center the eye before contact with the contact glass.
- ▶ Make sure that there is a sufficient film of fluid between the cornea and the contact glass when you make a lateral correction movement for centering after contact has been made. Make sure that the patient is still fixed and looking at the fixation light.
- ▶ In case of doubt, move the device head upwards again until there is no more contact and repeat the procedure.
- ▶ If the centering assistant is used, make sure that the pupil is detected by the software during the entire docking process.

CAUTION!

Incomplete incisions and poor tissue separation due to foreign bodies or dried crystalline substances between contact glass and eye

During docking, foreign bodies, meibomian secretion, anesthetics, tear film or saline solution may come between the cornea and the contact glass. Furthermore, by docking and removing the eye again, tear fluid or isotonic saline solution can dry on the contact glass and leave salt stains. These influences can later lead to incomplete incisions and poor tissue separation.

- ▶ When docking and after the eye has been suctioned, look for foreign objects between the contact glass and cornea, especially if you dock several times.
- ▶ Avoid undocking for excessive periods of time after suction has been applied and the suction has been released again.

CAUTION!

Suction loss due to excessive liquid on the eye

Using too much liquid when the eye is docked to the contact glass may cause the liquid to enter the vacuum system, resulting in a drop in suction pressure and thus a suction loss during laser treatment.

- ▶ Make sure that there is no excessive liquid on the eye when docking.

 CAUTION!

Suction loss due to patient movements

For safety reasons, the pressure force of the eye at the contact glass is limited in such a way that significant movement of the patient's head leads to suction loss. This prevents injury to the patient.

As a result, the patient's own movements can cause suction loss and interruption of the treatment, which can have a negative impact on the treatment result.

- ▶ Ensure that conditions which may distract the patient (background noise, other activities in the operating room) are kept to a minimum while the eye is under suction.
- ▶ Bear in mind that slight movements of the pupil may occur without any movement of the cornea.
- ▶ Encourage the patient to lie as still as possible.
- ▶ Instruct the patient not to speak while the eye is suctioned.

Prerequisite

- ☒ A new Treatment Pack is attached to the laser objective.

Action

1. Re-check the preparations for surgery of the eye.
2. Use the laser arm joystick to position the laser arm over the eye to be treated.
Ensure that the eye to be treated is located approximately in the middle of the live image display of the treatment screen.
3. Ask the patient to fixate upon the green fixation light and use the live image display of the treatment screen to inspect the patient's eye.
4. Make sure that no parts of the body, except the eye, come into contact with the contact glass or device. To avoid accidental nose contact with the laser objective, tilt or turn the patient's head. Make sure that the limbus is not covered by the speculum, outer eyelid angle or tear film meniscus.
5. Use the laser arm joystick to position the laser arm. Observe all movements of the laser arm and constantly check the position of the patient eye in relation to the contact glass on the treatment screen.
6. Position the laser arm so that the visual axis of the eye to be treated is exactly in the center of the contact glass and the eye meets the contact glass. When approaching, the treatment illumination reflex should be in the center of the live image display of the treatment screen.
7. Bring the cornea into contact with the contact glass, using the live image display on the treatment screen and the Centralign® centering assistant (overlay) to center on the planned treatment center. This will be described in detail in section Functional description of the Centralign centering assistant of the VISUMAX 600 / VISUMAX 800 instructions for use.

8. Switch on the vacuum suction by pressing the suction button on the laser arm joystick as soon as the cornea is in sufficient contact with the contact glass, and allow the eye to be suctioned onto the contact glass.
 - ⇒ The eye is suctioned onto the contact glass by under-pressure (vacuum).
 - ⇒ The suction pressure can be observed on the vacuum display on the treatment screen.
 - ⇒ When the suction pressure has reached the required range, the next treatment step is started.
 - ⇒ If the rotation assistant is not activated, the device switches directly to the READY operating mode after the eye is docked and suctioned.
9. Check again for proper centering after the eye is suctioned.
10. Check that the eye is securely suctioned.
11. Ensure that conditions which may distract the patient (background noise, other activities in the operating room) are kept to a minimum while the eye is under suction.

4.4.7 Alignment of the cutting pattern

CAUTION!

Complication due to excessive suction time

An excessively long suction time increases the risk of suction loss and unintentional treatment abortion due to the decreasing concentration of the patient.

- Keep the time between the start of eye suction and the start of laser treatment as short as possible.

CAUTION!

Angular errors due to incorrect alignment of the medical diagnostic device or the patient head

Incorrect alignment of the medical diagnostic device or the patient's head during acquisition of the iris image leads to angular errors.

- Ensure correct alignment of the diagnostic device and patient head.

CAUTION!

Complications due to rotation of the cutting pattern

By rotating the cutting pattern on the eye, all planned incisions are rotated, which may complicate treatment steps after laser treatment.

- Plan the geometry of the incisions so that you can safely perform the treatment steps after laser treatment despite maximum possible rotation.

⚠ CAUTION!

Possible deterioration of the prognosis for refractive correction due to rotation of the cutting pattern

Incorrect rotation of the cutting pattern on the eye can lead to a possible deterioration of the prognosis for refractive cylinder correction.

- ▶ Make sure that the orientation of the cutting pattern matches the horizontal orientation of the eye as closely as possible, and do not rotate the cutting pattern.

After the eye is suctioned, the joystick on the laser arm no longer causes mechanical adjustment of the laser arm.

Prerequisite

- ☑ The OcuLign® license for the orientation of the cutting pattern has been enabled.
- ☑ The patient eye is suctioned to the contact glass.
- ☑ The planning data contains a valid iris image, which is required for the automatic calculation of a proposal.

Action

1. Turn the laser arm joystick to adjust the rotation of the cutting pattern on the eye, if necessary, using the horizon lines of the overlay shown in the live video (OcuLign® rotation assistance).
 - ⇒ The pattern can be rotated $\pm 20^\circ$ using the laser arm joystick to match the markings on the cornea.
 - ⇒ During adjustment, the device leaves the READY mode, so that no treatment can be started by pressing the foot switch.
2. Move the joystick back to the neutral position to return to the READY mode.

If an iris image is available in the planning data, the device automatically switches to IR illumination and calculates a starting angle for the alignment of the cutting pattern. The starting angle is adopted for the treatment and the horizon lines of the overlay displayed in the live video are rotated around it.

3. Manually align the cutting pattern as described above by switching to VIS illumination.

Alternatively, you may proceed as follows:

4. Accept the calculated proposal of the rotation angle by checking the plausibility of the proposal.
5. Press and hold the treatment navigation key forward [➤] on the laser arm to display the iris image as an overlay over the live image.
 - ⇒ The size and orientation of the iris image is adapted to the live image by the software.

6. Compare the positions of iris structures between iris image and live image.
 - ⇒ When the iris image has been overlaid at least one time and hidden again, the "Laser ready" status is displayed on the treatment screen.
7. If necessary, press the treatment navigation key backward [←] on the laser arm to perform the automatic calculation of the rotation angle proposal again. This will be described in detail in section Functional description of the OcuLign rotation assistant of the VISUMAX 600 / VISUMAX 800 instructions for use.

4.4.8 Performing laser treatment

CAUTION!

Complications due to suction loss, treatment abortion, incomplete bubble pattern, incorrectly positioned or incomplete incisions

The sucking in of bubbles at the outer rim of the contact glass is an indication of imminent suction loss. There may also be lateral movements of the cornea without suction loss caused by the patient's eye movement.

If the extent and position of the incision surfaces do not correspond to the intended treatment, this can impact the treatment result.

- ▶ Observe the progress on the treatment screen during the entire laser operation.
- ▶ The process must be stopped immediately if the extent and position of the incision deviate from the intended treatment.
- ▶ Do not perform surgery if the incisions are incorrectly positioned or not complete.
- ▶ You may want to use the restart mode in the event of suction loss without incorrectly positioned incisions or consult the medical literature for further therapy options if you wish to perform secondary treatment.

CAUTION!

Incomplete bubble pattern due to faults in the beam delivery system

An incomplete bubble image can be an indication of an error in the beam delivery system, which means that the laser incisions are not completed. If in this case a surgical treatment is performed immediately after the laser treatment, there is a risk of damaging the patient's cornea.

- ▶ Do not perform surgery if the incisions are incorrectly positioned or not complete.

Prerequisite

- ☑ The patient eye is suctioned to the contact glass.
- ☑ The device is in the READY mode.

Action

1. Press the foot switch to start the treatment or resume the treatment after an interruption.
2. Keep the switch depressed during treatment. The laser treatment runs automatically.
 - ⇒ The emission of laser radiation is signaled by a warning on the treatment screen and "Laser emission" warning light lights up.
3. Carry out the entire treatment. Observe the developing bubble pattern in its temporal course on the treatment screen.
 - ⇒ The laser incisions are applied starting from the periphery from the outside to the center and ending with the flap side cut. Advise the patient that the fixation light will disappear but that he / she has to maintain fixation. Do not change the head position of the patient during laser treatment.
 - ⇒ A sensor in the device automatically compensates for slight vertical movements of the treatment objective. Lateral movements of the patient head can be prevented by gently touching the patient head with your hands.
4. Release the foot switch to pause the treatment if necessary.
5. Press the foot switch to resume the treatment.
6. If you want to abort the treatment completely, release the foot switch and detach the eye suction using the suction button on the laser arm joystick.

If the treatment is aborted by suction loss we recommend using the functions automatically offered by the device for continuing or resuming laser treatment (see section Restart of laser treatment [► 38]).

At the end of the surgery a message will appear on the treatment screen. In the event of abortion, additional safety queries and messages will appear.

4.4.9 Undocking the eye

When the laser treatment is completed, the device automatically releases the eye suction. After releasing the eye suction, the eye is automatically undocked by lifting the device head to a safe distance.

You can interrupt this movement by moving the joystick on the laser arm. Afterwards, the joystick only allows upward movement until the safe distance is reached.

4.4.10 Restart of laser treatment

In rare cases, there is a loss of eye suction during laser treatment. This causes the operation to be aborted.

CAUTION!

Incomplete incisions or unwanted incision geometry due to resumed or restarted laser treatment

In the case of a restarted treatment, if the centering is not perfect, the cut surfaces may not match exactly. A lack of caution during manual treatment may cause corneal components to be cut off completely or to be cut off incomplete, which may have a negative impact on the treatment result.

- ▶ When resuming or restarting the laser treatment, make sure that the centering of the initial treatment is reproduced as accurately as possible and that the incision surfaces match.
- ▶ Do not start manual treatment if you are not sure that the incisions are correctly completed and consult the medical literature for further therapy options if you wish to perform secondary treatment.

If the treatment is interrupted during laser incision we recommend using the functions automatically offered by the device for continuing or resuming laser therapy. The procedure automatically recommended by the device is based on the progress information acquired from electronic process monitoring. The process monitoring is not a substitute for monitoring by a physician. The automatic recommendation is not a substitute for the physician's decision on the time and method of continuing treatment. The decision on proceeding or resuming laser treatment must ensue on the basis of one's own observation of the respective treatment, the RSTPs and current information from medical literature by the physician in attendance.

Prerequisite

- ☒ The laser treatment was aborted without device error.
- ☒ Treatment is resumed immediately after abortion of the previous treatment.

Action

- ▶ Follow the safety prompts and messages on the treatment screen.

Case 1: Flap cut interruption

If the laser treatment is interrupted during the creating of the flap cut:

Action

- ▶ Repeat the procedure from the start of the flap cut.
- ▶ Use the same flap thickness as in the previous treatment.

Case 2: Flap side cut interruption

If the laser treatment is interrupted during the creation of a flap side cut and manual opening of the existing tissue bridge does not appear feasible in view of the treatment progress:

Action

- Repeat the procedure from the start of the flap side cut.

It should be noted that a substantial part of the side cut is located in the epithelium. Manual transsection of the remaining tissue bridge is often easily achieved during advanced laser progress of the flap side cut.

It is at the discretion of the physician to increase the depth of the side cut or reduce the flap diameter according to clinical requirements.

The purpose of increasing the depth of the flap side cut is to ensure the flap cut extends across the entire width, and to penetrate the cut surfaces. If needed, the complete treatment can be repeated to the same depth from the start of the flap cut.

4.4.11 Removing Treatment Pack

CAUTION!

Mechanical hazard from falling contact glass

If you click the [Release] button, the contact glass may fall off from the laser objective and onto the patient's opened eye.

- Hold the contact glass holder before pressing the [Release] button and then remove the contact glass from the patient environment.

Action

1. Hold the contact glass holder by the tube connection.
2. Tap the [Release] button on the treatment screen and remove the contact glass from the laser objective.
3. Turn the vacuum connection of Treatment Pack half a turn counterclockwise and pull it off the vacuum connection of the laser arm.
4. Discard Treatment Pack.

4.4.12 Treatment steps after laser treatment

CAUTION!

The light emitted by the OPMI integrated in the VISUMAX 800 is potentially hazardous

The longer the duration of exposure, the greater the risk of ocular damage. With this illumination unit, an irradiation period at maximum intensity without filter leads to exceeding the recommended hazard reference value of 2.2 J/cm^2 if the user does not reduce the irradiation intensity after 1.1 minutes.

At 2.2 J/cm^2 the risk of retinal injury is not high, but some patients are more vulnerable than others. Care should therefore be taken when exceeding this reference value. There is a significant risk of retinal injury if the reference value of 10 J/cm^2 is exceeded and the user should therefore avoid irradiation lasting more than 5 minutes. If the retinal protective filter is activated, an irradiation period with this illumination unit at maximum intensity of more than 30 minutes will result in the hazard reference value being exceeded.

The light dosage of the illumination is the product of light intensity and exposure time.

- ▶ Maintain the light intensity no higher than absolutely necessary and pay attention to the duration of exposure of the eye to minimize the radiation exposure of the patient.
- ▶ Activate the retinal safety filter in case of longer treatment periods.

Configuration	Maximum illumination	50% of maximum illumination
Without retinal safety filter	5 minutes	10 minutes
With retinal safety filter	30 minutes	60 minutes

Table 1: Maximum radiation intensity exceeding the hazard reference of 10 J/cm^2

 CAUTION!

The light emitted by the VIS slit illumination (white light LED) integrated in the VISUMAX 800 is potentially hazardous.

The longer the duration of exposure, the greater the risk of ocular damage. Irradiation with this illumination unit leads to exceeding the recommended hazard reference value of 2.2 J/cm² after 1.1 minutes.

At 2.2 J/cm² the risk of retinal injury is not high, but some patients are more vulnerable than others. Care should therefore be taken when exceeding this reference value. There is a significant risk of retinal injury if the reference value of 10 J/cm² is exceeded and the user should therefore avoid irradiation lasting more than 5 minutes. The light dosage from the illumination system is a product of light intensity and exposure time.

- Use the VIS slit illumination (white light LED) only as long as absolutely necessary.

 CAUTION!

Possible corneal injury due to surgical procedure performed too late without visible bubble formation

The laser incision creates microbubbles in the cornea, which are macroscopically visible and can be used for orientation during the surgical procedure. These microbubbles are slowly absorbed by the tissue so that they are no longer visible after some time.

- After the laser treatment, perform the eye surgery quickly, otherwise it is much more difficult to localize and identify the laser incisions.

Prerequisite

Action

- ☒ Completed laser treatment of patient eye.
- 1. When using a **VISUMAX 800**, press the observation mode button [OM] to activate the observation mode.
 - ⇒ The laser arm moves up and the laser objectives retracts back into the laser arm. The OPMI arm moves to the working position.
- 2. Adjust the focus using the joystick on the OPMI arm or the pedal on the foot control panel.
- 3. When using a **VISUMAX 600**, press the standby mode button [II] to swivel the laser arm to its standby position and bring an external surgical microscope into working position. For example, swivel the patient on the patient positioning device under an excimer laser in order to use the operating microscope there for the further course of treatment. Make sure that the minimum requirements for an external OPMI are met (see Minimum requirements for an external OPMI in the VISUMAX 600 / VISUMAX 800 instructions for use).
- 4. Examine the result of the laser treatment.

5. Return the patient's head back to a natural, relaxed position so the patient is relaxed.
6. Using a surgical microscope and an excimer laser, perform all the necessary steps to complete the treatment.

4.4.13 Complete the treatment

Prerequisite

- ☒ Completed or aborted treatment of the patient.

Action

1. Close the treatment mode of the device.
2. Bring the patient in position for the subsequent LASIK treatment. Remove the lid speculum if the patient has to leave his/her position on the patient supporting system. Follow the RSTPs of the device used.
3. Help the patient to stand up from the patient supporting system and guide him out of the treatment room.
4. Clear and disinfect the surgical area.

The RSTPs are not limited to this list. For a complete list of instructions on treatment, please consult medical literature, professional medical associations and current legislation in your particular country.

4.4.14 Follow-up examination / treatment

The patient should be re-examined after the treatment on the same day of surgery. It is strongly recommended to use a slit lamp to examine the cornea.

The next day and ideally also during a subsequent post-op appointment, further follow-up examinations should take place to determine the refractive and visual result. It is also recommended to examine the cornea with the slit lamp at each examination. The administration of tear substitutes for the early post-operative phase is recommended.

Depending on the indication, administration of the following medication may be necessary:

- Anti-inflammatory glucocorticoids (e.g. medication containing dexamethasone such as DEXA EDO or DEXA SINE)
- Antibiotics (e.g. FLOXAL EDO)

The choice of a suitable medication and its dosage is the responsibility of the attending physician.

5 Technical specifications

5.1 Thresholds for adjustment ranges for flap

Adjustment ranges for cutting geometry

	Value
Flap thickness	80 µm to 220 µm
Flap diameter	7.0 mm to 9.7 mm (depending on Treatment Pack size)
Hinge position	0° to 359°
Hinge angle	30° to 330° (minimum length 2 mm)
Side cut angle	45° to 135°

5.2 Maximum possible flap diameter

The effective maximum flap diameter is given in the table below. It depends on the following:

- Size of Treatment Pack
- Flap thickness
- Corneal curvature radius
- Side cut angle

The flap diameter is always given as the diameter of the flap bed in the naturally relaxed eye. Therefore, the side cut angle may reduce the available maximum flap bed diameter slightly. Please note the cutting geometry diagram on the right side of the screen for treatment planning.

Size of Treatment Pack: L

Maximum flap bed diameter (mm)		Flap thickness (µm)			
		80	100	120	140
Corneal curvature radius (mm)	6.5	9.2	9.2	9.2	9.2
	6.8	9.3	9.3	9.3	9.2
	7.1	9.4	9.4	9.3	9.3
	7.4	9.4	9.4	9.4	9.4
	7.7	9.5	9.5	9.5	9.5
	7.9	9.5	9.5	9.5	9.5
	8.2	9.6	9.6	9.6	9.6
	8.5	9.7	9.6	9.6	9.6

Size of Treatment Pack: M

Maximum flap bed diameter (mm)		Flap thickness (µm)			
		80	100	120	140
Corneal curvature radius (mm)	6.5	8.6	8.6	8.6	8.6
	6.8	8.7	8.7	8.7	8.6
	7.1	8.7	8.7	8.7	8.7
	7.4	8.8	8.8	8.8	8.8
	7.7	8.9	8.8	8.8	8.8
	7.9	8.9	8.9	8.9	8.8
	8.2	8.9	8.9	8.9	8.9
	8.5	9	9	8.9	8.9

Size of Treatment Pack: S

Maximum flap bed diameter (mm)		Flap thickness (µm)			
		80	100	120	140
Corneal curvature radius (mm)	6.5	7.8	7.8	7.8	7.8
	6.8	7.9	7.9	7.9	7.8
	7.1	7.9	7.9	7.9	7.9
	7.4	8	8	7.9	7.9
	7.7	8	8	8	8
	7.9	8	8	8	8
	8.2	8.1	8	8	8
	8.5	8.1	8.1	8.1	8

Product subject to change without notice in response to technical developments.

6 Accessories

These instructions for use also describe accessories that are not essential components of all deliveries. A current list of accessories 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 and spare parts which are approved by ZEISS for this device. If accessories and spare parts are used that are not approved by ZEISS, safe operation of the device cannot be guaranteed.

The following accessories are intended for this treatment option:

- Procedure Pack, consisting of:
 - REF 1013 Treatment Pack S with instructions for use
 - REF 1014 Treatment Pack M with instructions for use
 - REF 1015 Treatment Pack L with instructions for use
- and the included treatment license for the Flap option

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7 Disposal

Used Treatment Packs are waste articles whose collection and disposal is not subject to special requirements in terms of infection prevention. The regulations for this waste group applicable in the country of use must be complied with.

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Glossary

CentraLign

Assistance system for alignment of the treatment center

Flap

Corneal flap to expose the stroma

Hinge

Hinge of the flap

IEC

International Electrotechnical Commission

IR

Infrared

ISO

International Organization for Standardization

LASIK

Laser-in-situ keratomileusis

ME system

Medical electrical system

OcuLign

Assistant system for cyclotorsion compensation

RSTP

Recommended standard treatment procedures

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