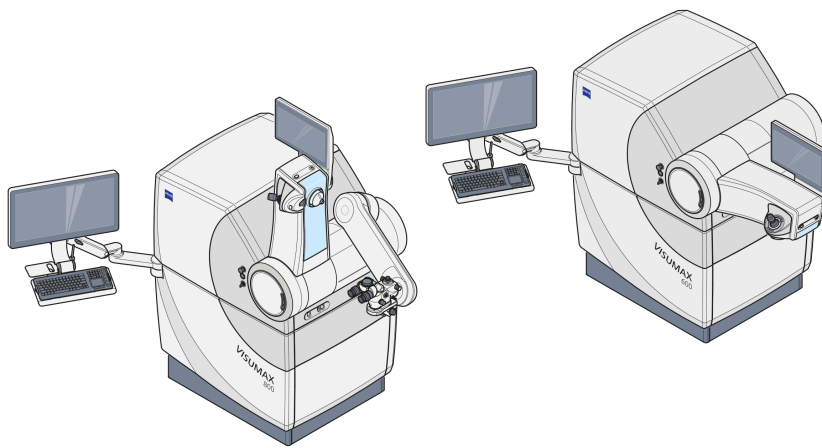


VISUMAX 600, VISUMAX 800

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 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: Conventions in this document [► 7].

This is **bold type**.

This is `software code or program text`.

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

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

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

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

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

- [START] key
- [Next] button

1.5.2 Conventions in a course of action

WARNING!

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

The warning message names the possible consequences.

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

CAUTION!

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

The warning message names the possible consequences.

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

NOTE

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

The warning message names the possible consequences.

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

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 conjunction with the associated instructions for use for the respective purchased and locally approved treatment options and for the other medical devices that are part of the system:

Documents

- Instructions for use of treatment options
- 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 [► 66] and the instructions for use of the patient supporting system.

When using the VISUMAX 600 in combination with a treatment option which involves observation with an operating microscope, an external operating microscope is required. In particular, familiarize yourself with section Minimum requirement for an external operating microscope (OPMI) [► 70] and the instructions for use of the operating microscope.

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2 Safety notes

2.1 Intended user profile

The 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 working 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 measurement results on the therapy
- Knowledge regarding consistency checks 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 working 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 measurement results on the therapy
- Knowledge regarding consistency checks of data used for treatment planning

User profile: Cleaning and disinfecting

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

- Knowledge of recognized cleaning and disinfection procedures in clinical operations
- Experience in handling detergents and disinfectants
- Experience in the cleaning and disinfecting of diagnostic and therapeutic devices in ophthalmology
- Regular training according to the regional guidelines for hospital hygiene and infection prevention

Further requirements for the user in connection with specific treatments are explained in the documentation accompanying the respective treatment option.

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

The device is intended for use in ophthalmological surgery to make lamellar and penetrating corneal incisions.

Any use of the device beyond the intended use described in this manual and in the instructions for use for combined treatment options is off-label use.

The specified intended use and respective contraindications, side effects and user profiles are contained in the documentation accompanying the respective treatment option.

2.2.2 Contraindications

CAUTION!

Negative effects on the treatment results if contraindications are ignored

The contraindications for using this device depend on the treatment option used and are described in the documentation accompanying the respective treatment option.

If you do not observe the contraindications, you could endanger the patient's health.

- ▶ Familiarize yourself with the specific contraindications for each treatment option before using it.
- ▶ Observe all contraindications cited in the literature of professional medical associations and in the relevant laws in force in your country.
- ▶ Consider the risks and contraindications, weighing the potential desirable and undesirable effects.

For further risks and contraindications, observe the instructions for use for the patient supporting system.

2.2.3 Side effects

The side effects when using this device depend on the treatment option used. The side effects are contained in the documentation accompanying the respective treatment option.

Explain to the patient the benefits, mode of operation, possible side effects, complications and risks associated with the treatment.

For further risks and contraindications, observe the instructions for use of the patient supporting system.

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, request additional 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 [▶ 16]).
- ▶ Regularly check compliance with the national laws and regulations concerning accident prevention and occupational health.

Safety inspections

- ▶ Have regular safety inspections performed in accordance with the applicable national regulations for this device.
This ensures reliability and basic safety of the device and prevents deterioration of the essential performance feature due to aging and wear.

Safety inspections may be carried out only by the manufacturer or by persons authorized by the manufacturer.

- ▶ Keep within the prescribed intervals.
- ▶ Perform the inspections to the prescribed extent and check the result for deviations.

The following safety inspections and checks should be performed as a minimum for the device:

- Check the presence of the instructions for use
- Visual inspection of the device and its accessories for damage, as well as legibility of markings and labels
- Leakage current test
- Protective ground conductor check

- Check the ventilation slits of the device. They should not be covered or obstructed.
- Check the device safety functions

Expected service life

The development, production and maintenance of the device, as well as the associated risks, are based on an expected service life of **eight years**, assuming that the device is operated and maintained as prescribed by the manufacturer.

Maintenance and inspection

- Adhere the bi-yearly maintenance and inspection intervals to ensure safe operation of the device and to achieve its expected operating life.

Changes to the product

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

Accessories and additional equipment

- If you want to connect accessories permanently connected to the device or additional devices to the device: contact your ZEISS contact (www.zeiss.com/med).
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 legal and normative requirements for medical electrical systems (see ME system [► 129]).
Local laws take precedence over the above normative requirements.
- Only accessories and software which correspond with the requirements stated in these instructions for use may be used.

Combination with defibrillators or cardiac defibrillator monitors

The use of this device in combination with defibrillators or cardiac defibrillator monitors may cause exceeding leakage currents, resulting in electric shock.

- ▶ Follow the instructions for use for these devices before using heart defibrillators and heart defibrillator monitors.

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**Electrical safety and electromagnetic compatibility**

- ▶ Perform the electrical installation in conformance to IEC 60364-7-710 or the applicable national regulations. This includes the integration of a ground fault circuit interrupter (GFCI). Insert the power plug only into a power outlet that has an intact protective ground connection.
- ▶ Never open the device.
- ▶ Do not touch the patient and the connections of the device simultaneously.
- ▶ Switch the device off every time before disconnecting it from the power supply, or if you are not going to use the device for any length of time. Also disconnect the device from the power supply before cleaning its surfaces or accessories.
- ▶ Do not use multiple sockets to connect the device to the power supply.
- ▶ Do not use extension cables.
- ▶ Use only cables and plugs which are in perfect working condition.

- ▶ Connect the device only to a power supply that corresponds to the values specified on the rating plate (see Device marking [► 26]).
- ▶ Please note the information on electromagnetic compatibility (EMC) (see Electromagnetic compatibility [► 120]).
- ▶ Set the device up so that the power cable can be disconnected from the power supply quickly and without any supplementary means.
- ▶ Connect the device using the power cable intended for use with the device.

Fire safety

- ▶ Do not operate the supplied devices under power,
 - on easily inflammable materials,
 - in the presence of inflammable anesthetics or volatile solvents, such as alcohol, benzene or similar,
 - in an oxygen-enriched environment.
- ▶ The use of flammable anesthetic gases or oxidizing gases such as nitrogen oxide (N₂O) and oxygen should be avoided. Some materials saturated with oxygen, for example cotton, can be ignited at the high temperatures that occur when the laser device is used according to its intended use.
- ▶ Allow cleaning agents and disinfectants containing flammable solutions to evaporate completely before the device is used or the emittance of laser radiation.
- ▶ When selecting the overcurrent fuse for the mains connection, observe the information on the type label regarding current consumption.

Radiation safety

Laser radiation

The device emits laser radiation for the purpose of treatment. Exposure of the skin and eyes to direct and scattered radiation (except for treatment of the target eye) may result in hazardous radiation exposure.

- ▶ Activate the laser emission using the foot switch only when a patient's eye is aspirated at the contact glass.
- ▶ Use the operating devices and adjustment options only as specified in these instructions for use. If the operating or adjusting functions of the device are used in a manner other than that described in this manual, this can lead to dangerous radiation exposure.

- ▶ Observe the information on the nominal distance for eye hazards underneath the laser exit aperture in section Optical data [▶ 118].
- ▶ The laser hazard area should be as small as possible and demarcated by suitable screens.
Ensure that unauthorized persons do not enter the laser area.
- ▶ Keep the number of persons in the laser hazard area to a minimum.
Persons who are not authorized to use the device may not be left unattended at or in the vicinity of the device.
- ▶ Ensure that the laser hazard area is clearly demarcated and marked as such during laser operation. Laser operation must be indicated by laser warning lights at the access to laser areas.
- ▶ Ensure that floors, ceilings, walls or other equipment belonging to the structural equipment of a room have diffusely reflecting surfaces in rooms intended for laser operation. Suitable covers should be provided for bare surfaces, such as windows.
- ▶ Secure the device against unauthorized use by logging out and withdrawing the key from the key switch when the device is not in use or unsupervised.
- ▶ Select a strong password which has at least 6, preferably 8 characters and contains upper case, lower case, numbers and special characters. Change your password after your first log-in and at least every 90 days.

In some countries the responsible organization is required to:

- notify the responsible authority about the operation of laser systems prior to their first use. This is not carried out by Carl Zeiss Meditec.
- appoint experts for the system as laser protection representative in writing.
- demarcate and label laser areas of laser equipment during operation.
- instruct persons who use laser equipment or who are in laser areas of laser equipment about the rules of conduct to be observed.
- refrain from employing minors in laser areas where laser equipment is operated.
- ▶ Observe national laws.

Illumination radiation

The light emitted by the illumination equipment of this device is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. The light dosage from the illumination system is a product of light intensity and exposure time.

- ▶ In order to minimize radiation exposure, limit one of these parameters to the medically required level for observing the patient's eye.
- ▶ 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 for longer treatment periods.

Mechanical safety

- ▶ Keep an eye on all automatic and manual movements of the device and the patient supporting system.
- ▶ Ensure that no parts of the body or objects are trapped between the patient supporting system and the basic device.
- ▶ Ensure that the patient is not wearing any loose items (e.g. clothing, hand bag, jewelry) that could be trapped between moving parts.
- ▶ Patients with long hair should wear a hair net.

If there is a risk of collision for the patient:

- ▶ Stop the current swivel movement of a device arm manually.
- ▶ Stop movements of the device head by releasing the joystick or foot control panel.
- ▶ If necessary, stop the movements of the patient supporting system in use. This is described in the instructions for use of the relevant patient supporting system.
- ▶ Operate the emergency stop button if there is danger for the patient or user.
- ▶ To provide a comfortable exit position for the patient or to free the patient, push the device arms upwards until they lock mechanically in the standby position.

Ambient conditions

- ▶ Make sure that the installation and ambient conditions of the device meet the following requirements:
 - Low vibration
 - Clean environment
 - Avoid extreme mechanical stress

- ▶ Operate, install or store the system in accordance with the prescribed environmental conditions (see Ambient conditions [▶ 119]).
- ▶ Do not operate, install or store the the device in damp rooms. Do not expose the device to water splashes, dripping water or sprayed water.
- ▶ Ensure that no liquids can enter the device.

Shutting down in the event of a technical failure or fault conditions

If one of the following events should occur:

- electric shock
- penetration of liquids
- occurrence of smoke, fire or burning odor
- frequently occurring error messages
- disimprovement of the system performance
- response of the system in contradiction with the information in these instructions for use
- faults that cannot be remedied based on the information provided in these instructions for use
- system related incidents or near incidents that have resulted or may have resulted in injury to the patient or physician (user)

the following steps for shutting down the device are required:

- ▶ Switch off the device via the software (if possible).
- ▶ Set the key switch to position OFF .
- ▶ Operate the emergency stop / emergency laser stop button on the device.
 - ⇒ This disconnects the internal UPS (if available) from its battery.
- ▶ Switch off the mains switch.
- ▶ Disconnect the power cable from power supply.
 - ⇒ To completely disconnect the device from the power supply, the power supply connector must be unplugged from the mains socket.
- ▶ Label the device clearly as **out of order**.
- ▶ When not in use, remove the key switch from the system to prevent its use by unauthorized persons.
- ▶ Notify ZEISS Service.

Symbols and labels

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

Transport

- ▶ Transport the device over long distances (e.g. move, return for repair, etc.) only in original packaging or special return packaging.
- ▶ For details, please contact your authorized ZEISS dealer or the ZEISS Service team (see Packaging and transport [▶ 133]).

2.5 Safety in product use

The safety instructions for the use of the product can be found in section Operation [▶ 77] and in the instructions for use of the individual treatment options.

2.6 Network integration

The device can be included into an Ethernet network to perform the following applications:

- Print
- Import / export of planning data
- Export of treatment data
- Export of system diagnostic data

The device has an integrated galvanic isolation (4 kV isolation voltage) at the network interface. An additional external galvanic isolation is therefore not necessary.

A clinic or practice network can be connected to the network connection (Ethernet interface) of the device.

Network addresses and port numbers must be specified by the responsible IT system administrator.

The DICOM® (Digital Imaging and Communication in Medicine) standard is the international standard for medical images and related information (ISO 12052). It defines the formats for medical images that can be exchanged together with the relevant data for clinical use in the required quality. For detailed information, please refer to ZEISS DICOM Conformance Statement, www.zeiss.com/dicom.

Data security

Integration of the device in an IT network which includes other ME devices may lead to risks for patients, operators, or other persons that were not previously known. The integrated safety design may not protect against as yet unknown methods of attack or prevent loss of data to be protected.

- ▶ Connect the device only to private networks which are protected from public networks (the internet) by measures which meet the latest technical requirements (e.g. firewalls).
- ▶ Contact your ZEISS contact partner (www.zeiss.com/med) to learn how to configure the interface.
- ▶ Note that if the system is integrated into an IT network and the patient treatment data are combined, undesired modification of the treatment data or unauthorized use of patient data with associated treatment data is possible.
- ▶ Observe the maintenance and inspection measures that are specified in these instructions for use and must be performed twice a year. This also brings the integrated IT safety design up to date.
- ▶ Perform risk management according to IEC 80001-1 when integrating the system into an IT network.
- ▶ The configuration and network settings should only be changed by a network administrator with experience.
- ▶ Note that a reassessment of risks is required for the following changes in IT networks:

IT network modifications are:

- Changes to the IT network configuration
- Connecting additional elements in the IT network
- Removal of elements from the IT network
- Updates or upgrades of devices that are connected to the IT network.

Data integrity

Patient or treatment data could be undetectably tampered with if the device is connected to a data management system (FORUM) with poor data security. The use of incorrect treatment parameters, mix-up of the patient, eye or treatment method can lead to unwanted treatment results.

- ▶ Use encrypted communication.
- ▶ 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.

Data protection and information security

- ▶ Ensure compliance with national data protection laws and regulations.
- ▶ Note that as responsible organizations of IT systems and IT networks you are responsible for defining the required security standards.
- ▶ Create the necessary technical and organizational conditions.
- ▶ Please note the following definitions:

Personal data:

- All information relating to the personal or material circumstances of an identified or identifiable person must be protected.
- All data that can be directly assigned to a person (patient, employee, customer, supplier) (e.g. marital status, employment relationship, religious affiliation, income) must be protected.

Data processing:

- The storage (input, recording or storage), transfer (transmission to third parties outside the organization), modification (fundamental changes, including anonymization and pseudonymization), deletion (removal) and blocking (marking to restrict further processing or use) of data

Use:

- The use of data (e.g. for company internal transmission)

Recipients:

- Persons or entities that receive data

Third parties:

- Persons or entities that are not part of the entity responsible (legal entity).
- The transmission of data to third parties is regarded as data transmission.

2.7 Software installation

The installation of software, uploading of data or the modification of software configurations is reserved exclusively to authorized service personnel.

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3 Description of the device

3.1 Package check list

The device is supplied with the following detachable accessories:

- Documentation set
- Foot switch (FS, material number 000000-0648-378)
- Dummy plug to bridge the remote-controlled safety interlock (material number 000000-1454-088)
- Country-specific power cable 2.5 m or 5 m
The delivery of the power cable is country-specific, for further information please contact your local ZEISS dealer.

Additionally for VISUMAX 800:

- Foot control panel (FCP, material number 000000-2308-828)

3.2 Available variants

- VISUMAX 800:
Device with integrated surgical microscope (OPMI).
- VISUMAX 600:
Device without integrated OPMI.

3.3 Device marking

This section contains adhesive labels and an explanation of the safety signs and icons contained thereon.

Labels on the device

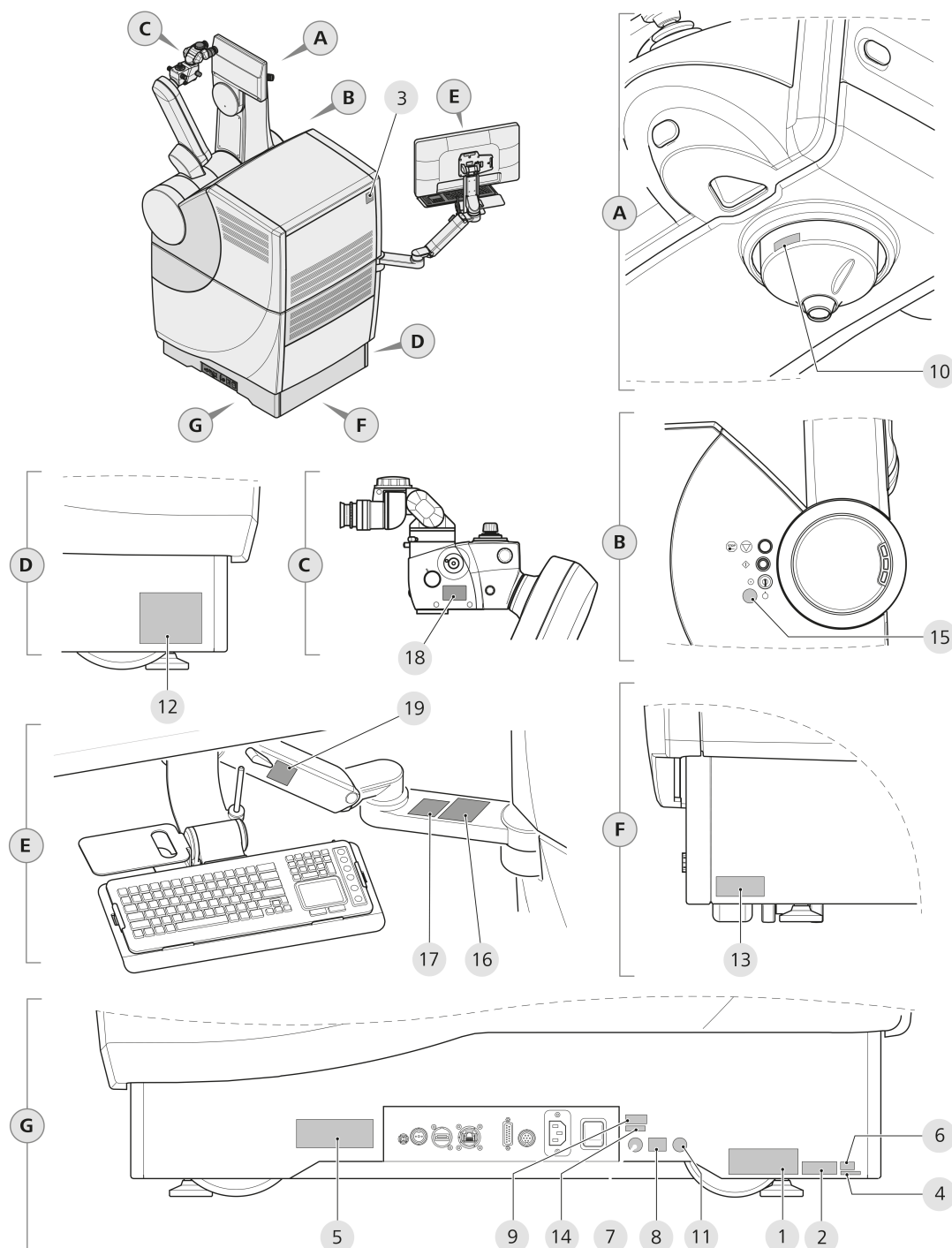
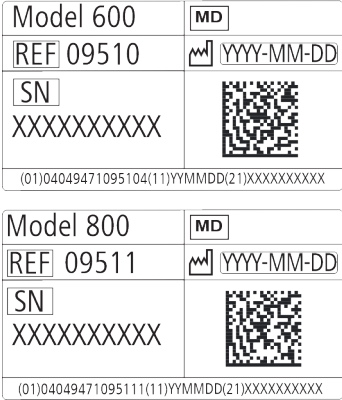


Figure 1: Position of labels on the device

No.	Labels	Explanation
1		VISUMAX type label
		 Manufacturer Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany
		 Applied part type B
		IP20 Ingress protection rating for housing (protected against solid foreign bodies of 12.5 mm in diameter and larger, no protection against penetration of water)
		100 V to 240 V~ Supply voltage range, AC voltage
		50/60 Hz Supply frequency
		<1350W Current consumption
2		Identification label with unique device identification code (Unique device identification label) VISUMAX 600 / VISUMAX 800
		 Article number / reference number
		 Serial number
		 Medical device
		 Date of manufacture
		 (01)04049471095104(11)YYMMDD(21)XXXXXXXXXX Unique device identification code (data matrix and plain text)

No.	Labels	Explanation
3	 SN XXXXXXXXXX VISUMAX 600  SN XXXXXXXXXX VISUMAX 800	Device identification code (data matrix, serial number, device name and model number)
4	MNR: 2383-580	Material number for VISUMAX 600
	MNR: 2383-581	Material number for VISUMAX 800
5	Not applicable	Not applicable
6		Label with CE approval and disposal advice for EU  EU conformity symbol with identification number of notified body  Disposal advice for EU
7		"Observe instructions for use" label
8	Not applicable	Not applicable
9	Made in Germany	Country of origin label
10		"Laser aperture" warning label
11	Not applicable	Not applicable
12		Laser warning label in accordance with IEC 60825-1: 2001/2007/2014
13	Not applicable	Not applicable
14	Not applicable	Not applicable

No.	Labels	Explanation
15		"Observe instructions for use" label
16		"Risk of tipping" warning label
17		"No heavy load" prohibition sign
18		"Optical radiation" warning label
19		Locking of monitor arm
		 Monitor arm locked
		 Monitor arm unlocked

In addition, the following icons are used on the device:

Icon	Explanation
	Input for foot switch
	Input for foot control panel
	Interface output for interlock / emergency stop for patient supporting system (4 kV galvanically isolated)
	USB port (not galvanically isolated)
	Plug connector for remote-controlled safety interlock [► 65] Connector for door contact and external laser warning lamp.

Icon	Explanation
HDMI	Interface output for HDMI devices (not galvanically isolated)
	Network interface (4 kV galvanically isolated)
	Emergency laser stop for immediate shutdown of the laser output and emergency stop equipment for stopping mechanical movements
	Mains switch (marking directly on the toggle switch)
	O OFF Power supply disconnected I ON Power supply connected
	Key switch ON
	Key switch OFF
	Start button
II	Standby mode button
OM	Observation mode button
LM	Laser mode button
	Laser emission display

3.4 Structure of the device

A patient supporting system (applied part) is mandatory for the use of the device.

This system must meet the minimum requirements [► 66].

3.4.1 VISUMAX 600

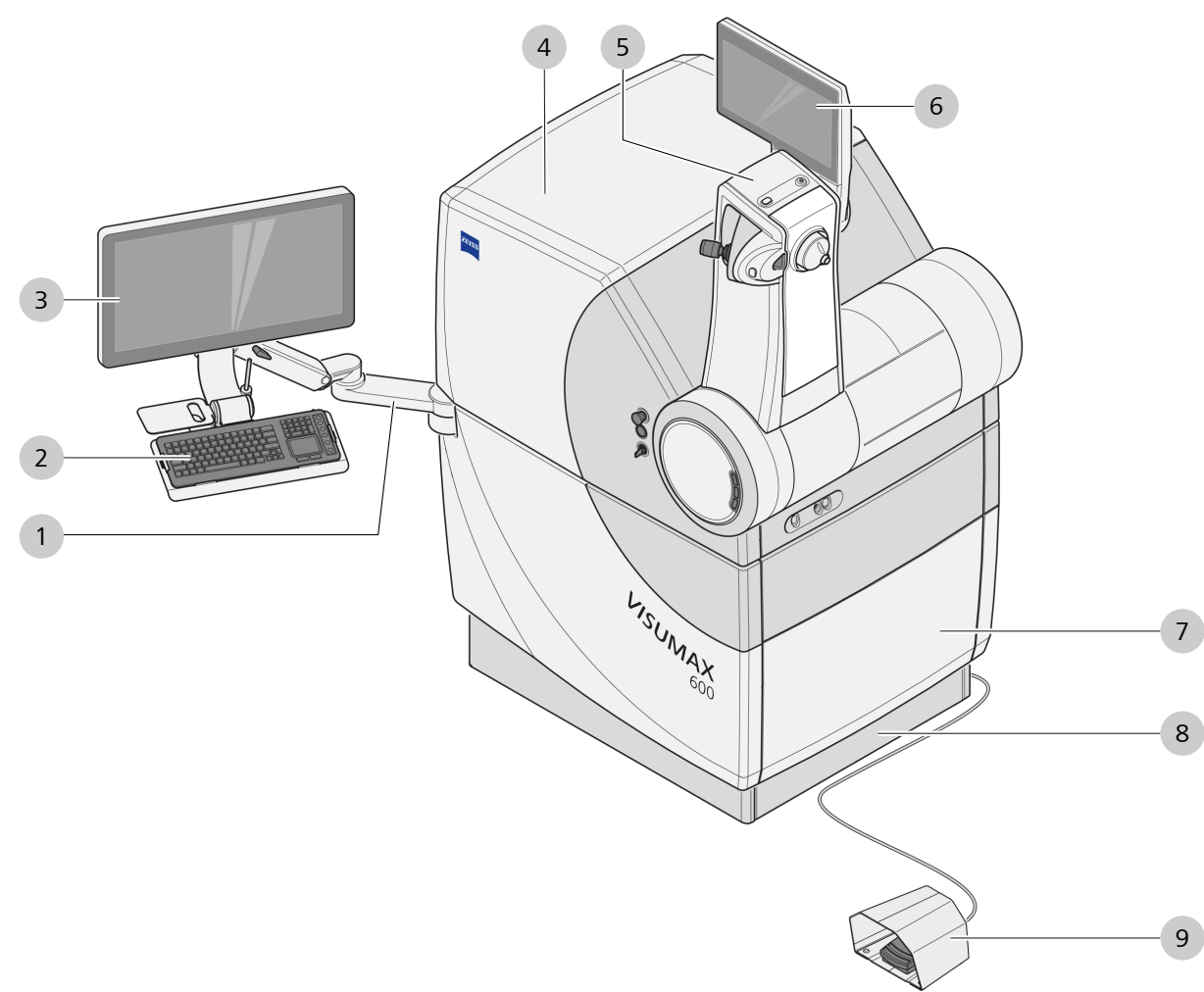


Figure 2: VISUMAX 600: Device view 1

1	Planning screen arm	2	Keyboard
3	Planning screen	4	Device head
5	Laser arm	6	Treatment screen
7	Device base	8	Device socle
9	Foot switch		

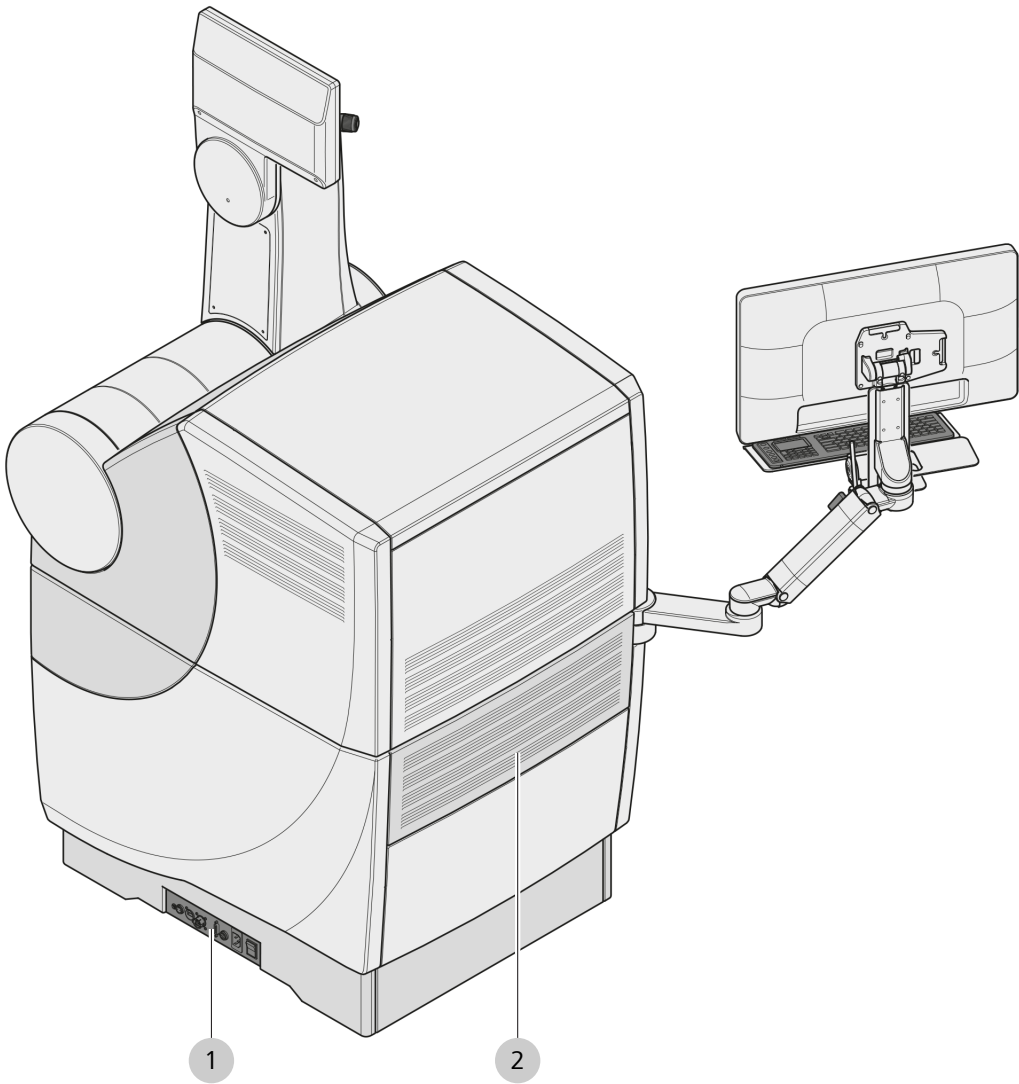


Figure 3: VISUMAX 600: Device view 2

1	Connector panel	2	Service hatch
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3.4.2 VISUMAX 800

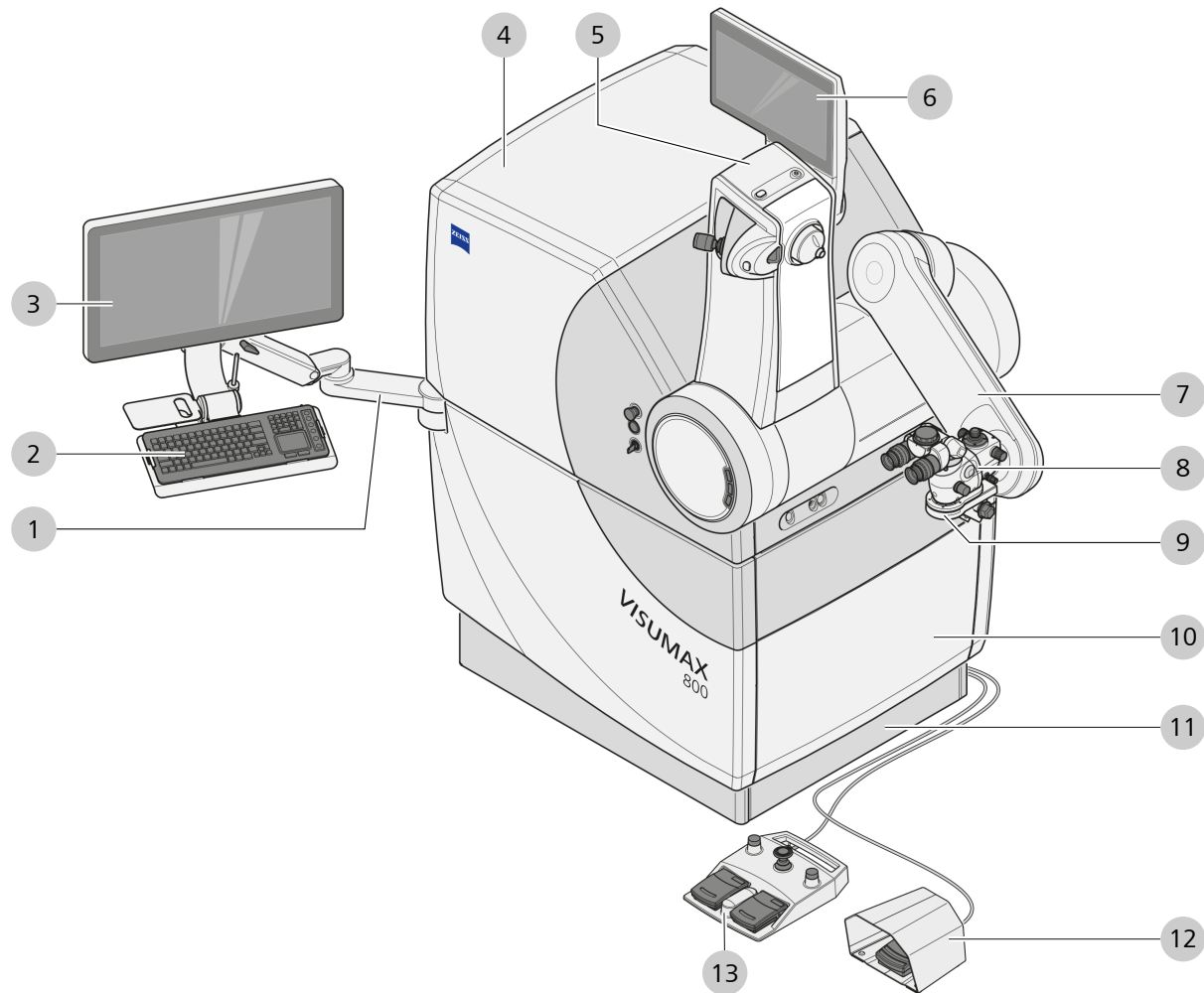


Figure 4: VISUMAX 800: Device view 1

1	Planning screen arm	2	Keyboard
3	Planning screen	4	Device head
5	Laser arm	6	Treatment screen
7	OPMI arm	8	OPMI
9	Slit projector	10	Device base
11	Device socle	12	Foot switch
13	Foot control panel		

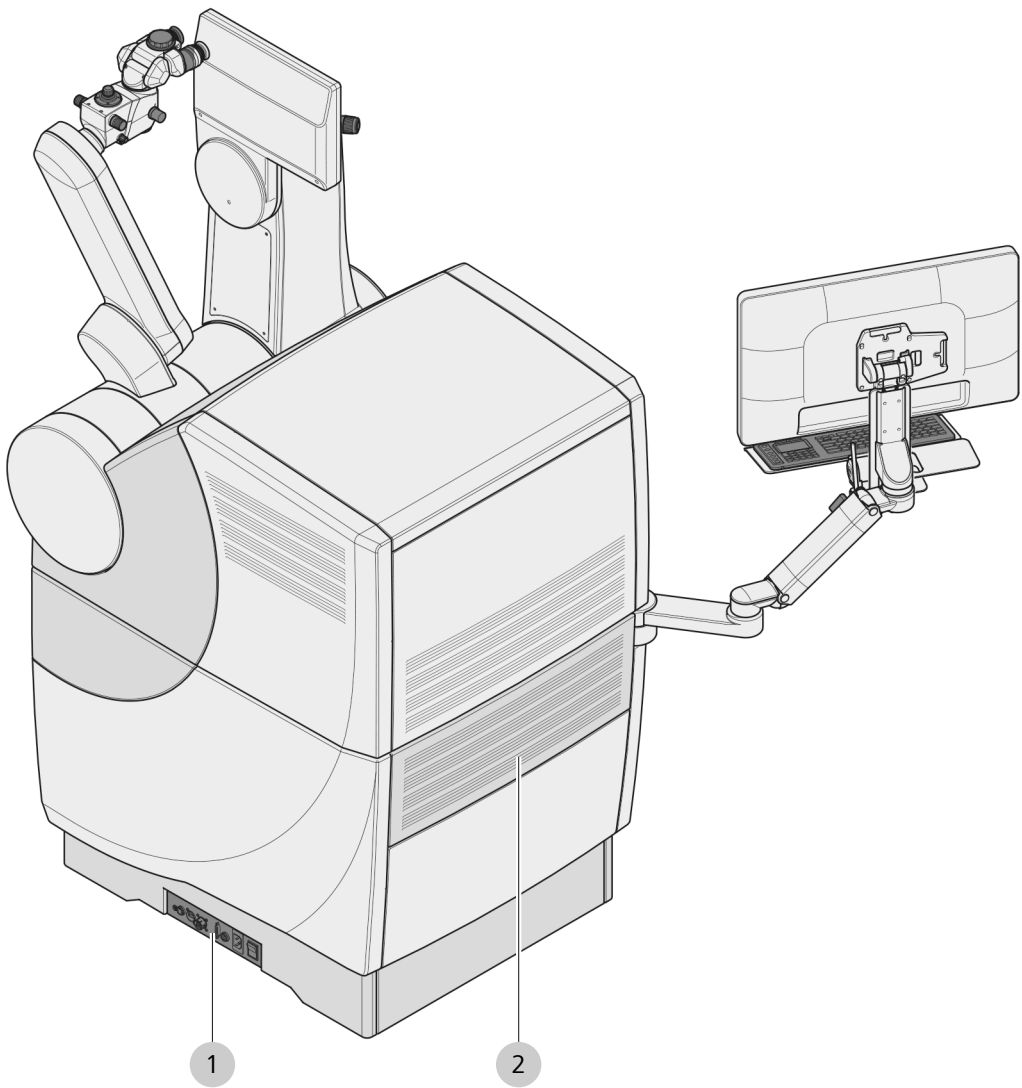


Figure 5: VISUMAX 800: Device view 2

1	Connector panel	2	Service hatch
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3.4.3 Connector panel on device socle

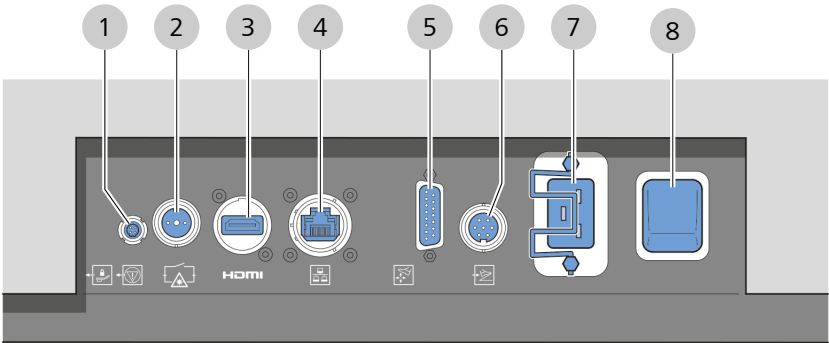


Figure 6: Connector panel on device socle

1	Interface output for interlock / emergency stop for patient supporting system (4 kV galvanically isolated)	2	Interface input for remote-controlled safety interlock (remote interlock)
3	Interface output for HDMI devices (not galvanically isolated)	4	Network interface (4 kV galvanically isolated)
5	Foot control panel interface	6	Foot switch interface
7	Mains input socket	8	Mains switch

Detailed view: Interface output for interlock / emergency stop for patient supporting system



Figure 7: Detailed view of the interface output for interlock / emergency stop for patient supporting system

When using a LEMO FGJ.0B.304 type connector, the individual pins have the following functions:

- The contact between pin 1 and pin 2 opens if one of the device arms is in working position.
TIP:
The contact can be used to trigger a lock when combined with a patient supporting system with interlock input.
- The contact between pin 3 and pin 4 opens when the emergency stop / emergency laser stop is activated.
TIP:
The contact can be used to trigger an emergency stop when combined with a patient supporting system with an external emergency stop input.

3.4.4 USB port on planning screen

WARNING!

Risk of electric shock

Since the USB interface is not insulated inside the device, there is a risk of electric shock if you connect an external device that is connected to the mains.

- Only use devices that are not connected to external power supply, such as a USB drive, on the interface.

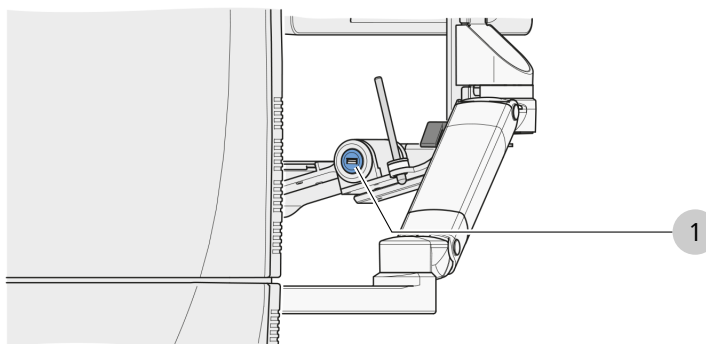


Figure 8: USB port on planning screen arm

1	USB port (not galvanically isolated)
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The USB port is used exclusively for connecting external USB storage media for data backup.

3.4.5 Treatment Pack

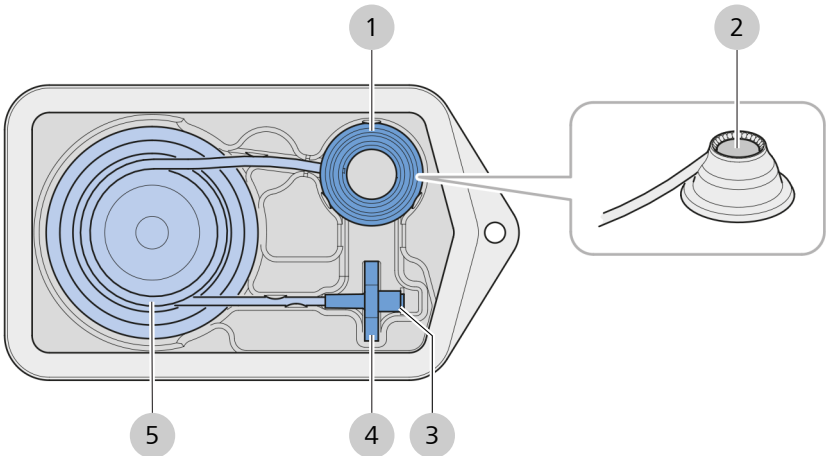


Figure 9: Treatment Pack

1	Contact glass holder	2	Contact glass (Applied part)
3	Vacuum port (Luer taper) to the laser arm	4	Filter
5	Connecting tube		

Further information on the use of Treatment Packs can be found in the instructions for use for the Treatment Pack.

3.5 Patient position and patient environment

Top view

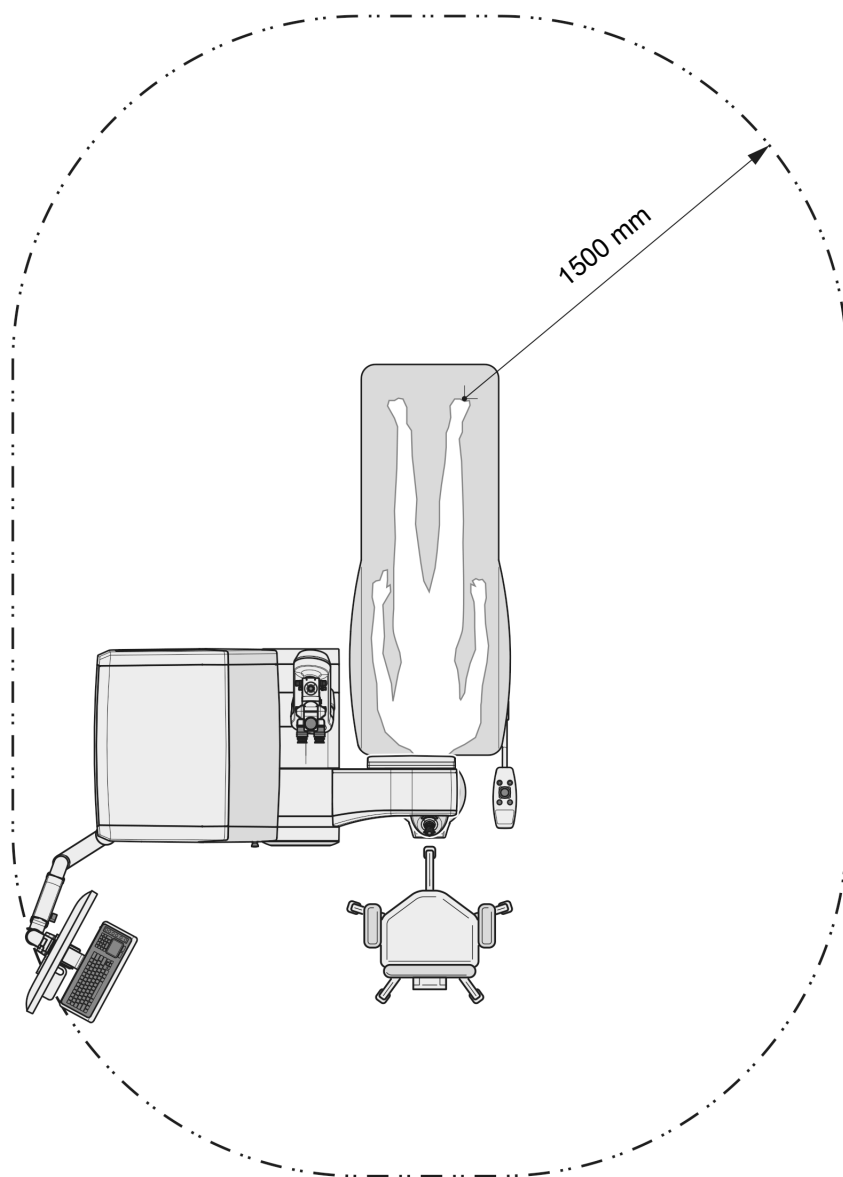


Figure 10: Expected position of patient and patient environment

3.6 Control elements and displays

3.6.1 Basic device

Device base

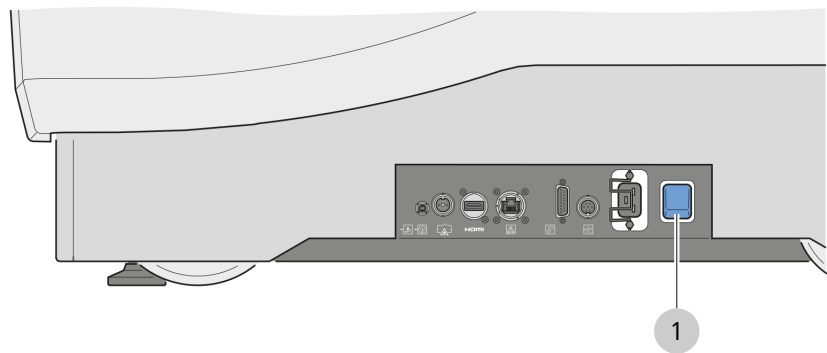


Figure 11: Control elements on device base

Item	Name	Description
1	Mains switch	Toggle switch for mains disconnection with integrated circuit breaker and indicator light for power on, provided the device is connected to the mains voltage supply.

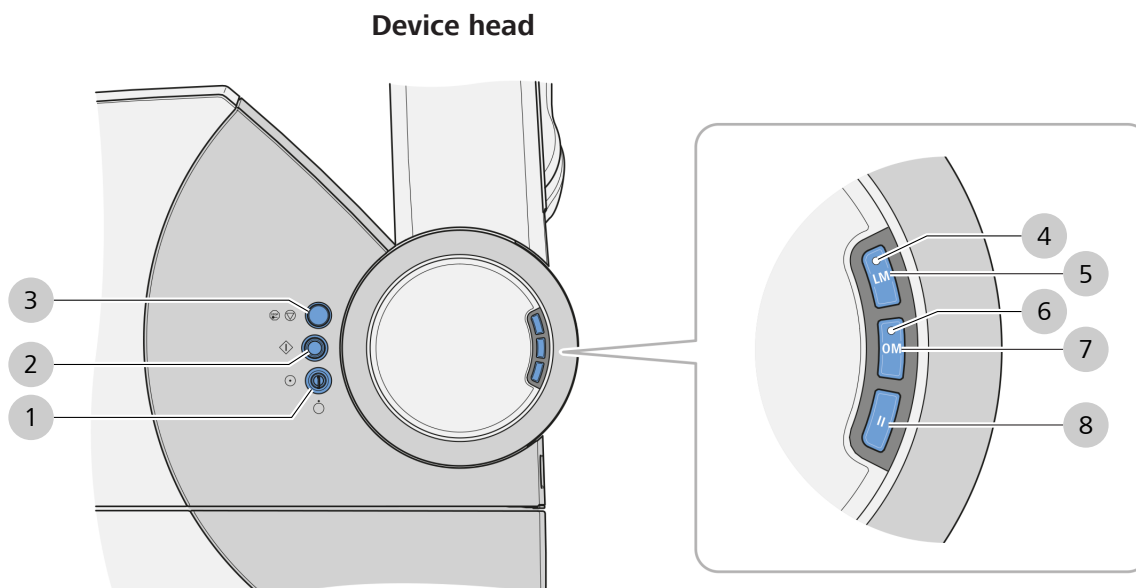


Figure 12: Control elements on device head

Item	Name	Description
1	Key switch	Position : OFF (the key is in vertical position and can be withdrawn) Position : ON (the key is in horizontal position and must remain in place during operation) The key switch turns on the part of the device that enables treatment planning. This requires power switch at the device base to be switched on. The planning software starts. In this state, data management and treatment planning are possible. The user must remove the key after using the device. If the key is removed, the laser cannot be triggered and the system cannot be put into operation by unauthorized persons.
2	Start button	Starts the standby mode of the device when the key switch is in position ON. The device changes to the standby mode. The illumination of the button turns on when the key switch is in the ON position. The illumination of the button switches off as soon as the transition to standby mode is activated by pressing this button.
3	Emergency stop / emergency laser stop button	Tapping stops the laser emission and all movements of the device head and arms. Furthermore the battery of the optional UPS is disconnected internally.
4	LED of laser mode button [LM]	This LED lights up when a possible collision of the laser arm in working position with the patient has been detected (risk of collision). In this case, the laser arm only swivels to the working position when the laser mode button [LM] is permanently pressed.

Item	Name	Description
5	Laser mode button [LM]	Pressing the button puts the device into laser mode (moves the laser arm into working position and the OPMI arm into standby position). The illumination of the button is always on when the device is not in laser mode. During movement into laser mode, the illumination flashes.
6	LED of observation mode button [OM]	This LED lights up when in working position a possible collision of the OPMI arm with the patient has been detected (risk of collision). In this case, the OPMI arm only swivels to the working position when the observation mode button [OM] is permanently pressed.
7	Observation mode button [OM]	Pressing the button puts the device into observation mode (moves the OPMI arm into working position and the laser arm into standby position). This button has no function on the VISUMAX 600. The illumination of the button is always on when the device is not in observation mode. During movement into observation mode, the illumination flashes.
8	Standby mode button [II]	Pressing the button puts the device into standby mode (moves the laser arm and the OPMI arm into standby position). The illumination of the button is always on when the device is not in standby mode. During movement into standby mode, the illumination flashes.

3.6.2 Planning

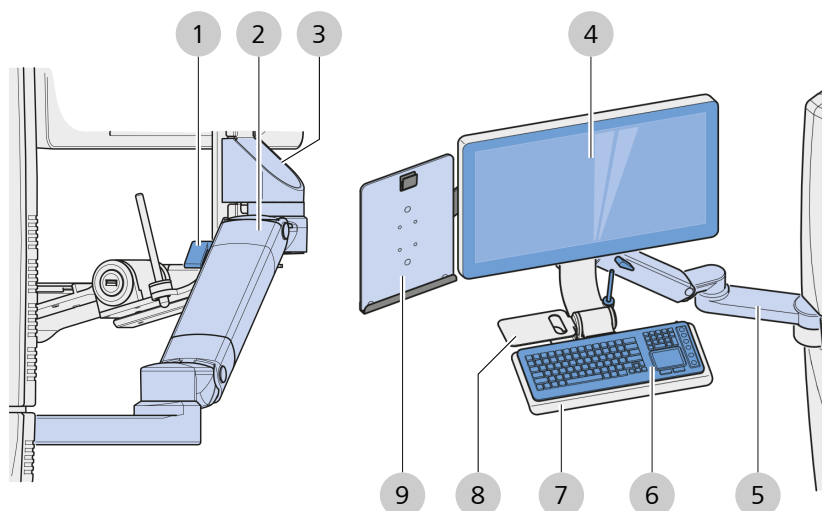


Figure 13: Control elements on planning screen

Item	Name	Description
1	Locking the monitor arm height adjustment	For fixing the position of the monitor arm height adjustment
2	Monitor arm height adjustment	For changing the height position of the planning screen using two swivel joints
3	Monitor swivel joints	For horizontal rotation of the monitor
4	Planning screen	For displaying the planning software and touch screen operation
5	Monitor swivel arm	For horizontal swiveling of the planning screen and the keyboard tray in a larger radius using two swivel joints
6	Keyboard	For entering planning data on the planning screen
7	Keyboard tray	For storing the keyboard when working with the planning screen
8	Dispenser bottle holder	For storing dispenser bottle for eye drops
9	Document holder	For storing paper documents or fixing tablets

3.6.3 Treatment

Treatment control

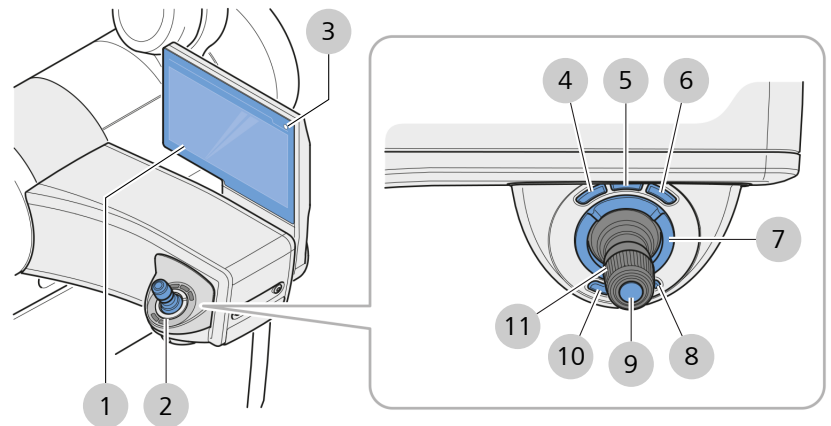


Figure 14: Control elements on the laser arm

Item	Name	Description
1	Treatment screen	Screen for displaying the treatment software and for touch screen control
2	Laser arm control panel	Control panel arranged around the laser arm joystick
3	Laser emission display	Active when laser radiation is emitted through the laser exit aperture on the laser objective
4	Illumination selection button [IR]	Button for preselecting IR or VIS treatment illumination.
5	Fixation light button [FIX]	Button for switching the fixation light on or off.
6	Treatment overlay button [OV]	Button for switching the overlay on or off over the live video image in the treatment screen
7	Illumination adjustment ring	Ring for adjusting the brightness of the treatment illumination Turn the ring to the right or left to adjust the brightness of the treatment illumination.
8	Treatment navigation button forward [>]	Arrow key alternative to touch screen control on treatment screen
9	Suction button	Button on laser arm joystick for switching the vacuum suction of the eye to the contact glass on or off When the suction has reached the defined pressure range, the device switches to the "Laser ready" state.

Item	Name	Description
10	Treatment navigation button backward [<]	Arrow key alternative to touch screen control on treatment screen
11	Laser arm joystick	Joystick on the laser arm for adjusting the spatial position of the arm in X and Y direction as well as in Z direction by turning the knurled ring Once the eye is aspirated, the joystick function for positioning the laser arm is deactivated. By turning the knurled ring of the joystick, depending on the treatment option, the laser shot pattern can now be rotated using the overlay on the treatment screen.

Laser arm

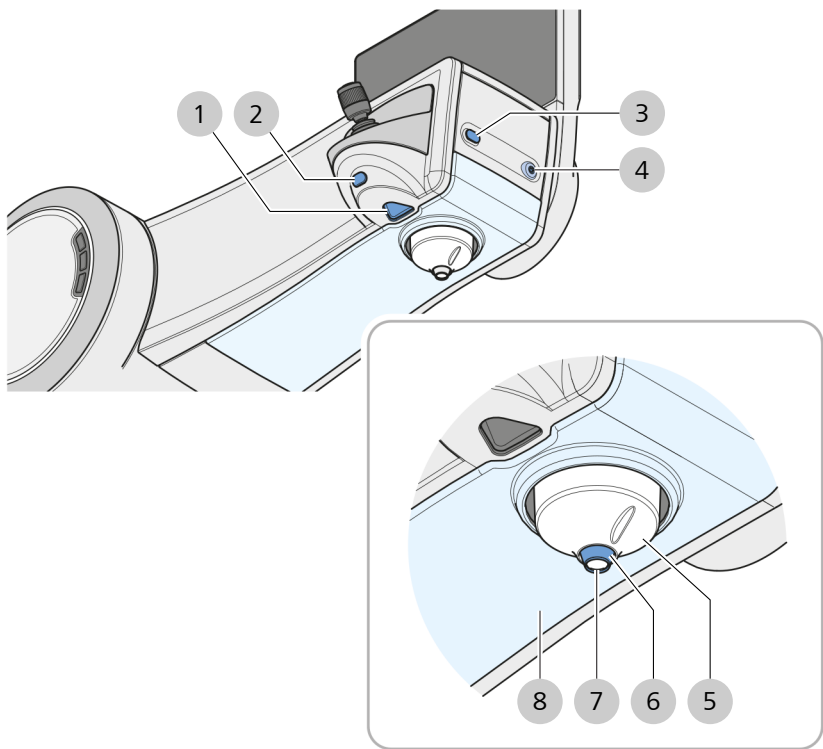


Figure 15: Functional elements on the laser arm

Item	Name	Description
1	Top view camera	For video recording of the treatment area from an angle from above while the patient lies under the laser arm
2, 3	Tube clips	For holding the Treatment Pack connecting tube
4	Vacuum port	For connecting Treatment Pack
5	Laser objective	For mounting the Treatment Pack contact glass
6	Treatment illumination	Exit aperture for treatment illumination during laser treatment

Item	Name	Description
7	Laser exit aperture	Exit aperture for the laser beam during treatment.
8	Patient environment illumination	For illuminating the patient environment

The treatment camera is integrated into the laser arm. It is used to observe the course of treatment during treatment.

Monitoring elements for treatment area

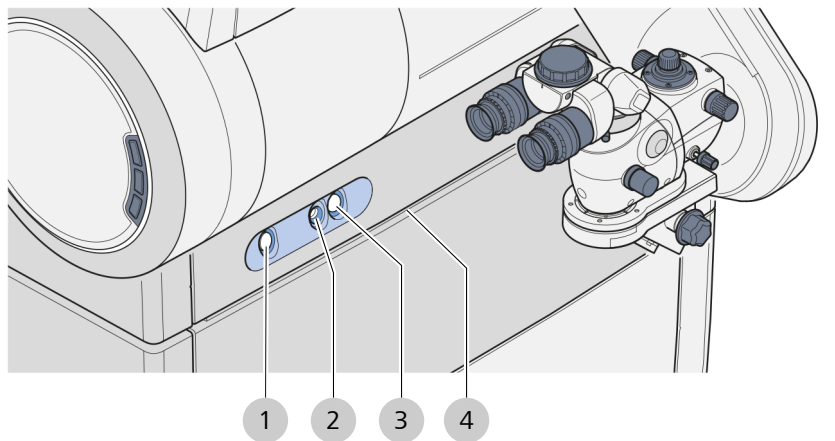


Figure 16: Collision sensors and side view camera on device head

Item	Name	Description
1	Front collision sensor	For indicating collisions with body parts prior to swiveling in the device arm
2	Side view camera	For recording the lateral video image of the treatment area and for pre-positioning the patient
3	Rear collision sensor	For indicating collisions with body parts prior to swiveling in the device arm
4	Crush protection bar	To prevent injuries during downward movements of the device head in extended condition Contact sensors stop the downward movement of the device head when a collision is detected.

Foot switch

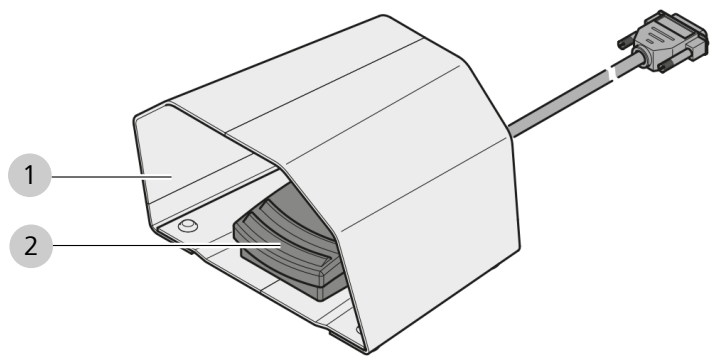


Figure 17: Foot switch

Item	Name	Explanation
1	Protective cover	For preventing the unintentional triggering of the laser
2	Trigger	The trigger is used to start or pause the laser treatment. Trigger pressed: Laser treatment is being performed (laser radiation is emitted). Trigger released: Laser treatment is paused (no laser radiation emitted). To perform the laser treatment, the trigger must be pressed permanently. When the treatment is finished completely, the laser emission stops.

The foot switch is to be placed separately on the floor next to the device.

3.6.4 Observation

Operating microscope (OPMI)

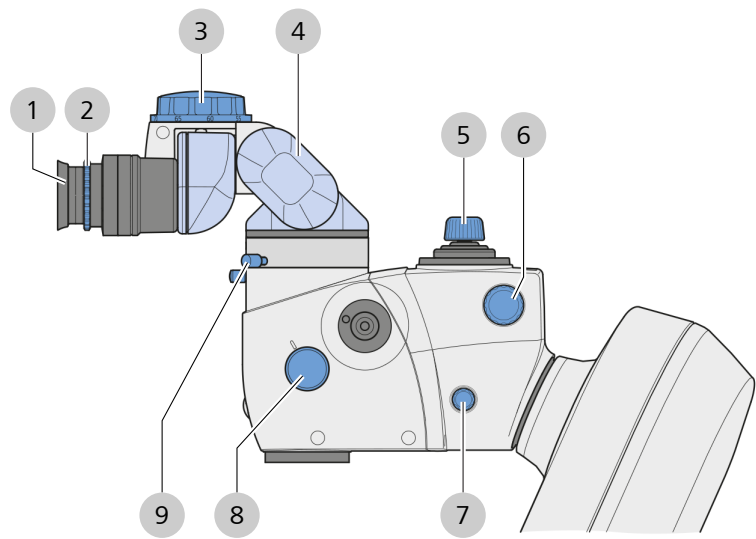


Figure 18: Control elements on the OPMI

Item	Name	Description
1	Eyecup	For adjusting the distance between eyepiece and eye
2	Diopter setting ring with scale	For setting the refraction value from +5 D to -8 D and for reading the set refraction value
3	Adjusting wheel for eye distance (interpupillary distance)	Increases or decreases the interpupillary distance on the binocular tube The correct position has been reached when the two eyepiece images merge into one. You can read off the interpupillary distance on the adjustment knob.
4	Angle adjustment of the binocular tube	For adjusting the angle of view of the eyepieces
5	OPMI arm joystick	For setting the spatial position of the device head in X, Y and Z direction (analogous to the laser arm joystick)
6	Illumination intensity adjustment knob	For adjusting the illumination intensity of the integrated OPMI illumination
7	Illumination filter changer	For changing the illumination filter Button in right position: retinal safety filter enabled Button in center position: no filter Button in left position: blue filter enabled
8	Magnification changer	For manual setting of the magnification to one of five click-stop positions ($\gamma = 0.4x$, $\gamma = 0.6x$, $\gamma = 1.0x$, $\gamma = 1.6x$, $\gamma = 2.5x$)
9	Observation filter changer	For swiveling the yellow filter in or out Lever in right end position: no filter Lever in left position: yellow filter swiveled in

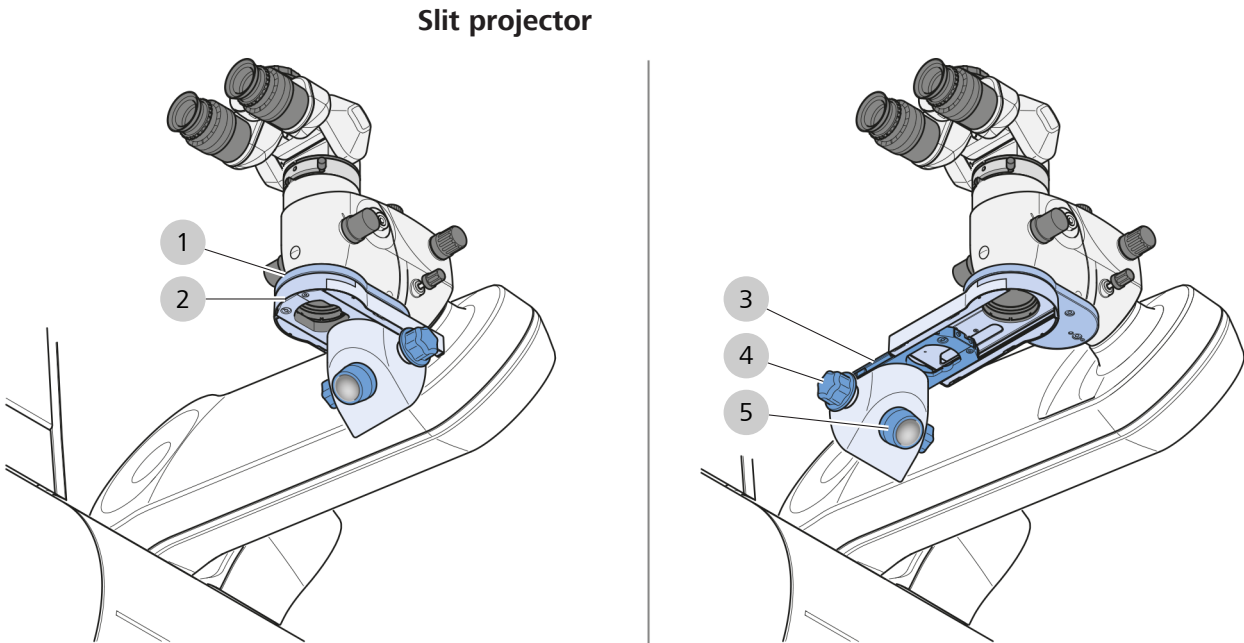


Figure 19: Slit projector

Item	Name	Description
1	Base	For mounting the slit projector to the OPML.
2	Swivel unit	For swiveling the slit illumination 90° to the right or left to adjust the working position
3	Extension carriage	For positioning the slit illumination into working position When the carriage reaches the end position, the slit illumination is switched on.
4	Adjustment knob	For fine adjustment of the slit position in the observation field and for setting the slit width (2 slit widths selectable) The changeover to the other slit width takes place in the respective end position while turning the adjustment knob and is signaled by an audible click.
5	Slit illumination	To project the slit into the observation field

Foot control panel

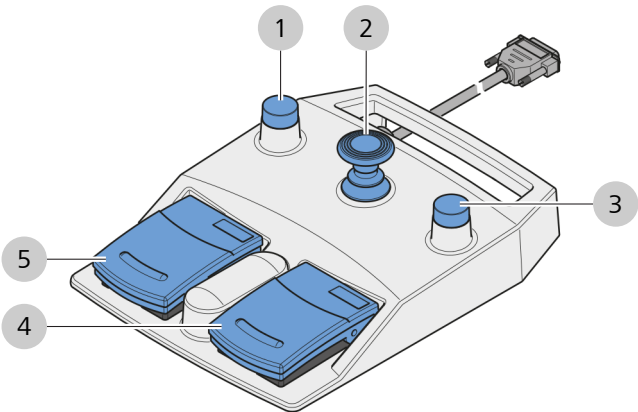


Figure 20: Foot control panel (FCP)

Item	Name	Description
1	Function key, left	For gradual reduction of the illumination intensity
2	Joystick	Moves the device head to the right, left, front or rear depending on the deflection of the joystick
3	Function key, right	For stepwise increase of the illumination intensity
4	Movement key, right	To adjust the OPMI focus point, moves the device head down
5	Movement key, left	To adjust the OPMI focus point, moves the device head up

The foot control panel should be placed separately on the floor next to the device.

3.6.5 Function of display elements and signals

Display element	Effect
LED in mains switch	Located on the device base. Lights up when switched on (position "I").
LED in start button	Located on the device head. Lights up when the key switch is set to ON. After pressing the start button to start the standby mode, the illumination of the button switches off.
LED in laser mode button [LM]	Located inside the [LM] button. The LED lights up when in working position a possible collision of the laser arm with the patient has been detected (risk of collision). In this case, the laser arm swivels to the working position only when permanently actuated.
LED in the observation mode button [OM]	Located inside the [OM] button. This LED lights up when in working position a possible collision of the OPMI arm with the patient has been detected (risk of collision). In this case, the OPMI arm swivels to the working position only when permanently actuated.

Display element	Effect
Backlight of the laser arm control panel	If the laser arm is in working position, the backlight of the laser arm operating panel is switched on.
Display: suction pressure	Display on treatment screen: The height of the area filled in blue on the left corresponds to the vacuum pressure currently applied between the contact glass and the eye. The device automatically changes to the state "Laser ready" if the vacuum is in the intended range.
 Display: Laser ready	Display on treatment screen: In the "laser ready" state the treatment can be released by pressing the foot switch.
Display: duration of laser treatment	Display on treatment screen: The height of the area filled in blue on the right corresponds to the duration of the laser treatment still to be performed. The remaining time of the laser treatment is displayed in seconds.
 Display: Laser emission	Indication on treatment screen: Signals when laser radiation is emitted through the laser exit aperture on the laser objective.
Warning light: Laser emission	Located above the treatment screen. Lights up yellow when laser radiation is emitted through the laser exit aperture at the laser objective.

Table 1: Display elements and signals

3.7 Safety functions

Safety feature	Function
Protective housing	This device has a protective housing which, when installed, prevents the user's access to laser radiation (including vagrant radiation) above the maximum permissible exposure levels (MPE).
Controls	The control and operating elements of this device are mounted in such a way that the user is not exposed to laser radiation above the maximum permissible radiation limits (MPE) when setting and operating the device.
Retinal safety filter	The retinal safety filter which is integrated in the OPMI illumination of the observation optics, attenuates the irradiation in such a way that an exposure time of one patient eye at maximum brightness is safe for up to 30 minutes.
Treatment screen	The surgeon should observe the progress of the laser treatment on the screen and stop it if necessary.
Safety feature for directionally changing radiation	If the deflection fails, or if the deflection speed or amplitude changes, the device does not emit accessible radiation above the maximum permissible limits (MPE).

Safety feature	Function
Energy monitoring of the treatment beam	Laser emission is automatically shut off when the energy exceeds a pre-defined range.
Electronic safety monitoring	The electronic systems monitor various functions and values. If any of these values are outside the permitted range, the system prevents the laser from being fired.
Crush protection of laser objective	The laser objective of the device is weight-compensated mechanically and can move upwards, so that crushing of the patient's eye during docking is impossible. The system monitors the mechanical position of the laser objective. As soon as the laser objective is deflected from its working position, a downward movement of the device head is impossible. One reason for the deflection can be a collision with the laser objective due to movement of the patient's head. During laser treatment, treatment is paused on extensive objective movements and will only be resumed when the objective position is correct again.
Crushing protection on the device arms	The device arms are weight compensated mechanically and can move upwards at any time. The motor speed of the swivel movement is limited so that in the event of a possible collision during movement no serious injury is caused.
Crushing protection on device head	There is a sensor on the device head which stops the downward movement of the device head in case of contact.
Fixation light	The fixation light makes it easier for the patient to align the fixation direction with the optical axis of the device to ensure optimal positioning of the laser cuts.
Eye suction monitoring	This function monitors the suction of the eye when it is activated. A laser treatment can only be started if the suction is sufficient. During treatment, a suction loss leads to an automatic stop of the laser treatment.
Contact glass calibration	This function checks the correct position of the contact glass on the laser objective and the internal beam path before each treatment.

Table 2: Overview of installed safety functions

3.8 Additional features

Device feature	Function
Remote-controlled safety interlock	The device has a connection for a remote-controlled safety interlock. Please contact ZEISS Service for information on the function of the remote-controlled safety interlock. An ongoing treatment with the device will be paused as soon as the remote door contact is interrupted (door is opened). After closing the door and confirming the displayed message, the treatment can be resumed when pressing the foot switch again. For operation without remote-controlled safety interlock, install the supplied dummy plug.
Height tracking of device head	Within certain limits, this mechanism ensures that the height position of the device head relative to the patient's eye is tracked during laser treatment in order to reduce the probability of suction loss.
Device head positioning	This function automatically adjusts the position of the device head to optimally support the treatment process, e.g. in observation mode the device head is moved so that the patient's eye is in the focal plane of the OPML.
Video recording	This function records the treatment process from different perspectives. The recording is temporarily stored internally and can be exported if required.
Import of externally planned treatment data	This function allows the user to plan treatments externally to the device and import this data for treatment.
Uninterruptible power supply (optional)	Ensures a power supply for at least 5 minutes in case of instability or failure of the power supply during treatment.
Centering assistant (optional)	When the eye is in contact with the contact glass, the device detects the patient's pupil and displays the location of the intended treatment center in relation to the center of the pupil. The deviation of the intended treatment center from the actual treatment center of the device is displayed as an overlay on the treatment monitor.
Rotation assistant (optional)	This function allows the user to adjust the artificial horizon in relation to the eye. When enabled, the treatment pattern is rotated by this angle.

Table 3: Additional features

3.9 Functional description

3.9.1 Functional description of the basic device

VISUMAX 600 / VISUMAX 800 generates ultrashort laser pulses, which are guided through an optical system including a controllable laser beam deflection unit to the laser exit aperture in the laser objective. The optical system focuses the laser beam on the corneal tissue. At its focal point, each ultrashort laser pulse triggers an optical breakthrough, thus creating plasma with a diameter of only a few micrometers, resulting in tissue separation of similar size. Continuous tracking of the laser beam through the optical system creates many tissue separations adjacent to each other which together form an incision surface within the cornea.

All desired incision surfaces are created in one working step. After laser treatment, the surgeon can open the incision with his special surgical instruments.

For laser treatment, the patient's eye is connected to the laser exit aperture via a contact glass. Contact glass and eye are each connected by the suction of a vacuum device: the contact glass is attached to the laser exit aperture, the eye to the contact glass. Before each treatment, the contact glass is measured to ensure the highest accuracy of the incision surface geometry.

The optional operating microscope allows the user to immediately examine and prepare the eye as well as perform necessary treatment steps according to the respective treatment option.

The integrated video camera allows observation of the laser treatment on the treatment screen and records the treatment process. The integrated computer with special software and corresponding touch user interfaces enables comfortable operation of the device and saves treatment data, more computers control and monitor the internal processes. The monitors or touch screens are used to plan the treatment, give instructions to the user and display the progress of the treatment.

3.9.2 Functional description of the Centralign centering assistant

The Centralign® centering assistant function supports the positioning of the device on the planned treatment center of the eye during the docking process.

For this purpose, as the patient's eye approaches the contact glass, the device tracks the patient's pupil and pupil center (blue outline and cross). Based on this, the device displays the planned treatment center (yellow dot) and its distance (yellow line) from the actual treatment center (center of the target mark) on the treatment screen. In addition, the distance is displayed on the treatment screen in figures below the centering icon .

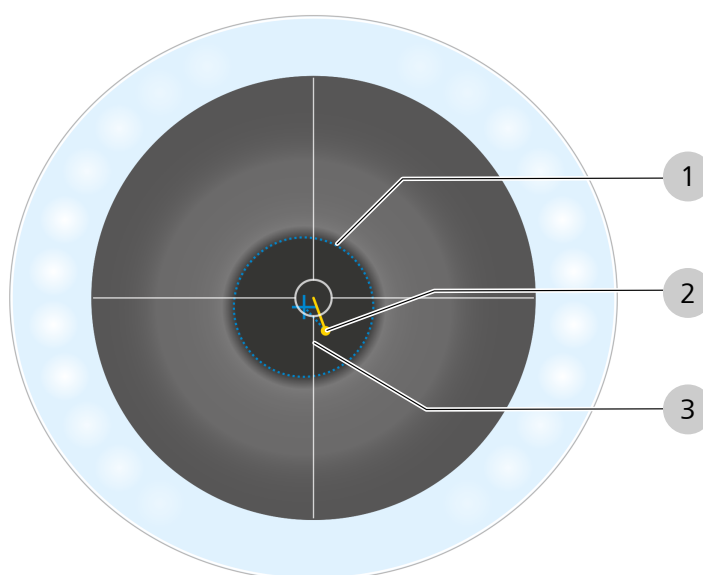


Figure 21: Centering assistant during docking

Item	Icon	Description
1		Display of pupil edge and pupil center
2		Display of planned treatment center (dot) and direction
3		Target mark

The laser arm joystick can now be used to laterally adjust the position of the device above the eye during the downward movement so that the planned treatment center can be centered on the target mark, thus minimizing the displayed distance between the target and actual positions. If the planned treatment center (yellow dot) is within the target mark, the display changes to a concentric circle (initially yellow) around the center of the actual treatment center, whose radius indicates the remaining distance to the planned target. The numerical value is still displayed on the treatment screen. If the remaining distance is less than 0.2 mm, the color of the concentric circle changes from yellow to blue.

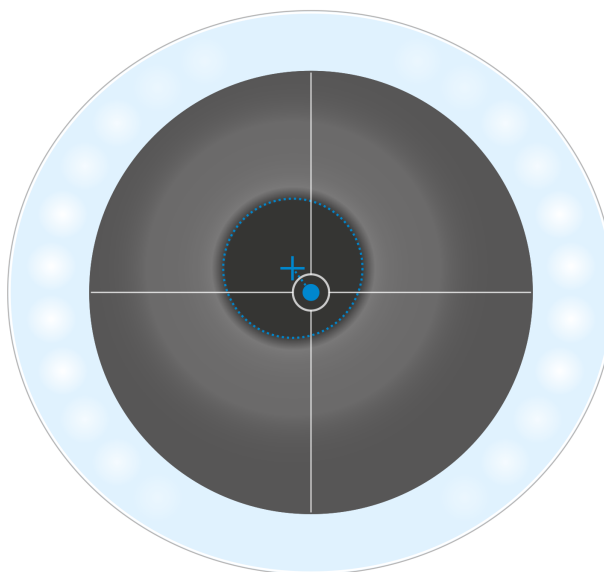


Figure 22: Centering assistant prior to eye suction

If possible, lateral movements for correct positioning of the planned treatment center should be made without contact between the contact glass and the eye. If more precise positioning is required after contact, the device must first be moved up again. Correct detection of the pupil by the device is a prerequisite for supporting the positioning of the treatment center, which must be visually controlled by the user during the entire docking process. If the pupil is not detected correctly, the blue outline representing the pupil edge and the numerical indication of the distance to the planned treatment center disappear. In addition, the centering icon is visually highlighted. In case of an incorrectly detected pupil, changing the illumination intensity or switching to IR illumination can be helpful.

3.9.3 Functional description of the OcuLign rotation assistant

The OcuLign® rotation assistant function enables the alignment of the cutting pattern to be adapted to the rotation of the eye in the lying position compared to the upright position (cyclotorsion). For this purpose, after successful docking and suction of the eye, horizontal reference lines are superimposed on the live image on the treatment screen. The position of these lines reflects the current orientation of the cutting pattern. In addition, the currently set rotation angle is displayed on the treatment screen. By default, the cutting pattern is initialized with a horizontal alignment (0°).

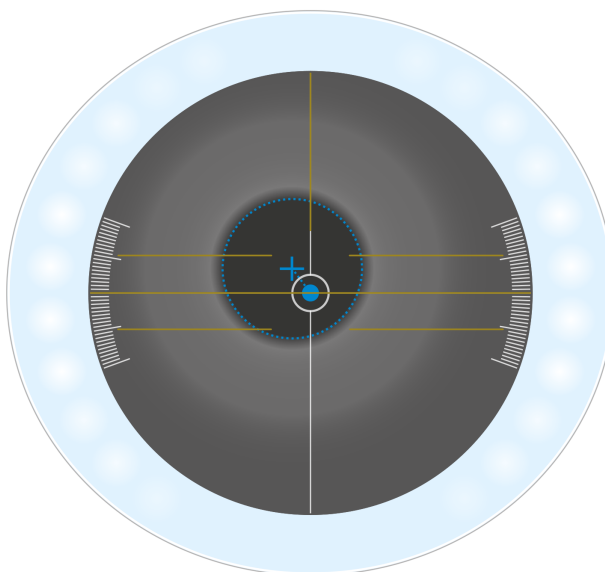


Figure 23: Rotation assistant after initialization with horizontal alignment

By turning the laser arm joystick, the cutting pattern can be rotated up to 20° in any direction in 1° increments to compensate for any rotation of the docked eye. For this purpose, the reference lines can be visually aligned on the treatment screen by using e.g. markings applied to the cornea of the eye.

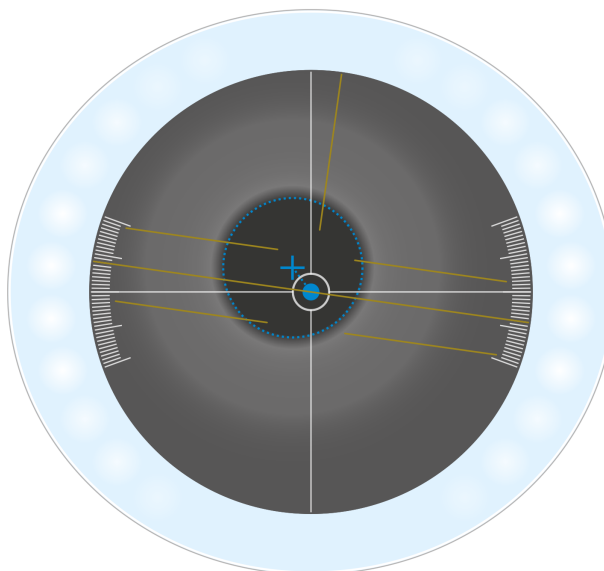


Figure 24: Rotation assistant after alignment of rotation angle

As soon as the joystick is in neutral position, the device switches back to "Laser ready" mode.

In addition to the standard horizontal initialization of the cutting pattern (0°), a starting angle can be suggested as an option. This starting angle is calculated automatically and determined from the comparison of an iris image with the live image. The iris image was taken prior to surgery with IR illumination on a diagnostic device. The live image is displayed in IR illumination on the treatment screen.

Availability of an iris image in the planning data is a prerequisite for calculation of the proposed rotation angle and triggers this calculation automatically in the treatment process. After determining the rotation angle, this is adopted for the treatment, i.e. the alignment of the cutting pattern is initialized with this angle. The reference lines displayed in the live video are also automatically rotated by this angle.

After automatic setting of the calculated starting angle, manual alignment of the cutting pattern can be performed by turning the laser arm joystick. It is also possible to accept the calculated rotation angle without further adjustments.

In this case, it is mandatory to check the proposed angle by comparing the iris structures on the treatment screen in order to start the treatment. For visual verification of the calculated rotation, the iris image, which has been automatically adjusted to the size

and orientation of the live image, must be overlaid with the live image by pressing the treatment navigation key forward [➤]. The device only switches to the "Laser ready" state after at least one iris image has been overlaid.

The automatic calculation of the rotation angle can be repeated at any time by pressing the treatment navigation key backwards [⬅].

If the automatic determination of the starting angle is not successful, a corresponding message appears and the alignment of the cutting pattern is initialized again to the horizontal default value (0°). Manual alignment of the cutting pattern is now possible without markers, by superimposing the adjusted iris image.

3.10 Functional diagram of the device

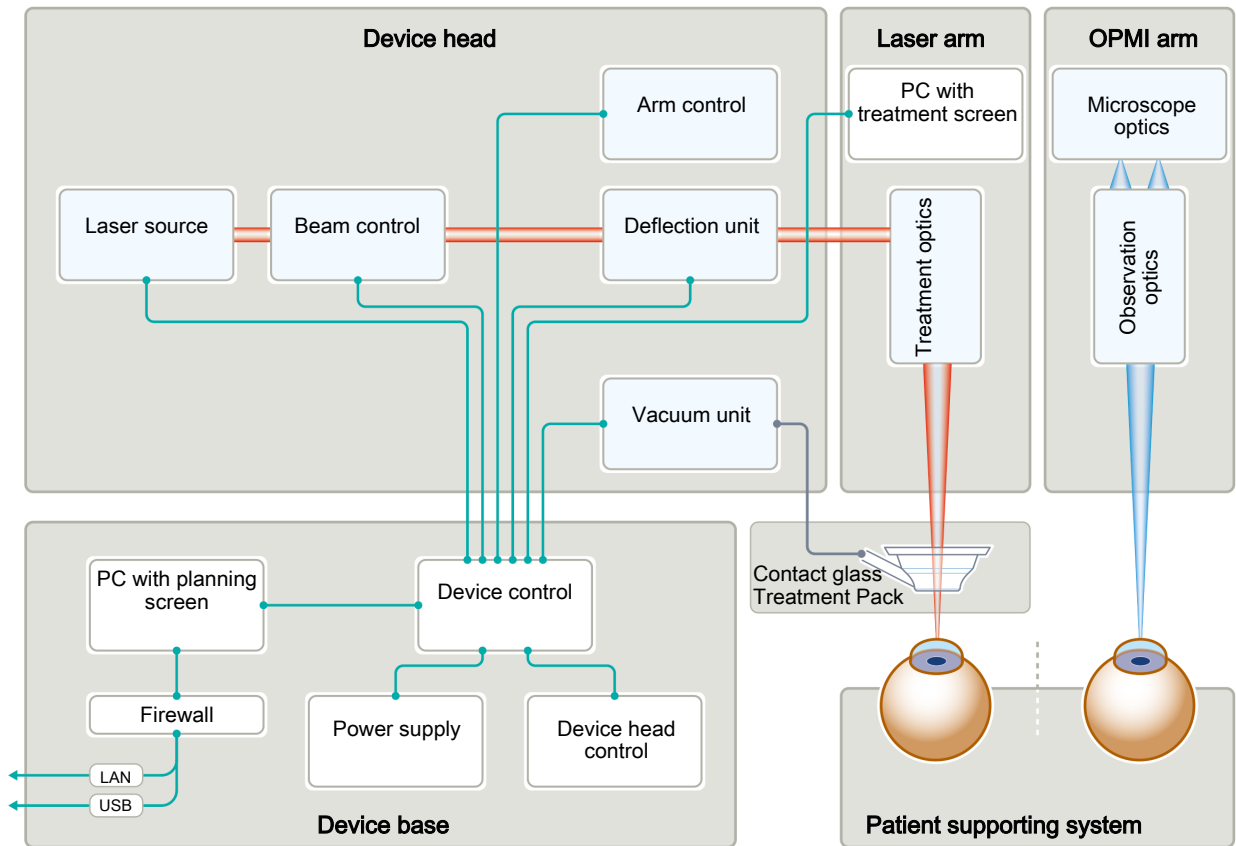


Figure 25: Functional diagram of the device

The laser source is located in the device head. The laser beam exits the laser source and passes through the beam control assembly. There the characteristics of the laser radiation are adjusted to the planned application. The deflection unit, treatment optics and contact glass allow the laser radiation to be focused into the cornea of the patient's eye and spatially guided there when the laser arm is in treatment position.

With VISUMAX 800, refractive treatment can be completed by manual treatment steps using the integrated operating microscope when the OPMI arm is in the observation position. The VISUMAX 600 is not equipped with an OPMI arm.

The device base contains the central device control, which controls all other control units and the laser. The power supply and a PC for treatment planning and data transfer are also integrated in the device base.

A patient supporting system is not part of the device, but is required for treatment execution.

Empty page, for your notes

4 Installation

4.1 Installation safety

WARNING!

Electrical hazard due to improper electrical installation

Improper electrical installation by connecting the device to a mains connection without a protective conductor or the use of incorrect or damaged power cables may result in a risk of electric shock.

- ▶ Perform the electrical installation in conformance to IEC 60364-7-710 or the applicable national regulations. This includes the integration of a ground fault circuit interrupter (GFCI). Insert the power plug only into a power outlet that has an intact protective ground connection.

⇒ Connect the device using the power cable intended for use with the device.

- ▶ Use only cables and plugs which are in perfect working condition.
- ▶ Ensure that the power supply plug is suitable and certified for the local connection.
- ▶ Observe the following specifications when replacing the supplied power cable:
 - Protective ground conductor resistance maximum 0.1 Ohm
 - Local certification of the power cable for connection to medical devices
 - Device plug C19 conforming to IEC 60320
 - Cross-section at least 0.75 mm² / AWG 18 Hospital Grade design for specific countries (e.g. USA, Canada) (for cables > 2.5 m the cross-section must be increased to 1.5 mm²).

WARNING!

Electrical hazard due to use of multiple sockets or extension cables

Connecting the device to a multiple socket or to an extension cable may cause an electric shock as the leakage current limitation may no longer apply.

- ▶ Do not use multiple sockets to connect the device to the power supply.
- ▶ Do not use extension cables.

 WARNING!

Electrical hazard due to improper installation

Improper installation of the device after recommissioning and changing the installation position can cause an electric shock.

- ▶ Note that this device may only be installed by persons specially authorized by Carl Zeiss Meditec.
- ▶ Do not change the position of the device if you are not trained to do so.
- ▶ Only use the device if it has previously been subjected to a functional test by the manufacturer or a person authorized by the manufacturer at the place of installation.

 WARNING!

Thermal hazard due to improper electrical installation

Fire can occur due to faults in the electrical installation.

- ▶ Ensure that the power consumption data on the type plate are met when selecting overcurrent protection.

 WARNING!

Thermal hazard due to improper installation

There may be smoke, fire or explosion which could result in injury or death to the user, patient or third parties.

The device is not suitable for operation in explosion risk areas (e.g. with a combustible mixture of anesthetic, cleaning or disinfecting agents and air, oxygen or nitrous oxide).

- ▶ Operate the device only in the ambient conditions defined by the manufacturer.

 WARNING!

Mechanical hazard due to tilting in transport position

The device will tip when placed in the transport position on a level that is inclined more than 10° from the horizontal plane.

- ▶ Make sure that the device is placed in transport position on a flat surface with a maximum inclination of 10°.
- ▶ Make sure that the brakes are always applied when positioning the device.
- ▶ Follow the service instructions if you want to change the device position.

 WARNING!

Mechanical hazard due to tilting

The device will tip if it is placed on a plane that is inclined at an angle of more than 5° to the horizontal plane for operation.

- ▶ Make sure that the device is installed or placed on a flat surface with a maximum inclination of 0.3° for operation.
- ▶ Make sure that the brakes are always applied when setting up the device at the place of installation

 WARNING!

Mechanical hazard due to tilting in standby mode

The device tips in standby mode when the monitor swivel arm of the planning screen is used for leaning, supporting or pulling up or is loaded with heavy objects.

- ▶ Do not use the device or its arms to lean, support or pull up.
- ▶ Do not place heavy objects on the keyboard support or the monitor swivel arm of the planning screen.

 WARNING!

Mechanical hazard due to tipping and due to the mass of the device

Improper lifting and setting down of the device may result in injuries. Be careful when moving the device over door sills. It may easily tip and / or injure a person next to it.

- ▶ Only transport the device over a door sill with the help of a second person.

 WARNING!

Hazard when combining additional medical devices into one system.

If other system components are connected to the device than those described in this manual, a non-medically-rated system is created in accordance with IEC 60601-1.

- ▶ Do not connect any components other than the system components described in these instructions of use.
- ▶ In case of system changes ensure that the current standard safety requirements as per IEC 60601-1-1 and IEC 60601-1 chapter 16 are met.

 WARNING!

Hazards due to improper installation outside the defined ambient conditions

If the location altitude specified in the technical data is exceeded, the probability increases that the insulation clearances are not observed, and thus the permissible leakage currents can be exceeded or an electrical short circuit occurs.

Furthermore, the reduced air pressure can lead to suction losses if the specified location altitude is not maintained.

- ▶ Operate the device only within the ambient conditions [▶ 119] for ambient air pressure defined by the manufacturer.

CAUTION!

Hazard due to unsuitable setting of system parameters

Unlimited access to settings and unwanted adjustment of system parameters can impact the treatment result. The installation of software, uploading of data or the modification of software configurations is reserved exclusively to authorized service personnel.

- ▶ Contact ZEISS Service if system parameters need to be changed, software needs to be updated or reinstalled, data needs to be uploaded or software configurations need to be changed.

CAUTION!

Mechanical hazards due to movements of the device head and trapping

Due to possible movements of the device head relative to permanently installed fixtures or movable objects, there is a risk of the patient, user or third parties being trapped and squeezed or the device being damaged. In all positions of the device head, the distance between the device head with device arm position in the standby position and all fixed installations must be at least 50 cm. This does not apply to the distance to the patient supporting system in the treatment position.

- ▶ Make sure that the basic device has a minimum distance of 50 cm to all fixed installations and movable objects in the room, even in its extreme positions.

CAUTION!

Incomplete tissue separation due to power failure

If no UPS is installed, a power failure will cause treatment abortion. In regions with unstable power supply:

- ▶ Ensure a reliable power supply by external measures (e.g. external UPS of the hospital network).

NOTE

Property damage due to improper storage

The device is designed for the ambient conditions defined in these instructions for use. Storage outside these conditions may shorten the operative lifetime or result in the system test not being successful and the device not being usable.

- ▶ Observe the ambient conditions [▶ 119] specified in these instructions for use.
- ▶ Operate your air conditioning also at night if the temperature or humidity deviates from the defined ranges.

4.2 Setting up and commissioning the device

Unpacking, installation and commissioning are performed entirely by ZEISS Service. During this process, ZEISS Service performs a safety and functional test of the device. ZEISS Application Support then instructs the operator in the operation of the device and treatment procedures.

The complete software required by the device is already installed and ready for operation on delivery. Subsequent installations or updates of the software may only be carried out by service personnel authorized by Carl Zeiss Meditec.

After installation and instruction, the operational state is confirmed by the receipt of the installation and instruction record.

4.3 Re-commissioning in the operating room

The device can be temporarily taken out of service and moved to a parking position in the operating room. Decommissioning and re-commissioning must be carried out by personnel trained for this purpose. The work steps are described in the corresponding service documents.

4.4 Remote-controlled safety interlock

WARNING!

Electrical hazard due to electric shock caused by improper installation of the remote-controlled safety interlock

The interface for connecting a remote-controlled safety interlock is not galvanically isolated. Incorrect installation of the remote-controlled safety interlock may cause an electric shock.

- Allow only authorized personnel to install the remote-controlled safety interlock. Please contact ZEISS Service.

CAUTION!

Risk of treatment abortion due to installation of the remote-controlled safety interlock

Connecting a remote-controlled safety interlock when activated will result in an extension of the suction time for the patient. This increases the probability of suction loss and thus of treatment abortion.

- Check carefully whether a remote-controlled safety interlock must be installed or whether alternative laser safety measures can be implemented.

The device has a connection for a remote-controlled safety interlock.

When delivered, a dummy plug is inserted in the remote safety interlock. If the device is to be operated without a remote safety interlock, the dummy plug should remain inserted.

If the device is to be operated with the remote safety interlock, please contact ZEISS Service.

When using the remote safety interlock, any ongoing treatment with the device will be interrupted as soon as the remote safety interlock contact is opened. After closing the contact, confirming the displayed message and re-triggering the foot switch, the treatment can be continued.

When opening the contacts of the plug connector, laser emission is interrupted. When delivered, a short-circuit plug is plugged into the plug connector.

Action

1. Note that using the remote safety interlock increases the probability of interrupting the laser treatment.

4.5 Minimum requirements for patient supporting system

WARNING!

Mechanical hazard due to combination with a patient supporting system

If the external patient supporting system causes unintentional movements relative to the device, severe crushing injuries may occur.

- If the electromechanical patient supporting system used has an external emergency stop input, connect it preferably to the emergency stop output on the device connector terminal (see Connector panel on device socle [► 35]). Thus, when the emergency stop on the device is activated, the emergency stop of the patient supporting system is also activated. Check the specifications in the instructions for use of the patient supporting system and contact ZEISS Service.
- When using a patient supporting system without external emergency stop input, make sure that the emergency stop of the patient supporting system is easily accessible from the user position.

CAUTION!

Treatment abortion due to unintentional movement of the patient supporting system

An unintentional movement of the patient supporting system during treatment can lead to treatment abortion.

- ▶ Check that unintentional actuation, which would lead to a spatial adjustment of the patient supporting system, is excluded.
- ▶ If the patient supporting system used has an interlock input for movement lock, preferably connect this input to the interlock output on the connector terminal to ensure the automatic interlock function (see Connector panel on device socle [▶ 35]).
- ▶ Check the specifications in instructions for use of the patient supporting system and contact ZEISS Service.

CAUTION!

Suction loss, docking and centering difficulties due to the use of an unsuitable patient supporting system

When using a patient supporting system with inadequate positioning of the patient head, docking and centering difficulties or suction loss due to head movements of the patient may occur. This leads to a negative impact on the treatment result.

- ▶ Select a patient supporting system which meets the following minimum requirements when combined with this device.

The use of a suitable patient supporting system is mandatory for the treatment procedure. Contact your local ZEISS dealer to identify a suitable patient supporting system.

The patient supporting system must meet the following requirements:

Approval

- The patient supporting system is an approved medical device or a part of such a product.

Intended use

- The intended use of the patient supporting system includes positioning a patient in dorsal position for a surgical treatment.

Width

- The width of the patient supporting system including the motorized travel range is less than or equal to 810 mm.

Height

- The position of the headrest including padding at the occiput has a fixed height in the range 653 mm to 685 mm or can be adjusted to a variable height in this range.

Emergency stop

- The patient supporting system has a local emergency stop button or there is a connection for an external emergency stop button. An emergency stop is not necessary if the patient supporting system does not have a motor-driven adjustment device.

Locking

- The patient supporting system can be fixed in such a way that, in particular, no unintentional movement of the headrest position in relation to a ground fixed point is possible during eye suction.

Stability

- The headrest incl. padding has a mechanical stability in vertical direction of at least 8 N/mm.

Lift load

- The lift load is at least 135 kg.

If a patient supporting system is used which was sold together with this device through a dealer authorized by Carl Zeiss Meditec, all minimum requirements are met and the safety of the device combination is ensured.

For other patient supporting systems, the instructions in ME system [► 129] must be observed.

4.6 Adjusting the patient supporting system

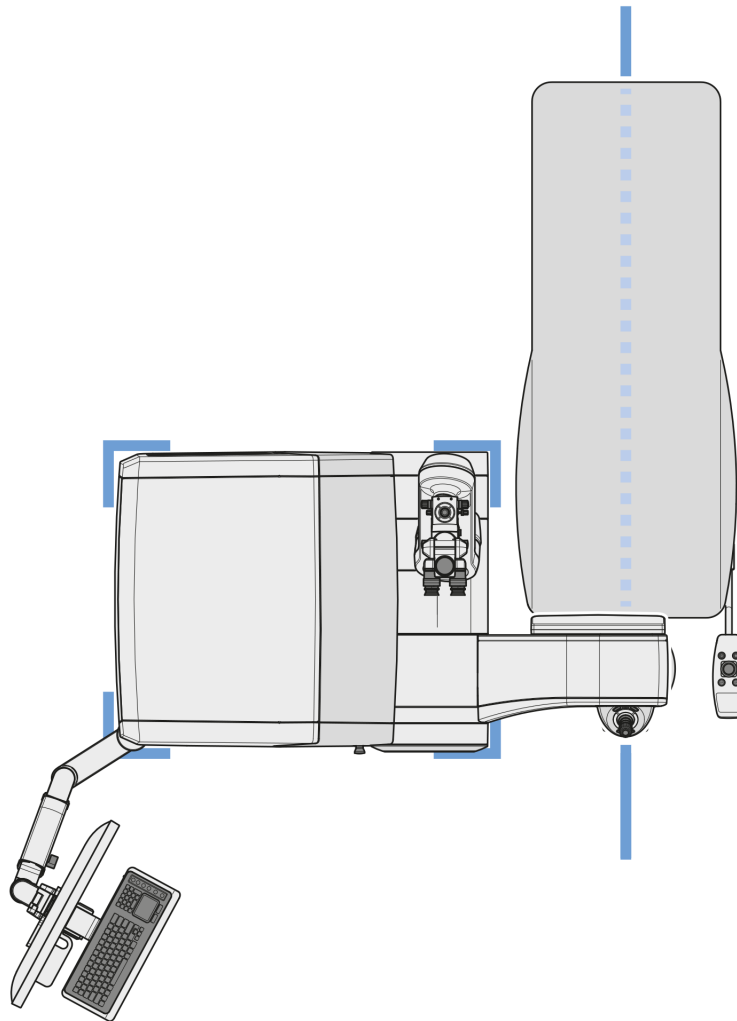


Figure 26: Top view of VISUMAX 600 / VISUMAX 800 with floor marking and adjusted patient supporting system

For a proper and safe function of the device, the patient supporting system must be correctly aligned in relation to the device.

To facilitate this, floor markings are placed under the device with respect to the patient central axis for alignment of the patient supporting system during the initial installation of the device. This is done by the ZEISS Service.

This floor marking should be used to align a patient supporting system.

4.7 Minimum requirement for an external operating microscope (OPMI)

The VISUMAX 600 device variant does not have an integrated OPMI.

However, most treatment options require the use of an appropriate OPMI for manual treatment.

To enable the correct selection of an external OPMI, the following minimum requirements must be met:

- Approved medical product complying with ISO 10936-1 and ISO 10936-2 standards.
- The working distance for performing a treatment is ≥ 150 mm.
- Image resolution is at least 25 μm .
- Field of view is ≥ 40 mm.
- Magnification change by factor 5 is possible.
- Time to possible radiation hazard is at least 5 minutes.

If an OPMI is used which was sold by Carl Zeiss Meditec in connection with this device, all minimum requirements are met and the safety of the device combination is ensured.

For other OPMI, the instructions in section ME system [► 129] must be observed.

4.8 Minimum requirements for connecting an external monitor

WARNING!

Electrical hazard due to missing galvanic isolation at the HDMI interface

The device has an HDMI interface to which a suitable multimedia device (observation monitor, video recorder, etc.) can be connected. As this HDMI interface is not galvanically isolated inside the device, there is a risk of electric shock when an external network-connected multimedia device is connected.

- Always use a medically approved 4 kV signal isolator between the device and a multimedia device.
- Position the multimedia device outside the patient's environment (1.5 m from the patient's position when positioned at the device).
- Switch off the multimedia device via its power switch before disconnecting the external HDMI cable and removing the medically approved 4 kV signal isolator.
- Contact ZEISS Service for the selection of suitable components.

4.9 Minimum requirements for a printer

WARNING!

Electrical hazard due to improper printer installation in the patient environment

The device has a network interface to which a network printer can be connected. This Ethernet interface is galvanically isolated inside the device, but there is a risk of increased leakage current and electric shock if the printer is within the patient environment and can be touched.

- Position the printer outside the patient's environment (1.5 m from the patient's position when positioned at the device).

CAUTION!

Chemical hazard from operating a laser printer in the patient environment

Operating an optional laser printer in the patient's environment can lead to an increased concentration of particulate matter in the ambient air. This is dangerous to the health of all persons in the room and can lead to permanent particulate matter deposits in the patient's eye.

- Ensure the ventilation is sufficient
- Operate the optional printer outside the patient environment and ensure that the hygiene standards applicable at the installation site are observed.

NOTE

Risk of data misuse

By printing treatment reports on a network printer, unauthorized persons could gain access to sensitive data.

- Handle printouts with patient data carefully and remove them from the printer immediately.

A postscript-compatible network printer with PostScript Level 3 may be used at the galvanically isolated Ethernet interface.

Empty page, for your notes

5 Daily startup

5.1 Preparation safety

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

WARNING!

Hazards due to damaged or missing components

Damage to the device, especially to the housing, can result in mechanical injuries when touching sharp corners and edges as well as the risk of electric shock when touching live components.

- Check the casing, the screens, exterior markings, instructions for use, accessories and power cable to ensure that they are present and intact. If parts are missing or damage is visible such as changes in material surfaces (cracks, embrittlement, sharp corners and edges), the device should not be used and should be taken out of service.

CAUTION!

Thermal hazard due to covered or blocked ventilation slots

Blocking ventilation can lead to internal overheating of the device and possibly to failure or fire hazard for the surrounding area.

- Check the ventilation slits of the device. They should not be covered or obstructed.

5.2 Safety in the preparation before each use

The device carries out a start-up test after switching on and a system test at regular intervals; during treatment the device monitors certain parameters.

Treatment cannot be started or resumed if one of these tests fails.

The user does not need to perform an external energy calibration.

5.3 Switching on the device and starting the software

Prerequisite

- ☑ The device is connected to the mains power supply.
- ☑ The emergency stop / emergency laser stop button is not pressed.

Action

1. Switch the mains switch on the device base to the "I" position.
⇒ The LED in the mains switch lights up.
2. Insert the key into the key switch on the device head and turn it to the "ON" position ⇒ The software starts automatically after 1-2 minutes.
3. Wait until the planning screen switches on after a short time.
⇒ The device starts in planning mode for patient management and treatment planning. The "Login" window appears on the planning screen.
4. If necessary, tap the [?] button at the top of the screen to access onscreen help.
5. Press the start button ⇒ The device control starts all components and performs the start-up test.
⇒ The device is ready for operation after approx. 10 min.

TIP:

If you only want to plan treatments but do not want to perform them, you do not have to press the start button.

5.4 Activation of function licenses

The device can only be used for treatments with a selected treatment option after the respective treatment option has been unlocked on the device.

The required licenses for the treatment options and assistance functions can be purchased together with the device. At a later date, further treatment option or assistance function licenses can be acquired from ZEISS or an authorized representative on the basis of a commercial agreement. Further treatment options and assistance functions can be activated by the trained user.

Prerequisite

- ☑ The device is switched on.
- ☑ The key switch is in the "ON" position ☺.
- ☑ The license file for the treatment option is located on a USB stick or a pre-configured network storage connected to the device.
- ☑ The software starts and the login window is displayed on the treatment screen.

Action

1. For login select your user name and enter your password.
2. Then click on the [Login] button.
⇒ The start screen appears on the planning screen.
3. Tap the [Add licenses] button.
4. Tap the [Import function license] button.

Result

- ✓ The license file has been imported.
- ✓ Licenses for treatment options are displayed in the overview on the planning screen.
- ✓ The treatment option which has been activated by a license is available to all users of the device.
- ✓ The assistance function is available to all users of the device during treatment.
- ✓ An overview of the functions is shown in "Function licenses" in the "Info" menu.

5.5 Adding and enabling treatment licenses

The device can only be used for treatments after a treatment license has been added and enabled. This treatment license is provided by Carl Zeiss Meditec or its authorized representatives on the basis of a commercial agreement.

If there are only a few treatment licenses left for one or more treatment options, an input field for the activation code for additional treatment licenses appears in the start window of the planning software.

Prerequisite

- ☒ The device is switched on.
- ☒ The key switch is in the "ON" position .
- ☒ The treatment software is started and the login window appears on the treatment screen.
- ☒ You have the activation code for the treatment licenses.

Action

1. For login select your user name and enter your password.
2. Then tap on the [Login] button.
⇒ The start screen appears on the planning screen.
3. Tap on the [Add licenses] button.
4. Enter the activation code in the input field.
5. Confirm by tapping the [Apply] button.
6. Close the input window.

Result

- ✓ The number of available treatment license will be updated.

6 Operation

6.1 Safety during operation

CAUTION!

Mechanical hazard by falling objects located on the device

Objects placed on the device can cause injuries if they fall down.

- ▶ Do not put any objects on top of the device.
- ▶ Use the document support and the tray on the planning screen.

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

For further instructions on device operation refer to the onscreen help and the instructions for use of the relevant treatment option.

6.2 Preparing treatment

CAUTION!

Hazards caused by the treatment if the contraindications and side effects are ignored

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

- ▶ Observe all contraindications in the instructions for use of the relevant treatment option and the current information according to the literature of medical professional associations and 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.
- ▶ 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 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 the professional medical associations and in the relevant laws in force in your country (e.g. keratoconus, irregular corneal topography etc.).

6.3 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.

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.

The maximum possible incision diameter for each Treatment Pack is specified in the Technical data section of each treatment option and will automatically be checked for the selected Treatment Pack.

6.3.1 Planning the treatment on the device

Prerequisite

- ☒ The mains switch is switched on. Key switch is set to ON.
- ☒ The treatment software is started and the login window appears on the treatment screen.

Action

1. For login select your user name and enter your password.
2. Then tap on the [Login] button.
 - ⇒ The start screen is displayed on the treatment screen.
3. Enter the patient list by tapping the [Patient management] button. To add a new patient, tap the  button and enter the data, then tap the [Treatment planning] button.

4. Enter the treatment parameters necessary for the treatment option.
5. Follow the further steps for treatment planning as described in the corresponding instructions for use for the treatment option.

6.3.2 Importing externally planned treatments

Importing data

Prerequisite

- ☑ Treatments planned with external planning software are available in the FORUM.
- ☑ The device is connected to a network and configured for FORUM integration.
- ☑ The mains switch is switched on. The key switch is set to ON.
- ☑ The treatment software is started and the login window appears on the treatment screen.

Action

1. For login select your user name and enter your password.
2. Then click on the [Login] button.
⇒ The start screen is displayed on the treatment screen.
3. Enter the patient list by tapping the [Patient management] button.
4. Tap the  button.
5. Use the filter to select only patients for whom a treatment has been planned.
6. Set further filter criteria if required (e.g. name).
7. Tap the [Find] button.
8. Select single, multiple or all patients displayed.
9. Tap the  button.
⇒ The selected patient and planning data is imported and patient and planning data already stored in the device is updated.

Result

- ✓ The planning data on the device is in the "not validated" state.

Checking imported data

Prerequisite

- ☑ The planning data on the device is in the "not validated" state.

Action

1. Check the data for correctness.
2. Enter the patient list by tapping the [Patient management] button.
3. If required, limit the patient selection list by entering "not validated" as filter criteria.
4. Select a patient and the corresponding treatment planning.
5. Check the correctness of displayed data.
6. Tap the [Save] button in the planning dialog to confirm.

Result

- ✓ The data is checked and can be used for treatment.

6.4 Performing treatment

Instructions for operating the patient supporting system are given in the corresponding instructions for use.

6.4.1 Preparing and positioning the patient

CAUTION!

Mechanical hazard due to trapping

Due to possible movements of the device head relative to the patient supporting system as well as automatic and manually controlled movements of the device head, the device arms and the patient supporting system, there is a risk of trapping the patient, moving or hanging objects.

- ▶ Keep an eye on all automatic and manual movements of the device head, the device arms and the patient supporting system.
- ▶ Ensure that no parts of the body or objects are trapped between the patient supporting system and the device.
- ▶ Make sure that no objects are placed next to the device head.
- ▶ Ensure that the patient is not wearing any loose items (e.g. clothing, hand bag, jewelry) that could be trapped between moving parts.
- ▶ Patients with long hair should wear a hair net.

CAUTION!

Tripping hazard

The patient may stumble easily without glasses or due to the medication.

- ▶ Guide the patient into the operating room and help him or her to lie down on the patient supporting system to avoid accidents due to tripping.

⚠ 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 Adjusting the patient supporting system [▶ 69]).

Prerequisite

- ☒ The device is switched on (mains switch on, key switch in ON position).
- ☒ Patient and treatment data is entered and checked.
- ☒ The device is ready for laser treatment (start button was pressed).
- ☒ The device is in standby mode (device arm(s) folded up).

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 / her 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.

6.4.2 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.

Action

- ▶ Prepare the patient's eye to be treated. Follow the steps according to the RSTP of the selected treatment option.

6.4.3 Activating laser mode

CAUTION!

Mechanical hazard due to collision with moving objects

The automatic and manually controlled movements of the device can cause injuries due to collision of body parts with the device. Before the laser or OPMI arm automatically swivels in, the device's collision sensor system checks whether there is a possibility of collision. If an obstacle is detected, the motorized swiveling movement of the arms is only possible by permanently pressing the [LM] or [OM] key. If there is a risk of collision for the patient:

- ▶ Stop the current swivel movement of a device arm manually.
- ▶ Stop movements of the device head by releasing the joystick or foot control panel.
- ▶ Operate the emergency stop if there is danger for the patient or user.
- ▶ If necessary, stop the movements of the patient supporting system in use. This is described in the instructions for use of the relevant patient supporting system.
- ▶ Release the patient and allow a comfortable exit position by manually swiveling the device arms upwards until they are mechanically locked in their standby position.

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

Action

Result

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

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

- ✓ The laser arm moves to 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 system 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.

6.4.4 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.

6.4.5 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/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.

- ▶ 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.

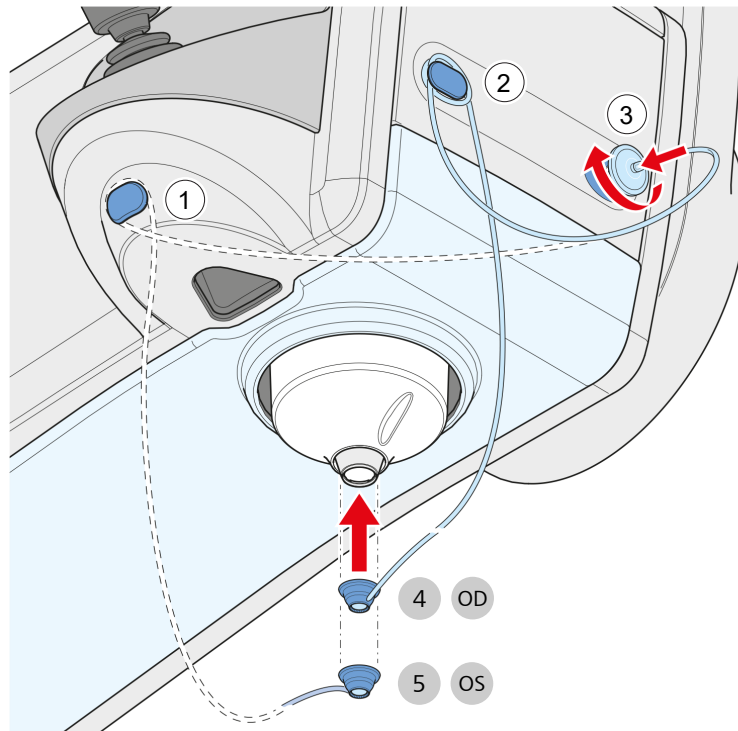
- ▶ Observe the current hygiene recommendations of the medical associations in all procedures on the patient's eye.
- ▶ Do not remove the sterile Treatment Pack from its wrappings until immediately before use and take precautions to ensure that it remains sterile.
- ▶ Use only originally wrapped Treatment 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. Do not touch the optical parts of the contact glass.
7. Hold the contact glass holder by the tube connection (4, 5) and guide it towards the laser objective until it is automatically aspirated.
8. When treating the left eye, make sure that the tube connection points to the left (5) from the surgeon's point of view and to the right (4) for the right eye.
9. Connect the filter connection of Treatment Pack to the vacuum connection on the laser arm (3) and turn it clockwise by about half a turn.
Do not overtighten the connection to avoid damage.
10. Fix the connecting tube of Treatment Pack in the tube holders on the laser arm (1, 2).
 - ⇒ The contact glass image is now displayed on the treatment screen.
 - ⇒ The system automatically takes a measurement of the contact glass and displays a message if the contact glass deviates from the planned values or if the selected size is not optimal for treating the eye.
11. Compare the Treatment Pack size used with the treatment plan, select a Treatment Pack size suitable for the eye and confirm the message if a deviation of the contact glass size from the planning values is desired.

6.4.6 Docking and suction of the eye

WARNING!

Mechanical hazard due to the speed of the patient supporting system

If the patient on the patient supporting system approaches the device too quickly, it may cause injury.

- ▶ Do not operate the movement control of the patient supporting system simultaneously with the device.
- ▶ Never use the foot control panel or patient supporting system, but always use the joystick on the laser arm to dock the patient eye.

WARNING!

Hazard due to the emission of laser radiation

The device emits laser radiation for the purpose of treatment. Exposure of the skin and eyes to direct and scattered radiation (except for treatment of the target eye) may result in hazardous radiation exposure.

- ▶ Activate the laser emission using the foot switch only if a patient's eye is suctioned at the contact glass.
- ▶ If the operating or adjusting devices of the device are used in a manner other than that described in these instructions of use, this can lead to dangerous radiation exposure. Use the operating devices and adjustment options only as specified in these instructions for use.
- ▶ Observe the information on the nominal distance for eye hazards underneath the laser exit aperture in section Technical specifications [▶ 115].

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. Irritation with this illumination unit leads to exceeding the recommended hazard reference value of 2.2 J/cm² after 2.2 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 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 unintended start of laser treatment

The system changes to READY mode upon activation of the vacuum suction and as soon as the suction pressure on the eye is reached. The laser beam to the patient's eye is triggered by pressing the foot switch.

- ▶ After suctioning the patient's eye, check its correct position
- ▶ After suctioning the eye, press the foot switch only if you want to perform the laser treatment

 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 fixating 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 or incorrectly positioned incisions due to movements of the patient supporting system during treatment

Any movement of the patient supporting system after the eye has been suctioned can lead to a suction loss and thus to an interruption of the treatment, which can have a negative impact on the treatment result.

- ▶ Immobilize the patient supporting system at any time when the device arms are not in standby position.
- ▶ Avoid any unwanted movement of the patient when his eye is held at the contact glass. The patient must be fixated in the room.

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.

NOTE

Property damage with integrated UPS

If an internal UPS is installed, complete discharge and battery leakage can damage the device.

- ▶ Connect the device to the power supply for 1 hour at least once a month and activate the standby mode.
- ▶ Have the device serviced regularly to prevent the battery from ageing, even if the device is not used for a long time.

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 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. (For a detailed description, see Functional description of the Centralign centering assistant [► 54]).

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 surgery) are kept to a minimum while the eye is under suction.

6.4.7 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, or do not rotate the cutting pattern.
- ▶ Check the plausibility of the automatically calculated suggestion of the rotation angle by visually comparing the iris image with the live image.

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 selected treatment option supports the alignment of the cutting pattern.
- ☑ The manifest astigmatism of the patient is ≥ 0 .
- ☑ 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 into neutral position to switch into 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 alignment 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 once 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 (for a detailed description, see Functional description of the OcuLign rotation assistant [► 56]).

6.4.8 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.

Laser treatment only starts:

- after activating the suction (press the button),
- after suctioning the patient's eye correctly to the device (required suction pressure reached),
- after pressing the foot switch.

The optical system focuses the laser beam on the corneal tissue. At its focal point, each ultrashort laser pulse triggers an optical breakthrough, creating a gas bubble with a diameter of a few micrometers. The continuous guiding of the laser beam through the optical system creates incision surfaces within the cornea, resulting in a visible bubble image.

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.

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. Perform the treatment completely.
Observe the developing bubble pattern in its temporal course on the treatment screen.
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 Restarting laser treatment [► 98]).

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.

6.4.9 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.

6.4.10 Restarting laser treatment

In rare cases, there is a loss of eye suction during laser treatment. This aborts treatment. For some treatment options, the device offers the user the option to resume the treatment later or to restart it immediately.

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.

Prerequisite

- ☒ The laser treatment was aborted without device error.

Action

- Follow the safety queries and messages on the treatment screen.

6.4.11 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.

6.4.12 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/cm² if the user does not reduce the irradiation intensity 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. 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 4: Maximum radiation intensity exceeding the hazard reference of 10 J/cm²

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.

After the device has made the desired incisions, depending on the treatment option, the surgical procedure must be continued manually by the physician to achieve the desired treatment result. The manual steps are usually observed using an operating microscope.

In the VISUMAX 800 device version, this operating microscope is already provided by the device as a convenience function to optimize the workflow. The optical properties are designed for the most demanding treatment option available.

This convenience function is not available in the VISUMAX 600 device version. The user must provide an external operating microscope for the further surgical steps. To ensure that the quality of optical observation is comparable to that of VISUMAX 800, the minimum requirements for such an operating microscope are listed in Minimum requirement for an external operating microscope (OPMI) [► 70].

Prerequisite

- ☒ Completed laser treatment of patient eye.

Action

1. Follow the instructions for use of the treatment options.
2. Press the standby mode button [II] or the observation mode button [OM].

Result

- ✓ The laser arm moves up and the laser objectives retracts back into the laser arm.

6.4.13 Ending the treatment

CAUTION!

Risk of tripping

The patient can easily stumble due to the affected visual acuity.

- Guide the patient when entering and leaving the operating area to avoid accidents due to stumbling.

Prerequisite

- ☒ Completed or aborted treatment of the patient.

Action

1. Finish the treatment mode of the device.
2. Help the patient to stand up from the patient supporting system and guide him / her out of the treatment room.
3. Clear and disinfect the operating area.

6.5 Backing up data

For each laser treatment, the device internally stores the set treatment data as well as a video of the course of treatment. To prevent data loss, it is recommended to perform an external data backup daily, before any maintenance and before any software update.

To protect against the execution of external programs or malware, it is recommended that you use an empty USB storage device or scan the USB storage device for viruses and malware before use.

Prerequisite

- ☑ The mains switch is switched on.
- ☑ The key switch is set to ON.
- ☑ The treatment software is launched and you are logged in.
- ☑ If required, the device is connected to the network and configured appropriately or a USB storage device is connected.

Action

- Use one of the three options available in the software to create backup copies.
 - Export data to FORUM
 - Export data to a locally connected USB drive
 - Export data to a network drive

Result

- ✓ The selected treatment data is saved externally.

6.6 Powering the device down

NOTE

Possible property damage due to data loss

Premature disconnection of the device from the power supply may result in loss of data. If the device is unplugged or switched off at the mains switch while the device is still running, the program cannot be closed and the operating system cannot be shutdown properly; this can lead to loss of saved data and / or defects in the device's control software. This does not present a hazard to patients or the user.

- Wait until the device is shut down before pulling the power supply plug or switching off at the mains switch.

6.6.1 Brief pause in use

Prerequisite

- ☑ The device is switched on and you are logged in.

Action

1. Shut down the software.
2. Set the key switch to the OFF position .

Result

- ✓ The device is switched off, but still connected to the power supply.

6.6.2 Switching the device off

WARNING!

Thermal and electrical hazard from live internal components

Internal components remain energized even after the device has been switched off with the key switch. In this case an internal malfunction can lead to hazards such as smoke emission or fire. The device must be switched off via the mains switch and unplugged to disconnect it completely from the power supply.

- ▶ To switch off the complete system, use the mains switch next to the power connection.

Prerequisite

- ☒ The device is switched on and you are logged in.

Action

1. Shut down the software.
2. Set the key switch to the OFF position .
3. Remove the key switch from the device to prevent its use by unauthorized persons.
4. Switch the mains switch on the device base to the "0" position.
5. For long-term decommissioning remove the power plug as well.

Result

- ✓ The device is switched off and disconnected from the power supply.

6.6.3 Taking out of service in the event of unintended mechanical movement and unintended laser radiation

WARNING!

Hazard due to unintended movements or unintended application of laser radiation:

If this device makes unintentional movements that could endanger the patient, or if the device emits laser radiation unintentionally, i.e. you have lost control of the laser treatment by means of the foot switch, take the following measures:

- ▶ Press the [Emergency stop / laser stop] button immediately.
- ▶ Turn the key switch to OFF position.
Some components are still live.
- ▶ Switch off the device at its mains switch.
- ▶ Disconnect the power cable.
To completely disconnect the device from the power supply, the power supply connector must be unplugged from the mains socket.
- ▶ Ensure that the system cannot be put back into operation.
- ▶ Inform the person authorized by the manufacturer that maintenance work needs to be carried out on the system.

6.6.4 Long-term decommissioning

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, which may result in incomplete incisions and poor tissue separation.

- ▶ For long-term decommissioning, protect all optical exits (laser exit aperture and operating microscope tube) with lens-caps 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.

NOTE

Property damage with integrated UPS

If an internal UPS is installed, complete discharge and battery leakage can damage the device.

- ▶ Connect the device to the power supply for 1 hour at least once a month and activate the standby mode.
- ▶ Have the device serviced regularly to prevent the battery from ageing, even if the device is not used for a long time.

7 Cleaning and disinfection

7.1 Safety during cleaning, disinfection and sterilization

WARNING!

Electrical hazard due to penetration of moisture

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

- ▶ Switch the device off via the mains switch and disconnect the power cable from the power supply before cleaning or disinfecting the device.
- ▶ Prevent moisture from penetrating the device or keyboard.
- ▶ Use a lint-free, slightly moistened (never dripping) cloth for cleaning.
- ▶ In general, make sure that electrically operated components may only be subjected to wipe disinfection.

CAUTION!

Infection or poor tissue separation through reuse, re-sterilization or cleaning of the Treatment Pack

Laser radiation, re-sterilization or cleaning measures will affect the optical properties of the contact glass, which could result in incomplete incision, poor tissue separation or infection if the Treatment Pack is reused.

- ▶ Do not resterilize the Treatment Pack.
- ▶ Use the Treatment Pack only once.
- ▶ Do not use a Treatment Pack if you are not certain that it is sterile.

CAUTION!

Biological hazard, risk of infection or cross-contamination due to missing or inadequate disinfection

A possible infection hazard can be effectively countered by thoroughly disinfecting all contaminated parts. For this purpose regular disinfection of all parts must be carried out. In case of no or inadequate disinfection of the device, the patient may be infected with germs.

- ▶ Contaminated parts with which the patient has come into contact during the treatment should be cleaned with a disinfectant approved for the purpose after each treatment.
- ▶ Cover control elements that must be operated with sterile gloves during treatment with sterile caps.
- ▶ Dispose of disposable items after each use.

CAUTION!

Biological or chemical hazard due to improper cleaning and disinfection

In the hospital and private practice setting where medical devices are used on humans, manual cleaning and disinfection of these devices must be performed using suitable validated procedures to demonstrate that reprocessing is traceably safe and effective. An only partial or even ineffective disinfection of the device can lead to a transmission of pathogenic germs from patient to patient, physician or third party, or to harmful release of particles.

- ▶ Observe the national disinfection regulations.
- ▶ When selecting cleaning agents and disinfectants, make sure that a disinfectant with certified effectiveness (e.g. VAH / DGHM or FDA approval or CE label) is used and that it is compatible with the cleaning agent used.
- ▶ Please note that only validated procedures may be used for cleaning / disinfection and that the basic conditions (concentration, temperature, time, etc.) underlying your validated procedure must be observed for each cycle.
- ▶ When selecting the cleaning agents and disinfectants, observe the safety instructions.
- ▶ Always adhere to the concentrations and exposure times specified by the manufacturer.
- ▶ Use combined detergents / disinfectants only for very low contamination without visible impurities.

NOTE

Property damage due to hygiene measures and lack of material resistance

Some cleaning agents and disinfectants or disinfecting procedures may have an adverse effect on parts inside the device, painted metal surfaces and plastic components. Damage caused by such disinfectants is not covered by our warranty.

- ▶ Use only disinfectants approved by the manufacturer for the treatment of plastics and painted surfaces.
- ▶ Do not use aggressive (e.g. Acetone) or abrasive cleaning agents.
- ▶ Never clean any applied, housing or touchable parts with abrasive cleaning agents, metal brushes, wire wool or other abrasive materials.
- ▶ Do not carry out disinfection with UV radiation.
The product has not been tested for resistance to UV radiation. Repeated or permanent exposure to UV radiation may result in color or mechanical changes.
- ▶ Do not carry out fogging disinfection. The fog can cause damage inside the device.

7.2 Cleaning and disinfection procedure

The surfaces of the device and other contaminated surfaces, such as the keyboard, OPMI eyecups, control units, should be cleaned and disinfected at least once a month.

When carrying out surface cleaning / disinfection, the requirements for personal protection must be observed.

Action

- ▶ Check that the mains switch next to the power input is switched off (green LED is not lit).
- ▶ Remove the power plug from the power socket.
- ▶ Wipe off all parts of the device casing with a moist but not drip-wet cloth.
- ▶ Wipe surfaces and objects until completely wetted.
- ▶ Make sure that the disinfectants are not squeezed out of the cloths too much to avoid foaming.
- ▶ Observe the exposure time of the disinfectant manufacturer.
- ▶ Wipe off any residues with distilled water, to which a drop of household detergent has been added.
- ▶ In case of direct skin contact or if the patient's medical history / diagnosis makes this necessary, surface disinfection must be performed immediately after application.

Procedure for third party products

Third party products are not covered by these hygiene instructions and are generally the responsibility of the original manufacturer.

Separately supplied manufacturer's instructions for cleaning and disinfection of third-party products (accessories) must be observed. The use of cleaning agents and disinfectants not recommended by the manufacturer can lead to damage.

Observe the disposal instructions of the original manufacturer. This applies specifically to disposables.

7.3 Cleaning and disinfecting agents

The surfaces of the device have been tested to withstand frequent and long-term treatment with alcoholic or peracetic acid-based disinfectants and cleaning agents.

The surface of the device is resistant to the following mixture of substances:

- 70 % isopropyl alcohol
- 2 % glutaraldehyde
- 0.2 % didecyldimethylammonium chloride
- Remainder: demineralized water

For disinfectants with a different composition, damage to the device cannot be excluded.

7.4 Sterilization

7.4.1 Sterilized Treatment Pack

The Treatment Pack is an applied part sterilized with ethylene oxide (EO) and is intended for single use.

The Treatment Pack is not suitable for reuse and sterilization after use.

Action

- Observe all safety instructions and warnings in the accompanying information of the Treatment Pack.

7.4.2 Autoclavable sterile caps

The sterile caps are suitable to withstand thermal stress caused by heat sterilization at 121 °C, 20 minutes and 2.1 bar without damage.

For information on the sterilization procedures of other manufacturers, please refer to their manufacturer's specifications.

Failure to observe validated sterilization procedures may result in unsterile surfaces or damage.

Designation	Use	Supplier	Material number
Sterile cap, 12 mm	■ Filter slider on OPMI (blue filter, no filter, yellow filter)	Carl Zeiss Meditec ¹	305810-9002-000
Sterile cap, 22 mm	■ OPMI magnification changer ■ OPMI brightness setting ■ Slit projector control	Carl Zeiss Meditec ¹	305810-9001-000
Sterile cap, 49 mm	Setting the interpupillary distance on the OPMI	Carl Zeiss Meditec ¹	305810-9007-000

Table 5: Overview of sterile caps

¹ Please contact ZEISS Service or your local ZEISS dealer for the purchase of sterile caps.

8 Maintenance

There are no user maintenance tasks for the device except the generation of system diagnostic data.

8.1 Safety during maintenance

WARNING!

Hazard from device modifications or improper maintenance and repair

Modifications to the device can negatively affect the safety of the device and in extreme cases can lead to serious injury or even death. Further maintenance procedures above and beyond those specified in this section (maintenance, safety inspections, calibration, repairs and modifications) may only be carried out by persons authorized by Carl Zeiss Meditec and solely according to the service instructions issued by Carl Zeiss Meditec.

- ▶ Do not perform any operations that are not described in these instructions for use.
- ▶ Do not make any changes to this device that are not permitted by the manufacturer.
- ▶ Do not carry out any service or maintenance work on the device that is not included in these instructions for use.
- ▶ Maintenance procedures (maintenance, safety inspections, calibration, repairs and modifications) may only be carried out by persons authorized by Carl Zeiss Meditec and solely according to the service instructions issued by Carl Zeiss Meditec. For planning and implementing these maintenance and care procedures please contact ZEISS Service or your local ZEISS dealer.

WARNING!

Danger from laser radiation when the housing is open

Laser radiation is generated inside the device, which is shielded by the laser protection housing. Contact with this laser radiation can permanently injure the skin or eye. The housing may be opened only by service personnel authorized by the manufacturer. There are no parts in the interior of the device to be serviced by the user. If the protective cover is removed by service personnel in case of repair, the laser is a class 4 laser.

- ▶ The protective cover may only be removed by qualified service personnel.
- ▶ In case of repair the laser area must be delimited.
- ▶ The entrances to the laser area must be marked to indicate the operation of the laser with the protective housing open.
- ▶ Persons who are working in this laser area must wear laser safety eyewear. The specification of the laser safety goggles can be found in the service instructions.

 WARNING!

Electrical hazard from live parts when the housing is open

Inside the device there are live parts whose contact can cause an electric shock.

- ▶ Never open the device.
- ▶ Switch the device off every time before disconnecting it from the power supply, or if you are not going to use the device for any length of time.
- ▶ Also disconnect the device from the power supply before cleaning surfaces or accessories.

 WARNING!

Danger from maintenance work during use

If service and maintenance work is carried out, safety devices can be disabled. Safe operation is then no longer ensured during this time and, in extreme cases, serious injury or even death of the patient, user or third parties may result.

- ▶ Never use the device during maintenance work (servicing, safety checks, repairs or modifications).

8.2 Safety inspections

Regardless of relevant regulations in your country regarding electrical equipment inspections, the responsible organization is required to have the device inspected for safety once every six months. The safety inspection also includes testing the electrical safety.

Safety inspections may only be carried out by persons authorized by Carl Zeiss Meditec and solely according to the service instructions issued by Carl Zeiss Meditec. For planning and implementing these maintenance and care procedures please contact ZEISS Service or your local ZEISS dealer.

9 Troubleshooting

9.1 Safety during troubleshooting

WARNING!

Hazards due to improper decommissioning in fault condition

There are fault conditions of the device where further dangers (electric shock, smoke emission, fire, faulty surgical result, etc.) are avoided by taking the device out of service. Improper decommissioning in the event of a fault condition of the device can lead to serious injury or even death of the patient, user or third parties.

The following steps are required for taking the device out of service:

- ▶ Switch off the device via the software (if possible).
- ▶ Set the key switch to position OFF .
- ▶ Operate the emergency stop / laser emergency stop on the device to separate the internal uninterruptible power supply, if present, from the electronics.
- ▶ Switch off the mains switch.
- ▶ Disconnect the power cable from power supply to completely disconnect the device from the mains socket.
- ▶ Label the device clearly as **out of order**.
- ▶ When not in use, remove the key switch from the system to prevent its use by unauthorized persons.
- ▶ Notify ZEISS Service.

Action

- ▶ In the following cases, label the device clearly as out of service and report the problem to ZEISS Service:
 - ⇒ electric shock
 - ⇒ penetration of liquids
 - ⇒ occurrence of smoke, fire or burning odor
 - ⇒ disimprovement of the system performance
 - ⇒ frequently occurring error messages
 - ⇒ response of the system in contradiction with the information in these instructions for use
 - ⇒ faults that cannot be remedied based on the information provided in these instructions for use
 - ⇒ system related incidents or near incidents that have resulted or may have resulted in injury to the patient or physician (user).

If errors occur during operation of the device, the device automatically switches to a safe state, analyzes the error and reports the cause to the monitor. Depending on the cause and situation, either the user can correct the fault him / herself or the

device must be shut down and ZEISS Service notified. If the device switches off suddenly during operation, the cause may be the thermal fuse in the mains switch of the unit. Wait for about one minute before switching the device back on. If the safety cutout is triggered repeatedly, please contact ZEISS Service.

Release of the patient

If it is necessary to remove the patient from the surgical environment very quickly, act as follows:

When the patient is fixed to the contact glass and a laser operation is being performed:

Action

- ▶ Release the foot switch.
- ▶ Release the suction by pressing the joystick button on the laser arm or disconnect the connection between vacuum connector and Treatment Pack.
- ▶ Move the laser arm manually to the standby position.

When the patient is below the OPMI:

- ▶ Move the OPMI arm manually to the standby position.

9.2 Localize faults

Generating system diagnosis data

The device has a function for generating system diagnosis data. This data can help in remote diagnostics to take the appropriate action if the device is not functioning properly.

Action

- ▶ Generate the system diagnosis data in the "Maintenance" dialog.
 - ⇒ This file is saved on an external USB storage device (USB stick).
- ▶ Copy the system diagnosis data to a computer with e-mail access and e-mail the file as an attachment to ZEISS Service.

9.3 Faults (with messages)

If errors occur during operation of the device, the system automatically switches to a safe state, analyzes the cause and reports it on the screen. Depending on the cause and situation, either the user can correct the fault him / herself or the device must be shut down and ZEISS Service notified.

Action

- ▶ If failures occur which you cannot resolve yourself, take the device out of service and contact ZEISS Service.

9.4 Faults (no messages)

If faults occur during operation of the device which the device does not automatically detect, it must be taken out of service and ZEISS Service must be notified.

Action

- Take the device out of service and contact ZEISS Service.

9.5 Service information

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

Empty page, for your notes

10 Technical specifications

10.1 Essential performance

Creation of corneal perforations whose correct positioning can be detected by the user.

10.2 Regulatory information

10.2.1 Classification of the device

The device is classified as follows:

- UMDNS-No: 17-446 GMDN 57995
- Type of protection against electric shock: Protection class 1
- Degree of protection against electric shock: applied part type B
- Ingress protection rating against penetration by water and solids: IP 20
- Ingress protection rating against penetration by water and solids: Foot switch / Foot control panel: IPX8
- Sterilization method: No sterilization method intended for the device
Note: Sterile use of components and accessories according to hygiene instructions. Treatment Pack is a sterile product for single use, sterilization method ethylene oxide (no resterilization).
- Protection rating for application in the presence of combustible mixtures of anesthetic, air, oxygen or nitrous oxide: Medical device not suitable for use in flammable mixtures of anesthetics with air or in flammable mixtures of anesthetics with oxygen or nitrous oxide
- Transport characteristics: stationary (recommissioning only by authorized personnel)
- Operating mode: continuous operation

10.2.2 Classification of the device according to IEC 60825-1

The device is classified as follows:

- Laser class: 3B (according to IEC 60825-1:2001, IEC 60825-1:2007 and IEC 60825-1:2014)

10.3 Electrical data

Parameter	Value
Rated voltage	100 V to 240 V AC ($\pm 10\%$)
Frequency	50 / 60 Hz
Power consumption during operation	max. 1350 W

Integrated uninterruptible power supply

The device can optionally be equipped with an integrated uninterruptible power supply (UPS). This can hold up operation of the device in case of power failure for a maximum of 5 minutes.

- Accessories may only be installed by a service technician certified by Carl Zeiss Meditec.

10.4 Dimensions and weights

10.4.1 Mechanical properties of the device

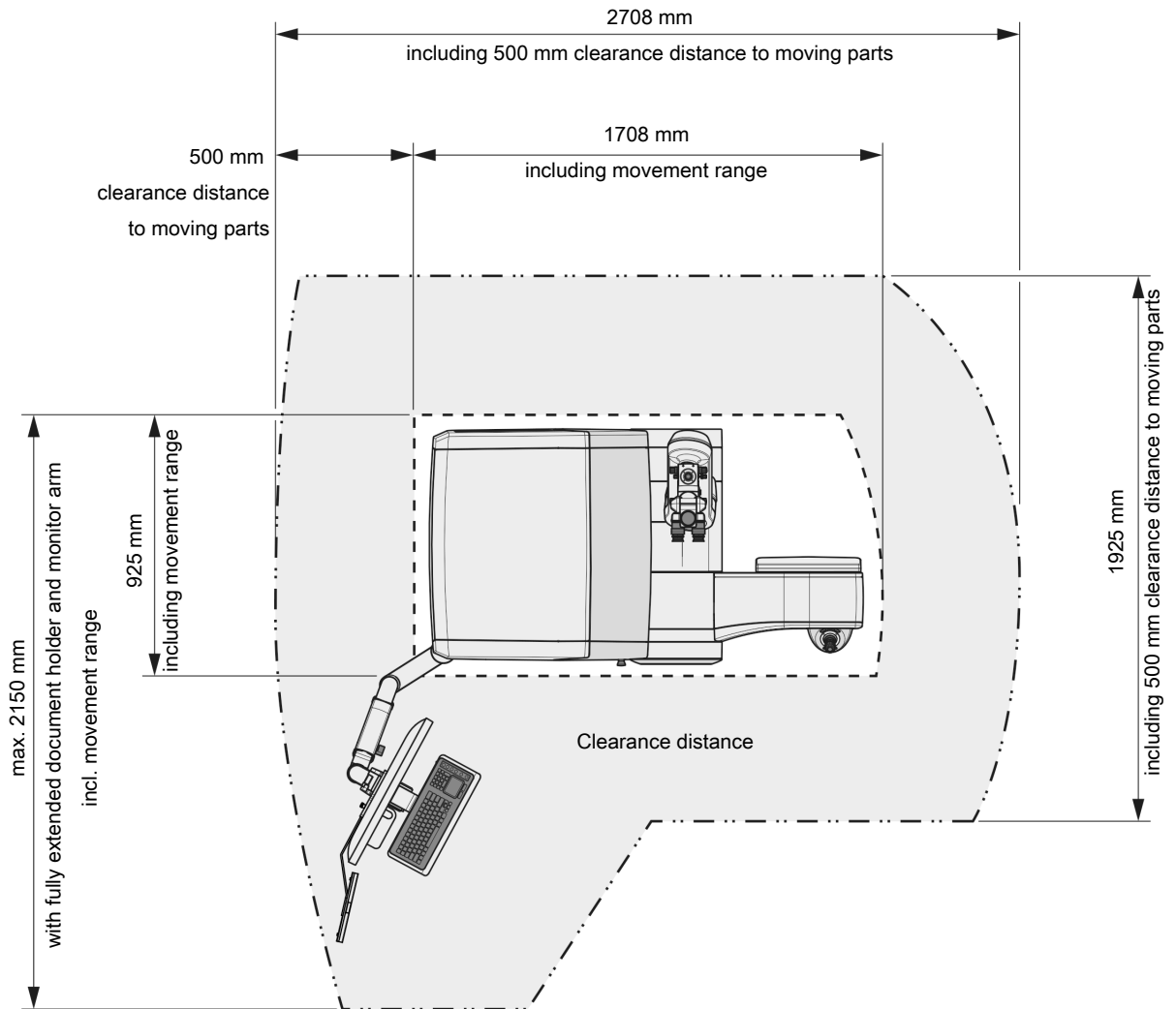


Figure 27: Required footprint

Parameter	Value
Device mass	Max. 520 kg
Footprint L x W	1710 mm x 925 mm
Minimum distance to all permanently installed fixtures (except the patient supporting system)	500 mm
Maximum inclination of installation surface	0.5 % (0.3°)

10.4.2 Requirements to room floor load

Parameter	Value
Minimum floor load	2.5 kN/m ²
Minimum concentrated load	2 kN

10.5 Optical data

10.5.1 Properties of laser radiation

Parameter	Value
Maximum power output	< 760 mW
Maximum laser sequence frequency	2 MHz ± 3%
Wavelength	1043 nm ± 20 nm
Pulse time	220 to 580 fs
Nominal ocular hazard distance (NOHD)	0.36 m
Beam divergence	≥ 690 mrad

10.5.2 Position accuracy of the laser incisions

Parameter	Value
Depths	< 10 µm*
Diameters / radii / lateral distances (corresponding to the specified parameters)	< 0.05 mm
Incision position relative to the contact glass center	< 0.1 mm

* The number given here is the positional accuracy of the incision depth of the device relative to the contact glass. The actual accuracy of the incision depth depends on a number of applicative secondary conditions, such as the thickness of the water film between contact glass and cornea, the individual refractive index variation of the cornea, etc.

10.5.3 Specifications of other radiation sources

Parameter	Value
VIS treatment illumination (white light LED)	Group 2 in accordance with ISO 15004-2
IR treatment illumination (IR-LED)	Group 1 in accordance with ISO 15004-2
Fixation light	Group 2 in accordance with ISO 15004-2
VIS observation illumination (white light LED)	Group 2 in accordance with ISO 15004-2
VIS slit illumination (white light LED)	Group 2 in accordance with ISO 15004-2

10.6 Ambient conditions

Ambient requirements for operation

Parameter	Value
Temperature	+18 °C to +25 °C
Relative humidity	30 % to 75 %
Operating altitude	max. 3000 m
Pressure range	700 hPa - 1060 hPa

The device must not be operated in an environment enriched with oxygen.

Ambient conditions for storage and transport in original packaging

Parameter	Value
Temperature	0 °C to +40 °C
Relative humidity	10 % to 95 % (non-condensing)
Pressure range	500 hPa - 1060 hPa

If the device is used in a medical system with other components, the ambient conditions with the largest restrictions of the system components involved apply to the system.

10.7 Other performance features

Parameter	Value
Duration of the switch-on phase	max. 10 min at a room temperature above 20 °C
Operating microscope magnification	Eyepieces 12.5x (10x) Magnification 0.7x Factors for magnification change 0.4 / 0.6 / 1 / 1.6 / 2.5
Slit illumination	Slit width ≤ 0.3 mm / 0.7 mm Slit height 11.0 mm

10.8 Electromagnetic compatibility

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

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

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

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

Special precautionary measures apply to this device with regard to electromagnetic compatibility (EMC). To avoid electromagnetic disturbances that could have a serious effect on the patient or the user, the device may only be installed, operated and serviced in accordance with the instructions for use and using components supplied by Carl Zeiss Meditec AG.

10.8.1 Ambient conditions for intended use

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

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

The device is not intended for operation in the following environments:

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

10.8.2 Restrictions on essential performance

CAUTION!

Electromagnetic interference radiation from stacked or directly adjacent devices

Using the device in direct proximity to other devices or stacked together with other devices should be avoided as this could result in faulty operation. As a result, the safety of the device is no longer ensured and control and monitoring processes in the device may be disturbed. In extreme cases, this can lead to injury to the patient, user or third parties.

- ▶ Only use the device in the proximity of device combinations described in these instructions for use.
- ▶ Do not stack other devices on top of the device.
- ▶ If it is nonetheless necessary to operate the device in the aforementioned manner, the device and the other devices should be observed to check for intended operation of the arrangement used.

 CAUTION!

Increased electromagnetic emissions and reduced immunity to interference when using non-specified accessories, converters of all types, cables, portable HF telecommunication devices or optional accessories from the field of information technology

The use of accessories, all types of transducers and cables not specified in these instructions for use or not sold by the manufacturer or distributor as replacement parts may result in higher electromagnetic emissions or especially a reduced immunity of the device.

As a result, the safety of the device is no longer guaranteed and control and monitoring processes in the device can be disturbed. In extreme cases, this can lead to permanent injury to the patient, user or third parties.

- ▶ Purchase spare parts including spare cables solely from Carl Zeiss Meditec AG or dealers authorized by Carl Zeiss Meditec AG.
- ▶ Optional information technology accessories (printers, additional monitors) which are connected to the medical device must be class B conforming to CISPR 32 or comparable devices.
- ▶ Do not use portable HF communications equipment (including peripheral devices such as antenna cable and external antennas) within a radius of 30 cm around the device, including cables specified by the manufacturer. Otherwise, deterioration in the performance of the device is to be anticipated.

The essential feature of the device is the creation of corneal perforations whose correct positioning can be detected by the user.

If, for example, due to strong electromagnetic interference on the device, the observation equipment necessary for detecting the correct positioning of the corneal perforations is disturbed or fails, the essential performance feature of the device remains intact, since the correct positioning of the corneal perforations can still be detected after switching the illumination back on or after the laser treatment.

Relevant accessories and cables and their maximum length

- Power supply cable (5.0 m)
- Keyboard
- HDMI cable (3.0 m)
- Ethernet cable (5.0 m)
- Cable for remote-controlled safety interlock (remote interlock cable) (10.0 m)
- DMO / ESO cable (1.5 m)

No regular inspections or maintenance are required in order to maintain electromagnetic compatibility (EMC). If obvious damage to the device is detected (e.g. housing, cables), contact ZEISS Service. It may be possible that a medical device having a damage still can be operated, but increased emission and / or decreased immunity may arise.

10.8.3 Electromagnetic emission

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

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for operation in an electromagnetic environment as specified below. The customer or the user of the device should ensure that it is operated in such an environment.

Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions as per IEC 61000-3-2	Class A
Emission of voltage fluctuation / flicker as per IEC 61000- 3-3	Compliant

10.8.4 Immunity

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for operation in an electromagnetic environment as specified below. The customer or the user of the device is responsible for ensuring that the device is operated in such an environment.

According to IEC 60601-1-2:2020

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) as per IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst immunity as per IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output lines	The quality of the supply voltage should be that of a typical business or hospital environment.
Surge as per IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to ground	±1 kV line(s) to line(s) ±2 kV line(s) to ground	The quality of the supply voltage should be that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines as per IEC 61000-4-11	0 % U_T for 1/2 cycle 0 % U_T for 1 cycle 70 % U_T for 25 / 30 cycles 0 % U_T for 250 / 300 cycles	0 % U_T for 1/2 cycle 0 % U_T for 1 cycle 70 % U_T for 25 / 30 cycles 0 % U_T for 250 / 300 cycles	The quality of the supply voltage should be that of a typical business or hospital environment. If the user of the device requires continued function even in the event of interruptions in the power supply, we recommend to power the device from an uninterruptible power supply or a battery.
Magnetic field in the power frequency (50 / 60 Hz) as per IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields in the power frequency should correspond to the typical values that are found in business and hospital environments.
Note: U_T is the AC voltage supply before application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for operation in an electromagnetic environment as specified below. The customer or the user of the device is responsible for ensuring that the device is operated in such an environment.

According to IEC 60601-1-2:2020

Immunity test	IEC 60601 test level	Compliance level
Conducted HF disturbances as per IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3V
	6 V _{rms} ISM bands ^a	6 V
Radiated RF disturbances as per IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m
Radiated RF disturbances from near fields of wireless communication devices as per IEC 61000-4-3	27 V/m 380 MHz to 390 MHz	27 V/m
	28 V/m 430 MHz to 470 MHz, 800 MHz to 960 MHz, 1.7 GHz to 1.99 GHz, 2.4 GHz to 2.57 GHz	28 V/m
	9 V/m 704 MHz to 787 MHz, 5.1 GHz to 5.8 GHz	9 V/m
Radiated HF disturbances as per IEC 61000-4-39	65 A/m 134.2 kHz (2.1 kHz pulse modulation)	65 A/m
	7.5 A/m 13.56 MHz (50 kHz pulse modulation)	7.5 A/m
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection by structures, objects and persons.		
^a The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.		

10.8.5 Recommended safety distances between portable and mobile RF communication equipment and the device

The device is intended for use in an electromagnetic environment in which RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and this device, depending on the output power of the communication equipment as specified below.

Rated power of the transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection by structures, objects and persons.

11 Accessories and spare parts

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

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

Accessories supplied with the device: see Package check list [► 25]

Additional accessories:

- 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
 - REF 1016 Treatment Pack KP with instructions for use
 - with corresponding treatment license
- UPS (000000-2296-848)
- Patient supporting system Brumaba (000000-2342-271)
- Sterile components (see Autoclavable sterile caps [► 108], sterile caps 12 mm, 22 mm, 49 mm)
- Network cable 5 m (000000-2378-277)
- optional treatment options (software)
- optional assistance functions (software)

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12 ME system

WARNING!

Electric hazard due to improper system installation

Incorrect installation may cause higher leakage currents or an electric shock.

- ▶ Do not use electrical products which do not have an approval for medical use in the patient environment (at a distance of 1.5 m from the patient).

The device necessarily requires a patient supporting system for its use. It may also be necessary to combine other non-medical devices such as printers or external monitors with the device.

When combined with other devices, safety is only ensured if the normative requirements for medical systems are complied with (see IEC 60601-1-1 or Section 16 of the 3rd edition of IEC 60601-1, as applicable). Anyone connecting additional equipment to medical electrical devices is considered to be a system configurer and as such is responsible for compliance of the system with the local legal and normative requirements for ME systems.

Local laws take precedence over the above normative requirements.

12.1 ME-system with patient supporting system

If the device is combined with a patient supporting system which is not distributed by Carl Zeiss Meditec, the distributor of the combination is responsible for its safety.

When selecting a patient supporting system, observe the minimum requirements in Minimum requirements for patient supporting system [▶ 66] and contact ZEISS Service if necessary.

12.2 ME system with external operating microscope (OPMI)

The VISUMAX 600 device variant does not have an integrated OPMI. Most treatment options require a manual surgical step after the laser treatment, for which an OPMI is necessary.

When selecting an appropriate external OPMI, observe the minimum requirements in Minimum requirement for an external operating microscope (OPMI) [▶ 70] and contact ZEISS Service if necessary.

12.3 ME-system with external monitor

An external monitor can be connected to the device.

When selecting an appropriate external monitor, observe the minimum requirements in Minimum requirements for connecting an external monitor [▶ 70] and contact ZEISS Service if necessary.

12.4 ME-system with printer

A printer can be connected to the device.

When selecting an appropriate external printer, observe the minimum requirements in Minimum requirements for a printer [► 71] and contact ZEISS Service if necessary.

13 Decommissioning

13.1 Safety during decommissioning

The device can only be relocated by ZEISS Service or authorized personnel. If you take the device out of service, perform the following steps:

Action

- ▶ Switch off the device via the software.
- ▶ Set the key switch to position OFF .
- ▶ Operate the emergency stop / emergency laser stop button on the device to separate the internal uninterruptible power supply, if present, from the electronics.
- ▶ Switch off the mains switch.
- ▶ Disconnect the power cable from power supply to completely disconnect the device from the mains socket.
- ▶ Label the device clearly as **out of order**.
- ▶ When not in use, remove the key switch from the system to prevent its use by unauthorized persons.

13.2 Cleaning the device and accessories

Action

- ▶ Clean the device and any accessories which are no longer needed as described in section Cleaning and disinfection [▶ 105].

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14 Packaging and transport

If you want to pack and transport the device, please contact ZEISS Service.

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

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15 Disposal

CAUTION!

Chemical hazard due to disposal of environmentally hazardous substances

The device contains electronic components and accumulators (lead and lithium) which are harmful to the environment if they are not disposed of properly.

- ▶ Dispose of the device and integrated batteries correctly, in accordance with national legislation.

- ▶ If you would like to dispose of the original packing material, send it in for recycling via a recognized collection system.



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

- ▶ For more information on disposing of the device, contact the ZEISS contact person in your country.

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

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

CAUTION!

Biological hazard of potentially infectious particles of the removed corneal tissue

Removed corneal tissue may contain viable and potentially infectious particles.

- ▶ Dispose of this material according to current guidelines for biological tissue.

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

CE labeling

The CE marking indicates that the product to which it is affixed meets the requirements of all EC directives applicable to this product.

CentraLign

Assistance system for alignment of the treatment center

DGHM

Deutsche Gesellschaft für Hygiene und Mikrobiologie e.V. (German Society for Hygiene and Microbiology)

DICOM

Digital Imaging and Communications in Medicine. A standard for data management, including a file format specification and a network communication protocol.

DMO

Device mode output

ESO

Emergency switch output (emergency stop output)

FCP

Foot control panel (wired)

FDA

Food and Drug Administration (U.S. authority)

FIX

Abbreviation for fixation light

HDMI

High Definition Multimedia Interface

IEC

International Electrotechnical Commission

IR

Infrared

ISO

International Organization for Standardization

ME system

Medical electrical system

NOHD

Nominal ocular hazard distance

OcuLign

Assistant system for cyclotorsion compensation

OPMI

Operating microscope

OV

Abbreviation for overlay (overlay of data into the video image)

RSTP

Recommended standard treatment procedures

UMDNS

Universal Medical Device Nomenclature System (nomenclature for medical products)

UPS

Uninterruptible power supply

USB

Universal serial bus (standard interface to connect peripheral devices)

VAH

Verbund für Angewandte Hygiene e.V. (Association for applied hygiene)

VIS

Visible

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