VISALIS V500 / VISALIS S500
Software Release 2.0

Instruction for Use

G-30-1787-en

Version 7.3

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About the document

These Instructions for Use are part of the delivery package.

- Carefully read them before using the device.
- Keep them at the site of use of the device.
- Store them for the entire service life of the device.
- Pass them on to every subsequent owner or user of the device.

Orientation guides

– The section summary at the beginning of these Instructions for Use provides an overview of the topics.

– You will also find a detailed table of contents at the beginning of each chapter.

– The index facilitates searching via keywords.

Scope

The existing Instruction for Use applies to surgical equipment with the following designated mark:

– Reference number: 640430 (VISALIS V500)

– Reference number: 640420 (VISALIS S500)

– Software Release 2.0

Trademark

Manufacturer

Carl Zeiss Meditec AG
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Germany

Internet: www.zeiss.com/med

Subject to changes in design and scope of delivery and as a result of ongoing technical development. Printed in Germany.

Copyright

Chapter overview

Safety measures

Key to symbols

We would like to inform you about safety aspects which must be observed when handling this device. This chapter contains a summary of the most important information concerning matters relevant to instrument safety.

Hazard symbols

The following safety information has been incorporated into the Instruction for Use. Note this information and be particularly careful in these cases.

⚠	**WARNING**	Indicates a hazard which can cause damage leading to **fatal** or **serious injuries.**
⚠	**CAUTION**	Indicates a hazard which can cause damage leading to **injuries in need of medical attention.**
	NOTE	Indicates a hazard which can cause damage leading to **injuries with no need of medical attention.**

Information symbols

The following information symbols are used in this Instruction for Use:

– Listing

✓ Requirements for an action

■ Prompt for action

→ Result of an action

ⓘ Additional information and tips

Target group

This Instruction for Use is intended for physicians, nurses and other medical staff who prepare, operate or maintain the device after appropriate training. It is the duty of the customer or institution operating the system to train and instruct all staff using the system.

Additional service activities are not part of this Instruction for Use. They will be performed by staff especially trained for this purpose by ZEISS.

Upgrade for VISALIS S500

By means of a hardware and software upgrade, the VISALIS 500 may also be used in retinal surgery. The conversion of the system must be carried out by the ZEISS Service.

Functions that only apply to the VISALIS V500 or the upgrade from VISALIS S500 to VISALIS V500 are indicated in this Instruction for Use with an asterisk ***** .

Field of use

Intended use

The VISALIS 500 Surgical System has been designed to be used in surgical theaters by qualified medical personnel (eye surgeon) for surgical methods of treatment of the anterior and posterior segment of the human eye. The equipment has been designed for the performance of irrigation, irrigation/suction, phacoemulsification of crystalline lens, anterior and posterior vitrectomy, bipolar diathermy coagulation techniques, air and silicone oil tamponade, endoocular illumination. The system is intended for use in clinics, hospitals or other human medicine institutions.

Normal use

The surgical systems VISALIS S500 and VISALIS V500 are intended for surgical treatments in the anterior and posterior segment of the human eye. The treatment is performed by qualified medical personnel (eye surgeons).

In combination with various components and accessories (foot switch, cassette quickset, tube systems for irrigation and aspiration, handpieces and other accessories) the system(s) allow to carry out phacoemulsification, anterior and posterior vitrectomy, irrigation, irrigation/aspiration and diathermy. The systems are movable and they are intended for use in clinics, hospitals and other human medicine institutions. Malfunctions during use of the systems are indicated by a message on the display and alarm signals.

The systems can be cleaned and wiped off.

For proper operation, regular maintenance is required in accordance with national regulations.

After expiry of the product life time the systems must be disposed of in accordance with national regulations.

Indications for use

The VISALIS S500 and VISALIS V500 Surgical System is indicated for surgical treatment of the antrior segment of the eye by performing irrigation, irrigation /suction, phacoemulsification of the crystaline lens, anterior vitrectomy and coagulation techniques using bipolar diathermy.

The VISALIS V500 is indicated for use in vitreo-retinal surgery such as retinal detachment and other pathologies of the vitreous body and the posterior segment of the human eye.

Contraindications

WARNING

Injury to the patient!

- The diathermy section of the VISALIS V500 or VISALIS S500 equipment must not be used on patients with a pacemaker or other cardiac stimulators without prior consultation of a cardiologist.

Notes for the operator

- Only operate the device within the scope of its intended use.
- Comply with the legal regulations regarding market surveillance and obligatory reporting applicable in the respective country, as well as any further regulations and standards.

User qualification

- Thoroughly familiarize yourself with the contents of the Instruction for Use before starting up the system. Also observe the Instruction for Use for accessories and other system components.
- Before using the system, all medical staff must have read and understood all instructions included in the present Instruction for Use.
- Keep the Instruction for Use in a place that is easily accessible at any time to the staff charged with operation of the system.
- The system may only be used by qualified medical employees who understand the possible risks associated with the use of this medical system and who have completed adequate training in the prevention and management of clinical complications, if any.
- For proper assembly and operation of the surgical equipment according to the purpose for which it has been defined, the appropriate training and orientation is required. It is the duty of the customer or institution operating the system to train and instruct all staff using the system. Training for the surgical systems is offered by ZEISS. Contact your local ZEISS Service for details.

Transportation

- For transport over extended distances (e.g. dismantling, returns for repair purposes, etc.), you must pack the system in its original package or in special return shipment packages. For details, contact the ZEISS Service.

Set-up and installation

NOTE

Risk of damaging the system!

- Make sure that the installation conditions and the use of the system meet surgical requirements:
  - Low vibration
  - Clean environment
  - Avoidance of extreme mechanical loads
- The system must not be used:
  - in areas where there is a risk of explosion,
  - if inflammable anesthetics or volatile solvents such as alcohol, benzene or similar chemicals, are present at a distance of less than 25 cm.
- Do not use or store the system in damp rooms. Do not expose the system to water splashes, dripping water or sprayed water.
- To ensure reliable operation, do not install the system in a location where it may be exposed to heating appliances or radiators, direct sunlight or any other source of heat with extremely high temperatures.
- The maximum height level for the infusion pole is 260 cm. Do not set up the system under a low ceiling.
- Closed or obstructed ventilation openings may cause the system to overheat. Install the system so that the ventilation openings are not closed or obstructed.
- Position the device so that you can disconnect it from the power supply at any time.

Operation

CAUTION

Injury to the patient!

- Note the maximum load for following components:
  - Maximum load for the console tray 2 kg.
  - Maximum weight for the infusion bottle 2 kg.

- Before each use, carry out the preparation for use and operating procedures described in this document. If a malfunction occurs which cannot be corrected using the chapter "Troubleshooting", label the device as non-functional and contact the ZEISS Service.
- Carefully follow the instructions when installing and using the device in order to prevent harmful interference by other devices. If the device causes harmful interference with the function of other devices (this can be detected by turning the device off and on again), the user is encouraged to try to remedy the interference by one or more of the following measures:
  - ✓ Re-orient or relocate the other devices.
  - ✓ Increase the distance between the devices.
  - ✓ Connect the device to an outlet of a circuit different from the one to which the other devices are connected.
  - ✓ Contact your ZEISS Service.
- The sound emission capability of the equipment is tested at start-up. Verify that an acoustical signal is emitted during system initialization.
- Malfunctions during the use of the system are indicated by a system alarm message on the display and alarm signals (see page 252).
  - Remove the malfunction and confirm the system alarm message by tapping the corresponding key on the touchscreen.
  - If a malfunction occurs which you cannot correct even after referring to the chapter "Troubleshooting", label the device as non-functional and contact the ZEISS Service.
- Do not pull on power cables or other connecting cables.
- Move the system in such a way that does not cause hoses to become pinched or pulled off.
- Never leave a system unattended while the light source is on in order to prevent retinal damage from excessive irradiation time to the eye of the patient.

Maintenance

- To ensure optimal performance and reliable working order, we recommend having the device checked by the ZEISS Service as part of regular scheduled maintenance.
- In order to prevent any impairment of the device's safety due to age, wear, etc., the user must ensure that the device is subjected to the necessary safety checks (see section "Care and Maintenance").
- This system must not be maintained during contact with the patient.

Modifications

WARNING

Injury to the patient's eye!

Modified products might break during use and cause malfunctioning in the system.

- Do not change the shape of a vitrectomy probe or PHACO TIP used with the VISALIS V500 or VISALIS S500 (i.e. do not kink, cut or scratch).

WARNING

Injury to the patient's eye!

Changes to or the application of manual force to the height level of the infusion pole may lead to an incorrect height level of the bottle and patient injury.

- The height level of the infusion pole must not be modified or changed by the application of manual force.

- Modifications and repairs of this system or any systems operated together with this system may only be performed by the ZEISS Service or other persons authorized by ZEISS.
- This system must not be modified. The manufacturer is not liable for damage caused by unauthorized persons tampering with the system. Furthermore, this will nullify any rights to claim under the warranty.

Approved accessories

WARNING

Injury to the patient's eye!

- Use only tubing sets that are approved and recommended by ZEISS.

CAUTION

Injury to the patient!

The use of non authorized parts or equipment in connection with VISALIS V500 or VISALIS S500 can lead to injuries to the patient or to malfunctioning of the device.

- Use only the original accessories and supply materials recommended by ZEISS.
- Review the compatibility of the original accessories or supply material based on its Instruction for Use.

CAUTION

Increased leakage current!

There is a risk that the user and patient may suffer an electrical shock.

- Never touch the plug connector contacts while in contact with the patient.
- Do not connect any defective or unapproved accessories to the plug connector contacts.
- The use of accessories and cables that are not included in the scope of delivery of the system may lead to increased emission of electromagnetic interference or reduced immunity of the system to interference. Only use spare parts approved by ZEISS for this system.

The malfunctioning of or damage to the DOUBLE LINEAR FOOTSWITCH II, IV-POLE FOOTSWITCH or the REMOTE CONTROL may cause the surgical system to malfunction.

- Test the accessories before use to check if they are functioning correctly.
- Do not pull the accessories by the cable connections.
- Do not use the accessories if they are defective or damaged, e.g. kinks or damaged isolations.

Electrical system

WARNING

Injury to the patient's eye!

- During strong, short-term voltage interruptions or loss, stop the surgery and test the proper settings of all critical parameters before continuing the surgery.

WARNING

Danger due to electrical current!

- To avoid the risk of electrical shock, this device may only be connected to a properly grounded supply unit.

WARNING

Danger due to electrical current!

- To avoid the risk of electrical shock, do not use multiple sockets or extension cables with this device.

- Only connect the VISALIS V500 or VISALIS S500 to an electricity supply that corresponds to the values indicated on the rear panel of the device.
- The maximum permissible apparent impedance of supply mains for this equipment is 0.4 Ω at 220 VAC (0.2 Ω at 110 VAC).
- To reduce the risk of electric shock, do not remove the protective cover.
- Before connecting the device to the power supply, or disconnecting it, make sure that the power switch is off.
- The power switch must be kept turned off when the surgical system is not in use.
- If required by the regulations or guidelines in the country of use, the system must be connected to an uninterruptible power supply.
- Do not place any fluid-filled containers on top of the system. Make sure that no cleaning agents can enter the system.
- Never attempt to connect any electrical connectors by force (plugs, sockets). If a connector does not fit into a socket, check whether it is intended for another one. If a connector is damaged, contact the ZEISS Service.

Diathermy

WARNING

Risk of injury in patients with cardiac pacemakers!

There is a possible risk in patients with a cardiac pacemaker or stimulation electrodes because the diathermy generator may generate RF (radio frequency) interference. The pacemaker or the stimulation electrodes can fail.

- If you have concerns in this regard, contact the cardiology division for advice.

CAUTION

Injury to the patient's eye!

- Always use the lowest output diathermy power level which is compatible with the surgical application.

CAUTION

Injury to the patient!

Interference between this surgical device and other medical equipment due to the use of a bipolar diathermy probe is possible.

- If abnormal performance is observed (determined by switching the surgical device on and off), additional measures may be necessary, such as reorienting or relocating the surgical device or other medical equipment.

- Risk of burns or fire; do not use diathermy near conductive materials such as metal bed parts, inner-spring mattresses, standalone IV Poles and the like. Replace the electrode cables as soon as there is any evidence of wear.
- Severe RF burns can result if the diathermy output current is diverted to the operator by careless handling.
- The DIATHERMY BIPOLAR CABLE should not touch the patient or other cables.
- Evidence of low output level or faulty operation of the bipolar diathermy probe, even though the equipment has been set for normal use, may indicate a bad contact in the electrodes connections.
- When using the bipolar diathermy probe, do not use flammable anesthetics, nitrogen monoxide or oxygen if insufficient ventilation by a suitable aspiration system is not guaranteed.
- Flammable materials such as disinfecting agents and cleaning agents should be evaporated before using a bipolar diathermy probe. Some materials such as cotton wool or gauze, if soaked with oxygen, can catch fire because of the sparks caused by the equipment in its normal use.
- Due to the low level of plume, plume evacuation is not required when using a bipolar diathermy probe.

Irrigation/Aspiration (I/A)

WARNING

Injury to the patient's eye!

An insufficient height of the IV Pole or an empty infusion bottle / infusion bag of balanced salt solution (BSS) reduces intraocular pressure.

- Keep an eye on the level of balanced salt solution (BSS) in the infusion bottle during surgery. If the infusion bottle or infusion bag is empty, inform the surgeon and replace the infusion bottle or infusion bag.

WARNING

Injury to the patient's eye!

ADVANCED IRRIGATION TUBINGS are inappropriate for patients with glaucoma or absolute glaucoma.

- Do not use this device for patients with glaucoma or absolute glaucoma.

CAUTION

Injury of the patient's eye!

ADVANCED IRRIGATION TUBINGS used with wrong GUI irrigation settings can lead to anterior chamber collapse or posterior capsule break.

- ADVANCED IRRIGATION TUBINGS have only to be used with the GUI irrigation settings "Combined high" or "Combined Low".

CAUTION

Injury to the patient's eye!

Changing aspiration rates or vacuum limits or lowering the IV Pole, may cause chamber shallowing or collapse which may result in patient injury.

- Select the irrigation and aspiration values so that the anterior chamber always remains stable and the aspiration is still effective.

- The correct set-up of irrigation and aspiration tubings is critical to ensuring the proper operation of the VISALIS V500 or VISALIS S500. Therefore carefully pay attention to the chapter "Mounting I/A cassette and fluidic system" on page 126.
- Switching from the peristaltic mode to venturi mode may cause the anterior chamber to collapse if a PHACO TIP with low resistance is used (i.e. a large bore PHACO TIP) and if the vacuum is set to a high level. To ensure patient safety, always check that the vacuum setting is proper for the desired type of pump before restarting the aspiration after switching pump types.
- Before any intervention make sure that a sufficient amount of balanced salt solution (BSS) is available.

Vitrectomy

CAUTION

Injury to patient or user!

- Do not check for vibrations by placing your hand or finger against the tip or sleeve of the vitrectomy probe. Prolonged exposure or direct contact to the vibrating tip may cause damage to healthy tissue.

Ultrasound (U/S)

WARNING

Injury to patient or user!

Prolonged exposure to or direct contact with the vibrating PHACO TIP while testing the PHACO TIP for vibrations may cause damage to healthy tissue.

- Never place your hand or finger on the PHACO TIP or the SILICONE SLEEVE of the ULITE PHACO HANDPIECE while testing the phaco handpiece.

CAUTION

Injury to the patient's eye!

Improper movement of the PHACO TIP/SILICONE SLEEVE in the incision may cause injury to the patient's eye.

- Do not twist against and do not apply pressure to the wound.

CAUTION

Injury to the patient's eye!

Using the ULITE PHACO HANDPIECE with insufficient quantity of balanced salt solution (BSS) may cause excessive heating and potential corneal incision thermal impact (may lead to corneal burn in worst case) to the patient´s eye.

- Make sure that irrigation and aspiration flow is always effective.
- Make sure that the ULITE PHACO HANDPIECE is properly connected to the irrigation/aspiration system and is used together with the system only.
- A loud buzz from the ULITE PHACO HANDPIECE at minimum power setting may indicate a malfunction of the power regulation circuitry which may cause corneal incision thermal impact at the tissue due to heat or endothelial damage. Contact the ZEISS Service.
- Never press the PHACO TIP/SILICONE SLEEVE against the wound as this will lead to restriction of fluid which will lead to PHACO TIP overheating.
- An undesirable increase of U/S power may be indicative of a malfunction of the surgical system. Contact the ZEISS Service.

Air infusion / silicone oil injection *

- During the injection of silicone oil, the intraocular pressure is not controlled by the VISALIS V500 so that the operator must be responsible for controlling the intraocular pressure. It is important to check silicone flow at the preset injection pressure before inserting the cannula in the eye.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Illumination *

WARNING

Injury to the patient's eye!

Retina damage through excessive intensity of irradiation.

- Adapt the irradiation intensity and the corresponding duration of exposure by selecting suitable illumination and filter settings. The values recommended by ZEISS are presented in the table, "Maximal irradiation exposure times". Any deviation from these values is permissible on medical grounds only.
- Always use the lowest sufficient level for use.

Maximum radiation exposure times

Type of ENDO-ILLUMINATION PROBE	Field angle a	Recommended working distance	Duration in minutes until possible hazard			
			Without retinal protection[1] at the **highest** light intensity	**Without** retinal protection[1] at **50%**[2] **of the highest** light intensity	**With** retinal protection[1] at the **highest** intensity	**With** retinal protection[1] at **50%**[2] **of the highest** light intensity
Lamp 1 (4300 K)						
303060-0600-000	38°	15 mm	27 min.	65 min.	163 min.	379 min.
303060-0601-000	68°	18 mm	77 min.	183 min.	456 min.	1082 min.
303060-0602-000	38°	15 mm	29 min.	67 min.	171 min.	395 min.
303060-0603-000	68°	18 mm	63 min.	159 min.	372 min.	941 min.
303060-0604-000	38°	15 mm	41 min.	99 min.	243 min.	586 min.
303060-0605-000	68°	18 mm	132 min.	313 min.	784 min.	1854 min.
303060-0606-000	38°	15 mm	86 min.	217 min.	508 min.	1283 min.
303060-0619-000	68°	18 mm	62 min.	145 min.	369 min.	860 min.
303060-0620-000	68°	18 mm	72 min.	176 min.	424 min.	1041 min.

Type of ENDO-ILLUMINATION PROBE	Field angle a	Recommended working distance	Duration in minutes until possible hazard			
			Without retinal protection[1] at the **highest** light intensity	**Without** retinal protection[1] at **50%**[2] **of the highest** light intensity	**With** retinal protection[1] at the **highest** intensity	**With** retinal protection[1] at **50%**[2] **of the highest** light intensity
Lamp 2 (5000 K)						
303060-0600-000	38°	15 mm	22 min.	49 min.	149 min.	353 min.
303060-0601-000	68°	18 mm	71 min.	158 min.	471 min.	1026 min.
303060-0602-000	38°	15 mm	25 min.	56 min.	168 min.	384 min.
303060-0603-000	68°	18 mm	56 min.	122 min.	383 min.	832 min.
303060-0604-000	38°	15 mm	38 min.	85 min.	260 min.	581 min.
303060-0605-000	68°	18 mm	120 min.	263 min.	816 min.	1791 min.
303060-0606-000	38°	15 mm	69 min.	155 min.	470 min.	1054 min.
303060-0619-000	68°	18 mm	53 min.	116 min.	363 min.	788 min.
303060-0620-000	68°	18 mm	88 min.	193 min.	601 min.	1315 min.

Note 1: Maximum exposure times are for the cumulative retinal exposure with a stationary distal tip of the light guide positioned at the specified distances from the retina. Changing the distance of the endoilluminator light guide from the retina will also significantly affect the risk factor.

Note 2: Lower intensities increase the maximum exposure times in direct proportion to the decrease in intensities.

Note 3: Movement of the light guide increases safe exposure time.

Note 4: Maxiumum exposure times are given for clear media. Vitreous haemorrhage will increase these times.

With field angles smaller than those specified above, the maximum irradiation time may be considerably reduced. The light of the present device may be harmful. See notes 1 - 4.

[1] retina protection device: rotating retina protection filter* (blue barrier filter).

[2] the allowed measurement inaccuracy is + /- 30% according to standard DIN EN ISO 15004-2:2007.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Requirements for operation

Prior to the very first use

⚠ **CAUTION**

Injury to the patient's eye!

The ZEISS Service or an expert authorized by ZEISS will install the system. Make sure that the following requirements continue to be met for further operation:

- ✓ The connecting parts must be seated properly. Screw connections are tightened.
- ✓ All cables and plugs are in perfect condition, i.e. show no signs of wear, kinks or other damage.
- ✓ The voltage set on the device corresponds to the rated line voltage on the site of installation.
- ✓ The power plug must be connected only to a socket provided with a faultless protective ground conductor.
- ✓ The device is connected to the power cable supplied for this purpose.

Before each use

⚠ **CAUTION**

Injury to the patient's eye!

- Make sure that all specified "Requirements for Operation" are fulfilled.
- Reattach all covers or caps that were previously removed. Close any existing openings with the relevant caps.
- Take note of any and all symbols and signs attached to the system.
- The ventilation openings must not be closed or covered.
- Check whether the VISALIS V500 or VISALIS S500 has enough area to maneuver in to avoid damage to the cables and ensure unrestricted movement of the system.
- Check the user settings of the selected user profile to avoid unexpected behavior of the system.

After every use

- Use the key shutdown and the power switch to switch off the system (see Page 246).

Requirements for decommissioning

NOTE	**Injury of the user!**
	■ Before disconnect the air tubing on the device side, insure that tube is de-pressurized.

Safety functions

1 System alarm messages

The VISALIS V500 and the VISALIS S500 usually report malfunctions by means of unambiguous text messages or alarm sounds. The system alarm messages are indicated by pop-up windows indicating the cause and the required user intervention. They are subdivided as follows:

- System alarm messages with yellow warning sign (example above left) indicate system malfunctions with medium priority.
- System alarm messages with blue information sign (example middle left) indicate system malfunctions with low priority.
- System alarm messages without a sign (example lower left) indicate recommendations on possible actions.

If you have dealt with the problem, tap the key "OK" in order to delete the system alarm message from the screen. An exact description of all system alarms messages can be found in the chapter "Troubleshooting" on page 252.

System alarm messages that had appeared during operation and which have not been remedied are displayed in the module "Active Alarms". For a more exact view of the system alarm messages, you can enlarge the module "Active Alarms" by touching the screen. Once the malfunction of the system alarm message has been remedied, the system alarm message is only visible in the submenu "History".

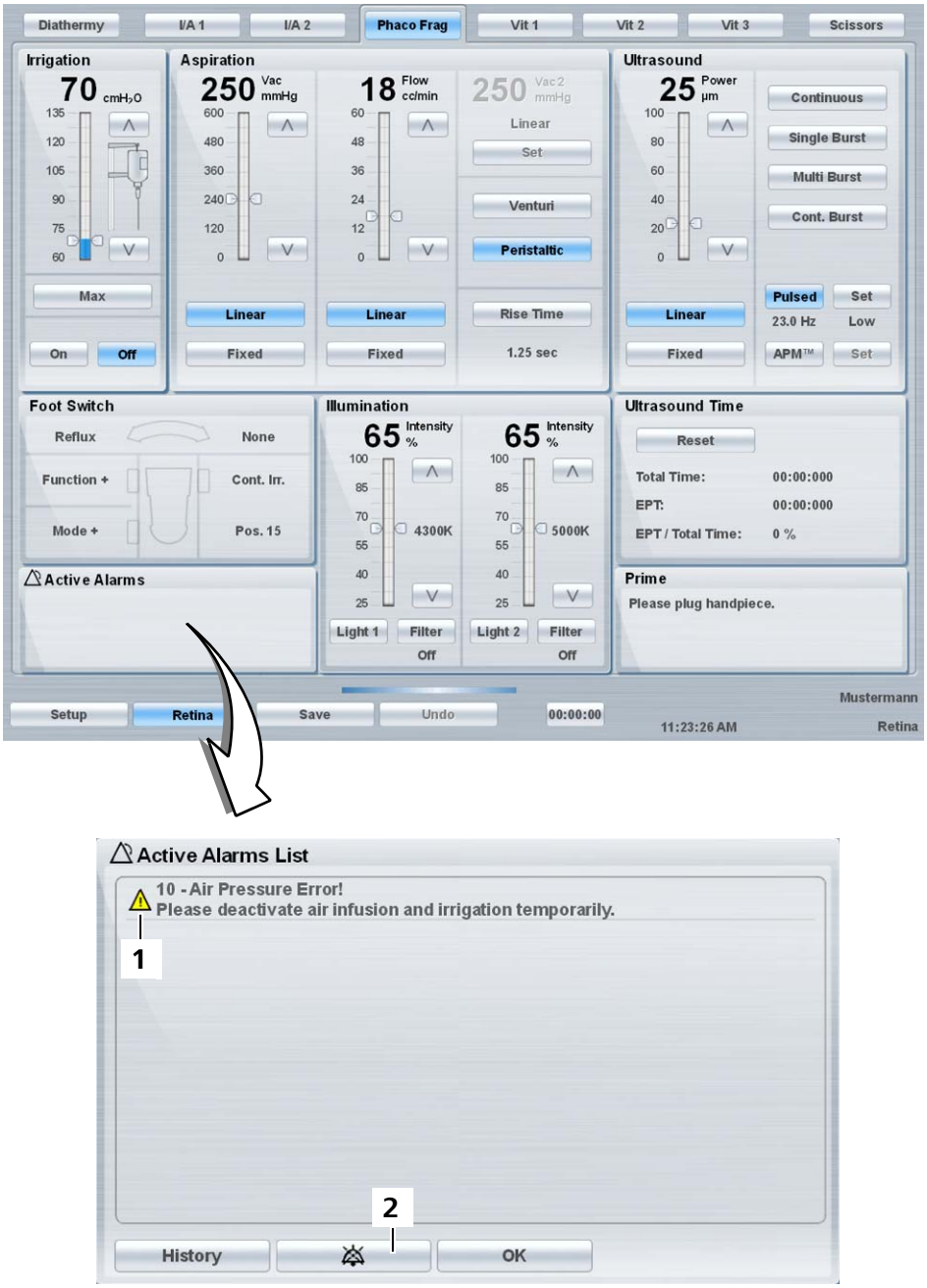
2 Alarm tones

In the enlarged module "Active Alarms List" you can temporarily deactivate the alarm tones of the device by touching the key  .

- The alarm tones are activated if the key  lights up grey.
- The alarm tones are deactivated if the key  lights up blue.

As soon as the system is restarted, the alarm tones are automatically reactivated and set to the last active value.

Fig. 1: Safety devices



3 Filter selection keys*
The keys open the pop-up windows "Select Filter For Light 1" or "Select Filter For Light 2" in which you can select between the following filters:

– Protect - Swivel in the retina protection filter. The retina protection filter reduces the blue portion of the light and enables a longer treatment period (see maximum irradiation time page 22).

– Green - Swivel in the green filter. The green filter emphasizes the structure and contour of the membrane.

– Off - Swivel the inserted filter out again.

The filter can be swiveled in separately for each surgical mode or surgical function. The filter status is below the respective filter selection key on the "Retina" page. Following displays are possible:

– Protect - the retina protection filter is swiveled in

– Green - the green filter is swiveled in

– Off - no filter is used or swiveled in

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

4 Pulsating bar
A pulsating bar on the lower edge of the user interface of the cataract and retina menus indicates that the system is working properly. If the bar ceases to move, the system is idle and you must stop the use of the system.

5 Functional self-test at system start (without picture)
The software performs a functional self-test after switching on the device. In case of mismatch, default safe calibration is stored and a calibration request message is displayed. Turn the device off and consult the ZEISS Service.

Fig. 2: Safety functions

Symbols and labels on the device

CAUTION

Risk of injury!

Observe all warnings and information labels!

- When discovering that one of the following labels is missing on the equipment or a label has become illegible, contact us or one of our authorized dealers. We will provide you with a replacement.

Labels on the front

1 Symbol "U/S socket"
Identifies the socket to which the ULITE PHACO HANDPIECE is connected.

Indicates that this socket is a type "B" applied part according to the description in IEC 60601-1. Type B applied parts provide protection from electrical shock in compliance with the permissible patient leakage and auxiliary current.

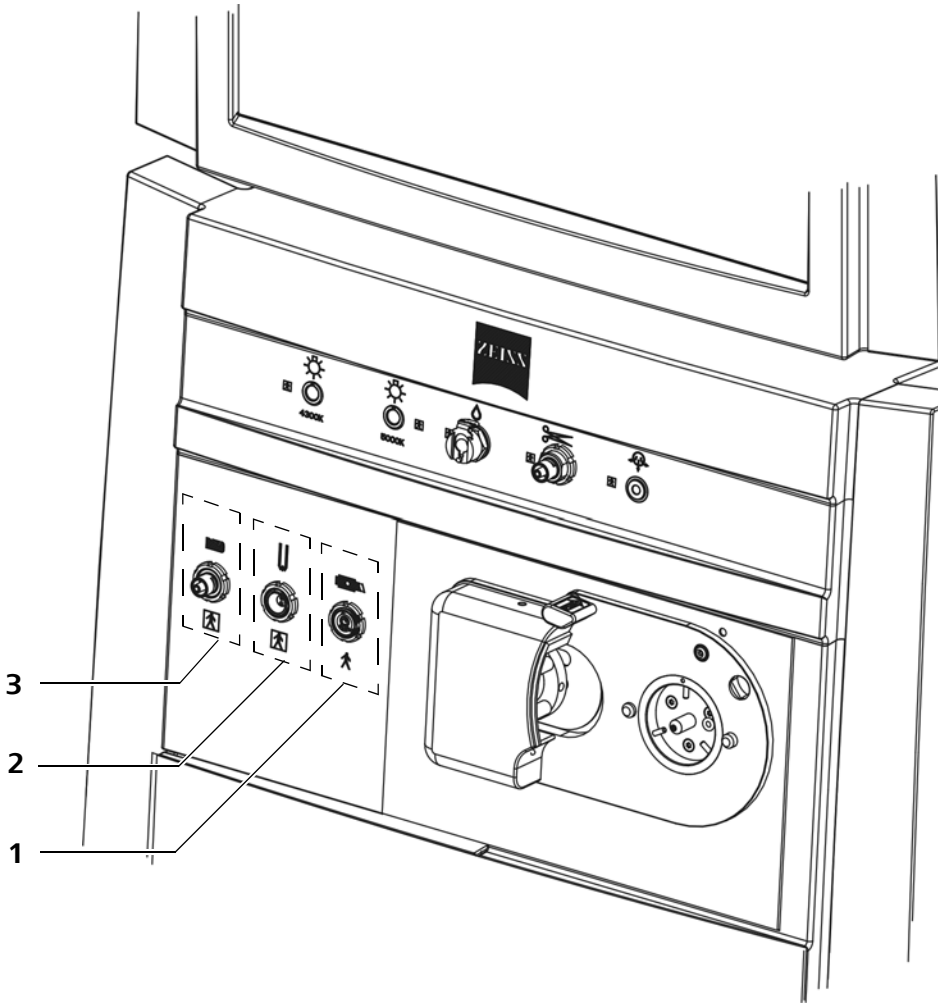
2 Symbol "Diathermy socket"
Identifies the diathermy socket to which a bipolar diathermy probe is connected.

Indicates that this socket is a type "BF" applied part according to the description in IEC 60601-1. Type BF applied parts provide increased protection from electrical shock in compliance with the permissible patient leakage current and patient auxiliary current as type B sockets.

3 Symbol "Vitrectomy socket"
Identifies the socket to which a vitrectomy probe is connected.

Indicates that this socket is a type "BF" applied part according to the description in IEC 60601-1. Type BF applied parts provide increased protection from electrical shock in compliance with the permissible patient leakage current and patient auxiliary current as type B sockets.

Fig. 3: Labels on the front



4 Symbol for "Light source socket 4300 K" *
Identifies the socket to which fiber optics are connected. Some fiber optics necessitate the use of an adapter.

5 Symbol for "Light source socket 5000 K" *
Identifies the socket to which fiber optics are connected. Some fiber optics necessitate the use of an adapter.

6 Symbol for "Silicone oil injection socket" *
Identifies the socket to which the SILICONE OIL INJECTION TUBE is connected.

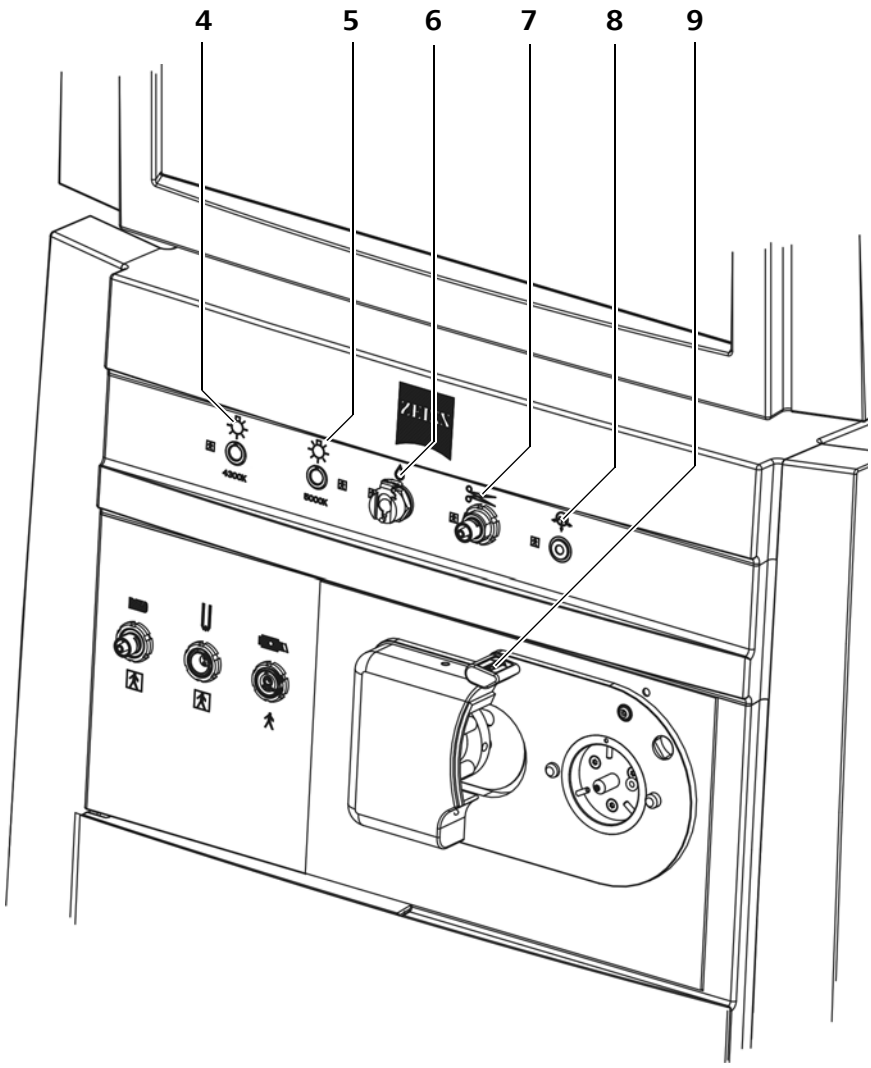
7 Symbol "Scissors socket" *
Identifies the socket to which pneumatic scissors are connected.

8 Symbol for "Air socket"
Identifies the socket to which the AIR INJECTION TUBE WITH FILTER is connected. The socket is also used as a connector for "Controlled irrigation".

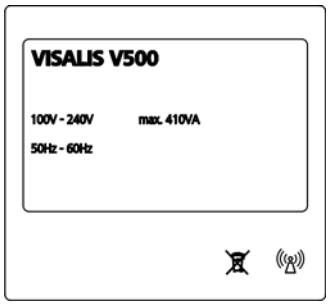
9 Symbol for "Push"
Identifies the button for unlocking the I/A cassette.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 4: Labeling on the front of the system

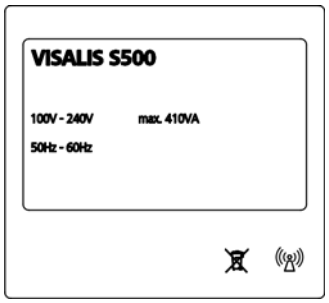


Labels on the back



10 Rating label VISALIS V500
The rating label includes the following information:

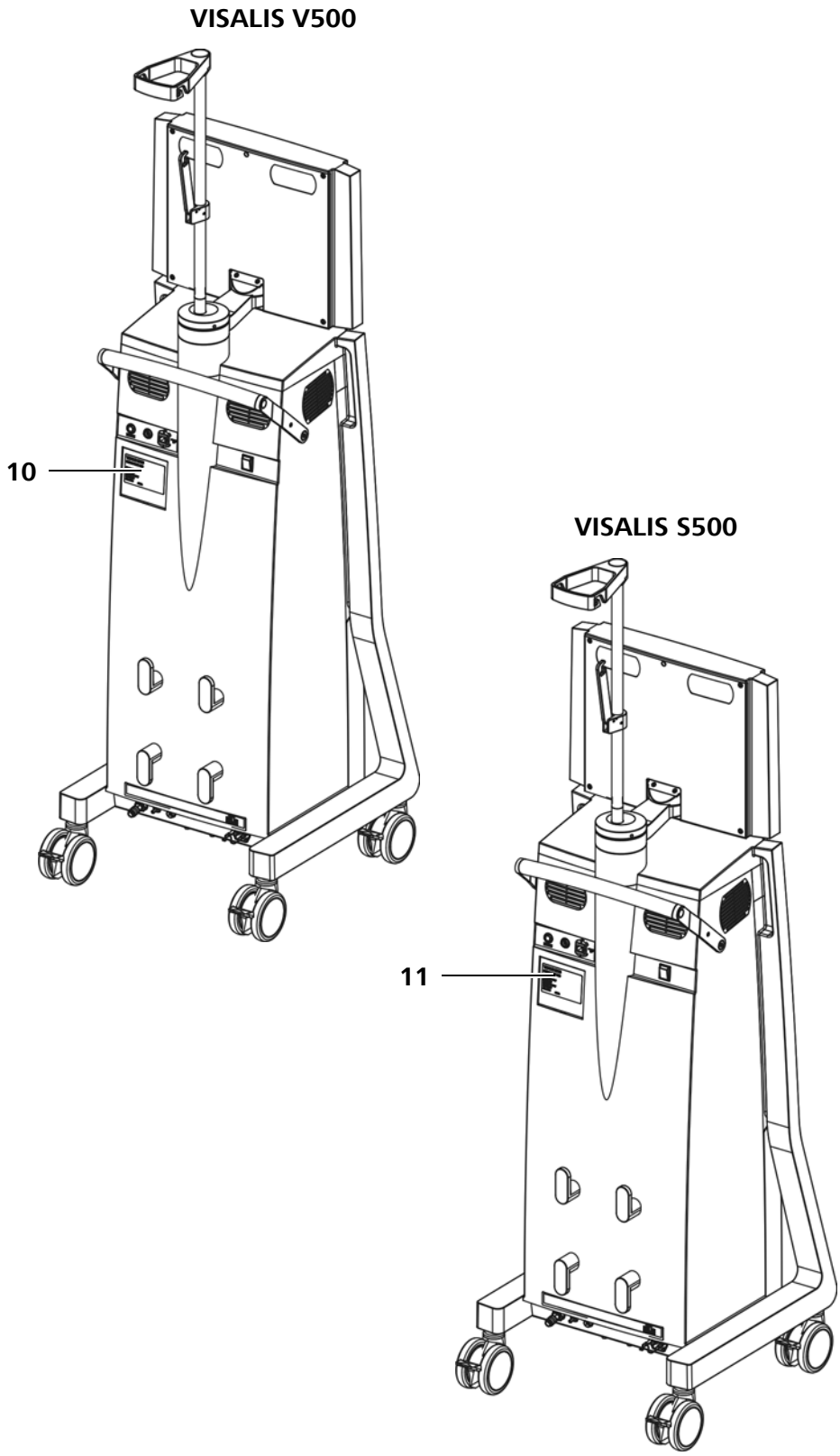
- Name of the system — VISALIS V500
- Rated voltage — 100V - 240VAC
- Power consumption — max. 410VA
- Line frequency range — 50Hz - 60Hz
- Disposal symbol
- Non - ionizing radiation



11 Rating label VISALIS S500
The rating label includes the following information:

- Name of the system — VISALIS S500
- Rated voltage — 100V - 240VAC
- Power consumption — max. 410VA
- Line frequency range — 50Hz - 60Hz
- Disposal symbol
- Non - ionizing radiation

Fig. 5: Labeling on the back of the system



12 Identification label VISALIS V500

The identification label includes the following information:

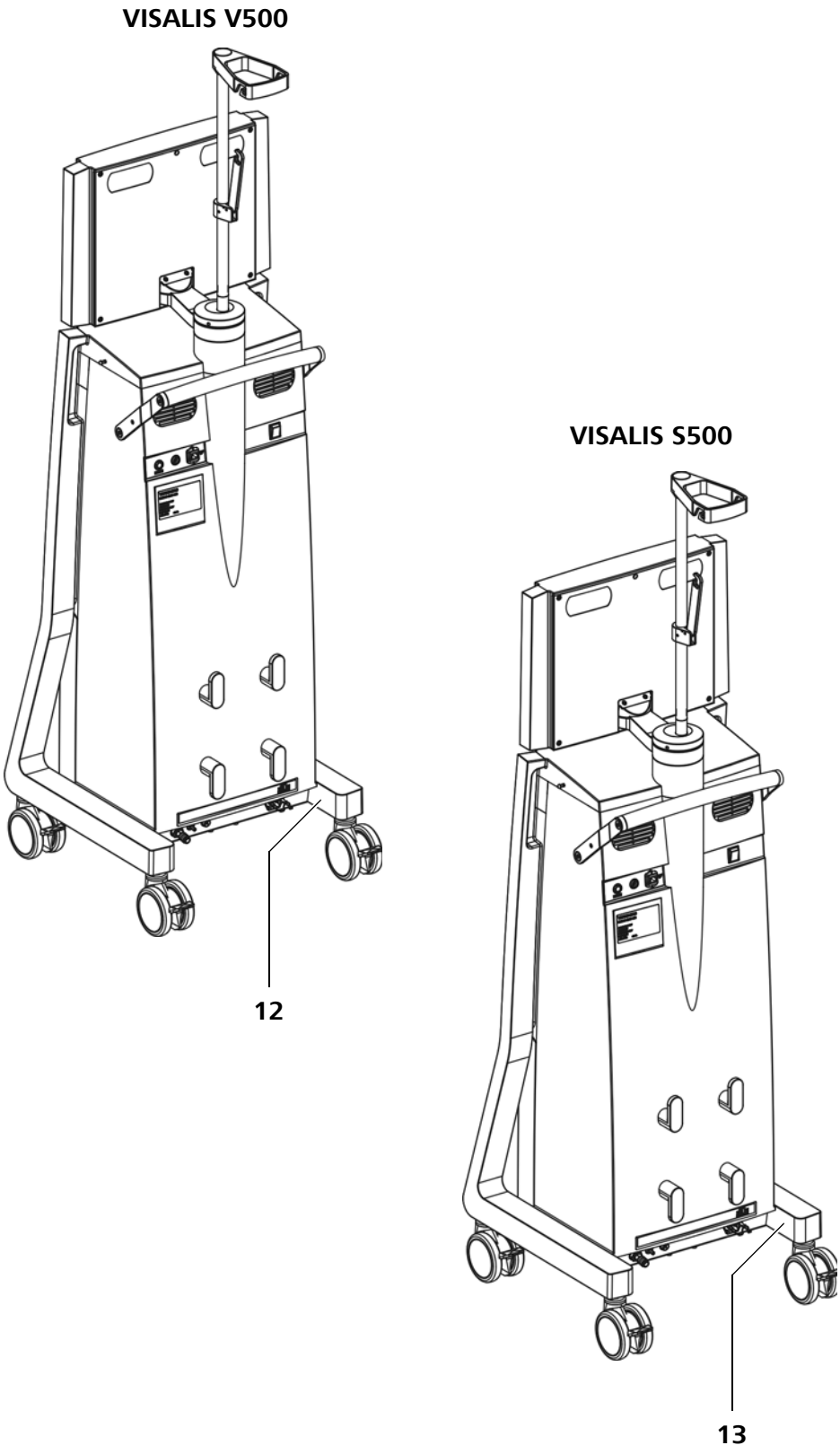
– Manufacturing symbol	
– Manufacturer (company name)	Carl Zeiss Meditec AG
– Manufacturer's address	Goeschwitzer Strasse 51-52 07745 Jena, Germany
– Serial number	SN
– System name	VISALIS V500
– Reference number	REF
– Protection type	IPX1
– CE mark	CE 0297

13 Identification label VISALIS S500

The identification label includes the following information:

– Manufacturing symbol	
– Manufacturer (company name)	Carl Zeiss Meditec AG
– Manufacturer's address	Goeschwitzer Strasse 51-52 07745 Jena, Germany
– Serial number	SN
– System name	VISALIS S500
– Reference number	REF
– Protection type	IPX1
– CE mark	CE 0297

Fig. 6: Labeling on the back of the system



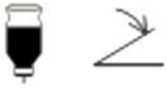
14 Label "External compressed air inlet"
This label indicates the position of the access for the external compressed air for using the Venturi pump, a vitrectomy probe, and the silicone oil injection.

500 - 800 kPa

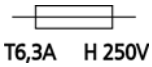
Air pressure has to be in the range between 500 and 800 kPa. The available flow has to be at least 38 Nl/min.

Comply with the Instruction for Use!

15 Symbol "Potential equalization according to the requirements of IEC 60601-1"
Indicates that potential equalization is available. The potential equalization connector allows another device to be grounded at the same ground potential as the VISALIS V500 and the VISALIS S500 system.

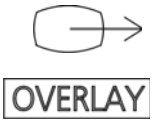


16 Symbol "IV Pole connector"
This graphic symbol indicates the position of the plug for the external IV-POLE FOOTSWITCH.

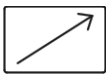


17 Symbol "Nominal fuse rating"
This symbol, located above the power input and the voltage selector switch, indicates the nominal value and type of fuses that must be installed.

18 Symbol "Observe the Instruction for Use"
This graphical symbol means: Observe the Instruction for Use or further applicable documents.



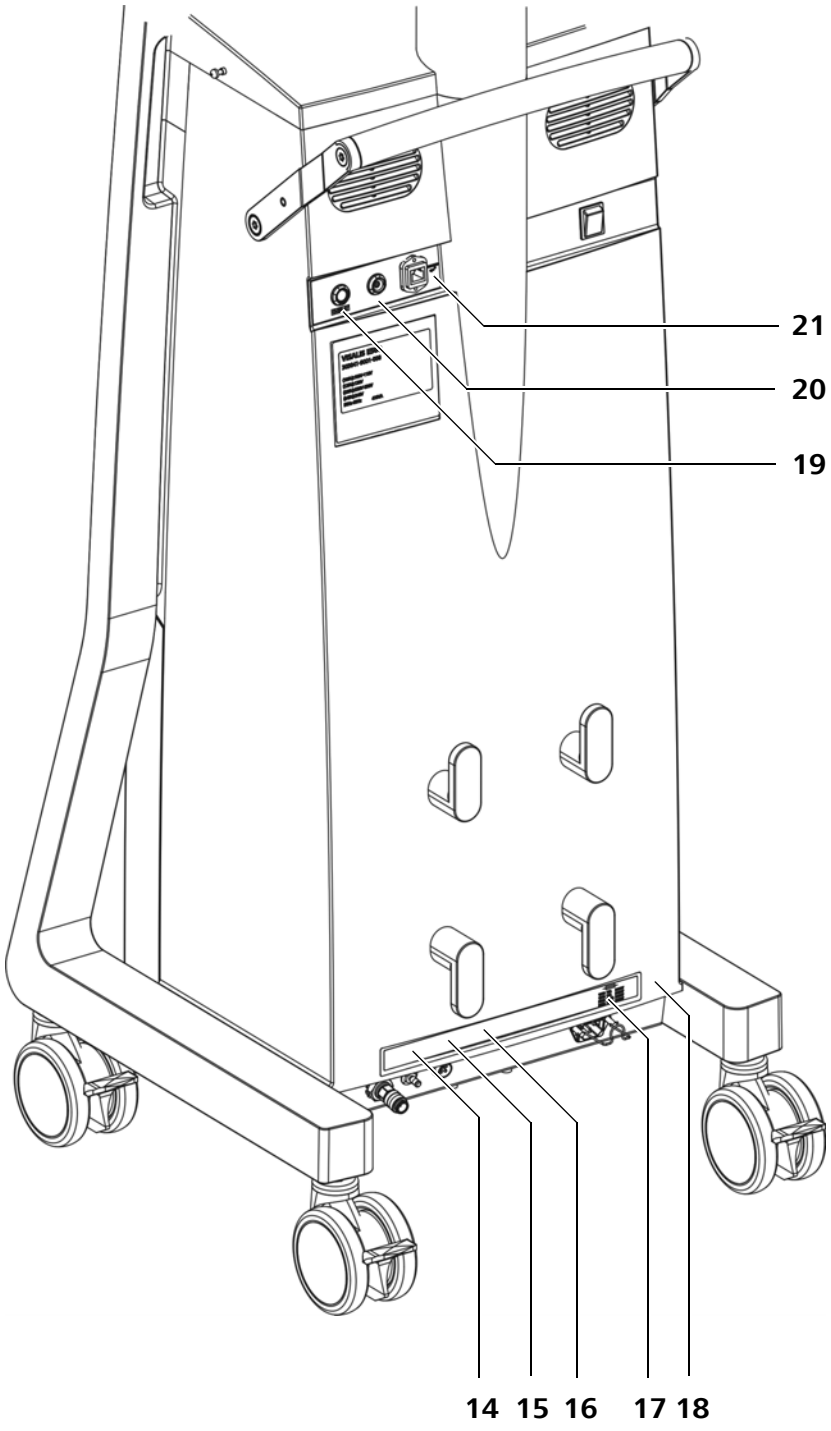
19 Symbol "Video Graphical Overlay System connection"
Identifies the output connector for the optionally available Video Graphical Overlay System that allows surgical parameters from the equipment to be additionally merged with the video signal from the microscope camera.

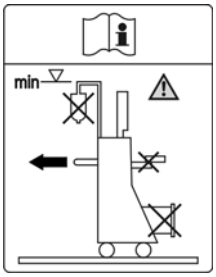


20 Symbol "REMOTE CONTROL/USB ADAPTER connection"
Shows the input connector for the optionally available REMOTE CONTROL and the optionally available USB ADAPTER FOR SOFTWARE UPDATES.

21 Symbol "Connector for CALLISTO eye"
Indicates the output connector for the optionally available surgery management system CALLISTO eye, with which the data in the operating room can be linked and exchanged between ZEISS devices.

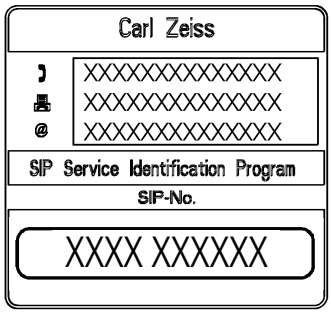
Fig. 7: Labels for rear panel connectors





22 Symbol "Transport position"
Indicates the transport position of the system. Note the following with regard to transporting the system:

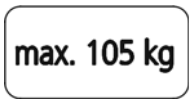
- Lower the infusion pole to its minimal height
- Fold-in the console tray
- Drive-in the foot switch compartment
- Remove the infusion bottle



23 SIP label
The SIP label contains the following information:

- Manufacturer (company name)
- Manufacturer's contact data,
  i.e., phone number, fax number and email address of the local contact of the national ZEISS sales organization.
- SIP number
  A unique identification number assigned to your system.

24 Date of manufacturing
This graphical symbol indicates the manufacturing date of the device.



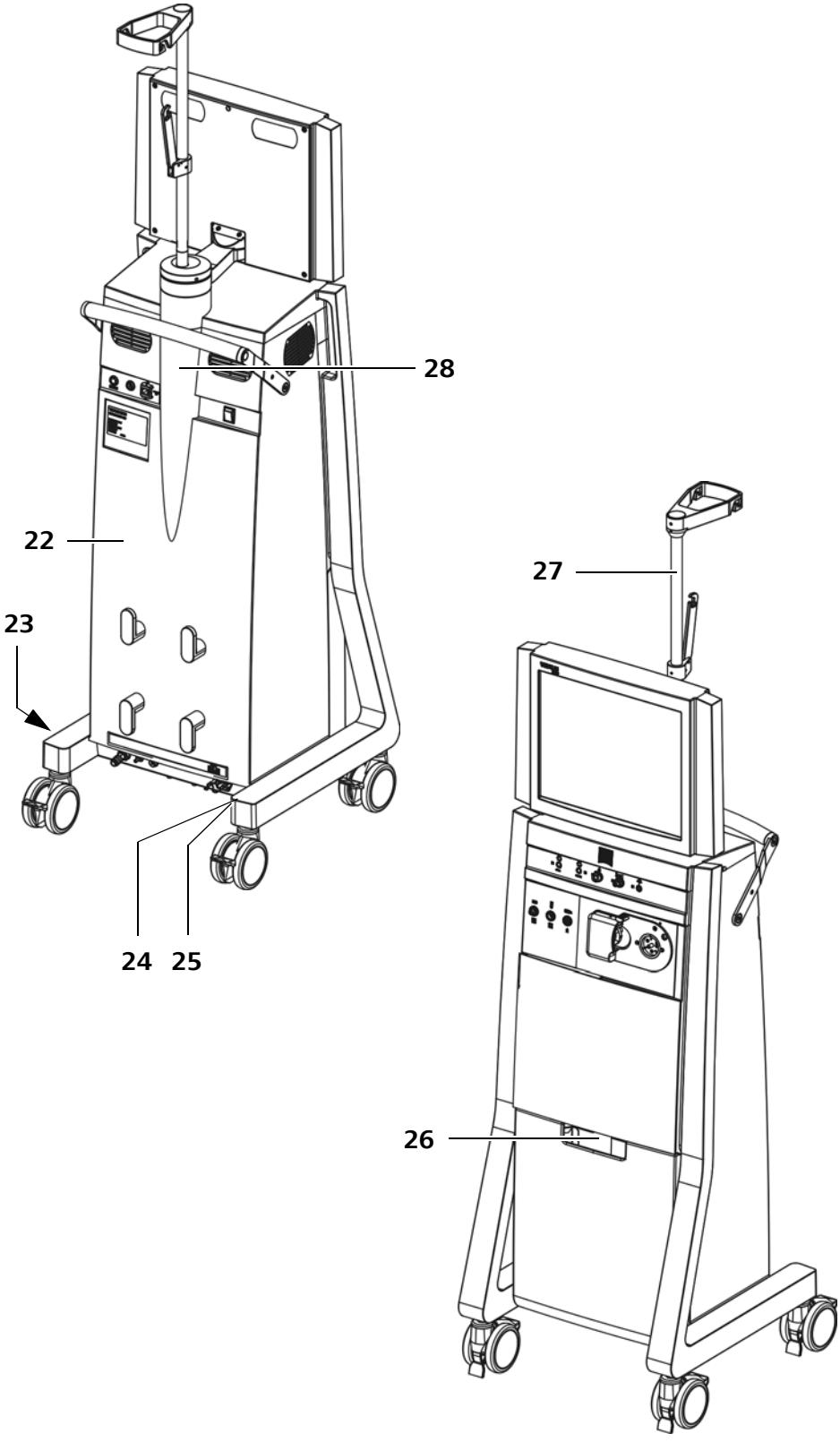
25 Symbol "Max. total weight"

26 Symbol "Foot switch"
This graphic symbol (inside the footswitch compartment) marks the connection socket for the DOUBLE LINEAR FOOTSWITCH II.

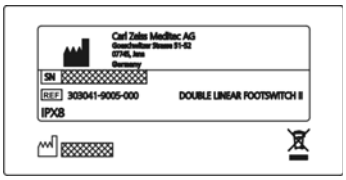
27 Warning symbol "Maximal load"
Shows that the infusion pole should be exposed to a maximal load of 2 kg only.

28 Mandatory label "Follow handling instructions"
Push the machine with two people slowly and carefully with the handle when moving it over 3 cm high door sills.

Fig. 8: Labeling on the back of the system



29 Warning symbol "Maximal load"
Indicates that the console tray may only be subjected to a maximum load of 2 kg.

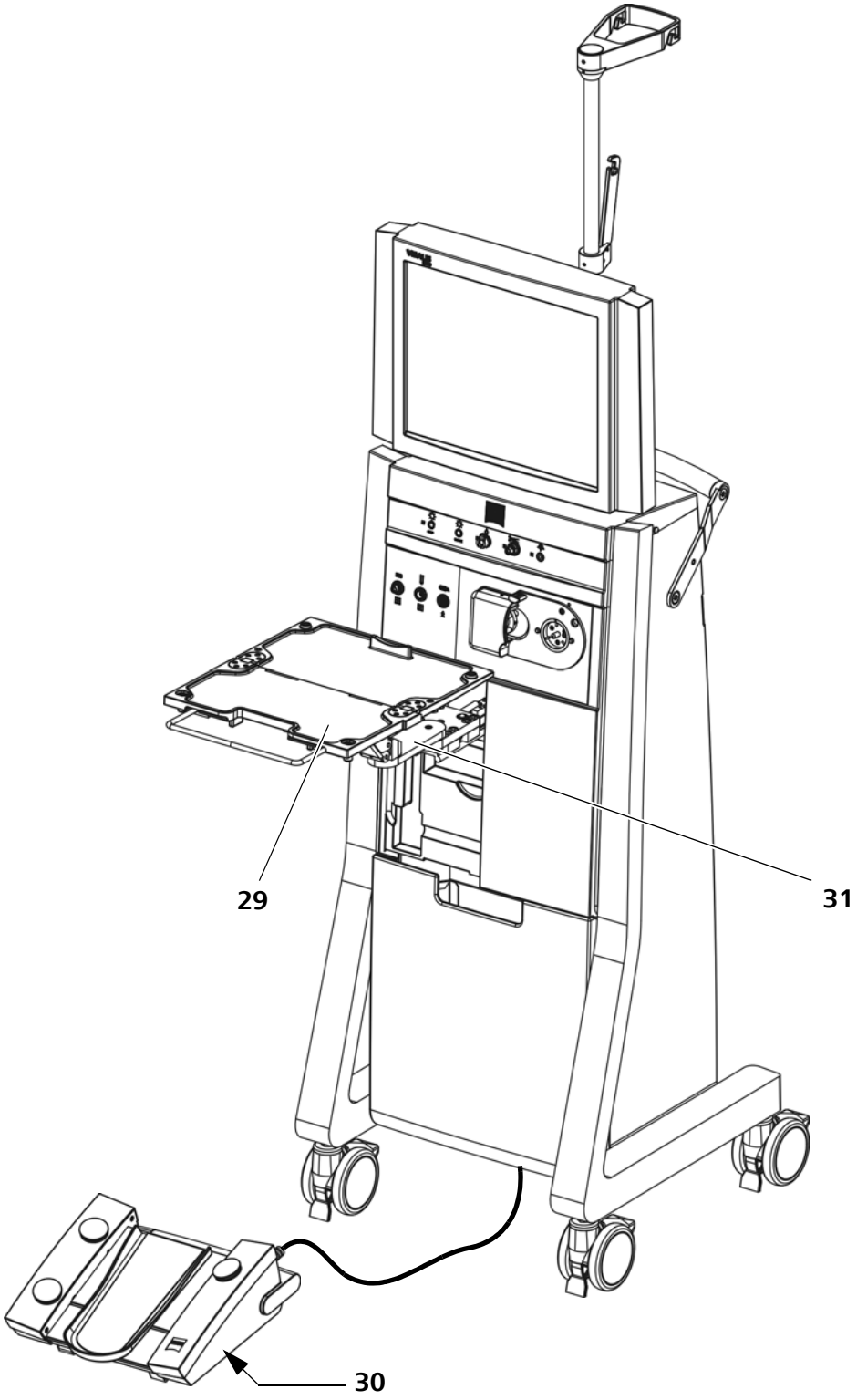


30 Identification label "DOUBLE LINEAR FOOTSWITCH II"
The identification label includes the following information:

- Manufacturing symbol
- Manufacturer (company name) — Carl Zeiss Meditec AG
- Manufacturer's address — Goeschwitzer Strasse 51-52, 07745 Jena, Germany
- Serial number — SN
- System name — DOUBLE LINEAR FOOTSWITCH II
- Reference number — REF
- Protection type — IPX8
- Year of manufacture
- Disposal symbol

31 Warning symbol "Risk of crushing"
Fingers may be crushed. Do not touch this area while moving the console tray.

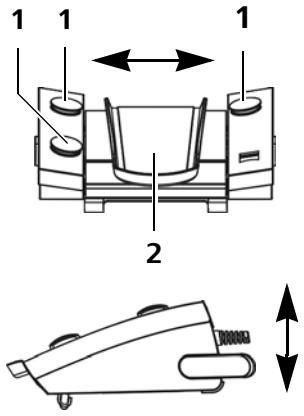
Fig. 9: Labels on the optional console tray



System Overview

System overview

DOUBLE LINEAR FOOTSWITCH II



By using the DOUBLE LINEAR FOOTSWITCH II the surgeon can activate the selected functions consistent with the settings on the device to which it is connected.

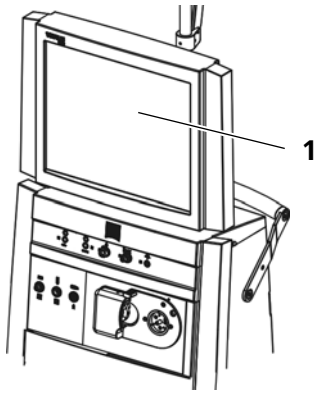
The three side buttons (1) carries out the following functions:

- switching functions on/off
- switching surgical functions and surgical modes forward
- adjusting the height of the infusion pole

The foot pedal (2) carries out the following functions:

- switching functions on/off
- switching surgical functions and surgical modes forward
- simultaneous linear control over two functions depending on how far the foot pedal is depressed or swiveled to the side. For example: U/S power and degree of aspiration or vitrectomy cutting rate and degree of aspiration.

Touchscreen



The surgical systems are equipped with an interactive touchscreen (1) (LCD, liquid crystal display). The user interface consists of simply structured menus and submenus that display the fundamental parameters in the foreground. By touching the appropriate site on the touchscreen, the user can select the surgical function and set the relevant parameters. The current values and the preset values are displayed for every parameter.

If a SCREEN DRAPE VISALIS 500 is placed over the touchscreen, the equipment can be operated by a sterile scrub nurse or other sterile nurse using a finger. If no sterile drape is used, the touchscreen can also be controlled by the TOUCHSCREEN PEN.

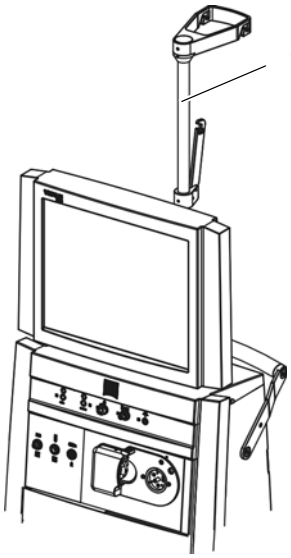
Irrigation system

Irrigation is used to replace aspirated liquids in order to maintain adequate intraocular pressure and fluid balance during surgery. The surgical systems feature:

– Gravity irrigation

– Controlled irrigation (not yet available)

– Combined irrigation



Gravity irrigation

An infusion bottle with balanced salt solution (BSS) is hung on the electrically operated infusion pole (1) with two hooks.

The flow rate of the fluid and the irrigation pressure is determined by the height at which the infusion bottle is mounted. The height of the infusion bottle can be set by the arrow keys on the touchscreen, by the side buttons of the DOUBLE LINEAR FOOTSWITCH II or the keys of the IV-POLE FOOTSWITCH.

Controlled irrigation (not yet available)

It has been designed to deliver balanced salt solution, at a controlled pressure, by means of an infusion bag inflated with pressurized air supplied by the equipment. The irrigation pressure can be set from 15 to 80 mmHg on the touchscreen. This kind of controlling the irrigation pressure offers a number of advantages as compared to simple gravity irrigation, both in cataract and in retinal surgery.

– In cataract surgery, the operation can be performed at the same vacuum, but at a lower irrigation pressure and with improved protection from anterior chamber collapse.

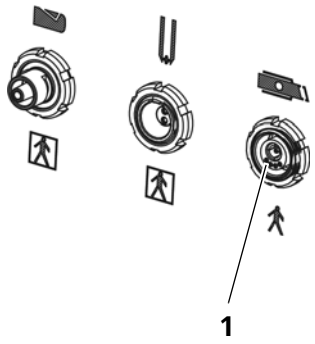
– In retinal surgery, it is feasible to set the desired irrigation pressure on the system and keep it constant.

With a valve, sterile on/off control of the irrigation can be done via the DOUBLE LINEAR FOOTSWITCH II or by means of a key on the touchscreen.

Combined irrigation

This is a combination of gravity and pressurized irrigation. The height of the infusion bottle on the infusion pole and the pressure of air transmitted into the drip chamber or infusion bottle can be set independently.

Phacoemulsification



The ULITE PHACO HANDPIECE from ZEISS must be connected to the U/S socket (1). The phaco handpiece contains a piezo transducer that vibrates at a frequency of 40 KHz (+4.5 kHz/-1 kHz) and an upward stroke of approximately 100 µm. The piezo transducer of the phaco handpiece is made up of three distinct components:

- The **piezoelectric ceramic element** converts the electrical energy supplied by the control console directly into mechanical vibratory motions of approx. 40,000 cycles per second (40 kHz).
- The **body** amplifies the movement of the piezoelectric ceramic element and transmits them mechanically to the PHACO TIP.
- The **PHACO TIP** vibrates longitudinally and facilitates the fragmentation of the tissue in a circumscribed area around the contact surface of the phaco tip. The maximum re-use cycles of the PHACO TIPS are described in the Instruction for Use enclosed with these products.

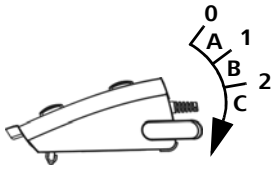
The internal energy loss processes of the piezo ceramic element cause the piezo transducer to heat up while it vibrates at high frequency such that the fluid aspirated from the eye is also used to dissipate the heat.

The VISALIS V500 und VISALIS S500 feature the patented **Adaptive Power Control (APC)** that enables the measurement of the PHACO TIP motion (stroke) in real-time. This information is used by the microprocessor to stabilize the stroke of the PHACO TIP.

Transmission of U/S power

The transmission depends on the following adjusted parameters on the touchscreen:

- **U/S operation mode:** The U/S power can be carried out in a duration mode (Continuous) or in one of five different impulse modes (Single Burst, Multi Burst, Cont. Burst, Pulsed, APM).
- **U/S control mode:** The U/S power can be carried out "Fixed" or "Linear". In the latter case, the U/S power is linearly controlled from 5 µm to the preset limit by using the foot pedal.

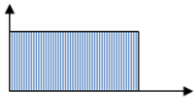


The U/S power can be activated by using the foot pedal in "Single linear" control (vertical direction only) and "Dual linear" control (vertical and horizontal direction). The "Single linear" control is active if the functions "U/S", "Cut" or "Vac2" are not assigned to the left or right of the foot pedal rotation.

The advantage of the "Dual linear" control is the simultaneous execution of two functions. Depending on configuration, e.g. the U/S power can be inde-

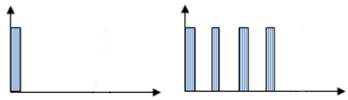
pendently controlled in linear mode during irrigation/aspiration.

Specific mode information

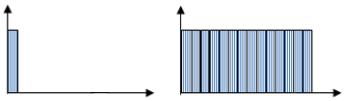


- In the **Continuous mode** the U/S power is supplied to the phaco handpiece continuously and without interruption when the foot pedal is depressed beyond (see page 64) pressure point 2 in area C. Accordingly, there is no need to adjust the pulse rate.
- In the **Pulse mode**, the U/S power is emitted in preset intervals in the form of pulses when the foot pedal is depressed beyond pressure point 2 in area C. The surgeon can select between the following settings in pulse mode:

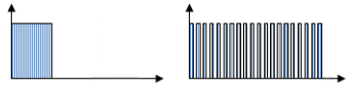
  - **Single Burst** (1 Hz)
    delivers U/S power in single pulses with a duration of 120 ms. The operator must return the foot pedal to area B, pause for approx. 1/2 sec and then press it back into area C to obtain another single burst.



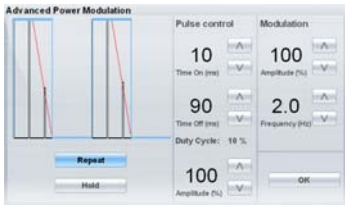
  - **Multi Burst** (1 Hz - 4 Hz)
    delivers ultrasound pulses with a duration of 80 ms with additional pulses generated (approx. 1 burst per second) when the foot pedal is depressed beyond pressure position 2 and reaches area C. By further depressing the foot pedal to the limit, the frequency of pulses increases up to a maximum rate of 4 pulses per second.



  - **Cont. Burst** (1 Hz - continuous)
    delivers ultrasound pulses with a duration of 80 ms. When the foot pedal has passed pressure position 2 and reaches area C, the ultrasound pulses are generated consecutively at an increasing rate. By depressing the foot pedal to the limit, the pulses blend together and the device delivers continuous U/S power.

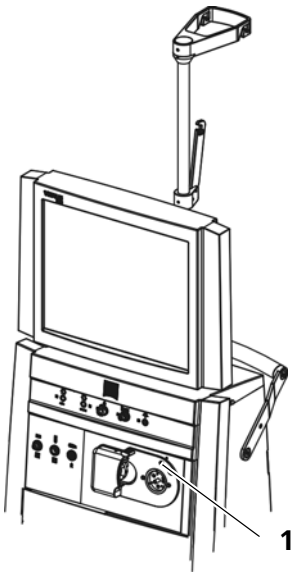


  - **Pulsed (**1 Hz - 40 Hz)
    delivers periodic pulses of U/S power. The user may select from a range of 1-40 pulses/sec. By depressing foot pedal the U/S power increases with continuous frequency.



In addition to the preprogrammed emission modes, VISALIS V500 and VISALIS S500 offer **Advanced Power Modulation (APM)**. APM allows the operator to design his/her own ultrasound emission pattern, that best suits his/her surgical techniques or cataract hardness. This function leads to a possible reduction of the U/S power needed for cataract removal. Detailed information to the APM mode are described on Page 190.

Aspiration system



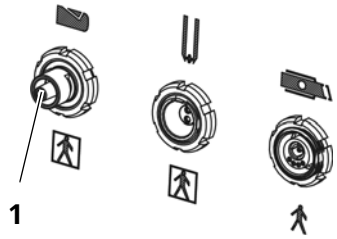
The surgical systems feature an aspiration function by action of their two-pump system. Depending on surgical needs or preference, the surgeon can select either a peristaltic pump or a venturi pump.

The purpose of the cassette receptacle (1) is to secure the I/A cassette. Fluids and particulate materials are aspirated at the distal end of the tip and subsequently deposited in the drainage bag of the disposable I/A cassette.

A safety vacuum sensor monitors the vacuum level in the aspiration tubing and adapts the pump action according to need. This vacuum monitoring is done by a "closed system": using a sterile membrane in the I/A cassette the vacuum sensor is completely separated from the sterile fluids.

The pumps in the VISALIS V500 and VISALIS S500 are controlled by a microprocessor. The vacuum level can either be preset on the touchscreen or controlled by the operator via the DOUBLE LINEAR FOOTSWITCH II (linear mode).

Vitrectomy



A VITRECTOMY PROBE from ZEISS can be connected to the vitrectomy socket (1). A vitrectomy probe consists essentially of two parts:

– **cutter tip** (blade) and

– **body** (containing the drive mechanism that is actuated by compressed air)

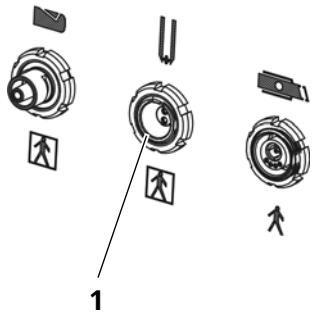
A vitrectomy probe uses the principle of the single acting actuator: pressure from a compressor in the surgical systems effects the out-stroke of the unit (extend). Once the pressure is no longer applied, the in-stroke is achieved by mechanical means, in this case by a built-in spring.

The tip contains the cutting element which consists of an outer (fixed) and an inner reciprocating tube acting in longitudinal direction, which are matched to each other.

The inner tube used for aspiration has a front end blade with a sharp outer edge. At the front end of the outer tube there is a lateral opening for cutting and aspiration. The tissue is simultaneously cut and aspirated by the longitudinal reciprocating action of the inner tube, generated by the pneumatic pulses originating from the surgical system.

The extremely close distance between the inner and outer tubes creates a slight constant tension that provides a self sharpening effect. The cutting speed (between 60 and 4000 cuts/min) and the vacuum level (from 5 to 600 mmHg) can be set with the keys on the touchscreen.

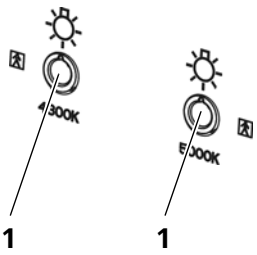
Bipolar diathermy



Bipolar diathermy uses radio frequency (RF) currents to produce heat in body tissues and thus cause coagulation. The energy of a high frequency oscillator (inside the surgical system) is conducted to a pair of electrodes (DIATHERMY FORCEPS or DIATHERMY PENCIL ERASER) that are touched against the biological tissues to be treated. The application of bipolar high frequency power contributes to the reduction of undesired neuromuscular stimulation.

Both surgical systems offer adjustable output power on the diathermy socket (1) from 0.1 to approx. 9 watt @ 200 Ω.

Illumination *



The surgical system VISALIS V500 is equipped with two independent illumination systems. Each of the two independent illumination systems is powered by a High Intensity Discharge (HID) lamp focused on the head of the fiber optic. The two lamps operate at different color temperatures (4300 K and/or 5000 K), as is evident from the information on the respective fiber connectors (1).

Both illumination systems have the following protection setups:

– Volume passport filter
  The filter removes all IR- and UV portions from the light.

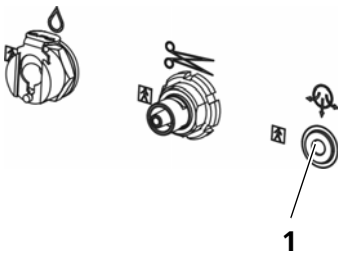
– Pivoting green filter
  The filter increases the contrast of the transparent membranes.

– Pivoting, retina protection filter (blue barrier filter)
  The filter reduces the blue portion of the light and allows for a longer treatment period (see maximum irradiation exposure time page 22).

The "TWO-WAY ADAPTER XENON-LIGHTSOURCE" makes is possible to simultaneously connect two fiber optics to each illumination system, i.e. entirely up to four fibers can be connected.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Air infusion *



The air infusion system uses a technology for automatic control of the ocular pressure. In conjunction with the AIR INJECTION TUBE WITH FILTER this allows the surgeon to introduce clean air at a preset value (in mmHg), while the system automatically balances variations due to possible losses from the surgical incisions.

The air delivery module of the VISALIS V500 is designed to supply clean air at adjustable low pressure settings over the entire range of 5-80 mmHg.

The AIR INJECTION TUBE WITH FILTER must be connected to the air socket (1).

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

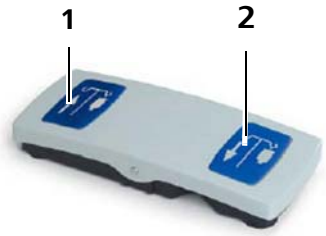
Silicone oil injection *

The silicone oil injection device is a compact, self-contained unit. It comprises a syringe, pre-filled with silicone oil, coupled via high pressure tubing to the front panel silicone oil injection socket (1) of the surgical system.

The syringe is activated by compressed air and evenly controlled by the DOUBLE LINEAR FOOTSWITCH II.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

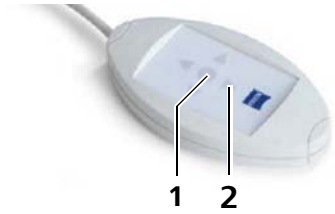
IV-POLE FOOTSWITCH (optional)



The optionally available IV-POLE FOOTSWITCH is used to lift or lower the electrically adjustable infusion pole of VISALIS V500 and VISALIS S500.

The IV-POLE FOOTSWITCH uses the foot rocker feature, two buttons and a connection cable for signal transmission. By pressing the key (1) the infusion pole is lifted upwards, by pressing the key (2) the infusion pole is lowered.

REMOTE CONTROL (optional)



The optionally available REMOTE CONTROL permits the operator to control the functions of VISALIS V500 and VISALIS S500 from a distance.

The selection of the functions takes place via the mouse pointer on the screen. With the four arrow keys (2), the mouse pointer can be positioned on the screen, with the central selection key (1) a function can be selected. For the sterile operation of the equipment, the REMOTE CONTROL with the REMOTE CONTROL COVER VISALIS can be used.

The mouse pointer only appears on the screen if the REMOTE CONTROL is connected to the surgical system.

Components of VISALIS V500 and VISALIS S500

System components

1 Infusion pole
The automatic infusion pole is used to fasten and adapt the height level of the infusion bottles for gravity irrigation.

2 17" Touchscreen
The touchscreen can be swiveled somewhat to the left or right or up and down to improve the handling features and visibility.

3 Cassette receptacle

4 Console Tray (optional)
The foldable Console Tray allows the surgeon or nurse to place down the requisite surgical set and accessories. For sterile use, the Console Tray can be provided with a sterile drape. The Console Tray can be kept inside the housing if it is not used. For optimal positioning, the Console Tray can be aligned as follows:

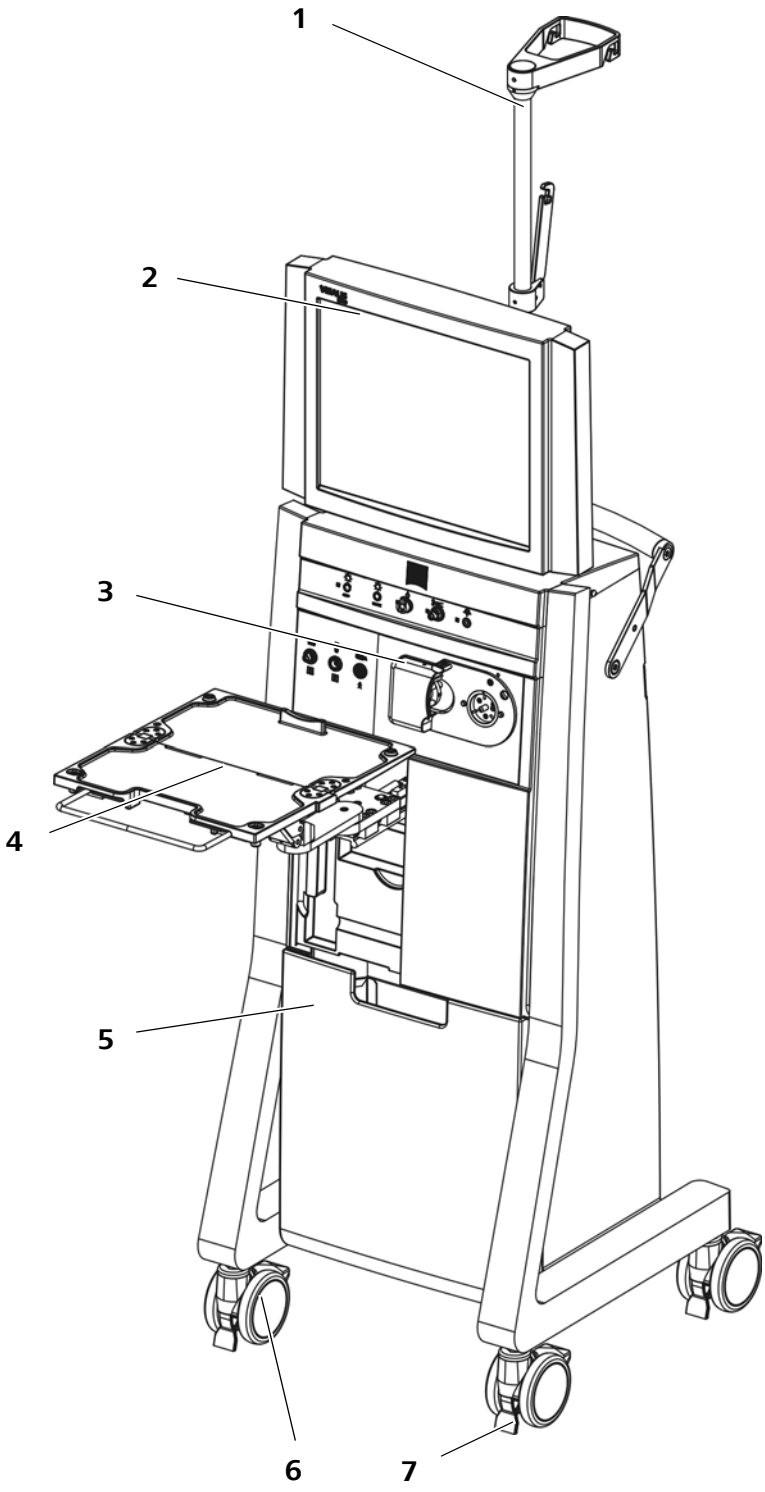
- rotation around 180°
- horizontal swivel via the carrier arm
- vertical height setting via the carrier arm

5 Foot switch compartment
serves for the storage of the DOUBLE LINEAR FOOTSWITCH II.

6 Steerable casters
The systems are equipped with four steerable casters which make it easier for you to position the system in the OR.

7 Cable deflector
Protects cables on the ground from being damaged by casters.

Fig. 10: Components v of the systems (front)



8 Infusion bottle holder
is used to suspend the infusion bottle with irrigation fluid during procedures involving gravity irrigation.

9 Holder for infusion bottle during retina surgery
is used, e.g., to take up a replacement infusion bottle with irrigation fluid.

10 Handgrip
is used to relocate the system.

11 Ventilation slots

12 Cable holder
is used to reel up the power cable.

13 Locking tabs (4x)
The locking tabs enable you to prevent the system from moving or rolling away of its own accord.

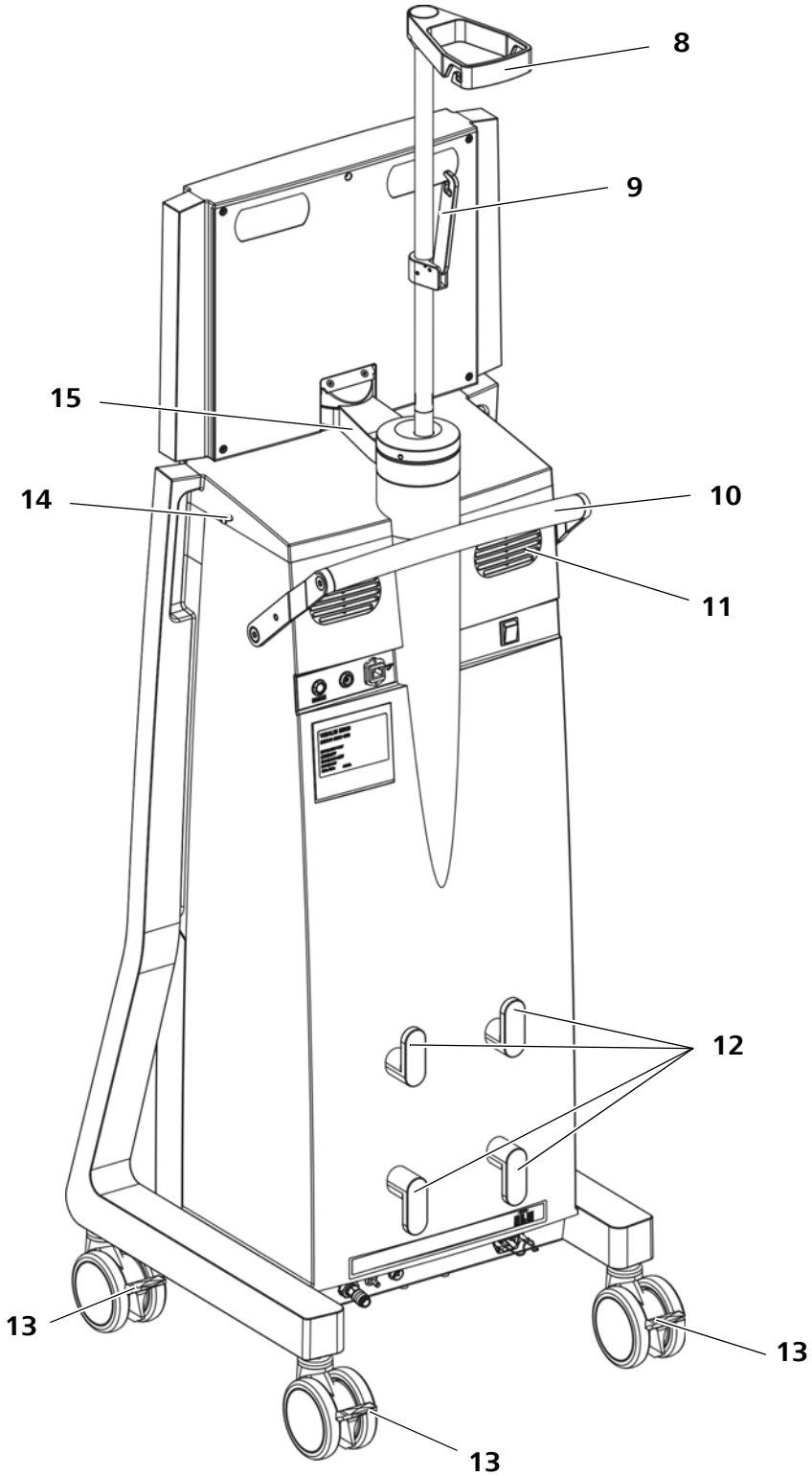
At least two locking tabs must be pressed down to position the system.

- Press locking tab down to block the caster.
- Pull the locking tab up to release the roll.

14 Infusion bag holder
is used for the suspension of the infusion bags with irrigation fluid when the "Controlled irrigation" is used.

15 Touchscreen hinge
The touchscreen can be swiveled to the left or right or somewhat up and down to improve the visibility.

Fig. 11: Components of the systems (rear)



Front panel connectors and control elements

1 Vitrectomy socket
The air connector tubing of the vitrectomy probes fits into this socket.

2 Diathermy socket
The connector of the DIATHERMY BIPOLAR CABLE fits into this socket.

3 U/S socket (ultrasound)
The connector of the ULITE PHACO HANDPIECE fits into this socket.

4 Light source socket 4300 K *
The connector of the fiber optics fits into this socket. Some fiber optics necessitate the use of an adapter.

5 Light source socket 5000 K *
The connector of the fiber optics fits into this socket. Some fiber optics necessitate the use of an adapter.

6 Silicone oil injection socket *
The connector of the SILICONE OIL INJECTION TUBE fits into this socket.

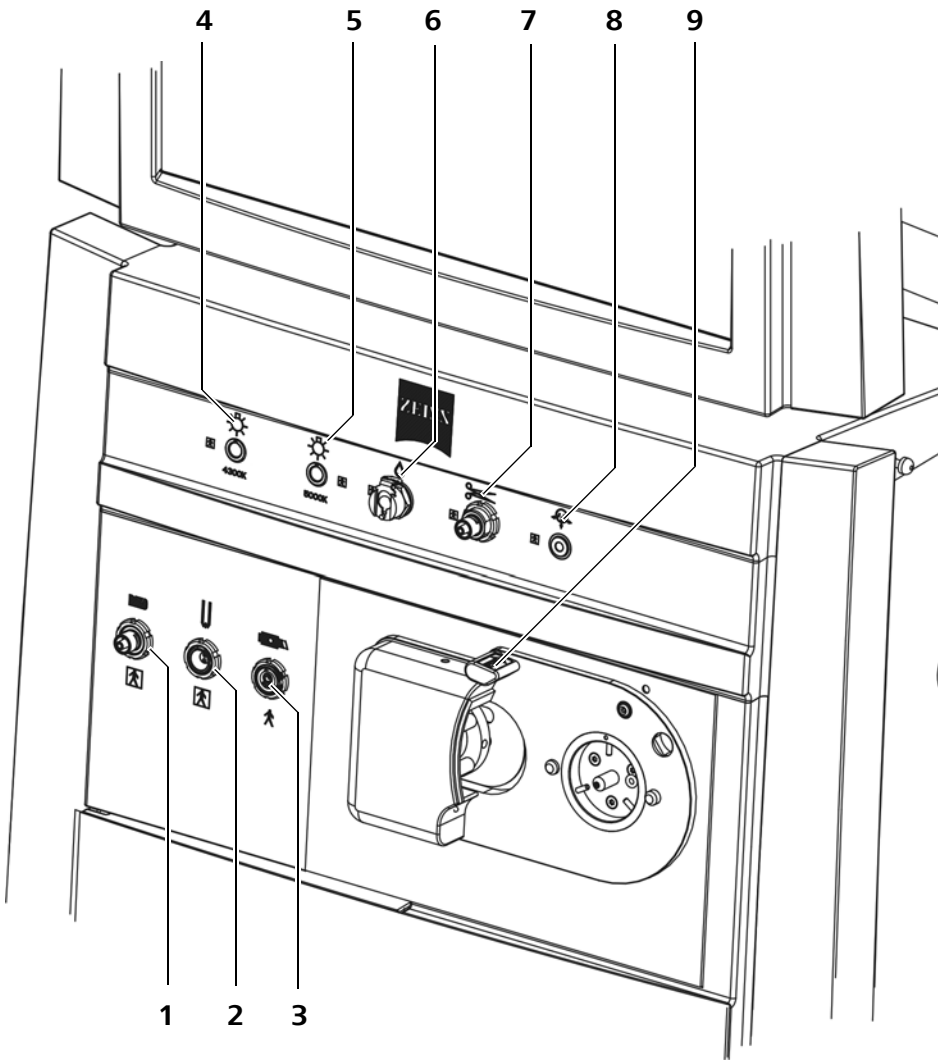
7 Scissors socket *
The connector for the pneumatic MICROSCISSORS fits into this socket.

8 Air socket
The connector of the AIR INJECTION TUBE WITH FILTER fits into this socket. Also used as a connector for the "Controlled Irrigation".

9 I/A cassette unlocking knob
This knob facilitates rapid exchange of the I/A cassette.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 12: Connectors and controls on the front panel



Rear panel connectors and control elements

1 Power switch
The power switch is used to turn the system on/off. When the system is on, the green indicator light in the switch is lit.

2 CALLISTO eye connection
Connection for the optional available OP Management System CALLISTO eye (from version 3.6). The system can be used to link and exchange data between ZEISS equipment in the operating room (OR).

3 REMOTE CONTROL / USB adapter connection
Connector for the optional remote control that allows equipment functions to be controlled without use of the touch screen. With the optionally available USB ADAPTER FOR SOFTWARE UPDATES open source licences and system alarm messages can be exported, users and programs can be exported or imported over this connection.

4 Video Graphical Overlay System connection
Connection for the optionally available Video Graphical Overlay System with which the surgical parameters from the equipment can be additionally merged with the video signal from the microscope camera.

5 Fuse holder and power plug
Contains the line fuses. The voltage selector switch, located on the fuse carrier's cover, must be set to the local voltage at the site of use of the system.

Only connect the system to an outlet which is equipped with a properly connected protective ground conductor.

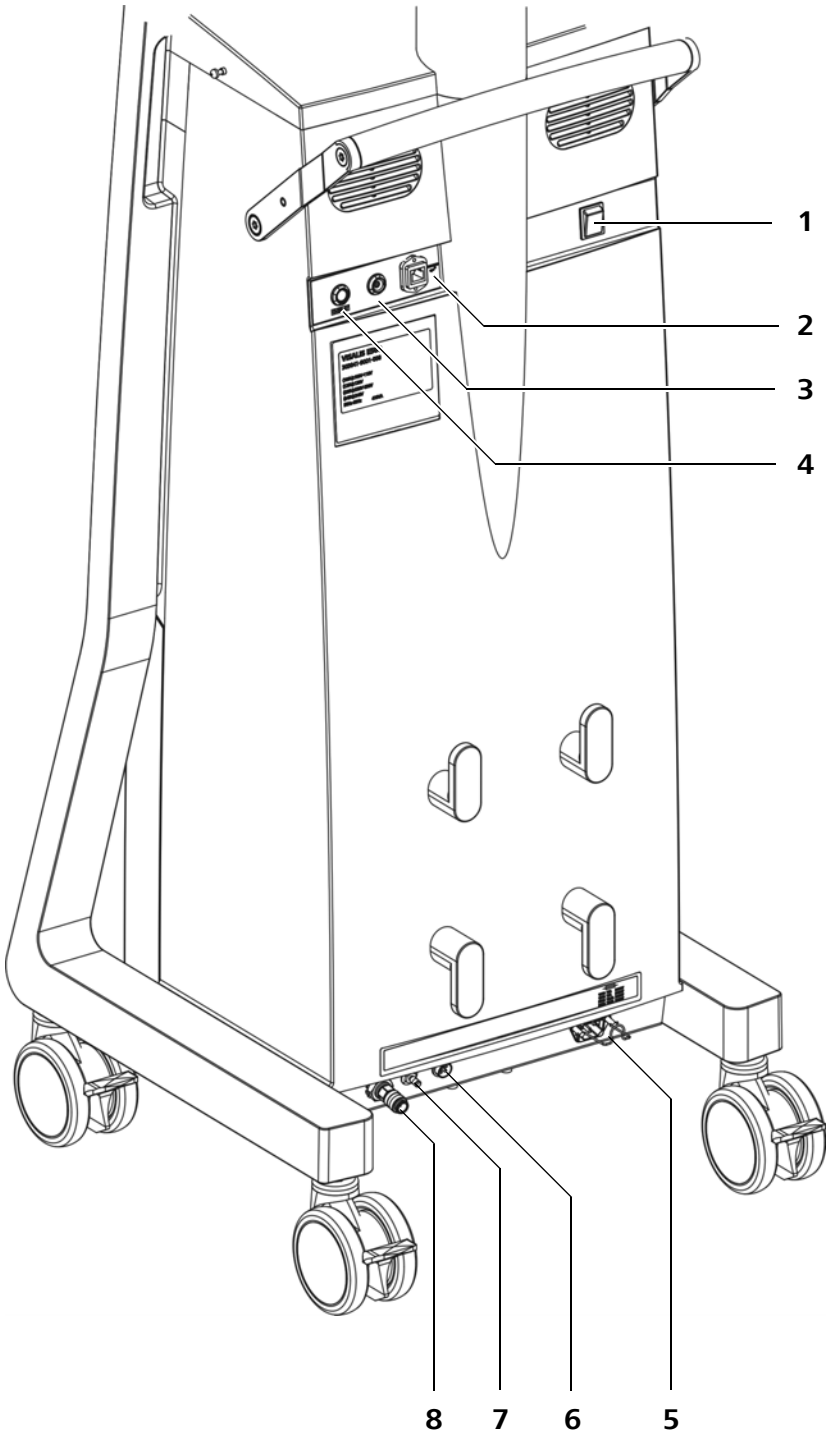
6 IV-POLE FOOTSWITCH connection
This socket is used to connect the optional IV-POLE FOOTSWITCH that can be used to control the infusion pole without using the touchscreen.

7 Potential equalization according to the requirements of IEC 60601-1
This connector can be used to connect the VISALIS V500 and the VISALIS S500 to the grounding of the system.

8 Air inlet plug
External compressed air inlet for the Venturi pump, vitrectomy probe, and silicone oil injection.

Air pressure has to be in the range between 500 and 800 kPa. The available flow has to be at least 38 Nl/min.

Fig. 13: Connectors and control elements on the rear panel



Control elements of the console tray (optional)

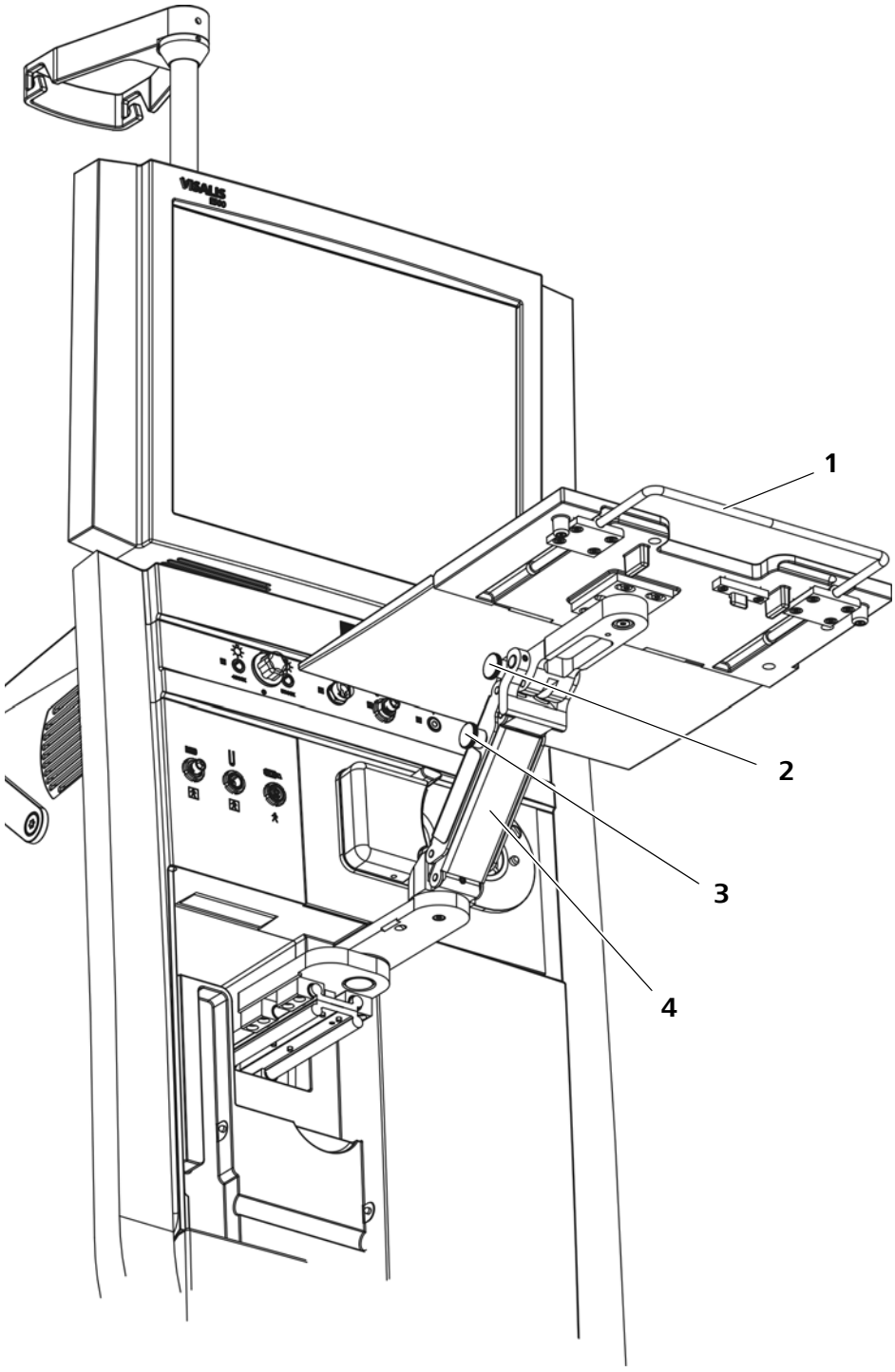
1 Handgrip
For positioning the console tray.

2 Locking button
For horizontally fixing the console tray.

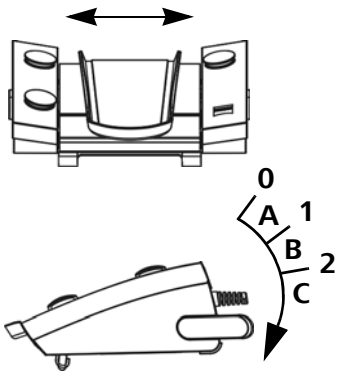
3 Locking button
For the vertical fixing of the height setting.

4 Carrier arm
To the vertical and horizontal alignment of the console tray.

Fig. 14: Control elements of the console tray



Components of the DOUBLE LINEAR FOOTSWITCH II



With the spray water protected DOUBLE LINEAR FOOTSWITCH II the user can control the different functions of instrument operation. The DOUBLE LINEAR FOOTSWITCH II is connected to the foot switch socket in the foot switch compartment.

The DOUBLE LINEAR FOOTSWITCH II consists of the following components:

1 Foot pedal
The foot pedal can be moved in horizontal and vertical directions to trigger certain functions.

The vertical direction of the foot pedal is subdivided into three areas with two tactile positions. Certain functions are assigned to each area and can be triggered by pressing the foot pedal.

- Resting position 0
  Area A is between the resting position and the first pressure position.
- Tactile position 1
  Area B is situated between the first pressure position and the second pressure position.
- Tactile position 2
  Area C is situated between the second pressure position and the end-limit position.

2 Side buttons

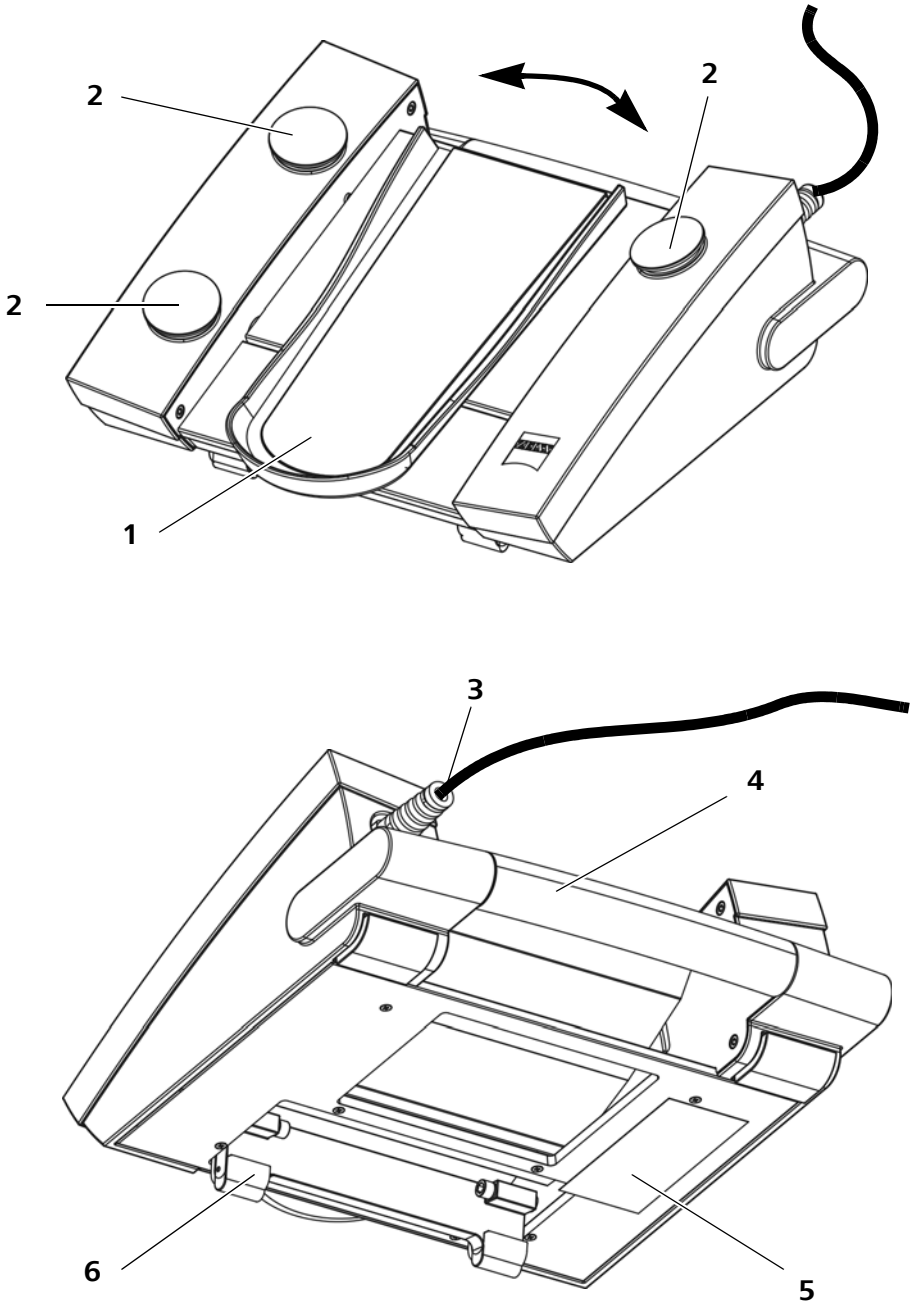
3 Connection cable
For the connection of the DOUBLE LINEAR FOOTSWITCH II to the connector block of the surgical system.

4 Carrier bracket
For carrying the DOUBLE LINEAR FOOTSWITCH II.

5 Rating label

6 Unfolding support
Puts the DOUBLE LINEAR FOOTSWITCH II in an ergonomic position and thereby facilitates its use.

Fig. 15: DOUBLE LINEAR FOOTSWITCH II



Preparations for use

Preparations for use

Adequate training is required for the proper installation and operation of the surgical system for its intended use. Training on the operation of the device is offered by ZEISS. For details, contact the ZEISS Service.

Unpacking the device

CAUTION

Injury to the patient's eye!

This system has been packaged to minimize the risk of damage in shipment.

- If you notice any shipping damage, notify the carrier and do not use the system.

Observe the relevant Instruction for Use during unpacking of sterile and micro-resterilizable surgery accessories and supplies.

- Open the package and examine the components for damage. When cutting the packing material, be careful not to damage the contents.
- Check that the contents correspond to those indicated on the enclosed shipping documents. Notify the ZEISS Service of any discrepancies without delay.

Connecting the device

Producing the compressed-air supply

- Check if the pressure of the pressure supply is consistent with the value indicated on the rear panel (from 500 to 800 kPa - 72.5 to 116 psi).
- Take the compressed air supply hose and connect the air input connector (2) with the local compressed air supply.

NOTE

Tripping hazard!

Cables inappropriately routed on the floor may constitute a tripping hazard.

- Always route cables in a manner that will not obstruct the workflow.

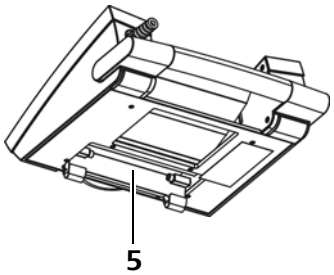
NOTE

Risk of crushing - mind your fingers!

There is a risk of crushing your fingers when you fold up the foot switch compartment (3).

- Always grasp the foot switch compartment by the recessed area (4).

Connecting the foot switch



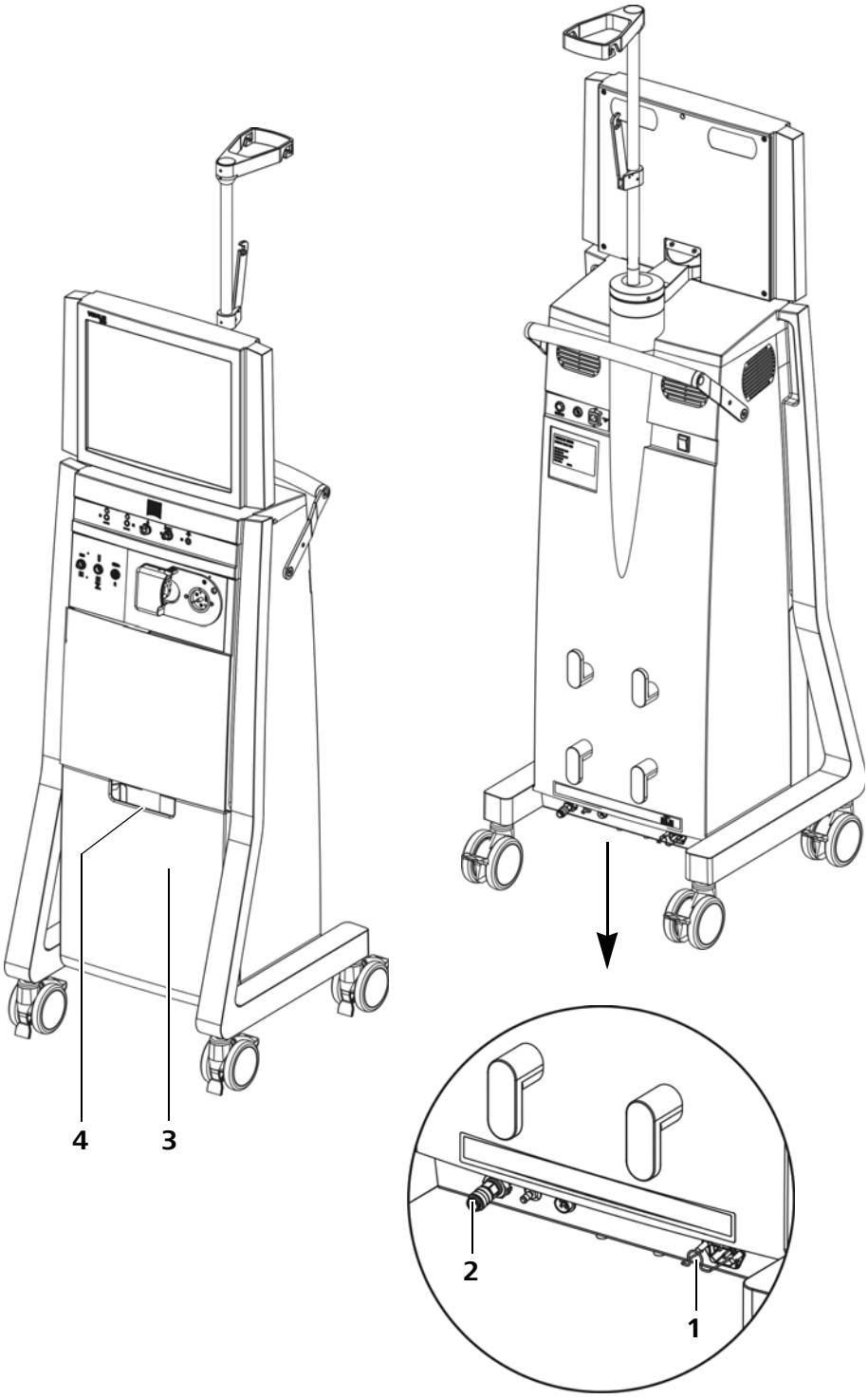
- Place the foot switch on the floor. If the position of the foot switch is not comfortable unfold the heel support (5) of the DOUBLE LINEAR FOOTSWITCH II.
- Connect the foot switch cable to the socket labeled "foot switch control" found in the foot switch compartment (3). Turn the holding ring clockwise to fasten the plug.

System to the power supply

- Check if the local default voltage corresponds to the voltage specified on the type plate.
- Connect the power cable to the power plug (1) and secure it with the pull-out prevention.
- Connect the other end of the power cable to a grounded wall socket.

  → The device can now be set up in the OP (see next page).

Fig. 16: Connecting the device



Positioning the device in the OR

Observe the following points when relocating the equipment:

CAUTION

Injury to patient or user!

Risk of tripping when crossing doorsteps.

- Push the device slowly and carefully by its handle over doorsteps of up to a maximum of 3 cm. If the doorstep is higher than 3 cm, the device must be moved over the doorstep by two people.

NOTE

Risk of damaging the system!

The maximum height of the infusion pole is 260 cm.

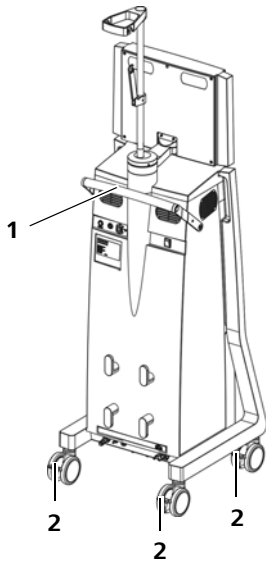
- Only set up VISALIS V500 or VISALIS S500 in areas with sufficient height.

NOTE

Risk of damaging the system!

Closed or obstructed ventilation openings may cause the system to overheat.

- Install the VISALIS V500 or VISALIS S500 system such that the ventilation openings are not closed or obstructed.



To simply and securely transport the device, a handle (1) and four controllable rolls are used. With the wheel locks (2) mounted on the four movable rollers, you can adjust the set up conditions correspondingly:

– None of the wheel locks are engaged:
  The equipment can be positioned exactly and in all orientations in the OR and at the operating table.

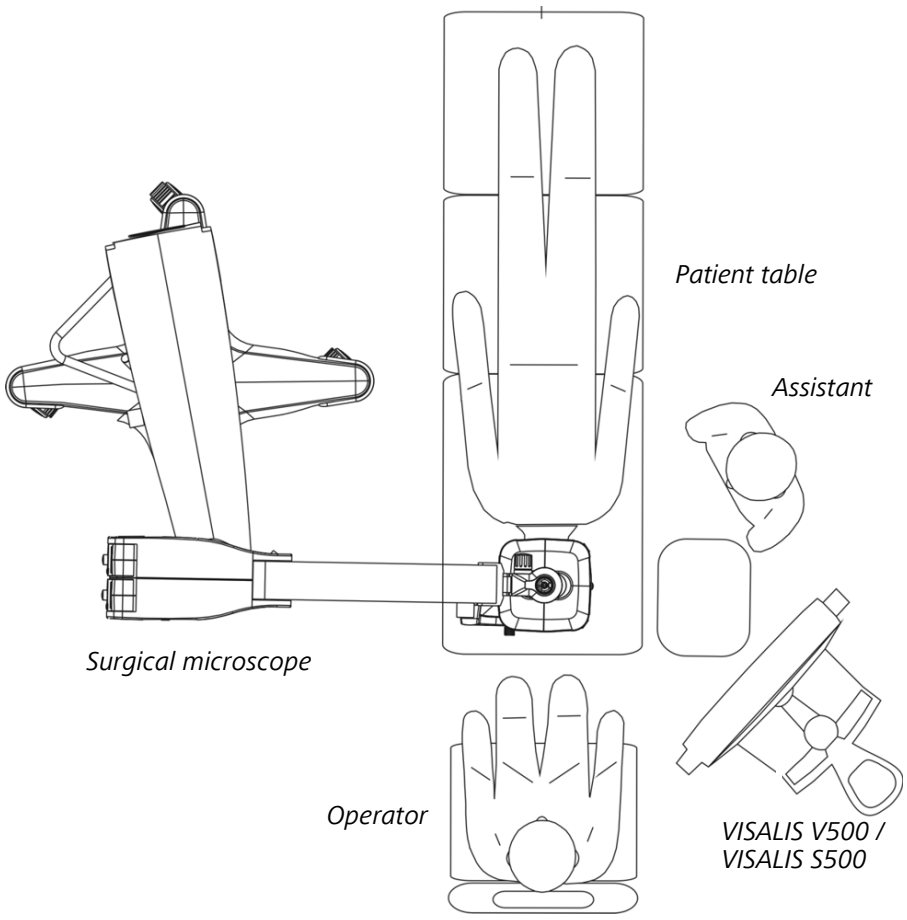
– All locking tabs have been pressed:
  The system is fixed in place preventing it from rolling away.

The device is set up in the OR:

- Release all the wheel locks (2).
- Hold the device firmly by the handle (1) and push it carefully to the desired location over a level surface.
- Engage at least two of the wheel locks (2) and make sure that the system cannot roll away.

The following image represents a possible OR situation.

Fig. 17: Installation of the system in the OR



Unfold console tray (optional)

CAUTION

Injury to the patient!

The console tray can break if overloaded and injure the patient.

- Do not exceed the console tray load capacity of 2 kg.

NOTE

Injury to the user!

There is a risk of crushing your fingers when you fold the console tray up or down.

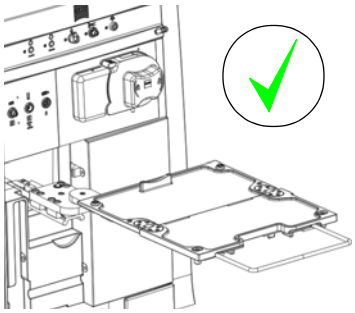
- Always fold the console tray up or down with great care!

Unfold the Console Tray as follows:

- (A) Grasp the lower edge (1) of the folded Console Tray (1) and slowly pull it out of the equipment until it stops.
- (B) Swivel the carrier arm (2) out by grasping it on the rubberized surface and swiveling it to the left by 180° until it is fully extended.
- (C) Swivel the Console Tray from the vertical to the horizontal position by pulling out the locking device (3) and swiveling the Console Tray upwards.

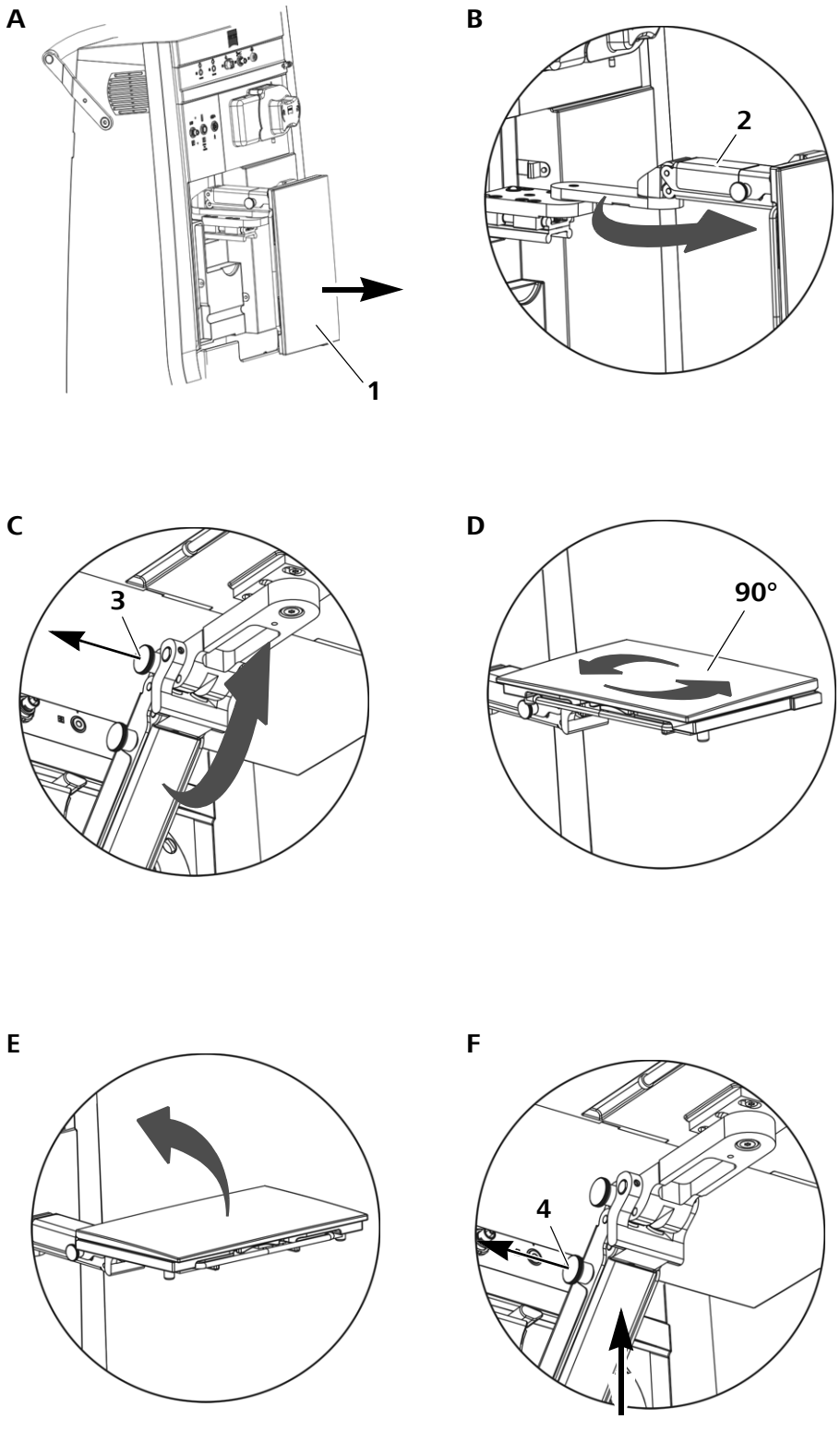
  → The Console Tray is properly locked when the locking device (3) is snapped into place.
- (D) Turn the Console Tray around 90° to the left.
- (E) Unfold the Console Tray.
- (F) Use your left hand to pull out the locking button for the height adjustment (4) of the carrier arm and press the Console Tray using your right hand to the desired height.

  → The carrier arm is properly locked when the locking button (4) is snapped into place.
- Set up the Console Tray by turning it horizontally around 180° or swing the carrier arm to the left and right.



To fold the Console Tray, proceed in reverse order.

Fig. 18: Console Tray unfolding



Preparing the device for sterile operation

CAUTION

Risk of infection!

The patient or user may be infected in the absence of sterile accessories.

- For sterile use of the touchscreen, use either the TOUCHSCREEN PEN or a sterile drape.
- If you use the REMOTE CONTROL and the console tray, use the corresponding drapes.
- The system may be operated by suitably instructed staff only.

Sterile single-use drapes can be used to cover the system in sterile condition.

The following drapes are available for the VISALIS 500 surgical systems:

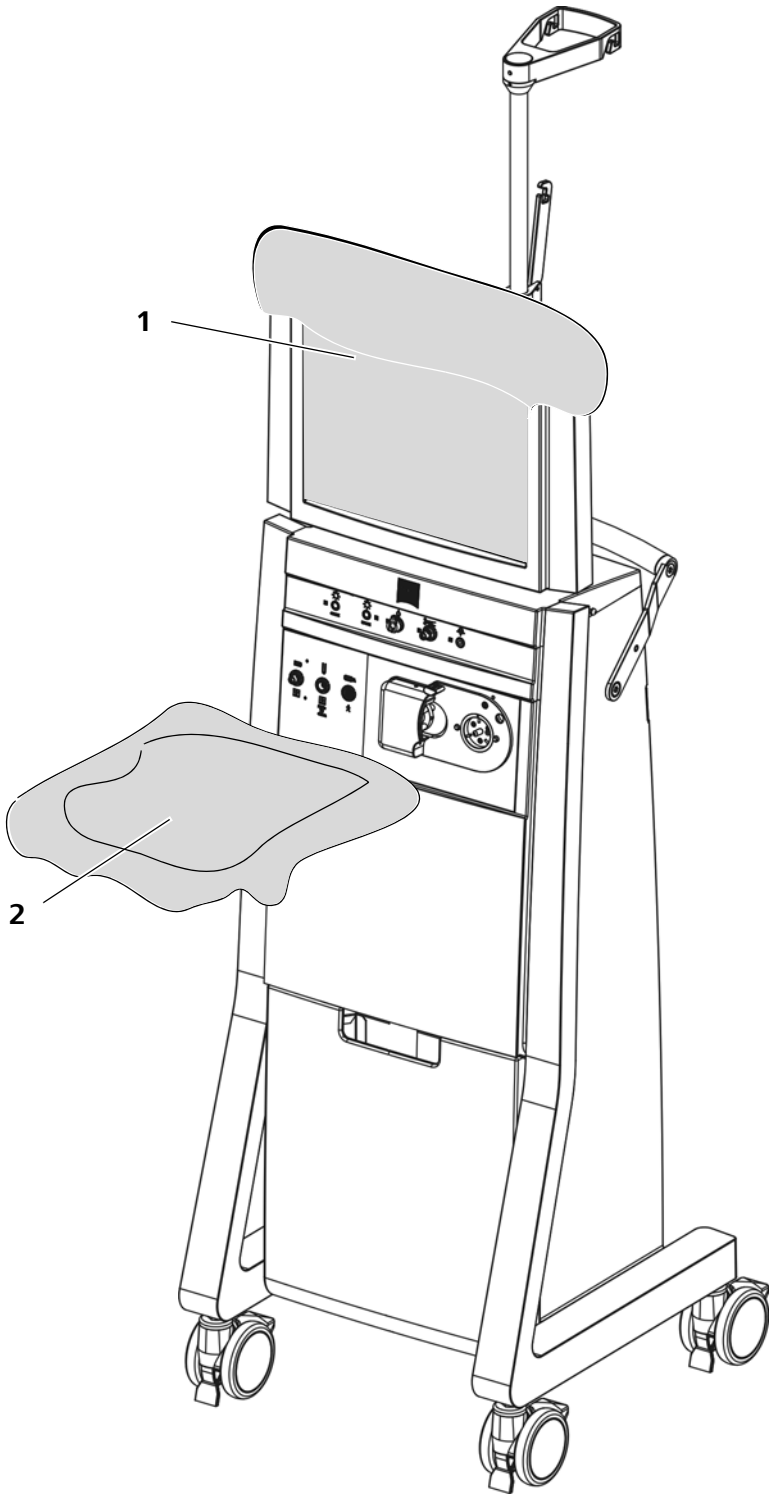
– SCREEN DRAPE VISALIS 500 (1)

– REMOTE CONTROL COVER VISALIS

– TRAY COVER VISALIS 500 (2)

Comply with the Instruction for Use of each drape when placing the drapes.

Fig. 19: Placing the drapes



Powering the device up

Requirements

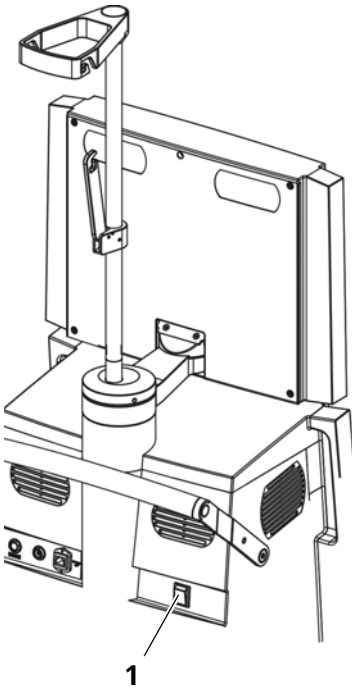
- ✓ The correct rated voltage is set (see page 70).
- ✓ The compressed-air supply is connected (see page 70).
- ✓ The power cable is connected (see page 70).
- ✓ The DOUBLE LINEAR FOOTSWITCH II is connected (see page 70).

WARNING

Injury to the patient's eye!

Audible hissing of air when switching on the equipment may indicate a malfunction of the silicone oil section or the exhaust of the excessive pressure from input air pressure source.

- Contact the ZEISS Service.



Proceed as follows to power the system up:

- Press the power switch (1) on the rear panel.
  - → The system has been switched on if the green lamp in the power switch (1) is lit.
  - → A black screen is displayed, after approximately 30 seconds a start screen with the ZEISS logo is displayed. During the 30 seconds the system performs a self-test,
    - – The infusion pole drives up and down.
    - – The system is checked. If there is any discrepancy, the safe default setting is stored and followed by a prompt continuous beep tone to turn off the device and contact your ZEISS Service.
  - → After the system is powered up the menu "Setup" (2) appears on the screen.
  - → At first start-up, the system displays the standard user profile, "Zeiss" (4), and the operating interface in English. During subsequent start up processes, the system sets the most recent user and the language assigned to the user.

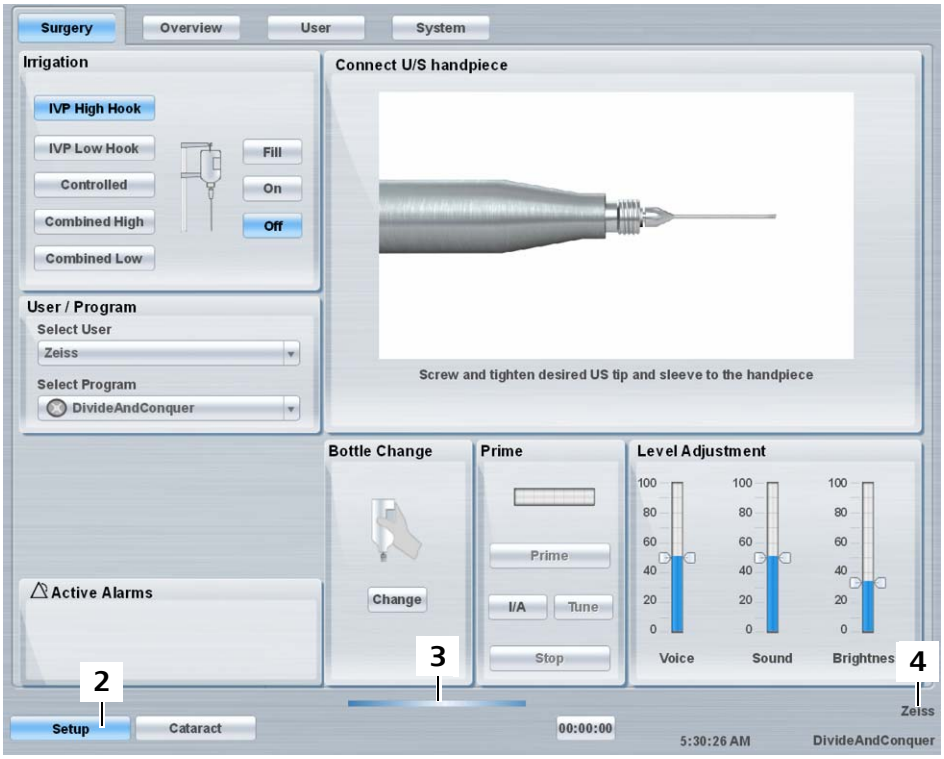
NOTE

Injury to the patient!

A pulsating bar (3) on the lower edge of the user interface indicates that the system is working properly.

- If the bar stops to move, the equipment is idle and you must discontinue the use of the equipment.

Fig. 20: Initial page after system start



Configuring users and programs

All default parameters of the VISALIS V500 and VISALIS S500 can be adapted to suit the individual needs of the user. The parameters thus set are saved for later re-use in programs and assigned to the users.

The VISALIS V500 and the VISALIS S500 can store up to 30 different users and up to 60 programs per user.

CAUTION

Injury to the patient!

Changes made to software settings during the application may lead to patient injury.

Setting a language

Here you can assign all self-created user profiles with a user language.

The language for the "Zeiss" user cannot be changed!

- Tap the key Setup (1).
- Tap the tab User (2).
- Select a self-created user (3).

  → The module "Language" is activated.
- Tap the key of the currently loaded language (4).

  → The "Language" list appears.
- Select the language to be assigned to the user interface.

  → The language will be loaded immediately.

Fig. 21: Setting a language

Loading a user or program

Under the user "Zeiss" the three following programs specially configured for the anterior and posterior eye section are available to you. You cannot configure these programs and you cannot delete them.

- "Divide & Conquer" for use in cataract surgery.
- "Phaco Chop" for use in cataract surgery.
- "Retina" for use in retina surgery.

Loading a user and a program

- Tap the key Setup (1).
  → The menu "Surgery" appears.
- Tap on the selected user (2).
  → The user list appears.
- Select the desired user by tapping the corresponding user key.
  → The name of the newly loaded user is displayed in the "User / Program" module and at the bottom of the touchscreen.
- Tap on the selected program (3).
  → The program list appears.
- Select the desired program by tapping the corresponding program key.
  → The name of the newly loaded program is displayed in the "User / Program" module and at the bottom of the touchscreen (4).

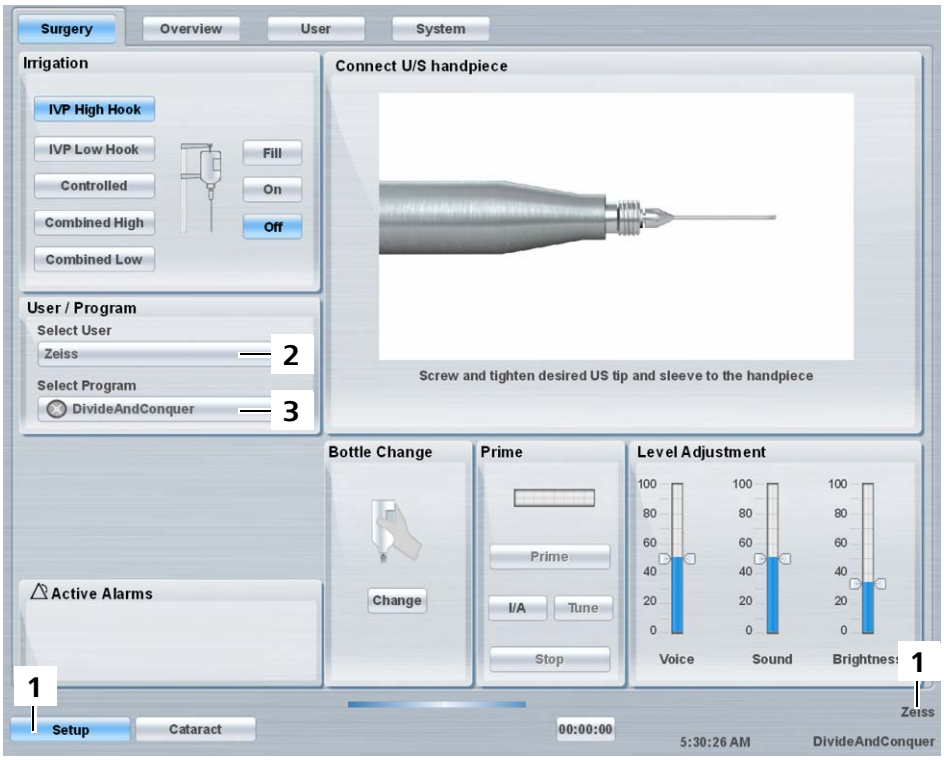
- To activate a newly loaded user or program, switch to the "Cataract" or "Retina" page.

Loading a program of the current user

- Tap the key Setup (1).
  → The menu "Surgery" appears.
- Tap on the selected program (3).
  → The program list appears.
- Select the desired program by tapping the corresponding program key.
  → The name of the newly loaded program is displayed in the "User / Program" module and at the bottom of the touchscreen (4).

- To activate a newly loaded program, switch to the "Cataract" or "Retina" page.

Fig. 22: Load a user or a program



Save a new or current program

Modifications cannot be stored under the "Zeiss" user. In order to save modifications, you need to create a new user or you need to load a self-created user.

Save the new program as follows:

- Tap the key Cataract (1).

  If you have adjusted a retina program in the setup menu the menu "Retina" is displayed.
- Adjust the desired parameters in the displayed program.
- To permanently save all changes in the displayed program, tap the key Save (2).

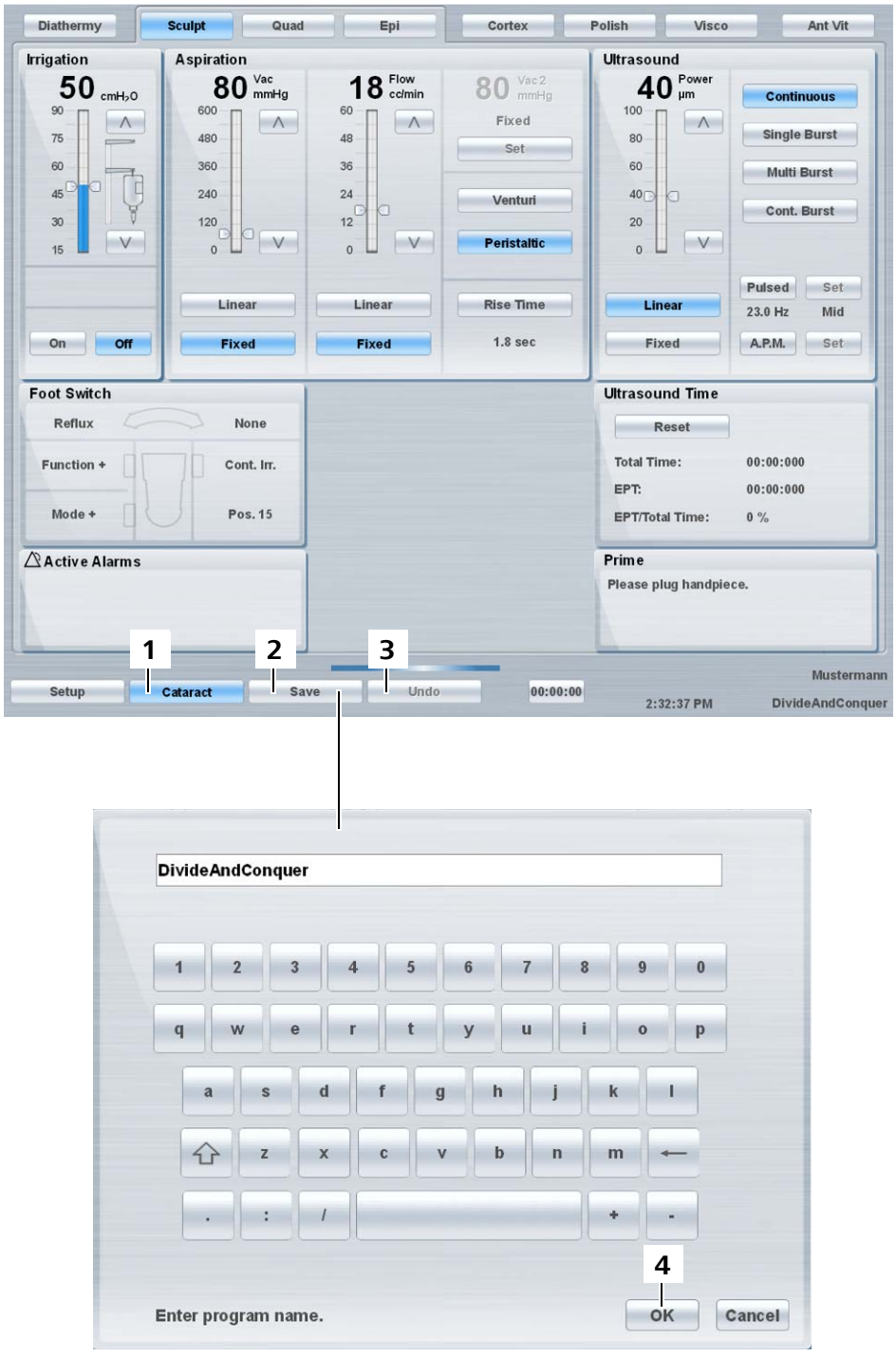
  → A virtual keypad with the currently loaded program is displayed.
- The new program can be saved in two different ways:
  - In order to save the modifications under the currently loaded program tap the key OK (4).
  - In order to save the modifications under a new program, type in the new program name and then tap the key OK (4).

Restore modified program settings

If you have changed a parameter in the menu cataract or retina without saving the program, the key Undo (3) is activated.

- Tap the key Undo (3) to delete all changes and to load the previous settings again.

Fig. 23: Save a new or current program



Creating users

Here you can store up to 30 different users.

- Tap the key Setup (1).
- Tap the tab User (2).
- In the module "Users" tap the key New (3).

  → The "Source For User" pop-up window appears.
- If the new user should get all programs of the currently selected user tap the key Selected User (4), if the new user should get only the DEFAULT programs of the "Zeiss" user tap the key Zeiss .

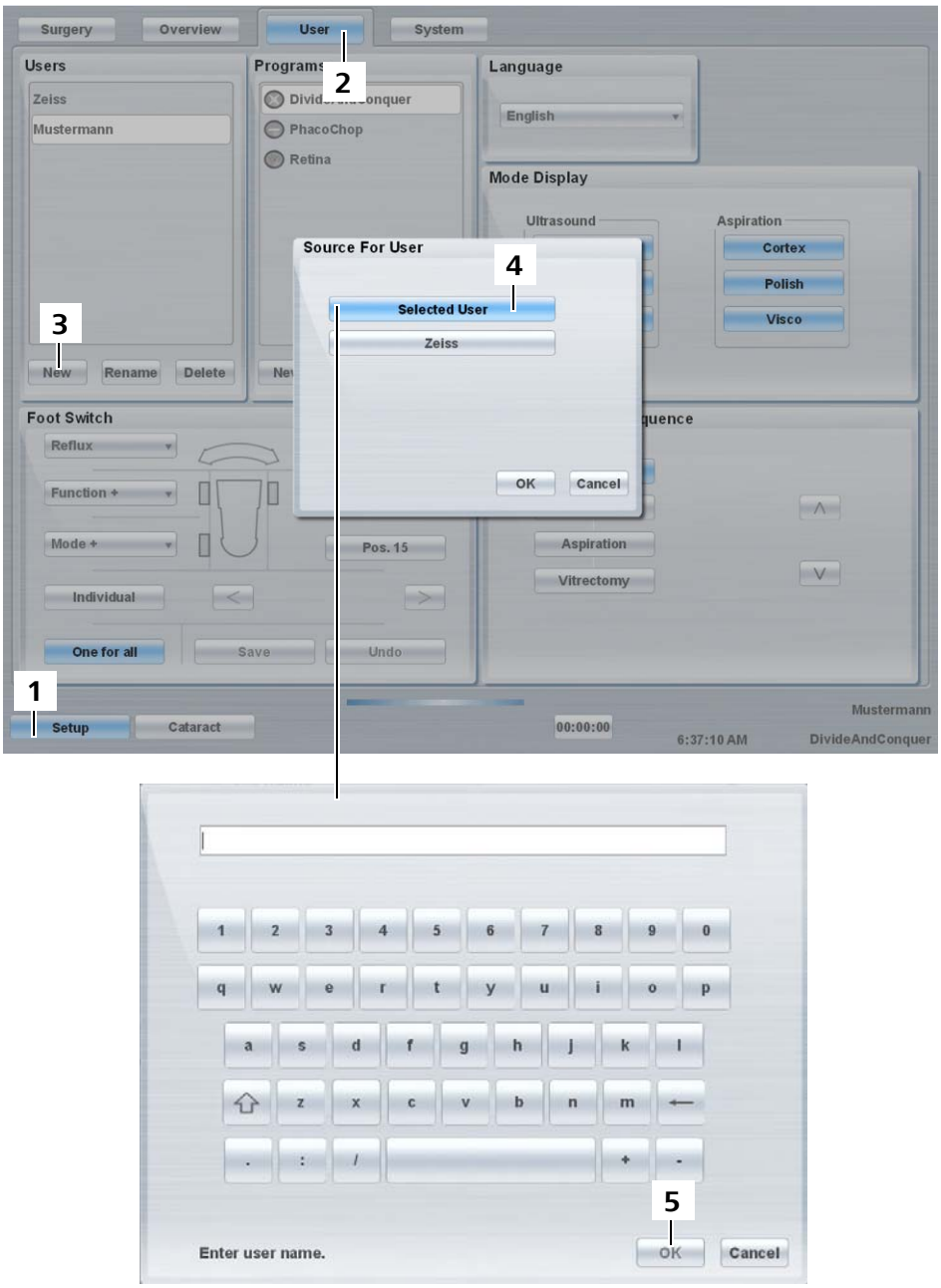
  → A virtual keypad is displayed.
- Type in the new user name.
- Tap the key OK (5) to save the user.

  → After the successful saving the virtual keypad closes and the name of the newly saved user is displayed in the module "Users".

  → All programs of the currently selected user or all DEFAULT programs of the "Zeiss" user will be loaded into the new user.

- Newly created users and programs are not activated immediately. To activate a newly created user or program, switch to the "Cataract" or "Retina" page.

Fig. 24: Create users



Creating programs

Here you can store up to 60 programs per user.

Requirements

✓ A new user has been created, cause a new program cannot be stored under the "Zeiss" user.

- Tap the key Setup (1).
- Tap the tab User (2).
- Select one of your **own-created** user profiles (3) in the module "Users".
- Tap the key New (4) in the module "Programs".

  → The pop-up window "Source For Program" appears. Here you can choose of following sources for the new program:

  – **Selected Program** (5): saves the new program with the parameters of the selected program.

  – **Current Settings** (6): saves the new program with the interim, still unsaved parameters of the selected users.

  – **Default Divide And Conquer** (7): saves the new program with the parameters of the default program "DivideAndConquer".

  – **Default Phaco Chop** (8): saves the new program with the parameters of the default program "PhacoChop".

  – **Default Retina** (9): saves the new program with the parameters of the default program "Retina".

- Select one of these sources and tap the key OK (10).

  → A virtual keypad is displayed. For a new program to be saved, the name of the new program must include at least one numeric character or one letter. When the maximum possible number of programs (max. 60) has been reached you are requested to delete an old program.

- The new program can be saved in three different ways.
  - In order to save the program to the same user, type in a new program name and tap the key OK (11).
  - In order to save the program to another existing user, select one of the stored users, then type in the new program name and tap the key OK (11).

- In order to save the program within a new user, type in the new user name, then type in the new program name and tap the key OK (11).

→ The virtual keypad closes and the name of the newly saved program or user is displayed in the regarding module.

- Newly created programs are not activated immediately. To activate a newly created program, switch to the "Cataract" or "Retina" page.

Fig. 25: Creating programs

Rename users and programs

Here you can rename all own-created user profiles or programs.

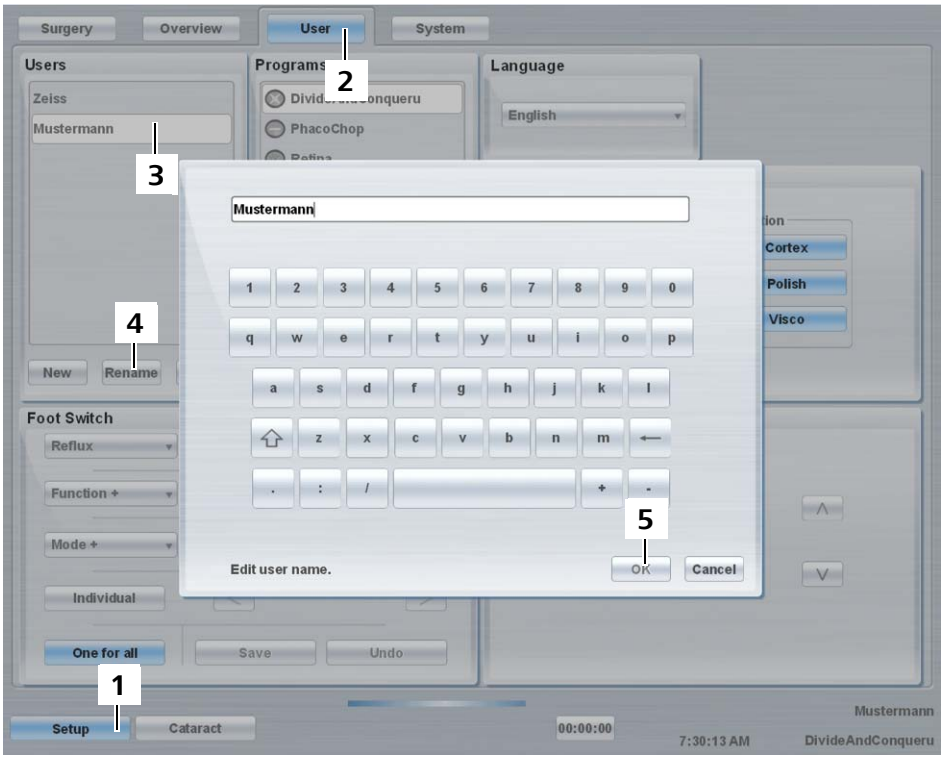
The "Zeiss" user cannot be renamed!

- Tap the key Setup (1).
- Tap the tab User (2).
- Select one of your **own-created** user profiles (3) or programs.
- Tap the key Rename (4) in the corresponding module.

  → A virtual keypad is displayed. For a new user or program to be saved, the name of the new user or program must include at least one numeric character or one letter.
- Type in the new user or program name.
- Tap the key OK (5) to save the new name.

  → The virtual keypad closes and the name of the saved user or program is displayed in the corresponding module and at the bottom of the touchscreen.

Fig. 26: Rename users and programs



Deleting users

The "Zeiss" user cannot be deleted!

- Tap the key Setup (1).
- Tap the tab User (2).
- Select the user to be deleted.
  → The selected user is marked in white.
- Tap the key Delete (3).
  → A warning appears "Deleting this user will also delete all of his programs. Do you want to proceed?"
- To delete the user confirm this procedure with the key Yes .
  → The system deletes the selected user and loads the program "Divide and Conquer" of the "Zeiss" user.

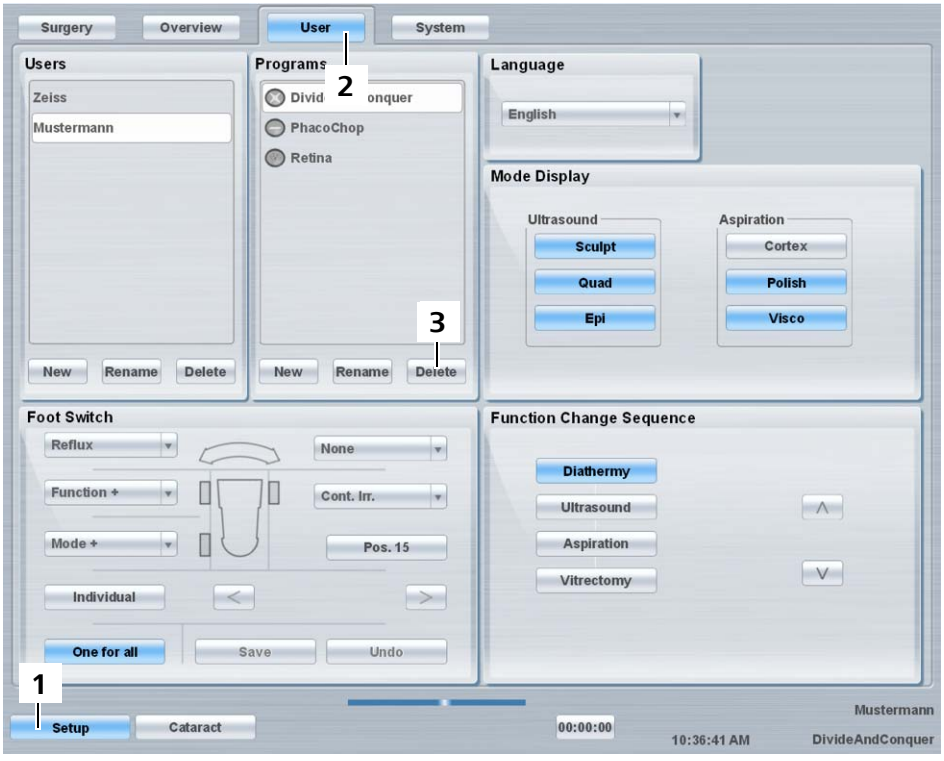
Fig. 27: Deleting users

Deleting programs

The programs of the "Zeiss" user cannot be deleted!

- Tap the key Setup (1).
- Tap the tab User (2).
- Select the program to be deleted.
  - → The selected program is marked in white.
- Tap the key Delete (3).
  - → A warning appears "Do you want to delete this program?"
- Confirm this procedure with the key Yes .
  - → The system deletes the selected program and loads the first program which appears in the program list.
  - → Before deleting the last program of a user a message is displayed indicating that deleting the program will delete the user.
  - → If all programs of the active user have been deleted, the user is removed and the system loads the "DivideAndConquer" program of the "Zeiss" user.

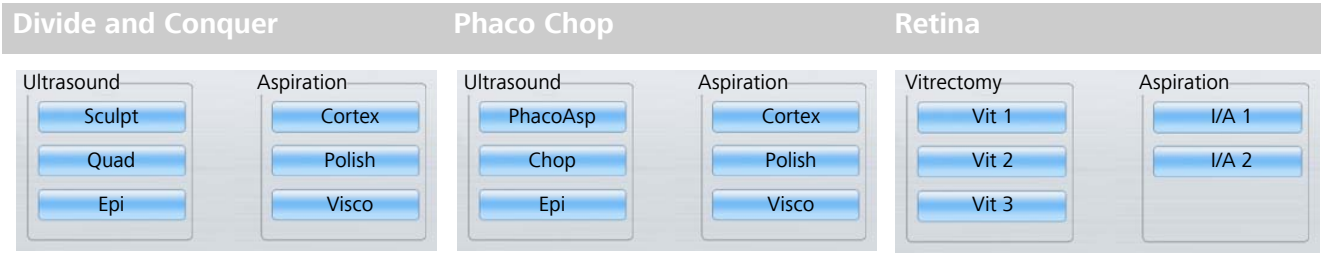
Fig. 28: Deleting programs



Activating or deactivating modes

The module "Mode Display" permits you to configure which modes (4) are active or inactive in the menu cataract or retina. Only active modes are displayed in the menu cataract or retina and can be selected by pressing down the programmed side button of the DOUBLE LINEAR FOOTSWITCH II or by tapping the related tab on the touchscreen.

The displayed list of modes depends on the selected program type:



If the module "Mode Display" is disabled (mode labels grayed out) the "Zeiss" user is loaded. In order to change and save modifications, you need to load a self-created user first.

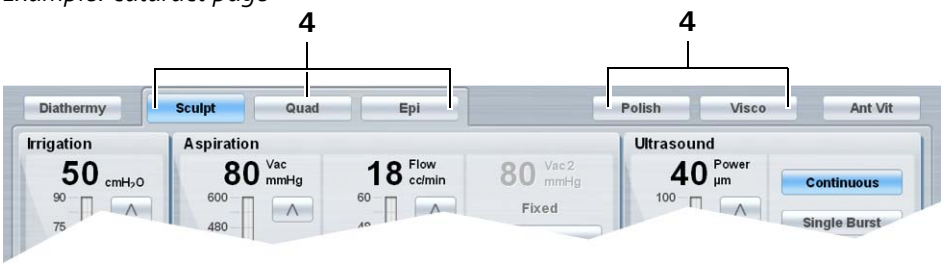
- Tap the key Setup (1).
- Tap the tab User (2).
- Select a self-created user and the program to be changed.
- Tap the mode (3) you wish to activate or deactivate. At least one mode is always active.

  → The mode is active when the key lights up in blue color.

  → The mode is inactive when the key is grayed out.

Fig. 29: Activating or deactivating modules

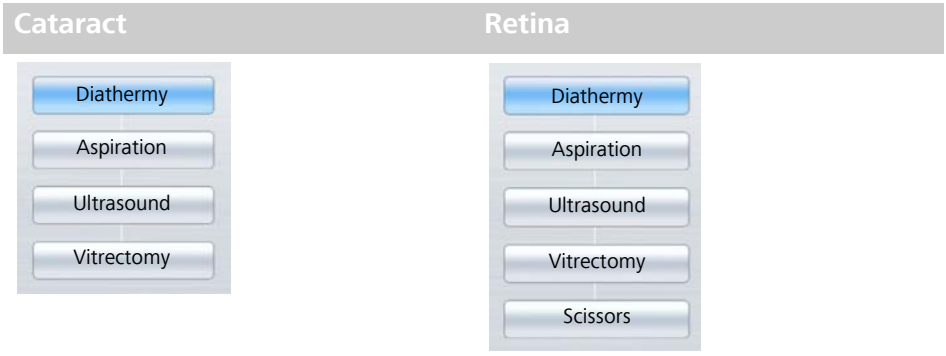
Example: cataract page



Change function sequence

The module "Function Change Sequence" permits you to change the sequence of the surgical functions (4) in the menu cataract and retina. This applies only to the sequence of function changes via DOUBLE LINEAR FOOTSWITCH II; the order of the tabs on the user interface remains unaffected.

The list of surgical functions displayed in the setup menu depends on the loaded program:



Proceed as follows for changing the sequence:

- Tap the key Setup (1).
- Tap the tab User (2).
- Select a self-created user and the program for which the sequence shall be changed.
- Select the surgical function (3).

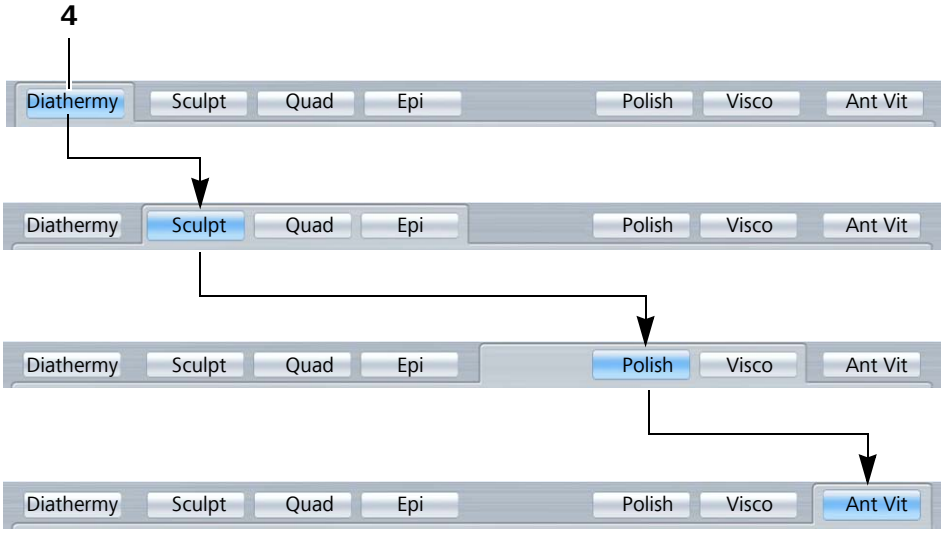
  → The selected key lights up in blue color.
- To change the sequence tap the arrow keys ∧ or ∨.

  → The sequence of the surgical function is changed.

You can switch between the surgical functions (4) in the menu cataract and retina by actuating the programmed element. If a surgical function consists of several surgical modes, like "Cortex, Polish, or Visco", then the left surgical mode is always activated first. In order to activate first the surgical mode in the middle or the right one, you have to deactivate the corresponding surgical mode(s) in the module "Mode Display" (see Page 94).

Fig. 30: Changing function sequence

Example: surgical function change



Configuring system

Adjusting the maximum IV Pole height

The module "IV Pole Height Limit" permits you to set up the maximum infusion pole height level for priming and maximum irrigation. This feature is useful to exploit the maximum available height in the building in order to avoid damaging the surgical system.

NOTE

Risk of damaging the system!

The irrigation height settings of your programs are unaffected by this setting. If you use this functionality then you must make sure that the irrigation height settings used in the environment with limited ceiling height are adjusted accordingly. This must be done for all tabs of all programs of all users. See table "Conversion of irrigation height into ceiling height" (Page 283).

- Using inappropriate irrigation height settings may cause the IV Pole to crash into a low ceiling (<260cm).

The maximum infusion pole height is set up automatically for following actions:

– Priming, I/A priming and Filling

– Activating the maximum irrigation pressure.
In the retina modes, the maximum available irrigation pressure can be reached by tapping the key Max in the module "Irrigation". This function serves for the increase of the irrigation pressure and the hemostasis during a posterior section surgery.

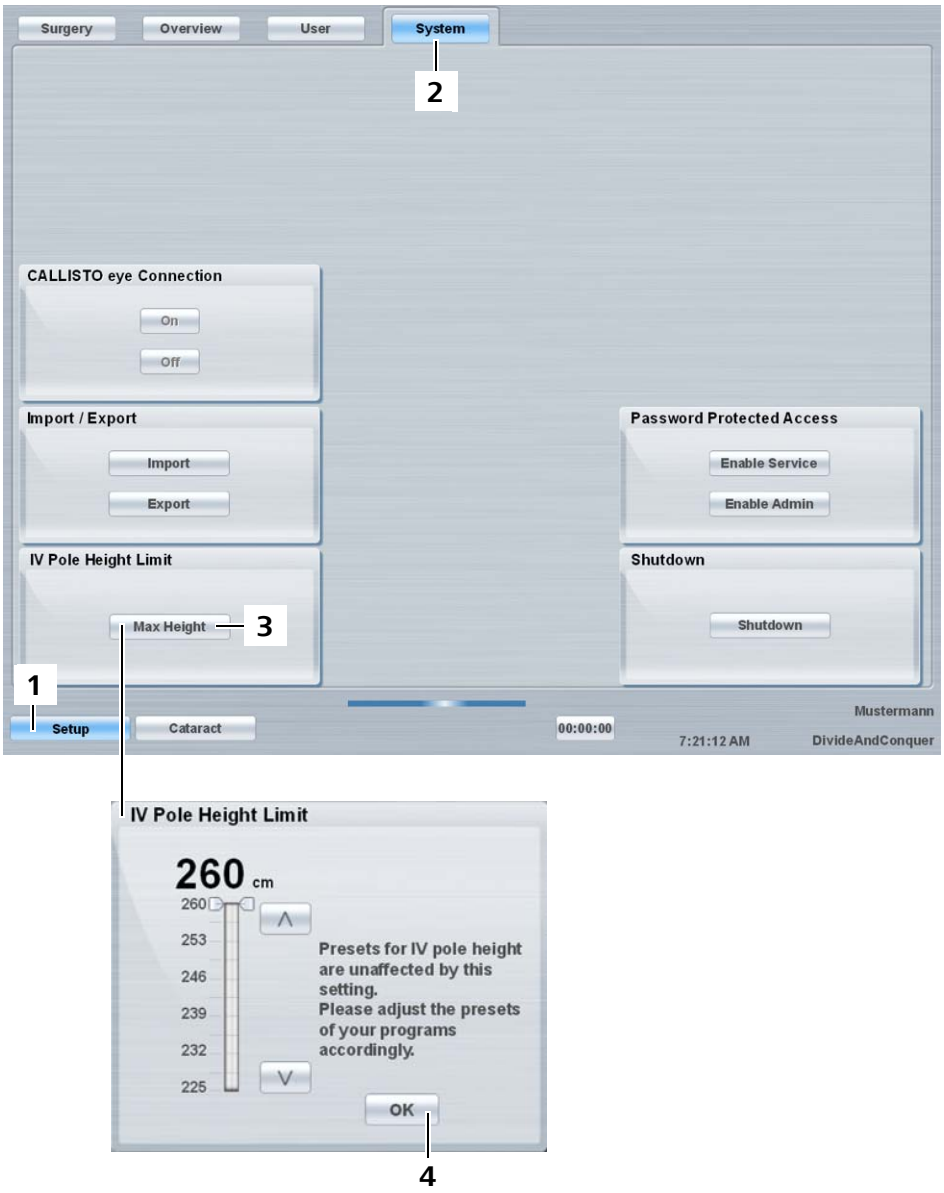
Proceed as follows to set up the maximum infusion pole height level:

- Tap the key Setup (1).
- Tap the tab System (2).
- Tap the key Max Height (3).

  → The pop-up window "IV Pole Height Limit" appears.
- Tap the arrow key ^ in order to increase the maximum infusion pole height limit (260 cm) or tap the arrow key v in order to decrease it to the minimum height level (225 cm). Alternatively you can regulate the maximum infusion pole height limit with the slide.
- Tap the key OK (4).

→ The pop-up window closes and the maximum infusion pole height level is saved.

Fig. 31: Configuring the maximum IV Pole Height Limit



Exporting users and programs

The export and import keys are deactivated by default. They are activated as soon as a USB storage device is connected to the surgical system.

NOTE

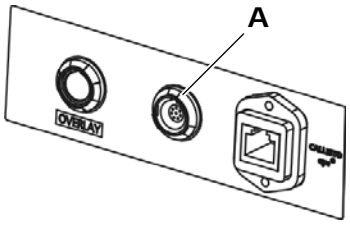
System malfunctions!

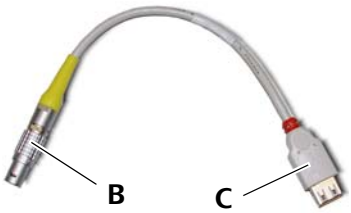
Computer viruses may cause system malfunctions!

- Use only tested and virus-free USB storage media.

Exporting all users and programs

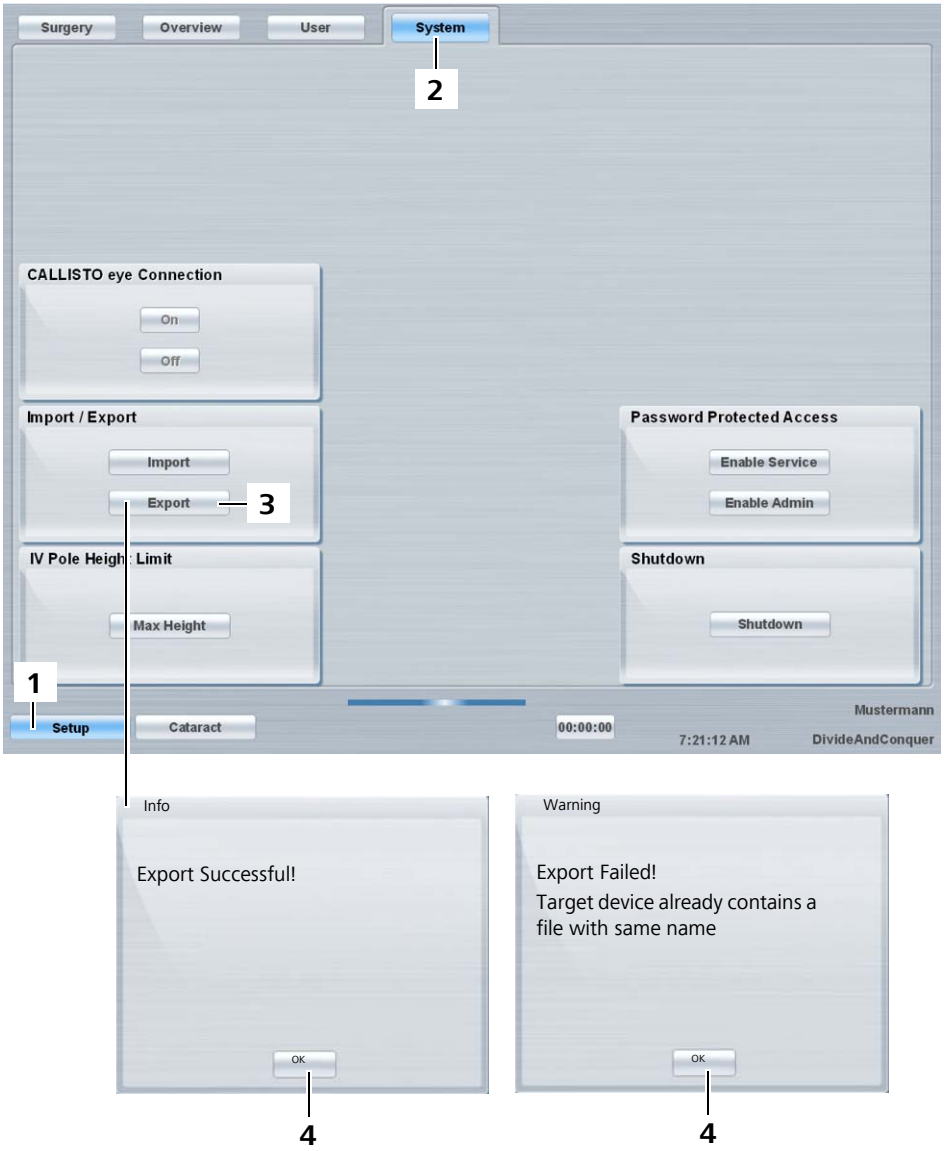
In the module "Export/Import" on the "System" page you can copy all users and programs created on the surgical system on a USB storage medium.





- Connect a USB storage medium to the USB ADAPTER FOR SOFTWARE UPDATES (C).
- Stick the USB ADAPTER FOR SOFTWARE UPDATES (B) in the REMOTE CONTROL connection (A) on the back of the surgical system.
- Tap the key Setup (1).
- Tap the tab System (2).
- Tap the key Export (3).
  - → After the successful export the message appears: "Export Successful".
  - → When an exported data set is already on the targeted storage device the message appears: "Export Failed! Target device already contains a file with same name".
- Confirm this with OK (4).

Fig. 32: Exporting users and programs



Importing users and programs

The export and import keys are deactivated by default. They are activated as soon as a USB storage device is connected to the surgical system.

– Note that the surgical system is case sensitive. Therefore account for correct spelling of user and program names!

– Only user and program files which have been exported by software release 2.0 can be imported again. Files from older software releases are not supported.

– When a user or a program is imported, the system automatically switches to the user "Zeiss", no matter which user had previously been selected.

NOTE

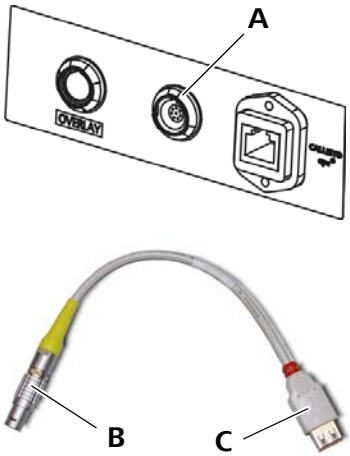
System malfunctions!

Computer viruses may cause system malfunctions!

- Use only tested and virus-free USB storage media.

Import all users with all programs

In the "Import / Export" module you can copy users and programs from your USB storage medium to the surgical system.



- Connect a USB storage medium to the USB ADAPTER FOR SOFTWARE UPDATES (C).
- Stick the USB ADAPTER FOR SOFTWARE UPDATES (B) in the REMOTE CONTROL connection (A) on the back of the surgical system.
- Tap the key Setup (1).
- Tap the tab System (2).
- Tap the key Import (3).

  → The pop-up window "Import Users" appears.

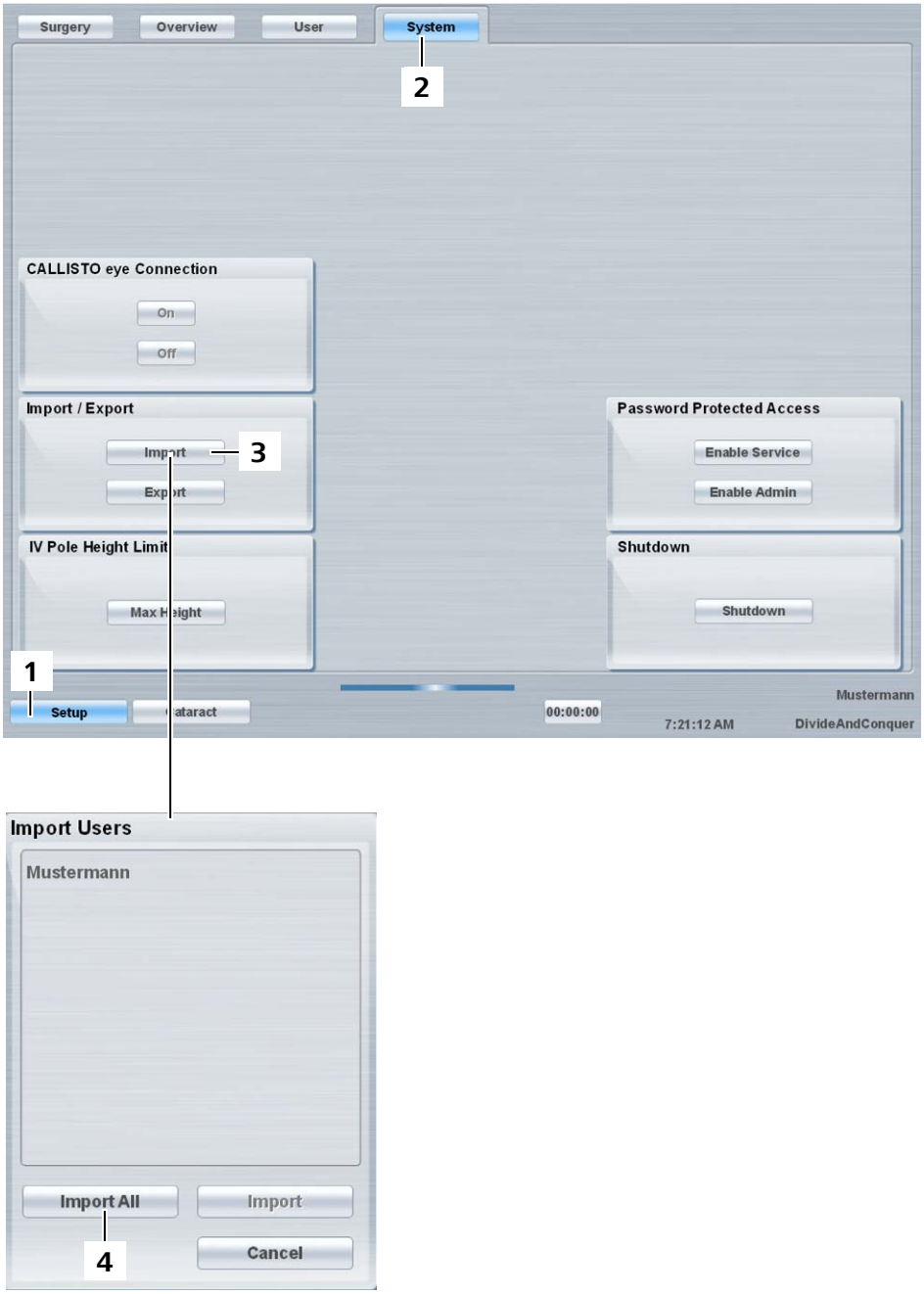
  → If no importable file is on the USB storage medium the message appears: "Import Failed! Could not find any valid file on input media!"

- To simultaneously import all users and programs, tap the key Import All (4).

  → The message appears: "Importing will overwrite all existing users. Do you want to proceed?"

- Confirm the individual step by tapping the key Yes or OK or stop it by tapping the key No .
- After the successful import the message appears: "Import successfull!"

Fig. 33: Importing users and programs



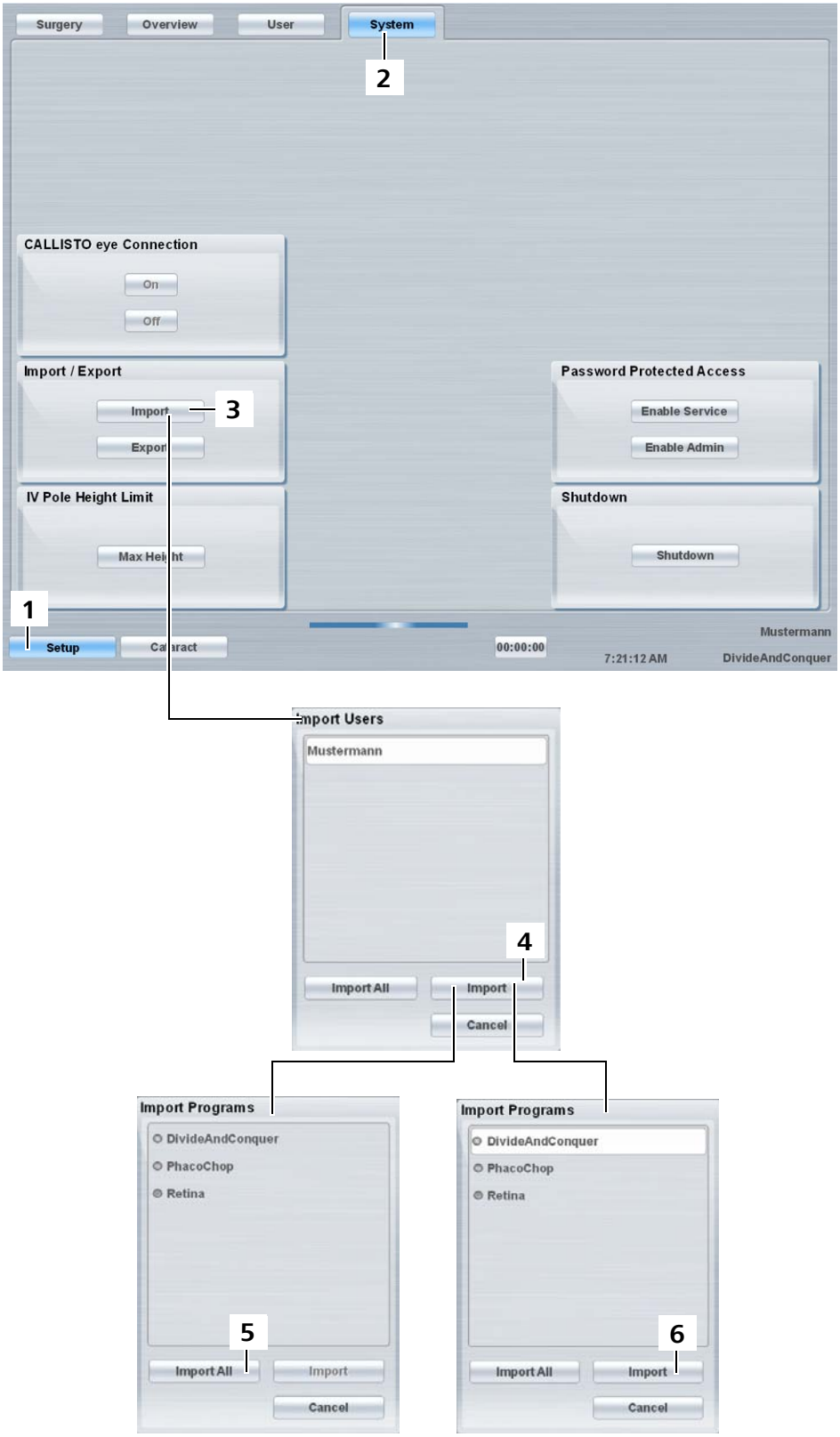
Import a specific user with all programs

- Tap the key Import (3).
  → The pop-up window "Import Users" appears.
- Select the desired user and tap the key Import (4).
  → The pop-up window "Import Programs" appears.
- To simultaneously import all programs, tap the key Import All (5).
  → If the user does not exist on the surgical system the message appears: "Import successfull!"
  → If the user does already exist on the surgical system the message appears: "Importing will overwrite all existing programs of this user. Do you want to proceed?"
- To overwrite the specific user and his programs confirm with the key Yes. If you want to cancel the process tap the key No.

Import a specific user and a specific program

- Tap the key Import (3).
  → The pop-up window "Import Users" appears.
- Select the desired user and tap the key Import (4).
  → The pop-up window "Import Programs" appears.
- Select the desired program and tap the key Import (6).
  → After the successful import the message appears: "Import successful!"
  → If a program already exists the message appears: Do you want to overwrite the existing program?"
- To overwrite the user confirm with the key Yes. If you want to cancel the process tap the key No.
  → After the successful import the following message appears: "Import successful".
- To close the pop-up window tap the key OK.

Fig. 34: Importing specific users and programs



Connecting network between VISALIS V500 / VISALIS S500 and CALLISTO eye (from version 3.6)

The module "CALLISTO eye Connection" permits you to connect the surgical system to CALLISTO eye (from version 3.6).

Prerequisites

✓ The network connection can only be used:

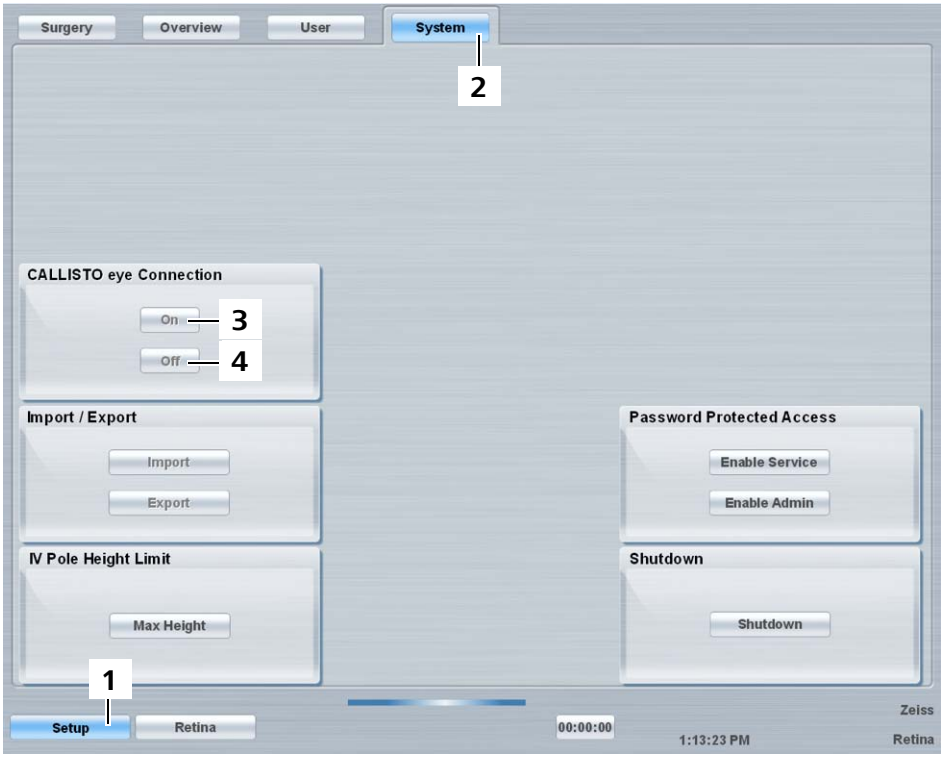
– if the system is connected to CALLISTO eye via a network cable

– if the network configuration is done in the Admin Submenu (see Page 114).

Connect the systems as follows:

- Tap the key Setup (1).
- Tap the tab System (2).
- To connect the surgical system with CALLISTO eye tap the key On (3).
- To disconnect the surgical system from CALLISTO eye tap the key Off (4).

Fig. 35: CALLISTO eye connection



Enabling "Admin" submenu

The submenu "Admin" (5) is a password protected area. It is used to carry out following procedures:

- Export currently loaded user settings
- Export Log files / Licences
- Configure network connection between the surgical system and CALLISTO eye (from version 3.6)
- Set System Time

Open the submenu "Admin" as follows:

Requirement Password: **V50020**

- Tap the key Setup (1).
- Tap the tab System (2).
- To open the protected area tap the key Enable Admin (4).

  → The menu "Enter admin pin" is displayed.
- Enter the password **V50020** and confirm this with OK.

  → The submenu "Admin" (5) is displayed.

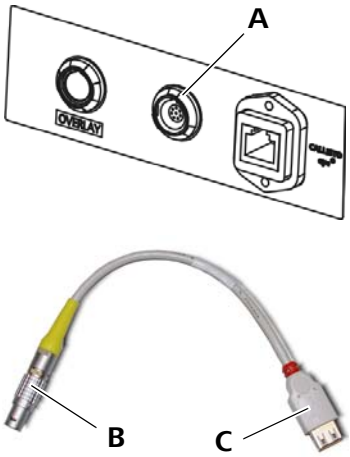
The submenu Enable Service (3) is only available for the ZEISS service.

Fig. 36: Enable Admin submenu

Exporting currently loaded user settings

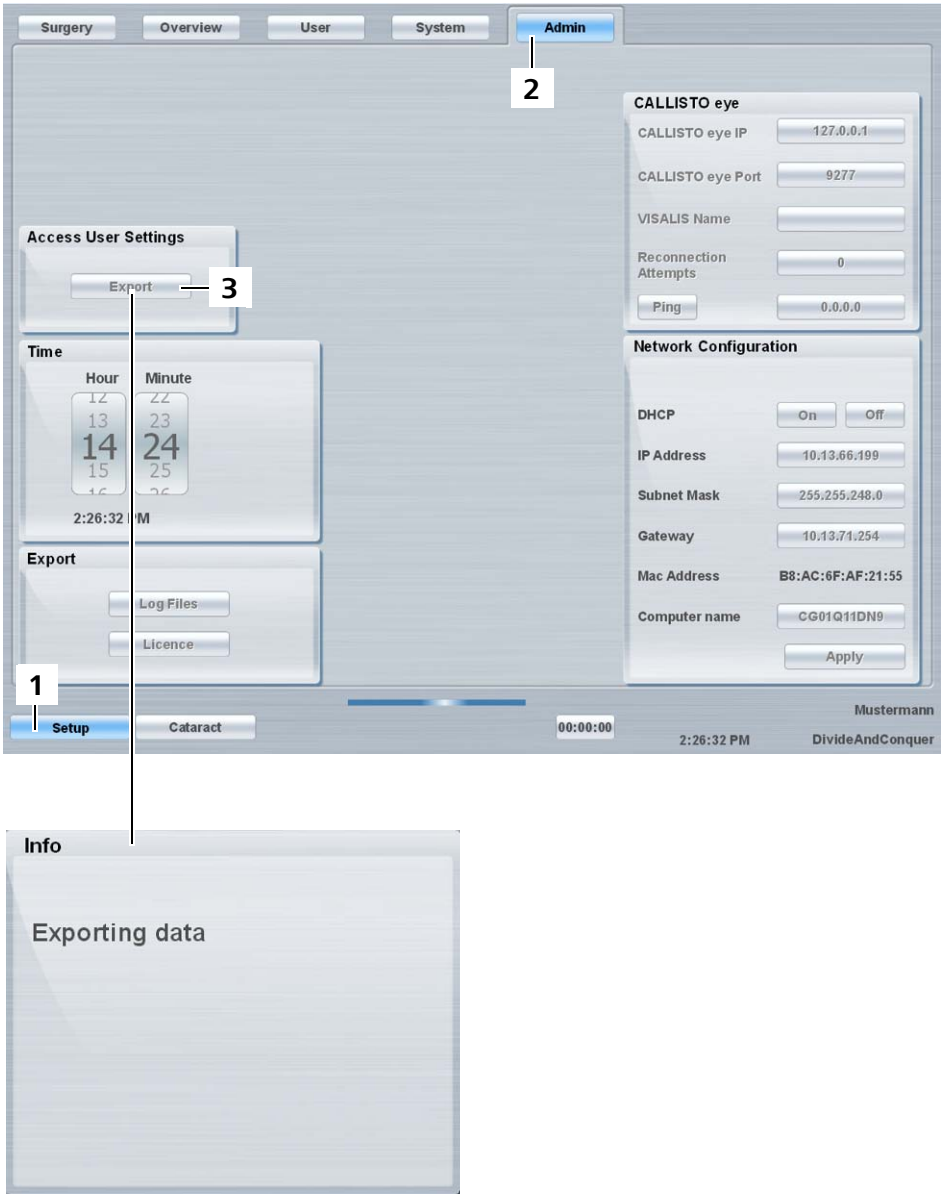
The module "Access User Settings" permits you to export the currently loaded user and his programs on a USB storage medium in a readable format.

The key "Export" is deactivated by default. It become activated as soon as a USB storage device is connected to the surgical system.



- Connect a USB storage medium to the USB ADAPTER FOR SOFTWARE UPDATES (C).
- Stick the USB ADAPTER FOR SOFTWARE UPDATES (B) in the REMOTE CONTROL connection (A) on the back of the surgical system.
- Tap the key Setup (1).
- Tap the tab Admin (2).
  If the submenu "Admin" is not yet displayed enable the submenu as described on Page 108.
- To export the currently loaded user and his programs tap the key Export (3).
  → After the successful export the message appears: "Export Successful".
  → After a failed export following messages could appear:
  – "Export Failed! Target device already contains a file with same name".
  – "Export Failed! Free disk space on the target device is insufficient!"
- Confirm this with OK (4).

Fig. 37: Export currently loaded user



Export Log Files / Licence

The module "Export" permits you to copy encrypted log files to a USB storage medium in the event of errors. You can then send these files to your ZEISS service technician who will be able to perform faster troubleshooting on this basis. Furthermore you can export the used open source licences.

Export the log files or licences as follows:

- Tap the key Setup (1).
- Tap the tab Admin (2).
  If the submenu "Admin" is not yet displayed enable the submenu as described on Page 108.
- Tap the key Log Files or Licence (3).

  → After the successful export the message appears: "Export Successful".
- Confirm this with OK.

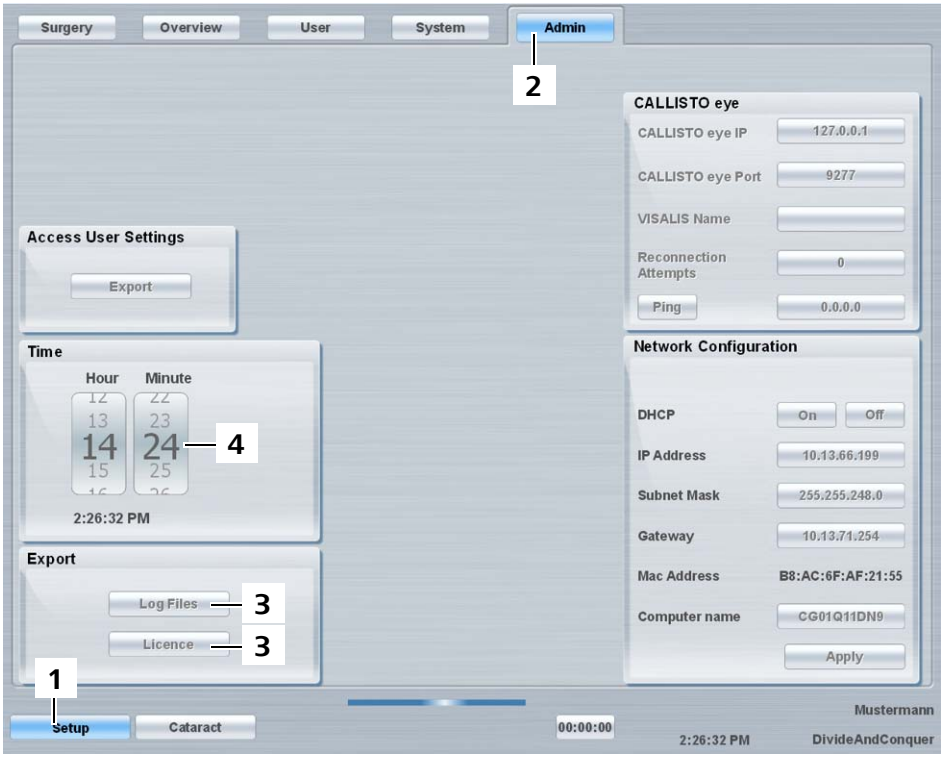
Set system time

The module "Time" permits you to set the system time. These settings affect the time shown in the status bar at the bottom of the screen.

Set the system time as follows:

- Tap the key Setup (1).
- Tap the tab Admin (2).
  If the submenu "Admin" is not yet displayed enable the submenu as described on Page 108.
- Set the time (4).

Fig. 38: Exporting Log Files and Licence



Configure network connection to CALLISTO eye (from version 3.6)

The "CALLISTO eye" (5) and the "Network Configuration" (6) module are used to configure the network connection between the surgical system and CALLISTO eye (from version 3.6).

Connect the surgical system as follows:

- Tap the key Setup (1).
- Tap the tab Admin (2).
  If the submenu "Admin" is not yet displayed enable the submenu as described on Page 108.

"CALLISTO eye" module

- Activate the entry box for the IP address of CALLISTO eye.

  → The keyboard dialog is opened.
- Enter the IP address of CALLISTO eye.
- Save the IP address by pressing the key OK.
- Repeat the last three steps to enter the "CALLISTO eye Port", "VISALIS Name" and "Reconnection Attempts".

"Network Configuration" module

Your local network administrator will tell you how to configure the Ethernet connection to ensure that it matches the network configuration at the place where it is to be used: "Static IP address" or "Dynamic IP address (DHCP)".

Dynamic IP address

A dynamic IP address is an IP address that is automatically assigned to the requesting device by an address service (DCHP server) available in the network.

- Tap the key DHCP On.

  → The entry keys "IP Address", "Subnet Mask" and "Gateway" are deactivated.

Static IP address

Static IP addresses are fixed IP addresses permanently assigned to a system (recommended operating mode). The data required for this purpose (IP address, subnet mask, gateway and computer name) will be communicated to you by your IT administrator. Names and addresses must not be assigned multiple times! They must occur only once in the network.

- Tap the key DHCP Off.
- Activate the entry box for the local, valid IP Address.

  → The keyboard dialog is opened.

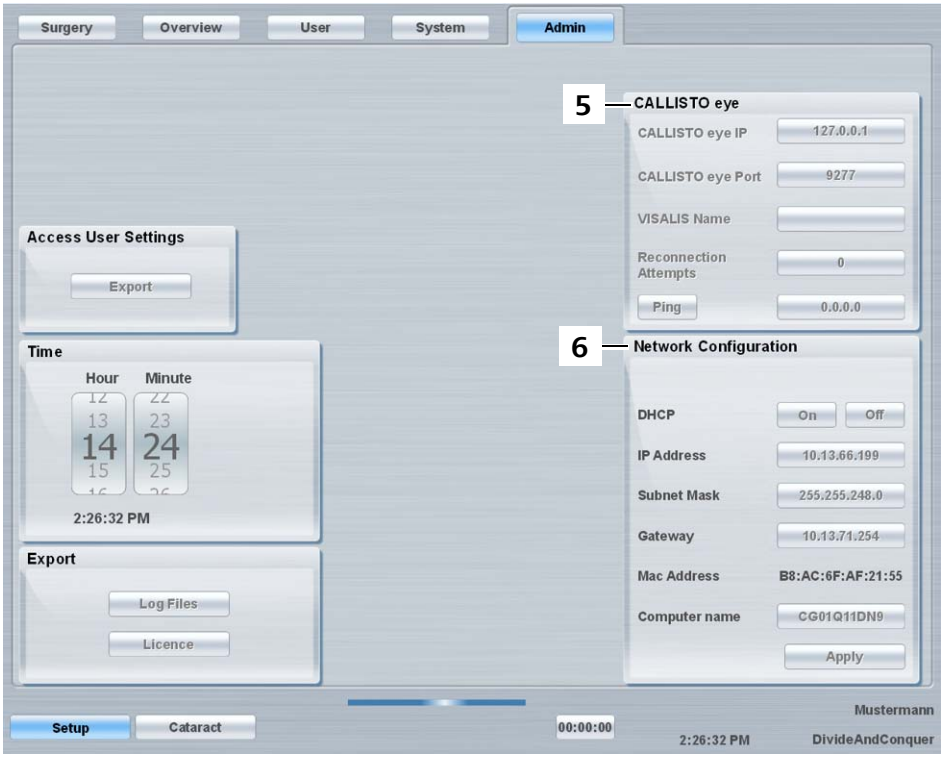
- Enter the static IP address to be used. Only numeric entries with the following syntax are possible: <No.>.<No.>.<No.>.<No.> (No. ranging between 0 and 255).
- Save the IP address by pressing the key OK.

  → The IP address is saved.
- Repeat the last three steps to enter the "Subnet Mask", "Gateway" and "Computer Name".
- Do a connection test. Press the key Ping in the CALLISTO eye module.

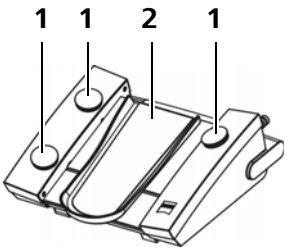
  → If the connection test failed, check your IP address and, if necessary, the subnet mask and gateway.
- Tap the key Apply.

The surgical system must be switched off and restarted after every change to the local network setting so that the surgical system can adopt the amended settings.

Fig. 39: Network connection



Configuring the DOUBLE LINEAR FOOTSWITCH II



General functionality

The DOUBLE LINEARL FOOTSWITCH II has a programmable central foot pedal (2) and three programmable side keys (1).

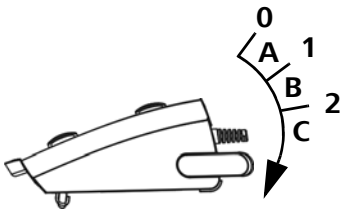
The foot pedal can be used either in single linear (vertical control only) or in dual linear mode (vertical and horizontal control). If the foot pedal is pressed down, the touchscreen displays the current foot pedal position 1, 2 or 3 in the module "Foot Switch". If the foot pedal is rotated to the left or right, then the current horizontal pedal direction >> << is displayed.

The functions of the three round side buttons and the function of left-right rotation of the foot pedal can be programmed in the module "Foot Switch" in two ways:

– One for all (see Page 118)

– Individual (see Page 120)

The functions for vertical control (see page 122) depend on the selected operating mode (e.g. "Diathermy") and cannot be changed.



If the foot pedal is pressed in area c (foot pedal position 3 on the touchscreen display) all side buttons are deactivated. If the upper left side button is pressed, the rotation function is deactivated.

The "Foot Switch" module in the cataract and retina modes and on the "Overview page" shows all current user assignments of the DOUBLE LINEAR FOOTSWITCH II.

CAUTION

Risk of injury to the patient!

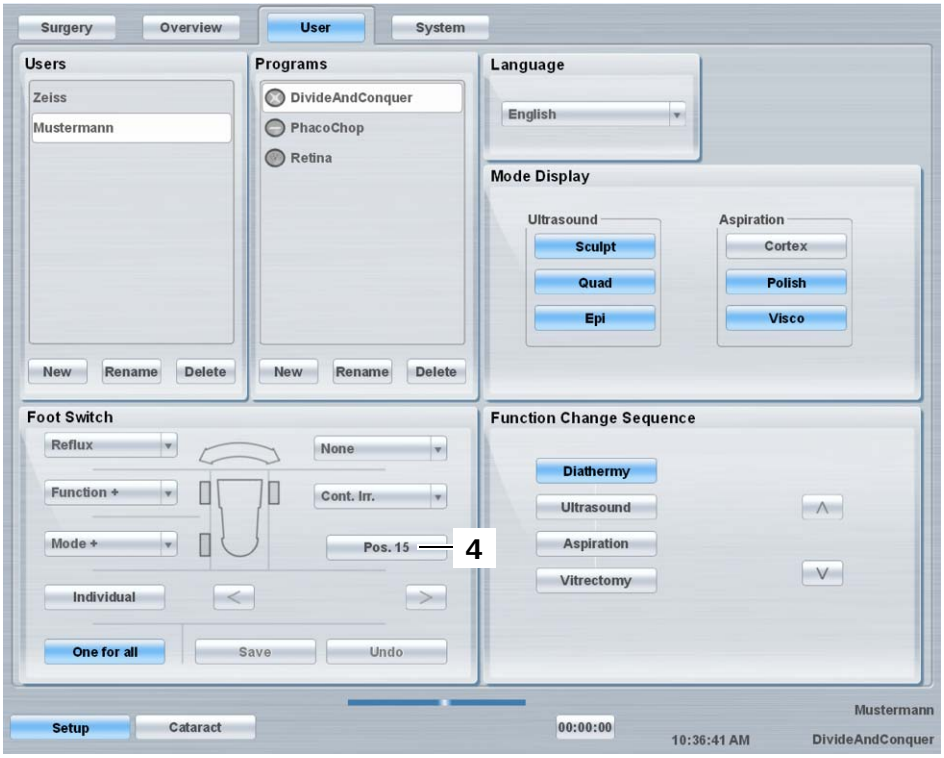
Because the actual response of the DOUBLE LINEAR FOOTSWITCH II to the actions of the user is programmable, some of the functions may not be where they are expected.

- Check the current assignment of the programmable switches before you commence the surgery.

In the module "Foot Switch" using the key "Pos 15" (4) you can access the menu "Set U/S Start Position". This allows you to set the trigger point for the application of ultrasound in terms of the foot pedal travel. The smaller the number of steps you set, the earlier the ultrasound application is started relative to aspiration.

This setting is only effective if the foot pedal is programmed for the ultrasound operation "single linear".

Fig. 40: Configuring the DOUBLE LINEAR FOOTSWITCH II



"One for all" programming

The "One for all" is a consistent configuration for all modes. The functions of the foot pedal and the side buttons are preconfigured similarly for each surgical function and surgical mode, but they can be customized to meet the user's specific requirements.

If you want to assign DOUBLE LINEAR FOOTSWITCH II elements to different surgical functions and surgical modes you can use the individual programming of the DOUBLE LINEAR FOOTSWITCH II (described on Page 120). This function makes it easy to determine the exact configuration.

Configure the "One for all" function as follows:

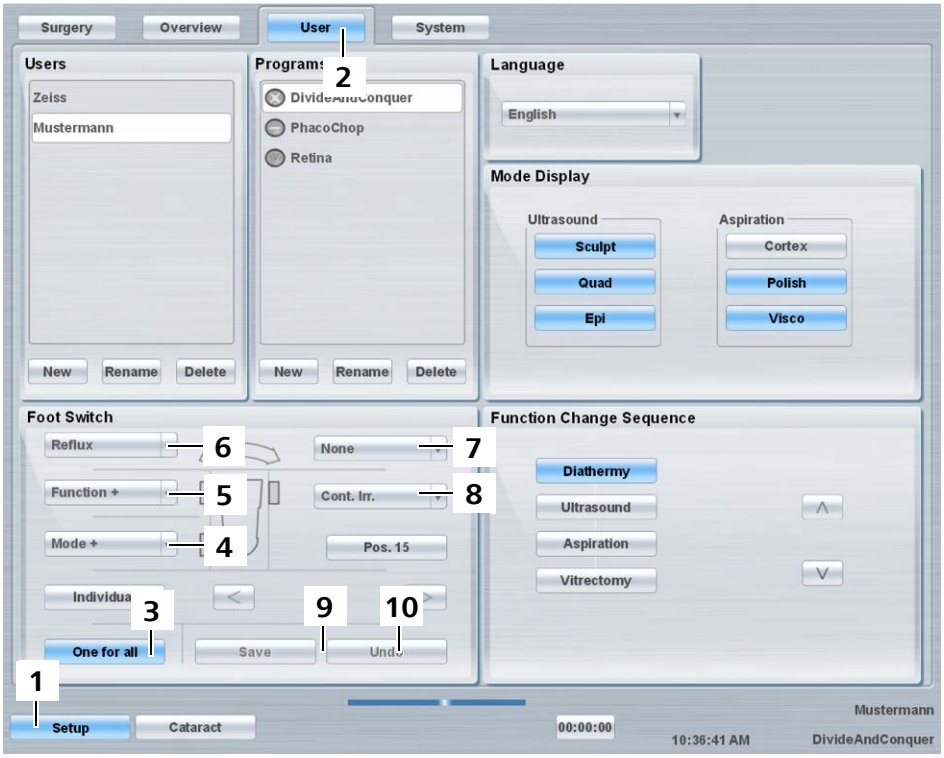
- Tap the key Setup (1).
- Tap the tab User (2).
- Tap the key One for all (3), if not already adjusted.
- In the module "Foot Switch", tap the function key (4 - 8) which you wish to reassign.

  → The assignables functions list (11) appears.
- Tap the function to be assigned.

  → The selected function appears next to the function key.

  → If a key has a function assigned to it that has already been assigned to a different button, the other button deactivates that function and is shown as "None" in the module "Foot Switch".
- Use this procedure for all DOUBLE LINEAR FOOTSWITCH II elements you wish to re-assign.
- In order to load the previous settings tap the key Undo (10).
- In order to save the settings tap the key Save (9).

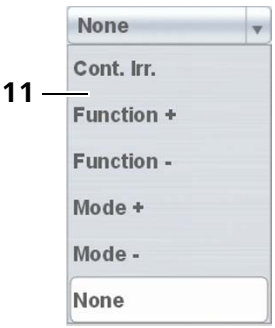
Fig. 41: "One for all" programming



"Individual" programming

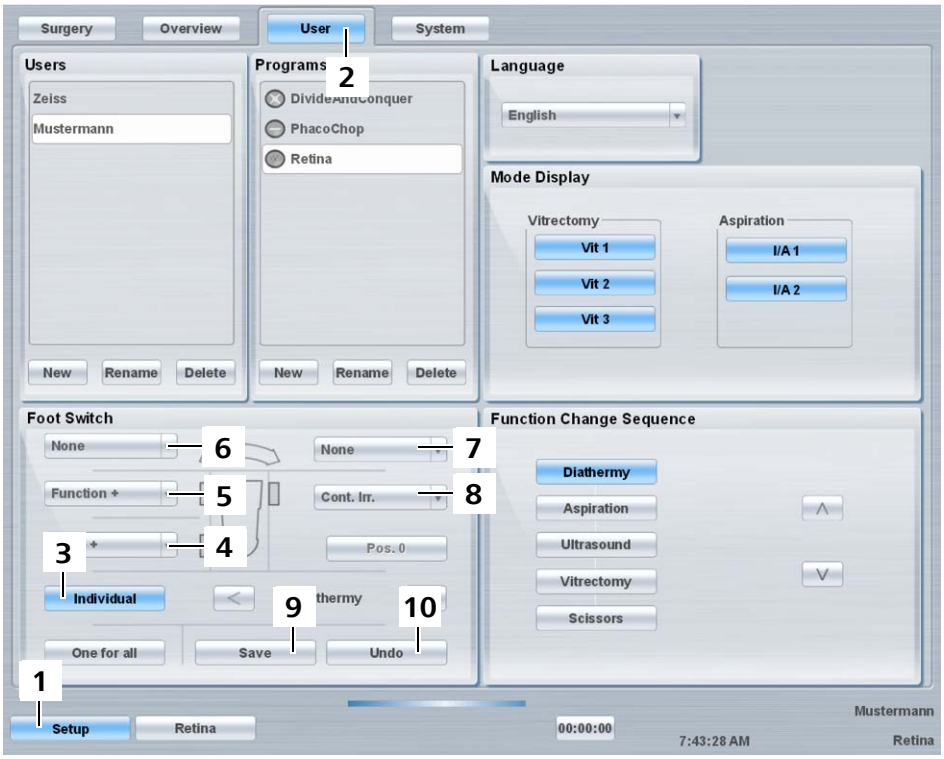
Configure the "Individual" function as follows:

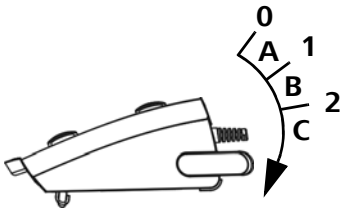
- Tap the key Setup (1).
- Tap the tab User (2).
- Tap the key Individual (3).
  - → The name of the currently loaded program function, for example "Diathermy" appears between the arrows keys.
  - → The adjustable functions of the foot pedal and side button for the currently loaded program function are activated.
- Select the surgical function or surgical mode you wish to modify by tapping the arrow keys < or >. The displayed surgical function or surgical mode depends from the adjusted program.
  - → The name of the selected surgical function or surgical mode appears between the arrow keys.
- Tap the function key (4 - 8) which you wish to reassign.
  - → The assignables functions list (11) appears.



- Tap the function to be assigned.
  - → The selected function appears next to the function key.
  - → If a key has a function assigned to it that has already been assigned to a different DOUBLE LINEAR FOOTSWITCH II element, the other element deactivates that function and is shown as "None" in the module "Foot Switch".
- Use this procedure for all DOUBLE LINEAR FOOTSWITCH II elements you wish to re-assign.
- In order to load the previous settings tap the key Undo (10).
- In order to save the settings tap the key Save (9).

Fig. 42: "Individual" programming

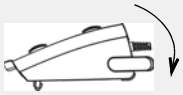


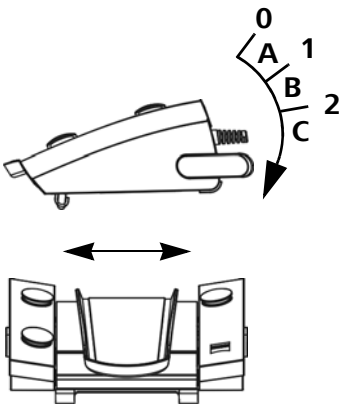


Use of the foot pedal with "single linear" control

In this control of function, the performance parameters of the foot pedal are supplied in vertical direction only. The "single linear" control is therefore active if the functions "U/S", "Cut" or "Vac2" are not assigned to the left or right of the foot pedal rotation.

The foot pedal has the resting position 0, two pressure positions (1, 2) and three areas (A, B, C). In the resting position 0, the foot pedal is in standby mode. In this position, no signals are transmitted to the equipment and so no functions are carried out. One exception to this rule is the "Continuous irrigation" function. If this function is activated, irrigation is active even with the foot pedal in resting position 0. The areas, A, B, and C have different functions depending on operating mode:

Mode	Rest position	Area A	Area B	Area C
I/A	-	Irrigation	Irrigation / Aspiration	
U/S	-	Irrigation	Irrigation / Aspiration	Irrigation / Aspiration / U/S power 
Vit	-	Irrigation	Irrigation / Aspiration / Cutting	
Diath	-	-	-	Diathermy

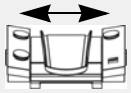
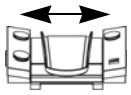


Use of the foot pedal with "dual linear" control

For this function control the foot pedal is moved in vertical and horizontal direction. The "dual linear" control is active if the surgical functions "U/S", "Cut" or "Vac2" of the foot pedal rotation are assigned to the left or right rotation.

The advantage of this type of control is the simultaneous execution of two functions. Depending on configuration, e.g. the U/S power can be independently controlled in linear mode during irrigation/aspiration.

The foot pedal has a resting position 0, two pressure positions (1, 2) and three areas (A, B, C). In the resting position, the foot pedal is in standby mode. In this position, no signals are transmitted to the equipment and so no functions are carried out. One exception to this rule is the "Continuous irrigation" function. If this function is activated, irrigation is active even with the foot pedal in resting position 0. The areas, A, B, and C have different functions depending on operating mode:

Mode	Rest position	Area A	Area B	Area C
I/A	-	Irrigation	Irrigation / Aspiration	
U/S	-	Irrigation	Irrigation / Aspiration / U/S power 	
			If the function "U/S" of the foot pedal rotation "left or right" is assigned, then the U/S power in the vertical direction is deactivated. Turn the foot pedal slightly to the left or right to activate the U/S power. If "Linear" mode is adjusted a further rotating the foot pedal creates a linear change of the U/S power from 0 µm up to the preset maximum value.	
Vit	Cutting	Irrigation / Cutting	Irrigation / Aspiration / Cutting 	
	If the function "Cut" of the foot pedal rotation is assigned "left or right", then the cutting function is deactivated in the vertical direction. Turn the foot pedal slightly left or right to activate the vitrectomy. If "Linear" mode is adjusted a further rotating the foot pedal creates a linear change of the cutting rate from 60 cuts/min up to the preset maximum value. If the function "Cut off" from the foot pedal rotation "left or right" is assigned, then you can turn the foot pedal from the area B to the left or to the right in order to disable the cutting function.			
Diath	-	-	-	Diathermy

Programmable functions of the DOUBLE LINEAR FOOTSWITCH II

Function	FSP left/right		Side buttons	Description	Mode	
	Linear control	On / Off	On / Off		Cataract	Retina
Cont. Irr.		x	x	Continuous irrigation is activated/disabled.	x	x
Cut	x			Cutting function is started up, while irrigation/aspiration continues to run in parallel. Works in vitrectomy and scissors modes only.	x	x
Cut off		x		The cutting function is stopped and only irrigation/aspiration is available. Works in vitrectomy and scissors modes only.	x	x
Function + (forward) Function - (backward) * If a surgical function consists of several surgical modes then the left surgical mode is activated first.		x	x	Switch between the following surgical functions in the catarct menu in both directions: – <**Diathermy**> - <**Sculpt**, Quad, Epi>* - <**Cortex**, Polish, Visco>* - <**Ant Vit**> Switch between the following surgical functions in the retina menu in both directions: – <**Diathermy**> - <**IA1**-IA2>* - <**Phaco frag**> - <**Vit1**-Vit2-Vit3>* - <**Scissors**> The module "Function Change Sequence" on the "Setup / User" page permits you to change the sequence of surgical functions (see Page 96).	x	x
Mode + (forward) Mode - (backward)		x	x	Switch between the following surgical modes in the cataract menu in both directions: – <Sculpt> - <Quad> - <Epi> – <Cortex> - <Polish> - <Visco> Switch between the following surgical modes in the retina menu in both directions: – <I/A1> - <I/A2> – <Vit1> - <Vit2> - <Vit3> Only active surgical modes are displayed in the menu cataract or retina. They can be selected by pressing down the programmed side button of the DOUBLE LINEAR FOOTSWITCH II or by tapping the related tab on the touchscreen (see Page 94).	x	x

Function	FSP left/right		Side buttons	Description	Mode	
	Linear control	On / Off	On / Off		Cataract	Retina
IVP Down			x	Conducts the infusion pole for the infusion bottle down.	x	x
IVP Up			x	Conducts the infusion pole for the infusion bottle up.	x	x
US/Cut	x	x		In phaco modes ultrasound is started, in vitrectomy and cissors modes cutting function is started. In both cases irrigation/aspiration continues to run in parallel. Works in phaco, vitrectomy and scissors modes only.	x	x
US/Cut off		x		The cutting or ultrasound function is stopped and only irrigation/aspiration is available. Works in vitrectomy or scissors/phaco modes only.	x	x
Ultrasound	x	x		Ultrasound function is started up while irrigation/aspiration continues to run in parallel. Works in phaco modes only.	x	x
Vac 2	x			Vacuum 2 is available.	x	x
Reflux		x		Introduces fresh balanced salt solution into the aspiration line and breaks vacuum.	x	x
None		x	x	Foot pedal rotation is disabled. Side key is disabled.	x	x
Oil	x	x	x	Oil is available. Works in retina modes only.		x
Air		x	x	Air is available. Works in retina modes only.		x
Light 1 / 2		x	x	Light 1 or 2 is available. Works in retina modes only.		x
Filter 1 / 2		x	x	Swivel in or out the filter "protect, green or off".		
Max Irrigation		x	x	Maximum irrigation is available. Works in retina modes only.		x

- **If the foot pedal is pressed in pedal position 3 all side buttons are deactivated.**
- **If the upper left side button of the foot switch is pressed, the rotation function is deactivated.**

Mounting I/A cassette and fluidic system

Mounting I/A cassette

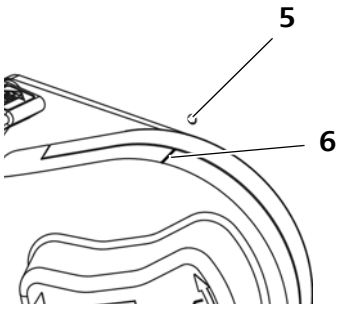
Always keep in mind the Instruction for Use of the I/A cassette before you unpack, connect and use it.

Circulating nurse

- Clean the outside of the packaging of the I/A cassette before entering the OR room; wear suitable clothing; bring it to the place where it will be used.
- Open the packaging without touching the contents.

OR nurse

- Remove the sterile I/A cassette (3) from the packaging. Avoid any contact with the unsterile outside of the packaging and other unsterile objects.
- Remove the banner from the drainage bag.



- (A) Set the sterile I/A cassette on the pump plate (1) on which you position the hole on the back of the I/A cassette on the pin (2) to the pump plate. The reference line (6) of the I/A cassette and the reference mark (5) of the pump plate must be congruent.
- (B) Press the sterile I/A cassette (3) entirely against the pump plate and turn it clockwise until it engages.
- (C) Review the correct assembly of the sterile I/A cassette on the basis of a visibility test in consideration of the following points:
  - there are no clamped tubes
  - the I/A cassette lies flush on the pump plate
  - the I/A cassette lies flush on the locking mechanism

Circulating nurse

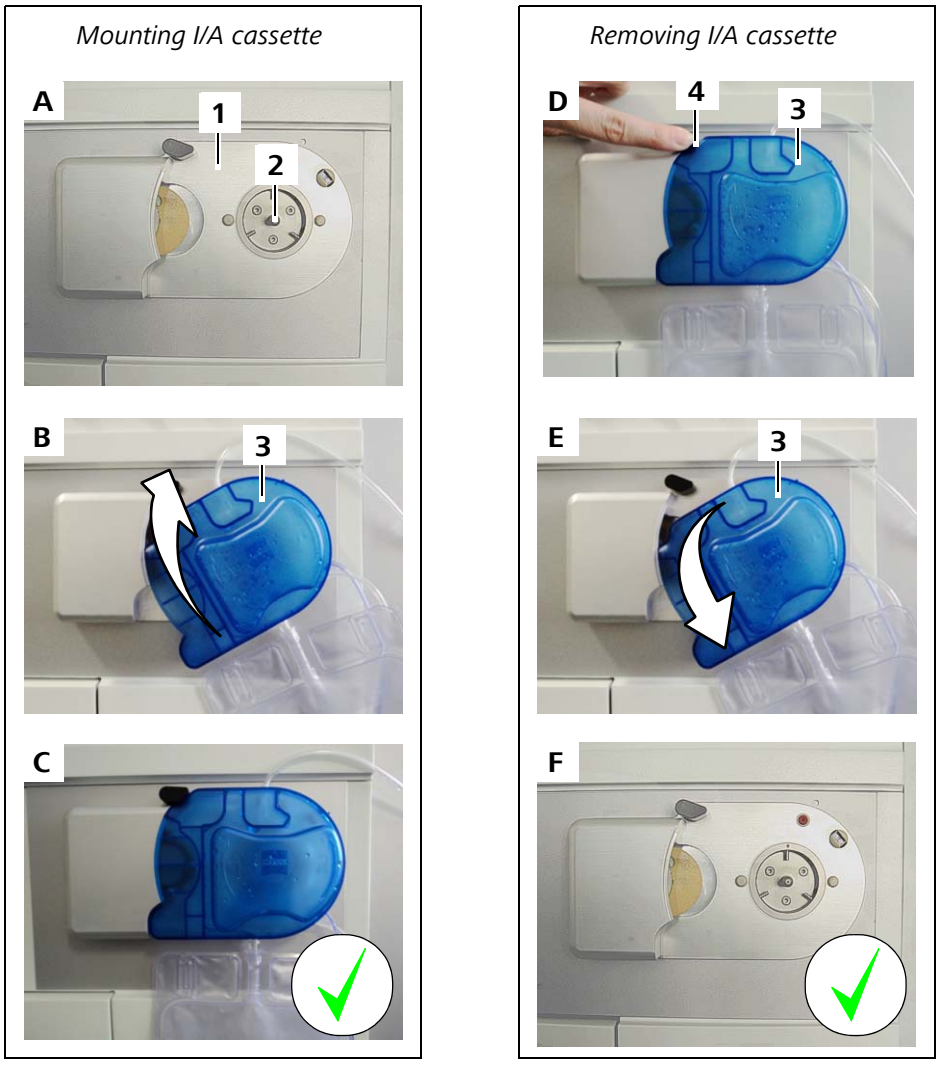
- Connect the suitable accessories for the desired irrigation type. You can choose from the following irrigation types:
  - Gravity irrigation (see page 128)
  - Controlled irrigation (see page 134)
  - Combined irrigation (see Page 130)

Removing I/A cassette

- (D) To remove the I/A cassette (3) after completing the operation press the "PUSH" button (4).

  → Wait for the peristaltic pump to be fully retracted.
- (E) Turn the I/A cassette (3) counterclockwise, until the reference line of the I/A cassette (6) and the reference mark of the pump plate (5) are congruent.
- (F) Remove the I/A cassette (3).

Fig. 43: Installing/removing I/A cassette



Mount fluidic system "Gravity irrigation"

Always keep in mind the Instruction for Use of the I/A cassette before you connect and use it.

Circulating nurse

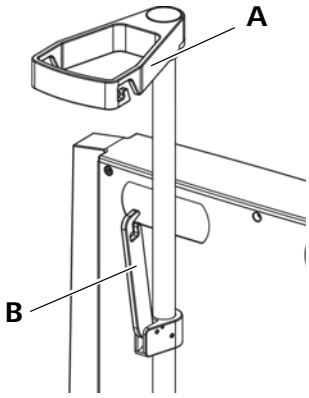
- Connect the male Luer lock of the flush line (3) of the flushing set (included in the delivery of the I/A cassette) with the female Luer lock of the flush line (2) of the I/A cassette (1).
- Close the clamp (5) of the infusion set to prevent an unintentional flow of balanced salt solution (BSS).

CAUTION

Risk of infection!

When exchanging the infusion bottle (6) pathogens may enter into the balanced salt solution and contaminate it.

- Perform the exchange of the infusion bottle in aseptical manner.



- Disinfect the cap of the infusion bottle (6) and stick the drip chamber spike (4) of the infusion set in the middle of the rubber stopper of the infusion bottle.
- Hold the infusion bottle in a vertical position. Compress the drop chamber and release it until it is half full.
- Suspend the infusion bottle on the infusion pole. For cataract use, use the upper hooks (A); for retina use the lower hooks (B).

For mounting the infusion bottle you can electronically lower the infusion pole.

CAUTION

Injury to the patient's eye!

When the infusion pole drives downward, the infusion bottle may touch the touchscreen and change settings of the system.

- Lowering the infusion pole, make sure that the infusion bottle does not touch the touchscreen.

OR nurse (only with a draped touchscreen)

- For lowering the infusion pole tap the key Change in the menu "Set-up".

  → The infusion pole moves down to its lowest height and the pop-up window "Info" appears.

- For lifting the infusion pole tap the key OK in the pop-up window.

Circulating nurse

- Open the clamp (5) of the infusion set to receive the flow again.

OR nurse

- Remove the safety caps on the free ends of the irrigation (7) and aspiration tubes (8).
- Connect the end of the irrigation (7) and aspiration tubes (8) to the corresponding connectors of the respective handpiece (see page 136).

Adjust the irrigation type and bottle height

OR nurse (only with a draped touchscreen)

- In the submenu "Surgery" tap the key IVP High Hook for cataract applications and the key IVP Low Hook for retina applications.

  → The infusion bottle symbol displays the selected hooks.

- Tap the key Cataract or Retina to access the desired operation mode.

Set the irrigation pressure for cataract applications by the height of the infusion bottle with the arrow keys or the slider in the module "Irrigation" (see page 200). The settings for the Irrigation pressure for retina applications is described on page 226 .

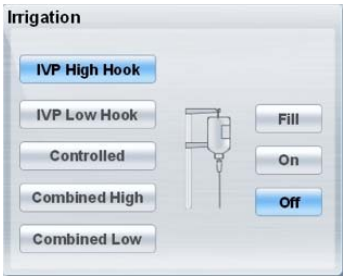
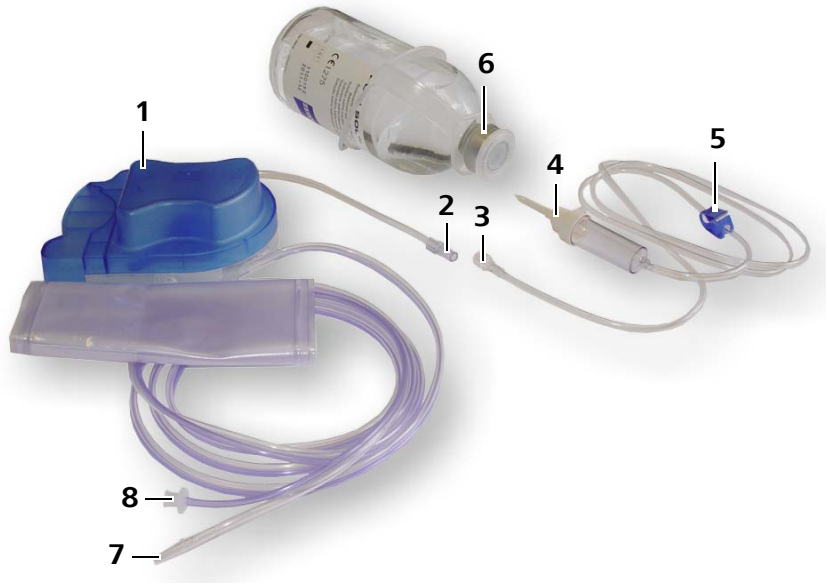


Fig. 44: Gravity irrigation



Mount fluidic system "Combined irrigation"

Always keep in mind the Instruction for Use of the ADVANCED IRRIGATION TUBINGS before you connect and use it.

Circulating nurse

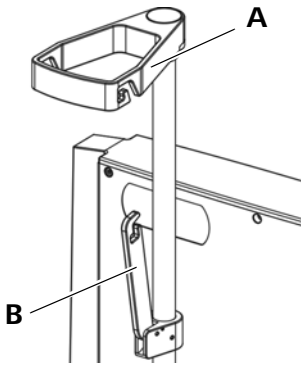
- Connect the male Luer lock of the flush line (3) of the flushing set with the female Luer lock of the flush line (2) of the I/A cassette (1).
- Close the clamp (5) of the ADVANCED IRRIGATION TUBINGS to prevent an unintentional flow of balanced salt solution (BSS).

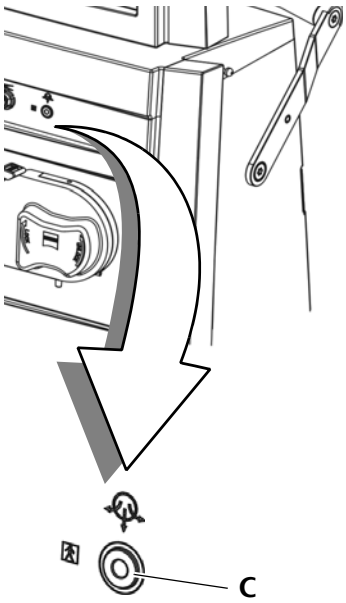
CAUTION

Risk of infection!

When exchanging the infusion bottle (6) pathogens may enter into the balanced salt solution and contaminate it.

- Perform the exchange of the infusion bottle in aseptical manner.



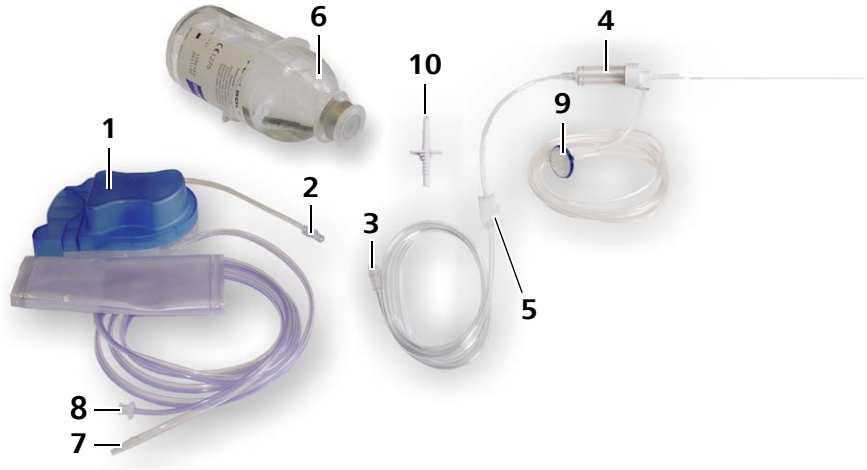


- Remove the sterile products from the packaging and place it on a sterile surface.
- Close the clamp (5) on the ADVANCED IRRIGATION TUBINGS to interrupt the flow.
- If the product with extended spike is used, push through the piercing tool (10) into the center of the bottle's rubber stopper and pull it out again. The originated guideway allows you to insert the extended spike without damaging.
- While the bottle of balanced salt solution is in a vertical position, insert the drip chamber's spike (4) into the center of the bottle's rubber stopper.
- Connect the male Luer lock connector to the female Luer lock connector of the ZEISS I/A cassette.
- Connect the air pressure tube (9) to the air pressure socket (C) of the ZEISS phaco system.
- Squeeze the drip chamber (4) and release it until it is half full.
- Attach the bottle of balanced salt solution (6) to the hook on the IV Pole. For cataract use, use the upper hooks (A); for retina use the lower hooks (B).
- Reopen the clamp (5) on the irrigation tube to allow the flow to resume.

For mounting the infusion bottle you can electronically lower the infusion pole.

Fig. 45: Combined irrigation CATARACT ADVANCED IRRIGATION TUBING

Fig. 46: Combined irrigation RETINA ADVANCED IRRIGATION TUBING



CAUTION

Injury to the patient's eye!

When the infusion pole drives downward, the infusion bottle may touch the touchscreen and change settings of the system.

- Lowering the infusion pole, make sure that the infusion bottle does not touch the touchscreen.

OR nurse (only with a draped touchscreen)

- For lowering the infusion pole tap the key Change in the menu "Set-up".

  → The infusion pole moves down to its lowest height and the pop-up window "Info" appears.

- For lifting the infusion pole tap the key OK in the pop-up window.

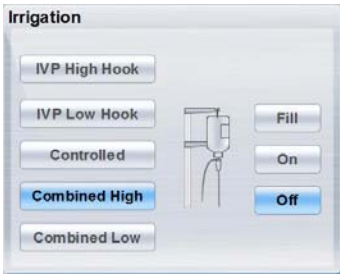
Circulating nurse

- Open the clamp (5) of the infusion set to receive the flow again.

OR nurse

- Remove the safety caps on the free ends of the irrigation (7) and aspiration tubes (8).
- Connect the end of the irrigation (7) and aspiration tubes (8) to the corresponding connectors of the respective handpiece (see page 136).

Adjust the irrigation type and bottle height



OR nurse (only with a draped touchscreen)

- In the submenu "Surgery" tap the key Combined High for cataract applications and the key Combined Low for retina applications.

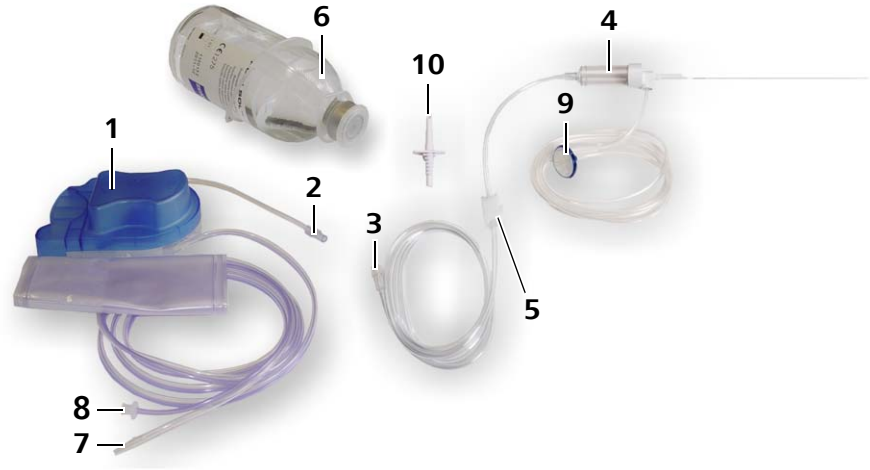
  → The infusion bottle symbol displays the selected hooks.

- Tap the key Cataract or Retina to access the desired operation mode.

Set the irrigation pressure for cataract applications by the height of the infusion bottle with the arrow keys or the slider in the module "Irrigation" (see page 200). The settings for the Irrigation pressure for retina applications is described on page 226 .

Fig. 47: Combined irrigation CATARACT ADVANCED IRRIGATION TUBING

Fig. 48: Combined irrigation RETINA ADVANCED IRRIGATION TUBING

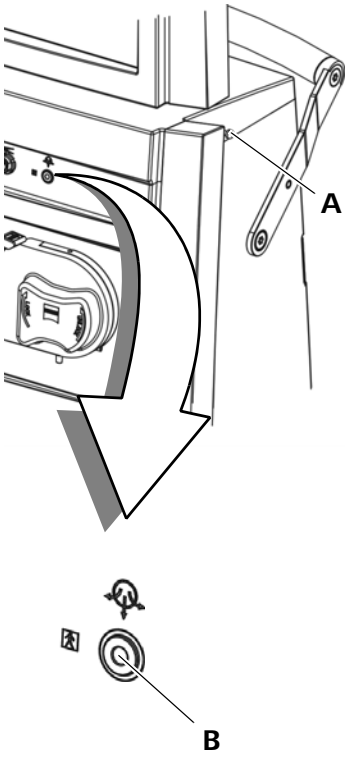


Mount fluidic system "Controlled irrigation" (not yet available)

The infusion bag looks inflated and is so independently of how much balanced salt solution (BSS) is still available. As a series of vertical lines printed on the internal surface of the infusion bag move forwards, the progressive consumption of the balanced salt solution (BSS) is indicated. When the vertical lines between the two horizontal lines printed on the front side of the bag become visible another 100 cc (ml) are still available.

Mount accessories

Always keep in mind the Instruction for Use of the accessories used before you unpack, connect, and use it.



Circulating nurse

- Hang the infusion bag (8) on the suspension device (A) on the right side of the surgical system.
- Connect the Luer connection (7) of the infusion bag to the air socket (B) of the surgical system.
- Close the clamp (4) of the infusion set (included in the delivery of the infusion bag) in order to prevent an unintentional flow of balanced salt solution (BSS).
- Disinfect the cap of the infusion bag and insert the drip chamber spike (5) completely and centered in the rubber plug of the infusion bag (6).
- Compress the drip chamber and release it until it is half filled.

OR nurse

- Remove the safety cap of the male Luer Lock connection (3) at the end of the flush line of the infusion set.
- Remove the safety cap of the female Luer Lock connection (2) on the flush line of the I/A cassette (1).
- Connect the two Luer Lock connections (2 and 3) to each other.

Circulating nurse

- Open the clamp (4) of the infusion set in order to reproduce the flow.

OR nurse

- Remove the safety caps on the free ends of the irrigation (9) and aspiration line (10).
- Connect the end of the irrigation (9) and aspiration lines (10) to the corresponding connectors of the respective handpiece (see page 136).

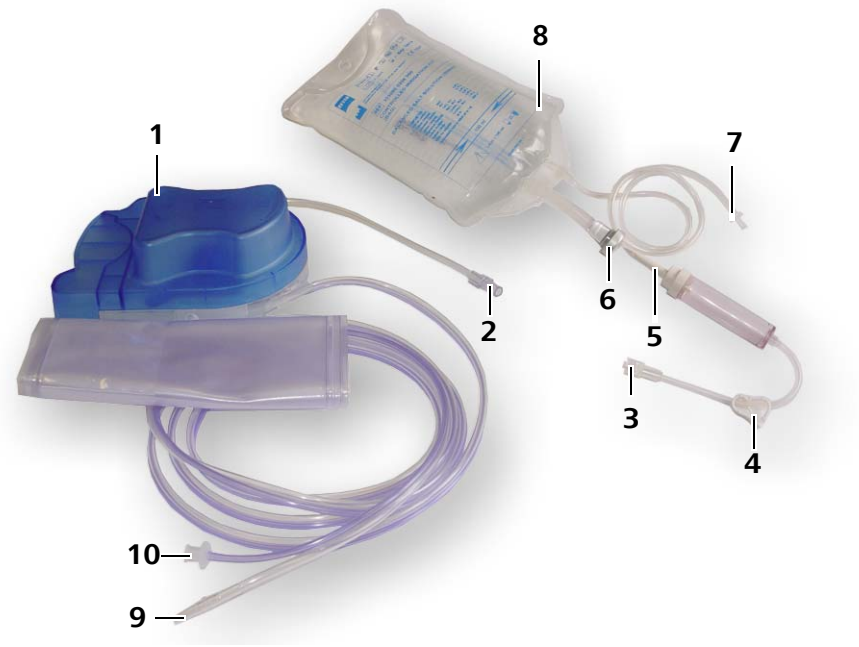
Fig. 49: Controlled Irrigation

Adjust the irrigation type

OR nurse

- In the menu "Setup" tap the key Controlled .
  → The symbol in the module "Irrigation" changes into an infusion bag with balanced salt solution (BSS).
- Tap the key Cataract or Retina to reach the desired surgical operation mode.

Set the irrigation pressure with the arrow keys or the slide in the module "Irrigation" (see page 200).



8 - CONTROLLED IRRIGATION KIT (not yet available)

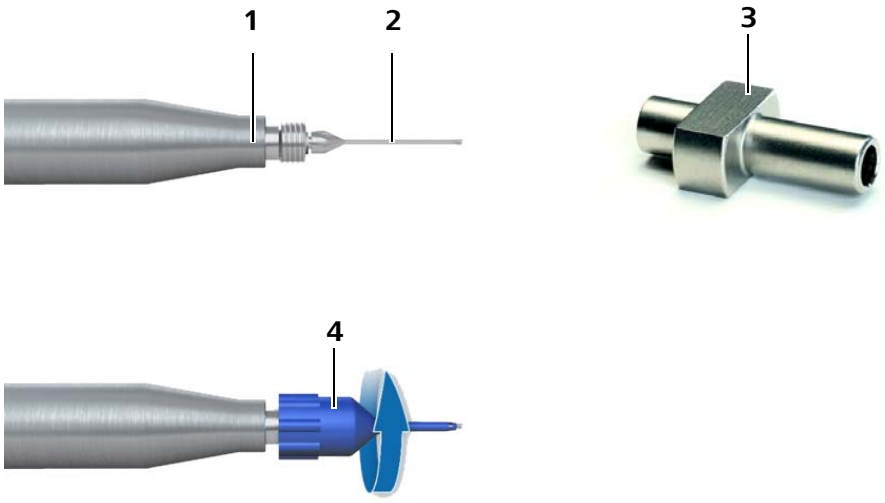
Mount accessories for cataract surgery and connect irrigation and aspiration tubes

Mounting and connecting phaco accessories

Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

- Screw the desired PHACO TIP (2) into the end of the ULITE PHACO HANDPIECE (1) so that the threads correctly mesh into each other. Tighten the tip firmly with your fingers.
- Guide the PHACO TIP WRENCH (3) on the flange side carefully over the PHACO TIP (2) so that the PHACO TIP WRENCH locks into the notches at the socket of the PHACO TIP.
- Carefully turn the PHACO TIP clockwise with the PHACO TIP WRENCH **firmly in**.
- Then remove the PHACO TIP WRENCH (3).
- Carefully slide the threaded SILICONE SLEEVE (4) over the PHACO TIP (2) until the threads engage.
- Turn the SILICONE SLEEVE (4) slowly on the ULITE PHACO HANDPIECE (1) firmly until the end of the SILICONE SLEEVE leaves an appropriate extent of PHACO TIP uncovered.

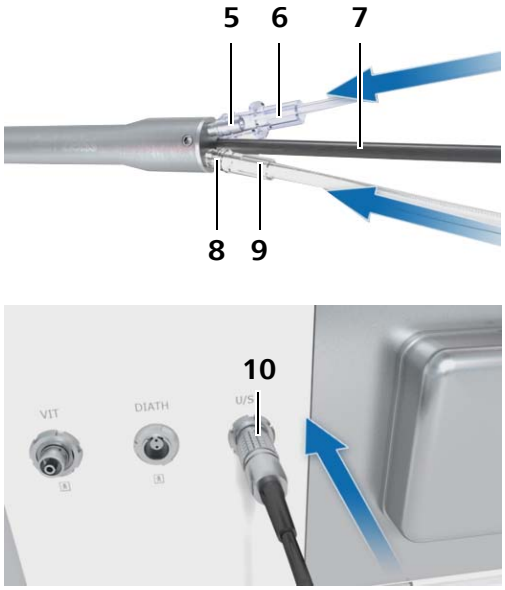
Fig. 50: Mounting and connecting phaco accessories



Connecting irrigation and aspiration tubes

- Push the aspiration tube (6) of the I/A cassette into the corresponding connection piece on the ULITE PHACO HANDPIECE (5) and turn it clockwise firmly on.
- Push the irrigation tube (9) of the I/A cassette into the corresponding connection piece on the ULITE PHACO HANDPIECE (8) and turn it clockwise firmly on.
- Plug the electrical power plug (7) of the ULITE PHACO HANDPIECE into the U/S socket (10) on the front of the unit.
- Connect the I/A cassette to the equipment, if this has not already been done, and connect it to the infusion bottle. For detailed information about this procedure, refer to page 126.

Fig. 51: Connecting irrigation and aspiration tubes



Prepare and carry out priming

The priming procedure is a combination of I/A priming and tuning in order to prepare the surgical system for phacoemulsification. During this procedure the fluidic system (I/A cassette with connected phaco handpiece and PHACO TIP) is filled with balanced salt solution. Furthermore it circulates the irrigation fluid through the aspiration tube into the collection bag.

The first priming after startup the surgical system and the first priming after changing the I/A cassette, the fluidic system is tested for correct vacuum or leakage. All consecutive optional 're-primings' are carried out without vacuum tests.

A priming procedure is essential:

– before first activating of aspiration, ultrasound or cutter

– after changing the I/A cassette

Requirements

✓ The completely mounted phaco handpiece is connected to the surgical system and located above the mounted I/A cassette.

✓ The clamp on the infusion set is opened.

✓ The foot pedal is in position "0" for more than 5 seconds.

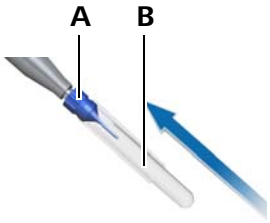
WARNING

Injury to the patient's eye!

Priming while using a handpiece on a patient's eye leads to possible eye injuries.

- Never carry out a priming while using a handpiece on a patient's eye.

Carry out priming



- Fill the TEST CHAMBER (B) with balanced salt solution (BSS) and install it on the SILICONE SLEEVE (A).
- Bring the TEST CHAMBER to the height of the I/A cassette.
- Tap the key Prime in the menu "Setup".
  → The message "I/A Prime/Flushing" appears.
  → The IV Pole is moved to the highest position defined by the adjusted IV Pole height limit. A complete automatic equipment test is only performed for mandatory primings (see above).
  → All consecutive 're-Primings' merely perform a reduced check (without tests for correct vacuum or leakage).
- If you want to stop the priming procedure tap the key Stop in the menu "Setup" or carry out a foot switch operation.

The priming procedure without I/A priming is called "Tuning" (see Page 140).

→ After the successful priming, the message "Ultrasound ready" appears. The message indicates that the device is ready for use.

→ If priming fails follow the direction for the respective system alarm message (see description page 252).

Prepare and carry out tuning

The tuning procedure prepares the surgical system for phacoemulsification, without testing the fluidic system for correct vacuum or leakage. The surgical system checks only the connected phaco handpiece with the PHACO TIP.

A tuning procedure is essential:

– after changing the PHACO TIP

– after tightening the PHACO TIP

Requirements

✓ The phaco handpiece is connected and successfully primed or I/A primed.

✓ The clamp on the infusion set is opened.

✓ The foot pedal is in position "0" for more than 5 seconds.

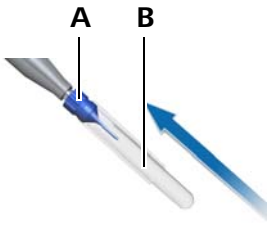
WARNING

Injury to the patient's eye!

Tuning while using a handpiece on a patient's eye leads to possible eye injuries.

- Never carry out a tuning while using a handpiece on the patient's eye.

Carry out tuning



- Fill the TEST CHAMBER (B) with balanced salt solution (BSS) and install it on the SILICONE SLEEVE (A).
- Tap the key Tune in the menu "Setup".
- If you want to stop the tuning procedure tap the button Stop on the "Setup" page or carry out a foot switch operation.

  → After the successful tuning, the message "U/S ready" appears. The message indicates that the device is ready for use.

  → If tuning fails follow the direction for the respective system alarm message (see description page 252).

Prepare and carry out I/A priming

The I/A priming procedure prepares the surgical system for irrigation/aspiration applications. During this procedure the fluidic system (I/A cassette with connected irrigation and aspiration tube) is filled with balanced salt solution. Furthermore it circulates the irrigation fluid through the aspiration tube into the collection bag.

The first I/A priming after startup the surgical system and the first I/A priming after changing the I/A cassette, the fluidic system is tested for correct vacuum or leakage. All consecutive optional 're-I/A primings' are carried out without vacuum tests.

An I/A priming procedure is essential:

- to perform anterior or posterior vitrectomy procedure only
- after changing the I/A cassette

Requirements

- ✓ If no handpiece is used the irrigation/aspiration tube has to be short-circuit.
- ✓ The clamp on the infusion set is opened.
- ✓ The foot pedal is in position "0" for more than 5 seconds.

Carry out I/A priming

- Remove the irrigation tube from the irrigation port of the I/A handpiece and the aspiration tube from the aspiration port of the I/A handpiece.
- Connect the irrigation and aspiration tube.
- Tap the key I/A in the menu "Setup".
  - → The IV Pole is moved to the highest position defined by the adjusted IV Pole height limit.
  - → The system flushes the aspiration tube and tests the vacuum generation.
- If you want to stop the I/A priming procedure tap the key Stop on the "Setup" page or carry out a foot switch operation.
  - → After the successful I/A priming, the message "Irrigation / Aspiration ready" appears. The message indicates that the device is ready for use.
  - → If I/A priming fails follow the direction for the respective system alarm message (see description page 252).

Mounting and connecting I/A accessories

Installation of I/A cassette and fluidic system

Information about the installation of the interchangeable I/A cassette and the fluidic system with its irrigation and aspiration tubing is described on page 126.

Connect accessories

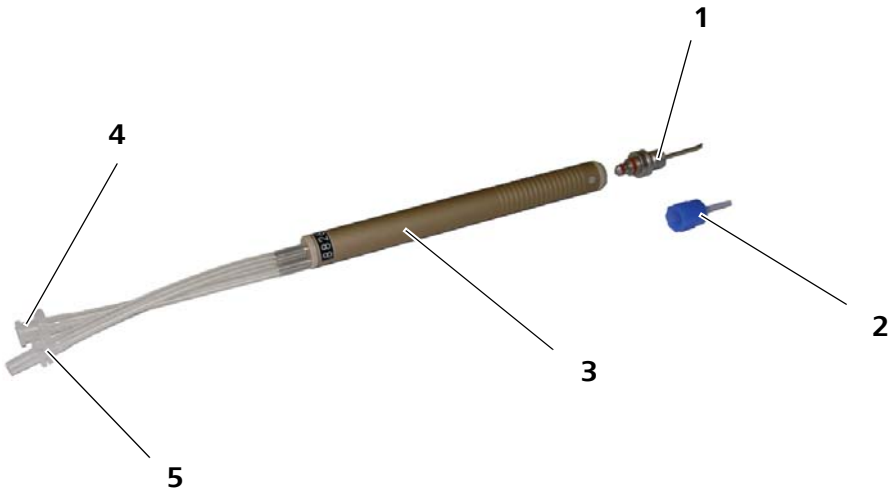
Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

- Select the necessary I/A cannula (1) and guide it carefully into the I/A HANDPIECE, COAXIAL (3).
- Turn the appropriate SILICONE SLEEVE (2) over the cap of the I/A cannula (1). This only applies to I/A cannulas with SILICONE SLEEVES (not to cannula with metal sleeves)

  The SILICONE SLEEVE (2) should be pressed gently onto the cap until it passes the suction connection of the I/A cannula (1).
- Connect the irrigation/aspiration tubes of the installed irrigation/aspiration lines by sliding the end connectors into the corresponding irrigation (4) and aspiration (5) connectors on the handpiece line.

For information on the installation and application of bimanual handpieces, refer to the Instruction for Use of the respective handpieces.

Fig. 52: I/A-accessories connection



Mounting and connecting diathermy accessories

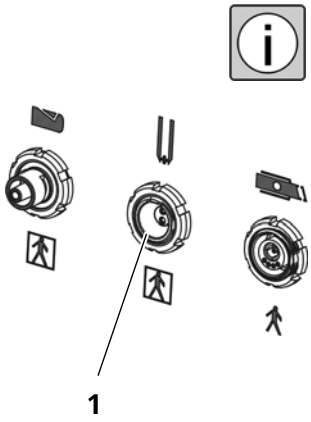
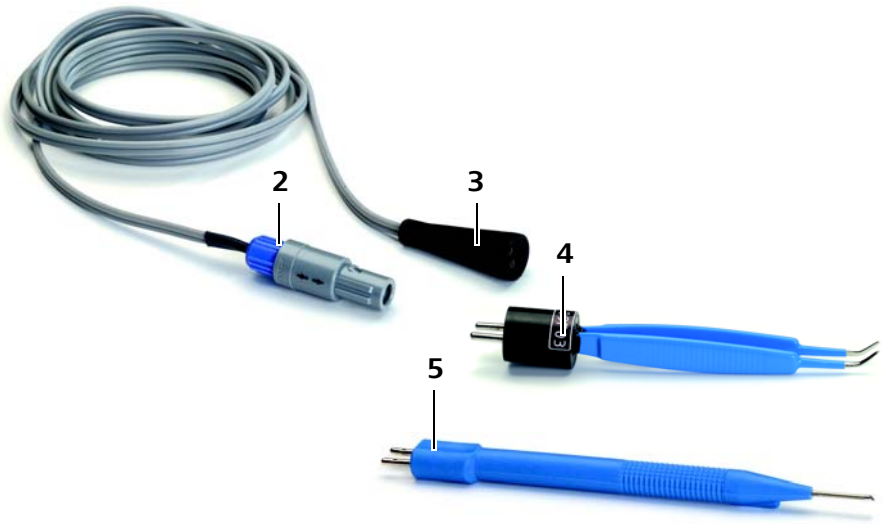


Fig. 53: Diathermy accessories connection

Connect accessories

Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

- Plug the desired diathermy handpiece, e.g. DIATHERMY FORCEPS (4) or DIATHERMY PENCIL ERASER (5) in the socket (3) of the DIATHERMY BIPOLAR CABLE (2).
- Stick the plug of the DIATHERMY BIPOLAR CABLE (2) in the diathermy socket (1) of the surgical system.



Connecting vitrectomy accessories

Installation of I/A cassette and fluidic system

Information about the installation of the interchangeable I/A cassette and the fluidic system with its irrigation and aspiration tubing is described on page 126.

Connect accessories

Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

- Connect the irrigation tube of the I/A cassette with the Luer Lock connection of the 20G A-VIT PROBE WITH SLEEVE (4).
- Connect the aspiration tube of the I/A cassette with the Luer Lock connection of the 20G A-VIT PROBE WITH SLEEVE (3). Turn the connections with light pressure together in order to guarantee a secure fit.
- Plug the pneumatic plug of the 20G A-VIT PROBE WITH SLEEVE (2) in the vitrectomy socket of the surgical system (1).

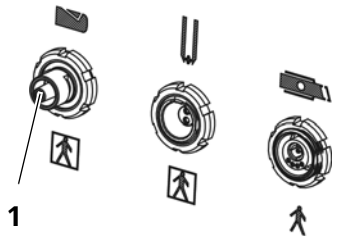
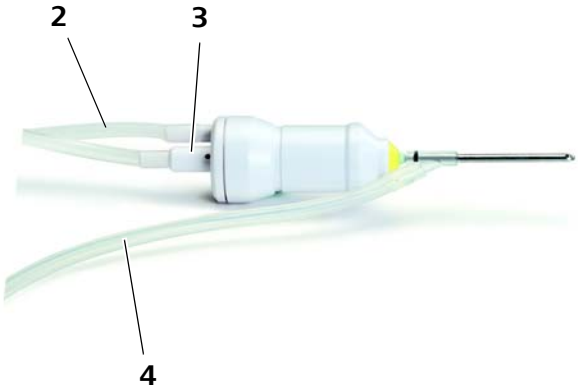


Fig. 54: Connect 20G A-VIT PROBE WITH SLEEVE



Mount accessories for retina surgery and connect irrigation and aspiration tubes *

Connecting posterior vitrectomy accessories *

Installation of I/A cassette and fluidic system

Information about the installation of the interchangeable I/A cassette and the fluidic system with its irrigation and aspiration tubing is described on page 126.

Connect accessories

Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

- Connect the aspiration tube (2) of the I/A cassette with the Luer Lock connector (3) of the posterior vitrectomy probe (5). Turn the connections with light pressure together in order to guarantee a secure fit.
- Plug the pneumatic plug (4) of the posterior vitrectomy probe into the vitrectomy socket (1) of the surgical device.

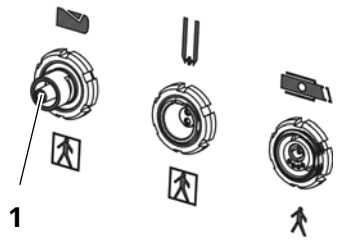
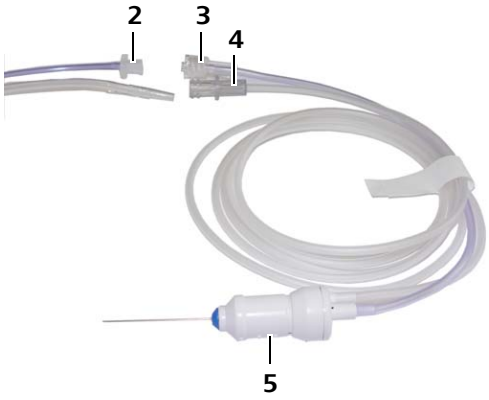


Fig. 55: Connect POSTERIOR VITRECTOMY PROBE



* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Mounting and connecting endodiathermy accessories *

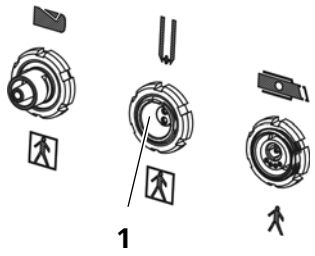


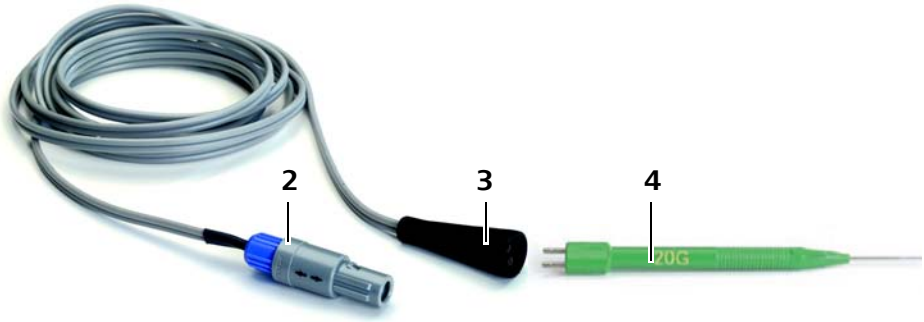
Fig. 56: Connect endodiathermy accessories

Connect accessories

Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

- Plug the desired ENDODIATHERMY PROBE (4) in the DIATHERMY BIPOLAR CABLE (3).
- Plug the plug of the DIATHERMY BIPOLAR CABLE (2) in the diathermy socket (1) of the surgical system.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500



Connecting illumination accessories *

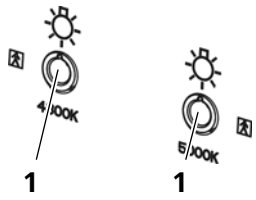
Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

NOTE

Injury to the user!

Light source sockets are hot when on.

- Turn off the light and wait several minutes before you touch the light output ports!



- Plug the connector (5) of the desired ENDO-ILLUMINATION PROBE into one of the two light source sockets (1) on the front plate of the surgical system.
- If you use an ENDO-ILLUMINATION PROBE, MULTIPORT (4) you must connect this with the aid of the TWO-WAY ADAPTER XENON-LIGHTSOURCE (2) to the front plate of the surgical system. You can then connect up to two light leaders per light source socket.

NOTE

Longer surgery time!

An active and open light source socket can blind the user or patient and prolong the surgery duration.

- Plug the glare protection (3) of the TWO-WAY ADAPTER XENON-LIGHTSOURCE (2) into the open light source socket.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 57: Connect illumination accessories

Connecting irrigation accessories *

Installation of I/A cassette and fluidic system

Information about the installation of the interchangeable I/A cassette and the fluidic system with its irrigation and aspiration tubing is described on page 126.

Connect accessories

Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

Irrigation via 20G SCLERAL INFUSION CANNULA

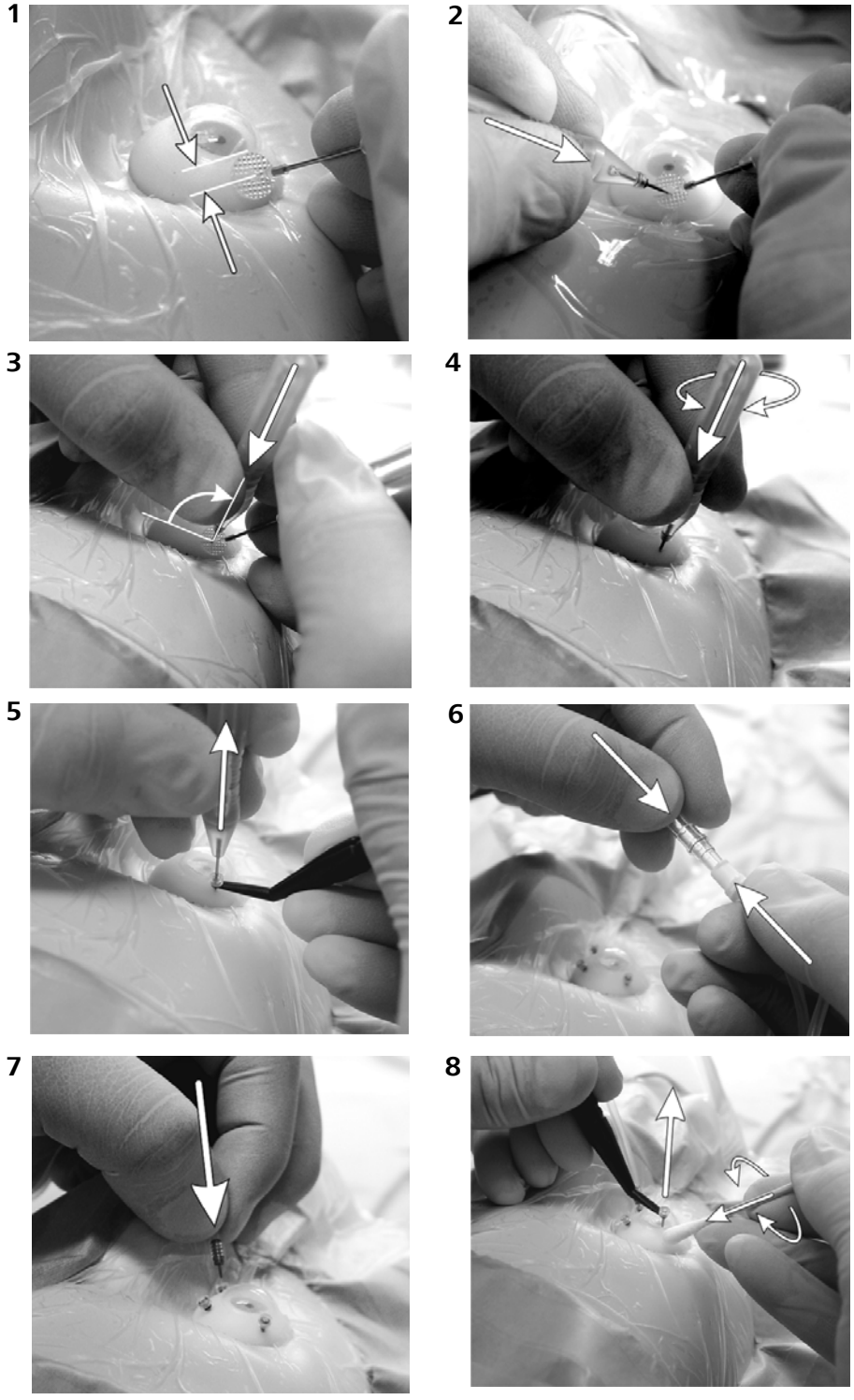
- Connect the female Luer Lock connection of a 20G SCLERAL INFUSION CANNULA to the infusion line of the I/A cassette.
- Introduce the 20G SCLERAL INFUSION CANNULA into the scleral incision.
- Sew the 20G SCLERAL INFUSION CANNULA to the sclera.

Irrigation via trocars

- Bring the trocars as shown on the right to the patient's eye (image 1 to 5).
- Close the female Luer Lock connection of an infusion cannula at the irrigation line of the I/A cassette (image 6).
- Stick the infusion cannula in the desired trocar (image 7).
- After finishing the operation remove the trocar as indicated in image 8.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 58: Irrigation via trocars



Mounting and connecting air fluid exchange accessories *

Installation of I/A cassette and fluidic system

Information about the installation of the interchangeable I/A cassette and the fluidic system with its irrigation and aspiration tubing is described on page 126.

Connect accessories

Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

Fluid exchange

- Connect the male Luer Lock connector (2) of a two-way adapter to the female Luer Lock connector (1) of a SCLERAL INFUSION CANNULA.
- Connect the irrigation tube (4) of the I/A cassette to one of the two female Luer Lock connectors (3 or 5) of a two-way adapter.
- If you have connected the irrigation tube to the female Luer Lock connector (3), (see example on the right), turn the valve of a two-way adapter to position A to enable the irrigation.

Air fluid exchange

If you would like an air fluid exchange during use, you must in addition connect the following accessories:

- Connect the male Luer Lock connector of the AIR INJECTION TUBE WITH FILTER (6) to the free female Luer Lock connector (5) of a two-way adapter.
- Connect the male Luer Lock connector (11) of the extension into one of the female outlets (10) or (14) of the Y piece.
- Close the clamp (12) of the extension.
- Plug the air connection (9) of the Y piece into the air socket (15) of the surgical system.
- Set the membrane filter (8) of the AIR INJECTION TUBE WITH FILTER (6) into the free outlets (10) or (14) of the Y piece.

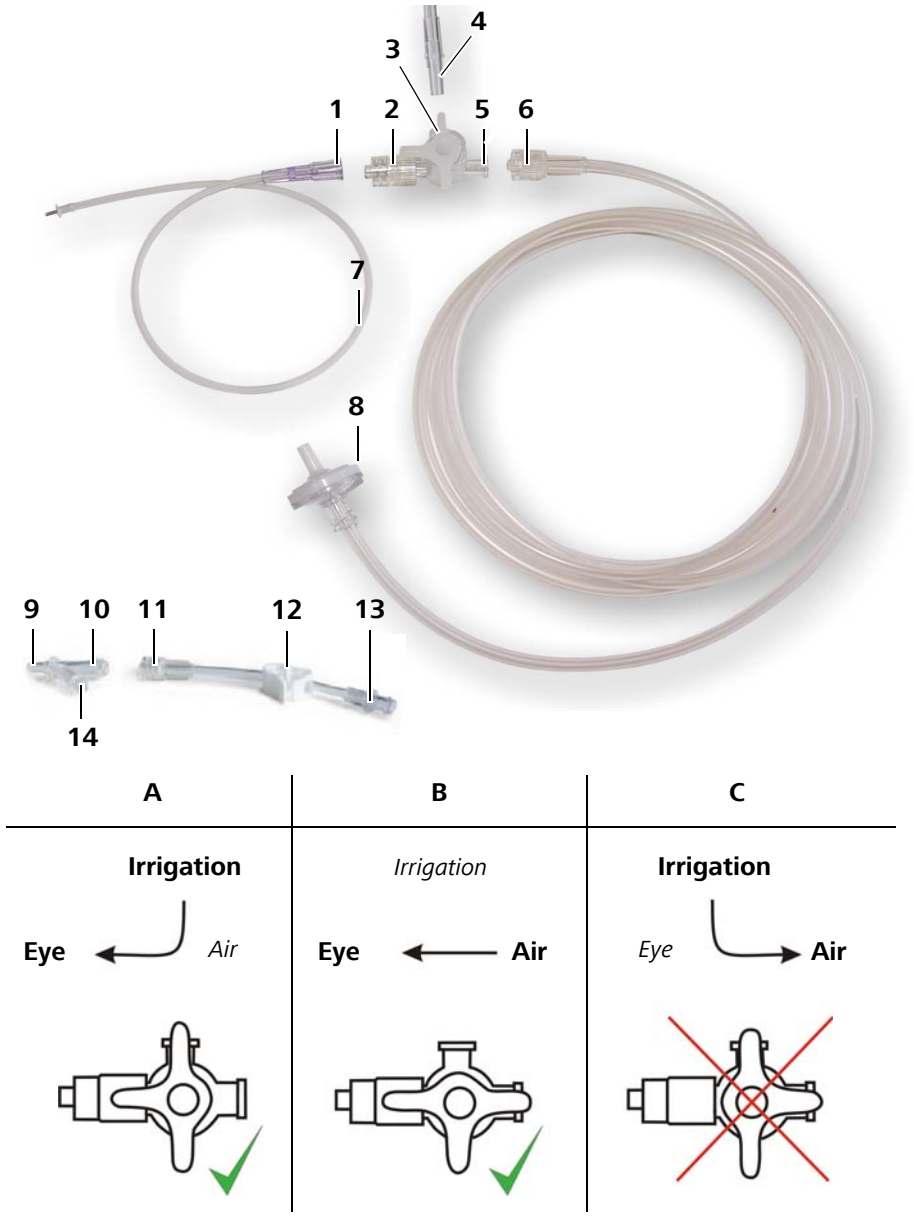
When using in connection with an infusion bag for "Controlled irrigation" (not yet available)

- Connect the air connection (Luer connector) of the infusion bag with the female Luer Lock connector (13) of the extension.
- Open the clamp.

- Turn the valve of a two-way adapter to position A or B to change between irrigation or air infusion.
  - Position A: Irrigation
  - Position B: Air infusion

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 59: Connection example for air fluid exchange



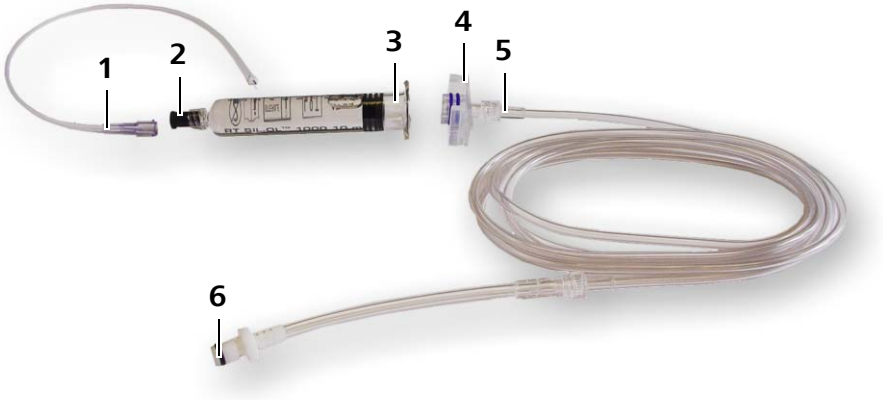
Mounting and connecting silicone oil fluid exchange *

Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

- Connect the adapter (4) to the back of the syringe (3) by pressing it into the cylinder.
- Turn the adapter (4) so that it is firmly in place on the sides of the cylinder.
- Connect the SILICONE OIL INJECTION TUBE (5) (Luer Lock connectors) behind on the adapter (4) (Luer Lock socket).
- Connect the Luer Lock connector of the silicone oil filled syringe (2) to the Luer Lock socket of the SCLERAL INFUSION CANNULA (1).
- Connect the other end of the SILICONE OIL INJECTION TUBE (6) to the silicone oil injection socket (7) on the surgical equipment.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 60: Connect Silicone oil injection



Remove silicone oil

- Connect the cannula (3) of the VISCOUS FLUID REMOVAL KIT included in delivery to the connector at the end of the longer lens barrel of the silicone oil collection tank (2).
- Connect the free connector to the shorter lens barrel of the silicone oil collection tank (2) on the aspiration line (1) from the I/A cassette.
- Select the mode "I/A", "Venturi" and set a vacuum value between 400 and 600 mmHg.

  → The system is now ready for use.

NOTE

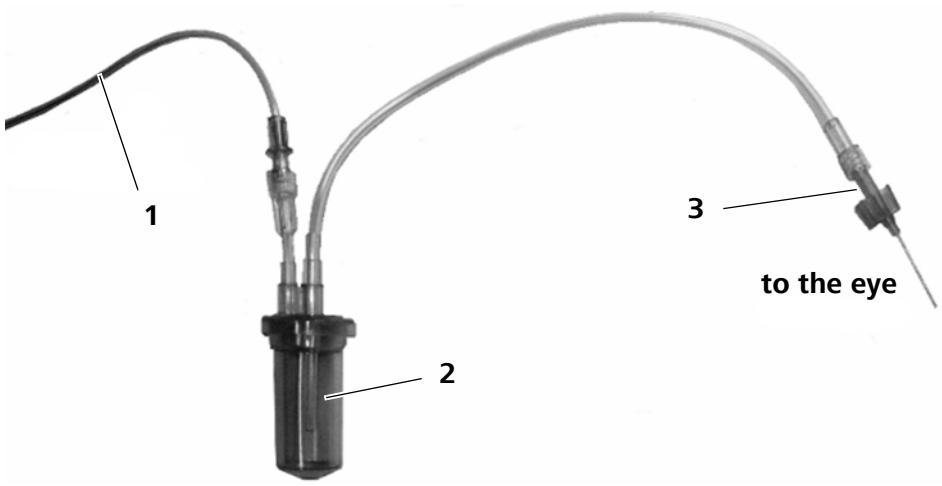
Silicone oil loss

- In order to prevent silicone oil from leaking into the aspiration line of the I/A cassette, the silicone oil collection tank should be kept in a vertical position and be replaced as soon as it is completely filled with silicone oil.

– In order to speed up the removal of high density silicone oil, the enclosed Y connector piece can be used to connect VISCOUS FLUID REMOVAL KIT and use them simultaneously.

– Further details are found in the Instruction for Use of the VISCOUS FLUID REMOVAL KIT.

Fig. 61: Remove silicone oil

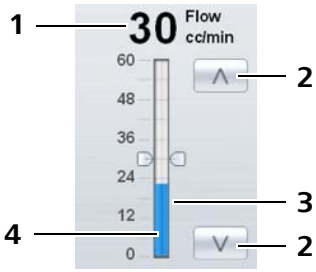
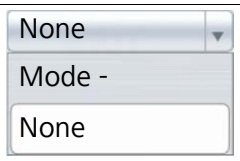


Operation

User interface

Controls

The surgical systems provides the following controls:

Operating element	Definition
	**Tabs** Tap a tab to switch between surgical functions and surgical modes. Surgical functions, such as e.g., "Diathermy" or "Ant Vit", are shown in a single tab. Complex surgical functions, such as, e.g. phacoemulsification, are subdivided into several surgical modes (each represented by a tab) in order to allow parameters for the various phases of the surgery to be set.
	**Bar with slide and blue graphic beam** The black number (1) indicates the preset value. The arrow keys (2) increase or decrease the preset value. Alternatively the preset value can be modified with the slide (3) or directly touched on the scale. The blue graphic beam (4) indicates the actual value which is triggered by the foot pedal.
	**Arrow keys** Tap the arrow key up or down to increase or reduce the numeric values of functions (e.g. light intensity). Tap the arrow key left or right to select between functions.
	**Keys** Tap a key to activate functions or to open menus or submenus.
	**Options** – Blue option => Function is activated – Gray option => Function is deactivated
	**List** – White list entry => Function is selected – Grey list entry => Function is not selected

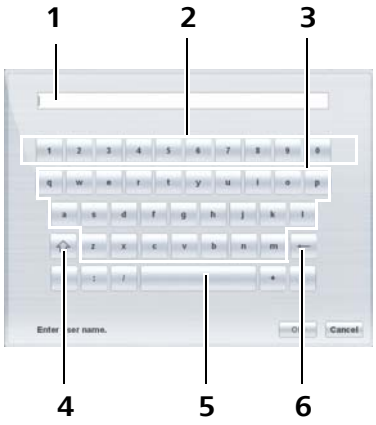
Status icons

The surgical systems have the following icons on the user interface:

Operating element	Definition
	Pulsating bar Indicates that the system is working properly. If the bar ceases to move, the system is idle and you must discontinue the use of the system.
<< >>	**Foot pedal direction** Displays the foot pedal direction (left/right).
	**Program symbol** Displays the program "Divide & Conquer".
	**Program symbol** Displays the program "Phaco Chop".
	**Program symbol** Displays the program "Retina".
	**Active Alarms** Displays the module "Active Alarms".
	**Sound on/off (temporarily)** Displays the status of the alarm tones.
	**IVP High Hook** Indicates that the system is set to gravity irrigation on high hook.
	**IVP Low Hook** Indicates that the system is set to gravity irrigation on low hook.
	**Controlled** Indicates that the system is set to controlled irrigation.
	**Combined High** Indicates that the system is set to pressurized irrigation and gravity irrigation on high hook.
	**Combined Low** Indicates that the system is set to pressurized irrigation and gravity irrigation on low hook.

Virtual keypad

If text entries need to be made, a virtual keyboard is displayed on the user interface and the following input options are offered:

Operating element	Definition
	**1** Text field The entered text is displayed here. **2** Numeric keypad Use this keypad to enter figures and characters. **3** ABC keypad Use this keypad to enter letters. **4** Shift key Use this key to switch between upper case and lower case letters. **5** Space key Use this key to enter spaces between numbers and characters. **6** Backspace key Use this key to delete characters on the left of the cursor.

Setup menu

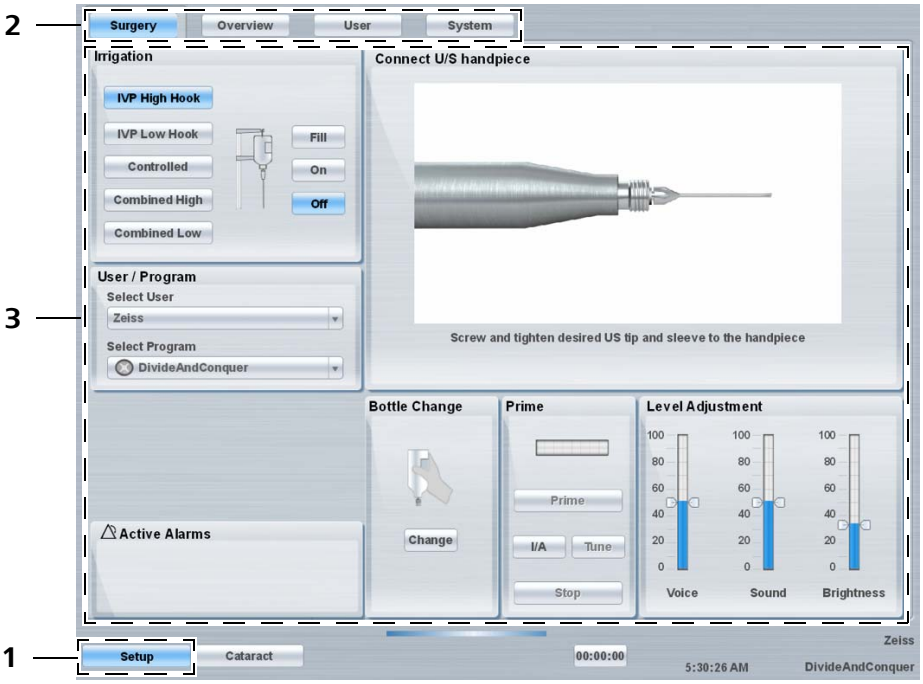
1 Menu "Setup"

2 Submenus in menu "Setup"

- Surgery
- Overview
- User
- System

3 Modules in submenu "Setup"

Fig. 62: Setup menu



Surgery submenu

This submenu provides following modules:

1 Operation procedures
Visual display of the actions to be performed by you. The videos and the instruction messages will run,

- if the system is started and the ULITE PHACO HANDPIECE is not connected,
- if the operator changes from menu "Cataract" or "Retina" to menu "Setup" and the ULITE PHACO HANDPIECE is not connected.

2 Irrigation
Here you can choose the irrigation types and determine the suspension height of the infusion bottle in order to maintain proper fluid balance in the patient's eye.

- The key On activates the continuous irrigation.
- The key Off deactivates the continuous irrigation.
- The key Fill activates the continuous irrigation for approximately 30 seconds.

3 User / Program
Here you can select between 30 users and you can assign every user pre-configured or self configured programs.

4 Active Alarms
The surgical system usually report malfunctions by means of unambiguous text messages or alarm sounds. The system alarms messages are self-explanatory. The alarm sounds can be temporarily turned off if required.

5 Bottle Change
Allows the infusion bottle to be changed.

6 Timer
In normal operation the timer shows the hours, minutes and seconds.

- Start measurement: tap the key 00:00:00.
- Stop measurement: tap the key 00:01:05 a second time.
- Reset timer: tap the key 00:00:00 a third time by double-clicking.

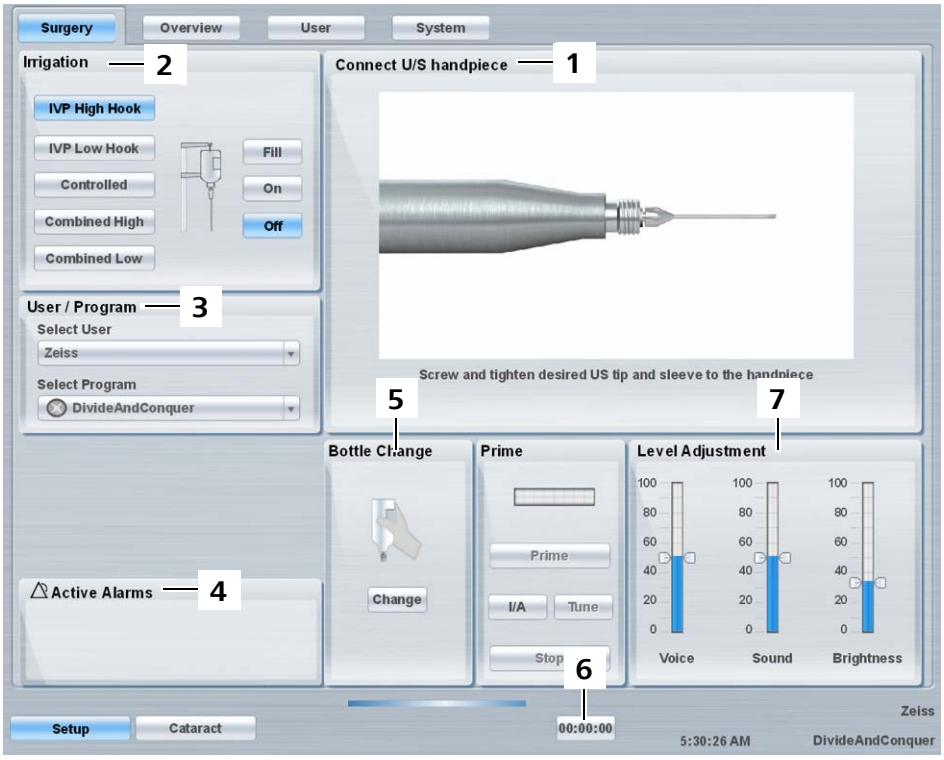
7 Level Adjustment

– Voice
Here you can adjust the volume of the voice messages and alarm tones in parallel from 0 % - 100 %. In order to guarantee that the alarm tones are always acoustically audible, they are generally issued 10 % more loudly than the voice messages. You can turn off the alarm tones as required by calling up the module "Active Alarms" and activating the key . As soon as the system is restarted, the alarm tones are automatically reactivated and set to the last active value.

– Sound
Here you can adjust the volume of the equipment tone from 0 % - 100 %. The equipment tones are recalled by pressing the foot pedal and informing the user about the status of the active function, as e.g. diathermy power. Note that in the selected diathermy function the volume of the equipment tone is only adjustable from 50 % to 100 %. A reduction of the volume under 50 % is not possible for safety reasons.

– Brightness
Here you can adjust the brightness of the touchscreen.

Fig. 63: Surgery submenu



8 Prime

Here you can prepare the surgical system for use.

Key Prime

The priming procedure is a combination of I/A priming and tuning in order to prepare the surgical system for phacoemulsification. During this procedure the fluidic system (I/A cassette with connected phaco handpiece and PHACO TIP) is filled with balanced salt solution. Furthermore it circulates the irrigation fluid through the aspiration tube into the collection bag.

The first priming after startup the surgical system and the first priming after changing the I/A cassette, the fluidic system is tested for correct vacuum or leakage. All consecutive optional 're-primings' are carried out without vacuum tests.

A priming procedure is necessary:

– before first activating of aspiration, ultrasound or cutter

– after changing the I/A cassette

A detailed operating priming procedure is described on Page 141.

Key I/A

The I/A priming procedure prepares the surgical system for irrigation/aspiration applications. During this procedure the fluidic system (I/A cassette with connected irrigation and aspiration tube) is filled with balanced salt solution. Furthermore it circulates the irrigation fluid through the aspiration tube into the collection bag.

The first I/A priming after startup the surgical system and the first I/A priming after changing the I/A cassette, the fluidic system is tested for correct vacuum or leakage. All consecutive optional 're-I/A primings' are carried out without vacuum tests.

An I/A priming procedure is necessary:

– to perform anterior or posterior vitrectomy procedure only

– after changing the I/A cassette

The detailed operating I/A priming procedure is described on Page 141.

Key Tune

The tuning procedure prepares the surgical system for phacoemulsification, without testing the fluidic system of correct vacuum or leakage. The surgical system checks only the connected phaco handpiece with the PHACO TIP.

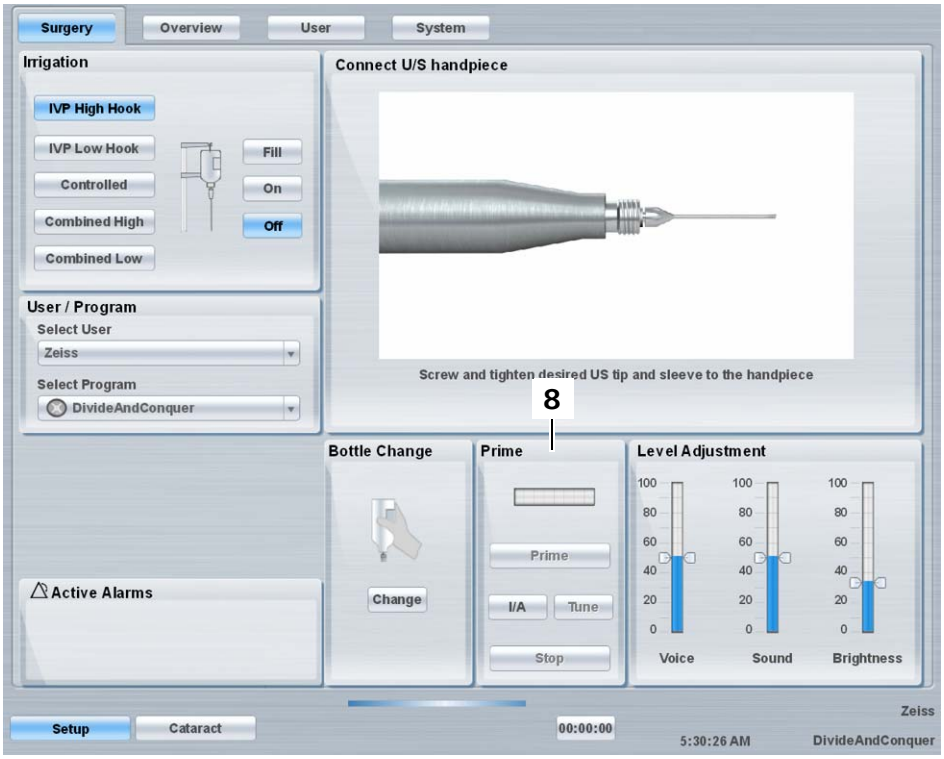
A tuning procedure is necessary:

– after changing the PHACO TIP

– after tightening the PHACO TIP

The detailed operating tuning procedure is described on Page 140.

Fig. 64: Surgery submenu



Overview submenu

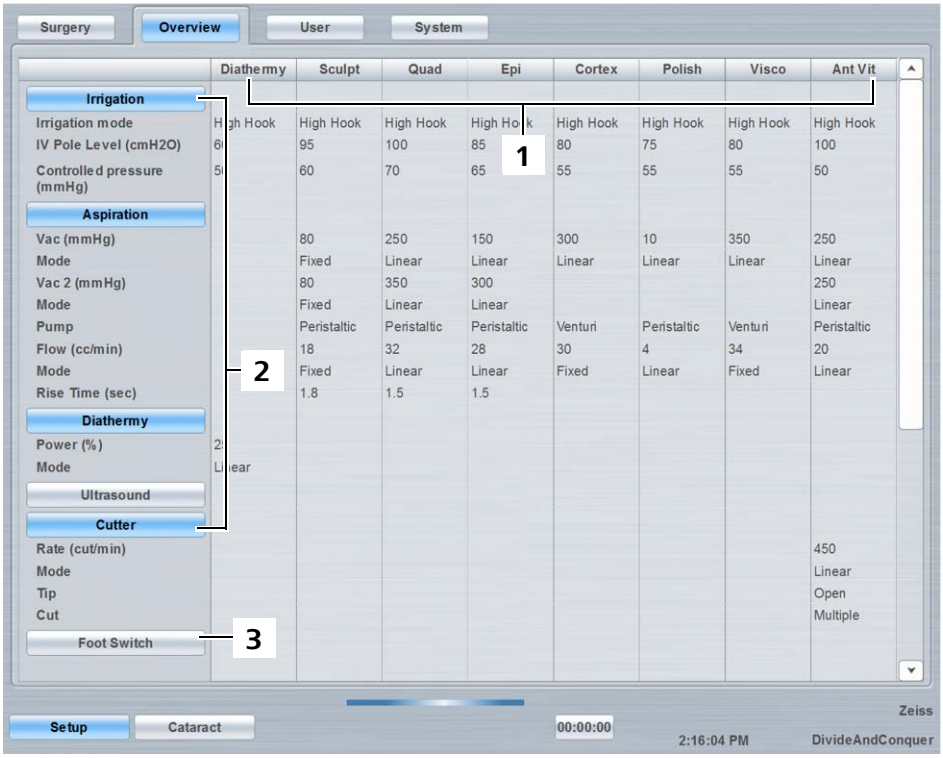
This submenu provides an overview of the currently selected program* with following settings:

1 Program settings

2 Function settings
The detailed function settings are summarized. To expand or collapse the summarized settings the corresponding key have to be tapped.

3 Foot switch settings
Only applicable functions will be displayed.

Fig. 65: Overview submenu



* The selected program may differ from the active program:

– If program ‘A’ was used, and then program 'B' was selected in the menu "Setup", then 'A' is still active, but 'B' is displayed in submenu "Overview".

– Program 'B' only becomes active when first entering menu "Cataract" or "Retina".

System submenu

This submenu provides following modules:

1 CALLISTO eye Connection (not yet available)
Here you can switch on/off the connection between the surgical systems and CALLISTO eye.

2 Import / Export
Here you can copy users and programs on a USB storage medium or vice versa.

3 IV Pole Height Limit
Here you can set up the maximum infusion pole height limit (see Page 98).

4 Password Protected Access
Here you can call up the service menus for ZEISS staff or for personnel authorized by ZEISS.

5 Shutdown
to power off by the power switch (see Page 246).

Fig. 66: System submenu

User submenu

This submenu provides following modules:

1 Users
Here you can create, rename and delete users.

2 Programs
Here you can create, rename and delete programs.

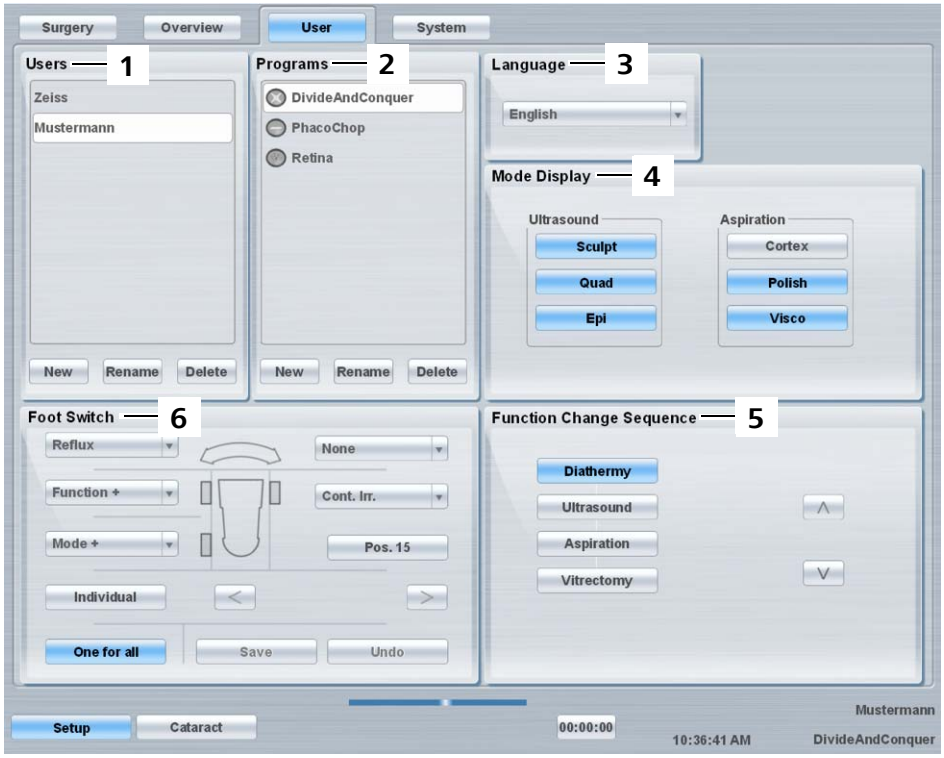
3 Language
Here you can select the desired language of the menu interface.

4 Mode Display
Here you can configure which function should be active or inactive in the menu "Cataract" or "Retina".

5 Function Change Sequence
Here you can configure the sequence of the function change.

6 Foot Switch
Here you can configure the functions of the DOUBLE LINEAR FOOT-SWITCH II.

Fig. 67: User submenu



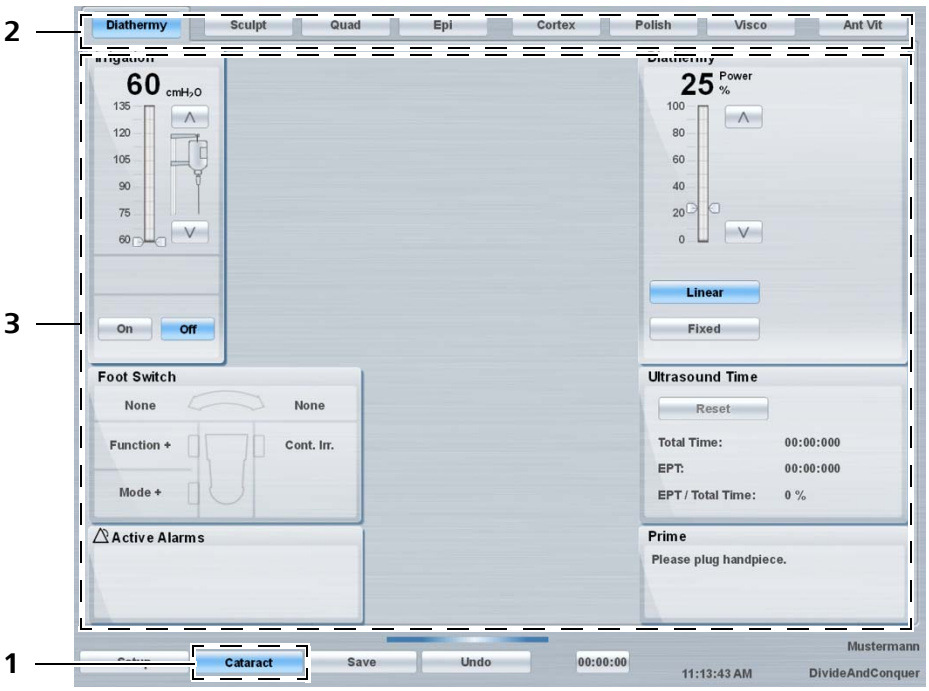
Cataract and Retina menu

1 Cataract or Retina menu

2 Surgical functions / Surgical modes
The programmed setting becomes part of the surgical function or surgical mode in which it was planned.

3 Cataract or Retina modules

Fig. 68: Cataract or Retina menu



Cataract menu with surgical functions / surgical modes

1 Surgical function "Diathermy"
Here you can define parameters for diathermy.

2 Surgical function "Phacoemulsification"
Here you can define parameters for phacoemulsification. The surgical function contains following surgical modes:
Sculpt, Quad, Epi* or PhacoAsp, Chop, Epi**

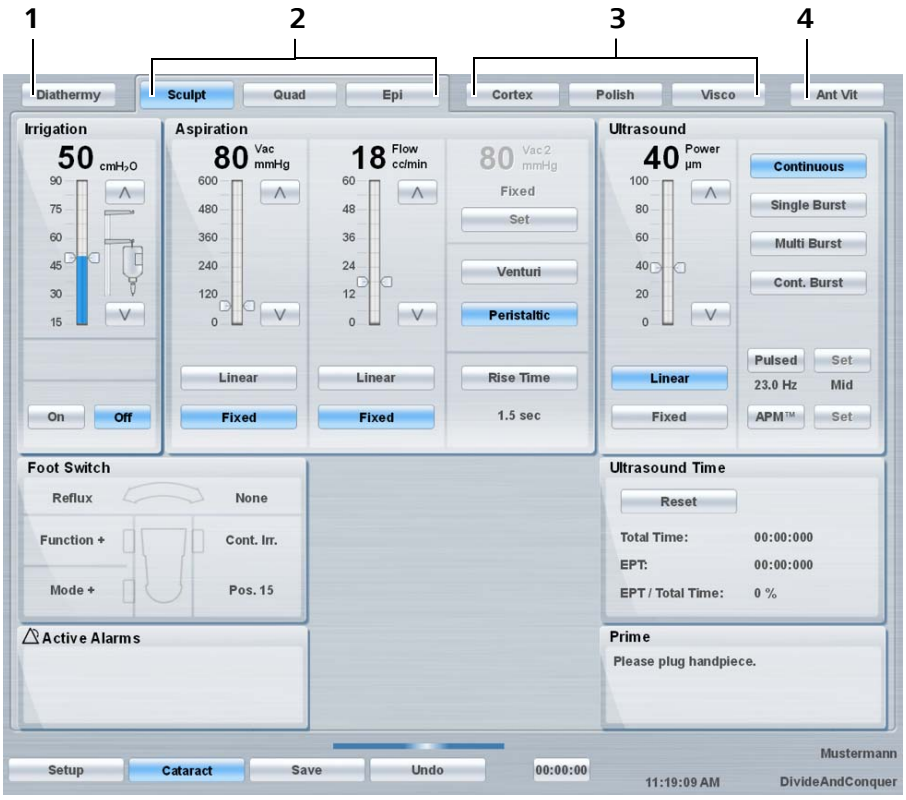
*These tabs appear if you load the program "DivideAndConquer".
**These tabs appear if you load the program "PhacoChop".

The three tabs behave identically: they provide different parameter configurations suitable for different phases of the phaco-surgery.

3 Surgical function "Irrigation/Aspiration"
Here you can define parameters for irrigation/aspiration. The surgical function contains following surgical modes: Cortex, Polish, Visco.

4 Surgical function "Anterior Vitrectomy"
Here you can define parameters for anterior vitrectomy.

Fig. 69: Functions in Cataract menu



Retina menu with surgical functions / surgical modes *

1 Surgical function "Endodiathermy"
Here you can define parameters for endodiathermy.

2 Surgical function "Irrigation/Aspiration"
Here you can define parameters for posterior irrigation/aspiration. The surgical function contains following surgical modes "I/A 1, I/A 2".

3 Surgical function "Phacofragmenatation"
Here you can define parameters for phacofragmentation.

4 Surgical function "Posterior Vitrectomy"
Here you can define parameters for posterior vitrectomy, such as cutter, irrigation/aspiration, light, oil, and air. The surgical function contains following surgical modes "Vit 1, Vit 2, Vit 3".

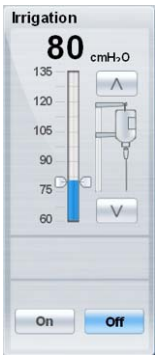
5 Surgical function "Scissors"
Here you can define parameters for the MICROSCISSORS.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

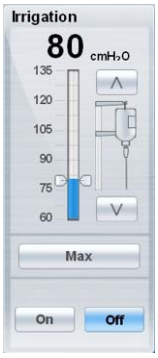
Fig. 70: Functions in Retina menu

"Irrigation" module

Cataract



Retina



Here you can adjust all irrigation parameters. This module is available in each surgical function.

– **cmH$_2$O -** Indicates the preset infusion pole height value.
Indicates the height of the balanced salt solution (BSS) over the pump (patient eye should be set to the pump level) in cm. This is an estimate that depends on the patient and infusion bottle height and/or the suspension setup of the infusion bottle.

– **mmHg** - Indicates the pressure in the infusion bag when using controlled irrigation or the pressure in the drip chamber/infusion bottle when using combined irrigation. In latter case both values have to be added to get the complete pressurised pressure.

– Key Max (retina only)
In the "Irrigation" module, the maximum available IV Pole height can be reached by tapping this key. This function serves for the increase of the irrigation pressure and the hemostasis during a posterior section surgery. If the maximum irrigation is active the adjusted IV Pole height limit will be set. If the maximum irrigation is deactivated again the irrigation will decrease to the preset height level.

– Key On / Off
Activate or deactivate continuous irrigation. According to programming of the DOUBLE LINEAR FOOTSWITCH II you can activate this function also over the relevant side key.

The appearance and the function selection of the menu "Irrigation" depends on the selected irrigation type in the submenu "Surgery" on the "Setup" page. Following irrigation types are selectable:

– IVP High Hook (Page 173)

– IVP Low Hook (Page 174)

– Controlled (Page 175)

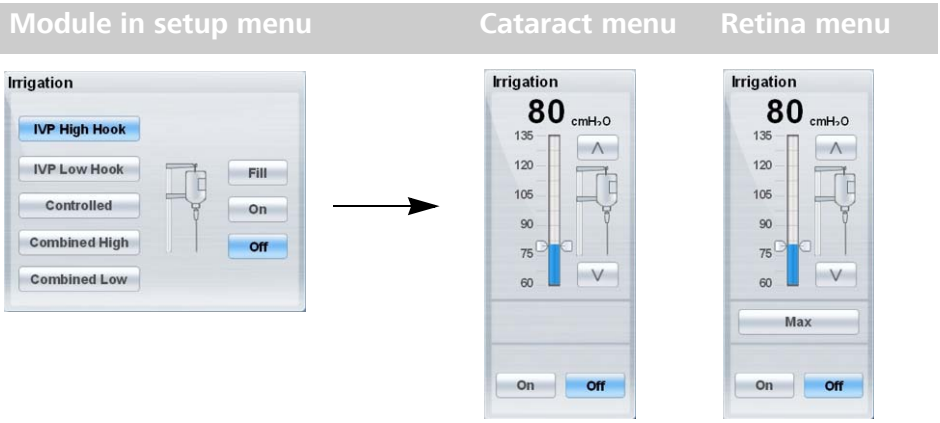
– Combined High (Page 176)

– Combined Low (Page 178)

IVP High Hook

This type of irrigation is suitable for **cataract** applications. When using it, the infusion bottle with balanced salt solution (BSS) is hung on the electrically operated infusion pole on the high hook.

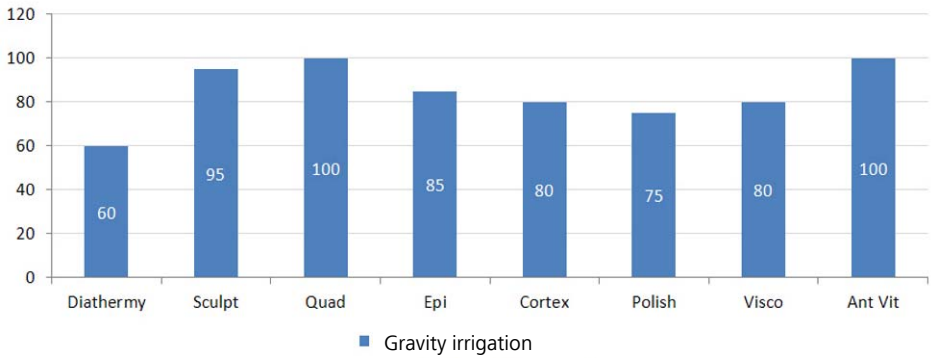
The irrigation flow rate of the fluid and the irrigation pressure is determined by the height at which the infusion bottle is mounted. The maximum preset height of the infusion bottle can be set by the arrow keys or the slider.



The graph below illustrates the default cmH_2O values for IVP High Hook irrigation. The default cmH_2O values below can be called up if you load following system settings:

- Irrigation type: "IVP High Hook"
- User: "Zeiss"
- Program: "DivideAndConquer"

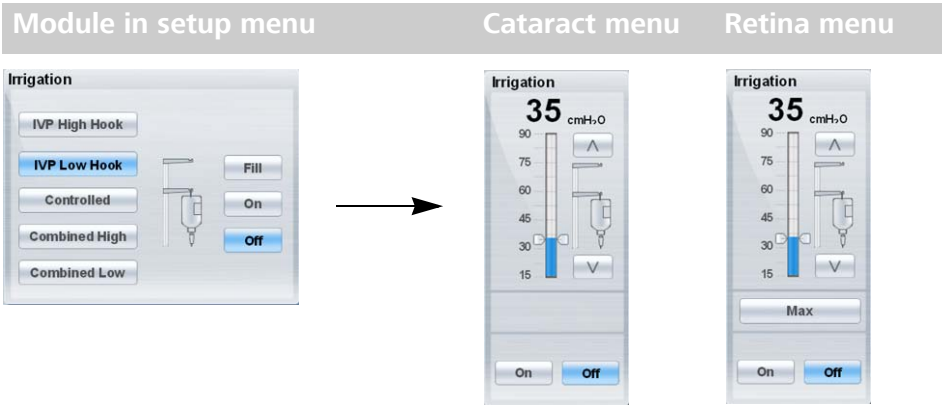
Fig. 71: Default values in cmH_2O



IVP Low Hook

This type of irrigation is suitable for **retina** applications. When using it, the infusion bottle with balanced salt solution (BSS) is hung on the electrically operated infusion pole on the low hook.

The irrigation flow rate of the fluid and the irrigation pressure is determined by the height at which the infusion bottle is mounted. The maximum preset height of the infusion bottle can be set by the arrow keys or the slide.



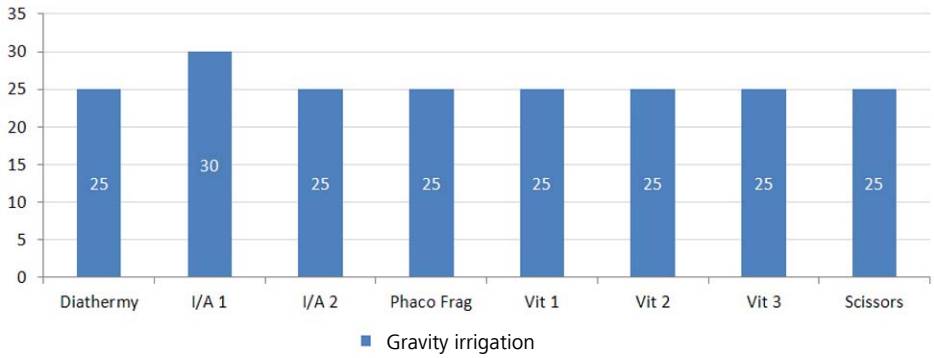
The graph below illustrates the default cmH_2O values for IVP Low Hook irrigation. The default cmH_2O values below can be called up if you load following system settings:

– Irrigation type: "IVP Low Hook"

– User: "Zeiss"

– Program: "Retina"

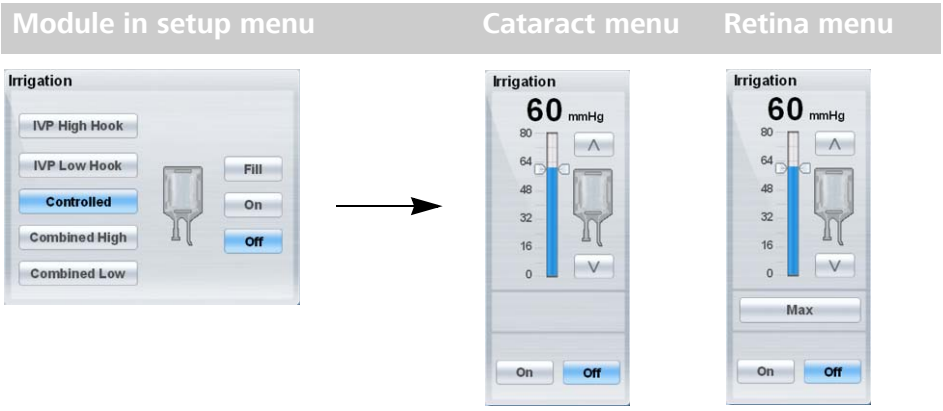
Fig. 72: Default values in cmH_2O



Controlled (not yet available)

This type of irrigation is suitable for **cataract** and **retina** applications. When using it an infusion bag with balanced salt solution (BSS) is hung on the suspension device on the right side of the surgical system.

It has been designed to deliver balanced salt solution, at a controlled pressure, by means of a infusion bag inflated with pressurized air supplied by the equipment.



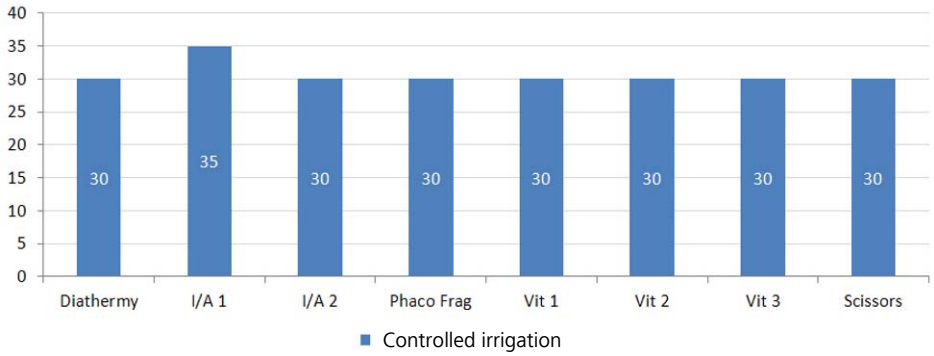
The graph below illustrates the default pressure values for "Controlled" irrigation. The default pressure values below can be called up if you load following system settings:

– Irrigation type: "Controlled"

– User: "Zeiss"

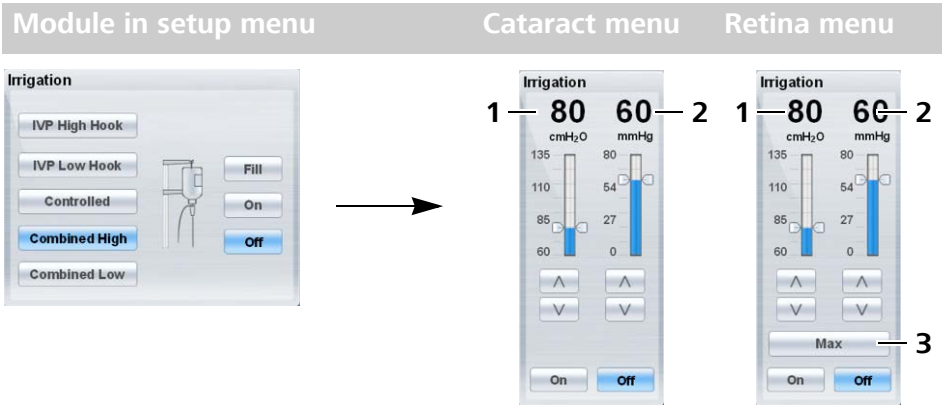
– Program: "Retina"

Fig. 73: Default values in mmHG



Combined High

This type of irrigation is suitable for **cataract** applications. When using it there is a combination of gravity and pressurized irrigation. The height of the infusion bottle (1) on the infusion pole and the pressure of air (2) transmitted into the drip chamber can be set independently.



The default pressure values for "Combined High" can be called up if you load following system settings:

– Irrigation type: "Combined High"

– User: "Zeiss"

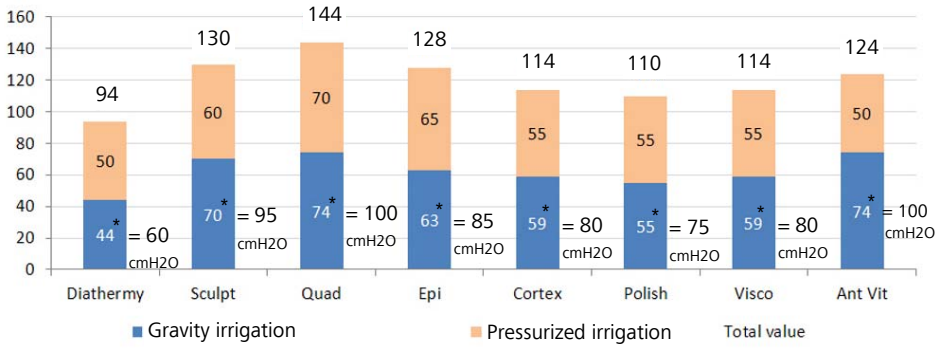
– Program: "DivideAndConquer"

If using "Combined High" irrigation for cataract, adjust the pressure and gravity values as required. The following types of cataract irrigation can be used alternatively:

– "IVP High Hook" (see Page 173)

The graph on the next page illustrates the default pressure values (converted in mmHg) for "Combined High" irrigation. The total value results from the sum of the default gravity irrigation pressure (in mmHg) and the calculated default pressurized irrigation (related to 1 mmHg = 1,36 cmH_2O).

Fig. 74: Default pressure values in mmHg for "Combined High"



* related to 1 mmHg = 1,36 cmH2O (refer also to the table below "Conversion cmH2O and mmHg)

Pay attention to following device properties when using "Combined High":

- The module "Air" on the retina page is deactivated.
- When activating the maximum irrigation (3), the pressurized irrigation is set to the maximum and the IV Pole height is maintained. The maximum irrigation is reseted as soon as the pressurized irrigation value has been changed.

Conversion cmH2O and mmHg

Air pressure [mmHg]

Hook height [cmH2O]	15	20	25	30	35	40	45	50	55	60	65	70	75	80
15	26,0	31,0	36,0	41,0	46,0	51,0	56,0	61,0	66,0	71,0	76,0	81,0	86,0	91,0
20	29,7	34,7	39,7	44,7	49,7	54,7	59,7	64,7	69,7	74,7	79,7	84,7	89,7	94,7
25	33,4	38,4	43,4	48,4	53,4	58,4	63,4	68,4	73,4	78,4	83,4	88,4	93,4	98,4
30	37,1	42,1	47,1	52,1	57,1	62,1	67,1	72,1	77,1	82,1	87,1	92,1	97,1	102,1
35	40,7	45,7	50,7	55,7	60,7	65,7	70,7	75,7	80,7	85,7	90,7	95,7	100,7	105,7
40	44,4	49,4	54,4	59,4	64,4	69,4	74,4	79,4	84,4	89,4	94,4	99,4	104,4	109,4
45	48,1	53,1	58,1	63,1	68,1	73,1	78,1	83,1	88,1	93,1	98,1	103,1	108,1	113,1
50	51,8	56,8	61,8	66,8	71,8	76,8	81,8	86,8	91,8	96,8	101,8	106,8	111,8	116,8
55	55,5	60,5	65,5	70,5	75,5	80,5	85,5	90,5	95,5	100,5	105,5	110,5	115,5	120,5
60	59,1	64,1	69,1	74,1	79,1	84,1	89,1	94,1	99,1	104,1	109,1	114,1	119,1	124,1
65	62,8	67,8	72,8	77,8	82,8	87,8	92,8	97,8	102,8	107,8	112,8	117,8	122,8	127,8
70	66,5	71,5	76,5	81,5	86,5	91,5	96,5	101,5	106,5	111,5	116,5	121,5	126,5	131,5
75	70,2	75,2	80,2	85,2	90,2	95,2	100,2	105,2	110,2	115,2	120,2	125,2	130,2	135,2
80	73,8	78,8	83,8	88,8	93,8	98,8	103,8	108,8	113,8	118,8	123,8	128,8	133,8	138,8
85	77,5	82,5	87,5	92,5	97,5	102,5	107,5	112,5	117,5	122,5	127,5	132,5	137,5	142,5
90	81,2	86,2	91,2	96,2	101,2	106,2	111,2	116,2	121,2	126,2	131,2	136,2	141,2	146,2
95	84,9	89,9	94,9	99,9	104,9	109,9	114,9	119,9	124,9	129,9	134,9	139,9	144,9	149,9
100	88,6	93,6	98,6	103,6	108,6	113,6	118,6	123,6	128,6	133,6	138,6	143,6	148,6	153,6
105	92,2	97,2	102,2	107,2	112,2	117,2	122,2	127,2	132,2	137,2	142,2	147,2	152,2	157,2
110	95,9	100,9	105,9	110,9	115,9	120,9	125,9	130,9	135,9	140,9	145,9	150,9	155,9	160,9
115	99,6	104,6	109,6	114,6	119,6	124,6	129,6	134,6	139,6	144,6	149,6	154,6	159,6	164,6
120	103,3	108,3	113,3	118,3	123,3	128,3	133,3	138,3	143,3	148,3	153,3	158,3	163,3	168,3
125	106,9	111,9	116,9	121,9	126,9	131,9	136,9	141,9	146,9	151,9	156,9	161,9	166,9	171,9
130	110,6	115,6	120,6	125,6	130,6	135,6	140,6	145,6	150,6	155,6	160,6	165,6	170,6	175,6
135	114,3	119,3	124,3	129,3	134,3	139,3	144,3	149,3	154,3	159,3	164,3	169,3	174,3	179,3

Low hook

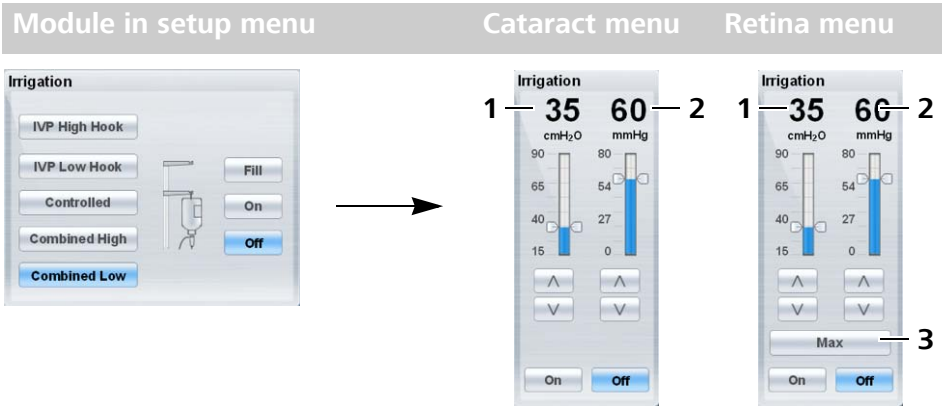
High hook

Hook height 125 - 135 cmH2O is only usable with software version 2.0 and the extended IV Pole.

Pressure in mmHg resulting from gravity (conversion cmH2O in mmHg) and pressurised air (mmHg).

Combined Low

This type of irrigation is suitable for **cataract** and **retina** applications. When using it there is a combination of gravity and pressurized irrigation. The height of the infusion bottle (1) on the infusion pole and the air pressure (2) transmitted into the drip chamber can be set independently.



The default pressure values for "Combined Low" can be called up if you load following system settings:

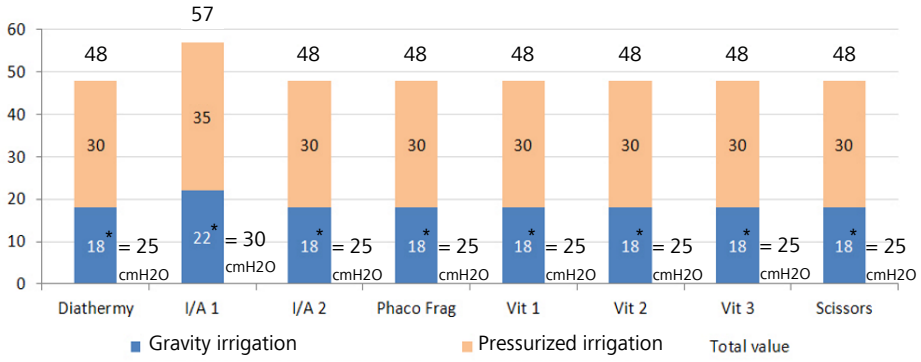
– Irrigation type: "Combined Low"
– User: "Zeiss"
– Program: "Retina"

If using the "Combined Low" irrigation for the retina, adjust the pressure and gravity values as required. The following types of retina irrigation can be used alternatively:

– "IVP Low Hook" (see Page 174)
– "Controlled" (see Page 175)

The graph on the next page illustrates the default pressure values (converted in mmHg) for "Combined Low" irrigation. The total value results from the sum of the default gravity irrigation pressure (in mmHg) and the calculated default pressurized irrigation (related to 1 mmHg = 1,36 cmH_2O).

Fig. 75: Default pressure values in mmHg for "Combined Low"



* related to 1 mmHg = 1,36 cmH2O (refer also to the table below "Conversion cmH2O and mmHg)

Pay attention to following device properties when using "Combined Low":

- The module "Air" on the retina page is deactivated.
- When activating the maximum irrigation (3), the pressurized irrigation is set to the maximum and the IV Pole height is maintained. The maximum irrigation is reseted as soon as the pressurized irrigation value has been changed.

Conversion cmH2O and mmHg

Air pressure [mmHg]

Hook height [cmH2O]	15	20	25	30	35	40	45	50	55	60	65	70	75	80
15	26,0	31,0	36,0	41,0	46,0	51,0	56,0	61,0	66,0	71,0	76,0	81,0	86,0	91,0
20	29,7	34,7	39,7	44,7	49,7	54,7	59,7	64,7	69,7	74,7	79,7	84,7	89,7	94,7
25	33,4	38,4	43,4	48,4	53,4	58,4	63,4	68,4	73,4	78,4	83,4	88,4	93,4	98,4
30	37,1	42,1	47,1	52,1	57,1	62,1	67,1	72,1	77,1	82,1	87,1	92,1	97,1	102,1
35	40,7	45,7	50,7	55,7	60,7	65,7	70,7	75,7	80,7	85,7	90,7	95,7	100,7	105,7
40	44,4	49,4	54,4	59,4	64,4	69,4	74,4	79,4	84,4	89,4	94,4	99,4	104,4	109,4
45	48,1	53,1	58,1	63,1	68,1	73,1	78,1	83,1	88,1	93,1	98,1	103,1	108,1	113,1
50	51,8	56,8	61,8	66,8	71,8	76,8	81,8	86,8	91,8	96,8	101,8	106,8	111,8	116,8
55	55,5	60,5	65,5	70,5	75,5	80,5	85,5	90,5	95,5	100,5	105,5	110,5	115,5	120,5
60	59,1	64,1	69,1	74,1	79,1	84,1	89,1	94,1	99,1	104,1	109,1	114,1	119,1	124,1
65	62,8	67,8	72,8	77,8	82,8	87,8	92,8	97,8	102,8	107,8	112,8	117,8	122,8	127,8
70	66,5	71,5	76,5	81,5	86,5	91,5	96,5	101,5	106,5	111,5	116,5	121,5	126,5	131,5
75	70,2	75,2	80,2	85,2	90,2	95,2	100,2	105,2	110,2	115,2	120,2	125,2	130,2	135,2
80	73,8	78,8	83,8	88,8	93,8	98,8	103,8	108,8	113,8	118,8	123,8	128,8	133,8	138,8
85	77,5	82,5	87,5	92,5	97,5	102,5	107,5	112,5	117,5	122,5	127,5	132,5	137,5	142,5
90	81,2	86,2	91,2	96,2	101,2	106,2	111,2	116,2	121,2	126,2	131,2	136,2	141,2	146,2
95	84,9	89,9	94,9	99,9	104,9	109,9	114,9	119,9	124,9	129,9	134,9	139,9	144,9	149,9
100	88,6	93,6	98,6	103,6	108,6	113,6	118,6	123,6	128,6	133,6	138,6	143,6	148,6	153,6
105	92,2	97,2	102,2	107,2	112,2	117,2	122,2	127,2	132,2	137,2	142,2	147,2	152,2	157,2
110	95,9	100,9	105,9	110,9	115,9	120,9	125,9	130,9	135,9	140,9	145,9	150,9	155,9	160,9
115	99,6	104,6	109,6	114,6	119,6	124,6	129,6	134,6	139,6	144,6	149,6	154,6	159,6	164,6
120	103,3	108,3	113,3	118,3	123,3	128,3	133,3	138,3	143,3	148,3	153,3	158,3	163,3	168,3
125	106,9	111,9	116,9	121,9	126,9	131,9	136,9	141,9	146,9	151,9	156,9	161,9	166,9	171,9
130	110,6	115,6	120,6	125,6	130,6	135,6	140,6	145,6	150,6	155,6	160,6	165,6	170,6	175,6
135	114,3	119,3	124,3	129,3	134,3	139,3	144,3	149,3	154,3	159,3	164,3	169,3	174,3	179,3

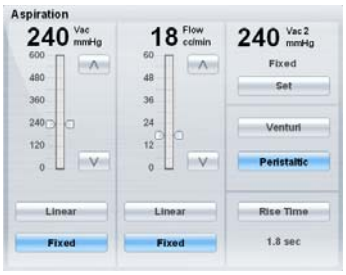
Low hook

High hook

Hook height 125 - 135 cmH2O is only usable with software version 2.0 and the extended IV Pole.

Pressure in mmHg resulting from gravity (conversion cmH2O in mmHg) and pressurised air (mmHg).

"Aspiration" module



Here you can adjust all aspiration parameters. This module is available in each surgical function, except of "Diathermy" and "Scissors".

– **Vac** - Indicates the preset main vacuum value.
When the maximum value is reached, for example in case of an occlusion, the peristaltic pump stops.

– **Flow** - Indicates the preset flow rate.
This function is available only if the peristaltic pump is selected.

– **Vac 2** - Indicates the second preset vacuum value.
With this function you can exceed the main vaccum value during phaco-emulsification or vitrectomy procedures.

– Key Set
Here you can open the Vac 2 configuration module. With the Vac 2 module you can change to a second higher preset value of vacuum during phacoemulsification or vitrectomy procedures.

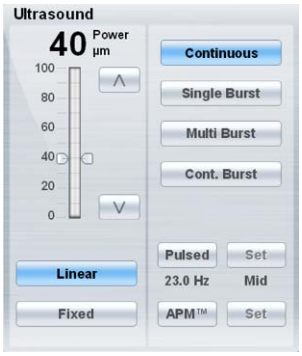
The key is activated when the foot pedal function "Vac 2" is assigned to rotation left or right.

– Key Venturi / Peristaltic
Here you can select the pump mode. The surgical system is equipped with an I/A cassette such that both a peristaltic pump and a venturi pump are available.

– Key Rise Time
This adjusts the time it takes for the peristaltic pump to stop upon complete occlusion. Smaller value means the pump stops faster upon full occlusion and higher value means the pump takes longer to stop upon full occlusion. Shorter rise times cause a faster increase of the vacuum to the pre-set level and more efficient fragment aspiration. The function "Rise Time" functions only if the peristaltic pump is activated and the key "Peristaltic" lights up blue.

– Key Fixed / Linear
Vac, Vac 2 and flow rate can be controlled in "Linear" and "Fixed" mode.
In "Fixed" mode the parameters are set immediately to the preset limit.
In "Linear" mode the parameter are controlled linearly between a minimal value and the preset limit.

"Ultrasound" module



Here you can adjust all ultrasound parameters. This module is available in the surgical function "Phacoemulsification" and "Phacofragmentation".

– **Power** - Indicates the preset U/S power value.
(Stroke length of a PHACO TIP in µm)

– U/S operation modes. Delivers U/S power in one duration mode or five different pulse modes.

  – Continuous mode (duration mode)

  – Single Burst mode

  – Multi Burst mode

  – Cont.Burst mode

  – Pulsed mode (configurable)

  – APM mode (fully configurable)

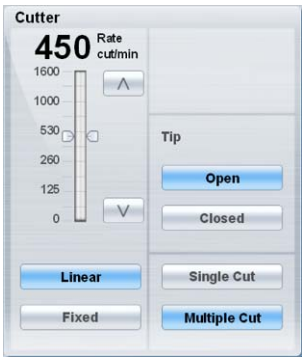
  The impulse modes reduces the quantity of the U/S power on the patient.
  A more detailed description of the individual modes is found on Page 214.

– Key Pulsed
Activates or deactivates the pulsed mode. The output is delivered by U/S power in pulses with an adjustable frequency from 1 to 40 Hz. Pulsed mode can further be modified by tapping the key "Set" to select Low, Mid or High. A more detailed description of the three pulse durations is found on Page 188.

– Key APM
Activates or deactivates the APM mode. In the APM mode you can plan the exact ultrasound pattern, that fits best to your work technique and the cataract. The programmed ultrasound pattern becomes part of the setting of the surgical mode, in which it was planned (e.g. Quad). In every surgical function (Sculpt, Quad and Epi), a different ultrasound pattern can be programed and stored. The desired settings can be adjusted by tapping the key "Set" next to the key "APM".

– Key Fixed / Linear
The U/S power can be controlled in "Fixed" and in "Linear" mode.
In "Fixed" mode the parameter is set immediately to the preset limit.
In "Linear" mode the parameter is controlled linearly between a minimal value and the preset limit.

"Cutter" module



Here you can adjust all vitrectomy or scissors parameters. This module is available in the surgical functions "Anterior Vitrectomy", "Posterior Vitrectomy" and "Scissors".

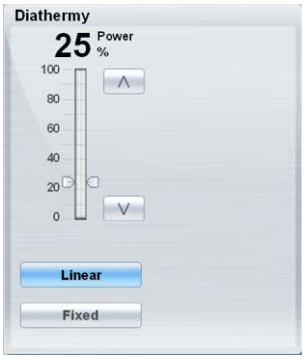
– **Rate cut/min** - Indicates the preset cut rate. The cut rate depends on the selected surgical function.

– Key Open / Closed
Here you can supply aspiration opening. The "Open" function leaves the cutter open when a VITRECTOMY PROBE is not running. The "Closed" function leaves the cutter closed when a VITRECTOMY PROBE is not running.

– Key Multiple Cut / Single Cut
Here you can select the cut mode. With “Single Cut” only one cut will be performed when vitrectomy is activated by the DOUBLE LINEAR FOOTSWITCH II. If this cut mode is chosen the control mode "Linear" and "Fixed" are deactivated. With “Multiple Cut” the cutting rate will be performed when vitrectomy is activated by the DOUBLE LINEAR FOOTSWITCH II.

– Key Fixed / Linear
The cut rate can be controlled in "Fixed" and in "Linear" mode.
In "Fixed" mode the parameter is set immediately to the preset limit.
In "Linear" mode the parameter is controlled linearly between a minimal value and the preset limit.

"Diathermy" module

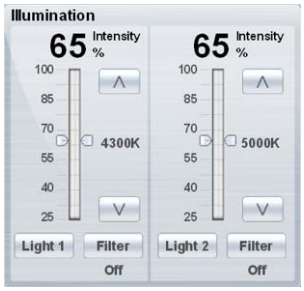


Here you can adjust all diathermy parameters. This module is available in the surgical function "Diathermy" and "Endodiathermy".

– **Power %** - Indicates the diathermy power output.

– Key Fixed / Linear
The diathermy power can be controlled in "Fixed" and in "Linear" mode.
In "Fixed" mode the parameter is set immediately to the preset limit.
In "Linear" mode the parameter is controlled linearly between a minimal value and the preset limit.

"Illumination" module *



Here you can adjust the illumination and filter settings of the two independent illumination systems.

– **Intensity %** - Indicates the current illumination value.
The value can be changed from 25 % to 100 % in 5 %- steps.

– Key Light 1 / Light 2
Here you can switch on/off the two lamps of the illumination system. A lamp is switched on when the key lights up in blue color. A lamp is switched off when the key lights up in grey color.

– Key Filter
Here you can call up the filter overview:

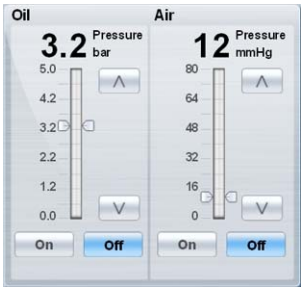
  – Protect - Reduces the blue portion of the light and enables a longer treatment period.

  – Green - Emphasizes the structure and contour of the membrane.

  – Off - Swivel the inserted filter out again.

  The filter can be swiveled in separately for each mode or function.

"Oil / Air" module *



Here you can adjust the silicone oil injection and air infusion.

– **Pressure bar** - Indicates the current silicone oil pressure.
The pressure can be changed from 0.4 to 5.0 bar in 0.2 bar steps.

– **Pressure mmHg** - Indicates the current air pressure.
The pressure can be changed from 5 to 80 mmHg in 1 mmHg steps.

– Key On / Off
Here you can activate or deactivate the silicone oil injection or air infusion.

  – If silicone oil injection is activated the modules "Diathermy", "Aspiration" and "Cutter" are deactivated in all surgical functions, except the surgical function "Phaco Frag".

  – When using the air infusion the following types of irrigation in the menu "Setup" are deactivated and vice versa:

    – "Controlled, Combined High and Combined Low"

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

"Active Alarms" module

System alarm messages that had appeared during operation and which has not been remedied are displayed in the module "Active Alarms". For a more exact view of the system alarm messages, you can enlarge the module "Active Alarms" by touching the screen. Once the malfunction of the system alarm message has been remedied, the system alarm message is only visible in the submenu "History"

In the enlarged module "Active Alarms List" you can temporarily deactivate the alarm tones of the device by touching the key .

– The alarm tone are activated if the key lights up grey.
– The alarm tone are deactivated if the key lights up blue.

As soon as the system is restarted, the alarm tones are automatically reactivated and set to the last active value.

"Foot Switch" module

Displays the current user assignments of the DOUBLE LINEAR FOOTSWITCH II of the respective function.

The foot pedal can be used either in single linear (vertical control only) or in dual linear mode (vertical and horizontal control).

– If the foot pedal is pressed down, the module displays the current foot pedal position (1, 2 or 3).
– If the foot pedal is rotated to the left or right, then the current horizontal pedal direction >> << is displayed.

The functions of the three round side buttons and the function of left-right rotation of the foot pedal can be programmed in the "Foot Switch" module in two ways:

– One for all (see Page 118)
– Individuall (see Page 120)

The functions for vertical control (see page 122) depend on the selected operating mode (e.g. "Diathermy") and cannot be changed.

"Ultrasound Time" module

- Display "Total Time: 00:00:000"
  Time duration of the total phacoemulsification time (TPT). As soon as the surgical system delivers U/S power to the ULITE PHACO HANDPIECE the measurement starts and as soon as no U/S power is further supplied the measurement will end.
- Display "EPT: 00:00:000"
  Time duration of the effective phaco time (EPT) considering the adjusted performance output and the previously selected U/S operation mode (Continuous, Single Burst, Multi Burst, Cont. Burst, Pulsed, APM).
- Display "EPT / Total Time: 0 %"
  The ratio, in percent, of EPT and Total Time (TPT).

"Prime" module

Displays the current status of the priming with following messages:

- Message "Please plug handpiece"
  This message indicates that the ULITE PHACO HANDPIECE is not connected or not recognized.
- Message "Please prime"
  This message indicates that a priming is required. By tapping the key "Prime" in the menu "Setup" the priming procedure will be activated. During this procedure the fluidic system (I/A cassette with connected phaco handpiece and phaco tip) is filled with balanced salt solution. Furthermore it circulates the irrigation fluid through the aspiration tube into the collection bag.
- Message "I/A Prime / Flushing"
  This message indicates that the priming or I/A priming procedure is in process.
- Message "Please tune"
  This message indicates that a tuning is required. By tapping the key "Tune" in the menu "Setup" the tuning procedure will be activated.
- Message "Ultrasound ready"
  This message indicates that a priming or tuning was successfully carried out and the surgical system is ready for use.

Basic settings cataract

Phacoemulsification

Connect accessories

Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

- Mount the necessary accessories, such as the PHACO TIP (1) and SILICONE SLEEVE (2), irrigation and aspiration tubes on the ULITE PHACO HANDPIECE (3) and connect it to the equipment (see page 136).
- Review the correct installation of the ULITE PHACO HANDPIECE by carrying out an initialization (see page 138).

Fig. 76: Phaco accessories

Configure user interface

- Adjust the parameters for the phacoemulsification on the user interface.
  - Selecting the phaco function (see page 187)
  - Configuring the ultrasound (see page 187)
  - Configuring the irrigation (see page 200)
  - Configuring the aspiration (see page 202)

Selecting the phaco function

The phaco function contains following surgical modes:

– "Sculpt", "Quad" and "Epi"
These tabs appear if the program "DivideAndConquer" is loaded.

– "PhacoAsp", "Chop" and "Epi"
These tabs appear if the program "PhacoChop" is loaded.

The three tabs behave identically: they provide different parameter configurations suitable for different phases of the phaco-surgery.

- Tap the key Cataract.
- Tap the tab of the desired surgical mode which you want to use, as for example Sculpt.

  → The appropriate user interface is displayed.
- For shifting between the surgical modes tap the key of the respective mode. With the side buttons or the rotation function of the DOUBLE LINEAR FOOTSWITCH II switching between the individual surgical modes is possible. Information about how to operate this is found in the section "DOUBLE LINEAR FOOTSWITCH II" on page 116.

Configure ultrasound

⚠ **CAUTION**

Injury to the patient's eye!

Corneal incision thermal impact (may lead to corneal burn in the worst case) can be caused by excessive U/S power or by extended use of U/S power when the PHACO TIP is occluded.

- Always use the lowest U/S power which is necessary for the surgical application.
- Vibration noise should increase with U/S power setting. A constant high noise at all power levels indicates equipment malfunction.

Adjust U/S power

The previously set U/S power (stroke of the phaco tip in µm) can be changed in the module "Ultrasound". If you are uncertain about using the U/S power, it is always advisable to begin with a low setting and eventually increase it gradually to obtain the desired surgical effect.

- Tap the arrow key ∧ in order to increase the U/S power or tap the arrow key ∨ in order to decrease it. Alternatively you can regulate the U/S power with the slider.

Select U/S control mode

The U/S power can be delivered in "Fixed" or "Linear" mode. In the latter case, the U/S power is linearly controlled from 5 µm to the preset limit by using the foot pedal.

- Tap the key Linear or Fixed in order to choose between the two modes.

Select U/S operation mode

- Choose between the following U/S operation modes by tapping the corresponding key on the touchscreen:
  - Continuous mode
  - Single Burst mode
  - Multi Burst mode
  - Cont. Burst mode
  - Pulsed mode (configurable)
  - APM mode (fully configurable)

  The impulse modes reduce the quantity of the U/S power on the patient. A more detailed description of the transmission of the U/S operation modes is found on page 49.

Configure mode "Pulsed"

The output of U/S power is in pulses selectable in the range of 1 Hz to 40 Hz.

- For the setting of the desired frequency tap the key Set next to the key Pulsed .

  → The pop-up window "Set U/S Pulse" appears.

  With the keys High , Mid and Low you can adjust the pulse on-time duration and adapt the U/S power.

  - **High:** the percentage ratio of on-time to off-time of the pulses is identical (50/50). The pulse duration depends on the set frequency, though. At 1 Hz, it would be 500 ms, at 40 Hz it would be 12.5 ms.
  - **Mid:** the pulse on time at this setting always is 16 ms regardless of the set frequency. The off time will increase depending on the frequency selected.
  - **Low:** the pulse on time at this setting always is 8 ms regardless of the set frequency. The off time will increase depending on the frequency selected.

  In general: the shorter the pulse time, the lower the energy delivered.

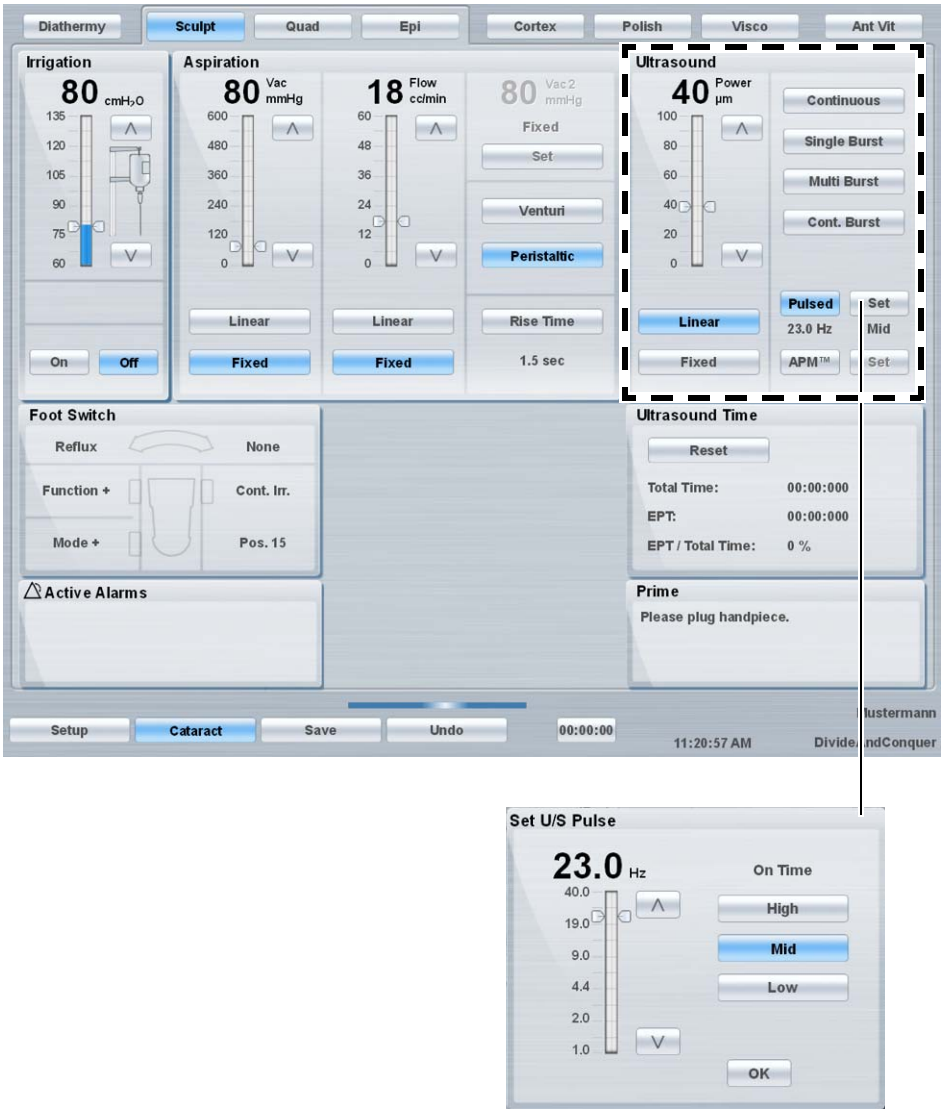


Fig. 77: Configure mode Pulsed

Configure mode "APM"
In the mode APM you can plan the exact ultrasound pattern, that fits best to your work technique and the cataract hardness.

ZEISS does not recommend a specific ultrasound pattern and no specific surgical procedure. This decision is at the discretion of the surgeon.

Set the mode APM as follows:

- In order to activate APM, touch the key APM .
  → If the mode APM is activated, the selection of the U/S control mode "Linear" or "Fixed" is disabled.
  → The U/S power is controlled by the APM software.
- For the configuration of the desired ultrasound pattern, tap the key Set next to the key APM .
  → The "Advanced Power Modulation" pop-up window appears.

The mode APM consists of:

1 Graphic display
The graphic display helps as a guide to understand the effect of the various settings on the pulse.

2 Pulse control (see Page 192)

3 Modulation (see Page 193)

4 Repeat (see Page 194)

5 Hold (see Page 194)

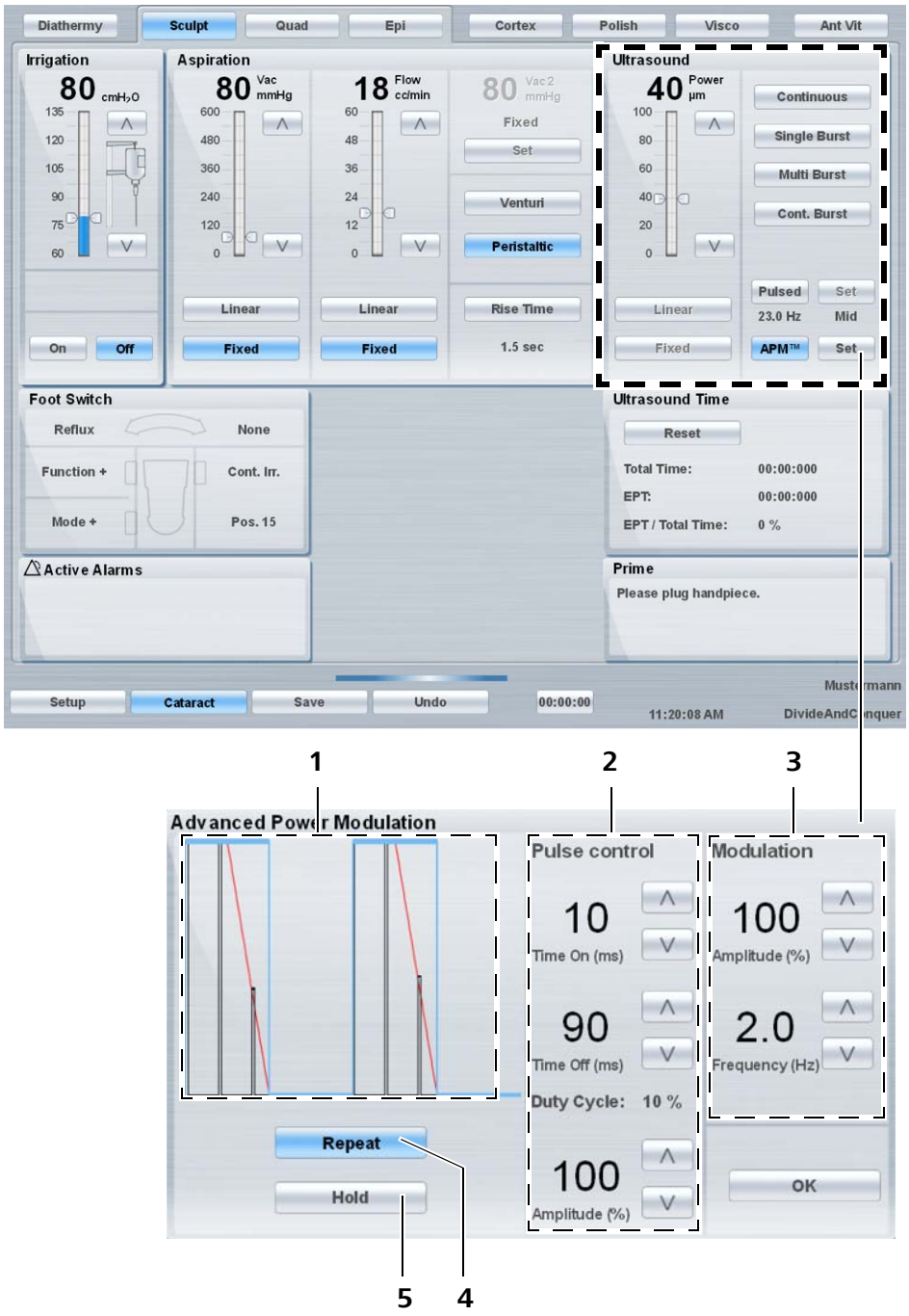


Fig. 78: Configure mode APM

Set Pulse control

In this section you can define the sequence of U/S pulses by modulating the "On Time & Off Time" of each pulse and the height (amplitude) of each pulse.

1 Adjust "Time On"
Defines and regulates the duration of each pulse (10 - 90 milliseconds).

- Tap the key ∧ in order to increase the duration of each pulse or tap the key ∨ in order to decrease it.

In general: the shorter the pulse time, the lower the U/S power.

2 Adjust "Time Off"
Defines and regulates the time between the pulses (10 - 90 milliseconds).

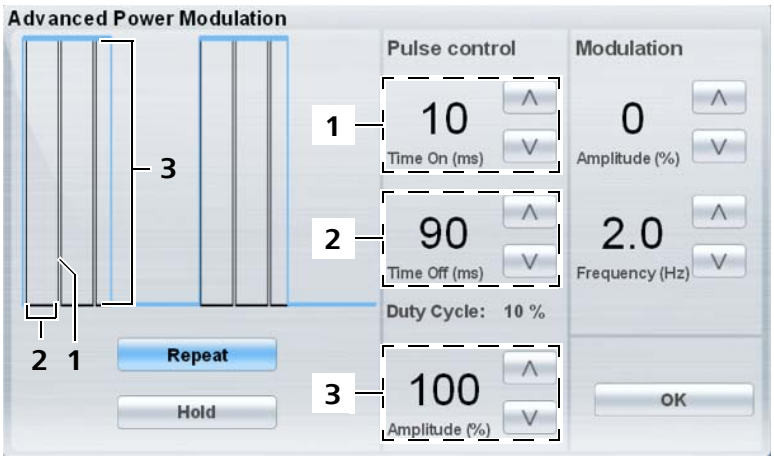
- Tap the key ∧ in order to increase the time between pulses or tap the key ∨ in order to decrease it.

3 Adjust "Amplitude"
Defines and regulates the pulse height (10 - 100 %) of the pre-set U/S power. For example, if the pre-set U/S power is 45 µm, you can half the power by setting the amplitude height to 50 %.

- Tap the key ∧ in order to increase the pulse height or tap the key ∨ in order to decrease it.

Pulse control amplitude at 100 % without amplitude modulation i.e no blocking of U/S pulse, this is 100 % of the preset U/S power.

Fig. 79: APM - Pulse control



Set Modulation

In this section you can move the triangular waveform (4) "Up" or "Down". Furthermore you can determine the period of the triangular wave by modulating the frequency.

1 Adjust "Amplitude"
The amplitude regulates the pulse height. A higher amplitude value will mean more U/S power and a lower amplitude value will mean reduced U/S power. If the amplitude is reduced to 50 % it reduces also the height of the pulse.

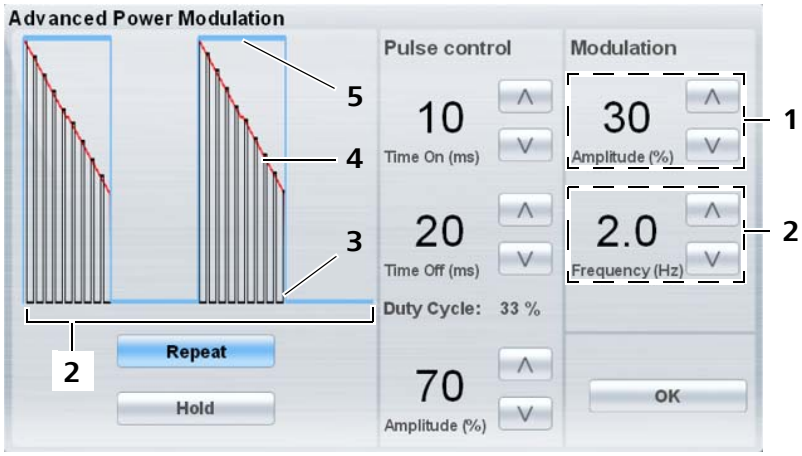
The start value (5) results from the addition of pulse control amplitude and modulation amplitude. The end value (3) results from the subtraction of pulse control amplitude and modulation amplitude.

- Tap the key ∧ in order to increase the triangular wave or tap the key ∨ in order to decrease it.

2 Adjust "Frequency"
The frequency regulates the frequency of the triangular wave (0.5 - 10 Hz). The reduction of the frequency value increase the U/S power per pulse.

- Tap the key ∧ in order to increase the frequency or tap the key ∨ in order to decrease it.

Fig. 80: APM - Modulation

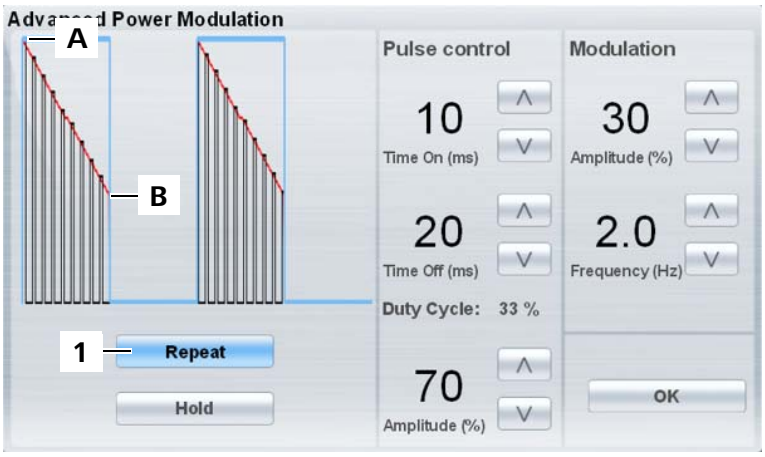


Set Repeat/Hold

The square waveform is used to disable U/S power during periods of triangular wave. It can be set in each of the two possible states:

1 Repeat
This key is used to disable U/S power during periods of triangular wave. When the triangular waveform is at high level (A) U/S bursts are emitted and when it is at a low level (B) U/S bursts are blocked. This also introduces a second semi pulse with a 50% on and 50% off time (follow the blue bars). The U/S modulation so designed is then repeated in a cyclical pattern.

Fig. 81: APM - Repeat



2 Hold

The square wave allows only U/S bursts in the first half-period (C) to pass unchanged. Following U/S bursts (D) are emitted with a frequency that corresponds to the end-level of the first half-period.

The initial pulse is with higher U/S power and then the U/S power reduces and becomes constant at a low power. The pattern is also cyclical.

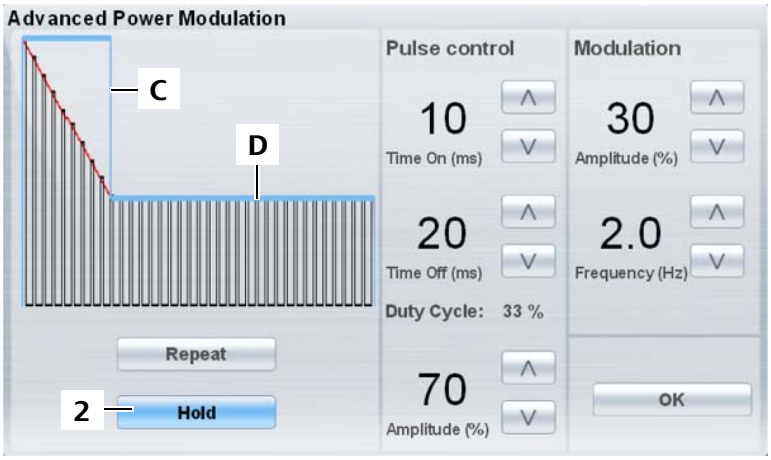


Fig. 82: APM - Hold

Foot switch operation for phacoemulsification

NOTE

Damage of the PHACO TIP!

- Do not activate the ULITE PHACO HANDPIECE as long as the PHACO TIP is surrounded by air. The U/S power should be supplied to the ULITE PHACO HANDPIECE when the PHACO TIP is immersed in a TEST CHAMBER filled with infusion fluid or a beaker filled with a sterile liquid at room temperature. Non-compliance with these instructions can lead to damage to the PHACO TIP and/or ULITE PHACO HANDPIECE.

Activate desired function(s)

⚠ **CAUTION**

Injury to the patient's eye!

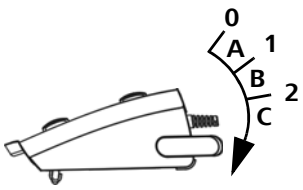
Pressing the foot switch pedal and a foot switch button at the same time, could lead to an unexpected performance of the surgical device.

- The foot switch must always be operated with <u>one</u> foot only!

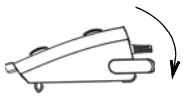
- Press the foot pedal into the respective areas downward in order to activate the desired function(s). The control of aspiration and U/S power depends on the configuration "Linear" or "Fixed".

  → By the activation of a function, the graphic beam in the individual modules indicates the current performance.

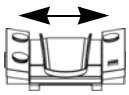
  → As soon as the pedal is returned to position 1 or fully released, venting occurs bringing down the vacuum and Vac 2 to zero.



Single linear control:

Area A	Area B	Area C
Irrigation	Irrigation / Aspiration	Irrigation / Aspiration / U/S power 

Dual linear control:

Area A	Area B	Area C
Irrigation	Irrigation / Aspiration / U/S power 	
	If the function "U/S" of the foot pedal rotation "left or right" is assigned, then the U/S power in the vertical direction is deactivated. Turn the foot pedal slightly to the left or right to activate the U/S power. If "Linear" mode is adjusted a further rotating the foot pedal creates a linear change of the U/S power from 0 µm up to the preset maximum value.	

Irrigation / Aspiration

Connect accessories

Information about the assembly and the connection of the irrigation and aspiration accessories is described on page 142 .

Configure user interface

- Adjust the parameters for the irrigation/aspiration at the user interface.
  - Select irrigation/aspiration function (see page 198)
  - Configuring the irrigation (see page 200)
  - Configuring the aspiration (see page 202)

Select irrigation/aspiration function

The module "Irrigation" and "Aspiration" is available in each surgical function "Diathermy, Phacoemulsification, Irrigation/Aspiration, Anterior Vitrectomy" for cataract surgery.

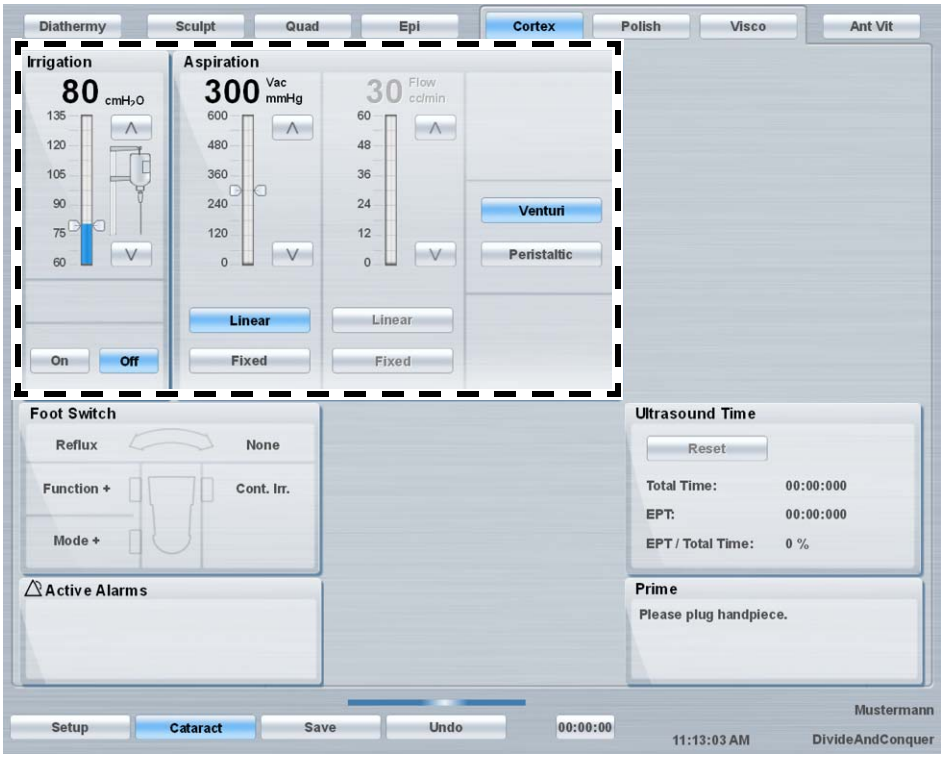
The three special irrigation/aspiration modes "Cortex", "Polish" and "Visco" can save individual parameters of irrigation/aspiration for different phases of the cataract surgery.

- "Cortex" can store settings for the cortex removal.
- "Polish" can store settings for the capsule polishing.
- "Visco" can store vacuum settings for the removal of visco elastic (OVD - Ophthalmic Viscoelastic Device).

- Tap the key Cataract .
- In order to select one of the three special irrigation/aspiration modes, tap the tab Cortex , Polish or Visco . In order to adjust the irrigation/aspiration for another function, e.g. "Ant Vit", tap the corresponding tab.

  → The appropriate user interface is displayed.
- Adjust the irrigation (see page 200) and aspiration (see page 202).
- For shifting between the surgical modes tap the tab Cortex , Polish or Visco . With the side keys or the rotation function of the footpedal switching between the surgical modes is possible. Information about how to operate this is found in the section "DOUBLE LINEAR FOOTSWITCH II" on page 116.

Fig. 83: Irrigation/Aspiration for cataract surgery



Configure irrigation

In the module "Irrigation" you can adjust all parameters for the Irrigation. Depending on the Irrigation type set in the menu "Setup", the following settings in the menu "Cataract" are possible:

– Infusion pole height level (cmH_2O)
  The value indicates the height of the balanced salt solution (BSS) over the pump (patient eye should be set to the pump level) in cm. This is an estimate that depends on the patient and infusion bottle height and the suspension setup of the infusion bottle.

– Pressurized irrigation (mmHg)
  The value indicates the pressure for the controlled irrigation (connected infusion bag) or the combined irrigation (pressurized infusion bottle).

Adjust the infusion pole height and pressurized irrigation

WARNING

Injury to the patient's eye!

A mechanical variation or manual height setting of the infusion pole can lead to the incorrect display of the bottle height!

- Adjust the height of the infusion pole only by the user interface of the surgical device.

WARNING

Injury to the patient's eye!

Positioning the infusion bottle too low may cause the pressure in the patient's eye to be too low.

- Make sure that the infusion bottle is always high enough to ensure fluidic stability in the chamber.

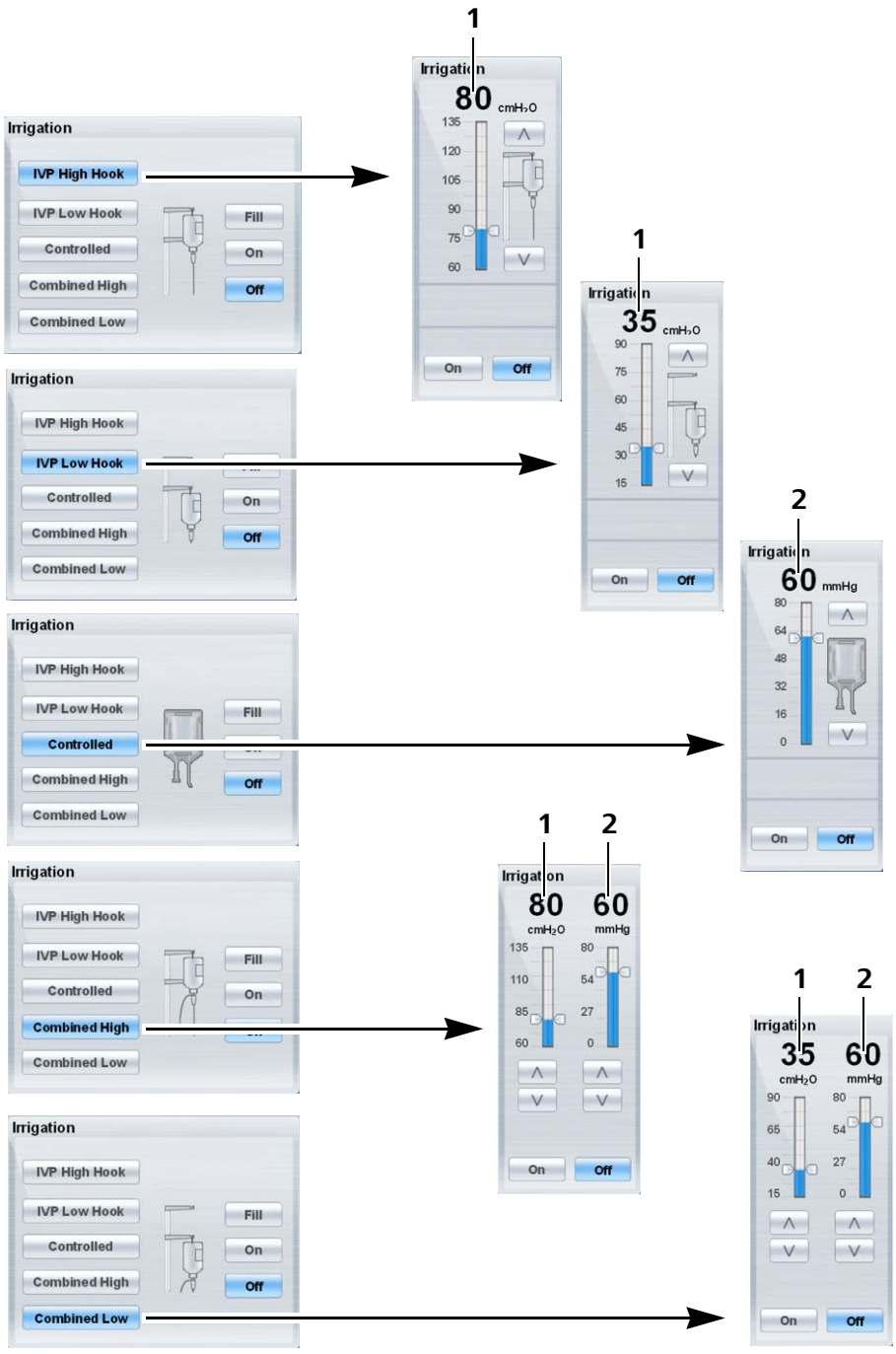
Set the parameter(s) to match the vacuum settings and the connected accessories, in order to maintain proper fluid balance and chamber stability in the patient's eye.

- Increase or decrease the preset infusion pole height level (1) and the preset infusion bag pressure (2) by tapping the arrow key ∧ or ∨. Alternatively you can adapt the values also with the slider.

Activate and deactivate continuous irrigation

- Activate the continuous irrigation by tapping the key On. According to programming of the DOUBLE LINEAR FOOTSWITCH II you can activate this function also over the relevant side button or by rotating the footpedal.
- Deactivate the continuous irrigation by tapping the key Off. According to programming of the DOUBLE LINEAR FOOTSWITCH II you can activate this function also over the relevant side button by rotating the footpedal.

Fig. 84: Configure irrigation for cataract surgery



Configure aspiration

In the module "Aspiration" you can adjust the aspiration settings of the surgical systems.

Select pump mode

The surgical systems are equipped with an I/A cassette such that both a peristaltic pump and a venturi pump are available.

Note that the vacuum limit can be set independently for the peristaltic pump, whereas only the vacuum can be set in case of the venturi pump. When using the venturi pump, the actual flow rate increases with the vacuum setting.

- You can change between both pump modes by tapping the key Venturi or Peristaltic.

Adjust vacuum value and flow value

CAUTION

Injury to the patient's eye!

Instability of the patient's eye may be caused if the height level of the infusion pole or the vacuum settings are incorrect!

- First start with low settings for the vacuum, gradually determine the correct settings for the vacuum and the height of the infusion pole while paying attention that the stability of the patient's eye is maintained.

CAUTION

Injury to the patient's eye!

Changing aspiration rates or vacuum limits or lowering the IV Pole, may cause chamber shallowing or collapse which may result in patient injury.

- Select the irrigation and aspiration values so that the anterior chamber always remains stable and the aspiration is still effective.

- Increase or decrease the vacuum or flow rate (only peristaltic) by tapping the arrow key ∧ or ∨. Alternatively you can adjust the values also with the slide.

If the value of the main vacuum exceeds the value of the Vac 2 vacuum, then the Vac 2 vacuum value is automatically adjusted to the main vacuum value.

Select vacuum modes and flow value modes

Vacuum and flow rate can be controlled both in "Fixed" and in "Linear" control mode. In the latter case, the vacuum and/or the flow rate are controlled linearly between a minimal value and the preset limit by using the foot pedal.

- Tap the key Fixed or Linear in order to choose between both modes.

Configure Rise Time

Rise time adjustment controls the speed with which the pump reach's a stop upon full occlusion and pre set vacuum. Smaller number will cause the pump to stop faster and higher number will stop the pump slower.

The function "Rise Time" functions only if the peristaltic pump was activated and the key Peristaltic lights up blue.

- Configure the rise time in by tapping the key Rise Time.

  → The pop-up window "Set Rise Time" appears.

- Increase or decrease the rise time by tapping the arrow key ^ or v. Alternatively you can adjust the rise time also with the slide.

Fig. 85: Aspiration for cataract

Configure Vac 2

With this function you can change to a second higher preset value of vacuum during phacoemulsification or vitrectomy procedures.

The function "Vac 2" is activated when the foot pedal function "Vac 2" is assigned and saved to rotation left or right.

- Configure "Vac 2" by tapping the key Set.

  → The pop-up window "Vacuum 2" appears.

Adjust maximum Vac 2 value

- Increase or decrease the value by tapping the arrow key ^ or v. Alternatively you can adjust the value also with the blue slide. The value must indeally be higher or equal to the main vacuum value.

Select Vac 2 modes

- Tap the key Fixed or Linear for shifting between both modes.
- Turn the foot pedal slightly left or right to activate the Vac 2 vacuum. In "Fixed" mode the parameters are set immediately to the preset value. In "Linear" mode further rotating the foot pedal creates a linear change of the vacuum from the preset vacuum value (grey slide) up to the preset value of Vac 2 (blue slide).

Fig. 86: Vac 2 settings

Foot switch operation for irrigation/aspiration

WARNING

Injury to the patient's eye!

An insufficient height of the IV Pole or an empty infusion bottle / infusion bag of balanced salt solution (BSS) reduces intraocular pressure.

- Keep an eye on the level of balanced salt solution (BSS) in the infusion bottle during surgery. If the infusion bottle or infusion bag is empty, inform the surgeon and replace the infusion bottle or infusion bag.

WARNING

Injury to the patient's eye!

The patient´s eye may be injured if the drainage bag of the I/A cassette is full.

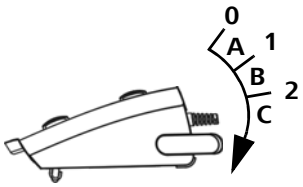
- Make sure not to exceed the capacity of the I/A cassette or drainage bag.

Activate desired function(s)

- Press the foot pedal into the respective areas downward in order to activate the desired function(s). The control of aspiration depends on the configuration "Linear" or "Fixed".

  → By the activation of the aspiration, the graphic bar in the module "Aspiration" indicates the present vacuum and the flow rate (only in activated peristaltic pump).

  → As soon as the foot pedal is released, the system venting with fluid happens and the vacuum is brought to zero.



Area A	Area B	Area C
Irrigation	Irrigation / Aspiration	

Bipolar diathermy

Connect accessories

Information about the assembly and the connection of the diathermy accessories is described on page 143.

Configure user interface

- Adjust the parameters for the diathermy on the user interface.
  - Select diathermy function (see page 206)
  - Configuring diathermy (see page 206)
  - Configuring irrigation - if required (see page 200)

Select diathermy function

- Tap the key Cataract.
- Tap the tab Diathermy.
  → The user interface displays all relevant parameters of the diathermy function.

Configure diathermy

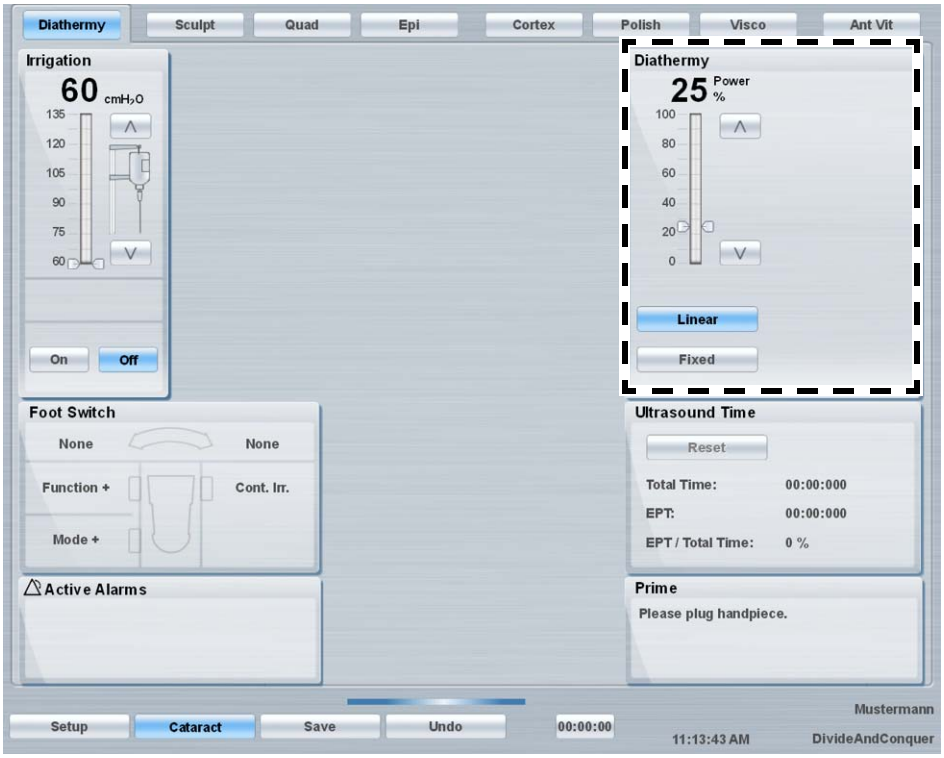
Adjust diathermy power
The previously set diathermy power can be changed in the module "Diathermy". If you are uncertain about the power to use, it is always advisable to begin with a low setting eventually increasing it gradually to obtain the desired surgical effect.

- Increase or decrease the preset value by tapping the arrow key ^ or v. Alternatively you can regulate the diathermy power with the slider.

Select diathermy control mode
The diathermy power can be delivered in "Fixed" or "Linear" mode. In the latter case, diathermy power is linearly controlled from 5 % to the preset limit by using the foot pedal.

- Tap the key Fixed or Linear in order to choose between the two modes.

Fig. 87: Bipolar Diathermy



Foot switch operation for diathermy

WARNING

Injury to the patient!

- The diathermy section of the VISALIS V500 or VISALIS S500 equipment must not be used on patients with a pacemaker or other cardiac stimulators without prior consultation of a cardiologist.

WARNING

Injury to the patient's eye!

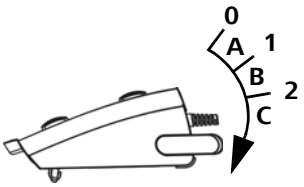
- When a bipolar diathermy probe and a monitoring system are used at the same time, all electrodes of the monitoring system that are not protected by resistors or high frequency inductors must be placed as far away as possible from the diathermy electrodes.

Activate desired function

- Press the foot pedal into the area C downward in order to activate the diathermy. The control of diathermy power depends on the configuration "Linear" or "Fixed".

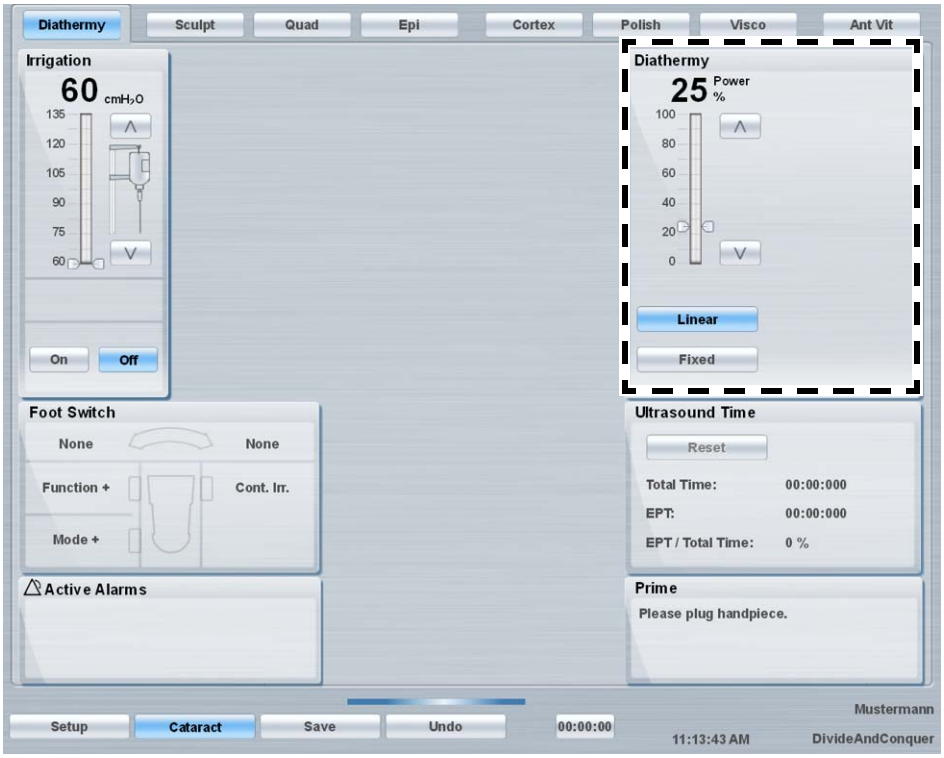
  → By the activation of the diathermy, the graphic bar in the module "Diathermy" indicates the present diathermy power.

  → Simultaneously a tone signal with uniform pitch sounds in order to signal the activation of the diathermy.



Area A	Area B	Area C
-	-	Diathermy

Fig. 88: Bipolar Diathermy



Anterior vitrectomy

Connect accessories

Information about the assembly and the connection of the vitrectomy accessories is described on page 145.

Configure user interface

- Adjust the parameters for the vitrectomy on the user interface.
  - Selecting the vitrectomy function (see page 210)
  - Configuring the vitrectomy (see page 210)
  - Configuring the irrigation (see page 200)
  - Configuring the aspiration (see page 202)

Select the vitrectomy function

- Tap the key Cataract.
- Tap the tab Ant Vit.
  → The user interface displays all relevant parameters of the vitrectomy mode.

Configure vitrectomy function

In the module "Cutter" you can define the settings for the connected VITRECTOMY PROBE.

Select aspiration opening

- If you intend to work with the aspiration open, tap the key Open.
  In order to return to the mode with a closed tip, tap the key Closed.

Set cutting rate

- Increase or decrease the cutting rate with the arrow key ∧ or ∨.
  Alternatively you can regulate the diathermy power with the slide.

Select vitrectomy mode

The anterior vitrectomy can be carried out "Fixed" or "Linear". In the latter case, the cutting rate is linearly controlled from 60 cuts/min to the preset limit by using the foot pedal.

- Tap the key Fixed or Linear in order to choose between both modes.

Select cut mode

- If you intend to work in "Single Cut" mode, tap the key Single Cut. In order to return to "Multiple Cut" mode, tap the key Multiple Cut.

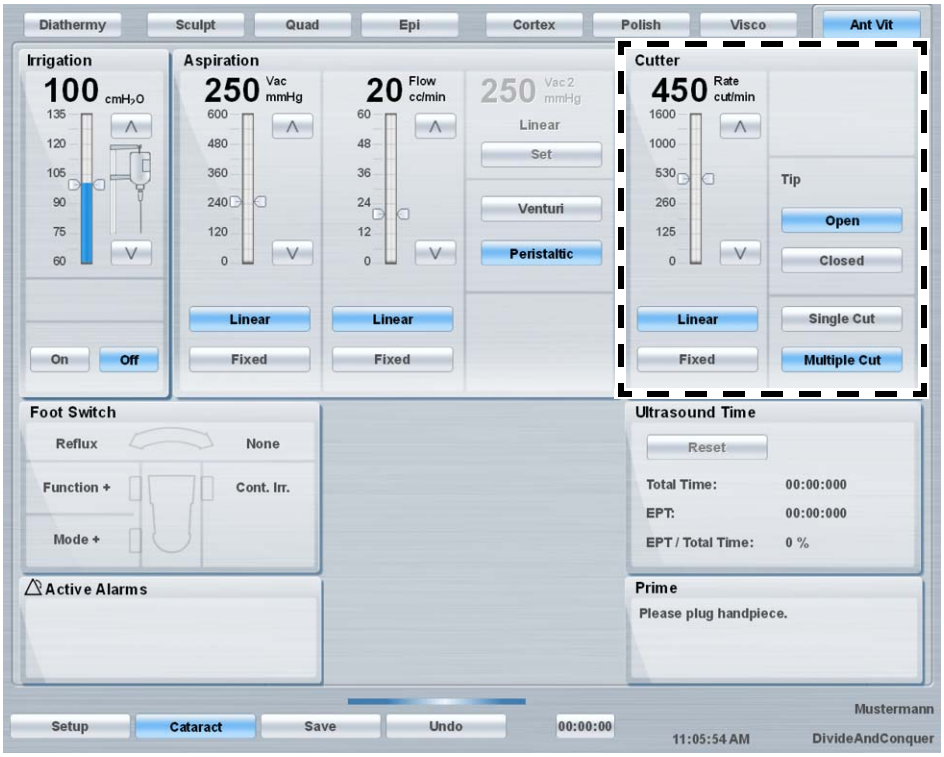


Fig. 89: Anterior vitrectomy

Foot switch operation for anterior vitrectomy

WARNING

Injury to the patient's eye!

Non-filtered air might enter into the patient's eye if a vitrectomy probe is connected incorrectly.

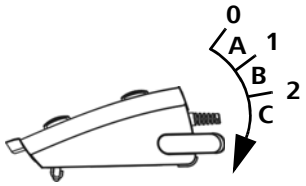
- A vitrectomy probe should always be tested for proper functioning by placing a vitrectomy probe in a bowl of sterile BSS and activated by pressing the foot switch to ensure proper functioning of the vitrectomy probe and to remove any air from the tubing, before placing the handpiece in the patient's eye.

Activate desired function(s)

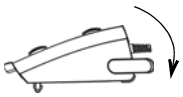
- Press the foot pedal into the respective areas downward in order to activate the desired function(s). The control of aspiration and cutting rate depends on the configuration "Linear" or "Fixed".

  → By the activation of a function, the graphic beam in the individual modules indicates the current performance.

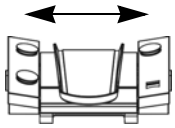
  → As soon as the foot pedal is returned to position 1 or fully released, venting occurs bringing down the vacuum and Vac 2 to zero.



Single linear control:

Area A	Area B	Area C
Irrigation	Irrigation / Aspiration / Cutting  (Press the foot pedal downward, to change the cutting rate linearly from 60 cuts/min to the previously adjusted maximum value)	

Dual linear control:

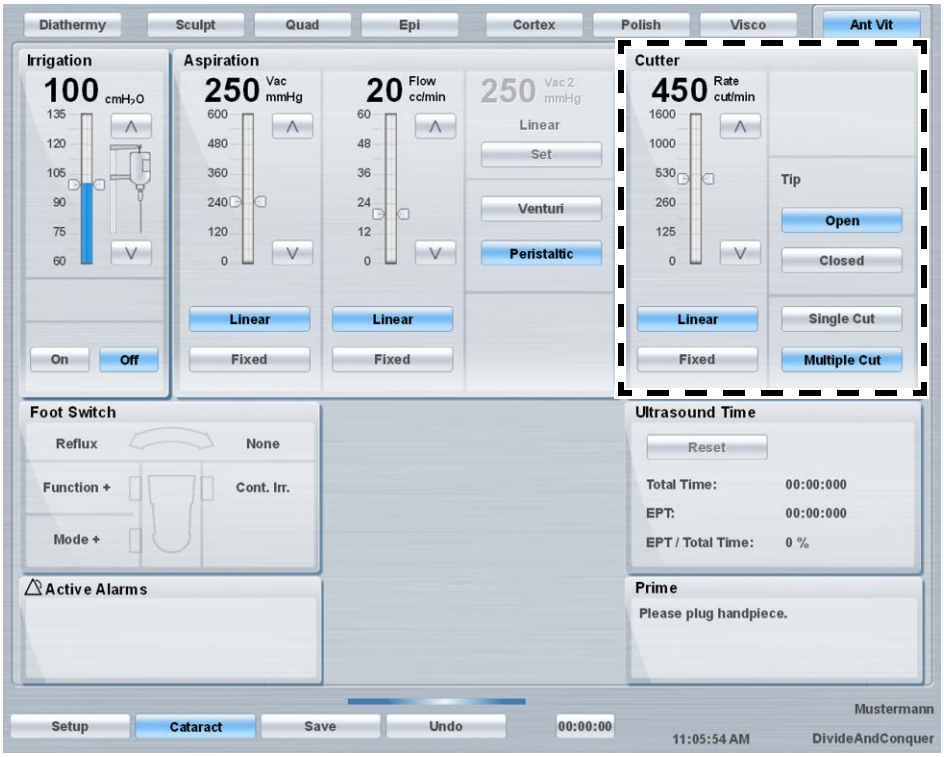
Rest position	Area A	Area B	Area C
Cutting	Irrigation / Cutting	Irrigation / Aspiration / Cutting 	

Rest position	Area A	Area B	Area C

If the function "Cut" of the foot pedal rotation is assigned "left or right", then the cutting function is deactivated in the vertical direction. Turn the foot pedal slightly left or right to activate the vitrectomy. In "Linear" mode further rotating the foot pedal creates a linear change of the cutting rate from 60 cuts/min up to the preset maximum value.

If the function "Cut off" from the foot pedal rotation "left or right" is assigned, then you can turn the foot pedal from the area B to the left or to the right in order to disengage the cutting function.

Fig. 90: Anterior vitrectomy



Basic settings retina *

Vitrectomy for retinal surgery *

Connect accessories

Information about the assembly and the connection of the posterior vitrectomy accessories is described on page 145.

Configure user interface

- Adjust the parameters for the posterior vitrectomy on the user interface:
  - Selecting the vitrectomy function
  - Configuring the vitrectomy function (see page 216)
  - Adjusting the irrigation (see page 226) and air (see page 228) - if necessary
  - Configuring the aspiration (see page 230)
  - Adjust illumination (see page 222) - if necessary
  - Adjust silicone oil injection (see page 234) - if necessary

Select the vitrectomy function

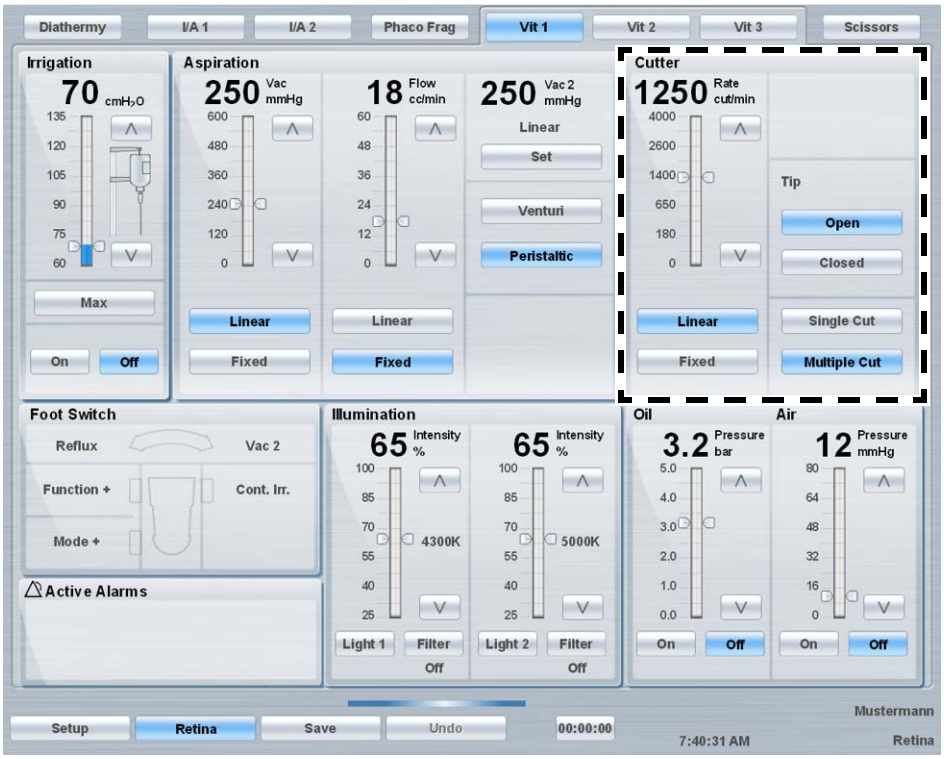
The surgical function "Vitrectomy" controls three independent surgical modes "Vit 1", "Vit 2" and "Vit 3" for the storage of irrigation, aspiration and cutting parameters for different phases of the retinal operation.

- Tap the key Retina.
- In order to select a surgical mode of the vitrectomy function, tap the tab Vit 1, Vit 2 or Vit 3.

  → The key of the selected surgical mode is highlighted blue.
- For shifting between the surgical modes tap the key Vit 1, Vit 2 or Vit 3. With the side keys or rotation function of the footpedal switching between the surgical modes "Vit 1", "Vit 2" and "Vit 3" is possible. Information about how to operate this is found in the section "DOUBLE LINEAR FOOTSWITCH II" on page 116.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 91: Posterior Vitrectomy



Configure vitrectomy function

In the module "Cutter" you can determine the settings for the connected handpiece.

Select aspiration opening

- If you intend to work with the aspiration open, tap the key Open. In order to return to the mode with a closed tip, tap the key Closed.

Set cutting rate

- Increase or decrease the cutting rate with the arrow key ^ or v. Alternatively you can regulate the cutting rate with the slider.

Select vitrectomy mode

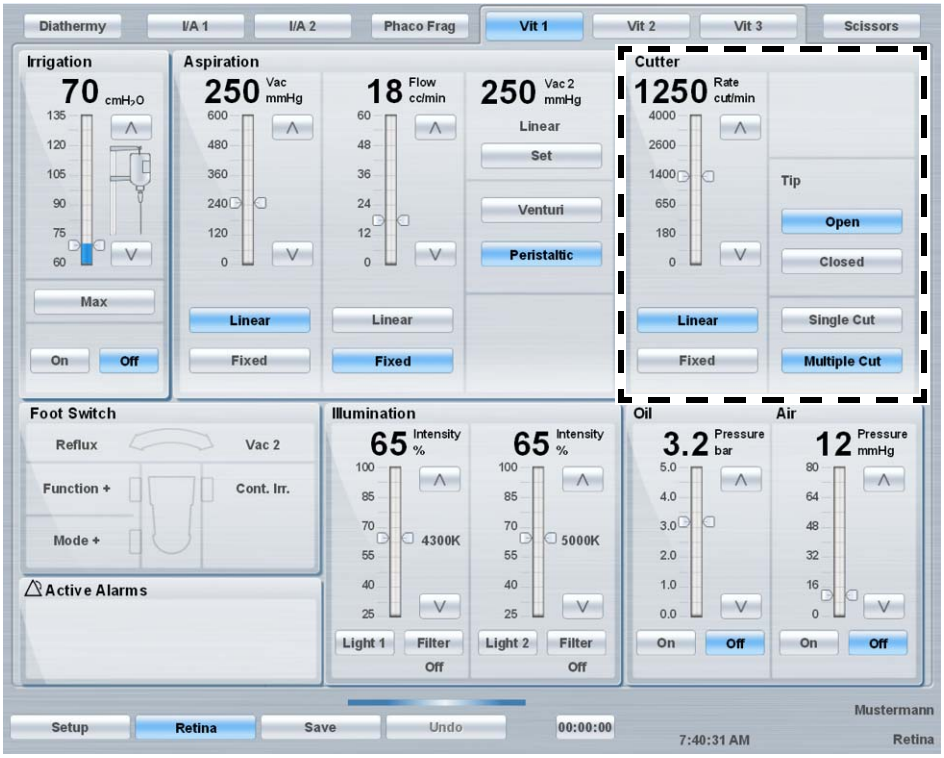
The vitrectomy can be carried out "Fixed" or "Linear". In the latter case, the cutting rate is linearly controlled from 60 cuts/min to preset cut rate by using the foot pedal.

- Tap the key Fixed or Linear in order to choose between both modes.

Select cut mode

- If you intend to work in "Single Cut" mode, tap the key Single Cut. In order to return to the "Multiple Cut" mode tap the key Multiple Cut.

Fig. 92: Posterior Vitrectomy



Foot switch operation for posterior vitrectomy *

WARNING

Injury to the patient's eye!

Non-filtered air might enter into the patient's eye if a vitrectomy probe is connected incorrectly.

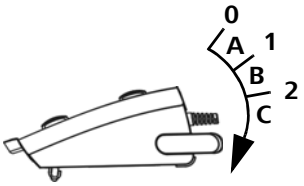
- A vitrectomy probe should always be tested for proper functioning by placing a vitrectomy probe in a bowl of sterile BSS and activated by pressing the foot switch to ensure proper functioning of the vitrectomy probe and to remove any air from the tubing, before placing the handpiece in the patient's eye.

Activate desired function(s)

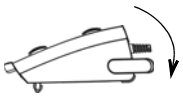
- Press the foot pedal into the respective areas downward in order to activate the desired function(s). The control of aspiration and cutting rate depends on the configuration "Linear" or "Fixed".

  → By the activation of a function, the graphic beam in the individual modules indicates the current performance.

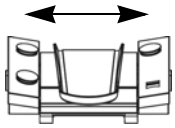
  → As soon as the foot pedal is returned to position 1 or fully released, venting occurs bringing down the vacuum and Vac 2 to zero.



Single linear control:

Area A	Area B	Area C
Irrigation	Irrigation / Aspiration / Cutting  (Press the foot pedal downward, to change the cutting rate linearly from 60 cuts/min to the previously adjusted maximum value)	

Dual linear control:

Rest position	Area A	Area B	Area C
Cutting	Irrigation / Cutting	Irrigation / Aspiration / Cutting 	

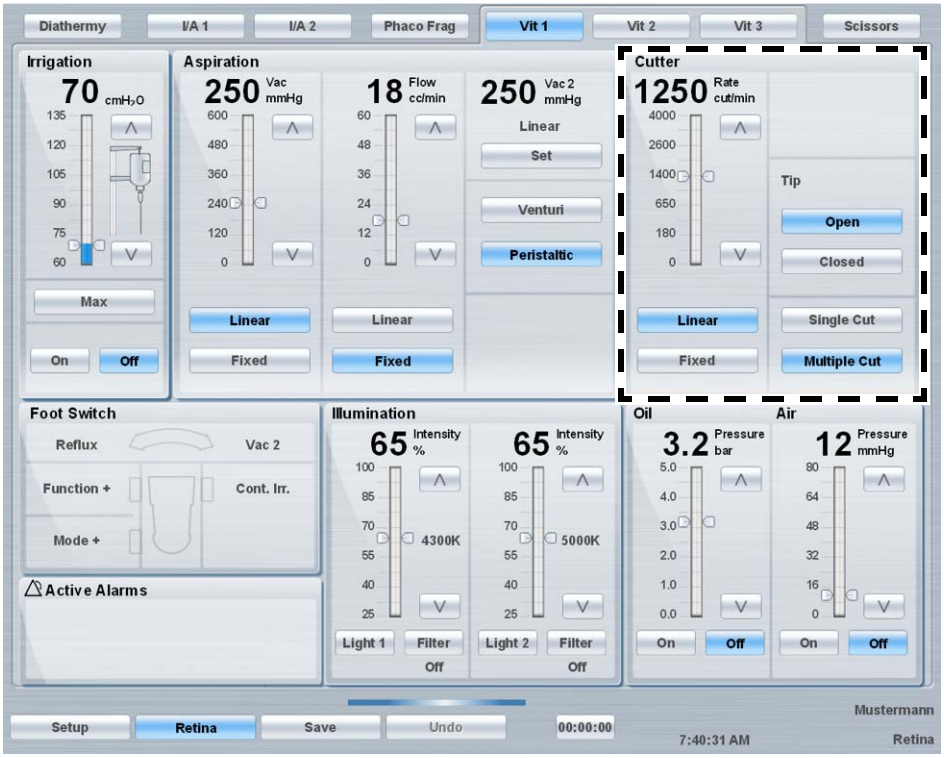
Rest position	Area A	Area B	Area C

If the function "Cut" of the foot pedal rotation is assigned "left or right", then the cutting function is deactivated in the vertical direction. Turn the foot pedal slightly left or right to activate the vitrectomy. In "Linear" mode further rotating the foot pedal creates a linear change of the cutting rate from 60 cuts/min up to the preset maximum value.

If the function "Cut off" from the foot pedal rotation "left or right" is assigned, then you can turn the foot pedal from the area B to the left or to the right in order to disengage the cutting function.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 93: Posterior Vitrectomy



Illumination for retinal surgery *

Connect accessories

Information about the assembly and the connection of the illumination accessories is described on page 147.

Configure user interface

- Adjust the parameters for the illumination on the user interface.
  - Selecting the illumination function (see page 220)
  - Switching the illumination on and off (see page 220)
  - Setting the illumination level (see page 222)
  - Swiveling filter in and out (see page 222)

Select illumination function

- Tap the key Retina.
- Tap the tab of the desired function for which you require the illumination, as for example Vit1.

  → The user interface shows all relevant parameters of the selected function and the relevant illumination settings.

Illumination, switching on and off

WARNING

Injury to the patient's eye!

- To reduce the risk of retinal damage, the edge of the fiber optic illumination probe should not be situated in the immediate vicinity of the retina.

NOTE

Injury to the user!

Light output ports that are turned on are hot.

- Turn off the light and wait several minutes before you touch the light output ports!

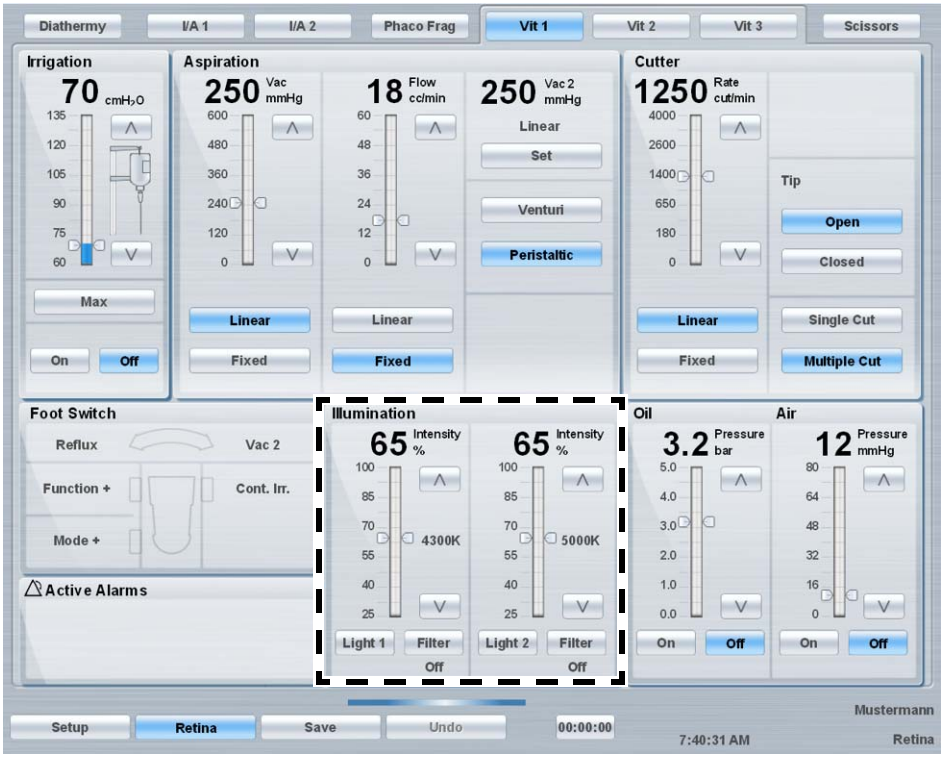
- Tap the keys Light 1 or Light 2 to switch the illumination on or off.

  → The light source is on when the key lights up blue.

  → The light source is off when the key is gray.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 94: Setting the illumination



Adjust illumination intensity

WARNING

Injury to the patient's eye!

Phototoxic effects of long exposure to high intensity illumination.

- Adapt the irradiation intensity and the corresponding duration of exposure by selecting suitable illumination and filter settings. The values recommended by ZEISS are presented in the table, "Maximal irradiation times". Any deviation from these values is permissible on medical grounds only.
- Always use the lowest yet most sufficient level for use.

WARNING

Injury to the user!

If the xenon lamps burst, notify the ZEISS Service.

- Do not attempt to change the lamps yourself.

In the module "Light" you can adjust the illumination of the surgical system VISALIS V500. The illumination intensity can be changed from 25 % to 100 % in 5 %- steps.

- Tap the arrow key ∧ in order to increase the illumination or tap the arrow key ∨ in order to decrease it. Alternatively you can regulate the illumination with the slider.

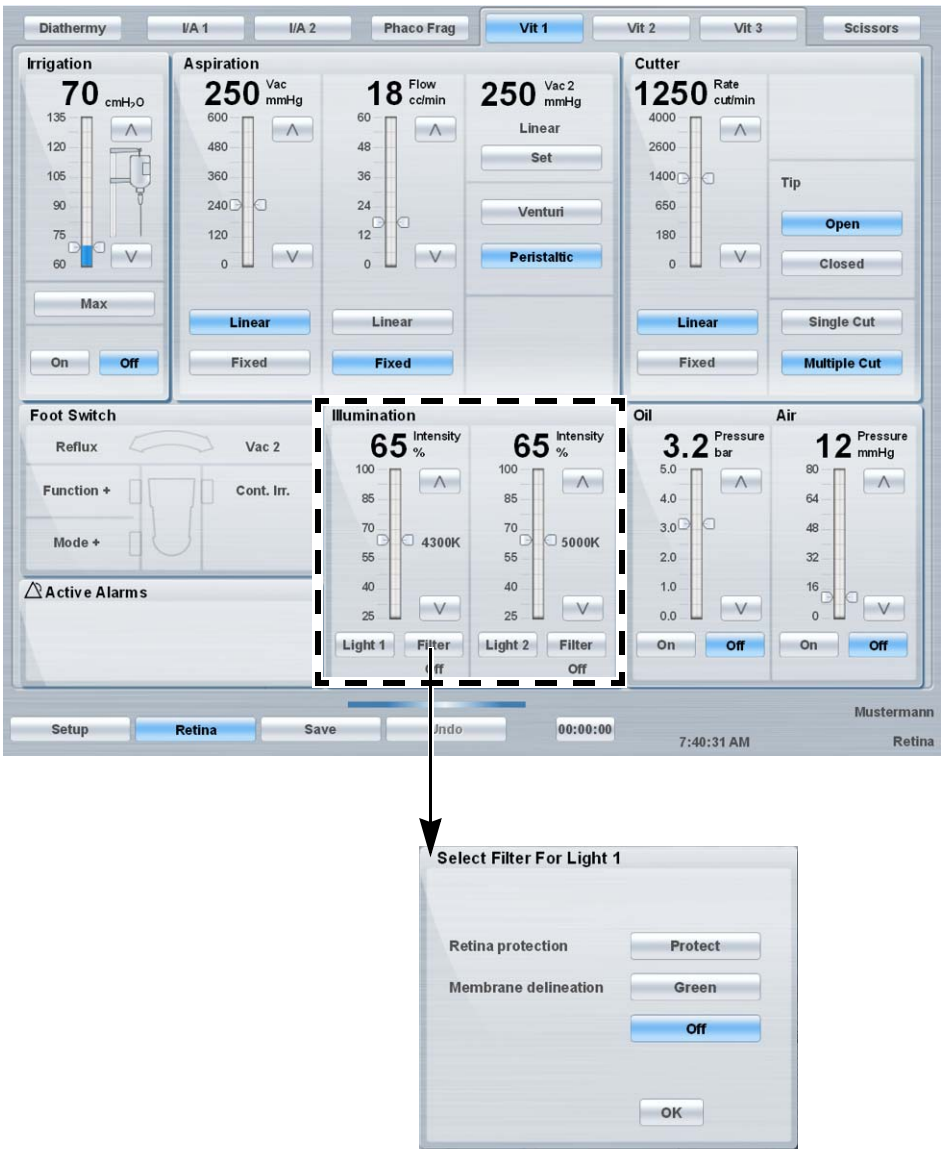
Swiveling the filter in and out

- Tap the key Filter, to call up the filter overview.
  - → The pop-up window "Select Filter For Light 1" or "Select Filter For Light 2" appears. Now you can choose between the following filters:
  - – Protect - Swivel in the retina protection filter. The retina protection filter reduces the blue portion of the light and enables a longer treatment period (see maximum irradiation time page 22).
  - – Green - Swivel in the green filter. The green filter emphasizes the structure and contour of the membrane.
  - – Off - Swivel the inserted filter out again.
- Tap the desired filter key to swivel a filter in or out.
  - → The selection is activated if the key lights up blue.
  - → The selection is deactivated if the key lights up grey.
- Tap the key OK.
  - → The filter status is displayed below the respective filter selection key.

- Protect - the retina protection filter is swiveled in
- Green - the green filter is swiveled in
- Off - no filter is used or swiveled in

The filter can be swiveld in separately for each surgical mode or surgical function. The filter status is also displayed in the Setup / Overview page / Illumination.

Fig. 95: Swiveling filter in and out



Air fluid exchange for retinal surgery *

Connect accessories

Information about the assembly and connection of the air-fluid exchange accessories is described on page 150.

Configure user interface

- Adjust the parameters for the air fluid exchange on the user interface as follows:
  - Select function, for example I/A (see page 224)
  - Configure irrigation (see page 226) and configure air (see page 228)

Select I/A function

The module "Irrigation" and "Aspiration" is available in every surgical function of the menu "Retina". The module "Aspiration" is not available in the surgical function "Diathermy" and "Scissors".

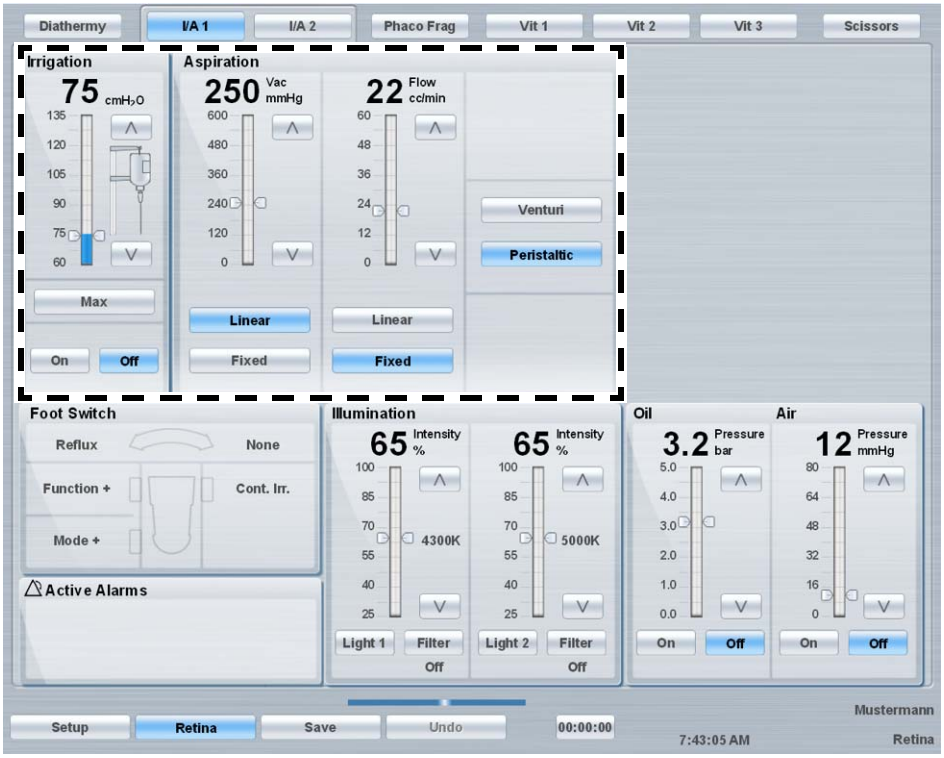
The two special irrigation/aspiration modes "I/A 1" and "I/A 2" control independent storage positions for the storage of irrigation/aspiration parameters for different phases of the retina surgery.

- Tap the key Retina .
- In order to select one of the two special irrigation/aspirations modes, tap the tab I/A1 or I/A2 . In order to adjust the irrigation/aspiration for another function, e.g. " Vit 1", you tap the corresponding tab.

  → After tapping the desired tab, the appropriate screen is displayed.
- Adjust the irrigation (see page 226) and aspiration (see page 230).
- For shifting between the surgical modes tap the tab I/A 1 or I/A 2 . With the side keys or the rotation function of the footpedal switching between the individual surgical modes is possible. Information about how to operate this is found in the section "DOUBLE LINEAR FOOTSWITCH II" onpage 116.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 96: Irrigation/Aspiration for retinal surgery



Configure irrigation

In the module "Irrigation" you can adjust all parameters for the Irrigation. Depending on the Irrigation type set in the menu "Setup", the following settings in the menu "Retina" are possible:

– Infusion pole height level (cmH_2O)
  The value indicates the height of the infusion bottle over the pump of the patient in cm. This is an estimate that depends on the patient and infusion bottle height and the suspension setup of the infusion bottle.

– Pressurised irrigation (mmHg)
  The value indicates the pressure for the controlled irrigation (connected infusion bag) or the combined irrigation (pressurized infusion bottle).

Adjust the infusion pole height and pressurized irrigation

WARNING

Injury to the patient's eye!

A mechanical variation or manual height setting of the infusion pole can lead to the incorrect display of the bottle height!

- Adjust the height of the infusion pole only by the user interface of the surgical device.

WARNING

Injury to the patient's eye!

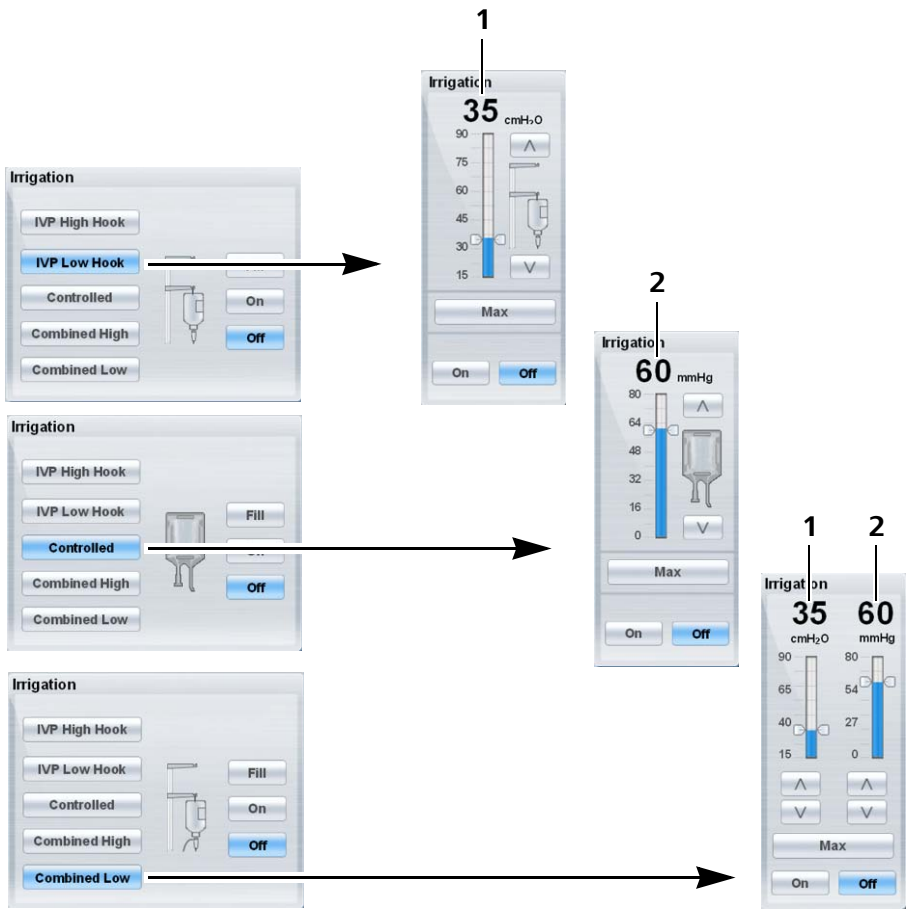
Positioning the infusion bottle too low may cause the pressure in the patient's eye to be too low.

- Make sure that the infusion bottle is always above the patient´s eye level.

Set the parameter(s) to match the vacuum settings and the connected accessories, in order to maintain proper fluid balance and chamber stability in the patient's eye.

- Increase or decrease the preset infusion pole height level (1) and the preset infusion bag pressure (2) by tapping the arrow key ∧ or ∨. Alternatively you can adapt the values also with the slider.

Fig. 97: Configurate irrigation for retina surgery



Activate and deactivate maximum irrigation pressure

In the retina modes, the maximum available irrigation pressure can be reached by tapping a single key. In case of bleeding and the need of hemostasis this function increases the irrigation pressure during a posterior section surgery.

- Activate the maximum irrigation pressure by tapping the key Max.
- In order to set the prior pressure value again tap the key Max.

Configure air infusion

In case of using one of the following controlled irrigation types the module "Air" is deactivated:

– Controlled

– Combined High

– Combined Low

When using one of the following gravity irrigation types use the "Oil/Air" module to control the air pressure:

– IVP High Hook

– IVP Low Hook

Activate and deactivate air infusion

- Tap in the module "Air" the key On in order to activate the air infusion. According to programming of the DOUBLE LINEAR FOOTSWITCH II you can activate this function also over the relevant side key or the rotation of the footpedal.

  → The key On lights up in blue.

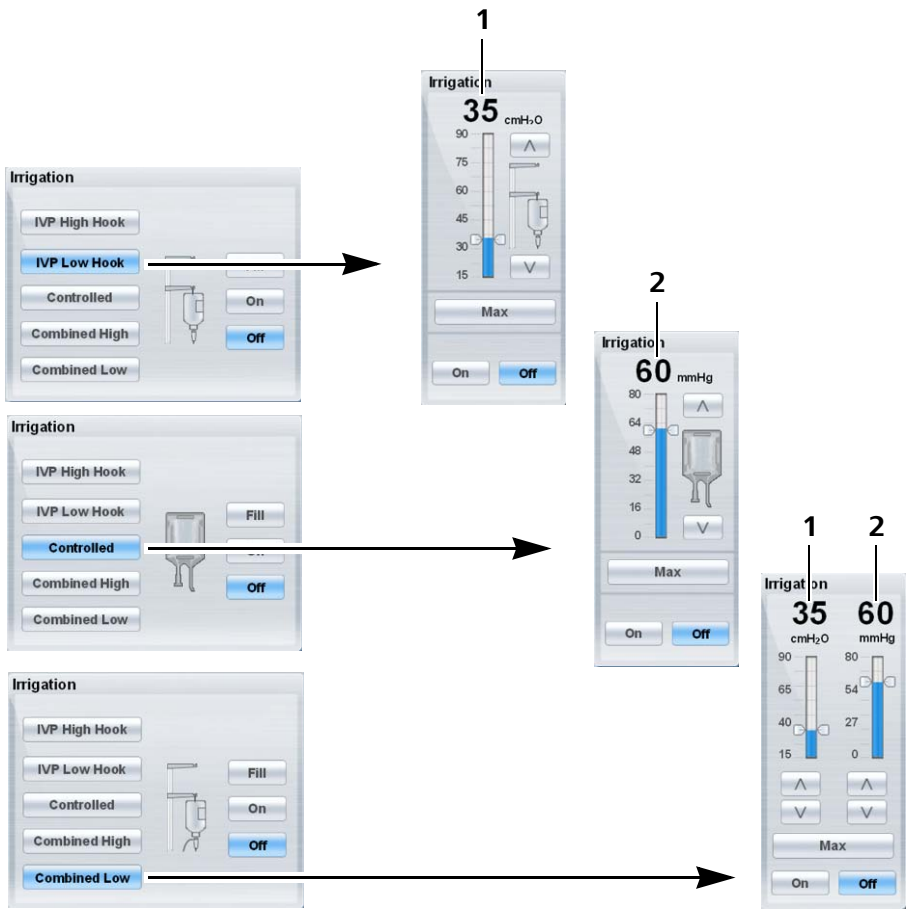
- Tap in the module "Air" the key Off, in order to stop the air infusion or once again the key programmed in addition on the DOUBLE LINEAR FOOTSWITCH II.

  → The key On turns to gray.

Adapt air infusion pressure

- Tap the arrow key ∧ in order to increase the air infusion pressure or tap the arrow key ∨ in order to decrease it. Alternatively you can regulate the air infusion pressure with the slide (1).

Fig. 98: Configurate irrigation for retina surgery



Configure aspiration

In the module "Aspiration" you can adjust the aspiration settings of the surgical systems.

Select pump mode
The surgical systems are equipped with an I/A cassette such that both a peristaltic pump and a venturi pump are available.

Note that the vacuum limit can be set independently for the peristaltic pump, whereas only the vacuum can be set in case of the venturi pump. When using the venturi pump, the actual flow rate increases with the vacuum setting.

- You can change between both pump modes by tapping the key Venturi or Peristaltic.

Adjust vacuum value and flow value

CAUTION

Injury to the patient's eye!

Instability of the patient's eye may be caused if the height level of the infusion pole or the vacuum settings are incorrect!

- First start with low settings for the vacuum, gradually determine the correct settings for the vacuum and the height of the infusion pole while paying attention that the stability of the patient's eye is maintained.

CAUTION

Injury to the patient's eye!

Changing aspiration rates or vacuum limits or lowering the IV Pole, may cause chamber shallowing or collapse which may result in patient injury.

- Select the irrigation and aspiration values so that the anterior chamber always remains stable and the aspiration is still effective.

- Increase or decrease the vacuum or flow rate (only peristaltic) by tapping the arrow key ∧ or ∨. Alternatively you can adjust the values also with the slide.

If the value of the main vacuum exceeds the value of the Vac 2 vacuum, then the Vac 2 vacuum value is automatically adjusted to the main vacuum value.

Select vacuum modes and flow value modes
Vacuum and flow rate can be controlled both in "Fixed" and in "Linear" control mode. In the latter case, the vacuum and/or the flow rate are controlled linearly between a minimal value and the preset limit by using the foot pedal.

- Tap the key Fixed or Linear in order to choose between both modes.

Configure Rise Time
Rise time adjustment controls the speed with which the pump reach's a stop upon full occlusion and pre set vacuum. Smaller number will cause the pump to stop faster and higher number will stop the pump slower.

The function "Rise Time" functions only if the peristaltic pump was activated and the key Peristaltic lights up blue.

- Configure the rise time in by tapping the key Rise Time.

  → The pop-up window "Set Rise Time" appears.

- Increase or decrease the rise time by tapping the arrow key ∧ or ∨. Alternatively you can adjust the rise time also with the slide.

Fig. 99: Aspiration for cataract

Configure Vac 2

With this function you can change to a second higher preset value of vacuum during phacoemulsification or vitrectomy procedures.

The function "Vac 2" is activated when the foot pedal function "Vac 2" is assigned and saved to rotation left or right.

- Configure "Vac 2" by tapping the key Set.

  → The pop-up window "Vacuum 2" appears.

Adjust maximum Vac 2 value

- Increase or decrease the value by tapping the arrow key ^ or v. Alternatively you can adjust the value also with the blue slide. The value must indeally be higher or equal to the main vacuum value.

Select Vac 2 modes

- Tap the key Fixed or Linear for shifting between both modes.
- Turn the foot pedal slightly left or right to activate the Vac 2 vacuum. In "Fixed" mode the parameters are set immediately to the preset value. In "Linear" mode further rotating the foot pedal creates a linear change of the vacuum from the preset vacuum value (grey slide) up to the preset value of Vac 2 (blue slide).

Fig. 100: Vac 2 settings

Foot switch operation for irrigation/aspiration *

WARNING

Injury to the patient's eye!

An insufficient height of the IV Pole or an empty infusion bottle / infusion bag of balanced salt solution (BSS) reduces intraocular pressure.

- Keep an eye on the level of balanced salt solution (BSS) in the infusion bottle during surgery. If the infusion bottle or infusion bag is empty, inform the surgeon and replace the infusion bottle or infusion bag.

WARNING

Injury to the patient's eye!

The patient may be injured if the drainage bag of the I/A cassette is full.

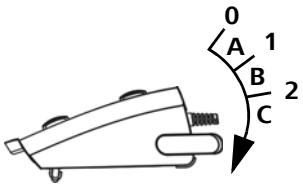
- Make sure not to exceed the capacity of the I/A cassette or drainage bag.

Activate desired function(s)

- Press the foot pedal into the respective areas downward in order to activate the desired function(s). The control of aspiration depends on the configuration "Linear" or "Fixed".

  → By the activation of the aspiration, the graphic bar in the module "Aspiration" indicates the present vacuum and the flow rate (only in activated peristaltic pump).

  → As soon as the foot pedal is released, the system venting with fluid happens and the vacuum is brought to zero.



Area A	Area B	Area C
Irrigation	Irrigation / Aspiration	

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Silicone oil injection for retinal surgery *

Connect accessories

Information about the assembly and connection of the silicone oil air-fluid exchange accessories is described on page 152.

Configure user interface

Adjust the parameters for the silicone oil injection on the user interface:

– Selecting the silicone oil injection function (see page 234)

– Silicone oil injection setting (see page 234)

Select silicone oil injection function

- Tap the key Retina.
- Tap the tab of the desired function, for which you require the silicone oil injection, such as for example VIT1.

  → The user interface shows all relevant parameters of the selected function and the relevant silicone oils injection settings.

Set silicone oil injection

WARNING

Injury to the patient's eye!

Audible hissing of air when switching on the equipment may indicate a malfunction of the silicone oil section or the exhaust of the excessive pressure from input air pressure source.

- Contact the ZEISS Service.

During the injection of silicone oil, the intraocular pressure is not controlled by the VISALIS V500. The operator must be responsible for controlling the intraocular pressure. It is important to check silicone oil flow at the preset injection pressure before inserting the cannula in the eye.

Activate and deactivate silicone oil injection

If silicone oil injection is activated the modules "Diathermy", "Aspiration" and "Cutter" are deactivated in all surgical functions, except the surgical function "Phaco frag".

- Tap in the module "Oil" the key On in order to activate the silicone oil injection. Oil is injected according to the programming of the DOUBLE LINEAR FOOTSWITCH II. You can activate this function either by depressing the foot pedal, over the relevant side key or the rotation of the foot-pedal.

→ The key On lights up in blue.

- Tap in the module "Oil" the key Off in order to stop the silicone oil injection. According to the programming of the DOUBLE LINEAR FOOTSWITCH II you can deactivate this function also over the relevant side key or the rotation of the footpedal.

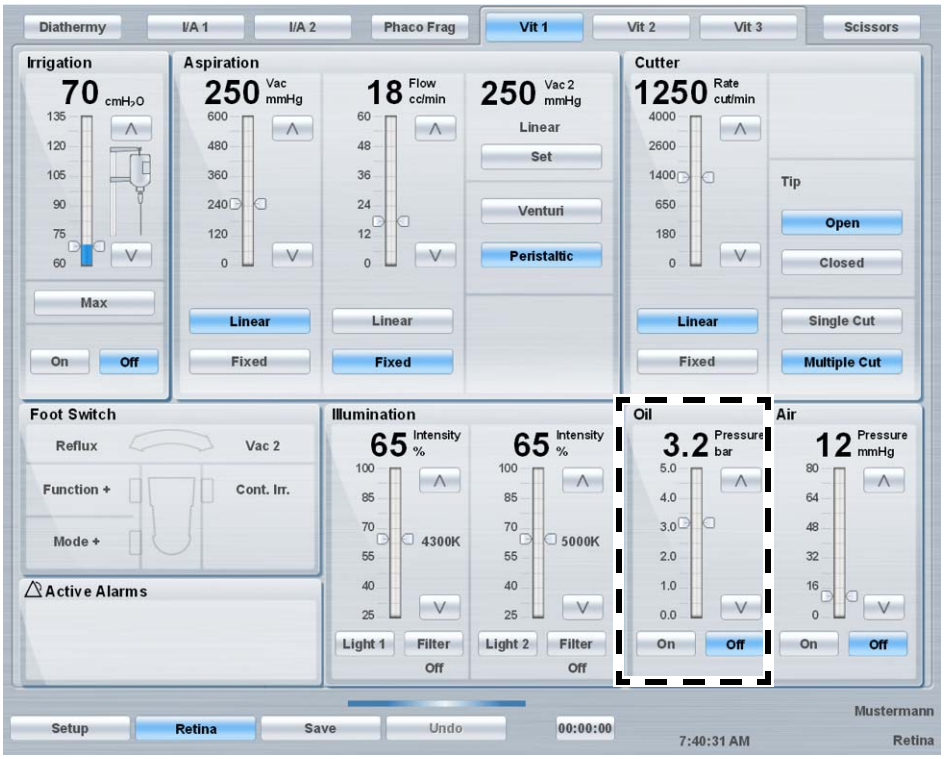
  → The key On turns to gray.

Configure silicone oil injection pressure

- Tap the arrow key ∧ in order to increase the silicone oil injection pressure or tap the arrow key ∨ in order to reduce it. Alternatively you can configure the silicone oil injection pressure with the slider.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 101: Silicone oil injection



Bipolar endodiathermy for retinal surgery *

Connect accessories

Information about the assembly and the connection of the endodiathermy accessories is described on page 143.

Configure user interface

- Adjust the parameters for the endodiathermy on the user interface:
  - Selecting the endodiathermy function (see page 236)
  - Configuring the endodiathermy (see page 236)
  - Adjusting irrigation (see page 226) and air (see page 228) - if necessary
  - Adjust illumination (see page 222) - if necessary
  - Adjust silicone oil injection (see page 234) - if necessary

Select endodiathermy function

- Tap the key Retina.
- Tap the tab Diathermy.
  → The user interface displays all relevant parameters of the endodiathermy function.

Configure endodiathermy

Adjust diathermy power

The previously set diathermy power can be changed in the module "Diathermy". If you are uncertain about the power to use, it is always advisable to begin with a low setting eventually increasing it gradually to obtain the desired surgical effect.

- Increase or decrease the preset value by tapping the arrow key ^ or v. Alternatively you can regulate the diathermy power with the slider.

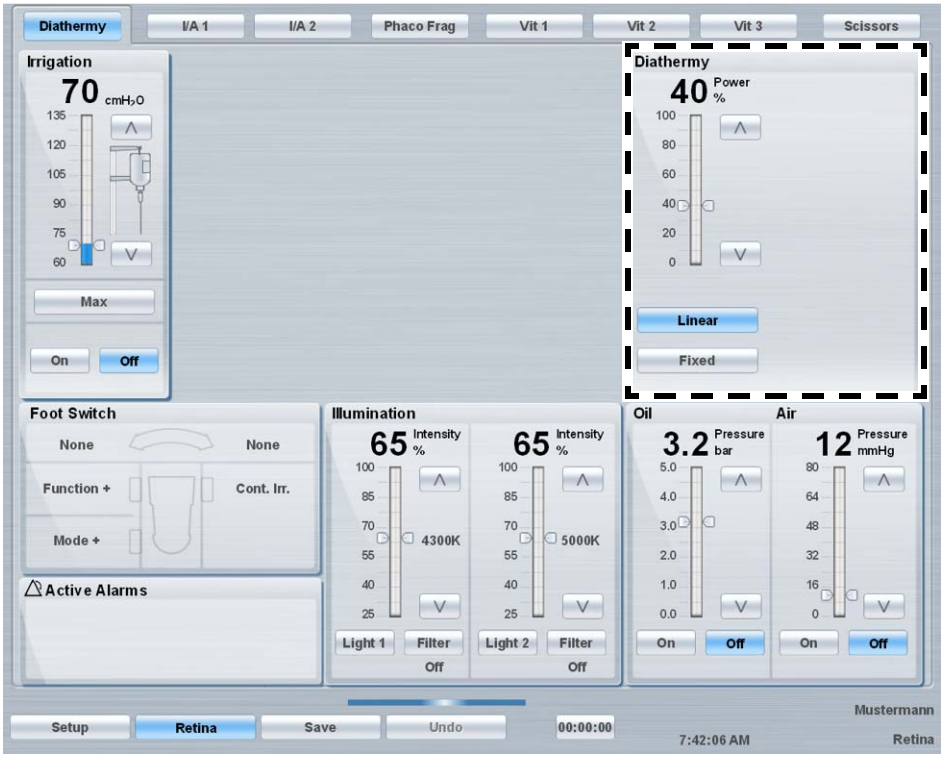
Select diathermy control mode

The diathermy power can be delivered in "Fixed" or "Linear" mode. In the latter case, diathermy power is linearly controlled from 5 % to the preset limit by using the foot pedal.

- Tap the key Fixed or Linear in order to choose between the two modes.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 102: Endodiathermy



Foot switch operation for endodiathermy *

WARNING

Injury to the patient!

- The diathermy section of the VISALIS V500 or VISALIS S500 equipment must not be used on patients with a pacemaker or other cardiac stimulators without prior consultation of a cardiologist.

WARNING

Injury to the patient's eye!

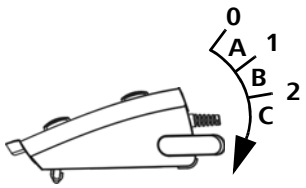
- When a bipolar diathermy probe and a monitoring system are used at the same time, all electrodes of the monitoring system that are not protected by resistors or high frequency inductors must be placed as far away as possible from the diathermy electrodes.

Activate desired function

- Press the foot pedal into the area C downward in order to activate the endodiathermy. The control of endodiathermy power depends on the configuration "Linear" or "Fixed".

  → By the activation of the endodiathermy, the graphic bar in the module "Diathermy" indicates the present endodiathermy power.

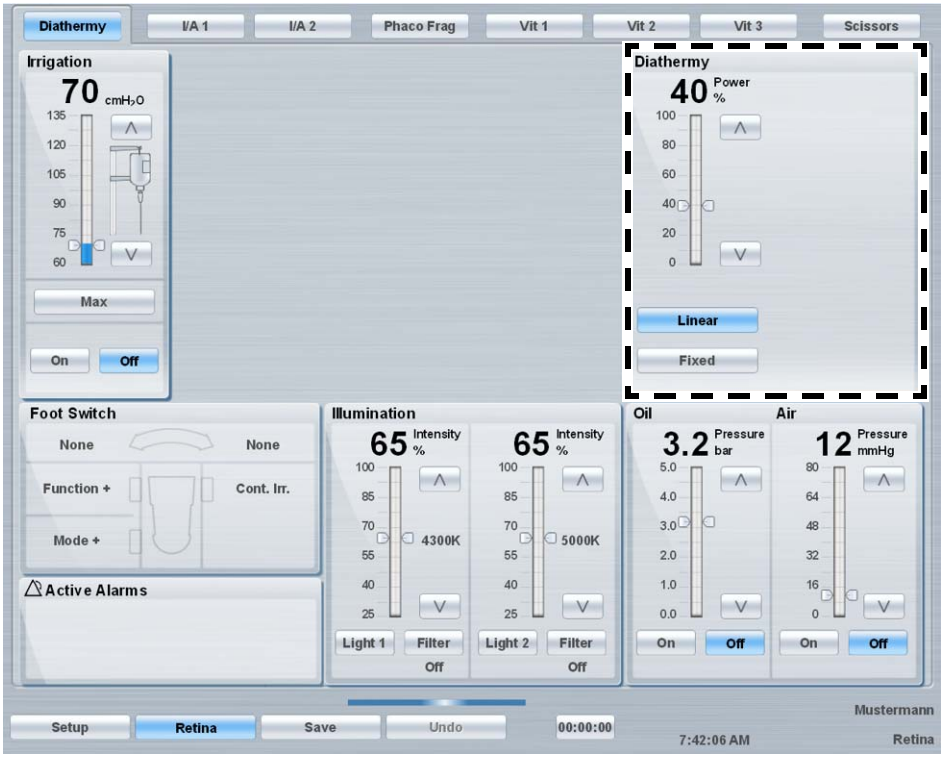
  → Simultaneously a tone signal with uniform pitch sounds in order to signal the activation of the endodiathermy.



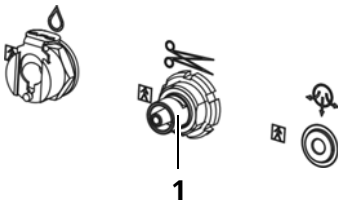
Area A	Area B	Area C
-	-	Diathermy

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 103: Endodiathermy



Scissors for retinal surgery *



Connect accessories

Note the respective Instruction for Use in the unpacking, connecting and use of sterile and resterilizable microsurgery accessories parts.

- Connect the Luer Lock connector of the MICROSCISSORS to the scissors socket (1) of the surgical system.

Select scissors function

- Tap the key Retina .
- Tap the tab Scissors .

  → The module "Cutter" includes keys for the preset cutting rate (Single/ Multiple Cut) and the cutting mode (Open/Closed).

Aspiration is disabled during the use of the MICROSCISSORS.

- If you intend to work with the open tip tap the key Open . In order to return to the mode with a closed tip, tap the key Closed .

Set cutting rate

- Increase or decrease the cutting rate with the arrow keys ^ or v . Alternatively you can regulate the cutting rate with the slider.

Select cutting mode

The scissors mode can be carried out "Fixed" or "Linear". In the latter case, the cutting rate is linearly controlled from 5 % to the preset limit by using the foot pedal.

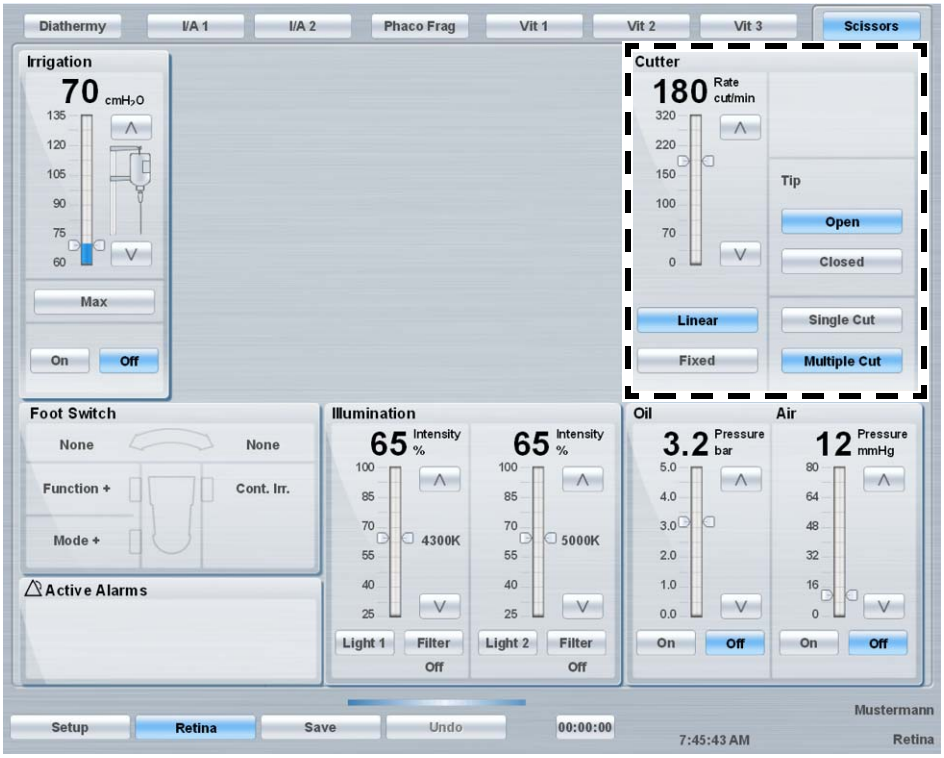
- Tap the key Fixed or Lixed in order to select between both modes.

Select cut mode

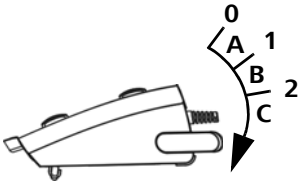
- If you intend to work in "Single Cut" mode, tap the key Single Cut . In order to return to the "Multiple Cut" mode, tap the key Multiple Cut .

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Fig. 104: Scissors



Foot switch operation for scissors *



Activate desired function

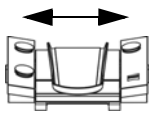
- Press the foot pedal into the respective areas downward in order to activate the desired function. The control of the cutting rate depends on the configuration "Linear" or "Fixed".

  → By the activation of the cut function, the graphic bar in the module "Cutter" indicates the present cutting rate.

Single linear control

Area A	Area B	Area C
-	Cutting (Press the foot pedal downward, to change the cutting rate linearly from 60 cuts/min to the previously adjusted maximum value) 	

Dual linear control

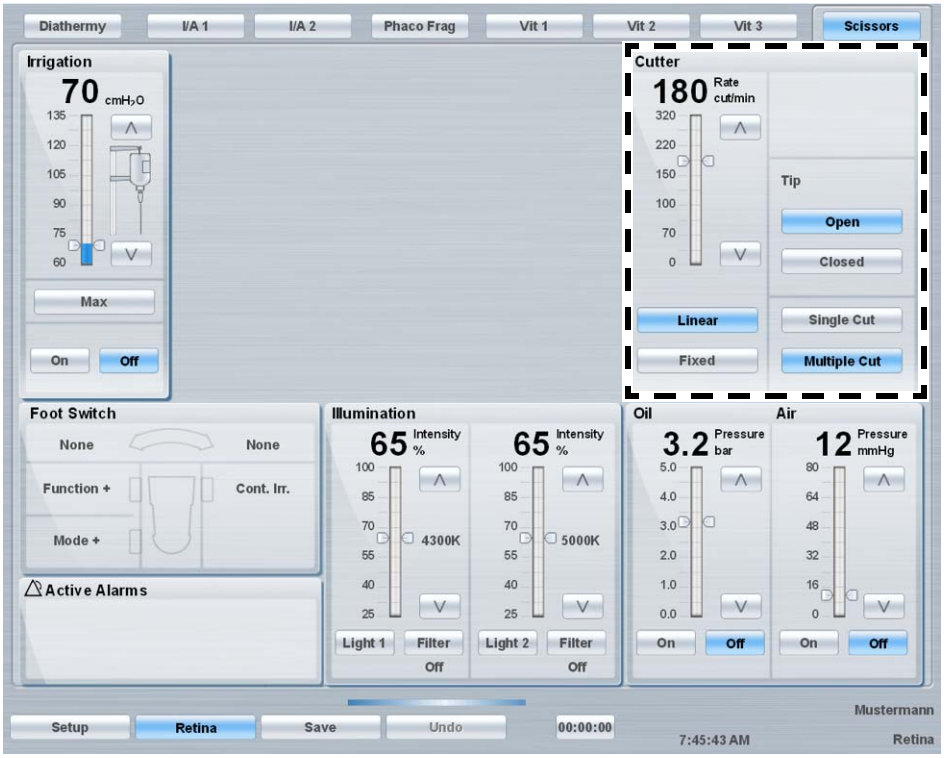
Rest position	Area A	Area B	Area C
Cutting	Cutting	Cutting 	

If the function "Cut" of the foot pedal rotation is assigned "left or right", then the cutting function is deactivated in the vertical direction. Turn the foot pedal slightly left or right to activate the vitrectomy. If "Linear" mode is adjusted a further rotating the foot pedal creates a linear change of the cutting rate from 60 cuts/min up to the preset maximum value.

If the function "Cut off" from the foot pedal rotation "left or right" is assigned, then you can turn the foot pedal from the area B to the left or to the right in order to disable the cutting function.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

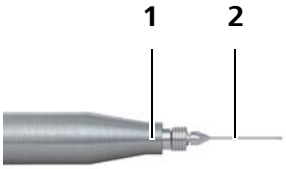
Fig. 105: Scissors



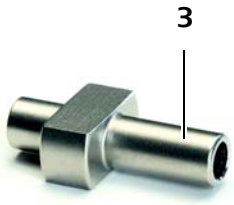
Phacofragmentation *

This mode enables an endo phacoemulsification that is carried out with a specially coated PHACO TIP without a SILICONE SLEEVE, e.g. the PARS PLANA PHACO TIP.

Mount PHACO TIP on the ULITE PHACO HANDPIECE



- Screw the desired PHACO TIP (2) into the end of the ULITE PHACO HANDPIECE (1) so that the threads correctly mesh into each other. Tighten the tip firmly with your fingers.
- Guide the key opening (on the flange side) carefully over the PHACO TIP (2) without damaging this so that the PHACO TIP WRENCH (3) fits into the slits at the socket of the PHACO TIP.

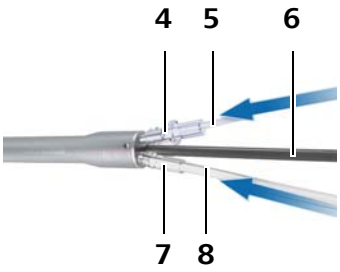


- Carefully turn the PHACO TIP clockwise with the PHACO TIP WRENCH **firmly in**.
- Then remove the PHACO TIP WRENCH (3).

  → Now the ULITE PHACO HANDPIECE (1) can connect the I/A tubes from the surgical system VISALIS V500 or VISALIS S500.

To dismantle the PHACO TIP, proceed in reverse order as during the assembly procedure.

Connect the tubes to the ULITE PHACO HANDPIECE



- For information about the installation of the exchangeable I/A cassette, refer to the section, "I/A cassette and fluidic system" on page 126.
- Push the aspiration tube (5) of the I/A cassette into the corresponding connection piece on the ULITE PHACO HANDPIECE (4) and turn it clockwise firmly on.
- Push the irrigation tube (8) of the I/A cassette into the corresponding adapter on the ULITE PHACO HANDPIECE (7) and turn it clockwise firmly on.

- Plug the power plug of the ULITE PHACO HANDPIECE (6) into the U/S socket (9) of the unit.

Select phacofragmentation function

- Tap the Retina key (10).
- Tap the Phaco frag tab (11).
- The user interface displays all relevant parameter of the phacofragmentation mode.

The settings for irrigation, aspiration, and ultrasound is described in the chapter Phacoemulsification on page 186.

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

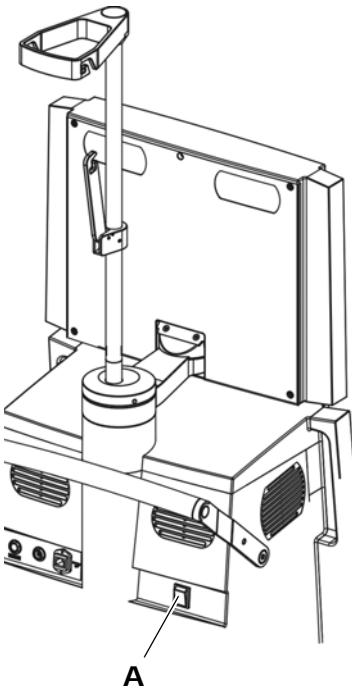
Fig. 106: Phacofragmentation

Turn off the device

The module "Shutdown" is used to bring the system in an adequate status at the end of the usage. During this procedure the system moves down the infusion pole, deactivates the foot switch and a message is displayed to remove the I/A cassette and to switch the off system.

After last change to settings, programs or users wait 10 seconds before switching off the device. Otherwise your latest changes may not be saved!

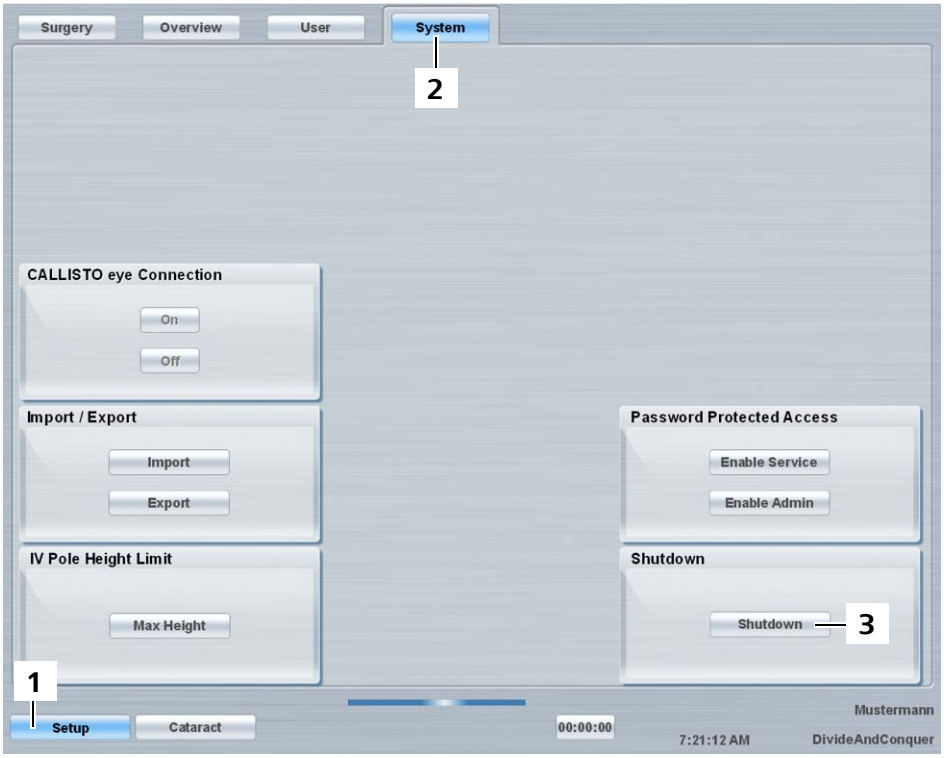
- Tap the key Setup (1).
- Tap the tab System (2).
- To shut down the system tap the key Shutdown (3).
  - → The infusion pole is moved down.
  - → A message is displayed to remove the I/A cassette and to switch off the system.



Turn off the device

- Close the clamp on the infusion set.
- Remove the irrigation and aspiration lines from the handpiece.
- Remove the I/A cassette of the device.
- Turn off the equipment by pressing the power switch (1) on the back of the equipment.
  - → The system is turned off if the power switch (A) is no longer lit.
- Take the power cable from the unit. Doing so, hold the plug rather than the cable.
- Separate the DOUBLE LINEAR FOOTSWITCH II from the unit.
- Disconnect the plugs of the handpieces from the surgical system.

Fig. 107: Shutting system down



What to do in the event of malfunctions

Insufficient quantity of balanced salt solution (BBS)

If the quantity of balanced salt solution (BSS) is not sufficient for the entire operation, replace the infusion bottle or the infusion bag.

In order to avoid a shallowing and collapse of the anterior chamber during the change of the infusion bottle, the physician or surgeon has to provide for a sufficient tonicity of the patient eye!

Replace infusion bottle (Gravity irrigation)

- Interrupt the surgical procedure and remove the tip of the surgical instrument from the incision.
- Close the clamp on the infusion set in order to prevent an unintentional flow of balanced salt solution (BSS).
- For lowering the infusion pole tap the key Change in the menu "Set-up" > "Surgery".

  → The infusion pole moves down to its lowest height and the pop-up window "Info - Please confirm change of the irrigation bottle" appears.

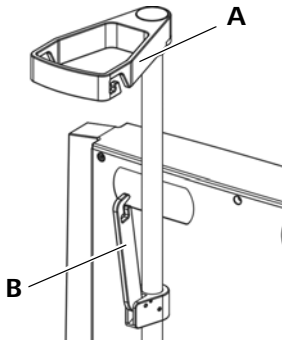
  → The foot switch is locked to avoid unintended use of aspiration and ultrasound / cutter function when bottle change is being performed as irrigation is insufficient or non existent during bottle change.
- Take the almost empty infusion bottle off the infusion pole.

CAUTION

Risk of infection!

When exchanging the infusion bottle, pathogens may enter and contaminate the balanced salt solution.

- Perform the exchange of the infusion bottle in aseptical manner.



- Take the drip chamber spike of the infusion set out of the almost empty infusion bottle.
- Insert the infusion set's spike in the cap of the new bottle and hook it to the IV Pole. For cataract use, use the upper hook (A); for retina use the lower hook (B).
- If the drip chamber becomes completely empty, squeeze it to fill it with balanced salt solution until it is approximately 50% full.

- Open the clamp at the infusion set in order to produce the flow again.
- For lifting the infusion pole tap the key OK in the pop-up window.

CAUTION

Injury to the patient's eye!

- If bubbles are observed then infusion and aspiration are used to aspirate the bubbles out.

Replace infusion bag (Controlled irrigation)

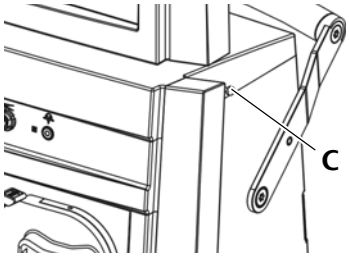
- Interrupt the surgical procedure and remove the tip of the surgical instrument from the incision.
- Close the clamp on the infusion set in order to prevent an unintentional flow of balanced salt solution (BSS).
- Remove the air tube from the air socket from the surgical system.
- Unhook the near-empty infusion bag from its support (C).

CAUTION

Risk of infection!

When exchanging the infusion bag, pathogens may enter and contaminate the balanced salt solution.

- Perform the exchange of the infusion bag in aseptical manner.



- Take the drip chamber spike of the infusion set out of the almost empty infusion bag.
- Insert the infusion set's spike in the cap of the new infusion bag and hook it to the support (C).
- Connect the air tube to the air socket of the device.
- Open the clamp at the infusion set in order to produce the flow again.

CAUTION

Injury to the patient's eye!

- If bubbles are observed then infusion and aspiration are used to aspirate the bubbles out.

Troubleshooting

For your safety

This system is a high-grade technological product. To ensure optimum performance and reliable working order, we recommend having it checked by our service representative as part of regular scheduled maintenance.

- If a malfunction occurs which you cannot correct even after referring to the chapter "Troubleshooting", attach a sign to the system stating that it is "Out of order" and contact the ZEISS Service.

System alarm messages

CAUTION

System alarm messages with yellow warning signs!

Indicate a system malfunction with medium priority.

- Note the explanations for each alarm message on the next pages.

NOTE

System alarm messages with blue information signs!

Indicate a system malfunction with low priority.

- Note the explanations for each alarm message on the next pages.

System alarm messages without yellow warning or blue information signs!

Info

Indicate recommendations on possible action(s).

- Note the explanations for each alarm message on the next pages.

General system alarm messages

Code	Message	Probable cause	Corrective measure
010 ⚠	Air Pressure Error! Please deactivate air infusion and irrigation temporarily.	Error in air / irrigation system (output pressure much higher or lower than preset).	Deactivate air infusion and irrigation temporarily.
020 ⚠	Failed to disable air pressure! Please shutdown and restart the system.	Incorrect pressure at output of proportional valve.	Shutdown and restart the system.
030 ⚠	Pressure Level Error! Please release foot pedal temporarily!	Vacuum exceeds preset value in Venturi mode.	Release foot pedal temporarily.
040 ⚠	Low input Pressure! Please check compressed air.	Pressure of the external air supply is too low or zero. Device is not connected to compressed air supply or stopcock is closed.	Connect the device to compressed air source or open the stopcock.
		Pressure of the external air supply is too low or zero.	Pressure of the compressed air supply of the device is less than 450 kPa. Check the pressure of the compressed air circuit.
050 ⚠	System Error! Please shutdown and restart the system.	Error in monitoring circuit (checked at start-up)	Shutdown and restart the system.
060 ⚠	System Error! Please shutdown and restart the system.	This error appears when the cycletime monitoring system times out because it is not re-triggered by the firmware in a timely manner, or when the operation voltage drops below 4,65 V.	Shutdown and restart the system.
070 ⚠	Serial Communication Fault! Please shutdown and restart the system.	Communication error.	Shutdown and restart the system.
080 ⚠	Power supply / reference voltage mismatch! Please shutdown and restart the system.	Incorrect voltage reference at A/D transducer or incorrect +5 V power value (checked at start-up).	Shutdown and restart the system.

Foot switch alarm messages

Code	Message	Probable cause	Corrective measure
100 Info	Function Not Allowed! Please confirm the bottle change before using the foot pedal.	During bottle change mode the foot pedal passes position 1.	Release foot pedal and confirm bottle change again.
110 ⚠	Foot Pedal Check! Please release the foot pedal temporarily.	Internal check of foot pedal position failed.	Release foot pedal temporarily.

Irrigation / air alarm messages

Code	Message	Probable cause	Corrective measure
200 ⚠	Irrigation Pressure Too High! Please reduce irrigation pressure.	The infusion pole is situated at too high a level.	Lower the infusion pole as far as possible.
210 ⚠	IV Pole Failure! Please shutdown and restart the system to use the IV Pole.	Error on the infusion pole.	Shutdown and restart the system to use the IV Pole.
220 Info	Function Already Active! Please change the irrigation type to use air infusion.	Air infusion cannot be activated by foot switch due to surgeon use both controlled irrigation and air infusion. Change infusion pressure from the irrigation section tab slider after turning the stopcock button to allow air and block fluid. When changing to fluid turn the stopcock key to allow irrigation and block air and set the infusion pressure to the desired level by usig the slider on the irrigation section tab.	Change the irrigation type to use air infusion.

Aspiration alarm messages

Code	Message	Probable cause	Corrective measure
300 ⚠	Vacuum Level Error! Please release foot pedal temporarily.	Vacuum exceeds preset value in Venturi mode.	Release foot pedal temporarily.

Code	Message	Probable cause	Corrective measure
310	Vacuum Offset Error! Please restart I/A prime/ priming.	Vacuum sensor offset excessive.	Restart priming procedure.
		Vacuum sensor offset excessive.	Vacuum sensor needs calibration. Contact the ZEISS Service for calibration of the unit.
320	Vacuum Sensor Error! Please shutdown and restart the system.	Actual vacuum value is out of the valid range.	Shutdown and restart the system.
330	Aspiration Pump Error! Please shutdown and restart the system.	The aspiration pump is running when it should be stopped, or when the speed exceeds the expected speed by the valid tolerance.	Shutdown and restart the system.
340	Vacuum Offset Error! Please restart I/A prime/ priming.	Vacuum sensor offset excessive.	Restart priming procedure.
350	Limited Venturi Vacuum Range! The System was calibrated for use at high altitudes.	The venturi pump calibration was performed at high altitude and “high altitude” calibration table is used.	No action neccessary.
360	Venturi Pump Not Calibrated! Please contact your authorized service partner.	No successful venturi pump calibration was performed.	Contact the ZEISS Service for calibration of the unit.
370	Install I/A cassette!	The I/A cassette is not installed.	Install I/A cassette!
380	Aspiration Halted! I/A cassette full.	I/A cassette is filled with fluid up to maximum level.	Interrupt aspiration or change the I/A cassette.

Diathermy alarm messages

Code	Message	Probable cause	Corrective measure
400	Diathermy Power Error! Please release the foot pedal.	Internal check of dissipated diathermy power failed.	Release foot pedal.
410	Diathermy Enable Failure! Please shutdown and restart the system.	Internal check of diathermy power enable failed.	Shutdown and restart the system.

Code	Message	Probable cause	Corrective measure
420 ⚠	Diathermy Disable Failure! Please shutdown and restart the system.	Internal check of diathermy power disable failed.	Shutdown and restart the system.

Ultrasound alarm messages

Code	Message	Probable cause	Corrective measure
500 ⚠	Ultrasound Power Error! Please release the foot pedal.	Internal check of dissipated U/S power failed.	Release the foot pedal.
510 ⚠	Ultrasound Enable Failure! Please shutdown and restart the system.	Internal check of U/S power enable failed.	Shutdown and restart the system.
520 ⚠	Ultrasound Disable Failure! Please shutdown and restart the system.	Internal check of U/S power disable failed.	Shutdown and restart the system.
530 Info	Low Stroke! Please check the handpiece.	ULITE PHACO HANDPIECE cannot deliver set stroke.	Tighten the PHACO TIP properly if loose. Use the PHACO TIP WRENCH.
		ULITE PHACO HANDPIECE cannot deliver set stroke.	It is common that the piezoceramic element deteriorates with use and number of sterilization cycles. Submit the ULITE PHACO HANDPIECE to the ZEISS Service.

I/A priming/tuning alarm messages

Code	Message	Probable cause	Corrective measure
700 ⓘ	No Irrigation! Please check irrigation clamp and restart I/A priming / priming.	No irrigation flow; the clamp on the tubing from the drip chamber is closed.	Check irrigation clamp and restart priming.
710 ⓘ	Minor Leakage! Please check I/A cassette and tubing and restart I/A prime/ priming.	Tubing system has a minor leakage.	Check the tubing set and the TEST CHAMBER. Restart priming.

Code	Message	Probable cause	Corrective measure
		Peristaltic pump cannot establish a vacuum of 300 mmHg cause the irrigation/aspiration tubing is not correctly connected to ULITE PHACO HANDPIECE.	Connect the irrigation/aspiration tubing from the I/A cassette to the ULITE PHACO HANDPIECE and restart priming.
		Peristaltic pump cannot establish a vacuum of 300 mmHg cause the SILICONE SLEEVE is not correctly mounted to the ULITE PHACO HANDPIECE.	Make sure that the SILICONE SLEEVE is attached correctly to the ULITE PHACO HANDPIECE and restart priming.
720	Major Leakage! Please check I/A cassette and tubing and restart I/A prime/ priming.	Tubing system has a major leakage.	Check the tubing set and the TEST CHAMBER. Restart priming.
		Peristaltic pump cannot establish a vacuum of 300 mmHg cause the irrigation/aspiration tubing is not correctly connected to ULITE PHACO HANDPIECE.	Connect the irrigation/aspiration tubing from the I/A cassette to the ULITE PHACO HANDPIECE and restart priming.
		Peristaltic pump cannot establish a vacuum of 300 mmHg cause the SILICONE SLEEVE is not correctly mounted to the ULITE PHACO HANDPIECE.	Make sure that the SILICONE SLEEVE is attached correctly to the ULITE PHACO HANDPIECE and restart priming.
		The I/A cassette is defective.	Replace I/A cassette.
730	Aspiration Line Occluded! Please check tubing and restart I/A prime/priming.	Irrigation clamp is closed.	Open irrigation clamp and restart priming.
		The I/A cassette is defective.	The I/A cassette is defective. Replace I/A cassette and restart priming.
750	Please check or exchange the tip and restart tuning.	PHACO TIP loose.	Screw in the PHACO TIP by means of the PHACO TIP WRENCH correctly into the ULITE PHACO HANDPIECE and restart tuning.

Code	Message	Probable cause	Corrective measure
		PHACO TIP damaged.	Inspect the TIP and replace according to need and restart tuning.
		ULITE PHACO HANDPIECE damaged.	Replace ULITE PHACO HANDPIECE and restart tuning.
770 Info	Low Ultrasound Power! Please check the handpiece.	ULITE PHACO HANDPIECE cannot deliver more than 50 µm.	Check if the PHACO TIP is loose and, if this is the case, tighten it properly using the PHACO TIP WRENCH.
		Not sufficient U/S power output. It is common that the piezoceramic element deteriorates with use and number of sterilization cycles.	Submit the ULITE PHACO HANDPIECE to the ZEISS Service.
780 Info	Handpiece Already Primed. Do you want to start priming again?	Handpiece already primed.	Abort priming procedure if no additional priming is required.
790 Info	Priming Aborted! Note: some manipulations of foot pedal, handpiece or I/A cassette stop priming procedures.	Priming, I/A priming or tuning is aborted by the user using the foot pedal.	Release the foot pedal and restart priming, I/A priming or tuning.
791 Info	Please perform Prime, I/A Prime or Tune to activate this foot pedal function!	System is not primed.	Start priming, I/A priming or tuning!

GUI lock alarm messages

Code	Message	Probable cause	Corrective measure
800 Info	Function not allowed in current foot pedal position!	Foot pedal is being pressed while a function is selected.	Release the foot pedal.
810 Info	Major Change! Do you want to proceed while foot pedal is pressed?	Foot pedal is being pressed while a function is selected.	Release the foot pedal.
820 Info	Mode Change! Do you want to proceed while foot pedal is pressed?	Function is to be switched and the foot pedal is depressed.	Confirm the change by touching the key "Yes" or cancel with "No".

Service alarm messages

Code	Message	Probable cause	Corrective measure
900 Info	Safety check according to IEC 62353 immediately necessary! Please inform your authorized service partner. Carl Zeiss recommends additionally performing maintenance.	Safety check according to IEC 62353 is immediately necessary!	Contact the ZEISS Service.
910 Info	Next safety check according IEC 62353 necessary in the next %d days! Please inform your authorized service partner. Carl Zeiss recommends additionally performing maintenance.	Safety check according to IEC 62353 is necessary!	Contact the ZEISS Service.
920 Info	Light 1 Bulb Lifetime Exceeded! Please inform your authorized service partner.	The Xenon lamp maximum illumination duration of 1000 hours has been exceeded.	Contact the ZEISS Service.
920 Info	Light 2 Bulb Lifetime Exceeded! Please inform your authorized service partner.	The Xenon lamp maximum illumination duration of 1000 hours has been exceeded.	Contact the ZEISS Service.

Information about the system alarm message protocol

- The protocol listing all errors and their priority, type, date, and time of day the error occurred is saved and stored in the mass storage of the device and can be inspected by the ZEISS service.
- The device deletes the oldest protocol data when the mass storage becomes full.
- The protocol is still available even after a complete loss of the power supply no matter how long the interrution has been taken.

Operating malfunctions

Operating malfunction of the DOUBLE LINEAR FOOTSWITCH II

Problem	Possible causes	Solution	See
Surgical system is out of order.	Power cable is not connected.	Connect the power cable to the surgical system and the power supply.	Page 70
	Blown line fuse.	Replace line fuse.	Page 266
The active equipment section is not activated by the DOUBLE LINEAR FOOT-SWITCH II.	Surgical system is turned off.	Turn on the surgical system.	Page 78
	DOUBLE LINEAR FOOT-SWITCH II is not connected.	Connect the DOUBLE LINEAR FOOTSWITCH II.	Page 70

Malfunctions of the irrigation system

Problem	Possible causes	Solution	See
No irrigation	Infusion pinch valve is closed.	Check for this by pressing the foot switch and checking if the infusion pinch valve opens and balanced salt solution (BSS) becomes available.	-
	Irrigation tube not connected to the handpiece.	Connect irrigation tube to the handpiece.	-
	Kinked or damaged irrigation tubing.	Check for kinks and straighten them, if any. Inspect for damage and replace according to need.	-
	Closed clamp on the connection tube to the irrigation fluid source.	Open the clamp to activate the irrigation.	-

Malfunctions of the aspiration system

Problem	Possible causes	Solution	See
Poor or no aspiration	Irrigation/aspiration tubing is not connected correctly.	Recheck the installation of the tubing.	Page 128
	The connectors of the irrigation/aspiration tubing are not connected properly to the corresponding connectors on the surgical handpiece.	Connect the connectors properly.	-
	Irrigation/aspiration tube set is damaged.	Replace the set.	-
	Low "VAC" level	Set a slightly higher value.	

Vitrectomy malfunctions

Problem	Possible causes	Solution	See
The vitrectomy probe does not work properly when the foot switch is depressed.	You are inadvertently activating aspiration only (right side).	Only press the foot switch down.	-
	The handpiece plug is not properly connected.	Make sure that the handpiece plug is properly connected.	-
	Vitrectomy probe defective.	Replace it.	-

Malfunctions of the diathermy system

Problem	Possible causes	Solution	See
No diathermy power is available on the diathermy handpiece although the foot switch is depressed.	Cable to the surgical system or to the diathermy handpiece (in case of micro-forceps) is loose.	Properly plug in the cable.	-
	diathermy handpiece defective.	Replace diathermy handpiece.	-
	DIATHERMY BIPOLAR CABLE defect.	Replace the cable.	-
	Contamination at the tip.	Clean the tip.	-

Malfunctions of the control panel

Problem	Possible causes	Solution	See
Pulsating bar at the bottom of the user interface stops moving.	System is in idle.	The application of the surgical system must be stopped.	-
There is no message "Calibration necessary" (Continuous peep tone).	Loss of RAM data.	Contact the ZEISS Service.	-
Air leaks from the connector to the plate while connecting the vitrectomy probe.	The Luer socket is not properly connected.	Make sure that the plug is properly connected by rotating it carefully until it snaps in place.	-
	Connector is damaged.	Replace vitrectomy probe.	-
Audible leakage of air from the surgical system.	Hose connectors or valve or solenoid valve need to be serviced.	Contact the ZEISS Service.	-
Malfunctions of the surgical system.	Malfunctions of the surgical system.	Contact the ZEISS Service.	-

Malfunctions during phacoemulsification

Problem	Possible causes	Solution	See
U/S power is to low.	Preset U/S power is too low.	Increase the preset U/S power.	-
	Foot pedal not pressed all the way.	Press the foot pedal as far as it will go.	-
	PHACO TIP defect.	Replace PHACO TIP.	-
	Not sufficient U/S power output.	It is common that the piezoceramic element deteriorates with use and number of sterilization cycles. Submit the ULITE PHACO HANDPIECE to the ZEISS Service.	-
	Insufficient aspiration level. If the aspiration level is too low, the nucleus of lens fragments may not be held properly during emulsification.	Increase the aspiration level while maintaining proper fluid balance.	-

Malfunctions of the illumination system

Problem	Possible causes	Solution	See
Insufficient illumination	Light intensity selector switch is set to minimal value.	Adjust the light level using the arrow buttons or the slider.	-
	Defective optic fiber.	Replace optic fiber.	-

Care and maintenance

System maintenance

Changing fuses

The fuses for the control devices of both surgical systems are located in the power supply socket on the back of the devices.

NOTE

Injury to the user!

Hot fuses can cause burn injuries.

- Before changing the fuses turn off the device and allow it too cool down for a few minutes.

NOTE

Risk of damaging the system!

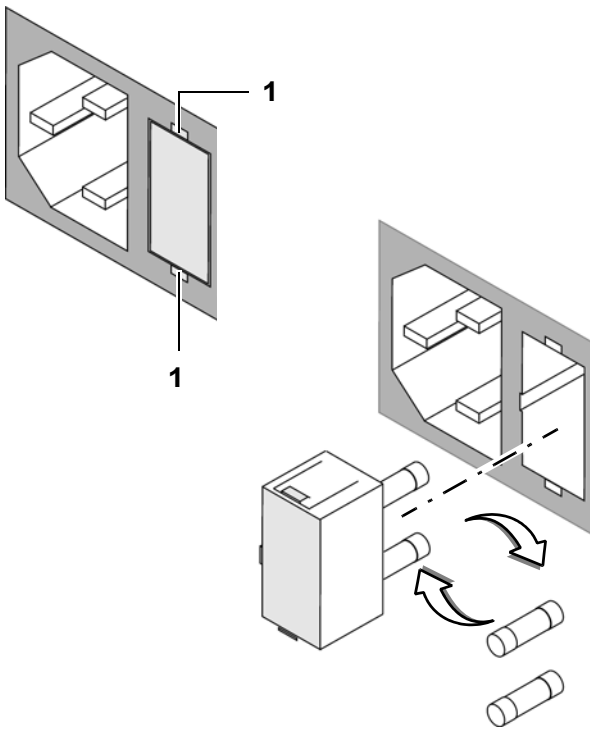
Incorrect fuses may damage the system.

- Use fuses with the correct ratings only! Fuses rating depend on the line voltage setting of the system; refer to the rear panel label for details.

To change the fuses, proceed as follows:

- Turn off the system using the power switch.
- Unplug the power cable.
- Press the two catches (1) inward using a suitable tool and remove the fuse holder.
- Remove the defective fuses and insert new fuses.
- Re-install the fuse holder. The catch (1) must be heard to click into place.
- Connect the power cable.
- Turn on the device at its power switch.

Fig. 108: Changing fuses



Maintenance intervals and safety inspection

Regular preventive maintenance is required to ensure reliable operation and a long service life of the system on an ongoing basis.

The following table lists the required work activities and shows at which intervals they must be performed.

The maintenance work requires device specific technical knowledge and may only be done by authorized specialists. Contact your local ZEISS Service punctually for the performance of these maintenance activities.

Regardless of the maintenance work listed, users of medical electrical equipment are obligated to perform safety related technical tests in accordance with IEC 62353.

Electromagnetic compatibility (EMC)

No regular inspections or maintenace are required in order to maintain electromagnetic compatibility (EMC).

CAUTION

Injury to the patient's eye!

Malfunction of the system may injure the patient!

- Have your authorized service partner perform a safety check on the equipment in accordance with IEC 62353 that includes the following items:
  - during the installation of the system
  - in regular intervals (every 12 months)
  - during maintenance work
  - after upgrades, repairs and calibration

General maintenance work

Procedure	1 year	2 year
Renew water stop filter	x	
Renew sealing of the venturi pump	x	
Renew air filter	x	
Check hours of operation of the HID lamps and renew where appropriate*	x	
Check all four swiveling rollers	x	

Procedure	1 year	2 year
Review foot switch compartment	x	
Check Console Tray**	x	
Check monitor carrier arm	x	
Replace security valve		x
Exchange BIOS battery		x

Maintenance work after upgrades, repairs and calibration

Procedure	1 year
Review ventilation	x
Review position and reinforcement of the ferrite core	x
Review cabling	x
Review unlocking mechanism I/A cassette	x
Measure flow rate of the peristaltic pump	x
Review vacuum (peristaltic and venturi)	x
Review air infusion	x
Review vitrectomy pressure	x
Review pressure of the silicone oil injection socket *	x
Review pressure of the scissors socket *	x
Review illumination *	x

* only applicable in VISALIS V500 or upgraded VISALIS S500
** Option

Safety examination according to IEC 62353

Procedure	1 year
Visual inspection	
External visibility test of VISALIS V500 / S500	x
Inner visibility test of VISALIS V500 / S500	x
Test network connection cable	x
Test foot switch	x
Test phaco handpiece	x
Check the accessories	x
Test inscriptions and markings	x
Test Instruction for Use	x
Test safety devices	x
Test Video Graphical Overlay System**	x
Electrical safety	
Measure protection lead resistance	x
Measure device leakage current	x
Measure leakage current of the type BF	x
Measuring the insulation resistance	x
Function tests	
Test of the functions of the alarm system	x
System start test	x
Test the functions of the touchscreen	x
Test the functions of the foot switch	x
Test the infusion pole	x
Test the functions of the I/A- and reflux valve	x
Test the functions of the peristatic pump	x
Test the functions of the venturi pump	x
Test vacuum	x
Test diathermy functions	x
Test ultrasound functions	x

Procedure	1 year
Test vitrectomy functions	x
Test scissors functions *	x
Silicone oil injections test *	x
Air infusion test	x
Illumination function of the HID lamps test *	x
– Switch function on/off	
– Pivot green filter in/out	
– Pivot retina protection filter in/out	
– Test the form of the light beam	

* only applicable in VISALIS V500 or upgraded VISALIS S500
** Option

Care of the device

The medical staff is responsible for keeping the medical device and further equipment in optimal operating condition. The simple steps described below constitute a practical guideline for defining a suitable care and maintenance program.

Cleaning

⚠ **CAUTION**

Risk of infection!

- Clean the front panel with a soft cloth dampened with distilled water. If necessary, use neutral detergent only.
- Never use corrosive or abrasive cleaning agents.
- More information about cleaning can be found in the relevant instructions for use.

Disinfection

It may be necessary to disinfect the surfaces.

NOTE

Damage to the surfaces on the instrument!

- Use a disinfectant based on aldehyde and/or alcohol. The addition of quaternary compounds is acceptable. To prevent damaging surfaces, disinfecting agents other than those listed below must not be used.

The maximum concentrations are:

– For alcohol (tested with 2-propanol): 60%

– For aldehyde (tested with glutaraldehyde): 2%

– For quaternary compounds (tested with DDAC): 0.2%

Environmental protection measures

CAUTION

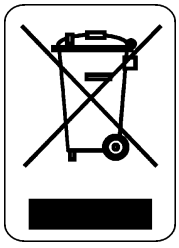
Pollution of the environment!

Inappropriate disposal may contaminate the environment!

- Do not dispose of the systems along with normal domestic waste. Separate disposal according to the local laws/regulations governing the disposal of electrical and electronic equipment is required.

Note on disposal

User information
concerning the disposal of electrical and electronic devices



This symbol means that electric and/or electronic products must not be disposed of as normal domestic waste. Correct disposal of electrical or electronic devices helps to protect the environment and prevent potential hazards to the environment and/or human health which may occur as a result of improper handling of the used device.

- For detailed information on the disposal of the product, contact your local dealer or the device manufacturer or its legal successor. Also note the manufacturer's current information on the Internet. In the event of resale of the product or its components, the seller is required to inform the buyer that the product must be disposed of in accordance with the applicable national regulations currently in force.

For customers in the European Union

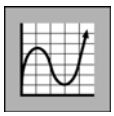
- Get in touch with your dealer or suppliers if you want to dispose of electric and electronic devices.

Information on disposal in countries outside the European Union

This symbol is only applicable in the European Union.

- For the disposal of electrical and electronic devices, observe the relevant national legislation and other regulations applicable in your country.

System data



Technical data

VISALIS V500 / VISALIS S500

Essential performance features

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

Electrical and pneumatic specifications

Component	Property
Pressure input:	500 - 800 kPa (flow min. 38 Nl/min)
Input voltage:	100 V - 240 V AC (± 10 %)
Frequency:	50 - 60 Hz
Power consumption:	410 VA
Fuses:	T6,3A H 250 V
The system is designed for continuous operation.	

Irrigation

Component	Property
Liquid supply:	Gravity irrigation - The intraocular pressure is controlled by the height level of the infusion bottle. Controlled irrigation - The intraocular pressure is controlled by a pressurized infusion bag. Combined irrigation - The intraocular pressure is controlled by the height and the pressure of the pressurized infusion bottle.
Pressure range: (Controlled, Combined High, Combined Low)	15 - 80 mmHg Increments:1 mmHg
Valve element:	Solenoid valve
Control:	DOUBLE LINEAR FOOTSWITCH II and touchscreen

Aspiration

Component	Property
Types of aspiration pumps:	Peristaltic and Venturi pump
Vacuum range:	5 to 600 mmHg
	Increments: 5mmHg
	Can be programmed by user
Flow rate range:	2 to 60 ml/min (peristaltic pump only)
	Increments: 2 ml/min
	Can be programmed by user
Aspiration rise time:	0.5 to 12 s (peristaltic pump only)
	Increments: 0.5 – 0.52 – 0.55 – 0.67 – 0.60 – 0.63 – 0.65 – 0.70 – 0.75 – 0.77 – 0.85 – 0.90 – 0.95 – 1.05 – 1.15 – 1.25 – 1.40 – 1.50 – 1.80 – 2.10 – 3.50 – 3 – 4 – 6 – 12
Surgeon mode:	Aspiration (vacuum and/or flow rate) controlled in "Fixed" or "Linear" mode by pressing the foot pedal.
Safety facility:	Vacuum sensor; monitors the vacuum in the aspiration tubing
Control:	DOUBLE LINEAR FOOTSWITCH II

Phacoemulsification

Component	Property
Type of handpiece:	piezoelectrical
Frequency:	40 kHz (+4.5 kHz/-1 kHz)
Peak stroke:	19G - 22G PHACO TIP, up to 100 µm (± 20 %) in 5 µm increments
Rating:	Control of U/S power "Fixed" or "Linear" by pressing the foot pedal
U/S mode:	"Fixed" or "Linear" (user interface); duration (Cont), pulse (1, 2, 3, 4, 5, 6, 8, 10, 13, 16, 20, 25, 32, 40Hz), Single Burst, Multi Burst, Cont Burst, APM
U/S timer:	0.00.000 minutes
Timer EPT:	0.00.000 minutes

Diath (Diathermy)

Component	Property
Type	Bipolar generator - generator stops when no HF power is required
Operating frequency:	2 MHz (± 20 %)
Rated power:	9 W (200 Ω resistive load)
Maximum output voltage (peak):	170 V
Rated accessory voltage (peak):	180 V
Available bipolar power:	5 - 100 % - Allows linear control of diathermy power by pressing the foot pedal
	Can be programmed by user
Type of handpiece:	Handpieces for bipolar diathermy, e.g. DIATHERMY FORCEPS, DIATHERMY PENCIL ERASER
BIPOLAR DIATHERMY CABLE:	Bipolar, 26 F, 75 Ω, suitable for steam autoclaving
Surgical mode:	Linear diathermy power between 0 and preset value controlled by foot pedal. Only use the original DIATHERMY BIPOLAR CABLE from ZEISS.
Controller:	DOUBLE LINEAR FOOTSWITCH II

Vit (Vitrectomy)

Component	Property
Type of handpiece:	Pneumatic cutting device with guillotine function (Vit)
Cutting mode:	Back-and-forth
Cutting rate:	Can be programmed by user
Available cutting rate:	20G - 25G VITRECTOMY PROBE, from 60 to 1600 cuts/min (± 20 %) (cataract), from 60 to 4000 cuts/min (± 20 %) (retina),
	Increments: 60 - 70 - 85 - 100 - 125 - 150 - 180 - 220 - 260 - 320 - 370 - 450 - 530 - 650 - 770 - 930 - 1000 - 1150 - 1250 - 1400 - 1600 [max. for Ant VIT] - 1750 - 2000 - 2250 - 2500 - 2750 - 3000 - 3300 - 3600 - 4000

Component	Property
Single cut:	Single cut mode available
Actuation medium:	compressed air from external source
Operating pressure:	220 kPa
Surgical mode (linear cut):	Linear cutting rate between 60 and preset value controlled by foot pedal.
Controller:	DOUBLE LINEAR FOOTSWITCH II

Scissors

Component	Property
Type of handpiece:	Pneumatic cutting device
Cutting mode:	Horizontal scissors
Cutting rate:	between 60 and 320 cuts/min (±20 %) (retina)
	Increments: 60 - 70 - 85 - 100 - 125 - 150 - 180 - 220 - 260 - 320
	Can be programmed by the user
Single cut:	Single cut mode available, with linear control of blade movement using the foot pedal
Actuation medium:	compressed air from external source
Operating pressure:	200 kPa
Surgical mode (linear cut):	Linear cutting rate between 60 and preset value controlled by foot pedal.
Controller:	DOUBLE LINEAR FOOTSWITCH II

Air infusion / Silicone oil injection *

Component	Property
Air infusion	
Pressure source:	integral rotary vane compressor
Tamponade pressure:	5 to 80 mmHg (in 1mmHg increments)
Air sterilization:	0,22 µm bacteriostatic filter
Silicone oil injection	
Pressure source:	Compressed air from external source
Injection pressure:	40 to 500 KPa

Component	Property
Control:	Linear injection control by foot switch

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

Illumination *

Component	Property
Type:	Two independent light sources
Type of illuminant:	HID Xenon lamp
Color temperature:	Lamp 1: 4300 K
	Lamp 2: 5000 K
Light intensity-setting:	16 steps, motorized aperture (from 25 % to 100 % in 5 % increments)
Filters:	Green filter, retina protection filter (blue barrier filter)
Safety filter:	IR-UV-blocking filter

* only applicable in VISALIS V500 or upgraded VISALIS S500 to VISALIS V500

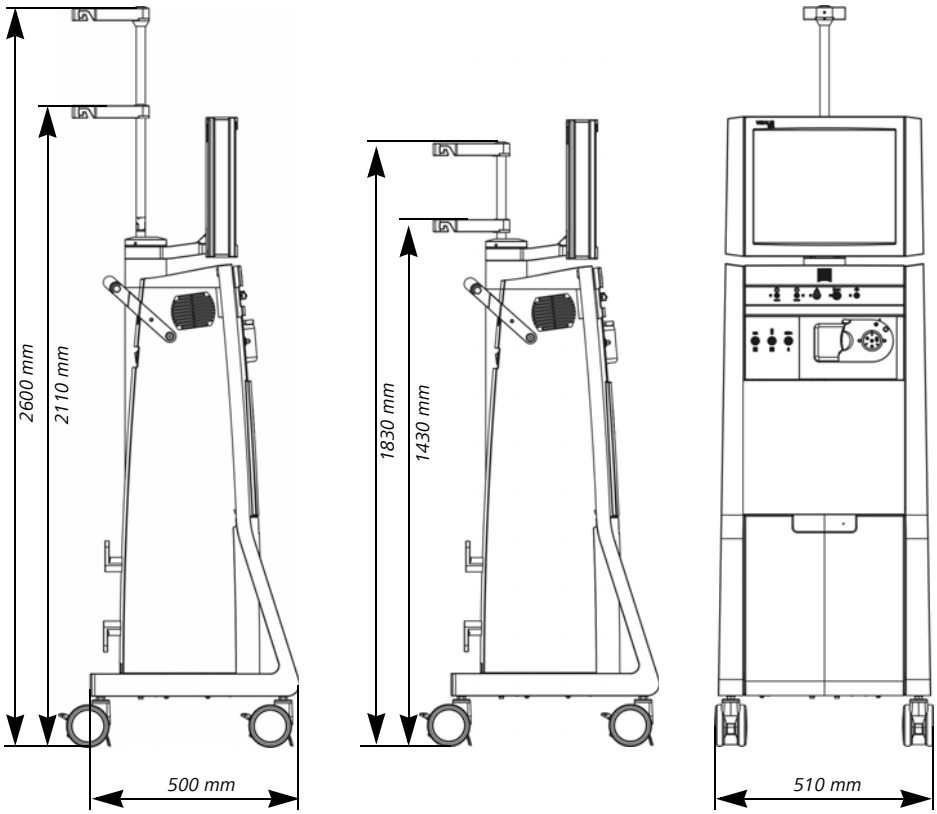
Sound pressure of the alarm sounds

Alarm sound	Volume	
Voice level	0 %	100 %
Low priority	47.6 dB	62.1 dB
Medium priority	43.2 dB	60.2 dB

Dimensions and weight

Component	Property
Height - IV Pole extended:	2600 mm (high hook) 2110 mm (low hook)
Height - IV Pole retracted:	1830 mm (high hook) 1430 mm (low hook)
Width:	510 mm
Depth:	500 mm
Weight:	94 kg

Fig. 109: Dimensional drawing VISALIS V500 / VISALIS S500



Conversion of irrigation height into ceiling height (high hook)

GUI	IV Pole high hook	IV Pole complete
60 cmH_2O	1800 mm	1835 mm
80 cmH_2O	2000 mm	2035 mm
100 cmH_2O	2190 mm	2225 mm
120 cmH_2O	2390 mm	2425 mm
135 cmH_2O	2540 mm	2575 mm

Conversion of irrigation height into ceiling height (low hook)

GUI [cmH2O]	IV Pole low hook	IV Pole complete
15 cmH_2O	1350 mm	1840 mm
35 cmH_2O	1560 mm	2050 mm
55 cmH_2O	1760 mm	2250 mm
75 cmH_2O	1950 mm	2440 mm
90 cmH_2O	2110 mm	2600 mm

Guidelines and manufacturer's declaration concerning electromagnetic compatibility

The device is subject to specific precautions with regard to electromagnetic compatibility (EMC) in the area of Professional Healthcare Facility Environment. In order to avoid the occurrence of EMC interference, the device may only be installed, operated and maintained in the manner indicated in these Instructions for Use and only with components supplied by ZEISS.

WARNING

Function deterioration!

Do not install or operate VISALIS V500 / VISALIS S500 in direct proximity to other devices with the exception of the combination of the devices described in these Instructions for Use.

- If it cannot be avoided that VISALIS V500 / VISALIS S500 is operated in proximity to other devices, the proper function of VISALIS V500 / VISALIS S500 must be monitored.

WARNING

Function deterioration!

Electrical devices can influence each other as a result of their electromagnetic radiation. The use of non-approved components can cause increased emissions or reduce the device's immunity.

- Only use accessories, transformers, cables and spare parts which are specified in these Instructions for Use or which are approved by ZEISS for this device.

WARNING

Deterioration of performance!

- Do not use any portable or mobile RF communication equipment or transmitters (including peripheral devices such as antenna cables or external antennas) in the proximity of VISALIS V500 / VISALIS S500 (minimum distance 30 cm), as it cannot be ruled out that the function of the device will be impaired or that the performance of the device will deteriorate.
- Do not use any cell phones near VISALIS V500 / VISALIS S500. They represent a potential risk for the proper functioning of medical equipment. Malfunctions may occur, depending on a variety of local factors. They cannot be predicted and can by no means be estimated.
- Follow the EMC guidelines on the following pages..

⚠ **CAUTION**

Injury to the patient!

Interference between this surgical device and other medical equipment due to the use of a bipolar diathermy probe is possible.

- If abnormal performance is observed (determined by switching the surgical device on and off), additional measures may be necessary, such as reorienting or relocating the surgical device or other medical equipment.

NOTE

Danger due to electromagnetic radiation!

VISALIS V500 / VISALIS S500 may be disturbed by other devices even when these other devices comply with the emission requirements applicable to them according to CISPR.

- Do not use VISALIS V500 / VISALIS S500 when it is located next to or stacked on top of other devices.
- If operation of the device located next to or stacked on top of other devices is required, observe VISALIS V500 / VISALIS S500 to ensure its normal operation in the arrangement in which it is used.

EMC - Electromagnetic compatibility as per IEC 60601-1-2: 2007 (3rd Edition)

Electromagnetic interference

The VISALIS V500 / VISALIS S500 is intended for operation in an electromagnetic environment as specified below. The customer or the user of the device VISALIS V500 / VISALIS S500 is responsible for ensuring that the device is operated in such an environment.

Interference measurements	Compliance	Electromagnetic environment - guidelines
RF emissions as per CISPR11	Group 1*	The VISALIS V500 / VISALIS S500 uses RF energy only for its internal functions. As a result, RF emissions are very low and unlikely to cause any interference in nearby electronic devices.
	Group 2	The VISALIS V500 / VISALIS S500 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions as per CISPR11	Class A	The device VISALIS V500 / VISALIS S500 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions as per IEC 61000-3-2	not applicable	
Emission of voltage fluctuations/flicker as per IEC 61000-3-3	not applicable	

* The device complies with "Group 1" if the diathermy function is not activated.

WARNING! Do not place VISALIS V500 / VISALIS S500 in the vicinity of other device as this may impair the device's function. If it is essential to use VISALIS V500 / VISALIS S500 next to other devices VISALIS V500 / VISALIS S500 should be monitored to verify normal operation.

Electromagnetic immunity for ME equipment and ME systems

The VISALIS V500 / VISALIS S500 is intended for operation in an electromagnetic environment as specified below. The customer or the user of the VISALIS V500 / VISALIS S500 is responsible for ensuring that the device is operated in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) as per IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be made of wood or concrete or be covered with ceramic tiles. If the flooring contains synthetic materials, the relative humidity must be at least 30%.
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.
Surges as per IEC 61000-4-5	± 1 kV phase-to-neutral voltage ± 2 kV phase/neutral to ground voltage	± 1 kV phase-to-neutral voltage ± 2 kV phase/neutral to ground voltage	The quality of the supply voltage should be that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations as per IEC 61000-4-11	< 5% UT (> 95% dip of UT) for 0.5 cycle 40% UT (60% dip of UT) for 5 cycles 70% UT (30% dip of UT) for 25 cycles < 5% UT (95% dip of UT) for 5s	< 5% UT (> 95% dip of UT) for 0.5 cycle 40% UT (60% dip of UT) for 5 cycles 70% UT (30% dip of UT) for 25 cycles < 5% UT (95% dip of UT) for 5s	The quality of the supply voltage should be that of a typical business or hospital environment. If the user of VISALIS V500 / VISALIS S500 requires continued function even in the event of interruptions in the power supply, we recommend to power the device VISALIS V500 / VISALIS S500 from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field as per IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels typical of business and hospital environments.

NOTE: UT is the AC supply voltage prior to application of the test level.

Electromagnetic immunity for non-life-supporting ME equipment and ME systems

The VISALIS V500 / VISALIS S500 is intended for operation in an electromagnetic environment as specified below. The customer or the user of the VISALIS V500 / VISALIS S500 is responsible for ensuring that the device is operated in such an environment.

Immunity tests	IEC 60601 - test level	Compliance level	Electromagnetic environment - guidelines
			Portable and mobile radio communication equipment should not be used closer to the VISALIS V500 / VISALIS S500, including cables, than the recommended safety distance that is calculated using the equation applicable to the transmission frequency involved. Recommended safety distance:
Conducted RF disturbances as per EN 61000-4-6	3 $V_{effective\ value}$ 150 kHz to 80 MHz	3 V	$d = 1{,}17\sqrt{P}$
Radiated RF disturbances as per EN 61000-4-6	3 $V_{effective\ value}$ 80 MHz to 2.5 GHz	3 V/m	$d = 1{,}17\sqrt{P}$ for 80 MHz to 800 MHz $d = 2{,}33\sqrt{P}$ for 800 MHz to 2.5 GHz Where P is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d is the recommended safety distance in meters (m). Field strengths from stationary RF transmitters, as determined by a site survey[a], should be less than the compliance level in all frequency ranges.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1	At 80 MHz and 800 MHz, the higher frequency range applies.		

Immunity tests	IEC 60601 - test level	Compliance level	Electromagnetic environment - guidelines
Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection by structures, objects and persons.		

[a] Field strengths of stationary transmitters such as base stations for mobile telephones and mobile land radio equipment, amateur radio stations, AM and FM radio broadcast and TV broadcast transmitters cannot be theoretically predicted accurately. To assess the electromagnetic environment with respect to stationary RF transmitters, a site study of the electromagnetic phenomena should be considered. If the measured field strength in the location where the device is used exceeds the compliance levels indicated above, the device should be monitored to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME equipment or ME system.

[b] Field strengths should be less than 3 V/m over the frequency range from 150 kHz to 80 MHz.

Recommended safety distances between portable and mobile RF communication equipment and the VISALIS V500 / VISALIS S500

The device VISALIS V500 / VISALIS S500 is intended for use in an electromagnetic environment in which RF disturbances are controlled. The customer or the user of the device VISALIS V500 / VISALIS S500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the VISALIS V500 / VISALIS S500 - depending on the output power of the communication equipment as specified below.

Rated power of the transmitter [W]	Separation distance depending on transmission frequency [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	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended safety distance d in meters (m) can be determined using the equation indicated for each column, with P being the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications.

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.

EMC - electromagnetic compatibility IEC 60601-1-2: 2014 (4th Edition)

Electromagnetic interference

The device VISALIS V500 / VISALIS S500 is intended to be operated in one of the electromagnetic environments specified below. The customer or the user of the device VISALIS V500 / VISALIS S500 is responsible for ensuring that it is operated in such an environment.

Measurements of emitted interference	Compliance
HF emissions according to CISPR 11	Group 1* * The device complies with "Group 1" if the diathermy function is not activated. WARNING! Do not place VISALIS V500 / VISALIS S500 in the vicinity of other device as this may impair the device's function. If it is essential to use VISALIS V500 / VISALIS S500 next to other devices VISALIS V500 / VISALIS S500 should be monitored to verify normal operation.
	Group 2 The VISALIS V500 / VISALIS S500 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
HF emissions according to CISPR 11	Class A
Harmonic emissions as per IEC 61000-3-2	not applicable
Emission of voltage fluctuations/flicker as per IEC 61000-3-3	not applicable

NOTE:
The emission properties are suitable for the use in industrial areas and hospitals (CISPR 11 Class A). If the device is used in a residential area (for which CISPR 11 Class B is normally required) this equipment may not provide the necessary protection with regard to radiofrequency communication services.

Electromagnetic immunity for all ME equipment and ME systems

The device VISALIS V500 / VISALIS S500 is intended to be operated in one of the electromagnetic environments specified below. The customer or the user of the device VISALIS V500 / VISALIS S500 is responsible for ensuring that it is operated in such an environment.

Immunity tests	IEC 60601 - test level	Compliance level
Electrostatic discharge (ESD) as per IEC 61000-4-2	±8 kV Contact discharge	±8 kV Contact discharge
	± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air discharge	± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air discharge
Fast transient/burst immunity as per to IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines
	±1 kV for input/output lines	±1 kV for input/output lines
Surges as per IEC 61000-4-5	±1 kV voltage phase/neutral to ground voltage	±1 kV phase/neutral to ground voltage
	±2 kV phase/neutral to ground voltage	±2 kV phase/neutral to ground voltage
Magnetic field for supply frequency (50 / 60 Hz) as per IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz
Voltage drops, short interruptions and supply voltage variations as per to IEC 61000-4-11	0 % U_T for 1/2 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U_T for 1/2 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
	0 % U_T for 1 cycle and	0 % U_T for 1 cycle and
	70 % U_T for 25/30 cycles Single phase: at 0°	70 % U_T for 25/30 cycles Single phase: at 0°
	0 % U_T for 250/300 cycles	0 % U_T for 250/300 cycles

Electromagnetic interference resistance for ME equipment or systems that are not life-sustaining

The device VISALIS V500 / VISALIS S500 is intended to be operated in one of the electromagnetic environments specified below. The customer or the user of the device VISALIS V500 / VISALIS S500 is responsible for ensuring that it is operated in such an environment.

Immunity tests	IEC 60601 - test level	Compliance level
Conducted HF disturbances as described in as per EN 61000-4-6	3 V 150 kHz to 80 MHz	3V
	6 V ISM bands between 150 kHz and 80 MHz SIP/SOPs with length < 3 m tested	6V
Radiated HF disturbances as per EN 61000-4-3	3 V/m 80 - 2700 MHz	3 V/m
Radiated HF disturbances by electromagnetic nearfields of wireless communication systems as per EN 61000-4-3	27 V/m 380 - 390 MHz	27 V/m
	28 V/m 430 - 470 MHz, 800 - 960 MHz; 1700 - 1990 MHz, 2400 - 2570 MHz	28 V/m
	9 V/m 704 - 787 MHz, 5100 - 5800 MHz	9 V/m

System combinations

CAUTION

Note system configuration!

Anyone connecting additional equipment to medical electrical devices is a system configurator and as such responsible for compliance of the system with the normative requirements for systems.

- Any additional equipment connected to medical electrical devices must demonstrably comply with the applicable standards and directives (e.g. IEC 60950 for data processing equipment).
- In addition, all configurations must meet the normative requirements for medical systems (see IEC 60601-1-1 or IEC 60601-1, chapter 16 of the 3rd edition). Note the following:
  - Never connect any additional multiple connectors or extension cords.
  - Only connect compatible components to the system.
  - Assembly of medical electrical systems and modifications during actual service life shall be evaluated based on the requirements of this standard.
- Note that local legislation takes priority over the above-mentioned normative requirements. If you have any questions, contact your local dealer or ZEISS Service.

NOTE

Setting up an ME system!

- Only connect compatible components to the system.

Requirements for integrating the device into an existing IT network

Please note the following instructions and measures pursuant to IEC 60601, Amend.1:2012-08 Chapter 14.13 when integrating the device into an existing IT network:

- The device can be connected to an existing IT network to link and exchange data between ZEISS equipment in the operating room (OR).
- The IT network into which the device is to be integrated must have the following features:
  - IPv4, static or dynamic address
  - Any IP address
- The IT network into which the device is to be integrated must be configured as follows:
  - The firewall is open for inbound ports.
  - All data is transmitted unsecured from the device to the customer's secured internal network.
  - No data is transmitted externally from the device.
- Requirements in relation to network connection with the device:
  - The IT network has an Ethernet connection via RJ45, at least Cat.5, 100 Mbit/s.
  - The device has a network isolator in compliance with 60601-1 which means it is not connected to the power supply.

The operator is responsible for the topology of the IT network, the flow of information and the routing between the device, the IT network and other devices.

CAUTION

If the IT network does not provide the features required in order to integrate the device into the IT network, the following hazards may arise:

- Risk of electrical shock if the user touches a live part of the casing or a patient.

⚠ **CAUTION**

If the IT network does not provide the features required in order to integrate the device into the IT network, the following hazards may arise:

- Higher current at power output sockets; risk of electrical shock if the user touches a live part of the casing or a patient

⚠ **CAUTION**

The connection of the device to an IT network that includes other equipment could result in previously unidentified risks to patients, operators or third parties.

– The operator should identify, analyze, evaluate and control these risks.

– Subsequent changes to the IT network could introduce new risks and require additional analysis:

  – changes in the IT network configuration

  – connection of additional items to the IT network

  – disconnecting items from the IT network

  – update of equipment connected to the IT network

  – upgrade of equipment connected to the IT network

NOTE!

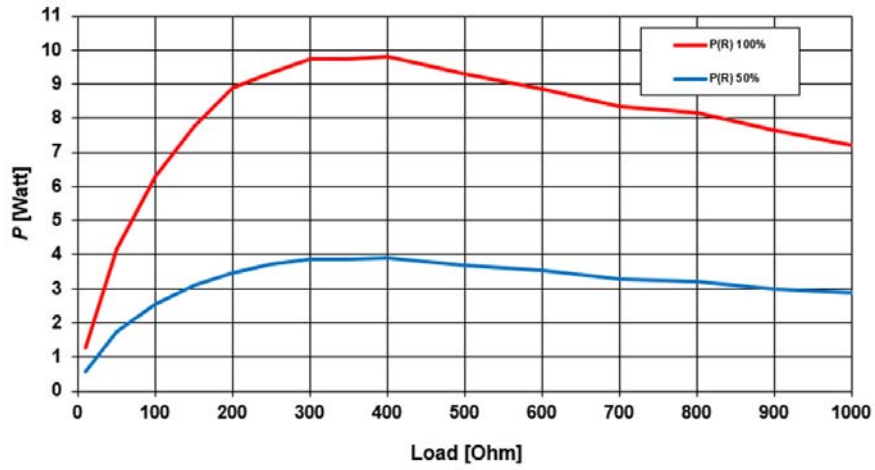
Connecting the system to an existing or external IT network may allow viruses to attack the system under certain circumstances!

This may cause system functions to be limited or to fail.

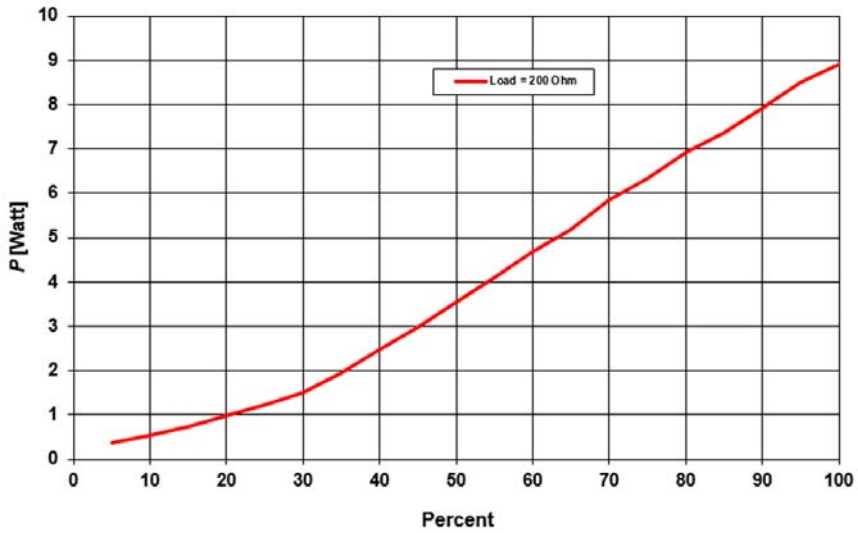
- Keep the IT network virus free. The institution operating the software is responsible for the security of the IT network.

Diathermy power characteristics

Fig. 110: Diathermy power VISALIS V500 / VISALIS S500 Diathermy power vs load



VISALIS V500 / VISALIS S500 Diathermy power vs preset



Ordering data

Operate the system only with the accessories included in the delivery package and recommended by ZEISS. You will find the contact responsible for orders in your country on this website:

www.meditec.zeiss.com

ZEISS Phaco Accessories

For connectable ZEISS phaco accessories for this system, please refer to the separate product overview G-30-2040.

Components

Designation	Specification	Order No.
DOUBLE LINEAR FOOTSWITCH II	non sterile	303041-9005-000
IV-POLE FOOTSWITCH	non sterile	303041-9006-000
REMOTE CONTROL	non sterile	303041-9008-000
TWO-WAY ADAPTER XENON-LIGHTSOURCE	non sterile	303041-0608-000
USB ADAPTER FOR SOFTWARE UPDATES	non sterile	303041-8615-000

Integrated Components

Designation	Specification	Order No.
Console Tray	non sterile	303041-9004-000

Power cords

Designation	Specification	Order No.
Power cord for Europe	2,5 m, grey	000000-0149-592
Power cord for Great Britan	2,5 m, grey	309850-9003-000
Power cord for Switzerland	2,5 m, grey	000000-0228-202
Power cord for China	2,5 m, grey	000000-0475-506
Power cord USA / Latin America	2,5 m, grey	397902-9058-000
Power cord for Brazil	2,5 m, grey	000000-0526-671

CALLISTO eye

Designation	Specification	Order No.
CALLISTO eye BASIC V3.6	with CALLISTO eye Panel PC (model I)	301640-3000-360
	with CALLISTO eye Panel PC (model II)	301640-4000-360
CALLISTO eye ASSISTANCE markerless V3.6	with CALLISTO eye Panel PC (model I)	301640-3020-360
	with CALLISTO eye Panel PC (model II)	301640-4020-360

Upgrade kits

The upgrade kits listed below are integrated in or on device and must be subsequently installed by ZEISS Service.

Designation	Specification	Order No.
VISALIS S500 Phaco Console Upgrade to Posterior Vitrectomy (VISALIS V500)	-	303041-9009-000
VISALIS 500 Phaco & Vitrectomy Console Upgrade to Software Release 2.0	-	303041-9012-000

Compliance

Guidelines with which the device complies

– The device complies with Medical Device Directive 93/42/EEC: Class II b

  It is labeled with: CE 0297

– The device complies with Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Classification of the device according to IEC 60601-1

The device is classified as follows:

– Degree of protection against electric shock: Class I

– Degree of protection against electric shock: Diathermy: Type BF, floating both at high and low frequencies

– Degree of protection against electric shock: U/S: Type B

– Degree of protection against entry of water: IP X1

– Electromagnetic compatibility (EMC): Fulfills IEC 60601-1-2, Class A (as per CISPR 11)

– Operating mode: continuous operation

Classification of the DOUBLE LINEAR FOOTSWITCH II and IV-POLE FOOTSWITCH according to IEC 60601-1

The devices are classified as follows:

– Degree of protection against electric shock: Class I

– Degree of protection against entry of water: IP X8

– Electromagnetic compatibility (EMC): Fulfills IEC 60601-1-2, Class A (as per CISPR 11)

– Safety of use in the presence of flammable anesthetic mixtures: Not suitable

Ambient conditions

WARNING

Risk of injury!

- To ensure safe operation, transport or storage, comply with the information in this section.

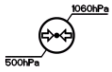
For operation

Property	Permissible range
Temperature	+ 10 °C ... + 35 °C
Rel. Humidity	30 % ... 75 %
Air pressure	950 hPa - 1060 hPa (for max vacuum) 810 hPa - 950 hPa (for vacuum of 500 mmHg with Venturi pump)

For transport and storage

Property	Permissible range
Temperature	- 20 °C ... + 60 °C
Rel. humidity (without condensation)	10 % ... 90 %
Air pressure	500 hPa ... 1060 hPa

Symbols for transportation and storage

Symbol	Meaning
	This way up Indicates the correct upright position of the package.
	Fragile, handle with care
	Keep dry
	Do not stack
	Permissible temperature range Temperature limits for storage and operation
	Number of packaging units
	Permissible range of relative humidity Humidity limits for storage and operation
	Permissible range of air pressure Air pressure limits for storage and operation

Indexes

List of technical terms

Term	Explanation
Ant Vit	Software module for anterior vitrectomy.
Chop	Surgical mode for storage of suitable parameters for a phase of the phaco operation.
Cortex	Surgical mode for storage of suitable parameters for a phase of the phaco operation.
Divide & Conquer	"Divide & Conquer" is a special application used for cataract surgeries.
Drape	Sterile protection cover
Epi	Surgical mode for storage of suitable parameters for a phase of the phaco operation.
Phaco Asp	Surgical mode for storage of suitable parameters for a phase of the phaco operation.
Phaco Chop	"Phaco Chop" is special application used for cataract surgeries.
Phaco frag	Software module for phaco fragmentation.
Polish	Storage place for the storage of suitable parameters of the irrigation/aspiration.
Quad	Surgical mode for storage of suitable parameters for a phase of the phaco operation.
Sculpt	Surgical mode for storage of suitable parameters for a phase of the phaco operation.
Visco	Storage place for the storage of suitable parameters of the irrigation/aspiration.
Vit	Software module for vitrectomy

List of abbreviations

Term	Explanation
AG	Incorporated company (Aktiengesellschaft)
APC	Adaptive Power Control
APM	Advanced Power Modulation
BBS	Balanced salt solution
BNC	Bayonet, Paul Neill, Carl Concelmann (Coaxial bayonet-locking connector for high frequencies, named after its inventor)
CE	Communauté Européenne (European Community) - The manufacturer declares that the device complies with the directives of the European Union.
Diath	Bipolar Diathermy
DIN	Deutsches Institut für Normung (German standards association)
EMC	Electromagnetic Compatibility - defines non-interference of electrical and electronic devices with their environment
EN	European Norm (European Standard)
EPT	Effective phaco time Time duration of the effective phaco time considering the set performance output and the previously selected signal form
HID	High Intensity Discharge (High pressure discharge lamp)
I/A	Irrigation / Aspiration
IEC	International Electrotechnical Commission
IOP	Intra Ocular Pressure (intraocular pressure)
IR	Infrared
IVP	Infusion pole
LCD	Liquid Crystal Display (LCD)
OR	Operating room
OVD	Ophthalmic Viscoelastic Device (Viskoelastikum)

Term	Explanation
RF	Radio frequency
SIP	Service Identification Program
TPT	Total Phaco Time Time duration of the total phacoemulsification. As soon as the surgical system delivers U/S power to the ULITE PHACO HANDPIECE the measurement starts and as soon as no U/S power is further supplied the measurement will end.
U/S	Ultrasound (Phacoemulsification)
USB	Universal Serial Bus
UV	Ultraviolet
VGOS	Video Graphical Overlay System
Vit	Vitrectomy

Keyword index

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CE 0297