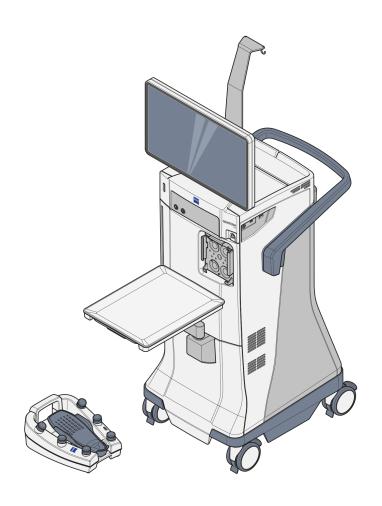
# QUATERA 700 Software Version 1.1

Instructions for Use





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QUATERA 700 1.1 System name

### 1 Notes on the instructions for use

#### 1.1 System name

QUATERA 700 is referred to as "system" in the present Instructions for Use.

## 1.2 Scope of application

The present Instructions for Use apply to QUATERA 700 with software version 1.1:

reference number: 6407

## 1.3 Purpose and storage of the documentation

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

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

- ► Read these Instructions for Use before starting and using the system.
- ▶ Keep the Instructions for Use accessible at all times for all users.
- ▶ Pass the Instructions for Use on to the next owner of the system.

#### 1.4 Questions and comments

▶ If you have any questions or comments concerning these Instructions for Use or the system, please contact ZEISS Service.

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

#### 1.5 Conventions in this document

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

Action

Action

#### 1.5.1 Conventions in all text areas

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

This is a cross-reference: Questions and comments [ 9].

#### This is **bold type**.

This is software code or program text.

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

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

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

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

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

- [START] key
- [Next] button

#### 1.5.2 Conventions in a course of action

## **⚠ WARNING!**

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

The warning message names the possible consequences.

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

# **⚠** CAUTION!

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

The warning message names the possible consequences.

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

#### NOTE

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

The warning message names the possible consequences.

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

Prerequisite

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

Action

- 1. This is a command.
- 2. CAUTION! This is a warning message about hazards that can occur during a single action. This is a command.
  - $\Rightarrow$  This is the result of a sequence of actions.

# 1.6 Other applicable documents

Document type	Document title	Document number
Instructions for Use	Unpacking BlueBox QUATERA 700	G-30-2113
Training record	Briefing Report for newly installed systems	G-30-2114
Product Overview	ZEISS Phaco Accessories	G-30-2040
Release Notes	Release Notes for QUATERA 700 Software Version 1.1.4	RN-30-9067
Instructions for Use	EDIS External Data Injection System	G-30-1913
Instructions for Use	CALLISTO eye	G-30-2003
Product Overview	ZEISS Video Accessories	G-30-1888

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Instructions for Use 2 Safety notes

QUATERA 700 2.1 Target group

# 2 Safety notes

## 2.1 Target group

These Instructions for Use are intended for physicians, nurses and other medical staff who prepare, operate or maintain the system after appropriate training. To train and instruct all staff preparing, operating or maintaining the system is duty of the customer or institution that operates the system.

Additional service activities are not covered by these Instructions for Use. Such activities are performed by staff especially trained for this purpose by ZEISS.

#### 2.2 Area of use

#### 2.2.1 Intended use

QUATERA 700 is intended for the emulsification and removal of cataracts and anterior segment vitrectomy. The device is designed for use in anterior segment surgery. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, anterior vitrectomy.

#### 2.2.2 Contraindications

The diathermy section of QUATERA 700 must not be used on patients with a pacemaker or other cardiac stimulators without prior consultation of a cardiologist.

Accessories not validated by ZEISS should not be used with QUATERA 700.

2.2 Area of use QUATERA 700

#### 2.2.3 Normal use

QUATERA 700 is designed for surgical treatments in the anterior segment of the human eye. Treatment's are performed by qualified medical personnel (eye surgeons). In combination with various components and accessories (foot switch, I/A cassette, tube systems for irrigation and aspiration, handpieces and other accessories) the system allows to carry out phacoemulsification, anterior vitrectomy, irrigation/aspiration and diathermy.

The phacoemulsification device is moveable and is used in clinics, hospitals and other human medicine institutions. The system actively supports the user with caution messages and alarms.

The phacoemulsification device can be cleaned and wiped off. For proper operation, regular maintenance is required in accordance with national regulations. After expiry of the product lifetime, the phacoemulsification device must be disposed of in accordance with national regulations.

#### 2.2.4 Discipline

Ophthalmic surgery in the anterior segment of the eye

#### 2.2.5 Patient target group

Age	All
Gender	All
State of health	Not relevant for the application
Weight	Not relevant for the application
Status during surgery	Under local, topical or general anesthesia

## 2.3 Responsibilities and duties of the operator

#### 2.3.1 Operating personnel

The operation of the product by insufficiently trained and qualified personnel can lead to operating errors and patient injuries.

- ► Make sure the operating personnel are appropriately trained and instructed.
- ► Make sure that the operating personnel have read and understood the Instructions for Use.
- ► Keep the Instructions for Use available at all times for the operating personnel.
- ► To facilitate access for all operating personnel, request additional copies of the Instructions for Use from ZEISS as required.
- ► Specify the competentcies for handling the system and state who is authorized to perform which tasks.
- ▶ Determine the reporting obligations for malfunction and damage and make them known to all operating personnel.

#### 2.3.2 Safety inspections

The safety of system parts may decrease due to aging and wear. If safety checks are not performed at regular intervals, occuring safety risks cannot be identified.

- ▶ Implement regular safety inspections as specified for the system by the applicable national regulations.
- ► Make sure the safety inspections are performed within the specified time limits.
- ► Make sure the safety inspections are performed by the manufacturer or qualified personnel.

The safety inspections should at least comprise the following points:

- Check for the availability of the Instructions for Use
- Visual inspection of the system and accessories for damage
- Check for the legibility of labels
- Leakage current test
- Test of the protective ground conductor
- Function and wear test of the brakes
- Function test of all switches, buttons, sockets and indicator lamps

#### 2.3.3 Care and maintenance

To ensure a safe operation of the system over the entire expected service life, the system must be maintained at regular intervals.

▶ Always comply with the maintenance and inspection intervals specified in these Instructions for Use [▶ 219].

The system must not be maintained during patient contact. Maintaining the system during patient contact can lead to injuries.

- ▶ Do not maintain the system during contact with the patient.
- ▶ Do not have the system maintained during contact with the patient.

During extended periods of non-use the batteries discharge, so certain safety features might not be available when the system is started the next time. Extended periods of non-use might also damage the batteries.

► Charge the batteries at least every 3 months by connecting the system to the power supply, switching it on and letting it run for about 6 hours.

#### 2.3.4 Product modifications

The system must not be modified without the manufacturer's approval and without suitable inspections and testing, to ensure that it can be used safely further on. In addition, any configurations must comply with normative requirements for medical systems (see IEC 60601-1, Ed. 3.1).

- ▶ Do not modify the system without explicit approval from ZEISS.
- ▶ Do not operate a modified system without having assured its safe operation by suitable inspections and testing.
- ▶ Always make sure to comply with the relevant normative requirements.

#### 2.3.5 Accessories and additional equipment

Any additional equipment connected to medical electrical devices must demonstrably comply with the applicable IEC or ISO standards (e.g. IEC 60950 for data processing equipment positioned outside of

the patient environment). In addition, any configurations must comply with normative requirements for medical systems (see IEC 60601-1, Ed. 3.1).

2.3 Responsibilities and duties of the operator

Anyone connecting additional equipment to medical electrical systems is a system configurer and as such is responsible for the compliance of the system with the standards for the systems. Local legislation has priority over the above normative requirements.

- ▶ Do not connect accessories and additional equipment without explicit approval from ZEISS.
- ► Always make sure to comply with the relevant normative requirements.

#### 2.3.6 Protection measures

Insufficient protection measures can lead to infections and injuries of the operating personnel or the patient.

- ▶ Provide the necessary protective clothing.
- ► Regularly check that the legal regulations with regard to accident prevention and work safety which are applicable in your country are complied with.

#### 2.3.7 Transport

Wrong transport conditions can damage the system.

- ► Only transport the system over long distances (e.g. relocation, return for repair) in its original packaging or special return packaging.
- ▶ If required, contact ZEISS for an adequate packaging.
- ► Set the [Battery disconnect] switch to **Off** to completely deenergize the system for packing and transport.

#### 2.3.8 IT network connection

Inadequate IT network connections can lead to injuries or damage.

► Make sure that the requirements for connecting the system to an IT network are met.

#### 2.3.9 Electromagnetic compatibility

The system is subject to special precautionary measures regarding electromagnetic compatibility. The following factors can cause EMC disturbances:

- Portable and mobile HF communication equipment in the vicinity of the system.
- Other devices set up in the vicinity or stacked together with the system.
- Accessories, cables and spare parts not specified in the Instructions for Use and not sold by ZEISS as spare parts.

EMC disturbances can lead to instabilities and function failures.

- ▶ Make sure the system is installed and initially commissioned in accordance with the EMC notes in the system's Instructions for Use [▶ 244].
- ▶ Only use accessories, transformers, cables and spare parts specified in the Instructions for Use or approved by ZEISS for the system.
- ▶ Make sure radio communication equipment or components for radio transmission are not used within a distance of 30 cm to all system components.
- ▶ If the system is installed near or stacked with other devices, make sure the system is operating correctly in this configuration.

#### 2.3.10 Messages to manufacturer and authorities

If a serious incident occurs in connection with this medical system affecting the operator or another person, the operator (or person responsible) must report this serious incidence to the manufacturer or seller of the medical system. In the European Union, the operator must report this serious incident to the responsible authorities in the applicable country.

# 2.4 Responsibilities and duties of the operating personnel

#### 2.4.1 Electrical safety

Contact to live parts can lead to death or severe injuries. Inadequate power supply connections can lead to fire or function failures.

- ▶ **Never** touch the touchscreen while you are in contact with the patient!
- ▶ **Never** touch the power outlet while you are in contact with the patient!
- ▶ Always switch off the system before connecting it to or disconnecting it from the power supply, for cleaning its surface, or if it will not be used for a prolonged period of time.
- ▶ Only connect the system to a power supply that complies with the values specified on the rating label [▶ 27].
- ▶ Do not connect the system to the power supply using multiple sockets or extension cables!
- ▶ Connect the system via the PE connection pin [▶ 40] (according to IEC 60601-1) to other active devices with the same ground potential or connect it to a protective ground connection to avoid different potentials between various parts of medical systems.
- ▶ Do not touch the system if your body is electrostatically charged and the system is not grounded.
- ▶ Position the system such that it can easily be disconnected from the power supply at any time.
- ▶ Note the information on electromagnetic compatibility.

The system contains freely accessible live components. If the housing is removed, there is a risk of electric shock.

Never open the system housing!

#### 2.4.2 Environmental conditions

- ▶ Make sure that the installation conditions and the operation of the system comply with the surgical requirements. Avoid high vibration. Avoid an extreme mechanical loading. Operate the system in a clean environment.
- ▶ Do not operate the system or power-operated system parts included in the delivery in explosive atmospheres or at distance of less than 25 cm from flammable anesthetics or volatile solvents such as alcohol, benzene or similar substances.
- ▶ Do not use or store the system in damp rooms. Do not expose the system to water splashes, dripping water or sprayed water.
- ▶ Make sure that no fluids can enter the system.

#### 2.4.3 Symbols and labels

Not obeying symbols and labels on the system or system parts can lead to application errors.

▶ Always note and obey the symbols, labels and markings attached to the system.

#### 2.4.4 Connections

Inadequate or damaged connections can lead to function failure, fire or injuries to the patient and the operating personnel. Cables inappropriately routed on the floor may constitute a tripping hazard.

- ▶ Make sure that the connecting components are properly set and that all screw connections are securely tightened.
- Make sure that all cables and plugs are in proper condition.
- ► Make sure the system voltage is set in accordance to the installation site's supply voltage.
- ▶ Make sure the system is connected to the power supply with the power cable provided within the scope of delivery.
- Always route cables in a manner that will not obstruct the workflow.

#### 2.4.5 System damage

Using a damaged or not fully functional product can lead to injuries.

- ▶ Do not use the system if it shows any sign of damage or if it is not fully functional.
- ▶ If an error occurs that cannot be solved following the instructions in the troubleshooting section [▶ 223], mark the system as non-functional and secure it against any further use.

#### 2.4.6 Accessories

The connection of incompatible accessories and tubings can lead to system malfunctions and patient injuries.

- ► Only use the system with accessories and tubings supplied or certified by ZEISS.
- ► For connectable accessories refer to the product overview G-30-2040.

The reuse of materials, components, accessories or ME equipment intended for single-use can lead to injuries to the patient. Using unsterile parts can lead to injuries to the patient.

- ▶ Do not reuse material, components, accessories or ME equipment marked with "Single Use Only", "Do Not Reuse" or with symbol 28 of table D.1 of ISO 7000-1051, DB:2004-01.
- ▶ Always use the appropriate sterile accessories for the system.

Attached accessories can cause the risk of fire, damage or injuries, if they are connected or placed in a wrong manner. Defective or unidentified accessories may lead to patient injuries.

- ► Read the instructions for use of accessories before connecting them and putting them to use.
- ▶ Do not connect any defective, modified or unidentified accessories
- Never use accessories showing damages, such as kinks or damaged isolators.
- ▶ Never exceed the system's maximum permitted weight load.
- ▶ Always route cables so that they do not hinder the user.
- ▶ Make sure not to cover any ventilation openings.
- ▶ Never attempt to forcefully connect any electrical connectors. If any connector is damaged contact the ZEISS Service for repair.
- ▶ Before using them, test accessories to ensure a proper functioning.
- Do not carry or pull accessories by their cables.

#### 2.4.7 Diathermy probes

Using the system's diathermy section in combination with other devices, including cardiac pacemakers and implanted defibrillator devices, can lead to function impairment or damage as well as to patient injuries.

- ▶ Before using the diathermy function with other devices creating high-frequency waves or high voltages, check the interference of the devices. If required, contact the device manufacturer or a cardiologist.
- ▶ Install the devices in such a way that the disturbances caused by high-frequency waves are minimized.

Using diathermy probes in an inadequate or improper manner or in inadequate environments can lead to injuries or damage.

- ▶ Do not use diathermy near conductive materials such as metal bed parts, inner-spring mattresses, standalone infusion poles and the like
- ▶ Do not use flammable anesthetics, nitrogen monoxide or oxygen if sufficient ventilation by a suitable aspiration system is not guaranteed.
- ▶ Do not touch the patient or other cables with the diathermy bipolar cable.
- ▶ Place active electrodes, which are currently not in use, at a location that is isolated from the patient.
- ▶ Before using diathermy probes, evaporate flammable materials such as disinfecting agents and cleaning agents.
- ▶ Do not use diathermy probes in the vicinity of materials like cotton wool or gauze. If soaked with oxygen, such materials can catch fire
- Replace the electrode cables as soon as there is any evidence of wear.

Due to the low level of plume, plume evacuation is not required when using a bipolar diathermy probe.

#### 2.4.8 After use

If the system is switched on, but not supervised, it may cause injuries or damage.

▶ If you are not using the system, switch it off.

# 3 Description of the system

# 3.1 System marking

## **⚠** CAUTION!

#### Risk of injury due to illegible labels!

Over time, labels can become dirty and thus unidentifiable, making it difficult or impossible for hazards to be recognized or necessary operating instructions to be followed.

- ► Keep all safety and warning labels and operating instructions in good condition at all times.
- ▶ Damaged labels are to be replaced immediately. For replacement labels, contact the ZEISS Service or an authorized ZEISS representative.

3.1 System marking QUATERA 700

# 3.1.1 Labeling on the system front

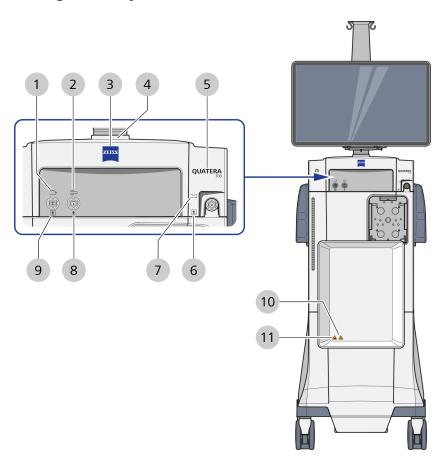


Figure 1: Labeling on the system front

Pos.	Symbol	Explanation
1	•	Diathermy port
2		U/S port (for phaco handpiece)
3	ZEISS	ZEISS logo
4		Warning: hazard of finger crushing

Pos.	Symbol	Explanation
5	QUATERA 700	Product name
6	<b> </b>	Applied part type BF
7	<b>\</b>	Vitrectomy port
8	<b>†</b>	Applied part type B
9	<b>†</b>	Applied part type BF
10	max. 5 kg	Max. load capacity 5 kg
11		Warning: hazard of finger crushing

QUATERA 700

# 3.1.2 Labeling on the system side

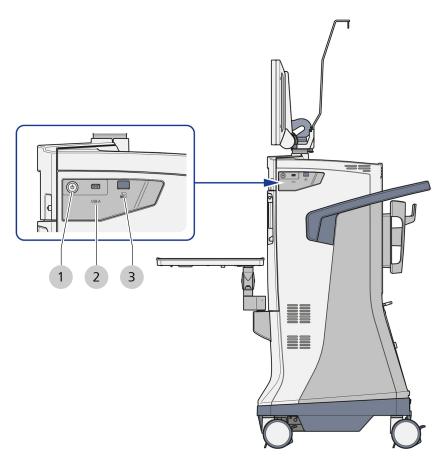


Figure 2: Labeling on the system side

Pos.	Symbol	Explanation
1		[Device power on/off] operating button
2	USB-A	USB-A port
3		Barcode scanner  Note: The barcode scanner is not functional.

QUATERA 700 3.1 System marking

# 3.1.3 Labeling on the system back

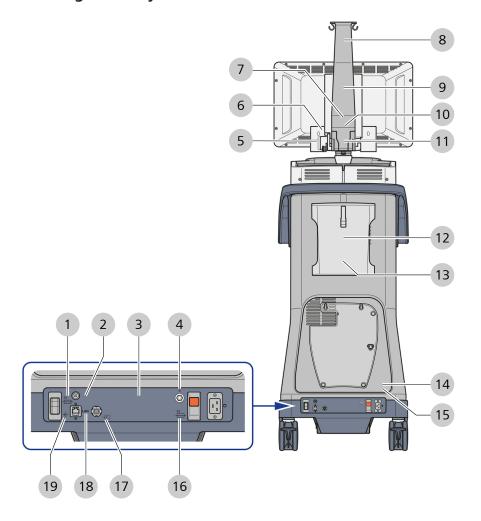


Figure 3: Labeling on the system back

Pos.	Symbol	Explanation
1	F2	Circuit breaker
2	<u>*</u>	Foot switch
3	Carl Zeiss Meditec AG  Goeschwitzer Strasse 51-52 07745 Jena, Germany  QUATERA 700  REF 6407  SN 640710xxx  (11)YYY-MM-DD (10)4049539064073 (11)YYY-MMDD(21)640710xxx 100V - 240V max. 1200VA 50Hz - 60Hz MADE IN GERMANY IPX1  max. 185kg	Approval label [▶ 30] for QUATERA 700, provides information on:  ■ manufacturer  ■ system data ■ power data ■ UDI labeling ■ type of disposal ■ total weight ■ CE label
4	<b>♦</b>	Equipotential connector
5		Warning: hazard of finger crushing
6	2)	Monitor rotation direction
7	Carl Zeiss  J. J. SIP Service Identification Program SIP-No.	Service identification program label, provides information on:  manufacturer manufacturer's contact information SIP number of the device
8	mx. 2 kg	Max. load capacity 2 kg
9	min	Min. bottle height
10	640710xxxx	Serial number

QUATERA 700

Pos.	Symbol	Explanation
11		Warning: hazard of finger crushing
12		Handling note
13		Moving position
14	Rx Only	For professional use only
15		Read and observe the Instructions for Use
16	F1	Automatic circuit breaker
17	$\rightarrow$	Video input
18	LAN	LAN port
19	4	[Battery disconnect] switch

3.1 System marking QUATERA 700

#### 3.1.4 Approval label

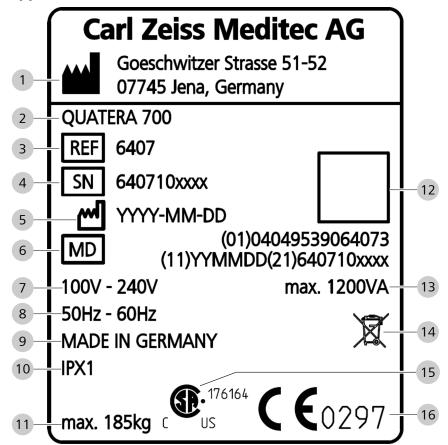


Figure 4: Markings on the approval label

Pos.	Symbol	Explanation	
1		Manufacturer's name and address	
2		Product name	
3	REF	Reference number	
4	SN	Serial number	
5		Date of manufacture, year-month-day	
6	MD	Medical device	
7		Rated voltage	
8		Line frequency range	
9		Designation of origin for industrial products: MADE IN GERMANY	
10		Ingress protection class	
11		Maximum total weight	
12		UDI label, data matrix according to GS1 standard	
13		Maximum connected load	
14		WEEE mark	
15	C US	CSA mark	
16	<b>C C</b> 0297	CE marking	

# 3.2 Labeling on the packaging

Symbol	Explanation
<u>11</u>	Position the package with the indicated side up.
I	Fragile, handle with care.
<del></del>	Keep dry.
	Do not stack. Do not place any load on the package.
-20°C +60°C	Range of permissible temperature for transport and storage: -20 °C to 60 °C
90%RH	Range of permissible relative air humidity for transport and storage: 10 % to 90 %
1060hPa	Range of permissible atmospheric pressure for transport and storage: 500 hPa to 1060 hPa
$\sum_1$	Quantity
ZEISS	ZEISS logo
QUATERA 700	Device name
+++	Center of gravity

QUATERA 700

Symbol	Explanation
( <del>0-0</del> ) — — — — — — — — — — — — — — — — — — —	Minimum forklift length
WARNING	Shock indicator
	Tilt indicator
UN 3481 +49 736420 XXXX	Shipping label for lithium-ion batteries

Table 1: Symbols for transport and storage

# 3.3 Structure of the system

# 3.3.1 Components of the system (front side)

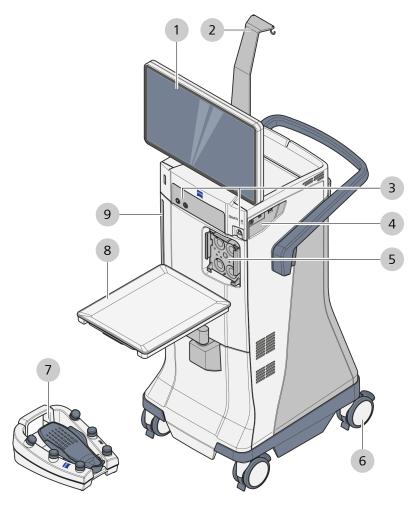


Figure 5: Components of the system (front side)

1	Touchscreen monitor	2	Bottle holder
3	Front panel connectors	4	Side panel connectors
5	Cassette interface	6	Steerable casters
7	QUATERA FCP	8	Console tray
9	Patient eye level indicator		

QUATERA 700

## 3.3.2 Components of the system (rear side)

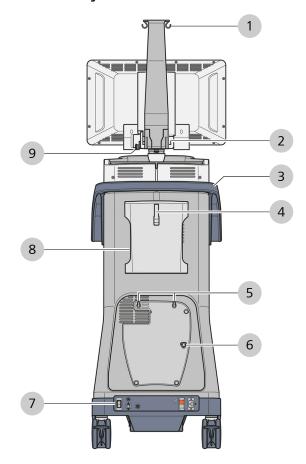


Figure 6: Components of the system (rear side)

1	Bottle holder	2	Monitor suspension
3	Handgrip	4	Cable holder
5	QUATERA FCP holding pins	6	QUATERA FCP charging pins
7	Rear panel connectors and control elements	8	Opening for vitrectomy emergency case
9	Monitor fixation pin		

#### 3.3.3 Patient eye level indicator

The patient eye level indicator is used to ensure the correct irrigation pressure. It facilitates the identification of the vertical distance between the patient's eye level and the aspiration port. If the patient eye is not at the same level as the aspiration port, the system can correct the offset in the range of -15 cm to +15 cm. The zero point of the patient eye level indicator is at the same height as the center of the QUATTRO CASSETTE's irrigation chambers.

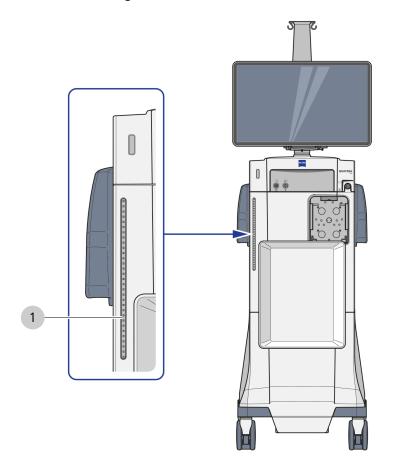


Figure 7: Patient eye level indicator

1 Patient eye level indicator

The patient eye level indicator comprises a strip of 31 LEDs mounted behind a translucent part of the system paneling.

## 3.3.4 Console tray

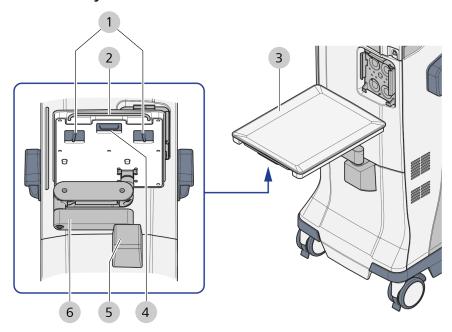


Figure 8: Console tray

1	Lateral handgrips	2	Metal bracket
3	Console tray	4	Anterior handgrip
5	Tray base	6	Tray arm

#### 3.3.5 Steerable casters

The steerable casters are used to position the system in the OR.

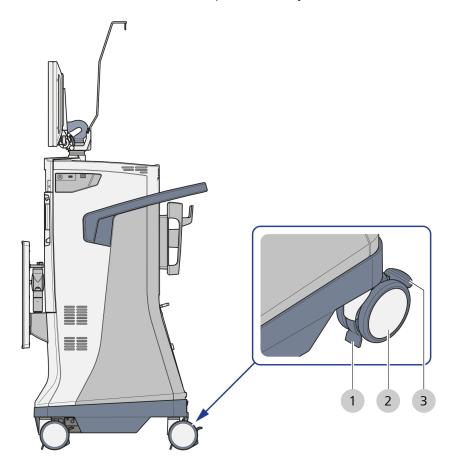


Figure 9: Steerable casters

1	Cable deflector	2	Caster wheel
3	B Locking tab		

QUATERA 700 3.3 Structure of the system

## 3.3.6 QUATERA FCP holder

At its rear panel the system has a holder where to store and charge the QUATERA FCP between surgeries.

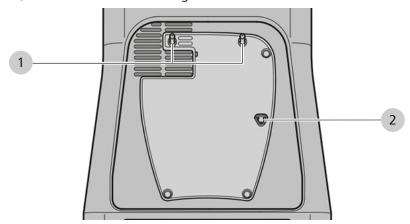


Figure 10: QUATERA FCP holder

1	QUATERA FCP holding pins	2	QUATERA FCP charging pins
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## 3.3.7 Front panel connectors

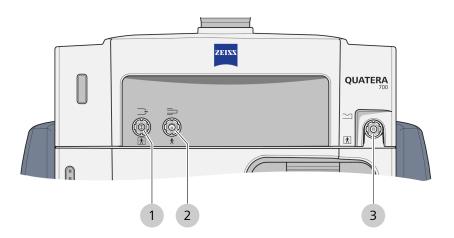


Figure 11: Front panel connectors

1	Diathermy socket	2	U/S socket
3	3 Vitrectomy socket		

## 3.3.8 Rear panel connectors

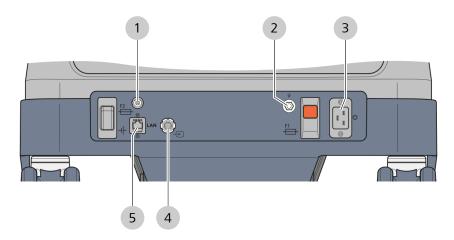


Figure 12: Rear panel connectors

1	QUATERA FCP socket	2	PE connection pin
3	Power supply socket	4	Video intput socket
5	Network socket		

# 3.3.9 Side panel connectors

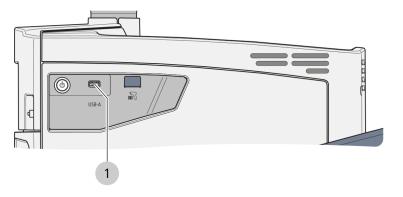


Figure 13: Side panel connector

1	USB-A port

## 3.4 Control elements and displays

## 3.4.1 Side panel

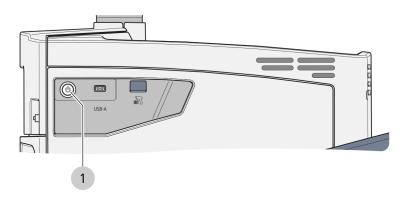


Figure 14: Control elements on the side panel

Pos.	Designation	Description
1	[Device Power on/ off] operating button	<ul> <li>Indicates the current system state (see table below)</li> </ul>
		<ul><li>Switches the system on or off, when pressed</li></ul>

To the operator, the system states are indicated by dedicated LED blinking sequences of the [Device Power on/off] operating button. The sequences are explained in the following table.

LED blinking sequence	System state	Explanation
permanently off	power off	The mains supply is not connected.
0.5 seconds white / 2.5 seconds off	power off and charging	The mains supply is not connected. The QUATERA FCP is charging.  Note that offline charging may not be allowed in your country and therefore deactivated.
permanently white	ready	The mains supply is connected, the system can be switched on. The QUATERA FCP and the main battery are not charging.
2.5 seconds white / 0.5 seconds off	ready and charging	The mains supply is connected, the system can be switched on. The QUATERA FCP and the main battery are charging.
permanently green	active	The system is switched on.
2 seconds green / 2 seconds white	active and power off	The system is shutting down.
0.5 seconds green / 0.5 seconds off	power emergency	The mains supply is interrupted. The current workflow can be finished with limited functionality.
0.5 seconds green / 0.5 seconds white	power emergency and power off	The system is shutting down from the power emergency mode. The current workflow cannot be finished.
0.1 seconds green / 0.1 seconds white	safe state	An error occurred. Only a reboot or service work can be performed at the system.

## 3.4.2 Rear panel

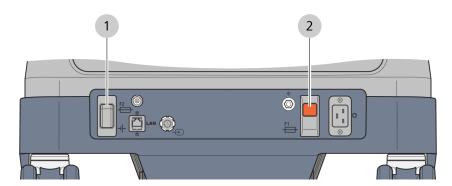


Figure 15: Control elements on the rear panel

Pos.	Designation	Description
1	[Battery disconnect] switch	<ul> <li>"On" position:</li> <li>The main battery is charged when the system is connected to the mains supply.</li> <li>Backup energy is provided by the main battery in case of a mains supply interruption of at least 1 minute.</li> <li>The QUATERA FCP is charged via the QUATERA FCP charging pins, if it is connected and the system is turned off.</li> <li>"Off" position:</li> <li>The main battery is disconnected from the power supply and is not charged.</li> <li>No backup energy is provided by the main battery.</li> </ul>
2	[Manual circuit breaker] switch	Protects the system against overloading and short circuits.

#### 3.4.3 QUATERA FCP

The QUATERA FCP is a controlling device to be operated with one foot only. It enables the surgeon to activate and control system functions, if configured accordingly [ 169].

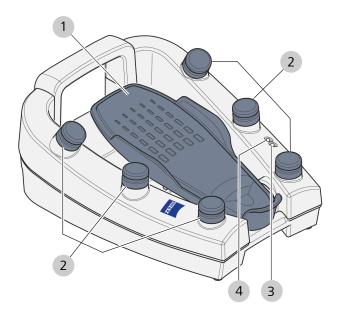


Figure 16: Control elements of the QUATERA FCP

Pos.	Designation	Explanation
1	Foot pedal	Triggers default or user-defined functions if moved in horizontal (yaw) or vertical (pitch) direction
2	Side button	Triggers default or user-defined functions when pushed
3	Connection status LED	Indicates the current connection status (permanently blue: connected, flashing amber: not connected)
4	Charging status LED	Indicates the current charging status (see below)

To the operator, the QUATERA FCP charging states are indicated by dedicated blinking sequences of the charging status LED. The most important sequences are explained in the following table.

LED blinking sequence	Operation state	Explanation
permanently green	charging	The FCP is connected to the system's charging pins and the charge level is > 80 %.
flashing amber		The FCP is connected to the system's charging pins and the charge level is < 80 %.
permanently green	discharging	The FCP is not connected to the system's charging pins and the charge level is $> 40 \%$ .
permanently amber		The FCP is not connected to the system's charging pins and the charge level is between 15 % and 40 %.
flashing amber		The FCP is not connected to the system's charging pins and the charge level is < 15 %.
none	externally powered	The FCP is not connected to the system's charging pins but is powered via power supply cable.
> 1 second white	self test	The system performs a self test.

# 3.5 Software description

## 3.5.1 General display and control elements

#### 3.5.1.1 Header and footer elements

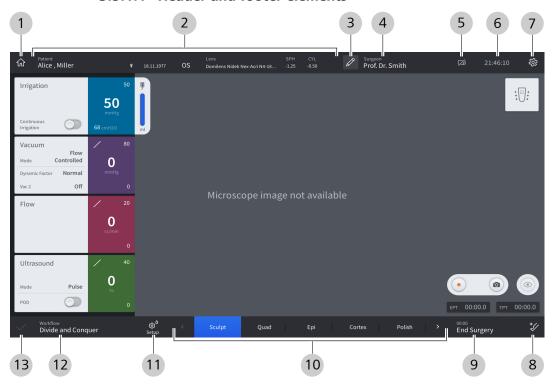


Figure 17: Header and footer elements

Pos.	Symbol	Name	Explanation
1	命	[Live Screen] button	Opens the "Live Screen" menu [▶ 53] when tapped
2		Patient information section	Displays information about the currently treated patient
			Note: The display of patient information requires the connection of a CALLISTO eye with software version 3.7 or higher.
3	0	[Surgeon Settings] button	Opens the "Surgeon Settings" dialog when tapped
4		[Surgeon] button	<ul> <li>Displays the name of the currently active user</li> <li>Opens the "Change Surgeon" dialog when tapped</li> </ul>
5		[USB Information] button	<ul> <li>Indicates whether or not a USB storage medium is connected (crossed: no medium present, not crossed: medium present)</li> </ul>
			■ Opens the "USB Information" dialog [▶ 64] when tapped

Pos.	Symbol	Name	Explanation
6	- <b>,</b>	System Time	Displays the current system time in hours, minutes and seconds
7	£	[Settings] button	Opens the "Settings" menu [▶ 65] when tapped
8	¥	[Additional Instruments] button	Opens access to additional instruments steps ("Anterior Vitrectomy" and "Diathermy") when tapped
9		[End Surgery] button	<ul> <li>Displays the duration of the current surgery in hours and minutes</li> <li>Opens the "End Surgery" dialog when tapped</li> </ul>
10		Workflow bar	<ul> <li>Displays the steps of the workflow with the current step highlighted blue</li> </ul>
			<ul> <li>Allows to switch the workflow step by tapping</li> </ul>
11	<b>⊚</b> <sup>♠</sup> Setup	[Setup] button	<ul> <li>■ Opens the "Setup" menu [▶ 51] when tapped</li> <li>■ Indicates whether the preparation procedures for the used instruments have been performed or not (warning sign: procedures not performed, no warning sign: procedures performed)</li> </ul>
12		[Workflow] button	<ul> <li>Displays the name of the currently active workflow</li> <li>Opens the "Change Workflow" dialog when tapped</li> </ul>
13	$\checkmark$	"Default settings" indicator	Indicates that the currently used settings are identical to the default settings
	S	[Set as Default] button	<ul> <li>Indicates that the currently used settings are not identical to the default settings</li> <li>Adapts the default settings to the currently used settings when tapped</li> </ul>

#### Information:

While the elements in the header are present on any screen, the presence of the individual footer elements depends on the screen that is currently active.

#### 3.5.1.2 Interactive control elements

The following control elements can be present in various contexts, i.e. wherever values can be adapted.

Symbol	Name	Explanation
$\mathcal{S}$	"Settings adapted" indicator	Indicates that the current settings of a module are not identical to the default settings
	Function switch	<ul> <li>Indicates the activation status of the related function (blue: active, gray: inactive)</li> </ul>
		Activates or deactivates the related function when tapped
	Function button	Triggers the related function when tapped
	Option button	■ Indicates the activation status of 2 mutually exclusive options (blue: active, white: inactive)
		<ul> <li>Activates the related option (while deactivating the other) when tapped</li> </ul>
265	Slider (with fixed lower limit)	<ul> <li>Indicates the currently set value/value range of the respective parameter</li> </ul>
		<ul> <li>Adapts the upper limit of the value range continuously when the control is dragged</li> </ul>
0 40 100	Value range indicator	Indicates the currently set value range of the related parameter
-+	+/- buttons	Increases or decreases the value of the related parameter stepwise when tapped
	Checkbox	<ul> <li>Indicates the activation status of the related function (checked: active, unchecked: inactive)</li> </ul>
		<ul> <li>Activates or deactivates the related function when tapped</li> </ul>
0	Radio button	■ Indicates the activation status of mutually exclusive options (blue: active, white: inactive)
		<ul> <li>Activates the related option (while deactivating others) when tapped</li> </ul>
~	Selection field	Indicates the currently active of various mutually exclusive options
		<ul> <li>Opens a drop-down menu for the selection between mutually exclusive options when tapped</li> </ul>

QUATERA 700

3.5 Software description

## 3.5.1.3 Screen keyboard

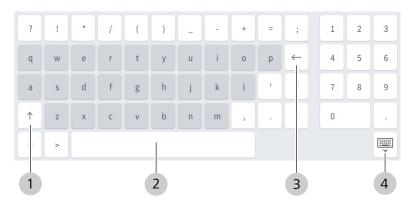


Figure 18: Screen keyboard key assignment

Pos.	Symbol	Name	Explanation
1	1	[Shift] key	Switches between upper-case and lower-case letters
2		[Space] key	Enters a blank space
3	<b>←</b>	[Delete] key	Deletes the character to the left of the cursor
4		[Close] button	Ends the input and closes the screen keyboard

#### 3.5.2 Change Surgeon dialog

The dialog displays the created users and allows to change users. It is opened by tapping on the [Surgeon] button in the touchscreen's header [> 46]. A derivate of the "Change Surgeon" dialog is automatically opened after starting the system.

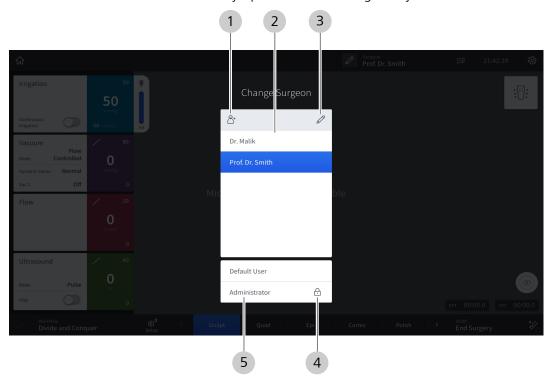


Figure 19: "Change Surgeon" dialog

Pos.	Name	Explanation
1	[Create user] button	Opens the "Create new Surgeon" dialog when tapped
2	Custom users list	<ul> <li>Displays all users created by the customer</li> <li>Indicates the currently active user (highlighted blue)</li> <li>Allows to activate a custom user by tapping on it</li> </ul>
3	[Edit surgeon list] button	Opens the "Edit Surgeon List" dialog when tapped
4	Lock indicator	Indicates that activating the respective user requires a password
5	Default users list	<ul><li>Displays the default users</li><li>Allows to activate a default user by tapping on it</li></ul>

#### 3.5.3 Setup menu

The "Setup" menu is opened after initially selecting the surgeon after system start, or by tapping on the [Setup] button in the touchscreen's footer [> 46].

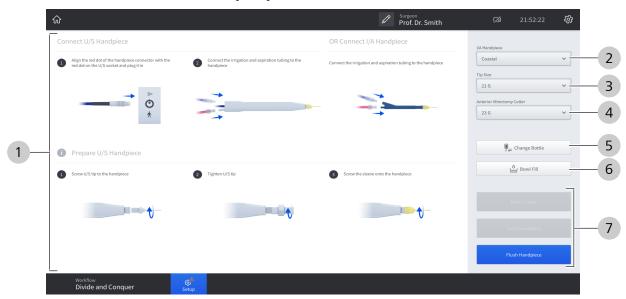


Figure 20: "Setup" menu (example from workflow "Divide and Conquer")

Pos.	Name	Explanation
1	Instruction section	Displays illustrated instructions on the accessories preparations required for the respective preparation step
2	"I/A Handpiece" selection field	Opens a drop-down menu for the selection of the I/A handpiece type
3	"Tip Size" selection field	Opens a drop-down menu for the selection of the phaco handpiece's and I/A handpiece's tip size
4	"Anterior Vitrectomy Cutter" selection field	Opens a drop-down menu for the selection of the vitrectomy cutter's tip size
5	[Change Bottle] button	Resets the bottle fill level  Note: The bottle fill level is also reset automatically when the user is changed.

Pos.	Name	Explanation
6	[Bowl Fill] button	Activates the release of a defined quantum of BSS (used e.g. for cutter priming)
		Note: The calling of the function must be confirmed on an additional prompt.
7	Preparation function buttons	<ul> <li>Indicate the current status of the preparation workflow necessary for the selected surgery workflow.</li> </ul>
		<ul> <li>blue: The function is available and corresponds to the next required step of the preparation workflow.</li> </ul>
		<ul> <li>light gray: The function is currently not available, but requires a certain step of the preparation workflow to be carried out first.</li> </ul>
		<ul> <li>dark gray: The function is available but is not part of the minimum preparation workflow.</li> </ul>
		Note: The calling of the function must be confirmed on an additional prompt.
		<ul> <li>Activate the respective preparation function</li> </ul>
		Note: The number, type and status of the buttons vary depending on the status of the preparation workflow.

For the display and control elements of the header and footer, see Header and footer elements  $[\triangleright 46]$ .

#### 3.5.4 Live Screen menu

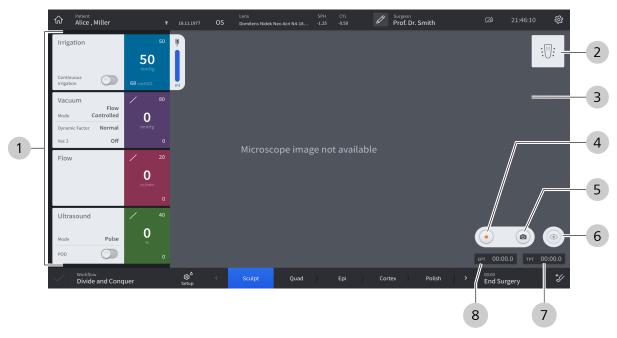


Figure 21: "Live Screen" menu (example from workflow "Divide and Conquer")

Pos.	Name	Explanation
1	Surgical function tiles	<ul> <li>Display the available surgical functions for the current step of the surgical workflow</li> </ul>
		<ul><li>Irrigation (blue) [▶ 55]</li></ul>
		<ul><li>Vacuum (violet) [▶ 56]</li></ul>
		<ul><li>Flow (purple) [▶ 58]</li></ul>
		<ul><li>Ultrasound (green) [▶ 59]</li></ul>
		– Diathermy (blue) [▶ 61]
		– Cutter (dark gray) [▶ 60]
		<ul> <li>Allow to adjust the respective function settings when a tile is tapped</li> </ul>
2	QUATERA FCP status indicator	<ul> <li>Displays the current connection status of the QUATERA FCP (crossed out: not connected, not crossed out: connected)</li> </ul>
		■ Displays the current pitch and yaw position of the foot pedal [▶ 62]
		<ul> <li>Opens the "Foot Control Panel" dialog when tapped</li> </ul>
		Note: The QUATERA FCP status indicator is crossed out and inactive when no FCP is connected.
3	"Live Video" section	Displays the live video from the operation field, if active
		Note: A surgical microscope with an integrated or external HD camera must be connected to the system in order to enable the "Live Video" function.

Pos.	Name	Explanation
4	[Record] button	Activates/Deactivates CALLISTO eye's video acquisition function when tapped
		Note: CALLISTO eye must be connected to the system in order to have access to the control.
5	[Camera] button	Activates CALLISTO eye's image acquisition function when tapped
		Note: CALLISTO eye must be connected to the system in order to have access to the control.
6	[Live Video] button	Activates/Deactivates the "Live Video" function when tapped
7	ТРТ	Displays the Total Phacoemulsification Time (in minutes, seconds and milliseconds), i.e. the sum of active U/S times
8	EPT	Displays the Effective Phacoemulsification Time (in minutes, seconds and milliseconds), considering the active U/S power settings and the U/S operation mode [ 91]

For the display and control elements of the header and footer, see Header and footer elements  $[\triangleright 46]$ .

## 3.5.4.1 Irrigation module

The tile displays the irrigation parameters. Tapping on it opens the "IOP" settings dialog. The module is available in each surgery step.



Figure 22: "Irrigation" tile and "IOP" settings dialog

Pos.	Name	Explanation
1	"Continuous Irrigation" switch	Activates/deactivates whether irrigation is applied when the foot pedal is in its resting position
2	Irrigation pressure indicator	Displays the current irrigation pressure in cmH <sub>2</sub> O
3	Current IOP indicator	Displays the current IOP in mmHg  Note: If the required preparation steps have not been completed yet, a respective information appears here instead.
4	Preset IOP indicator	Displays the preset IOP in mmHg
5	Bottle fill indicator	Displays the volume of BSS remaining in the bottle
6	IOP presetting controls	Allows to change the preset IOP

#### 3.5.4.2 Vacuum module

The tile displays the aspiration parameters in terms of vacuum pressure. Tapping on it opens the "Vacuum" settings dialog. The module is available in each surgery step, except for "Diathermy" and the CALLISTO eye surgery steps "Incision", "Rhexis" and "LRI".

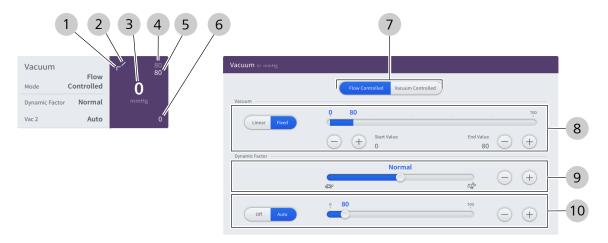


Figure 23: "Vacuum" tile and "Vacuum" settings dialog (example with activated "Vacuum 2" function)

Pos.	Name	Explanation
1	Vacuum control mode indicator	Displays the current vacuum control mode (diagonal: linear, angular: fixed) [> 88]
2	Vacuum 2 control mode indicator	Displays the current vacuum 2 control mode (diagonal: linear, angular: fixed)
		Note: Linear control is only available if the foot pedal is configured for vacuum 2 activation.
3	Current vacuum pressure	Displays the current vacuum pressure in mmHg
	indicator	Note: If the required preparation steps have not been completed yet, a respective information appears here instead.
4	Maximum vacuum 2 pressure indicator	Displays the preset maximum vacuum 2 [▶ 88] pressure in mmHg
5	Maximum vacuum pressure indicator	Displays the preset maximum vacuum pressure in mmHg
6	Minimum vacuum pressure indicator	Displays the preset minimum vacuum pressure in mmHg
7	Aspiration control mode [▶ 88] option button	<ul> <li>Indicates the currently active aspiration control mode (highlighted blue)</li> <li>Allows to switch the aspiration control mode</li> </ul>

Pos.	Name	Explanation
8	"Vacuum" controls	■ Indicate the currently active vacuum control mode (highlighted blue)
		Allow to switch the vacuum control mode
		Allow to adapt the preset minimum and maximum vacuum pressure
		Note: Regardless of the settings applied here, the preset maximum volume flow rate cannot be exceeded, if "Flow controlled" is selected as aspiration control mode.
9	"Dynamic Factor" slider	Allows to adapt the reaction time of the aspiration function relative to the foot pedal actuation (turtle: most delayed reaction; hare: immediate reaction)
10	"Vac 2" controls	With the foot pedal not configured for vacuum 2 activation:
		<ul> <li>Indicate the currently active vacuum 2 activation status (highlighted blue)</li> </ul>
		<ul> <li>Allow to switch the vacuum 2 function off and on</li> </ul>
		<ul> <li>Allow to adapt the preset vacuum 2 pressure</li> </ul>
		With the foot pedal configured for vacuum 2 activation:
		■ Indicate the currently active vacuum 2 control mode (highlighted blue)
		<ul> <li>Allow to switch the vacuum 2 control mode</li> </ul>
		<ul> <li>Allow to adapt the preset vacuum 2 pressure</li> </ul>

#### **3.5.4.3 Flow module**

The tile displays the aspiration parameters in terms of flow rate. Tapping on it opens the "Flow" settings dialog. The module is active only if "Flow controlled" is set as aspiration control mode [> 88]. If active, it is available in each surgery step, except for "Diathermy" and the CALLISTO eye surgery steps "Incision", "Rhexis" and "LRI".



Figure 24: "Flow" tile and "Flow" settings dialog

Pos.	Name	Explanation
1	Flow control mode indicator	Displays the current flow control mode (diagonal: linear, angular: fixed)
2	Current volume flow rate indicator	Displays the current volume flow rate in cc/min
		Note: If the required preparation steps have not been completed yet, a respective information appears here instead.
3	Maximum volume flow rate indicator	Displays the preset maximum volume flow rate in cc/min
4	Minimum volume flow rate indicator	Displays the preset minimum volume flow rate in cc/min
5	Flow controls	■ Indicate the currently active flow control mode (highlighted blue)
		■ Allow to switch the flow control mode
		■ Allow to adapt the preset minimum and maximum volume flow rate
		Note: Regardless of the settings applied here, the preset maximum vacuum pressure cannot be exceeded, i.e. the maximum flow set here might not be reached.

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#### 3.5.4.4 Ultrasound module

The tile displays the U/S parameters and allows to switch the POD mode. Tapping on it opens the "Ultrasound" settings dialog. The module is available in the surgery steps for phacoemulsification.

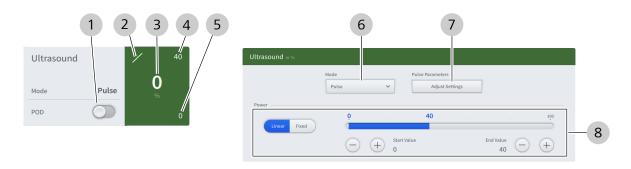


Figure 25: "Ultrasound" tile and "Ultrasound" settings dialog

Pos.	Name	Explanation
1	"POD" switch	<ul> <li>Indicates the current POD mode status (blue: active, gray: inactive)</li> <li>[&gt; 94]</li> </ul>
		Switches the POD mode status when tapped
2	U/S control mode indicator	Displays the current U/S control mode (diagonal: linear, angular: fixed) [> 94]
3	Current U/S power	Displays the U/S power applied (in % of the system's maximum power)
	indicator	Note: If the required preparation steps have not been completed yet, a respective information appears here instead.
4	Maximum U/S power indicator	Displays the preset maximum power that can be applied (in % of the system's maximum power)
5	Minimum U/S power indicator	Displays the preset minimum power that can be applied (in % of the system's maximum power)
6	"Mode" selection field	■ Indicates the currently active U/S operation mode [▶ 91]
		■ Allows to select the U/S operation mode when tapped
7	[Adjust Settings]	Opens the currently active U/S operation mode's settings when tapped Note: The presence of the button and the options provided by it differ depending on the currently active U/S operation mode.
8	"Power" controls	<ul> <li>Indicate the currently active U/S control mode (highlighted blue)</li> <li>Allow to switch the U/S control mode</li> <li>Allow to adapt the preset minimum and maximum U/S power that can</li> </ul>
		be applied (in % of the system's maximum power)

#### 3.5.4.5 Cutter module

The tile displays the vitrectomy parameters. Tapping on it opens the "Cutter" settings dialog. The module is available in the surgery step "Anterior Vitrectomy".



Figure 26: "Cutter" tile and "Cutter" settings dialog

Pos.	Name	Explanation
1	Cutter control mode indicator	Displays current cutter control mode (diagonal: linear, angular: fixed) [▶ 95]
2	Current cutting rate indicator	Displays the current cutting rate in cut/min  Note: If the required preparation steps have not been completed yet, a respective information appears here instead.
3	Maximum cutting rate indicator	Displays the preset maximum cutting rate in cut/min
4	Minimum cutting rate indicator	Displays the preset minimum cutting rate in cut/min
5	Cutter controls	<ul> <li>Indicate the currently active cutter control mode (highlighted blue)</li> <li>Allow to switch the cutter control mode</li> <li>Allow to adapt the preset minimum and maximum cutting rate</li> </ul>
6	"Cut Mode" option button	<ul> <li>Indicates the currently active cut mode (highlighted blue) [▶ 95]</li> <li>Allows to switch the cut mode</li> </ul>

## 3.5.4.6 Diathermy module

The tile displays the diathermy parameters. Tapping on it opens the "Diathermy" settings dialog. The module is available in the additional instruments step "Diathermy".

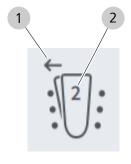


Figure 27: "Diathermy" tile and "Diathermy" settings dialog

Pos.	Name	Explanation
1	Diathermy control mode indicator	Displays the current diathermy control mode (diagonal: linear, angular: fixed) [> 96]
2	Current diathermy power indicator	Displays the currently applied diathermy power (in % of the system's maximum diathermy power) [> 96]
3	Maximum diathermy power indicator	Displays the preset maximum diathermy power (in % of the system's maximum diathermy power)
4	Minimum diathermy power indicator	Displays the preset minimum diathermy power (in % of the system's maximum diathermy power)
5	Diathermy controls	<ul> <li>Indicate the currently active diathermy control mode (highlighted blue)</li> <li>Allow to switch the diathermy control mode</li> <li>Allow to adapt the preset minimum and maximum diathermy power that can be applied</li> </ul>

#### 3.5.4.7 Foot Control Panel module

The tile displays the QUATERA FCP's current pitch and yaw positions. Tapping on it opens the "Foot Control Panel" dialog which displays the current key assignments. The module is available in each surgery step.



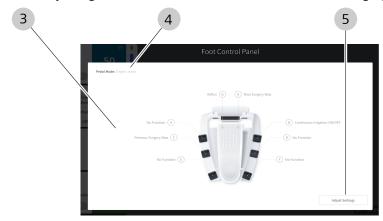


Figure 28: QUATERA FCP status indicator and "Foot Control Panel" dialog

Pos.	Name	Explanation
1	Yaw position indicator	Displays the foot pedal's current yaw position [> 69]
		arrow left: pedal in left yaw position
		no arrow: pedal in central position
		arrow right: pedal in right yaw position
		Note: Whether the pedal's left or right position corresponds to the outer yaw position, depends on the selected "Pedal Position" option [▶ 69].
2	Pitch zone indicator	Displays the foot pedal's current pitch position [> 71]
		■ nine points: pedal in start position / not pressed
		■ "1": pedal in pitch zone 1
		■ "2": pedal in pitch zone 2
		■ "3": pedal in pitch zone 3
		Note: For surgery steps with no functions assigned to zone 3, "2" is the maximum displayed number.
3	Key assignment overview	Displays the QUATERA FCP's current key assignments [▶ 69]
4	"Pedal Mode" indicator	Displays the QUATERA FCP's current pedal mode [▶ 69]
5	[Adjust Settings] button	Opens the "Settings" menu's "Foot Control Panel" section [▶ 69]

## 3.5.4.8 End Surgery dialog

The dialog summarizes basic information about the current surgery. The dialog can be opened at any time of a surgery with the footer's [End Surgery] button [> 46].

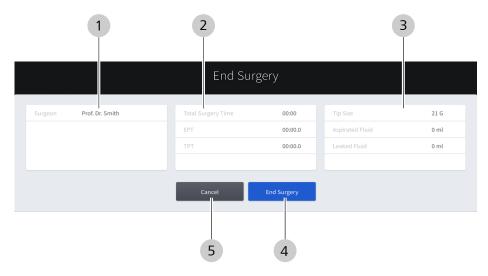


Figure 29: "End Surgery" dialog

Pos.	Name	Explanation
1	Surgeon section	Displays the name of the surgeon
2	Times section	Displays information about the times used:  Total Surgery Time (in hours and minutes)  EPT (in minutes, seconds and milliseconds)  TPT (in minutes, seconds and milliseconds)
3	Surgery metrics section	Displays information about consumed accessories and the cataract grade  Tip Size Aspirated Fluid (in ml) Leaked Fluid (in ml)
4	[End Surgery] button	Ends the surgery, resets all values and opens the "Setup" menu [▶ 51] when tapped
5	[Cancel] button	Closes the dialog without ending the surgery and opens the "Live Screen" menu [> 53] when tapped

## 3.5.4.9 USB Information dialog

The dialog allows to safely eject a connected USB storage medium. The dialog can be opened at any time with the header's [USB Information] button [> 46].

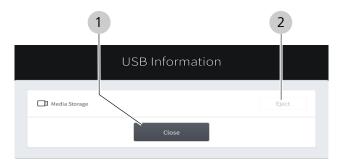


Figure 30: "USB Information" dialog

Pos.	Name	Explanation
1	[Close] button	Closes the dialog when tapped
2	[Eject] button	Safely ejects the connected storage medium when tapped

#### 3.5.5 Settings menu

The "Settings" menu is opened by tapping on the [Settings] button in the touchscreen's header [▶ 46].

#### 3.5.5.1 Surgical Parameters - Irrigation

In this menu you configure the preset irrigations settings.

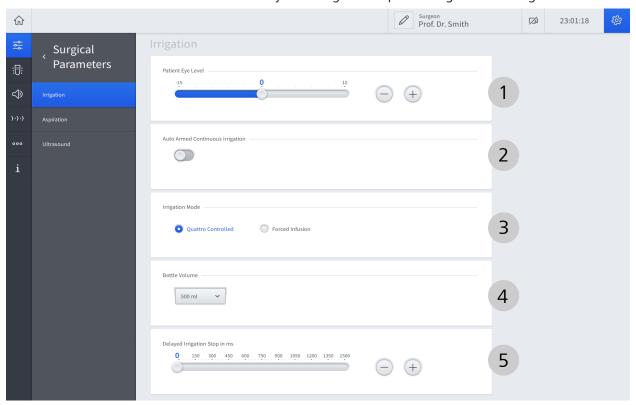


Figure 31: Surgical parameters settings, "Irrigation" section

Pos.	Name	Explanation
1	"Patient Eye Level" controls	The value for the patient eye level must be set such that the height of the patient eye level indicator's [> 36] illumination matches the level of the surgery patient's eye.
		Indicate the currently set patient eye level in cm
		Allow to adjust the patient eye level
2	"Auto Armed Continuous Irrigation" switch	If active, continuous irrigation is started when the foot pedal is pressed for the first time in a surgery.
		■ Indicates whether auto armed continuous irrigation is active
		■ Activates/deactivates auto armed continuous irrigation
		Note: Once activated, continuous irrigation does not stop until it is deactivated via the "Irrigation" tile's "Continuous Irrigation" switch [ 55] or a QUATERA FCP key to which the "Continuous Irrigation Toggle" function is assigned.
		Note: Auto armed continuous irrigation has no effect for "Diathermy" steps.

Pos.	Name	Explanation
3	"Irrigation Mode" radio buttons	■ Indicates the currently set irrigation mode (highlighted blue)
		<ul> <li>Allows to switch the irrigation mode</li> </ul>
		The following modes are selectable:
		<ul> <li>Quattro Controlled</li> </ul>
		■ Forced Infusion
4	"Bottle Volume" selection field	The bottle volume is used to calculate the remaining fill level by relating it to the consumed irrigation fluid.
		■ Indicates the currently set bottle volume
		<ul> <li>Allows to adjust the bottle volume when tapped</li> </ul>
		The following volumes are selectable:
		■ 250 ml
		■ 500 ml
		■ 1000 ml
		Note that the bottle fill level is reset automatically when the bottle volume settings are changed!
5	"Delayed Irrigation Stop in ms" controls	<ul> <li>Indicate the currently set delay of the irrigation to stop after the foot pedal is released</li> </ul>
		<ul> <li>Allow to adjust the delay of the irrigation to stop after the foot pedal is released</li> </ul>

## 3.5.5.2 Surgical Parameters - Aspiration

In this menu you configure the preset aspiration settings.

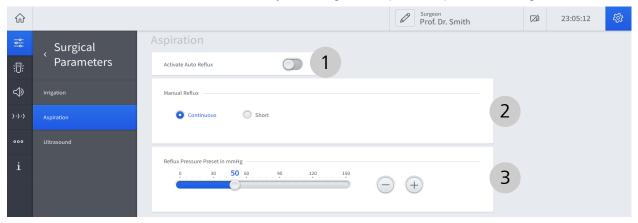


Figure 32: Surgical parameters settings, "Aspiration" section

Pos.	Name	Explanation
1	"Activate Auto Reflux" switch	The "Auto Reflux" function automatically breaks the vacuum and applies positive pressure to the aspiration line for a short time when the foot pedal is released.
		■ Indicates whether the "Auto Reflux" function is active (blue) or not (gray)
		■ Activates/deactivates the "Auto Reflux" function when tapped
2	"Manual Reflux" radio buttons	The manual reflux mode determines if the reflux function is performed as long as the corresponding QUATERA FCP key is pressed (Continuous) or if reflux is performed for a defined period of time (Short).
		■ Indicates the currently set manual reflux mode (highlighted blue)
		■ Allows to switch the manual reflux mode
3	"Reflux Pressure Preset in mmHg" controls	<ul> <li>Indicate the currently set reflux pressure</li> <li>Allow to adjust the reflux pressure</li> </ul>

## 3.5.5.3 Surgical Parameters - Ultrasound

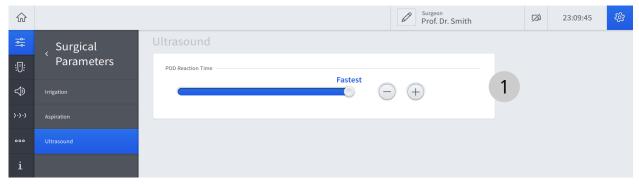


Figure 33: Surgical parameters settings, "Ultrasound" section

Pos.	Name	Explanation
1	"POD Reaction Time" controls	<ul> <li>Indicate the currently set relative time for the U/S impulse to be delivered after an occlusion has been detected</li> </ul>
		<ul> <li>Allow to adjust the relative time for the U/S impulse to be delivered after an occlusion has been detected</li> </ul>

#### 3.5.5.4 Foot Control Panel - Key Assignment

In this menu you assign pedal modes and the controls of the QUATERA FCP per surgery step.



Figure 34: FCP settings, "Key Assignment" section

Pos.	Designation	Explanation
1	"Surgery Step" selection field	<ul> <li>Indicates which surgery step the current assignment applies to</li> <li>Allows to select a different surgery step, the FCP shall be configured for, when tapped</li> <li>Note: The selectable options depend on the loaded workflow.</li> </ul>
2	"Edit Layout for all Steps" checkbox	Allows to apply consistent key assignments to all steps of the currently loaded workflow, when checked
3	"Pedal Position" radio buttons	Switches the function of the buttons [G] and [H] [▶ 103]
4	"Pedal Mode" selection field	<ul> <li>■ Indicates the currently set foot pedal mode [▶ 103]</li> <li>■ Allows to select a different foot pedal mode when tapped</li> <li>Note: The selectable options depend on the loaded surgery step [▶ 105].</li> </ul>
5	Key functions menu	<ul> <li>Indicates the function (highlighted blue) that is currently assigned to the selected key</li> <li>Displays all functions that are assignable to the selected key</li> <li>Allows to assign a function to the selected key by tapping on the function</li> <li>Note: The selectable options depend on the loaded surgery step.</li> </ul>
6	Button [G]	<ul> <li>Indicates the function that is currently assigned to the left yaw position</li> <li>Opens the key functions menu (for assignment adaption) when tapped</li> </ul>

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Pos.	Designation	Explanation
7	Button [H]	<ul> <li>Indicates the function that is currently assigned to the right yaw position</li> </ul>
		<ul> <li>Opens the key functions menu (for assignment adaption) when tapped</li> </ul>
8	Buttons [A] - [F]	■ Indicate the function that is currently assigned to the respective key
		<ul> <li>Opens the key functions menu (for assignment adaption) when tapped</li> </ul>

## 3.5.5.5 Foot Control Panel - Pitch Settings

In this menu you configure the control behavior, pressure points and tactile feedback of the QUATERA FCP.

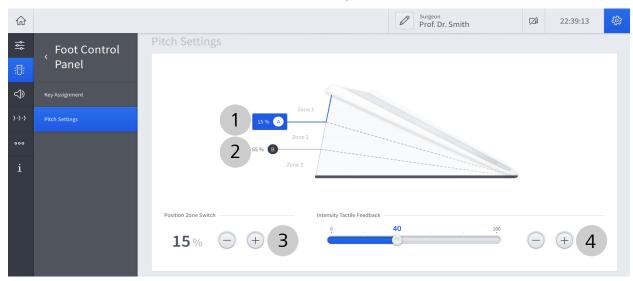


Figure 35: FCP settings, "Pitch Settings" section

Pos.	Designation	Explanation
1	Button [A]	Button [A] represents the transition point (zone switch) between zone 1 and zone 2.
		<ul> <li>Indicates the currently set zone switch position as a proportion of the foot pedal's full pitch range</li> </ul>
		<ul> <li>Opens the "Position Zone Switch" and "Intensity Tactile Feedback" controls for the transition point</li> </ul>
2	Button [B]	Button [B] represents the transition point (zone switch) between zone 2 and zone 3.
		<ul> <li>Indicates the currently set zone switch position as a proportion of the foot pedal's full pitch range</li> </ul>
		<ul> <li>Opens the "Position Zone Switch" and "Intensity Tactile Feedback" controls for the transition point</li> </ul>
		Note: The value for the zone switch position of transition point B is always higher than that of transition point A.
3	"Position Zone Switch" controls	<ul> <li>Indicates the currently set zone switch position for the selected transition point</li> </ul>
		<ul> <li>Allows to adjust the zone switch position for the selected transition point</li> </ul>
		Note: The value range for the zone switch positions lies between 1 % and 99 %. The minimum zone size is 6 %.
4	"Intensity Tactile Feedback" controls	<ul> <li>Indicate the currently set intensity of the tactile feedback emitted when the selected transition point is crossed</li> </ul>
		<ul> <li>Allow to adjust the tactile feedback intensity for the selected transition point</li> </ul>

#### 3.5.5.6 Audio

In this menu you configure the audio settings of the system.

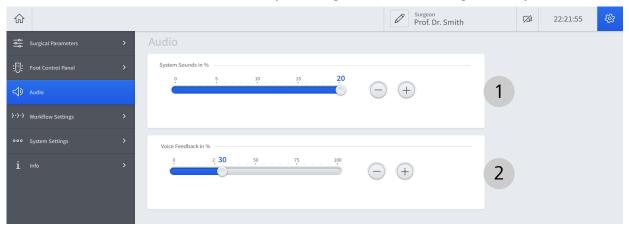


Figure 36: Audio settings

Pos.	Name	Explanation
1	"System Sounds in %" controls	■ Indicate the currently set volume of audio feedback tones [▶ 99] in a range from "0" (audio off) to "20"
		<ul> <li>Allow to adjust the audio feedback tone volume</li> </ul>
2	"Voice Feedback in %" controls	■ Indicate the currently set volume of voice feedback [▶ 99] in a range from "0" (audio off) to "100"
		<ul> <li>Allow to adjust the voice feedback volume</li> </ul>

#### 3.5.5.7 Workflows

In this menu you manage your workflows, create new workflows, rearrange workflows and adapt surgery steps. The available workflows are sorted by type (Divide and Conquer, Phaco Chop).

#### Note:

When logged in as "Default User" you have no rights to create, delete or adapt workflows and surgery steps, but can only view them.

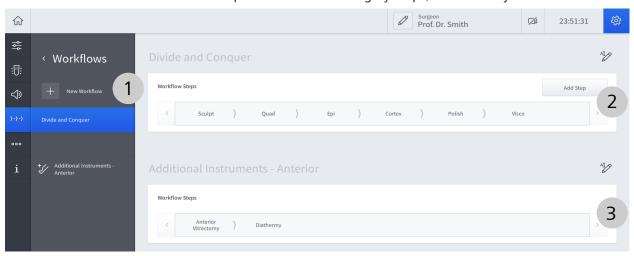


Figure 37: Workflows settings

Pos.	Name	Explanation
1	"New Workflow" button	Opens the "Define your Defaults for the Workflow" wizard to create a new workflow
2	Workflow section	<ul> <li>Displays the current workflow properties (name, surgery steps, surgery step sequence)</li> </ul>
		<ul> <li>Provides controls to delete or adapt the respective workflow (name, surgery steps, surgery step sequence)</li> </ul>
		Note: The possibility to integrate and adapt CALLISTO eye surgery steps depends on whether CALLISTO eye is connected and a valid license is available. The current CALLISTO eye connection and license status is indicated by a special design of the CALLISTO eye workflow step icons (see table below).
3	Additional instruments section	<ul> <li>Displays the additional instruments that are available for surgery</li> <li>Provides controls to rename the section and the additional instruments</li> </ul>

# The following icons display the status of the CALLISTO eye surgery steps:

Symbol	Explanation
	CALLISTO eye is connected and a license is available. The surgery step is available.
	CALLISTO eye is connected, but no license is available. The surgery step is not available.
7	CALLISTO eye is not connected. The surgery step is not available.

# 3.5.5.8 System Settings - Network

In this menu you can configure the network connection with CALLISTO eye.

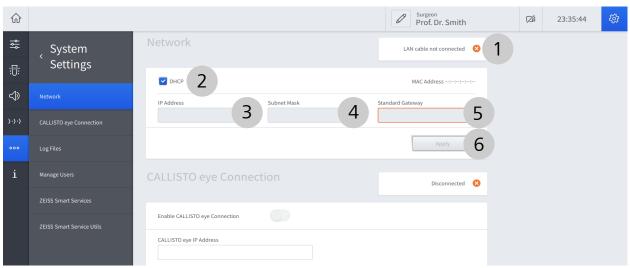


Figure 38: System settings, "Network" section

Pos.	Name	Explanation
1	Connection status indicator	Indicates the current connection status
2	"DHCP" checkbox	Allows the network connection to be assigned via DHCP, when checked
3	"IP Address" field	<ul> <li>Indicates the currently specified IP address for LAN connection</li> <li>Allows to adapt the IP address for LAN connection</li> </ul>
4	"Subnet Mask" field	<ul> <li>Indicates the currently specified subnet mask for LAN connection</li> <li>Allows to adapt the subnet mask for LAN connection</li> </ul>
5	"Standard Gateway" field	<ul> <li>Indicates the currently specified gateway for LAN connection</li> <li>Allows to adapt the gateway for LAN connection</li> </ul>
6	[Apply] button	Saves changes when tapped

# 3.5.5.9 System Settings - CALLISTO eye Connection

In this menu you can enable the connection between the system and CALLISTO eye.

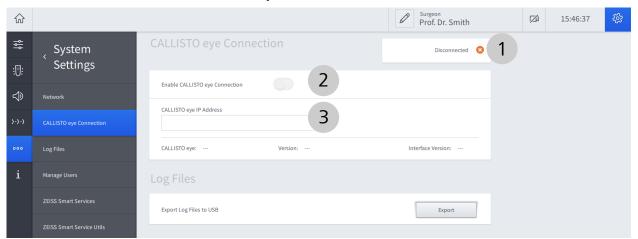


Figure 39: System settings, "CALLISTO eye Connection" section

Pos.	Name	Explanation
1	Connection status indicator	Indicates the current CALLISTO eye connection status  The following values are possible:  Connected  Disconnected
2	"Enable CALLISTO eye Connection" switch	<ul> <li>Indicates the current activation status of the CALLISTO eye connection (blue: activated, gray: deactivated)</li> <li>Activates/deactivates the CALLISTO eye connection when tapped</li> </ul>
3	"CALLISTO eye IP Address" field	<ul> <li>Indicates the currently specified CALLISTO eye IP address</li> <li>Allows to adapt the CALLISTO eye IP address</li> </ul>

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# ${\bf 3.5.5.10 \ \ System \ Settings-Time \ and \ Date}$

## Information:

The access to this section is restricted to "Administrator" users. In this menu you can configure the time and date of the system.

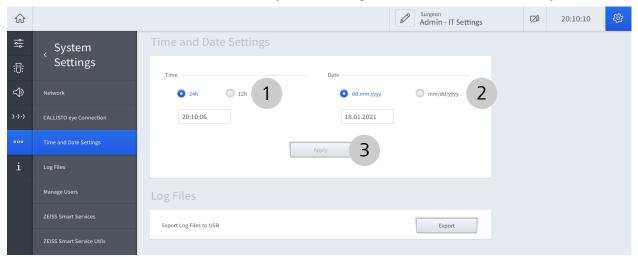


Figure 40: System settings, "Time and Date Settings" section

Pos.	Name	Explanation
1	"Time" controls	■ Indicate the currently set time and time format
		Allow to adapt the time and time format
2	"Date" controls	■ Indicate the currently set date and date format
		■ Allow to adapt the date and date format
3	[Apply] button	Opens a prompt to confirm the changes and restart the system
		Note: For the changes to take effect, a system restart is required. Confirm the upcoming prompt to restart the system and apply your changes.

# 3.5.5.11 System Settings - Log Files

In this menu you can export log files to a connected USB storage device.

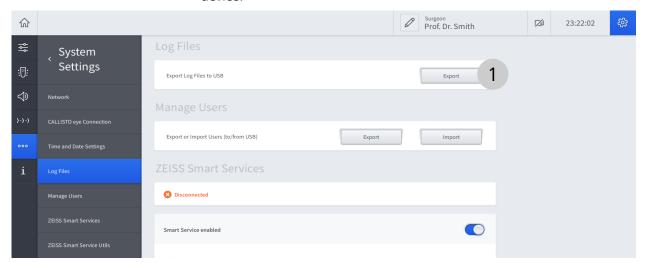


Figure 41: System Settings, "Log Files" section

P	os.	Name	Explanation
	1	[Export] button	Starts the log file export when tapped

## 3.5.5.12 System Settings - Manage Users

In this menu you can export and import custom user data to or from a connected USB storage device.

## Information:

User passwords are not part of an export. They must be set new on the target system after an import.

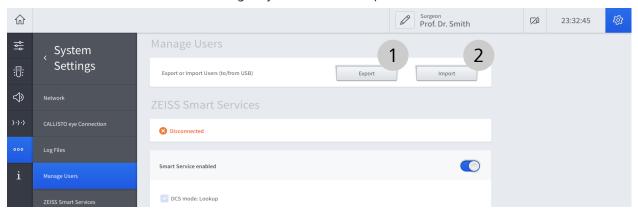


Figure 42: System Settings, "Manage Users" section

Ро	s. Name	Explanation
1	[Export] button	Starts the user data export when tapped
2	[Import] button	Starts the user data import when tapped

# 3.5.5.13 System Settings - ZEISS Smart Services

In this menu you can establish a connection to the ZEISS Service.

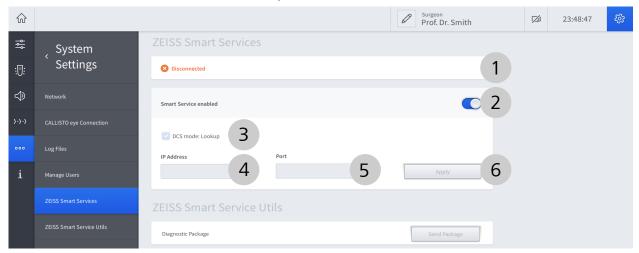


Figure 43: System Settings, "ZEISS Smart Services" section

Pos.	Name	Explanation
1	Connection status indicator	Indicates the current connection status
2	"Smart Service enabled" switch	<ul> <li>Indicates whether smart service connections are enabled (blue: enabled, gray: disabled)</li> <li>Enables/disables smart service connections</li> </ul>
3	"DCS mode: Lookup" checkbox	Allows to automatically find the SCU server for smart service communication
4	"IP Address" field	<ul> <li>Indicates the IP address of the SCU server to connect to</li> <li>Allows to adapt the IP address of the SCU server to connect to</li> </ul>
5	"Port" field	<ul> <li>Indicates the currently set port for smart service communication</li> <li>Allows to adapt the port for smart service communication</li> </ul>
6	[Apply] button	Saves changes when tapped

# 3.5.5.14 System Settings - ZEISS Smart Service Utils

This menu provides some tools to support the ZEISS Smart Service.

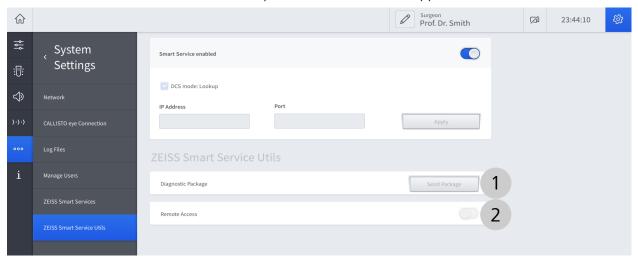


Figure 44: System Settings, "ZEISS Smart Service Utils" section

Pos.	Name	Explanation
1	[Send Package]	Initiates the sending of a diagnostic package to the ZEISS Service when tapped
2	"Remote Access" switch	<ul> <li>Indicates whether remote access is enabled (blue: enabled, gray: disabled)</li> </ul>
		■ Enables/disables remote access

## 3.5.5.15 Info - License information

In this menu you can export license information to a connected USB storage device.



Figure 45: Info settings

Ро	S. Name	Explanation
1	[Export] button	Starts the license information export when tapped

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# 3.5.5.16 System Settings - User Administration - Custom User Administration

#### Information:

The access to this section is restricted to "Administrator" users.

In this menu you can reset the passwords of custom users, in the case they have been lost or forgotten.

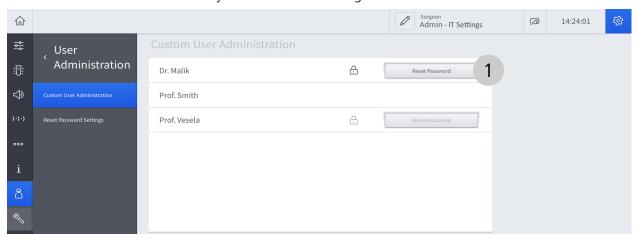


Figure 46: User Administration, "Custom User Administration" section

Pos	Name	Explanation
1	[Reset Password] button	Resets the respective custom user's password when tapped

The following icons display the status of the respective user's password:

Symbol	Explanation
	No password is assigned.
<del>C</del>	The has not been reset. The original password is valid.
-	The password has been reset. The original password is invalid.

# 3.5.5.17 System Settings - User Administration - Reset Password Settings

## Information:

The access to this section is restricted to "Administrator" users. In this menu you can reset the passwords of "Administrator" users.

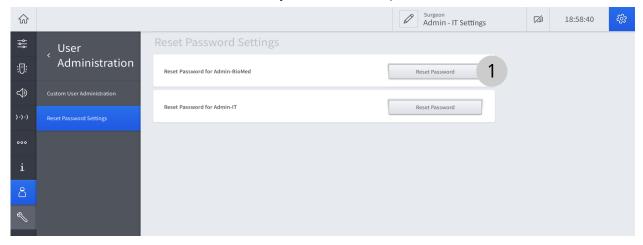


Figure 47: User Administration, "Reset Password Settings" section

P	os.	Name	Explanation	
	1	[Reset Password] button	Resets the respective "Administrator" user's password when tapped	

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# 3.5.5.18 System Settings - Service PC - Irrigation Information:

The access to this section is restricted to "Administrator" users. In this menu you can adapt the irrigation performance factor [ \ 88].

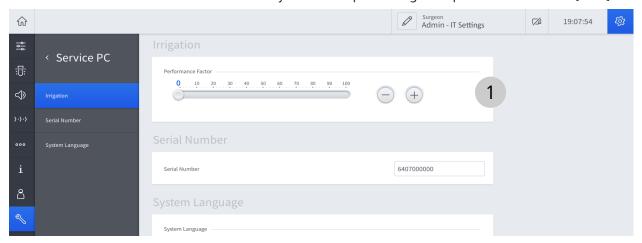


Figure 48: Service PC, "Irrigation" section

Pos.	Name	Explanation
1	"Performance Factor" controls	<ul><li>Indicate the currently set irrigation performance factor</li><li>Allow to adjust the irrigation performance factor</li></ul>
		Note: No matter how high the performance factor, the maximum irrigation adaption does not result in an IOP higher than 50 mmHg. The performance factor remains without effect if the preset IOP is higher than 50 mmHg.

# 3.5.5.19 System Settings - Service PC - Serial Number Information:

The access to this section is restricted to "Administrator" users. In this menu you can set the system's serial number.

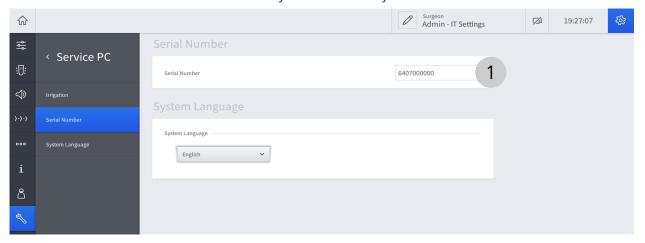


Figure 49: Service PC, "Serial Number" section

Pos.	Name	Explanation	
1	"Serial Number" field	-	Indicates the currently specified system serial number
		•	Allows to adapt the system serial number

# 3.5.5.20 System Settings - Service PC - System Language Information:

The access to this section is restricted to "Administrator" users. In this menu you can adapt the system language.

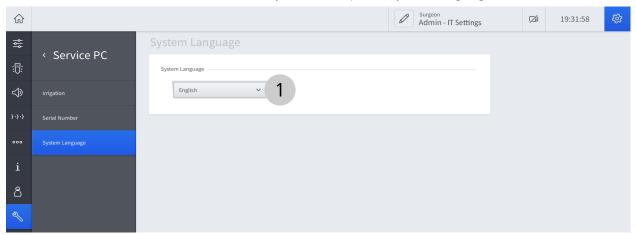


Figure 50: Service PC, "System Language" section

Pos. Name		Explanation	
1	"System Language"	■ Indicates the currently set system language	
	selection field	<ul> <li>Allows to adapt the system language when tapped</li> </ul>	

# 3.6 Functional description

# 3.6.1 Irrigation/aspiration

When connected to the proper accessories, the system removes fluids and materials, e.g. lens fragments, from the patient's eye. The aspiration is complemented by an irrigation mechanism that delivers BSS at a controlled pressure. This irrigation/aspiration interplay fulfills the following tasks:

- It replaces aspirated liquids and maintains a constant surgeonselected IOP, thus eliminating the risk of anterior chamber instability.
- It cools the phaco tip upon activation of U/S.

#### **Irrigation modes**

The irrigation can be controlled by the system in one of two user-selectable modes:

- "Quattro Controlled": The system adapts the irrigation pressure to the aspiration pressure, thus maintaining a constant IOP.
- "Forced Infusion": The system delivers a constant irrigation pressure, regardless of the aspiration pressure.

The irrigation mode can be set in the "Irrigation" section [▶ 65] under "Settings / Surgical Parameters".

#### **Aspiration control modes**

According to the user's preferences, the aspiration parameters can be set and displayed in one of two ways:

- "Flow controlled": The aspiration parameters are set and displayed in terms of flow rate. The displays and controls for vacuum pressure, however, are still available in this mode.
- "Vacuum controlled": The aspiration parameters are set and displayed exclusively in terms of vacuum pressure.

The aspiration control modes can be set on the "Vacuum" settings dialog [> 56].

#### Vacuum and flow control modes

The system provides two vacuum and flow control modes:

- "Linear": The performance of the function is adapted in linear relation to the foot pedal's pitch position.
- "Fixed": The function is performed with a preset fixed parameter value when the foot pedal is pressed. Otherwise it is not performed at all.

The vacuum control mode can be set on the "Vacuum" settings dialog [> 56]. The flow control mode can be set on the "Flow" settings dialog [> 58].

3.6 Functional description

#### Vacuum 2 function

The vacuum 2 function provides additional vacuum pressure. The preset vacuum 2 pressure is at least as high as the preset maximum vacuum pressure.

The vacuum 2 function can be set to the following states:

- "Off": Vacuum 2 is not applied.
- "Auto": Vacuum is automatically created at the preset vacuum 2 pressure if an occlusion of the phaco tip is detected during phacoemulsification.
- "Manual": Vacuum 2 is created in either linear or fixed mode by bringing the foot pedal into the yaw position the function is assigned to.

The vacuum 2 function can be activated and adjusted on the "Vacuum" settings dialog [> 56]. Manual vacuum 2 can be activated by assigning the "Vac 2" function to one of the foot pedal's yaw positions, to be done in the "Settings" menu under "Foot Control Panel / Key Assignments" [> 69].

# Irrigation performance factor

The irrigation performance factor leads to an additional positive IOP offset during tip occlusion, to compensate for the short drop in IOP during occlusion break. The offset is adapted relative to the applied vacuum. The irrigation performance factor determines this adaption's degree of progression.

The irrigation performance factor setting is not a required feature, but it might be desired by surgeons for reasons of confidence.

The irrigation performance factor can be adjusted in the "Settings" menu under "Service PC / Irrigation" [> 85].

## 3.6.2 Phacoemulsification

The system is intended to power a piezoelectric ZEISS phacoemulsification handpiece for standard anterior segment cataract procedures.

The handpiece's piezoelectric ceramic element converts the supplied electrical energy into vibratory motions with a frequency of about 40 kHz (+4.5 kHz / -0.5 kHz). These movements are amplified and transferred to the phaco tip, causing it to vibrate longitudinally with an upward stroke of a maximum of approximately 100  $\mu$ m.

The U/S power, i.e. the stroke applied, can be adjusted on the "Ultrasound" settings dialog [> 59] and activated with the QUATERA FCP. The transmission of U/S power depends on the status of the following parameters:

- U/S operation mode [▶ 91]
- U/S control mode [▶ 94]
- Power on demand mode [▶ 94]

#### 3.6.2.1 U/S operation mode

The system provides several U/S operation modes that can be selected and adjusted on the "Ultrasound" settings dialog [▶ 59].

In all modes the U/S power, i.e. the stroke, can be set as a percentage of the basic stroke of about 100  $\mu m$ . The U/S operation modes differ in terms of the pulse rate and the duty cycle:

- The **pulse rate** determines how many U/S pulses are applied within one second. A pulse thereby includes one "On" and one "Off" phase.
- The duty cycle determines the proportion of the "On" phase of a pulse. (The "Off" phase is used for aspiration and for cooling the phaco tip.)



#### **Continuous**

The "Continuous" mode delivers uninterrupted U/S power when the foot pedal is pressed.

As U/S is delivered continuously, the pulse rate cannot be adjusted. The stroke can be altered with the foot pedal, if the U/S control mode is "Linear" [> 94].

#### **Pulse**

The "Pulse" mode delivers constant periodic pulses of U/S power.

The pulse rate and the duty cycle can be adjusted on the touchscreen. The stroke can be altered with the foot pedal, if the U/S control mode is "Linear" [> 94].

## **Single Burst**

The "Single Burst" mode delivers a single burst of U/S.

The absolute duration of the burst can be adjusted on the touchscreen.

#### **Multi Burst**

The "Multi Burst" mode delivers periodic pulses with fixed "On" time and variable "Off" time. The minimum "Off" time is 2 ms.

The duration of the "On" time and the spectrum of "Off" times can be adjusted as absolute values on the touchscreen. The "Off" times are shortened the deeper the foot pedal is pressed. The stroke cannot be altered.











#### **Continuous Burst**

The "Continuous Burst" mode delivers periodic pulses with fixed "On" time and variable "Off" time. The "Off" time can be reduced to almost 0 ms for continuous U/S emission.

The duration of the "On" time and the spectrum of "Off" times can be adjusted as absolute values on the touchscreen. The "Off" times are shortened the deeper the foot pedal is pressed. The stroke cannot be altered.

## **Advanced Power Modulation (APM)**

The APM modes deliver burst and pulse ultrasound energy in defined modulation patterns and with preselected "On" and "Off" phases. The patterns are designed on the basis of surgeons' experiences and allow for a better control of the energy entering the nucleus. The names of the individual APM modes indicate for which application the respective parameter set is recommended (e.g. "Soft Sculpt" for the sculpting of a soft cataract lens).

The following parameters are relevant for the description of the APM modes:

- pulse-on time: the period of time U/S power is applied without interruption
- pulse-off time: the period of time no U/S power is applied without interruption
- power range: range between the preset minimum and the preset maximum U/S power that can be applied during phacoemulsification. Other than the APM mode's further parameters, the power range's upper and lower limits can be adjusted on the touchscreen.
- hold power level: the power level to be held constantly after the modulation phase, defined in percentage of the power range
- modulation time: duration of the modulation phase







The "Sculpt" APM modes are defined by the following ultrasound emission patterns.

Name			Hold power level	Modulation time
Soft Sculpt	medium	short	n/a	n/a
Hard Sculpt	long	short	n/a	n/a

The "Quad" and "Epi" APM modes are defined by the following ultrasound emission patterns.

Name	Pulse-on time	Pulse-off time	Hold power level	Modulation time
Soft Quad	short	long	40 %	long
Hard Quad	short	long	70 %	short
Soft Quad Slow	medium	medium	30 %	long
Hard Quad Slow	short	long	70 %	long
Soft Epi	short	long	30 %	medium
Soft Quad Alternative	medium	short	30 %	short

The "Quad" and "Epi" APM modes start with the emission of ultrasound power at the preset maximum level, in order to ease the impaling of the nucleus. The ultrasound power is then reduced until a lower level, the hold power level, is reached. This allows for a higher efficiency, a better traceability and a reduced chattering and energy input.

The hold power level then is applied until the QUATERA FCP foot pedal leaves the pitch or yaw position, U/S emission is assigned to. The emission pattern is retriggered as soon as U/S emission is activated again (by FCP or PoD).

#### Information:

It is recommended for the "Quad" and "Epi" APM modes to set the U/ S control mode [▶ 94] to "Fixed", in order to achieve the peak stroke right in the beginning.

#### 3.6.2.2 U/S control mode

The system provides two U/S control modes:

- "Linear": The delivered U/S power increases and decreases in linear relation to the foot pedal's pitch position.
- "Fixed": The U/S power is delivered with the preset fixed value when the foot pedal is pressed. Otherwise it is not delivered at all.

The U/S control mode can be adjusted on the "Ultrasound" settings dialog [> 59].

#### 3.6.2.3 POD mode

When the "Power on demand" (POD) mode is activated (and the foot pedal is in a position configured for U/S emission), the system does not provide U/S power unless the phaco tip's aspiration channel is occluded. The particle then is emulsified and removed and the U/S is automatically switched off again, while aspiration continues. In this way, the emittance of heat to the patient's eye can be reduced significantly.

The POD mode can be activated/deactivated on the "Live Screen" menu's "Ultrasound" tile.

## 3.6.3 Vitrectomy

The system can pneumatically drive a vitrectomy cutter, which is connected to the QUATTRO CASSETTE for the aspiration of cut-out material. The cutter handpiece's tip consists of two tubes, one lying inside the other: the fixed aspiration tube and the longitudinally reciprocating cutter tube with a front end cut edge. The cut-out vitreous material is evacuated through the aspiration tube's side opening.

The cutting rate can be adjusted on the "Cutter" settings dialog [> 60] and controlled with the QUATERA FCP.

#### Cut mode

The system provides two cut modes:

- "Multiple Cut": When the foot pedal is pressed, the cutting is performed continuously within the preset range of cutting rates.
- "Single Cut": When the foot pedal is pressed, only one single cut is performed.

The cut mode can be set on the "Cutter" settings dialog [▶ 60].

#### **Cutter control mode**

The system provides two vitrectomy cutter control modes:

- "Linear": The cutting rate is adapted in linear relation to the foot pedal's pitch position.
- "Fixed": The cutting is performed with a preset fixed rate when the foot pedal is pressed. Otherwise it is not performed at all.

The cutting control mode can be set on the "Cutter" settings dialog [> 60].

## 3.6.4 Diathermy

The system contains a low power RF generator, designed to drive surgical instruments for bipolar coagulation, including surface probes for anterior segment surgeries. The generator operates with a base frequency of about 2 MHz ( $\pm$  20 %).

The diathermy power applied can be set as proportion of the base frequency on the "Diathermy" settings dialog [ 61].

### Diathermy control mode

The system provides two diathermy control modes:

- "Linear": The diathermy radiation frequency is adapted in linear relation to the foot pedal's pitch position.
- "Fixed": The diathermy radiation is performed with a preset fixed frequency when the foot pedal is pressed. Otherwise it is not performed at all.

The diathermy control mode can be set on the "Diathermy" settings dialog [ 61].

# 3.6.5 Data injection

The system can inject phaco data into the microscope image of the CALLISTO eye software and into the microdisplay or heads-up display of a connected surgical microscope of one of the following types:

- S7/OPMI Lumera
- OPMI Lumera i floor stand
- S88/OPMI Lumera T
- OPMI Lumera 700 + RESCAN 700
- OPMI LUMERA 700 floor stand
- ARTEVO 800 + RESCAN 700
- EDIS (External Data Injection System)
- CALLISTO eye Panel PC (hardware version II, software version 3.7.1 or higher)

When CALLISTO eye steps are active, the injection of step-dependent CALLISTO eye data into the system's live video and into the microscope displays can be controlled by step selection via QUATERA FCP or the touchscreen.

The data injection can be configured in the CALLISTO eye software and activated on the system's touchscreen.

3.6 Functional description

## 3.6.6 Safety features

QUATERA 700 provides certain safety features, some of which alter the system's working state while others just inform the user about safety relevant events or settings.

#### 3.6.6.1 Safety functions

#### Safe state

If the system detects a malfunction that prevents it from correct operation, it enters into the safe state. During the safe state:

- All surgical functions are disabled and blocked.
- Gravity irrigation is applied.
- No more energy is released to the patient.
- The [Device Power on/off] operating button displays a special LED blinking sequence. [▶ 41]

In order to exit the safe state, the system must be re-booted by first pressing the [Device power on/off] operating button for 5 seconds and subsequently starting the system again by pressing the [Device power on/off] operating button once more.

#### Information:

In the course of booting, the system performs a self test. If the test shows that the malfunction could not be eliminated, the system will enter the safe state again. In this case, a special screen allows to directly export the system's log files to a USB drive, so the problem can be reported to the ZEISS Service.

#### **Restart state**

If an operation parameter deviates from the expected value, the system enters the restart state. During the restart state:

- All surgical functions are disabled and blocked.
- Gravity irrigation is applied.
- No more energy is released to the patient.

In order to exit the restart state, the QUATERA FCP has to be released once.

#### Power emergency mode

If the system is disconnected from the power supply, it enters into the power emergency mode. During the power emergency mode:

- The system is powered by the battery.
- All surgical functions except irrigation are disabled and blocked.
- The irrigation is maintained according to the preset values.
- No more energy is released to the patient.

- The [Device Power on/off] operating button displays a special LED blinking sequence. [▶ 41]
- A system message is displayed on the touchscreen. [▶ 223] In order to exit the power emergency mode, the following measures have to be taken:
- The system must be reconnected to the power supply.
- The resolution of the problem has to be confirmed by tapping [OK] at the corresponding system message.
- In order to reactivate all surgical functions: The QUATERA FCP has to be released once.

## Venting

As soon as the QUATERA FCP's foot pedal is released to zone 1 [> 104], the system automatically releases the vacuum to the level of irrigation pressure.

#### Reflux

The system provides a reflux function to break occlusions of the aspiration channel: When the function is activated the system immediately releases the vacuum and applies positive pressure on the aspiration channel to release and push out material caught at the tip's aspiration opening.

The reflux function can be activated with a pre-assigned QUATERA FCP button or yaw position.

Note that, if the QUATTRO CASSETTE's currently used aspiration chamber runs out of fluid, reflux is cancelled automatically. To reactivate reflux, the corresponding control has to be released shortly and then pressed again. The reflux function then resorts to the second aspiration chamber.

#### **Irrigation/aspiration limitations**

The following limitations are imposed on irrigation and aspiration during the phacoemulsification steps:

- In the Forced Infusion irrigation mode, the system does not apply irrigation/aspiration parameters that would lead to an IOP smaller than 15 mmHg. Contrary user settings remain without effect.
- In some instances the maximum preset flow may not be reached due to the flow resistances of the handpiece in use.

#### 3.6.6.2 Audio feedback

The system generates audio feedback to indicate the activation and the performance level of certain functions. Audio feedback is also given when a critical system or function state is reached.

#### **Function selection**

When an important function is activated, a voice feedback signals the change. The change of an important parameter's value is indicated by a tone feedback.

#### U/S activation

When the U/S is activated a dedicated tone is produced.

#### Vacuum state

When vacuum is created a dedicated tone is produced. The tone pitch corresponds to the vacuum level: the higher the vacuum level, the higher the tone.

## Tip occlusion

When the aspiration channel of a handpiece is occluded by a particle and full vacuum is active, a dedicated tone is produced.

## **Diathermy intensity**

When diathermy power is emitted a dedicated tone is produced. The tone pitch corresponds to the diathermy intensity level: the higher the intensity level, the higher the tone.

# **Critical parameter change**

If a change in a parameter value exceeds a certain threshold, an acoustic warning tone is produced. The parameter change becomes active with a delay of one second and is indicated by another warning tone.

Critical parameter changes are classified as follows:

Surgical function	Mode	Parameter	Change in para- meter value
Diathermy		start value	> 30 %
Diathermy		preset value	> 30 %
Ultrasound		start value	> 30 %
Ultrasound		preset value	> 30 %
Ultrasound	Pulse	pulse time	> 30 %
Ultrasound	Pulse	pulse time range	> 30 %
Ultrasound	Pulse	pause time	> 30 %
Ultrasound	Pulse	pause time range	> 30 %
Ultrasound	Pulse		change of mode during U/S dissi- pation
Ultrasound	APM		change of APM mode during U/S dissipation
Vitrectomy		cutting rate	> 30 %
Vitrectomy		cutting rate	change of mode during activation
Irrigation	IOP	preset value	> 30 %
Aspiration	Vacuum	start value	> 30 %
Aspiration	Vacuum	preset value	> 30 %
Aspiration	Vacuum 2	start value	> 30 %
Aspiration	Vacuum 2	preset value	> 30 %
Aspiration	Flow	start value	> 30 %
Aspiration	Flow	preset value	> 30 %

# 3.6.6.3 System messages

The system reports or signals malfunctions by means of system messages. The messages appear as pop-up windows, often accompanied by audio feedback. They are subdivided as follows:

Symbol	Description
$\otimes$	System messages with an orange warning sign indicate error messages.
$\triangle$	System messages with an yellow warning sign indicate warning messages.
i	System messages with an blue warning sign indicate info messages.

In order to resolve the problem, the following measures have to be taken:

- The problem must be dealt with in accordance with the information given in the section General system messages [▶ 223].
- The resolution of the problem has to be confirmed by tapping [OK] at the corresponding system alarm message.

# 3.6.7 Workflows and surgery steps

The system offers predefined surgery workflows that are combined of characteristic surgery steps. In order to ensure that the optimal system settings are available at a certain step, surgical functions and the functions of additional instruments are preconfigured for each workflow step. These settings can be adjusted and stored for the respective step in which they were modified.

#### Information:

The availability of CALLISTO eye surgery steps depends on whether CALLISTO eye is connected and a valid license is available.

Surgical functions are not activated unless the system has been primed successfully for the selected workflow. When a workflow is started, the surgery step on the left-most workflow bar position is activated.

Workflow	Effect			
Divide and Conquer				
z.mac ama conque.	<ul> <li>The CALLISTO eye steps "Incision" and "Rhexis" store settings for phaco-surgery preparation steps.</li> </ul>			
	"Sculpt, Quad and Epi" store settings suitable for different phases of the phaco- surgery.			
	■ "Cortex" stores settings for the cortex removal.			
	■ "Polish" stores settings for the capsule polishing.			
	■ "Visco" stores settings for the removal of visco elastic material (OVD).			
	■ The CALLISTO eye step "Z Align" stores settings for the positioning of toric lenses.			
	■ The CALLISTO eye step "LRI" stores settings for limbal relaxing incisions.			
	Additional Instruments Steps			
	"Anterior Vitrectomy" stores settings for cutting and aspirating vitreous material that comes from the posterior segment of the eye due to a capsular bag rupture.			
	■ "Diathermy" stores settings to cauterize (stop bleeding) small vessels.			
Phaco Chop	Surgery Steps			
	■ The CALLISTO eye steps "Incision" and "Rhexis" store settings for phaco-surgery preparation steps.			
	■ "Phaco Aspiration, Chop and Epi" store settings suitable for different phases of the phaco-surgery.			
	■ "Cortex" stores settings for the cortex removal.			
	■ "Polish" stores settings for the capsule polishing.			
	■ "Visco" stores settings for the removal of visco elastic material (OVD).			
	■ The CALLISTO eye step "Z Align" stores settings for the positioning of toric lenses.			
	■ The CALLISTO eye step "LRI" stores settings for limbal relaxing incisions.			
	Additional Instruments Steps			
	"Anterior Vitrectomy" stores settings for cutting and aspirating vitreous material that comes from the posterior segment of the eye due to a capsular bag rupture.			
	■ "Diathermy" stores settings to cauterize (stop bleeding) small vessels.			

## 3.6.8 QUATERA FCP functions

The surgeon can use the QUATERA FCP's foot pedal and buttons to control the system's functions, e.g. to select functions or workflow steps or to alter parameter values of currently used functions.

The QUATERA FCP's actual pitch and yaw position is displayed on the "Live Screen" menu's "Foot Control Panel" module [ 62].

## 3.6.8.1 Foot pedal modes

The foot pedal can be rotated in two dimensions:

- pitch (vertically)
- yaw (horizontally)

The pedal can be operated in the following modes.

Pedal Mode	Effect
Single Linear	The performance parameters are supplied in the vertical pedal direction only.
	The surgical functions "Ultrasound" or "Cutter" are permanently assigned to the zones 2 or 3.
Dual Linear	The performance parameters are supplied in the vertical and horizontal pedal direction.
	The surgical functions "Ultrasound" or "Cutter" are permanently assigned to the outer yaw position (rotation away from the user) [> 103].
	The advantage of this type of control is the simultaneous execution of two functions. Depending on the configuration, e.g. the U/S power or the aspiration can be independently controlled in linear mode during phacoemulsification steps.

## 3.6.8.2 Foot pedal position

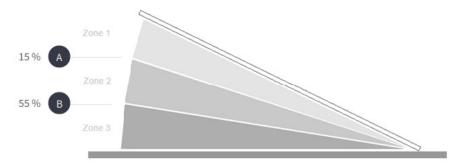
The function assignment of the foot pedal's horizontal positions (yaw) can be adjusted according to the user preferences. Two options are available:

- Right Foot key H (right-hand side) corresponds to the outer yaw position
- Left Foot key G (left-hand side) corresponds to the outer yaw position

The adjustment can be done in the "Settings" menu's "Key Assignment" section [▶ 69].

# 3.6.8.3 Foot pedal pitch controls

In pitch direction, the foot pedal has a resting position, two tactile positions (A, B) and three zones. However, tactile position B and zone 3 remain without effect for surgery steps with no functions assigned to zone 3.



Positions	Effect
Resting position	The foot pedal is in standby mode and no signals are transmitted to the system and thus 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.
Zone 1	Irrigation is activated, except for the surgery step "Diathermy".
A	Tactile position with default start value to supply performance for zone 2.
Zone 2	The functions depend on the selected surgery step and pedal mode.
	Note that if "Anterior Vitrectomy" is performed in foot pedal mode "Single Linear", the range of zone 2 is fixed to 6 %, in order to prevent vitrectomy from being carried out without aspiration for too long. The value for tactile position B is adapted accordingly.
В	Tactile position with default start value to supply performance for zone 3.
	■ Default start value to activate cutter: 18 %
	■ Default start value to activate ultrasound: 55 %
Zone 3	The functions depend on the selected surgery step and pedal mode.

# 3.6.8.4 Default FCP pitch assignments for cataract steps

Surgery step	Sculpt, Phaco Aspiration, Quad, Chop, Epi	Cortex, Polish, Visco, Z Align	Incision, Rhexis, LRI
Pedal Mode	Single Linear	Single Linear	Single Linear
Zone 1	Irrigation	Irrigation	Irrigation
Zone 2	Irrigation Aspiration	Irrigation Aspiration	-
Zone 3	Irrigation Aspiration Ultrasound	-	-

# 3.6.8.5 Default FCP pitch assignments for emergency cataract steps

Surgery step	Anterior Vitrectomy	Diathermy	
Pedal Mode	Dual Linear	Single Linear	
Zone 1	Irrigation	-	
Zone 2	Irrigation Aspiration Cutter (outer yaw position [▶ 69])	Diathermy	
Zone 3	-	-	

# 3.6.8.6 Assignable side button and yaw functions

	Name	Explanation	Assignment possible	
			Foot pedal yaw	Side buttons
Aspiration	Flow +	Increases the maximum flow rate	-	х
	Flow -	Decreases the maximum flow rate	-	x
	Flow / Vacuum controlled Mode	Switches the aspiration control mode	-	х
	Reflux	Activates/deactivates the reflux function	Х	-
	Vacuum +	Increases the maximum vacuum pressure	-	Х
	Vacuum -	Decreases the maximum vacuum pressure	-	Х
	Vac 2	Activates/deactivates the vacuum 2 function	Х	-
Cutter	Cutter On / Off	Activates/deactivates the cutter	Х	-
Diathermy	Diathermy +	Increases the maximum diathermy power	Х	х
	Diathermy -	Decreases the maximum diathermy power	Х	х
Irrigation	Continuous Irrigation Toggle	Activates/deactivates whether irrigation is applied when the foot pedal is in its resting position	х	х
	IOP +	Increases the preset IOP	-	х
	IOP -	Decreases the preset IOP	-	Х
System	No Function		Х	Х

	Name	Explanation	Assignment possible	
			Foot pedal yaw	Side buttons
Ultrasound	Next U/S Mode	Activates the next U/S operation mode	-	X
	Previous U/S Mode	Activates the previous U/S operation mode	-	Х
	U/S +	Increases the maximum U/S power	Х	Х
	U/S -	Decreases the maximum U/S power	Х	X
Workflow	Next Surgery Step	Activates the next surgery step of the workflow sequence	-	Х
	Previous Surgery Step	Activates the previous surgery step of the workflow sequence	-	Х

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# 4 Installation and Commissioning

# **⚠ CAUTION!**

#### Risk of injury caused by electrical voltage.

Connecting unrecognized, defective or non-permitted accessories to live ports may result in electric shock.

- ► Connect only recognized, functioning and permitted accessories to live ports.
- ▶ When configuring your ME system, please make sure to comply with the requirements of IEC 60601-1.
- ➤ You must also comply with the Medical Device Operator Ordinance or other national laws.

#### **NOTE**

#### Incompatible or defect accessories

Connecting unknown and/or defect accessories to the signal interfaces can lead to system failure in the course of a surgery.

- ▶ Do not connect defect or non-approved accessories to the signal interfaces.
- ▶ When configuring your system, make sure to comply with the requirements of IEC 60601-1.
- ► Comply with the Medical Device Operator Ordinance or other national laws.

# 4.1 Unpacking the system

#### Information:

For the complete instruction on unpacking the system, consult the respective unpacking instructions.

## **⚠** CAUTION!

#### **Inappropriate shipping contents!**

Using inappropriate accessories can lead to malfunctions and patient injuries.

- ► Check that the contents correspond to those indicated on the enclosed shipping documents.
- ▶ Notify the ZEISS Service of any discrepancies without delay.

## **⚠** CAUTION!

Action

#### Injury to the patient!

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.
- 1. **NOTE! The contents can be damaged if the packaging material is cut carelessly.** Open the package and examine the components for damage.
- 2. Check that the contents correspond to those indicated on the enclosed shipping documents. Notify the ZEISS Service of any discrepancies without delay.

# 4.2 Initially installing the system

The system's initial installation is carried out by the ZEISS Service or a technician authorized by ZEISS.

# **⚠** CAUTION!

#### Inadequate installation

Faulty connections or an inadequate supply can lead to system malfunctions and bear the risk of injury to persons.

- ▶ Do not try to install the system yourself.
- ► Have the system installed by ZEISS Service or an expert authorized by ZEISS.

#### Information:

All installation requirements for the site must be met in advance of the installation.

#### **NOTE**

#### Ambient requirements for operation

Directly switching on the system after transport or storage in a cold environment may result in malfunctions or safety functions being triggered.

▶ Allow the system to acclimatize to room temperature before switching it on.

# 4.3 Bringing the system into normal position

#### Prerequisite

- ☑ The touchscreen monitor and the bottle holder are in their transport position.
- ☑ All caster brakes are locked.
- ☑ The console tray is folded in [ ≥ 212].

- 1. Grab the bottle holder and tilt it upwards until the mechanical end stop.
- 2. **CAUTION!** The pin might bruise fingers if it is carelessly grabbed. From in front of the system, pull the monitor fixation pin to the left.
  - ⇒ The pin is released from its locking hole.
- 3. Tilt the monitor upwards and release the pin.
- 4. Tilt the monitor further upwards until the pin snaps into the second locking hole.
- 5. Turn the monitor by 180° in clockwise direction around its vertical rotation axis.
  - ⇒ The touchscreen points to the system's front.

# 4.4 Connecting the power supply

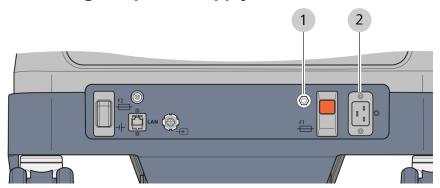


Figure 51: Connecting the power supply

|--|

# **⚠ WARNING!**

## **Ungrounded power supply connection**

The system must be connected to a properly grounded mains supply only. Otherwise there is a risk of death or severe injury due to electric shocks.

▶ Do not connect the system to a mains supply that is not properly grounded.

☑ The system is switched off [ ≥ 210].

- 1. If required: Connect an appropriate PE connection cable to the PE connection pin and to the OR's equipotential bonding bar.
- 2. Connect the power cable to the system's power supply socket.
- 3. Connect the other end of the power cable to a grounded wall socket.

## QUATERA 700

# 4.5 Connecting the QUATERA FCP

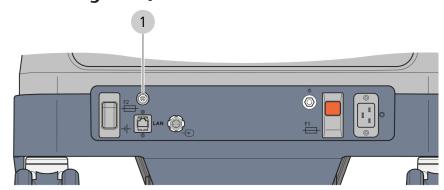


Figure 52: Connecting the QUATERA FCP

- 1 QUATERA FCP socket
- ☑ The system is switched off [ ≥ 210].
- 1. Place the QUATERA FCP on the floor.
- 2. Plug the 4-pin connector of the QUATERA FCP cable into the system's QUATERA FCP socket.
- 3. Open the cap that closes the socket on the QUATERA FCP.
- 4. Plug in the cable's opposite connector into the socket on the QUATERA FCP.
- 5. Lay the surplus cable to a loop and suspend it from the system's cable holder.

# 4.6 Establishing a video connection to a microscope

In order to use the "Live Video" function, a microscope with an integrated or an external video camera must be connected to the system.

#### Information:

For applicable video cables, please consult the document G-30-1888.

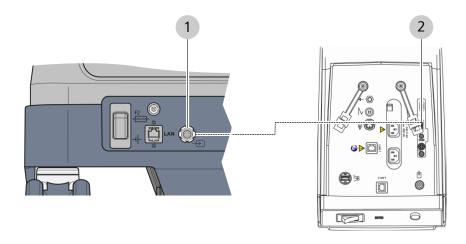


Figure 53: Connecting a surgical microscope (example with OPMI LUMERA 700)

1	1 Video input socket			2	Output socket
Mat	Material		Special in/out video cable		deo cable

- ☑ The system [▶ 210] and the microscope are switched off.
- 1. Insert the video cable's connector into the system's video input socket.
- 2. Insert the cable's opposite connector into the microscope's video output socket.

# 4.7 Setting up a physical network connection to a microscope and CALLISTO eye

To inject phaco data into the microscope image of a CALLISTO eye PC and/or a microscope's eyepiece (IDIS/EDIS), the system must be connected to CALLISTO eye and to the microscope via network cable.

## **⚠** CAUTION!

## Risk of damage caused by viruses!

Connecting the system to an existing IT network may infect the system with viruses. This may lead to limited functionality or malfunctions in the system.

► Keep the IT network free of viruses. The institution operating the software is responsible for the safety of the IT network.

# **⚠** CAUTION!

### Unknown risks due to network integration

Integrating the system into an existing IT network may lead to unknown risks for patients, operators or other persons. The operator of the system must determine, analyze, evaluate and control these risks before the system is integrated in the IT network.

- ► Conscientiously analyze the risks and consequences of your doing before you apply any of the following changes to the IT network:
  - Changing the IT network configuration.
  - Attaching auxiliary elements to the IT network.
  - Removing elements from the IT network.
  - Updating devices which are connected to the IT network.

# **△** CAUTION!

#### Risk of electric shock!

If the IT network cannot provide the features required to integrate the system into the IT network [> 240], electric shocks may arise from touching the system housing or the patient.

▶ Make sure the network the system is integrated to complies with the specified IT network requirements [▶ 240].

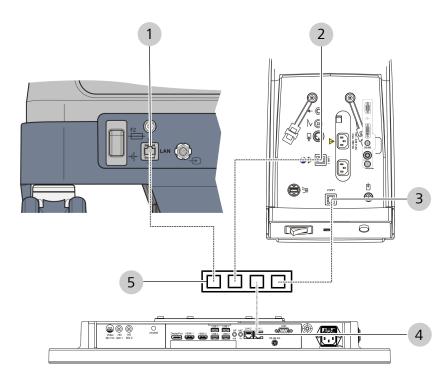


Figure 54: Network connections (example with OPMI LUMERA 700 and CALLISTO eye Panel PC model II)

1	QUATERA 700 network socket	2	OPMI LUMERA 700 network socket LAN1
3	OPMI LUMERA 700 network socket LAN2 (optional)	4	CALLISTO eye network socket LAN1
5	Network switch		

Material	-	3x network cable, 5 m or 10 m
	-	Network switch

# ☑ The system [ ≥ 210], the microscope (e.g. OPMI LUMERA 700) and the CALLISTO eye Panel PC are switched off.

- 1. Connect the network socket of QUATERA 700 with an appropriate cable to the network switch.
- 2. Connect the LAN1 network socket of the OPMI LUMERA 700 to the network switch.
- 3. Continue depending on whether CALLISTO eye is integrated or external to the microscope:
  - CALLISTO eye is integrated: Connect the LAN2 network socket of OPMI LUMERA 700 to the network switch.
  - CALLISTO eye is external: Connect the LAN1 network socket of CALLISTO eye to the switch.
- 4. Configure the network settings. [▶ 117]

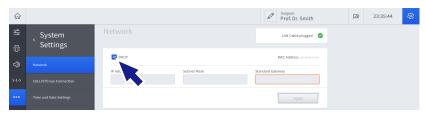
Prerequisite

# 4.8 Configuring the network settings

Please consult your local network administrator on whether to configure the network connection with static or with dynamic IP addresses.

## Configuring for a network with dynamic IP addresses

- ☑ The system is connected to the respective network via network cable. [▶ 115]
- ☑ You are logged in to the system. [▶ 132]
- 1. Open the "Settings" menu and navigate to "System Settings / Network".



- 2. Check the "DHCP" checkbox.
  - ⇒ The "IP Address", "Subnet Mask" and "Standard Gateway" fields are deactivated.
- 3. Tap on [Apply].

Prerequisite

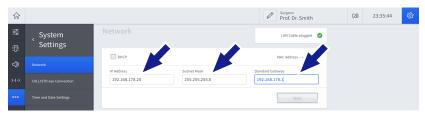
#### Configuring for a network with static IP addresses

Prerequisite

Action

- ☑ The system is connected to the respective network via network cable. [▶ 115]
- $\square$  You are logged in to the system.

 Open the "Settings" menu and navigate to "System Settings / Network".



- 2. Uncheck the "DHCP" checkbox.
- 3. Enter the IP address, the subnet mask and the standard gateway into the respective setting fields.
- 4. Tap on [Apply].

#### Note

The network settings of all devices to be connected have to be configured accordingly, before a network connection can be established.

# 4.9 Establishing a network connection

If a physical network connection is set up and the network settings of all devices are configured, a network connection is established automatically when the devices are switched on.

- ☑ The physical network connection is set up. [▶ 115]
- ☐ The system's network settings are configured. [▶ 117]
- ☑ The network settings of the microscope and CALLISTO eye are configured.
- 1. Switch off the system.
- 2. Switch off the microsocpe and CALLISTO eye.
- 3. Switch on the microscope.
- 4. Switch on CALLISTO eye.
- 5. Switch on the system.
  - ✓ The devices are automatically connected to each other.

Prerequisite

Action

Result

# 4.10 Enabling CALLISTO eye connection

When connected to CALLISTO eye, the system can deliver phaco data to CALLISTO eye and the microscope as well as control certain CALLISTO eye functions, such as video recording or the switching of CALLISTO eye workflow steps.

Prerequisite

- ☑ A network connection between the system and CALLISTO eye is established. [▶ 118]
- ☑ The "Phaco/Vit Interface Control" function is activated on CALLISTO eye.
- 1. Open the "Settings" menu and navigate to "System Settings / CALLISTO eye Connection".
- 2. Enter the CALLISTO eye's IP address into the corresponding setting field.



- 3. Tap on the "Enable CALLISTO eye Connection" switch.
  - ⇒ The switch illuminates blue.
- 4. On the CALLISTO eye, confirm the connection.
  - ✓ The system and CALLISTO eye are connected.

Action

Result

# 4.11 Activating the phaco data injection into the microscope eyepiece

#### Note:

The following instruction refers to the microscope LUMERA 700 as an example.

Prerequisite

☑ The phaco data transmission has been configured on the system.

[▶ 119]

Action

- 1. On the CALLISTO eye, tap on [Microscope].
- 2. Call up the configuration view.
- 3. Tap on [Displays].
- 4. Tap on [Parameter].
  - ⇒ The "Parameter" tab is displayed.
- 5. In the "Parameter Allocation" section, check the "Phaco/Vit" option.
- 6. In the "Additional Settings" section, check the "DIS On/Off" option.
  - ✓ The phaco data injection into the microscope eyepiece is started immediately.

## Result

# 4.12 Activating the phaco data injection into the CALLISTO eye live image

Prerequisite

☑ The phaco data transmission has been configured on the system.

[▶ 119]

Action

- 1. On the CALLISTO eye, tap on [Live Video] or on [Assistant].
- 2. Call up the configuration view.
- 3. Tap on [Video].
  - ⇒ The "Parameter" tab is displayed.
- 4. Select the "Phaco/Vit" cockpit.

Result

✓ The phaco data injection into CALLISTO eye's live image is started immediately.

Prerequisite

Action

# 4.13 Setting the system time and date

#### Information:

Performing the following procedure is restricted to "Administrator" users.

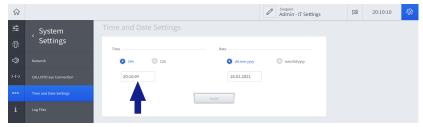
- ☑ You are logged in to the system as "Administrator" [▶ 133].
- 1. Open the "Settings" menu and navigate to "System Settings / Time and Date Settings".



2. Tap on the required time format option.



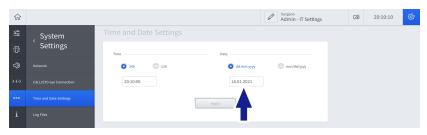
3. Tap on the time field and enter the time via the screen keyboard.



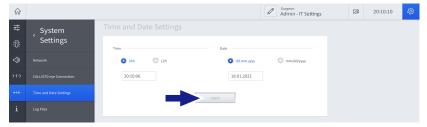
- 4. If applicable, select the "am" or "pm" entry from the drop-down menu
- 5. Tap on the required date format option.



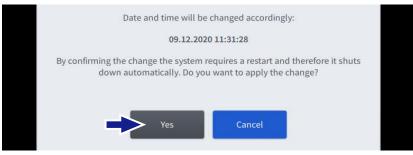
6. Tap on the date field and enter the date via the screen keyboard.



7. Tap on [Apply].



- ⇒ The "Change Time And Date" dialog appears.
- 8. Tap on [Yes].



- ⇒ The system enters the safe state.
- 9. Press the [Device Power on/off] operating button for 5 seconds.



- $\Rightarrow$  The system is switched off.
- 10. Press the [Device Power on/off] operating button.
  - $\Rightarrow$  The system is started.

# 4.14 First-time setting the "Administrator" password

The possibility to log in as "Administrator" and the extend of the granted rights depends on your specific role. There are two "Administrator" roles accessible for authorized clinic personnel:

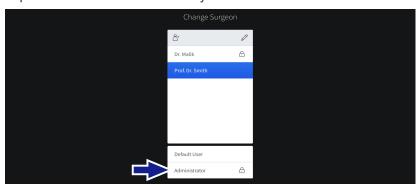
- Admin IT Settings
- Admin BioMed

The authentication code required for the first-time setting of the "Administrator" passwords is contained in a sealed envelope supplied within the scope of delivery.

#### Information:

It is highly recommended not to include language-specific characters (such as "ä" or "ñ") in the password, as those characters might not be available on the login keyboard. The login with the selected user must fail in this case.

- ☑ The respective "Administrator" user's authentication code is at hand.
- ☐ The "Change Surgeon" or the "Welcome" dialog [> 50] are opened.
- 1. Tap on the "Administrator" entry.



- ⇒ The "Enter Password" dialog appears.
- 2. Select the administrator role from the respective selection field.



Prerequisite

3. Enter the authentication code into the respective input field.



- 4. Tap on [Done].
  - $\Rightarrow$  A further dialog appears.
- 5. Enter and confirm the new password.
- 6. Tap on [Done].
  - ✓ The password for the respective "Administrator" user is saved.
  - ✓ The "Administrator" user is activated.

#### Information:

The password can be reset in the "Settings" menu under "User Administration / Reset Password Settings" [> 84].

Result

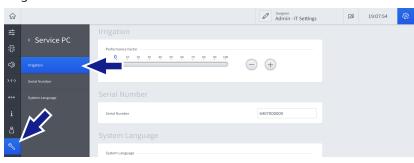
# 4.15 Setting the irrigation performance factor

#### Information:

Performing the following procedure is restricted to "Administrator" users.

☑ You are logged in to the system as "Administrator" [▶ 133].

1. Open the "Settings" menu and navigate to "Service PC / Irrigation".



2. Adjust the irrigation performance factor continuously by dragging the slider button, or stepwise using the +/- buttons.



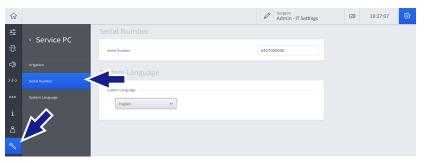
# 4.16 Setting the system serial number

#### Information:

Performing the following procedure is restricted to "Administrator" users.

☑ You are logged in to the system as "Administrator" [▶ 133].

1. Open the "Settings" menu and navigate to "Service PC / Serial Number".



2. Enter the system serial number into the "Serial Number" setting field.



# 4.17 Setting the system language

#### **Information:**

Performing the following procedure is restricted to "Administrator" users.

☑ You are logged in to the system as "Administrator" [▶ 133].

1. Open the "Settings" menu and navigate to "Service PC / System Language".



2. Tap on the "System Language" selection field and select the required system language from the drop-down menu.



Empty page, for your notes

# 5 Daily startup

# 5.1 Positioning the system in the operating room

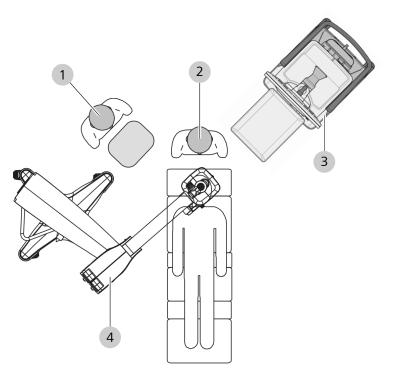


Figure 55: Positioning the system in the OR

1	Assistant	2	Surgeon
3	QUATERA 700	4	Surgical microscope

# **NOTE**

## Risk of damaging the system!

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

▶ Install the system such that the ventilation openings are not closed or obstructed.

**Action** 

QUATERA 700

#### Note:

The following instructions do only apply to the positioning of the system within the OR. For transporting the system between ORs, the system must be brought into its transport position.

- NOTE! The system might tip over if it is pushed with the caster brakes locked. Grab the system's handgrip and unlock all casters' locking tabs.
- 2. Use the handgrip to carefully move the system to its designated position. Make sure no cables obstruct the workflow.
- 3. Press down the locking tabs of at least 2 casters.
- 4. Verify that the system stands safe and stable. Gently push and pull on the handgrip for that purpose.

# **5.2 Unfolding the console tray**

# **⚠ CAUTION!**

#### Hazard of finger crushing

Careless handling of the console tray can result in injuries.

- ▶ Always act very carefully when handling the console tray.
- ▶ Do not touch the area around hinges of the console tray, including its support arm.

# **△ 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 5 kg.

- 1. From in front of the system, grab the console tray with both hands, one at each side of the tray.
- 2. Carefully pull the tray towards you, so it is released from the magnet in the tray base and the tray arm unfolds.
- 3. Grab the tray's lower rim and swivel it upwards until the tray noticeably snaps into its vertical position.
- 4. To adjust the console tray's vertical position, grab the lateral handgrips located at the underside of the tray and gently pull them outwards.
- 5. Hold the handgrips and position the tray as necessary. Then release the handgrips.
- 6. If required, pull out the metal bracket.

5 Daily startup Instructions for Use

QUATERA 700

5.3 Powering the system up

# 5.3 Powering the system up



Figure 56: Side panel

[Device Power on/off] operating button

# **⚠ WARNING!**

#### **Pressure loss**

Audible hissing of air when switching on the system may indicate a malfunction that can lead to patient injuries.

- ▶ Do not operate the system if you hear a hissing of air after switching on the system.
- ▶ In case of hissing air, switch off the system, secure it against further use, and contact the ZEISS Service.

Prerequisite

☑ The system is connected to the power supply [▶ 112].

☑ The QUATERA FCP is connected [ 113].

1. Press the [Device Power on/off] operating button.

 $\Rightarrow$  The system is started.

In the first 45 seconds after the [Device Power on/off] operating button has been pushed, the system performs a self test. After the test has been finished, the button shines green.

# 5.4 Logging in to the system

After a successful powering-up procedure [> 131], the "Welcome" dialog appears on the touchscreen.

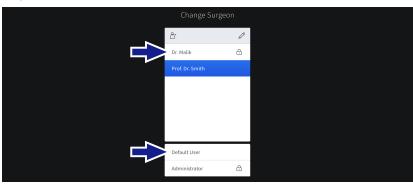
The dialog basically contains the same elements as the "Change Surgeon" dialog [> 50]. Besides selecting and activating existing users it also allows to create new users [> 155].

# 5.4.1 Logging in as "Default User" or custom user

#### Information:

If the password of a password protected custom user has been lost or forgotten, it can be reset by the administrator [> 161].

- ☐ The "Change Surgeon" or the "Welcome" dialog [> 50] are opened.
- 1. Tap on the "Default User" entry or the entry for a custom user, as required.



2. If required, enter the user's password into the password field.



- 3. Tap on [Done].
  - ⇒ If more that one workflow is available for the selected user, the "Change Workflow" dialog appears.

Prerequisite

Instructions for Use 5 Daily startup

QUATERA 700

5.4 Logging in to the system

4. If applicable, tap on the entry for the required workflow.



Result

✓ The user and the workflow are activated.



#### Automatic reset of the bottle fill level

When the user is changed, the bottle fill level is automatically reset. Not changing the infusion bottle in conjunction with the user change might result in a wrong calculation of the remaining fill level and in the late detection of an empty bottle.

- ▶ When changing the user, always replace infusion bottles which are not completely full.
- ▶ When changing the user, always replace infusion bottles with a volume that deviates from the active user's bottle volume settings.

## 5.4.2 Logging in as "Administrator"

The possibility to log in as "Administrator" and the extend of the granted rights depends on your specific role. There are two "Administrator" roles accessible for authorized clinic personnel:

- Admin IT Settings
- Admin BioMed

## Information:

For safety reasons, the system performs a restart when the "Admin - BioMed" is deactivated.

- ☑ The respective "Administrator" user's password has been set.
- ☑ The "Change Surgeon" or the "Welcome" dialog [ > 50] are opened.
- 1. Tap on the "Administrator" entry.

Action

Prerequisite

G-30-2080-en-US - 2.6 - 2022-04-05



- ⇒ The "Enter Password" dialog appears.
- 2. Select the administrator role from the respective selection field.



- 3. Enter the user's password into the password field.
- 4. Tap on [Done].
  - ✓ The "Administrator" user is activated.

Result

# 6 Before use

# **⚠ WARNING!**

#### Improper accessories

The use of non-authorized accessories, parts or tubing systems in connection with the system can lead to injuries to the patient or to malfunctioning of the system. All ZEISS accessories are marked with a respective identification label.

▶ Use only the original accessories and supply materials recommended and certified by ZEISS.

# **⚠ WARNING!**

#### **Modified accessories**

Modifications of accessories such as handpieces or tips can lead to injuries to the patient or to malfunctioning of the system.

▶ Do not modify accessories by bending, cutting or engraving them.

# **△ CAUTION!**

#### Risk of accessory contamination

The reuse of material, components, accessories or equipment intended for single-use can lead to injuries to the patient or to malfunctioning of the system. Using unsterile parts and accessories can lead to injuries to the patient.

- ▶ Do not reuse material, components, accessories or equipment marked with "Single Use Only", "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01).
- ▶ Always use the appropriate sterile accessories for the system.

6.1 Placing drapes QUATERA 700

# 6.1 Placing drapes

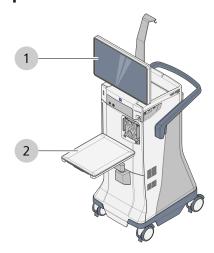


Figure 57: Drape positions

1	Monitor			2	Console tray	
Material		-	SCREEN DRAPE QUATERA 700: 1			
		-	TRAY COVER QUATERA 700: 1			

# **⚠ WARNING!**

#### **Risk of contamination**

Compromising the sterility of the operating area can lead to patient injuries.

- ▶ Be very careful not to compromise the sterility of the operating area.
- ▶ Do not leave the sterile product unattended.

## **6.1.1 Preparing the product**

# Procedure performed by the non-sterile nurse

- 1. Clean the outside of the product packaging before entering the OR.
- 2. Bring the closed product packaging to the place where it will be used.
- 3. Open the product packaging.

Instructions for Use 6 Before use

QUATERA 700 6.1 Placing drapes

## 6.1.2 Applying the SCREEN COVER

## Procedure performed by the sterile nurse

**Action** 

- 1. Remove the **SCREEN COVER** from the packaging and unfold it, such that the cuff points towards you.
- 2. Remove the covering strip from the stripe of adhesive tape.
- 3. With the fingers of both hands, slip under the cuff.
- 4. Attach the stripe of adhesive tape horizontally to the upper edge of the monitor's screen glass.
- 5. Firmly skim along the adhesive tape in outward direction.

## 6.1.3 Applying the TRAY COVER

## Procedure performed by the non-sterile nurse

Action

1. Pull out the metal bracket from the underside of the console tray.

#### Procedure performed by the sterile nurse

- 1. Remove the **TRAY COVER** from the packaging and unfold it, such that the cuff points towards you.
- 2. With both hands, slip under the cuff.
- 3. Beginning from the tray's metal bracket, completely guide the cover over the console tray and its arm.
- 4. If desired, push down the cover through the metal bracket, to form a bag for instruments or waste.

# 6.2 Setting the patient eye level

The patient eye level indicator facilitates the identification of the vertical distance between the patient's eye level and the aspiration port. The zero point of the patient eye level indicator and the optimum position of the patient eye is at the height of the QUATTRO CASSETTE irrigation chamber's vertical center.

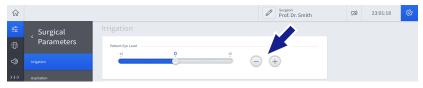
To compensate for deviations from the optimum position, the active LED on the patient eye level indicator [> 36] must be lined up with the vertical position of the patient eye.

# **⚠** CAUTION!

#### **Inadequate IOP**

Not to verify and eventually adjust the patient's eye level before a surgery can lead to a too high or too low irrigation pressure which might injure the patient's eye.

- ▶ **Before every** surgery, control and adjust the patient eye level indicator to the actual level of the patient's eye.
- 1. Open the "Settings" menu and navigate to "Surgical Parameters / Irrigation".
- While observing the patient eye level indicator on the console, adjust the "Patient Eye Level" controls such that the patient eye level indicator's LED illumination height matches the actual level of the patient's eye.



# 6.3 Preparing the QUATTRO CASSETTE

## 6.3.1 Installing the QUATTRO CASSETTE

# **⚠ WARNING!**

#### **Risk of contamination**

Compromising the sterility of the operating area can lead to patient injuries.

- ▶ Be very careful not to compromise the sterility of the operating area.
- ▶ Do not leave the sterile product unattended.

## Action

#### Procedure performed by the non-sterile nurse

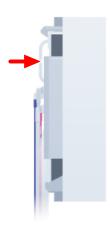
- 1. Clean the outside of the product packaging before entering the OR.
- 2. Open the packaging.
- 3. Aseptically transfer the packaging to the sterile field.

#### Procedure performed by the sterile nurse

- 1. Remove the tape from the I/A tubing. Make sure the tubing stays in the sterile field!
- 2. Beginning with its lower edge, set the cassette into the system's cassette slot.



3. Press the cassette entirely against the pump plate until it engages noticeably. Make sure that the cassette lies flush on the system's pump plate and that the drain bag hangs freely!



## 6.3.2 Priming the QUATTRO CASSETTE

## Procedure performed by the sterile nurse

Prerequisite

Action

☑ The QUATTRO CASSETTE has been mounted [▶ 139].

1. Short-circuit the I/A tubing by connecting the connectors of the twin tube.



2. Hand the irrigation fluid administration tube over to the nonsterile nurse.

## Procedure performed by the non-sterile nurse

Action

1. Remove the irrigation fluid administration tube's safety cap and connect the tube to the infusion bottle or bag.



- 2. Make sure that the air filter is open.
- 3. Suspend the infusion bottle or bag on the bottle holder.
- 4. Make sure that the irrigation fluid administration tube's clamp is open.



## Procedure performed by the sterile nurse

- Navigate to the software's "Setup" menu and tap on [Change Bottle].
- 2. Tap on [Prime Cassette].
  - ⇒ The QUATTRO CASSETTE is primed. When the priming is completed, the [Flush Handpiece] button becomes available on the touchscreen.
- 3. Disconnect the connectors of the twin tube.

# 6.4 Preparing the ULITE PHACO HANDPIECE

## 6.4.1 Installing the ULITE PHACO HANDPIECE

Prerequisite Action ☑ The QUATTRO CASSETTE has been primed [▶ 140].

1. Screw the desired phaco tip into the end of the phaco handpiece so that the threads correctly mesh into each other. Tighten the tip firmly with your fingers.



- 2. NOTE! Using a tool other than the dedicated phaco tip wrench might damage the tip or the handpiece. Do not use a tool other than the phaco tip wrench. Guide the phaco tip wrench on the flange side carefully over the phaco tip so that the wrench locks into the notches at the socket of the tip.
- 3. Screw in the phaco tip into the handpiece in clockwise direction.
- 4. Remove the phaco tip wrench.
- 5. Carefully slide the silicone sleeve over the phaco tip until it engages in the handpiece's thread.



- 6. Screw the sleeve onto the handpiece in clockwise direction, until an appropriate extend of the phaco tip's front end remains uncovered.
- 7. Push the aspiration tube of the QUATTRO CASSETTE into the corresponding connection piece on the handpiece and fasten it by turning it in clockwise direction.

QUATERA 700



- 8. Push the irrigation tube of the QUATTRO CASSETTE into the corresponding connection piece on the handpiece and fasten it by turning it in clockwise direction.
- 9. NOTE! Connecting a wet handpiece can lead to damage. Do not connect the handpiece if it is not completely dry. Plug the electrical power plug of the phaco handpiece into the system's U/S socket [> 39].



#### 6.4.2 Tuning the ULITE PHACO HANDPIECE

In advance of the tuning procedure, the handpiece is flushed, i.e. filled with BSS. Flushing makes sure that no air remains in the tubing, the handpiece and the test chamber. The handpiece can be flushed various times, before and in the course of a surgery. But it is mandatory to have it flushed once before it is used for the first time after connecting it.

During the tuning of the phaco handpiece itself, the individual handpiece's optimum U/S frequency is determined and the accordance of the irrigation and aspiration flow properties with the selected tip size is double-checked.

Note that a tuning procedure is necessary every time a phaco tip has been tightened (e.g. in the course of mounting the handpiece, of changing the phaco tip or even of re-tightening it).

## **⚠ 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 a patient's eye.

#### Information:

When flushing or tuning are performed outside of the mandatory preparation procedure (button color: dark gray), the calling of the function must be confirmed on an additional prompt.

Prerequisite

- ☑ The phaco handpiece has been mounted [▶ 142].
- ☑ The irrigation fluid administration tube's clamp is opened.
- ☑ The QUATERA FCP foot pedal is in its resting position [▶ 104] since more than five seconds.

Action

1. Hold the phaco handpiece's front end into the test chamber. Don't attach the test chamber to the handpiece yet.



- 2. In the "Setup" menu, tap on [Flush Handpiece].
  - ⇒ The handpiece is flushed, the test chamber is filled with irrigation fluid and the [Tune Handpiece] button becomes available on the touchscreen.
- 3. As soon as the test chamber is filled, put it firmly onto the front end of the handpiece.



4. Hold the handpiece roughly at the height of the patient eye level or place it upright the bag formed by the tray cover.



- 5. **NOTE!** Dry tuning can cause premature tip failure. Do not tune the handpiece if the tip is not immersed in BSS. Tap on [Tune Handpiece].
  - $\Rightarrow$  The handpiece is tuned.
- 6. Remove the test chamber from the handpiece.

QUATERA 700

6.5 Preparing the I/A accessories

## 6.5 Preparing the I/A accessories

#### Note:

The following instruction applies to coaxial I/A handpieces. For information on the installation and application of bimanual handpieces, refer to the Instructions for Use of the respective handpieces.

In advance of using the handpiece, it is flushed, i.e. filled with BSS. Flushing makes sure that no air remains in the tubing or the handpiece. The handpiece can be flushed various times, before and in the course of a surgery. But it is mandatory to have it flushed once before it is used for the first time after connecting it.

## **⚠ WARNING!**

#### Flushing with contact to the patient's eye

Flushing while using a handpiece on a patient's eye can lead to eye injuries.

▶ Never carry out a flushing procedure while using a handpiece on a patient's eye.

#### Information:

When flushing is performed outside of the mandatory preparation procedure (button color: dark gray), the calling of the function must be confirmed on an additional prompt.

- ☑ The QUATTRO CASSETTE has been primed [ 140].
- ☑ The irrigation fluid administration tube's clamp is opened.
- ☑ The QUATERA FCP foot pedal is in its resting position [▶ 104] since more than five seconds.
- 1. Slide the connector of the QUATTRO CASSETTE's aspiration tube (red) into the handpiece's aspiration tube connector.

**Action** 

Prerequisite



- 2. Slide the connector of the QUATTRO CASSETTE's irrigation tube (blue) into the handpiece's irrigation tube connector.
- 3. In the "Setup" menu, tap on [Flush Handpiece].
  - ⇒ The handpiece is flushed.

## 6.6 Preparing the vitrectomy accessories

#### 6.6.1 Installing the vitrectomy accessories

Prerequisite Action

- ☑ The QUATTRO CASSETTE has been primed [▶ 140].
- 1. Take the irrigation handpiece out of the blister.
- 2. Connect the QUATTRO CASSETTE's irrigation tube (blue) to the irrigation handpiece.



- 3. Place the irrigation handpiece on the console tray.
- 4. Unwind the vitrectomy cutter's tubing from the blister.
- 5. Connect the female Luer fitting of the QUATTRO CASSETTE's aspiration tube (red) to the corresponding male fitting at the end of the cutter's aspiration tube.



- 6. Turn the fittings together with gentle pressure to guarantee a secure fit.
- 7. Insert the connector of the cutter's pneumatic tube into the system's vitrectomy socket [> 39].



- 8. If required, slightly bend the vitrectomy cutter's handle to the side to loosen it from the cutter.
- 9. Pull the handle away from the cutter and let it hang from the tubes.

#### 6.6.2 Priming the vitrectomy accessories

Cutter priming is an essential prerequisite for performing a vitrectomy procedure. In the course of the priming procedure the irrigation and aspiration tubing is flushed with BSS and the correct functioning of the vitrectomy handpiece is checked.

## **⚠ WARNING!**

#### Priming with contact to the patient's eye

Priming the vitrectomy accessories while using them on a patient's eye can lead to eye injuries.

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

#### Prerequisite

- ☑ The I/A accessories have been flushed.
- A separate bowl (e.g. the vitrectomy handpiece's priming blister) has been filled with sufficient BSS to cover the cutter tip's opening when it is immersed.
- ☐ The vitrectomy accessories have been mounted [▶ 148].
- ☑ The irrigation fluid administration tube's clamp is opened.
- ☑ The QUATERA FCP foot pedal is in its resting position [▶ 104] since more than five seconds.
- 1. Hold the bowl or priming blister filled with BSS roughly at the height of the patient eye level.
- Insert the front parts of the irrigation handpiece and of the vitrectomy cutter into the bowl filled with BSS, such that the irrigation and aspiration openings of the handpieces are covered with BSS.
- 3. In the "Setup" menu, tap on [Prime Cutter].
- 4. Confirm the upcoming prompt.
  - ⇒ The vitrectomy accessories are primed.

## 6.7 Installing the diathermy accessories

Action

1. Insert the diathermy handpiece into the diathermy bipolar cable's corresponding socket.



2. Insert the diathermy bipolar cable's plug into the system's diathermy socket [> 39].



QUATERA 700 6.8 Configuring users

## 6.8 Configuring users

A maximum of 60 users can be managed in the "Change Surgeon" dialog. The users can be divided into the following categories:

#### **Custom users**

Custom users can be created to store preferences and settings for specific users. Its main characteristics are as follows.

Password protection Password protection is activated per default,

> but can be deactivated at any time. The password can be chosen individually.

Language The user language is customizable at any

time.

Workflows One workflow (either "Divide and Conquer"

> or "Phaco Chop") is set during the user creation. Further workflows can be created

as required.

Surgery function settings The default settings can be adapted. The

adapted settings can be saved permanently

for the user.

#### "Default User"

The "Default User" is a predefined user that cannot be deleted. It is intended as a kind of fallback for surgeons without dedicated custom user or who forgot their password and had no chance to have it reset in advance of the next surgery. Its main characteristics are as follows.

Password protection No password protection available.

Language The user language is English and cannot be

changed.

Workflows A "Divide and Conquer" and a "Phaco

Chop" workflow are part of the user profile.

No further workflows can be created.

The settings can be adapted for the current Surgery function settings

session, but are discarded with the next

logout or user change.

6.8 Configuring users QUATERA 700

#### "Administrator"

The "Administrator" is a predefined user that cannot be deleted. In fact, it is a conglomerate of the following user roles with extended, role-specific rights:

- Admin IT Settings
- Admin BioMed
- Admin Carl Zeiss Service
- Admin Factory

The "Admin - IT Settings" and the "Admin - BioMed" are available for the respective clinic personnel. The main characteristics of the "Administrator" are as follows.

Password protection The user is protected by password. The pro-

tection cannot be deactivated.

Language The user language is English and cannot be

changed.

Workflows A "Divide and Conquer" and a "Phaco

Chop" workflow are part of the user profile. No further workflows can be created.

session, but are discarded with the next

logout or user change.

QUATERA 700 6.8 Configuring users

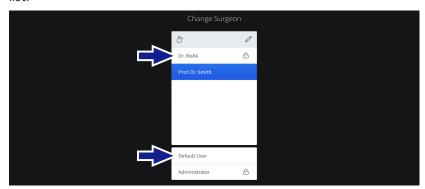
### 6.8.1 Changing users

#### Information:

This section instructs you on how to activate custom users or the "Default User". For activating an "Administrator", see Logging in as "Administrator" [▶ 133].

1. On the touchscreen header, tap on the [Surgeon] button [▶ 46].

- ⇒ The "Change Surgeon"s dialog appears with the currently active user highlighted blue.
- 2. Select the desired user from the custom users or the default users list.



3. If required, enter the user's password into the password field.



- 4. Tap on [Done].
  - ⇒ If more than one workflow is available for the selected user, the "Change Workflow" dialog appears.
- 5. If applicable, tap on the entry for the required workflow.



✓ The user and the workflow are activated.

Action

6 Before use Instructions for Use

6.8 Configuring users QUATERA 700

## **⚠** CAUTION!

#### Automatic reset of the bottle fill level

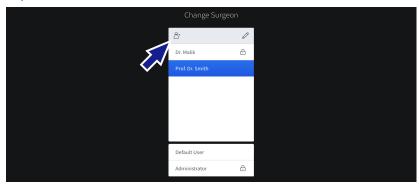
When the user is changed, the bottle fill level is automatically reset. Not changing the infusion bottle in conjunction with the user change might result in a wrong calculation of the remaining fill level and in the late detection of an empty bottle.

- ▶ When changing the user, always replace infusion bottles which are not completely full.
- ▶ When changing the user, always replace infusion bottles with a volume that deviates from the active user's bottle volume settings.

QUATERA 700 6.8 Configuring users

### 6.8.2 Creating users

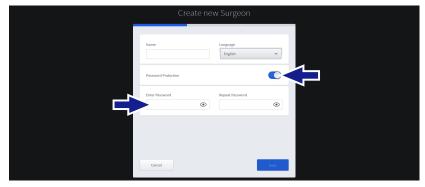
- 1. If required, tap on the [Surgeon] button in the touchscreen's header [> 46].
  - ⇒ The "Change Surgeon" menu [> 50] appears.
- 2. Tap on the [Create user] button.



- ⇒ The "Create new Surgeon" dialog appears.
- NOTE! The user is responsible for the selected user name (indication of personal data etc.). Enter the user name into the respective field.



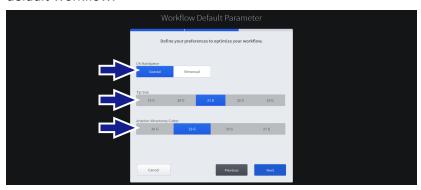
- 4. Select the user language from the respective drop down menu.
- 5. NOTE! If the password protection is deactivated, the respective user is solely responsible for the integrity of his profile! If required, tap on the "Password Protection" switch to deactivate the password protection.



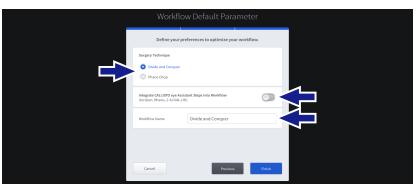
- 6. Alternatively, enter and confirm the user specific password via the corresponding input fields.
- 7. Tap on [Next].

6.8 Configuring users QUATERA 700

8. On the next screen, select the I/A handpiece type for the user's default workflow.



- 9. Select the tip size for the phaco handpiece and the I/A handpiece.
- 10. Select the tip size for the vitrectomy cutter.
- 11. Tap on [Next].
- 12. On the next screen, select the surgery technique for the user's default workflow.



- 13. If required, activate the integration of CALLISTO eye assistant steps into the workflow.
- 14. If required, enter a new name for the user's default workflow into the respective setting field.
- 15. Tap on [Finish].
  - ✓ The user is created and activated. The "Create new Surgeon" dialog is closed.

QUATERA 700 6.8 Configuring users

#### 6.8.3 Editing users

The following settings of the currently active custom user can be edited:

- surgeon name
- language
- password protection activated/deactivated
- password

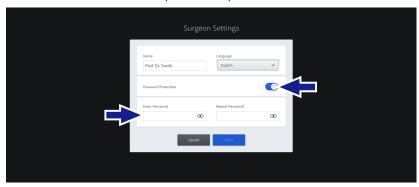
The user settings of "Default User" and "Administrator" cannot be edited.

☑ The user whose settings are to be edited is active [▶ 153].

- On the touchscreen header, tap on the [Surgeon Settings] button.
   ⇒ The "Surgeon Settings" dialog appears.
- 2. If required, tap on the "Name" input field and edit the user name.



- 3. If required, tap on the "Language" selection field and select the language from the drop down menu.
- 4. NOTE! If the password protection is deactivated, the respective user is solely responsible for the integrity of his profile! If required, tap on the "Password Protection" switch to activate or deactivate the password protection.



- 5. If required, tap on the "Enter Password" input field, enter a new user specific password and confirm it via the "Repeat Password" field.
- 6. Tap on [Done].
  - ✓ The user settings are saved.

Prerequisite Action

6.8 Configuring users QUATERA 700

### 6.8.4 Deleting users

The "Default User" and the "Administrator" cannot be deleted.

1. On the touchscreen header, tap on the [Surgeon] button.

- ⇒ The "Change Surgeon" dialog appears with the currently active user highlighted blue.
- 2. On the dialog's header, tap on the [Edit Surgeon List] button.



- ⇒ The "Edit Surgeon List" dialog appears with all custom users in alphabetical order.
- 3. Check the checkbox of the users to be deleted.



- 4. Tap on the [Delete] button.
- 5. Confirm the upcoming prompt with [Yes].
  - ⇒ The user is deleted.

#### Information:

If the previously active user has been deleted, the "Default User" is activated.

QUATERA 700 6.8 Configuring users

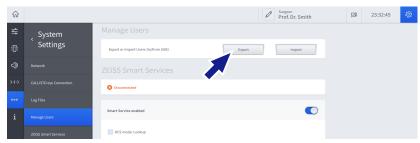
#### 6.8.5 Exporting users

Users and their corresponding settings can be exported to an USB drive for backup purposes or in order to transfer them to another system.

#### Information:

User passwords are not part of an export. They must be set new on the target system after an import.

- ☑ A USB drive formatted as FAT32 is connected to the system's USB-A port [▶ 40].
- 1. Open the "Settings" menu and navigate to "System Settings / Manage Users".
- 2. Tap on [Export].



- ⇒ The "Select Users to Export" dialog appears.
- 3. Check the checkbox of the users to be exported.



- 4. Tap on the [Export] button.
  - ✓ The respective user's data are exported to the USB drive.

Prerequisite

Action

6.8 Configuring users QUATERA 700

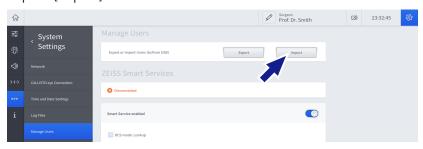
#### 6.8.6 Importing users

Users and their corresponding settings can be imported from a USB drive for restoring a backup of the user data or for the transfer of users from another system.

#### Information:

User passwords are not part of an import. They must be set new on the target system after an import.

- ☐ The USB drive containing the user data is connected to the system's USB-A port [▶ 40].
- 1. Open the "Settings" menu and navigate to "System Settings / Manage Users".
- 2. Tap on [Import].



✓ All user data sets found on the USB drive are imported.

#### Information:

If the import would result in duplicate user names, a consecutive number is added at the end of the newly imported user's name.

Prerequisite

Action

QUATERA 700 6.8 Configuring users

#### 6.8.7 Resetting user passwords

#### Information:

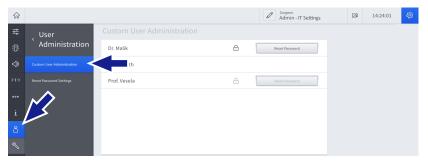
Performing the following procedure is restricted to "Administrator" users.

#### Resetting custom user passwords

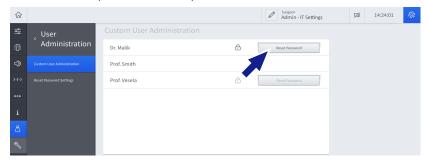
Prerequisite **Action** 

☑ You are logged in to the system as "Administrator" [▶ 133].

Open the "Settings" menu and navigate to "User Administration / Custom User Administration".



Behind the respective user, tap on [Reset Password].



Result

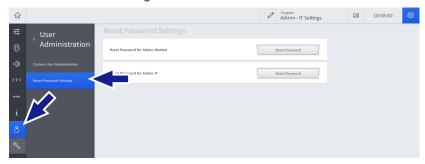
✓ The password is reset.

At the next login the user is urged to set a new password.

#### Resetting "Administrator" passwords

☑ You are logged in to the system as "Administrator" [▶ 133].

Open the "Settings" menu and navigate to "User Administration / Reset Password Settings".



Behind the respective user, tap on [Reset Password].

Prerequisite Action

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6.8 Configuring users QUATERA 700



Result

The password is reset.

At the next login the user is urged to set a new password.

#### Information:

It is highly recommended not to include language-specific characters (such as "ä" or "ñ") in the password, as those characters might not be available on the login keyboard. The login with the selected user must fail in this case.

QUATERA 700

6.9 Configuring workflows

## 6.9 Configuring workflows

## 6.9.1 Changing workflows

Action

On the touchscreen footer, tap on the [Workflow] button [▶ 46].
 ⇒ The "Change Workflow" dialog appears.



- 2. Tap on the desired workflow.
  - ✓ The workflow is selected.

Prerequisite

Action

6.9 Configuring workflows

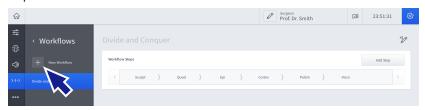
QUATERA 700

#### 6.9.2 Creating workflows

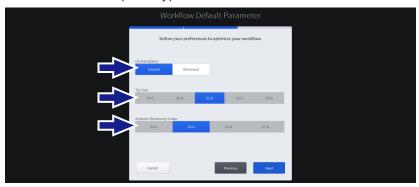
Customized workflows can be created for currently active custom users.

☑ The user for whom to create a workflow is active [▶ 153].

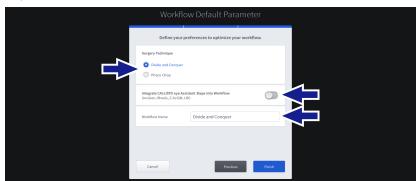
- 1. Open the "Settings" menu and navigate to "Workflows".
- 2. Tap on the "New Workflow" button.



- ⇒ The "Workflow Default Parameter" dialog opens.
- 3. Select the I/A handpiece type for the workflow.



- 4. Select the tip size for the phaco handpiece and the I/A handpiece.
- 5. Select the tip size for the vitrectomy cutter.
- 6. Tap on [Next].



- 7. On the next screen, select the surgery technique for the workflow.
- 8. If required, activate the integration of CALLISTO eye assistant steps into the workflow.
- 9. If required, enter a new name for the workflow into the respective setting field.
- 10. Tap on [Finish].

QUATERA 700 6.9 Configuring workflows

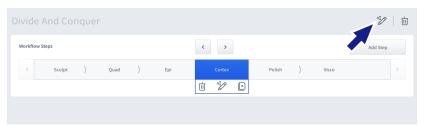
#### 6.9.3 Editing workflows

The currently active custom user's workflow can be edited in the following ways:

- renaming the workflow
- adding surgery steps
- renaming surgery steps
- changing the surgery step sequence
- duplicating surgery steps
- deleting surgery steps

#### Renaming workflow

- ☑ The user whose workflow is to be edited is active [▶ 153].
- ☑ The "Settings / Workflow" menu is open.
- In the section of the respective workflow, tap on the [Rename Workflow] button.



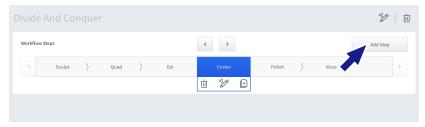
- ⇒ The "Rename Workflow" dialog appears.
- 2. Enter the new workflow name into the respective input field.
- 3. Tap on [Done].
  - ✓ The workflow is renamed.

#### Adding surgery steps

#### Information:

The availability of CALLISTO eye surgery steps depends on whether CALLISTO eye is connected and a valid license is available.

- ☐ The user whose workflow is to be edited is active [▶ 153].
- ☑ The "Settings / Workflow" menu is open.
- In the section of the respective workflow, tap on [Add Step].



⇒ The "Add Step to ..." dialog appears.

Prerequisite

**Action** 

Result

Prerequisite



- 2. From the upper section, select the step type for the new step.
- 3. From the middle section, select the step.
- 4. If required, enter a new name for the step into the respective setting field.
- 5. Tap on [Done]
  - ✓ The new step is added to the workflow.

#### **Renaming surgery steps**

- ☐ The user whose workflow is to be edited is active [▶ 153].
- ☑ The "Settings / Workflow" menu is open.
- 1. In respective workflow's section, tap on the workflow step to be edited.
  - ⇒ The step is highlighted and additional controls expand.
- 2. Tap on the [Rename Step] button.



- ⇒ The "Rename Step" dialog appears.
- 3. Enter a new name for the step into the respective setting field.
- 4. Tap on [Done].
  - ✓ The surgery step is renamed.

#### Changing the surgery step sequence

- ☐ The user whose workflow is to be edited is active [▶ 153].
- ☑ The "Settings / Workflow" menu is open.
- 1. In respective workflow's section, tap on the workflow step to be edited.
  - ⇒ The step is highlighted and additional controls expand.
- 2. Tap on the arrow buttons to move the selected step to the desired position of the workflow sequence.

Result

Prerequisite

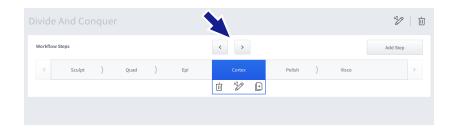
**Action** 

Result

Prerequisite

QUATERA 700

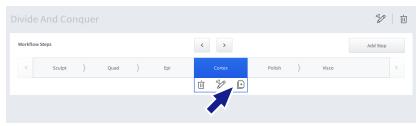
6.9 Configuring workflows



#### **Duplicating surgery steps**

Prerequisite

- ☑ The user whose workflow is to be edited is active [▶ 153].
- ☑ The "Settings / Workflow" menu is open.
- 1. In respective workflow's section, tap on the workflow step to be edited.
  - ⇒ The step is highlighted and additional controls expand.
- 2. Tap on the [Duplicate Step] button.

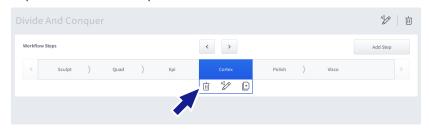


✓ A duplicate of the surgery step is inserted on the subsequent position of the workflow sequence.

#### **Deleting surgery steps**

Note that the currently active surgery step and the final surgery step of a workflow cannot be deleted.

- ☑ The user whose workflow is to be edited is active [▶ 153].
- ☑ The "Settings / Workflow" menu is open.
- 1. In respective workflow's section, tap on the workflow step to be edited.
  - ⇒ The step is highlighted and additional controls expand.
- 2. Tap on the [Delete Step] button.



- 3. Confirm the upcoming prompt with [Yes].
  - ✓ The surgery step is deleted.

Frerequisit

Action

Result

Prerequisite

**Action** 

6 Before use Instructions for Use QUATERA 700

6.9 Configuring workflows

Prerequisite

Action

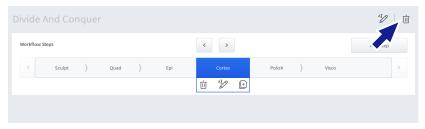
### 6.9.4 Deleting workflows

The currently active custom user's workflows can be deleted.

☑ The user whose workflow is to be deleted is active [▶ 153].

☑ The "Settings / Workflow" menu is open.

1. In the respective workflow's section, tap on the [Delete Workflow] button.



- 2. Confirm the upcoming prompt with [Yes].
  - ✓ The workflow is deleted.

QUATERA 700

6.10 Configuring the QUATERA FCP

## 6.10 Configuring the QUATERA FCP

#### 6.10.1 Configuring the key assignments

The pedal position [▶ 103] can be configured for the user. The settings are apply to all of the user's workflows and workflow steps.

The following settings can be configured for each surgery step of the currently active workflow:

- foot pedal mode [≥ 103]
- functions for the buttons and the foot pedal's yaw positions [▶ 106]

#### Adjusting the pedal position

When switching the pedal position, the function assignments of the buttons G and H (yaw positions) are switched.

- ☑ The user whose FCP settings are to be edited is active [▶ 153].
- ☑ The "Settings / Foot Control Panel / Key Assignment" menu is opened.
- 1. Tap on the desired "Pedal Position" radio button.



✓ The selected option (highlighted blue) is applied to all of the user's workflows and workflow steps.

#### Selecting the surgery step

Unless you want to apply the QUATERA FCP configurations to all workflow steps at once, the respective workflow step for which to adjust the configurations must be selected.

- ☐ The user whose FCP settings are to be edited is active [ 153].
- ☑ The workflow the FCP key assignments of which are to be edited is active [▶ 163].
- ☑ The "Settings / Foot Control Panel / Key Assignment" menu is opened.
- 1. Tap on the "Surgery Step" selection field.



Prerequisite

Action

Result

Prerequisite

Result

- ⇒ A drop-down menu with all steps of the current workflow opens.
- 2. Select the desired workflow step from the drop-down menu.
  - ✓ The workflow step is selected. The further adjustments are applied to just the selected step.

#### Applying configurations to all workflow steps at once

It is possible to assign the same QUATERA FCP configuration to all steps of the current workflow. Adjustments then only have to be performed once.

- ☐ The user whose FCP settings are to be edited is active [▶ 153].
- ☑ The workflow the FCP key assignments of which are to be edited is active [▶ 163].
- ☑ The "Settings / Foot Control Panel / Key Assignment" menu is opened.
- 1. Check the "Edit Layout for all Steps" checkbox.

Surgery Step

Pedal Position

Left Foot

Pedal Mode Ultrasound

Single Linear

Vac 2 6 II Next Surgery Step

- ⇒ The "Surgery Step" selection field becomes inactive and additional controls appear.
- 2. Adjust the QUATERA FCP pedal modes and key assignments as necessary (see below).
- 3. In the menu's lower section, tap on [Apply to all steps].



✓ The current QUATERA FCP configurations are applied to all steps of the workflow.

Prerequisite

Action

QUATERA 700

Prerequisite

6.10 Configuring the QUATERA FCP

#### Adjusting the pedal mode

Note that the pedal modes for phaco (U/S) and vitrectomy steps have to be adjusted separately via distinct selection fields.

- ☐ The user whose FCP settings are to be edited is active [▶ 153].
- ☑ The workflow the FCP key assignments of which are to be edited is active [▶ 163].
- ☑ The "Settings / Foot Control Panel / Key Assignment" menu is opened.
- $\square$  The desired surgery step is selected.
- 1. Tap on the "Pedal Mode" selection field.



- ⇒ A drop-down menu with the available pedal modes opens.
- 2. Select the desired pedal mode from the drop-down menu.
  - ✓ The pedal mode is applied to the selected workflow step.

#### Adjusting the key functions

## **⚠ WARNING!**

#### Non-audible voice feedback

If workflow steps are changed via the QUATERA FCP and no audible feedback on the current workflow step is received, the overview of the workflow and step-related parameter settings might be lost. Calling a function with unexpected working parameters can lead to patient injury.

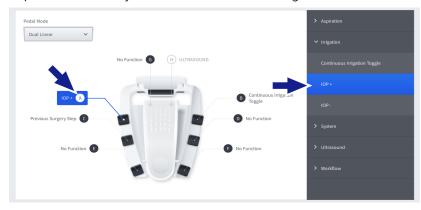
▶ When assigning the functions "Next Surgery Step" or "Previous Surgery Step" to FCP keys, make sure that the voice feedback volume is adjusted to a level which makes the feedback audible against the background noise.

Note that certain buttons are pre-configured for certain workflow steps per default and cannot be re-assigned. Those buttons are displayed white.

Result

#### Prerequisite

- ☑ The user whose FCP settings are to be edited is active [▶ 153].
- ☐ The workflow the FCP key assignments of which are to be edited is active [▶ 163].
- ☑ The "Settings / Foot Control Panel / Key Assignment" menu is opened.
- $\square$  The desired surgery step is selected.
- $\square$  The desired pedal mode is selected.
- 1. Tap on the button you want a function to assign to.



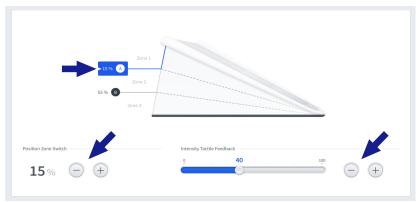
- ⇒ The key functions menu opens on the right-hand side.
- 2. Tap on the desired entry of the key functions menu.
  - The function is assigned to the key for the selected workflow step.

Action

#### 6.10.2 Configuring the pitch settings

The following settings can be configured for the currently active workflow:

- zone switch positions for the transition points A and B [▶ 104]
- intensity of the tactile feedback at transition points A and B
- ☐ The user whose FCP settings are to be edited is active [▶ 153].
- ☑ The workflow the FCP pitch settings of which are to be edited is active [▶ 163].
- ☑ The "Settings / Foot Control Panel / Pitch Settings" menu is opened.
- 1. Tap on the transition point the settings of which you want to configure.



- ⇒ The transition point's "Position Zone Switch" and "Intensity Tactile Feedback" controls expand.
- 2. Adjust the transition point's zone switch position with the "Position Zone Switch" controls.
- 3. Adjust the intensity of the tactile feedback at the transition point with the "Intensity Tactile Feedback" controls.
  - ✓ The configurations are applied to the current workflow.

Prerequisite

Action

Empty page, for your notes

## 7 Operation

## **⚠ WARNING!**

#### System malfunctions

Working with a malfunctioning system or not resolving errors can lead to patient injuries. Usually, malfunctions and errors are indicated by respective system messages [> 101].

- ► Take precautions to be able to finish a surgery even in the case of an occurring system malfunction.
- ▶ If in the course of a surgery a system message appears, solve the corresponding malfunction and confirm the message before continuing the surgery.
- ▶ If a malfunction occurs that cannot be solved following the instructions in the troubleshooting section [▶ 223], mark the system as non-functional and secure it against any further use. Continue the surgery with an alternative device.

## **⚠ WARNING!**

#### **Unexpected system settings**

If the active software settings are not checked before a surgery, it might not be detected that working parameters or the QUATERA FCP's key assignments are not set as expected. Calling a function with unexpected working parameters can lead to patient injury.

▶ Before each use, check the active software settings and the FCP key assignments.

## **⚠ WARNING!**

#### Immediate application of energy or pressure

If workflow steps or function parameters are changed via the touchscreen while the foot pedal is pressed or rotated, the changes made might be applied instantly.

- ▶ Before changing surgical functions or parameters via the touchscreen, check the current foot pedal position by the "Live Screen" menu's QUATERA FCP status indicator.
- ▶ Always make sure the changes to be made on the touchscreen are safe considering the current foot pedal position.

## **⚠ WARNING!**

#### Weak or absent irrigation

An obstructed or interrupted irrigation flow reduces the IOP and leads to chamber instability and injury to the patient.

- ▶ Before entering the eye, always test if an appropriate irrigation flow is given.
- ▶ Be careful not to kink the irrigation tube during the surgery.

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## **⚠ WARNING!**

#### **Empty infusion bottle**

An empty infusion bottle reduces the IOP and will lead to chamber instability and injury to the patient.

- ▶ Observe the infusion bottle during the surgery to make sure that it does not run out of BSS.
- ▶ If the infusion bottle is getting empty, interrupt the surgery and replace the bottle. Do not continue the surgery until the bottle change is completed.

## **⚠ WARNING!**

#### Full drainage bag

A full drainage bag of the QUATTRO CASSETTE will impede a proper functioning of the fluidic system and lead to patient injury.

- ▶ Observe the drainage bag during the surgery to make sure that the capacity of the QUATTRO CASSETTE and its drainage bag are not exceeded.
- ▶ If the drainage bag is getting full, interrupt the surgery and replace the cassette.

## **△ CAUTION!**

#### Imbalanced irrigation/aspiration

Air bubbles inside the irrigation tubing could result in imbalanced irrigation/aspiration settings. Operating on the patients eye with imbalanced settings can result in major injuries.

- ▶ Regularly check for air bubbles inside the irrigation tubing.
- ▶ If air bubbles are detected inside the irrigation tubing, remove the irrigation handpiece from the patients eye and activate just irrigation until the bubbles are removed, before reinserting the handpiece in the patient's eye.

## **△ CAUTION!**

#### Air in aspiration tubes

Air in aspiration tubes can impede a proper performance of the fluidic system.

- ▶ Always flush the handpiece before using it the first time.
- ► Avoid applying aspiration when the aspiration tip is not in the patient's eye.

## **⚠** CAUTION!

#### Leakage current

Leakage current might lead to patient injuries.

- ▶ Never touch the touchscreen while you are in contact with the patient.
- ▶ Never touch the power outlet while you are in contact with the patient.

Instructions for Use 7 Operation

QUATERA 700

## **⚠ CAUTION!**

#### **Inadequate IOP**

Not to verify and eventually adjust the patient's eye level before a surgery can lead to a too high or too low irrigation pressure which might injure the patient's eye.

▶ **Before every** surgery, control and adjust the patient eye level indicator to the actual level of the patient's eye.

## **⚠ CAUTION!**

#### Frozen display

When the display is frozen and performance parameters are changed via the QUATERA FCP, the current levels of pressure, vacuum, energy or vitrectomy cutting rate become non-transparent. Calling a function with unexpected working parameters can lead to patient injury.

- ► Frequently check the system time to make sure that the display is not frozen.
- ▶ If the display is frozen (clock has stopped), stop using the system, mark it as non-functional and secure it against any further use.

## 7.1 Configuring the working parameters

## 7.1.1 Selecting surgery steps

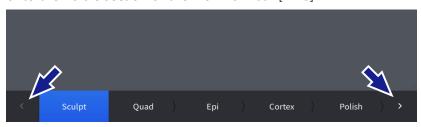
#### 7.1.1.1 Selecting surgery steps of a workflow

Surgery steps can be activated via touchscreen or the QUATERA FCP.

#### Selecting surgery steps via touchscreen

☑ The "Live Screen" menu [▶ 53] is opened.

1. If required, tap on the arrows to move the desired surgery step onto the visible section of the workflow bar [▶ 46].



2. Tap on the desired surgery step.



✓ The surgery step is activated and highlighted blue in the workflow bar.

#### Selecting surgery steps via QUATERA FCP

- ☑ QUATERA FCP keys have been assigned the functions "Next Surgery Step" and "Previous Surgery Step" [ 169].
- 1. To select the next surgery step of the workflow, tap on the QUATERA FCP key for "Next Surgery step".
  - ⇒ The next surgery step is activated and highlighted blue in the "Live Screen" menu's workflow bar.
- 2. To select the previous surgery step of the workflow, tap on the QUATERA FCP key for "Previous Surgery step".
  - ⇒ The previous surgery step is activated and highlighted blue in the "Live Screen" menu's workflow bar.

Prerequisite Action

Result

Prerequisite

#### 7.1.1.2 Selecting additional instruments steps

Parallel to each workflow the following additional instruments steps are available:

- "Anterior Vitrectomy"
- "Diathermy"

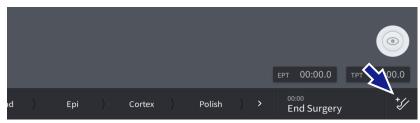
#### **Selecting additional instruments**

Prerequisite

Action

☑ The "Live Screen" menu [▶ 53] is opened.

1. In the "Live Screen" menu's footer [▶ 46], tap on the [Additional Instruments] button.



- ⇒ The workflow bar disappears and the available additional instruments are displayed instead.
- 2. Tap on the desired instrument.



✓ The instrument is selected and highlighted blue.

Prerequisite

Action

Result

#### **Unselecting additional instruments**

☑ The additional instruments are selected.

1. In the "Live Screen" menu's footer, tap on the [Additional Instruments] button.



✓ The additional instruments disappear and the workflow bar is displayed.

#### 7.1.2 Configuring the IOP settings

The IOP settings can be configured for all steps. The IOP can be adjusted within a range from 30 to 120 mmHg.

#### Adjusting the IOP via touchscreen

☐ The surgery step to be configured is active [▶ 178].

- 1. On the "Live Screen" menu [▶ 53], tap on the "Irrigation" tile.
  - ⇒ The "IOP" settings dialog opens.



- 2. Adjust the IOP continuously with the slider or stepwise with the +/- buttons.
- 3. Verify your settings by means of the value that is displayed in blue color, right above the slider button.
- 4. To close the dialog, tap on the "Live Video" section.
  - ⇒ The new preset IOP is saved and displayed on the "Irrigation" tile.

#### Adjusting the preset IOP via QUATERA FCP

- ☐ The surgery step to be configured is active [ 178].
- ☑ The "IOP +" and "IOP -" functions have been assigned to footswitch keys [▶ 169].
- 1. Actuate the respective footswitch keys to stepwise increase or decrease the preset IOP.
  - ⇒ The new preset IOP is saved and displayed on the "Irrigation" tile.

#### Information:

For custom users, any adaptions to the configuration can be saved as default for the selected workflow step. [> 195]

# Action

*Prerequisite* 

Prerequisite

# 7.1.3 Activating/deactivating continuous irrigation

With the "Continuous Irrigation" function activated, irrigation is also applied when the foot pedal is in its resting position. The function can be activated with the QUATERA FCP or on the touchscreen.

## Activating continuous irrigation via touchscreen

Prerequisite

Action

- ☐ The system has been completely prepared for operation [ 135].
- ✓ The patient eye level has been set [ 138].
- ☑ The "Live Screen" menu [ 53] is opened.
- 1. Tap on the "Irrigation" tile's "Continuous Irrigation" switch.
  - ⇒ The switch turns blue.
  - ⇒ Continuous irrigation is activated.



- Tap on the "Irrigation" tile's "Continuous Irrigation" switch.
  - $\Rightarrow$  The switch turns gray.
  - ⇒ Continuous irrigation is deactivated.

# Activating continuous irrigation via QUATERA FCP

Prerequisite

- ☐ The system has been completely prepared for operation [▶ 135].
- ☑ The patient eye level has been set [▶ 138].
- ☑ The "Continuous Irrigation Toggle" function is assigned to a footswitch key [> 169].
- Action 1. Press the respective footswitch key.
  - ⇒ The "Irrigation" tile's "Continuous Irrigation" switch turns blue.
  - ⇒ Continuous irrigation is activated.
  - 2. Press the respective footswitch key.
    - ⇒ The "Irrigation" tile's "Continuous Irrigation" switch turns gray.
    - ⇒ Continuous irrigation is deactivated.

# 7.1.4 Selecting the aspiration control mode

Prerequisite Action

- ☑ The surgery step to be configured is active [▶ 178].
- 1. On the "Live Screen" menu [▶ 53], tap on the "Vacuum" tile.
  - ⇒ The "Vacuum" settings dialog opens.
- 2. To set the aspiration control mode, tap on the respective part of the corresponding option button.



- ⇒ The selected option is highlighted blue.
- 3. To close the dialog, tap on the "Live Video" section.

## Information:

For custom users, any adaptions to the configuration can be saved as default for the selected workflow step [> 195].

Instructions for Use 7 Operation

# 7.1.5 Configuring the aspiration settings in the vacuum controlled mode

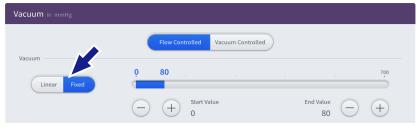
The aspiration settings can be configured for all steps but "Diathermy". The following settings can be configured:

- aspiration control mode [▶ 182]
- vacuum control mode
- vacuum pressure
- dynamic factor
- vacuum 2 activation status
- manual vacuum 2 control mode
- vacuum 2 pressure

# Adjusting the vacuum control mode

☑ The surgery step to be configured is active [▶ 178].

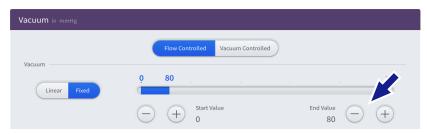
- 1. On the "Live Screen" menu [▶ 53], tap on the "Vacuum" tile.
  - ⇒ The "Vacuum" settings dialog opens.
- 2. To set the vacuum control mode, tap on the respective part of the corresponding option button.



- ⇒ The selected option is highlighted blue.
- 3. To close the dialog, tap on the "Live Video" section.

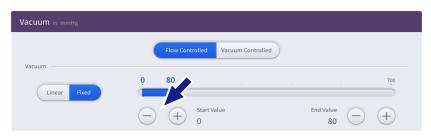
## Adjusting the vacuum pressure range via touchscreen

- ☑ The surgery step to be configured is active [▶ 178].
- On the "Live Screen" menu [▶ 53], tap on the "Vacuum" tile.
   ⇒ The "Vacuum" settings dialog opens.
- 2. Adjust the maximum vacuum pressure using the "End Value" +/- buttons.



 Adjust the minimum vacuum pressure using the "Start Value" +/buttons.

Prerequisite Action



- 4. Verify your settings by means of the values that are displayed in blue color, right above the slider.
- 5. To close the dialog, tap on the "Live Video" section.

# Adjusting the maximum vacuum pressure via QUATERA FCP

- ☐ The surgery step to be configured is active [▶ 178].
- ☑ The "Vacuum +" and "Vacuum -" functions have been assigned to footswitch keys.
- 1. Actuate the respective footswitch keys to stepwise increase or decrease the maximum vacuum pressure.
  - ⇒ The new maximum vacuum pressure is saved and displayed on the "Vacuum" tile.

# Adjusting the dynamic factor

- ☐ The surgery step to be configured is active [▶ 178].
- 1. On the "Live Screen" menu [ $\triangleright$  53], tap on the "Vacuum" tile.
  - ⇒ The "Vacuum" settings dialog opens.
- 2. Adjust the dynamic factor continuously with the slider or stepwise with the +/- buttons.



- 3. Verify your settings by means of the value that is displayed in blue color, right above the slider button.
- 4. To close the dialog, tap on the "Live Video" section.

Prerequisite

Action

Instructions for Use 7 Operation 7.1 Configuring the working parameters

QUATERA 700

## Adjusting the vacuum 2 activation status

**Prerequisite** 

- ☑ The surgery step to be configured is active [ 178].
- ☑ The vacuum 2 function is not assigned to yaw [▶ 169].
- 1. On the "Live Screen" menu [▶ 53], tap on the "Vacuum" tile. ⇒ The "Vacuum" settings dialog opens.
- 2. To set the vacuum 2 activation status, tap on the respective part of the corresponding option button.



- ⇒ The selected option is highlighted blue.
- 3. To close the dialog, tap on the "Live Video" section.

# Adjusting the manual vacuum 2 control mode

- ☑ The surgery step to be configured is active [▶ 178].
- ☑ The vacuum 2 function is assigned to yaw [ 169].
- 1. On the "Live Screen" menu [▶ 53], tap on the "Vacuum" tile. ⇒ The "Vacuum" settings dialog opens.
- 2. To set the vacuum 2 activation status, tap on the respective part of the corresponding option button.



- ⇒ The selected option is highlighted blue.
- 3. To close the dialog, tap on the "Live Video" section.

## Adjusting the vacuum 2 pressure

- ☑ The surgery step to be configured is active [▶ 178].
- 1. On the "Live Screen" menu [▶ 53], tap on the "Vacuum" tile. ⇒ The "Vacuum" settings dialog opens.
- 2. Adjust the vacuum 2 pressure continuously with the slider or stepwise with the +/- buttons.



Action

Prerequisite

Action

- 3. Verify your settings by means of the value that is displayed in blue color, right above the slider button.
- 4. To close the dialog, tap on the "Live Video" section.

#### Information:

For custom users, any adaptions to the configuration can be saved as default for the selected workflow step [> 195].

# 7.1.6 Configuring the aspiration settings in the flow controlled mode

The flow module is not active unless the aspiration control mode [> 88] is set to "Flow controlled".

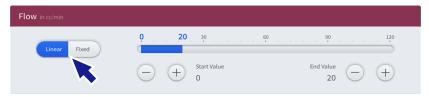
The aspiration settings can be configured for all but diathermy steps. The following settings can be configured:

- flow control mode
- flow rate

# Adjusting the flow control mode

☐ The surgery step to be configured is active [▶ 178].

- 1. On the "Live Screen" menu [> 53], tap on the "Flow" tile.
  - ⇒ The "Flow" settings dialog opens.
- 2. To set the flow control mode, tap on the respective part of the corresponding option button.



- ⇒ The selected option is highlighted blue.
- 3. To close the dialog, tap on the "Live Video" section.

## Adjusting the flow rate via touchscreen

☐ The surgery step to be configured is active [▶ 178].

- 1. On the "Live Screen" menu, tap on the "Flow" tile.
  - ⇒ The "Flow" settings dialog opens.
- 2. Adjust the maximum flow rate using the "End Value" +/- buttons.



3. Adjust the minimum flow rate using the "Start Value" +/- buttons.

Prerequisite Action

Prerequisite



- 4. Verify your settings by means of the values that are displayed in blue color, right above the slider.
- 5. To close the dialog, tap on the "Live Video" section.

# Adjusting the flow rate via QUATERA FCP

- ☑ The surgery step to be configured is active [▶ 178].
- ☑ The "Flow +" and "Flow -" functions have been assigned to footswitch keys [▶ 169].
- 1. Actuate the respective footswitch keys to stepwise increase or decrease the maximum volume flow rate.
  - ⇒ The new maximum volume flow rate is saved and displayed on the "Flow" tile.

## Information:

For custom users, any adaptions to the configuration can be saved as default for the selected workflow step [> 195].

Prerequisite

# 7.1.7 Configuring the U/S settings

The U/S settings can be configured for all phacoemulsification and phacofragmentation steps. The following working parameters can be configured:

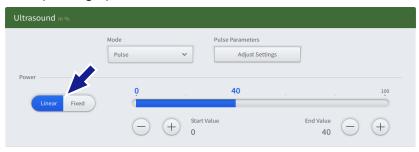
- U/S control mode
- U/S power range
- U/S operation mode

Additional settings related to the U/S operation mode can be configured on special subordinate dialogs.

## Adjusting the U/S control mode

☐ The surgery step to be configured is active [ 178].

- 1. On the "Live Screen" menu [ $\triangleright$  53], tap on the "Ultrasound" tile.
  - ⇒ The "Ultrasound" settings dialog opens.
- 2. To set the U/S control mode, tap on the respective part of the corresponding option button.

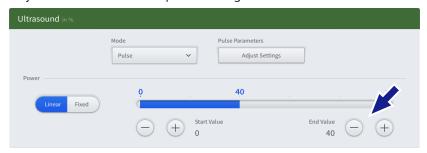


- ⇒ The selected option is highlighted blue.
- 3. To close the dialog, tap on the "Live Video" section.

## Adjusting the U/S power range via touchscreen

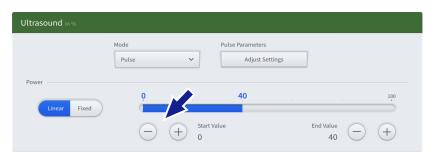
☑ The surgery step to be configured is active [▶ 178].

- On the "Live Screen" menu [▶ 53], tap on the "Ultrasound" tile.
   ⇒ The "Ultrasound" settings dialog opens.
- 2. Adjust the maximum U/S power using the "End Value" +/- buttons.



3. Adjust the minimum U/S power using the "Start Value" +/-buttons.

Prerequisite Action



- 4. Adjust the minimum U/S power continuously by dragging the active slider button, or stepwise using the +/- buttons.
- 5. Verify your settings by means of the values that are displayed in blue color, right above the slider.
- 6. To close the dialog, tap on the "Live Video" section.

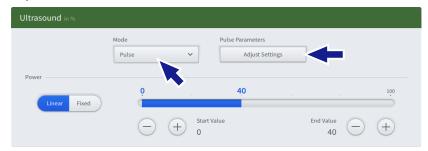
## Adjusting the maximum U/S power via QUATERA FCP

- ☑ The surgery step to be configured is active [▶ 178].
- ☑ The "U/S +" and "U/S -" functions have been assigned to footswitch keys [▶ 169].
- 1. Actuate the respective footswitch keys to stepwise increase or decrease the maximum U/S power.
  - ⇒ The new maximum U/S power is saved and displayed on the "Ultrasound" tile.

## Adjusting the U/S operation mode

☑ The surgery step to be configured is active [ 178].

- On the "Live Screen" menu [▶ 53], tap on the "Ultrasound" tile.
   ⇒ The "Ultrasound" settings dialog opens.
- 2. Tap on the "Mode" selection field.



- $\Rightarrow$  A drop-down menu with the available U/S operation mode opens.
- 3. Select the desired operation mode from the drop-down menu.
  - ⇒ An additional button might appear to open the settings for the selected operation mode.
- 4. If required, tap on the button and adjust the respective operation mode settings (see below).
- 5. To close the dialog, tap on the "Live Video" section.

Prerequisite

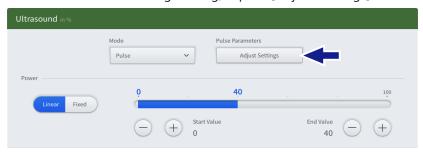
Action

## Adjusting the operation mode settings

Depending on the operation mode, additional settings such as the "On" and "Off" times, the duty cycle or the pulse rate etc. can be adjusted to meet the individual demands of the surgeon or the requirements imposed by the surgery situation.

The pulse mode settings can be adjusted for the following U/S operation modes:

- Pulse
- Single Burst
- Multi Burst
- Continuous Burst
- ☑ The "Ultrasound" settings dialog is opened.
- ☑ The desired operation mode is selected on the "Mode" selection field.
- 1. In the "Ultrasound" settings dialog, tap on [Adjust Settings].



- ⇒ The operation mode's settings dialog opens.
- 2. Adjust the operation mode settings continuously by dragging the slider buttons, or stepwise using the +/- buttons.



3. Tap on [Done] to save the settings and return to the "Ultrasound" settings dialog.

## Information:

For custom users, any adaptions to the configuration can be saved as default for the selected workflow step [> 195].

Prerequisite

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# 7.1.8 Configuring the cutter settings

The cutter settings can be adjusted for the "Anterior Vitrectomy" [> 95] step. The following settings can be configured:

- cutter control mode
- cutting rate
- cut mode

# Adjusting the cutter control mode

☑ The surgery step to be configured is active [▶ 178].

- 1. On the "Live Screen" menu [▶ 53], tap on the "Cutter" tile.
  - ⇒ The "Cutter" settings dialog opens.
- 2. To set the cutter control mode, tap on the respective part of the corresponding option button.

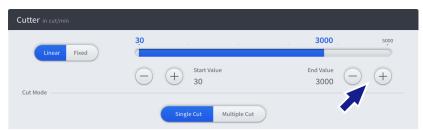


- ⇒ The selected option is highlighted blue.
- 3. To close the dialog, tap on the "Live Video" section.

# Adjusting the cutting rate

☑ The surgery step to be configured is active [▶ 178].

- On the "Live Screen" menu [▶ 53], tap on the "Cutter" tile.
   ⇒ The "Cutter" settings dialog opens.
- 2. Adjust the maximum cutting rate using the "End Value" +/- buttons.



 Adjust the minimum cutting rate using the "Start Value" +/buttons.



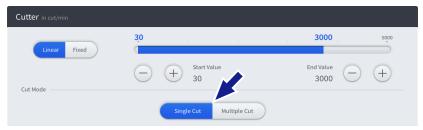
Prerequisite Action

- 4. Verify your settings by means of the values that are displayed in blue color, right above the slider.
- 5. To close the dialog, tap on the "Live Video" section.

## Adjusting the cut mode

Prerequisite Action

- ☑ The surgery step to be configured is active [▶ 178].
- 1. On the "Live Screen" menu [ $\triangleright$  53], tap on the "Cutter" tile.
  - ⇒ The "Cutter" settings dialog opens.
- 2. To set the cut mode, tap on the respective part of the corresponding option button.



- ⇒ The selected option is highlighted blue.
- 3. To close the dialog, tap on the "Live Video" section.

#### Information:

For custom users, any adaptions to the configuration can be saved as default for the selected workflow step [> 195].

# 7.1.9 Configuring the diathermy settings

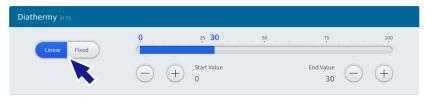
In the surgery step "Diathermy" the following diathermy pre-settings can be configured:

- diathermy control mode
- diathermy power

# Adjusting the diathermy control mode

☑ The surgery step to be configured is active [▶ 178].

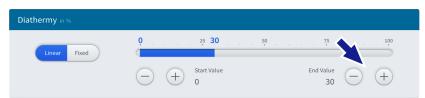
- On the "Live Screen" menu [▶ 53], tap on the "Diathermy" tile.
   ⇒ The "Diathermy" settings dialog opens.
- 2. To set the diathermy control mode, tap on the respective part of the corresponding option button.



- ⇒ The selected option is highlighted blue.
- 3. To close the dialog, tap on the "Live Video" section.

# Adjusting the diathermy power via touchscreen

- ☑ The surgery step to be configured is active [▶ 178].
- On the "Live Screen" menu [▶ 53], tap on the "Diathermy" tile.
   ⇒ The "Diathermy" settings dialog opens.
- 2. Adjust the maximum diathermy power using the "End Value" +/-buttons.



3. Adjust the maximum diathermy power using the "End Value" +/- buttons.



- 4. Verify your settings by means of the values that are displayed in blue color, right above the slider.
- 5. To close the dialog, tap on the "Live Video" section.

Prerequisite Action

# Adjusting the maximum diathermy power via QUATERA FCP

Prerequisite

- ☑ The surgery step to be configured is active [▶ 178].
- ☑ The "Diathermy +" and "Diathermy -" functions have been assigned to footswitch keys.
- 1. Actuate the respective footswitch keys to stepwise increase or decrease the maximum diathermy power.
  - ⇒ The new maximum diathermy power is saved and displayed on the "Diathermy" tile.

## Information:

For custom users, any adaptions to the configuration can be saved as default for the selected workflow step [> 195].

# 7.1.10 Saving modified values as default

#### Information:

The information of this section is not applicable unless a custom user is active. Permanently saving adapted function settings is not possible for the "Default User" and the "Administrator".

After having changed any values, a symbol (circle of two arrows) on the "Live Screen" menu's [> 53] respective tile indicates that the current settings deviate from the default settings of the current workflow step (in the current workflow of the current user). The new settings can be saved as default for the workflow step.

- $\square$  A custom user is active.
- ☑ The surgery step to be configured is active [▶ 178].
- 1. To save the new values as default, tap on the [Set to Default] button in the footer bar.



- ⇒ The [Set to Default] button changes to a check. The symbol on the tile disappears.
- ⇒ The settings are saved as default for the selected workflow step.

Prerequisite

# 7.2 Replacing the infusion bottle

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! If the infusion bottle's quantity of BSS is not sufficient for the entire operation, the bottle must be replaced.

# **△ CAUTION!**

# Injury to the patient's eye due to air bubbles in the infusion tubing or irrigation tubing!

Unbalanced irrigation/aspiration settings appear.

- ▶ If air bubbles are observed activate irrigation to remove the bubbles out before reinserting the surgical instrument tip in the eye of the patient.
- 1. Interrupt the surgical procedure and remove the tip of the surgical instrument from the incision.
- 2. Close the clamp on the infusion set in order to prevent an unintentional flow of BSS.
- 3. Unhook the near-empty infusion bottle from its support.
- 4. Take the infusion set's spike out of the bottle.
- 5. Insert the infusion set's spike in the cap of the new infusion bottle and hook the bottle to the support.
- 6. Open the clamp at the infusion set in order to produce the flow again.
- 7. In the "Setup" menu, tap on [Change Bottle].



Prerequisite

**Action** 

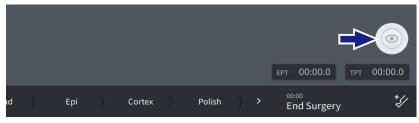
# 7.3 Activating the "Live Video" function

The "Live Video" function enables the large-scale display of a connected surgical microscope's image.

☑ A video connection to a microscope is established [▶ 114].

☑ The "Live Screen" menu [▶ 53] is opened.

1. Tap on the [Live Video] button.



Result

✓ The live video is displayed.

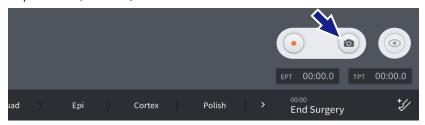
# 7.4 Activating image or video acquisition

# Acquiring an image

Prerequisite

**Action** 

- ☑ The CALLISTO eye connection is enabled [▶ 119].
- ☑ The "Live Screen" menu [▶ 53] is opened.
- 1. Tap on the [Camera] button.



⇒ The image is captured and saved to CALLISTO eye.

# Acquiring a video

Prerequisite

Action

- ☑ The CALLISTO eye connection is enabled [▶ 119].
- ☑ The "Live Screen" menu [▶ 53] is opened.
- 1. Tap on the [Record] button.



- $\Rightarrow$  The video acquisition starts.
- 2. Tap on the [Record] button.



⇒ The video acquisition stops and the video is saved to CALLISTO eye.

# 7.5 Performing "Sculpt", "Phaco Aspiration", "Quad", "Chop" or "Epi"

This section gives exemplary instructions on the activation of surgical functions according to the default pitch assignments for the cataract steps "Sculpt", "Phaco Aspiration", "Quad", "Chop" and "Epi" [▶ 105]. The procedure shows the principle of the user/system interaction, but it can be modified, e.g. by applying different QUATERA FCP key assignments.

# **⚠ WARNING!**

## **Excessive IOP**

Too high and enduring irrigation pressure may lead to injuries.

▶ Limit the level of intraocular pressure to the level needed for the specific surgery [▶ 180].

# **⚠ WARNING!**

## **Excessive U/S power emission**

Too high and enduring U/S power emission may lead to corneal burns.

- ► Limit the level of U/S power to the level needed for the specific surgery [▶ 188].
- ► Make sure the I/A flow is sufficient to properly dissipate the heat that occurs during U/S power emission.
- ▶ If unsure, start with a low value and increase the U/S power as required, while observing the effects.

# **⚠ WARNING!**

## Tissue damage due to U/S exposure

Prolonged exposure to or direct contact with the vibrating tip may cause damage to healthy tissue.

- ▶ Be careful not to expose non-lens tissue, such as iris or capsule, to U/S power.
- ▶ Do not check the vibration by placing hand or finger against the handpiece tip or sleeve.

# **⚠ WARNING!**

## Accidental release of metal particles

Inadvertently touching second instruments with the phaco handpiece's running tip may set free metal particles, which could injure the patient.

▶ Be careful not to touch second instruments with the running phaco tip.

## NOTE

## Dry running handpiece

Activating U/S emission when the phaco handpiece's tip is not immersed in BSS and not in surgical use can damage the handpiece and the tip.

▶ Do not activate U/S emission when the handpiece's tip is not immersed in BSS and is not in surgical use.

# **NOTE**

# Piezo damage due to quenching

Quenching the hot phaco handpiece in water can irreversibly damage the handpiece's piezo elements.

- ▶ Do not quench a hot handpiece in water.
- ▶ Let the handpiece cool down in room air.

## Prerequisite

- ☐ The IOP settings have been configured as required. [▶ 180]
- ☑ The aspiration settings (vacuum [▶ 183] or flow [▶ 186]) have been configured as required.
- ☐ The U/S settings have been configured as required. [▶ 188]
- ☐ The system has been completely prepared for operation. [▶ 135]
- ☐ The patient eye level has been set [ 138].
- ☑ The workflow steps "Sculpt", "Phaco Aspiration", "Quad", "Chop" or "Epi" are activated. [▶ 178]
- 1. Depress the foot pedal into zone 1.
  - ⇒ The system plays an audio signal. The irrigation starts and increases the deeper the pedal is pressed.
- 2. Depress the foot pedal into zone 2.
  - ⇒ The aspiration starts and increases the deeper the pedal is pressed.
  - ⇒ The irrigation increases to maintain the preset IOP.
- 3. Depress the foot pedal into zone 3.
  - ⇒ The U/S emission starts and increases up to the preset maximum, the deeper the pedal is pressed.
  - ⇒ The aspiration increases up to the preset maximum, the deeper the pedal is pressed.
  - ⇒ The irrigation increases to maintain the preset IOP.
- 4. Release the foot pedal into zone 2.
  - ⇒ The system plays an audio signal. The U/S emission stops.
  - $\Rightarrow$  The aspiration decreases until the foot pedal is in zone 1.
  - ⇒ The irrigation decreases to maintain the preset IOP.

7.5 Performing "Sculpt", "Phaco Aspiration", "Quad", "Chop" or "Epi"

- 5. Release the foot pedal into zone 1.
  - ⇒ The vacuum is released from the aspiration tube (venting) and the aspiration stops.
  - ⇒ The irrigation decreases until the foot pedal is in its resting position.
- 6. Completely release the foot pedal.
  - $\Rightarrow$  The irrigation stops.
  - ⇒ The system plays an audio signal when irrigation has stopped.

# 7.6 Performing "Cortex", "Polish", "Visco" or "Z Align"

This section gives exemplary instructions on the activation of surgical functions according to the default pitch assignments for the cataract steps "Cortex", "Polish", "Visco" or the CALLISTO eye surgery step "Z Align" [▶ 105]. The procedure shows the principle of the user/system interaction, but it can be modified, e.g. by applying different QUATERA FCP key assignments.

# **⚠ WARNING!**

## **Excessive IOP**

Too high and enduring irrigation pressure may lead to injuries.

▶ Limit the level of intraocular pressure to the level needed for the specific surgery [▶ 180].

*Prerequisite* 

- ☐ The IOP settings have been configured as required. [▶ 180]
- ☑ The aspiration settings (vacuum [▶ 183] or flow [▶ 186]) have been configured as required.
- ☐ The system has been completely prepared for operation. [▶ 135]
- ☐ The patient eye level has been set. [▶ 138]
- ☑ The workflow steps "Cortex", "Polish", "Visco" or "Z Align" are activated. [▶ 178]
- 1. Depress the foot pedal into zone 1.
  - ⇒ The system plays an audio signal. The irrigation starts and increases the deeper the pedal is pressed.
- 2. Depress the foot pedal into zone 2.
  - ⇒ The aspiration starts and increases up to the preset maximum, the deeper the pedal is pressed. A continuous audio feedback informs about the vacuum intensity level.
  - ⇒ The irrigation increases to maintain the preset IOP.
- 3. Release the foot pedal into zone 1.
  - ⇒ The vacuum is released from the aspiration tube (venting) and the aspiration stops.
  - ⇒ The irrigation decreases until the foot pedal is in its resting position.
- 4. Completely release the foot pedal.
  - $\Rightarrow$  The irrigation stops.
  - ⇒ The system plays an audio signal when irrigation has stopped.

7.7 Performing "Incision", "Rhexis" or "LRI"

# 7.7 Performing "Incision", "Rhexis" or "LRI"

This section gives exemplary instructions on the activation of surgical functions according to the default pitch assignments for the CALLISTO eye surgery steps "Incision", "Rhexis" or "LRI" [> 105]. The procedure shows the principle of the user/system interaction, but it can be modified, e.g. by applying different QUATERA FCP key assignments.

- ☐ The IOP settings have been configured as required. [▶ 180]
- ☐ The system has been completely prepared for operation. [▶ 135]
- ☑ The patient eye level has been set. [▶ 138]
- ☑ The workflow steps "Incision", "Rhexis" or "LRI" are activated. [▶ 178]
- 1. Depress the foot pedal into zone 1.
  - ⇒ The system plays an audio signal. The irrigation starts and increases the deeper the pedal is pressed.
- 2. Completely release the foot pedal.
  - $\Rightarrow$  The irrigation stops.
  - ⇒ The system plays an audio signal when irrigation has stopped.

Prerequisite

# 7.8 Performing "Anterior Vitrectomy"

This section gives exemplary instructions on the activation of surgical functions according to the default pitch assignments for the emergency cataract step "Anterior Vitrectomy" [> 105]. The procedure shows the principle of the user/system interaction, but it can be modified, e.g. by applying different QUATERA FCP key assignments.

# **⚠ WARNING!**

#### **Excessive IOP**

Too high and enduring irrigation pressure may lead to injuries.

▶ Limit the level of intraocular pressure to the level needed for the specific surgery [▶ 180].

# **⚠ WARNING!**

#### Limited IOP surveillance

During vitrectomy, a constant IOP is not maintained over the entire vacuum pressure range. A reduced IOP can lead to chamber instability and injury to the patient.

- ▶ Do not apply excessive vacuum pressure.
- ▶ Observe the IOP and adapt the applied vacuum pressure, if necessary.

# **⚠ WARNING!**

# Non-filtered air entering the patient's eye

Non-filtered air might enter into the patient's eye if vitrectomy is activated with no or an incorrectly connected probe.

- ▶ Do not activate the vitrectomy function if no cutter is connected to the system.
- ▶ Do not use a vitrectomy cutter without having it primed first [▶ 149].

# **⚠ WARNING!**

## **Defective cutter**

Using a defective cutter can lead to serious injuries to the patient's eye.

- ▶ Before use, immerse the cutter tip into a bowl of BSS (e.g. the vitrectomy handpiece's priming blister) and visually check the cutter's functioning at a low cutting rate.
- ▶ Do not use the cutter if its opening does not close completely.
- ▶ Do not use the cutter if its opening is partly closed in idle state.
- ▶ If a reduction of cutting capability or vacuum is observed during the use of the cutter in the surgical procedure, immediately stop cutting and replace the cutter.

Prerequisite

7 Operation

# **⚠** CAUTION!

## Dry running cutter

Activating vitrectomy when the cutter is not immersed in BSS and not in surgical use can damage the handpiece and set free metal particles, which might enter the patient's eye.

- ▶ Do not activate vitrectomy when the cutter is not immersed in BSS and is not in surgical use.
- ☐ The IOP settings have been configured as required. [▶ 180]
- ☐ The aspiration settings (vacuum [▶ 183] or flow [▶ 186]) have been configured as required.
- ☐ The diathermy settings have been configured as required. [▶ 193]
- ☐ The system has been completely prepared for operation. [▶ 135]
- ☑ The patient eye level has been set [▶ 138].
- ☑ The cut mode is set to "Multiple Cut" [> 191].
- ☐ The workflow step "Anterior Vitrectomy" is activated. [▶ 179]
- 1. Depress the foot pedal into zone 1.
  - ⇒ The system plays an audio signal. The irrigation starts and increases the deeper the pedal is pressed.
- 2. Depress the foot pedal into zone 2.
  - ⇒ The aspiration starts and increases up to the preset maximum, the deeper the pedal is pressed. A continuous audio feedback informs about the vacuum intensity level.
  - ⇒ The irrigation increases to maintain the preset IOP.
- 3. Rotate the foot pedal in direction of the outer yaw position.
  - ⇒ The cutter starts and increases the cutting rate up to the preset maximum, the further the pedal is rotated.
- 4. Release the pedal into the central yaw position.
  - $\Rightarrow$  The cutter stops.
- 5. Release the foot pedal into zone 1.
  - ⇒ The vacuum is released from the aspiration tube (venting) and the aspiration stops.
  - ⇒ The irrigation decreases until the foot pedal is in its resting position.
- 6. Completely release the foot pedal.
  - $\Rightarrow$  The irrigation stops.
  - ⇒ The system plays an audio signal when irrigation has stopped.

QUATERA 700

# 7.9 Performing "Diathermy"

This section gives exemplary instructions on the activation of surgical functions according to the default pitch assignments for the emergency cataract step "Diathermy" [> 105]. The procedure shows the principle of the user/system interaction, but it can be modified, e.g. by applying different QUATERA FCP key assignments.

# **⚠ WARNING!**

## Interference with high-frequency devices

The diathermy section of QUATERA 700 can impair the function of other devices.

- ▶ Prior to using it in combination with other devices creating highfrequency waves or high voltages, check the effects of the QUATERA 700's diathermy function on those devices and vice versa.
- ▶ Install the devices in such a way that the disturbances caused by high-frequency waves are minimized.

# **⚠ WARNING!**

## Increased output power

Malfunction of the diathermy handpiece can lead to an unwanted increase of diathermy power.

- ▶ Before using the diathermy function, make sure that interference with adjacent devices creating high-frequency waves or high voltages can be excluded.
- ▶ Check the function of the diathermy handpiece before using it.

# **⚠ WARNING!**

#### Interference with cardiac stimulators

Using the device on patients with a cardiac pacemaker or other cardiac stimulators can lead to patient injuries.

▶ Do not use the diathermy section of QUATERA 700 on patients with a pacemaker or other cardiac stimulators without prior consultation of a cardiologist.

# **⚠ WARNING!**

## Interference with monitoring systems

When a bipolar diathermy probe is used at the same time with a monitoring system with electrodes that are not protected by resistors or high frequency inductors, the monitoring system's measurement results can be distorted and the monitoring system can be damaged.

▶ Place all electrodes of the monitoring system that are not protected by resistors or high frequency inductors as far away as possible from the diathermy electrodes.

Instructions for Use 7 Operation

QUATERA 700 7.9 Performing "Diathermy"

# **⚠ CAUTION!**

## Contact to live parts

Contact to live parts can lead to injuries.

- ▶ Make sure that the cable connecting the diathermy handpiece to the system does not come into contact with either the patient or any other cables before treatment.
- ▶ Place active electrodes, which are currently not in use, at a location that is isolated from the patient.

# **↑** CAUTION!

# Too low diathermy power

Too low diathermy power applied can lead to injuries to the patient.

► Adapt and limit the diathermy power to the level needed for the specific surgery.

Prerequisite

- ☐ The diathermy settings have been configured as required. [▶ 193]
- ☑ The system has been completely prepared for operation. [▶ 135]
- ☑ The workflow step "Diathermy" is activated. [▶ 179]

- 1. Depress the foot pedal into zone 2.
  - ⇒ The diathermy power emission starts and increases up to the preset maximum, the deeper the pedal is pressed. A continuous audio feedback informs about the diathermy intensity level.
- 2. Release the foot pedal into zone 1.
  - ⇒ The diathermy power emission stops.

Empty page, for your notes

# 8 After use

# 8.1 Removing QUATTRO CASSETTE

The QUATTRO CASSETTE must be removed when its draining bag is full or when the surgery has been finished.

☑ The accessories are disconnected from the cassette.

Action

Prerequisite

1. Short circuit the I/A tubing by connecting the connectors of the twin tube.



2. Grab the QUATTRO CASSETTE's handgrip and push the upper clamp of the system's cassette interface upwards with your thumb.



3. Tilt the cassette's upper edge away from the system and remove the cassette from the cassette slot.



QUATERA 700

# 8.2 Powering the system down

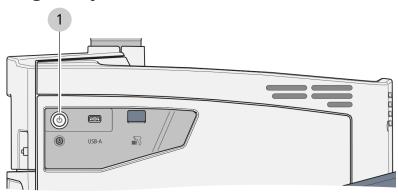


Figure 58: Side panel

- 1 [Device Power on/off] operating button
- 1. Press the [Device Power on/off] operating button.
  - ⇒ The system enters the "power off" state [ 41].

# Information:

Due to its battery buffer, the system is still not de-energized, even after the power supply has been disconnected.

Instructions for Use 8 After use

QUATERA 700

8.3 Charging the QUATERA FCP

# 8.3 Charging the QUATERA FCP

Provided that the system is not in its **power off** state [> 41] and that the [Battery disconnect] switch [> 43] is set to **On**, the QUATERA FCP can be charged wirelessly, when not in use. The respective charging pins are located on the QUATERA FCP holder.

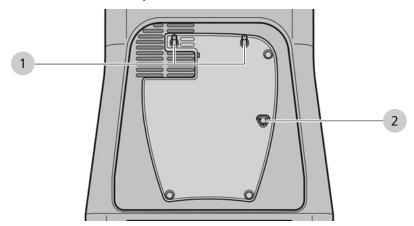


Figure 59: QUATERA FCP holder

1	QUATERA FCP holding pins	2	QUATERA FCP charging pins
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- I. Take up the QUATERA FCP by its handle.
- Attach the QUATERA FCP bottom-first to the system's QUATERA FCP holder, matching the system's holding pins to the corresponding recesses in the QUATERA FCP.
  - ⇒ The system's charging pins snap in on the QUATERA FCP bottom.

QUATERA 700

# 8.4 Folding in the console tray

# **⚠ CAUTION!**

## Hazard of finger crushing

Careless handling of the console tray can result in injuries.

- ▶ Always act very carefully when handling the console tray.
- ▶ Do not touch the area around hinges of the console tray, including its support arm.

# **⚠** 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 5 kg.
- 1. If required, push the metal bracket back into the console tray.
- 2. From in front of the system, grab the console tray's anterior handgrip, located at the underside of the tray, and pull it towards you.
- 3. Hold the handgrip and gently push the tray downwards until the mechanical end stop. Then release the handgrip.
- 4. Grab the lateral handgrips at the underside of the tray and gently pull them outwards.
  - ⇒ The mechanism that locks the tray in its horizontal position is released.
- 5. Carefully swivel the console tray down into its vertical position.
- 6. Push the tray against the system so the support arm folds completely and the tray snaps in to the magnet in the tray base.

# 8.5 Bringing the system into transport position

## **NOTE**

## Wrong handling

Tilting the monitor or the bottle holder down to their transport position when the touchscreen is not facing to the back of the device might damage the system.

- ▶ Do not loosen the monitor fixation pin as long as the touchscreen is not facing to the back of the device.
- ▶ Do not tilt the bottle holder while the monitor is in its normal position.

## Prerequisite

- ☑ The touchscreen monitor and the bottle holder are in their normal position.
- ☑ All caster brakes are locked.
- ☑ The console tray is folded in [ ≥ 212].

- 1. From in front of the system, turn the monitor by 180° in counterclockwise direction around its vertical rotation axis.
  - ⇒ The touchscreen points to the system's back.
- 2. **CAUTION!** The pin might bruise fingers if it is carelessly grabbed. From in front of the system, pull the monitor fixation pin to the left.
  - ⇒ The monitor's tilt axis is released.
- 3. Carefully tilt the monitor to the system's back (with the touch-screen face-down) until the mechanical end stop.
- 4. **CAUTION!** The pin might bruise fingers if it is carelessly grabbed. From in front of the system, pull the bottle holder fixation pin downwards.
  - ⇒ The bottle holder's tilt axis is released.
- 5. Tilt the bottle holder to the system's back until the mechanical end stop.

8.6 Moving the system

# 8.6 Moving the system

# **NOTE**

## Transport damage

The monitor suspension might suffer from damage by vibration if the system is transported in its normal position.

▶ Always bring the system into transport position before transporting or storing it outside the OR.

Prerequisite

- ☑ The touchscreen monitor and the bottle holder are in transport position [> 213].
- ☑ The console tray is folded in [ ≥ 212].

- 1. NOTE! The system might tip over if it is pushed with the caster brakes locked. Grab the system's handgrip and unlock all casters' locking tabs.
- 2. NOTE! The system might tip over if it is pushed, especially when passing thresholds etc. Pull the system on its handgrip to the designated location.
- 3. Press down the locking tabs of at least 2 casters.
- 4. Gently push and pull on the handgrip to verify that the system stands safe.

# 9 Cleaning and disinfection

#### Information:

The current section provides information on how to clean and disinfect the system. For information on how to clean and disinfect reprocessable accessories, please consult the document G-30-2070 or the accessory's respective Instructions for Use.

# **⚠** CAUTION!

# Contact to live parts

Liquid-mediated or direct contact to live parts can lead to electric shocks and injuries.

➤ Switch off the system and disconnect it from the mains supply before starting to clean and disinfect the system.

# NOTE

# **Incompatible agents**

Applying abrasive, corrosive or otherwise incompatible cleaning and disinfection agents may damage the system.

- ► Clean the system and its components only with agents listed as compatible in this document.
- ▶ Do not clean or disinfect the system and its components with cleaning agents that are not compatible with plastic parts.

## NOTE

## Penetrating moisture

Moisture penetrating the system can lead to malfunctions and damages.

- ▶ Prevent any moisture from entering the system or its components.
- ▶ Do not spray any liquids onto the system or even into its ventilation openings.

## **NOTE**

## Piezo damage due to quenching

Quenching the hot phaco handpiece in water can irreversibly damage the handpiece's piezo elements.

- ▶ Do not quench a hot handpiece in water.
- ▶ Let the handpiece cool down in room air.

# 9.1 Cleaning and disinfection schedule

The system and its components must be cleaned and disinfected in the following turns:

- according to your hospital's specified routines
- at least once every day at the end of the day's surgery schedule
- whenever necessary to keep up the patient's and the personnel's safety as well as the system's proper functioning

# 9.2 Cleaning

# **⚠** CAUTION!

## Debris on contacts and operating parts

Debris and liquid residues on operating elements and contacts may cause malfunctions of the respective control and connection elements.

- ► Comply with the applicable schedule for cleaning the system and its components.
- ▶ While operating the device, permanently observe if there are any delays or deficient functions that could be related to debris on contact surfaces.
- ▶ If required, remove debris (e.g. liquids as BSS around the handpiece connectors) immediately.
- ▶ Apply measures to protect the system and its components against being soiled when they are not in use.

# 9.2.1 Cleaning the touchscreen

Tools	■ Soft cloth (e.g. towel)
Consumables	■ Mild window cleaner

- $\square$  The system is switched off.
- 1. Apply window cleaner to the cloth.
- 2. Wipe down the touchscreen with the cloth.

QUATERA 700 9.2 Cleaning

# 9.2.2 Cleaning the console

Tools	■ Cloth
Consumables	<ul> <li>Cleaning mixture of mild soap, distilled water and, if required, alcohol at a share of maximum 60 %</li> </ul>

### Prerequisite

Action

- ☑ The BSS bottle is removed from the bottle holder.
- ☐ The QUATTRO CASSETTE is removed from the system [ ≥ 209].
- ☑ The system is switched off, disconnected from the mains supply and the [Battery disconnect] switch is set to Off.
- ☑ The QUATERA FCP is disconnected from the system.

- 1. Moisten the cloth with cleaning mixture. Do not soak the cloth.
- 2. If required, wipe down the bottle holder.
- 3. If required, wipe down the monitor's rear panel.
- 4. Wipe down all required surfaces on the console, beginning from the top and ending at the bottom.

### 9.2.3 Cleaning the QUATERA FCP

Tools	■ Cloth
Consumables	<ul> <li>Cleaning mixture of mild soap, distilled water and, if required, alcohol at a share of maximum 60 %</li> </ul>

# Prerequisite Action

- ☑ The QUATERA FCP is disconnected from the system.
- Moisten the cloth with cleaning mixture. Do not soak the cloth.
- 2. Wipe down the QUATERA FCP's bottom cover.
- Conscientiously wipe down the area under the foot pedal.

### 9.3 Disinfection

### 9.3.1 Disinfection agents

The maximum application concentrations of disinfection agents are:

- for alcohol (tested with isopropyl alcohol): 60 %
- for aldehyde (tested with glutaraldehyde): 2 %
- for quaternary compounds (tested with DDAC): 0.2 %

To achieve maximum disinfection, disinfectants with an alcohol concentration higher than 70 % can be used. There is a chance that long-term use of such disinfectants may cause the device's surfaces to become dull or matte, or may loosen the adhesive labels on the device without causing them to fall off. However, the use of such disinfectants will never impair device performance or endanger patients.

### **NOTE**

### Surface damage caused by wrong disinfectants!

Performing disinfection with the wrong disinfectants may result in damage to the surfaces of the system.

- ▶ Use an aldehyde and/or alcohol-based disinfectant. The addition of quaternary compounds is acceptable.
- ▶ In order to prevent surface tensions, you may only use the disinfecting components specified above.

## 9.3.2 Disinfecting the system

Tools	■ Cloth
Consumables	■ Disinfection agent

### Prerequisite

- ☑ The BSS bottle is removed from the bottle holder.
- ☑ The QUATTRO CASSETTE is removed from the system.
- ☑ The system is switched off, disconnected from the mains supply and the [Battery disconnect] switch is set to **Off**.
- 1. Moisten the cloth with cleaning mixture. Do not soak the cloth.
- 2. Wipe down all surfaces to be disinfected.

Action

# 10 Maintenance

# 10.1 Maintenance schedule for the operator

# 10.1.1 Without regular maintenance intervals

Component	Task
Electromagnetic compatibility (EMC)	► No regular inspections or maintenance are required in order to maintain electromagnetic compatibility.

# 10.1.2 According to country-specific regulations

Component	Task
Safety inspection	<ul> <li>Checking the device and electrical safety</li> </ul>

### 10.2 Maintenance schedule for the authorized service

### 10.2.1 After commissioning and servicing

Component	Task	
Entire system	► Perform a system safety inspection according to IEC 62353. [▶ 221]	

### 10.2.2 Every two years

# **⚠ CAUTION!**

### **Unauthorized servicing**

Opening or servicing the system by personnel that is not adequately trained and is not authorized by ZEISS can lead to damage and personal injury. Opening the system will void the warranty.

- ▶ Do not try to service the system or any system parts yourself.
- ► Have the system serviced by ZEISS Service or an expert authorized by ZEISS.

Component	Task	
QUATERA FCP	► Replace the battery pack.	
	► Replace the side button rubber covers.	
Power supply	► Replace the batteries	
Air dryer	► Replace the air dryer.	
Software	▶ Update the system software to the latest version.	
	Action	
	▶ Update all component's firmware to the latest version.	
Entire system	► Check the log files for errors.	
	► Check all mechanical interfaces for proper functioning.	
	► Perform a system safety inspection according to IEC 62353. [▶ 221]	

### 10.2.3 Every four years

# **⚠** CAUTION!

### **Unauthorized servicing**

Opening or servicing the system by personnel that is not adequately trained and is not authorized by ZEISS can lead to damage and personal injury. Opening the system will void the warranty.

- ▶ Do not try to service the system or any system parts yourself.
- ► Have the system serviced by ZEISS Service or an expert authorized by ZEISS.

The following tasks have to be performed **additionally** every fourth year.

Component	Task
PC	► Replace the PC battery.

# 10.3 Performing a system safety inspection

The system safety inspection serves to determine and evaluate system safety. Safety inspections according to IEC 62353 must be performed and documented by the manufacturer or qualified persons at the following instances:

- after commissioning
- after preventive maintenance activities
- after corrective maintenance activities
- at least once every two years

# **△** CAUTION!

### Risk of injury without safety inspection!

Hazards and system deficiencies will not be detected in time and can have a negative effect on patients, users, or others.

▶ Have a safety inspection in compliance with IEC 62353 performed on time and to the prescribed extent. At the same time, be sure to observe the relevant national regulations.

- Prerequisite
- Action

- ☑ You are qualified and authorized by ZEISS to perform a system safety inspection on the QUATERA 700.
- Perform the safety inspection procedure as a whole, starting from the beginning and going through each step subsequently until the end.
- ▶ Document the inspection results in the system checkout protocol.
- ▶ If you determine any errors or damages on the system, change or correct the respective parts before performing the safety inspection anew.

Empty page, for your notes

Instructions for Use 11 Troubleshooting

QUATERA 700

11.1 Locating malfunctions

# 11 Troubleshooting

# 11.1 Locating malfunctions

If a malfunction occurs, the corresponding information is displayed on the touchscreen in the form of a message.

Information about malfunctions is also saved on the system's mass storage as log files, which can be analyzed by the ZEISS Service. The log files list all errors with information on their priority, type, date, and daytime of occurrence. Once the mass storage capacity is exhausted, the system deletes the oldest log file entries when creating new ones. The log files remain available even after a complete loss of the power supply, no matter how long the interruption lasted.

# 11.2 Faults (with messages)

### 11.2.1 General system messages

Message type	Message/Fault	Remedy
Error	A deviation in I/A pressure was detected. The system was switched to gravity mode.	Check and adjust the aspiration vacuum.
Error	The power supply is interrupted. The system functionality is limited.	Immediately check the power supply and interrupt the surgery.
Error	Data cannot be written on USB drive.	Please check USB drive and repeat procedure.
Error	The backup battery is defective. A buffered operation is not available.	▶ Please contact ZEISS Service.
Error	An error occurred.	► Please contact ZEISS Service.
Error	A problem with one module was detected.	▶ Please contact ZEISS Service.
Error	The device has been shut down and needs to be restarted.	Please restart the device by pressing the power button for at least 5 seconds.
Error	An internal error occurred.	► Please restart the system. If the error remains, please contact ZEISS Service.
Error	Database error.	► Please restart the system. If the error remains, please contact ZEISS Service.
Error	An error occurred.	► Please restart the system. If the error remains, please contact ZEISS Service.
Error	Change in eye level could not be conducted. Eye level is [value] at the moment.	Please try again to change the eye level. Ensure that the foot control panel is not in use.

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Message type	Message/Fault	Remedy
Error	An error occurred during the log file export.	► Please try again.
Error	An error occurred during the configuration of the user profile.	► Please try again. If the error remains, please contact ZEISS Service.
Error	An error occurred during the loading of the user profile.	► Please try again. If the error remains, please contact ZEISS Service.
Error	Changes could not be saved.	Please try again. If the error remains, please contact ZEISS Service.
Error	An error occurred during the loading of the workflow.	► Please try another workflow.
Warning	The backup battery is defective.	Please disable the backup battery by switching-off the related switch. The function of the battery has been disabled. Please contact ZEISS service.
Warning	Data could not be saved.	Please try it again or contact ZEISS Service.
Warning	Restart of the device is required.	► The device has to be restarted within the next 24 hours. Please restart the device.
Warning	Battery mode	► The device is in battery mode. The batteries are almost empty. To avoid an unintended shutdown, please connect the device to mains.
Warning	An internal error occurred.	► The system can still be used. The functionality may be limited. If the error remains, please contact ZEISS Service.
Information	The device has entered the battery mode. All surgical functions except irrigation have been disabled.	► Please re-connect the device to mains to have all surgical functions back.
Information	Power supply is available.	Please confirm to reactivate full functionality.
Information	The measured device temperature is too low for correct working.	► Shut down.  Action
		► Leave the device at room temperature for one hour for the temperature to adjust.
Information	USB drive with multiple partitions or multiple USB drives connected.	Please connect only one USB drive with one partition.
Information	There is not enough free memory on the USB drive.	► Please create at least 10 MB of free memory on USB drive.

11.2 Faults (with messages)

Message type	Message/Fault	Remedy
Information	Selected users could not be deleted.	Please try again. If the error remains, please restart the system.
Information	User could not be created.	► Please try again. If the error remains, please restart the system.
Information	Workflow could not be deleted.	► Please try again. If the error remains, please restart the system.
Information	Workflow name could not be changed.	► Please try again. If the error remains, please restart the system.

# 11.2.2 QUATERA FCP system messages

Message type	Message/Fault	Remedy
Error	An error with the foot control panel communication occurred.	▶ Please check the connection with the foot control panel. If necessary, establish a connection with the foot control panel. Please restart the system. If the error remains, please contact ZEISS Service.
Error	The change in the Auto-Reflux settings could not be conducted. Auto-Reflux status is [value] at the moment.	Please try again to activate the settings. Ensure that the foot control panel is not in use.
Warning	The foot control panel has been tilted for more than 10 degrees.	Please place foot control panel on plain surface.
Warning	A button of the foot control panel has been pressed too long and has been disabled.	Please release the button to re-enable it.
Information	Button of the foot control panel could not be configured.	Please release the foot control panel and retry.
Information	The foot control panel is missing.	► Please connect the foot control panel.

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# 11.2.3 Irrigation system messages

Message type	Message/Fault	Ren	nedy
Error	A negative I/A flow was detected.	•	Please check the correct position of the cassette and the tubes. If necessary, replace the cassette with a new one. If the error remains, please contact ZEISS Service.
Error	Irrigation has stopped.	•	Verify that the clamp at the irrigation line is open.
		Act	tion
		•	Check whether the infusion bottle is empty.
		•	If required, replace the infusion bottle [> 196] and re-install and re-prime the cassette [> 139].
Error	Change of irrigation mode could not be conducted. Irrigation mode is <value> at the moment.</value>	•	Please try again to activate the settings. Ensure that the foot control panel is not in use.
Error	Surgical functions not ready for use.	•	Please lift the foot control panel and then confirm the error message.
Information	Irrigation bottle is almost empty.	<b>•</b>	Replace the infusion bottle. [▶ 196]

# 11.2.4 Aspiration system messages

Message type	Message/Fault	Rer	nedy
Error	A deviation in I/A pressure was detected. The system was switched to gravity mode.	•	After releasing the foot control panel, continue with the procedure. If the error remains, please contact ZEISS Service.

# 11.2.5 Diathermy system messages

Message type	Message/Fault	Ren	nedy
Error	An error with the diathermy function occurred. The diathermy function has been disabled.	•	Please release the foot control panel. The system can still be used. If the error remains, please contact ZEISS Service.

# 11.2.6 Ultrasound system messages

Message type	Message/Fault	Remedy
Error	An error with the ultrasound function occurred. The ultrasound function has been disabled.	▶ Please check if the ultrasound tip is tightened correctly and it is not damaged. If the error remains, please check with a new handpiece.
Error	The ultrasound tuning procedure was unsuccessful.	► Please check if the ultrasound tip is tightened correctly and it is not damaged. If the error remains, please check with a new handpiece.
Error	An error with the connection of the U/S handpiece occurred.	▶ Please ensure that the connection of the U/S handpiece to the U/S socket on the console is secure. If the error remains, please contact ZEISS Service.
Error	An error with the ultrasound function occurred. The ultrasound function has been disabled.	► Please release the foot control panel. The system can still be used. If the error remains, please contact ZEISS Service.
Error	The ultrasound tuning procedure was unsuccessful.	▶ Please repeat the tuning procedure. If the error remains, please check with a new handpiece.
Error	The configured ultrasound tip size does not match. The measured flow is too high. Therefore, the used tip size is too low.	▶ Please check the selected tip size.
Information	The U/S handpiece is not connected.	► Please connect the U/S handpiece.
Information	Ultrasound power cannot be activated due to missing tuning process.	▶ Please tune the U/S handpiece.
Information	APM could not be activated. Therefore, CONTINUOUS was activated as U/S mode.	Please try again to activate the settings. Ensure that the foot control panel is not in use.

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# 11.2.7 I/A priming/tuning system messages

Message type	Message/Fault	Rer	nedy
Error	The selected vitrectomy cutter gauge size does not match to the connected vitrectomy cutter.	•	Please check if the chosen vitrectomy cutter gauge size matches to the connected one. Make sure that the vitrectomy cutter is not damaged.
Information	A prior I/A priming is required.	•	Please start the I/A priming procedure.
Information	To activate irrigation or aspiration a I/A priming must be performed.	•	Execute I/A priming successfully.
Information	The vitrectomy cutter has not been primed.	•	Start the priming procedure.

# 11.2.8 CALLISTO eye system messages

Message type	Message/Fault	Remedy
Error	The selected Assistant Step was not accepted by CALLISTO eye.	▶ Please contact ZEISS Service.
Information	The CALLISTO eye assistance function could not be activated at CALLISTO eye.	At CALLISTO eye, please switch to application area assistant.
Information	The connection to CALLISTO eye was interrupted.	Please check connection to CALLISTO eye.

# 11.2.9 QUATTRO CASSETTE system messages

Message type	Message/Fault	Remedy
Error	The QUATTRO CASSETTE is not inserted into the cassette interface correctly.	Please release the foot control panel. The system can still be used. If the error remains, please contact ZEISS Service.
Warning	Drainage bag is full.	Please change the QUATTRO CASSETTE.
Information	QUATTRO CASSETTE is missing.	Please mount a QUATTRO CASSETTE and prime the cassette.

# 11.3 Faults (without messages)

# 11.3.1 Operating malfunction of the QUATERA FCP

Fault	Cause	Remedy
The system is out of order.	The power cable is not connected.	Connect the power cable to the system and the power supply.
	Blown line fuse	► Replace line fuse.
The active equipment section is	The system is turned off.	► Turn on the system.
not activated by the QUATERA FCP.	The QUATERA FCP is not connected (as indicated by the QUATERA FCP indicator).	► Connect the QUATERA FCP.
The QUATERA FCP does not react.	Firmware error	► Release the QUATERA FCP's foot pedal.
		Action
		In the "Live" menu's workflow bar, tap on the next workflow step.
		► Tap on the previous, i.e. the original workflow step.
The QUATERA FCP does not react.	Firmware error	► Reboot the FCP. [▶ 234]

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# 11.3.2 Malfunctions during irrigation

Fault	Cause	Remedy
No Irrigation	Infusion pinch valve is closed	Press the foot pedal and check if the infusion pinch valve opens.
	Irrigation tube not connected to the handpiece	Connect irrigation tube to the handpiece.
	Kinked irrigation tubing	Check for kinks and straighten them, if any.
	Damaged irrigation tubing	Inspect for damage and replace according to need.
	Closed clamp on the irrigation tube of the infusion set	<ul> <li>Open the clamp on the irrigation tube of the infusion set.</li> </ul>
	Closed air filter on the irrigation tube of the infusion set	<ul> <li>Open the air filter on the irrigation tube of the infusion set.</li> </ul>
	Blocked or moist air filter on the irrigation tube of the infusion set	► To verify that the air filter is blocked, pull it out of its socket in the irrigation tube.
		Action
		► If air bubbles rise up in the infusion bottle: Replace the QUATTRO CASSETTE.
	Empty infusion bottle	► Replace the infusion bottle. [▶ 196]

Fault	Cause	Remedy
No Irrigation	Irrigation/aspiration tubing is not connected correctly.	Recheck the installation of the tubing.
	The connectors of the irrigation/ aspiration tubing are not connected properly to the corres- ponding 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.

# 11.3.4 Malfunctions during phacoemulsification

Fault	Cause	Remedy
U/S power is too 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 the phaco tip.
	The piezoceramic element is deteriorated due to the number of passed sterilization cycles.	Use an alternative handpiece to complete the surgery.
		Action
		Submit the handpiece to the ZEISS Service.
	The aspiration level is too low to properly hold the lens fragments during emulsification.	► Increase the aspiration level while maintaining proper fluid balance.

# 11.3.5 Malfunctions during vitrectomy

Fault	Cause	Remedy
The vitrectomy probe does not work properly when the foot pedal is depressed.	Vitrectomy is not activated properly.	Check the QUATERA FCP key assignments and make sure to actuate the correct key.
	The handpiece plug is not properly connected to the vitrectomy socket.	Make sure that the handpiece plug is properly connected.
	Vitrectomy probe defective.	► Replace the vitrectomy probe.
	The cut mode is set to "Single Cut"	Set the cut mode to "Multiple Cut".

# 11.3.6 Malfunctions during diathermy

Fault	Cause	Remedy
No diathermy power is available on the diathermy handpiece although the foot pedal is	Cable to the system or to the diathermy handpiece (in case of micro-forceps) is loose.	▶ Properly plug in the cable.
depressed.	Diathermy handpiece defective.	► Replace diathermy handpiece.
	Diathermy bipolar cable defect.	► Replace the cable.
	Tip contaminated.	► Clean the tip.

# 11.3.7 Malfunctions of the system

Fault	Cause	Remedy
The clock of the touchscreen stops moving.	System is idle.	► Restart the system.
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 the vitrectomy probe.
Audible leakage of air from the system.	Hose connectors or valve or solenoid valve need to be serviced.	► Contact the ZEISS Service.

# 11.3.8 Malfunctions related to CALLISTO eye connection

Fault	Cause	Remedy
The phaco data transmission has been activated on the system, but the connection to CALLISTO eye is not established. The connection status indicator keeps showing "Connecting".	The "Phaco /Vit Interface Control" is not activated on CALLISTO eye.	Contact the ZEISS Service.

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11.4 Troubleshooting work

# 11.4 Troubleshooting work

## 11.4.1 Response to faults with messages

**Action** 

- 1. Check the message.
- 2. Once you have dealt with the issue, tap the message to remove it from the display.
  - $\Rightarrow$  The message is saved to a log file and can be exported.
- 3. If the problem persists, export the log file and send it to the ZEISS Service.

## 11.4.2 Exporting log files

### **NOTE**

### **System malfunctions!**

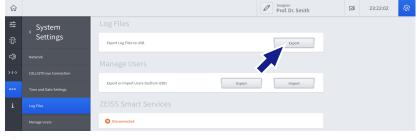
Computer viruses may cause system malfunctions!

▶ Use only tested and virus-free network and USB storage devices.

### Prerequisite

**Action** 

- ☑ A USB drive formatted as FAT32 is connected to the system's USB-A port [▶ 40].
- 1. Open the "Settings" menu and navigate to "System Settings / Log Files".
- 2. Tap on [Export].



Result

✓ The log files are copied to the USB drive.

#### Information:

The log files are saved on the USB drive in a password-protected zip file.

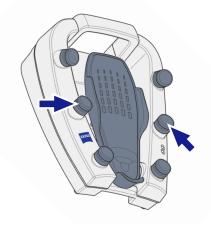
11.5 Service information QUATERA 700

### 11.4.3 Rebooting the QUATERA FCP

In case the QUATERA FCP does not respond anymore, it can be reactivated by manually switching it off and on again.

▶ Disconnect the cable from the QUATERA FCP.

- ► Take up the FCP with both hands and hold it vertically in front of you, with the handle facing upwards.
- ▶ Simultaneously press both middle side buttons for 5 seconds.



- ⇒ The foot pedal vibrates noticeably.
- ⇒ The QUATERA FCP is switched off after 5 further seconds.
- ▶ NOTE! Do not plug in the cable until the FCP's LEDs are off. When the LEDs are turned off, connect the cable to the QUATERA FCP.
  - ⇒ The QUATERA FCP is switched on.

# 11.5 Service information

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

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Action

# 12 Technical specifications

# 12.1 Essential performance features

The system does not have any essential performance features as defined in IEC 60601-1.

# 12.2 Regulatory information

# Classification of QUATERA 700 according to IEC 60601-1

QUATERA 700 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

### 12.3 Technical data

### 12.3.1 Electrical data

	Value
Rated voltage	100 V - 240 V AC (±10 %)
Rated frequency	50 Hz - 60 Hz
Power consumption	1200 VA
Fuse	Automatic fuse
USB	2.0
Network socket	RJ45

# 12.3.2 Irrigation

	Value
Type of irrigation	Quattro Controlled Irrigation
IOP range	30 - 120 mmHg
IOP increments	1 mmHg
Controller	QUATERA FCP

# 12.3.3 Aspiration

	Value
Type of aspiration pump	Quattro Pump
Vacuum range	0 to 700 mmHg
	Note that the maximum available vacuum pressure might be limited by the environmental pressure.
Vacuum increments	5 mmHg
Flow rate range	0 to 120 cc/min
Flow rate increments	1 cc/min
Control mode	"Fixed" or "Linear" mode by pressing the foot pedal.
Controller	QUATERA FCP

# 12.3.4 Phacoemulsification

	Value
Type of handpiece	Piezoelectrical
Frequency	40 kHz (+4.5 kHz / -0.5 kHz)
Stroke at maximum U/S power (21G phaco tip)	100 μm (±20 %)
U/S operation modes	<ul> <li>continuous</li> <li>pulse</li> <li>single burst</li> <li>multi burst</li> <li>continuous burst</li> <li>APM</li> </ul>
U/S power range	0 - 100 %
U/S power increments	5 %
U/S control mode	"Fixed" or "Linear" controlling via QUATERA FCP pedal pitch
Controller	QUATERA FCP

QUATERA 700

12.3 Technical data

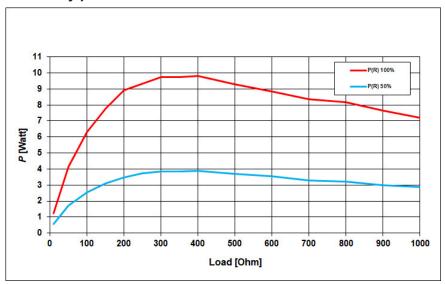
# 12.3.5 Diathermy

	Value
Туре	Bipolar generator - generator stops when no HF power is required
Type of handpiece	Handpieces for bipolar diathermy, e.g. DIATHERMY FORCEPS, DIATHERMY PENCIL ERASER
Maximum cable length	2150 mm
Operating frequency	2 MHz (±20 %)
Rated power	9 W (200 Ω resistive load)
Maximum rated power	9.795 W (400 Ω resistive load)
Maximum output voltage (peak)	170 V
Rated accessory voltage (peak)	180 V
Maximum output current	360 mA
Diathermy power range	0 - 100 %
Diathermy power increments	1 %
Control mode	"Fixed" or "Linear" mode by pressing the foot pedal.
Controller	QUATERA FCP

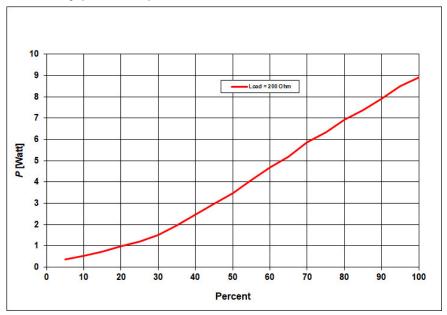
12.3 Technical data QUATERA 700

# 12.3.6 Diathermy power characteristics

# Diathermy power vs load



# Diathermy power vs preset



# 12.3.7 Vitrectomy

	Value
Type of handpiece	23G ANTERIOR VIT CUTTER, pneumatic cutting device with guillotine function (back-and-forth)
Actuation medium	Compressed air from internal source
Operating pressure	207 kPa
Cutting rate range anterior vitrectomy	30 - 5000 cuts/min (±20 %)
Cutting rate increments	<ul> <li>10 cuts/min (30 - 200 cuts/min)</li> <li>50 cuts/min (200 - 1500 cuts/min)</li> <li>100 cuts/min (1500 - 5000 cuts/min)</li> </ul>
Cut mode	Single Cut or Multiple Cut
Control mode	"Fixed" or "Linear" mode by pressing the foot pedal.
Controller	QUATERA FCP

# 12.3.8 Patient eye level indicator

	Value
LED strip	31 LEDs in a line
Distance between neighboring LEDs	10 mm

# 12.3.9 Digital video input

	Value
HDMI	1080p / 50/60 Hz

# 12.4 IT network requirements

The IT network to which the system is connected must meet the following specifications as per IEC 60601, Amend.1:2012-08 Chapter 14.13:

Name	Value
Ethernet protocol IPv4	TCP/IP
Gigabit Ethernet	1000BASE-T, IEEE 802.3 Paragraph 40
Assignment of IP addresses	Static IP or DHCP (configurable within the device)
Shared network drive	SMB protocol, also known as CIFS

The IT network to which the system is connected must have the following configuration:

- The firewall is open for inbound ports.
- All data is transmitted unsecured from the system to the customer's secured internal network.
- No data is transmitted externally from the system.
- The IT network has a RJ45 network connection, at least Cat.5, 100 Mbit/s.

The system has a network isolator in compliance with IEC 60601-1, i.e. it is not connected to the IT network power supply.

# 12.5 Dimensions, weight and angles

# **Dimensions and weight**

	Value
Height	1835 mm
Width	556 mm
Depth	758 mm
Tray arm length (from tray front to console)	875 mm
Weight	160 kg

# **Angles**

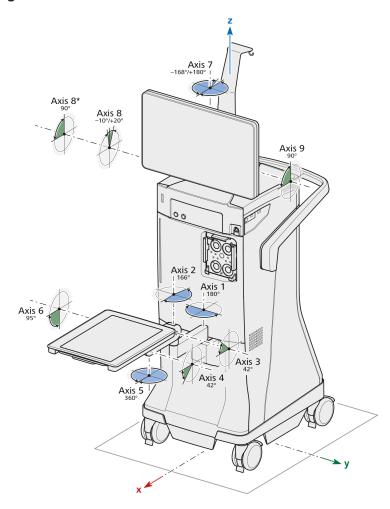


Figure 60: QUATERA 700, Axes and angles

The following values are given as seen from the system front and according to the pictured component positions (normal position, tray extended).

Axis	Angles
Axis 1	■ leftwards: 90°
	rightwards: 90°
Axis 2	■ leftwards: 0°
	rightwards: 166°
Axis 3	■ backwards: 42°
	■ frontwards: 0°
	Note: The axis does not tilt independently from axis 4.
Axis 4	■ backwards: 0°
	■ frontwards: 42°
	Note: The axis does not tilt independently from axis 3.
Axis 5	■ leftwards: 360°
	■ rightwards: 360°
Axis 6	■ backwards: 0°
	■ frontwards: 95°
Axis 7	■ leftwards: 168°
	■ rightwards: 180°
Axis 8	<ul> <li>frontwards: 10° / 90° (with locking pin released)</li> </ul>
	■ backwards: 20°
Axis 9	■ frontwards: 90°
	■ backwards: 0°

# 12.6 Ambient requirements for operation

	Value
Temperature	+10 °C +35 °C
Rel. humidity (without condensation)	30 % 75 %
Air pressure	700 hPa 1060 hPa

# 12.7 Ambient requirements for transport and storage

	Value
Temperature	-20 °C +60 °C
Rel. humidity (without condensation)	10 % 90 %
Air pressure	500 hPa 1060 hPa

# 12.8 Guidance and manufacturer's declaration – electromagnetic immunity

The system 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 disturbances, the system may only be installed, started up and maintained in the manner indicated in these Instructions for Use and only with components supplied by ZEISS.

# **⚠ WARNING!**

### Malfunction caused by other devices

Installing and operating the system in direct proximity to other devices (except for combinable devices mentioned in this document) may impair its functioning.

- ▶ If possible, do not install or operate the system in direct proximity to devices not mentioned as compatible in this document.
- ▶ If it cannot be avoided that the system be operated in proximity to other devices, strictly monitor the system's proper functioning.

# **↑ WARNING!**

### Malfunction caused by non-approved components!

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 system's immunity.

▶ Only use accessories, transformers, cables and spare parts which are specified in these Instructions for Use or which have been approved by ZEISS for this system.

# **⚠ WARNING!**

### Loss of performance caused by HF units

Portable or mobile HF communication equipment or transmitters in the proximity of the system may impair or deteriorate its proper functioning. Malfunctions may occur depending on a variety of local factors, which cannot be predicted and can by no means be estimated.

- ▶ Make sure radio communication equipment or components for radio transmission (such as antenna cables and external antennas) are not used within a distance of 30 cm to all system components.
- ▶ Do not use cell phones near the system.
- ▶ Always follow the EMC guidelines given by this document.

### **NOTE**

### Disturbances caused by electromagnetic radiation

The system may experience interference from other devices, even if they comply with the emission requirements applicable as per CISPR.

- ▶ Do not use the system next to or stacked on top of other devices.
- ▶ If it is necessary to operate the system next to or stacked on top of other devices, monitor the system to ensure its normal operation in the present arrangement.
- ▶ If the system shall be operated together with devices generating HF waves or high voltages, check the devices' effects on the system before using it.
- ► Install the system in such a way so as to minimize disturbances caused by HF waves.

The following criteria have been defined for the immunity test:

- No value changes occur without user input.
- The system's entering into the safe state or the restart state is allowed.
- The occurrence of system messages, including error messages, is allowed.
- A temporary flickering of the graphic user interface or the incoming video signal is allowed.

The all-time accordance with these criteria was confirmed by the surveillance of the system's user interfaces.

## 12.8.1 Electromagnetic interference

The QUATERA 700 is intended for operation in an electromagnetic environment as specified below. The customer or the user of the QUATERA 700 is responsible for ensuring that the system is operated in such an environment.

Interference measurements	Compliance
HF emissions as per CISPR 11	Group 1
HF emissions as per CISPR 11	Class A
Harmonic emissions as per IEC 61000-3-2	Class A
Emission of voltage fluctuations/ flicker as per IEC 61000-3-3	Compliant

#### NOTE

The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11, Class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

When used in a residential area, this equipment may interfere with the public low-voltage power supply network if its mains supply is not properly isolated from the network by transformers or substations. The user must take measures to provide an appropriate mains connection.

# 12.8.2 Electromagnetic immunity for ME equipment and ME systems

The QUATERA 700 is intended for operation in an electromagnetic environment as specified below. The customer or the user of the QUATERA 700 is responsible for ensuring that the system is operated in such an environment.

Electromagnetic 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
	±15 kV air discharge	±15 kV air discharge
Electrical fast transient / burst immunity as per 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 phase-to-neutral voltage	±1 kV phase-to-neutral 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 dips, short interruptions	0 % U <sub>T</sub> for 1/2 cycle	0 % U <sub>T</sub> for 1/2 cycle
and voltage variations as per IEC 61000-4-11	0 % U <sub>⊤</sub> for 1 cycle	0 % U <sub>T</sub> for 1 cycle
	70 % U <sub>T</sub> for 25/30 cycles	70 % U <sub>T</sub> for 25/30 cycles
	0 % U <sub>T</sub> for 250/300 cycles	0 % U <sub>T</sub> for 250/300 cycles

# 12.8.3 Electromagnetic interference resistance for ME equipment or systems that are not life-sustaining

The QUATERA 700 is intended for operation in an electromagnetic environment as specified below. The customer or the user of the QUATERA 700 is responsible for ensuring that the system is operated in such an environment.

Electromagnetic immunity tests	IEC 60601 test level	Compliance level
Conducted HF disturbances as per IEC 61000-4-6	3 V 150 kHz to 80 MHz	3 V
	6 V ISM- and ham radio frequency bands between 150 kHz and 80 MHz	6 V
Radiated HF disturbances as per IEC 61000-4-3	3 V/m 80 MHz to 2700 MHz SIP/SOPs with length < 3 m tested	3 V/m
Radiated HF disturbances from near fields of wireless communi- cation devices as per IEC	27 V/m 380 MHz to 390 MHz	27 V/m
61000-4-3	28 V/m 430 MHz to 470 MHz, 800 MHz 960 MHz, 1700 MHz to 1990 MHz, 2400 MHz to 2570 MHz	28 V/m
	9 V/m 704 MHz to 787 MHz, 5100 MHz to 5800 MHz	9 V/m

QUATERA 700 13.1 Accessories

# 13 Accessories and components

## 13.1 Accessories

These Instructions for Use describe accessories that are not essential components of the individual deliveries. A current list of accessories can be obtained from your ZEISS contact partner.

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

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

### 13.1.1 ZEISS Phaco Accessories

For connectable ZEISS phaco accessories for this system, please refer to the separate product overview G-30-2040.

# 13.2 Components

# 13.2.1 QUATERA FCP

Designation	Specification	Order no.
QUATERA FCP	Wired	303044-9130-000

# 13.2.2 Country-specific cables

Designation	Specification	Order no.
Europe	Power cord, length: 6 m	000000-0594-821
Netherlands	Power cord, length: 6 m	000000-0603-410
USA	Power cord, length: 6 m	000000-0594-822
UK	Power cord, length: 6 m	000000-0594-823
Switzerland	Power cord, length: 6 m	000000-0584-947
Argentina	Power cord, length: 6 m	000000-0594-906
China	Power cord, length: 6 m	000000-0594-824
Brazil	Power cord, length: 6 m	000000-0594-905
Australia / New Zealand	Power cord, length: 6 m	000000-0616-997

Instructions for Use 14 Disposal

QUATERA 700

14.1 Safety during disposal

# 14 Disposal

# 14.1 Safety during disposal

# **⚠ CAUTION!**

# Inappropriate disposal may contaminate the environment!

Pollution of 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.

# 14.2 Disposal of the system

- ▶ Keep packing material in the event of a relocation or repair.
- ▶ If you want to dispose of the packing material: Dispose of packing material by sending it for recycling through an acknowledged collection system.

The system contains electronic components with integrated batteries.

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



The system specified on the delivery note must not be disposed off via household waste or communal disposal companies according to the applicable EU guidelines valid at the time the system was placed on the market.

► For more information about the disposal of the system, please contact the ZEISS contact partner in your country.

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

▶ If you want to sell on the system or its components: Inform the purchaser that they must dispose of the system according to the regulations valid at that time.

Empty page, for your notes

# Glossary

#### **APM**

Advanced Power Modulation

### **Applied Part Type B**

Term of the EN 60601, designating a part of medical electrical equipment that is designed to or likely to come into physical contact with the patient (but not with the heart) and that is usually earth-referenced and complies with the requirements for protection against electric shocks as specified by the norm

### **Applied Part Type BF**

Term of the EN 60601, designating a part of medical electrical equipment that is designed to or likely to come into physical contact with the patient (but not with the heart) and that is isolated from earth and other parts of the equipment

#### **BSS**

**Balanced Salt Solution** 

### **CIFS**

Common internet file system, communication protocol for shared access to files, printers and serial ports within a network

#### **DHCP**

a client/server protocol that automatically provides an Internet Protocol (IP) host with its IP address and other related configuration information such as the subnet mask and default gateway.

#### **EMC**

**Electromagnetic Compatibility** 

### **EPT**

Effective Phaco Time, the duration of the effective phaco time considering the adjusted performance output and the previously selected U/S operation mode

#### **FCP**

Foot Control Panel

#### HD

**High Definition** 

#### HF

High Frequency

### I/A

Irrigation and Aspiration

#### **IDIS**

Integrated Data Injection System

#### **IOP**

Intraocular Pressure

### IΡ

Internet Protocol

### LAN

LAN (local area network)

#### **LED**

Light-Emitting Diode, a semiconductor light source

#### **LRI**

Limbal Relaxing Incision

### **ME** equipment

Medical electrical equipment

### OR

Operating Room

### **OVD**

Ophthalmic Viscoelastic Device

#### PC

Personal Computer

Glossary Instructions for Use QUATERA 700

#### PE

Potential Equalization, grounding system to protect persons from dangerous contact voltage

#### **POD**

Power On Demand

#### **RF**

Radio Frequency

### **SCU**

Site Control Unit, a server in the hospital network that provides ZEISS Smart Services access to connected ZEISS devices

#### SIP

Service Identification Program

#### **SMB**

Server message block, communication protocol for shared access to files, printers and serial ports within a network

### TCP/IP

a suite of communication protocols used to interconnect network devices on the internet.

### **TPT**

Total Phacoemulsification Time, the sum of the phaco times when the ultrasound is repeatedly turned on and off

### U/S

Ultrasound

#### **USB**

Universal Serial Bus

### Venting

The release of aspiration pressure to ambient pressure. This happens automatically, when releasing the foot control panel from aspiration to irrigation, this happens always

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