

From Eye to Insight



PROVEO 8x

User Manual

10 735 160 version 03

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Thank you for purchasing a Leica surgical microscope system.
In developing our systems, we have placed great emphasis on simple, self-explanatory operation. Nevertheless, we suggest studying this user manual in detail in order to utilize all the benefits of your new surgical microscope.
For valuable information about Leica Microsystems products and services, and the address of your nearest Leica representative, please visit our website:

www.leica-microsystems.com

Thank you for choosing our products. We hope that you will enjoy the quality and performance of your Leica Microsystems surgical microscope.



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Legal disclaimer

All specifications are subject to change without notice.

The information provided by this manual is directly related to the operation of the equipment. Medical decision remains the responsibility of the clinician.

Leica Microsystems has made every effort to provide a complete and clear user manual highlighting the key areas of product use. Should additional information regarding the use of the product be required, please contact your local Leica representative.

You should never use a medical product of Leica Microsystems without the full understanding of the use and the performance of the product.

Liability

For our liability, please see our standard sales terms and conditions. Nothing in this disclaimer will limit any of our liabilities in any way that is not permitted under applicable law, or exclude any of our liabilities that may not be excluded under applicable law.

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1 Introduction

1.1 About this user manual

In this user manual the surgical microscope PROVEO 8x is described.



In addition to notes on the use of the instruments, this user manual gives important safety information (see chapter 3 "Safety notes", page 4).



► Read this user manual carefully before operating the product.

The full name of this operation microscope is **PROVEO 8x**.

1.2 Symbols in this user manual

The symbols used in this user manual have the following meaning:

Symbol	Warning word	Meaning
	Warning	Indicates a potentially hazardous situation or improper use that could result in serious personal injuries or death.
	Caution	Indicates a potentially hazardous situation or improper use which, if not avoided, may result in minor or moderate injury.
	Note	Indicates a potentially hazardous situation or improper use which, if not avoided, may result in appreciable material, financial and environmental damage
		Information about use that helps the user to employ the product in a technically correct and efficient way.
►		Action required; this symbol indicates that you need to perform a specific action or series of actions.
		Medical Device

1.3 Optional product features

Different product features and accessories are optionally available. The availability varies from country to country and is subject to local regulatory requirements. Please contact your local representative for availability.

2 Product identification

The model and serial numbers of your product are located on the identification label on the stand system closed to the power plug.

► Enter this data in your user manual and always refer to it when you contact us or the service workshop regarding any questions you may have.

Type	Serial no.
...	...

3 Safety notes

The PROVEO 8x surgical microscope is state-of-the-art technology. Nevertheless, hazards can arise during operation.

- Always follow the instructions in this user manual, and in particular the safety notes.

3.1 Intended purpose

- The PROVEO 8x surgical microscope is an optical and digital visualization system for improving the visibility of objects through magnification and illumination. It can be applied for observation, documentation and for human medical treatment.
- The major field of use is ophthalmology.
- The PROVEO 8x surgical microscope may be used only in closed rooms and must be placed on a solid floor.
- It is available on the floor stand.
- The floor stand is for the positioning of the PROVEO 8x in the room.
- The PROVEO 8x surgical microscope is subject to special precautionary measures for electromagnetic compatibility. It must be installed and commissioned in accordance with the guidelines and manufacturer's declarations and recommended safety distances (according to EMC tables based on EN60601-1-2).
- Portable and mobile as well as stationary RF communications equipment can have a negative effect on the functionality of the PROVEO 8x surgical microscope.
- Always release the brakes to move or relocate the PROVEO 8x surgical microscope.
- The essential performance of the PROVEO 8x is to provide illumination of the optics carrier.

3.2 Clinical benefit

The PROVEO 8x improves visualization of surgical areas, providing visual information in support to the surgeon decisions during surgery, thus impacting positively on the desirable clinical outcome of the procedure and patient health and management.

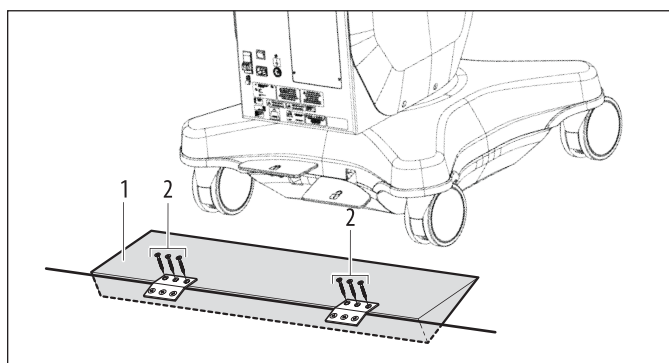
3.3 Limitations of use

The PROVEO 8x may be used only in closed rooms and must be placed on a solid floor.

Without auxiliary equipment, the PROVEO 8x can be moved across thresholds up to a max. height of 5 mm. The PROVEO 8x is not suitable for crossing thresholds higher than 20 mm.

To move the surgical microscope over thresholds of 20 mm, the wedge (1) included in the packaging can be used.

- Loosen the screws (2) on one side of the hinge in order to remove the wedge (1).



- Place the wedge (1) in front of the threshold.
- Move the surgical microscope across the threshold in transport position, pushing it by the handgrip.

3.4 Indications for use

The PROVEO 8x surgical microscope is used for surgical procedures in Ophthalmology.

3.5 Contraindication

The PROVEO 8x must not be used in microsurgery (Neurosurgery, Plastic/Reconstructive, Ear, Nose and Throat surgeries).

3.6 Intended target population

The intended target population are patients undergoing a surgical procedure as defined within the intended purpose and indications for use.

3.7 Intended user

The PROVEO 8x surgical microscope is intended for professional use only. The user must have corresponding technical qualification and have been trained in the use of the instrument.

3.8 Directions for the person responsible for the instrument

- Ensure that the PROVEO 8x surgical microscope is used only by persons qualified to do so.
- Ensure that this user manual is always available at the place where the PROVEO 8x surgical microscope is in use.
- Carry out regular inspections to make certain that the authorized users are adhering to safety requirements.
- When instructing new users, do so thoroughly and explain the meanings of the warning signs and messages.
- Allocate responsibilities for commissioning, operation and maintenance. Monitor compliance with this.
- The PROVEO 8x is intended for professional use only.

**WARNING****Risk of electric shock!**

- Connect this equipment only to a supply mains with protective earth.

- Only use the PROVEO 8x surgical microscope if it is free of defects.
- Inform your Leica representative or Leica Microsystems (Schweiz) AG, Medical Division, 9435 Heerbrugg, Switzerland, immediately about any product defect that could potentially cause injury or harm.
- In case of any serious incident that has occurred in relation to the device, immediately inform your Leica representative or Leica Microsystems (Schweiz) AG, Medical Division, 9435 Heerbrugg, Switzerland, as well as the competent authority of the country in which the user and/or patient is established.
- If you use accessories from other manufacturers with the PROVEO 8x surgical microscope, make sure that these manufacturers confirm that the combination is safe to use. Follow the instructions in the user manual for those accessories.
- Modifications, installations to or service on the PROVEO 8x surgical microscope may be carried out only by technicians who are explicitly authorized by Leica to do so.
- Only original Leica replacement parts may be used in servicing the product.
- After service work or technical modifications, the device must be readjusted in accordance with our technical specifications.
- If the instrument is modified or serviced by unauthorized persons, is improperly maintained (as long as maintenance was not carried out by a qualified trained service engineer), or is handled improperly, Leica Microsystems will not accept any liability.
- The effect of the surgical microscope on other instruments has been tested as specified in EN 60601-1-2. The system passed the emission and immunity test. Comply with the usual pre-cautionary and safety measures relating to electromagnetic and other forms of radiation.
- The electric installation in the building must conform to the national standard, e.g., current-operated ground leakage protection (fault-current protection) is suggested.
- Like any other instrument in the operating theater, this system may fail. Leica Microsystems (Schweiz) AG therefore recommends that a backup system be kept available during the operation.
- The responsibility for determining whether the patient's condition and overall health permit the use of Leica Surgical Microscope for its specified "Intended Use" lies with the individual surgeon or physician. Take note on the intended use(s) and contra-indication.
- The PROVEO 8x surgical microscope must not be used directly

adjacent to other instruments. If it is necessary to operate it in the vicinity of other instruments, the devices should be monitored to ensure that they function properly in this arrangement.

3.9 Directions for the operator of the instrument

- Follow the instructions described here.
- Follow the instructions given by your employer regarding the organization of work and safety at work.

Phototoxic damage to the retina during eye surgery

**WARNING****Damage to the retina due to prolonged exposure!**

The light of the instrument may be harmful. Risk of retina damage increases with the duration of exposure.

- During exposure to the light from this instrument, do not exceed the hazard reference values. If the exposure time exceeds the value in the tables "Main light" and "Coaxial Red Reflex illumination" (see chapters "Main light", page 6 and "Coaxial Red Reflex illumination", page 6) with this instrument at maximum output power, the hazard reference value will be exceeded.

The following table is intended to serve as a guideline and make the surgeon aware of the potential hazard. The data have been calculated for the worst-case scenario:

- Eye with aphakia
- Completely unmoving eye (continuous irradiation of the same region)
- Uninterrupted light exposure, e.g. no surgical instruments in the eye
- Pupils dilated to 7 mm

The calculations are based on the corresponding ISO standard ¹⁾ and the exposure limit values recommended in that standard.

Sources:

- 1) DIN EN ISO 15004-2; Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection.

Main light

Light setting	Maximum exposure time according to 1) [min.]
25%	14
50 %	4.5
75%	3
100 %	2
Retina Protection Function Activated	39

Coaxial Red Reflex illumination

Light setting	Maximum exposure time according to 1) [min.]
25%	9.5
50 %	4
75%	2.5
100 %	2
Retina Protection Function Activated	12

! If both illuminations are used, the lower of the two values for the permitted exposure time must be used according to the configured light output. The two hazards do not have to be set off against each other, as their reflections on the retina are not superimposed.

Protect the patient with the following safeguards:

- Short exposure times
- Low brightness settings
- Switching off the illumination during breaks in the operation

It is recommended to adjust the brightness to the minimum necessary for the surgery. Infants, patients with aphakia (whose eye lens has not been replaced by an artificial lens with a UV protection screen), small children and persons with diseases of the eye are at greater risk. The risk is also increased if the person being treated or operated on has, within the last 24 hours, already been exposed to illumination from the same or any other ophthalmological instrument that uses a bright visible light source. This applies especially to patients that have been examined via retinal photography.

Decisions about brightness must be made case by case. In any event, the surgeon must evaluate the risks and benefits of the used light intensity. Despite all efforts to minimize the risk of retinal injury by surgical microscopes, damage may still occur. Photochemical retinal damage is a possible complication of the necessity to use bright light to make eye structures visible during difficult ophthalmological processes.

In addition, the Retina Protection function can be activated during the surgery to reduce the main light intensity below 10% and Red Reflex below 20%.

3.10 Dangers of use



WARNING

Risk of electric shock!

- ▶ Connect this equipment only to a supply mains with protective earth.



WARNING

Damage to the retina due to prolonged exposure!

The light of the instrument may be harmful. Risk of retina damage increases with the duration of exposure.

- ▶ During exposure to the light from this instrument, do not exceed the hazard reference values. If the exposure time exceeds the value in the tables "Main light" and "Coaxial Red Reflex illumination" (see chapters "Main light", page 6 and "Coaxial Red Reflex illumination", page 6) with this instrument at maximum output power, the hazard reference value will be exceeded.



WARNING

Danger of injury due to:

- **uncontrolled lateral movement of the parallelogram**
- **tilting of the stand**
- **feet in lightweight shoes could become trapped beneath the casing of the base**
- ▶ For transportation, always move the PROVEO 8x surgical microscope into the transport position.
- ▶ Never move the stand while the unit is extended.
- ▶ Never roll over cables lying on the floor.
- ▶ Always push the PROVEO 8x surgical microscope; never pull it.



WARNING

Danger to the patient due to changes in the user settings!

- ▶ Never change the configuration settings or edit the user list during an operation.

**WARNING****Risk of injury due to downward movement of the surgical microscope!**

- ▶ Complete all preparations and adjustments to the stand before the operation.
- ▶ Never change the accessories or attempt to rebalance the microscope while it is above the field of operation.
- ▶ If settings need to be altered during the operation, first swing the microscope away from the operating field.
- ▶ If the microscope needs to be re-equipped, do this before the operation.
- ▶ Balance the PROVEO 8x after re-equipping it.
- ▶ Before changing accessories, always lock the parallelogram (see chapter 7.8.2 "Locking the parallelogram", page 31).
- ▶ Do not release the brakes when the instrument is in an unbalanced state.
- ▶ Do not use the handles or remote brake release when the instrument is in an unbalanced state.
- ▶ Before re-equipping, always lock the parallelogram.
- ▶ Before re-equipping during the operation, first swing the microscope away from the operating field.
- ▶ After re-equipping, always rebalance the microscope on the parallelogram.
- ▶ Always lock the parallelogram:
 - when transporting the microscope
 - when re-equipping

**WARNING****Risk of injury from parts falling down!**

- ▶ Before the operation, make sure that the optical components and accessories are sufficiently secured and cannot move.

**WARNING****Risk of infection!**

- ▶ Always use the PROVEO 8x surgical microscope with sterile controls and knobs.

**WARNING****Danger of fatal electrical shock!**

- ▶ Operate the system only with all equipment in its proper position (all covers fitted, doors closed).
- ▶ The PROVEO 8x surgical microscope may be connected to a grounded socket only.

**WARNING****Motors return to their park position!**

- ▶ Before switching on the microscope, ensure that the travel paths of XY-unit, tilt and focus are free of obstructions.

**WARNING****Light that is too intense can damage the retina!**

- ▶ Observe the warning messages in the chapter on "Safety notes".

**WARNING****Danger to the patient due to failure of the magnification motor!**

If the magnification motor fails, the magnification can be manually adjusted using the rotary knob.

**CAUTION****Surgical microscope can move without warning!**

- ▶ Always lock the footbrake when you are not moving the system.

**CAUTION****Damage to the PROVEO 8x surgical microscope due to uncontrolled movement!**

- ▶ Hold the handle when releasing the brake.

**CAUTION****Damage to the PROVEO 8x surgical microscope during transportation!**

- ▶ Never move the stand in the extended condition.
- ▶ Never roll over cables lying on the floor.
- ▶ Do not transport or store the system in areas with an elevation angle bigger than 10°.

**CAUTION****Risk of damage to the surgical microscope due to uncontrolled tilting!**

- ▶ Firmly hold the handles before triggering the "All Brakes" function.



CAUTION

Danger of damage!

- ▶ Before lifting the optics carrier make sure that the area above the parallelogram is clear to avoid collisions with OR lamps, ceiling, etc.



CAUTION

Risk of infection!

- ▶ Leave sufficient space around the stand to ensure that the microscope does not come into contact with non-sterile components.



CAUTION

Damage of the magnification motor!

- ▶ Only adjust the magnification manually if the magnification motor is defective.



CAUTION

Risk of injury!

- ▶ Pay special attention to the required safety distances if you use the Combination Mode function together with accessories from other manufacturers that can reduce the working distance to less than 140 mm (non-contact wide-angle observation systems), since focus together with Combination Mode is a semi-automated function.



CAUTION

Danger of collision!

The surgical microscope can collide with surrounding components, the ceiling or lamps.

- ▶ Check the danger area before moving the swing arm.

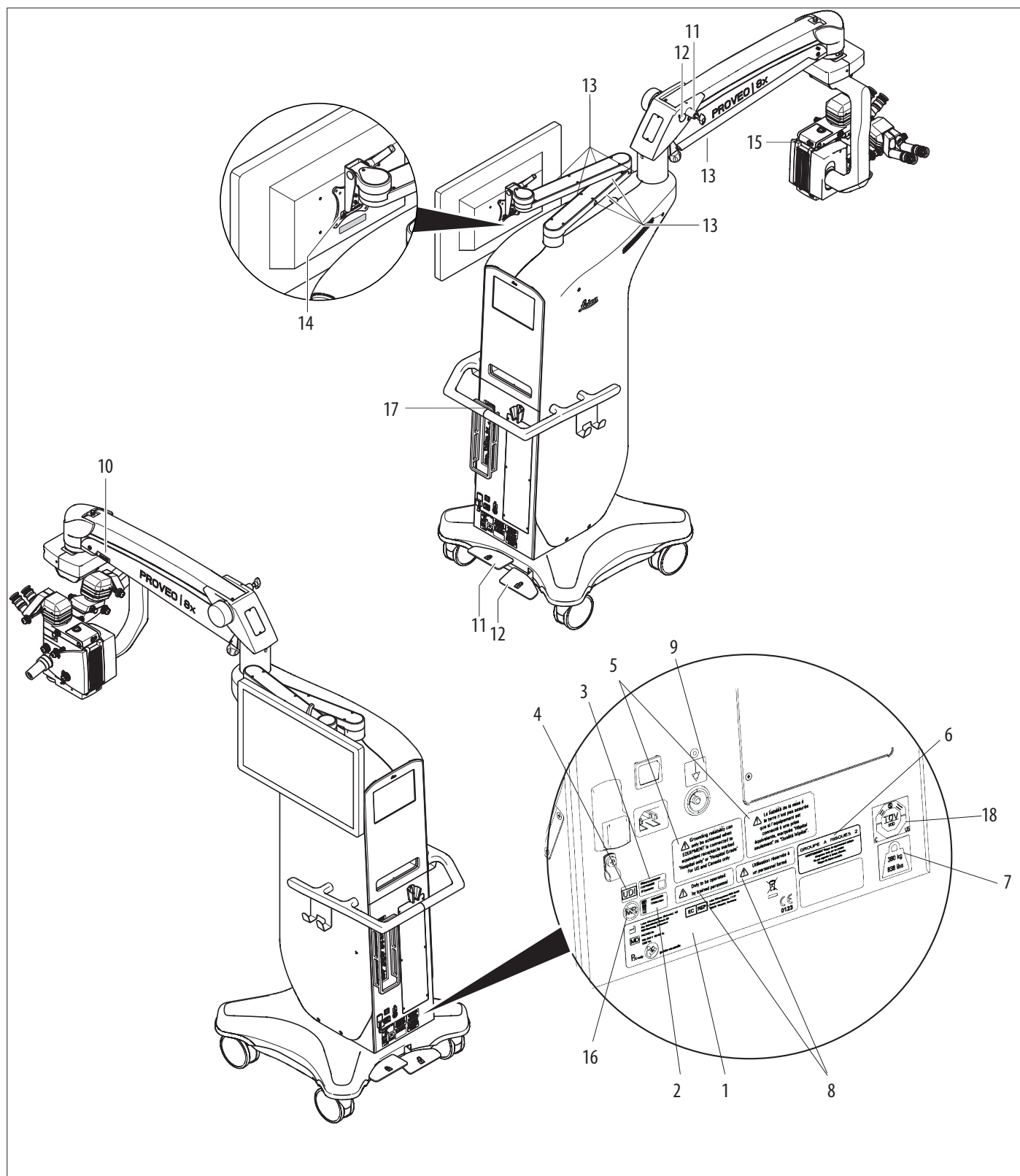
3.11 MRI Safety Information


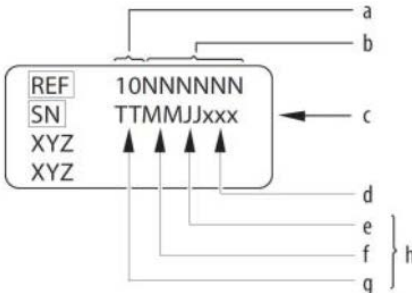














The PROVEO 8x surgical microscope is Magnetic Resonance (MR) Unsafe.



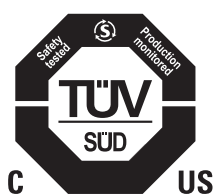
3.12 Signs and labels

3.12.1 Floor stand



1	Type label		6	<div>RISK GROUP 2</div> <div>CAUTION Possibly hazardous optical radiation emitted from this product. Do not stare at operating lamp. May be harmful to the eyes.</div> <div>GROUPE A RISQUES 2</div> <div>AVERTISSEMENT Risque de rayonnement optique dangereux émis par ce produit. Ne pas regarder la lampe allumée. Risque de lésion oculaire.</div>	Light risk label	
2	Fabrication label	 <p>a Prefix number b Leica system article no. c Serial number d Incremental number starting at 1 for each batch e JJ = year (2 digits) f MM = month (2 digits) g TT = day (2 digits) h Production starting date</p>	7		System weight label	
			8	<div> Only to be operated by trained personnel</div> <div>Utilisation réservée à un personnel formé</div>	Trained personnel	
			9		Equipotential bonding	
			10	<div> Max. 8kg (17.64lb)</div>	Max. load for Optics Carrier	
			11		Open	
			12		Closed	
			13		Crushing hazard label	
			14	<div> Max. 16kg (35.27lb)</div>	Monitor weight label	
4	UDI label					
5	Grounding label	<div> Grounding reliability can only be achieved when EQUIPMENT is connected to equivalent receptacle marked "Hospital only" or "Hospital Grade". For US and Canada only</div> <div> La fiabilité de la mise à la terre n'est assurée que si l'équipement est connecté à une prise équivalente, marquée "Hôpital seulement" ou "Qualité hôpital".</div>		15		Controller Area Network (CAN) label
			16		MR unsafe label	
			17	<div> Non-Protected Signal Inputs/Signal Outputs Entrées/sorties de signal non protégées 无保护信号输入/信号输出</div>	SIP/SOP warning label	

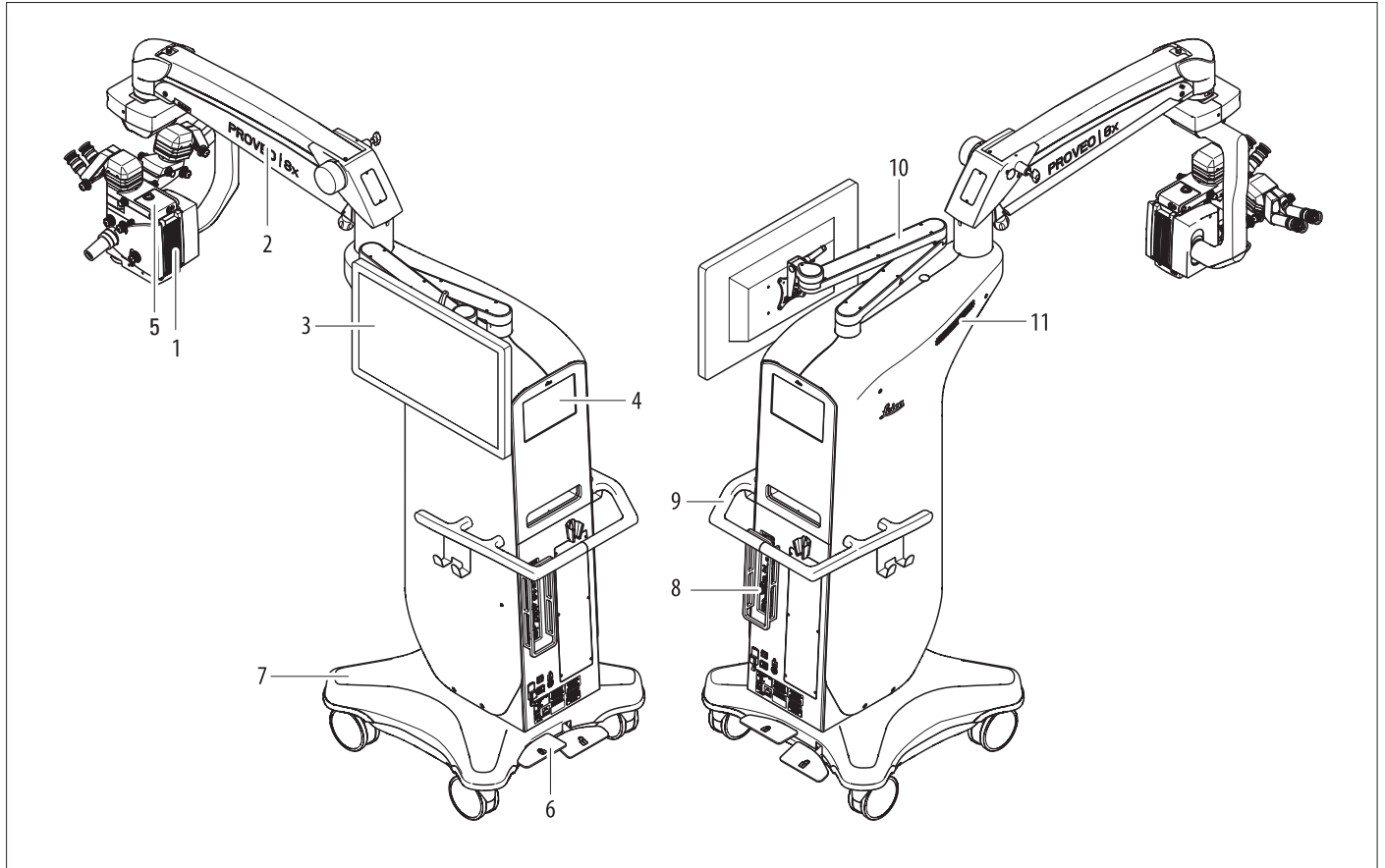
18



NRTL label (TÜV)

4 Design

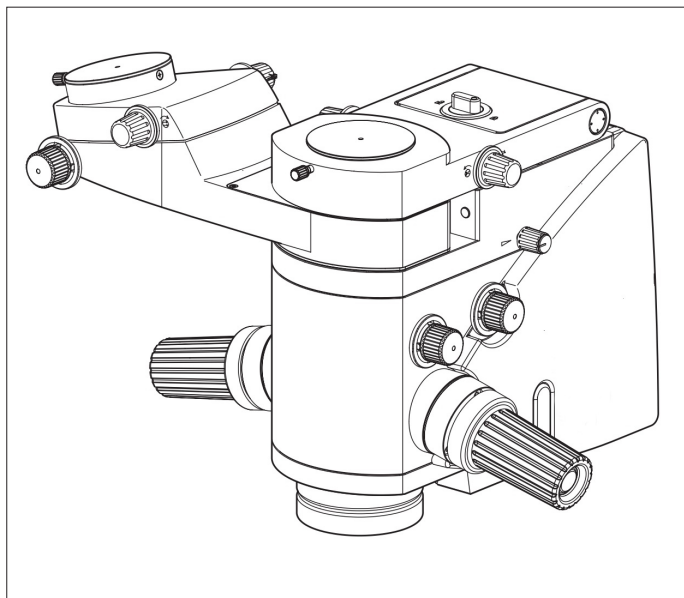
4.1 Floor stand



- 1 PROVEO 8x optics carrier
- 2 Parallelogram
- 3 Stand monitor
- 4 Control unit with touch panel
- 5 Integrated video camera (IVC)
- 6 Footbrake
- 7 Base
- 8 Terminals (e.g. electrical, video, etc.)
- 9 Handrail
- 10 Monitor arm
- 11 Speaker

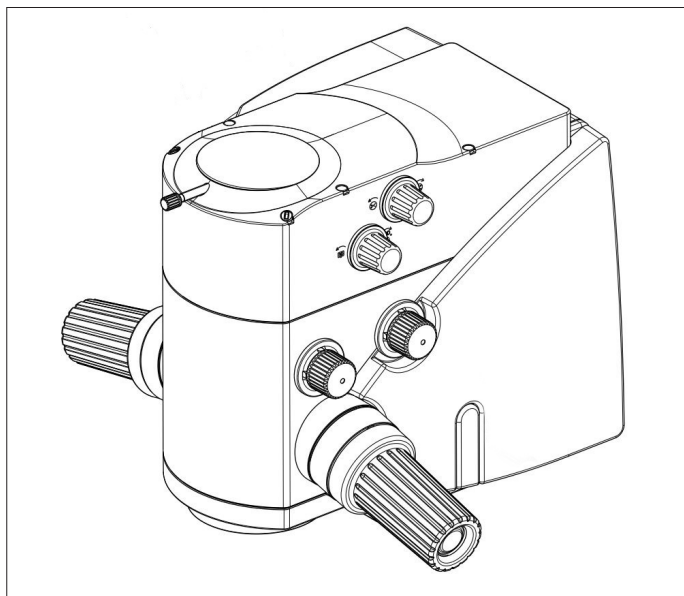
4.2 PROVEO 8x Optics carrier modules

4.2.1 PROVEO 8x 2D 4K IVC



- Optics carrier with integrated 2D 4K camera and integrated inverters

4.2.2 PROVEO 8x 3D 4K IVC



- Optics carrier with integrated 3D 4K camera and integrated inverters

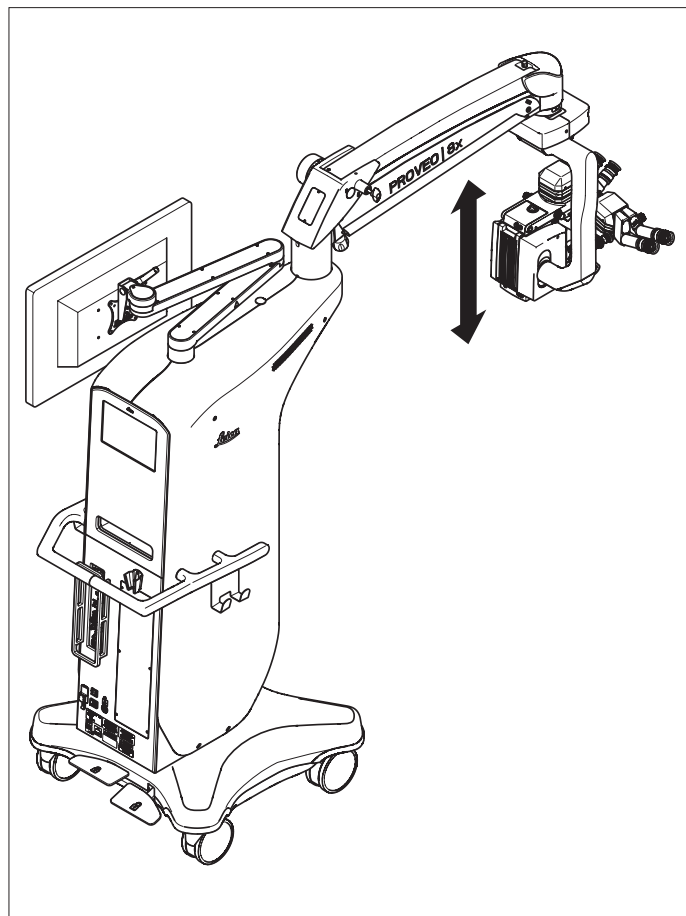
5 Functions

5.1 Balancing system

With a balanced surgical microscope PROVEO 8x you can move the optics carrier to any position without tilting or moving down. After balancing, all movements during operation only need a minor force when brakes are released.

The parallelogram balances the up/down movement (see chapter 7.8.1 "Balancing the parallelogram", page 31).

Balancing the optics carrier at the floor stand

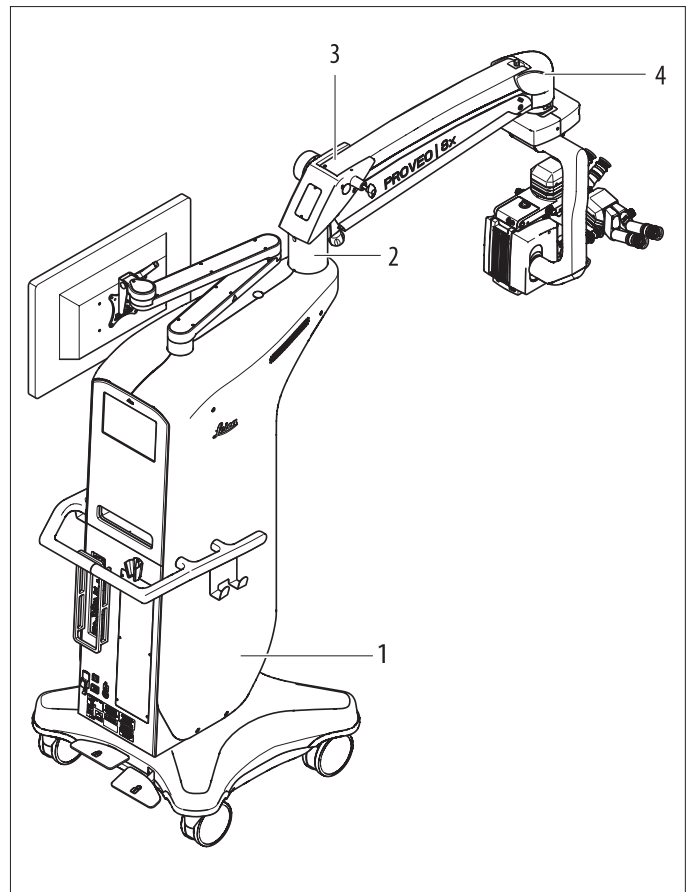


5.2 Brakes

The PROVEO 8x surgical microscope has 4 electromagnetic brakes which stop the movements of the stand and the surgical microscope:

The electromagnetic brakes can be released via handle or nurse switch.

5.2.1 Brakes at the floor stand

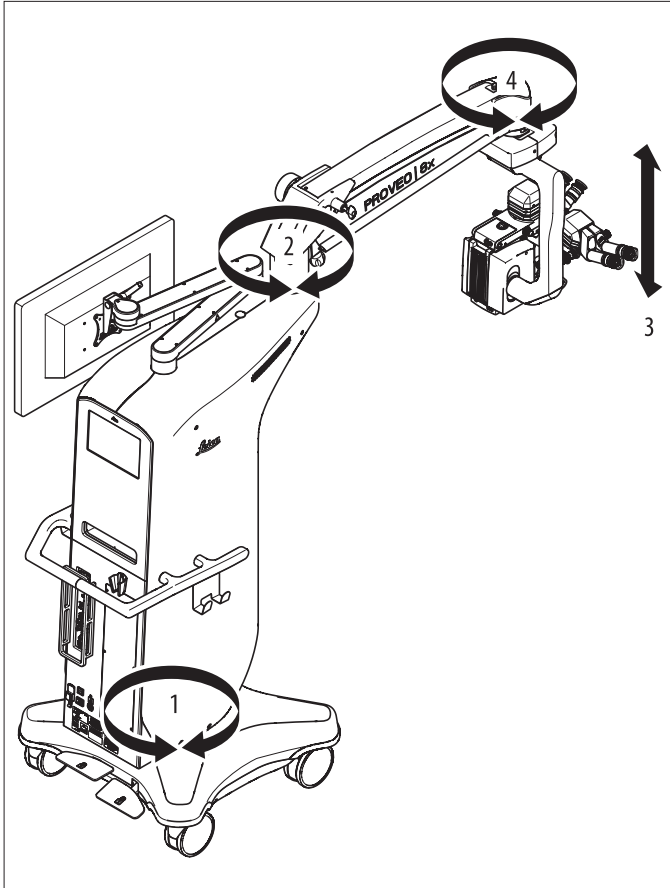


- 1 Rotation of the tower
- 2 Rotation of parallelogram
- 3 Up/Down movement of parallelogram
- 4 Rotation of microscope carrier

5.2.2 Selected brakes at the floor stand

With the function "Selected brakes" the user can release any individual brake.

! Only a Leica representative can configure or modify this function.



- 1 Rotation of tower
- 2 Rotation of parallelogram
- 3 Up/Down movement of parallelogram
- 4 Rotation of microscope carrier

! Do not move the system without released brakes.

5.3 Illumination

The illumination of the surgical microscope PROVEO 8x consists of two LED modules and are located in the optics carrier. There are two lamps, main lamp and Red Reflex lamp.

5.4 3D Camera and Heads-Up Display

! For further information refer to the heads-up ophthalmology instructions 10735165 distributed separately.

PROVEO 8x can be connected to various 3D monitors to provide on-screen visualization of the surgical field.

The following monitors are compatible:

- 32" 3D 4K
- 55" 3D 4K

NOTE

Due to the characteristics of LCD and OLED panel, the monitors are susceptible to image smearing and burn-in, especially in areas where static images are displayed over extended periods. Refer to the monitor's user manual on how to prevent such issue.

The binoculars on the PROVEO 8x 3D 4K IVC can be removed to provide an unblocked full 3D heads-up surgical experience. For more instructions, refer to the heads-up ophthalmology instructions 10735165 distributed separately.

! Binoculars may be removed at the user's discretion. Please keep binoculars in an easily accessible location in the event this needs to be installed back on PROVEO 8x.



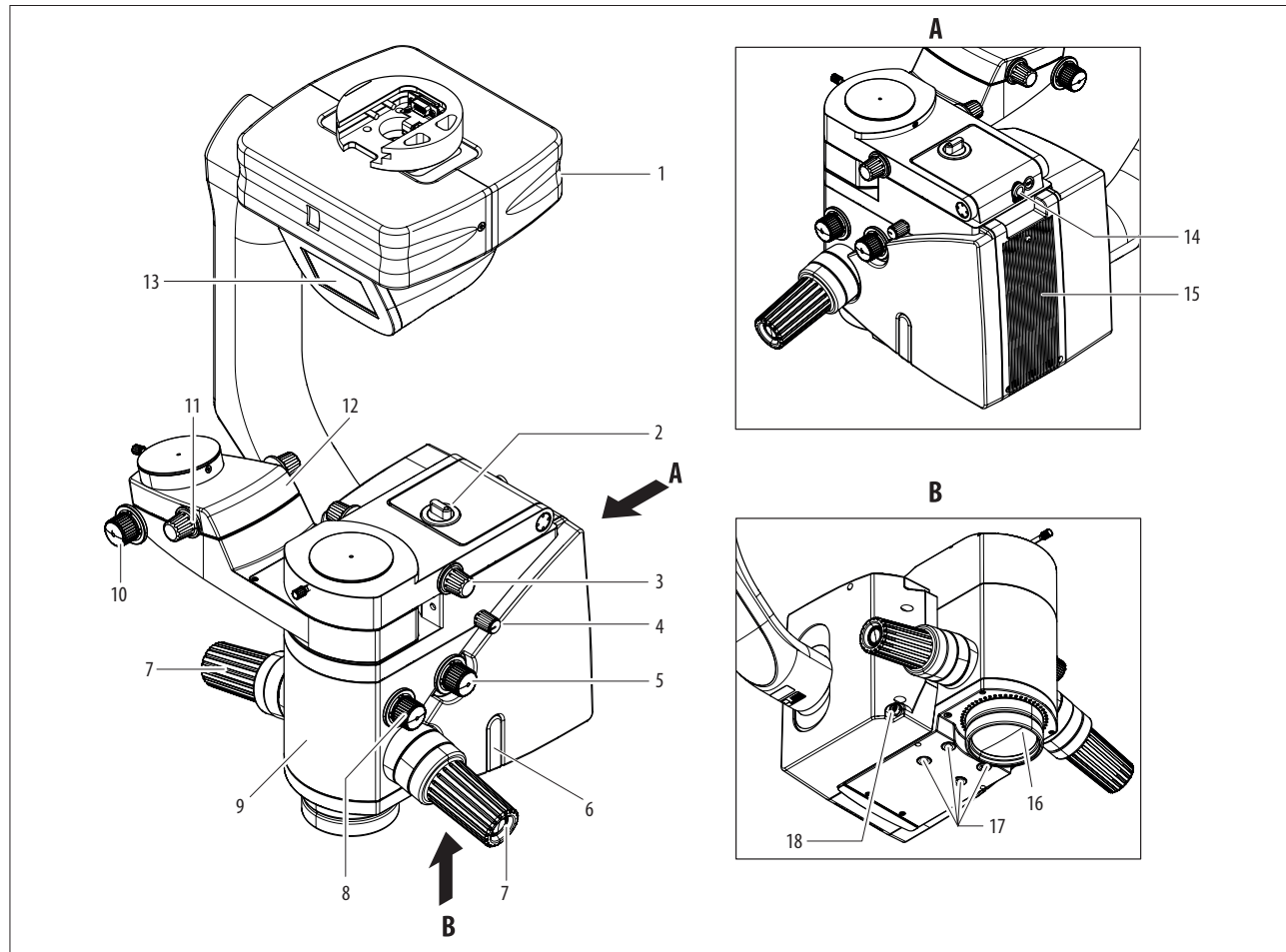
WARNING

Risk of injury due to downward movement of the surgical microscope!

- ▶ Never change the accessories or attempt to rebalance the microscope while it is above the field of operation.
- ▶ After re-equipping, always rebalance the microscope on the parallelogram.

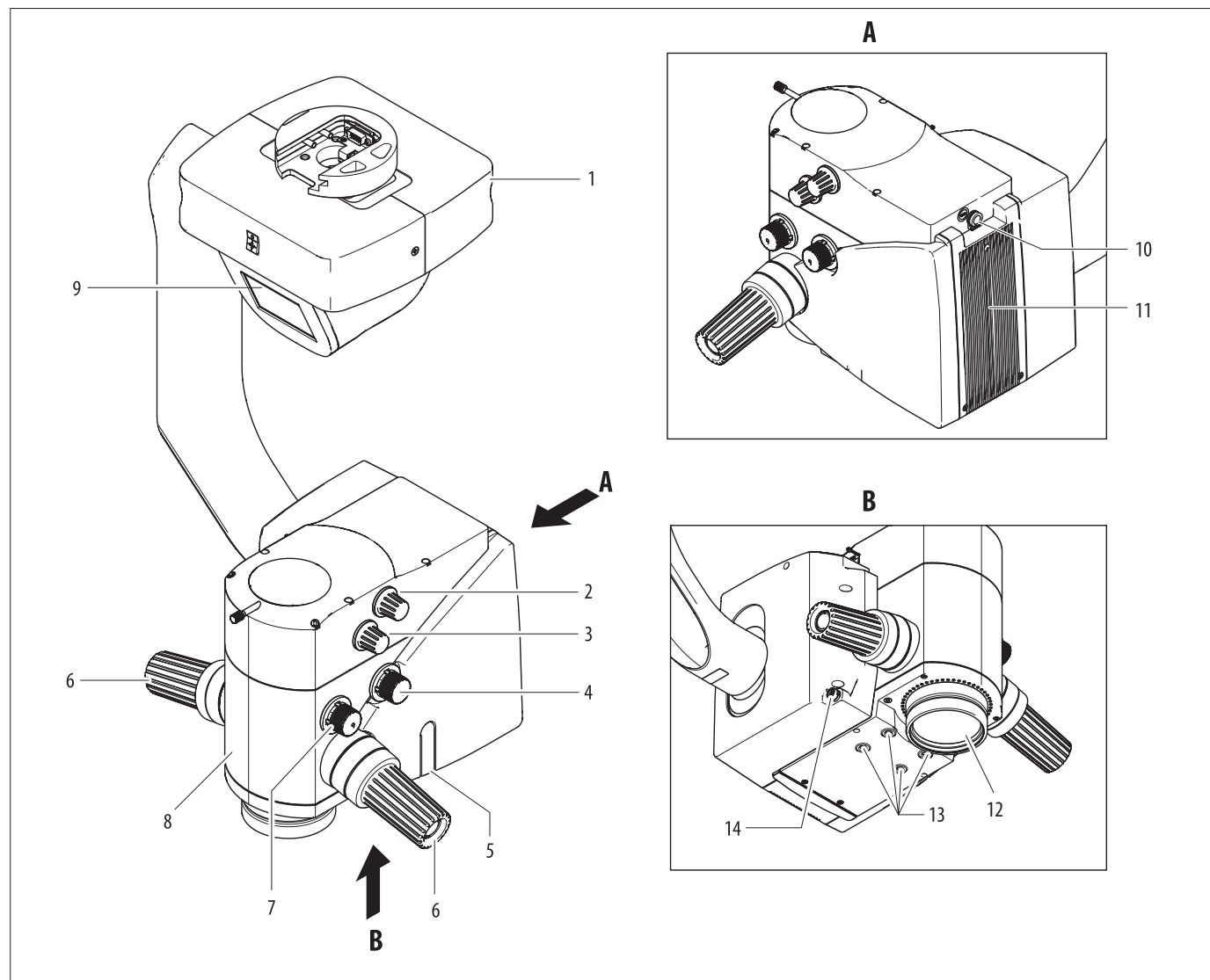
6 Controls

6.1 PROVEO 8x optics carrier including focus, tilt and XY with 2D4K IVC



- | | |
|--|--|
| 1 XY Coupling | 10 Fine focus for assistant |
| 2 Rotary knob for changing the 0° assistant position | 11 Rotary knob "Inverter" assistant (emergency operation only) |
| 3 Rotary knob "Inverter" for main surgeon (emergency operation only) | 12 0° assistant |
| 4 Fine focus for integrated camera | 13 Surgeon panel |
| 5 Rotary knob "Magnification" (emergency operation only) | 14 1× CAN socket - only for Leica accessories |
| 6 Slot for filter slide | 15 Cooling slots |
| 7 Handle | 16 Objective |
| 8 Rotary knob for Red Reflex illumination diameter | 17 Mounting threads for accessories |
| 9 PROVEO 8x optics carrier | 18 Socket for BIOM |

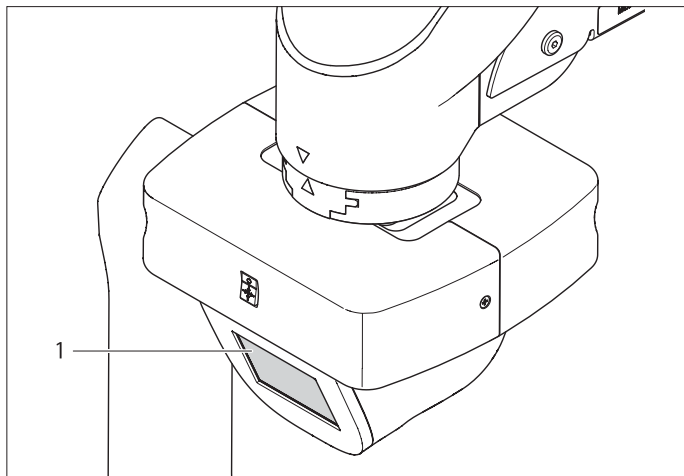
6.2 PROVEO 8x optics carrier including focus, tilt and XY with 3D4K IVC



- 1 XY Coupling
- 2 Rotary knob "inverter" (emergency operation only)
- 3 Rotary knob "3D digital/3D Hybrid"
- 4 Rotary knob "Magnification" (emergency operation only)
- 5 Slot for filter slide
- 6 Handle
- 7 Rotary knob for Red Reflex illumination diameter
- 8 PROVEO 8x optics carrier

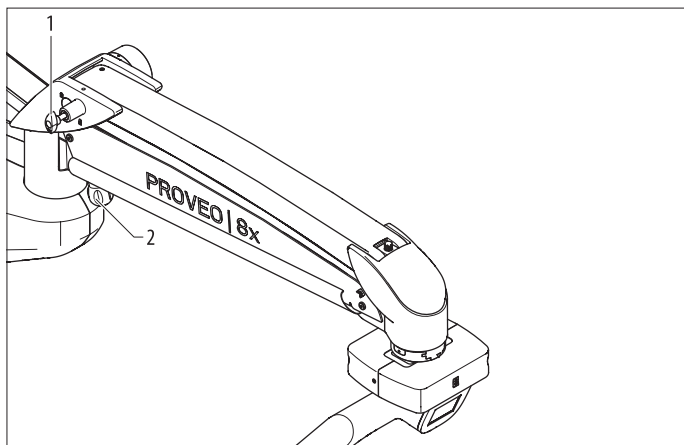
- 9 Surgeon panel
- 10 1× CAN socket - only for Leica accessories
- 11 Cooling slots
- 12 Objective
- 13 Mounting threads for accessories
- 14 Socket for BIOM

6.3 Surgeon panel



1 Surgeon panel

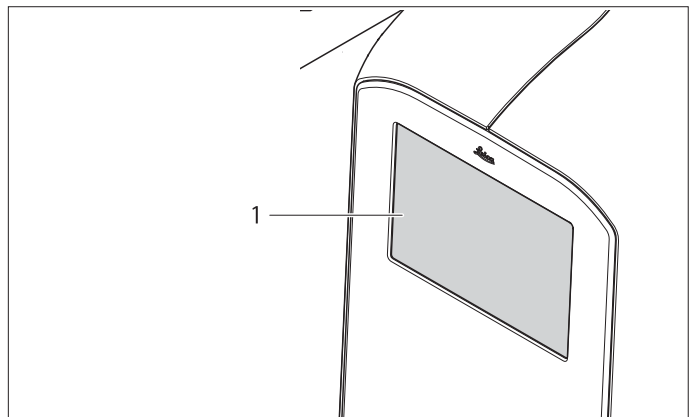
6.4 Balancing



- 1 Transport lock (block parallelogram)
- 2 Balancing knob

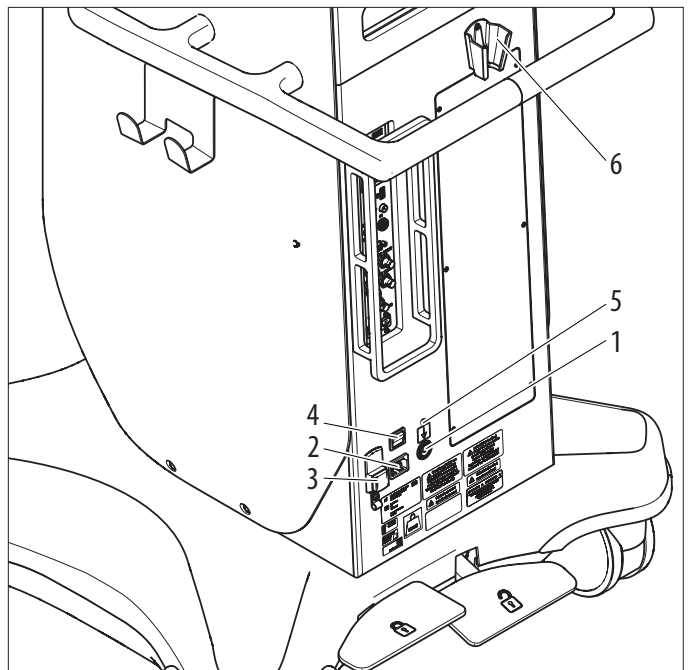
Balancing the parallelogram (see chapter 7.8.1 "Balancing the parallelogram", page 31).

6.5 Control unit



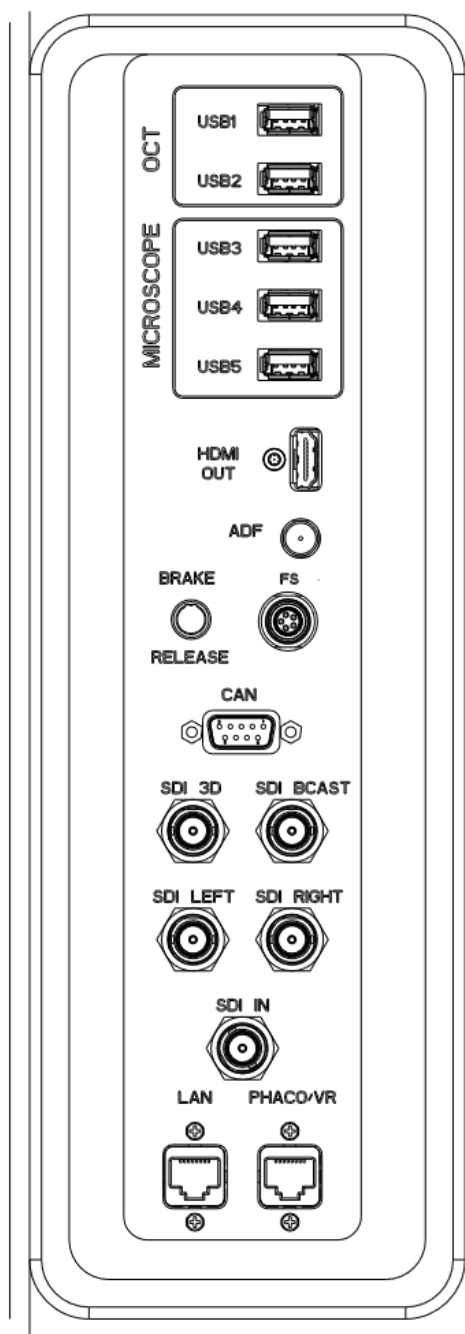
1 Touch panel (graphical user interface)

6.6 Floor stand



- 1 Equipotential bonding socket
For connecting the PROVEO 8x to an equipotential bonding device. This is part of the customer's building installation. Observe the requirements of EN 60601-1 (§ 8.6.7).
- 2 Power input
- 3 Thermal Magnetic Circuit Breaker
- 4 Main switch for PROVEO 8x surgical microscope
- 5 Power LED Indicator
- 6 Nurse switch holder

6.7 Terminals



OCT only: USB ports for external storage

MICROSCOPE: USB ports for external storage

HDMI OUT*: Video output to connect to a 4K external monitor

ADF: additional function

BRAKE RELEASE: for nurse switch only

FS: for secondary wireless footswitch receiver

CAN: for Leica device only

SDI 3D: 3D 4K live output

SDI BCAST*: 4K video output to connect to a 4K external monitor

SDI LEFT: 3D Full HD live output (left view)

SDI RIGHT: 3D Full HD live output (right view)

SDI IN*: Full HD external video input

LAN*: to connect to DICOM/Hospital network

PHACO/VR: to connect to a phacoemulsification/vitreoretinal surgical device (Leica compatible)

* connect medical equipment only

The following devices can only be connected to the PROVED 8x surgical microscope if they are certified accordingly:

Device	Signal	Voltage output	Certified according to
External monitor	SDI	5 V (DC)	IEC 62368-1
MyVeo	CAN	24 V (DC)	IEC 62368-1
External monitor	HDMI OUT	5 V (DC)	IEC 62368-1
External hard drive	USB 3-5	5 V (DC)	IEC 62368-1

6.8 Footswitch and handles

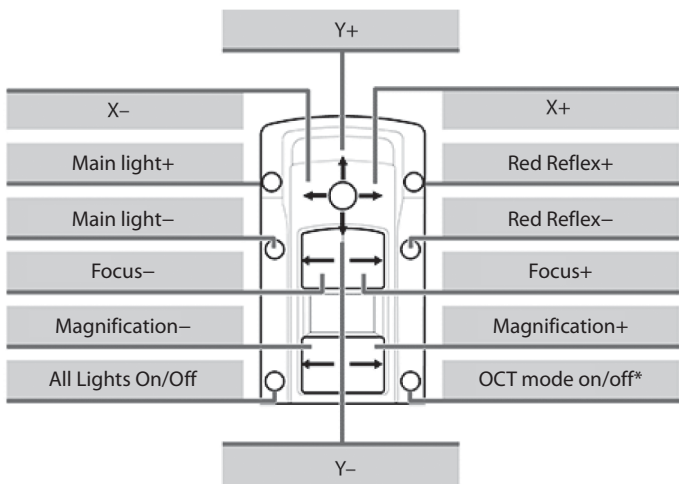
! See also User manual Wireless Footswitch, 14 functions.

6.8.1 Pre-set Surgeon Profile "Cataract"

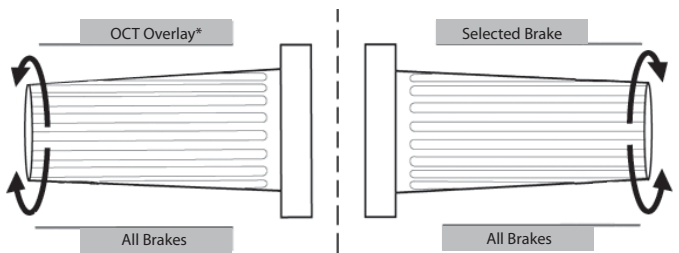
! Footswitch and handles can be assigned individually for each user in the configuration menu.

Anterior mode

Footswitch



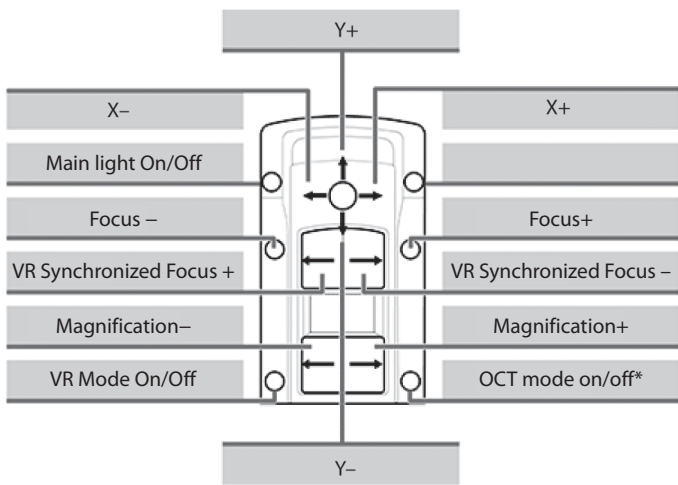
Handles



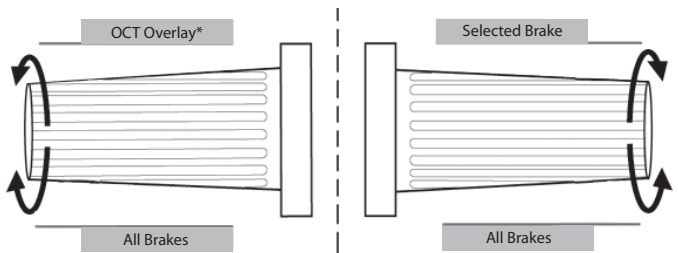
! * When OCT is available.

VR mode

Footswitch



Handles



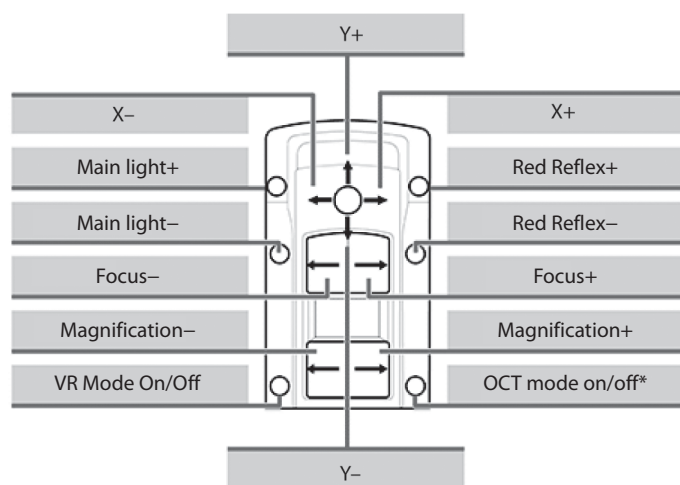
6.8.2 Pre-set Surgeon Profile "Vitreoretinal"



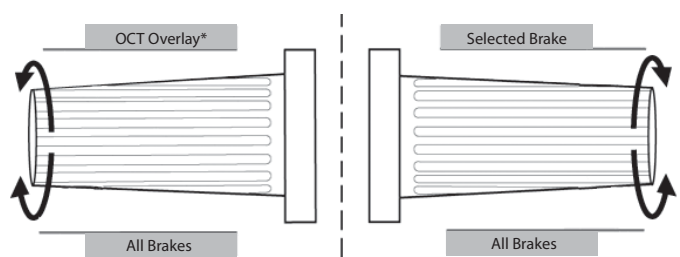
Footswitches and handles can be assigned individually for each user in the configuration menu.

Anterior mode

Footswitch

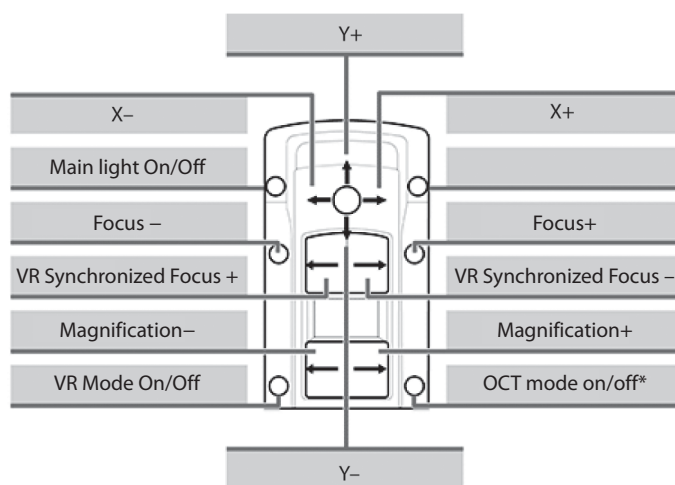


Handles

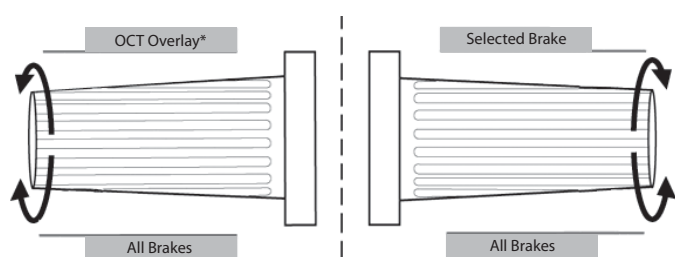


VR mode

Footswitch



Handles



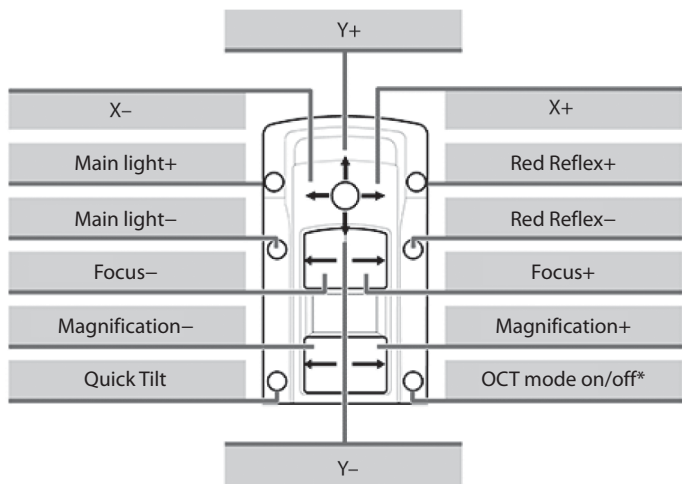
* When OCT is available.

6.8.3 Pre-set Surgeon Profile "Glaucoma"

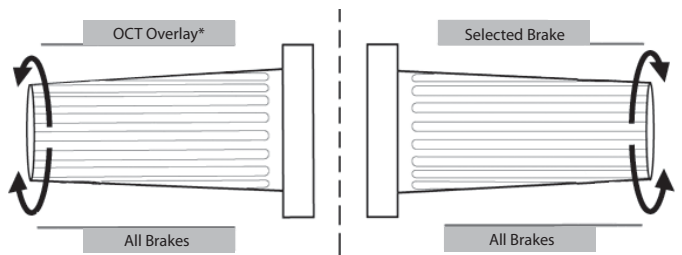
! Footswitches and handles can be assigned individually for each user in the configuration menu.

Anterior mode

Footswitch



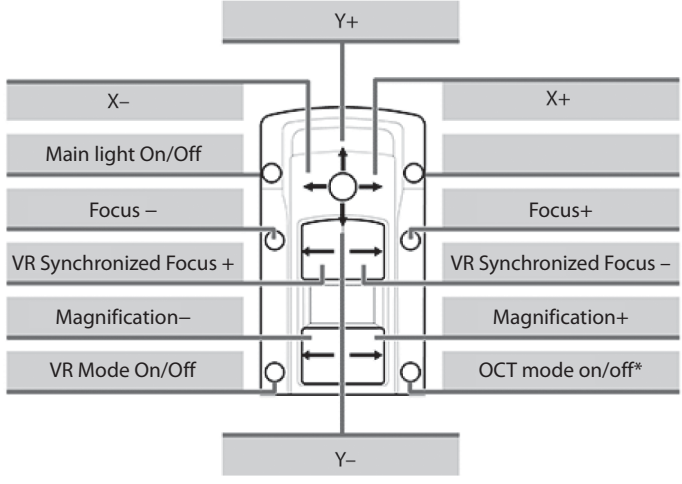
Handles



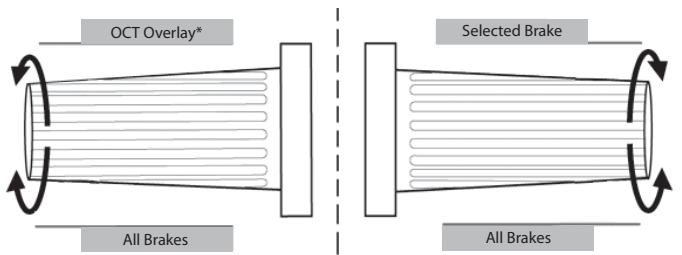
! * When OCT is available.

VR mode

Footswitch



Handles



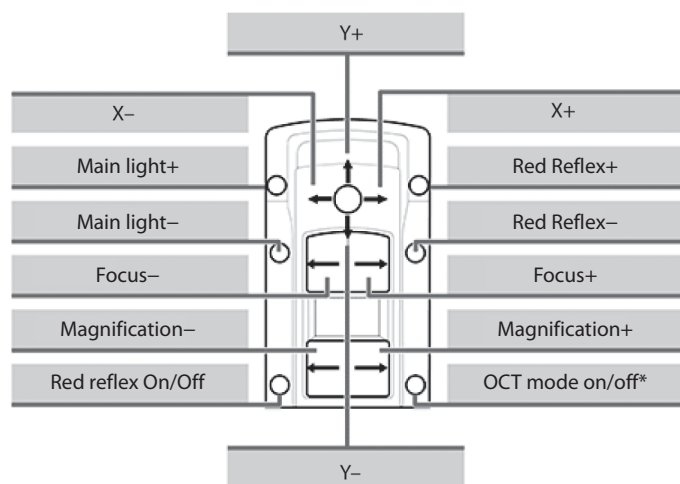
6.8.4 Pre-set Surgeon Profile "Cornea"



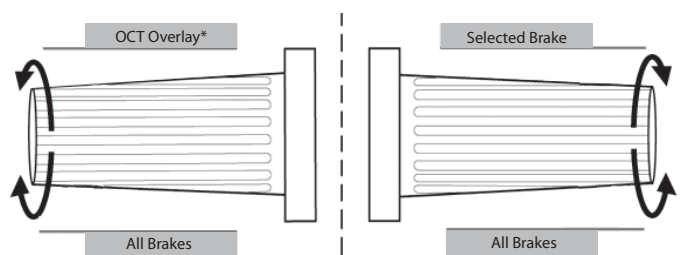
Footswitches and handles can be assigned individually for each user in the configuration menu.

Anterior mode

Footswitch



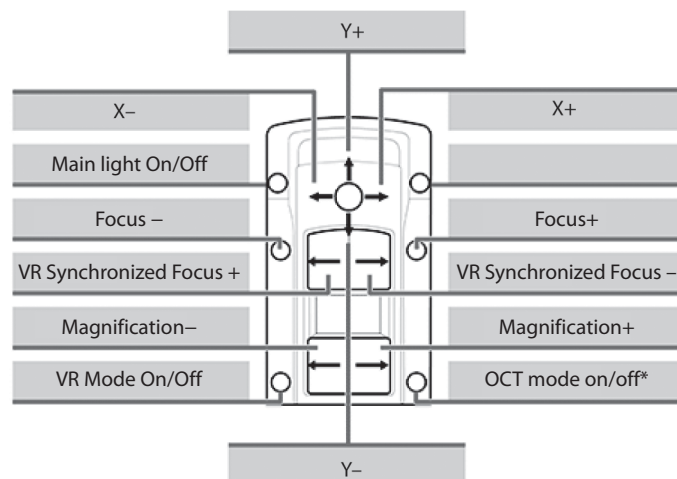
Handles



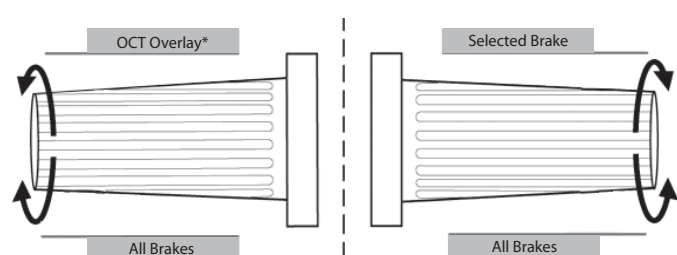
* When OCT is available.

VR mode

Footswitch

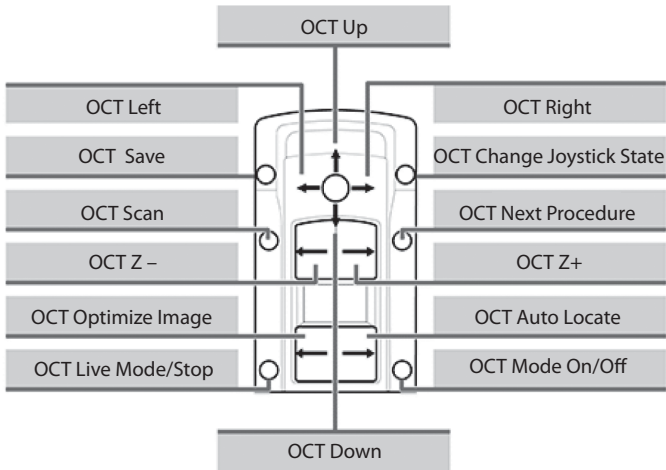


Handles

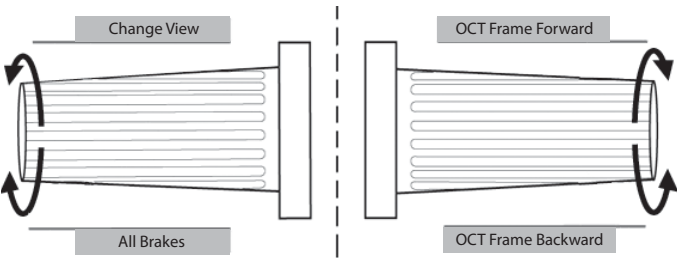


6.8.5 Pre-set "OCT Mode" and "VR OCT Mode" handles and footswitch configuration for all Surgeon Profiles

! Footswitches and handles can be assigned individually for each user in the configuration menu.



Handles



7 Preparation before surgery

7.1 Transportation



WARNING

Danger of injury due to:

- **uncontrolled lateral movement of the parallelogram**
 - **tilting of the stand**
 - **feet in lightweight shoes could become trapped beneath the casing of the base**
- For transportation, always move the PROVEO 8x surgical microscope into the transport position.
- Never move the stand while the unit is extended.
- Never roll over cables lying on the floor.
- Always push the PROVEO 8x surgical microscope; never pull it.



CAUTION

Surgical microscope can move without warning!

- Always lock the footbrake when you are not moving the system.



CAUTION

Damage to the PROVEO 8x surgical microscope due to uncontrolled movement!

- Hold the handle when releasing the brake.



CAUTION

Damage to the PROVEO 8x surgical microscope during transportation!

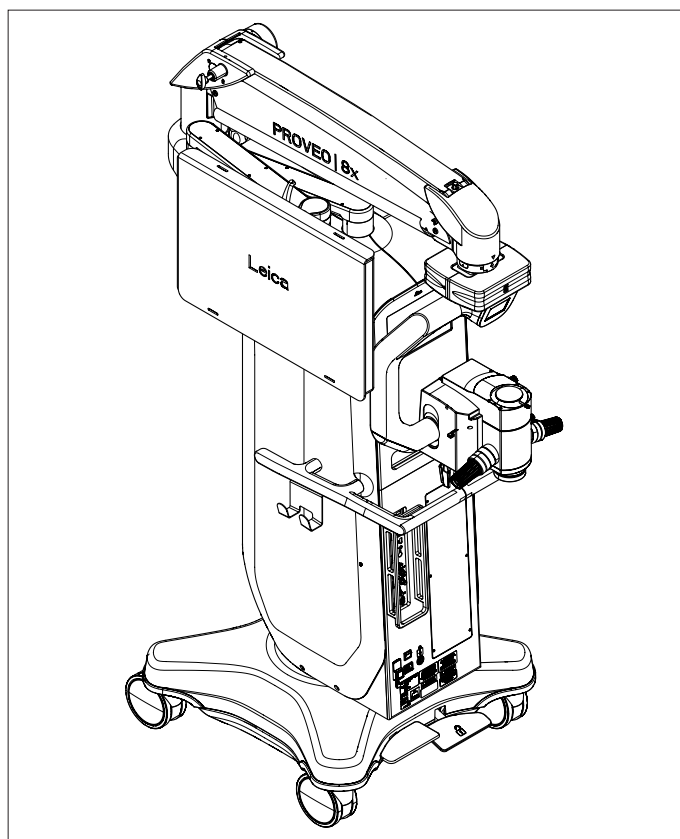
- Never move the stand in the extended condition.
- Never roll over cables lying on the floor.
- Do not transport or store the system in areas with an elevation angle bigger than 10°.

NOTE

If the optics carrier is moved into the transport position or from the transport position to the operating position:

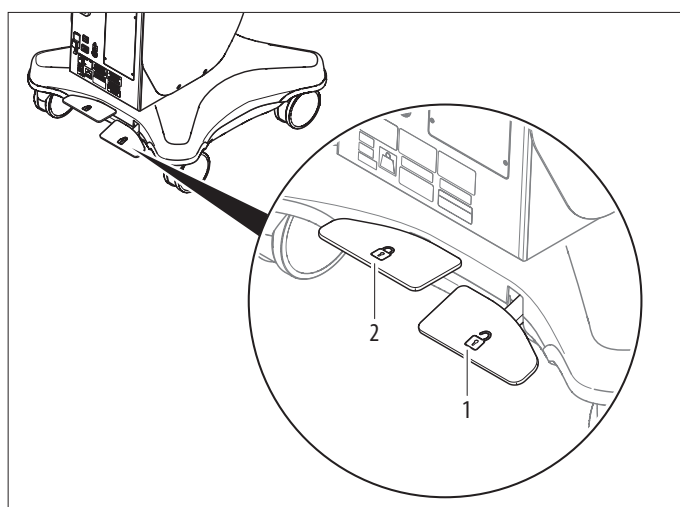
- Ensure that the transport lock is locked.

- Ensure that the PROVEO 8x is in the transport position.



In case the PROVEO 8x is not in transport position, refer to chapter 8.5 "Transport position", page 40.

- Press the foot pedal at the right (1) (open lock). The footbrake disengages and is released.
- Move the PROVEO 8x using the handrail.
- Press the foot pedal at the left (2) (lock closed) until the footbrake engages.



7.2 Installing the monitor cover

- ▶ Unpack the packaging box carefully.
- ▶ Retrieve the display cover from its packaging and unwrap it from the protective bubble wrap.
- ▶ Prior to installation, unlock the buckles on the straps.

! Keep the straps attached to the slots on the display cover.

- ▶ Position the display cover over the monitor, securing the straps along the sides and looping them around the back of the monitor.
- ▶ Adjust the cover and straps to ensure proper alignment.
- ▶ Secure the cover in place by hooking the straps over the back of the monitor, aiming to position the buckles on the lower part of the device.
- ▶ Once the cover is properly positioned, pull and tighten the straps.
- ▶ Lock the buckles to complete the installation process.

- The monitor display cover serves to protect the monitor during storage at medical facilities, and must be removed before surgeries in the operating theater. Installation and removal should be conducted by trained personnel outside of the operating theater.
- In the rare event of the display cover falling and becoming damaged during handling, it is important to take appropriate precautions to prevent any potential personal injury from broken parts or sharp edges.
- Please contact your local Leica Microsystems representative promptly to discuss replacement options with a new cover. Leica Microsystems will be able to provide guidance and assistance in ensuring the safe replacement of the damaged cover to maintain the integrity and safety of your equipment.
- For shipment preparation, the monitor cover should be removed from the stand and packed separately.
- If necessary, wipe dust from the cover using a soft cloth.

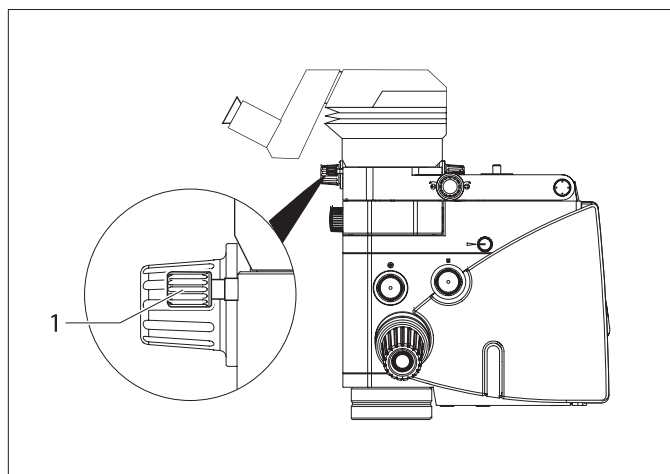
7.3 Installing a binocular tube



WARNING

Risk of injury due to downward movement of the surgical microscope!

- ▶ Complete all preparations and adjustments to the stand before the operation.
 - ▶ Never change the accessories or attempt to rebalance the microscope while it is above the field of operation.
 - ▶ Before changing accessories, always lock the parallelogram (see chapter 7.8.2 "Locking the parallelogram", page 31).
 - ▶ Balance the PROVEO 8x after re-equipping it.
 - ▶ Do not release the brakes when the instrument is in an unbalanced state.
 - ▶ Before re-equipping during the operation, first swing the microscope away from the operating field.
- ▶ Make sure that the optical accessories are clean and free of dust and dirt.
 - ▶ Loosen the clamping screw (1).
 - ▶ Insert the accessories into the dovetail ring.
 - ▶ Tighten the clamping screw (1).



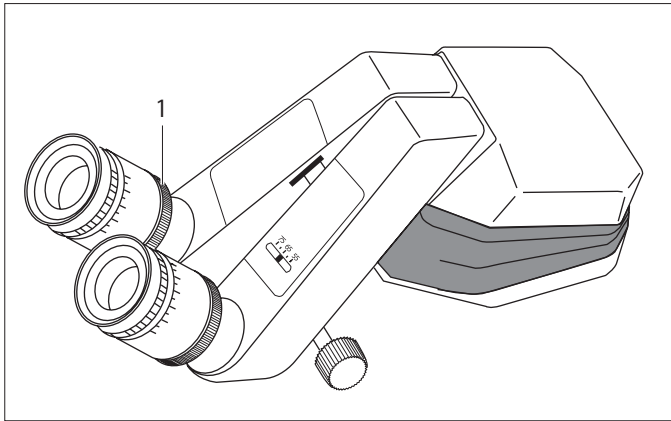
WARNING

Risk of injury from parts falling down!

- ▶ Before the operation, make sure that the optical components and accessories are sufficiently secured and cannot move.

7.3.1 Installing the eyepieces

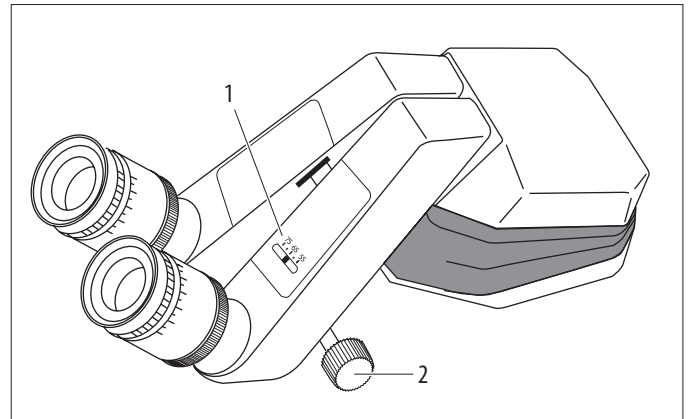
- Make sure that the optical accessories are clean and free of dust and dirt.
- Screw the knurled nut (1) of the eyepieces on the binocular tube as far as end stop.



7.4 Setting the binocular tube

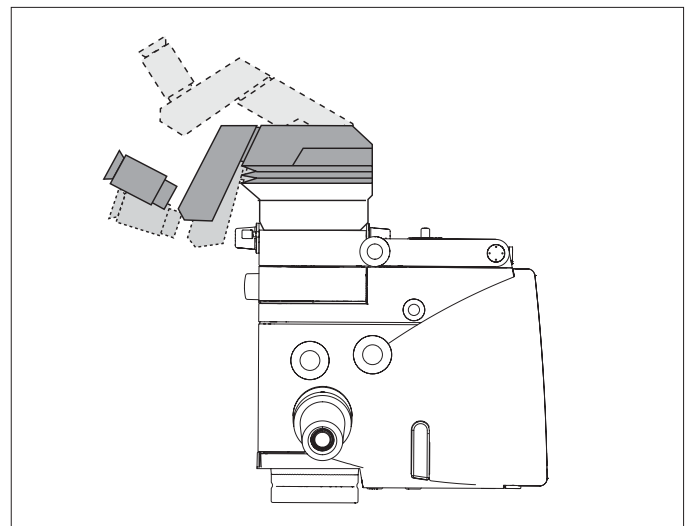
7.4.1 Setting the interpupillary distance

- Adjust the interpupillary distance to a value between 55 mm and 75 mm, see on the scale (1).
- Using the adjusting wheel (2), set the interpupillary distance such that a circular image field can be seen.



7.4.2 Adjusting the tilt

- Hold the binocular tubes with both hands.
- Tilt the binocular tube upwards or downwards until a comfortable position for viewing is reached.



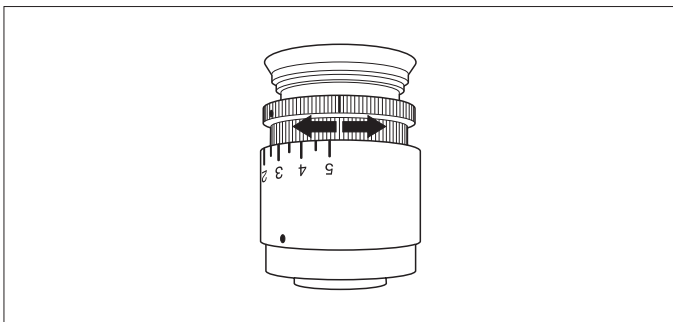
7.5 Adjusting the eyepiece

7.5.1 Determining/adjusting diopter settings for users

The individual diopters can be adjusted continuously for each eyepiece from +5 to -5. The diopters must be set exactly and separately for both eyes. Only this method will ensure that the image will stay in focus within the entire magnification range = parfocal. The surgical microscope ensures a high degree of fatigue resistance when the diopter setting is correct for both eyes.

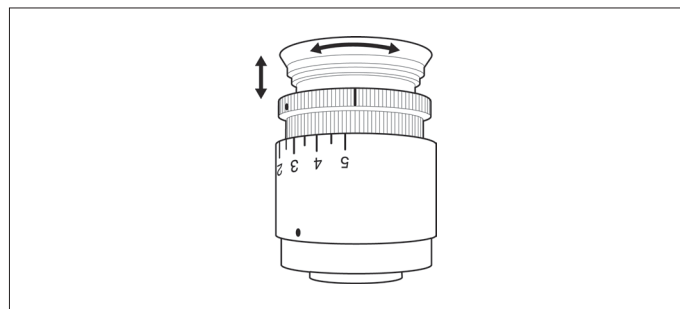
! A parfocally adjusted microscope ensures that user's view and monitor image will always remain sharp, regardless of the selected magnification.

- ▶ Select the minimum magnification.
- ▶ Place a flat test object with sharp contours under the lens at working distance.
- ▶ Focus the microscope.
- ▶ Set the maximum magnification.
- ▶ Focus the microscope.
- ▶ Set the minimum magnification.



- ▶ Without looking into the eyepieces, turn both eye lenses to +5 diopters.
- ▶ Slowly turn the eyepieces towards -5 individually for each eye until the test object appears in sharp focus.
- ▶ Select the highest magnification and check the sharpness.

7.5.2 Adjusting the pupillary distance



- ▶ Rotate the eyecups up or down until the desired distance is set.

7.5.3 Checking parfocality

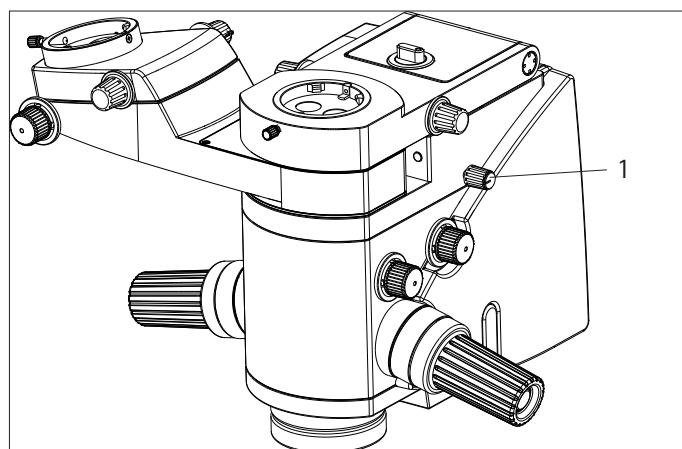
- ▶ Place a flat test object with sharp contours under the objective at working distance.
- ▶ Zoom to the highest magnification.
- ▶ Focus on the test object.
- ▶ Zoom through the whole magnification range, observing the test object.
- ▶ Perform the steps above for 3D viewing.

! The image sharpness must remain constant at all magnifications. If this is not the case, check the diopter settings of the eyepieces.

7.6 2D 4K IVC

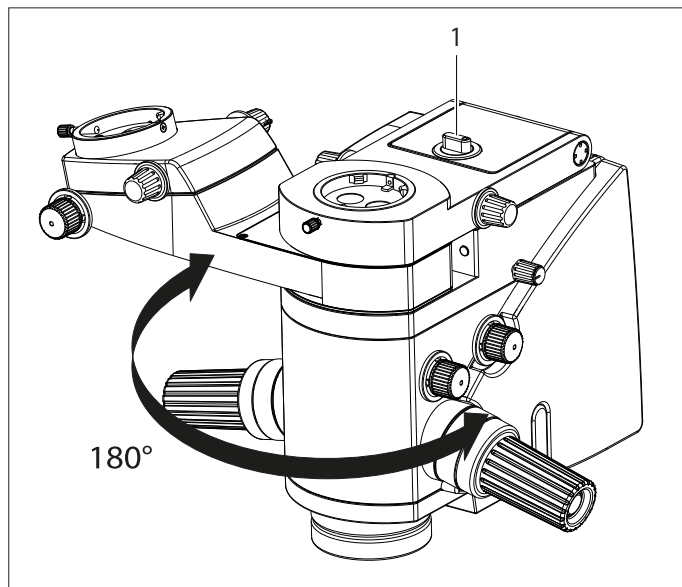
7.6.1 Parfocality for 2D 4K IVC

- ▶ After parfocality is ensured, select the minimum magnification.
- ▶ Adjust the fine focus knob (1) until you see a sharp image on the monitor.
- ▶ Zoom through the whole magnification range. The image must be sharp at all magnifications.

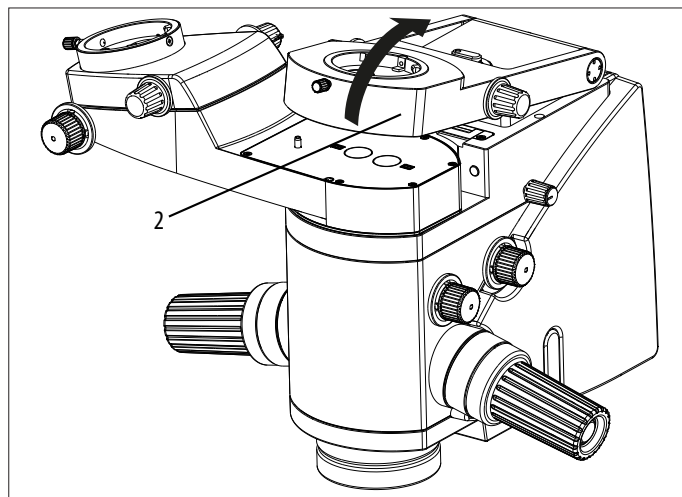


7.6.2 Laser filter for 2D 4K IVC

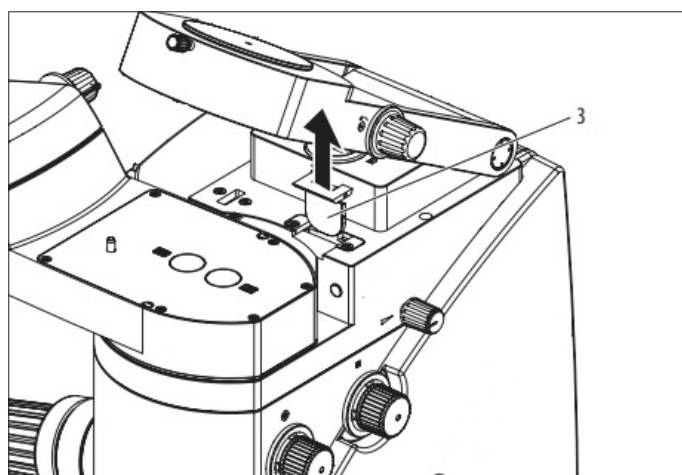
- Unlock knob (1).



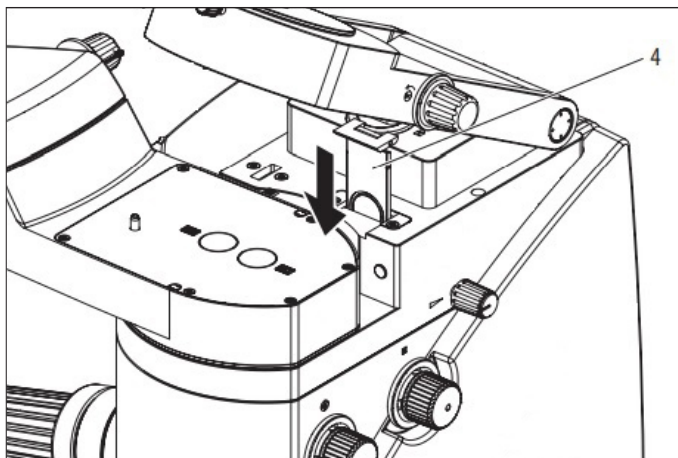
The top (2) is lifted.



- Remove the dummy laser filter (3).



- Insert the laser filter IVC (4) into the laser filter slot of the optics carrier.

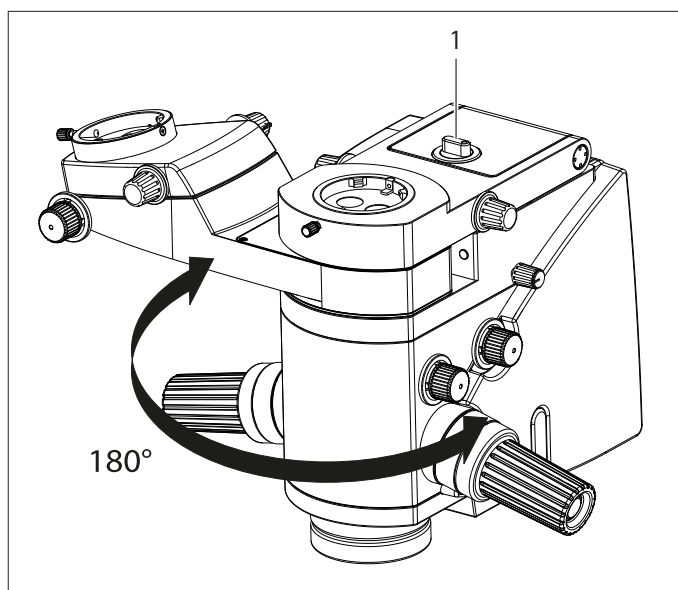


! The laser filter is built in for the 3D 4K IVC.

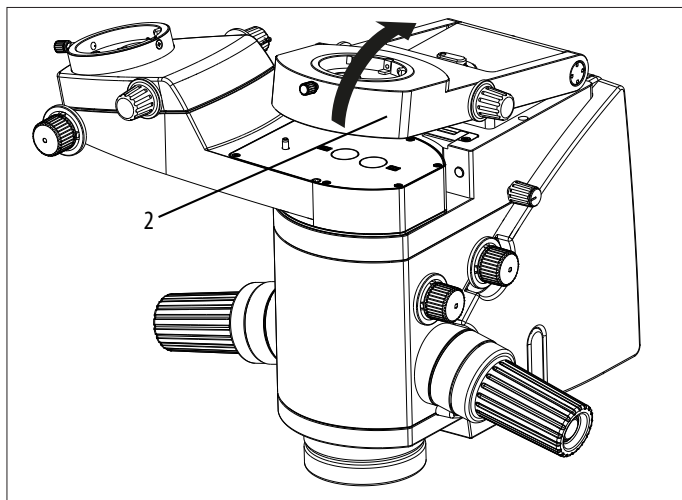
7.6.3 Change the 0° assistant to another position

The 0° assistant can be positioned on the left and on the right side.

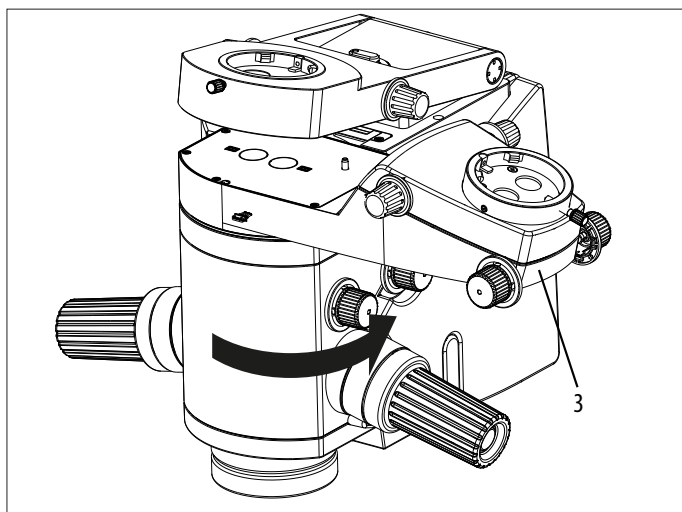
- Unlock knob (1).



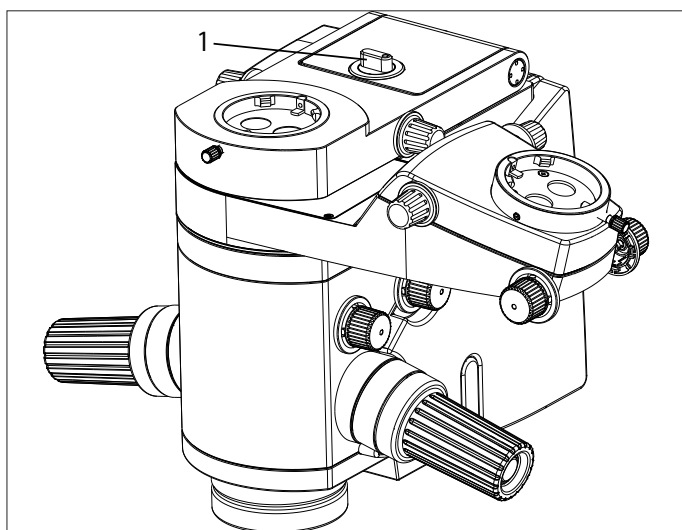
The top (2) is lifted.



► Change the 0° assistant position (3).



► When the desired position is reached, push the top down and lock the knob (1) again.



7.7 Changing the filter

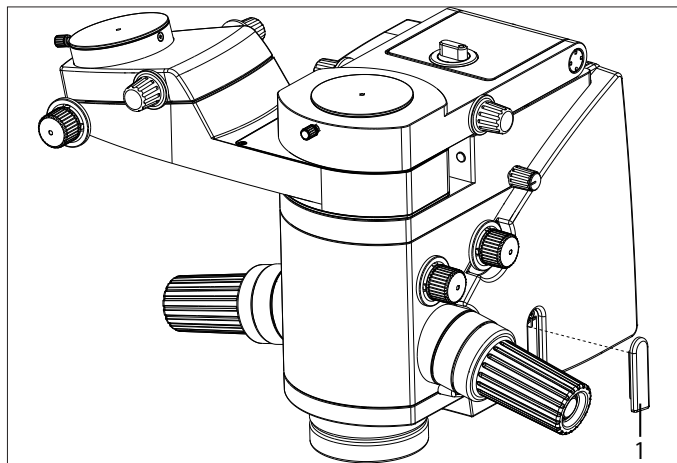
7.7.1 Slot for color and special filters

There is a slot in the optics carrier housing into which filter slides can be inserted.

► Remove the cover (1).

There are two slots for filters.

- Left filter slot: Color temperature filter for main LED
- Right filter slot: Special filters or diaphragms



The plane of filter is sharply imaged in the same plane as the object. The GG420 UV protection filter is built in. In addition, the BG12 cobalt blue filter, KW65 and KW90 color conversion filter are available.

► Remove the filter cover (1).

► Push in the filter slide, inclined slightly upwards, until it engages.

7.8 Balancing and locking the parallelogram

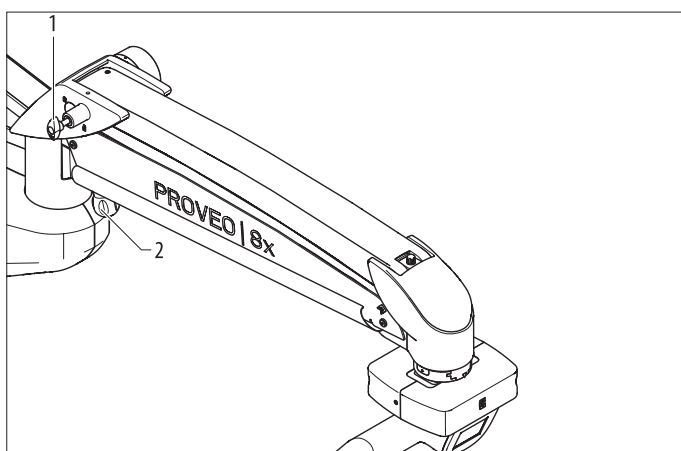
7.8.1 Balancing the parallelogram



WARNING

Risk of injury due to downward movement of the surgical microscope!

- ▶ Never change the accessories or attempt to rebalance the microscope while it is above the field of operation.
- ▶ After re-equipping, always rebalance the microscope on the parallelogram.



- ▶ Release the parallelogram (see chapter 7.8.3 "Releasing the parallelogram", page 32).
- ▶ Hold the microscope by the handles.
- ▶ Use handle to release the brakes (All Brakes).
- ▶ Check whether the microscope drifts up or down.

Microscope drifts downwards:

- ▶ Turn balancing knob (2) clockwise.

Microscope drifts upwards:

- ▶ Turn balancing rotary knob (2) counterclockwise.

7.8.2 Locking the parallelogram

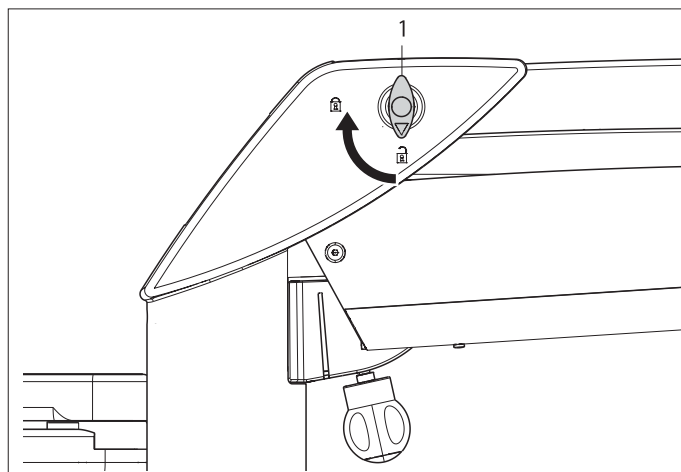


WARNING

Risk of injury due to downward movement of the surgical microscope!

- ▶ Always lock the parallelogram:
 - when transporting the microscope
 - when re-equipping

- ▶ Pull the transport lock (1) and bring it into a horizontal position.



- ▶ Hold and turn one or both handles to release the brakes (All Brakes).



CAUTION

Risk of damage to the surgical microscope due to uncontrolled tilting!

- ▶ Firmly hold the handles before triggering the "All Brakes" function.

- ▶ Move the parallelogram up and down until the transport lock engages.

The parallelogram is now locked.

7.8.3 Releasing the parallelogram

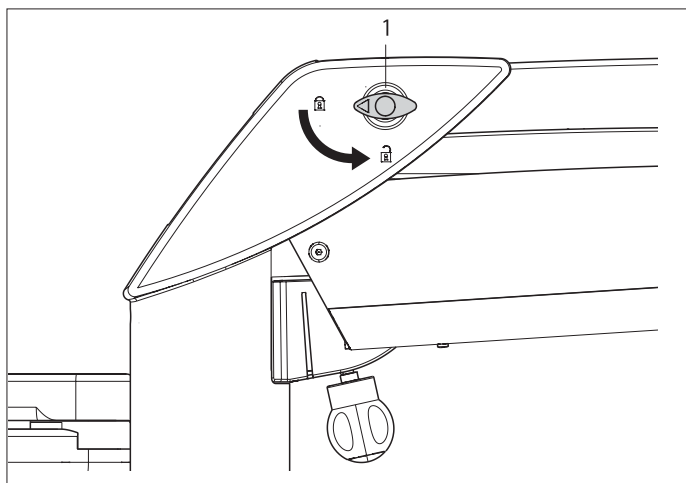


CAUTION

Risk of damage to the surgical microscope due to uncontrolled tilting!

- ▶ Firmly hold the handles before triggering the "All Brakes" function.

- ▶ Grip and turn one handle to release the brakes.
- ▶ At the same time, pull the transport lock (1) and bring it into a vertical position.



The parallelogram is now released.



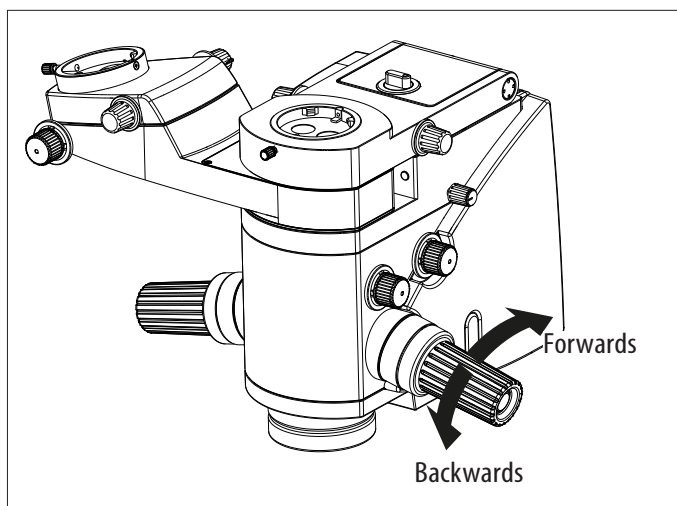
If necessary, rebalance the parallelogram (see chapter 7.8.1 "Balancing the parallelogram", page 31).



WARNING

Risk of injury due to downward movement of surgical microscope!

- ▶ Complete all preparations and adjustments to the stand before the operation.
- ▶ If settings need to be altered during the operation, first swing the microscope away from the operating field.
- ▶ If the microscope needs to be re-equipped, do this before the operation.
- ▶ Before re-equipping, always lock the parallelogram.
- ▶ Do not use the handles or remote brake release when the instrument is in an unbalanced state.



Unless they are individually configured for the current user, the brakes are released by turning the handles as follows:

- ▶ Turn backwards and hold: All brakes are released
- ▶ Turn forwards and hold: Selected brakes are released



The handles can be individually assigned up to 4 functions for each user in the "User Settings" menu. The function "All Brakes" must be selected at least once.



Selected brake can be configured by a qualified person only.

7.9 Positioning on the operating table

7.9.1 Floor stand



WARNING

Danger of injury due to:

- **uncontrolled lateral movement of the parallelogram**
 - **tilting of the stand**
 - **feet in lightweight shoes could become trapped beneath the casing of the base**
- ▶ For transportation, always move the PROVEO 8x surgical microscope into the transport position.
 - ▶ Never move the stand while the unit is extended.
 - ▶ Never roll over cables lying on the floor.
 - ▶ Always push the PROVEO 8x surgical microscope; never pull it.



WARNING

Risk of injury due to downward movement of the surgical microscope!

- ▶ Complete all preparations and adjustments to the stand before the operation.
- ▶ Never change the accessories or attempt to rebalance the microscope while it is above the field of operation.
- ▶ Before changing accessories, always lock the parallelogram (see chapter 7.8.2 "Locking the parallelogram", page 31).
- ▶ Balance the PROVEO 8x after re-equipping it.
- ▶ Do not release the brakes when the instrument is in an unbalanced state.
- ▶ Before re-equipping during the operation, first swing the microscope away from the operating field.

- ▶ Using the handrail, carefully push the surgical microscope to the operating table and position it as desired.



- All positions are also possible as the mirror image position.
- The instrument must be positioned such that the range of movement is large enough for the expected tasks.

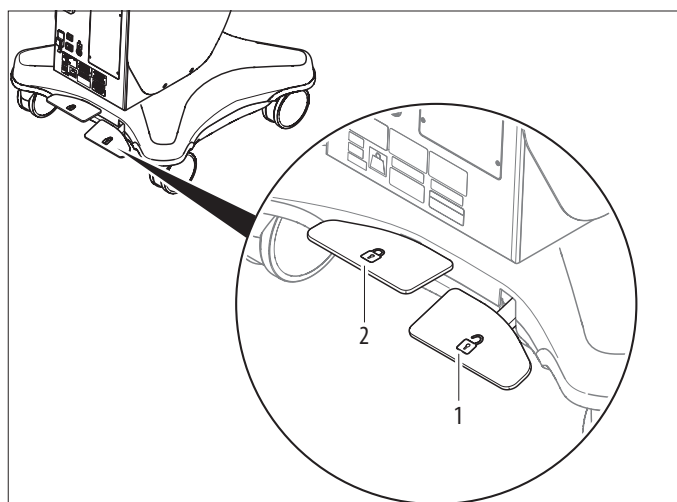
- ▶ Press the foot pedal at the front end (2) (lock closed) until the footbrake engages.



CAUTION

Surgical microscope can move without warning!

- ▶ Always lock the footbrake when you are not moving the system.



- ▶ Position the microscope in such a way that the switches or plug can be reached easily.
- ▶ Position the footswitch below the operating table.
- ▶ Plug the power cable into the power outlet.

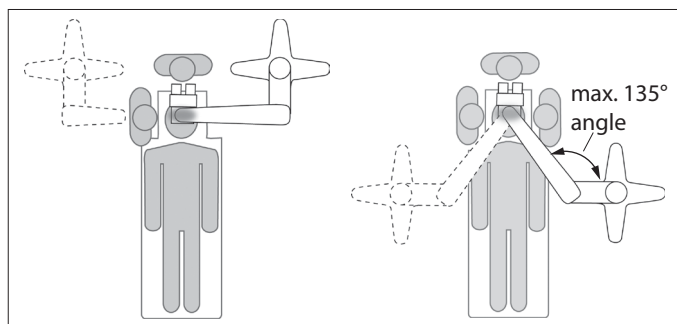


WARNING

Danger of fatal electrical shock!

- ▶ The PROVEO 8x surgical microscope may only be connected to a grounded socket.

- ▶ Connect the equipotential bonding to the stand.
- ▶ Start the system.
- ▶ Release the brakes (see chapter 7.8.4 "Releasing the brakes", page 32) and bring the system to a possible position (see picture below).
Maximum swing arm extension is at 135° angle.



7.10 Attaching sterile controls



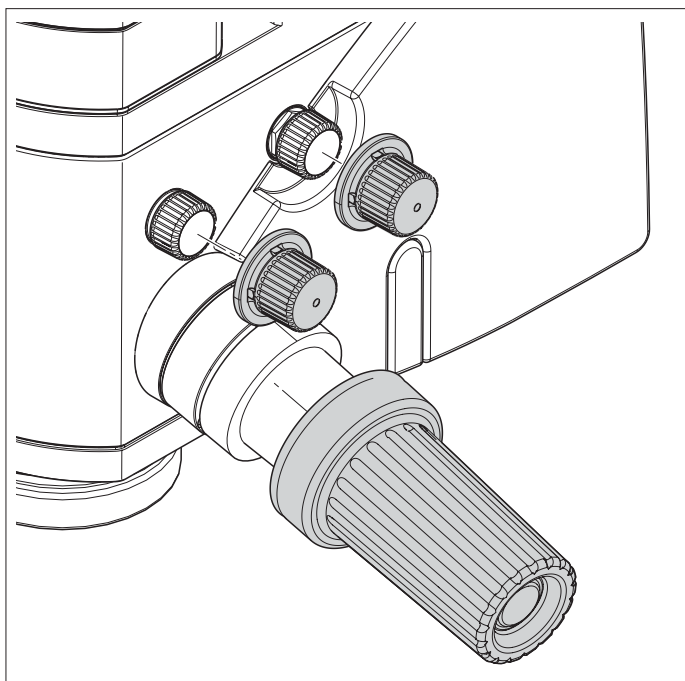
WARNING

Risk of infection!

- Always use the PROVEO 8x surgical microscope with sterile controls and knobs.

7.10.1 Covers for rotary buttons

- Attach steam-sterilizable covers on the handles, rotary knob for Red Reflex illumination diameter and rotary knob "Magnification".



- Attach steam-sterilizable covers to accessories as well (if present).

7.11 Function check

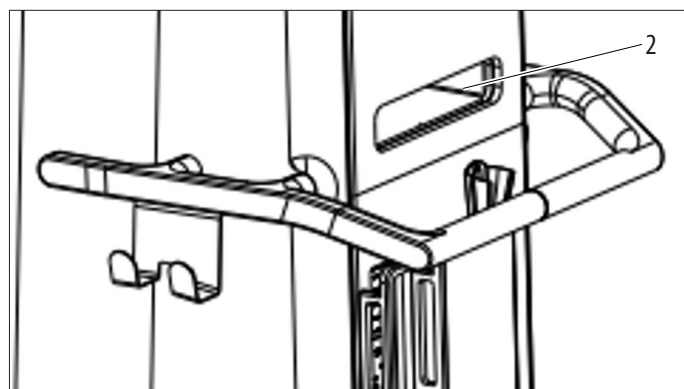
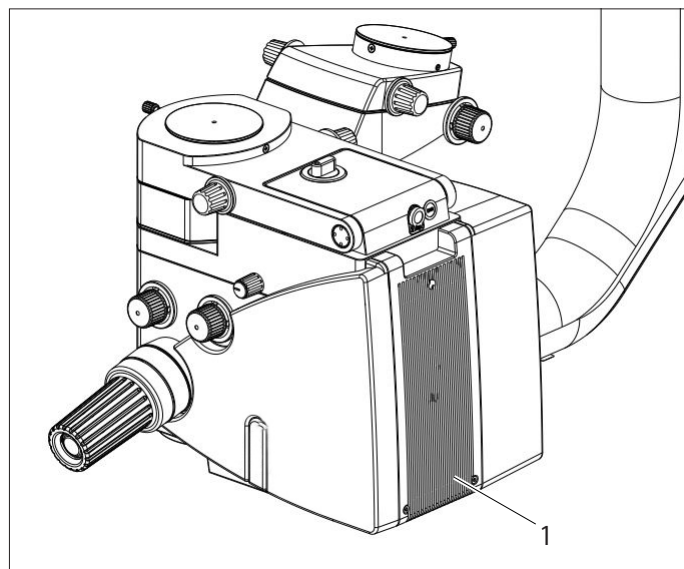


Refer to the checklist before operation (see chapter 17.1 "Checklist before the operation", page 89).

NOTE

Covering the air inlets (1) and (2) can result in a controlled shutdown of the system due to overheating.

- Make sure that there is always some space around the air inlet (1) and the external hard disk storage compartment opening (2)



8 Operation

8.1 Switching the microscope on



WARNING

Danger of fatal electrical shock!

- The PROVEO 8x surgical microscope may be connected to a grounded socket only.



WARNING

Danger of fatal electrical shock!

- Operate the system only with all equipment in its proper position (all covers fitted, doors closed).



WARNING

Motors return to their park position!

- Before switching on the microscope, ensure that the travel paths of XY-unit, tilt and focus are free of obstructions.

- Switch on the microscope using the power switch (1) on the stand.

The system is starting an initialization procedure.



When built-in Enfocus module is available, please wait for 2–3 min for the microscope to boot-up completely and do not touch the microscope before it is ready.



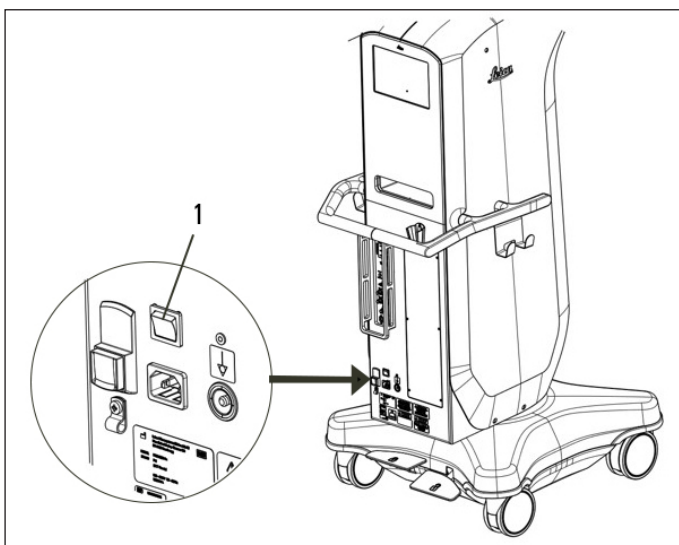
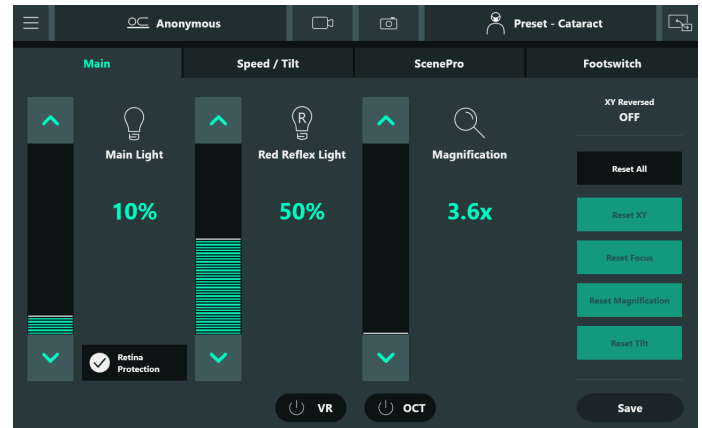
To avoid malfunctions, please always make sure the microscope is properly start up and shut down especially if OCT is connected.



Check basic functions of the system:

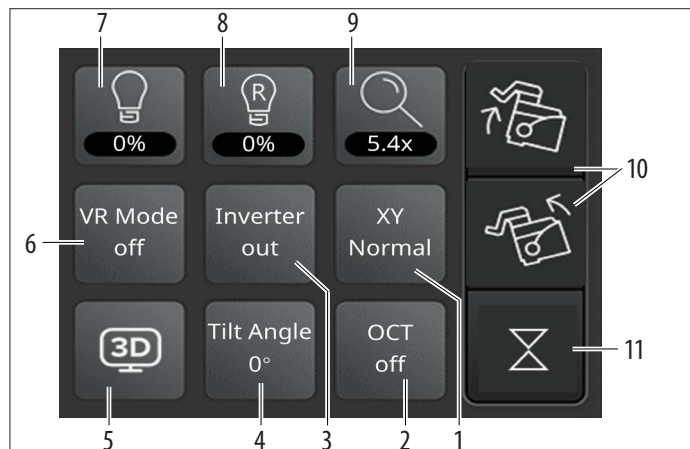
- Check the Main and Red Reflex illumination.
- Check the footswitch functions.
- Check the rotary handles.
- Check if the brakes work reliably.
- Check for errors flagged during boot-up. Errors are shown in pop-up windows and/or toast notification or alert warning sign.

The main screen is displayed on the touch panel of the control unit.



8.2 Surgeon panel

On the surgeon panel, the following screen is displayed:



The icons have the following meaning (only for information):

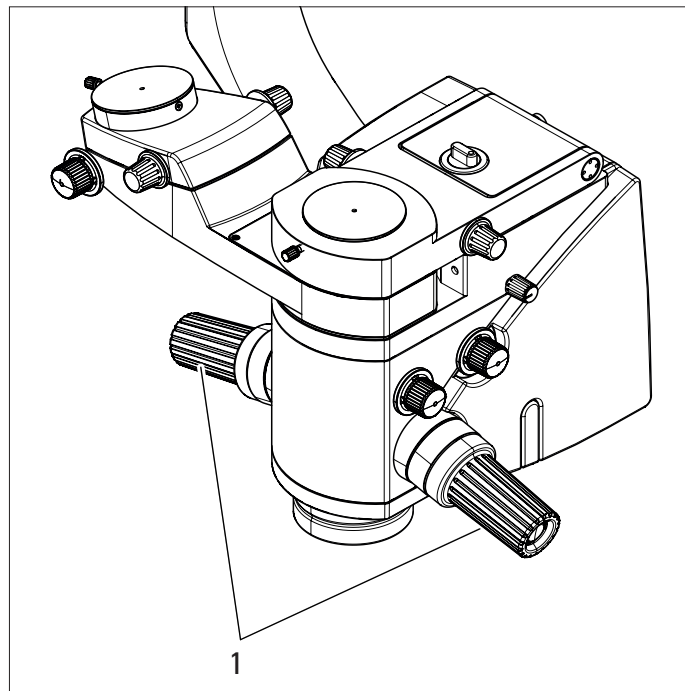
- 1 Status of XY-Unit
- 2 Status of OCT
- 3 Status of Inverter
- 4 Tilt angle/Retina Protect
- 5 3D digital/3D Hybrid/2D
- 6 Status of VR Mode
- 7 Value of main illumination
- 8 Value of Red Reflex illumination
- 9 Value of magnification

Keys with touch function:

- 10 Adjusting the tilt angle
- 11 Reset button for focus (line shows position of focus)

8.3 Positioning the optics carrier

8.3.1 Initial positioning



CAUTION

Danger of damage!

- Before lifting the optics carrier make sure that the area above the parallelogram is clear to avoid collisions with OR lamps, ceiling, etc.

- Grasp the optics carrier by both handles (1).
- Turn one handle to release the brakes (All Brakes).



CAUTION

Damage to the PROVEO 8x surgical microscope due to uncontrolled movement!

- Hold the handle when releasing the brake.

- Position the optics carrier and release the handle.

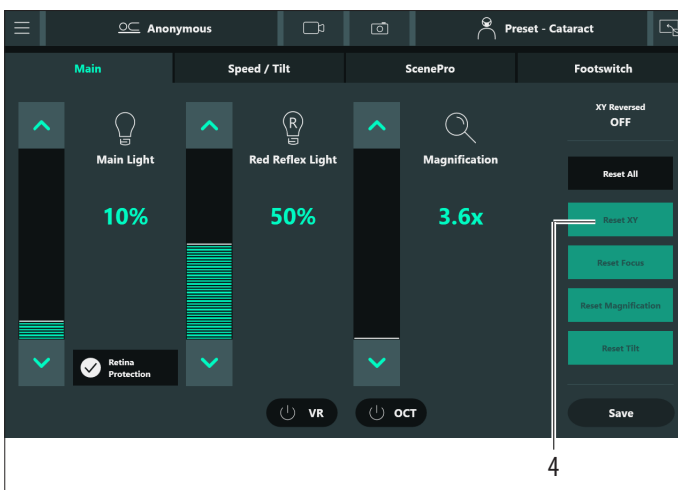
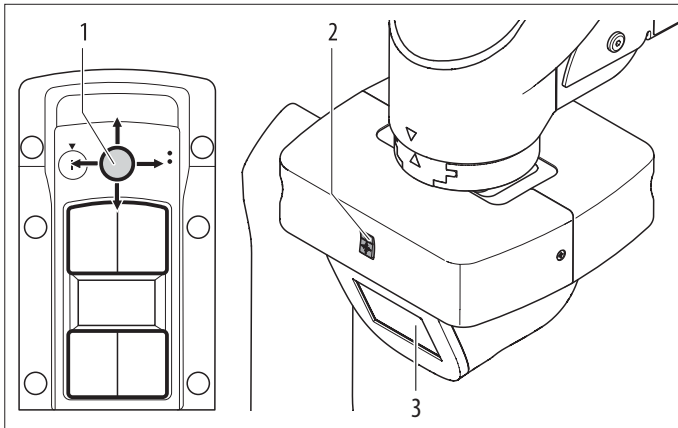


Also refer to chapter 7.8.4 "Releasing the brakes", page 32.

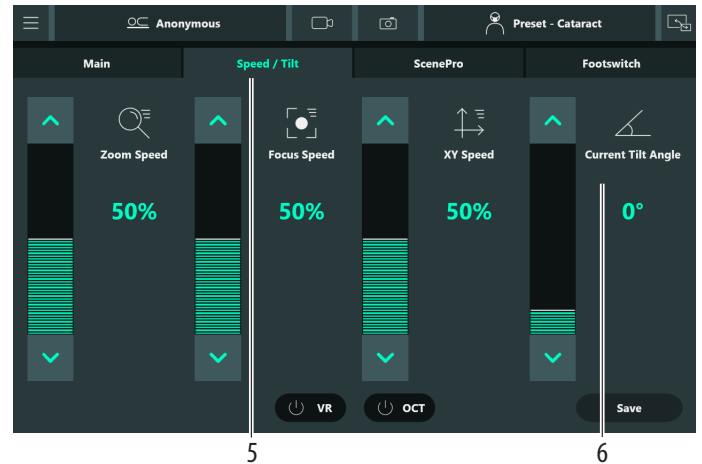
8.3.2 Fine positioning

- Position the optics carrier with the XY drive using the joystick (1) on the footswitch.

! Return to middle position by pressing the "Reset XY" key (2) or "Reset XY" button in the GUI (4).



! The speed at which the XY motors move on the "Speed/Tilt" can be changed in the "Quick Access" screen (5). This value can be saved individually for each user.



8.3.3 Adjusting the tilt

- Press the tilt + button or – button on the surgeon panel (3), or adjust the current tilt angle (6) in the desired direction and hold it there.

The microscope tilts in the desired direction.

The microscope can be tilted 15° forwards and 105° backwards without vitreoretina viewing accessories attached. Pressing the "Reset Tilt" button (7) returns the microscope to home position (0°).



- Tilt angle range of movement is limited to ± 10 degrees under VR mode.
- Tilt movement is disabled with the electrical BIOM connected.
- Attachment of Enfocus scan head does not limit the tilt angle range of movement.

8.4 Adjusting the optics carrier

8.4.1 Adjusting the brightness



WARNING

Light that is too intense can damage the retina!



- Observe the warning messages in the chapter on "Safety notes".

Main light and the Red Reflex Illumination can be adjusted by using either the touch panel of the control unit, a footswitch, or handle.





The default GUI interface on stand monitor does not allow changing illumination.

In "Main" tab in the "Quick Access" screen (touch panel of control unit):

- Press the  or  button on the bar for adjusting the brightness of the Main Light and the Red Reflex Light.
 - or –
 - Press the brightness adjustment bar directly.
- The brightness of the active illumination changes.



- Press the  or  button once to adjust illumination in single increments. Hold down the button with your finger until you reach the desired illumination.
- The start setting can be saved individually for each user (see chapter 9.10 "Microscope settings", page 49).

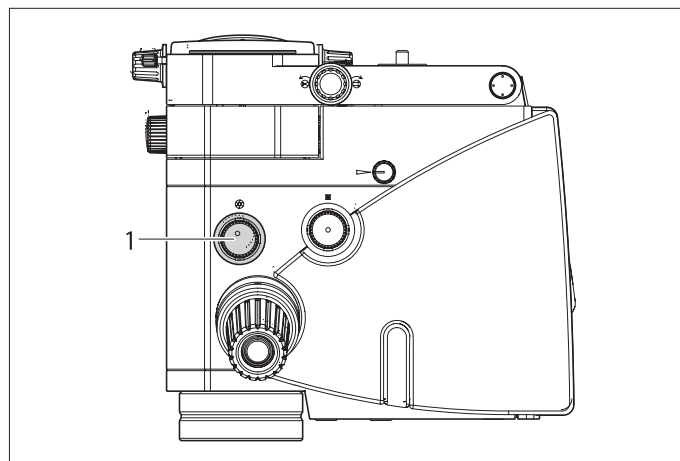
On the footswitch/handle

Depending on the footswitch/handle assignment (see chapters 9.8 "Footswitch assignments", page 46 and 9.9 "Handle assignment", page 47), the brightness of the illumination can also be increased and decreased. Use the correspondingly assigned buttons on the footswitch/handle.

8.4.2 Adjusting the Red Reflex illumination diameter

The Red Reflex illumination diameter can be adjusted using the rotary knob (1) or the footswitch/handle.

- Turn rotary knob (1) and set the Red Reflex illumination diameter as required.

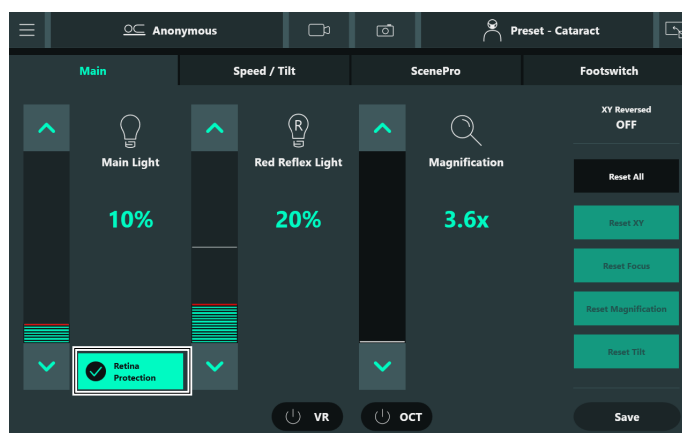


8.4.3 Exposure time

For further information see chapter "Phototoxic damage to the retina during eye surgery", page 5).

8.4.4 Retina Protection



You can activate the Retina Protection function during the surgery via the footswitch or the touch panel of the control unit. When Retina Protection function is activated, the main light intensity is reduced to 10% and the Red Reflex intensity is reduced to 20%. You can still adjust the light intensity below the threshold. When you deactivate the Retina Protection function, the light intensity will go back to previous intensity.

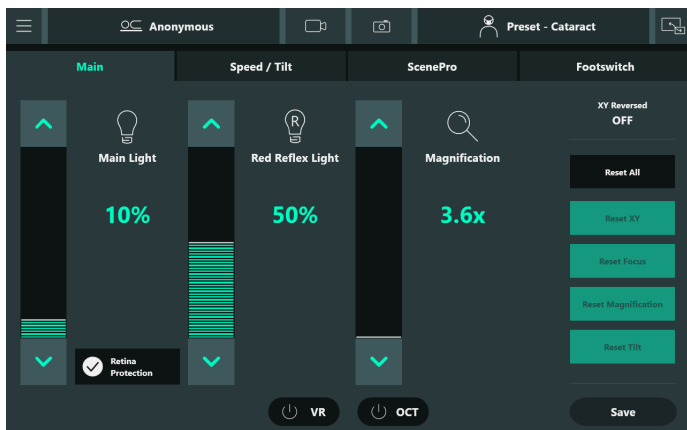




8.4.5 Adjusting the magnification (zoom)

The magnification can be adjusted using a footswitch/handle or the "Magnification" adjustment bar on the "Main" menu screen of the touch panel of the control unit.

On the touch panel of the control unit in the "Main" menu screen

- ▶ Press the  or  button on the bar for adjusting the magnification.
- or –
- ▶ Press the magnification adjustment bar directly. The magnification changes.



- Press the  or  button once to adjust magnification in single increments. Hold down the button with your finger until you reach the desired magnification.
- You can adjust the magnification motor speed in the "Speed/Tilt" menu screen. These values can be saved individually for each user (see chapter 9.10.1 "Set the "Speed/Tilt" start values", page 49).

Adjusting the magnification on the footswitch/handles

The magnification can also be adjusted based on the footswitch/handles assignment (see chapters 9.8 "Footswitch assignments", page 46 and 9.9 "Handle assignment", page 47). Use the correspondingly assigned buttons on the footswitch/handle.

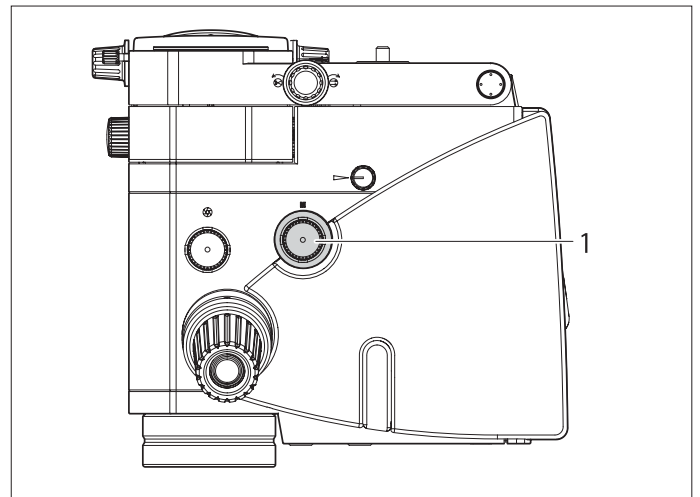
Manually adjusting the magnification (zoom)



WARNING

Danger to the patient due to failure of the magnification motor!

If the magnification motor fails, the magnification can be manually adjusted using the rotary knob (1).



- ▶ Push in rotary button (1).
- ▶ Set the desired magnification by turning the knob.



CAUTION

Damage to the magnification motor!

- ▶ Only adjust the magnification manually if the magnification motor is defective.

8.4.6 Adjusting the focus



- If the focus motor fails, adjust the focus manually by releasing the brakes.
- Grasp the optics carrier (see chapter 8.3.1 "Initial positioning", page 36).

You can focus the microscope using the focus keys on the footswitch.



- You can change the speed at which the zoom motor moves in the "Speed/Tilt" menu screen (see chapter 9.10.1 "Set the "Speed/Tilt" start values", page 49).
- You can return the focus motor to the middle position by pressing the "Reset Focus" key on the touch panel of the control unit or on the surgeon panel.

8.5 Transport position

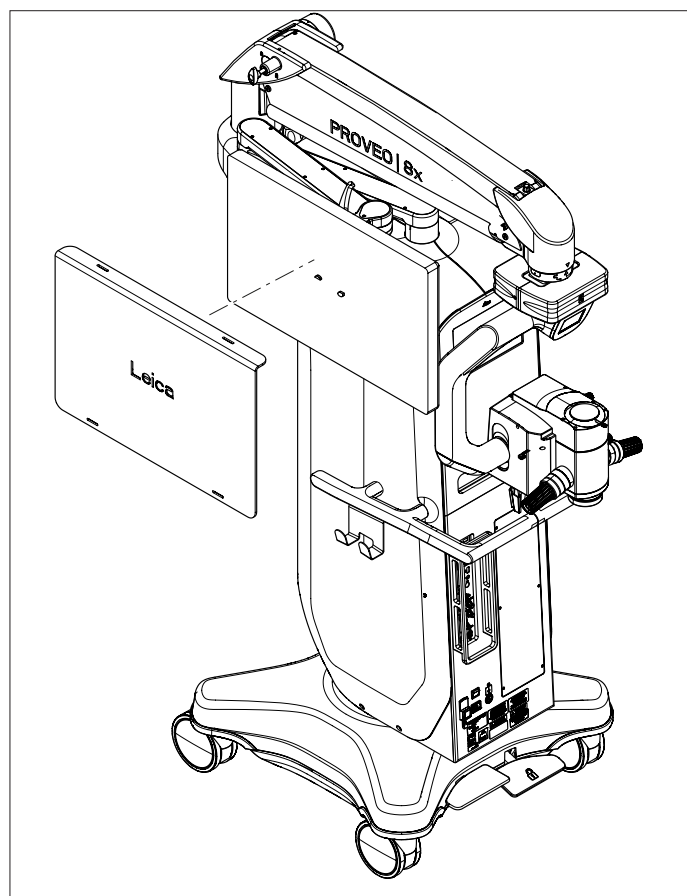
NOTE

If the optics carrier is moved into the transport position or from the transport position to the operating position:

- Ensure that the transport lock is locked.
- Lock the parallelogram (see chapter 7.8.2 "Locking the parallelogram", page 31).
- Unplug all storage devices from the system.
- Press the "All Brakes" button or the nurse switch and move the PROVEO 8x into the transport position.

NOTE

- Make sure that the video monitor does not collide with the parallelogram of the stand.



- Strap the monitor cover onto the stand monitor.

8.6 Shutting down the surgical microscope

NOTE

Wait for at least 1 minute for the system to shut down completely and do not unplug the power cable before the system is completely shut down.

- Bring the surgical microscope into the transport position.
- Shut down the system by switching off the surgical microscope at the power switch (see chapter 8.1 "Switching the microscope on", page 35).
- Unplug and secure the power cable.
- Store the footswitch on the stand.

9 User Interface

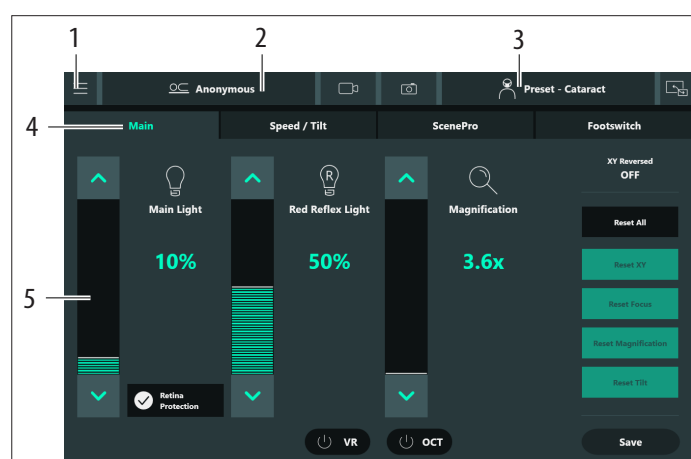
The user interface is displayed on the touch panel of the control unit.

NOTE


Avoid damage of the touch panel!

- ▶ Operate the touch panel using your fingers only.
Never use hard, sharp or pointed objects made out of wood, metal or plastic.
- ▶ Never clean the touch panel using cleaners that contain abrasive substances. These substances can scratch the surface and cause it to become dull.

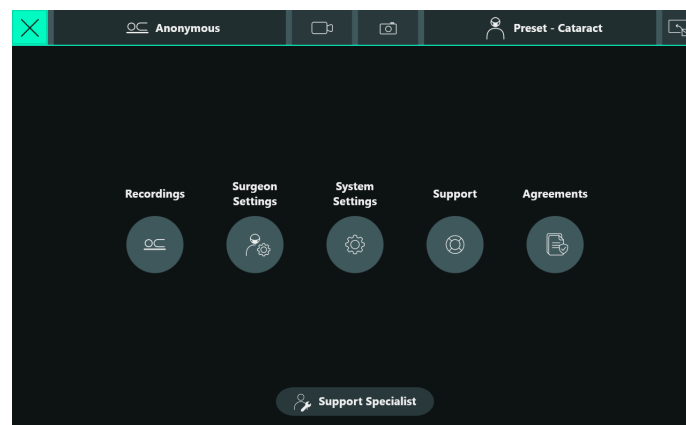
9.1 Structure of user interface



- 1 Access "Main Menu" button
- 2 Patient information
- 3 Surgeon information
- 4 "Quick-access" settings tabs
- 5 Current settings

With  in the upper right corner of the screen, the user interface on the 10" monitor can be switched over to the stand monitor.

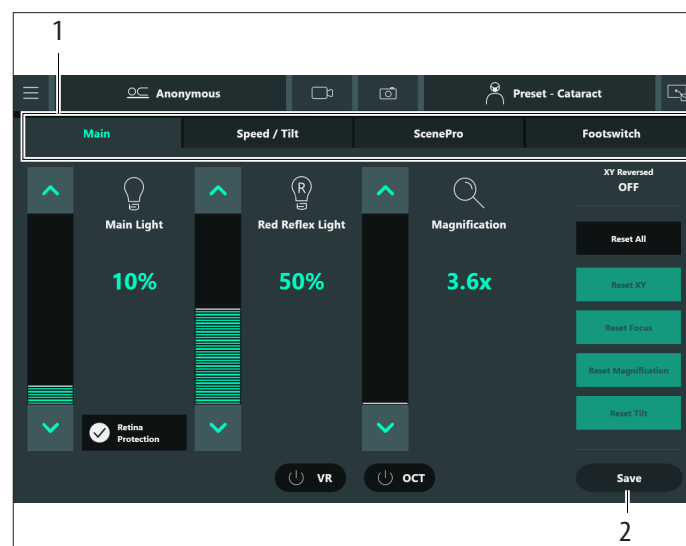
9.2 Main menu



9.3 Quick Access tabs

Quick Access tabs (1) allow you to adjust the most common settings during surgery. Settings can be adjusted without saving into the surgeon profile. It will be reset to the selected surgeon profile settings after the case has ended or when the parallelogram is moved to the auto-reset position (when auto-reset setting is ON).

 Approach Leica Service to make adjustments for auto-reset setting.



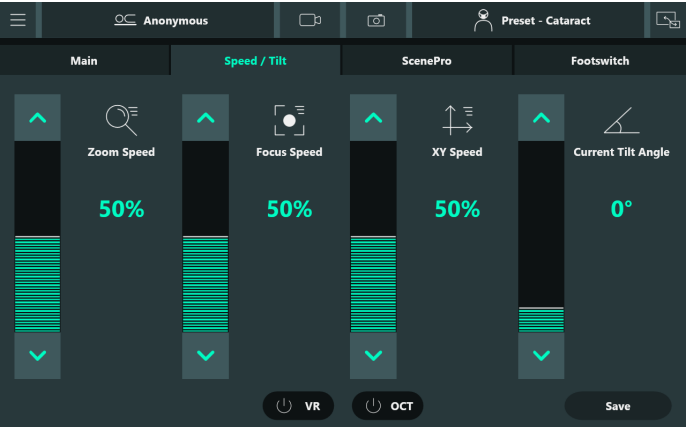
- ▶ After adjusting the settings, tap the "Save" button (2) to save and persist the settings to the active surgeon profile.

Main

Allows you to change the illumination and magnification settings.

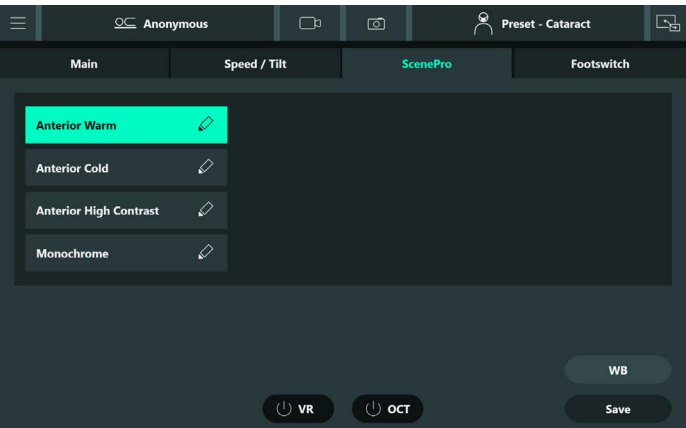
Speed/tilt

Allows you to change the speed of the motors and tilt angle of the optics carrier.



ScenePro

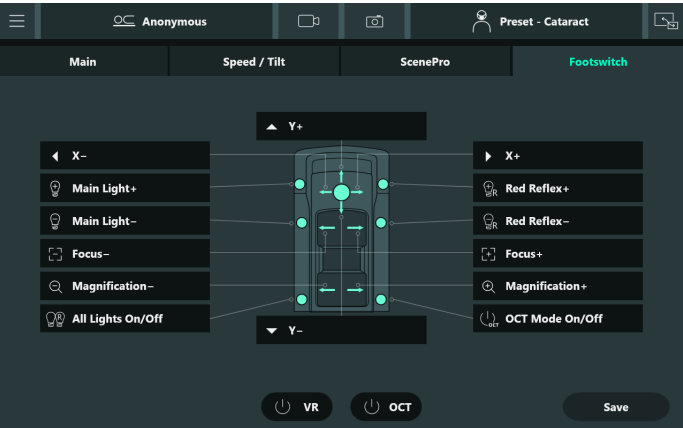
Allows you to toggle between scene files and adjust the camera settings.



Footswitch

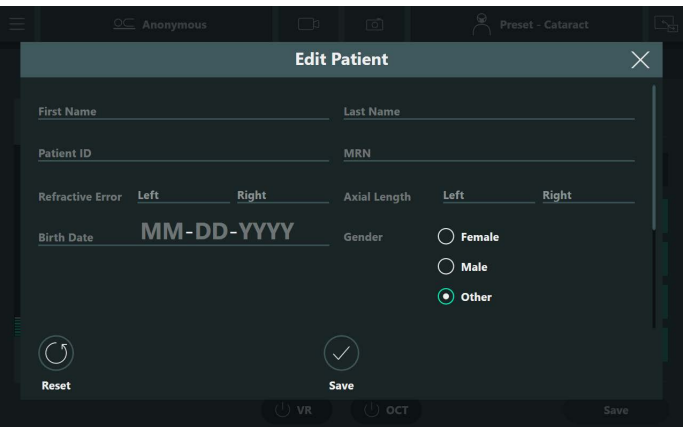
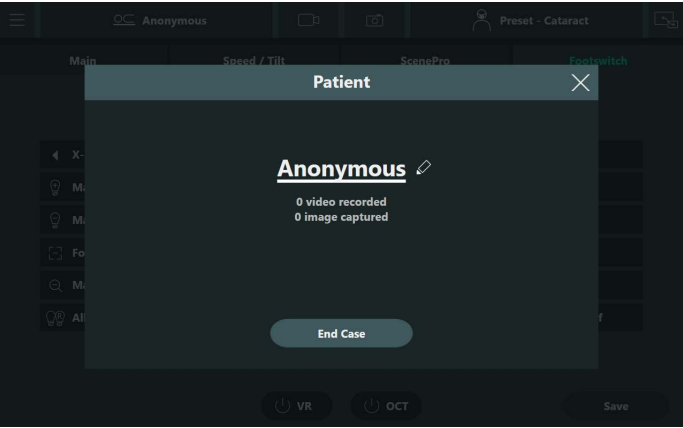
Allows you to quickly view the current footswitch settings

- Changing a function without pressing "Save", persists it only for duration of surgery.
- Changing a function and pressing "Save", persists it to the profile.



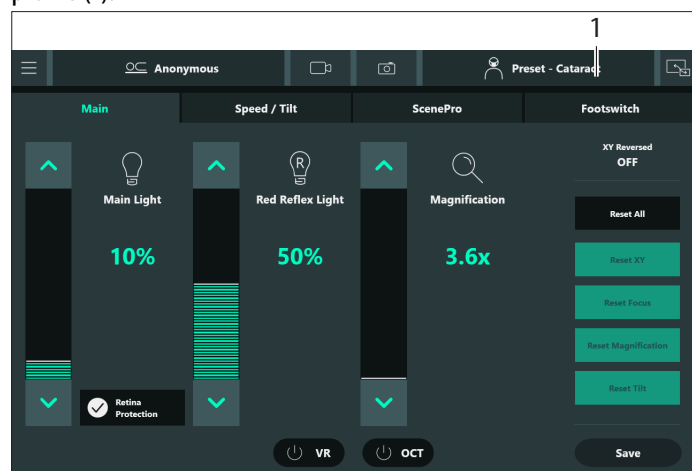
Patient Information

By default, patient information is set to anonymous. Click on "Anonymous" to access and edit the patient details.

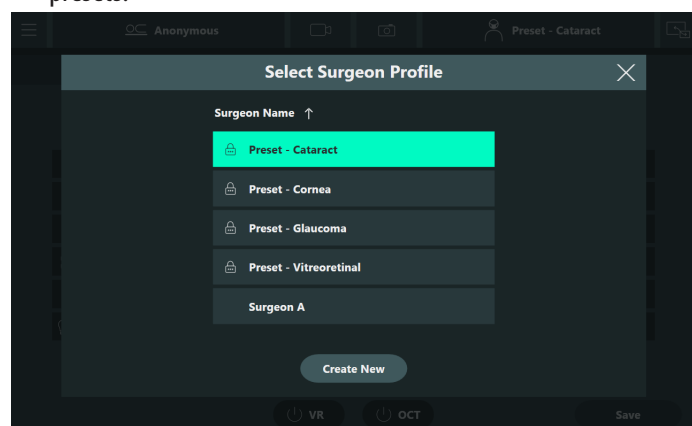


9.4 Select a surgeon profile

On top right section of the screen you can see the currently selected profile (1).



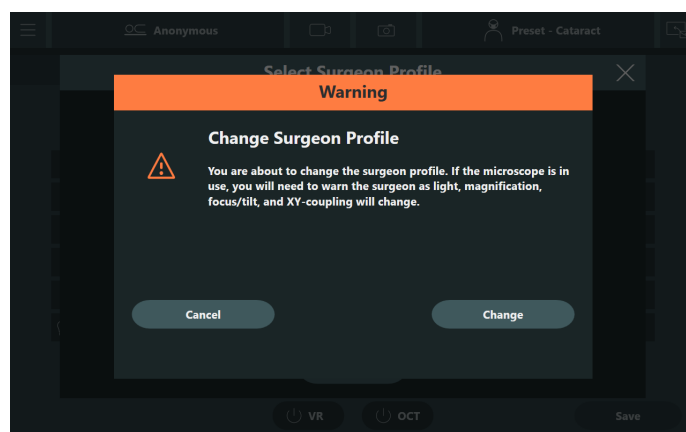
- Tap the profile button (1) to display a list of surgeon profiles and presets.



Presets

You can find a list of default users preset by Leica for the most common types of operation under the profile names prefixed with "Preset -".

- Tap on a surgeon profile to make that selection active. The PROVEO 8x surgical microscope is ready to use. The system will ask you to confirm that you are changing profiles.

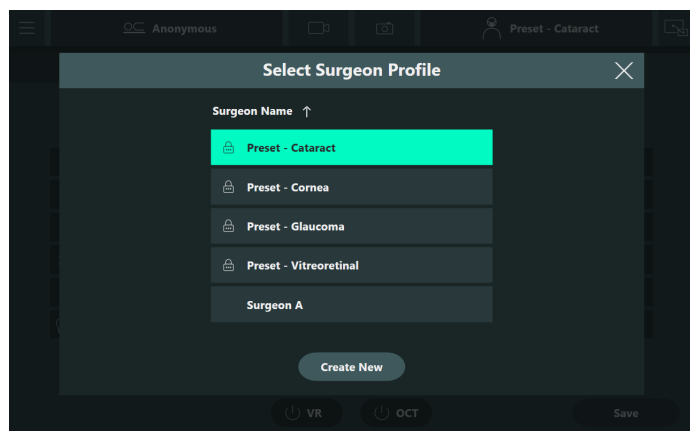


NOTE

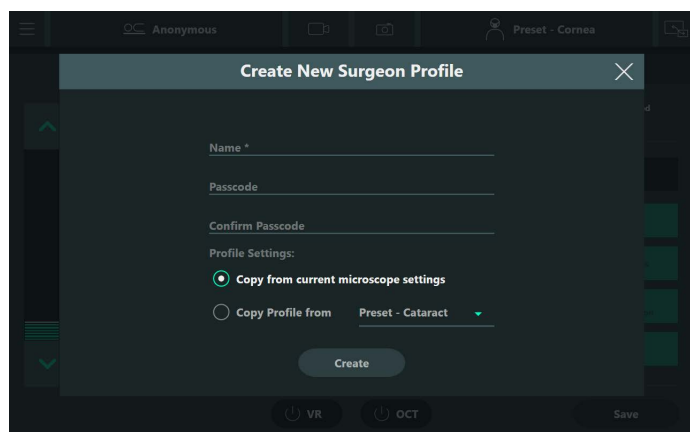
- Switching surgeon profile cannot be done when in VR mode.

9.5 Create a surgeon profile

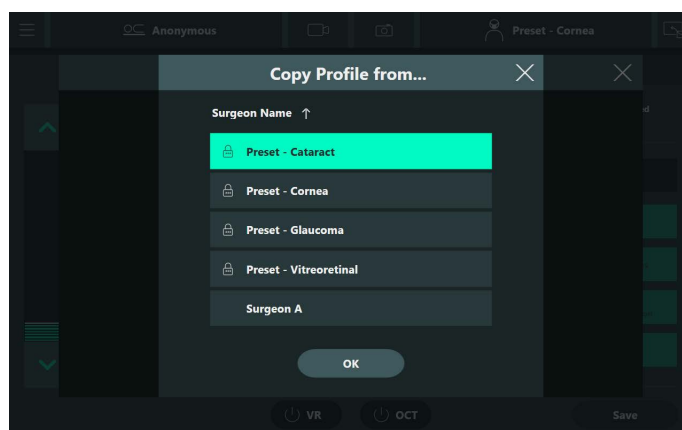
You can create a new surgeon profile by selecting "Create New".



New profiles can be copied from the current surgeon profile setting or from existing surgeon profiles. Profile settings adjustments under Media Settings, Quick Focus & Quick Tilt, Surgeon Panel brightness, VR Mode, and Combination will not take effect until they are saved to the surgeon profile. Other profile settings that are adjusted are applied on the microscope even if they have not been saved to the surgeon profile. The "Copy from Current Microscope Settings" option allows you to copy the profile settings currently adjusted on the microscope from the loaded surgeon profile.



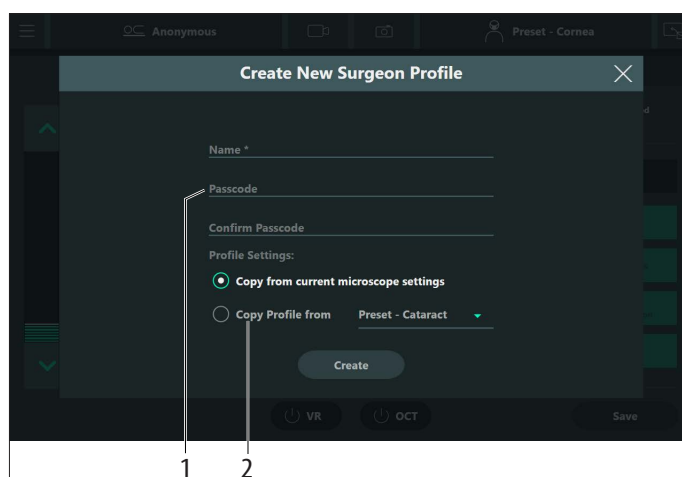
You can optionally add a passcode (see chapter 9.6 "Create a passcode", page 44).



9.6 Create a passcode

To avoid unauthorized or accidental changes of profiles, each surgeon profile can be protected by a passcode. This keeps the working parameters identical each time you load a protected profile setting.

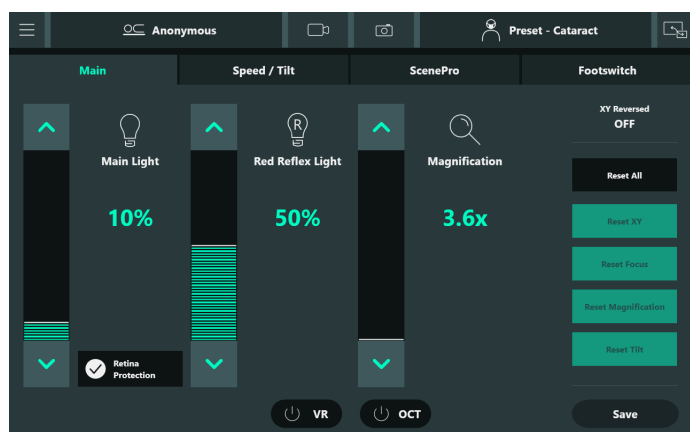
- Set the passcode when creating a new surgeon profile (1):



- To change a passcode or for a forgotten passcode, you can create a new surgeon profile with a different name and select the surgeon profile to copy from (2).

Changes to the profile can be done during the operation but will not be stored unless saved with the correct passcode.

- To overwrite and save settings to the selected surgeon profile, select "Save" in the bottom right corner of the screen.

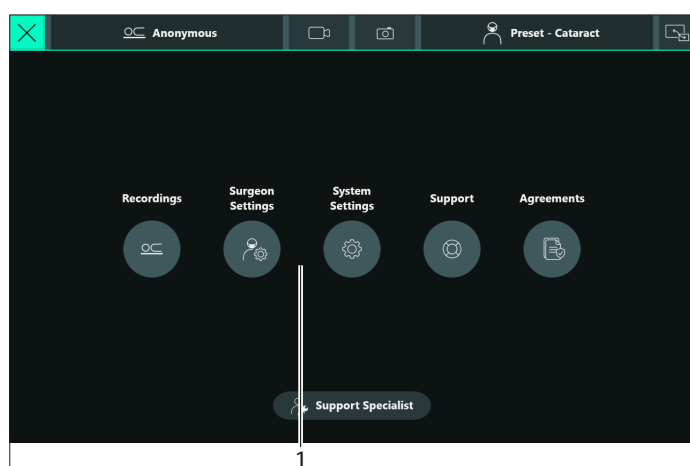


- If the surgeon profile is passcode-protected, key in the passcode from the prompt to save.

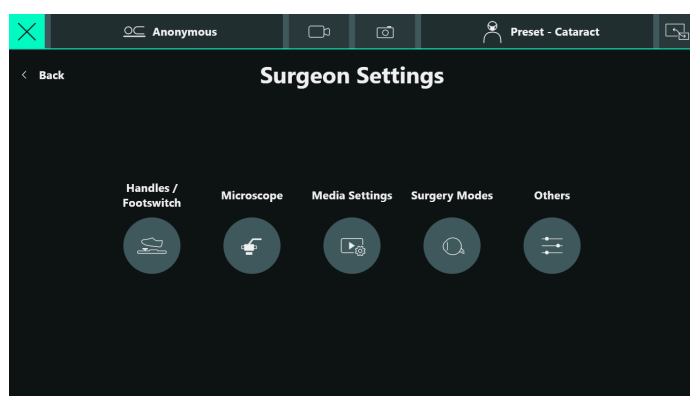
9.7 Surgeon profile settings

You can configure all surgeon profile settings in this menu.

- Click the "Main Menu" button and select "Surgeon Settings" (1).



The "Surgeon Settings" screen is displayed:

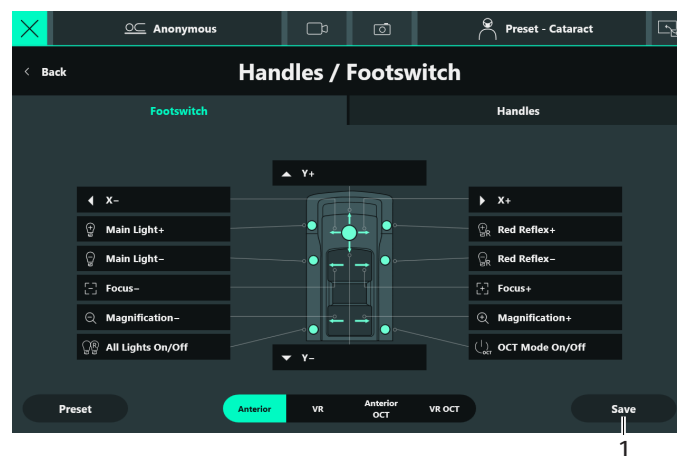


9.7.1 Save surgeon profile settings



Protect your settings with a passcode (see chapter 9.6 "Create a passcode", page 44).

- Click the "Save" button (1).



- Saving surgeon profile settings cannot be done when the VR mode is activated.
- Settings of default users preset by Leica cannot be overridden and saved.
- Save applies not only to changes on the current surgeon setting page but also to all adjusted surgeon profile settings.

9.8 Footswitch assignments

- ▶ To configure individual settings for the footswitch, go to Quick Access > Footswitch tab or Main Menu > Handles/ Footswitch.



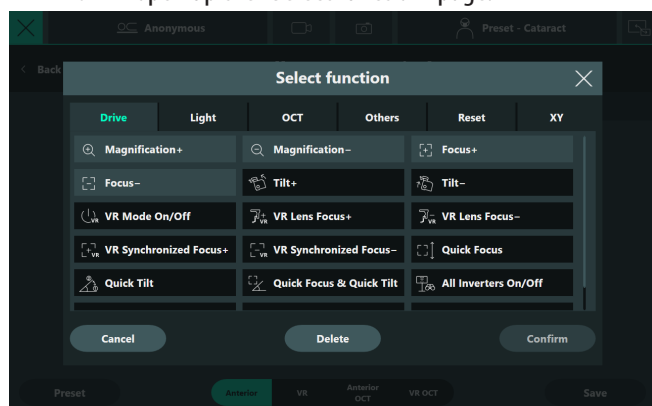
- ! The built-in footswitch wireless receiver is Main Footswitch, the inserted optional footswitch is Secondary Footswitch. Only 1 footswitch can be used at a time (see chapter 9.17.5 "Microscope Setup", page 61).

- ! Press "Preset" to revert the setting to the last saved user profile settings.

- ▶ Use the segmented controls options at the bottom of the page to select the mode: Anterior, VR, Anterior OCT, VR OCT. The default settings are assigned to the footswitch.
- ▶ You can then modify these settings as you like.

9.8.1 Configure individual keys

- ▶ Tap the caption of the desired key you wish to assign a function to. This will open up the "Select function" page.



- ▶ You can navigate the different categories through the tabs.
- ▶ Select the desired function.
- ▶ Tap the "Confirm" button".

9.8.2 Overview of function groups

The possible configuration is divided into the following function groups:

XY

- XY Reverse
- Y-
- Y+
- X-
- X+

Reset

- Reset Magnification
- Reset Focus
- Reset Tilt
- Reset XY
- Reset All

Light

- Main Light On/Off
- Red Reflex On/Off
- All Lights On/Off
- Main Light+
- Main Light-
- Red Reflex+
- Red Reflex-
- Red Reflex Diameter+
- Red Reflex Diameter-
- Keratoscope On/Off
- Fixation Light On/Off
- Retina Protection

Drive

- Magnification+
- Magnification-
- Focus+
- Focus-
- Tilt+
- Tilt-
- VR Mode On/Off
- VR Lens Focus+
- VR Lens Focus-
- VR Synchronized Focus+
- VR Synchronized Focus-
- Quick Focus
- Quick Tilt
- Quick Focus & Quick Tilt
- All Inverters On/Off
- Main Inverters On/Off
- Camera Aperture+
- Camera Aperture-

Others

- Start/Stop Recording
- Playback Start/Pause
- Capture Image
- ScenePro
- Footswitch Overlay
- Combination Mode
- ADF Toggle
- ADF Pulse
- Toggle Stand Monitor
- Toggle HDMI Out

OCT

- OCT Mode On/Off
- OCT Overlay
- Change View
- OCT Up
- OCT Down
- OCT Left
- OCT Right
- OCT Change Joystick State
- OCT Optimize Image
- OCT Auto Locate
- OCT Auto Sharpen
- OCT Auto Brighten
- OCT Live Mode/Stop
- OCT Continuous Scan
- OCT Scan
- OCT Save
- OCT Focus+
- OCT Focus-
- OCT Z+
- OCT Z-
- OCT Next Workflow
- OCT Crosshair On/Off
- OCT Reset DSC
- OCT Frame Backward
- OCT Frame Forward
- OCT First Frame
- OCT Last Frame
- OCT Next Procedure
- OCT Previous Scan
- OCT Toggle Image Lock
- OCT Toggle Image Contrast
- OCT Interface On/Off

- You can change the status of a function with the "Toggle" function (e.g. on/off or next). The "Pulse" function continuously changes a status (such as increasing the brightness).
- To remove an assignment, select the "Delete" button.

9.9 Handle assignment

You can assign up to 3 functions of your choosing to the handle. The fourth function must always be "All Brakes".

However, you can assign this function to any position you like. To do that, go to Main Menu > Handles/Footswitch



- To configure individual keys, see chapter 9.8.1 "Configure individual keys", page 46.

9.9.1 Overview of function groups

The possible configuration is divided into the following function groups:

XY

- XY Reverse

Reset

- Reset Magnification
- Reset Focus
- Reset Tilt
- Reset XY
- Reset All

Light

- Main Light On/Off
- Red Reflex On/Off
- All Lights On/Off
- Main Light+
- Main Light-
- Red Reflex+
- Red Reflex-
- Red Reflex Diameter+
- Red Reflex Diameter-
- Keratoscope On/Off
- Fixation Light On/Off
- Retina Protection

Drive

- Magnification+
- Magnification-
- Focus+
- Focus-
- Tilt+
- Tilt-
- VR Mode On/Off
- VR Lens Focus+
- VR Lens Focus-
- Quick Focus
- Quick Tilt
- Quick Focus & Quick Tilt
- All Inverters On/Off
- Main Inverters On/Off
- Camera Aperture+
- Camera Aperture-

Others

- All Brakes
- Selected Brakes
- Start/Stop Recording
- Playback Start/Pause

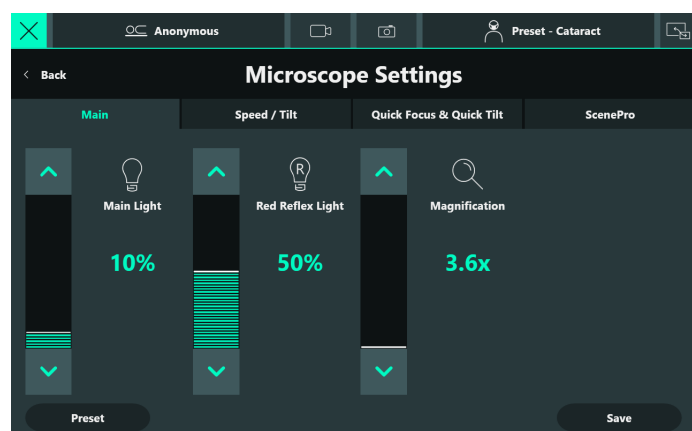
- Capture Image
- ScenePro
- Footswitch Overlay
- Combination Mode
- ADF Toggle
- ADF Pulse
- Toggle Stand Monitor
- Toggle HDMI Out



OCT

- OCT Mode On/Off
- OCT Overlay
- Change View
- OCT Up
- OCT Down
- OCT Left
- OCT Right
- OCT Change Joystick State
- OCT Optimize Image
- OCT Auto Locate
- OCT Auto Sharpen
- OCT Auto Brighten
- OCT Live Mode/Stop
- OCT Continuous Scan
- OCT Scan
- OCT Save
- OCT Focus+
- OCT Focus-
- OCT Z+
- OCT Z-
- OCT Next Workflow
- OCT Crosshair On/Off
- OCT Reset DSC
- OCT Frame Backward
- OCT Frame Forward
- OCT First Frame
- OCT Last Frame
- OCT Next Procedure
- OCT Previous Scan
- OCT Toggle Image Lock
- OCT Toggle Image Contrast
- OCT Interface On/Off

9.10 Microscope settings

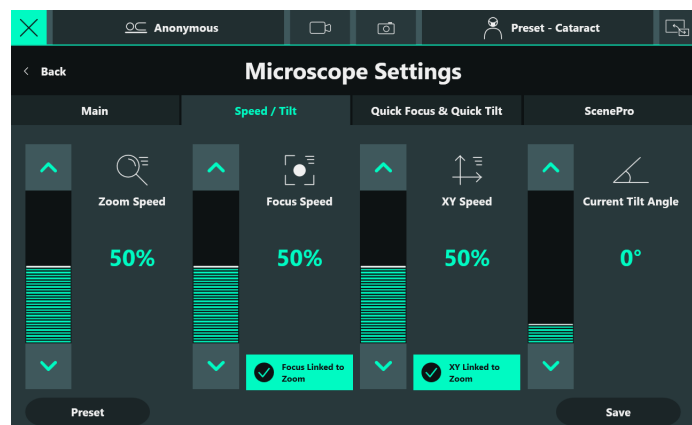
For the selected user, the initial values for the main light, Red Reflex light and magnification can be set on this screen.





- ▶ Press the  or  button once to adjust in single increments. Hold down the button with your finger until you reach the desired value.
- ▶ You can also set the desired value by directly clicking the bars.

9.10.1 Set the "Speed/Tilt" start values

For the selected user, the start values for the travel speed of the magnification, focus and XY motors can be set on this screen.



- ▶ Press the  or  button once to adjust in single increments. Hold down the button with your finger until you reach the desired value.
- ▶ It can be set to a desired value by directly clicking the bars.

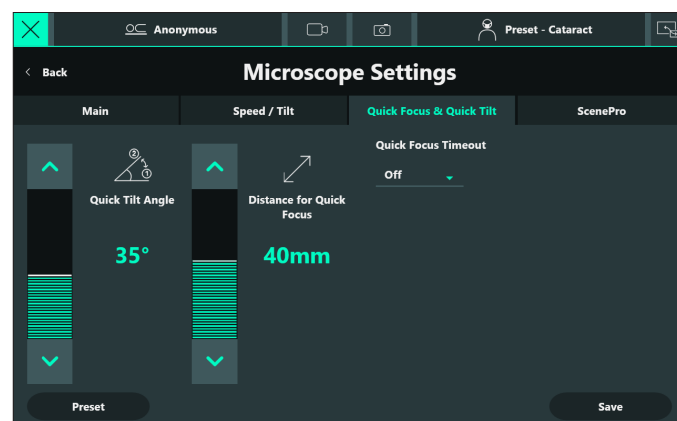
Focus Linked to Zoom When activated, the focus speed depends on the magnification:

- low magnification – fast focus speed
- high magnification – slow focus speed

XY Linked to Zoom When activated, the XY speed depends on the magnification:

- low magnification – fast XY speed
- high magnification – slow XY speed

9.10.2 Quick tilt/Quick focus



You can set desired values for quick focus and quick tilt according to your preferences.

- ▶ Activate the footswitch button assigned to the quick focus or quick tilt function by clicking it.

Distance for quick focus Distance to move upwards from current position after activating the assigned key.

Quick focus timeout 1 to 10 minutes or off (default).

Within the timeout duration, when the assigned key is activated again, the optics carrier will return to the start position. If timeout has expired, the quick focus function will be deactivated and the microscope will stay at the current position.

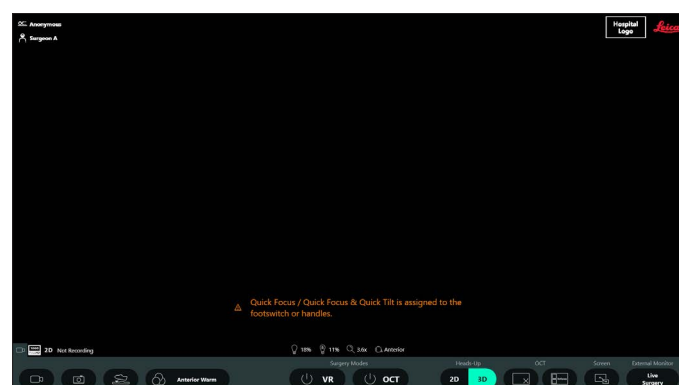
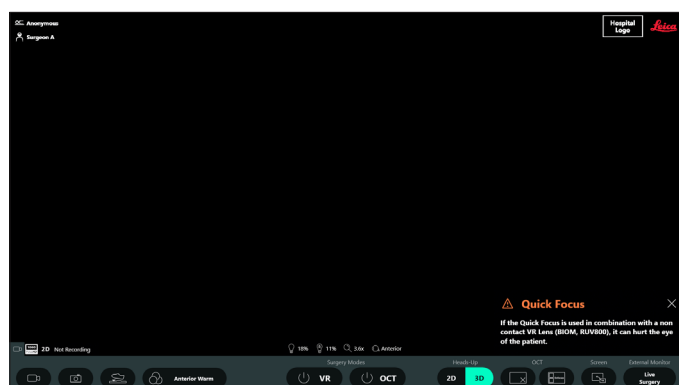
Note

In case the user releases the electromagnetic brakes by the handles, the quick focus function will be deactivated.

Quick tilt angle Angle at which the optics carrier move when the quick tilt function is activated. The default tilt angle is 35°.

! The quick tilt function is disabled when electrical BIOM is connected.

- Tilt angle range of movement is limited to ± 10 degrees under VR mode.
- Attachment of Enfocis scan head does not limit the tilt angle range of movement.
- Quick Focus can be enabled or disabled under VR mode in VR mode settings (see chapter 9.11 "VR mode", page 52).
- When Quick Focus and Quick Tilt are activated, they will automatically reset to a deactivated state when switching to a different surgeon profile.



When a surgeon profile that has the "Quick Focus" or "Quick Focus & Quick Tilt" function assigned to the footswitch or handles is selected or saved, a warning message will be displayed on both the stand monitor and the heads-up monitor.

NOTE

- This warning message can be dismissed on the stand monitor.

9.10.3 Auto Reset

If you move the parallelogram up to its end position after the operation, you trigger the auto Reset function:

- Motors (zoom, focus and XY) move to their reset position.
- Video recording stops.
- The tilt motor is not reset.
- The current user settings are reloaded.
- The illumination is switched off.

If you move the PROVEO 8x back downwards across the operating field, the illumination switches on and the PROVEO 8x is ready to operate immediately.

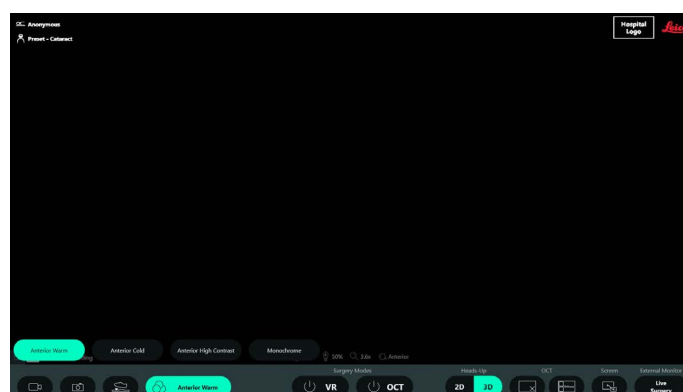
NOTE

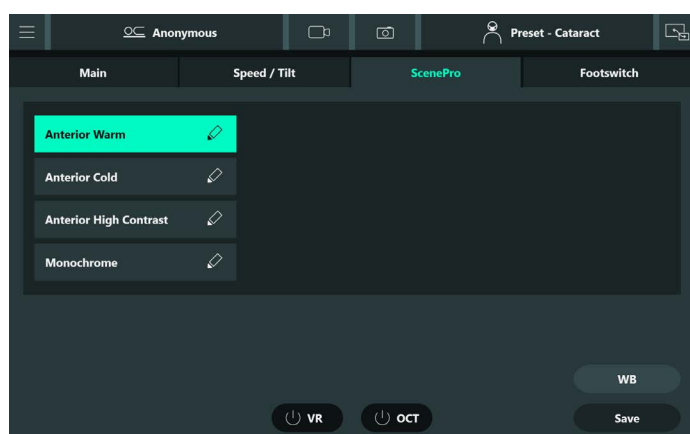
- This function can be deactivated by an authorized Leica Microsystems Service personnel.

9.10.4 Digital enhancement

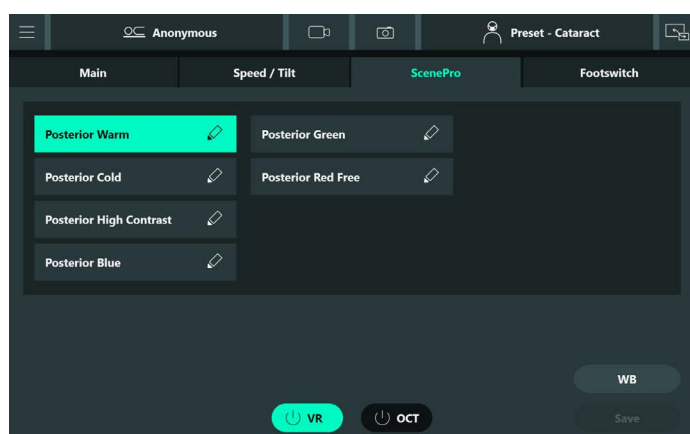
- ScenePro allows you to select scene files of optimized digital color filters that enhance what you see on the digital monitor
- This visual enhancement is applied to the live image displayed on 3D display and stand monitor
- The surgeon can choose which scene file is to be applied when VR On and VR Off. You have the option to set your preferred scene file to be applied correspondingly when VR Mode is activated and deactivated. Note that saving surgeon profile settings cannot be done when the VR mode is activated. To enable saving of settings, deactivate VR mode.

- You can change scene file through the:
 - Toolbar on 27" stand monitor,
 - Camera Settings under "ScenePro" or
 - footswitch/handles control

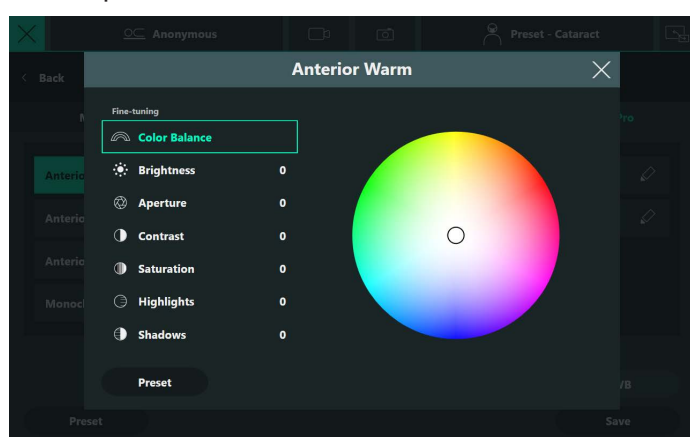




- ▶ Activate or deactivate VR mode on the stand monitor to toggle the scene files for anterior mode (VR mode OFF) and posterior mode (VR mode ON).



You can save your default scene file for anterior mode (VR mode OFF) and posterior mode (VR mode ON).



In addition, you can customize each scene file setting to your preferred visualization and 'Save' the new settings into the surgeon profile.

9.10.5 White balance of camera

You can set the white balance of the camera to ensure an accurate representation of the live image colors.

Set white balance

- ▶ Fill the camera view with a neutral target (e.g. a white or grey card).
- ▶ Evenly illuminate the target with the light source to be used in operations.
- ▶ Focus the camera.
- ▶ Press the on-screen "WB" button.

The new white balance setting is applied to all scene files in the same group for the current surgeon profile:

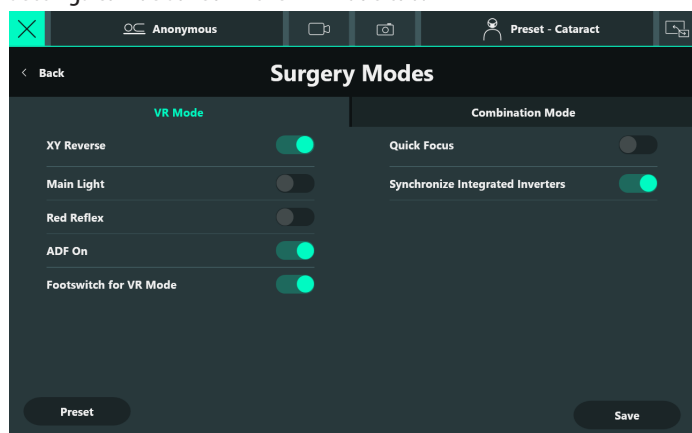
- When VR mode is OFF: WB is applied on all Anterior Scenes in the current surgeon profile.
- When VR mode is ON: WB is applied on all Posterior Scenes in the current surgeon profile.

To avoid color deviations, it is recommended to perform the white balancing in absolute darkness.

- ▶ Cover the eyepieces/tube interfaces and protect them for external light.
- ▶ To perform white balancing in anterior mode, use the light source (main and Red Reflex illumination) from PROVEO 8x.
- ▶ To perform white balancing in posterior mode, use only the light source which is used in the posterior segment surgical workflow.

9.11 VR mode

VR mode (vitreoretinal mode) enables you to perform posterior surgeries. The VR mode functions can be controlled by the footswitch, handles or user interface. VR mode activation allows to change user-specific vitreoretinal mode settings. The VR mode settings can be saved in the VR mode tab:



The settings (ON/OFF) of the following functions can be stored specifically for VR mode:

XY Reverse – reverse X and Y

Main Light – switch on/off main light

Red Reflex – switch on/off Red Reflex illumination

ADF On – signal to trigger external systems, e.g., switching off room light

Footswitch for VR Mode – activate separate assignment of the footswitch (see chapter 9.10.1)

Quick Focus – activate the quick focus (see chapter 9.10.2 "Quick tilt/Quick focus", page 49)

Synchronize Integrated Inverters – On: both inverters active, Off: only inverter of the main surgeon active

9.11.1 Footswitch assignment (VR)

You can store a special footswitch assignment for VR (vitreoretinal) mode here.



To switch between the "anterior" assignment and assignment in VR mode, the following conditions must be met:

- In the "VR Mode" tab, "Footswitch for VR mode" must be activated.
- In each of the two footswitch assignments, "VR Mode on/off" must be assigned.



The adjustment is the same as for the footswitch assignment (see chapter 9.8 "Footswitch assignments", page 46).

Activate VR mode

- Press the "VR" button on the "Quick Access" page, toolbar on stand monitor or "VR Mode On/Off" on footswitch/handles control to activate VR mode. The settings under surgeon profile VR mode will be activated.



If VR mode is activated, the following functions will be disabled: saving settings to surgeon profile and switching surgeon profile.

To change it, first deactivate VR mode.

Deactivate VR mode

- Press the "VR" button on the "Quick Access" page, toolbar on stand monitor or "VR Mode On/Off" on footswitch/handles control again to deactivate VR mode.

The microscope undoes all actions again.



When an electrical BIOM is in use the VR mode is automatically activated/deactivated.

9.12 OCT mode

OCT enables you to see hidden details beneath the surface of the eye to confirm or change the surgical plan during surgery. OCT mode activation allows to change user-specific settings for intraoperative optical coherence tomography (OCT). The OCT functions can be controlled by the footswitch or handles by assigning OCT functions in the OCT mode or by the user interface.

9.12.1 Footswitch assignment (OCT)



You can switch from anterior footswitch mode to OCT mode. To switch between "anterior" assignment to OCT on the footswitch, the following conditions must be met:

- In the "Footswitch" tab, "OCT Mode On/Off" function must be assigned on the footswitch.
- In the "Footswitch OCT Mode" tab, "OCT Mode On/Off" must be assigned on the footswitch.

The recommended workflow is to go from anterior mode to OCT mode, capture and review OCT images, and back to anterior mode. You can also program OCT functions in the "Handles OCT" and control OCT functions with the handles when OCT mode is activated (ex. play frame forward).

Activate OCT mode

- ▶ Press the "OCT" button on the "Quick Access" page, toolbar on stand monitor or "OCT Mode On/Off" on footswitch / handles control to activate OCT mode. The actions activated in the user settings are carried out once.

An active OCT mode is highlighted in green on the "Quick Access" page and toolbar on stand monitor.

Deactivate OCT mode

- ▶ Press the "OCT" button on the "Quick Access" page, toolbar on stand monitor or "OCT Mode On/Off" on footswitch/handles control again to deactivate OCT mode.

The microscope undoes all actions again.

9.12.2 Footswitch assignment (VR OCT)



You can switch from VR footswitch mode to VR OCT footswitch mode. To switch between "VR mode" to OCT on the footswitch, the following conditions must be met:

- In the "Footswitch" tab, select "VR" under the segmented controls at the bottom of the page, "OCT Mode On/Off" must be assigned on the footswitch.
- In the "Footswitch" tab, select "VR OCT" under the segmented controls at the bottom of the page, "OCT Mode On/Off" must be assigned on the footswitch.

Where an electrical BIOM is in use, the VR mode is automatically activated/deactivated. You can press "OCT mode On/Off" to go from VR mode to VR OCT mode; capture and review OCT images, and go back to VR mode by pressing "OCT mode On/Off" on the footswitch. If a mechanical BIOM or contact lens is used, the "VR mode On/Off" must be programmed on the normal footswitch to activate the VR mode. To go from VR mode into VR OCT mode, you can press "OCT mode On/Off", and press again to go back to VR mode. You can also program OCT functions in the "Handles VR OCT" and control OCT functions with the handles when OCT mode is activated (ex. play frame forward).

Activate VR OCT mode

- ▶ Press the "OCT" button on the "Quick Access" page, toolbar on stand monitor or "OCT Mode On/Off" on footswitch/handles control to activate VR OCT mode. The actions activated in the surgeon profiles are carried out once.

Deactivate VR OCT mode

! An active OCT mode is highlighted in green on the "Quick Access" page and toolbar on stand monitor.

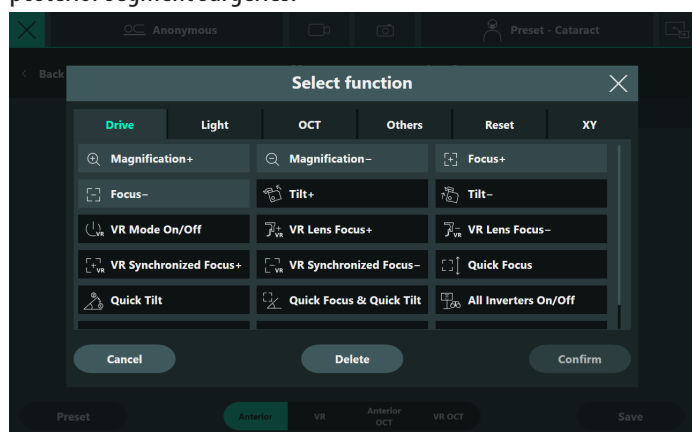
- ▶ Press the "OCT" button on the "Quick Access" page, toolbar on stand monitor or "OCT Mode On/Off" on footswitch/handles control again to deactivate OCT mode.

The microscope undoes all actions again.

! For a detailed explanation of individual OCT function, please refer to Enfocus user manual.

9.13 BIOM synchronized focus

The BIOM (Binocular Indirect Ophthalmo Microscope) is used for posterior segment surgeries.



The VR Synchronized Focus+ / VR Synchronized Focus– synchronizes the focusing of both the PROVEO 8x optics carrier and BIOM front lens, providing the following:

- **VR Synchronized focus:** Synchronized focusing of the optics carrier and BIOM front lens ensuring that the BIOM front lens no longer needs to move vertically in relation to the eye
- **Focus:** Narrow view and wider view at the same magnification and focus just by pressing an assigned button on the footswitch
- **VR Lens Focus:** Independent focusing of the BIOM front lens for faster focusing of the retina prior to the vitreoretinal procedure

! **Footswitch Automatic Change to VR Mode:** When working on the posterior segment, the BIOM can be swung into the beam path and the footswitch will change the settings automatically to VR mode including the synchronized focus if programmed.

9.14 Combination mode

With the Combination Mode, you can create an individual procedure for each user. You can save the following parameters for various frequently recurring phases (1–5 steps, with a minimum of 1 step) of the operation:

- Main Light brightness
- Red Reflex brightness
- Magnification
- Focus Mode
- Inverter
- ADF On (Additional Function)



In this screen, you can enable or disable the desired Combination Mode parameters for the individual users.

! When switching through the Combination Mode function, only the actively set parameters for the individual user are activated.

- ▶ Navigate between each step by tapping the step number at the bottom of the screen.



- ▶ Set the number of steps using "-" to remove a step and "+" to add a step.
- ▶ Select the appropriate parameters for each step in "Step".
- ▶ Set the valid focus mode "Relative" or "Absolute" for all parameters.
 - Relative range: –75 mm ... +75 mm
 - Absolute range: –37.5 mm ... +37.5 mm
- ▶ Tap the "Save" button when finished.

9.14.1 Combination mode parameters

- Magnification for activating (on) and deactivating (off). When set to "off" the magnification stays at the current value.
- Inverter signal, e.g. for triggering internal inverter from SDI Oculus
- ADF On signal for triggering external systems, e.g. Room Light on/off, ...

The focus can take on two states:

- "Absolute": the learned, absolute position is accurately approached.
Range: $-37.5\text{ mm} \dots +37.5\text{ mm}$
- "Relative": the learned distance between 2 dots, e.g. for defined contact lenses for retina operations.
Range: $-75\text{ mm} \dots +75\text{ mm}$



CAUTION

Risk of injury!

- Pay special attention to the required safety distances if you use the Combination Mode function together with accessories from other manufacturers that can reduce the working distance to less than 140 mm (non-contact wide-angle observation systems), since focus together with Combination Mode is a semi-automated function.



For the Combination Mode function to be available, you must first assign it to a key on your footswitch.

9.14.2 Activate combination mode

- Activate the key of your footswitch to which the Combination Mode function is assigned by clicking it.
You run through a continuous loop of the stored steps.

9.14.3 Deactivate combination mode

Exit Combination Mode by activating the key of your footswitch to which the Combination Mode function is assigned on by clicking after the last step (e. g. steps 1,2,3,4,5, EXIT)

- Main Light and Red Reflex Light intensity will revert to values before Combination Mode is activated.
- Magnification and Focus values will remain as per the last Combination Mode step settings.

9.15 Surgery recordings

PROVEO 8x incorporates the medical recording and documentation system and provides an integrated and seamless experience to the user. The microscope is capable of capturing images in HD/4K format or videos in 2D/3D or HD/4K format and store the recordings with patient information.

Surgery Started Date/Time	Patient Name	Patient ID	Surgeon Name	Recordings
02-28-2024, 05:17:30 PM	Anonymous		Preset - Cataract	38.6GB
02-28-2024, 01:38:49 PM	Anonymous		Preset - Cataract	340.0KB
02-26-2024, 03:19:36 PM	Anonymous		Preset - Cornea	6.6MB
02-26-2024, 03:08:31 PM	Anonymous		Preset - Cornea	11.7MB
02-22-2024, 04:20:02 PM	Anonymous		Preset - Cornea	3.7MB
02-22-2024, 04:10:10 PM	Anonymous		Preset - Cornea	3.3MB
02-22-2024, 01:36:09 PM	Anonymous		Preset - Cornea	202.3MB

You can access all surgery recordings stored in the system here. The recordings are sorted with the latest surgery at the top and can be sorted by patient name and surgeon profile used (1).

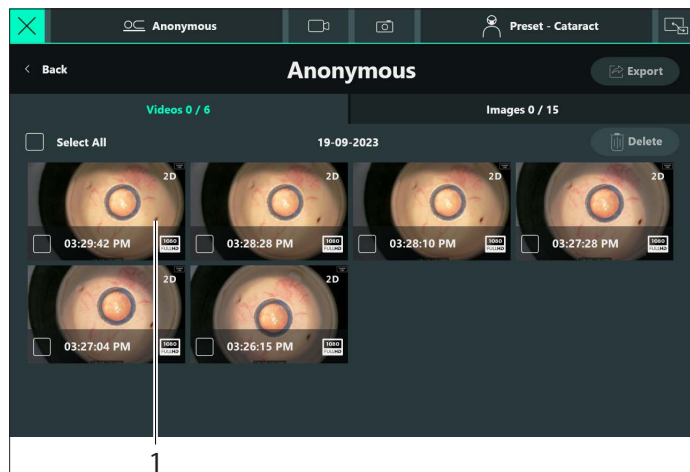
You can select the surgeries you like to remove from the system or export to external storage system.

You can also edit the patient information and notes after the surgery by clicking on the "edit" icon (2) at the end of each record row.

Ongoing surgery recordings will not appear under the list until the case is ended.

9.15.1 Preview videos/images

- ▶ Tap one of the surgery recordings.
This opens the Videos and Images lists for that patient.
- ▶ Tap the thumbnail (1) to preview the video/image.



9.15.2 Media Settings

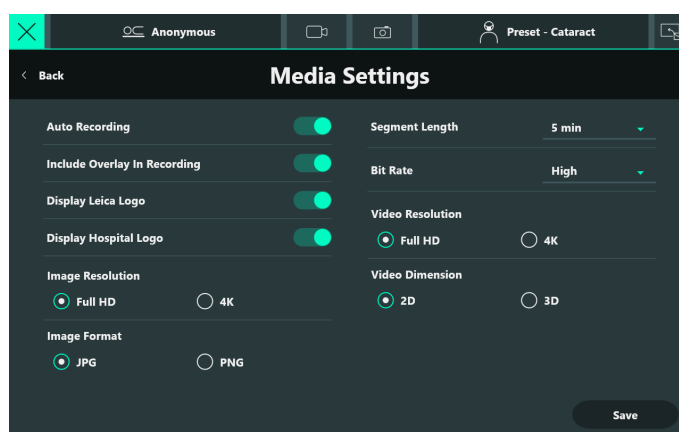
You can set the settings and format the video and image to be captured.

- ! For optimal video export experience, set the video to your desired video format to minimize the need for video conversion.

PROVEO 8x automatically starts video recording when the surgeon pulls the parallelogram down and stops video recording when the parallelogram is pushed up into the "auto-reset" position.

Auto-recording can be enabled or disabled as part of surgeon profile settings.

- If Auto-recording is enabled, PROVEO 8x automatically starts video recording when the surgeon pulls the parallelogram down.
- If Auto Recording is disabled, you will be required to manually start the recording either via the user interface, handles or footswitch.



- ▶ Surgeon moves the parallelogram down, away from the "auto-reset" position:
Recording Starts
- ▶ Surgeon moves the parallelogram up to the "auto-reset" position:
Recording Stops

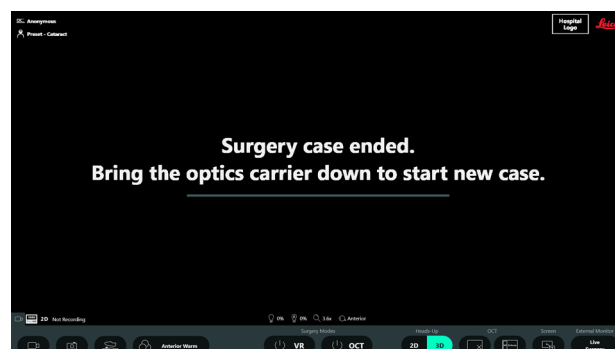
- ! "Include Overlay in Recording" setting will affect the recording of hospital/Leica logo, microscope settings and PHACO/VR values.

Recording of OCT overlay is not affected by "Include Overlay in Recording" setting, i.e., OCT overlay will be recorded when it is set to be visible on screen, even if "Include Overlay in Recording" is set as OFF.

Before Surgery



10" Touch Panel



27" Stand Monitor (Touchscreen)

- Surgeon moves the parallelogram down, away from the "auto-reset" position
Recording starts

During Surgery



10" Touch Panel



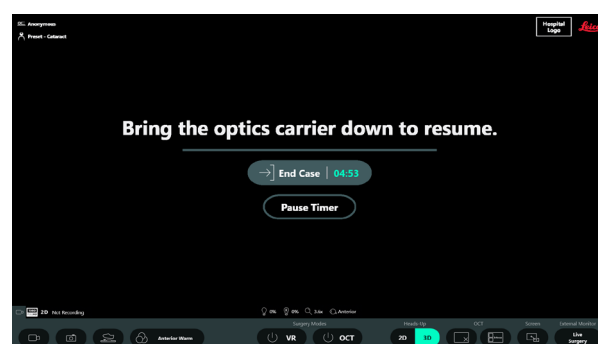
27" Stand Monitor (Touchscreen)

- Surgeon moves the parallelogram up to its end position, to the "auto-reset" position
Recording stops

End of surgery



10" Touch Panel



27" Stand Monitor (Touchscreen)

- Current case can either be ended by selecting "End Case" or automatically when the countdown timer has stopped

9.15.3 Export recordings

Multiple surgeries

You can export all the videos and images of selected surgeries in "Recording page" to external storage device (USB drive, DICOM).

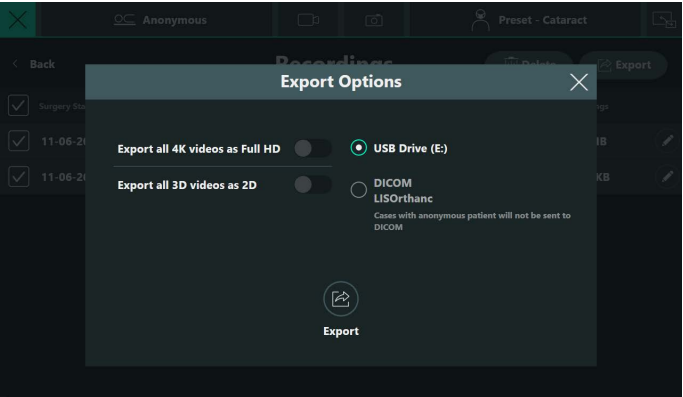
Individual surgeries

You can export selected videos and images of a particular surgery to external storage device (USB drive, DICOM).

NOTE

Videos and images on the destination (USB drive, DICOM) may be overwritten if files or folders have identical names. It is recommended to back up any important data.

Surgeries data with anonymous patient will not be able to export to DICOM.
Resolution: Edit the patient information to export the data to DICOM.



9.15.4 Simultaneous recordings

You can simultaneously record your media into 2 external storage devices which are connected to the microscope. The recommended file system of the external storage device is either NTFS or exFAT.

! The maximum possible size for a file on a FAT32 formatted storage device is 4 GB. You will not be able to proceed with export if the selected recording files are bigger than 4 GB..

- ▶ To enable the simultaneous recording feature, plug in the external storage drive before the recording starts. It is recommended to use an external storage with high writing speed (USB 3.0 and above) capability.
- ▶ Always test the USB drive's performance before critical recording sessions.
- ▶ When recording videos and capturing images simultaneously, the device generates a significant amount of data that needs to be written to the USB drive quickly and reliably. USB drive with insufficient performance can cause errors, leading to corrupted or failure to capture video or image files to the USB drive.
- ▶ Ensure the external storage drive has sufficient storage. If the

external storage drive is running out of disk space, recording will stop automatically and there will be no prompting from the system.

! Always check the external storage and ensure there is enough free space prior surgery to avoid potential data loss.

! Protect the microscope from potential USB viruses by avoiding the use of unknown or unverified USB drives. Always ensure the safety of your system by using trusted and secure USB devices.

9.15.5 Playing recordings

Video recordings are provided in the MP4 format, ensuring accessibility across both Windows and macOS platforms. However, please note that certain QuickTime versions may encounter compatibility issues with the codec used.

Resolution: To address this, we recommend using the VLC player for seamless video playback. VLC is a versatile media player that supports a wide range of codecs, ensuring a smooth viewing experience.

9.15.6 Delete videos and images from multiple surgeries

You can select the surgeries in "Recording page" and select the "Delete" button.

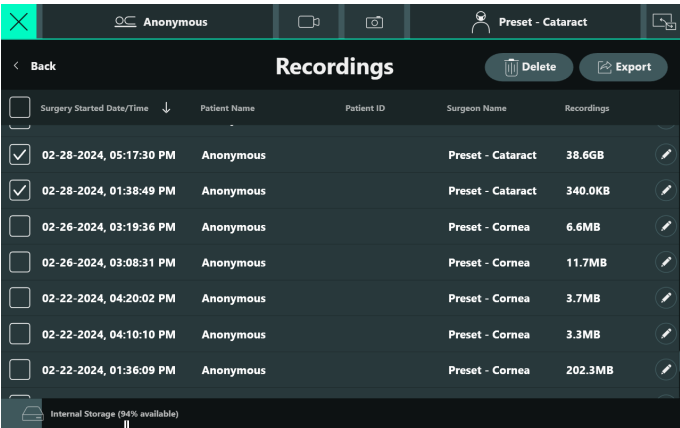
9.15.7 Delete videos and images from individual surgeries

You can select the videos and images in the individual surgery and select "delete" button.


9.15.8 Data management

The microscope comes with 4TB storage to cater for high quality video recordings.

The screen will indicate available disk space (1).




1

 The available storage varies depending on the operating system and software installed. Storage capacity is subject to change based on the current operating system and software version requirements.

9.15.9 Configuration: Auto-deletion

When auto deletion is set ON:

The system will automatically delete video and image data from the oldest surgeries when available storage space is running out of space. Be aware that this setting affects data from all patients performed by all surgeons for all future surgeries.

 Depending on the size of the surgery records, the system may require some time to complete the deletion process. Kindly navigate out and return to the recordings page to view the updated surgery list after deletion.

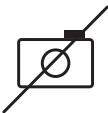
When auto deletion is set OFF:

You will not be able to perform video recording or image capture when storage space runs out of space. You have to clear disk space by deleting recorded media from the microscope to continue performing recording. This configuration can be set by hospital IT (see chapter 9.18 "Hospital IT", page 62).

Low Disk Space



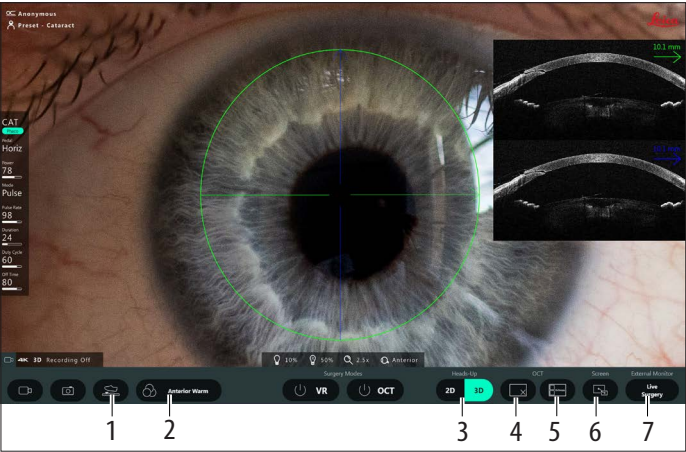
Out of Disk Space



Recordings					
<div><div>Back</div><div>Anonymous</div><div>Preset - Cataract</div></div>					
<div><div>Delete</div><div>Export</div></div>					
<input type="checkbox"/>	Surgery Started Date/Time	Patient Name	Patient ID	Surgeon Name	Recordings
<input type="checkbox"/>	02-28-2024, 05:17:30 PM	Anonymous		Preset - Cataract	38.6GB
<input type="checkbox"/>	02-28-2024, 01:38:49 PM	Anonymous		Preset - Cataract	340.0KB
<input type="checkbox"/>	02-26-2024, 03:19:36 PM	Anonymous		Preset - Cornea	6.6MB
<input type="checkbox"/>	02-26-2024, 03:08:31 PM	Anonymous		Preset - Cornea	11.7MB
<input type="checkbox"/>	02-22-2024, 04:20:02 PM	Anonymous		Preset - Cornea	3.7MB
<input type="checkbox"/>	02-22-2024, 04:10:10 PM	Anonymous		Preset - Cornea	3.3MB
<input type="checkbox"/>	02-22-2024, 01:36:09 PM	Anonymous		Preset - Cornea	202.3MB
<input type="checkbox"/>	02-20-2024, 10:17:42 AM	Anonymous		Test Service	85.0KB
Internal Storage (3% available)					

9.16 Stand monitor controls

Nurse and assistant surgeon can assist the surgeon on common functions, which are listed in the table below and view the ongoing surgery.



- | | | |
|---|--------------------|---|
| 1 | Footswitch Overlay | Display footswitch configuration |
| 2 | ScenePro | Select different visual enhancement |
| 3 | 2D/3D Display | Select 2D/3D display on heads-up monitor* |
| 4 | OCT Overlay | Select Hide/Quad/50:50 Left/50:50 intraoperative OCT view |
| 5 | Enfocus | Switch screen to intraoperative OCT software interface |
| 6 | Swap Screen | Switch GUI from 10" touchscreen to stand monitor |
| 7 | External Monitor | Select connected HDMI external monitor output |

* Selecting the 2D/3D display only affects the heads-up monitor. It will not affect the recording settings (see chapter 9.15.2 "Media Settings", page 56).

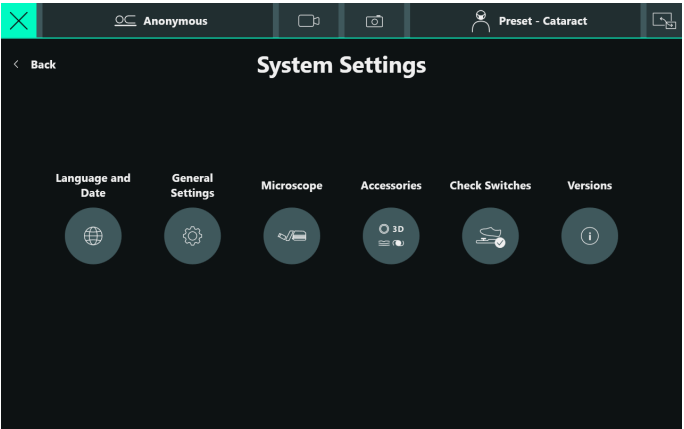
9.17 System settings

You can configure system settings such as language, accessories and perform basic functional checks on the footswitch, handles and controls on microscope.

Starting from the Main Menu, tap the "System Settings" button. The "System Settings" screen appears.

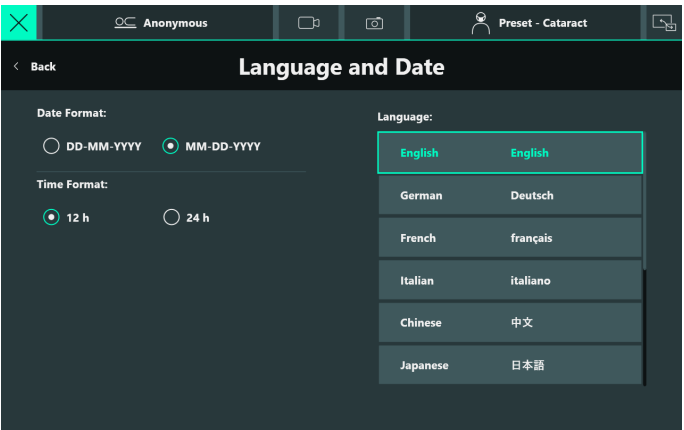
This page allows access to:

- Language and Date
- General Settings/Lamp History
- Microscope Settings
- Accessories
- Check Switches
- Versions



9.17.1 Language and Date

On the "Language and Date" tab, you can configure the language of the GUI menus and define how the Date and Time should be displayed.

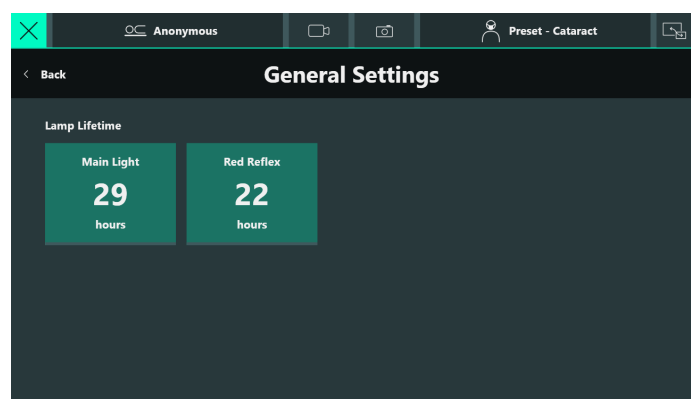


The following languages are available for the GUI:

- English
- German
- French
- Italian
- Chinese
- Japanese
- Turkish
- Russian
- Swedish
- Spanish
- Portuguese

9.17.2 Lamp History

On this screen, you can view the operating hours of Main Light and Red Reflex Light.

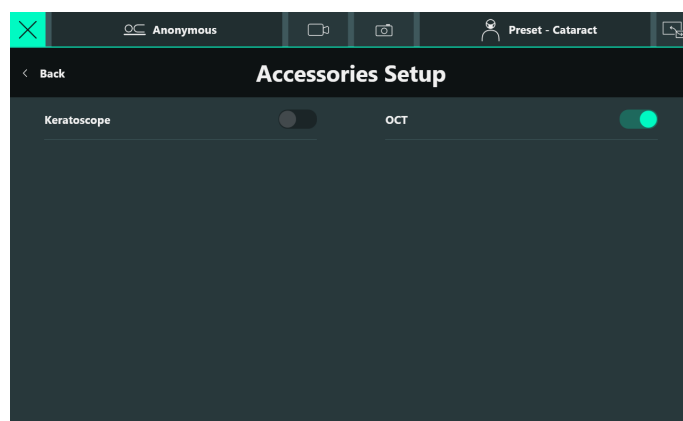


9.17.3 Accessories

You can configure to enable/disable accessories. Ensure the keratoscope and OCT is enabled under System Settings > Accessories to use the functions.

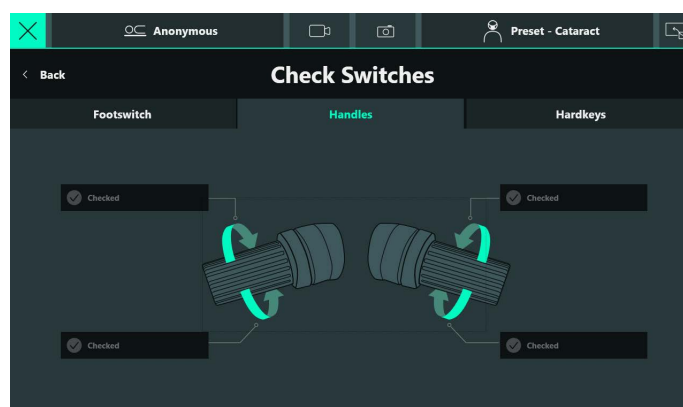


Check that the keratoscope and OCT accessories are enabled on this page if keratoscope or OCT functions are not found in the footswitch and handles assignment list (see chapters 9.8 "Footswitch assignments", page 46 and 9.9 "Handle assignment", page 47).



9.17.4 Check Switches

On this screen, you can test the switches on the handles, the footswitches or the hard keys.



9.17.5 Microscope Setup

On this screen, you can configure the accessories you are using. This ensures that the correct magnification is shown on the "Quick Access" page.



Select Surgeon Tube

In this field, you can select the binocular tube currently being used by the surgeon.

Select Eyepiece

In this field, you can select the type of the eyepieces being used by the surgeon.



If you do not make a selection, the selected accessories by default are:
binocular tube ultra low III and eyepiece with 8.33× magnification.

Select Objective

In this field, you can select the objective currently being used by the surgeon.

9.17.6 Versions

This menu shows the software and hardware versions of the accessories and the licenses of the software used on the microscope.

Device	Release Version	Software Version	Hardware Version
PROVEO 8x Software	1	1.0.1.1900	
Microscope Device Controller	1	1.0.20	1.2
Camera Control Unit	1	1.0.2.19	3.0
Camera Head Unit 2D-4K	1	1.0.2.3	2.0
Proveo 8x Controller	1	1.4.1	1.0

Please contact your local service representative for updating the software.

9.17.7 Licenses

Certain functions in the PROVEO 8x system are only activated if the licenses are installed.

Please contact your local representative for purchasing of licenses.

Install the license

- ▶ To open the Licenses menu tap Main Menu > System Settings > Versions.
- ▶ Tap on "Licenses".
- ▶ Tap on "Import" icon to install the license from the USB drive.

License activation is then carried out automatically and the screen is updated accordingly.

License	Expiration
Posterior Blue	Permanent
Posterior Green	Permanent
Posterior Red Free	Permanent
DICOM	Permanent

9.18 Hospital IT



Please refer to the cybersecurity instructions 10735164 distributed separately.

RemoteCare utilizes the hospital LAN connection of the microscope to establish a connection with the Leica data server. This server is responsible for collecting and distributing microscope data to authorized service personnel, facilitating diagnostics and support. It is important to note that patient data will not be collected through this process.

To achieve this capability, the hospital IT needs to enable RemoteCare and requires that the hospital provide incoming and outgoing internet access through firewalls on the hospital network.

RemoteCare environment conditions

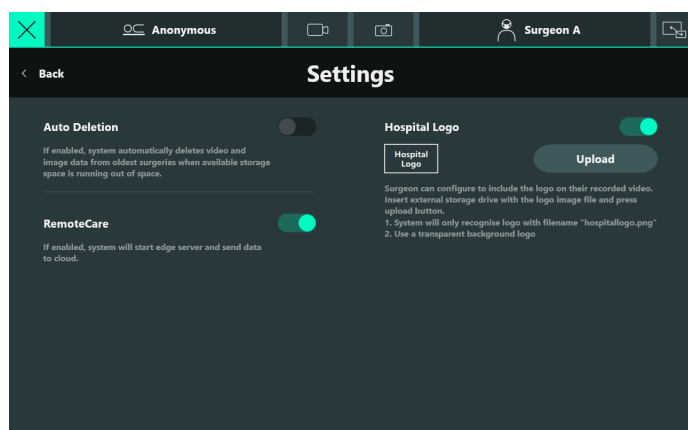
For Leica RemoteCare, an Internet connection is required. The instrument can be connected to the Internet using RJ45 network connection.



It is recommended to use a category 6 (Cat. 6 and above) ethernet cable.

When the system is connected to the Internet, you have the ability to obtain remote support, and connect to Leica RemoteCare. For this purpose, ensure that your local IT technician is available during the system installation to establish the connection.

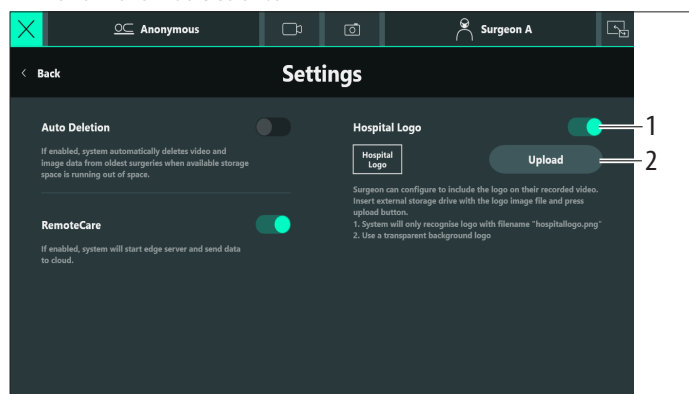
If you have further questions, email iot@leicams.com



Uploading a hospital logo

You can upload a hospital logo on this screen.

- ▶ Enable or disable the Master Control (1) to allow hospital logo to be shown or hidden from the interface.
- ▶ Click Upload (2) to upload a hospital logo to the system and follow the instructions.

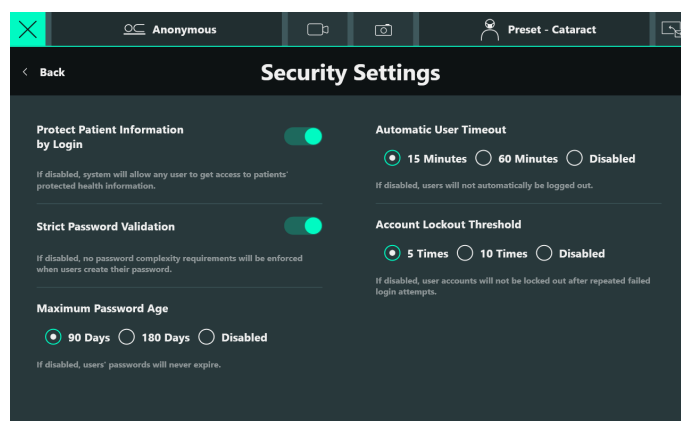


Security settings

Proveo 8x security features are enabled by default; there are some security features that may be disabled at the discretion of IT users. These decisions on security configuration are applied to all system users once applied.

Strict password validation

Require clinical user passwords to meet minimum password requirements: one uppercase, one lowercase, one numeric, one special character and a minimum of 10 characters.



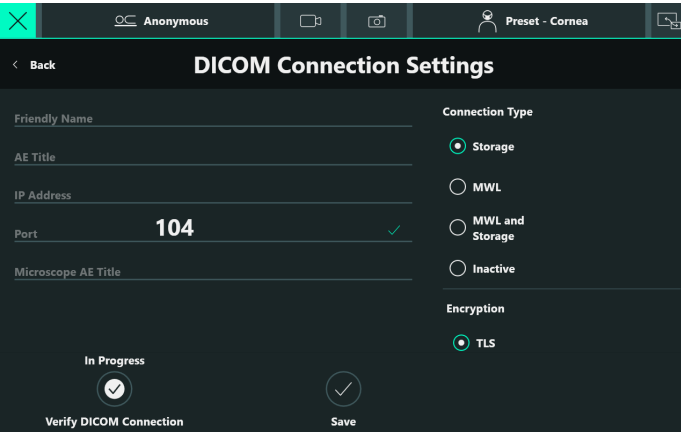
When the timeout period elapses and the clinical user is logged out, patient name displayed on the interface will be automatically masked to protect sensitive information. Ongoing surgical case or recordings will continue unaffected by the timeout.

DICOM

Proveo 8x DICOM functionality is a licensed feature that when purchased will be configured by Leica Microsystems' personnel at time of installation or at a subsequent service visit. The following instructions are provided for any cases where changes must be made after installation with Leica Microsystems' personnel supporting remotely rather than being on site. Proveo 8x allows the user to configure multiple DICOM nodes that may be used simultaneously for obtaining modality work list for the microscope and for storage of acquired data. The following settings are configured for each DICOM node that the Proveo 8x will connect:

- **Friendly Name** – Name that Proveo 8x application uses to identify the node during export and communication reporting.
- **AE Title** – Application Entity Title of the DICOM node the microscope will connect. It is locally unique identifier that the node uses within DICOM messages to identify itself.
- **IP Address** – This is the network address of the DICOM node that Proveo 8x should use for establishing connection.
- **Port** – This is the port on the DICOM node that will accept DICOM communications from Proveo 8x.
- **Microscope AE Title** – Application Entity Title that Proveo 8x uses to identify itself while communicating with this node. It must be a unique identifier that the node only uses when communicating with the microscope.
- **Connection Type** – Setting to be configured depending on what the relationship between the DICOM node and Proveo 8x is. "Storage" identifies the node as a location where Proveo 8x should export data. "MWL" identifies the node as a location where Proveo 8x should get a modality work list of which patients are scheduled for the microscope. "MWL and Storage" identifies the node as being used for both purposes. "Inactive" means the node should not be used for DICOM communications.

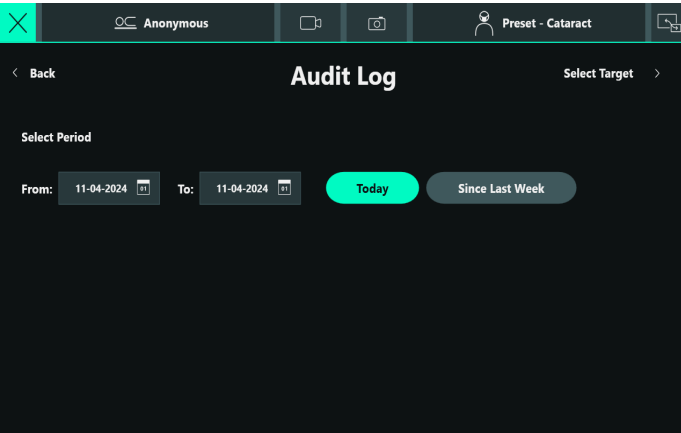
- **Encryption** – Select "TLS" if it is known that the node supports encrypted DICOM communications or if support is unknown. Select "Unencrypted" if encrypted DICOM communications are known to not be supported by the node. This support should be defined in the DCIOM conformance statement of the software that runs on the DICOM node.
- **Preferred Image Compression** – Select "Compressed" if it is known that the node supports compressed JPEG DICOM syntax and storing compressed files to minimize space is preferred to storage of uncompressed images; otherwise select "Uncompressed". This support should be defined in the DICOM conformance statement of the software that runs on the DICOM node.
- **Video Storage** – Select the default "Left & Right Channel" option which works on both 3D IVC and 2D IVC systems.



! For further information related to cybersecurity, refer to the cybersecurity instructions 10735164 distributed separately.

Exporting audit log files

You can export audit log files on this screen.

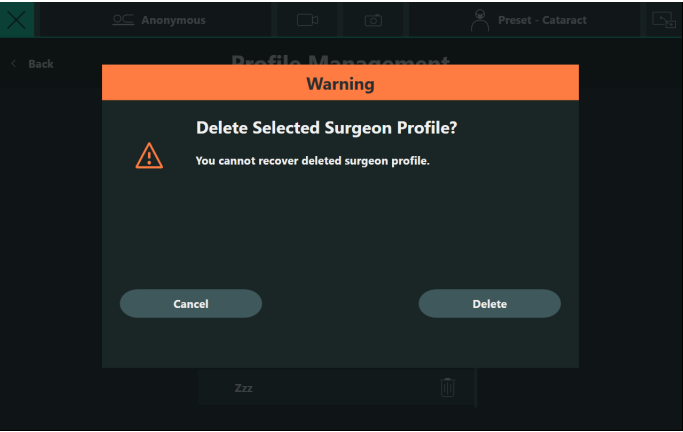


Profile Management

You can delete user-created surgeon profiles.



A warning message prompts to cancel or confirm the deletion.



WARNING

Danger to the patient due to changes in the user settings!

- Never change the configuration settings or edit the user list during an operation.

9.19 User Management

User role access rights are in place to manage protected resources and functions that require authorized access. This is different from Surgeon Profiles.

Users are divided into 3 categories:

Role	Default User	Default password *)	Functions
Any user	–	No password	<ul style="list-style-type: none"> • Start the system • Select, create, copy surgeon profiles • Configure surgeon profile settings • Configure system settings • Consult video tutorial, user manual, issue list • Create camera images and video recordings during surgery, and save them under anonymous patient
Clinical	Clinical	Le1ca_EasySurgery	<ul style="list-style-type: none"> • Review and edit patient data and surgical records • Review, export and deletion of surgical recordings and images
Hospital IT	IT	Le1ca_WhoHasAccess	<ul style="list-style-type: none"> • Audit Log • Create new users • User account list • Reset user password • Activate/deactivate user account • Enable/disable auto-deletion of surgeon records • Upload hospital logo • Configure cybersecurity settings

A request to update with a new password will be prompted upon first login.



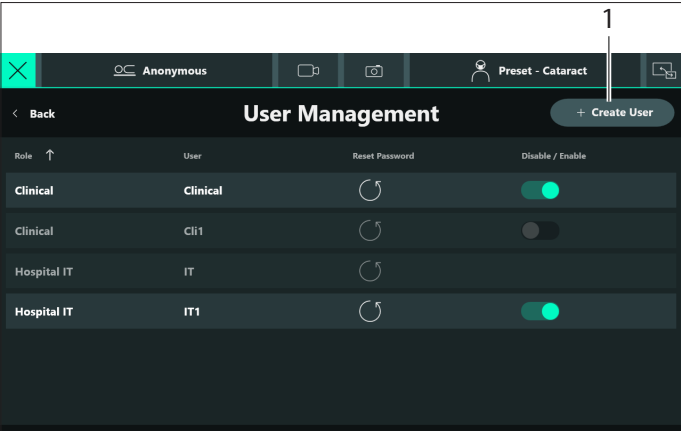
The default password is valid only when logging in for the first time. Afterwards, it must be changed individually.

In the event the Clinical User password is forgotten, the Hospital IT User is able to reset the password.

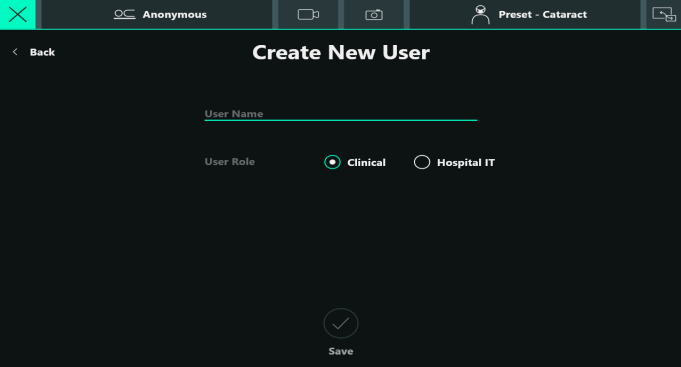
In the event the Hospital IT User password is forgotten, please contact your service representative for assistance.

9.19.1 Create a new user

- ▶ Tap the button "Create User" (1).



- ▶ In the menu field that opens select the role of the new user: Clinical or Hospital IT.



- ▶ Enter a username that is not yet being used on the system.
- ▶ Confirm with "Enter".

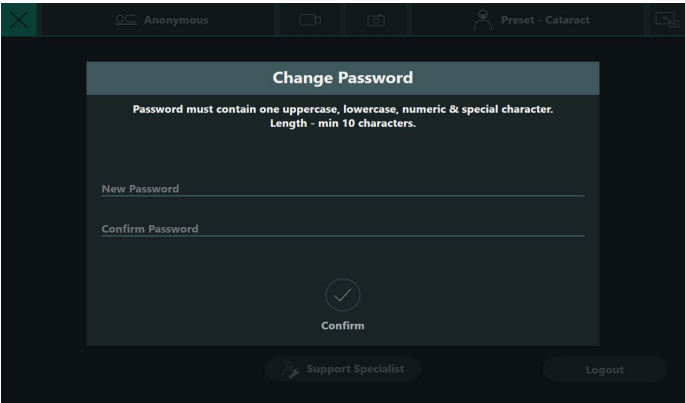
The newly created user now appears in the list.

9.19.2 First use of a user with default password

When entering a new user for the first time, the default password from chapter 9.19 "User Management", page 65 must be used. A prompt then appears to enter a new individual password and to repeat the entry with the same password.

! The new user should change the default password as soon as it is created. Use a secure password with a combination of at least 8 characters with at least one capital letter, one lower-case letter, one number and one special character.

Only the Hospital IT user can reset these passwords to the default password.

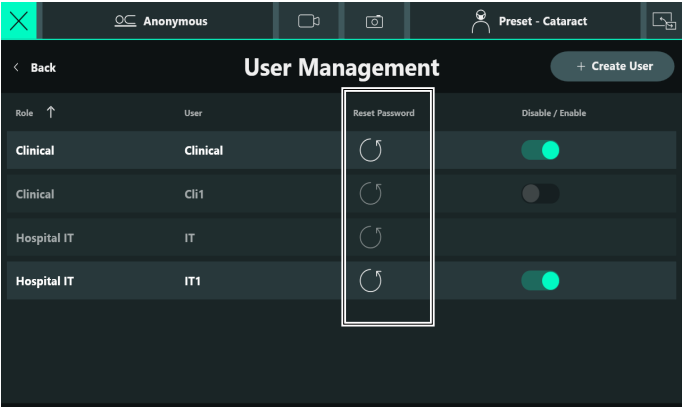


9.19.3 Reset password

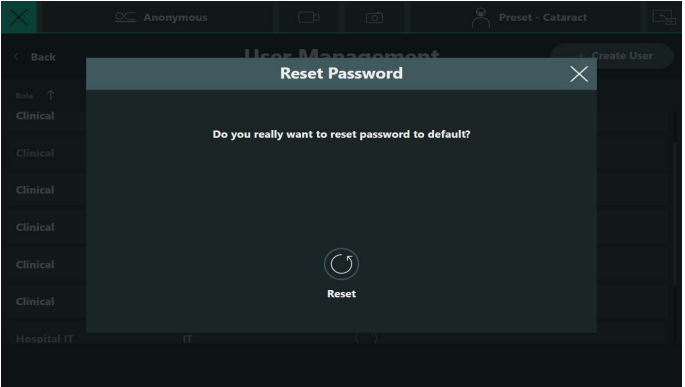
If a user forgets the password or the system has been disabled because incorrect passwords have been entered too many times, the Hospital IT user can reset this password.

Exception: Users who have been deactivated cannot have their password reset.

- ▶ Tap the reset password icon of the respective user.



- ▶ Tap the reset icon.

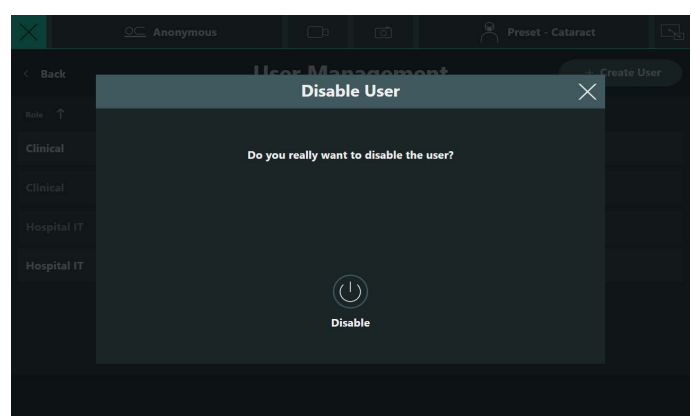
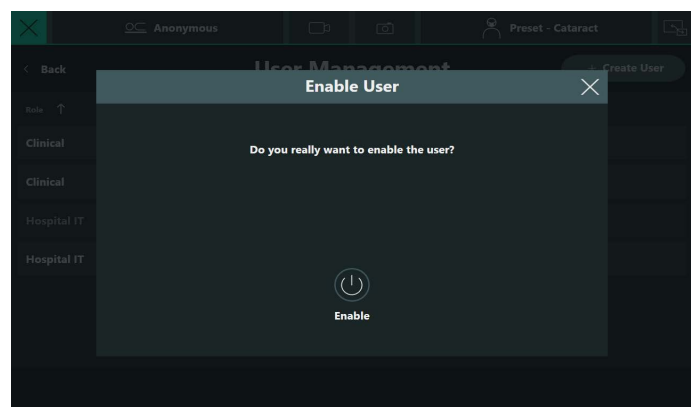
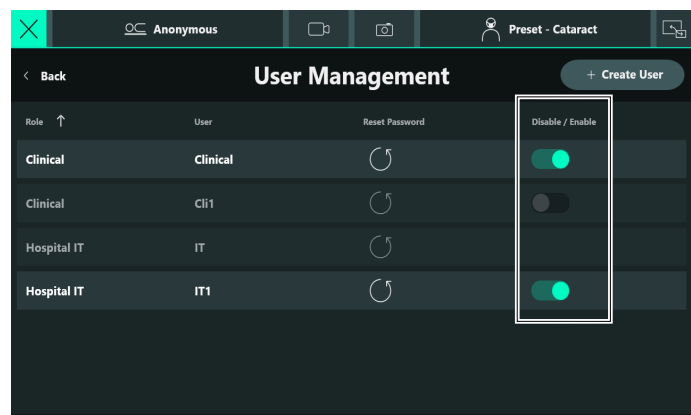


The password reset is confirmed.

9.19.4 Activate and deactivate users

Hospital IT users can disable users after they have been created. The user can be reactivated after having been disabled.

Exception: The default "IT" user cannot be disabled/enabled.

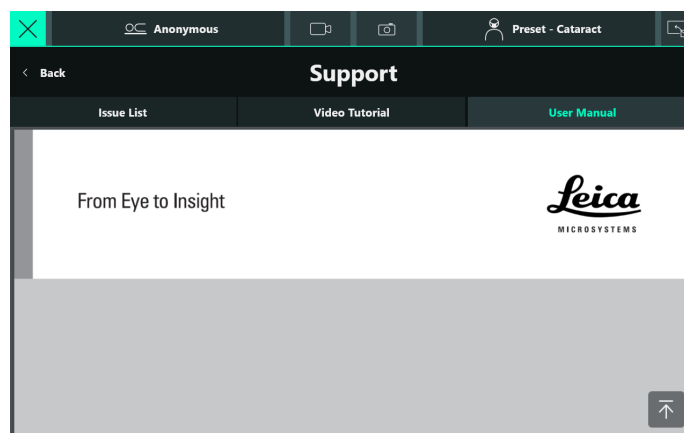
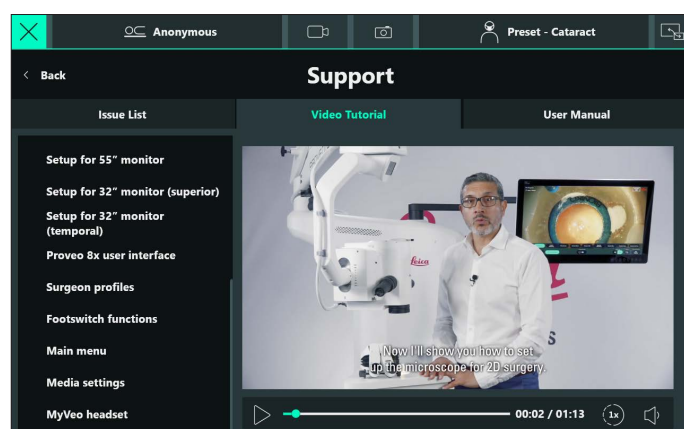
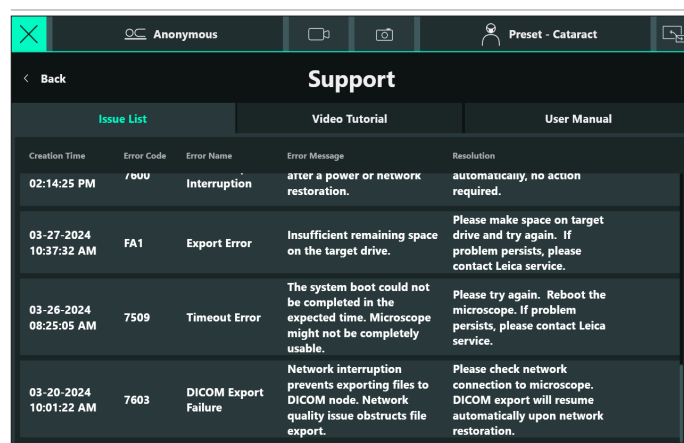


9.20 Support

- ▶ Starting from the Main Menu screen, tap the "Support" button. The "Support" screen appears. This page allows you to:
 - browse the issue list
 - watch video tutorials (only available in English)
 - read the user manual

NOTE

The user manual in the system might not be the latest, access the most recent user manual on the Leica eIFU website.





9.20.1 Support specialist

This is the access page for hospital IT and Leica specialists.
This area is password-protected.




10 Phaco/VR

The surgeon can view Phaco VR information on the surgical cockpit at a glance. Simply connect the supported Phaco/VR machine to PROVEO 8x (see chapter 6.7 "Terminals", page 19, Phaco/VR LAN port).

-  The information presented by the Phaco/VR machine is intended for reference purposes only and should not be used for diagnostic decisions.
-  Contact the Leica representative for a list of supported Phaco/VR machines.

Cybersecurity options

-  For further information related to cybersecurity, refer to the cybersecurity instructions 10735164 distributed separately.

11 Accessories

A broad range of accessories enables the PROVEO 8x surgical microscope to be matched to the requirements of the user. Your Leica representative will be pleased to help you select the appropriate accessories.

11.1 Leica Devices and Accessories

Binoculars and Eyepieces

- Binocular tube, inclinable 5-25° white
- Binocular tube, ultra low III white
- Binocular tube 10-50° with PD
- Binocular tube var. 30-150° T, type II L
- Eyepiece 8,33x/22B, type II
- Eyepiece 10x/21B
- Eyepiece f. spect.w's 12.5x/17B, type II
- Toric Eyepiece 10x, type II

Objectives

- Objective WD = 225 mm, OCT ready
- Objective WD = 200 mm, OCT ready
- Objective WD = 175 mm, OCT ready
- Protective glass M84x
- Ring mount for protective glass Obj. M84x

Covers

- Sterilizable cover (MultiFoc)
- Dust cover
- Clip-on handle
- Drive knob cover

Filters

- Laser filter 532/810 nm for IVC850
- BG12 filter, 32 mm. Cobalt Blue filter

Other accessories

- Ergo Wedge white, 5-25°
- Stereo adapter
- Beamsplitter M500 50/50%
- Beamsplitter 70/30%, observation
- Stereo attachment for second observer
- RUV800 WD200
- RUV800 WD175
- RUV800 sterile cover
- Keratoscope adapter
- Remote brake release switch
- Wireless footswitch, 14-functions, Type B, incl. receiver
- Back-up cable for wireless footswitch
- Ethernet cable (10 m)
- DICOM License



The binocular tube ultra low III with 8.33x eyepieces is recommended for the main observer.

11.2 Third Party Devices and Accessories

- BIOM 5cl (long version)
- BIOM 5c
- BIOM 5ml – manual focus
- BIOM 5m – manual focus
- Adapter Leica M8xx for BIOM5
- Reduction lens BIOM5 f = 200 mm
- Reduction lens BIOM5 f = 175 mm
- 90 D-Lens for BIOM 3/4 diamond line
- 100D WiFi HD Lens (steam autoclavable)
- Wide-Field(E) for BIOM 3/4 diamond line
- HiRes lens BIOM 2/3 (steam autoclavable)
- Mini WiFi HD lens (steam autoclavable)
- Steri-container with inserter for BIOM5
- Cable support (steam autoclavable)



Do not use third party accessories that are not approved by Leica.

11.3 Accessories list for upgradable configurations

Enfocus OCT system

- Enfocus 2300 Integrated OCT System
- Enfocus 2 Mounting kit for PROVEO 8x

Camera systems

- Upgrade Kit for PROVEO 8x 2D-4K to 3D-4K
- Upgrade Kit for PROVEO 8x 3D-4K to 2D-4K

Stand monitor

- 27" 2D-4K

Cart monitors

- 32" 3D-4K
- 55" 3D-4K

3D Glasses

- 3D glasses with frame

Cables

- PROVEO 8x Video Output Kit (10449139)
- Ethernet Cable (10m) (10449211)

Head mounted viewer

- All-in-one visualization headset "MyVeo"
- Hub Mounting Set for PROVEO 8x

12 Care and maintenance

To ensure that the PROVEO 8x surgical microscope operates safely and reliably over time, we recommend scheduling an annual preventive maintenance (PM) visit to maintain equipment specifications over time, as well as perform an electrical system safety check.

We recommend purchasing a service contract from Leica Service & Support (or authorized Service Providers) to ensure regular inspection, timely response and a direct access to our parts inventory. Please note that only genuine parts from Leica shall be used for maintenance.

- Put a dust cover over the instrument while the brakes are in work.
- Keep accessories in a dust-free place when not in use.
- Remove dust with a pneumatic rubber pump and a soft brush.
- Clean the objectives and eyepieces with special optics cleaning cloths and pure alcohol.
- Protect the surgical microscope from damp, vapors, acids, alkalis, and corrosive substances.
Do not keep chemicals near the instrument.
- Protect the surgical microscope from improper handling.
Install other device sockets or unscrew optical systems and mechanical parts only when explicitly instructed to do so in this user manual.
- Protect the surgical microscope from oil and grease.
Never oil or grease the guide surfaces or mechanical parts.
- Remove coarse debris with a moistened disposable cloth.
- To disinfect the surgical microscope, use compounds from the surface disinfectant group based on the following active ingredients:
 - aldehydes,
 - alcohols,
 - quaternary ammonium compounds,
 - hypochlorite (chlorine-based) disinfectant.




Due to potential damage to the materials, never use products based on

- halogen-splitting compounds,
 - strong organic acids,
 - oxygen-splitting compounds.
- Follow the disinfectant manufacturer's instructions.



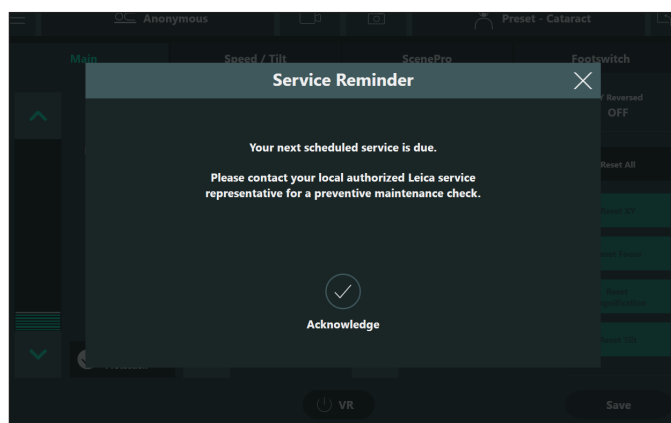
It is recommended to conclude a service contract with Leica Service.

-  It is recommended to conclude a service contract with Leica Service.

- ▶ Operate the touch panel using your fingers only. Never use hard, sharp or pointed objects made out of wood, metal or plastic.
- ▶ Never clean the touch panel using cleaners that contain abrasive substances. These substances can scratch the surface and cause it to become dull.

12.2 Maintenance

- It is recommended to conclude a service contract with Leica Service.
- Use only original spare parts for servicing.
- You will be reminded that the inspection is due when you switch on the microscope.



- Press the "Acknowledge" button.
The dialog window is closed.

12.3 Notes on reprocessing of resterilizable products

12.3.1 General

Products

Reusable products supplied by Leica Microsystems (Schweiz) AG such as rotary knobs, objective protective glasses and capping pieces.

Occupational safety and health protection

Particular attention must be paid to the occupational safety and health protection of the persons responsible for preparing contaminated products. Current regulations of hospital hygiene and prevention of infection must be observed in the preparation, cleaning and disinfection of the products.

Limitations of reprocessing

For the medical devices used on patients suffering from Creutzfeldt Jacob Disease (CJD) or suspected of having CJD or variant CJD, the local statutory requirements have to be met. Normally resterilizable products used on this group of patients are to be eliminated without risk by incineration.

Frequent reprocessing has little effects on these products. The end of the product life cycle is usually determined by wear and tear and damage through use.

12.3.2 Instructions

Workplace

- Remove surface contamination with a disposable cloth/paper cloth.

Storage and transport

- Refer to chapter 15.6 "Ambient conditions", page 84.
- It is recommended to perform the reprocessing of a product immediately following its use.

Preparation for cleaning

- Remove the product from the PROVEO 8x surgical microscope.

Cleaning: manually

- Equipment: water, detergent, alcohols, microfiber cloth

Procedure

- Rinse surface contamination off of the product (temp. < 40 °C). Use some rinsing agent depending upon degree of contamination.
- Alcohol may also be used to clean the optics if heavy contamination such as fingerprints, grease streaks, etc. is present.

- Dry off products, except for optical components, with a disposable cloth/paper cloth. Dry off optical surfaces with a micro-fiber cloth.

Cleaning: automatically

- Equipment: cleaning/disinfecting device

It is not recommended to clean products with optical components in a cleaning/disinfecting device. In addition, optical components must not be cleaned in ultrasonic baths in order to prevent damage.

Disinfection

The alcohol disinfection solution "Mikrozid Liquid" may be used in accordance with the instructions on the label.

Please note that after disinfection, the optical surfaces must be rinsed thoroughly with fresh drinking water, followed by fresh demineralized water. The products must be dried thoroughly before the subsequent sterilization.

Maintenance

See information in chapter 12.2 "Maintenance", page 71.

Control and functional test

Check the snap-on behavior of rotary knobs and handles.

Packaging

Individual: A standard PE bag may be used. The bag must be large enough for the product so that the closure is not under tension.

Sterilization

See Sterilization table in chapter 12.3.3 "Sterilization components", page 73.

Storage

Refer to chapter 15.6 "Ambient conditions", page 84.

Additional information

None

Contact information of manufacturer

Address of local agent

Leica Microsystems (Schweiz) AG verified that the aforementioned instructions for the preparation of a product are suitable for its reuse. The processing person is responsible for reprocessing with the equipment, materials and personnel and for achieving the desired results in the reprocessing installation. In general, this requires validations and routine monitoring of the process. Every deviation from the supplied instructions should also be examined carefully by the processing person to determine effectiveness and possible detrimental consequences.

12.3.3 Sterilization components

The following table gives an overview of the available sterilizable components to the surgical microscopes of Leica Microsystems (Schweiz) AG, Medical Division.

Article No.	Designation	Permissible sterilization methods	Product
		Steam autoclave 134 °C, t > 10 min.	PROVEO 8x
10180591	Clip-on handle	✓	✓
10428328	Drive knob cover	✓	✓
10448581	Cover, sterilizable for RUV800	✓	✓
10446467	Protective glass M84x	✓	✓
10446468	Ring mount f.prot.glass Obj. M84x	✓	✓
10731202	Sterilizable Cover (MultiFoc)	✓	✓

13 Disposal

After a system usage period of 8 years, an annual maintenance and electrical system safety check is considered mandatory. We recommend purchasing a service contract from Leica Service and Support.



The system shall not be used to perform critical use applications after 8 years of system usage.

At the end of the product service life, please contact the Leica branch office in your country with regard to disposal.

NOTE

The system, its accessory components and consumable materials must not be disposed of with general household waste! Be sure to follow the national laws and regulations.

Before disposing of the old instrument:

- ▶ Delete all personal data from the old instrument to be disposed of.
- ▶ Remove rechargeable batteries, other batteries and lamps from the old instrument to be disposed of.
- ▶ Make sure that the system is cleaned and disinfected completely and thoroughly and is free of hazardous substances and infectious agents.

14 What to do if ...?

! If your instrument has a malfunction that is not described here, please contact your Leica representative.

14.1 Faults

14.1.1 Device setup

Fault	Cause	Remedy
The stand of the PROVEO 8x moves.	Footbrakes not applied fully.	► Press the footbrake until it engages (see chapter 7.1 "Transportation", page 25).
Stand wobbles.	Floor not level. Wheel on protruded object.	► Reposition the stand base.
Parallelogram cannot be moved.	Parallelogram locked in position.	► Release the locking mechanism (see chapter 7.8.3 "Releasing the parallelogram", page 32).
PROVEO 8x is not correctly balanced.	Position of accessory was changed after balancing.	► Balance out PROVEO 8x (see chapter 7.8.1 "Balancing the parallelogram", page 31).

14.1.2 Foot switch

Fault	Cause	Remedy
Functions cannot be activated using the footswitch.	Incorrect assignment entered at control unit.	► Change the assignment using the control unit.
	Different footswitch assignment for surgery mode.	► Check the footswitch assignment for the corresponding surgery mode using footswitch overlay (see chapter 9.16 "Stand monitor controls", page 60).
	Button malfunction.	► Check the button function using the "Check Switches" function (see chapter 9.17 "System settings", page 60). ► Assign the function to an alternative button (see chapter 9.8 "Footswitch assignments", page 46). ► Contact Leica service.
	Wrong microscope setup for footswitch.	► Select "main" for default supplied footswitch. ► Select "secondary" for externally connected footswitch.
Footswitch assignment for VR mode does not activate in VR surgery mode.	Footswitch assignment for VR is disabled.	► Enable "footswitch assignment for VR" under surgery mode selection (see chapter 9.11 "VR mode", page 52).

14.1.3 Visualization

Fault	Cause	Remedy
The image remains unfocussed.	Eyepieces are not mounted correctly.	► Screw the eyepieces all the way on.
	Diopters not set correctly.	► Perform dioptric correction exactly according to the instructions (see chapter 7.5.1 "Determining/adjusting diopter settings for users", page 28).

What to do if ...?

Fault	Cause	Remedy
Image loses sharpness/defocused when changing magnification.	Parfocality is out.	► Perform dioptic correction exactly according to the instructions (see chapter 7.5.1 "Determining/adjusting diopter settings for users", page 28).
The image appears shaded through the microscope at the edges and the illumination field is outside the field of vision.	Accessories not installed properly.	► Install the accessories exactly in the holders (see chapter 7.2 "Installing the monitor cover", page 26).
Magnification cannot be adjusted electrically.	Failure of magnification motor.	► Press the magnification rotary knob. ► Set magnification by turning (see chapter 8.4.5 "Adjusting the magnification (zoom)", page 39).
Image does not invert in VR mode.	Failure of inverter motor.	► Activate/deactivate by turning rotary knob "inverter" (see chapters 6.1 "PROVEO 8x optics carrier including focus, tilt and XY with 2D4K IVC", page 16 and 6.2 "PROVEO 8x optics carrier including focus, tilt and XY with 3D4K IVC", page 17).
Video pictures of 2D-4K IVC unfocused.	Microscope or fine focus not precisely focused.	► Focus precisely, use graticule if necessary. ► Perform diopter correction exactly according to the instructions.
No or partial visualization via eyepiece with 3D-4K IVC.	The rotary knob is at "3D digital" mode position.	► Turn the rotary knob to "3D Hybrid" position (see chapter 6.2 "PROVEO 8x optics carrier including focus, tilt and XY with 3D4K IVC", page 17).
	The inverters are at halfway position.	► Turn the inverters to "in" or "out" position fully (see chapter 6.2 "PROVEO 8x optics carrier including focus, tilt and XY with 3D4K IVC", page 17).
Blurry or absent 3D image on the heads-up display.	Video output selected for heads-up monitor is "2D".	► Switch video output for heads-up monitor to "3D" (see chapter 9.16 "Stand monitor controls", page 60).
	Monitor input signal set as "2D".	► Set monitor input signal to "3D".
	Wrong 3D glasses in use.	► Use 3D glasses supplied by Leica Microsystems.
	Out of viewing range of 3D monitor.	► Reposition 3D monitor.
	3D monitor not compatible.	► Use 3D monitor supplied by Leica Microsystems.
	Wrong connection of output terminal.	► Connect to "SDI 3D" output terminal (see chapter 6.7 "Terminals", page 19).
The color perception of digital image is different from ocular.	ScenePro has been changed.	► Select "Anterior Warm" or "Posterior Warm" for close color perception to ocular.
	Color out of calibration.	► Perform white balance of camera (see chapter 9.10.5 "White balance of camera", page 51).
The color perception of digital image is poor.	Color out of calibration.	► Perform white balance of camera (see chapter 9.10.5 "White balance of camera", page 51).

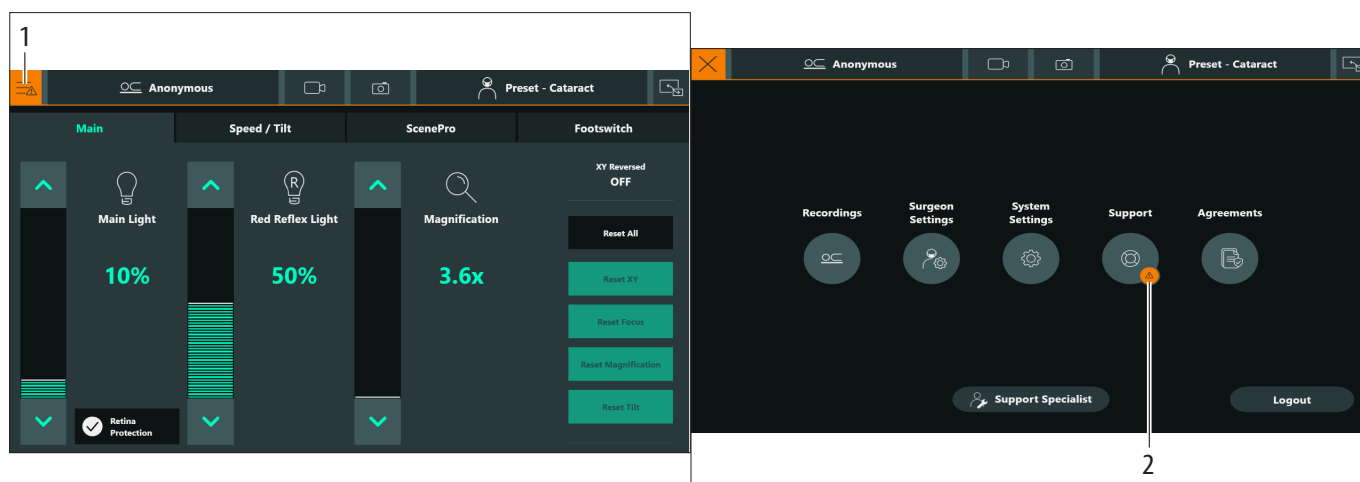
14.1.4 Documentation

Fault	Cause	Remedy
External storage medium not recognized.	The storage medium is unformatted.	► Format the external storage medium, preferably in exFAT or NTFS format.
	The storage medium requires higher current to run.	► Try with alternative storage medium, preferably solid-state storage device.
Recording starts unintendedly.	Auto-recording is activated.	► Disable "Auto Recording" in media settings (see chapter 9.15.2 "Media Settings", page 56).

14.2 Error messages on the control unit

Alert priority levels

- Errors/Warnings that require immediate attention will be visible as pop-up windows and/or toast notification.
- Errors/Warnings that occur but do not require immediate action are indicated with an alert sign in orange (1) on the Access "Main Menu" button that points to the issue list (2).



The alert sign disappears as soon as the user opens the issue list.
All user-relevant errors/warnings are visible in the "Issue List".
The issue list always displays all previous errors.

The following is a list of possible error messages.

Error Code	Error Name	Error Message	Resolution
112**	PROVEO 8x Optics Carrier M850	Main LED temperature exceeds limit.	<ul style="list-style-type: none"> • Main LED too hot. • No air flow possible. • Optics carrier might be covered. ► Contact Leica service.
113**	Optics Carrier M850	Main LED current exceeds limit.	<ul style="list-style-type: none"> • Main LED current too high. • Optics controller board or LED defective. ► Contact Leica service.
904~	Camera	Camera overheating, no live feed, binoculars required.	► Contact Leica service.

What to do if ...?

Error Code	Error Name	Error Message	Resolution
906~	Camera	Camera overheating, no live feed, binoculars required.	► Contact Leica service.
910**	Camera	Fan 2 rotation stopped.	► If the problem persists, contact Leica service.
7001**	Software	MDC is overloaded.	► Reboot the microscope. ► If the problem persists, contact Leica service.
7002**	Software	Communication error between computing unit and MDC.	► Reboot the microscope. ► If the problem persists, contact Leica service.
7003**	Software	Communication error between computing unit and MDC.	► Reboot the microscope. ► If the problem persists, contact Leica service.
7004**	Software	Communication error between computing unit and MDC.	► Reboot the microscope. ► If the problem persists, contact Leica service.
7101***	Software	Unexpected behavior while performing this action.	► Reboot the microscope. ► If the problem persists, contact Leica service.
7102*	Software	Unexpected behavior while performing this action.	► Try the last action again. ► Reboot the microscope. ► If the problem persists, contact Leica service.
7103*	Software	Unexpected behavior while performing this action.	► Try the last action again. ► Reboot the microscope. ► If the problem persists, contact Leica service.
7104**	Software	Inactive LAN connection hinders external storage export.	► Contact hospital IT support.
7105**	Software	Network storage drive not available due to incorrect or outdated credentials of the remote disk.	► Check with hospital IT support for credentials of the disk configuration.
7106**	Software	Failed to delete recording.	► Try the last action again. ► Reboot the microscope. ► If the problem persists, contact Leica service.
7107~	Software	Disk space is running low.	► Delete previous recordings via Recordings (see chapters 9.15.6 "Delete videos and images from multiple surgeries", page 58 and 9.15.7 "Delete videos and images from individual surgeries", page 58).
7108~	Software	System has run out of disk space. You will not be able to initiate any new recordings unless you have deleted previous recordings.	► Delete previous recordings via Recordings (see chapters 9.15.6 "Delete videos and images from multiple surgeries", page 58 and 9.15.7 "Delete videos and images from individual surgeries", page 58).
7201***	Software	Unexpected behavior while performing this action.	► Reboot the microscope. ► If the problem persists, contact Leica service.
7202*	Software	Unexpected error while performing this action.	► Try the last action again. ► Reboot the microscope. ► If the problem persists, contact Leica service.
7203*	Software	Unexpected exception while performing this action.	► Try the last action again. ► Reboot the microscope. ► If the problem persists, contact Leica service.

Error Code	Error Name	Error Message	Resolution
7205*	Software	Camera is disconnected. All camera features cannot be used.	<ul style="list-style-type: none"> • Missing/outdated driver. <ul style="list-style-type: none"> ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service. • USB port failure or faulty USB device. <ul style="list-style-type: none"> ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service. ▶ Check the camera cable.
7301**	Software	Unexpected behavior while performing this action.	<ul style="list-style-type: none"> ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
7302*	Software	Unexpected behavior while performing this action.	<ul style="list-style-type: none"> ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
7303*	Software	Unexpected exception while performing this action.	<ul style="list-style-type: none"> ▶ Try the last action again. ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
7304**	Software	Failed to retrieve main power supply status.	<ul style="list-style-type: none"> ▶ Reboot the microscope. ▶ If problem persists, contact Leica service.
7305**	Software	Communication error with UPS module.	<ul style="list-style-type: none"> ▶ Reboot the microscope. ▶ If problem persists, contact Leica service.
7401**	Software	Unexpected behavior while performing this action.	<ul style="list-style-type: none"> ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
7402*	Software	Unexpected error while performing this action.	<ul style="list-style-type: none"> ▶ Try the last action again. ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
7403*	Software	Unexpected exception while performing this action.	<ul style="list-style-type: none"> ▶ Try the last action again. ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
7410**	Software	Communication error with camera.	<ul style="list-style-type: none"> ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
7501*	Software	Unexpected exception while performing this action.	<ul style="list-style-type: none"> ▶ Try the last action again. ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
7502*	Software	User interface may not display system status.	<ul style="list-style-type: none"> ▶ Try the last action again.
7503*	Software	User interface may not display system status.	<ul style="list-style-type: none"> ▶ Try the last action again.
7504*	Software	White Balance could not be completed.	<ul style="list-style-type: none"> ▶ Try the last action again. ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
7505*	Software	Picture could not be taken.	<ul style="list-style-type: none"> ▶ Try the last action again. ▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
7510	Application Files Tampered	The integrity of the application files has been compromised. Continuing to use the application may pose risks and lead to unforeseen consequences. Do you want to proceed despite the detected tampering?	<ul style="list-style-type: none"> ▶ Contact hospital IT and Leica service.

What to do if ...?

Error Code	Error Name	Error Message	Resolution
7600*	Software	DICOM export has resumed after a power or network restoration.	DICOM export resumed automatically, no action required.
7601*	Software	Could not export files to DICOM due to issues with DICOM storage node. DICOM storage node reported that it was out of resources.	<ul style="list-style-type: none"> ► Use alternate DICOM storage location or contact hospital IT support. ► Resolve issue on storage node.
7602*	Software	An error occurred while executing a DICOM export. Issue prevented export of files to DICOM node.	<ul style="list-style-type: none"> ► Contact hospital IT support.
7603*	Software	Network interruption prevents exporting files to DICOM node. Network quality issue obstructs file export.	<ul style="list-style-type: none"> ► Check network connection to microscope.
7604**	Software	Could not retrieve patient information from MWL. Issue preventing MWL query from properly executing.	<ul style="list-style-type: none"> ► Check network connection to microscope then retry query. ► Contact hospital IT support if problem persists.
7605*	Software	Could not export selected file type to DICOM node. SOP class or transfer syntax not supported by selected DICOM storage node.	<ul style="list-style-type: none"> ► Contact hospital IT support. ► Modify DICOM node configuration for compatibility or contact Leica support to resolve.
7606**	Software	Cannot export anonymous patient information to DICOM.	<ul style="list-style-type: none"> ► Enter valid patient information and retry DICOM export.
750C*	Software	Could not export to target drive.	<ul style="list-style-type: none"> ► Contact hospital IT support. ► Check the write permissions. ► Reboot the microscope. ► If the problem persists, contact Leica service.
750D*	Software	Could not export to target drive.	<ul style="list-style-type: none"> ► Contact hospital IT support. ► Make space on target drive and try again. ► Reboot the microscope. ► If the problem persists, contact Leica service.
750E*	Software	User interface may not display system status.	<ul style="list-style-type: none"> ► Try the last action again. ► Reboot the microscope. ► If the problem persists, contact Leica service.
750F*	Software	User interface may not display system status.	<ul style="list-style-type: none"> ► Try the last action again. ► Reboot the microscope. ► If the problem persists, contact Leica service.
90C**	Camera	Camera control unit firmware error	<ul style="list-style-type: none"> ► Reboot the microscope. ► If the problem persists, contact Leica service.
90D~	Camera	Camera CHU temperature is too high.	<ul style="list-style-type: none"> ► If the problem persists, contact Leica service.
90E~	Camera	Camera CCU temperature is too high.	<ul style="list-style-type: none"> ► If the problem persists, contact Leica service.
90F**	Camera	Fan 1 rotation stopped.	<ul style="list-style-type: none"> ► If the problem persists, contact Leica service.
B01**	Camera	IVC Iris motor initialization error	<p>Diaphragm PCBA or stepper motor has no power.</p> <ul style="list-style-type: none"> ► Contact Leica service.

Error Code	Error Name	Error Message	Resolution
B02**	Camera	Limit switch initialization error	Limit switch to indicate home position damaged. ▶ Contact Leica service.
B03**	Camera	IVC Iris motor initialization error	IVC Iris motor damaged. ▶ Contact Leica service.
FA1***	Software	Insufficient remaining space on the target drive.	Not enough space left on target drive. ▶ Make space on target drive and try again. ▶ If the problem persists, contact Leica service.
FA2***	Software	Data export failed due to an unexpected error.	An unexpected error occurred; data could not be exported. ▶ Contact hospital IT support. ▶ If the problem persists, contact Leica service.
FA3***	Software	The selected target drive is restricted with read or write access.	The target drive you have chosen has read or write access restrictions. ▶ Contact hospital IT support. ▶ If the problem persists, contact Leica service.
FA4***	Software	External storage device or network drive is disconnected.	The external storage device or the network drive is disconnected. ▶ Check the drive connection and try again. ▶ If the problem persists, contact Leica service.
FA5***	Software	Data export failed due to an unexpected error.	An unexpected error occurred; data could not be exported. ▶ Contact hospital IT support. ▶ If the problem persists, contact Leica service.
FA6***	Software	Could not export data due to corrupt files.	Could not export data due to corrupt files. ▶ Contact hospital IT support. ▶ If the problem persists, contact Leica service.
FE01**	MDC	Optics carrier not found.	▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
FE02**	MDC	XY controller not found.	▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
FE03**	MDC	PROVEO 8x controller not found.	▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
FE06**	MDC	Diaphragm not found.	▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
FE07**	MDC	GUI-MDC communication, unknown message type.	▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.
FE09**	MDC	Camera control unit not found.	▶ Reboot the microscope. ▶ If the problem persists, contact Leica service.

~ Errors/Warnings as a toast notification

* Errors/Warnings as a pop-up

** Errors/Warnings with a yellow triangle in the Main Menu that points to the issue list

*** Errors/Warnings only in the issue list

15 Specifications

15.1 Microscope features

Magnification	6:1 zoom, motorized Magnification factor
Magnification factor	4.1–24.5 (using 10x eyepiece, ultra low III binocular tube, and WD 175mm objective)
Objective / working distance	OptiChrome WD 175 mm/f = 200 mm WD 200 mm/f = 225 mm WD 225 mm/f = 250 mm WD: Working distance f: Focal length
Eyepieces	Wide-field eyepieces for persons wearing glasses 8.3×, 10× and 12.5× dioptic adjustment ±5 diopter settings; adjustable eyecup
Illumination	Main light: Integrated LED illumination system for intensive, uniform illumination of the field of view. Continuously adjustable brightness with halogen like color temperature. Coaxial illumination: Illumination unit for generating a clear and stable Red Reflex, decreasing stray light through the sclera and increasing the image contrast. Integrated LED illumination system for intensive, uniform illumination of the field of view. Continuously adjustable brightness with halogen like color temperature.
Adjustable Iris	Working diameter of coaxial illumination can be adjusted from 4 mm to 23 mm.
Fine focus	Available for assistant and 2D4K IVC

15.2 Optical data

With ultra low III binocular tube

Eyepiece	Objective OptiChrome WD = 175 mm/f = 200 mm	
	Total magnification	Field of view (mm)
8.33×	3.4×–20.4×	53.9–9.0
10×	4.1×–24.5×	51.4–8.6
12.5×	5.1×–30.7×	41.6–6.9

Eyepiece	Objective OptiChrome WD = 200 mm/f = 225 mm	
	Total magnification	Field of view (mm)
8.33×	3.0×–18.2×	60.6–10.1
10×	3.6×–21.8×	57.8–9.6
12.5×	4.5×–27.3×	46.8–7.8

Eyepiece	Objective OptiChrome WD = 225 mm/f = 250 mm	
	Total magnification	Field of view (mm)
8.33×	2.7×–16.3×	67.3–11.2
10×	3.3×–19.6×	64.3–10.7
12.5×	4.1×–24.5×	52.0–8.7

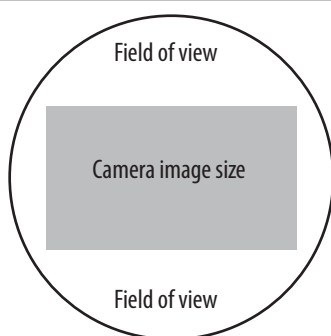
The values above contain a tolerance of ±5 %.

15.3 Microscope carrier

Rotation of optics	380°
Inclination tilt	–15° / +105° (without retinal viewing accessories)
XY speed	Zoom linked XY speed
XY range	62 × 62 mm
Focus range	75 mm
Focus speed	Zoom linked focus speed

Camera image size with respect to the field of view

- Camera for visible light



15.4 Camera

Image sensor	1× 1/3" or 2× 1/3"
Resolution	3840×2160

15.5 Floor stand

Electrical data

Power connection	1300 VA 100–240 V~ 50/60 Hz
Protection class	Class 1
Type	Floor stand with 4 electromagnetic brakes
Base	770 × 770 mm with four 360° rotating castors with a diameter of 150 mm each, one parking brake
Balancing	Adjustable gas spring via balancing knob
Floor stand control unit	The latest electronics control for the continuous governing of all motor functions and the light intensity. Menu selection based on unique software for user-specific configuration, with built-in electronic auto-diagnosis and user support
Control unit stand	Open architecture for future software developments
Control elements	14 function wireless footswitch and rotary handles
Integrated documentation	Prepared for integration of video camera system and digital recording system
Connectors	Numerous built-in connectors for video and control data transfer
Carrier for monitor	960 mm long and flexible arm with 4 axis for rotation and inclination to carry video monitor. Max. monitor weight: 16 kg
Materials	Use of RoHS conform materials
Surface coating system	The Proveo 8x microscope is coated with a white paint which provides an antibacterial effect on surfaces
Maximum height	In park position: 1950 mm
Range cantilever value change	Max. 1557 mm
Load	Max. 8.0 kg from microscope dovetail ring interface
Weight	Approx. 380 kg without load

15.6 Ambient conditions

In use	+10 °C to +30 °C +50 °F to +86 °F 20 % to 90 % rel. humidity (noncondensing) 800 mbar to 1013 mbar atmospheric pressure
Storage	−30 °C to +70 °C −22 °F to +158 °F 10 % to 95 % rel. humidity (noncondensing) 500 mbar to 1013 mbar atmospheric pressure
Transport	−30 °C to +70 °C −22 °F to +158 °F 10 % to 95 % rel. humidity (noncondensing) 500 mbar to 1013 mbar atmospheric pressure

15.7 Standards fulfilled

CE conformity

- Medical Device Regulation 2017/745 including amendments.
- Medical electrical equipment, Part 1: Generally defined for the safety in IEC 60601-1; EN 60601-1; UL 60601-1; CAN/CSA-C22.2 NO. 601.1-M90.
- Electromagnetic compatibility
IEC 60601-1-2; EN 60601-1-2; EN 61000-3-2; IEC 61000-3-2.
- Further applied harmonized standards: IEC 62366, EN 15004-2, EN 10936-2, EN 62471, EN ISO 15223-1.
- The Medical Division, within Leica Microsystems (Schweiz) AG, holds the management system certificate for the international standard ISO 13485 relating to quality management and quality assurance.

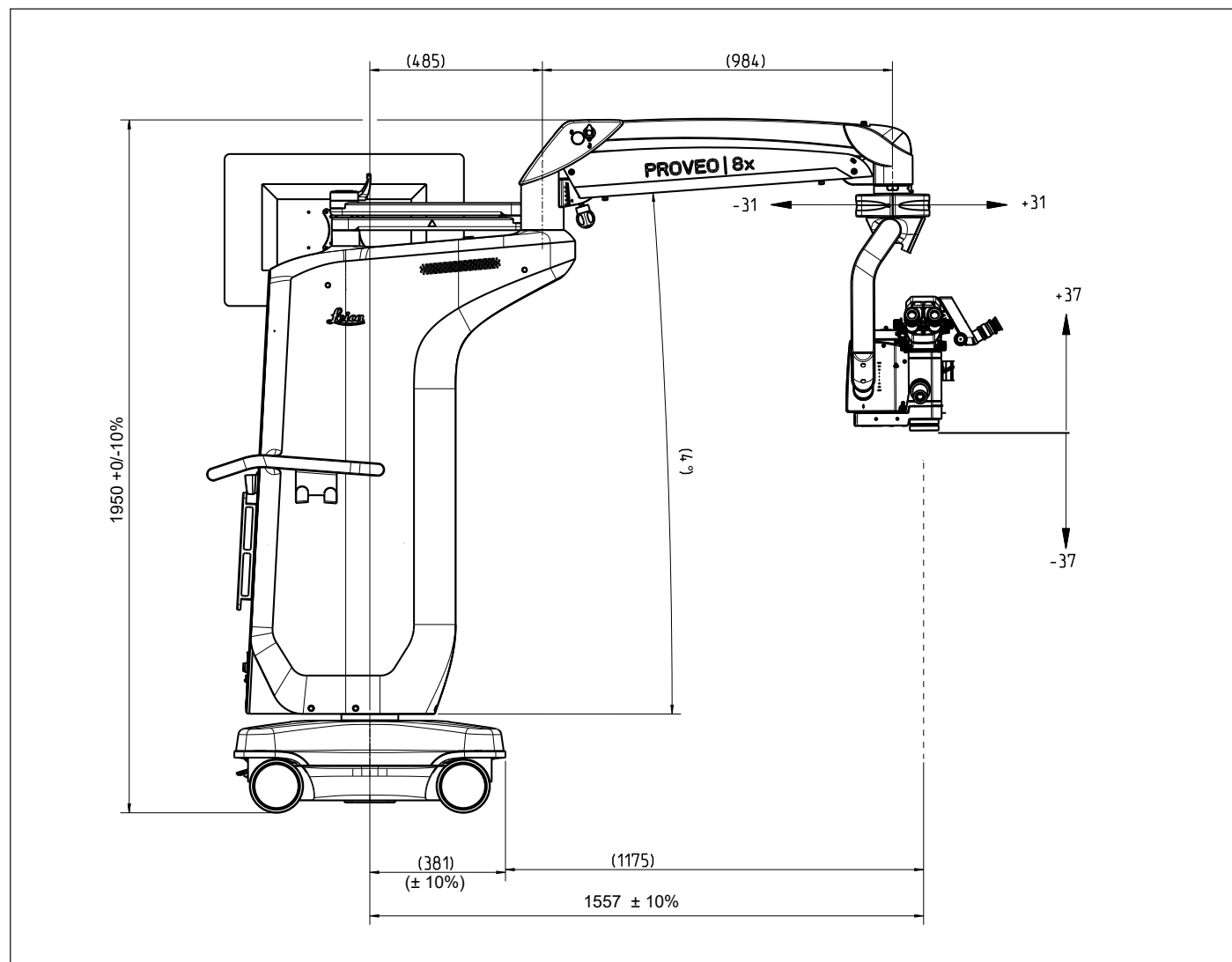
15.8 Dimensional drawings



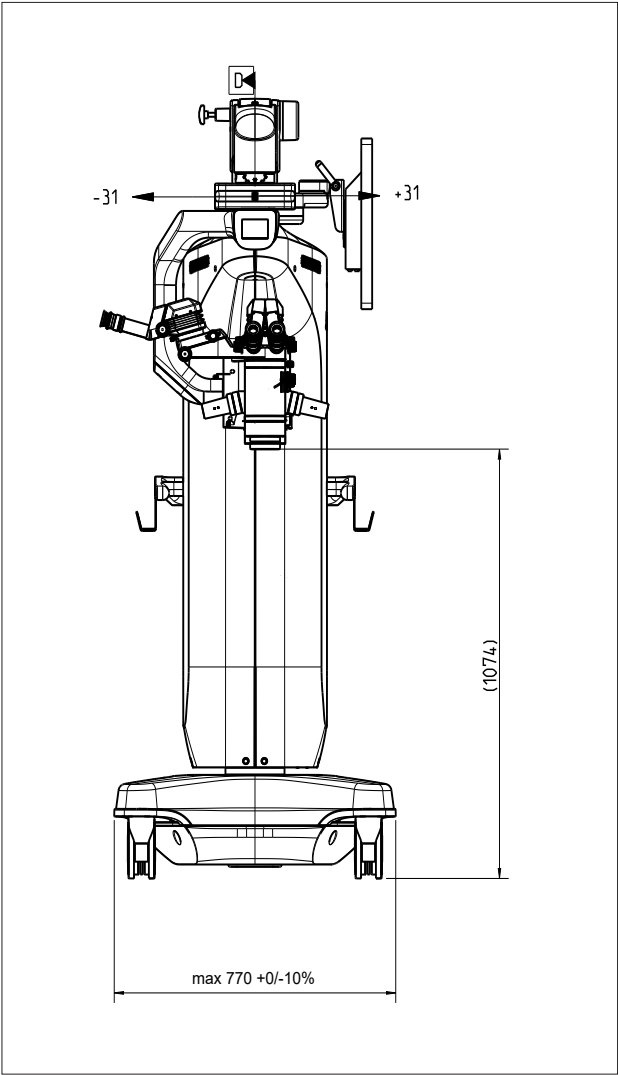
Statements given in parentheses are only for information and do not constitute an integral part of the specifications/requirement.

15.8.1 Floor stand

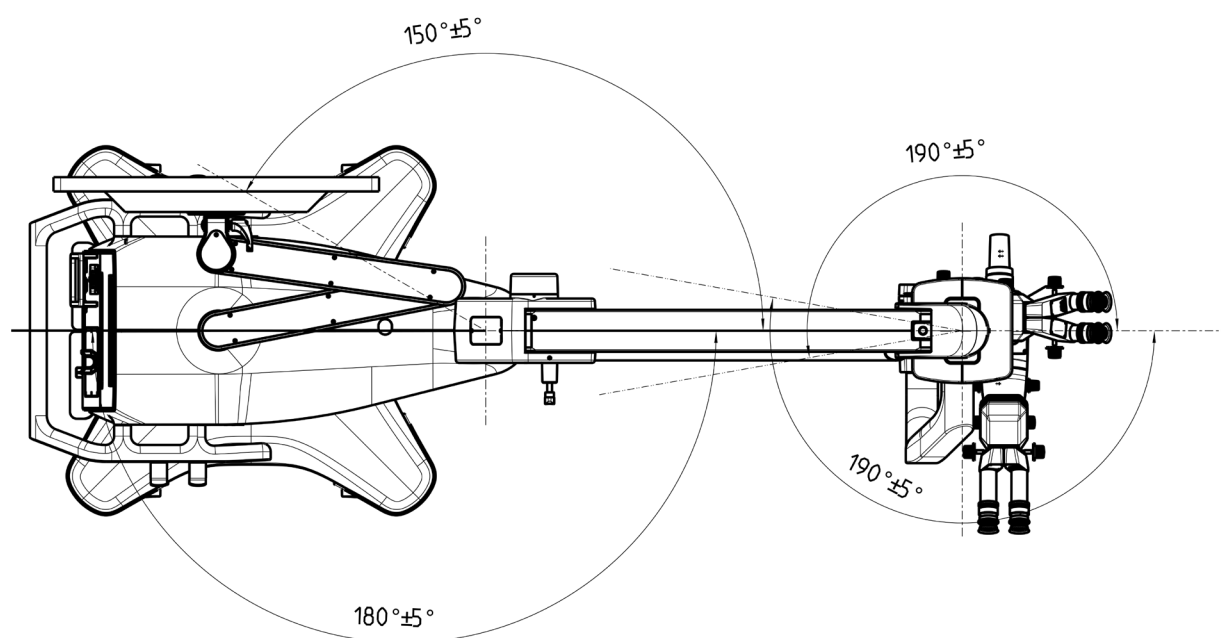
Side view dimensions



Front view dimensions



Top view dimensions



16 Electromagnetic compatibility (EMC)

! The emissions 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.

! If use is made of accessories or cables other than those specified in this user manual or approved by the manufacturer of the PROVEO 8x surgical microscope, this can lead to an increase in electromagnetic radiation or a reduction in EMC.

Environment for which the instrument is suitable

Hospitals except for near active HF Surgical Equipment and the RF shielded room of an ME System for magnetic resonance imaging, where the intensity of EM Disturbances is high.

Compliance IEC 60601-1-2

Emissions	CISPR 11, Class A, Group 1 Conducted Emissions Class A Harmonic Distortion per IEC 61000-3-2 Class A Voltage Fluctuation and Flicker per IEC 61000-3-3
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- Immunity
- Electrostatic discharge IEC 61000-4-2:
CD ± 8 kV,
AD ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV
 - Radiated RF EM Fields IEC 61000-4-3:
80 MHz–2.7 GHz: 3 V/m
 - Proximity Wireless fields IEC 61000-4-3:
385–5785 MHz: 9 V/m; 27 V/m; 28 V/m
 - Electrical Fast Transients and bursts IEC 61000-4-4:
 ± 2 kV: Power supply lines
 ± 2 kV: Input and output lines
 - Surges IEC 61000-4-5:
 ± 1 kV Line-to-line
 ± 2 kV Line-to-ground
 - Proximity magnetic fields IEC 61000-4-39:
30 kHz: 8 A/m
134,2 kHz: 65 A/m
13,56 MHz: 7,5 A/m
 - Conducted disturbances, induced by RF fields IEC 61000-4-6: 150 kHz–80 MHz, 6 V rms
 - Rated Power-frequency Magnetic Field IEC 61000-4-8: 30 A/m
 - Voltage dips and interruptions IEC 61000-4-11: according to IEC 60601-1-2:2014
 - Acceptable operating conditions/responses:
 - Flickering/noise on the displays
 - Interruptions on the displays
 - Restorable to the pre-test state with operator intervention.
 - Specific compliance criteria for the voltage dips and interruptions test:
 - The equipment is allowed a deviation at the immunity levels (0% of nominal voltage for 5s), provided the equipment remains safe, experiences no component failures and is restorable to the pre-test state with operator intervention.

17 Annex

17.1 Checklist before the operation

Patient

Surgeon

Date

Step	Procedure	Details	Checked / Signature
1	Cleaning the optical accessories	<ul style="list-style-type: none"> ▶ Check the tubes, eyepieces and the documentation accessories (if used) for cleanliness. ▶ Remove dust and dirt. 	
2	Installing the accessories	<ul style="list-style-type: none"> ▶ Lock PROVEO 8x in place and install all accessories on the microscope so it is ready for use (see chapter 7.2 "Installing the monitor cover", page 26). ▶ Position the handles as desired. ▶ Connect the mouth switch and/or footswitch, if used. ▶ Check the camera image on the monitor and re-align if necessary. ▶ Check that all equipment is in its proper position (all covers fitted, doors closed). 	
3	Checking the tube settings	<ul style="list-style-type: none"> ▶ Check the tube and eyepiece setting for the selected user. 	
4	Function check	<ul style="list-style-type: none"> ▶ Connect the power cable. ▶ Switch on the microscope. ▶ Test all functions on the handles and the footswitch. ▶ Check the user settings on the control unit for the selected user. 	
5	Balancing	<ul style="list-style-type: none"> ▶ Balance PROVEO 8x (see chapter 7.8.1 "Balancing the parallelogram", page 31). ▶ Press the "All Brakes" button on the handle and check the balancing. 	
6	Sterility	<ul style="list-style-type: none"> ▶ Fit sterile components. ▶ Repeat balancing. 	
7	Positioning at the OP table	<ul style="list-style-type: none"> ▶ Position PROVEO 8x in the operating room as required and lock the footbrake (see chapter 7.1 "Transportation", page 25). 	



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