From Eye to Insight

Leica
MICROSYSTEMS

# ARveo 8x

Software version: 1.2

## User Manual

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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 ARveo 8x is described.

- ► Read this user manual carefully before operating the product.
- ► Pay special attention to the safety information (see chapter 2 "Safety", page 6).

## 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. |
| → | | Open menus in this order |
|  | | 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.

## 1.4 Product identification

The model and serial numbers of your product are located on the identification label on the illumination unit.

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

| Type | Serial no. |
|---|---|
| | |
| ... | ... |

# 2 Safety

The ARveo 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.

## 2.1 Intended purpose

The ARveo 8x surgical microscope is an optical and digital instrument for improving the visibility of objects through magnification and illumination. It can be applied for observation and documentation and for medical treatment.

- The ARveo 8x surgical microscope may be used only in closed rooms and must be placed on a solid floor.
- The ARveo 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 reliability of the ARveo 8x surgical microscope's functionality.

The essential performance of the ARveo 8x is providing sufficient light to the situs and to guarantee mechanical locking of the optics carrier in any possible positioning.

## 2.2 Clinical Benefit

ARveo 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.

## 2.3 Indications for use

The ARveo 8x is primarily used, but not limited, to surgical procedures in neuro/spine surgery, ENT (ear, nose and throat) and PRS (plastic and reconstructive surgery) applications, at the discretion of the surgeon.

## 2.4 Contra-indications for use

The ARveo 8x must not be used in ophthalmology.

## 2.5 Patient target group

The ARveo 8x can be widely used in the clinical procedures defined in "Indication for Use"; it applies to patients with all gender, age, ethnicity and language groups.

## 2.6 Intended user

The ARveo 8x is intended for professional use only. Users must have corresponding technical qualification and have been trained in the use of the instrument.

## 2.7 Directions for the person responsible for the instrument

► Ensure that the ARveo 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 ARveo 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.
► Only use the ARveo 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 ARveo 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 to or service on the ARveo 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.
- If the instrument is modified or serviced by unauthorized persons, is improperly maintained (as long as maintenance was not carried out by us), 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 Microsystem (Schweiz) AG therefore recommends that a backup system be kept available during the operation.
- The ARveo 8x 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.
- Use of accessories and cables other than those specified or provided by the manufacturer of his equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**NOTE:**
The emissions characteristics of this equipment make it suitable for use in industrial areas and in a professional healthcare environment, e.g. hospital (CISPR 11 class A). If it is used in a home healthcare 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.

## 2.8 Directions for the operator of the instrument

► Follow the instructions described in this manual.
► Follow the instructions given by your employer regarding the organization of work and safety at work.

## 2.9 Safety notes

**WARNING**

**Danger of injury to the eyes.**
► Do not use the ARveo 8x in ophthalmology.

**WARNING**

**Danger of injury due to:**
- **uncontrolled lateral movement of the arm system**
- **tilting of the stand**
- **feet in lightweight shoes could become trapped beneath the casing of the base**

► For transportation, always move the ARveo 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 ARveo 8x surgical microscope; never pull it.
► Make sure that the movement range is free.

**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 ARveo 8x.
► Balance the ARveo 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.
► Never carry out the intraoperative AC/BC balancing above the patient.
► Check fitting and good connection of all parts and cables during the preparation of the system prior to the surgery. Not well fitted parts and bad connections can lead to hazardous situations and system failures.

**WARNING**

**Danger of injury due to movement of the microscope during the balancing process.**
► Do not sit or stand immediately next to the microscope during the balancing process.

**WARNING**

**Risk of infection.**
► Always use the ARveo 8x surgical with sterile controls and a sterile drape.

**WARNING**

**Danger of fatal electrical shock.**
► The ARveo 8x surgical microscope may be connected to a grounded socket only.
► Operate the system only with all equipment in its proper position (all covers fitted, doors closed).

**WARNING**

**Danger of eye injury due to possibly hazardous optical infrared and UV radiation.**
► Do not look at the operating lamp.
► Minimize exposure to eyes or skin.
► Use appropriate shielding.

**WARNING**

**Danger of burn injuries in otologic surgery.**

- ► Use the lowest comfortable light intensity.
- ► Adjust the field of view to match the operating field.
- ► Irrigate the wound frequently.
- ► Cover the exposed parts of the pinna with a moist surgical sponge.

**WARNING**

**Danger of injury to the eyes.**
**At a short focal distance, the light source of the illumination unit may possibly be too bright for the operating physician and the patient.**

- ► Begin with the lower-intensity light source and slowly increase it until the operating physician has an optimally illuminated image.

**WARNING**

**Danger to the patient due to failure of the magnification or working distance motor.**

- ► If the magnification motor fails, adjust the magnification manually.
- ► If the working distance motor fails, adjust the working distance manually.

**WARNING**

**Danger of severe damage to tissue due to incorrect working distance.**

- ► When using lasers, always set the working distance of the microscope to laser distance and lock the microscope in position.
- ► Do not adjust the rotary button for manual setting of the working distance while using the laser.
- ► Please refer to the user manual of the external laser manipulator.

**WARNING**

**Danger injury to the eyes due to laser radiation.**

- ► Never point the laser directly or indirectly via reflecting surfaces to the eyes.
- ► Never point the laser to the eyes of the patient.
- ► Do not look into the laser beam.

**WARNING**

**Degradation of performance**

- ► Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of ARveo 8x, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

**WARNING**

**Risk of compromised surgery**

- ► Do not use the device if pre-operational defect detected prior to surgical procedure.

**CAUTION**

**Surgical microscope can move without warning.**

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

**CAUTION**

**Risk of infection.**

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

**CAUTION**

**If the field diameter is greater than the field of view and the light intensity is too high, uncontrolled tissue heating may occur outside of the area visible through the microscope.**

- ► Do not set the light intensity too high.

**CAUTION**

**Danger to the patient due to changes in the user settings.**

- ► Never change the configuration settings or edit the user list during an operation.
- ► Check fitting and good connection of all parts and cables during the preparation of the system prior to the surgery. Not well fitted parts and bad connections can lead to hazardous situations and system failures.

**CAUTION**

**Danger of skin burns. The lamp insert gets very hot.**

- ► Check that the cover has cooled before you replace the lamp.
- ► Do not touch the hot lamp insert.

**CAUTION**

**Risk of compromised surgery**

- A system safety check will need to be performed accordingly to your country-specific requirements. Leica recommends an annual system and safety check. After a system usage period of 8 years, an annual system and safety check is considered mandatory.
- The systems shall not be used to perform critical use applications after 8 years of system usage or up to 12 years with annually passed system and safety check.
- As all maintenance activities require product specific know-how, it is recommended to contact your responsible service organization.

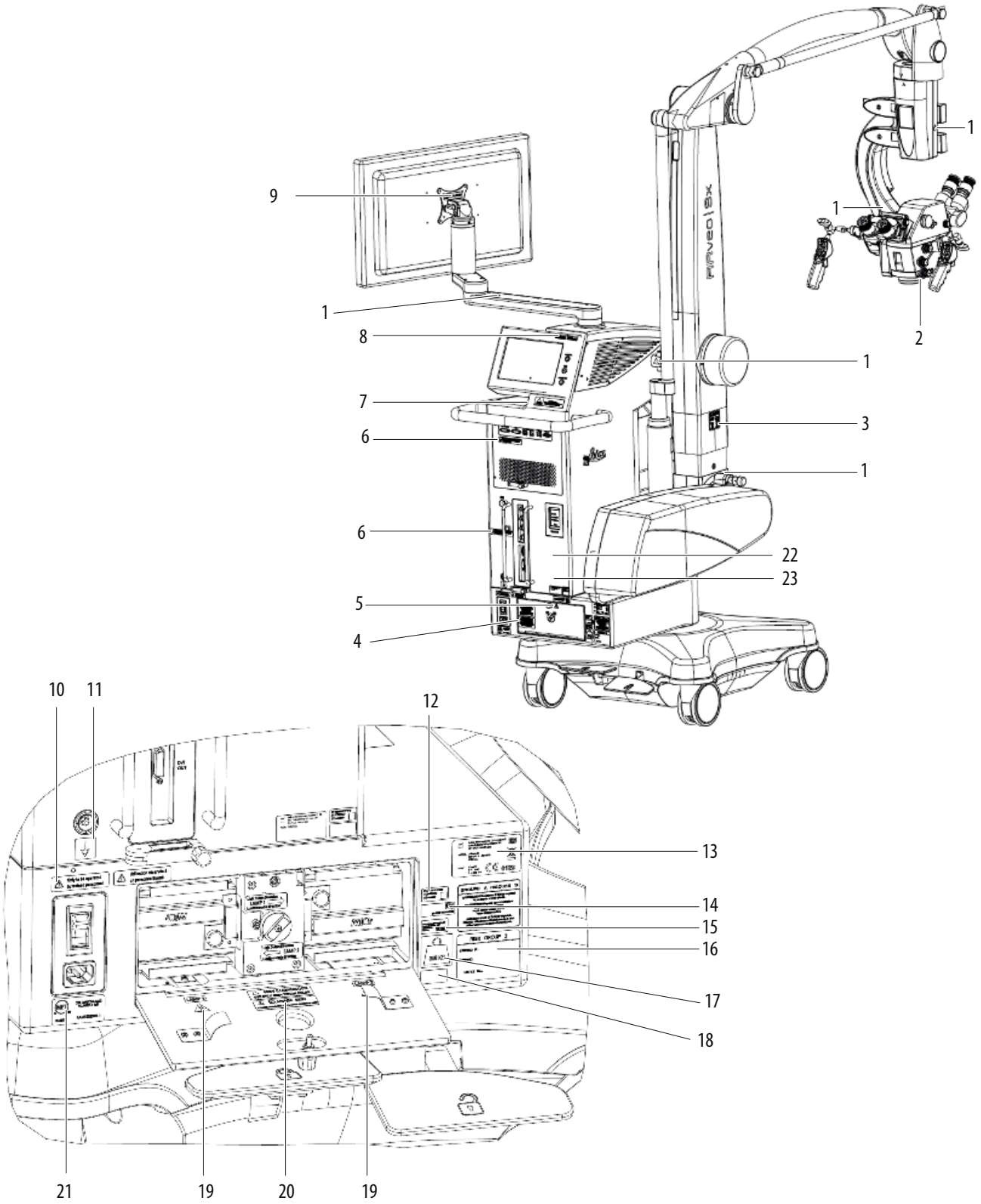
### 2.9.1 MRI Safety Information




The ARveo 8x surgical operating microscope including all accessories (i. e. GLOW800, FL560, FL400, WFS) may be safely used in the MR environment under the following conditions. Failure to follow these conditions may result in unsafe use, failure of the device, and potential injury or serious injury.

| | |
|---|---|
| Device name | ARveo 8x (incl. all accessories: GLOW800, FL560, FL400, WFS) |
| Maximum static magnetic field [mT] and [Gauss] | Do not exceed 0.5 mT (5 Gauss). |
| Instructions to be followed before and/or after the MR exam | ▶ For operation in an MR environment the ARveo 8x with accessories must be positioned in such a way that all system components (suspension system, microscope, foot switch etc.) remain outside the 0.5 mT (5 Gauss) line.<br>▶ The ARveo 8x must be powered down during MR image capture.<br>▶ Only use the ARveo 8x when no MR image capture is in progress. |

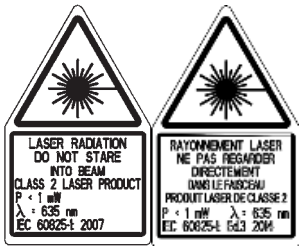
## 2.10 Signs and labels



**1** Squeezing hazard



**2** Laser label




**3** Locked/Free




**4** Grounding label

*Grounding reliability can only be achieved when EQUIPMENT is connected to equivalent receptacle marked "Hospital only" or "Hospital Grade".*

*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".*

**5** High voltage warning



**6** SIP/SOP label




**7** MRI label




**8** Contraindication

DO NOT USE IN OPHTHALMOLOGY

NE PAS UTILISER EN OPHTHALMOLOGIE

**9** Monitor arm weight




**10** Trained personnel

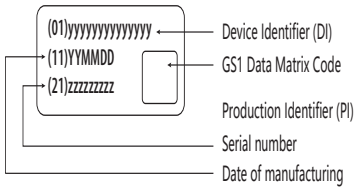
Only to be operated by trained personnel

Utilisation réservée à un personnel formé

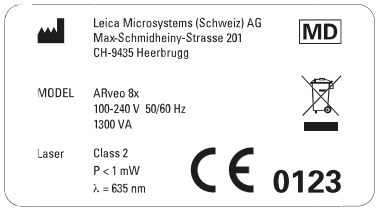
**11** Equipotential bonding



**12** UDI marking




**13** Type label



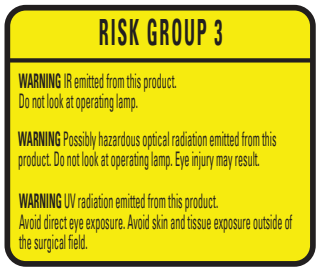

**14** Follow the user manual.




**15** EU Representative




**16** Warning of XENON light emission



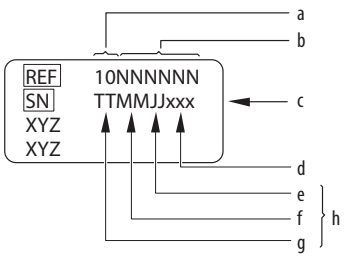




**17** System weight 350 kg / 772 lb



**18**




Fabrication label

- a Prefix number
- b Leica system article no.
- c Serial number
- d Incremental numbers 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

**19**



Hot surface

**20**




400W lamp

**21**




MET label

**Brazil specific labels:**

**22**




Etiqueta do INMETRO (apenas no Brasil)

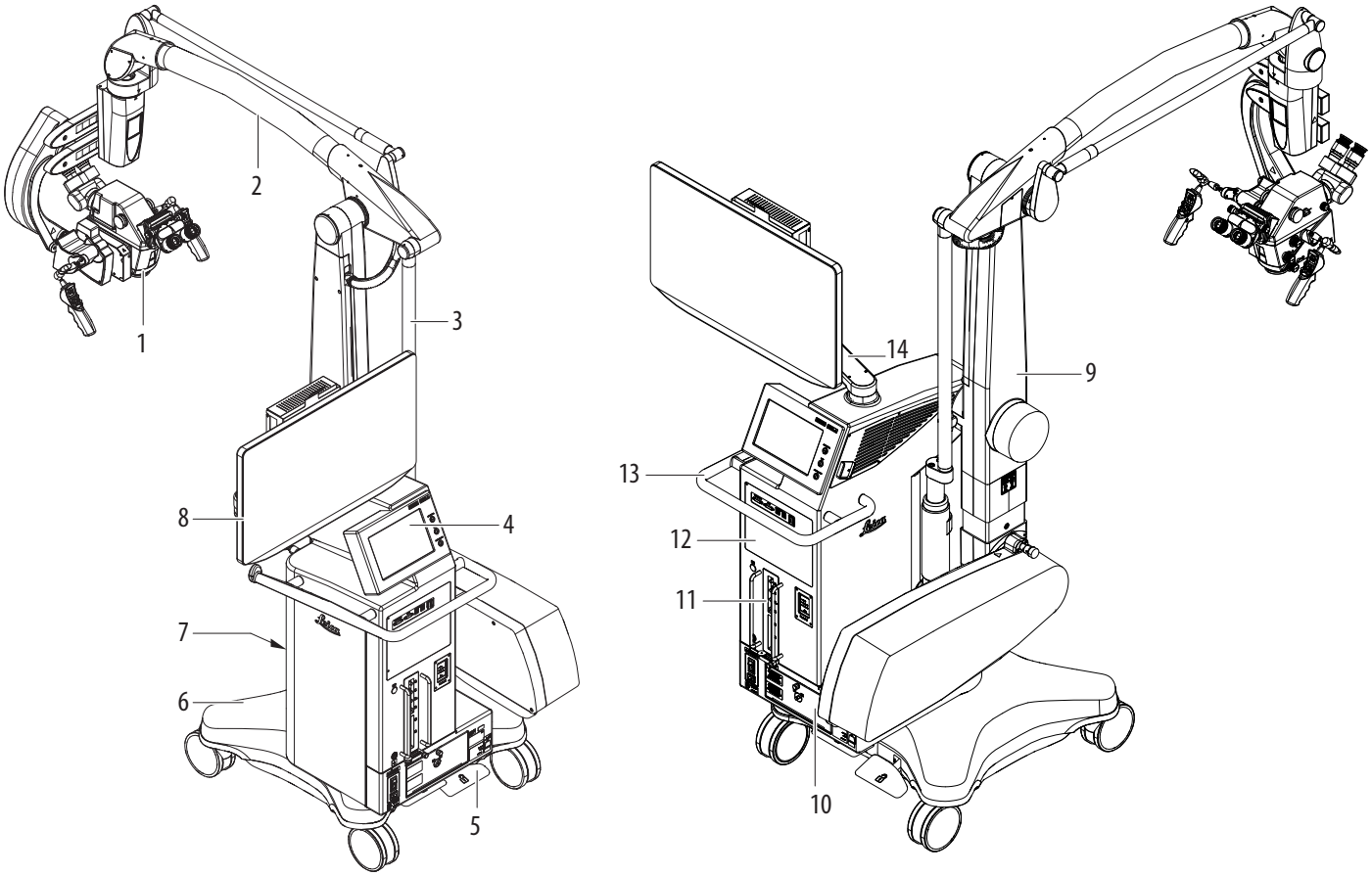
**23**




Etiqueta da ANVISA (apenas no Brasil)

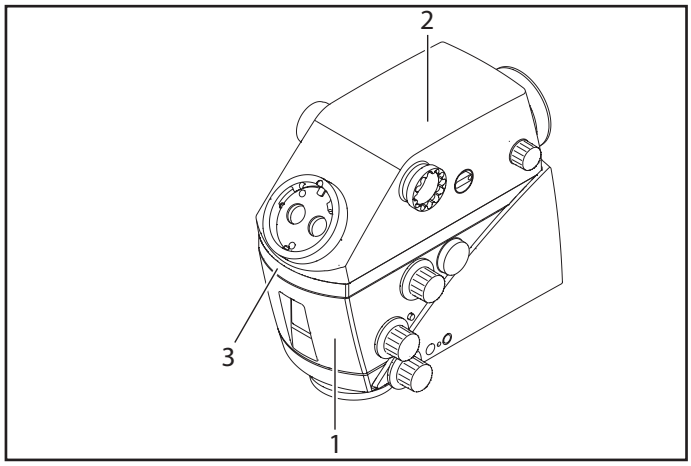
# 3 Design

## 3.1 ARveo 8x stand




1 M530 optics carrier
2 Arm system
3 Tension rod
4 Control unit with touch screen
5 Footbrake
6 Base
7 Suspension device for foot switch
8 Stand monitor
9 Vertical arm
10 Illumination unit
11 Terminals
12 Recording unit
13 Handrail
14 Monitor arm

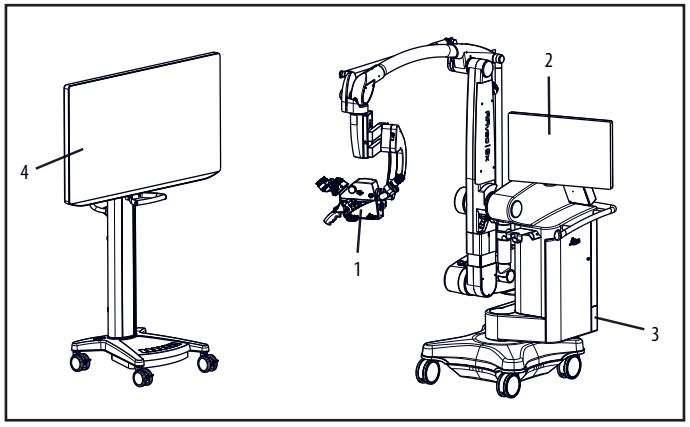
## 3.2 M530 optics carrier




1 M530 optics carrier
2 ULT
3 Fluorescence module Leica FL400, FL560 or FL400/560

- Interface for assistants, either to the left and right side or to the back
- Main surgeon and back assistant interface, rotatable both 360°
- Back assistant interface with fine focus knob

## 3.3 2D and 3D view




The optional Heads-up Microsurgery accessory for ARveo 8x Leica surgical microscope system displays the surgical field in 2D or 3D (stereoscopic) on a visualization device.

The technology provides ergonomic advantages as the user can maintain an upright posture while observing the surgical field. The Heads-up Microsurgery accessory contains a cart-mounted monitor, which can be flexibly positioned to achieve optimal viewing positions. (Please see the Heads-up Microsurgery equipment user manual).

The external monitor on cart (4) can display a stereoscopic 3D image when used in conjunction with 3D glasses. The stand monitor (2) can be supplied as 2D or 3D capable only depending on your selected configuration.

The 3D capable monitors automatically switch between 2D and 3D mode when required by the visualization.

**WARNING**

**Risk of compromised surgery.**

► Use only compatible monitors provided by Leica Microsystems.

**3D glasses**

With the external 3D Video Monitor on cart and the 3D stand monitor, the below 3D glasses are provided

**Leica Microsystems supplied glasses 10747283**

| Plastic frame glasses |
|---|



| Clip-on goggles |
|---|



**CAUTION**

**Caution to the user.**

► Use only compatible 3D glasses provided by Leica Microsystems.

**CAUTION**

**Caution to the user.**

► Check the perception of the 3D view prior to surgery. If you do not feel confident with the 3D view, switch to 2D view.

**CAUTION**

**Caution to the user.**

- ► Do not use 3D glasses on 2D monitor

**WARNING**

**Risk of infection.**

- ► The 3D glasses must not be touched by sterile personnel.

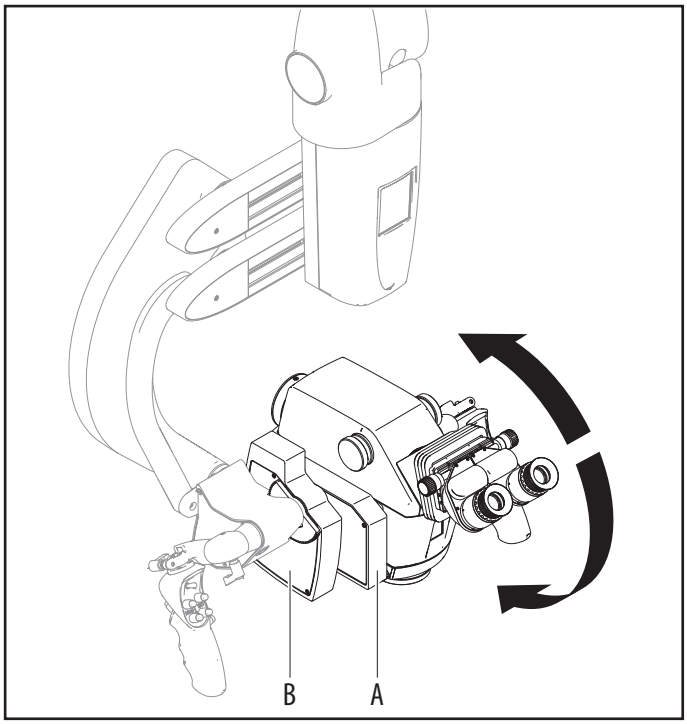
# 4 Functions

## 4.1 Balancing system

With a balanced surgical microscope ARveo 8x you can move the optics carrier in any position without tilting or falling down.
After balancing all movements during operation only need a minor force.

### 4.1.1 Balancing the optics carrier

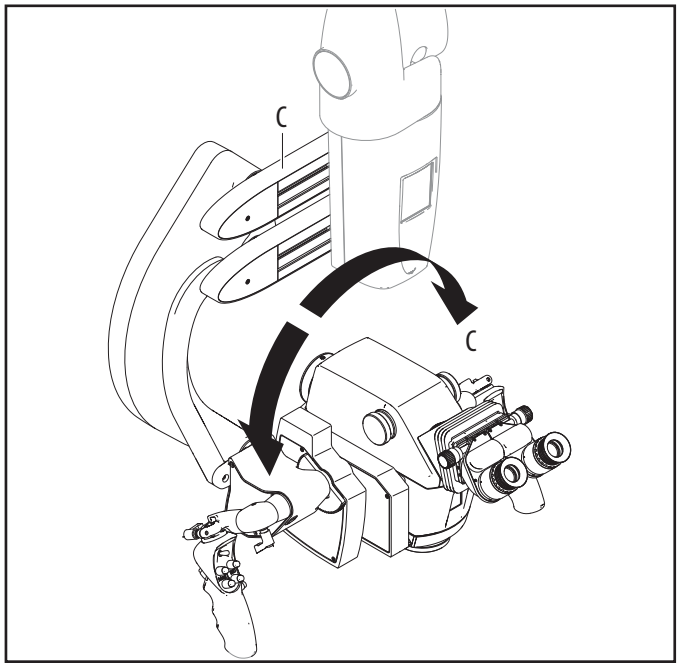
On the M530 optics carrier two directions of movement are balanced: A and B.




The optics carrier can be balanced in the A/B direction until up to the 20° options.

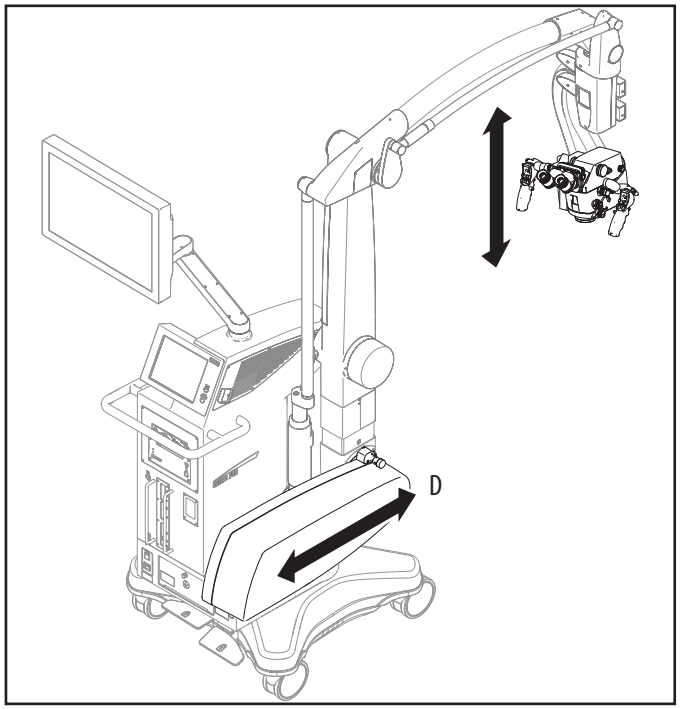
### 4.1.2 Balancing the arm system

On the arm system the direction of movement C is balanced.




### 4.1.3 Balancing the parallelogram

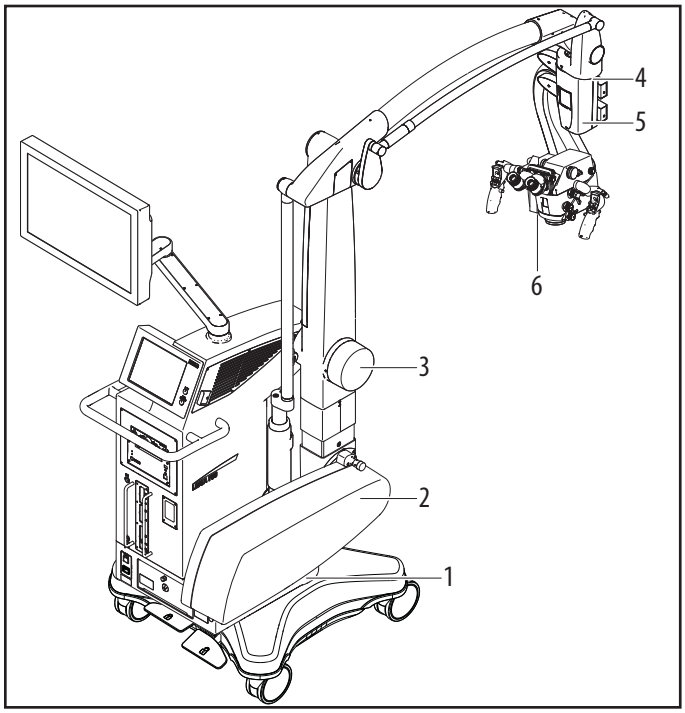
The parallelogram balances the up/down movement (direction D).




## 4.2 Brakes

The ARveo 8x may be moved only with released brakes.
► Do not perform any movements when the brakes are locked.

The ARveo 8x surgical microscope has 6 electromagnetic brakes which stop the movements of the stand and surgical microscope:



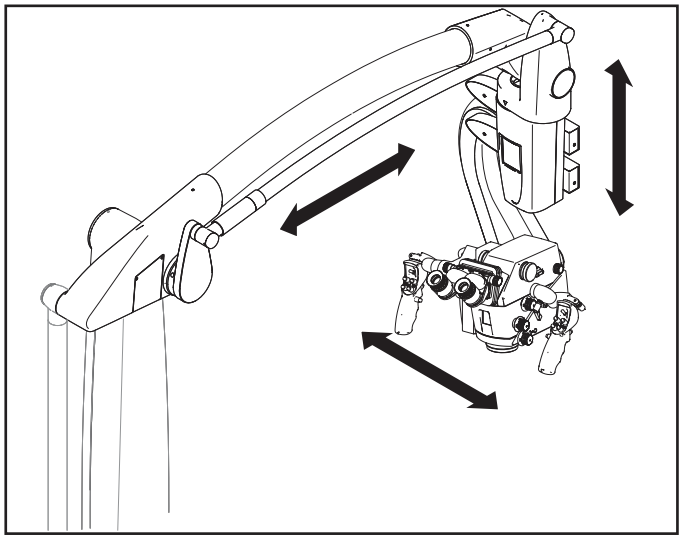

I

1 Foot
2 Up/down in parallelogram
3 Forward/back in parallelogram
4 In the rotary joint
5 In arm system
6 On the A and B sledges of surgical microscope

Brakes are operated via the handle. The button of the handle with the assigned function "Selected Brakes" can trigger individual or two predefined brake combinations: "Cranial" or "Spine".

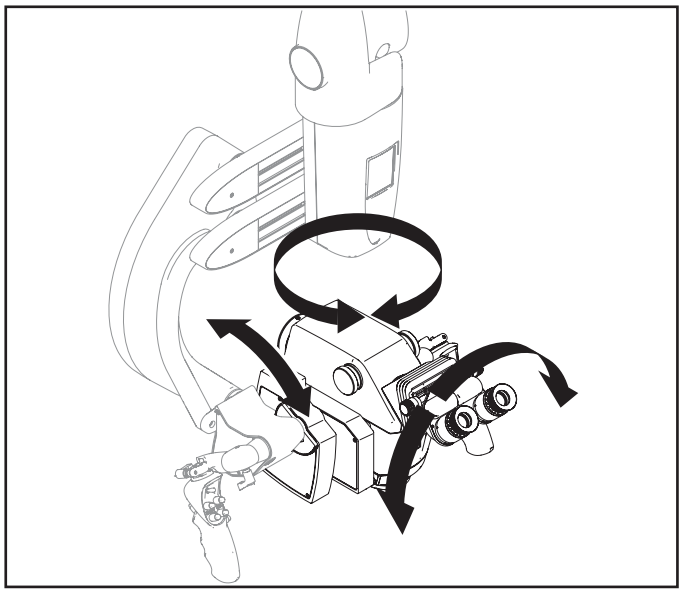
### 4.2.1 Selected Brakes – Spine

The following movements can be performed with the surgical microscope when the brake combination "Spine" is activated:



### 4.2.2 Selected Brakes – Cranial

The following movements can be performed with the surgical microscope when the brake combination "Cranial" is activated:



## 4.3 Illumination

The illumination of the ARveo 8x is a xenon lamp and is located in the stand. Illumination is routed to the optics carrier via fiber optic light guide.
There are two identical lamps. In case of a failure of the lamp in use, the other lamp can be selected, either on the touchscreen or manually.

### 4.3.1 AutoIris

AutoIris synchronizes the illumination field automatically according to the magnification factor. Using the manual override, the illumination field can be adjusted manually.

### 4.3.2 BrightCare Plus

BrightCare Plus is a safety function which automatically limits the maximum brightness depending on the working distance
Excessively bright light can, in combination with a short working distance, cause burns in patients.

When shipped from the factory, the "BrightCare Plus" safety function is activated for all users.

**Luminous energy**

The optics of the ARveo 8x surgical microscope have a variable working distance of between 225 and 600 mm. The system is designed in such a way that it delivers sufficient light to produce a bright image even at a long working distance of 600 mm.
In accordance with the formula Ev=Iv/d2, the light quantity continually increases by 710 % when the working distance is changed from 600 to 225 mm.
(Ev = light intensity, Iv= brightness,
d= distance from light source).
This means that less light is required to work with the microscope at a shorter distance than at a greater distance.

It is advisable to begin with a low light intensity and increase it until an optimum level of illumination is achieved.

**Heat release**

Heat from non-visible light (over 700 nm) is filtered out of the light from the used xenon light source. Nevertheless, white light also always develops heat. An excessive amount of white light can lead to overheating of tissue and metal objects.

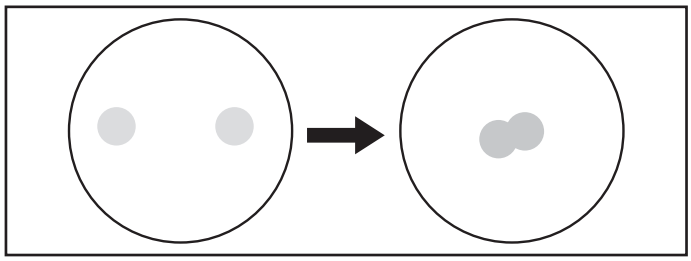
It is advisable to begin with a low light intensity and increase it until an optimum level of illumination is achieved.

## 4.4 Leica Fusion Optics

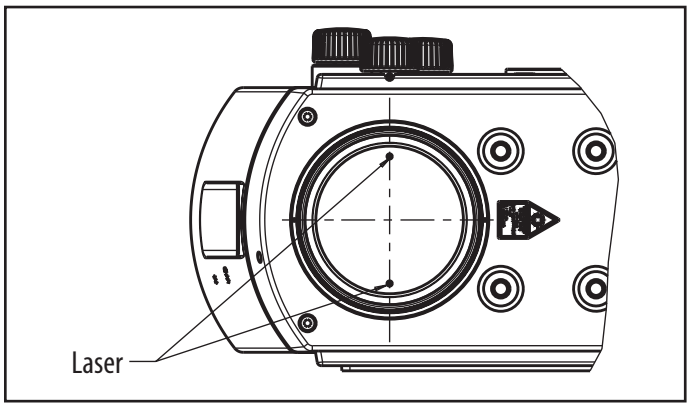
This feature provides an augmentation in resolution and depth of field for an ideal 3-D optical image. Leica FusionOptics operates with two separate beam paths with different information: the left beam path is optimized for high resolution, the right beam path for optimum depth of field. The human brain merges these two very different images to a single, optimal spatial image.

## 4.5 Leica SpeedSpot

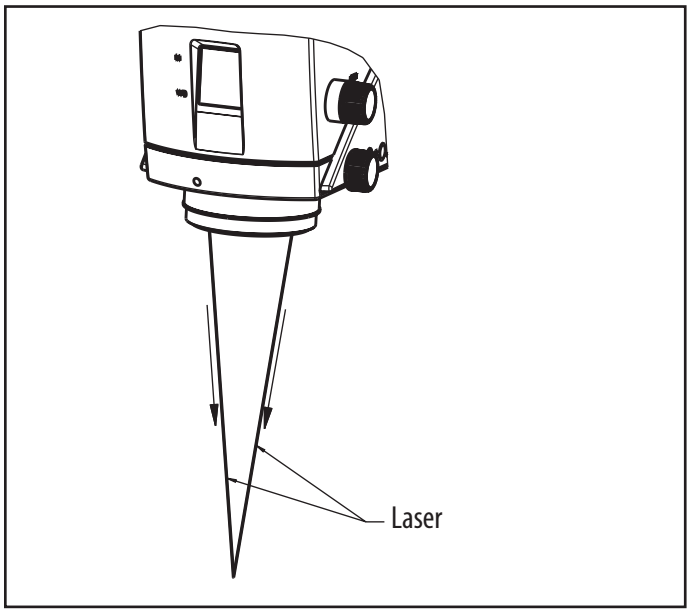
ARveo 8x is equipped with the laser focussing aid Leica SpeedSpot. If Leica SpeedSpot is enabled for the current surgeon profile (see chapter 9.2.2 "Basic settings", page 55), the focussing aid is activated when releasing the brakes, changing the focus or when activating XY movement. Two convergent light beams meet exactly in the focussing point of the microscope.



**Exit of the laser beams**

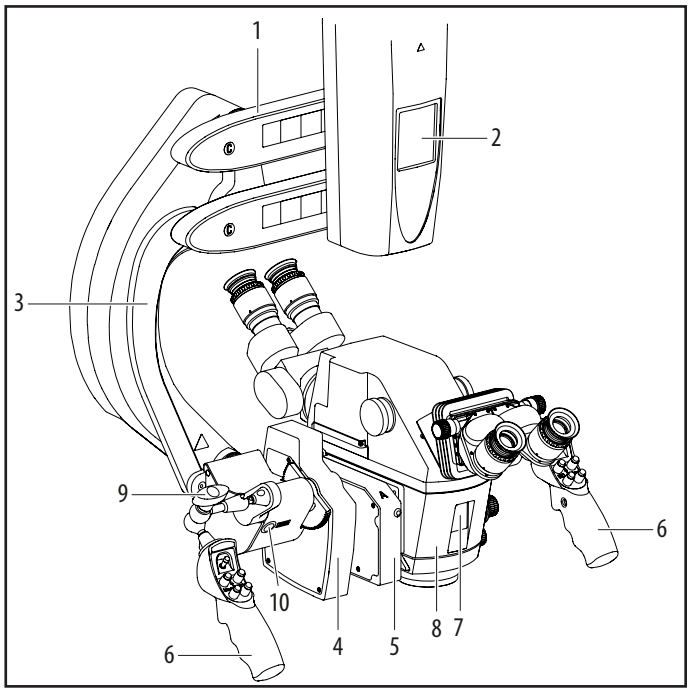



**Course of the laser beams**



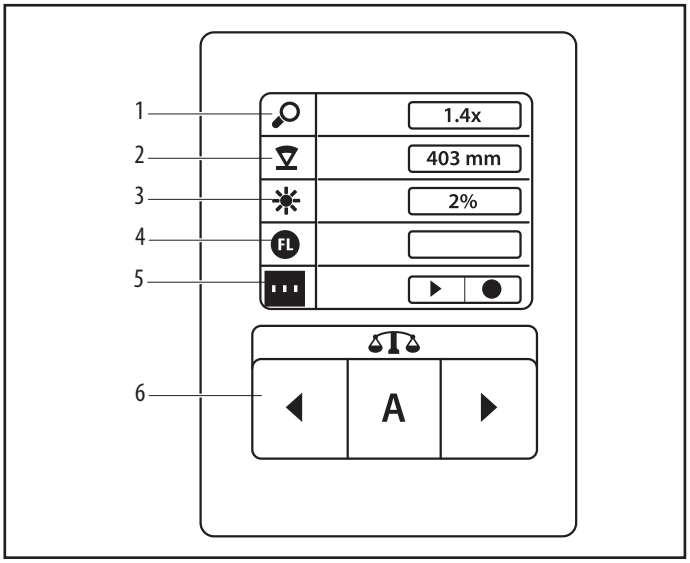
# 5 Controls

## 5.1 ARveo 8x microscope with arm system



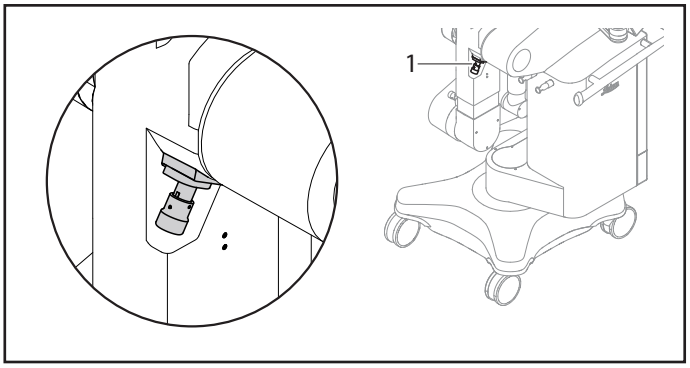

1 C sledge
2 Surgeon panel
3 Microscope carrier
4 B sledge
5 A sledge
6 Handle
7 Display of set working distance and magnification
8 M530 optics carrier
9 Handle clamping lever
10 Pushbutton for intraoperative AC/BC balancing

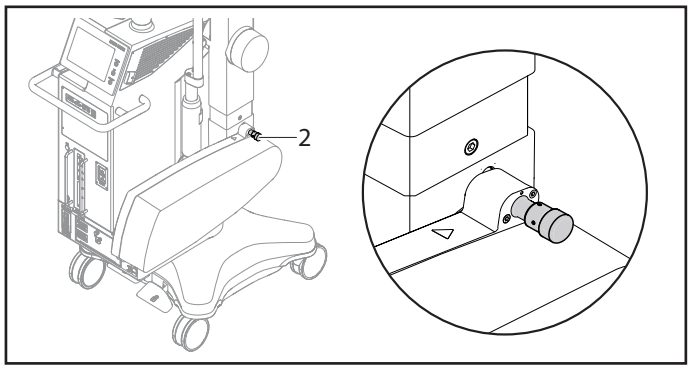
### 5.1.1 Surgeon panel




1 Magnification
2 Working distance
3 Brightness
4 FL mode
5 Recording status
6 Manual balancing

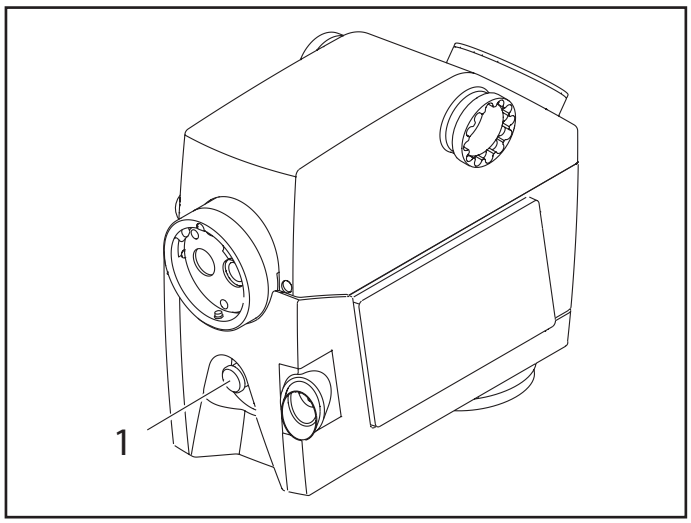
### 5.1.2 Locks





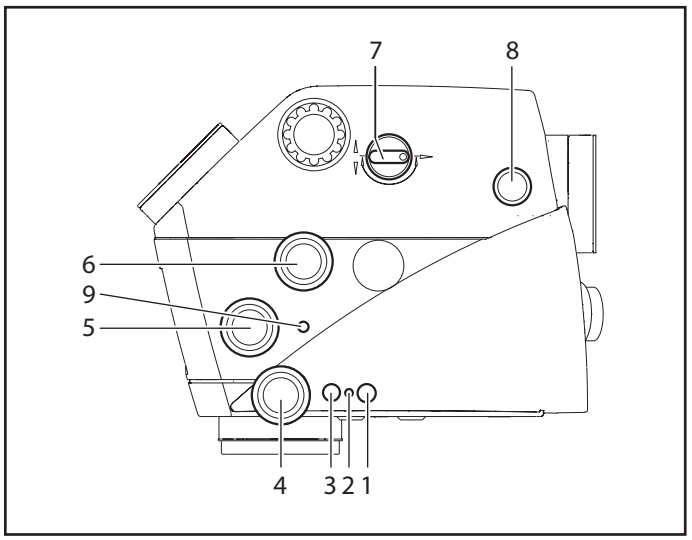

1 Locking in horizontal direction
2 Locking in vertical direction

### 5.1.3 Optics carrier – rear



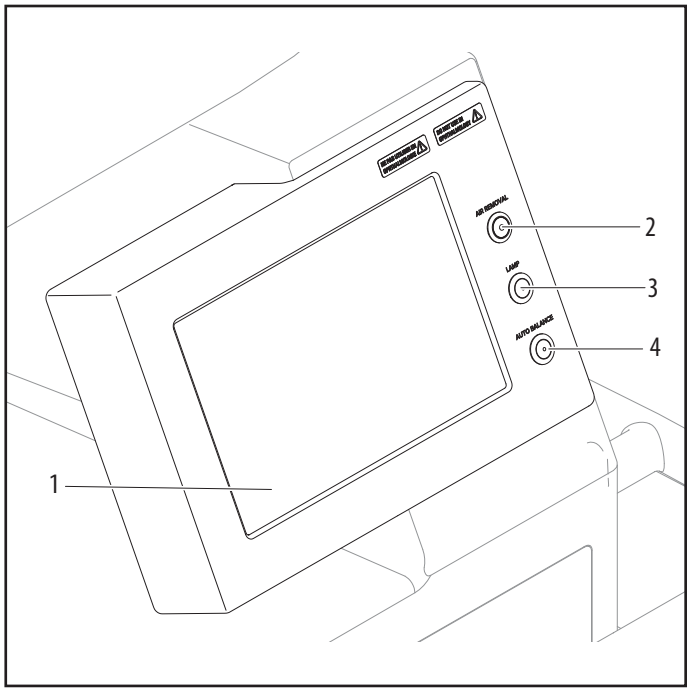

1 Optical fiber connection

### 5.1.4 Optics carrier – controls



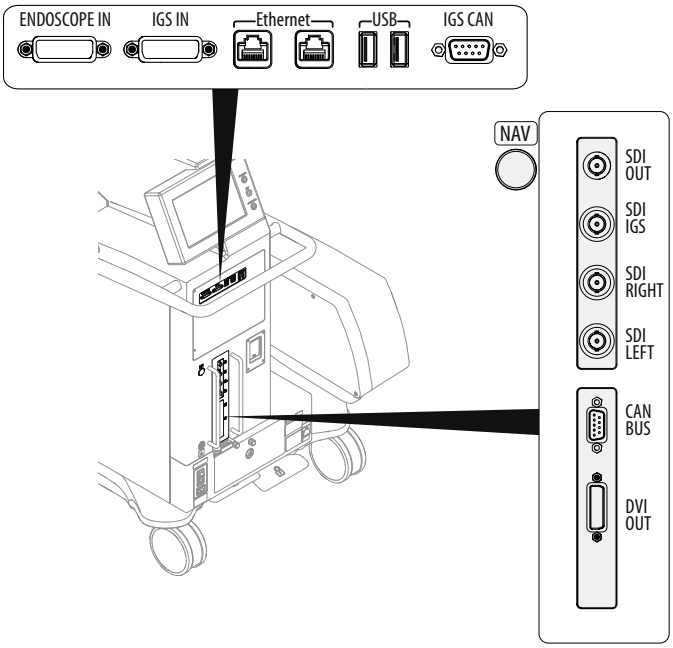

1 Button "WD Lock" (counter-sunk)
2 LED "WD Lock" active
3 No function
4 Rotary knob "Working distance" (emergency operation only)
5 Rotary knob "Manual override AutoIris"
6 Rotary knob "Magnification" (emergency operation only)
7 Assistant back/side
8 Fine focus back assistant
9 Button "Reset AutoIris"

## 5.2 Control unit




1 Touch screen
2 Pushbutton for air removal with LED (blinking = removing air / on = sustain vacuum)
3 Pushbutton for lamp (on/off) with LED (on = green / off = not illuminated)
4 Pushbutton for autobalance with LED (flashes green while autobalance in progress)

## 5.3 Terminals

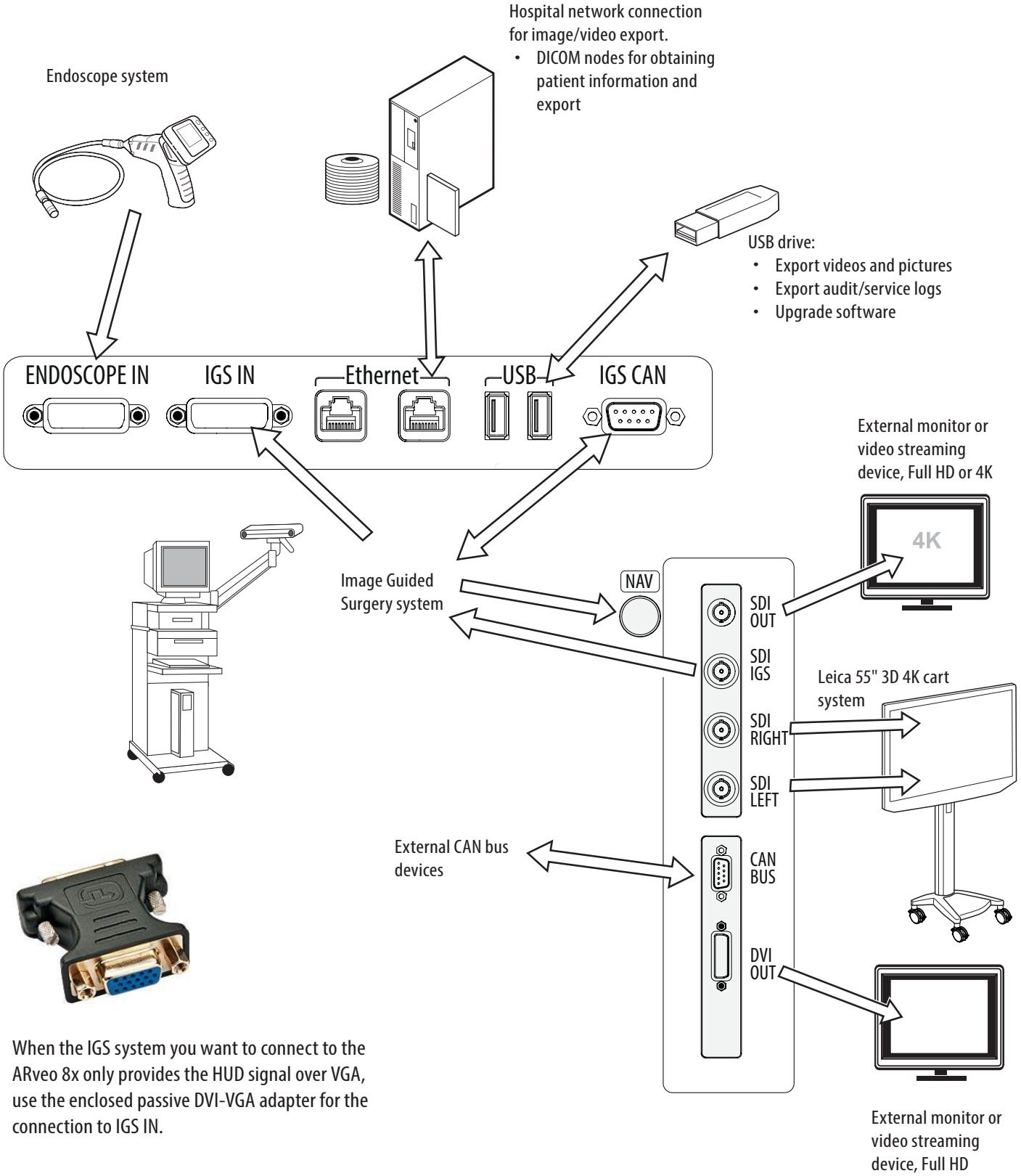



| Socket | To connect... | IN/OUT |
|---|---|---|
| ENDOSCOPE IN | endoscope (video OUT) | IN |
| IGS IN | IGS systems (HUD OUT) | IN |
| ETHERNET (2×) | network (max. 30 m) | OUT/IN |
| USB (2×) | USB 3.0 storage media | OUT/IN |
| IGS CAN* | IGS System (communication) | OUT/IN |
| NAV | navigation (IGS) | OUT/IN |
| SDI OUT | external monitor | OUT |
| SDI IGS | IGS Systems (video IN) | OUT |
| SDI RIGHT | 3D monitor (right channel) | OUT |
| SDI LEFT | 3D monitor (left channel) | OUT |
| CAN BUS* | compatible Leica accessory | OUT/IN |
| DVI OUT | external monitor | OUT |

* Only systems verified by Leica Microsystems (Schweiz) AG may be connected here.

Additional devices connected to medical electrical equipment must demonstrably comply with their corresponding IEC or ISO standards (e.g. IEC60950 or IEC 62368 for data-processing devices). Furthermore, all configurations must comply with the normative requirements for medical systems. Whoever connects additional devices is the system configurator and is therefore responsible for ensuring that the system complies with the normative requirements for systems.

### 5.3.1 Connection diagram






When the IGS system you want to connect to the ARveo 8x only provides the HUD signal over VGA, use the enclosed passive DVI-VGA adapter for the connection to IGS IN.

**CAUTION**

**Microscope network connection**

Connecting the microscope to the hospital network exposes the microscope to additional risks of the network that could result in unidentified risks to patient, operator, or 3rd parties.

- ► Hospital organization responsible for the network should work with the microscope users to identify, analyze, evaluate and control these risks.

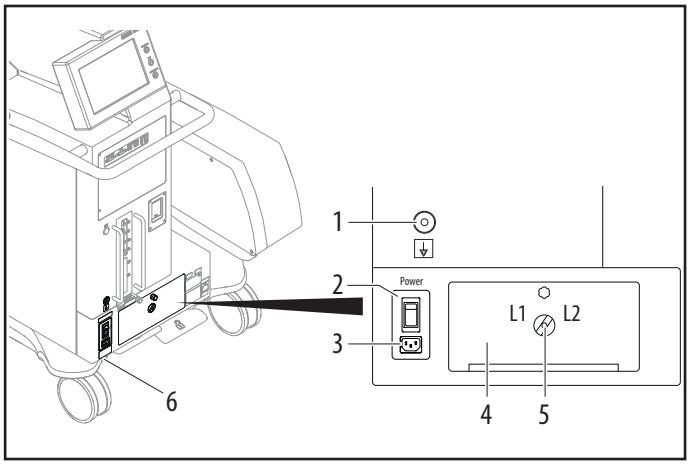
**CAUTION**

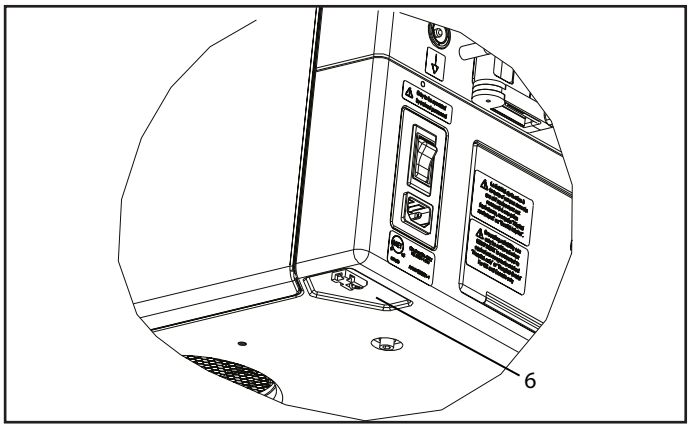
**Risks due to changing microscope configuration**

- ► Once the configuration that control potential cyber security risks is established, take care not to change the configuration without assessing the potential risk impact. These changes would include but are not limited to network configuration changes, connection of additional items to the microscope, disconnection of items from the microscope, update of equipment.

For further information related to network and cybersecurity, please refer to the cybersecurity instructions 10747996 distributed separately.

## 5.4 Stand




1 Equipotential bonding socket
For connecting the ARveo 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 Main switch for ARveo 8x surgical microscope with integrated circuit breaker

3 Power input

4 Access door illumination unit

5 Illumination switch (lamp 1 / lamp 2)

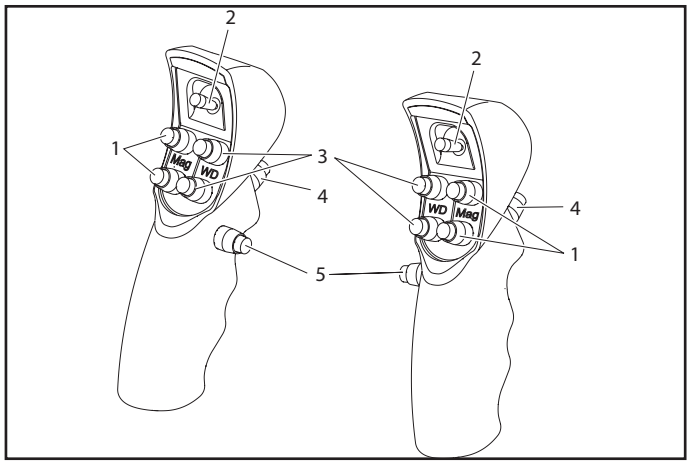
6 Cable fixation underneath the tower
Use a cable tie to fix the power cable to the tower for proper strain relief.

The ARveo 8x surgical microscope has a primary illumination source and an equivalent standby illumination source.

## 5.5 Handles

You can assign switches 1, 2, 3 and 5 of the handles individually for each user in the configuration menu. In all possible handle configurations, key (4) releases all brakes. This key cannot be configured. For the joystick and the other keys presets are available according to your task.

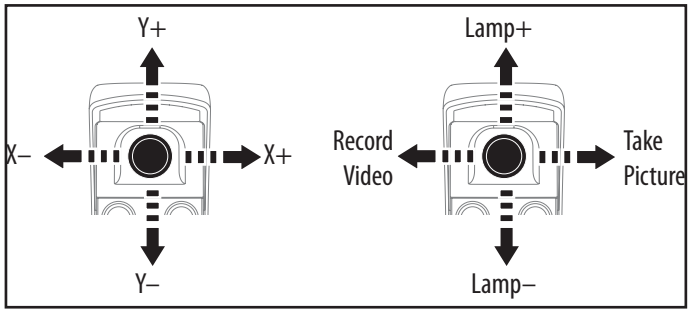
### 5.5.1 Button assignments in the factory setting




1 Magnification
2 4-function joystick
3 Working distance
4 Release all brakes
5 Release preselected brakes

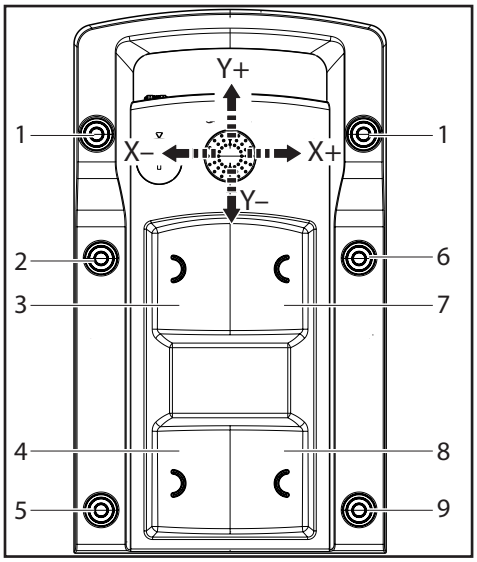
### 5.5.2 Joystick assignments in the factory setting

Settings for left and right handle:




## 5.6 Foot switch

You can use this foot switch to control your ARveo 8x surgical microscope.
Foot switch, 12 functions (Individually assignable):




1 No function
2 Lamp +
3 Working distance +
4 Magnification +
5 not assigned
6 Lamp –
7 Working distance –
8 Magnification –
9 not assigned

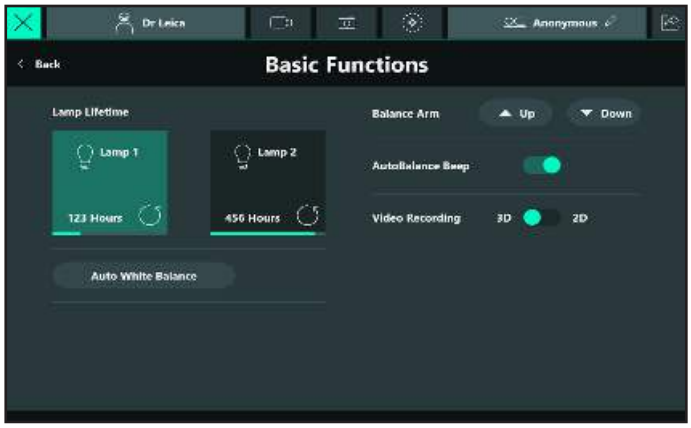
## 5.7 Control connected screens

The ARveo 8x system allows to connect up to 4 different monitors or other targets for video streams. Always connected is the stand monitor which can be, depending on the acquired configuration, a 2D or a 3D monitor. Additionally, external monitors can be connected via the "DVI OUT" and the "SDI OUT" connectors. The monitor connected to "SDI OUT" can be Full HD or 4K (see chapter 9.4.3 "Video Settings", page 58).

### 5.7.1 Auto White Balance

Auto White Balance can only be activated in Whitelight mode.

► Go to Main Menu ☰ → "System Settings" → "Basic Functions".



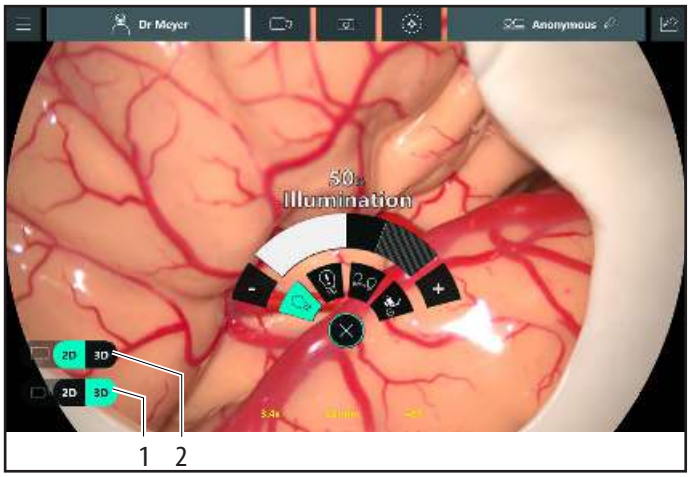

► Tap "Auto White Balance".
A dialog appears for confirmation/cancellation.
► Place a white paper/object underneath the microscope and confirm the dialog.

Please note that a Leica sales representative can additionally adjust the color settings of the camera for each fluorescence mode. Please ask a Leica representative.

### 5.7.2 3D 4K stand monitor

The system can be configured with a 3D 4K stand monitor.
The following points must be observed:

- This feature requires a "3D" license to be installed (see chapter 12.1 "Check installed licenses", page 78).
- In order to use this monitor in 3D mode, the toggle 3D display on stand monitor must be activated (see chapter 9.2.2 "Basic settings", page 55). Of course, you can also choose to use this monitor in 2D mode only, by keeping the toggle in 2D position.
- Alternatively, the 3D display can also be toggled from the "Live Screen" (2):




► Tap (1) to toggle the 3D recording
► Tap (2) to toggle the 3D display

### 5.7.3 3D heads-up surgery

You can connect an additional 55" 3D 4K cart system to the ARveo 8x microscope, connected to the SDI LEFT and SDI RIGHT connectors (see chapter 5.3 "Terminals", page 21). Find all required information in the user manual for the "Heads-up-microsurgery" product.
Also, you can use MyVeo, the all-in-one surgical visualization headset. For further information refer to the MyVeo user manual.

It is mandatory to always have binoculars installed on the OC (in case the image fails on monitors during heads-up procedures).

### 5.7.4 3D file recording

- You can optionally record video files in 3D.
- This feature requires a "3D" license to be installed (see chapter 12.1 "Check installed licenses", page 78).
- In order to activate this feature, the toggle 3D recording must be activated in the Basic Functions menu. If you set the toggle to "3D", all videos will be recorded in two separate files (left and right). Note that this feature will double the required disk space (see chapter 10.7 "Data management", page 73).
- Alternatively, the 3D recording can also be toggled on the live screen (1).

## 5.8 Customize/prepare export of videos and pictures

The system allows the user to export videos and pictures after surgery. Before surgery, the system needs to be set up to allow for the export.

### 5.8.1 Export to USB drive

Please have a USB storage device available. Note that only the USB 3.2 Gen 1 (USB3.0) standard guarantees fast file transfer. Follow export workflow (see chapter 10.5 "Export data", page 67).

### 5.8.2 DICOM export

This feature requires a DICOM license to be installed (see chapter 12.1 "Check installed licenses", page 78). Follow the export workflow (see chapter 10.5.5 "DICOM export", page 70).

If not yet done, please check with your Leica Sales representative on technical feasibility of this feature in your hospital before requesting a DICOM license.
Please ask Leica Service and your Hospital IT department to set this up. This process involves changes to your hospital storage solution and the hospital information workflows. You will need the microscope physically connected via ethernet cable to access the hospital storage system during data export.

# 6 Before surgery

## 6.1 Install optical accessories

**WARNING**

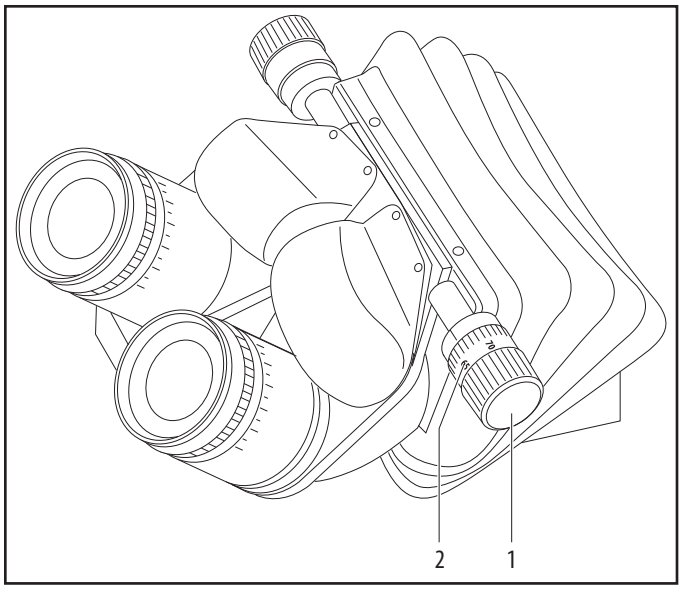
**Risk of injury due to downward movement of the surgical microscope.**

- ► 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 ARveo 8x.
- ► Balance the ARveo 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.
- ► Never carry out the intraoperative AC/BC balancing above the patient.
- ► Check fitting and good connection of all parts and cables during the preparation of the system prior to the surgery. Not well fitted parts and bad connections can lead to hazardous situations and system failures.

► Make sure that the optical accessories are clean and free of dust and dirt.

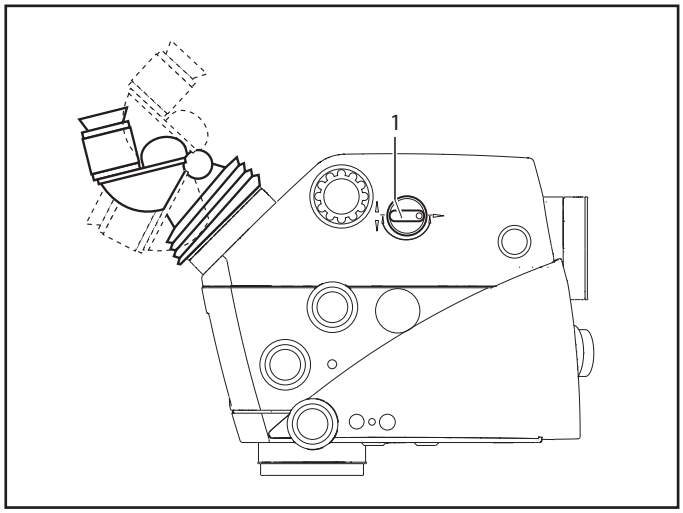
### 6.1.1 Set the interpupillary distance

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



### 6.1.2 Adjust the tilt

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



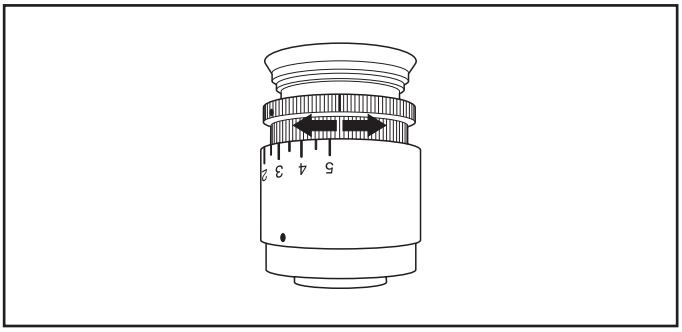

### 6.1.3 Adjusting the eyepiece

**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.

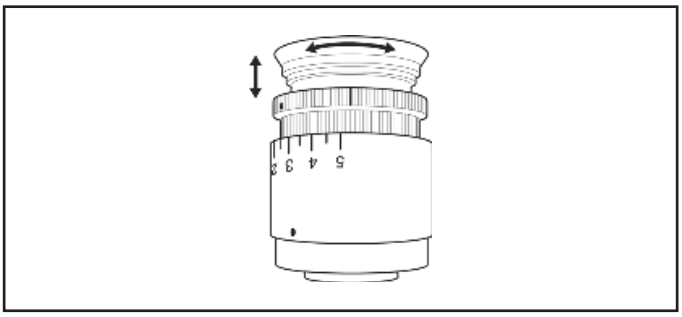
**!** A parfocally adjusted microscope ensures that assistant's view and monitor image will always remain sharp, regardless of the selected magnification.

- ► 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.

**Adjusting the pupillary distance**



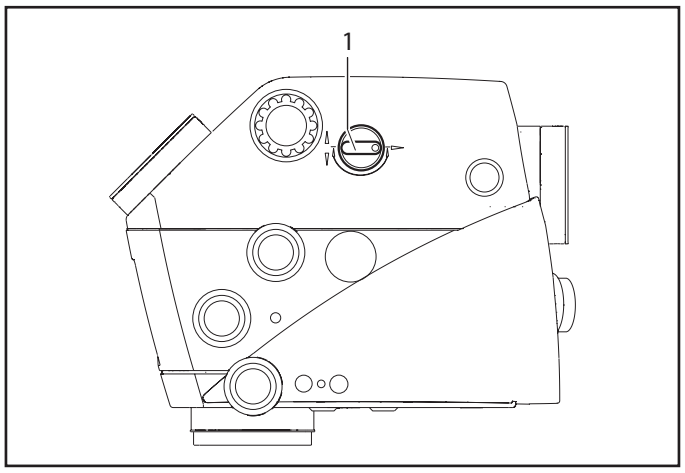
- ► Rotate the eyecups up or down until the desired distance is set.

**Checking parfocality**

- ► Place a flat test object with sharp contours under the objective at working distance.
- ► Zoom through the entire range, observing the test object.

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

### 6.1.4 Selecting the assistant




► Using knob (1) to switch the light from the back assistant to the side assistants.

## 6.2 Transportation

**WARNING**

**Danger of injury due to:**

- uncontrolled lateral movement of the arm system
- tilting of the stand
- feet in lightweight shoes could become trapped beneath the casing of the base

► For transportation, always move the ARveo 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 ARveo 8x surgical microscope; never pull it.
► Make sure that the movement range is free.

**CAUTION**

**Surgical microscope can move without warning.**

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

**NOTE**

**Damage to the ARveo 8x surgical microscope due to uncontrolled tilting.**

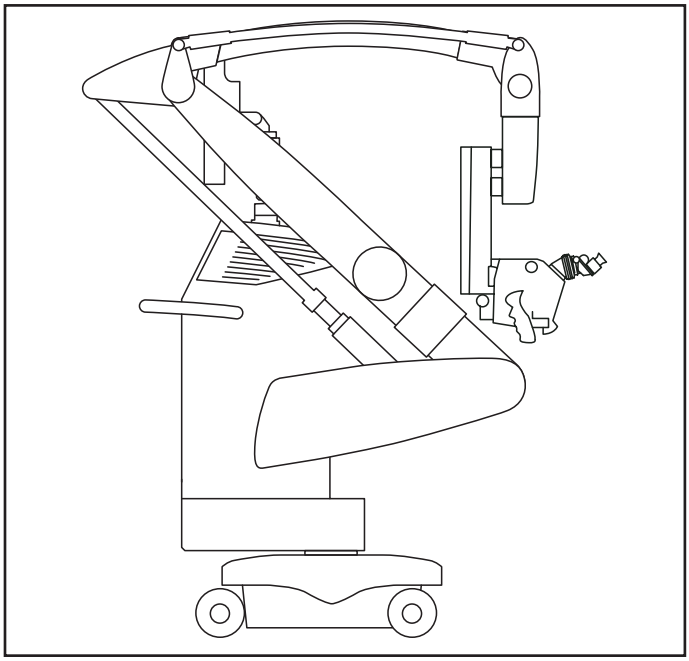
► Hold the handrail when releasing the foot brake.

**NOTE**

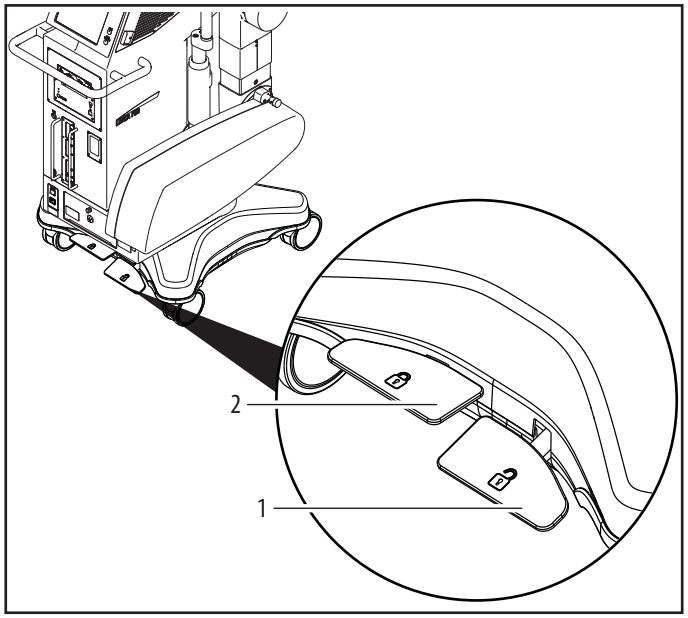
**Damage to the ARveo 8x surgical microscope during transportation.**

► Never move the stand in the extended condition.
► Never roll over cables lying on the floor.
► Do not drive on ramps with an inclination bigger than 10°.
► Do not move the stand in areas with an elevation angle bigger than 10°.
► Do not tilt the system to more than 10° as it might tip over.

Ensure that the ARveo 8x is in the transport position (see chapter 8.1 "Transport position", page 47).



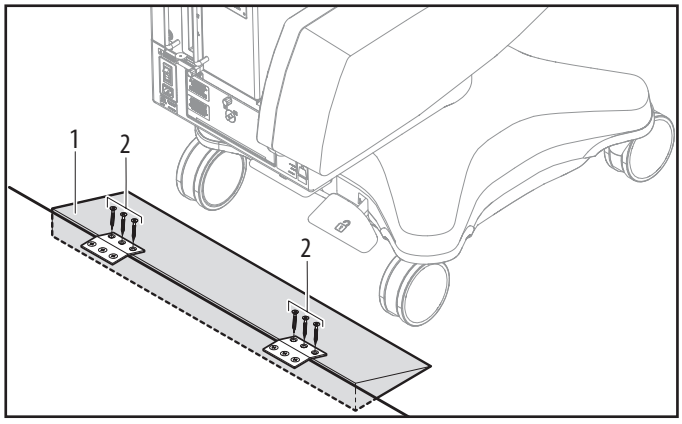
► Press the footbrake pedal on the right (1) to unlock the castor wheels.
► Move the microscope using the handrail.
► Press the footbrake pedal on the left (2) to lock the castor wheels.
► Put the system to transport position before switching it off.




### 6.2.1 Transport across thresholds

The ARveo 8x is not suitable for crossing thresholds higher than 10 mm. To move the surgical microscope over thresholds of 10 mm, the wedge (1) included in the packaging can be used.

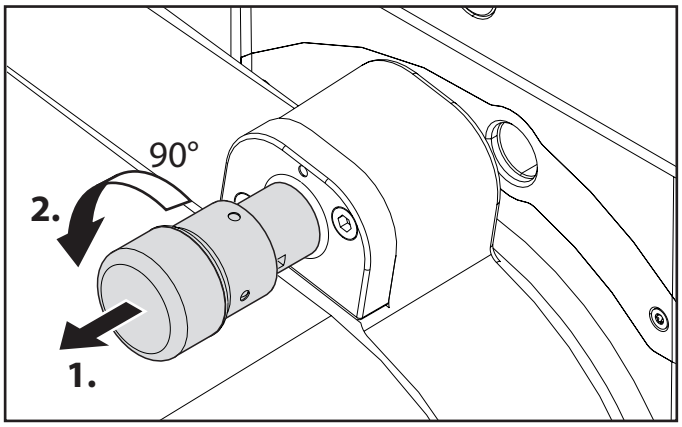
► Loosen the screws (2) on one side of the hinge in order to remove the wedge (1).




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

Without auxiliary equipment, the ARveo 8x can be moved across thresholds up to a max. height of 5 mm.

## 6.3 Locking/unlocking the ARveo 8x




► To unlock the ARveo 8x, pull the locking knob for vertical or horizontal direction and rotate 90°.
The red dot on the knob is pointing away from the red dot on the stand by 90°. The microscope is free to move in the selected direction.
► To lock the ARveo 8x, rotate the locking knob for vertical or horizontal direction 90° in reverse direction and release the knob.
The red dot on the stand is facing the red dot on the knob. Movement in the selected direction is locked.

## 6.4 Positioning on the operating table

**WARNING**

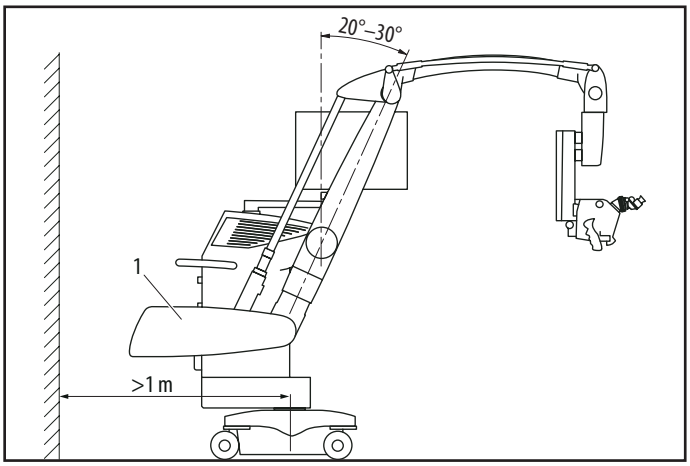
**Risk of injury due to downward movement of the surgical microscope.**

► 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 ARveo 8x.
► Balance the ARveo 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.
► Never carry out the intraoperative AC/BC balancing above the patient.
► Check fitting and good connection of all parts and cable during the preparation of the system prior to the surgery. Not well fitted parts and bad connections can lead to hazardous situations and system failures.

**NOTE**

**Risk of damage.**

- ► Before lifting the microscope make sure that the area above the stand is clear to avoid collisions with OR lamps, ceiling etc.
- ► Make sure that the movement range is free before you move the arm with the monitor.
- ► Parts of the stand might collide with the ceiling, wall or other equipment in the environment. Make sure that the movement range is free before you move the microscope or stand.
- ► Only move the surgical microscope when all brakes are released.




**NOTE**

**Risk of damage to the surgical microscope due to collision.**

- ► Make sure that there is free space of about 1 m around the foot.

**WARNING**

**Risk of compromised surgery**

- ► Do not use the device if pre-operational defect detected prior to surgical procedure.

The ARveo 8x can be positioned easily on the operating table and offers a variety of possibilities for operations on the head or spinal column.

- ► Release the footbrake.
- ► Move the microscope into position using the handrail.
- ► Set the footbrake.
- ► Position the foot switch.
- ► Plug the power cable into the stand.
- ► Connect the equipotential bonding to the stand.
- ► Power on the microscope.
- ► Move the microscope carefully over to the operating table by the handle and into the required position for the operation.

The ideal working position for the arm system is 20–30° tilted to the front.

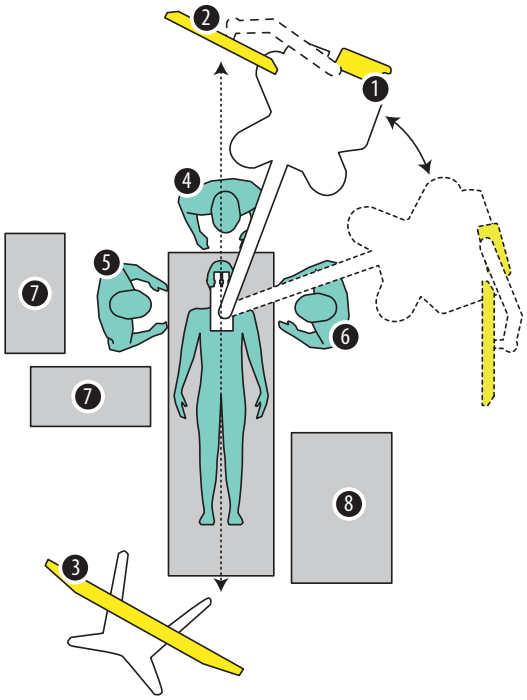
**NOTE**

**Risk of collision in the moving range of the counterweights (1).**

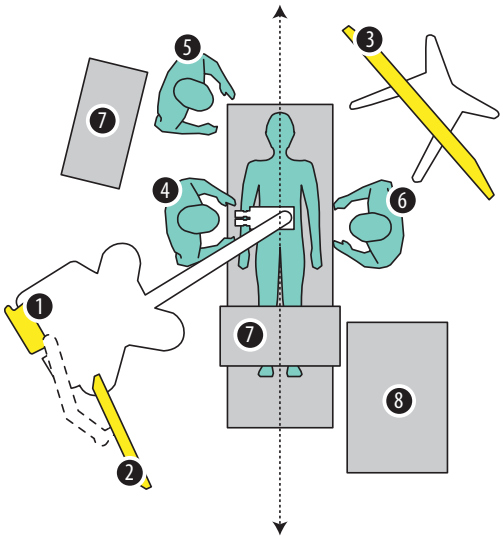
- ► Make sure to have a free moving space around the center of the base.

### 6.4.1 Positioning options examples

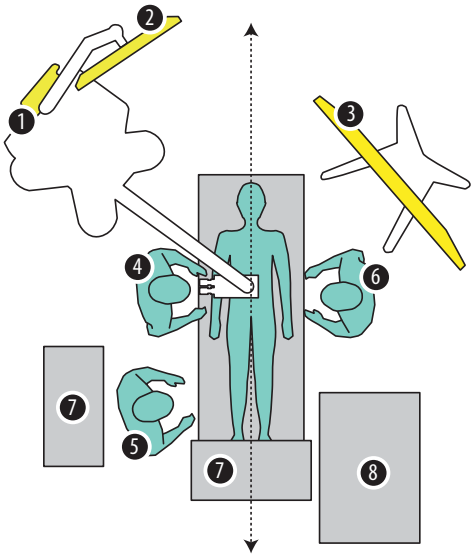
**Brain surgery**




**Spine surgery 1**




**Spine surgery 2**




1 Touch panel
2 27″ or 32″ Monitor
3 55″ Monitor cart
4 Main surgeon
5 Scrub nurse
6 Surgeon's assistant
7 Table
8 Anesthesia machine
Axis of symmetry: Each position can be mirrored

## 6.5 Switching the microscope on

**WARNING**

**Danger of fatal electrical shock.**

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

**WARNING**

**Danger of eye injury due to possibly hazardous optical infrared and UV radiation.**

- ► Do not look at the operating lamp.
- ► Minimize exposure to eyes or skin.
- ► Use appropriate shielding.

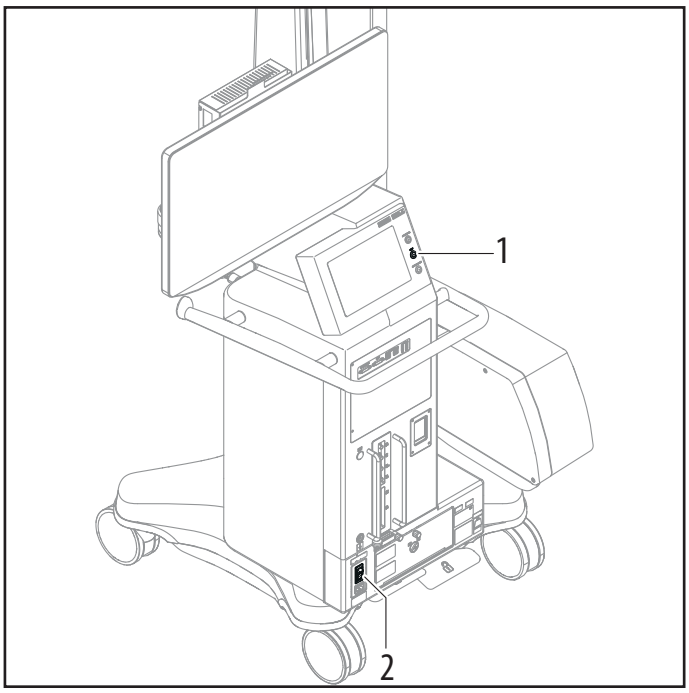
**WARNING**

**Danger of burn injuries in otologic surgery.**

- ► Use the lowest comfortable light intensity.
- ► Adjust the field of view to match the operating field.
- ► Irrigate the wound frequently.
- ► Cover the exposed parts of the pinna with a moist surgical sponge.

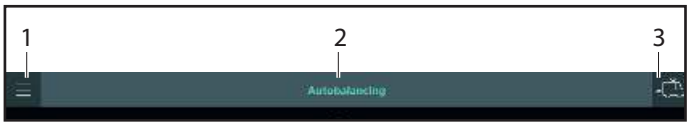
During the boot-up process the screen may go black and display pop-up messages. This process lasts approximately 1 to 2 minutes. Please let this process run until the microscope is operational and the "autobalancing" screen is visible.

- ► Connect the microscope to a grounded socket.
- ► Secure power cable at the stand.
- ► Switch on the microscope at the power switch (2) on the stand.
- ► Let the system boot up completely. Boot-up usually takes 1 to 2 minutes.
  After the microscope is switched on, a lamp test for both lamps is carried out. If a defective lamp is detected, a warning message is displayed.
- ► Check the fiber optics cable connection to the optics carrier.
- ► Switch on the illumination with the key (1) on the control unit.




### 6.5.1 Titlebar of the touch screen

You will find the following functions in the title bar:




- Main menu (1): access to microscope settings, handle and foot switch configuration, issue list, recorded surgery data
- Title (2): Pre-surgical workflow step (autobalancing, select surgeon profile, etc.)
- Emergency button (3): The emergency button (3) makes it possible to skip the subsequent steps of "Autobalancing", "Selecting the surgeon profile" and "Selecting a patient" and thus to begin the operation immediately. In this case, a default surgeon profile is selected that can be adapted, but cannot be altered.

If you skip auto-balancing, the existing balancing is taken over, but this incurs the risk that the microscope will be unbalanced.

**WARNING**

If the Emergency button is tapped, there is no guarantee that the system is balanced. As a result, there may be a risk of injury from uncontrolled movement of the arm system

- ► Optics carrier could fall onto patient.
- ► Optics carrier could move unexpectedly when releasing brakes.

## 6.6 Balance the microscope

### 6.6.1 Automatic balancing

**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 ARveo 8x.
- ► Balance the ARveo 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.
- ► Never carry out the intraoperative AC/BC balancing above the patient.
- ► Check fitting and good connection of all parts and cable during the preparation of the system prior to the surgery. Not well fitted parts and bad connections can lead to hazardous situations and system failures.

**WARNING**

**Danger of injury due to movement of the microscope during the balancing process.**

Do not sit or stand immediately next to the microscope during the balancing process.

**NOTE**

**Risk of damage to the surgical microscope.**

- ► Do not balance in A/B direction further than the 20° positions.

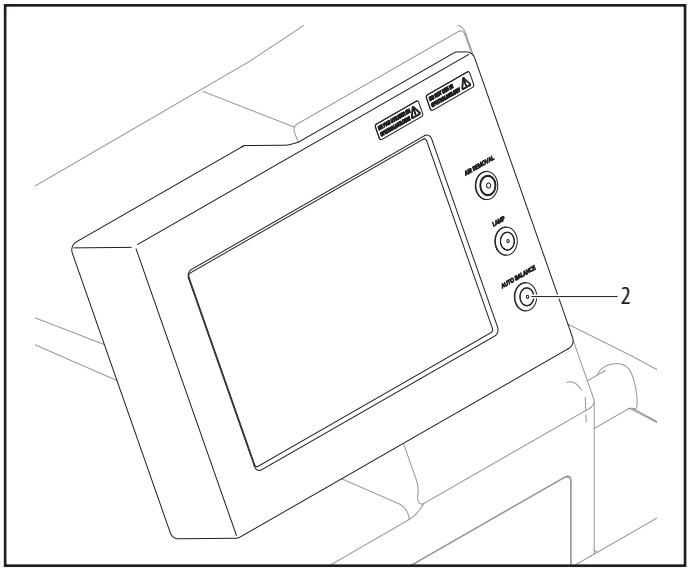
**NOTE**

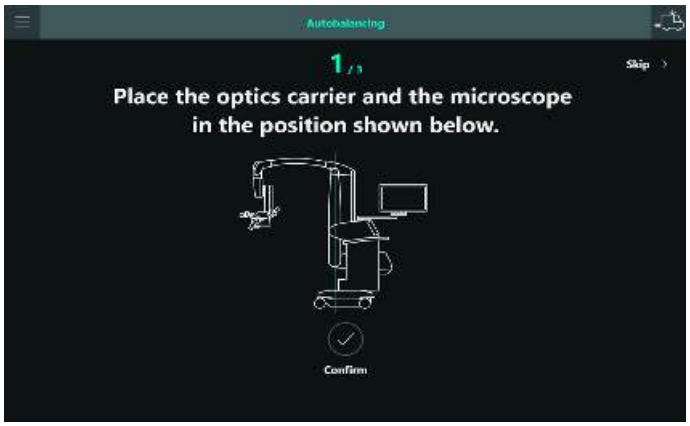
**Risk of damage to the surgical microscope due to collision.**

Even in balanced condition and with the approved accessories, collisions might happen due to extensive movement and rotation range of the microscope.

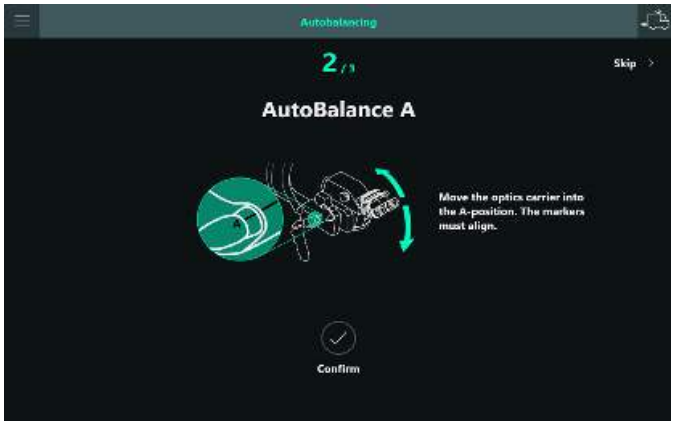
- ► When mounting accessories on the side of the microscope carrier arm do consider that the movement range will be limited and that it might collide with the arm.
- ► Always check the movement range during preparation prior to the surgery and correct the positioning of the accessories, if required.

- ► Switch on the microscope (see chapter 6.5 "Switching the microscope on", page 32).
- ► Install the tubes and all required accessories and align them in working position.
- ► Make sure that the equipment is within the allowed weight range (see chapter 19 "Weight calculation of equipment", page 96).
- ► Press the autobalance pushbutton (2) on the control unit. During the balancing procedure, the pushbutton flashes green and an acoustic signal sounds (can be deactivated in the basic functions) (see chapter 9.3.1 "Basic Functions", page 57).

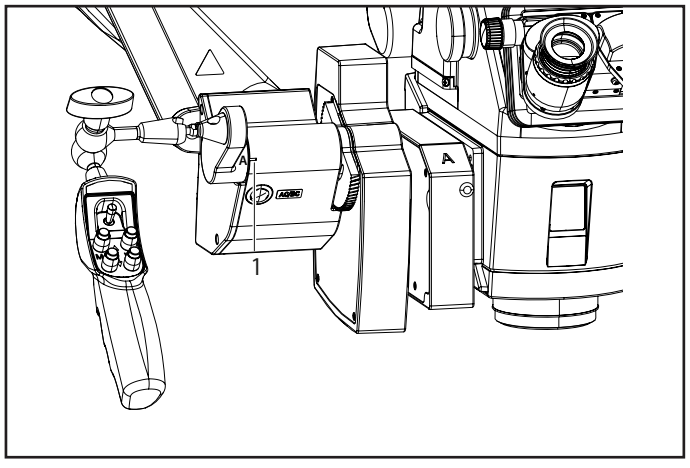





► Follow the steps on the screen. The vertical arm must be in a vertical position.

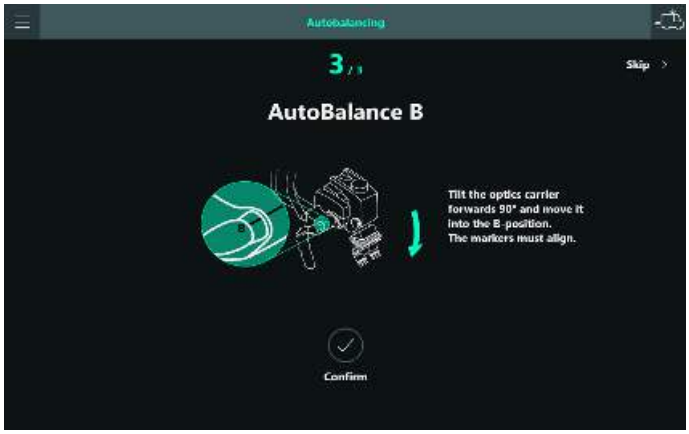



► Press "Confirm" on the touch screen or the autobalance pushbutton on the control unit.
► Press the "All Brakes" button on the handle and move the optics carrier into the A-position.
The marking (1) must point towards A.



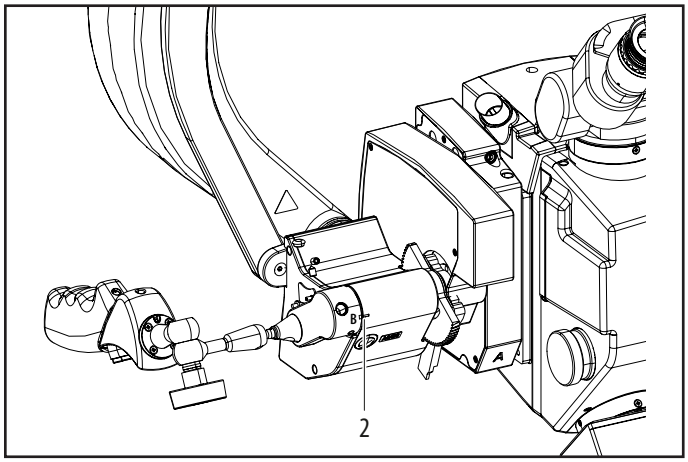

► Press the confirm button on the touch screen.
During the balancing procedure, the pushbutton flashes green and an acoustic signal sounds (can be deactivated in the service menu).

The following dialog window appears on the touch screen:



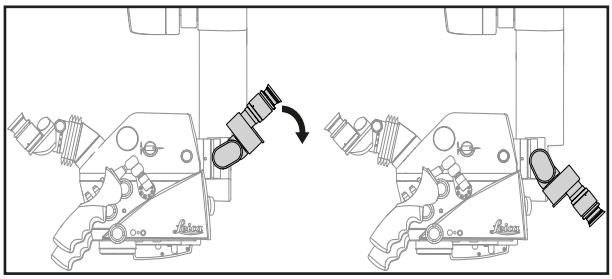

► Make sure any back assistant tubes and side assistant tubes are in a position used during surgery.

► Press the "All Brakes" button on the handle, tilt the optics carrier forwards 90° and move it into the B-position.




The marking (2) must be pointing towards B.

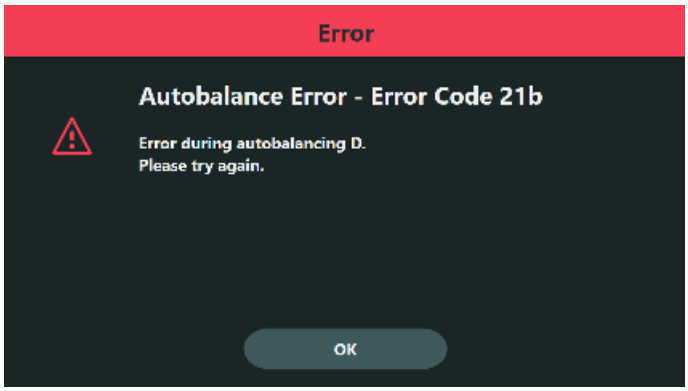
► If the back assistant tube locks the movement to B position, then tilt it downwards.



► After B-balancing, turn the assistant tube back to its original position.

- ► Press the confirm button on the touch screen.
  Balancing is completed when the acoustic signal no longer sounds and the autobalance pushbutton is no longer flashing.
  A dialog window indicates that balancing has been completed.
  The dialog window is closed automatically after 5 seconds.
- ► Check the balancing.
- ► Press the "All Brakes" button on the handle and position the microscope.

If the autobalancing procedure could not be finished successfully, the following error message will appear (example):




- ► Repeat the auto-balancing procedure, if needed, using the auto-balancing pushbutton (see chapter 6.6.1 "Automatic balancing", page 33).

### 6.6.2 Skip automatic balancing

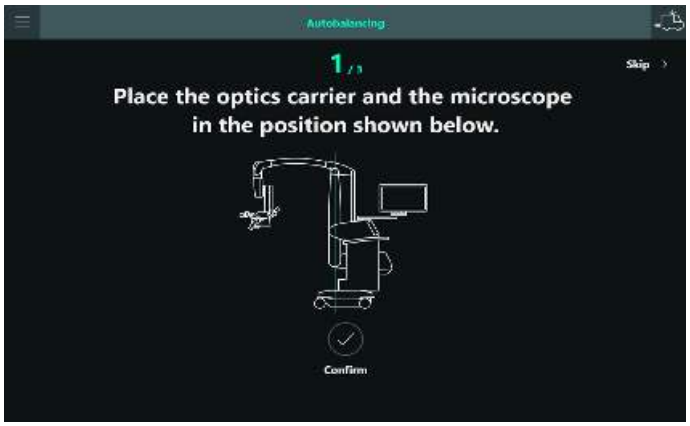
Only if the microscope has just been balanced and no changes to the optics carrier have been made, autobalancing can be skipped. If autobalancing is interrupted by tapping the main menu or the emergency button, a warning message appears:




**WARNING**

If autobalancing is skipped either via "Skip" or via "Emergency button", there may be a risk of injury from uncontrolled movement of the arm system.

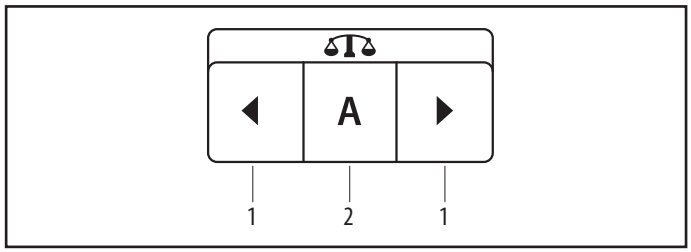
- ► Optics carrier could fall onto patient.
- ► Optics carrier could move unexpectedly when releasing brakes.




- ► Tap on "Skip" in the upper right corner of the screen.

### 6.6.3 Manual balancing

For manual balancing, the axes A, B and C can be moved manually using the balancing panel on the arm system.



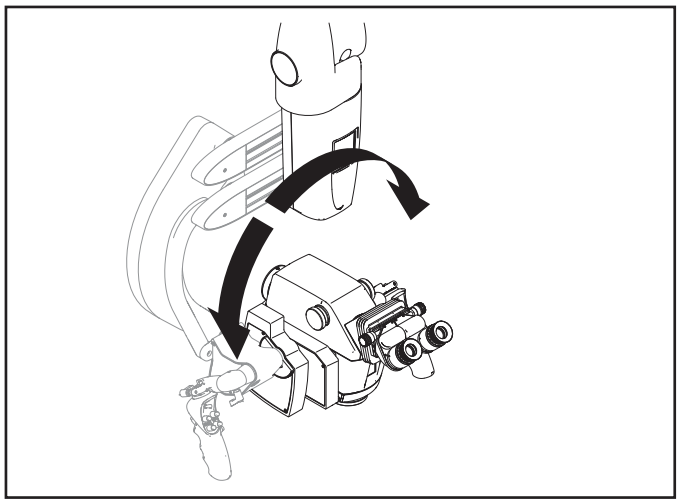

1 Arrow keys for moving to the right or left in the indicated direction
2 Balancing direction (A, B or C)
A/B is selected automatically

- ► Press field (2) to select the balancing direction.
  Only the currently available directions are displayed.
- ► Press and hold the desired arrow key (1) to move in the desired direction until the direction is balanced.

Make sure no accessories collide with the microscope during balancing.

- ► Check the balancing.
- ► Press the "All Brakes" button on the handle.

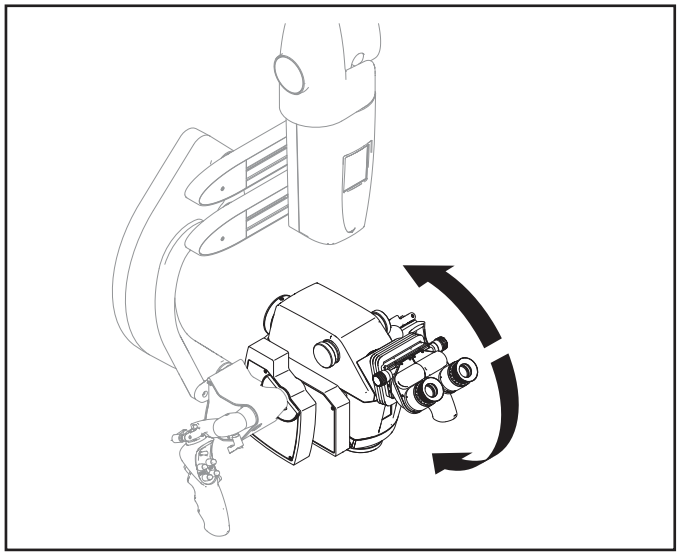
**Optics carrier tilting to the right/left**



► Move the C-axis until the optics carrier is balanced.

| | |
|---|---|
| Optics carrier tilting to the right | move to the left |
| Optics carrier tilting to the left | move to the right |

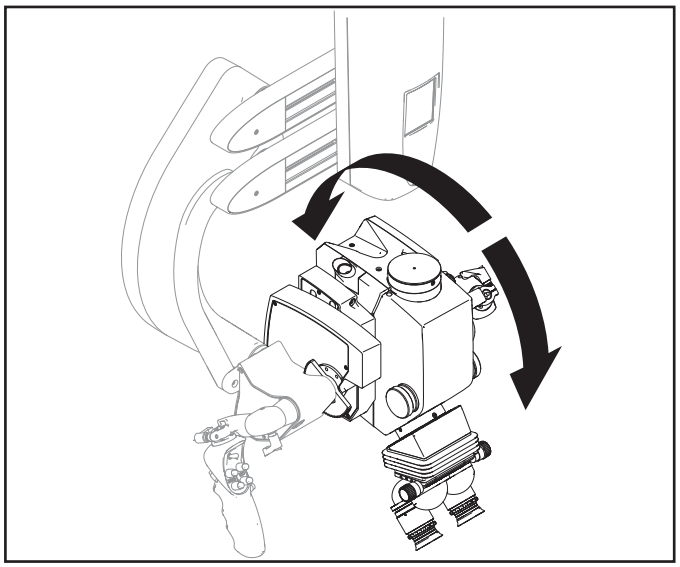
**Optics carrier tilting back/forwards**



► Move the A-axis until the optics carrier is balanced.

| | |
|---|---|
| Optics carrier tilting back | move A-axis forwards (to the right) |
| Optics carrier tilting forwards | move A-axis back (to the left) |

**Optics carrier tilting back/forwards in the B-position**



► Move the B-axis until the optics carrier is balanced.

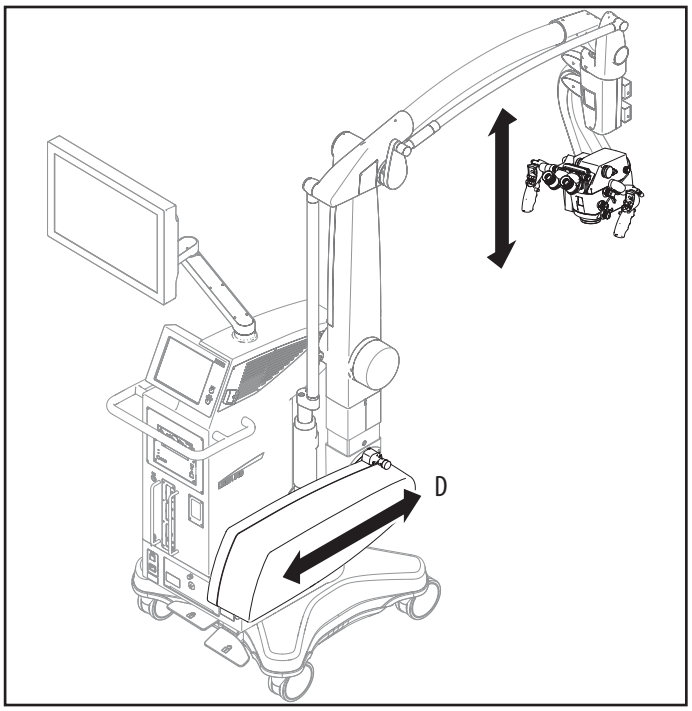
| | |
|---|---|
| Optics carrier tilting back | move B-axis forwards (to the right) |
| Optics carrier tilting forwards | move B-axis back (to the left) |

If the microscope cannot be balanced manually, the weight of the accessories is probably outside the balanceable weight range. This can only be done for A, B and C axes by reducing or increasing the accessory weight to within the permitted range.

### 6.6.4 Correct the D-balancing

An internal weight in the stand compensates for the weight of the surgical microscope and the installed accessories.

It may be necessary to correct the D-balancing after fitting a sterile drape on the microscope




► Correct D-balancing in the basic functions:
Main Menu ☰ → "System Settings" → "Basic Functions" → "Balance Arm" → "Up" and "Down".

## 6.7 Function check

### 6.7.1 Check errors/warnings

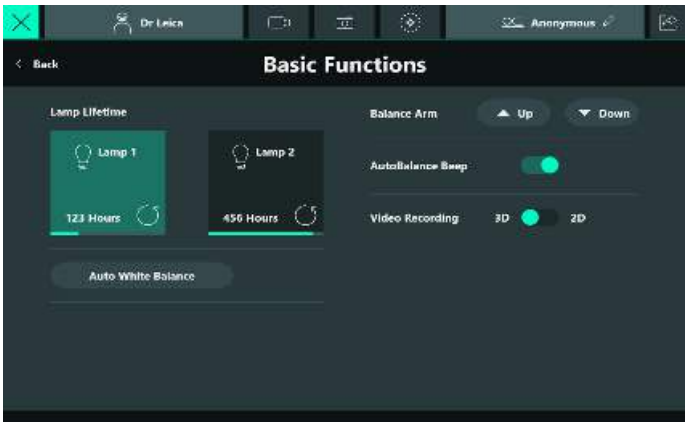
If the main menu button is highlighted orange and marked with a triangle, check for errors/warnings (see chapter 17.3 "Check errors/warnings (issue list)", page 90).

### 6.7.2 Check lamps

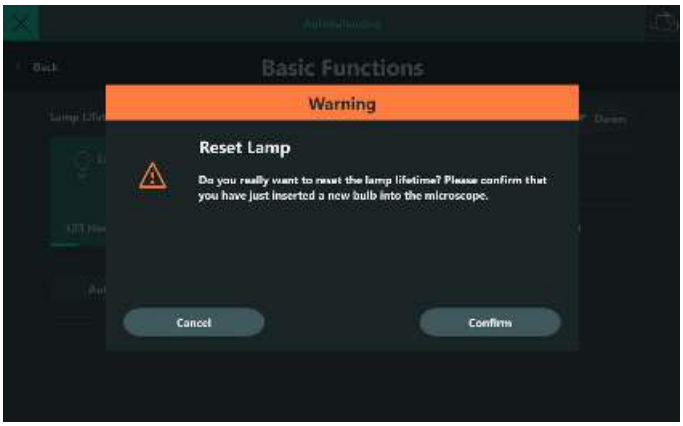
To guarantee a good light performance the lifetime shall not exceed 500 hours. When using FL400 it should not exceed 150 hours. A reminder appears when lamp 1 has reached 150 hours and lamp 2 has reached 500 hours.

► Open the "Basic Functions" menu to check the lamps as follows:
Main Menu ☰ → "System Settings" → "Basic Functions".
► Check both lamp hour counters.

**NOTE**
Danger that an old lamp will be shown as a new lamp.
Risk that the lamp hour counter shows the wrong time if reset accidentally.




► To change the lamp, tap the whole button and **not** the reset icon ↺.




► If you have accidentally tapped the reset icon ↺, tap "Cancel" when asked if you want to reset the lamp lifetime.
► If the xenon primary illumination fails, use the button "Lamp 2".

► Replace the defective lamp at the next opportunity (see chapter 15.2 "Change lamps", page 81).
► Never begin an operation with only one functioning xenon lamp.

A dialog window informs you when the xenon lamp is losing luminosity and is no longer sufficient (all other applications). We recommend that you keep a replacement lamp handy.

Refer to chapter 20.1 "Checklist before the operation", page 100.

## 6.8 Attaching sterile controls and drape

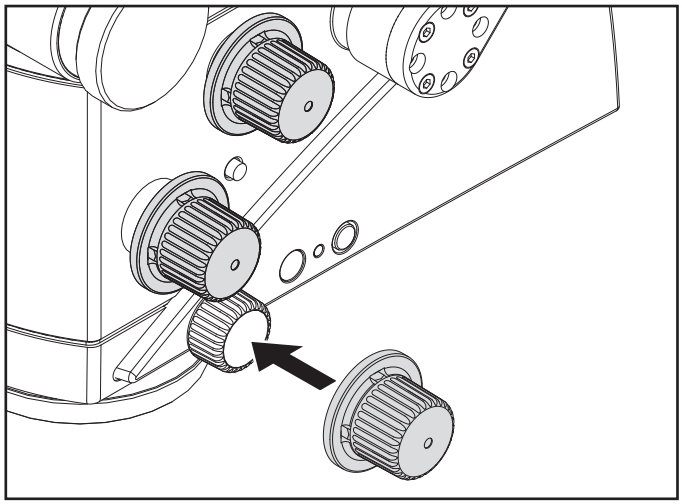
**WARNING**

**Risk of infection.**

- ► Always use the ARveo 8x with sterile controls and a sterile drape.

### 6.8.1 Attach covers to rotary knobs

- ► Fit steam-sterilizable covers on the magnification, working distance and AutoIris manual override knobs.



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

Use the covers also when you use sterile disposable drapes. The controls will be easier to grasp.

### 6.8.2 Attach cover to foot switch

Packaging the foot switch in a plastic bag protects it against dirt.

### 6.8.3 Attach drape to microscope arm

- Only use the sterile Leica tested drapes specified in the Accessories section.
- Drape only as far as the arm system.

**CAUTION**

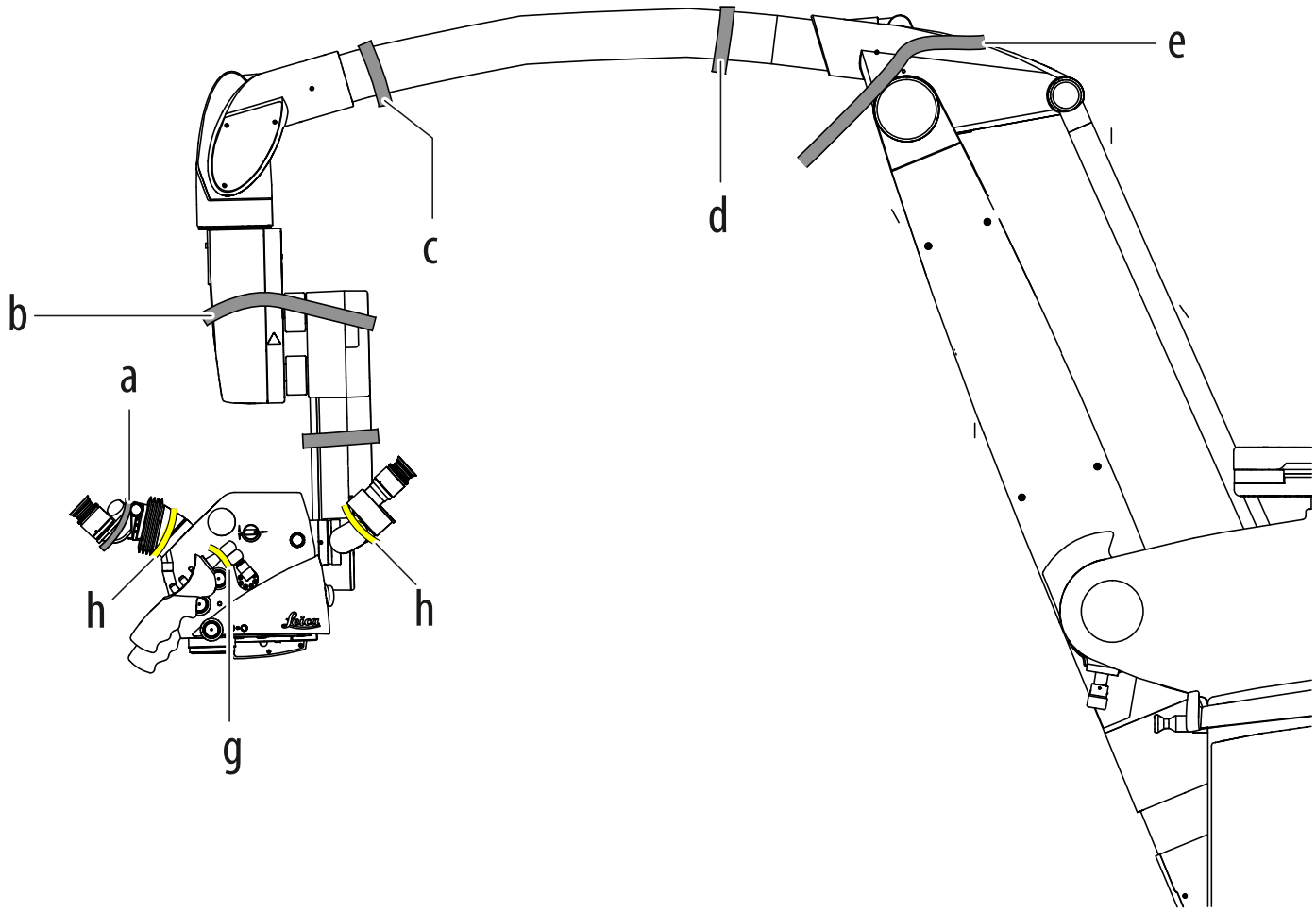
**Risk of infection.**

- ► Leave sufficient space around the stand to ensure that the sterile drape does not come into contact with non-sterile components.
- ► Activate the "All Brakes" function on the handle and extend the arm system.
- ► Put on sterile gloves.
- ► Attach all the sterile controls.
- ► Unpack the sterile drape carefully and drape it over the ARveo 8x surgical microscope as far as the arm system.

Scan the QR code to access video tutorial on how to install drape.

- ► Clamp the protective glass (optional) onto the objective (see chapter 6.8.4 "Attach protective glass to objective", page 40).

Follow the instructions provided by the manufacturer of the sterile drape.

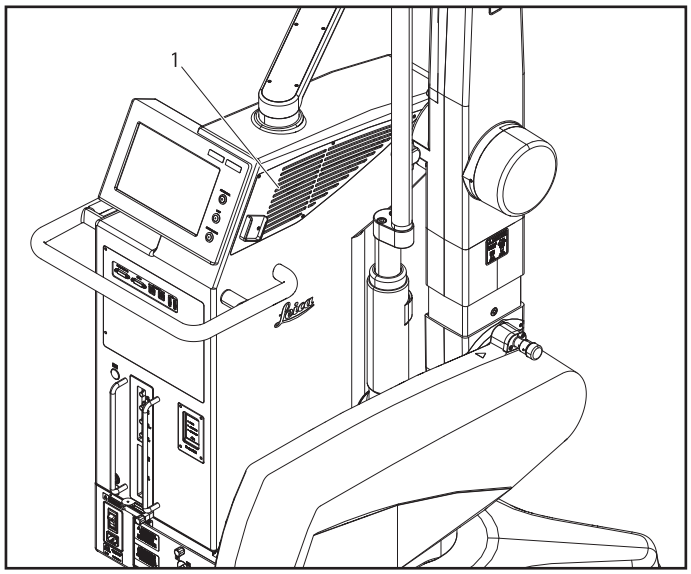



- ► Apply straps (a) to (e), i.e. 2 straps on each arm segment.
- ► Make sure that strap (b) is positioned between the dark blue and white paint, otherwise it will be difficult to rotate.
- ► Place a rubber band (h) at each binocular to prevent the sterile drape from falling in the field of view or from touching the surgeon's non-sterile face mask.
- ► Place a rubber band (g) at each handle.
- ► Tuck excess drape under rubber bands so it does not hang down by the lens.
- ► Do not attach the sterile drape too tightly with the provided ribbons. It must still be easy to move the instrument.
- ► Check the ease of movement of the instrument.

**NOTE**

**Risk of overheating of the system.**

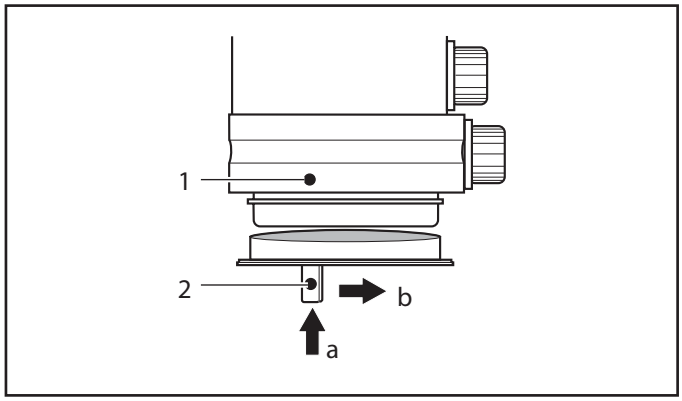
- ► Make sure the air inlet (1) is always kept free.




Always use the drape with a protective glass.

### 6.8.4 Attach protective glass to objective

- Place the sterilized protective glass on the optics carrier so that the markings on the ARveo 8x (1) and on the protective glass (2) are aligned.




- Insert the protective glass upwards into the bayonet mount in direction (a).
- Turn the protective glass in direction (b) until it engages.

### 6.8.5 Remove air from drape

- Press the air removal pushbutton on the control unit (see chapter 5.2 "Control unit", page 21).
  The pushbutton flashes green.
- The vacuum drape system will start suctioning at its highest speed for 90 seconds and automatically switch to low speed.
  The pushbutton lights up.
- Press the air removal pushbutton again to stop suctioning or in case of emergency.

# 7 During surgery

## 7.1 Position the microscope

**NOTE**

**Damage to the ARveo 8x surgical microscope due to uncontrolled tilting.**

- Hold the handle when releasing the brake.

- Hold the microscope by both handles.
- Press the button for releasing all brakes and position the microscope.
- Release the brakes button.
- For fine positioning with the XY drive, use the joystick on the handle or foot switch.

Also refer to chapter 6.3 "Locking/unlocking the ARveo 8x", page 29.

## 7.2 Adjust illumination

You can increase or decrease the illumination using either the touch screen, a foot switch, or handle.

### 7.2.1 Handle/foot switch adjustments

Depending on the configuration, you can also increase and decrease the brightness of the main illumination using two correspondingly assigned buttons on the handle/foot switch.

### 7.2.2 Touch screen adjustments

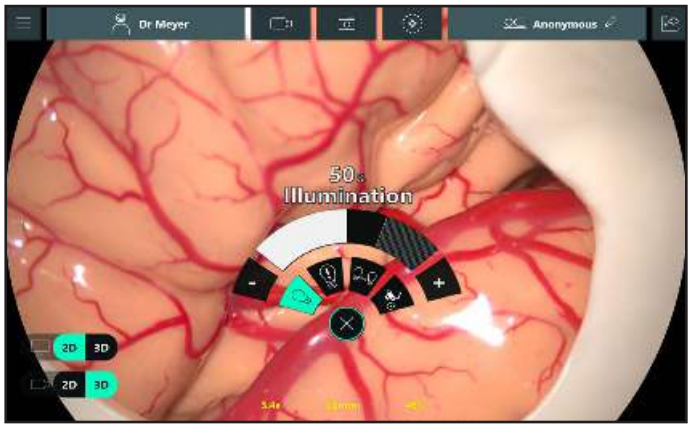
**WARNING**

**Danger of injury to the eyes.**

At a short focal distance, the light source of the illumination unit may possibly be too bright for the operating physician and the patient.

- Begin with the lower-intensity light source and slowly increase it until the operating physician has an optimally illuminated image.

When the working distance is reduced too much at a set brightness, the brightness is reduced automatically.




► Tap the + or – button at both ends of the half-moon bar or drag the position with your fingers.

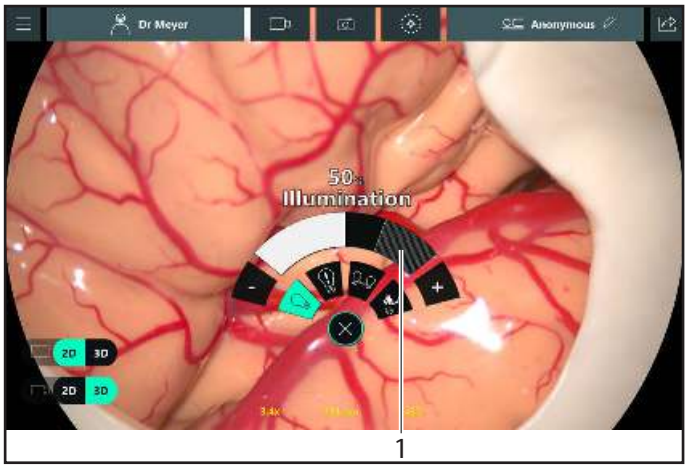
– or –

► Tap the brightness adjustment bar directly.
The brightness of the active main illumination changes.

- Tapping the + or – button changes the brightness value in increments of 1.
- The main illumination can only be switched on and off using the illumination pushbutton on the stand. In addition, it is also possible to assign a button of the handles or foot switch to switch on/off the main illumination.
- The brightness setting is also visible when the illumination is off.

### 7.2.3 BrightCare Plus

The maximum brightness defined by the BrightCare Plus function depends on the working distance. As a consequence, the brightness may be reduced automatically when lowering the working distance. The maximum configurable brightness with BrightCare Plus is shown with the hatched area (1). The non-crosshatched field shows the maximum adjustable brightness for the current working distance. The brightness cannot be set outside the non-crosshatched area.




BrightCare Plus can also be used in GLOW mode.

**Activate BrightCare Plus**

► Open Main Menu ☰ → "Surgeon Settings" → "Basic Settings".
► In the "Basic Settings" menu, activate "BrightCare" (2).




**Deactivate BrightCare Plus**

**WARNING**

**Danger of injury to the eyes**

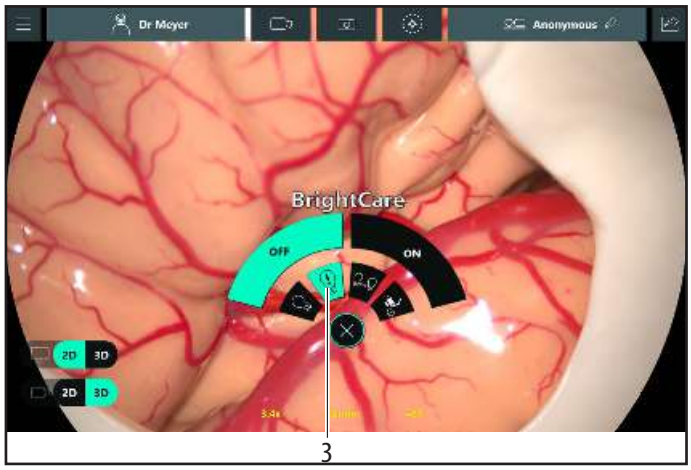
At a short focal distance, the light source of the illumination unit may possibly be too bright for the operating physician and the patient.

► Begin with the lower-intensity light source and slowly increase it until the operating physician has an optimally illuminated image.

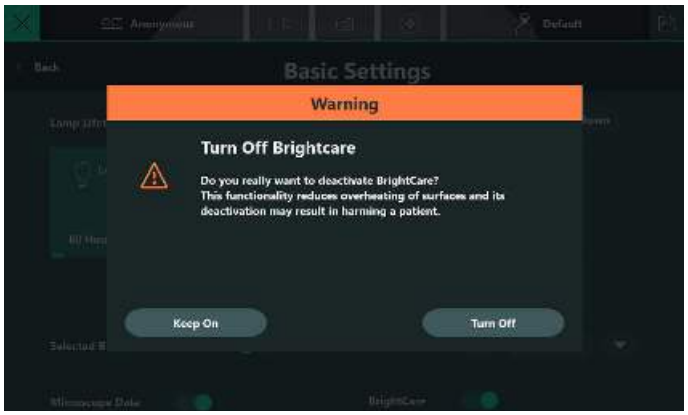
► In the "Basic Settings" menu, disable "BrightCare" (2).

A dialog window opens in which you have to confirm that you want to deactivate the safety function. After BrightCare Plus has been switched off once, it will be enabled again in the next session.

**Alternative ways to deactivate BrightCare Plus**




- ► Tap on the cross-hatched area (1) and confirm the dialog window.
- ► Select the BrightCare option in the rotary menu (3) and enable/disable the BrightCare from there.
  The following message appears asking you to confirm deactivation of "BrightCare":




## 7.3 Intraoperative balancing

The intraoperative balancing allows a fast adaption to unbalanced situations caused by position changes of accessories. It considers the position of the microscope and does automatically balance it in the current position.
In the case of adding or removing accessories a full autobalance has to be performed.

**WARNING**

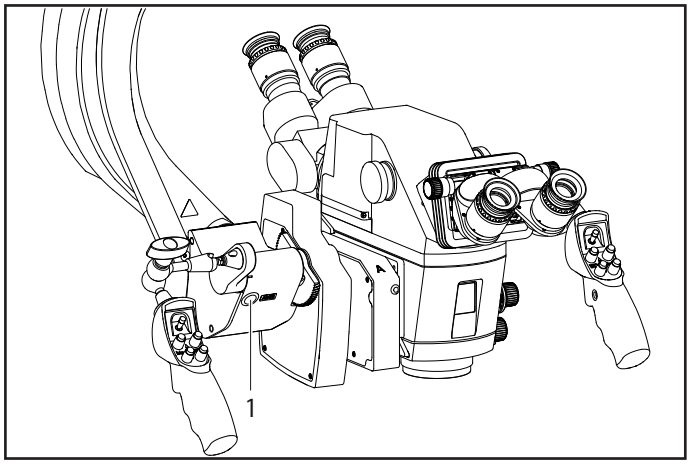
**Risk of injury due to downward movement of the surgical microscope.**

- ► Before re-equipping during the operation, first swing the microscope away from the operating field.
- ► Never carry out the intraoperative AC/BC balancing above the patient.

**NOTE**

**Risk of damage to the surgical microscope.**

- ► Do not balance in A/B direction further than the 20° positions.




- ► Press the AC/BC button (1) to activate the intraoperative balancing.
  During balancing, an acoustic signal sounds.

## 7.4 Switch fluorescence modes

**WARNING**

The surgeon is at risk of losing orientation, e.g. when choosing an FL fluorescence mode.

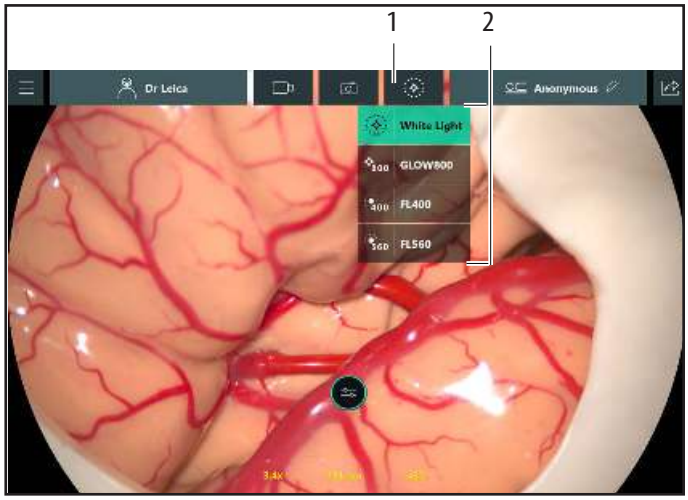
- ► Do not switch modes during surgery from the touch screen, unless explicitly requested by the surgeon.

### 7.4.1 Via handles/foot switch

See section "Fluorescence", page 53.

### 7.4.2 On touch screen

You can freely choose any fluorescence mode that you have licensed from the touch screen.



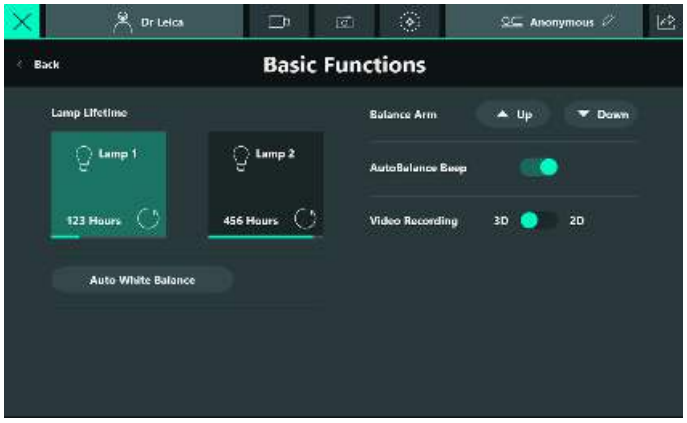

► Tap the mode switching button (1).
The menu (2) appears.
► Choose the intended mode including whitelight mode by tapping on it.

It may take a few fractions of a second before the mode is fully activated.

## 7.5 Change lamps

If the xenon primary illumination fails or you have the impression of too low light intensity, you can switch to the backup illumination using the touch screen.

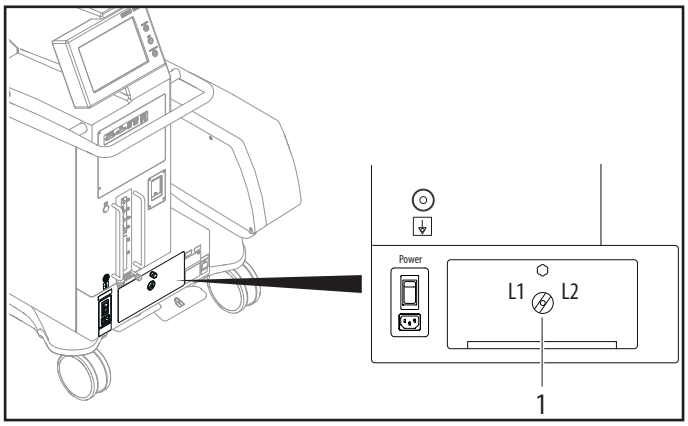
► Open the Microscope Settings Menu as follows:
Main Menu ☰ → "System Settings "→ "Basic Functions".
The currently active lamp is highlighted in green.




► To change the lamp, tap on the button of the other lamp.
► Alternatively, you can use the Quick Access Menu to change the lamp (see chapter 7.8 "Quick Access Menu", page 45).

### 7.5.1 Change lamps manually (emergency use only)

► Switchover to backup illumination using knob (1).




## 7.6 Setting the working distance (WD, focus)

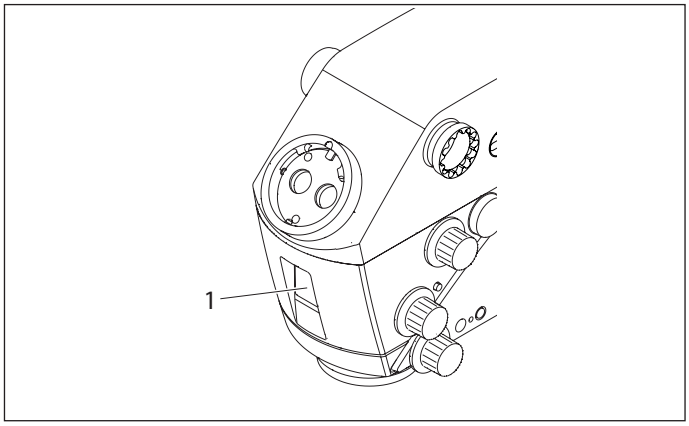
You can adjust the working distance using a handle or a foot switch.

**WARNING**

**Danger of injury to the eyes due to laser radiation.**

► Never point the laser directly or indirectly via reflecting surfaces to the eyes.
► Never point the laser to the eyes of the patient.
► Do not look into the laser beam.

You can see the currently set working distance on the surgeon panel (1) and on the connected monitors when microscope data is enabled.



**WARNING**

**Danger to the patient due to failure of the working distance motor.**

- ► If the working distance motor fails, adjust the working distance manually.

### 7.6.1 Setting the working distance manually

**WARNING**

**Danger of serious damage to tissue due to incorrect working distance.**

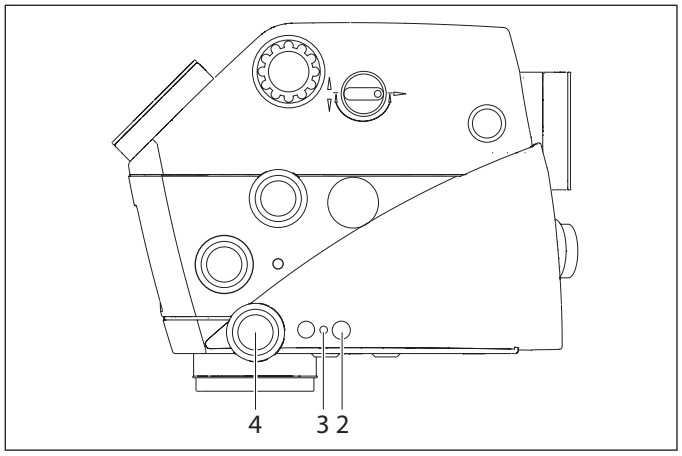
- ► When using lasers, always set the working distance of the microscope to laser distance and lock the working distance.
- ► Do not adjust the rotary button for manual setting of the working distance while using the laser.

**NOTE**

**Destruction of the working distance motor.**

- ► Only adjust the working distance manually if the working distance motor is defective.

If the working distance motor fails, working distance can be manually adjusted using the rotary knob (4).




- ► Turn rotary button (4) and set the working distance as required.

### 7.6.2 Locking/releasing the working distance

It is necessary to lock the working distance when working at a fixed distance or when using a laser.

- ► Press key (2).
  The yellow LED (3) turns on and the working distance is locked. In addition, a pop-up warning appears indicating that the working distance is now locked.
- ► Press key (2) again.
  The yellow LED (3) turns off and the working distance is released.

## 7.7 Adjusting the magnification (zoom)

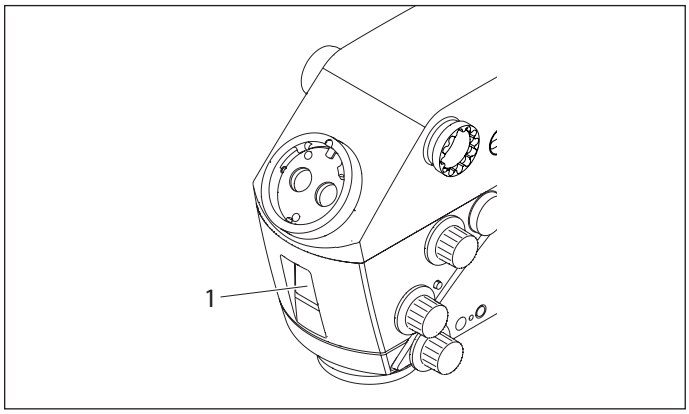
You can adjust the magnification using a handle or foot switch.

**WARNING**

**Danger to the patient due to failure of the magnification motor.**

- ► If the magnification motor fails, adjust the magnification manually.

You can see the currently set magnification on the surgeon panel (1) and on the connected monitors when microscope data is enabled.




**Manually adjusting the magnification (zoom)**

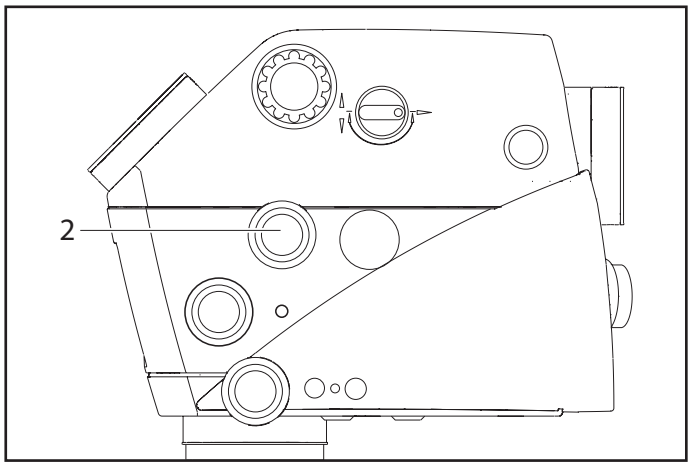
**NOTE**

**Destruction of the magnification motor.**

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

If the magnification motor fails, the magnification can be manually adjusted using the rotary knob (2).

- ► Push in rotary button (2).
- ► Set the desired magnification by turning the knob.




### 7.7.1 Setting the illumination field diameter

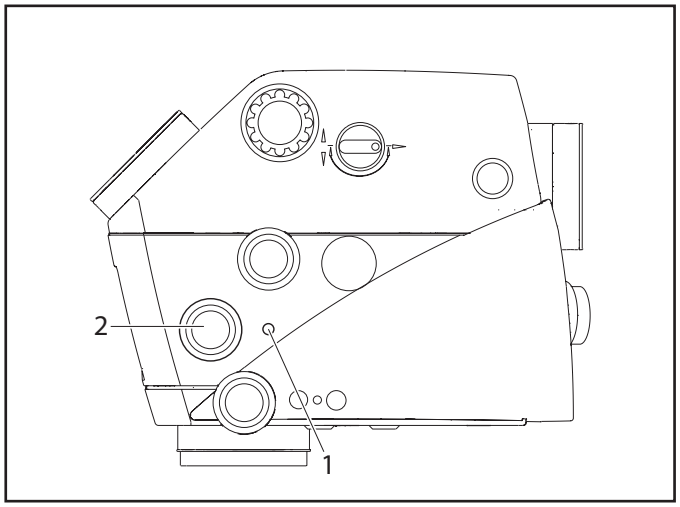
**CAUTION**

If the field diameter is greater than the field of view and the light intensity is too high, uncontrolled tissue heating may occur outside of the area visible through the microscope.

► Do not set the light intensity too high.

Thanks to AutoIris, the field diameter is automatically adapted to the size of the field of view at the M530 optics carrier.

► To adjust the illumination field diameter manually, use rotary button (2).
Automatic adjustment AutoIris is deactivated.
► To reactivate AutoIris press the Reset button (1).



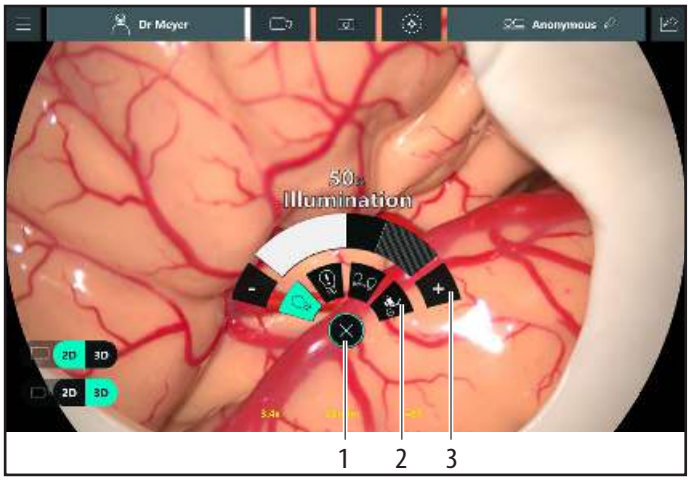

If the illumination field diameter is blocked at a high light intensity in a high magnification setting, and cannot be adjusted automatically or manually, then the light intensity must be reduced in order to protect the tissue.

If the field diameter is locked in a small position and cannot be adjusted either automatically or manually, you can use an OP lamp to better illuminate a large field of view (small magnification position).

## 7.8 Quick Access Menu

The "Quick Access Menu" on the "Live Screen" allows you to adjust the following 4 settings without the need to enter the main menu:

- Illumination
- BrightCare
- Lamp in use
- Microscope Data



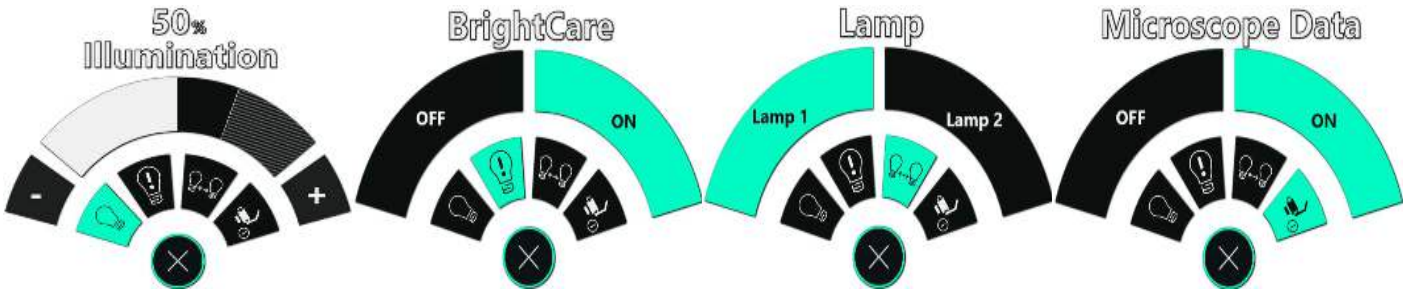

► Tab the X button (1) to open/close the "Quick Access Menu".
► Select the desired setting with the respective icon (2).
The selected setting is highlighted in green.
► Change to the desired setting (3).

Illumination: Adjust the illumination brightness in a range of 0 to 100% (see chapter 7.2.2 "Touch screen adjustments", page 40).

BrightCare: Turn on/off the BrightCare protection (see chapter 7.2.3 "BrightCare Plus", page 41).

Lamp in use: switch between Lamp 1 and Lamp 2 (see chapter 7.5 "Change lamps", page 43).

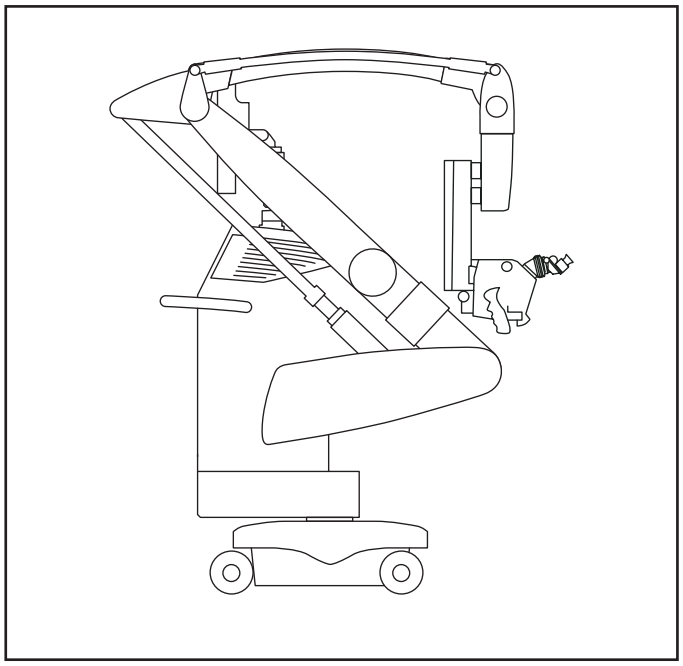
Microscope Data: Turn on/off the overlay of the Microscope Data on the connected monitors.



# 8 After surgery

## 8.1 Transport position

- ► Press the "All Brakes" button and move the ARveo 8x into the transport position.
- ► Make sure that the stand monitor does not collide with the horizontal arm and the vertical arm of the stand.



- ► Shut down the system according to chapter 8.2 "Shut down the microscope", page 47.
- ► Unplug and secure the power cable.
- ► If present, store the foot switch on the stand.

**NOTE**

**Damage to the ARveo 8x surgical microscope during transportation.**

- ► Never move the stand in the extended condition.
- ► Never roll over cables lying on the floor.
- ► Do not drive on ramps with an inclination bigger than 10°.
- ► Do not move the stand in areas with an elevation angle bigger than 10°.
- ► Do not tilt the system to more than 10° as it might tip over.

**NOTE**

**Risk of damage.**

- ► Do not park the system in an area with an inclination of more than 5°. The foot brake will not be able to hold the weight and the system could start to move.

## 8.2 Shut down the microscope

- ► Switch off the light at the light switch.
- ► Bring the surgical microscope into the transport position.
- ► Switch off the surgical microscope at the power switch.
  The computer will keep running for a short time after switching off, in order to properly shut down the system. When the touch screen of the computing unit turns off, shutdown has completed.

# 9 Control unit with touch screen

## 9.1 Surgeon profile

The user can choose between different surgeon profiles from the "wheel" on the touch screen. If more than 5 profiles have been defined, the user can rotate through all defined and activated profiles.
Profiles are alphabetically sorted by first name. The list is "infinite", i.e. after the last item in the list, the first item will appear as the next one.

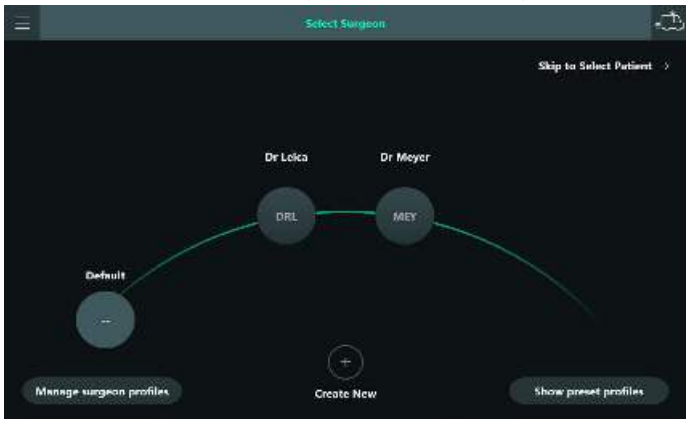
### 9.1.1 Choose surgeon profile

The "Select surgeon" menu can be reached as follows:

- Directly after autobalancing following system startup

or

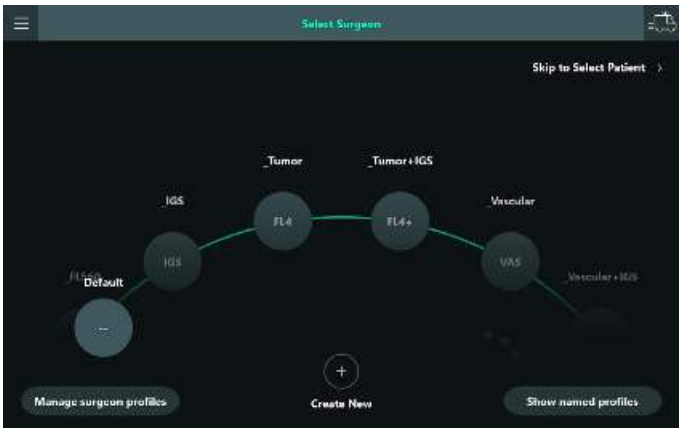
- After tapping "New surgery" on the "End surgery" screen




► Tap on the surgeon profile.
The settings of the selected surgeon profile are activated and the patient selection screen appears.
► Tap "Default" to select a default surgeon profile.
Any changes to the default settings are applied immediately, but will not be stored. I.e. the next surgery using this default profile will start with the original factory settings again.
► Tap "Skip to Select Patient" to skip the profile selection.
The default surgeon profile is activated and the patient selection screen appears.
► Tap "Create New" to create a new surgeon profile (see chapter 9.1.2 "Create new surgeon", page 49).

**Preset profiles**

When the user taps "Show preset profiles", a "wheel" of preset profiles appears, depending on the installed licenses:



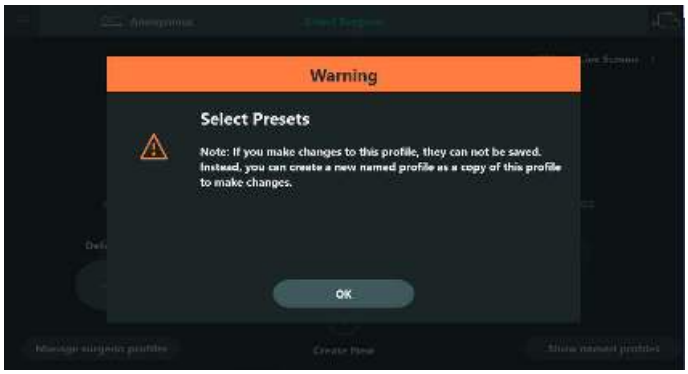

| Preset name | Preset acronym | Handle configuration for preset | Dependent on license to be installed |
|---|---|---|---|
| _Vascular | VAS | Left joystick:<br>• left: GLOW800<br>• right: play loop<br>• down: prior loop<br>• up: empty<br>Right joystick:<br>• default | "GLOW800" |
| _Vascular+IGS | VA+ | Left joystick:<br>• left: GLOW800<br>• right: play loop<br>• down: prior loop<br>• up: empty<br>Right joystick:<br>• left: IGS left<br>• right: IGS right<br>• up: IGS up<br>• down: IGS down | "GLOW800" |
| _Tumor | FL4 | Left joystick:<br>• left: FL400<br>• up, down, right: empty | "FL400" |
| _Tumor+IGS | FL4+ | Left joystick:<br>• left: FL400<br>• up, down, right: empty<br>Right joystick:<br>• IGS (see above) | "FL400" |
| _FL560 | FL5 | Left joystick:<br>• left: FL560<br>• up, down, right: empty | "FL560" |

| Preset name | Preset acronym | Handle configuration for preset | Dependent on license to be installed |
|---|---|---|---|
| _IGS | IGS | Left joystick:<br>• left: IGS left<br>• right: IGS right<br>• up: IGS up<br>• down: IGS down<br>Right joystick:<br>• default | |

There are two ways of making use of these profiles:

**Direct use**

In this case, the profile can be used and modified, but any changes to the user settings will not be stored, i.e. the same default settings will be applied to the next surgery using this profile. After choosing one of these profiles, a pop-up will appear to notify the user about this fact.

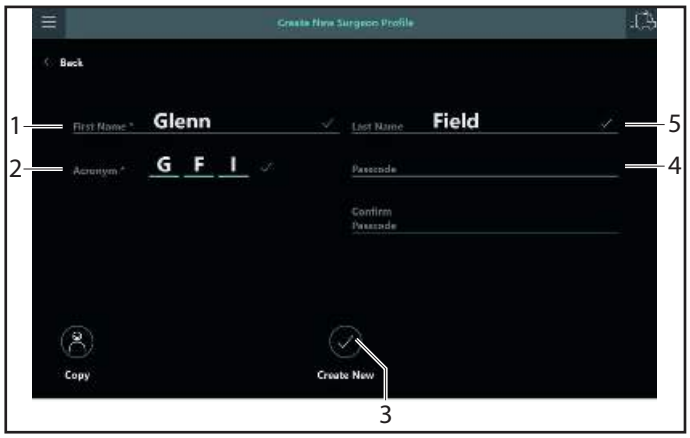



**Use as copy**

By making use of the "copy from profile" functionality, users can create a new profile as a copy of these presets. See next section.

### 9.1.2 Create new surgeon

► In the "Create New Surgeon Profile" dialog, fill out at least the mandatory data for a surgeon profile, i.e. first name (1) and a unique three-letter acronym (2).




► Fill out the other items optionally: Last name (5) and, if required, a passcode (4) to protect this profile from unintended changes.

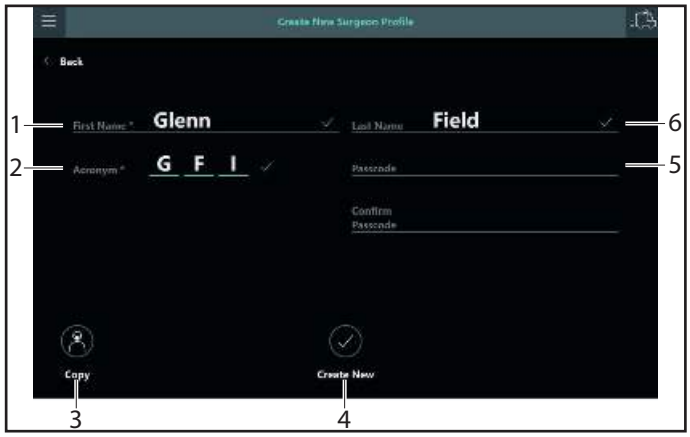
► Tap "Create New" (3) in order to create it and you will see the "Select Patient" screen.

**Copy from profile**




► Tap "Create New" in the "Select Surgeon" menu.

► In the "Create New Surgeon Profile" dialog, fill out at least the mandatory data for a surgeon profile, i.e. first name (1) and a unique three-letter acronym (2).




► Fill out the other items optionally: Last name (6) and, if required, a passcode (5) to protect this profile from unintended changes.

► Tap "Copy" (3).
The list of existing profiles appears with the preset profiles first.

Note that you can choose from both presets and existing surgeon profiles.

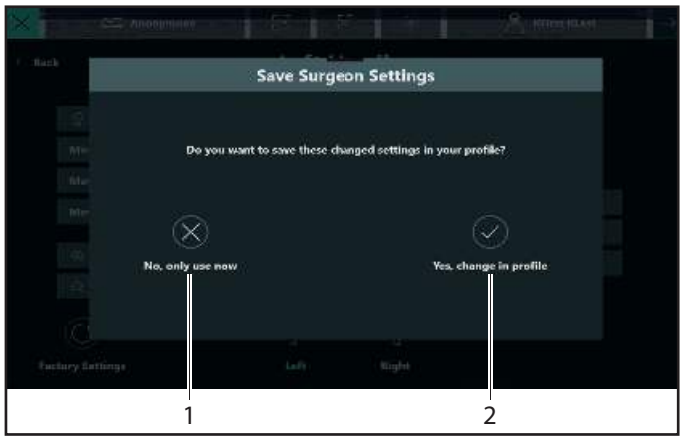
► Choose one of the items to copy from and tap "OK" or cancel with ✕.

► Tap "Create New" (4) in order to create the new profile and you will see "Select Patient" screen.

If you want to change an existing surgeon profile, e.g. by changing the name or removing a passcode, you can create a new profile as a copy of the existing one, and hide the existing one.

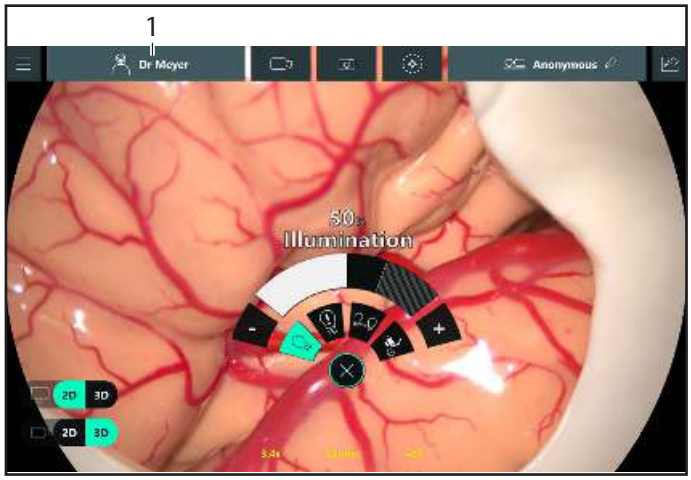
### 9.1.3 Applying changes to a surgeon profile

You can then continue on the "Live screen" with the chosen surgeon profile. If no preset or default profile has been chosen, then after any changes applied to any user settings, the system will ask whether the changes shall be saved to the profile or not.




| | |
|---|---|
| No, only use now (1) | The settings will be applied to the current surgery, but will revert to the stored settings the next time the user chooses this profile. |
| Yes, change in profile (2) | The settings will be stored in the system, and if this profile is chosen in a future surgery, the changed settings will be applied. |

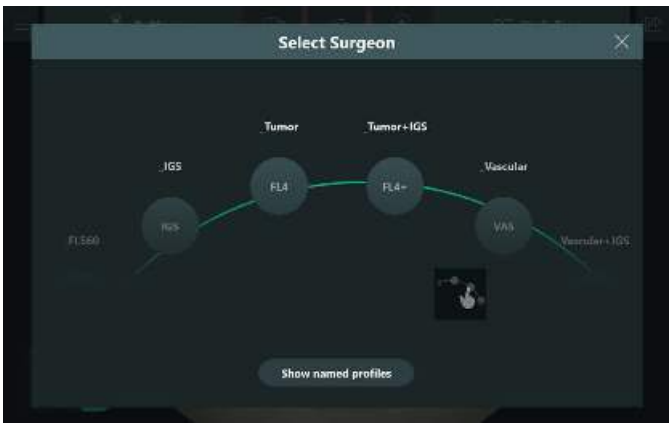
### 9.1.4 Change the surgeon profile during surgery

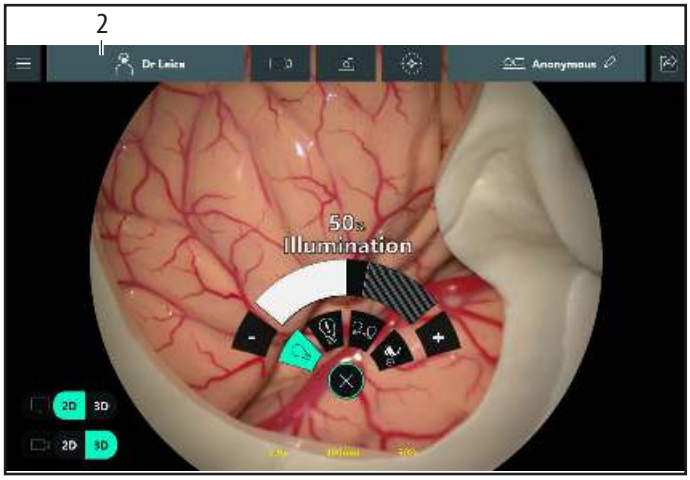



- To change the selected surgeon profile during a surgery, tap the surgeon name (1) in the title bar.




- Choose a different surgeon profile in the "wheel" (currently active surgeon profile is not shown in the list) and tap on it. The settings of the newly selected surgeon profile (2) are activated and the surgeon name is updated in the title bar
- To choose a preset profile, tap "Show preset profiles" to show the "wheel" of preset profiles.

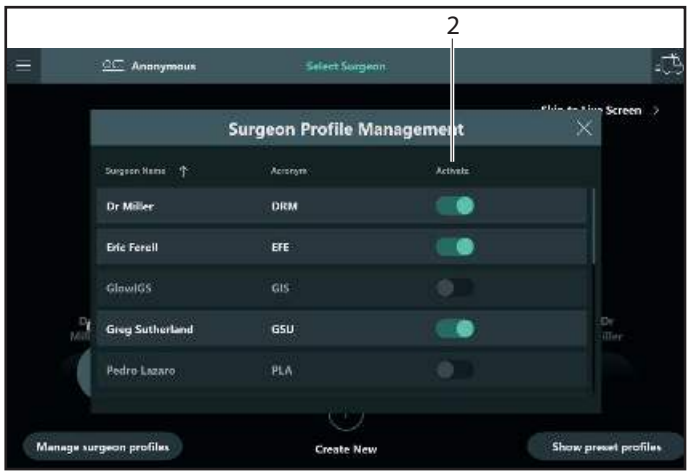


### 9.1.5 Deactivate or reactivate surgeon profiles




► Tap "Manage surgeon profiles" in the "Select Surgeon" menu.
A dialog appears where the user can choose profiles and deactivate or reactivate them.




► Tap the toggle "Activate" (2) to deactivate or reactivate the respective profile(s).
A dialog appears for confirmation.

- Deactivated profiles will **not** appear in the list of surgeon profiles on the "Select surgeon" screen, nor on the list of profiles to copy from.
- Note that any user can deactivate or reactivate any surgeon profile.

### 9.1.6 Surgeon settings versus system settings

Note that only certain settings are stored as surgeon settings and can be saved in surgeon profiles. System settings are **not** stored in surgeon profiles. Anyone can change them at any time, and any change will affect any user, independent of their chosen surgeon profile.

These settings are saved in surgeon profiles:

- Handle configuration
- Foot switch configuration
- Basic settings:
  - Selected brakes: Individual, Cranial or Spine
  - Microscope data: On vs. Off
  - Auto Focus: On vs. Off (only during whitelight and GLOW)
  - SpeedSpot: On vs. Off (only during whitelight and FL560)
  - 3D Display: 3D vs. 2D (only if 3D license is installed)

BrightCare in whitelight can be deactivated, but will be on by default the next time the system is started.

- AR settings:
  - For GLOW800:
    - Color (Blue, Green, Off)
  - Brightness - IGS as Overlay
  - Endoscope: enable or disable picture-in-picture
- Fluorescence settings:
  - For GLOW800:
    - Lower/Upper threshold
    - Intensity
    - Excitation (start value for Illumination in this mode)
    - BrightCare for GLOW
  - For each of FL400/FL560:
    - Excitation (start value for Illumination in this mode)
- View configuration:
  - For GLOW800:
    - Full screen, Picture-in-picture, Side-by-side
    - Applied to Pseudocolor image
    - Applied to Monochrome image
- Start Settings
  - Start Values
  - Motor Speed Settings
- Recording Settings: choose the file type for pictures

All other settings are system settings.

## 9.2 Personalized settings

In the "Surgeon Settings" menu, you can configure all settings necessary to work with the ARveo 8x.

► Tap the main menu ☰ → select "Surgeon Settings".




### 9.2.1 Set handles and foot switch

Here, you can configure individual settings for each user for your handles and the optional foot switch.

► Main Menu ☰ → "Surgeon Settings".

► In the "Surgeon Settings" menu select "User Inputs".

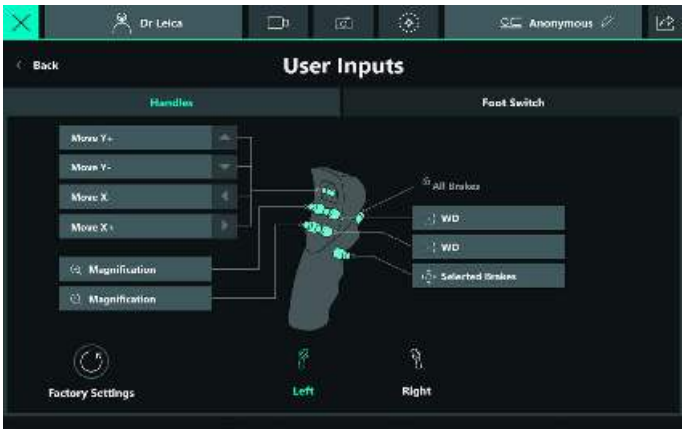



**Configuring the handles**

► In the menu at the bottom, tap "Left" or "Right".

The selected "Left Handle" or "Right Handle" is indicated with a green icon.

► Click the selection field of the desired key on the handle.

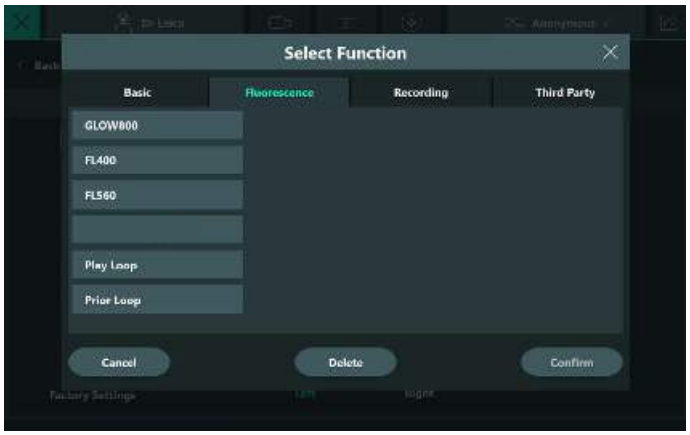


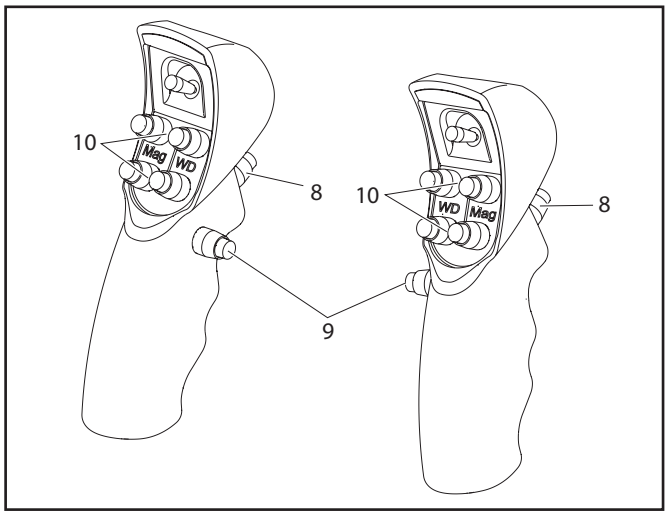

The following selections can be made for handles:

**Basic**

| | |
|---|---|
| Move X/Y +/- | Fine tuning of the optics carrier – activating the lateral movement |
| Lamp +/- | Lamp brighter (+). In GLOW800 and FL modes, this corresponds to increased "Excitation Intensity"<br>Lamp darker (-) |
| Magnification +/- | Increase/reduce magnification |
| WD +/- | Increase/reduce working distance.<br>Bring into sharp focus in eyepiece and on the monitor. |
| Microscope Data | Overlay of microscope data as a line of text on the screen (on/off) |
| Auto Focus | Manually trigger the Auto Focus. |
| Lamp On/Off | Turn on/off the lamp. |
| Digital Zoom Toggle | Toggle through the 3 digital zoom modes. |




The "All Brakes" function is always assigned to the rear switch (8) for both handles and can neither be overwritten nor deleted. Selected brakes function can only be assigned to the switch (9).

We recommend to keep the MAG & WD functions programmed to the pre-programmed buttons (10).

**Fluorescence**

GLOW800, FL400, FL560 toggle are enabled or disabled.

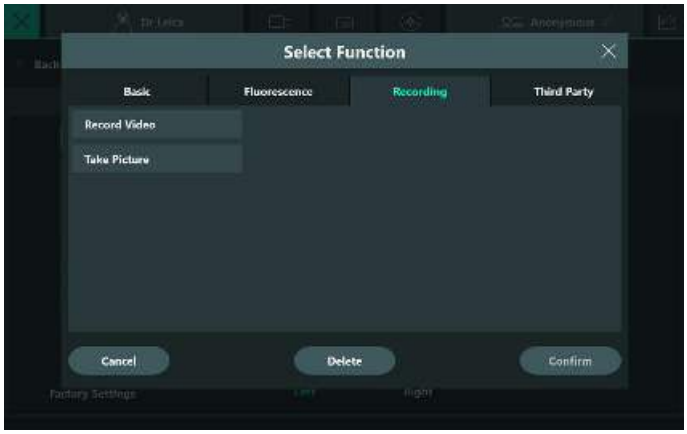
Prior Loop — Only for GLOW800:
Play back the previous (in chronological order) GLOW video loop of this operation.
Can be repeated until the first GLOW video loop (for an explanation, see chapter 9.7 "Setting up fluorescence products", page 61).

Play Loop — Only for GLOW800:
Play back last GLOW video loop (for an explanation, see chapter 9.7 "Setting up fluorescence products", page 61).

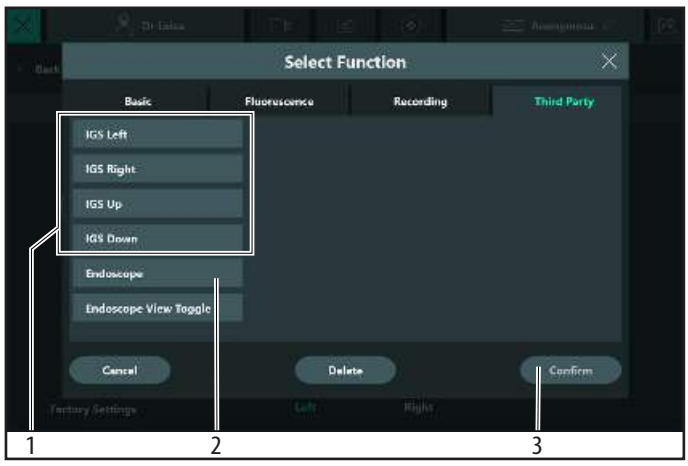
**Recording**

Record Video — Video start/stop

Take Picture — Create a live camera image



**Third Party**




IGS (x4) (1) Function allocations are defined in the navigation system.
Each function is a "remote control" of the navigation system

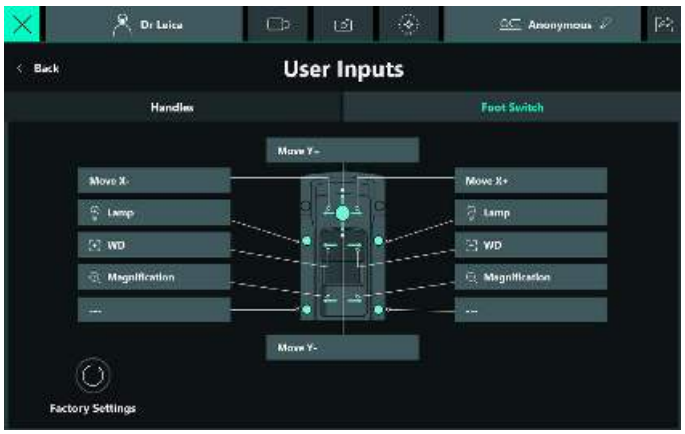
The default configuration is as follows. Right and Left joystick:
- IGS left = Left
- IGS right = Right
- IGS up = Up
- IGS down = Down

The "Endoscope" function (2) activates the display of the endoscope on the monitor. The "Endoscope View Toggle" allows to toggle through picture-in-picture visualizations (see chapter 9.6.2 "Endoscope", page 60).

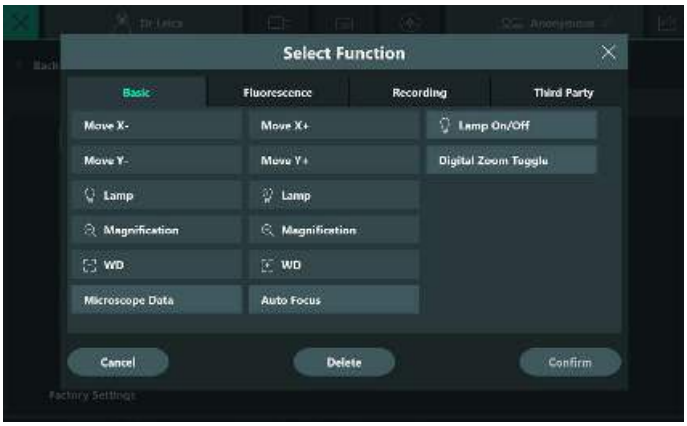
► Select the desired function and apply with "Confirm" (3).
The selected function is displayed in the selection field.

**Configuring the foot switch**

► Change to the "Foot Switch" tab and tap the selection field of the desired key on the foot switch.

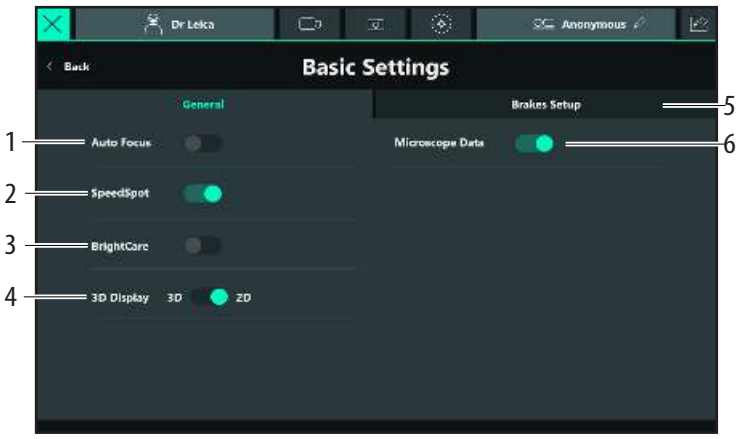



The following selection menu opens:




► Select the desired function and apply with Confirm (1).
The selected function is displayed in the selection field.
The selections are identical to those for the handles with the exception of the brakes (see chapter "Configuring the handles", page 52).

### 9.2.2 Basic settings



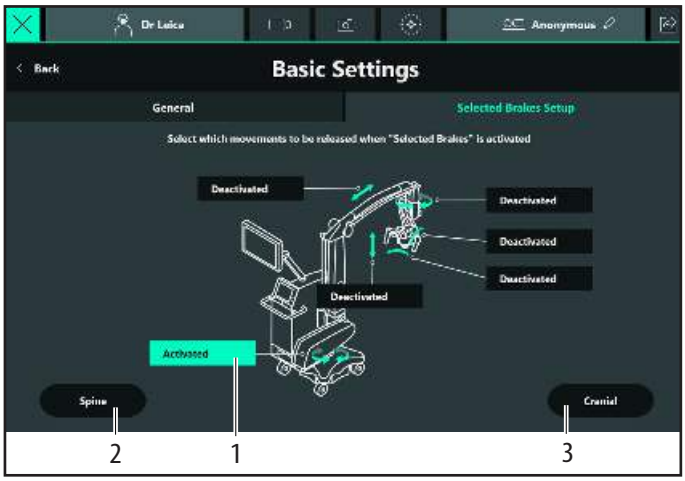

| | | |
|---|---|---|
| 1 | Auto Focus* | Auto Focus on/off<br>The Auto Focus only works when the microscope is positioned in a working distance between 225–600 mm. |
| 2 | SpeedSpot* | SpeedSpot on/off (see chapter 4.5 "Leica SpeedSpot", page 18) |
| 3 | BrightCare | BrightCare Plus on/off (see chapter 4.3.2 "BrightCare Plus", page 17) |
| 4 | 3D Display | Toggle between 3D and 2D (see chapter 5.7.2 "3D 4K stand monitor", page 25). |
| 5 | Brakes Setup | Toggle the brakes individually or use the predefined selections for Cranial and Spine types of operation (see chapter 4.2 "Brakes", page 16). |
| 6 | Microscope Data | Display the microscope data overlay on the monitors. |

* For constraints depending on the fluorescence mode, see following table:

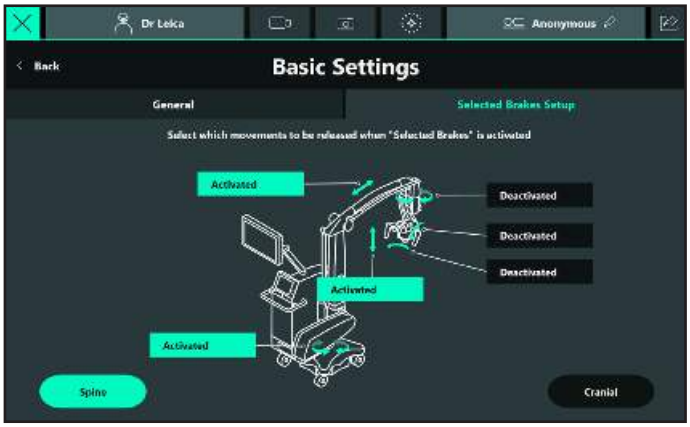
| | SpeedSpot | Auto Focus | Limit defaults | Limitations of WD and Mag – access |
|---|---|---|---|---|
| **Whitelight** | User toggle | User toggle | – | – |
| **GLOW800** | OFF | User toggle | 6x at WD 325mm | Setting reserved for "Sales" (Application specialist) users only. Requires separate log-in. |
| **FL400** | OFF | OFF | 7x at WD 350mm | |
| **FL560** | User toggle | OFF | 8x at WD 400mm | |

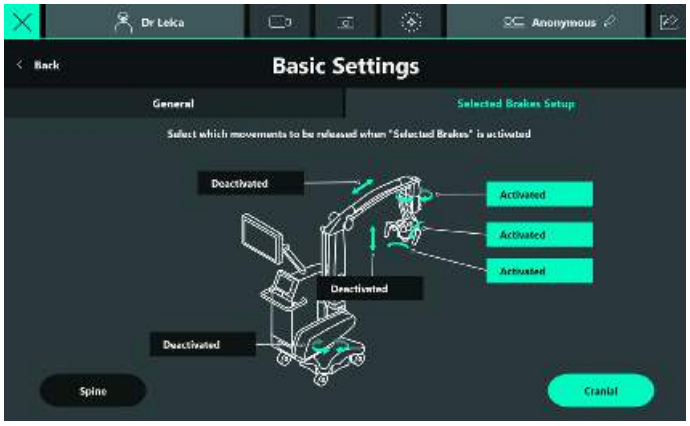
**Selected Brakes Setup**

In this tab, you can select which movements to be released when the "Selected Brakes" is activated from the handles (see chapter 4.2 "Brakes", page 16).




- ► To configure individual brakes, tap on the "Activated" or "Deactivated" button (1) to toggle the state.
  Activated brakes are highlighted in green.
- ► Alternatively, you can choose between 2 predefined brake selections for Spine (2) and Cranial (3). See chapters 4.2.1 "Selected Brakes – Spine", page 17 and 4.2.2 "Selected Brakes – Cranial", page 17 for details on these selections.



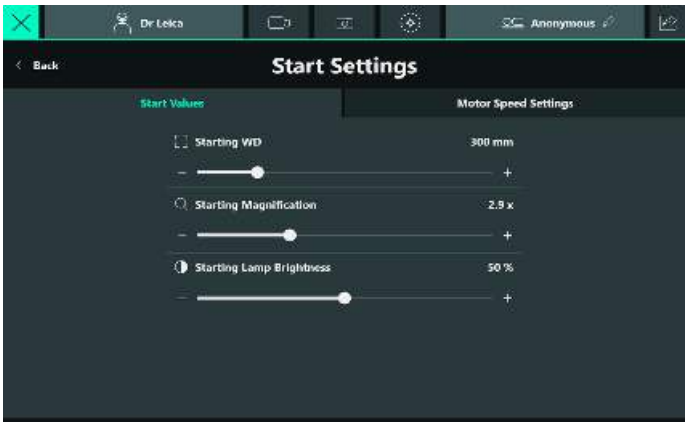

## 9.2.3 Start settings

In the "Start Settings" menu, you can define settings related to the M530.

- ► Open the "Start Settings Menu" as follows:
  Main Menu ☰ → "Surgeon Settings "→ "Start Settings".

**Start values**

For the selected surgeon profile, you can set the start values for the lamp brightness, working distance (WD) and magnification on the “Start Values” tab. These settings define the values, to which the microscope is set when a new surgery is started. Changes to these values will only get effective in the next surgery.




- ► To change the values, tap + or – or move the slider to the desired value.

**Motor speed settings**

You can set the travel speed of the magnification, working distance and XY motors on the "Motor Speed Settings" tab. Changes to these settings are effective immediately and will also be used for subsequent surgeries.



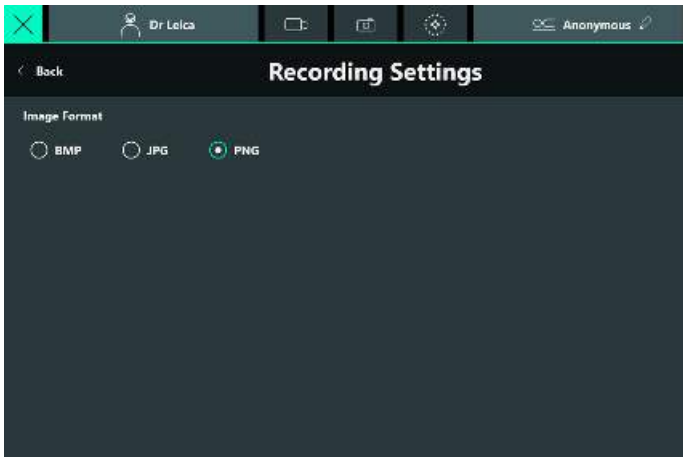

- ► To change the values, tap + or – or move the slider to the desired value. If "WD Speed linked to Magnification" is activated, the focus speed automatically adapts to the current magnification.

| | |
|---|---|
| High magnification: | low speed |
| Low magnification: | high speed |

### 9.2.4 Recording settings

In the "Recording Settings" menu, you can define the file format in which the pictures (see chapter 10.1 "Take pictures", page 62) should be stored.

► Open the "Recording Settings" menu.
Main Menu ☰ → "Surgeon Settings" → "Recording Settings"




► Choose the file format. There are 3 options for file format in which taken pictures are stored:
- BMP: uncompressed picture with large file size
- JPG: lossy compressed picture with small file size
- PNG (default): lossless compressed picture with medium file size

## 9.3 Further microscope settings

These settings are bound to the microscope and not part of customized surgeon settings, see explanation in chapter 9.1.6 "Surgeon settings versus system settings", page 51.

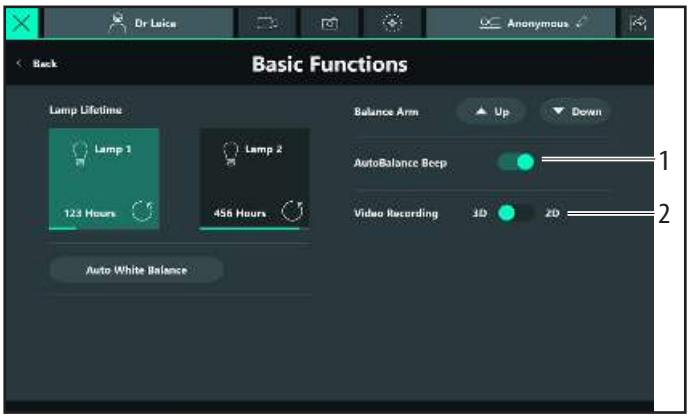
► Tap Main Menu ☰ → "System Settings".




### 9.3.1 Basic Functions

In the Basic Functions menu you can configure the following settings:
- Autobalance Beep
- 3D recording

► Open the Microscope Settings Menu as follows:
Main Menu ☰ → "System Settings "→ "Basic Functions".

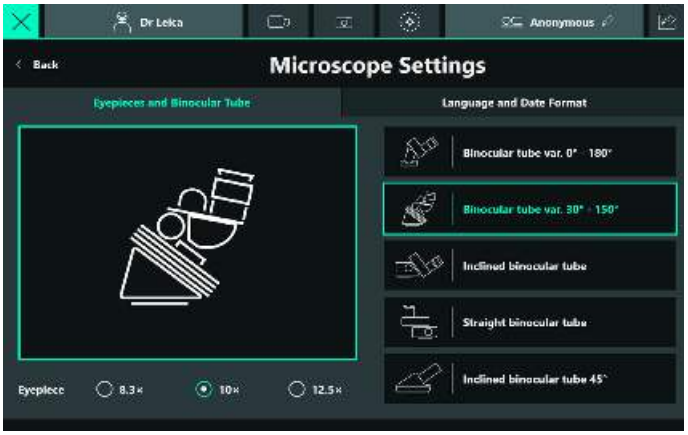



1 Autobalance Beep: toggle on/off the beeping sound during autobalancing.
2 Video Recording: toggle between 3D and 2D recording (see chapter 5.7.4 "3D file recording", page 25).

## 9.4 Microscope settings

### 9.4.1 Eyepieces and Binocular Tube

► On the "Eyepieces and Binocular Tube" tab, configure the installed eyepieces and binocular tube for the main surgeon. This ensures the correct calculation and display of the Magnification value.




### 9.4.2 Language and Date Format

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




The following languages are available for the GUI:

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

The date format can be changed between DD-MM-YYYY and MM-DD-YYY

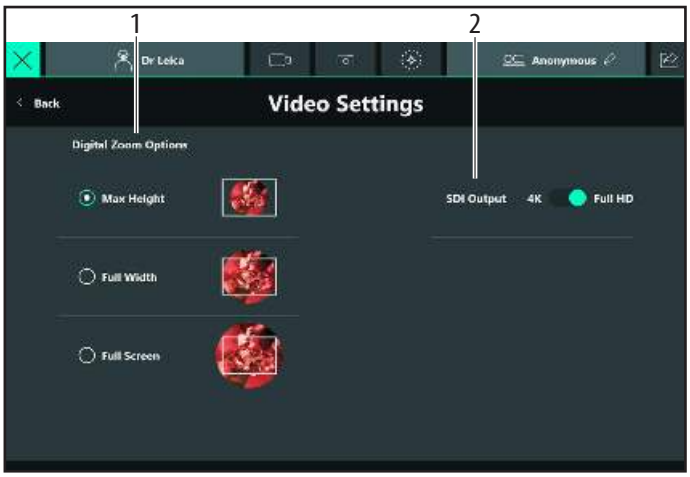
DD: day of the date as two-digit value
MM: month of the date as two-digit value
YYYY: year of the date as four-digit value

The time format can be changed between 12 h and 24 h format. When set to "12 h", the time will be represented with the addition of "AM" and "PM" to indicate the time of the day.

### 9.4.3 Video Settings

In the "Video Settings" menu, you can configure the following settings:

- Digital zoom mode
- Video resolution for SDI OUT (see chapter 5.3 "Terminals", page 21)




► Open the "Video Settings" menu as follows:
Main Menu ☰ → "System Settings" → "Video Settings".

**Digital Zoom Options (1)**

With "Digital Zoom" the display format is adjusted to your needs. There are 3 formats available which can be selected. See the image next to the selection for a representation of the respective mode. Default setting is "Max Height".

**Max Height**

Fits the maximum detected field of view in the center of the screen of the connected monitors.

- nearly round image format

**Full Width**
Fits the full horizontal field of view on the screen of the connected monitors.
- format with rounded edges

**Full Screen**
Fits the diagonal of the field of view into the diagonal of the screen of the connected monitors.
- rectangular image format

The digital zoom mode can also be changed by using the "Digital Zoom Toggle" function assigned to a handle or foot switch key (see chapter 9.2.2 "Basic settings", page 55). Activating this function toggles to the next digital zoom mode.

**SDI Output (2)**

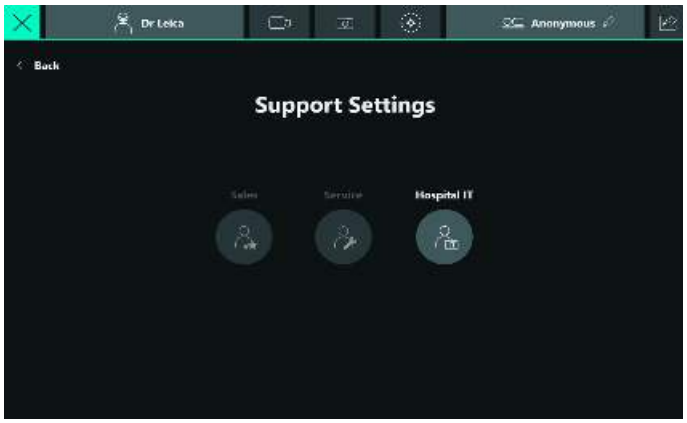
► Tap the control to switch the video resolution of SDI OUT between Full HD and 4K. The 4K option requires a monitor supporting 12G-SDI video input.

## 9.5 Settings for Leica authorized personnel

Certain settings are reserved for dedicated user groups who require reserved authentication (individual password) or protected dongle access.
These are the following:
- Hospital IT: One or more persons in the hospital who can manage all users who have access to patient information, as well as configuration of auto-deletion of data and activation/ deactivation of password protection for access to patient information.
- Leica authorized personnel such as sales personnel, application specialists and service personnel.

### 9.5.1 Hospital IT

► Main Menu ☰ → "Support".
The following menu appears:




One person in the hospital must have access to the "Hospital IT" menu. This function is password-protected.

► Tap "Hospital IT".
The login menu for the Hospital IT appears (username and password).

The password for the Hospital IT role is provided in chapter 11.2 "User types", page 75. The first time a user logs in, this password must be changed to an individual, instrument-specific one that must be written down for safekeeping.
After the password is entered, the Hospital IT functions are enabled, all of which can be accessed by the user.




► In the "Hospital IT" menu, select the "Settings" menu.

In the "Settings" menu, you can configure the "Auto-Deletion" and "Removal of patient data protection" as well as User Management functions and password requirements. You can find additional information on Hospital IT in chapter 11 "Hospital IT user", page 74.

### 9.5.2 Sales

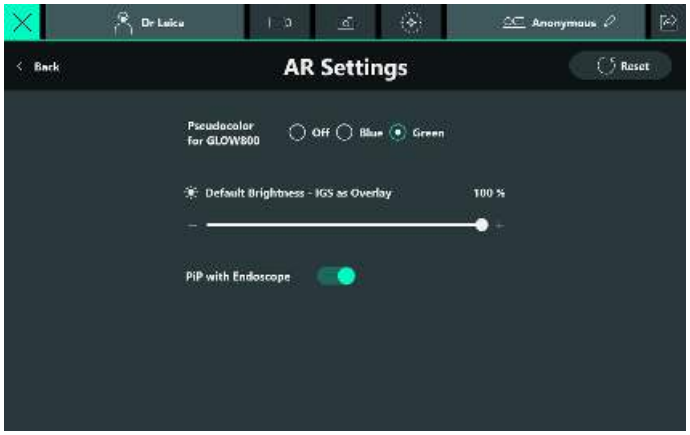
The following functions require a login with a protected dongle by a Leica specialist with separate access:
- Setting for navigation systems
- Zoom range limiter - setting the limit of the magnification
- Configuring special fluorescence settings, e.g. limits for magnification and focus
- Fine adjustment of the video display
- 3D calibration of the GLOW display on the screen. This is necessary if the GLOW display does not match the microscope image or appears skewed.
- Setting up the DICOM export

## 9.6 Connecting external devices

### 9.6.1 Navigation system (IGS)

Please check with your Leica representative on compatibility of your system with your navigation system.

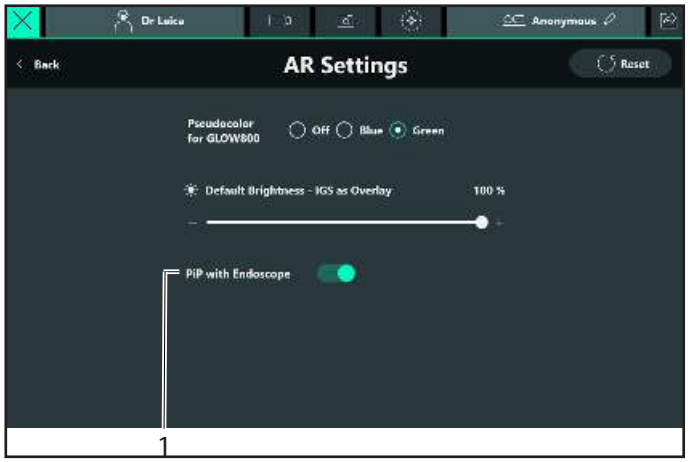
- ► Use handle preset for IGS (see chapter 9.1.1 "Choose surgeon profile", page 48).
- ► Configure brightness of image overlay (Menu AR Settings).




You can set the brightness with which the IGS overlay is displayed on the monitors.

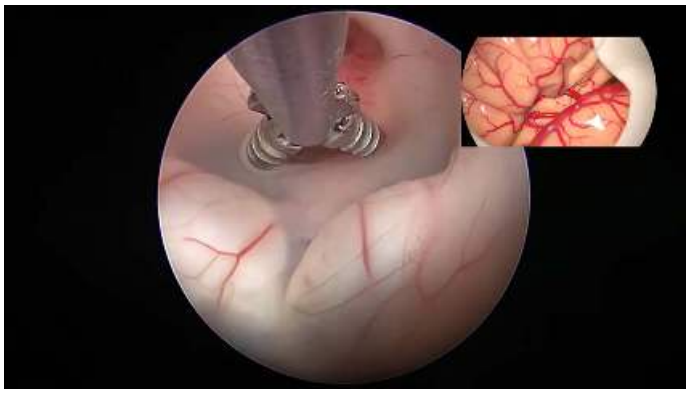
### 9.6.2 Endoscope

- ► Setup handles or foot switch to enable endoscope view and to toggle through picture-in-picture (PiP) visualizations (see chapter 9.2.1 "Set handles and foot switch", page 52). Select function → Third Party.
- ► Configure the PiP view of the endoscope (1) (Menu AR Settings).




- ► Press the handle or footswitch button with the assigned "Endoscope" function to activate the visualization of the endoscope video on the monitors.
- ► When the "PiP with Endoscope" option is disabled, the endoscope is visualized in full screen on the monitors.
- ► When the "PiP with Endoscope" option is enabled, the endoscope is visualized together with the live image as picture-in-picture on the monitors and you can use the "Endoscope View Toggle" function to toggle through the following views in the provided order. When the last view is reached and the toggle function is pressed again, it goes back to the first view.

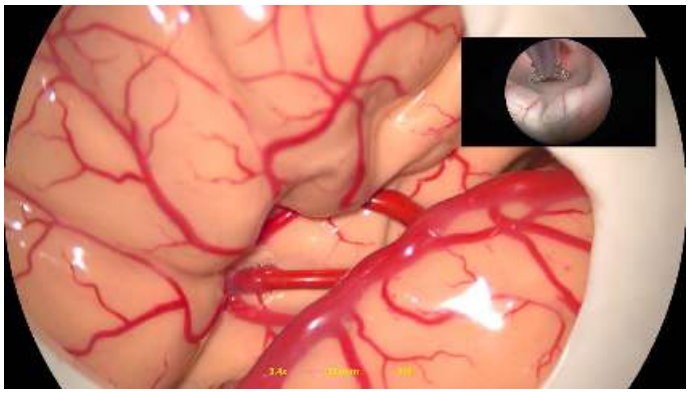
**1. Picture-in-picture view: Endoscope with live image**



**2. Mono view: Endoscope**



**3. Picture-in-picture view: Live image with Endoscope**



- ► Press the handle or footswitch button with the assigned "Endoscope" function again to deactivate the visualization of the endoscope video on the monitors.

## 9.7 Setting up fluorescence products

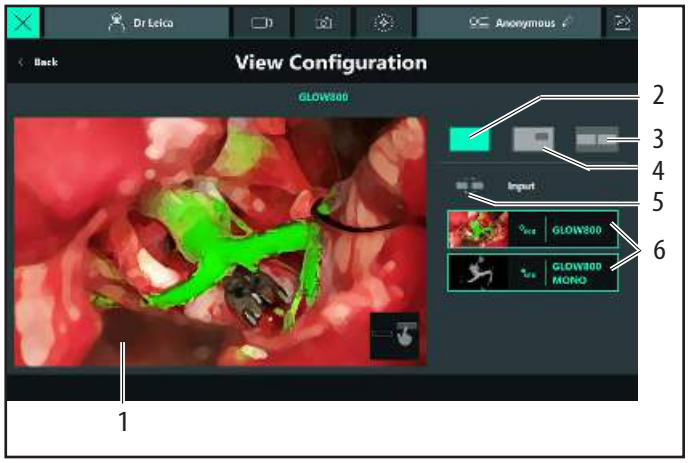
These features require licenses to be installed (see chapter 12.1 "Check installed licenses", page 78).

### 9.7.1 GLOW800

Note that a Leica representative can make further adjustments, using special authentication (see chapter 9.5.2 "Sales", page 59).

**View Configuration**

This menu can be used to configure the screen display in GLOW mode.

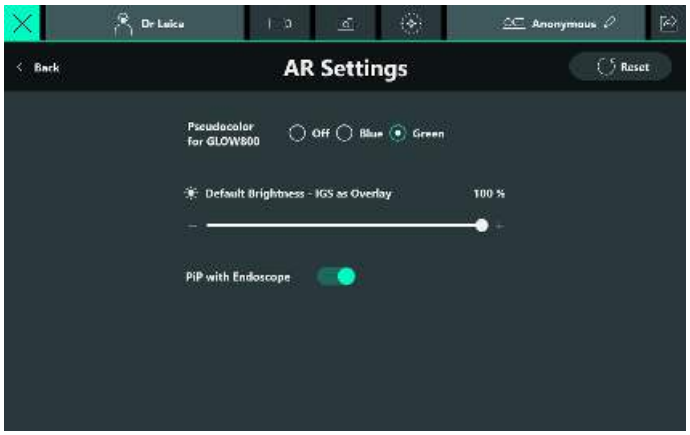



You can choose between the following displays:

- Fullscreen image (1);
  Select the icon (2) and drag one of the two icons (6) into the full screen using drag and drop.
- Picture-in-Picture display;
  Select the icon (4) and drag one of the two icons (6) into the full screen using drag and drop.
- Side-by-side display;
  Select the icon (3) and drag one of the two icons (6) into the full screen using drag and drop.
  You can swap the two images using the "Swap" button (5).

The images shown here are for illustration purposes only and have nothing in common with the actual images during the operation.

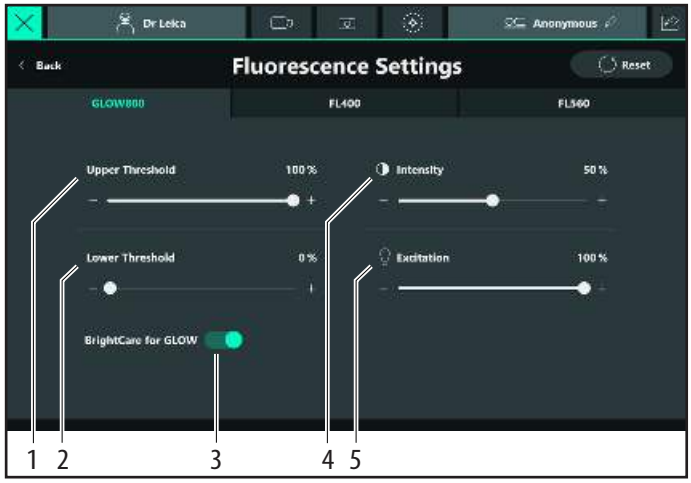
**AR Settings**




- Pseudocolor: Color display in GLOW mode.

A more detailed description of the GLOW800 is provided in the corresponding User Manual.

**Fluorescence Settings**




For GLOW800, you can configure the following values here:

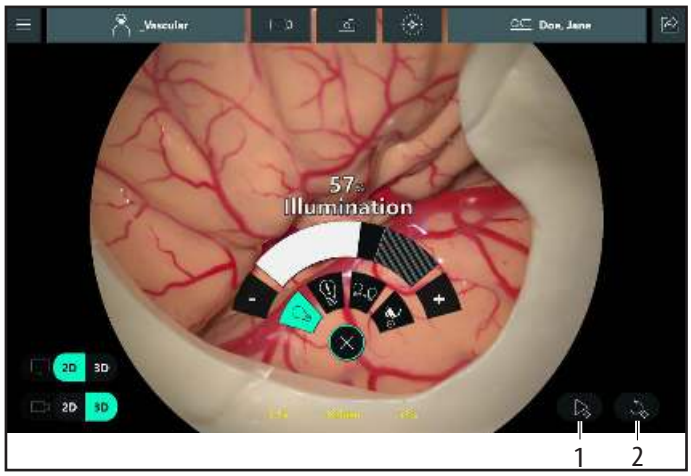
- The start value of the lamp brightness (5)
- The intensity value of the GLOW display (4)
- The upper (1) and lower threshold value (2) of the GLOW display
- BrightCare Plus for GLOW ON/OFF (3)
  Note that BrightCare Plus during GLOW can be switched on and off independently of your BrightCare Plus for whitelight setting (see chapter 7.2.3 "BrightCare Plus", page 41). This setting can be saved in your surgeon profile.

**Play Loop and Prior Loop functions (GLOW800 only)**

You can assign the functions "Play loop" and "Prior loop" on the handles or foot switch. Or you can activate the functions from the touch screen:

- "Play Loop" (1) displays the last recorded GLOW800 video sequence.

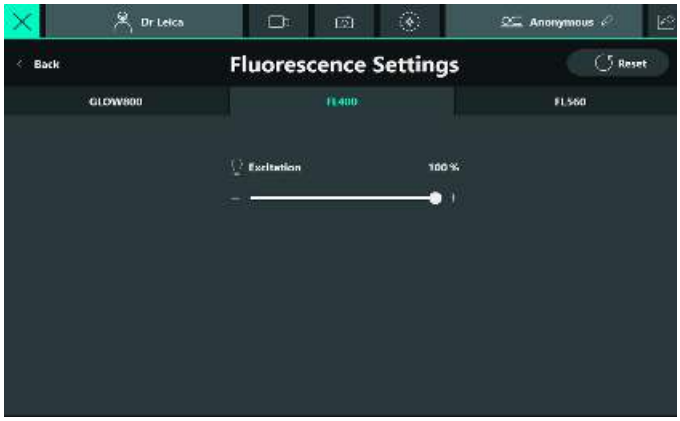
- "Prior Loop"(2) shows the previous GLOW800 video sequence in reverse chronological order. When the first recorded sequence is reached, pressing the button again returns to the last recorded video sequence.




For details on the "Play loop" and "Prior loop" functions, refer to the GLOW800 User Manual.

### 9.7.2 FL400/FL560

**Fluorescence Settings**




For FL400/FL560, you can configure the start value of the lamp brightness here.
For details about this, refer to the FL400/FL560 User Manuals.

Note that a Leica representative can make further adjustments, using special authentication (see chapter 9.5.2 "Sales", page 59).

# 10 Built-in Recording System

## 10.1 Take pictures

**Via handles/foot switch:**
For function assignment, see section "Recording", page 53.

**Via touch screen:**

► Tap the icon in the title bar of the live screen.
The screen flashes white. A photo of the live image is taken and stored.

## 10.2 Start/Stop videos

In case of approaching full hard disk (20 % available), a warning will indicate that data should be deleted to free up disk space. In case of a full hard disk, a warning will indicate that no more video recording is possible. See also chapter 10.6 "Manage recorded surgeries", page 72.

Video recording is enabled automatically in fluorescence modes. This cannot be switched off manually.

**Via handles/foot switch:**
For function assignment, see section "Recording", page 53.

**Via touch screen:**

► Tap the icon in the title bar of the live screen.
Recording starts. The recording time is displayed.
► To stop the recoding, tap the icon again.

## 10.3 Review pictures and videos during surgery

► For a quick review of pictures and videos during the surgery, tap on the patient name or "Anonymous" in the title bar.

Note that recordings can only be accessed from the title bar when the "Live Screen" is in view.

A preview window opens as a pop-up. You can select the Videos or Pictures tab.







► Select the picture or video that you want to preview.
The following menu appears:




From here, you can directly playback recorded videos or review captured pictures on the touch screen. In addition, you can delete single or multiple recordings from this menu.

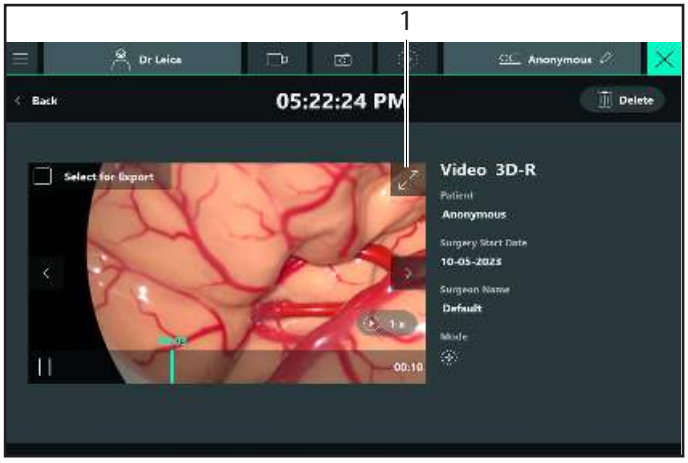
► If you want to review the videos and pictures in full screen on the stand monitor, tap the "Data review" icon in the title bar.
The following menu appears:




► Tap the "Preview & Export" button.




► Select the picture or video that you want to preview.
The following menu appears:




► If you want to display the current video/picture on the stand monitor, then tap on button (1).
In this case, the video/picture will be shown full screen on the touch panel, but also on the stand monitor, marked with a yellow frame.






At any time, you can use the "Back" button to go back to the “End Surgery” screen and you can go back to “Live surgery screen” using the X icon.

## 10.4 Name a patient

**CAUTION**

**Risk of breach to patient's personal information.**

Breach of patient identifying information is a HIPAA violation. Steps must be taken to ensure its integrity.

- ► Take precautions to protect patient data and patient's personal information from unauthorized access and/or use.
- ► Do not leave the system unattended when patient's identifying information is displayed.
- ► When exporting patient data to external storage devices, take steps to ensure the security of the device.
- ► Patient data should be regularly archived to a secure long-term storage location.

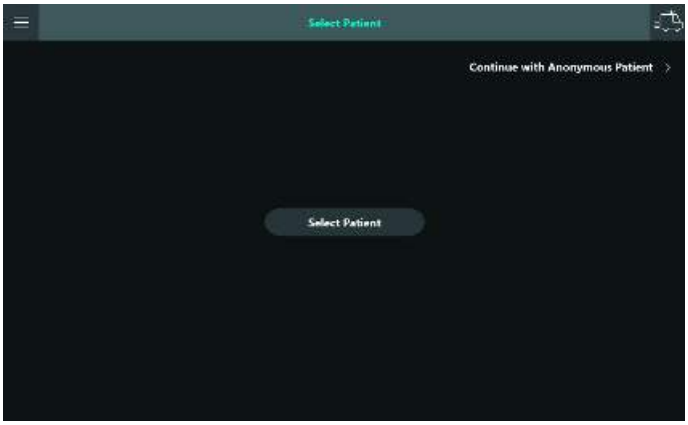
**Risk of damage to the system due to a computer virus.**

- ► Use caution when connecting the system to a network, thumb drive, or other device as the connection could result in the introduction of a computer virus to the system.

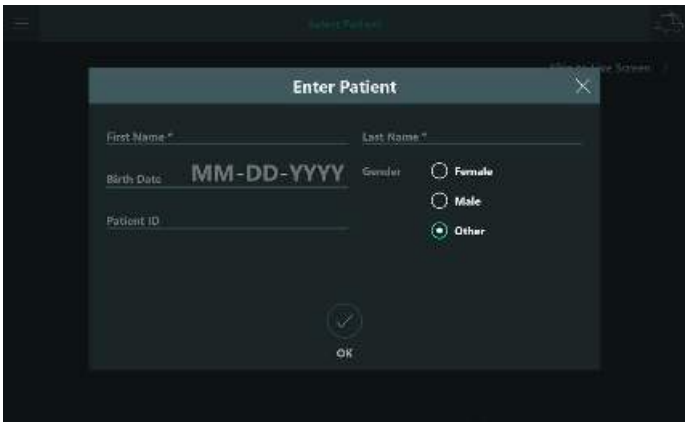
You have the option to enter patient information either before or during a surgery.

### 10.4.1 Name a patient before surgery

After selecting a surgeon profile (see chapter 9.1.1 "Choose surgeon profile", page 48), you are guided to the patient selection screen.




- ► Tap "Select Patient". Log in if needed (see chapter 11.3 "Enabling user management", page 76).



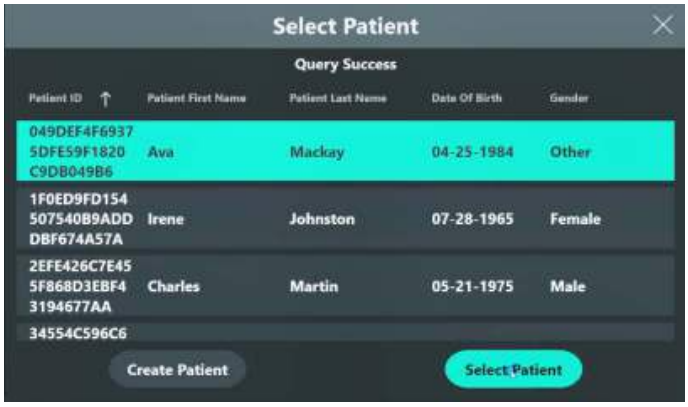

Unless DICOM is enabled, you can now create a patient record with patient name, patient ID, gender, and Birth Date. Note that patient first and last name are mandatory fields, whereas Birth Date, patient ID and gender are optional fields.

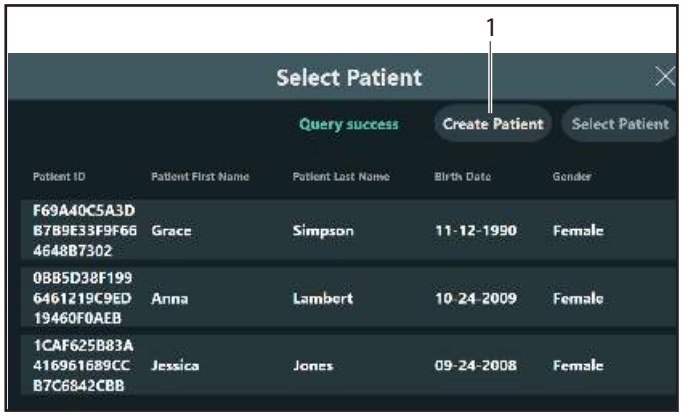
- ► Enter the patient information.
- ► Confirm with OK.

If you have purchased and installed a DICOM license, DICOM has been activated and a Modality Worklist node has been defined,

then you will see a dialog that tries to pull data from the defined "Modality Worklist" after tapping "Select Patient".



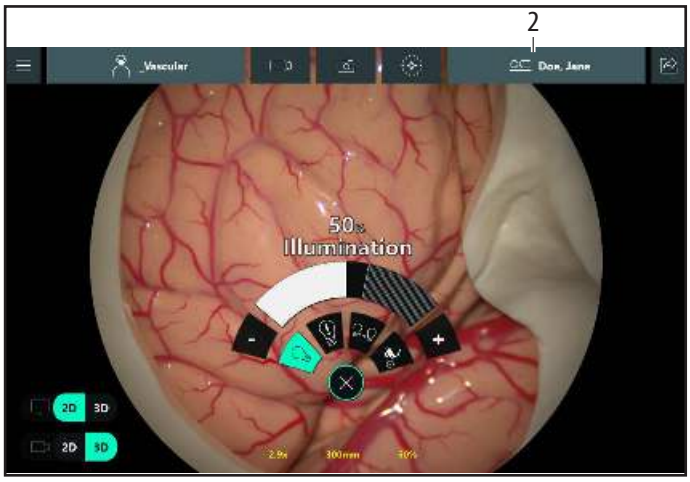




- If the list contains the intended patient, then you can choose this patient by tapping on the entry.
- If the list shows an error message, please first check whether the microscope is physically connected to a hospital network plug using an ethernet cable.
- If that is the case and there is still an error message, please ask your Hospital IT and Leica representative for help.
- If the list does not contain your intended patient, please ask your Hospital IT and Leica representative for help. Note that patients will have to be marked to be scheduled in order to appear in this list.
- In any case, you can also manually create a patient record with patient name, patient ID, gender, Birth Date by tapping on the "Create Patient" button (1).

Note that you will not be able to export the data to DICOM storage for manually created patients

After selecting or creating the patient, the "Live Surgery" screen is shown and the patient name (2) appears in the title bar.

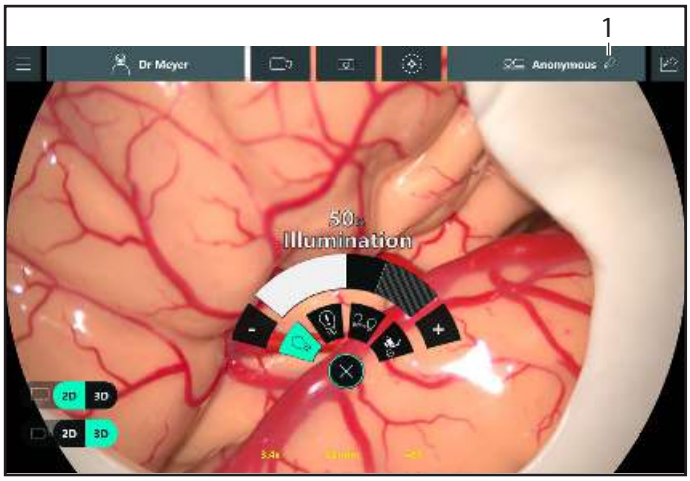



Note that you cannot rename the current or select a different patient during the same surgery. To change the patient, you have to start a new surgery (see chapter 10.5.6 "Start new surgery", page 72).

### 10.4.2 Name a patient during surgery

If the patient selection was skipped after selecting the surgeon profile, a patient can also be named during surgery.

- Tap the pencil icon (1) next to "Anonymous" in the title bar.



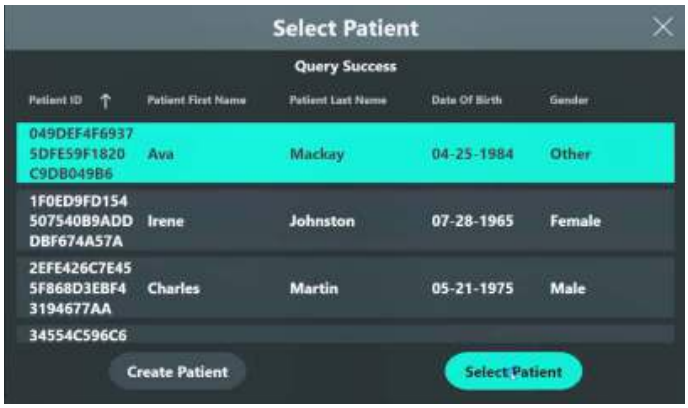

Unless DICOM is enabled, you can now create a patient record with patient name, patient ID, gender, and Birth Date. Note that patient

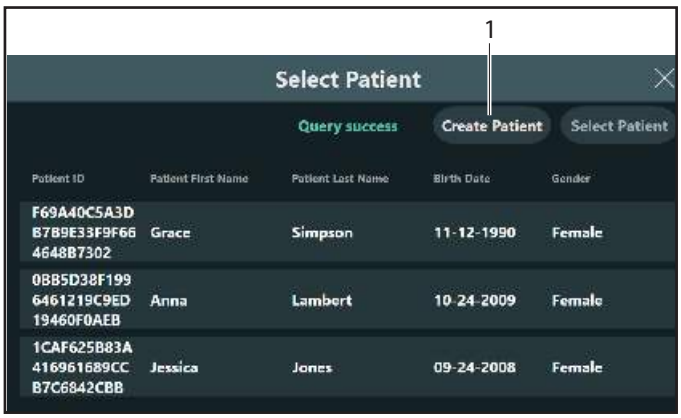
first and last name are mandatory fields, whereas Birth Date, patient ID and gender are optional fields.

- ► Enter the patient information.
- ► Confirm with OK.

If you have purchased and installed a DICOM license and DICOM has been activated and a Modality Worklist node has been defined, then you will see a dialog that tries to pull data from the defined "Modality Worklist" after tapping "Select Patient".



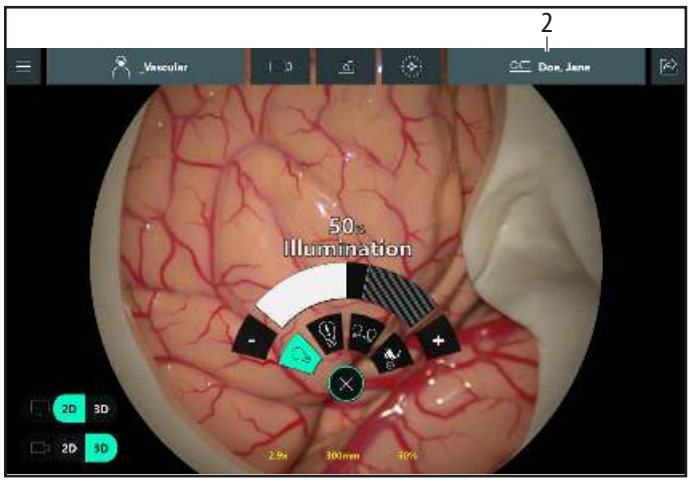




- ► If the list contains the intended patient, then you can choose this patient by tapping on the entry.
- ► If the list shows an error message, please first check whether the microscope is physically connected to a hospital network plug using an ethernet cable.
- ► If that is the case and there is still an error message, please ask your Hospital IT and Leica representative for help.
- ► If the list does not contain your intended patient, please ask your Hospital IT and Leica representative for help. Note that patients will have to be marked to be scheduled in order to appear in this list.
- ► In any case, you can also manually create a patient record with patient name, patient ID, gender, Birth Date by tapping on the "Create Patient" button (1).

**!** Note that you will not be able to export the data to DICOM storage for manually created patients

After selecting or creating the patient, the "Live Surgery" screen is shown and the patient name (2) appears in the title bar.




**!** Note that you cannot rename the current or select a different patient during the same surgery. To change the patient, you have to start a new surgery (see chapter 10.5.6 "Start new surgery", page 72).

## 10.5 Export data

To protect patient information from access by unauthorized persons, use a personal log-in.

Two workflows affected:
- Export of patient information from "End surgery" screen via DICOM (see chapter 10.5.5 "DICOM export", page 70).
- Export of patient information via DICOM from "All surgeries" (see chapter 10.6 "Manage recorded surgeries", page 72).

### 10.5.1 "Export during surgery" versus "Export of data of previous surgeries"

► For exporting data of current surgery, tap the "Data review" icon and then choose "Preview & Export".
► For export of previously recorded surgeries, access Main Menu → "Recorded Surgeries".

Entering patient data requires a login unless this function has been switched off for the entire system in User Management. Normally, access to patient data is protected for privacy reasons.

### 10.5.2 Export data during or after surgery

You can now choose 2 different workflows:
- Export to USB drive (see chapter 10.5.4 "Review, delete, select, export recording data", page 67).
- DICOM export (see chapter 10.5.5 "DICOM export", page 70).

The required log-in to protect access to patient information can be disabled. In order to do that, the Hospital IT user can disable this feature (see chapter 11 "Hospital IT user", page 74). Note that, in this case, the hospital will have to take responsibility to ensure that access to the microscope is restricted to persons authorized to access patient information.

After tapping the "Data review" icon in the upper right corner of the "Live surgery" screen, the current list of created videos and Pictures will be displayed.

Note that you can leave this screen by tapping on the icon in the upper right corner. Note that any currently running video recording will not be displayed in the list. However, you can already start to export all other data.

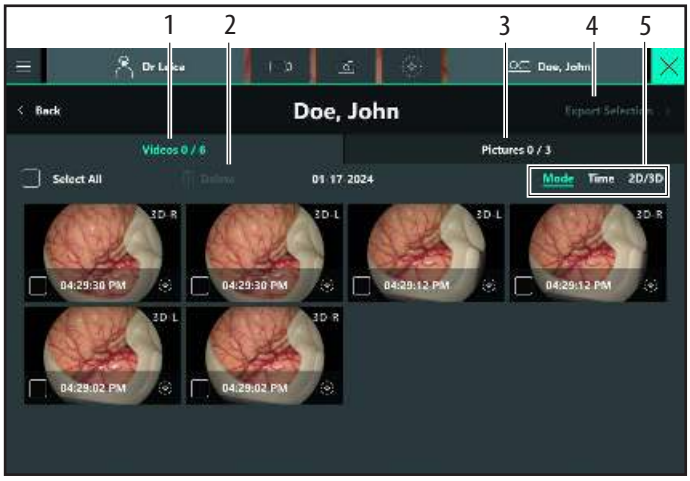
### 10.5.3 Data export targets

Targets can belong to the following groups:
- USB drive,
- DICOM node.

A **USB drive** can be of any form capable to store data (solid state or hard disk). Note that the USB 3.2 Gen 1 (USB3.0) standard is required to allow for high transfer speeds - this is especially relevant when video data files are being exported. Data exported to a USB drive will always be anonymized, no matter if a patient has been named beforehand or not.
A **DICOM node** allows the user to export pictures and videos in DICOM format to a DICOM storage device. These can be set up by your hospital IT together with your Leica Service staff and allows the user to store patient data on a DICOM storage PACS, but this only works if the patient has been chosen beforehand from a Modality Worklist, which also needs to be configured. Note that you have to purchase and install a DICOM license and configure the DICOM export before you can use it.

### 10.5.4 Review, delete, select, export recording data

After tapping the "Preview & Export" button on the "End Surgery" screen, a menu appears that displays all video data (1) in the left tab and the pictures (3) in the right tab.



- You have to select videos from the "Videos" tab and Pictures from the "Pictures" tab separately. The number of selected items will be shown on top of the tab, next to the total number of available items.
- The displayed date is the start date of the surgery. The start date is defined by first tapping on the "Choose surgeon profile" screen after starting the microscope or after tapping "New surgery" on the "End surgery" screen.
- If a surgery happens to start before midnight of that date and further videos/Pictures will be created after midnight, the date will still show the date of the day when surgery started.

**Sort the thumbnails**

You can sort the thumbnails as follows (5):

- by Mode (GLOW800 and FL videos will be first in the list)
- by Time

- or

- by "2D/3D".

**Delete the selected items**

► Tap on "Delete" (2).

The selected items are deleted.

A confirmation dialog will ask you to confirm this step. Note that deleted items cannot be recovered.

**Export selection**

► Tap on "Export selection" (4).

You will be led to the "Select Target" screen to choose the destination of your export.

For an explanation of the 3 diverse types of export targets, see chapter 10.5.3 "Data export targets", page 67.

► Choose an item to export to from the list of Target Drives and confirm.

In case of USB drives, this screen will be shown. It will show the progress of the export process and display when the export was successfully completed.

**Abort the export**

You can abort the export process at any time by tapping on the icon ✕ in the upper right corner or the "Back" button or the "Main Menu button ☰ in the upper left corner.

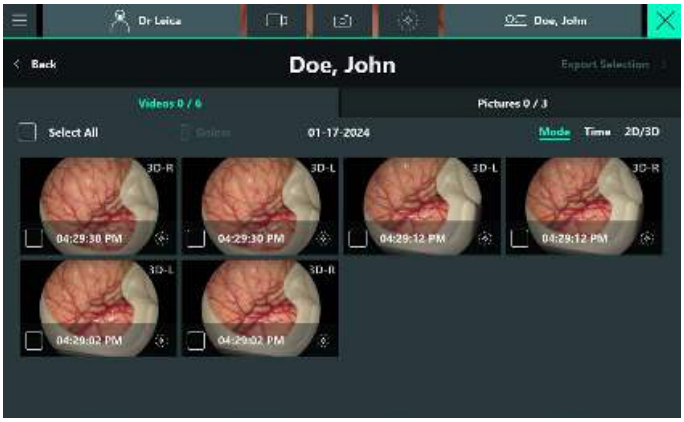
You will then be asked to confirm that you want to abort the export or to continue without aborting.

► You can go back to "Live Surgery" if needed, or proceed to export.

► After export, "New surgery" allows the user to start a new surgery with a new patient (see chapter 10.5.6 "Start new surgery", page 72).

► Select the desired destination and then "Confirm" (1).

For example, a USB drive:




The following screen appears and the green bar indicates the progress of the export process:




The data is being saved. If the patient name was specified earlier, it is displayed. Otherwise, "Anonymous" appears as the patient name.

The following summary appears after the export:




► You can return to "live surgery" view afterwards by tapping "Back" or on the icon ✕.

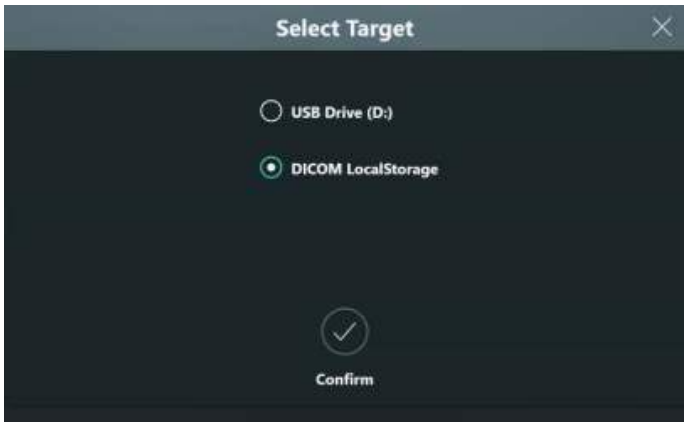
**Possible errors during USB export**

| Reason | Message |
|---|---|
| Insufficient space on USB drive | Not enough space left on target drive.<br>▶ Make space on target drive and try again. |
| Write access denied | Could not export to target drive.<br>▶ Check the write permissions and try again. |
| Drive disconnected during export | Could not export to target drive.<br>▶ Check the drive connection and try again |
| Corrupt file | Could not export data due to corrupt files.<br>▶ Get in touch with hospital IT or Leica Service for help. |
| For any unspecified errors | Could not export data.<br>▶ Get in touch with hospital IT or Leica Service for help. |

### 10.5.5 DICOM export

- This feature requires a DICOM license to be installed (see chapter 12.1 "Check installed licenses", page 78).
- Log in if needed (see chapter 11.3 "Enabling user management", page 76).
- DICOM export is only possible for patients selected from a Modality Worklist beforehand (see chapter 10.4 "Name a patient", page 64), not for manually created patients.

► Follow the workflow in chapter 10.5.4 "Review, delete, select, export recording data", page 67.
► When choosing the target, choose the preconfigured DICOM node.




If you do not see a DICOM target, please ask your Hospital IT and Leica representative for help.

Note that the export dialog will show the total size of exported data as well as the total estimated remaining hours of video recordings that can be stored on the microscope.
Note that the space available on the target drive is not displayed.
In the case of a DICOM export, the size of the exported data is omitted, as it will depend on the DICOM conversion process.

**Possible errors during DICOM export**

| Error Code | Reason | Message |
|---|---|---|
| 7601 | DICOM storage node has reported that data cannot be exported to it because the storage node is out of resources (disk space or other) | Could not export files to DICOM node due to issues with DICOM storage node.<br>▶ Use alternate DICOM storage location or contact hospital IT support. |
| 7602 | DICOM storage node has reported that data cannot be exported to it because of some other issue that requires manual intervention to resolve | An error occurred while executing a DICOM export.<br>▶ Contact hospital IT support. |
| 7603 | Service network quality or connection issue has stopped the export. Issue may be anywhere on network path. | Could not export files to DICOM node due to network interruption.<br>▶ Check network connection to microscope.<br>DICOM export will resume automatically upon network restoration. |
| 7605 | Storage node is not compatible with the file type selected for export or the transfer syntaxes that the microscope is compatible with. | Could not export selected file type to DICOM node.<br>▶ Contact hospital IT support. |
| 7604 * | MWL node has reported that patient information query cannot be completed due to compatibility of request (port change, AE title change or other) | Could not retrieve patient information from MWL.<br>▶ Check network connection to microscope then retry query.<br>▶ Contact hospital IT support if problem persists.<br>Issue preventing MWL query from properly executing.<br>▶ See DICOM log for detailed information, resolve issue, and then retry. |
| 7600 * | DICOM export has resumed after a power or network restoration. | Could not export data.<br>▶ Get in touch with hospital IT or Leica Service for help.<br>DICOM export resumed automatically, no action required. |
| | Less available Dicom space | Could not export files to DICOM node due to issues with DICOM storage node.<br>▶ Use alternate DICOM storage location or contact hospital IT support. |
| | Dicom file type error | An error occurred while executing a DICOM export.<br>▶ Contact hospital IT support. |
| | DataContext not supported | Could not export selected file type to DICOM node.<br>▶ Contact hospital IT support. |
| | Dicom network quality | Could not export files to DICOM node due to network interruption.<br>▶ Check network connection to microscope.<br>DICOM export will resume automatically upon network restoration. |

* Issue list only

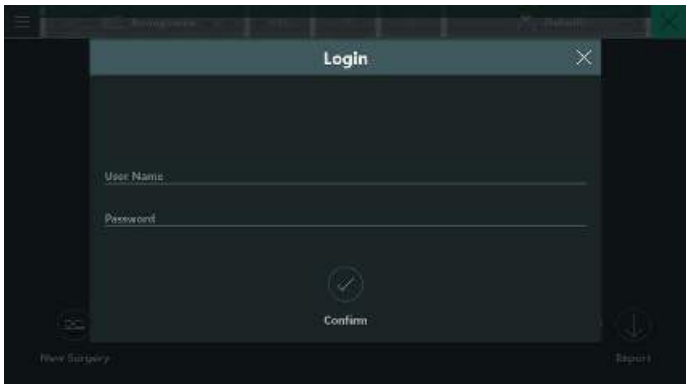
### 10.5.6 Start new surgery




On the export surgery screen you can tap "New Surgery" at any time. When you tap "New surgery" and a recording is still running, or a fluorescence mode is still active, you will be asked to confirm that the recording as well as any fluorescence mode will be stopped before continuing. You will then be guided to the "Select surgeon" screen.
Any newly created video/picture data will then be collected in a new surgery record with the time stamp of this moment as start of the surgery.
You can now export this data either anonymously or as a named entry.

## 10.6 Manage recorded surgeries

► Tap Main Menu ☰ → "Recorded Surgeries".
A login is required only if the last login was more than 20 minutes ago.




► Log in if needed (see chapter 11.3 "Enabling user management", page 76).
You will see a list of previously recorded surgeries (videos/pictures).




The list shows surgery start date and time, patient name, patient ID, surgeon name and size of recorded data.

► Search recordings by patient or surgeon name within a selectable time period.
► Tap the title of a column to sort recordings by the respective field.
► Tap on a list item to select/deselect a recording.
Check marks appear/disappear in the check boxes on the left.
► Tap "Export" to export all videos and pictures of all surgeries marked with a check mark. If only one surgery is selected, the preview menu is opened and the recorded data of this surgery can be reviewed and exported (see chapter 10.5.4 "Review, delete, select, export recording data", page 67).

### 10.6.1 Delete recorded surgeries

Note that deleted items cannot be recovered. All data of these patients including videos, pictures and personal information will be deleted.

► Tap "Delete".
The selected items are deleted. A confirmation dialog will ask you to confirm this step.

### 10.6.2 Export recorded surgeries

► Tap on "Export".
If only one surgery is selected, then the thumbnail overview is shown which allows the user to select and preview data of a single patient.
If several surgeries are selected, all data of these surgeries will be exported and selection of certain videos/pictures is not possible. In this case, the next visible screen after tapping "Export" will be the "Select target" screen.
If multiple items are selected, you can export all. Proceed as described in chapter 10.5.4 "Review, delete, select, export recording data", page 67.

## 10.7 Data management

The hospital is responsible for data management on the hard disk. The system hard disk has a size of 2 TB. You can manually or automatically delete data from the hard disk.

- ► For export of previously recorded surgeries, access Main Menu ☰ → "Recorded Surgeries".
- ► Log-in if necessary.




Note that the color coding of the bar changes dependent on the status. If red, no more recordings can be added (see chapter 10.6.2 "Export recorded surgeries", page 72). Even in GLOW800 mode, GLOW loops will not be automatically recorded any more in this case.
There are two ways to control disk space:

### 10.7.1 Manual Deletion

See also chapter 10.6.1 "Delete recorded surgeries", page 72.

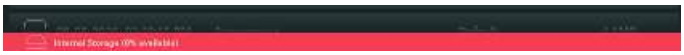
You can then select surgeries for deletion. Note that you can sort the surgery data by disk space. Note that these will be permanently deleted. Leica cannot recover the data after deletion. The disk space indicator bar will inform you of the current status after deletion.

### 10.7.2 Auto Deletion

You can configure an auto-deletion feature which automatically deletes the oldest data on the system until at least 20 % of the hard disk is available again. Configuring this feature requires special authentication of the "Hospital IT" role in the system (see chapter 9.5.1 "Hospital IT", page 59).

At the bottom of the screen, a disk state indicator shows the usage of the hard disk on the microscope. It is displayed in gray until 80 % of the disk is filled. Then it will be displayed in yellow until no additional data can be recorded any more. At this point, it will appear in red (see below).





Note that, at this point, the current surgery can be continued, but no additional video recordings nor pictures can be triggered, neither manually nor from handles/foot switches.

GLOW and fluorescence surgeries automatically activate the recording function. Note that this function will not be active anymore if less than 10 % disk space is available.

# 11 Hospital IT user

## 11.1 The basics

The ARveo 8x microscope complies with the latest data privacy and security standards.
This requires the use of individual personal and instrument-specific passwords to access specific instrument functions.

The basic workflow for setting up and using the system can be used even without a password.

This also ensures compliance with the data protection requirements of all health care providers whereby any access to individual patient information can be traced.
Thus the hospital, as owner of the system, has sole control over all persons with special access. An individual instrument-specific system password is created when handing over and setting up the system and put in writing for secure safekeeping.

**NOTE**

**Danger of noncompliance with data protection requirements!**

- ► For security reasons, make this password available to only one or two specially trained and authorized employees in the hospital.

The password can be reset only by the Hospital IT user or by Leica service.
If the password is known, it can be reset by the Hospital IT role.
If the password has been forgotten, Leica Service can reset the password. This is not possible during an operation. Any operation that is in progress must be interrupted for this purpose.

With the system password, "Hospital IT" users have the special role of controlling who may have access to the specially secured areas of the microscope. They can create new users, deactivate them and reset passwords. In addition, the system password makes it possible to enable and/or disable the "Auto-Deletion" and "Reset login" functions.

## 11.2 User types

The special roles defined in the system are:

| Role | Default User | Default password *) | Functions |
|---|---|---|---|
| Any user, no password | - | – | • Starting the System<br>• Auto-balancing<br>• Selecting, creating, copying, disabling, reactivating surgeon profiles<br>• Changing handle and foot switch functions<br>• Changing basic functions<br>• Creating and storing videos and camera images during an operation (only anonymously) |
| Clinical | Clinical **) | Le1ca_EasySurgery | Access to personal patient information (name, patient ID, birth date) with corresponding image information.<br>This applies to the following tasks:<br>• Entering this data into the system<br>• Exporting the image information (video recordings and camera images) to external data carriers along with the patient name<br>• Deleting this data (individually per video/camera image or as a group).<br>Note that without authorization of the hospital by the "Hospital IT" user, Leica personnel has **no** access to patient information protected in this manner. |
| Hospital IT | IT ***) | Le1ca_WhoHasAccess | • Creating new users<br>• Resetting passwords<br>• Deactivating/reactivating users created earlier<br>• Configure cybersecurity options. Please refer to the cybersecurity instructions 10747996 distributed separately. |

* this is valid **only** when logging in for the first time; afterwards, it must be changed individually

** with the default 'Clinical' user, it is not possible to access personal patient information. When logging in using the 'Clinical' default user, the "Create New User" menu appears and a new user with Clinical role has to be created first.

*** when logging in as the 'IT' default user the first time and after changing the password accordingly, the "Create New User" menu appears and a new user with Hospital IT role has to be created. After that, the default 'IT' user is deactivated and cannot be used anymore.

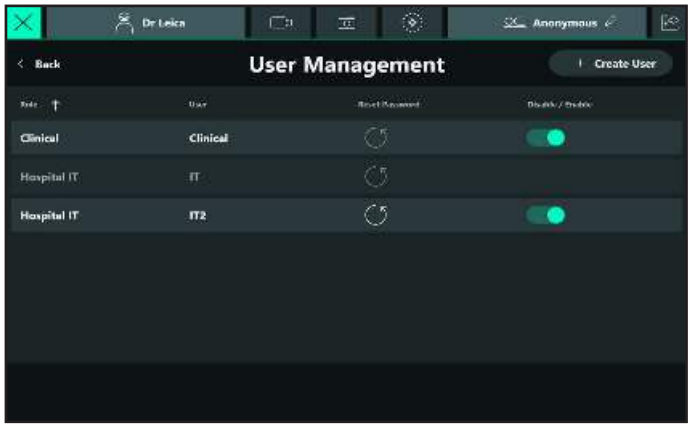
## 11.3 Enabling user management

### 11.3.1 Create a new user

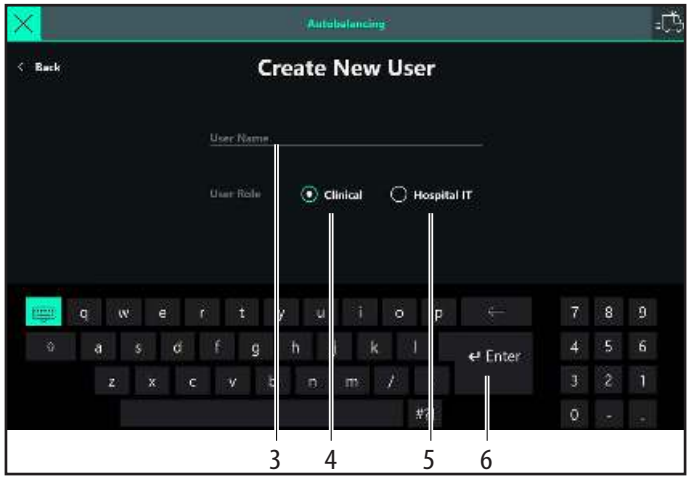
► Call up the Hospital IT menu (see chapter 9.5.1 "Hospital IT", page 59).




► Tap on "User Management".




► Tap the "Create User" button.
The following menu field opens:




► Select the role of the new user: Clinical (4), or Hospital IT (5).
► Enter a user name (3) that is not yet being used on the system.
► Confirm with "Enter" (5).
The newly created user now appears in the list.

### 11.3.2 First use of a user with default password

When entering a new user for the first time, the default password from the table must be used (see chapter 11.2 "User types", page 75). A prompt then appears to enter a new individual password and to repeat the entry with the same password.

Use a secure password with a combination of at least 10 characters with at least one capital letter, one lower-case letter, one number and one special character, if the safe password option is enabled (please refer to the cybersecurity instructions 10747996 distributed separately.). Only the Hospital IT user can reset these passwords to the default password.




You can postpone this entry by clicking the icon ✕ in the top right corner, but the prompt will appear at the next login.

### 11.3.3 Reset password

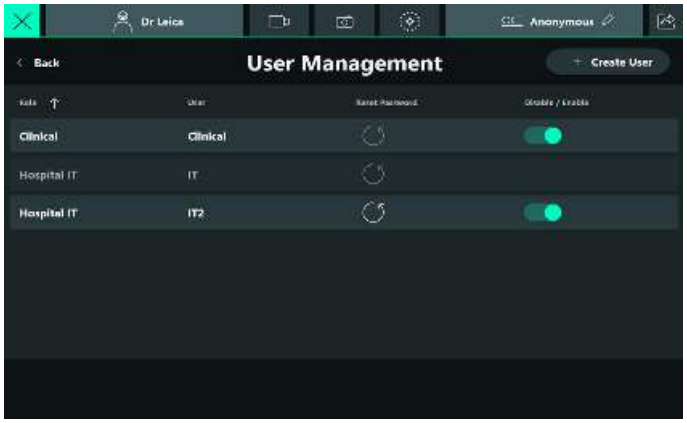
If a user forgets the password or the system has been disabled because incorrect passwords have been entered too many times, the "Hospital IT" user can reset this password.
Exception: Users who have been deactivated cannot have their password reset.

► Go to the "User Management" menu like in chapter 11.3.1 "Create a new user", page 76.
► Tap the reset password icon ↺ of the respective user.
A dialog appear to confirm password reset.
► Tap the icon ↺ again in the dialog.
The password reset is confirmed.
► Create the new password (see chapter 11.3.2 "First use of a user with default password", page 76).
The prompt to create a new password does not appear until this password is needed for the first time after entering the corresponding username and the default password. There are two cases for this:

- Clinical user: When activating the "Recorded surgeries" button or creating/selecting a patient.
- Hospital IT: When entering the "Hospital IT" menu on the "Support" screen.

### 11.3.4 Activate/reactivate users

Hospital IT users can disable users after they have been created and then reactivate them in a later step. Exception: The initial "Hospital IT" user cannot be disabled.




► Tap the toggle "Disable/Enable" for the respective user(s).
A dialog appears for confirmation.

### 11.3.5 Cybersecurity options

Please refer to the cybersecurity instructions 10747996 distributed separately.

## 11.4 Surgeon profile

Surgeon profiles are **not** treated as part of user management. Without entering a password, any user can create new surgeon profiles, copy existing profiles in this process, and disable and reactivate profiles. This does not require "Hospital IT" access.

If someone forgets a passcode for a surgeon profile, a new profile can be created by copying the existing one and creating a new passcode in the process.
Explanation of terms:

Passcode "Passcode" is used for surgeon profiles because these are not subject to any sort of restrictions. They can optionally also consist of only one letter. Surgeon profiles are not subject to any special protection. It should not be possible for others to change a surgeon's preferred settings.

Password Passwords must be classified as secure from a data security standpoint. They must consist of a combination of at least 10 characters with at least one capital letter, one lower-case letter, one number and one special character if the safe password option is enabled (please refer to the cybersecurity instructions 10747996 distributed separately).

# 12 System Information

► Access the "System Information" menu as follows:
Main Menu ☰ → "System Information".

The "System Information" screen consists of 3 tabs:
- Versions (software and hardware versions of the system components and accessories)
- Licenses (software licenses used for the microscope)
- Help (read user manuals for the microscope and installed accessories)

## 12.1 Check installed licenses

Certain functions in the ARveo 8x system are only activated if the following licenses are installed:

| | |
|---|---|
| FL400: | Usage of FL400 mode activation from GUI, handles or foot switch, access to FL400 settings pages |
| FL560: | Usage of FL560 mode activation from GUI, handles or foot switch, access to FL560 settings pages |
| GLOW800: | Usage of GLOW800 mode activation from GUI, handles or foot switch, access to multiple GLOW800 settings pages |
| 3D: | Use of 3D toggle on the Basic settings page, and 3D recording toggle |
| DICOM: | Functionality to set up and use export of patient data to external DICOM storage |

If licenses are not pre-installed with the purchased microscope, they can be purchased at your Leica representative and activated later by an authorized Leica Microsystems Service Technician.

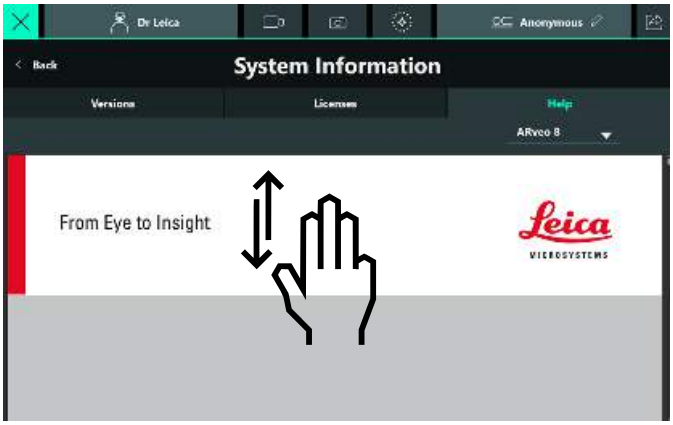
► Tap on "Licenses".
The table shows all licenses that are either installed or available (pre-installed) for the system.



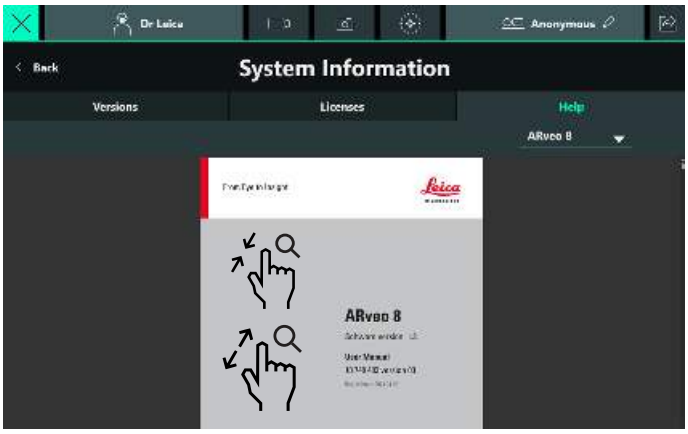

## 12.2 Read user manuals

**NOTE**
User manuals are subject to regular updates. Check the Leica website for the most recent user manual versions:
go.leica-ms.com/ifu

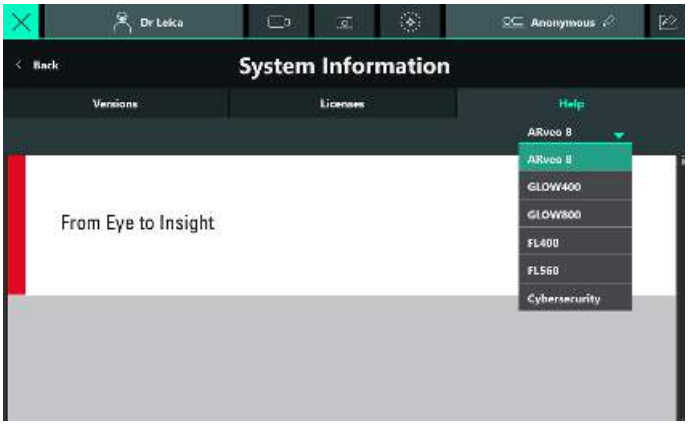
► Tap on "Help".
The user manual of the surgical microscope is displayed. If available, the user manual is displayed in the configured GUI language. If a specific user manual is not available in the configured language, the English user manual is displayed instead.
► Scroll through the pages by swiping up and down with your finger on the touch screen.




► Use a pinch gesture with two fingers on the touch screen to zoom in and out on the pages.

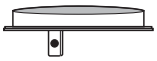
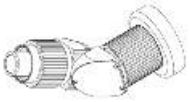
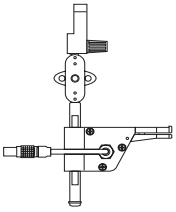



► Select the user manual you want to read from the drop-down menu. The user manuals for accessories are only listed, if a valid license is installed (see chapter 12.1 "Check installed licenses", page 78).




# 13 Accessories

A comprehensive range of accessories enables the ARveo 8x surgical microscope to be matched to the requirements of the task in hand. Your Leica representative will be pleased to help you select the appropriate accessories.

| Picture | Devices and accessories |
|---|---|
|  | Protective glass |
|  | Binocular tube var. 0° - 180°, T, Type II |
|  | Binocular tube var. 30° - 150°, T, Type II L |
|  | Inclined binocular tube, T, Type II |
|  | Straight binocular tube, T, Type II |
|  | Inclined binocular tube 45°, Type II |
|  | Eyepiece 10×<br>Eyepiece 12.5×<br>Eyepiece 8.3× |
|  | Magnification multiplier |
|  | Stereo attachment second observer |
|  | Mouth Switch |

**Foot switch**
- Wireless foot switch with 12 functions

**Stand monitors**
- 27" 2D-4K
- 32" 3D-4K

**Cart monitor**
- 55" 3D-4K

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

# 14 Drapes

| Supplier | Article No. |
|---|---|
| Microtek Medical Inc. | 8033650xx<br>8033651xx<br>8033652xx<br>6140VL2 |
| Pharma-Sept Medical Products Ltd | 81-420H<br>81-229H<br>81-298H |
| Fuji Systems Corporation | 0823155 |
| Premier Guard Zhongsham Limited | 10-3166APxx<br>10-3166AGxx<br>10-3167APxx<br>10-3167AGxx<br>10-3168APxx<br>10-3168AGxx<br>10-3168BAxx |
| Medical Technique IMD | 5950-150FL |
| American Surgical Products | ASP54-150 |
| Exact Medical Manufacturing Inc. | E5512G<br>E5513G<br>E5515G |

The use of the Leica Protective glass 10446058 is recommended (to prevent reflections and holograms).

# 15 Care and maintenance

To ensure that the ARveo 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.

**CAUTION**

**Risk of compromised surgery**

- A system safety check will need to be performed accordingly to your country-specific requirements. Leica recommends an annual system and safety check. After a system usage period of 8 years, an annual system and safety check is considered mandatory.
- The systems shall not be used to perform critical use applications after 8 years of system usage or up to 12 years with annually passed system and safety check.
- As all maintenance activities require product specific know-how, it is recommended to contact your responsible service organization.

- Put a dust cover over the instrument while the system is not in use.
- 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.

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.

## 15.1 Clean the touch screen

► Before cleaning the touch screen, switch off your ARveo 8x and disconnect it from the power supply.
► Use a soft, lint-free cloth to clean the touch screen.
► Do not apply cleaning agent directly to the touch screen; rather, apply it to the cleaning cloth.
► Use a commercially available glass/eyeglass cleaner or plastic cleaner to clean the touch screen.
► Do not apply pressure to the touch screen while cleaning it.

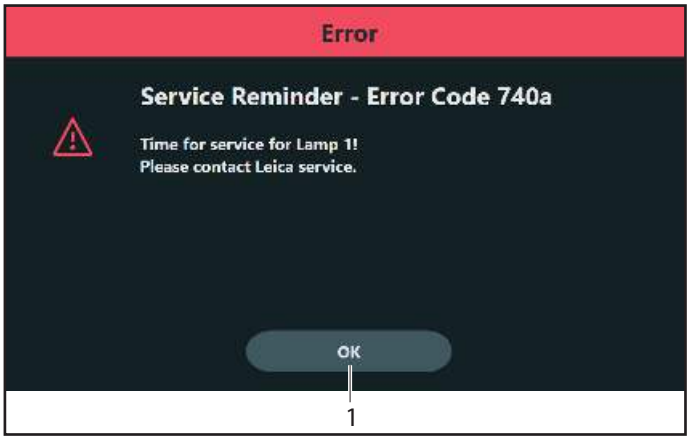
**NOTE**

**Damage of the touch screen.**

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

## 15.2 Change lamps

A dialog window opens when the lamp reached the maximum lamp hour level.



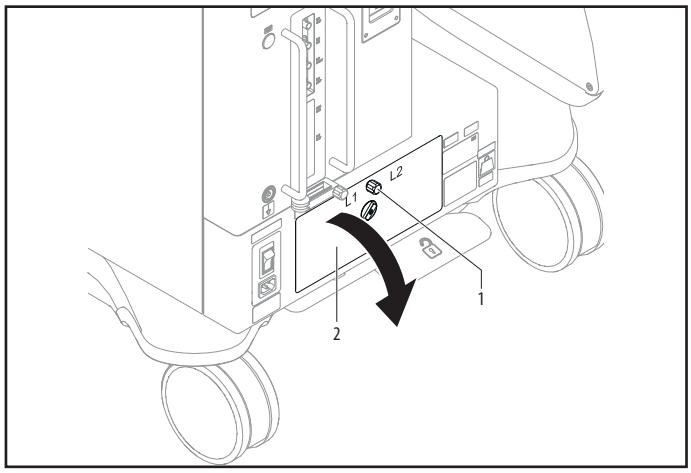

► Tap the "OK" button (1).
  The dialog window is closed.

- ► Disconnect the microscope from the power supply.
- ► Replace the old or defective lamps.

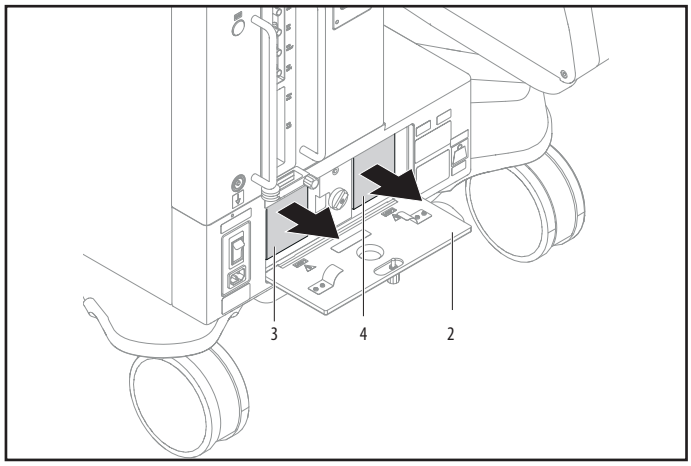
**CAUTION**

**Danger of skin burns. The lamp gets very hot.**

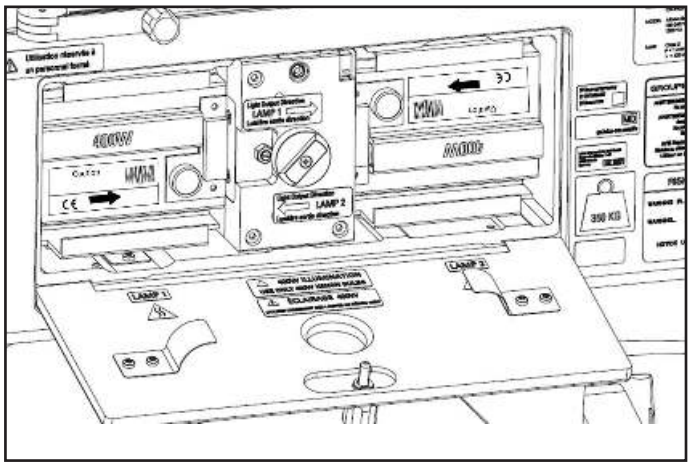
- ► Check that the cover has cooled before you replace the lamp.



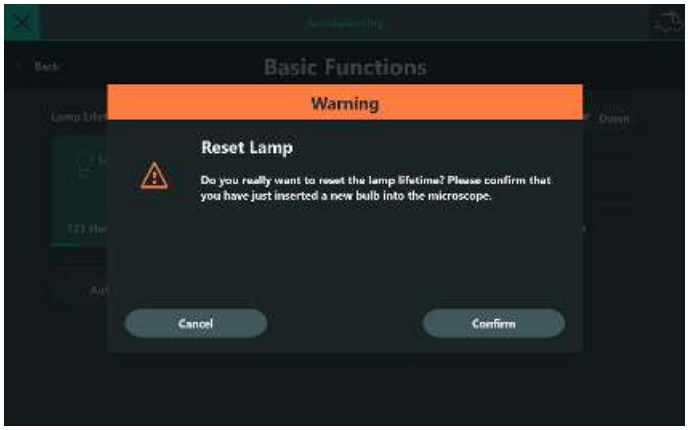

- ► Open access door (2) for lamp insert by unscrewing knob (1).




- ► Remove the defective lamp (3 or 4). available from Leica Microsystems.



- ► When installing the lamp, make sure that the arrow (5) is pointing to the indicated direction.
- ► Close the access door.
- ► Reconnect the microscope to the power supply.
- ► Switch on the microscope.
  A lamp test for both lamps is carried out.
- ► Reset the hour counter of the respective lamp (see chapter 6.7.2 "Check lamps", page 37).
  The following warning message appears:



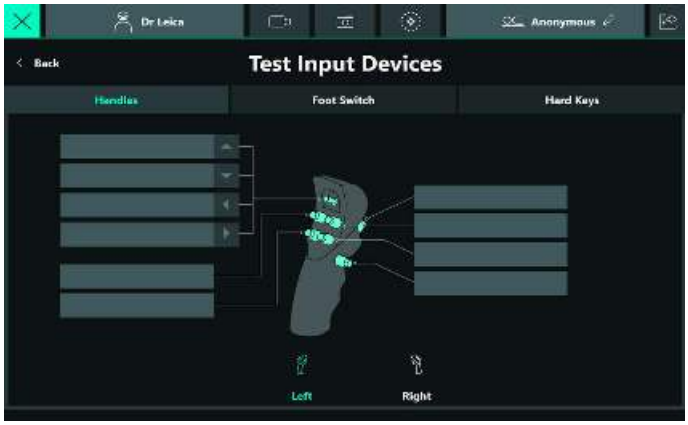

- ► Tap "Confirm".

## 15.3 Test input devices

You can test the proper function of the input devices (handles, foot switch, hard keys) in the "Test Input Devices" menu.

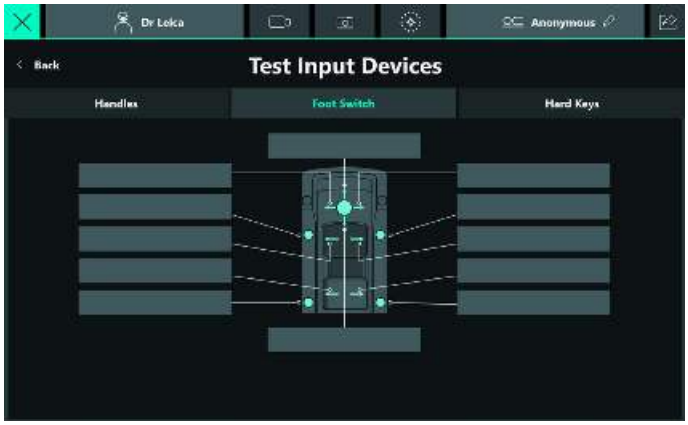
- ► Go to Main Menu ☰ → "System Settings".
- ► Tap the "Test Input Devices" button.
  The "Test Input Devices" screen is displayed.

### 15.3.1 Handles



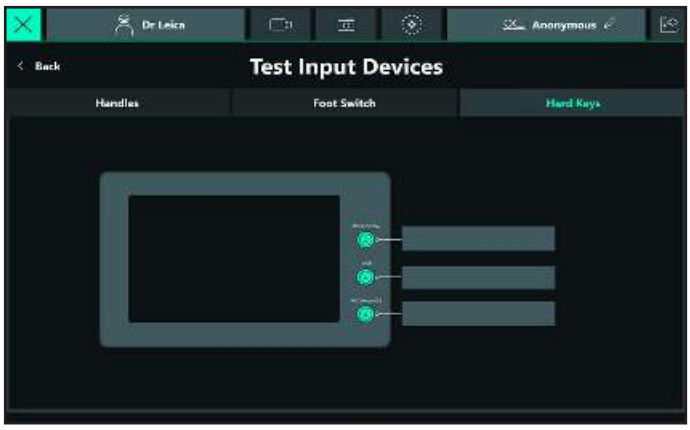

- ► Select the "Handles" tab to test the keys on the handles. You can select between left or right handle.
- ► Press all keys of the handle you want to test one after the other. If the key you have pressed is functioning properly, the caption field of to the respective key turns green and the comment "Checked" appears.

### 15.3.2 Foot switch




- ► Select the "Foot Switch" tab to test the keys on the foot switch.
- ► Press all keys of the foot switch one after the other. If the key you have pressed is functioning properly, the caption field of to the respective key turns green and the comment "Checked" appears.

### 15.3.3 Hard Keys




- ► Select the "Hard Keys" tab to test the air removal, autobalance and lamp pushbuttons on the control unit.
- ► Press all pushbuttons one after the other.
  If the button you have pressed is functioning properly, the caption field of to the respective key turns green and the comment "Checked" appears.

## 15.4 Notes on reprocessing of resterilizable products

### 15.4.1 General

**Products**

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

**Limitation 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.

**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.

**Limitation of reprocessing**

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.

### 15.4.2 Instructions

**Workplace**

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

**Storage and transport**

- No specific requirements.
- It is recommended to perform the reprocessing of a product immediately following its use.

**Preparation for cleaning**

► Remove the product from the ARveo 8x surgical microscope.

**Cleaning: manually**

- Equipment: running 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 chapter 15 "Care and maintenance", page 81.

**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 15.4.3 "Sterilization table", page 85.

**Storage**

See chapters 8.1 "Transport position", page 47 and 18.4 "Ambient conditions", page 93.

**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.

### 15.4.3 Sterilization table

The following table gives an overview of the available sterilizable components to the surgical microscope.

| | | Permissible sterilization methods | |
|---|---|---|---|
| **Article No.** | **Designation** | **Steam autoclave 134°C, t > 10 min.** | **Ethylene oxide max. 60°C** |
| 10428328 | Rotary knob, binocular tubes T | ✓ | |
| 10446058 | Protective glass, multifocal lens | | ✓1) |

1) Products with optical components can be steam-autoclaved using the conditions listed above. However, this may cause a layer of dots and streaks to form on the glass surface, which may reduce the optical performance.

# 16 Disposal

The respective applicable national laws must be observed for disposal of the products, with the involvement of corresponding disposal companies. The unit packaging is to be recycled.

# 17 What to do if ...?

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

## 17.1 Malfunctions

| Malfunction | Cause | Remedy |
|---|---|---|
| The microscope tilts when you press the "All Brakes" button. | The arm system is not correctly balanced. | ▶ Balance microscope carrier (see chapter 6.6 "Balance the microscope", page 33). |
| The microscope cannot be moved or moved only with a great deal of effort. | A cable is sticking. | ▶ Reroute affected cable. |
| | ARveo 8x is locked. | ▶ Release the locking mechanism (see chapter 6.2 "Transportation", page 28). |
| Functions cannot be activated using the foot switch or the controls on the handles. | Incorrect assignment entered at control unit. | ▶ Change the assignment using the control unit (see chapter 9.2.1 "Set handles and foot switch", page 52). |
| No light in the microscope. | The fiber-optic light guide has been disconnected. | ▶ Check the connection of the fiber-optic light guide. |
| | Main illuminator and/or auxiliary illumination defective. | ▶ Switch to the other illuminator (see chapter 7.5 "Change lamps", page 43). |
| Light intensity below expectation. | The fiber optics cable not properly connected | ▶ Check the connection of fiber optics cable. |
| | Lamp lifetime over | ▶ Check lamp lifetime and change bulbs, if required (see chapter 15.2 "Change lamps", page 81). |
| Back/side assistants have no light. | Selection of the assistants not correct | ▶ Check selection of the assistants (see chapter 6.1.4 "Selecting the assistant", page 28). |
| Left/right side assistant has no light. | Selection of the assistant not correct | ▶ Check selection of assistant (see chapter 6.1.4 "Selecting the assistant", page 28). |
| The image is unfocussed. | The 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 "Determining/adjusting diopter settings for users", page 27). |
| | The Auto Focus does not work properly. | ▶ Ensure that the microscope is positioned in a working distance between 225–600 mm. |
| The microscope or arm system moves up/down or rotates on its own accord. | Arm system is not correctly balanced. | ▶ Balance out the ARveo 8x (see chapter 6.6 "Balance the microscope", page 33). |
| | ARveo 8x was balanced in a locked state. | ▶ Release the locking mechanism (see chapter 6.2 "Transportation", page 28) and balance the microscope (see chapter 6.6 "Balance the microscope", page 33). |
| The microscope and microscope carrier can be moved only with difficulty or not at all. | Automatic balancing has not been completed. | ▶ Make sure that position B has been assumed (see chapter 6.6.1 "Automatic balancing", page 33)<br>▶ Press the pushbutton for autobalance again. |

| Malfunction | Cause | Remedy |
|---|---|---|
| Automatic balancing cannot be performed. | Microscope is tilted at too great an angle. | ▶ Align the A/B-axes on the microscope according to the A/B marking (see chapter 6.6.3 "Manual balancing", page 35).<br>▶ Carry out automatic balancing again. |
| Magnification cannot be adjusted electrically. | Failure of magnification motor | ▶ Press the magnification rotary knob.<br>▶ Set magnification by turning (see chapter 7.7 "Adjusting the magnification (zoom)", page 44). |
| No XY movements possible at one of the two handles. | No XY movements configured for the handles in the control unit. | ▶ Set the joystick to XY movement (see chapter "Configuring the handles", page 52). |
| The microscope has not been balanced exactly in the B-axis. | Installed accessory was not turned back to the working position when balancing the B-axis. | ▶ Rebalance the B-axis.<br>▶ Make sure that the accessory is turned back to the working position when balancing the B-axis (see chapter 6.6.3 "Manual balancing", page 35).<br>▶ Perform intraoperative B/C balancing (see chapter 6.6.3 "Manual balancing", page 35). |
| Pushbutton for automatic balancing flashes, but acoustic signal does not sound (nothing happens). | Balancing process is not yet completed. | ▶ Rotate the microscope to the B-position and press the autobalance pushbutton. |
| Arm system cannot be moved. | Arm system locked in position. | ▶ Release the locking mechanism (see chapter 6.2 "Transportation", page 28). |
| The stand of the ARveo 8x moves. | Footbrakes not applied. | ▶ Fix footbrakes in place (see chapter 6.2 "Transportation", page 28). |
| The range of movement of the ARveo 8x is limited (swing, tilt, rotate, XY movement). | Cable laid too tightly. | ▶ Re-lay the cable. |
| | Drape too tight. | ▶ Slightly loosen drape. |
| ARveo 8x is not correctly balanced. | Position of accessory was changed after balancing. | ▶ Balance out ARveo 8x (see chapter 6.6 "Balance the microscope", page 33). |
| | | ▶ Perform intraoperative AC/BC balancing (see chapter 6.6.3 "Manual balancing", page 35). |
| ARveo 8x cannot be balanced. | ARveo 8x was balanced in the transport position. | ▶ Take the ARveo 8x out of transport position and rebalance it. |
| Iris does not follow magnification. | AutoIris in override mode | ▶ Press the AutoIris reset button (see chapter 5.1.4 "Optics carrier – controls", page 20). |
| Stand brakes remain open. | Mouth switch remains closed. | Disconnect mouth switch cable from optics carrier. |
| Working distance does not move. | Working distance emergency drive is blocked by drape. | ▶ Unblock the working distance emergency drive and try again.<br>▶ Use the rotary knob "Working distance" (emergency operation only) to adjust the working distance. |
| Working distance on microscope cannot be adjusted. | The working distance lock is activated. | ▶ Check the working distance lock (see chapter 7.6.2 "Locking/releasing the working distance", page 44).<br>Exception: You are working with a laser micromanipulator on which this function has been programmed for safety reasons. |

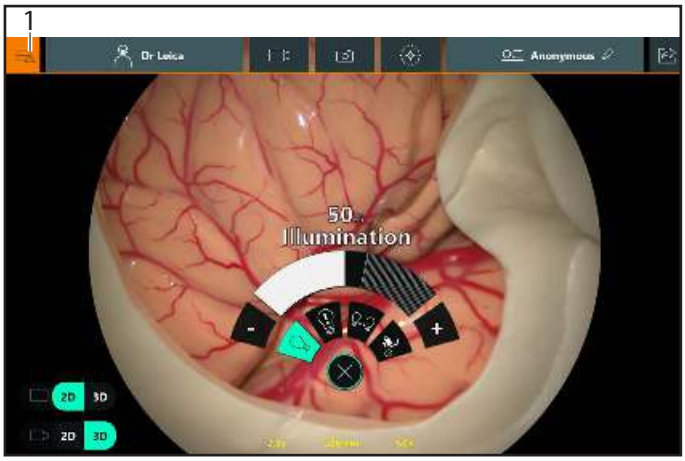
| Malfunction | Cause | Remedy |
|---|---|---|
| The image appears shaded through the microscope at the edges and the illumination field is outside the field of vision. | Accessories not installed exactly. | ▶ Install the accessories exactly in the holders (see chapter 6.3 "Locking/unlocking the ARveo 8x", page 29). |
| The device switches off, system has no power. | The circuit breaker has been tripped and the power supply has been interrupted. | ▶ Switch the device on again using the main switch. This will reset the circuit breaker.<br>▶ If this has to be done repeatedly, please inform Leica service. |

## 17.2 Malfunctions of the documentation system

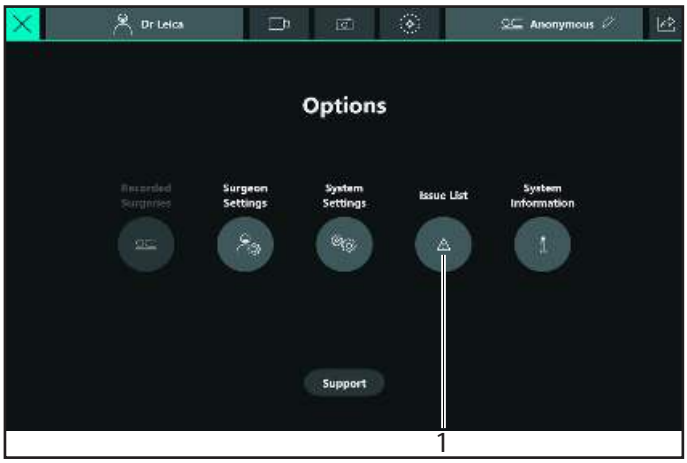
| Malfunction | Cause | Remedy |
|---|---|---|
| The video pictures are unfocussed. | The microscope is not focussed precisely. | ▶ Focus precisely, use graticule if necessary.<br>▶ Perform diopter correction exactly according to the instructions. |

## 17.3 Check errors/warnings (issue list)

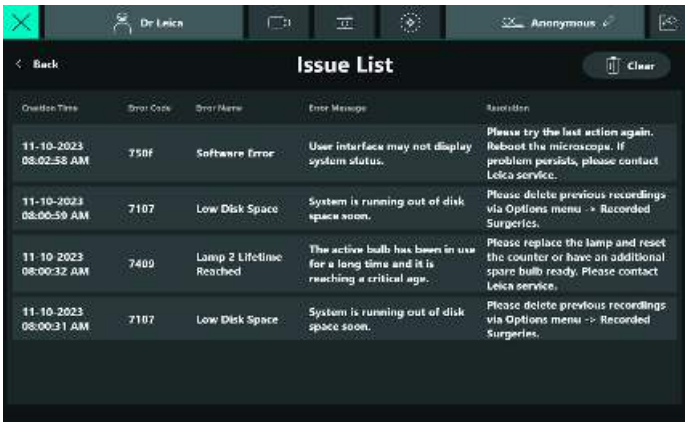
- Critical errors/warnings that require immediate attention will be visible as pop-ups.
- If the main menu button is highlighted orange and marked with a triangle (1), there are less critical errors/warnings in the issue list. The orange triangle disappears as soon as user opens the issue list.




- All errors/warnings are visible in the "Issue list".
- The issue list always displays all previous errors.




► In order to inspect the issue list, access Main Menu ☰ → "Issue List" (1).
The error messages that have occurred during operation appear:




► Tap "Clear" to delete the whole issue list.
A dialog appears to confirm the deletion.
► Confirm or cancel the dialog.

# 18 Specifications

## 18.1 Electrical data

| | |
|---|---|
| Power connection for ARveo 8x | 100–240 V 50/60 Hz<br>1300 VA<br>Integrated circuit breaker |
| Protection class | Class 1 |

## 18.2 Microscope features

| | |
|---|---|
| Magnification | 6:1 zoom, motorized |
| Objective / working distance | 225-600 mm, motorized multifocal lens, continuously adjustable;<br>manual adjustment option |
| Eyepieces | Wide-field eyepieces for persons wearing glasses 8.3×, 10× and 12.5× dioptric adjustment<br>±5 diopter settings;<br>adjustable eyecup |
| Illumination | Illumination system specially developed for microsurgical applications;<br>Continuously variable illumination field diameter with Gaussian light distribution.<br>Continuously adjustable brightness at constant color temperature |
| AutoIris | Built-in automatic zoom-synchronized illumination field diameter, with manual override and reset feature |
| Main illuminator | High-output xenon lamp 400 W,<br>via fiber optics cable |
| Emergency lamp | 400 W xenon arc-lamp with redundant electrical high voltage part |
| BrightCare Plus | Safety function through working distance-dependent limitation of the brightness, controlled by a built-in luxmeter |
| SpeedSpot | Laser focussing aid for fast and exact positioning of the microscope<br>Laser Class 2<br>Optical power < 1 mW<br>Wavelength 635 nm |
| Fine focus | Available for back side assistant |
| Magnification multiplier | 1.4× |

### 18.2.1 Optical data

| Zoom magnification binocular tubes with focal length f162.66 | | Working distance | | | |
|---|---|---|---|---|---|
| | | 225 mm | | 600 mm | |
| | | $M_{tot}$ | FoV [mm] | $M_{tot}$ | FoV [mm] |
| **Eyepiece 8.3×** | min. | 1.60 | 114.5 | 0.80 | 230.4 |
| | max. | 9.6 | 19.1 | 4.8 | 38.4 |
| **Eyepiece 10×** | min. | 1.92 | 109.3 | 0.96 | 219.9 |
| | max. | 11.5 | 18.2 | 5.7 | 36.7 |
| **Eyepiece 12.5×** | min. | 2.40 | 88.5 | 1.19 | 178.0 |
| | max. | 14.4 | 14.7 | 7.2 | 29.7 |

| Zoom magnification binocular tubes with focal length f170.0 | | Working distance | | | |
|---|---|---|---|---|---|
| | | 225 mm | | 600 mm | |
| | | $M_{tot}$ | FoV [mm] | $M_{tot}$ | FoV [mm] |
| **Eyepiece 8.3×** | min. | 1.68 | 109.4 | 0.83 | 220.2 |
| | max. | 10.1 | 18.2 | 5.0 | 36.7 |
| **Eyepiece 10×** | min. | 2.01 | 104.4 | 1.0 | 210.2 |
| | max. | 12.1 | 17.4 | 6.0 | 35.0 |
| **Eyepiece 12.5×** | min. | 2.51 | 84.5 | 1.25 | 170.1 |
| | max. | 15.1 | 14.1 | 7.5 | 28.35 |

Mtot Total magnification
FoV Field of View

The values above contain a tolerance of ±5 %

**Binocular tubes**

| Binocular tube | Focal length | Art. No |
|---|---|---|
| **Type A** | **f162.66** | 10448088: Binocular tube var. 0–180°<br>10446574: Inclined binocular tube<br>10446618: Inclined binocular tube 45° |
| **Type B** | **f170.0** | 10446797: Binocular tube var. 30–150° |
| **Type C** | **f131.65** | 10448386: Straight tube |

* not recommended

### 18.2.2 Selectable options

| | |
|---|---|
| FL400 for M530 | FL400 observation filter module |
| FL560 for M530 | FL560 observation filter module |
| GLOW800 | GLOW800 augmented reality module |

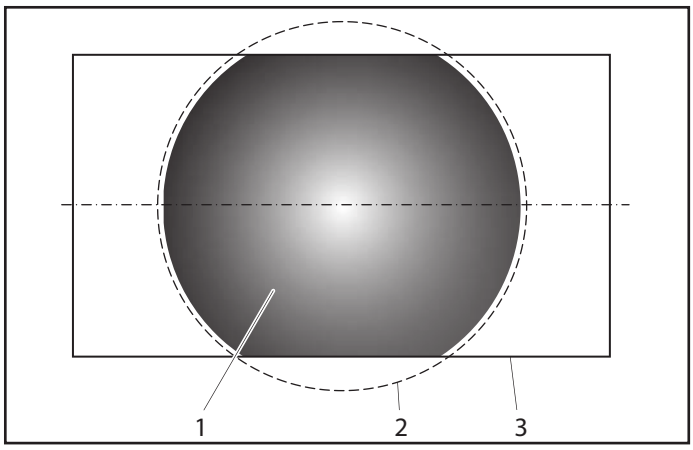
### 18.2.3 ARveo 8x microscope carrier

| | |
|---|---|
| Rotation of optics | 540° |
| Lateral tilt | 50° to left / 50° to right |
| Inclination tilt | –30° / +120° |
| XY speed | Zoom linked XY speed |
| Balancing | A, B, C and D axes fully automatic, each can be corrected manually |
| Brakes | 1 brake for A/B axis<br>1 brake for C axis |
| Indicator | Surgeon panel for the indication of fluorescence mode and video recording status |

**ARveo 8x with ULT**

| | |
|---|---|
| FusionOptics | for increased depth of field<br>for main surgeon and back assistant |
| Manual fine focus | for back assistant, ±5 dpt |
| Integrated 360° rotatable adapter | for main surgeon and back assistant binocular |

**Camera image size with respect to the field of view**




1 Camera image size
2 Field of view
3 Screen size

The figure shows the camera image size with respect to the field of view for the visual video camera and the NIR camera. Please be aware that the field of view is not fully covered by the documentation system.

### 18.2.4 IGS/Endoscope

| | |
|---|---|
| Interface/ Compatibility | Open architecture for IGS & Endoscope systems |
| Input Interface | Type: DVI-I |
| compatible with | • DVI 1.0<br>• HDMI 1.4a (with DVI to HDMI adapter, not included)<br>• VGA (with DVI to VGA connector, included) |
| Resolution | up to 1920x1200 |
| Frame rate | up to 144 fps |
| Color depths | 8-bit |
| Color format (VGA) | RGB |
| Color samplings (HDMI) | RGB 4:4:4 |

### 18.2.5 Cameras

| | |
|---|---|
| Image sensor | 4 × 1/1.2" inch |
| NIR camera | High-sensitivity, HD color camera |

### 18.2.6 IGS

| | |
|---|---|
| Interface/ Compatibility | Open architecture for IGS systems<br>Please ask your Leica representative. |

## 18.3 ARveo 8x floor stand

| | |
|---|---|
| Type | Floor stand with 6 electromagnetic brakes and air removal system |
| Base | 760 × 760 mm with four 360° rotating castors with a diameter of 150 mm each,<br>one parking brake |
| Balancing | Autobalance: completely automatic balancing of stand and optics |
| Intraoperative balancing | Automatic intraoperative AC/BC balancing of AC and BC axes |
| Floor stand control unit | The latest electronics control for the continuous governing of all motor functions and the light intensity.<br>Built-in BrightCare Plus safety function for limiting brightness depending on working distance.<br>Menu selection based on unique software for user-specific configuration, with built-in electronic auto-diagnosis and user support. |
| Control unit stand | Software independent hard keys for air removal, illumination and auto-balancing.<br>Indicator for Main/backup illumination and Fluorescence modes.<br>Open architecture for future software developments. |
| Light source | Dual Xenon arc-lamp illumination system and built in automatic lamp quick changer. |
| Control elements | Pistol handle with 10 functions for magnification, working distance, "All Brakes" button releases 6 brakes, side knob releases selected brake combinations, motorized side tilt (XY). All buttons other than "All Brakes" are freely assignable.<br>Mouthswitch for releasing the selected brake combination.<br>Foot switch. |
| Integrated documentation | Integration of video camera system and digital recording system. |
| Connectors | Numerous built-in connectors for Video, IGS and control data transfer. Internal power supply 12 VDC, 24 VDC and AC terminals |
| Carrier for stand monitor | 700 mm long and flexible arm with 4-axis rotation and inclination |
| Materials | All solid metal construction |
| Surface coating system | Coated with antimicrobial paint |
| Minimum height | In park position: 1950 mm |
| Range Cantilever | Max. 1925 mm |
| Load | Min. 6.7 kg, max. 12.2 kg from microscope dovetail ring interface |
| Weight | Approx. 335 kg (without load) |

## 18.4 Ambient conditions

| | |
|---|---|
| In use | +10 °C to +30 °C<br>+50 °F to +86 °F<br>30 % to 95 % rel. humidity<br>800 mbar to 1060 mbar atmospheric pressure |
| Storage | −40 °C to +70 °C<br>−40 °F to +158 °F<br>10 % to 100 % rel. humidity<br>500 mbar to 1060 mbar atmospheric pressure |
| Transport | −40 °C to +70 °C<br>−40 °F to +158 °F<br>10 % to 100 % rel. humidity<br>500 mbar to 1060 mbar atmospheric pressure |

## 18.5 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.

### 18.5.1 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.

### 18.5.2 Compliance IEC 60601-1-2

**Emissions**

- CISPR 11, Class A, Group 1
  Conducted Emissions Class B
- Harmonic Distortion per IEC 61000-3-2 Class A
- Voltage Fluctuation and Flicker per IEC 61000-3-3

**Immunity**

- Performance of medical electrical equipment and medical electrical systems IEC/TS 60601-4-2
- Electrostatic discharge IEC 61000-4-2:
  CD ± 8 kV
  AD ± 2kV, ± 4kV, ± 8kV, ± 15kV
- Radiated RF EM Fields IEC 61000-4-3:
  80 MHz – 6 GHz: 10 V/m
- Proximity Wireless fields IEC 61000-4-3:
  380–5800 MHz: 9 V/m; 27 V/m; 28 V/m
- Proximity magnetic fields IEC 61000-4-39:
  30 kHz: 63 A/m
  134.2 kHz: 67 A/m
  13.56 MHz: 7.5 A/m
- Electrical Fast Transients and bursts IEC 61000-4-4:
  ± 2kV: Power supply lines
  ± 1kV: Input and output lines
- Surges IEC 61000-4-5:
  ± 0.5kV, ± 1kV Line-to-line
  ± 0.5kV, ± 1kV, ± 2kV Line-to-ground
- Conducted disturbances, induced by RF fields
  IEC 61000-4-6: 10 Vrms
- Rated Power-frequency Magnetic Field IEC 61000-4-8:
  > 85 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 HD monitor
- Interruptions on the HD monitor
- Freeze of the live image on the monitors, restorable to the pre-test state with operator intervention

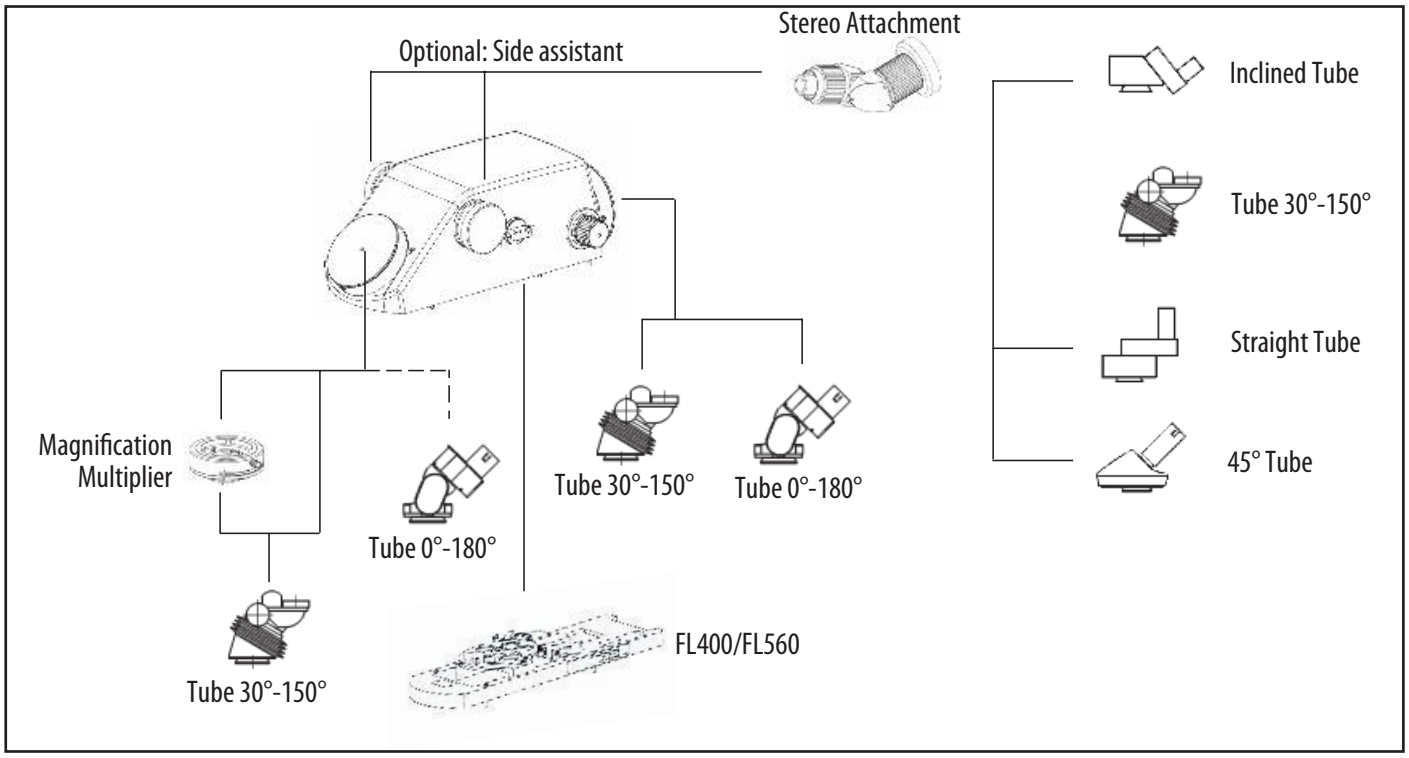
**Specific compliance criteria for the voltage dips and interruptions test**

- The equipment is allowed a deviation at the immunity levels (0% of nominal voltage), provided the equipment remains safe, experiences no component failures and is restorable to the pre-test state with operator intervention.
- Interruption of the main illumination, restorable to the pre-test state with operator intervention
- If use is made of accessories or cables other than those specified in this user manual or approved by the manufacturer of the ARveo 8x, this can lead to an increase in in electromagnetic radiation or a reduction in EMC.

**WARNING**

**Improper operation**

► Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.




Please follow the recommended tube/eyepiece configuration to ensure that balancing of the configured device is possible.

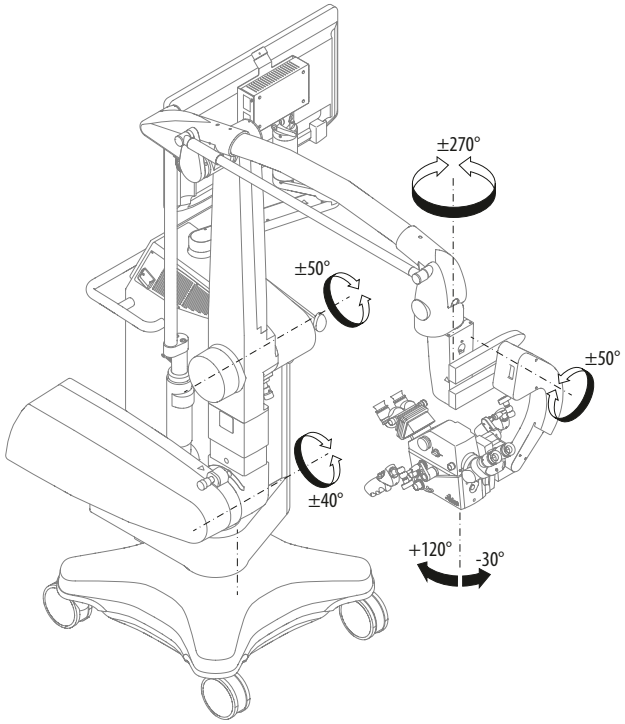
# 19 Weight calculation of equipment

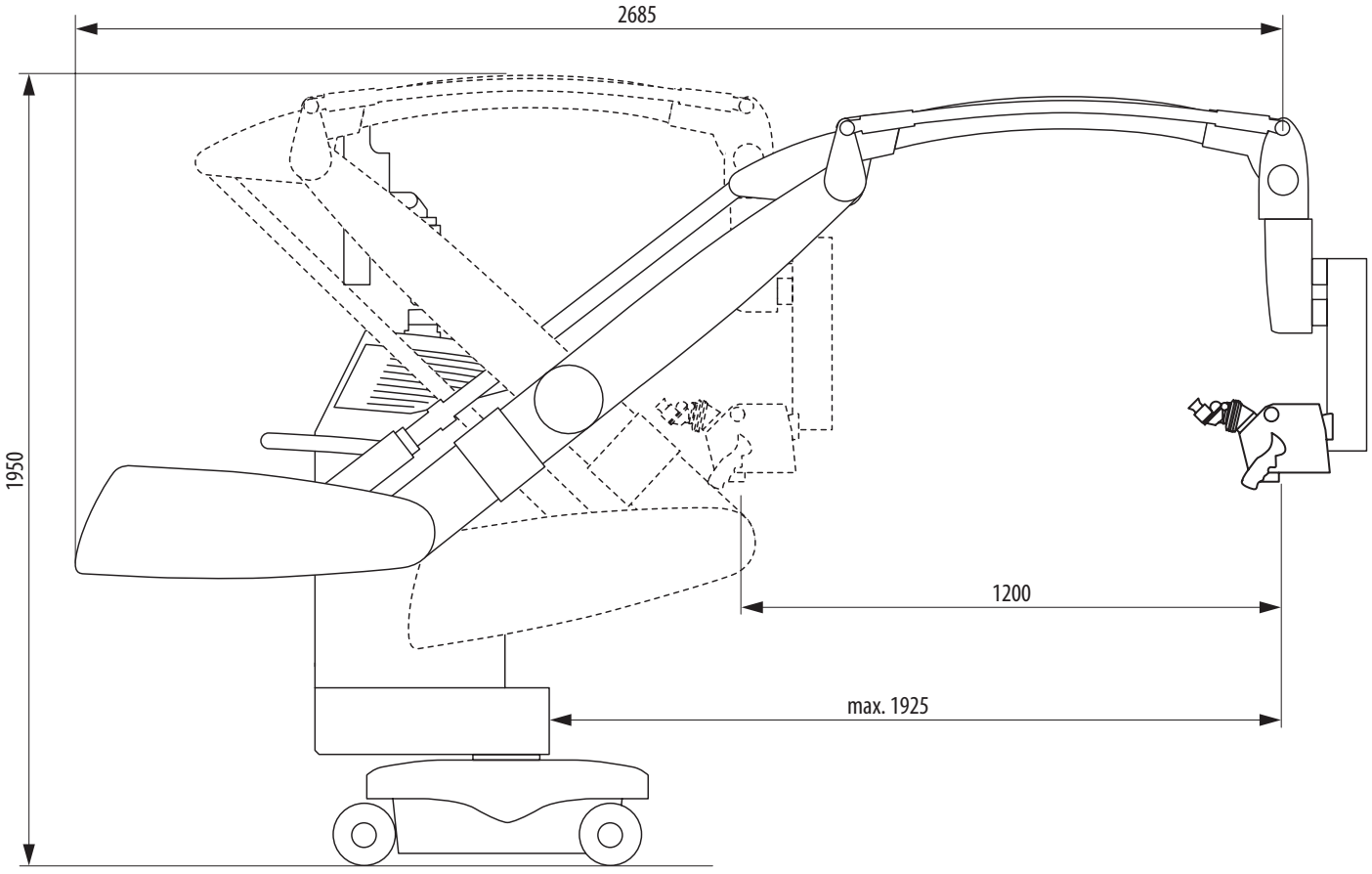
**Equipment of ARveo 8x Serial No.** ..... **Max. load from microscope dovetail ring interface: 12.2 kg**

| Equipment of ARveo 8x with ULT | | | | | Installation | |
|---|---|---|---|---|---|---|
| **Art. No.** | | **Description** | **Comment / Restrictions** | **Weight** | **#** | **Total** |
| 10448704 | **M** | **M530 optics carrier** | | 3.5 kg | | . |
| 10748182 | M | Leica FL400/FL560 module | | 0.50 kg | | |
| | **M** | **Interface to ULT** | | | | . |
| | M | ULT | | 1.9 kg | | . |
| | **M** | **Binocular tube for main surgeon** | Maybe the orientation of the tubes must be adapted to balance the system. | | | . |
| 10446797 | S | Binocular tube var. 30°-150° T, Type II L | Recommended | 0.81 kg | | . |
| 10448088 | S | Binocular tube var. 0°-180° T, Type II | Not recommended (vignetting) | 1.42 kg | | . |
| | **M** | **Binocular tube for back assistant** | | | | . |
| 10446797 | S | Binocular tube var. 30°-150° T, Type II L | Recommended | 0.81 kg | | . |
| 10448088 | S | Binocular tube var. 0°-180° T, Type II | | 1.42 kg | | . |
| | **O** | **Side observation** | 0, 1 or 2 side assistants | | | . |
| 10448597 | S | Stereo attachment | | 1.01 kg | | . |
| | **M** | **Binocular tube on Stereo attachment** | If Stereo attachment is selected | | | . |
| 10446797 | S | Binocular tube var. 30°-150° T, Type II L | Recommended | 0.81 kg | | . |
| 10446587 | S | Straight binocular tube T, Type II | | | | . |
| 10446618 | S | Inclined binocular tube 45°, Type II | | 0.56 kg | | . |
| 10446574 | S | Inclined binocular tube T, Type II | | 0.74 kg | | . |
| 10448668 | O | Magnification multiplier | Only 1 piece, only main surgeon and only with binocular tube 30°-150° (vignetting) | 0.28 kg | | . |
| M = Must, O = Option, S = Selection | | | continued on next page | | **Load** | . |

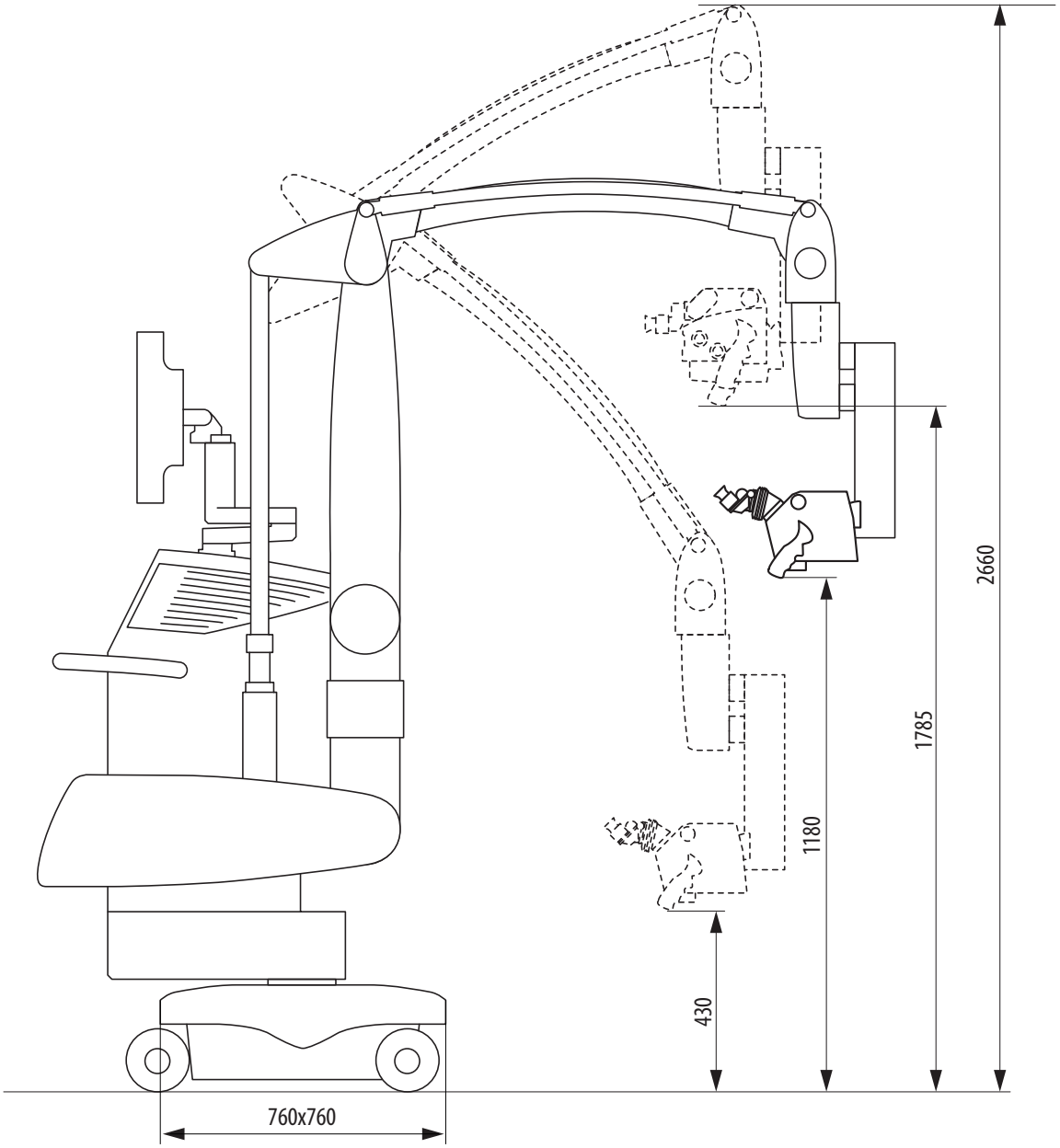
| Equipment of ARveo 8x with ULT for ARveo 8 | | | | | Installation | |
|---|---|---|---|---|---|---|
| **Art. No.** | | **Description** | **Comment / Restrictions** | **Weight** | **#** | **Total** |
| 10448028 | O | Eyepiece 10x | 2 eyepieces per binocular tube | 0.10 kg | | . |
| 10448125 | O | Eyepiece 8.3x | | 0.10 kg | | . |
| 10443739 | O | Eyepiece 12.5x | | 0.10 kg | | . |
| 10448245 | O | Mouth switch | | 0.22 kg | | . |
| 10446058 | O | Protective glass | | 0.02 kg | | . |
| | O | IGS Frame | | | | . |
| | | | | | | |
| Load from previous page | | | | | | . |
| | | | | | | |
| | | | | | **Total** | |
| M = Must, O = Option, S = Selection | | | | | **Load** | . |

## 19.1 Dimensional drawings




Dimensions in mm




Dimensions in mm

# 20 Annex

## 20.1 Checklist before the operation

Patient .....

Surgeon .....

Date .....

| Step | Procedure | Details | Checked / Signature |
|---|---|---|---|
| 1 | Cleaning the optical accessories | ▶ Check the tubes, eyepieces and the documentation accessories (if used) for cleanliness.<br>▶ Remove dust and dirt. | |
| 2 | Installing the accessories | ▶ Position the handles as desired.<br>▶ Connect the mouth switch and/or foot switch if used.<br>▶ Check the camera image on the monitor and realign if necessary. | |
| 3 | Power on the microscope | ▶ Connect the power cable.<br>▶ Switch on the microscope. | |
| 4 | Checking the tube settings | ▶ Check the tube and eyepiece setting for the selected surgeon profile. | |
| 5 | Balancing | ▶ Balance the ARveo 8x.<br>▶ Press the "All Brakes" button on the handle and check the balancing. | |
| 6 | Function check | ▶ Check the fiber optics cable connection to the optics carrier.<br>▶ Switch on the illumination at the control unit.<br>▶ Leave the illumination on for at least 5 minutes.<br>▶ Check the lamp history and make sure that the remaining lifetime is sufficient for the planned surgery.<br>▶ Replace defective bulbs before the surgery.<br>▶ Test all functions on the handles and the foot switch.<br>▶ Check the user settings on the control unit for the selected surgeon profile.<br>▶ Check the 2D and/or 3D image on the monitors and in the eyepieces. | |
| 7 | Safety check | ▶ Check accessories for secure seating. | |
| 8 | Positioning at the OP table | ▶ Position the ARveo 8x on the OP table as required and lock the footbrake. | |
| 9 | Sterility | ▶ Fit sterile components and sterile drape if used. | |
| 10 | Final work | ▶ Check that all equipment is in its proper position (all covers fitted, doors closed). | |

# 21 Glossary

| Term | Explanation |
|---|---|
| Auto White Balance | A process to re-calibrate the built-in camera in whitelight mode to display white as white. The user can trigger this function from the "Basic Settings" screen. Note that a Leica specialist can also readjust the camera's color settings individually, dependent on the fluorescence mode. |
| Autobalancing | The user workflow supporting the semi-automatic process that leads to a balanced, i.e. apparently free-floating optics carrier when releasing the brakes. |
| Auto Focus | A microscope function to automatically re-focus to the image portion in the center of the current image after changes of working distance, magnification or release of brakes. |
| BrightCare Plus (in the software, just "BrightCare") | "A Leica microscope feature to reduce the risk of damage to human tissue by reducing the maximum light intensity depending on working distance. The feature can be switched off, but will be on at next system start.<br><br>Separately, ""BrightCare for GLOW"" is the equivalent limitation during GLOW800 mode - this can be switched off and the status can be saved as part of the surgeon profile settings." |
| DICOM export | In this system, a dedicated approach to store still images and video data in a hospital's PACS (Picture Archiving and Communication System) archive, following the DICOM (Digital Imaging and Communications in Medicine) standard. |
| Excitation | In the context of fluorescence, the photonic radiation that induces fluorescence activity in a fluorophore substance. In our system, excitation corresponds to the brightness of the lamp during a fluorescence mode. |
| Hospital IT | In this system, this is a dedicated role within the customer team with administrative rights and a special password to allow other user's access, reset passwords, or switch the password protection for clinical data off. The special password should not be given to all clinical users as it indicates responsibility for the cybersecurity of the system. |
| IGS | "Image Guided Surgery" system or "navigation system". A device to display preoperative 3D imaging information in relation to physical reference markers during surgery. Such reference markers can be attached to the Leica surgical microscope and allow the user to combine the microscopic view with preoperative 3D image data. |
| Issue list | A list of any microscope warnings and errors, visible to hospital staff and service personnel. All issues are clearly marked with a time stamp. |
| Live screen | The main surgical screen shown on the touch screen interface which displays the current live camera screen. It also features the Main Menu, and allows access to all settings, as well as recording features. |
| Live surgery screen | The screen visible on the touch screen during surgery, showing a live image of the surgery, and allowing quick access to change illumination, trigger recordings, or access settings. |
| Modality Worklist | A list of patients provided by the digital hospital information system and scheduled for a certain medical procedure on a certain day, in this case, for use of the microscope, connected to DICOM export. |
| Mode | In our system, a fluorescence mode is one of the following: whitelight, GLOW800, FL560, FL400. |
| Main Menu | Icon in the upper left corner of the "Live surgery" screen for accessing "Options", i.e. microscope settings as well as access to previous recording data or microscope errors |
| Password/Passcode | We use the term "passcode" for a simple way to protect your surgeon profile from modification by others. The passcode can be as simple as one letter or as complex as needed.<br>We use the term "password" for a secure password to protect access to sensitive patient information. The complexity of the password is determined by the "Hospital IT" role. |
| Preset profile | A predefined collection of customizable microscope settings. You can use such a preset directly or create a new surgeon profile as a copy of a preset. If you use it directly, you can only apply it, but not modify it. |
| Quick Access Menu | Half-moon shaped GUI control on the "Live surgery" screen on the GUI touch screen, to control illumination and three other microscope stand settings, depending on the current fluorescence mode |

| Term | Explanation |
|---|---|
| Picture | A still image of the currently active camera stream, as seen on the stand monitor |
| Surgeon profile | A personalized collection of customizable microscope settings. This includes configuration of the microscope handles. A surgeon can create and name a new profile and any changes to the settings can be stored in this profile (see chapter 9.1 "Surgeon profile", page 48). |
| ULT | Ultra Observer Module |
| Video | A file of a recording snippet (max. 5min) of the currently active microscope camera, as seen on the stand monitor (can be 3D). |

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