

# Leica M530 OHX

**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

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7.5 Adjusting the eyepiece 22 7.6 Selecting the assistant 23 7.7 Stand settings 23 7.8 Positioning on the operating table 28 7.9 Attaching sterile controls and drape 29 7.10 Function check 30  8 Operation 31 8.1 Switching the microscope on 31		7.3	Installing optical accessories	21				
7.6 Selecting the assistant 23 7.7 Stand settings 23 7.8 Positioning on the operating table 28 7.9 Attaching sterile controls and drape 29 7.10 Function check 30  8 Operation 8.1 Switching the microscope on 31		7.4	Setting the binocular tube	22				
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7.8 Positioning on the operating table 7.9 Attaching sterile controls and drape 7.10 Function check 30  8 Operation 8.1 Switching the microscope on 31		7.6	Selecting the assistant	23				
7.9 Attaching sterile controls and drape 29 7.10 Function check 30  8 Operation 31 8.1 Switching the microscope on 31		7.7	Stand settings	23				
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# 1 Introduction

# 1.1 About this user manual

In this user manual the surgical microscopes Leica M530 OHX is described.



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



 Read this user manual carefully before operating the product.

# 2 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 the service workshop regarding any questions you may have.

Туре	Serial no.
•••	

# 1.2 Symbols in this user manual

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

Symbol	Warning word	Meaning
$\triangle$	Warning	Indicates a potentially hazardous situation or improper use that could result in serious personal injuries or death.
$\triangle$	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.
<b>&gt;</b>		Action required; this symbol indicates that you need to perform a specific action or series of actions.

# 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.

# 3 Safety notes

The Leica M530 OHX surgical microscope is state-of-the-art technology. Nevertheless, hazards can arise during operation.

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

## 3.1 Intended use

- The Leica M530 OHX surgical microscope is an optical instrument for improving the visibility of objects through magnification and illumination. It can be applied for observation and documentation and for medical treatment.
- The Leica M530 OHX surgical microscope may be used only in closed rooms and must be placed on a solid floor.
- The Leica M530 OHX 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 Leica M530 OHX surgical microscope's functionality.
- The Leica M530 OHX is intended for professional use only.



#### WARNING

## Danger of injury to the eyes.

▶ Do not use the Leica M530 OHX in ophthalmology.

# 3.2 Directions for the person responsible for the instrument

- ► Ensure that the Leica Leica M530 OHX surgical microscope is used only by persons qualified to do so.
- ► Ensure that this user manual is always available at the place where the Leica M530 OHX 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 Leica M530 OHX 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.

- ► If you use accessories from other manufacturers with the Leica M530 OHX 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 Leica M530 OHX surgical microscope may be carried out only by technicians who are explicitly authorized by Leica to do so.
- Only original Leica replacement parts may be used in servicing the product.
- After service work or technical modifications, the device must be readjusted in accordance with our technical specifications.
- If the instrument is modified or serviced by unauthorized persons, is improperly maintained (as long as maintenance was not carried out by 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 precautionary 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

# 3.3 Directions for the operator of the instrument

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

# 3.4 Dangers of use



### WARNING

### Danger of injury to the eyes.

▶ Do not use the Leica M530 OHX 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 Leica M530 OHX 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 Leica M530 OHX 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 Leica M530 OHX.
- ▶ Balance the Leica M530 OHX 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

# 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

### Risk of infection.

Always use the Leica M530 OHX surgical with sterile controls and a sterile drape.



#### WARNING

### Danger of fatal electrical shock.

- ► The Leica M530 OHX 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 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 microscope in position.
- Do not adjust the rotary button for manual setting of the working distance while using the laser.



#### 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.



## **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 nonsterile 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**

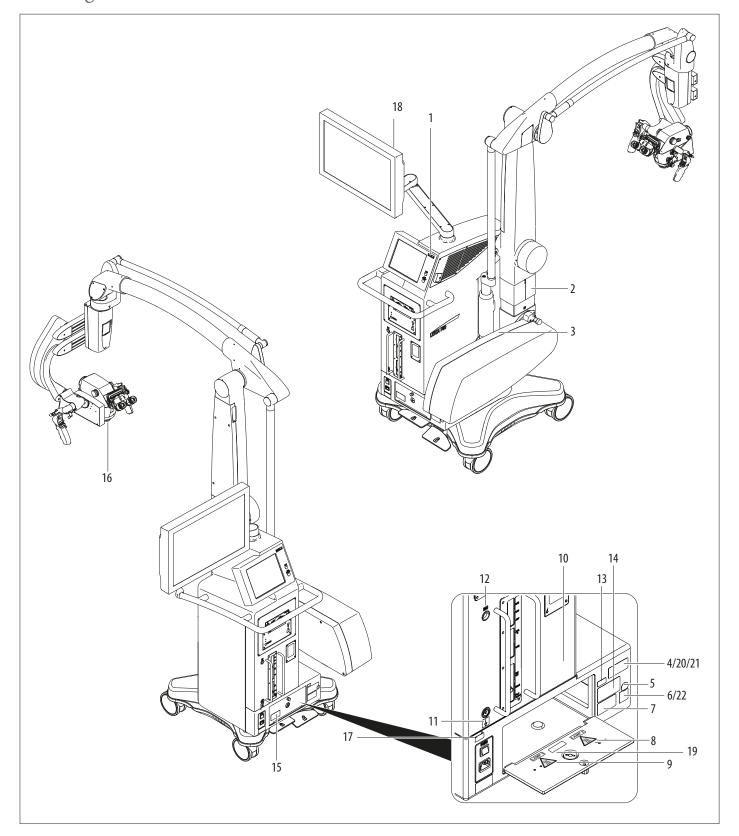
## Risk of compromised surgery

- 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 organisation.



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.

# 3.5 Signs and labels



**INMETRO** label

(Brazil only)

**ANVISA label** 

(Brazil only)

Equipotential

bonding

Type label

Medical device

label (only USA

and Canada)

Laser label

Warning

personnel

Monitor arm

weight label

Warning use

Xenon Bulbs

trained

Grounding

Contra-10 1 DO NOT USE IN Segurança OPHTHALMOLOGY indication NE PAS UTILISER EN OPHTHALMOLOGIE ANVISA n 2 Locked/Free XXXXXXXXXX 11 3 Danger sign for squeezing hazard 12 NAV 4 MET Label 13 Fabr. Nr. CSA CAN/CSA-C22.2 NO. 60601-1-6: 11 (MET) CSA CAN/CSA-C22.2 NO. 60601-1: 14 14 MD E114637 AAMI ES60601-1 Follow the 5 User Manual. System weight 6 MD label 350 kg 15 Grounding reliability can only be achieved when EQUIPMENT is connected 7 Warning of **RISK GROUP 3** to equivalent receptacle XENON light marked "Hospital only" or "Hospital WARNING IR emitting from this product. Do not emission Grade". look at operating lamp. WARNING Possibly hazardous optical radiation emitted from this product. Do not look at operating lamp. Eye injury may result. La fiabilité de la mise à la NOTICE UV emitted from this product. Minimise exposure to eyes or skin. Use appropriate shielding. terre n'est assurée que si l'équipement est connecté à une prise équivalente, marquée «Hôpital seulement» ou «Qualité hôpital». GROUPE A RISQUES 16 AVERTISSEMENT Rayonnement IR émis par ce produit. Ne pas regarder la lampe allun AVERTISSEMENT Risque de rayonnement optique dangereux émis per ce produit. Ne pes regarder la lampe allumé: Risque de lésion oculaire LASER RADIATION DO NOT STARE RAYONNEMENT LASER
NE PAS REGARDER
DIRECTEMENT
DANS LE FAISCEAU
PRODUIT LASER DE CLASSE 2 AVIS Rayonnement UV émis par ce produit. éduire au minimum l'exposition aux yeux et à la pea Utiliser un écran de protection adéquat. 8 17 Lamp number Unly to be operated

18

19

with danger

sign for hot

surface

by trained personnel

Max. 16kg (35.27lb)

400W ILLUMINATION

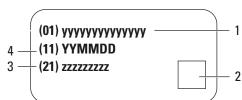
LAMP 2

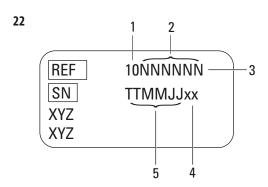
LAMP 1

9

21







### **EU** representative label

## **UDI (Unique Device Identification) label**

- 1 Device identifier
- 2 UDI code as GS1 data matrix code
- 3 Serial number
- 4 Manufacturing date

### **Fabrication label**

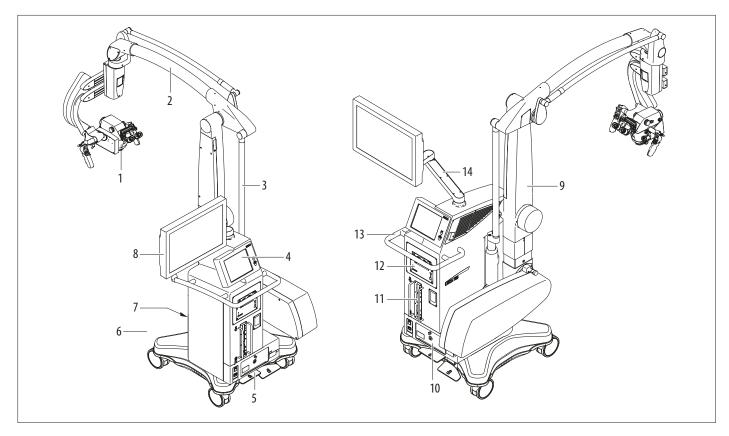
- 1 Prefix number
- 2 Leica system article number
- 3 Serial number
- 4 Incremental numbers starting at 1 for each batch
- 5 Production starting date

  JJ = year (2 digits)

  MM = month (2 digits)

# 4 Design

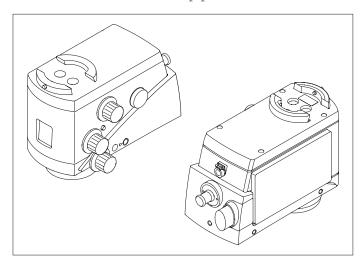
# 4.1 Leica OHX stand



- 1 Leica M530 OHX optics carrier
- 2 Arm system
- 3 Tension rod
- 4 Control unit with touch panel
- 5 Footbrake
- 6 Base
- 7 Suspension device for footswitch
- 8 Video monitor (optional)
- 9 Vertical arm
- 10 Illumination unit
- 11 Terminals
- 12 Camera and recording unit (optional)
- 13 Handle
- 14 Monitor arm
- With its open architecture the Leica M530 OHX provides space for holding the camera and recording units.

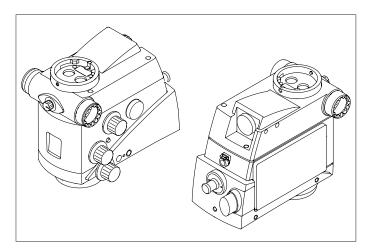
# 4.2 Leica M530 Optics carriers

## 4.2.1 Leica M530 with Top plate



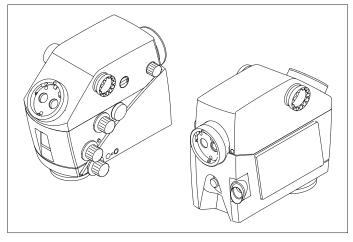
· Basic optics carrier

### 4.2.2 Leica M530 with IVA530



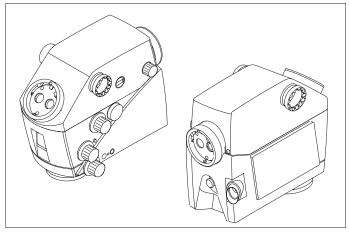
- Optics carrier with integrated C-mount video adapter for installing a camera
- Assistant interface, switchable either to the left or to the right side

### 4.2.3 Leica M530 with ULT530



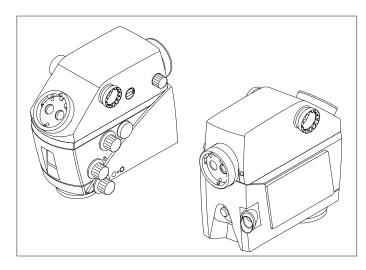
- Optics carrier with integrated camera for visible light Leica HD C100 (optional)
- Interface for assistants, either to the left and right side or to the back
- Main surgeon and back assistant interface, 360° rotatable both
- Back assistant interface with fine focus knob
- For use with Image Injection Module Leica CaptiView

## 4.2.4 Leica M530 with Leica FL800 ULT/ GLOW800



- Optics carrier with integrated camera for visible light Leica HD C100 (optional)
- Interface for assistants, either to the left and right side or to the
- Main surgeon and back assistant interface, 360° rotatable both
- · Back assistant interface with fine focus knob
- Leica FL800 ULT/GLOW800 system components built into the common housing of the ULT
- For use with Image Injection Module Leica CaptiView

# 4.2.5 Leica M530 with Leica FL400 for M530 / Leica FL560 for M530 / Leica FL800 ULT / GLOW800



- Optics carrier with integrated camera for visible light Leica HD C100 (optional)
- Interface for assistants, either to the left and right side or to the back
- Main surgeon and back assistant interface, 360° rotatable both
- Back assistant interface with fine focus knob
- Fluorescence observation filter module (Leica FL400 for M530 / Leica FL560 for M530)
- Leica FL800 ULT system components built into the common housing of the ULT
- · For use with Image Injection Module Leica CaptiView



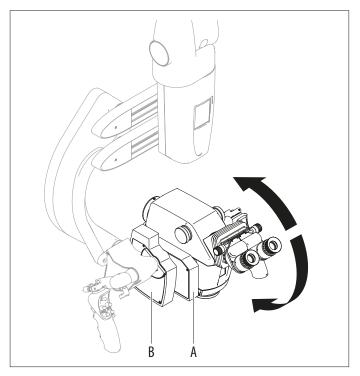
# 5 Functions

# 5.1 Balancing system

With a balanced surgical microscope Leica M530 OHX 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.

## 5.1.1 Balancing the optics carrier

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



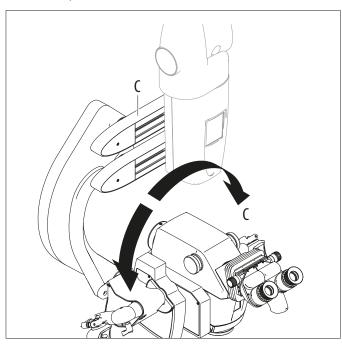
!

The optics carrier can be balanced in the A/B direction until up to the  $20^{\circ}$  options .

The essential performance of Leica M530 OHX is to provide illumination of the field of view and mechanical stability of the optics carrier.

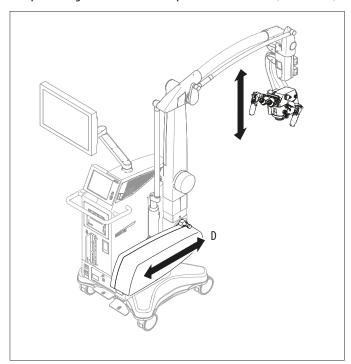
## 5.1.2 Balancing the arm system

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



# 5.1.3 Balancing the parallelogram

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



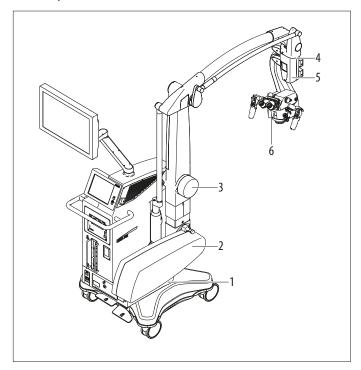
# 5.2 Brakes



The Leica M530 OHX may be moved only with released brakes

▶ Do not perform any movements when the brakes are locked.

The Leica M530 OHX surgical microscope has 6 electromagnetic brakes which stop the movements of the stand and surgical microscope:



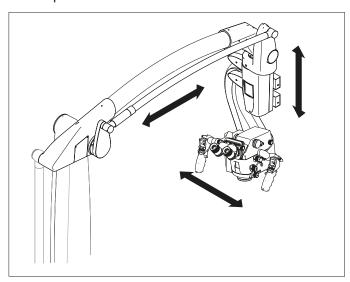
- 1 Foot
- 2 Up/down in parallelogram
- 3 Forward/back in parallelogram
- 4 In the rotary joint
- 5 In arm system
- 6 On the A and B sledges of surgical microscope

Brakes are operated via the handle.

The button of the handle with the assigned function "Selected Brakes" (refer also to the chapter on "Assigning handles", page 44) can trigger two different brake combinations: "Focus Lock" or "XYZ Free".

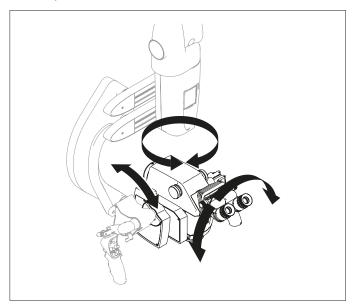
### 5.2.1 Selected Brakes - XYZ Free

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



### 5.2.2 Selected Brakes – Focus Lock

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



## 5.3 Illumination

The illumination of the surgical microscope Leica M530 is a xenon lamp and is located in the stand. Illumination is routed to the optics carrier via fibre 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.

### 5.3.1 AutoIris

Autolris synchronizes the illumination field automatically according to the magnification factor.

Using the manual override, the illumination field can be adjusted manually.

### 5.3.2 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 Leica M530 OHX 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.

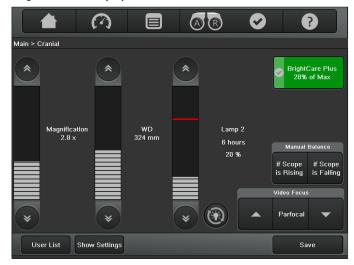
### **Heat release**

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.

### **BrightCare Plus display**



When BrightCare Plus is activated, the red line on the brightness adjustment bar shows the maximum adjustable brightness for the current working distance.

The brightness cannot be set to a level beyond the red line unless the BrightCare Plus function is intentionally deactivated.

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

# 5.4 Leica Fusion Optics

This feature provides an augmentation in resolution and depth of field for an ideal 3-D optical image.

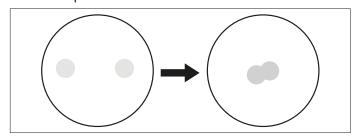
Leica FusionOptics operates with two separate beam paths with different information: the left beam path is optimized for high resolution, the right beam path for optimum depth of field. The human brain merges these two very different images to a single, optimal spatial image.

# 5.5 Leica SpeedSpot

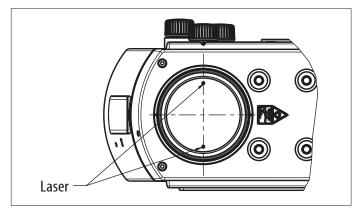
Leica M530 OHX is equipped with the Laser focussing aid Leica SpeedSpot.

If Leica SpeedSpot is activated for the current user (see page 45), the focussing aid is released when the brakes are released or when focussing.

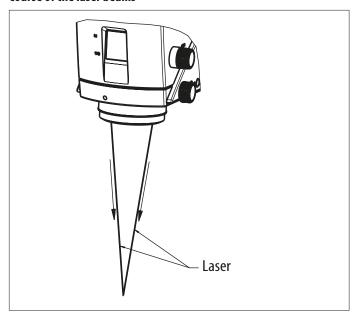
Two convergent light beams meet exactly in the focussing point of the microscope.



### Exit of the laser beams

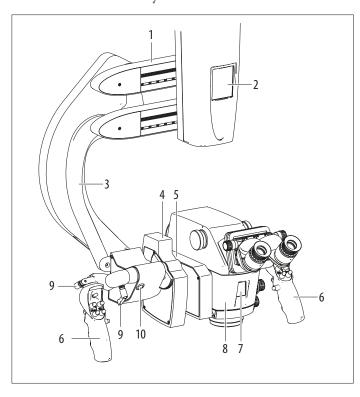


#### Course of the laser beams



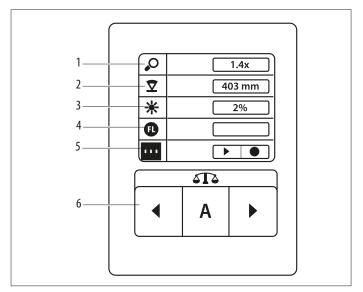
# 6 Controls

# 6.1 Leica M530 OHX microscope with arm system



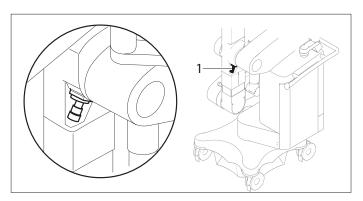
- 1 C sledge
- 2 Surgeon panel
- 3 Microscope carrier
- 4 B sledge
- 5 A sledge
- 6 Handle
- 7 Display of set working distance and magnification
- 8 Leica M530 OHX surgical microscope
- 9 Handle clamping lever
- 10 Push button for intraoperative AC/BC balancing (not available for Japan)

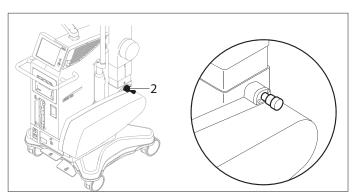
# 6.1.1 Surgeon panel



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

### 6.1.2 Locks

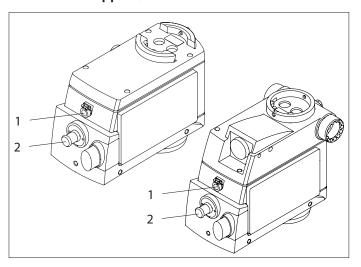




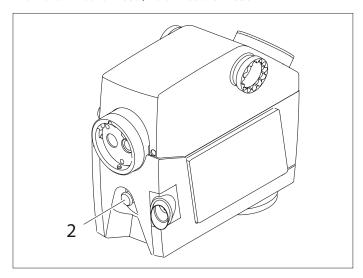
- 1 Locking in horizontal direction
- 2 Locking in vertical direction

## 6.1.3 Optics carrier – rear

### Leica M530 with Top plate / Leica M530 with IVA530



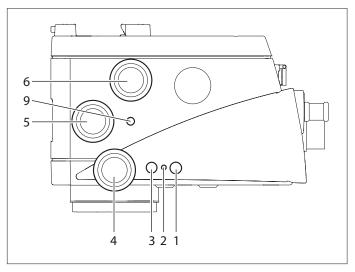
Leica M530 with ULT530 and Leica FL800 ULT or with Leica FL400 for M530 / Leica FL560 for M530



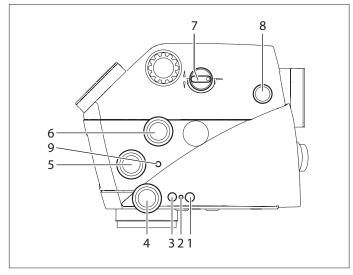
- 1 CAN socket (Leica M530 with Top plate and IVA530 only)
- 2 Optical fiber connection

## 6.1.4 Optics carrier – controls

### Leica M530 with Top plate / Leica M530 with IVA530

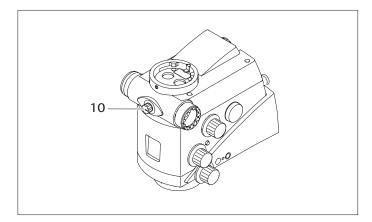


Leica M530 with ULT530 and Leica FL400 for M530 / Leica M560 for M530 or with Leica FL800 ULT



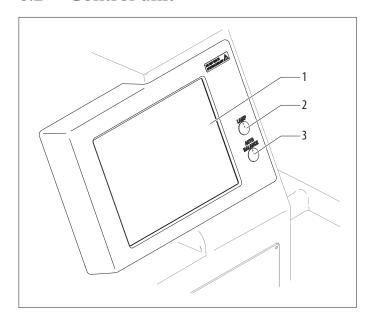
- 1 Button "Focus lock" (counter-sunk)
- 2 LED Focus lock active
- 3 Receiver Remote Control Camera
- 4 Rotary knob "Working distance" (emergency operation only)
- 5 Rotary knob "Manual override Autolris"
- 6 Rotary knob "Magnification" (emergency operation only)
- 7 Assistant back/side
- 8 Fine focus back assistant
- 9 Button "Reset Autolris"

### Leica M530 with IVA530



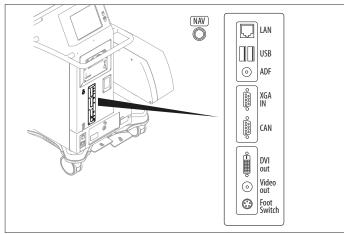
10 Assistant right/left

# 6.2 Control unit



- 1 Touch panel
- 2 Push-button with illumination LED (On/Off)
- 3 Push-button with illumination LED for Auto Balance

# 6.3 Terminals



LAN to connect to Dicom \*
USB1/2 e.g. for upgrades
AD.F. Additional Function

XGA in to connect an external video source \*\*

CAN to connect CAN devices \*\*

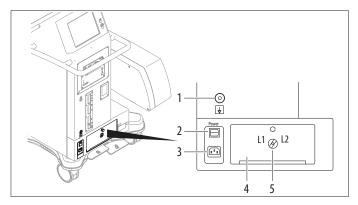
DVI out to connect an external monitor

Video out to connect an external monitor

NAV to connect a navigation system

- \* May not be used during surgery
- \*\* Connect medical equipment only

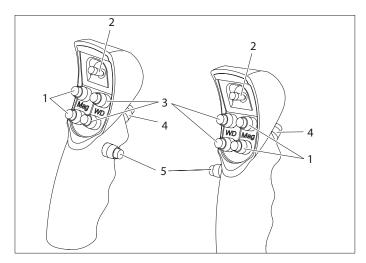
# 6.4 Stand



- 1 Equipotential bonding socket
  For connecting the Leica M530 OHX 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 Leica M530 OHX surgical microscope with integrated circuit breaker
- 3 Power input
- 4 Access door illumination unit
- 5 Illumination switch (lamp 1 / lamp 2)
- illu

The Leica M530 OHX surgical microscope has a primary illumination source and an equivalent standby illumination source.

# 6.5 Handles



### Assignment in the factory setting

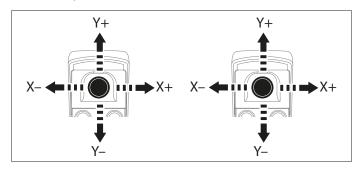
- 1 Magnification
- 2 4-function joystick
- 3 Working distance
- 4 Release all brakes
- 5 Release preselected brakes



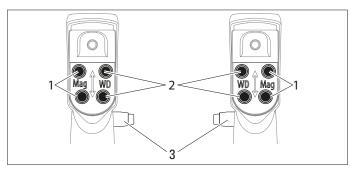
You can assign switches 1, 2, 3 and 5 of the handles individually for each user in the configuration menu. In all presets, key (4) releases all brakes. This key cannot be configured. For the joystick and the other keys presets are available according to your task.

## 6.5.1 Presets for Cranial / Spinal / ENT

## Handles – Joystick



### Handles – Buttons



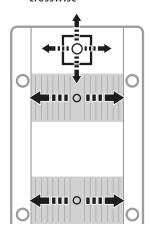
- 1 Magnification
- 2 Working distance
- 3 Release preselected brakes

# 6.6 Footswitch

This is an overview of all possible footswitches you can use to control your Leica M530 OHX surgical microscope.

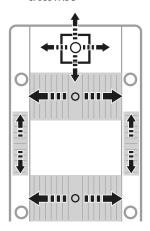
### Footswitch

- 12 functions
- crosswise



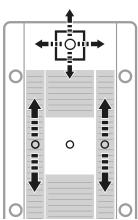
### Footswitch

- 16 functions
- crosswise



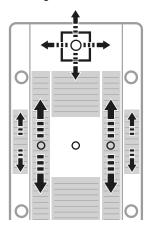
## Footswitch

- 12 functions
- · lengthwise



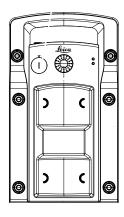
### Footswitch

- 16 functions
- lengthwise



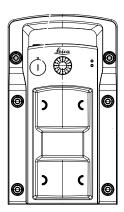
### Footswitch

- 12 functions
- · crosswise



### Footswitch

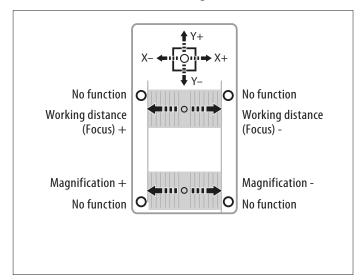
- 14 functions
- crosswise



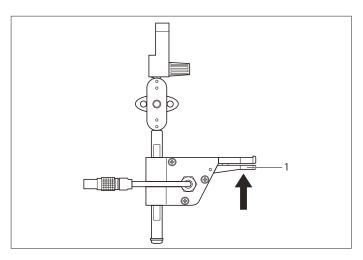
# !

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

# 6.6.1 Presets for Cranial / Spinal / ENT



# 6.7 Mouthswitch



1 Release "XYZ Free" brakes

# 7 Preparation before surgery

# 7.1 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 Leica M530 OHX 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 Leica M530 OHX 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 Leica M530 OHX surgical microscope due to uncontrolled tilting.

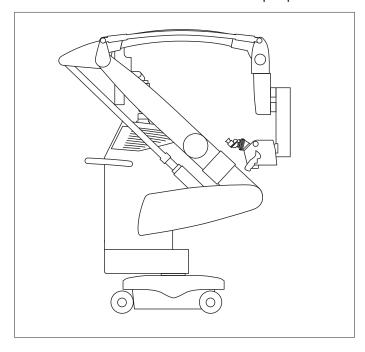
► Hold the handle when releasing the brake.

### **NOTE**

# Damage to the Leica M530 OHX 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 a tilt  $\ge 10^\circ$  the system in areas with an elevation angle bigger than  $10^\circ$ .
- ▶ Do not tilt the system to more than 10° as it might tip over.

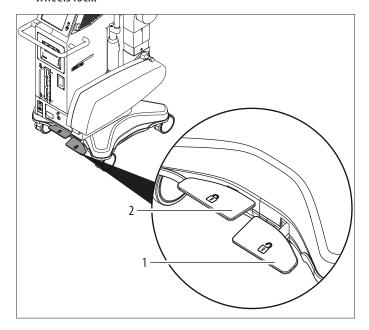
► Ensure that the Leica M530 OHX is in the transport position.



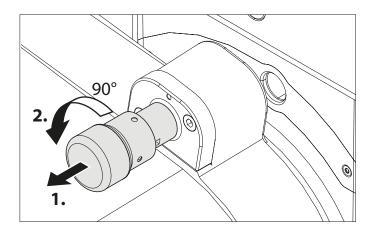


In case the Leica M530 OHX is not in transport position, refer to section 8.4.

- Press the footbrake padel on the right (1) to unlock the castor wheels lock.
- ► Move the microscope using the handle.
- ► Press the footbrake padel on the left (2) to lock the castor wheels lock.



# 7.2 Locking/unlocking the Leica M530 OHX



- ► To unlock the Leica M530 OHX, pull the locking knob for vertical or horizontal direction and rotate 90°.
  - The red dot on the stand is facing the black dot on the knob. The microscope is free to move in the selected direction.
- ► To lock the Leica M530 OHX, 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.

# 7.3 Installing optical accessories

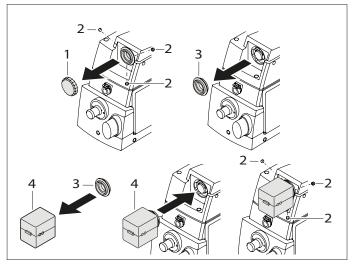


#### WARNING

# 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 Leica M530 OHX.
- ▶ Balance the Leica M530 OHX 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.

# 7.3.1 Installing a C-mount camera (Leica M530 with IVA530 only)



- ► Remove the cover (1) from the c-mount adapter.
- ► Loosen the screw (2).
- ► Remove the adapter (3).
- ► Set the camera (4) to the adapter (3).
- Install and adjust camera (4) with adapter (3).
- Fix the screw (2).

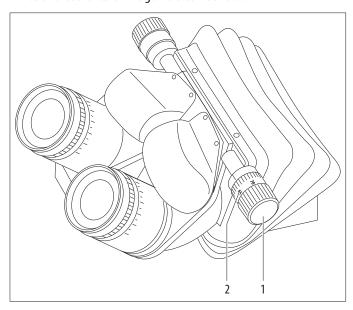


For further information refer to the user manual of the camera.

# 7.4 Setting the binocular tube

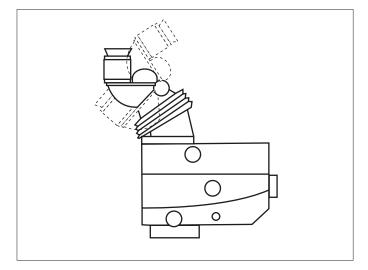
# 7.4.1 Setting the interpupillary distance

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



# 7.4.2 Adjusting the tilt

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



# 7.5 Adjusting the eyepiece

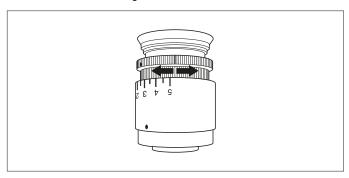
# 7.5.1 Determining/adjusting diopter settings for users

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



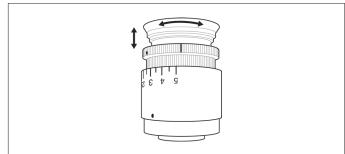
A parfocally adjusted microscope ensures that assistant's view and monitor image will always remain sharp, regardless of the selected magnification.

- 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.

## 7.5.2 Adjusting the pupillary distance



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

### 7.5.3 Checking parfocality

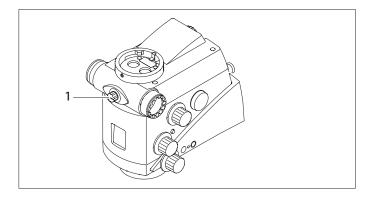
- ► Place a flat test object with sharp contours under the objective at working distance.
- Zoom through the whole range, observing the test object.



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

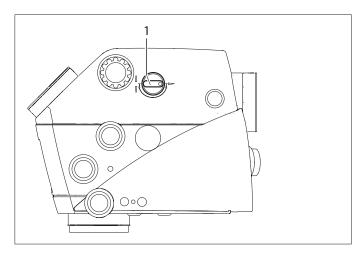
# 7.6 Selecting the assistant

### 7.6.1 Leica M530 with IVA530



Using knob (1) switch the light for the assistant from left to right or vice versa.

# 7.6.2 Leica M530 with ULT530 or Leica FL800 ULT



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

# 7.7 Stand settings

# 7.7.1 Automatic balancing of the Leica M530 OHX



#### 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 Leica M530 OHX.
- ► Balance the Leica M530 OHX 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.



#### 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.

### NOTE

### Risk of damage to the surgical microscope.

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

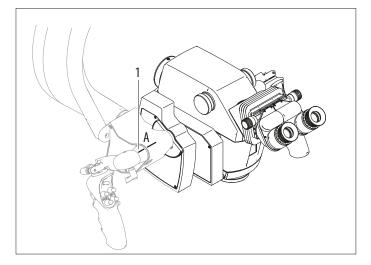
### NOTE

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

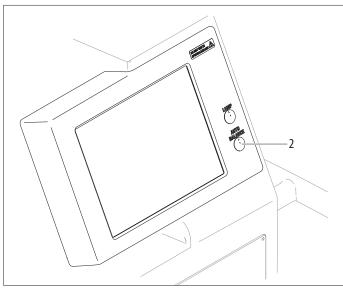
Even in balanced condition and with the approved accessories, collisions might happen due to extensive movement and rotation range of the microscope.

- 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 section 8.1.
- Make sure that all accessories needed are installed and that they are in the permitted weight range (see "Specifications" on page 58).
- Align the accessories in working position.
- ► Press the "All Brakes" button on the handle and move the optics carrier into the A-position.

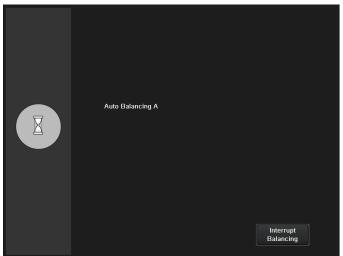
The dash (1) must point towards A.



Press the autobalancing push-button (2) on the control unit. During the balancing procedure, the push-button flashes green and an acoustic signal sounds (can be deactivated in the service menu).



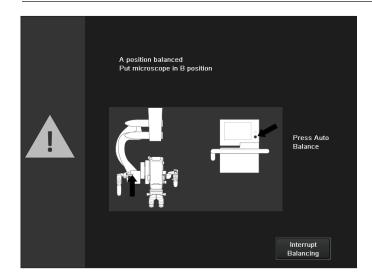
The following dialog window appears on the touch panel monitor:



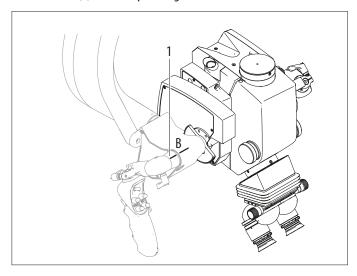


The balancing procedure can be canceled at any time using "Interrupt Balancing".

The first balancing step is completed when the acoustic signal no longer sounds and the autobalancing push-button is no longer flashing.

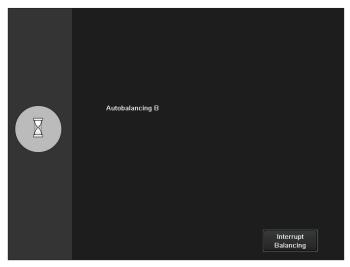


 Press the "All Brakes" button on the handle, tilt the optics carrier forwards 90° and move it into the B-position.
 The dash (1) must be pointing towards B.



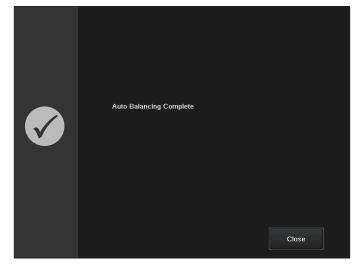
- If the mounted accessories (e.g., the assistant's binocular tube) do not allow a 90° tilt movement, turn the binocular tube upwards, tilt the optics carrier forwards and move the binocular tube back into its working position.
- Press the autobalancing push-button on the control unit again. During the balancing procedure, the push-button flashes yellow and an acoustic signal sounds (can be deactivated in the service menu).

The following dialog window appears on the touch panel:



Balancing is completed when the acoustic signal no longer sounds and the autobalancing push-button is no longer flashing.

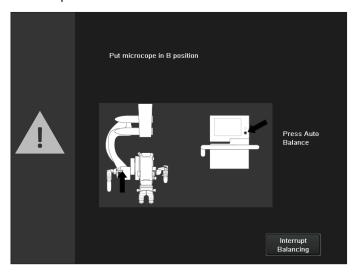
A dialog window indicates that balancing has been completed.



- ► Press the "Close" button or wait until the dialog window is closed automatically after 5 seconds.
- ► Check the balancing.
- Press the "All Brakes" button on the handle and position the microscope.

The microscope must remain fixed in any position.

If the optics carrier is not oriented correctly, the following dialog window opens:



- Acknowledge with the "Close" button.
- Correct the orientation of the optics carrier (B-position).
- Press the autobalancing push-button. Autobalancing re-starts.

# 7.7.2 Intraoperative balancing of the Leica M530 OHX (not available for Japan)

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

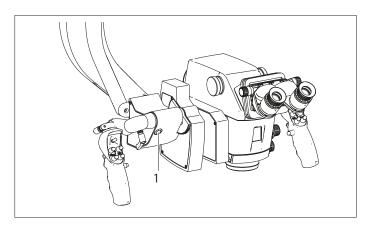
Risk of injury due to downward movement of the surgical microscope.

- ► 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.

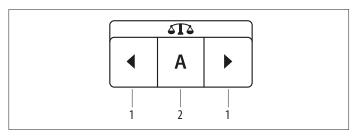


Press the AC/BC button (1) to activate the intraoperative balancing.

During the balancing an audio signal is activated.

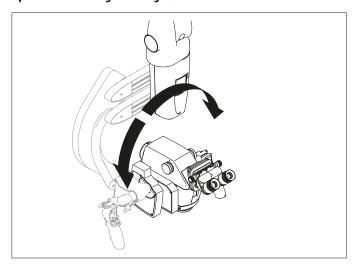
### 7.7.3 Manual balancing of the Leica M530 OHX

For manual balancing, the axes A, B and C can be moved manually using the balancing touch 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

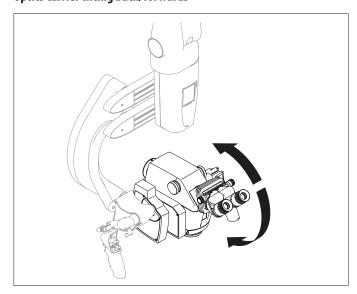


► Move the C-axis until the optics carrier is balanced.

Optics carrier tilting to the right move to the left

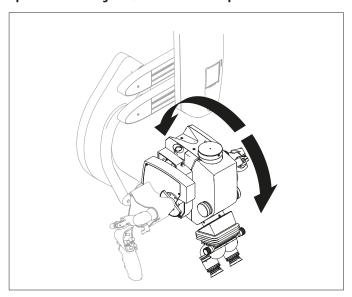
Optics carrier tilting to the left move to the right

# 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)

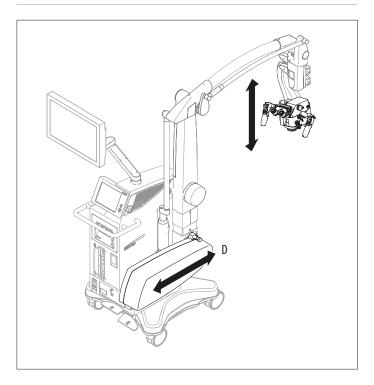
If the microscope cannot be balanced manually, the weight of the accessories is probably outside the balanceable weight range. This can only be done for A, B and C axes by reducing or increasing the accessory weight to within the permitted range (see page 64).

## 7.7.4 Correcting the D-balancing manually

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 the D-balancing of the stand with one of the keys "If Scope is Rising" and "If Scope is Falling" on the "Main" screen of the control unit.



Microscope is too heavy Microscope is too light touch "If Scope is Falling" touch "If Scope is Rising"

# 7.8 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 Leica M530 OHX.
- ► Balance the Leica M530 OHX 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.

The Leica M530 OHX can be positioned easily on the operating table and offers a variety of possibilities for operations on the head or spinal column.

The Leica M530 OHX achieves this large range of positions through its very long and high arm system.

- ► Release the footbrakes (see page 20).
- ► Move the Leica M530 OHX surgical microscope carefully over to the operating table by the handle and into the required position for the operation.

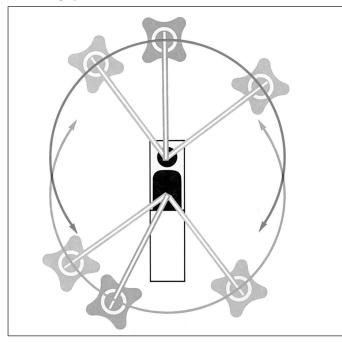
The ideal working position for the arm system is  $20-30^{\circ}$  tilted to the front.

#### NOTE

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

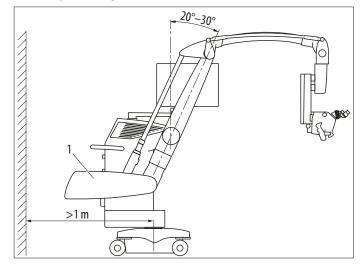
Make sure to have a free moving space around the center of the base.

### **Positioning options**



- Set the footbrake.
- Plug the footswitch into the stand and position it.
- ▶ Plug the power cable into the stand.
- ► Connect the equipotential bonding to the stand.

### **Notes on positioning**



- Arm system inclined by  $20^{\circ}$  to  $30^{\circ}$
- Distance to the wall/furniture: min. 1 m
- 7.9 Attaching sterile controls and drape



### WARNING

### Risk of infection.

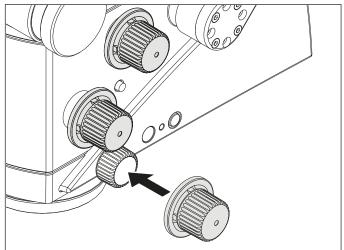
► Always use the Leica M530 OHX surgical with sterile controls and a sterile drape.

## 7.9.1 Covers for rotary buttons



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

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



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

### 7.9.2 Cover for footswitch



Packaging the footswitch in a plastic bag protects it against dirt.

### 7.9.3 Sterile drape for stand



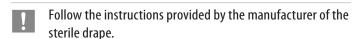
- Only use the sterile Leica tested drapes specified in the Accessories section.
- Drape only as far as the arm system (see picture below).



### CAUTION

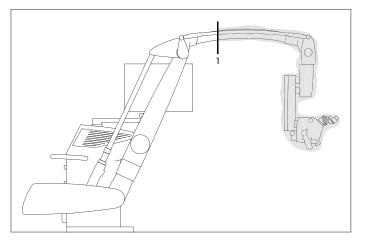
### Risk of infection.

- Leave sufficient space around the stand to ensure that the sterile drape does not come into contact with nonsterile 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 Leica M530 OHX surgical microscope as far as the arm system.
- ► Clamp the protective glass (optional) onto the objective.
- ► 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.





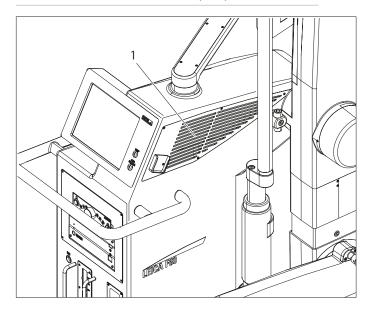




### NOTE

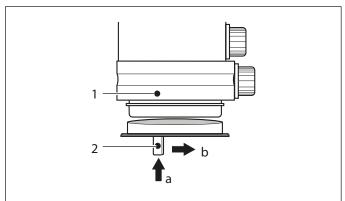
### Risk of overheating of the system.

- Covering the air inlet (1) can result in a controlled shutdown of the system due to overheating.
- ► Make sure the air inlet (1) is always kept free.



## 7.9.4 Attaching the protective glass to the objective

Place the sterilized protective glass on the optics carrier so that the markings on the Leica M530 OHX (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.

## 7.10 Function check



Refer to the checklist before operation on page 72.

# 8 Operation

# 8.1 Switching the microscope on



### WARNING

### Danger of fatal electrical shock.

- ► The Leica M530 OHX 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.

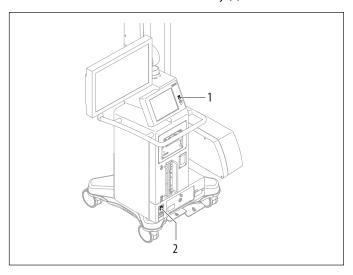
- ▶ Use the lowest comfortable light intensity.
- Adjust the field of view to match the operating field.
- ► Irrigate the wound frequently.
- Cover the exposed parts of the pinna with a moist surgical sponge.
- ► Connect the microscope to a grounded socket.
- ► Secure power cable at the stand.
- Switch on the microscope at the power switch (2) on the stand. After the surgical microscope is switched on, a lamp test for both lamps is carried out and the settings of the last active user are loaded.



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.



The main screen is displayed.



► Check both lamp hour counters by switching from lamp 1 to lamp 2 with button (1).

To guarantee a good light performance the life time shall not exceed 500 hours.

# 8.2 Positioning the microscope

## 8.2.1 Coarse positioning

- ► Hold the microscope by both handles.
- Press the button for releasing all brakes and position the microscope.
- ► Release the brakes button.



Also refer to the "Locking/unlocking the Leica M530 OHX" on page 21.

#### **NOTE**

# Damage to the Leica M530 OHX surgical microscope due to uncontrolled tilting.

► Hold the handle when releasing the brake.

## 8.2.2 Fine positioning

- Position the microscope with the XY drive using the joystick on the handle or the joystick on the footswitch.
- You can change the speed at which the XY motors move on the "Speed" menu screen.

  This value can be saved individually for each user (see page 41).



# 8.3 Adjusting the microscope

# 8.3.1 Adjusting the brightness

You can make the illumination brighter or darker using either the touch panel monitor, a hand/footswitch, or handle.

### On the touch panel monitor in the "Main" menu screen



- ▶ Press the or button on the bar for adjusting the brightness of the illumination.
- or –
- Press the brightness adjustment bar directly.
   The brightness of the active main illumination changes.



- Clicking the or button changes the brightness value in increments of 1. Holding down the button with your finger changes the value in increments of 5.
- The start setting can be saved individually for each user (see page 43).
- The main illumination can only be switched on and off using the illumination push-button on the stand.
- The brightness setting is also visible when the illumination is off. However, the display bar will appear darker.

### On the handswitch/footswitch/handle

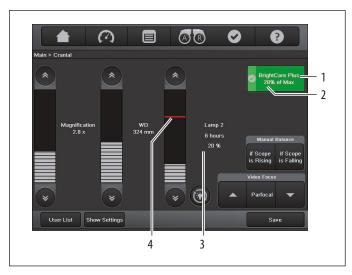
Depending on the assignment (see page 43), you can also increase and decrease the brightness of the main illuminator using two correspondingly assigned buttons on the handswitch/footswitch/handle.

### 8.3.2 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.

The BrightCare Plus function is part of the "Main" menu screen.



1 BrightCare Plus button

green BrightCare Plus is enabled yellow BrightCare Plus is switched off

- 2 Configured illumination condition for BrightCare Plus (configured brightness (3)/ max. configurable brightness (4) in %)
- 3 Percent value of the configured brightness
- 4 Red line for maximum configurable brightness with BrightCare Plus

The red line on the brightness adjustment bar shows the maximum adjustable brightness for the current working distance.
The brightness cannot be set to a level beyond the red line.
When the working distance is reduced at a set brightness, the brightness is reduced automatically.



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



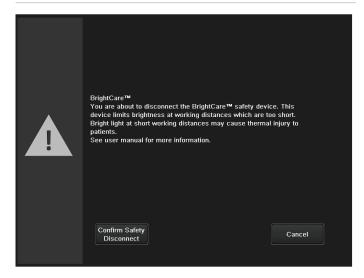
When shipped from the factory, the "BrightCare Plus" safety function is activated for all users

### **Deactivating BrightCare Plus**



Deactivating BrightCare Plus is only possible if this function is enabled in the service menu.

If enabled, by clicking the "BrightCare plus" button a dialog window opens in which you have to confirm that you want to deactivate the safety function.



When the "BrightCare plus" safety function is deactivated, the color of the "BrightCare plus" button changes from green to yellow.



#### 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.



The status of the "BrightCare plus" safety function can only be changed permanently in the "User settings" menu. A change in status during operational procedures will not be stored when the user settings are saved with "Save" or "Save as"!

### Reactivating the "BrightCare Plus" safety function:

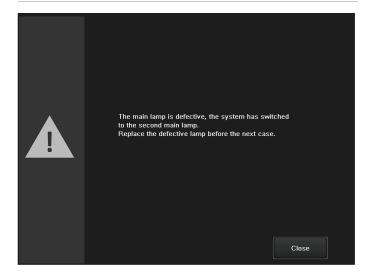
Click the yellow "BrightCare plus" button again.
 "BrightCare plus" is now activated and the button is again lit green.

## 8.3.3 Changing lamps

If the xenon primary illuminator fails, you can use the button (1) on the "Main" menu screen to switch to the auxiliary illuminator.



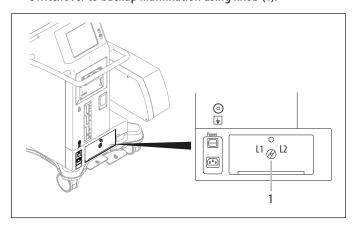
- !
- Replace the defective lamp at the next opportunity.
- Never begin a surgery with only one functioning xenon lamp.
- A dialog window informs you when the xenon lamp is losing luminosity and is no longer sufficient either for blue light (FL400 application only) or for white light (all other applications). We recommend that you keep a replacement lamp handy.



- Press the "Close" button. The dialog window is closed.
- ► Replace the defective lamps, see section 11.3.

# Changing over manually to backup illumination (emergency use only)

Switchover to backup illumination using knob (1).



# 8.3.4 Setting the illumination field diameter



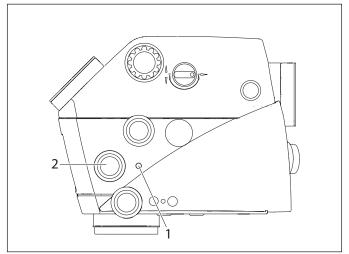
### **CAUTION**

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 Autolris, the field diameter is automatically adapted to the size of the field of view at the Leica M530 OHX optics carrier.

- ► To adjust the illumination field diameter manually, use rotary button (2).
  - Automatic adjustment Autolris is deactivated.
- ► To reactivate Autolris 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).

#### 8.3.5 Adjusting the magnification (zoom)

You can adjust the magnification using a footswitch/handswitch/handle or the "Magnification" adjustment bar on the "Main" menu screen of the control unit.

#### On the touch panel monitor in the "Main" menu screen:



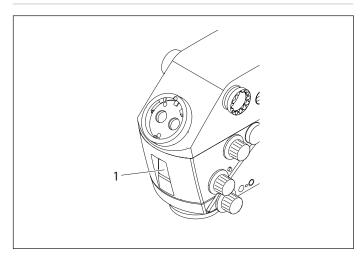
- ► Press the or button on the bar for adjusting the magnification.
- or –
- Press the magnification adjustment bar directly. The magnification changes.
  - Clicking the or button changes the magnification value in increments of 1. Holding down the button with your finger changes the value in increments of 5.
    - You can adjust the magnification motor speed in the "Speed" menu.
    - These values can be saved individually for each user (see page 41).



#### WARNING

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

- ► If the magnification motor fails, adjust the magnification manually.
- You can read the currently set magnification on the display (1) on the Leica M530 OHX optics carrier and on the surgeon panel.



#### Manually adjusting the magnification (zoom)

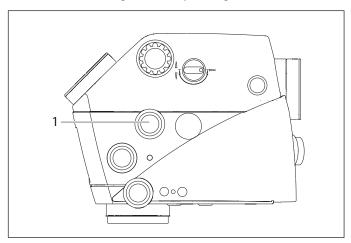
#### NOTE

#### 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 (1).

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



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



#### 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 microscope in position.
- ► Do not adjust the rotary button for manual setting of the working distance while using the laser.



#### 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 adjust the working distance using the footswitch/handle or the "WD" adjustment bar on the "Main" menu screen of the control unit.

#### On the touch panel monitor in the "Main" menu screen:



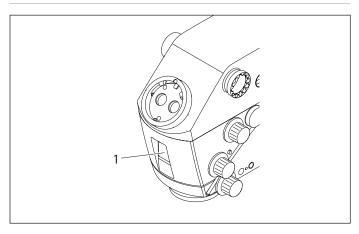
- ► Press the or button on the bar for adjusting the working distance.
- or –
- Press the working distance adjustment bar directly. The working distance changes.



- Clicking the or button changes the working distance in increments of 1. Holding down the button with your finger changes the value in increments of 5.
- You can adjust the working distance motor speed in the "Speed" menu.
- These values can be saved individually for each user (see page 43).
- You can return the working distance motor to the working distance saved for the current user using the "WD Reset" button.



- You can save the currently set working distance on the "Main" screen of the control unit or read it off the display (1) on the Leica M530 OHX optics carrier.
- You can read the currently set working distance off the display (1) on the Leica M530 OHX optics carrier and on the surgeon panel.





#### WARNING

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

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

#### Setting the working distance manually



#### WARNING

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

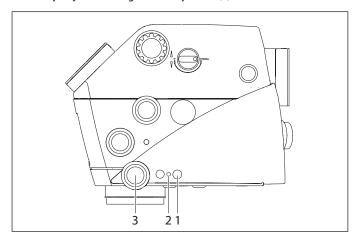
- ► When using lasers, always set the working distance of the microscope to laser distance and lock the microscope in position.
- ► Do not adjust the rotary button for manual setting of the working distance while using the laser.

#### 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, the working distance can be manually adjusted using the rotary knob (3).



► Turn rotary button (3) and set the working distance as required.

#### 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 (1).
  The yellow LED (2) turns on and the working distance is locked.
- Press key (1) again.
  The yellow LED (2) turns off and the working distance is released.

#### 8.3.7 Adjusting the video fine focus (optional)

The Leica FL800 ULT and ULT530 offer fine focusing and parfocality reset of the video focus.



► The video focus can be adapted to your needs by pressing the focus button up (3) or/and down (1). This command can be given to the GUI and from the handle, if defined.



Focus adjustment operates in both directions with an endless circular movement.

The video fine focus can be re-adjusted to parfocality position by pressing the parfocality button (2). The video focal plane will then be aligned for all observers with zero diopters respectively with correct individual diopter settings. This command can be as well given on the GUI and from the handle, if defined.

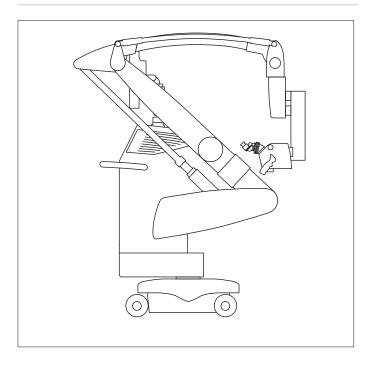
### 8.4 Transport position

► Press the "All Brakes" button and move the Leica M530 OHX into the transport position.

#### **NOTE**

#### Damage to the Leica M530 OHX surgical microscope.

Make sure that the video monitor does not collide with the horizontal arm and the vertical arm of the stand.



- ► Shut down the system according to section 8.5.
- ► Unplug and secure the power cable.
- ► If present, store the footswitch on the stand.

#### NOTE

## Damage to the Leica M530 OHX 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 a tilt  $\ge 10^\circ$  the system in areas with an elevation angle bigger than  $10^\circ$ .
- 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 base brake will not be able to hold the weight and the system could start to move.

# 8.5 Shutting down the surgical microscope

- ► If present, turn off the recording system according to the manufacturer's instructions.
- 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.

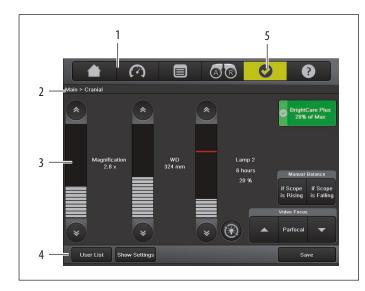
# 9 Control unit with touch panel

#### NOTE

#### Damage to the touch panel.

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

#### 9.1 Menu structure



- 1 Quick access to the screens "Main" , "Speed" , "Menu" 
  "AR" and "Help" ?
- 2 Status line
- 3 Display range
- 4 Dynamic button bar
- 5 Warning messages
- In operational mode, the status line displays the current user and specifies the current location in the menu at all times.

## 9.2 Selecting users

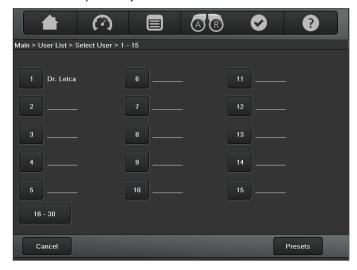
In the "Main" and "Speed" menu screens, the two buttons "User List" and "Show Settings" appear in the dynamic button bar at all times.





#### 9.2.1 User list

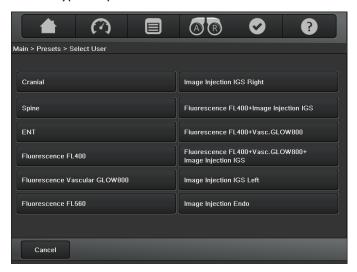
The "User List" opens a two-page user list from which you can select one of up to thirty users that can be saved.



- ► Click the "1-15" or "16-30" button to switch between screens.
- Select a user.
  The "Select" button is shown.
- Click "Select". The user settings are loaded.
- !
- When the user list is open, it can be edited at any time.
- Before each operation, make sure that your desired user is selected and familiarize yourself with the assignment of the handles and the optional footswitch (if used).

#### 9.2.2 Presets

You can find a list of default users preset by Leica for the most common types of operation under "Presets".



Click one of the default users, then click "Select". The Leica M530 OHX surgical microscope is ready to operate straight away.



- You can adapt and save the settings of these default users as required (see page 41).
- You can click the "Show Settings" button at any time to see an overview of the user settings of the current user.

#### 9.2.3 Show Settings

► Press the "Show Settings" button in the dynamic button bar to see an overview of the user settings of the current user.



### 9.3 Menu – User Settings

You can configure user settings in this menu.

► Click the "Menu" button and select "USER SETTINGS".



The following screen is displayed:



"Load" Loads the settings of an existing user from the

user list for modifying.

"New User" Opens a new user with "blank" settings.

"New (Preset)" Opens the "Preset" screen for selecting a default

user in order to create a new user with the settings of the desired preset and to load or

modify the user's settings.

"Edit User List" Allows to rename, to move or to delete users.



- You can also add a user from the operational menu.
- If you want to keep the current settings, you can save them by clicking the "Save" button (which appears as soon as the basic settings of the current users have been changed), either for the current user ("Save") or under a new username ("Save as New").

#### **Editing the user list**

Various functions are available in the user list depending on the situation.



Select the user.

The available functions are displayed in the dynamic button line:

"Move" Moves the selected user to another available

location of your choosing.

"Delete" Deletes the selected user.

"Rename" Renames an existing user. The user's settings

are not changed.

"Change Password" Changes the password.



#### **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.

#### 9.3.1 User Setting Protection

To avoid unauthorized or accidental changes of user settings, each user setting can be protected by a password/PIN. This keeps the working parameters identical each time you load a protected user setting. Changes can be done during the application, but will not be stored unless "Saved as "current" or "Saved as new" with entering the correct password/PIN.

Saving and protecting the user settings is done in two ways:

#### As a current user setting

You will receive a prompt for the password/PIN.

If a password/PIN was defined save the changes of the user settings with entering the correct password/PIN.

If it is incorrect the system will go back to "Start values main".

- ► Choose "Save as current" and enter the password/PIN again. If no password/PIN was defined, you can define a password/PIN (4-10 characters).
- ► Press "OK" for re-entering and confirmation.

If the re-entered password/PIN does not match the enter/re-enter process has to be repeated.

If no password/PIN should be defined, you can exit the procedure by pressing "Skip" or before re-entering with "Cancel".

#### As a new user setting

You will receive a screen message and a prompt for the password/ PIN after entering the name of the user setting. If the settings should be protected:

Enter a password/PIN (4-10 characters) and press "OK" for re-entering and confirmation.

If no password/PIN should be defined you can exit the procedure by pressing "Skip" or before re-entering with "Cancel".

If the re-entered password/PIN does not match the enter/re-enter process has to be repeated.

The protection of a user setting by a password/PIN is indicated by "(locked)" right after the user setting name on the GUI main page or by a lock icon in front of the user setting name in the Select User page.





#### 9.3.2 Setting the "Main" start values

For the selected user you can set the start values for the illuminator, working distance and magnification on this screen.



- ► Clicking the or key changes the values in increments of one. Holding down the button with your finger changes the value in increments of five.
- ► You can also set the desired value by directly clicking the bars.

#### **Brightcare Plus**

Set the status of the BrightCare Plus safety function for the selected user.

#### 9.3.3 Setting the "Speed" start values

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



- ► Clicking the or key changes the values in increments of one. Holding down the button with your finger changes the value in increments of five.
- ► You can also set the desired value by directly clicking the bars.

#### **Intelligent Focus Speed**

► If "Intelligent Focus Speed" is activated, the focus speed automatically adapts to the current magnification.

High magnification low speed Low magnification high speed

#### **WD Reset**

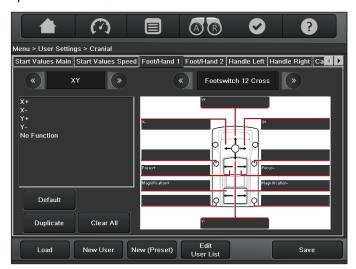
► Set the default settings for WD-Reset.

If "WD Reset" is activated, the working distance motor automatically moves to the working distance saved for each user in the user settings when "All Brakes" are released.

This function is deactivated in the factory default configuration.

## 9.3.4 Footswitch/handswitch assignment (Foot/Hand 1 and Foot/Hand 2)

Here, you can configure individual settings for each user for your optional footswitch/handswitch.



1

The numbering of Foot/Hand 1 and Foot/Hand 2 is according to the terminal assignment, see page 17.

- ► First select a Foot/Hand switch.
- In the right selection field, select the footswitch/handswitch you are using.
- ➤ You can scroll forwards or backwards in the list by clicking the arrowheads.
- You can also connect the optional 6-function footswitch to the Leica M530 OHX. The 6 available switches work similar to those of the currently selected 12 or 16-function footswitch.
- Click the "Default" button. The default settings are assigned to the selected footswitch/ handswitch.
- You can then modify these settings as you like. Clicking the "Clear All" button clears the assignments for all keys.

#### **Configuring individual keys**

- ► In the right selection field, select the footswitch/handswitch you are using.
- ➤ You can scroll forwards or backwards in the list by clicking the arrowheads.
- ► In the left selection field, select the function group with the desired functions.
- ► You can scroll forwards or backwards in the list by clicking the arrowheads.
- Select the desired function.
- Click the caption of the desired key to assign the selected function to it.

#### Overview of function groups

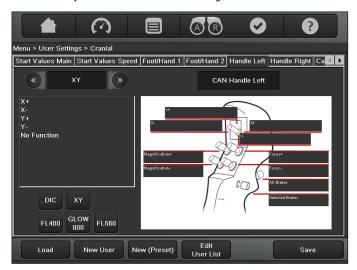
The possible configuration is divided into the following function groups:

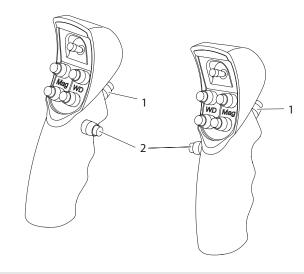
- Drive
- Extra
- Illumination
- XY
- Fluorescence
- DIC/IGS
- ► You can change the status of a function with the "Toggle" function (e.g. on/off). The "Pulse" function continuously changes a status (such as increasing the brightness).
- With the "XY Complete" function, you can assign all four functions of the joystick simultaneously.
- ► To delete an assignment which you do not want, select the "No Function" element which can be found in all function groups and assign it to the key in guestion.
- If you are creating only one footswitch/handswitch configuration for one user, we recommend duplicating it to the second footswitch/handswitch input by pressing the "Duplicate" button.

This ensures that your footswitch/handswitch functions the way you want it to, regardless of which input it is plugged into.

## 9.3.5 Handle assignment (Handle Left / Handle Right)

On the two handle assignment screens, you can assign up to nine functions of your choice to the left and right handles.

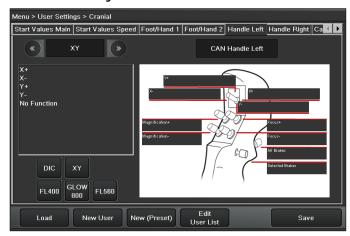




- The "All Brakes" function is always assigned to the rear switch (1) for both handles, and can neither be overwritten nor deleted.
- ► In the left selection field, select the function group with the desired functions.
- ➤ You can scroll forwards or backwards in the list by clicking the arrowheads.
- Select the desired function.
- Click a free caption of the desired key to assign the selected function to it.
- ► The inner switch (2) to which "Selected Brakes" is pre-assigned can be freely assigned, as required.

  You can also assign one of the five defaults "X/Y", "FL400", "DIC", "GL0W800" or "FL560" completely to each handle.

#### **Default handle assignments XY**



#### 9.3.6 Leica Image Injection settings

For more Information see the CaptiView user manual.

#### 9.3.7 Leica SpeedSpot Settings

Leica SpeedSpot is **not** available with FL800 mode and deactivated FL400 mode per default.



#### **SpeedSpot Function**

Select from the following: Active, Not active

#### **SpeedSpot Trigger**

Leica SpeedSpot can automatically be switched on and off depending on the following conditions:

Focus Movement of working distance motor

Brakes Brakes released

XY Movement of XY motors

#### **SpeedSpot Delay**

For switching off Leica SpeedSpot a timeout can be configurated

from 0 to 10 seconds.

Default timeout is 5 seconds.

0 seconds means that the function is switched off immediately.

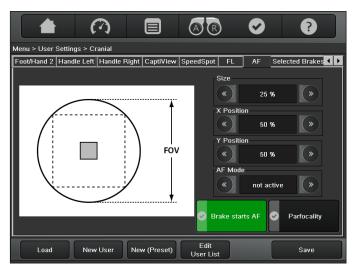
#### 9.3.8 Accessories settings

The Accessories settings are described in the corresponding user manuals.

#### 9.3.9 AutoFocus Settings



- AutoFocus is an optional function and can be ordered additionally.
- AutoFocus is **not** available in all countries.
- AutoFocus is **not** available with FL800 mode and FL400 mode.



The small grey field in the middle represents the AutoFocus window.

#### Size

Adjust the size of the AutoFocus window
 Possible settings: 10 % to 100 %
 Default setting: 25 %

#### X Position / Y Position

Adjust the X and Y position of the AutoFocus window

Possible settings: 0 % to 100 %

Default setting: 50 % each, so the AutoFocus window is

exactly in the middle

#### **AF Mode**

Select from the following: Active, Not active

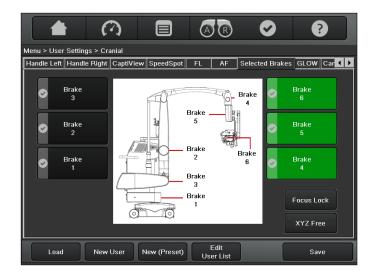
#### **Brake starts AF**

When activated, releasing the brakes starts the AutoFocus function.

#### **Parfocality**

- When activated, the objective is automatically brought into working distance at maximum magnification.
- When deactivated, the objective is automatically brought into working distance at the current magnification settings.
- AutoFocus functions can be operated via footswitch/ handswitch/handle. AutoFocus settings are part of the function group "Extra", see page 43.

#### 9.3.10 Selected Brakes



- Use the "Toggle" buttons to activate/deactivate the selected brake.
- or –
- Activate the desired brake combination "Focus Lock" or "XYZ Free" by clicking the relevant button.

The button for the preselected brake combination lights up green.

#### NOTE

#### Risk of damage.

Only move the surgical microscope when all brakes are released.

#### 9.3.11 Saving user settings

- ► Click the "Save" button.
- Select an available location in the user list at which you want to store your user.



If you like, you can edit the user list first.



► Enter the desired username using the keyboard.



► Click the "Save" button to save the user at the desired location under the name you have entered.

#### 9.4 Menu – Maintenance menu

► Press the Menu button and select "Maintenance".



The Maintenance menu offers the following screens:

- Lamp History
- Check Switches
- Microscope Settings

#### 9.4.1 Maintenance -> Lamp History

On this screen, you can view and reset the operating hours of xenon lamp 1 and xenon lamp 2.

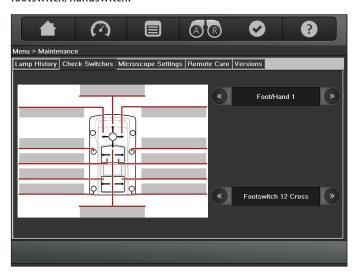


Whenever you replace a bulb, reset the bulb's hour meter to 0 by double-clicking the "Reset" button.

A dialog window informs you when the xenon lamp is losing luminosity and is no longer sufficient either for blue light (FL400 application only) or for white light (all other applications).

#### 9.4.2 Maintenance -> Check Switches

On this screen, you can test your handles and the optional footswitch/handswitch.



#### Top right selection field

In this field you can select the connection you are using or the desired handle.

Scroll forwards or backwards in the list by clicking the arrowheads to select the connection.

#### **Bottom right selection field**

In this field you can select the footswitch/handswitch you want to check.

- Scroll forwards or backwards in the list by clicking the arrowheads to select the footswitch/handswitch.
- Press all of the keys, one after the other, of the footswitch/ handswitch or handle you want to test.

If the key you have pressed is functioning properly, a green dot appears on it on the display. The comment "Tested" appears in the caption field of the key.

#### 9.4.3 Maintenance -> Microscope Settings

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



#### **Select Surgeon Tube**

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

Scroll forwards or backwards in the list by clicking the arrowheads.

#### **Select Eyepiece**

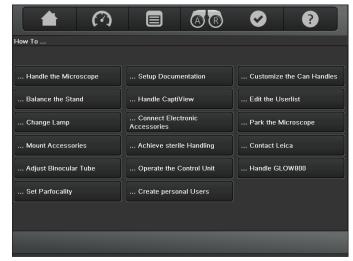
In this field you can select the magnification of the eyepieces being used by the surgeon.

- Scroll forwards or backwards in the list by clicking the arrowheads.
- If you do not make a selection, the magnification is calculated for the standard equipment: binocular tube 30°–150° and eyepiece with 10× magnification.

### 9.5 Menu – "How to..."



This screen displays, in short form, user instructions for operating your surgical microscope.



Press the button for the topic desired.
Detailed information "How to ..." is displayed.



The "Help" button in the static menu bar provides access to the "How To..." screens at all times.

### 9.6 Menu – "Service"



This area is password-protected.



Before starting the service menu, end the recording procedure on the documentation system. Otherwise data could be lost.

## 10 Accessories

A comprehensive range of accessories enables the Leica M530 OHX 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×
11111 2 6 7 9	Eyepiece 12.5×
	Eyepiece 8.3×
	Magnification multiplier
	Stereo attachment second observer
	Tube for second observer
	Universal Laser Adapter

Picture	Devices and accessories
	Mouth Switch



Leica HD C100, for IVA530 only

#### **Footswitches**

- Wireless Footswitch, 12 functions, type B
- Wireless Footswitch, 14 functions, type B

#### **Recording Systems**

- HDMD PRO
- Evolution 4K

#### **Camera System**

• Leica Camera System HD C100

#### **Stand monitors**

- 27" 2D-4K
- 32" 3D-4K

#### **Other Accessories**

- · Leica AutoFocus
- Leica CaptiView
- Leica FL800 ULT
- Leica FL400 for M530
- Leica FL560
- GLOW800

#### **Cart monitor**

• 55" 3D-4K

!

See the corresponding instruction for use.



Only original country-specific power cords from Leica must be used.



Do not use third party products without permission of Leica.

#### **Drapes**

Supplier	Article No.	Main Front	Back assistant	Assistant left	Assistant right
Mikrotek	8033650EU 8033651EU 8033652EU 8033654EU	J	<b>√</b>	1	1
Pharma- Sept	9228H 9420H	✓	_	✓	1
Fuji System	0823155	✓	_	✓	✓
	0823154	✓	✓	_	✓
Spiggle & Theis	2500130H	1	_	1	1
Advance Medical	09-GL800	✓	_	1	1



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

### 11 Care and maintenance

To ensure that Leica M530 OHX 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.

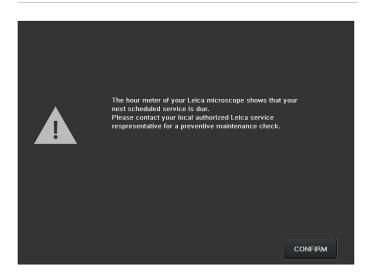
We recommend purchasing a service contract from Leica Service & Support (or authorized Service Providers) to ensure regular inspection, timely response and a direct access to our parts inventory. Please note that only genuine parts from Leica shall be used for maintenance.

## $\Lambda$

#### **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 organisation.



Press the "Close" button. The dialog window is closed.

#### 11.1 Maintenance instructions

- Put a dust cover over the instrument while the brakes are in work.
- Keep accessories in a dust-free place when not in use.
- Remove dust with a pneumatic rubber pump and a soft brush.
- · Clean the objectives and eyepieces with special optics cleaning

- cloths and pure alcohol.
- Protect the surgical microscope from damp, vapors, acids, alkalis, and corrosive substances.
  - Do not keep chemicals near the instrument.
- Protect the surgical microscope from improper handling. Install
  other device sockets or unscrew optical systems and mechanical
  parts only when explicitly instructed to do so in this user
  manual.
- Protect the surgical microscope from oil and grease.
   Never oil or grease the guide surfaces or mechanical parts.
- Remove coarse debris with a moistened disposable cloth.
- To disinfect the surgical microscope, use compounds from the surface disinfectant group based on the following active ingredients:
  - · aldehydes,
  - · alcohols,
  - · quaternary ammonium compounds.



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.

## 11.2 Cleaning the touch panel

- Before cleaning the touch panel, switch off your Leica M530 OHX and disconnect it from the power supply.
- ► Use a soft, lint-free cloth to clean the touch panel.
- ► Do not apply cleaning agent directly to the touch panel; rather, apply it to the cleaning cloth.
- Use a commercially available glass/eyeglass cleaner or plastic cleaner to clean the touch panel.
- ▶ Do not apply pressure to the touch panel while cleaning it.



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

#### NOTE

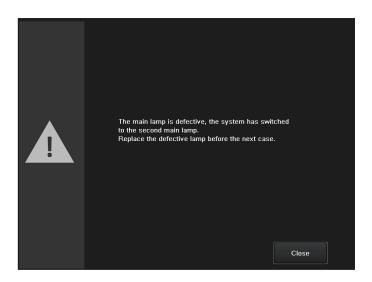
#### Damage of the touch panel.

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

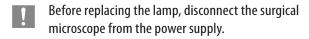
## 11.3 Changing bulbs

!

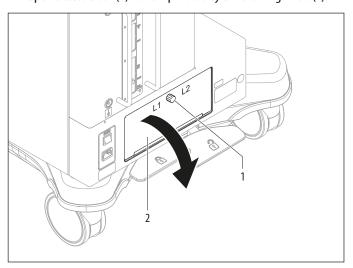
A dialog window opens when the lamp power drops below the recommend minimum level.



- Press the "Close" button. The dialog window is closed.
- ► Replace the defective lamps.



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



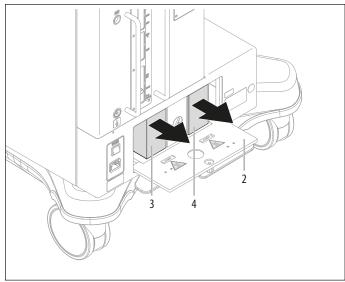


#### CAUTION

#### 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.

► Remove the defective lamp insert (3 or 4) and install a new lamp insert (available from Leica Microsystems).



- ► Close the access door.
- Switch on the surgical device.A lamp test for both lamps is carried out.
- ► Set the respective lamp timer to zero ("Maintenance → Lamp History" on page 47)

# 11.4 Notes on reprocessing of resterilizable products

#### 11.4.1 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.

#### 11.4.2 Instructions

#### Workplace

 Remove surface contamination with a disposable cloth/paper cloth

#### Storage and transport

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

#### **Preparation for cleaning**

Remove the product from the Leica M530 OHX 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

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

No special requirements.

#### 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 on page 54.

#### Storage

No special requirements.

#### **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.

#### 11.4.3 Sterilization table

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

		Permissible sterilization methods			F	Products					
Article No.	Designation	Steam autoclave 134°C, t > 10 min.	Ethylene oxide max. 60°C	STERRAD® 1)	M320	M220	M620	M844 M822 M820	M525	M530	M720
10180591	Clip-on handle	✓	_	✓	_	_	✓	✓	_	_	_
10428328	Rotary knob, binocular tubes T	✓	_	_	_	✓	_	✓	✓	✓	✓
10384656	Rotary knob, transparent	✓	_	✓	_	✓	✓	_	_	_	_
10443792	Lever extension	✓	_	_	_	_	✓	✓	_	_	_
10446058	Protective glass, multifocal lense	✓	✓	✓	_	_	_	_	✓	✓	_
10448439	Protective glass	✓	✓	_	_	_	_	✓	_	_	✓
10448440	Cover, sterilizable	✓	_	_	✓	_	_	_	_	_	_
10448431	Protective objective glass	✓	✓	✓	✓	_	_	_	_	_	_
10448296	Protective objective glass, spare part (package of 10)	✓	✓	_	_	_	_	✓	_	_	✓
10448280	Protective objective glass, complete, sterilizable	✓	✓	_	_	_	_	✓	_	_	✓
10448581	Cover, sterilizable for RUV800	✓	_	_	_	_	_	✓	_	_	_
10731702	Cover, sterilizable	✓	_	✓	✓	_	_	✓	_	_	_
10429792	Sleeve for slit illuminator	✓	_	✓	_	_	_	_	_	_	_

<sup>1)</sup> This medical device falls within the validated sterility claims of the STERRAD® 100S / STERRAD® 100NX™ / STERRAD® 50 / STERRAD® 200 Systems. Please follow the instructions for use of your STERRAD® System User's Guide prior to sterilizing devices in STERRAD® Systems.

## 12 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.

## 13 What to do if ...?

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

### 13.1 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 page 23).
The microscope cannot be moved or	A cable is sticking.	► Reroute affected cable.
moved only with a great deal of effort.	Leica M530 OHX locked.	Release the locking mechanism (see page 20).
Functions cannot be activated using the	A cable connection has come loose.	► Check the footswitch connection.
footswitch or the controls on the handles.	Incorrect assignment entered at control unit.	Change the assignment using the control unit.
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 page 34).
Light intensity below expectation	Fiber optics cable not in place properly	► Check connection of fiber optics cable
	Lamp life time over	► Check lamp life time and change bulbs, if required
Back assistant / side assistants have no light	Selection of the assistants not correct	► Check selection of the assistants (see page 23)
Left / right side assistant has no light	Selection of the assistant not correct	Check selection of the assistant (see page 23)
The image remains unfocussed.	Eyepieces are not mounted correctly.	Screw the eyepieces all the way on.
	Diopters not set correctly.	Perform dioptric correction exactly according to the instructions (see page 22).
	AutoFocus not working properly	► Check AutoFocus settings (see page 45)
The microscope or arm system moves up/	Arm system is not correctly balanced.	▶ Balance out Leica M530 OHX (see page 23).
down or rotates on its own accord.	Cables are not correctly laid or have slipped out of position and exert force on the system (possibly additional video cable).	Route cables according to installation guide and implement strain relief.
	Leica M530 OHX was balanced in a locked state.	Release the locking mechanism (see page 20) and balance the Leica M530 OHX (see page 23).
The microscope and microscope carrier can be moved only with difficulty or not at all.	Automatic balancing has not been completed.	<ul> <li>Make sure that position B has been assumed (see page 25).</li> <li>Press the push-button for auto-balance again.</li> </ul>

Malfunction	Cause	Remedy
Automatic balancing cannot be performed.	Microscope is tilted at too great an angle.	<ul> <li>Align the A/B-axes on the microscope according to the A/B marking (see page 26).</li> <li>Carry out automatic balancing again.</li> </ul>
Magnification cannot be adjusted electrically.	Failure of magnification motor.	<ul><li>Press the magnification rotary knob.</li><li>Set magnification by turning (see page 35).</li></ul>
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 page 44).
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.	<ul> <li>Rebalance the B-axis.</li> <li>Make sure that the accessory is turned back to the working position when balancing the B-axis (see page 26).</li> <li>Perform intraoperative B/C balancing (see page 26).</li> </ul>
Push button 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 Autoblance push-button.
Arm system cannot be moved.	Arm system locked in position.	► Release the locking mechanism (see page 20).
The stand of the Leica M530 OHX moves.	Footbrakes not applied.	Fix footbrakes in place (see page 20).
The range of movement of the Leica M530 OHX is limited (swing, tilt,	Cable laid too tightly.	► Re-lay the cable (see assembly instructions Leica M530 OHX).
rotate, XY movement).	Drape too tight.	► Slightly loosen drape.
	Video camera was not correctly mounted and touches the arm system.	Properly install the video camera.
Leica M530 OHX is not correctly balanced.	Position of accessory was changed after	▶ Balance out Leica M530 OHX (see page 23).
	balancing.	Perform intraoperative AC/BC balancing (see page 26).
Leica M530 OHX cannot be balanced.	Leica M530 OHX was balanced in the transport position.	Take the Leica M530 OHX out of transport position and rebalance it.
Iris does not follow magnification	Autolris in override mode	Press the Autolris reset button.
Working distance does not move	Working distance emergency drive blocked by drape	Release working distance emergency drive.
Working distance on microscope cannot be adjusted.	Leica FocusLock activated.	<ul> <li>Check Leica FocusLock settings.</li> <li>Exception: You are working with a laser micromanipulator on which this function has been programmed for safety reasons.</li> </ul>
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 page 21).
The device switches off, system has no power	The circuit breaker has been tripped and the power supply has been interrupted.	<ul> <li>Switch the device on again using the main switch. This will reset the circuit breaker.</li> <li>If this has to be done repeatedly, please inform Leica service.</li> </ul>

## 13.2 Malfunctions documentation accessories

Malfunction	Cause	Remedy
Video pictures unfocussed.	Microscope or Video Adapter not precisely focussed.	<ul> <li>Focus precisely, use graticule if necessary.</li> <li>Perform diopter correction exactly according to the instructions.</li> </ul>

## 13.3 Error messages on the control unit

When the control unit detects an error, the yellow "Check" button lights up.

- Press the "Check" button.
  The list with error messages is displayed.
- To acknowledge a message, select the message and press the "Confirm" button. When there is no error message pending, the yellow "Check" button disappears.

Message	Cause	Remedy
"The main lamp is defective, the system has switched to the second main lamp. Replace the defective lamp before the next case."	Lamp 1/2 is defective.	► After the operation of the defective lamp 1/2, check and replace.
"Warning: The current FL400 light intensity is below the minimum."	Lamp 1/2 is loosing luminosity	► Replace lamp 1/2
"Warning: The current luxmeter light intensity is below the minimum."	Lamp 1/2 is loosing luminosity	► Replace lamp 1/2
"xy not found"	The connecting cable has been disconnected or is defective.	<ul> <li>Check corresponding connection cable for proper seating and function.</li> <li>Contact your Leica representative.</li> </ul>
"Right limit switch pressed during autobalancing of A/B"	The accessories being used cannot be balanced.	Reduce the load on the rear side of the optics carrier.
"Left limit switch pressed during autobalancing of A/B"	The accessories being used cannot be balanced.	Reduce the load on the front side of the optics carrier.
"Right limit switch pressed during autobalancing of C"	The accessories being used cannot be balanced.	Reduce the load on the left side of the optics carrier.
"Left limit switch pressed during autobalancing of C"	The accessories being used cannot be balanced.	Reduce the load on the right side of the optics carrier.
"Lamp door is open"	The access door of the illumination unit is not closed. The push button for Illumination on/off flashes.	Close the access door of the illumination unit and lock it using the turn knob.
"Luxmeter defective error"		Contact your Leica representative.

## 14 Specifications

## 14.1 Electrical data

Power connection for Leica M530 OHX	1200 VA 100–240 V~ 50/60 Hz Integrated circuit breaker
Protection class	Class 1

### 14.2 Leica M530

### 14.2.1 Microscope features

Objective / working distance continuously adjustable; manual adjustment option  Eyepieces Wide-field eyepieces for persons wearing glasses 8.3×, 10× and 12.5× dioptric adjustment ±5 diopter settings; adjustable eyecup  Illumination Illumination system specially developed for microsurgical applications; Continuously variable illumination field diameter with Gaussian light distribution. Continuously adjustable brightness at constant color temperature  Autolris Built-in automatic zoom-synchronized illumination field diameter, with manual override and reset feature  Main illuminator High-output xenon lamp 400 W, 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 Laser Class 2 Wave length 635 nm Optical power <1 mW  Fine focus Available for back side assistant  Magnification multiplier  IR sensor For remote control of the Leica HD C100	Magnification	6:1 zoom, motorized					
8.3×, 10× and 12.5× dioptric adjustment ±5 diopter settings; adjustable eyecup  Illumination  Illumination system specially developed for microsurgical applications; Continuously variable illumination field diameter with Gaussian light distribution. Continuously adjustable brightness at constant color temperature  Autolris  Built-in automatic zoom-synchronized illumination field diameter, with manual override and reset feature  Main illuminator  High-output xenon lamp 400 W, 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 Laser Class 2 Wave length 635 nm Optical power <1 mW  Fine focus  Available for back side assistant  Magnification multiplier	•	continuously adjustable;					
microsurgical applications; Continuously variable illumination field diameter with Gaussian light distribution. Continuously adjustable brightness at constant color temperature  Autolris Built-in automatic zoom-synchronized illumination field diameter, with manual override and reset feature  Main illuminator High-output xenon lamp 400 W, 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 Laser Class 2 Wave length 635 nm Optical power <1 mW  Fine focus Available for back side assistant  Magnification multiplier	Eyepieces	8.3×, 10× and 12.5× dioptric adjustment ±5 diopter settings;					
field diameter, with manual override and reset feature  Main illuminator High-output xenon lamp 400 W, 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 Laser Class 2 Wave length 635 nm Optical power <1 mW  Fine focus Available for back side assistant  Magnification multiplier	Illumination	microsurgical applications; Continuously variable illumination field diameter with Gaussian light distribution. Continuously adjustable brightness at constant					
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 Laser Class 2 Wave length 635 nm Optical power <1 mW  Fine focus Available for back side assistant  Magnification multiplier	Autolris	field diameter,					
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 Laser Class 2 Wave length 635 nm Optical power <1 mW  Fine focus  Available for back side assistant  Magnification multiplier	Main illuminator						
dependent limitation of the brightness, controlled by a built-in luxmeter  SpeedSpot  Laser focussing aid for fast and exact positioning of the microscope Laser Class 2 Wave length 635 nm Optical power <1 mW  Fine focus  Available for back side assistant  Magnification multiplier	Emergency lamp	The state of the s					
the microscope Laser Class 2 Wave length 635 nm Optical power <1 mW  Fine focus Available for back side assistant  Magnification nultiplier	BrightCare Plus	dependent limitation of the brightness,					
Magnification 1.4× multiplier	SpeedSpot	the microscope Laser Class 2 Wave length 635 nm					
multiplier	Fine focus	Available for back side assistant					
IR sensor For remote control of the Leica HD C100		1.4×					
	IR sensor	For remote control of the Leica HD C100					

### 14.2.2 Optical data

Zoom magnification binocular tubes with focal length f162.66		Working distance					
		22	5 mm	600 mm			
		M <sub>tot</sub>	FoV [mm]	M <sub>tot</sub>	FoV [mm]		
Eypiece 8.3×	min.	1.60	114.5	0.80	230.4		
	max.	9.6	19.1	4.8	38.4		
Eypiece 10×	min.	1.92	109.3	0.96	219.9		
	max.	11.5	18.2	5.7	36.7		
Eypiece 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					
		22	5 mm	600 mm			
		M <sub>tot</sub>	FoV [mm]	M <sub>tot</sub>	FoV [mm]		
Eypiece 8.3×	min.	1.68	109.4	0.83	220.2		
	max.	10.1	18.2	5.0	36.7		
Eypiece 10×	min.	2.01	104.4	1.0	210.2		
	max.	12.1	17.4	6.0	35.0		
Eypiece 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  $\pm 5~\%$ 

Binocular tube	Focal length	Art. No
Type A	f162.66	10447701, 10446575, 10448088, 10446574, 10446587, 10446618
Type B	f170.0	10446797, 10448159, 10448217

### 14.2.3 Selectable options

### Leica M530 with Top Plate

#### Leica M530 with IVA530

IVA530	Full stereo view for main surgeon
	Semi stereo view for 2 side assistants
	C-mount interface for camera (HD or SD)

#### Leica M530 with ULT530

ULT530	Full stereo view for main surgeon and back assistant Semi stereo view for 2 side assistants Optional: HD Camera integrated (Leica HD C100)
Leica FL800 ULT	ULT with the Leica FL800 function
Leica GLOW800	ULT with GLOW800 function
Leica FL400 for M530	Leica FL400 Observation filter module
Leica FL560 for M530	Leica FL560 Observation filter module

#### 14.2.4 Leica M530 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 and C axes fully automatic, each can be corrected manually
Brakes	1 brake for A/B axis 1 brake for C axis
Indicator	LED for Fluorescence mode status LED for Video record status
IR sensor	for remote control of the external Leica HD C100 camera

#### Leica M530 with IVA530

for attachment of an external C-mount video camera, preferably with sensor size 1/3"
for increased depth of field for main surgeon
for main surgeon binocular
Selectable, left or right
67 % for surgeon 23 % for side assistant 10 % for C-mount port

#### Leica M530 with ULT530

Integrated camera for visible light	Leica HD C100 built in 1/2.8" progressive 1-chip CMOS (optional)
FusionOptics	for increased depth of field for main surgeon and back assistant
Manual fine focus	for back assistant, $\pm 5$ Dpt
Integrated 360° rotatable adapter	for main surgeon and back assistant binocular
Light distribution	50 % for main surgeon assistants switchable: either 15 % for side assistant or 30 % for back assistant
Usage	Leica CaptiView to be mounted between Leica M530 and ULT530
	·

#### Leica M530 with Leica FL800 ULT

Integrated camera for visible light	Leica HD C100 built-in 1/2.8" progressive 1-chip CMOS (optional)
Camera	1/1.2" CMOS
FL800 observation filter	built-in
FusionOptics	for increased depth of field for main surgeon and opposite assistant
Manual fine focus	±5 Dpt, for back assistant
Integrated 360° rotatable adapter	for main surgeon and back assistant binocular
Light distribution	50 % for main surgeon assistantsswitchable: either 15 % for side assistant or 30 % for back assistant
Usage	Leica CaptiView to be mounted between Leica M530 and FL800 ULT

#### Leica M530 with GLOW800

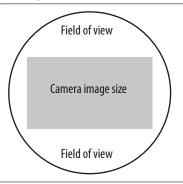
Integrated camera for visible light	2 × 1/1.2" CMOS
Camera IR	1/1.2" CMOS
GLOW800 observation filter	built-in
FusionOptics	for increased depth of field
	for main surgeon and opposite assistant
Manual fine focus	±5 Dpt, for back assistant
Integrated 360° rotatable adapter	for main surgeon and back assistant binocular
Light distribution	50 % for main surgeon,
J	assistants switchable,
	either 15 % for side assistant
	or 30 % for back assistant
Usage	CaptiView to be mounted between Leica M530 and GLOW800

## Leica M530 with Leica FL400 for M530 / Leica FL560 for M530 and Leica FL800 ULT

Integrated camera for visible light	Leica HD C100 built-in 1/2.8" progressive 1-chip CMOS (optional)
FL400/FL560 observation filter	built-in
FusionOptics	for increased depth of field for main surgeon and opposite assistant
Manual fine focus	±5 Dpt, for opposite assistant
Integrated 360° rotatable adapter	for main surgeon and opposite assistant binocular
Light distribution	50 % for main surgeon assistantsswitchable: either 15 % for lateral assistant or 30 % for opposite assistant
Usage	Leica CaptiView to be mounted between Leica FL400/Leica FL560 for M530 and Leica FL800 ULT

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

- Camera for visible light
- Leica FL800 ULT NIR camera





The figure shows the camera image size with respect to the field of view for the visual video camera and the Leica FL800 ULT NIR camera. Please be aware that the field of view is not fully covered by the documentation system.



For further information refer to the corresponding user manuals.

#### 14.2.5 IGS

Interface/	Open architecture for IGS systems
Compatibility	Please ask your Leica representative.

### 14.3 Leica OHX floor stand

Туре	Floor stand with 6 electromagnetic brakes
Base	$760\times760$ mm with four $360^\circ$ rotating castors with a diameter of 150 mm each, one parking brake
Balancing	Auto-Balance: completely automatic balancing of stand and optics
Intraoperative balancing	Automatic intraoperative AC/BC balancing of AC and BC axes (not available for Japan)
Floor stand control unit	New generation touch panel technology.  The latest electronics control for the continuous governing of all motor functions and the light intensity.  Data shown by means of LCD.  Built-in BrightCare Plus safety function for limiting brightness depending on working distance.  ISUS ™ Intelligent Setup System.  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 illumination and auto-balancing. Indicator for Main/backup illumination and Fluorescence modes. 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. Mouthswitch for releasing the selected brake combination.  Footswitch and handswitch.
Integrated documentation	Prepared for integration of video camera system and digital recording system.  Open architecture
Connectors	Numerous built-in connectors for Video, IGS and control data transfer. Internal power supply 12 VDC, 19 VDC, 24 VDC and AC terminals
Carrier for monitor	700 mm long and flexible arm with 4 axis for rotation and inclination to carry optional video monitor
Materials	All solid metal construction
Surface coating system	Coated with antimicrobial paint

Minimum height  Range Cantilever		In park position: 1950 mm
		Max. 1925 mm
Load		Min. 6.7 kg, max. 12.2 kg from microscope dovetail ring interface
Weight		Approx. 335 kg (without load)
14.4	Ambi	ent conditions
In uco		110°C to 1.40°C

In use	+10 °C to +40 °C
	+50 °F to +104 °F
	30 % to 95 % rel. humidity
	800 mbar to 1060 mbar atmospheric pressure
Storage	−30 °C to +70 °C
	–22 °F to +158 °F
	10 % to 100 % rel. humidity
	500 mbar to 1060 mbar atmospheric pressure
Transport	−30 °C to +70 °C
	–22 °F to +158 °F
	10 % to 100 % rel. humidity
	500 mbar to 1060 mbar atmospheric pressure

## 14.5 Standards fulfilled

#### **CE** conformity

- Medical electrical equipment: IEC 60601-1, EN 60601-1, UL 60601-1, CAN/CSA C22.2 NO. 60601-1
- Electromagnetic compatibility:
   IEC 60601-1-2, EN 60601-1-2, EN 61000-3-2, IEC 61000-3-2,
   IEC TS 60601-4-2
- Further applied harmonized standards:
   IEC 62366, IEC 60825-1, EN 60825, IEC 62471, EN 62471
- The Medical Division, within Leica Microsystems (Schweiz) AG, holds the management system certificates for the international standard ISO 13485 relating to quality management and quality assurance.



#### 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.

## 14.6 Electromagnetic compatibility (EMC)

#### 14.6.1 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.

14.6.2 Compliance IEC 60601-1-2

#### **Emissions**

- · CISPR 11, Class A, Group 1
- Harmonic Distortion per IEC 61000-3-2 Class A
- Voltage Fluctuation and Flicker per IEC 61000-3-3 Class A, Figures 3-7

#### **Immunity**

- · Performance of medical electrical equipment and medical electrical systems IEC TS 60601-4-2
- Electrostatic discharge IEC 61000-4-2:  $CD \pm 2kV^*, \pm 4kV^*, \pm 6kV^*, \pm 8 kV$  $AD \pm 2kV^*, \pm 4kV^*, \pm 8kV^*, \pm 15kV$ \* lower test levels tested to fulfill IEC 60601-1-2 ed.3 additionally
- Radiated RF FM Fields IFC 61000-4-3: 80 MHz-6 GHz: MHz: 10 V/m
- Proximity fields from RF wireless communication equipment IEC 61000-4-3: 380-5785 MHz: 9 V/m; 27 V/m; 28 V/m
- Electrical Fast Transients and bursts IEC 61000-4-4:  $\pm$  1kV: Input and output lines,  $\pm$  2 kV: Power supply lines
- Surges, IEC 61000-4-5:  $\pm$  0.5kV,  $\pm$  1kV Line-to-line  $\pm$  0.5kV,  $\pm$  1kV,  $\pm$  2kV Line-toground
- Conducted disturbances, induced by RF fields IEC 61000-4-6:
- Rated Power-frequency Magnetic Field IEC 61000-4-8: 30 A/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

Voltage dips and interruptions IEC 61000-4-11: according to IEC 60601-1-2:2014

#### Acceptable operating conditions/responses:

- Flickering/noise on the monitors
- Interruptions on the external monitor

## Specific compliance criteria for the voltage dips and interruptions

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 Leica M530 OHX, this can lead to an increase in in electromagnetic radiation or a reduction in EMC.



If use is made of accessories or cables other than those specified in this user manual or approved by the manufacturer of the Leica M530 OHX surgical microscope, this can lead to an increase in electromagnetic radiation or a reduction in EMC.

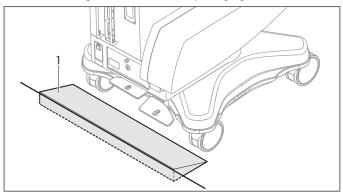


The Leica M530 OHX surgical microscope must not be used directly adjacent other instruments. If it is necessary to operate it in the vicinity of other instruments, the devices should be monitored to ensure that they function properly in this arrangement.

#### 14.7 Limitations of use

The Leica M530 OHX may be used only in closed rooms and must be placed on a solid floor.

The Leica M530 OHX is not suitable for crossing thresholds higher than 20 mm. To move the surgical microscope over thresholds of 20 mm, the wedge (1) included in the packaging can be used.



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

Without auxiliary equipment, the Leica M530 OHX can be moved across thresholds up to a max. height of 5 mm.

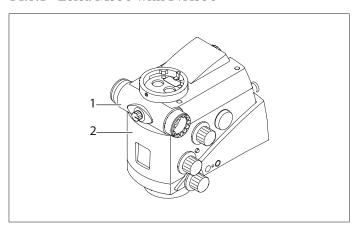
#### NOTE

## Damage to the Leica M530 OHX 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 a tilt  $\ge 10^\circ$  the system in areas with an elevation angle bigger than  $10^\circ$ .
- ► Do not tilt the system to more than 10° as it might tip over.

## 14.8 List of weights of balanceable configurations

#### 14.8.1 Leica M530 with IVA530

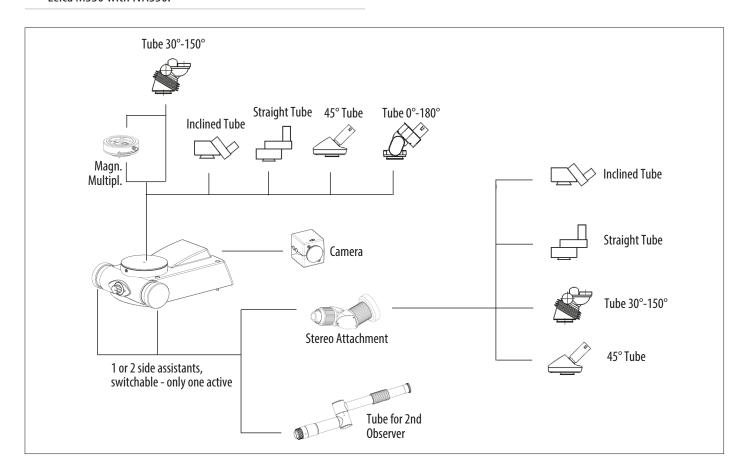


- 1 Leica with IVA530
- 2 Leica M530 Optics carrier

#### NOTE

#### Destruction of the IVA530 optics.

► Do not use the Zoom Video Adapter in combination with Leica M530 with IVA530.



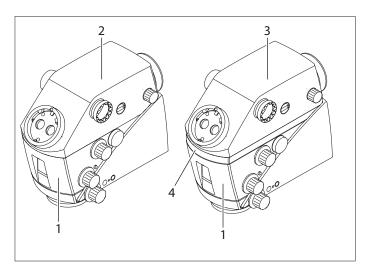
Equipment of Leica M530 OHX Serial No.

## Max. load from microscope dovetail ring interface: 12.2 kg

Equipment of Leica M530 with IVA530					Installation	
Art. No.		Description	Comment / Restrictions	Weight	#	Total
10448700	М	Leica M530 Optics carrier		2.52 kg		
10448691	М	IVA530		0.82 kg		
	M	Binocular tube for main surgeon	<b>1</b> 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		
10446587	S	Straight binocular tube T, Type II		0.72 kg		
10446618	S	Inclined binocular tube 45°, Type II		0.56 kg		
10446574	S	Inclined binocular tube T, Type II		0.74 kg		
10448088	S	Binocular tube var. 0°-180° T, Type II		1.42 kg		
10448668	0	Magnification multiplier	Only 1 piece, only main surgeon and only with binocular tube 30°-150°	0.28 kg		
	1xM 1x0	Side observation	Only left or right side observation gets light at the same time (switch)			
10446815	S	Tube for second observer		1.26 kg		
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		0.72 kg		
10446618	S	Inclined binocular tube 45°, Type II		0.56 kg		
10446574	S	Inclined binocular tube T, Type II		0.74 kg		
10448028	0	Eyepiece 10x	2 eyepieces per binocular tube	0.10 kg		
10448125	0	Eyepiece 8.3x		0.10 kg		
10 1 10 123	0	Eyepiece 12.5x		0.10 kg		•
10443739	0					
	0	Camera	Max. 1 camera			

Equipment of Leica M530 with IVA530					Installation	
Art. No.		Description	Comment / Restrictions	Weight	#	Total
10448079	0	Universal laser adapter				
	0	Laser micro manipulator				
	0	Laser filter	0-3 pieces, (main, side)			
10448245	0	Mouth switch				
10446058	0	Protective glass		0.22 kg		
	0	IGS Frame		0.02 kg		
oad from pre	vious p	page				
					Total	
M = Must, 0 = 0	Option,	S = Selection			Load	

#### 14.8.2 Leica M530 with ULT530 or Leica FL800 ULT or GLOW800

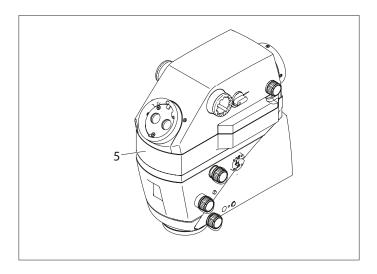


- 1 Leica M530 Optics carrier
- 2 ULT530 or Leica FL800 ULT or GLOW800
- 3 Leica FL800 ULT or GL0W800
- 4 Leica FL400 for M530 / Leica FL560 for M530

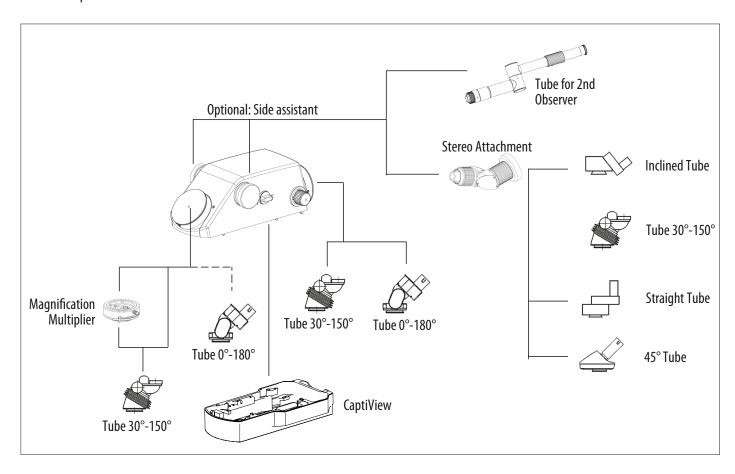
#### NOTE

#### Destruction of the ULT530 optics.

► Do not use the Zoom Video Adapter in combination with the ULT530.



### 5 Leica CaptiView



Equipment of Leica M530 OHX Serial No.

Max. load from microscope dovetail ring interface: 12.2 kg

Equipment of Leica M530 with ULT530					Inst	Installation	
Art. No. Description			Comment / Restrictions	Weight	#	Total	
10448704	M	Leica M530 Optics carrier		3.5 kg			
10448775	S	Leica FL560 for M530		0.48 kg			
10448776	S	Leica FL400 for M530/Leica FL560 for M530		0.50 kg			
	M	Leica CaptiView		1.20 kg			
	М	Interface to ULT530					
10449022	S	ULT530		1.64 kg			
10449023	S	Leica FL800 ULT		1.76 kg			
10448962	S	GL0W800		1.90 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			
	М	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			
	0	Side observation	0, 1 or 2 side assistants				
10446815	S	Tube for second observer		1.26 kg			
10448597	S	Stereo attachment		1.01 kg			
	М	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	0	Magnification multiplier	Only 1 piece, only main surgeon and only with binocular tube 30°-150° (vignetting)	0.28 kg			
10449016	0	Leica HD C100 for ULT530					
I = Must, 0 = 0	Option,	S = Selection	continued on next page		Load		

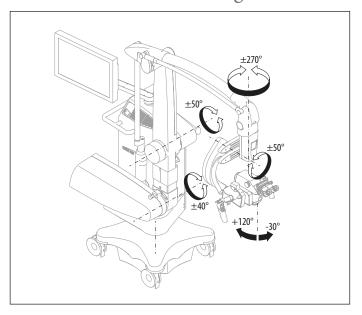
Equipment of Leica M530 with ULT530					Installation	
Art. No.		Description	Comment / Restrictions	Weight	#	Total
10448079	0	Universal laser adapter				
	0	Laser micro manipulator				
	0	Laser filter	0-4 pieces, (main, back, sides)			
10448028	0	Eyepiece 10x	2 eyepieces per binocular tube	0.10 kg		
10448125	0	Eyepiece 8.3x		0.10 kg		
10443739	0	Eyepiece 12.5x		0.10 kg		
10448245	0	Mouth switch		0.22 kg		
10446058	0	Protective glass		0.02 kg		
	0	IGS Frame				
Load from prev	/ious p	page				
M = Must, 0 = 0	Option,	S = Selection			Total Load	

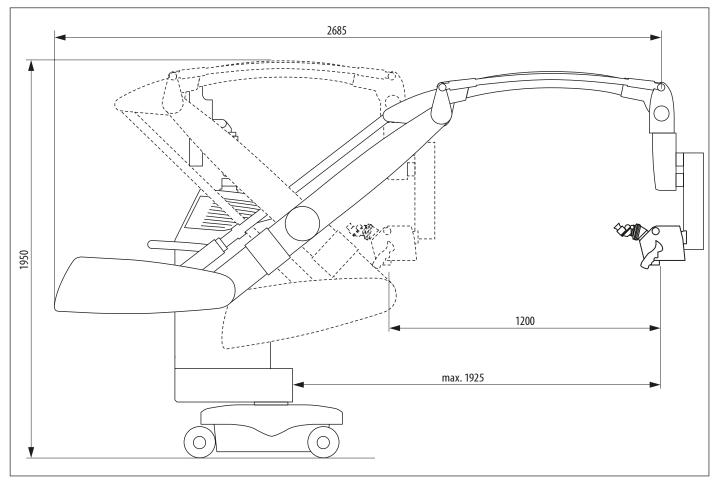
#### NOTE

## Destruction of the ULT530 optics.

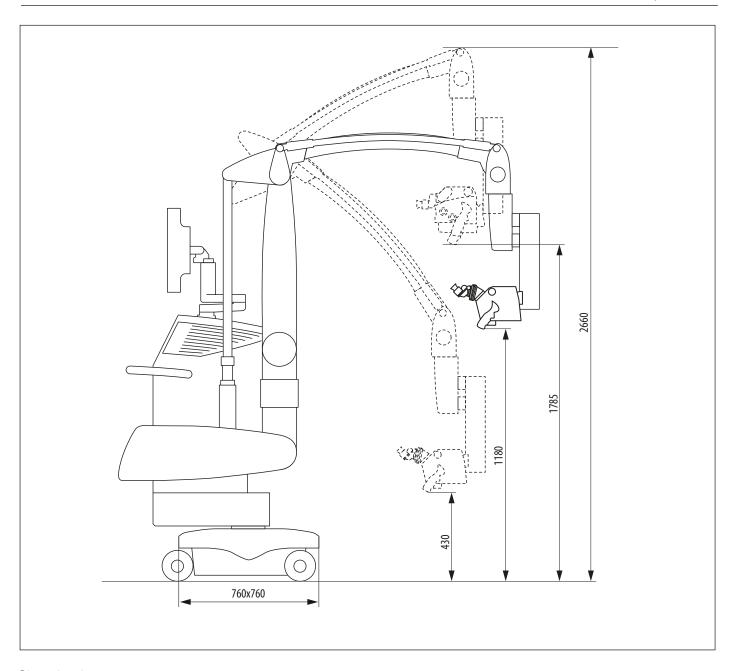
▶ Do not use the Zoom Video Adapter in combination with the Leica M530 with ULT530.

## 14.9 Dimensional drawings





Dimensions in mm



Dimensions in mm

## 15 Annex

## 15.1 Checklist before the operation

atient	
urgeon	
ate	

Step	Procedure	Details	Checked / Signature
1	Cleaning the optical accessories	<ul> <li>Check the tubes, eyepieces and the documentation accessories (if used) for cleanliness.</li> <li>Remove dust and dirt.</li> </ul>	
2	Installing the accessories	<ul> <li>Lock the Leica M530 OHX in place and install all accessorie on the microscope so it is ready for use (see page 21).</li> <li>Position the handles as desired.</li> <li>Connect the mouthswitch and/or footswitch, if used.</li> <li>Check the camera image on the monitor and realign if necessary.</li> <li>Check that all equipment is in its proper position (all covers fitted, doors closed).</li> </ul>	S
3	Checking the tube settings	► Check the tube and eyepiece setting for the selected user.	
4	Function check	<ul> <li>Check the fiber optics cable connection to the optics carrier.</li> <li>Connect the power cable.</li> <li>Switch on the microscope.</li> <li>Switch on the illuminator at the control unit.</li> <li>Leave the illumination on for at least 5 minutes.</li> <li>Check the lamp history and make sure that the remaining life time is sufficient for the planned surgery.</li> <li>Replace defective bulbs before the surgery.</li> <li>Test all functions on the handles and the footswitch.</li> <li>Check the user settings on the control unit for the selected user.</li> </ul>	I
5	Balancing	<ul> <li>Balance the Leica M530 OHX (see page 23).</li> <li>Press the "All Brakes" button on the handle and check the balancing.</li> </ul>	
6	Sterility	<ul> <li>Fit sterile components and sterile drape if used (see page 29).</li> <li>Repeat balancing.</li> </ul>	
7	Positioning at the OP table	Position the Leica M530 OHX on the OP table as required and lock the foot brake (see page 28).	





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