From Eye to Insight



# **Heads-up Microsurgery**

# User Manual

10 747 501 version 02

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Thank you for purchasing a Leica surgical microscope system. In developing our systems, we have placed great emphasis on simple, selfexplanatory 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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### Korea only: 부작용보고 문의처: 한국의료기기안전정보원, 080-080-4183

#### Legal disclaimer

All specifications are subject to change without notice.

The information provided by this manual is directly related to the operation of the equipment. Medical decision remains the responsibility of the clinician. Leica Microsystems has made every effort to provide a complete and clear user manual highlighting the key areas of product use. Should additional information regarding the use of the product be required, please contact your local Leica representative.

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

#### Liability

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

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# Section A: Heads-up Microsurgery for M530 OHX, M530 OH6, ARveo or ARveo 8 (10449063)

# 1 Introduction

## 1.1 About this user manual

This user manual describes the functions of the system combination (see chapter 3 "System combination", page 6).



 Read this user manual carefully before operating the product.

In addition to notes on the use of the instruments, this user manual gives important safety information (see chapter 2 "Safety notes", page 4).

For information, description, specification and compliance to standards refer to the respective user manuals of the system components.

## 1.2 Nomenclature

In the following, the term "heads-up monitor" refers to the monitor 55" 3D-4K.

# 1.3 Symbols in this user manual

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

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

# 2 Safety notes

The Heads-up Microsurgery 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.

Ensure that the Heads-up Microsurgery is used only by persons qualified to do so.

# 2.1 Intended use

The following surgical microscope systems are intended to be used as optical instrument for improving the visibility of objects through magnification and illumination.

- M530 OHX
- M530 OH6
- ARveo
- ARveo 8 (10449063)

The systems can be applied for observation and documentation and for human and medical treatment.

M530 OHX, M530 OH6, ARveo or ARveo 8 (10449063), equipped with GLOW800, can be combined with the heads-up monitor.

## 2.2 Contraindications for use

The System shall not be used for ophthalmology. Heads-up microsurgery is not intended to be used during activated fluorescence modes of GLOW800, FL400 and FL560.

# 2.3 Dangers of use

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### **Risk of injury**

- Before connecting the power cable to the outlet, perform visual check of the cable to ensure that it is not damaged.
- Do not place the cable between the heads-up monitor and the surgical microscope where persons in the operating room can trip over it.

### Note

- Plug the cable directly into the wall outlet.
- ▶ Do not use a multiple socket or extension cable.



## WARNING

# Loss of image on heads-up monitor Do not use a wireless connection between the microscope and the heads-up monitor for image transfer.

### Note

### Loss of heads-up monitor settings

The heads-up monitor settings are pre-defined to the best possible performance. Therefore, the settings of the heads-up monitor must remain unchanged.

Do not change the settings of the heads-up monitor.

### WARNING

### Risk of compromised decision making

- Do not perform heads-up surgery during activated fluorescence modes of GLOW800, FL400 and FL560 (no depth perception).
- Always keep the binocular tubes for the main surgeon mounted on the microscope and ready for use.
- Do not use a wireless connection between the microscope and the heads-up monitor for image transfer.

CAUTION

### **Risk of compromised surgery**

- Perform a pre-operative check to confirm Heads-up Microsurgery is working as intended.
- Check the perception of the 3D view prior to surgery. If you are not able to perceive 3D or you do not feel confident using 3D, switch back to binocular tubes.
- Use only compatible 3D glasses provided by Leica Microsystems.
- ► Do not use 3D glasses on the 2D monitor.

# 2.4 Directions for the use of the system combination

- For best performance, do not change the settings of the headsup monitor.
- When performing heads-up surgery always keep the binocular tubes for the main surgeon mounted on the microscope and ready for use. In case of image loss on the heads-up monitor, the surgery can always be completed by using the binocular tubes.

For detailed information on the system components, refer to the respective user manuals.

# 3 System combination

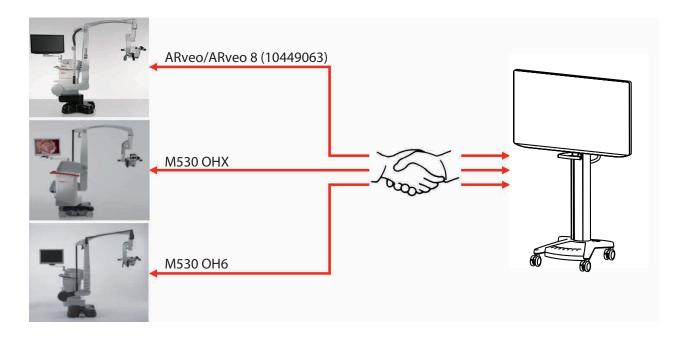
The option for performing heads-up microsurgery is based on the system combination of

- surgical microscope M530 OHX, M530 OH6, ARveo or ARveo 8 (10449063)
- accessory GLOW800
- monitor 55" 3D-4K

The Heads-up Microsurgery provides ergonomic advantages as the user can maintain an upright posture while observing the surgical field. The heads-up monitor(1) is mounted on a cart and can be moved across the room to achieve optimal viewing positions (see chapter 5.2 "Position the heads-up monitor", page 9).

Depending on the microscope system combination and connected accessories, the Heads-up Microsurgery displays different visualization modes.

- In 3D view (stereoscopic): white light surgical field visualization
- In 2D view: all other visualization modes



## 3.1 GLOW800

The GLOW800 is a Leica surgical microscope accessory used in viewing intra-operative blood flow. When not in fluorescence mode, the GLOW800 provides two video signals that display the real-time image of the left and the right beam path of the microscope.

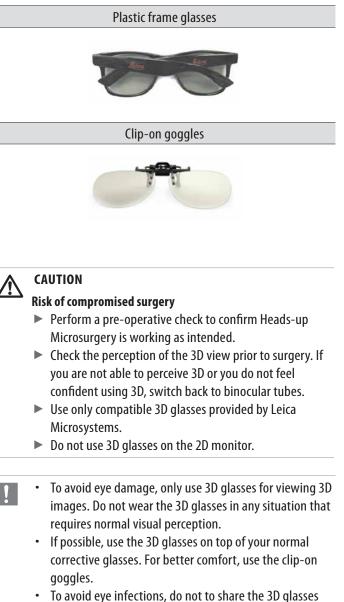
## 3.2 Heads-up monitor

The heads-up monitor is intended to provide 4K, 2D and 3D color video displays of images from endoscopic/laparoscopic camera systems, surgical microscope and other compatible medical imaging systems. The heads-up monitor is a wide screen, ultra-high definition, medical grade monitor for real-time use during surgical procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctor's offices and similar medical environments.

## 3.3 3D Glasses

With the Heads-up Microsurgery Leica provides the following 3D glasses:

### Leica Microsystems supplied glasses 10747283



- To avoid eye infections, do not to share the 3D glasses among users and clean the glasses before every procedure.
- Do not use the 3D glasses as sunglasses.
- Do not touch or scratch the lens surface of the 3D glasses.
- Do not leave the 3D glasses near heating equipment.

# 4 Setting up the Heads-up Microsurgery

#### Note

Installation may only be carried out by trained personnel.



### **Risk of injury**

- Before connecting the power cable to the outlet, perform visual check of the cable to ensure that it is not damaged.
- Do not place the cable between the heads-up monitor and the surgical microscope where persons in the operating room can trip over it.

#### Note

- Plug the cable directly into the wall outlet.
- Do not use a multiple socket or extension cable.



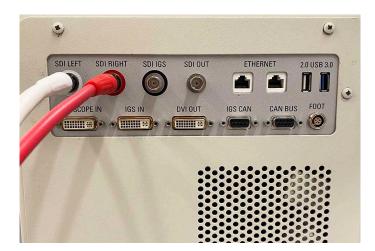
### WARNING

Loss of image on heads-up monitor

Do not use a wireless connection between the microscope and the heads-up monitor for image transfer.



Connect the cable of the power socket at the bottom of the cart to the power outlet.



• Connect the 2 SDI cables of the heads-up monitor to ARveo 8.



Connect the 2 SDI cables of the heads-up monitor to the GLOW800 faceplate of M530 OHX.



 Connect the 2 SDI cables of the heads-up monitor to M530 OH6 or ARveo.

|--|

Press the on/off switch (1) on the bottom side of the heads-up monitor to switch it on.

### Note

### Loss of heads-up monitor settings

The heads-up monitor settings are pre-defined to the best possible performance. Therefore, the settings of the heads-up monitor must remain unchanged.

Do not change the settings of the heads-up monitor.

# 5 Preparation before surgery

Before using the system like intended to perform heads-up surgery from a monitor, a pre-operative check must be done.

## 5.1 Check the system performance

- Ensure that the Heads-up Microsurgery has been properly installed and connected (see chapter 4 "Setting up the Heads-up Microsurgery", page 7).
- Check if an image is displayed.
- Ensure that the 3D image is properly displayed by matching the left and right view to the corresponding eye (a suitable 3D test object is needed).
- If the image on the heads-up monitor is lost during surgery, the surgeon can always perform surgery by using the binocular tubes that are required to be mounted on the microscope.

## 5.2 Position the heads-up monitor

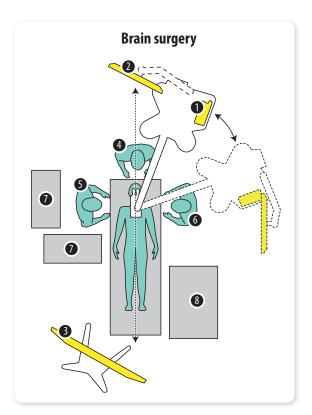
- Move the heads-up monitor by the handrail on the backside of the cart.
- Position the heads-up monitor in the OR as shown in the image below.

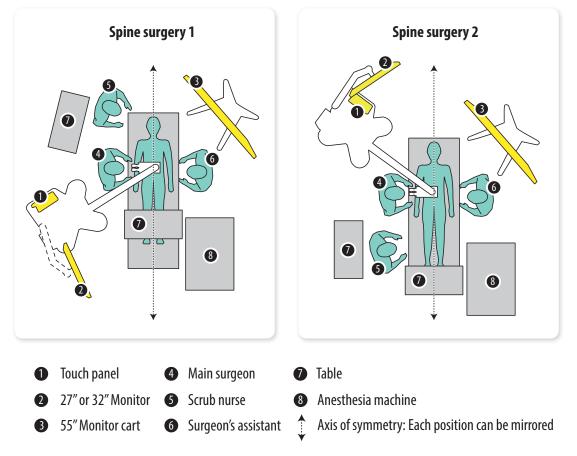
The heads-up monitor shall be positioned in a way that the surgeon has an unobstructed view and that the surface of the heads-up monitor is perpendicular to the line of sight of the surgeon.

### Note

The orientation of the image on the monitor depends on the orientation of the optics carrier.

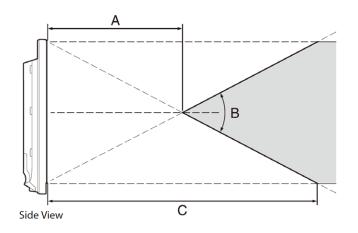
For best eye-hand coordination, keep a small relative angle between optics carrier and surgeon view on the monitor.





### 5.2.1 Viewing distance and angle

The optimal viewing distance should be at approximately 2000 mm (C) and should never be less than 1000 mm (A) away from the heads-up monitor.



A (Typical)	B (Typical)	C (Typical)
1000 mm	37°	2000 mm
Crosstally ratio < 70/		

Crosstalk ratio  $\leq 7\%$ 

- Move the heads-up monitor by the handrail on the backside of the cart.
- Position the heads-up monitor at a distance between 1000 mm and 2000 mm.
- Tilt the heads-up monitor vertically by the handle on the front side of the cart. For best 3D depth perception, ensure a vertical viewing angle of max. 37° (B) from the minimum viewing distance (A).

!

# 6 What to do if..?

If electrically operated functions do not work properly, always check these points first:

- Is the power switch switched on?
- Are the power cables attached correctly?
- Are all connecting cables attached correctly?
- Are all video cables attached correctly?

Observation	Cause	Remedy
No display of 3D image	The selected visualization mode is only available in 2D.	Check if the selected visualization mode is available in 3D (see chapter 3 "System combination", page 6).
	The monitor settings have been modified.	Contact Leica Microsystems Service.
Display of blurred or double image	The user is not wearing 3D glasses.	The user must wear 3D glasses to obtain correct 3D vision.
Display of "twisted" or "distorted" image or no image at all	The left and right video cables are connected incorrectly.	Connect the video cables correctly (see chapter 4 "Setting up the Heads-up Microsurgery", page 7).
Insufficient 3D perception	The surgeon's viewing angle is not perpendicular to the monitor.	Rotate and tilt the monitor so that the surgeon's line of sight is perpendicular to the monitor surface (see chapter 5.2 "Position the heads-up monitor", page 9).

# 7 Maintenance instructions

- Keep accessories in a dust-free place when not in use.
- ▶ Remove dust with a pneumatic rubber pump and a soft brush.
- Protect the devices from damp, vapors, acids, alkalis, and corrosive substances.
- ▶ Do not keep chemicals near the devices.
- Protect the devices from oil and grease.
- ► Never oil or grease the guide surfaces or mechanical parts.
- To disinfect the heads-up microsurgery, 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.
    - We recommend concluding a service contract with Leica Service.

# 8 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.

# 9 Technical Data

For specifications of the Leica surgical microscope, refer to the user manual of M530 OHX, M530 OH6, ARveo or ARveo 8 (10449063).

## 9.1 Ambient Conditions

In use	0 °C to +40 °C
	+32 °F to +104 °F
Recommended	+20 °C to +30 °C
	+68 °F to +86 °F
	30% to 85% relative humidity (no condensation)
	700 mbar to 1060 mbar atmospheric pressure
Storage and	–20 °C to +60 °C
Transport	-4 °F to +140 °F
	20% to 90% relative humidity
	700 mbar to 1060 mbar atmospheric pressure

## 9.2 Electrical data

Power connection	100 V–240 V
for Heads-up	50/60 Hz
Microsurgery:	3.1 A–1.1 A

# 9.3 Electromagnetic compatibility (EMC)

The Heads-up Microsurgery was tested in combination with Leica surgical microscopes. For electromagnetic compatibility data refer to the user manual of M530 OHX, M530 OH6, ARveo or ARveo 8 (10449063).

# Section B: Heads-up Microsurgery for ARveo 8 (10449157) or ARveo 8x

# 1 Introduction

## 1.1 About this user manual

This user manual describes the functions of the system combination (see chapter 3 "System combination", page 18).



 Read this user manual carefully before operating the product.

In addition to notes on the use of the instruments, this user manual gives important safety information (see chapter 2 "Safety notes", page 16).

For information, description, specification and compliance to standards refer to the respective user manuals of the system components..

## 1.2 Nomenclature

In the following, the term "heads-up monitor" refers to the monitor 55" 3D-4K.

## Symbols in this user manual

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

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

# 2 Safety notes

The Heads-up Microsurgery 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.

Ensure that the Heads-up Microsurgery is used only by persons qualified to do so.

## 2.1 Intended use

The following surgical microscope system is intended to be used as optical instrument for improving the visibility of objects through magnification and illumination.

- ARveo 8 (10449157)
- ARveo 8x

The systems can be applied for observation and documentation and for human and medical treatment.

ARveo 8 (10449157) or ARveo 8x, equipped with GLOW400 and GLOW800, can be combined with the heads-up monitor. 3D vision is possible for white light, GLOW400 and GLOW800.

# 2.2 Contraindications for use

The System shall not be used for ophthalmology.

Heads-up microsurgery is not intended to be used during activated fluorescence modes of FL400 and FL560.

# 2.3 Dangers of use

# 

### **Risk of injury**

- Before connecting the power cable to the outlet, perform visual check of the cable to ensure that it is not damaged.
- Do not place the cable between the heads-up monitor and the surgical microscope where persons in the operating room can trip over it.

### Note

- Plug the cable directly into the wall outlet.
- ▶ Do not use a multiple socket or extension cable.



## WARNING

# Loss of image on heads-up monitor Do not use a wireless connection between the microscope and the heads-up monitor for image transfer.

### Note

### Loss of heads-up monitor settings

The heads-up monitor settings are pre-defined to the best possible performance. Therefore, the settings of the heads-up monitor must remain unchanged.

Do not change the settings of the heads-up monitor.

### CAUTION

### Risk of compromised surgery

- Perform a pre-operative check to confirm Heads-up Microsurgery is working as intended.
- Check the perception of the 3D view prior to surgery. If you are not able to perceive 3D or you do not feel confident using 3D, switch back to binocular tubes.
- Use only compatible 3D glasses provided by Leica Microsystems.
- Do not use 3D glasses on the 2D monitor.



### WARNING

### Risk of compromised decision making

- Do not perform heads-up surgery during activated fluorescence modes of FL560 (no depth perception) and FL400.
- Always keep the binocular tubes for the main surgeon mounted on the microscope and ready for use.
- Do not use a wireless connection between the microscope and the heads-up monitor for image transfer.

# 2.4 Directions for the use of the system combination

- For best performance, do not change the settings of the headsup monitor.
- When performing heads-up surgery always keep the binocular tubes for the main surgeon mounted on the microscope and ready for use. In case of image loss on the heads-up monitor, the surgery can always be completed by using the binocular tubes.

For detailed information on the system components, refer to the respective user manuals.

# 3 System combination

The option for performing heads-up microsurgery is based on the system combination of

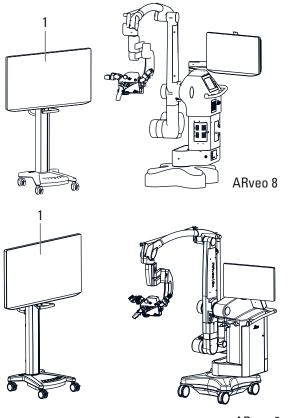
- surgical microscope ARveo 8 (10449157) or ARveo 8x
- accessories GLOW400 and GLOW800
- monitor 55" 3D-4K

3D vision is possible for white light, GLOW400 and GLOW800.

The Heads-up Microsurgery provides ergonomic advantages as the user can maintain an upright posture while observing the surgical field. The heads-up monitor(1) is mounted on a cart and can be moved across the room to achieve optimal viewing positions (see chapter 5.2 "Position the heads-up monitor", page 20).

Depending on the microscope system combination and connected accessories, the Heads-up Microsurgery displays different visualization modes.

- In 3D view (stereoscopic): white light, GLOW800 and GLOW400, IGS data visualization as a 2D overlay on the 3D image (overlaid on both channels)
- In 2D view: FL560 for M530, Endoscopic video stream or any other external video signal connected and routed to the Headsup Microsurgery system



# 3.1 Heads-up monitor

The heads-up monitor is intended to provide 4K, 2D and 3D color video displays of images from endoscopic/laparoscopic camera systems, surgical microscope and other compatible medical imaging systems. The heads-up monitor is a wide screen, ultra-high definition, medical grade monitor for real-time use during surgical procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctor's offices and similar medical environments.

## 3.2 3D Glasses

With the Heads-up Microsurgery Leica provides the following 3D glasses:

#### Leica Microsystems supplied glasses 10747283



- To avoid eye damage, only use 3D glasses for viewing 3D images. Do not wear the 3D glasses in any situation that requires normal visual perception.
- If possible, use the 3D glasses on top of your normal corrective glasses. For better comfort, use the clip-on goggles.
- To avoid eye infections, do not to share the 3D glasses among users and clean the glasses before every procedure.
- Do not use the 3D glasses as sunglasses.
- Do not touch or scratch the lens surface of the 3D glasses.
- Do not leave the 3D glasses near heating equipment.

# 4 Setting up the Heads-up Microsurgery

#### Note

Installation may only be carried out by trained personnel.

WARNING

### **Risk of injury**

- Before connecting the power cable to the outlet, perform visual check of the cable to ensure that it is not damaged.
- Do not place the cable between the heads-up monitor and the surgical microscope where persons in the operating room can trip over it.

#### Note

- Plug the cable directly into the wall outlet.
- Do not use a multiple socket or extension cable.



### WARNING

Loss of image on heads-up monitor

Do not use a wireless connection between the microscope and the heads-up monitor for image transfer.



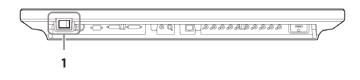
Connect the cable of the power socket at the bottom of the cart to the power outlet.



Connect the 2 SDI cables of the heads-up monitor to ARveo 8.



Connect the 2 SDI cables of the heads-up monitor to ARveo 8x.



Press the on/off switch (1) on the bottom side of the heads-up monitor to switch it on.

# 5 Preparation before surgery

Before using the system like intended to perform heads-up surgery from a monitor, a pre-operative check must be done.

## 5.1 Check the system performance

- Ensure that the Heads-up Microsurgery has been properly installed and connected (see chapter 4 "Setting up the Headsup Microsurgery", page 19).
- Check if an image is displayed.
- Ensure that the 3D image is properly displayed by matching the left and right view to the corresponding eye (a suitable 3D test object is needed).

If the image on the heads-up monitor is lost during surgery, the surgeon can always perform surgery by using the binocular tubes that are required to be mounted on the microscope.

# 5.2 Position the heads-up monitor

- Move the heads-up monitor by the handrail on the backside of the cart.
- Position the heads-up monitor in the OR as shown in the image below.

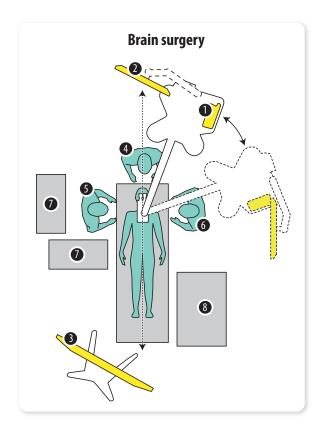
The heads-up monitor shall be positioned in a way that the surgeon has an unobstructed view and that the surface of the heads-up

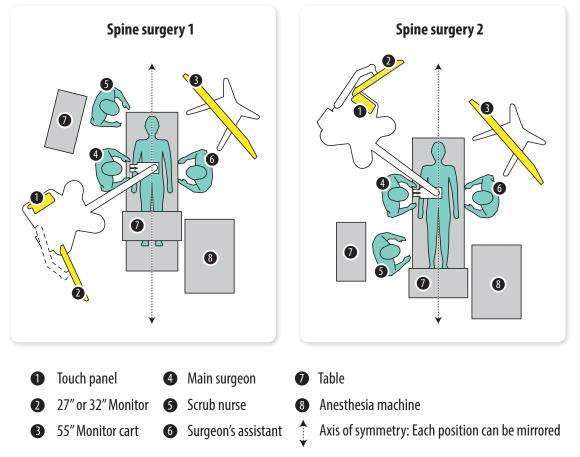
monitor is perpendicular to the line of sight of the surgeon.

### Note

The orientation of the image on the monitor depends on the orientation of the optics carrier.

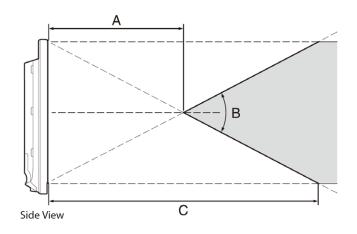
For best eye-hand coordination, keep a small relative angle between optics carrier and surgeon view on the monitor.





### 5.2.1 Viewing distance and angle

The optimal viewing distance should be at approximately 2000 mm (C) and should never be less than 1000 mm (A) away from the heads-up monitor.



A (Typical)	B (Typical)	C (Typical)
1000 mm	37°	2000 mm
Constallentia + 70/		

Crosstalk ratio  $\leq 7\%$ 

- Move the heads-up monitor by the handrail on the backside of the cart.
- Position the heads-up monitor at a distance between 1000 mm and 2000 mm.
- Tilt the heads-up monitor vertically by the handle on the front side of the cart. For best 3D depth perception, ensure a vertical viewing angle of max. 37° (B) from the minimum viewing distance (A).

# 6 What to do if..?

If electrically operated functions do not work properly, always check these points first:

- Is the power switch switched on?
- Are the power cables attached correctly?
- Are all connecting cables attached correctly?
- Are all video cables attached correctly?

Observation	Cause	Remedy
No display of 3D image	The selected visualization mode is only available in 2D.	Check if the selected visualization mode is available in 3D (see chapter 3 "System combi- nation", page 18).
	The monitor settings have been modified.	Contact Leica Microsystems Service.
Display of blurred or double image	The user is not wearing 3D glasses.	The user must wear 3D glasses to obtain correct 3D vision.
Display of "twisted" or "distorted" image or no image at all	The left and right video cables are connected incorrectly.	Connect the video cables correctly (see chap- ter 4 "Setting up the Heads-up Microsurgery", page 19).
Insufficient 3D perception	The surgeon's viewing angle is not perpendi- cular to the monitor.	Rotate and tilt the monitor so that the surgeon's line of sight is perpendicular to the monitor surface (see chapter 5.2 "Position the heads-up monitor", page 20).

# 7 Maintenance instructions

- ► Keep accessories in a dust-free place when not in use.
- Remove dust with a pneumatic rubber pump and a soft brush.
- Protect the devices from damp, vapors, acids, alkalis, and corrosive substances.
- ▶ Do not keep chemicals near the devices.
- Protect the devices from oil and grease.
- ► Never oil or grease the guide surfaces or mechanical parts.
- To disinfect the heads-up microsurgery, 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.
  - We recommend concluding a service contract with Leica Service.

# 8 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.

# 9 Technical Data

For specifications of the Leica surgical microscope refer to the user manual of ARveo 8 (10449157) or ARveo 8x.

## 9.1 Ambient Conditions

In use	0°C to +40°C
	+32 °F to +104 °F
Recommended	+20 °C to +30 °C
	+68 °F to +86 °F
	30% to 85% relative humidity (no condensation)
	700 mbar to 1060 mbar atmospheric pressure
Storage and	-20 °C to +60 °C
Transport	-4 °F to +140 °F
	20% to 90% relative humidity
	700 mbar to 1060 mbar atmospheric pressure

## 9.2 Electrical data

Power connection	100 V–240 V
for Heads-up	50/60 Hz
Microsurgery:	3.1 A–1.1 A

# 9.3 Electromagnetic compatibility (EMC)

The Heads-up Microsurgery was tested in combination with Leica surgical microscopes. For electromagnetic compatibility data refer to the user manual of ARveo 8 (10449157) or ARveo 8x.





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