From Eye to Insight

Leica
MICROSYSTEMS

PROVEO 8x
Heads-up Digital Visualization System

User Manual

10 735 165 version 00

Date of issue: 2024-10-10

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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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EC REP

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Legal disclaimer

All specifications are subject to change without notice.
The information provided by this manual is directly related to the operation of the equipment. Medical decision remains the responsibility of the clinician.
Leica Microsystems has made every effort to provide a complete and clear user manual highlighting the key areas of product use. Should additional information regarding the use of the product be required, please contact your local Leica representative.
You should never use a medical product of Leica Microsystems without the full understanding of the use and the performance of the product.

Liability

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

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1 Introduction

1.1 About this user manual

This user manual describes the functions of the system combination (see chapter 3 "PROVEO 8x Heads-up Digital Visualization System", page 7).

► Read this user manual carefully before operating the product.

In addition to notes on the use of the instrument, this user manual gives important safety information (see chapter 2 "Safety notes", page 3).

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 used in conjunction with PROVEO 8x.

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 PROVEO 8x Heads-up Digital Visualization System 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 Digital Visualization System is used only by persons qualified to do so.

2.1 Intended purpose

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

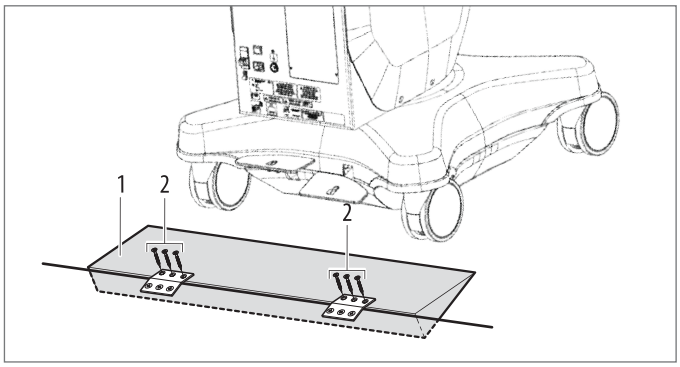
2.2 Clinical benefit

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

2.3 Limitations of use

The PROVEO 8x may be used only in closed rooms and must be placed on a solid floor.
Without auxiliary equipment, the PROVEO 8x can be moved across thresholds up to a max. height of 5 mm. The PROVEO 8x with heads-up monitor cart is not suitable for crossing thresholds higher than 20 mm.
To move the surgical microscope over thresholds of 20 mm, the wedge (1) included in the packaging can be used.

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



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

2.4 Indications for use

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

2.5 Contraindication

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

2.6 Intended target population

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

2.7 Intended user

The Heads-up Digital Visualization System is intended for professional use only. The user must have corresponding technical qualification and have been trained in the use of the instrument.

2.8 Dangers of use

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.
- ► Do not roll over obstacles lying on the floor.
- ► Do not transport or store the system and carts in areas with an elevation angle bigger than 10°.
- ► Before the operation, make sure that all accessories are sufficiently secured and cannot move.
- ► Do not mount monitor and accessories exceeding the permitted payload weight.
- ► Only use the system if it's 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.
- ► Always push the monitor cart, instead of pulling it.
- ► Always lock the wheels when not moving the monitor cart.

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.

WARNING

Risk of compromised decision making

- ► If the binocular tubes are removed for the main surgeon, always keep the binoculars in an easily accessible location and ready for use if required.

CAUTION

Risk of compromised surgery

- ► Perform a pre-operative check to confirm the Heads-up Digital Visualization System 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..

2.9 MRI Safety Information

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

2.10 Directions for the use of the PROVEO 8x Heads-up Digital Visualization System

- For best performance, do not change the settings of the heads-up monitor.
- If the binocular tubes are removed for the main surgeon, always keep the binoculars in an easily accessible location and ready for use if required.

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

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

2.11 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.

WARNING

Damage to the retina due to prolonged exposure!

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

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

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

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

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

Source:

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

Main light

Light setting	Maximum exposure time according to 1) [min.]
25%	6.5
50 %	2.5
75%	1.5
100 %	1
Retina Protection Function Activated	16.5

Coaxial Red Reflex illumination

Light setting	Maximum exposure time according to 1) [min.]
25%	10
50 %	4.5
75%	3
100 %	2
Retina Protection Function Activated	14

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

Protect the patient with the following safeguards:

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

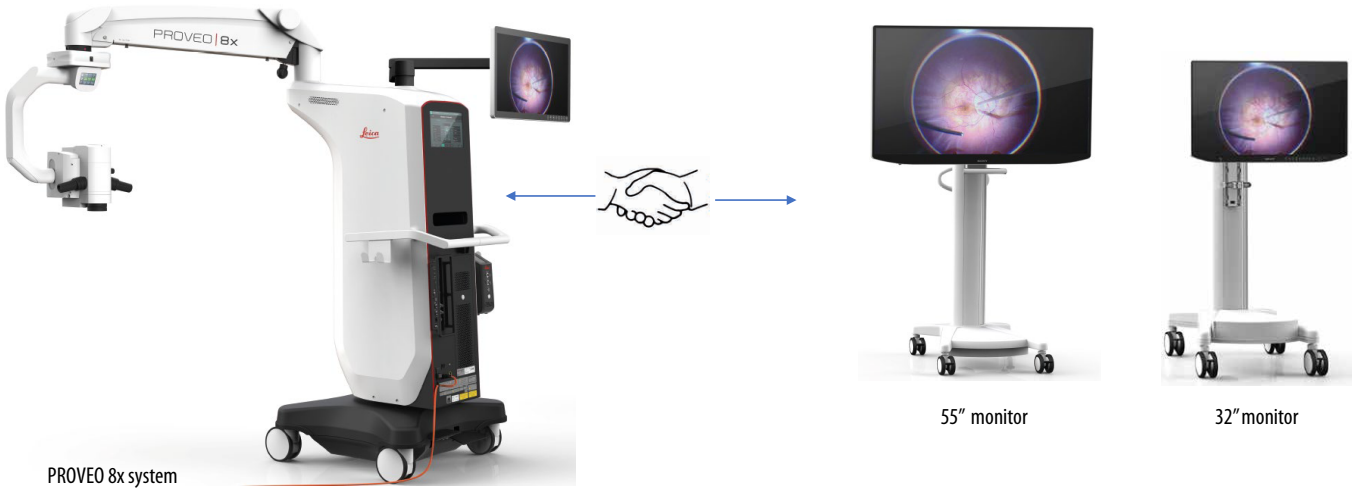
It is recommended to adjust the brightness to the minimum necessary for the surgery. Infants, patients with aphakia (whose eye lens has not been replaced by an artificial lens with a UV protection screen), small children and persons with diseases of the eye are at greater risk. The risk is also increased if the person being treated or operated on has, within the last 24 hours, already been exposed to illumination from the same or any other ophthalmological instrument that uses a bright visible light source. This applies especially to patients that have been examined via retinal photography.
Decisions about brightness must be made case by case. In any event, the surgeon must evaluate the risks and benefits of the used light intensity. Despite all efforts to minimize the risk of retinal injury by surgical microscopes, damage may still occur.
Photochemical retinal damage is a possible complication of the necessity to use bright light to make eye structures visible during difficult ophthalmological processes.
In addition, the Retina Protection function can be activated during the surgery to reduce the main light intensity below 10% and Red Reflex below 20%.

3 PROVEO 8x Heads-up Digital Visualization System

The option for performing heads-up ophthalmology is based on the system combination of compatible monitors with PROVEO 8x provided by Leica Microsystems.
The PROVEO 8x Heads-up Digital Visualization System provides ergonomic advantages as the user can maintain an upright posture while observing the surgical field. The heads-up monitor 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 10).

Depending on the requirements in the operating theater, the PROVEO 8x Heads-up Digital Visualization System displays different visualization modes.

- In 3D view (stereoscopic): white light surgical field visualization in 3D
- In 2D view: white light surgical field visualization in 2D



PROVEO 8x system

3.1 Heads-up monitor

The heads-up monitor is intended to provide 4K, 2D and 3D color video displays of images from PROVEO 8x. 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

3D glasses are provided with the purchase of the heads-up monitor from Leica Microsystems. The following optional 3D glasses accessory can also be ordered:

Leica Microsystems supplied 3D Glasses with Frame 10449171

Plastic frame glasses


CAUTION

Risk of compromised surgery

- ► Perform a pre-operative check to confirm the system 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 view for surgery, switch back to binocular tubes.
- ► Use only compatible 3D glasses provided by Leica Microsystems.
- ► Do not use 3D glasses on the 2D monitor.

- 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.
- To avoid eye infections, do not 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 PROVEO 8x Heads-up Digital Visualization System

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.
- ► Do not roll over obstacles lying on the floor.
- ► Do not transport or store the system and carts in areas with an elevation angle bigger than 10°.
- ► Before the operation, make sure that all accessories are sufficiently secured and cannot move.
- ► Do not mount monitor or accessories exceeding the permitted payload weight.

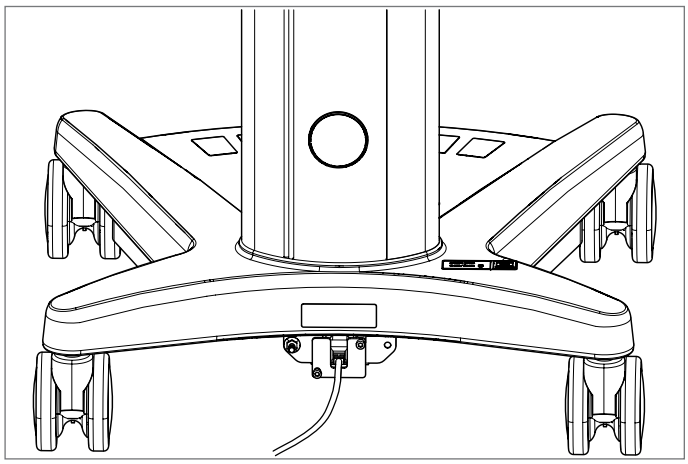
Note

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

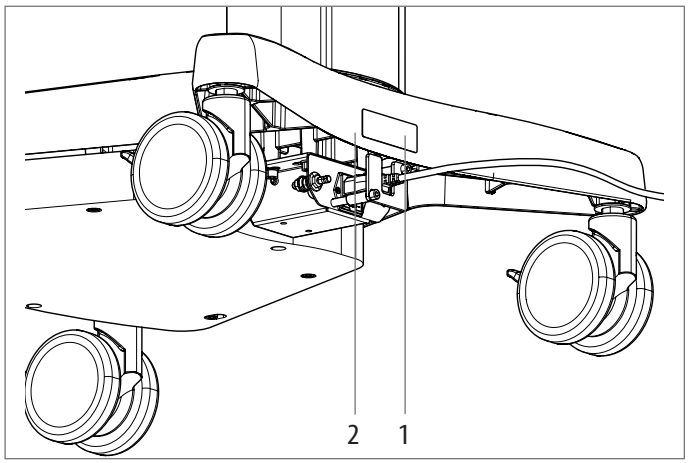
WARNING

Loss of image on heads-up monitor

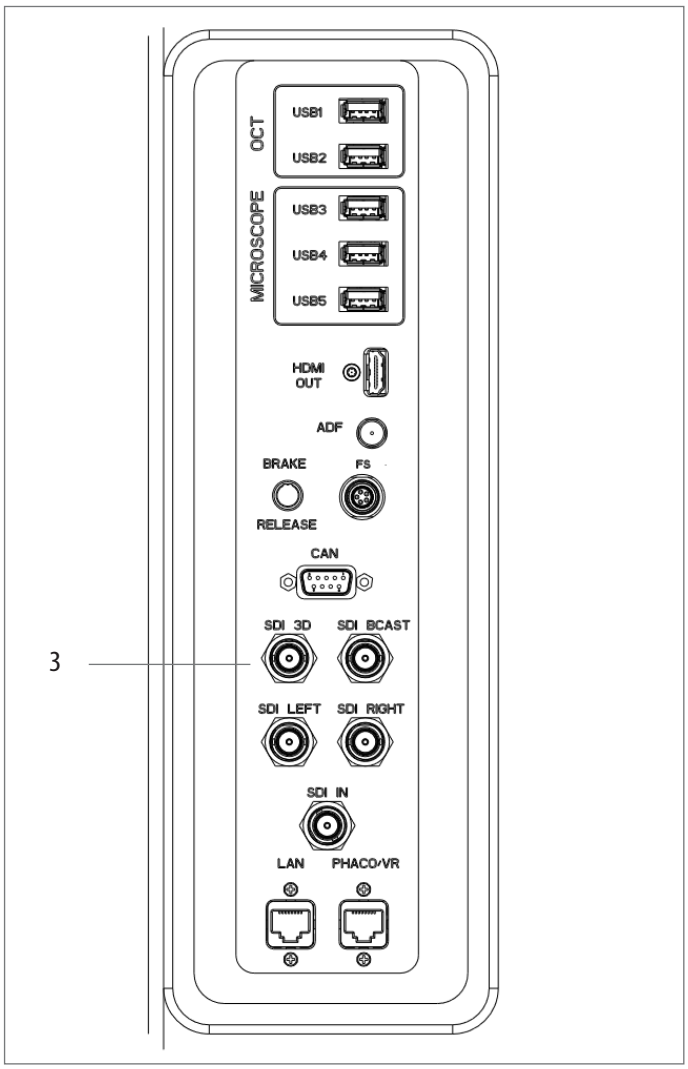
- ► Do not use a wireless connection between the microscope and the heads-up monitor for image transfer.



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



► Secure the power cable with plate (1) and plastic spacers (2) as illustrated.



► Connect an SDI cable of the heads-up monitor to port "SDI 3D" of PROVEO 8x (3).

► The PROVEO 8x Video Output Kit should be used to connect the PROVEO 8x microscope with the first SDI port on the monitor.

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 Digital Visualization System has been properly installed and connected (see chapter 4 "Setting up the PROVEO 8x Heads-up Digital Visualization System", page 8).
► 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.

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

WARNING

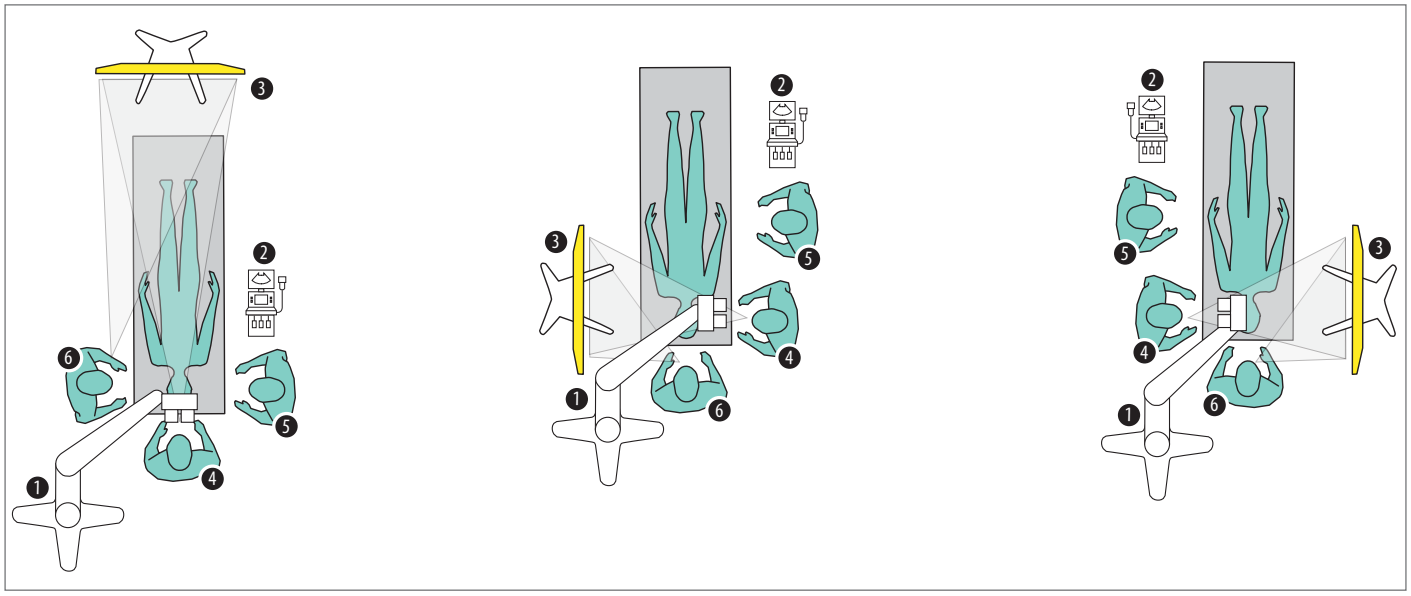
Risk of compromised decision making

► If the binocular tubes are removed for the main surgeon, always keep the binoculars in an easily accessible location and ready for use if required.

5.2 Position the heads-up monitor

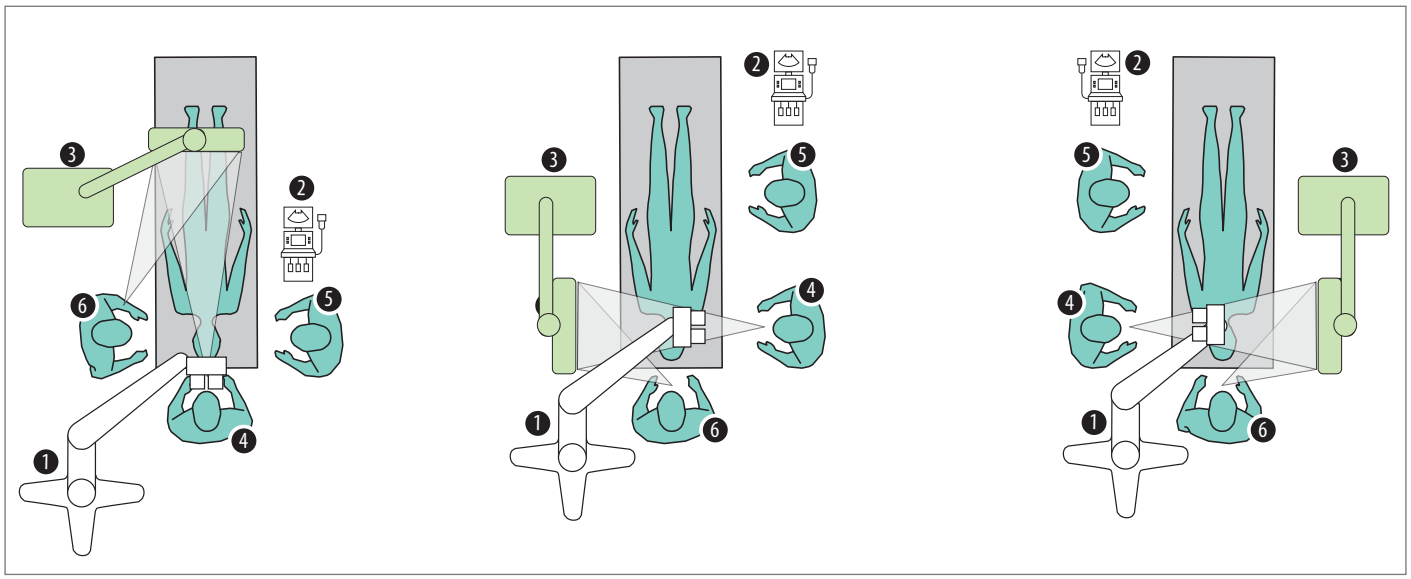
► Move the heads-up monitor by the handrail on the backside of the cart.
► Position the heads-up monitor in the OR as shown in the image on page 11.
The heads-up monitor shall be positioned in a way that the surgeon has an unobstructed view and that the surface of the heads-up monitor is perpendicular to the line of sight of the surgeon.

Superior and temporal working position with a 55" monitor and cart



1. Microscope
2. Phaco-vitrectomy system
3. Heads-up monitor and cart
4. Main surgeon
5. Sterile nurse
6. Assistant surgeon

Superior and temporal working position with a 32" monitor and cart

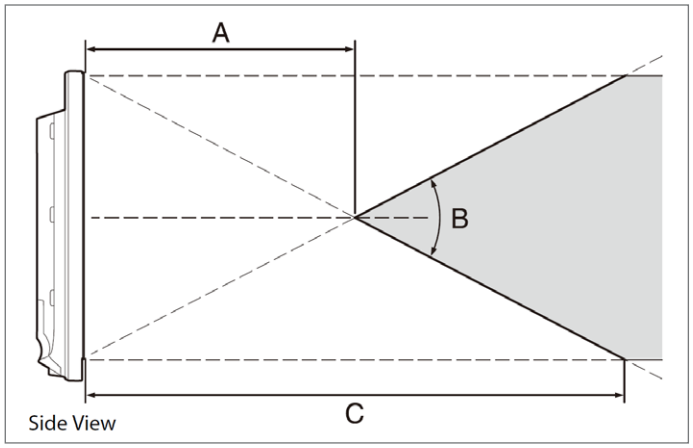


1. Microscope
2. Phaco-vitrectomy system
3. Heads-up monitor and cart
4. Main surgeon
5. Sterile nurse
6. Assistant surgeon

5.2.1 Viewing distance and angle

The optimal viewing distance for the 32" monitor should be positioned at approximately 1000 mm and at least 690 mm, and the 55" monitor at approximately 1500 mm and at least 1000 mm, to provide a few centimeters of vertical tolerance.

The user should be looking at the center of the display perpendicularly.



Monitor	A		B	C
	(Minimum)	(Recommended)	(Typical)	(Typical)
55"	1000 mm	1500 mm	37°	2000 mm
32"	690 mm	1000 mm	32°	1380 mm

Crosstalk ratio ≤ 7%

- ► Move the heads-up monitor by the handrail on the backside of the cart.
- ► The heads-up monitor can be tilted vertically. For best 3D depth perception, ensure a vertical viewing angle of max. 37° (B, for 55" monitor) or 32° (B, for 32" monitor) from the minimum viewing distance (A).

Note

- ► Image quality and depth perception may be affected when viewing the monitor outside of the viewing distance and angle.

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. The monitor settings have been modified.	Check if the selected visualization mode is available in 3D (see chapter 3, page 7). 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 video cables are connected incorrectly. The monitor settings have been modified. The left and right signals on the heads-up monitor is swapped incorrectly.	Connect the video cables correctly (see chapter 4, page 8).
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, page 10).

7 Maintenance instructions

For care and maintenance, please refer to the user manual of PROVEO 8x (10735160).

- ► 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 Ophthalmology System, use compounds from the surface disinfectant group based on the following active ingredients:
  - 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 PROVEO 8x (10735160).

9.1 Ambient conditions

In use	+10 °C to +30 °C +50 °F to +86 °F 30% to 75% relative humidity (no condensation) 700 mbar to 1060 mbar atmospheric pressure
Storage and Transport	–20 °C to +60 °C –4 °F to +140 °F 20% to 85% relative humidity 700 mbar to 1060 mbar atmospheric pressure

9.2 Electrical data

Power connection	100 V–240 V 50/60 Hz 3.1 A–1.1 A

9.3 Electromagnetic compatibility (EMC)

The PROVEO 8x Heads-up Digital Visualization System was tested in combination with Leica surgical microscopes. For electromagnetic compatibility data refer to the user manual of PROVEO 8x (10735160).

9.4 Standards fulfilled

CE conformity

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

10 Annex

10.1 Checklist before the operation

Patient .....

Surgeon .....

Date .....

Step	Procedure	Details	Checked / Signature
1	Cleaning the optical accessories	► Check the tubes, eyepieces and the documentation accessories (if used) for cleanliness. ► Remove dust and dirt.	
2	Installing the accessories	► Lock the PROVEO 8x in place and install all accessories on the microscope so it is ready for use. ► Position the handles as desired. ► Connect the footswitch if used. ► Check the camera image on the monitor and re-align if necessary. ► Check that all equipment is in its proper position (all covers fitted, doors closed).	
3	Checking the tube settings	► Check the tube and eyepiece setting for the selected user.	
4	Function check	► Connect the power cable. ► Switch on the microscope. ► Test all functions on the handles and the footswitch. ► Check the user settings on the control unit for the selected user.	
5	Balancing	► Balance the PROVEO 8x. ► Press the "All Brakes" button on the handle and check the balancing.	
6	Sterility	► Fit sterile components. ► Repeat balancing.	
7	Positioning at the OP table	► Position the PROVEO 8x in the operating room as required and lock the footbrake.	
8	Connecting the heads-up monitor to PROVEO 8x	► Connect an SDI cable of the heads-up monitor to port "SDI 3D" of PROVEO 8x. ► Check the system performance. ► Position the heads-up monitor.	

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