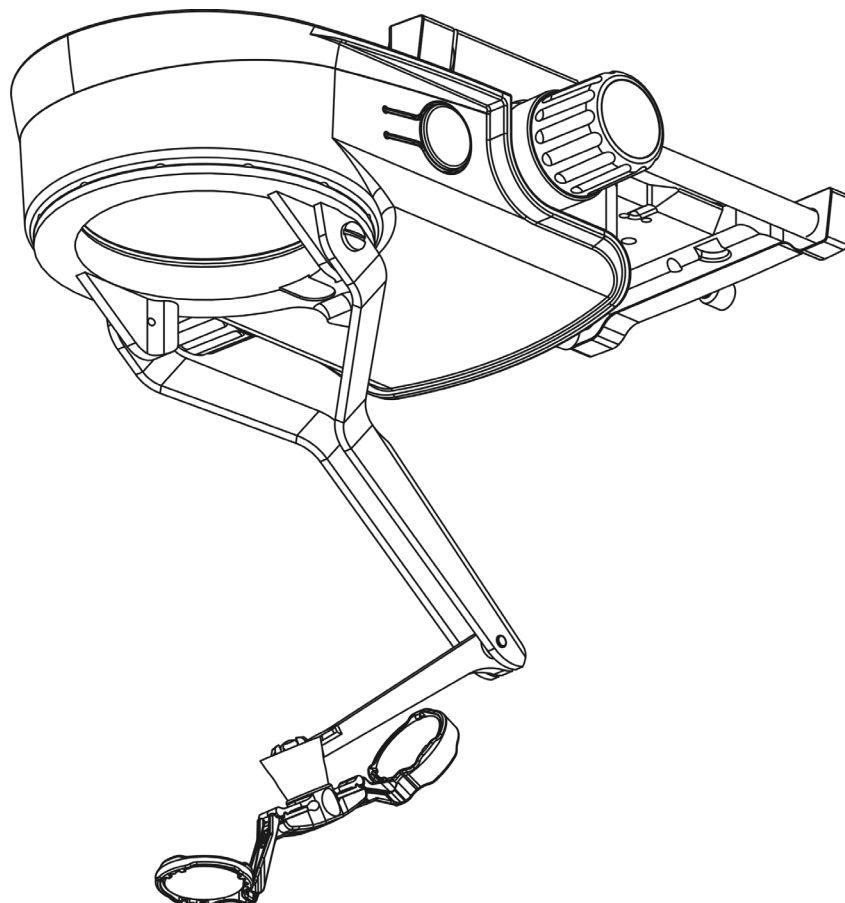


RESIGHT 500 & RESIGHT 700

Manual and Electrical

Fundus Viewing System



Instructions for Use

G-30-1695-en

Version 7.0

10/16/2012



- About this manual* These instructions for use are part of the delivery package.
- Carefully read it before using the device.
 - Keep it at the site of use of the device.
 - Store it for the entire service life of the device.
 - Pass it on to every subsequent owner or user of the device.
- Orientation aids*
- The table of contents at the beginning of these Instructions for Use provides an overview of all subjects.
 - A list of abbreviations, key words and technical terms in the annex facilitates the search for specific terms.
- Applicable area* These instructions for use applies to devices with the following identification:
- 302721-9030-000 (RESIGHT 700)
 - 302721-9020-000 (RESIGHT 500)
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Safety Measures



Key to symbols

We would like to inform you about safety aspects which must be observed when handling this device. This chapter contains a summary of the most important information concerning matters relevant to instrument safety.

Hazard symbols

The following safety information has been incorporated into the Instructions for Use. Please note this information and be particularly careful in these cases.



WARNING

Indicates a hazard which **can lead to death** or **severe injury** if it is not prevented.



CAUTION


Indicates a hazard which can cause **minor** to **moderate injury** if it is not prevented.

NOTE

Indicates a hazard which can cause **damage to material** if it is not prevented.

Information symbols

The following information symbols are used in these instructions for use:

- Listing
- ✓ Requirements for an action
- Prompt for action
- Result of an action
-  Additional information and hints

Target group

These Instructions for Use are intended for physicians, nurses and other medical staff who prepare, operate or maintain the system after the appropriate training and in accordance with the instructions given in these Instructions for Use. It is the duty of the customer or institution operating the system to train and instruct all staff using the system.

Installation and service work not described in these Instructions for Use must only be performed by specialists from Carl Zeiss.

Field of use

Intended use

The fundus viewing system is an accessory for surgical microscopes which is used for surgery on the posterior segment of the eye. It is used for stereoscopic imaging of the posterior segment and the retina.

Normal use

RESIGHT 500 and RESIGHT 700 are fundus imaging systems that are attached underneath the surgical microscope on the objective lens and are pivoted into the beam path of the surgical microscope. Both units enable stereoscopic imaging of the posterior segment of the eye (so-called fundus), which is required for special surgical procedures.

You have the choice between the electrically controlled RESIGHT 700 fundus imaging system and the manually operated RESIGHT 500 fundus imaging system.

In the electrical version, you can control the focusing function via a foot control panel.

Due to the internal focus, there is no longer a need for shifting the surgical microscope in vertical direction. Therefore, for working in the anterior segment of the eye, the fundus imaging system can be slid out without causing the surgical microscope image to become blurred.

You can switch between normal and wide-angle imaging by exchanging the re-sterilizable aspheric lenses on the lens holder.

The system is intended for use in hospitals, clinics or other human medicine institutions. For disposal, please comply with the instructions in this manual as well as the applicable legal regulations in your country.

Notes for the operator

The correct use of the system is absolutely vital for safe operation. Therefore, please thoroughly familiarize yourself with the contents of these Instructions for Use before starting up the system. Please also observe the respective Instructions for Use of any additional equipment.

Duties of the operator

- Use this instrument only for the applications described.
- Check that the connecting components which are relevant to system safety (details in the instructions for use) have been properly connected and that screw connections have been firmly tightened.
- For further information on the operation of the surgical microscope and the suspension system used, please see the relevant instructions for use.
- This device must not be modified without the manufacturer's approval. If the instrument is modified, suitable inspections and testing must be completed to ensure that it can still be used safely.
- Observe the legal regulations for accident prevention and occupational health and safety applicable in the country concerned.
- Use suitable packaging only to transport the instrument over longer distances (e.g. relocation, return for repair, etc).
- When mounting this accessory, please make sure that the admissible total weight of the surgical microscope is not exceeded. Detailed information can be found in the user's manual of the respective surgical microscope.
- Please ensure that sufficient space is available for focus positioning when the RESIGHT 500 or RESIGHT 700 fundus viewing system is mounted on the surgical microscope.
- For the RESIGHT 700 fundus viewing system, please note the EMC information (electromagnetic compatibility) in the "System data" chapter on page 90.

- Any additional equipment connected to medical electrical devices must demonstrably comply with the applicable IEC or ISO standards (e.g. IEC 60950 for data processing equipment). In addition, all configurations must meet the normative requirements for medical systems (see IEC 60601-1-1 or Clause 16 of the 3rd edition of IEC 60601-1). Anyone connecting additional equipment to medical electrical devices is a system configurer and as such responsible for compliance of the system with the normative requirements for systems.
Please note that local legislation takes priority over the above-mentioned normative requirements. If you have any questions, please contact your local dealer or Carl Zeiss Service.

Requirements to be met by the user

- This device must be used by properly trained personnel only. It is the responsibility of the customer or institution operating the device to train and instruct all staff using the device.
- Please keep these Instructions for Use where there are easily accessible at all times for the persons operating the system.

Warranty and liability

Warranty and liability depend on the applicable contractual stipulations.

NOTE

Loss of warranty

The manufacturer is not liable for damage caused by unauthorized persons tampering with the system. Furthermore, this will forfeit any rights to claim under warranty.

Requirements for operation

- ✓ The connecting components have been properly connected. The screw connections have been firmly tightened.
- ✓ All cables and plugs are in perfect condition.

Before every use

- Make sure that all requirements specified above are fulfilled.
- Please check that the RESIGHT fundus viewing system can be easily moved in and out.
- Ensure that the lens holder can be properly moved into and out of position.

During use

- If you have mounted the RESIGHT fundus viewing system on the underside of the microscope and steeply tilt the microscope, the RESIGHT fundus viewing system may unintentionally move in and injure the patient. Remove the RESIGHT fundus viewing system before steeply tilting the microscope.

After every use

Please note the following general guidelines within your area of responsibility for the sterility of the products during use:

- Use only procedures validated by ZEISS to clean, disinfect and sterilize.
- Adhere to the validated parameters with each cycle.

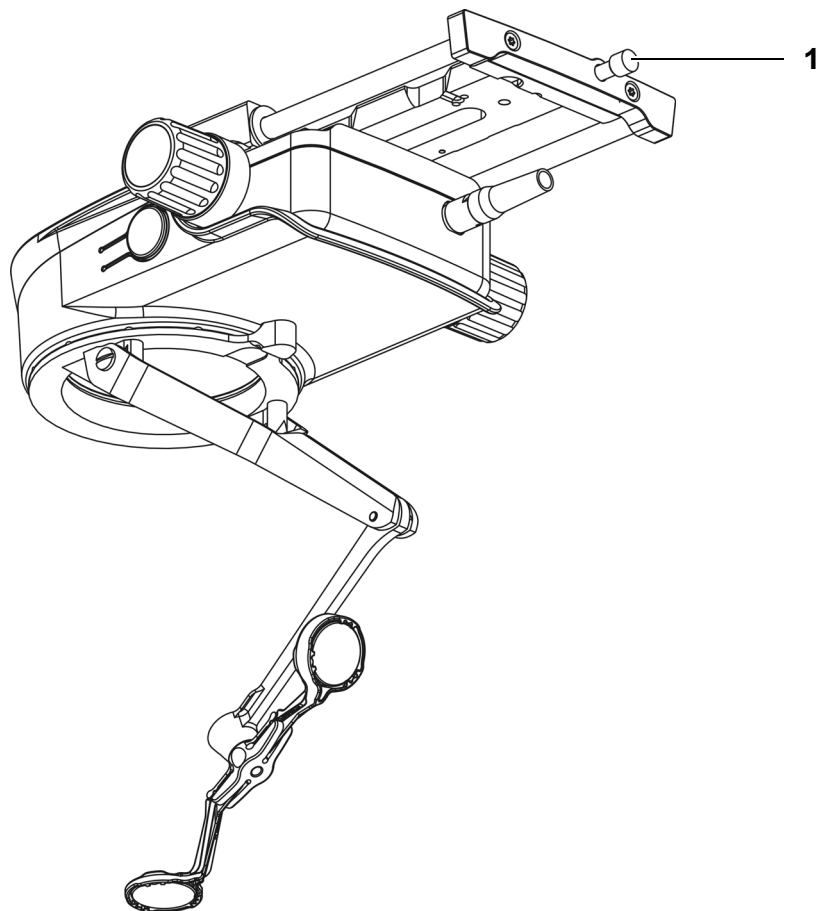
- Disinfect, clean and sterilize the instrument in accordance with this user's manual. Insufficient, incorrect or wrong preparation can lead to infections in the patient or medical staff.

Safety devices

1 Focusing unit locking screw

This screw is used to secure the focusing unit on the adapter plate of the surgical microscope.

Fig. 1: Safety devices



Symbols and labels on the device



Note the warning labels and notes!

- If you notice that any label is missing on your system or has become illegible, please contact us or one of our authorized representatives. We will supply a replacement.

Labels on the RESIGHT 700 fundus viewing system



1 Observe disposal regulations
Electrical or electronic devices must not be disposed of as normal domestic waste. For more information on the disposal of electrical and electronic devices, please see the chapter on "Maintenance and care."



2 Date of manufacturing
This graphical symbol indicates the manufacturing date of the device.



3 RESIGHT 700 rating plate

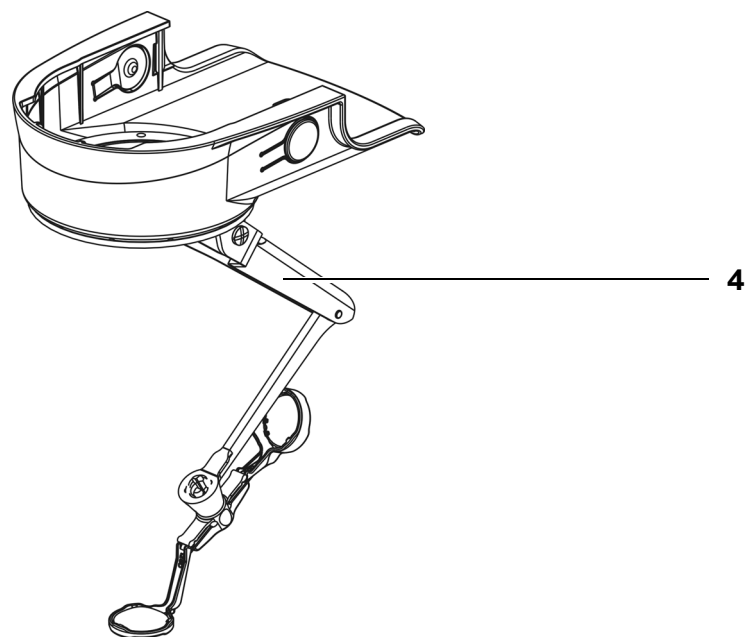
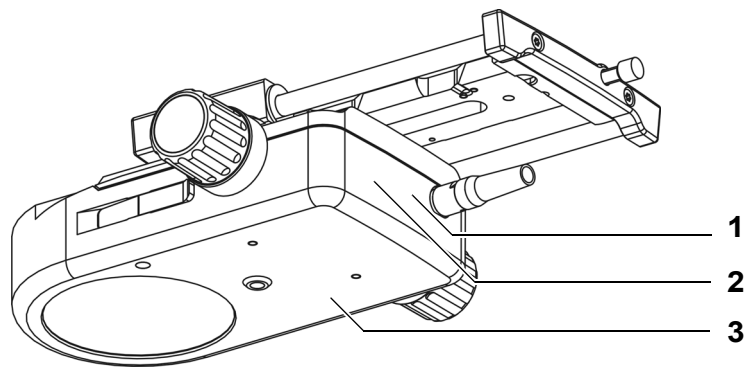
– Symbol of the manufacturer	
– Manufacturer (company name)	Carl Zeiss Meditec AG
– Manufacturer's address	Goeschwitzer Strasse 51-52 07745 Jena, Germany
– Serial number (SN)	
– System name	RESIGHT 700
– Material number (REF)	
– CE label	

**LH175
LH200**

4 Lens holder label
These labels identify the lens holders

- LH175 for the main objective lens with focal length $f = 175$ and
- LH200 for the main objective lens with focal length $f = 200$

*Fig. 2: Labels on the
RESIGHT 700
fundus viewing system*



Labels on the RESIGHT 500 fundus viewing system



- 1

"RESIGHT 500" rating plate

– Symbol of the manufacturer


– Name of the manufacturer (company name)

– Manufacturer's address

– Serial number (SN)


– System name

– Material number (REF)




Carl Zeiss Meditec AG

Goeschwitzer Strasse 51-52
07745 Jena, Germany




RESIGHT 500



1

CE label



LH175
LH200

- 2

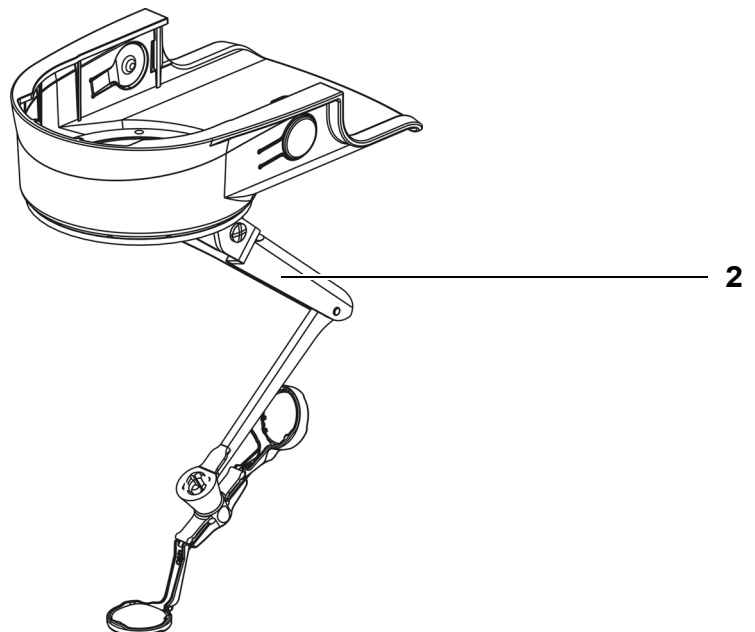
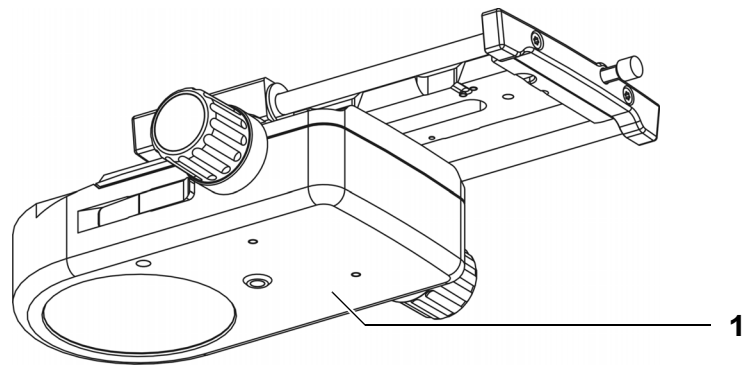
Lens holder label

These labels identify the lens holders

– LH175 for the main objective lens with focal length $f = 175$ and

– LH200 for the main objective lens with focal length $f = 200$

*Fig. 3: Labels on the
RESIGHT 500
fundus viewing system*



System Overview



General information

You have the choice between the electrically controlled RESIGHT 700 fundus viewing system and the manually operated RESIGHT 500 fundus viewing system. In the electrical version, you can control the internal focus via a foot control panel.

RESIGHT 700

Ši versija turėtų būti naudojama tik su šiais chirurginiais mikroskopais

This version must only be used on the following surgical microscopes:

- OPMI VISU 200 / 210 (on S8, S81 and S88 suspension systems)
- 1.1. – OPMI Lumera T and OPMI LUMERA 700

The electrical communication between the RESIGHT 700 fundus viewing system and the surgical microscope occurs via the "accessory port upgrade kit" that is integrated in the suspension system. The upgrade kit is installed in the suspension system by our service personnel. In addition to the control electronics, it contains an additional remote connector to control external devices.



CAUTION

Risk of injury!

If the switching voltage is too high or the switching current on the remote connector is too high, the housing can be live and injure operating personnel and patients.

- Use no more than 24V/0.5A for the remote connector.

RESIGHT 500

This version must only be used on the following surgical microscopes:

- OPMI VISU 150 / 160 / 200 / 210 (on S7, S8, S81 and S88 suspension systems)
- OPMI Lumera, Lumera T, OPMI Lumera i and OPMI LUMERA 700

Components of RESIGHT 500 / 700

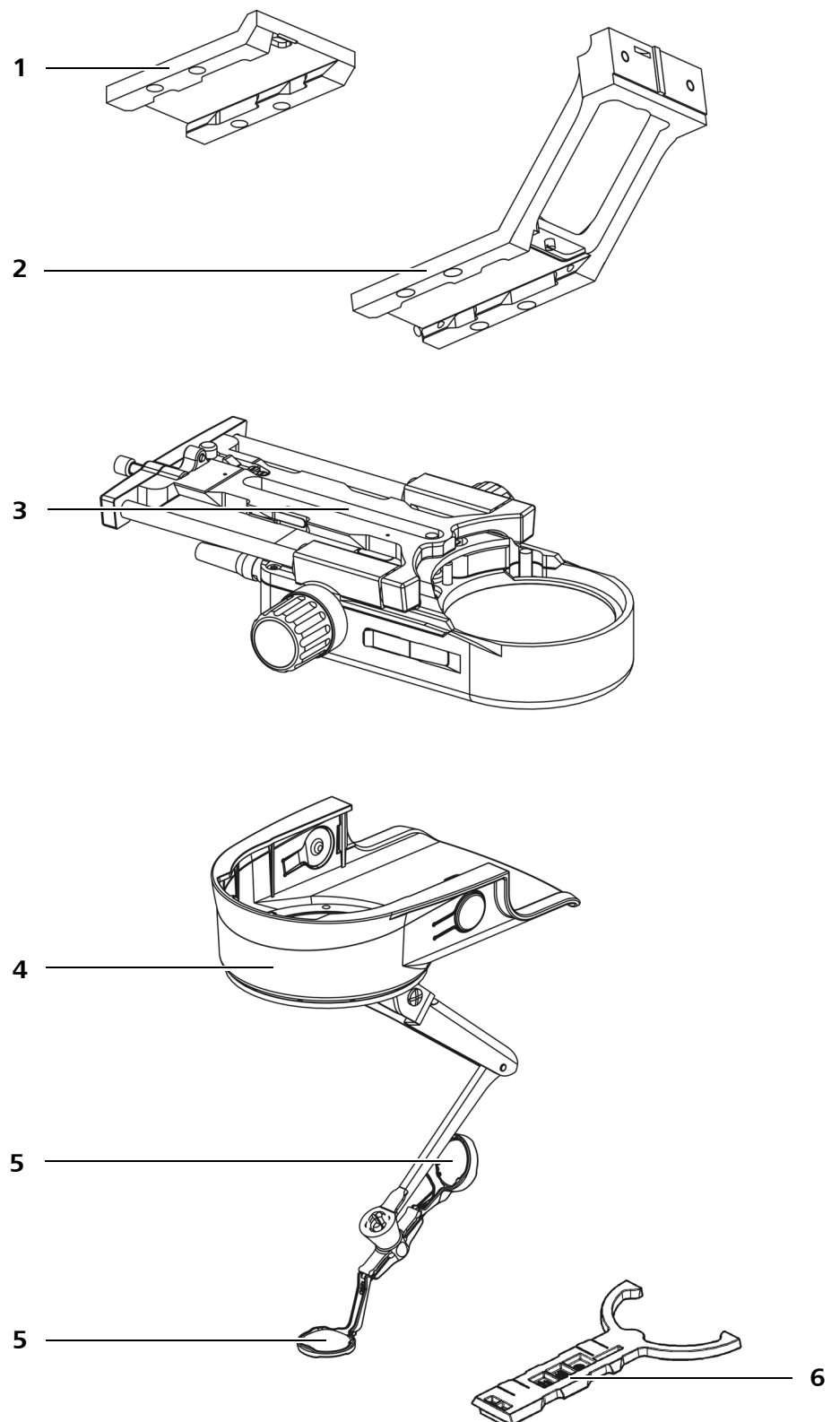
- 1 Adapter plate
Used for permanent installation of the device on the surgical microscope.
- 2 Adapter plate with accommodation for VISULUX (optional)
Used for permanent installation of the device on the surgical microscope.
- 3 Focusing unit with internal focus
Used for focusing and positioning on the surgical microscope.
- 4 Lens holder (resterilizable)
Used to mount and change the aspheric lenses. The lens holder can be turned in 30° increments to set the optimum working position. It is available in the LH175 and LH200 versions:

NOTE

For correct visualization of the fundus image, the lens holder must match the focal length of the main objective lens. Therefore, if you use a main objective lens with a focal length of $f=200$ mm on the surgical microscope, you must use the LH200 lens holder. If you use both lens holder versions, we would recommend marking them on the sterilization packaging to avoid confusion.

- 5 Aspheric lenses (resterilizable)
The aspheric lens is selected primarily according to the retinal section to be viewed and the desired magnification. For very small pupils, it may be necessary to select a lens with higher refractive power.
 - The green aspheric lens 60D has a refractive power of 60 diopters and is used to display the fundus area.
 - The yellow aspheric lens 128D has higher refractive power and thus a larger viewing angle. This enables you to observe a larger area of the fundus.
- 6 Installation aid
For alignment of the adapter plate for the focusing unit on the surgical microscope.

Fig. 4: System overview:



Controls and connections

Focusing unit

- 1 Focusing unit locking screw
Used to secure the focusing unit on the adapter plate of the surgical microscope.
- 2 Power supply connector (RESIGHT 700 only)
Used to control the motorized focusing unit.
- 3 Focusing knob (left/right)
Used to operate the manual internal focus on the RESIGHT fundus viewing system. In the event of failure of the motorized internal focus on the RESIGHT 700 fundus viewing system, you can also use the knobs to focus the system.
- 4 Alignment screw
Used to horizontally align the objective lens of the fundus viewing system with the main objective lens of the surgical microscope.



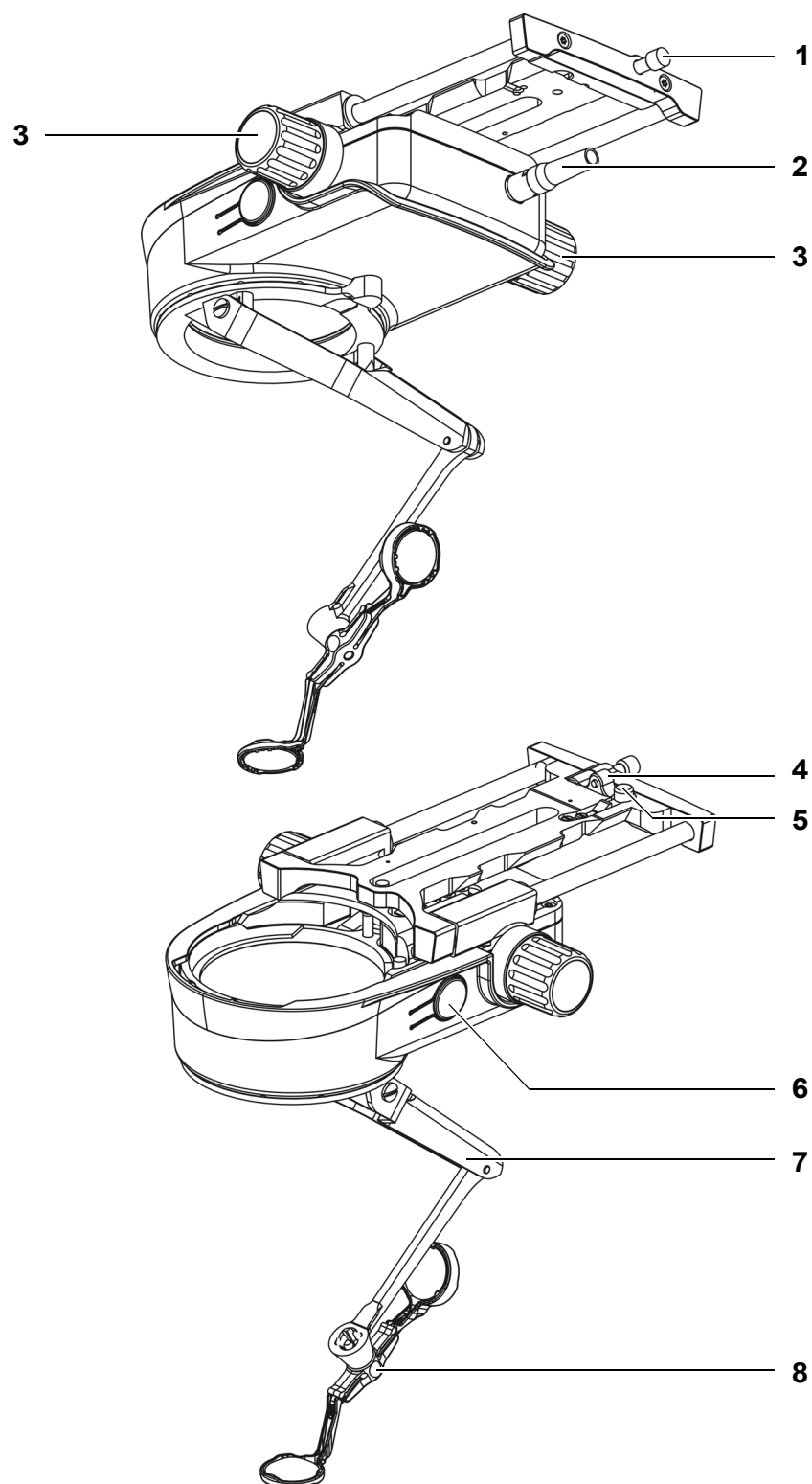
To obtain an optimum image quality, the beam path of the surgical microscope must coincide with the beam path of the fundus viewing system (see page 26).

- 5 Unlocking button
Used to separate the focusing unit from the adapter plate of the surgical microscope.

Lens holder (resterilizable)

- 6 Unlocking buttons of the sterilizable lens holder
You can unlock the resterilizable lens holder and pull it forward by pressing both unlocking buttons at the same time.
- 7 Hinged lens holder mechanism
Used to fold the resterilizable aspheric lenses up and down.
- 8 Lens joint
Used to fasten and change the resterilizable aspheric lenses.

Fig. 5: Control element & connections



Preparations for use



Installing the RESIGHT 500 and RESIGHT 700

The adapter plate can be used to attach the RESIGHT 500 or RESIGHT 700 fundus imaging system on surgical microscopes of the VISU or Lumera series. Two different versions of the adapter plate are available:

- Adapter plate (302721-9040-000) features no attachment device for the VISULUX fiber slit illuminator.
- Adapter plate (302721-9050-000) features an attachment device for the VISULUX fiber slit illuminator.

Either of these versions can be attached permanently to the surgical microscope.

The installation and configuration steps are described on the following pages.

Mounting the adapter plate and focusing unit

- Secure the suspension arm against inadvertent lowering or abrupt upward movement before installing the RESIGHT fundus imaging system (see the Instructions for Use of your suspension system).

Attaching the adapter plate

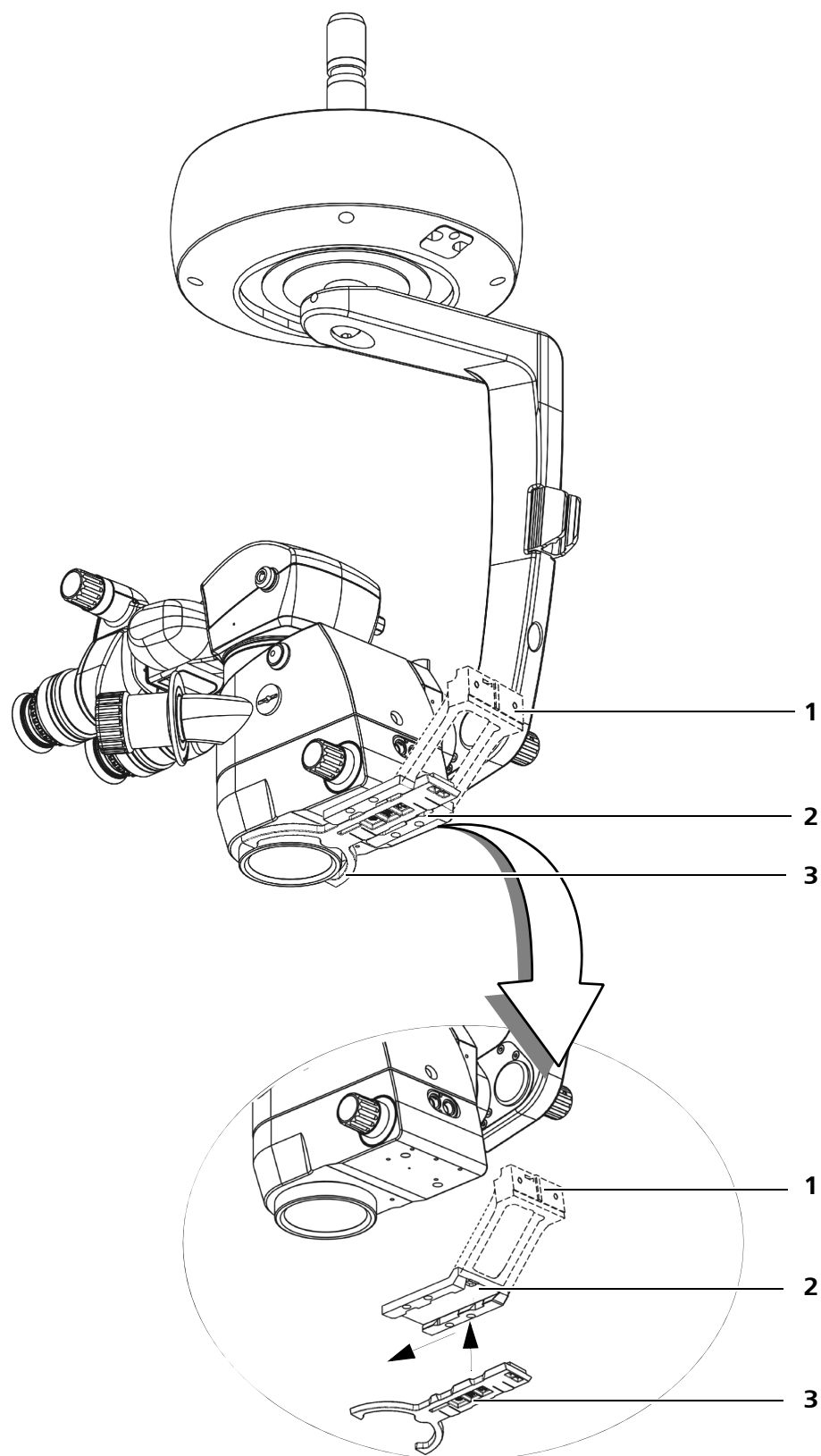
- Press the installation aid (3) onto the adapter plate (2) from below such that the cutouts on the installation aid line up with those on the adapter plate.
- Slide the installation aid (3) to the left and forward on the adapter plate (2) as far as it will go.



If you intend to use the RESIGHT fundus imaging system in combination with the VISULUX fiber slit illuminator, you need to use the adapter plate (2) featuring the attachment device (1) for the fiber slit illuminator.

- Adjust the adapter plate (2) using the installation aid (3) on the surgical microscope. The three contact sites of the installation aid must rest against the objective lens of the surgical microscope.
- Screw the adapter plate (2) under the surgical microscope by firmly tightening the four enclosed screws clockwise.
Please make sure that the three contact sites of the installation aid rest against the objective lens of the surgical microscope during this process.
- Slide the installation aid (3) away from the main objective lens of the surgical microscope such that the cutouts on the installation aid line up with those on the adapter plate.
- Take the installation aid (3) out of the guidance of the adapter plate (2).

Fig. 6: Attaching the adapter plate



**CAUTION****Risk of injury caused by parts falling down!**

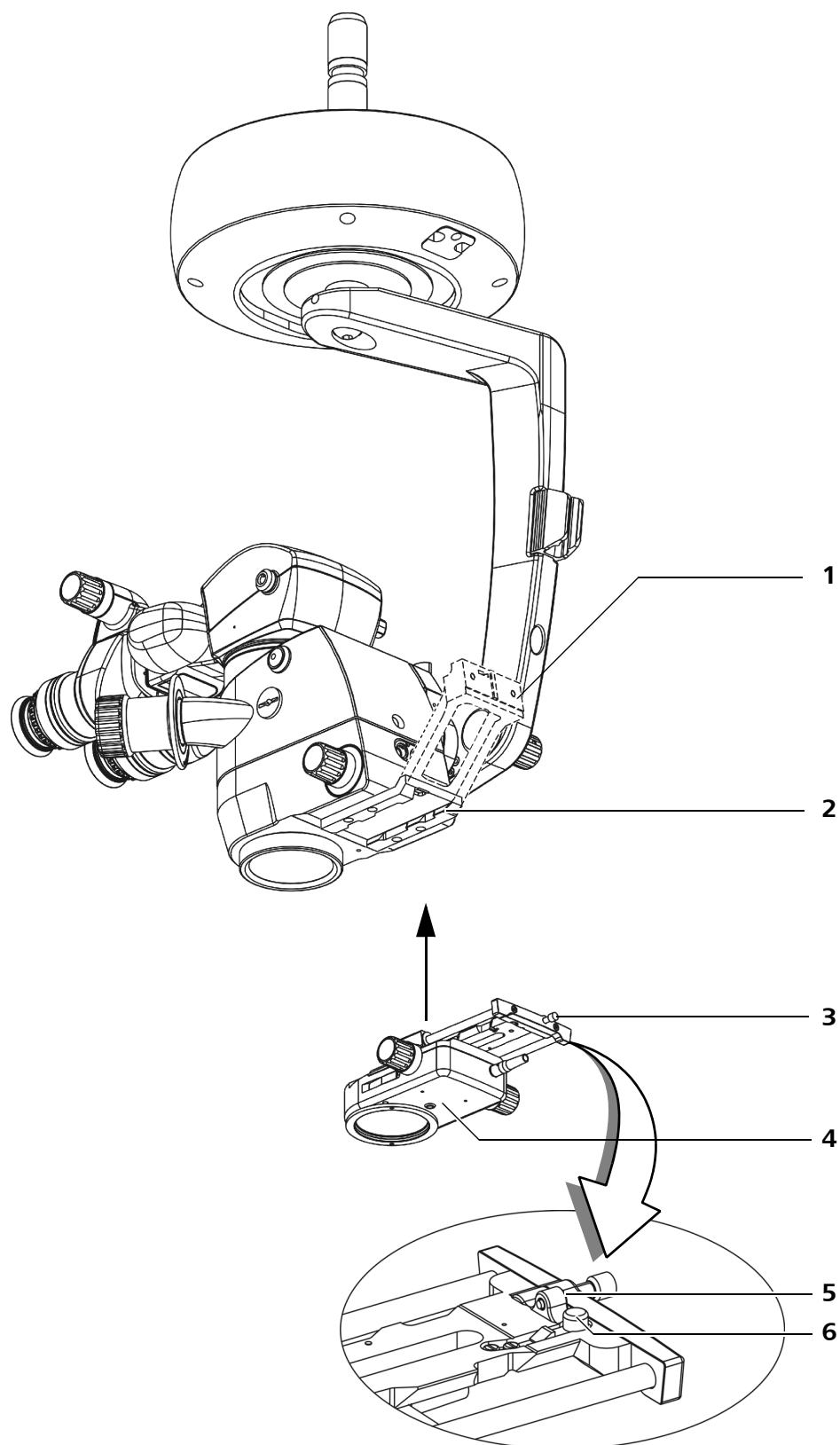
The focusing unit can become separated from the adapter plate if it is not engaged. Therefore please observe the following points when attaching the focusing unit:

- Before attaching the focusing unit, loosen locking screw (3) so that you can push in the unit as far as it will go.
- Make sure that alignment screw (5) is turned only to an extent where the locking mechanism is not blocked.
- The focusing unit must audibly snap into place when it is pushed on the adapter plate as far as it will go.
- Check that the focusing unit is securely locked in position: it must not be possible to remove the focusing unit from the adapter plate without activating unlocking button (6).

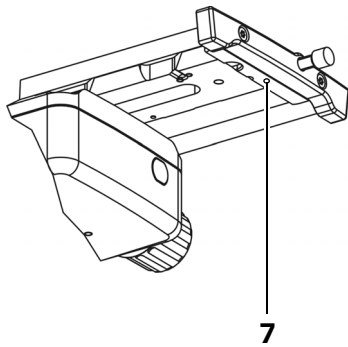
Mounting the focusing unit

- Press the focusing unit (4) from below onto the adapter plate (2) so that the cutouts on the focusing unit line up with those on the adapter plate.
- Slide the focusing unit (4) forward on the adapter plate (2) towards the main objective lens of the surgical microscope as far as it will go.

Fig. 7: Mounting the focusing unit



Aligning the components



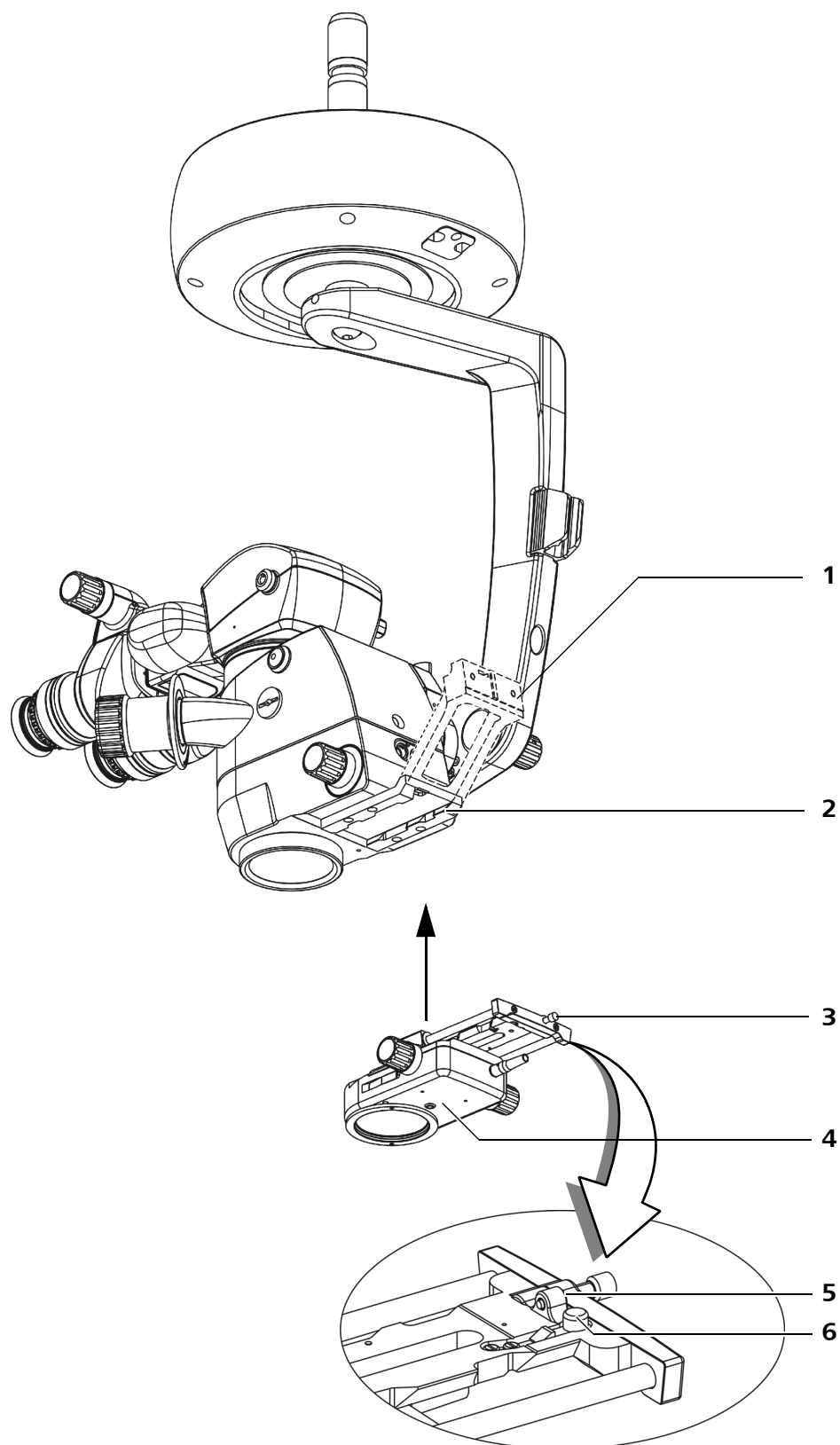
To achieve optimal image quality, the beam path of the surgical microscope must coincide with the beam path of the focusing unit. Align the components as follows the first time the focusing unit is mounted:

- Adjust the alignment screw (5) on the focusing unit such that there is a gap of 0.5 mm between the focusing unit and the main objective lens of the surgical microscope.
- Fix the gap, as set, by locking the alignment screw (5) using the threaded pin (7). For this purpose, tighten the slotted screw of the threaded pin (7) by turning it clockwise.
- Tighten locking screw (3).
- Check if the focusing unit (4) is properly mounted and does not wobble.

Establishing the electrical connections (optional)

If you are installing the RESIGHT 700 fundus imaging system, connect the electrical power cable of the focusing unit (4) to the surgical microscope. The connector is located on the back of the surgical microscope.

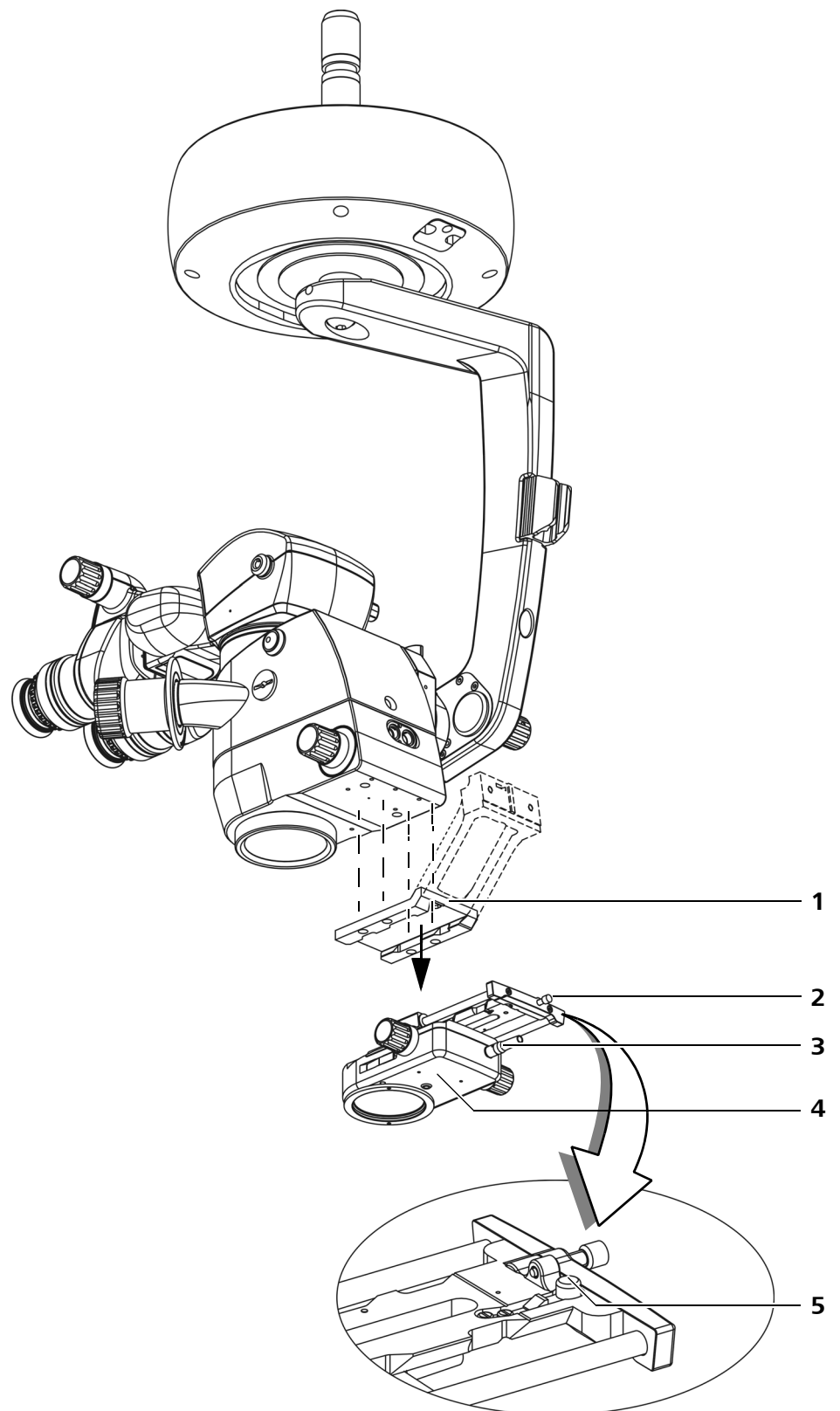
Fig. 8: Mounting the focusing unit



Removing the adapter plate and focusing unit

- Removing the focusing unit*
- If you are removing the RESIGHT 700 fundus viewing system, disconnect the electrical connection (3) of the focusing unit from the surgical microscope.
 - Hold the focusing unit (4) with one hand.
 - Loosen the locking screw (2) by turning it counterclockwise.
 - Press and hold down the unlocking button (5) and pull the focusing unit (4) backwards from the adapter plate (1).
- Removing the adapter plate*
- Remove the adapter plate (1) by turning the four screws on the underside of the adapter plate counterclockwise.

Fig. 9: Removing RESIGHT

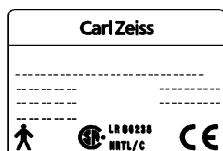


Configuring the foot control panel

Configuration on the S8, S88 and S81 suspension systems (OPMI VISU 200 / 210 / OPMI Lumera T)

To control the motorized internal focus of the RESIGHT 700 fundus viewing system via the foot control panel, you must configure the S8, S88 and S81 suspension systems accordingly.

The configuration settings of the suspension systems differ, depending on the electronics integrated into the S8, S88 and S81 suspension systems.



- The type label tells you which version of the S8, S88 and S81 suspension system you have:
 - Suspension system cat. no. **1078-582 / 1154-525 / 305952-9940 / 305952-9950 / 1176-968 / 1176-969** or
 - Suspension system cat. no. **305952-9910 / 305952-9920**

Setting the configuration

For S8 suspension systems with cat. no. 1078-582 / 1154-525 / 305952-9940 / 305952-9950 / 1176-968 / 1176-969:

- In configuration mode 1 (illustration on the left), assign the "SDI" function to button C or D on the foot control panel. For details, see the instructions for use for the S8 suspension system, user interface for OPMI VISU on S8 suspension system. This setting is saved under the current user ID.

For S8 / S88 suspension systems with cat. no. 305952-9910 / 305952-9920:

- In configuration mode 1 (illustration on the left), assign the "PHOTO" function to button C or D on the foot control panel. For details, see the instructions for use for the S8 suspension system, user interface for OPMI VISU on S8 suspension system. This setting is saved under the current user ID.

Controlling the internal focus of the RESIGHT 700 focus viewing system



Please note that the button assignment on the foot control panel depends on your system configuration. The button functions available to you after completing the configuration and connecting the Invertertube E and/or the VISULUX fiber slit illuminator are described on page 35.

Electronic control via the S8, S88, S81 suspension systems

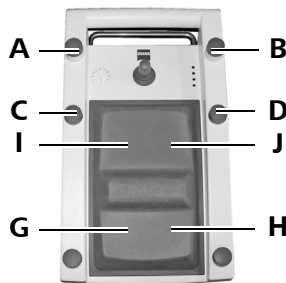
After configuring buttons C and D, you can operate the motorized focusing function of RESIGHT 700 via the foot control panel.



Please note that the button assignment on the foot control panel depends on your system configuration. The following pages describe the button functions available to you after the following devices have been connected:

- RESIGHT 700
- Invertertube E (tiltable tube with motorized inversion)
- VISULUX (fiber slit illuminator with motorized positioning)

Example: FCP-WL



None of the above devices has been connected

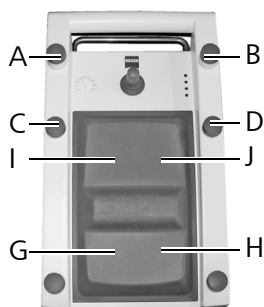
- Buttons A and B are used to increase or reduce lamp brightness.
- Buttons C and D are used to activate the previous functions.
- The rocker switches (I, G, J, H) enable you to increase or reduce the focal distance or magnification (zoom).
The assignment of functions to the rocker switches depends on the system configuration and may vary between vertical or horizontal configuration.

Only Invertertube E connected

- Buttons A and B are used to increase or reduce brightness.
- Buttons C and D are used to switch the inverter position.
- The rocker switches (I, G, J, H) enable you to increase or reduce the focal distance or magnification (zoom).
The assignment of functions to the rocker switches depends on the system configuration and may vary between vertical or horizontal configuration.

Only fiber slit illuminator connected

- Buttons A and B are used to control the functions which you can select via button C or D.
- Buttons C and D are used to switch between the functions "brightness" and "fiber slit illuminator movement."
- The rocker switches (I, G, J, H) enable you to increase or reduce the focal distance or magnification (zoom).
The assignment of functions to the rocker switches depends on the system configuration and may vary between vertical or horizontal configuration.

Example: FCP-WL**Invertertube E and fiber slit illuminator connected**

- Buttons A and B are used to adjust lamp brightness or move the fiber slit illuminator.
- Button C or D is used to switch the position of Invertertube E and changes the functions assigned to buttons A and B (switch between "brightness" and "fiber slit illuminator movement").

Function 1: Proceed as follows if you want to switch the functions assigned to buttons A and B and turn Invertertube E at the same time:

- Press button C or D once.

Function 2: Proceed as follows if you want to retain the functions assigned to buttons A and B and only want to change the position of Invertertube E at the same time:

- Press button C or D once and press it once again while the position of Invertertube E is being switched.

The first press of the button starts inversion and changes the functions assigned to buttons A/B. Any further pressing of the button while Invertertube E is moving will be ignored by the Invertertube, but change the A/B button assignment of functions as usual.

Function 3: Proceed as follows if you want to switch the functions assigned to buttons A and B without changing the status of Invertertube E:

- Proceed as described for function 2 and press button C or D a third time when inversion has been completed. The functions assigned to buttons A / B are changed and the inversion status remains unchanged.
- The rocker switches (I, G, J, H) enable you to increase or reduce the focal distance or the magnification (zoom).
The assignment of functions to the rocker switches depends on the system configuration and may vary between vertical or horizontal configuration.

Only RESIGHT 700 connected

Button assignment with RESIGHT 700 fundus viewing system in the beam path:

- Buttons C and D are used to activate the previous functions.
- Buttons A and B are used to increase or reduce the focal distance via the surgical microscope.
- The rocker switches (I, G, J, H) enable you to increase or reduce the focal distance via the RESIGHT 700 fundus viewing system, or to increase or reduce the magnification (zoom).

Button assignment with RESIGHT 700 fundus viewing system out of the beam path:

- Buttons C and D are used to activate the previous functions.
- Buttons A and B are used to increase or reduce lamp brightness.
- The rocker switches (I, G, J, H) enable you to increase or reduce the focal distance of the surgical microscope or the magnification (zoom).

RESIGHT 700 and fiber slit illuminator connected



If the RESIGHT 700 fundus viewing system and the VISULUX fiber slit illuminator are connected, motorized movement of the fiber slit illuminator is no longer possible, but only manual movement in a limited range.

- Buttons C and D are used to activate the previous functions.

Button assignment with RESIGHT 700 fundus viewing system in the beam path:

- Buttons A and B are used to focus via the surgical microscope.
- The rocker switch is used to focus via the RESIGHT 700 fundus viewing system.

Button assignment with RESIGHT 700 fundus viewing system out of the beam path:

- Buttons A and B are used to adjust lamp brightness.
- The rocker switch is used to focus via the surgical microscope.

RESIGHT 700 and Invertertube E connected



- Invertertube E automatically inverts the image when the RESIGHT fundus viewing system is moved into the beam path.

- Buttons C and D can be used to additionally switch the inverter position.

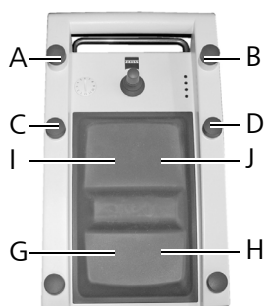
Button assignment with RESIGHT 700 fundus viewing system in the beam path:

- Buttons A and B are used to focus via the surgical microscope.
- The rocker switch is used to focus via the RESIGHT 700 fundus viewing system.

Button assignment with RESIGHT 700 fundus viewing system out of the beam path:

- Buttons A and B are used to adjust lamp brightness.
- The rocker switch is used to focus via the surgical microscope.

Example: FCP-WL



RESIGHT 700, Invertertube E and fiber slit illuminator connected



Invertertube E automatically inverts the image when the RESIGHT fundus viewing system is moved into the beam path.

If the RESIGHT 700 fundus viewing system and the VISULUX fiber slit illuminator are connected, motorized movement of the fiber slit illuminator is no longer possible, but only manual movement in a limited range.

- Button C or D can be used to additionally switch the inverter position.

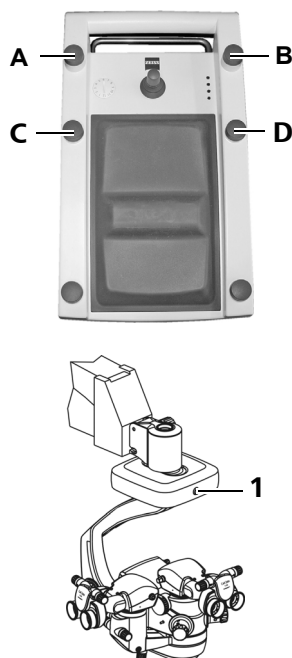
Button assignment with RESIGHT 700 fundus viewing system in the beam path:

- Buttons A and B are used to focus via the surgical microscope.
- The rocker switch is used to focus via the RESIGHT 700 fundus viewing system.

Button assignment with RESIGHT 700 fundus viewing system out of the beam path:

- Buttons A and B are used to adjust lamp brightness.
- The rocker switch is used to focus via the surgical microscope.

Configuring the OPMI Lumera 700



Button functions with swung-in RESIGHT 700

If you swing the RESIGHT 700 in, the external focus of the surgical microscope is placed on the upper buttons of the foot control panel and the internal focus of the RESIGHT 700 is placed on the rocker switches.

- Button A increases (+) the external focus
- Button B decreases (-) the external focus

If this is not the desired configuration, you can also assign the functions of the buttons of the OPMI LUMERA 700 to buttons C (+) and D (-) in the "Links" menu. Furthermore, the "Links" menu allows you to synchronize the focus direction of the RESIGHT 700 with the OPMI focus.

In addition to the individually adjustable functions, the RESIGHT 700 focus is reset by pressing the XY reset button (1) or when the parking position of the OPMI LUMERA 700 is reached. This reset sets the focus of a connected RESIGHT 700 to the central position.

Button functions with swung-out RESIGHT 700



When the RESIGHT 700 is swung out, user-specific functions are assigned to buttons A and B.

- To avoid any contact with the patient by accidentally lowering the surgical microscope, functions which are required during application of the RESIGHT 700 should not be assigned to these buttons.

Changing the button assignment on the foot control panel

Touchscreen of the control panel:



- Press the <User Config> button in the main menu, then press the <Foot Control Panel> button.
 - This opens the "Foot Control Panel" submenu.
- Press the button whose function you want to change:
 - A list of the selectable functions is displayed. If several selectable functions are available, a scroll bar is displayed. Use the arrow buttons to scroll up and down.
- Tap on the function to be assigned to the button.
- Repeat the two steps above until you have assigned the required functions to all buttons of the foot control panel.
- Press the  button to save the changes.
 - The setting is saved for the current user.
- Press the  button twice to return to the main menu.
 - The main menu is displayed again.
- For more information on how to configure the foot control panel, please see the instructions for use for OPMI LUMERA 700 (G-30-1673).

Attaching resterilizable components



CAUTION

Risk of infection!

The patient or user can become contaminated if sterile accessories are not used.

- Clean, disinfect and sterilize the products of the sterile accessories before each use. This also applies to the first use after delivery.
- Only use the system with suitable, sterile accessories.

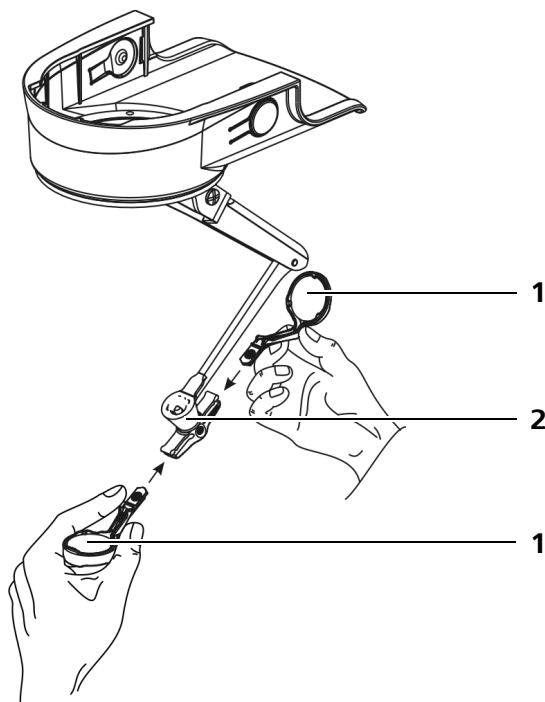
Mounting the aspheric lenses



Make sure to touch sterilized components only with sterile hands! Instructions on cleaning, disinfecting and sterilizing the aspheric lenses (1) can be found on page 68.

- Attach the sterile aspheric lenses (1) to the sterile lens joint (2) on the lens holder.

Fig. 10: Attaching aspheric lenses



Mounting the resterilizable lens holder



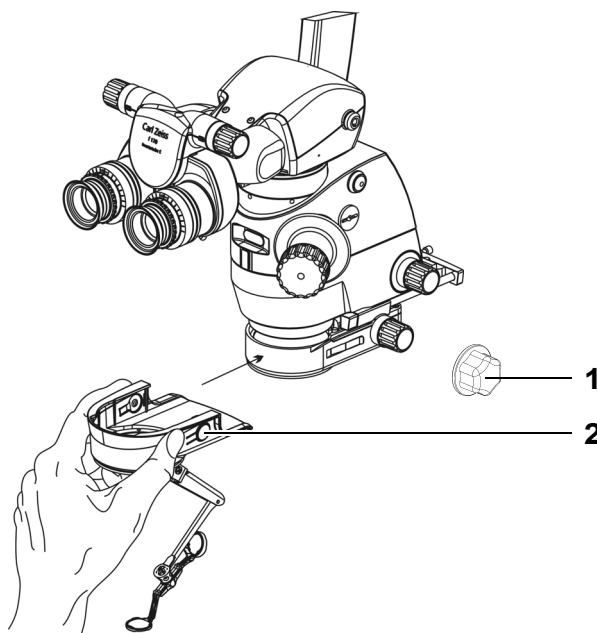
Make sure to touch sterilized components only with sterile hands! Instructions on cleaning, disinfecting and sterilizing the lens holder (2) can be found on page 68.

- Unfold the sterile lens holder (2) and slide it onto the focusing unit from the front until it audibly snaps into place.

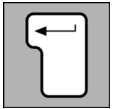


For information on how to sterilize the caps (1), please see the enclosed instructions "Preparation of resterilizable products" or page 68 of this user manual.

Fig. 11: Attaching the lens holder



Operation



- Requirements*
- ✓ The RESIGHT 500 fundus viewing system has been mounted on the surgical microscope and the locking knob has been firmly tightened (see page 26).
 - ✓ The electrical connection between the RESIGHT 700 fundus viewing system and the suspension system has been made (see page 26).
 - ✓ The foot control panel has been connected to the suspension system and configured (see page 34).



CAUTION

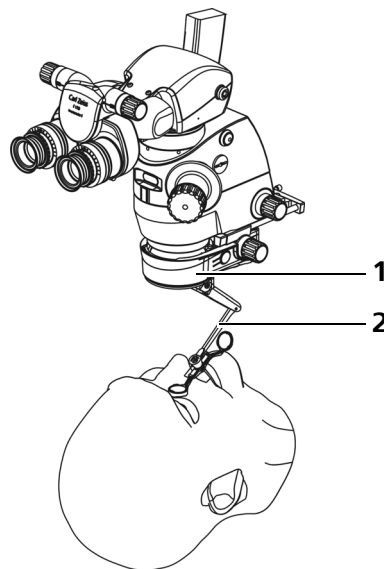
Risk of injury!

A jammed lens holder mechanism (2) can injure the patient's eye if the surgical microscope is moved downward.

- Before every operation, ensure that the lens holder mechanism can be easily folded and unfolded.

When you are working on the anterior segment or the anterior chamber, the RESIGHT fundus viewing system initially remains moved out of the beam path. If you are working on the posterior segment or on the fundus, slide the RESIGHT fundus viewing system (1) into the beam path and fold down the lens holder mechanism (2). For more information on the exact working method, please see the following pages.

Fig. 12: Working position

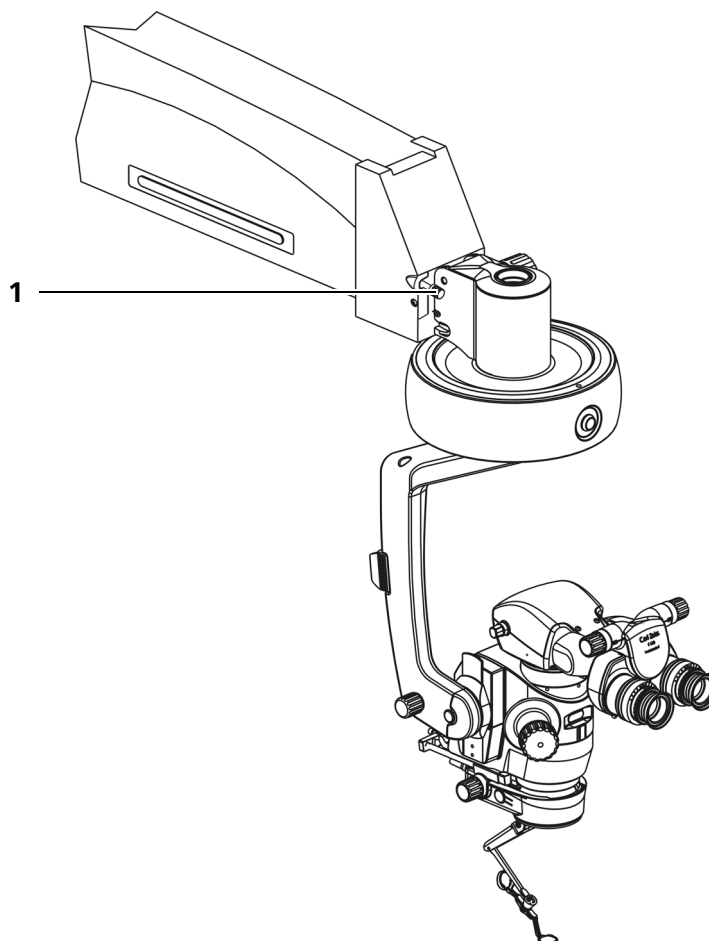


Limiting the carrier system's downward movement

S8, S88 and S81 suspension systems, OPMI LUMERA 700

- Loosen the orange adjustment screw (1).
- Press one of the magnetic brake release buttons on the surgical microscope and lower it until it can be focused on the surgical field (depending on the focal length of the objective lens). At the same time, ensure that there is sufficient safety distance to the surgical field.
- Turn orange adjustment screw (1) clockwise as far as it will go.
- Check this setting before moving the aspheric lens into the beam path and before each surgical procedure.

Fig. 13: Example: OPMI Lumera T with RESIGHT

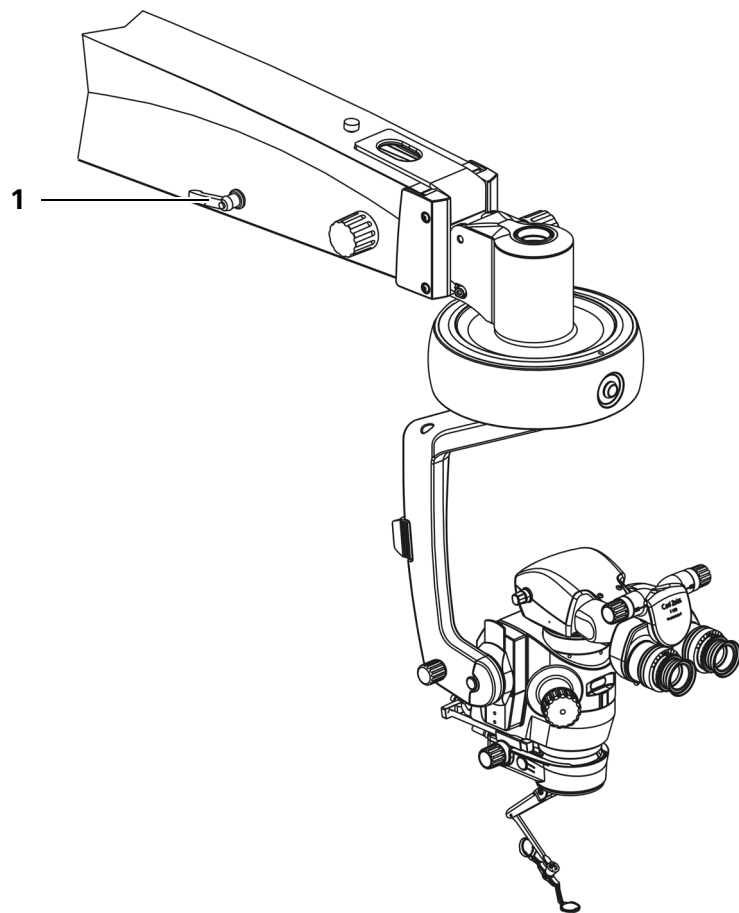


S7 suspension systems, OPMI Lumera i

Proceed as follows to limit downward movement:

- Loosen the locking lever (1) for upward/downward movement.
- Lower the surgical microscope until it can be focused on the surgical field (depending on the focal length of the objective lens). At the same time, ensure that there is sufficient safety distance to the surgical field.
- Firmly retighten locking lever (1) for upward/downward movement.

Fig. 14: Example: OPMI Lumera with RESIGHT



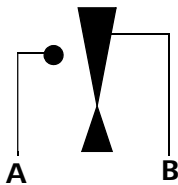
Setting up and operating RESIGHT



CAUTION

Injury to the patient's eye

Incorrect operation, or a jammed lens holder mechanism on the RESIGHT fundus viewing system may cause injury to the patient's eye and impair image quality. To avoid this hazard, always make the following system settings next to and not above the patient first:



- Adjust the illumination of the patient's eye through the surgical microscope to a level which ensures that the fundus is exposed to as little light as possible.
- With the RESIGHT fundus viewing system moved out of the beam path, always position the microscope body in such a way that index dot (A) (if present on the microscope) of the microscope's focal point is in the middle of the upper triangle (B) of the marking.
- Select a medium magnification (e.g. 1.0).
- With the RESIGHT fundus viewing system moved out of the beam path, lower the surgical microscope to a point where the RESIGHT fundus viewing system never touches the patient.
- Set the limitation of downward travel (see page 44) of the respective suspension system so that the suspension arm cannot be lowered beyond the required level.

To use the RESIGHT fundus viewing system, complete the following steps:

Step	Action	See page
1	Focus the surgical microscope	page 47
2	Fold down the lens holder mechanism	page 48
	Method 1	page 48
	Method 2	page 50
	Method 3	page 52
3	Slide RESIGHT into the beam path	page 54
4	Change the lenses	page 58
5	Slide RESIGHT out of the beam path	page 58

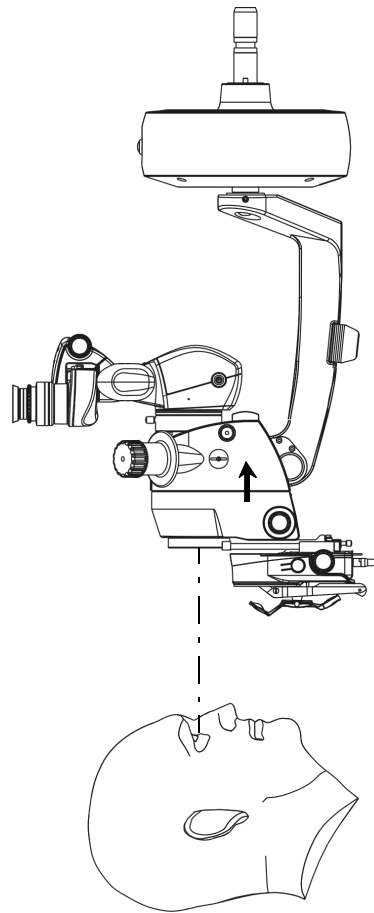
Step 1: focusing the surgical microscope

- Focus the surgical microscope on the patient's cornea using the foot control panel.
- To compensate for the depth of field range of the surgical microscope which totals several millimeters at a low magnification, move the surgical microscope upward to a level just before the image goes out of focus.



We recommend that you deactivate the depth of field (DoF) management system for focusing.

Fig. 15: Focusing using the external focusing module



Step 2: folding down the lens holder mechanism



If only little space is available above the patient's face (due to respiratory tubing, etc.), you can first move the RESIGHT fundus viewing system (1) into position with the lens holder mechanism folded up (step 3, page 54) and then fold down the lens holder mechanism as described below.

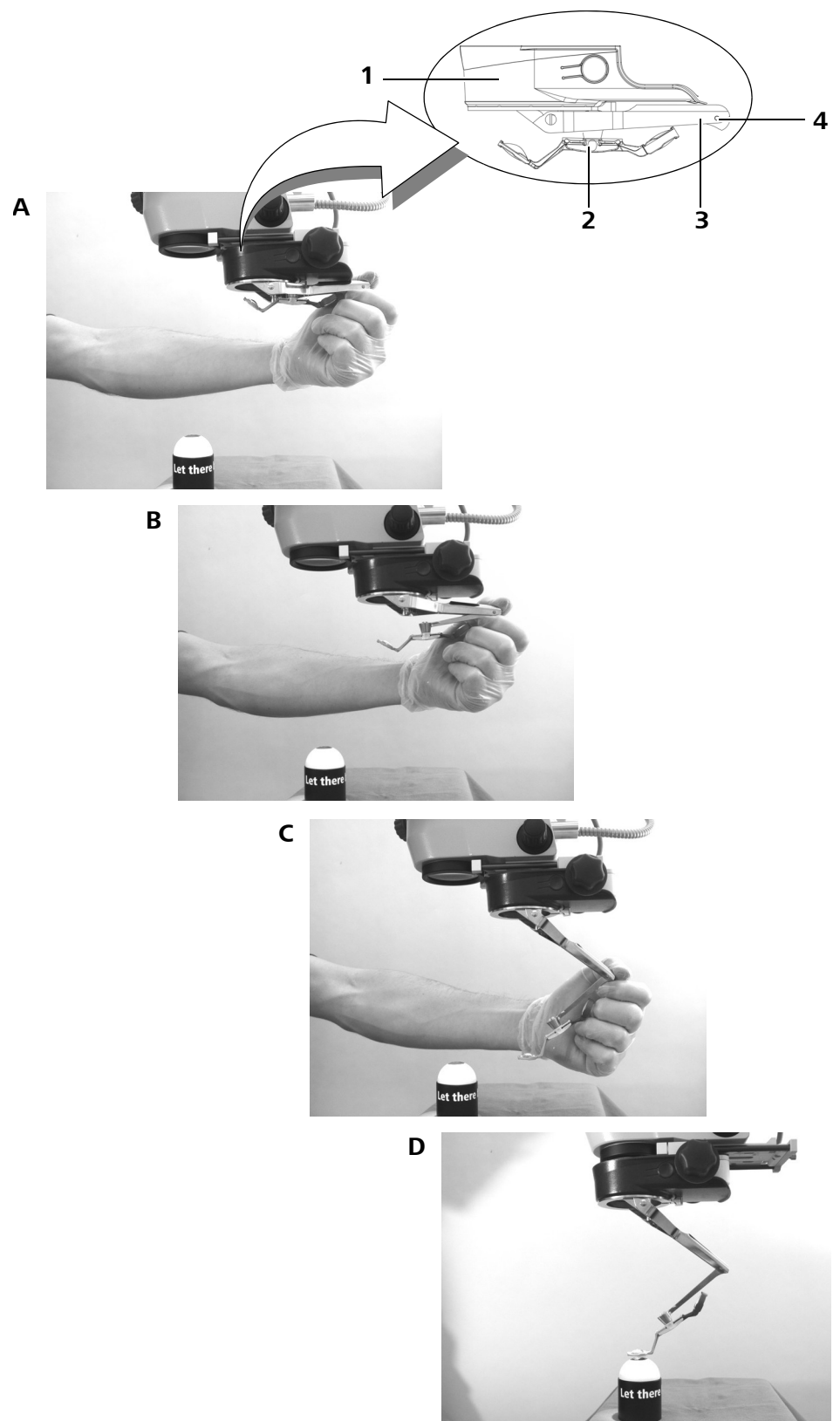
The lens holder mechanism (3) is magnetically held in position on the lens holder. You first have to overcome the magnetic force when folding down the lens holder mechanism (3).

There are three methods of folding down the lens holder mechanism (3):

Method 1:

- Hold the lens holder mechanism (3) at the hinge (4) with your thumb and forefinger (A). Place your forefinger under the lens holder mechanism to ensure that the lens holder mechanism cannot fall on the patient's eye.
- Slowly pull down the lens holder mechanism at the hinge until it has folded out completely (B to D). Make sure not to touch the non-sterile RESIGHT fundus viewing system (1) in this process.

*Fig. 16: Folding down the
lens holder mechanism,
method 1*



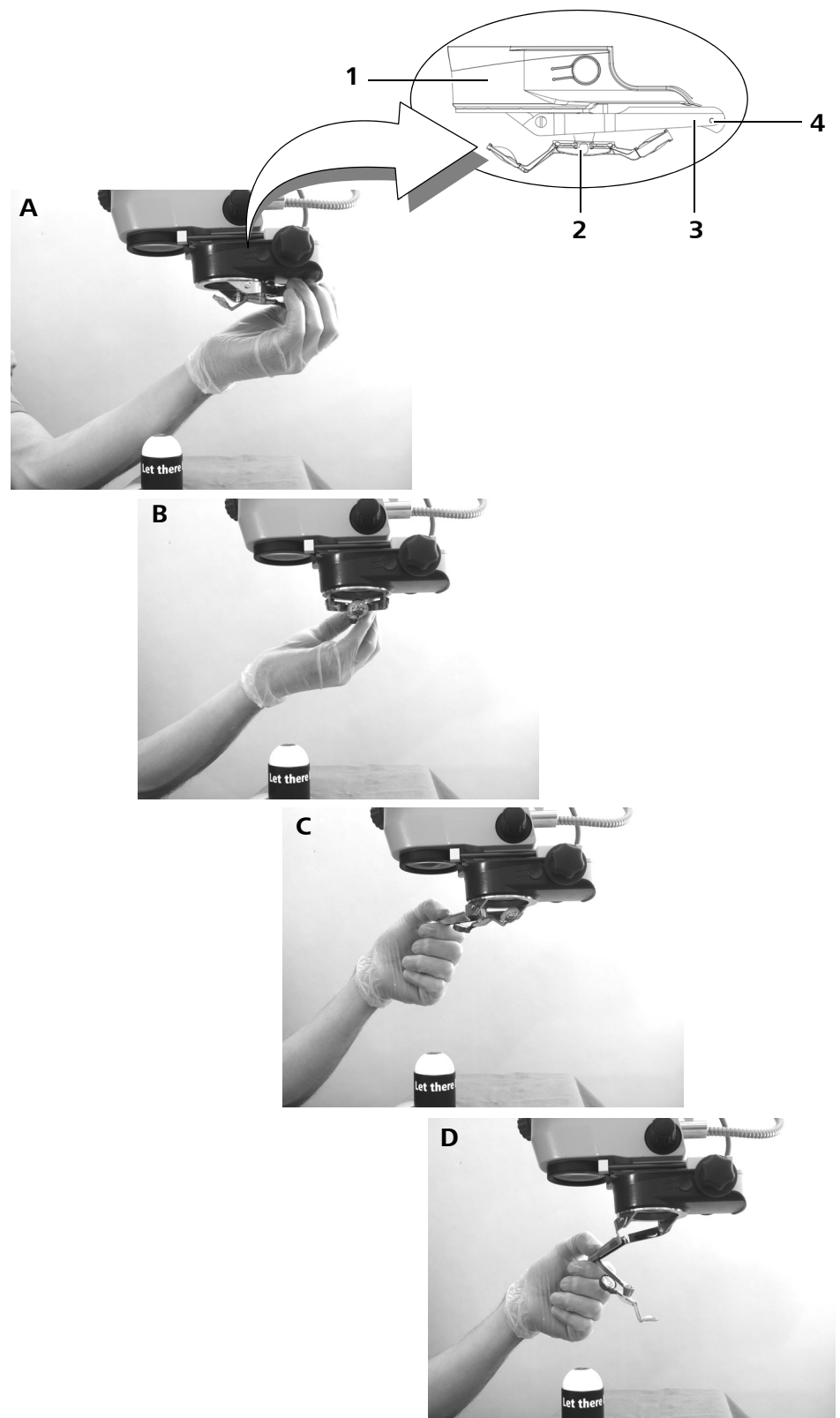
Method 2:



The lens holder mechanism can be rotated clockwise or counterclockwise through 360°. You can turn the lens holder mechanism towards you and then fold it down:

- Hold the lens holder mechanism (3) at the hinge (4) with your thumb and forefinger (A). Place your forefinger under the lens holder mechanism to ensure that the lens holder mechanism cannot fall on the patient's eye.
- Turn the lens holder mechanism towards you (B and C).
- Slowly pull down the lens holder mechanism at the hinge until it has folded out completely (B to D).

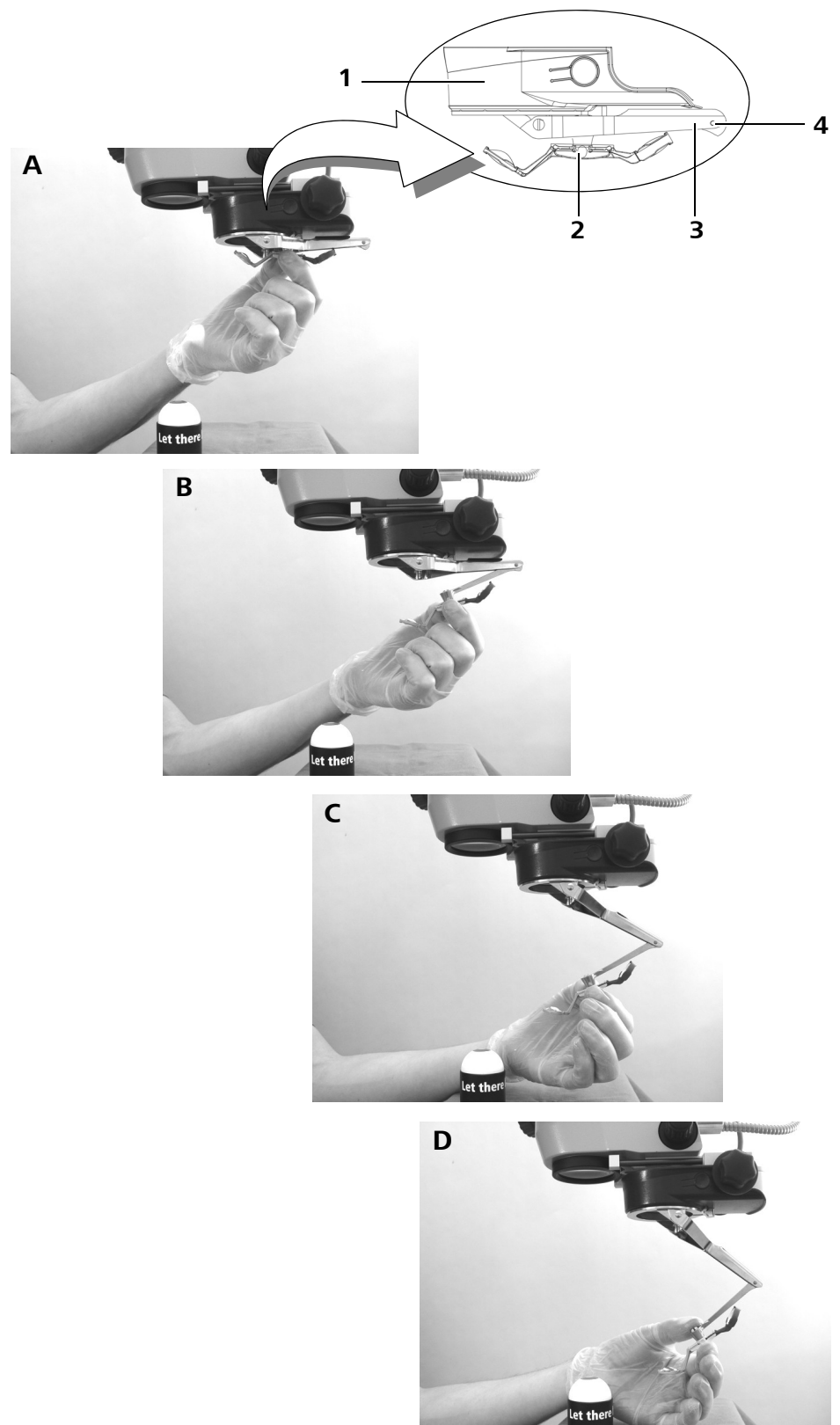
Fig. 17: Folding down the lens holder mechanism, method 2



Method 3:

- Hold the joint (2) with your thumb and forefinger (A).
- Apply counterpressure to the joint with the back of your thumb to detach the lens holder mechanism from the magnetic lock (A and B).
- Slowly pull down the lens holder mechanism (3) until it has folded out completely (C and D).

Fig. 18: Folding down the lens holder mechanism method 3



Step 3: sliding RESIGHT into the beam path

- Move the RESIGHT fundus viewing system (1) over the patient's eye, while lifting the lens holder mechanism (2) to prevent the aspheric lens (3) from accidentally hitting the patient's eye.
- Slide in the RESIGHT fundus viewing system (1) as far as it will go; it must audibly snap into place. If you see a shadow in the image, the RESIGHT fundus viewing system is not properly in position.

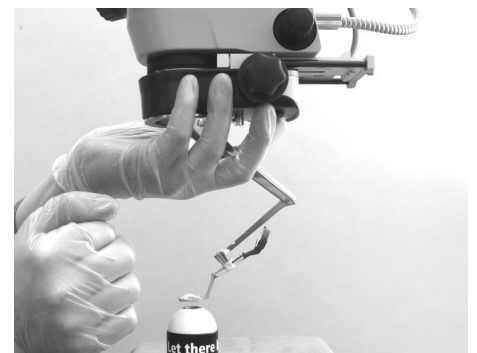
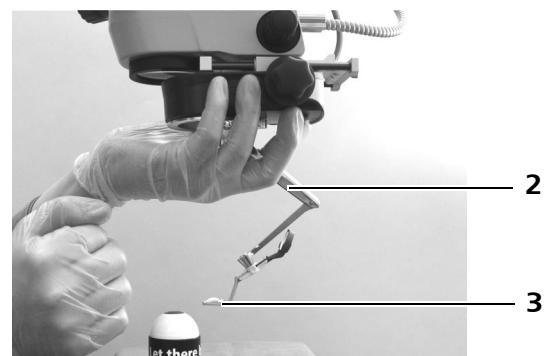
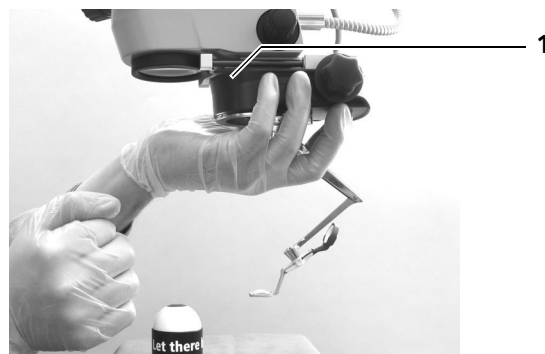


If only little space is available above the patient's face (due to respiratory tubing, etc.), you can first move the RESIGHT fundus viewing system (1) into position with the lens holder mechanism folded up and then fold down the lens holder mechanism (step 2, page 48).



If you use Invertertube E, it inverts the image automatically when you move the RESIGHT fundus viewing system (1) into the beam path.

Fig. 19: Sliding RESIGHT into position



- Turn off the illumination on the surgical microscope and turn on the endo illumination.
- Focus the RESIGHT fundus viewing system (1) on the retina. Use the focusing knobs (2) on the RESIGHT fundus viewing system for manual focusing, or the buttons on the foot control panel for motorized focusing. You can configure these buttons in such a way that they are used for the focusing function of the RESIGHT fundus viewing system when it has been moved into the beam path (see page 35).
- The surgical microscope no longer needs to be vertically moved for focusing. When working on the anterior segment, you can therefore move the RESIGHT fundus viewing system (1) out of the beam path without causing blurring of the image.

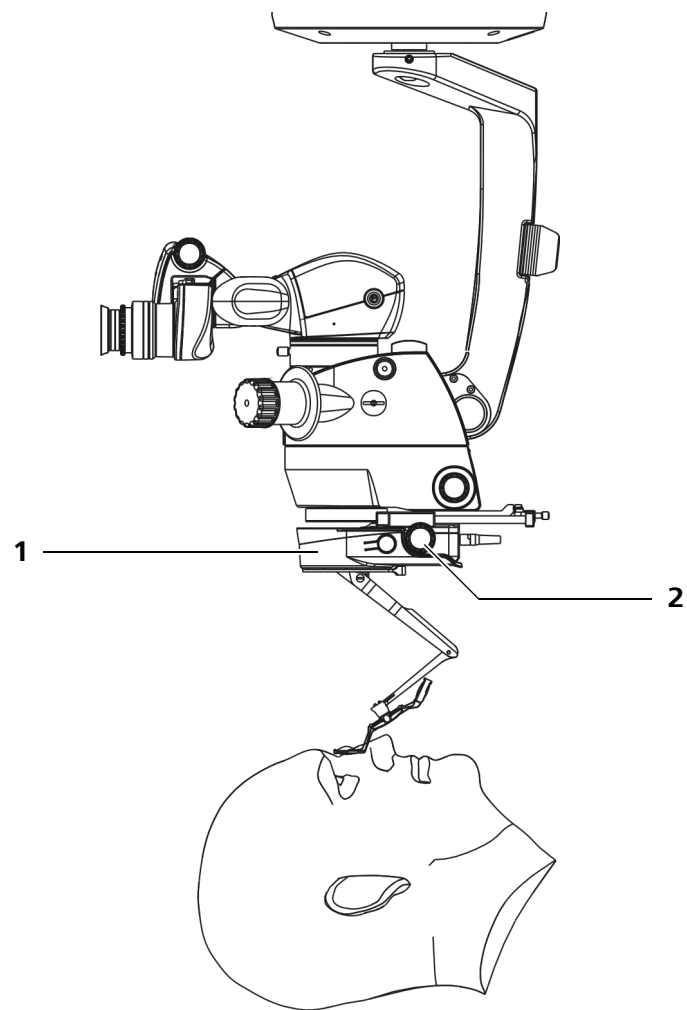
**CAUTION****Risk of injury!**

When you use the external focusing module for focusing, the distance of the RESIGHT fundus viewing system from the patient's eye is changed.

If the distance is too short, the lens holder mechanism may touch the patient's eye.

- When using the external focusing module, make sure that the lens holder mechanism does not come into contact with the patient's eye.
- To obtain a larger or smaller image section, use the buttons on the foot control panel for focusing the external focusing module. Please note that the assignment of the foot control panel buttons has been automatically reconfigured if the RESIGHT 700 fundus viewing system is used (see page 39).

Fig. 20: Focusing RESIGHT



Step 4: changing the aspheric lenses (optional)

- To change the aspheric lens, turn the lens joint (4) in 90° increments until the desired position has been reached.
- Refocus the RESIGHT fundus viewing system (1) using the focusing knobs (2) or the buttons on the foot control panel.

Step 5: sliding RESIGHT out of the beam path

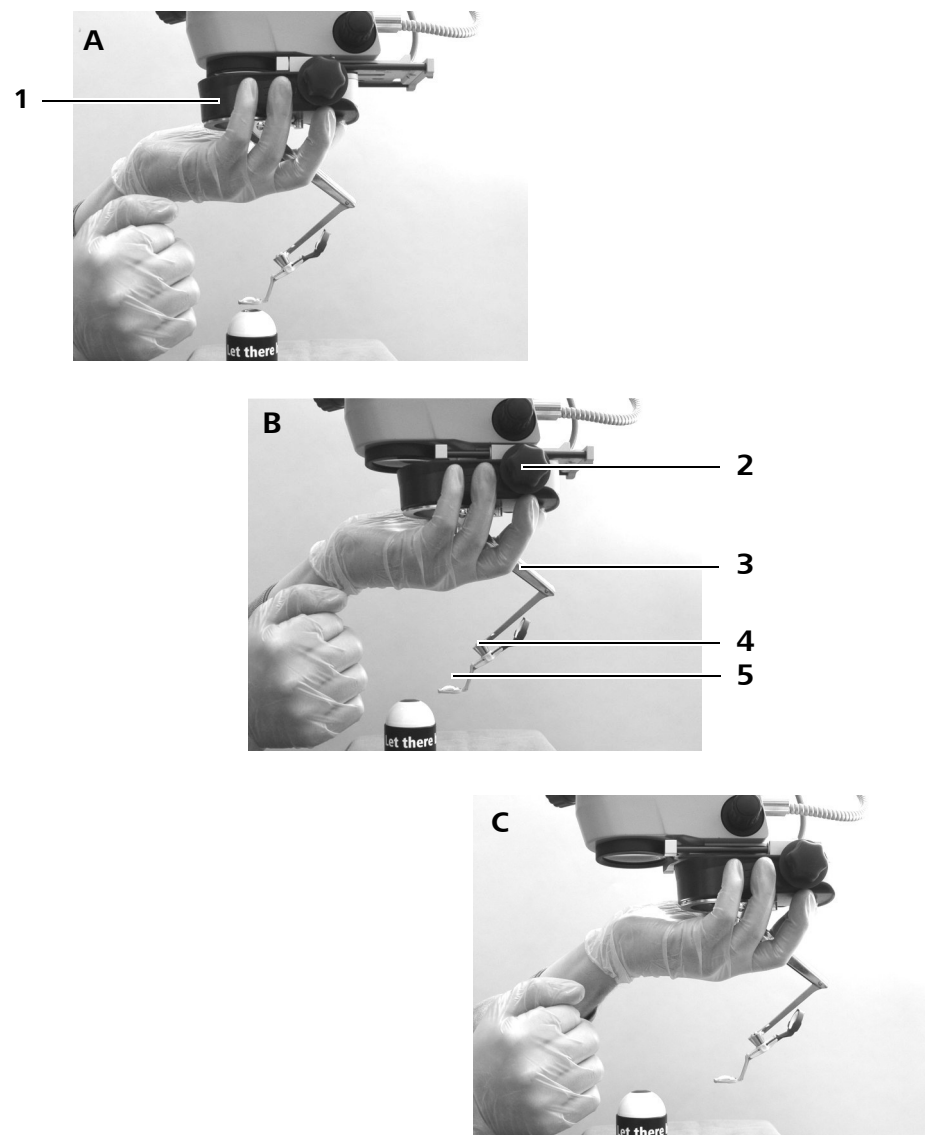
- After using the RESIGHT fundus viewing system (1), slide it out as far as it will go, until it you hear it snap into the standby position. If you see a shadow in the image, the RESIGHT fundus viewing system has not been moved out to the stop.



If you use Invertertube E, it automatically cancels the inversion when you move the RESIGHT fundus viewing system (1) out of the beam path.

- Lift the lens holder mechanism (3) in this process to prevent the aspheric lens (5) from accidentally hitting the patient's eye.

Fig. 21: Sliding RESIGHT out



What to do in the event of malfunctions



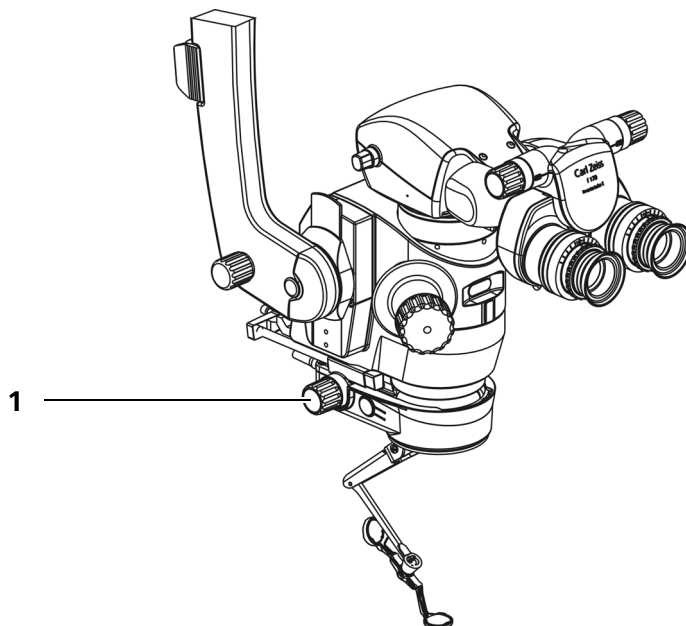
Failure of RESIGHT 700

NOTE**Failure or malfunction of RESIGHT 700**

You can operate the RESIGHT 700 fundus viewing system manually if the motorized focusing function fails or malfunctions:

- Disconnect the RESIGHT 700 fundus viewing system from the power supply by disconnecting the power cable from the surgical microscope.
- Turn the focusing knob (1) on the RESIGHT 700 fundus viewing system until you can see a sharp image through the eyepieces of the surgical microscope.

Fig. 22: Failure of the focusing function



Troubleshooting

For your safety

- If a failure occurs which you cannot correct with the aid of the chapter "What to do in the event of malfunctions", attach a sign to the system stating it is out of order and contact our service representative.

Malfunctions of the RESIGHT 700 fundus viewing system

Problem	Possible cause	Remedy	See
Motorized focusing system in-operative	Power cord of suspension system not plugged in	Plug in power cord	-
	Suspension system not turned on	Press power switch	-
	RESIGHT power supply cable not connected	Connect RESIGHT power supply cable	page 26
	Foot control panel not plugged in	Plug in connectors	-
	Line power failure	Contact in-house electrician	-
Poor image	Objective lenses of the focusing unit's internal focus are contaminated	Clean objective lenses	Note OPMI instructions for use
	Interpupillary distance not correctly set on the tube	Set interpupillary distance on the tube	-

Problem	Possible cause	Remedy	See
Temporary failure of wireless foot control panel (FCP WL)	Weak radio signal	Connect the cable, if available	Note the instructions for use for FCP WL
	Disrupted radio signal	Connect the cable, if available	Note the instructions for use for FCP WL
	Batteries are empty	Replace batteries	Note the instructions for use for FCP WL
	No pairing with suspension system	Perform pairing with suspension system	Note the instructions for use for FCP WL

Care and Maintenance



Retrofitting the accessory port

The electrical communication between the RESIGHT 700 fundus viewing system and the surgical microscope occurs via the "accessory port upgrade kit" that is integrated in the suspension system.



CAUTION

Damage caused by incorrect retrofitting!

If a retrofit is performed, the accessory port upgrade kit is installed by a service technician; new systems come with a factory-installed port.

- Do not retrofit the accessory port for the RESIGHT 700 fundus viewing system by yourself; contact the Carl Zeiss service department.

Care of the device

The following cleaning, disinfecting and sterilization work must be completed to ensure that the RESIGHT 500 and RESIGHT 700 always work properly. Please comply with the applicable regulations of your hospital.

- Preparation of non-sterilizable components
- Preparation of resterilizable components (see page 68)

Preparation of non-sterilizable components

Cleaning optical surfaces

Image quality is impaired by even slight contamination of the optics or by a fingerprint. Store the RESIGHT 500 or RESIGHT 700 in a dust-free container when it is not in use.

Clean the exterior surfaces of the optical components (objective lenses) only when necessary:

- Do not use any chemical cleaning agents.
- Remove dust from the optical surfaces using a squeeze blower or a clean, grease-free brush.

Prevention of fogging

To keep the objective lenses from fogging, we recommend using an anti-fogging agent. Anti-fogging agents provided by eyecare professionals for use with eyeglass lenses are also suitable for Zeiss objective lenses.



- Please observe the instructions for use supplied with each anti-fogging agent.

Anti-fogging agents not only ensure fog-free eyepiece optics, they also clean the eyepiece optics and protect them from dirt, grease, dust, lint and fingerprints.

Cleaning mechanical surfaces

All mechanical surfaces of the system can be cleaned by wiping them with a damp cloth. Do not use any aggressive or abrasive cleaning agents.

Clean off any residue using a mixture of 50 % ethyl alcohol and 50 % distilled water plus a dash of household dish-washing liquid.

It may be necessary to disinfect the surfaces.



CAUTION

Damage to the surfaces on the device!

- Use a disinfectant based on aldehyde and/or alcohol. The addition of quaternary compounds is acceptable. To prevent damaging surfaces, disinfecting components other than those listed below must not be used.

The maximum concentrations are:

- For alcohol (tested with 2 propanol): 60%
- For aldehyde (tested with glutaraldehyde): 2%
- For quaternary compounds (tested with DDAC): 0.2%

Preparation of resterilizable components

Basic information

The following re-sterilizable components need to be cleaned, disinfected, and sterilized after each use:

- Lens holder (302721-9060-000, 302721-9070-000)
- Aspheric lenses (302721-9100-000, 302721-9080-000)
- Caps of focusing buttons (305810-9001-000)

Lens holder, aspheric lenses, and caps need to be cleaned, disinfected, and sterilized before each use; this applies especially to the first use after delivery, since all components are shipped in non-sterile condition (cleaning and disinfection after removal of transport protection packaging; sterilization after packing).

Effective cleaning and disinfection are indispensable for the efficacy of sterilization. Preferably, a washer/disinfector should be used for cleaning and disinfection. A manual procedure should be used only if no rinsing apparatus/disinfector is available, because the efficacy and reproducibility are clearly lower. For cleaning, disinfection, and sterilization, we recommend to use the validated procedures of ZEISS listed in the present Instructions for Use.

- Please note that the following sterilization procedures are not permissible:
 - immediate use sterilization,
 - dry heat sterilization,
 - radiosterilization,
 - formaldehyde or ethylene oxide sterilization,
 - plasma sterilization.
- In the scope of your responsibility for sterility of the lens holders, aspheric lenses, and caps for application purposes, please make sure
 - that the equipment used (washer/disinfector, sterilizer) is serviced and checked regularly.
 - to comply with the validated parameters during each cycle.

- For use with the RESIGHT tray only:
Always clean and disinfect the contaminated lens holder, aspheric lenses, and caps outside of the RESIGHT tray in order not to contaminate the RESIGHT tray. Return cleaned and disinfected parts to the RESIGHT tray and then sterilize the fully loaded RESIGHT tray.



Machine cleaning and disinfecting of the lens holder, aspheric lenses and caps in the RESIGHT metal tray is also possible.

- Also observe the legal provisions applicable in your country and the hygiene regulations of the doctor's office or hospital. This applies in particular to the different regulations concerning effective prion inactivation.

EU: Classification as semi-critical B according to the RKI (Robert Koch Institut) guideline is recommended; the final classification is to be made by the user based on the actual application field.

Pre-cleaning

Directly after use, remove any gross contamination from the lens holder, aspheric lenses and caps (within 2 hours at most). Use a damp lint-free cloth, soft brush, wipe or a ph-neutral enzymatic cleaner to loosen contamination and prevent excessive drying. This step is typically done in the OR.



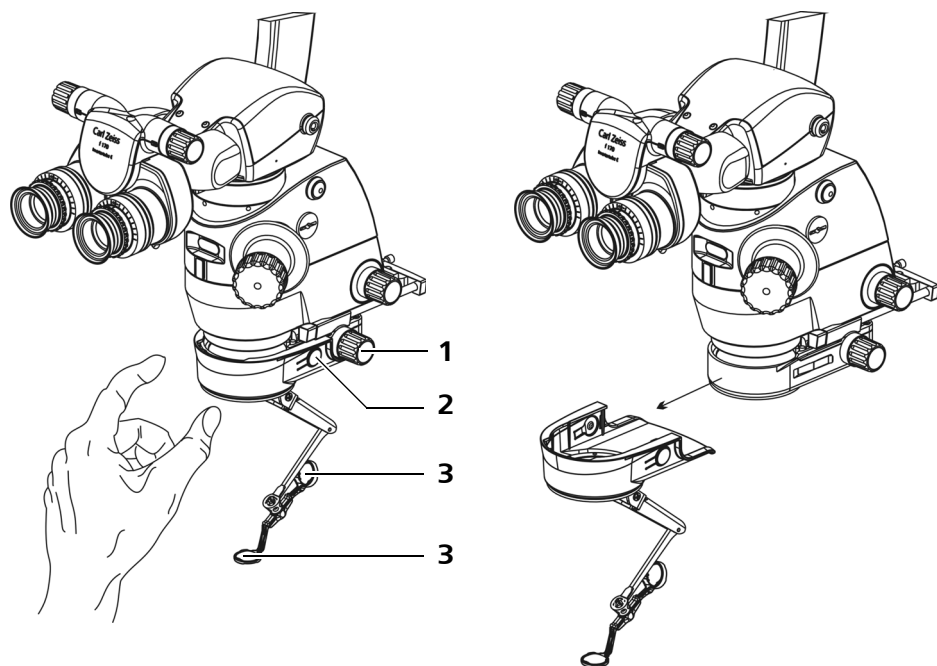
The lens holder, aspheric lenses and caps can be damaged during pre-treatment if not handled properly.

- The optical surfaces of lenses may not come into contact to other lens surfaces or metal.
- Ensure that you do not scratch the lens holder, aspheric lenses and caps during the reprocessing procedure.
- Do not clean the lens holder, the aspheric lenses and the caps with a hard brush or abrasive agents. Only use a lint free cloth.

Removing components from the device

- Remove the lens holder from the RESIGHT 500 or RESIGHT 700 fundus viewing system by pressing the unlocking button of the lens holder (2) together and pulling the lens holder to the front.
- Pull the aspheric lenses (3) out of the lens revolver.
- Pull off the caps (1) from the two focusing buttons of the fundus viewing system.

Fig. 23: Removing the lens holder



Materials for pre-cleaning

The following cleaning agents (not included in the scope of delivery) are required for pre-cleaning:

- Water of at least drinking water quality
- Cleaning solution which
 - does not contain any aldehyde (this would fix blood contaminants),
 - is verified effective (e.g., DGHM, FDA cleared or CE marked),
 - is suitable for cleaning the lens holder, the aspheric lenses and the caps and is compatible with the components (see "Material compatibility")
- Soft brush or clean lint-free cloth

Pre-cleaning the lens holder, aspheric lenses and caps

NOTE

Do not use metal brushes, steel wool, rigid brushes or aggressive substances when cleaning the lens holder, the aspheric lenses and the caps in order to prevent damage to the surfaces.



Please note that the disinfectant used during pretreatment serves only for decontamination purposes to protect persons against blood-borne pathogens. It is no substitute for the subsequent disinfection.

Clean the lens holder, the aspheric lenses and the caps as follows:

- Place the components into a pH-neutral enzymatic cleaning agent with surfactants (consisting of no more than 5% surfactants).
- Soak for the time specified for effectiveness of the cleaning agent, but at least for 20 minutes
- Rotate the lens revolver and move the hinges back and forth about 10 times to wet all hinged surfaces and joints.
- Rinse the components under running warm water (at least drinking water quality) for at least one minute.

Machine cleaning and disinfection

Materials for machine cleaning and disinfection

The following cleaning and disinfection means are required for the cleaning/disinfecting device and for disinfection:

- Cleaning system:
When selecting the cleaning system, ensure
 - that it is suitable for cleaning the RESIGHT tray or RESIGHT metal tray (if used), the lens holder, the aspheric lenses and the caps which are made of metal and plastic materials,
 - that it has either a neutral pH or alkaline pH,
 - that a suitable disinfectant with certified effectiveness (e.g. DGHM or FDA cleared or CE marked), if no thermal disinfection is applied, and that the disinfectant is compatible with the cleaning agent used.,
 - that the used chemicals are compatible with the RESIGHT tray (if used), the lens holder, the aspheric lenses and the caps (see "Material compatibility").
- Washer/disinfector:
When selecting the washer/disinfector, ensure
 - that the disinfector has a certified effectiveness (e.g., DGHM or FDA clearance or CE marking pursuant to EN ISO 15883:2009),
 - that a validated program is used for thermal disinfection if possible (e.g., DGHM or FDA cleared or CE marking pursuant to EN ISO 15883:2009),



Cleaning with a washer/disinfector must comply with the validated parameters described in the following chapter. EU customers: An automatic washer/disinfector of type Miele G 78823 was used for validation.

- that the used program is suitable for the RESIGHT tray or RESIGHT metal tray (if used), the lens holder, the aspheric lenses and the caps and that it provides the appropriate rinse cycles,
- that you only use freshly prepared solutions, water quality suitable for the process being done, and clean (filtered) compressed air for drying,
- that the washer/disinfector is serviced and checked at regular intervals.

It is absolutely necessary that the concentrations specified by the manufacturer of the cleaning agent and, if necessary, disinfectant are kept.

EU customers: If possible, a validated program should be used for thermal disinfection (A_0 value > 3000 or, if older devices are used, at least 10 min at 93 °C / 199 °F). Otherwise, chemical disinfection would pose the risk of residual disinfectant on RESIGHT tray or RESIGHT metal tray, lens holder, aspheric lenses and caps.

Machine cleaning and disinfection of lens holder, aspheric lenses and caps



CAUTION

Contamination hazard!

Cleaning the lens holder, the aspheric lenses and the caps in the RESIGHT tray is prohibited.

- Always clean and disinfect the contaminated lens holder, aspheric lenses and caps outside of the RESIGHT tray to prevent contaminating the RESIGHT tray.



Machine cleaning and disinfecting of the lens holder, aspheric lenses and caps in the RESIGHT metal tray is also possible.

- Put the RESIGHT tray, the lens holder, the aspheric lenses and the caps separately into the washer/disinfector.
- Rinse the components with water (at least drinking water quality).
- Clean the components with a neutral or alkaline cleaning agent.
- When using an alkaline cleaning agent, neutralize the components with water having at least drinking water quality and a neutralizer.
- Rinse the components with water (at least drinking water quality). Using demineralized and deionized water for the last rinse cycle prior to thermal disinfection may prolong the service life of the components because it removes tap water residues which might react with the components under the influence of heat.
- Perform thermal disinfection at 93 °C (+5 °C, -0 °C) 200 °F (+9 °F, -0 °F) for ten minutes, using demineralized and deionized water or water with a higher quality (e.g., RO).
- Allow the components to air dry at least 10 minutes or until completely dry or dry them using clean compressed air.
- Verify that the components are completely dry after completion of the cleaning and disinfection cycle.
- Verify that any residual cleaning agents and disinfectants have been removed from the components after completion of the cleaning/disinfection cycle (if necessary, use an appropriate residue indicator test or a suitable indicator paper which is recommended by the manufacturer of the cleaning agent/disinfectant).

EU customers: The agents used for validation are the cleaning agent Sekumantic Multiclean (0,7% V/V) and the neutralizer Sekumantic FNP (0.1 % V/V).

Manual cleaning and disinfection



If possible, a washer/disinfector should be used for cleaning and disinfecting. Due to the reduced effectiveness and reproducibility, a manual method should only be used if a cleaning and disinfecting device is not available.

Materials for manual cleaning and disinfection

The following cleaning and disinfecting materials are required for manual cleaning and disinfecting. When selecting the cleaning and disinfecting agents, make sure that:

- they are suitable for cleaning and/or disinfecting the RESIGHT tray or RESIGHT metal tray (if used), the lens holder, the aspheric lenses and the caps,
- you use a disinfectant with certified effectiveness (e.g., DGHM or FDA clearance or CE marking) and that this disinfectant is compatible with the used cleaning agent,
- the used chemicals are compatible with the RESIGHT tray or RESIGHT metal tray (if used), the lens holder, the aspheric lenses and the caps (see "Material compatibility").



If possible, combined cleaning agents and disinfectants should not be used. Combined cleaning agents/disinfectants are only allowed in cases of very low contamination (no visible contaminants).

It is absolutely necessary that the concentrations and exposure times specified by the manufacturer of the cleaning agent and, if necessary, the disinfectant are followed. Only use freshly prepared solutions, water quality suitable for the process being done, and clean (filtered) compressed air for drying.

Manually cleaning the lens holder, aspheric lenses and caps



Do not use metal brushes, steel wool, etc. when cleaning the lens holder, aspheric lenses and caps in order to prevent damage to the surfaces.

- Immerse the components in an enzymatic pre-soak/cleaning solution containing a surfactant or wetting agent (maximum 5% surfactant) for 20 minutes at room temperature.
- Use a medium-hard toothbrush to clean the entire surface under running water of at least drinking water quality for at least one minute until no visible residue remains.
- Brush and rinse the components under cold demineralized and deionized water or higher quality water (e.g., RO) for at least one additional minute.

EU customers: A 1% MediZym solution (V/V) was used for validation.

Manually disinfecting the lens holder, aspheric lenses and caps



Do not dry the lens holder, aspheric lenses and caps in an oven, a microwave, a drying oven, etc. in order to prevent damage to the materials.

- Immerse the components in a solution of disinfectant containing enzymes and a surfactant concentration of no more than 5% for 30 minutes at room temperature.
- Then completely immerse the lens holder, aspheric lenses and caps into cold demineralized and deionized water or into water of a higher quality (e.g., RO) for one minute.
- Subsequently, wipe the surface of the components with a dry lint-free cloth.
- Verify that any residual cleaning agents and disinfectants have been removed from the components after completion of the cleaning / disinfection cycle. If necessary, use an appropriate residue indicator strip or a suitable indicator paper which is recommended according to the operating instructions issued by the manufacturer of the cleaning agent/disinfectant.
- Let the components air dry or dry the components with clean (filtered) compressed air.
- Make sure that the components are completely dry after completion of the cleaning and disinfection cycle.

EU customers: A 2.5% Sekusept Plus solution (V/V) was used for validation.

Control

Cleaning, disinfection and sterilization of the lens holder, aspheric lenses, caps, RESIGHT tray and RESIGHT metal tray have been done as part of the validation as follows:

- Lens holder: 200 times
- Aspheric lenses: 200 times
- Caps: 250 times
- RESIGHT tray: 500 times
- RESIGHT metal tray: 500 times
- After completion of the cleaning or cleaning/disinfection cycle, check the lens holder, aspheric lenses, caps and RESIGHT tray or RESIGHT metal tray for corrosion, damaged surfaces, chippings and contaminants (in particular inside).
- Remove any damaged components and dispose them in compliance with applicable local, state and federal regulations/requirements
- Components that are still contaminated must be cleaned and disinfected again.

Maintenance

Lubricating the lens holder



To enable an easy use and a smooth rotation the hinges of the lens holder shall be lubricated regularly. Validated for this purpose is Aesculap STERILITi® oil spray. Apply the oil sparingly. Do not use oil from the dropper bottle.

- Dry the completely cleaned and disinfected lens holder.
- Spray some STERILITi® oil spray onto the hinges of the lens holder.
- Move the oiled hinges several times.
- Remove any excess oil using a lint-free cloth.

Fig. 24: Lubricating the lens holder



Packing for sterilization

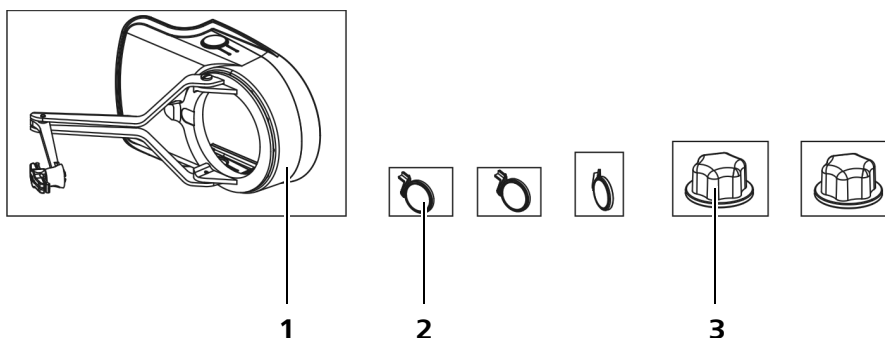
For sterilization, the components need to be packaged in a suitable container for steam sterilization or a packaging material with a sterile barrier that is suitable for steam sterilization (permeable for air exit and steam ingress). This protects the lens holder, aspheric lenses, and caps during the sterilization and allows steam to enter and air to exit. Inclusion of air can render the sterilization ineffective.

There are two options for packing the cleaned and disinfected lens holder, aspheric lenses, and caps for sterilization.

Option 1 - Package components separately

- Package the lens holder (1), aspheric lenses (2), and caps (3) separately in packaging that is suitable for steam sterilization and seal the packaging as appropriate.

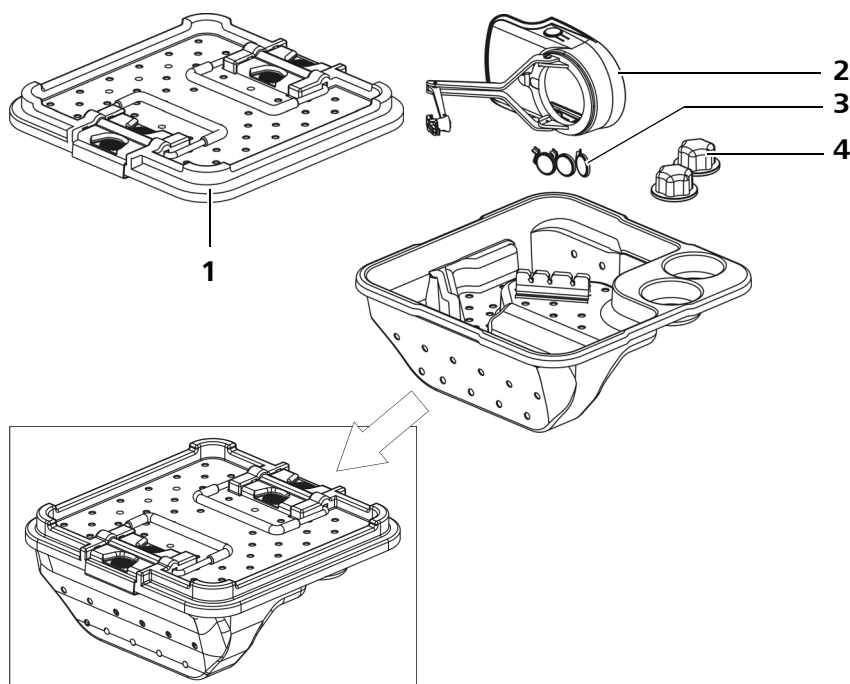
Fig. 25: Packaging for sterilization



Option 2: Package the RESIGHT tray in container with sterile barrier

- Place the lens holder (2), aspheric lenses (3), and caps (4) in the designated troughs of the RESIGHT tray.
- Press the aspheric lenses (3) into the designated silicone holders by rotating them.
- Close the lid (1) of the RESIGHT tray.
- Before sterilization, package the RESIGHT tray containing the components in a suitable container or packaging with a sterile barrier. Sterilization container and filter must comply with ANSI AAMI ISO 11607-1:2006.

Fig. 26: Packing the RESIGHT tray in a packaging for sterilization



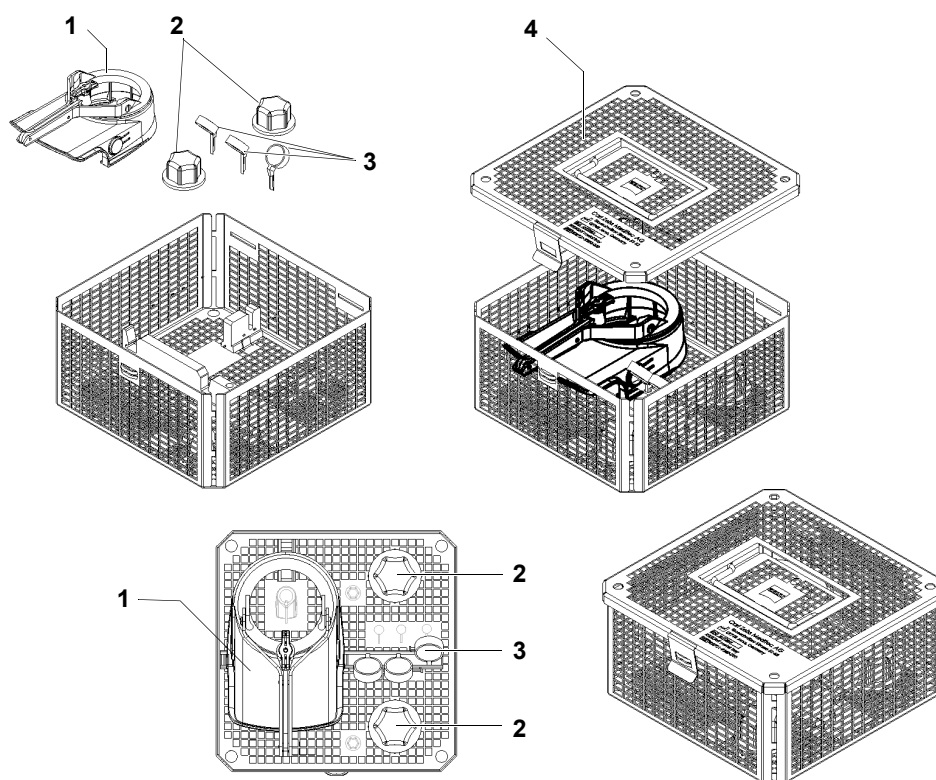
1.2. RESIGHT metalinis sterilizavimo padėklas

Version 3: Pack the RESIGHT metal tray in a container with a sterile barrier

- Place the lens holder (1), the aspheric lenses (2) and the caps (3) into the marked inlets of the RESIGHT metal tray.
- Press the aspheric lenses (3) into the designated silicone holders by rotating them.
- Close the lid (4) of the RESIGHT metal trays.

Before sterilizing, pack the RESIGHT metal tray with the components into a suitable container with a sterile barrier (e.g. a sealed bag). The sterilization container and the filter must comply with ANSI AAMI ISO 11607-1:2006.

Fig. 27: Pack the RESIGHT metal tray into a package for the sterilization



Sterilization

In the scope of your responsibility for sterility of the RESIGHT tray, RESIGHT metal tray, lens holder, aspheric lenses, and caps for application purposes, please make sure

- that the sterilizer used is serviced and checked regularly,
- to comply with the validated parameters during each cycle.

For sterilization, we recommend using the methods validated by Zeiss described below.

Steam sterilization of single components

- Fractionated vacuum (pre-vacuum) method or gravity displacement method (with sufficient drying time of the product)
- Steam sterilizer in accordance with EN 13060:2010, EN 285:2009 or ANSI/AAMI ISO ST79:2006
- The steam sterilizer should be validated in accordance with EN ISO 17665:2006, or ANSI/AAMI ISO 17665:2006.
- Sterilization temperature 132 °C - 138 °C (270 °F - 280 °F; add tolerance in accordance with EN ISO 17665:2006, ANSI/AAMI ISO 17665:2006)
- Fractionated vacuum method:
Pre-vacuum steam sterilization cycle with an exposure time of 4 min at 132°C +/-1°C (131-133°C; 268-271°F) with sufficient product drying time
or
Pre-vacuum steam sterilization cycle with an exposure time of 3 min at 134°C +/- 1°C (133-135°C; 271-275°F) with sufficient product drying time
- Gravity displacement method:
Sterilization cycle with an exposure time of 10 min at 132°C (270°F) up to a max. 138°C (280°F)



It is generally possible to prolong the time of sterilization, but this may have a negative effect on the service life of the RESIGHT tray, RESIGHT metal tray, lens holder, aspheric lenses, and caps.

Steam sterilization using the RESIGHT tray or RESIGHT metal tray

- Fractionated vacuum (pre-vacuum) method or gravity displacement method (with sufficient drying time of the product)
- Steam sterilizer in accordance with EN 13060:2010, EN 285:2009 or ANSI/AAMI ISO ST79:2006

- The steam sterilizer should be validated in accordance with EN ISO 17665:2006, ANSI/AAMI ISO 17665:2006.
- Sterilization temperature 132 °C - 138 °C (270 °F - 280 °F; add tolerance in accordance with EN ISO 17665:2006, ANSI/AAMI ISO 17665:2006)
- Fractionated vacuum method:
Pre-vacuum steam sterilization cycle with an exposure time of 4 min at 132°C +/-1°C (131-133°C; 268-271°F) with sufficient product drying time
or
Pre-vacuum steam sterilization cycle with an exposure time of 3 min at 134°C +/- 1°C (133-135°C; 271-275°F) with sufficient product drying time
- Gravity displacement method:
Sterilization cycle with an exposure time of 10 min at 132°C (270°F) up to a max. 138°C (280°F)



It is generally possible to prolong the time of sterilization, but this may have a negative effect on the service life of the RESIGHT tray, RESIGHT metal tray, lens holder, aspheric lenses, and caps.

Lęšių laikiklio, asferinių lęšių, gaubtelių, RESIGHT padėklo ir RESIGHT metalinio padėklo sterilizavimas

1.2.

Sterilizing lens holder, aspheric lenses, caps, RESIGHT tray and RESIGHT metal tray

- Sterilize these products according to any of the steam sterilization procedures listed above (ANSI/AAMI ISO 17665:2006).
- Do not expose the RESIGHT tray or RESIGHT metal tray to temperatures above 141 °C (286 °F)!
- Allow the RESIGHT tray, RESIGHT metal tray, lens holder, aspheric lenses, and caps to cool down to ambient temperature after sterilization, before you re-use or dispose of them.



The caps for the focusing buttons delivered by ZEISS can also be sterilized in accordance with the Instructions for Use, "Reprocessing of sterilizable products" (G-30-1560, G-30-1690, G-30-1691). The corresponding Instructions for Use are enclosed with the caps.

Storage

**CAUTION****Patient contamination!**

The lens holder, the aspheric lenses, the caps, RESIGHT tray and the RESIGHT metal tray may become recontaminated if they are stored too long. If the sterile barrier is compromised, bacteria can recontaminate the sterile components.

- After completion of the cleaning or cleaning/disinfection cycle, check the lens holder, aspheric lenses, caps, RESIGHT tray and RESIGHT metal tray for corrosion, damaged surfaces, chippings and contaminants (especially inside).
- It is suggested that the respective sterilization date be written on the container(s) or external sterile barrier and the maximum storage time be defined. Follow local regulatory or facility policy if it differs from this suggested approach.

**CAUTION****Patient contamination!**

If the lens holder, the aspheric lenses, the caps, RESIGHT tray and RESIGHT metal tray enter into the area of sterile goods without having been sterilized or if the user fails to recognize that the RESIGHT tray and RESIGHT metal tray has not been sterilized, there is the risk of contamination to the patient.

- It is therefore suggested that the respective sterilization date be written on the container(s) or external sterile barrier and the maximum storage time be defined. Follow local regulatory or facility policy if it differs from this suggested approach.
- After completed sterilization, store the lens holder, the aspheric lenses, the caps, RESIGHT tray and RESIGHT metal tray in a clean and dry place.
- Protect the lens holder, the aspheric lenses, the caps, RESIGHT tray and RESIGHT metal tray from direct sunlight.

Use inside the sterile area

**CAUTION**

Contamination of the lens holder, aspheric lenses, and caps!

- Only handle the RESIGHT tray or RESIGHT metal tray and its contents under sterile conditions and only in sterile area.
 - Have a non-sterile person present to give you access to the sterilized components.
 - Ensure that the RESIGHT tray or RESIGHT metal tray or the cover of the RESIGHT tray or RESIGHT metal tray is removed under sterile conditions
 - Take out the sterilized products and attach the components to the system. Make sure that the sterile parts are securely attached.
 - Put the RESIGHT tray aside.
 - Repeat the procedure (cleaning, disinfection and sterilization) after use of the sterile parts. Please read the corresponding chapter in these Instructions for Use regarding this.
-

Reusability

Lens holder, aspheric lenses, caps, RESIGHT tray and RESIGHT metal tray can be reused provided they are treated with the appropriate care and they are undamaged and clean.

**CAUTION**

Risk of infection!

The user is responsible for using damaged and/or contaminated components. Failure to comply with this requirement excludes any liability.

Material compatibility

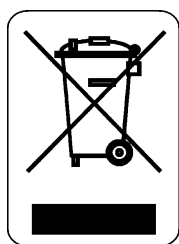
- When selecting the cleaning agents and disinfectants, please ensure that they do not contain any of the following ingredients:

- Organic, mineral and oxidizing acids (minimum permissible pH value: 5.5)
- Strong lyes (maximum permissible pH value: 11 at application temperature)
- Organic solvents (e.g., alcohols, ethers, ketones, benzene)
- Oxidants (e.g., hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons
- Do not use metal brushes or steel wool to clean the lens holder, the aspheric lenses, the caps, RESIGHT tray and the RESIGHT metal tray.
- The use of ultrasound is not permitted.
- Do not expose the lens holder, the aspheric lenses, the caps, RESIGHT tray and the RESIGHT metal tray to temperatures above 141 °C (286 °F).

Environmental protection measures

Disposal notes for RESIGHT 700

User information on the disposal of electrical and electronic devices



This symbol means that the product must not be disposed of as normal domestic waste.

The correct disposal of electrical or electronic devices helps to protect the environment and to prevent potential hazards to the environment and/or human health which may occur as a result of improper handling of the devices concerned.

For detailed information on the disposal of the product, please contact your local dealer or the device manufacturer or its legal successor. Please also note the manufacturer's current information on the Internet. In the event of resale of the product or its components, the seller is required to inform the buyer that the product must be disposed of in accordance with the applicable national regulations currently in force.

For customers in the European Union

Please contact your dealer or supplier if you wish to dispose of electrical or electronic devices.

Information on disposal in countries outside the European Union

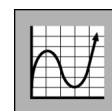
This symbol is only applicable in the European Union. For the disposal of electrical and electronic devices, please observe the relevant national legislation and other regulations applicable in your country.

User information for the disposal of resterilizable components



- All resterilizable components must be completely cleaned, disinfected and sterilized before disposal.
- For disposal, also observe the legal provisions applicable in your country and the hygiene regulations of the doctor's office or hospital.

System Data



Technical data

Electrical data of RESIGHT 700

Component	Feature
Maximum power consumption	15 W
Rated voltage	+ 15 V (13.5 - 16.5 V)
Current consumption	max. 1 A
Electrical outlets	Remote control socket for an external signal of max. 24 V / 0.5 A.

The device has been designed for continuous operation.

Mechanical data of RESIGHT 500 and RESIGHT 700

Component	Feature
Focusing range with lens holder LH175	31 mm (position of the intermediate image)
Focusing range with lens holder LH200	38 mm (position of the intermediate image)
Lens joint rotation angle	0° - 360° (in 90° increments)
Lens holder rotation angle	0° - 360° (in 30° increments)
Weight	RESIGHT 500: 0.45 kg RESIGHT 700: 0.50 kg
Adapter plate	with VISULUX adapter: 0.081 kg without VISULUX adapter: 0.033 kg
Dimensions (L x W x H)	138 x 128 x 198 mm (out of beam path) 200 x 128 x 198 mm (in beam path)

Fig. 28: Dimensional drawing, front

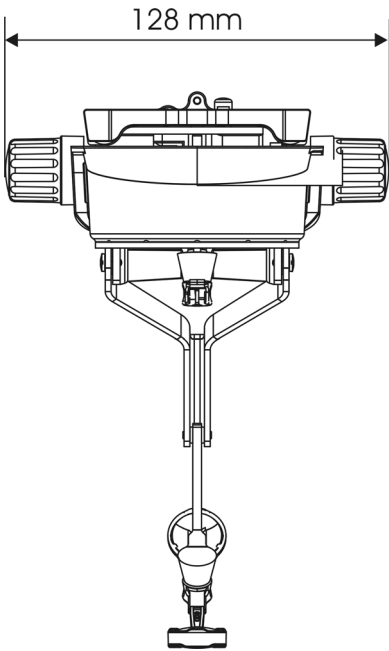
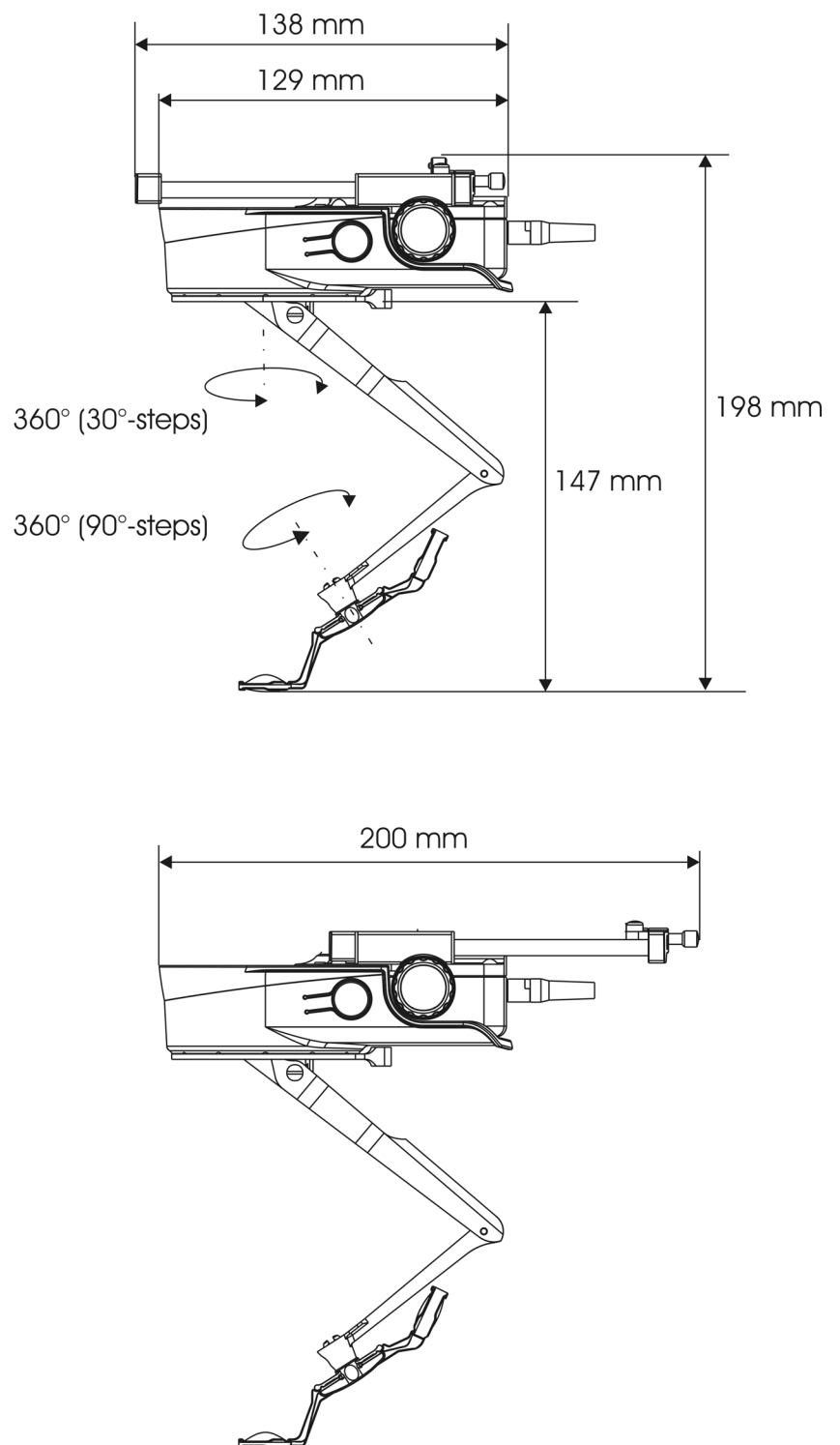


Fig. 29: Dimensional drawing,
right



EMC - electromagnetic compatibility of RESIGHT 700

The device complies with the EMC requirements of IEC 60601-1-2:2008. While operating the device, observe the EMC precautions specified below.

- Only use spare parts approved by Carl Zeiss for this device.
- Do not use any portable or mobile RF communication equipment in the vicinity of the device as this may impair the device's function.
- Do not use a mobile phone in the vicinity of the equipment because the radio interference can cause the equipment to malfunction. The effects of radio interference on medical equipment depend on a number of various factors and are therefore entirely unforeseeable.
- Please note the EMC guidelines on the following pages.

Electromagnetic radiation disturbance

Table 1: Guidelines and manufacturer's declaration - electromagnetic emissions - for all ME equipment and ME systems

Guidelines and manufacturer's declaration - electromagnetic interference		
The device is intended for operation in an electromagnetic environment as specified below. The customer or the user of this device is responsible for ensuring that the device is operated in such an environment.		
Interference measurements	Compliance	Electromagnetic environment - guidelines
RF emissions as per CISPR 11	Group 2	To properly function, the device must emit electromagnetic energy. This can affect nearby electronic devices.
RF emissions as per CISPR 11	Class A	The device is intended for use in all facilities, including locations in residential environments and those directly connected to the public power supply network which also supplies residential buildings.
Harmonic emissions as per IEC 61000-3-2	Not applicable	
Voltage fluctuations and flicker as per IEC 61000-3-3	Not applicable	

Electromagnetic immunity

Table 2: Guidelines and manufacturer's declaration - electromagnetic immunity for ME equipment and ME systems


Guidelines and manufacturer's declaration - electromagnetic immunity			
The device is intended for operation in an electromagnetic environment as specified below. The customer or the user of this device is responsible for ensuring that the device is operated in such an environment.			
Immunity tests	Test level as per IEC 60601-1-2	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) as per IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or be covered with ceramic tiles. If the flooring contains synthetic materials, the relative humidity must be at least 30%.
Fast transient/burst immunity as per IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	For the key performance features: ± 2 kV for power supply lines ± 1 kV for input/output lines Reduced compliance level for video signals, i.e. fast transients/ bursts on the power supply line or on signal and video lines may cause disturbances in the video image.	The quality of the supply voltage should be that of a typical business or hospital environment.
Surges as per IEC 61000-4-5	±1 kV line-to-line voltage ±2 kV line-to-ground voltage	±1 kV line-to-line voltage ±2 kV line-to-ground voltage	The quality of the supply voltage should be that of a typical business or hospital environment.

Guidelines and manufacturer's declaration - electromagnetic immunity

Voltage dips, short interruptions and voltage variations as per IEC 61000-4-11	<p>< 5% U_T (> 95% dip of U_T) for 0.5 cycle</p> <p>40% U_T (60% dip of U_T) for 5 cycles</p> <p>70% U_T (30% dip of U_T) for 25 cycles</p> <p>< 5% U_T (>95% dip of U_T) for 5 s</p>	<p>The test level achieved in the test corresponds to active medical devices not equipped with an integrated power source (battery, UPS ...).</p> <p>Line voltage dips may therefore lead to flickering of the light source.</p> <p>Major or prolonged voltage dips may cause flickering and deactivation of the light source or system.</p>	<p>The quality of the supply voltage should be that of a typical business or hospital environment. If the user of the device requires continued function even in the event of interruptions in the power supply, we recommend to power the device from an uninterruptible power supply.</p>
Power frequency (50/60 Hz) magnetic field as per IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels typical of business and hospital environments.

NOTE: U_T is the AC supply voltage prior to application of the test level.

Table 4: Guidelines and manufacturer's declaration - electromagnetic immunity - for non-life-supporting ME equipment and ME systems

Guidelines and manufacturer's declaration - electromagnetic immunity			
The device is intended for operation in an electromagnetic environment as specified below. The customer or the user of this device is responsible for ensuring that the device is operated in such an environment.			
Immunity tests	Test level as per IEC 60601-1-2	Compliance level	Electromagnetic environment - guidelines
			Portable and mobile radio communication equipment should not be used closer to the device, including cables, than the recommended distance that is calculated using the equation applicable to the transmission frequency involved.
			Recommended safety distance:
Conducted RF disturbances as per IEC 61000-4-6	3 V _{effective value} 150 kHz to 80 MHz	3 V	$d = \left[\frac{3,5}{U_1} \right] \sqrt{P}$
Radiated RF disturbances as per IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m (80 MHz to 1 GHz) 3 V/m (1 GHz to 2.5 GHz)	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad \text{for 80 MHz to 800 MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad \text{for 800 MHz to 2.5 GHz}$
where P is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d is the recommended safety distance in meters (m).			
Field strengths from stationary RF transmitters, as determined by a site survey ^a , should be less than the compliance level in all frequency ranges. ^b			
Interference may occur in the vicinity of equipment marked with the following symbol:			
			

Guidelines and manufacturer's declaration - electromagnetic immunity

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection by structures, objects and persons.

^a Field strengths of stationary transmitters such as base stations for cellular telephones and mobile land radio equipment, amateur radio stations, AM and FM radio broadcast and TV broadcast transmitters cannot be theoretically predicted accurately. To assess the electromagnetic environment with respect to stationary RF transmitters, a site study of the electromagnetic phenomena should be considered. If the measured field strength in the location where the device is used exceeds the compliance levels indicated above, the device should be monitored to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME equipment or ME system.

^b Field strengths should be less than $[U_1]$ V/m over the frequency range from 150 kHz to 80 MHz.

Recommended safety distances

Table 6: Recommended safety distances between portable and mobile RF communication equipment and the ME equipment or ME system - for non-life-supporting ME equipment or ME systems

Recommended safety distances between portable and mobile RF communication equipment and the ME equipment or ME system

The device is intended for use in an electromagnetic environment in which RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and this device, depending on the output power of the communication equipment as specified below.

Rated power of the transmitter	Safety distance depending on transmission frequency m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
W	$d = \left[\frac{3,5}{U_1} \right] \sqrt{P}$	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.04	0.23
0.1	0.37	0.11	0.74
1	1.17	0.35	2.33
10	3.69	1.11	7.38
100	11.67	3.50	23.33

For transmitters rated at a maximum output power not listed above, the recommended safety distance d in meters (m) can be determined using the equation indicated for each column, with P being the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection by structures, objects and persons.

Ordering data

Only operate the system with the accessories included in the delivery package and approved by Carl Zeiss. You will find the contact responsible for orders in your country on this website:

www.meditec.zeiss.com

Aspheric lenses and accessories (sterilizable)

Description	Cat. No.
Aspheric lens 60D	302721-9100-000
Aspheric lens 128D	302721-9080-000
RESIGHT tray, tray for lens holder and aspheric lenses	302721-9200-000
RESIGHT metal tray, tray for lens holder and aspheric lenses	302721-9250-000

Lens holder (sterilizable)

Description	Cat. No.
Lens holder LH200	302721-9060-000
Lens holder LH175	302721-9070-000

Adapter plate sets for RESIGHT


Description	Cat. no.
Adapter plate set <u>without</u> attachment device for fiber slit illuminator	302721-9040-000
– Adapter plate	
– Installation aid	
– 4x screws (M3 x 8)	

Description	Cat. no.
Adapter plate set <u>with</u> attachment device for fiber slit illuminator	302721-9050-000
<ul style="list-style-type: none">– Adapter plate + attachment device– Installation aid– 4x screws (M3 x 8)	

Focusing units (including upgrade kit)

Description	Cat. No.
Electronic focusing unit for the S8, S88 and S81	302721-9030-000
– Accessory port upgrade kit	302721-8500-500
Manual focusing unit for the S7, S8, S88 and S81	302721-9020-000

Consumables

	Description	Cat. No.
	Optics cleaning set	000000-1216-071
	Asepsis set - sterilizable caps for the focusing knobs on the RESIGHT 500 and RESIGHT 700 fundus viewing systems	305810-9001-000
	– Internal diameter 22 mm	
	– (pack of 6)	

Classification

Classification

Description	Identification
Electrical standard	IEC / EN / UL 60601-1
EMC requirements	RESIGHT 700 meets the EMC requirements of IEC 60601-1-2, Class A.
CE label	The RESIGHT 500 and RESIGHT 700 fundus viewing systems meet the essential requirements stipulated in Annex I to the 93/42/EEC directive governing medical devices.

The system bears the label:



Ambient conditions

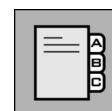
For operation

Feature	Admissible range
Temperature	+ 10 °C ... + 40 °C
Rel. humidity	30 % ... 75 %

For transportation and storage

Feature	Admissible range
Temperature	- 40 °C ... + 70 °C
Rel. humidity (without condensation)	10 % ... 90 %
Air pressure	500 hPa ... 1060 hPa

Indexes



List of technical terms

Term	Explanation
Inverter	Used in posterior segment surgery for the correction of image orientation when using a fundus imaging system or widefield optics.
RESIGHT tray	Tray for resterilization of the lens holder, aspheric lenses and caps.
RESIGHT metal tray	Tray for resterilization of the lens holder, aspheric lenses and caps.

List of abbreviations

Term	Explanation
CE	C ommunauté E uropéenne (European Community) - The manufacturer declares that the device complies with the directives of the European Union.
D	D iopters
DIN	D eutsches I nstitut für N ormung (German Institute for Standardization)
EMC	E lectromagnetic C ompatibility - defines non-interference of electrical and electronic devices with their environment
EN	E uropean S tandard
RF	R adio f requency

Term	Explanation
IEC	I nternational E lectrotechnical C ommission
OPMI	Surgical microscope
RN	R eference n umber (Cat. No.)
SN	S erial n umber

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