ZEISS EXTARO 300

Instructions for Use





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1 Before you read

1.1 Name of product

EXTARO 300 is designated as “device” in this Instructions for Use.

1.2 Scope

The Instructions for Use apply to EXTARO 300 with the following identification:

- EXTARO 300 (table mount - mobile version)
- EXTARO 300 (table mount - stationary version)

1.3 Symbols in the manual

Hazard symbols

⚠ **WARNING!**	**Hazards that can cause fatal or severe injuries if not avoided.**

⚠ **CAUTION!**	**Hazards that can cause moderately severe injuries if not avoided.**

NOTE	**Hazards that can cause property damages if not avoided.**

Information symbols

Additional information, not hazards related.

2 Safety notes

2.1 Target group

This user manual is intended for physicians, nurses and other medical staffs who prepare operate or maintain the device after appropriate training. It is the duty of the equipment owner/operator to train and instruct all staff using the system.

Installation and service work that is not described in this user manual must only be performed by specialists from ZEISS or staff specially trained for this purpose by ZEISS.

2.2 Intended use

EXTARO 300 is a surgical microscope intended for the illumination and magnification of the surgical area during surgical procedures (except ophthalmic surgeries).

⚠ CAUTION!

Injury to the patient's eye!

- The EXTARO 300 must not be used for ophthalmic procedures!
- Make sure that no illumination light of the microscope enters the patient's eyes.

⚠ CAUTION!

Live video images and recorded video sequences, video clips (cut sequences) and single images must not be used for diagnosis purposes. Visualized images may contain variations in shape, contrast and color.

2.3 Notes for operation

- Observe the legal regulations for accident prevention and occupational health & safety applicable in the country concerned;
- Use original accessories or accessories approved by Zeiss. Use only original Zeiss parts in maintenance work;
- The surgical microscope can only be used by properly trained personnel within the scope of its intended use;
- This equipment must not be modified without the manufacturer's approval. If the equipment is modified after consulting the manufacturer, appropriate examinations and tests must be performed to guarantee the further secure use of the device. The manufacturer is not liable for any damage caused by unauthorized use of the equipment;
- Do not place any fluid-filled containers on top of the instrument. Make sure that no fluids will seep into the instrument; Do not cover up the ventilation openings, as it can cause the device to overheat during operation and become damaged;

- The system will not have light output without plugging the light guide correctly.
- Always switch off the system before disconnecting it from / connecting it to line power, for cleaning its surface or if it will not be used for a prolonged period of time.
- Avoid looking directly into the light source, e.g. into the microscope objective lens or into the light guide, in order to prevent damage to the eye. Do not shine lights in anyone's eyes.
- EXTARO 300 can only be used in professional healthcare facility environments such as physician offices, dental offices, clinics, hospitals (emergency rooms, patient rooms, intensive care and surgical rooms without high-frequency surgical equipment). Additionally, it should be used outside the RF shielded room of medical electrical systems for MRI.
- The EXTARO 300 has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of EXTARO 300 in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.
- Use of EXTARO 300 adjacent to or stacked with other equipment may result in improper operation. If such use case cannot be avoided, the user must verify that the EXTARO 300 and its adjacent equipment are functioning normally before operation.
- Depending on the type of application, take appropriate precautions to ensure that the surgical procedure or treatment can still be completed even if the full functionality of this microscope (e.g. illumination) is not available.
- For the purpose of its operation, the equipment has wireless communication function, it includes RF transmitter and receiver, 2.4GHz, Pulse modulation.
- When using the ZEISS EXTARO 300 with the MORA interface, please check before using the system if the connection between the OPMI head and MORA interface is secure or if there is any movement present. If there is movement, please stop using the system immediately and contact your local ZEISS Service or an authorized partner to fix it.
- Please check and make sure that the product identification information (i.e. serial number) on the transport boxes are correct before unpacking.
- Before using the system, please check the rotation range of each axis, reference to chapter 11.2 mechanical data for details. If any abnormality is observed, please stop using the system and contact your local ZEISS Service or an authorized partner.
- Never release the column till it is fastened firmly in the mounting plate to prevent tipping over.
- Always keep the device structure within the specified rotation limit range and ensure the arms are over the table surface, make sure that the device won’t tilt or fall down.
- Hang the E-box stably underneath the mounting plate in order to prevent it falling down.
- The table shall withstand 4 times the weight of the device configuration, so as to stabilize the system to prevent any tipping motions. The table legs must be fixed to the ground to prevent the device tip over.
- Only connect to power supply when all the components are installed completely and everything is ready.
- Pay attention to avoid hitting patient or other objects when moving the OPMI.

3 Stands and labels

3.1 Stands

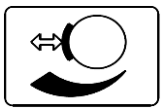


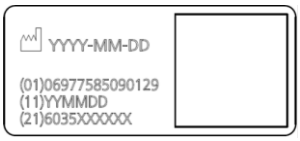
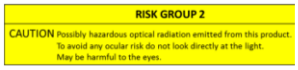
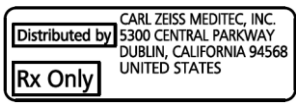
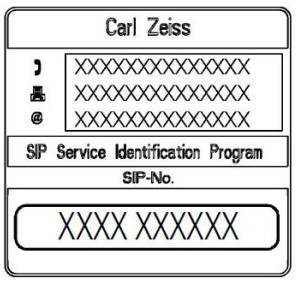
Mobile version



Stationary version

3.2 Labels

#	Symbol	Designation	Description
1		Friction adjustment	Adjust the braking force (friction) of the movement axis by turning the friction knob.
2		Adjust balance of suspension arm	To increase the lifting force of suspension arm: turn the screw in the direction of bigger weight; To decrease the lifting force: turn in the direction of smaller weight.
3		Risk of pinching hand	Fingers may be crushed. Do not touch this area while moving the surgical microscope.
4		Maximum load on suspension arm	The maximum load on the suspension arm must not exceed 8Kg.

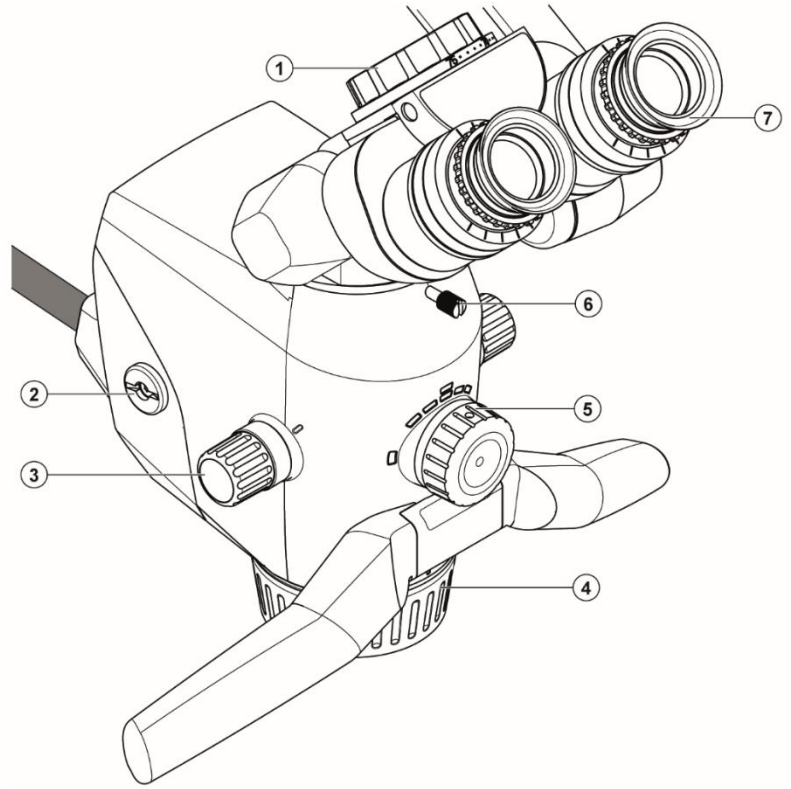
5	~100-240V 50/60HZ T3.15A H250V	Input voltage	The input voltage at the power socket should be compliant with the specification on this label.
6		UDI label	1) YYYY-MM-DD: manufacturing date in the sequence of Year-Month-Day 2) UDI (Unique Device Identification) contents: – (01): company & product code – (11): manufacturing date – (21): serial number
7		"Observe the Instructions for Use" label	This label tells the user to read the user manual for detailed function of the control
8		Observe disposal regulations	Electrical or electronic devices must not be disposed of as normal domestic waste, see Section 13 for details.
9		Power switch	Power switch that can be pressed to toggles between on/off status
10		Warning of light hazard	Possibly hazardous optical radiation emitted from this product. To avoid any ocular risk, do not look directly at the light. May be harmful to the eyes.
11		Distributor information (for North America)	1) Carl Zeiss Meditec Inc. is responsible for the distribution and complaint handling for EXTARO 300 in the USA and Canada. 2) Rx only: this symbol means the product is only for professional use
12		Service identification label	The SIP number is a unique identification number assigned to your system for service purpose.

13	Contains FCC ID: 2AK34-IAR630C This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. 000000-2222-807	FCC Conformity label	FCC Declaration of Conformity
14	Carl Zeiss Meditec (Suzhou) Co., Ltd. 4F, No. 26 Wu Sheng Road, SIP 215126 Suzhou China MD SN 6035XXXXXX EXTARO 300 REF 6035 C 305161 US EC REP Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52, 07745 Jena, Germany	System identification label (for treatment unit only)	Manufacturer information SN Serial number REF Reference number CE mark EC REP Authorized representative in the European Community C 265366 US CSA approval MD MD labelling
15		Tipping warning label	Possibly hazardous from this product. To avoid any risk, ensure the table is stable enough and perform properly in line with the operation guides introduced in this device instruction for user.
16	(01)06909262100043 (11)YYMMDD (21)XXXXXXXXX (241)0000002165387 REF 000000-2165-387 SN XXXXXXXXX YYYY-MM-DD Fluorescence Mode	UDI label for Fluorescence Mode	REF Reference number SN Serial number Manufacturing date in the sequence of Year-Month-Day UDI (Unique Device Identification) contents : - (01): company & product code - (11): manufacturing date - (21): serial number - (241): Reference number
17		Label for Electro-Static Discharge	The sudden transfer of charge between bodies of differing electrostatic potentials that may produce voltages or currents that could destroy or damage electrical components

18		Lighting symbol on E-BOX	The USB port with lightning symbol is designed only for charging, which shall not be connected to camera control unit.

4 Controls

4.1 Controls on the microscope

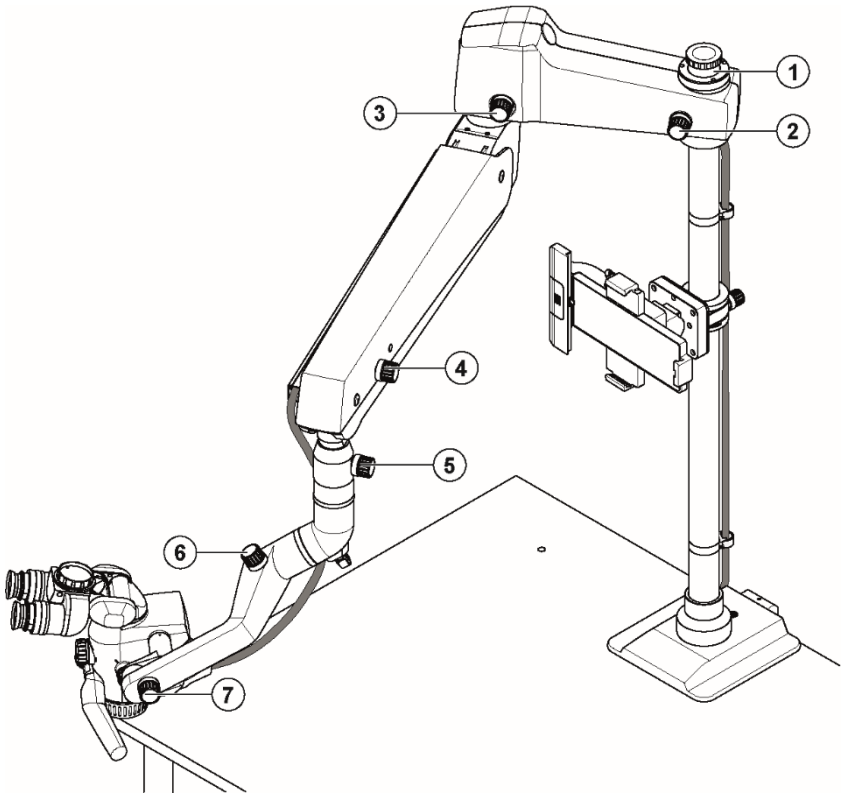


Controls on the microscope

Item No.	Component name	Item No.	Component name
1	Pupillary distance adjustment	2	Emergency Knob
3	Knob of Magnification Changer (MC)	4	Varioskop 230 for focus adjustment
5	Mode Control knob	6	Securing screw
7	Diopter setting on eyepiece		

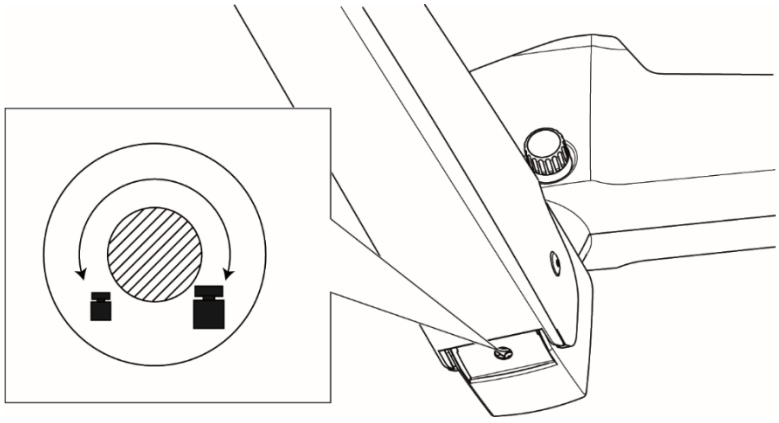
NOTE	**Loosening the securing screw may cause the tube to fall off!**

4.2 Controls on the arm and yoke assembly



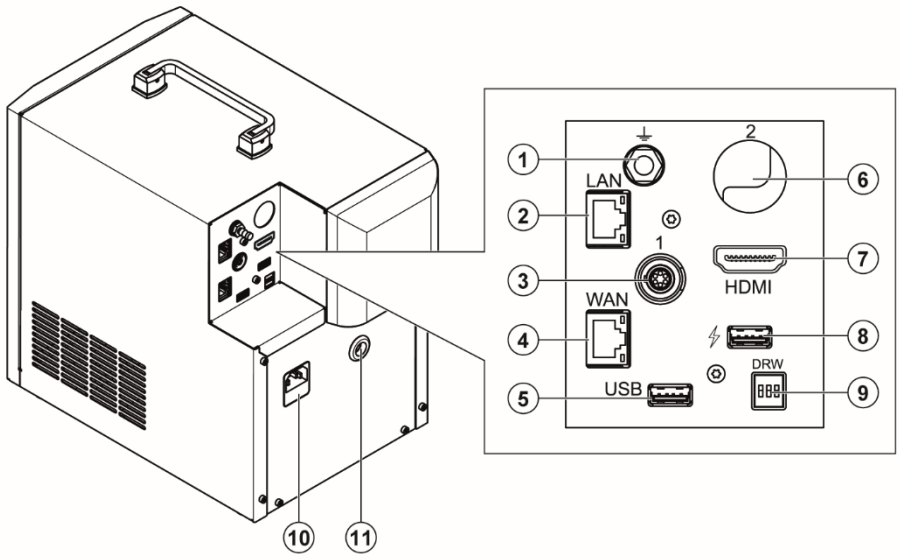
Controls on the arm and yoke assembly

Item No.	Component name	Item No.	Component name
1	Rotation limiter of carrier arm	2	Brake of axis 1 for locking the carrier arm
3	Brake of axis 2 for locking the suspension arm	4	Brake of axis 3 for locking the vertical position of suspension arm
5	Brake of axis 4 for locking yoke orientation	6	Brake on yoke for locking swivel angle
7	Brake for locking tilt angle		



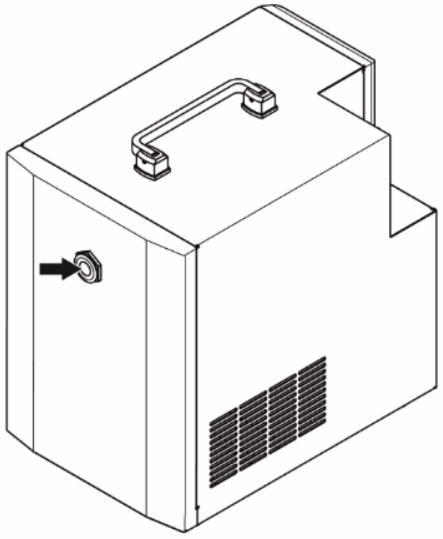
Screw for adjusting lifting force of suspension arm

4.3 Connections and power button of E-box



Connections on the rear side of E-box

Item No.	Component name	Item No.	Component name
1	Earth connection	2	LAN connection for iPad
3	OPMI connection for power supply and signal control	4	WAN connection for clinic network
5	USB connection for data storage	6	Camera connection
7	HDMI connection	8	USB connection for charging
9	WIFI module settings dip switches	10	Power connection
11	Light guide connection		



Power button on the front side of E-box

5 Description of system options

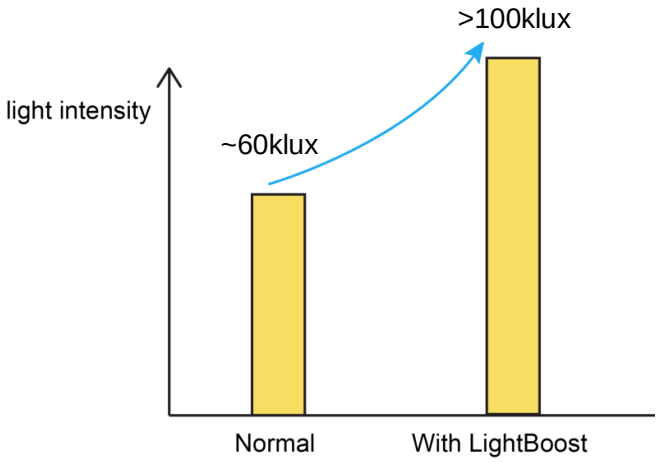
The availability of features can vary depending on the configuration of the device.

For detailed ordering information of all options, please consult your authorized ZEISS partner.

5.1 LightBoost

LightBoost is used to increase the maximum light output of the illumination lamp by approximately 60%, see illustration below for reference. The values shown below are under following conditions:

- White Light Mode (color temperature: 5500K±500K)
- no filter inserted into light path
- at 250 mm working distance



⚠CAUTION!

Protective eyewear to mitigate risk of illumination on the eye

During surgery/examination, it's suggested that the patient wear a protective eyewear to avoid hazardous illumination light directly entering his/her eye. For details of the eyewear, please contact your authorized ZEISS partner.

To lower the risk of phototoxic injury of the patient's eye, EXTARO 300 also provides a function called SpotLight that supports the user to control the illuminated-field diameter via the Mode Control knob. For details, please refer to Section 7.3.

5.2 Augmented visualization

Always bear in mind that all necessary protective measures shall be taken to prevent any potential injuries.

⚠ WARNING! **Risk of irreversible damage to eyesight and even blindness!**

During surgery/examination, it's suggested that the patient wear a protective eyewear to avoid hazardous illumination light directly entering his/her eye. For details of the eyewear, please contact your authorized ZEISS partner.

5.2.1 Fluorescence Mode

Fluorescence Mode is an optional accessory to EXTARO 300 surgical microscope.

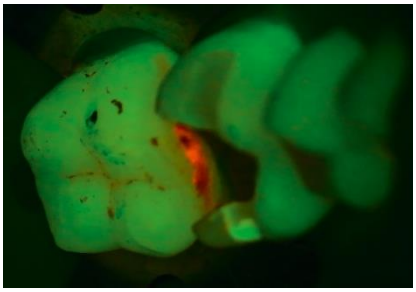
Indication for use

The Fluorescence Mode is intended to be used by dentist as an aid in the detection of dental caries.

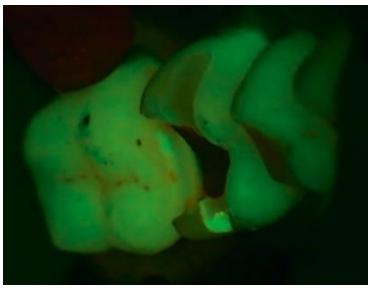
Visual identification of suspected carious lesions

The energy rich blue-violet light (405 nm) of the Fluorescence Mode causes the tooth structure (tooth enamel, dentine) and the metabolites of cariogenic bacteria (porphyrins) to fluoresce.

For healthy dental enamel, the fluorescence light has a greenish color with a peak wavelength around 500 nm. By contrast, carious teeth will exhibit extra red fluorescence light with peak wavelengths around 635 nm and 680 nm[1,2]. The red fluorescence is the emission from porphyrin compounds in oral bacteria associated with the caries. Example images of red and green fluorescence are provided below:



Suspected tooth with carious lesion (red) that should be confirmed through clinical examination



Same area observed after caries removal

Citation:

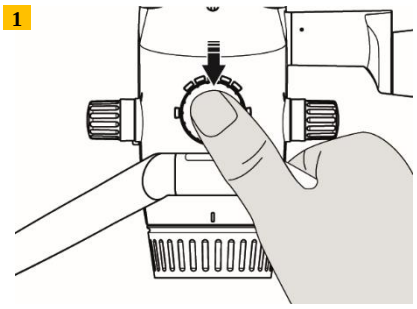
1) Clinical trial for detection of dental caries using laser-induced fluorescence ratio reference standard, Journal of Biomedical Optics Vol.15(2), 2010.

2) Buchalla W, Attin T, Niedmann Y, Niedmann PD, Lennon AM: Porphyrins are the cause of red fluorescence of carious dentine: Verified by gradient reversed-phase HPLC. Caries Res; 42, 223 (2008).

Instructions for use to aid in the detection of dental caries

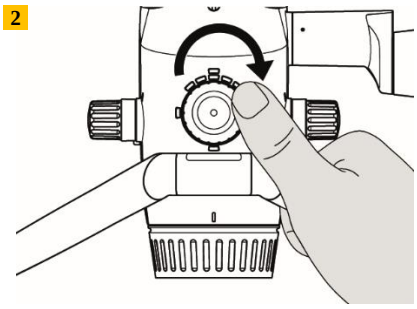
Follow the instructions below to properly set the OPMI in Fluorescence Mode:

1



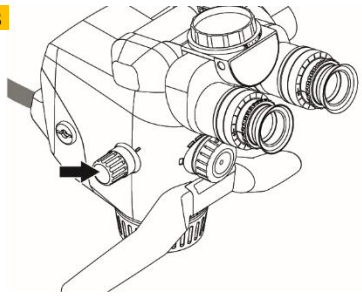
Short press the Mode Control knob to activate the Fluorescence Mode (for details, see Section 7.4 . The white illumination light will then be turned off and violet light will be turned on.

2



Adjust the light intensity to 100% by rotating the Mode Control knob. Refer to Section 7.2 for details of how to adjust the light intensity.

3



Set MC to the magnification factor of 1x which will give the user a balanced performance of image brightness and resolution under Fluorescence Mode.

Conditions for using the Fluorescence Mode are summarized in the table below:

Parameter	Ideal Conditions	Effect of Variation
Magnification factor	1	Increase magnification in order to obtain higher magnification of the image, which may be accompanied by a decrease in brightness. Decrease magnification in order to get a larger field of view, which may be accompanied by an increase in brightness.
Working distance	300 mm	Increase in order to set the ergonomic distance between the dentist and patient if the dentist is tall. Decrease in order to set the ergonomic distance between the dentist and patient if the dentist is short.
Intensity	100 %	Increase in order to obtain brighter image. Decrease in order to make the image darker.

Working outside of these parameters may lead to a darker image in the eyepiece. In this case, the contrast between red and green will be low and a detection of porphyrins (red fluorescence) may be difficult.

If the image appears too dark, try adjusting the three parameters toward the ideal conditions above until a satisfactorily bright image is achieved.

If adjustments do not improve the quality of the image, external light may be interfering with image quality. If the image appears appropriately bright, but has reduced contrast or a slightly orange image, this may be the problem. Strong background light cast on the tooth from a large oblique angle is most likely to interfere. In order to improve image quality, reduce any suspected sources of background light such as sunlight from windows, ceiling lights, or examination lights.

If the image cannot be remedied, switch back to the white light (standard mode) of the device and continue the procedure conventionally.

⚠WARNING!

The Fluorescence Mode uses color to provide information that may aid in the detection/ location of caries by red color of metabolites of cariogenic bacteria. It is not suitable for use by persons who are red/green color blind.

This device is not to be used for the diagnosis of caries; the definitive diagnosis of caries should be performed using the standard of care (e.g. visual/tactile examination and radiographic evaluation if necessary). The device is not to be used to guide tooth debridement during treatment of dental caries.

Recommended procedure for detecting caries

The following procedure steps are recommended for the detection of caries:

- Perform professional teeth cleaning.
- Remove polishing paste using the air/ water spray.
- Dry the teeth.
- Select ideal parameters for Fluorescence Mode: see the parameter table in the previous page.
- Observe teeth through eyepieces directly or with the help of dental mirror. Green signal: tooth enamel, dentine. Red signal: metabolites of cariogenic bacteria that may aid in the detection of dental caries.
- For patient information purposes, a video image of optional integrated camera can be displayed on a video screen.
- After viewing locations of potential caries in Fluorescence Mode, definitive diagnosis of caries should be performed using visual and tactile examination, with radiographic evaluation if necessary.

Artificial substances that show a similar auto-fluorescence signal than porphyrins could in principle be present in the oral cavity. Before caries detection with the Fluorescence Mode, it is therefore recommended to perform a professional tooth cleaning which removes artificial substances from the teeth.

Similarly, the professional tooth cleaning removes plaque and therefore helps to avoid false positives on the tooth's surface. Tartar, however, might not be completely removed by the tooth cleaning. Tartar and caries can be distinguished in the white light image since only tartar is an additional structure on the tooth's surface. Generally, caries, plaque, tartar and artificial substances can be distinguished through visual and tactile inspection under white light illumination.

If unsure of the status of tooth's surface when viewing under fluorescence, switch the device to white light illumination and continue examination using conventional methods.

Troubleshooting summary

Fault	Cause	Rectification
Image too dark	Inappropriate parameter setting of the working conditions (mag. Factor, working distance and intensity)	Adjust values of the parameters toward the base recommendation aforementioned.
Bright image but poor contrast	Strong background light	Reduce any suspected sources of background light (e.g. sunlight from windows, ceiling lights, or examination lights).
Orange tint	Strong background light	Reduce any suspected sources of background light (e.g. sunlight from windows, ceiling lights, or examination lights).

⚠CAUTION!

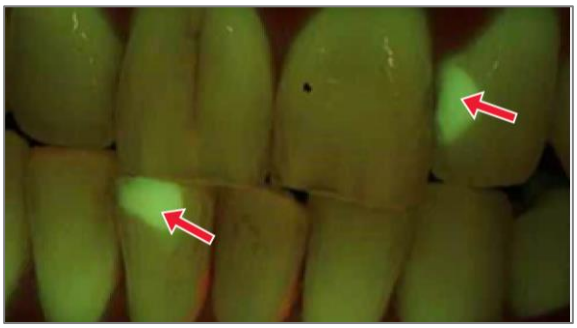
Strong background light (i.e. room light) may have an impact on the appearance of colors being observed in Fluorescence Mode. Sources of strong background light can be dental examination light, direct sunlight or intense ceiling lights. In case you experience reduced contrast or a slightly orange image during use of the Fluorescence Mode, remove examination light, dim ceiling light or block direct sunlight.

Composite detection

For most dental composite resins, the contrast between composite and healthy tooth are greater in Fluorescence Mode than in white light mode (*Dental Materials Journal 2015; 34(6): 754–765, Photodiagnosis and Photodynamic Therapy 13 (2016) 114–119*). This contrast enhancement leads to a more reliable identification of tooth-colored composite resins (*Clin Oral Invest (2017) 21:347- 355*).



Composite resin under White Light Mode



Composite resin under Fluorescence Mode

5.2.2 Orange Color Mode and TrueLight Mode

Orange Color Mode and TrueLight Mode are both optional accessories to EXTARO 300 surgical microscope.

Both Orange Color Mode and TrueLight Mode fall in the category of Delay Curing Mode which prevents the premature polymerization of widely used contemporary light curing composite resins during the modeling process under the microscope.

In contrast to the Orange Color Mode, the TrueLight Mode supports you to identify relevant dental tissues in a more natural, white-light setting. For most common composite resins with typical

camphorquinone-amine based photoinitiating systems, the TrueLight Mode extends the working time by a factor of 2 compared to the White Light Mode.



White Light Mode



Orange Color Mode



TrueLight Mode

5.2.3 Green Color Mode

The Green Color Mode is used to enhance image contrast between blood and tissue so that they can be better distinguished.



Blood strain in White Light Mode

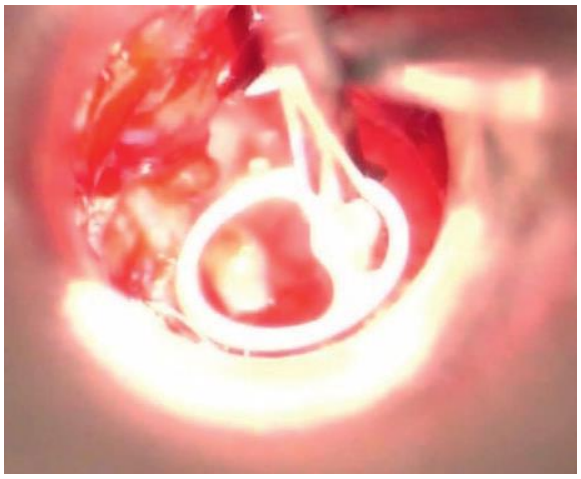


Blood stain in Green Color Mode

5.2.4 NoGlare Mode

NoGlare Mode is an optional accessorie to EXTARO 300 surgical microscope.

The NoGlare Mode aids in reducing specular light reflections from the surface and make sub-surface information more visible.



Stapedectomy in White Light Mode



Stapedectomy in NoGlare Mode

By effectively suppressing the obtrusive light reflections from the tooth surface, this mode supports to

precisely analyze the color shades of the teeth. The elimination of glare helps very much when true color has to be determined and compared.



Case 1: White Light Mode



Case 1: NoGlare Mode



Case 2: White Light Mode



Case 2: NoGlare Mode

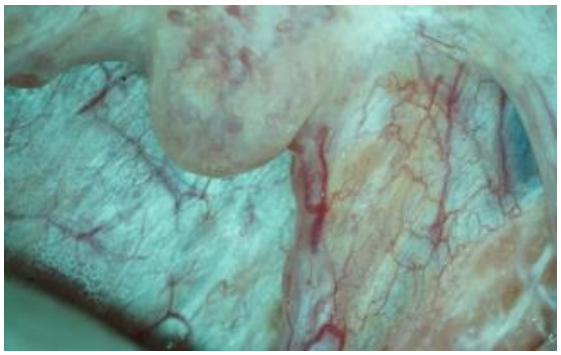
All the above clinical images were recorded by camera. The visual impression through the eyepiece might be different from the representation displayed in this manual.

5.2.5 Multispectral Mode

The Multispectral Mode is an optional accessory to EXTARO 300 surgical microscope. It is used to enhance contrast between tissue and vasculature.



Tissue image under white light

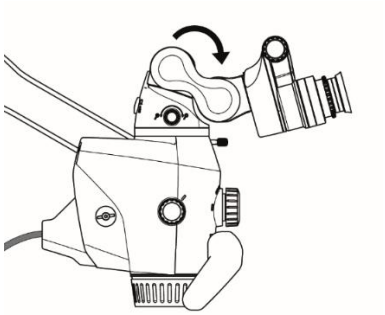


Tissue image under Multispectral Mode

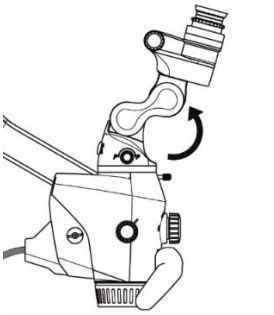
5.3 Ergonomics

5.3.1 Foldable tube

Foldable tube is used to satisfy the needs of users with different heights and with different postures. It has two axles so that the tube can be both folded and straightened.



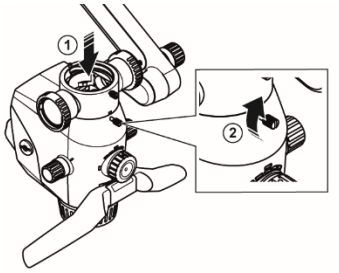
Folded



Stretch out

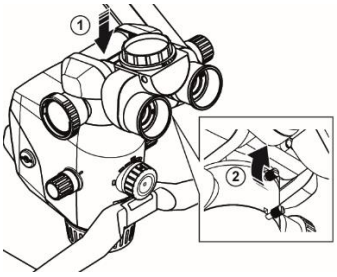
5.3.2 Co-observation tube & straight tube (optional)

1 With the co-observation tube & straight tube, the operation assistants can observe the surgical areas without affecting the operation of attending physicians. Refer to the following installation steps.



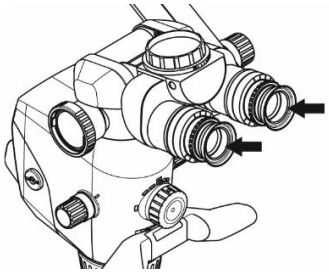
Place the beam splitter on OPMI, tighten it by rotating securing screw clockwise.

2



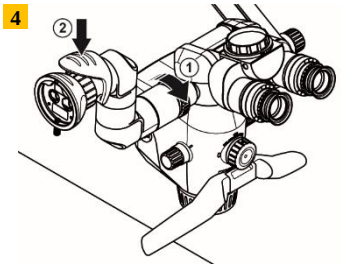
Place the tube on the beam splitter and fasten it by rotating the securing screw clockwise.

3



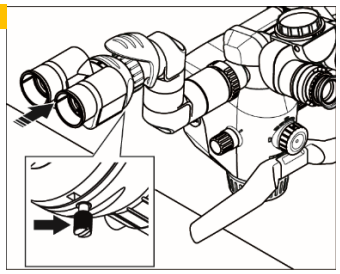
Insert two eyepieces into the tubes one by one. Eyepieces will be sucked in automatically with the help of magnetic action.

4



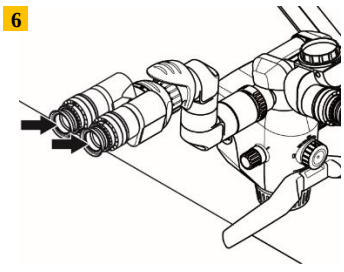
Rotate the co-observation tube into beam splitter till it reaches the resting position. Press and hold the black lever to adjust the directions of the tube.

5



Tighten straight tubes onto co-observation tube by rotating straight tubes clockwise.

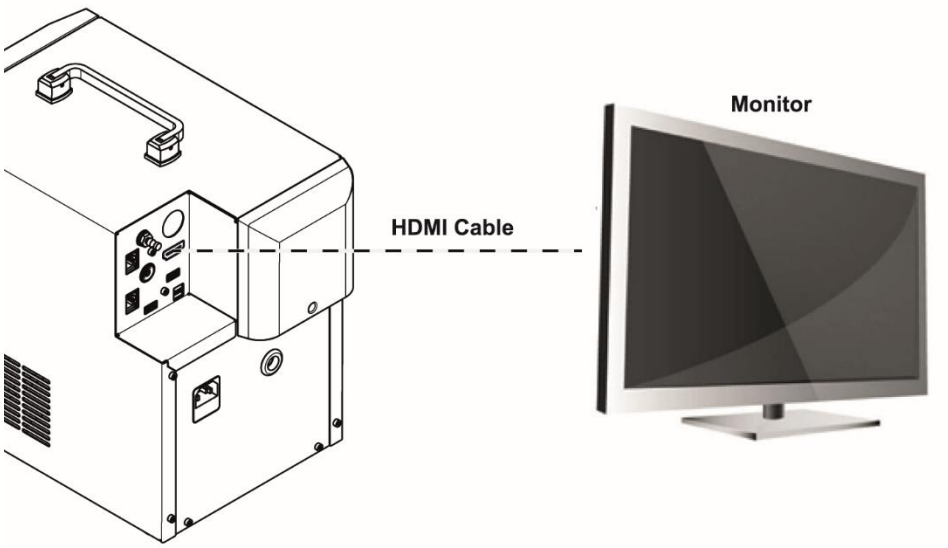
6



Install two eyepieces onto the straight tubes. Eyepieces will be sucked in automatically with the help of magnetic action.

5.4 Documentation

In terms of image acquisition and video recording, the EXTARO 300 come with the following package:



5.4.1 Complete Communication package

Clients like the Communicator software and the IP Camera can connect to the AP and exchange video stream data and other signals.

Aside from providing the AP, the Wi-Fi module can simultaneously connect to an existing network (for example the hospital network) via wired connection, allowing the Communicator software to interface with the PMS (Patient Management System) or IAS (Image Archiving System) of the user, as well as allowing a client in the user's network to access the IP Camera of the Surgical Microscope system.

Main features:

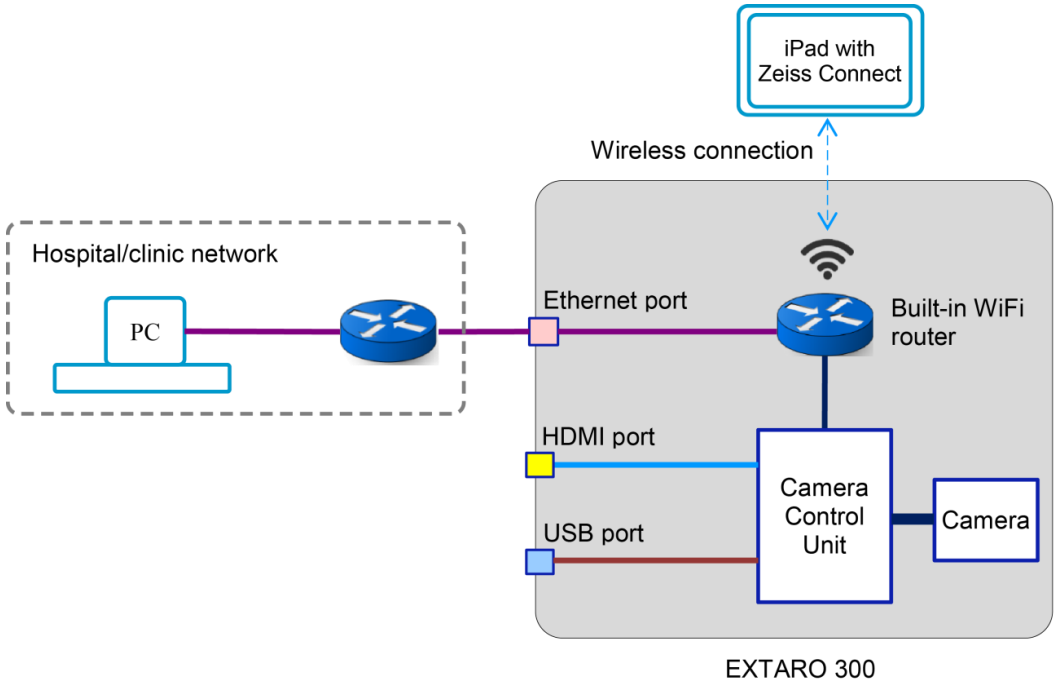
- Integrated HD (1080p) camera
- Video interface
  - HDMI output to monitor
  - USB port for image & video recording (e.g. with a USB disk)
- Trigger from microscope or with ZEISS Connect App
- Network interface (including wireless & wired Ethernet connection)
- ZEISS Connect (iPad app) for
  - Camera control including smart recording
  - Chair side patient consultation
  - Media asset management
  - Essential adjusting of images and video



- It is recommended that the capacity of USB disk not exceed 256GB.

- We recommend the user to use the "SD formatter" software (freely downloadable from https://www.sdcard.org/downloads/formatter_4/index.html) to format their USB disk before using it on the EXTARO 300 system, otherwise the USB disk may not work properly for image and video storage.

The Connect app is available for download in the Apple app store. For more details please refer to separate user manual of the Connect app.



NOTE	**1）The USB port with lightning symbol is designed only for charging, which shall not be connected to camera control unit!** **2）Consult your local dealer for more information of the network connectivity.**

5.5 Asepsis & drapes & drape adapter

5.5.1 Reusable asepsis sets

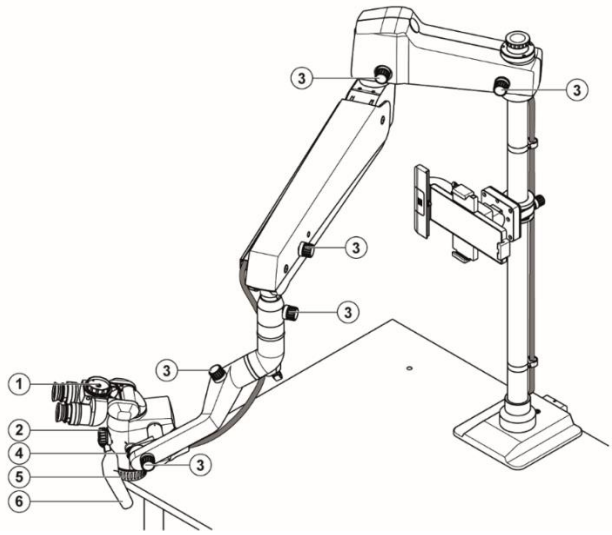
For sterile use, the system can be equipped with asepsis rubber caps that can be sterilized in autoclaves. For EXTARO 300, the following asepsis caps are now available for use:

Item No.	Name	Material No.	Used Position
1	Asepsis caps	305810-9003-000	180° tiltable tube for PD adjustment
2	Asepsis caps	305935-8041-000	Mode control knob

3	Asepsis caps, 27 mm	305810-9008-000	knobs on yoke and arm
4	Asepsis caps, 22 mm	305810-9001-000	knobs of magnification changer
5	Asepsis ring	305935-8022-000	Varioskop 230
6	Asepsis sleeves	305935-8083-000	Handgrips

For detailed ordering information of all asepsis products, please consult your authorized ZEISS partner.

These asepsis caps can be used on the parts marked with corresponding numbers shown as below, i.e. using No.3 asepsis caps on knobs marked with ③ on yoke and arm:



⚠ CAUTION!

Risk of infection caused by contamination!

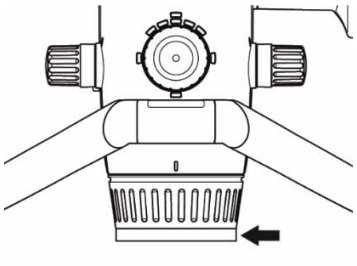
Clean, disinfect and sterilize asepsis caps before each use. This also applies to the first use after delivery.

5.5.2 Drapes

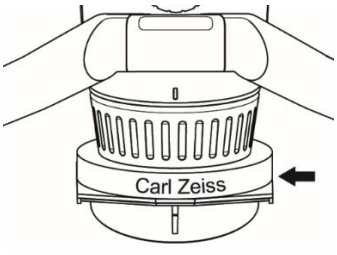
To ensure sterile covering of the EXTARO 300 system, it is possible to use the following three kinds of single-use drapes:

Name	Drape Type	Material No.
Sterile shower cap drape	No. 84	306084-0000-000
OPMI sterile drape	No. 70	306070-0000-000
sterile drape	No. 25	306025-0000-000

5.5.3 Drape adapter



Mount the drape adapter below Varioskop 230



Slide the VisionGuard of the drape onto the drape adapter

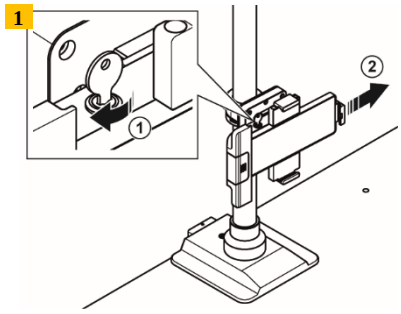
⚠ WARNING! **Risk of device damages due to improperly rotate the drape adapter!**

- Make sure mount and rotate the drape adapter properly.
- Only turn the Varioskop for focusing.
- Do not exert any rotational force on the drape adapter itself.

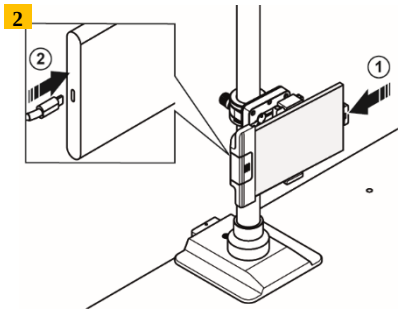
5.6 iPad holder

The mobile version microscope is equipped with an iPad holder as the standard configuration, which can be used to hold an iPad (self-provided) on the column. The iPad holder can provide power to the iPad as well as achieve ethernet connection. It comes in two versions, USB Type C or Lightning. Please make sure that you use the correct iPad type for your given iPad holder.

You can see the following diagram to fasten your iPad on the iPad holder.



Turn the key clockwise and then stretch the right side of iPad holder outwards.



Push the right side of the iPad holder inwards till the iPad is clamped firmly. Open the small cover on the left side and insert the power connector into iPad.

Please refer to the product datasheet of EXTARO 300 or consult your local dealer for more information of the iPad holder.

NOTE **Applicable iPad**

The iPad holder only applies to iPad and is compatible with the following

types of iPad only:

- Screen size of iPad varies from 9.7 inch to 11 inch.
- iPad thickness varies from 5.5 to 7.6mm.
- the weight of iPad shall be less than or equal to 1 kg.

Using other types of iPad or tablet PC would potentially damage that device or the EXTARO 300 system.

⚠ CAUTION! **Risk of breaking the iPad!**

- Never release iPad till it is clamped into the iPad holder firmly.
- Do not touch these area with ESD sticker during normal use. Otherwise it may cause iPad connection break.



It should be noted that, the iPad holder is an optional configuration for the stationary version microscope.

6 Preparing system for use

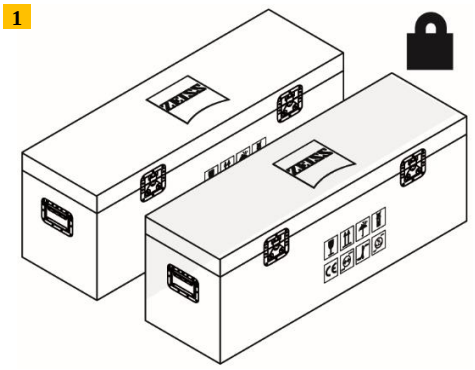
6.1 Unpacking and inspection

6.1.1 Delivery list (basic configuration for mobile version)

- Transport boxes (2x)
- Table clamp (1x)
- Column assembly (1x)
- Arm assembly (1x)
- Yoke and OPMI assembly with cables (1x)
- Tube (1x)
- Eyepieces (2x)
- E-box (1x)
- Instruction for user (1x)
- Quick guide (1x)
- Tooling package (1x)

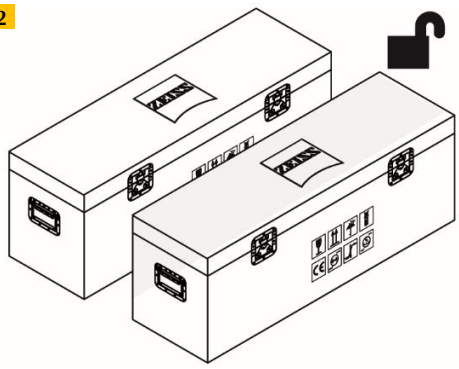
6.1.2 Unpacking and inspection steps

1



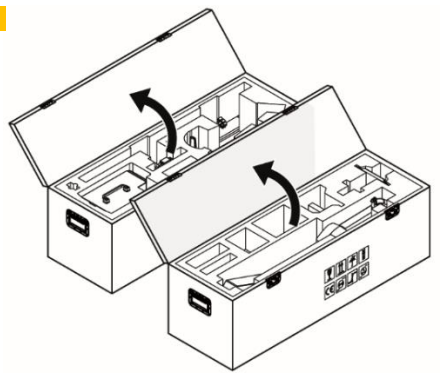
Place the two mobile transport boxes near the mounting position. Check for any transport damages and if the product identification information (i.e. serial number) are correct.

2

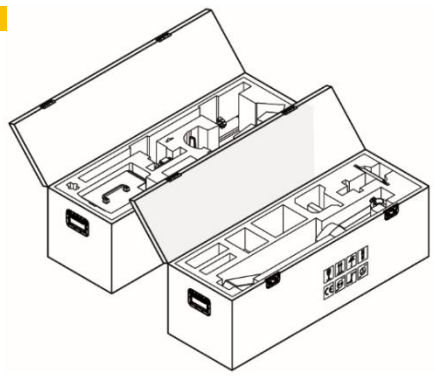


Unlock the mobile transport boxes.

3



4



Lift covers up slowly to its end position.	Inspect all the parts for any transport damage. Check for any missing parts against delivery list.

⚠ **CAUTION!**	**Risk of damaging instruments in event of knocking down the cover accidentally!**

- The unpacking position shall be shall be clean, level and commodious.
- The unpacking personnel shall be well trained, have read and understand fully relevant instructions in advance.
- Report to responsible person immediately if any damages or missing parts.

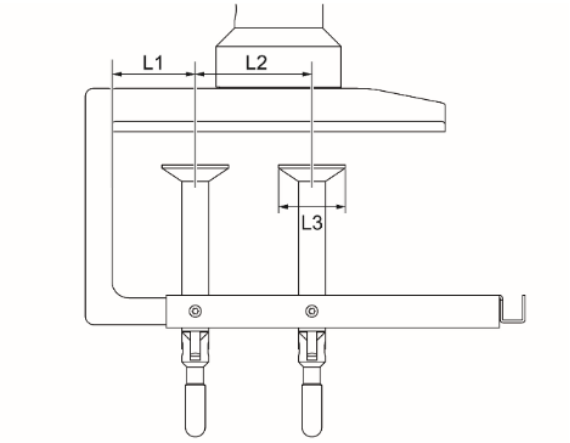
6.2 Mounting the microscope

6.2.1 Recommended table specification

First of all, the recommended specification of the table for mounting the microscope shall meet the following value requirements in the table:

Designation	Value
Length	≥1500mm
Width	≥750mm
Height	730~770mm
Thickness	20mm-40mm (for stationary version) 20mm-70mm (for mobile version)
Weight	≥60Kg
Bearing capacity	The table shall withstand 4 times the weight of the device configuration.
Distance between feet center and the surface edge in the projection view	<50mm

In addition, the following dimension requirements of the table clamp shall be also considered so as to choose a proper table to mount the microscope.



Dimensions:

L1 = 50 mm;

L2 = 70 mm;

L3 = 40 mm.

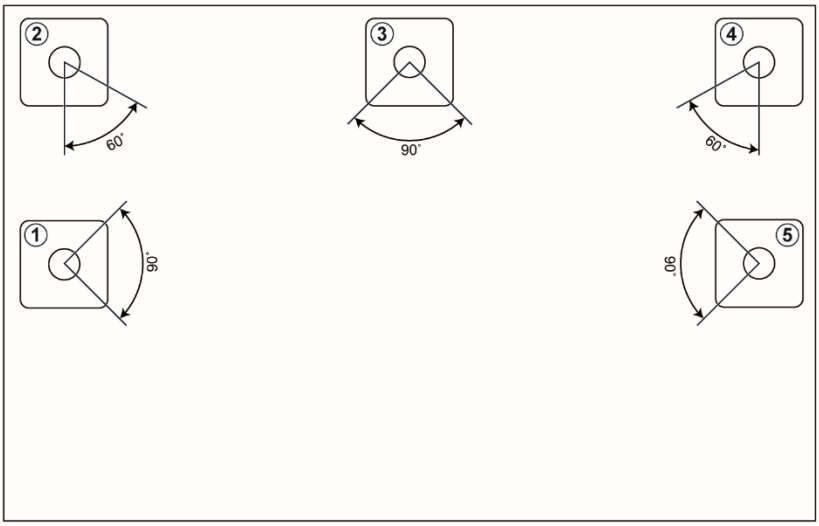
⚠ CAUTION!

Risk of tipping over!

The table legs must be fixed to the ground to prevent the device tip over.

6.2.2 Rotation limiter

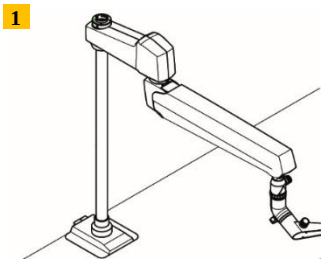
Rotation limiter shall be set to 90° or 60° in accordance with the five mounting scenarios shown on the following diagram.



Rotation range in different mounting scenarios

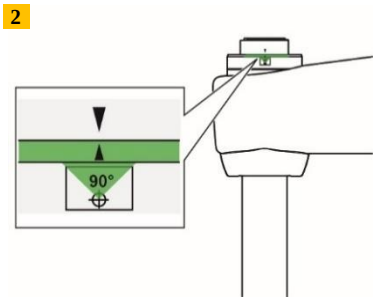
Set to 90° in Case 1 & Case 3 & Case 5

1



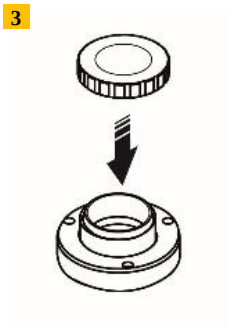
Position the carrier arm over the table and adjust the carrier arm till it is perpendicular to the mounted table edge (i.e. perpendicular to the long table edge in case 3 and perpendicular to the short table edge in case 1 and case 5).

2



Lift up the rotation limiter and turn it till the arrow on the limiter aligns with the 90° rotation range on the side of the column.

3

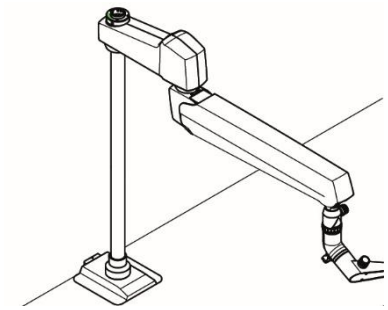


Take the black column cap and screw it on top of the column.

The movement of the carrier arm should be limited to green range.

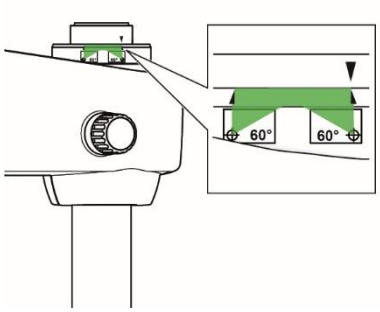
Set to 60° in Case 2 & Case 4

1



Position the carrier arm over the table and adjust the carrier arm till it is perpendicular to the long table edge

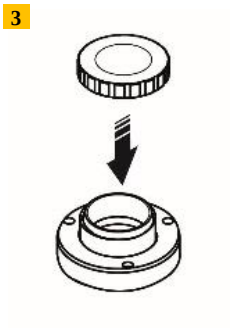
2



Lift up the rotation limiter and turn it till the arrow on the limiter aligns with the 60° rotation range on the side of the column.

Align the arrow on the limiter with the right arrow on the column in case 2 and the left one in case 4.

3



Take the black column cap and screw it on top of the column.

The movement of the carrier arm should be limited to green range.

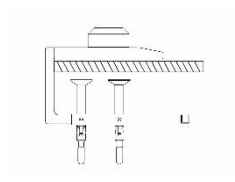
6.2.3 Mounting procedures

For the stationary version table-mounted microscope, ZEISS service personnel will provide mounting services for you onsite at the appointed time.

While for the mobile version table-mounted microscope, it allows to be mounted in anywhere if only

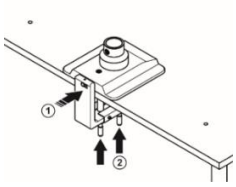
meets the recommended table and space specification as well as environment requirements. To mount the mobile microscope, please refer to the procedures shown as below and read the safety notes carefully attached:

1



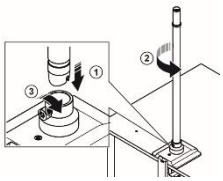
Take the **mounting plate** out of **Box B** and **position** it on the edge of the table in one of the positions as shown in **picture 2.**

2



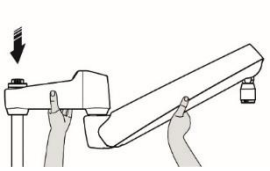
(1) Ensure the **mounting plate** sits properly against the edge of table
(2) Tightening the two **lever screws** on the bottom side of the clamp.

3



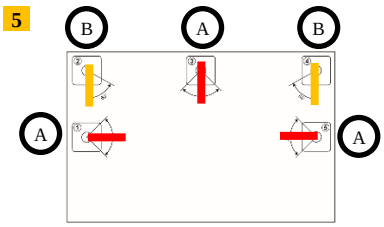
(1) Take the **column assembly** out of **Box A** and insert the end with the teeth into **the mounting plate.**
(2) Rotate it till it slides into the resting position.
(3) Tighten the securing screw on the rear side of the plate.

4



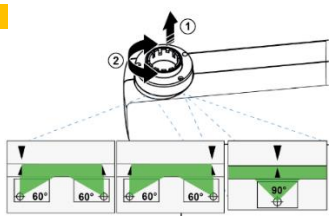
Take the **arm assembly** out of **Box B** and mount the carrier arm (short arm) onto the **column**.
Hint: Keep the arm as **straight as possible** so that the arm may slide onto the column without getting stuck.

5



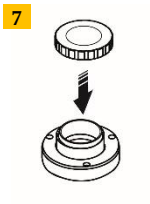
(A) Position the **carrier arm** over the table and adjust it, until it is **perpendicular** to the mounted table edge.
(B) If mounted in a **corner**, the carrier arm should be **parallel** to the **short table edge**.

6



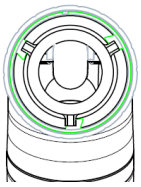
(30)Lift up the **silver rotation limiter** ring on the top of the column and **(2)** turn it till the two **arrows** on the limiter and on carrier arm **align**. Choose **60°** for a **corner** setup or **90°** if the setup is in the **middle** of the table (**picture 2**).
For 60°: choose the arrow that is on the side where the **crosshair** marks the **table corner** that the system is attached to.
(3) Release the ring in that position.

7



The **arrows** are **aligned**, The movement of the carrier arm should now be limited to the green range.
Take the **black column cap** from **Box A** and screw it on top of the column

8

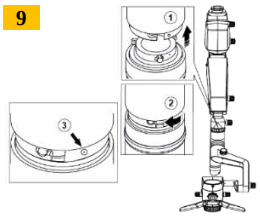


Take the **yoke** out of **Box A** and ensure that the **bayonet pins** and rotatable **safety ring inside** the yoke are properly aligned. If not use a finger or tool to align the pins underneath each other.

⚠ **Ensure that the suspension arm is over the table surface.**

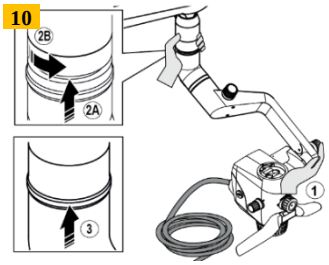
⚠**Hint**: For easier mounting, tighten all the friction brakes on the axis's, especially the one on the end of the carrier arm, to which the yoke will be connected to.

9



(1) Attach the yoke to the suspension arm by **aligning** the **bayonet pins** and the **pins** of the rotatable **safety ring inside** with the bayonet **grooves** in the suspension arm.
(2) Rotate the **yoke** into the arm so that the pins **rest** in the **grooves**.
(3) The arm is **positioned correctly** when the **holes** on the rear side of the yoke **align**.

10

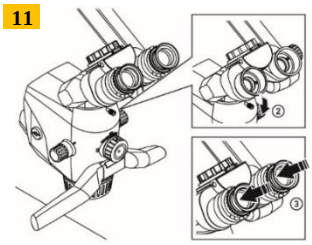


(1) Push the **microscope head** slightly **upward** to straighten the yoke.
(2) Lift up the **yoke ring** and **tighten it** till the yoke is **secured** to the suspension arm.

⚠ **Check that no movement between yoke and suspension arm is possible.**

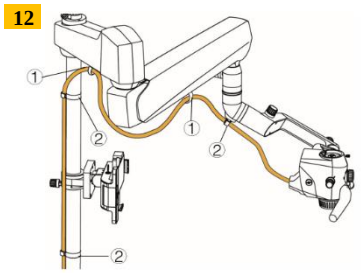
(3) Place the rubber ring back in the groove underneath the yoke ring.

11



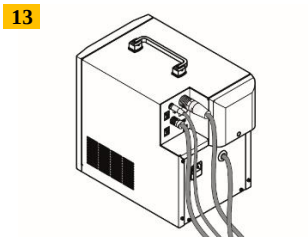
(1) Remove the black **protective cover** from the **microscope head** by **loosening** the **screw** on the front side of the microscope head. Store the cover in **Box B**.
(2) Take the **tube** from **Box B** and fasten it onto the microscope head by placing it into the dovetail and **tightening** the securing **screw** on the **front side**.
(3) Insert the two eyepieces into the tubes. Eyepieces will be kept in place by the help of the magnetic force.

12



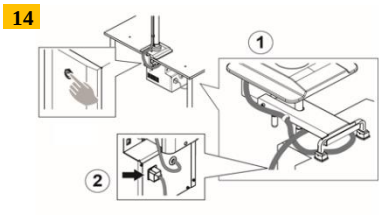
(1) Route the **cables** as indicated **alongside** the **arm** starting at the microscope head, through the **two rings** and down along the column. Use the **markings** on the cables as **indicators** for the length at which they should be **fastened**.
(2) Fasten the cables in place with the **strappings** on the yoke and on the column.

13



Take the **E-Box** out of **Box A** and **connect** the **cables** into their corresponding connections on the **backside** of the E-box. Match the Cables according to their color and number coding.
Hint: Ensure that the light fiber is inserted all the way, otherwise the system won't start up.
Hint: Use a hex wrench to tighten the PE cable (green) if needed.

14

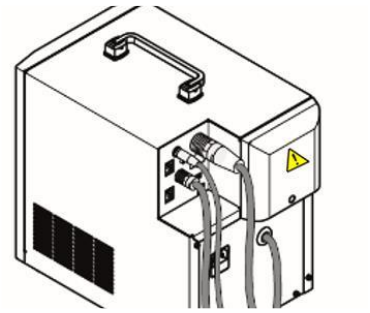


(1) Hang **E-box** on the **hook underneath** the mounting plate,**route cable** and **fix** it on the E-BOX.
(2) Connect the **power cable** and press the **power button** on the **front side** of the E-Box to **start-up the system**.

For disassembly
go through the steps in
reverse order.

⚠ WARNING! **Risk of personal injury and system damages!**

- Do not power the system when the light guide is not plugged into the socket.
- Hang the E-box stably underneath the mounting plate to ensure the E-box won't fall down.
- Only connect to power supply when all the components are installed completely and everything is ready, otherwise the operator may suffer an electric shock and the system may suffer heavy damages.
- Do not grip the housing to move the E-BOX,otherwise may lead to damages on the housing and Wi-Fi antena.



- Only used devices that are not connected to external power supply, such as a USB drive, on the USB interface.

NOTE **Risk of accidentally damages due to arm swing!**

- After inserting the arm assembly onto the column, check and verify that axis 2 is locked and axis 1 is unlocked.
- Do not switch on quickly after the power is off, otherwise the light sourcing could not initialize.

⚠ CAUTION! **Risk of tipping over during mounting the system!**

- Never release the column till it is fastened firmly in the mounting plate to prevent the column tipping over.
- Keep the device structure within the specified rotation limit range and ensure the arms are over the table surface, make sure that the device won't tilt or fall down.
- The table shall withstand 4 times the weight of the device configuration, so as to stabilize the system to prevent any tipping motions.
- Make sure the table is stable enough and don't place anything else on the table, otherwise it could cause the table tipping over.

6.3 Preparing sterility

6.3.1 Attaching asepsis caps

For sterile use, the system can be equipped with resterilizable products. The asepsis sets available from ZEISS contain various caps that can be sterilized in autoclaves.

⚠ CAUTION! **Risk of infection caused by contaminated asepsis caps and drapes**

- Only use sterile asepsis accessories and drapes suitable for the system
- Clean, disinfect and sterilize asepsis accessories before each use. This also applies to the first use after delivery.

6.3.2 Attaching the drapes

To ensure sterile covering of the system, it is also possible to use the single-use drapes (i.e. M/N: 306070-0000-000).

The steps of attaching the drapes are as follows:



Hang a rubber band around one side of the handgrip, then twist and stretch the rubber band toward the other side.



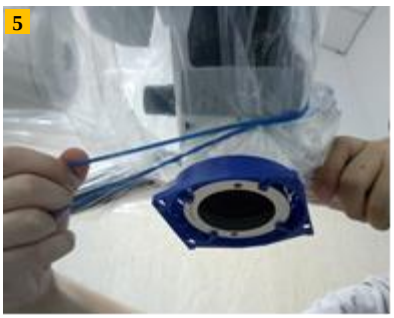
Secure the other end of the rubber band as shown above.



Make sure there is enough slack in the drapes to allow easy operation of Varioskop, handgrip and other controls.



Hang the second rubber band on the locking screw and stretch it sideward.



Wind the rubber band around the bottom of the OPMI.



Secure the other end of the rubber band on the locking screw.

NOTE **Risk of overheating**

- Never cover any ventilation openings.

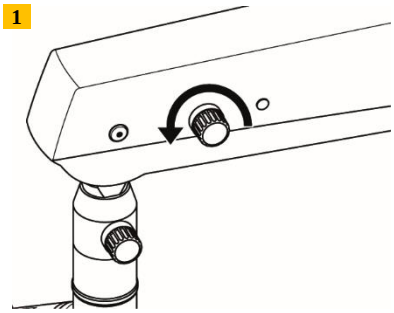
- When attaching the sterile drapes, make sure there is enough slack in the drapes to allow for movement of the microscope carrier and surgical microscope. It is especially important that the drapes are completely loose around the handgrips. The surgeon must be able to reliably operate the controls through the drape.

- A drape adapter is needed for attaching the drape on Varioskop 230. For details, please see Section 5.5.3 .

For detailed information on sterilization, please refer to the product datasheet of EXTARO 300 or consult your local authorized ZEISS partner.

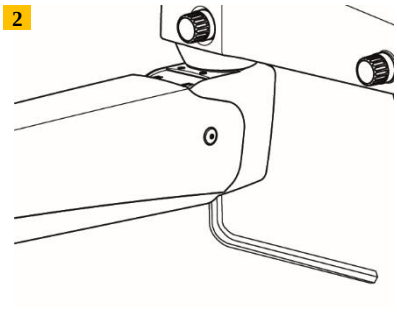
6.4 Balancing

1



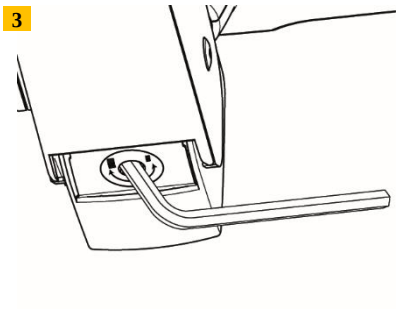
Loosen the friction adjustment screw of the suspension arm.

2



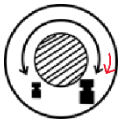
Insert a 8 mm (M10) hex key into opening of the articulated joint cover.

3

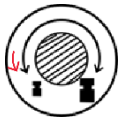


Slightly lift the suspension arm by 10° from its horizontal position. Use the hex key to adjust the balance screw until balance is achieved.

To increase the lifting force, turn the hex key in the direction toward bigger weight;
To decrease the lifting force, turn the hex key in the direction toward smaller weight.



increase lifting force



decrease lifting force

⚠ CAUTION!

Risk of injury!

With an incorrectly balanced system, brake release may lead to uncontrolled movements of the suspension arm.

- Balance the surgical microscope before surgery, without the patient
- The suspension arm is under spring force. Hold the suspension arm securely in place before you loosen the locking knob.
- Never exceed the maximum permissible weight capacity of the suspension arm (See Label #4 in Section 3.2).
- Readjust the balance of the suspension arm after every change of accessories.
- Check the balance at different heights of the suspension arm

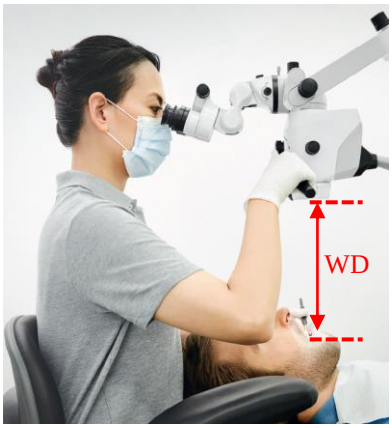
⚠ CAUTION!

Risk of crushing -–mind your fingers!

Fingers may be crushed in the areas marked with the ""isk of crushing""label.

- Do not touch these areas while the system is being moved or brought in its working / transport position.

6.5 Finding ergonomic working position



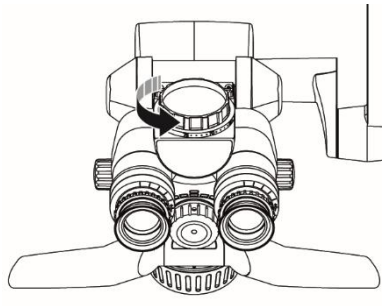
1. Adjust the height of suspension arm and the chair to bring the microscope to working area. The user should keep his/her back upright while working with the microscope. The working distance (WD) of the microscope can be varied from 200 to 430mm.
2. Adjust the focus to get a sharp image by rotating the knurled ring of the Varioskop in clockwise or counterclockwise directions.

⚠WARNING!

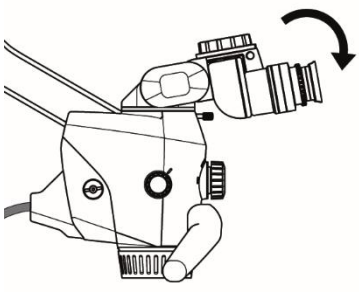
Risk of serious system damages or personal injury!

Pay attention to avoid hitting patient or other objects when moving the OPMI and during finding the ergonomic working position.

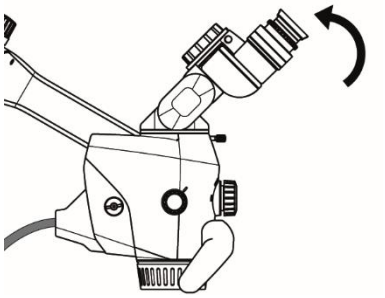
6.6 Adjusting the tube



Rotate PD knob to adjust pupillary distance (Unit: mm)

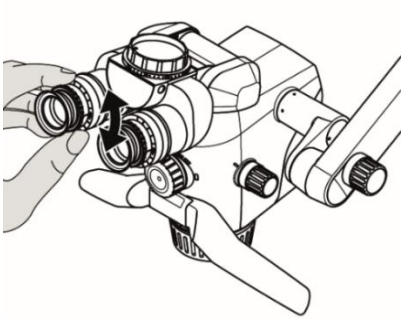


Adjust tube to a proper angle

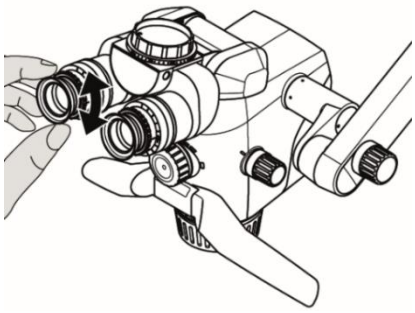


Adjust tube to a proper angle

6.7 Adjusting eyepieces



Rotate diopter setting ring to adjust prescription according to the diopter scale.



Rotate eyecups to define a proper position for resting the eye.

The eyepieces provide ametropia compensation between -–8 D and + 5 D. Eyeglass wearers who wear eyeglasses during their work set the diopter setting ring to the zero position.

NOTE

Eyepieces with magnetic coupling

Please keep in mind the usual rules for the handling of magnets in regard of eyepieces that have been removed from the tube.

- Do not place the eyepiece near instruments which may be magnetizable.
- Do not place the eyepiece on sensible devices such as infusion pumps, pacemakers, measuring devices or magnetic data media such as floppy disks, audio and video tapes or credit cards.
- Always store the eyepiece in its original packaging when not in use.

⚠CAUTION!

Injury to the eye due to light radiation!

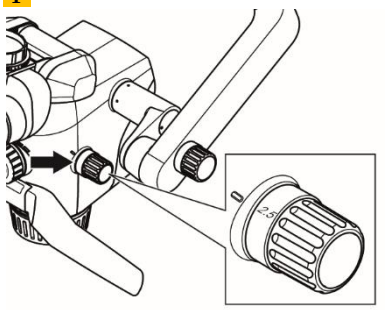
Looking into a light source through a tube, an objective lens or an eyepieces may cause eye injury.

- Never look into a light source or the sun with a tube, an objective lens or an eyepiece.

6.8 Parfocal imaging

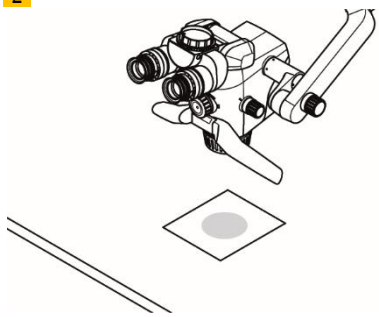
Parfocal imaging means that the image will remain sharp under different magnifications once it gets focused under the maximum magnification. Setting the correct diopter of the eyepiece is critical to ensuring parfocal imaging. If you don't know the diopter of your eyes and would not like to wear any corrective eyeglasses during operation, you can follow the procedure described below to properly adjust the diopter of the eyepieces.

1



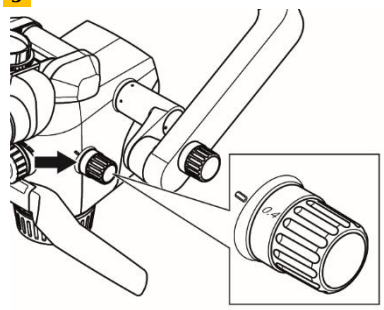
Set MC to maximum magnification (2.5x). Position the OPMI head over a piece of paper with writings on it. Adjust the height of OPMI to get a proper working distance to the paper and then lock the suspension arm.

2



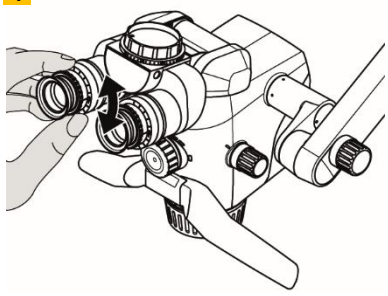
Adjust the Varioskop to get a sharp image of the writing on the paper. You can observe the image of the writing by outputting it to a monitor with an iItegrated camera iI the OPMI, or by directly looking into the eyepiece if no camera available.

3



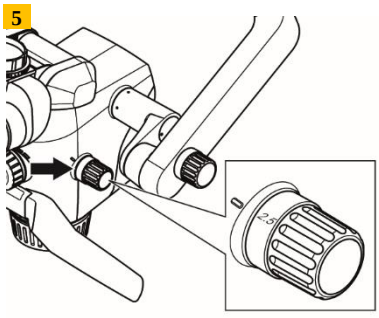
Set MC to minimum magnification (0.4x).

4



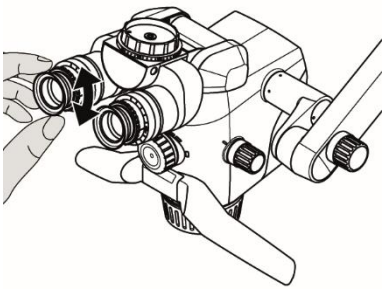
Look into each eyepiece with the corresponding bare eye and adjust diopter until the eye sees the writing in sharp focus. Make sure the working distance is unchanged during diopter adjustment.

5



Set the MC to 2.5x, check if the image of writing now remains sharp (i.e. the parfocal status). If not, repeat Step 1~Step 4.

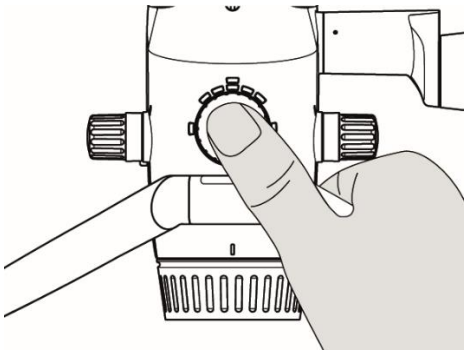
6



Turn the eyecup to the desired distance.

7 Working with the microscope

7.1 Recording image/video with Mode Control Mode



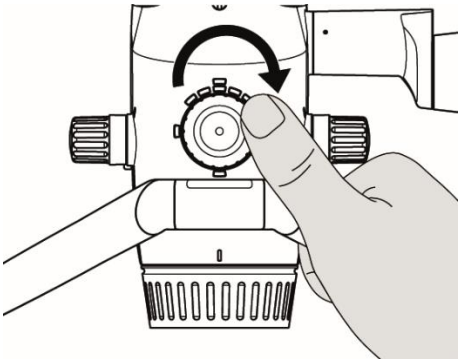
Capturing image

Short click (t ≤ 0.8s) at the center of the Mode Control knob to capture an image.

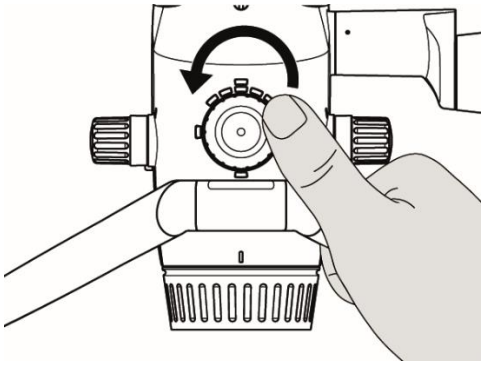
Recording video

Long click (t>0.8s) at the center of the Mode Control knob to start video recording. To stop the recoding, long click at the center again.

7.2 Adjusting light intensity



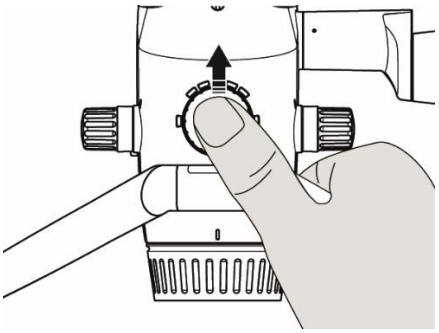
Rotate clockwise to increase light intensity



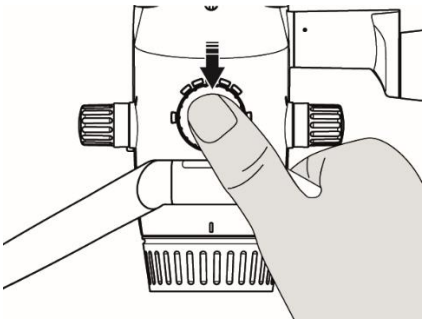
Rotate counter-clockwise to decrease light intensity

On the front face of the OPMI, there are 5 white-colored LED indicators arranged in an arc above the Mode Control knob. These LEDs are designed to roughly indicate the set intensity level of the illumination under the corresponding mode. Note that the illumination intensity of each mode can be set independently and will be automatically memorized by the microscope even after power off.

7.3 SpotLight function

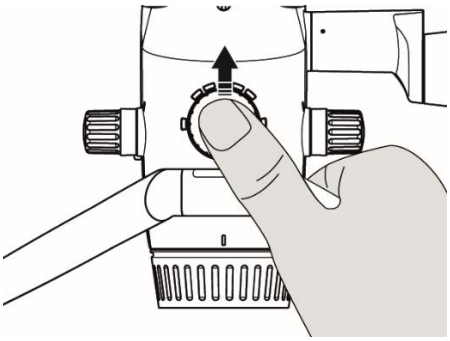


Long press (t>0.8s) the Mode Control knob upward to enlarge the illumination spot. Release the knob when you get the desired spot size.

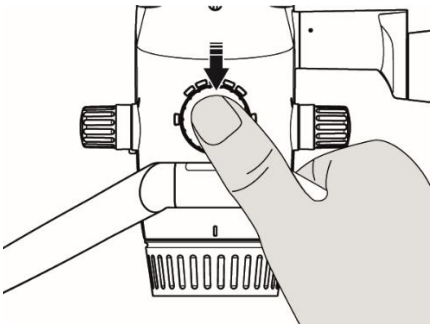


Long press (t>0.8s) the Mode Control knob downward to shrink the spot. Release the knob when you get the desired spot size.

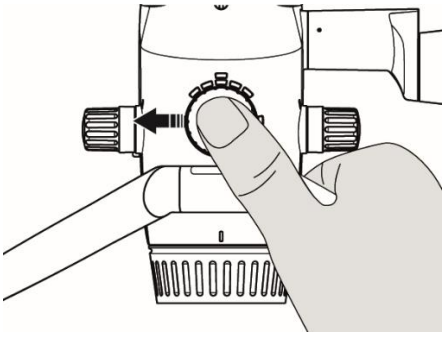
7.4 Switching between Augmented Visualization modes



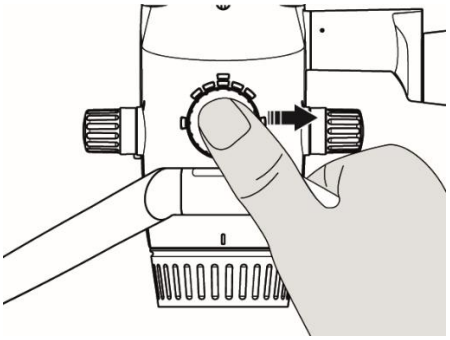
Short press (t<0.8s) the Mode Control knob upward to activate NoGlare Mode.



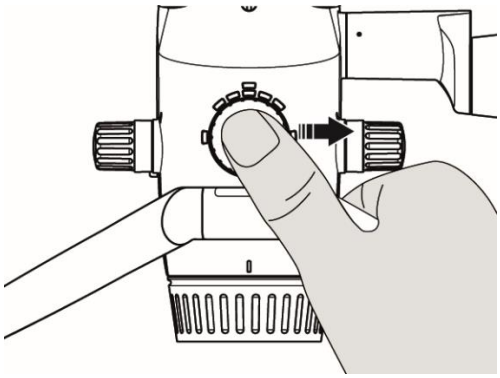
Short press (t<0.8s) the Mode Control knob downward to activate Fluorescence Mode (Optional).



Press the Mode Control knob leftward to activate Green Color Mode.



Press the Mode Control knob rightward to activate TrueLight Mode or Orange Color Mode. If both modes are available, then a short press (t≤0.8s) activates the TrueLight Mode, and a long one (t>0.8) results in Orange Color Mode (Optional).



Press the Mode Control knob rightward to activate Multispectral Mode (Optional).

- Availability of some Augmented Visualization modes are hardware and license dependent.
- Once a mode is activated by a single press of the Mode Control knob in a certain direction, a second press at the same direction will deactivate the mode and returns to normal white light.
- Delay Curing Mode (TrueLight Mode or Orange Color Mode) and NoGlare Mode can be turned on at the same time.

8 Cleaning

8.1 Cleaning optical surfaces

The multi-layer T* coating of the optical components (e.g. eyepieces, objective lenses) ensures optimum image quality.

Image quality is impaired by even slight contamination of the optics or by a fingerprint. To protect the internal optics from dust, the system should never be left without the objective lens, binocular tube and eyepieces. After use, cover the system to protect it from dust. Always store objective lenses, eyepieces and accessories in dust-free cases when they are not being used.

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

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

For the regular cleaning of objective lenses and eyepieces of the surgical microscope, we recommend the optics cleaning set available from ZEISS.

8.2 Prevention of fogging

To protect the eyepiece optics 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 eyepieces.

Please observe the Instructions for Use supplied with each anti-fogging agent.

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

8.3 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.



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%

9 Maintenance

9.1 Maintenance intervals

Regular preventive maintenance is required to ensure safe and correct operation and a long service life of the system on an ongoing basis.

The following table lists the relevant maintenance activities and shows at which maximum intervals they must be performed.

All maintenance activities listed here require device-specific knowledge. Please contact your local ZEISS Service or an authorized partner for performing maintenance activities in due time.

According to country-specific interval requirements

Component	Procedure / Criteria
Safety check	According to country-specific requirements

Before each use

Component	Procedure / Criteria
Brakes	Mechanical function testing: Tighten brakes completely; braking force holds microscope securely in place without any change of position.
Suspension Arm	Balance checking: 1. Loosen the friction adjustment screw of the suspension arm 2. Slightly lift the suspension arm from its horizontal position to check whether the balance could be achieved. 3. If not, re-conduct the balance adjustment procedure refer to Clause 6.4

When specified operating hours have been reached

Component	Procedure / Criteria
Lamp	We recommend replacing the lamp after 40,000 operating hours have been reached.

Every 12 months

Component	Procedure / Criteria
Documentation and identification labels	Visual inspection: Manuals and identification labels available, undamaged, complete and legible
Carrier system including microscope mount	Function test: – Play-free movement of bearings, stops and suspensions – Locking screws are in place and tightened – Movement of the gas pressure spring is homogeneous and jolt-free and the gas pressure spring is not operated in the limit range – Brakes operational at maximum permissible OPMI configuration
OPMI	Function test: Check of optical imaging and illumination of the field of view
Focus	Function test: Play-free adjustability of focus
Varioskop, tube and other accessories mounted on the OPMI (camera, etc.)	Function test: Attached parts without mechanical play, knurled screws tightened and other removable microscope components securely mounted

Every 2 years

Component	Procedure / Criteria
Filters of the filter wheel assembly inside OPMI	Check the filter wheel assembly (if applicable)

Every 4 years

Component	Procedure / Criteria
Carrier system including microscope mount	Visual inspection: – No signs of wear on the supporting structure – No signs of wear or damage on the interfaces and couplings
Cables, plugs and switches	Visual inspection: – Undamaged insulation and connectors on system/cable – Check cable guide including fasteners

9.2 Safety check

The safety checks may only be carried out by the manufacturer or by qualified persons.

The scope of the safety checks of the system should comprise at least the following points:

- Availability of the Instructions for Use
- Visual inspection of system and accessories for damage and legibility of labels
- Leakage current test
- Test of protective ground conductor
- Function test of all switches, buttons, sockets and indicator LED of the system
- Securing screws are in place and tightened

⚠WARNING!

Risk of injury!

Cables and plug connections may come loose and parts of the housing may then conduct a live electrical current. The user and patient may suffer an electric shock.

- To prevent any impairment of the system'' safety as a result of aging, wear etc., the operating company must ensure, in accordance with the applicable national regulations, that the regular technical safety checks defined for this system are performed on schedule and to the stipulated extent.

10 Trouble shooting

10.1 Causes of malfunctions and remedies

Fault	Cause	Rectification
No function at all	Power plug of E-box not inserted.	Plug in the power cord.
	Power switch of E-box not switched on	Press power switch.
	Automatic circuit breaker in power switch of E-box responds.	Press power switch.
	Defective power cord	Replace the power cord.
	Power failure	Contact in-house electrician.
Motion of suspension arm too stiff	Adjustment screw over tightened.	Slightly loosen adjustment screw.
Suspension arm cannot hold the OPMI in position	Balance of the suspension arm needs to be adjusted	Adjust balance of suspension arm using M10 hex key
Motion of OPMI too stiff	Friction adjustment screw on stand over tightened	Loosen friction adjustment screw on stand as required.
Stand wobbles	Floor not level. Stand base not appropriately positioned	Slightly change the stand base position
LED light source remains dark and fan is running	For LED light source: Defective LED light source	Illuminate surgical area with an OR illuminator. Contact Service.
	Defective stand electronics.	
	LED light source is overheated.	
LED light source goes constantly off and on again during operation	Defective stand electronics.	Illuminate surgical area with an OR luminaire. Contact Service.
	Ventilation openings are covered or dirty.	Ventilation openings must be clear; clean them if necessary.
Insufficient surgical field illumination	Lamp aging may lead to reduced light intensity.	Contact Service to replace light source.

Fault	Cause	Rectification
Camera installed but no image output on the monitor	HDMI connector not in well contact with the HDMI socket.	Plug the connector in the HDMI socket correctly.
	Defective CCU	Contact Service.
No video image, only color bars	Camera head not connected	Connect the camera head
Image saving failed	No USB data carrier inserted.	Insert USB data carrier.
	USB data carrier is inserted but there is insufficient memory space.	Delete some files on the USB data carrier to release some memory space.
	USB data carrier does not contain any file system or a damaged file system.	Format the USB data carrier or replaced it.

10.2 Failure of the Mode Control knob

In the event that switching between illumination modes by clicking the Mode Control knob doesn't take any effect:

1) Power off the system.
2) If user still wants to continue work with the OPMI before fixing the issue, he/she can use the Emergency knob to return to normal white light mode (e.g. use a coin to rotate it), and then power on the system again.
3) Contact Zeiss Service.

10.3 Failure of the motorized filter wheel (optional)

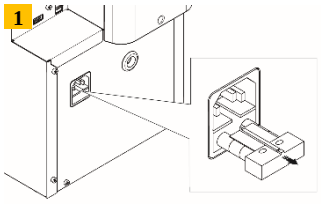
In case the motor of the filter wheel assembly cannot move:

1) If user still wants to continue work with the OPMI before fixing the issue, he/she can use the Emergency knob to rotate the filter wheel (e.g. using a coin).
2) Contact Zeiss Service.

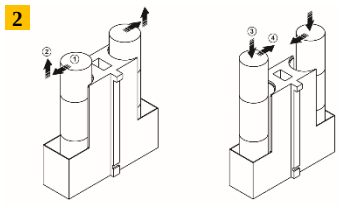
10.4 Failure of the power socket

In case the system cannot be powered on:

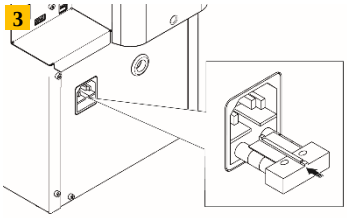
1) Switch off the power, and then unplug the power cord from power socket.
2) Change the fuse as shown and described below.



Press down the groove underneath the triangle plug and then pull out the fuse holder.



Pull out two old fuses and replace them with new ones (H250V T3.15A).



Insert the fuse holder into its original place.

3) Contact Zeiss Service if the above-mentioned method doesn't work.

11 Technical specification

11.1 Electrical data

Designation	Value
Power connection	Only connect the device to wall outlets which are equipped with a properly connected protective ground conductor.
Rated voltage	100VAC – 240 VAC 50Hz/60Hz
Power consumption	Max. 120 VA
Electrical interfaces	1) Power input： 100VAC – 240 VAC, max. 5 A 2) Integrated video interface (optional): – HDMI – USB 2.0 (for recording of pictures and videos) 3) RJ45 Ethernet interface for connecting integrated Wi-Fi router (optional) 4) USB interface for iPad device charging
Light source	Rated power: approx. 80 W

11.2 Mechanical data

Designation	Value
Microscope tilt mechanism	Tilt angle from -50° to +60°
Weight of microscope	Approx. 2 kg (without tube and eyepieces)
Suspension arm	Length: 620 mm (axis to axis) Swivel angle: ±150° Vertical lift: 600 mm(+265mm,-335mm)
Carrier arm	Length: 300 mm (axis to axis) Swivel angle: 60°/90°
Yoke	− Angled (120°) yoke − Straight yoke(optional)
Height of table clamp/ table stand	90 mm
Size of table stand area	approx.200mmX200mm
E-BOX	approx.210X320X280(WxDxH)(with antenna cover)
Maximum permissible load of suspension arm	With complete microscope equipment, including accessories: must not exceed 8kg
Total weight of EXTARO 300	Approx. 45 kg (with all accessories).

System dimensions

System dimensions may vary slightly depending on the stretching state of the equipment.

H = 1025 mm

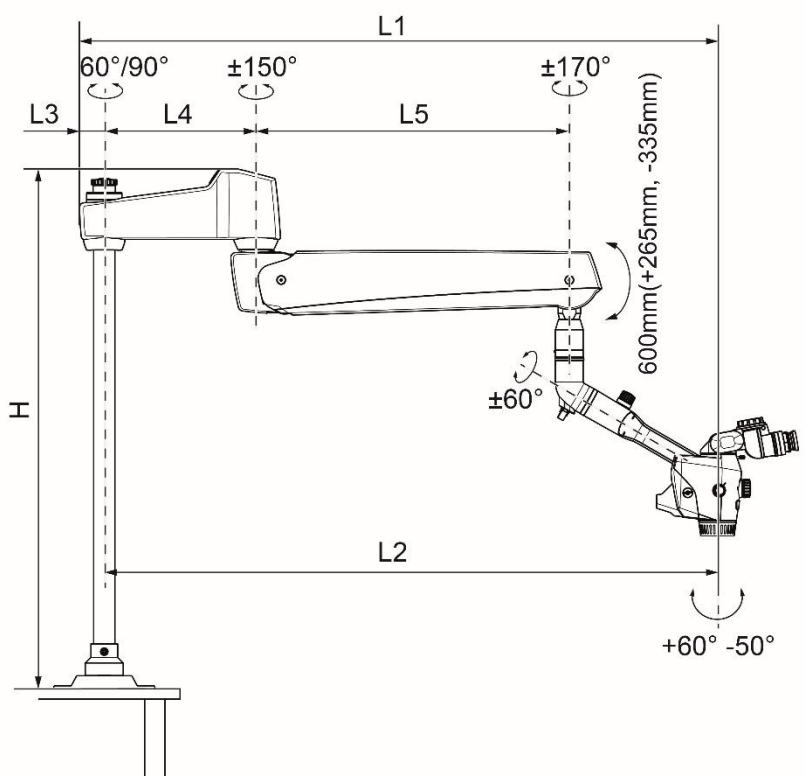
L1 = 1262 mm

L2 = 1214 mm

L3 = 48 mm

L4 = 300 mm

L5 = 620 mm



11.3 Optics data

Designation	Value
Magnification	5-step apochromatic magnification changer, manual adjustment. Magnification factors: γ = 0.4x, γ = 0.6x, γ = 1.0x, γ = 1.6x, γ = 2.5x
	Total magnification (10.0x eyepiece): • 2.4x – 15.4x at a working distance of 200 mm • 1.4x – 8.7x at a working distance of 430 mm
Focusing	Manual, focusing range: 230 mm
Working distance of Varioskop 230	200 ~ 430 mm
Field of view (with 10.0x eyepiece)	13.5 mm – 84.4 mm at a working distance of 200 mm 23.9 mm – 149.1 mm at a working distance of 430 mm
Tubes/Eyepieces	Co-observation tube & straight tube (optional)
	180° tiltable tube, f = 170mm

	Foldable tube, f170/f260 (optional)
	10.0x (option: 12.5x) widefield eyepieces
Illumination	6 different operation modes: – White light Mode – Fluorescence Mode (Optional) – Orange Color Mode & TrueLight Mode (Optional) – Green Color Mode – NoGlare Mode (Optional) – Multispectral Mode (Optional)
	Option 1:Minimum diameter of luminous spot at a working distance of 200mm: ⩽ 20 mm Option 2: Minimum diameter of luminous spot at a working distance of 200mm: ⩽ 12 mm
	Color temperature of white light: approx. 5500 K (± 500 K)
	Central wavelength of violet light: 405 nm

11.4 Documentation package

	Complete Communication
Image sensor	1 chip 1/3 inch progressive scan Color CMOS Sensor
Active pixels	1920 (H) x 1080 (V) (Pixel size: 2.8 µm x 2.8 µm)
Video output HDMI	<60 Hz setting> 1080/59.94p, <50 Hz setting> 1080/50p,
Signal/Noise Ratio	54 db
Horizontal resolution	900 lines (typical)
Network Interface	- Built-in Wi-Fi router with Access Point - LAN port (RJ45) for connection to iPad Holder - WAN port (RJ45) for connection to clinic network
Network streaming	RTSP video stream with H.264 encoding
Network streaming bit rate	4Mbit/s
Recorded image file format	JPEG
Recorded video file encoding	H.264
Recorded video file format	MP4/MOV
Recorded video file frame rate	30 FPS (When refresh rate is 60Hz) 25 FPS (When refresh rate is 50Hz)
Recorded video file bit rate	4 Mbit/s
Smart recording duration (max)	1 minute
USB drive file system	FAT32
Storage destination	USB or iPad
Remote Archiving	NAS drive, remote storage, DICOM compatible database

11.5 Ambient requirements for operation

Designation	**Value**
Temperature	+ 10°C ... + 40°C
Rel. humidity	30% ... 75%
Air pressure	700 hPa ... 1060 hPa

11.6 Ambient requirements for transport and storage

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

11.7 Wireless communication

11.7.1 Wi-Fi router information

- Release version of firmware: V1.2
- Frequency band(s): 2.4G:2.412 – 2.472 GHz
- RF Output Power:
  - 802.11b: 19.75 dBm (EIRP)
  - 802.11g: 19.85 dBm (EIRP)
  - 802.11n 20MHz: 19.95 dBm (EIRP)
  - 802.11n 40MHz: 19.75 dBm (EIRP)
- Antenna type: Dipole Antenna
- Antenna gain: 2.0 dBi
- Maximum radio-frequency power transmitted: 20 dBm ± 2.0 dBm
- Operation modes: Duplex
- Modulation Type: DSSS/OFDM
- Data security: WEP, WPA/WPA2, WPA-PSK, 802.1X, TKIP

11.7.2 Statement of Class B digital device (Part 15 of the FCC Rules)

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

11.7.3 Conformity of FCC Rules

This device complies with Part 15 of the FCC Rules. Operation is subject to the two following conditions: (1) the device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

11.8 Manufacturer's declaration for electromagnetic compatibility

The device is subject to specific precautions with regard to electromagnetic compatibility (EMC). In order to avoid the occurrence of EMC interference, the device may only be installed, operated and maintained in the manner indicated in these Instructions for Use and only with components supplied by ZEISS.

It's recommended to use ZEISS-approved accessories for this device, in particular the power cable as below:

Material Number	Name	Description
Country-specific M/N	External AC Power Cable	Cable length: 5m

Recommend cables and their maximum length:

- HDMI cable (less than 5.0 m, shielded)
- Ethernet cable (less than 5.0 m, shielded)

The following important performances of EXTARO 300 can still be retained even at the presence of the electromagnetic disturbances mentioned in subsequent sections:

- The light source can offer illumination of specified brightness without flashing and the light intensity can be adjusted normally.
- The various modes of the microscope can be controlled as intended.
- The focus, magnification and pupillary distance can be adjusted as intended.

⚠CAUTION!

Danger from electromagnetic radiation

Electrical devices can influence each other as a result of their electromagnetic radiation. The use of non-approved components (accessories, transformers of all types, cables) can cause increased emissions or reduce the device's immunity.

- With the exception of the combination of the devices described in these Instructions for Use, do not operate the device in direct proximity to other devices.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Do not use any portable or mobile RF communication equipment near the device as it is not possible to exclude the possibility that the function of the device will be affected.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EXTARO 300, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Please follow the EMC guidelines in the following pages.

11.8.1 Electromagnetic emission

The device conforms to EN 60601-1-2:2015 / IEC 60601-1-2:2020

for both immunity and emissions. The classification of electromagnetic emission is shown as below:

Emission test	Compliance
RF emissions as per CISPR11	Group 1
RF emissions as per CISPR11	Class A
Harmonic emissions as per IEC 61000-3-2	Class A
Emission of voltage fluctuation / flicker as per IEC 61000-3-3	Compliant

11.8.2 Electromagnetic immunity for ME equipment and ME systems

The device conforms to EN 60601-1-2:2015 / IEC 60601-1-2:2020 for both immunity and emissions. The capability of electromagnetic immunity is shown as below:

Immunity test	Compliance level
Electrostatic discharge (ESD) as per IEC 61000-4-2	±8 kv contact discharge ±15 kv air discharge
Radiated RF fields as described in IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz 80 % AM at 1kHz
Proximity fields from RF wireless communications equipment as described in IEC 61000-4-3	Table 9 of IEC 60601-1-2
Fast transient/burst immunity as per IEC 61000-4-4	±2 kv for power supply lines ±1 kv for input/output lines
Surges as per IEC 61000-4-5	± 1 kv phase-to-neutral voltage ± 2 kv phase/neutral to ground voltage

Immunity test	Compliance level
Conducted disturbances induced by RF fields as described in IEC 61000-4-6	3V 0.15 MHz – 80 MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips as per IEC 61000-4-11	0% U_T; 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T 1 cycle (0°) 70% U_T 25 cycles at 50Hz or 30 cycles at 60Hz (0°)
Voltage interruptions as per IEC 61000-4-11	0% U_T 250 cycles at 50Hz or 300 cycles at 60Hz
Rated power frequency Magnetic field as per IEC 61000-4-8	30 A/m 50Hz or 60Hz
Proximity magnetic fields as per IEC 61000-4-39	65 A/m, 134,2 kHz 7,5 A/m, 13,56 MHz

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

NOTE: When the AC input voltage is interrupted, the equipment will shut down and if the power supply restored, it could be recovered automatically, this degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance

11.8.3 Use of class A device

Note: the EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment and checking the immunity levels of the surrounding devices, which *Home healthcare environment* of IEC60601-1-2 is necessary.

11.8.4 Requirements for auxiliary equipment

Ambient conditions for intended use

The device is intended for use in professional healthcare facilities with regard to electromagnetic

compatibility. These include in particular hospitals and medical practices, including those connected to the public power supply (e.g. in residential areas).

The properties of the device determined by emissions permit its use in industrial areas and in hospitals (CISPR 11, Class A). If used in a residential area (for which Class B usually is required as per CISPR 11), the device may not provide the necessary protection with regard to radio frequency communication services. The user may have to take corrective measures such as moving or realigning the device.

The device is not intended for operation in the following environments:

• Home health care (e.g. residential accommodation, nursing homes)

• Outdoor environments

• Other special environments (e.g. military facilities, heavy industry, facilities for medical treatment or diagnosis with high-power devices. These include in particular high-frequency surgical

⚠CAUTION!

Danger from electromagnetic radiation

- Increased electromagnetic emissions and reduced immunity to interference when using non-specified accessories, converters of all types, cables, portable HF telecommunication devices or optional accessories from the field of information technology
- Optional information technology auxiliary parts (e.g. router, additional monitors) which are connected to the medical device must be class B conforming to CISPR 32 or comparable devices.
- Relevant cables and their maximum length
  - HDMI cable (5.0 m, shielded)
  - Ethernet cable (5.0 m, shielded)

11.9 Ordering data

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

www.zeiss.com/meditec

The product configurations, accessories and spare part that are applicable for authorized ZEISS partners are stipulated by contract.

For more information, please contact your authorized ZEISS partner.

11.10 Regulatory information

Electrical safety	The medical device meets the requirements according to IEC 60601-1:2020 andANSI/AAMI ES60601-1:2005/AMD2:2021. Classification according to level of protection against electrical shock: Protection class I.
Electromagnetic compatibility	The medical device is allocated to class A (acc. To IEC 61000-3-2) in line with IEC 60601-1-2:2020.
Classification	The medical device is allocated to class I in line with Annex VIII of the Medical Device Regulation 2017/745. The medical device meets the General safety and performance requirements stipulated in Annex I of the Medical Device Regulation 2017/745.
CE marking	In line with Annex V of the Medical Device Regulation 2017/745 the medical device is labeled with CE
Radio frequency approval labelling	The medical device contains radio modules and fulfills the requirements of 2014/53/EU. The medical device is labeled with CE
RoHS compliance	The product is RoHS compliant in accordance with Directive 2011/65/EU.

RoHS Directive 2011/65/EU including the commission delegated directive 2015/863/EU and their amending of Annex II to directive 2011/65/EU.

12 Simplified EU declaration of conformity

Hereby, Carl Zeiss Meditec (Suzhou) Co., Ltd., declares that the radio equipment type EXTARO 300 is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.zeiss.com/meditec.

13 Disposal

The device specified on the delivery note must not be disposed of via household waste or communal disposal companies in accordance with the applicable EU guidelines valid at the time the device was placed on the market.



For detailed information on the disposal of the product, please contact your local dealer or the device manufacturer or its legal successor.

14 List of abbreviations term

Term	Explanation
CCU	**C**amera **C**ontrol **U**nit
CE	**C**ommunauté **E**uropéenne (European Community)
CSA	**C**anadian **S**tandards **A**ssociation (a non-governmental organization that test and certifies product safety)
EMC	**E**lectro**m**agnetic **C**ompatibility Define non-interference of electrical and electronic devices with their environment
EIRP	**E**ffective **I**sotropic **R**adiated **P**ower
FCC	**F**ederal **C**ommunications **C**ommission
HD	**H**igh **D**efinition (providing high resolution)
IR	**I**nfra-**R**ed
LAN	**L**ocal **A**rea **N**etwork
LED	**L**ight **E**mitting **D**iode
HDMI	**H**igh **D**efinition **M**ultimedia **I**nterface (digital interface for video and auto data)
MC	**M**agnification **C**hanger
MRI	**M**agnetic **R**esonance **I**maging
OPMI	**Op**eration **Mi**croscope
PD	**P**upillary **D**istance
RF	**R**adio **F**requency
UDI	**U**nique **D**evice **I**dentification
WD	**W**orking **D**istance

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