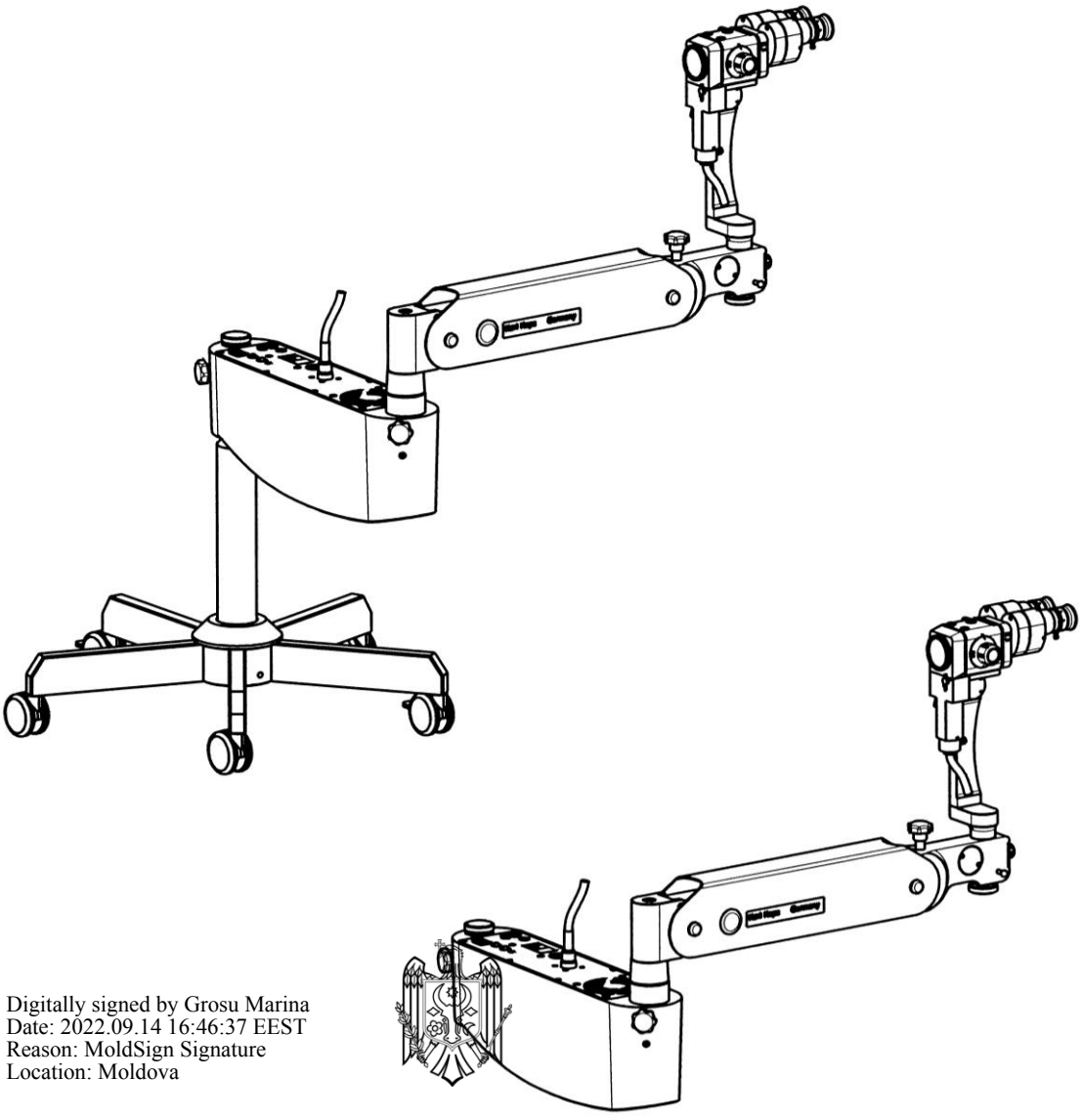
Instructions for use

SOM 52/ 42 LED



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Contents

1 General

Thank you for selecting one of our quality products. Kaps devices combine excellent illumination, easy and exact positioning, and very good optical performance in a variable and modular system. Your product can be subsequently aligned to different requirements at any time without problem. The ergonomic design of our products enables users to work without becoming tired. A brilliant 3-dimensional image with high depth of focus enables best possible success quotas in your diagnostics.

This instruction manual is an integral part of the deliverables and is part of the medical product. It must be kept in an easily accessible place by the operator for all users, and remains part of the product even when the product is sold on.

We reserve the express right to make changes to specifications shown in this instruction manual that result from technical enhancements.

This instruction manual is not subjected to change management. Please contact the product manufacturer for the current revision.

2 Symbols used and what they mean

Important visual instructions are on the device packaging, in the instruction manual and on the device. The symbols used have the following meanings:

Symbol	Explanation
	By attaching the CE mark, the manufacturer confirms compliance of the medical device with the basic requirements of EU Regulation (EU) 2017/745 concerning medical devices.
	This shows the manufacturer of the medical device according to the EU Regulation (EU) 2017/745
	Shows the serial number of a device so that a particular medical device can be identified
	Shows the date on which the medical device was manufactured
	Follow the instruction manual. Failure to follow the instruction manual can result in injury or material damage.
	**Caution** The warning triangle makes reference to potential sources of danger for people, to injury risks or to health risks
	General instruction sign. Denotes mandatory action by the user.
	General prohibition sign. Denotes prohibited action by the user.
	Shows a medical device that should not be used if the packaging is damaged or open
	Denotes a medical device that can break or be damaged if not handled with due care

Instructions for use SOM 52/ 42 LED

Symbol	Explanation
	Denotes the upper and lower temperature values to which the medical device can be exposed safely
	Denotes the moisture range to which the medical device can be exposed safely
	Denotes a medical device that must be protected from moisture
	Denotes the necessity for the user to refer to the instruction manual for important information pertaining to safety (such as warning signs and precautionary measures) that cannot be affixed to the medical device itself for a number of reasons
	The product entered into circulation after 13 August 2005 and may only be disposed of in a separated waste stream (i.e. not in household waste)

Specifies a handling instruction, failure to comply with which does not result in injury or material damage

CAUTION Denotes a danger that can cause minor injury or material damage

WARNING Denotes a danger that can cause semi-serious injury or material damage

3 Warning and safety advice

Follow the instructions in this operating manual for proper function and safety of the device.
Do not use the device when faults occur.

3.1 Installation instructions

WARNING

The mains plug of the device is used to isolate the device from the mains power supply. Set up the device such that the mains plug can be accessed without obstruction at all times.

Caution. To prevent the risk of electrical shock, this device may only be connected to a supply having a protective earth connector.

Only use approved components. Unapproved components can have a bearing on the load-carrying capacity and stability of the device, and can cause damage to the device.

Do not lean on or push the device to prevent it tipping.

The ventilation for the device may not be obstructed.

To prevent damaging the device, do not drop it or parts of it, or expose it/them to other mechanical forces.

If the power lead is defective, immediately disconnect the device from the mains supply and contact the manufacturer.

3.2 Notes for use and disposal

WARNING

The microscope may only be deployed for its intended use (as specified in these instructions).

Maintenance and repairs may only be carried out when required by authorised specialists or by factory customer service.

Only spare parts and accessory components approved by the manufacturer may be used. Please contact the manufacturer in the event of doubt.

Only replace defective fuses with those having the same ratings (nominal voltage, nominal current and switch-off characteristics).

Use of the microscope is only permitted in dry rooms.

Ensure that the device is only run on voltages specified on the nameplate.

The device is fitted with a high-performance light source. Ensure that neither user nor patient is blinded by the light.

Whilst the device is being used, ensure the patient does not look into the illumination unit of the microscope.

Penetration of liquids into system components must be reliably prevented.

When a fault occurs (such as when a fan is defective or ventilation slits are covered), immediately switch off the device so as not to cause any damage to it.

Whilst the device is in use, all fuse components must be correctly inserted as described in this manual.

Unplug the mains connector before changing fuses.

Do not use the device near sources of electromagnetic radiation.

Modifications to the device are strictly forbidden without consent from the manufacturer.

The residual risk of a hazard is assessed as extremely low if all instructions are followed and the device is used as intended.

4 Delivery state

4.1 Deliverables for SOM 52 / 42 LED

The device is delivered as four (three) individual sub-assemblies:

- Wheeled stand with five rollers (only SOM 52)
- Column
- Swivel and floating arms with electrical supply and lighting
- Microscope head including attachment
- Instruction manual

Fasteners for all components are included.

4.2 Transportation/packaging/unpacking/checking

The device is delivered as separate assemblies as described above, and installed and tested for correct function by the specialist retailer or support personnel.

Check the packaging for damage before unpacking the device. If the packaging is damaged, the contents may be as well. If the packaging is visibly damaged, please notify the carrier immediately.

4.2.1 Unpacking

All packaging and filler material must be disposed of in line with applicable local regulations.

After unpacking all of the components, use the delivery note to check the delivery is complete. If it is not, notify the supplier immediately.

5 Intended use

The product is intended for general-purpose operative and diagnostic medical deployment. It is used for optimum illumination and magnification of the treatment area. The product may only be used by trained specialists for the medical application described in this instruction manual. Training is held by the manufacturer or by personnel authorised by the manufacturer. Intended use does not include contact with the patient. The device may only be used in interior rooms having sufficient levels of illumination and cleanliness.

The device must be used in rooms that were designed for the requirements of the device and the medical equipment of qualified personnel. Examples of such rooms include private or public medical practices, hospitals or healthcare facilities.

⚠ WARNING

Setting up or using the device on a floor with a slope greater than 5° can cause the device to tip over and reduce the operability of the device.

6 Installation

The device may only be installed by personnel assigned by the manufacturer, or by the manufacturer itself. Only the fixing and installation materials supplied may be used.

6.1 Installation of wheeled stand and column (SOM 52)

Carry out the following installation steps as in Figure **1**

- The five rollers (2) are already screwed to the foot (1). Two rollers are fitted with brakes. Engage/ disengage the brakes on the rollers when moving and securing the device.
- Place the column (3) into the flange of the foot and tighten it with threaded pin (4), using the tool provided.

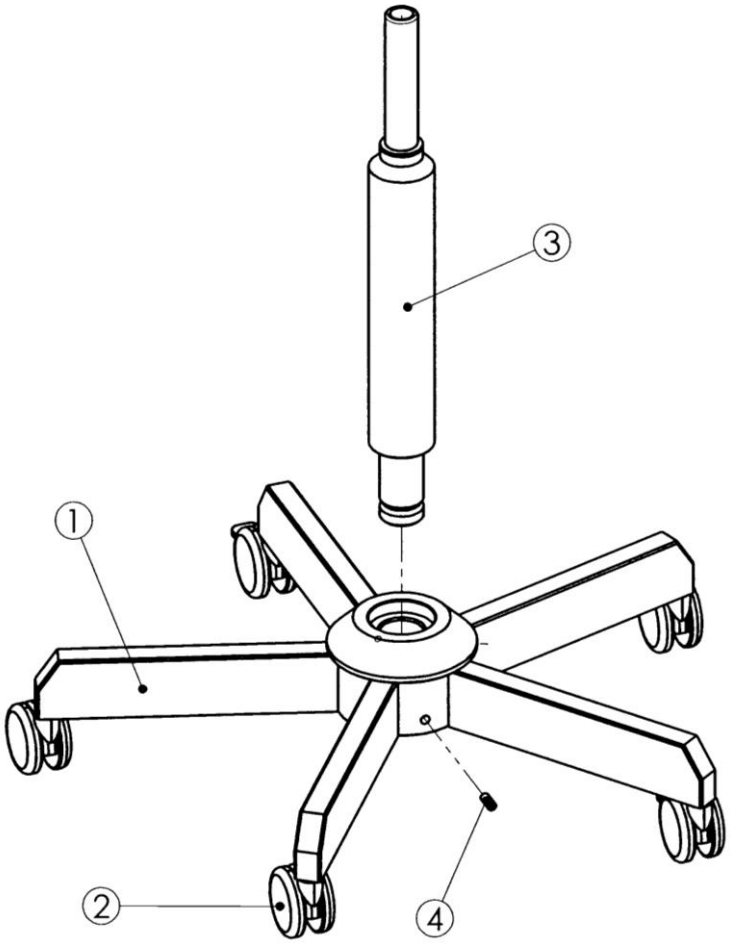

Figure 1

Indication:

The colposcope SOM 42 is identical with SOM 52.
Instead of mobile supporting base be on offer different holders.

6.2 Installation of swivel arm, suspension arm and microscope

Carry out the following installation steps as in Figure 2

- Undo the lock screw (3) on the upright guide cylinder (1) of the column (2)
- Put on the swivel arm (5). Ensure in the process that the star knob (4) is undone.
- Screw the lock screw (3) back on.
- Undo the safety cap (6) from the guide cylinder (7) of the microscope carrier (8)
- Press in the lock pin (10) and push in all the way the guide cylinder of the microscope carrier. The star knob (9) must be undone for this. Release the lock pin - it engages into place and prevents the microscope head (11) from falling out.
- Hand-tighten the lock cap (6) onto the projecting threaded part of the guide cylinder.

⚠ CAUTION

Always ensure that the lock screw (3) for securing the swivel arm, and the lock screw (6) for securing the microscope head, are mounted correctly.

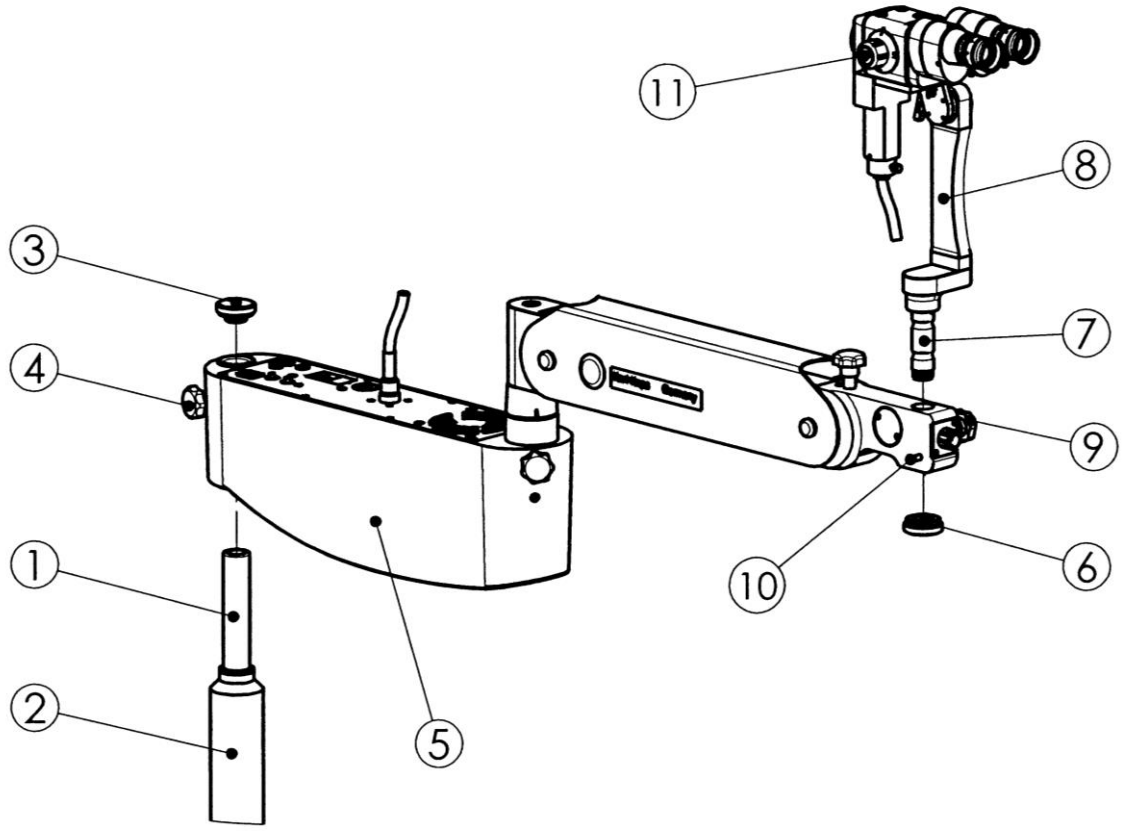

Figure 2

7 Device description

7.1 Identification and nameplates

The nameplate is used for accurate identification of your product. It may not be removed or modified. Figure 4 shows the position of the nameplate. It is located on the flat side of the swivel arm (1), regardless of device variant.

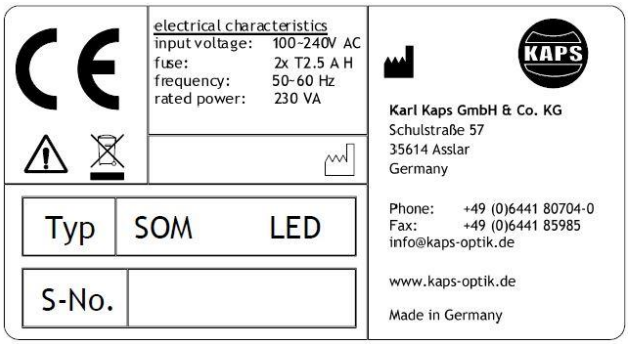

Figure 3

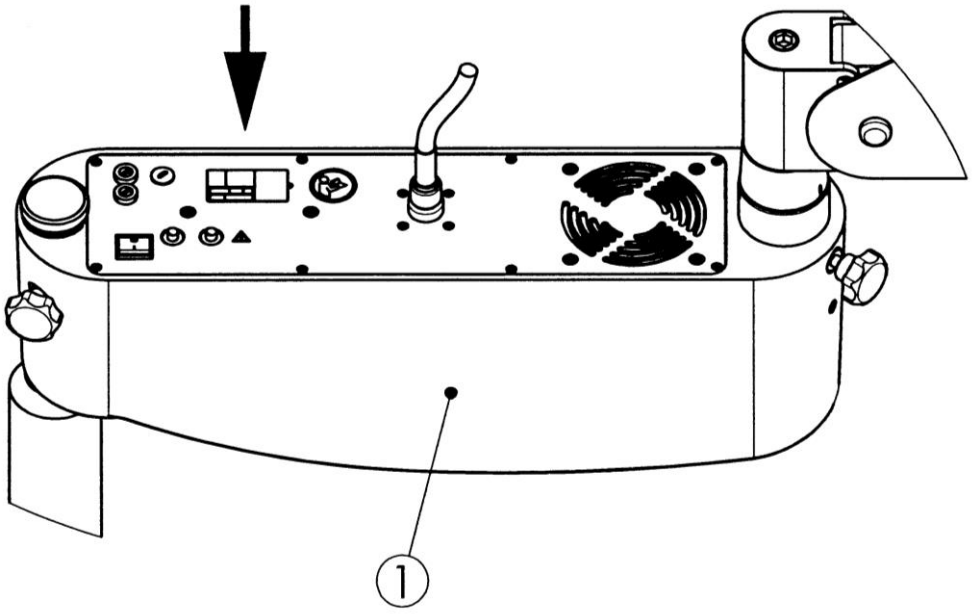

Figure 4

7.2 Controls

- Roller stand (SOM 52)
  5 rollers to move the appliance, see Figure 1 (two brakes to lock the appliance)
- Star knob (1) for determining the swivel arm position
- Main switch (11)
- Potentiometer (8) for regulation of lighting
- Star knob (3) for determining the height movement for the suspension arm
- Star knob (5) for rotation protection of the microscope head
- Knurled screw (6) for exchanging the binocular lens tube
- Knob (9) for adjusting the magnification changer
- Locking pin (4) to protect the microscope head from falling out during installation
- Star knob (2) for determining the rotation movement for the suspension arm
- Nameplate (10)
- Clamp lever (7) for adjusting the required friction to tilt the microscope head
- Lever (12) for swivelling in/out the colour filter (if available)

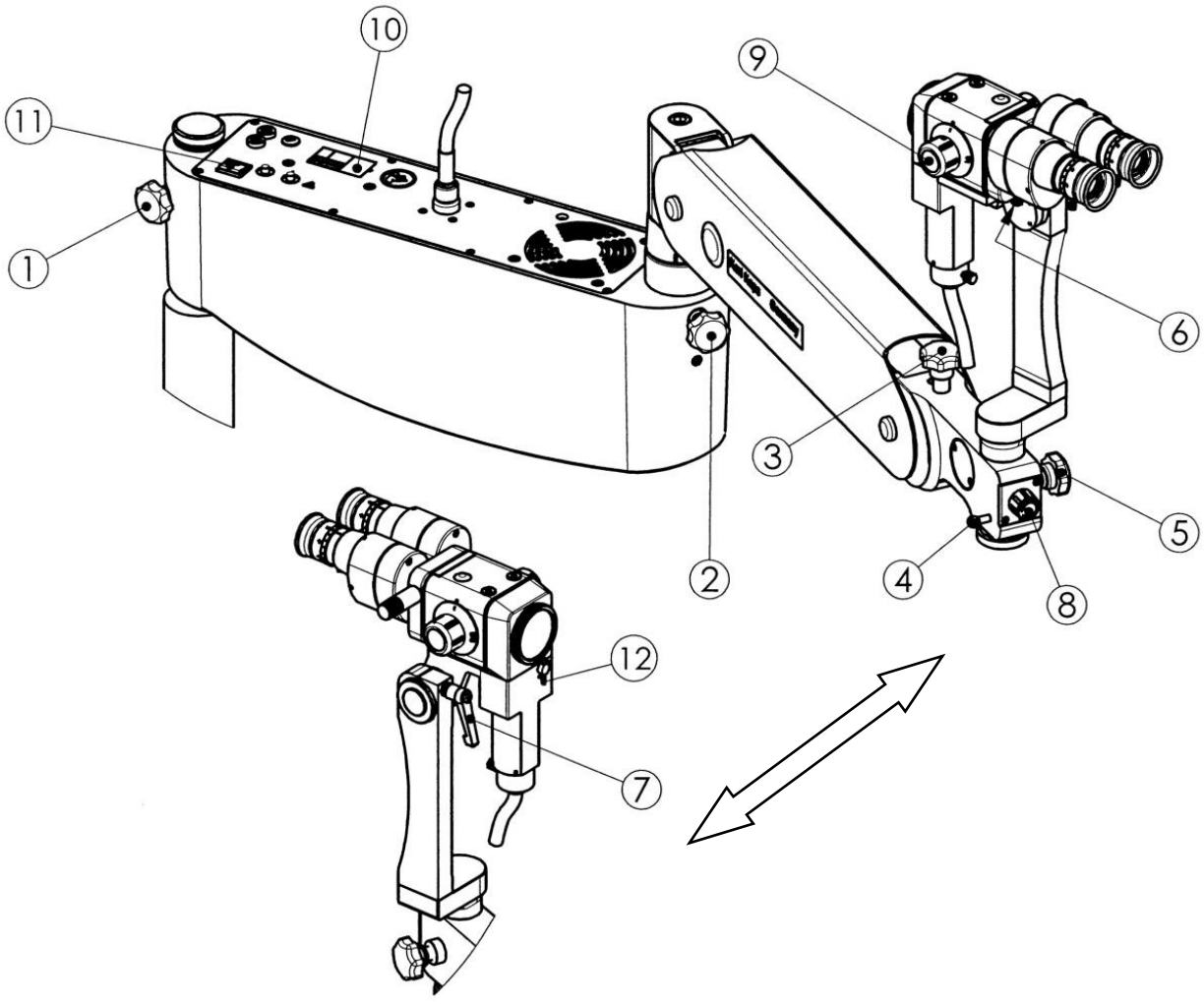

Figure 5

The nameplate (10) must be legible at all times. If the nameplate is not legible, or is missing, a replacement must be sought.

7.3 Medical performance data

The medical performance data pertains to the required medical performance data of the medical device. This performance data is listed in Section **15 Technical description**.

7.4 Additional loads

The load capacity and tipping stability of the systems are aligned to the components in our product range. Only approved components may be installed and used.
The maximum Load of the device is equal to 3,5 kg.

⚠ **Caution**	A load higher than 3,5 kg can cause a tipping of the device.

7.5 Suspension arm adjustments

The weight adjustment of the suspension arm is set at the factory to the requirement on delivery. The suspension arm adjustment may have to be aligned when components are used on or removed from the device head. (Anti) clockwise adjustment of the Allen screw (1) is used for this.

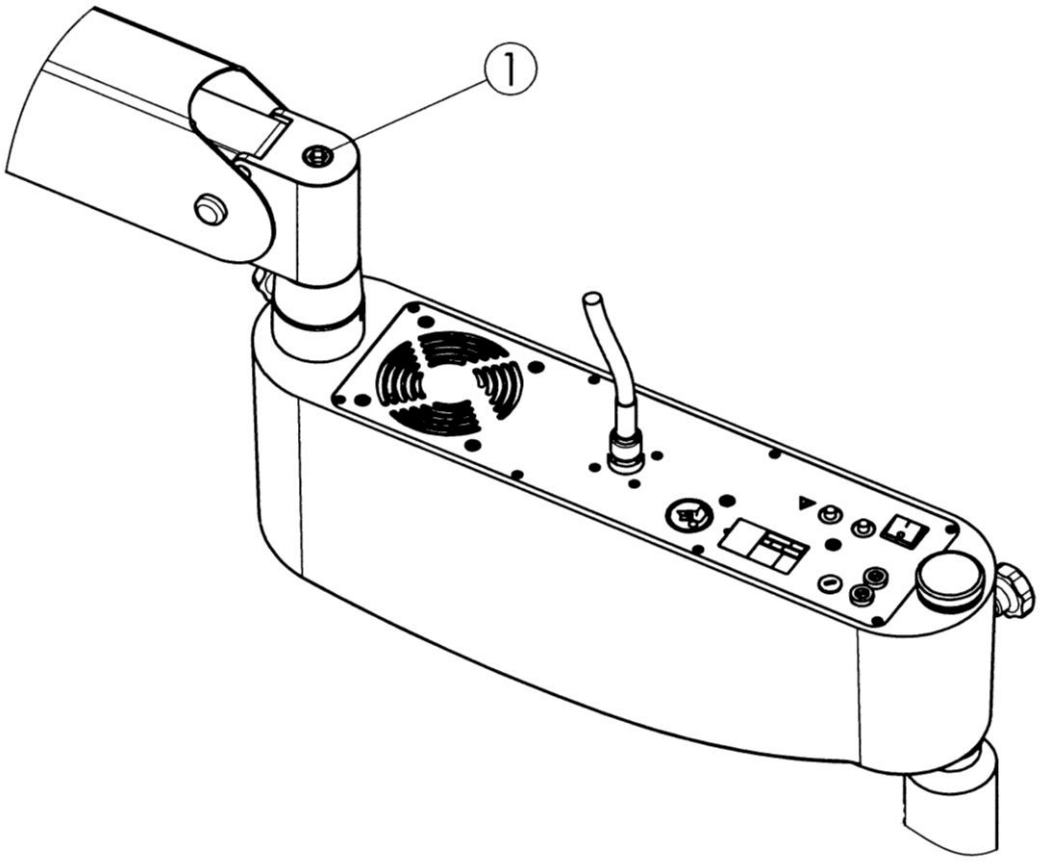

Figure 6

8 Preparation

8.1 Power supply

Use the power lead to connect the device to the local voltage supply.

8.2 Brakes

The clamps are adjusted by tightening/ loosening the star-knob screws (see Section **7.2**). The device clamps must be adjusted so that the degree of free movement satisfies the respective requirements.

⚠ CAUTION	Never fasten the brake of the suspension arm (Pos.3 in Figure 5) when the suspension arm has no load. Never move the suspension arm when its brakes are activated.

8.3 Adjusting eye distance

The eye distance must be set individually for every user.

To do this, move the microscope to the working position and view an object through the eyepieces (2). The eyepieces must be set to Index 0. The object must now be brought into focus by adjusting the working distance. The distance of the eyepieces is now set in line with the lens tube (1) used by turning the knob (3). It must be possible for both eyes to make out the object by the same amount, i.e. the object should be seen as a single 3-dimensional image.

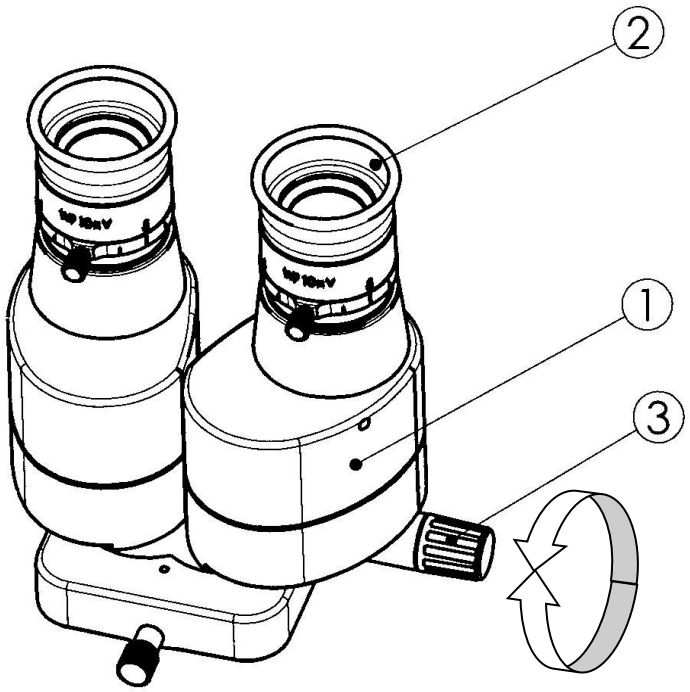

Figure 7

8.4 Focusing

For dioptre adjustment, first undo the clamping screw (4) on the eyepieces (6). Then line up the "Zero" on the dioptre scale (8) of the eyepieces (6) with the index mark (7) and move the microscope towards the object until it appears in focus.
Those wearing glasses and with spherical ametropia for long distances can set the relevant dioptre number on the eyepieces without glasses, and are able to focus as described above.
Ametropes with astigmatic eye failures keep on their glasses for distances, peel back the rubber eye cups (5) of the eyepieces (9) and adjust the dioptre ring of the eyepieces to "Zero". Focusing is then also as described above.
The clamping screw (4) must be re-tightened after the dioptre adjustment.

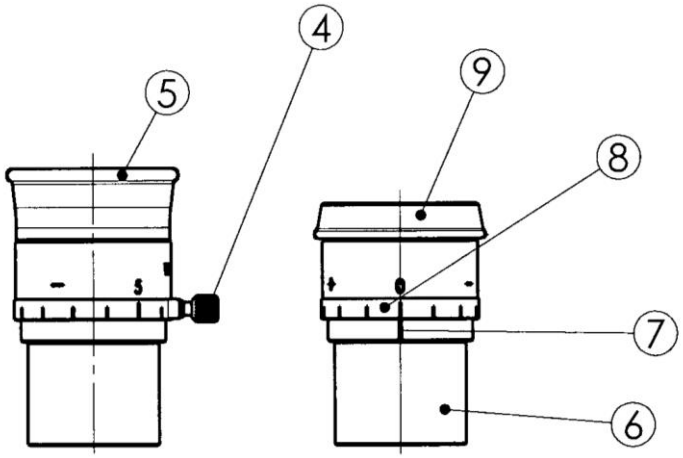

Figure 8

8.5 Checklist

Working through the following checklist prior to every use is a requirement to ensure safe use for patient and user.

Function	OK
Is the device connected to a suitable voltage source?	
Are all parts and accessory parts installed correctly and fully operational?	
Are all cover caps removed?	
Are illumination and brightness control working correctly?	
Is the zoom/magnification unit working correctly?	
All outer parts of the microscope are cleaned and free of dirt and impurities.	
A check must be made in the operation area on whether the sterilisation hood is being used properly.	

9 Operation

9.1 Transport position / rest position (SOM 52 LED only)

The device must be moved into a transport position for safe transportation. For this, the clamps of the axes must be undone and the device moved into the transport position shown in Figure 9.

⚠ WARNING	**The device is at risk of tipping over if not moved into the transport position described.**

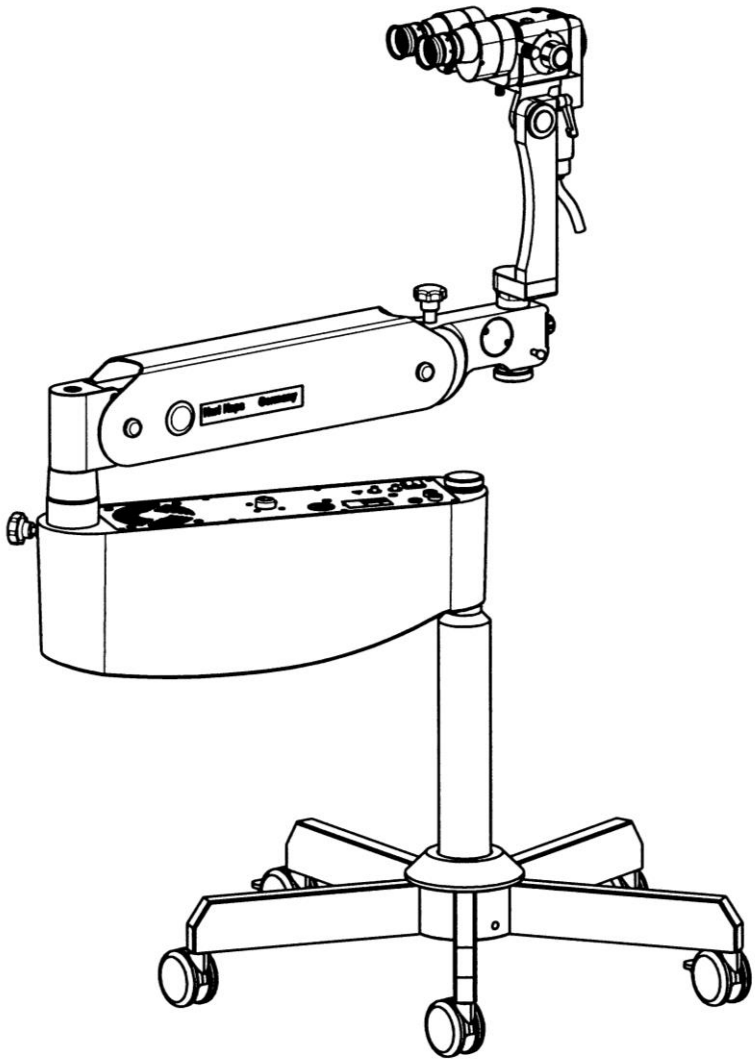

Figure 9

9.2 working position (SOM 52 LED only)

The working position is mainly affected by the angle between the invalid working position and the recommended. For a valid working position, the angle must be greater than 15°. **Figure 10** is showing the invalid working area and the recommended angle, must be avoided. Otherwise the tipping stability is affected.

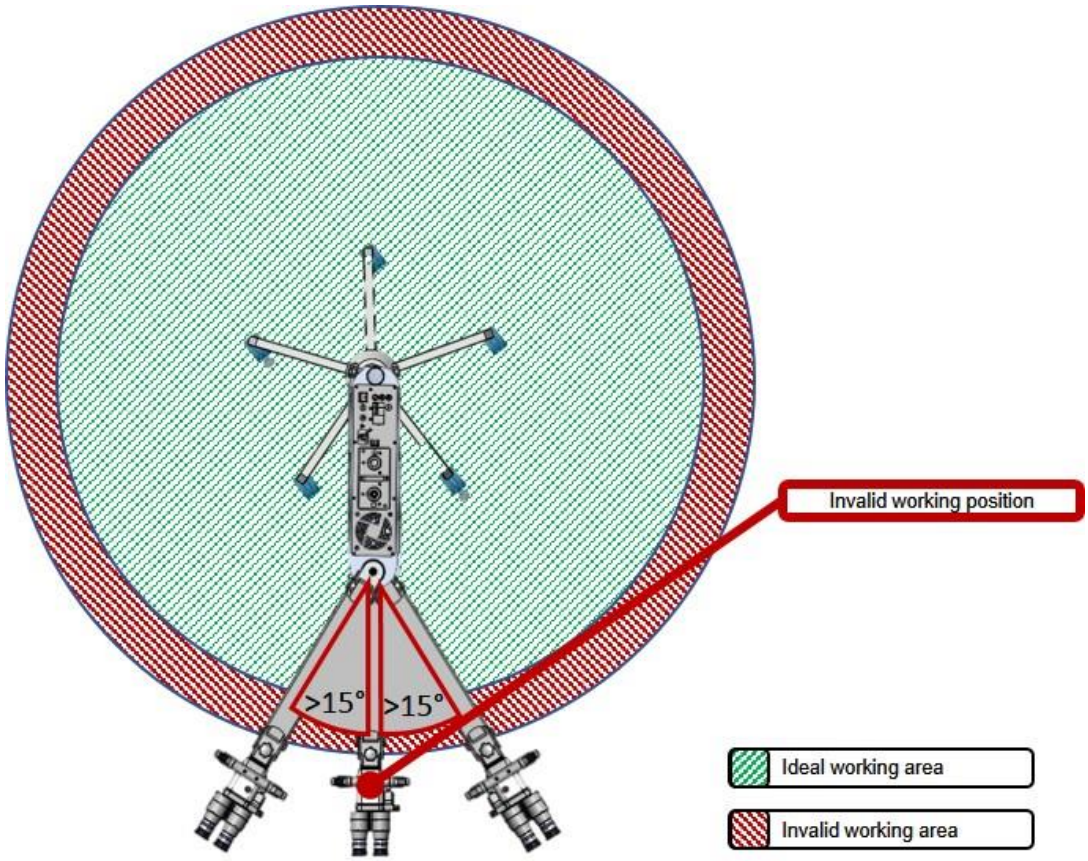

Figure 10

9.3 Replacing objective and eyepieces

The following steps are required to replace lenses and eyepieces (refer to Figure **11**):

- The objective (1) has a screwed socket. Turn to the left to release the objective and to the right to affix it. Only hand-tighten them.
- The eyepieces (2) are inserted. To remove them, they are simply pulled out, and the replacements are inserted.

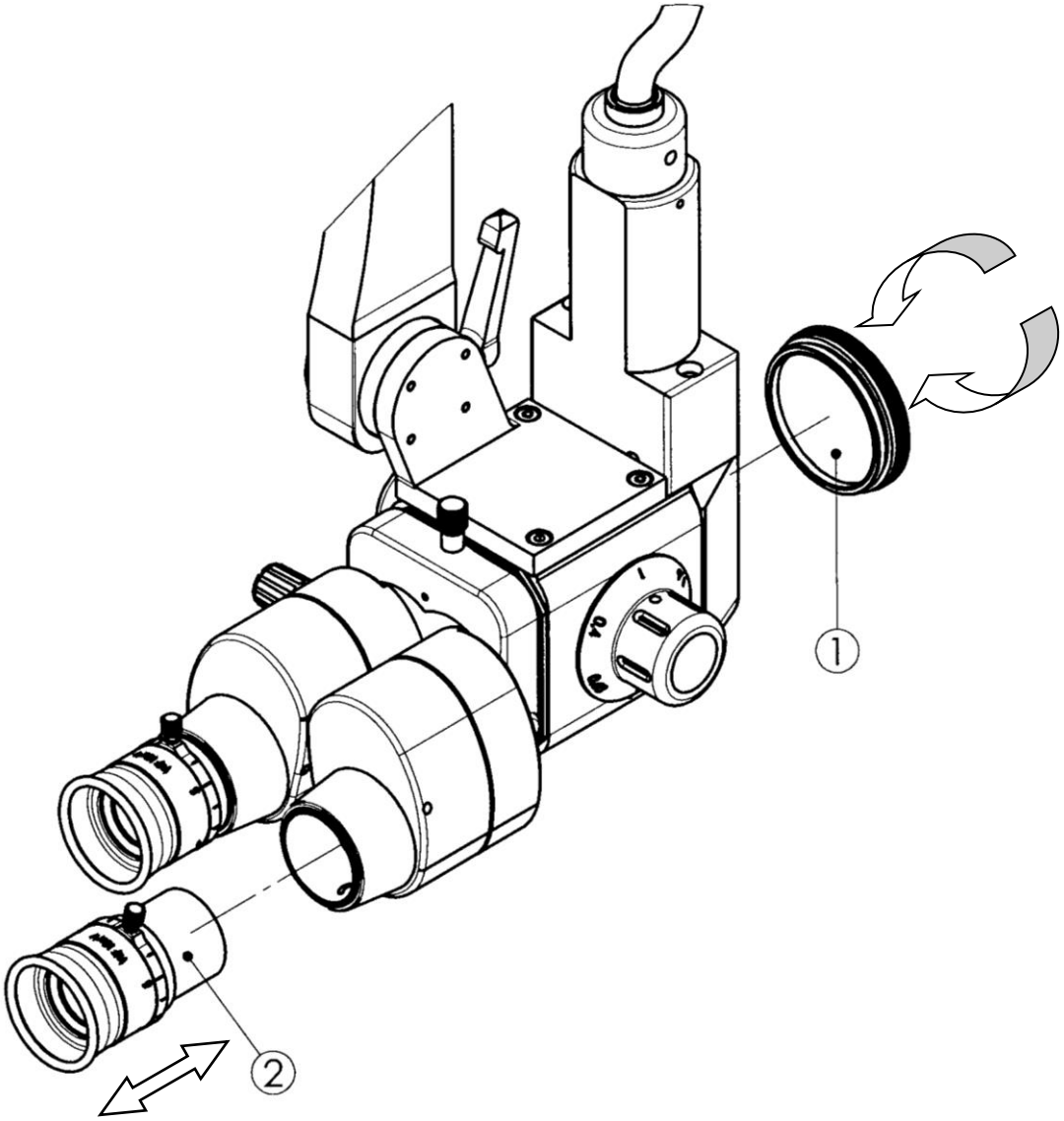

Figure 11

9.4 Switching the device on and off

The main switch (1) of the device is located on the flat side of the swivel arm. The device is ready to use when the green status light (2) is ON.
The red status light indicates overheating of the electronics.
If the red status light (3) is ON, immediately switch off the device and check the ventilation slits. If they are dirty, try to remove the dirt with a brush or slightly moist cloth. Then switch the device back on. If the red status light is still ON, immediately switch off the device and call customer service.

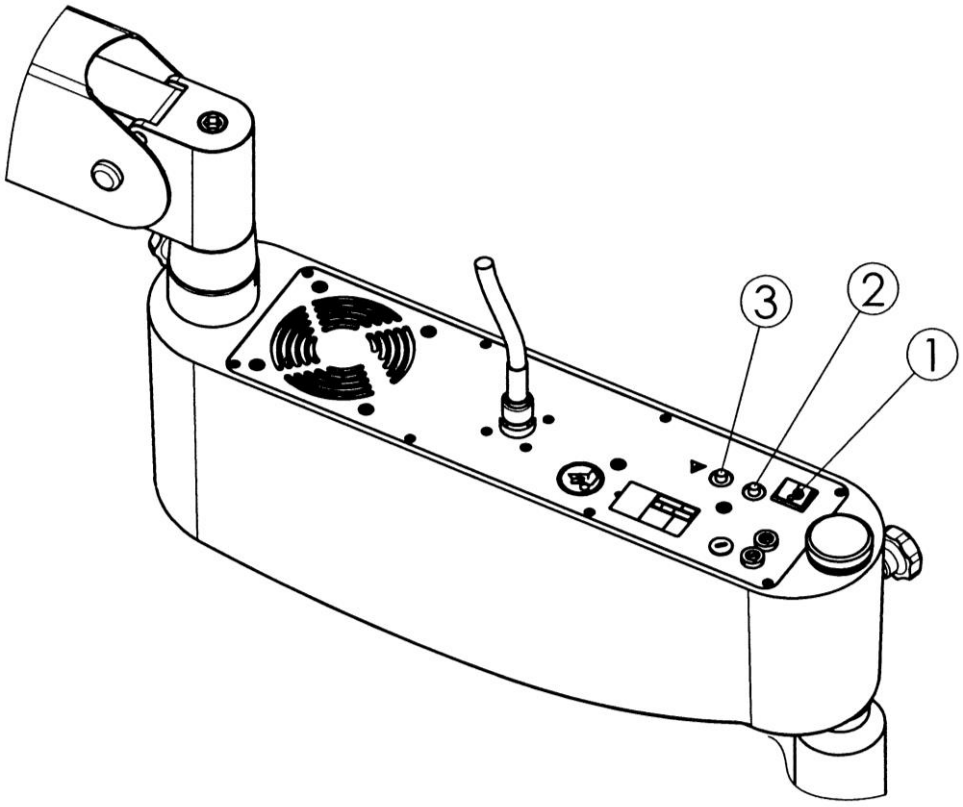

Figure 12

⚠ **CAUTION**	Do not use the device when the red status light is ON as it can result in damage to the electronics.

9.5 Brightness control

Turning the potentiometer (1) enables continuously variable adjustment of the LED brightness to the requirements of the user.

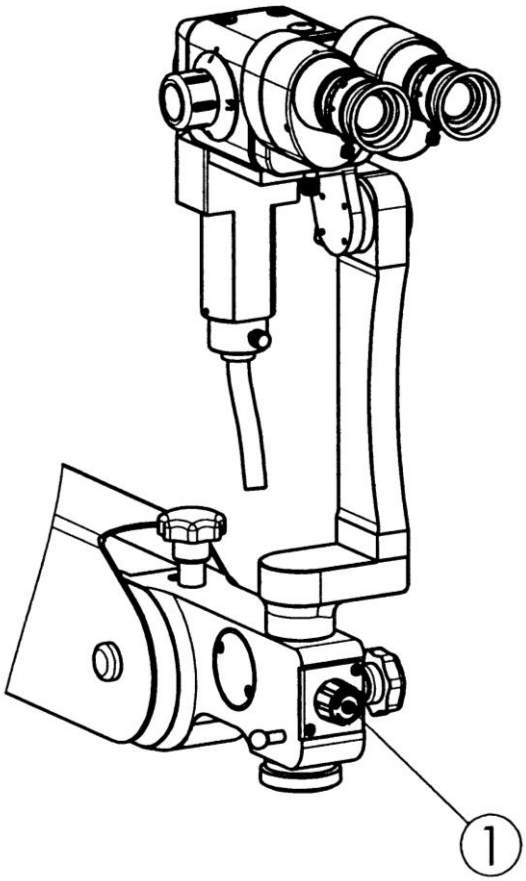

Figure 13

9.6 Magnification adjustment on the changer

Magnification is used to make the finest of structures visible. 3-level (0.63, 1, 1.6) or 5-level (0.4, 0.63, 1, 1.6, 2.5) magnification can be selected depending on model. Turn the knob (1) to set the magnification required. Engaging of the knob at the marking indicates that the magnification has been set correctly.

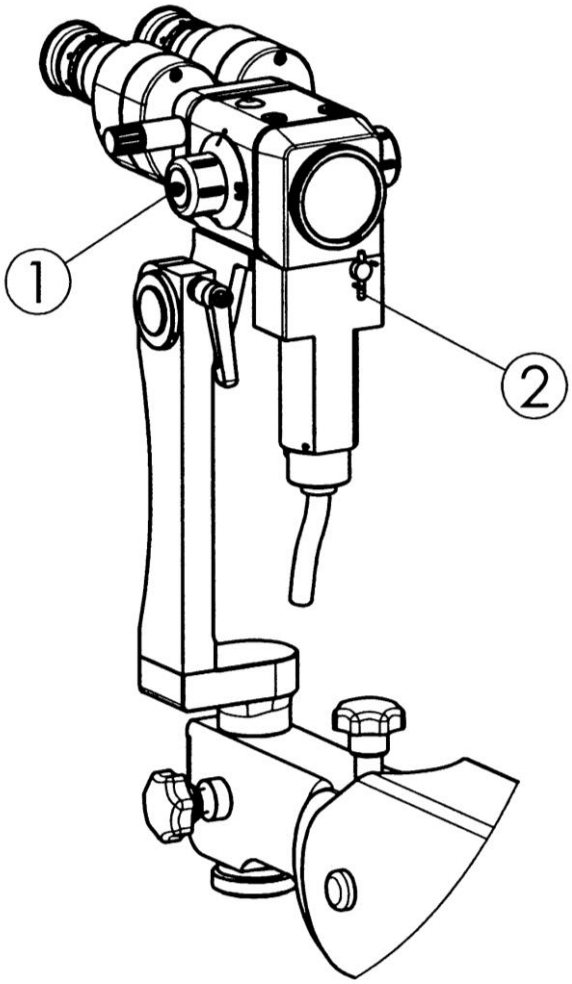

Figure 14

9.7 Swivelling in/out the filter

The device can be fitted with a colour filter as an option. Move the lever (2) to swivel in the colour filter (Figure **14**)

9.8 Removing/exchanging the binocular tube

- Undo the knurled screw (1) and remove the tube (2)

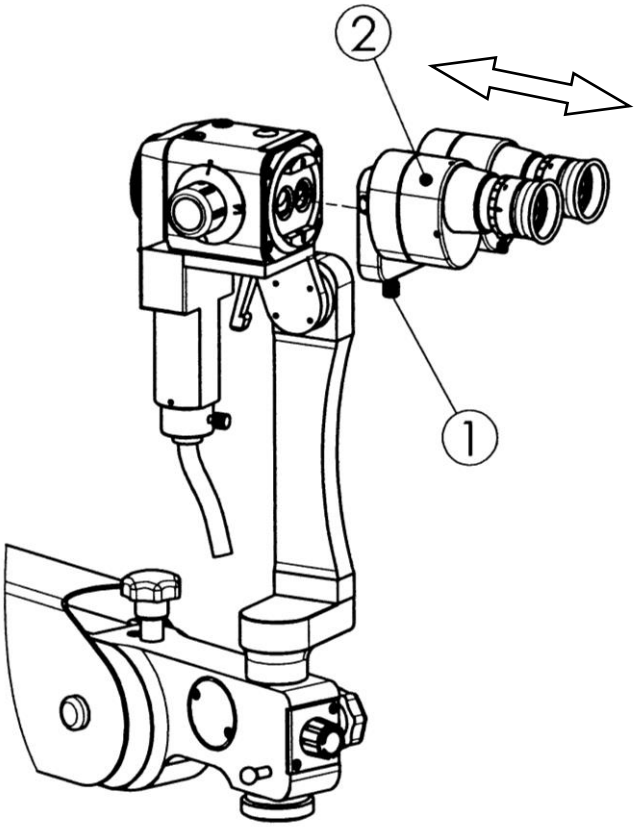

Figure 15

10 Shutting the system down

After every treatment, the device must be cleaned and disinfected depending on application and in accordance with the specifications in **11 Cleaning and maintenance**. The device must then be moved into the transport position described in **9.1 Transport position/ rest position**. This is the optimal idle position when the device is not in use. If the device is not used for longer than 24 hours, putting on the lens covers (supplied) and pulling the protective cover (supplied) over the device are recommended. Similarly, unused accessories should be removed and placed into the storage packaging provided. This prevents damage to the lenses and dirtying of the device.

11 Cleaning and maintenance

11.1 Fuse replacement

Carry out the following steps as in Figure **16**:

- Unplug the mains connector. Insert a screwdriver into the slit of the fuse holder (1) and turn it anticlockwise by 90°. A spring presses the cap up.
- Remove the cap and replace the fuse attached in the cap
- Insert the cap with a new fuse in, press it down and lock it into place by turning the screwdriver clockwise by 90°

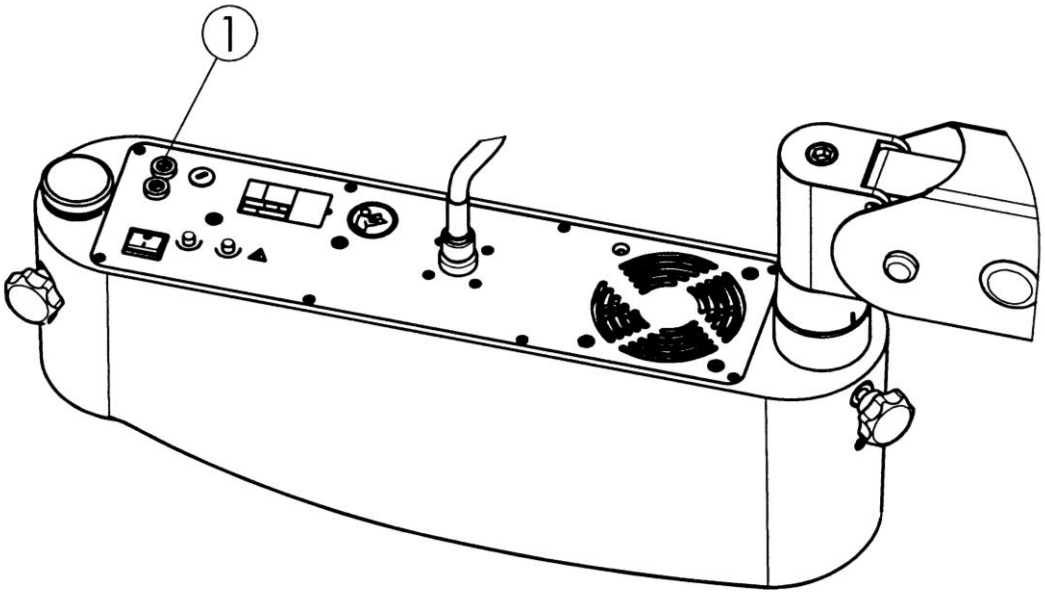

Figure 16

⚠ **CAUTION**	Only replace defective fuses with those having the same ratings (nominal voltage, nominal current and switch-off characteristics).

11.2 Disinfection and sterilisation

Moisten a cloth with antiseptic liquid (such as Sagrotan – P). Wipe as required the parts of the microscope touched most often (such as knobs and hand grips).

For some controls, sterilizable covers are available. We recommend replacing these after 30 sterilization cycles with new ones. The sterilization may be carried out with an autoclave at a temperature of 134 ° C and a pressure of 2 bar.

11.3 Cleaning optical surfaces

Remove coarse dirt particles from outer optical surfaces with a clean, dry hair brush (lens, eyepiece, eyepiece lens). Beforehand, clean the brush in pure alcohol or ether, and allow it to dry. Then moisture a soft cotton cloth with pure alcohol and wipe the lens with a circular motion from the centre of the lens outwards. Breathe on the lens and re-polish it with a dry cotton cloth (cleaning kits suitable for glasses can also be used).
The anti-reflex coats are extremely resistant because they have been hot coated. The coats are not damaged if cleaning is as described above.

11.4 Cleaning painted parts

Moisten a soft cotton cloth with water (to which just a little washing-up liquid has been added) and wipe it over the dirty parts. For any remaining spots, moisten the cloth with pure alcohol or cleaning solvent and wipe the spots carefully.

11.5 Maintenance

The device need not be serviced at regular intervals. The recommendation nevertheless, depending on frequency of use, is to have an inspection carried out by a service centre authorised by the manufacturer. Contact the manufacturer for information on these service centres.

11.6 Replacing LEDs

The stand-out feature of LEDs is their very long service life. Should faults occur with the LED lighting unit however, maintenance may only be carried out by authorised specialists or the factory customer service team.

11.7 Replacing the power lead

The power lead may only be replaced by the manufacturer or a person authorised by the manufacturer.

12 Disposal

User information on disposing electrical equipment:
This symbol denotes products that may not be disposed of in household waste. Proper disposal is to the benefit of us and the environment.
For more detailed information on disposal, please contact the local sales outlet or the manufacturer.

Disposal within the European Union
Please contact the local sales outlet or the manufacturer specified.

Disposal outside the European Union
Please enquire into which disposal regulations are applicable in your country.

13 Accessories

The system is a medical product and has been developed and tested in accordance with applicable standards. Do not use any accessory parts that are not approved for the device or do not satisfy the applicable standards/directives. Please contact the manufacturer in the event of doubt.

14 When faults occur

The device works extremely reliably when used as intended. Should faults occur nevertheless, please follow the instructions in Section 15.1.

14.1 Summary of potential faults

Fault	Cause	Fault Rectification
No microscope lighting	Mains switch in OFF position	Move the switch to "ON"
	Mains switch of lighting unit in OFF position	Move the switch to "ON"
	Mains cable not connected to socket	Plug in the cable
	LED defective	Send in the lighting unit
	No voltage supply to the lighting unit	Set the contacts correctly via the plug connectors
	In-house power supply outage	Have the electrical installation checked
System cannot be positioned with the foot rollers or can only be moved with high level of exertion	One of more brakes applied	Disengage the brake
	Rollers dirty	Clean the rollers
	Roller defective	Have the roller replaced by Service
Floating arm can only be tilted with difficulty, or not at all	Brake too tight	Loosen the brake from the star knob
Floating arm drops slowly	Pressure spring defective	Have the floating arm corrected by Service
	Load too high	Align the pre-tension or replace the spring arm
Swivel arm can only be moved with difficulty, or not at all	Brake too tight	Loosen the brake from the star knob
Microscope head can only be moved with difficulty, or not at all	Brake too tight	Loosen the brake from the star knob
Only one optical channel visible through the lens tube	View not set correctly to the eye distance	Adjust the view (eye distance)
Vignetting visible in image	Changer to intermediate position	Use the knob to set the changer to the magnification required until the position engages noticeably
Uneven focus in right and left views	Incorrect dioptre setting	Adjust the dioptre as per the instructions
Image foggy	Eyepieces or lens dirty	Clean the lens as per the instructions
Dirt in image	Eyepieces, lens or light guide dirty	Clean the lens as per the instructions
Sudden drop in light power	The lighting is overheated	Switch the device off. Clean the ventilation openings of the lighting unit with a slightly moist cloth. Notify the manufacturer if the fault still occurs.

15 Technical description

15.1 Technical details

Model	SOM 52 LED, SOM 42 LED
Dimensions and weight	
Dimensions of SOM 52/SOM 42	See Figure **17**/ Figure **18**
Weight of SOM 52/SOM 42	Approx. 63 kg / approx. 24 kg
Function data	
Function displays	Status display on ON/OFF switch
Supply connectors	Mains connector, 1-phase AC
Isolation	Power lead
Operation	All controls are mechanical. Refer to the description for the mode of operation.
Operational information	
Place of use	Enclosed rooms, not in oxygen-rich environments
Protective class	I, protective earth conductor
Equipment protection	IP 20
Duty type	Long-term usage
Electrical safety	DIN EN ISO 60601-1:2005
Mains voltage	100 ~ 240 V AC
Mains frequency	50 ~ 60 Hz
Fuse	2x T2,5A H
Illumination type	LED
Enviromental conditions	
Operational ambient temperature	+10°C to +35°C
Operational ambient humidity	30% to 85%
Air pressure	800 hPa to 1060 hPa
Storage ambient temperature	-20°C to +70°C
Storage ambient humidity	Maximum 100%
Regulatory information	
Classification to (EU) 2017/ 745	I (Rule 13 Annex VIII)
Protection class	1
Manufacturer	Karl Kaps GmbH & Co. KG / Asslar
CE mark	CE

15.2 Dimensions

15.2.1 SOM 52 LED

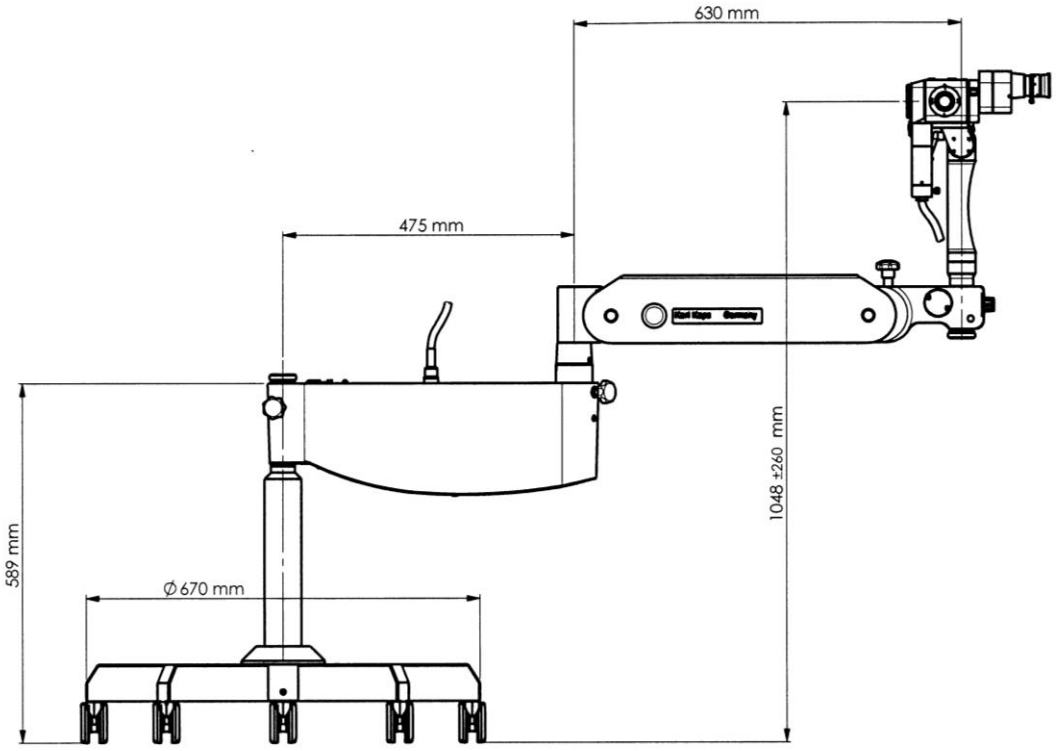

Figure 17

15.2.2 SOM 42 LED

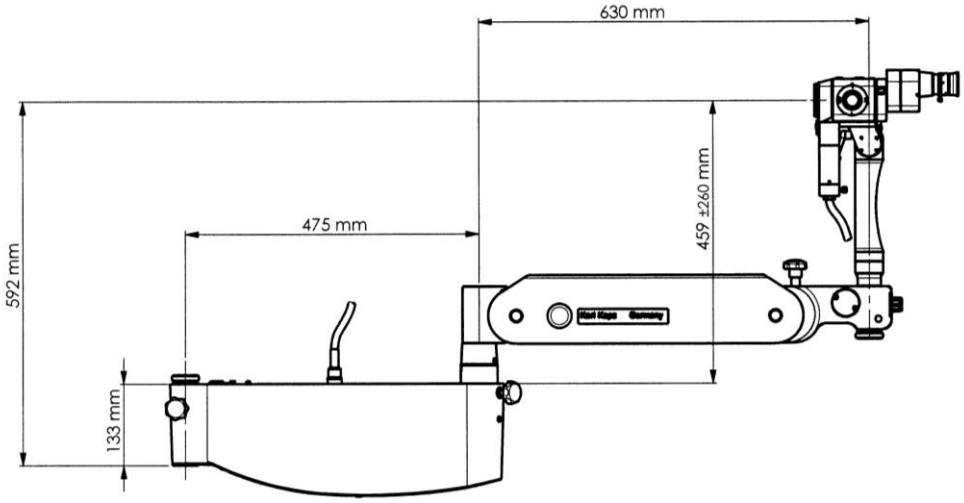

Figure 18

16 Warranties

We provide a warranty for the respective period stipulated legally from the time of transfer of the product to the purchaser. Complaints due to incomplete or incorrect delivery, and objections due to evident deficiencies, must be communicated immediately after receipt of the delivery, and immediately after their discovery in writing in the event of other deficiencies.
The purchaser must preserve right of recourse against third parties (such as for a factual report in the event of damage during transit). Processing or further sale, or combination or mixing, shall be deemed to constitute unconditional approval. In the event of notice of defects being submitted in due time, we shall accept liability within the framework of the provisions set out hereinafter. Our liability due to deficiencies (warranty) extends to providing products free of defects to the degree possible in accordance with best available technology. Modifications to design or implementation carried out by us prior to delivery do not provide entitlement to complaint or objection.
In the event we have warranty claims against our suppliers, our liability is fulfilled through assignment of these claims to the purchaser who already agrees to accept this assignment for this case.
If a claim cannot be asserted against the supplier or if the supplier refuses to accept any liability in respect of the purchaser, our liability shall be limited to supplementary performance, i.e. delivery of a substitute or repair at our discretion. The purchaser must release the defective goods or parts replaced to us.
If supplementary performance fails or we are not in a position to deliver, the purchaser is entitled to withdraw from the contract or lower the purchase price. All liability restrictions are not applicable to consumer goods or batteries, or improper use or installation of the device.
Any entitlement of the purchaser to reimbursement of costs incurred in conjunction with the assertion of claims against a supplier shall in all cases be excluded if any actions triggering the costs, specifically the initiation of legal proceedings, were not agreed with us beforehand.

All warranty claims must be directed to the organisation that sold you the device. In special cases, please contact:

Karl Kaps GmbH & Co. KG

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