

COLPOSCOPE MK-300

Operation Manual



COLPOSCOPE MK-300



Operation Manual

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1. Safe Usage Guidelines



ATTENTION. Before using this product, please read this manual carefully.

This manual contains important safe usage guidelines and technical maintenance of the colposcope MK-300 (hereinafter referred to as colposcope). To ensure operational safety, follow the instructions and warnings contained in this manual.



ATTENTION. In case of using colposcope for purposes that are different from described in this manual, there is a risk of getting injuries and material damage.

This manual does not explain the clinical procedures of colposcopy. The personnel using the colposcope must have an appropriate level of qualification and training, or use colposcope under the supervision of a doctor with an appropriate level of qualification.

This manual must be kept in a safe and accessible place, so that the personnel using the colposcope always have access to it.

If you have any questions related to the operation, adjustment or maintenance of the colposcope, please contact the manufacturer or the authorized representative of the manufacturer.

Manufacturer:

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The company Science & Engineering Center Scaner, Ltd. develops and produces medical devices in accordance with the quality management system ISO 13485:2016. The entire production process is subject to constant quality inspection and undergoes a periodic check by inspection audits.

The colposcope MK-300 corresponds to the provisions of the European Directive of Medical Devices 93/42/EEC and the Technical Regulations on Medical Devices of Ukraine.

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ТОВ "Науково-інженерний центр "СКАНЕР"
Україна, 18019, Черкаси, вул. Смілянська 122/1

Проектування та розробка, виробництво, реалізація та сервісне обслуговування кольпоскопів, мікроскопів і хірургічних бінокулярних луп

Для цього сертифікату qualityaustria підтримуватиметься щорічними наглядовими аудитами і ресертифікаційними аудитами, які проводяться кожні три роки.

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Science & Engineering Center SCANER, Ltd.
122/1 Smilianska st., 18019 Cherkasy, Ukraine

Development, design, production, distribution and service of Colposcopes, Microscopes and Surgical binocular loupes

The validity of the qualityaustria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

This qualityaustria certificate confirms the application and further development of an effective **QUALITY MANAGEMENT SYSTEM** complying with the requirements of standard **ISO 13485:2016**
Medical devices - Quality management systems - Requirements for regulatory purposes

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Ing. Andreas Aichinger, MSc
Specialist representative

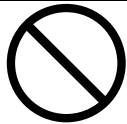
The current validity of the certificate is documented exclusively on the Internet under <http://www.qualityaustria.com/en/eact> EAC: 19

1.1. Symbols used in the manual

The text with warnings and mandatory requirements for safety is marked with graphic symbols and words: ATTENTION or PROHIBITED.



ATTENTION. It is necessary to pay special attention to the instructions in order to avoid the mistakes during operation.



PROHIBITED. Actions, which are strictly prohibited and pose a danger to human health or may damage the device.

1.2. Operating conditions

The colposcope is intended for use in medical institutions of health. According to the operating conditions the colposcope is intended for work at ambient temperature from +10°C to +40°C, relative humidity from 30% to 75%, and atmospheric pressure from 700 hPa till 1060 hPa.

Depending on the potential usage risk in medical practice, the colposcope belongs to the class I according to DSTU (National Standard of Ukraine) 4388 (Class I, Medical Device Directive 93/42/EEC).

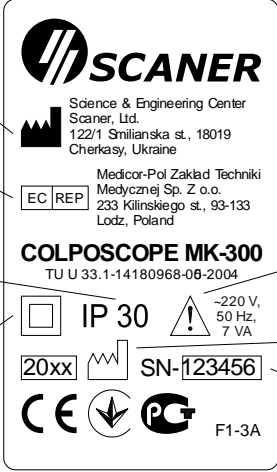


ATTENTION. Avoid getting any liquid inside the colposcope.



PROHIBITED. To keep and use the colposcope in places with prolonged exposure of direct sunlight, as well as with impact of X-ray beams or strong electromagnetic radiation.

1.3. Marking and symbols



A symbol indicating the name and address of the manufacturer, who is responsible for the device. According to DSTU EN ISO 15223-1

The symbol indicating the name and address of the authorized representative in the European Union According to DSTU EN ISO 15223-1

A protection degree symbol of electrical devices. Protection against penetration of the tool covering, wires etc. with diameter or thickness > 2.5 mm and size of solids > 2.5 mm. According to DSTU EN 60529

A device symbol of class II. The device has a double reinforced insulation – the conducting parts are provided with additional (to the operational) protective insulation. Grounding connection is prohibited. According to DSTU EN 60601-1-1

A symbol "Attention! Refer to the accompanying documents" DSTU EN 60601-1-1, DSTU EN ISO 15223-1

A symbol indicating the date of the device manufacture. According to DSTU EN ISO 15223-1

A serial (factory) number of the device. According to DSTU EN ISO 15223-1

1.4. Warnings and cautions

When assembling, operating and maintaining the colposcope, follow the warnings and cautions below. This information should be updated with warnings and cautions given in each chapter



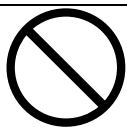
ATTENTION. Before operation, make sure that the colposcope is in good working condition.



ATTENTION. For safety reasons the continuous work time of the colposcope (work of the illuminator) should be no more than 4 hours with following break for 30 minutes at least.



ATTENTION. The colposcope connection to the single-phase AC mains with voltage of 220 V is carried out only with electric cable from the supply kit.



PROHIBITED. To disconnect and disassemble any parts of the colposcope, other than specified in this manual.



PROHIBITED. To fully unscrew and remove the force adjustment knob and the movement adjustment handle of the colposcope moving parts during its operation.



ATTENTION. Each moving part of the colposcope has its limited range of motion. Do not try to increase this range by moving the colposcope beyond these limits with excessive force.



ATTENTION. Ensure that the electrical cable plugs are firmly fixed in the appropriate sockets during work with colposcope, and the cables do not get into the moving parts of the device and do not wrap around during manipulations and displacements.



PROHIBITED. To look into the illuminator of the colposcope when it is on, this can cause damage to the retina.



ATTENTION. Before cleaning and disinfection of external surfaces it is necessary to turn off the colposcope from the power source.

2. The field of use, design and appearance

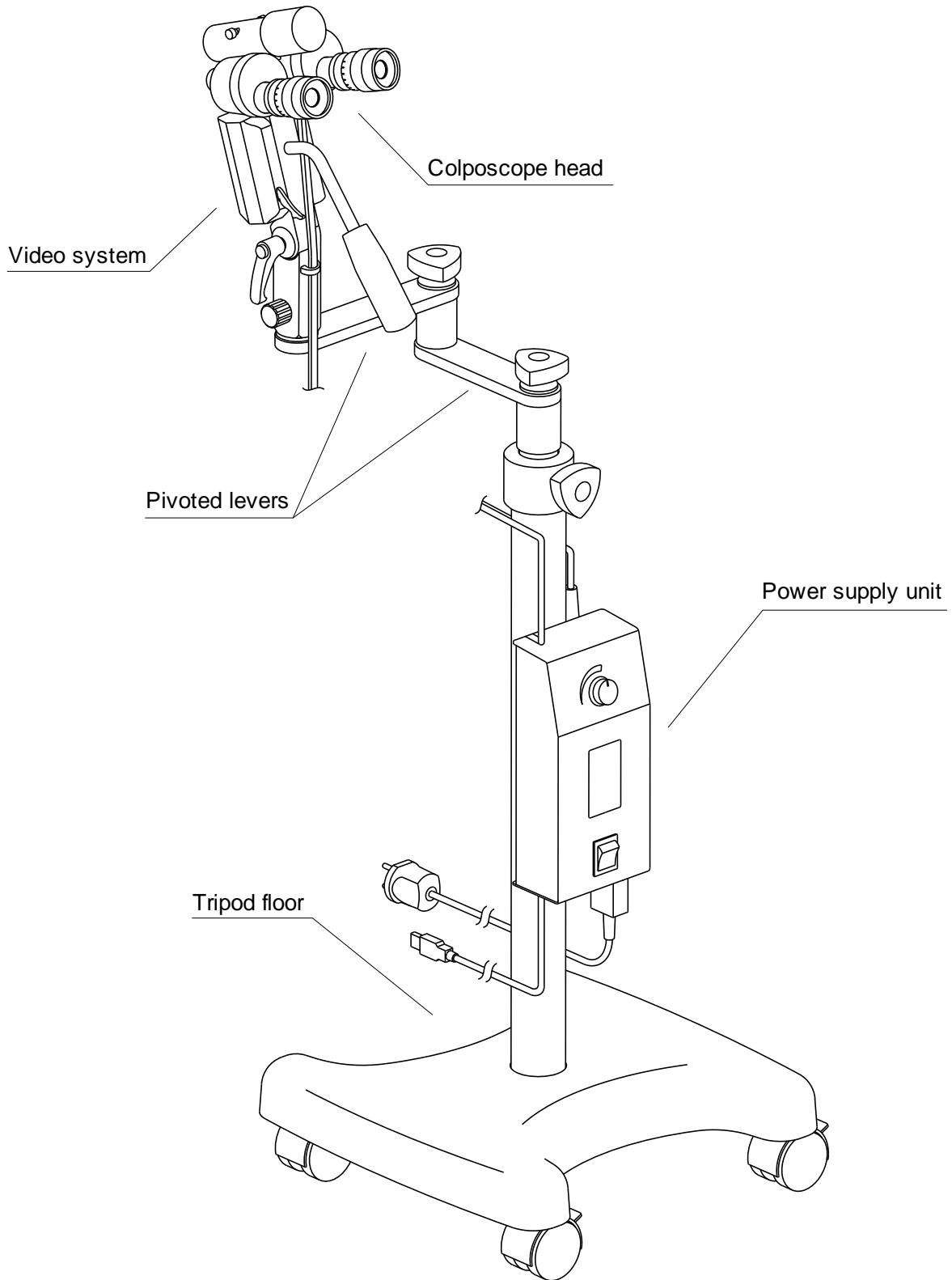
The colposcope MK-300 is a medical device intended for stereoscopic observation with optical magnification by a non-contact method: of the vagina, cervix and the lower third of the cervical canal during gynecology and oncogynecology research. The construction of the colposcope has all necessary moving elements and a large number of freedom degrees that allows focusing smoothly and fixing securely the colposcope head at the observation object. The colposcope is mounted on a tripod floor with self-aligning rollers which enables free movement of the device across the floor.

The colposcope field of use: gynecology and oncogynecology.

The colposcope is required for:

- observation under optical magnification the condition of the epithelium of cervix, vagina and vulva;
- identification of the location and lesion borders;
- differentiation of benign changes from suspicious regarding the malignancy;
- a target cytoscemes and biopsy that essentially increase the informativeness;
- medical treatment under optical control (operational colposcopy);
- monitoring the treatment results;
- dynamics assessment of the process development when choosing a conservative tactics of patient management.

The colposcope can be supplied with a video system intended for digital photo and video documentation.



2.1. Tripod floor

Tripod floor (hereinafter referred to as tripod) is a mobile base on 4 self-aligning rollers. The rollers of the tripod have a locking feature rolling to prevent spontaneous movements.

2.2. Power unit

The power unit of the colposcope provides the LED illuminator with stabilized constant current. The power unit is mounted on the tripod floor and can be dismantled.

2.3. Colposcope head

The colposcope head consists of:

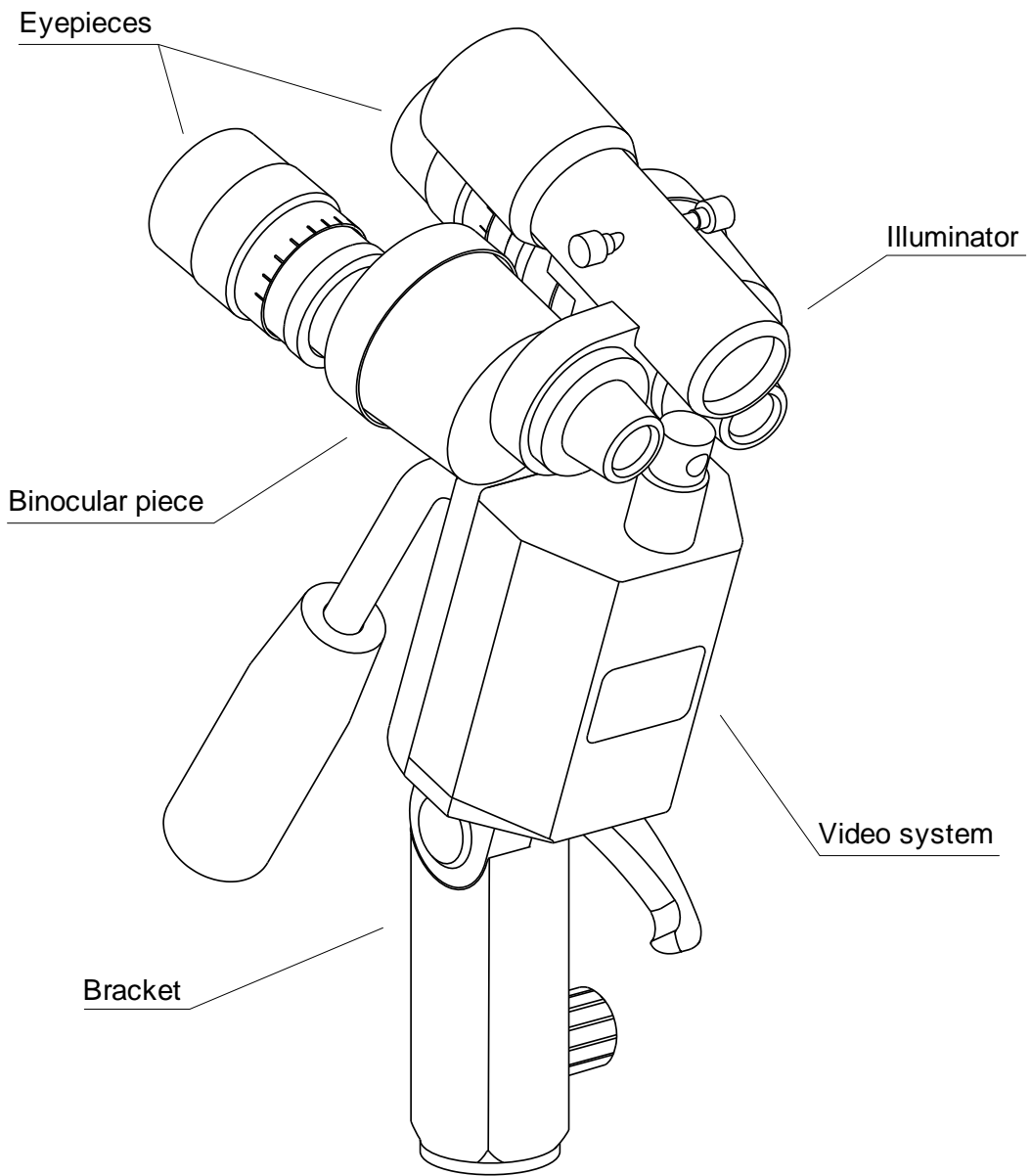
- binocular piece with eyepieces;
- illuminator;
- video system;
- bracket.

The binocular piece consists of two microscopes, the optical axes of which are arranged at an angle and converge in the plane of the objects at a distance of 250 mm from the lens (конвергентное расположение оптических осей). The binocular piece has a mechanism of interpupillary distance variation (hereinafter referred to as interpupillary distance) between the eyepieces in the range from 56 mm to 74 mm.

The eyepieces have a mechanism for changing dioptries within +5 -5 D, for each eyepiece. Diopter correction enables doctors to work with ametropia without glasses.

Illuminator is designed for coaxial illumination of the object. The optical system of the illuminator forms in the observation plane a bright, even and unflickering light spot with clear borders from the integrated LED source. The illuminator has the possibility of the introduction of green filter intended to enhance contrast of the blood vessels.

The video system is intended to view a colorful image of the observed area at the computer screen in real time, as well as video recording and taking high resolution snapshots (1920x1080).



3. Complete set

Colposcope head	1
Colposcope video system MK-300: <i>(may not be supplied, at the customer's request)</i>	
- digital video system	1
- additional USB cable of (5 m) <i>(only for export, or at the request of the customer)</i>	1
- software for colposcopic diagnosis MEDVisor-EVA	1
- the protection key for the software	1
- the user manual for software MEDVisor-EVA	1
Power unit	1
Tripod floor	
- stand	1
- casing	1
- mobile base	1
Network cable	1
Set of spare parts and accessories:	
- fuse	2
- screwdriver	1
- allen key	1
- protective case	1
Operation Manual	1
Passport	1
Packaging	1



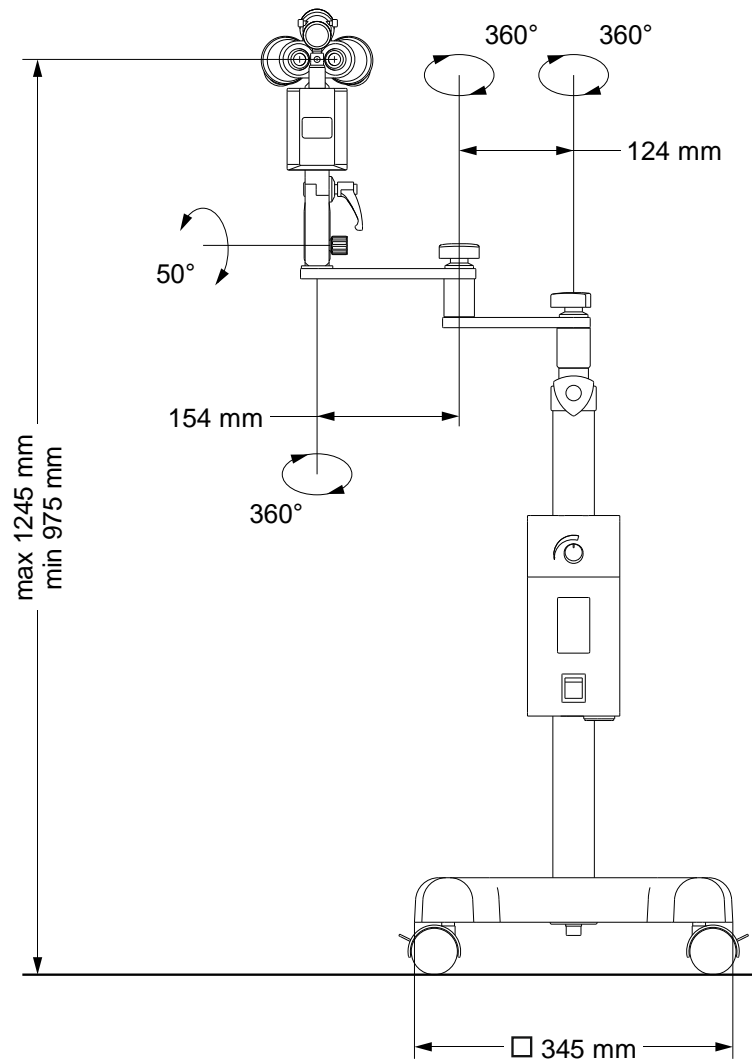
ATTENTION. Before starting the installation and operation of of colposcope, the availability of all components in the supply kit must be checked. In the absence of any supplied component, please contact the supplier.



ATTENTION. Ensure that there is no possible damage of the colposcope components associated with transportation, such as: constrained deformation, holes and cracks, breach of lacquer coating.
If you find damage, contact the supplier.

4. Specifications

Magnification, x	10 ^{+0,5}
Field of view, mm	20 ^{+1,0}
Resolution in the object space, lines/mm, not less	85
Working distance, mm, not less	250
The eyepiece diopter movement, D	+5 -5
The range of interpupillary distance variation, mm	from 56 to 74
The diameter of the illuminated field of view, mm, not less	25
Maximal illuminance in the object place, lux, no less	60 000
Power supply voltage from the single phase AC current with frequency of 50 Hz, V	from 90 to 250
Power consumed by the colposcope, VA, not more	7
The colposcope weight, kg, not more	18.5



5. Mounting and installation

Before the start of device mounting, it is necessary to extract all its components from the transport container and remove the packaging material.

Use the tools from the supply kit (spare tools and equipment) for the colposcope mounting and installation.



ATTENTION. Before starting the installation and operation of of colposcope, the availability of all components in the supply kit must be checked. In the absence of any supplied component, please contact the supplier.



ATTENTION. Ensure that there is no possible damage of the colposcope components associated with transportation, such as: constrained deformation, holes and cracks, breach of lacquer coating. If you find damage, contact the supplier.

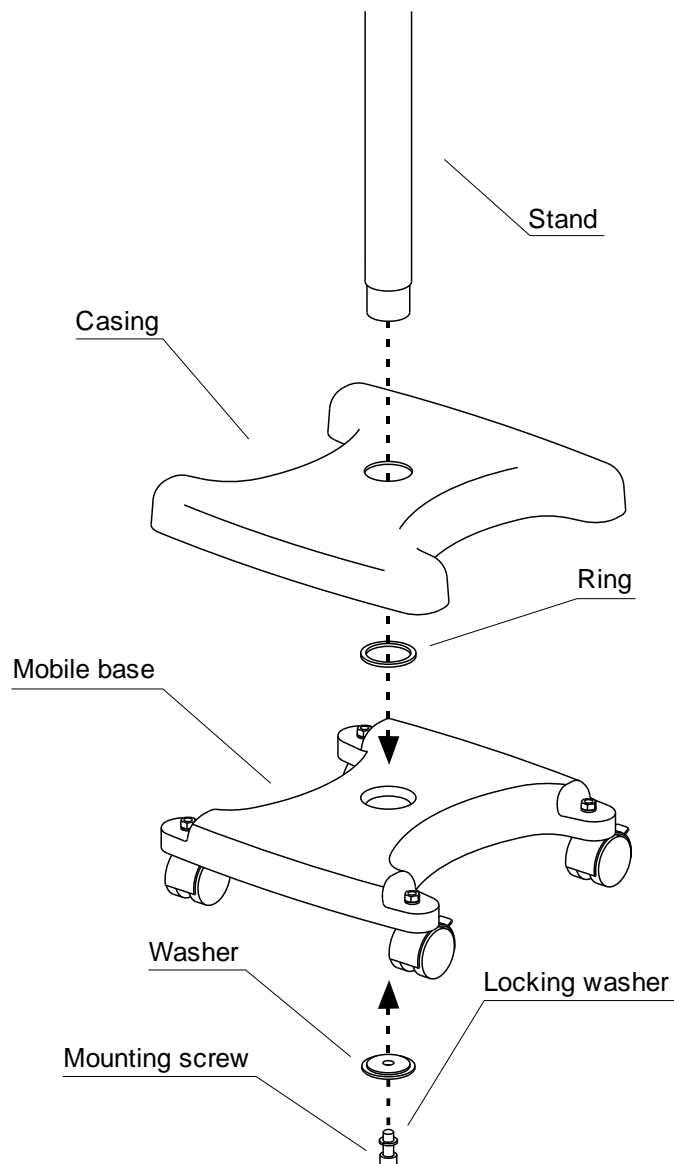
5.1. Mounting of the tripod floor

1. Unscrew from the holder a fastening screw, washer and locking washer by an Allen key from the supply kit.
2. Remove from the holder the fastening screw, the locking washer, the washer and the ring.
3. In turn insert the holder through the hole in the casing, the ring and the hole in the mobile base, as shown in the figure below, avoiding bumps and drops.



ATTENTION. The mobile base on the rollers is very heavy! The mounting of the tripod must be carried out with the help of several people.

4. Insert the fastening screw through the locking washer and the washer, then screw it into the threaded hole of the holder from the bottom of the base, until it stops completely.
5. Place the assembled tripod on the floor.

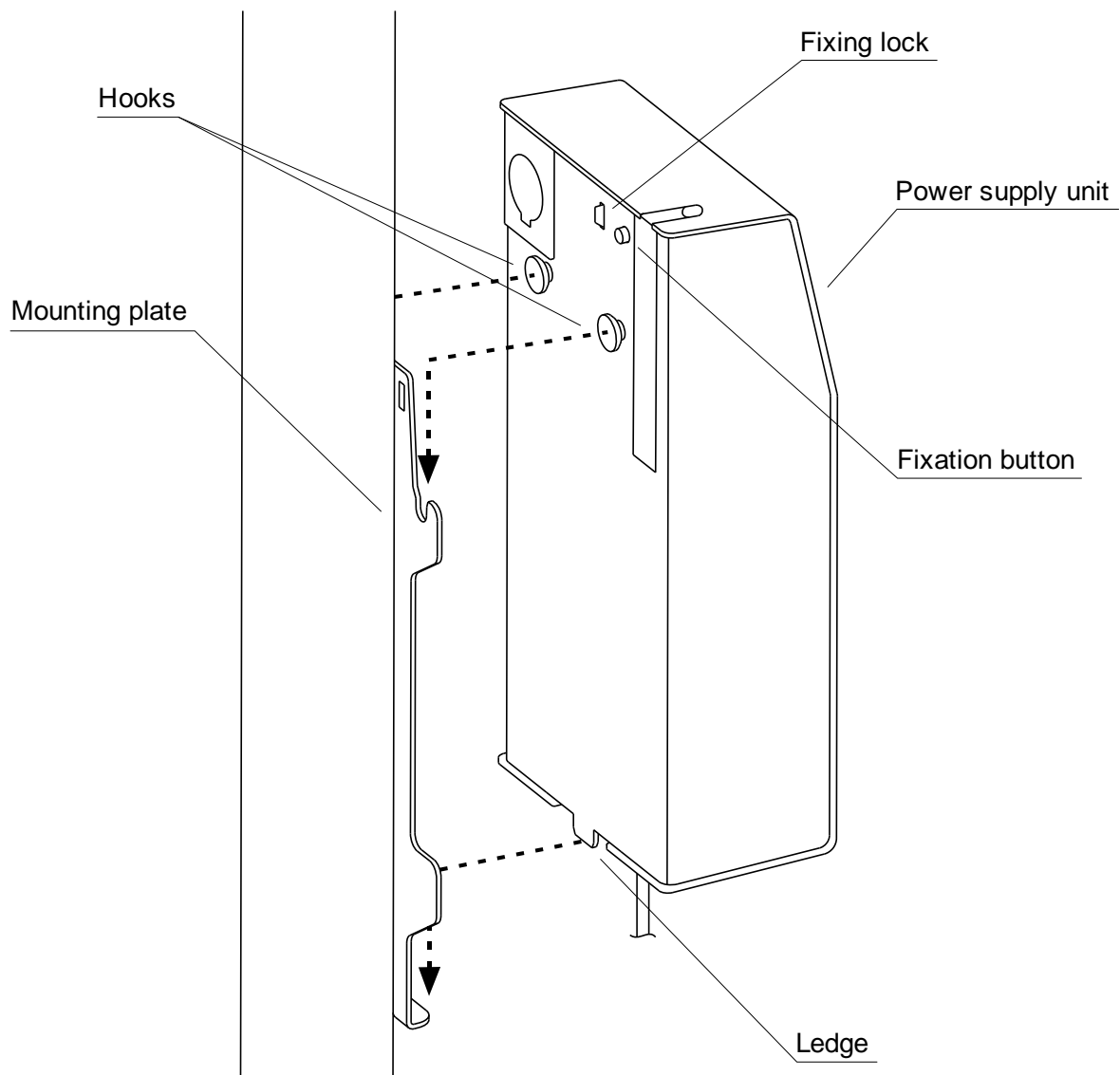


5.2. Power unit installation

1. Position the power supply unit relative to the mounting plate on the stand so that the hooks and ledge on the casing of the power supply unit were a little higher than the corresponding grooves on the mounting plate.
2. Firmly press the power unit to the mounting plate and lower it down until the click of the fixing lock.
3. Ensure that the installation and fixing of the power supply unit are reliable.

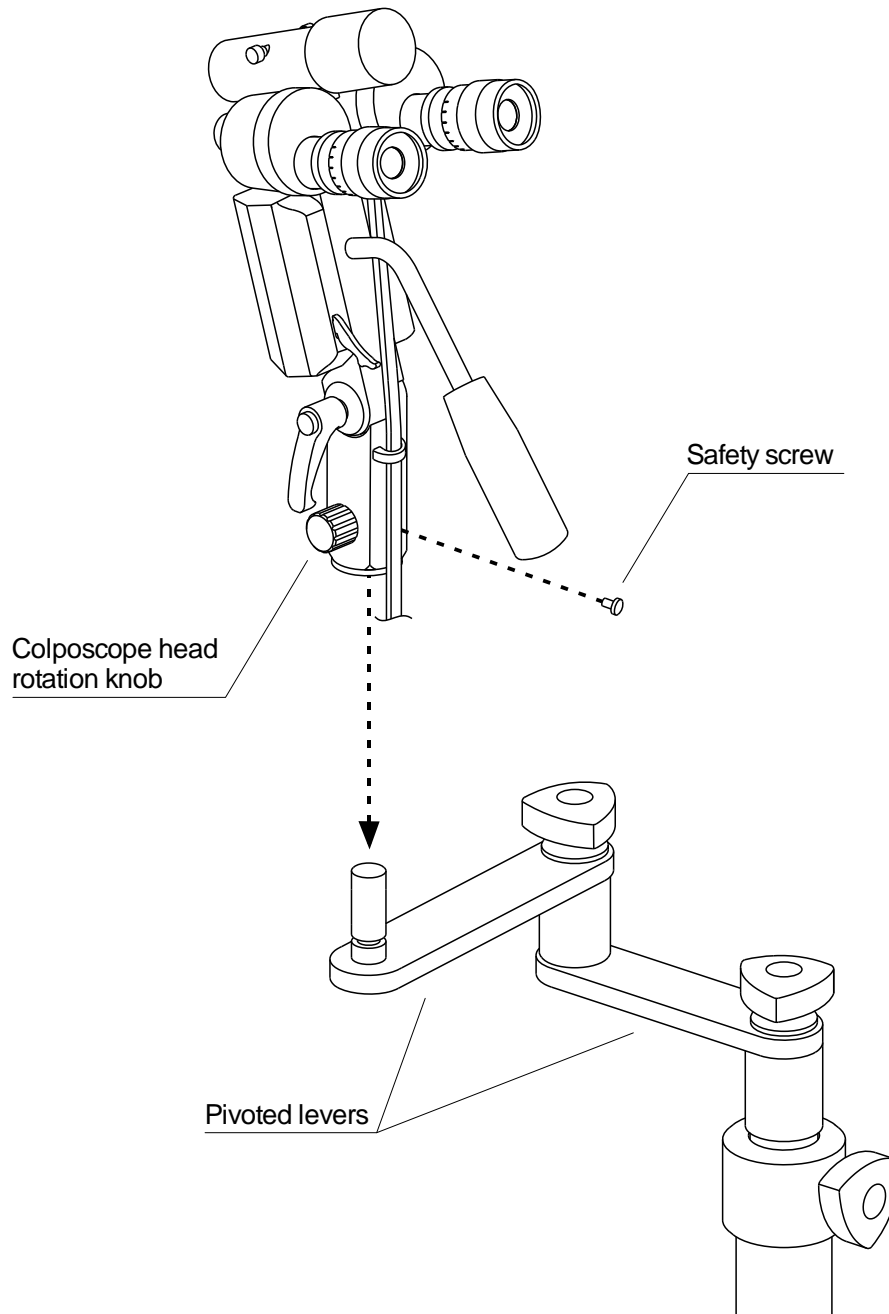


ATTENTION. If necessary, remove the power supply unit, and push it up relative to the mounting plate, holding down the fixation button.



5.3. Installation of colposcope head

1. Remove the safety screw and the colposcope head rotation knob from the bracket.
2. Install the bracket on the swivel arms axis.
3. Tighten the safety screw and the colposcope head rotation lock knob in the bracket.



5.4. Connecting the cables



ATTENTION. The colposcope connection to the single-phase AC mains with voltage of 220 V is carried out only with electric cable from the supply kit.

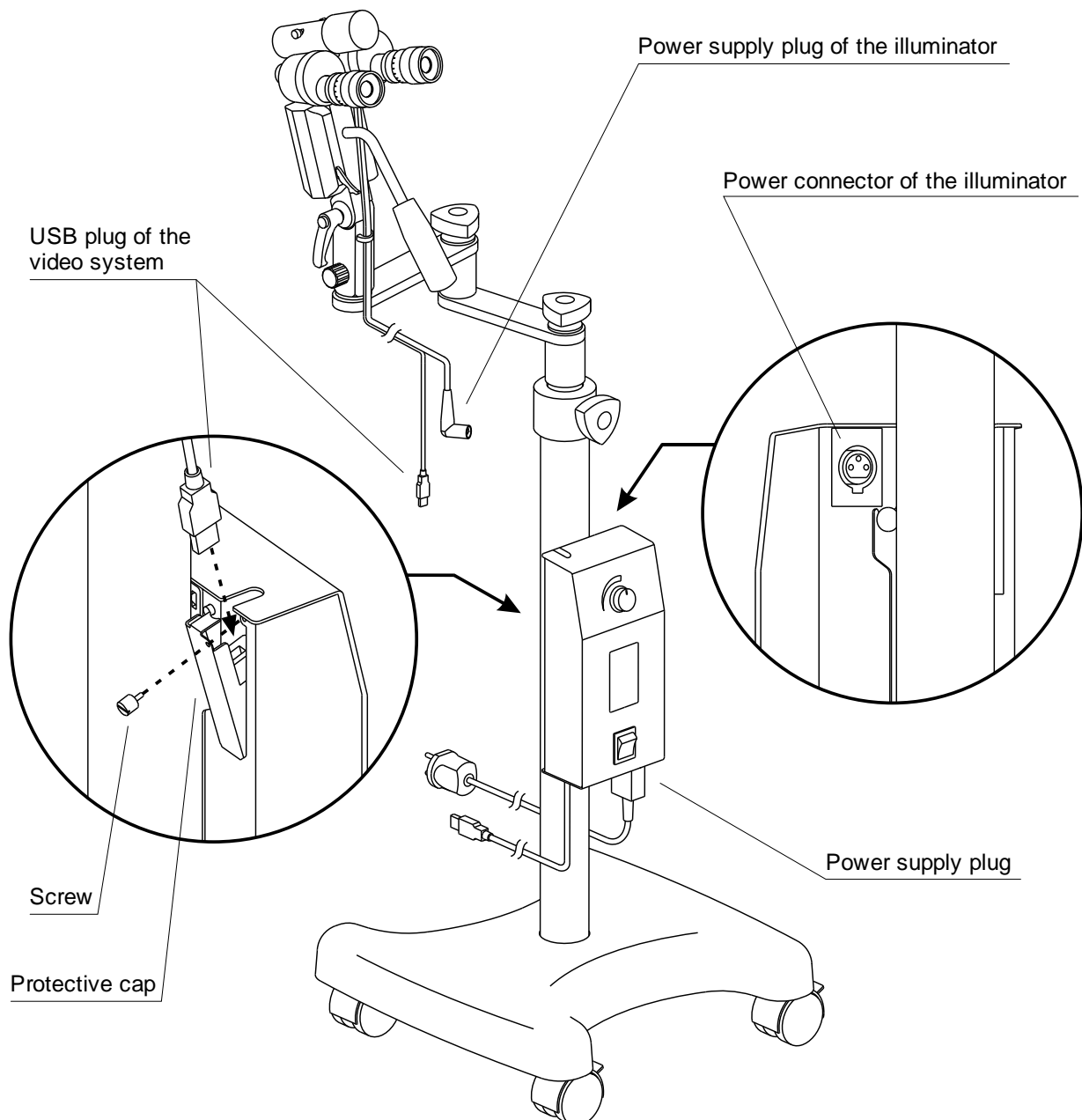
1. Connect the power plug of the illuminator with the cable coming from the colposcope head illuminator into the connector on the side of the power supply.

When a colposcope is supplied with a video system

2. Remove the screw from the protective cap that is attached to the power supply and open it.

3. Connect the video system USB plug to the connector inside the protective cap.

4. Close the protective cap and tighten the screw completely until it stops.



5. Connect the power plug of the colposcope into the network connector on the bottom of the power unit.

6. Secure the power plug with holding lock.



PROHIBITED. To use a colposcope, when power supply plug is not secured with lock.

7. Connect the colposcope to the power supply.

8. When using a video system, install the software MEDVisor-EVA on the PC.

9. Connect the USB plug that goes from the bottom of the power supply to PC.

10. When operating a colposcope more than 5 meters away from the PC, use the additional USB extension cable from the supply kit (available only in case of export, or at the request of the customer).

6. Operation



ATTENTION. Before operation, make sure that the colposcope is in good working condition.



ATTENTION. For safety reasons the continuous work time of the colposcope (work of the illuminator) should be no more than 4 hours with following break for 30 minutes at least.



ATTENTION. Each moving part of the colposcope has its limited range of motion. Do not try to increase this range by moving the colposcope beyond these limits with excessive force.

6.1. Turning on the colposcope. Moving, fixing and adjusting the travel force of its movable parts

The power button on/off of the illuminator with the light indicator switch and the brightness adjustment knob of the illuminator are located on the side of the power unit. The brightness of the illuminator is adjustable by rotation of the knob according to the scale marked on the power unit.

When you move the colposcope it is necessary to keep both hands on the colposcope head move handle and tripod stand. The locking of tripod rollers (2 rollers) is carried out by pressing the pedal lock.

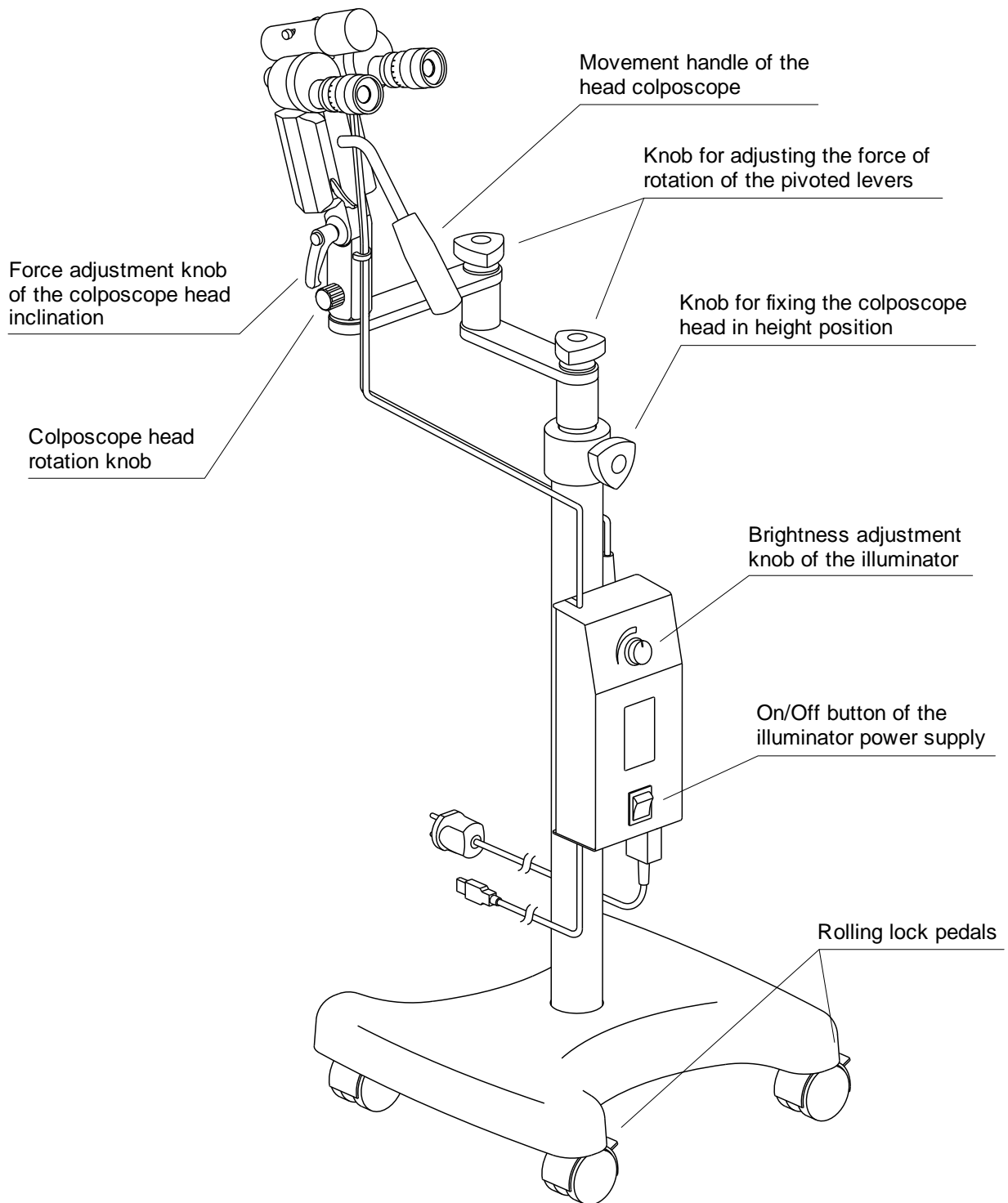
Перемещение головки кольпоскопа осуществляется с помощью 2-х поворотных рычагов с фрикционными рукоятками, которые размещены на стойке штатива.

Fixation and adjustment of the travel force of moving parts of the colposcope is carried out by rotating the handles on the case.

The colposcope head height adjustment is realized by a spring-loaded tripod stand. Чтобы отрегулировать положение головки кольпоскопа по высоте you need to unscrew the colposcope head height position knob with one hand, and with the other hand, while holding the swivel arms, raise or lower the colposcope head upwards, then fix its position by turning the knob.



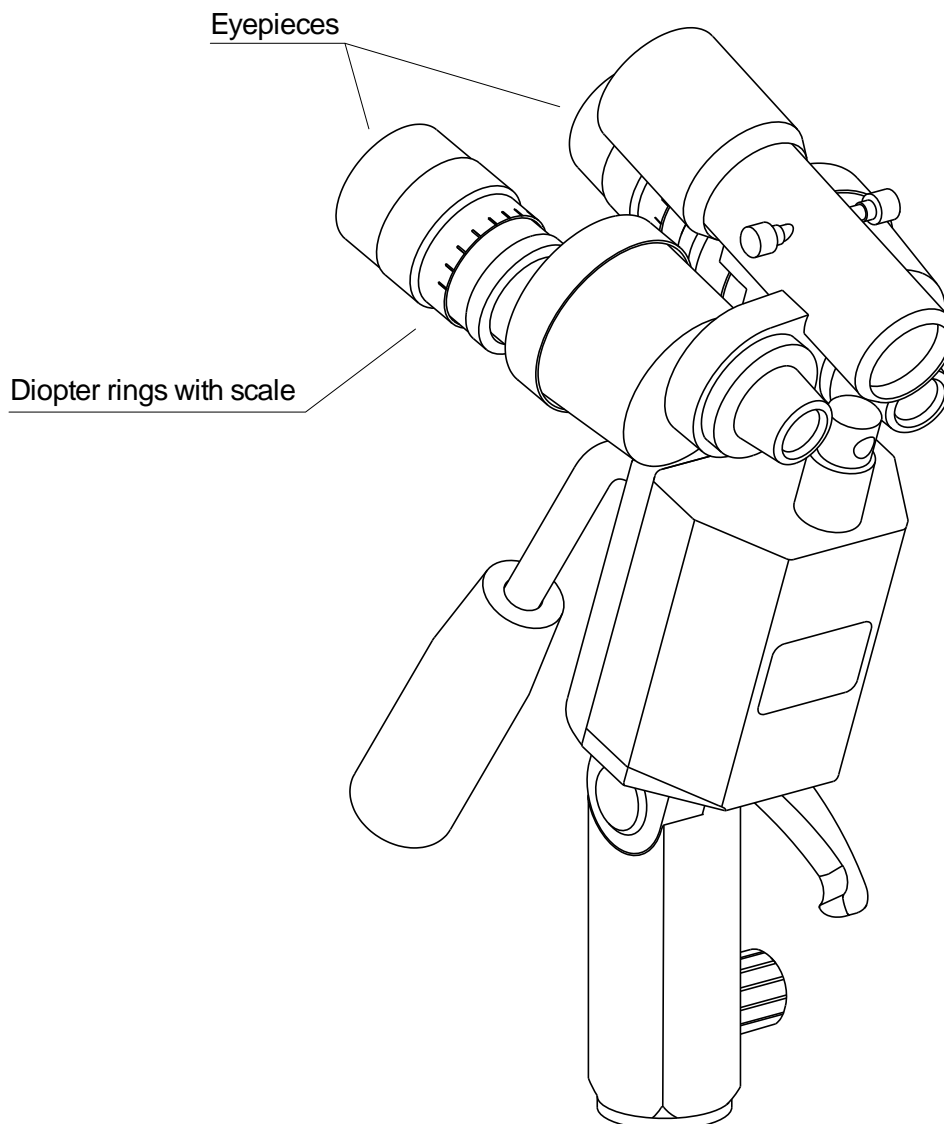
PROHIBITED. To fully unscrew and remove the force adjustment knob and the movement adjustment handle of the colposcope moving parts during its operation.



6.2. The adjustment of interpupillary distance of the eyepieces and adjustment of the diopter values

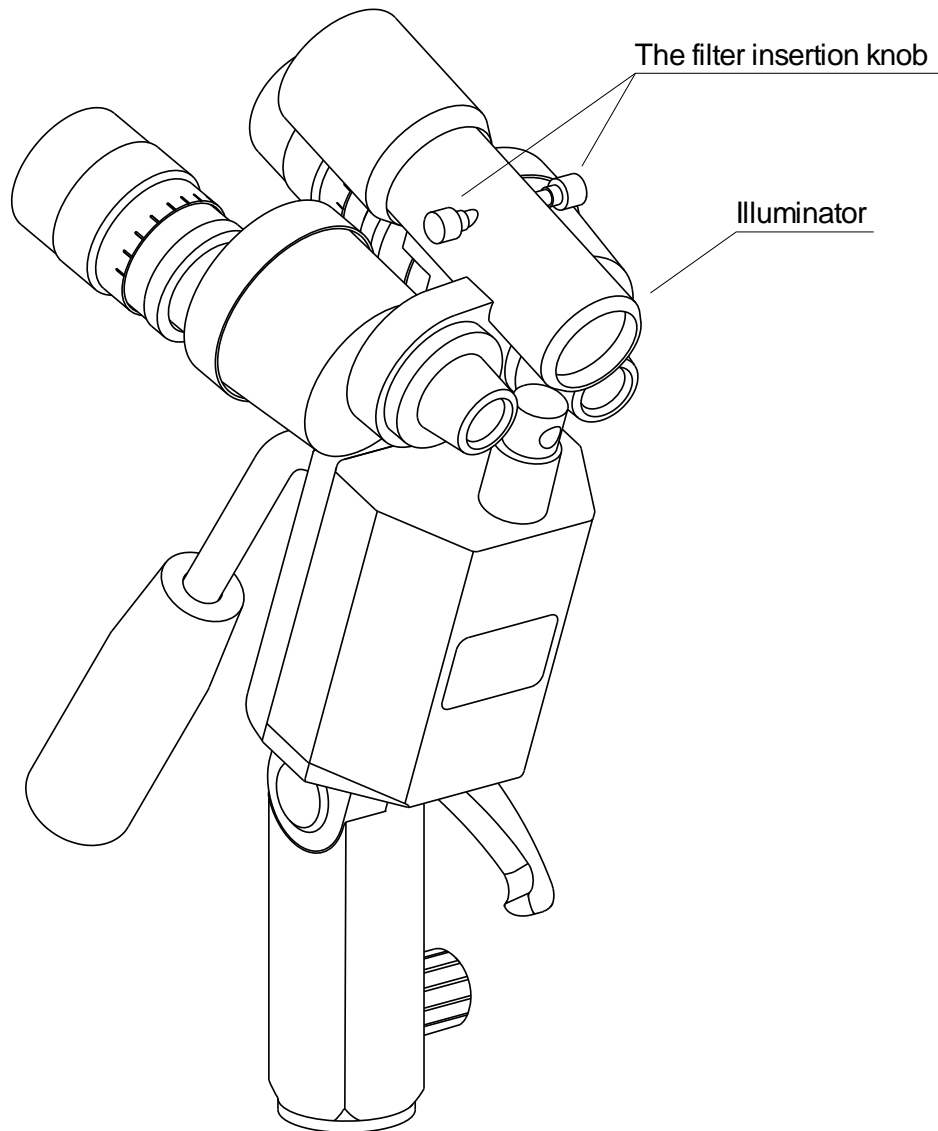
To obtain a stereoscopic view, the interpupillary distance should be set according to the distance between the user's eye pupils. The change in interpupillary distance may range from 56 mm to 74 mm. To adjust the interpupillary distance, it is necessary to look through the eyepieces and adjust them with both hands until the full alignment of the observed subject image in the left and right channels.

The eyepieces have a mechanism for changing dioptries within +5 -5 D, for each eyepiece. Diopter correction enables doctors to work with ametropia without glasses. For dioptric eyepieces correction, it is necessary, rotating the diopter rings around its axis, set them according to the eyes dioptry, on the dioptric scale.



6.3. The use of the filter lens

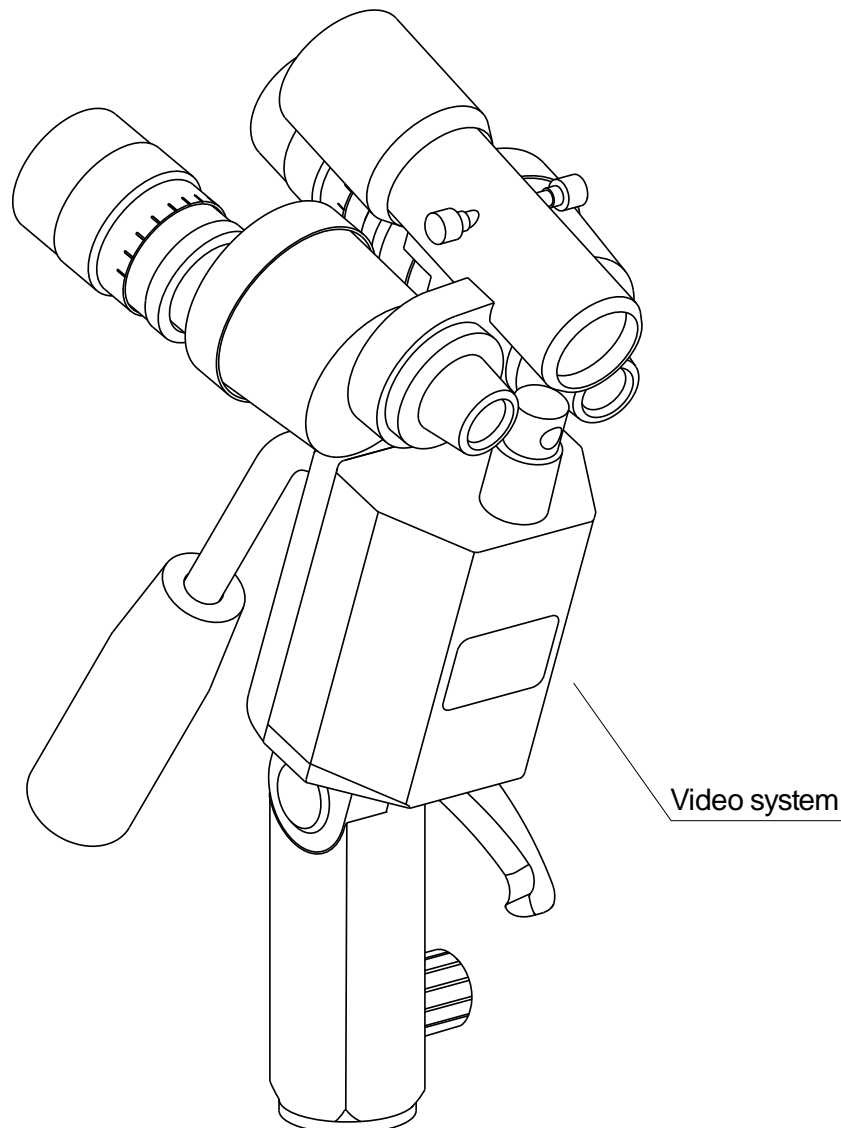
The illuminator has an integrated green filter that is intended to enhance contrast of the blood vessels, when it is in the light channel. To insertion a filter lens into a light channel it is necessary to turn the filter insertion knob clockwise until it stops (the specific click). To output a filter lens from the light channel it is necessary to turn the knob in the opposite direction.



6.4. The use of video system

The video system is intended to view a colorful image of the observed area at the computer screen in real time, as well as video recording and taking high resolution snapshots (1920x1080).

1. Install the software MEDVisor-EVA on the PC.
2. Connect the USB plug that goes from the protective cap to the PC plug.
3. When operating a colposcope more than 5 meters away from the PC, use the additional USB extension cable from the supply kit (available only in case of export, or at the request of the customer).
4. To get a snapshot of the observed object press the photo taking button on the video system body (the function works only when using software MEDVisor-EVA).



7. Colposcope care

To provide safe and reliable operation of the colposcope, it is necessary to check the cleanliness of external and optical surfaces each time before and after the operation. If the external or optical surfaces of the product are soiled, it is necessary to carry out the procedure of cleaning and disinfection as described further.



ATTENTION. When operating a colposcope, there is a risk of getting patient's tissue on its surface that potentially contains an infection. It is necessary to carry out the procedure of cleaning and disinfection of the colposcope using personal protective equipment.

7.1. Cleaning and disinfecting external surfaces

1. When the colposcope surfaces are soiled except for optical components, it is necessary to wipe them with a clean cotton cloth and cleansing agent.



ATTENTION. It is recommended to not use harsh and aggressive cleansing agents; this can damage the lacquer coating.



ATTENTION. Avoid getting any liquid inside the colposcope.

2. After cleaning and disinfection, before using the colposcope, its external surfaces should be completely dry.

7.2. Cleaning optical surfaces

1. When the external optical surfaces are soiled, clean them with cotton swab or clean cotton lint-free cloth soaked in 70% ethanol.

2. Then wipe them with dry cotton swab.

3. After cleaning, before using the colposcope, the optical surface must be completely dry and have no traces of streaks.

8. Possible malfunctions and ways of their elimination

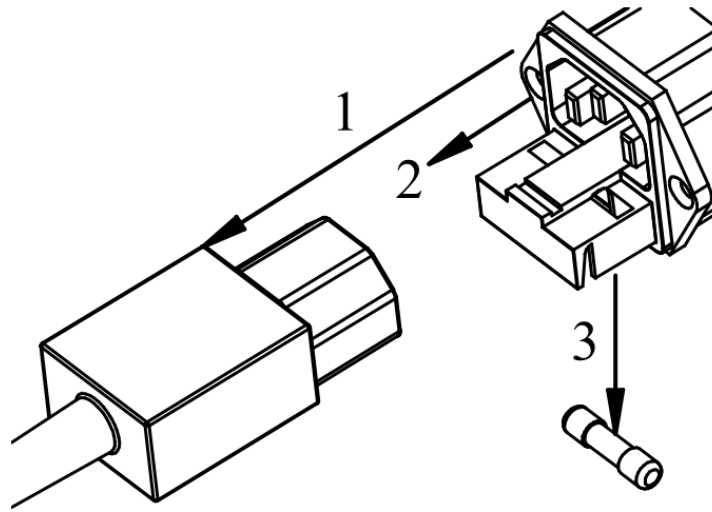
This section describes problems that can occur during operation with colposcope as well as their probable causes and solutions.

If a trouble occurs, refer to the recommendations for their resolution. If the problem is not solved, or the recommendation was not found, please contact the manufacturer of the authorized representative of the manufacturer.

Malfunction symptoms	Possible cause	Solution
The light indicator does not work at the on/off button of the illuminator power supply.	There is no mains voltage 220 v, 50 Hz	Connect the colposcope to the working network with a voltage of 220 V, 50 Hz
	No contact in the network connector of the power unit	1. Disconnect the power supply plug from the power unit; 2. check the cable consistency for mechanical damage and in case of their absence, reconnect as tightly as possible; 3. fix the plug with a locking connector.
The light indicator is lit, but the Illuminator does not work	The fuse element is out of order (safety fuse)	Replace the fuse element (safety fuse) to another one from the supply kit (8.1)
	There is no contact in the connectors of the illuminator power supply	1. Disconnect the power connector of the illuminator; 2. check the cable consistency for mechanical damage and in case of their absence, reconnect as tightly as possible;
The object image is unclear	The surface of the lens optics is soiled	Clean the outer optical surfaces (7.2)
	The surface of the eyepieces optics is soiled	
The left and right fields of view do not match	The interpupillary distance of the eyepieces does not match the distance between the user's eye pupils	Adjust the interpupillary distance (6.2)
The image of the object is not focused	The focus distance to the observation object is not sustained	1. Place the colposcope head at the distance from the observation object equal to approximately 250 mm; 2. move the colposcope head closer or further from the object until the image will not become sharp
Eyes get tired during observation	Diopter adjustment of eyepiece correction is not correctly displayed	Adjust the values of the diopter of the eyepieces (6.2)
There is no signal of the video system	USB cable is out of order	1. Disconnect the USB plug of the video system in the protective cap and connect directly to the USB connector on the computer to check for the presence of a signal; 2. restart the computer
	USB computer connector is defective	Connect the USB plug to another USB connector

8.1. Replacement of the fuse element

The fuse element (safety fuse) is located inside a special compartment of the fuse holder in the power network connector body on the power unit.



1. Disconnect the power supply plug 1.
2. Pull out the fuse element compartment 2.
3. Remove the fuse element 3 and replace it with new one from the supply kit of the spare parts.
4. Close the fuse compartment and connect the power supply plug.
5. Secure the power plug with holding lock.



PROHIBITED. To use a colposcope, when power supply plug is not secured with lock.