

COLPOSCOPE MK-200

Operation Manual



COLPOSCOPE MK-200





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-200 (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-200 corresponds to the provisions of the European Directive of Medical Devices 93/42/EEC and the Technical Regulations on Medical Devices of Ukraine.





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).



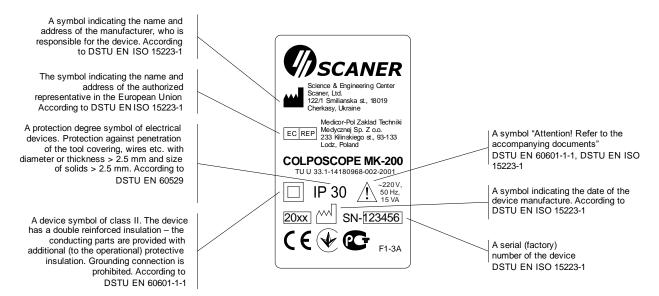
ATTENTION. Avoid getting any liquid inside the colposcope.



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



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 lens of the colposcope, when the illuminator 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-200 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.

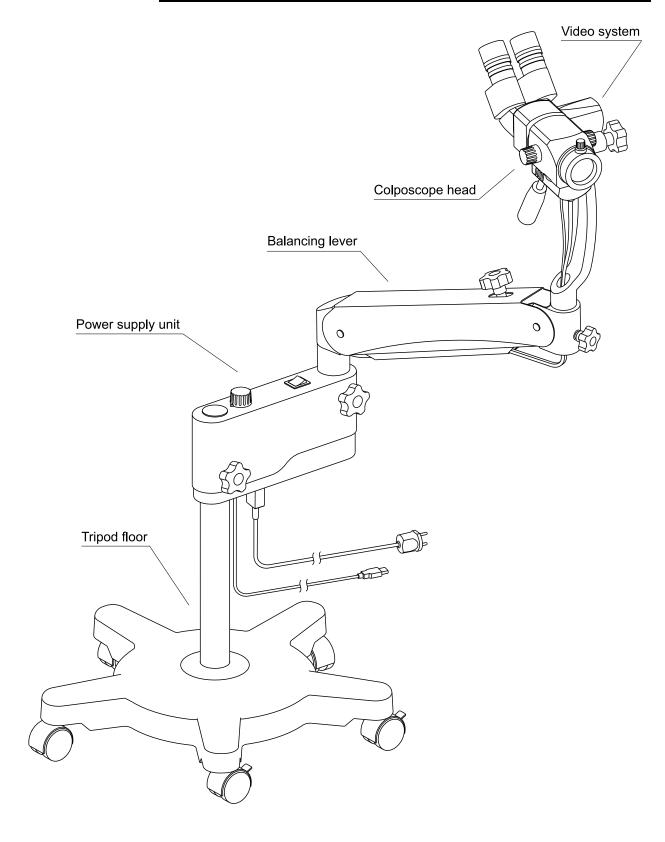
The colposcope field of use: gynecology and oncogynecology.

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 cytosmears 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 5 self-aligning rollers. The rollers of the tripod have a locking feature rolling to prevent spontaneous movements.



2.2. Power supply unit

The power supply unit of the colposcope provides the LED illuminator with stabilized constant current. The power supply unit is mounted on the tripod floor and used as a pivoted lever.

2.3. Balancing lever

The balancing lever is intended to hold and trim the colposcope head. The balancing lever is installed at the power unit and it forms two pivoted levers in connection with it.

2.4. Colposcope head

The colposcope head consists of:

- optical head;
- lens;
- video system;
- binocular adjustment with eyepieces;
- illuminator.

The optical head has a built-in 5-step drum of the magnification changer performed in optical systems of Galileo that have magnification ratio of: 0,4x; 0,6x; 1x; 1,6x; 2,5x.

The lens is intended to focus on the observation object. The lens has a fine focusing mechanism, which can adjust the visible sharpness of the image in the range of 12 mm without changing the position of the colposcope head. A colposcope can be supplied with lenses with a focal length:

- f=200 mm (with fine focus) (option);
- f=250 mm (with fine focus);
- f=300 mm (with fine focus) (option);
- f=350 mm (option);
- variable lens 200 400 mm (with handle) (option).

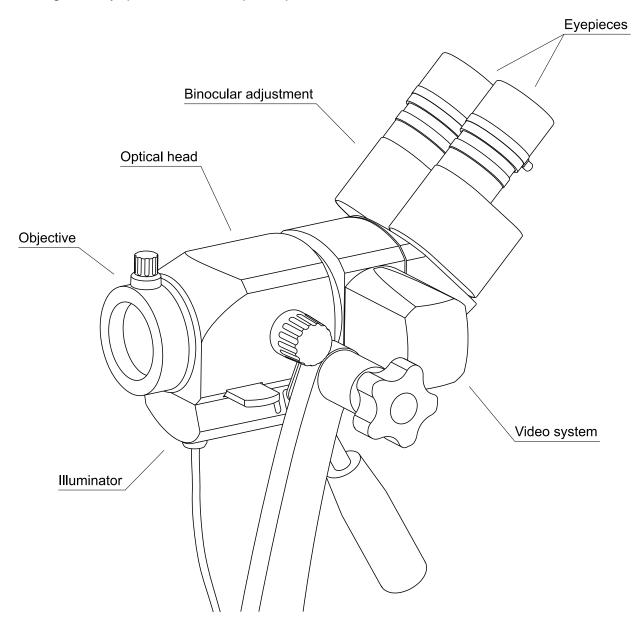
The binocular adjustment is intended for stereoscopic image output of the observed object on the retina. The binocular adjustment consists of the lens-prism unit with eyepieces at a 45° angle on the colposcope sighting axis and has a mechanism of interpupillary distance variation (hereinafter referred 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. The colposcope can be supplied with eyepieces magnification of 12,5x or 16x (option).



The integrated into the optical head **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). The video system is installed between the optical head and the binocular adjustment of the colposcope without compromising of the optical characteristics, and the transmitted video image coincides with the image observed through the eyepieces of the colposcope.





3. Complete set

Optical head	1
Lens:	1
- f=200 mm (with fine focus) (optional)	
- f=250 mm (with fine focus)	
- f=300 mm (with fine focus) (optional)	
- f=350 mm <i>(optional)</i>	
- variable lens 200 – 400 mm (with handle) (optional)	
Binocular adjustment 45°	1
Eyepieces:	2
- 12.5x	
- 16x (optional)	
U-shaped handle (optional)	1
Colposcope video system MK-200:	
(may not be supplied, at the customer's request)	
- digital video system	1
- additional USB cable (5 m)	1
(only for export, or at the request of the customer)	
- software for colposcopic diagnosis MEDVisor-EVA	1
- the protection key for the software	1
- the user manual for software MEDVisor-EVA	1
Power supply and balancing lever	1
Tripod floor	
- stand	1
- casing	1
- mobile base	1
Power cord	1
Spare parts, tools and accessories (SPTA):	
- fuse	2
- screwdriver	1
- allen key	1
- protective case	1
Operation Manual	1
Passport	1
Packaging	4





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

4.1. Optical parameters

Magnification of eyepieces			12.5x					16x		
Optical head magnification, ratio	0.4	0.6	1	1.6	2.5	0.4	0.6	1	1.6	2.5
	Lens f=200									
General magnification, ratio	4.1	6.6	10.5	16.9	27	4.9	7.9	12.6	20.3	32.4
Field of view Ø, mm	53.6	33.3	21	13	8.1	44.9	27.8	17.5	10.8	6.8
Resolution, lines/mm	40	60	75	85	90	44	70	85	90	90
Lens f=250										
General magnification, ratio	3.3	5.3	8.5	13.6	22	4	6.4	10.2	16.3	26
Field of view Ø, mm	66	42	26	16	10	55	34	21.6	13.5	8.5
Resolution, lines/mm	32	50	70	85	90	35	55	75	85	90
					Lens	f=300				
General magnification, ratio	2.8	4.5	7.1	11.4	18.3	3.3	5.3	8.5	13.6	22
Field of view Ø, mm	78.6	48.9	31	19.3	12	66	42	26	16	10
Resolution, lines/mm	26	40	60	70	75	32	50	70	85	90
Lens f=350										
General magnification, ratio	2.4	3.8	6.1	9.8	15.7	2.9	4.6	7.3	11.8	18.8
Field of view Ø, mm	91.6	57.9	36	22.4	14	75.8	47.8	30.1	18.6	11.7
Resolution, lines/mm	23	36	50	60	65	26	40	60	70	75

Variofocal lens

With magnification of eyepiece 12.5x					
Working distance, mm	General magnification, ratio	Field of view Ø, mm			
200	2.9 - 18.9	75.8 - 11.6			
250	2.5 - 16.2	88.0 - 13.6			
300	2.2 - 14.3	100 - 15.4			
350	2.0 - 12.8	110 - 17.2			
400	1.8 - 11.6	122.2 - 19			
With magnification of eyepiece	16x				
Working distance, mm	General magnification, ratio	Field of view Ø, mm			
200	3.7 - 24.2	59.4 - 9.1			
250	3.2 - 20.7	68,8 - 10.6			
300	2.8 - 18.3	78.6 - 12			
350	2.6 - 16.4	84.6 - 13.4			
400	2.3 - 14.8	95.6 - 14.8			

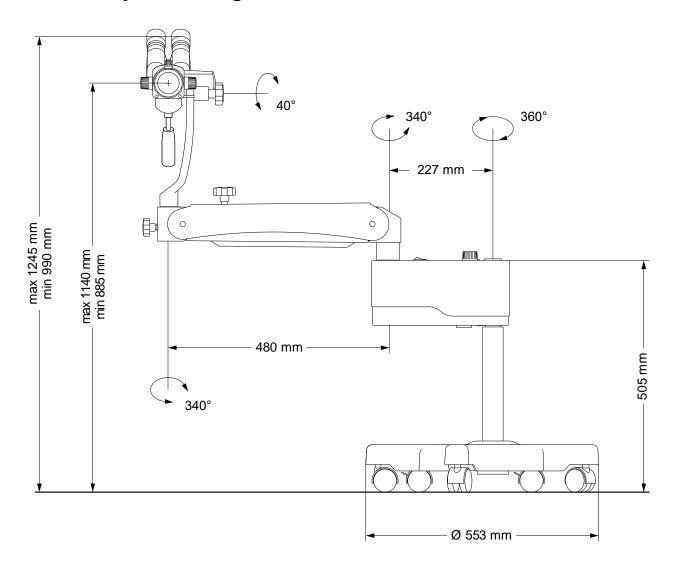


4.2. Technical parameters

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:		
- with installed lens f=200 mm	55	
- with installed lens f=250 mm	68	
- with installed lens f=300 mm	80	
- with installed lens f=350 mm	90	
The maximum illumination in the subject plane, lux, not less:		
- with installed lens f=200 mm	90 000	
- with installed lens f=250 mm	60 000	
- with installed lens f=300 mm	40 000	
- with installed lens f=350 mm	30 000	
Power supply voltage from the single phase AC current with	from 90 to 250	
frequency of 50 Hz, V	110111 90 10 230	
Power consumed by the colposcope, VA, not more	15	
The colposcope weight, kg, not more	36.5	



4.3. System settings





5. Mounting and installation

The colposcope MK-200 is supplied in a package consisting of 4 seats.

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.



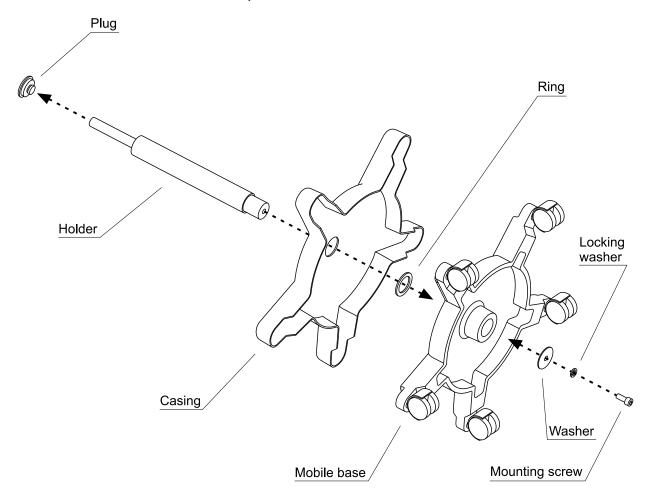
5.1. Mounting of the tripod floor

- 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. Unscrew and remove the plug from the opposite side of the holder.
- 4. 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 is very heavy! The mounting of the tripod must be carried out with the help of several people.

- 5. 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.
 - 6. Place the assembled tripod on the floor.





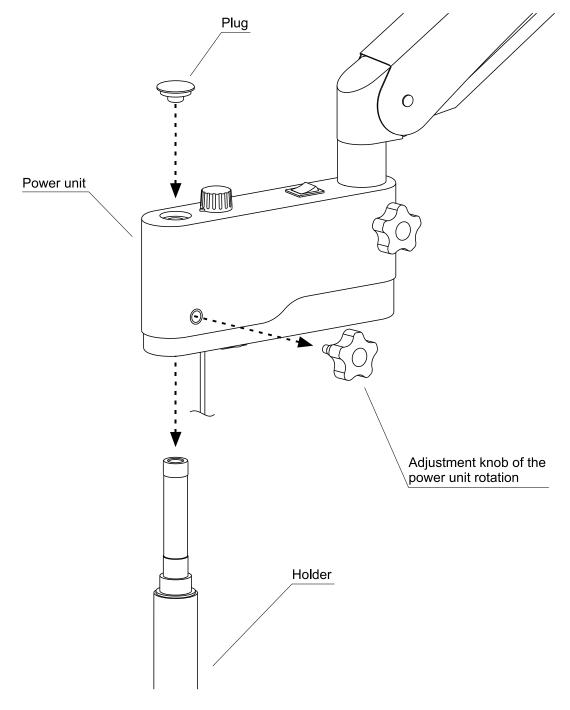
5.2. Power supply unit installation

- 1. Unscrew the force adjustment knob of the power supply unit rotation at the side part of the power unit.
- 2. In alignment without inclination install the power supply and balancing lever on top of the tripod passing the axis of the holder through the power unit nozzle.



ATTENTION. The power supply and balancing lever is heavy! The mounting of the power unit must be carried out with the help of several people.

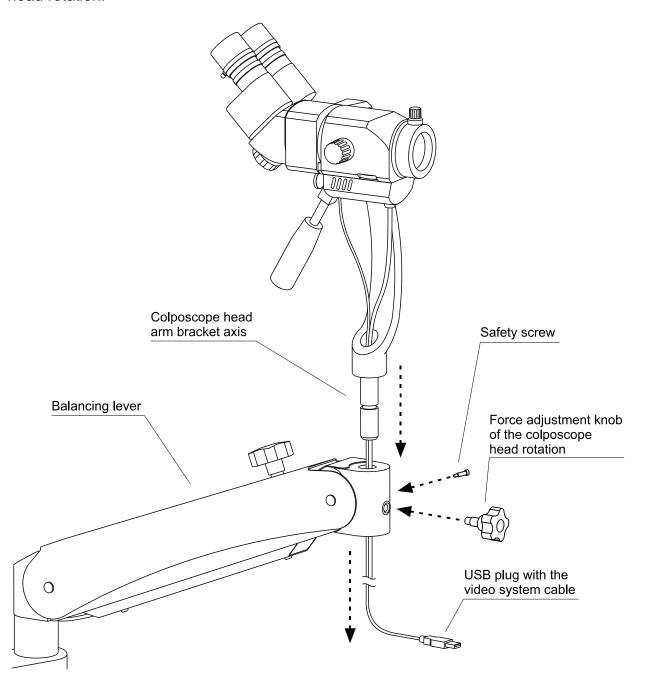
3. Tighten the plug into the holder axis until it stops completely.





5.3. Installation of colposcope head

- 1. Unscrew the safety screw and the force adjustment knob of the colposcope head rotation from the balancing lever body.
- 2. In turn insert the plug with illuminator power supply cable and the USB plug with video system cable (when the colposcope is supplied with video system) that protrude from the axis of the colposcope head bracket into the nozzle of the balancing lever.
- 3. In alignment without inclination install the colposcope head on the balancing lever inserting the axis of the colposcope head bracket into the nozzle of the lever.
- 4. Tighten the safety screw and the force adjustment knob of the colposcope head rotation.



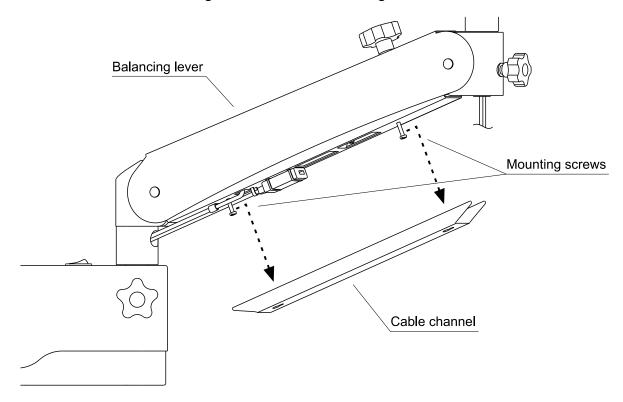


5.4. Connecting the cables



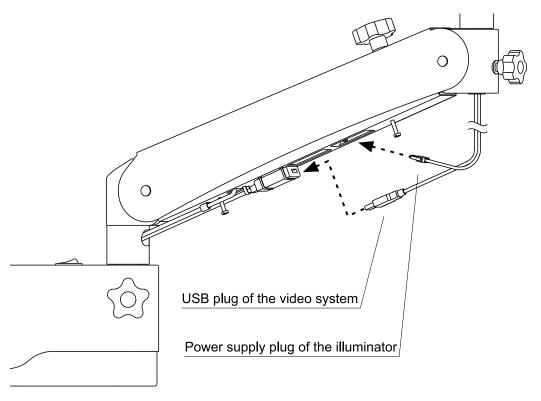
ATTENTION. The colposcope connection to the single-phase AC mains with voltage of 220 V is carried out only with electric cable from the supply kit.

- 1. Use the supplied screwdriver to loosen the screws (2 pcs.) at the bottom of the balancing lever, holding the cable channel.
- 2. Remove the cable channel, pushing it slightly to the side so that the screw heads can be inserted through the extensions in the grooves.

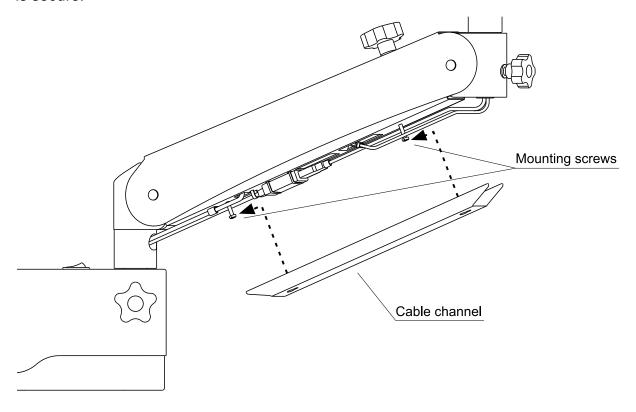


- 3. Connect the power plug of the illuminator with the cable coming from the colposcope head illuminator into the connector on the bottom of balancing lever (above the cable channel).
- 4. Connect the USB plug of the video system (when the colposcope is supplied with video system) into the connector on the bottom of balancing lever.





- 5. Install the cable channel, inserting the screw heads into the extensions in the grooves, then move it slightly to the side so the screw heads were under the narrow parts of the grooves.
- 6. Fasten the cable channel by tightening the mounting screws completely until it is secure.

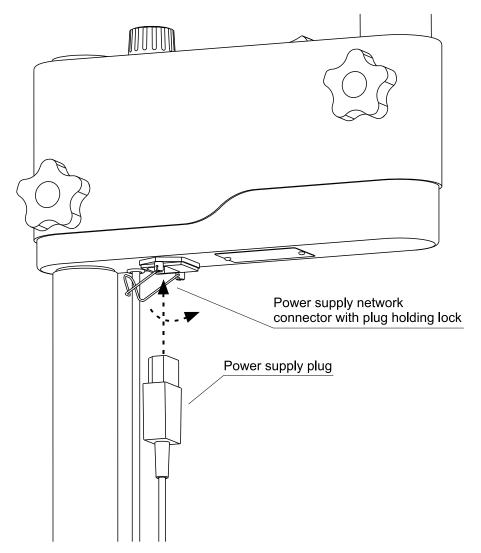




- 7. Connect the power plug of the colposcope into the network connector on the bottom of the power unit.
 - 8. Secure the power plug with holding lock.



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

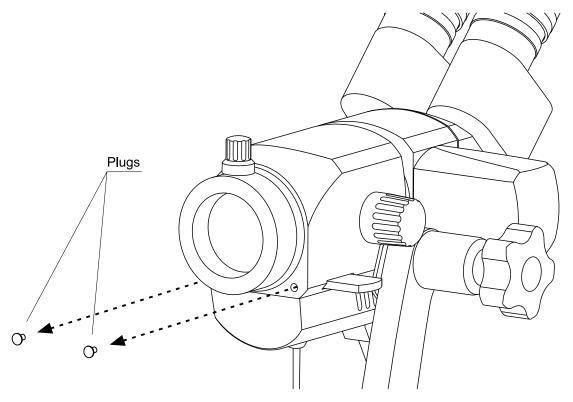


- 9. Connect the colposcope to the power supply.
- 10. When using a video system, install the software MEDVisor-EVA on the PC.
- 11. Connect the USB plug that goes from the colposcope power unit to PC.
- 12. When operating a colposcope more than 5 meters away from the PC, use the additional USB extension cable from the supply kit (available only in case of export, or at the request of the customer).

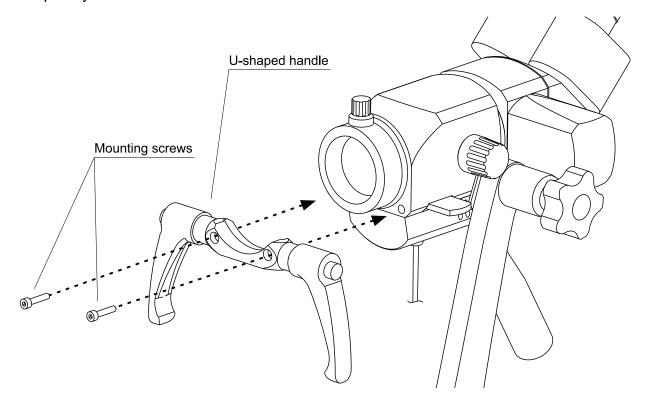


5.5. Installation of the U-shaped handle

1. Remove the plugs on the body of the optical head.



- 2. Place the U-shaped handle so that the holes in her body will match the threaded holes in the body of the optical head.
- 3. Install the U-shaped handle by tightening the fastening screws from the kit, completely until it is secure.





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 top 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.

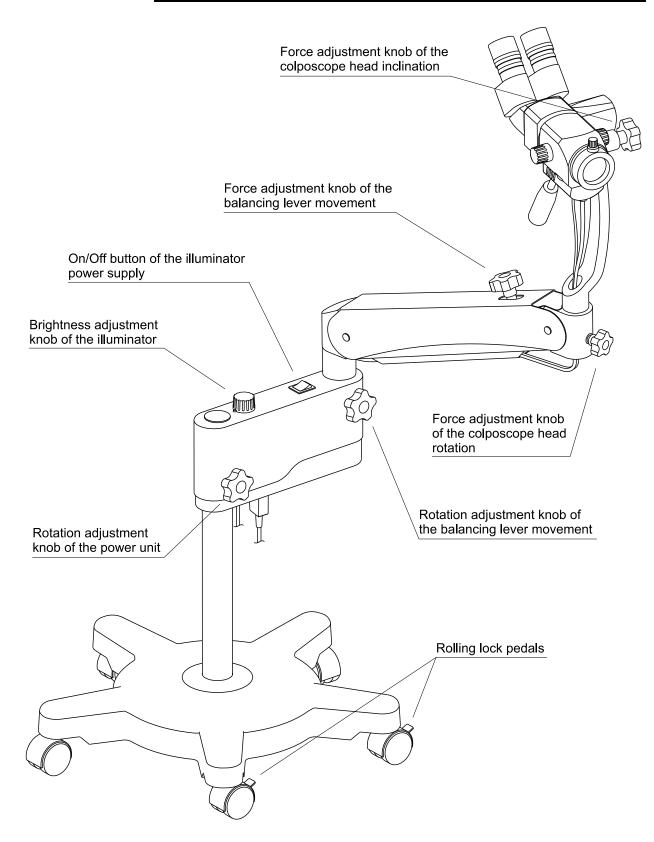
When you move the colposcope it is necessary to keep both hands on the power supply and balancing lever. The locking of tripod rollers (3 rollers) is carried out by pressing the pedal lock.

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



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





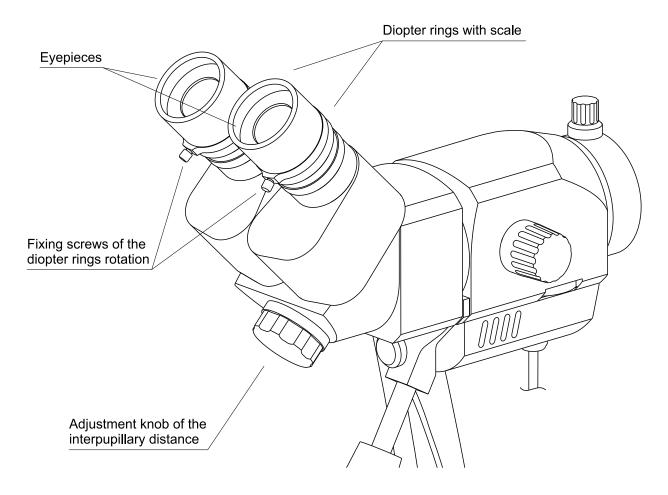


6.2. The adjustment of interpupillary distance of the eyepieces and adjustment of the diopter values

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 rotate the adjustment knob 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.

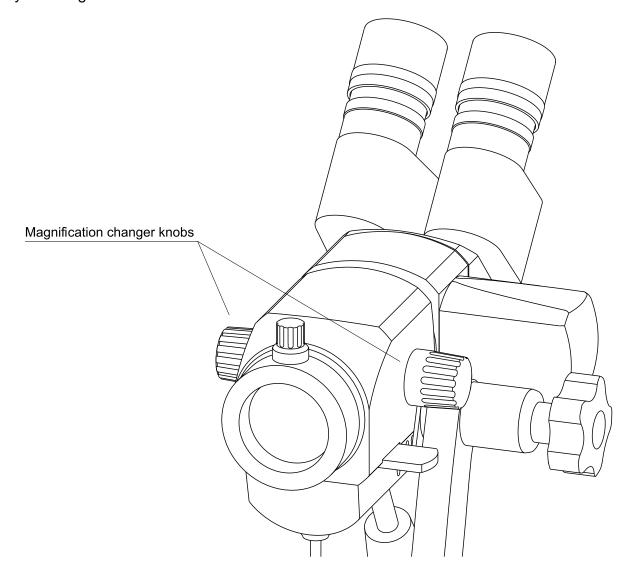
- 1. Loosen (do not remove completely) the screws fixing the rotation of the diopter rings.
- 2. Rotating the diopter rings around their axis, set them according to the eye diopter on the diopter scale.
 - 3. Fix the position of the diopter rings with fixing screws until it stops completely.
- 4. Focus on the observation object and in turn change the magnification of the optical system (6.3), to ensure that the image is sharp at all magnifications.





6.3. The switching of magnifications of the optical system

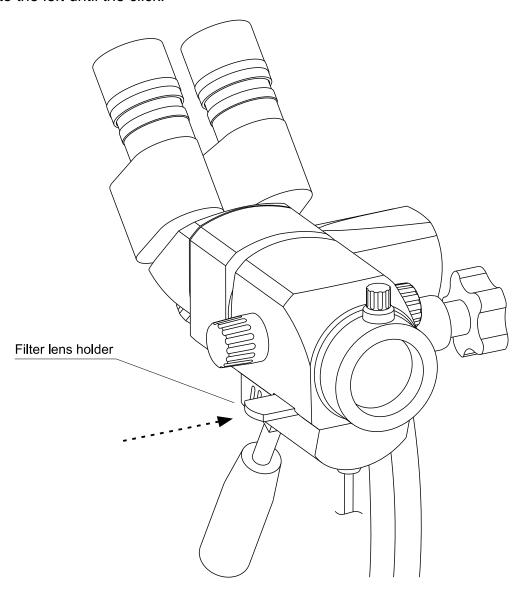
To switch the magnification of the colposcope optical system, it is necessary to rotate the magnification changer knobs that are located at the optical head body on both sides. The knobs have a position marking of the optical head magnification ratio (6 positions) relative to the position of the knobs. The overall magnification of the optical system is given in 4.1.





6.4. 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 input a filter lens into a light channel it is necessary to move the filter holder to the right, completely until it stops (the specific click). To output a filter lens from the light channel it is necessary to move the holder to the left until the click.



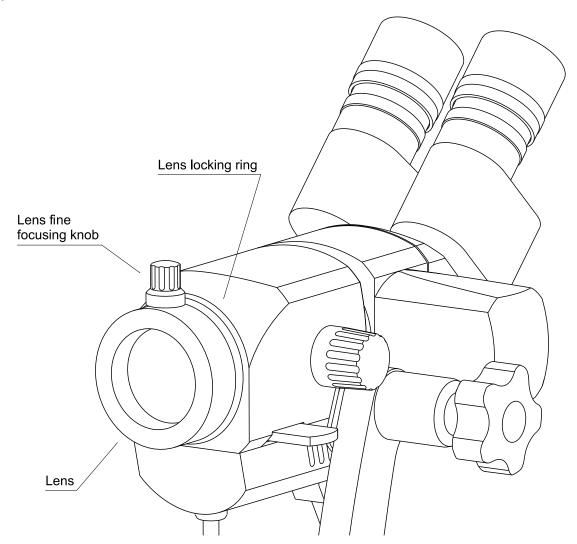


6.5. Fine focusing lens

Lenses: f=200 mm, f=250 mm and f=300 mm have a mechanism of fine focusing that allows to adjust the apparent sharpness of the image in the range of 12 mm, without changing the position of the colposcope head. To adjust the image sharpness, it is necessary to rotate the fine focusing knob. When using a variable lens (with handle), the rotation of the knob changes the working distance of observation in the range from 200 mm to 400 mm.

The fine focusing knob can be placed in any convenient position relative to the axis of rotation of the lens.

- 1. Loosen a locking ring of the lens.
- 2. When rotating lens, place the fine focusing knob in a position convenient for the work.
- 3. Fix the position of the knob by tightening the locking ring completely, until it stops.

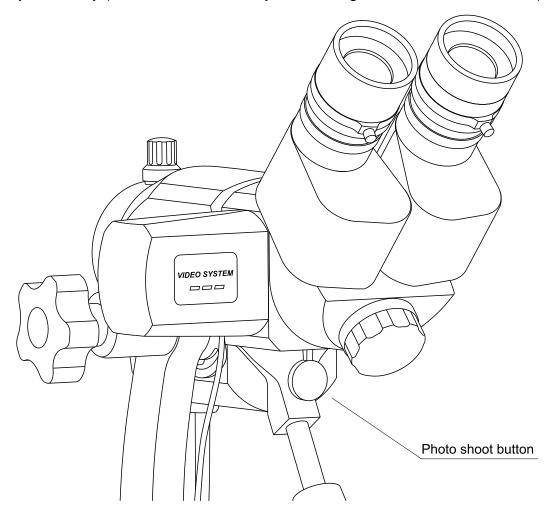




6.6. The use of video system

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).

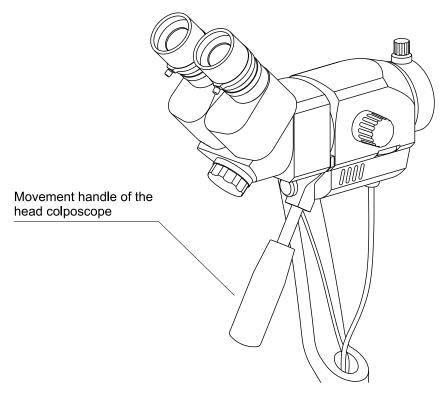
- 1. Install the software MEDVisor-EVA on the PC.
- 2. Connect the USB plug that goes from the power unit to the PC plug.
- 3. When operating a colposcope more than 5 meters away from the PC, use the additional USB extension cable from the supply kit (available only in case of export, or at the request 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).



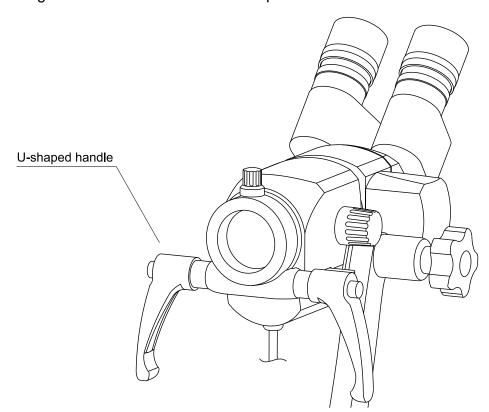


6.7. Spatial movement of the colposcope head

Spatial movement of the colposcope head is performed using the movement handle and/or u-shaped handle (optional).



The U-shaped handle has the ability to change the angle of the handles in a convenient position (for each handle separately). To change the inclination angle of the U-shaped handle, it is necessary to pull them aside from each other, then turn them to the desired angle and let them down until the specific click.

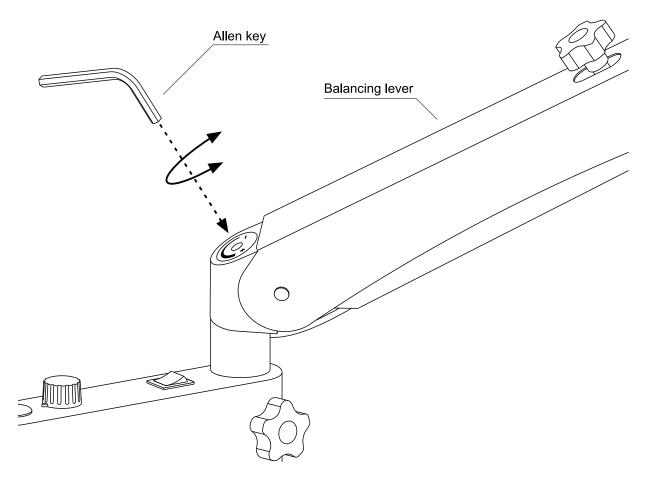




6.8. Adjustment of the tilt of the balancing leaver

The need to adjust the tilt of the balancing leaver can take place when changing the tension of the gas spring during long-term operation of the colposcope.

- 1. Install the Allen key from the supply kit, in the recess on the balancing lever.
- 2. Turn the key in the direction of strengthening "+" or weakening "-" according to the markings.
- 3. Check the tilt force of the balancing lever in different positions at the time of the retention.





ATTENTION. The tension force of the gas springs may vary depending on the ambient temperature.



PROHIBITED. To adjust the tension of a gas spring with a sudden change of the ambient temperature.



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 in EU.

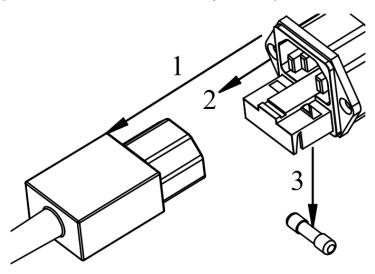
Malfunction symptoms	Possible cause	Solution
The light indicator does not work at the on/off	There is no mains voltage 220 v, 50 Hz	Connect the colposcope to the working network with a voltage of 220 V, 50 Hz
button of the illuminator power supply.	No contact in the network connector of the power unit	 Disconnect the power supply plug from the power unit; check the cable consistency for mechanical damage and in case of their absence, reconnect as tightly as possible; fix the plug with a locking connector.
	The fuse element is out of order (safety fuse)	Replace the fuse element (safety fuse) to another one from the supply kit (8.1)
The light indicator is lit, but the Illuminator does not work	There is no contact in the connectors of the illuminator power supply	 Disconnect the power connector of the illuminator guided by (5.4); 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 The surface of the eyepieces optics is soiled	Clean the outer optical surfaces (7.2)
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	Place the colposcope head at the distance from the observation object according to its focus distance; move the colposcope head closer or further from the object until the image will not become sharp Rotate the knob of the objective fine focusing on the lens body until the image will not become sharp (6.5)
When changing the magnification the image is blurred	Diopter adjustment of eyepiece correction is not correctly displayed	Adjust the values of the diopter of the eyepieces (6.2)
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	Disconnect the USB plug of the video system on the power unit and connect directly to the USB connector on the computer to check for the presence of a signal; restart the computer



Malfunction symptoms	Possible cause	Solution
	USB computer connector is	Connect the USB plug to another USB
	defective	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.