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ATTENTION! Please carefully read this operation manual prior to the use of the product.

1. Purpose

MK-300 colposcope (hereinafter - colposcope) is a medical device for stereoscopic observation with optical non-contact magnification of vagina, cervix, and the lower third of the cervical channel during gynecological and oncogynecological examinations.

Field of use – gynecology, gynecologic oncology.

The colposcope is necessary for:

- Examination of the state of the epithelium of cervix, vagina and vulva with the help of optical magnification;
- Detection of localization and borders of lesion foci;
- Differentiation of benign formations from suspected malformations;
- Targeted cytological smear and biopsy material sampling which increases the efficiency of the latter method;
- Medical procedures requiring visual control (operative colposcopy);
- Control of the treatment outcome;
- Assessment of the process dynamics in case a conservative treatment strategy has been selected.

ATTENTION! At the customer's request the colposcope can be supplied with the video system, the video system can be also supplied later.

The video system is designed for view of colored images of the examined region on the computer display in real-time mode, and, if necessary, for a parallel displaying on the second monitor at the place of patient's examination. The image on display completely coincides with the image observed through the colposcope's oculars. The video system allows making high-resolution snapshots by pushing the shooting button placed on the colposcope.

The video system does not impair the optical characteristics of the colposcope.



2. Technical characteristics

Magnification, times	10 ± 0.5
Field of vision, mm	20 ± 1.0
Resolution in the object space, lines per mm, NLT	85
Working distance, mm	250
Ocular diopter shift, diopter, NLT	+5 -5
Interpupillary distance adjustment range, mm	56 to 74
Diameter of illuminated field of vision, mm, NLT	25
Max. Illumination of the object plane, lux, NLT	60 000
Supply voltage from a 50 Hz single-phase alternating current network, V	90 to 250
Colposcope's power consumption, W, NMT	6
Distance from the floor to the exit pupils of the colposcope, mm:	
- maximal	1300
- minimal	1000
Overall dimensions of the colposcope, mm, NMT:	
- length	510
- width	350
- height	1360
Weight of the colposcope, kg, NMT	17.4



3. Delivery set

Colposcope head	1 pc
Colposcope video system with the set of instruments and accessories:*	1 pc
- digital video system	1 pc
- USB cable, 5 m	1 pc
- screwdriver	1 pc
Vertical stand	1 pc
PSU	1 pc
Basis	1 pc
Network cable	1 pc
Set of spare parts and accessories (SPA):	
- fusing element (safety device)	2 pcs
- hex-nut wrench	1 pc
- screwdriver	1 pc
- cases	2 pcs
Documentation:	
- operating manual	1 pc
- instruction for commissioning	1 pc
- State Registration Certificate	1 pc
- Conclusion of the State sanitary and epidemiological expertise	1 pc
- DVD with a video instruction for mounting	1 pc
Packaging	1 pc
* The video system may not be initially supplied and be supplied later at the customer's request.	



4. Construction and principle of operation

The colposcope (fig. 1) consists of the colposcope head 1, pivoted levers 5, telescopic leg 8, power supply unit 9, and basis 14.

The colposcope head (fig. 2) consists of the optical head 1, video system 9 (if the colposcope is supplied with the video system), illuminator 2 and arms 6.

The optical head 1 (fig. 2) consists of two microscopes, which optical axes are situated angularly related to each other and overlap 250 mm from the lenses. The construction of the optical head allows adjustment of the interpupillary distance within the range of 56 to 74 mm.

The diopter shift within the range from +5 to -5 diopter according to the user's vision properties is made by rotation of the oculars 3 (fig. 2).

The video system 16 (fig. 1) consists of a prism inverting system, a lens and a digital video camera. The shooting button 15 is situated on the left side of the video system casing.

A 2 MP digital camera is used in the video system (see Schedule A for detailed description of the video system).

On the side of the PSU there is a slot covered with a protective housing that connects the video system cable 17 and the USB cable 18 used for the connection of the video system with the computer.

Illuminator optical system 2 (fig. 2) forms a bright and homogenously lit light spot with clear borders in the observed plain. Practically unlimited service life of the LED is possible due to high power supply stabilization from the network AC/DC switch-mode power supply. Insertion of the cyan light filter into the lighting channel of the optical system is performed by the knob 4

Illuminator power supply is performed with the help of the colposcope PSU 9 (fig. 1) which contains a switch 11 and light adjustment knob 10. The PSU is protected against overload, overheating and short circuit.

On the lower surface of the PSU there is a network slot with the compartment for the fusing element (fuse) to which the network cable 13 is connected. On the back PSU wall there is a slot 12 for illuminator LED power cable.

The optical head is moved with the help of the knob 2 (fig. 1). The high degree of freedom of the construction allows exact and fast focusing on the object.

Fast and exact focusing of the colposcope is performed by moving of the optical head 1 along the sighting axis with the help of the knob 2 due to rotation of the pivoted levers. Knobs 6 serve for snub of the pivoted levers and prevention of spontaneous colposcope head shift. Smoothness of movement and absence of gaps is ensured by rotation bearings and efficient braking mechanisms.

Tilting of the optical head 1 (fig. 2) is performed along the connecting axis of the arms 6. The braking effort in the connecting axis of the arms is regulated by the rotation of the handle 7 (the flag of the handle 7 has the idle rotation function for its placing into the convenient position).

Rotation of the optical head 1 (fig. 1) in the horizontal plane is performed around the axis connecting arms and pivoted levers 5. The optical head is locked from rotation by the knob 4.

The height of the colposcope head is adjusted by the telescopic leg 8. To adjust it you need to push the fixation button 7 with one hand at the same time pushing or pulling pivoted levers 5.

The colposcope is moved on rubberized castor wheels with brakes. The distance between the floor and exit pupil of the colposcope is suitable for all types of gynecological chairs.



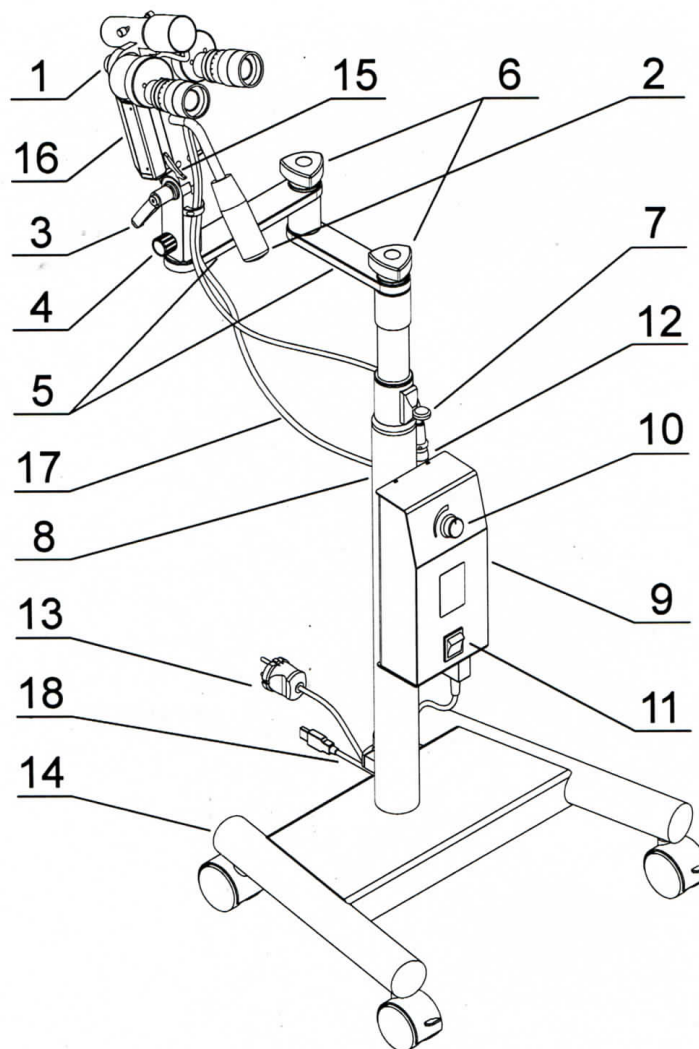


Figure 1 – Overall view of the MK-300 colposcope.

1- colposcope head; 2- handle; 3,4,6- fixation knobs; 5- pivoted levers; 7 – fixation button; 8- telescopic leg; 9- PSU; 10 – brightness adjustment handle; 11- switch; 12 – slot for illuminator power cable; 13- power cable; 14 - basis; 15- shooting button; 16 – video system; 17 – video system cable; 18 - USB cable for PC connection.

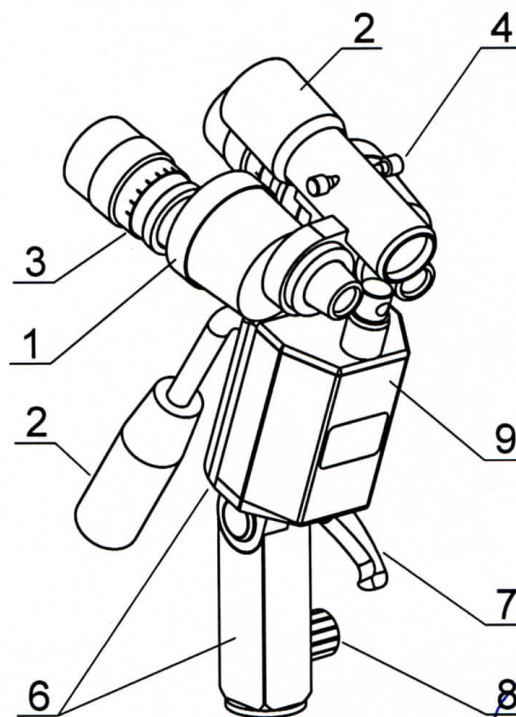


Figure 2 – Colposcope head with the video system.

1- optical head; 2 - illuminator; 3 - ocular; 4 – light filter insertion handle; 5 - handle; 6- pivoted levers; 7,8 – fixation knobs; 9 – video system.



5. Safety precautions

- According to their operating conditions, the colposcope and the video system are attributed to the climatic construction UHL 4.2 according to GOST 15150 and are designed for operation at the temperature range from +10°C to +40°C, relative air humidity 30% - 75% and atmospheric pressure from 700 to 1600 hPa.

- According to the potential risk class for application in the medical practice the MK-300 colposcope is attributed to class I according to DSTU 4388.

- According to the electrical shock protection the colposcope is attributed to class II, protection type B according to DSTU 3798 (IEC 601-1). The colposcope is connected to 220 V single-phase alternating current network with the frequency of 50 Hz with the help of a network cable with a wall plug.

The colposcope has no open live contacts and is safe during operation.




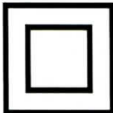



ATTENTION! Switching the PSU on without PSU casing is prohibited.

ATTENTION! Disconnect the colposcope from network before replacement of the fusing element (safety device).

ATTENTION! Repair of electronic details of the colposcope must be carried out only by qualified personnel allowed to work with electrical voltage up to 1000 V with due observance of all safety standards for maintenance and repair of similar devices.



6. Labeling and symbols

	Conformity marking that confirms that the labeled products comply with the requirements of EU Directives and harmonized standards.
	RCT conformity marking for declaration of products' conformity.
	Symbol "Warning! Please refer to the supporting documentation" (operation manual). In accordance with DSTU (State Standard of Ukraine) 3798 (IEC 601-1) and DSTU EN 980
	Class II product symbol. The product has double reinforced insulation – the live parts are provided with additional insulation (to the working one). Grounding is prohibited. In accordance with DSTU 3798 (IEC 601-1).
IP30	Marking of degree of protection of electrotechnical products. Protection from penetration of tools, wires, etc. with the diameter or thickness of >2.5 mm and solids with the dimensions of >2.5 mm into the casing of the instrument. According to GOST 14254 (MEC 529).
	Type B product symbol B. Product that provides certain protection from electric injuries relating to allowed leakage current in case of absent grounding. In accordance with DSTU 3798 (IEC 601-1).
	Symbol of the manufacturing date of the product. In accordance with DSTU EN 980.
	Symbol of the name and address of the manufacturer responsible for the product. In accordance with DSTU EN 980.



7. Mounting of the device

ATTENTION! The mounting of the device must be performed with caution and with due observance of all instructions given below.

1) Take the colposcope out of its container and remove packaging.

2) Insert the telescopic leg 4 (fig. 4) into the basis 6 and fix it with screws 7 using the hex-nut wrench included into the delivery set of the colposcope.

3) Mount the PSU 5 onto the telescopic leg 4, performing the following steps:

ATTENTION! PSU mounting requires certain efforts. Hold the PSU securely during mounting in order to prevent its fall.

a) Place the PSU 1 (fig. 3) relative to the mounting plate 2 onto the telescopic leg so that the top hitches 4 and lower lug 3 on its casing are situated slightly under the corresponding slots on the mounting plate, as shown on the figure 3.

b) Tightly press the PSU against the mounting plate and pull it down until the lock 5 closes (you hear characteristic clicking).

c) Ensure that the PSU is securely mounted and locked.

d) In case you need to remove the PSU press and hold the locking button 6 and move the PSU until it is disconnected.

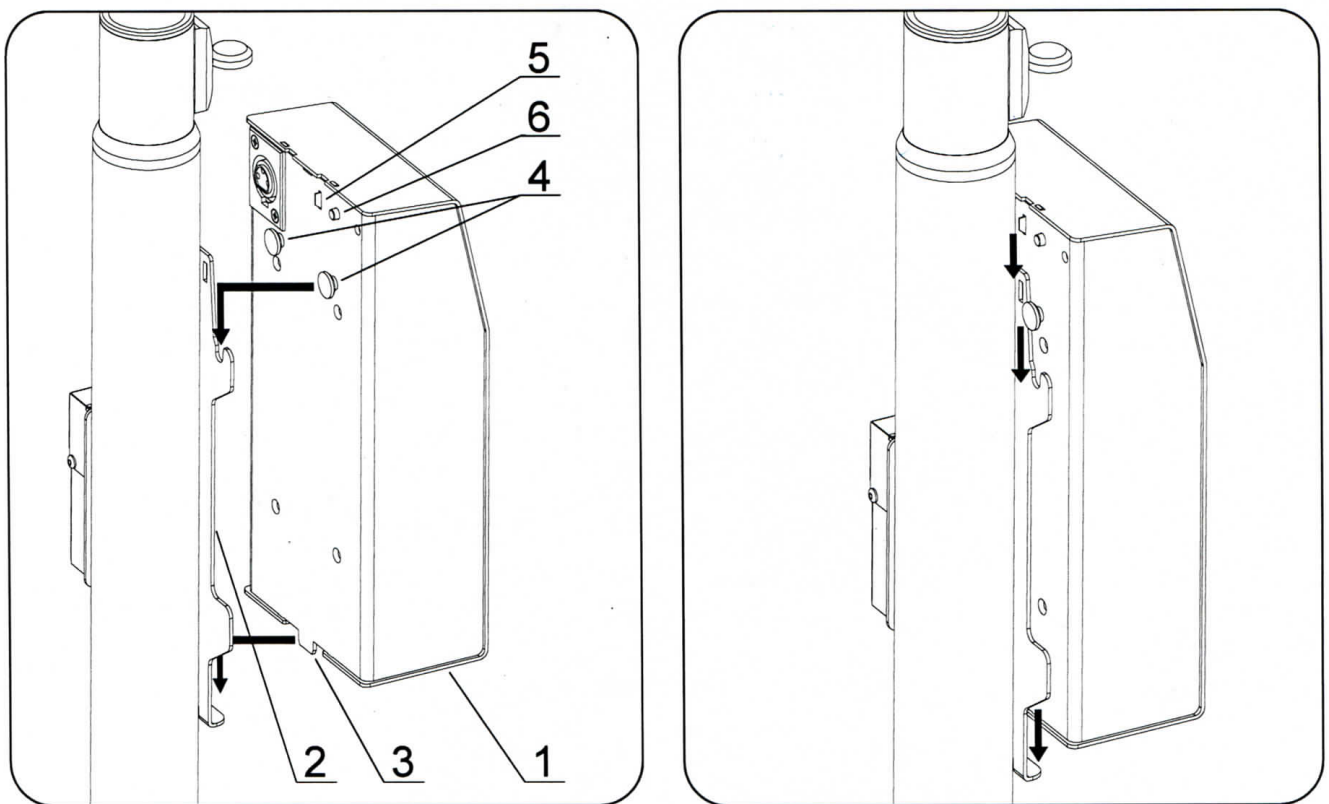


Figure 3 – Mounting of the PSU onto the telescopic leg

1 - PSU; 2 – mounting plate on the telescopic leg; 3- lower lug; 4 - top hitches; 5 - lock; 6- locking button.



4) Unscrew the knob 15 and screw 3 (fig. 4), install the colposcope head 1 with the arm onto the arm axis 2, fasten it with the screw 3 against the stop and screw the knob 15 back.

5) To connect the illuminator insert slot 8 into the socket 9 of the PSU 5.

For the colposcope with the video system:

6) Open the protective cover 14 on the back side of the PSU (fig. 14), by unscrewing the screw 13.

7) Connect the slot 11 (video system cable and cable for connection of the video system with the PC 12).

8) Attach the protective cover 14 on the back side of the PSU 5 with the screw 13.

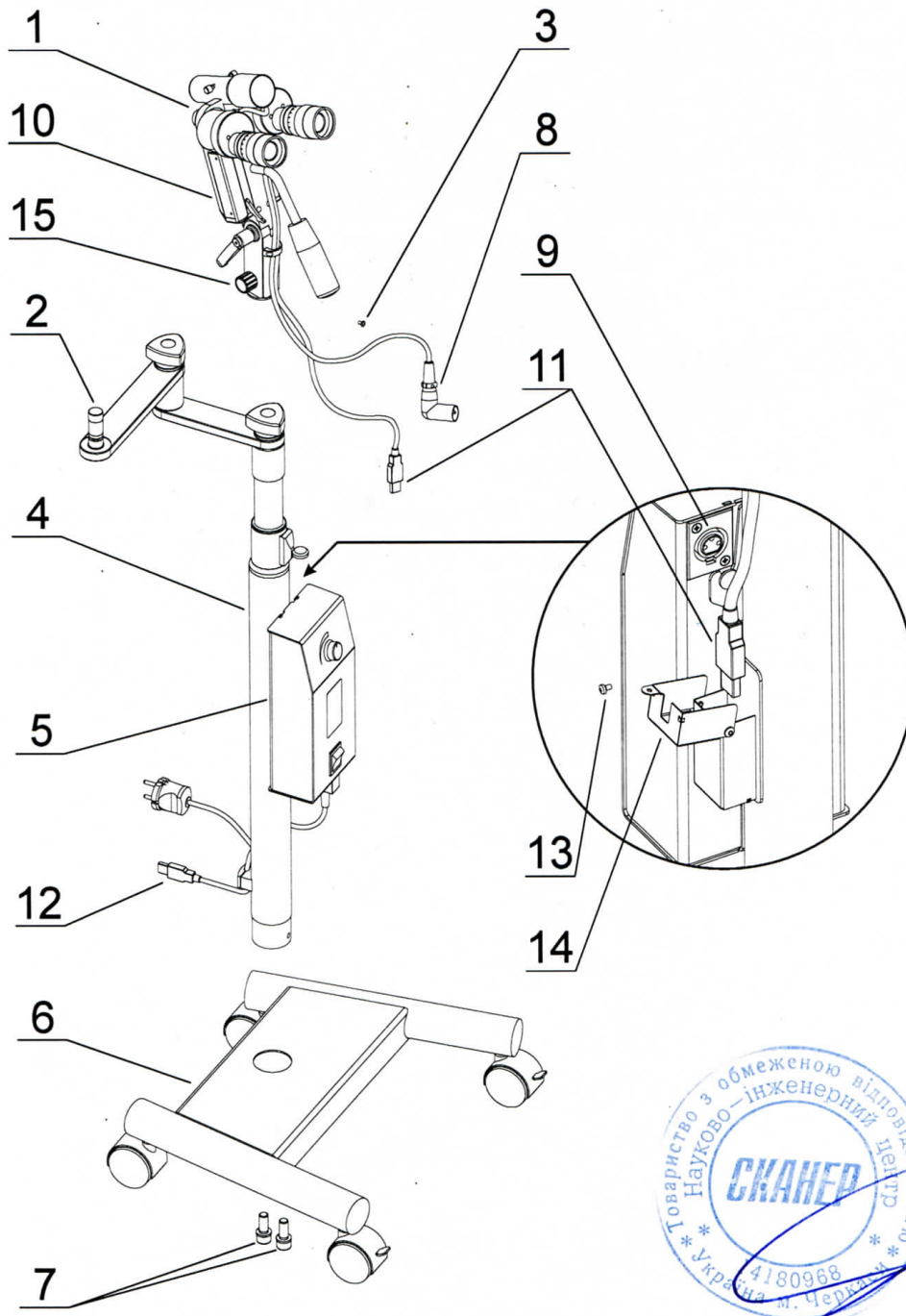


Figure 4 – Assembly diagram for the colposcope with the video system.

1 – colposcope head; 2- axis; 3,13 - screws; 4- telescopic leg; 5 - PSU; 6- basis; 7 - bolts; 8 – illuminator cable slot; 9 – slot connection socket 8; 10- video system; 11- USB slot; 12- USB slot for a cable for the connection of the video system with the PC; 14 - cover; 15 – locking knob.

8. Working order

- 1) Connect the colposcope to the network.
 - 2) Turn the illuminator of the colposcope on with switch 11 on the PSU (fig.1).
 - 3) Put the colposcope into convenient position (fig. 5).
 - 4) By rotating the oculars 3 (fig. 2) around their axis adjust them according to the eye diopter rate of the user according to the diopter scale.
 - 5) Adjust the height of the colposcope head position. To do this, push the locking button 7 (fig. 1) and lift (pull down) the colposcope head on the telescopic leg 8. Let the locking button 7 off.
 - 6) Hold the handle 2 (fig. 1), loosen the locking handles 6 and put the colposcope head into the position for convenient work, approximately 250 mm over the observed object.
 - 7) Position the oculars according to the distance between the user's eyes by turning them with the both hands until the images of the observed object from the left and the right channel overlap.
 - 8) Obtain sharp image of the observed object in the oculars by moving the colposcope head with the handle 2.
- To prevent spontaneous shift of the pivoted levers tighten the knobs 6. To fix the turning of the colposcope head in the horizontal plane tighten the knob 4.
- 9) Obtain necessary object illumination with the brightness adjustment knob 10 (fig. 1).
 - 10) If necessary insert (remove) the light filter with the help of handle 4 (fig. 2).

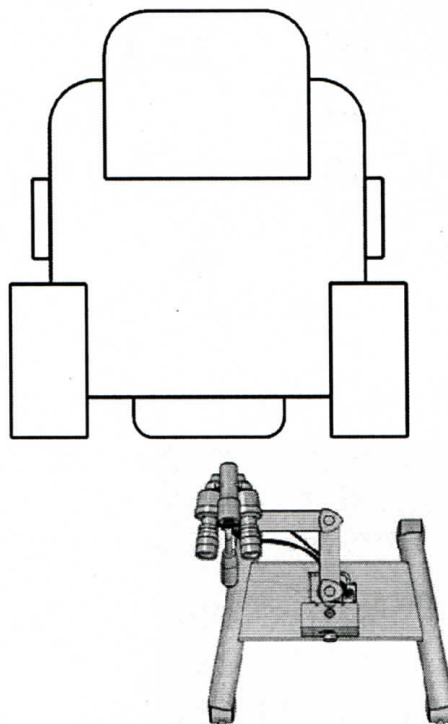


Figure 5 – Recommended position of the colposcope relative to the gynecological chair.



9. Maintenance

To ensure secure work of the colposcope, maintenance works should be performed each time during preparation of the colposcope for work.

During maintenance of the colposcope, the technicians should perform the following steps:

- 1) check the cleanness of the colposcope's external optical details by visual inspection;
- 2) clean the external surfaces of optical details from dust and dirt with a wad of cotton wool moistened in ethanol;
- 3) check the power cable and the plug for damages (the cable surface must be free of breaks through which cable conductors are visible; the cable must be firmly fixed in the plug and contain no twists; plug pins are not to be bent; there should be no cracks or spalls on the plug casing);
- 4) when the work is finished clean the external surfaces of the colposcope with the well wrung wad of cotton wool moistened in 3% hydrogen peroxide solution according to GOST 177-88 with 0.5% detergent solution according to DSTU 2972;
- 5) cover the colposcope head with the dust cover to prevent dusting of the external optical surfaces.



10. Common troubles and remedies

Malfunction symptoms	Possible cause	Remedy
The indicator "Network" is not on at the power switch button	No supply voltage 220 V, 50 Hz	Check the 220 V, 50 Hz supply network voltage
	The fusing element (fuse) is out of order)	Replace the fusing element (fuse) on the lower panel of the PSU
	No contact in the network connector of the power supply unit, the power cable is damaged	Unplug the power cable from the PSU, check the cable for mechanical damage and reconnect, make sure the setup is secure and fixing of the network plugs.
	The network switch of the PSU is out of order	Contact the maintenance department
No light of the illuminator diode, the indicator "Network" is on at the power switch button	No contact in the power cable connector of the illuminator, or the power cable of the illuminator is damaged	Disconnect the cable of the illuminator from the power supply unit, check the cable for mechanical damage and in their absence, reconnect, make sure the setup is secure and the plugs are securely fixed in appropriate slots
	The illuminator LED or the colposcope's PSU is out of order	Contact the maintenance department
The image of the object is blurred in spite of the fact the focusing has been performed appropriately	The external surface of the optical elements is dirty	Clean the external surface of the optical components with rectifying ethyl alcohol.



The replacement of the fusing element (fuse):

- 1) Disconnect the plug of the colposcope network cable 1 (fig. 6);
- 2) Pull the compartment of the fusing element 2;
- 3) Pull the fusing element 3, and replace it with a new set of spare parts;
- 4) Close the compartment of the fusing element and connect the plug of the power cable of the microscope.

ATTENTION! The plug of the power cable of the microscope must be fixed by a special holder to prevent inadvertent disconnection.

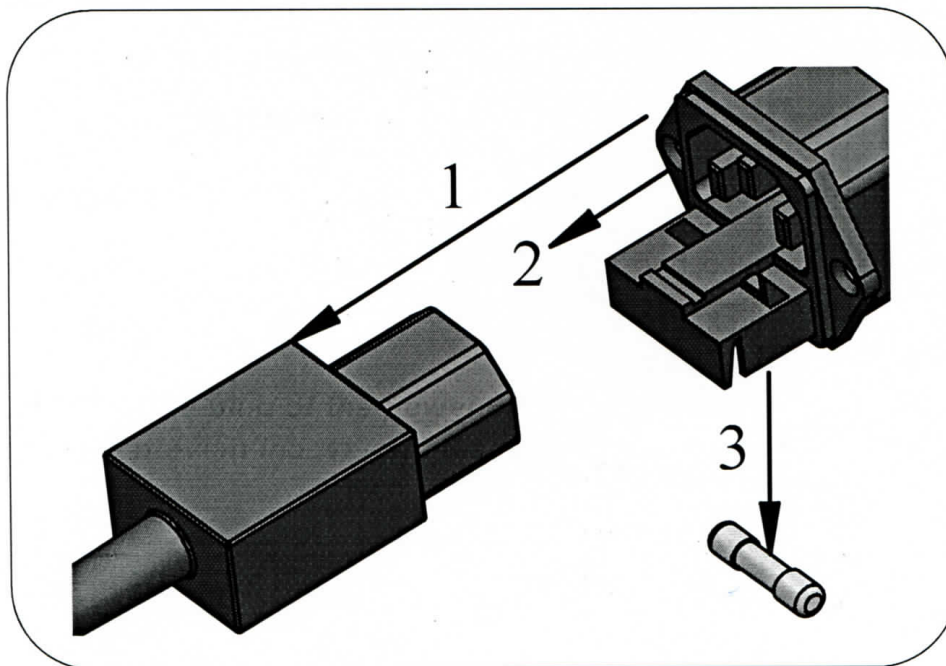


Figure 6 – Replacement of the fusing element

1- network cable plug (placed in the lower part of the PSU); 2- compartment of the fusing element;
3- fusing element (fuse).



11. Acceptance certificate

Medical device **COLPOSCOPE MK-300**

- ☐ with video system
☐ without video system

serial (factory) № _____, complies with the specification

TU U 33.1-14180968-005-2004 and is accepted as ready for operation.

Date _____
(year, month, day)

Signature _____
(inspector responsible for the acceptance)

SEAL

Address of the manufacturer:

122/1 Smelianskaya str.,
Cherkassy, Ukraine, 18019
Science and Engineering Center "Scanner", Ltd.
Phone/fax +380 472 55 27 34 (35)
E-mail: sr@scanner.ck.ua
www.scanner.ck.ua

Address of the Authorized Representative/Importer

Pharma Complex Solutions Ltd
Górczewska 200C/344, 01-460 Warsaw
Phone/fax +48 (0)22 722-23-05
E-mail: kontakt@pcsolutions.pl
www.pcsolutions.pl



12. Manufacturer's warranty

- All products of the SEC "Scanner" Ltd. are tested and have anti-defect materials and assembly warranty as well as warranted compliance with the declared characteristics. If the colposcope MK-300 or its video system fail within the warranty period because of some defects of materials, assembly or production, provided they have been operated according to the recommended conditions, the SEC "Scanner" Ltd. shall repair them or exchange for the analogous.

- The warranty period for this device is **5 years** from the date of its purchase or from the date of commissioning if commissioning by an authorized representative is needed, but not later than 3 months from the date of the purchase.

- The guaranteed operation period begins with the day the customer receives the device provided the date of receipt is proven with a document. If the date of the device receipt by the customer or the date of its commissioning cannot be ascertained, the guaranteed operation period begins with the date of signing the purchase and sale agreement. (*Decree of the Cabinet of Ministers of Ukraine No. 506 of 11.04.2002 with amendment No. 103 of 02.02.2011*).

- The SEC "Scanner" Ltd. shall repair and replace failing components at its own expense during the guaranteed operation period.

- The device can be accepted for the guaranteed maintenance (repairs) upon availability of the User Manual (registration certificate) with marks of the manufacturer and seller in the warranty leaflet and without any damage of the device that results from incorrect operation and could cause failure. The guaranteed operation period for the device is prolonged for the period of it being repaired.

- The warranty does not cover the devices damaged as a result of an accident, mishandling, unwarranted intrusion in the device, natural disasters or emergency power failure.

- After the termination of the guaranteed operation period the broken-down device is repaired by the SEC "Scanner" Ltd. at the expense of the customer.

ATTENTION! In case of any questions concerning the commissioning of the colposcope and its guaranteed operation period contact the service department of the SEC Scanner Ltd.

Phone/fax +380 472 55 27 34 (35)

E-mail: sr@scanner.ck.ua



Digital video system of the colposcope MK-300

The video system is intended for online examination of a coloured image of the investigated area on a computer monitor and (if necessary) its simultaneous transmitting to the second monitor at the site of the patient's examination.

The video system allows seeing an image on a computer monitor with the same sharpness and size as the image examined through the eyepieces of the colposcope. The video system does not interfere with the operational and optical characteristics of the colposcope.

The video system helps:

- To get in contact with a patient and increase her trust to the doctor and the hospital by means of visual diagnosing and presenting the process of her treatment;
- To take high-quality pictures using a button that is suitably situated on the colposcope;
- To create comfortable conditions for a patient during training of doctors.

Digital video camera (USB 2.0 - Digital) ensures:

- High quality of the image with transmitting mode of 960×720 pixels (15 frames/sec) or 640×480 pixels (30 frames/sec);
- Getting pictures with resolution of 2 million pixels;
- Ideal colour rendition of colpoimages by means of deep control of colour, contrast, brightness and white balance.

Delivery set:

- 1) Digital video system.
- 2) Additional active USB-2.0 cable, 5 m long.
- 3) Screwdriver.



SEC "Scanner" Ltd.

122/1 Smelianskaya str., Cherkassy, Ukraine, 18019, service department

Phone/fax +380-472-55-27-34(35),

0 800 30 10 19 (free of charge on the territory of Ukraine from stationary phones)

E-mail: sr@scanner.ck.ua

WARRANTY LEAFLET
For repairs (replacement) within warranty period

Medical device Colposcope MK - 300

TU U 33.1-14180968-005-2004

(filled in by the manufacturer)

Works (serial) № _____

Date of manufacture _____
(year, month, day)

(full name of the responsible person) _____
(signature) SEAL

(filled in by a seller)

Seller _____
(name of the selling company)

Date of sale _____
(year, month, day)

Signature and seal of the seller _____
(signature) SEAL

(Filled in by an performer in case of commissioning)

Performer _____
(name of the company or the person responsible for commissioning)

Date of commissioning _____
(year, month, day)

Signature and seal of the responsible person (performer) _____
(signature) SEAL

Signature of the customer to certify the commissioning

(signature)

