delmont imaging

EN - Instructions for use
Colposcope system

D900 700 109 C EN

2025-09

℞ Only

This manual is addressed exclusively to trained and qualified personnel. Carefully read these instructions before using Delmont imaging devices. Keep them in a safe place for future reference.

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MD

This manual relates to the generic medical device group Colposcope system manufactured by Delmont imaging with basic UDI-DI 37012178COLPHQ. See declaration of conformity for the complete list of devices concerned.

Symbols used in this manual	
⚠	Safety information to prevent injury.
ⓘ	Special information requiring the user's attention.
☑	Prior information that the user must check.
→	Instruction information that the user must follow.

This instruction for use can be supplied in hard copy on request from our customer within 6 days by contacting ifu@delmont-imaging.com or calling +33 9 51 51 30 30.

You can access instructional videos to help you use of our medical devices on: www.youtube.com/@delmontimaging

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1. General device information

1.1. Intended use

W.I

This device and this manual are intended exclusively for trained and qualified personnel. This document describes the correct handling and function of the colposcope system. This document may not be used to carry out colposcope examinations, nor may be used for training purposes.

If, as a user of this device, you feel you need more detailed information regarding the use and care of the device, contact your representative.

This colposcope is intended to provide magnified visualization of the tissues of the vulva, vagina, cervix, and anogenital area.

1.2. Indications for use

The device is indicated for use by healthcare professional in colposcopy procedures in a healthcare centre such as evaluating tissues, select areas for biopsy, conization, or LEEP.

1.3. Target population

Population group	Restrictions
Sex	Female
Age	No restrictions
Weight	No restrictions
Health condition	No restrictions

1.4. Device description

The device is an optical system performing a magnification combined with a high intensity light source for appropriate illumination and view of the area of interest.

The may device may be combined with accessories such as a camera.

Figure 1: Colposcope head

Legend	Function
[1] Eyepieces	Adjusts the dioptre when the user turns it.
[2] Fine focus knob	Focus and get a sharp image when the user turns it.
[3] Objective lens protection	Project the objective lens.
[4] Beam splitter connector	Connects accessories like video adapter
[5] Zoom selector	Selects the desired zoom when the user turns it.
[6] Binocular head clamping screw	Fixes the position of the binocular head tilt when the user turns it.
[7] Green filter trigger	Slide the green filter when the user pulls it.
[8] Handle	Positions the binocular head to the right position.
[9] Light cable	Connects the binocular head to the light source to bring the light

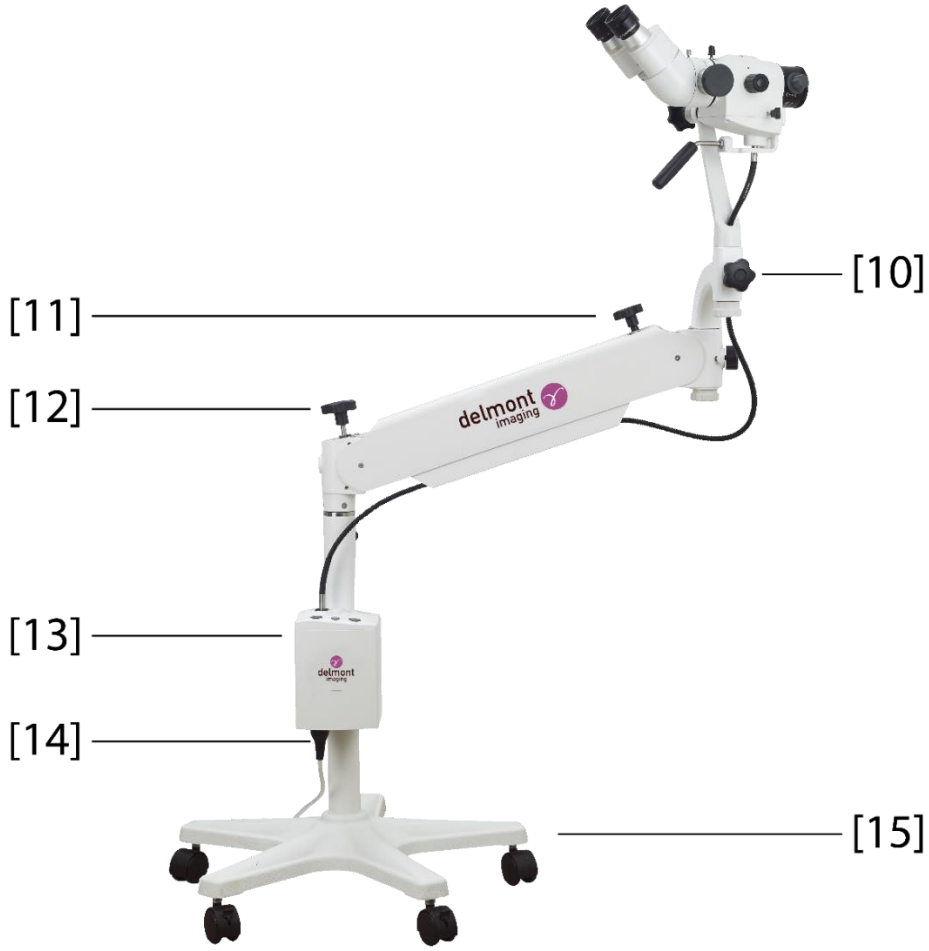


Figure 2: Models with a pantographic arm

Legend	Function
[10] Colposcope head rotation clamping screw	Fixes the position of the binocular head rotation when the user turns it..
[11] Swing arm clamping screw	Fixes the position of the binocular head height when the user turns it.
[12] Load adjustment screw	Adjusts the pantographic arm balance when the user turns it.
[13] Light source	Provides illumination to the binocular head
[14] Power cable	Provides power to the light source
[15] Base with casters	Moves the colposcope to the desired place.

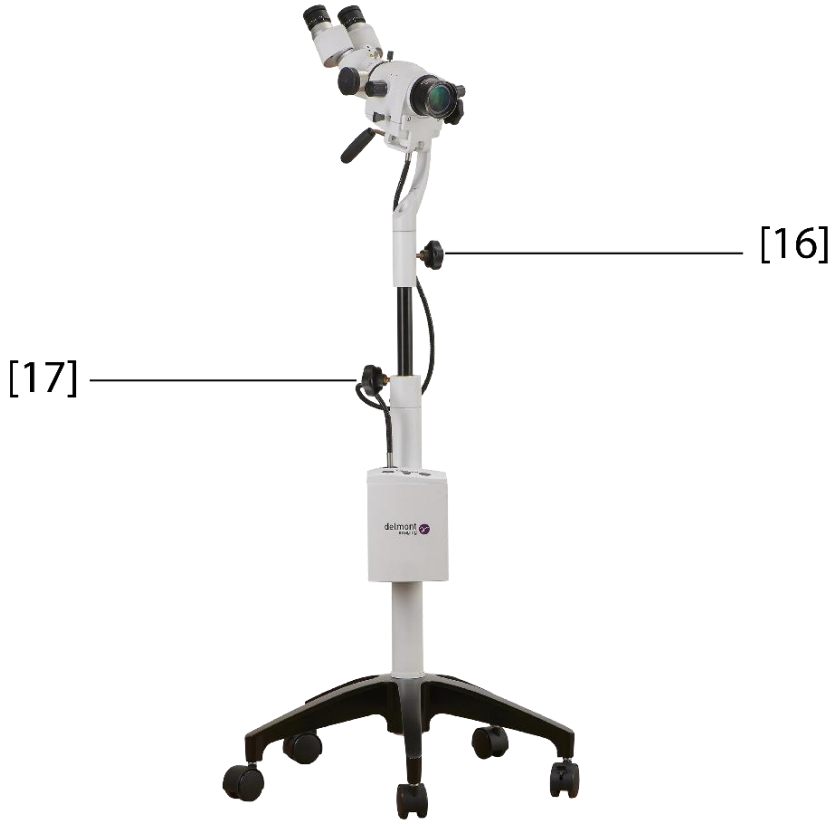


Figure 3: Models without a pantographic arm

Legend	Function
[16] Colposcope head rotation clamping screw	Fixes the position of the binocular head rotation when the user turns it..
[17] Column height adjustment screw	Fixes the position of the binocular head height when the user turns it.

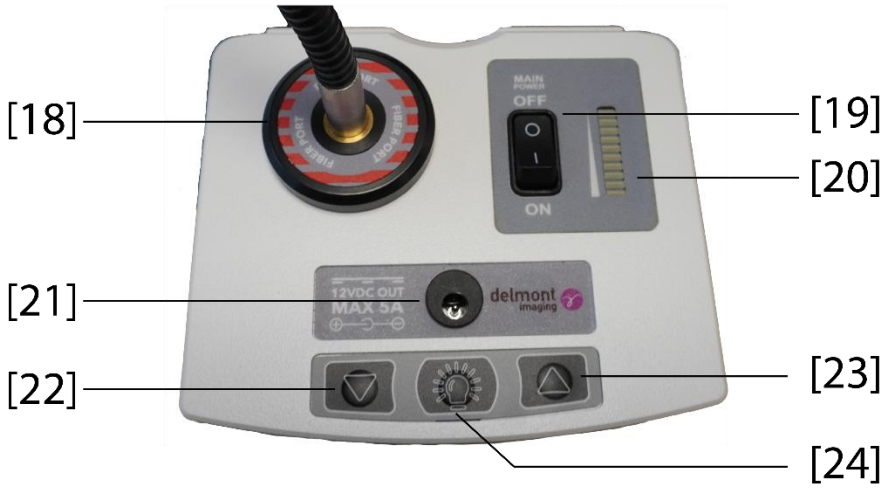


Figure 4: Light source front panel

Legend	Function
[18] Light cable socket	Connects a light cable
[19] Mains ON/OFF switch	Supplies power to the control unit, the user can set it on (I) or off (O)
[20] Luminosity indicator	Indicates the intensity of the light source
[21] Camera power socket	Connects an accessory camera to power it
[22] DOWN arrow button	Decreases the light intensity when the user presses it
[23] UP arrow button	Increases the light intensity when the user presses it
[24] Standby button	Switches the device from standby mode to light on mode and vice versa

Figure 5: Light source rear panel

Legend	Function
[25] Exhaust fan	Extract the air from the device to cool it down
[26] Service connector	Connects to Delmont imaging servicing tools
[27] Power cable socket	Connects a power cable.
[28] Equipotential plug	Brings other equipment to the same potential as the device

1.5. Combination and accessories


W.II

Using incompatible equipment may lead to injury of the patient and/or the user as well as damage to the product. Delmont imaging recommends to only use Delmont imaging devices and accessories.


W.III

Equipment accessories connected to the analogue and digital interfaces must be certified to the respective IEC standards (i.e. IEC 60950 for data analysis equipment and IEC 60601-1 for medical equipment). In addition, all configurations must comply with the IEC 60601-1-1 standard. Any equipment connected to the signal input or signal output part configures a medical system. Therefore, this equipment, and any new configuration, must comply with the requirements of IEC 60601-1-1.


W.IV

Use the light cable and the power supply cable supplied with the equipment. Contact the manufacturer or its distributor in case of replacement.

All colposcopes can be equipped with one of the following objectives:

REF	Description
D100 300 020	Colposcope objective lens F=175mm
D100 300 021	Colposcope objective lens F=200mm
D100 300 022	Colposcope objective lens F=250mm
D100 300 023	Colposcope objective lens F=300mm
D100 300 024	Colposcope objective lens F=400mm
D100 300 004	Objective with variable focal between 200mm and 350mm

They can also be equipped with a beam splitter allowing the installation of a recording device.

REF	Description
D100 300 003	Beamsplitter dual port - 50/50 & 20/80
D100 300 005	Video camera adapter
D100 300 006	C-mount to endoscope eye-piece adapter
D100 300 009	Colposcope to Camera/Video Adapter

Please contact the manufacturer or its approved representative for more details.

2. Safety instructions

Observe the use and safety instructions of the manufacturer. Non-observance of these use and safety instructions may lead to injuries, malfunctions, or other unexpected incidents.

2.1. Contraindications


W.V

Do not use the device if, in the opinion of a qualified physician, the general condition of the patient is not adequate or if endoscopic methods are contraindicated.

No contraindication directly related to the medical device is known today.

The responsible physician must decide on the basis of the patient's general condition, whether the intended application can be carried out. Country-specific regulations and laws must be observed. Further information can be found in the current literature.

2.2. Warning


W.VI

Make sure that the products are used exclusively by trained and qualified personnel. Make sure that the user is proficient, theoretically, and practically, in the approved medical techniques. The user is responsible for the correct execution of the operation.


W.VII

Move the colposcope on flat surfaces only. Transport on uneven surfaces may cause the colposcope to tilt, resulting in injury to personnel or damage to equipment.


W.VIII

Do not tilt the colposcope nor push the colposcope's support post. Tilting or pushing the colposcope creates an imbalance that can cause injury or damage to equipment.

2.3. Precautions specific to the light source


W.IX

Connect the device to a grounded main source to avoid the risk of electric shock.


W.X

Do not look directly to the light source or light cable to avoid eye injury.


W.XI

Do not illuminate a patient until everything is ready and turn off the light when the procedure is complete. Protect the patient's eyes if necessary.


W.XII

Do not place or use the device near flammable materials, including flammable gases and liquids to avoid risk of fire, burns or ignition of flammable materials.

 W.XIII	***Do not switch on the light source in a dangerous, explosive atmosphere***
 W.XIV	***Keep at least 15cm around the fans [25] to avoid overheating.***
 W.XV	***The device is not an applied part and is not intended for patient contact.***

Although this device complies with electromagnetic compatibility EMC standards, it is possible that under very special circumstances it may cause interferences to other devices or may itself be affected by other devices or an adverse electromagnetic environment. To avoid these situations, it is recommended:

- ***To ensure the quality of the electrical network (especially the grounding of all equipment and trolleys).***
- ***To keep the device away from electromagnetic sources (for example, a compressor, a motor, a transformer, an HF generator, etc.).***

2.4. Vigilance

Definition of serious incident may depend on your local regulation. If any doubt exists, we encourage our users to proactively report any incidents. Contact your Delmont imaging representative for more information about reportability.

Medical information must be anonymized prior to be sent to us. Contact our data protection officer at dpo@delmont-imaging.com for more information related to confidentiality.

→ Notify without delay any serious incident or risk of serious incident occurring during the use of this device to:
- vigilance@delmont-imaging.com,
- Your Delmont imaging representative,
- Your competent authorities in accordance with your local regulation.

→ We encourage the users to gather and transfer all appropriate information regarding the incident which includes but is not limited to:
- Patient condition,
- Indications of the procedure,
- Date of incident,
- Reference number and serial/lot number of the device,
- Any pertinent information related to the incident,
- A preferred contact that Delmont imaging can reach in the best delay.

→ Send back the device following recommendation from 5.3, if required by your Delmont imaging representative:

3. Use of the device

3.1. Initial set up of the device


W.XVI

On straight colposcope, the binocular head must be installed on the stand before loosening the height adjustment screw column [17]. The stand contains springs that can slacken and injure someone if the height adjustment screw is loosened before the colposcope head is set.


W.XVII

The binocular head can fall off if mooting screws are not tightened enough.


W.XVIII

If, at any time during or after installation, there is a fall, fluid ingress, or other event that could potentially cause damage or danger, stop and call-in qualified maintenance personnel for verification.


W.XIX

If, at any time, you suspect a fault, or you determine that the essential performance of the device has been impaired (due to electromagnetic interference or other cause), then discontinue installation and contact the manufacturer or its distributor before continuing.


W.XX

Make sure that there is no packaging residue inside the device.


W.XXI

The use of a disposable cloth on the unit to prevent liquids from splashing on the unit is strongly discouraged. Should this be used, it is the responsibility of the installer to ensure that no air outlet is obstructed AND that it is not a flammable material. Failure to follow this instruction could result in a fire hazard.

The eyepieces are equipped with protective shields. The eye protectors protect the eyes, prevent the entry of side lights and create a dark room suitable for the observer.

The binocular head contains internal optical parts that cannot be cleaned without disassembly. It is therefore advisable to keep the eyepieces inserted at all times in order to prevent impurities from entering the interior of the head. If the eyepieces are removed, it is recommended that a clean cloth be placed over the openings.

☑ Before installation, check that the packing boxes are intact. If any damage is found, stop and contact the manufacturer.

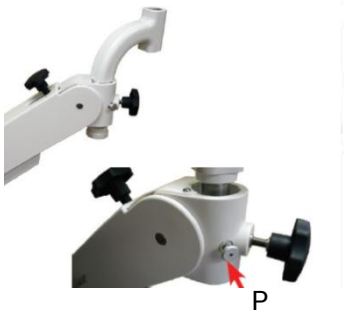
Instructions for colposcopes assembly

→ Place post into base with pin in base, lined up with notch in post.

→ Install bolt and tighten securely with Allen wrench (provided)

→ Place pantographic arm into post if applicable
→ Tighten, without locking it, the clamping screw on the post.

→ Install the light cable into bottom cover of arm, if applicable
→ Connect it to the light source.



→ Untighten the clamping screw and pull the plunger (P) to install extension arm by inserting it into the pantographic arm.
→ Release the plunger and tighten the clamping screw back.

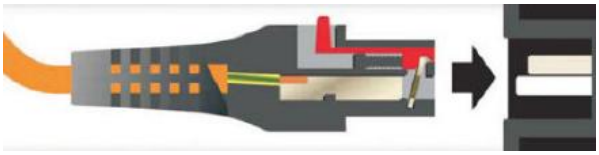
Instructions for colposcopes assembly

→ Install Optic Pod into the extension arm.
→ Loosen the lamping screw on the extension arm while inserting the pin. Fully insert the pin and then tighten the tension knob just enough to prevent it from drifting.

→ Install Binocular Head onto the Optic Pod and tighten thumb screw.
→ Adjust the inclination and tighten the screw.
→ Check the stability of the assembly.

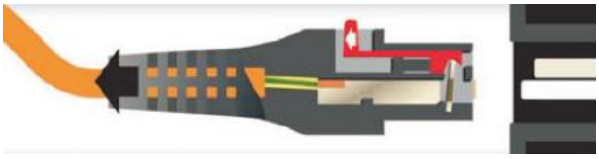
The power cable can now be connected.

IEC LOCK™ power connector instructions



→ Push the connector into the inlet until it is in position.

→ The connector is locked and cannot be disconnected accidentally by pulling or vibrating out of the socket.



→ Slide the "red" tab back to release and remove the connector from the input.

→ To ensure that the unit has been correctly installed, check that:

- ☑ The installed light cable is suitable for both sides (light source and device requiring lighting).
- ☑ The power cable is medical grade and is correctly installed.
- ☑ Check that the fuses are good.
- ☑ The unit is not placed near critical equipment that may be influenced by electromagnetic energy levels.

☑ The ventilation of the unit is unobstructed.

☑ There is no damage to the unit.

☑ There are no flammable gases and liquids at the place of use.

→ Perform a visual inspection and functional tests before using the device (see Section 3.5)

3.2. Operating the device

3.2.1. Settings of the pantographic arm

Do not adjust the load adjusting screw [12] when installing the colposcope. This knob is preset at the factory to match the colposcope configuration. Install the optics without adjusting the tension knob.

Do not set the load adjusting screw [12] to the lowest setting. Failure to observe this warning may result in personal injury or damage to the equipment. When set to the lowest tension, the pantographic arms may not support the weight of the lens and its accessories, which may result in damage if the device falls down.

The balance of the pantographic arm is adjusted at the factory to effortlessly position the colposcope head in the desired viewing position. The colposcope must not drift after release and remain in the desired position. If the pantographic arm drifts upwards or downwards, a tension adjustment is necessary:

→ Turn the load adjusting screw [12] counterclockwise to add tension, clockwise to release tension on the pantographic arm. This will achieve the position desired by the user.

This may be necessary if accessories are added to the colposcope such as a video camera. The pantographic arm may also need to be in a horizontal position to make certain adjustments.

3.2.2. Eyepieces adjustment

The eyepieces are adjustable for use with or without glasses. For optimal viewing with glasses, fold the eyepieces down. For use without glasses, make sure that the eyepieces are folded up.

3.2.3. Inter-pupil distance adjustment

The interpupillary distance (DIP) of the eyepiece is adjustable to match the distance between the pupils of the user's eyes and provide a stereoscopic view through the colposcope. A stereoscopic view is necessary for depth perception.

Look through both eyepieces with both eyes and hold each eyepiece in your hand. With slight semi-rotary movement, adjust the DIP until the image of each eye overlaps and appears as a single image.

3.2.4. Diopter adjustment

The eyepieces allow the diopter to be adjusted for use of the colposcope with or without glasses/corrective lenses. However, this adjustment can only accommodate near-sightedness and/or farsightedness. Other vision defects, such as astigmatism, cannot be corrected using the diopter adjustment and require the use of glasses/corrective lenses. The diopter should only be adjusted during the para-focusing procedure. During normal use of the colposcope, do not adjust the diopter.

- → Set each eyepiece to zero (0) and leave them in this position until it is indicated to adjust them in a later step.
- → Turn the magnification knob to the highest level and focus on a target such as a sheet of paper with an "X" drawn on it. Focus coarsely by moving the colposcope all the way and then focus precisely using the objective knob.
- → Without moving the position of the colposcope or the focus adjustment knob on the lens, turn the magnification knob to the lowest level (1). Then focus the diopter for each eyepiece by turning either clockwise or counterclockwise until visual sharpness is achieved.
- → Once the image is sharp on each side, para-focusing is completed. To check, repeat the previous two steps until the diopter adjustment is no longer necessary to achieve perfect sharpness.
- → Prepare the colposcope for use by following the previous instructions.
- → Switch on the light source and set the desired brightness following the instructions below.

3.2.5. Position of the colposcope

- → Position the colposcope at a distance approximately equal to the focal length of the lens in use that is engraved on the outside of the lens. For example, with a 300mm lens, keep a distance of about 300mm between the lens and the area of interest.
- → To adjust the height, hold the head of the colposcope firmly while loosening the height adjustment screw. Once the column is loose, lower or raise the colposcope head to the desired position and then tighten the height adjustment screw.

3.2.6. Focusing the colposcope

- → The first focusing is done by fully approaching the colposcope.
- → While looking through the colposcope, move the colposcope away from or closer to the area of interest.
- → Observe which direction the focus increases and then continue to move the colposcope in that direction until the focus is relatively accurate.
- → Precise focusing is achieved by turning the focus knob on the lens. Turn the knob until the image is in focus. Re-focus when precise focusing cannot be completed. This is the case if the focus point is beyond the fine focus range.

3.2.7. Magnification parameters

All colposcopes offer a 3 or 5 position magnification knob. To set the magnification, simply turn the knob to the desired position. Setting 1 offers the lowest magnification and the widest field of view. As the number of selector switches increases, the magnification increases but the field of view decreases. See 1.6 for details.

3.2.8. Color filter

A green color filter is available to help highlight vascular samples and offers a tissue contrast viewing option. Use the push button to select white or green light.

3.2.9. Light source functioning

Turn off [19] the light source when the colposcope is not in use.

Standby mode will turn off the lighting but will leave the other circuits active in order to allow a faster response time than the main ON/OFF switch.

There are four basic operations via the light source front panel :

- → Switch ON or OFF the device via the ON/OFF switch [19],
- → Switch the device from STANDBY to RUN mode via the switch with a lamp symbol [24],
- → Increase the light intensity with the "UP" arrow button [23],
- → Decrease the light intensity with the "DOWN" arrow [22].

The DOWN and UP arrows can be activated in two modes:

- → Push and release: this increase the intensity of a level.
- → Push and hold: this allow you to slowly scroll through all the available intensity levels.

The intensity indicator [20] indicates the status and the level of light intensity: STANDBY or RUN. And each SQUARE represents 10% of the intensity level. (i.e. 3 SQUARE equals 30% of the maximum lighting level).

3.3. Visual inspection and functional test

W.XXIV

Do not use the colposcope if any component is damaged, missing, or has a safety defect. This could result in property damage and/or personal injury.

W.XXV

Always make sure that the on/off switch and the exhaust fan are accessible and unobstructed.

- → Before each use, inspect the colposcope including the power cable, base, casters, light source, and light cable to detect any damages or safety defect.
- → Perform the following functional test for essential performance for the device:

- ☑ Check that the light cable is properly connected to the light source and optical module.
- ☑ Press the ON/OFF switch [19], (blue switch with international designation 0/I).
- ☑ Make sure that the LCD display indicates (active) and is in STANDBY mode.
- ☑ Switch to RUN mode by pressing the RUN / STANDBY button [24].
- ☑ Select the brightness level by pressing the UP [23] or DOWN button [22].
- ☑ Check thee free air circulation.
- ☑ Check the lightning is continuous, not blinking,

- ☑ Check there is no inconsistent noise (no scratching, clicking, etc.).
- ☑ Check there is no interference near critical equipment
- ☑ Check the light output is not directed towards someone's eyes.

3.4. Troubleshooting

In the absence of lighting:

- → Confirm the device is plugged and powered,
- → Confirm that the hardware is in RUN mode (not standby).
- → Select the highest brightness level.
- → Confirm that the light cable is installed correctly.
- → Make sure that the fans are not obstructed.
- → Make sure the fans are running.

4. Reprocessing

W.XXVI ***This device must be reprocessed by trained professionals and the protocols used should be done according to the national and local standards and regulations.***

W.XXVII ***If necessary, repeat the reprocessing process until the device is optically clean.***

W.XXVIII ***The light source is not designed to withstand liquid splashes from any direction. Do not spray any cleaning products that could enter through the ventilation outlets and damage the unit.***

The device is not intended to come into contact with the patient and therefore does not require sterilization prior each use.

The lenses shall be free of stains so as not to obstruct the passage of light.

4.1. Preparation

The lens can be protected by using the protective cap. It is adapted to the outer diameter of the lens bezel and thus protects against mechanical damage and stains.

☑ Before cleaning the device, turn the device off and unplug the main power cable.

4.2. Cleaning of the colposcope

Step	Instructions
Cleaning	→ Use lukewarm water added to a mild detergent, applied with a clean piece of cotton, or equivalent wipes to remove any stains on the device. ☑ Follow up detergent manufacturer instructions. → Apply with gentle, circular movements on the entire device. ☑ Follow your facility's internal procedures for removing stains or other contaminants from your unit. → If the device is too stained, change the cotton or wipes for each circular motion to avoid spreading more dirt. → Do not allow exposed lenses windows to air dry. 70% isopropyl alcohol may be applied to glass surfaces with a soft cotton applicator to prevent streaks and spots. Dry the surfaces thoroughly with a cotton applicator after applying the alcohol. → Allow to dry completely before the next use. → After cleaning, follow up visual inspection and functional test (see 3.3)

5. After-sales service and maintenance

5.1. Maintenance

5.1.1. Replacing the fuse


W.XXIX

To avoid the risk of fire, use only fuses of the value specified on the fuse label located on the rear panel of the control unit.

- Unplug the power cord from the wall outlet and remove the cord from the light source.
- Unlatch the fuse holder above the AC inlet and remove it. You may need to press the tab on the fuse holder with a slender screwdriver to release the latch.
- Replace the fuse with the same value and rating as indicated on the rear panel.
- Reinstall the fuse holder until the tab snaps in place.

5.1.2. Lubricate

It is recommended to lubricate the colposcope head after 5 years of use :

- Dismount the colposcope head, and if applicable, the swing arm from the stand,
- Use appropriate lubricant on rotating parts,
- Reassemble the different parts following 3.1 instruction,
- Remove excess of visible lubricant from the joints with a clean, soft tissue.

5.2. Repair


W.XXX

Do not perform repairs or maintenance operations other than the ones specified in these instructions. There is a risk of injury to the patient and/or the user caused by unauthorized repairs and device modification. Possible injuries include mechanical injuries, electric shocks, burns and intoxication.

Delmont imaging service centre does not accept warranty claims for damage caused by inadequate packaging.

Repairs may only be performed by qualified servicing personnel that have been authorized by Delmont imaging. Contact a Delmont imaging representative for repair information and process.

Delmont imaging does not supply original parts to independent workshops or other similar devices manufacturers. Thus, only Delmont imaging is in position to carry out repairs using original parts. The original technical specifications and the operational safety of the device can only be guaranteed by using original parts. Delmont imaging does not accept responsibility for devices that have been modified from the original device.

5.3. Return of the device


W.XXXI

Do not return a device without prior complete reprocessing (see 4). There is risk of infection when returning a used medical device. Returning used medical devices is exclusively permitted when cleaned and disinfected, and with written verification thereof. If reprocessing could damage the device completely, clean the device as thoroughly as possible and mark it accordingly.

→ If you need to return the device:
→ Reprocess the device according to the process described in 4.
→ Use the original cardboard packaging for the transport of the device. If this is not possible, wrap each component individually in sufficient paper or sheets of foamed material and place them in a cardboard box.

5.4. Warranty

This device is guaranteed against defects in workmanship and material. In the event of defects, the device will be replaced, or the charges refunded at the manufacturer's discretion.

The warranty for Delmont imaging devices shall become void if repairs, attempted repairs, alterations or other tampering of this device is carried out by unauthorized personnel. In this case Delmont imaging is also no longer responsible for the technical specifications or safety of the device. In the event of a fall of the device, do not reconnect the device but return it to your authorized distributor or directly to the Delmont imaging after-sales service.

5.5. Disposal


W.XXXII

Keep the used device out of reach of unauthorized person.


W.XXXIII

Do not trash the device with unsorted municipal waste. The device contains electrical waste, it must be collected separately in accordance with applicable national or institutional related policies relating to obsolete electronic equipment.

We encourage our customers to recycle this device whenever possible or to return the device to Delmont imaging who will then take the appropriate steps to recycle the device.

6. Technical data

6.1. General specifications

Mains voltage range [V]	100 - 230
Supply frequency range [Hz]	50 / 60
Equipotential plug (yes/no)	Yes

6.2. Mechanical specifications

Models	with vertical stand	with swing arm	over the shoulder
Base	Five casters, two of which have brakes		
Ground-to-lens distance	1016mm to 1193mm	635 mm to 1295 mm	635 mm to 1295 mm
Angular rotation	360°	340°	340°
Total weight	18 kg	44 kg	44 kg
Horizontal reach	NA	725 mm first arm 600 mm, second arm 110 mm	725 mm first arm 600 mm, second arm 110 mm
Load adjustment	NA	4 to 7kg	4 to 7kg

6.3. Optical specifications

Colposcope	Galilean system		
Binocular	Straight, F=170 mm.	Tilted, F=135	
Fixed objective lens	200 mm	300mm	400mm
Focusing	11 mm		
Variofocus	Optional. Focus between 200mm and 350mm		
Eyepiece	Wide-angle type 12.5x, adjustable (-6 to +6 diopters)		
Magnification	Refer to the tables below		
Pupil distance	Between 42mm and 75 mm		
Filter	Green		

The optical magnifications achieved with the colposcope are determined by 3 variables: the focal length of the objective, the position of the magnification and the eyepiece.

The following tables show the optical magnification and the diameter (Ø) of the observed field, in millimeters, according to these variables. The last line of the table gives the diameter (Ø) of the illuminated field. It corresponds to the disc of light in the incident plane, its diameter depends only on the focal length of the objective and therefore on the colposcope/area of interest distance. The magnification selector has 3 or 5 positions depending on the model.

For 3 positions models, the 2nd position is repeated in the selector. The working position is the position aligned with the optical black point and the magnification field table.

Eyepiece	Magnification Selecter	Objective lense									
		F=175		F=200		F=250		F=300		F=400	
		Magnification (x)	Ø field (mm)	Magnification (x)	Ø field (mm)	Magnification (x)	Ø field (mm)	Magnification (x)	Ø field (mm)	Magnification(x)	Ø field (mm)
10X/18	1(0.6)	5.83	30.88	5.10	35.29	4.08	44.12	3.4	52.94	2.55	70.59
	2(1.0)	9.71	18.53	8.50	21.18	6.80	26.47	5.67	31.76	4.25	42.35
	3(1.6)	15.54	11.58	13.60	13.24	10.88	16.54	9.07	19.85	6.80	26.47
12.5X/16	1(0.6)	7.29	27.45	6.38	31.37	5.10	39.22	4.25	47.06	3.19	62.75
	2(1.0)	12.14	16.47	10.63	18.82	8.50	23.53	7.08	28.24	5.31	37.65
	3(1.6)	19.43	10.29	17.00	11.76	13.60	14.71	11.33	17.65	8.50	23.53
16X/16	1(0.6)	9.33	27.45	8.16	31.37	6.53	39.22	5.44	47.06	4.08	62.75
	2(1.0)	15.54	16.47	13.60	18.82	10.88	23.53	9.07	28.24	6.80	37.65
	3(1.6)	24.87	10.29	21.76	11.76	17.41	14.71	14.51	17.65	10.88	23.53
Ø illuminated field		65		72		90		108		144	

For the 5 positions model, position 3 is repeated in the selector. The working position is the position aligned with the optical black point and the magnification field table.

Ocular	Magnification selector	Objective lens									
		F=175		F=200		F=250		F=300		F=400	
		Magnification (x)	Ø field (mm)	Magnification (x)	Ø field (mm)	Magnification (x)	Ø field (mm)	Magnification (x)	Ø field (mm)	Magnification (x)	Ø field (mm)
10X/18	1(0.4)	3.89	46.32	3.40	52.94	2.72	66.18	2.27	79.41	1.70	105.88
	2(0.6)	5.83	30.88	5.10	35.29	4.08	44.12	3.4	52.94	2.55	70.59
	3(1.0)	9.71	18.53	8.50	21.18	6.80	26.47	5.67	31.76	4.25	42.35
	4(1.6)	15.54	11.58	13.60	13.24	10.88	16.54	9.07	19.85	6.80	26.47
	5(2.5)	24.29	7.41	21.25	8.47	17.00	10.59	14.17	12.71	10.63	16.94
12.5X/16	1(40.)	4.86	41.18	4.25	47.06	3.40	58.82	2.83	70.59	2.13	94.12
	2(0.6)	7.29	27.45	6.38	31.37	5.10	39.22	4.25	47.06	3.19	62.75
	3(1.0)	12.14	16.47	10.63	18.82	8.50	23.53	7.08	28.24	5.31	37.65
	4(1.6)	19.43	10.29	17.00	11.76	13.60	14.71	11.33	17.65	8.50	23.53
	5(2.5)	30.36	6.59	26.56	7.53	21.25	9.41	17.71	11.29	13.28	15.06
16X/16	1(0.4)	6.22	41.18	5.44	47.06	4.35	58.82	3.63	70.59	2.72	94.12
	2(0.6)	9.33	27.45	8.16	31.37	6.53	39.22	5.44	47.06	4.08	62.75
	3(1.0)	15.54	16.47	13.60	18.82	10.88	23.53	9.07	28.24	6.80	37.65
	4(1.6)	24.87	10.29	21.76	11.76	17.41	14.71	14.51	17.65	10.88	23.53
	5(2.5)	38.86	6.59	34.00	7.53	27.20	9.41	22.67	11.29	17.00	15.06
Ø illuminated field		65		72		90		108		144	

6.4. Light source specifications

Specification area	Specification value
Light source	Light emitting diode
Lifetime	30.000 hours
Input voltage range	100 – 240 V
Frequency range of the input power	50 - 60 Hz
Input current power range	1.5 A
Total energy consumption	100 W
Modes	RUN, STANDBY
Fusibles	250VAC 1.5A, GMA 5mm X 20mm

6.5. Conditions of use

6.5.1. Transport conditions

Ambient temperature	- 30°C to 50°C
Relative humidity	10% to 90%, non-condensing
Atmospheric pressure	20.0 kPa to 106.0 kPa

6.5.2. Storage conditions

Ambient temperature	10°C to 35°C
Relative humidity	10% to 85%, non-condensing
Atmospheric pressure	70.0 kPa to 106.0 kPa

6.5.3. Operating conditions

Ambient temperature	10°C to 30°C
Relative humidity	30% to 75%, non-condensing
Atmospheric pressure	70.0 kPa to 106.0 kPa

6.6. Electromagnetic compatibility specifications

Guidance and manufacturer's declaration: electromagnetic emissions

The medical equipment is intended for use in the electromagnetic environment specified below. The user must ensure that it is actually used in this environment.

Emissions test	Compliance	Electromagnetic environment Guidance
RF emissions CISPR 11	Group 1	The medical equipment only uses radio power for its subsystems. It therefore emits very low RF energy and is not likely to interfere with nearby electronic devices. The medical equipment must be used in all installations, other than residential installations and premises directly connected to the public low voltage power distribution network intended to supply residential buildings.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Compliant	
Voltage fluctuations/Flicker IEC 61000-3-3	Compliant	

Guidance and manufacturer's declaration: electromagnetic immunity

The medical equipment has been designed for use in the electromagnetic environment specified below. The user must ensure that it is actually used in this environment.

Immunity test	IEC 60601 Severity Level	Compliance Level	Electromagnetic environment-Guidance
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV via contact ± 15 kV via air	± 8 kV ± 15 kV	The floor must be made of wood, concrete or tiles. If the floor is covered with a synthetic material, the relative humidity must be at least 30%.
Rapid transient peaks IEC 61000-4-4	± 2 kV power lines	± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Electric shocks IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV ± 2 kV	
Power outages, short power outages and voltage fluctuations IEC 61000-4-11	<5% Ut for 10 ms 40% Ut for 100 ms 70% Ut for 500 ms <5% Ut for 5 s	5% Ut 10 ms <40% Ut 100 ms <70% Ut 500 ms <5% Ut 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device must be able to continue working during power outages, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	The magnetic field at the mains frequency must be at a characteristic level of a location (50/60 Hz) in a typical commercial or hospital environment. The device should be kept at least 15 cm away from the source of power frequency magnetic fields during use.

Guidance and manufacturer's declaration: electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below. The user must ensure that it is actually used in this environment.

Safety test	IEC 60601 Severity Level	Compliance Level	Electromagnetic environment: Guidance[1]
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[2], should be less than the compliance level in each frequency range. Other portable RF emitting equipment should be kept away at a minimum separation distance based on the maximum effective radiated power specified by the manufacturer of the equipment. The required separation can be calculated as: $d = 2.33 \times \sqrt{ERP}$ where d is the distance in meters (m) and ERP is the effective radiated power in watts (W). Interference may occur in the vicinity of equipment marked with the following symbol : 
Conducted RF IEC 61000-4-6	3 V[3] (6 V in ISM and amateur radio bands[4]) 150 kHz to 80 MHz	3 V (6 V in ISM and amateur radio bands) 150 kHz to 80 MHz	

Recommended distances between portable and mobile RF communication systems for this product

The equipment has been designed for use in the electromagnetic environment in which the emitted RF interference is controlled. The user can help avoid electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication systems (transmitters) and this equipment, as recommended below, as a function of the maximum output power of the communication system.

[1] These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[2] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the medical equipment is used exceeds the applicable RF compliance level above, the medical equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

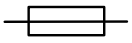
[3] A conducted interference level of 3 V corresponds to a field strength of 3 V/m. A conducted interference level of 6 V corresponds to a field strength of 6 V/m.

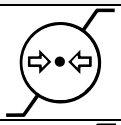
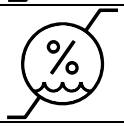
[4] The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 - 6.795 MHz; 13.553 - 13.567 MHz; 26.957 - 27.283 MHz; and 40.66 - 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 - 2.0 MHz; 3.5 - 4.0 MHz; 5.3 - 5.4 MHz; 7 - 7.3 MHz; 10.1 - 10.15 MHz; 14 - 14.2 MHz; 18.07 - 18.17 MHz; 21.0 - 21.4 MHz; 24.89 - 24.99 MHz; 28.0 - 29.7 MHz; and 50.0 - 54.0 MHz.

Maximum assigned transmitter output power in W	Separation distance as a function of transmitter frequency (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1{,}16 \sqrt{P}$	$d = 1{,}16 \sqrt{P}$	$d = 2{,}33 \sqrt{P}$
0.01	0.116	0.116	0.233
0.1	0.366	0.366	0.736
1	1.16	1.16	2.33
10	3.66	3.66	7.36
100	11.6	11.6	23.3

7. Symbols used

Symbol	Description
	Symbol for “Caution”. Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Symbol for “Refer to operating instructions”. Indicates to the user that it is necessary to consult the operating instructions.
	Symbol for “Refer to user manual/brochure”. Indicates mandatory action to read the instructions for use.
	Symbol for “Manufacturer”. Indicates the manufacturer of the medical device.
	Symbol for “Date of manufacture”. Indicates the date the medical device was manufactured
	Symbol for “Country of manufacture”. Identifies the country in which the products were manufactured.
	Symbol for “CE marking”. Indicates that a device has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements.
	Symbol as an alternative to the prescription device labeling statement. Indicates that U.S.A. Federal law restricts this device to sale by or on the order.
	Symbol for “RoHS compliant”. Indicates that a device has been assessed by the manufacturer and deemed to meet European Union’s restrictions of certain dangerous substances used in electronic and electrical equipment
	Symbol for “Medical device”. Indicates that the item is a medical device.
	Symbol for “Serial Number”. Indicates the manufacturer's serial number in order to formally identify a specific medical device.
	Symbol for “Lot code”. Indicates the manufacturer's lot code so that the lot can be formally identified.

Symbol	Description
	Symbol for “Catalogue number”. Indicates the manufacturer's catalog number so that the medical device can be positively identified.
	Symbol for “Unique Device Identifier”. Denotes a medium that contains information about a unique device identifier.
	Symbol for "Quantity". Indicates the number of devices included in the package.
	Symbol for “Not made with natural rubber latex”. Indicates, that product is not made with natural rubber latex.
	Symbol for “Non-sterile”. Denotes a medical device that has not been subjected to a sterilization process.
	Symbol for “Do not use if package is damaged”. Indicates a medical device that should not be used if the packaging has been damaged or opened and the user should consult the instructions for use for further information.
	Symbol for “Standby” Indicates the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition.
	Symbol for “On Power”. Indicates connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.
	Symbol for “Off Power”. Indicates disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved.
	Symbol for “Direct Current”. Indicate the type of mains supply.
	Symbol for “Both direct and alternating current”. Indicate the type of mains supply.
	Symbol for “Equipotential plug”. Indicates the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential.
	Symbol for “UL/CSA tied fuses” Indicates the fuses boxes or their location marked with type and rating.
	Symbol for “Temperature limit”. Indicates the minimum and maximum temperatures to which the medical device may be safely exposed.

Symbol	Description
	Symbol for “Atmospheric pressure limit”. Indicates the range of atmospheric pressure to which the medical device may be safely exposed.
	Symbol for “Humidity limit”. Indicates the minimum and maximum humidity to which the medical device may be safely exposed.
	Symbol for “Protect from heat and radioactive sources”. Indicates a medical device that is sensitive to heat and radioactive sources.
	Symbol for “Moisture Sensitive”. Indicates a medical device that is moisture sensitive.
	Symbol for “Fragile, handle with care”. Indicates a medical device that may be broken or damaged if not handled with care
	Symbol for “Transport conditions”. Indicates the transport conditions that should be respected.
	Symbol for “Storage conditions”. Indicates the storage conditions that should be respected.
	Symbol for “Handle with care”. Indicates the package should be handled with precaution
	Symbol for “This way up”. To indicate correct upright position of the transport package.
	Symbol for “WEEE; waste electrical and electronic equipment; crossed-out wheeled bin”. Indicates that separate collection for waste electric and electronic equipment (WEEE) is required.
	Symbol for “Warning; Electricity” Warns of electricity.
	Symbol for “Warning; Hot surface” Warns of a hot surface .
	Symbol for “Visible radiation, instructional safeguard” Provides an instructional safeguard "WARNING: Do not stare into beam", "WARNING: Turn off the lamp before opening" and "WARNING: Use eye protection during servicing".

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