EN - Instructions for use

Colposcope

REF This manual relates to a medical device designated by colposcope system and their accessories with basic UDI-ID 37012178COLPHQ :

List of devices
D100 300 000 to D100 300 599

Carefully read these instructions before using any medical device. Keep them in a safe place for future reference. It is recommended that all personnel involved read this manual before using the device.

Symbols used in this manual	
⚠	Instructions for preventing personal injury and material damage.
❗	Instructions for preventing material damage only.
ⓘ	Informations to facilitate understanding or workflow optimization.
✓	Prerequisite.
➢	Instruction.

TABLE OF CONTENT

1. Device description

1.1. Intended use

This manual is intended exclusively for trained and qualified healthcare personnel. This colposcope is intended to provide magnified visualization of the tissues of the vulva, vagina, cervix, and anogenital area. It is used to evaluate these tissues, select areas for biopsy, as necessary, and to facilitate related procedures, e.g, LEEP or conization.

It is combined with a high intensity continuous light source to have appropriate illumination. Light source is intended to be used as accessories to the colposcope and not as stand-alone devices.

W.I

This document describes the correct use and operation of a colposcope. This document should not be used for colposcopic examinations, surgeries or training purposes. This device must be used by qualified personnel in a health care facility.

As a minimum, personnel working with the device must have the following qualifications:

- ✓ Installation: Medical engineer or similar training accompanied by specific training provided by the supplier or a broader medical system.
- ✓ Procedure: Medical training in surgical procedures plus specific training provided by the provider or a broader medical system.

1.2. Specific details

Figure 1 Colposcope head

1: Eyepieces
2: Binocular head
3: Thumb screw for binocular head
4: Magnification knob
5: Objective lens
6: Inclination clamping screw
7: Green Filter
8: Fine focus knob
9: Handle
10: light cable

Figure 2 Models with pantographic arms

1: Binocular clamping screw
2: Colposcope head rotation clamping screw
3: Swing arm clamping screw
4: Load adjustment screw
5: Pantographic arm
6: Light cable
7: Light source
8: Power cable
9: Base with casters

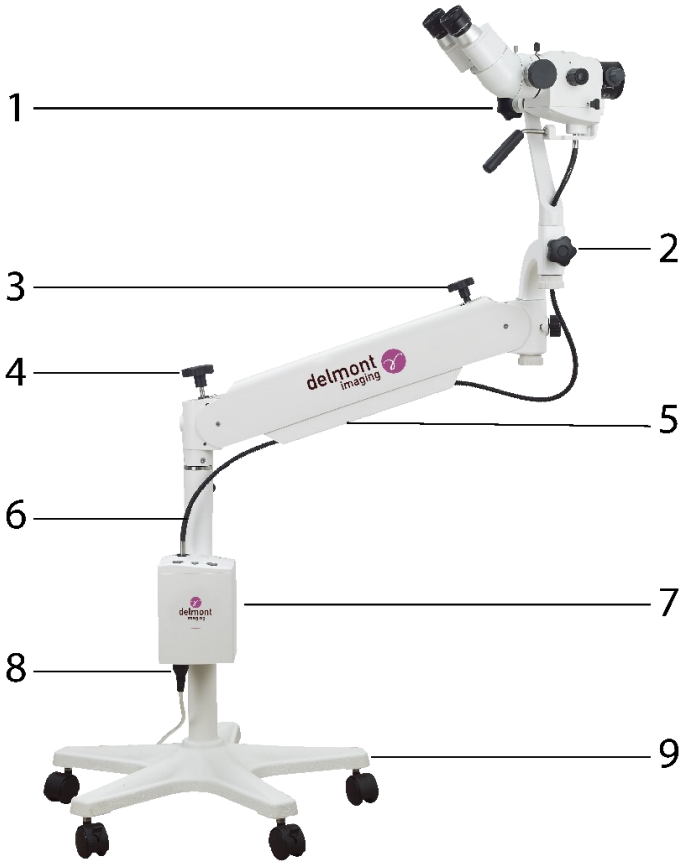
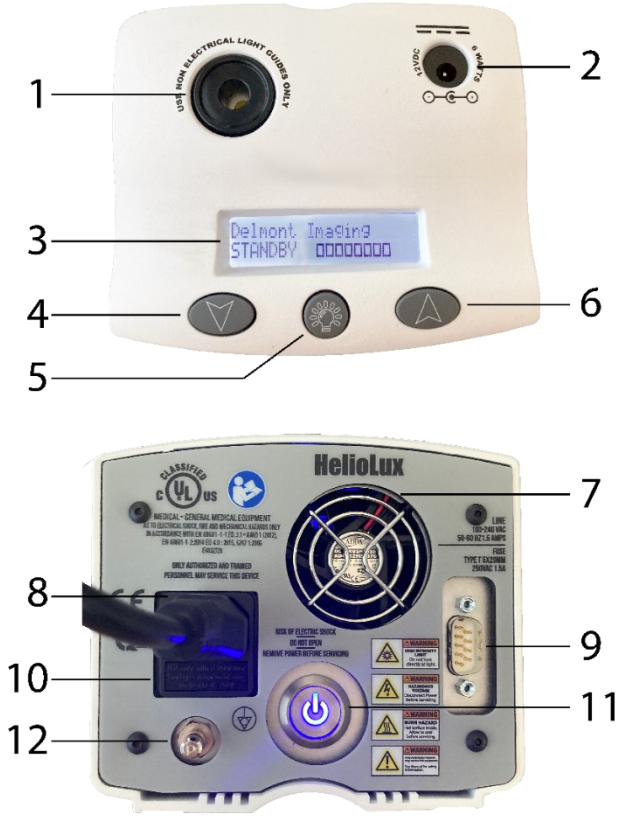


Figure 3 Models without pantographic arm

1: Colposcope head
2: Colposcope head rotation clamping screw
3: Column height adjustment screw
4: Light source
5: Base with casters

Figure 4 Light source details



1: Light cable connection socket
2: Camera power socket (12VDC at 500 mA max)
3: LCD Display
4: DOWN arrow button
5: Standby button
6: UP arrow button
7: Exhaust fan
8: IFC mains power socket
9: Service connector
10: Power cable
11: Mains ON/OFF switch
12: Equipotential plug

1.3. 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.

Use only cameras that operate at 12 VDC at 500 mA or less when plugged on the light source power socket.

Use only approved non-electric liquid or fiber-based light cables.

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

2.1. Warning and precautions

W.V

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

W.VI

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.VII

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

2.2. Instructions specific to light source

W.VIII

To avoid the risk of electric shock, this equipment must be connected to a grounded main source. Make sure that a main source is available within range of the medical grade cable.

W.IX

This unit emits intense light that can cause damage.

- ***Use only with protective equipment in place. Protect eyes and skin from exposure to intense light.***
- ***Never look directly at the LED ports or LED reflections or fiber optic light guides.***
- ***Limit the exposure of your limbs or organs other than what is required for useful surgical procedures.***
- ***Do not illuminate a patient until everything is ready and turn off the light when the procedure is complete.***
- ***Do not direct the light beam into the patient's eyes / protect the patient's eyes if necessary.***
- ***Do not switch on the lighting unless the light guides are connected.***
- ***Do not place the unit near materials that could be affected by high light intensity (such as photosensitive materials, etc.)***

W.X

This device is capable of causing fire, burns or ignition of flammable materials.

- ***Do not place or use the appliance near flammable materials, including flammable gases and liquids.***
- ***Keep at least 15cm around the fan inlets (Figure 4, (7)) and outlets to avoid overheating.***
- ***Do not switch on the light source in a dangerous, explosive atmosphere.***

W.XI

This device emits a certain level of electromagnetic energy.

- ***Do not use the light source near equipment sensitive to electromagnetic interference (30 cm or less). Communication, portable and mobile RF equipment can affect electrical medical equipment.***
- ***Select a suitable location and power source for the unit as described below.***
- ***Ensure that there is sufficient separation distance between the unit and any equipment that may be affected by electromagnetic energy from the unit.***
- ***Power the unit from a circuit different from any circuit containing a device that may be affected by electromagnetic energy from the illuminator.***
- ***Do not turn on the light source in an MRI area.***

This device complies with the international standards for electromagnetic compatibility for electrical medical equipment. These standards are designed to provide reasonable protection against harmful interference in a typical medical installation. However, due to the proliferation of radio frequency transmission equipment and other sources of electrical interference in medical environments, it is possible that high levels of such interference, due to the proximity or force of a source, may hinder the performance of this device. Electrical equipment requires special precautions regarding electromagnetic compatibility (EMC), and all equipment must be installed and commissioned according to the EMC information specified in this manual.

2.3. Contraindication

W.XII

The use of colposcope is contraindicated when colposcopy practice is contraindicated for the patient.

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.

2.4. Vigilance

Any serious incident occurring during the use of this device must be notified to the manufacturer Delmont Imaging (vigilance@delmont-imaging.com), or its representative and to the competent authorities in accordance with the national laws in force.

3. Use of the device

3.1. Conditions of use

3.1.1. Transport conditions

Ambient Temperature	-40°C to 50°C
Relative Humidity	10% to 90%, non-condensing
Atmospheric Pressure	50.0 kPa to 106.0 kPa

3.1.1. Storage conditions

Ambient Temperature	0°C to 50°C
Relative Humidity	10% to 90%, non-condensing
Atmospheric Pressure	50.0 kPa to 106.0 kPa

3.1.2. 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

3.2. Installation of the device

W.XIII

On straight colposcope, the binocular head must be installed on the stand before loosening the height adjustment screw column (see Figure 3, (3)). The stand contains springs that can slacken and injure someone if the height adjustment screw is loosened before the colposcope head is set.

W.XIV

The binocular head (see Figure 1, (3)) can fall off if the screw is not tightened.

W.XV

Failure to choose a suitable installation site is dangerous.

- ***Use only authorized and properly trained personnel to perform the installation.***
- ***Care should be taken when installing the device.***
- ***Incorrectly long fasteners can damage the internal circuitry and printed circuit boards.***

W.XVI

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.XVII

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.XVIII

Do not use sharp instruments during installation, as this will damage internal components and cause hazards.

W.XIX

Make sure that there is no packaging residue (pieces of foam, etc.) inside the unit

W.XX

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.

Handle these parts from the packing case, with maximum care:

- ***Optical head support,***
- ***Binocular,***
- ***Objective lens.***

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

Instructions for colposcopes assembly

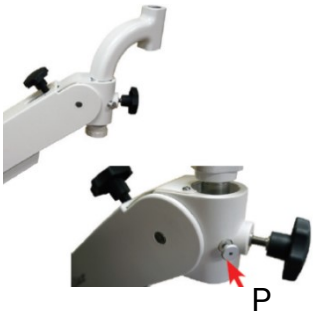
➢ Place post into base with pin in base, lined up with notch in post.

Instructions for colposcopes assembly

- 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.

- 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.

Instructions for colposcopes assembly

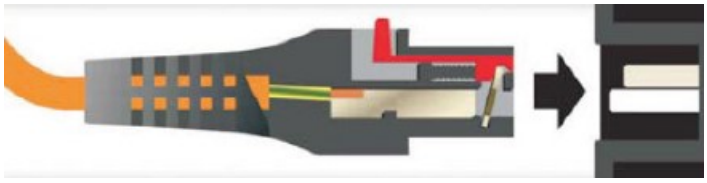
- Install Binocular Head onto the Optic Pod and tighten thumb screw.
- Adjust the inclination and tighten the screw.
- Check the stability of the assembly.

The 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.

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)

3.3. Settings

3.3.1. Settings of the pantographic arm

W.XXI

Do not adjust the load adjusting screw (see Figure 2, (4)) when installing the colposcope. This knob is preset at the factory to match the colposcope configuration of the control. Install the optics without adjusting the tension knob.

W.XXII

Do not set the load adjusting screw (see Figure 2, (4)) 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 (see *Figure 2*) 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.

3.3.2. 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.

3.3.3. 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. Using the thumb knob or a slight semi-rotary movement, adjust the DIP until the image of each eye overlaps and appears as a single image.

3.3.4. 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.

3.4. Functioning

Prepare the colposcope for use by following the previous instructions (see 3.2 and 3.3). Switch on the light source and set the desired brightness following the instructions below.

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

3.4.1. 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.

3.4.2. 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.

3.4.3. 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.

3.4.4. 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.

3.4.5. Light source functioning

There are three basic operations via the control panel (see Figure 4 Light source details).

- Switch the unit from STANDBY to RUN mode via the switch with a lamp symbol (Figure 4, (5)).
- Increase the light intensity with the "UP" arrow button (Figure 4, (4)),
- Decrease the light intensity with the "DOWN" arrow (Figure 4, (6)),

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.

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 LCD screen 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).

If the unit detects a fault, it will indicate FAULT followed by the type of fault.

To switch off the lighting for short periods (less than 60 minutes) press STANDBY. Beyond that (when lighting is not required within 60 minutes), press the ON/OFF button.

3.5. Visual inspection and functional test

W.XXIII ***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.XXIV ***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, (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 (see Figure 4).
  - ✓ Select the brightness level by pressing the UP or DOWN button.
  - ✓ Free air circulation.
  - ✓ Lightning
  - ✓ Consistent noise (no scratching, clicking, etc.).
  - ✓ No interference near critical equipment
  - ✓ No interference in the vicinity of running equipment (large unshielded motors, etc.)
  - ✓ The light outputs do not violate the hazard mitigation instructions (light is not directed towards someone's eyes).
  - ✓ Confirm that the blue light on the back of the ON/OFF button is off after turning off the device.
  - ✓ Confirm that there is no fault detected/displayed on the LCD.

3.6. Troubleshooting

In the absence of lighting:

- Confirm that the hardware is in RUN mode (not standby).
- Select the highest brightness level.
- Confirm that the light cable is installed correctly.

If the system indicates a TEMPERATURE FAULT:

- Make sure that the fans are not obstructed.
- Make sure the fans are running.

4. Reprocessing

W.XXV

This device must be cleaned according to the applicable national and local standards and regulations.

Do not use bleach, steam sterilization (autoclave) or automatic cleaning machine.

4.1. Preparation

The device is not intended to come into contact with the patient and therefore does not require sterilization prior each use. Stains on the lens may obscure the passage of light, and all type of stains on the device should be removed as deemed necessary by the user.

➢ Before cleaning the device, turn it off and unplug it.

4.2. Cleaning of the colposcope

The light source is not designed to withstand liquid splashes from any direction. Always keep the material free from splashes and do not spray any cleaning products that could enter through the ventilation outlets and damage the unit.

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.

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 3.5)

5. After-sales service and maintenance

5.1. Maintenance

W.XXVI ***Before carrying out any maintenance work, wait at least 10 minutes after disconnecting the power cable from the appliance to allow any energy reserves to dissipate from the appliance. Failure to follow this procedure could cause danger.***

5.1.1. 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 following instructions in 3.2,
- Use appropriate lubricant on rotating parts,
- Reassemble the different parts following 3.2 instruction,
- Remove excess of visible lubricant from the joints with a clean, soft tissue.

5.1.2. Replacing the fuse

W.XXVII ***To avoid the risk of fire, use only fuses of the value specified on the fuse label located on the rear panel of the light source.***

- 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.

5.2. Repair

W.XXVIII ***There is a risk of injury to the patient and/or user due to unauthorized repairs and production modifications. Possible injuries include mechanical injuries, electrical shocks, burns.***

W.XXIX ***The return of used medical devices is only permitted when they are cleaned and disinfected and with a written check of the devices.***

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

In the event that the above troubleshooting operations have failed to correct a condition or other defect, such as visible damage, irregular noise, excessive heat, no lighting, code anomaly, etc., take note of the conditions and contact the manufacturer or its distributor to receive the necessary instructions.

Do not attempt to repair or modify the device. Repairs may only be performed by qualified service personnel authorized by Delmont Imaging, using genuine parts supplied by Delmont Imaging. The original technical specifications and operational safety of our devices can only be guaranteed by using original parts.

The warranty on Delmont imaging products is void if repairs are performed by a workshop not authorized by Delmont Imaging. In this case, Delmont Imaging is also no longer responsible for the technical specifications or safety of the product.

Use the original cardboard packaging for transporting the product. If this is not possible, wrap each component individually in a sufficient amount of paper or foam sheets and place them in a cardboard box.

5.3. Warranty

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

The warranty does not cover equipment subject to misuse, accidental damage, normal wear and tear, or if it is transferred to a new owner without authorization from Delmont imaging.

5.4. Disposal

W.XXX

Keep the used device out of the reach of unauthorized persons.

This device contains electrical waste. It must be sorted and collected separately in accordance with applicable national and local environmental regulations.

We encourage our customers to recycle this product whenever possible. Please contact Delmont imaging or its representative for information on how to dispose and recycle your medical device in your area.

6. Technical data

6.1. 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

6.2. 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

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)
Ø illuminated field		65		72		90		108		144	

6.3. Light source specifications

Specification area	Specification value
Light source	Light emitting diode
Lifetime	Minimum 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

6.4. 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	±2.4.6.8 kV contact ±2.4.8.15 kV air	Floors should be wood. concrete, or ceramic tile. If floors are covered with synthetic material. the relative humidity should be at least 10 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines (directly coupled) ±1 kV for input/ output lines (capacitively coupled)	±2 kV for power supply lines (directly coupled) ±1 kV for input/ output lines (capacitively coupled)	The quality of the main power supply must be the one of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential mode ± 2 kV Common mode	±0.5, 1 kV differential mode ±0.5, 1, 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0% Ut (100% dip in Ut) for 0.5 cycle 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 0.5 sec. 0% Ut (interruption) for 5 sec.	0% Ut (100% dip in Ut)for 0.5 cycle 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 0.5 sec. 0% Ut (interruption) for 5 sec.	The quality of the main power supply must be the one of a typical commercial or hospital environment. If the user of this medical equipment requires continued operation during power mains interruptions, it is recommended that this product 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	Power-frequency magnetic fields should not exceed levels characteristic of a typical commercial or hospital environment.

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 “CE marking”. Indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements.
	Symbol for “Ukrainian marking”. Indicates that a product has been assessed by the manufacturer and deemed to meet Ukrainian safety, health and environmental protection requirements.
	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 “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 “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	Description
	Symbol for “Moisture Sensitive”. Indicates a medical device that is moisture sensitive.
	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 “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 “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".

CE

Delmont imaging - Zone Athélia V
390, Avenue du Mistral - 13600 La Ciotat - FRANCE
Tel. +33 (0) 9 51 51 30 30
Fax. +33 (0) 9 57 51 31 00
contact@delmont-imaging.com
www.delmont-imaging.com

delmont
imaging