



# EN - Instructions for use Colposcope system (2<sup>nd</sup> generation)

# Instructions for use Colposcope system (2<sup>nd</sup> generation)



**R<sub>x</sub>** 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.***



**Delmont imaging**  
390 Avenue du Mistral – 13600 La Ciotat – France  
Phone : +33 9 51 51 30 30 – Fax : +33 9 57 51 31 00  
[contact@delmont-imaging.com](mailto:contact@delmont-imaging.com) – [www.delmont-imaging.com](http://www.delmont-imaging.com)

**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](mailto: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](http://www.youtube.com/@delmontimaging)***



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## 1. General device information

### 1.1. Intended use



***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 illumination and 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 digital camera.

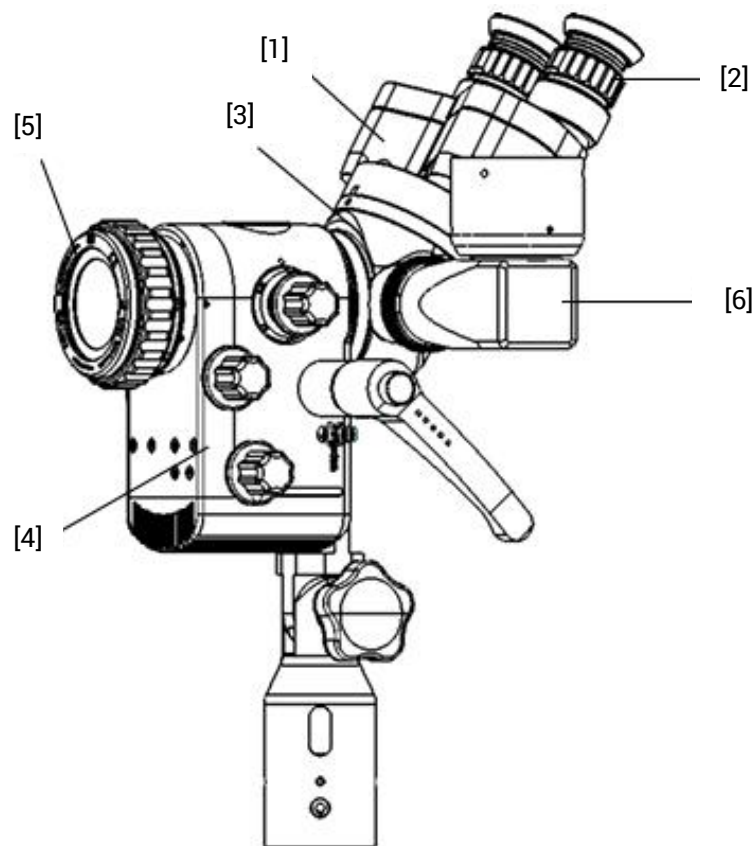


Figure 1: Colposcope head

| Legend             | Function                                                 |
|--------------------|----------------------------------------------------------|
| [1] Binocular tube | Adjusts the inter-pupil distance when the user turns it. |
| [2] Eyepiece       | Adjusts the individual dioptrre when the user turns it.  |
| [3] Ergo-Optik     | Inclines the optical path to improve ergonomic           |
| [4] Lighting unit  | Provides the illumination to the targeted area           |
| [5] Objective      | Sets the desired focal length.                           |
| [6] Camera adapter | Fixes the camera accessory for digital recording         |

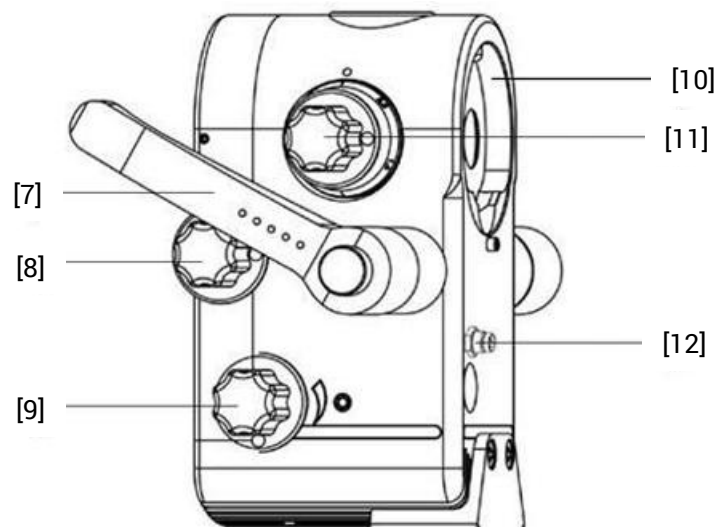


Figure 2: Left side of the colposcope head from the practitioner's point of view

| Legend                      | Function                                                                |
|-----------------------------|-------------------------------------------------------------------------|
| [7] Handle                  | Moves the colposcope head to the desired place                          |
| [8] Green filter            | Places a green filter into the illumination beam when turned.           |
| [9] Diaphragm               | Adapts the diaphragm diameter when the user rotates it.                 |
| [10] Binocular thread       | Connects the binocular head                                             |
| [11] Magnification selector | Change to one of the five magnification levels when the user rotates it |
| [12] Output DC 24V / 3.2A   | Fixes the power cable to supply the lighting unit.                      |

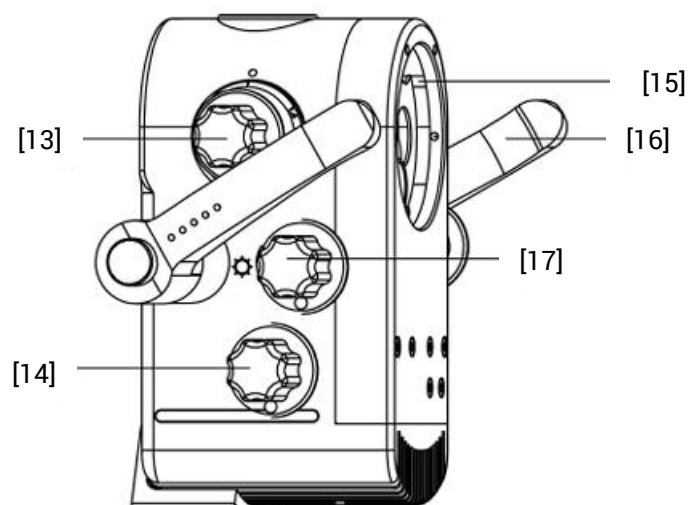


*Figure 3: Right side of the colposcope head from the practitioner's point of view*

| Legend                      | Function                                                                 |
|-----------------------------|--------------------------------------------------------------------------|
| [13] Magnification selector | Change to one of the five magnification levels when the user rotates it  |
| [14] Standby                | Turns the light source on or off when the user rotates it.               |
| [15] Objective thread       | Connects the objective to the binocular head                             |
| [16] Handle                 | Moves the colposcope head to the desired place                           |
| [17] Light intensity        | Changes the light intensity of the light source when the user rotates it |

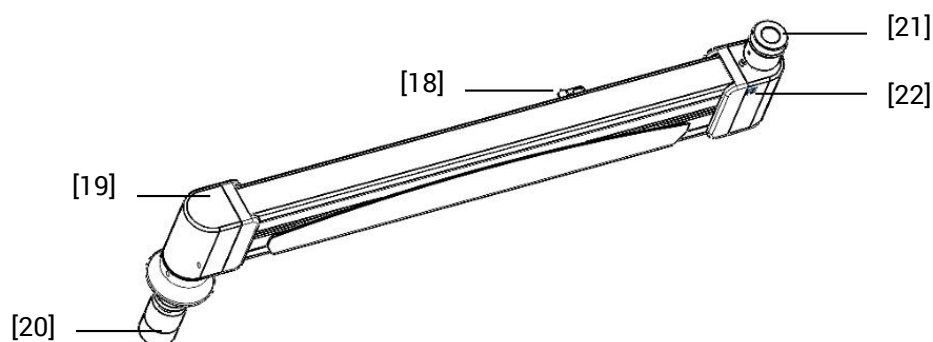


Figure 4: Pantographic arm

| Legend                            | Function                                                                               |
|-----------------------------------|----------------------------------------------------------------------------------------|
| [18] Transport lock               | Locks the pantographic arm in resting position for ease of transport                   |
| [19] Weight adjustment            | Adjusts the weight balance of the pantographic when screwed with special tools         |
| [20] Mounting bolt                | Mounts the pantographic arm to the swing arm                                           |
| [21] Colposcope head interface    | Mounts the colposcope head                                                             |
| [22] Brake of the colposcope head | Adjusts the rotation smoothness of the colposcope head when screwed with special tools |

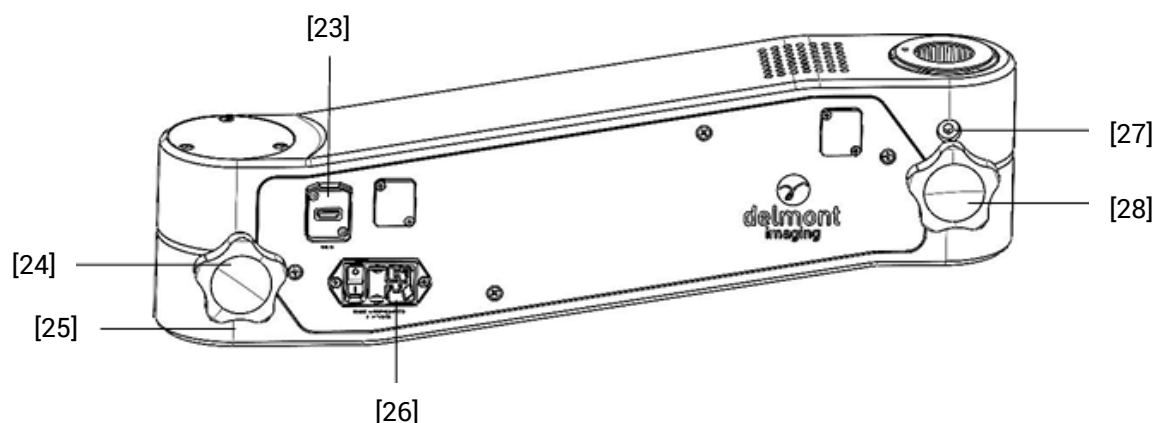


Figure 5: Swing arm

| Legend                               | Function                                       |
|--------------------------------------|------------------------------------------------|
| [23] HDMI output                     | Connects an external monitor via an HDMI cable |
| [24] Swing arm locking screw         | Locks the swing arm in place                   |
| [25] Swing arm clamping screw        | Fixes the rotation of the swing arm            |
| [26] Power cable socket              | Connects the power cable to the main source.   |
| [27] Pantographic arm locking screw  | Locks the pantographic arm in place            |
| [28] Pantographic arm clamping screw | Fixes the rotation of the pantographic arm     |

## 1.5. Combination and accessories



**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.**



**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.**



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



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

### 1.5.1. List of models

All colposcopes can be equipped with :

- A swing arm,
- A Variofocus or a 300mm objective
- A beamsplitter with the adapter on the right or left side one of the following objectives:

| REF          | Description                                                                |
|--------------|----------------------------------------------------------------------------|
| D100 300 600 | Swing arm colposcope, 300mm, 5x magnification, with beamsplitter left      |
| D100 300 601 | Swing arm colposcope variofocus, 5x magnification, with beamsplitter left  |
| D100 300 602 | Swing arm colposcope, 300mm, 5x magnification, with beamsplitter right     |
| D100 300 603 | Swing arm colposcope variofocus, 5x magnification, with beamsplitter right |
| D100 300 604 | Straight colposcope, 300mm, 5x magnification, with beamsplitter left       |
| D100 300 605 | Straight colposcope, variofocus, 5x magnification, with beamsplitter left  |
| D100 300 606 | Straight colposcope, 300mm, 5x magnification, with beamsplitter right      |
| D100 300 607 | Straight colposcope, variofocus, 5x magnification, with beamsplitter right |

### 1.5.2. List of accessories

They can also be equipped with various accessories such as :

- A video system for recording,
- An external monitor.

| REF          | Description                                  |
|--------------|----------------------------------------------|
| D100 300 100 | Video camera adapter for iCare or iCare mini |

# Instructions for use

## Colposcope system (2<sup>nd</sup> generation)

| REF          | Description                                           |
|--------------|-------------------------------------------------------|
| D100 300 006 | C-mount to endoscope eye-piece adapter                |
| D100 300 113 | DSLR Camera adapter                                   |
| D100 300 109 | Monitor stand for swing arm colposcope                |
| D100 300 103 | Objective with variable focal between 210mm and 500mm |
| D100 300 105 | Colposcope objective with fixed focal F=200mm         |
| D100 300 106 | Colposcope objective with fixed focal F=250mm         |
| D100 300 104 | Colposcope objective with fixed focal F=300mm         |
| D100 300 107 | Colposcope objective with fixed focal F=350mm         |
| D100 300 108 | Colposcope objective with fixed focal F=400mm         |

## 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



***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



***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.***



***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.***



***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



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



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



***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.***



***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.***



***Do not switch on the light source in a dangerous, explosive atmosphere***



***The device is not an applied part and is not intended for patient contact.***



***Do not look into sunlight with eyepieces or other optics. Retinal damage can occur***



***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](mailto: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](mailto: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



***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.***



***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.***



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



***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.***



***After prolonged transport at temperatures below freezing, the colposcope must be left at room temperature for up to 48 hours before it can be used for the first time. If the colposcope is not acclimatized, it must not be put into operation.***



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

Step 1



- Remove the individual parts of the tripod base
- Attach the struts to the base plate using
- Position the pre-assembled column on
- the base and screw it together with the
- four included cap screws

Step 2



- Attach the swing arm to the guide bearing.

# Instructions for use Colposcope system (2<sup>nd</sup> generation)

Step 3



- Loosen the hexagon socket screw. The required wrench is included.
- Tighten the hexagon socket screw

Step 4



- Pull the cable through the mono hinge of the head.

Step 5



- Place the mono hinge on the bearing.
- The transport lock [18] on the pantographic arm must be engaged

Step 6



- Screw in the countersunk screw

Step 6



- Screw in the four threaded screws

Step 7



- Adjust the load only if a different weight is mounted than in the original delivery condition (e.g. if an camera accessory is added)

Step 8



- Loosen the hexagon socket screw. The required wrench is included.
- Tighten the hexagon socket screw

Step 9



- Adjust the load only if a
- different weight is mounted than in the
- original delivery condition

## 3.2. Operating the device

### 3.2.1. Settings of the pantographic arm and binocular head



***Do not adjust the load adjusting screw [19] 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 [19] to the lowest setting. When set to the lowest tension, the pantographic arms may not support the weight of the lens and its accessories, which may result in personal injury or damage to the device 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. This may be necessary if accessories are added to the colposcope such as a video camera

- Turn the load adjusting screw [19] counterclockwise to add tension.
- Turn the load clockwise to release tension on the pantographic arm.

### 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.



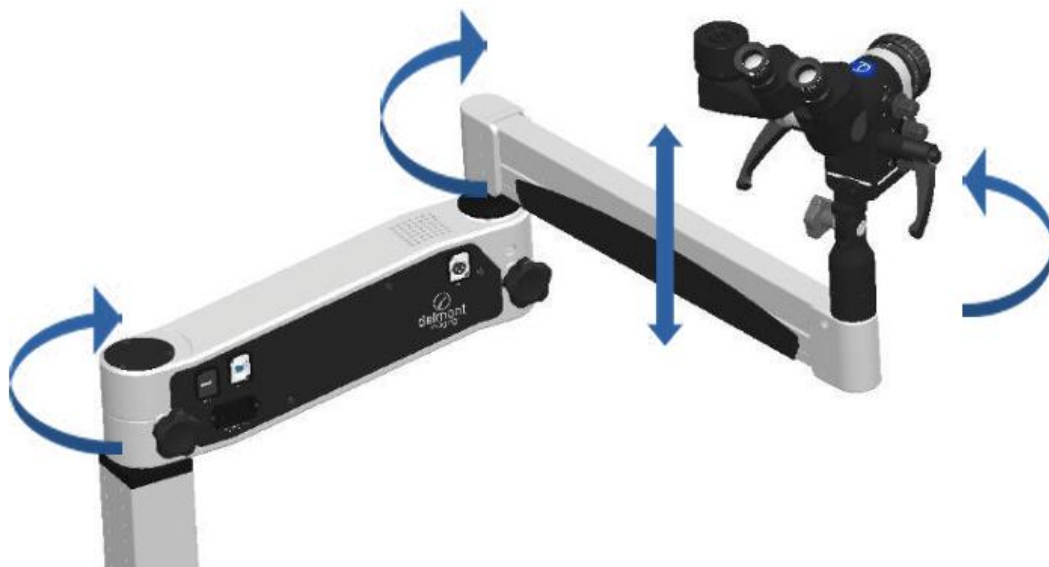
## 3.2.4. Diopter adjustment

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 5 position magnification knob. To set the magnification :

- Turn the knob [11] 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.

### 3.2.8. Color filter

A green colour filter is available to help highlight vascular samples and offers a tissue contrast viewing option.

- Turn the knob [8] to select white or green light.

### 3.2.9. Light source functioning



***Turn off [14] 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 [26].***

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

- Switch ON or OFF the device via the ON/OFF switch [26].
- Switch the device from STANDBY to RUN mode via the standby switch [14].
- Increase/decrease the light intensity with the knob arrow [17].

## 3.3. Visual inspection and functional test



***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.***

The visual inspection and functional test shall be performed before each use :

- ☒ Inspect visually the colposcope including the power cable, base, casters, light source to detect any damages or safety defect.
  - Press the ON/OFF switch [26].
  - Switch to RUN mode by pressing the RUN / STANDBY button [14].
  - Set the brightness level by Turing the light intensity knob [17].
- ☒ 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

| Issue type                                           | Solution                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The light source does not emit light                 | <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Check the device is plugged to main power</li> <li><input checked="" type="checkbox"/> Check the light turns green when you switch it on</li> <li>→ Rotate potentiometer clockwise until it is switched on</li> </ul> |
| Poor lighting                                        | <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Check the objective is clean</li> <li>→ Rotate potentiometer clockwise until the desired brightness is reached</li> </ul>                                                                                             |
| The pantographic arm does not balance the colposcope | <ul style="list-style-type: none"> <li>→ Readjust weight compensation on the pantographic arm (3.1)</li> </ul>                                                                                                                                                                                   |
| Swivel tube does not hold in the set position        | <ul style="list-style-type: none"> <li>→ Readjust the fine adjustment of the tilting torque</li> </ul>                                                                                                                                                                                           |

- Contact your Delmont imaging representative if the issue persists.

## 4. Reprocessing



W.XXII

***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.XXIII

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



W.XXIV

***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 water added to a mild detergent, applied with a clean piece of cotton, or equivalent wipes to remove any stains on the device.                                                                                                                  |
|          | <input checked="" type="checkbox"/> Follow up detergent manufacturer instructions.                                                                                                                                                                    |
|          | → Apply with gentle, circular movements on the entire device.                                                                                                                                                                                         |
|          | <input checked="" type="checkbox"/> 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



***To avoid the risk of fire, use only fuses of the value specified on the fuse label and in 6.***

---

- 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.

#### 5.1.3. Periodic electrical safety check

At a minimum of every 12 months perform the following maintenance according to IEC/EN 60601-1 for test methods:

- Ensure the earth leakage current is 500 $\mu$ A, ground protective earth impedance is <0.1 ohms, power consumption is less than or equal to the rated power,
- The unit passes a dielectric withstand test of 1500V without breakdown.
- If the unit fails these tests, contact your Delmont imaging representative.

### 5.2. Repair



***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.***

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

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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.XXVII

***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.
- Contact our after-sales service at [sav@delmont-imaging.com](mailto:sav@delmont-imaging.com) or calling +33 9 51 51 30 30 to get a Return Merchandise Authorization number and form.

## 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.

The warranty depending on your location is available on our website at [www.delmont-imaging.com](http://www.delmont-imaging.com).

## 5.5. Disposal



W.XXVIII

***Keep the used device out of reach of unauthorized person.***



W.XXIX

***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.***

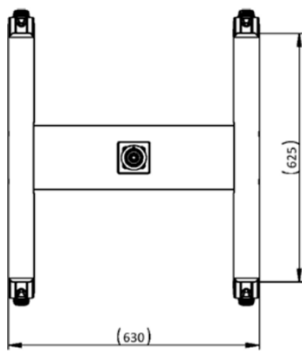
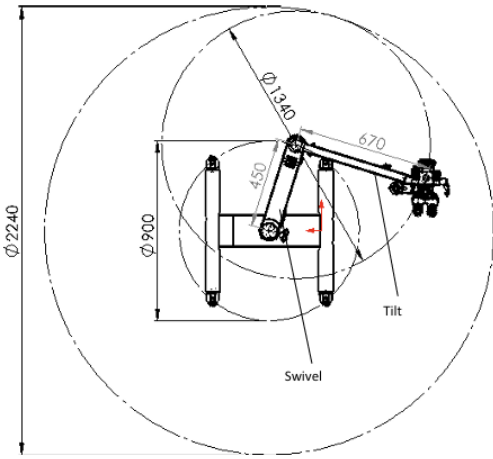
We encourage our customers to recycle this device whenever possible or to return the device to Delmont imaging who will then take the appropriate steps to recycle the device.

## 6. Technical data

### 6.1. General specifications

|                                             |           |
|---------------------------------------------|-----------|
| Mains voltage range [V]                     | 100 - 240 |
| Supply frequency range [Hz]                 | 47 - 63   |
| Power consumption [VA]                      | Max 100   |
| Fuses                                       | 2 x 3.15A |
| Degree of protection                        | IP 20     |
| Protection class (IEC 60601-1 / EN 60601-1) | I         |
| Equipotential plug                          | No        |

### 6.2. Mechanical specifications

| Models                           | with vertical stand                                                                 | with swing arm                                                                       |
|----------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Base                             | Four casters with brakes                                                            |                                                                                      |
| Floor-to-objective distance [mm] | 855 mm to 1193mm                                                                    | 855mm to 1365mm                                                                      |
| Angular rotation [°]             | – Head rotation : 335                                                               | – Head rotation : 335<br>– Swing arm : 360<br>– Pantographic arm 310                 |
| Total weight [kg]                | 18                                                                                  | 44                                                                                   |
| Reach                            |  |  |

### 6.3. Optical specifications

|            |                     |
|------------|---------------------|
| Colposcope | Galilean system     |
| Binocular  | Tilted 45°, F=170mm |

|                          |                                                         |
|--------------------------|---------------------------------------------------------|
| Focal length [mm]        | – Fixed (200 / 300 / 400)<br>– Or Variable (210 to 500) |
| Eyepiece                 | 12.5x / 16mm                                            |
| Diopter adjustment       | -5 to +5                                                |
| Magnification levels     | 0.4x / 0.63x / 1.0x / 1.6x / 2.5x                       |
| Magnification @30cm [mm] | 15 / 24 / 39 / 61 / 96                                  |
| Field of view [mm]       | See Table 1                                             |
| Pupil distance [mm]      | 42 to 75                                                |
| Filter                   | Green                                                   |

Table 1 - Field of view [mm]

| Working distance [mm] | Total Magnification |      |    |     |     |
|-----------------------|---------------------|------|----|-----|-----|
|                       | 0.4                 | 0.63 | 1  | 1.6 | 2.5 |
| 210                   | 74                  | 47   | 29 | 18  | 12  |
| 250                   | 84                  | 53   | 33 | 21  | 13  |
| 300                   | 96                  | 61   | 39 | 24  | 15  |
| 350                   | 109                 | 69   | 44 | 27  | 17  |
| 400                   | 121                 | 77   | 49 | 30  | 19  |
| 470                   | 139                 | 88   | 56 | 35  | 22  |
| 500                   | 147                 | 93   | 59 | 37  | 23  |

## 6.4. Light source specifications

|                       |                                                                                         |
|-----------------------|-----------------------------------------------------------------------------------------|
| Light source          | Light emitting diode                                                                    |
| Illuminance [kLux]    | 31 – 120 <i>Note : depends on working distance, lens type and LED intensity setting</i> |
| Color temperature [K] | 5 500 ± 10%                                                                             |
| Cooling               | Fanless/passive                                                                         |
| Lifetime              | 60.000 hours                                                                            |

## 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

### 6.6.1. Electromagnetic emissions

This device 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<br>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<br>CISPR 11                      | Class B    |                                                                                                                                                                                                                                                                                                                                                                                                   |
| Harmonic emissions<br>IEC 61000-3-2           | Compliant  |                                                                                                                                                                                                                                                                                                                                                                                                   |
| Voltage fluctuations/Flicker IEC<br>61000-3-3 | Compliant  |                                                                                                                                                                                                                                                                                                                                                                                                   |

### 6.6.2. 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<br>Severity Level           | Compliance Level  | Electromagnetic environment-Guidance                                                                                                              |
|----------------------------------------------------|---------------------------------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic<br>discharges (ESD)<br>IEC 61000-4-2 | ± 8 kV via contact<br>± 15 kV via air | ± 8 kV<br>± 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%. |

| Immunity test                                                                 | IEC 60601<br>Severity Level                                                              | Compliance Level                                                          | Electromagnetic environment-Guidance                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rapid transient peaks<br>IEC 61000-4-4                                        | $\pm 2$ kV power lines                                                                   | $\pm 2$ kV                                                                | Mains power quality should be that of a typical commercial or hospital environment.                                                                                                                                                                                    |
| Electric shocks<br>IEC 61000-4-5                                              | $\pm 1$ kV differential mode<br>$\pm 2$ kV common mode                                   | $\pm 1$ kV<br>$\pm 2$ kV                                                  |                                                                                                                                                                                                                                                                        |
| Power outages, short power outages and voltage fluctuations<br>IEC 61000-4-11 | <5% $U_t$ for 10 ms<br>40% $U_t$ for 100 ms<br>70% $U_t$ for 500 ms<br><5% $U_t$ for 5 s | 5% $U_t$ 10 ms<br><40% $U_t$ 100 ms<br><70% $U_t$ 500 ms<br><5% $U_t$ 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)<br>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.     |

### 6.6.3. Electromagnetic emissions

This device 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<br>Severity Level          | Compliance Level  | Electromagnetic environment- Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------------------------------------------|--------------------------------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Conducted disturbances induced by RF fields<br>IEC 61000-4-6 | 3 V <sub>eff</sub><br>0,15 to 80 MHz | 3V <sub>eff</sub> | <p>Portable and mobile RF communication devices should not be used at a distance, including cables, from this device that is less than the recommended distance, calculated by applying the formula that corresponds to the transmitter frequency.</p> <p><math>d = 1,16 \sqrt{P}</math><br/> <math>d = 1,16 \sqrt{P}</math> 80 MHz to 800 MHz<br/> <math>d = 2,33 \sqrt{P}</math> 800 MHz to 2,7 GHz</p> <p>Where "P" is the maximum output power of the transmitter, in Watts (W), assigned by its manufacturer and "d" is the recommended separation distance in meters (m).</p> <p>Field strength levels emitted by fixed RF transmitters - which must be established by in situ electromagnetic measurement must be below the compliance level in each frequency band. Interference may occur with devices marked with the following symbol: </p> |
| Radiated RF IEC 61000-4-3                                    | 3 V/m<br>80 MHz to 2.7 GHz           | 3 V/m             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

**Note 1:**  $U_T$  is the a.c. mains voltage prior to application of the test level.

**Note 2:** At 80 MHz and 800 MHz, the highest frequency band should be used.

**Note 3:** Guidelines regarding conducted disturbances induced by RF fields or radiated RF fields may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**Note 4:** The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

**Note 5:** 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

**Note 6:** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

### 6.6.4. 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.

| Test frequency (MHz) | Band (MHz) | Service                                                 | Modulation                                | Maximum power (W) | Minimum separation distance (m) | EC / EN60601 test level (V/m) | Compliance level (V/m) |
|----------------------|------------|---------------------------------------------------------|-------------------------------------------|-------------------|---------------------------------|-------------------------------|------------------------|
| 385                  | 380-390    | TETRA 400                                               | Pulse modulation: 18Hz                    | 1.8               | 0.3                             | 27                            | 27                     |
| 450                  | 430-470    | GMRS 460, FRS 460                                       | FM - $\pm 5$ kHz deviation<br>1 kHz sinus | 2                 | 0.3                             | 28                            | 28                     |
| 710                  | 704-787    | LTE Band 13, 17                                         | Pulse modulation: 217 Hz                  | 0,2               | 0.3                             | 9                             | 9                      |
| 745                  |            |                                                         |                                           |                   |                                 |                               |                        |
| 780                  |            |                                                         |                                           |                   |                                 |                               |                        |
| 810                  | 800-960    | GSM 800 / 900, TETRA 800, iDEN 820 CDMA 850, LTE Band 5 | Pulse modulation: 18Hz                    | 2                 | 0.3                             | 28                            | 28                     |
| 870                  |            |                                                         |                                           |                   |                                 |                               |                        |
| 930                  |            |                                                         |                                           |                   |                                 |                               |                        |
| 1720                 | 1700-1990  | GSM 1800. CDMA 1900.                                    |                                           | 2                 | 0.3                             | 28                            | 28                     |

# Instructions for use Colposcope system (2<sup>nd</sup> generation)

| Test frequency (MHz) | Band (MHz) | Service                                              | Modulation                  | Maximum power (W) | Minimum separation distance (m) | EC / EN60601 test level (V/m) | Compliance level (V/m) |
|----------------------|------------|------------------------------------------------------|-----------------------------|-------------------|---------------------------------|-------------------------------|------------------------|
| 1845                 |            | GSM 1900.<br>DECT.<br>LTE Band 1, 3, 4, 25.<br>UMTS  | Pulse modulation:<br>217 Hz |                   |                                 |                               |                        |
| 1970                 |            |                                                      |                             |                   |                                 |                               |                        |
| 2450                 | 2400-2570  | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation:<br>217 Hz | 2                 | 0.3                             | 28                            | 28                     |
| 5240                 | 5100-5800  | WLAN 802.11 a/n                                      | Pulse modulation:<br>217 Hz | 0.2               | 0.3                             | 9                             | 9                      |
| 5500                 |            |                                                      |                             |                   |                                 |                               |                        |
| 5785                 |            |                                                      |                             |                   |                                 |                               |                        |

**Note 1:** For some services, only the uplink frequencies are included.

**Note 2:** Carrier waves are modulated using a 50 % duty cycle square wave signal.

For other portable and mobile RF communication equipment (transmitters), minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

| 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                |

**Note 1:** At 80 MHz and 800 MHz, the separation distance given in the upper frequency band applies.

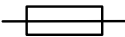
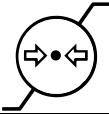
**Note 2:** These recommendations may not be applicable in all situations. The propagation of electromagnetic waves is altered by absorption and reflection from structures, objects and people. For transmitters whose maximum output power is not listed in the table above, the recommended separation distance  $d$ , in meters (m) can be established using the equation applicable to the transmitter frequency, where  $P$  is the maximum output power of the transmitter in Watts (W) assigned by the transmitter manufacturer.

## 7. Symbols used

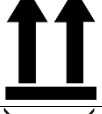
| Symbol                                                                              | Description                                                                                                                                                                                                                                          |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Symbol for "Caution".<br>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".<br>Indicates to the user that it is necessary to consult the operating instructions.                                                                                                                   |
|    | Symbol for "Refer to user manual/brochure".<br>Indicates mandatory action to read the instructions for use.                                                                                                                                          |
|    | Symbol for "Manufacturer".<br>Indicates the manufacturer of the medical device.                                                                                                                                                                      |
|   | Symbol for "Date of manufacture".<br>Indicates the date the medical device was manufactured                                                                                                                                                          |
|  | Symbol for "Country of manufacture".<br>Identifies the country in which the products were manufactured.                                                                                                                                              |
|  | Symbol for "CE marking".<br>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.<br>Indicates that U.S.A. Federal law restricts this device to sale by or on the order.                                                                                       |
|  | Symbol for "RoHS compliant".<br>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".<br>Indicates that the item is a medical device.                                                                                                                                                                         |
|  | Symbol for "Serial Number".<br>Indicates the manufacturer's serial number in order to formally identify a specific medical device.                                                                                                                   |
|  | Symbol for "Lot code".<br>Indicates the manufacturer's lot code so that the lot can be formally identified.                                                                                                                                          |

# Instructions for use

## Colposcope system (2<sup>nd</sup> generation)

| Symbol                                                                              | Description                                                                                                                                                                                                                    |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Symbol for "Catalogue number".<br>Indicates the manufacturer's catalog number so that the medical device can be positively identified.                                                                                         |
|    | Symbol for "Unique Device Identifier".<br>Denotes a medium that contains information about a unique device identifier.                                                                                                         |
|    | Symbol for "Quantity".<br>Indicates the number of devices included in the package.                                                                                                                                             |
|    | Symbol for "Non-sterile".<br>Denotes a medical device that has not been subjected to a sterilization process.                                                                                                                  |
|    | Symbol for "Do not use if package is damaged".<br>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".<br>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".<br>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".<br>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".<br>Indicate the type of mains supply.                                                                                                                                                             |
|  | Symbol for "Both direct and alternating current".<br>Indicate the type of mains supply.                                                                                                                                        |
|  | Symbol for "UL/CSA tied fuses".<br>Indicates the fuses boxes or their location marked with type and rating.                                                                                                                    |
|  | Symbol for "Temperature limit".<br>Indicates the minimum and maximum temperatures to which the medical device may be safely exposed.                                                                                           |
|  | Symbol for "Atmospheric pressure limit".<br>Indicates the range of atmospheric pressure to which the medical device may be safely exposed.                                                                                     |
|  | Symbol for "Humidity limit".<br>Indicates the minimum and maximum humidity to which the medical device may be safely exposed.                                                                                                  |

# Instructions for use Colposcope system (2<sup>nd</sup> generation)

| Symbol                                                                              | Description                                                                                                                                                                                  |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Symbol for "Protect from heat and radioactive sources".<br>Indicates a medical device that is sensitive to heat and radioactive sources.                                                     |
|    | Symbol for "Moisture Sensitive".<br>Indicates a medical device that is moisture sensitive.                                                                                                   |
|    | Symbol for "Fragile, handle with care".<br>Indicates a medical device that may be broken or damaged if not handled with care                                                                 |
|    | Symbol for "Transport conditions".<br>Indicates the transport conditions that should be respected.                                                                                           |
|    | Symbol for "Storage conditions".<br>Indicates the storage conditions that should be respected.                                                                                               |
|   | Symbol for "Handle with care".<br>Indicates the package should be handled with precaution                                                                                                    |
|  | Symbol for "This way up".<br>To indicate correct upright position of the transport package.                                                                                                  |
|  | Symbol for "WEEE; waste electrical and electronic equipment; crossed-out wheeled bin".<br>Indicates that separate collection for waste electric and electronic equipment (WEEE) is required. |



  
**Delmont imaging**  
**390 Avenue du Mistral – 13600 La Ciotat – France**  
**Phone : +33 9 51 51 30 30 – Fax : +33 9 57 51 31 00**  
**contact@delmont-imaging.com – www.delmont-imaging.com**

