delmont
imaging

EN - Instructions for use
Colposcope camera

D900 700 206 A EN

2024-07

Rx Only

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

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MD

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

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

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

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

TABLE OF CONTENTS

1. General device information

1.1. Intended use

W.I

This device and this manual are intended exclusively for trained and qualified personnel. This document describes the correct handling and function of the device. This document may not 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.

The colposcope camera accessory is an externally powered unit that, when used with an appropriate colposcope is designed to:

- Provide an additional digital visualization of the image from the colposcope on a display monitor or a digital tablet,
- Record image or videos.

The provided image shall not be used for diagnostic purpose.

1.2. Indications or use

The device is indicated for use by healthcare professional in procedure involving a colposcope in healthcare centre equipped with an appropriate configuration.

1.3. Target population

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

1.4. Device description

Figure 1: control unit, front panel

Legend		Function
[1]	Center action button	– In the menu: o Validates your action. – In the live mode: o Performs a snapshot when the user presses the centre action button, o Captures a video when the user presses and hold the centre action button, to stop the video capture the user needs to press and hold a second time the centre action button. o In the preview screen: Displays the selected snapshot in full screen.
[2]	Left side action button	– In the menu: Navigates in the menu. – In the live mode: Performs a white balance when the user presses and hold the button. – In the preview screen: Navigates through the taken snapshots during the current procedure.
[3]	Right side action button	– In the menu: Navigates in the menu. – In the live mode: Switch to preview screen when the user presses and hold the button. – In the preview screen: Navigates through the taken snapshots during the current procedure.
[4]	Record status indicator	– Continuous flashes red when a video is captured.
[5]	Standby button	– Turns on the live mode of the device.
[6]	Standby status indicator	– Turns on when the device is powered on. – Flashes rapidly white when the device is booting. – Flashes slowly white when the device is in standby mode. – Shows a continuous white indicator when the device is in live mode.

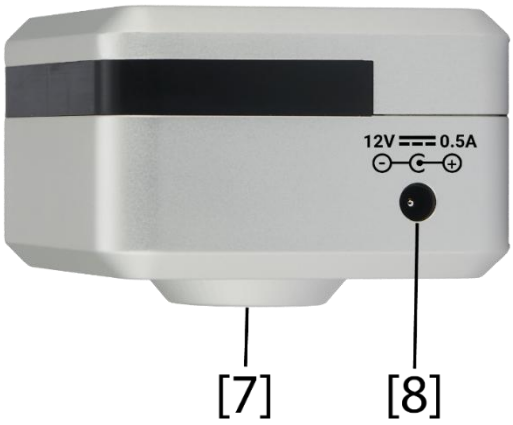


Figure 2 : control unit, left rear panel

	Legend	Function
[7]	CS-mount interface	Connects the device to a compatible colposcope.
[8]	External power supply plug	Connects the external power supply (12V DC 0.5A).

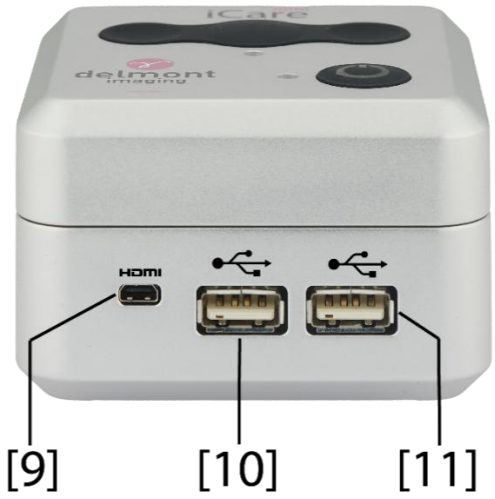


Figure 3 : control unit, back panel

	Legend	Function
[9]	Micro-HDMI cable socket	Connects a micro-HDMI to a display.
[10]	USB socket	Connects either a USB storage drive or a USB Wi-Fi antenna to connect the colposcope camera to the centre Wi-Fi.
[11]	USB socket	Connects either a USB storage drive or a USB Wi-Fi antenna to connect the colposcope camera to the centre Wi-Fi.

1.5. Combination and accessories


W.II

Use only recommended accessories with Delmont imaging devices. Using incompatible equipment may lead to:

- ***increase electromagnetic emissions or decreased electromagnetic immunity of this equipment and improper operation.***
- ***damage to the device.***


W.III

Use the monitor provided by Delmont imaging for best visualization. Otherwise make sure that the monitor used has a minimum resolution of a 1920x1080, 24'' and is compatible with YCbCr 4:4:4 colours. Check the manufacturer manual for more details. It is important to ensure that the monitor settings used are optimized so that a clear, noise-free colour image is obtained.


W.IV

Use the power supply provided by Delmont imaging. Otherwise make sure that the power supply is of medical grade and complies with specification given in 6.1. Using non-compliant device may lead to injury of the user as well as damage to the device.


W.V

When used in connection with other devices, you constitute a system as per IEC 60601-1 definition. It is the responsibility of the user to make sure that such system complies with IEC 60601-1 and IEC 60601-1-2 requirements, including equipotential specifications. Using non-compliant system may lead to damage to the device.

The colposcope interface must be compatible with the CS-mount standard ISO 10935. Use a C-mount adapter if necessary.

If any doubt subsists on compatible accessories, contact the manufacturer or its approved representative for more details.

→ Use accessories supplied with the unit or offered as an option by the manufacturer such as:

- External power source,
- HDMI cable,
- USB key,
- Wi-Fi dongle,
- CS-mount to C-mount adapter
- Monitor.

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

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. Warnings

 W.VI	***Make sure that the devices are used exclusively by trained and qualified personnel. The physician is responsible for the correct execution of the operation.***
 W.VII	***Do not modify the device.***
 W.VIII	***Do not insert metal objects into the unit to avoid damaging it.***
	***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, ensure the quality of the electrical network (especially the grounding of all equipment and trolleys) and the device is away from electromagnetic sources (for example, a compressor, a motor, a transformer, an HF generator, etc.).***
	***The device has no essential performance***

2.3. Vigilance

	***Definition of serious incident may depend on your local regulation. If any doubt exists, we encourage our users to proactively report any incidents. Contact your Delmont imaging representative for more information about reportability.***
	***Medical information must be anonymized prior to be sent to us. Contact our data protection officer at dpo@delmont-imaging.com for more information related to confidentiality.***

→ Notify without delay any serious incident or risk of serious incident occurring during the use of this device to:

- vigilance@delmont-imaging.com,
- Your Delmont imaging representative,
- Your competent authorities in accordance with your local regulation.

→ We encourage the users to gather and transfer all appropriate information regarding the incident which includes but is not limited to:

- Patient condition,
- Indications of the procedure,
- Date of incident,
- Reference number and serial/lot number of the device,
- Any pertinent information related to the incident,
- A preferred contact that Delmont imaging can reach in the best delay.

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

3. Use of the device

3.1. Initial set up of the device

3.1.1. Location


W.IX

The device is only to be used in a healthcare facility.


W.X

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally


W.XI

The device shall not be used near active HF surgical equipment nor equipment with magnetic resonance imaging.


W.XII

When using a portable RF communication equipment, keep it 30 cm (12-inch) or more away from any part, including cables, of the device. Otherwise, degradation of the performance of this equipment could result.


W.XIII

Do not expose the device to water splashes or in a place that is too humid.

☑ Check the colposcope is well mounted and stable before connecting the device to the colposcope.

3.1.2. Unpack the device


W.XIV

Do not use the device if the integrity of the primary packaging is deteriorated and the device appear to be damaged.

→ Unpack all parts and accessories from the packaging.
→ Save the original packaging in a safe place, to eventually return the device in proper conditions.

3.1.3. Installation

Choose the right or left side of the colposcope to connect the device depending on your need.

Step 1

→ Connect the colposcope camera C-mount interface [7] to the video camera adapter of the colposcope.

Step 2

→ Connect the HDMI cable to the socket [9] on the back panel of the unit.

→ Connect the second end of the HDMI cable to the corresponding input on the monitor.

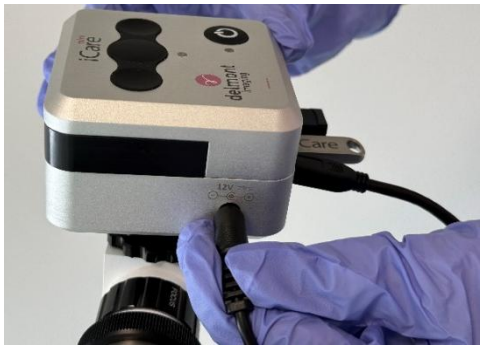
Step 3

→ Connect the storage USB key on one of the USB sockets [10] on the bottom panel.

Step 4

→ Connect the Wi-Fi dongle to the remaining USB port [11] on the bottom panel.

Step 5



→ Connect the external power supply to the power socket [8] on the left panel of the unit.

→ Connect the other end of the external power supply cord to an electrical outlet.

3.2. Operating the device

3.2.1. Powering on

→ Make sure the external power supply is connected to the power socket of the device.
→ Connect the other end of the external power supply cord to an electrical outlet.

The device enters in a booting sequence:
- The monitor displays a boot screen with Delmont imaging logo (see Figure 4).
- This booting sequence last 30 seconds approximatively.

Then, the unit goes into standby mode:
- The welcome screen appears on the monitor (see Figure 5).

3.2.2. Navigating in the menu

To be in the welcome screen, make sure you are in standby mode by pressing [5].

→ Use the Device buttons to navigate the menu.
→ Press [2] or [3] to move the selection cursor.
→ Validate your choice by pressing [1].

You can, in the welcome screen:
- See and go to the USB key storage information,
- See and go to the settings menu.

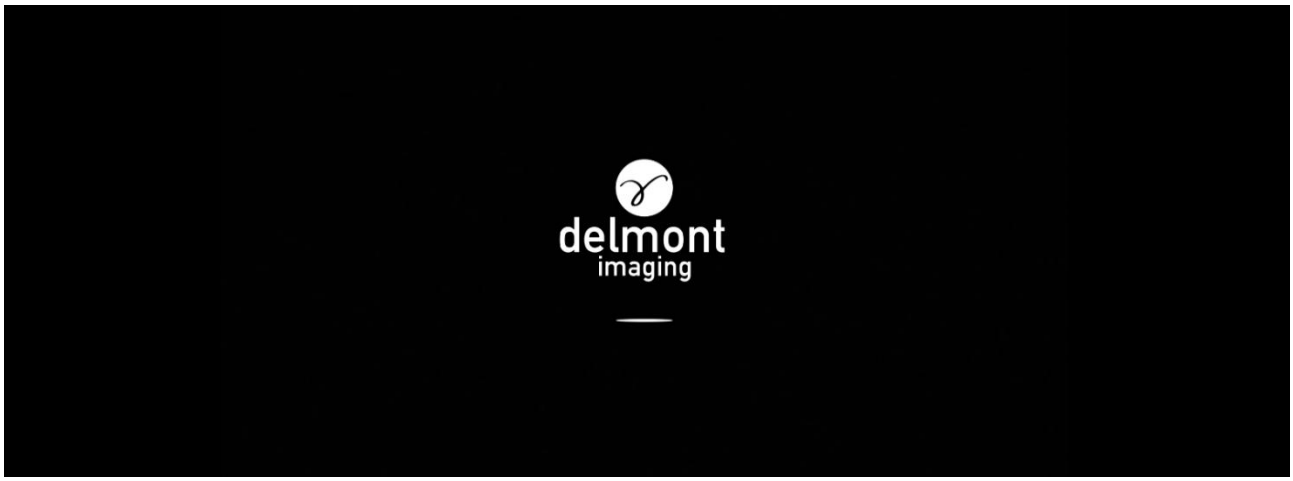


Figure 4: Booting screen

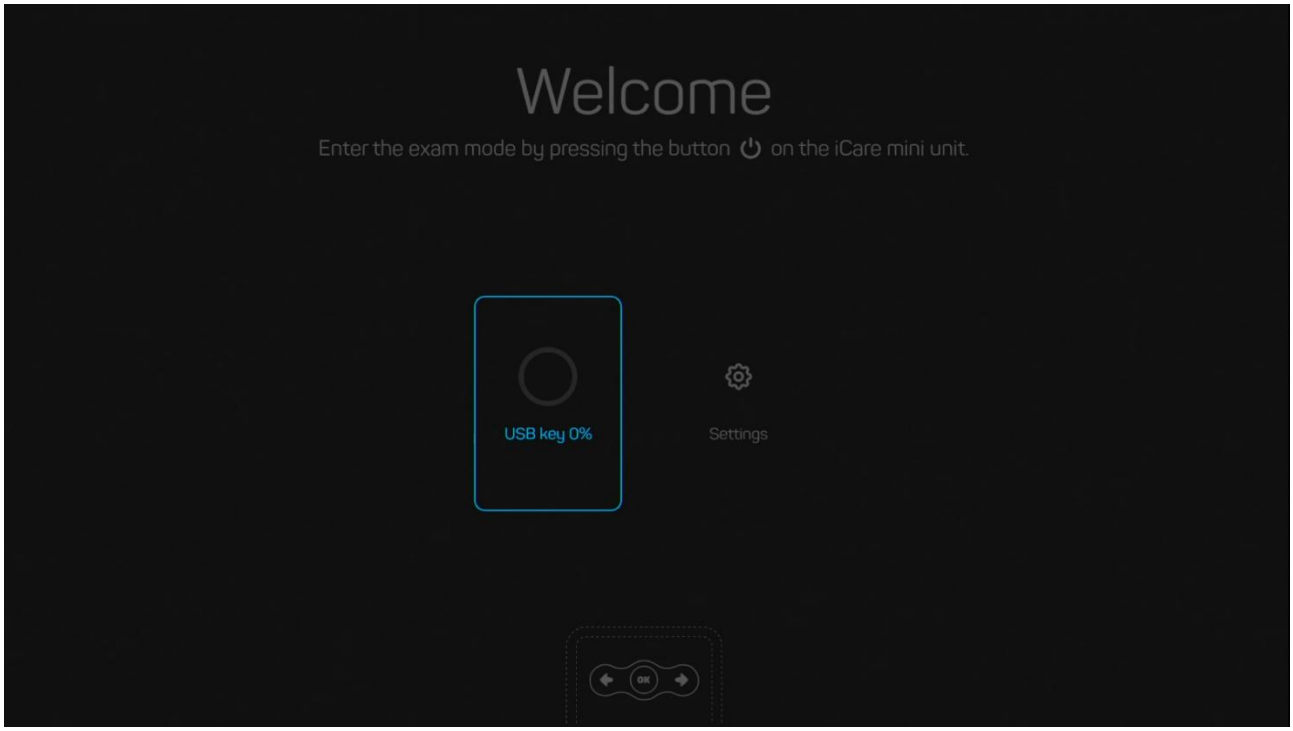


Figure 5: Welcome menu

3.2.3. Enter in live mode

→ When the unit is on, enter in live mode by pressing the standby button [5].

3.2.4. White balance

Ensure that the light of the colposcope is on before attempting a white balance.

Once the camera of the device is paired with the colposcope and that the light source of the colposcope is on:

→ Film an appropriate white surface.
→ Start the white balance by pressing and holding the button [2], «Processing AWB» appears on the screen.
→ Continue to film the white surface as long as the message is on, but you can release the button. The finish of white balance is confirmed on the screen.

3.2.5. Capturing images and videos

Once the device is connected to the colposcope and in live mode:

→ Capture an image by short press on [1] (see Figure 6).

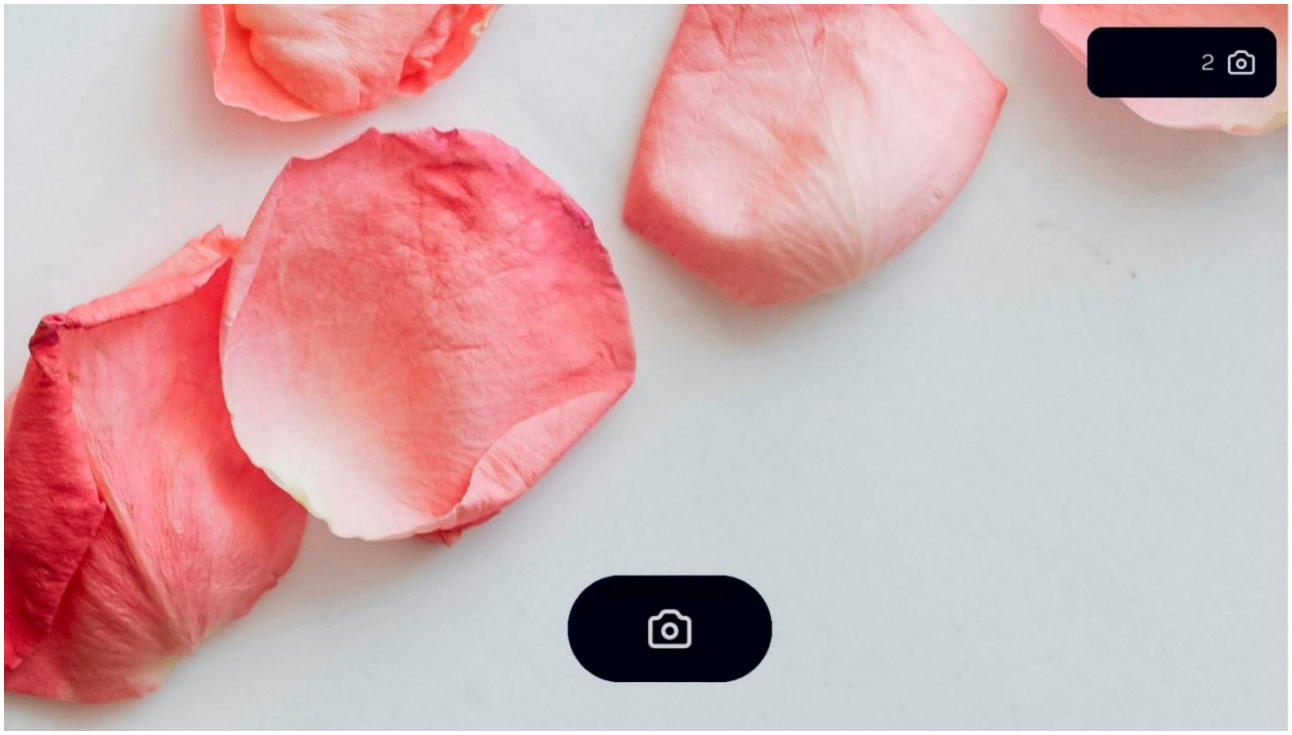


Figure 6: Confirmation of image taken

→ Start a video recording by long press on [1] (see Figure 7).
→ Stop the recording with another long press on [1].

Figure 7: Start video record

3.2.6. Preview screen

In live mode once the device has captured at least one image you can access to preview screen (see Figure 8):

→ Long press on [3].

The captured images are displayed at the bottom of the screen.

→ Press [2] and [3] to navigate between images.
→ Press [1] to display the desired image full screen.
→ Long press [3] to come back to the live screen.

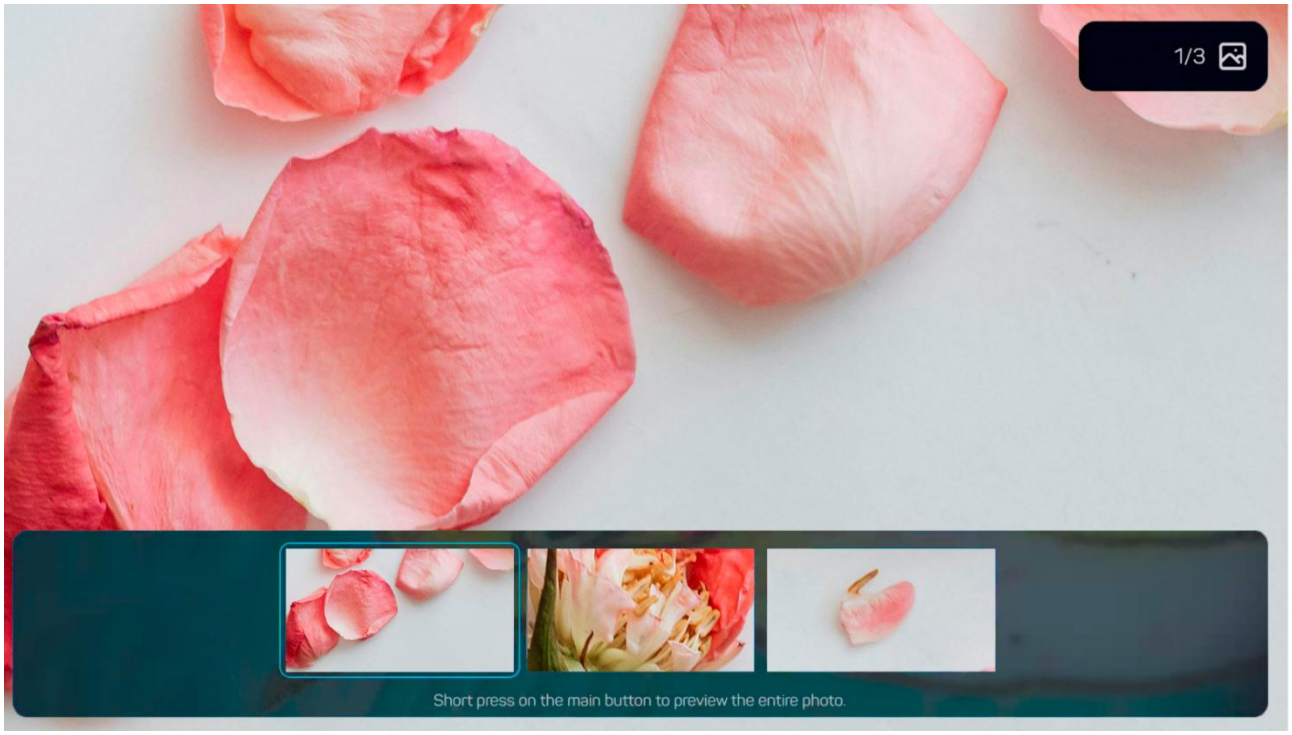


Figure 8: Preview screen

3.2.7. Powering off the device

W.XV

Unplug the external power supply to cut completely the connection to main power. Always grasp the plug of the power cable when unplugging; never pull on the cable itself.

→ Press the standby button[5].
→ Unplug the power socket from the camera [8].
→ Unplug the external power from the main power.

3.3. Device configuration

→ To configurate the device, in the welcome menu select Settings to get to the Settings menu (see Figure 9).

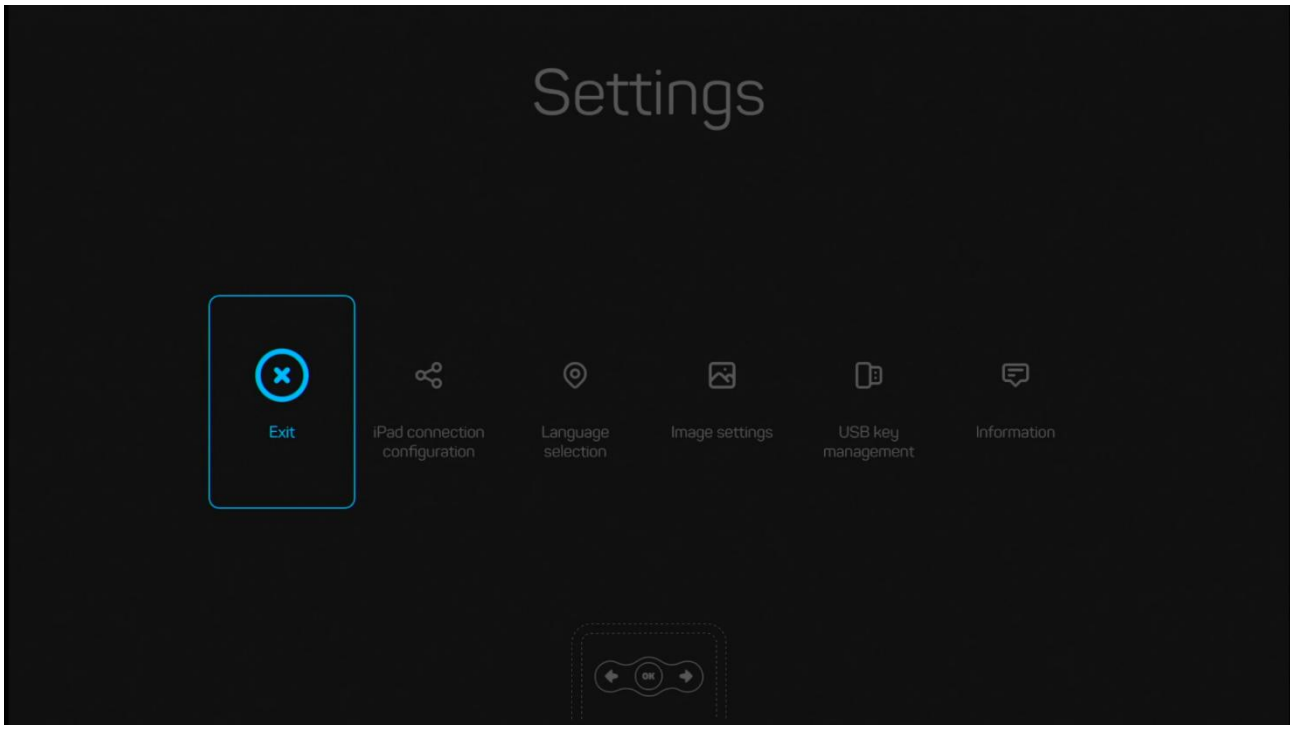


Figure 9: Settings menu

3.3.1. iPad connection configuration

In the network menu (see Figure 10), you can:
- Show the QR code for Wi-Fi connection to the device.
- Activate MAC filtering.
- Hide Wi-Fi SSID.

Contact the manufacturer or its approved representative for more details on iPad connection configuration and cybersecurity.

3.3.2. Language configuration

In the language menu (see Figure 11), you can:
- Select the appropriate language.

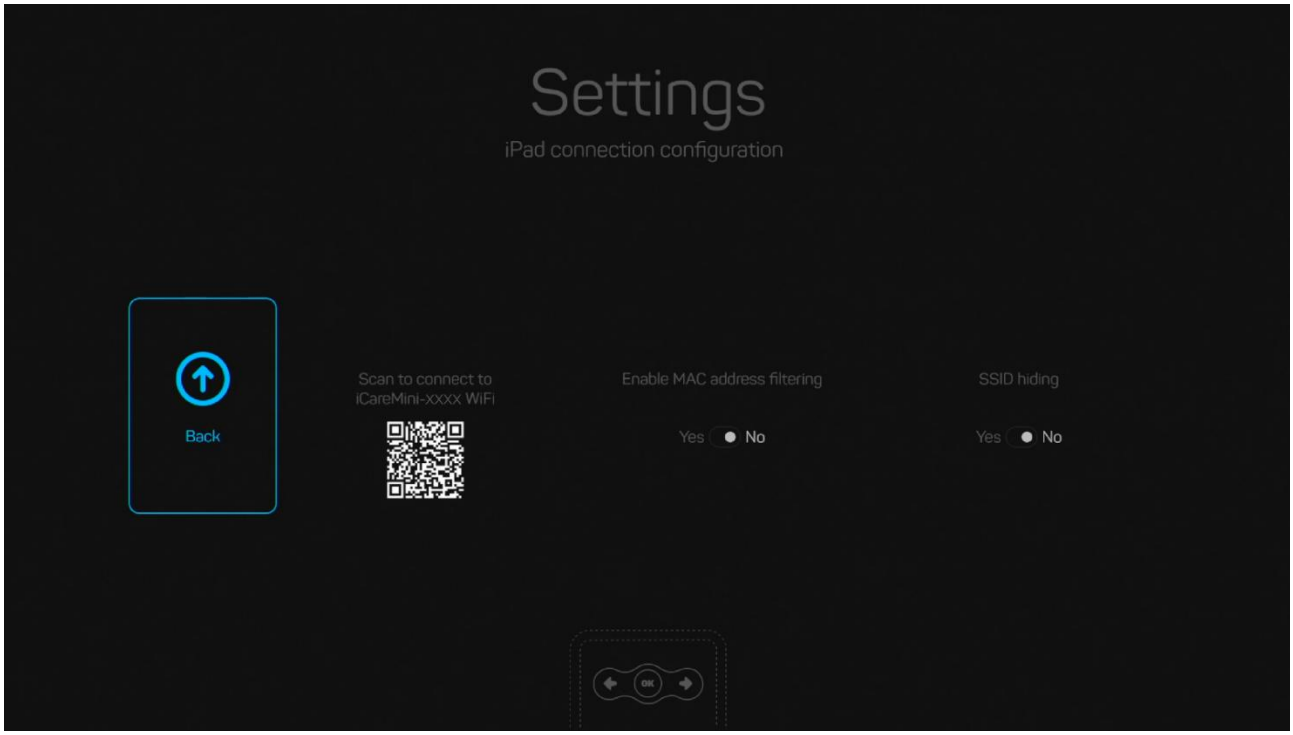


Figure 10: iPad connection configuration

Figure 11: Language settings

3.3.3. Image settings configuration

To obtain the best image settings, set up the device in the final conditions, with a colposcope at appropriate distance from the patient.

In the image setting configuration (see Figure 12)., you can:
- Select a predefined image preset
- Manually setup your image parameters.

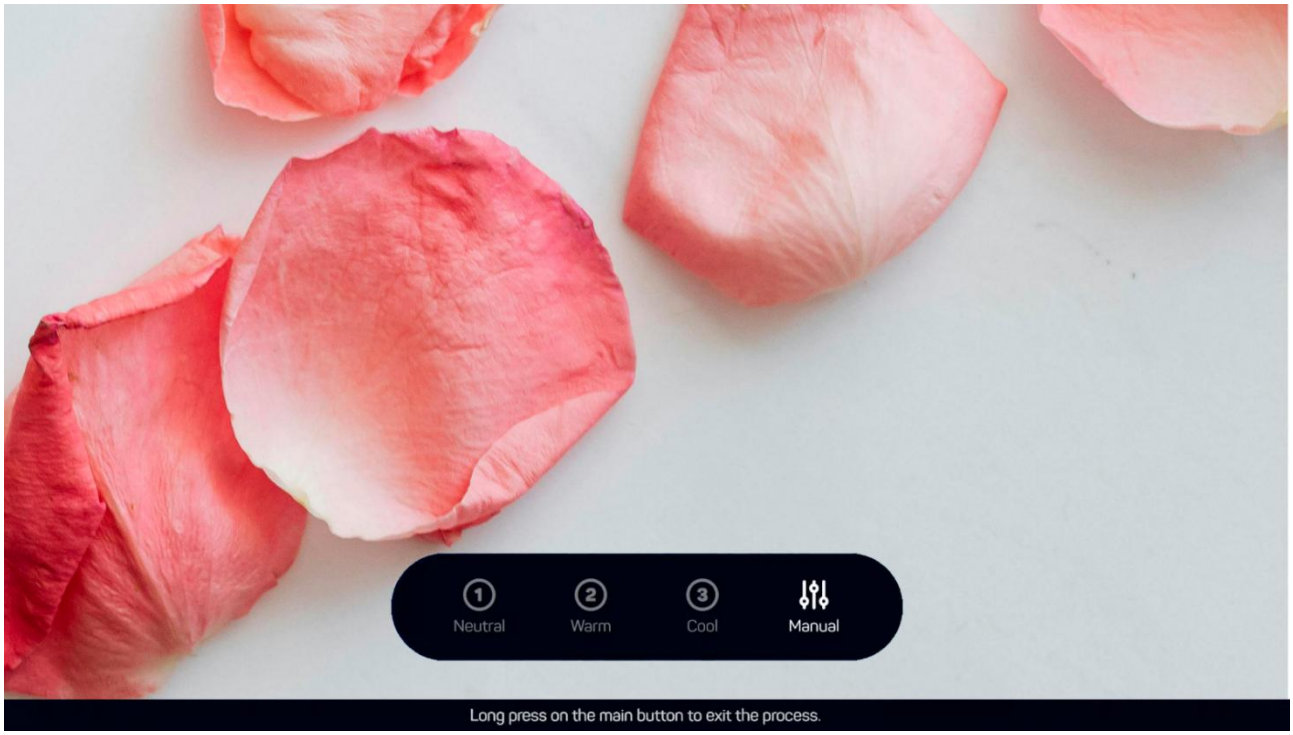


Figure 12: Image settings screen

3.3.4. USB key configuration

In the USB menu (see Figure 13), you can:
- See the storage level (in %).
- Erase the USB key storage.

3.3.5. Device information

In the device information menu (see Figure 14), you can:
- See information about the device: serial number, date of manufacture, software version and network information.
- Launch the update of the firmware (see 5.1.1).
- Reset the settings to the factory values.

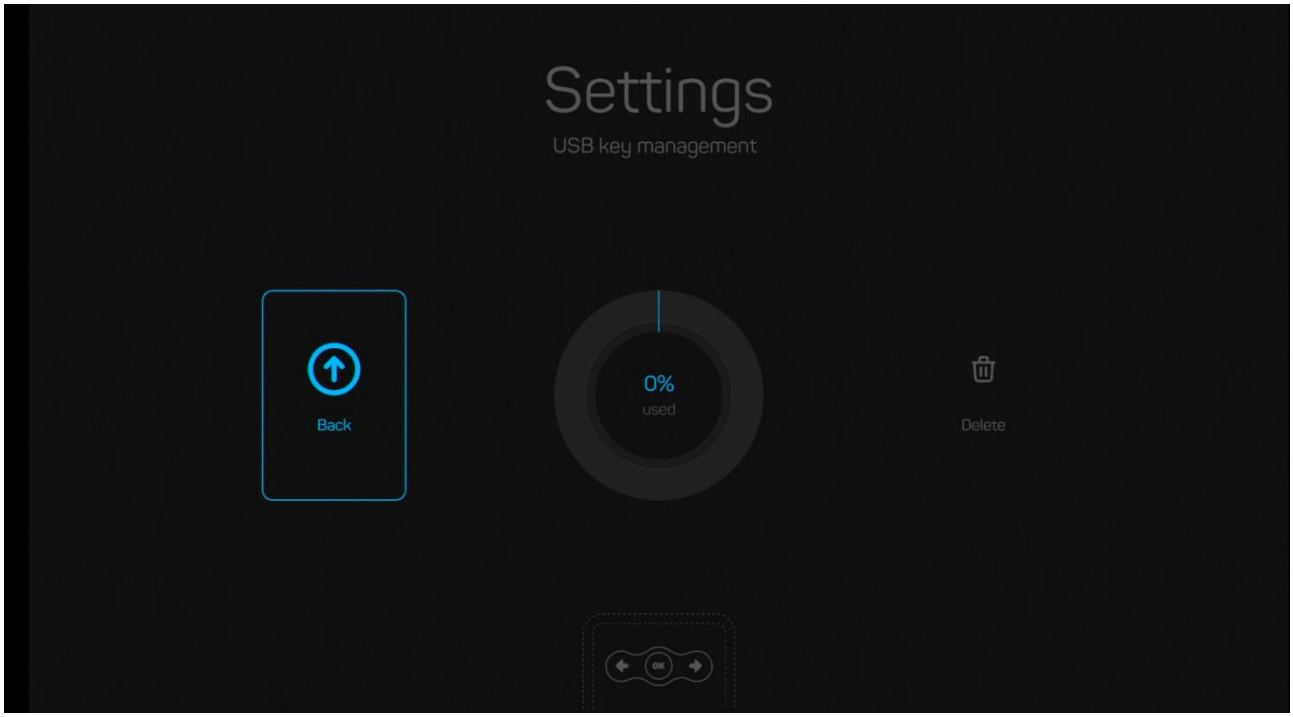


Figure 13: USB key management screen

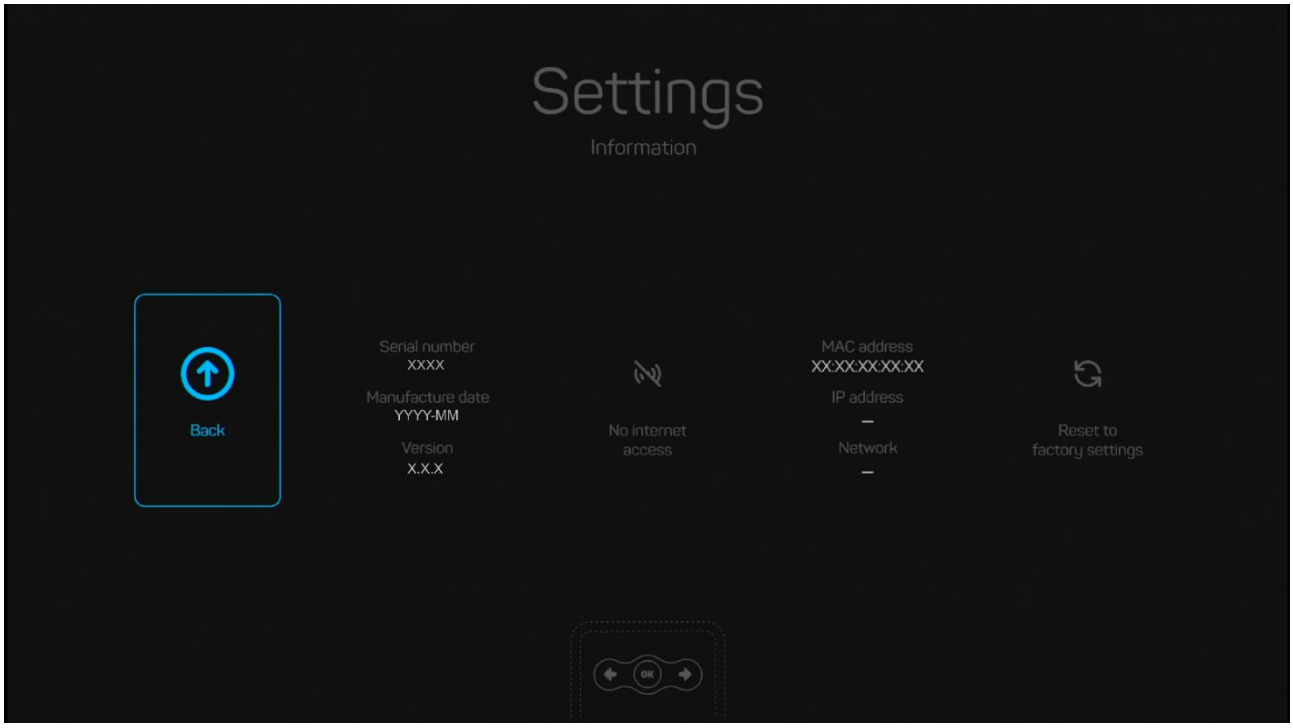


Figure 14: Device information menu

3.4. Safety and service life checklist

W.XVI

Do not use a damaged device or a device with improper functioning. The use of a damaged device or of a device with improper functioning may cause an electric shock, mechanical injury, and/or thermal injury. Replace a damaged device or a device with improper functioning.

W.XVII

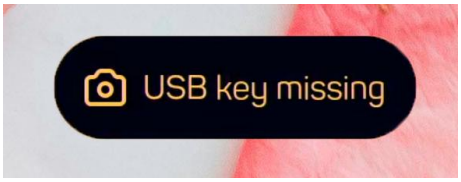
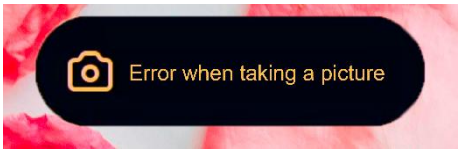
The user must perform this checklist after first installation and prior to each use of the device.

- ☑ Check the device for no visible wear and damage.
- ☑ Check external power supply and HMDI cords for no trace of wear and damage.
- ☑ Make sure the device is well connected on the colposcope and stable.
- ☑ When the control unit is powered on and ready, the welcome menu should appear on the screen.
- ☑ When the device is in live mode, the image should appear.

3.5. Trouble shooting

3.5.1. Error messages

The device continuously monitors its proper functioning and can alert the user when an error is detected:

Error message	Solution
 Error when capturing image or video	→ Make sure the USB key for storage is correctly plugged, → If the error persists, turn off and on the device, → If the error persists, try to format the USB key with the device or in exFAT, → If the error persists, contact Delmont imaging or its official representative.
 Error when capturing image (or video)	→ Make sure the USB key for storage is correctly plugged, → Make sure the USB key for storage is not full, → If yes, empty it or replace it, → If the error persists, turn off and on the device, → If the error persists, try to format the USB key with the device or in exFAT, → If the error persists, contact Delmont imaging or its official representative.

Error message	Solution
 Error System	→ Turn off and on the device, → If the error persists, contact Delmont imaging or its official representative.

3.5.2. Device wrong behaviour

Issue	Solution
The device doesn't switch on	→ Check that the external power supply is connected to the network and the device. → If the problem persists, check if the external power supply cord is in proper condition. → If the problem persists, replace the external power supply (with another 12V power supply, certified for medical purpose). → If the issue persists, contact Delmont imaging or its official representative.
The image is blurred.	→ Remove any fog or stains on the camera adapter of the colposcope and on the device camera. → If the issue persists, check the focus of the colposcope or the eventual adapter. → If the issue persists, contact Delmont imaging or its official representative.
The Wi-Fi network generated by the device is not visible	→ Verify the Wi-Fi setting is turn on the iPad. → Verify the device is turned on (status LED on [6]). → Turns off the "Hide SSID setting" on the camera (see 3.3.1) → Restart the camera. → If the issue persists, contact Delmont imaging or its official representative.

4. Reprocessing


W.XVIII

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.XIX

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


W.XX

The device is not intended to come in contact with the patient.


W.XXI

If the chemicals described below are not available, it is the responsibility of the user to validate his process accordingly to ensure that the reprocessing process, including resources, materials, and personnel, is appropriate to achieve the required results:

- **Do not use detergents noncertified for use on aluminium and plastic.**
- **Do not use other method such as autoclave and automatic washer.**
- **Do not use fixating cleaning agents or hot water (>40°C) as this will fix residues.**
- **Do not use abrasive cleaning agent, brushes or other objects that could damage the device.**


W.XXII

The instructions of the cleaning agents' manufacturers must be observed. The cleaning and disinfection results must be confirmed by the corresponding manufacturers.

The instructions provided have been validated by the manufacturer of the medical device as being capable of preparing the medical device for reuse. This requires verification and/or validation and routine monitoring of the process.

4.1. Reprocessing of the unit

Step 1 Preparation before cleaning	→ Turn off the device by unplugging the device from the external power supply ([8]).
Step 2 Manual Cleaning	→ Use single use cleaning drapes or soaked cloth with cleaning disinfectant to clean the surface of the control unit. Always use cleaners with a neutral pH value to prevent damage to the surface. Comply with the manufacturer instructions of the cleaning agent. → Dry the equipment with a lint-free soft cloth. → After cleaning, inspect the device for cleanliness and free damage.

4.2. Reprocessing limitation and service life of the device

Delmont imaging´s devices are made of different materials. They were chosen for their ability to withstand multiple cycles of cleaning. Repeated treatment has minimal effect on the device.

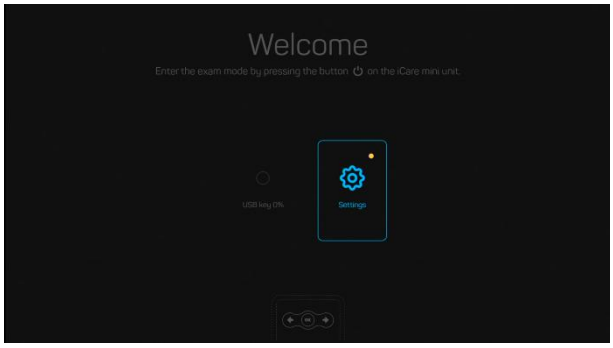
The service life is generally determined by wear and tear and inappropriate reprocessing parameters. You can verify the proper functioning of device following instruction in section 3.4.

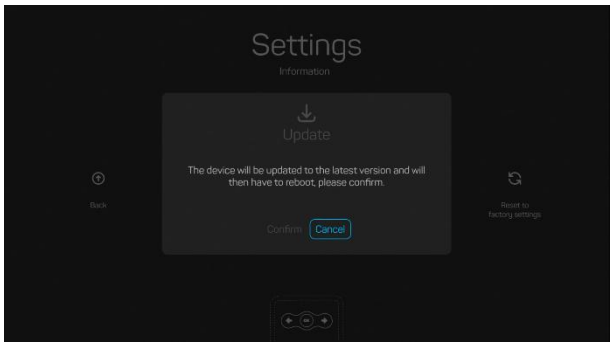
5. After-Sales service and maintenance

5.1. Maintenance

5.1.1. Updating the firmware device

If the device is connected to a network that has access to Internet, it will periodically check for available updates.

Step 1	Step 2
	
☑ Check if an update is available: it is notified by a yellow mark located on the settings button of the welcome screen	☑ Check if an USB key storage is connected and that there is enough remaining space. → Go in device information menu → Press and validate update process

Step 3

→ The device will download update files and reboot for installation. This process can take several minutes.

5.1.2. Periodic maintenance schedule

No periodic maintenance is required for the safe use of the device. Make sure to follow all recommendations from 3.4, prior each use.

5.2. Repair


W.XXIII

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

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

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

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

5.3. Return of the device


W.XXIV

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 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.

5.5. Disposal


W.XXV

Keep the used device out of reach of unauthorized person.


W.XXVI

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]	12V DC
Fuses	No
Protection class (I, II)	NA
Defibrillator protection (yes/no)	No
Equipotential plug (yes/no)	No
Conformity with the following standards (in the currently valid version)	IEC 60601-1/EN 60601-1 IEC 60601-1-2/EN 60601-1-2
Maximum dimensions of the control unit	80x80x56mm
Weight of the control unit	0,550 kg
Mode of operation	Continuous
Software version	Displayed in the service menu, see 3.3.5.
USB	USB 2.0 5V DC 0.5A
HDMI	HDMI 1.4 5V DC
Power source specification	12V DC, 6W, with positive polarity in the centre certified IEC 60601-1/EN 60601-1 or IEC 62368-1/EN 62368-1 for the countries concerned.

6.2. Camera specifications

Sensor	CMOS
HDMI output specification	1920x1080 / 50fps or 60fps / YCbCr 4:4:4
Video recording specification	1920x1080 / 30fps / CODEC H.264
Video streaming specification	1920x1080 / 30fps / CODEC H.264
Snapshot specification	2688 x 1520 / CODEC JPG
Vertical Scanning Frequency	30 Hz
Interface	CS-mount, C-mount with an accessory
Other specification	Progressive scanning Automatic electronic shutter (1/50 to 1/75 000) White balance

6.3. Wireless specifications

Wi-Fi standards	WLAN IEEE 802.11a/n (5 GHz) 2x2 MU-MIMO
Encryption	WPA2
Frequency band (GHz)	5.180-5.240 5.260-5.320 5.500-5.700 5.745-5.845
Maximum radio frequency power transmitted (dBm)	13

6.4. Conditions of use

6.4.1. 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

6.4.2. 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

6.4.3. 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

6.5. Guidance on electromagnetic compatibility

6.5.1. 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 CISPR 11	Group 1	This device must emit electro-magnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The device is suitable for use in all installations, other than residential installations and premises directly connected to the public low voltage power distribution network intended to supply residential buildings.
Harmonic emissions IEC 61000-3-2	Compliant	
Voltage fluctuations/Flicker IEC 61000-3-3	Compliant	

6.5.2. Electromagnetic immunity

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

Immunity test	IEC 60601 Severity Level	Compliance Level	Electromagnetic environment-Guidance
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV via contact ± 15 kV via air	± 8 kV ± 15 kV	The floor must be made of wood, concrete or tiles. If the floor is covered with a synthetic material, the relative humidity must be at least 30%.
Rapid transient peaks IEC 61000-4-4	± 2 kV power lines	± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Electric shocks IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV ± 2 kV	
Power outages, short power outages and voltage fluctuations IEC 61000-4-11	<5% Ut for 10 ms 40% Ut for 100 ms 70% Ut for 500 ms <5% Ut for 5 s	5% Ut 10 ms <40% Ut 100 ms <70% Ut 500 ms <5% Ut 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device must be able to continue working during power outages, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	The magnetic field at the mains frequency must be at a characteristic level of a location (50/60 Hz) in a typical commercial or hospital environment. The device should be kept at least 15 cm away from the source of power frequency magnetic fields during use.
Proximity magnetic fields IEC 61000-4-39	65 A/m at 134.2 kHz 7,5 A/m 13.56 MHz	65 A/m 7,5 A/m	The device should be kept at least 15 cm away from the source of power frequency magnetic fields during use.

6.5.3. 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 Severity Level	Compliance Level	Electromagnetic environment- Guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms 0,15 to 80 MHz 6 Vrms in ISM bands 0,15 to 80 MHz	3V 6V	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. d = 1,16 P d = 1,16 P 80 MHz to 800 MHz d = 2,33 P 800 MHz to 2,7 GHz 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). 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:
Radiated RF IEC 61000-4-3	3 V/m 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.

6.5.4. Recommended distances between portable and mobile RF communication systems for this device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device.

Immunity to proximity fields from following RF wireless communication equipment has been confirmed:

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 - ± 5 kHz deviation 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; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation: 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation: 217 Hz	2	0.3	28	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation: 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.

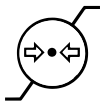
For other portable and mobile RF communication equipment (transmitters), minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

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. Used Symbols

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 device has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements.
	Symbol for “RoHS compliant”. Indicates that a device has been assessed by the manufacturer and deemed to meet European Union’s restrictions of certain dangerous substances used in electronic and electronic equipment.
	Symbol for “Medical device”. Indicates that the item is a medical device.
	Symbol for “Serial Number”. Indicates the manufacturer's serial number in order to formally identify a specific medical device.
	Symbol for “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 “Temperature limit”. Indicates the minimum and maximum temperatures to which the medical device may be safely exposed.
	Symbol for “Atmospheric pressure limit”. Indicates the range of atmospheric pressure to which the medical device may be safely exposed.
	Symbol for “Humidity limit”. Indicates the minimum and maximum humidity to which the medical device may be safely exposed.
	Symbol for “Protect from heat and radioactive sources”. Indicates a medical device that is sensitive to heat and radioactive sources.
	Symbol for “Moisture Sensitive”. Indicates a medical device that is moisture sensitive.
	Symbol for “Fragile, handle with care”. Indicates a medical device that may be broken or damaged if not handled with care.
	Symbol for “Transport conditions”. Indicates the transport conditions that should be respected.
	Symbol for “Storage conditions”. Indicates the storage conditions that should be respected.
	Symbol for “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 “Direct Current”. Indicate the type of mains supply.
	Symbol for “HDMI video output”. Indicates the terminals which the HDMI cord should be plugged.
	Symbol for “WEEE; waste electrical and electronic equipment; crossed-out wheeled bin”. Indicates that separate collection for waste electric and electronic equipment (WEEE) is required.
	Symbol for “USB output”. Indicates the terminals which the USB key should be plugged.

CE

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