delmont imaging

EN - Instructions for use

Endoscopic image processing & light source system

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.

MD This manual relates to the generic medical device group *Endoscopic image processing & light source system* manufactured by Delmont imaging with basic UDI-DI 37012178ICARG9. See declaration of conformity for the complete list of devices concerned.

Symbols used in this manual	
⚠	Instructions for preventing personal injury
ⓘ	Information to facilitate understanding or workflow optimization
✓	Prerequisite
➢	Instruction

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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 endoscopic image processing & light source system. This document may not be used to carry out endoscopic examinations or surgeries, 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.

Endoscopic image processing & light source system is a main electricity powered unit that, when used with an appropriate endoscope (not included) is designed to both:

- Provide illumination of an interior cavity of the body
- Provide visualization sent from the endoscopic video camera connected to the endoscope.

It includes image recording features and an image display monitor; however, it does not include features to steer, propel or otherwise control the movement of the endoscope.

1.2. Indications for use

The device is indicated for use by healthcare professional in diagnostic and operative endoscopic procedures for gynecology, urology and laparoscopy medical field in a healthcare center equipped with an appropriate endoscopic configuration.

1.3. Device description

Figure 1 - Control unit, front panel

1: Light cable plug

2: Endoscopic camera head plug

Figure 2 - Control unit, right panel

3: Standby button

4: Luminosity set up “-“ button

5: Luminosity set up “+” button

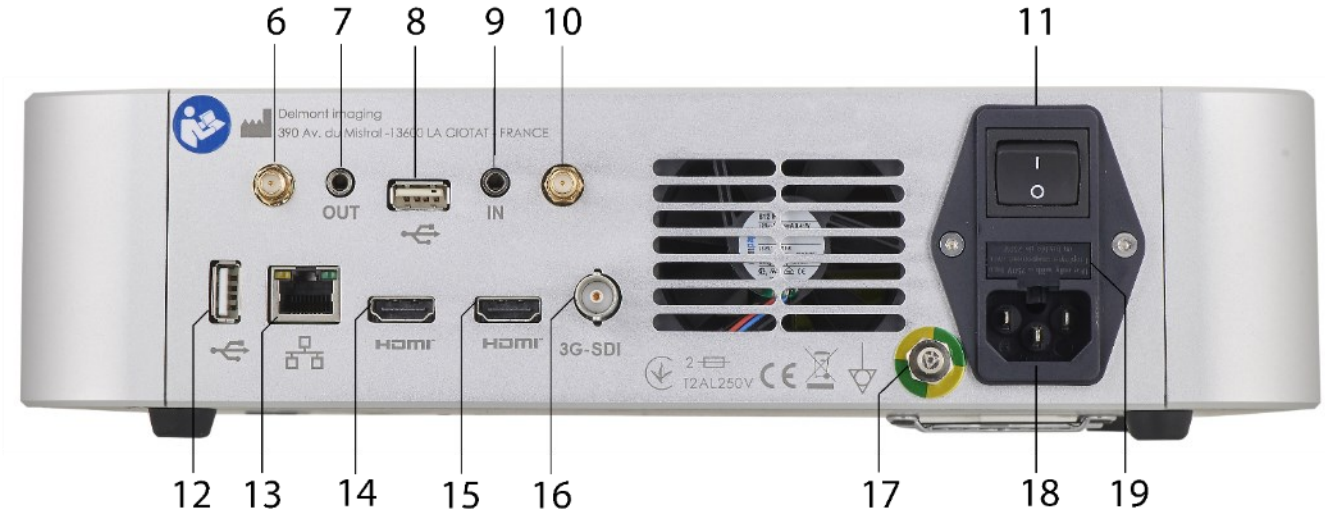


Figure 3 - Control unit, rear panel

6: Wi-Fi antenna socket
7: Output jack
8: USB socket
9: Input jack
10: Wi-Fi antenna socket
11: Power ON/OFF switch
12: USB socket
13: Ethernet socket
14: HDMI cable socket
15: HDMI cable socket
16: 3G-SDI cable socket
17: Equipotential socket
18: Power cable socket
19: Fuses holder

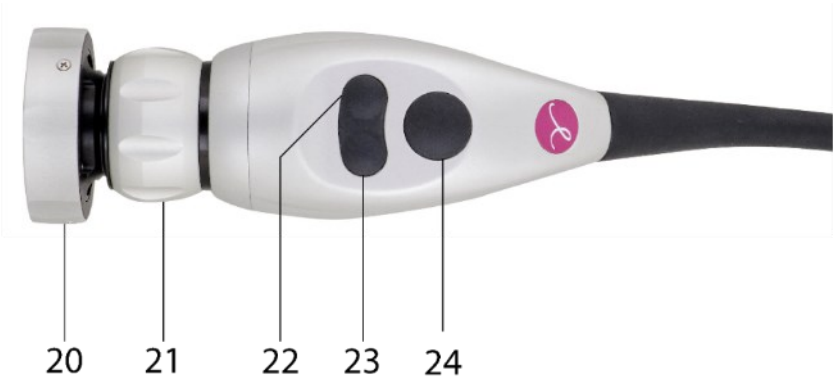


Figure 4 - Camera head

20: Endoscope holder
21: Focus ring
22: Right side action button
23: Left side action button
24: Center action button

1.4. 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.***
- ***injury of the patient and/or the user.***


W.III

Use the monitor provided by Delmont imaging to prevent errors or delays in diagnosis. Otherwise make sure that the monitor used has a minimum resolution of a 1920x1080, 24'', and is set in sRGB colors. Check the manufacturer manual for more details. It is important to ensure that the monitor settings used are optimized for the procedure being performed so that a clear, noise-free color image is obtained.


W.IV

Use only devices connected to the inputs/outputs that comply with IEC 60601-1. Using non-compliant device may lead to injury of the patient and/or 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 60601-2-2 requirements, including equipotential specifications. Using non-compliant system may lead to injury of the patient and/or the user as well as damage to the device.

- Use accessories supplied with the unit or offered as an option by the manufacturer.
- The endoscopic image processing & light source system should be used with endoscopes and light cables provided by Delmont imaging.
- If any doubt subsists on compatible equipment, the user should contact Delmont imaging or its authorized representative.

The device is supplied with the following items:

REF	Description
D100 100 000	iCare SLIDe. Camera control unit only
D100 110 000	iCare camera head without coupler
D100 120 000	Coupler of focal length 22mm

REF	Description
D200 150 000	Light cable, grey, Ø: 3.5mm, L: 2.3m
D200 150 001	Connector Storz for light cable - endoscope side
D200 150 002	Connector Storz for light cable - light source side

The following accessories and variants are also available:

REF	Description
D100 100 001	iCare without SLIDe. Camera control unit only
D100 120 001	Coupler of focal length 18mm
D100 120 002	Zoom coupler (f=16 to 34mm)
D100 120 003	Zoom coupler (f=16 to 34mm). Autoclavable
D200 150 003	Connector Olympus for light cable - light source side
D200 150 007	Connector Wolf for light cable - light source side
D200 150 005	Light cable, grey, Ø: 4,8mm, L: 2,3m
D200 100 000	Cart. 2 fixed shelves. 1 infusion stand. 1 camera holder
D200 100 003	Cart. 2 fixed shelves. 1 infusion stand. 1 camera holder, 1 transfo.
D200 110 004	Monitor 24'' - Medical grade

The iCare without SLIDE version is compatible with light cables of Storz standard only.

Contact the manufacturer or its approved representative for more details on accessories.

2. Safety instructions

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

2.1. Contraindications


W.VI

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. Warnings


W.VII

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


W.VIII

Use the Power ON/OFF switch on control unit rear side (see Figure 3) to isolate the device from the main power. Make sure this switch is always accessible.


W.IX

Turn off the power immediately if the cord is damaged, there is a risk of electric shock if the power cord is damaged.


W.X

Connect this device to a power supply equipped with a protective ground to avoid the risk of electric shock.


W.XI

Do not modify the device. A modification could cause electric chocks or mechanical injuries. If the device is modified, a check and test must be carried out to ensure that the device complies with the safety instructions.


W.XII

Do not insert metal objects into the unit to avoid electric shock, fire, short circuit or dangerous emission.


W.XIII

Do not use this device in presence of a mix of flammable anesthetics with air, oxygen, or nitrogen protoxyde.


W.XIV

Do not obstruct the fans on the rear and side of the device. Ensure sufficient air circulation to avoid overheating inside the unit: at least 15cm all around the unit.


W.XV

Camera head, and light cables are not applied parts and are not intended for patient contact.

The light source is equipped with an automatic safety feature that stops the lighting if the internal temperature becomes excessive.

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.).***

2.3. Precautions specific to the light source


W.XVI

Do not look directly at the light to avoid any ocular risk and handle the light cable carefully when the device is in use. This device is equipped with Group 1 LED according to IEC 62471.


W.XVII

Do not place the distal end of the light cable or endoscope directly on the patient or on any other flammable material (sheets, gauze pads, operating fields, etc.). The temperature can be very hot and cause burns and fire.


W.XVIII

Do not touch both ends of the light cable just after removing it from the light source. The temperature on the metal coupler of the fiber is very high and can cause burns.

Do not insert anything other than intended light cables into the socket provided for this purpose. Otherwise, the optical system may be damaged.

2.4. Vigilance

Any serious incident or risk of serious incident occurring during the use of this device must be notified to the manufacturer Delmont imaging without delay to vigilance@delmont-imaging.com, or its local representative and to the competent authorities in accordance with the national laws in force. We encourage the users to:

- Send back the device following recommendation from 5.3,
- Gather and transfer all appropriate information regarding the incident which include 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.

3. Use of the device

3.1. Initial set up of the device

3.1.1. Location

 W.XX	***The device is only to be used in a healthcare facility.***
 W.XXI	***Do not place heavy objects on the unit.***
 W.XXII	***The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.***
 W.XXIII	***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.XXIV	***Do not expose the control unit to water splashes or in a place that is too humid.***
 W.XXV	***Use only medical cart supplied by Delmont imaging or with appropriate certification if you chose to use another one, to avoid failure of the device when moving.***

- Choose a level and stable surface to install the device.
- If you place it in a compartment, make sure that it is sufficiently ventilated: at least 15 cm around the unit.

3.1.2. Unpack the device

 W.XXVI	***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.
- Always check all items immediately after receiving the shipment.

➢ Save the original packaging in a safe place, to eventually return the device in proper conditions.

3.1.3. Installation

To install the device, perform the following actions:

➢ Connect the HDMI cable(s) to the socket [14] or [15] on the rear of the unit.

➢ Connect the second end of the HDMI cable(s) to the corresponding input on the monitor(s).

➢ Connect the storage USB key on one of the USB socket [8] or [12] on the rear panel.

➢ Connect the camera head connector to the front of the control unit [2]. A red coding is present on the connector of the camera head and above the corresponding socket of the control unit. Align these two coded pins to connect the camera head.

✓ A « click » lock must be heard.

➢ Connect the power cord to the power socket [18] on the rear of the unit.

➢ Connect the other end of the power cord to an electrical outlet.

➢ Connect the Wi-Fi antennas on the two Wi-Fi sockets [6] and [10] on the rear panel.

➢ Connect the Ethernet cable to the socket [13] on the rear panel for a wired connection to the care center or connect a Wi-Fi dongle to the remaining USB port [8] or [12] for a Wi-Fi connection to the care center.

➢ Connect the equipotential socket [17] on the rear panel.

3.2. Operating the device

3.2.1. Powering on

➢ Set the power supply button on the rear panel of the unit to position « I ».

➢ Power on the monitor.

➢ The device enters in a booting sequence:
- The monitor displays a boot screen with Delmont imaging logo (see Figure 5).
- The standby button [3] led flashes quickly.
- This booting sequence last 30 seconds approximatively.

➢ Then, the unit goes into standby mode:
- The standby button led flashes slowly.
- The welcome screen appears on the monitor (see Figure 6).

Figure 5 - Booting screen

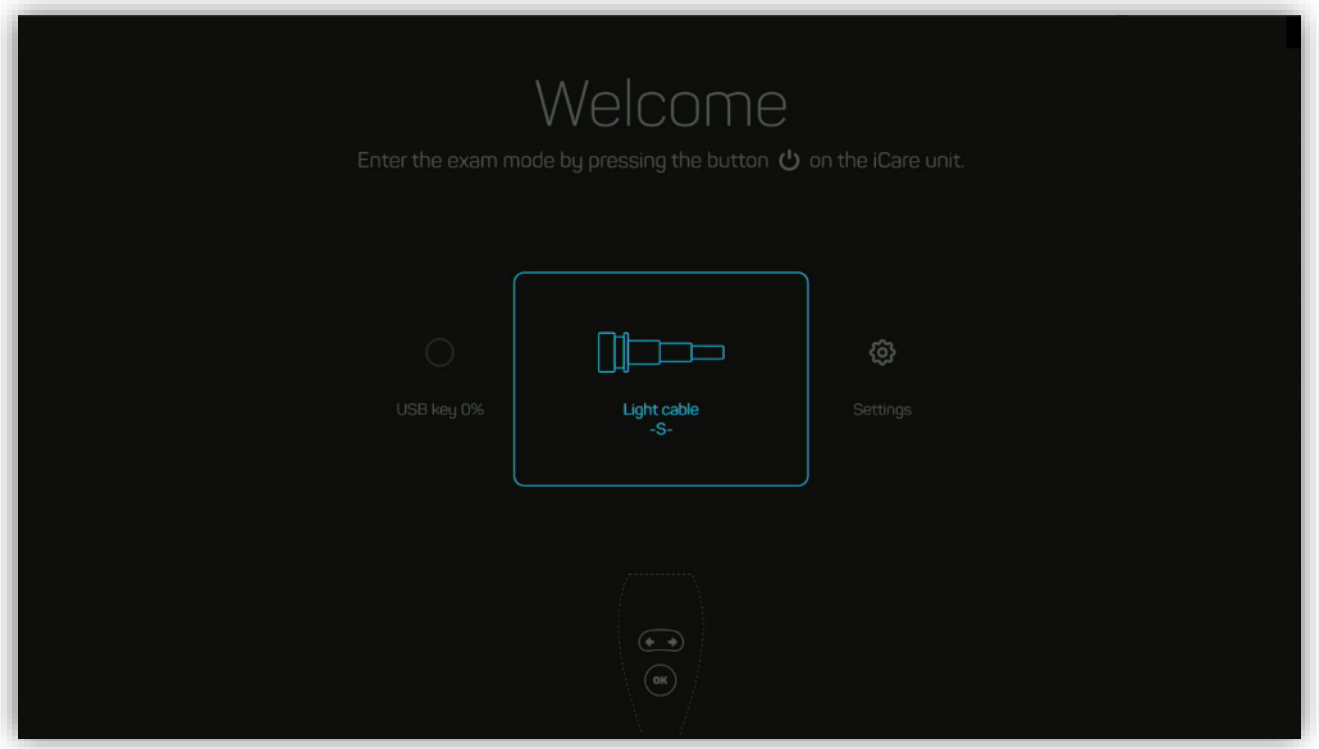


Figure 6 - Welcome screen

3.2.2. Navigating in the menu

To be in the welcome screen, make sure you are in standby mode by pressing [3].

- Use the camera head to navigate the menu.
- Press [22] or [23] to move the selection cursor (see Figure 6).
- Validate your choice by pressing [24].
- You can, in the welcome screen:
  - For the SLIDe version, see and go to the light cable type selection (see 3.2.3),
  - See and go to the USB key storage information,
  - See and go to the settings menu (see 0).

3.2.3. Changing light cable standard-SLIDe function

When you are in the welcome menu, the set light cable type is displayed on the screen (see Figure 6).

Depending on your light cable type (Storz, Olympus, Wolf), set the device correctly:

- Make sure there is no light cable inserted, disconnect it otherwise.
- Select the light cable standard setting and validate, you arrive on the following screen (see Figure 7).
- Choose between the three standards:
  - Olympus (O),
  - Wolf (W),
  - Storz (S).
- Confirm your choice, the change is being done.

3.2.4. Connecting the endoscope to the camera head

W.XXVII

In order to prevent any contamination of operating field or a patient contamination, place the camera head (including its coupler) into a sterile drape such as Deroyal™ (CLOSED CAMERA SYSTEM DRAPE, ref 28-0403) or equivalent. We recommend you refer to its user manual for proper use.

- Place the sterile drape.
- Turn clockwise the endoscope holder [20] to insert the endoscope, then release.

➢ Turn clockwise the endoscope holder [20] to free it.

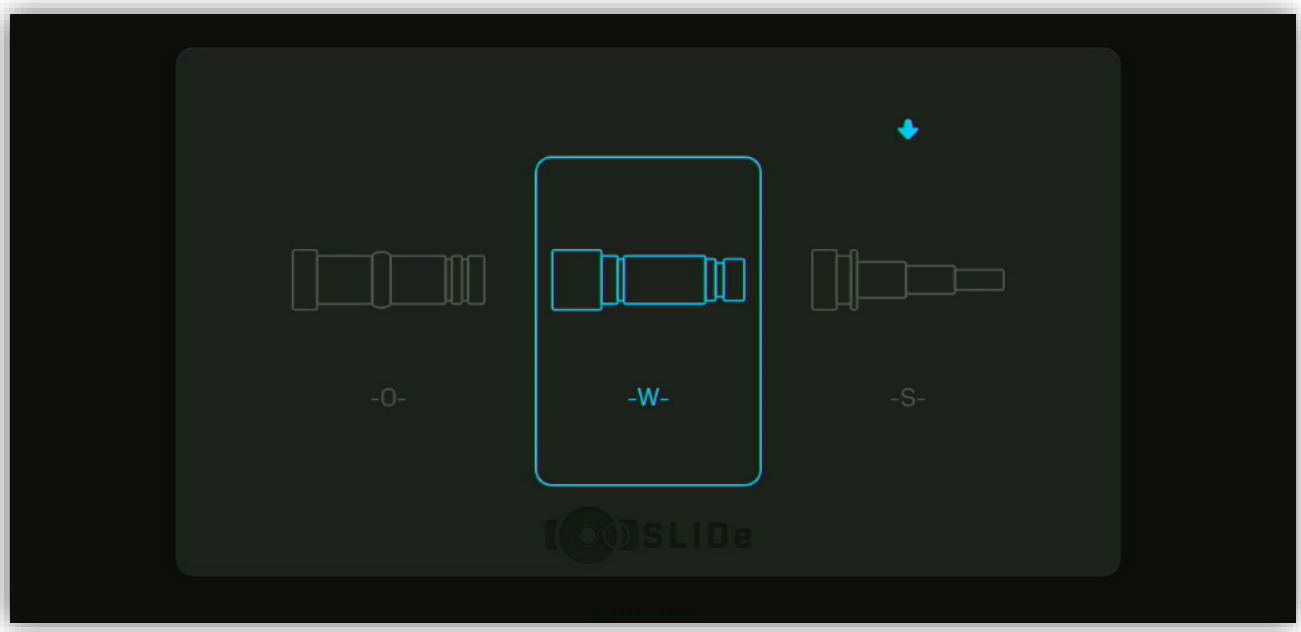


Figure 7 - Light cable selection menu

3.2.5. Enter in live mode and set light intensity

The light source is set to the last power used or to the value saved by the physician.

➢ Connect the light cable into the corresponding socket [1].
➢ Connect the other end of the light cable to your endoscope.
➢ Enter in live mode by pressing [3], the standby button led stops blinking.
➢ Use the "+" [5] and "-" [4] buttons from the control unit right side to increase or decrease the light intensity (see Figure 8).

3.2.6. White balance

Once the camera is paired with the endoscope and the light source is on:

➢ Film an appropriate white surface.
➢ Start the white balance by pressing and holding the button [22], «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.

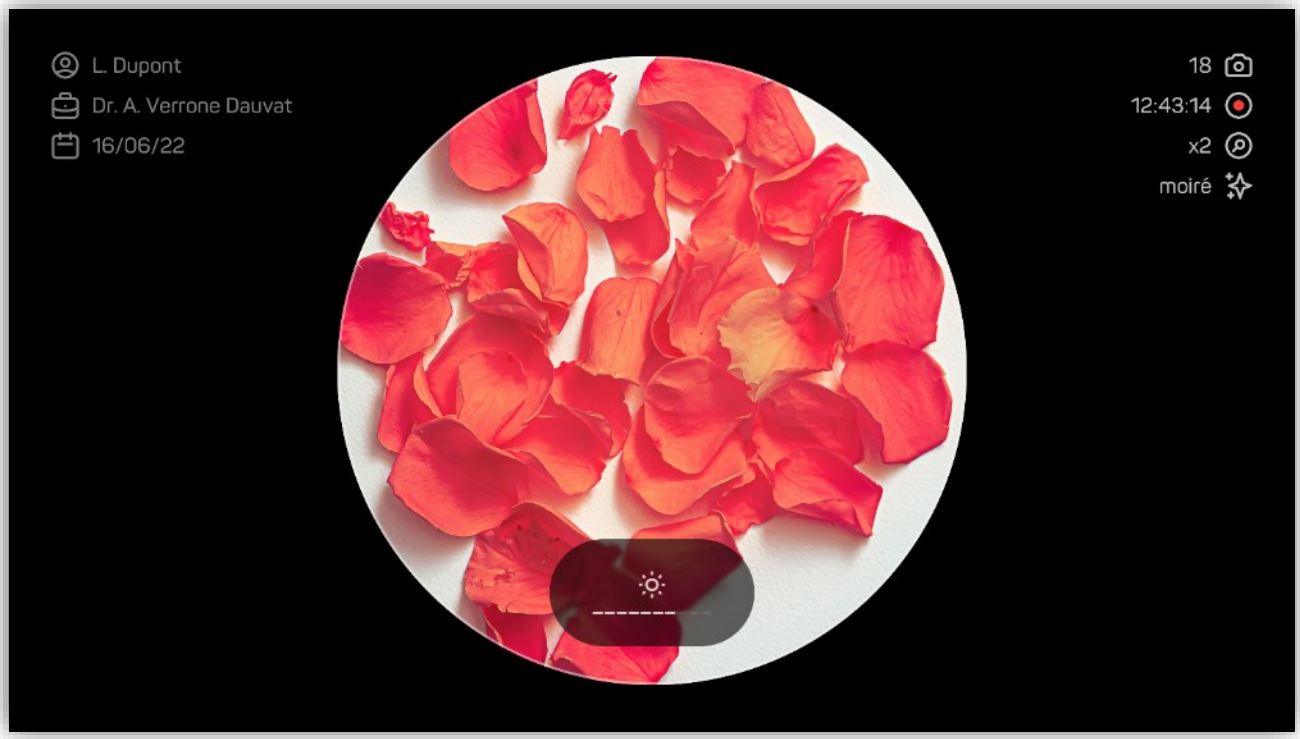


Figure 8 - Light intensity change

3.2.7. Focus

Focusing far away enough allows a sufficient depth of field to be obtained for the operation, thus avoiding regular focusing.

Once the endoscope is connected and the light source is on:

➢ Slowly turn the focus ring [21] to find a position where the objects observed are sharp.

3.2.8. Capturing images and videos

Once the endoscope is connected and the system is in live mode:

➢ Capture an image by short press on [24].

➢ Start a video recording by long press on [24]. Stop the recording with another long press.

3.2.9. Turning off the device

➢ Put the switch on the rear panel of the control unit to the « O » position to turn off the device.

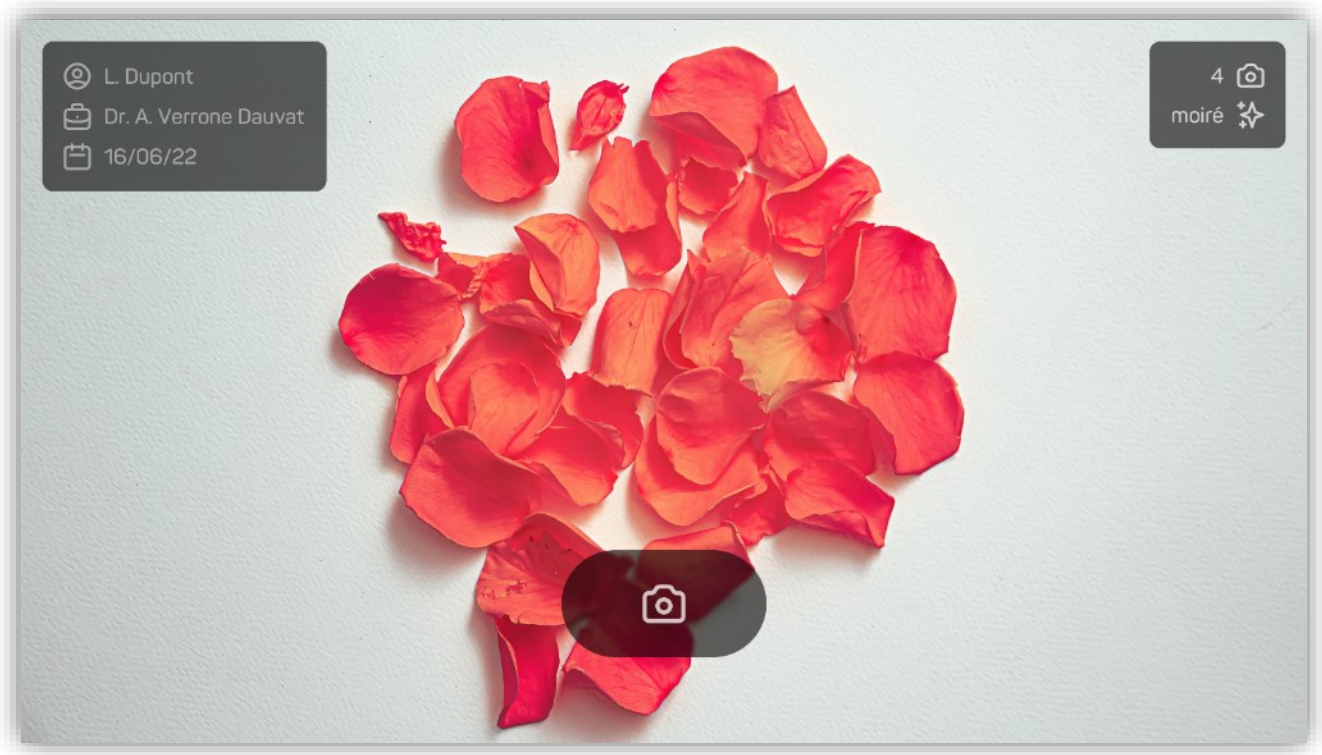


Figure 9 - Confirmation of image taken

3.3. Device configuration

➢ To configurate the device, in the welcome menu select Settings to get to the Settings menu (see Figure 10).

3.3.1. Network configuration

In the network menu (see Figure 11), you can:

➢ Choose the network connection mode: Wi-Fi or Ethernet.

➢ Activate MAC filtering.

➢ Hide Wi-Fi SSID.

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

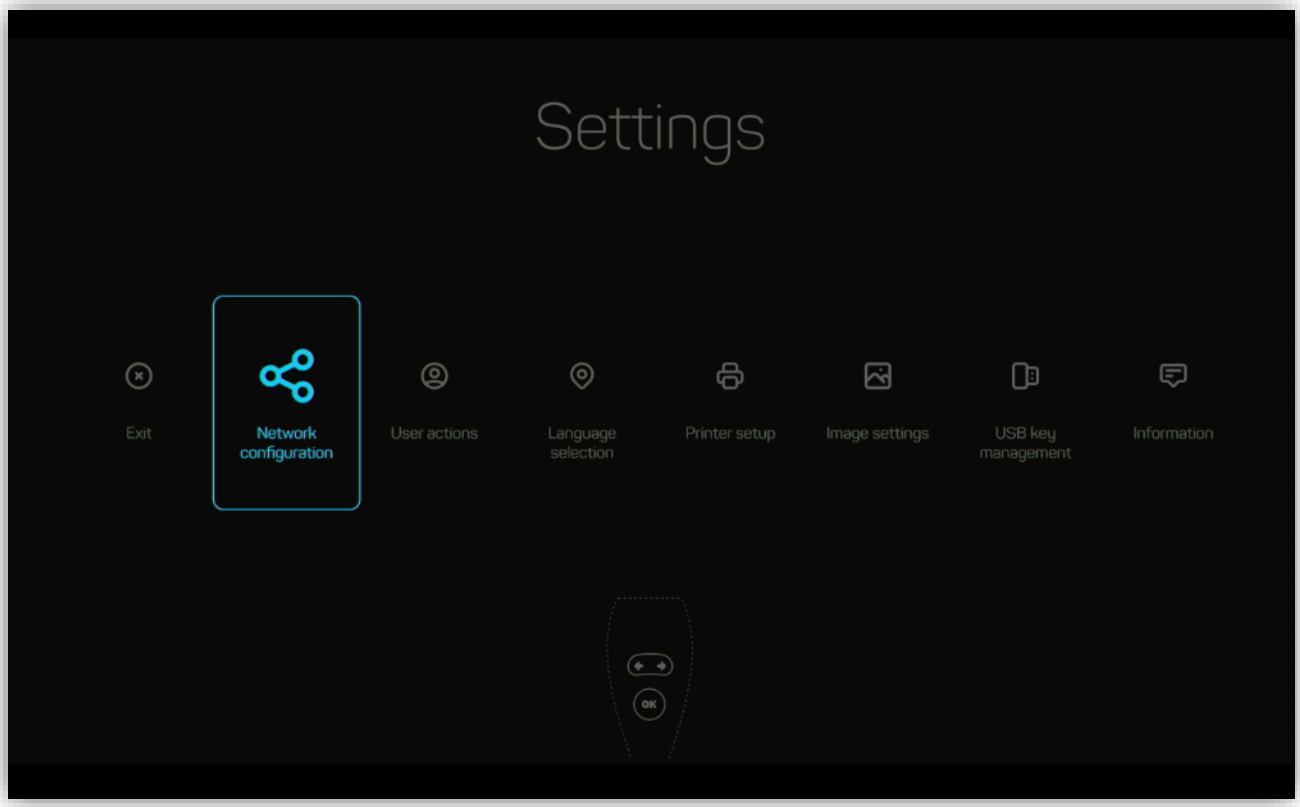


Figure 10 - Settings menu

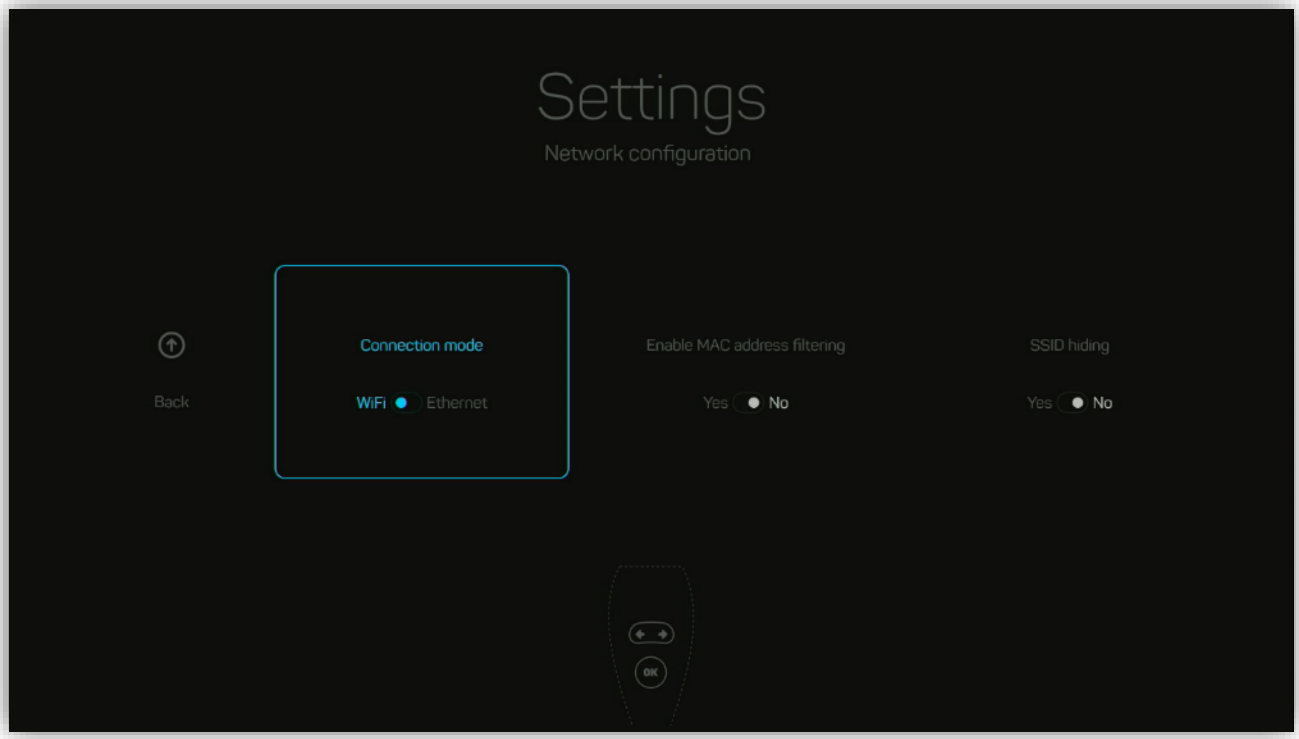


Figure 11- Network settings menu

3.3.2. User's action configuration

In the User's action menu (see Figure 13), you can:

- Configure action related to short press or long press on button [22].
- Configure action related to input jack [9].
- Configure action related to output jack [7].

3.3.3. Language configuration

In the language menu, you can:

- Select the appropriate language.

3.3.4. Image settings configuration

To obtain the best image settings, set up the device in the final conditions, with an endoscope.

In the image setting configuration, launch it to:

- Select a predefined image preset.
- Manually setup your image parameters.

3.3.5. USB key configuration

In the USB menu, you can:

- See the storage level (in %).
- Erase the USB key storage.

3.3.6. Device information

In the device information menu (see Figure 12), you can:

- See information related to the device.
- Launch the update of the firmware (see 5.1.2).
- Reset the settings to the factory values.

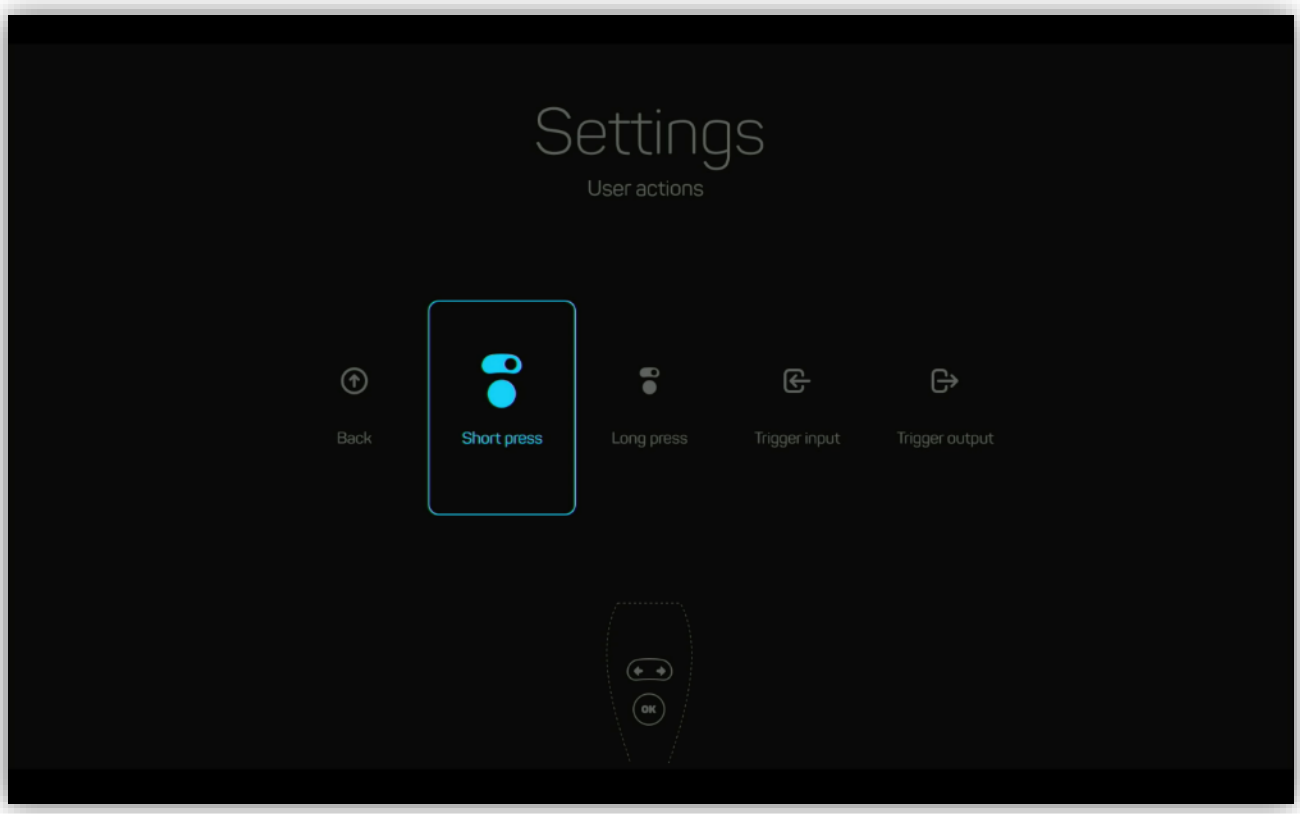


Figure 13 - User's actions menu

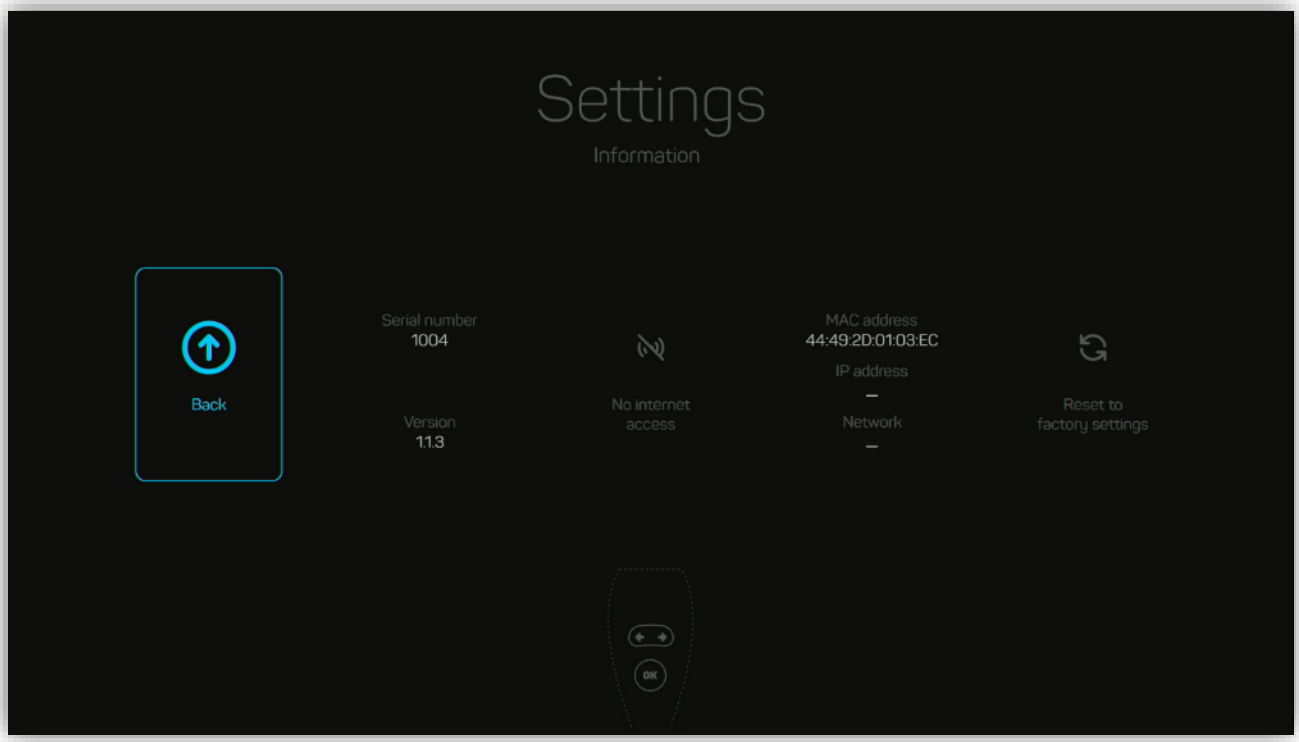


Figure 12 - Device information menu

3.4. Visual inspection and functional test

W.XXVIII

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, infection, and/or thermal injury. Replace a damaged device or a device with improper functioning.

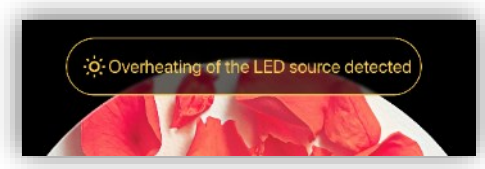
➢ The user must perform this functional checklist after first installation and prior to each use of the device:

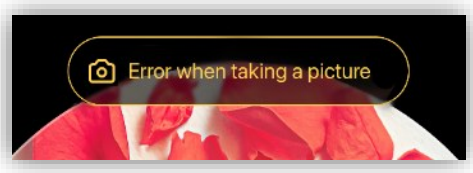
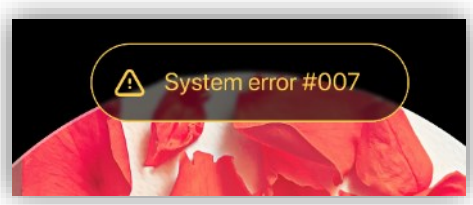
- ✓ Check the control unit for no visible wear and damage.
- ✓ Check the camera head for no visible wear and damage.
- ✓ Check power and HMDI cords for no trace of wear and damage.
- ✓ Make sure the control unit is on a level and stable surface.
- ✓ Make sure the control unit is sufficiently ventilated (at least 15cm free around the unit).
- ✓ When the control unit is powered on and ready, the welcome menu should appear on the screen and the standby button [3] should flash slowly.
- ✓ When you connect a light cable and press the standby button the ventilator should start, and light appears. The standby button led should stop blinking.
- ✓ When the camera head is plugged and 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
 Overheating of the light source	➢ Stop current operation by pressing standby button, ➢ Make sure the fans of the device are not obstructed, ➢ Wait 10 minutes, ➢ If the message disappears, resume to the operation,

Error message	Solution
	➢ If the problem persists, turn off the device for one hour, ➢ 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 in exFAT, ➢ If the error persists, contact Delmont imaging or its official representative.
 Error System	➢ Turn off and on the device, ➢ If the error persists, contact Delmont imaging or its official representative.

3.5.2. Device wrong behavior

Issue	Solution
The light indicator of the standby button does not illuminate when power is turned on.	➢ Check that the power cord is connected to the network and the device, and that the power switch on the rear panel of the unit is in the « I » position. ➢ If the problem persists, check fuses for proper condition (use T2A - 250V - UL/CSA fuses only). ➢ If the issue persists, contact Delmont imaging or its official representative.

Issue	Solution
The LED source lights up, but the luminous flux is insufficient.	➢ Check if the light source power is set to maximum power. ➢ If the issue persists, check if the light cable is properly plugged. ➢ If the issue persists, check the condition of your light cables and endoscopes. ➢ If the issue persists, contact Delmont imaging or its official representative.
The light indicator of the standby button illuminates but no image appears on the screen.	➢ Check that the camera head is connected to the control unit, ➢ If the issue persists, check that the control unit is correctly connected to the monitor (video cable in good condition and plugs properly inserted). ➢ If the issue persists, check that the monitor is turned on, that the correct video input is selected and that the screen image settings are not in the minimum position (color, brightness, and contrast). ➢ If the issue persists, check for the presence of light by inspecting the light source, light cable and endoscope. ➢ If the issue persists, contact Delmont imaging or its official representative.
The image is blurred.	➢ Check that there is no fog or stains on the camera coupler or the endoscope. ➢ If the issue persists, check the focus of the coupler. ➢ If the issue persists, contact Delmont imaging or its official representative.

4. Reprocessing


W.XXIX

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.XXX

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


W.XXXI

Neither the control unit nor the camera head are intended to come into contact with the patient. Sterile drapes should be used as instructed in 3.2.4.


W.XXXII

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 aluminum and plastic.***
- ***Do not use alkaline solutions for disinfection of the camera head.***
- ***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.XXXIII

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 camera head and coupler

Steps	Instructions
1. Preparation before cleaning	➢ Remove and dispose of the sterile drape. ➢ Disconnect the camera head from the control unit. ➢ Connect on the soaking cap on the camera connector cable and ensure it is completely closed. ➢ Detach the coupler from the camera head.
2. Manual Cleaning	➢ Prepare a detergent bath using cold utility (tap) water. ✓ Use enzymatic cleaning solution (Endozime AW at 8ml/L, 1oz/gallon). ➢ Completely immerse the camera head and cable in the detergent solution for at least 6 minutes. Ensure all air bubbles are removed from the surface. ➢ While still immersed, brush the device for at least 4 minutes with a sterilized soft bristled brush to remove excess soil. ✓ Use M16 style brush. ➢ Prepare a distilled water bath rinse, immerse the entire device for at least 2 minutes to aid in removal of detergent. The rinse water should be discarded at the end as it will be contaminated with the cleaning solution. Thorough rinsing of the camera head assembly is necessary for removing any debris or detergent which could interfere with disinfection. ➢ Dry the device using a clean lint-free cloth. ➢ Wipe the exposed glass window using a soft cotton applicator soaked with 70% isopropyl alcohol to avoid streaks and spots. ➢ After cleaning, inspect the camera head assembly and camera head cable for cleanliness and damage. Repeat the operation if necessary.

Steps	Instructions
3. Manual high-level disinfection	➢ Equilibrate a disinfecting bath by diluting the active ingredient. ✓ Use solution: Cidex® OPA, to 0.40% ortho-Phthalaldehyde at 20 ± 2°C. ➢ Fully immerse the device in the disinfectant bath and using a sterile lint-free cloth remove any air bubbles that is visible. ➢ Flush the locking system and focus ring on the coupler with 60mL of total disinfectant using a forceful flush. See areas indicated by arrows:  ➢ Actuate the coupler locking system for a total of 3 times to ensure exposure of the areas to the disinfectant. ➢ Allow the device to soak for 15 minutes. ➢ Prepare a purified water (PURW) rinse bath and fully immerse the device by agitating, flushing with a minimum of 60mL PURW and actuating the coupler locking mechanism and focus ring several times. ➢ Allow the device to soak for 15 minutes at least. ➢ Prepare a purified water (PURW) rinse bath and fully immerse the device by agitating and allowing the device to soak for a minimum of 1 minute. ➢ Repeat previous step two more times for a total of 3 rinses using a fresh batch of purified water (PURW) each time.
4. Drying	➢ Dry the device using a sterile lint-free cloth.
5. Maintenance, inspection and testing	➢ Prior to reuse the device, follow instruction from 3.4.
6. Packaging and storage	➢ Disinfected equipment should be used immediately or stored in a manner to avoid any contamination.

4.2. Reprocessing of the control unit

Steps	Instructions
1. Preparation before cleaning	➢ Turn off and disconnect the control unit from the power grid.
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 control unit for cleanliness and free damage.

4.3. 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 and disinfection. 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 “Visual inspection and functional test".

5. After-Sales service and maintenance

5.1. Maintenance

5.1.1. Replacing the fuse


W.XXXIV

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

- Unplug the power cord from the wall outlet and remove the cord from the device.
- 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.
- Follow instruction from “Visual inspection and functional test” prior to each use.

5.1.2. Updating the firmware device

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

When an update is available, you will be notified by a yellow mark located on the settings button of the welcome screen (see Figure 6).

- Make sure a USB key storage is connected and that there is enough remaining space.
- Go in device information menu and validate update process.
- The device will download update files and reboot for installation. This process can take several minutes.

5.1.3. Periodic maintenance schedule

At a minimum of every 12 months perform the following maintenance:

- Ensure the earth leakage current is 500µA, ground protective earth impedance is <0.1 ohms, power consumption is less than or equal to the rated power,

➢ The unit pass a dielectric withstand test of 1500V without breakdown.

See IEC 60601-1 for test methods. If the unit fails these tests, contact Delmont imaging or its representative.

5.2. Repair


W.XXXV

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

Delmont imaging service center 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.XXXVI

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

If you need to return the device:

➢ Reprocess the device according to the process described in 4.

➢ Use the original cardboard packaging for the transport of the device. If this is not possible, wrap each component individually in sufficient paper or sheets of foamed material and place them in a cardboard box.

5.4. Warranty

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

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

5.5. Disposal


W.XXXVII

Keep the used device out of reach of unauthorized person.


W.XXXVIII

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

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

6. Technical data

6.1. General specifications

Mains voltage range [V]	100-230
Supply frequency range [Hz]	50 / 60
Fuses	2x T2A - 250V UL/CSA 5 x 20 mm
Protection class (I, II)	I
Application part type (B, BF, CF)	BF
Defibrillator protection (yes/no)	No
Equipotential plug (yes/no)	Yes
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	310 x 75 x 310 mm
Weight of the control unit	4,4 kg
Weight of camera head	0,4 kg
Mode of operation	Continuous
Software version	Can be determined through the service menu

6.2. Camera head specifications

Sensor	HD CMOS
Resolution	1920 x 1080
Vertical Scanning Frequency	50/60 Hz
Lens	22 mm C-mount coupler
Protection class (IP code)	IPX7
Other specification	Progressive scanning Automatic electronic shutter (1/50 to 1/50 000) White balance Color bar Programmable buttons

6.3. Light source specifications

Technology	LED
Nominal power (W)	95
Color temperature (°K)	6 000
Color rendering Index	> 70
LED typical lifetime (hours)	50 000
Compatible light cable standard	Storz Wolf and Olympus additionally with SLIDe function
Safety specification	Automatic thermal protection system Automatic detection of the light cable.

6.4. Wireless specifications

Wi-Fi standards	WLAN IEEE 802.11a/n/ac (5 GHz)
Encryption	WPA2
Frequency band (GHz)	5.18 – 5.845
Maximum radio frequency power transmitted (dBm)	15

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. Guidance on electromagnetic compatibility

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 CISPR 11	Group 2	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	

6.6.2. 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.

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 Severity Level	Compliance Level	Electromagnetic environment- Guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	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 de- vices 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 bands between 150 kHz 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.
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 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.

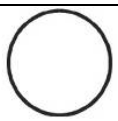
For other portable and mobile RF communication equipment (transmitters), minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

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 “Ukrainian marking". Indicates that a device has been assessed by the manufacturer and deemed to meet Ukrainian 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	Description
	Symbol for “Do not use if package is damaged". Indicates a medical device that should not be used if the packaging has been damaged or opened and the user should consult the instructions for use for further information.
	Symbol for “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 “Keep out of direct sunlight". Indicates a medical device that should be kept away from all sources of light.
	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 “Type BF applied part". Identifies a type BF applied part complying with IEC 60601-1: Classification of protection against electrical shock.
	Symbol for “Standby". Indicates the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition.
	Symbol for “On Power". Indicates connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.
	Symbol for “Off Power". Indicates disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved.
	Symbol for “Direct Current". Indicate the type of mains supply.

Symbol	Description
	Symbol for “Both direct and alternating current". Indicate the type of mains supply.
	Symbol for “Equipotential plug". Indicates the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential.
	Symbol for “UL/CSA tied fuses". Indicates the fuses boxes or their location marked with type and rating.
	Symbol for “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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