



delmont
imaging



Instructions for use

iCare

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1. Preface

iCare is a handset combining a HD CMOS camera and a LED light source in a single camera control unit for use by qualified gynecologists when performing surgical or diagnostic endoscopy procedures.


iCare comes with:


- A control camera unit which contains a LED light source 64 Watts.
- An HD CMOS sensor with its C-mount lens of 22mm focal length, equipped with 3 pre-programmed buttons, a 2.99m cable, a connector and its sealing cap.
- An EU power cable.
- An HDMI cable.
- An USB key.
- Two wifi keys that allow the correct operation of our imagyn application, installed on iPad Pro (for more information on the imagyn application, refer to the corresponding instructions for use).


On the camera side, this is a mono CMOS HD 1/4" color camera, with remote electronics. Its small and ergonomically designed sensor, automatic shutter, good sensitivity, excellent resolution and faithful colour-rendering make it ideal as a medical tool.

On the light side, this LED source is specially designed for use in various endoscopic diagnostic or surgical applications. Its ease of use, as well as its lighting power make it the ideal multidisciplinary medical tool.

In order to make the best use of iCare while having all the necessary precautions at your disposal, it is essential for you to become acquainted with this manual.

The sentences displaying the  symbol correspond to points requiring special attention.


The sentences displaying the  symbol represent items of information.

 This equipment has been delivered to you in a packaging. Keep it for possible transport.

2. Safety instructions

2.1. General instructions

- Read the instructions for use,
- Comply with the conditions of use and storage,
- The product should be opened only by a competent technician authorised by the manufacturer,
- Do not insert metal objects into the product. This is to avoid any risk of electrical shock, fire, short-circuit or hazardous emissions,
- Do not expose the product to splashed water or to damp,
- Use only the accessories supplied with the product or recommended as options by the manufacturer,
- Do not place heavy objects on top of,
- This product is not sterile,
- If the power cord is damaged, immediately turn the power off. It is dangerous to operate this device with a damaged cord. To disconnect the cord, pull it by the plug. Never pull on the cord itself,
- Unplug the device from AC outlet if you are not going to use it for a few days or more,
- Ensure sufficient air circulation to prevent overheating inside the device: at least 15 cm around the device. Do not cover it and ensure that the feet of the device are present,
- Do not use corrosive or abrasive products to clean the device, but only the disinfectant liquids recommended in the relative chapter,
- Prior each use, ensure that the device has no rough surface, sharp edges, or protrusions that could cause safety problems,
- The surface temperature can reach 41°C (after a few minutes' use). Therefore, avoid any skin contact with this area,
- To avoid any risk of electrical shock, this device must be connected only to a power system equipped with protective grounding,
- Products connecting to the input/output ports must comply with the IEC 60950-1 standard,
- Any modification of this device without authorisation from the manufacturer is prohibited. If the medical device is modified, an inspection and a test must be carried out to ensure that the medical device complies with the safety regulations,
- Check with the manufacturer regarding the compatibility of your endoscope, prior to use,
- To prevent any error or delay in the diagnosis, it is necessary to ensure that the settings of the monitor used are optimized for the operation performed, so that they provide a clear color image without noise,
- This device is to be used on individuals (patients) fit to undergo an endoscopic procedure.
- Applied parts of electro-medical devices that can be used in conjunction with iCare must be BF or CF type in accordance with 60601-2-18 standard. Check this compatibility before each operation for safe use.

 It is advisable to have a second surgical camera in the operating theatre so that action can be taken if the device fails to perform or if a deterioration in performance is noticed.

2.2. Specific instructions for the light source

- Never look at the light output or the end of the light cable,
- Do not insert anything other than a cable of light into the slot provided for this purpose as this may damage the optical system,
- The use of other cables or accessories than specified may result in increased emissions or decreased immunity to the device,
- After use of the source, upon removal of the fiber from its light guide, the temperature on the metal coupler of the fiber is very high and can cause burns,
- The light output power of the fiber can cause eye damage. Be careful when handling the fiber when the device is in use,
- Do not place the distal end of the light cable or the endoscope directly on the patient or any other flammable material (such as sheets, gauzes, surgical drapes, etc.), as its may be very hot and may cause burns.



This product is equipped with Group 1 LEDs according to IEC 62471 standard. Do not look directly at the light to avoid any eye hazard.

2.3. Contraindication

The use of iCare is contraindicated when hysteroscopy is contraindicated for the patient.

3. Regulatory notices

3.1. Compliance

This product was designed and manufactured by a company with a certified quality system. It meets the requirements of European directive 93/42/CEE, on medical devices. Consequently, it particularly meets the standards of electrical safety (IEC) and electromagnetic compatibility (CEM) ad hoc.

3.2. Electromagnetic interferences and electrostatic discharge

Although this product complies with CEM standards, it may in very special circumstances interfere with other devices, or itself be the object of interference from other apparatuses or an unfavourable electromagnetic environment.

In order to avoid these situations, it is advisable to:

- Ensure of the quality of the electric power system (especially the grounding of all apparatuses and medical carts).
- Keep the apparatus away from electromagnetic sources (e.g. compressors, motors, transformers, HF generators, etc.).


3.3. Medical device vigilance

Like any medical device, this apparatus is subject to the stipulations governing medical device vigilance, and therefore any serious malfunction must be reported to the competent authorities and to the manufacturer as quickly and as accurately as possible.

Manufacturer's contact details: refer to the last page of the manual.

3.4. End of life cycle

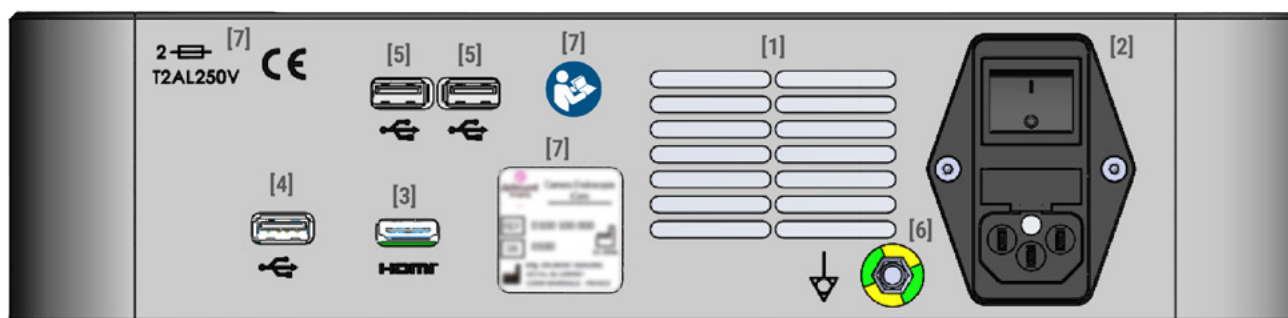
This device carries the recycling symbol in compliance with European directive 2002/96/CEE on Waste Electrical And Electronic Equipment (DEEE or WEEE).

By correctly disposing of this device you are helping to prevent harmful effects on the environment and on human health. The  symbol displayed on the device and on the accompanying documentation indicates that this product cannot under any circumstances be treated as household waste. It must therefore be delivered to a waste collection centre for the recycling of electrical and electronic equipment.

In disposing of it, please comply with the waste elimination norms in effect in the country where it is installed. For further details on the treatment, recovery and recycling of this device, kindly contact your nearest retailer who will advise you on the procedure to follow.

4. Product description


4.1. Control camera unit description



[1] : The aerators on the back panel of the device must not be clogged to avoid overheating. The light source is equipped with an automatic safety device that stops the lighting if the internal temperature becomes excessive. Aerators on the left panel and under the device are also present for better ventilation.

[2] : The device receives electrical power by means of the mains plug located on the back panel, which must be connected to the mains power supply by the lead supplied with the device. This plug carries a fuse trap as well as a master switch for powering up. When replacing a fuse, the device must be unplugged and the same type of fuse must be used. The T in "T2.5A" means "time-delayed". Only use fuses marked UL/CSA.

[3] : The device has an HDMI video output.

 The devices connecting to the "VIDEO OUT" outlets must be compliant with standard IEC 60950.

[4] : The device has a USB output for a storage key.

[5] : The device has two USB outputs for two Wifi keys.

[6] : The device has an equipotential plug, which can be connected to other electro-medical devices in order to reduce the formation of different electrical potentials.

[7] : The keys and symbols on the back panel are for identifying the device in accordance with international standards IEC 60601-1, IEC 60601-2-18, IEC 60417 and EN 980 (See the corresponding section 12).



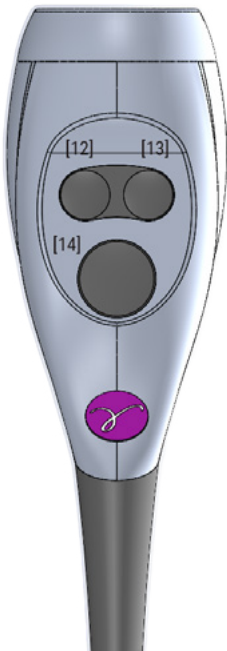
[8] : The device has a connector for connecting the light cable

[9] : The device has an light indicator that alerts the user of the different phases of use of the product.

[10] : The device has a connector for connecting the iCare sensor.

[11] : The device has a stand-by button.

4.2. Sensor description



[12] : This button allows, by a long press, to start a white balance.

[13] : This button allows, by a short press, to go from a minimum value of light power to a maximum value, and vice versa. These values are respectively 75% and 100% of the light power.

[14] : This button allows:

- By short press, to launch an image capture.
- By long press, to start or stop a video recording.

5. Installing the product

No special training is required to install this medical device. Kindly refer to the instructions in this section of the manual.

Once all iCare's items have been unpacked from their original packaging, please do the following:

- Place the control camera unit on a flat, stable surface. If you place it in a compartment, make sure it is sufficiently ventilated (at least 15 cm around the device).
- Connect the power cord to the mains plug [2] on the back plane of the device.
- Connect the other end of the power cord to an electrical outlet.
- Connect the HDMI cable to the corresponding output [3] on the back panel of the device.
- Connect the second end of the HDMI cable to the corresponding input on the monitor.
- Place the two Wifi keys on the two USB outputs [5] on the back panel.
- Place the USB key on the USB output [4] on the back panel.
- Turn the activation switch of the mains plug to the position «I» on the back panel of the device. The device enters the start sequence: the indicator light [9] on the front panel flashes quickly. This startup sequence ends after approximately 1 minute 30. The device enters the standby mode: the front panel indicator light flashes slowly.
- Connect the sensor connector to the front of the control camera unit [10]. A red keying is present on the connector of the sensor and above the corresponding orifice of the control camera unit. Align these two keyings to connect the sensor. A «click» of locking must be heard.
- Push the light cable into the opening provided therefor [8]. A «click» of locking must be heard. Connect the other end of the light cable to your endoscope.
- Place an endoscope in front of the camera lens.
- Turn on the monitor.
- Press the stand-by button [11] on the right panel of the control camera unit to start the device: the front panel indicator light becomes fixed. Another press will put it back into standby mode.

It is then possible to check the correct functioning of the camera and especially to make sure that the settings of the monitor are completely satisfactory thanks to the colour bar which appears when disconnecting the sensor.

6. Operating guidelines

6.1. Powering up

The device is equipped with an activation switch located on the back panel [2]. It is activated by switching this switch to position «I». The light source is set to the last power used or to the value saved by the physicians in imagyn.

6.2. Connecting the endoscope to the sensor

Close the lugs on the lens ring until you can insert the endoscope. Once the endoscope is inserted, release the two lugs.

Simply bring the lugs together to unlock the endoscope.

6.3. Automatic White Balance (AWB)

The white balance is triggered by a long press on the sensor button [12]. It should be done as follows:

- Once the camera is paired with the endoscope and the light source activated, film a white surface.
- Trigger the white balance,
- Continue to film the white surface as long as the «AWB in progress» message is on the screen,
- Keep the button pressed until «AWB OK» message appears on the monitor. This delay avoids untimely presses.

6.4. Focusing

Use the lens focus ring associated with the sensor to focus.

Once the endoscope is connected and the light source is activated, slowly turn the lens focus ring to find a position where the objects being observed are sharp.

Focusing on a fairly distant point helps obtain adequate field depth for the operation and therefore avoids having to do retouching too regularly.

6.5. Other Sensor Buttons Features

The sensor button [13] switches from a light power value A to a value B. These values are set at 75% and 100% of the light power output, but can be set via imagyn.

The [14] button allows:


- By short press, to launch an image capture.
- By long press, to start a video recording. Another long press stops recording.


6.6. Powering off


To stop the device, turn the activation switch on the back panel of the control camera unit [2] into position «0».


7. Sensor decontamination procedures


Pre-disinfection cleaning	Disinfection	Sterilization	
Immersion in an enzymatic cleaning solution (Aniosyme DD1, Hexanios G+R or surface cleaning ((Anios wipes)).	Immersion in a glutaraldehyde solution (Anios Laboratory - Steranios 2%)	Sterilization using the STERRAD process	Sterilisation with ethylene oxide

 Any other disinfection methods are prohibited, and the manufacturer accepts no liability for any damage caused by using such methods.

 It is advisable to use a disposable, sterile, protective cover on the camera regardless of the sterilization procedure followed, and throughout the surgical operation.


 The camera is not autoclavable.


 The camera is not compatible with automatic washer-disinfectors.

 Existing alkaline solutions for the pre-disinfection of certain medical devices are NOT RECOMMENDED for pre-disinfecting our cameras.

 It is essential for the parts coming into contact with the disinfectant to be thoroughly rinsed.

 Use soft non-woven cloths for wiping the lenses dry so as not to scratch them..

 The procedures described in this section are given as guidance, and cannot under any circumstances be substituted for official recommendations or directives.

 As decontamination is linked to the products, methods and/or tools used is the sole responsibility of the staff concerned.

8. Troubleshooting

8.1. The indicator light on the front panel does not light up on powering up

- Check that the mains socket at the back of the device is properly connected to the power supply and that the general switch at the back panel of the device is in the operating position «I».
- Check that the fuses are in good condition (only use T2A - 250V - UL/CSA fuses).

8.2. The source lights on but the light flux is insufficient

Check the actual value of the light power output via imagyn. If necessary, set it to 100%. If the problem persists, check if the light cable is clipped. If necessary, check the status of your light cable and optic.

8.3. There is no more light but the fans continue to operate

Check that the light cable is properly connected. If so, wait a few minutes: the light source is equipped with a safety device that switches off the power to the LED if the temperature inside the device is too high. Once the temperature has dropped, the source can be used again.

As a reminder, there must be enough space around the device to ensure adequate cooling (15 cm all around) and nothing should obstruct the ventilation grilles on the back and on the left panel of the device.

If the fault persists and it is necessary to return the device to the after-sales service, be sure to ship it to us in its original packaging after disinfecting it.

8.4. The indicator light on the front panel is fixed but no image appears on the screen

- Check that the sensor is properly connected to the control camera unit (if not, a colour bar will be displayed),
- Check that the control camera unit on the camera is correctly connected to the monitor (cable in good condition, plugs correctly pushed in).
- Check that the monitor is in fact switched on, that the HDMI video input is selected and that the image settings are not at the minimum-point position (colour, light and contrast).
- Check for light by inspecting the light source, light cable and endoscope.

8.5. The image is blurred

- Check that there is no condensation on the camera lens or the endoscope,
- Check the lens focus.

9. After-sales service and maintenance

This device does not require any special maintenance operations.

Only ensure that the aerators are not obstructed by dust. If this is the case, unplug the device and vacuum up the dust.



Misuse of the device is not covered by the warranty.

If a fault persists and the device has to be returned to the after-sales service department, ensure that it is shipped in its original packaging.

Similarly, it is advisable to return the device in its entirety (control camera unit, sensor, lens, cables, etc).

Kindly attach to the shipping order a short explanatory note about the fault noted.



The product must be disinfected before it is returned for repair.

When returning the product, check its condition and note any exceptions on the shipping order if necessary, and confirm these with the shipper by registered mail within 48 hours. If any equipment shipped by us suffers damage during transport, the total amount for repairs will be charged either to the shipper if notification of the exceptions has been given within the deadline, or failing such, to the recipient.

In the event of an incident, kindly contact our customer service department or your nearest sales representative.

10. Technical characteristics

Camera side:

- Waterproof CMOS sensor (IP67)
- 22mm C-mount lens
- Resolution : 1920 x 1080 pixels
- Progressive scan technology
- Definition > 900 lines
- Sensitivity : 2 000 lux at F8
- Signal/Noise ratio: 54 dB
- Automatic electronic shutter (1/50 to 1/10 000)
- Pre-programmed camera head button functions
- Color bar tester
- Automatic white balance
- 1 HDMI output
- 2 USB ports for Wifi connection
- 1 USB port for a storage key

Light source side:

- LED technology
- Nominal power 64 W
- Color temperature: 6 000 °K
- Typical LED lifetime : 50 000 hours
- Compatible light cable types: Storz
- Automatic thermal protection system

General features:

- Electric power supply: (100-230 V~; 50/60 Hz)
- Electricity consumption: 130 VA
- Two T2A - 250V UL/CSA 5 x 20 mm fuses
- Equipotential grounding socket conductor.
- Control camera unit dimensions (w x h x d) : 310 x 75 x 310 mm
- Control camera unit weight : 4 200 g

Environement :

- Operating temperature: +10°C / +40°C
- Operating humidity: 30% to 75%
- Transport and storage temperature: -10°C / +40°C
- Transport and storage humidity: 20 to 85%
- Operating, storage and transport atmospheric pressure: 800hPa to 1 060hPa
- Control camera unit is not drip-proof (IPX0)
- Not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide

Regulatory:

- Class 1 electrical safety, BF-type
- Compliant with European directive 93/42/CEE.
- Compliant with international standards IEC 60601-1; IEC 601-2-18; IEC 60417 and EN 980.
- IEC 62471: group 1 risk

11. Electromagnetic compatibility

11.1. Manufacturer's guide and declaration: electromagnetic emissions

This referenced product «CMOS camera + LED source» is intended for use in the electromagnetic environment specified below. The user must ensure that it is used in this environment.

Emission test	Compliance	Electromagnetic environment: guide
RF emissions CISPR 11	Group 1	This product «CMOS camera + LED source» only uses radio energy for its internal functions. Consequently, its RF emissions are very weak and are not likely to interfere with nearby electronic equipment.
RF emissions CISPR 11	Class A	This product «CMOS camera + LED source» must be used on premises other than domestic premises and premises directly connected to a low-voltage public energy distribution network providing power to buildings for domestic purposes.
Harmonic Emissions EN 61000-3-2	Compliant	
Voltage fluctuations / Flicker EN 61000-3-3	Compliant	

11.2. Manufacturer's guide and declaration: electromagnetic immunity

This referenced product «CMOS camera + LED source» is intended for use in the electromagnetic environment specified below. The user must ensure that it is used in this environment.


Immunity test	IEC 60601 Level of gravity	Compliance level	Electromagnetic environment: guide
Electrostatic discharges EN 61000-4-2	± 6 kV in Contact ± 8 kV in air	± 6 kV ± 8 kV	The floor must be wooden, concrete or tiled. If the floor is covered with a synthetic material, the relative humidity must be at least 30%.
Rapid transient peaks EN 61000-4-4	± 2 kV for power lines ± 1 kV for input/output lines	± 2 kV ± 1 kV	The quality of the main power supply must be that of a commercial or typical hospital environment.
Electric shocks EN 61000-4-5	Differential mode ± 1 kV Shared mode ± 2 kV	± 1 kV ± 2 kV	The quality of the electric power supply must be that of a commercial or typical hospital environment.

Power dips, power failures, short power interruptions and variations in power voltage EN 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	The quality of the main power supply must be that of a commercial or typical hospital environment. If the user of this camera requires it to continue functioning during interruptions of the main power supply, it is advisable for this camera to be powered by an inverter or a battery.
System frequency magnetic field (50/60 Hz)	3 A/m	3 A/m	The system frequency magnetic field must be at a level (50/60 Hz) that is characteristic of location in a commercial or typical hospital environment.

Remarque : UT is the nominal value of the power voltage applied during the test.

Manufacturer's Guide and Declaration: Electromagnetic Emissions

This referenced product «CMOS camera + LED source» is intended for use in the electromagnetic environment specified below. The user must ensure that it is used in this environment.

Safety test	IEC 60601 Level of gravity	Compliance level	Electromagnetic environment: guide
RF conducted EN 61000-4-6	3 Vrms 150 kHz at 80 MHz	3V	<p>Portable and mobile RF communication devices must not be used nearer to the product, including the cables, than the recommended separation distance, calculated using the applicable formulas based on the transmitter frequency.</p> <p> $d = 1,16 \sqrt{P}$ $d = 1,16 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,33 \sqrt{P}$ 800 MHz to 2,5 GHz </p> <p>Where P is the maximum output power from the transmitter in Watts (W), assigned by the manufacturer of the transmitter and d is the recommended separation distance in metres (m).</p> <p>The field strengths emitted by fixed RF transmitters, determined from electromagnetic measurements of site a, must be lower in terms of compliance in each frequency band.</p> <p>Interference may be caused by nearby devices displaying the following symbol: </p>
RF emitted EN 61000-4-3	3 V/m 80 MHz at 2.5 GHz	3V/m	

Note 1 : at 80 MHz and 800 MHz, the higher frequency band applies.

Note 2 : These recommendation may not be applicable in all situations. The propagation of electromagnetic waves is modified by absorption and reflection due to structures, objects and people. For transmitters for which the maximum output strength is not shown in the table above, the recommended separation distance d , in metres (m) can be determined by using the equation applicable to the frequency of the transmitter, where P is the maximum output strength of the transmitter in Watts (W) assigned by the manufacturer of the transmitter.

11.3. Recommended separation distances between portable and mobile RF communication systems and this product


This referenced product «CMOS camera + LED source» is intended for use in an electromagnetic environment in which the RF interference produced is controlled. The user of this product can help avoid electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communication systems (transmitters) and this product, as recommended below, based on the maximum output strength of the communication equipment.

Assigned maximum output strength of the transmitter in W	Separation distance depending on the frequency of the transmitter 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

Remarque 1 : at 80 MHz and 800 MHz, the separation distance given in the higher frequency band applies.


Remarque 2 : These recommendation may not be applicable in all situations. The propagation of electromagnetic waves is modified by absorption and reflection due to structures, objects and people. For transmitters for which the maximum output strength is not shown in the table above, the recommended separation distance d , in metres (m) can be determined by using the equation applicable to the frequency of the transmitter, where P is the maximum output strength of the transmitter in Watts (W) assigned by the manufacturer of the transmitter.


12. Symbols

 Date of manufacture.

 Manufacturer.


 Compliant with European directive 93/42/CEE.

 BF-type device.


 Electronic and electrical equipment marketed after 13/08/2005. This symbol indicates that this product is not to be treated with household waste.

 Equipotential grounding socket conductor.

 **T** UL/CSA time-delay fuses.

 Read the user manual.

 **HDMI** HDMI video output.

 USB output.



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