EN - Instructions for use

iCare

REF This manual relates to the following articles:

List of devices
D100 100 000 ; D100 100 001; D100 100 002; D100 110 000; D100 120 000 to D100 120 003

Carefully read these instructions before using Delmont Imaging devices Keep them in a safe place for future reference.

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

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1. Device description

1.1. Intended Use

This manual is intended exclusively for trained and qualified personnel (doctors, medical assistants supervised by a doctor). iCare should only be used by trained and qualified personnel to perform clinical applications in hospitals and medical rooms with appropriate endoscopic equipment. The products should not be used if, in the opinion of a qualified physician, the general condition of the patient is not adequate or if endoscopic methods are contraindicated.

iCare is a combined HD CMOS endoscopic camera and LED light source in a single control unit, designed for use by qualified physician when performing surgical endoscopy or diagnostic procedures.

For the benefit and safety of patients, doctors must choose a method that they deem appropriate based on their experience. If, as a user of this device, you feel you need more detailed information regarding the use and care of the product, please contact your representative.

⚠ ***This document describes the correct handling and function of iCare imaging station. This document may not be used to carry out endoscopic examinations or surgeries, nor may be used for training purposes. This device must be used by qualified and trained personal.***

1.2. Specific details

The iCare device includes the following elements:

- A control unit that contains a 64 Watts LED light source,
- An HD CMOS sensor with its 22mm C-mount focal length lens, 3 pre-programmed buttons, 2.99mm cable, connector and sealing cap,
- A power cable,
- An HDMI cable,
- A USB key,
- Two Wi-Fi keys that allow our imagyn application to work properly (for more information on the imagyn software, please refer to the corresponding instructions for use).

On the camera side, it is a 1/4'' color CMOS mono HD camera with remote electronics. On the light source side, this LED source is specially designed for use in various endoscopic diagnostic or surgical applications.

[1]: The fans on the rear of the unit must not be blocked to prevent overheating. The light source is equipped with an automatic safety feature that stops the lighting if the internal temperature becomes excessive. Fans on the left side and under the unit are also present for better ventilation.

[2]: Power is supplied through the rear panel power outlet, which must be connected to the power supply via the cord provided with the product. This socket has a fuse cover and the main switch for powering on. When replacing a fuse, it is imperative to disconnect the product from the network and use a fuse of the same type. The T of «T2A» means «time-delay». Use only fuses marked UL/CSA.

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

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

[5]: The unit has two USB outputs for two Wi-Fi keys.

[6]: The unit has an equipotential plug, which can be connected to other electromedical devices in order to reduce formation of different electrical potentials.

[7] : The indications and symbols on the rear of the unit enable it to be identified in accordance with international standards IEC 60601-1, IEC 60601-2-18, IEC 60417 and EN 980 (see the corresponding section 12).

[8]: The unit has a connector for plugging in the light cable.

[9]: The unit has a light indicator that alerts the user to the different phases of use of the product.

[10]: The unit has a connection for plugging in the iCare camera head.

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

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

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

[14]: This button allows:
- By short press, to launch an image capture.
- By long press, to start or stop a video recording.

1.3. Combination

Using incompatible equipment may lead to injury of the patient and/or the user as well as damage to the product. Delmont imaging recommends to only use Delmont Imaging devices and accessories.

To prevent errors or delays in diagnosis, we recommend the use of the iCare with the monitor provided by Delmont Imaging only. Otherwise make sure that the monitor used have a minimum resolution of a 19020x1028, 22'', 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.

Use accessories supplied with the unit or offered as an option by the manufacturer. The iCare system should be used with endoscopes and light cable provided by Delmont Imaging. If any doubt subsists on compatible equipment, the user should contact Delmont Imaging or its authorized representative.

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. Warning and precautions

There is a risk of electric chock if the power cord is damaged. Turn off the power immediately if the cord is damaged.

This device may not be modified without the manufacturer's permission. A modification could cause electric chock or mechanicals injuries. If the medical device is modified, a check and test must be carried out to ensure that the medical device complies with the safety instructions.

To avoid the risk of electric shock, always connect this device to a power supply equipped with a protective ground.

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

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

The devices connected to the inputs/outputs must comply with IEC 60950-1. Applied parts of electro-medical devices that can be used in conjunction with iCare shall be of BF-type or CF according to standard 60601-2-18. Check this compatibility before each operation for safe use.

The device meets the requirements of European Directive 93/42/EEC on medical devices. It therefore complies with the relevant electrical safety (IEC) and electromagnetic compatibility (EMC) standards. Although this product complies with EMC standards, it is possible that under very special circumstances it may cause interference 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.).

2.2. Instructions specific to the light source

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 product is equipped with Group 1 LEDs according to IEC 62471.

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

After using the source, when removing the fiber from its light guide, the temperature on the metal coupler of the fiber is very high and can cause burns.

Do not insert anything other than a light cable into the hole provided for this purpose, otherwise the optical system may be damaged.

2.3. Contraindication

The use of iCare is contraindicated when endoscopic practice is contraindicated for the patient.

The responsible physician must decide, on the basis of the patient's general condition, whether the intended application can be carried out. Country-specific regulations and laws must be observed. Further information can be found in the current literature.

2.4. Vigilance

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

3. Use of the device

3.1. Installing

Do not place heavy objects on the unit. Ensure sufficient air circulation to avoid overheating inside the unit: at least 15cm all around the unit. Do not expose the unit to water splashes or in a place that is too humid.

No special training is required to install this medical device. Please refer to the instructions in this section of the user manual. Once all iCare components have been unpacked from their original packaging, please perform the following actions:

- Place the control unit on a level and stable surface. If you place it in a compartment, make sure that it is sufficiently ventilated (at least 15cm around the unit).
- Connect the power cord to the power outlet [2] on the rear of the unit.
- Connect the other end of the power cord to an electrical outlet.
- Connect the HDMI cable to the corresponding output [3] on the rear of the unit.
- Connect the second end of the HDMI cable to the corresponding input on the monitor.
- Place the two Wi-Fi keys on the two USB outputs [5] on the rear panel.
- Place the USB key on the USB output [4] on the rear panel.
- Set the power supply button on the rear panel of the unit to position « I ». The unit enters in a booting sequence: the indicator light [9] on the front panel flashes rapidly. This booting sequence ends shortly. Then, the unit goes into standby mode: the front panel indicator light flashes slowly.
- Power on the monitor. A color bar should appear on the screen.
- Plug the camera head connector to the front of the control unit [10]. 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.
- Insert the light cable into the hole provided for this purpose [8]. A « click » lock must be heard. Connect the other end of the light cable to your endoscope.
- Connect an endoscope to the camera head.
- Press the stand-by button [11] on the right side of the control unit to start the light source: the indicator light on the front panel becomes fixed. Another press will turn off the light source.

It is then possible to check the correct operation of the camera and specially to ensure that the settings of the monitor give full satisfaction thanks to the color bar which appears when disconnecting the sensor.

3.2. Functioning

3.2.1. Powering on

The device is equipped with a switch placed on the rear of the device [2]. It is activated by changing this switch to position « I ». The light source is set to the last power used or to the value saved by the practitioner in imagyn[1].

3.2.2. Connecting the endoscope to the camera head

In order to prevent any contamination of operating field or a patient contamination, it is recommended to place the iCare 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 in order for proper use.

Bring the dewclaws on the ring of the lens closer together until the endoscope can be inserted. Once the endoscope is inserted, release the two dewclaws. The endoscope can be unlocked by simply bringing the dewclaws closer together.

3.2.3. White balance

White balance is triggered by pressing and holding the [12] button on the camera head. The following procedure should be followed:

- Once the camera is paired with the endoscope and the light source is activated, film a white surface.
- Start the white balance by pressing and holding the corresponding button.
- Once «Processing AWB...» appears on the screen, you can release the button but continue to film the white surface as long as the message is on.

3.2.4. Focus

Use the lens ring associated to the camera head to focus. Once the endoscope is connected and the light source activated, slowly turn the ring to find a position where the objects observed are sharp. Focusing far enough away allows a sufficient depth of field to be obtained for the operation, thus avoiding regular focusing.

3.2.5. Setting Light intensity

The [13] button on the camera head switches from a A value to a B value of the light source. These basic values are set at 75% and 100% light output but can be adjusted via imagyn[2].

[1] See D300 700 052 for more information about imagyn
[2] See D900 700 052 for more information about internet connection and imagyn

3.2.6. Capturing images and videos

Use the [14] button as following :

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

3.2.7. Access settings menu

Press [11] and [13] at the same time for a short time. The settings menu will appear. You can use it to:

- change the language of the device,
- see the information on the device,
- switch from Wi-Fi to Ethernet connection,
- Mask the SSID,
- Filter MAC address,
- reset to factory settings.

3.2.8. Turning off the product

To turn off the device, put the switch on the rear panel of the control unit [2] to the « O » position.

3.3. Visual inspection and functional test

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

- Make sure the control unit is on a level and stable surface and is sufficiently ventilated (at least 15cm around the unit).
- When the CCU is powered on, the frontal panel should blink slowly, and a color bar image should appear on the screen.
- When you connect the camera head, the image should appear.
- When you connect a light cable and press the light source stand by button the ventilator should start, and light appears.

3.4. Trouble shooting

The light indicator of the front panel 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.
- Check fuses for proper condition (use T2A - 250V - UL/CSA fuses only) and contact Delmont Imaging or its official representative.

The LED source lights up but the luminous flux is insufficient.

- Check if the light source power is set to Pmax (100% of the power) thanks to the button of the camera head. If the problem remains even with Pmax value, check if the light cable is properly plugged. Check eventually the condition of your light cable and optics.

There is no light, but the fans continue to work.

- Disconnect the sensor and check that the output test pattern appears on the screen.
- Check that the light cable is properly connected. If this is the case, wait a few minutes: the light source is equipped with a safety device that cuts off the power supply 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 unit to ensure enough cooling (15cm all around) and nothing must obstruct the fan grids below, on the back and on the left side of the device. If the defect persists and it is necessary to return the device to the after-sales service, take care to send it to us in its original packaging after having disinfected it.

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

- Check that the camera head is connected to the control unit (otherwise a color bar will be displayed).
- Check that the control unit is correctly connected to the monitor (cable in good condition and plugs properly inserted).
- 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, light and contrast).
- Check for the presence of light by inspecting the light source, light cable and endoscope.

The image is blurred.

- Check that there is no fog on the camera lens or endoscope.
- Check the focus of the lens.

The indicator light on the front panel does not stop flashing for more than 3 minutes.

- Switch off the device, disconnect it and switch it on again
- If no changes are observed, contact the after-sales service.

4. Reprocessing the camera head


W.XVI

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

Existing alkaline solutions for pre-disinfection of certain medical devices are FORBIDDEN for pre-disinfection of our cameras.

Use non-woven compresses to dry the optical parts so as not to scratch them.

The procedures described in this chapter are provided as advice, not in any way to replace official recommendations or guidelines.

Use only appropriate cleaning and disinfectant agents, certified for use on stainless steel and plastic, in accordance with the manufacturer's instructions.

Any other method of disinfection is prohibited. Damage caused by these other methods cannot be borne by the manufacturer.

This product is not autoclavable. It is not compatible with automatic washers/disinfectors.

The iCare control unit and iCare camera head are not intended to come into contact with the patient. Sterile drapes should be used as instructed in 3.2.2.

Both are indirectly in contact with the patient and thus are considered noncritical and should be cleaned and disinfected only.

4.1. Preparation

- Disconnect the camera head from the control unit,
- Turn off and disconnect the control unit from the power grid,
- Place on the soaking cap on the camera head cable,
- Dismount the coupler from the camera head.

4.2. Cleaning and disinfection of the camera head and coupler

Step	Instructions
Cleaning	➢ Completely immerse the camera head assembly and camera head cable in the detergent solution ✓ Use enzymatic cleaning solution (Aniosyme DD1, Hexanios G+R) ➢ Remove any residual debris and contaminants from the camera head assembly with a soft brush. ✓ Cleaning brushes should be cleaned and high level disinfected or sterilized daily. ➢ Triple-rinse the camera head assembly with distilled water, for a minimum of one minute for each rinse. The rinse water should be discarded at the end of each rinse, 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 or sterilization . ➢ Dry the equipment with a lint-free soft cloth. ➢ Do not allow exposed glass windows to air dry. 70% isopropyl alcohol may be applied to glass surfaces with a soft cotton applicator to prevent streaks and spots. Dry the surfaces thoroughly with a cotton applicator after applying the alcohol. ➢ After cleaning, inspect the camera head assembly and camera head cable for cleanliness and damage.
Disinfection	➢ Equilibrate a disinfecting bath to 20 ± 2°C. Fully immerse the device and ensure all air bubbles are removed from the surface of the device. ✓ Use solution : Cidex® OPA or Revital-Ox™ Resert® ➢ Allow the device to soak for 12 minutes. ➢ Thoroughly rinse the device by fully immersing it in purified water (PURW), agitating, and allowing the device to soak for a minimum of 1 minute. ➢ Repeat the previous step two more times for a total of 3 rinses using a fresh batch of purified water (PURW) each time. ➢ Dry the device. Disinfected equipment should be used immediately or stored in a manner to minimize recontamination.

4.3. Cleaning and disinfection of the Camera Control Unit

Step	Instructions
Cleaning and disinfection	➢ 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's cleaning instructions ➢ Dry the equipment with a lint-free soft cloth. ➢ After cleaning, inspect the control unit for cleanliness and damage.

4.4. Storage condition


W.XVII

Disinfected devices must be stored in a dry, clean and dust-free environment. The applicable national guidelines must be followed.

Non disinfected devices must be stored in a clean, dry environment under the recommended conditions:

- ✓ Transport and storage temperature: -10°C/+40°C
- ✓ Transport and storage humidity: 20 to 85%
- ✓ Working, transport and storage atmospheric pressure: 800 hPa to 1 060 hPa

5. After-Sales service and maintenance

5.1. Maintenance

No specific maintenance is required for the use of this device. Make sure to follow instruction from “Visual inspection and functional test“ prior to each use.

5.2. Repair

There is a risk of injury to the patient and/or the user caused by unauthorized repairs and production modification. Possible injuries include mechanical injuries, electric shock, burns and intoxication.

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 product completely, clean the product as thoroughly as possible and mark it accordingly.

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

Do not attempt to repair or modify the product. Repairs may only be performed by qualified servicing personnel that have been authorized by Delmont Imaging. Contact a Delmont Imaging representative or an authorized service center for repair information.

Delmont Imaging does not supply original parts to independent workshops or other similar products manufacturers. Thus, only Delmont Imaging is in a 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. The warranty for Delmont Imaging products shall become void if repairs are carried out by a workshop not authorized by Delmont Imaging. In this case Delmont Imaging is also no longer responsible for the technical specifications or safety of the product. 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 after-sales service

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

5.3. Warranty

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

Repairs, attempted repairs, alterations or other tampering of this product carried out by unauthorized personnel renders the guarantee invalid. Delmont Imaging exclusively provides its customers with tested and impeccable products. All products are designed and manufactured to meet the highest quality requirements. We accept no responsibility for products that have been modified from the original product, misused or handled or misused.

5.4. Disposal

Keep the used device out of reach of unauthorized person.

We encourage our customers to recycle this product whenever possible. Disposal of this device should be carried out in accordance with the applicable local environmental regulations.

6. Technical data

General Specification	
Power supply	100-230 V ~; 50/60 Hz Equipotential plug
Power consumption	130 VA
Fuses	Two T2A - 250V UL/CSA 5 x 20 mm
Dimensions of the control unit	310 x 75 x 310 mm
Weight of the control unit	4,2kg
Working temperature	+10°C/+40°C
Working humidity	30 to 75%
Transport and storage temperature	-10°C/+40°C
Transport and storage humidity	20 to 85%
Working, transport and storage atmospheric pressure	800 hPa to 1 060 hPa
Waterproofing of the control unit	Not protected against water splashes (IPXO)
Connectors	1 HDMI output 2 USB outputs for WiFi connection 1 USB output for a storage key
Compliance	Complies with European directive 93/42/EEC and international norms: IEC 60601-1, IEC 60601-2-18, IEC 60601-1-2, IEC 60417
Electrical Safety	Electrical safety class 1, type BF. IEC 62471: group 1 risk

Camera Head	
Sensor	HD CMOS
Resolution	1920 x 1080
Definition	> 900 lines
Sensibility	2 000 lux at F8
Signal-to-noise ratio	54 dB
Lens	22 mm C-mount lens
Waterproofing	IP67
Other specification	Interlaced scanning Automatic electronic shutter (1/50 to 1/10 000) White balance Color bar Preprogrammed buttons

Light source	
Technology	LED
Nominal power	64 W
Color temperature	6 000°K
LED typical lifetime	50 000 hours
Compatible light cable type	Storz
Other specification	Automatic thermal protection system Automatic detection of presence/absence of the light cable Not suitable for use in the presence of flammable anesthetic mixture with air with oxygen or nitrous oxide

Guidance and manufacturer's declaration: electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment: Guidance
RF emissions CISPR 11	Group 1	This « CMOS camera + LED source » product only uses radio power for its subsystems. It therefore emits very low RF energy and is not likely to interfere with nearby electronic devices.
RF emissions CISPR 11	Class A	This « CMOS camera + LED source » product must be used in all installations, other than residential installations and premises directly connected to the public low voltage power distribution network intended to supply residential buildings.
Harmonic emissions IEC 61000-3-2	Compliant	
Voltage fluctuations/Flicker IEC 61000-3-3	Compliant	

Guidance and manufacturer's declaration: electromagnetic immunity

The « CMOS camera + LED source » reference equipment has been designed for use in the electromagnetic environment specified below. The user must ensure that it is actually used in this environment.

Immunity test	IEC 60601 Severity Level	Compliance Level	Electromagnetic environment: Guidance
Electrostatic discharges IEC 61000-4-2	± 6 kV via contact ± 8 kV via air	± 6 kV ± 8 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 ± 1 kV input/output lines	± 2 kV ± 1 kV	The quality of the main power supply must be the one of a typical commercial or hospital environment.
Electric shocks IEC 61000-4-5	Differential mode ± 1 kV Common mode ± 2 kV	± 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 ms	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 the one of a typical commercial or hospital environment. If the user of this product must be able to continue working during power outages, it is recommended that this product be powered by UPS or battery.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 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.

Note: UT is the nominal value of the electrical voltage applied during the test.

Guidance and manufacturer's declaration: electromagnetic emissions

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

Safety test	IEC 60601 Severity Level	Compliance Level	Electromagnetic environment: Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V 3 V/m	Portable and mobile RF communication devices should not be used at a distance, including cables, from this product 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 2,5 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 metres (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:

Note 1: At 80 MHz and 800 MHz, the highest frequency band should be used.

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.

Recommended distances between portable and mobile RF communication systems for this product

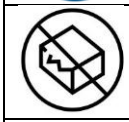
The « CMOS camera + LED source » reference equipment has been designed for use in the electromagnetic environment in which the emitted RF interference is controlled. The user of this equipment can help avoid electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication systems (transmitters) and this equipment, as recommended below, as a function of the maximum output power of the communication system.

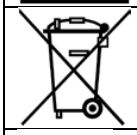
Maximum assigned transmitter output power in W	Separation distance as a function of transmitter frequency (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1{,}16 \sqrt{P}$	$d = 1{,}16 \sqrt{P}$	$d = 2{,}33 \sqrt{P}$
0.01	0.116	0.116	0.233
0.1	0.366	0.366	0.736
1	1.16	1.16	2.33
10	3.66	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 “Manufacturer”
	Symbol for “Date of manufacture”
	Symbol for “CE marking”
	Symbol for “Catalogue number”
	Symbol for “Lot number”
	Symbol for “Consult the Instruction for Use”
	Symbol for “Operating Instructions”
	Symbol for “Do not use if package is damaged”
	Symbol for “Non-Sterile”
	Symbol for “Temperature limit”
	Symbol for “Atmospheric pressure limit”
	Symbol for “Humidity limit”
	Symbol for “Keep away from sunlight”

Symbol	Description
	Symbol for “Keep dry”
	Symbol for “Fragile, handle with care”
	Symbol for “Type BF applied part”
	Symbol for “Recycle Electronic Equipment: do not trash”
	Symbol for “Equipotential plug”
	Symbol for “UL/CSA timed fuses”
	Symbol for “HDMI video output”
	Symbol for “USB output”

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