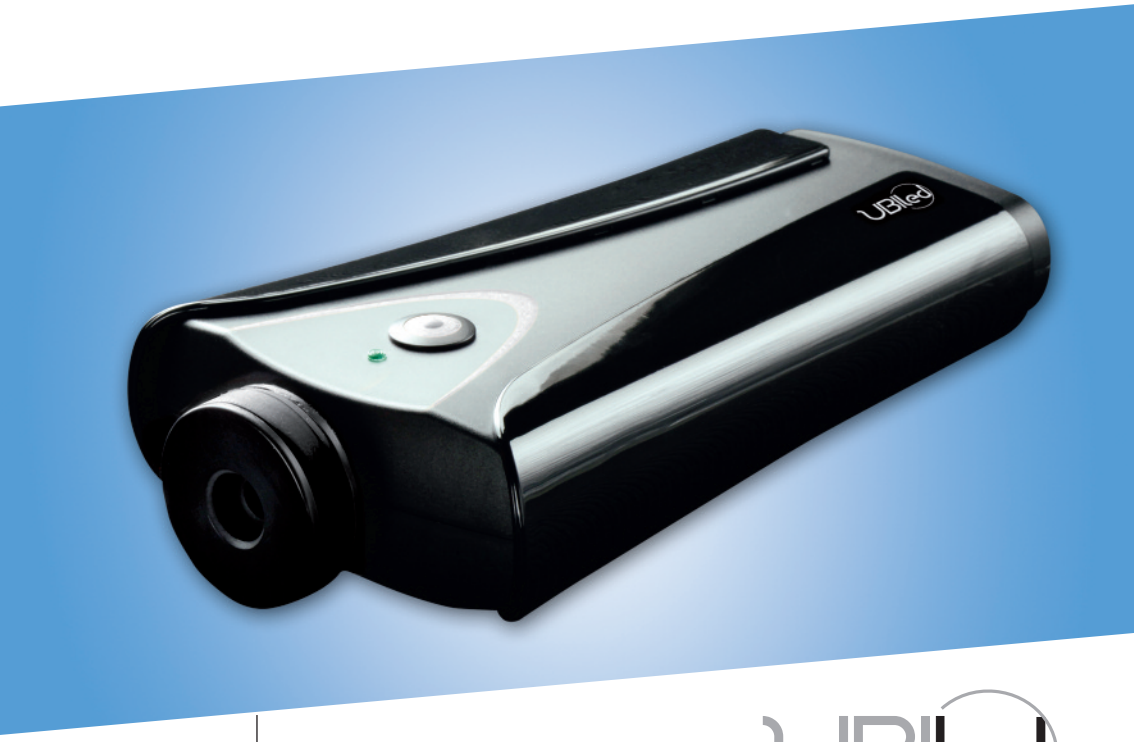

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USER MANUAL

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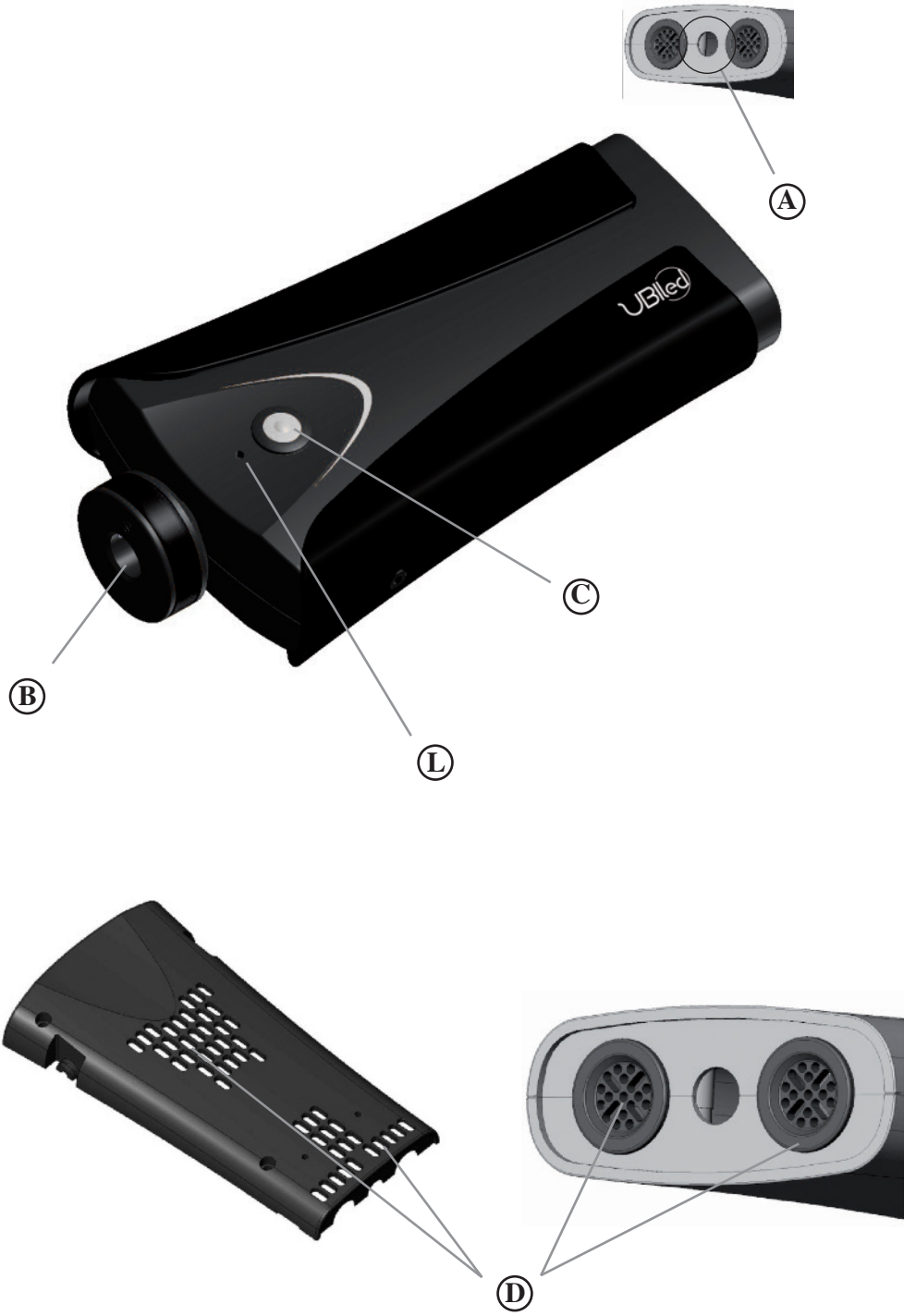
A
B
C
L
D

USER MANUAL

ENGLISH

CONTENT

1 INTRODUCTION

We would like to thank you for the confidence you showed in us by purchasing this device.
Please read this manual carefully in order to fully benefit from the device while complying with all necessary precautions.

Sentences marked with this symbol ⚠ require particular attention.
Sentences marked with this symbol i contain useful information.

In order to facilitate the installation and utilisation of this device we intended to make this manual more practical. Therefore, throughout the manual you will find references to the image page on the back of the cover (e.g. in form of [D1]) which will help you to identify the corresponding parts of the product.

2 DESCRIPTION OF LIGHT SOURCE

This 30 Watt LED light source has been especially designed for endoscopic diagnosis applications in medical practices of the following special fields: ent, gynecology, urology, veterinary. It is equipped with an electronic iris with fibre optic sensor, an automatic thermal protection system and a power level memory.
Its ease of use, its illuminating power and a precise manual light intensity regulation make it an ideal medical device for multiple disciplines.

It comprises:
- the light source itself
- the power adapter (12V transformer) including a set of international plugs.
- the user manual

⚠ In order to ensure conformity of the product please only use the supplied transformer.

This equipment was supplied to you in a cardboard packaging, which you should keep for potential transport.

Recommended accessories:
- Light cable: ø: 4.5mm; L: 2.5m (power supply connector: “Storz” only)
- Endoscopes with diameter: 1.9; 2.7; 3; 4; 8.5mm

3

SAFETY INSTRUCTIONS

- ✓ Read the user manual carefully.
- ✓ Observe the conditions of use and storage.
- ✓ Before connecting the light source to the mains supply, check if the parameters of your power circuit match the specifications on the device. Information regarding the electric voltage, the consumption etc. can be found on the power supply unit.
- ✓ Never look directly in the light source or the end of the light cable.
- ✓ Do not submit the device to excessive dust exposure.
- ✓ The device should only be opened by a qualified technician authorized by the manufacturer.
- ✓ Do not insert any other objects than the light cable in the socket [B] as otherwise damage to the optical system may result.
- ✓ Do not insert metallic objects in the device as this may result in risk of electric shock, fire, short circuit or hazardous emission.
- ✓ Do not expose the device to splash water or use in an environment with excessive humidity.
- ✓ Do only use the accessories supplied with the device or recommended by the manufacturer as an option.
- ✓ The device is not explosion-proof. Therefore, never use it together with flammable anaesthetics.
- ✓ Do not place heavy objects on the device.
- ✓ If the power cord or the transformer are damaged, immediately isolate the light source from the electric circuit. It is extremely dangerous to operate the device with a defective power cord.
- ✓ To disconnect the cable from the power supply always pull the plug, never the cable itself.
- ✓ Disconnect the device from the power supply, if you intend not to use it for several days or a longer period.
- ✓ Do not place the light source on textile surfaces (carpet, blankets, etc.)
- ✓ This light source is exclusively intended for use with the endoscopes recommended in chapter 2.
- ✓ If other cables or accessories are used than the ones specified this may result in an increase emissions or a decrease of the noise immunity of the device.
- ✓ The fans must not be covered [D].

- ✓ Ensure sufficient ventilation in order to avoid overheating inside the device: at least 15cm at all sides of the device. Do not cover the device and ensure that the legs of the device are always visible.
- ✓ Never place the device near a heat source or in a location where it is exposed to vibration and/or shock.
- ✓ Never use corrosive or abrasive products to clean the device, but only the disinfectant agents as recommended in chapter “Cleaning”.
- ✓ This device is not suitable for use in an ionizing environment.
- ✓ Do not expose the device to laser radiation.
- ✓ The device is not sterile.
- ✓ Before every use, check the device for rough surfaces, sharp edges or protruding elements which could present a safety risk.
- ✓ When removing the fibre from its light guide after use of the lamp the temperature of the metal coupler is very high and injuries may occur when touching.
- ✓ The luminous power at the outlet of the cable can cause damage to the eye. Be careful when handling the light cable when the lamp is operating at full power.
- ✓ Never touch the patient or other flammable material (bed sheets, dressings, surgical drapes) directly with the end of the light cable or the endoscope as it can become very hot: risk of burning.

⚠ Class Laser : risk group 2

Caution : Possibly hazardous optical radiation emitted from this product. Do not stare at operating lemp. may be harmful to the eyes.

4 REGULATIONS

4.1 CONFORMITY

This product was designed and manufactured by a company which has a certified quality system in place. It complies with the requirements of EU directive 93/42/EEC on medical products. It therefore also complies with the electrical safety standards (IEC) and the applicable standards for electromagnetic compatibility (EMC).

4.2 ELECTROMAGNETIC INTERFERENCE AND ELECTROSTATIC DISCHARGE

Despite compliance with the EMC standards, it may occur under certain circumstances that the device interferes with other devices or is subjected to interferences by other devices and/or in an electromagnetic environment.
In order to avoid such incidents we recommend the following:

- Ensure the quality of the electric supply (especially grounding of all devices and tables/trolleys)
- Keep the device away from electromagnetic sources (such as compressors, motors, transformers, HF generators, etc...).

4.3 MEDICAL DEVICES VIGILANCE

Like all medical products this device is subject to the Medical Devices Vigilance regulations. Therefore any serious malfunction must be immediately notified to the relevant authorities and the manufacturer as detailed as possible.
For manufacturer contact details see last page of manual

4.4 DISPOSAL

This device is marked with the recycling symbol pursuant to EU directive 2002/96/EC on waste electrical and electronic equipment (WEEE).
By correctly disposing of this device you avoid potential damage to the environment or human health.
The symbol  on the device or on the documents supplied means that the device must not be treated as household waste. It must be deposited at a designated collection facility which is dedicated to the recycling of waste electrical and electronic equipment.
In addition, all local regulations regarding disposal applicable in the country in which you work must be observed.
For more information on treatment, recovery and recycling of the device please contact your nearest distributor who will instruct you on the procedure to be followed.

5 INSTALLATION

Place the device on a stable surface and connect the different accessories which are required for operation. If using a cabinet ensure sufficient ventilation at all sides (min. 15 cm around the device).

5.1 POWER SUPPLY CONNECTION

- Select the suitable connector at the power adapter.

⚠ Only use the wall-mounted transformer supplied: FRIWO type FW 7362M/12.

- Connect the power cable to the light source [A].
- Connect the power adapter to the mains supply.

5.2 CONNECTION OF LIGHT CABLE

⚠ Do not attempt to unscrew or pull the round connector at the front of the device.

- As a standard, the light source is equipped with a fixed adapter for the "Storz" type light cable which cannot be replaced.
- Insert the cable in the intended opening [B], you should hear a clicking noise indicating that the cable in locked.
- Connect the other end of the light cable to your endoscope.

i Before connecting an endoscope (or a fiberscope) check the condition of the endoscope (clean, distal lens, quality of optical fibres, adjust if necessary).

6 USER SETTINGS

6.1 SWITCHING ON

The LED source is equipped with a switch at the top of the device [C]. After switching on the device an automatic test of 3 seconds is performed to check all components. Then the lamp switches in standby mode and the indicator light [L] flashes yellow.

6.2 ADJUSTING THE LIGHT INTENSITY

When switched on the device is started at its maximum power.

> Connect a light cable (to have luminous power).
> Press the button [C], the luminous power is set to the maximum (continuous blue light).
> By pressing button [C] for a longer period the luminous power is decreased (flashing blue) to reach the low intensity level (continuous green light), release.
> From the low intensity level, a long pressure on [C] will increase the luminous power (flashing green) until you reach the maximum power (continuous blue light), release.

> Select then the required luminous power, the LED may flash green or blue which indicates that a long pressure will respectively increase or decrease the luminous power.

6.3 POWER LEVEL MEMORY

To switch the LED in standby mode (light and fans off) simply press button [C] for a short time. If pressed again the light will come back with the same luminous power as before satnad by mode (except in case of power cut).

7 DESCRIPTION

7.1 DESCRIPTION OF FANS

- The fans must not be covered in order to prevent overheating.
- The light source is equipped with an automatic safety device which stops the light intensity in case of excessive internal temperature.

7.2 MAINS TRANSFORMER PLUG

The power supply of the device is realised by means of a mains transformer supplied with the system.

7.3 SPECIFICATIONS AND SYMBOLS ON THE PRODUCT

The specifications and symbols at the bottom of the product allow identification of the camera complying with the international standards IEC 60601-1, IEC 60601-2-18, IEC 60417 and DIN EN 980 (see annex 1).

8

RECOMMENDED DECONTAMINATION PROCEDURE

⚠ This procedure applies exclusively to the enclosure of the LED light source.

⚠ The LED light source is a medical product which is not heat resistant and must not be immersed in liquid. Consequently, disinfection is made using a non-woven fabric cloth to which a disinfecting agent is applied.

⚠ The disinfecting agent can be chosen from the category F in the list of admitted disinfectants by the French Society of Hospital Hygiene.

⚠ The cleaning depends on the selected products, methods and/or tools and is thus the sole responsibility of the involved personnel.

⚠ The disinfection procedures indicated for this type of material indicate that disinfection is made with either one or the other of these two solutions for the entire life cycle of the product.

⚠ The device is not autoclavable.

⚠ Alkaline solutions available for disinfection of certain medical products are NOT allowed for disinfection of this device.

⚠ The procedures described in this chapter are to be understood as guidelines only and can in no event replace official recommendations or directives.

9

CUSTOMER SERVICE & MAINTENANCE

Make sure that the fans [D] are not obstructed by dust. If this is the case, isolate the device from the mains supply and vacuum the dust.
In case of incidents please contact our customer service or our nearest distributor.
We remind you that faults due to incorrect use are not covered by the guarantee.

9.1 THE INDICATOR LIGHT [L] DOES NOT GO ON AFTER THE DEVICE HAS BEEN SWITCHED ON

Check if the mains transformer is connected properly to the mains supply.

9.2 THE LIGHT GOES ON BUT THE LUMINOUS POWER IS POOR

Check if the requirements of chapter 6 “User settings”, are met.
Check the condition of the light cable and your optical system.

9.3 THE DELIVERED IMAGES ARE TOO BRIGHT OR SATURATED

Check if the light intensity is set too high.
Check the camera settings.

9.4 THERE IS NO LIGHT BUT THE FANS CONTINUE TO OPERATE

- The light cable is disconnected.
- The light source has an integrated safety device which automatically switches off the light in case of excessive internal temperature of the device. After the temperature decreased, the lamp can be used again:
  - Ensure that there is sufficient space around the device for adequate cooling (minimum 15cm at all sides of the device).
  - Ensure that the ventilation slots at the rear and the bottom of the source are not covered.

If the fault persists and you need to return the device to customer service please return the device in its original packaging after disinfecting it.

⚠ **The product must be disinfected before returning it for repair.**

When returning a product check its condition and inform the carrier of any comments to be recorded on the delivery note by registered letter within 48 hours. If goods shipped by us are damaged during transport the repair amount will be either charged to the carrier, if the comments were made in a timely manner, or otherwise they will be charged to the receiver.

9.5 THE LIGHT ALTERNATELY SWITCHES ON AND OFF

Check if the light cable has been connected correctly.

9.6 THE INDICATOR LIGHT ILLUMINATES CYAN

The light source is in temperature protection mode, check if the temperature range specified in the present manual is observed.

10

TECHNICAL SPECIFICATIONS

Main functions

- LED technology
- Power rating: 30W – the light intensity corresponds to a 100 watt Xenon lamp
- Colour temperature: > 4500°K
- Typical LED life span: 50,000 hours (under normal conditions of use).
- Compatible light cable: “Storz” only
- Electronic aperture
- Adjustment of light intensity: manual
- Anti blinding system with light cable sensor
- Automatic overheat protection system
- Power level memory
- Supply voltage of the transformer: 100-240VAC / 50 - 60Hz
- Transformer: 12VDC
- Power consumption: 30VA
- Dimensions: L: 180mm; D: 95mm; H: 35mm
- Weight: 320g
- Continuous service

Environment

- Operating temperature +10°C / +40°C
- Operating humidity: 30% to 75 %
- Transport and storage temperature: -10°C / +45°C
- Humidity during transport and storage: 20 to 85%
- Atmospheric pressure during operation, transport and storage: 700hPa to 1,060hPa
- Not splash-proof (IPXO)
- Not suitable for use with mixtures of flammable anaesthetics with air and oxygen or nitrous oxide

Regulatiory

- Electrical safety class 2, type BF ⊡
- Compliant with EU directive 93/42/EEC – class 1
- Compliant with international standards IEC 60601-1; IEC 601-2-18; IEC 60417 and DIN EN 980
- Class Laser: risk group 2

11

ELECTROMAGNETIC COMPATIBILITY

11.1 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The device is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This device is suitable for use in all establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker IEC 61000-3-3	Compliant	

11.2 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

This device is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV dans contact ± 8 kV dans air	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	± 2 kV pour les lignes d'alimentations ± 1 kV pour les lignes d'entrée/sortie	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	Mode différentiel ± 1 kV	± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an inverter or a battery.
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF EN 61000-4-6 Radiated RF EN 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}16\sqrt{P}$ $d = 1{,}16\sqrt{P}$ 80MHz to 800MHz $d = 2{,}33\sqrt{P}$ 800MHz to 2.5GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE : *UT is the nominal value of the supply voltage applied during the testing.*
NOTE 1 : *At 80MHz and 800MHz, the higher frequency range applies.*
NOTE 2 : *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

a 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.

b Above the frequency range 150kHz to 80MHz, field strengths should be less than 10 V/m.

11.3 RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE DEVICE

This device is intended for use in an environment in which radiated RF disturbances are controlled. 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 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter in W	Separation distance according to frequency of 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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 : *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

NOTE 2 : *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

ANNEXE 1

SYMBOLS-SYMBOLES-PICTOGRAMAS-SIMBOLI-BILDZEICHEN:

Manufacturing date/ Date de fabrication / Fecha de fabricacion / Data di produzione / Herstellung datum

Manufacturer / Fabricant / Fabrica / Produzione / Hersteller

Comply with the European Directive 93/42/CEE / Conforme à la directive européenne 93/42/42/CEE / Conforme a la directiva europea 93/42/CEE / Conforme alla direttiva europea 93/42/CEE / Entspricht des Europäischen Weisung 93/42/CEE

Read the User Manual / Lire le manuel d'utilisation / Observe la documentacion adjunta / Leggere la documentazione allegata / Begleitpapiere beachten

Dispositif de type BF / Type BF device / Apparecchio mod.BF / Aparato del tipo BF / Gerät des Typs BF

UK : Disposal of electric and electronic equipment marketed after 13/August/2005. This symbol indicates that the product cannot be treated with domestic waste.

Appareil de classe II / Class II device / Apparecchio di classe II / Aparato del classe II Gerät des Klasse II

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