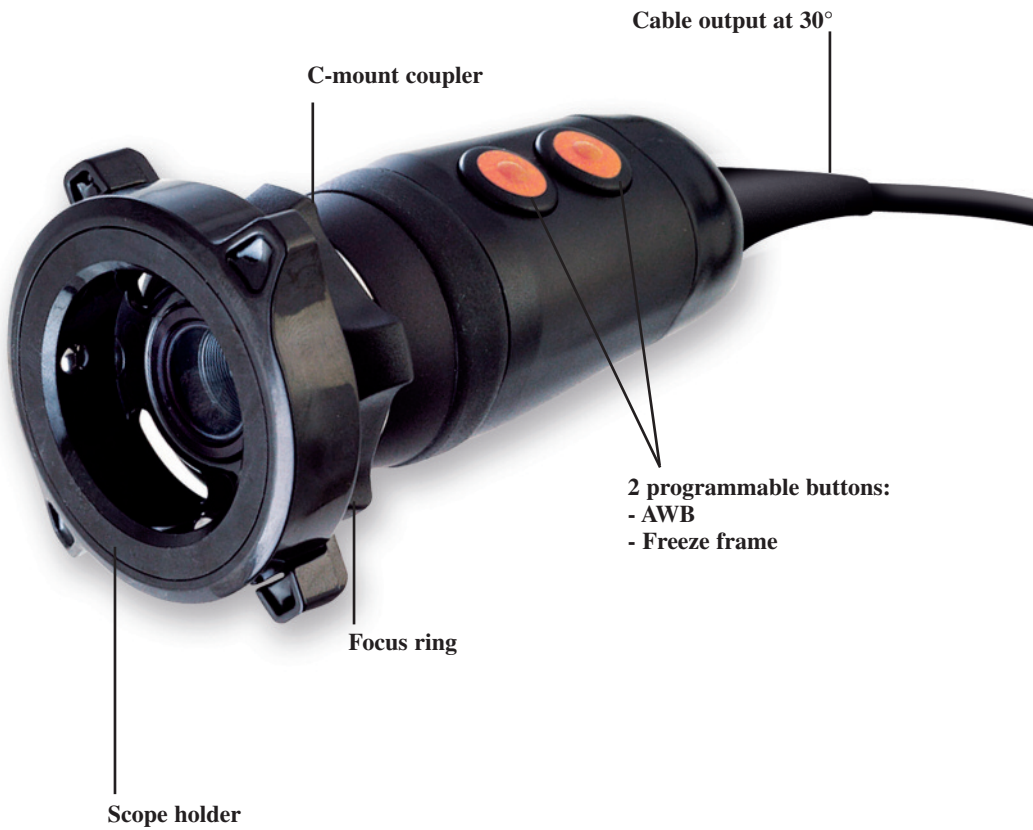




**SOPRO**  
181

USER MANUAL

**SOPRO**  
**COMEG**



Connector S181:



## CONTENTS


<b>1</b>	INTRODUCTION . . . . .	3
<b>2</b>	PRESENTATION OF THE CAMERA . . . . .	3
<b>3</b>	PRECAUTION FOR USE . . . . .	4
<b>4</b>	REGULATORY RECOMMENDATION . . . . .	5
	4.1 CONFORMITY	
	4.2 ELECTROMAGNETIC INTERFERENCES AND ELECTROSTATIC DISCHARGES	
	4.3 MATERIO VIGILANCE	
	4.4 END OF LIFE	
<b>5</b>	INSTALLATION . . . . .	7
	5.1 INSTALLATION OF THE CAMERA ON THE COMPUTER - MINIMUM CONFIGURATION	
	5.2 INSTALLATION OF THE IMAGINE SOFTWARE AND OF THE DRIVERS	
	5.3 OPTIMIZING THE IMAGE	
<b>6</b>	USER ADJUSTMENTS . . . . .	8
	6.1 PRESENTATION OF THE CONTROL SOFTWARE OF THE CAMERA	
	6.2 WHITE BALANCE	
	6.3 VIDEO PARAMETERS	
	6.4 TOOLS	
	6.5 FLEXIBLE/RIGID	
	6.6 THE SHORTCUTS	
<b>7</b>	RECOMMENDED PROCEDURE FOR DECONTAMINATION . . . . .	11
<b>8</b>	AFTER SALE SERVICE . . . . .	12
<b>9</b>	TECHNICAL SPECIFICATIONS . . . . .	13
<b>10</b>	ELECTROMAGNETIC COMPATIBILITY . . . . .	14

## INTRODUCTION

Thank you for your confidence shown in us by your purchase of this device.

To take full advantage and comply with all necessary precautions, you should carefully read this manual and be well acquainted with its contents.

Sentences containing the symbol  are points requiring special attention.

Sentences containing the symbol  are for information.

To facilitate the installation and the use of the camera we wanted to make his handbook easier to use. Thus, references in the page of presentation in the back of the cover (in the form of [D1] for example) are proposed for you to visualize easily the parts of the product concerned.

## PRESENTATION OF THE CAMERA

It is a waterproof, USB2 colour micro camera with detachable sensor, designed for consulting offices diagnosis directly from your PC computer. Its lightness, its auto-shutter, its performances in terms of sensitivity, resolution as well as its fidelity in the respect of colours make of it the ideal diagnosis tool.

### It includes:


- A 1/4" CCD, C-Mount camera head, at the end of a 3m cable.
- A USB2 cable with its waterproofness cap.
- A CD including: - The patient management software limited to 2 patients, integrating the S181 software for the adjustment of the camera and the programming of the two buttons.
  - A User Manual.
  - A USB2 driver.

### In option:

- A 12 or 17mm waterproof objective and its endoscope holder ring.
- A Dongle allowing to unlock SIM and thus to manage an illimited number of patients.
- A 5m USB2 extension cord.

**This equipment was delivered in a cardboard box. You must keep this element for further transport of the camera.**

## PRECAUTION FOR USE

 **Read the user manual.**

- ✓ Respect the use and storage conditions.
- ✓ Install the camera in a clean, dry and well ventilated place.
- ✓ The installation of the camera must be exclusively done by a competent technician trained by the manufacturer.
- ✓ To avoid risk of electrical shocks, fire, short-circuits or dangerous emanations, do not insert any metallic object in the apparatus.
- ✓ Do not expose the camera to water and do not store it in damp places without the waterproof cap on the USB connector (risk of electric shock).
- ✓ Use only the accessories supplied with the apparatus or proposed as option by the manufacturer.
- ✓ Do not use this camera near any flammable anaesthetics.
- ✓ This camera must not be used in a ionizing environment.
- ✓ This camera is not a sterile device.

## REGULATORY RECOMMENDATION

### 4.1 CONFORMITY

This device has been designed and manufactured by a company with a certified quality system. It complies with the requirements of the European Directive 93/42/EEC related to medical devices. As a result, it complies in particular with the ad hoc electric safety (IEC) and Electromagnetic Compatibility (EMC) standards.

### 4.2 ELECTROMAGNETIC INTERFERENCE AND ELECTROSTATIC DISCHARGES

Although this product complies with the EMC standards, it is possible under very special circumstances that it may interfere with other devices or be interfered by other devices or by an unfavourable electromagnetic environment.

To prevent such situations, it is recommended  :

- To take care of the quality of the electric network (and particularly the grounding system of all the devices and carriages) ;
- To keep the device away from Electromagnetic sources (e.g., compressor, motor, transformer, HF generator, etc.).

### 4.3 MATERIO VIGILANCE

As for any medical system, this device is subject to the provisions pertaining to materio vigilance; any serious malfunction must be promptly communicated to the competent authorities and the manufacturer with the greatest possible precision.

For the address of the manufacturer please see the last page of manual.


Caution: US Federal law restricts this device to sale by or on the order of a Physician

This camera is intended to be used by qualified physicians in general and plastic surgery to provide access, illumination and allow observation or manipulation of body cavities, hollow organs, and canals.

### 4.4 END OF LIFE

This appliance is marked according to the European Directive 2002/96/EEC on Waste Electrical and Electronic Equipment (WEEE).

By ensuring this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.

The symbol  on the product, or on the documents accompanying the product, indicates that this appliance may not be treated as household waste. Instead it shall be handed over to the applicable collection point for recycling of electrical and electronic equipment.

Disposal must be carried out in accordance with local environmental regulations for waste disposal.

For more detailed information about treatment, recovery and recycling of this product, please contact the local dealer to whom you purchased the product from and who will tell you how to proceed.

# INSTALLATION

### 5.1 INSTALLATION OF THE CAMERA ON THE COMPUTER-MINIMUM CONFIGURATION

A minimum configuration of the computer is necessary, see chap 9 (Technical specifications)

Minimum System Requirements	Recommended System Requirements
Pentium IV - 1.3 GHz processor.	Intel Core2 processor or more.
512 MB of RAM.	4 GB of RAM.
250 GB of hard disk space.	1 TB of hard disk space.
2 USB 2.0 Hi-Speed ports.	4 USB 2.0 Hi-Speed ports.
Operating system: XP Pro SP3, VISTA Business SP1.	Operating system: Windows XP Pro SP3, Windows 7 Professional.
Graphics Card: 32 MB of unshared video RAM with support for DirectX 9 or higher.	Graphics Card with NVIDIA or ATI chipset / 512 MB of unshared video RAM with support for DirectX 9 or higher.
USB chipset: Intel or NEC.	USB chipset: Intel or NEC.
Screen Resolution: 1024 x 768.	Screen Resolution: 1280x 1024 or higher.
PC conform to IEC 60950	PC conform to IEC 60601-1

A USB2 driver included on the CD-ROM is necessary to the functioning of the camera.

 **DO NOT PLUG THE CAMERA ON A USB PORT ON THE FRONT PANEL OF THE PC.**

 **INSTALL THE SOFTWARE BEFORE PLUGGING THE CAMERA.**

### 5.2 INSTALLATION OF THE IMAGING SOFTWARE AND OF THE DRIVERS


See Chapters 2 & 3 of the Imaging software user manual available in the Directory Documents of the CD-ROM.


## 5.3 OPTIMIZING THE IMAGE

**i** Considering the disparity of video performances between PC, it is peremptory to adapt the adjustments of the system ( graphic board, screen,...) to obtain the best image quality.

This procedure must be performed once at the installation of the camera.

> Plug the camera to the PC, connect the endoscope, the light cable and start the light source.

> > Launch the software with the shortcut  on the desktop

> Press on the icon  to start the video

> Launch an AWB: wrap the endoscope in a white gaze to avoid any dark area on the image

> Shift the resolution of the video to 720 x 576 (Go to Files, Configuration, camera, capture connection).

> Adapt the parameters of : Brightness/Contrast/ Saturation/ Sharpness in the following manner:

- Go to Files, Configuration, camera, filter of capture, Amp proc video
- Adjust the contrast to have a bright image, without white saturation or noise.
- Adjust the brightness to have a bright and noiseless image.
- Adjust the saturation of the colors of the images to obtain realistic colors.
- Adjust the sharpness to enhance details without increasing the noise.

> If necessary, modify the adjustments of the monitor to adjust colors and brightness.

> Save the parameters and leave.

**i** A mode "By default" is available to come back to factory settings. These values are kept and reloaded at each starting of the system.

Before connecting your telescope or fibroscope on the camera, you must check its condition (clean distal lens, focus if necessary) and link it to your light source.

Then check if the image produced with such a configuration is good. Power your light source and place the extremity of your telescope in the palm of your hand, thus simulating the basic conditions of endoscopy (beware of the working distance "filmed object-telescope" which must be similar to reality, i.e. some centimetres).

1. Wait a few seconds in order to have a stabilised light;
2. Launch the Automatic White Balance (see following chapter);
3. Place the extremity of your telescope in the palm of your hand, thus simulating the basic conditions of endoscopy (beware of the working distance "filmed object-endoscope" which must be similar to reality, i.e. some centimetres). If you obtain a fuzzy image, modify the focus of the lens and if necessary of the endoscope. Check also if there is neither fog nor dust on your lens.



## USER ADJUSTMENTS

### 6.1 PRESENTATION OF THE CONTROL SOFTWARE OF THE CAMERA

When the imaging software is launched and the camera plugged, an interface dedicated to the camera appears. It allows to adjust the video parameters of the camera, to start a white balance and to give functions to the 2 buttons of the camera head.

### 6.2 WHITE BALANCE

**i** Prior to performing an AWB, the camera must be plugged to the PC with the endoscope and the light source connected. If there is not enough light, the AWB will not be done.

- Film a white surface (beware the produced image is clear), see Chap. 5.3;
- Press on the button of the white balance of the camera (factory settings : cable side button) or of the software;
- A white square appears on the screen indicating a pending white balance, do not move until this square disappears, indicating the end of the white balance.

Each balance is memorised. Thus, the next time you turn on the camera (and if no parameters of your image chain were modified), you will find the same colours.

You need to do a new white balance if:

- You change the type of light source;
- You change your lamp (new one);
- You change the optics;
- You change the light cable;
- You not satisfied with the reproduction of the colours.

**i** If you are not satisfied with the quality of the colours, think to check the adjustments of your monitor (Chroma, contrast,...)

## 6.3 VIDEO ADJUSTMENT




EXPOSURE	-16 to +56 : Control of the amount of light received by the CCD sensor.
WINDOW	1 (small) to 5 (full screen): window of analyze of the image on which the camera analyzes the amount of light received. This function allows obtaining a right exposure even when the image holds areas with different lightings (example : a dark hole, and its very lighted surroundings will require a small window).
DETAILS	0 to 15 : Control the level of detail in the image, this parameter is inactive in FLEXIBLE mode.
RED SHIFT	(-16 to +16) shift of the colorimetry of the white for the red part
BLUE SHIFT	(-16 to +16) shift of the colorimetry of the white for the blue part.
GAMMA	(-2 to +1) modifies the dynamic of colors in dark areas: +1 decreases the difference between dark and bright areas, the dark areas then appear less dark. -2 does the opposite: the dark parts appear darker.

## 6.4 TOOLS



ACTION TOUCH 1	Programmation of the function of touch 1 amongst : Image or video CAPTURE (according to the mode), AWB, FLEXIBLE
ACTION TOUCH 2	Programmation of the function of touch 2 amongst : Image or video CAPTURE (according to the mode), AWB, FLEXIBLE
LANGUAGE	French, Italian, Spanish, English, German
Automatic gestion of the video parameters	Clicking on this case activates the function but forbids the access to video parameters. During the white balance, the camera selects automatically the best video parameters.
Save the present adjustments	A validation on « OK » saves the modified parameters.
Reduce in the bar	When the interface of control of the camera is closed, it is reduced in the windows tasks bar.

## 6.5 FLEXIBLE/RIGID

 This function is used to guarantee an excellent image quality whatever the used endoscope. The name of the activated function appears at the pressure on the icon.

**FLEXIBLE:** this function activates the ANTIMOIRE filter of the camera and inhibits the DETAILS adjustment of the Video Menu. It is used only for flexible endoscopes made with optic fibers.


**RIGID:** this function cancels the ANTIMOIRE filter of the camera and allows getting back the DETAILS of the image. It is used for rigid and semi-rigid endoscopes.


## 6.6 THE SHORTCUTS

The following icons permanently appear when the control interface of the camera is active. They allow a direct access to the functions most used by the doctor while being discreet.



## RECOMMENDED PROCEDURE FOR DECONTAMINATION

 CAUTION: This procedure is only to be used if the cap of the USB connector is correctly closed.

 The camera sensor and the lens are designed for a cold decontamination by immersion (Steranios, Chlore Dioxyde, Hexanios, Tristel swipes)....). All other methods of decontamination are prohibited. The damages due to these other methods could not be taken over by us.

 Only immerse the C-Mount sensor with its objective screwed on it.

It is peremptory to respect the procedure consisting in cleaning the parts to immerse before decontamination and after decontamination, to rinse carefully with sterile water all the parts which have been in contact with the decontaminant.

 CAUTION !

- It is peremptory to rinse abundantly the parts which have been in contact with the decontaminant.
- Use unwoven compresses for the drying of the distal lens so not to scratch it.
- The procedures described are advisory, they can, in no cases, be substituted to official recommendations or directives.
- The decontamination being linked to the products, methods and/or selected tools, remains entirely under the total responsibility of the people concerned.

## AFTER SALE SERVICE

No special maintenance is necessary on the camera. Here is a list of common problems which are easy to troubleshoot. For all other cases, contact our Maintenance Service that will help you in best delay. We remind you that the mishandlings are not guaranteed.

### 8.1 NO IMAGE ON SCREEN

- Check if the camera is correctly connected and if the imaging software is opened and correctly installed (See Chap. 5).

### 8.2. FLICKERING IMAGE

- Check the minimal configuration of the PC in Chap.5.
- Keep only the imaging software active, close any other software.
- Do not plug the camera on the front panel of the PC.

### 8.3. THE IMAGE IS FUZZY UNIFORMLY WHITE

- Check if there is no blur on the lens.
- Check if the sensor does not aim at a too lighted object.
- Check the focus of the lens.

### 8.4. THE IMAGE IS TOO CLEAR OR TOO DARK

- Check if the "EXPOSURE" parameter is not at its maximum or minimum (in the control software of the camera).
- Check if the " BRIGHTNESS" and "CONTRAST" parameters are well adjusted (See Chap.5).

If the problem remains and if you are led to send us back the camera, be careful to do it in its original packing. Likewise, you must send us the whole system (sensor, lenses, and cords). Be kind enough to join an explanatory note relative to the observed default to the expedition bill.

At the reception of your equipment, you will have to check its state and to enter a reservation on the delivery bill if necessary. You will then have 48 hours to confirm them by recommended letter addressed to the carrier. Beyond this delay, the carrier may deny these reservations. In the case where equipment shipped by us suffers damages during the travel, the amount of the repairing will be charged whether to the carrier if the reservation were entered in the delays, or to the consignee in the contrary.

Think to check rapidly the good functioning of the equipment which has just travelled.

Any other interventions being performed by our After Sales Service, no Service Manuals will be supplied.

# TECHNICAL SPECIFICATIONS

- BF Type camera
- Sensor: CCD 1/4" high sensitivity
- Resolution of the sensor: (752 x 582) PAL ; (768 x 494) NTSC
- Definition: 470 lines
- Sensitivity : 2 lux
- Signal/Noise Ratio : 52 dB
- Electronic shutter: Automatic (1/50 to 1/100 000)
- Variable surface of analyse of the shutter
- White Balance: Automatic
- Video enhancement "SHARPNESS"; electronic anti-moire filter for flexible fibroscope
- Modification of the viseo parameters
- Automatic detection of the colour temperature according to the used light source
- Automatic saving of the adjustments parameters
- 2 programmable buttons
- Cable length: 3 meters,  $\varnothing = 5$  mm
- 1 USB 2.0 output
- Power supply: 5 V DC
- Power consumption : 2.5 VA
- Operating temperature range:  $+10^{\circ}\text{C}$  /  $+35^{\circ}\text{C}$
- Operating relative humidity range: 30 to 75 %
- Transport and storage temperature range:  $-10^{\circ}\text{C}$  /  $+45^{\circ}\text{C}$
- Transport and storage relative humidity range: 20% to 85%
- Operating, transport and storage atmospheric pressure range: 700hPa to 1060hPa
- Continuous Service
- Not adapted to a use close to a mixture of inflammable anaesthetic with air or oxygen or nitrous oxide.
- $\text{C} \in$  Comply with the European Directive 93/42/EEC.

## FEATURES OF THE CAMERA HEAD:

- ABS waterproof camera head
- Front part of the C-Mount made of aluminium
- Size of the sensor: L = 87mm;  $\varnothing = 30$  mm
- Weight of the sensor: 210 g

## ACCESSORIES

- Objective F=12 or 17mm with endoscope holder
- Weight of the objective : 60g

## 1 CD-ROM including:

- The pilot of the camera
- The imaging software limited to the gestion of 2 patients with the control software of the camera
- Software tools.

# ELECTROMAGNETIC COMPATIBILITY


## 10.1 GUIDE AND DECLARATION BY MANUFACTURER - ELECTROMAGNETIC EMISSIONS

This camera is designed to be used within the electromagnetic environment specified below. The user should ensure that it is indeed used within this environment.

Emissions test	Compliance	Electromagnetic environment - Guide
RF emissions CISPR 11	Group 1	This camera only uses radioelectrical energy for its internal subsystems. Therefore, it emits very low RF energy and is not likely to interfere with nearby electronic devices.
RF emissions CISPR 11	Class B	This camera can be used in all domestic premises, included premises directly connected to the public low-voltage power distribution network used for powering buildings for residential use.
Harmonic emissions EN 61000-3-2	Conform	This camera can be used in all premises other than residential premises and premises connected directly to the public low-voltage power distribution network used for powering residential buildings.
Voltage fluctuations / flicker EN 61000-3-3	Conform	

## 10.2 GUIDE AND DECLARATION BY THE MANUFACTURER - ELECTROMAGNETIC IMMUNITY

This camera is designed to be used within the electromagnetic environment specified below. The user should ensure that it is indeed used within this environment.

Immunity test	CEI 60601 severity level	Compliance level	Electromagnetic environment - Guide
Electrostatic discharges EN 61000-4-2	± 6 kV via contact ± 8 kV via air	± 6 kV ± 8 kV	The floor should be in timber, concrete or tiling. If the floor is covered with a synthetic material, the relative humidity should be at least 30%.
Quick transients in bursts EN 61000-4-4	± 2 kV for power lines ± 1 kV for input/output lines	± 6 kV via contact ± 8 kV via air	The quality of the main power supply should be that of a typical commercial or hospital environment.
Voltage shocks EN 61000-4-5	Differential mode ± 1 kV Common mode ± 2 kV	0± 6 kV via contact ± 8 kV via air	The quality of the main power supply should be that of a typical commercial or hospital environment.
Brown-outs, brief power failures and voltage variations EN 61000-4-11	<5% UT - for 10 ms 40% UT - for 100 ms 70% UT - for 500 ms >5% UT - for 5 s	± 6 kV via contact ± 8 kV via air	The quality of the main power supply should be that of a typical commercial or hospital environment. If the user of this camera requires to be able to continue to work during interruptions in the main power supply, it is recommended that this camera be powered via a UPS or battery.
Magnetic field at network frequency (50/60 Hz)	3 A/m	± 6 kV via contact ± 8 kV via air	The magnetic field at the network frequency should be at a level characteristic of a location within a typical commercial or hospital environment.
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communication devices must not be used at a distance from this camera - including cables - that is less than the recommended separation distance calculated using applicable formulae according to the transmitter's frequency.  <b>Recommended separation distance</b>  $d = 1,16\sqrt{P}$ $d = 1,16\sqrt{P}$ 80 MHz à 800 MHz
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	$d = 2,33\sqrt{P}$ 800 MHz à 2,5 GHz  In which $P$ is the maximum output power of the transmitter, in Watts (W), assigned by the manufacturer of the transmitter and the recommended separation distance ( $d$ ) in meters (m). The field levels emitted by immobile RF transmitters - which are to be established by an electromagnetic measurement at the site - must be lower than the compliance level in each frequency band. Interference can occur nearby devices bearing the following symbol: 

**NOTE :**  $UT$  is the nominal value of the power voltage applied during the test.

**NOTE 1 :** At 80 MHz and 800 MHz, the higher frequency band applies.

**NOTE 2 :** These recommendations may not apply in all situations. The propagation of electromagnetic waves is modified by absorption and reflection due to structures, objects and people.

a The field level of immobile transmitters, such as radio telephone base stations (cellular and cordless) and mobile terrestrial radio systems, amateur radio systems, AM/FM radio communication systems, and TV systems cannot be evaluated theoretically with precision. To ascertain the electromagnetic environment due to immobile RF transmitters, a site measurement must be performed. If a field level measured within the environment in which this camera is used exceeds the above applicable compliance levels, check that this camera operates in a satisfactory manner. If abnormal operation is observed, additional measurements should be taken, such as reorientation or relocation of the reference system.

b Outside the frequency band of 150 kHz to 80 MHz, the field level should be less than 3 V/m



## 10.3 SEPARATION DISTANCES RECOMMENDED BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS SYSTEMS AND THIS CAMERA

This camera is designed to be used within an electromagnetic environment in which radiated RF interference is controlled. The user of this camera can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication systems (transmitters) and this camera, such as recommended below, as a function of the maximum output power of the communications system.

Maximum assigned output power of the transmitter W	Separation distance as a function of the transmitter's 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

For transmitters of which the maximum output power is not listed above, the recommended separation distance  $d$  in meters (m) can be established by using the equation applicable for the transmitter frequency, in which  $P$  is the transmitter's maximum output power in Watts (W) assigned by the transmitter's manufacturer.

**NOTE 1 :** At 80 MHz and 800 MHz, the separation distance stated for the higher frequency range should be applied.

**NOTE 2 :** These recommendations may not apply in all situations. The propagation of electromagnetic waves is modified by absorption and reflection due to structures, objects and people.

## SYMBOLS-SYMBOLS-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 /  
Observe la documentacion adjunta / Leggere la documentazione allegata /  
Begleitpapiere beachten



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



WEEE 2002/96 CEE Compliant / Conforme à la norme DEEE 2002/96/CEE / Conforme  
a la directiva WEEE 2002/96/CEE / Conforme alla direttiva WEEE 93/42/CEE /  
Entspricht WEEE 2002/96/CEE Richtlinie



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