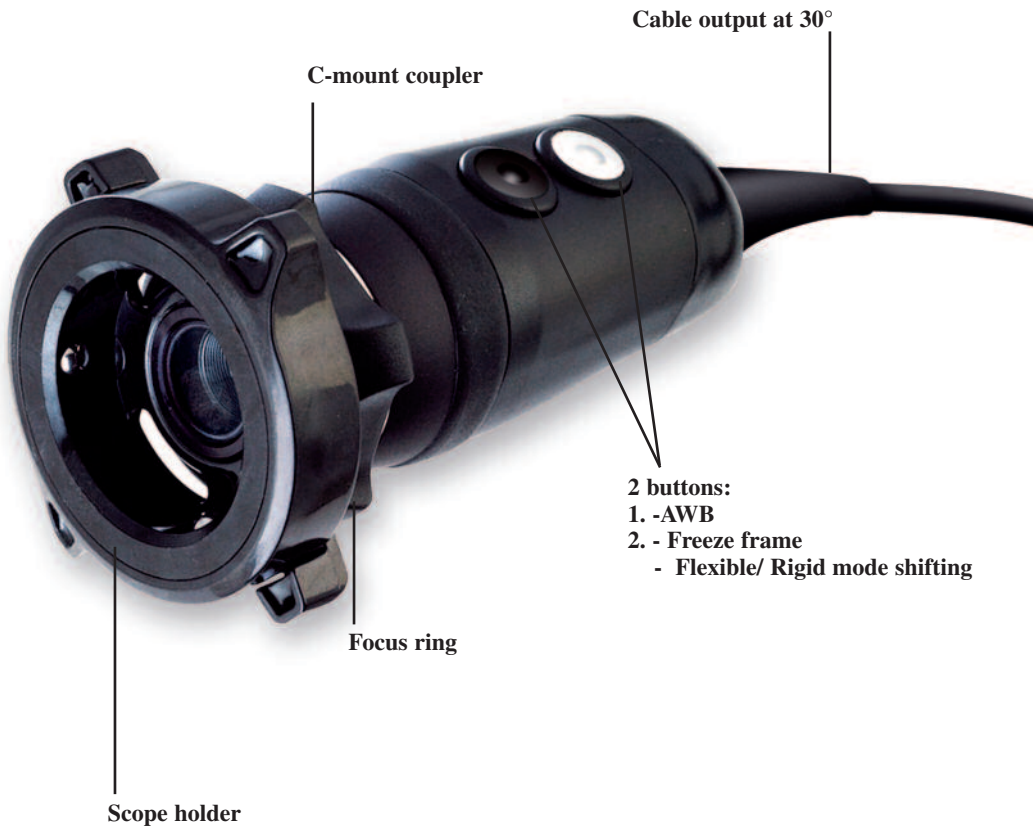




UBICAM_®
digital diagnosis set

USER MANUAL





Camera connector



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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
 - A User Manual.
 - A USB2 driver.

In option:

- A 12 or 17mm waterproof objective and its endoscope holder ring.
- 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

A minimum configuration of the computer is necessary.

Minimum System Requirements	Recommended System Requirements
Intel® Pentium iv - 1,3 ghz processor	Intel® core i5 processor
512 Mb of RAM	2 Gb of RAM
250 Gb of hard disk space	320 Gb of hard disk space
2 USB 2.0 Hi-Speed ports	4 USB 2.0 Hi-Speed ports
Operating system: Windows® xP Pro sP3	Operating system: Windows® 7 Pro sP1
Graphics Card: 32 MB of unshared video RAM withsupport for DirectX 9	Graphics Card with NVIDIA or ATI chipset / 512 MB of unshared video RAM with support for DirectX 9
USB chipset: Intel ou NEC® / Renesas®	USB chipset: Intel ou NEC® / Renesas®
Screen Resolution: 1024 x 768	Screen Resolution: 1280x 1024 or higher

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 COMPUTER.**

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

5.2 INSTALLATION OF THE IMAGING SOFTWARE AND OF THE DRIVERS

Refer to the software installation manual located in the document directory of the Imaging software CD-ROM.


5.3 OPTIMIZING THE IMAGE

i Considering the disparity of video performances between computers, 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 computers, 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 for a PAL camera (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

6.2 WHITE BALANCE

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

- Film a white surface, a white gaze preferably and take care it is properly placed before the endoscope. (beware the produced image is clear), see Chap. 5.3.
- Press on the button of the white balance of the camera (white 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,...)

6.2 THE ICE FUNCTION

With the new "ICE" (Intelligent Control Endoscope) device built in this camera, the white balance you just performed also allows to optimize all the settings whatever the endoscope used is.

For each white balance, this exclusive process analyses:

- the size of the endoscope to adapt the field of vision of the camera,
- the color temperature from the light source to determine its wavelength,
- the color temperature of the light going through the endoscope to restore realistic colors during the white balance.
- the minimum level of light to warn the user in case of failure.

6.3 IMAGE CAPTURE

A short pressure on the black button will allow you to capture an image.

According to the parameter settings of your Imaging software, the image will remain frozen on the screen and you will have to press again on the same button to come back to live, or the image will automatically shift to the live mode.

In both cases, the captured image is automatically saved in the patient file.

6.4 FLEXIBLE/RIGID

i This function is used to guarantee an excellent image quality whatever the used endoscope.

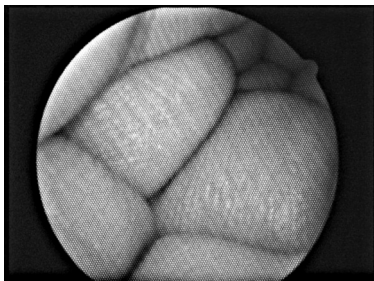
FLEXIBLE: this function activates the ANTIMOIRE filter of the camera. It is used only for flexible endoscopes made with optic fibers.

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.

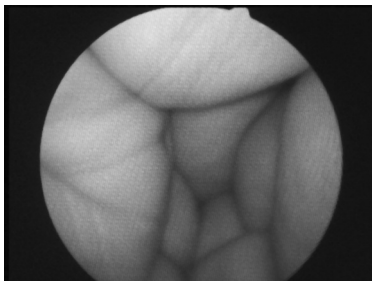
A long pressure on the capture button (black) will active the anti-moiré*. A new long pressure will shift back to Rigid.

When the anti-moiré* mode is activated, an F appears on the low right side of your screen.

*Anti-moiré : correction of the natural default of aliasing due to the association of a CCD camera with an endoscope with optic fibres.





Moiré



Anti-moiré

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

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 " 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 fibrescope
- Modification of the video 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°C / +35°C
- Operating relative humidity range: 30 to 75 %
- Transport and storage temperature range: -10°C / +45°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, IEC 60601-2-18 and Amendment for CANADA and USA.

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 patient management imaging software
- 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	± 2 kV ± 1 kV	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	± 1 kV ± 2 kV	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	<5% UT 10 ms <40% UT 100 ms <70% UT 500 ms <5% UT 5 s	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	3 A/m	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 Radiated RF EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V 3V/m	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. Recommended separation distance $d = 1,16\sqrt{P}$ $d = 1,16\sqrt{P}$ 80 MHz à 800 MHz $d = 2,33\sqrt{P}$ 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



UK : Disposal of electric and electronic equipment marketed after 13/August/2005.
This symbol indicates that the product cannot be treated with domestic waste.
FR : Equipement électronique et électrique mis sur le marché après le 13/08/2005.
Ce symbole indique que ce produit ne doit pas être traité avec les déchets ménagers.
ESP : Equipamiento electrónico introducido en el mercado después del 13/08/2005.
Este símbolo indica que este producto no debe ser tratado junto a los residuos
domésticos.
ITA : Apparechiatura elettronica ed elettrica messa sul mercato dopo il 13/08/2005.
Questo simbolo indica che questo prodotto non deve essere trattato come un rifiuto
domestico.
DE : Elektronische und elektrische Geräte, die nach dem 13.08.2005 auf den Markt
gebracht wurden. Dieses Symbol weist darauf hin, dass dieses Produkt nicht über den
Haushaltsmüll entsorgt werden darf



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