Owandy RADIOLOGY

OWANDY-CAM HD

USER'S MANUAL

EN • NOCMEN010A • 03/2021

Contents

1 FOREWORD

To optimize the use of this device, whilst taking all the necessary precautions, we recommended you read carefully and follow the owner's manual.

Please carefully consider the messages "CAUTION", "WARNING", and "NOTE" when using the system.

⚠ CAUTION: the term CAUTION describes potential incidents likely to jeopardize safety.

WARNING: the term WARNING refers to the incidents likely to disturb the smooth running of the imaging system.

NOTE : the term NOTE highlights particular points in order to facilitate the system maintenance or to clarify important information.

2 CAMERA INTRODUCTION

Congratulations on your purchase of the Owandy-Cam HD.

It is an extra- and intra-oral camera designed for dental applications. It allows the user to see anatomical and pathological details that cannot be seen with the naked eye, as well as pathology control and post-treatment.

This fluorescence Imaging device is composed of a handpiece (Owandy-Cam HD) and a connection box (MINI DOCK USB2) as well as various accessories necessary for it to work.

Owandy-Cam HD
- 1 handpiece integrating the camera electronics and lighting.
- 1 handpiece holder.
- 10 dental barriers.
- USB key of QuickVision software including camera and software user's manuals.
- A quick start of Owandy-Cam HD

MINI DOCK USB2
- A USB2 connection box with a 2.5 metre connecting cable.

This device has been packaged in a custom carton. This carton should be kept for future possible transportation. As a complement to the dental camera, we provide some dental barriers necessary for intra-oral use of dental camera. For more details about these products, please refer to our catalogue or contact our commercial service.

NOTE :
The device was designed and developed with its accessories in order to guarantee to you safety and performance maximum. The use of different origin accessories can represent a risk for you, your patients and your device.

3 SAFETY INSTRUCTIONS

• DO NOT expose the camera to water spray and do not store it in a humid environment (to prevent risk of electrocution).
• When handling camera and dental barriers, always take the appropriate hygiene measures and precautions in order to prevent cross contamination risks.
• Infection control procedures must be observed when using accessories such as dental barriers. When using accessories always follow the manufacturer's instructions on how to use said accessory and prevent cross contamination risk from one patient to another.
• Install the camera in a clean, dry, and well-ventilated place.
• Disconnect the connection box from the power supply if you are not going to use it for several days. Do not pull on the cable.
• DO NOT compress or nip the handpiece cable.
• DO NOT expose the product to high vibrations.
• DO NOT drop the handpiece.
• Handpiece should NEVER be immersed in any liquid, NOR should it be autoclaved.
• For each new patient, it is essential to use the dental barriers provided with the handpiece. Before using the camera, make sure it does not have any sharp edges.
• The surface temperature in the light emission area can reach above 41°C (after several minutes of use). Therefore avoid maintaining this emission area in contact with the patient's mouth.
• The camera is a product using group 1 LEDs according to IEC 62471. To avoid any ocular risk do not look directly at the light.

NOTE :
If the hygienic protection is torn while examining a patient or if the handpiece was "infected" while withdrawing the hygienic protector, it is essential to totally disinfect the handpiece. In order to do this: please refer to the maintenance chapter.

CAUTION:
Modification of the product, without the permission of the manufacturer, is prohibited.

CAUTION:
If the medical equipment is changed, an appropriate control and test should be performed to ensure that the medical equipment still can be used safety.

4 REGULATORY REQUIREMENTS

4.1. COMPLIANCE WITH STANDARDS AND REGULATIONS

This product was designed and manufactured by a company having an authorized quality system. It meets the European directive 93/42/EEC requirements relative to medical devices. Therefore, it particularly meets electrical safety and electromagnetic compatibility standards (IEC) (CEM).

4.2. ELECTROMAGNETIC INTERFERENCE AND ELECTROSTATIC DISCHARGES

Electromagnetic compatibility (CEM) is the ability of electronic device elements to correctly interact in an electronic environment. Although the Owandy-Cam HD system was designed according to this compatibility and complies with the electromagnetic interference thresholds established by the regulatory agency, there is no guarantee about interference likely to occur on a particular installation. If the device generates interference with radio communication services (which can be determined by switching it off and on), it is recommended to try to correct this phenomenon by taking whole or part of the following measures:

- Change the receiving antenna orientation
- Reposition the product according to the receiver.
- Take the computer away from the receiver.

The Owandy-Cam HD camera is designed and tested to be used in a home environment, class B Group 1, according to CISPR11 standard.

4.3. MEDICAL DEVICE VIGILANCE

As with any medical device, this device is subjected to medical device vigilance dispositions; any serious dysfunction should then be the subject of a description to the competent authorities and to the manufacturer as soon as possible and as precisely as possible.

4.4. END OF LIFE

This device bears the recycling symbol according to the European directive 2002/96/EC about electric and electronic equipment waste (DEEE or WEEE). By correctly disposing of this device, you will contribute to avoiding any damage to the environment and human health.

The symbol  on the device or on the accompanying documentation indicates this product cannot be, in any case, treated as household waste. Therefore, it should be transferred to a waste collection centre that handles electric and electronic equipment recycling. Please respect the standards relative to waste disposal in force in the installation country. For more details about the device treatment, recuperation and recycling, please contact your dental device distributor (or failing that, www.owandy.com), so that you can be informed of the procedure.

4.5. ELECTROMAGNETIC COMPTABILITY

<table>
<tr><th colspan="3">Guide and declaration of the manufacturer - electromagnetic emissions</th></tr>
<tr><td colspan="3">Owandy-Cam HD device is intended to be used in the electromagnetic environment specified below.
The user should make sure it is used in this environment.</td></tr>
<tr><th>Emission trial</th><th>Compliance</th><th>Electromagnetic environment - Guide</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>Owandy-Cam HD device only uses radio energy for its internal functions. Therefore, its RF emissions are very low and are unlikely to cause interference with nearby electronic devices.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">Owandy-Cam HD device may be used in all domestic environments, including the ones directly connected to the public low voltage power distribution network used to supply household buildings.</td></tr>
<tr><td>Harmonic emissions
EN 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations /
Flicker
EN 61000-3-3</td><td>Applicable</td></tr>
</table>

Guide and declaration of the manufacturer - electromagnetic immunity			
Owandy-Cam HD device is intended to be used in the electromagnetic environment specified below. The user should make sure it is used in this environment.			
Immunity trial	**CEI 60601 Severity level**	**Compliance level**	**Electromagnetic environment Guide**
Electrostatic discharges EN 61000-4-2	± 6 kV when in contact ± 8 kV in the air	± 6 kV ± 8 kV	The floor should be wooden, concrete or tile. If the floor is covered with a synthetic material, the relative humidity should be at least 30%.
Far transient bursts EN 61000-4-4	± 2 kV for the feed cables ± 1 kV for the input/output cables	± 2 kV ± 1 kV	The main power supply quality should be one of a traditional commercial or hospital environment.
Voltage shocks EN 61000-4-5	Differential mode ± 1 kV Common mode ± 2 kV	± 1 kV N.A.	The main power supply quality should be one of a traditional commercial or hospital environment.
Dips, brief outages and power voltage variation 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 main power supply quality should be one of a traditional commercial or hospital environment. If the user of Owandy-Cam HD device requires it to continue to operate during main power supply outages, it is recommended Owandy-Cam HD device is fed by an inverter or a battery.
Magnetic field with the network frequency (50/60 Hz)	3 A/m	3 A/m	The magnetic field with the network frequency should be at a characteristic level of a location in a traditional commercial or hospital environment.
Note: Ut is the power voltage nominal value applied during the trial.			

Guide and declaration of the manufacturer - electromagnetic immunity			
Owandy-Cam HD device is intended to be used in the electromagnetic environment specified below. The user should make sure it is used in this environment.			
Immunity trial	**CEI 60601 Severity level**	**Compliance level**	**Electromagnetic environment Guide**
			Portable and mobile RF communication devices should not be used at a distance from Owandy-Cam HD device including the cables, lower than the recommended separation distance, calculated with the applicable formulas depending on the emitter frequency. **Recommended separation distance**
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	$d = 1.16\sqrt{P}$
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d = 1.16\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum rated output of the transmitter in watts (W) by the transmitter manufacturer and d the recommended separation distance in metres (m). The field levels emitted by the fixed RF transmitters, determined by an electromagnetic measurement of the sitea, should be lower than the compliance level in each frequency band b. Interference may occur in the vicinity of the devices bearing the following symbol: 
Note 1 : At 80 MHz and 800 MHz, the higher frequency band applies. **Note 2 :** These recommendations may not apply in every situation. Electromagnetic wave propagation is modified by the absorption and reflection due to the structures, objects and persons.			

a The fixed transmitter field levels, such as the base stations of the radio telephones (cellular/wireless) and the terrestrial mobile radios, domestic radio, AM, FM, and TV radio communication cannot be theoretically assessed precisely. To obtain the electromagnetic environment due to the fixed RF transmitters, a site measurement should be performed. If a field level measured in the use environment of Owandy-Cam HD device exceeds the compliance levels above applicable, the good operation of Owandy-Cam HD device should be checked. If abnormal operations are proved, some further measures should be taken, such as reorientation or relocation of the standard device.

b Above the 150 kHz to 80 MHz frequency band, the field level should be lower than 3 V/m.

Recommended separation distances between the portable and mobile RF communication devices and Owandy-Cam HD device

Owandy-Cam HD device is intended to be used in an electromagnetic environment in which the irradiated RF disturbances are checked. The user of Owandy-Cam HD device can help to avoid electromagnetic interference by maintaining a minimal distance between the portable and mobile RF communication devices (transmitters) and the recommended Owandy-Cam HD device such as recommended below, depending on the maximum output power of the communication device.

Rated maximal output power of the transmitter W	**Separation distance depending on the transmitter frequency - m**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2,5 GHz**
	$d = 1.6 \sqrt{P}$	$d = 1.6 \sqrt{P}$	$d = 2.33 \sqrt{P}$
0.001	0.116	0.116	0.233
0.1	0.366	0.366	0.736
1	0.16	1.16	2.33
10	3.66	3.66	7.36
100	11.6	11.6	23.3

For the transmitters whose maximal output is not listed above, the recommended separation distance d in metres (m) can be determined by using the equation applicable to the transmitter frequency, where P is the maximal output of the transmitter in watts (W) rated by the transmitter manufacturer.

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

Note 2 : These recommendations may not apply in every situation. The electromagnetic wave propagation is modified by absorption and reflection due to the structures, objects and persons.

5 INSTALLATION

The device is intended to be used by a dental practitioner. Its installation does not require any special training. Consult the instructions in this manual.

5.1. CONNECTING

Fastening the handpiece holder:
1. Choose a plain area that can be easily accessible for use.
2. Use the wipe provided to clean the surface on which you are going to fasten the holder.
3. Remove the double-sided adhesive tape protection that is on the support, place it, and then press it into place several times. The maximum sticking performances are obtained after two hours,so avoid any stress on the holder during this two hour period.

CAUTION :
This holder is equipped with magnets that can damage devices sensitive to magnetic fields. Make sure you do not install this holder near these devices (cathode ray tube video screen, magnetic videotapes, etc.)

5.2 FURTHER CONNECTION BOXES (optional)

You can install a connection box near each dental chair (no limitation). You will just have to transport the handpiece from one chair to the other.

The handpiece holder is intended to maintain the connecting cable connector when the cable is not linked to the handpiece.

6 CONNECTING TO A COMPUTER

6.1. REQUIRED CONFIGURATION FOR THE COMPUTER

To use the Owandy-Cam HD device, you must make sure the computer and its peripherals do not have any usage limitation that could concern personal safety. It should also meet the following requirements:

Windows® configuration:

	Minimal Configuration	**Recommended Configuration**
Operating system	Windows® 7 SP1	Windows® 10
Processor	Intel® Core 2 duo – 3 GHz	Intel® Core i5
Memory	2 Go	4 Go or more
Hard disk	250 Go	1 To or more
USB ports	4 ports USB2.0 Hi-Speed	4 ports USB2.0 Hi-Speed
Video board	512 Mo unshared RAM Compatible with DirectX 9	Chipset Nvidia or ATI / 2 Go of unshared RAM. Memory compatible with DirectX 9 or higher
USB Chipset	Intel or NEC® / RENESAS®	Intel or NEC® / RENESAS®
Screen resolution	1 280 x 1 024	1 280 x 1 024 or better

MAC® configuration:

	Minimal Configuration	**Recommended Configuration**
Computer	MacBook® Pro 13.3'' or iMac® 21.5''	iMac® 27''
Operating system	MacOS® X Mavericks	MacOS® X El Capitan
Processor	Intel® Core 2 duo	Intel® Core i7
Memory	2 Go	4 Go

6.2. MINI DOCK USB2 CONNECTION

- Connect the USB cable to one of the computer USB ports.
- Connect the connecting cable to the handpiece.

6.3. IMAGING SOFTWARE INSTALLATION

Refer to the QuickVision user manual located on the USB key in the « Document » directory.

6.4. IMAGING SOFTWARE CONFIGURATION WITH THE CAMERA

Refer to the QuickVision user manual located on the USB key in the « Document » directory.

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DESCRIPTION OF THE CONNECTION BOXES

⚠ **CAUTION**:
Devices that connect to the inputs / outputs must be conformed to IEC 60950-1 standard.

7.1. MINI DOCK USB2 POWER SUPPLY

The dental camera electrical supply is directly performed through the computer USB port. The voltage powering the camera is of continuous 5 V low voltage type ⎓ (0.5 A).

7.2. USB OUTPUT

This camera has a has a digital USB 2.0 output that can be connected to a computer USB2 port.

7.3. IDENTIFICATION

The indications born on the boxes identify the Owandy-Cam HD device according to the international standards IEC 60601-1, IEC 60601-2-18 and IEC 60417.


Class II power supply not grounded.


Dental barriers for single use.


Handpiece connection.

 Footswitch connection.

 Continuous voltage.

 USB2 output.

 "BF type camera".

 Follow instructions for use.

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

 For medical devices, this symbol is associated to the manufacturing year
(expressed with four digits).

 For medical devices, this symbol is associated to the manufacturer name and address.

 Product compliance according to the European directive 93/42/EEC relative to medical devices.

 Electronic user instructions.

The devices that connect to USB outputs should comply with IEC 60950 standard.

8

MAINTENANCE

The camera Owandy-Cam HD does not need any maintenance if it is used according to the manufacturer's use and cleaning instructions.
Before first using it, it is imperative to follow the complete disinfecting procedure.

Any camera returned from servicing or maintenance should be completely disinfected before being used.

WARNING:
Do not use products containing:
- *Ammoniac, trichloroethylene*
- *Dichloroethylene*
- *Ammonium hydrochlorid*
- *Chlorinated and aromatic hydrocarbon*
- *Ethylene dichloride*
- *Methylene chloride*
- *Ketones*

Use of these chemicals subject plastic parts to risk of deterioration.

WARNING:
Do not directly spray disinfecting products on Owandy-Cam HD products.

WARNING:
Infection control procedures must be observed when using accessories such as dental barriers in order to prevent cross contamination risk from one patient to another.

8.1. HANDPIECE OR CONNECTION BOX MAINTENANCE

NOTE:
In case of contact with blood or excessive soiling, it is strongly recommended to follow a disinfecting process. First of all, clean the handpiece with disinfecting wipes, then wrap the handpiece in several disinfecting wipes and leave for 15 minutes.

DESCRIPTION	RECOMMENDATIONS	USE INSTRUCTIONS AND PRECAUTIONS	
		✓	✗
Disinfecting	Surface cleaning and disinfecting wipes	✓ Take the wipe, remove excess moisture, and then wipe the equipment until visible cleanliness is obtained. ✓ Allow to dry in the open air. ✓ Carefully close the packaging box.	✗ Do not scrub ✗ Do not rinse. ✗ Do not immerse in a disinfecting liquid.

9

AFTER-SALES SERVICE

9.1. WARRANTIES

OWANDY RADIOLOGY ensures its products to be free from material and manufacturing defects for a period of two (2) years from the date of purchase, with 5 years warranty extension in option. This warranty does not apply to misused, modified, untended, or accidentally damaged products, or products subject to abnormal use and handling conditions. The distributors, other than OWANDY RADIOLOGY subsidiaries, are not authorized to apply an extended warranty period on behalf of OWANDY RADIOLOGY.

The entire liability of OWANDY RADIOLOGY is limited to its convenience when replacing or repairing, free of charge the defective product, if it has been sent to OWANDY RADIOLOGY After-Sales Service. This applies for the warranty period.

Outside of France, access to the warranty is only possible if the product was bought at a point of sale by an authorized OWANDY RADIOLOGY dealer in the country where it will be used.

THIS WARRANTY APPLIES ONLY TO THIS UNIQUE REMEDY. IT REPLACES ANY OTHER WARRANTY, FOR EXAMPLE, A WARRANTY OF ADEQUACY TO A PARTICULAR AIM, SHOULD IT BE EXPLICIT OR IMPLICIT. OWANDY RADIOLOGY SHALL NOT BE LIABLE FOR ANY PARTICULAR DAMAGE, INDIRECT, ACCIDENTAL OR CONSEQUENTIAL NOR FOR ANY DETERIORATION OR DATA LOSS, ON A CONTRACTUAL, NON-CONTRACTUAL OR OTHER BASIS.

The liability exclusion or limitation for direct or indirect damages does not apply under the regulatory or legal rules in force in some countries and the present exclusion may not apply to a purchaser in those countries.

9.2. IN CASE OF FAILURE

PROBLEMS	CAUSES	SOLUTIONS
With a computer		
No image displays on the screen and the camera LEDs are not on.	• Defective power supply. •connection problem.	1. Check the power supply is correctly connected to the network and to the connection box. 2. Check the connecting cable is correctly connected to the handpiece and to the connection box.
The camera switches on but no image displays on the screen.	•Configuration •Driver • Connection problem.	1. Check the camera is correctly set up in the imaging software (please, refer to user's manual). 2. Check the camera is correctly detected in the device driver (correct installation of its driver). 3. Check the USB cable coming from the DOCK is correctly connected to the HUB.
An image displays on the screen, but the quality is not satisfactory.	Camera driver configuration	Check the camera configuration in the imaging software (brightness, contrast, saturation, etc.). Please refer to user's manual.
An image displays, but it is not really clear (blurry)	• Hygienic protector.	Check the hygienic protector is correctly positioned on the camera head.

The camera should be sent to us in its totality (connection box, handpiece, cables). Please enclose your packing list with a brief explanatory note relative to the noticed defect.

If some parts constituting the camera happen to break, it is imperative to send in everything so that the defective parts can be replaced.

When your material is returned to you, you should check its condition and note any discrepancies on the delivery slip, if necessary. You will then have 48 hours to confirm by registered letter sent to the carrier. After 48 hours, the carrier will be able to deny these discrepancies.

If any material we sent was damaged during transportation, the repair charges will be billed either to the carrier (if the discrepancies were made within the period) or to the recipient. Check as soon as possible that all material is correctly working.

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TECHNICAL FEATURES

Owandy-Cam HD
- High sensitivity CCD 1/4".
- Resolution: (752 x 582) PAL; (768 x 494) NTSC.
- Definition: 470 lines.
- Sensitivity: 2 lux.
- Lighting: eight LEDs.
- Adjustment: automatic.
- Non-inverted image.
- Image capture through touch button or footswitch (optional).
- Angle of view: 70°.
- Cable length: 2.5m.
- Handpiece dimensions: L: 205; W: 28; H: 24 mm.
- Usable part dimensions: W: 16 x D: 11.10 mm.
- Handpiece weight: 55 g.

MINI DOCK USB2
- Cable length: 2,5 m.
- 1 digital USB output 2.0.
- Controller dimensions: L : 64,50 ; W : 26 ; H : 11 mm.
- Dock weight: 97 g.

- BF-type applied part.
- Operating temperature: +10°C to +40°C.
- Storage temperature: -20°C to +45°C.
- Relative humidity: 10 % to 90 %.
- Atmospheric pressure: 900 hPa to 1060 hPa.
- Continuous service.
- Not protected against water chutes (IPX0).
- Not adapted to the use in presence of an anaesthetic mixture flammable with air, oxygen or dinitrogen monoxide.
- Complies with the European directive 93/42/EEC.
- Complies with IEC60601-1 standard.
- Complies with IEC60601-2-18 standard.
- Complies with UL 60601-1 et CSA 60601-1 standard.

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