



EN • INSTALLATION AND USER MANUAL

7735006300 • Version 08, October 2017



SIMPLIFY YOUR COMMUNICATION

Intra-Oral USB2 digital camera

Index

1 INTRODUCTION	4
1.1 COMPLIANCE WITH REGULATIONS.....	4
1.2 POWER SUPPLY	4
1.3 INSTALLATION PRECAUTIONS	4
1.4 LIABILITY AND OPERATORS	5
1.5 PACKAGING AND ENVIRONMENT	5
1.6 MARKING AND LABELLING SYMBOLS.....	6
2 CONTENT.....	7
3 INSTALLATION	8
3.1 PRECAUTIONS.....	8
3.2 SOFTWARE INSTALLATION.....	9
3.3 EQUIPMENT INSTALLATION.....	10
3.4 CONFIGURATION IN THE OWANDY IMAGING SOFTWARE	12
3.5 SHARING HANDPIECE BETWEEN DIFFERENT WORKSTATIONS	12
4 USE.....	13
4.1 PRECAUTIONS.....	13
4.2 BUTTONS ON THE HANDPIECE	13
4.3 CAPTURING AN IMAGE	14
5 HYGIENE AND MAINTENANCE	19
5.1 HYGIENE AND DISINFECTION	19
5.2 MAINTENANCE	19
6 TROUBLESHOOTING	20
6.1 GENERAL.....	20
6.2 IMAGE QUALITY	21
7 SPECIFICATIONS.....	22
8 ACCESSORIES.....	23

OWANDY RADIOLOGY reserves the right to modify its products or their specifications in order to improve their performance, quality or productibility. The specifications of the products or accessories can be modified without prior notification.

No part of this manual can be reproduced without the express permission of the company OWANDY RADIOLOGY.

Language in which original document written: French.



Year CE marking assigned: 2009

OWANDY RADIOLOGY
2, rue des Vieilles Vignes
77183 Croissy-Beaubourg
FRANCE
Téléphone : +33 1.64.11.18.18
Fax : +33 1.64.11.18.10

1 Introduction

You have just received your **OwandyCam** intraoral imaging set. We thank you for the confidence you have placed in us and hope that this product will provide you a complete satisfaction.

We advise you to read this manual carefully prior to installation. Observance of the use and installation precautions in this document removes risks to the patient and for the care team. Please keep it with your equipment so that you can refer to it later.

Your intraoral camera is a new generation of digital imaging equipment with USB2 connection. With its ergonomic design and tailored shape, it enables you to obtain quickly and simply a perfect and clear image of the endobuccal cavities of your patients. This equipment does not involve backup on a flash memory card, so avoiding any loss of quality due to compression. Therefore, the USB2 connection enables images to be transferred and integrated directly into your image processing software, without even relying on an external power supply box or built-in battery.

1.1 Compliance with regulations

The **OwandyCam** unit is a class I medical system in accordance with European Directive 93/42/CEE relating to EC branding. It is also a class I type BF system under the terms of regulation EN/IEC60601-1.

The **OwandyCam** is, therefore in compliance with that directive and that regulation, as also with regulation EN/IEC60601-1-2 regarding electromagnetic compatibility.

Under certain conditions (see paragraph "1.3 Installation precautions") is necessary for any other components of the system connected (computer and optional peripherals) also to be in compliance with regulation CEI950 (EN60950) and that the installation is in compliance with regulation EN/IEC60601-1.

1.2 Power supply

The power supply for the handpiece which lights the 6 LEDs is assured via the USB connection linking it to the computer, i.e. by a 5V DC supply.

1.3 Installation precautions



The regulations require that your computer is at least in compliance with regulation CEI/EN60950-1. If you have a Class 1 computer, see that its earth is connected to the building's earth.

As the handpiece of the **OwandyCam** is located in the patient environment (less than 1.5 metres / 4.9 feet from the patient), it is imperative that your computer complies with regulation EN/CEI60601-1, or that your installation including the computer has been made compliant with regulation EN/CEI60601-1. When your whole installation is in compliance with regulation EN/CEI60601-1, you can then connect the box to your computer without further precautions being necessary.

If the computer is not located in the patient environment and is not in compliance with regulation EN/CEI60601-1, it is imperative to insulate the handpiece from the patient by placing it in a non-conducting envelope (hygienic covers).

1.4 Liability and operators

Installer: installation of the set requires computer equipment and software knowledge. For equipment and software installation, follow the recommendations and directions in the installation chapter.

User: the unit must be used by a dental practitioner.



In no event must the handpiece be opened by the user. Only the manufacturer is authorised to open it and carry out necessary repairs. Return the equipment to your distributor in the case of failure and/or if the documentation in your possession does not contain the information needed for the (authorised) maintenance of the failed part.

The manufacturer will not be liable in case of:

- interventions or repairs carried out by persons not authorised by the manufacturer or distributor and not included in the actions accepted,
- use of the unit with an installation that is not in compliance with the applicable regulations and decrees, in particular in cases of non-compliance with regulation EN/CEI60601-1-1 relating to the safety rules for electromedical systems. Ensure that the installation of the equipment is in compliance with the legislation in current effect,
- use other than that specified in this manual (use of the unit in normal conditions of use and in accordance with its original purpose).

1.5 Packaging and environment

Transport, storage and environment: the set is delivered to you in a packaging that guarantees its safety (protection against mechanical shocks and antistatic packaging). It must be stored under the following conditions:

Ambient temperature: +5°C to +68°C / 41°F to 154°F

Relative humidity: under 80%

Atmospheric pressure: 860hPa to 1060hPa

Operation: In accordance with international safety regulation EN/CEI60601-1 (section 2), the set was designed to respect the following operating conditions, in normal use:

Ambient temperature: +5°C to +68°C / 41°F to 154°F

Relative humidity: under 80%

Atmospheric pressure: 860hPa to 1060hPa

Packaging of equipment when returning to distributor: should it prove necessary to return the **OwandyCam** set to the distributor, take care to package it in its original packaging after carefully cleaning it.

Loss of documentation: every set is delivered with its own documentation. Should this documentation be lost, please contact your distributor in order to obtain replacement documentation.

1.6 Marking and labelling symbols

These symbols are used on the product labels, or the product itself, and inform you as to the component's compliance with the regulations and the technical specifications.

	Reference of the set		Serial number of the system
	Year of make of the system		Type BF equipment – under regulation EN/CEI 60601-1.
	CE marking certifies that this product is in compliance with European directive 93/42 CEE.		Important information: follow this manual's written instructions.



Equipment is subject to a selective collection in accordance with directive 2002/96/EC relating to electrical and electronic equipment waste (WEEE) and Decree 2005-829 of 20 July 2005 relating to the composition of electrical and electronic equipment and to the elimination of waste produced by this equipment (only in France).

2 Content

Your **OwandyCam** set is made of the following parts (illustrations not contractually binding):



Handpiece



Wall support with 2 fixing screws



One braided USB 2.0 cable (3m)



One bag of single-use, disposable hygienic covers



Installation CD-ROM
Imaging software CD-ROM (optional)



One installation and use manual

3 Installation

3.1 Precautions



The set must be handled with care, minimising twisting, pulling and bending of the USB cable connecting to the PC. Do not walk or drive over the cable. To disconnect the cable, do not pull on it but rather on the connector plug.



In order to avoid interference in the image, do not use the system in the presence of strong magnetic fields. Also avoid nearness to sources of electrostatic radiation.



Refer to paragraph “1.3 Installation precautions” to ensure the installation is in compliance with the regulations.

Install your imaging software before the installation of the drivers and utilities and the *OwandyCam* equipment set.

3.1.1 Minimum recommended configuration



Failure of the computer installations to meet the minimum configuration can prevent the proper operation or the start-up of your *OwandyCam* set. Check the specifications of your computer(s) before installation.

Operating systems	Windows 7, 8, 10 (32 and 64 bits)
Computer	Marked CE-CE1950
Motherboard	Intel Pentium III, 800MHz chipset and processor
USB port	USB 2.0 High-Speed compatible
Graphics card	DirectX 9.0 compatible
Monitor	1024x768 (15inch) high resolution
Random access memory (RAM)	256Mb
Hard disk	10Gb
CD-ROM reader	24x
Backup system	external/extractable disks, CD-ROM/DVD...
Printer	Laser, inkjet, thermal
Mouse and keyboard	
At capture station	<i>OwandyCam</i> set with appropriate drivers Imaging software

3.1.2 Equipment recommendations

The computer and screen with which the USB2.0 digital intraoral camera will be used, will preferably be located near the seat, in the practitioner’s field of view, in order to enable immediate use. Also provide a view for the patient so that he can share the imaging information.

The screen must be placed so as to avoid any reflection or direct light that could be detrimental to the display of the intraoral images. It must be regulated (for contrast and luminosity) so as to display contrasted, luminous and coloured images.

3.2 Software installation

Install the Owandy (or third party's) imaging software and check its proper operation before installing the equipment and its drivers. Refer to the software manual for the installation and configuration instructions.



You need administrator rights for the installation and use of the software and equipment. Consult your computer specialist for the creation of an appropriate user account.

3.2.1 Installation of drivers



The **OwandyCam** drivers are compatible with Windows 7, 9, 10 (32 or 64 bits) operating systems.

To install the drivers:

1. Insert the CD-ROM in the CD-ROM-driver or download the drivers on our website <http://www.owandy.com/support/>
2. Click on the **OwandyCam** icon and follow the instructions.



3.2.2 Drivers update

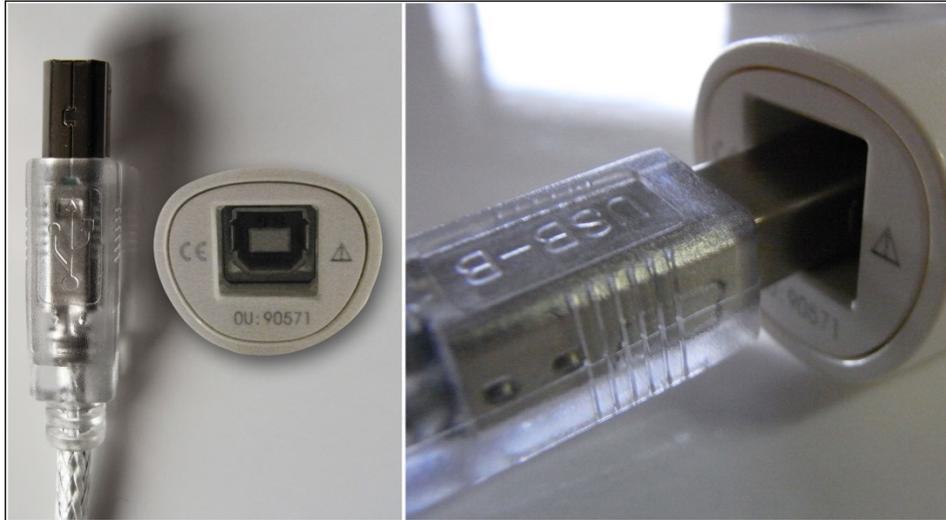
If you need to update your driver:

1. Insert the CD-ROM in the CD-ROM-driver or download the drivers on our website <http://www.owandy.com/support/>
2. Click on the **OwandyCam** icon and follow the instructions.

3.3 Equipment installation

3.3.1 Connecting the handpiece

The intraoral camera is connected directly to the braided USB 2.0 cable supplied in the kit, via its female socket located directly at the rear of the handpiece (see image below).

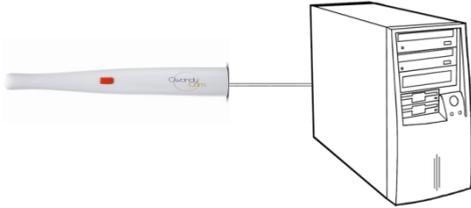


3.3.2 Connections to computer

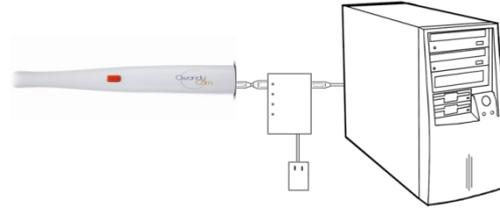
The cable so connected to the handpiece can be connected directly to your computer. Connect the plug of the USB 2.0 cable to one of your computer's available ports – do not exert force when inserting the plug as this could damage the connector (see image below).



If the distance between the camera body and the computer is greater than the 3 metres of USB cable supplied with the set, it is possible to add longer USB cables, by using a powered USB hub between each cable.



Connection without USB2.0 hub



Connection with powered USB2.0 hub



The computer's USB port must be a USB 2.0 port. Only use USB 2.0 cables and hubs with a USB 2.0 port and ensure that the hub has its own external power supply (do not use a hub that is self-supplied by the USB cable). No USB cable may exceed 5 metres / 16.3 feet in length.



Check the correct connection of the handpiece by pressing the camera's general switch. If the LEDs light up, the camera is correctly supplied.

3.3.3 Wall support

The **OwandyCam** can be placed on the support delivered with the set. The support can take the handpiece alone or connected to its USB2.0 cable.



Do not fix this wall support the wrong way round or horizontally, as the camera could fall to the floor and be damaged.

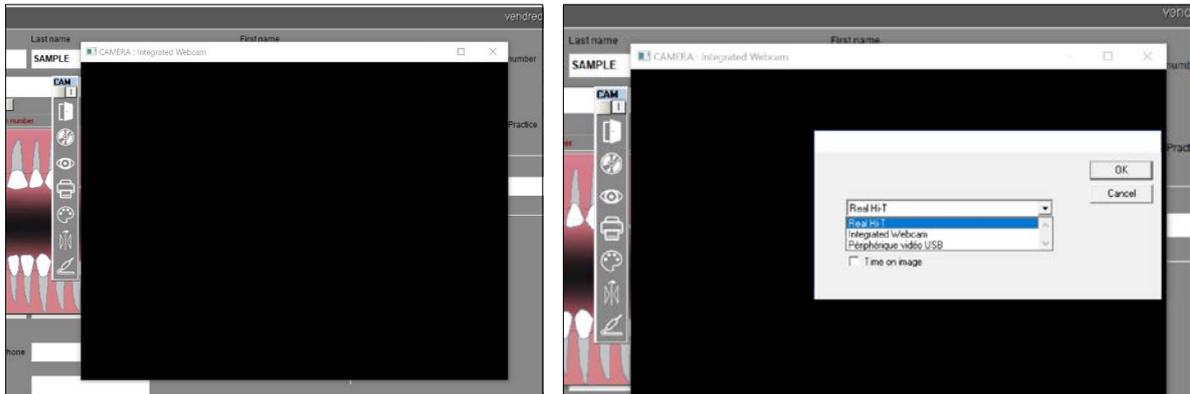
Attach the support with the screws: you can fix the support permanently to a working surface using the screws delivered in the set. Depending on the material of the support you can use plugs or make holes in advance, spaced 20 mm. apart along the vertical axis.



3.4 Configuration in the Owandy imaging software

In order to use correctly your set, you must configure your equipment in the following manner, after starting up it, in case of the use under **Quickvision**:

1. Start up the imaging software (double click on the desk icon or use the link under "**Start/All programs/Owandy/QuickVision**").
2. In the main menu bar, click on the "**Mouth or Imaging**" button.
3. Click on "**Camera**" icon  from the dental regime module.
4. Right-Click on the window opened and select the "**Périphérique vidéo USB**" model by the drop-down menu.



Your **OwandyCam** set is now ready to be used (see 4.3.2 "Use of Owandy software").

3.5 Sharing handpiece between different workstations

Sharing **OwandyCam** enables one or more handpieces to be used in turn in a practice equipped with more than one seat. It is recommended to link the various workstations in a network in order to allow the central storage and sharing of images.

The **OwandyCam** set can be shared between different workstations, by moving only the handpiece from station to station. A USB cable must be provided at each computer workstation.

Windows will automatically recognise the equipment when it is connected and it will be available immediately for image capture.

In order to allow sharing of one set between different workstations, it is necessary first to install the imaging software that enables image capture, the drivers on all the computers on which the **OwandyCam** is to be used.

4 Use

4.1 Precautions



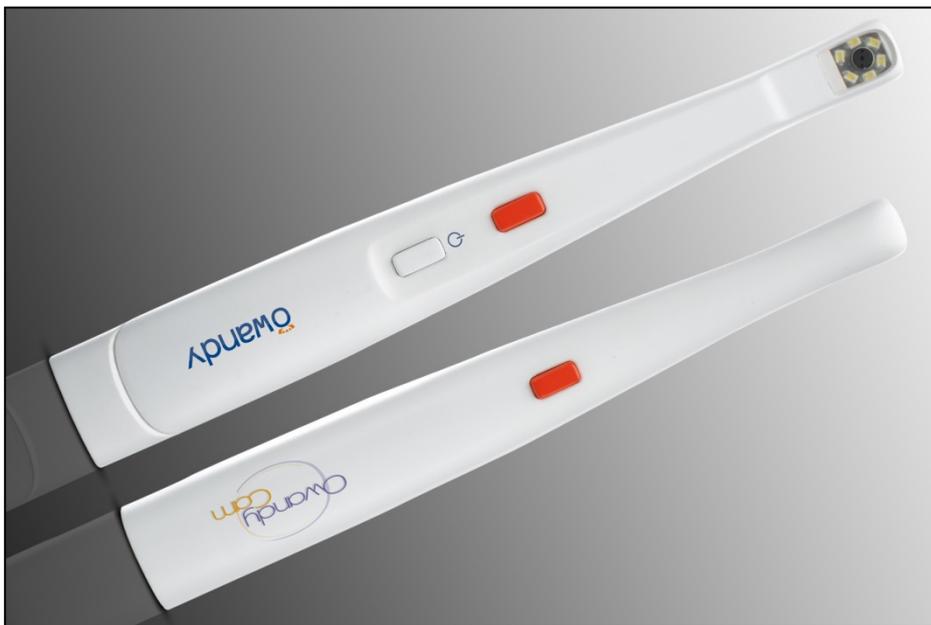
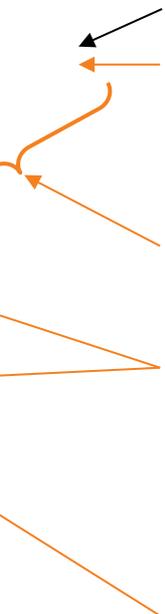
The set must be handled with care, minimising twisting, pulling and bending of the connecting cables. Do not walk or drive over the cable.



Although the camera is shock-resistant, it is strongly recommended not to drop it on the floor. In the event of a physical shock which might somehow occur, contact your distributor and do not try to take any action yourself.

4.2 Buttons on the handpiece

You will find below a description of all the actuators provided on the **OwandyCam** set's handpiece.



6 white light LEDs

Focus-free lens

Endoscope section

Image capture buttons

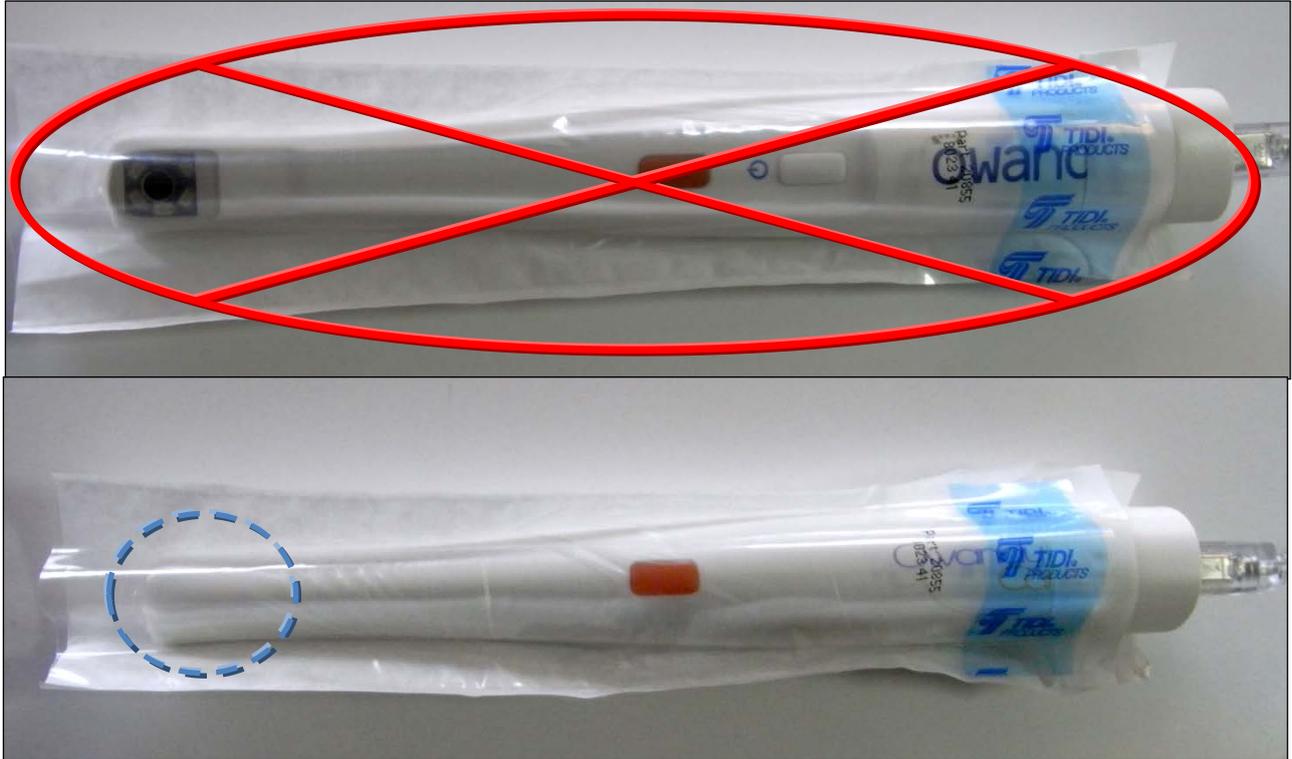
LEDs On/Off Button

4.3 Capturing an image

4.3.1 Preparing the handpiece

In order to record an intraoral image, you must first proceed according to the following methodology:

1. First start up your computer and your imaging software.
2. Connect the USB cable to your computer's configured port and then to the handpiece.
3. Insert the handpiece into the case composed of the hygienic cover and its packaging. The lens of the endoscope should be facing the white peel-off paper. Then pull on the blue strip to tear the packaging while keeping the hygienic cover in place on the handpiece.



In order to avoid any opaque or blurred fogging on the image, make sure that the transparent part of the hygienic cover is perfectly tight on the lens and the 6 LEDs on the handpiece's endoscope. If necessary readjust the positioning of the cover by stretching the transparent plastic over the head of the endoscope.

4. You are now ready to examine. The camera can then be positioned manually in front of the patient's teeth or in his endobuccal cavity.

4.3.2 Use of the Owandy software

Modes of operation

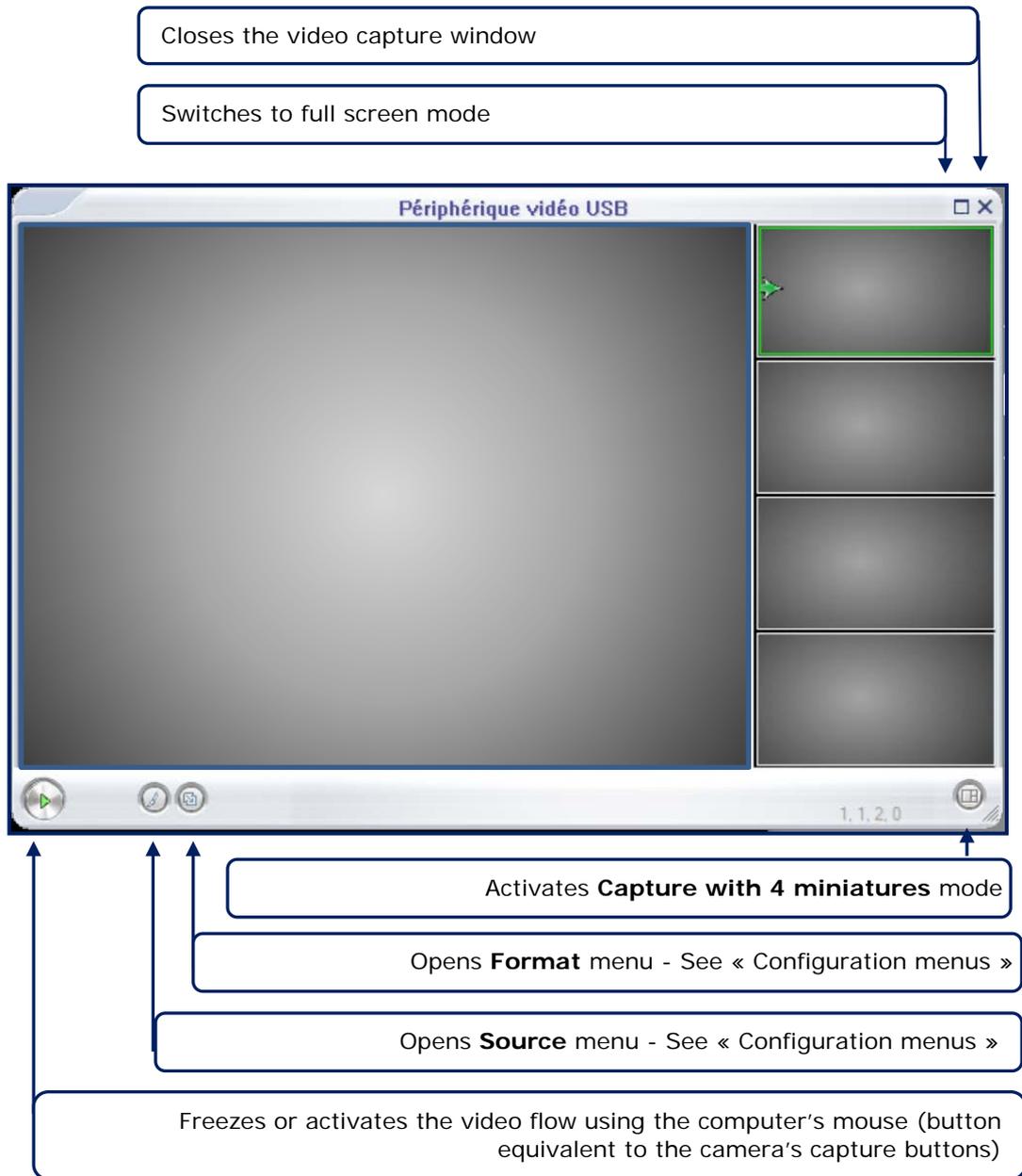
The **OwandyCam** set can operate according to two methods:

- By the **Twain protocol**: select the “**OwandyCam USB**” driver under the TWAIN capture option in your imaging software. Then run the desired TWAIN capture.
- By the **Owandy imaging software**: click on the “**Camera**” icon from the dental regime module. Then click on the “**Video**” icon from the toolbar “**CAM**” that has just been opened, to launch the camera video window.

Icons	Description
	Icon “ Camera ”: launch the image capture interface with camera, from the dental regime module.
	Toolbar “ CAM ”: include the tools linked to the images capture with a camera: <ul style="list-style-type: none"> • Exit of the menu, • Save an image, • Image information, • Print an image, • Tools of cosmetics module. • Horizontal and vertical symmetries, • Video camera.
	Icon “ Video ”: activate the video camera window.

Camera Video Windows

On clicking on the aforementioned icon, the simple video capture window opens. You then have access to the functions described below:



By clicking on the appropriate icon, you will be able to use the **Video with 4 miniatures mode** shown below:



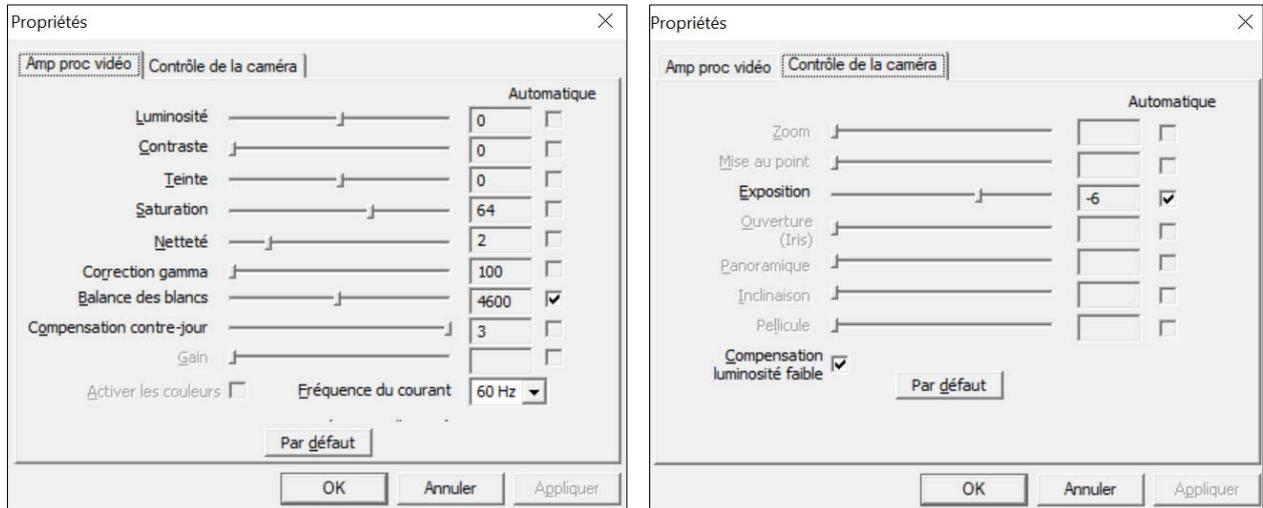
You will then be able to freeze 4 miniatures while keeping video active. A green marker (frame+arrow) indicates on which miniature the next image captured will be recorded; if an image is already entered on it, the new image captured will replace it. When your intraoral imagery session has ended, you will then be able, by clicking on the following cursor, , to select which images you want to keep and export to your imaging software.



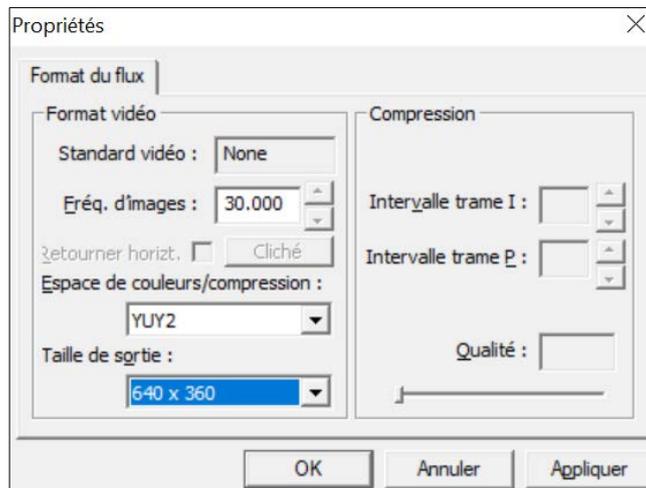
When an image is captured and replaces a miniature already selected, the latter is definitively removed from your capture database and cannot be recovered to export it to your imaging software.

Configuration menus

The **source menu** gives you access to all the imaging adjustments shown in the 2 tabs below. In particular, you will be able to adjust the luminosity and contrast of your image, and also its sharpness by software correction. The symmetries and rotations of the video image can also be modified: in this way you will more easily adapt the movements of the camera to your way of working.



The **format menu** specifically gives you access to image resolution adjustment (from 160x120px up to 1280x1024px). The more you increase the resolution of your image, the more the size of the file so generated will increase, and the more the image flow frequency will decrease.



5 Hygiene and maintenance

5.1 Hygiene and disinfection

5.1.1 Cable

The cable does not require any particular maintenance; it must be cleaned with a rag and non-abrasive detergents.

5.1.2 Handpiece

In order to avoid any contamination between patients, it is imperative to use single-use biocompatible hygienic covers (approved by the FDA for the USA, and marked CE for Europe). Hygienic covers suitable for your country are delivered with each set.

To do this, insert the handpiece directly into the bag containing the hygienic cover (cf. 4.1 Installation precautions).

After each use on a patient, the hygienic cover used must be disposed of with the dental practice's other biologically dangerous waste. Even with the use of these hygienic covers, the head of the camera must be decontaminated at least once a day using wet wipes or cleaning products suitable for disinfecting non-immersible devices. You can also use a non-fluffy rag lightly moistened with medical alcohol.



- **The handpiece must not be immersed in a liquid solution or the device could be destroyed: the degree of water resistance of the camera's endoscope was not designed for this purpose.**
- **As the handpiece is composed of an electronic card and plastic casings, it must not be decontaminated by hot sterilisation or it may be destroyed.**

Covers validated for North America: BANTA HEALTHCARE or TIDI PRODUCTS radiological sensor covers and STERI-SHIELD PRODUCTS RS covers.

5.2 Maintenance

5.2.1 Handpiece and cable

Before each use, check that the lens is clean. If it is not, clean it with a moist non-fluffy rag or a special optical paper.



Make sure not to use a dry tissue or rough paper to clean the lens: you will risk scratching it irreversibly.

Periodically check the good condition of the connections between the USB cable and the female socket fixed to the base of the handset. The connecting socket must not show any play in relation to the plastic joining part.

Also check periodically the proper operation of the handpiece's LEDs On/Off button, the working of the 6 white light LEDs, and the correct independent use of the 2 image capture buttons (the diametrically opposite orange buttons).

5.2.2 Protection of computer data

Your patient and image databases must be subject to a regular backup in order to be able to recover them if the need should arise (damage to hard disk or computer). Ask your computer retailer for advice as to the most suitable backup system for your computer configuration (external or extractable disk, Zip or Jaz system, CD-ROM or DVD writer, etc.). Test and store copies in a safe place.

6 Troubleshooting

If a problem arises during use, check the points in this quick troubleshooting guide. If you do not manage to solve your problem, consult your retailer.

6.1 General

Symptom	Cause / Solution
The LEDs do not light up when you press the handpiece's On/Off button	<ul style="list-style-type: none"> Check that the USB cable's connectors are correctly inserted.
There is no automatic equipment recognition response when you insert the USB cable into the computer's connector.	<ul style="list-style-type: none"> Check that the handpiece is switched on (LEDs lit): if necessary press the camera's LEDs On/Off button. Re-insert the USB cable into the computer's connector. Disconnect the cable, restart your computer and then try connecting again.
Images cannot be frozen.	<ul style="list-style-type: none"> Check that the USB cable's connectors are correctly inserted. Check the installation and redo if necessary, proceeding in the following strict sequence: first install the driver via OSP, then connect and switch on the camera via the USB cable. Restart your computer after installing the driver and imaging software in order to complete the installation of the files correctly.
Images are not clear.	<ul style="list-style-type: none"> To re-adjust the image parameters, see paragraph 6.2 below. Position the camera stably: using a firm base avoids superfluous movement. Check that the hygienic cover has not been placed the wrong way round: with the opaque area covering the display lens
The computer displays images showing black marks.	<ul style="list-style-type: none"> Check your computer's screen to determine whether the black marks result from a fault in it. If necessary, change it. Clean the camera lens gently. If necessary contact your retailer or computer specialist.

6.2 Image quality

Symptom	Cause / Solution
<p>Images are too light, for example:</p> 	<ul style="list-style-type: none"> Readjust the “luminosity” parameter in the “properties” tab of the camera video window’s source menu.
<p>Images lack contrast, for example:</p> 	<ul style="list-style-type: none"> Readjust the “contrast” parameter in the “properties” tab of the camera video window’s source menu.
<p>Images are pale, for example:</p> 	<ul style="list-style-type: none"> Readjust the “saturation” parameter in the “properties” tab of the camera video window’s source menu. You can also adjust the “tone” parameter to strengthen certain colours in particular in relation to others.
<p>Image is blurred.</p> 	<p>Retake the image:</p> <ul style="list-style-type: none"> The patient or the operator moved during exposure. The positioning of the camera in relation to the subject you want to capture is located outside the field of sharpness. Readjust the “sharpness” parameter in the “properties” tab of the camera video window’s source menu. Check that the hygienic cover has not been installed the wrong way round on the head of the endoscope: refer to chap. 4.3.1.

7 Specifications

Handpieces

External dimensions of handpiece:	197 x 28 x 26mm / 7.8 x 1.1 x 1.0inches Thickness of end of endoscope 13mm / 0.5inch
Weight of handpiece alone	80 grams
Sensor	CMOS ¼" colour, 1.3M pixels Resolution ≥9.36lp/mm Image resolution: 1280x720 pixels at 30images/sec 1280x1024 pixels at 10images/sec
Lighting	6 white light LEDs, ≥500Lux
Focus	Focus-free wide-angle lens Depth of field:5 to 35mm Angle of view: 80° +/- 5%
Freeze frame:	By two diametrically opposite push buttons

Technical specifications

Connection	USB standard: USB 2.0 High-Speed (480Mbit/s)
Power consumption of set	2.5 W max.
Input voltage of handpiece Input current of handpiece	5V (via USB connection) 0.5 A max.
Use temperature	+5°C to +68°C / 41°F to 154°F
Atmospheric pressure for use	860hPa to 1060hPa
Humidity for use	≤80%

Regulations

Compliance with regulations	NF EN/CEI60601-1 NF EN/CEI60601-1-2
-----------------------------	--

8 Accessories



Disposable, single-use hygienic covers (for handpieces)

7835000500 Bag of 20



USB 2.0 Cable

7758000700 3m / 9.8foot cable

This page is intentionally left blank for your notes:

TECHNICAL SPECIFICATIONS

Image: ¼ inch CMOS sensor

Format: Up to 1280x1024 pixels at 10 images per second, up to 1280x720 pixels at 30 images per second.

Focus-Free: Wide angle lens, depth of field macro from one tooth to full smile

Angle of view: 90 °

Lighting: 6 integrated, high-luminosity white LEDs

Freeze frame: By two independent, diametrically opposite buttons

Video interface: High-speed USB 2.0.

External power supply: None (via USB connection)

Software: 100% QuickVision integrated

Handpiece dimensions: L214xW27xH24mm

EC compliance: Class 1 device according to directive 93/42/EC

Standards: Class 1 type BF device according to EN 60601-1 and electromagnetic compatibility according to EN 60601-1-2.

Accessories: Wall support, USB cable, hygiene protection kit, installation manual and QuickVision imaging software



Owandy Radiology is an internationally-recognised manufacturer of dental radiology systems and developer of imaging software. Its software is currently used by almost half of the dental practitioners in France and its range of digital imaging solutions is made available to dentists in more than 50 countries worldwide. In addition to its products and services, **Owandy Radiology** strives to contribute to the improvement of oral health and patients' well-being. As a committed and innovative company, **Owandy Radiology** has been a partner of choice for dentists for more than 20 years.

Dealer's stamp

Owandy Radiology

2 rue des Vieilles Vignes
77183 Croissy-Beaubourg
FRANCE
Tel.: +33 (0)1 64 11 18 18
Fax: +33 (0)1 64 11 18 10
info@owandy.com
www.owandy.com

<https://stomshop.pro>



SOFTWARE
DIGITAL SENSORS
20 - 30 PANORAMICS
INTRAORAL RADIOLOGY
CAMERAS

001100
111000
001100

BR_OWANDYCAM_EN_REV00