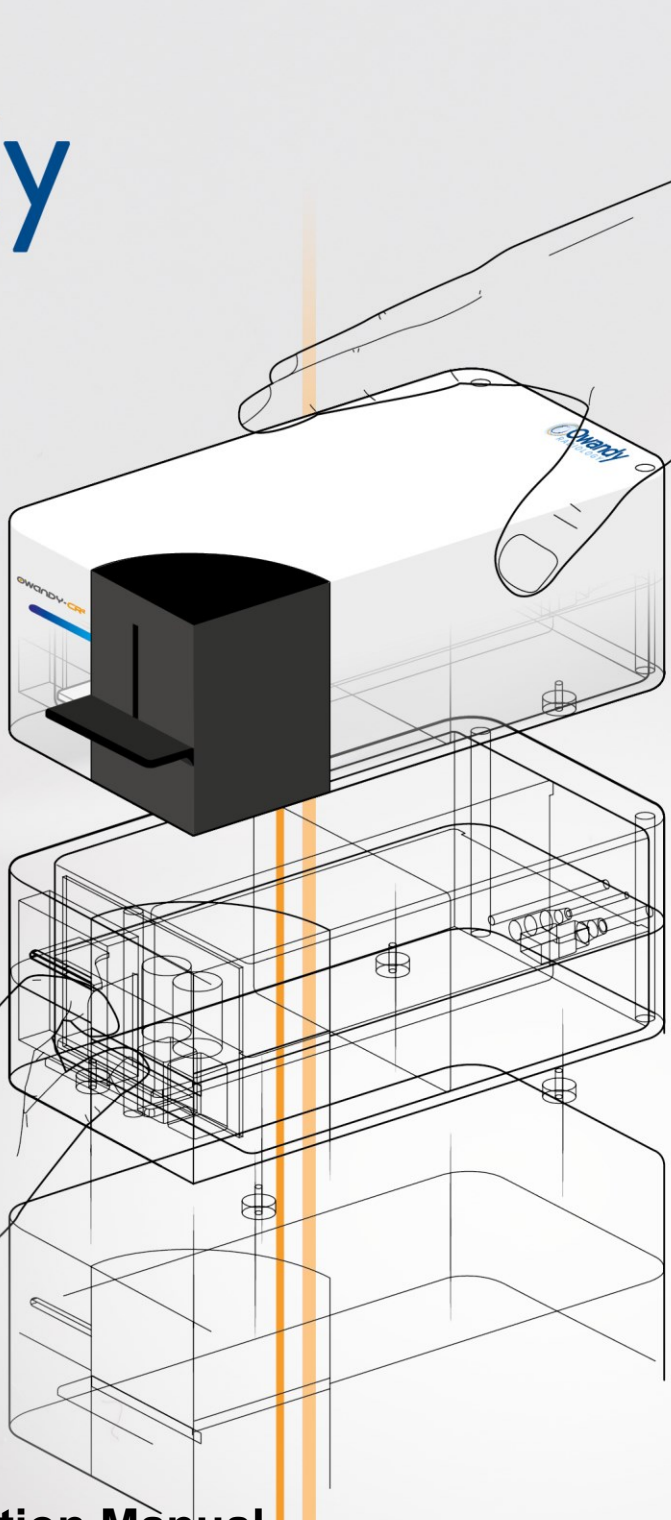
Owandy RADIOLOGY



EN • User and Installation Manual

NOCREN010D • June 2024

OWANDY-CR²

INTRAORAL IMAGING PLATE SCANNER

SO COMPACT, YET SO EFFECTIVE...

Revision history Manual code NOCREN010D

Rev.	Date	Page/s	Modification description
00	16.05.2017	--	First release
01	14.09.2017	--	New logo Owandy-CR²
02	09.10.2018	--	Ethernet / USB version
C	05/2021		New reference, new installation window
0D	06/2024		New configuration of the Owandy-CR for the Ethernet version

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CE 0051

Year CE marking assigned: 2015

1. INTRODUCTION

Thank you for choosing **OWANDY RADIOLOGY**; we feel confident that the performances of this device can meet your requirements and can be fully satisfactory.

The present guide contains a detailed description of all operating instructions and procedures for a correct use of the system, as well as all specifications relating to digital image treatment.

We are in any case at your complete disposal for any additional information you may require, as well as for any suggestion aimed at an improvement in the device performance or in the service landed.

The development process of conventional films is, with this new scanning unit, completely eliminated as well as the possible influences on image quality; such as the type and age of the chemical product, the temperature of the baths or the development tim

You can use 4 different plates sizes with your scanner unit : size 0, size 1, size 2 and size 3 intra-oral plates.

The instructions and information in this manual refer to both plates sizes, unless specifically stated. The size of the plate is marked on the plate itself.

1.1. Purpose of the guide

The present manual is aimed at supplying the following instructions:

- general knowledge of the system
- correct installation
- safe, correct and efficient use of the equipment
- general technical data
- maintenance procedures
- analysis of possible problems and their solution.

1.2. Symbols used in the guide

NOTE
Pay close attention when reading the topics identified by such symbol.

WARNING
Possible danger to overall equipment. Act in accordance with the procedures indicated in the guide, in order to prevent possible damage to materials, equipment and/or properties.

DANGER
Possible danger to people.
Act in accordance with the procedures indicated in the manual, in order to prevent possible damage to patient and/or operator.

The device components must be disposed of in compliance with the EEC regulation N° 2011/65.

1.3. Applicable EEC regulations

The system described in this manual was designed and manufactured in compliance with the highest safety standards, and is not dangerous to the operator when utilized according to the instructions herein described. The device was manufactured in compliance with the Medical Device Directive MDD 93/42 in IIa class (Ann.IX – Rule 16).

The symbol CE 0051 presents on the relevant documentations certify this conformity.

1.4. Intended purpose

Owandy-CR² is exclusively aimed at the acquisition, storage and treatment of intra-oral digital images.

The phosphor plates are exposed to X-ray, so the device must be used solely by qualified personnel with the necessary competence in matter of X-ray protection.

During the X-ray exposure all safety exposure factors must be observed and appropriate cautions must be taken during X-ray emission, in order to avoid possible damages to patient and/or operator.

WARNING

The equipment must be used solely by qualified personnel. Unauthorized or untrained people are strictly forbidden to use or handle the system.
The device must not be used for purposes different from the ones indicated in the present manual.

NOTE

All information contained in the present manual is subject to variation without prior notice.
OWANDY RADIOLOGY does not take any responsibility for direct, indirect, accidental damages which are consequent or relating to the supply or use of this information.
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2. SAFETY ASPECTS

The device must always be used in accordance with the procedures explained in the present manual, and shall never be used for purposes other than those it was designed for.

WARNING

The user is responsible for the fulfillment of the legal requirements regulating the handling of the equipment. In case of incorrect use and/or maintenance, the manufacturer will not take any responsibility for possible breaking, malfunctioning, damage or injury to equipment and/or people.

WARNING

Do not modify this equipment without authorization of the manufacturer.

2.1. General warnings

In order to prevent unsafe situations, with possible consequent damage or injury to the equipment or people, the following cautions must be taken:

- Read carefully the procedures described in the present manual
- The system must be connected to an EN 60601-1 approved power supply which must be connected to ground.
- Make preliminary tests on phosphor plate using the device on image phantom, before acquiring images on patients
- Apply the regulations in matter of X-ray protection, as described in par.2.2
- Don’t use the device at a distance less than 3 m from devices offering no protection from electromagnetic fields
- Don’t use flammable liquids near the device
- Don't pour any kind of liquids onto the device.
- Don’t use the device in presence of gas or explosive or inflammable vapors
- Don’t use the system when working with electronic cutters or similar devices nearby
- Always check, before powering the system on, that all cables are in perfect conditions
- Use and keep the device in places protected by dust and humidity:
    - Humidity within a range from 30% to 75%
    - Temperature within a range from 10°C and 40°C
- Any technical intervention on the system must be performed only by qualified personnel authorized by the manufacturer
- Use only original accessories supplied by the manufacturer: including phoshor plates and power supply. Don’t connect components not compatible with the system

WARNING

The manufacturer will not take any responsibility in case of non -fulfillment of the above indicated procedures.

2.2. X-ray cautions

The phosphor plate used with **Owandy-CR²** system is used jointly with an intra-oral X-ray system. The operator during exposure must take all the appropriate x-ray precautions and protections to prevent damage to himself and the patient.

DANGER
Protection to x-rays is subject to government regulation.
Only authorized operators having deep specific knowledge of regulations and standards are allowed to use the device.
Non-fulfillment of the procedures indicated below may cause damage to the operator's health.

- During the exposure, make sure no one except the patient is present in the X-ray area. The operator must work at a distance of at least 3 m from the x-ray source.
- Use, whenever possible, lead aprons and thyroid guards to protect the patient.
- The phosphor plate, with or without support, must be held in the correct position by the patient or by proper support devices.
- The frame plate is only used to see the picture and the DICOM is only used to archive the picture not to make diagnosis or change the x-ray dose or focus.

2.3. Electrical safety

Owandy-CR² has been designed in compliance with all regulations regarding electrical safety. While using the system always follow the security precautions here below:

- To reduce the electric shock risk:
    - Do not put containers with liquids near the system
    - Do not force or open the PC or the equipment connected to it

WARNING
Only personnel authorized by OWANDY RADIOLOGY are allowed to repair the electrical device.
The incorrect reassembly of the devices may cause risk of electrical shock.

- Use only the provided original cables and accessories supplied with the system. The use of accessories not supplied by **OWANDY RADIOLOGY** may cause fires, electrical shocks, or accidents. It may also void the warranty.
- Verify that the values shown on the voltage label are the same at the installation site.
- Verify that all the cables are connected correctly. Never pull a connector out while device is being used. Avoid any excessive voltage on the cable.
- Before making the connection to the system verify that the power cable is connected and grounded according to your electrical safety codes.
- Never disconnect any cable while the system is working.
- Place the system (and its components) in a way to grant an ergonomic use. If necessary, to optimize the ergonomics, consult **OWANDY RADIOLOGY** qualified personnel.

The device must be powered with a power supply with following features

1. Conformity to IEC/EN 60601 third edition
2. Power 24 W
3. Output Voltage 24V dc
4. Output current 1 A
5. Frequency of output current 50/60 Hz

WARNING

The Owandy-CR² is supplied by OWANDY RADIOLOGY with the parts designed and developed by the manufacturer itself.
The support devices to the system, such as PC, developer or others, are at customer's choice, he has to check that those devices for electrical safety are in compliance with the EN60601-1 standard.

To guarantee the total electrical safety it is recommended the connection of all the system devices through a power strip connected to an isolated transformer, furthermore, this power strip should not be used to feed any other device different from the **Owandy-CR²**.

2.4. EMC compatibility advertising

The **Owandy-CR²** has been designed and realized in accordance with the regulation of EN 60601-1-2 standard:

"Electro-medical devices – Part 1: General safety standards- 2 Collateral standard: Electromagnetic compatibility- Regulations and tests" and is in compliance with it.

Nevertheless, it is not guaranteed that in any particular installation interference may not arise.

The **Owandy-CR²**, as a medical device, needs particular precautions as electromagnetic compatibility is concerned and has to be installed and used according to the information given in the technical manual.

WARNING

The Owandy-CR² can be used in an electromagnetic environment as specified here below, it is the user's responsibility to observe the specifications.

Electromagnetic emissions.
Manufacturer's guide and declaration.

Emission test	Limits	Guide to the electromagnetic environment
Irradiated emission /Conducted CISPR11	Group 1	The system uses RF energy only for its inner function. So, its RF emissions are very low and do not cause any interference near any electrical device.
Irradiated emission /Conducted EN55011 - CISPR11	Class [B]	The system is suitable to be used in every environment, including the domestic ones and the ones directly connected to the public distribution net which gives power supply to environment used for domestics purposes.
Harmonic IEC/EN 61000-3-2	Class [A]	Not applicable
Voltage fluctuation / flicker IEC/EN 61000-3-3	[Fulfill]	Not applicable
Electrostatic discharge (ESD) IEC/EN61000-4-2	±6kV contact ±8kV in air	Pass
Radiated RF electromagnetic Fields IEC/EN 61000-4-3	80 MHz÷2500MHz	Pass
Fast transient/burst IEC/EN61000-4-4	±2kV supply	The power supply should be the one of a commercial or hospital environment.
Surge IEC/EN61000-4-5	±2kV common mode ±1kV differential mode	Not applicable
Conducted immunity IEC/EN61000-4-6	3Vrms 150kHz a 80MHz (for not life-supporting device)	Pass

To make the device work properly and provide the required performances it is necessary to pay maximum attention to the below instructions.

- Portable and mobile radio communications equipment (such as mobile phone, cordless units, walkie-talkie) may influence the functioning of the device, do not use these units near the system.
- Electrical equipment (such as: TV, loudspeakers, microwaves ovens etc) may be source of noise. To avoid these risks it is strongly recommended the use of this device at an adequate distance from the other equipment. In the event the system has to be used near other electrical units, verify that no anomalous operation occurs.
- Avoid the contact of the metallic part of the USB/LAN connectors with any part of the body.
- Before making any USB/Ethernet connection, perform the ESD precautionary procedures: In case, discharge the static electricity stored by grounding.
- Always connect or disconnect the system when device is off.
- Use only the cables supplied by the manufacturer. The use of different cables may cause the increase of emissions or a decrease in sterility.

2.5. Infection risks

As provided by the regulations in force, operators and patients must be protected from infections coming from contact with blood (HIV, hepatitis, etc.).

Maintenance and cleaning instructions described in the present manual must be strictly followed, in order to reduce the above mentioned infection risks. Besides, all the standards of personnel safety, indicated by the officer responsible for the Emergency Medical Service, must be followed.

In detail always protect plates with dedicated disposable caps before to insert into the patient mouth.

The plastic enclosure of frame plate is a single used part and is to change from patient to patient. At the exam end throw out the cap that never must be re-used.

2.6. Environmental risks and disposal

Some of **Owandy-CR²** components contain materials that, at the end of the equipment life cycle, must be disposed of at the recycling centers appointed by the Local Health Units. In particular, the system contains the following materials and/or components:

- **Phosphor plate:** Plastics, phosphor coating.
- **Scanner unit:** Plastics, iron, and copper.

WARNING

INFORMATION TO USERS SUBJECT TO EEC REGULATIONS: in compliance with Directives 2012/19/EU (WEEE) and 2011/65/EU (Rohs) about the reduction in use of dangerous materials in electric and electronic devices, as well as about waste material disposal"

The symbol of a crossed waste box printed on a device or on its package indicates that the product, at the end of its life-cycle, must be separately disposed of.
The differentiate collection of the system is being organized and managed by the manufacturer himself. Therefore, the user who intends to get rid of such device must get in touch with the manufacturer and follow the procedure adopted by the same.
A proper differentiate collection and the subsequent destination to recycling, treatment or disposal, prevents any possible environmental impact and promotes at the same time the re-employment and/or recycling of the materials the device is made of.
An abusive disposal of such materials by the user will cause the pursuance of the administrative sanctions provided for by law.

2.7. Laser Risk

The **Owandy-CR²** uses a 30mW laser diode to scan the phosphor image plate exposed to an x-ray.

LASER (Light Amplification by Stimulated Emission of Radiation) is included in the source of non-ionized radiation. The ionized radiation emitted is coherent, aimed, and very intense.

The directive CEI-EN 60825-1 defines the laser as" any device that produces or amplifies electromagnetic radiation in a coherent manner which includes a wave lengths from 180nm to 1mm by means of a stimulated emission. In reference to this directive the **Owandy-CR²** is part of Laser class 3B.

A laser in class 3B can be potentially dangerous if the ray is reflected into the eyes by a mirror, watch, a ring etc. The warning label below is affixed to the **Owandy-CR²** to indicate a laser in class 3B is mounted internally and caution is advised:

CAUTION – CLASS 3B LASER RADIATION WHEN OPEN

- AVOID EXPOSURE TO BEAM

ATTENZIONE – RADIAZIONE LASER DI CLASSE 3B QUANDO APERTO

- EVITARE L'ESPOSIZIONE AL RAGGIO

3. SYSTEM COMPOSITION

The Owandy-CR² is delivered with the following components:

- OWANDY CR 2 reader
- Power Supply
- 2.0 USB cable or RJ45 Ethernet cable
- USB key (drivers, diagnostic tools, QuickVision software)
- Starter kit (2 plates size 0 + 2 plates size 2 + 10 paper protections + 50 hygienic single-use protection sleeves).

Always protect plates with dedicated disposable plastic sleeves before inserting the plates into the patient mouth. Suitable disposable sleeves are supplied with the unit's starter kit and can be re-ordered as consumable accessories.

After the opening of the box perform following checks:

- the system matches with purchase specification

- all parts are present and do not suffered any damage

WARNING

Do not use the device in case of damaged or missing parts. Danger of cross contamination or loss of performance

3.1. Environmental conditions

The system must be kept in a closed, dry and clean place. For a proper functioning of the system, the following environmental conditions must be ensured:

- **Temperature of the scan reader:** from +10° C to +40° C
- **Temperature of the PSP:** from +15° C to +34° C
- **Humidity:** from 30% to 75%
- **Pressure:** from 700 hPa to 1060 hPa

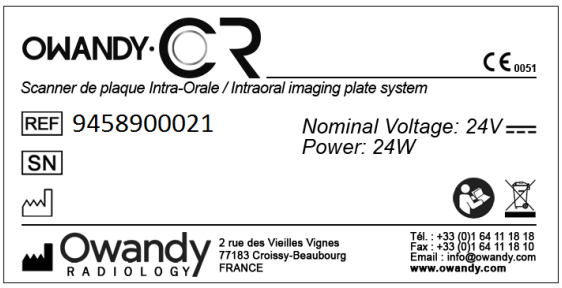
The system can be moved or stocked within a range of environmental limits as indicated below:

- **Temperature:** from -20° C to +60° C
- **Humidity:** ≤ 95% no condensate
- **Atmospheric pressure:** from 50 to 106 kPa

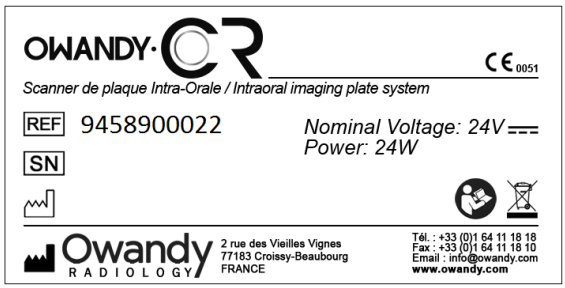
4. LABELING

Owandy-CR² identification label presents on the bottom side:

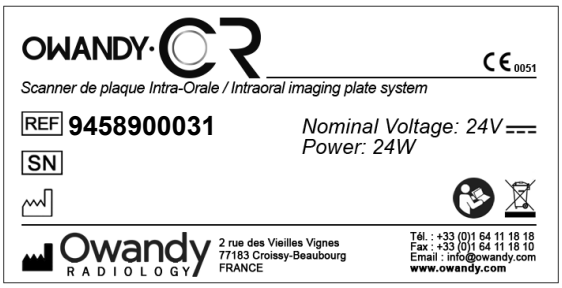
USB / EU version



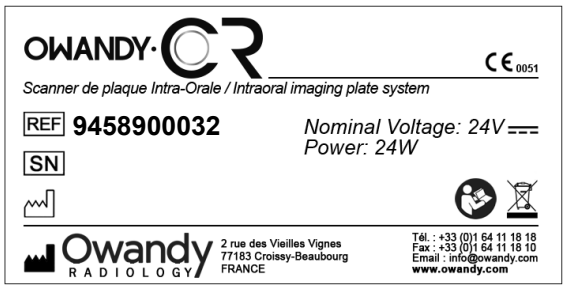
USB / USA version



Ethernet / EU version



Ethernet / USA version

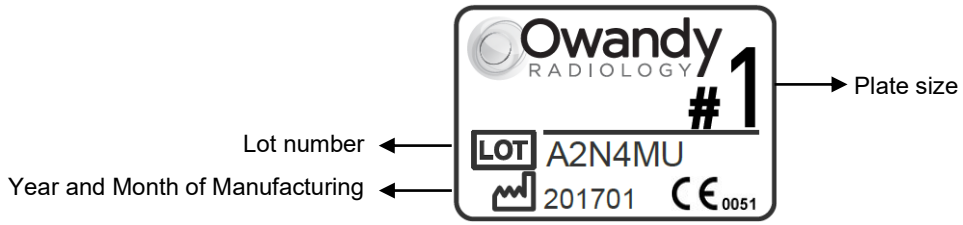


Symbols present on labels have the following meaning:

⎓	Direct current		Important information: follow the instructions printed in this manual
CE 0051	The CE marking certifies that this product complies with European directive 93/42 CEE		Manufacturer designation
REF SN	Product reference Product serial number (year and month)		Manufacturing date

Equipment subject to a selective collection in accordance with Directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

Phosphor plates are labelled as described below:



5. INTRODUCTION TO THE SYSTEM

Owandy-CR² is the latest **OWANDY RADIOLOGY** device used for the acquisition and processing of digital intra-oral images. It is the newest unit generation based on a Windows platform, with a great modularity.

In case the customer uses their own PC, it is necessary to check that its technical features meet or surpass with the ones described in the present chapter (see paragraph 5.2.1) to allow the system correct functioning.

Owandy-CR² is designed to offer a large range of options and meet different requirements.

Owandy-CR² is the best system for professionals who demand maximum quality in X- ray digital imaging.

5.1. Initial check

Remove the system from its original packaging and check that the system configuration supplied correspond to the one specified in your order. Please refer the information indicated in paragraph 3.1.

5.2. General features

Owandy-CR² is a digital image acquisition and processing device that can read different phosphor intra-oral plates. The system can scan 4 different sized plates:

- Size 0 – 31x22 mm (726x1024 pixel)
- Size 1 – 40x24 mm (792x1321 pixel)
- Size 2 – 41x31 mm (1024x1352 pixel)
- Size 3 – 54x27 mm (891x1783 pixel)

5.3. System PC Recommended minimal configuration

PC on which **Owandy-CR²** will be installed and all the relating peripheral devices must match the accessory equipment requisites, as indicated in the IEC 60601-1.

Any computer configuration that does not comply with the minimal recommended configuration can prevent the starting or proper functioning of the unit. Verify the specifications of the computer(s) before the installation.

Operating system	Windows 10 (32 and 64 bits)
Computer Motherboard USB port Ethernet port	Compliant CE-IEC60950 Intel 1.4GHz chipset and processor USB 2.0 or 3.0 High-Speed (recommended) 10/100/1000
Graphics card Monitor	128MB High resolution 1280x1024 (17 or 19 inch)
RAM memory Hard disk	> 1 GB > 100 GB
CD-ROM drive Backup system	24x External/removable disk, Zip or Jaz system, CD-ROM/DVD…
Printer Keyboard and mouse	Laser, inkjet, thermal

5.4. Technical features

Owandy-CR² scanner model

Certification and class	MDD 93/42 – Ann. IX Rule16: Classification IIa
Spot Size	30 µm
A/D Conversion	16 bit input
Power supply	24 V ±10%
Current absorbed	1 A
Power absorbed	24 W
Dimensions and weight of the unit • Weight: • Height: • Depth: • Width:	 4,25 kg 104 mm 286 mm 151 mm

Intra-oral phosphor plates

Certification and class	MDD 93/42 – Ann. IX Rule16: Classification IIa
External dimensions of each plate • Size 0: • Size 1: • Size 2: • Size 3:	 22x31 mm 24x40 mm 31x41 mm 27x54 mm
Phosphor composition	BaSrFBr:Eu
Luminescence	400 nm
Readout	Within 1h after exposure
Packaged temperature	<34° C (93°F)
Not packaged temperature	15+34° C (59+93° F)

6. INSTALLATION

6.1. Owandy-CR² installation on computer

WARNING

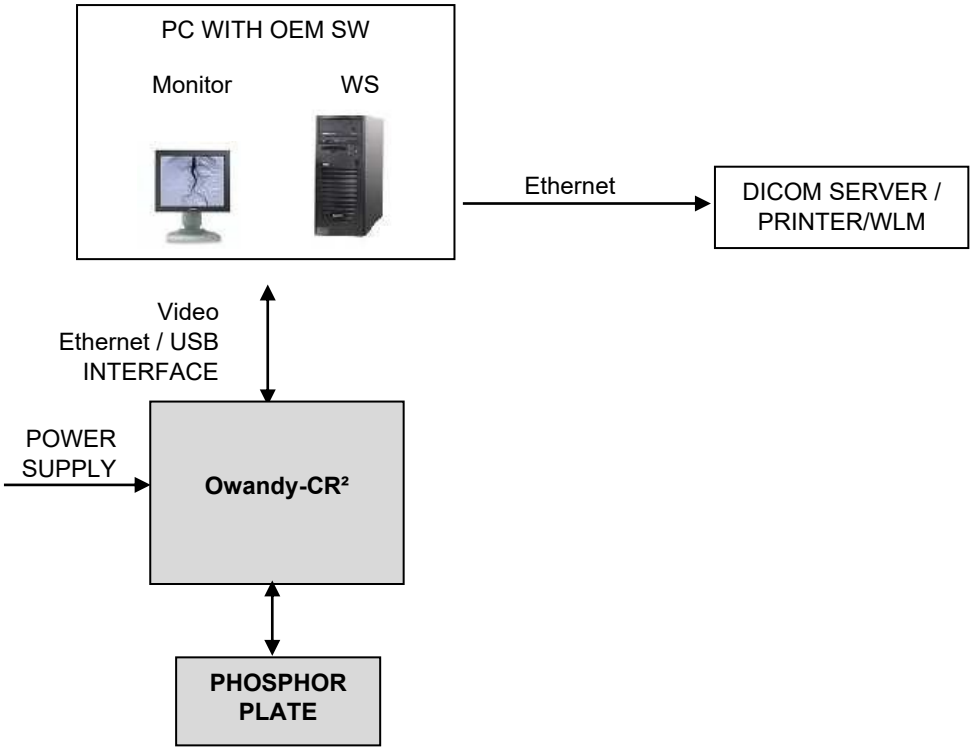
Before installing the system, check that the PC features match with those described in paragraph 5.3.
If not, the system might not work, or perform incorrect operations, different from the ones described in this manual.
OWANDY RADIOLOGY will not be held responsible for malfunctioning due to such reasons.

6.2. Software connection

The assembling of **Owandy-CR²** is very easy and it could be made in a few minutes.

The system must be connected to the external power supply and to the computer thanks an USB cable, after the operating software has already been installed.

The following blocks diagram shows all the connections:



- For USB unit:

If the distance between the unit and the computer is greater than the 3m / 9.8ft of USB cable, it is possible to add USB cables by using a USB distributor (“hub”) connected to an external mains power supply, between each cable.

Make sure the USB port of the computer is preferably a USB 2.0 port. Only use USB 2.0 cables and hubs with a USB2.0 port and make sure that the hub has its own external power supply (do not use self-powered hubs, drawing the power from the USB cable). Each USB cable should not be longer than 3m / 9.8ft. The kit is compatible with USB 1.1 ports but with reduced image transmission speed.

The USB cable can be connected / disconnected without the need to power down the computer.

- For ethernet unit:

At first connection, PC's network card must be on the same sub-net of the unit.

Default configuration of the unit:

- IP: 192.168.0.253
- subnet mask: 255.255.255.0

The network card must be compatible with 100Mbit/s or Gigabits network and its speed connection configured either as **autodetection or 100Mbit/s**.

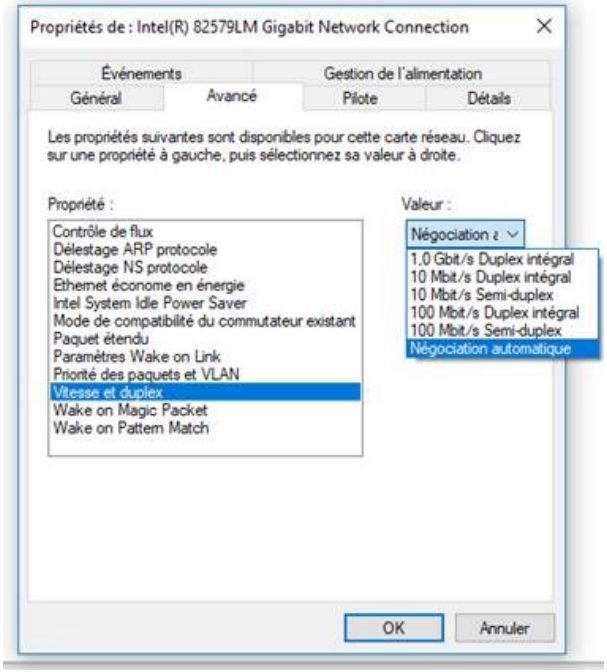


Figure 1: ethernet board properties window

For both USB and ethernet units, power the unit on and check that the **Owandy-CR²** unit is correctly connected: the toolbar turns green after the unit has been activated.

WARNING

The kit must be handled with care, minimise the twisting, pulling and bending of connection cables (USB and power supply). Do not step or roll on the cables. Do not pull on the cable itself but on the connection plug to disconnect the USB cable.

WARNING

To avoid interferences in the image, do not use the system close to strong magnetic fields and avoid proximity to electrostatic emission sources.

WARNING

Install your imaging software before the installation of the kit, its drivers and O.S.P. tools.

• **Ethernet version FIXED IP**

When connecting for the first time, the computer's network card must be on the same subnet as the scanner. Default scanner configuration :

FIXED IP with Owandy-CR SN < 24042131

o IP: 192.168.0.253
o Subnet mask: 255.255.255.0

The network card must be compatible with a 100Mbits/s or Gigabit network and the connection speed configured as auto-detect or 100Mbits/s.

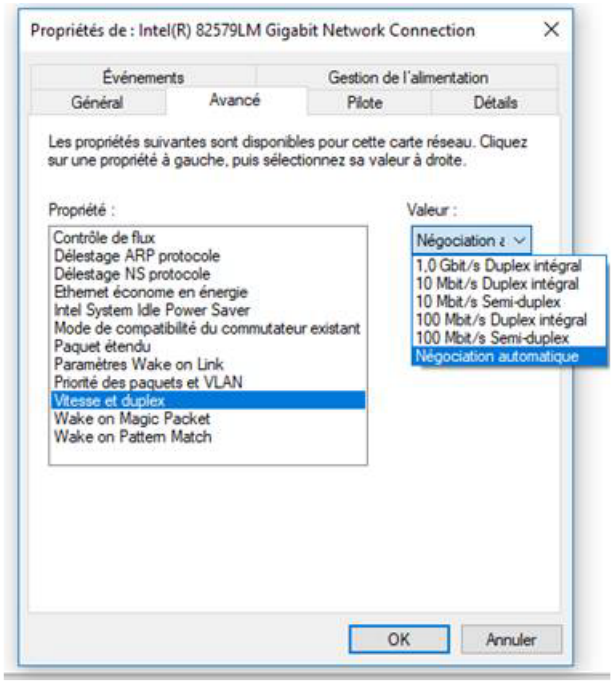


Figure 1: Ethernet card properties window

6.3. Setup guidelines

The computer and the screen with which the **Owandy-CR²** is used, should preferably be situated close to the chair, within the field of vision of the practitioner, to allow for immediate use. Provide visual access for the patient to be able to share the radiological information with him/her.

The screen must be placed so as to avoid any reflections or direct overhead illuminations that could be detrimental to the visualization of the radiological images. It must be set up (contrast and brightness) to display as many grey levels as possible in the image.

The X-ray generator has a great influence on the quality of the acquired images. The kit is compatible with any kind of generator, be it high-frequency or conventional. The generator must be equipped with an electronic timer (allowing for very short exposure times) and must emit a dose sufficient for the acquisition of a good image (with enough grey levels). Make sure that your generator is not worn as the dose emitted will be insufficient and could influence the quality of the acquired image. The energy emitted by a generator diminishes over time; when in doubt have your generator checked by a qualified technician. Make sure he had of the generator is stable, any movement of the head will induce movement blur in the acquired image.

6.4. Software installation

Install the **QuickVision** imaging software and check its proper functioning before installing the equipment and its drivers. Refer to the software manual for the installation instructions.

WARNING

You need administrator rights for the installation of the software and equipment.
Please contact your IT specialist to create a suitable user account.

6.4.1. Installation of the driver and the software

The **Owandy-CR²** drivers are compatible with Windows 7, 8 and 10 operating systems – 32 and 64 bits.

To install the drivers and the diagnostic tools:

1. Connect the USB stick to the PC, or download drivers and diagnostic tools on our website www.owandy.com/support.
2. Select OWANDY-CR², and follow instructions.

Another window will open, allowing you to choose between LAN and USB.

6.4.2. Driver update

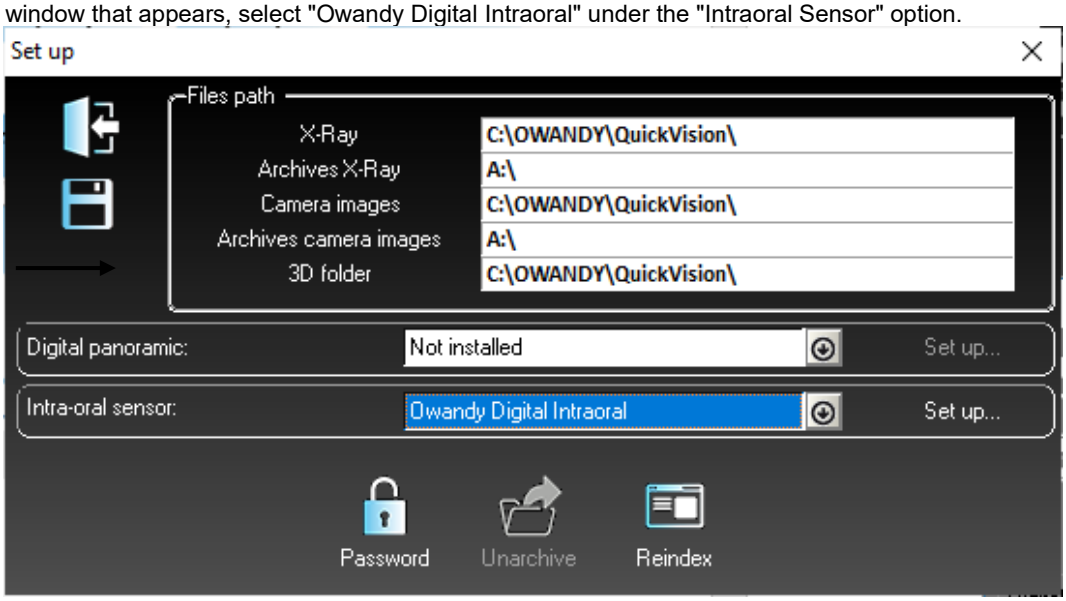
If you need to update your Driver:

3. Connect the USB stick to the PC, or download drivers and diagnostic tools on our website www.owandy.com/support.
4. Select OWANDY-CR², and follow instructions.

6.5. Configuration in the QuickVision imaging software

In order to use the system with the QuickVision imaging software, you need to set up your equipment.

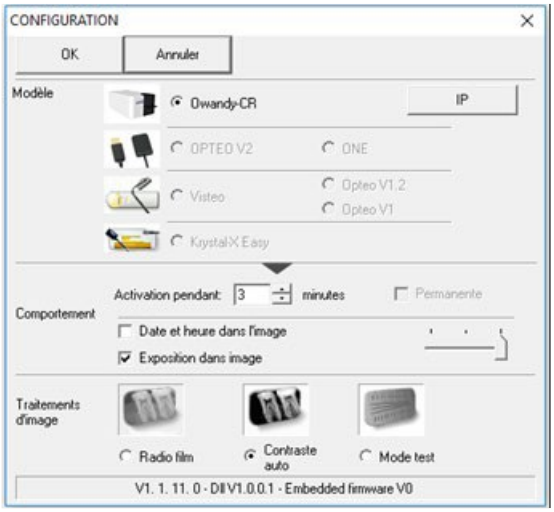
1. Start the imaging software
2. Click on the "Configure" button on the main screen.
3. In the window that appears, select "Owandy Digital Intraoral" under the "Intraoral Sensor" option.



4. Click on “Configure” at the right of the menu.

In the configuration window:

◄ Select "Owandy-CR".
For the Ethernet version, you can change the IP address by clicking on "IP" (see §6.6 Network configuration).
◄ Set the box activation time (*)
◄ Set the display and size of the date and time and exposure parameters in the acquired image.
◄ Select image processing



(*) For USB unit, default value: 15 min. Available values: from 1 to 15 min. For Ethernet unit, default value: 3 min. Available values: from 1 to 10 min.

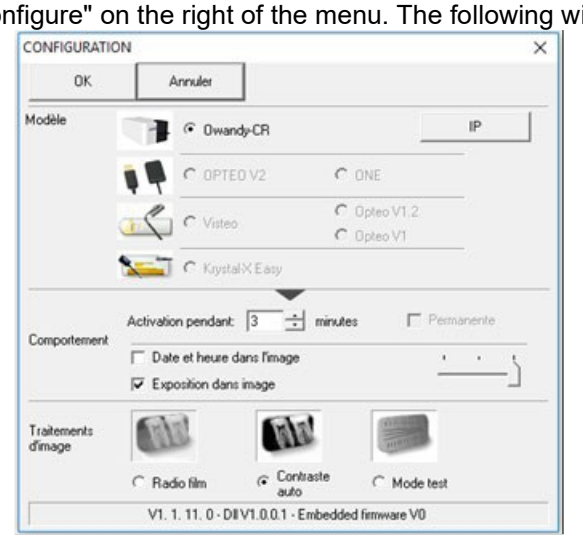
5. Click on “OK” to confirm your choice.
6. Then click on the “Save” button to validate the settings.

The use of the kit is identical to the use of the Owandy XIO StandAlone software described below.

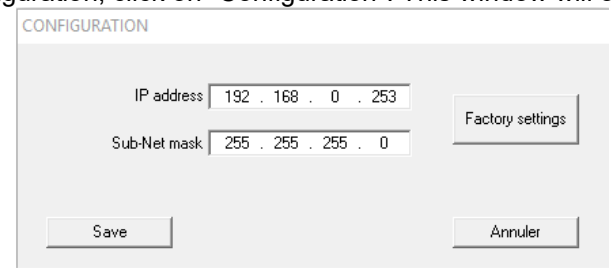
6.6. Network configuration

6.6.1. From the software (FIXED IP)

To open the network configuration menu :
- Launch the imaging software (double-click on the desktop icon or Start / Programs / QuickVision)
- Click on the "Configuration" button on the main screen
- Click on "Configure" on the right of the menu. The following window opens:



To change the network configuration, click on "Configuration". This window will open:



If you click on "Factory settings", the fields will be filled in with the factory configuration
- Cancel: the window will close, but the changes will not be saved
- Save: 1. if the unit is connected, the IP address of the unit and the configuration of the PC are modified

WARNING: the new configuration will be available after rebooting the unit.
2. If the unit is not connected, only the PC configuration will be modified.

NB: the PC must be on the same subnet as the Owandy-CR (192.168.0.X), otherwise it will not be visible.

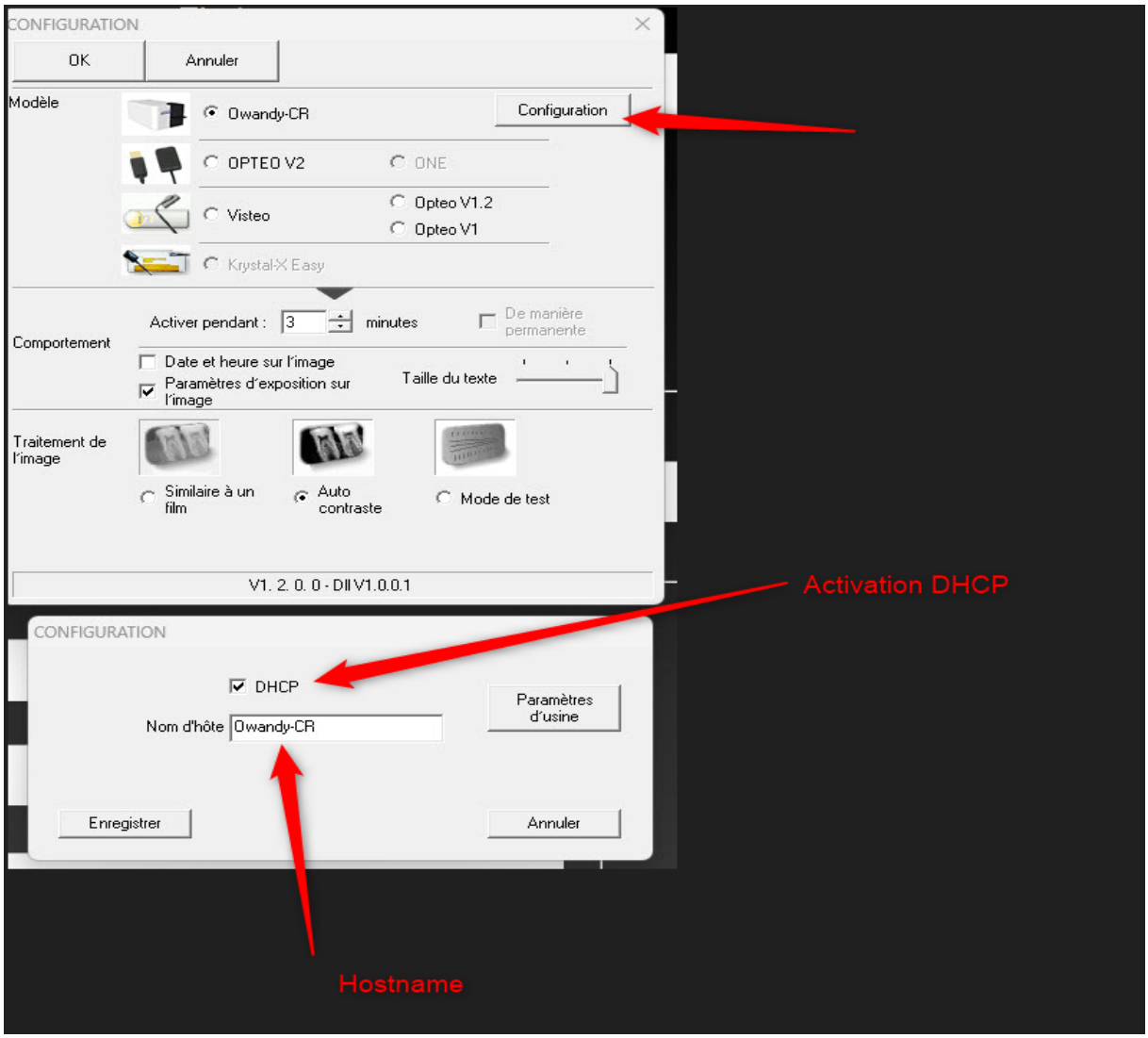
6.6.2. Using the unit's reset button

A reset button is located on the rear of the unit.
- Press the button for a few seconds to reset the scanner to its factory configuration:
 IP: 192.168.0.253
 Subnet mask: 255.255.255.0

6.6.3. From the software (DHCP)

Automatic IP for Owandy-CR SN > 24042131

-If there are two network cards on the PC, it is possible that switching to DHCP will be prioritised on one or other card, causing communication on the CR to fail.
To activate the DHCP option, go to "Configuration" and tick "DHCP".
If you have several CRs on the same network, you can change the name of the CR. You then need to replace the hostname for each CR (capitalisation is not taken into account).



-In the logs, there will be a DHCP Discover line with the name and IP address of the CR; the log can be searched for "HOSTNAME" and "DHCP".

6.6.4. Using the unit's Reset button

- If the CR does not receive a response from the DHCP server, it automatically switches to the fixed address 192.168.0.253 after approximately 30 seconds.

  RESET procedure if connection identifiers are lost (unknown IP and hostname) :

  After pressing the physical Reset button, the plate reader will be configured in DHCP, without changing its hostname.

  To connect, the user must :

  1. Click on the "default configuration" button on the interface to configure communication with a fixed IP = 192.168.0.253.
  2. Power up and press the RESET button for 10 seconds, then switch off the power supply.
  3. Disconnect the Ethernet cable from the CR (to prevent communication with the DNS server), power up the CR.
  4. Wait 90 seconds.
  5. Connect the Ethernet cable and connect to the default fixed IP.
  6. Once connected, configure communication as required (fixed IP or DHCP).

WARNING
The new configuration will be available only after the reboot of the unit.

7. USE

7.1. Precautions

WARNING
Make sure the sensitive surface (the blue surface) of the plates is directed towards the X-ray generator.
Be careful not to damage the plates when removing the hygienic protective sleaves.
Even though the plates are quite resistant to impacts, it is strongly recommended to not let them fall on the floor.
Do not ask the patient to bite on the plates.

WARNING
The unit must be manipulated with care, minimising the twisting, pulling and bending of the cables. Do not step or roll on the cable.

WARNING
After exposing the plate to X-ray, it is recommended to insert it into the scanner within 2 minutes to avoid image degradation.

WARNING
EVEN WHEN THE PLATES ARE INSIDE THE HYGIENIC DISPOSABLE COVERS, do not expose them to strong light sources or to UV lights, such as sterilizers and curing lights.

WARNING
Use of a mobile phone or an RF communications device near the Owandy-CR² unit may affect the device working.

WARNING
Before inserting the plates in the scanner, make sure that the icon in the task bar of the destination PC has become green, indicating that the next image scanned will be properly sent to the selected PC. This is especially important in case of network installations with more than one PC connected to the scanner in an Ethernet environment, to avoid mixing the images.

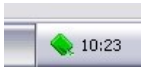
7.2. Use of the Owandy XIO StandAlone software

7.2.1. Modes of operation

The unit can function in two ways:

- Through the **Twain protocol** (for scanners): to use this mode select “Owandy Intra Oral X-rays…” in the TWAIN acquisition option of your imaging software. Subsequently start the TWAIN acquisition; the interface is identical to that of the independent mode described below.

- In **independent mode**: the independent software program can be started with the  icon (on the Windows desktop) or by starting an Owandy software program. This memory resident software package allows the use of the unit outside any software program. If an image is acquired without a program ready to receive it, the resident program will display the image on-screen for a few seconds and save it in the “C:\Program Files\OWANDY\OSP - XRAYS BOX STANDALONE\StandAlone\Data” directory on the hard disk. A sensor icon appears in the Windows taskbar, next to the clock. The colour of the icon indicates the state of the unit:

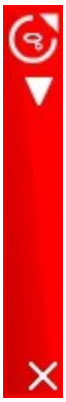
	Red: unit inactive
	Yellow: unit initialising or in scanning mode
	Green: unit ready for acquisition

7.2.2.Standalone toolbar

It is possible to display the toolbar by clicking with the right mouse button on the sensor icon in the taskbar. The colour of the toolbar indicates the state of the unit:

	USB & Ehternet unit: disconnected
	USB unit: unit in scanning mode Ethernet unit: unit in scanning mode or connection pending
	USB & Ehternet unit: unit ready for acquisition

Options of the unit toolbar:



◄ Orientation of the plates (vertical or horizontal), double-click the icon to change the orientation of the plates.

◄ Connect/Disconnect the unit

NB: for Ethernet unit, if a computer is already connected to the unit, then, the connection is pending until the unit becomes available.

◄ Iconize the toolbar in the taskbar.

For Ethernet units:

The scanner can be shared amongst different PC within the same network.

- First scanner connection request:

  When the triangle is clicked on the toolbar of one PC, the scanner is "locked" for that PC and the toolbar turns green. You now have 3 minutes to go to the scanner and insert your plates.

  After 3 minutes, or if the square is clicked, the scanner is "released" and any other PC in the network can connect. The toolbar turns red.

- Additional scanner connection request :

  If a PC asks for a connection while the scanner is already connected, the new connection is pending and the toolbar turns yellow. The connection is pending until the scanner becomes available (toolbar turns green) or the square is clicked (toolbar turns red).

WARNING

The unit automatically switches to disconnection mode after a few minutes of not being used; the standalone toolbar turns red.
Check that the standalone toolbar is displayed in green before each acquisition.

WARNING

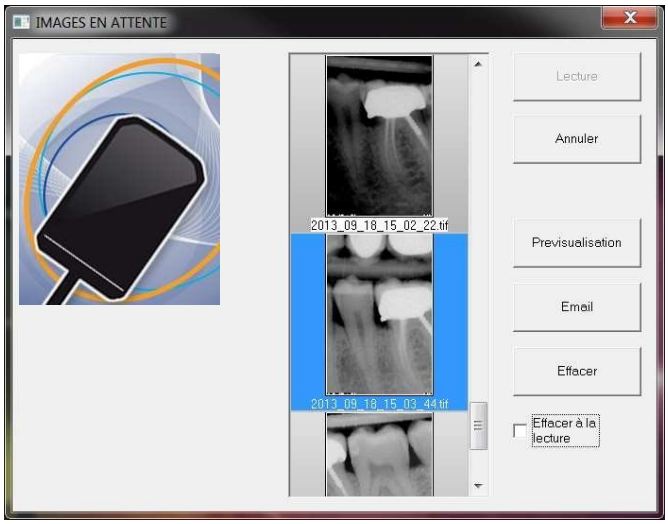
If the scanner is far from the PC, double check that the status icon has turned to green, indicating that the scanner is now ready to acquire and send images to this PC.
This is especially important in case of network installations with more than one PC connected to the scanner in an Ethernet environment, to avoid mixing the images.

7.2.3. Configuration menu

A right-click on the icon in the taskbar or on the standalone toolbar displays the configuration menu:

X-ray sensor	Displays the standalone intraoral toolbar.
Start when Windows starts	Once checked, the StandAlone program will be launched each time your computer is started.
Configuration	Displays the configuration menu (see “6.5 Configuration in the QuickVision imaging software”).
Display new images for	Adjusts the display time of the image.
Remaining images	Allows you to browse through the images waiting to be transferred. If no image is acquired this option is not displayed.
Exit	Closes the resident software program. **Warning**: the acquisition will no longer be available until the resident program is restarted

7.2.4. Image transfer interface



Options of the image transfer interface:

Image display	When an image is selected, it is displayed on a blue background.
“Load” button	Transfers the selected image to the software program.
“Cancel” button	Cancels the image selection and starts the toolbar for a new acquisition (only when in a software program).
“Preview” button	Displays the selected image full-screen.
“Email” button	Opens a blank email and attaches the image in a zip file.
“Delete” button	Deletes the selected image.
“Delete on load” option	Deletes the selected image from the list after it has been transferred to a software program.

7.3. Acquisition of an image

7.3.1. Acquisition procedure

The image acquisition goes through several steps:

1. Before being able to acquire an image with the plates, you need to start the computer to which it is connected and start the imaging software. Check that the standalone toolbar or the icon in the task bar is green.
2. Program the different parameters (exposure time, etc.) on the X-ray generator (see “7.4 Exposure times” for more information).
3. Cover the plates and the paper protection with a hygienic protective sleeve.

WARNING
Turn the sensitive blue surface of the plate towards the X-ray generator.

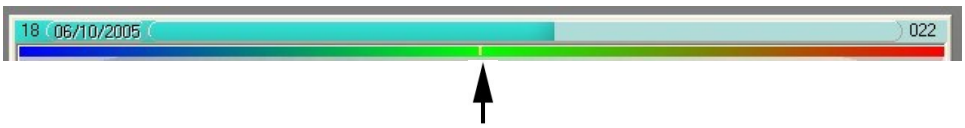
4. Position the generator so as to cover the whole sensitive area of the plate. The paralleling technique is strongly recommended and the use of positioners allows you to correctly place the generator thanks to the aiming ring (see “7.6 Phosphor plates exposure” for more information).
5. Activate the generator and the Xray exposure.
6. Tear the sleeve and take the plate with the paper protection to introduce the whole in the scanning unit.
7. The stadalone toolbar turns yellow to indicate the treatment and transmission of the acquired image. Once the image treated, it appears in the imaging software and the standalone toolbar turns green allowing a new plates scaning.

7.3.2. Imaging software functions

An exposure percentage is displayed in the acquired image:

- 0 to 80% - under-exposed image, the X-ray dose is too low; increase the X-ray dose on the generator.
- 80 to 120% - correctly exposed image
- 120 to 200% - over-exposed image, the X-ray dose is too high; reduce the X-ray dose on the generator.

When the image is displayed in the **QuickVision** imaging software, a coloured bar appears in the top part of the image, this is the exposure bar. This function is available only to users of the **QuickVision** imaging software.



The white cursor displayed in this bar indicates the exposure level of the image:

- If the cursor is in the green, the image is correctly exposed.
- If the cursor is in the red, the image is over-exposed; reduce the exposure time on the generator.
- If the cursor is in the blue, the image is under-exposed; increase the exposure time on the generator.

7.4. Exposure times

Recommended exposure times in seconds for the Owandy Radiology X-ray generators:

Description (Current/Voltage)	Owandy-RX (6mA / 60-65-70KV)	
Exposure Time tables	**Pediatric**	**Adult**
Lower incisor / canine	0.05 – 0.10	0.07 – 0.16
Lower premolar	0.06 – 0.11	0.08 – 0.17
Lower molar	0.07 – 0.13	0.11 – 0.20
Upper incisor / canine	0.05 – 0.10	0.07 – 0.16
Upper premolar	0.06 – 0.11	0.08 – 0.17
Upper molar	0.07 – 0.13	0.13 – 0.24

Equivalent typical doses delivered to patient in mGy:

Description (Current/Voltage)	Owandy-RX (6mA / 60-65-70KV)	
Exposure Time tables	**Pediatric**	**Adult**
Lower incisor / canine	0.25 – 1.04	0.33 – 1.04
Lower premolar	0.33 – 1.31	0.62 – 1.57
Lower molar	0.37 – 1.34	0.64 – 1.88
Upper incisor / canine	0.25 – 1.04	0.33 – 1.04
Upper premolar	0.33 – 1.31	0.62 – 1.57
Upper molar	0.37 – 1.34	0.64 – 2.04

Reference conditions:

- *Adult patients, or paediatric patients of average size*
- *Distance focal spot to plate* *200mm / 7.9inch*
- *Total (inherent) filtration* *equivalent to 2mm / 0.08inch Al*

The values indicated in the table above can vary from one generator to another. It is the responsibility of each user to calibrate his/her doses before use.

If an image is over or under-exposed, it can be corrected afterwards with the imaging software (contrast, brightness, etc.) to improve its visualisation.

The table below allows you to note the exposure times specific to your generator:

Exposure Time tables	Pediatric	Adult
Lower incisor / canine		
Lower premolar		
Lower molar		
Upper incisor / canine		
Upper premolar		
Upper molar		

To help address the challenges related to pediatric imaging, the user can refer to the following two sources:

- (1) the Image Gently Back to Basics campaign materials: http://pedrad.org/associaions/536/ig/Procedures/DigitalRadiography/EducationalMaterials.aspx,
- (2) the FDA Pediatric X-ray Imaging webpage: http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm.

7.5. Preparing the Phosphor Plate

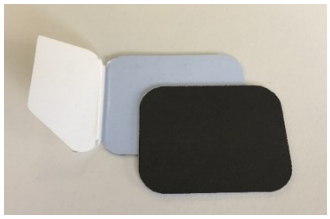
WARNING
Before inserting the phosphor plate into the cover inspect the plate for any scratches or visual defects. The plate must also be correctly cancelled and free of previous images.

WARNING
Use always paper protection of the same size of phosphor plate.
If different size is used the plate can be stuck into the equipment.
If the plate is stuck into the system, make reference to chapter 10 for the resolution of the problem.

Place the image plate on the long portion of the protective cover.

The blue side of the plate must be placed on the blue part of the plate cover as shown below in the diagram.

When in place fold the short end over the phosphor plate as shown below.



Always protect plates with dedicated disposable plastic sleeves before inserting the plates into the patient mouth. Suitable disposable sleeves are supplied with the unit's starter kit and can be re-ordered as consumable accessories.

WARNING
The hygienic sleevee is a disposable device and must be changed from patient to patient.

WARNING
If the disposable hygienic bag has a transparent side, make sure that the black side of the paper cover with the “TUBE SIDE” label is placed towards the black side of the disposable bag.

WARNING
It is not necessary to disinfect the hygienic cover before use.

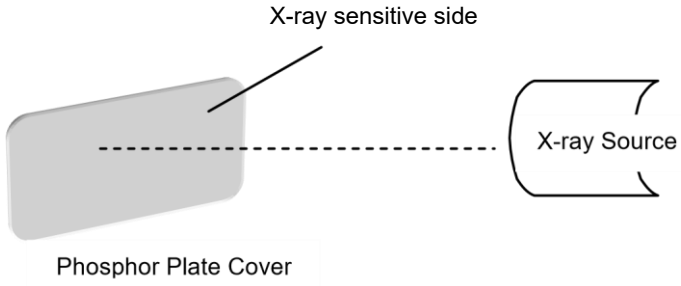
Peel off the sealing tape and close the hygienic cover. It is now airtight and ready for use.

7.6. Phosphor Plate Exposure

Place the image plate into the patient's mouth at the desired position to obtain the required image. REMEMBER the back side of the hygienic cover with the sealed flap must be furthest away from the x-ray source.

WARNING

Pay attention to the plate orientation. The side labelled "TUBE SIDE" shall be facing the x-ray tubehead.



Select the appropriate dose and take an X-ray (see "7.4 Exposure times" for more information).

Remove the hygienic cover from the patient's mouth cleaning any saliva residue. Before opening the hygienic cover disinfect it with an approved solution, i.e. disinfecting soap or similar.

7.7. Reading the phosphor plate

WARNING

Before inserting the image plate in the scanner, make sure that the plate and the protective cover have the same size.
If the size of the plate and the cover are mixed, **the plate will remain stuck into the scanner.**
In such case, follow the procedure described in the "Troubleshooting" paragraph to eject the plate.

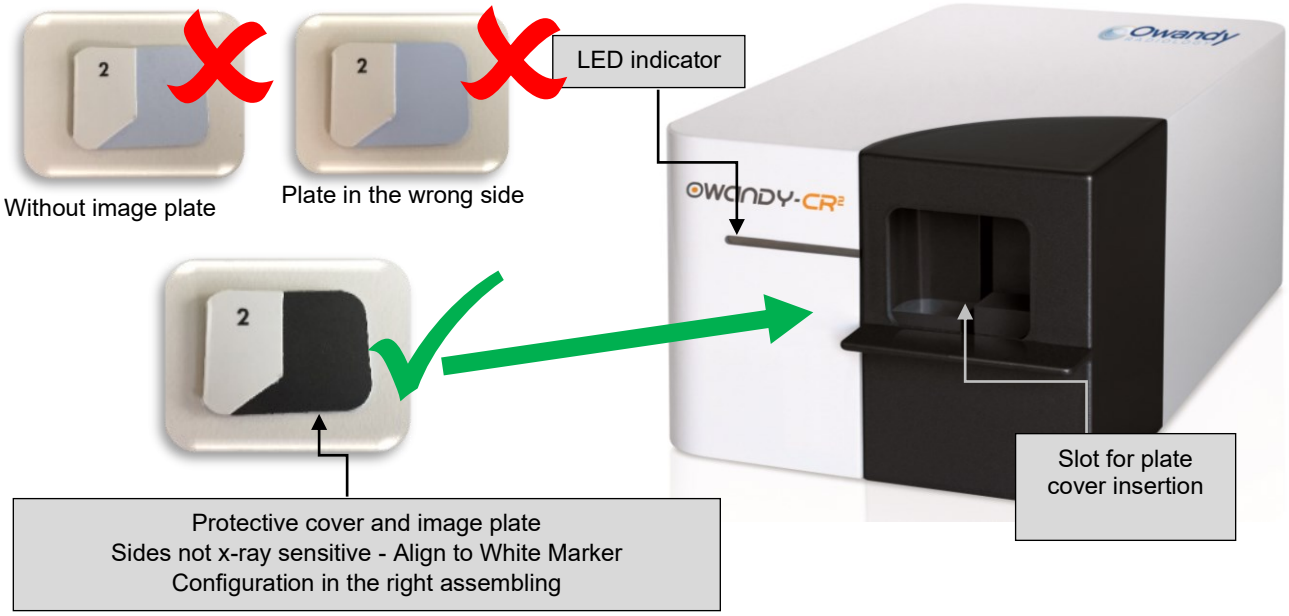
WARNING

After exposing the plate to X-ray, it is recommended to insert it into the scanner within 2 minutes to avoid image degradation.

WARNING

EVEN WHEN THE PLATES ARE INSIDE THE HYGIENIC DISPOSABLE COVERS, do not expose them to strong light sources or to UV lights, such as sterilizers and curing lights.

Open the hygienic cover and remove the protective plate cover containing the phosphor plate just before inserting into the device. Do not expose the phosphor plate to the light.



Insert the image plate paper protective cover.

Place the light cover and plate on the bottom of the slot. Make sure of the correct horizontal alignment of light cover and plate. Do not insert the plate not aligned with the slot.

Push the plate into the slot of the reader until it stops.

At the same time it stops, ease the pressure of the fingers on the light cover and remove it from the plate.

WARNING

Missing the procedure above will lead the reader not to recognize the plate and the inability to scan.

In this moment the phosphor plate is engaged by the magnetic drive system and automatically dragged inside the reader for scanning.

The blue led will start to blink for the automatic reading of the plate as described in §7.8.

7.8. Owandy-CR² led sequence

The **Owandy-CR²** unit can advise the operator about all the different system status (errors, functions, etc).

The different system status modes can be obtained by the external leds mounted in the front of the system and the following table explains their meaning:

Standard Working Sequence ID		LED Colour / Colori LED			
		Blue	White	Red	Green
1	device powered and not connected to the SW	C			
2	device powered and connected to the SW				C
3	Plate insertion				F
4	Light cover removal for scanning start				F (*)
5	Plate scanning	C			
6	Start of the return of the plate		F		
7	Erasing		C		
8	Authorization to plate removal.		F		

C_ Continuous light

F_ Flickering Light

F(*) Only one flicker

Blank space or Off: _ Light off

In case of other combinations of light, extract the plate and wait for the auto reset of the device, as long as the continuous blue light will appear again.

The most frequent errors of use are highlighted by the following combination of LEDs:

Common errors in use		LED Colour / Colori LED			
		Blue	White	Red	Green
1	The device does not start the insertion of the plate: the plate is inserted with the reader disconnected	F	F		
2	The device does not start the insertion of the plate: the plate is inserted without protective light cover with tube-side facing the reading side of the reader		F		
3	The device does not start the insertion of the plate: Inversion of plate / light cover + insertion side error. Insertion of the plate without light cover with the blue side facing the reading side of the reader.		F		
4	The device does not start the insertion of the plate: In the extraction phase of the light cover (phase 4 to phase 5 of the normal operation) the plate was held improperly.			F	

After the operational time (adjustable by the user on the configuration window of the Standalone IO) due to inactivity, the **Owandy-CR²** enters into stand-by mode (SAVE POWER STATUS). The blue led decreases in brightness. In order to return from SAVE POWER STATUS introduce a new plate in the **Owandy-CR²,** and wait some seconds before the reactivation of the unit.

8. MAINTENANCE INSTRUCTIONS

Owandy-CR² must be properly used in order to ensure safety and prevent damage to the system.

Besides, the operators will have to look periodically after all the system safety standards, in order to ensure its perfect working.

The following table indicates all maintenance and prevention actions to be performed, as well as periodicity and personnel in charge of such actions.

Action	Frequency	Responsibility
Check that connection cable are in good conditions	Daily	Operator
Check the phosphor plates and the scanner unit	Daily	Operator
PC functionality	Daily	Operator
Check image quality	Twice a year	Authorized service technician

NOTE

In case the operator may notice any fault in the course of the above mentioned checking operations, he will have to contact the authorized Technical Assistance service immediately.

9. CLEANING AND DISINFECTION

Owandy-CR² does not require daily cleaning and disinfection, but the phosphor plate used by the patient must be protected by a dedicated disposable protective cover before positioning into the mouth of the patient. When the exam is finished dispose of the protective cover as it must NEVER be re-used.

Particular care must be devoted to the phosphor plates, although protected by the dedicated mono-use envelope it is however positioned into the patients' mouth.

Anyway, no sterilizing operation is needed, as the contact with patient and operator is superficial and occurs only through minimal contact. Also an autoclave must not be used in order to avoid damage to the phosphor plate.

WARNING

Alcohol, alkaloid and abrasive liquids must never be used to clean and disinfect the Owandy-CR² and phosphor plates.
Don't plunge any of the device parts into liquids. Don't use autoclave.
Carefully comply with the instructions described in Par.2.1 – General warnings.

10. TROUBLESHOOTING

10.1. General

Owandy-CR² might present problems during its use, and their solution might require the assistance of a qualified technician.

The following guide indicates checks and actions you can perform if the system does not operate correctly.

WARNING

In order to prevent any possible damages or injury to the operator or to the system, do not attempt to solve problems by yourselves when it is clearly indicated the authorized Service Agent assistance is needed.

WARNING

In order to limit the dose administered, in case of poor quality image or no image, before proceeding to a further x-ray on the patient, the user is required to perform a test image using the phantom or the specific test items for intraoral radiology.

Symptom	Possible cause	Solution	Intervention
The application does not install	Non compatible PC type	Check the PC features and compare with those listed on paragraph 5.2.1.	Authorized service technician
The application does not perform some functions correctly	Non compatible PC type	Check the PC features and compare with those listed on paragraph 5.2.1.	Authorized service technician
Phosphor plate is not recognized	Connection error. Driver not correctly installed. Bad system configuration.	Check the phosphor plate conditions. Repeat the driver installation procedure. Check system configuration.	Authorized service technician
No image displayed	No X-Ray emission. Phosphor plate damaged	Check the X-Ray system correct functioning. Possible damage to the system.	Operator Authorized service technician
Out of focus images	System settings. Wrong phosphor plate positioning. Movement during exposure.	Check the correct parameters settings Check the correct phosphor plate positioning. Check that the patient stays motionless during the exposure.	Authorized service technician Operator
Block of software functioning	Electrostatic discharge or processor fault.	Check that no wrong operation has been performed. Turn the PC off, then power up again.	Operator
Unit does not connect	Network board speed configuration	Set board speed to autodetection or 100 Mbit/s	Operator

10.2. Image quality specifications

Symptom	Cause / Solution
The images are cut off, e.g.:  	The plate is badly positioned with regard to the X-ray beam. • Reposition the plate, making sure it is well within the field of the Xray beam. • Use a positioners kit with the plates for optimal positioning.
The images are too light or contain noise, e.g.:   *Film alike mode* *Auto contrast mode*	• The image is under-exposed, the X-ray dose is too low; increase the X-ray dose on the generator. The percentage that is displayed in the image indicate the exposure level: ▪ 0 to 80% - under-exposed image ▪ 80 to 120% - correctly exposed image ▪ 120 to 200% - over-exposed image • Check the dose emitted by the X-ray generator, due to age the dose can be insufficient. Have the generator checked by a technician when in doubt. • The generator is positioned too far from the patient with regard to the selected dose. • Check the parameters of your monitor (contrast and brightness) and avoid reflections on the screen.
The images are too dark, e.g.: 	• The image is over-exposed, the X-ray dose is too high; reduce the X-ray dose on the generator. The percentage that is displayed in the image indicate the exposure level: ▪ 0 to 80% - under-exposed image ▪ 80 to 120% - correctly exposed image ▪ 120 to 200% - over-exposed image • Check the parameters of your monitor (contrast and brightness) and avoid reflections on the screen.
Grey levels seem to be missing in the image (flat areas of grey appear)	• Check the quality and parameters of the monitor. • Check the connection of the cable of the screen at the side of the graphics card and the monitor. • Heck the screen configuration under Windows (screen configuration panel, it must display colours in at least 24bits.
The image is blurred.	Re-acquire the image: • The patient has moved during the exposure. • The generator head was not stabilised and has moved.
Stripes on the image	Stripes can be caused by vibrations during the plate scanning. Avoid hitting or touching the scanner or the desk during scanning.

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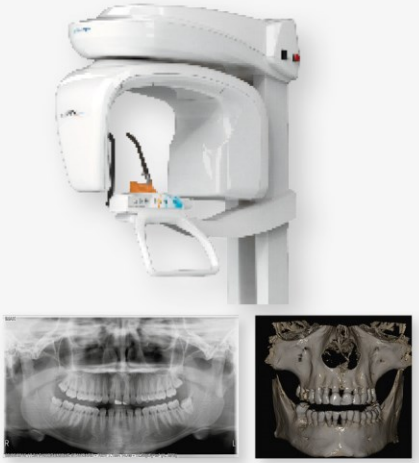
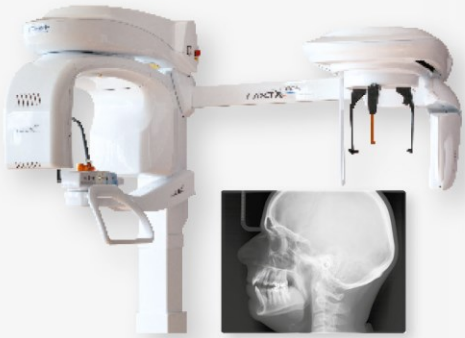
DIGITAL WORKFLOW OWANDY RADIOLOGY

A COMPREHENSIVE RANGE TO MEET ALL YOUR REQUIREMENTS



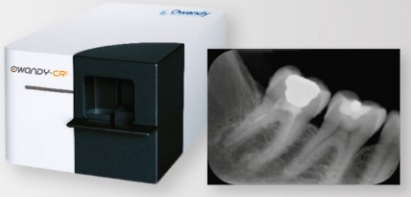
2D/3D UNITS



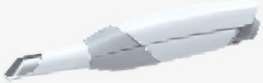
CEPHALOMETRIC UNITS

HF INTRA-ORAL GENERATOR

FACE SCAN
.PLY IMPORT



INTRAORAL
PLATE SCANNER



DENTAL IMPRESSIONS
.STL IMPORT

SURGICAL
GUIDE

DIGITAL USB
INTRAORAL CAMERA

EXPORT TO
3D PRINTER

DIRECT USB
SENSORS

Owandy RADIOLOGY

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