Owandy RADIOLOGY

EN • INSTALLATION AND USER MANUAL

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ONE

SIMPLICITY WITHIN REACH

Direct USB intraoral sensor

Index

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

CE 0051
Year CE marking assigned: 2013

1 INTRODUCTION

You have just received your ***ONE*** new generation digital intra-oral radiology kit, with direct USB connection. We thank you for the confidence you have in us and hope that this product will give you entire satisfaction.

We recommend you to read this manual thoroughly before installation; following the guidelines for installation and usage described in it will exclude risks to the patient and the care team. Please keep it close to your equipment so you can refer to it at a later date.

Your sensor uses an X-ray sensitive electronic detector (the flat part at the bottom of the sensor) that replaces the conventional film used for the acquisition of radiological intra-oral images. The X-rays are automatically detected by the sensor which triggers image acquisition. The acquired image is displayed almost instantaneously on the screen of the computer to which the sensor is connected. These digital images can then be manipulated, analysed, saved as files or printed.

The development process of conventional films is thus 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 time.

The sensor is available in two sizes; depending on the kit you have ordered you received a size 1, a size 2 sensor or both:

- The size 1 sensor allows you to acquire the majority of intra-oral images (peri-apical and retro-coronary) both vertically and horizontally.
- The size 2 sensor furthermore allows you to easily acquire horizontal “bitewing” images.

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

1.1 Intended use

ONE intraoral sensor is an hand held device used to provide digital images of human oral tissues and teeth without the use of a conventional x-ray film.

Placed in the oral cavity of the patient, the sensor is subjected to X radiation from an x-ray generator (not part of the device) a few tenths of a second. The sensor, upon radiation exposure, captures the image that is then transferred and viewed on the practitioner's computer.

ONE is used for diagnosis purpose by dental practitioners or radiologists.

1.2 Intended patient population

One sensor can be used with the following type of patient:

- Age peadiatric to geriatric
- Patient status/Health: the patient is conscious
- Nationality: multiple

Note: PATIENT is not an OPERATOR

1.3 Application environments

One kit may be used in dental practice environment.
One may be used in professional buildings or in residential buildings. For the purpose of EMC environment classification, both installations are classified as “Professional healthcare facility environment and Home healthcare environment”.

1.4 Applied parts

During normal use, One sensor is in contact with the patient via intraoral sensor and part of cable near to the sensor. The intraoral sensor and cable are inside a protective sheath during use .These parts are classified as Type BF applied parts.

1.5 Frequency of use

The maximum duration of use correspond to 10 minutes. It’s very probable that for a given patient, total contact will not exceed one hour in patient lifetime

1.6 Prescription Use Statement

Caution: Federal law restricts this device to sale by or on the order of a dentist or any other practitioner licensed by the law of the State in which he practices to use or order the use of the device

1.7 Compliance with standards

The ***ONE*** kit is class IIa equipment within the meaning of the European Directive 93/42/CEE concerning CE markings. The ***ONE*** kit complies with the IEC60601-1, IEC 60601-1-6, IEC 60601-1-2 and IEC62304 medical devices standards.

It is necessary that the other components of the system that are possibly connected (computer and optional peripherals) are compliant to standard IEC60950-1
The intra-oral sensor is contained within a hermetic and sealed case (resistant to immersion). There is no physical or electrical connection between the ***ONE*** kit and the X-ray generator.

1.8 Power supply

The power to the ***ONE*** box is provided directly by the power supply of the USB cable connecting it to the computer. For the procedure for switching the device ON and OFF refer to the computer instructions

1.9 Installation precautions

Warning
The computer connected to the sensor MUST necessarily comply with standard IEC 60950-1.

Warning
The One sensor is an electrical medical device requiring special precautions regarding electromagnetic compatibility. Please observe the recommendations in this manual during the commissioning and use of the equipment.

Warning
The use of cables or accessories other than those specified in this manual can cause an increase in the emissions or a reduction in the immunity of the One sensor.

1.10 Liability and operators

Installer: the installation of the kit requires computer skills relating to both equipment and software. Follow the recommendations and guidelines of the installation chapter to install the equipment and software.
User: the kit must be used by a dental practitioner or radiologist with computer skill.

Warning
The sensor should never be opened by the user. Only the manufacturer is authorised to open and make repairs to the sensor. Return the equipment to the distributor in case of malfunction and/or if the documentation you possess does not contain the necessary information for the (authorised) maintenance of the malfunctioning equipment.

Warning
Any modification of the ***ONE*** device is forbidden. All repairs of this same device can only be performed by Owandy Radiology personnel.

The manufacturer will not be liable if:

- Interventions or repairs have been made by persons without the authorization of the manufacturer or distributor and are not part of accepted interventions.
- The equipment is used with an installation that is not compliant with the applicable standards and decrees - in particular when not compliant with the IEC 60601-1 standard relating to the security rules for electro medical systems. Make sure the installation of the equipment is compliant with the applicable regulations.
- Used in ways other than those mentioned specifically in this manual (use of the kit in normal conditions of use and in compliance with its intended purpose).

1.11 Packaging and environment

Transport, storage and environment: the kit is supplied in protective packaging (protection against physical impacts and antistatic packaging). It must be stored under the following conditions:

Ambient temperature:	-10°C to +70°C / 14°F to 158°F
Relative humidity:	<95% without condensation
Atmospheric pressure:	500hPa to 1060hPa

Operation: the kit has been designed for normal use under the following conditions:

Ambient temperature:	+10°C to +35°C / 50°F to 95 °F
Relative humidity:	30% to 75%
Atmospheric pressure:	700hPa to 1060hPa

Equipment packaging for return to distributor: should a return to the distributor be necessary, make sure to package the sensor and box kit in its original packaging after having cleaned it thoroughly.

Documentation loss: all kits are shipped with its documentation. Please contact your distributor for a replacement manual if this documentation is lost.

1.12 Marking and labelling symbols

These symbols are used on the product labels and inform you about the compliance with standards and the technical specifications of the component.

⎓	Direct current.		Type BF applied parts, IEC 60601-1
	Insulation class II		Important information: follow the instructions for use
CE 0051	The CE marking certifies that this product complies with European directive 93/42/EEC and its revised versions..		Name and address of manufacturer
REF SN	Product identification code Serial number		Manufacturing date (year and month)
IP X 7	Sensor waterproofness standard, EN/CEI 60529 regulation. **Only the part of the sensor putted in month, complies with this standard.**		Storage condition: temperature limitations.
	Storage condition: relative humidity limitations		Storage condition: Atmospheric pressure limitations.

In some of its parts, the device contains materials and liquids that, at the end of the lifespan of the unit, must be disposed of at the appropriate disposal centres

1.13 Electromagnetic information

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents

Portable and mobile RF communications equipment can affect medical electrical equipment.

The equipment can be installed both in professional buildings and in residential buildings. Residential buildings, according to IEC 60601-1-2 4th edition, are intended to be connected to dedicated power supply system (normally fed by separation transformers).

For the purpose of EMC environment classification according to IEC 60601-1-2 4th edition, both installations are classified as “Professional healthcare facility environment and home healthcare environment”

Warning
One should not be used adjacent to or stacked with other equipment; if adjacent use is necessary, One has to be observed to verify if it operates in a normal way.

Interference may occur in the vicinity of equipment marked with the symbol 

Warning
Portable and mobile RF communications equipment should be used no closer to any parts of One including cable. Minimum distance 30 cm.

1.14 Electromagnetic emissions

In accordance with IEC 60601-1-2 4th edition standard, One is suitable for use in the electromagnetic environment specified below.
The customer or user of the system must ensure that it is used in the said environment.

Guidance and manufacturer’s declaration – Electromagnetic emissions		
One is suitable for use in the specified electromagnetic environment. The purchaser or user of the **One** should assure that it is used in an electromagnetic environment as described below:		
Emissions test	**Compliance**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	One uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	One is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

1.15 Electromagnetic immunity

In accordance with the IEC 60601-1-2 4th edition standard One is suitable for use in the electromagnetic environment specified below.
The customer or user of the system must ensure that it is used in the said environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2/4/8/15 kV air	IEC 60601-1-2 Test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Radiated electromagnetic field IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of One including cable. Minimum distance 30 cm
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines > 3 m	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	0.5/1 kV differential mode 0.5/1/2 kV common mode	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V ISM frequencies	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of One, including cable. Minimum distance 30 cm
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	10 ms – 0 % a 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms – 0% a 0° 500 ms – 70% a 0° 5 s – 0%	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the One requires continued operation during power mains interruptions, it is recommended that the One be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	IEC 60601-1-2 Test level	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment

1.16 Environmental risks and displacement

Some parts of the device contain materials that, at the end of the unit's lifecycle, must be disposed of at appropriate disposal centres. In particular the device contains the following materials and/or components:

- Non biodegradable plastic materials
- Copper
- Printed circuit boards with electronic components
- Metal parts

Note Information for users of European Community according to 2011/65/EU Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment

The symbol with the waste bin crossed on the equipment or its packaging, indicates that the product must be separately collected from other waste at the end of its life. The separate collection of the present equipment that has reached end of its life is organised and managed by the manufacturer.
The user who wishes to dispose of this equipment must contact the manufacturer and follow their system to enable the separate collection of the equipment at the end of its life.
Suitable separate waste collection for the subsequent start of the equipment discarded for recycling, for treatment and for environmentally friendly disposal, contributes in preventing possible adverse effects on the environment and health and promotes the reuse and/or recycling of materials of which the equipment is comprised.
Illegal disposal of the product by the holder implies the application of administrative sanctions provided by law.

1.17 Manufacturer identification

Manufacturer:

Owandy Radiology sas.
2, rue des Vieilles Vignes
77183 Croissy-Beaubourg
FRANCE

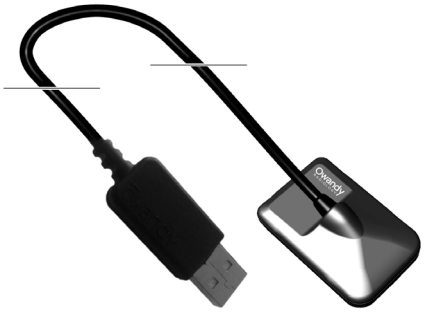
1.18 Identification label

One sensor size 1 identification label

One sensor size 2 identification label

2 CONTENTS

Your ***ONE*** kit consists of the following elements (illustrations may vary from items supplied):



An ONE sensor - size 1 or size 2 (cable of 3m)

1 self-adhesive sensor wall support

A bag of disposable single-use hygienic protective sleeves (compatible with size 1 and 2 sensors)

An USB Stick with the sensor calibration files and manuals

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1 Mouse Pad

A packing list

A « Quick Start guide »

3 INSTALLATION

3.1 Precautions

Warning
The kit must be handled with care, minimise the twisting, pulling and bending of the attachment cable. Do not step or roll on the cable. 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
Read paragraph 1.9 to ensure the installation complies with the standards

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

3.1.1 Recommended minimal configuration

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

Operating system	Windows 10 / 32 and 64 bits
Computer Motherboard USB port	Compliant -IEC60950-1 Intel 3GHz Chipset and processor USB 2.0 High-Speed
Graphics card Monitor	1 GB High resolution 1024x768 (15inch)
RAM memory Hard disk	2 GB 500 GB
CD-ROM drive Backup system	24x External/removable disk, CD-ROM/DVD…
Printer Keyboard and mouse	Laser, inkjet, thermal

Warning
The computer connected to the sensor MUST be compliant with standard IEC 60950-1.

3.1.2 Setup guidelines

The computer and the screen with which the sensor and the box are 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.

3.2 Equipment installation

3.2.1 Connection

The ONE sensor is fitted directly to a cable equipped with a USB connector linking it directly to the computer.

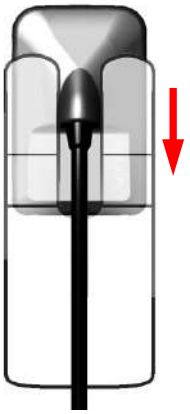
Warning
Make sure the USB port of the computer is preferably a USB 2.0 port.Only use USB 2.0 cables with a USB 2.0 port. Each USB cable should not be longer than 3m / 9.8ft. The kit is compatible with USB 1.1 ports but with reduced image transmission speed.

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

Check that the sensor is correctly connected: if the sensor toolbar turns green after removing the sensor from its support, it is powered correctly.

3.2.2 Sensor support

The sensor can be placed on its self-adhesive support supplied with the kit. The support is compatible with sensors of size 1 or size 2. This support can be fixed on any type of flat surface: worktop or a part of the chair. The sensor will then be inserted into the fork of the support taking care not to impede the cable.



Warning
Do not mount the wall support upside-down or horizontally, the sensor could fall on the ground and be damaged.

3.3 Software installation

Install the Owandy QuickVision (or third party) 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 and use of the software and equipment. Please contact your IT specialist to create a suitable user account.

3.3.1 Installation of OSP and drivers

Warning
The ONE drivers are only compatible with Windows 7, 8, 10 (32 and 64 bits) operating systems.

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 ONE, and follow instructions.

3.3.2 Sensor installation files

Warning
Each kit is provided with a sensor installation USB stick of its own; the serial number of the sensor is written on the USB stick and on the connection box. You can therefore not use the same USB stick to install several sensors; each sensor requires its own USB stick.

Before installing the sensor **installation files**, make sure that:

- The drivers of the kit are installed.
- The imaging software is not started.

1. Insert the USB stick
2. Open CALIBRATION partition
3. Click on install.bat
4. Close the window

3.3.3 O.S.P. update

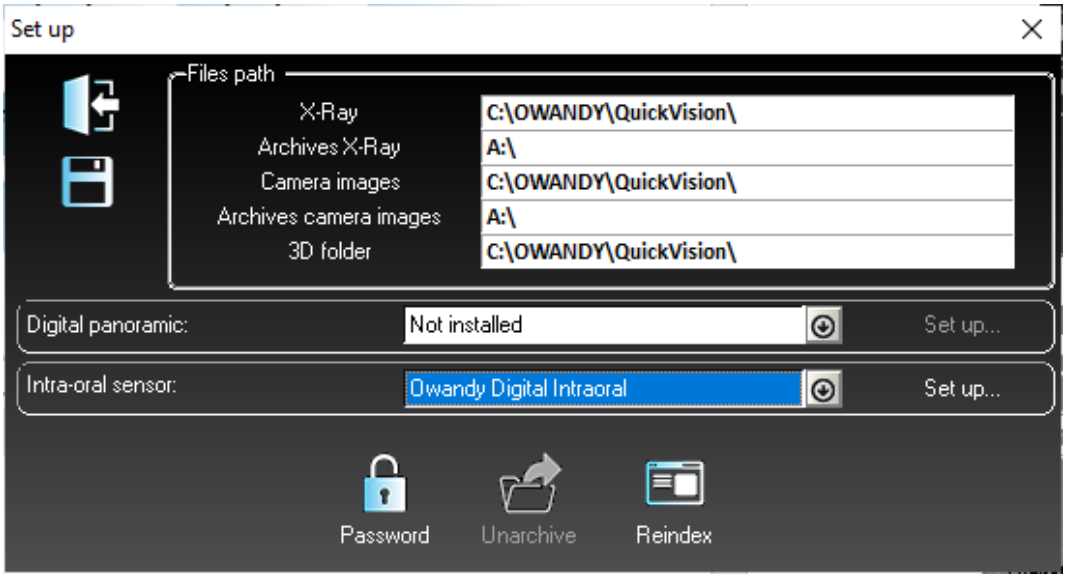
If you need to update your O.S.P.:

1. Connect the USB stick to the PC, or download the OSP on our website www.owandy.com/support
2. Select ONE, and follow instructions.

3.4 Configuration in the Owandy imaging software

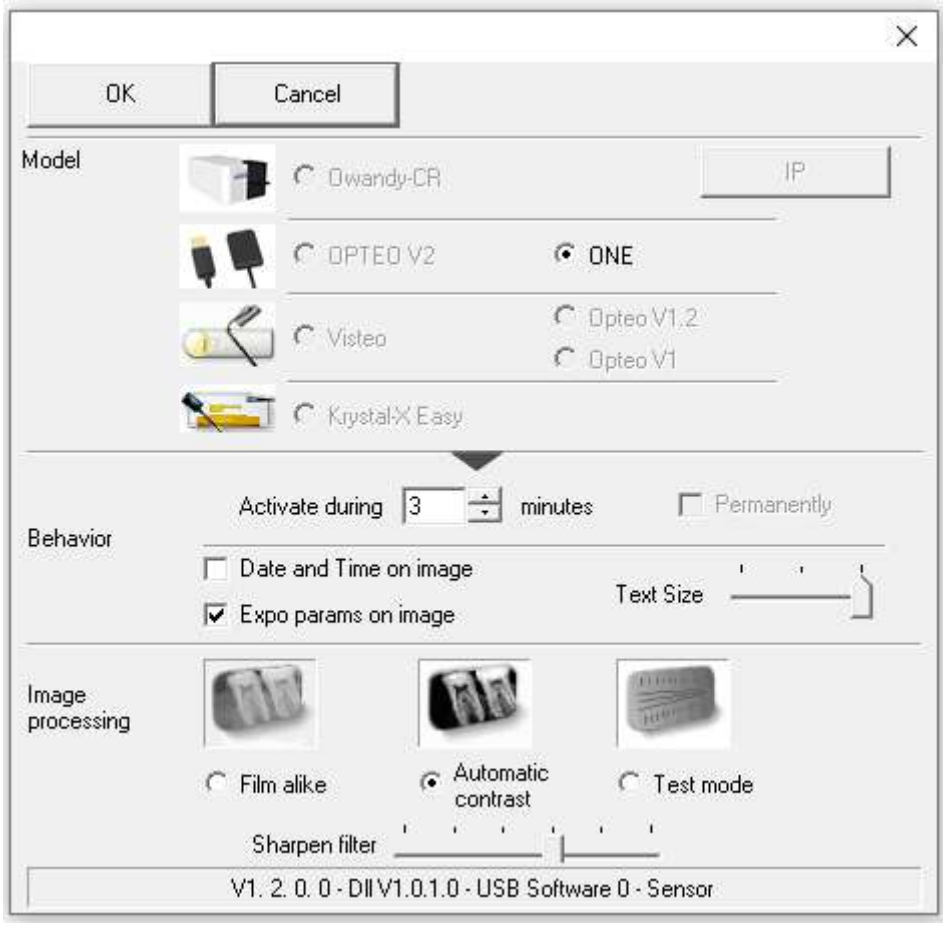
To be able to use your kit with the Owandy QuickVision imaging software you must configure your equipment.

1. Start the imaging software
2. Click on the “SETUP” button in the main screen.
3. Select “Owandy Digital Intraoral” under the “Intra-Oral sensor” option in the window that appears.



4. Click on “Set up” at the right of the menu.

In the configuration window:



◄ Select “ONE” kit.

◄ Set the activation time of the box (default 3min).

◄ Set the inlay and size of the date & time and exposure parameters in the acquired image.

◄ Select the image treatment (*).

(*) When the “Film alike” option is activated, the contrast depends on the exposure time. Adjust the X-ray dose on the generator to obtain a good image.
(*) When you select the option “Auto contrast” the contrast is constant. Exposure errors are corrected automatically, which reveals noise in badly exposed images.

In both cases, the exposure bar (blue/green/red) helps to find the correct exposure of the images..

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

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

3.5 Sharing the sensor and box between different workstations

Sharing the sensor allows you to use one or more sensors in turn in a practice with multiple chairs. It is recommended to link the different workstations in a network to allow for the central storage and sharing of the images.

A USB port must be plugged into each workstation to allow for an easy connection of the box. Windows will automatically recognise the equipment when it is connected and it will be available immediately for image acquisition.

To enable the sharing of a kit between different workstations, it is necessary to first install the imaging software for the acquisition of the images, the drivers, O.S.P. tools and sensor installation files on all the computers with which your ***ONE*** will be used.

4 USE

4.1 Precautions

Warning
ALWAYS use protective sheaths to cover the sensor, the part of the cable proximal to the sensor and the positioner, if used.

Warning
ALWAYS keep (or ask the patient to keep) in place the protective sheath during the use.

Warning
Make sure the sensitive surface (the flat surface) of the sensor is directed towards the X-ray generator. The active surface of the sensor is marked by a frame. The back of the sensor (rounded) does not react to X-rays and does not produce an image on-screen.

Warning
The kit must be manipulated with care, minimising the twisting, pulling and bending of the attachment cable. Do not step or roll on the cable. Be careful not to pull on the cable when removing the hygienic protective sheaths.

Warning
Do not pull on the cable itself, but on the plug to disconnect the USB cable.

Warning
Even though the sensor is resistant to impacts, it is strongly recommended to not let it fall on the floor. If a physical impact should exceptionally happen, contact your distributor and do not try to intervene yourself.

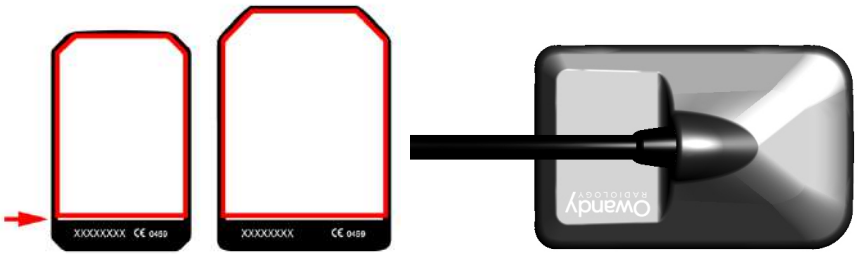
Warning
Do not ask the patient to bite on the sensor or cable.

Warning
Use of a mobile phone or an RF communications device near the ONE sensor may affect the sensor.

4.2 Sensor principles

4.2.1 Sensor

The sensor's sensitive area is delimited by a horizontal line; the area below this line is not sensitive to X-rays. When the sensor is placed in the mouth it is necessary to check that this area is turned towards the radiation source and that the whole sensitive area is irradiated.



Active surface ***Sensor's rear shell: inactive surface***

4.2.2 Sensor activation

The sensor automatically puts itself on standby after a period which can be configured in the configuration window (see "3.4 Configuration in the Owandy imaging software" - the default period is 3 minutes). The sensor's toolbar is then in its red state.

To activate your sensor physically, just click on the corresponding icon in the sensor IO tollbar (see "4.3.2 Sensor toolbar"). The state of the toolbar will change automatically to the green color.

4.3 Use of the Owandy XIO StandAlone software

4.3.1 Modes of operation

The sensor kit can function in 2 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 sensor 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 sensor:

	Red: sensor inactive
	Yellow: sensor initialising
	Green: sensor ready for acquisition

Warning
When the sensor is in "ready status" (green icon) and receive X-ray, it acquires image also in case the user software has not been activated or a patient has not been selected.

4.3.2 Sensor toolbar

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

	Red: sensor inactive
	Yellow: sensor initialising
	Green: sensor ready for acquisition

Options of the sensor toolbar:

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

◄ Activate/deactivate the sensor.

◄ Selection of the sensor to activate (case of simultaneous use of a size 1 sensor and size 2 sensor on the same computer).

◄ Iconize the toolbar in the taskbar.

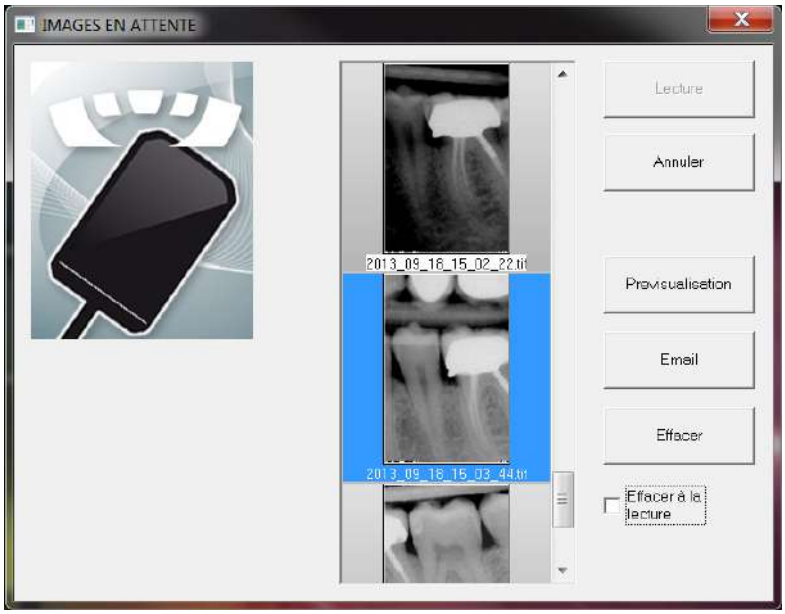
Warning
The sensor automatically switches to standby mode after a few minutes of not being used; the sensor toolbar turns red.
Check that the sensor toolbar is displayed in green before each acquisition.

4.3.3 Configuration menu

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

X-ray sensor	Displays the sensor 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 “3.4 Configuration in the Owandy 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.

4.3.4 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.

4.4 Acquisition of an image

4.4.1 Acquisition procedure

The image acquisition goes through several steps:

1. Before being able to acquire an image with the sensor, you need to start the computer to which it is connected and start the imaging software. Check that the sensor toolbar or the sensor icon in the task bar is green.

2. Program the different parameters (exposure time, etc.) on the X-ray generator (see “4.5 Exposure times” for more information).

3. Cover the sensor with a hygienic protective sheath making sure to cover a sufficient length of cable.

4. A set of positioners is provided with the kit to place the sensor in the different parts of the mouth; their use is recommended to ensure the sensor is positioned perpendicularly to the X-ray beam. The sensor can also be positioned manually, maintained by the patient as with conventional film. This can be necessary for children with a small oral cavity. Position the sensor in the mouth, behind the tooth of which you want to acquire an image. If you do not use a positioner, a cotton roll can be helpful to position the sensor parallel to the tooth.

Warning
ALWAYS use protective sheaths to cover the sensor, the part of the cable near to the sensor and the positioner, if used.

Warning
ALWAYS keep (or ask the patient to keep) in place the protective sheath during the use.

Warning
Turn the sensitive surface of the sensor (the flat surface) towards the generator; if it is facing the other way, the sensor will not be able to acquire images.

5. Position the generator so as to cover the whole sensitive area of the sensor. The paralleling technique is strongly recommended and the use of positioners allows you to correctly place the generator thanks to the aiming ring.

6. Activate the generator. The sensor 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 sensor toolbar turns green allowing a new acquisition.

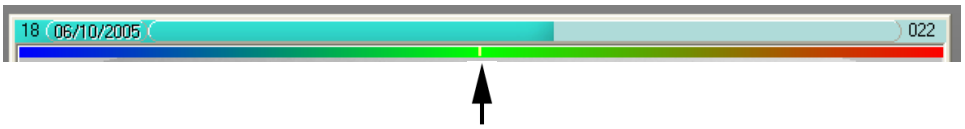
Warning
In case the sensor is used with intra oral system with low mA emission (i.e. hand held systems that typically provide 2mA), it is necessary to position X-ray source as close as possible to the sensor, without any extension and set the exposure time between the range 50ms and 500ms. Without this setup, the dose is not enough to trigger the sensor and acquire the image.

4.4.2 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 Owandy 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 Owandy 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.

4.5 Exposure times

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

Voltage/Current	65 kV 6 mA
Lower incisor / canine	0.06 – 0.09
Lower premolar	0.06 – 0.10
Lower molar	0.07 – 0.11
Upper incisor / canine	0.08 – 0.10
Upper premolar	0.08 – 0.11
Upper molar	0.11 – 0.16
Front bitewing	0.06 – 0.09
Rear bitewing	0.11 – 0.16

Reference conditions:

- *Adult patients, or paediatric patients of average size*
- *Distance focal spot to sensor* *200mm*
- *Total filtration* *equivalent to 2,5 mm 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	
Lower incisor / canine	
Lower premolar	
Lower molar	
Upper incisor / canine	
Upper premolar	
Upper molar	
Front bitewing	
Rear bitewing	

5 HYGIENE AND MAINTENANCE

5.1 Hygiene and disinfection

5.1.1 USB Connector

The connector does not require any particular maintenance, it should be cleaned using a cloth and non-abrasive detergents.

5.1.2 Sensor

To avoid cross-contamination between patients during use, it is necessary to protect the sensor with hygienic single-use protective sheaths (FDA cleared for the USA, CE marked for Europe). Some hygienic protective sheaths suited for your region are provided with each system.

Before each use on a patient, the used sheath should be thrown away and the sensor disinfected applying a high level disinfection procedure (see “5.2 Recommended cleaning and decontamination procedure”). A new protective sheath is applied to the sensor for each new patient. We recommend the disposal of the hygienic protective sheaths with the biologically hazardous waste of your practice.

Validated protections for North America: BANTA HEALTHCARE or TIDI PRODUCTS X-ray sensor sheaths, STERI-SHIELD PRODUCTS RS barriers.

Warning
Do not pull on the cable when removing the used protective sheath.

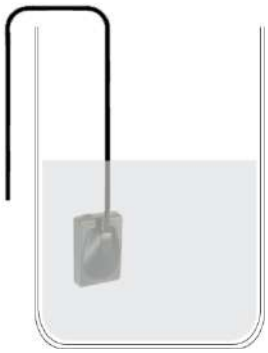
5.1.3 Cables

The cable can be cleaned with caution by using a disinfecting wipe. Hold the sensor with one hand and, with the other hand, apply a disinfecting wipe from the side of the sensor along the first 20cm / 8inch of the cable without pulling on the cable; subsequently clean the remainder of the cable in segments of 20-30cm / 8-12inch with as little pinching of the cable as possible, the wipe should slide without applying force.

5.2 Recommended cleaning and decontamination procedure

Remove the hygienic protective sheath (dispose of it appropriately with the contaminated waste). Vigorously wipe down the sensor to remove any visible residues. If necessary rinse with copious amounts of water. Then place the sensor in the disinfecting agent.

Warning
Only immerse the sensor and the head of the positioner or sensor connection cable in the disinfectant for 15min, never immerse the connector on the box side of the positioner or sensor connection cable in the liquid.



During the immersion, brush the submerged parts with a soft brush. Then rinse thoroughly the sensor and the positioner or the sensor connection cable with copious amounts of fresh water.

Warning
Do not put the sensor in a sterilizer or an autoclave, the high temperature and excessive high pressure will seriously damage the electronics of the sensor and connectors.

Warning
Do not clean the sensor with inappropriate instruments (knife…).

If the sensor, positioner or sensor connection cable are not being used immediately upon rinsing, as in the case of allowing them to air-dry overnight at the end of a working day, they should be rinsed with sterile water.

When the sensor, positioner or sensor connection cable are not being used, to protect them from any damage, it is recommended to store them in their box or to hang them in the sensor wall support.

Even when using protective sheaths, the sensor should be disinfected regularly. Immerse the sensor in cold sterilisation fluid in accordance with the instructions of the manufacturer after having cleaned it from all residues. Never leave the sensor immersed for longer than necessary.

5.2.1 Recommended decontaminating product for North-America

The sensor being sealed watertight and to minimize the potential for device-associated infections, the sensor and the part of the positioner or sensor connection cable inserted in the mouth shall be disinfected with an FDA-cleared high level disinfection agent following the instructions of the manufacturer for use, storage, handling and warning.

The following disinfectant agent has been validated with the sensor: CIDEX OPA solution (0.55% Ortho-phthalaldehyde solution). The maximum soaking period is 24 hours.

5.2.2 Recommended decontaminating products outside North-America

The following disinfectants are compatible with the sensor and the part of the positioner or sensor connection cable that is inserted in the mouth:

- 2% Sodium Hypochlorite (maximum immersion time of 24 hours)
- Ethyl alcohol (maximum immersion time of 24 hours)
- Quaternary ammonium

5.3 Maintenance

5.3.1 Computer data-protection

Your patient and image database must be backed-up to be able to recuperate them if needed (in case of hard disk or computer problems). It's recommended to do the back up once a week

Ask the advice of your IT specialist with regard to the backup system that is best suited to your computer configuration (external or removable hard disk, CD-ROM or DVD writer, etc.). Test and store the copies in a safe place. It's recommended to do the system back up twice a month

NOTE: The device is not serviced or maintained while in use with the patient

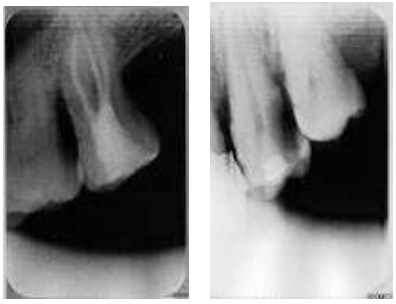
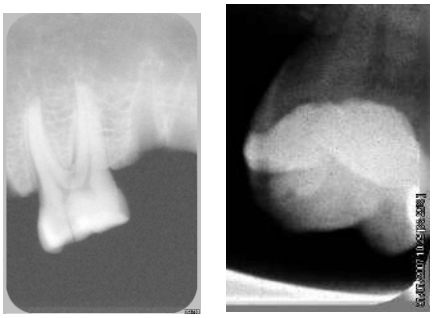
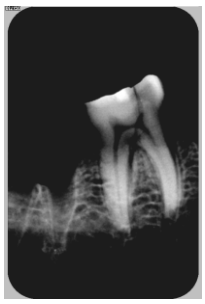
6 TROUBLESHOOTING AND TESTS METHOD

If an error occurs during operation, check the different items in this troubleshooting guide. If you cannot resolve your problem please contact your distributor.

6.1 General

Symptom	Cause / Solution
The kit does not power up or it does not acquire images.	• Check that the active surface of the sensor is directed towards the X-ray generator and is positioned correctly in the field of the X-ray beam. • Check that the kit is correctly configured in the imaging software and that the drivers are correctly installed. • Check the connection between the sensor and the PC, and ensure that the PC is powered externally. • Check that the generator is emitting X-rays (with another sensor or with conventional film).
No image appears on the screen.	• An error has occurred during acquisition, disconnect the cable and wait a few seconds before reconnecting it. • Check that the outer sheath of the cable connection from the sensor does not show any signs of tearing.
The sensor is slightly warm.	This is normal. The temperature of the sensor can exceed 6°C (43°F) when the kit is activated for a prolonged period (e.g. when taking many consecutive images) and has no bearing on the functioning of the kit. • Reduce the standby time in the configuration screen.

6.2 Image quality

Symptom	Cause / Solution
The images are cut off, e.g.: 	The sensor is badly positioned with regard to the X-ray beam. • Reposition the sensor, making sure it is well within the field of the X-ray beam. • Use the positioners provided with the sensor 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: o 0 to 80% - under-exposed image o 80 to 120% - correctly exposed image o 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: o 0 to 80% - under-exposed image o 80 to 120% - correctly exposed image o 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. • Check 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.

6.3 Tests Method

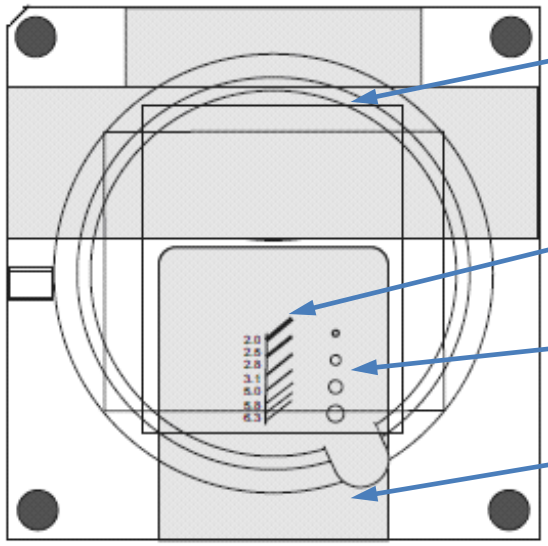
It is recommended to the practitioner to test regularly the quality of the imaging digital devices complete line.
You can refer to the standard IEC 61223-3-4 (V2000) which describes the acceptance tests imaging performance of dental X-ray equipment.

Two parameters have to be inspected to verify the performance of both the X-ray generator unit and the Intra-oral sensor (see chapters 5.8 and 5.9 of the standard IEC 61223-3-4):

- Spatial resolution (pl/mm)
- Low contrast resolution (mm)

To control these two parameters, you can use a phampton test object, placed directly in front of the exit of your Xray unit collimator, and in which you introduce the intra-oral sensor.

Example of an intra-oral test phampton (QUALIMEDIS ref. OTN):

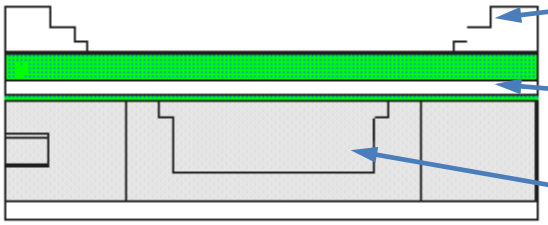


Various circular and rectangular guides sizes for X-ray units collimator centring

Spatial resolution Phampton test details
Lead thickness: 0.05mm
Spatial resolutions of 2.0, 2.5, 2.8, 3.1, 5.8, 6.3 pl/mm

Low contrast resolution Phampton test details
Ø 1.0, 1.5, 2.0, 2.5mm

Intra-oral sensor location compatible with different sizes

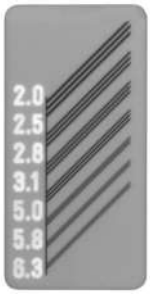


Collimator centring guide (compatible with rectangular and circular design)

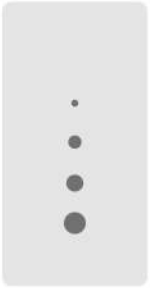
- **Aluminium filter 6.0mm thickness,**
- **Plexiglas filter 3.0mm thickness,**
- **Aluminium filter 0.5mm thickness.**

Intra-oral sensor location

- Spatial resolution control object:



- Low contrast resolution control object:



The image quality control acquisition goes through several steps:

1. Before acquiring an image with the sensor, you need to position the intra-oral test phampton just in front of the collimator of your X-ray generator unit. You can inclinate the tubehead in vertical position to manage this operation, or put the test phampton directly on a table and move the tubehead collimator directly on it.

2. Place the sensor in its location dedicated for. Take care that the sensitive surface of your sensor covers completely all the details objects of the low-contrast and spatial resolutions phamptons (see image opposite).

3. Set up your X-ray generator with your usual radiological paramaters corresponded at an upper molar, then activate the exposure time of your X-ray generator unit.

4. Look at the image obtained at your computer screen to verify the spatial and low-contrast resolutions parameters. Save both the image and the results in your quality control file.

This protocol gives you a complete procedure to verify the quality of your intra-oral digital installation (both intra-oral sensor and X-ray generator). To conclude that your devices deliver acceptable images, we recommend you to use the acceptance criteria recommended by the ANSM (French Agency for the Security of Medical Device – http://ansm.sante.fr/) and published by decree on December, the 26th 2008 (“Journal official de la République Français” - Text 79/192):

- **Images Spatial Resolution for numerical devices: minimum value accepted=5pl/mm** (refer to chapter 5.4.4 of the decree),

- **Images Low-Contrast Resolution for numerical devices: minimum value accepted=1mm** (refer to chapter 5.5.3 of the decree).

7 SPECIFICATIONS

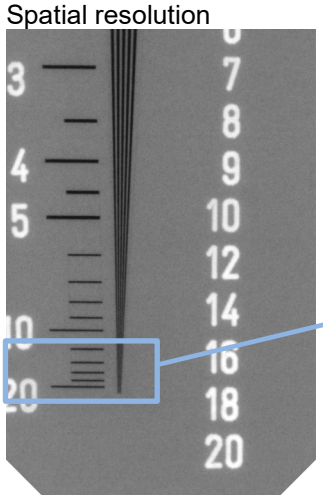
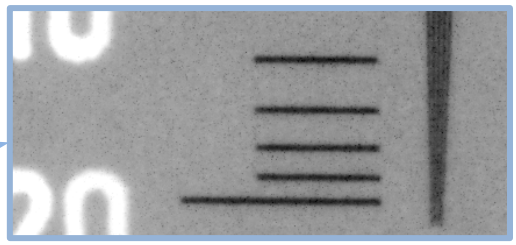
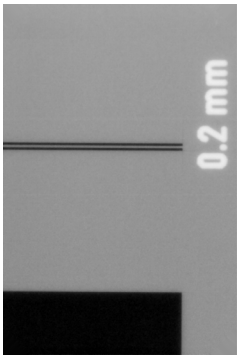
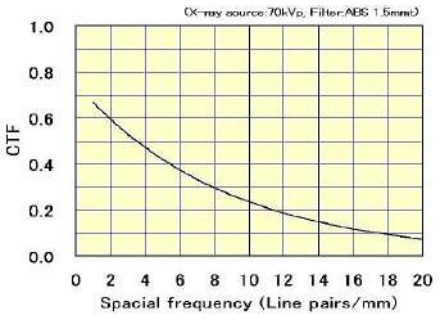
7.1 General specifications

ONE Sensor - Size 1	
External dimensions size 1 sensor	38.6 x 24.7 x 5.2mm / 1.6 x 1.0 x 0.2inch
CMOS matrix size 1 sensor (cut corners) • Sensitive area in size • Sensitive area in pixels • Pixel dimensions	 30 x 20mm (600mm^2) / 1.2 x 0.8inch (1.0inch^2) 1500 x 1000pixels 20 x 20µm

ONE Sensor - Size 2	
External dimensions size 2 sensor	43.2 x 30.8 x 5.2mm / 1.7 x 1.2 x 0.2inch
CMOS matrix size 2 sensor (cut corners) • Sensitive area in size • Sensitive area in pixels • Pixel dimensions	 34 x 26mm (900mm^2) / 1.3 x 1.0inch (1.3inch^2) 1700 x 1300pixels 20 x 20µm

Technical specifications (size 1 and 2 sensors)	
Length sensor cable	3m / 9.9ft
Grey levels	14bits (16384 grey levels)
Connection	USB standard: USB 2.0 High-Speed (480Mbit/s) and USB 3.0
Consumption kit	0.5VA under 5V (USB port)
Input voltage sensor Sensor current absorption	5V (USB port) 0.15A
Operating temperature	+10°C to +35°C / 50°F to 95°F
Lifespan CMOS	Min. 100,000 cycles
Standards	
Conformity to standards	IEC60601-1 3ed (2005)+A1 (2012) IEC 60601-1-6 3ed (2010)+A1 (2013) IEC 62304 1ed (2006)+A1 (2015) IEC60601-1-2 4ed (2014) CFR21 Medical Device Directive 93/42/EEC (as amended)

Non clinical testing specifications

Spatial resolution 	***15pl/mm*** 
Low-Contrast resolution 	***Minimum value measured: 0.2mm***
Dynamic range	14bits (16384 grey levels). Sensor saturated at 130ms with no absorbing material (no object in the X-ray field - X-ray generator radiological parameters 7mA/65kV)
Signal to noise ratio	Between 33 dB and 40dB
Contrast function	0,24 @ 10lp/mm 
Image decay and latency	Image is integrated in the sensor for 0,5 second. Image is read-out just after integration. Image decay and latency don't affect the system.

8 ACCESSORIES

Introduction packs of positioners:

Code 7758003400	Size 1
Code 7758003500	Size 2

Refill packs of 10 positioners:

Code 7758012600	Size 1 bitewing
Code 7758012800	Size 1 endo
Code 7758012300	Size 1 posterior
Code 7758013000	Size 1 peri-apical
Code 7758012700	Size 2 bitewing
Code 7758012900	Size 2 endo
Code 7758013100	Size 2 posterior
Code 7758013300	Size 2 peri-apical

Hygienic single-use disposable protection sleeves (for size 1 and 2 sensors)

Code 7758003800 Bag of 500 pieces

Mounting accessories

Code 5458000000 Self-adhesive wall support

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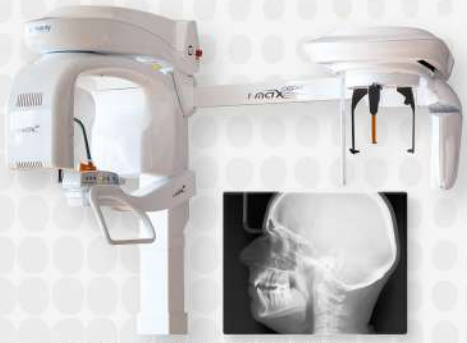
DIGITAL WORKFLOW OWANDY RADIOLOGY

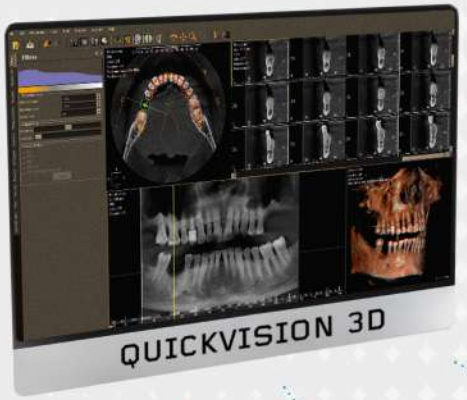
A COMPREHENSIVE RANGE TO MEET ALL YOUR REQUIREMENTS

2D/3D UNITS



CEPHALOMETRIC UNITS

HF INTRA-ORAL GENERATOR



FACE SCAN
.PLY IMPORT

INTRAORAL
PLATE SCANNER

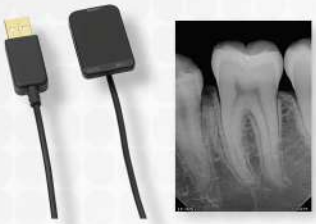
DENTAL IMPRESSIONS
.STL IMPORT

SURGICAL
GUIDE

DIGITAL USB
INTRAORAL CAMERA

EXPORT TO
3D PRINTER

DIRECT USB
SENSORS



Owandy RADIOLOGY

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