



EN • INSTALLATION AND USER MANUAL

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OPTCO

DIGITAL IMAGING MADE SIMPLE

USB direct intra-oral Sensor

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1 Introduction

You have just received your **Opteo** 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 Indication For Use

The **Opteo** digital system is designed to collect instant images of human oral tissue and teeth without the use of conventional X-ray film. It is used with a conventional X-ray tube and a computer for dental radiographic imaging. The **Opteo** is covered with a single use disposable sheath and positioned in the oral cavity opposite the tooth the dentist wishes to X-ray. The dental X-ray tube (which is not part of **Opteo**) is pointed at the sensor and activated. The emitted radiation from the X-ray tube is detected by the sensor and transmitted as a data stream to the computer system that the device is connected to.

1.2 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.

1.3 Compliance with standards

The **Opteo** kit is class IIA equipment within the meaning of the European Directive 93/42/CEE concerning CE markings. The **Opteo** kit complies with the EN/IEC60601-1 medical standard.

Under certain conditions (see chap. 1.3 "Installation precautions") it is necessary that the other components of the system that are possibly connected (computer and optional peripherals) are also compliant to standard IEC950 (EN60950) and that the installation complies with the EN/IEC60601-1 standard.

The intra-oral sensor is contained within a hermetic and sealed case (resistant to immersion). There is no physical or electrical connection between the **Opteo** kit and the X-ray generator.

1.4 Power supply

The power to the **Opteo** box is provided directly by the power supply of the USB cable connecting it to the computer.

1.5 Installation precautions



As the intra-oral sensor is situated inside the patient environment (less than 1,5m / 4.9ft from the patient), your computer must necessarily comply with standard EN/IEC60601-1, or your installation including the computer must have been rendered compliant with standard EN/IEC60601-1-1. You can connect the sensor to your computer without additional precautions once your complete installation is compliant with standard EN/IEC60601-1.

If the computer is not situated in the patient environment and is not compliant with standard EN/IEC60601-1, it is necessary to place the sensor in non-conductive packaging.



The **Opteo** 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.



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 **Opteo** sensor.

1.6 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.



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.



Any modification of the **Opteo** 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 EN/IEC60601-1-1 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).

1.7 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: in compliance with the international safety standard EN/IEC601-1 (section 2), the kit has been designed for normal use under the following conditions:

Ambient temperature: +10°C to +40°C / 50°F to 104°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.

1.8 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 B equipment, EN/IEC 60-601-1, annexes I and II. |
|  | The CE marking certifies that this product complies with European directive 93/42 CEE. |  | Important information: follow the instructions printed in this manual. |
|  | Product reference Product serial number |  | Manufacturing date |
|  | 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. |



Equipment subject to a selective collection in accordance with Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) and with Decree 2005-829 of the 20th July 2005 regarding the composition of electrical and electronic equipment and the elimination of waste coming from this equipment.

2 Contents

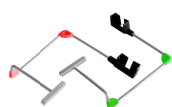
Your **Opteo** kit consists of the following elements (illustrations may vary from items supplied):



An Opteo sensor - size 1 or size 2
(cable of 3m / 9.9foot)



1 self-adhesive sensor wall support



Metal positioner kit
(available for size 1 sensor as default)



An introductory pack of plastic positioners
(available for size 2 sensor as default)



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



An O.S.P. installation CD-ROM
(drivers/diagnostic tools)
A CD-ROM with the installation files of the sensor



A manual - A packaging checklist

3 Installation

3.1 Precautions



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.



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



Read paragraph “1.5 Installation precautions” 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



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 XP SP2, Vista or Seven (32 and 64 bits) |
| Computer Motherboard USB port | Compliant CE-IEC950 Intel 1.4GHz chipset and processor USB 2.0 High-Speed |
| Graphics card Monitor | 64MB High resolution 1024x768 (15inch) |
| RAM memory Hard disk | 256MB 10GB |
| CD-ROM drive Backup system | 24x External/removable disk, Zip or Jaz system, CD-ROM/DVD... |
| Printer Keyboard and mouse | Laser, inkjet, thermal |
| At acquisition workstation | Opteo kit with appropriate drivers Imaging software X-ray generator with electronic timer |

If your computer does not possess USB 2.0 ports, these can be added as PCI/PCI express cards (for desktop computers) or PCMCIA cards (for laptops). If the USB ports do not provide enough current, please use a powered hub (with its own power supply). The PCMCIA cards need to be powered by an external power supply or connected to a powered hub if they do not provide enough current. Please contact your IT specialist for further information.

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

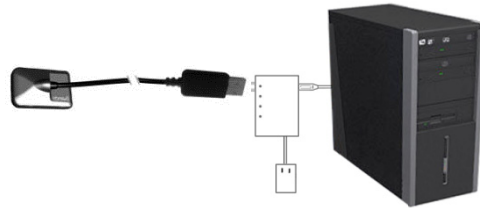
3.2.1 Connection



The **Opteo** sensor is fitted directly to a cable equipped with a USB connector linking it directly to the computer. If the distance between the sensor 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.



Connection without hub



Connection with power supplied hub



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 USB 2.0 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.

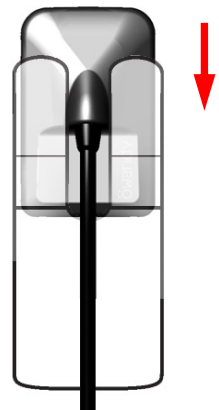
Check that the sensor is correctly connected: if the sensor toolbar turns green after removing the sensor from its support, it is powered correctly.

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.



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.



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 the drivers



The **Opteo** drivers are only compatible with the Windows XP (service pack 2 or higher), Windows Vista and Windows Seven operating systems – 32 and 64 bits.

Automatic installation: insert the O.S.P. CD-ROM in the CD-ROM-drive. The interface will launch automatically and will guide you through the different installation steps. Refer to the Windows help if the CD-Rom does not launch automatically.

1. Select the desired language in the main screen. The tabs at the top of the page link to different pages of the OWANDY RADIOLOGY website and provide more information regarding OWANDY RADIOLOGY.
2. Select "USB" in the menu that appears.
3. Connect the USB cable to the connection box and the USB 2.0 port of the computer. Windows will automatically detect your box.
4. Cancel the window "Add hardware wizard" that appears then click on "Click here" in the window of the O.S.P. installer.
5. In the new window, confirm the location of the drivers that is displayed by clicking on "Install". This location must correspond to the directory of the drivers on the O.S.P. CD-ROM. The driver files are then copied to your hard disk.
6. Click on "Continue" in the message window "Equipment installation" that appears.
7. A confirmation window is displayed after the files have been copied, it confirms the drivers have been installed correctly by displaying "Opteo V2 USB: Installed". Click on "OK" to close this window.
8. Then continue the installation of the O.S.P. with reference to paragraph "3.3.2 Installation of the O.S.P."

Manual installation: it is also possible to install the drivers manually by using the "New hardware detected assistant" of Windows. Follow these steps:

1. Connect the connection box to the USB 2.0 port of the computer. Windows will automatically detect your equipment and will display the "Found New Hardware Wizard" window.
2. If the wizard requests the authorization to connect to the Windows Update site, select "No, not this time", then click on "Next". This window does not appear depending on your version of Windows.
3. The wizard will inform you it has detected your "Opteo V2 USB" kit. Select "Install from a list or specific location" then click on "Next" after making sure the O.S.P. CD-ROM is inserted in the CD-ROM drive.
4. Select "Don't search. I will choose the driver to install" and click on "Next".
5. Click on "Have Disk" under the list that is displayed. If the window containing this list does not appear, click on "Show All Devices" then click on the "Have Disk" button.
6. The next window will allow you to navigate to the directory that contains the required files; click on "Browse".

7. Navigate to the “\drivers\WIN_2000_XP\OWandy USB” directory on the O.S.P. CD-ROM; this directory contains the file “ow_usb.inf”. Click on “OK” to select this directory.
8. The previous window now displays the location of the files to be installed: “E:\drivers\WIN_2000_XP\OWandy USB” (E : representing the letter of your CD-ROM drive, this can be different depending on your computer configuration). Click on “OK” to start the installation.
9. The “Opteo V2 USB” drivers are displayed in the list (see opposite); click on “Next”.
10. Click on “Continue” in the warning window “Device installation” that appears.
11. Finally click on “Exit” in the last window of the wizard.



The “Opteo V2 USB” is installed under “Universal Serial Bus controllers” in the “Device manager”. To reach this window click on the Workstation icon with the right mouse button and select “Manage” in the drop-down menu. In the window that appears select “Device manager”.

3.3.2 Installation of the O.S.P.

Automatic installation: the installation of the O.S.P. tools is automatically proposed after the installation of the drivers. Refer to the procedure below.

1. Select the desired language in the window that appears and click on “Next”.
2. In the welcome screen click on “Next”.
3. Select the target directory (the directory where the software will be installed) by clicking on “Browse” and by navigating to the desired directory. If you use the QuickVision imaging software select the directory where you installed QuickVision (proposed by default). After having selected the target directory click on “Next”.
4. Click on “Install” to start the copying the files.
5. After the files have been copied, select “Opteo V2 USB” in the list that appears and click on “OK”.
6. A window will inform you of the successful installation, close it by clicking on “Exit”.
7. The last window displays the location of the O.S.P. tools; close this window by clicking on the red cross of the window (top right).
8. Close the main O.S.P. installation window if it is still displayed on-screen.

Manual installation: if you have followed the manual installation of the drivers, you must start the manual installation of the O.S.P. tools:

1. Insert the O.S.P. CD-ROM in the CD-ROM drive.
2. Navigate to the “\setups\CMOS_XRAYS_BOX_W2000_WXP” directory on the O.S.P. CD-ROM.
3. Launch “setup.exe”.
4. Refer to the automatic installation of the O.S.P. mentioned above.

3.3.3 Sensor installation files



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

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

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

Insert the sensor **installation** CD-ROM, a window appears and the files are copied to the hard disk. Close the window after the files have been copied by pushing any key of the keyboard when asked for.

3.3.4 O.S.P. update

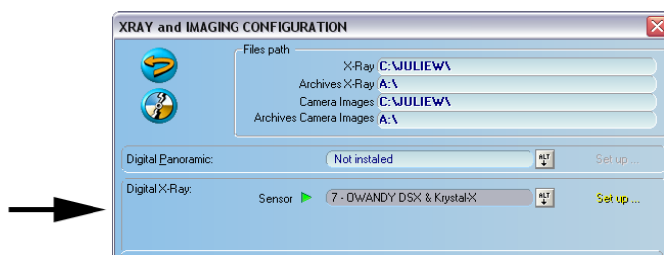
If you need to update your O.S.P.:

1. Insert the O.S.P. CD-ROM.
2. Navigate to the “\setups\CMOS_XRAYS_BOX_W2000_WXP” directory on the CD-ROM.
3. Launch “setup.exe”.
4. Click on “Install or Reinstall” and follow the instructions on-screen.

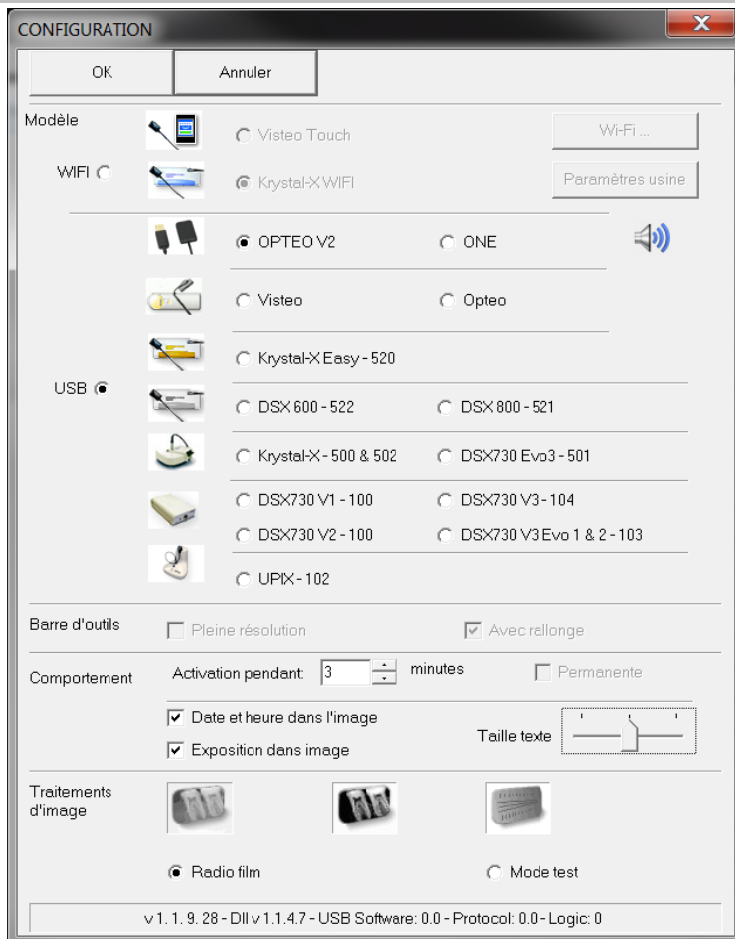
3.4 Configuration in the Owandy imaging software

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

1. Start the imaging software (double-click on the desktop icon or use the link in Start / Programs / QuickVision).
2. Click on the “Configuration” button in the main screen.
3. Select “OWANDY DSX & Krystal-X” under the “Intra-Oral sensor” option in the window that appears.



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



In the configuration window:

- ◀ Check the “USB” type.
- ◀ Select the “Opteo V2” kit.
- ◀ Set the activation time of the box (default 5min).
- ◀ Set the inlay and size of the date & time and exposure parameters in the acquired image.
- ◀ Select the image treatment (*).
- ◀ Configure the Owandy software (**).


(*) 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.

(**) This option appears only when the sensor is used from certain Owandy software programs; it allows the change of the sharpness setting or the high resolution for each acquired image.

5. Click on “OK” to confirm your choice.

6. Then click on the “Save”  button (QuickVision 3) or on the “Validate” button (QuickVision 4) to validate the settings.

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 **Opteo** will be used.

4 Use

4.1 Precautions



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.



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.

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



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.



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

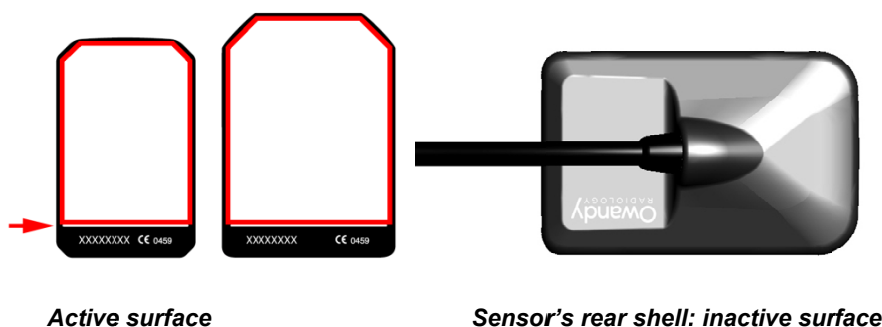


Use of a mobile phone or an RF communications device near the **Opteo** sensor may affect the sensor.

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.



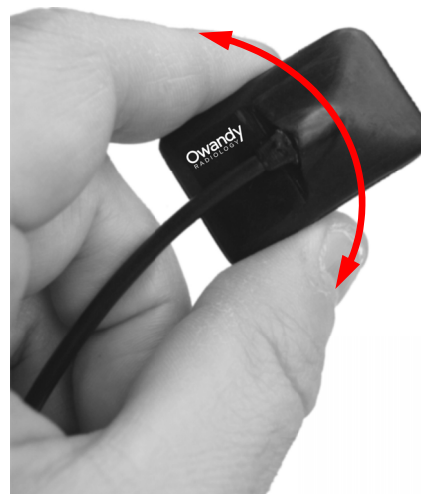
4.2.2 Sensor activation

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 5 minutes). The sensor's toolbar is then in its red state.

To activate your sensor physically, just remove it from its support and and/or give it a slight jerk. The **Opteo** is equipped with a gravity sensor which will detect this movement and will so activate the embedded electronics. The sensor's sensitivity to gravity is programmed so as not to activate the **Opteo** intra-oral sensor inopportunely by an involuntary movement.




When activating the sensor physically, take care to hold the sensor by both sides of its shells and not by the cable in order to avoid any risk of the cable connections breaking or the sensor falling and breaking.






4.3 Use of the Owandy XIO StandAlone software

4.3.1 Modes of operation




The sensor kit 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 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 - XRAY 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 |

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. |



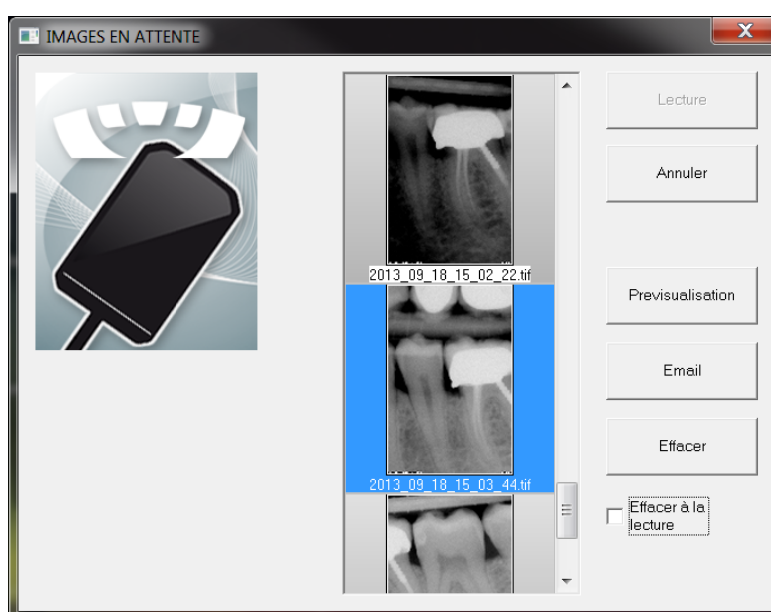
The sensor automatically switches to standby mode after a few minutes of not being used; the sensor toolbar turns red.
Check that the sensor toolbar is displayed in green before each acquisition.

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.



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.

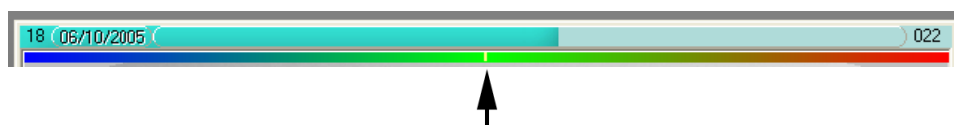
5. Position the generator so as to cover the whole sensitive area of the sensor. The paralleling technique is strongly recommended and the use of positioners allows you to correctly place the generator thanks to the aiming ring.
6. Activate the generator. The sensor toolbar turns yellow to indicate the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

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:

| Description (Current/Voltage) Exposure Time tables | Owandy-RX (6mA / 60-65-70KV) | |
|---|------------------------------|-------------|
| | Pediatric | Adult |
| Lower incisor / canine | 0.04 – 0.06 | 0.06 – 0.12 |
| Lower premolar | 0.05 – 0.07 | 0.07 – 0.13 |
| Lower molar | 0.06 – 0.10 | 0.08 – 0.17 |
| Upper incisor / canine | 0.04 – 0.06 | 0.06 – 0.12 |
| Upper premolar | 0.05 – 0.07 | 0.07 – 0.13 |
| Upper molar | 0.07 – 0.11 | 0.11 – 0.22 |

Equivalent typical doses delivered to patient in mGy:

| Description (Current/Voltage) Exposure Time tables | Owandy-RX (6mA / 60-65-70KV) | |
|---|------------------------------|-------------|
| | Pediatric | Adult |
| Lower incisor / canine | 0.21 – 0.65 | 0.33 – 1.04 |
| Lower premolar | 0.25 – 0.78 | 0.37 – 1.31 |
| Lower molar | 0.33 – 1.04 | 0.62 – 1.57 |
| Upper incisor / canine | 0.21 – 0.65 | 0.33 – 1.04 |
| Upper premolar | 0.25 – 0.78 | 0.37 – 1.31 |
| Upper molar | 0.41 – 1.31 | 0.62 – 1.96 |

Reference conditions:

- Adult patients, or paediatric patients of average size
- Distance focal spot to sensor 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>.

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.



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.

5.1.4 Positioners

The positioners provided with the system should be covered by the hygienic protective sheath together with the sensor.



Do not pull on the cable when removing the sensor from the positioner.

They should be cleaned and disinfected according to the same procedure as for the sensor (see “5.2 Recommended cleaning and decontamination procedure”). They can be sterilised, either in an autoclave (classic steam-sterilizer, distilled water, 134°C / 273°F, 3bar, 4min) or using cold sterilisation (see product instructions). They withstand a maximal temperature of 145°C / 293°F.

A defective positioner can be thrown away with the regular waste.

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.



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.

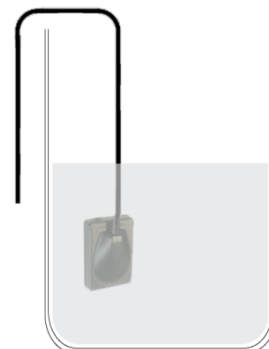
During the immersion, brush the submerged parts with a soft brush. Then rinse thoroughly the sensor and the positioner or the sensor connection cable with copious amounts of fresh water.



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.



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 regularly to be able to recuperate them if needed (in case of hard disk or computer problems). 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, Zip or Jaz system, CD-ROM or DVD writer, etc.). Test and store the copies in a safe place.

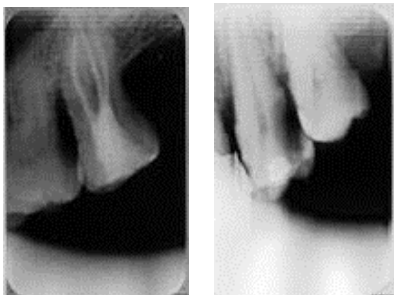
6 Troubleshooting and tests method

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

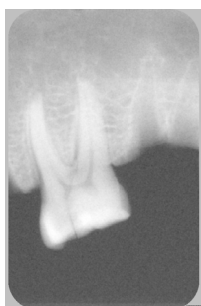
6.1 General

| Symptom | Cause / Solution |
|--|--|
| The kit does not power up or it does not acquire images. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> 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. | <p>This is normal. The temperature of the sensor can exceed 12°C (54°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.</p> <ul style="list-style-type: none"> Reduce the standby time in the configuration screen. |

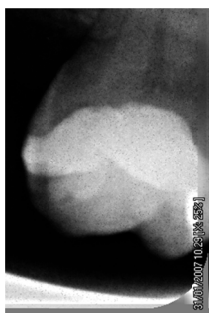
6.2 Image quality

| Symptom | Cause / Solution |
|--|---|
| <p>The images are cut off, e.g.:</p>  | <p>The sensor is badly positioned with regard to the X-ray beam.</p> <ul style="list-style-type: none"> 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:
 - 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.
- 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

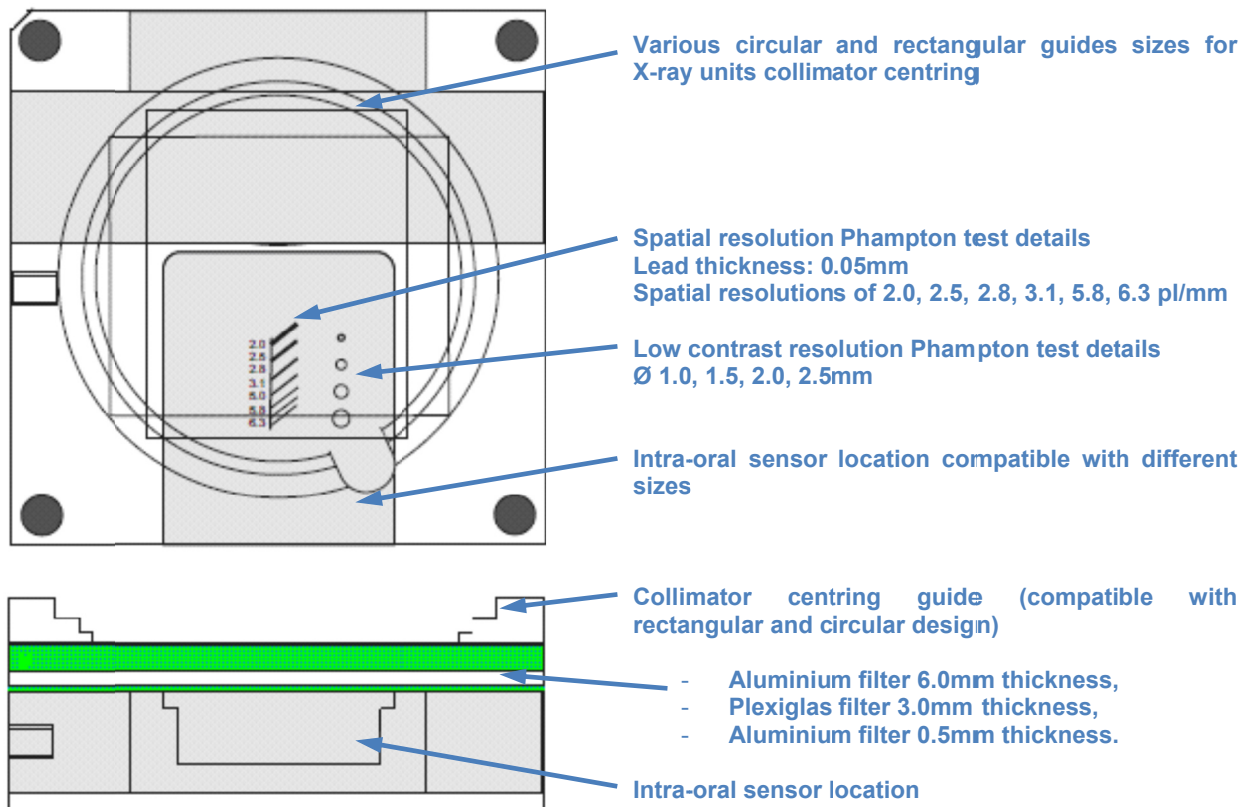
It is recommended to the practitioner to test regularly the quality of the imaging digital devices complete line. You can refer to the standard IEC 61223-3-4 (V2000) which describes the acceptance tests imaging performance of dental X-ray equipment.

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):

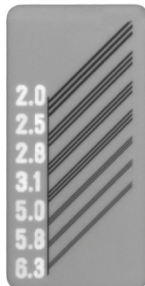
- Spatial resolution (pl/mm)
- Low contrast resolution (mm)

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.

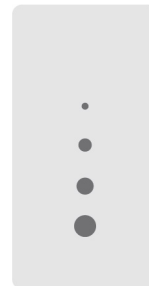
Example of an intra-oral test phampton (QUALIMEDIS ref. OTN):



- Spatial resolution control object:

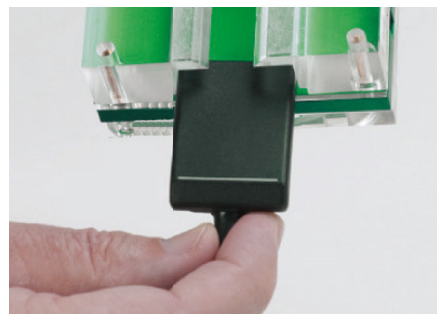


- Low contrast resolution control object:



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 phampton (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 officiel 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

Opteo 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 | 30 x 20mm (600mm ²) / 1.2 x 0.8inch (1.0inch ²) |
| • Sensitive area in pixels | 1500 x 1000pixels |
| • Pixel dimensions | 20 x 20µm |

Opteo 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 | 34 x 26mm (900mm ²) / 1.3 x 1.0inch (1.3inch ²) |
| • Sensitive area in pixels | 1700 x 1300pixels |
| • Pixel dimensions | 20 x 20µm |

Technical specifications (size 1 and 2 sensors)

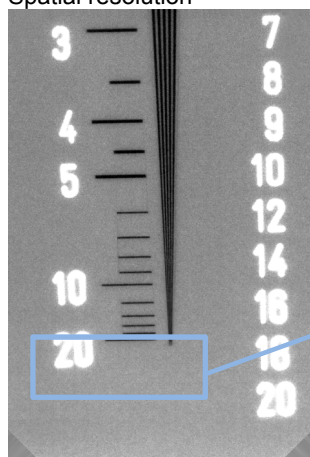
| | |
|--|--|
| Length sensor cable) | 3m / 9.9ft |
| Grey levels | 14bits |
| Connection | USB standard: USB 2.0 High-Speed (480Mbit/s) and USB 3.0 |
| Consumption kit | 0.5VA under 5V (USB port) |
| Input voltage sensor Input current sensor | 0.15A Max |
| Operating temperature | +10°C to +40°C / 50°F to 104°F |
| Lifespan CMOS | Min. 100,000 cycles |

Standards

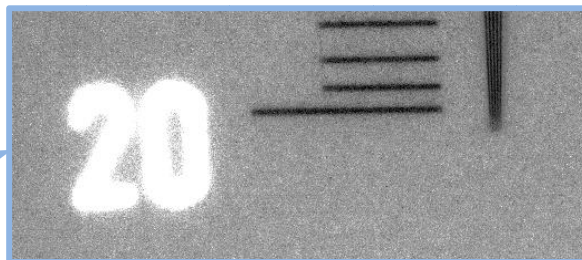
| | |
|-------------------------|--|
| Conformity to standards | NF EN/IEC60601-1 NF EN/IEC60601-1-2 |
|-------------------------|--|

Non clinical testing specifications

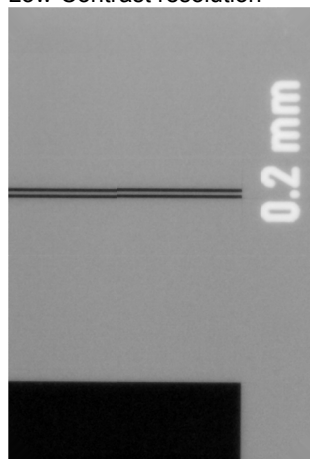
Spatial resolution



20lp/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

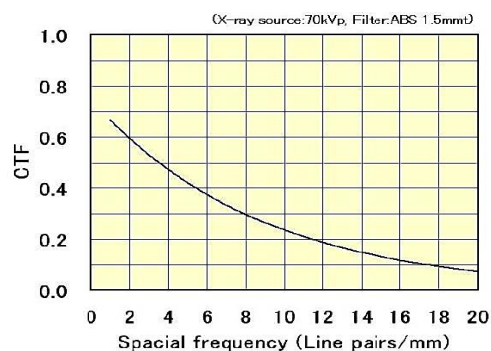


Image decay and latency

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.

7.2 Regulatory Declarations

Table 1

| Manufacturer's instructions and declaration – electromagnetic emissions | | |
|--|----------------|---|
| The OPTEO model is designed for use in the electromagnetic environment specified below. The OPTEO customer or user must ensure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment - instructions |
| RF emissions CISPR 11 | Group 1 | The OPTEO model only uses RF energy for its internal functions. Consequently, its RF emissions are very low and are not capable of causing interference in nearby electronic equipment. The OPTEO model is suitable for use in all premises, including domestic premises and those directly connected to the low voltage public electricity supply network supplying buildings for domestic use. |
| RF emissions CISPR 11 | Class B | |
| Harmonic emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/ flicker IEC 61000-3-3 | Not applicable | |

Table 2

| Manufacturer's instructions and declaration – electromagnetic immunity | | | |
|--|--|---------------------|---|
| The OPTEO model is designed for use in the electromagnetic environment specified below. The OPTEO customer or user must ensure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 Test level | Compliance level | Electromagnetic environment - instructions |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV at contact | ± 6 kV at contact | Floors must be of wood, concrete or ceramic tiles. If floors are covered with synthetic materials, the relative humidity must be at least 30%. |
| | ± 8 kV in the air | ± 8 kV in the air | |
| Rapid transients in bursts IEC 61000-4-4 | ± 2 kV for electricity supply lines ± 1 kV for input/output lines | Not applicable | The quality of the electricity supply network must be that of a typical commercial or hospital environment. |
| Transient overvoltage IEC 61000-4-5 | ± 1 kV between phases ± 2 kV between phase and earth | Not applicable | The quality of the electricity supply network must be that of a typical commercial or hospital environment. |
| Voltage dips, brief power cuts and variations in voltage on electricity supply input lines IEC 61000-4-11 | <5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5s | Not applicable | The quality of the electricity supply network must be that of a typical commercial or hospital environment. If the OPTEO user requires continuous operation during power cuts in the electricity supply network, it is recommended to supply OPTEO from an uninterruptible energy supply or a battery. |
| Magnetic field at the frequency of the electricity network (50/60 Hz) IEC 61000-4-8 | 3 A/m | 3 A/m | Magnetic fields at the frequency of the electricity network must have the same characteristic levels as a representative place located in a typical commercial or hospital environment. |
| NOTE: U_T is the voltage of the alternative network before application of the test level. | | | |

Table 3

| Manufacturer's instructions and declaration – electromagnetic immunity | | | |
|---|--|-------------------------|---|
| The OPTEO model is designed for use in the electromagnetic environment specified below. The OPTEO customer or user must ensure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 Test level | Compliance Level | Electromagnetic environment - instructions |
| Conducted interference RF IEC 61000-4-6 | 3 V _{eff} from 150 kHz to 80 MHz | 3 V | Portable and mobile RF communications equipment must not be used nearer to any part of OPTEO , including the cables, than the recommended separation distance, calculated on the basis of the equation applicable to the frequency of the transmitter. |
| Radiated interference RF IEC 61000-4-3 | 3 V/m from 80 MHz to 2.5 GHz | 3 V/m | <p>Recommended separation distance</p> $d=1.16\sqrt{P}$ $d=1.16\sqrt{P} \text{ from 80 MHz to 800 MHz}$ $d=2.33\sqrt{P} \text{ from 800MHz to 2.5 GHz}$ <p>where P is the transmitter's maximum output power rating in watts (W), according to the transmitter's manufacturer and d is the recommended separation distance in metres (m).</p> <p>The field intensities of fixed RF transmitters, determined by an on-site electromagnetic investigation^a, must be below the compliance level, in each frequency range^b.</p> <p>Interference can occur near a device marked with the following symbol: </p> |
| NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. | | | |
| NOTE 2: These directives may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection by structures, objects and people. | | | |
| <p>a: The field intensities of fixed transmitters, like base stations for radiotelephones (cellular/cordless) and mobile land radios, amateur radio, AM and FM radio broadcasting and TV broadcasting, cannot be theoretically foreseen with exactitude. In order to assess the electromagnetic environment produced by fixed RF transmitters, an on-site electronic investigation must be considered. If the field intensity, measured at the location where OPTEO is used, exceeds the applicable RF compliance level below, OPTEO must be observed to check that its operation is normal. If abnormal performance is observed, additional steps may be necessary, like reorienting or repositioning OPTEO.</p> <p>b: For the frequency range from 150 kHz to 80 MHz, field intensities must be below 3 V/m.</p> | | | |

Table 4

| Recommended separation distances between portable and mobile RF communications equipment and OPTEO | | | |
|---|--|--|---|
| <p>OPTEO is designed for use in the electromagnetic environment where radiated RF interference is controlled. The OPTEO customer or user can help to prevent electromagnetic interference by keeping a minimum distance between the portable and mobile RF communications (transmission) device and OPTEO, as recommended below, based on the maximum transmission power of the communications device.</p> | | | |
| Assigned maximum output power of transmitter W | Separation distance by transmitter frequency | | |
| | From 150 kHz to 80 MHz $D=1.16\sqrt{P}$ | From 80 MHz to 800 MHz $D=1.16\sqrt{P}$ | From 800 MHz to 2.5 GHz $D=2.33\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.16 | 1.16 | 2.33 |
| 10 | 3.67 | 3.67 | 7.37 |
| 100 | 11.60 | 11.60 | 23.3 |
| <p>For transmitters whose assigned maximum transmission power is not given above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the transmitter frequency, where P is the transmitter's maximum transmission power rating in watts (W), according to its manufacturer.</p> <p>NOTE 1: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2: these directives may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection by structures, objects and people.</p> | | | |

The essential performance of the **OPTEO** intra-oral sensor (in terms of image transfer) remains complete in an electromagnetic environment that respects the regulatory limits.

8 Accessories

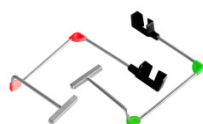


Introduction packs of positioners:

| | |
|------------|--------|
| 7758003400 | Size 1 |
| 7758003500 | Size 2 |

Refill packs of 10 positioners:

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



Metal positioner kit

| | |
|------------|-------------|
| 7758001200 | Size 1 only |
|------------|-------------|



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

| | |
|------------|-------------------|
| 7758003800 | Bag of 500 pieces |
|------------|-------------------|



Mounting accessories

| | |
|------------|----------------------------|
| 5458000000 | Self-adhesive wall support |
|------------|----------------------------|

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TECHNICAL SPECIFICATIONS

Sensor technology: CMOS

**Outer dimensions of the sensor
(length x width x thickness):**

39 x 25 x 5 mm (T1)

43 x 31 x 5 mm (T2)

Sensitive surface:

30 x 20 mm (600 mm²) - (T1)

34 x 26 mm (900 mm²) - (T2)

Surface in pixels:

1500 x 1000 pixels (T1)

1700 x 1300 pixels (T2)

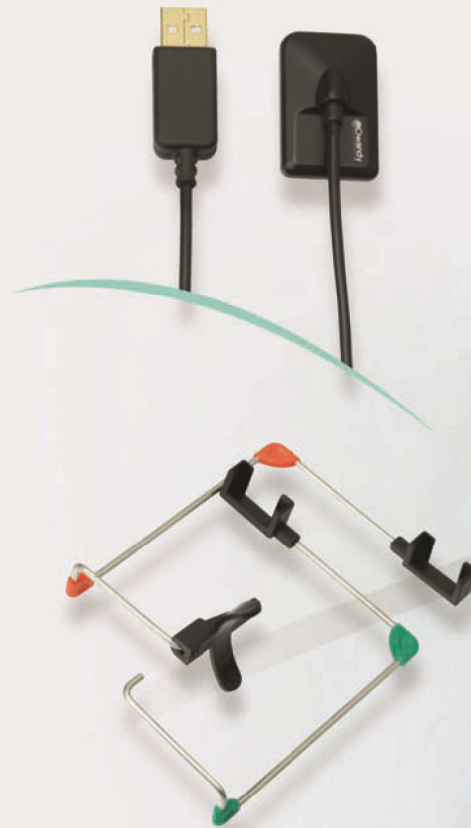
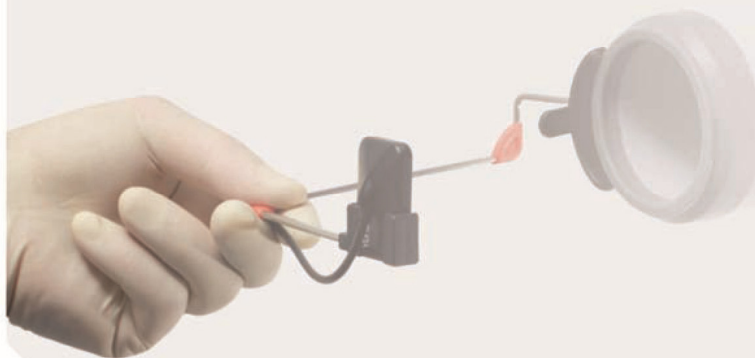
Sensor resolution: > 20 pl/mm (T1 and T2)

Sensor cable length: 3 m

Grey levels: 14 bits (16384 grey levels)

Connexion: Standard USB:

USB 2.0 High-Speed (480Mbit/s) and USB 3.0.



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SOFTWARE

DIGITAL SENSORS

2D - 3D PANORAMICS

INTRAORAL RADIOLOGY

CAMERAS