Owandy RADIOLOGY

EN • INSTALLATION AND OPERATOR MANUAL

ZOPTEN0104 • September 2025

OPTEO

DIGITAL IMAGING MADE SIMPLE

USB DIRECT INTRAORAL SENSOR

3rd generation

Revision history

Rev.	Date	Page/s	Modification description
01	30.05.2023	--	First draft for MDR
02	12.02.2024	42	Updated DoC due to IMQ NC
03	20.01.2025	6,8,10,14,18,32,33,40 40,41	Updated DoC due to IMQ NC Introduction of alternative variants with X-CMOS CMOS sensors
04	11.09.2025	8, 16, 20-21, 32, 38, 46-47	Updated IOP labels Updated technical data for X-CMOS sensors to align with CB report Updated Section 2.2 with information on positioners Updated Section 5 on cleaning Updated power supply sections to align with CB report Updated user interface description

Index

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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 three sizes; depending on the kit you have ordered you received a size 1, size 1.5, size 2 sensor:

- 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 1.5 sensor allows you to perform both bitewing and periapical exams using only one sensor.
- The size 2 sensor furthermore allows you to easily acquire horizontal “bitewing” images.

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

1.1 Intended use

The Opteo digital equipment is used to provide instant digital images of human oral tissue and teeth without the use of a conventional x-ray film. It is used for diagnosis purpose.

1.2 Intended operators

Opteo is operated and used by dentists, radiologists, and other legally qualified healthcare professionals.
In no case the device can be used directly by the patient.
It has therefore to be used exclusively in specific healthcare environment.

1.3 Intended patient population

Opteo can be used with the following types of patients:

- Age paediatric (from 7 years old) to geriatric
- Patient status/Health: the patient is conscious
- Nationality: multiple

Note

PATIENT is NOT an *OPERATOR*

1.4 Medical condition to be diagnosed

Opteo is used in dental practices. It is used in combination with an external source of x-rays, i.e., intraoral x-ray medical device.
The device, used in combination with an extra-oral source of X-rays, permits to acquire diagnostic dental radiographs of teeth, jaw and oral structures.
Its intended medical indications are:

- generic dentistry (As detect caries)
- dental implantology
- dental surgery.

This device can be indicated for the following kinds of examinations:

- Retro-alveolar (visualization of the whole of a tooth: crown + alveolus),
- Posterior (visualization of molars and premolars),
- Bitewing (visualization of the crowns of the upper and lower arches centered on a bite)

This device is indicated for studies on adult patients with carious lesions, bone fractures, implant placement control.

1.5 Application environments

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

1.6 Applied parts

During normal use, Opteo 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.

Note
During operation, the surface of the intraoral sensor may reach temperatures exceeding 41 °C, but these do not cause harm to the patient and remain within the safety limits defined by IEC 60601-1.

1.7 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 Opteo hour in patient lifetime

1.8 Compliance with standards

The Opteo kit is classified as a Class IIa medical device in accordance with Regulation (EU) 2017/745 on medical devices (MDR).
The Opteo kit complies with the IEC60601-1, IEC 60601-1-6, IEC 60601-1-2, IEC TS 60601-4-2:2024 and IEC62304 medical devices standards.

It is necessary that the other components of the equipment that are possibly connected (computer and optional peripherals) are compliant to standard IEC 62368-1:2018/COR1:2020.

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.

1.9 Power supply

The power to the Opteo 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 computer instructions.

Warning
To reduce the risk of damage or overheating in the event of a sensor fault, ensure that the USB port of the workstation used to power the device does not exceed an output of 5 V and 3 A, ensuring compliance with applicable safety standards IEC 60601-1.
Use only standard USB 2.0 or USB 3.0 ports that comply with USB specification.

Priority should be given to use the USB ports of the workstation. In case this is not possible, to prevent power-related issues, it is recommended to use an external device, such as a USB repeater cable or an externally powered USB hub (the power supply must comply with IEC 60950-1:2005), when operating the sensor with a workstation, all-in-one PC, or portable PC. Do not use bus-powered USB hubs or simple extension cables, as these may affect the power provided to the sensor and cause malfunctioning.

When using the intraoral sensor with a portable PC, always operate the PC powered by its power supply. Do not operate the sensor with the portable PC in battery-only mode.

Note
it is recommended to disable the USB power-saving options in the Settings panel of Windows to avoid issues with the sensor operation.

1.10 Installation precautions

Warning
The computer connected to the sensor MUST necessarily comply with standard IEC 62368-1:2018/COR1:2020.

Warning
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.

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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 Opteo sensor.

1.11 Contraindications

Opteo has been designed to acquire radiography images for dental intraoral x-ray imaging only.
Opteo must not be used for x-ray imaging of other body parts!

Warning
Before exposing patients with pacemakers, contact the manufacturer of the latter to ensure that the exposure to X-rays does not interfere with its functionality

Warning
Before exposing to X-ray equipment, please refer to the regulation in force concerning paediatric patients, pregnant women and anyone with health issues that contraindicate the use of x-rays

Warning
Do not carry out tests in the presence of hair clips, metal jewellery, food in the oral cavity (candies, gums), removable orthodontic devices

Note
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the operator and/or patient is established.

1.12 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.
Operator: the kit must be used by a dental practitioner or radiologist with computer skills.

Warning
The sensor should never be opened by the operator. 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 Opteo device is forbidden. All repairs of this same device can only be performed by Owandy Radiology SAS 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 equipment. 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).

1.13 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 +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.

1.14 PC protective measures

As the host PC is not supplied as part of the device, protective measures can't be incorporated into the device itself.
It is recommended to follow the below listed protective measures:

- It is recommended to install an Antivirus on the host PC to prevent an attack on the PC by virus and malware, for instance through network, USB ports or CD/DVD media
- It is recommended to activate the Windows Firewall on the host PC to prevent external connections to the PC through the network
- User accounts at Windows login shall be protected by username and password (user-defined, not hardcoded) to prevent unauthorized personnel from accessing the programs and patient data
- A password-protected screen saver with a 5–10-minute timeout is recommended to prevent unauthorized access when the PC is left unattended by the operator
- Operating System updates shall be activated to keep the OS updated with the latest security patches.
- Any software installation or upgrade has to be done by authorized and trained personnel only.

It is recommended not to install any untrusted software on the computer.

1.15 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 equipment (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
Opteo should not be used adjacent to or stacked with other equipment; if adjacent use is necessary, Opteo 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 Opteo including cable. Minimum distance 30 cm.

1.16 Electromagnetic emissions

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

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – Electromagnetic emissions</th></tr>
<tr><td colspan="3">Opteo is suitable for use in the specified electromagnetic environment. The purchaser or operator of Opteo should ensure that it is used in an electromagnetic environment as described below:</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic Environment</th></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td>Opteo 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.</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Class B</td><td rowspan="3">Opteo 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.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions

IEC 61000-3-3</td><td>Complies</td></tr>
</table>

1.17 Electromagnetic immunity

In accordance with the IEC 60601-1-2 4th edition standard Opteo is suitable for use in the electromagnetic environment specified below.
The customer or operator of the equipment 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 Opteo 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 Opteo, 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 operator of the Opteo requires continued operation during power mains interruptions, it is recommended that the Opteo 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

1.18 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

Note Information for operators of the European Community according to Directive 2012/19/EU - WEEE on waste electrical and electronic equipment (WEEE).

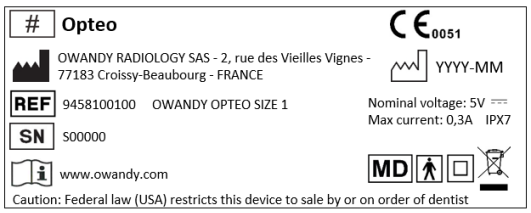
The symbol with the waste bin crossed on the equipment or its packaging, indicates that the product must be separately collected from other waste at the end of its life. The separate collection of the present equipment that has reached the end of its life is organised and managed by the manufacturer.
The operator who wishes to dispose of this equipment must contact the manufacturer and follow their equipment 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 to 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.

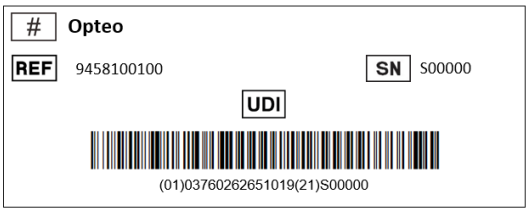
1.19 Manufacturer identification

Manufacturer:

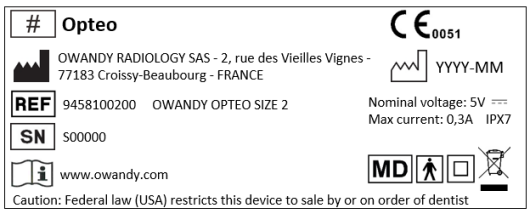
OWANDY RADIOLOGY SAS
2, rue des Vieilles Vignes
77183 Croissy-Beaubourg
FRANCE

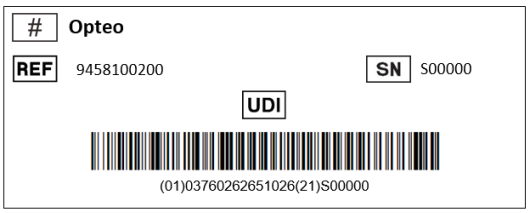
1.20 Identification label



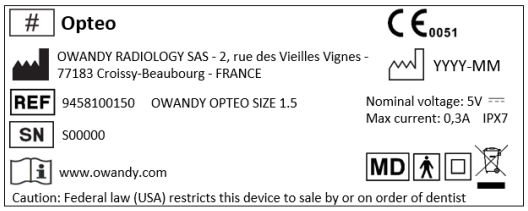


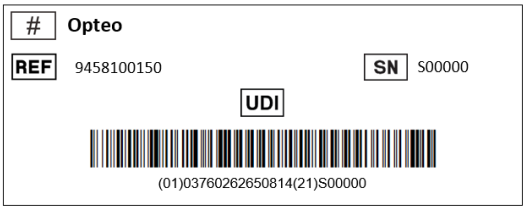
Opteo size 1





Opteo size 2





Opteo size 1.5

1.20.1 Meaning of information reported on the labels

Information that cannot be expressed through the use of symbols is written as a text inside the labels.
The translation is provided in the following table:

INFORMATION	TRANSLATION (ENGLISH)
Nominal Voltage	Nominal Voltage
Max current	Max current
Size	Size

1.21 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 Regulation (EU) 2017/745 on medical devices (MDR) and its revised versions.		Name and address of the 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 put in the mouth, 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		Electronic instructions for use symbol for medical devices, according to EN ISO 15223-1: 2021
MD	This symbol states that the device is a Medical Device, according to ISO 15223-1	#	Model number
	This symbol indicates a general warning according to ISO 7010-W001. Carefully read the instructions for use before operating or handling the device.		

2. CONTENTS

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

An Opteo sensor - size 1, size 1.5, or size 2

1 self-adhesive sensor wall support

A bag of disposable single-use hygienic protective sleeves (compatible with size 1, size 1.5 and 2 sensors)

An USB Stick with the sensor calibration files and manuals

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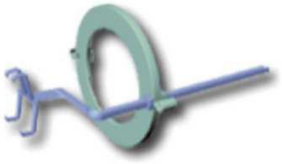
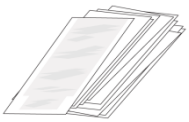
1 Mouse pad

A Packing list

A « Quick Start guide »

2.1 Optional parts in conjunction

NAME	DESCRIPTION
Sensor Positioners 	Interface part between the collimator cone of an extra-oral source of x-rays and the sensor, the positioner holds the device perpendicularly with respect to the cone. It helps the positioning of the sensor inside the patient's oral cavity.
Hygienic protections 	Plastic single-use hygienic protections are intended to cover the whole sensor and a part of the cable in order to avoid cross-contamination and suffocation risks. (for size 1, size 1.5 and size 2 sensors) - 20 pieces
Wall support 	A self-adhesive support, compatible with sensors of size 1, size 1.5 and size 2. This support can be fixed on any type of flat surface. The sensor will then be inserted into the fork of the support taking care not to impede the cable.
USB Stick 	USB stick with sensor calibration files and manual.

2.2 Positioners

The recommended sensor positioners (also referred to as sensor holders) for use with the intraoral sensor are listed in the table in the SPARE PARTS chapter. The positioners are classified as Class I medical devices under Regulation (EU) 2017/745 - MDR. Positioners ensure correct intraoral sensor placement in the patient mouth following the parallel technique. When using a positioner, always refer to the instructions in the operator manual of the intraoral X-ray device and the instructions and precautions provided by the manufacturer of the positioner. The positioners are designed for reuse and must be handled, cleaned, disinfected, and sterilized following the manufacturer's instructions to ensure safety and longevity.

Usage

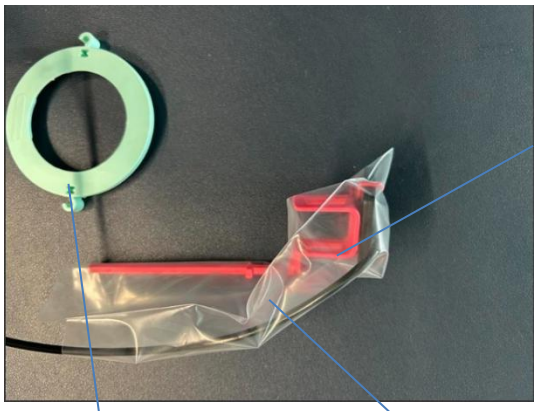
Select the appropriate positioner based on sensor size, application (Bitewing, Posterior, Periapical, Endodontic images), and the tooth region (see the table in the SPARE PARTS chapter).

- Size 1 positioners are compatible with size 1 sensors.
- Size 2 positioners are compatible with size 1.5 and size 2 sensors.
- Bitewing positioners cover left and right halves of the dentition.
- Posterior, Periapical, and Endodontic positioners are angled for covering specific dentition quadrant pairs (Upper-Right/Lower-Left or Upper-Left/Lower-Right).

The sensor positioner should be used with the positioning ring to optimize cone-to-sensor centering, avoid misalignment, and orient the sensor cable. Do not clamp or lock the cone onto the positioning ring. The positioning ring is compatible with both circular and rectangular cones. Rotate the positioner insertion within the positioning ring to select the correct right or left placement in the mouth.

Placing

- Hold the positioner by the bite area between the thumb and fingers.
- *Horizontal sensor loading (Bitewing and Posterior):* Insert the sensor into the lower clamp of the positioner, press lightly downwards toward the bite platform until it clicks and fully insert in the positioner. Ensure the active area of the sensor is centred to the positioner's mark.
- *Vertical sensor loading (Periapical and Endodontic):* Slide the sensor into one clamp of the positioner, lightly press it into the second clamp until it clicks and fully insert in the positioner, then slide it downward.
- Cover with the protective sheath and insert the positioning ring correctly. Use the cable clip on the positioning ring to secure both the sensor cable, routing it out of the mouth on the side to avoid damage from biting, and the protective sheath, keeping it properly in place.
- Follow instructions in chapter 4 of this manual and in the operator manual of the intraoral X-ray device to correctly use the sensor, place it inside the patient's mouth and position the intraoral X-ray device to the sensor.



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

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.

Cleaning and Sterilization

For detailed cleaning, disinfection, sterilization instructions and to prevent any risk of cross-contamination please refer to the documentation provided by the sensor positioner manufacturer and always observe the necessary precautions and hygiene measures.

3. INSTALLATION

The Opteo sensor is intended to be used in conjunction with:

- An external X-ray source, such as intraoral X-ray equipment, which must be marked as a medical device and have dental radiography as intended use (see paragraph 3.1.2).
- A PC/workstation (see paragraph 3.1.1).

The Opteo sensor can be used with an imaging software installed on the PC/workstation (see paragraph 3.3).

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 equipment close to strong magnetic fields and avoid proximity to electrostatic emission sources.

Warning
Read paragraph 1.10 “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

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, 11 / 32 and 64 bits
Computer Motherboard USB port	Compliant CE - IEC 62368-1:2018/COR1:2020 Intel 3GHz Chipset and processor USB 2.0 High-Speed
Graphics card Monitor	1GB High resolution 1024x768 (15inch)
RAM memory Hard disk	2GB 500GB
CD-ROM drive Backup system	24x External/removable disk, 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

Warning
The computer connected to the sensor MUST be compliant with standard IEC 62368-1:2018/COR1:2020.

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). The PCMCIA cards need to be powered by an external power supply 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.

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.

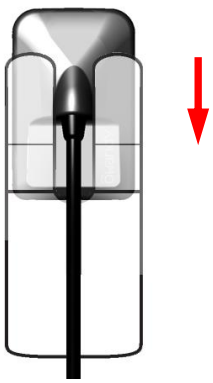
Warning
Do not use self-powered hub with Opteo devices

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, size 1.5 and 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 operator account.

3.3.1 Installation of OSP and the drivers

Warning
The Opteo drivers are only compatible with Windows 7, 8, 10, 11 (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 Opteo, 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 OSP updating

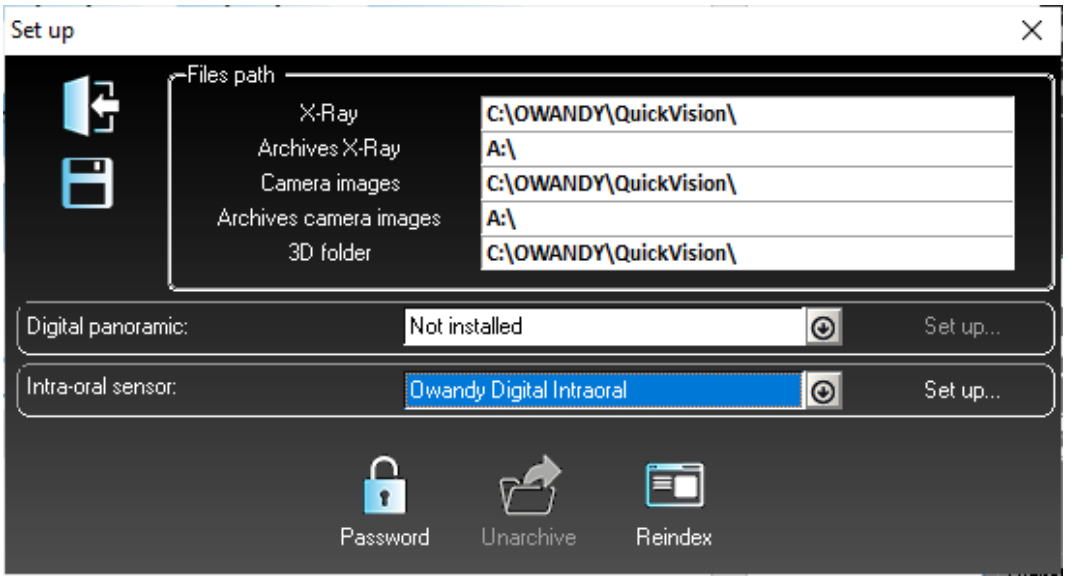
If you need to update driver:

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

3.4 Configuration in the QuickVision imaging software

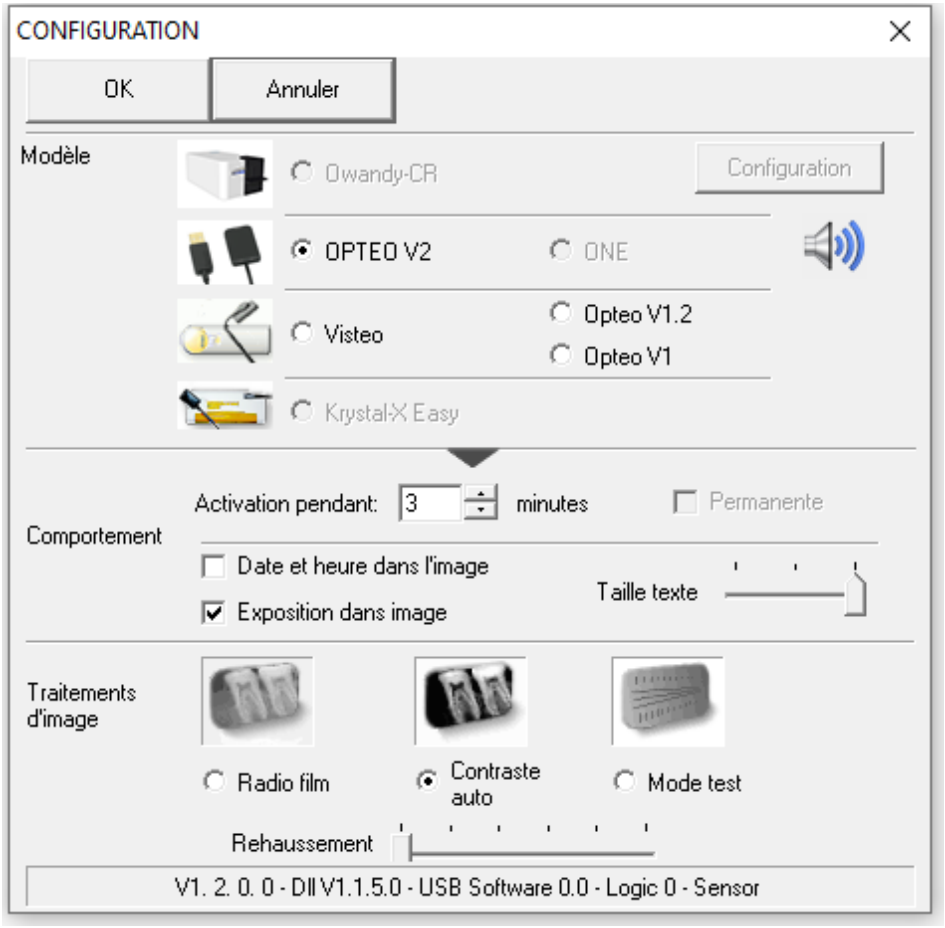
To be able to use your kit with the Owandy QuickVision imaging software you must configure your equipment.

1. Start the imaging software
2. Click on the “Set up” button on 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 the “Opteo V2” 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.

3.5 Sharing the sensor and box between different workstations

Sharing the sensor allows you to use Opteo 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 to 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

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 toward 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.

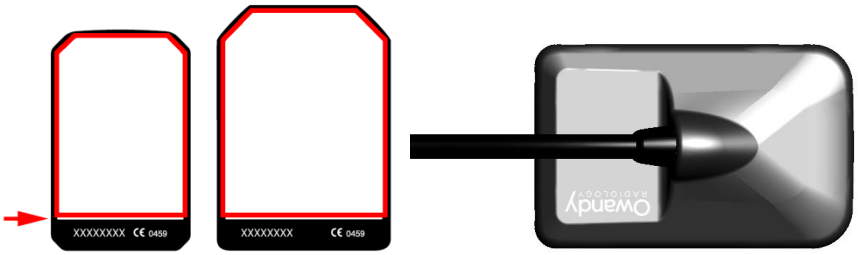
Warning
Do not ask the patient to bite on the sensor or cable.

Warning
Use of a mobile phone or an RF communications device near the 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.



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.

4.2.3 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 – Warning: The sensor is inactive and not ready to receive X-rays. The steady red light indicates that the device is either not properly connected or an incorrect sensor has been inserted. The operator must not take immediate action but should wait for the sensor to be ready for acquisition (i.e., green light), or then replace it with the correct sensor.
	Yellow – Caution: The sensor is initializing or processing data and is not ready to receive X-rays. The steady yellow light indicates that the device is either initializing after being connected to the workstation or is processing image data following X-ray exposure and acquisition. The operator must not take prompt action but should wait for the sensor to be ready for acquisition (i.e., green light).
	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.

◄ Indicator of sensor status: activate/deactivate the sensor.

◄ Active sensor size

◄ Iconize the toolbar in the taskbar.

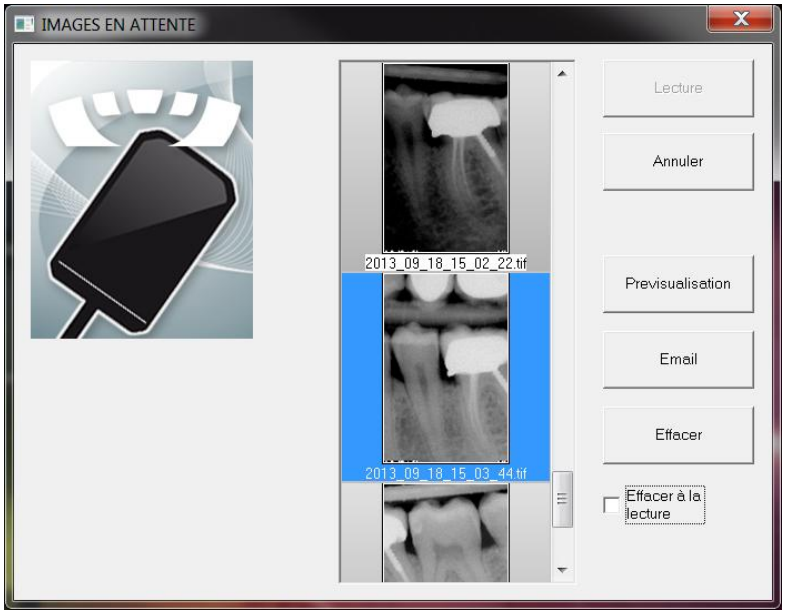
Warning
The sensor automatically switches to standby mode after a few minutes of not being used; the sensor toolbar turns red.
Check that the sensor toolbar is displayed in green before each acquisition.

4.2.4 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 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.

4.2.5 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.

4.3 Acquisition of an image

4.3.1 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 taskbar 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. Sensor positioners should be used 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.

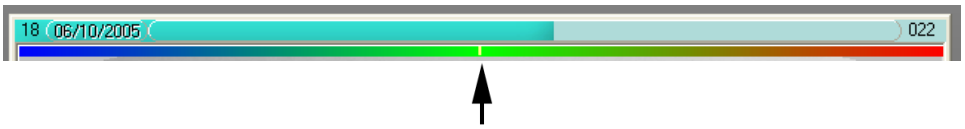
Warning
In case the sensor is used with intra oral equipment with low mA emission (i.e. hand-held equipment that typically provide 2mA), it is necessary to position the X-ray source as close as possible to the sensor, without any extension and set the exposure time between the range 50ms and 500ms.
Without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

4.3.2 Imaging software functions

An exposure percentage is displayed in the acquired image:

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

When the image is displayed in the 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 operators 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.

4.4 Exposure times

Recommended exposure times in seconds for the Owandy Radiology SAS 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: 200 mm*
- *Total filtration: equivalent to 2,5 mm Al*

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

If an image is over or under-exposed, it can be corrected afterward 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

Warning
Before using the equipment for the first time, carry out the cleaning operations listed in the following paragraphs

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 equipment.

Warning
It is mandatory to use the protective sheaths provided with the sensors until they are exhausted.

Once exhausted, it must be used the same provided protection sheaths that can be purchased (see *SPARE PARTS* chapter) or other alternative protective sheaths which must have the following characteristics:

- They must be a Class I medical device
- They must be CE marked
- They must comply with biocompatibility standards according to ISO 10993 series

Before each use on a patient, the used sheath should be thrown away and the sensor disinfected by 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 Opteo 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

Warning
Before using the equipment for the first time, carry out the cleaning operations listed in the following paragraphs

Warning
Please note that the positioners are optional parts in conjunction with the equipment (Refer to par. 2.1)

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

Warning
Do not pull on the cable when removing the sensor from the positioner to avoid any risk of suffocation for the patient due to accidental ingestion of the protection.

The positioners should be cleaned and disinfected according to the instructions and precautions provided by the manufacturer of the positioners.

The recommended sensor positioners can be cleaned and disinfected according to the same procedure as for the sensor (see paragraph 5.2). 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.

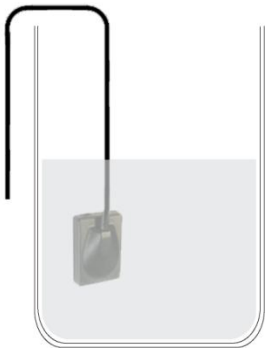
For detailed cleaning, disinfection, sterilization instructions and to prevent any risk of cross-contamination please refer to the documentation provided by the sensor positioner manufacturer and always observe the necessary precautions and hygiene measures.

Do not use after expiration date.
For proper disposal always follow local and national regulations.

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 1.5 min, never immerse the connector on the box side of the positioner or sensor connection cable in the liquid.



Remove the sensor from the solution and clean the immersed parts with a soft cloth. Then, thoroughly rinse the sensor, sensor adapter, and/or sensor connection cable with a copious amount of fresh water. This cleaning cycle must be carried out after every test.

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…).

Warning
In case of disinfection through ozonating machines it is recommended to limit the exposure time in which the machine is active, in order to avoid damage to the plastic components of the device.

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).

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:

- Ethyl alcohol
- 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). It's recommended to do the back up once a week.

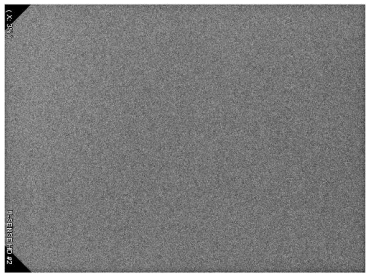
Ask the advice of your IT specialist with regard to the backup system that is best suited to your computer configuration (external or removable hard disk, CD-ROM or DVD writer, etc.). Test and store the copies in a safe place. It's recommended to do the system back up twice a month.

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

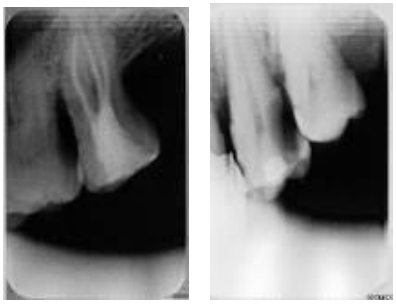
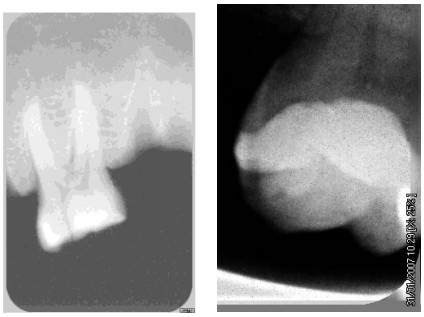
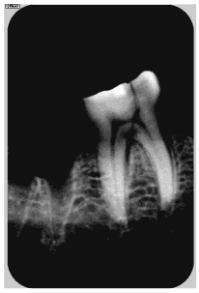
6. TROUBLESHOOTING AND TESTS METHOD

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 toward 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 sensor can reach temperatures exceeding 41 °C (106°F) but not causing harm to the patient. The temperature of the sensor can exceed 6°C (43°F) ambient temperature 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.
The sensor acquires an image similar to the one shown without X-rays being emitted. 	If this happen, the cause may be insufficient power from the USB port. It is suggested to connect the sensor to a different USB port and verify that the USB port is not defective or damaged. Preferably, use an externally powered USB hub or a USB repeater cable. Disable the USB power-saving options in the Settings panel of Windows.

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 recommended for the sensor to ensure 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 indicates 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 indicates 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

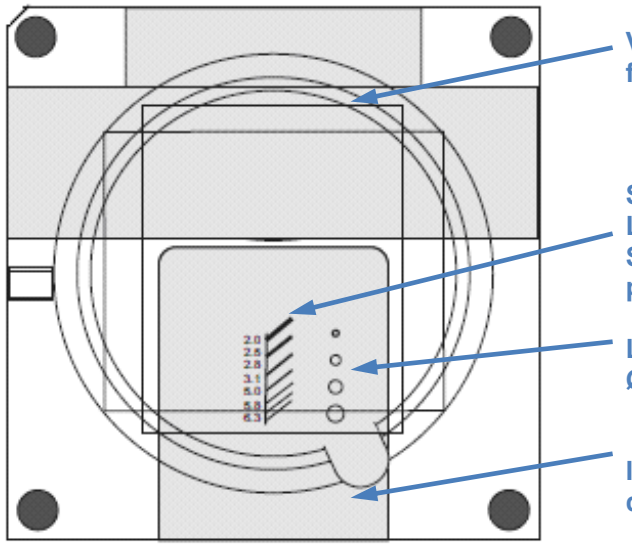
It is recommended to the practitioner to test regularly the quality of the imaging digital devices complete line.
You can refer to the standard IEC 61223-3-4 (V2000) which describes the acceptance tests imaging performance of dental X-ray equipment.

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):

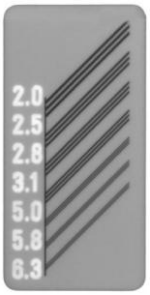
- Spatial resolution (pl/mm)
- Low contrast resolution (mm)

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

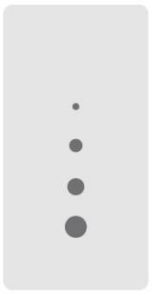
Example of an intra-oral test phampton (QUALIMEDIS ref. OTN):



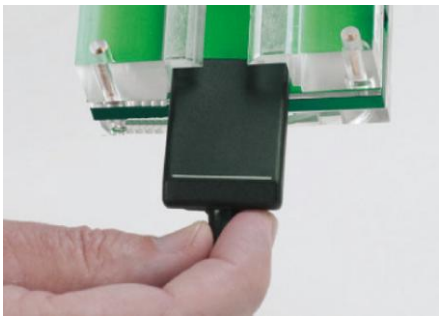
- Spatial resolution control object:



- 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 phamptons (see image opposite).

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

4. Look at the image obtained on your computer screen to verify the spatial and low-contrast resolution 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

The Opteo device exists in different models and sizes of the sensor.

Opteo	
Size 1	
External dimensions sensor	38.6 x 24.7 x 5.2 mm / 1.6 x 1.0 x 0.2 inch
CMOS matrix sensor (cut corners) • Sensitive area in size • Sensitive area in pixels • Pixel dimensions	 30 x 20 mm (600 mm^2) / 1.2 x 0.8 inch (1.0 $inch^2$) 1500 x 1000 pixels 20 x 20 µm
Scintillator	Cesium Iodide (CsI)
External dimensions sensor	38 x 27.4 x 6 mm / 1.5 x 1.1 x 0.2 inch
CMOS matrix sensor (cut corners) • Sensitive area in size • Sensitive area in pixels • Pixel dimensions	 30 x 22.5 mm (675 mm^2) / 1.2 x 0.9 inch (1.1 $inch^2$) 1600 x 1200 pixels 18.5 x 18.5 µm
Scintillator	Cesium Iodide (CsI)
Size 1.5	
External dimensions sensor	41 x 29.4 x 6 mm / 1.6 x 1.2 x 0.2 inch
CMOS matrix sensor (cut corners) • Sensitive area in size • Sensitive area in pixels • Pixel dimensions	 32.8 x 24 mm (787 mm^2) / 1.3 x 0.9 inch (1.2 $inch^2$) 1772 x 1296 pixels 18.5 x 18.5 µm
Scintillator	Cesium Iodide (CsI)
Size 2	
External dimensions sensor	43.2 x 30.8 x 5.2 mm / 1.7 x 1.2 x 0.2 inch
CMOS matrix sensor (cut corners) • Sensitive area in size • Sensitive area in pixels • Pixel dimensions	 34 x 26 mm (884 mm^2) / 1.3 x 1.0 inch (1.3 $inch^2$) 1700 x 1300 pixels 20 x 20 µm
Scintillator	Cesium Iodide (CsI)
External dimensions sensor	43 x 31.6 x 6 mm / 1.7 x 1.2 x 0.2 inch
CMOS matrix sensor (cut corners) • Sensitive area in size • Sensitive area in pixels • Pixel dimensions	 35 x 26 mm (884 mm^2) / 1.4 x 1.0 inch (1.4 $inch^2$) 1888 x 1402 pixels 18.5 x 18.5 µm
Scintillator	Cesium Iodide (CsI)

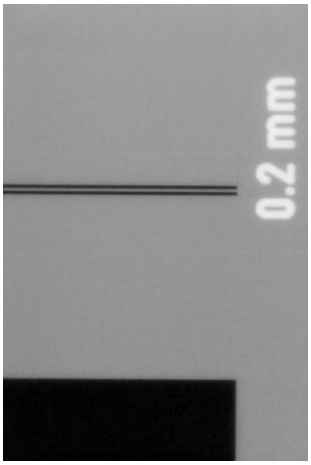
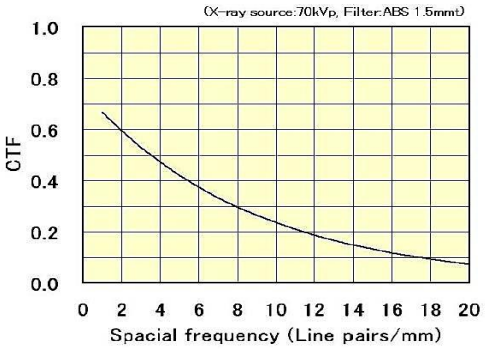
Technical specifications (size 1, size 1.5 and 2 sensors)	
Length sensor cable)	3 m / 9.9 ft - 2 m / 6.6 ft
Spatial Resolution	≥14 Lp/mm

Grey levels	14bits (16384 grey levels)
Connection	USB standard: USB 2.0 High-Speed (480 Mbit/s) and USB 3.0
Consumption kit	0.5VA under 5V (USB port)
Input voltage sensor Sensor current absorption	5V (USB port) 0.3A max.
Operating temperature	+10°C to +40°C / 50°F to 104°F
Max Operating Sensor temperature	6°C (43°F) over environment temperature
Lifespan CMOS	Min. 100,000 cycles

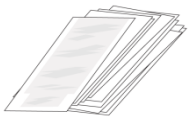
Standards

Conformity to standards	IEC 60601-1:2005 + Amd1: 2012 + Amd2: 2020 (ed.3.2) IEC 60601-1-6:2010 + Amd1: 2013 + Amd2: 2020 (ed.3.2) IEC 62304:2006 + Amd1:2015 (ed. 1.1) IEC 60601-1-2:2014 + Amd1:2020 IEC TS 60601-4-2:2024 CFR21 Regulation (EU) 2017/745 on medical devices (MDR) (as amended)

Non clinical testing specifications

Low-Contrast resolution 	***Minimum value measured: 0.2mm***
Dynamic range	14 bits (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 4 0dB
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 equipment.

8. SPARE PARTS

	Hygienic single-use disposable protection sleeves (for size 1, size 1.5 and 2 sensors) **6658004500 IO SENSOR HYGIENIC SLEEVES TROLL BAG XL REF 13190099 (20pcs)**
	Sensor Wall Mounting support **6658004300 IO SENSOR WALL SUPPORT REPLACEMENT KIT**

Sensor Positioners

CODE	Description	Box Content	Sensor type	Application
7758003400	SIZE 1 ANGULATOR STARTER KIT	1 x BITEWING HOLDER SIZE 1 1 x POSTERIOR HOLDER UL* SIZE 1 1 x POSTERIOR HOLDER UR** SIZE 1 1 x PERIAPICAL HOLDER UL* SIZE 1 1 x PERIAPICAL HOLDER UR** SIZE 1 1 x ENDO HOLDER SIZE UL* SIZE 1 1 x ENDO HOLDER SIZE UR** SIZE 1 1 x POSITIONING RING	Opteo Size 1 One Size 1	BiteWing images Endo images Posterior images Periapical images
7758003500	ANGULATOR STARTER KIT (SIZE 2)	1 x BITEWING HOLDER SIZE 2 1 x POSTERIOR HOLDER UL* SIZE 2 1 x POSTERIOR HOLDER UR** SIZE 2 1 x PERIAPICAL HOLDER UL* SIZE 2 1 x PERIAPICAL HOLDER UR** SIZE 2 1 x ENDO HOLDER SIZE UL* SIZE 2 1 x ENDO HOLDER SIZE UR** SIZE 2 1 x POSITIONING RING	Opteo Size 1.5 Opteo Size 2 One Size 2	BiteWing images Endo images Posterior images Periapical images
7758012600	SIZE 1 BITEWING	10 x BITEWING HOLDER SIZE 1	Opteo Size 1 One Size 1	BiteWing images
7758012800	SIZE 1 ENDO	3 x ENDO HOLDER SIZE UL* SIZE 1 3 x ENDO HOLDER SIZE UR** SIZE 1	Opteo Size 1 One Size 1	Endo images
7758012300	SIZE 1 PERI-APICAL	5 x PERIAPICAL HOLDER UL* SIZE 1 5 x PERIAPICAL HOLDER UR**SIZE 1	Opteo Size 1 One Size 1	Periapical images
7758013000	SIZE 1 POSTERIOR	5 x POSTERIOR HOLDER UL* SIZE 1 5 x POSTERIOR HOLDER UR** SIZE 1	Opteo Size 1 One Size 1	Posterior images
7758012700	SIZE 2 BITEWING	10 x BITEWING HOLDER SIZE 2	Opteo Size 1.5 Opteo Size 2 One Size 2	BiteWing images
7758012900	SIZE 2 ENDO	3 x ENDO HOLDER UL* SIZE 2 3 x ENDO HOLDER UR** SIZE 2	Opteo Size 1.5 Opteo Size 2 One Size 2	Endo images
7758013100	SIZE 2 POSTERIOR	5 x POSTERIOR HOLDER UL* SIZE 2 5 x POSTERIOR HOLDER UR**SIZE 2	Opteo Size 1.5 Opteo Size 2 One Size 2	Posterior images
7758013300	SIZE 2 PERI-APICAL	5 x PERIAPICAL HOLDER UL* SIZE 2 5 x PERIAPICAL HOLDER UR** SIZE 2	Opteo Size 1.5 Opteo Size 2 One Size 2	Periapical images

7758013400	POSITIONING RING	5 x POSITIONING RING	Opteo Size 1 Opteo Size 1.5 Opteo Size 2 One Size 1 One Size 2	BiteWing images Endo images Posterior images Periapical images

*All positions indicated as Upper Left (UL) jaw can be used also on the Lower Right (LR) jaw by rotating the holder to change holder position in ring to select right or left side position in the mouth.
** All positions indicated as Upper Right (UR) jaw can be used also on the Lower Left (LL) jaw by rotating the holder to change holder position in ring to select right or left side position in the mouth.

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EU DECLARATION OF CONFORMITY

ACCORDING TO THE REGULATION (EU) 2017/745

OWANDY RADIOLOGY SAS - 77183 CROISSY BEAUBORG - 2, Rue des Vieilles Vignes (FRA) - France

SRN CODE: FR-MF-000010352

BASED ON CERTIFCATE NO.	
ISSUED BY	**IMQ S.P.A No. 0051**

Evaluation of conformity based on the quality management system according to Annex IX chapter I,III of Regulation (EU) n. 2017/745

Declares on his sole responsability that the medical device:

Sensors for digital x-rays

MODEL:	**Opteo**
REF. CODE:	
TRADE MARK:	**Owandy Radiology SAS**
BASIC UDI-DI:	376026265945CG
INTENDED USE:	The Opteo digital equipment is used to provide instant digital images of human oral tissue and teeth without the use of a conventional x-ray film. It is used for diagnosis purpose.
RISK CLASS:	IIa
S/N:	
MANUFACTURING DATE:	mm-yyyy

Complies with the Regulation (EU) 2017/745 and Directive 2011/65/EU-RoHs.

Complies with the general safety and performance requirements defined by Annex I of the Regulation (EU) 2017/745 and it is classified as **Active** medical device in class IIa according to Annex VIII Classification rules, Rule 17.

Furthermore,
It is here declared that subscribing company will keep all the technical documentation mentioned in Annex II of the Regulation (EU) 2017/745 available for Sanitary Authority for a period of 10 years from the last production of the device to which this declaration is addressed to.

Has been adopted the procedure relative to the Declaration of Conformity according to Annex IV of the Regulation (EU) 2017/745.

Croissy-Beaubourg

Representante legal

Eric FAUVARQUE
Directeur Général
General Manager
Director General

OWANDY RADIOLOGY
2, rue des Vieilles Vignes
77183 CROISSY-BEAUBOURG - FRANCE

DIGITAL WORKFLOW OWANDY RADIOLOGY

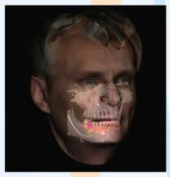
A COMPREHENSIVE RANGE TO MEET ALL YOUR REQUIREMENTS

CEPHALOMETRIC UNITS

2D/3D UNITS

HF-INTRAORAL GENERATOR

INTRAORAL PLAQUE SCANNER



FACE SCAN .PLY IMPORT

EXPORT TO 3D PRINTER

3D INTRAORAL SCANNER

SURGICAL GUIDE

DIGITAL USB INTRAORAL CAMERA

DIRECT USB SENSORS

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