

# Velopex Digital Wi-Fi INSTALLATION AND USER MANUAL

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# 1 Introduction

You have just received your Velopex Digital Wifi digital intra-oral radiology kit. We thank you for the confidence you have in us and hope that this product will give you complete satisfaction.

We recommend you to read this manual thoroughly before installing the product. By following the guidelines for installation and usage described in it, you will exclude risks to your patients and your colleagues. Please keep it close to your equipment so you can refer to it at a later date.

Your Velopex Digital Wifi 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 Compliance with standards**

The Velopex Digital Wifi sensor is class IIA equipment within the meaning of the European Directive concerning CE markings, annexe IX of book Vbis of the Public Health code, supplementing Directive 93/42/CEE of the 14<sup>th</sup> of June 1993. The Velopex Digital Wifi sensor complies with medical standard EN/IEC60601-1. The Velopex Digital Wifi kit complies with directive 93/42 CE (annexe VII) of decree 95-292 of the Public Health code.

The Velopex Digital intra-oral sensor is contained within a hermetic case, sealed in compliance with standard IPX7.

The Velopex Digital Wifi interface box is electrically insulated from the mains power supply as the transmission of data to the computer is done through radio waves. It is insulated from the mains power supply through the power supply (double insulation, medical standard) when the batteries are charging.

There is no physical or electrical connection between the Velopex Digital Wifi kit and the X-ray generator.

# 1.2 Power supply

The Velopex Digital Wifi kit is powered by batteries located inside the box. To recharge these batteries it is necessary to connect the box to the power supply and to the mains.



Use only the normalised power supply provided with the Velopex Digital Wifi kit, or the safety standards applicable to this type of equipment might not be respected. Switch off the box with the button, the batteries must be recharged in standby mode.

# 1.3 Liability and operators

**Installer**: the installation of the Velopex Digital Wifi 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 Velopex Digital Wifi kit must be used by a dental practitioner.



The Velopex Digital Wifi box should never be opened by the user. Only the manufacturer is authorised to open and make repairs to the sensor or box. 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.

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 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).

# **1.4 Packaging and environment**

**Transport, storage and environment**: the Velopex Digital Wifi 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: 10% to 100% 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.

# 1.5 Marking and labelling symbols

equipment.

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.	★	Equipement type BF, EN/CEI 60-601-1, annexes I et II.
	Sealing standard of the sensor, regulation EN/IEC 60529.		Important information: follow
	Only the part of the sensor that is inserted in the mouth complies with this standard.	<u>/•</u> `\	manual.
<b>C E</b> 0459	The CE marking certifies that this product complies with European directive 93/42 CEE.		Class II device within the meaning of standard NF EN/IEC 60601-1-1 (reinforced or double insulation).
	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 20 <sup>th</sup> July 2005 regarding the composition of electrical and electronic equipment and the elimination of waste coming from this		

# 2 Contents

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



# 3 Installation

# 3.1 Precautions



The Velopex Digital Wifi 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 attachment cable.

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

Install your imaging software before the installation of the Velopex Digital Wifi kit, its drivers and O.S.P. tools and the personalisation files.



The batteries of the box are partially charged when leaving the factory. Charge the batteries completely before using the kit (see "3.2.2 Charging the batteries").

# 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 or the Velopex Digital Wifi kit. Verify the specifications of the computer(s) before the installation.

Operating system	Windows XP service pack 1, Millennium or 98 second edition
Computer	Compliant CE-IEC950
Motherboard	Intel 1.2GHz chipset and processor
USB port (for Wi-Fi antenna)	Compatible USB 1.1; USB 2.0 High-Speed recommended
Graphics card	64MB
Monitor	High resolution 1024x768 (15inch)
RAM memory	256MB
Hard disk	10GB
CD-ROM drive	24x
Backup system	External/removable disk, Zip or Jaz system, CD-ROM/DVD…
Printer Keyboard and mouse	Laser, inkjet, thermal
At acquisition workstation	Velopex Digital Wifi 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 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 place 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 Velopex Digital Wifi 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 Connections

The Velopex Digital Wifi interface box provides connectors for the sensor and the power supply (to recharge the batteries).

Connect the sensor cable connector to the box by aligning the red dot on the plug with the red dot on the socket of the box – do not try to force the insertion of the plug, it could damage the connector. The Velopex Digital Wifi interface box accepts size 1 or 2 Velopex Digital sensors.





Do not connect or disconnect the sensor waiting for an acquisition or during an acquisition, you could damage the sensor. Make sure the box is in standby mode before disconnecting the sensor.

The Velopex Digital Wifi kit is powered by batteries located inside the box. To recharge these batteries it is necessary to connect the box to the power supply and to the mains.

The Velopex Digital Wifi box communicates with the computer by using a Wi-Fi radio link. A Wi-Fi antenna is provided with the kit to be plugged in a USB 2.0 port of the computer.

Check that the box is correctly connected: switch it on with the button; if the green light on the box is switched on, it is powered correctly.

# 3.2.2 Charging the batteries



Use only the normalised power supply provided with the Velopex Digital Wifi kit, or the safety standards applicable to this type of equipment might not be respected. Switch off the box with the button, the batteries must be recharged in standby mode.

When the red light on the box blinks once per second or that the box does not switch on after a period of inactivity, it is necessary to recharge the batteries:

- 1. Switch off the box with the button, the batteries must be recharged in standby mode.
- 2. Connect the power supply to the box and the mains.
- 3. The red light blinks several times per second while it is recharging.
- 4. When the batteries are completely charged, the red light switches off; disconnect the power supply.

A complete charge provides 2 hours running time in continuous use. Recharge the batteries at least once every 2 weeks. Leave the box in charge mode for longer periods of inactivity.



If the batteries of the box are completely discharged after a long period of inactivity and the box does not immediately go into charge mode, wait for 1 minute. If the red light does not blink after 1 minute, refer to chapter "6 Troubleshooting".

#### 3.2.3 Installation Wi-Fi antenna

Refer to chapter "3.3 Software installation" for detailed installation instructions.



Make sure the USB port of the computer, used to connect the Wi-Fi antenna, is 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).

## 3.2.4 Box and sensor supports

The box can be mounted or placed on different supports using the accessories provided with the box.

Place the box on a worktop: stick the non-slip feet provided with the kit to the back of the box if you want to place the box on a worktop.

Attach the box with the strap: if you want to use the strap to position the box, attach the base plate of the wall support to the back of the box using the 4 self-tapping screws (use only the screws provided with the kit or you could damage the box).

Pass the strap under the base plate (as indicated in the drawing underneath) and close it on itself to ensure the Velcro fastening holds.





Your box can now be attached to a support with the strap, e.g. to the arm of your X-ray generator, to the headrest or armrest of your chair.



Mount the box using the wall support: it is also possible to insert the box with the base plate in the wall support of the box.

The wall support can be mounted on a wall, a worktop or object either by using the screws or by using the strap, passing it through the slits provided for that purpose in the wall support of the box.

To mount the wall support of the box, drill 2 holes

according to the outline opposite. Insert the plugs, screw in

the screws and hook on the wall support to these attachments. Slide the box in the wall support using the

5mm / 1.9inch diameter

33mm / 1.3inch of space

 $\triangle$ 

base plate.

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







**Storing the sensor**: it is possible to store the sensor in the space provided in the box.

An adapter is included to store the size 1 sensors in the box's storage area. Remove the protective film from the double sided adhesive at the back of the adapter before inserting it in the sensor storage space. The part of the adapter with the adhesive must be inserted last, this to allow you to remove the adapter at a later date.



The kit is also provided with a wall support for the sensor; this support is compatible with size 1 and 2 sensors and can be mounted to a wall, a worktop or to equipment. It allows you to store the sensor within easy reach and to protect it against eventual impacts or drops.

# 3.3 Software installation

Install the Velopex Digital 'Easy use' (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.

#### 3.3.1 Installation and configuration of the Wi-Fi antenna

Install the drivers before connecting the Wi-Fi antenna to the USB port. Refer to the manufacturer's documentation of the antenna for more information.

Insert the CD-ROM of the Wi-Fi antenna Wi-Fi 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 automatically launch.

- 1. Select the desired language in the main screen then click on "Install".
- 2. Click on "Click here to start".
- 3. Accept the license agreement in window number 1 by clicking on "Next", the files are copied to your hard disk.
- 4. Connect the Wi-Fi antenna to the USB 2.0 port when asked for. A message in the toolbar will confirm the detection, installation and availability of your Wi-Fi antenna. Click on "Next".
- 5. The "Creating a profile" window allows you to enter the parameters of the connection, refer to the procedure below to configure the Wi-Fi antenna.

An icon in the toolbar next to the click provides access to the tools for the Wi-Fi antenna. To configure or reconfigure the antenna you need to:

- 1. Double click on the Wi-Fi antenna icon.
- 2. Click on "Manual configuration".
- 3. In the window "Network configuration" select "Specify network parameters" then enter "192.168.77.91" in the "IP address" field and "255.255.255.0" in the "Subnet mask" field and click on "Next". This mask allows computers whose IP address starts with the same three groups of numbers to communicate.
- 4. In the "Wireless mode" window select the "Ad Hoc Mode" and enter "Velopex Digital Wifi" in the "SSID" field then click on "Next".
- 5. In the "Ad Hoc parameters" window select channel "11" then click on "Next".
- 6. In the "Wireless security" window select security "Disabled" and click on "Next".
- An overview of your parameters is displayed, click on "Save".
- 8. A window will confirm the saving, click on "Connect to network".
- 9. Activate the box by pushing the button. The box will automatically be detected and a window will inform you that you are connected in ad hoc mode.



If the window does not display "Access to Ad hoc network succeeded":

- 1. Click on the "Search for site" tab.
- 2. Click on the "Refresh" button to display all available Wi-Fi connections, the "Velopex Digital" connection should appear in the list.
- Select the "Velopex Digital" connection then click on "Connect".
- Click on "No" if a warning message asks to automatically obtain an IP address (see opposite).
- 5. The box will automatically be detected and an "Access to Ad Hoc network succeeded" window is displayed.

Moniteu	ır de réseau sans fil Link	sys	×
?	Votre PC utilise actuellement "obtenir automatiquement ur	une "adresse IP statique e adresse IP" pour la co	". Souhaitez-vous nnexion sans fil ?
	Oui	Non	



The parameters of the Wi-Fi antenna must be consistent with the parameters of the Velopex Digital Wifi interface box, refer to chapter « 3.4.1 Advanced configuration panel of the box » for more information.

#### Use with a firewall

If a firewall is installed in Windows, it must authorise the following software programs:

- Ping.exe
- Ingxsrvr.exe
- Wifix test.exe

#### Calculate the strength of the Wi-Fi signal

To calculate the power of the Wi-Fi signal:

- 1. Start the tools of the Wi-Fi antenna by double clicking on the icon in the toolbar, next to the clock.
- 2. Select the "Connection information" tab and click on "More information".
- 3. Click on the "State" to display the noise level and signal strength.

To calculate the signal / noise ratio you need to:

"Signal strength" – "Noise level" (e.g. (-56) - (-99) = 43)

If the result is inferior to 20 you need to change the setup to obtain a more important signal to noise ratio, e.g. by modifying the orientation of the antenna, by positioning the antenna closer to the box, by clearing the line of field between the antenna and the box...

#### 3.3.2 Installation of the drivers and the O.S.P.

Automatic installation for Windows 98SE and Millennium: insert the O.S.P. CD-ROM in the CD-ROMdrive. 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 automatically launch.

- 1. Click on the button to start the installation.
- 2. Select the desired language in the window that appears and click on "Next".
- 3. In the welcome screen click on "Next".
- 4. Select the target directory by clicking on "Browse" and by navigating to the desired directory. After having selected the target directory (the directory where the software will be installed) click on "Next".
- 5. Click on "Install" to start the copying the files.
- 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.

Automatic installation for Windows 2000 and XP: 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 automatically launch.

- 1. Select the desired language in the main screen. The tabs at the top of the page link to different pages of the Owandy website and provide more information regarding Owandy.
- 2. Click on "Install", then on "Next".
- 3. Select "WIFI" in the menu that appears.
- 4. Confirm the installation of the Velopex Digital Wifi drivers by clicking on "WIFI".
- 5. Select the desired language in the window that appears and click on "Next".
- 6. In the welcome screen click on "Next".
- Select the target directory by clicking on "Browse" and by navigating to the desired directory. After having selected the target directory (the directory where the software will be installed) click on "Next".
- 8. Click on "Install" to start the copying the files.
- 9. A window will inform you of the successful installation, close it by clicking on "Exit".
- 10. 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).
- 11. Close the main O.S.P. installation window if it is still displayed on-screen.

Manual installation: if you want to start the manual installation of the drivers and O.S.P. tools:

- 1. Insert the O.S.P. CD-ROM in the CD-ROM drive.
- Navigate to the "\setups\WIFI\_XRAYS\_BOX\_W98\_WME\_W2000\_WXP" directory on the O.S.P. CD-ROM.
- 3. Launch "setup.exe". Refer to the automatic installation of the O.S.P. mentioned above.

#### 3.3.3 Personalisation files



Each kit is provided with a sensor personalisation CD-ROM of its own; the serial number of the Velopex Digital sensor is written on the CD-ROM. You can therefore not use the same CD-ROM to install several Velopex Digital sensors.

Before installing the sensor personalisation files, make sure that:

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

Insert the sensor personalisation CD-ROM, a window appears and the personalisation 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.
- Navigate to the "\setups\WIFI\_XRAYS\_BOX\_W98\_WME\_W2000\_WXP" directory on the CD-ROM.
- 3. Launch "setup.exe".
- 4. Click on "Install or Reinstall" and be guided by the instructions on-screen.

# 3.4 Configuration in the Velopex Digital imaging software

To be able to use your kit with the Velopex Digital 'Easy use' 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 DSX730 & Velopex Digital" under the "Intra-Oral sensor" option in the window that appears.

	- Chemins des fic Archive Images Archive:	hiers Radios es radios couleur s images	C:\JULIEW\ A:\ C:\JULIEW\ A:\		
Panoramique numériq	ue:	Non	installé(e)	нцт	
Radios numériques:	Capteur Intra-Oral	(7.0)	VANDY DSX730 & Krystal-X	₽ĻT	Configurer

4. Click on "Configure" at the right of the menu.

CONFIGURAT	юн		In the configuration window:
ок	Annuler		Check the "WIFI" model.
Modèle Krystal-X WIFI	• 독	Wi-Fi	<ul> <li>Advanced configuration panel of the Wi-Fi connection of the box, see 3.4.1.</li> <li>Reinitialise the default factory settings, see 3.4.2</li> </ul>
	<b>1</b>	🕫 Krystal×Easy - 520	300 0.4.2.
USB	0 6	C Krystal X Light - 510	
		C Krystal-X - 500 & 502	
	-	🔿 DSX730 Evo3 - 501	
		C DSX730 V1 - 100 C DSX730 V3 - 104	
		○ DSX730 V2 - 100 ○ DSX730 V3 Evo 1 & 2 - 103	
	2	C UPIX - 102	
Barre d'outils	Pleine résol	ution 🔽 Avec rallonge	
Comportement	Activation penda	ant: 2 ininutes Permanente	
			<ul> <li>Set the activation time of the box (par default 2min). A short activation time</li> </ul>
	Date et heu	e dans l'image	allows you to save the batteries by
d'image	Els	The second se	switching off the box quickly.
	Radio film	C Contraste C Mode test	<ul> <li>Select the image treatment (*).</li> </ul>
	Filtre		<ul> <li>Configure the Velopex Digital software</li> </ul>
V 1.	1. 6. 1 • DII V 1.4.0	1.0 - Wi-Fi Software: 0.0 - Protocol: 0.0 - Logic: 0	(**).

(\*) 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 <u>your choice</u>.
- 6. Then click on the "Save" without to validate the settings.

The use of the kit is identical to the use of the Velopex Digital software described under 4.3.

# 3.4.1 Advanced configuration panel of the box

In the configuration panel (see above) click on the "WIFI" button to access the settings of the Velopex Digital Wifi interface box. This window allows you to modify:

- The IP address of the box
- The subnet mask of the box
- The channel (refer to the table below for the channels available per country)
- The name (SSID) of the connection



Click on "Memorise" to save the parameters in the box,

on "Cancel" to exit the window without changing the parameters of the box or on "Read actual" to display the settings of the connection.



Make sure the settings of the box are consistent with the settings of the Wi-Fi antenna. Start the configuration tools of the antenna to modify the parameters (see "3.3.1 Installation and configuration of the Wi-Fi antenna").

#### Domain X'10' X'31' X'32' X'40' X'41' X'20' X'30' Frequency Channel (MHz) FCC (\*) IC (\*) ETSI (\*) Spain France Japan Japan 2412 1 Х Х Х \_ \_ Х 2 2417 Х х Х -х -2422 3 Х Х Х ---Х 4 2427 х х х \_ \_ х 5 2432 ---Х х Х Х 6 2437 Х х Х --х 7 2442 х х х \_ -х 2447 8 Х Х X ---Х 9 2452 Х Х Х -Х \_ \_ 2457 10 -Х Х Х Х Х Х 11 2462 Х х Х Х Х -Х 12 2467 Х х х \_ \_ -13 2472 --X -Х -Х 14 2484 х

#### Wi-Fi channels available by region (extract of standard IEEE Std 802.11b)

(\*) FCC: USA, IC: Canada, ETSI: Europe except Spain and France

# 3.4.2 Re-initialisation of factory settings

If you want to re-initialise the factory settings, you need to re-initialise the settings of the Wi-Fi antenna, the box and the connection (in the imaging software). Factory settings:

- IP address: 192.168.77.92
- Subnet mask: 255.255.255.0
- Channel: 11
- SSID: Velopex Digital

To re-initialise the parameters of the connection in the software, click on the "Factory settings" button in the configuration panel (see above). Click on "OK" in the confirmation window that is displayed to configure the default parameters of the Wi-Fi connection Wi-Fi with the box.

To re-initialise the factory settings of the box:

- 1. Activate the box by pushing the button.
- 2. Push the button and keep it pushed in.
- 3. Release the button when the three lights have blinked 5 times; the box will restart with the factory settings.

To re-initialise the parameters of the Wi-Fi antenna you need to start the configuration tools (see "3.3.1 Installation and configuration of the Wi-Fi antenna").

# 3.5 Sharing the sensor and box

Sharing the sensor and the box 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 Wi-Fi antenna must be available at each workstation.

#### 3.5.1 Use of a kit with one computer

For use with a single workstation the default factory parameters can be used. These can be modified taking into account the guidelines under 3.3.1 and 3.4.

To allow the sharing of the Velopex Digital Wifi kit between different workstations, it is necessary to install the imaging software used for the acquisition of the images, the drivers, O.S.P. tools and personalisation files on all the computers with which the box will be used beforehand.



IP: 192.168.77.91

Connection: Ad Hoc Subnet mask: 255.255.255.0 Channel: 11 SSID: Velopex Digital



IP: 192.168.77.92

#### 3.5.2 Use of a kit with multiple computers

When the kit is shared between multiple computers, beforehand, on each workstation you need to:

- 1. Install the imaging software used for the acquisition.
- 2. Install the drivers and O.S.P. tools.
- 3. Install the personalisation files of the sensor that will be used on that workstation.
- Configure the computers with a different IP address but starting with the same first 3 groups of numbers e.g. 192.168.77.91, 192.168.77.90, 192.168.77.89.
   Check the option "Disable connection if time elapsed" and uncheck the option "Activate
- 5. Check the option "Disable connection if time elapsed" and uncheck the option "Activate connection" in the sensor configuration menu (see "4.3.3 Configuration menu").

The kit is used in turn with the different computers. To switch the sensor from one computer to another the connection on the workstation receiving the acquired images must be activated by right clicking on the sensor toolbar and selecting the "Activate connection".

If the kit is in use with another workstation, the toolbar will only turn green when the kit becomes available. The sensor toolbar is grey when the Wi-Fi connection Wi-Fi is not active.

#### Configuration example:



IP: 192.168.77.89

Connection: Ad Hoc Subnet mask: 255.255.255.0 Channel: 11 SSID: Velopex Digital



IP: 192.168.77.88



IP: 192.168.77.92







IP: 192.168.77.91

## 3.5.3 Use of multiple kits with multiple computers

To share multiple kits between multiple computers, each box and Wi-Fi antenna must be configured with a different IP address to create box and computer pairs. Beforehand, on each workstation you need to:

- 1. Install the imaging software used for the acquisition.
- 2. Install the drivers and O.S.P. tools.
- 3. Install the personalisation files of the sensor that will be used on that workstation.
- 4. Configure the computers with a different IP address for each sensor e.g. 192.168.77.91, 192.168.77.90, 192.168.77.89. Write down these parameters in the first columns of the overview table below.

Computer name	IP address computer	SSID	Channel	Serial number box	IP address box

Configure subsequently the computer and box pairs:

- 1. Power up only one Velopex Digital Wifi interface box.
- 2. Open the sensor configuration window in the Velopex Digital 'Easy use' imaging software (see 3.4).
- 3. Click on the "Wifi" button and modify the SSID, the channel and IP address of the box. **Caution:** be careful not to use the network parameters of a computer or another box. Write down these parameters in the last columns of the overview table above (the serial number can be found under the box).
- 4. Power down the box that is configured with the button and configure another box and computer pair.

#### Configuration example:



Station 1 IP: 192.168.77.80



Station 2 IP: 192.168.77.79

Connection: Ad Hoc Subnet mask: 255.255.255.0 Channel: 11 SSID: Velopex Digital Wifi X1

Connection: Ad Hoc Subnet mask: 255.255.255.0 Channel: 12 SSID: Velopex Digital Wifi X2



Box: 121 IP: 192.168.77.93



Box: 122 IP: 192.168.77.94

Computer name	IP address computer	SSID	Channel	Serial number box	IP address box
Station 1	192.168.77.80	Velopex Digital Wifi X1	11	121	192.168.77.93
Station 2	192.168.77.79	Velopex Digital Wifi X2	12	122	192.168.77.94

# 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 attachment cable. Do not connect or disconnect the sensor waiting for an acquisition or during an acquisition, you could damage the sensor. Make sure the box is in standby mode before disconnecting the sensor.



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.

# 4.2 Lights and button on the interface box

During initialisation of the box, the green and yellow lights light up; once the initialisation finished, only the green light remains lit.

The box automatically switches to standby mode after a period that can be set in the configuration window (see below - the default period is 2 minutes). All lights are off when the box is in standby mode and the sensor toolbar turns red. To reactivate the box you only need to push the button on the box.

The lights inform the user about the state of the box:

- Green light only sensor ready for image acquisition.
- Yellow light: sensor not available (in preparation, transmitting or Wi-Fi connection not available).
- Yellow light blinking: sensor not found.
- Red light only: an error occurred, restart the box.
- Red light blinking several times per second: battery level low, recharge them.

The red light blinks several times per second when the box is connected to the power supply to recharge the batteries.



# 4.3 Use of the Velopex Digital StandAlone software

#### 4.3.1 Modes of operation

The Velopex Digital Wifi kit can function in two ways:

- Through the Twain protocol (for scanners): to use this mode select "Velopex Digital USB Intra Oral Twain drivers" 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 program icon (on the Windows desktop) or by starting a Velopex Digital 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 USB XRAYS BOX\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:

10:23	Red: sensor inactive
10:23	Yellow: sensor initialising
10:23	Green: sensor ready for acquisition
10:23	Grey: Wi-Fi connection between the box and the computer is disabled

## 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:

ų 📖 😵 🕓 👻	Red: sensor inactive
	Yellow: sensor initialising
	Green: sensor ready for acquisition
	Grey: Wi-Fi connection between the box and the computer is disabled

Options of the sensor toolbar:

- Orientation of the sensor (vertical or horizontal), double-click on the icon to change the orientation of the sensor.
  Charge level indicator of batteries of the box:

  Battery indicator green and full: charged at 100%
  Battery indicator orange and half full: low charge
  Battery indicator red and empty: recharge batteries
  Extension/reduction of the toolbar to hide/display the options.

  Configuration of the resolution: check the option to acquire images in full resolution; uncheck the option to switch to standard resolution.
  - Iconize the toolbar in the taskbar.

The resolution and operation mode can only be modified when the green light of the box is on. The box needs a few seconds to change the parameters.



The box automatically switches to standby mode after a few minutes of not being used; the lights will switch off and the sensor toolbar turns red. Push the button on the box to restart the kit.

Check the state of the lights on the box and the colour of the sensor toolbar before each acquisition: the green light must be switched on and the toolbar must be displayed in green.

# 4.3.3 Configuration menu

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

Intra-oral sensor	Displays the sensor toolbar.
Start with Windows	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 Velopex Digital imaging software").
Display new images during	Adjusts the display time of the image.
Images pending	Allows you to browse through the images waiting to be transferred. If no image is acquired this option is not displayed.
Activate connection	Activates the Wi-Fi connection; check this option when the kit is used with a single workstation, for use with multiple workstations see " <b>Error! Reference source not found.</b> Configuration in the Velopex Digital imaging software".
Disable connection if time elapsed	Shuts down the Wi-Fi connection after a period of inactivity defined in the configuration menu (see "3.4 Configuration in the Velopex Digital imaging software").
Exit	Closes the resident software program. <b>Warning</b> : 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.
"Read" 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.
"Delete" button	Deletes the selected image.
"Delete on read" 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 with which the box will be used and start the imaging software. Check that the sensor toolbar or the sensor icon is green and that the green light on the box is lit and the yellow light is not lit.
- 2. Program the different parameters (exposure time, etc.) on the X-ray generator (see "4.5 Exposure time" 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.

Refer to the poster provided with the positioners for more information regarding the positioning for anterior, posterior, endo and bitewing 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 green and yellow lights of the box will light up to indicate the treatment of the acquired image. Once the image treated, it appears in the imaging software and the green light of the box lights up allowing a new acquisition.

If the red light blinks, the charge level of the batteries is low, recharge them.

## 4.4.2 Owandy imaging software functions

This function is available only to users of the Velopex Digital imaging software.

When the image is displayed in the Velopex Digital 'Easy use' imaging software, a coloured bar appears in the top part of the image, this is the exposure bar.



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.

# 4.4.3 Third party imaging software functions

If you do not possess the Velopex Digital imaging software, 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.

# 4.5 Exposure time

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

Description	Owandy Altis DC	Owandy Elios AC
Current / Voltage	4mA / 65KV	8mA / 70KV
Lower incisor / canine	0.06 – 0.10	0.02 - 0.06
Lower premolar	0.06 - 0.10	0.04 - 0.08
Lower molar	0.10 – 0.14	0.08 – 0.12
Upper incisor / canine	0.06 – 0.10	0.04 - 0.08
Upper premolar	0.08 – 0.12	0.06 – 0.10
Upper molar	0.10 - 0.14	0.08 - 0.12

Reference conditions:

- Adult patient, young man or woman of average size
- Distance focal spot to sensor 250mm / 9.8inch
- 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:

Description	Adult	Child
Lower incisor / canine		
Lower premolar		
Lower molar		
Upper incisor / canine		
Upper premolar		
Upper molar		

# 5 Hygiene and maintenance

# 5.1 Hygiene and disinfection

## 5.1.1 Box

The box 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 disinfection 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 disinfection procedure"). They can be sterilised, either in an autoclave (classic steam-sterilizer, distilled water,  $134^{\circ}$ C /  $273^{\circ}$ F, 3bar, 4min) or using cold sterilisation (see product instructions). They withstand a maximal temperature of  $145^{\circ}$ C /  $293^{\circ}$ F.

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

# 5.2 Recommended disinfection 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 beginning of the cable in the disinfectant for 15min, never immerse the connector of the sensor or the connection box in the liquid.

Then rinse thoroughly the sensor 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.



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

If the sensor is not being used immediately upon rinsing, as in the case of allowing it to air-dry overnight at the end of a working day, it should be rinsed with sterile water.

When the sensor is not being used and to protect it from any damage, it is recommended to store it in its protective case or to hang it in the sensor wall support.

# 5.2.1 Recommended disinfectants for North-America

The sensor being sealed watertight and to minimize the potential for device-associated infections, the device 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 Velopex Digital sensor: CIDEX OPA solution (0.55% Ortho-phthalaldehyde solution). The maximum soaking period is 24 hours.

## 5.2.2 Recommended disinfectants outside North-America

The following disinfectants are compatible with the Velopex Digital sensor:

- 2% Glutaraldehydes (maximum immersion time of 24 hours)
- 2% Sodium Hypochlorite (maximum immersion time of 24 hours)
- Ethyl alcohol (maximum immersion time of 24 hours)
- CIDEX

Even when using protective sheaths, the sensor should be disinfected each evening. 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.

# 5.3 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.). Store the copies in a safe place.



# 6 Troubleshooting

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 Velopex Digital Wifi kit does acquire images.	<ul> <li>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.</li> </ul>	
	• Check that the kit is correctly configured in the imaging software and that the drivers are correctly installed.	
	• Check that the green light on the box is on and that the sensor toolbar is green; if this is not the case reactivate the box by pushing on the button.	
	Check that the sensor is connected correctly to the box.	
	• Check that the generator is emitting X-rays (with another sensor or with conventional film).	
The kit cannot communicate with the computer.	The Wi-Fi connection could be lost.	
	<ul> <li>Check the network settings of the Wi-Fi antenna (see "3.3.1 Installation and configuration of the Wi-Fi antenna").</li> </ul>	
	• Switch the box off and back on, the green light should be on and the yellow light off.	
The kit cannot communicate with the computer after changing the network	The changes of the network settings have not been taken into account.	
settings.	• Reconfigure the box with the factory settings (see "3.4.2 Re-initialisation of factory settings"). If you cannot modify the factory settings, contact your distributor.	
The kit re-initialises by itself.	When a problem with the kit occurs, it re-initialises; the red light remains lit for 30 seconds before restarting.	
	• If the box continuously re-initialises, switch it off and back on with the button. If the problem persists, contact your distributor.	
The red light of the box lights up.	<ul> <li>An error has occurred, switch the box off and back on with the button.</li> </ul>	

# 6.2 Power supply of the box

Symptom	Cause / Solution	
The red light of the box blinks once per second.	• The charge level of the box is low, recharge the batteries.	
The box does not switch on when the button is pushed.	• The batteries are discharged, recharge them.	
The box switches off.	The box automatically switches off after a period of inactivity (set in the configuration menu). Push the button to restart the kit.	
	• The charge level of the box is low, recharge the batteries.	
	• The batteries of the box are partially charged when leaving the factory. Charge the batteries completely before using the kit.	

Refer to chapter "3.2.2 Charging the batteries" for more information.

# 6.3 Charging of the batteries

Symptom	Cause / Solution
The box heats up when the batteries are charging.	It is normal that the batteries heat up during the charge cycle.
The red light of the box lights up when the power supply is connected.	• Disconnect the power supply from the box and the mains then reconnect it.
The red light of the box blinks several times per second during the charge cycle.	This indicates the batteries are charging.
The red light lights up during the charge cycle.	This indicates the batteries have heated up during the charge cycle. Disconnect the power supply and use the kit.
The batteries of the box do not charge (when the power supply has been connected for more than a minute the red light still does not blink).	<ul> <li>Use the button to re-initialise the charging of the box before recharging the batteries.</li> <li>Connect the power supply to the box.</li> <li>Push the button with a pen.</li> <li>Keep the button pushed in for 10 to 15 seconds then release it.</li> <li>The box will go into charge mode ad the red light blinks several times per second. Wait for the charging to be complete before disconnecting the power supply.</li> </ul>

The network parameters are not modified when re-enabling the charge mode of the box.

Refer to chapter "3.2.2 Charging the batteries" or more information.

# 6.4 Image quality

## Symptom

#### Cause / Solution

The images are cut off, e.g.:



The sensor is badly positioned with regard to the X-ray beam.

- Reposition the sensor, making sure it is well within the field of the X-ray beam.
- Use the positioners provided with the sensor for optimal positioning.

The images are too	light, e.g.:	•	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:
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:
Grey levels seem to image (flat areas of	b be missing in the 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-a	acquire the image: The patient has moved during the exposure.
		•	The generator head was not stabilised and has moved.

# 7 Specifications

# Velopex Digital size 1 sensor

External dimensions size 1 sensor	38,9 x 26,5 x 7,4mm / 1.5 x 1.0 x 0.3inch	
<ul> <li>CCD matrix size 1 sensor</li> <li>Sensitive area in size</li> <li>Sensitive area in pixels</li> <li>Pixel dimensions</li> </ul>	30 x 20mm (600mm <sup>2</sup> ) / 1.2 x 0.8inch (0.9inch <sup>2</sup> ) 1500 x 1000pixels 20 x 20µm	
Velopex Digital size 2 sensor		
External dimensions size 2 sensor	42,7 x 28,5 x 7,4mm / 1.7 x 1.1 x 0.3inch	
<ul> <li>CCD matrix size 2 sensor</li> <li>Sensitive area in size</li> <li>Sensitive area in pixels</li> <li>Pixel dimensions</li> </ul>	34 x 24mm (816mm²) / 1.3 x 0.9inch (1.3inch²) 1790 x 1260pixels 19 x 19μm	
Technical specifications (size 1 and 2 sensors)		
Maximum external dimensions connection box	18,6 x 8,4 x 2,4cm / 7.3 x 3.3 x 0.9inch	
Length sensor cable (in polyurethane)	80cm / 2.6ft	
Grey levels	10bits (1024 grey levels)	
Connection	Wi-Fi standard: 802.11b	
Consumption kit	4W	
Input voltage connection box for charging batteries Input current connection box for charging batteries	12V direct current 1A	
Maximum recharging time Number of charge cycles supported by the batteries	80mins 500 minimum	
Running time in standby mode Running time in use	2 weeks 2 hours	
Operating temperature	+10°C to +40°C / 50°F to 104°F	
Lifespan CCD	Min. 100.000 cycles	
Standards		
Sealing standard Velopex Digital sensor	IPX 7	
Conformity to standards	NF EN/CEI60601-1 NF EN/CEI60601-1-1 NF EN/CEI60601-1-2	

# 8 Optional kits and accessories

# 8.1 Optional kits

The optional kits allow you to add a sensor or box to your kit to evolve according to your needs. Each optional kit is supplied with its accessories.



# 8.2 Accessories

Refill packs of 10 positionners:

Cray Sensor Holder	DORT1ANGUBW DORT1ANGUZE DORT1ANGUZP DORT1ANGUZPA DORT2ANGUBW DORT2ANGUZE DORT2ANGUZP DORT2ANGUZPA	Size 1 bitewing Size 1 endo Size 1 posterior Size 1 peri-apical Size 2 bitewing Size 2 endo Size 2 posterior Size 2 peri-apical
	Hygienic single-use di (for size 1 and 2 senso D0PROTECCAPXL	sposable protection sleeves rs) Bag of 20 pieces
	Supports and adaptors D0SUPCAP730 D0SUPKW D0ADAPTW/2V1 D0RSANGKW	Sensor wall support Box wall support (with base plate & strap) Adaptor size 2 > 1 Strap (3 pieces)
	D0BACCU1KW WUSB54GP	Power supply Wi-Fi antenna (USB key)