Tuxedo Intraoral Sensor Operation Manual

A-Series

(PN 6100A & PN 6101A)

Tuxedo Imaging
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Chapter 1: Introduction

About This Manual

This manual provides information on the safe and effective use of the Tuxedo Intraoral Sensor (A-Series) and associated software along with the proper installation, maintenance and care of the device. The dentist, hygienist, and entire team should thoroughly review this manual and become familiar with it and the Tuxedo Intraoral sensor prior to using the device during patient care.

Indications for Use

The Tuxedo Digital Dental Sensor is a CMOS sensor for the capturing of digital diagnostic x-ray images on a patient for evaluation by an appropriately trained oral healthcare professional. The Tuxedo sensor itself is a single piece comprised of the image capture components on one end, with a USB 2.0 plug on the other end. The sensor is designed to be used in conjunction with a disposable, single-use hygienic sheath as well as a positioning device to allow for proper alignment within the patient's mouth. Images are acquired with the Tuxedo sensor by plugging it into a USB port and properly placing it in the patient's mouth, while an operator exposes radiation toward the sensor from an approved intraoral x-ray generator.

Product & Technical Description

This Tuxedo sensor product is a digital intraoral sensor system that contains the components necessary to acquire and manage high quality digital intraoral x-ray images when connected to a USB 2.0 compatible port on a Windows PC and used together with an approved intraoral x-ray generator. The CMOS sensor is provided in either size 1 (active image area of 19.95mm x 30.02mm, 1050 x 1580 pixels) or size 2 (active image area of 25.99mm x 36.00mm, 1368 x 1896 pixels) and incorporates photodiodes along the long edges of the sensor that can detect the presence of x-ray radiation at the face of the sensor. These photodiodes allow the sensor to detect incident x-ray radiation so that it can start integrating the signal to acquire an x-ray image. The sensor is designed to be controlled by the user running the Apteryx Imaging software on a Windows PC after having installed the appropriate drivers and software. The user readies the sensor to acquire an image in the Apteryx Imaging software and then activates the x-ray generator and exposes the sensor; the image is then acquired by the sensor and communicated back to the PC for display to the user. The Apteryx Imaging software provides a great deal of functionality in terms of controlling the sensor, processing the resulting images and storing them appropriately associated with patient information.

To use the system the user first puts the size 1 or size 2 sensor housing and distal end of the USB cable into a disposable barrier or sheath and then inserts it into the applicable adjustable sensor holder which is attached to a universal positioning arm and ring in the appropriate position for the type of radiograph being acquired (universal positioning arm and adjustable sensor holder kits are recommended and sold separately). After the patient bites down onto a bite block to hold the assembly in position, the user is free to use the ring as the guide to correctly position the x-ray generator head and then activate the x-

ray source to acquire the image. The user can subsequently view, manipulate and store the resulting image with the Apteryx Imaging software.

Package Contents

- Digital X-ray sensor with attached cable and USB connector
- Sample pack of 50 Digital X-Ray Sensor Sheaths
- Drivers and files are available at www.tuxedoimaging.com

Chapter 2: Safety & Disposal

General Safety

- The Tuxedo Intra-oral sensor must be installed and used in accordance with the instructions and procedures contained in this manual.
- Under no circumstances should an attempt be made to modify or repair the device unless by authorized Tuxedo Imaging service personnel. Such an action will void the warranty and may result in a safety hazard.

Electrical Safety

- The Tuxedo sensor is not to be operated in oxygen rich and/or explosive environments. Do not use the Tuxedo sensor within 25 cm (10 in. approx.) of flammable anesthetic equipment.
- Prior to using the Tuxedo sensor, briefly inspect the sensor housing, cable attachment and connector to see if there are any signs of damage such as overheating, cracking or damage to cabling. If you notice any visible damage, discontinue use of the device and call Tuxedo Imaging Customer Support.

X-ray Safety

- Even though you are using digital x-ray sensor, please continue to use the same x-ray protection for your patients as you have always used. Please clear the immediate area when exposing the sensor to x-rays.

Infection Control

- Disinfect the image sensor before its first use and whenever there is a risk of contamination.
- Always use a new disposable sheath to cover the sensor head and distal end of the cable to keep these areas clean and minimize the risk of cross-contamination between patients.
- Discard used disposables after use.
- After use, disinfect the sensor head and nearby cable before using on a new patient.
- Follow the provided instructions on disinfecting the universal positioning arm, ring and sensor holders.

Disposal

- The Tuxedo sensor hardware contains electronic components and should be recycled or disposed of following local or regional guidelines and regulations.
- Used disposable sheaths should be considered as biomedical waste and disposed of appropriately according to local guidelines on the handling of biomedical waste products.

Chapter 3: Software & Driver Installation

Recommended Computer System Specifications

- 32- and 64-bit Windows Vista®, Windows® 7, Windows® 8, Windows® 10, Windows Server® 2008 / 2008 R2, Windows Server® 2012, and Windows Server® 2016 operating systems, including Remote Desktop Services (formerly Terminal Services) and Citrix®.
- Intel multi-core processor 2.0 GHz or higher
- 2 GB of RAM or higher, 100GB or higher available hard drive space (depending on expected database growth)
- Powered USB 2.0 port(s) for USB capture support
- CD-R/DVD-R drive
- 1000 Mbps or higher Local Area Network (TCP/IP preferred)
- USB mouse, USB keyboard
- Video adapter and monitor with 1024 x 768 or higher resolution

Software Installation for Existing Users of Apteryx Imaging/XrayVision Software

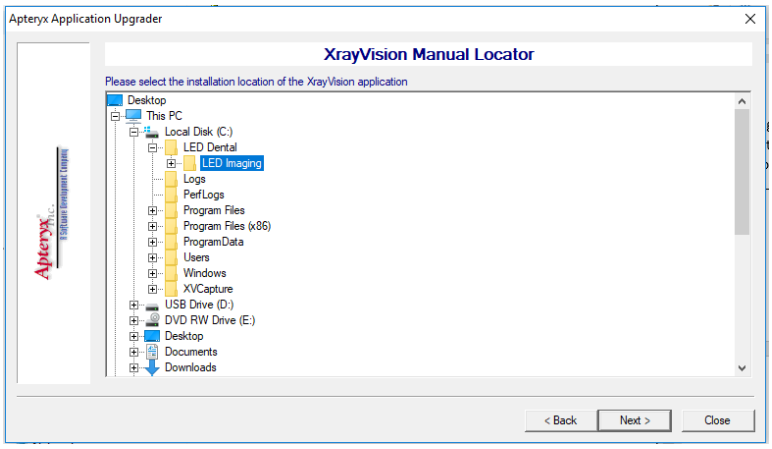
All necessary software required to operate the Tuxedo A-Series Intraoral Sensor is available on the USB drive supplied within the sensor package.

Step A: Tuxedo A-Series Driver Installation

1. Navigate to the Tuxedo A-Series Driver Folder and run the executable file.
2. Follow the on-screen prompts to install the drivers.

Step B: Tuxedo A-Series Plugin Installation

1. Navigate to the Tuxedo A-Series Plugin Folder and run the executable file.
2. Follow the on-screen prompts. If the installation directory of the Apteryx Imaging application is not detected automatically, you will be prompted to specify it manually by the *XrayVision Manual Locator*. If so, navigate to the Apteryx Imaging Folder/XrayVision Folder under Local Disk as shown for the default location in the example below.



NOTE: The latest Tuxedo A-Series Driver and Plug-in updates can be found under the "Imaging Devices" section on the Apteryx website, http://www.apteryx.com/apteryx-updates-site.

Software Installation Guide for New Users of Apteryx Imaging Software

All necessary software required to operate the Tuxedo A-Series Intraoral Sensor is available on the USB drive supplied within the sensor package.

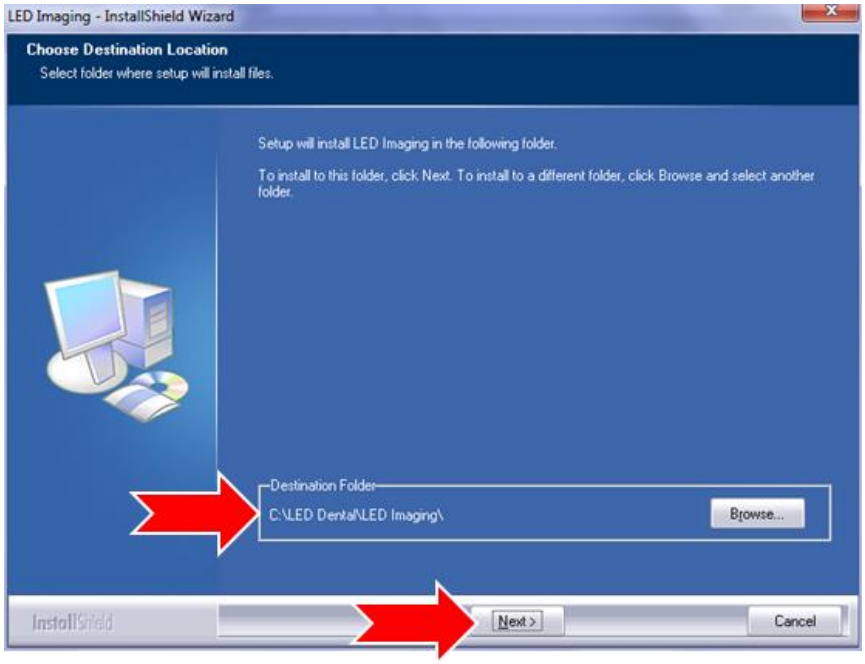
Step A: Tuxedo A-Series Driver Installation

1. Navigate to the Tuxedo A-Series Driver Folder and run the executable file.
2. Follow the on-screen prompts to install the drivers.

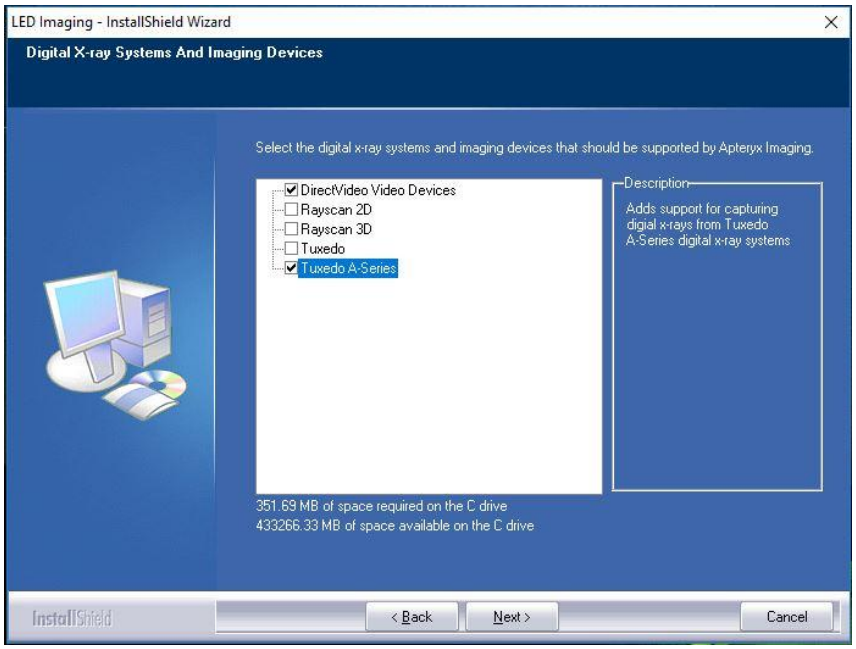
Step B: Apteryx Imaging Software Installation

If the sensor needs to be used on multiple workstations on a single network, it is highly recommended that the Apteryx Imaging Software be installed on a shared drive on the server. This allows for one installation yet use on multiple workstations. It should be noted that Step A must be done for each workstation and each workstation will require its own license.

1. Navigate to the Apteryx Imaging Software Installer Folder and run the installer executable file.
2. When you arrive at the *Choose Destination Location* prompt, if you are using a single workstation, simply select Next. If you are using multiple workstations on a single network, set the Destination Folder to a location that will be accessible from all required workstations using the Browse button before selecting Next.



3. Please note that the recommended configuration options are selected by default. However, when you arrive at the *Digital X-ray Systems and Imaging Devices* prompt, select Tuxedo A-Series as shown below.

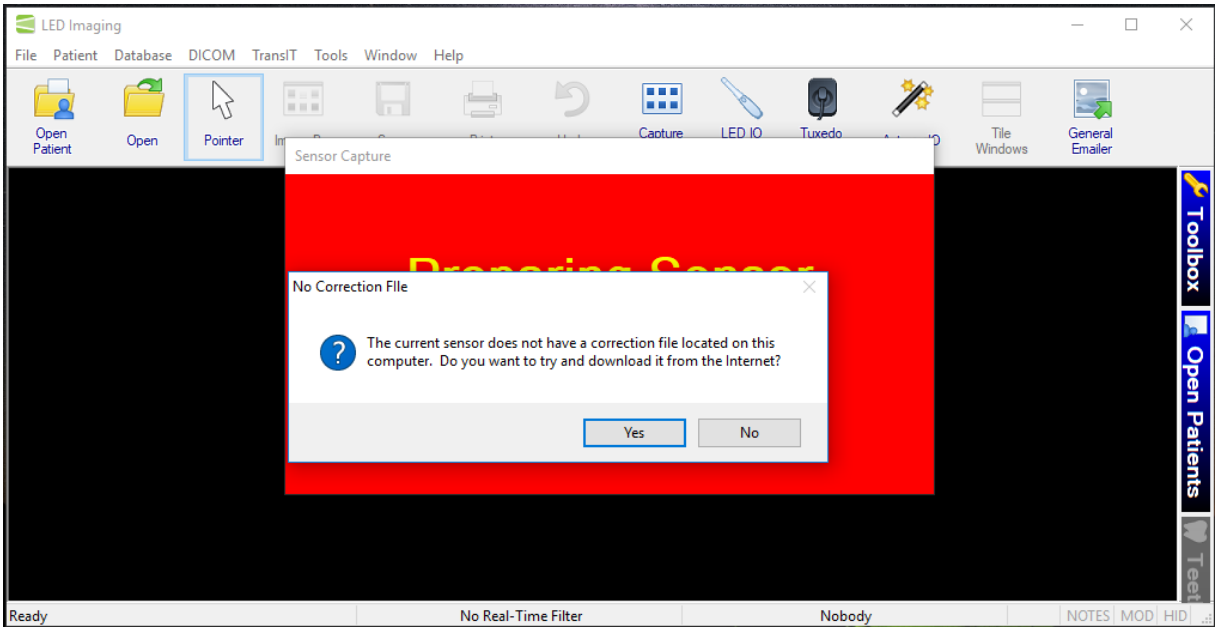


4. Once the installation has completed, the Apteryx Imaging application can be launched from the desktop shortcut or program menu.
    a. If installed on a server, to launch from another workstation, navigate to the Destination Folder for Apteryx Imaging selected in step 4 and find the Apteryx Imaging application file.
    b. You may find it helpful to create a shortcut for this application on the various workstations on the network.
5. Instructions on setting up and registering the software can be found in Section 3 of the *Apteryx Imaging Software Installation Guide*. Details for setting up shortcut on multiple workstations are provided in Section 3.4.

NOTE: The latest Tuxedo A-Series Driver and Plug-in updates can be found under the “Imaging Devices” section on the Apteryx website, http://www.apteryx.com/apteryx-updates-site. Updates to the Apteryx Imaging Software can also be found on the same website under “XrayVision 4 and OEM versions”.

Sensor Calibration

It is recommended that the Tuxedo A-Series Intraoral Sensor be calibrated before use. When using the sensor for the first time a calibration file unique to your sensor is automatically retrieved and applied. You will see the following message:



Simply click 'Yes' and the calibration file will be stored in the Devices Folder in the Apteryx Imaging Folder in the installation directory selected in step 4 of the Apteryx Imaging Software Installation above.

Note: The option to manually calibrate the sensor is available. For more information on manually calibrating your sensor contact Apteryx Technical Support at (877) APTERYX.

Chapter 4: Apteryx Imaging Software

An extensive user manual is available online at the http://www.apteryx.com/edocs. See *XV_UserManual.PDF.*

For troubleshooting tips and answers to frequently asked questions, search the knowledgebase online at http://www.apteryx.com/knowledgebase.

If desired, training is also available through Apteryx Technical Support at (877) APTERYX.

Chapter 5: Using the Tuxedo Intraoral Sensor

Preparing the Sensor

- Before connecting the sensor to the Windows PC, check that the USB connector is clean and not wet or dirty.
- Plug the sensor into the USB 2.0 port on the Windows PC. Connect and disconnect the USB connector by holding the connector body with your fingers. Do remove or try to insert the USB connector by holding on to the cable as doing so can damage the wiring inside the cable.

- Carefully place the sensor and the length of cable that comes into contact with the patient in a disposable protective barrier sheath. The barrier sheath is designed for single use and should be disposed of and replaced between patients.
- Remove the protective cover and wrap the protection sheath as shown below. Double check the protection sheath integrity before proceeding. If the protective sheath is compromised, discard and replace it with a new one.

- Insert the detector end of the sensor into the desired positioning device.

Preparing the Software

- Enter Apteryx Imaging Software via a bridge from a practice management software or by opening Apteryx Imaging Software as a standalone program.
- Create a New Patient or open an existing patient within Apteryx Imaging Software.
- Click on ***File > Acquire*** and choose the desired acquisition method from the submenu:
    - Capture Sensor Image (*for acquiring a single image*)
    - Capture Layout Image (*for acquiring multiple images in a desired display layout*)

Radiographic Image Acquisition

- Position the sensor and positioning device into the patient's mouth, with the active surface of the sensor behind and facing the anatomy that is to be imaged.
- Set the positioning ring that accompanies that position device as close to the patient face as possible.

- Using an approved intraoral x-ray generator, place the cone of the x-ray generator in line with the aiming bar and ring that is attached to the positioning device.
- Set the exposure parameters appropriately on the x-ray generator, based on the manufacturer's recommendations for the anatomical region that is being radiated.
    - The x-ray generator may require routine inspection to ensure that the output of the x-ray generator is within the manufacturer's recommended tolerance. This may be validated with a calibrated kV meter.
- Press and hold the exposure button of the x-ray generator. Release once the radiation emission is complete.
- The intraoral radiograph should appear on the computer screen within 5 seconds.

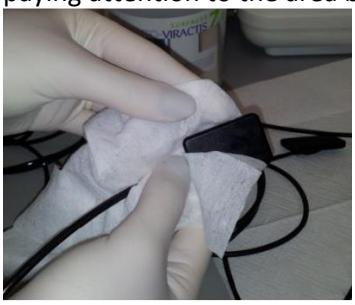
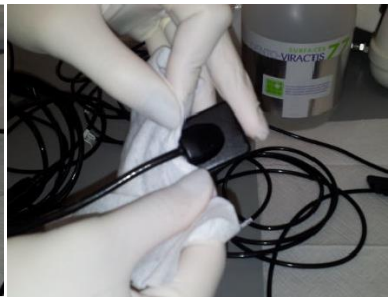
Post Image Capture

- Images are automatically saved once they are acquired, but modifications of the image may be saved or discarded.
- Remove and disinfect the positioning device per the manufacturer's recommendations.
- Remove and discard the barrier sheath.
  After use, the sensor head and the first 10cm of the cable near the sensor head should be disinfected using a sterile compress and recommended hospital-grade surface disinfectant. Additional immersion disinfection is possible if there are no nicks to the sensor's head.
- Unplug the sensor from the Windows PC. The sensor should be disconnected when not in use and stored in a safe place to protect from damage caused by striking or static electric shock.

Detailed Steps for Cleaning and Disinfection

- A single-use disposable hygienic barrier sheath should be used to cover the sensor whenever the sensor is in use. The following hygienic sheath is recommended for use with the Tuxedo Intraoral sensor:
    - TIDIShield® Digital X-Ray Sensor Sheaths or equivalent
- The following surface disinfectants have been found to be effective in achieving a desired level of disinfection and is available from most dental equipment suppliers.
    - <u>Preferred Disinfectants:</u>
        - ANIOXY TWIN™ (ANIOS Laboratories)
        - PHAGOCIDE D™ (PHAGOGENE DEC. Laboratories)
    - <u>Other Authorized Disinfectants:</u>
        - CIDEX OPA™ (JOHNSON & JOHNSON)
        - DENTASEPT ultra™ (ANIOS Laboratories)
        - RELYON PERASAFE™ (PHAGOGENE DEC. Laboratories)
    - <u>Forbidden Products, Do not use:</u>
        - ALCOHOLS (Isopropyl Alcohol, Methanol)
        - SEKUSID-N™ (ECOLAB PARAGERM Laboratories)
        - SEKUSEPT Easy™ or Aktiv™ (ECOLAB PARAGERM Laboratories)
        - FD333™ or FD322™ (DÜRR DENTAL Laboratories)

- In a clinical use environment, the health care provider should wear protective disposable gloves and cover the sensor with a hygienic barrier. Before using the sensor the first time, and before every new patient, the following protocol is recommended:
    1. Remove and discard all protective hygienic barriers and / or sheaths from the Sensor prior to removing disposable gloves.
    2. Place the Sensor on a tray covered by a disposable liner, or in a receptacle that can be thoroughly disinfected.
    3. Remove and discard gloves.
    4. Wash hands and put on a new pair of disposable gloves.
    5. If the Sensor or cable are visibly soiled (e.g., with blood or saliva), each should be cleaned with a soapy cloth or paper towel, and then dried with a clean lint-free cloth or paper towel.
    6. Thoroughly wipe the Sensor and cable with the disinfecting product recommended above. Do not expose the contacts of the sensor/ USB connection to liquid. If deemed necessary and there are no nicks to the sensor head, perform immersion disinfection.
        a. Wiping Disinfection Instructions:
            i. Apply disinfecting solution on a sterile compress.
            ii. With the sterile compress, completely wipe the sensor's head paying attention to the area between the cable and the sensor shell.

            iii. Wipe the first 10cm of the sensor cable with the sterile compress.
            iv. Observe other possible recommendations provided by the manufacturer of the disinfecting solution.

        b. Immersion Disinfection Instructions
            i. Prepare the solution based on the manufacturer's recommendation. Respect the accurate titration.
            ii. Immerse the sensor head according to the manufacturer's recommendation. Do not immerse the connector.
            iii. Observe other possible recommendations provided by the manufacturer of the disinfecting solution.


7. Remove potential chemical build-up from the Sensor by wiping it with a sterile lap sponge saturated with de-ionized water.
8. Use a sterile dry lap sponge to dry the Sensor or cable, as needed.
9. Place the Sensor in a clean environment, ready for next use.

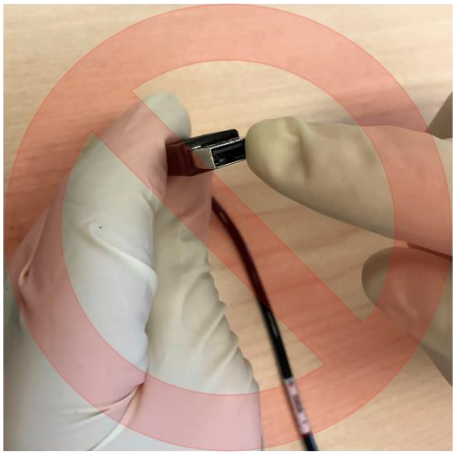
Sensor Cleaning, Disinfection & Storage Precautions

- Disinfect the image sensor before its first use and whenever there is a risk of contamination. It is recommended to disinfect the sensor after each use even with the use of a disposable sheath.
- Do not expose the device to any unspecified liquid.
- Do not sterilize this product (autoclave, dry heat, UV, or otherwise)
- Keep the product away from direct sunlight, dust, or corrosive gases such as chlorine or fluorine, etc.
- Do not apply pressure on the product during storage.

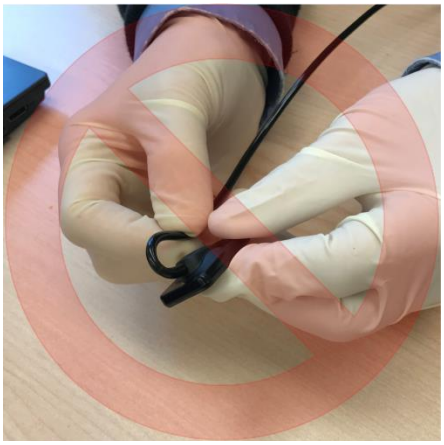
General Sensor Handling Precautions

- To handle the sensor safely always:
    - Keep the patient in your field of view when the sensor is in the patient's mouth.
    - Manipulate the sensor with a high degree of care.
    - Ensure that the cable is not tangled when in use.
    - Coil the cable in large loops when moving it from place to place or to prevent from touching the floor.

- This device is sensitive to static electricity; refrain from touching the pins inside the USB connector.



- Do not twist, bend, pull or pinch the cable using excessive force; these actions can cause damage to the cable.



- Although the Tuxedo sensor has a built-in shock absorbing system, always use care in handling the sensor, and avoid dropping or otherwise exposing it to excessive mechanical shock. Avoid using any tools (e.g. pliers) that might exert excessive pressure on the sensor body, cable or USB connector.

- USB cable extensions are not recommended. If an extension is required, a USB hub with an external power supply or USB active repeater cable is required.

Chapter 6: Quality Assurance Program for Digital X-ray Sensors

The purpose of this quality assurance program is to recommend to the user the steps for maintaining the continued proper functioning of the Tuxedo Intraoral Sensor hardware and software.

Requirements for the Quality Assurance Program

Personnel Qualifications:

- For cleaning and disinfection: A trained dental technician.
- For calibration or annual image evaluation: A trained dental technician experienced in the acquisition intraoral radiographs.

The program consists of four main components:

1. Periodic Visual Inspection
2. Periodic Cleaning and Disinfection (between each patient)
3. Periodic Calibration
4. Periodic Evaluation of Image Quality

Quality Control Test and Frequency

Test Item	Frequency	Purpose
Visual Inspection • Check Cabling • Look for Physical Damage	Before use, each time the system is used	Confirms the connections of the cables to make sure the system is ready to operate
Cleaning and Disinfection	Between each patient, (see Chapter 5: Using the Tuxedo Intraoral Sensor)	Maintain Infection control and Image Quality
Calibration	Initial installation, when changing sensors, then periodically as required.	Maintain Image Quality
Image Evaluation	Annually (Recommend use of Radchex System)	Verify Continued Image Quality

Visual Inspection & Cleaning

Visual Inspection

- Objective: To confirm that the system is properly installed, that there is no defect or damage to the parts that are visible and that the system is ready to use.
- Frequency: Whenever the system is to be used.
- Equipment: Visual Inspection using suggested Report Form below
- Procedure: As per the suggested Report Form below

Cleaning

- Objective: Maintain infection control and image quality
- Frequency: Between each patient
- Equipment: See Chapter 5: Using the Tuxedo Intraoral Sensor
- Procedure: See Chapter 5: Using the Tuxedo Intraoral Sensor and report as in suggested form below

Visual Inspection & Cleaning Report Form
Installation Site Information: _____ Date: _____ Operator: _____ Sensor Serial #: _____
Check Cabling: Check and record result USB Cable: _____ Comment: _____
Visual Inspection: Check and record result as OK or describe the result and activity done Visual Inspection: _____
USB Test: Record result and Activity Done Result: _____ Error Message: _____ Activity Done: _____ Comment: _____
Cleaning and Disinfection _____check OK

Calibration and Image Evaluation

Calibration & Image Evaluation Record (Initial Installation and Annually)

Perform Calibration

X-ray Exposing Condition: _____

X-ray image: _____

Result: _____

Comment: _____

Annual Image Evaluation
(See for example DISC DR Radchex PLUS Instruction Manual)

X-ray Exposing Condition: _____

X-ray image: _____

Result: _____

Comment: _____

Chapter 7: Troubleshooting

Additional technical assistance can be found at http://www.apteryx.com/knowledgebase or by contacting Tuxedo Imaging Technical Support at 1-844-952-7327.

Description	Possible Cause	Corrective Action
Image from X-ray exposure does not have sufficient contrast.	Underexposure (too light).	Increase exposure time setting; or see Incomplete Exposure below.
	Overexposure (too dark).	Decrease exposure time setting.
Image from X-ray exposure is blur.	Combined movements of patient and operator during exposure produced too much distortion.	Check the exposure time setting and re-enable when operator and patient are again properly positioned.
Software does not detect Sensor.	Interference from various cause.	Re-connect Sensor.
	Sensor connected on front USB port of PC.	Connect sensor on back USB port of PC.
No Images.	Sensor not in path of X-ray source	Re-align in path of X-ray source to sensor.
	X-ray source not active while acquisition software was waiting to take Xray.	Re-align in path of X-ray source to sensor. Close the SID(Source to Imager Distance)
	Insufficient battery strength of X-ray source	Recharge the Battery
	Sensor connected on front USB port of PC.	Connect sensor on back USB port of PC.

Chapter 8: Specifications & Standards

Specifications:

Physical/Electrical	
Sensor Dimensions (mm)	Size 1: 36.8 x 24.4 x 11.5 (5.3) Size 2: 42.8 x 30.5 x 11.5 (5.6)
Sensor Array Size (mm)	Size 1: 19.95 x 30.02 Size 2: 25.99 x 36.00
Image Size (number of effective pixels)	Size 1: 1050 x 1580 Size 2: 1368 x 1896
Pixel Size (µm)	19 x 19
USB Cable length (m)	3
Interface	USB 2.0 High Speed mode
Electrical Rating	5V, 100mA max
Device Operating Temperature (°C)	Min: 5; Max: 40
X-ray	
Incident X-ray energy (kVp)	Min: 50; Typical: 70
Total Dose Irradiation (Gy)	Max: 20
Theoretical Resolution (lp/mm)	20
Saturation Level (µGy)	Min: 800; Typical: 850
Environmental	
Operating Temperature (°C)	Min: 5; Max: 35
Operating Relative Humidity (non-condensing)	Min: 5%; Max: 85%
Storage/Transport Temperature (°C)	Min: -40; Max: 70
Storage/Transport Relative Humidity (non-condensing)	Min: 10%; Max: 90%
Storage/Transport Ambient Pressure (kPa)	Min: 50; Max: 106
Ingress Protection Rating	IP67

Applicable Standards

- ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN 60601-1:2006/AC:2010 Medical Electrical Equipment – Part 1: General Requirements for Safety
- EN 60601-1-2:2007/AC:2010 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- EN 1041:2008 Information supplied by the manufacturer of medical devices
- ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

Chapter 9: Electromagnetic Compatibility

The Tuxedo sensor needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided herein.

Portable and mobile RF communications equipment can affect the Tuxedo sensor.

The Tuxedo sensor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Tuxedo sensor should be observed to verify normal operation in the configuration in which it will be used.

> **WARNING**: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Tuxedo sensor or shielding the location.

The EMC information in this chapter is provided for the medical system established by connecting the Tuxedo sensor to a computer. This computer must be compliant with IEC 60950-1 (if located outside the patient environment) or IEC 60601-1 (if located inside the patient environment). Please consult the documentation of the computer for complete EMC information.

The Tuxedo sensor is a USB compliant device and shall be used with USB compliant cables suitable for high speed/USB 2.0 cables. Such cables are either marked “USB 2.0” or “USB Hi-Speed.” USB certified hubs can be used to extend the distance to the USB host/computer. The length of the cable connection to the hub or between hubs shall not exceed 5 m.

> **Caution:** Using non-USB compliant cables or hubs, or exceeding the maximum count of USB hub devices for extending the distance, can degrade the immunity of the Tuxedo sensor to electromagnetic fields or increase the emission of electromagnetic fields from the sensor.

Guidance and manufacturer’s declaration – electromagnetic emissions		
The Tuxedo sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the Tuxedo sensor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Tuxedo sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Tuxedo sensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 60000-3-2	Class B (*)	
Voltage fluctuations/ flicker emissions IEC 60000-3-3	Complies (*)	

(*) Computer used with Tuxedo sensor must meet this rating

Guidance and manufacturer's declaration – electromagnetic immunity			
The Tuxedo sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the Tuxedo sensor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential Mode ±2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Tuxedo sensor requires continued operation during power mains interruptions, it is recommended that the Tuxedo sensor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The Tuxedo sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the Tuxedo sensor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Tuxedo sensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz	V1 = 3 V	$d = [3.5/V1]\ \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	E1 = 3 V/3	$d = [3.5/E1]\ \sqrt{P}$ 80 MHz to 800 MHz $d = [3.5/E1]\ \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Tuxedo sensor is used exceeds the applicable RF compliance level above, the Tuxedo sensor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Tuxedo sensor.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [$V1$] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Tuxedo sensor

The Tuxedo sensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Tuxedo sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Tuxedo sensor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = [3.5/V1]\sqrt{P}$	**80 MHz to 800 MHz** $d = [3.5/E1]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [3.5/E1]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where E1 is 3(V/m), V1 is 3 (V) and P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

This Class B digital apparatus complies with Canadian ICES-003.

RADIO AND TELEVISION INTERFERENCE

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and the receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

You may also find helpful the following booklet, prepared by the FCC: "How to Identify and Resolve Radio-TV Interference Problems." This booklet is available from the U.S. Government Printing Office, Washington D.C. 20402.

Changes and Modifications not expressly approved by the manufacturer or registrant of this equipment can void your authority to operate this equipment under Federal Communications Commission rules.