



CLEARVISION™ SENSOR

DIGITAL SENSOR SYSTEM



USER AND INSTALLATION GUIDE

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General Information

Indications for Use

ClearVision™ Sensor is intended to be used by dentists and other qualified professionals for producing diagnostic x-ray radiographs of dentition, jaws and other oral structures.

Contraindications

None known.

Warnings/Precautions

Radiation Safety

- Only qualified and authorized personnel may operate this equipment observing all laws and regulations concerning radiation protection.
- The operator at all times must remain at a safe distance from the focal spot and the X-ray beam for operator protection.
- Full use must be made of all radiation safety features on the X-ray equipment.
- Full use must be made of all radiation protection devices, accessories and procedures available to protect the patient and operator from X-ray radiation.

Electrical Safety

- The ClearVision™ Sensor cable should be handled with care. Do not sharply bend or crimp the sensor cable. Doing so could permanently damage the sensor.
- This equipment must only be used in rooms or areas that comply with all applicable laws and recommendations concerning electrical safety in rooms used for medical purposes, e.g., IEC, US National Electrical code, or VDE standards.
- Before cleaning or disinfecting, this equipment must always be disconnected from the electrical supply.
- The computer and any other associated equipment (like USB hub) shall be placed outside the patient's environment (i.e.: more than 1.5 meters away from the chair). The operator shall not access the patient and such devices at the same time.
- The computer and any other associated equipment shall be compliant with IEC 60950 or IEC 60601.

Patient Safety

- Prior to use **always** cover the sensor with a disposable hygienic protective cover. A new cover must be used for each patient. It is recommended to disinfect the sensor between uses.
- The ClearVision™ Sensor, Computer, and provided cables comprise a Medical Electrical System. The Computer is not intended to be located in the patient environment (within a 1.5 m radius of the patient).
- System installation shall be in accordance with the requirements of IEC 60601-1, the Standard for Safety Requirements of Medical Electrical Systems

Product Description

| | |
|--------------------------|--|
| | <p>ClearVision™ Sensor is a digital imaging system for dental radiographic application. The product is to be used for routine dental radiographic examinations. Two different sized sensors (size 1 and size 2) are utilized to image different anatomy and for different patient sizes. The CMOS sensor connects directly to a USB connection in a PC without the need for an intermediate electrical interface. ClearVision™ Sensor works with a standard dental intraoral x-ray source without any connection to the x-ray source. ClearVision™ Sensor captures an image automatically upon sensing the production of x-ray and after the x-ray is complete, transfers the image to an imaging software program on the PC. Disposable sheaths are used with each use to prevent cross-contamination between patients. ClearVision™ Sensor is a state of the art intraoral x-ray detector intended for digital imaging of teeth and the oral cavity. The components of the ClearVision™ Sensor system are the Digital Sensor, the Sensor Calibration Files and Progeny Imaging software.</p> |
| Digital Sensor | <p>The digital sensor is designed to transform a two dimensional X-ray picture into an electrical signal. The structure of the sensor is assembled with a first layer of phosphor material (scintillator) which, when exposed by incident X-rays, emits a luminous radiation. This light is then transferred to the photo sensitive elements of the Sensor where it is transformed to electrical potential. The electrical signal is sent to the computer for processing.</p> |
| Sensor Calibration Files | <p>During installation of the ClearVision™ Sensor system, files specific to the sensor serial number are stored on each computer where the sensor will be used. For more details, refer to the ClearVision™ Sensor Installation section of this manual.</p> |
| Progeny Imaging | <p>Provides the user interface to acquire, store, retrieve, transmit, review and post process images acquired by the ClearVision™ Sensor system. For more details refer to the ClearVision™ Sensor Installation section of this manual or the Progeny Imaging User Manual.</p> |
| NOTE | <p>The ClearVision™ Sensor digital sensor is sensitive to intense UV light. Therefore, the sensor should be stored in the box provided and never exposed to direct sunlight for extensive periods of time.</p> |

Explanation of Symbols on Technical Labels



Caution, consult accompanying documents



Refer to operating instructions



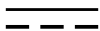
Class II equipment – provides double Isolation to protect against electric shock



Type BF – provides additional protection against electric shock

IP67

Degree of protection – IP67 means that sensor casting is :
totally protected against dust,
protected against the effect of immersion between 15 cm and 1 m.



Direct current



Serial number



Catalogue number



Date of manufacture




Place of manufacture (manufacturer)

Compliance with Applicable Standards

The following regulatory documents apply:

| | |
|----------------------|--|
| General Safety | <p>IEC 60601-1:1995</p> <p>Protection against electrical shock – Class II</p> <p>Degree of protection against electrical shock – Type BF Applied Part</p> <p>Degree of protection against ingress of water – IP67</p> <p>Not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.</p> |
| EMI/EMC | <p>IEC 60601-1-2:2007</p> |
| Degree of Protection | <p>IEC 60529: 2001</p> <p>Degree of protection against ingress of water – IP67</p> |
| Imaging Performance | <p>IEC 61223-3-4:2002</p> <p>Line pair resolution – better than 8 lp/mm</p> <p>Low contrast resolution – all holes visible</p> |
| EMC Statement | <p>Information regarding potential EMC interference and advice for avoidance</p> <ul style="list-style-type: none">• The ClearVision™ Sensor is considered as non-life-supporting equipment. While using ClearVision™ Sensor sensors adjacent to other equipment, configuration should be carefully adjusted to ensure that electromagnetic interference (EMI) does not degrade performance. Specifically, mobile RF communications equipment can effect medical electrical equipment. Please refer to the EMC table below.• Usage limitation: ClearVision™ Sensor shall be used with IEC 60950 or IEC 60601 compliant computer. Also, any device between ClearVision™ Sensor and the computer (USB Hub) shall be compliant with IEC 60950 or IEC 60601. If not, this may result in degraded electromagnetic compatibility. |

| Guidance and manufacturer's declaration - electromagnetic emissions | | | |
|---|---|--|---|
| The ClearVision™ Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the ClearVision™ Sensor should assure that it is used in such an environment. | | | |
| Emission test | Compliance | Electromagnetic environment – guidance | |
| RF emission CISPR 11 | Group 1 | The ClearVision™ 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 emission CISPR 11 | Class B | | |
| Harmonic emission IEC 61000-3-2 | Not Applicable | | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not Applicable | | |
| Guidance and manufacturer's declaration - electromagnetic immunity | | | |
| The ClearVision™ Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the ClearVision™ 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 the 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 transient/ burst supply lines typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | Not Applicable. | |
| Voltage dips, 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. | |
| 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 ClearVision™ Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the ClearVision™ 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 ClearVision™ Sensor equipment, 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 | 3 V | $d = 1.2 \times \sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | $d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5 GHz |
| | | | Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture and d is the recommended separation distance in meters (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 ClearVision™ Sensor is used exceeds the applicable RF compliance level above, the ClearVision™ Sensor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ClearVision™ Sensor. | | | |
| ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m. | | | |

| Recommended separation distances between portable and mobile RF communications equipment and ClearVision™ Sensor | | | |
|---|--|--|--|
| The ClearVision™ Sensor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 $d = 1.2 \times \sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2 \times \sqrt{P}$ | 80 MHz to 2.5 GHz $d = 2.3 \times \sqrt{P}$ |
| 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 meters (m) can be determined using the equation applicable to the frequency of the transmitter, where 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. | | | |

Obtaining Technical Support

Contact

Midmark Corporation
1001 Asbury Drive
Buffalo Grove, IL 60089

Phone: 1-800-MIDMARK (US only); 1-844-856-1231 (direct)

its@midmark.com

To facilitate your service call, the following information should be ready and available:

- Computer operating system
- Version of Progeny Imaging software
- Serial number of your sensor
- Type of Progeny Imaging installation (standalone, peer-to-peer network, client-server network)

NOTE: It is recommended that the installing technician review the complete instructions before attempting to install or upgrade any component

Authorized Representatives

Europe

CE Partner 4U
Esdoornlaah 13
3951DB Maarn
The Netherlands
Phone: +31 (343) 442-524
Fax: +31 (343) 442-162

Installation

Overview

The ClearVision™ Sensor System is an intraoral digital sensor used with an intraoral X-Ray generator to capture digital images of dentition and the surrounding skeletal structures. The Sensor is available in two configurations:

- Standalone – Sensor, connected directly to a PC
- Integrated – Integrated into and part of the Preva Plus system or provided separately and connected to Preva 2.0.

Before You Begin

Computer and Software

You must have a dedicated Computer with a 32-bit or 64-bit Windows operating system and have at least one **High-speed** USB port available. The computer requirements are listed in Table 1.

Image capture and management software must be installed on all computers that will host the ClearVision™ Sensor. The performance of that software is affected by the amount of RAM and storage memory available to the system for acquisition, displaying, storing, and printing digital X-Ray images. The recommended requirements are listed as a guideline only.

NOTE: Be aware that the patient volume, and the specific demands of your practice, may require adjusting these guidelines accordingly. The system requirements of other programs operating on the same computer or network may affect these guidelines as well.

Table 1: Recommended System Requirements

| Component | Requirement |
|-----------------------|---|
| Computer Hardware | PC - compatible Pentium 4 / 1.4 GHz or greater computer |
| Memory System | 2 GB RAM or higher recommended (minimum 1 GB) |
| Operating System | Microsoft Windows XP Professional with Service Pack 3; Microsoft Vista (Business or Ultimate editions); Microsoft Windows 7 (Professional or Ultimate editions) |
| Disk Space | 450 MB minimum NOTE: Additional disk space is needed depending on the size of the practice, the number of images, and other information you plan to store. Each image is approximately 4 MB. For example, approximately 300 GB are needed to store 75 000 images. |
| Display Settings | 1024 x 768 (16 - bit or higher) with 32 MB (or higher) of Video RAM NOTE: It is possible to increase these settings based on the actual video adapter installed. As a rule, the better your video adapter or capture card the better your images. |
| | <p>Midmark requires the use of Progeny Imaging or Progeny Imaging Twain software. It must be installed on every computer that will interface with the Sensor. If you are not intending to use Progeny Imaging, then compatible image capture and management software must be installed on all computers to be used. This software may support direct integration with ClearVision™ Sensor (direct integration) or may use TWAIN interface.</p> <p>For installation and use of Progeny Imaging software, refer to the Progeny Imaging Installation Manual, or contact Technical Support.</p> <p>For installation and use of third party software that supports direct integration, refer to that software installation and user manuals.</p> |
| Check System Contents | Verify that all items listed on the Packing List are contained in your system order. If any item appears to be missing, contact Technical Support immediately. For guidance refer to Figure 1. |
| Tools Required | No tools are required to install ClearVision™ Sensor System. |

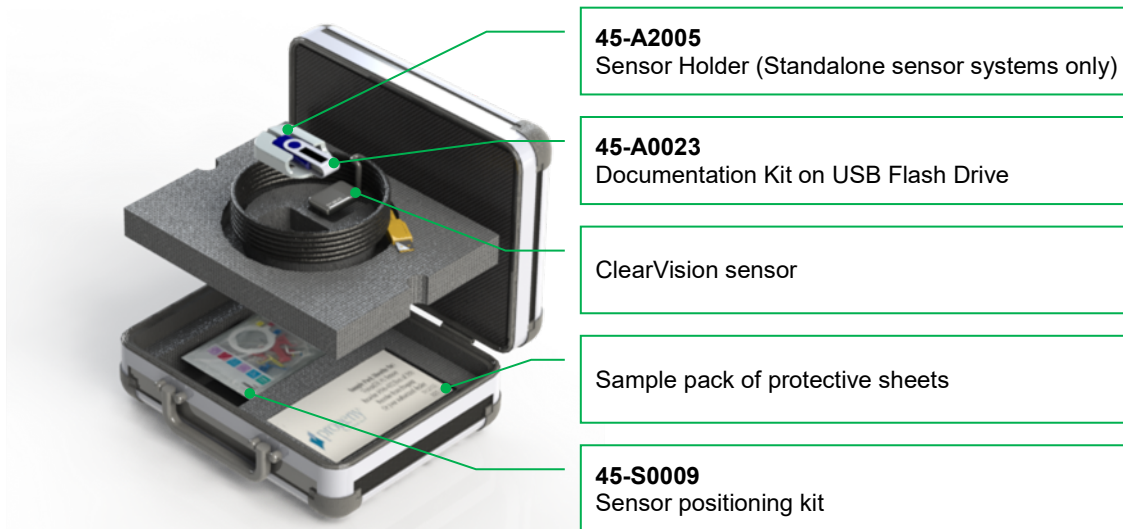


Figure 1: Contents of ClearVision™ Sensor System

Installation Procedure

Installing
together with
Progeny
Imaging
Software

When installing the ClearVision™ Sensor drivers and associated software, it is assumed that previous versions of the Progeny Device Suite and Progeny Imaging image management software are not present.

NOTE: Proper operation requires any previous version of Progeny Device Suite and Progeny Imaging to be removed (uninstalled) prior to the installation process to begin.

Execute the following steps:

- Insert the USB Flash Drive into an available USB port on your computer and allow the computer to recognize the flash drive.
- The main screen of the installation software is shown on Figure 2. If the software on the USB flash drive does not start automatically, navigate to Windows Explorer™ and select the “Progeny” drive letter. Browse to the content of the flash drive and start “Setup.exe”. This step begins the installation process.

NOTE: The installation software requires Microsoft .NET Framework revision 3.5. This software will be installed if it is not yet present to the operating system. Follow all on screen prompts.

NOTE: If the intended configuration is based on Windows XP, the Service Pack 3 update is required. This update is included on the USB flash drive and can be installed from folder named ‘Utilities’. Another option is to use the Windows update tool provided by Microsoft.

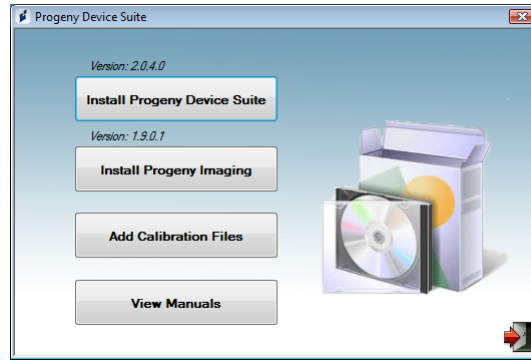


Figure 2: Main screen of the Installation software

- Start the installation process by clicking on 'Install Progeny Device Suite' button (Figure 3).

NOTE: The installed software requires multiple software components that may already be available in your system. These components will be installed if they are not yet present. Follow all on screen prompts.

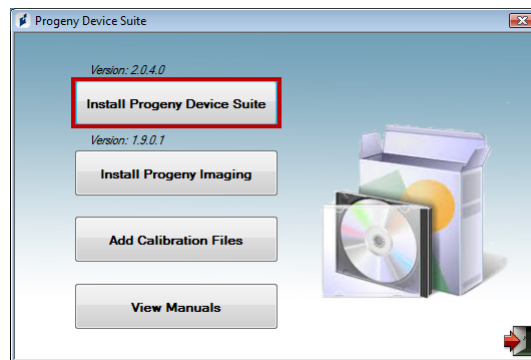


Figure 3: Starting the Progeny Device Suite installation

- The screen on Figure 4 will be displayed. Choose ClearVision and all other device families that have to be supported by the Imaging Software.

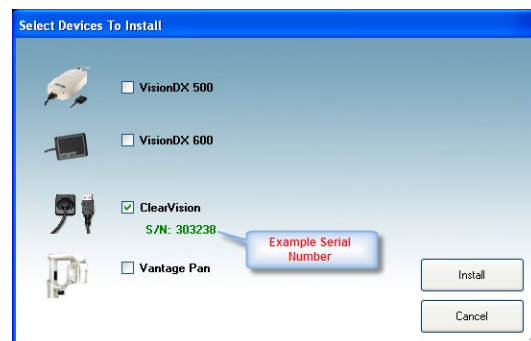


Figure 4: Selecting the device families to be installed

- The dialog box shown on Figure 5 may appear when Progeny Device Suite is installed in Windows Vista and Windows 7 environments. Select 'Always trust software from Midmark' check box and click on the Install button.

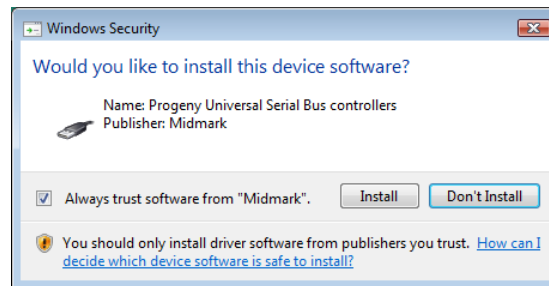


Figure 5: Enable Midmark software installation

- A green check mark next to the 'Install Progeny Device Suite' button will appear when Progeny Device Suite installation is completed. Continue by installing Progeny Imaging software by clicking on 'Install Progeny Imaging' button (Figure 6) and follow the prompts on the screen to perform the installation.



Figure 6: Starting the Progeny Imaging installation

- Green check marks next to each of the 'Install Progeny Device Suite' and 'Install Progeny Device Suite' buttons will appear when both the Progeny Device Suite and Progeny Imaging are installed (Figure 7).



Figure 7: Progeny Device Suite and Progeny Imaging are installed

Installing Sensor Calibration Files

The ClearVision™ Sensor requires a calibration file to be installed for each device to operate correctly. This calibration file is unique for each sensor and it is provided on the USB flash drive.

NOTE: The USB flash drive contains the unique sensor calibration file, the operation instructions and the sensor support software. Do not discard or reuse. Save and store the USB flash in a convenient location to allow future references to its content.

The calibration files for the ClearVision™ Sensor are installed during the Progeny Device Suite installation from the provided USB flash drive. No additional installation is needed if only one sensor will be used in the installed configuration and the sensor support software was installed from the provided USB flash drive.

Install the sensor calibration file by executing the following steps, if more than one sensor is needed, or if the current sensor is installed after the support software is installed, or if you are uncertain whether the sensor calibration file was installed.

- Insert the USB flash drive that came with the ClearVision™ Sensor into an available USB port on your computer and allow the computer to recognize the flash drive.
- The main screen of the calibration file installation is shown on Figure 8. If the software on the USB flash drive does not start automatically, navigate to Windows Explorer™ and select the drive letter labeled “Progeny”. Browse to the content of the flash drive and start “Setup.exe”. This step begins the installation process.

NOTE: Do not run the Progeny Device Suite installation as that software is now installed.

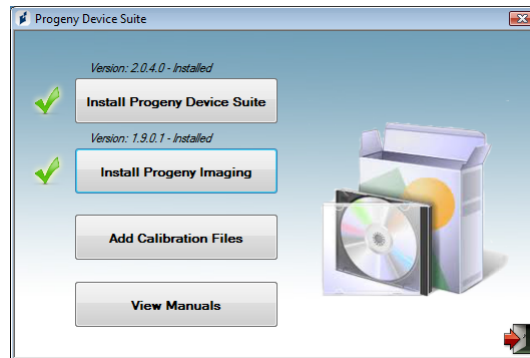


Figure 8: Main screen of the calibration file installation

- To add the calibration file onto your computer click on the “Add Calibration Files” button (Figure 9).

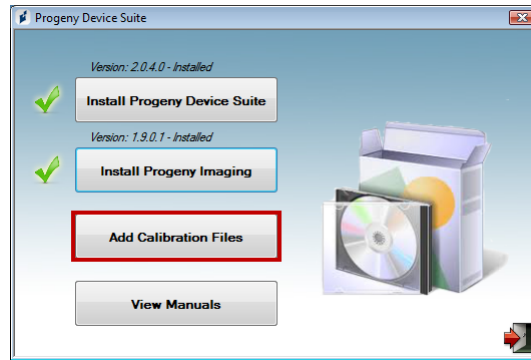


Figure 9: Calibration file installation

- The dialog box shown on Figure 10 will appear to allow selection of the calibration file(s) source folder. The initial selection will point to the source folder on the current USB flash drive. Navigate to the calibration file source folder if needed and click on the 'OK' button to continue.

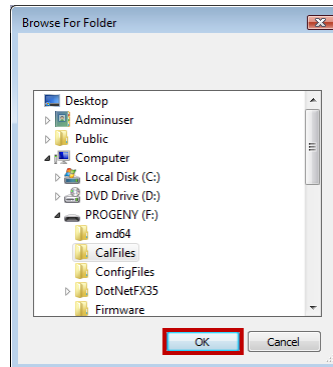


Figure 10: Select the source folder for the calibration file

- A green check mark next to the 'Add Calibration Files' button will appear when the calibration files are installed (Figure 11). Exit from the installation by clicking on the 'Exit door' icon as highlighted on Figure 11.

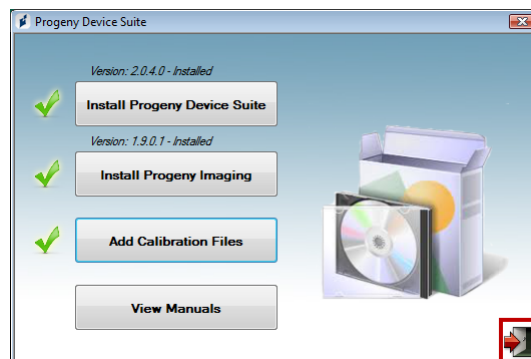


Figure 11: Calibration files are installed

**Sensor
Installation**

If a Standalone version is installed, plug the sensor into an available High-speed USB port on the computer with installed sensor support software. Attach the Sensor Holder to a secure location near the computer and use it as a sensor storage location.

If an Integrated version is installed, plug the sensor in the USB port available at the end of the Articulated Arm, near to the tube-head. Verify also that the USB hub embedded in the integrated system is connected with the provided cable to a High-speed USB port of the computer that contains the sensor support software. That connection has to be present for the Sensor to be operational. Attach the Sensor Holder to Articulated Arm near to the tube-head if it is provided separately. Use the Sensor Holder as a sensor storage location.

A Windows device driver installation message will be displayed when the sensor is connected to an USB port for the first time.

NOTE: A Windows device driver installation message will be displayed every time when the sensor is connected to a new USB port for the first time.

No additional interaction is needed when the ClearVision™ Sensor is used in a Windows Vista and Windows 7 environment. If the ClearVision™ Sensor is used in a Windows XP environment, an installation device wizard may appear (Figure 12). Follow the steps bellow to complete the installation.

- Select 'Yes, this time only' from the dialog box and press the 'Next' button (Figure 12).



Figure 12: Found New Hardware Wizard in Windows XP (first screen)

- Select 'Install the software automatically' and continue by pressing the 'Next' button (Figure 13). Follow the wizard instructions and prompts to complete the drive installation.



Figure 13: Found New Hardware Wizard in Windows XP (second screen)

The ClearVision™ Sensor could be used once Progeny Imaging software is started as it is described in Progeny Imaging Installation Manual. To select the ClearVision™ Sensor use the ‘Device Control Toolbar’ by following the steps below.

- Select ClearVision as shown on Figure 14.

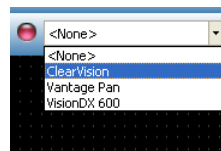


Figure 14: Selecting ClearVision™ Sensor in Progeny Imaging

- Once ClearVision is selected you will see a green LED (Figure 15). This verifies the sensor is now connected to the computer.

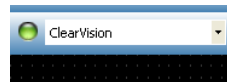


Figure 15: Successful ClearVision™ Sensor selection

Select the “Device Status” (Indicator) to open the “Device Configuration” (Screen).

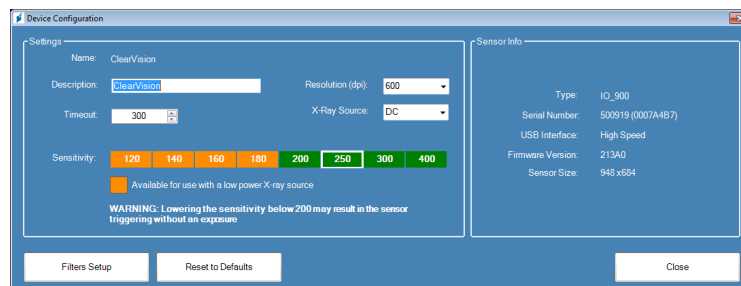


Figure 16: Device Configuration Screen

Settings options:

Name: This is the Sensor name that will appear in the Device Menu

| | |
|---------------------------|---|
| Description: | This allows user to enter more information about the Sensor. |
| Timeout: | <p>This option allows the user to adjust the length of the timeout period (in seconds).</p> <p>If image is not taken within the timeout period, the sensor returns to “unarmed” state.</p> |
| Resolution (dpi): | This option allows the user to set the image resolution |
| X-Ray Source: | This option allows the user to change the X-ray source (AC or DC). |
| Sensitivity: | <p>This option allows the users to adjust the “Trigger Level” (sensitivity) of the Sensor.</p> <p>The “Sensitivity” (Selector) is default to the setting of “250”.</p> <p>(Note: This setting is useful when acquiring images with a “Low Emitting” X-Ray Source, however, lowering the sensitivity below 200 may result in the sensor triggering without an exposure.)</p> |
| Sensor Info: | |
| Type: | Displays the Sensor type |
| Serial Number: | Displays the serial number |
| USB Interface: | Displays the USB Interface (High Speed) |
| Firmware Version: | Displays the firmware version |
| Sensor Size: | Displays the Sensor Size |
| Screen Buttons: | |
| Filters Setup: | This allows the user to configure the filter settings that is applied automatically to an image upon acquisition. |
| Reset to Defaults: | This allows the user to restore the “Device Configuration” (Window) to default factory settings |
| Close | This closes the “Device Configuration” (Screen) |

Operating the ClearVision™ Sensor

Acquiring Images

| | |
|--------------------|--|
| Prerequisites | <ul style="list-style-type: none">• Install the imaging software following the installation steps provided with the product.• Connect the ClearVision™ Sensor as described in this guide.• It is recommended to use the RINN DS-FIT sensor positioning device that is included in this package since that is the only positioning device that has been verified. Always follow the manufacturer's instructions for use and disinfection. |
| Connect the Sensor | <ol style="list-style-type: none">1. Connect the ClearVision™ Sensor to the computer (standalone configuration) or to the USB Interface connector on the Progeny Articulated Arm (in the case of the integrated system configuration). <p>NOTE: Always attach the sensor and the integrated system to an USB port that complies with the USB specification and supports High-speed transfer. Use only USB certified components that support High-speed transfer if an additional USB hub or USB cable is needed. Attaching the sensor to a different port or using different components and cables will degrade sensor performance. (Contact Midmark technical support or refer to the Service and Installation manual for further information).</p> |
| Taking images | <ol style="list-style-type: none">1. Refer to the specific imaging software manual for X-ray image acquisition. <p>NOTE: We recommend the use of Progeny Imaging image management software. Incompatible software will not allow sensor operation.</p> <ol style="list-style-type: none">2. Verify that the X-ray system exposure parameters are adequate for the desired examination.3. Insert the ClearVision™ Sensor into a sensor sheath and then position the sensor inside the patient's mouth in the desired position.4. Position the tube head of the X-ray system to the patient, using standard positioning procedures.5. Activate the ClearVision™ Sensor via the imaging software (refer to the software guide).6. Repeat steps 1-5 for additional images. |

Taking images using a “Low Emitting” X-Ray Source

1. Refer to your specific “Low Emitting” X-Ray Source manual for X-ray image acquisition settings.
2. Verify that the X-ray system exposure parameters are adequate for the desired examination.
3. Insert the ClearVision™ Sensor into a sensor sheath and then position the sensor inside the patient’s mouth in the desired position.
4. Position the X-ray system to the patient, using standard positioning procedures.
5. Activate the ClearVision™ Sensor via the imaging software (refer to the software guide).
6. Repeat steps 2-5 for additional images.

Note: See the Device Configuration Screen within the “Installation procedure” above to adjust the sensitivity (Trigger level) of the sensor.

Using the Sensor Sheaths

A sample pack of sanitary sheaths is included with your sensor. Sheaths are necessary to avoid patient cross contamination. Care must be exercised when placing sheaths on sensors or in positioning device. If you suspect the sheath integrity has been compromised, discard and do not use. The sheaths are not sterile and are intended as a single use item. Dispose of used sheaths appropriately.

To order more sheaths, contact Midmark or your Midmark dealer.

1. Follow the procedure below prior to every use of the sensor. Hold sheath and insert sensor into opening between the white tab and the paper.
2. Gently slide the sensor into the sheath until it reaches the tip of the sheath. Do not force it.
3. Peel back the protective cover.
4. Peel away the paper backing. The sensor is now protected and ready for normal use.



Figure 17: Using protective sensor sheath

5. After use, slide the sensor out of the sheath delicately using the thumb. DO NOT pull the cable while removing the protective sheath.

Using a Sensor Positioning Device

To facilitate correct positioning of the ClearVision™ Sensor in the patient's mouth it is **recommended** a positioning device be used. Refer to the manufacturer's manual for instructions for optimal usage.

Recommended Maintenance

ClearVision™ Sensor sensors do not require maintenance. Disinfection is recommended between every use.

Cleaning and Disinfecting

NOTE: Disinfection of the ClearVision™ Sensor is the sole responsibility of the user according to their practice protocol and the instructions, requirements, and limitations of the disinfecting agent being used, as per the manufacturer of the agent.

The ClearVision™ Sensor should be cleaned according to the following procedure:

1. The ClearVision™ Sensor and associated cables may be disinfected by wiping with a high level EPA registered hospital disinfectant as per manufacturer's directions.
2. Use personal protection equipment during the disinfecting process.
3. Disinfect the sensor and the first 10 centimeters of the sensor cable only, before first use, and before any new patient.
4. Use a new sanitary sheath for each patient. The sheath must be biocompatible following the standard ISO 10993-1. Sheaths provided by Midmark meet this standard.
5. Wipe the sensor surface (not the cable) with a gauze sponge moistened with a disinfecting solution.
6. Disinfection by immersion with a disinfecting solution is preferred. Follow the disinfectant manufacturers recommended immersion time, and other instructions.
7. The sensor cable can be soaked in a disinfecting solution as long as there is no mechanical damage to the sensor or the cable. If mechanical damage is recognized, consult with Midmark technical support before attempting to immerse the sensor or cable.
8. Dry the sensor before placement in the next sanitary barrier.
9. Important:
 - Do not immerse the USB connector in a disinfecting solution.
 - Do not clean the sensor or cable with abrasive tools.
 - Do not use disinfectants that contain bleach or alcohol.

Do not heat sterilize or autoclave the sensor as this will damage the electronics and enclosure, thus voiding the warranty.

Preferred disinfecting liquids:

- CIDEX OPA (trademark of Johnson and Johnson)
- DENTASEPT (trademark of Anios Laboratories)
- RELYON (trademark of Phagogene Dec. Laboratories)

Never use:

- Alcohols (Isopropyl Alcohol, Methanol)
- SEKUSID-N (trademark of Ecolab Paragerm Laboratories)
- SEKUSEPT Easy (trademark of Ecolab Paragerm Laboratories)
- FD333 (trademark of Durr Dental Laboratories)
- FD322 (trademark of Durr Dental Laboratories)

Specifications

X-Ray Sensor

| | |
|------------------------|--|
| Film Size equivalent | Size 1 (37 mm x 24 mm) Size 2 (43 mm x 30 mm) |
| Active Area | (Size 1) 600 mm ² (Size 2) 900 mm ² |
| Number of Pixels | 1.65 million Pixels (Size 1) 2.59 million Pixels (Size 2) |
| Pixel Size | 19 µm x 19 µm |
| Theoretical Resolution | 27 lp/mm |
| Dynamic Range | 72 dB |
| Sensor Cable | 3 m or 0.9 m |
| Connection type | High Speed USB |
| Power Supply | +5 V, per USB 2.0 specification |
| Level of Protection | IP67 (sensor only, per IEC 60529) |

Environmental










| | |
|-----------------------|--|
| Operating Temperature | between +5 °C and +35 °C (between +41 °F and +95 °F) |
| Storage Temperature | between -40 °C and +70 °C (between -40 °F and +158 °F) |
| Operating humidity | 5% to 85 % operating humidity |
| Storage humidity | 10% to 90% non-condensing, storage humidity |

Terms

| | |
|------------------------|---|
| Film Size Equivalent | The size of the X-ray sensor active area in relation to traditional film based X-ray systems available to the dentistry profession. |
| Active Area | The equivalent sensor area used to produce an image, measured in square millimeters (mm ²). The larger the number, the larger the active area. |
| Number of Pixels | The total number of pixels in the sensor active area. It has no unit value; however, a larger number results in a finer image. |
| Pixel Size | The size of the smallest discrete picture element used in the process of image acquisition, measured in micrometers (μm). The smaller the pixel size, the finer the image. |
| Theoretical Resolution | Measures the maximum level of detail that the sensor system is capable of acquiring, measured in line-pairs per millimeter (lp/mm). The larger the number, the finer the image. |
| Dynamic Range | Represents the largest output of the device as a ratio to the smallest output, measured in decibels (dB). A larger number shows a greater X-ray exposure range in which the X-ray sensor system can produce an image without degradation. |
| Sensor Cable | Identifies the type and length of the sensor cable. |
| Connection Type | Specifies the connection type used to attach the sensor system to the computer. |

Dose Information

The following table provides recommendations for typical loading factors at specified distances between the focal spot and the skin to achieve the nominal X-ray image receptor air kerma range (in mGy) needed for the intended use of the ClearVision Digital Sensor System.

| Setting | | 8-inch Cone (20 cm) | | 12-inch Cone (30 cm) | |
|---|-----|--|--|--|--|
| | | Adult  | Child  | Adult  | Child  |
| Incisor  | kV | 60 | 60 | 60 | 60 |
| | mA | 7 | 7 | 7 | 7 |
| | sec | 0.125 | 0.064 | 0.250 | 0.125 |
| | mGy | 1.202 | 0.616 | 2.405 | 1.202 |
| Bicuspid  | kV | 60 | 60 | 60 | 60 |
| | mA | 7 | 7 | 7 | 7 |
| | sec | 0.125 | 0.064 | 0.250 | 0.125 |
| | mGy | 1.202 | 0.616 | 2.405 | 1.202 |
| Bitewing  | kV | 60 | 60 | 60 | 60 |
| | mA | 7 | 7 | 7 | 7 |
| | sec | 0.160 | 0.080 | 0.320 | 0.160 |
| | mGy | 1.539 | 0.769 | 3.078 | 1.202 |
| Lower Molar  | kV | 60 | 60 | 60 | 60 |
| | mA | 7 | 7 | 7 | 7 |
| | sec | 0.160 | 0.080 | 0.320 | 0.160 |
| | mGy | 1.539 | 0.769 | 3.078 | 1.539 |
| Upper Molar  | kV | 60 | 60 | 60 | 60 |
| | mA | 7 | 7 | 7 | 7 |
| | sec | 0.200 | 0.100 | 0.400 | 0.200 |
| | mGy | 1.924 | 0.962 | 3.847 | 1.924 |

Warranty

A separate Warranty Registration form has been included with your system. Please complete and return it immediately to validate your warranty and receive technical support. **Midmark cannot offer technical support or assistance unless your product has been registered.**

Extended Warranty Options are available. For more details, contact Midmark or your dealer.

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Technical Library

www.midmark.com/technical-library