CADI Optimum AIR Sensor

Product Description

The CADI Optimum AIR sensor is a direct converting X-ray detector, which converts X-ray photons directly into digital image data. The CADI Optimum AIR sensor system supports wireless Bluetooth® 5.0 communications protocol and supports USB 2.0 connectivity to Personal Computers (PCs).

Intended Use

CADI Optimum AIR is intended to be used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw, and oral structures.

The CADI Optimum AIR sensor is a digital wireless sensor that is intended to acquire dental intraoral radiographic images. The CADI Optimum AIR sensor shall be operated by healthcare professionals, who are educated and competent in performing the acquisition of dental intraoral radiographs. The CADI Optimum AIR sensor is used in combination with special positioning devices to facilitate positioning and alignment with the X-ray beam.

CADI Optimum AIR is for use as prescribed by dentists, dental assistants, registered hygienists, or other qualified dental healthcare personnel trained in the use of the system.

CADI Optimum AIR is intended for use by the general population. Suitability of use of the CADI Optimum AIR is restricted by the anatomy and size of the patient's oral cavity. Professional judgement must be used to determine whether the sensor is suitable for use with a particular patient with minimum discomfort based on the anatomy and size of the patient, and the ability to position the sensor in the oral cavity with minimum discomfort.

Contraindications

This device is not designed, sold, or intended for use except as indicated. The user may not replace or remove any parts of the system. Only the provided USB cable and antenna are authorized for use with the system.

Safety Precautions

WARNING

Take the necessary steps to protect yourself from radiation. For proper operator positioning, refer to the 'Instructions for Use' of your intraoral X-ray equipment.

WARNING

Under no circumstances should the dental professional hold the sensor by hand during X-ray exposure.

Changes or modifications not expressly approved by the party

X-Ray Protection

The rules of dental radiography still apply to digital X-ray systems. Please continue to use protection for your patients. As a clinician, clear the immediate area when exposing the sensor.

Prevention of Cross-Contamination

To help prevent cross-contamination between patients, place a new hygienic sensor barrier on the sensor for each new patient. The hygienic barrier must cover the sensor.

Disposal Protocols

Dispose of sensor barriers and other consumable products following the normal dental office procedure for biomedical waste.

Sensor Inspection

Always inspect the sensor and positioning devices for physical damage prior to every use. Do not use the sensor if its housing has visible damage in the form of open cracks or punch through dents.

CLEANING AND DISINFECTION

When cleaning the CADI Optimum AIR sensor or the docking station, follow the cleaning and disinfection protocol described in this section.

Cleaning and Disinfection of CADI Optimum AIR Sensor

Only use the approved disinfectants with CADI Optimum AIR sensors. Using unapproved disinfectants may produce issues with the physical appearance of the product and potentially its operation.

The CADI Optimum AIR sensor should be thoroughly cleaned after each use. The following cleaning and disinfection recommendations are intended to accomplish intermediate-level disinfection and will prepare the product to be safely used and reused during its life.

Approved Disinfectants

The following surface disinfectants have been found to be effective in achieving an appropriate level of disinfection and are available from dental product dealers:

Trade name:	Manufacturer:
CaviWipes™ (original)	Metrex Research (distributed by Kerr Dental)
ADVANTACLEAR Surface Disinfectant	Wipes Hu-Friedy Manufacturing Co Inc
OPTIM® 1 Wipes	COLTENE SciCan
Opti-Cide3® Surface Wipes	Micro-Scientific
Isopropyl (70%)	Multiple

Cleaning and Disinfection Protocol

⚠️ CADI Optimum AIR sensor must be cleaned and disinfected after each patient.

⚠️ Always follow the instructions of the manufacturer of the cleaning and disinfecting wipe when disinfecting the CADI Optimum AIR sensor.

⚠️ **CAUTION** Do not submerge the CADI Optimum AIR sensor in any liquid at any time. Do not autoclave the CADI Optimum AIR sensor. Autoclave sterilizers will permanently damage the device.

The following procedure is recommended before using the sensor for the first time and after each patient:

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 is visibly soiled (e.g., with blood or saliva), clean the sensor with a soapy cloth or paper towel or using a recommended disinfectant wipe and dry it with a clean lint-free cloth or paper towel.
6. Thoroughly wipe the sensor (min. 30 seconds) with one of the disinfecting products recommended above. Make sure that all impurities are removed, and the sensor is thoroughly disinfected. Use multiple wipes, if needed.
7. Repeat step 6.
8. Place the sensor on the docking station to allow charging.
9. Store the sensor and/or the docking station in a clean environment for the next use.

Cleaning of CADI Optimum AIR Docking Station

The CADI Optimum AIR docking station is not intended to be moved or to come in contact with a patient during clinical use. Accordingly, it does not require routine cleaning. If the CADI Optimum AIR docking station becomes soiled or comes into contact with a patient, it should be cleaned using the cleaning agents recommended for the CADI Optimum AIR sensor recommended above.

Do not wipe or press against the clips that hold the sensor onto the Docking Station. Avoid cleaning the center of the dock to avoid damage to the clips and to avoid cleaning liquid leaking into the electronics causing damage.

	Do not submerge the CADI Optimum AIR docking station in any liquid at any time. Do not autoclave the CADI Optimum AIR docking station. Autoclave sterilizers will permanently damage the device.

Sensor Barriers and Sleeves

Sensor barriers and sleeves (sensor covers) are disposable, and they must not be reused in any circumstances. Remove and dispose of the cover after each patient.

Installation of CADI Optimum AIR Sensor

The instructions provided are limited to the installation of the CADI Optimum AIR intraoral dental x-ray sensor. This document does not provide detailed installation or operation instructions for imaging management software. The user must refer to the individual software manufacturer user documentation for all information specific to installing the application and its subsequent detailed operation.

<u>**ASSEMBLY OF THE CADI OPTIMUM AIR DOCKING STATION**</u>

Locate the CADI Optimum AIR Docking Station, antenna, and the USB cable provided.

Connect the USB cable to the Docking Station and screw in the antenna firmly.

Now connect the USB to the computer.

It is recommended to connect the cable to the back of the PC.

IMPORTANT: The CADI Optimum AIR Docking Station **SHOULD NOT** be moved around and stay connected on the PC it has been configured on.

The CADI Optimum AIR Docking Station when plugged in will flash blue two or three times before going dark.

When a CADI Optimum AIR Wireless Sensor is docked, it will then start to pulse blue indicating a charging status.

If a CADI Optimum AIR Wireless Sensor is placed onto the Docking Station before it is plugged into the computer, it will not start to pulse until the sensor is removed and then placed back on.

The CADI Optimum AIR Wireless Sensor should be docked for a continuous 1-hour to allow charging before first use.

PLACEMENT OF THE OPTIMUM-AIR DOCKING STATION

The signal strength between the Optimum-Air Wireless Sensor and the Optimum-Air Docking Station uses Bluetooth®.

It does not use the Wi-Fi network; however, it does use the same frequency (2.4 GHz). There are variables that can be controlled (or avoided) to reduce interference and help maintain the signal strength.

The Docking station should be placed on the countertop (if possible) in front of or to the side of the patient chair within 6-9 feet of the patient's head. The strength of the connection will be taxed if the Docking station is directly behind the patient's head. If behind is the only position available, entertain placement on the outmost part of the countertop furthest from directly behind the patient's head.

Having other wireless devices can also deter the signal. In the event there are other devices (wireless keyboards, mouse, etc.), it is encouraged that the respective receivers are placed on the opposite side of the desk whenever possible.

The docking station should also not be placed next to a sink or where it could get splashed or a trash bin where it can be fumbled and fall in.

INSTALL CADI OPTIMUM AIR TWAIN SOFTWARE

Use the provided Installation Package to install the drivers.
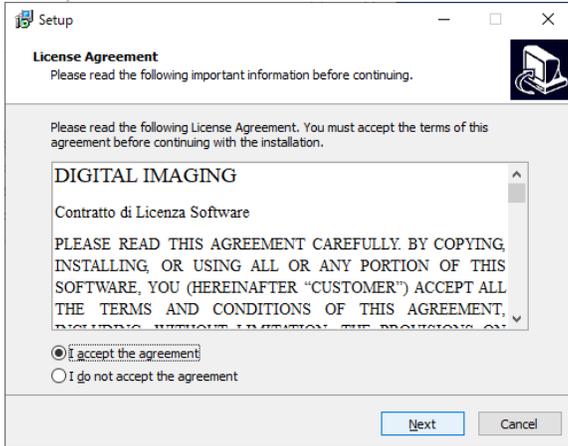
Put the dot in the "**I accept the agreement**" and then click "**Next**"
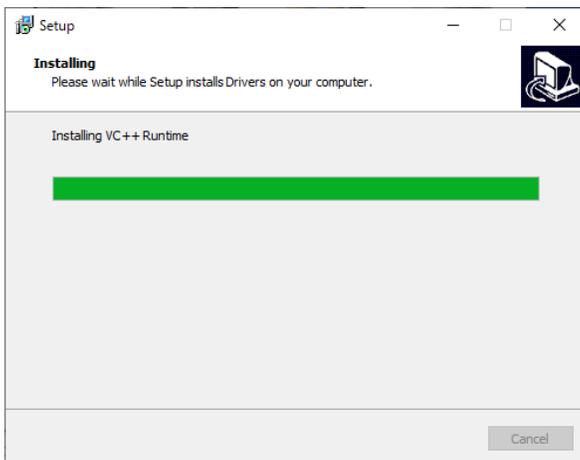
The installation window will appear and stuff will happen, just let it do its work.
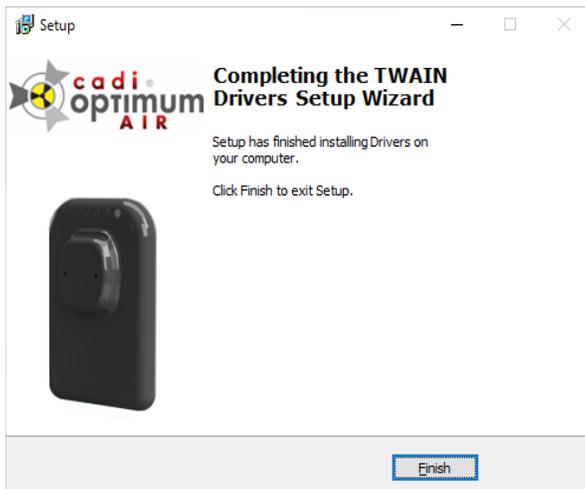
Click on "**Finish**" once the installation is done.

To bridge the CADI Optimum AIR™ sensor with your Image Management Software, refer to their directions to add the sensor and acquire x-ray images.

For assistance or information call CADI support.

Quick Start Guide to Use CADI Optimum AIR in CADI

Installation (might be done already)
You need to install the drivers for the CADI Optimum AIR in order for it to be recognized by Windows.

Simply run the AIR sensor installer package location in Device Drivers / Optimum Air

Testing
CADI Optimum AIR must be tested so that your exposure gives good results.

- Lay the sensor flat on a table (bump facing up)
- Place the x-ray head above it, just like when taking an x-ray.
- Set the exposure time on the x-ray head around .22 and do an exposure (Example 70kv, 6 or 7 ma head). Adjust the exposure accordingly to your settings.
- Once you've shot the sensor, get to the log file for the sensor located in the acquisition, under the item **MAINTENANCE**, choose "**View Sensor log**"
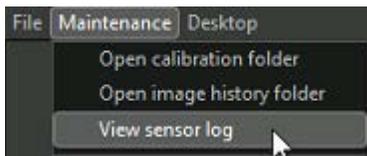
- (Or Windows Explorer, c:\CADI\Log\AthlosAir, open the newest file according with the date of the test)
- Look for the word MEDIAN in that log (Use F3 to search for the word). Check the date and time to make sure you are looking at the right one.


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HorizontalFlip]
[2023-11-24 11:14:08.631] [AthlosLog] [debug] Polynomial calibration: mean level = 678.61, median = 733,
[2023-11-24 11:14:08.681] [AthlosLog] [debug] ImageProcessor: Processing image 3 with filters [Calibratio
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- 900+ is good exposure for a self-test, 1100 is desirable though (average 0.25 seconds at 70kv)
- 600+ when using a handheld x-ray head, 800+ is desirable (.4-.7 seconds)

(In the example, the exposure is not high enough since it is a 733)

REMARK:
An image of a human should not be below 200, that is too low exposure or too much distance between the head and the client. Medians in 300 range is good, 400 range is better. Medians above 500 are at peak quality.

In order to calibrate the sensors, you must put them on the docking, one by one, and enter the capture mode in CADI, that will download the calibration to the PC. This must be done for EVERY sensor and EVERY PC that will be using it.

For assistance or information call CADI support.