DC-Air™ by FTG

Operator's Manual

Language: The original language of this manual is English.

CONTENTS

1 INTRODUCTION

1.1 About the DC-Air™

DC-Air™ is a wireless intraoral sensor that uses Bluetooth® 5.0 communication standards for reliable and rapid transmission of radiographic images. DC-Air™ is also the world's first intraoral X-ray sensor to utilize direct-conversion X-ray technology which converts X-ray photons directly into digital image data without scintillating photons into visible light. This process ensures the highest possible Modulation Transfer Function (MTF), a measure expressing true resolution and sharpness, that is natively achieved.

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1.2 Intended Use

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

1.2.1 Additional Information on Use of DC-Air™

DC-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.

DC-Air™ is intended for use for the general population. Suitability of use of the DC-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.

1.3 Contraindications

This device is not designed, sold, or intended for use except as indicated.

This device must be installed by a professional installer of an authorized dealer. 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.

1.3.1 Warnings, Cautions and Notes

Alerts the operator that failure to follow the procedure could cause damage to the equipment or loss of data.

Alerts the operator that failure to follow the procedure could result in bodily harm or death.

Alerts the operator of potential risks related to radiation exposure.

Informs the operator of proper instructions for device use or a process involving the device and components.

Informs operator of unusual or important point of device use or process.

1.4 Essential Performance

Essential performance of the DC-Air™ sensor system is to be able to generate an X-ray image of acceptable quality. The essential performance is dependent on the functionality and performance of the DC-Air™ intraoral sensor.

1.5 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 responsible for compliance of this device may void the user's authority to operate the equipment.

1.6 About This Manual

This manual describes the DC-Air™ Intraoral Sensor System. The revision number shown in this revision history table relates to the release level of this document.

Identifier:	Revision:
0000679	18 January 2022

1.6.1 Printed Copy of the Manual18.1.2022

A paper copy of this manual will be provided upon request (in the U.S.). Contact distributor of this product and request the English manual.

1.6.2 Conventions Used in This Manual

Service or service personnel refer to service personnel trained by Athlos, or a service provider trained and authorized by Athlos.

In this manual, DC-Air™ Intraoral Sensor model WIOS-S2 is referred to as DC-Air™ Intraoral Sensor or intraoral sensor or sensor.

In this manual, DC-Air™ Docking Station model WIOS-DS2 is referred to as DC-Air™ Docking Station or docking station.

When referring to different sections in this manual, section names are enclosed in double quotes.

Any illustrations appearing in this manual are provided as examples only.

2 PRODUCT OVERVIEW

2.1 Product Description

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

Wireless Interface Characteristics

Parameter:	**Description:**
Technology:	Bluetooth® 5.0 - Low Energy
Frequency:	2.4GHz: 2402 – 2480 MHz (Channels 0 – 39) | US, Canada, E.U, China, Japan, UK, South Korea
Modulation Technology:	Frequency – Hopping Spread Spectrum (FHSS)
Modulation Type:	Gaussian Frequency Shift Keying (GFSK)
Wireless Data Rates:	LE 1M PHY: 1Mbps or LE 2M PHY: 2Mbps
Security Protocols:	LE Security Manager
Effective Radiated Power	Sensor: < 0.5mW, Docking Station: < 3.5mW

Imaging Performance

The DC-Air™ sensor has an excellent MTF reproducing small object details with high accuracy and sharpness. The MTF is approximately 80 % at 2 lp/mm, 40 % at 10 lp/mm and 20 % at 16 lp/mm. The DQE of the DC-Air™ sensor at zero spatial frequency (which describes the efficiency of the use of X-rays) is between 5 and 10 % depending on the thickness and density of the material (teeth) to be imaged.

2.2 DC-Air™ Intraoral Sensor System

The DC-Air™ intraoral digital sensor system includes the DC-Air™ sensor (model: WIOS-S2), the DC-Air™ docking station (model: WIOS-DS2), and USB cable(s). See also the list of accessories at the back of this manual (“Appendix E: Accessories”) for additional accessories and kits.

2.2.1 DC-Air™ Sensor

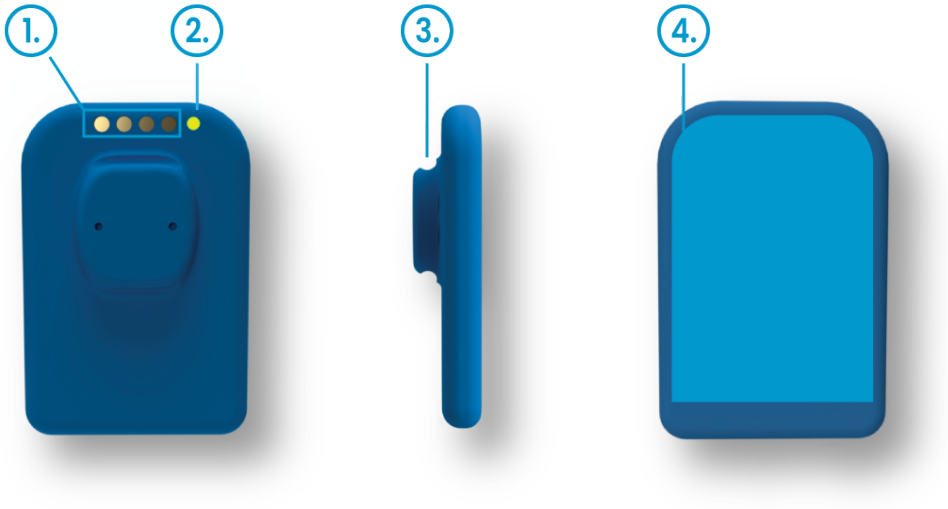


Figure 1: Back, side, and front view of the DC-Air™ Sensor. (1) Sensor's contact points, (2) sensor indicator light (green or yellow), (3) sensor connection hub, and (4) sensor active area (35.1 X 24.7 mm²)

Sensor Indicator Lights

The sensor indicator light (green or yellow) locates at the back of the sensor next to the sensor's contact points and above the battery compartment (see Figure 1, item (2) above).

Color:	Function:	Indication:
Green	Docked: Constant ON	Sensor ready for use.
Green	Docked: Flashing; Period 2s	Sensor charging.
Green	Un/Docked: Flashing; Non-specific interval	Data transfer (Bluetooth or USB).
Green	Undocked: Flashing; 1 x 50ms ON – 4s OFF	Sensor advertising. Sensor not ready.
Green	Undocked: Flashing; 2 x 50ms ON – 4s OFF	Sensor connected. Sensor ready.
Yellow	Docked: Flashing; Period 2s	Sensor Charging. Battery low.
Yellow	Undocked: Flashing; 1 x 50ms ON – 4s OFF	Sensor advertising, Battery low. Sensor not ready.
Yellow	Undocked: Flashing; 2 x 50ms ON – 4s OFF	Sensor connected. Battery low. Sensor ready.
Yellow	Un/Docked: Constant ON	Sensor error. Sensor not ready.
Yellow	Undocked: Flashing; Period Approx. 0.25s	Sensor error. Power Fault. Sensor not ready.
Yellow	Un/Docked: Flashing: Non-specific interval	Data transfer (Bluetooth or USB). Battery low.

Color:	Function:	Indication:
Green/ Yellow	Un/Docked: Flash; 2 x 0.1s Yellow & 2 x 0.1s Green	Sensor reset.
Green/ Yellow	Un/docked: Flash; 0.5s Green, 0.1s pause, 0.5s Yellow	Sensor bootloader mode.

2.2.2 DC-Air™ Docking Station

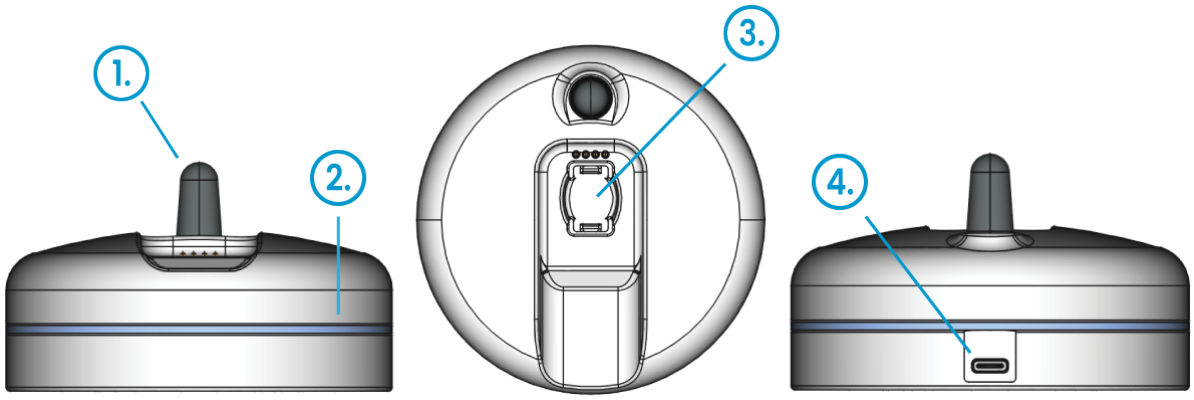


Figure 2: Front, top and back view of the DC-Air™ docking station. (1) Docking station antenna, (2) docking station indicator light (blue), (3) docking station sensor port, and (4) docking station USB-C port.

Docking Station Indicator Lights

The docking station indicator light (blue) located around the docking station housing (see Figure 2 (2) above).

Color:	Function:	Indication:
Blue	Sensor docked: LEDs fade; period 1s	Sensor on docking station
Blue	Sensor undocked: Cyclic motion; Period 0.5s	Docking station scanning.
Blue	Sensor undocked: All LEDs ON	Docking station connected to sensor.
Blue	Sensor undocked: All LEDs OFF	Docking station Idle. No scanning, no error, no connection.
Blue	Sensor un/docked: All LEDs flashing; Period 1s	Docking station error.
Blue	Sensor un/docked: Diagonal flashing; Period 1s	Docking station bootloader mode.
Blue	Sensor un/docked: Sequence flash; Left 0.5s, Left 0.5s, pause 0.5s, Right 0.5s, Right 0.5s	Docking station reset.

2.2.3 DC-Air™ USB-C Connection Cables

Use the DC-Air™ docking station with USB type A to USB-C cable delivered with the docking station. Cable length is 2m (~6.5 ft.).

2.3 Hardware and Software Requirements

The DC-Air™ sensor system is compatible with the following minimum specifications of PC (Windows), operating systems and components.

IMPORTANT

All IT components used in connection with the DC-Air™ sensor system need to be in compliance with the applicable safety standards. Refer to “Appendix B: Specifications and Standards” and “Appendix C: EMC Information“ for more information.

2.3.1 PC (Windows)

The supported operating system is Windows 10 & 11. The absolute minimum requirements for PC hardware for the sensor and software combination would be an Intel i5 6th Generation processor or equivalent. At least 4 GB of RAM, 100GB of hard drive space to accommodate a) the software, b) the space necessary for the repository of images generated by DC-Air backup, and c) for logging of errors and messages should be available. The PC should have a USB 2.0 Port. Finally, the PC must meet all requirements (if in excess of the above) of the used third-party Practice Management Software (PMS) or Imaging Software, if installed on the same PC.

2.3.2 Display

The minimum requirements of the display used with the DC-Air sensor system is pixel resolution of 1920x1080 and 24bit RGB Full HD (High-Definition).

2.4 Conformance to Standards

All X-ray equipment for dental intra-oral radiography used with the DC-Air™ sensor system must conform to requirements of standard IEC 60601-2-65.

The DC-Air™ sensor and the DC-Air™ docking station conform to safety requirements in standard IEC 60601-1.

The power supply of any IT components electrically connected to the DC-Air™ sensor system must use an IEC/UL 60950-1/62368-1 CAT II approved power supply.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT

US Federal law restricts this device to sale by or on the order of a dentist or other licensed practitioner.

2.5 Safety Considerations

All external surfaces of the DC-Air™ sensor, sensor holders, and the sensor barriers are considered to be applied parts and are safe for normal or accidental patient contact during use.

Serviceable parts of the DC-Air™ sensor include the battery of the sensor. Battery is changeable only by service personnel. Do not try to open the device to service it. All aspects of the sensor that are meant to be attended to by the operator are accessible without opening the internal components of the device. If there is a service problem, contact a qualified dealer service representative or the DC-Air™ Technical Support.

2.5.1 Mains Isolation

Disconnection from the supply mains occurs at the input to the computer (PC or laptop). The DC-Air™ docking station can also be disconnected from the computer.

2.5.2 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.

2.5.3 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. For information about cleaning the sensor, refer to section “5.2.1 Cleaning and Disinfection of DC-Air™ Sensor”.

2.5.4 Disposal Protocols

Dispose of sensor barriers and other consumable products following the normal dental office procedure for biomedical waste. Improper disposal of biomedical waste can lead to the spread of illness or disease.

Properly dispose of the sensor and the docking station when they have reached their end of life. For information, refer to the explanation of this symbol in “Appendix D: Symbols”.

2.5.5 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.

Remove sensor from service if damage to the housing is observed in the form of open cracks or punch through dents. Otherwise, improper functionality may result.

2.5.6 Termination of Operation

To terminate the operation of the DC-Air™ docking station, unplug its USB cable from the power source (PC or laptop).

The operation of the DC-Air™ sensor cannot be terminated. Do not use the sensor in case you have any doubt the sensor is not fully functional. Contact DC-Air™ Technical Support.

2.6 Protection Against Cybersecurity Threats

Protecting your practice against cybersecurity threats is the shared responsibility between Athlos Oy as the manufacturer of DC-Air™ and you as the operator of the device and as a health care provider. Athlos Oy has taken precautions to ensure that DC-Air™, as shipped from our factory, is protected against such threats. However, we cannot protect your network system. We highly recommend you ensure that your office network system is appropriately protected against viruses, malware, and intrusions (e.g., anti-virus software, and/or use of firewall) and that your IT equipment are appropriately protected against unintended and inappropriate access (e.g., IT/ premise's access control).

Failure to maintain cybersecurity can result in compromised device functionality, loss of data (medical or personal) availability or integrity, or exposure of other connected devices or networks to security threats.

2.7 Operating Modes

DC-Air™ sensor system has the following operating modes.

Installation

This mode is used when the docking station is connected to the PC for the first time. When the DC-Air™ system is connected to a PC or laptop for the first time, the user needs to contact DC-Air™ Technical Support for installing the TWAIN interface, activate the TWAIN license and download the calibration files from the cloud. Refer to TWAIN interface user guide.

Docked | Charging | Recovering the Last Image

This mode is used when the DC-Air™ sensor is placed on the docking station. The battery charges until it reaches full capacity. When docked, the DC-Air™ sensor will also be seen by the USB port in the PC or laptop. Every time access is granted to Technical Support to access the PC remotely, the DC-Air™ sensor should be docked as a default position. When docked via USB or undocked via Bluetooth®, the last image stored in the memory of the DC-Air™ sensor can be recovered via the third-party TWAIN interface. Refer to TWAIN interface user guide.

Connected | Bluetooth® Wireless Link

In this mode the sensor is waiting for X-rays. The third-party TWAIN interface indicates the status of the sensor as being ready for exposure. Refer to TWAIN interface user guide.

When the exposure occurs, the third-party TWAIN interface will indicate the automatic triggering to the incoming X-rays, followed by the wireless transfer indication status bar. Once the image is received it is

processed and displayed. The third-party TWAIN interface will send the image to the Imaging Software that called the TWAIN. The Imaging Software can initiate a new TWAIN instance either as a single exposure or as part of a predefined template and the TWAIN interface will indicate that the sensor is ready for the next exposure.

Never acquire an x-ray exposure until the TWAIN interface indicates the green “Sensor Ready” status. Refer to the TWAIN interface user guide for more information.

Never acquire an x-ray exposure until the image corresponding to the previous exposure has been successfully sent via the TWAIN interface to the Imaging Software. If the last image has not been acquired, use “Download last image” button. The last image will be downloaded either with the DC-Air™ in wireless connection or docked. Refer to TWAIN interface user guide for more information.

Sleep, Standby

When connected via Bluetooth® wireless link, the DC-Air™ sensor will enter in “sleep” or standby mode after user defined period of inactivity. While in sleep mode, the battery capacity is preserved better. To exit sleep mode, place the sensor onto the DC-Air™ docking station until the indication “Docked” is shown on the third-party TWAIN interface. Refer to TWAIN interface user guide.

2.8 Battery Low or System Failure

2.8.1 Battery Low

When the battery of the DC-Air™ sensor runs low, the sensor indicator light (see also “Sensor Indicator Lights”) at the back of the sensor will start flashing yellow. In such a case, the DC-Air™ sensor should be placed onto the docking station for at least 15 minutes. This recharging period will provide enough power for at least one Full Mouth Series (FMX).

If the battery of DC-Air™ is empty, the sensor indicator light will stop flashing altogether. In such a case, place the sensor onto the DC-Air™ docking station. Wait at least for 25 minutes before removing the sensor.

The TWAIN interface software will alarm the user to place the DC-Air™ onto the docking station when the battery level reached a critical stage.

It is strongly recommended that whenever the DC-Air™ is not in clinical use that it is placed on the docking station so that it is kept charged.

Place the DC-Air™ as soon as possible onto the docking station for re-charging when the TWAIN interface shows the “Battery level critical” alarm sign. Ignoring the alarm may lead to an exposure without an image taken if the DC-Air™ switches off due to low battery level.

2.8.2 System Failure

In rare occasions, the DC-Air™ sensor system may fail in a way that an X-ray image has been acquired, but not returned to the PC or the third-party TWAIN interface or third-party Imaging Software freeze. In such a case, follow the steps defined below:

1. Place the DC-Air™ sensor onto the docking station.
2. Close the TWAIN.
3. Exit the GUI service on the task bar but right clicking on the icon and choosing “Close DC-Air™ service”.
4. If the icon is not responsive, then kill the DC-Air™ service using the Windows task manager.
5. Close the third-party Imaging Software.
6. Disconnect the USB cable of the docking station form the PC side.
7. Wait for 10 seconds.
8. Reconnect the USB cable of the docking station to the PC.
9. Restart the third-party Imaging Software and relaunch the TWAIN interface.

After restarting the third-party Imaging Software, retrieve the latest X-ray image stored in the memory of the DC-Air™ sensor by placing the sensor onto the docking station. Refer to TWAIN interface user guide.

Do not retake the X-ray image. Retrieve the latest X-ray image from the memory of the DC-Air™ sensor by clicking “Download last image” icon (or similar) on the third-party Imaging Software. Refer to TWAIN interface user guide.

3 SET-UP INSTRUCTIONS

3.1 Connecting the DC-Air™ Docking station

Place the DC-Air™ docking station in desired location on a countertop, which must be in front of the treatment dental chair or if this is not possible sideways to the dental chair. The distance between the DC-Air™ and the docking station should not be more than 8 feet. Connect the USB cable provided in the package of the docking station to the USB port on the docking station and to the USB port in your PC or laptop.

Avoid placing the DC-Air™ docking station behind dental chair in a location behind the head and neck of a sitting patient. Any obstacles between the sensor and the docking station will degrade the quality of the Bluetooth® signal and slow down the transmission.

The DC-Air™ connection cables have a length of 2m (~6ft.). Other lengths may be available. Ask technical support for options.

3.2 Pairing the DC-Air™ Sensor with Docking Station

To pair any DC-Air™ sensor to any DC-Air™ docking station place the sensor on the docking station and wait for the third-party TWAIN interface software to display the “Sensor docked” status message. In some cases, the status message goes momentarily to “Sensor docked” before pairing, then goes to “Busy” and a few seconds later to “Sensor docked”. Repeat these steps when moving a DC-Air™ sensor from one room to another. Each time a sensor is relocated to a different operatory it needs to be paired to the docking station of that operatory.

When the “Sensor docked” status message comes up, wait for an additional three (3) seconds prior to lifting off the sensor from the docking station.

After picking up the DC-Air™ from the docking station wait for the “Sensor ready” status message prior to taking an x-ray image. Refer to TWAIN interface user guide.

Never acquire an x-ray exposure unless the TWAIN interface indicates the Green “Sensor Ready” status. Refer to TWAIN interface user guide.

Never attempt to acquire an x-ray image with the docking station placed behind a wall or a different room.

3.3 Calibration

The DC-Air™ sensor is factory-calibrated. The calibration is available in the web service of Athlos and matches the DC-Air™ UDI. When connecting the DC-Air™ to the PC or laptop for the first time, and when changing the previously used PC or laptop to another, dock the DC-Air™ and wait 30 seconds for the calibration to be downloaded from the cloud to the specific PC or laptop. If the practice does not have internet access contact Technical Support to send you the calibration files in a flash memory. If the calibration file is not found or if it does not match the UDI of the sensor the third-party TWAIN interface will produce an error. Refer to TWAIN interface user guide.

4 TAKING X-RAYS AND WORKFLOW FOR OPTIMAL USE

Refer to the third-party TWAIN interface user guide for instructions how to use the TWAIN and acquire images.

4.1 Placing the Sensor into a Sensor Barrier

Place the sensor into a disposable sensor barrier before each use, before placing the sensor onto the holder and into the patient's mouth. See the list of accessories in "Appendix: E: Accessories" for more information on recommended sensor barriers and sleeves.

Never use or place the DC-Air™ sensor in a patient's mouth without the use of an approved sensor barrier. Barriers recommended for use with DC-Air™ sensor are listed in "Appendix E: Accessories".

Only use intact bags. Remove and dispose of the bag after each use.

4.2 Positioning in the Holder

Position the sensor in the sensor holder as per the instructions provided by the manufacturer or the distributor of the holder.

4.3 Exposing the Sensor

DC-Air™ sensor captures X-rays using a direct conversion layer. Direct conversion produces images of the highest sharpness. Additionally, CMOS behind the direct conversion layer has a High Dynamic Range (HDR) feature which gives the user the easiness in the workflow to choose one exposure setting for an entire Full Mouth Series of X-rays (FMX).

DC-Air™ sensor system can be used with any approved wall- or wheel-mounted intraoral X-ray generator, and portable and handheld X-rays generator. The type of X-ray systems that integrate with the DC-Air™ sensor system are wall-mounted or wheeled X-ray generators (both AC and DC) with a tube current between 2 and 15 mA inclusive, and with a tube voltage between 50 and 75 kV inclusive, with in-built controls to set exposure parameters. Generators allow variable mA/kV to be selected, all will control the exposure time. Alternatively, the DC-Air™ sensor system can be used in conjunction with a portable, handheld X-ray generator with a tube current between 2 and 10 mA inclusive, and with a tube voltage between 50 and 75kV inclusive.

The nominal DC-Air sensor air kerma range for intended use is from 450 uGy to 4500 uGy.

Recommendations for typical loading factors and focal spot to skin distance: Tube voltage 60-70 kVp, tube current 7-8 mA, exposure time 160-500 ms, and distance 20-30 cm (~8-12 inches).

The **optimal exposure time of the DC-Air™ sensor will depend on the mA** available by the X-ray generator. In a typical case of a wall- or wheel-mounted X-ray generator operating in the range of **6-8 mA** with an **20cm (8”) cone**, a recommended **exposure time is 0.2s to 0.25s** for any position in an FMX or any other X-ray intraoral template. This means that due the HDR feature of the DC-Air™, there is no need for the user to adjust the generator settings regardless the position in the patient’s mouth, therefore improving workflow.

Furthermore, for ultra-high-definition images, the user may expose DC-Air™ sensor up to 0.5s.

The **DC Air™ docking station** with the receiving PC or laptop should be positioned **not further than 2.5m (8ft.)** from the dental chair where the X-ray examination is performed, and if possible, **sideways to the patient or in front of the patient.**

Avoid positioning the docking station behind the patient's head as the Bluetooth® signal would be severely degraded at that position. The docking station can be placed up to 2m (6ft.) away from the PC with the USB cable provider by the manufacturer.

Once the exposure button is pushed and to **optimize return time and comfort the user, remove the DC-Air™ sensor from the patient’s mouth,** wait for the preview, and reposition the sensor for the next exposure.

Usually when the docking station has a direct line of sight to the DC-Air™ the preview image will arrive in about 4sec – 8sec. In rare cases and usually when the DC-Air™ remains inside the mouth the preview may take up to 30seconds.

Under no circumstances proceed to the next x-ray exposure before the previous x-ray image has been properly transferred via the third-party TWAIN interface to the Imaging Software. If for whatever reason (e.g., loss of Bluetooth link or freezing of the Imaging Software or third-party TWAIN interface) the preview image and the final image are not sent to the Imaging Software, follow the steps described in 0 and then retrieve the last image from the “Download last image” button on the third-party TWAIN interface software.

With **fully charged battery**, DC-Air™ sensor can take at least **150 X-ray exposures in a continuous fashion (e.g. one image every 40 seconds)**. After completing an FMX or another X-ray template series and in between patients, the sensor should always be placed back onto its docking station for re-charging. **When not in use, the sensor should always be placed back onto its docking station**. When depleted for a full recharge, the DC-Air™ sensor requires approximately 2.5 hours, while a 20-minute recharge will allow 40 X-ray exposures to be taken in a sequential fashion.

If left away from the docking station, the DC-Air™ sensor will enter **sleep mode after a user defined interval** from the last X-ray to preserve its battery. There is a special “ENDO” mode that disables the sensor entering sleep mode. To exit sleep mode, place the sensor onto its docking station and leave it there for 10 seconds.

5 PEDIATRIC USE: SUMMARY

5.1 Introduction

Use special care when imaging patients outside the typical adult size range.

Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g., patients less than 50 kg (110 lb) in weight and 150 cm (59 in) in height.

Exposure to ionizing radiation is of particular concern in pediatric patients because:

1) For certain organs and tumor types, younger patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher for younger patients),
2) Use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients, and
3) Younger patients have a longer expected lifetime over which the effects of radiation exposure may manifest as cancer.

To help reduce the risk of excessive radiation exposure, you should follow the ALARA (As Low As Reasonably Achievable) principle and seek to reduce radiation dose to only the amount necessary to obtain images that are adequate clinically.

5.2 References for Pediatric Dose Optimization

When in pediatric use, the exposure for the DC-Air™ must be reduced in accordance with the instructions and protocols established by the x-ray tube manufacturer for each specific x-ray tube available in your dental practice, for pediatric use. In addition, it is recommended that you familiarize yourself with the information on the radiation safety in pediatric imaging and/or dental radiography devices found in the following sources:

- Dental radiographic examinations: Recommendations for patient selection and limiting radiation exposure (AMERICAN DENTAL ASSOCIATION Council on Scientific Affairs and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service Food and Drug Administration, Revised 2012)
- https://www.imagegently.org/
- https://www.imagegently.org/Procedures/Dental

For example, the dose recommendations for pediatric imaging using MyRay RXDC Hypersphere F15 (Cefla S.C.) are, as follows:

	Target:	[kV]	[mA]	[ms] SSD 30cm (12'')	[ms] SSD 20cm (8'')
CHILD	UPPER MOLAR	65	8	125	63
	UPPER PREMOLAR/CANINE	60	8	140	71
	UPPER INCISOR	60	8	110	56
	LOWER MOLAR	65	8	100	50
	LOWER PREMOLAR/CANINE	60	8	110	56
	LOWER INCISOR	60	8	90	45

5.3 Device Specific Features and Instructions

When deciding whether the device should be used for a specific pediatric patient, use your professional judgement on the anatomy and size of the patient and their oral cavity to decide whether the device can be used with minimum discomfort. In case this is not possible, DC-Air should not be used with that particular patient.

6 MAINTENANCE

6.1 Care and Maintenance

6.1.1 DC-Air™ Sensor

DC-Air™ sensor is reusable and can be used with multiple patients. Clean the sensor after each use by following the disinfection protocols described in this manual in section 6.2.

Always place the DC-Air™ sensor with proper positioning into its docking station after use to allow charging and to avoid misplacement of the sensor.

Do not drop or forcibly place DC-Air™ sensor onto any surface. Do not use the sensor if its housing has been damaged with visible deep cracks or punch through dents.

Battery

DC-Air™ sensor incorporates a rechargeable Li-Ion battery. The battery is changeable only by service personnel. Do not try to open the battery compartment of the sensor to service it.

Do not attempt to open battery compartment or replace battery in compartment. All battery repairs or replacements must be performed by authorized service personnel.

Charging the DC- Air™ Sensor

DC-Air™ sensor incorporates a rechargeable Li-Ion battery. To allow battery charging, place the sensor onto the sensor port on its docking station. Indicator lights on the docking station indicate that the sensor is charging and when it is fully charged (see “Sensor Indicator Lights”).

6.1.2 DC-Air™ Docking Station

Only use the USB cable provided with the DC-Air™ docking station when connecting the docking station to a PC or laptop.

Do not drop or forcibly place the DC-Air™ docking station onto any surface. Do not use the docking station if its housing has been damaged.

6.2 Cleaning and Disinfection

When cleaning the DC-Air™ sensor or the docking station, follow the cleaning and disinfection protocol described in this section.

6.2.1 Cleaning and Disinfection of DC-Air™ Sensor

Only use the approved disinfectants with DC-Air™ sensors. Using unapproved disinfectants may produce issues with the physical appearance of the product and potentially its operation.

The DC-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

DC-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 DC-Air™ sensor.

Do not submerge the DC-Air™ sensor in any liquid at any time.
Do not autoclave the DC-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.

6.2.2 Cleaning of DC-Air™ Docking Station

The DC-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 DC-Air™ docking station becomes soiled or comes into contact with a patient, it should be cleaned using the cleaning agents recommended for the DC- Air™ sensor in section “5.2.1 Cleaning and Disinfection of DC-Air™ Sensor”.

Do not submerge the DC-Air™ docking station in any liquid at any time.

Do not autoclave the DC-Air™ docking station. Autoclave sterilizers will permanently damage the device.

6.2.3 Cleaning and Disinfection of Holders

Sensor holders and related other items are to be cleaned and disinfected according to the instructions provided by the manufacturer of the holder and/or related items.

6.2.4 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.

Appendix A: Additional Help and Support

DC-Air™ on the Internet

Website homepage— https://www.ftgimaging.com

Online Store— https://www.ftgimaging.com/store

Online Support / Help— https://www.ftgimaging.com/support

DC-Air™ Customer Care (United States)

Call within the U.S. 1 (260) 208-8762

Or Toll Free 1 (855) 664-1953

E-mail questions to: info@ftgimaging.com

For support e-mail: support@ftgimaging.com

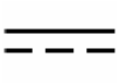
Appendix B: Specifications and Standards

DC-Air™ Sensor Specifications

SENSOR ARCHITECTURE	Direct converting dental IO X-ray sensor bonded to CMOS 1350 by 950 pixels 26 µm pixel pitch 19 lp/mm visible MTF: 90% @ 2lp/mm, 70% @ 5lp/mm, 40% @10lp/mm, 10% @ 16lp/mm
X-RAY PARAMETERS	Sensor can be used with dental X-ray generators in the range of 50 to 75 kV; at minimal 40µGy incident dose.
SOFTWARE ARCHITECTURE	Wireless and wired interface with the DC-Air™ Docking station
ELECTRICAL RATINGS	Battery-operated, nominal voltage 3.5V – 4.2V, 19mAh
CONNECTION TO DC-Air DOCKING STATION	Bluetooth®, USB
PROTECTION AGAINST SHOCK	Type BF applied part 
MODE OF OPERATION	Continuous
METHOD OF STERILIZATION	Sensor is not suitable for sterilization

ENVIRONMENTAL CONDITIONS	Humidity	Air Pressure	Ambient Temperature
USAGE DC-Air™ sensor is not suitable to be operated in oxygen rich and/or explosive environment	30%RH to 95%RH	70kPa to 106kPa	+10°C to +35°C
TRANSPORTATION AND (STORAGE) Transport in the supplied protective package	5%RH to 95%RH		-20°C to +50°C
Protection against water/matter – IP67, IP64			

DC-Air™ Docking Station Specifications

ELECTRICAL RATINGS	DC 5V, 0.5A 
CONNECTION TO PC	USB 2.0 compliant
MODE OF OPERATION	Continuous
METHOD OF STERILIZATION	Docking station is not suitable for sterilization

ENVIRONMENTAL CONDITIONS	Humidity	Air Pressure	Ambient Temperature
USAGE DC-Air™ docking station is not suitable to be operated in oxygen rich and/or explosive environment	30%RH to 95%RH	70kPa to 106kPa	+10° to +35°C
TRANSPORTATION AND STORAGE Transport in the supplied protective package	5%RH to 95%RH		-20°C to +50°C

Appendix C: EMC Information

The DC-Air™ sensor and the DC-Air™ docking station[1] are subject to electromagnetic interactions with other electronic devices. The EMC information in this chapter is provided for the medical system established by establishing the connection between the DC-Air™ sensor and the DC-Air™ docking station and by connecting the DC-Air™ docking station to a computer (PC or laptop).

The power supply of this computer must be an IEC/UL 60950-1/62368-1 CAT II approved power supply evaluated for operator-accessible secondary outputs that meet the requirements for SELV/ES1. The power supply must be certified for reinforced insulation between primary and secondary.

The DC-AIR™ sensor system is suitable for use in hospitals except for near active HF surgical equipment and the RF shielded room of an ME system for Magnetic Resonance (MR) imaging, where the intensity of EM disturbance is high.

Portable/mobile radio frequency communications equipment can affect the function of the DC-Air™ sensor system, as well as any other electronic medical equipment. This affect may result in failure of the image or degradation in the image quality.

The DC-Air™ docking station is a USB-compliant device and shall be used with USB-compliant cables suitable for full speed/USB 2.0. Such cables are either marked “USB 2.0” or “USB full 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 5m (~16.4ft.).

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: 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 DC-Air™ docking station to electromagnetic fields or increase the emission of electromagnetic fields from the DC-Air™ docking station. Consult technical support for more details on cable lengths and USB hubs.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12inches) to any part of the DC-Air™ sensor system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

[1] In this section, term “DC-Air™ sensor system” is to be understood to include the DC-Air™ sensor and the DC-Air™ docking station.

Guidance and Manufacturer's Declaration – ELECTROMAGNETIC EMISSIONS		
The DC-Air™ sensor system is intended for use in the electromagnetic environment specified below. The customer or the user of the DC-Air™ sensor system should assure that it is used in such an environment.		
EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The DC-Air™ sensor system utilizes Bluetooth® technology to transmit data. RF emissions in the ISM band are expected when the system is transmitting. This may cause interference in nearby electronic equipment operating in the same band. RF emissions in other frequencies are very low and not likely to cause any interference.
RF emissions CISPR 11	Class B	The DC-Air™ sensor system 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 61000-3-2	Class A (*)	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies (*)	

(*) Computer used with the DC-Air™ sensor system must meet this rating.

Guidance and Manufacturer's Declaration – ELECTROMAGNETIC IMMUNITY			
The DC-Air™ sensor system is intended for use in the electromagnetic environment specified below. The customer or the user of the DC-Air™ sensor system should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2kV, ±4 kV, ±8 kV, ±15 kV air	Complies	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	Complies (*)	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	Complies (*)	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	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle 70% UT; 25/30 cycles for 50 Hz and 60 Hz, respectively Single phase: at 0° 0% UT; 250/300 cycle for 50 Hz and 60 Hz respectively Single phase: at 0°	Complies (*)	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – ELECTROMAGNETIC IMMUNITY			
The DC-Air™ sensor system is intended for use in the electromagnetic environment specified below. The customer or the user of the DC-Air™ sensor system should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
	VDI specs per 3rd edition: <5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s		
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	Not applicable	Not applicable	-

(*) Computer used with the DC-Air™ sensor system must meet this rating.

Guidance and Manufacturer's Declaration – ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2)			
The DC-Air™ sensor system is intended for use in the electromagnetic environment specified below. The customer or the user of the DC-Air™ sensor system should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted RF IEC 61000-4-6	AC Mains: 3 V, 0.15 MHz – 80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz SIP/SOPS: 3 V, 0.15 MHz – 80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Complies (*)	Portable and mobile RF communications equipment should be used no closer to any part of the DC-Air™ sensor than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left(\frac{3.5}{V_1}\right)\sqrt{P}$ 150 kHz to 80 MHz $d = \left(\frac{3.5}{E_1}\right)\sqrt{P}$ 80 MHz to 800 MHz $d = \left(\frac{7}{E_1}\right)\sqrt{P}$ 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 meters (m). $V_1 = 3V_{rms}$ $E_1 = 3\frac{\mathrm{V}}{\mathrm{m}}$ 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:
Radiated RF IEC 61000-4-3 Ed. 3.0 (with A1:2007 + A2:2010)	3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	Complies (*)	

Guidance and Manufacturer's Declaration – ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2)			
The DC-Air™ sensor system is intended for use in the electromagnetic environment specified below. The customer or the user of the DC-Air™ sensor system should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
			
NOTE 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
The ISM (Industrial, Scientific, and Medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.			
[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 DC-Air™ sensor is used exceeds the applicable RF compliance level above, the DC-Air™ sensor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DC-Air™ sensor.			
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

(*) Computer used with the DC-Air™ sensor system must meet this rating.

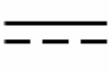
Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the DC-Air™ sensor			
The DC-Air™ sensor system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DC-Air™ sensor system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DC-Air™ sensor system 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 $d = \left(\frac{3.5}{V_1}\right)\sqrt{P}$	80 MHz to 800 MHz $d = \left(\frac{3.5}{E_1}\right)\sqrt{P}$	800 MHz to 2,5 GHz $d = \left(\frac{7}{E_1}\right)\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0. 74
1	1. 17	1. 17	2. 33
10	3. 69	3. 69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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.

Appendix D: Symbols

Symbols Used on Device Labeling

Symbol:	Meaning:	Reference No.:	Standard Containing the Symbol:	Title of the Standard:	Description of the Symbol:
	Caution	5.4.4	ISO 15223-1 [FR Recognition #5-117]	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Type BF applied part	Table D.2, Symbol 20 (IEE 60417-5333)	ANSI AAMI ES60601-1 [FR Recognition #19-4]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	To identify a Type BF applied part complying with IEC 60601-1.
	Recycle in electronic waste	N/A	EN 50419	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)	This device should not be disposed as unsorted municipal waste but must be sent to separate collection facilities for recovery and recycling.
	Manufacturer	5.1.1	ISO 15223-1 [FR Recognition #5-117]	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	Indicates the date when the medical device was manufactured. Indicates the medical device manufacturer.
IP67 **IP64**	Ingress protection code	(IEC 60529) Table D.3; Code 2 6.3; Table D.3; Code 2	ANSI AAMI ES60601-1 [FR Recognition #19-4]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	The sensor is completely protected against ingress of dust and airborne particles. The sensor is protected against water and liquids up to and including immersion in up to one meter of water.
Rx ONLY	Prescription only	N/A N/A	21 CFR 801.15(c)(1)(i)(F) 21 CFR 801.109	Labeling - Medical devices; prominence of required label statements Labeling - Prescription devices	Requires a prescription in the United States of America Caution: In the United States of America, federal law restricts this device to sale or use by, or on the order of, a physician.
	Model number of the device	6050	IEC 60417 DB [FR Recognition #5-102]	Graphical symbols for use on equipment	Identifies the model number or type number of a product. In the application of this symbol, the model number or type number of the product is accompanied with this symbol.
	Serial number of the device	5.1.7	ISO 15223-1 [FR Recognition #5-117]	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	Indicates the manufacturer's serial number so that a specific medical device can be identified.

Symbol:	Meaning:	Reference No.:	Standard Containing the Symbol:	Title of the Standard:	Description of the Symbol:
	Consult instructions for use	5.4.3	ISO 15223-1 [FR Recognition #5-117]	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	Indicates the need for the user to consult the instructions for use.
	Follow instructions for use	Table D.2, Safety sign 10 (ISO 7010-M002)	ANSI AAMI ES60601-1 [FR Recognition #19-4]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	To signify that the instruction manual/booklet must be read.
FCC ID	FCC identifier	N/A	47 CFR Subpart J §2.925	Identification of equipment	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. For DC-Air™ intraoral sensor FCC ID: 2AX53DC015 For DC-Air™ docking station FCC ID: 2AX53DCDS1
		N/A	47 CFR Subpart J §2.926	FCC identifier	
	Non-ionizing electromagnetic radiation	5140	IEC 60417 DB [FR Recognition #5-102]	Graphical symbols for use on equipment	Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g., in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	The Bluetooth combination mark	N/A	Bluetooth® Brand Usage Guide, Updated: October 2019 Bluetooth SIG Proprietary		This device contains a Bluetooth® device
	Direct current	IEC 60417-5031	ANSI AAMI ES60601-1 [FR Recognition #19-4]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Indicates that the equipment is suitable for direct current only.
	Keep dry	5.3.4	ISO 15223-1 [FR Recognition #5-117]	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	Indicates a medical device that needs to be protected from moisture.
	Temperature limit	5.3.7	ISO 15223-1:2016 [FR Recognition #5-117]	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	Indicates the temperature limits to which the medical device can be safely exposed.
	Atmospheric pressure limitation	5.3.9	ISO 15223-1 [FR Recognition #5-117]	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Symbol:	Meaning:	Reference No.:	Standard Containing the Symbol:	Title of the Standard:	Description of the Symbol:
	Humidity limitation	5.3.8	ISO 15223-1:2016 [FR Recognition #5-117]	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	Indicates the range of humidity to which the medical device can be safely exposed.

Label Information

The Unique Device Identifier (UDI) of the DC-Air™ intraoral sensor is provided as direct markings on the enclosure of the sensor. The UDI identifies each individual sensor. The UDI is replicated on the packaging label of the sensor. Label of the DC-Air™ sensor is available on the outside of the package the sensor is delivered in.

Type label of the DC-Air™ docking station is affixed to the bottom of the docking station. For more information, see illustration below.

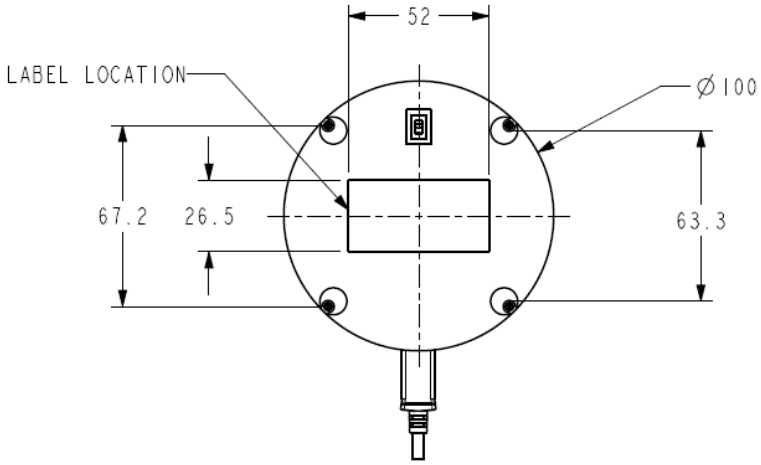
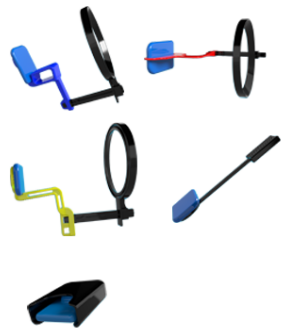


Figure 3: Location of the label on the DC-Air™ docking station (bottom view)

Appendix E: Accessories (United States)

DC-Air™ sensor system is intended for use with third-party accessories suitable and intended for use with size 2 intraoral sensors. These accessories include those listed below.

List of Recommended Sensor Holders

Part Information:	Manufacturer:	Part/ Catalogue No.	Description:	Figure:
DC-Air™ Sensor Holder Pack	Athlos Oy	DC-HP-1	DC-Air™ Holder Pack	
		DC-HP-2	DC-Air™ BW Holder	
		DC-HP-3	DC-Air™ Posterior Holder	
		DC-HP-4	DC-Air™ Anterior holder	
		DC-HP-5	DC-Air™ Endo Holder	
		DC-HP-6	DC-Air™ Ring	
		DC-HP-7	DC-Air™ Sticks	
		DC-HP-8	DC-Air™ Adaptor	
		DC-HP-9	DC-Air™ Occlusal Sleeve	
Trollbyte Kimera Sensor Holders	TrollDental UK LTD	1520432905	TROLLBYTE KIMERA KIT	
		1521290503	TROLLBYTE KIMERA BLUE	
		1522290503	TROLLBYTE KIMERA RED	
		1523430503	TROLLBYTE KIMERA YELLOW	
		1524432905	TROLLBYTE KIMERA ENDO	
		1519001001	AIMING RING	

XCP-DS FIT® Universal Sensor Holder	Dentsply Rinn	559900	XCP-DS FIT® Hygiene Kit	
		559901	XCP-DS FIT® Bitelock Refill Packs – Anterior (2-pack)	
		559921	XCP-DS FIT® Bitelock Refill Packs – Anterior (10-pack)	
		559906	XCP-DS FIT® Bitelock Refill Packs – Anterior Thin (2-pack)	
		559926	XCP-DS FIT® Bitelock Refill Packs – Anterior Thin (10-pack)	
		559902	XCP-DS FIT® Bitelock Refill Packs – Posterior (2-pack)	
		559922	XCP-DS FIT® Bitelock Refill Packs – Posterior (10-pack)	
		559903	XCP-DS FIT® Bitelock Refill Packs – Horizontal Bitewing (2-pack)	
		559923	XCP-DS FIT® Bitelock Refill Packs – Horizontal Bitewing (10-pack)	
		559904	XCP-DS FIT® Bitelock Refill Packs – Vertical Bitewing (2-pack)	
		559924	XCP-DS FIT® Bitelock Refill Packs – Vertical Bitewing (10-pack)	
		559905	XCP-DS FIT® Bitelock Refill Packs – Endodontic (2-pack)	

List of Recommended Protective Barriers

Part Information:	Manufacturer:	Part/ Catalogue No.	Description:
Disposable Barrier Sleeves And Covers	DENTSPLY SIRONA INC	050500	Universal digital sensor covers (bulk)
		550500	Universal digital sensor covers
		550143	Tight digital sensor Cover – Size 1.5/2, 300-pack
		055574	Tight digital sensor Cover – Size 1.5/2, 25-pack
		055629	Tight digital sensor Cover – Size 1.5/2
Plasdent	Plasdent Corporation	PS520	Sensor cover

Part Information:	Manufacturer:	Part/ Catalogue No.	Description:
Disposable Barrier Sleeves and Barrier Film		PS-SUNI-2	X-ray sensor sheaths
		PS-DEXIS-2	X-ray sensor sheaths
		PS-6100-2	X-ray sensor sheaths
		PS-GXDR-2	X-ray sensor sheaths
		PS-SHICK-2	X-ray sensor sheaths
BH Medical Dental Barrier Sleeves And Barrier Film	BH Medical Products Co., Ltd.	#991372	Digital x-ray sensor sleeve
		#991371	Digital x-ray sensor sleeve
UNiPACK Barrier Sleeve And Barrier Film And UNiGLIDE Barrier Envelope	UNiPACK Medical Corporation	UBC-8038	Sensor sleeve, Size 2 - large
		UBC-820825	X-ray sensor sheath
		UBC-820861	X-ray sensor sheath
		UBC-820979	X-ray sensor sheath
		UBC-820999	X-ray sensor sheath
Premium Plus Disposable Barrier Sleeve	Premium Plus International Limited	140L	X-ray sensor sleeves, large, 500 pcs/box
		140M	X-ray sensor sleeves, medium, 500 pcs/box
		183-2	X-ray sensor sleeves two step, Size 2, 500
Pac-Dent Barrier Sleeve, Cover-It(TM) Barrier Film	Pac-Dent International, Inc.	100L	Digital sensor sleeve
		DX-406	X-ray sensor sheaths
		DX-824	X-ray sensor sheaths
		DX-825	X-ray sensor sheaths
		DX-890	X-ray sensor sheaths
		DX-979	X-ray sensor sheaths
		DX-999	X-ray sensor sheaths

DC-Air™ by FTG

Signatures:

Document Reviewed:	I have reviewed the contents of this document		
Name:	**Matt Powell** **ATHLOS\matt.powell** Matt Powell	Title:	
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