OPERATOR'S MANUAL

DC-AIR™

Information in this manual applies to DC-Air™ Intraoral Sensor System (DC-Air™ Intraoral Sensor model WIOS-S2 and DC-Air™ Docking Station model WIOS-DS2). This manual and the product described herein are protected by copyright laws and international copyright treaties, as well as other intellectual property laws and treaties.

This manual contains original instructions by Athlos Oy. Athlos Oy reserves the right at any time to revise this manual and the product described herein and assumes no obligation to notify any person or entity of such revisions.

Language: The original language of this manual is English.

CONTENTS

1   INTRODUCTION

1.1   About the DC-Air™

DC-Air™ is the world's first wireless intraoral sensor that uses the latest 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.

Manufacturer information:

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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 physicians, physician assistants, registered nurses, or other qualified medical personnel trained in the use of the system.

1.3   Contraindications

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

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.

IMPORTANT

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

NOTE

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	18.12.2020

1.6.1 Printed Copy of the Manual18.12.2020

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

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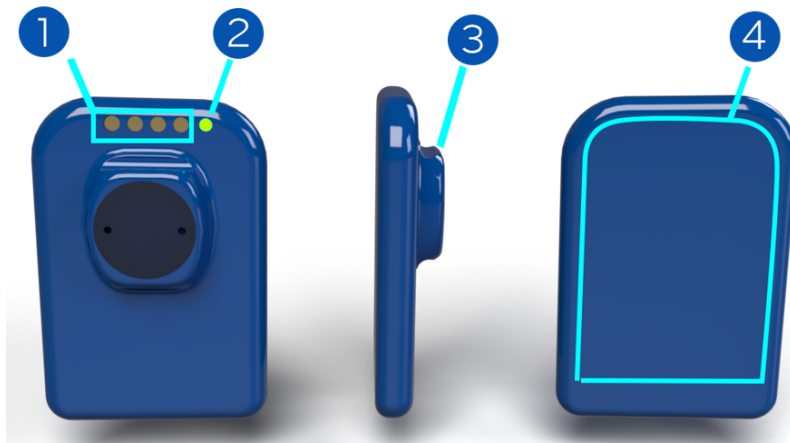
Figure 1: Back, side, and front view of the DC-Air™ Sensor. (1) Sensor's contact points, (2) sensor indicator light (green or yellow), (3) sensor connection hub, and (4) sensor active area (35.1 X 24.7 mm^2)

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	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.
Green	Un/Docked: Flashing; Non-specific interval	Data transfer (Bluetooth or USB).
Yellow	Docked: Flashing; Period 2s	Sensor Charging. Battery low.
Yellow	Undocked: Flashing; Period 250ms	Sensor error. Power Fault. Sensor not ready.
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: Flashing: Non-specific interval	Data transfer (Bluetooth or USB). Battery low.
Yellow	Un/Docked: Constant ON	Sensor error OR Bootloader. Sensor not ready.

Color:	Function:	Indication:
Green/ Yellow	Un/Docked: Flash; 2 x 100ms Green & 2 x 100ms Yellow	Sensor reset.
Green/ Yellow	Undocked: Flash; 1 x 75msec Green, 100ms pause, 25ms Yellow; Period 2s	Sensor in sleep 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 lights (blue), (3) docking station sensor port, and (4) docking station USB-C port.

Docking Station Indicator Lights

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

Color:	Function:	Indication:
Blue	Sensor docked: Cyclic motion; Period 1sec	Sensor charging.
Blue	Sensor docked: Left/Right flashing; Period 1s	Sensor not charging
Blue	Sensor undocked: Cyclic motion; Period 0.5s	Docking station scanning.
Blue	Sensor undocked: Left/Right flashing; Period 1s	Docking station not scanning
Blue	Sensor undocked: All LEDs ON	Docking station connected to sensor.
Blue	Sensor un/docked: All LEDs flashing; Period 1s	Docking station error.
Blue	Sensor un/docked: Sequence flash; Left 500ms, Right 500ms, pause 3s, Left 500ms	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 7 and 10. 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.

2.4   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.

Remove sensor from service if damage to the housing is observed. Otherwise, exposure to elevated surface temperature or 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 (PS and 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.

2.6   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 run the installation application included in the flash memory delivered together with the system.

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, the last image stored in the memory of the DC-Air™ sensor can be recovered via the third-party Imaging Software.

Connected | Bluetooth® Wireless Link

In this mode the sensor is waiting for X-rays. The third-party Imaging Software indicates the status of the sensor as being ready for exposure. When the exposure occurs, the third-party Imaging Software will indicate the automatic triggering to the incoming X-rays, followed by the wireless transfer indication. Once the image has been received by the PC, the third-party Imaging Software will indicate that the sensor is ready for the next exposure.

Sleep, Standby

When connected via Bluetooth® wireless link, the DC-Air™ sensor will enter in "sleep" or standby mode after five (5) minutes 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 Imaging Software.

2.7   Battery Low or System Failure

2.7.1 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.

2.7.2 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 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 third-party Imaging Software.
3. Disconnect the USB cable of the docking station form the PC side.
4. Wait for 10 seconds.
5. Reconnect the USB cable of the docking station to the PC.
6. Restart the third-party Imaging Software.

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.

IMPORTANT	Do not retake the X-ray image. Retrieve the latest X-ray image from the memory of the DC-Air™ sensor by placing it onto the docking station and clicking "Retrieve Last X-ray" icon (or similar) on the third-party Imaging Software.

3   SET-UP INSTRUCTIONS

3.1   Connecting the DC-Air™ Docking station

Place the DC-Air™ docking station in desired location on a countertop. 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.

IMPORTANT   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

The DC-Air™ sensor is delivered as factory-paired to its docking station. The sensor and the docking station it has been paired with are identified with a common number indicating that they are paired and ready for use.

3.3   Calibration

The DC-Air™ sensor is factory-calibrated. The calibration folder is available in a memory flash provided with the sensor and its docking station. 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, insert the flash memory into a USB port on the PC when prompted by the third-party Imaging Software.

4 TAKING THE FIRST HUMAN X-RAY

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 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 **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**, the **optimal exposure time is 0.2s** 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 3m (9ft.)** from the dental chair where the X-ray examination is performed, and if possible, **sideways to the patient or in front of the patient.**

IMPORTANT Avoid positioning the docking station behind the patient's head as the Bluetooth® signal would be weakest at that position. The docking station can be placed up to 5m (15ft.) away from the PC.

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.

With **fully charged battery**, DC-Air™ sensor can take at least **150 X-ray exposures in a continuous fashion**. After completing an FMX or another X-ray template series and in between patients, the sensor should 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**. For a full recharge, the DC-Air™ sensor requires approximately 70 minutes, 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 five (5) minutes** from the last X-ray to preserve its battery. In the sleep mode, the sensor can run 12 hours with one battery charge cycle. To exit sleep mode, place the sensor onto its docking station and leave it there for 10 seconds.

5   MAINTENANCE

5.1   Care and Maintenance

5.1.1 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 "5.2.1 Cleaning and Disinfection of DC-Air™ Sensor".

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.

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").

5.1.2 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.

5.2   Cleaning

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

5.2.1 Cleaning and Disinfection of DC-Air™ Sensor

Disinfect the DC-Air™ sensor after each use in accordance with the CDC – or your country's standards (e.g., OSAP) – for infection control. We recommend that you clean the DC-Air™ sensor by wiping it with one of the following cleaning agents:

Product:	Manufacturer:
CaviWipes™	Kerr Dental
ADVANTACLEAR Surface Disinfectant Wipes	Hu-Friedy
OPTIM® 1 Wipes	Coltene

⚠️ DC-Air™ sensor must be cleaned and disinfected after each patient by following the Cleaning Agent guidelines.

⚠️ **CAUTION**
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 sensor.

5.2.2 Cleaning of DC-Air™ Docking Station

DC-Air™ docking station does not require routine cleaning. In case cleaning is needed, the docking station may be wiped using the cleaning agents recommended for the DC- Air™ sensor in section "5.2.1 Cleaning and Disinfection of DC-Air™ Sensor".

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

5.2.3 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.

5.2.4 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

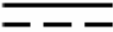## DC-Air™ on the Internet

TBD

DC-Air™ Customer Care (United States)

TBD

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	10%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	10%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 imaging, where the intensity of EM disturbance is high.

IMPORTANT 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.).

⚠ 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.

⚠ 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.

⚠ 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.

⚠ 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.

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[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.

	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). $V_1 = 3 V_{rms}$ $E_1 = 3\dfrac{V}{m}$
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 (*)	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: *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 $d = \left(\dfrac{3.5}{V_1}\right)\sqrt{P}$	80 MHz to 800 MHz $d = \left(\dfrac{3.5}{E_1}\right)\sqrt{P}$	800 MHz to 2,5 GHz $d = \left(\dfrac{7}{E_1}\right)\sqrt{P}$
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

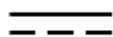|	
⚠	Attention.
👤 (BF)	Type BF applied part.
🗑	WASTE OF ELECTRICAL AND ELECTRICAL EQUIPMENT (WEEE): This symbol indicates that this device should not be disposed as unsorted municipal waste but must be sent to separate collection facilities for recovery and recycling.
🏭	Manufacturer: This symbol is accompanied by the name and address of the manufacturer.
⌂	Manufacturing date: This symbol is accompanied by the date of manufacture.
IP67 **IP64**	This device is completely protected against ingress of dust and airborne particles. This device is protected against water and liquids up to and including immersion in up to one meter of water (IEC 60529).
Rx ONLY	US FDA Prescription Devices symbol for: "Caution: Federal law restricts this device to sale by or on the order of a dentist or other licensed practitioner."
#	Model number of the device
SN	Serial number of the device.
📖	Consult instructions for use.
📘	Follow instructions for use.
FC	FCC logo (Federal Communications Commission, U.S.)
FCC ID	FCC identification number of the device. For DC-Air™ intraoral sensor **FCC ID: 2AX53DC015** For DC-Air™ docking station **FCC ID: 2AX53DCDS1**
((•))	This device contains a Bluetooth® device.

Symbol	Meaning
	Bluetooth trademark.
	USB port.
	Direct current (DC)
	Keep away from rain. Keep dry.
	Temperature limitations.
	Atmospheric pressure limitations.
	Humidity limitations.

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 identified each individual sensor. The UDI is replicated on the type 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.
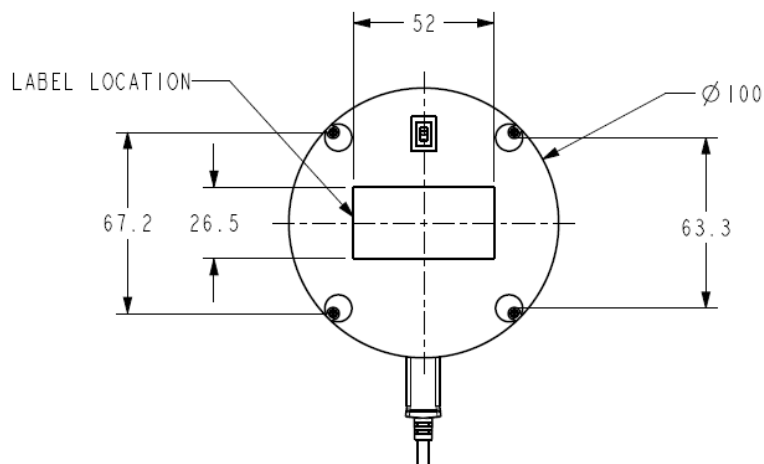

Figure 3: Location of the label on the DC-Air™ docking station (bottom view)

Appendix E: Accessories

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.

Device/ Part Information:	Description:	Figure:
XCP-DS® Digital Sensor Holders, Dentsply Rinn	Dental X-ray film holder	
XCP-DS FIT Universal Sensor Holder, Dentsply Rinn	Dental X-ray film holder	
TrollBag Sensor Covers, Troll Dental	Dental barriers and sleeves	
TIDIShield® Digital X-Ray Sensor Sheaths, TIDI Products	Dental barriers and sleeves	
Universal RS Barriers - Sensor Barrier Sleeves, Steri-Shield®	Dental barriers and sleeves	

Signatures:

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