Dentsply Sirona
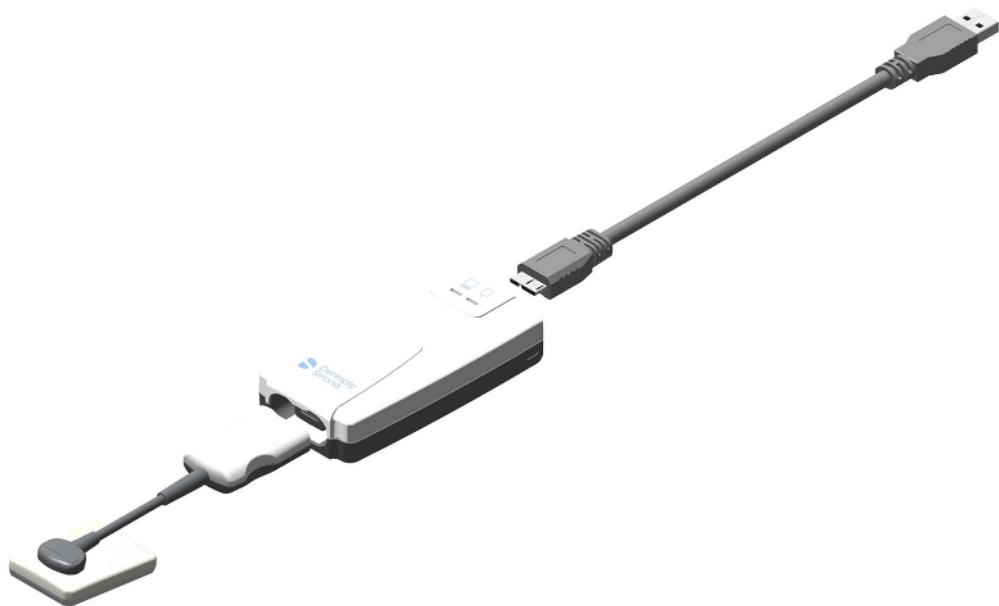
AE Sensor USB interface and Xios AE sensors

Operating Instructions

English

Table of contents

1 General information

1.1 Dear Customer,

We are pleased that you have equipped your practice with the Xios AE digital Intraoral X-ray system from Dentsply Sirona. The system is characterized by many features and a high day-to-day reliability.

Xios AE and sensors are available in three sizes (0, 1 and 2) and use enhanced image processing functions in Sidexis 4 through special filters. Depending on the indication, a corresponding filter can be applied to the X-ray image to amplify the relevant structures.

In addition to Sidexis 4 (version 4.3 and above), the Sidexis 4 Sensor plug-in must be installed for Xios AE.

Both the installation manual and these operating instructions should be helpful to you before you start using the system and at any time afterwards as reference materials.

We wish you a great deal of success with Xios AE.

Your Xios AE Team

1.2 Contact information

Customer Service Center

In the event of technical queries, please use our online contact form at the following address:
http://srvcontact.sirona.com

Authorized agent in the EU

Sirona Dental Systems GmbH
Fabrikstrasse 31
64625 Bensheim
Germany

Tel.: +49 (0) 6251/16-0
Fax: +49 (0) 6251/16-2591
e-mail: contact@dentsplysirona.com
www.dentsplysirona.com

Manufacturer's address

Sirona Dental, Inc
30-30 47th Avenue, Suite 500
Long Island City
New York, 11101
U.S.A.

1.3 General information about this operating manual

Observe the Operating Instructions

Please familiarize yourself with the unit by reading through these Operating Instructions before putting it into operation. It is essential that you comply with the specified warning and safety information.

Keep documents safe

Always keep the operating instructions handy in case you or another user require(s) information at a later point in time. Save the Operating Instructions on the PC or print them out.

If you sell the unit, make sure that the operating instructions are included with it either as a hard copy or on an electronic storage device so that the new owner can familiarize himself with its functions and the specified warning and safety information.

Online portal for technical documents

We have set up an online portal for the Technical Documents at www.dentsplysirona.com/manuals. There, you can download these operating instructions and further documents. Please complete the online form if you would like a hard copy of a particular document. We would be delighted to send you a printed copy, free of charge.

Help

If you continue to have difficulties despite having thoroughly studied the Operating Instructions, please contact your dental depot.

1.4 Other valid documents

The X-ray system includes other components, such as PC software, which are detailed in other documents. Instructions and warning and safety information provided in the following documents must be taken into account:

- Sidexis 4 Installation Instructions
- Sidexis 4 User Manual

Keep these documents handy at all times (file them in the X-ray System Logbook in the FR of Germany).

The system integrator must complete the enclosed declaration of conformity.

To safeguard your warranty claims, please complete the attached "Installation Report / Warranty Passport" together with the service engineer immediately after the installation of your unit.

1.5 Intended use

The Xios AE X-ray system is designed for digital acquisition of intraoral X-ray images for diagnostic purposes. The system is used on patients by dental professionals. The digital images produced are transferred to a PC and displayed on a monitor. The images can be edited, saved and printed on the PC.

The product must not be operated in hazardous areas.

1.6 Indications and contraindications

Indications in the areas:
- Conservative dentistry
- Caries diagnosis, especially of proximal lesions
- Endodontics
- Periodontology
- Prosthodontics
- Functional diagnosis and treatment of craniomandibular dysfunctions
- Surgical dentistry
- Implantology
- Oral and maxillofacial surgery
- Orthodontics

Contraindications:
- Display of cartilage structures
- Display of soft tissue

1.7 Structure of the document

1.7.1 Identification of the danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in these operating instructions. Such information is highlighted as follows:

⚠ DANGER
An imminent danger that could result in serious bodily injury or death.

⚠ WARNING
A possibly dangerous situation that could result in serious bodily injury or death.

⚠ CAUTION
A possibly dangerous situation that could result in slight bodily injury.

NOTE
A possibly harmful situation which could lead to damage of the product or an object in its environment.

IMPORTANT
Application instructions and other important information.

Tip: Information for simplifying work.

1.7.2 Formats and symbols used

The formats and symbols used in this document have the following meaning:

✔ Prerequisite **1.** First action step **2.** Second action step or ➢ Alternative action ↳ Result ➢ Individual action step	Requests you to do something.
See "Formats and symbols used [→ 10]"	Identifies a reference to another text passage and specifies its page number.
● List	Designates a list.
"Command / menu item"	Indicates commands / menu items or quotations.

2 Safety instructions

2.1 Qualifications of operating personnel

The system may only be operated by skilled or properly trained personnel.

The system may only be installed and operated by skilled or properly trained personnel.

Xios AE installation is to be performed exclusively by trained and authorized distributors of Dentsply Sirona or service technicians designated by Dentsply Sirona. For more information, please refer to the section on Contact Information and use the e-mail address or phone number to reach us directly.

Personnel undergoing education or training, or who are using the unit as part of general training, may only operate the unit under the constant supervision of a properly trained person.

2.2 Hygiene

Suitable hygienic measures must be taken to prevent cross contamination between patients, users and other persons.

The hygienic protective sleeves and sensor holder tabs are single use devices which must be renewed for each patient. Do not use single use devices more than once.

The sterilizable exposure accessories such as the rods and rings of the sensor holder must be sterilized to prevent any possible transmission of infective agents which might under certain circumstances cause serious illnesses.

Before autoclaving sensor positioning parts, be sure to clean them properly with an appropriate soap and / or disinfectant and follow the manufacturers' instructions regarding usage. After the parts have been cleaned, rinse them thoroughly with water to remove any chemical residue that might remain. Observe this practice whenever preparing sensor positioning parts for autoclaving as discoloration in the components may occur if such steps are not performed. (Discoloration will not affect function or use.)

The sensors and the cable must be disinfected before each patient. Refer to Hygiene.

2.3 Radiation protection

The valid radiation protection regulations and measures must be observed. The statutory radiation protection equipment must be used. Please follow the manual for your X-ray tube assembly.

2.4 PC system and software

During the exposure, the data connection and power supply must be ensured via the USB port. Under Power Options on the control panel set the PC so that it never switches to stand-by operation or goes to sleep.

Sidexis 4 may not be terminated until the end of the exposure. Before image acquisition, close all programs that are not required for the operation of Sidexis 4. Any programs running in the background, such as media players, print managers, backup software, etc., may cause Sidexis 4 to crash during the exposure. In cases of doubt, consult your system administrator.

These operating instructions presuppose that you are familiar with the use of the Sidexis 4 software.

2.5 Allocation of acquisition system to patient

During routine practice, the clear allocation of the acquisition system to the patient to be examined is ensured. This also applies to the allocation of the X-rays to the patient data stored by Sidexis 4.

2.6 Trouble-free operation

Use of this unit is permissible only if it works properly without malfunctions. If trouble-free operation cannot be ensured, the unit must be taken out of service, checked by authorized technicians for malfunctions and, if necessary, repaired or replaced.

2.7 Maintenance

In the interest of the safety and health of patients, users and other persons, inspections must be performed at scheduled intervals to ensure the operational reliability and functional safety of your product (IEC 60601-1 / DIN EN 60601-1 etc.), see "Regular Inspections".

The owner is responsible for making sure that all inspections are performed.

In the event that the system owner fails to fulfill the obligation to perform scheduled inspection activities or ignores error messages, Sirona Dental Systems GmbH and its authorized dealers cannot assume any liability for damages.

As manufacturers of medical electrical equipment we can assume responsibility for the safety-related features of the equipment only if **maintenance and repair** are carried out only by ourselves or agencies expressly authorized by us, and if components affecting safe operation of the system are replaced with **original spare parts** upon failure.

We suggest that you request a certificate showing the nature and extent of the work performed from those who carry out such work; it must contain any changes in rated parameters or working ranges (if applicable), as well as the date, the name of the company and a signature.

2.8 Modifications and extensions of the system

Modifications to this system which might affect the safety of the system owner, patients or other persons are prohibited by law.

For reasons of product safety, this product may be operated only with original Dentsply Sirona accessories or third-party accessories expressly approved by Dentsply Sirona. The user assumes the risk of using non-approved accessories.

If any devices not approved by Dentsply Sirona are connected, they must comply with the applicable standards, e.g.:

- IEC 60950-1 or IEC 62368-1 for information technology equipment (e.g. PC) and
- IEC 60601-1 for medical electrical equipment.

In case of doubt, contact the manufacturer of the system components.

2.9 Combination with other units

Permissible combinations are specified in the Declaration of Conformity by the system integrator.

2.10 Additional instructions

2.10.1 Operate Sensor as Directed

Always use the sensor and in accordance with the directions and recommendations contained in these operating instructions. Do not attempt to modify the sensor or use it in system configurations not specified in this document.

Before each usage, check the outer surface of the sensor and cable for any signs of physical damage or defect. Sensor surfaces should have a smooth finish with no evidence of chipping or damage. If detected, contact your local distributor of Dentsply Sirona products for further instructions.

2.10.2 Do Not Touch Exposed Connectors on Non-Medical Equipment and the Patient at the Same Time

When the sensor is in use, avoid touching exposed connectors on non-medical electrical equipment and the patient at the same time. The human body is capable of conducting electrical current and may cause a shock hazard to patients if appropriate safety practices are not observed.

2.10.3 RF Interference Considerations

Although the sensor is designed to provide a reasonable degree of protection from electromagnetic interference, according to IEC International regulations, they must be installed at an adequate distance from electricity transformer rooms, static continuity units, two-way amateur radios and cellular phones. To ensure proper operation, the latter (meaning, electricity transformer rooms, static continuity units, two-way amateur radios and cellular phones) can be used only at a minimum distance of 5 feet (1.5m) from any part of the sensor.

Any instrumentation or equipment for professional use located near the sensor must conform to Electromagnetic Compatibility regulations, to which the EMC tables in this document serve as guidance. Non-conforming equipment, with known poor immunity to electromagnetic fields, may not operate properly unless they are installed at a distance of at least 10 feet (3m) and supplied by a dedicated electrical line.

2.10.4 Apply Recommended Procedures for Cleaning

Safe and proper operation of the equipment requires following a regular schedule of preventive maintenance. To help ensure proper hygiene and to protect against infectious disease, refer to the Hygiene section and observe all device cleaning and patient protection recommendations specified there.

Although water-resistant, the sensor should never be soaked or submerged in disinfecting solution during any cleaning procedure. Failure to comply with this precaution may cause liquid to enter the sensor and can prevent it from operating properly.

2.10.5 Do Not Connect Items that are Not Part of the System

Only items specified for use with the sensor are to be connected to it. The device should not be used adjacent to other equipment that is not part of the system. If, however, use with adjacent equipment is necessary, normal operation should be observed and verified in that configuration.

2.10.6 Ensure Proper System and PC Workstation Installation and Operation

The sensor has been determined to be in accordance with international safety standards and is deemed suitable for use within the patient area, which extends from the patient for a distance of 5 ft (1.5m). To comply with these standards, do not operate non-medical equipment (such as a PC workstation) inside the patient area. Outside the patient area, the presence of approved non-medical grade equipment and Listed / Approved / IEC 60950-1 certified Information Technology Equipment (ITE) computer equipment is acceptable.

The host computer (PC workstation) should be CE-approved and conform with the Low Voltage [73/23/EC] and EMC Directive [89/336/ERC]. Also, to help ensure optimal performance, ensure that all software programs residing on the workstation are virus-free and have been adequately tested so they will not impact imaging applications after installation.

2.10.7 Only Dentists or Authorized Designees Are Permitted to Operate the System

To ensure the correct use of the sensor in a clinical environment, for purposes that correspond to its intended design and application, only dentists, or their designees, are authorized to operate the system.

2.10.8 Protect Sensor from Potential ESD Damage

Like other electronic devices, the sensor is susceptible to electrostatic discharge (ESD), particularly when the device is used in or around

carpeted areas or low-humidity environments. During cable replacement, when sensor contacts are exposed, it is especially important to protect the device from potential ESD damage. Touching a metal surface prior to replacing the cable will reduce the risk of damaging sensor components by accidental static discharge. Using anti-static floor mats or floor treatments (for example Staticide 2005/2002) will also help eliminate static build-up in your office.

2.10.9 Wait for Appropriate Prompts before Operating X-ray Source

To avoid exposing the patient to unnecessary X-rays, ensure that the viewbox is flashing green (default color) before triggering the X-ray Source.

2.10.10 Always Use Sheaths with Sensors

Use Dentsply Sirona sheaths every time the sensor is used. Never use the sensor without a protective sheath. Never use a damaged sheath. Always dispose of the sheath after every patient. Protective sheaths are single-use items and must not be reused under any circumstance. Reuse of single-use items/instruments may cause them to become contaminated, compromise their intended function, and result in patient and user infection, injury and/or illness.

2.10.11 Take Appropriate Precautions during X-ray Operation

Always observe the safety guidelines and precautions supplied with your X-ray generator and by local regulatory authorities.

2.10.12 Product Manuals from Dentsply Sirona

The contents of this manual are subject to change without prior notice. For the latest version of this user guide and other product information, please visit our website at www.denstplysirona.com.

2.10.13 Product Damage during Shipment

All Dentsply Sirona products are carefully inspected prior to shipment. Upon receipt of a delivery from us, please check the package and note any signs of visible damage. Do not use products that indicate improper handling or potential damage. If you suspect an item was damaged, please contact our Support department for more information.

2.10.14 Use Only Approved Disinfectants

Use only approved disinfectants with Dentsply Sirona intraoral sensors and their USB, WiFi, and Ethernet interfaces.

Using unapproved disinfectants can produce issues with the physical appearance of the product and potentially its operation. These issues include discoloration of product surfaces, loss of legibility on product labels, cracking or chipping of enclosures, or exposure of internal components to disinfecting solution.

2.11 Electrostatic discharge

Protective measures

ESD stands for **E**lectro**S**tatic **D**ischarge.

Electrostatic discharge from people can damage electronic components when the components are touched. Damaged components usually have to be replaced. Repairs must be performed by qualified personnel.

Measures to protect against ESD include:

- Procedures to avoid electrostatic charging via
    - air conditioning
    - air humidification
    - conductive floor coverings
    - non-synthetic clothing
- discharging the electrostatic charges from your own body through contact with
    - a metallic unit casing
    - a larger metallic object
    - any other metal part grounded with the protective earth
- Wearing an antistatic band that creates a connection between the body and a protective ground wire.

Areas at risk are indicated on the unit with the ESD warning label:

We recommend that all persons working with this system are made aware of the significance of the ESD warning label. A training course should also be held to inform users about the physics of electrostatic charges.

Physics of electrostatic charges

An electrostatic discharge requires prior electrostatic charging.

There is a danger of electrostatic charges building up whenever two bodies rub against each other, e.g. when:

- walking (soles of shoes against the floor) or
- moving (chair casters against floor).

The amount of charge depends on several factors. The charge is:

- higher at low air humidity than at high air humidity, and
- higher with synthetic materials than with natural materials (clothing, floor coverings).

The following rule of thumb can be applied to assess the transient voltages resulting from an electrostatic discharge.

An electrostatic discharge is:

- perceptible at 3,000 V or higher
- audible at 5,000 V or higher (cracking, crackling)
- visible at 10,000 V or higher (arc-over)

The transient currents resulting from these discharges have a magnitude of over 10 amps. They are not hazardous for humans because they last for only several nanoseconds.
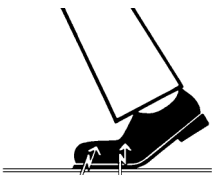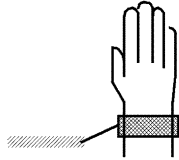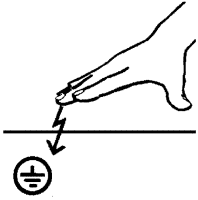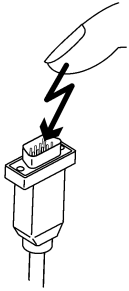
Note: nanosecond = 1/1,000,000,000 second = 1 billionth of a second

Voltage differentials exceeding 30,000 volts per centimeter may lead to a charge transfer (electrostatic discharge, lightning, spark-over).

Integrated circuits (logical circuits and microprocessors) are used in order to implement a wide variety of functions in a device. The circuits must be miniaturized to a very high degree in order to include as many functions as possible on these chips. This leads to structure thicknesses as low as a few ten thousandths of a millimeter. Integrated circuits that are connected to wires leading externally are therefore particularly at risk from electrostatic discharge.

Even voltages that are imperceptible to the user can cause breakdown of the structures, thus leading to a discharge current that melts the chip in the affected areas. Damage to individual integrated circuits may cause malfunction or failure of the unit.

3 System description

3.1 System structure
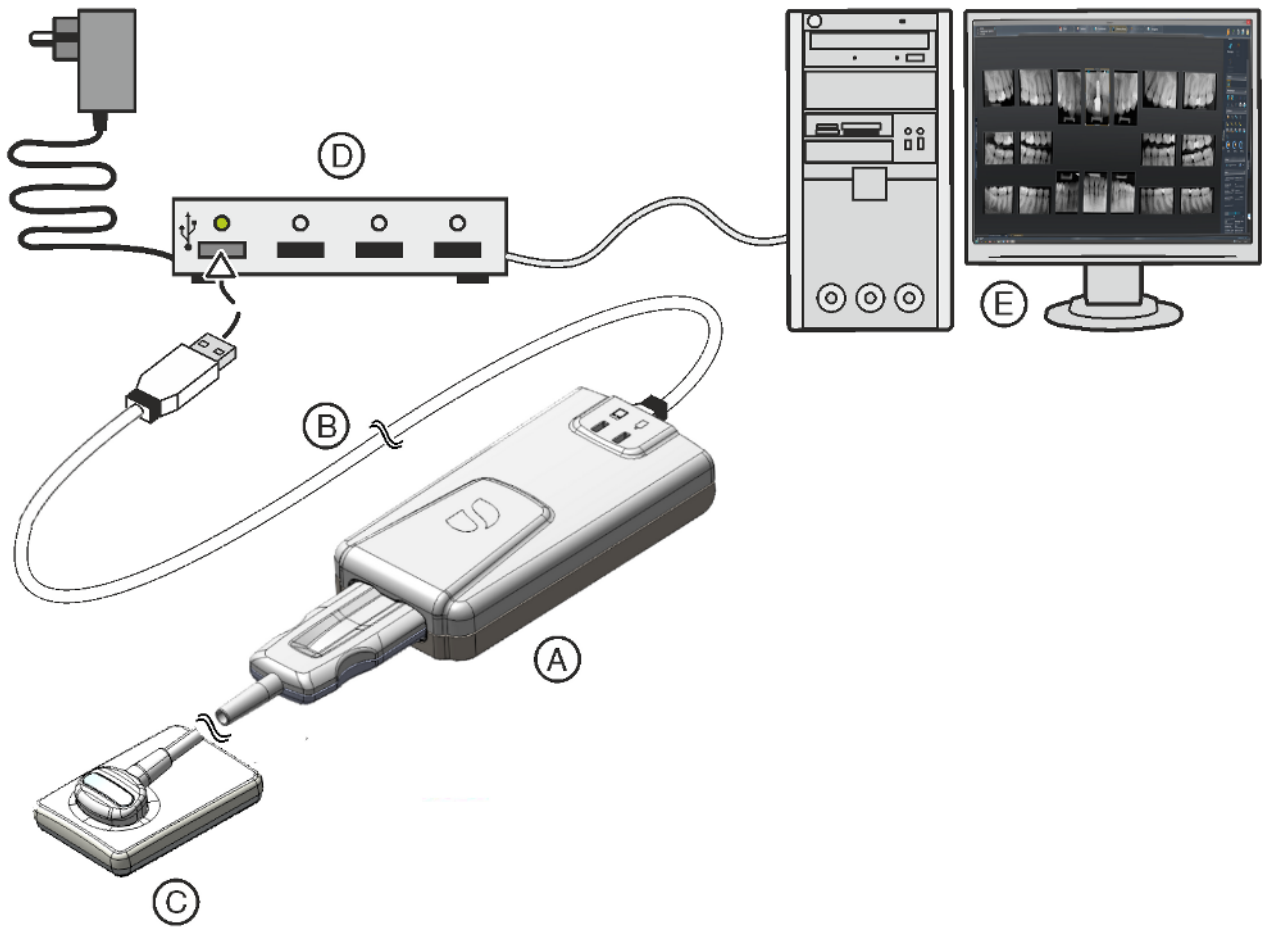
A	USB interface
B	USB cable
C	Sensor (size 0, 1 or 2) with cable and plug
D	USB hub (optional)
E	Sidexis PC with • Sidexis 4 version 4.3 or higher • Sidexis 4 Sensor Plugin

3.2 USB interface

The AE Sensor USB interface is connected between the sensor and the PC. Image data is transferred to a PC via the AE Sensor USB interface and USB cable. The interface also provides important feedback on the status of the imaging system through its LEDs.
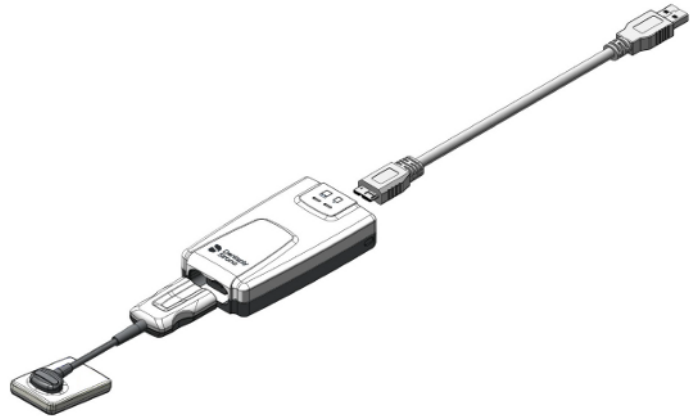
3.3 USB cable

A special USB cable is supplied. It provides a USB 3.0 series "A" connection (A) to the PC workstation and a USB 3.0 "micro-B" connection (B) to the USB module. The USB cable conforms to USB 2.0 and USB 3.0 standards and is designed especially for use with Xios AE.

⚠ CAUTION
Standard commercial USB cables do not offer adequate protection from electromagnetic interference.
➢ Only use the special USB cable supplied by Dentsply Sirona.

3.4 USB hub (optional)

The AE Sensor USB interface can be connected to the USB port of a PC either directly or via an active USB hub. An active USB hub is only required if there is inadequate power supply via the USB port of the PC.

The USB hub is not included in the scope of supply. It must meet the following requirements:

Type of protection against electric shock:	Protection class II ▣
USB standard:	2.0 and 3.0
Power supply:	Separate power supply (**not** bus-powered!)
Safety:	The USB hub must comply with standard IEC 62368-1 or be certified by a testing laboratory which requires compliance with this standard (e.g. VDE, UL, CSA)

3.5 Sensors

Xios AE sensors are available in three sizes (0, 1 and 2).
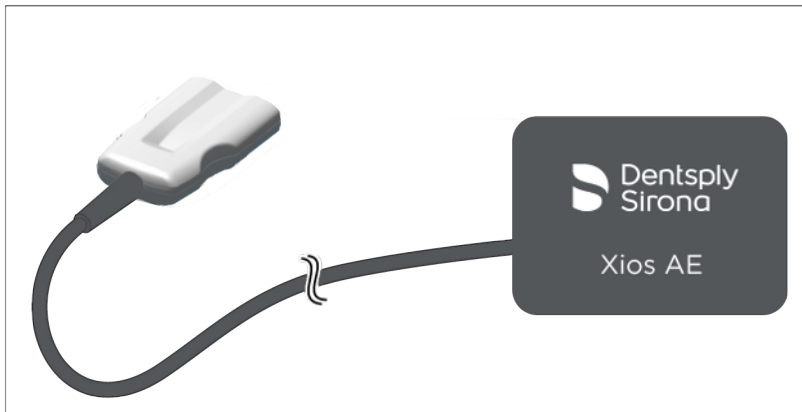
By using Xios AE sensors enhanced image processing functions are available to you in Sidexis 4 through special filters. Depending on the indication you can apply the corresponding filter to the X-ray image in order to amplify the relevant structures. Information regarding the filters can be found in this document.

3.6 Sensor holder systems

3.6.1 Single-use sensor holder system

There are different sensor holders available depending on the type of exposure. The localizer rings and sensor holder tabs are color-coded.
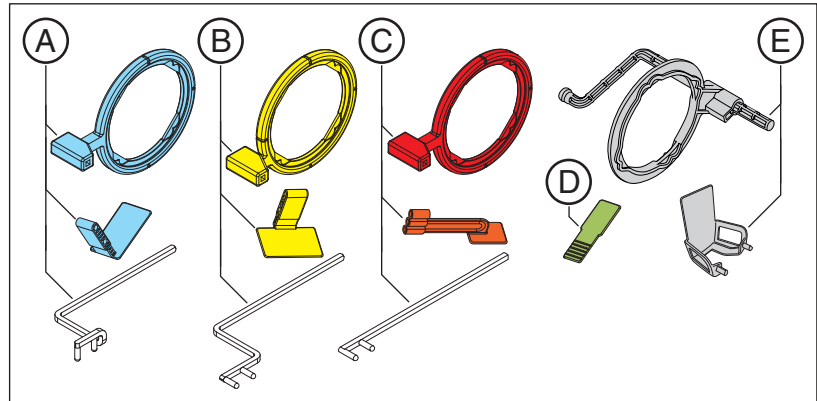
A	Blue for anterior tooth exposure
B	Yellow for posterior tooth exposures
C	Red for bite wing exposures
D	Green for endodontics exposures with the half-angle technique
E	Grey for endodontics (measurement exposure)

3.6.2 Aimright reusable sensor holder system

There are different sensor holders available depending on the type of exposure. The sensor holders are color-coded.

The same localizer ring is used for all sensor holders.

The sensor holders are available for sensor sizes 1 and 2.
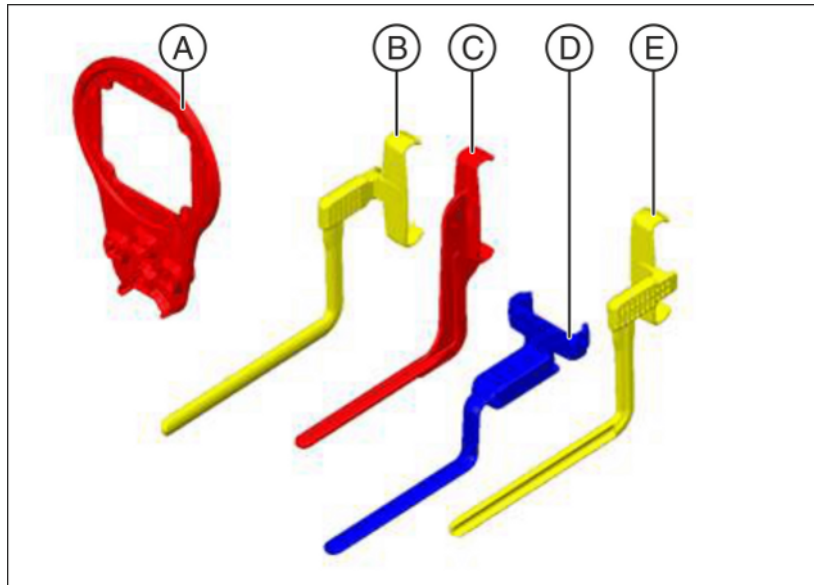
A	Localizer ring
B	Sensor holder for posterior tooth exposures right upper jaw / left lower jaw, yellow
C	Sensor holder for bite wing exposures, red
D	Blue for anterior tooth exposures, blue
E	Sensor holder for posterior tooth exposures left upper jaw / right lower jaw, yellow

3.7 Intraoral X-ray tube assembly

The following requirements apply to the intraoral X-ray tube assembly:

Intraoral X-ray tube assembly with multipulse technology (direct current) 0.14 – 1.4 mAs at 60 – 70 kV and 8" cone

This information must be modified accordingly for other tube lengths or single-pulse X-ray tube assemblies.

For optimal image quality we recommend using a multipulse X-ray tube assembly with a 12"cone.

IMPORTANT
The intraoral X-ray tube assembly must be installed in accordance with the manufacturer's instructions and requirements. Please follow the manual for your X-ray tube assembly.

3.8 PC system

The digital X-ray exposures are transferred to a PC via a USB port.

In addition to Sidexis 4 the Sidexis 4 Sensor Plugin must be installed. Information on the PC software can be found in the "Sidexis 4 Sensor Plugin Operator's Manual".

Minimum PC requirements for Sidexis 4:

Processor:	> 2 GHz DualCore
RAM:	> 4 GB
Free hard disk storage:	> 5 GB for Sidexis 4 installation and database
Removable medium:	CD/DVD drive
Graphics card:	> 512 MB
Screen:	suitable for diagnostics applications, e.g. in accordance with DIN 6868-57
Resolution:	1280 x 1024 pixels
Network card:	Network RJ45, 100 MBit/s
USB port:	in accordance with USB 2.0 and USB 3.0 standard or higher

The following operating systems are supported:
- Windows 7 Professional SP 1 (32-bit and 64-bit)
- Windows 8.1 Professional (64-bit)
- Windows 10 Professional (64-bit)

The following software is needed for Xios AE:
- Sidexis 4 version 4.3 or higher
- Sidexis 4 Sensor Plugin version 2.0 or higher

3.9 Technical data

AE Sensor USB interface

Electric class:	Protection class II ▢
Type of protection against electric shock:	Applied part type **BF**
Degree of protection against ingress of water:	Usual device (without protection against ingress of water), corresponds to protection class IPX0
USB port:	Version 2.0 and 3.0
Operating voltage:	5 V DC Device is supplied with power via the USB connection of the PC.
Supply current:	0.5 A
Power consumption:	1.25 W
Maximum USB cable length:	5 m
Dimensions L x W x H:	107 x 62 x 28 mm
Weight:	approx. 50 g

Xios AE Sensors

Technology:	CMOS-APS (Active Pixel Sensor)
Physical pixel size:	15 µm, image acquisition in 15 µm
Line pairs:	33.3 lp at 15 µm
Measured resolution:	28 Lp/mm
Theoretical resolution:	33.3 Lp/mm
Active sensor area:	Size 0 - sensor = 18 x 24 mm Size 1 - sensor = 20 x 30 mm Size 2 - sensor = 25.6 x 36 mm
External dimensions:	Size 0 - sensor = 19.4 x 28.2 x 7.5 mm Size 1 - sensor = 21.5 x 34.2 x 7.5 mm Size 2 - sensor = 27.1 x 40.2 x 7.5 mm
Cable length:	max. 2.70 m

Operating and transport conditions

Mode of operation:	Continuous operation
Additional information:	The unit must not be used near flammable anesthesia gas mixtures containing air, oxygen or nitrogen oxide.
Transport and storage conditions:	Temperature: -25 °C (-13 °F) to 70 °C (158 °F) Relative humidity: 20 % to 85 % Air pressure: 500 to 1060 hPa

Operating conditions:	Temperature: 10 °C (50 °F) to 35 °C (95°F)
	Relative humidity: 20 % to 85 %
	Air pressure: 700 to 1060 hPa
Operating altitude:	≤ 2000 m

3.10 Certification and standards

The Xios AE sensor and the AE Sensor USB Interface comply with the following standards, among others. They comply with the requirements of these regulations.

EMC / safety

- IEC 60601-1 (Standard for Safety Medical Electrical Equipment - Part 1: General Requirements for Safety)
- IEC 60601-1-1 (Medical electrical equipment - Part 1-1: General requirements for safety; 1. Collateral standard: Safety requirements for medical electrical systems)
- IEC 60601-1-2 (Medical electrical equipment - Part 1: General requirements for safety; 2. Collateral standard: Electromagnetic compatibility - Requirements and tests)

Quality

- AAMI TIR12:2004 (Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers)
- CAN/CSA C22.2 No.601.1-M90 (Medical Electrical Equipment - Part 1: General Requirements for Safety)

CE 0413

This product bears the CE mark in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices.

Original language of the present document: English

3.11 Symbols
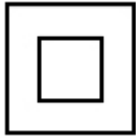
Unit with protection class II in accordance with IEC 60601-1

Type BF applied part according to IEC 60601-1

This symbol indicates the need for the user to consult the instructions for use.

CE mark in accordance with Council Directive 93/42/EEC, stating the manufacturer's Notified Body.

This identification signifies fulfillment of the requirements of the national standards of the USA and Canada.

Year of manufacture and manufacturer address

Denotes sterilizable accessories.

Item is approved for single use only.

Refers to Directive 2002/96/EC and EN 50419
Do not dispose of device with domestic waste

3.12 Position of the labels

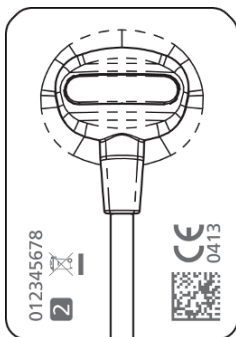The following labels are attached to components of the Xios AE USB system:

AE Sensor USB interface

AE Sensor (size 2 shown)

Sensor cable

4 Operation

4.1 Determine unit status

The AE Sensor USB interface features two LEDs. They indicate the unit status.

Connection Status LED Indications

Interface	Connection status LED	Description
Not Connected	Off	Cable is not connected. Check cable connection to PC.
Connected	Amber	USB Interface is connected and powered but no connection to imaging software is detected.
Connected	Green	USB Interface is connected and powered and connection to PC is detected.
Connected	Green "breathing"	Ready for acquisition.
Connected	Green "pulsing"	Sidexis server not configured (from Sensor Plugin Configuration page).

Sensor Status LED Indications

Sensor	Sensor status LED	Description
Not Connected	Off	Sensor is not connected. Connect sensor and start Sidexis 4 (or other imaging program).
Connected	Amber	Error condition, such as incompatible sensor.
Connected	Green	Xios AE sensor and USB Interface are connected. Sidexis is configured properly and has detected the USB Interface. Start Sidexis 4 (or other imaging program).
Connected	Green "flashing"	USB Interface is transferring image from sensor to PC. LED flashes for duration of the image transfer.

4.2 Connect the sensor

4.2.1 Connect sensor and USB interface

To connect the sensor and the USB interface, please perform the following steps:

1. Connect the USB interface to the USB port of a PC either directly or via a USB hub. When attached, the Connection status LED on the USB interface displays a green indication.
2. Connect the sensor to the USB interface. When attached, the Sensor status LED on the USB interface also displays a green indication.

4.3 Register the patient

To register a patient in Sidexis 4, please perform the following steps:

✓ Sidexis 4 is open and running.

1. Click on the *"Patient:"* button in the phase bar.
2. Click on the desired patient in the patient list.
3. Click the *"Register and exposure"* button to prepare the software for a new exposure.
   ⇨ Sidexis 4 software enters the Exposure phase.
4. Select the Xios AE sensor in the device screen.

4.4 Slide the hygienic protective sleeve over the sensor

Hygienic protective sleeves for use with Xios AE sensors are available depending on the size of the sensor (0, 1 or 2).

To reorder the hygienic protective sleeves, see "Consumables and spare parts."

⚠ WARNING
Sensors and sensor cables must be disinfected prior to initial use.
Patients may become sick due to components that have not been disinfected.
➢ Remove the sensor connector from the unit.
➢ Clean the sensor and the sensor cable thoroughly with disinfectant at least twice. Refer to Hygiene.

⚠ WARNING
The hygienic protective sleeves and sensor holder tabs are single use devices.
Patients may become sick due to unsterilized accessories.
➢ Replace the hygienic protective sleeves and sensor holder tabs after each patient. However, they can be used multiple times on the same patient. The adhesive on the sensor holder tabs is suitable for gluing and detaching them from the hygienic protective sleeve repeatedly.
➢ Under no circumstances should you slide a hygienic protective sleeve over a sensor where a sensor holder tab is already glued on it.
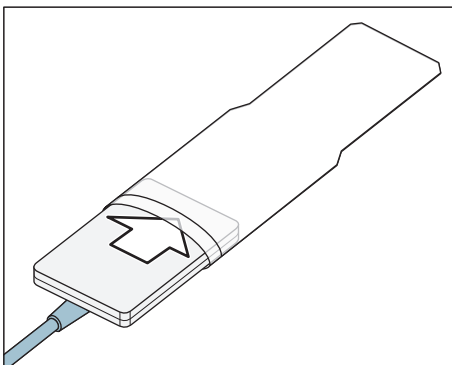
1. Please select a hygienic protective sleeve with a size that matches the sensor.
2. Slide the sensor into the hygienic protective sleeve.
   ↳ The hygienic protective sleeve is slightly undersized, so that it surrounds the sensor tightly and prevents the sensor from slipping out of place.

4.5 Enable exposure readiness

4.5.1 Select a template

Templates (or exposure series) are available in Sidexis 4, enabling clinicians to perform multiple intraoral X-ray exposures on the same patient without repeating some steps manually. Templates are available in Sidexis 4 for different intraoral exposure series (A).

Example of selecting an exposure series

There are two types of templates:

- A template in which *exposures of different anatomical regions* are acquired, e.g., for *"Bitewings"*.
- A template in which several *exposures of the same anatomical region* are acquired, e.g., for *"Vertical Endo"*.

When using a template, exposure readiness resumes after each exposure without any further user interaction. This can be a great advantage in terms of efficient workflow, or if the PC and X-ray sensor are located in different rooms.

4.5.1.1 Example of taking an image (series)

✓ The Sidexis 4 Sensor Plugin is installed.
✓ The patient is registered.
✓ The *"Exposure"* work phase is opened.
✓ An intraoral device (such as Xios AE) is selected.

Work phase "Exposure" with selected intraoral sensor

1. Select the *"Bitewings"* template (A).
2. Enter the indication (B).
3. Click on the *Start Acquisition* button.
   - ✎ The *"Bitewings"* series opens.
   - ✎ The first exposure window changes from red to green, indicating that the sensor is ready for an exposure.
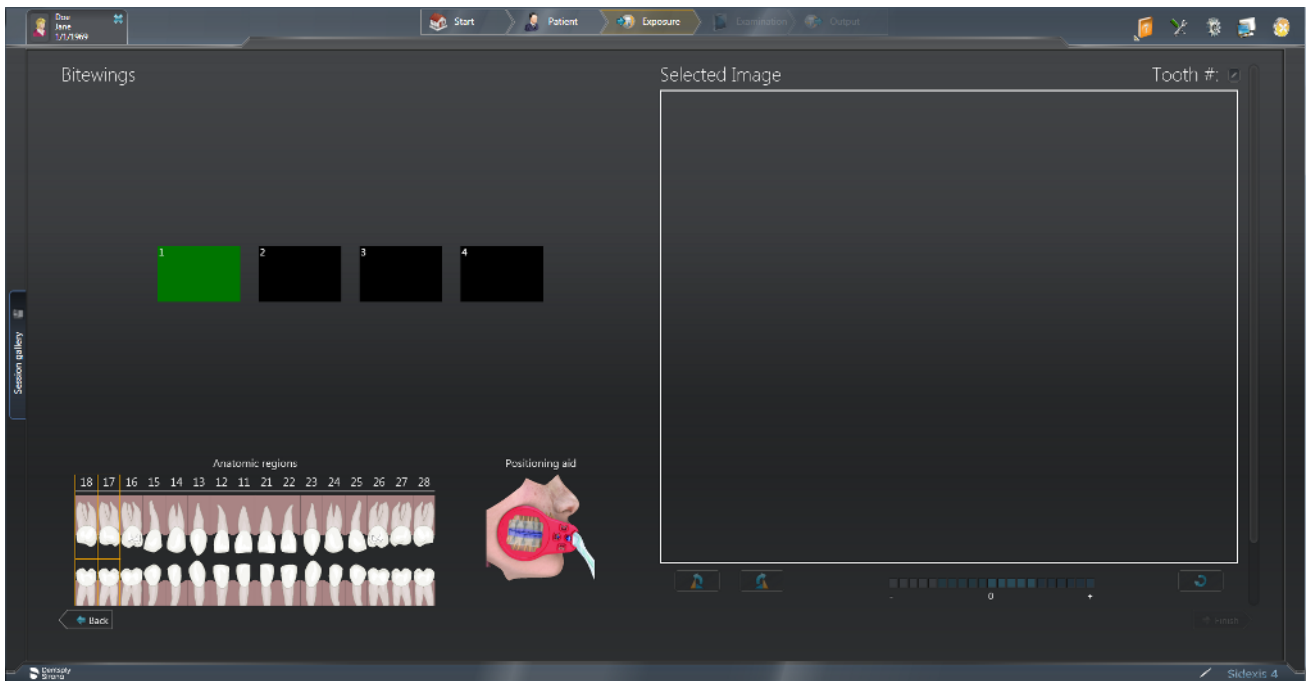
"Bitewings" exposure series

4. Take the X-ray exposure.
   ⮑ Following the exposure, the X-ray image is displayed in the preview window. The next anatomic region is selected (automatically) and the exposure cycle begins again.
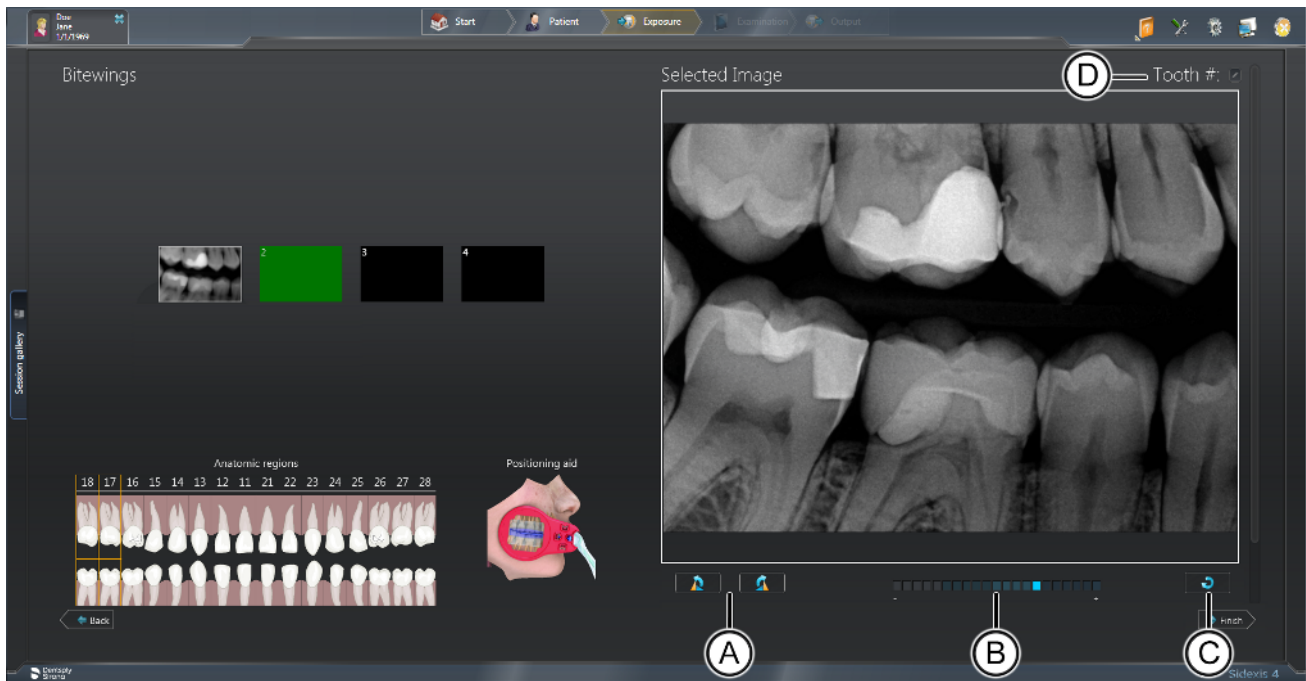
Post-exposure options

IMPORTANT
Other actions are also available after each exposure. These include changing image orientation (A), using the Exposure meter (B), performing an image retake (C), and changing the tooth numbering (D). For more information about these features, refer to the Sidexis 4 Sensor Plugin Operating Instructions

5. Repeat the process until all the exposures have been taken.
6. When you have completed taking the exposures, click *"Finish"* to close the exposure series).
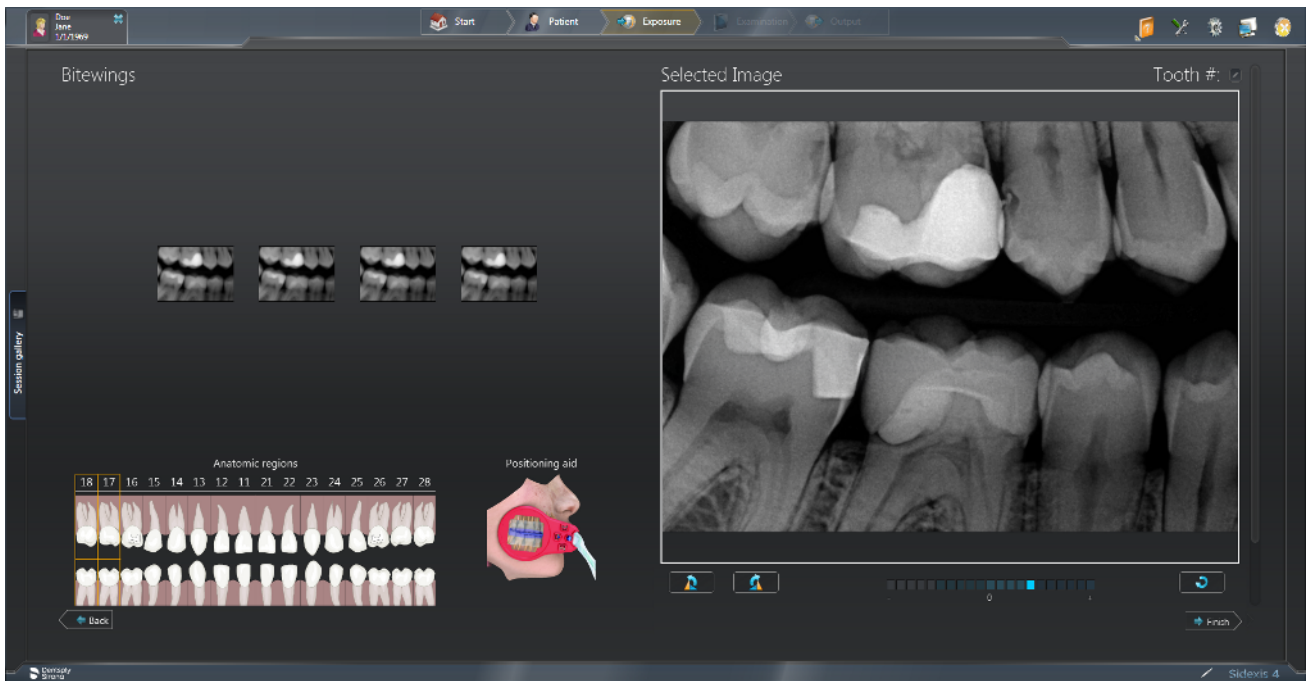
Exposure series complete
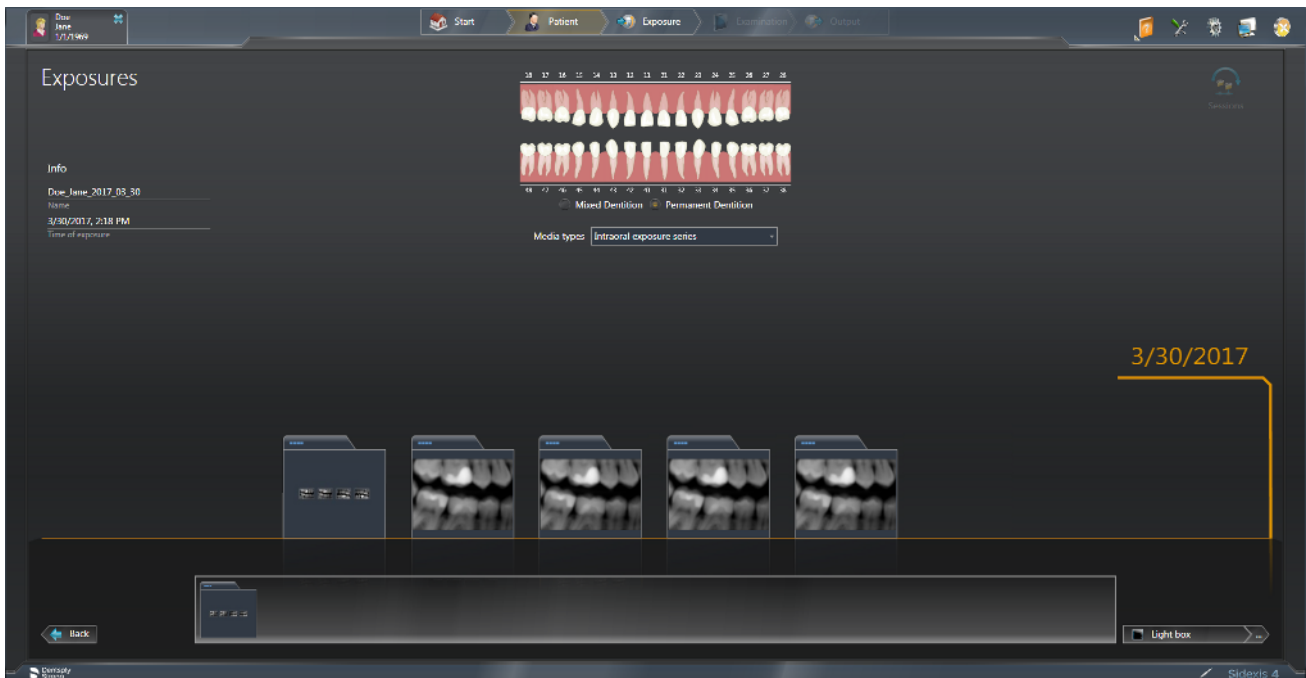
Exposure series (individual images and exam) in the "Timeline"

↪ The individual exposures as well as the exposure series are displayed in the *"Exposures"* view of the *"Timeline"* and can also be re-opened through the *"Light box"*.

4.5.1.2 Repeating an exposure in the series

Performing an image retake — a feature also available in the *"Light Box"* — is available for any image in the current exam at any time. Most commonly, this feature is used immediately after an image is acquired. Some typical reasons for retaking an image would be the result of unexpected patient or sensor movement, adjustment in X-ray settings, or improvement in image placement or quality.

To retake an image, perform the following steps:

1. Click on any image in the Acquisition view.
2. Locate the Retake button below the *"Selected Image"* window and click on it.
3. When the Retake image window is displayed, two exposure windows — *"Current Image"* and *"New Image"* — are shown.
4. *New Image* is just like any empty exposure window selected for imaging. It flashes red initially, as the sensor prepares for an exposure, and flashes green when the sensor is ready.
5. Take the X-ray exposure to acquire the new image.
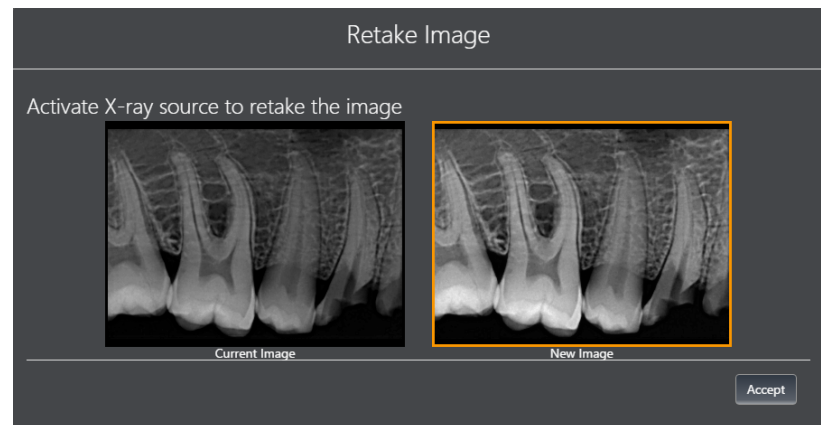
6. Compare and select the desired image and click on the *"Accept"* button. The rejected image is removed from the series, although it is still present in the *"Timeline"*.
   ✎ The selected image is used in the series.
7. Perform other actions in Acquisition view, if any, then click the *"Finish"* button to continue to the *"Light Box"*

4.5.1.3 Canceling an exposure series

An exposure series can be canceled or closed at any time, even if one or more of the exposure windows are not used during the patient exam and do not contain images.
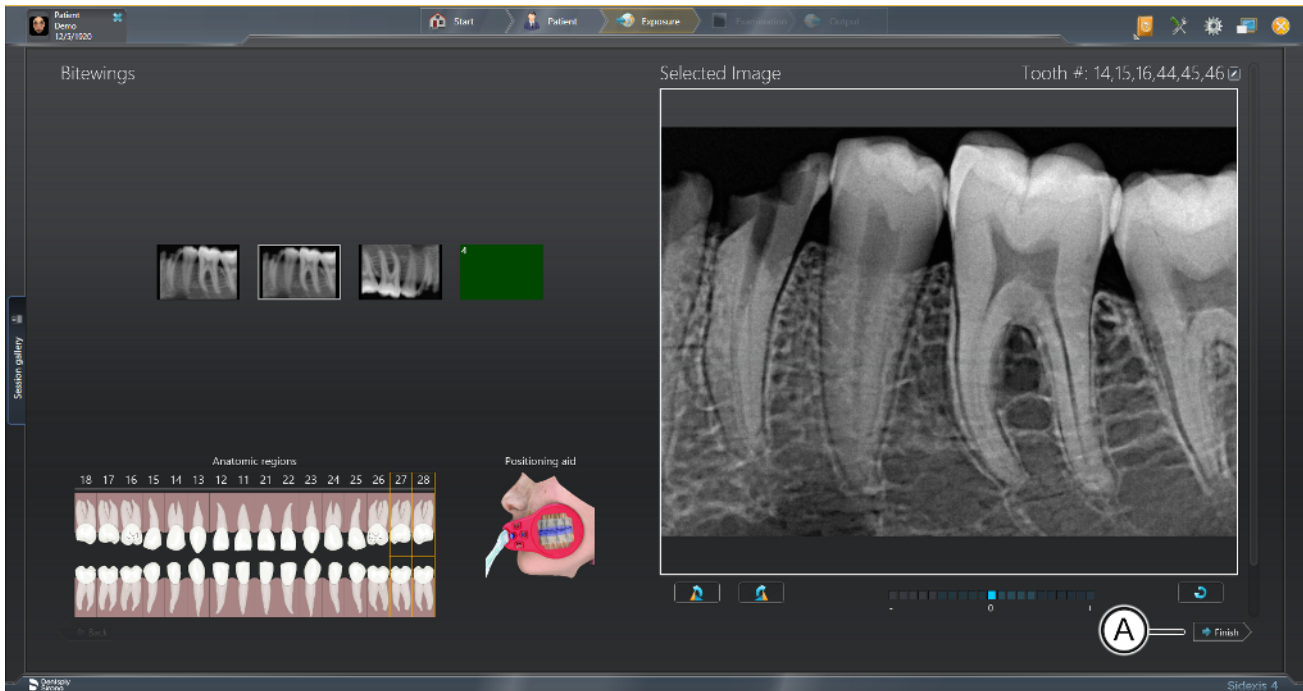
Empty exposure window

➤ Click on the *"Finish"* button (A) to close the exposure series for the patient.

   ↳ The exposure series has been closed.

Empty exposure window in the "Light box"

        ✤ The empty exposure window (B) is displayed in the *"Light box"* of the *"Examination"* work phase along with the exposures that were taken in the series. It is also a placeholder in the event that the series is resumed at a later time.

4.5.1.4 Continuing an exposure series

An exposure series that has been canceled can be continued later at any time.

1. Open the compilation of the exposure series from the *"Timeline"* (see the "Opening exposures for examination" section).

Continuing an exposure series

2. Right-click on the placeholder of the exposure on which you want to continue the exposure series.

3. Click the "*Resume viewset*" button.
   - ✥ If more than one intraoral device is connected or detected, Sidexis will prompt you to select the one you wish to use. If there is only one device, Sidexis will return to the exposure series, ready to take an X-ray image.
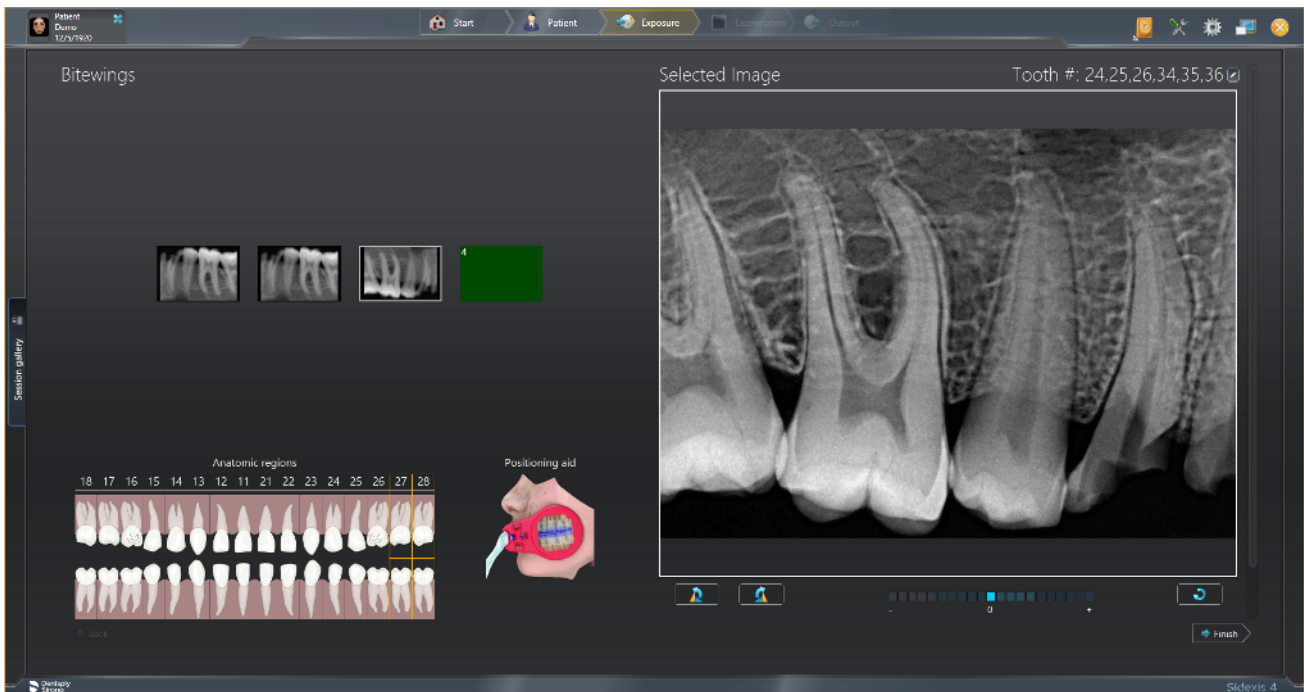
Ready to continue the series

4. Take the X-ray exposure to continue with the exposure series.
   ↳ The exposure series continues.

4.5.2 Templates for the exposure series

Use the menu *"Global tools"* ⇒ *"Exposure"* ⇒ *"Intraoral templates"* to manage the templates for intraoral exposure series, edit and delete templates that have been set up or to create new templates.

NOTE: Standard templates cannot be edited or deleted.

4.6 Position the AE sensor

Since the positioning of the sensors in the beam path of the cone strongly influences the image quality, using the parallel technique with the single use holder system or with the AimRight sensor holder system is recommended for optimal positioning of the sensors.

With the single use holder system the sensor is affixed to the sensor holder with a sensor holder tab. Sensor holder tabs may be detached and reaffixed several times during an exposure series on the same patient. The sensor holder tabs must be glued to the active sensor surface (A) in all cases.

The AimRight sensor holder system is a plug-in system. No sensor holder tabs are required.

Since the positioning of the sensors in the beam path of the cone strongly influences the image quality, using the parallel technique with the Xios AE sensor holders is recommended for optimal positioning of the sensors.

Sensor holder tabs may be detached and re-applied several times during an exposure series on the same patient. The sensor holder tabs must be applied to the active sensor surface (A) in all cases.

Always use a hygienic protective sleeve.
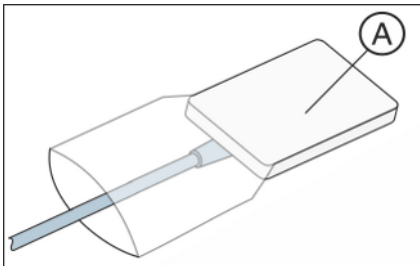
NOTE
The sensor cable is sensitive to mechanical influences.
The cable may become damaged or may wear out prematurely.

➢ Avoid bending, creasing or rotating the cable or exposing it to other strains. Do not ride over the sensor cable, e.g., in a chair. Do not swirl the sensor about by its cable.
➢ When removing the plug pull on the plug and not on the cable.
➢ Make sure that the sensor cable is run out of the patient's mouth in such a way that the patient cannot bite it.
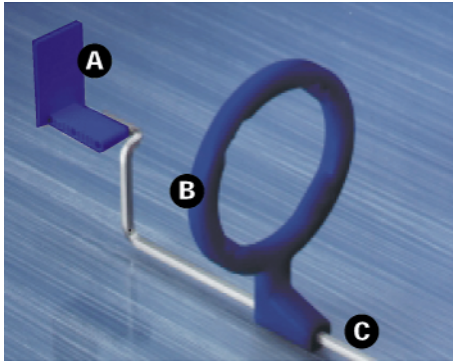➢ Inspect the sensor cable visually for damage every day.

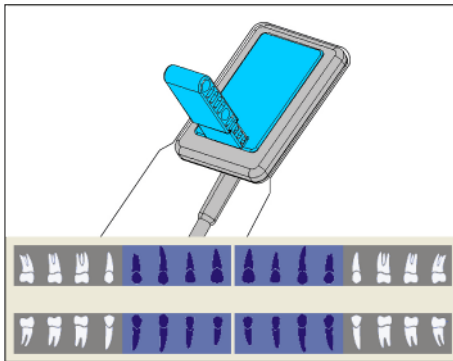| NOTE |
| --- |
| This AE Sensor USB Interface components and the Xios AE sensor must not be exposed to any mechanical influences such as vibrations from impacts or falls. |

4.7 Position sensor with single-use sensor holder system

4.7.1 Anterior tooth exposure

For anterior tooth exposures use the **blue** sensor holder.

1. Place the blue localizer ring (B) onto the **triple-angled** guide rod (C).
2. Place the blue sensor holder tab (A) onto the guide rod (C).
3. Slide the sensor into the hygienic protective sleeve, see section "Slide the hygienic protective sleeve over the sensor".

4. Glue the sensor holder tab onto the sensor's hygienic protective sleeve. Place the tab **in the center** of the sensor as shown in the diagram.

5. Position the sensor in the patient's mouth.
6. Bring the X-ray tube assembly into the correct position and take an X-ray exposure.
7. Remove the sensor from the hygienic protective sleeve. For this follow the instructions in section "Remove the hygienic protective sleeve from the sensor". The used sensor holder tab and hygienic protective sleeve must be disposed of after the examination.
8. Clean and sterilize the guide rod and localizer ring.
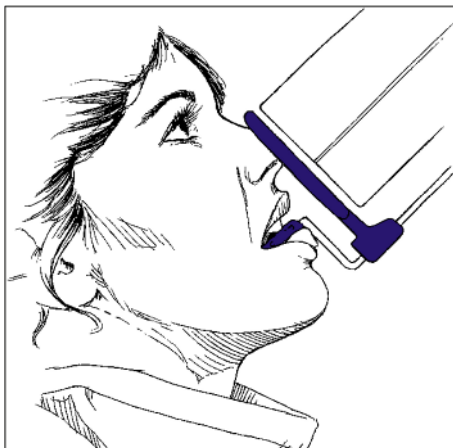
4.7.2 Posterior tooth exposures

For posterior tooth exposures use the **yellow** sensor holder.

1. Place the yellow localizer ring (B) onto the **double-angled** guide rod (C).
2. Place the yellow sensor holder tab (A) onto the guide rod (C).
3. Slide the sensor into the hygienic protective sleeve, see section "Slide the hygienic protective sleeve over the sensor".
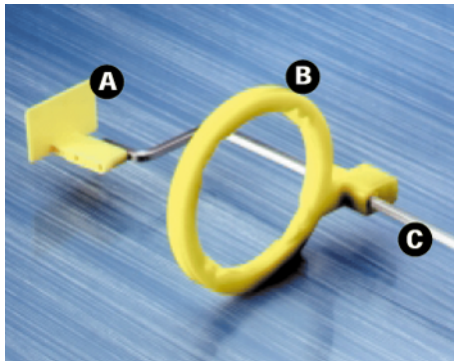
4. **For the left upper jaw and right lower jaw:** Glue the sensor holder tab onto the sensor's hygienic protective sleeve. Place the tab **in the center** on the sensor. The edge of the tab must **lock** with the **edge** of the sensor, as shown in the diagram.

5. **For the right upper jaw and left lower jaw** the sensor holder tab must be placed in the mirrored position. See the adjacent drawing.
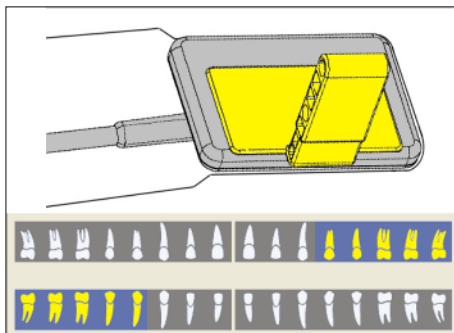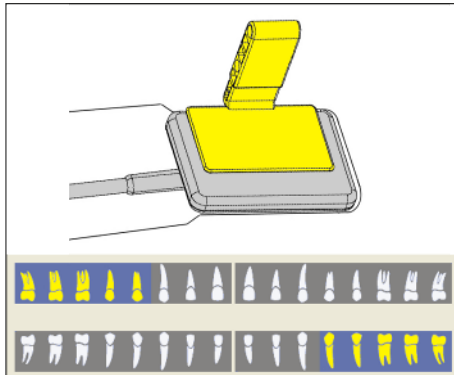
6. Position sensor in patient's mouth.
7. Bring the X-ray tube assembly into the correct position and take an X-ray exposure.
8. Remove the sensor from the hygienic protective sleeve. For this follow the instructions in section "Remove the hygienic protective sleeve from the sensor". The used sensor holder tab and hygienic protective sleeve must be disposed of after the examination.
9. Clean and sterilize the guide rod and localizer ring.

4.7.3 Bite wing exposures
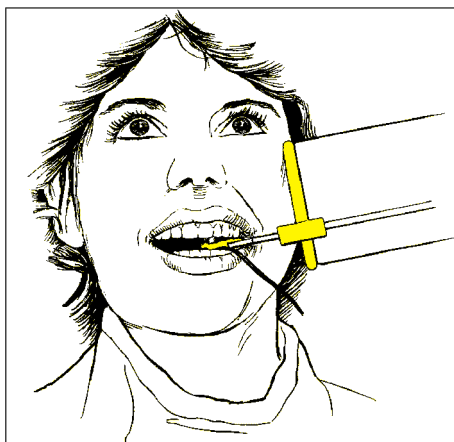
For bite wing exposures use the **red** sensor holder.
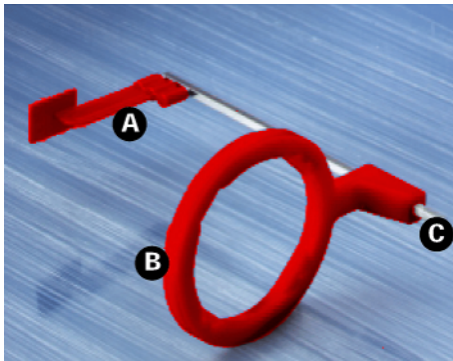
1. Place the red localizer ring (B) onto the **straight** guide rod (C).
2. Place the red sensor holder tab (A) onto the guide rod (C).
3. Slide the sensor into the hygienic protective sleeve, see section "Slide the hygienic protective sleeve over the sensor".
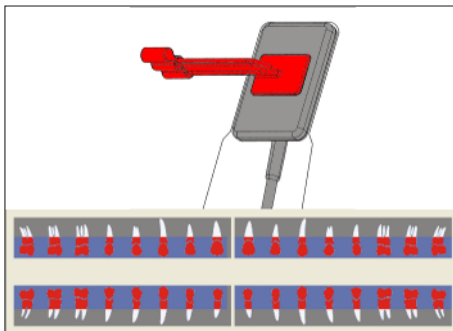
4. **For vertical bite wing exposures:** Glue the sensor holder tab onto the sensor's hygienic protective sleeve. Align the tab **vertically** to the sensor and place it **in the center** on the active sensor surface, as shown in the diagram.

5. **For horizontal bite wing exposures** the tab must be placed aligned **horizontally** to the sensor. See the adjacent drawing.
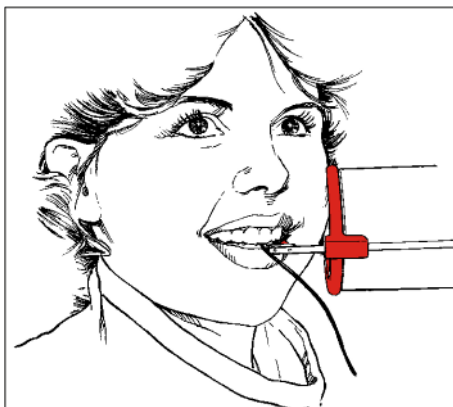

6. Position the sensor in the patient's mouth.
7. Bring the X-ray tube assembly into the correct position and take an X-ray exposure.
8. Remove the sensor from the hygienic protective sleeve. For this follow the instructions in section "Remove the hygienic protective sleeve from the sensor". The used sensor holder tab and hygienic protective sleeve must be disposed of after the examination.
9. Clean and sterilize the guide rod and localizer ring.
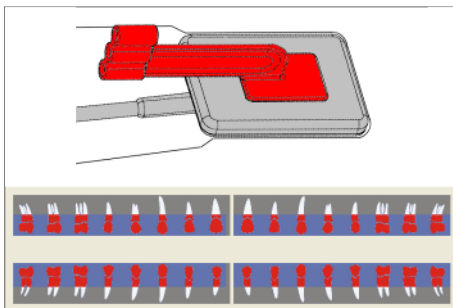
4.7.4 Endodontics exposures with the half-angle technique

For endodontics exposures with the half-angle technique use the **green** universal sensor holder tab.

1. Slide the sensor into the hygienic protective sleeve, see section "Slide the hygienic protective sleeve over the sensor".

2. Glue the green universal sensor holder tab onto the sensor's hygienic protective sleeve. Place the tab **in the center** of the sensor as shown in the diagram.

3. **For anterior tooth exposures:** Glue the sensor holder tab onto the sensor's hygienic protective sleeve. Align the tab **to the sensor edge of the cable** and place it **in the center** on the sensor, as shown in the diagram.
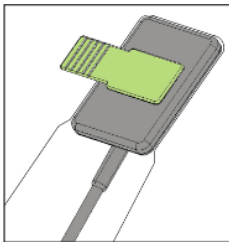
4. **For posterior tooth exposures** the tab must be aligned **vertically** to the sensor and placed **in the center** on the sensor. See the adjacent drawing.

5. Position sensor in patient's mouth.

6. Bring the X-ray tube assembly into the correct position and take an X-ray exposure.

7. Remove the sensor from the hygienic protective sleeve. For this follow the instructions in section "Remove the hygienic protective sleeve from the sensor". The used sensor holder tab and hygienic protective sleeve must be disposed of after the examination.

8. Clean and sterilize the tab.

4.7.5 Measurement exposure for endodontics

Endodontic needles and files can remain in the root canal for the measurement exposure.

For endodontics exposures use the **grey** sensor holder.
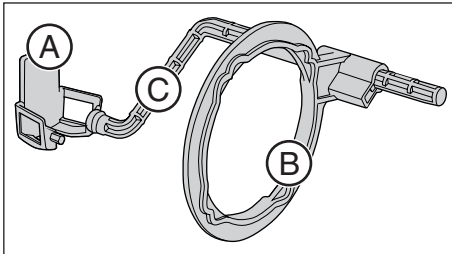
1. Place the grey localizer ring (B) onto the **plastic guide rod** (C).
2. Place the grey sensor holder tab (A) onto the guide rod (C).
3. Slide the sensor into the hygienic protective sleeve, see section "Slide the hygienic protective sleeve over the sensor".

4. Glue the sensor holder tab onto the sensor's hygienic protective sleeve. Place the tab **in the center** of the sensor as shown in the diagram.
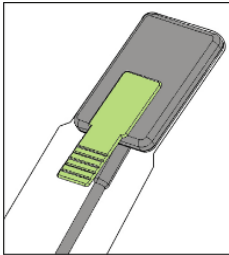5. Position the sensor in the patient's mouth.
6. Bring the X-ray tube assembly into the correct position and take an X-ray exposure.
7. Remove the sensor from the hygienic protective sleeve. For this follow the instructions in section "Remove the hygienic protective sleeve from the sensor". The used sensor holder tab and hygienic protective sleeve must be disposed of after the examination.
8. Clean and sterilize the guide rod and localizer ring.

4.8 Position sensor with AimRight reusable sensor holder system

4.8.1 Anterior tooth exposure

Preparing the sensor holder
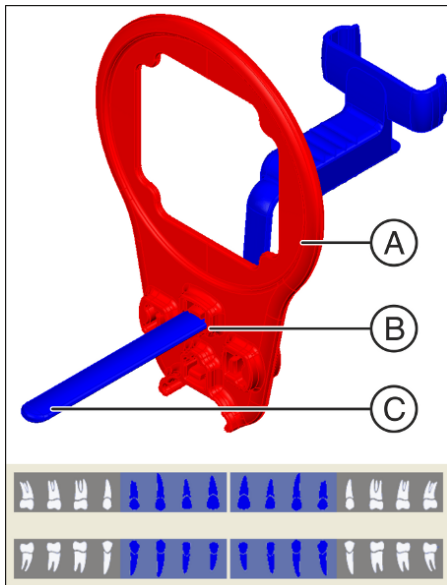
For anterior tooth exposures use the **blue** sensor holder.

1. Fasten the guide rod for the sensor holder (C) in the perforation (B) of the localizer ring (A).
2. Slide the sensor into the hygienic protective sleeve; see "Slide the hygienic protective sleeve over the sensor".

3. To do this, place the sensor on the palm of your hand and clip the sensor holder onto the sensor.

4. Push the sensor into the sensor holder up to the stop.

Positioning the sensor for exposures of the lower jaw

1. Look through the localizer ring to check the alignment of the sensor. The sensor must be located centrally in front of the opening in the localizer ring.
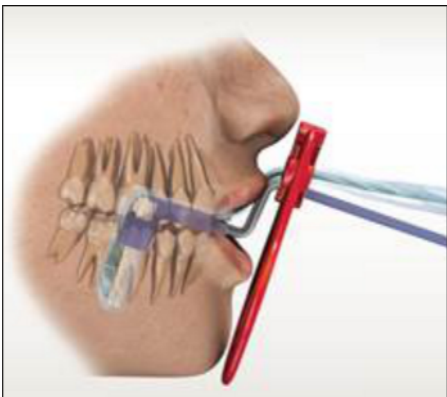

2. Position the sensor in the patient's mouth.
3. Use light pressure to align the sensor so that it lies parallel with the lower front teeth.
4. Ask the patient to close their mouth slowly and bite down on the sensor holder.
5. Slide the localizer ring onto the patient's lips.

6. Align the cone of the X-ray tube assembly parallel to the sensor directly on the localizer ring.
7. Release an X-ray exposure. Refer to sections Select the exposure parameters for the X-ray tube assembly and Releasing the exposure. Also observe the operating instructions for the X-ray tube assembly.

Positioning the sensor for exposures of the upper jaw

1. Look through the localizer ring to check the alignment of the sensor. The sensor must be located centrally in front of the opening in the localizer ring.

2. Position the sensor centrally in the oral cavity without it touching the roof of the mouth.
3. Ask the patient to close their mouth slowly and fix the sensor holder to the cutting edge.
   Tip: A cotton roll on the lower cutting edge stabilizes the sensor holder support and supports parallelism with the bite block on the sensor holder.

   ✍ The sensor is parallel with the upper front teeth.

4. Slide the localizer ring to the patient's face.

5. Align the cone of the X-ray tube assembly parallel to the sensor directly on the localizer ring.

6. Release an X-ray exposure. Refer to sections Select the exposure parameters for the X-ray tube assembly and Releasing the exposure. Also observe the operating instructions for the X-ray tube assembly.

After the exposure

1. Ask the patient to open their mouth.

2. Remove the sensor from the patient's mouth.

3. Remove the sensor from the hygienic protective sleeve. Follow the instructions in the section Removing the hygienic protective sleeve from the sensor. The hygienic protective sleeves must be disposed of after the examination.

4. Clean and sterilize the sensor holder and localizer ring.

4.8.2 Posterior tooth exposures

Preparing the sensor holder

For posterior tooth exposures use the **yellow** sensor holders.
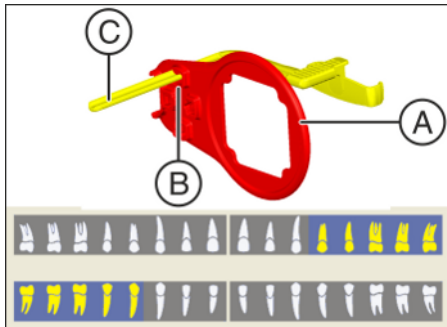
1. **For the right upper jaw and left lower jaw:** Fasten the guide rod for the sensor holder (C) in the perforation (B) of the localizer ring (A).
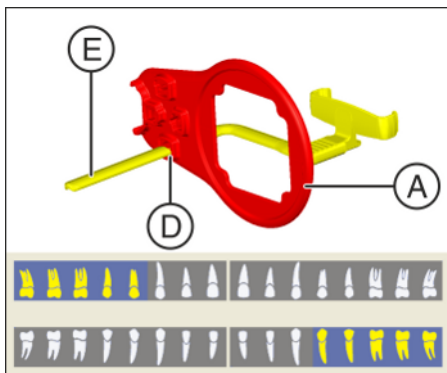
2. **For the left upper jaw and right lower jaw:** Fasten the guide rod for the sensor holder (E) in the perforation (D) in the localizer ring (A).
3. Slide the sensor into the hygienic protective sleeve, see section "Slide the hygienic protective sleeve over the sensor".

4. Place the sensor on the palm of your hand and clip the sensor holder onto the sensor.
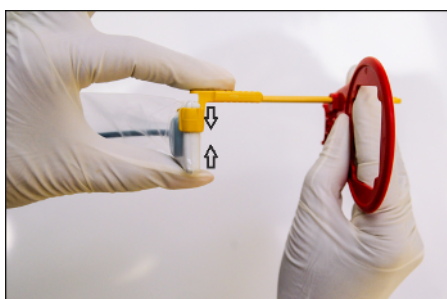
5. Push the sensor into the sensor holder up to the stop.
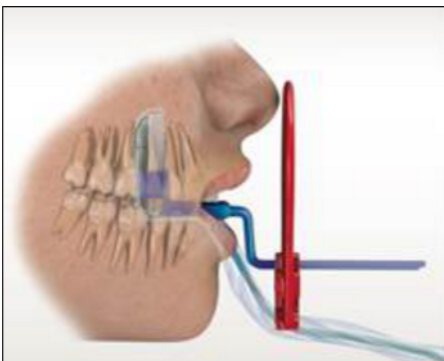
Position the sensor

1. Look through the localizer ring to check the alignment of the sensor. The sensor must be located centrally in front of the opening in the localizer ring.

2. Position the sensor in the patient's mouth and align it so that it is parallel with the posterior teeth.
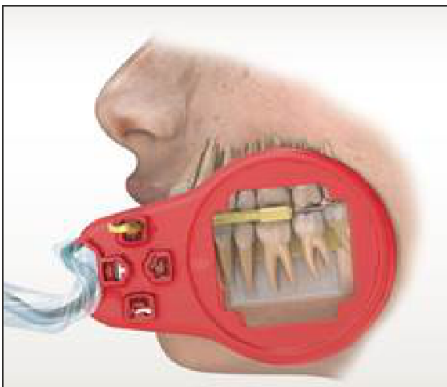
↪ Example: Positioning on the lower jaw

    ✣   Example: Positioning on the upper jaw

3. Align the cone of the X-ray tube assembly parallel to the sensor directly on the localizer ring.

4. Release an X-ray exposure. Refer to sections Select the exposure parameters for the X-ray tube assembly and Releasing the exposure. Also observe the operating instructions for the X-ray tube assembly.

After the exposure

1. Ask the patient to open their mouth.
2. Remove the sensor from the patient's mouth.
3. Remove the sensor from the hygienic protective sleeve. Follow the instructions in the section Removing the hygienic protective sleeve from the sensor. The hygienic protective sleeves must be disposed of after the examination.
4. Clean and sterilize the sensor holder and localizer ring.

4.8.3 Horizontal bite wing exposures

Preparing the sensor holder

For bite wing exposures use the **red** sensor holder.
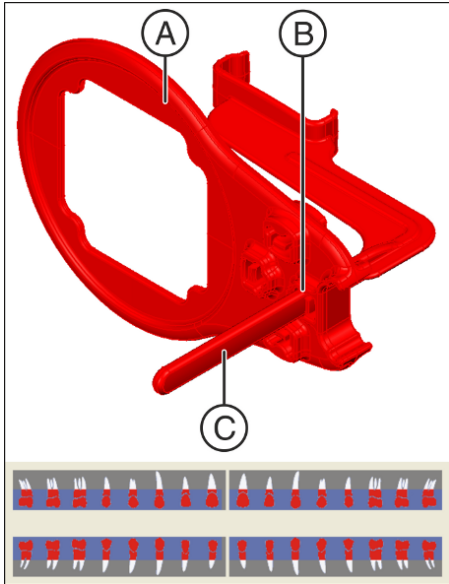
1. Fasten the guide rod for the sensor (C) in the perforation (B) of the localizer ring (A).
2. Slide the sensor into the hygienic protective sleeve, see section "Slide the hygienic protective sleeve over the sensor".

3. Place the sensor on the palm of your hand and clip the sensor holder onto the sensor.
4. Slide the sensor into the center of the sensor holder.
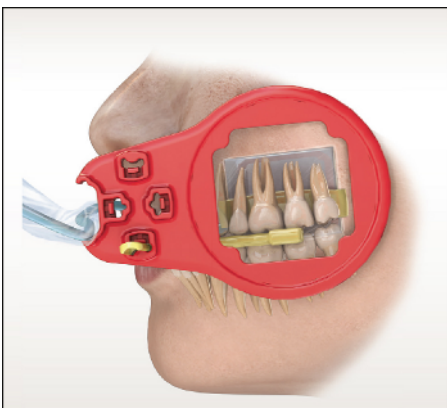
Position the sensor

1. Look through the localizer ring to check the alignment of the sensor. The sensor must be located centrally in front of the opening in the localizer ring.

4 Operation
4.8 Position sensor with AimRight reusable sensor holder system   Dentsply Sirona
Operating Instructions AE Sensor USB interface and Xios AE sensors
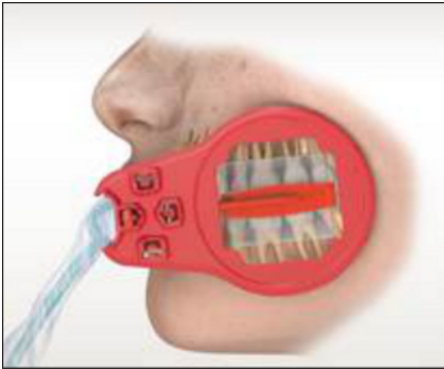
2. Position the sensor directly on the dental arch.
   - ↳ The bite block of the sensor holder must be located between the upper molars, parallel to the occlusal plane.
   - ↳ In order to avoid superimpositions, the sensor must be positioned parallel to the dental arch line.

3. Slide the localizer ring to the patient's face.

4. Align the cone of the X-ray tube assembly parallel to the sensor directly on the localizer ring.
5. Release an X-ray exposure. Refer to sections Select the exposure parameters for the X-ray tube assembly and Releasing the exposure. Also observe the operating instructions for the X-ray tube assembly.

After the exposure

1. Ask the patient to open their mouth.
2. Remove the sensor from the patient's mouth.
3. Remove the sensor from the hygienic protective sleeve. Follow the instructions in the section Removing the hygienic protective sleeve from the sensor. The hygienic protective sleeves must be disposed of after the examination.
4. Clean and sterilize the sensor holder and localizer ring.

4.9 Release the exposure

4.9.1 Selecting the exposure parameters for the X-ray tube assembly

4.9.1.1 X-ray doses and image quality

Factors for determining the X-ray doses

The dose to be set for X-ray exposure depends primarily on the following:

- Type of X-ray tube assembly (manufacturer, AC/DC, etc.)
- Distance between focal spot and sensor
- Morphology of patient
- Object, which tooth is to be X-rayed

The dose is adjusted through tube voltage and tube current (specified by kV/mA) as well as exposure time.

Effects of too low or too high dose

For physical reasons, the lower the dosage value the higher the image noise, which in turn generally leads to a poorer detection of details.

⚠ CAUTION
Image degradations caused by overexposure of the sensor cannot be compensated using subsequent image processing!

Default setting for brightness and contrast

Default settings for brightness and contrast can always be optimally adjusted through the image preprocessing function, independent of dose.

4.9.1.2 Recommended dose for Xios AE sensors

Xios AE sensors have a very wide effective dose area, so that, depending on the object and diagnostic question at hand, the selection of an optimal parameter adjustment is always possible.

IMPORTANT
Since the exposure time depends on the diagnostic problem as well as the respective clinical situation, the selection of an optimal adjustment is the responsibility of the treating physician.

Corresponding values apply to X-ray tube assemblies from other manufacturers and to AC tube units. However, for optimal image quality DC tube units should be used.

Please follow the manual for your intraoral X-ray tube assembly.

4.9.1.3 Heliodent Plus exposure times

4.9.1.3.1 Pre-programmed exposure times for Xios AE sensors with 200 mm (8") FHA cone

0.01	0.02	0.03	0.04	0.05	0.06	0.08	0.10	0.12	0.16	0.20	0.25	0.32	0.40

		0.01–0.04	0.05–0.06	0.08–0.10	0.12–0.16	0.20–0.25	0.32–0.40
(adult)	Upper jaw						
	Lower jaw						
(child)	Upper jaw						
	Lower jaw						

Exposure time in seconds with:	⬇					
60kV		0.06	0.08	0.10	0.12	0.16
70kV		0.03	0.04	0.05	0.06	0.08
Freely programmed values						

4.9.1.3.2 Pre-programmed exposure times for Xios AE sensors with 300 mm (12") FHA cone

0.03 0.80	0.04	0.05	0.06	0.08	0.10	0.12	0.16	0.20	0.25	0.32	0.40	0.50	0.64

		0.03/0.80	0.04	0.05	0.06	0.08	0.10	0.12	0.16	0.20	0.25	0.32	0.40	0.50	0.64
(adult)	Upper jaw										◉ ◉			◉
	Lower jaw								◉		◉			◉
(child)	Upper jaw			◉		◉			◉					
	Lower jaw			◉		◉			◉					

Exposure time in seconds with:	→				
60kV	0.12	0.16	0.20	0.25	0.32
70kV	0.06	0.08	0.10	0.12	0.16
Freely programmed values					

4.9.2 Releasing the exposure

✓ The exposure parameters for the X-ray tube assembly are set. Please refer to "Select the exposure parameters for the X-ray tube assembly".

✓ The sensor is positioned in the patient's mouth with the corresponding auxiliary exposure equipment. Please refer to "Position the sensor".

1. Ensure that the system is ready for exposures. The Connection status LED on the USB interface must display a "breathing" green indication and the Sensor status LED must be solid green. Please refer to Determine unit status

2. Ensure that Sidexis 4 is ready for exposures. The exposure window must be flashing green.

3. Check that the X-ray tube assembly is in the correct position, with the appropriate technique factors, and take the X-ray exposure.

4. Remove the sensor from the hygienic protective sleeve. To do this please follow the instructions in section "Remove the hygienic protective sleeve from the sensor".

5. The used sensor holder tab and hygienic protective sleeve must be disposed of after the examination. The guide rod and localizer ring must be cleaned and sterilized. The sensor must be wiped with disinfectant before it is used for another patient.

6. Following the X-ray exposure, carefully place the sensor on a stable surface or store it to prevent it from damage.

7. Continue with image processing in Sidexis 4.

5 After the exposure

5.1 Remove the hygienic protective sleeve from the sensor

5.1.1 With single-use sensor holder system

Have the sensor holder tab and the sensor holder glued onto the hygienic protective sleeve. This makes it easier to remove the hygienic protective sleeve.

NOTE
The sensor cable is sensitive to mechanical influences.
The cable may become damaged or may wear out prematurely.
➢ Do not pull on the sensor cable when pulling the sensor out of the hygienic protective sleeve. Slide the sensor further out of the hygienic protective sleeve with your thumb as described below.
➢ Avoid bending, creasing or rotating the cable or exposing it to other strains.

1. Grasp the guide rod in one hand so that you can touch the side of the sensor facing away from the sensor cable with your thumb.

2. Carefully push the sensor out of the part of the hygienic protective sleeve that is glued to the sensor holder tab with your thumb.

3. Slide the sensor further out of the hygienic protective sleeve with your thumb.

4. Hold the sensor cable firmly to prevent the sensor from falling out of the hygienic protective sleeve.

5.1.2 With Aimright reusable sensor holder system

NOTE
The sensor cable is sensitive to mechanical influences.
The cable may become damaged or may wear out prematurely.
➢ Do not pull on the sensor cable when pulling the sensor out of the hygienic protective sleeve. Slide the sensor further out of the hygienic protective sleeve with your thumb as described below.
➢ Avoid bending, creasing or rotating the cable or exposing it to other strains.
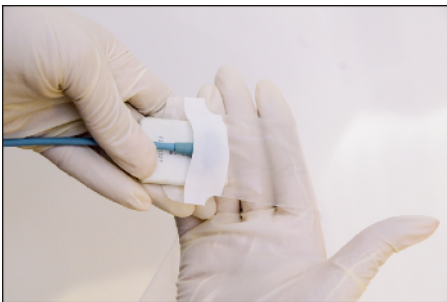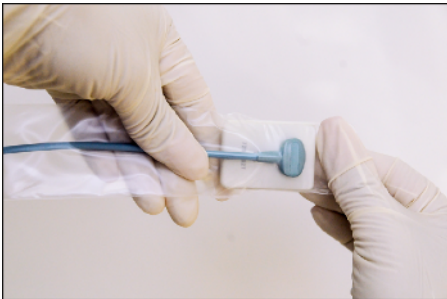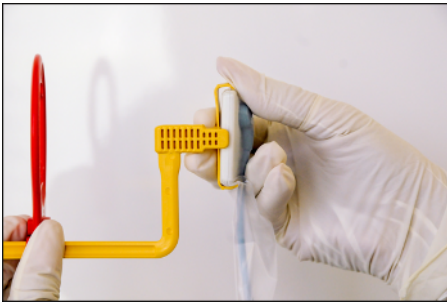
1. Remove the sensor with the hygienic protective sleeve from the sensor holder. To do this, open up the sensor holder by pressing gently on one side as shown in the figure.

2. Carefully push the sensor out of the narrow part of the hygienic protective sleeve with two fingers.
3. Slide the sensor further out of the hygienic protective sleeve.

4. Hold on to the sensor and remove it from the hygienic protective sleeve.

6 Edit exposures

6.1 Edit exposures in X-ray series

6.1.1 Swapping images

Swapping is a simple drag-and-drop action so you can move an image to a different exposure window in the same series or to swap two images in different exposure windows.

To swap images, please perform the following steps:

✓ There is at least one image in the series and one or more additional exposure windows.

1. In the Acquisition view, select an image to be swapped to a new position by clicking on it.
2. While holding the mouse button down, start moving the image to its new exposure window.
   ↳ As the image moves from its current position, the exposure window outline changes to orange.
   ↳ When the image reaches its new position, the exposure window outline will change to blue, indicating that this exposure window is selected as the new destination for the image.
3. Release the mouse button to finish swapping.
   ↳ If the destination exposure window contains an image, the two images will swap positions. If the destination exposure window is empty, the image will move to this new position
4. Perform other actions in Acquisition view, if any, then click the *"Finish"*button to continue to the *Light box*.

6.1.2 Rotating images 90°

Changing the orientation of the acquired image — a feature also available in the *"Light Box"* — is possible using the appropriate buttons located below the *"Selected Image"* window.

To change the image orientation, please perform the following steps:

✓ There is at least one image in the exposure series.

1. Click on an image in the Acquisition view.
2. Change the orientation of the selected image by clicking on the appropriate buttons. Use the direction of the arrow in the icon to reorient the image accordingly.
   ↳ As the image is re-oriented, the smaller viewbox in the template also reflects those changes.
3. Perform other actions in Acquisition view, if any, then click the *"Finish"* button to continue to the *Light box*.

6.1.3 Changing tooth numbers

Changing tooth numbers — a feature also available in the *"Light Box"* — is possible using the edit button located after any *Tooth #* assignments. It is also possible to assign new tooth numbers, to change the dentition, and to clear any currently assigned tooth numbers.

IMPORTANT
The odontogram located above the *Selected Image* will add, change, or remove dental notations for the teeth in the current series only. This is the odontogram described in the following procedure. In contrast, the odontogram located below the exposure windows reflects the choices and dental notations made on the previous screen, the Indications screen, and indicates the teeth intended for exposure.

To change tooth numbers, please perform the following steps:

✓ There is at least one image in the series.

1. Locate the edit button (after *Tooth #*) and click on it.
   - ↳ When the odontogram is displayed, any currently assigned tooth numbers will be highlighted.
2. Click on any currently assigned tooth number to de-select it. As tooth numbers are de-selected, the *Tooth #* list is updated.
   - ↳ To clear all currently assigned tooth numbers in one action, hover the mouse over the odontogram, and when the clear selection button appears, click on it to remove all currently assigned tooth numbers.
3. Click on any tooth number currently unassigned to add it to the Tooth #" list. As tooth numbers are added, the *Tooth #* list is updated.
4. Change the dentition by clicking on the appropriate button or text label. The standard tooth numbering for the selected dentition is changed automatically.
5. Perform other actions in Acquisition view, if any, then click the *"Finish"* button to continue to the *"Light Box"* .
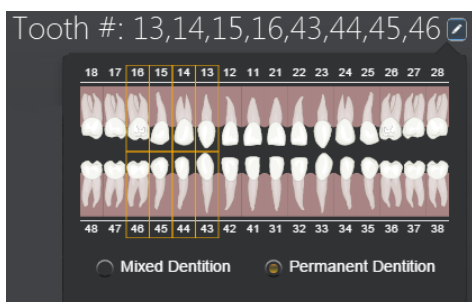
6.1.4 Checking exposure quality

The exposure meter — a feature also available in the *"Light Box"* — is designed to convey exposure quality. Exposure quality is an assessment of an image in a range where exposure is considered optimal.
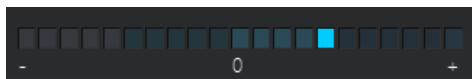
To understand the results from the exposure meter, please refer to the following:

- The middle of the meter ("0") indicates that the image has been exposed optimally for the technique factors that were used.
- At one end of the meter ("-") indicates that the image was underexposed. Adjusting technique factors would improve image quality.
- At the other end of the meter ("+") indicates is that the image was overexposed. Adjusting technique factors would reduce patient dose without reducing image quality.

6.1.5 Retaking images

Performing an image retake — a feature also available in the *"Light Box"* — is available for any image in the current exam at any time. Most commonly, this feature is used immediately after an image is acquired. Some typical reasons for retaking an image would be the result of unexpected patient or sensor movement, adjustment in X-ray settings, or improvement in image placement or quality.

To retake an image, please perform the following steps:

✓ There is at least one image in the series.

1. Click on an image in the Acquisition view.
2. Locate the *Retake* button below the *"Selected Image"* window and click on it.
   - ↳ The Retake image window is displayed, consisting of two exposure windows— *"Current Image"* and *"New Image"*.
   - ↳ *New Image* functions just as any empty exposure window selected for imaging. It flashes red initially, as the sensor prepares for an exposure, and flashes green when the sensor is ready.
3. Check that the X-ray tube assembly is in the correct position and take the X-ray exposure.
4. Select the desired image and click on the *Accept* button. The alternate image is removed from the exam, although it is still present in the *"Timeline"*.
5. Perform other actions in Acquisition view, if any, then click the *"Finish"* button to continue to the *"Light Box"* .

6.2 Edit exposures in Light box

6.2.1 Optimizing images with Xios AE sensors

Specific features for the Xios AE sensors are available in the *"Light Box"*.

To apply a filter enhancement and additional image sharpening, please perform the following steps:

✓ A Xios AE image is open in the *"Light Box"*.

1. Click on the *"Tools"* docking window.
2. In the *Filter* tool kit, expand the *Task* menu and select a filter that provides the appropriate degree of image enhancement.
   ↳ The image reflects the filter setting selected.
3. Adjust the dynamic sharpening slider located below the *Task* menu for further refinement.
   ↳ The image reflects the sharpening value selected.
4. Perform other actions in the *"Light Box"*, as needed.

IMPORTANT
To change the preset task for newly acquired images and sharpness, go to Global tools> Exposure> Intraoral Enhancements (AE).

IMPORTANT
Intraoral Enhancements, like other tools available in the Light box, can be removed by clicking on the recycle container. To restore Intraoral Enhancements, if deleted, click on the Reset feature in the Analysis toolkit.
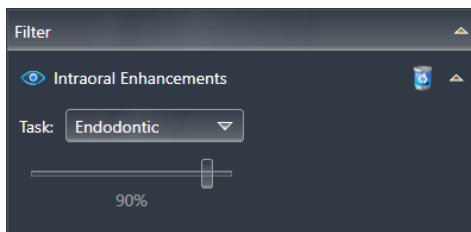
Intraoral Enhancements Filter Panel

6.2.2 Editing exposures with Sidexis 4

Additional tools for image analysis such as brightness, contrast, and Gamma, are available for exposures.

See the Sidexis 4 Operator's Manual concerning this.

6.2.3 Setting image filters

Any enhancement filter can be set as a default and will be applied automatically to the image when it is opened in the *"Light Box"*

✓ Sidexis 4 is open.

1. Click on *"Global tools"* in the upper right area of Sidexis 4.
2. In the *"Exposure"* section, click on the "*Intraoral Enhancements (AE)*" link.
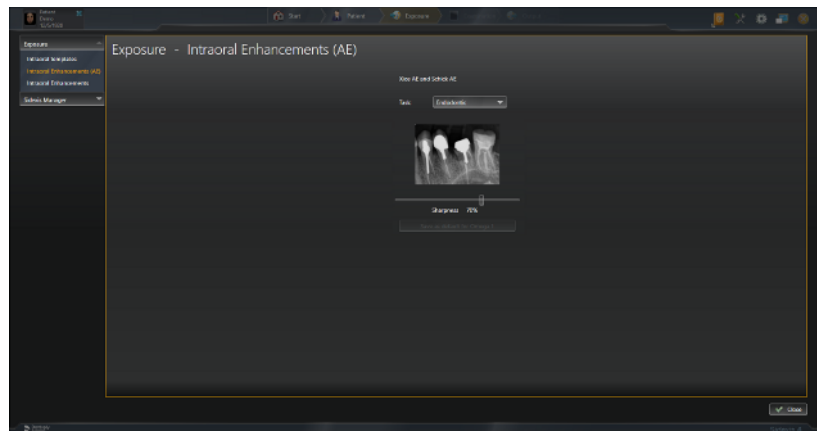
3. Click on the "*Task*" menu to select an enhancement filter that will be used as the new default filter.
4. If you would also like to customize the sharpness level for the selected filter, click on the slider and adjust the image for more or less sharpness.
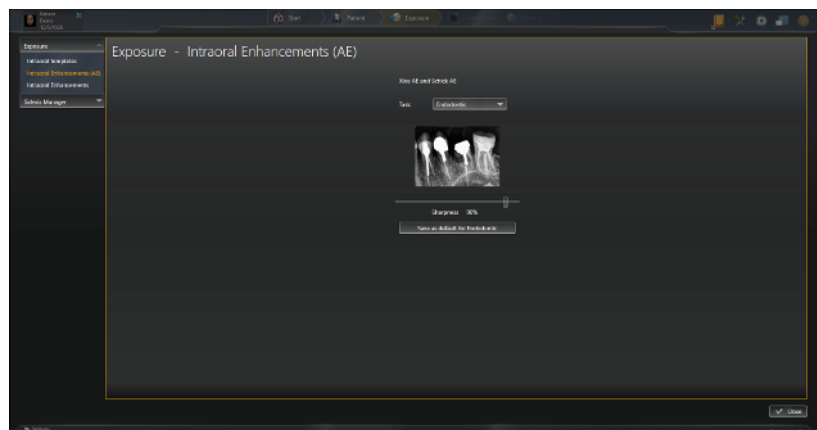
5. When you are satisfied with image sharpness, click on the "*Save as default*" button.
   ↳ The new enhancement filter selection will be saved automatically even if you choose to leave the image sharpening value unchanged.
6. Click *"Close"* to exit.

7 Resend exposures

7.1 Information

During normal use, Sidexis software saves patient data and images to the server and makes them available whenever needed. In some situations, however, communication with the Sidexis server may be disrupted, preventing images from being saved properly.

Several reasons can cause this issue, but the most common include:

- Connection to the Sidexis server is lost
- Network connection is interrupted
- Incorrect software or system configuration.

In the event of a disruption, only images in the current exam would be affected, but the clinician will be able to complete the exam if one was in progress. In a typical recovery the issue is corrected, whatever its cause, and the images are saved automatically without further interaction from the clinician.

If the images could not be saved properly to the server the Sidexis 4 Sensor Plugin will enter Rescue mode. Rescue mode means that there are images that have not been stored in the patient database and further action is needed to resolve the problem. Rather than exposing the patient to additional radiation as a result of these unstored images, the Sidexis 4 Sensor Plugin can be used to rescue them.

A clinician is alerted to Rescue mode by the appearance of a special icon (in Sidexis) on the currently connected sensor, USB Interface, or WiFi Interface. This icon does not indicate a hardware problem with those devices, but the presence of unsaved images requiring user action. Substituting different hardware, by itself, will not resolve the issue.

7.2 Resend images in Rescue mode (recommended)

To rescue unsaved images, please perform the following steps:

✓ Resolve the issue that caused the Sensor plugin to enter Rescue mode.

1. Click on Windows Start menu > All Programs > Sidexis 4 Sensor Plugin.

2. Click on Sidexis 4 Sensor Configuration.

3. Click *"Devices"* at the Sidexis 4 Sensor Configuration page.

4. Select the device in Rescue mode. If several devices are connected, choose the one in Rescue Mode.

5. The Exposure Information area provides the number of unsaved images and patient-related information. Click *"Resend Images"*.

6. When all the images are resent, click *"Finish"*.

↳ The *"Devices"* page will now indicate that the system is ready. No additional recovery steps are needed.

↳ In Sidexis, on the device selection screen, the Rescue icon is removed. If, for some reason, the images cannot be resent, they can still be rescued by exporting them from this page and then importing them manually into Sidexis and saving them in that way. This alternate procedure is described in the following section.

7.3 Export images in Rescue mode (alternate)

To rescue unsaved images by exporting them, please perform the following steps:

✓ This procedure is an alternate approach to rescue images if you are unable to resend them using the recommended procedure.

1. Click on Sidexis 4 Sensor Configuration.
2. Click *"Devices"* at the Sidexis 4 Sensor Configuration page.
3. Select the device in Rescue mode. If several devices are connected, choose the one in Rescue Mode from the drop down list.
4. The Exposure Information area provides the number of unsaved images and patient-related information. Click *"Export Images"*.
5. Click *Save As* to save a zip file of unsaved images to a known location on the workstation
6. Browse for the zip file, select it, and extract the contents.

IMPORTANT
Before importing images into Sidexis, check the patient information box located in the phase bar area. This is the patient to whom the imported images will be assigned.

7. In Sidexis, in the Exposure phase, click *File Import* and browse for the images just extracted.
8. Select the images and click *Open*.
9. The File Information table will list the selected images and their status. Click *Import*.
   ↳ The File Information table will list the selected images and their status.
10. Click Import.
   ↳ The images will open in the *"Light Box"*. They will also be available in the *"Timeline"* for that patient.
11. On the Sidexis 4 Sensor Configuration page, click *"Finish"*. If you have not attempted successfully to rescue images by resending them, which is the recommended approach, this is an opportunity to do so. Otherwise, click *OK* to conclude the rescue procedure.

↳ The *"Status"* will now indicate that the system is ready and no additional recovery steps are needed.

↳ In Sidexis, on the device selection screen, the Rescue icon is removed.

8 Configuration

8.1 Device information

8.1.1 Displaying serial number and firmware

To obtain information about a sensor and USB interface, please perform the following steps:

✓ Verify that the USB Interface and the sensor are connected to the PC workstation.

1. In Sidexis 4 click on *Settings* > *Exposure* > *Devices-2*.
2. At the *Configuration* button, select the device you wish information about.

↳ Serial number information of the sensor and firmware information of the sensor and USB interface are displayed.

8.1.2 Updating USB interface

When new firmware is available, it is typically provided with a software release and becomes part of the update to your existing system. When an update button for the USB Interface is displayed in Sidexis 4, we recommend that you perform the update, following the procedure below.

To update the USB Interface, please perform the following steps:

✓ Verify that the USB Interface and the sensor are connected to the PC workstation.

1. In Sidexis 4 click on *Settings* > *Exposure* > *Devices-2*.
2. Select the configuration button for the USB Interface to be upgraded.

↳ If only the USB Interface is connected, the words *AE USB Sensor Interface* will appear instead of the sensor name. If the sensor is connected also, select the sensor connected to the USB Interface to be upgraded.

3. If the firmware for the USB Interface is up-to-date, no further action is needed. If the *"Update AE Sensor USB Interface"* button is enabled, perform a firmware upgrade by continuing with the following steps.

4. Click on the *"Update AE Sensor USB Interface"* button.

↳ A short message will appear as a reminder to keep all hardware connected during the update.

↳ When the update is complete, another short message will appear to confirm a successful upgrade.

5. Click *OK* to close the message.

↳ USB update is complete and the firmware version displayed.

8.1.3 Updating sensor

When new firmware is available, it is typically provided with a software release and becomes part of the update to your existing system. In the event an update button for the sensor is displayed, we recommend that you perform the update, referring to the procedure below.

To update the sensor, please perform the following steps:

✓ Verify that the USB Interface and the sensor are connected to the PC workstation.

1. In Sidexis 4 click on *Settings > Exposure > Devices-2*.
2. Select the configuration button for the sensor to be upgraded.
   ↳ If only the USB Interface is connected, the words *"AE USB Sensor Interface"* will appear instead of the sensor name. In this case attach the sensor as it must be connected before it can be updated.
3. If the firmware for the sensor is up-to-date, no action is needed. If the *"Update Sensor"* button is enabled, perform a firmware upgrade by continuing with the following steps.
4. Click on the *"Update Sensor"* button.
   ↳ A short message will appear as a reminder to keep all hardware connected during the update.
   ↳ When the update is complete, another short message will appear to confirm a successful upgrade.
5. Click *OK* to close the message.
↳ Sensor update is complete and the firmware version displayed.

8.1.4 Updating from file

This is an alternate method for updating sensors and USB Interfaces. In almost all cases the preferred approach to updating firmware will be to follow the procedures described previously. In specific instances, as directed by support personnel, this method may be appropriate.

This method requires the availability of a special file (in zip format) not normally distributed with the Sidexis 4 Sensor Plugin software. The update from file process will recognize that special file only. All other files will be ignored.

To update from file, perform the following steps:

✓ Verify that the USB Interface and the sensor are connected to the PC workstation.

1. In Sidexis click on *Settings > Exposure > Devices-2*.
2. Select the sensor to be upgraded.
   ↳ If only the USB Interface is connected, the words *"AE USB Sensor Interface"* will appear instead of the sensor name. In this case attach the sensor as it must be connected before it can be updated.
3. Click on *"Choose file..."*
4. Browse to the special zip file containing the appropriate firmware versions for the sensor and USB Interface.
5. Click on the *Update...* button.
   ↳ A short message will appear as a reminder to keep all hardware connected during the update.
   ↳ When the update is complete, another short message will appear to confirm a successful upgrade.
6. Click *OK* to close the message.
↳ Sensor and USB Interface updates are complete and the firmware version displayed.

8.2 Diagnostics

8.2.1 Performing USB interface test

This diagnostic checks the connection between the USB Interface and the host computer.

IMPORTANT
Please make sure that the USB Interface is connected to the PC.

A *"Passed"* condition indicates that this test was completed and successful. A *"Failed"* condition indicates that this test was completed, but a problem exists with the system. Several reasons can cause this issue, but the most common include:

- Problem with the USB Interface or its USB connector
- Problem with the USB cable and / or port
- Corrupt firmware inside the USB Interface.

If another USB Interface is available, connecting it to the USB cable and repeating the USB Interface Test may help to identify the possible cause of the problem.

8.2.2 Performing sensor test

This diagnostic checks the connection between the USB Interface and the sensor.

IMPORTANT
Please make sure that the USB Interface is connected to the PC and the sensor is connected to the USB Interface.

A *"Passed"* condition indicates that this test was completed and successful. A *"Failed"* condition indicates that this test was completed, but a problem exists with the system. Several reasons can cause this issue, but the most common include:

- Problem with the USB Interface or its sensor connector
- Problem with the sensor cable
- Corrupt firmware inside the sensor.

If another sensor is available, connecting it to the USB cable and repeating the Sensor Test may help to identify the possible cause of the problem.

9 Maintenance and inspection

9.1 Hygiene

Disinfect and sterilize accessories prior to initial use and after each patient.

9.1.1 Care, cleaning agents, and disinfectants

NOTE
Approved care, cleaning, and disinfecting agents
Use only care, cleaning, and disinfecting agents approved by Dentsply Sirona!

A continuously updated list of approved agents can be downloaded from the Internet on the online portal for technical documents. You can reach this portal at the address: www.dentsplysirona.com/manuals
.Click on the menu item *"General documents"* and then open the *"Care, cleaning and disinfection agents"* document.

If you do not have access to the internet, please contact your dental depot to order the list (REF 59 70 905).

9.1.2 USB interface and sensors
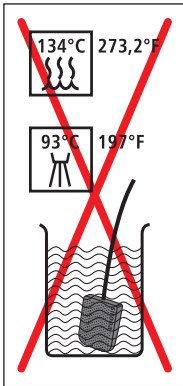
NOTE
Liquids can get into the USB module or the sensor during cleaning and disinfection. The plug contacts may become wet.
The USB module, sensor and PC can be damaged or destroyed by a short circuit.
➢ Before cleaning and disinfection, remove the USB plug on the PC or USB hub. The system must be disconnected from the mains. Also remove the sensor plug from the USB module.
➢ The USB module and the sensor must not be thermal disinfected, sterilized or immersed in disinfectant. They must not be disinfected or sterilized with radiation. Apply wipe disinfectant only.
➢ Never spray plug connections with disinfectants or cleaning solutions. Make sure that the plug contacts do not become wet.

NOTE
Drugs have a chemical reaction with the surface of the unit.
Due to their high concentrations and the substances they contain, many drugs can dissolve, etch, bleach, or stain surfaces.
➢ Wipe any drug residues off the unit immediately with a moist, white cloth!

✓ All plug connections are disconnected.

1. Clean the sensor, the sensor cable and the USB module with a cloth soaked in soapy water. After this, dry the components with a lint-free cloth.

2. The sensor and the sensor cable must be wiped clean with disinfectant completely and thoroughly at least twice. Then wipe the USB module clean with disinfectant.

3. Remove any chemical residues by wiping the components clean with a sterile cloth. The surfaces should then be dry.

4. Store the sensor and the USB module in a clean place for the next treatment.

9.1.3 Sensor holders

The rods and rings of the single-use sensor holder system recommended for the Xios AE sensor and all parts of the reusable sensor holder system can be sterilized.

The rods and rings must be sterilized before initial use and once a treatment has ended. Rods and rings must be cleaned before each sterilization.

The rods and rings or sensor holder and rings must be sterilized before initial use and once a treatment has ended. All parts must be cleaned before each sterilization.

NOTE
The plastic parts of the sensor holder must not be exposed to high sterilization temperatures.
The plastics may melt, warp or become brittle as a result of improper sterilization.
➢ Sterilize metallic and plastic parts in separate sterilization pouches.
➢ Ensure that the temperature in the steam sterilizer does not exceed 134°C (273°F) during the sterilization process. Operate the steam sterilizer according to the manufacturer's instructions.
➢ Do not use phenol-based glutaraldehyde, ultrasonic cleaners, chemiclaves or hot-air sterilizers for sterilization. Do not use cold sterilization.

IMPORTANT
Plastic parts have a limited lifetime. This is reduced with each sterilization cycle. As a result replace the plastic parts of the sensor holder on a regular basis.

1. Separate the rods and rings or the sensor holder and rings.

2. Remove any residues with hot soapy water or mild dishwashing liquid.

3. Put the components, metal parts separated from plastic parts, into individual sterilization pouches.

4. Put the sterilization pouches into the middle tray of the steam sterilizer, ensuring sufficient distance to the walls of the steam sterilizer and the heating element.

5. Sterilize in a steam sterilizer at **134°C (273.2°F) for at least 3 min. holding time and 2.1 bar (30.5 psi) overpressure**.

9.2 Regular inspections

Inspections must be performed at scheduled intervals to protect the health and safety of patients, users and other persons.

Before and during operation

The system owner or an appointed person must ensure that:

- there are no changes to the additional second protective ground conductor connection of the PC
- the PC used is outside the patient environment (up to 1.5 m around the patient) if it is installed without a second protective ground conductor
- the USB hub is outside the patient environment if the USB interface is not connected directly to the PC
- all components, such as cables, sensors and housing parts, are in sound condition

Monthly

Once a month the system owner or an appointed person must:

- check the sensor cable thoroughly for wear and tear
- make sure the connector housing is fastened securely at the sensor cable

Annually

The image quality must be assessed by the system owner or an appointed person at regular intervals, at least once a year.

On digital sensors, the degree of postprocessing (brightness or contrast adjustment) that is required in the image processing software (e.g., Sidexis 4) to produce satisfactory results is used as an assessment criterion.

If these assessment criteria are regarded as given irrespective of the patient's anatomy and/or possible sources of error such as patient positioning, a service engineer should be called in immediately to rectify any possible system faults.

⚠ CAUTION
Should you identify faulty components on your Xios AE product, please inform your appointed service engineer. In this case, the device should no longer be used for patient exposures.

Observe any additional country-specific requirements.

Please also check the all labels on the underside of the USB Interface are undamaged and legible.

⚠ CAUTION
The USB interface must not be opened or repaired by the user.
All parts of the device are maintenance-free. In case of malfunctioning, please always contact your specialized dealer.

9.3 Replace the sensor cable

The sensor cable can be replaced with a new one in the event of damage.

A "sensor cable" replacement set is required for this, see Accessories and spare parts. This contains the required spare parts and tool:

- Sensor cable
- Screwdriver
- 2 protective screw caps
- 2 Elastomer strips or Elastomer frames
- 4 flathead screws
- Gel disks

NOTE
The electric plug contacts of the sensor are exposed during installation.
The sensor may be destroyed by the electrostatic discharge at the contacts.
➢ Before installation discharge at a conductive grounded item, e.g., a water faucet or a bare heating pipe.

NOTE
No dirt or moisture must be allowed to get into the exposed plug contacts.
Dirt causes contacts faults, moisture may lead to a short circuit.
➢ Wash and dry your hands. Do not wear powdered gloves. The powder could become deposited in the plug contacts of the sensor.
➢ Place the sensor on a clean, dry and stable surface.

NOTE
Incorrect cable replacement may affect sensor performance
Failure to assemble the cable onto the sensor in accordance with the following instructions could result in an intermittent connection between cable and sensor and may impact the sensor's performance.

Unscrew a damaged cable from the sensor

1. Disconnect the Xios AE sensor from the USB interface.
2. With a dental instrument remove the protective screw cap from the rear side of the sensor.
3. Using the screwdriver supplied with the set remove the 2 screws which fasten the cable to the sensor.
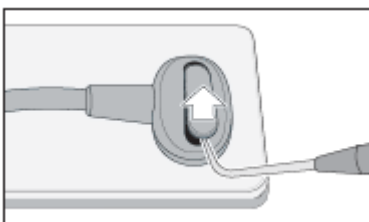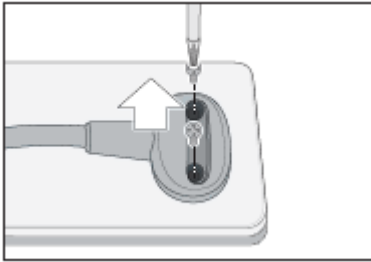
Replace the Elastomer

1. Check the contents of the spare parts kit.
2. Your spare parts kit contains a white elastomer frame. Carefully place the white frame into position, flat surface facing up and notched cutout facing the longer side of the sensor. Avoid contact with the gold elastomer strip in the center.
   After inserting the frame, apply a small amount of finger pressure around the outer edges to ensure that the material is seated correctly.

IMPORTANT
Use the new parts supplied with the cable for the assembly!

| IMPORTANT |
| --- |
| The spare parts for the Xios AE sensor are white. The Elastomer strip (or frame) must be placed exactly in the slot so that the sensor works. |

Attach a replacement cable

1. Place the plug for the sensor cable properly on the sensor. Both parts must interlock.
2. Screw the sensor cable to the sensor using the screws supplied. Initially only tighten the screws until a light resistance can be felt. After this tighten both screws carefully.
3. For each screw just tightened, remove a gel disk from its paper backing and place it over the screw. make sure that the gel completely covers the screw.

4. Cover the screw heads with a new protective screw cap. Press the cap into the plug of the sensor cable until it locks in place.
↳ The cable replacement is now completed. The sensor can be used again.
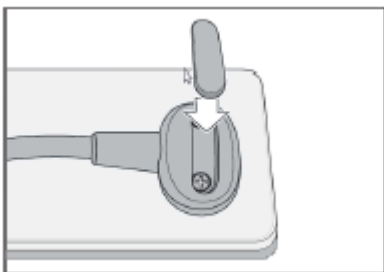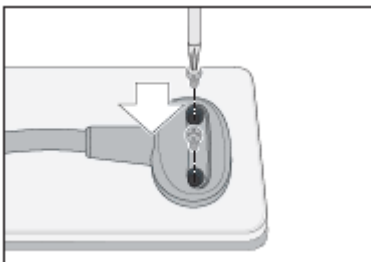
NOTE
Improperly tightened screws may affect sensor performance
Be sure to tighten both screws completely until they cannot be turned any further. Inadequate tightening may create a poor connection between the elastomer and the sensor contacts and could affect the ability of the sensor to acquire and transfer images optimally.

10 Consumables and spare parts

10.1 Consumables and spare parts

Hygienic protective sleeves for sensors
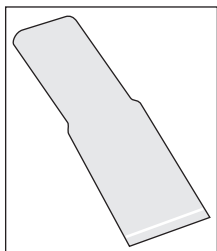
Hygienic protective sleeves for sensor size 0 and 1, quantity 300
REF 64 09 960

Hygienic protective sleeve for sensor size 2, quantity 300
REF 64 09 952

Sensor holder tabs for single-use sensor holder system
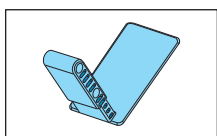
Blue sensor holder tab for front tooth exposure (anterior), quantity 100
REF 61 76 510
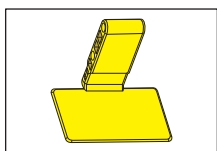
Yellow sensor holder tab for side tooth exposures (posterior), quantity 100
REF 61 76 528
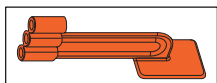
Red sensor holder tab for bite wing exposures, quantity 100
REF 61 76 536
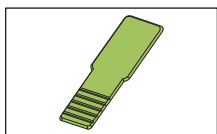
Green sensor holder tab for endodontic exposures using half-angle technique, quantity 100
REF 61 76 544
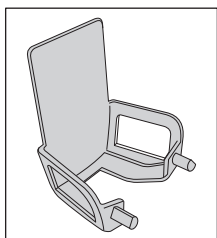
Gray sensor holder tab for endodontics (measurement exposure), quantity 50
REF 61 76 551

Starter kits for single-use sensor holder system

Starter kits include the localizer ring and the guide rod along with 15 sensor holder tabs each for the blue, yellow, red, green and gray sensor holder. The kit also includes 50 hygienic protective sleeves for one sensor size.

Sensor holder starter kit for sensor size 0 and 1
REF 64 11 289

Sensor holder starter kit for sensor size 2
REF 64 11 297

Aimright reusable sensor holder system
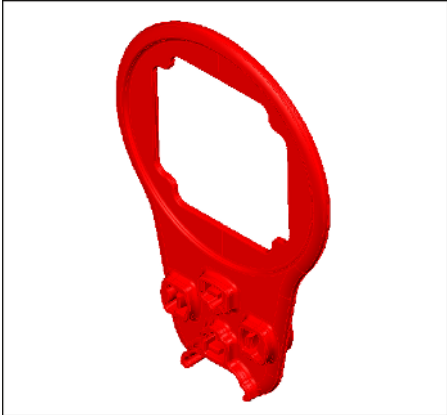
Localizer ring (red), quantity 1
REF 65 45 599
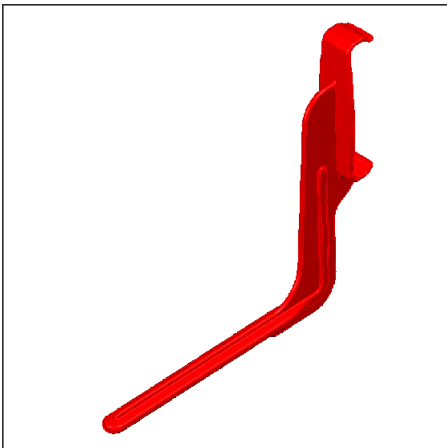
Sensor holder for bite wing exposures (red), for sensor size 1, quantity 2
REF 65 45 557

Sensor holder for bite wing exposures (red), for sensor size 2, quantity 2
REF 65 45 565
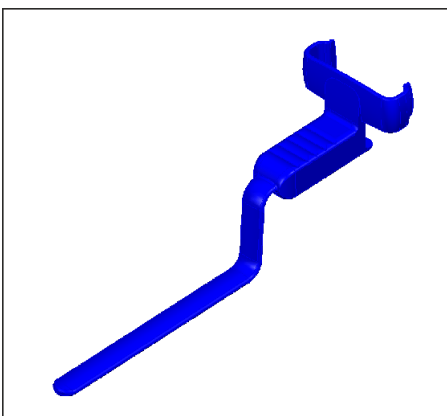
Sensor holder for anterior tooth exposures (blue), for sensor size 1, quantity 2
REF 65 45 573

Sensor holder for anterior tooth exposures (blue), for sensor size 2, quantity 2
REF 65 45 581
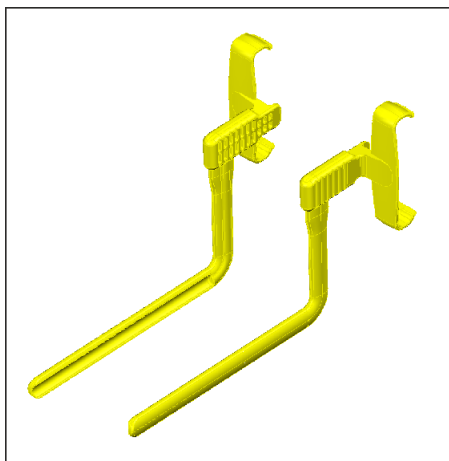
Sensor holder for posterior tooth exposures (yellow), for sensor size 1, quantity 4
(2 for right lower jaw / left upper jaw and 2 for left lower jaw / right upper jaw)
REF 65 45 532

Sensor holder for posterior tooth exposures (yellow), for sensor size 2, quantity 4
(2 for right lower jaw / left upper jaw and 2 for left lower jaw / right upper jaw)
REF 65 45 540

Starter kits for Aimright reusable sensor holder system

The starter kits are available for sensor sizes 1 and 2. Starter kits include the following:

- 2 localizer rings
- 2 sensor holders for horizontal bite wing exposures (red)
- 2 sensor holders for posterior tooth exposures left upper jaw / right lower jaw (yellow)
- 2 sensor holders for posterior tooth exposures right upper jaw / left lower jaw (yellow)
- 2 sensor holders for anterior tooth exposures (blue)
- 100 hygienic protective sleeves
- 1 poster showing sensor positioning

Aimright sensor holder starter kit for sensor size 1
REF 65 45 607

Aimright sensor holder starter kit for sensor size 2
REF 65 45 615

Test phantom

Test phantom for sensor size 0, 1 and 2 for consistency test
REF 64 00 449
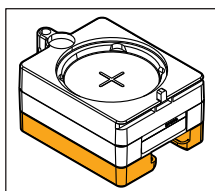
Sensors with cable for USB port

Xios AE USB size 0, 270 cm
REF 67 24 749

Xios AE USB size 1, 270 cm
REF 67 24 756

Xios AE USB size 2, 270 cm
REF 67 24 764

Sensor cable for USB module

Xios AE USB cable kit 90 cm
REF 67 24 772

Xios AE USB cable kit 180 cm
REF 67 24 780

Xios AE USB cable kit 270 cm
REF 67 24 798

Radiated field limitation for HELIODENT[PLUS]

Radiation field limitation for sensor size 0, white
REF 64 00 142

Radiation field limitation for sensor size 1, black
REF 62 42 007

Radiation field limitation for sensor size 2, blue
REF 62 41 991

Turning handle with locking hook
REF 63 52 319

Locking hook
REF 51 67 965

USB interface and USB cable

AE Sensor USB interface
REF 67 24 806

USB cable A/micro-B 2 m
REF 67 24 731

Holders

Wall-mounted sensor holder
REF 67 24 814

Wall-mounted USB Interface holder
REF 67 24 822

11 Electromagnetic compatibility

Xios AE complies with the requirements for electromagnetic compatibility (EMC) according to IEC 60601-1-2.

Xios AE is hereinafter referred to as the "UNIT". Observance of the following information is necessary to ensure safe operation regarding EMC aspects.

11.1 Accessories

Designation of the interface cable:
USB 3 cable A/micro-B

The UNIT may only be operated with accessories and spare parts approved by Sirona. Unapproved accessories and spare parts may lead to an increased emission or to a reduced immunity to interference.

The UNIT should not be operated in the immediate vicinity of other devices. If this proves to be unavoidable, the UNIT should be monitored to check and make sure that it is used properly.

11.2 Electromagnetic emission

The UNIT is intended for operation in the electromagnetic environment specified below.

The customer or user of the UNIT should make sure that it is used in such an environment.

Emission measurement	Conformity	Electromagnetic environment - guidelines
RF emissions according to **CISPR 11**	Group 1	The **UNIT** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions according to **CISPR 11**	Class B	The **UNIT** is intended for use in all facilities, including residential areas and in any facilities connected directly to a public power supply providing electricity to buildings used for residential purposes.
Harmonics according to **IEC 61000-3-2**	Class A	
Voltage fluctuations / flicker according to **IEC 61000-3-3**	coincides	

11.3 Immunity to interference

The **UNIT** is intended for operation in the electromagnetic environment specified below.

The customer or user of the **UNIT** should make sure that it is used in such an environment.

Interference immunity tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) according to **IEC 61000-4-2**	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be made of wood or concrete or finished with ceramic tiling. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst **according to IEC 61000-4-4**	± 1 kV for input and output lines ± 2 kV for power supply lines	± 1 kV for input and output lines ± 2 kV for power supply lines	The quality of the line power supply should be that of a typical commercial or hospital environment.
Surge voltages according to **IEC 61000-4-5**	± 1 kV differential mode voltage ± 2 kV common mode voltage	± 1 kV differential mode voltage ± 2 kV common mode voltage	The quality of the line power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and variations of the power supply according to **IEC 61000-4-11**	Voltage dips: 0% U_T with 1/2 period at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T with 1 period and 70% U_T with 25 periods at 50 Hz and 30 periods at 60 Hz each at 0° Short interruptions: 0% U_T with 250 periods at 50 Hz and 300 periods at 60 Hz		The quality of the line power supply should be that of a typical commercial or hospital environment. If the user of the **UNIT** requires it to continue functioning following interruptions of the power supply, it is recommended to have the **UNIT** powered by an uninterruptible power supply or a battery.
Magnetic field of power frequencies (50/60 Hz) according to **IEC 61000-4-8**	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC supply voltage prior to application of the test level.			
			Portable and mobile radio equipment must not be used within the recommended working clearance from the **UNIT** and its cables, which is calculated based on the equation suitable for the relevant transmission frequency. Recommended working clearance:

Interference immunity tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidelines
Conducted RF interference **IEC 61000-4-6**	3 V_{eff} 150 kHz to 80 MHz[1]	3 V_{eff}	`d= [1.2]` $\sqrt{P}$
Radiated RF interference **IEC 61000-4-3**	3 V/m 80 MHz to 800 MHz[1] 3 V/m 800 MHz to 2.7 GHz[1]	3 V_{eff} 3 V_{eff}	`d= [1.2]` $\sqrt{P}$ at 80 MHz to 800 MHz `d= [2.3]` $\sqrt{P}$ at 800 MHz to 2.7 GHz with `P` as the power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications and `d` as recommended safety distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[2] should be less than the compliance level[3] in each frequency range. Interference is possible in the vicinity of equipment bearing the following graphic symbol.

1. The higher frequency range applies at 80 MHz and 800 MHz.

2. The field strengths of fixed transmitters, such as base stations of radiotelephones and mobile agricultural radio broadcast services, amateur radio stations, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. A site survey is recommended to assess the electromagnetic environment due to fixed RF transmitters. If the measured field strength in the location in which the **UNIT** is used exceeds the applicable RF compliance level above, the **UNIT** should be observed at every location to verify normal operation. If unusual performance characteristics are observed, it may be necessary to take additional measures such as reorientation or repositioning of the **UNIT**.

3. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Test frequency (MHz)	Frequency band[(a)] (MHz)	Radio service (a)	Modulation (b)	Power max. (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation (b) 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM(c) ± 5 kHz stroke 1 kHz sinus	2	0.3	28
710 745 780	704 - 787	LTE band 13, 17	Pulse modulation (b) 217 Hz	0.2	0.3	9

Test fre-quency (MHz)	Frequency band[a] (MHz)	Radio service (a)	Modulation (b)	Power max. (W)	Distance (m)	Immunity test level (V/m)
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modula-tion (b) 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modula-tion (b) 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modula-tion (b) 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modula-tion (b) 217 Hz	0.2	0.3	9

Note:
If necessary, the distance between the transmitting antenna and the ME unit or ME system can be reduced to 1 m in order to achieve the immunity test level. The 1 m test distance conforms to IEC 61000-4-3.

(a) For some radio services, only the frequencies for the radio link between the mobile communication device and the base station (en: uplink) have been recorded in the table.

(b) The carrier must be modulated with a square-wave signal with 50% duty cycle.

(c) Alternatively to the frequency modulation (FM), a pulse modulation with 50% duty cycle at 18 Hz can be used, as this, if not the actual modulation, would represent the worst case.

11.4 Working clearances

The UNIT is intended for operation in an electromagnetic environment, where radiated RF interference is checked. The customer or the user of the UNIT can help prevent electromagnetic interference by maintaining a minimum distance between mobile RF communications equipment (transmitters) and the UNIT - depending on the maximum output power of the communication device, as shown below.

Power rating of the transmitter [W]	Working clearance according to transmission frequency [m]		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	d= [1.2] √P	d= [1.2] √P	d= [2.3] √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3

Power rating of the transmitter [W]	Working clearance according to transmission frequency [m]		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
10	3.8	3.8	7.3
100	12	12	23

The recommended safety distance d in meters (m) can be determined for transmitters, whose maximum power rating is not specified in the above table, using the equation that belongs to the corresponding column, wherein P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

REMARK The higher frequency range applies at 80 MHz and 800 MHz.

REMARK These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12 Disposal

In accordance with Directive 2012/19/EU and national disposal regulations regarding old electrical and electronic devices, please be advised that such items must be disposed of in a special way within the European Union (EU). These regulations require the environmentally friendly recycling/disposal of old electrical and electronic devices. Such items must not be disposed of as domestic refuse. This has been expressed using the icon of the "crossed out trash can".

Disposal procedure

We feel responsible for our products from the first idea to their disposal. For this reason, we give you an option to return our old electronic and electrical devices.

If you wish to dispose of your devices, please proceed as follows:

In Germany

To initiate return of the electrical device, please send a disposal request to enretec GmbH. You have the following options here:

- Use the 'Returning an electrical device' button under the 'eom' menu item on the enretec GmbH homepage (www.enretec.de).
- Alternatively, you can also contact enretec GmbH directly.

  enretec GmbH
  Kanalstraße 17
  16727 Velten, Germany

  Phone: +49 3304 3919-500
  E-mail: eom@enretec.de

In accordance with the national disposal regulations regarding old electrical and electronic devices (ElektroG), as the manufacturer, we assume the costs for disposing of the electrical and electronic devices in question. Disassembly, transport and packaging costs shall be borne by the owner / operator.

Prior to disassembly/disposal of the unit, it must be prepared professionally (cleaned/disinfected/sterilized).

If your unit is not permanently installed, it will be collected from the practice. If it is permanently installed, it will be picked up curbside at your address by appointment.

Other countries

For country-specific information on disposal, contact your local dental dealers.

We reserve the right to make any alterations which may be required due to technical improvements.

Sirona Dental Systems GmbH

Fabrikstr. 31   Order No   **67 29 433 D3780**
64625 Bensheim
Germany

www.dentsplysirona.com