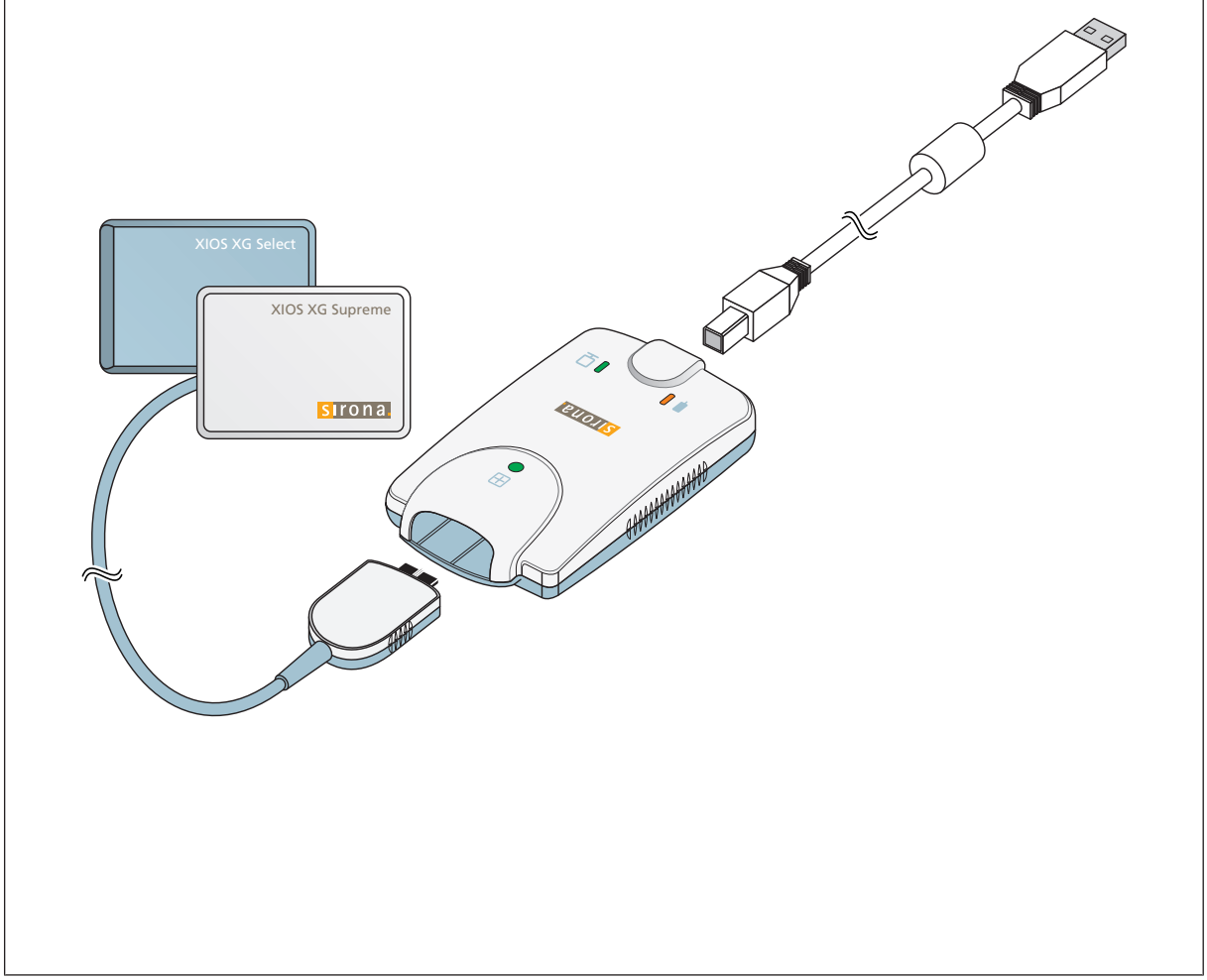
New as of: 11.2017

sirona
The Dental Company

XIOS XG USB Module and Sensors

Operating Instructions and Installation

English



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1 General information

1.1 Dear Customer,

We are pleased that you have equipped your practice with the digital Intraoral X-ray system XIOS XG from Sirona. The system is characterized by many features including outstanding image quality and a high day-to-day reliability.

XIOS XG can be operated with two types of sensor – the XIOS XG Select and XIOS XG Supremesensors. Both types of sensor are available in three sizes (0, 1 and 2). By using XIOS XG Supreme sensors enhanced image processing functions are available to you in SIDEXIS XG / 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. XIOS XG Supreme sensors offer higher resolution compared with XIOS XG Select sensors.

In addition to SIDEXIS XG / SIDEXIS 4 (SIDEXIS XG version 2.5.6 and above) the SIDEXIS plug-in must be installed for XIOS XG. Information on the PC software can be found in the "SIDEXIS Plug-in for XIOS XGOperator's Manual".

This operating manual should be of good help to you before use as well as serve anytime later as a reference material.

We wish you a great deal of success and pleasure with XIOS XG.

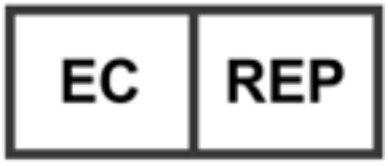
Your XIOS XG Team

1.2 Contact information

Customer service center

For technical questions, use the contact form on the internet at the following address:
http://srvcontact.sirona.com

Authorized agent in the EU



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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.

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 http://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 will then be happy to send you a printed copy free of charge.

Help

If you require additional help 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
- SIDEXIS XG Installation Instructions
- SIDEXIS XG Operator's Manual
- SIDEXIS Plug-in for XIOS XG Operator's 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 XG 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.

NOTICE

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	Prompts you to do something.
See “Formats and symbols used [→ 9]”	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.

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 an experienced 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 XIOS XG sensor holder must be sterilized to prevent any possible transmission of infective agents which might under certain circumstances cause serious illnesses.

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 XG / 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 XG / SIDEXIS 4. Any programs running in the background, such as media players, print managers, backup software, etc., may cause SIDEXIS XG / 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 XG / SIDEXIS 4software.

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 XG / 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" [→ 66].

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 Changes and extensions to the device

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 Sirona accessories or third-party accessories expressly approved by Sirona. The user is responsible for any damage resulting from the use of non-approved accessories.

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

- IEC 60950-1 or IEC 62368-1 for IT equipment (e.g. PC) and
- IEC 60601-1 for medical devices.

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

2.9 Combination with other units

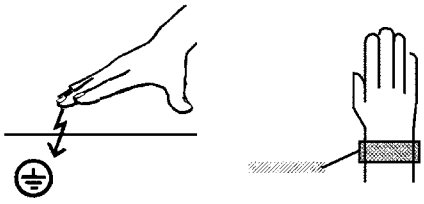
Permissible combinations are specified in the Declaration of Conformity by the system integrator.

2.10 Radiotelephones

Mobile RF communications equipment can affect electro-medical equipment. Therefore, the use of mobile wireless phones in medical office or hospital environments must be prohibited.

2.11 Electrostatic discharge

Protective measures



Electrostatic discharge (abbreviated: ESD – **E**lectro**S**tatic **D**ischarge)

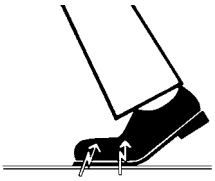
Electrostatic discharge from people can damage electronic components when the components are touched. Damaged components usually have to be replaced. Repairs must be performed by qualified personnel.

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

Endangered regions are indicated on the unit by 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.

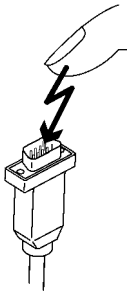
An electrostatic discharge is:

- 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.

Tip: 1 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, arc-over).

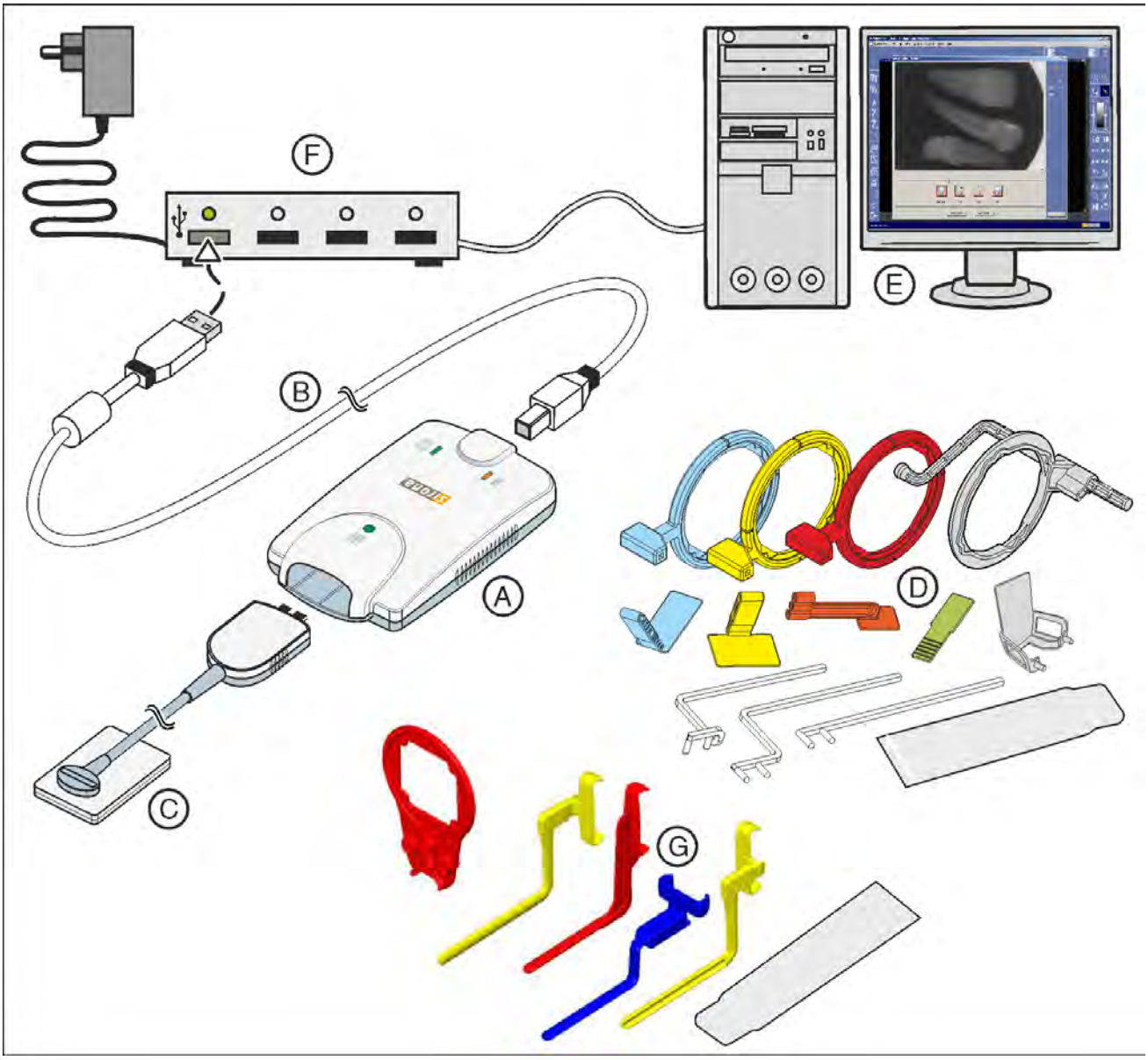


Integrated circuits (logical circuits and microprocessors) are used in order to implement a wide variety of functions in a device. The circuits must be miniaturized to a very high degree in order to include as many functions as possible on these chips. This leads to structure thicknesses as low as a 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

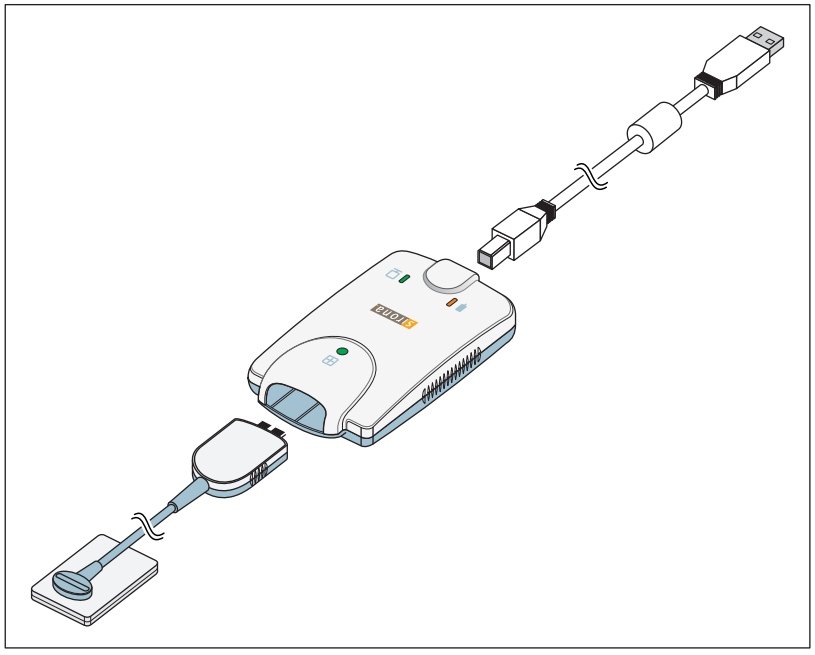


A	USB module [→ 16]
B	USB cable [→ 16]
C	Sensor (size 0, 1 or 2) with cable and plug [→ 17]
D	Single-use sensor holder system with localizer rings, guide rods, sensor holder tabs, [→ 17] and hygienic protective sleeves [→ 37]

E	SIDEXIS PC [→ 20] with • USB interface • SIDEXIS XG / SIDEXIS 4 (SIDEXIS XG version 2.56 or higher) • SIDEXIS plug-in for XIOS XG
F	USB hub (optional) [→ 21]
G	Aimright reusable sensor holder system [→ 18] with localizer ring, sensor holders, and hygienic protective sleeves [→ 37]

3.2 USB module

The USB module is connected between the sensor and the PC. Image data is transferred to a PC via the USB module and USB cable. Further information can be found in the "Operation" [→ 33]section.



3.3 USB cable

A USB cable is supplied by Sirona with the delivery. It meets the USB 2.0 standard and is designed especially for use on XIOS XG.

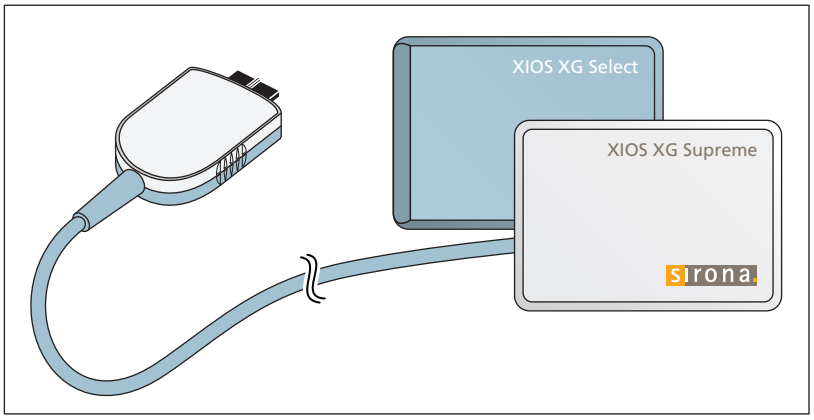
⚠ CAUTION

Standard commercial USB cables do not offer adequate protection from electromagnetic interference.

➢ Only use the special USB cable supplied by Sirona with the delivery.

3.4 Sensors

XIOS XG can be operated with two types of sensor – the XIOS XG Select and XIOS XG Supreme sensors. Both types of sensor are available in three sizes (0, 1 and 2).

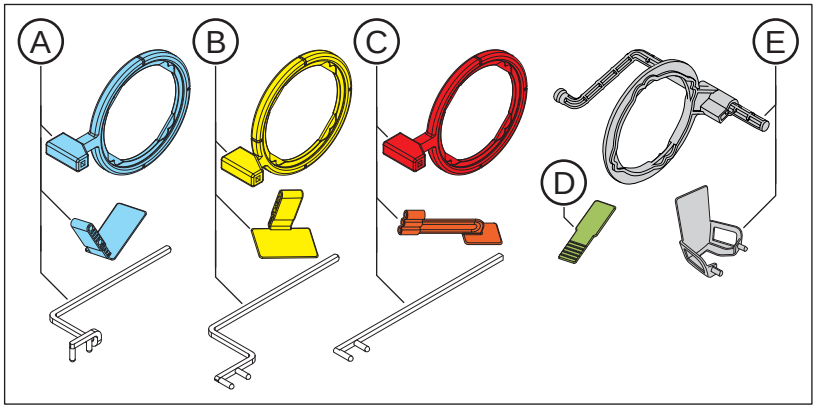


By using XIOS XG Supreme sensors enhanced image processing functions are available to you in SIDEXIS XG / SIDEXIS 4 through special filters. Depending on the indication you can apply the corresponding filter to the X-ray image in order to amplify the relevant structures. Information on the PC software can be found in the "SIDEXIS Plug-in for XIOS XG Operator's Manual".

3.5 Sensor holder systems

3.5.1 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.



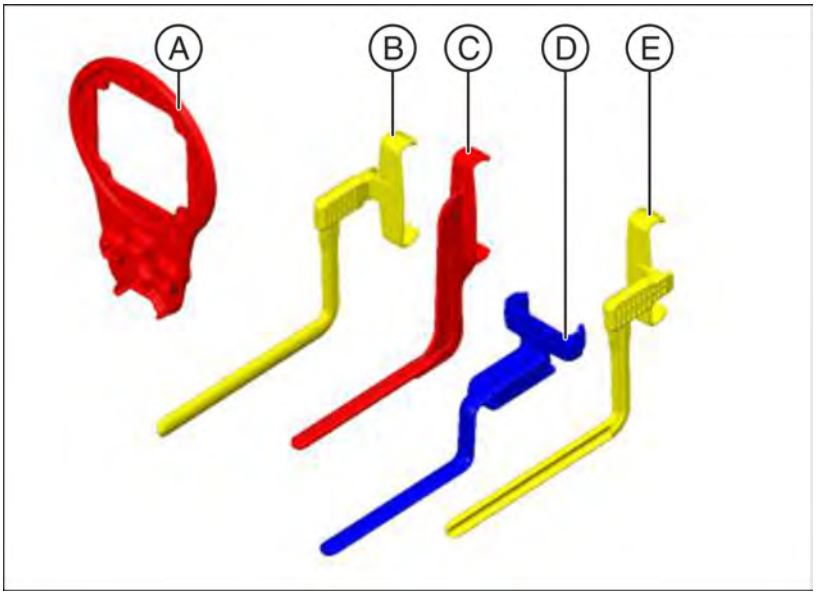
A	Blue for anterior tooth exposure
B	Yellow for posterior tooth exposures
C	Red for bite wing exposures
D	Green for endodontics exposures with the half-angle technique
E	Grey for endodontics (measurement exposure)

3.5.2 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

3.6 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.

3.7 PC system

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

In addition to SIDEXIS XG / SIDEXIS 4 (SIDEXIS XG version 2.56 and above) the SIDEXIS plug-in for XIOS XG must be installed. Information on the PC software can be found in the "SIDEXIS Plug-in for XIOS XG 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 standard or higher

Minimum PC requirements for SIDEXIS XG:

Processor:	32-bit (x86), 1 GHz
RAM	2 GB
Free hard disk storage:	5 GB for SIDEXIS XG installation and database
Removable medium:	CD/DVD drive
Graphics card:	> 128 MB, minimum resolution 1024 x 768 pixels, 16.7 million colors (TrueColor)
Screen:	suitable for diagnostics applications, e.g. in accordance with DIN 6868-57
Network card:	Network RJ45, 100 MBit/s
USB port:	in accordance with USB 2.0 standard or higher

The following operating systems are supported:

- Windows 7 Professional SP 1 (32-bit and 64-bit)
- Windows 7 Ultimate SP 1 (32-bit and 64-bit)
- Windows 8.1 Professional (32-bit and 64-bit)
- Windows 10 Professional (64-bit)

3.8 USB hub (optional)

A USB module 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
Power supply:	Separate power supply (**not** bus-powered!)
Safety:	The USB hub must comply with standard IEC 60950-1 or be certified by a testing laboratory which requires compliance with this standard (e.g. VDE, UL, CSA)

3.9 Technical data

USB module

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
Operating voltage:	5 V DC Device is supplied with power via the USB connection of the PC.
Supply current:	250 mA
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 XG Select Sensors

Technology:	CMOS-APS (Active Pixel Sensor)
Physical pixel size:	15 µm, image acquisition in 30 µm
Line pairs:	16.7 lp at 30 µm
Measured resolution:	16 Lp/mm
Theoretical resolution:	16.7 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 = 23.5 x 32 x 6.3 mm Size 1 - sensor = 25.3 x 38.4 x 6.3 mm Size 2 - sensor = 31.2 x 43.9 x 6.3 mm
Cable length:	max. 2.70 m

XIOS XG Supreme 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 = 23.6 x 32 x 7.5 mm Size 1 - sensor = 25.4 x 38.3 x 7.5 mm Size 2 - sensor = 31.2 x 43 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: -40 °C (-40 °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 40 °C (104 °F) Relative humidity: 20 % to 85 % Air pressure: 700 to 1060 hPa
Operating altitude:	≤ 2000 m

3.10 Certification, registration and standards

The XIOS XG USB system complies with the following standards, among others. It complies 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

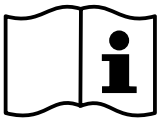
This product bears the CE mark in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices.

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 that the user must read the operating manual before use.

CE 0413

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.

This identification signifies fulfillment of the requirements of the national standards of the Brazilian market.

Year of manufacture

Denotes sterilizable accessories.

Item is only approved for one-off use.

USB connection socket

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 XG USB system:

USB module

sensors

Sensor cable

4 Installation

4.1 Fitting a second protective ground conductor on the PC

Depending on whether the PC is operated inside or outside of the patient environment (up to 1.5 m around the patient), an additional protective ground conductor must be provided on the PC housing.

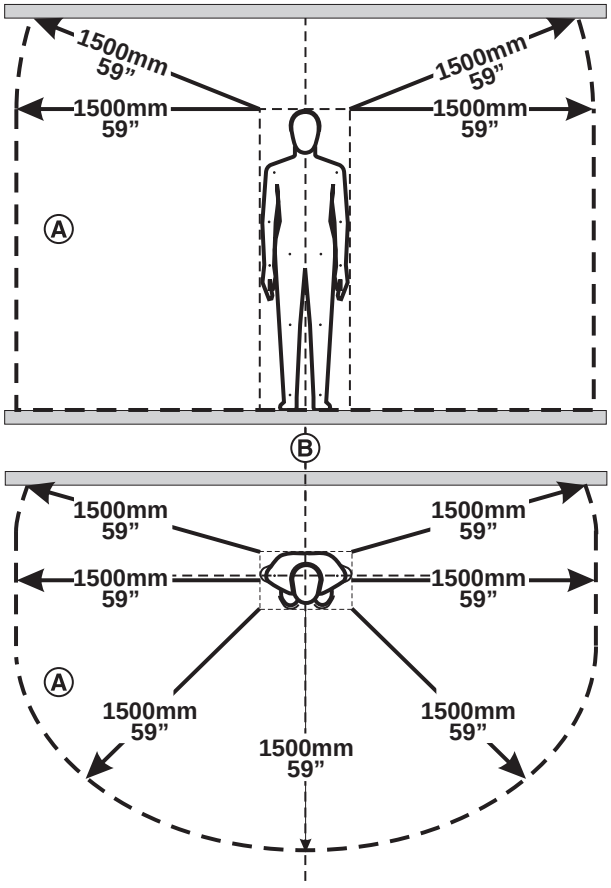
⚠ CAUTION

Leakage currents from the PC are transmitted to the X-ray system.

If a PC is not sufficiently grounded, there is a risk of electric shock for both the patient and the user.

- ➢ The PC must be connected to a grounded electric outlet when in operation.
- ➢ If the PC is operated in the patient environment (up to 1.5 m around the patient), it must also be fitted with an additional protective ground conductor.

Definition of the patient environment in accordance with IEC 60601-1



Within the patient environment (A), direct contact is only permissible with devices or system parts that are approved for use in the patient

environment (A). This applies to all possible patient positions (B) during the examination or treatment.

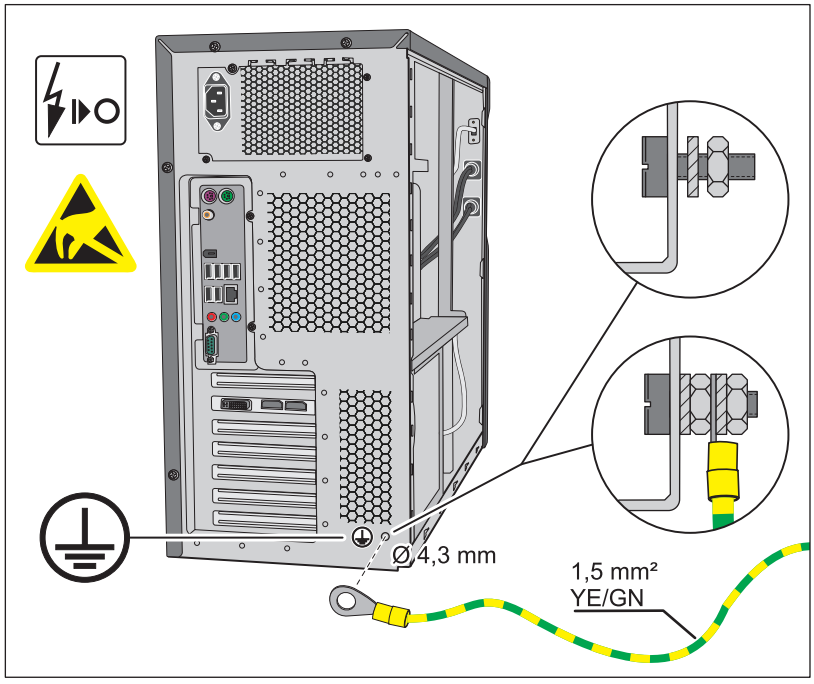
Variant: PC located outside the patient environment

⚠ CAUTION

The PC must not then be moved closer to the patient. A distance of 1.5 m should be maintained at all times.

Variant: PC located inside the patient environment

If the PC is operated inside the patient environment, the system integrator must fit a second protective ground conductor on the PC housing. To do this, proceed as follows:



✓ The PC is switched off and the mains cable removed.

1. Put on an ESD wrist band or discharge your body by touching an equipotential bonding conductor.
2. Loosen the PC housing screws and remove a PC cover. Refer to the manual for the PC.
3. Find a location to connect the protective ground conductor on the rear side of the metal PC housing that is readily accessible from the inside and from the outside.

NOTICE

Drilling may damage the PC.

➢ When drilling, ensure that no part of the PC is damaged and no swarf gets inside the PC.

4. Drill a suitable hole for an M4 screw at this location.
5. Remove any paint around the drill hole to achieve a good metal contact.

6. Fasten the M4 connecting screw to the PC casing firmly with a toothed lock washer and nut.
7. Screw down the protective ground conductor as shown.
8. Affix the "Grounding point" label provided next to the protective ground conductor connection.
9. Connect the protective ground conductor to a suitable equipotential bonding conductor.

4.2 Install the PC software

The PC must be in a state of operational readiness before the installation of the XIOS XG Intraoral System. Make sure that the hardware and the operating system are properly installed. Refer to the manuals for your PC and operating system.

The installation of SIDEXIS XG / SIDEXIS 4 is described in the installation instructions for SIDEXIS XG / SIDEXIS 4.

The SIDEXIS XG / SIDEXIS 4 plug-in for the XIOS XG USB module must be installed in addition to SIDEXIS XG. To do this, proceed as follows:

NOTICE

The USB module must not be connected to the PC during installation of the SIDEXIS plug-in for XIOS XG.

✓ SIDEXIS XG / SIDEXIS 4 (SIDEXIS XG 2.5.6 or higher) is installed on the PC.

1. Log onto your PC with an administrator account.
2. Insert the *"Sirona XIOS XG Select/Supreme 1.2 - Installation"* CD into your PC's CD/DVD drive.
3. The setup normally starts automatically. If the setup does not start, double-click on the "Autorun.exe" file in the main directory of the installation CD.
   ↳ The setup window opens.

4. Click on *"Installing the device connection with USB support"* in the setup window.
5. Follow the additional instructions.
6. Restart the PC if you are required to do so.

↳ The SIDEXIS plugin for XIOS XG USB system is installed.

4.3 Connecting the USB module and hub to the PC

The USB module can be connected to the USB port of a PC either directly or via an active USB hub (with separate power supply).

An active USB hub is required if there is inadequate power supply via the USB port of the PC.

⚠ CAUTION

Leakage currents from the USB hub are transmitted to the X-ray system.

There is a risk of electric shock for both the patient and the user.

➢ The USB hub should only be operated outside the patient environment (up to 1.5 m around the patient).

➢ Please also refer to the technical requirements for the USB hub, see "USB hub (optional)" [→ 21].

IMPORTANT

Only one XIOS XG USB module may be connected to a PC.

✓ SIDEXIS XG / SIDEXIS 4 and the required plug-in is installed on the PC.

1. If an active USB hub is required, install it according to the manufacturer's instructions.
2. Connect the USB module directly with the PC or with the hub. Use the USB cable supplied by Sirona.

↳ The operating system detects the USB module. A message appears in the info area of the Windows taskbar (Systray).

NOTICE

Ensure safe cable installation

When installing the USB cable and the individual components, make sure that the connections cannot be accidentally loosened, disconnected or damaged, e.g. due to tripping over or pulling them, etc.

4.4 Install holder for the USB module

A holder is supplied with the USB module. It can be screwed to a wall using the drywall screws provided or any other mounting material. Alternatively, the holder can be glued to an even surface, for example using a self-adhesive Velcro strip or double-sided adhesive tape.

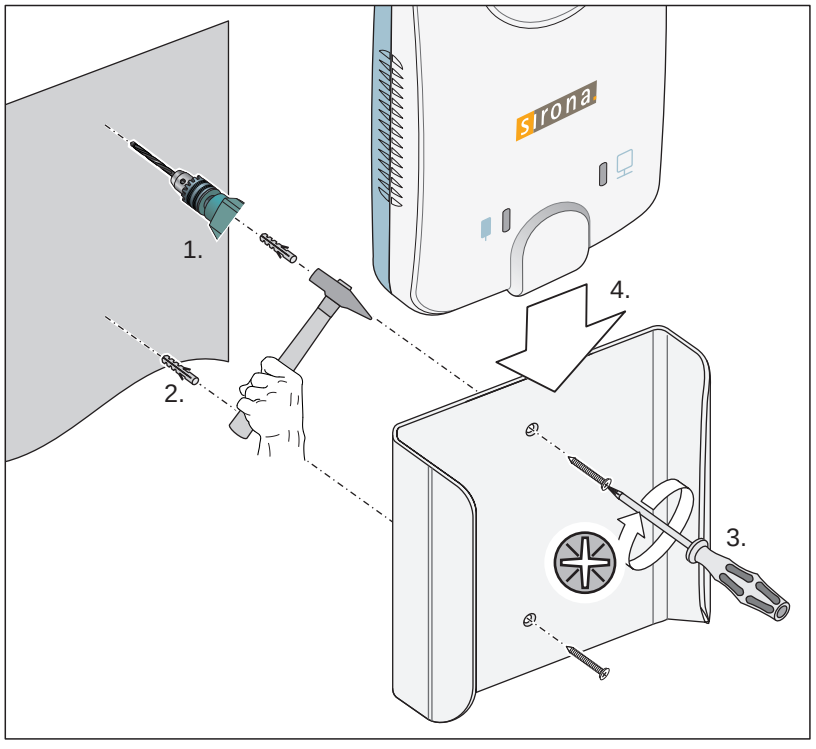
Position the holder so that the USB module can be accessed easily during the treatment and the LED displays are clearly visible.

NOTICE

There may be cables in the wall.

Drilling can damage these cables.

➢ Make sure that drilling does not accidentally damage any cables.



4.5 Connect sensor

A calibration file is saved on the XIOS XG Select and XIOS XG Supreme sensors which is transferred to the PC the first time that the sensor is used.

✓ The USB module can be connected to the USB port of a PC either directly or via a USB hub. The orange LED on the USB module lights up, see also "Determine unit status" [→ 36].

1. Start SIDEXIS XG / SIDEXIS 4.
2. Plug the connector of the sensor into the front socket of the USB module.
3. Register a patient in SIDEXIS XG / SIDEXIS 4 and establish readiness for intraoral exposures.
   ↳ A sensor calibration file is installed automatically if you are using the XIOS XG Select or XIOS XG Supreme sensor on this PC for the first time. If this does not occur and no exposure readiness is established, disconnect the sensor from the USB module and plug the cable in again.

4.6 Complete test exposures/acceptance tests

A test exposure must be completed after installing a XIOS XG USB module or a new sensor.

An acceptance test must be completed by a service engineer from a specialist retailer in Germany (Austria and Switzerland).

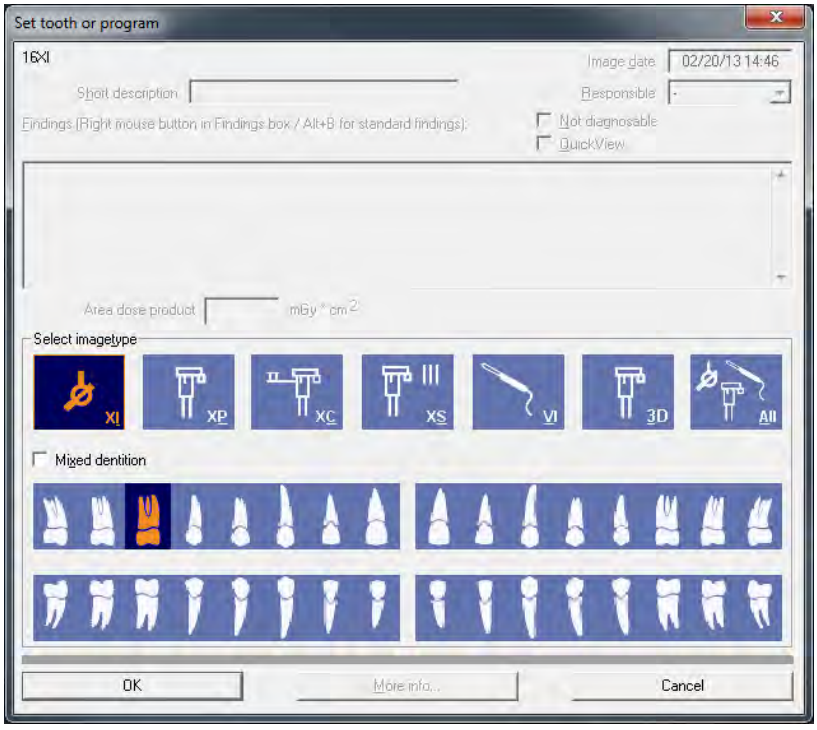
For completing test exposures, use a test phantom, see Consumables and spare parts [→ 70]. Do not complete test exposures on a patient.

5 Operation

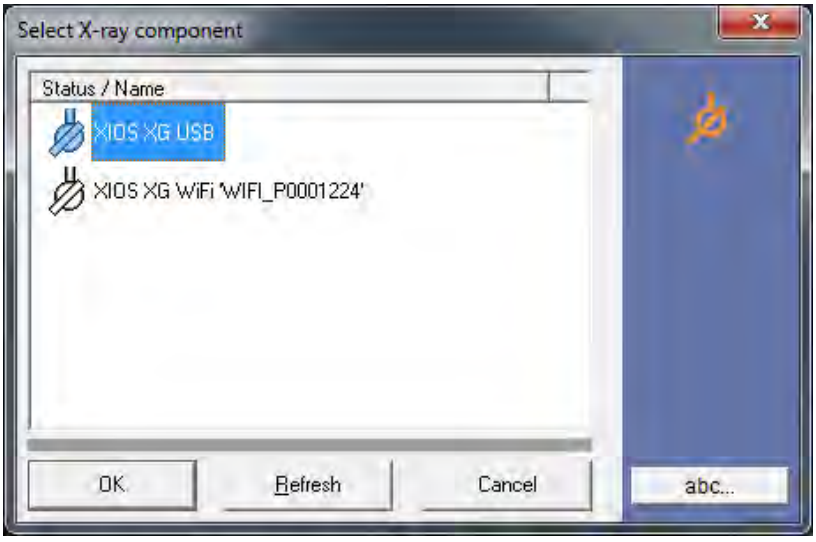
5.1 Enable exposure readiness

✓ The USB module and the sensor are installed in accordance with the instructions in the "Installation" [→ 26] section.

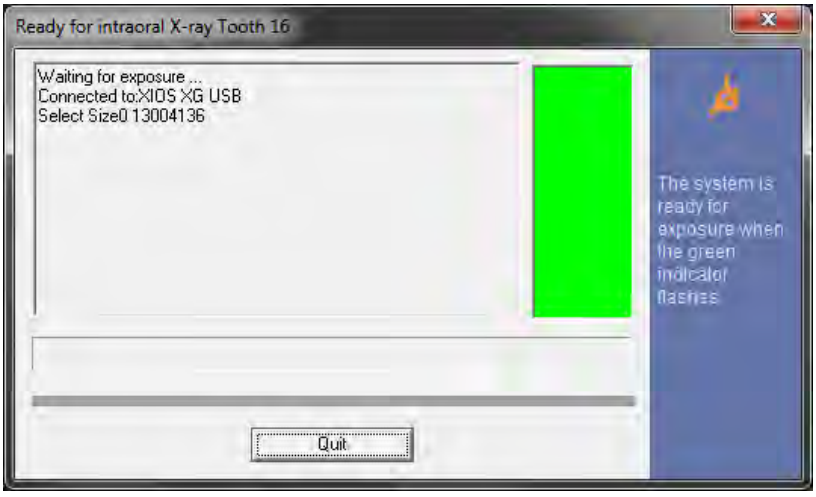
1. Connect a sensor to the USB module.
2. Register the patient in SIDEXIS XG / SIDEXIS 4. Detailed information can be found in the SIDEXIS XG / SIDEXIS 4 operator's manual.
3. Establish exposure readiness for intraoral exposures. Click on the *"[I]ntraoral X-ray"* button.
   ↳ The *"Set tooth or program before exposure"* window opens. The intraoral exposure is selected as the image type.



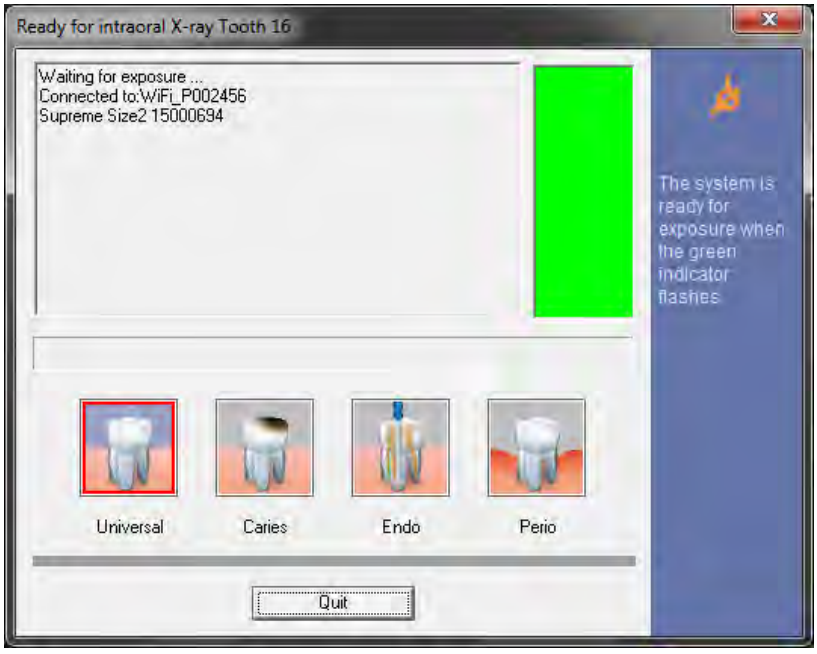
4. Click on the tooth for which the intraoral exposure is being produced. Information on the tooth displays can be found in the SIDEXIS XG / SIDEXIS 4 operator's manual. Confirm your selection with the *"OK"* button.
   ↳ The *"Select X-ray device"* window appears where multiple intraoral X-ray system are registered in *"SIDEXIS XG / SIDEXIS 4"*.



5. Select the XIOS XG USB module.
   ↳ The *"Exposure readiness "* window is displayed. *"SIDEXIS XG / SIDEXIS 4"* Is ready for exposures when the green display is flashing here.



"Exposure readiness " window when using a "XIOS XG Select" sensor



"Exposure readiness " window when using a "XIOS XG Supreme" sensor

6. When using a XIOS XG Supreme sensor: Select the desired filter to be applied to the x-ray image produced depending on the indication. The selection can also be changed after the exposure.
   ↳ The button for the selected image filter is shown inside a red frame. The *"Universal"* image filter is pre-selected by default.

↳ The orange LED on the USB module flashes, the adjacent LED lights up green, see "Determine unit status" [→ 36]. The USB module is now also ready for exposures. The exposure can be released now.

⚠ WARNING

Connecting / replacing a sensor on the USB module

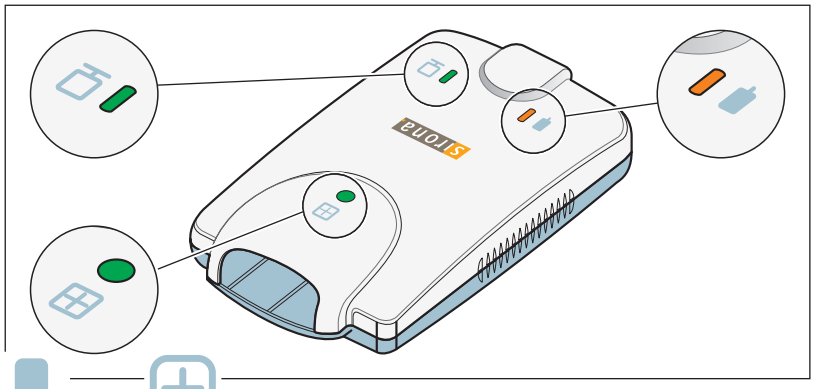
You can connect or replace the sensor on the USB module until the radiation is released. The sensor can also be exchanged when the exposure readiness is already created.

When you separate the sensor from the USB module, after the radiation is released, and the image has not yet been transferred, the image data will be lost.

➢ Do not disconnect the sensor from the USB module before the image data has been transferred to SIDEXIS XG / SIDEXIS 4.

5.2 Determine unit status

The XIOS XG USB module features three LED displays. They indicate the unit status.



Sensor	SIDEXIS XG / SIDEXIS 4	Sensor status LED, green	Exposure readiness LED, orange	Sensor connection LED, green	Status / bug fixing
Connected	Running	at	Flashes every half to one and a half seconds	at	Ready for exposure
Connected	Running	on	off	on	Exposure in progress
Connected	Not running	off	off	on	Start SIDEXIS XG / SIDEXIS 4 to establish unit exposure readiness
Connected	Running or not running	off	on	off	Short circuit or overcurrent condition. Replace the sensor cable. If the problem persists, replace the sensor.
Connected	Running or not running	off	on	flashing	Undercurrent condition. Replace the sensor cable. If the problem persists, replace the sensor.
Not connected	Not running	off	on	off	Connect the sensor and start SIDEXIS XG / SIDEXIS 4.
Connected or not connected	Running or not running	On or off	flashing	off	USB voltage supply too low. Use another original USB cable, another USB port on the PC or use a hub.

5.3 Sliding the hygienic protective sleeve over the sensor

Hygienic protective sleeves are available depending on the size of the sensor (0, 1 or 2). They fit both XIOS XG Select and XIOS XG Supreme sensors.

To reorder the hygienic protective sleeves, see"Consumables and spare parts" [→ 70].

⚠ WARNING

Sensors and sensor cables must be disinfected prior to initial use.

Patients may become sick due to components that have not been disinfected.

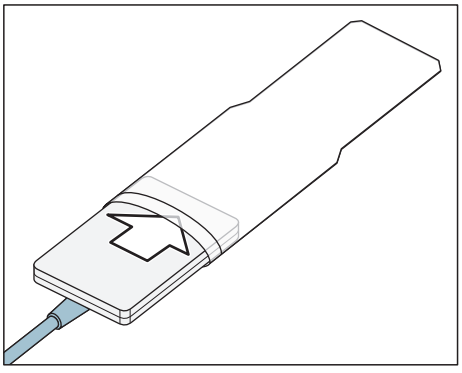
- ➢ Remove the sensor connector from the unit.
- ➢ Clean the sensor and the sensor cable thoroughly with disinfectant at least twice. Refer to Hygiene.

⚠ 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.



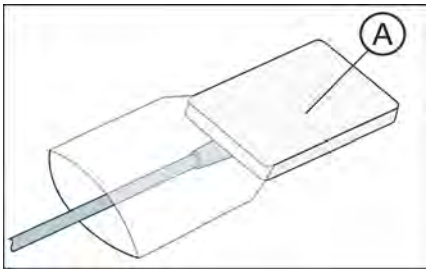
1. Please select a hygienic protective sleeve with a size that matches the sensor.
2. Slide the Sensor into the Sheath
   - ↳ The hygienic protective sleeve is slightly undersized, so that it surrounds the sensor tightly and prevents the sensor from slipping out of place.

5.4 Position the 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 XIOS XG sensor holder system or with the #AimRight# sensor holder system is recommended for optimal positioning of the sensors.

With the XIOS XG sensor 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.



NOTICE

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.

5.4.1 Position sensor with single-use sensor holder system

5.4.1.1 Notes on the sensor holder tabs

IMPORTANT

The sensor holder tabs are single use devices and cannot be reused.

YYYY-MM-DD

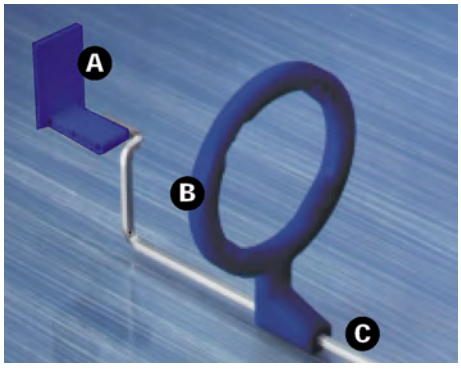
IMPORTANT

Adhesive properties may deteriorate over time based on age and storage conditions.

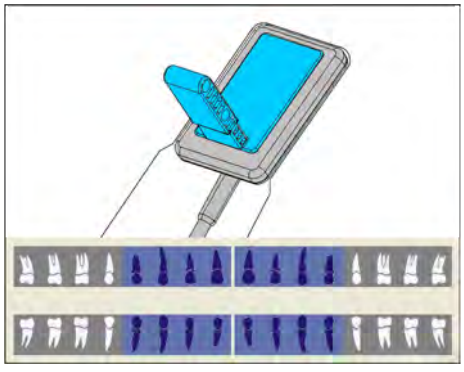
➢ If more than one year has passed since the manufacture date, check adhesive strength before use.
Do not use if holder does not securely adhere to sheath.

5.4.1.2 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".

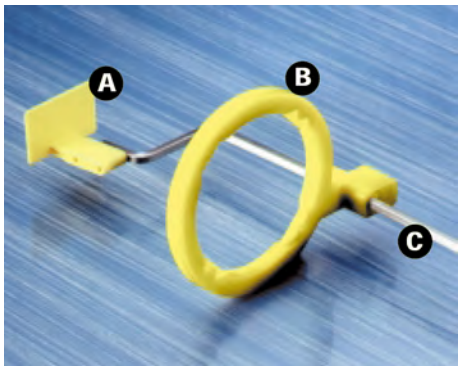


4. Glue the sensor holder tab onto the sensor's hygienic protective sleeve. Place the tab **in the center** of the sensor as shown in the diagram.

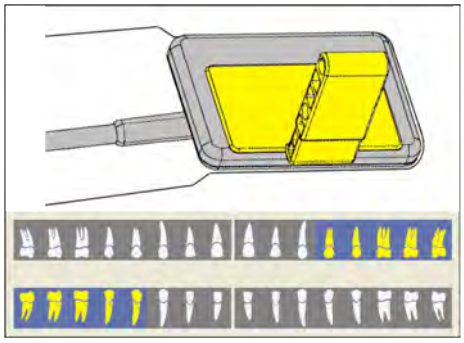
5. Position the sensor in the patient's mouth.
6. Bring the X-ray tube assembly into the correct position and take an X-ray exposure.
7. Remove the sensor from the hygienic protective sleeve. For this follow the instructions in section "Remove the hygienic protective sleeve from the sensor" [→ 59]. The 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.

5.4.1.3 Posterior tooth exposures

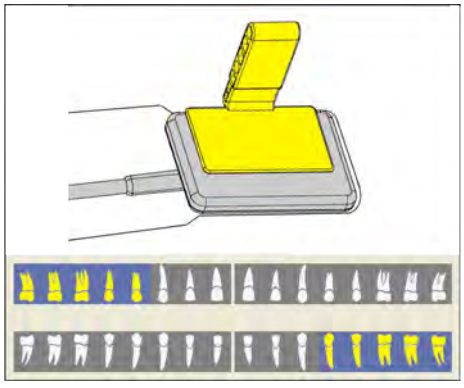
For posterior tooth exposures use the **yellow** sensor holder.



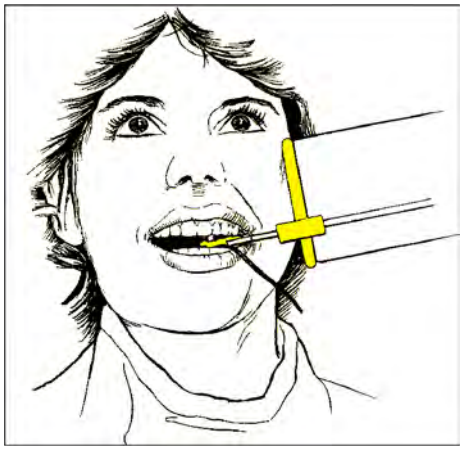
1. Place the yellow localizer ring (B) onto the **double-angled** guide rod (C).
2. Place the yellow sensor holder tab (A) onto the guide rod (C).
3. Slide the sensor into the hygienic protective sleeve, see section "Slide the hygienic protective sleeve over the sensor".



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.



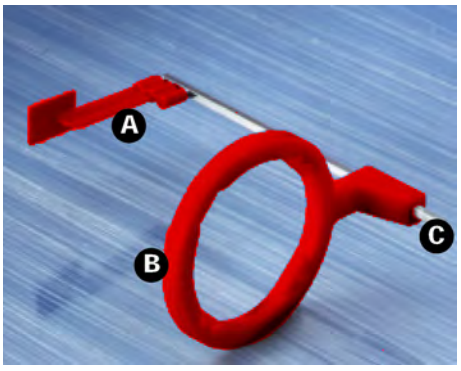
5. **For the right upper jaw and left lower jaw** the sensor holder tab must be placed in the mirrored position. See the adjacent drawing.



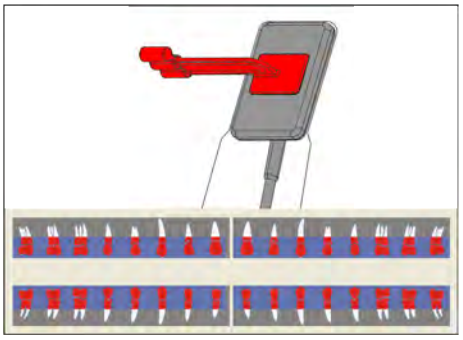
6. Position sensor in patient's mouth.
7. Bring the X-ray tube assembly into the correct position and take an X-ray exposure.
8. Remove the sensor from the hygienic protective sleeve. For this follow the instructions in section "Remove the hygienic protective sleeve from the sensor" [→ 59]. The used sensor holder tab and hygienic protective sleeve must be disposed of after the examination.
9. Clean and sterilize the guide rod and localizer ring.

5.4.1.4 Bite wing exposures

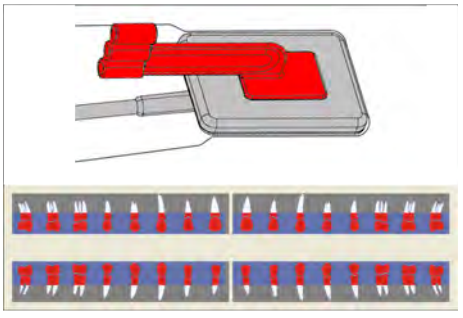
For bite wing exposures use the **red** sensor holder.



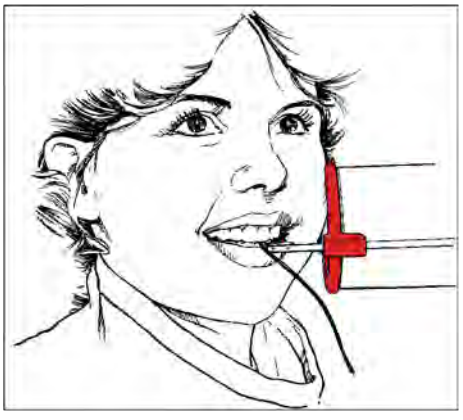
1. Place the red localizer ring (B) onto the **straight** guide rod (C).
2. Place the red sensor holder tab (A) onto the guide rod (C).
3. Slide the sensor into the hygienic protective sleeve, see section "Slide the hygienic protective sleeve over the sensor".



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.

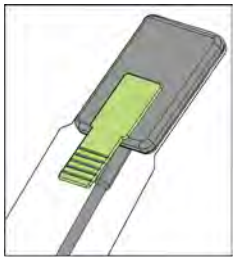


6. Position the sensor in the patient's mouth.
7. Bring the X-ray tube assembly into the correct position and take an X-ray exposure.
8. Remove the sensor from the hygienic protective sleeve. For this follow the instructions in section "Remove the hygienic protective sleeve from the sensor" [→ 59]. The 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.

5.4.1.5 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.

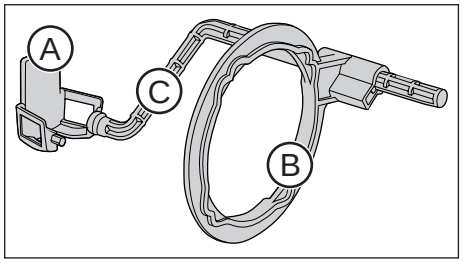


4. **For posterior tooth exposures** the tab must be aligned **vertically** to the sensor and placed **in the center** on the sensor. See the adjacent drawing.
5. Position sensor in patient's mouth.
6. Bring the X-ray tube assembly into the correct position and take an X-ray exposure.
7. Remove the sensor from the hygienic protective sleeve. For this follow the instructions in section "Remove the hygienic protective sleeve from the sensor" [→ 59]. The used sensor holder tab and hygienic protective sleeve must be disposed of after the examination.
8. Clean and sterilize the tab.

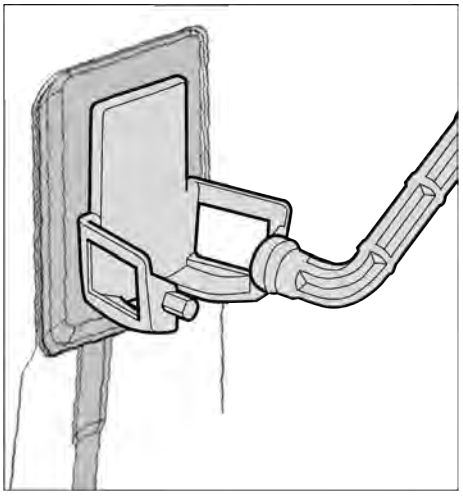
5.4.1.6 Measurement exposure for endodontics

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".



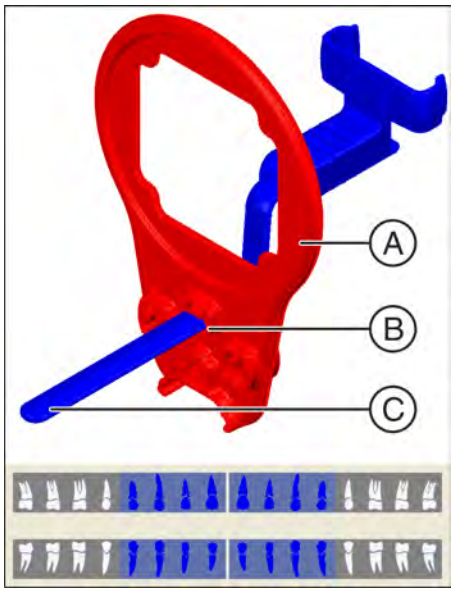
4. Glue the sensor holder tab onto the sensor's hygienic protective sleeve. Place the tab **in the center** of the sensor as shown in the diagram.
5. Position the sensor in the patient's mouth.
6. Bring the X-ray tube assembly into the correct position and take an X-ray exposure.
7. Remove the sensor from the hygienic protective sleeve. For this follow the instructions in section "Remove the hygienic protective sleeve from the sensor" [→ 59]. 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.

5.4.2 Position sensor with Aimright reusable sensor holder system

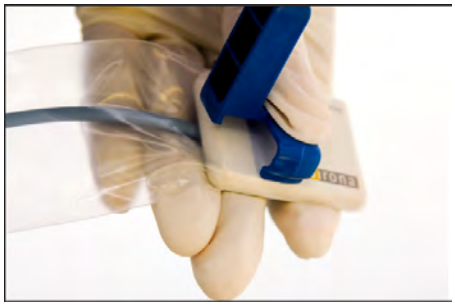
5.4.2.1 Anterior tooth exposure

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".

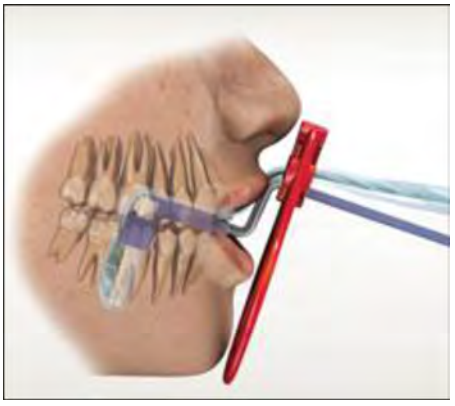


3. To do this, place the sensor on the palm of your hand and clip the sensor holder onto the sensor.

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.

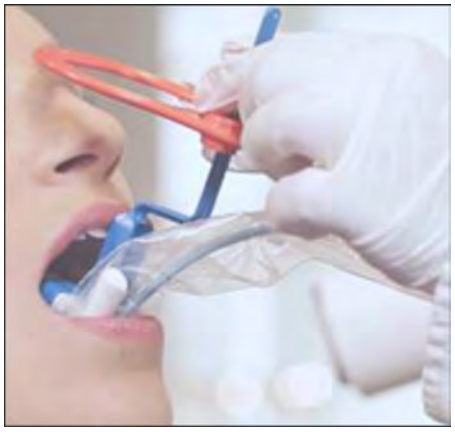


2. Position the sensor in the patient's mouth.
3. Use light pressure to align the sensor so that it lies parallel with the lower front teeth.
4. Ask the patient to close their mouth slowly and bite down on the sensor holder.
5. Slide the localizer ring onto the patient’s lips.

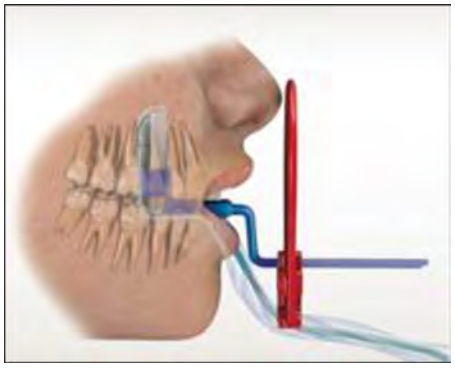
6. Align the cone of the X-ray tube assembly parallel to the sensor directly on the localizer ring.
7. Release an X-ray exposure. Refer to sections Select the exposure parameters for the X-ray tube assembly [→ 55] and Releasing the exposure. Also observe the operating instructions for the X-ray tube 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 [→ 55] and Releasing the exposure. Also observe the operating instructions for the X-ray tube assembly.

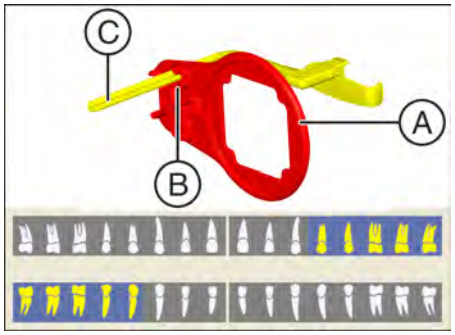
After the exposure

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 [→ 59]. The hygienic protective sleeves must be disposed of after the examination.
4. Clean and sterilize the sensor holder and localizer ring.

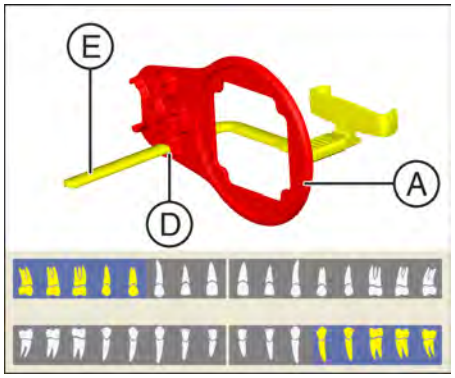
5.4.2.2 Posterior tooth exposures

Preparing the sensor holder

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

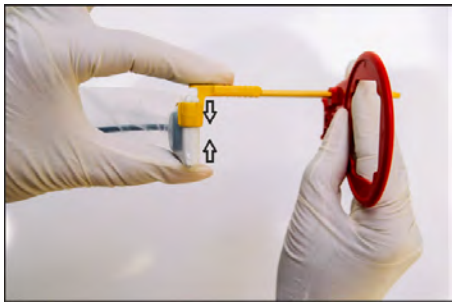


1. **For the right upper jaw and left lower jaw:** Fasten the guide rod for the sensor holder (C) in the perforation (B) of the localizer ring (A).



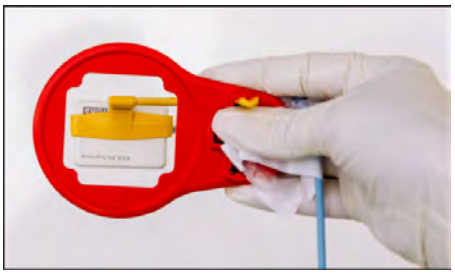
2. **For the left upper jaw and right lower jaw:** Fasten the guide rod for the sensor holder (E) in the perforation (D) in the localizer ring (A).
3. Slide the sensor into the hygienic protective sleeve, see section "Slide the hygienic protective sleeve over the sensor".

4. Place the sensor on the palm of your hand and clip the sensor holder onto the sensor.



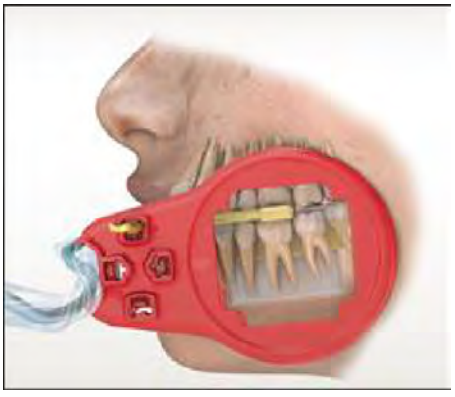
5. Push the sensor into the sensor holder up to the stop.

Position the sensor

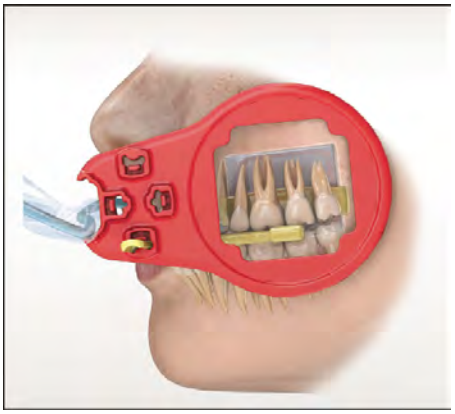


1. Look through the localizer ring to check the alignment of the sensor. The sensor must be located centrally in front of the opening in the localizer ring.

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 [→ 55] and Releasing the exposure. Also observe the operating instructions for the X-ray tube assembly.

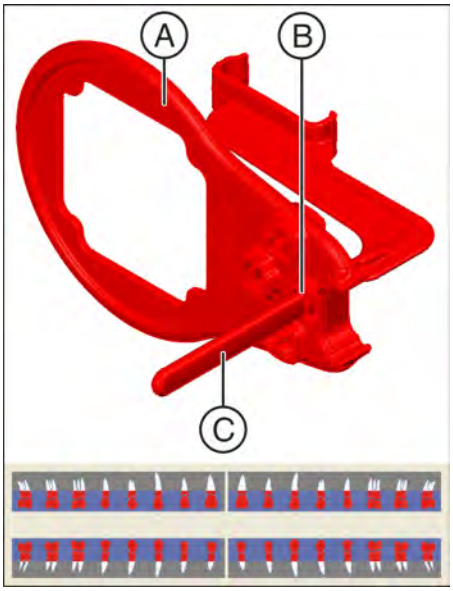
After the exposure

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 [→ 59]. The hygienic protective sleeves must be disposed of after the examination.
4. Clean and sterilize the sensor holder and localizer ring.

5.4.2.3 Horizontal bite wing exposures

Preparing the sensor holder

For bite wing exposures use the **red** sensor holder.

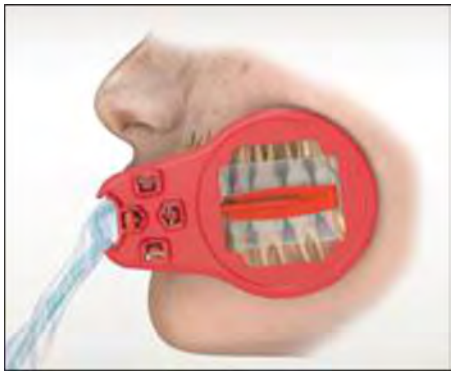


1. Fasten the guide rod for the sensor (C) in the perforation (B) of the localizer ring (A).
2. Slide the sensor into the hygienic protective sleeve, see section "Slide the hygienic protective sleeve over the sensor".

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.

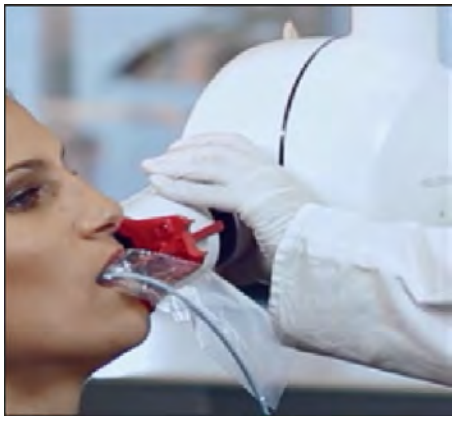
Position the sensor

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.



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 [→ 55] 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 [→ 59]. The hygienic protective sleeves must be disposed of after the examination.
4. Clean and sterilize the sensor holder and localizer ring.

5.5 Select the exposure parameters for the X-ray tube assembly

5.5.1 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.

Please refer to the operating instructions for the X-ray unit.

Effects of too low or too high a dose

For physical reasons the digital X-ray sensors behave in the same way as with X-ray film. The lower the dosage value the higher the image noise, which in turn generally leads to a poorer detail resolution.

⚠ 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.

5.5.2 Recommended dose for XIOS XG sensors

XIOS XG 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.

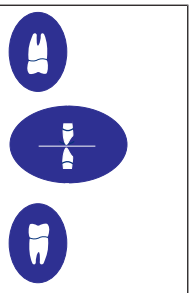
Corresponding values apply to X-ray tube assemblies from other manufacturers and to AC tube units. However, for optimal image quality DC tube units should be used.

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

5.5.3 HELIODENT Plus exposure times

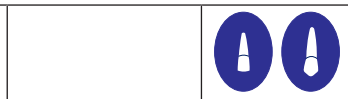
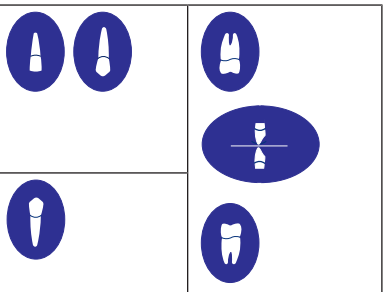
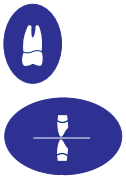
5.5.3.1 Pre-programmed exposure times for XIOS XG sensors with 200 mm (8") FHA cone

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

	Upper jaw					
	Lower jaw					
	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						

5.5.3.2 Pre-programmed exposure times for XIOS XG sensors with 300 mm (12") FHA cone (round or square cone)

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

	Upper jaw					
	Lower jaw					
	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					

5.6 Releasing the exposure

- ✓ The exposure parameters for the X-ray tube assembly are set, see "Select the exposure parameters for the X-ray tube assembly" [→ 55].
- ✓ The sensor is positioned in the patient's mouth with the corresponding auxiliary exposure equipment, see "Position the sensor" [→ 38].

1. Ensure that the USB module is ready for exposures. The orange LED on the USB module must flash, the adjacent LED must light up green, see "Determine unit status" [→ 36].
2. Ensure that SIDEXIS XG / SIDEXIS 4 is ready for exposures. The green display must be flashing in the Exposure readiness window.
3. Check that the X-ray tube assembly is in the correct position and take the X-ray exposure.
4. Remove the sensor from the hygienic protective sleeve. For this follow the instructions in section "Remove the hygienic protective sleeve from the sensor" [→ 59]. 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.
5. Following the X-ray exposure, carefully remove the sensor to prevent it from falling down.
6. Continue with image processing in SIDEXIS XG / SIDEXIS 4.

5.7 Removing the hygienic protective sleeve from the sensor

5.7.1 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.

NOTICE

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.

5.7.2 With Aimright reusable sensor holder system

NOTICE

The sensor cable is sensitive to mechanical influences.

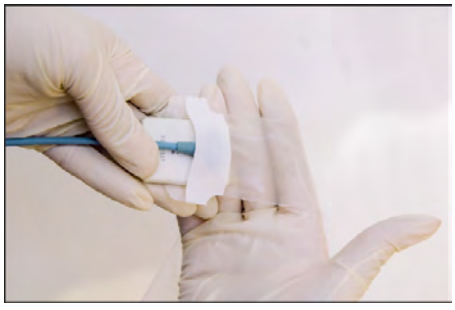
The cable may become damaged or may wear out prematurely.

➢ 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.

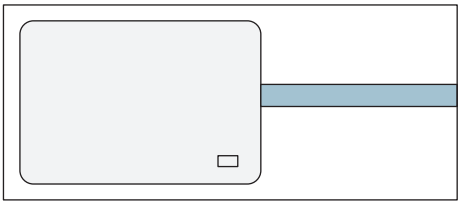
2. Carefully push the sensor out of the narrow part of the hygienic protective sleeve with two fingers.
3. Slide the sensor further out of the hygienic protective sleeve.

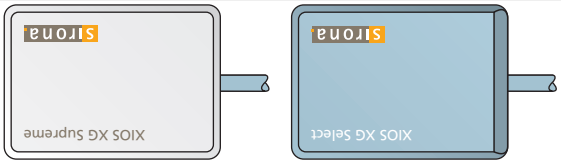
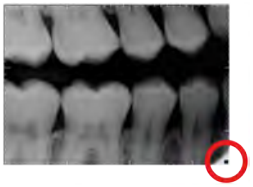
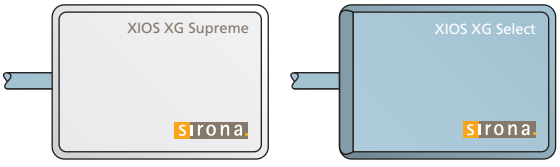
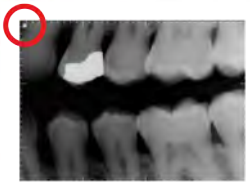
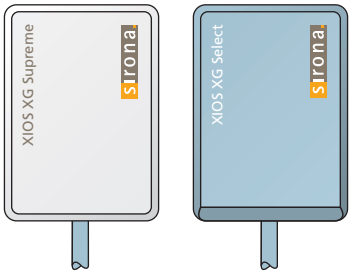
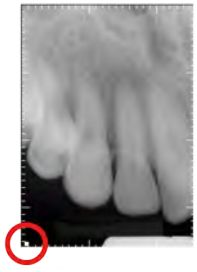
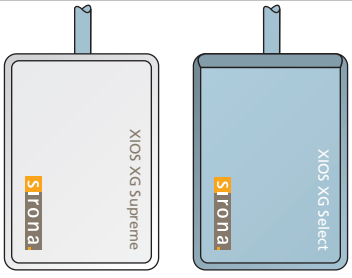
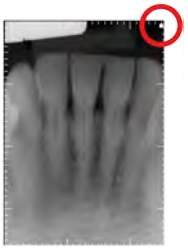


4. Hold on to the sensor and remove it from the hygienic protective sleeve.

5.8 Alignment of the X-ray image

The sensor alignment is shown on the X-ray image by a small rectangle of inverted pixels.



Positioning the sensor	Sensor alignment	Inverted pixels (encircled) and image alignment
Patient's right side		 Right bite wing
Patient's left side		 Left bite wing
Upper jaw		 Upper jaw anterior teeth
Lower jaw		 Lower jaw anterior teeth

6 Maintenance and inspection

6.1 Hygiene

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

6.1.1 Care, cleaning agents, and disinfectants

NOTICE

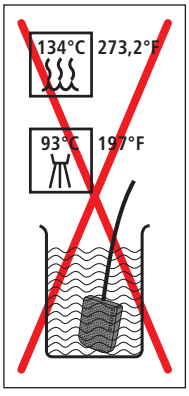
Approved care, cleaning, and disinfecting agents

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

A continuously updated list of approved media can be downloaded from the internet via 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 internet access, please contact your dental depot to order the list (REF 59 70 905).

6.1.2 USB module and sensors



NOTICE

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.

NOTICE

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.

6.1.3 Sensor holders

The rods and rings of the XIOS XG single-use sensor holder system and all parts of the reusable sensor holder system can be sterilized.

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.

NOTICE

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**.

6.2 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 module 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 XG / 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 XG product, please inform your appointed service engineer. In this case, the device should no longer be used for patient exposures.

Observe any possible additional country-specific requirements.

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

⚠ CAUTION

The USB module 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.

6.3 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 Consumables and spare parts"Consumables and spare parts". This contains the required spare parts and tool:

- Sensor cable
- Screwdriver
- 2 protective screw caps
- 2 Elastomer strips
- 4 flathead screws

NOTICE

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.

NOTICE

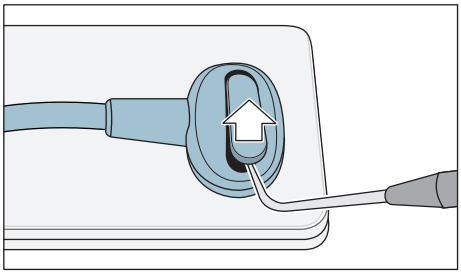
No dirt or moisture must be allowed to get into the exposed plug contacts.

Dirt causes contacts faults, moisture may lead to a short circuit.

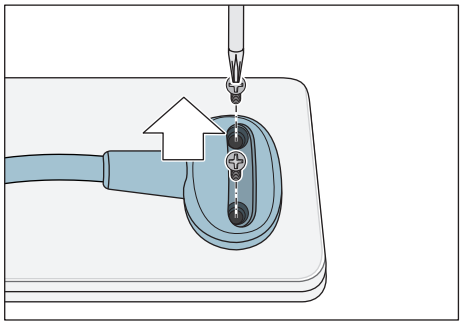
➢ Wash and dry your hands. Do not wear powdered gloves. The powder could become deposited in the plug contacts of the sensor.

➢ Place the sensor on a clean, dry and stable surface.

Unscrew a damaged cable from the sensor

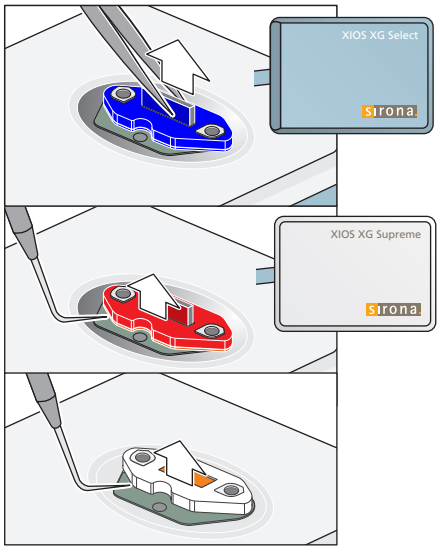


1. Disconnect the sensor from the XIOS XG system.
2. With e.g. a dental instrument remove the protective screw cap from the rear side of the sensor.



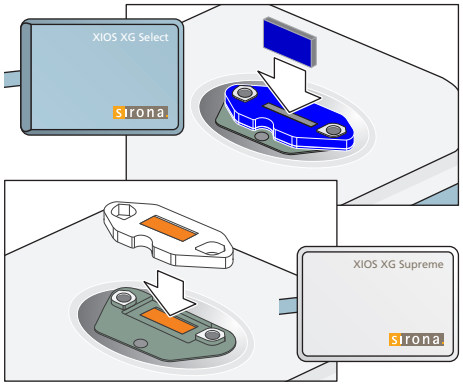
3. Using the screwdriver supplied with the set remove the 2 screws which fasten the cable to the sensor.

Replace the Elastomer strip



1. For XIOS XG Select sensors:
   Remove the existing elastomer strip from the sensor with tweezers. The blue plastic frame remains on the sensor.
   For XIOS XG Supreme sensors:
   When a red plastic frame with elastomer strip is used: Remove the entire plastic frame with the elastomer strip using a suitable tool. It is replaced with a white elastomer part.
   When a white elastomer part is used: Remove the entire elastomer part using a suitable tool.

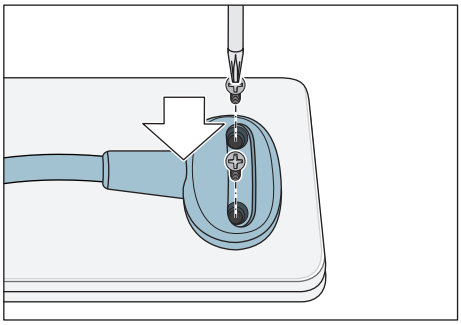
IMPORTANT
Use the new parts supplied with the cable for the assembly!



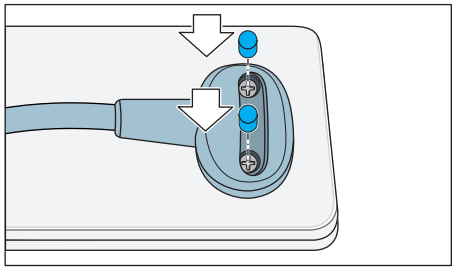
2. For XIOS XG Select sensors:
   Insert a new blue Elastomer strip in the slot. Check that it is positioned correctly by pressing lightly with tweezers. The Elastomer strip must be placed exactly in the slot so that the sensor works.
   For XIOS XG Supreme sensors:
   Place a new white elastomer part on the sensor.

Attach a replacement cable

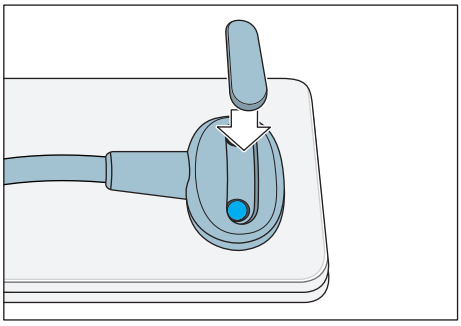
1. Place the plug for the sensor cable properly on the sensor. Both parts must interlock.



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. Place a silicon protective cap on each screw.

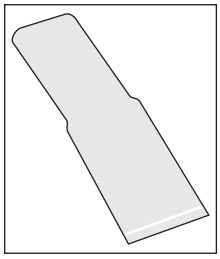


4. Cover the screw heads with a new protective screw cap. Press the cap into the plug of the sensor cable until it locks in place.

↳ The cable replacement is now completed. The sensor can be used again.

7 Consumables and spare parts

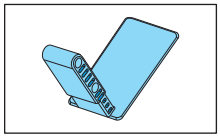
Hygienic protective sleeves for sensors



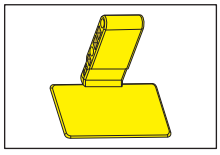
Hygienic protective sleeves for sensor size 0 and 1, quantity 300
REF 64 09 960

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

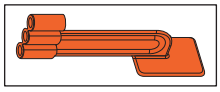
Sensor holder tabs for single-use sensor holder system



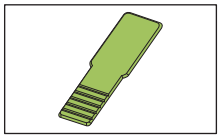
Blue sensor holder tab for front tooth exposure (anterior), quantity 100
REF 61 76 510



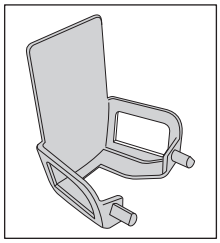
Yellow sensor holder tab for side tooth exposures (posterior), quantity 100
REF 61 76 528



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

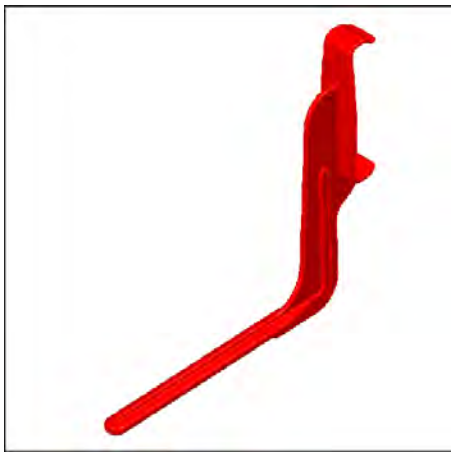
Starter kits include the localizer ring and the guide rod along with 15 sensor holder tabs each for the blue, yellow, red, green and gray sensor holder. The kit also includes 50 hygienic protective sleeves for one sensor size.

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

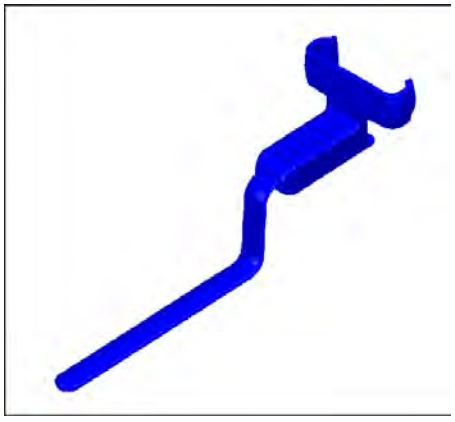
Aimright reusable sensor holder system

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

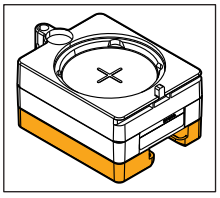
The starter kits are available for sensor sizes 1 and 2. Starter kits include the following:

- 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 XG Select USB size 0, 270 cm
REF 64 83 478

XIOS XG Select USB size 1, 270 cm
REF 64 83 486

XIOS XG Select USB size 2, 270 cm
REF 64 83 494

XIOS XG Supreme USB size 0, 270 cm
REF 64 83 502

XIOS XG Supreme USB size 1, 270 cm
REF 64 83 510

XIOS XG Supreme USB size 2, 270 cm
REF 64 83 528

Sensor cable for USB module

XIOS XG USB cable kit 90 cm
REF 64 04 169

XIOS XG USB cable kit 180 cm
REF 64 04 177

XIOS XG USB cable kit 270 cm
REF 64 04 185

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 module and USB cable

XIOS XG USB module
REF 64 04 656

USB cable A/B 2 m with ferrite
REF 64 04 235

Holders

XIOS XG wall-mounted sensor holder
REF 64 04 151

XIOS XG USB box wall fastening
REF 64 04 326

8 Electromagnetic compatibility

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

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

8.1 Accessories

Designation of the interface cable:
USB cable A/B 2 m with ferrite, REF 64 04 235

System components	Manufacturer	Order No.	Serial No.
CDR Remote	SIRONA USA	Not applicable	10171017
CDR Elite Intraoral Sensor & Cable Assembly	SIRONA USA	Not applicable	20000102

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.

8.2 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	

8.3 Interference immunity

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**	± 6 KV contact discharge ± 8 KV air discharge	± 6 KV contact discharge ± 8 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**	<5% U_T for ½ period (>95% dip of U_T) 40% U_T for 5 periods (60% dip of U_T) 70% U_T for 25 periods (30% dip of U_T) <5% U_T for 5 sec. (>95% dip of U_T)	<5% U_T for ½ period (>95% dip of U_T) 40% U_T for 5 periods (60% dip of U_T) 70% U_T for 25 periods (30% dip of U_T) <5% U_T for 5 sec. (>95% dip of U_T)	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**	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the 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] √P
Radiated RF interference **IEC 61000-4-3**	3 V/m 80 MHz to 800 MHz[1] 3 V/m 800 MHz to 2.5 GHz[1]	3 V_{eff} 3 V_{eff}	d= [1.2] √P at 80 MHz to 800 MHz d= [2.3] √P at 800 MHz to 2.5 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.

8.4 Working clearances

Recommended working clearances between portable and mobile RF communication devices and the UNIT

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 portable and 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 - 80 MHz	80 MHz - 800 MHz	800 MHz - 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
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.

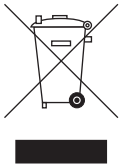
Note 1

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

Note 2

These guidelines may not apply in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and persons.

9 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
  Tel.: +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 product, it must be fully prepared (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.

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