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New as of: 08.2011

sirona
The Dental Company

XIOS USB

Operating Instructions and Installation

English



This product is covered by one or more of the following US patents:

- US 5,912,942
- US 5,434,418
- US 6,811,312
- US 6,069,935
- US 6,134,298
- US 5,841,126
- US 6,549,235
- US 6,570,617
- US 5,513,252

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1 Dear Customer,

Thank you for purchasing your XIOS USB intraoral X-ray system.

The X-ray sensor and USB module enable digital acquisition of intraoral X-ray images.

A PC with the SIDEXIS XG software installed, version 2.2 and higher, is required to operate the USB module.

Your **XIOS** Team

1.1 Contents of this document

Table of contents

These operating and installation instructions describe the handling of the USB module and the sensor as well as the installation of the system hardware and software.

1.2 General conventions

General conventions

You should familiarize yourself with the unit by reading through the operating instructions before taking patient exposures. Please always observe the valid **radiation protection directives** and the **safety information** in these instructions.

These operating instructions are based on the assumption that you are familiar with the SIDEXIS XG software.

In case you get stuck despite having thoroughly studied the operating instructions, please contact your dental depot.

To prevent any personal injury or material damage, pay special attention to any notes printed in bold type or highlighted with signal words such as **NOTICE**, **CAUTION** or **WARNING**:

1.3 Structure of the document

1.3.1 Identification of danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in this document. 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.

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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 on making work easier.

1.3.2 Formats and symbols used

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

✓ Prerequisite **1.** First action step **2.** Second action step or ➢ Alternative action ↳ Result	Requests you to do something.
See "Formats and symbols used [→ 6]"	Identifies a reference to another text passage and specifies its page number.
• List	Identifies a list item.
"Command/menu item"	Identifies commands, menu items or quotations.

1.4 Other valid documents

In addition to the present document, the following documentation is also required (not part of the delivery).

- SIDEXIS XG Installation Instructions
- SIDEXIS XG Operator's Manual (for working with SIDEXIS XG software).

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

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2 Warning and safety information

Symbols used



Symbols used

Observe accompanying documents (on rating plate)

Intended use

This product has been designed for the digital acquisition of intraoral X-ray images.

This product must not be used in areas subject to explosion hazards.

Indications in the areas:

- Conservative dentistry
- Caries diagnosis, especially of proximal lesions
- Endodontics
- Periodontology
- Prosthodontics
- Functional diagnosis and therapy of craniomandibular dysfunctions
- Surgical dentistry
- Implantology
- Oral and maxillofacial surgery
- Orthodontics

Contraindications:

- Display of cartilage structures
- Display of soft tissue

Maintenance and service recommendations

Inspection and maintenance must be performed at scheduled intervals to ensure the operational and functional reliability of your product and to protect the safety and health of patients, users and other persons. In accordance with IEC 60601-1.

The system owner must ensure that all inspections and maintenance events take place.

If the system owner fails to fulfill the obligation to have inspections and maintenance work performed or ignores error messages, Sirona Dental Systems GmbH and its authorized dealers cannot assume any liability for resulting damage.

As manufacturers of medical electrical equipment, we can assume responsibility for the safety properties of the system only if maintenance and repair work on the system is performed by ourselves or by agencies expressly authorized by us, and if components affecting safe operation of the system are replaced by original spare parts in case of 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

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any changes in rated parameters or working ranges (if applicable), as well as the date, the name of the company and a signature.

Modifications to the unit

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 assumes the risk of using non-approved accessories.

CAUTION! PC extensions can lead to impairment of the system's functional reliability (e.g. patient safety and electromagnetic compatibility). The guarantee of the system's functional reliability will automatically be transferred to anyone who implements a system extension which has not been expressly approved by Sirona.

Use the XIOSPlus USB module and the XIOS sensors only as described in these Operating Instructions.

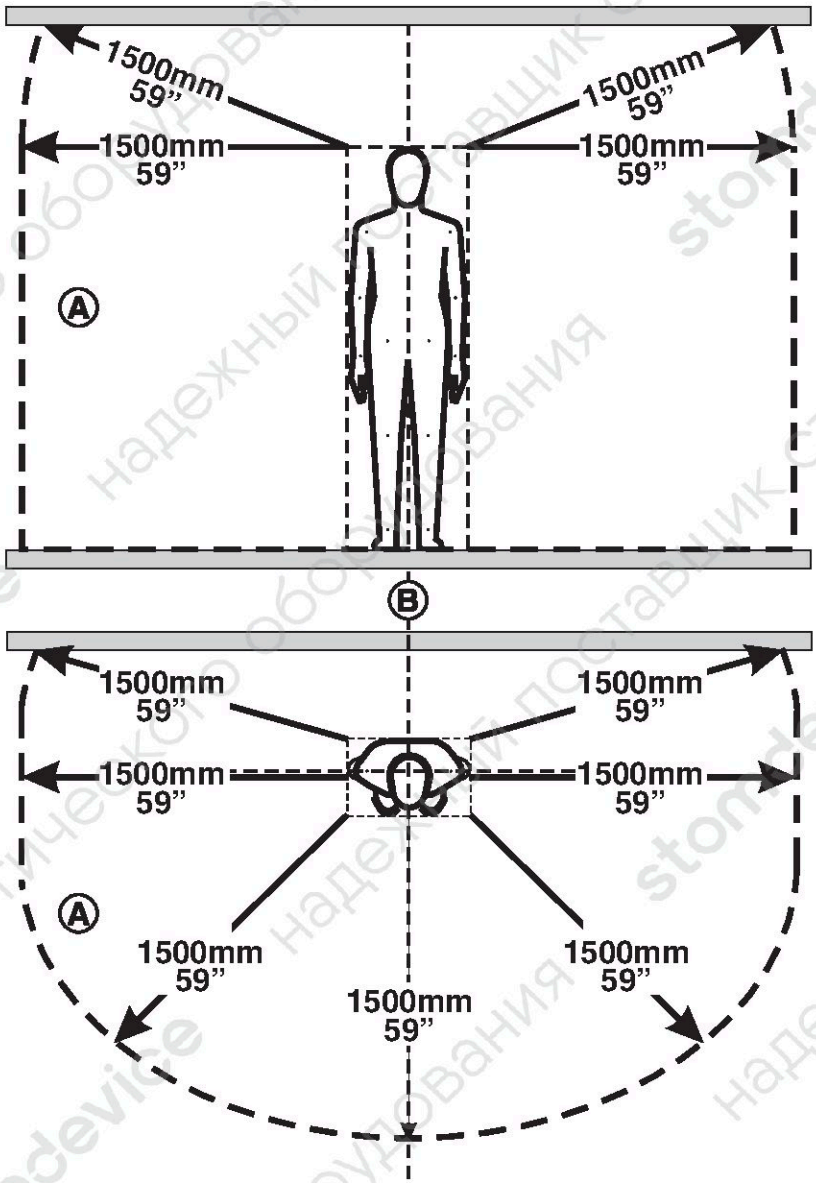
Combination with other equipment

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

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Patient environment



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.

X-raying of patients

X-rays of patients must be taken only when the system works without errors.

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

Do not leave the patient at the unit unattended.

Use the XIOSPlus USB module and the XIOS sensors only as described in these Operating Instructions.

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Electromagnetic compatibility (EMC)

The XIOS USB module complies with the requirements of IEC 60601-1-2.

Medical electrical devices are subject to special precautionary measures regarding EMC. It must be installed and operated as specified in the document “Installation Requirements”.

Portable and mobile RF communications equipment may interfere with medical electrical equipment. Therefore, the use of mobile wireless phones in medical office or hospital environments must be prohibited.

Allocation of acquisition system to patient

Within the scope of practice operations, unambiguous allocation of the acquisition system to the examinee must be ensured to guarantee reliable allocation of X-ray exposures to the patient data saved by SIDEXIS!

Hygiene information

The XIOS protective sleeves and the XIOS sensor holder tabs are single use devices and must be renewed for each patient. The sterilizable exposure accessories should be resterilized for each new patient to prevent any possible transmission of infective agents which might under certain circumstances cause serious illnesses.

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

The sensors and the cable must be wiped disinfected before each patient!

Disturbance of electronic devices worn on the patient's body

To prevent the malfunctioning of electronic devices and data memories, e.g. radio-controlled watches, telephone cards etc., these objects must be removed prior to the X-ray exposure.



Your product is marked with the adjacent symbol. Within the European Economic Area, this product is subject to Directive 2002/96/EC as well as the corresponding national laws. This directive requires environmentally sound recycling/disposal of the product. The product must not be disposed of as domestic refuse!

Please observe the disposal regulations applicable in your country.

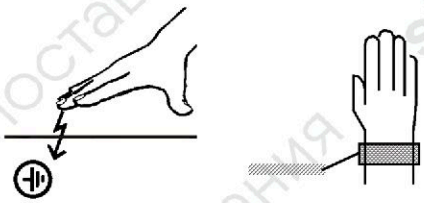
2.1 ESD protective measures

ESD

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

ESD protective measures

ESD protective measures include:



- Procedures for preventing electrostatic charge build-up (e.g. air conditioning, air moistening, conductive floor coverings and non-synthetic clothing)
- Discharging the electrostatic charges of your own body on the frame of the UNIT, the protective ground wire or large metallic objects
- Connecting yourself to ground using a wrist band.

Training

We therefore recommend that all persons working with this system be instructed on the significance of this warning label. Furthermore, they also should receive training in the physics of electrostatic discharges which can occur in the practice and the destruction of electronic components which may result if such components are touched by electrostatically charged USERS.

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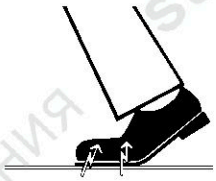
The content of this training is explained in the Chapter "About the physics of electrostatic charges" [→ 11].

2.2 About the physics of electrostatic charges

What is an electrostatic charge?

An electrostatic charge is a voltage field on and in an object (e.g. a human body) which is protected against conductance to ground potential by a nonconductive layer (e.g. a shoe sole).

Formation of an electrostatic charge



Electrostatic charges generally build up whenever two bodies are rubbed against each other, e.g. when walking (shoe soles against the floor) or driving a vehicle (tires against the street pavement).

Amount of charge

The amount of charge depends on several factors:

Thus the charge is higher in an environment with low air humidity than in one with high air humidity; it is also higher with synthetic materials than with natural materials (clothing, floor coverings).

NOTICE

Electrostatic discharge must be preceded by electrostatic charging.

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

An electrostatic discharge is:

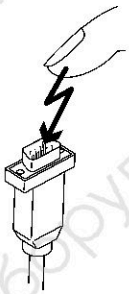
- perceptible at 3,000 V or higher
- audible at 5,000 V or higher (cracking, crackling)
- visible at 10,000 V or higher (arc-over)

The transient currents resulting from these discharges have a magnitude of 10 amperes. They are not hazardous for humans because they last for only several nanoseconds.

Background

Integrated circuits (logical circuits and microprocessors) are used to implement a wide variety of functions in dental/X-ray/CAD/CAM systems.

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.



It is obvious that integrated circuits which are connected to plugs leading outside of the unit via cables are sensitive to electrostatic discharge.

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

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To prevent this from happening, the ESD warning label next to the plug warns of this hazard. ESD stands for **E**lectro**S**tatic **D**ischarge.

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3 Technical description

3.1 General data

The XIOS Digital Intraoral Radiography System, type D 3495, was tested by the VDE Testing and Certification Institute for compliance with IEC 60 601-1.

It complies with the requirements of these regulations.

Original language of the present document:	German
CE 0123	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.
Patents	US 5,912,942 US 5,434,418 US 6,811,312 US 6,069,935 US 6,134,298 US 5,841,126; US 6,549,235; US 6,570,617 US 5,513,252 Additional patents pending.

3.2 Sensors

Technology:	CMOS-APS (Active Pixel Sensor)
Physical pixel size:	40 µm
Active surface:	Size 1 - sensor = 20 x 30 mm Size 2 - sensor = 25.6 x 36 mm
External dimensions:	Size 1 - sensor = 25.0 x 37.7 x 5.3 mm Size 2 - sensor = 30.8 x 43.5 x 5.3 mm
Cable length:	2.90 m
Degree of protection against electrical shock:	 Type BF
Ambient temperature:	10° (50°F) – 40°C (104°F)
Storage temperature:	-40°C (-40°F) – 70°C (158°F)
Relative humidity in operation	< 75%

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Air pressure (storage and transport)	500 – 1060 hPa
Air pressure (operation)	700 – 1060 hPa

3.3 USB module

Type of protection against electric shock:	Protection class II
Degree of protection against ingress of water:	Ordinary equipment (without protection against ingress of water)
Year of manufacture	20XX (on the rating plate)
Dimensions H x W x L (in mm):	132 x 80 x 37
Weight:	104 g
USB port of USB module:	Version 2.0 or 1.1
Ambient temperature:	10° (50°F) – 40°C (104°F)
Storage temperature:	-40°C (-40°F) – 70°C (158°F)
Relative humidity in operation	< 75%
Air pressure (storage and transport)	500 – 1060 hPa
Air pressure (operation)	700 – 1060 hPa

3.4 USB cable (supplied by Sirona)

USB Version 2.0

- A USB (=**U**niversal **S**erial **B**us) is a serial bus system used to connect a computer to external devices.

Length: 3 m

NOTICE

Special cable!

Conventional USB cables are not suitable for use in combination with a USB module.

In case of replacement, always order the (3m) USB cable listed in the section "Accessories and spare parts" [→ 25].

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3.5 Ambient conditions

Ambient temperature:	10° (50°F) – 40°C (104°F)
Storage temperature:	-40°C (-40°F) – 70°C (158°F)
Relative humidity (storage and transport)	10% – 95%
Relative humidity in operation	10% – 75%
Air pressure (storage and transport)	500 – 1060 hPa
Air pressure (operation)	700 – 1060 hPa
Operating altitude:	≤ 3000 m

3.6 Minimum requirements for PC systems

Processor:	32-bit (x86), min. 1GHz
Hard disk:	> 5 GB / database > 50 MB / SIDEXIS installation
RAM:	at least 1 GB
Drives:	CD-ROM writer
Operating systems:	• Windows® 2000 SP4 • Windows® XP SP3 32-bit • Windows® Vista Professional SP1 32-bit • Windows® 7 Professional 32-bit (64-bit not tested) • Windows® 7 Ultimate 32-bit and 64-bit
Graphics system:	Resolution at least 1024 x 768 pixels, 16.7 mil. colors ("TrueColor")
USB port of PC system:	Version 1.1 or 2.0
Safety:	The PC must conform to EN 60950-1. A second protective ground wire must be attached as described in the present instructions [→ 21].

3.7 Requirements for intraoral X-ray tube assemblies

Multipulse units (DC), mAs product:	0.14 – 1.4 mAs, at 60 – 70 kV and 8" cone This information must be modified accordingly for single-pulse units or other cone lengths.

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NOTICE

The intraoral X-ray tube assembly must be installed in accordance with the manufacturer's instructions and requirements. Please refer to the manuals supplied with your intraoral X-ray unit for more information.

NOTICE

For optimal image quality we recommend using a multipulse unit as well as a 12" cone.

3.8 Requirements for the USB hub (optional)

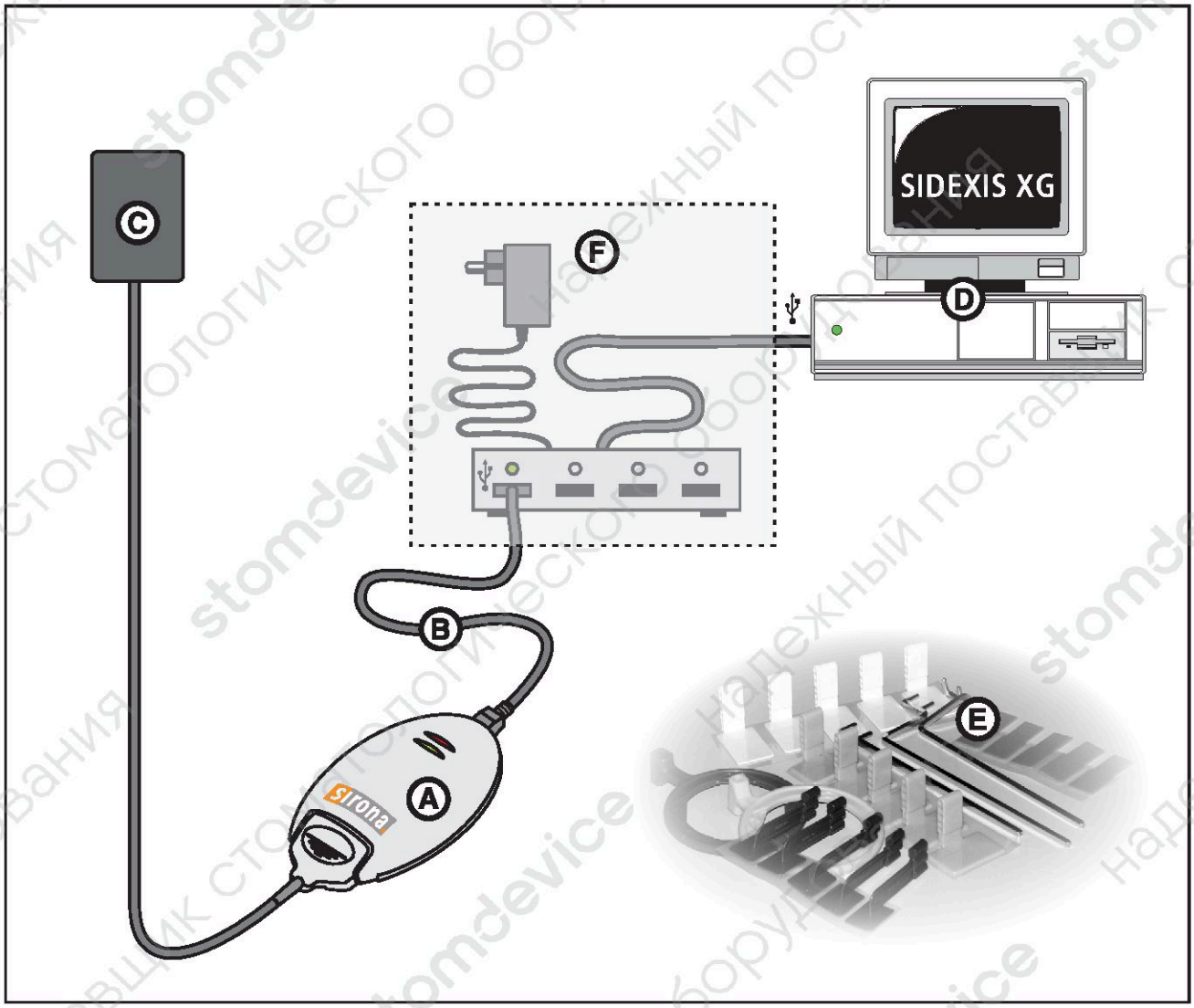
Type of protection against electric shock:	Protection class II ⧈
USB standard:	USB 1.1 or higher
Power supply:	Separate power supply (**not** bus-powered!)
Safety:	The USB hub must comply with standard 60950-1 or be certified by a testing laboratory which requires compliance with this standard (e.g. VDE, UL, CSA)

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4 Operating and display elements

4.1 System design



A	USB module
B	USB cable
C	Sensor with cable and connector (size 1 or size 2)
D	PC with integrated USB interface and installed Windows® operating system incl. SIDEXIS XG software (version 2.2 or higher)
E	XIOS sensor holder set with localizer rings and guide rods
F	USB hub (optional)

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4.2 USB module



The USB module is connected between the sensor and the PC. The image data are transferred to a conventional PC with a Windows® operating system via the USB module and USB cable, after which they can be further processed with the SIDEXIS XG software.

- Signal LED (green) (**A**)
- Ready LED (orange) (**B**)
- Sensor socket (**C**)
- USB socket (**D**)

4.3 LED displays

Explanation

The USB module indicates the current operating status via two (green and orange) LEDs. An overview of the different operating statuses is provided here.

Green LED



Green LED display off:

- The USB module is **not** supplied with voltage.

Green LED display on:

- The USB module is supplied with voltage.

Orange LED



NOTICE

The orange-colored LED functions only if the USB module is supplied with voltage (green LED on).

Orange LED display off:

- No sensor is connected to the USB module.

Orange LED display on:

- A sensor is connected to the USB module.

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Orange LED display flashing:

- Exposure readiness. The exposure readiness dialog box opens on the SIDEXIS XG user interface.
  The green bar in the exposure readiness dialog box starts flashing.

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5 Installation

NOTICE

Installation on multiple SIDEXIS XG PCs

The complete installation must be performed on each SIDEXIS XG PC to which USB modules are to be connected!

NOTICE

Standby mode

The computer should never be switched to the standby mode during operation of the USB module. Otherwise the system could be temporarily deactivated.

5.1 Prior to installation

The PC

The PC must be in a state of operational readiness before the installation of the XIOS Intraoral System.

- Make sure that the hardware and the operating system are properly installed.
- Also observe the “Installation Instructions” and “Operator’s Manual” for SIDEXIS XG as well as the relevant manuals for your PC and its operating system.

⚠ WARNING

Shock hazard

The PC must be connected to a grounded electric outlet when in operation.

⚠ WARNING

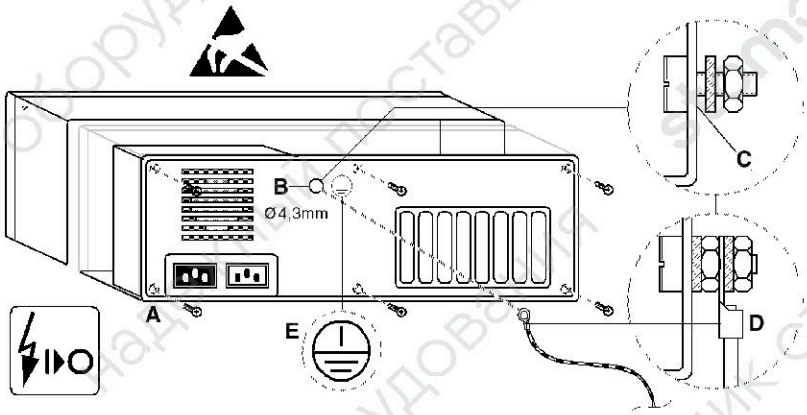
Shock hazard

The PC may not be operated in the patient environment [→ 9] without an additional protective ground wire. See "Installation Instructions".

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5.2 Installation of the additional protective ground wire



NOTICE

The illustration is a case example.

Preparation

- ✓ All running programs have been terminated.
- ✓ The PC and all connected components have been switched off.
- ✓ The power cord has been removed.

1. Put on an ESD wrist band or discharge your body by touching the equipotential bonding conductor.
2. Undo the screws of the PC casing (**A**) (see the PC operator's manual) and remove the cover of the PC.

Drilling

NOTICE

Risk of damage

Be careful not to damage any parts of the PC when drilling!

NOTICE

Risk of short circuit

Make sure that no swarf get inside the PC when drilling.

1. Find a location to connect the protective ground wire on the rear side of the metal casing frame (**B**) that is readily accessible from the inside and from the outside.
2. Drill a hole with a suitable diameter for an M4 screw at this location (**B**).
3. Remove any paint around the drill hole (**C**) to achieve a good metal contact.

Installation

1. Fasten the enclosed connecting screw firmly with a toothed lock washer and nut.
2. Screw down the protective ground wire (**D**) as shown.

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3. Affix the attached label (E) next to the protective ground wire connection.
4. Connect the protective ground wire to the equipotential bonding conductor.

5.3 Installing USB modules

5.3.1 Hardware requirements

Explanation

A USB module can be connected to your PC either directly or via a USB hub.

NOTICE

Operational reliability

If multiple USB modules are connected simultaneously, a suitable USB hub with a separate power supply must be used!

⚠ WARNING

The USB hub must be set up and operated outside of the patient environment [→ 9].

Prerequisites

- The USB port of the PC selected for USB modules should never be shared with other USB components!
- If multiple USB modules are connected to a single PC, all of them must be connected to the PC via a common USB hub with a separate power supply!
  The technical requirements for the common USB hub are described in the chapter "Technical description".
  The USB hub must be installed prior to the actual installation of a USB module.
  Install the USB hub as described in the relevant operating instructions.

5.3.2 Installation instructions

Operational reliability

NOTICE

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.).

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5.3.3 Installation of a USB module on a PC

Prerequisites

- The PC is ready for operation.
- SIDEXIS XG Version 2.2 or higher is installed.
- Optionally: A USB hub has been installed as specified by Sirona.

Installation

✓ Connect the USB module to the PC or to the USB hub only after being prompted to do so.

1. Insert the Installation CD in the relevant PC.
2. Select *"XIOS Installation"*.
3. Click the *"Next"* button.
4. Follow the instructions in the dialog boxes of the setup program and click the *"Next"* buttons in between until the *"Finish"* button appears.
5. Click the *"Finish"* button.
6. Connect the USB module to the PC or the USB hub with the supplied USB cable.

↳ The USB module is now installed.

5.3.4 Installation of additional USB modules on a PC

Prerequisites

- The PC is ready for operation.
- A USB hub has been installed as specified by Sirona.
- A USB module has already been installed.

Installation

➢ Connect the USB module to the USB hub with the supplied USB cable.

↳ The operating system then detects the new USB module and automatically installs the matching driver.

5.4 Installing a sensor

Explanation

The sensor data are managed centrally.

The software installation thus has to be performed only once for each individual sensor in a SIDEXIS XG network environment.

5.4.1 Installation of hardware

➢ Plug the connector of the sensor into a completely installed USB module.

NOTICE

Risk of damaging the sensor and the sensor cable

- The sensor cable must not be bent, folded or twisted or subjected to any other form of mechanical stress.

- Do not unplug the sensor by pulling on the cable.

- Inspect the sensor cable visually for damage every day.

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5.4.2 Software installation

Prerequisites

- The hardware installation has been successfully completed

Installation via Sensor Installation CD

➢ Insert the Sensor Installation CD supplied for the relevant sensor in the CD drive of the PC with the installed USB module.

↳ The setup program starts automatically. If this is not the case, install the sensor by double-clicking the sensor correction file (*.SGF) located on the Sensor Installation CD.

↳ This program automatically installs the sensor.

Installation via internet

When activating exposure readiness, SIDEXIS XG checks whether the sensor has been installed.

If the sensor has not yet been installed, the user is asked whether it should be installed automatically via the Internet.

NOTICE

Software installation via the internet is possible only for computers with internet access.

Installation via internet with the SIDEXIS Manager

Explanation

If your XIOS computer has no access to the internet, you can also download the sensor correction file (*.SGF) from another SIDEXIS computer which does have access to the internet using the SIDEXIS Manager.

Installation

1. Start the SIDEXIS Manager on the computer with internet access by selecting *"start"* -> *"programs"* -> *"SIDEXIS"* -> *"SIDEXIS Manager"*.
2. Select the application `NGIO3Update`.
3. Enter the serial number of your XIOS sensor there.
4. Select the *"Saving only"* check box.
5. Press the *"Download"* button.
6. A save dialog box appears.
7. Select the folder where you would like to store the sensor correction file (*.SGF).
8. Copy the sensor correction file (*.SGF) to your XIOS computer (using e.g. a USB stick).
9. Install the sensor on your XIOS computer by double-clicking on the sensor correction file (*.SGF).

5.5 Following installation

Test exposure

Take a test exposure after the following installations:

- After installation of a XIOS module.
- Following the initial installation of a new sensor.

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6 Accessories and spare parts

NOTICE

Not all of the accessories listed here are included in the scope of supply.

NOTICE

Sensor holder tabs and hygienic protective sleeves are single use devices!

They can, however, be used repeatedly on the same patient. The adhesive on the sensor holder tabs is suitable for gluing and detaching them from the protective sleeve repeatedly.

Identification of single use devices



Single use devices are identified with the symbol shown at left.

6.1 Accessories

XIOS sensor holder starter kit, size 2

Order No.: 61 73 624

Contents:

- 15x sensor holder tab, anterior (blue), including localizer ring and guide rod
- 15x sensor holder tab, posterior (yellow), including localizer ring and guide rod
- 15x sensor holder tab, bite wing (red), including localizer ring and guide rod
- 15x sensor holder tab, universal (green)
- 15x sensor holder tab, endo (gray), including localizer ring and guide rod
- 15x hygienic protective sleeves, size 2

XIOS sensor holder starter kit, size 1

Order No.: 61 73 632

Contents:

- 15x sensor holder tab, anterior (blue), including localizer ring and guide rod
- 15x sensor holder tab, posterior (yellow), including localizer ring and guide rod
- 15x sensor holder tab, bite wing (red), including localizer ring and guide rod

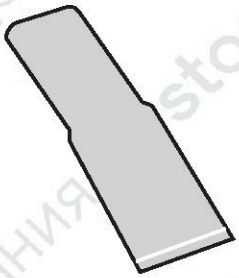
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- 15x sensor holder tab, universal (green)
- 15x sensor holder tab, endo (gray), including localizer ring and guide rod
- 15x hygienic protective sleeves, size 2

Hygienic protective sleeves, size 2 (single use device, 300 pcs)

Order No.: 61 76 569



Hygienic protective sleeves, size 1 (single use device, 300 pcs)

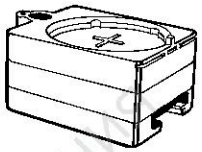
Order No.: 61 76 577

Wall holder for XIOS X-ray sensors

Order No.: 61 74 879

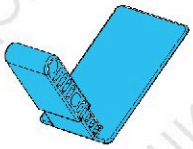
Phantom XIOS sensor sizes 1 and 2 for constancy test (only for Germany)

Order No.: 61 77 328



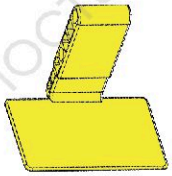
XIOS sensor holder tab, anterior, blue (single use device, 100 pcs)

Order No.: 61 76 510



XIOS sensor holder tab, posterior, yellow (single use device, 100 pcs)

Order No.: 61 76 528



XIOS sensor holder tab, bite wing, red (single use device, 100 pcs)

Order No.: 61 76 536



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XIOS sensor holder tab, universal, green (single use device, 100 pcs)

Order No.: 61 76 544



XIOS sensor holder tab, endo, gray (single use device, 50 pcs)

Order No.: 61 76 551

Radiation limiter 3x4 for HELIODENT DS, replacement

Order No.: 46 81 974

Radiation limiter 2x3 for HELIODENT DS, replacement

Order No.: 60 00 579

RINN sensor holder set for XIOS X-ray sensor

Order No.: 61 76 585

USB cable (3 m)

Order No.: 61 77 401

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7 Use of the X-ray sensor

The X-ray sensor should be placed according to the well-known parallel or half-angle technique.

⚠ CAUTION

Illustrations without hygienic sleeves

For the sake of clarity, no hygienic sleeves are shown in some of the illustrations. However, a hygienic sleeve always must be slipped over the sensor before using it on a patient.

NOTICE

Risk of damage

- Handle the sensor carefully.
- Do not drop the sensor!
- Do not swirl the sensor about by its cable.
- Do not bend the sensor and USB cables or run over them (e.g. with a chair)!
- Avoid laying the sensor and USB cables on the floor if possible.
- Make sure that the patient does not bite on the sensor or the sensor cable.
- When pulling the connector out of the USB module, do not pull on the cable, but rather on the plug.

NOTICE

Operational reliability

- The sensor must be checked to ensure that it is plugged in correctly before releasing an exposure!
- The user must check the LEDs to verify system readiness prior to radiation release!
- Never place two sensors in the beam path at the same time!
- All sensor systems that are connected to a single PC must be located in the same treatment room in order to prevent patient mix-ups.

7.1 Preparation

Checklist

NOTICE

Check the sensor cable and sensor for damage, e.g. cracks or splinters, prior to each exposure. In case of visible damage to the sensor, please contact your dealer.

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NOTICE

Check all adhesive labels at regular intervals, and at least once a month, to make sure that they are intact, legible and properly affixed.

Also check the XIOS USB module and the cables connected to it for damage.

In case of visible damage to the XIOS USB module, cables or adhesive labels, please contact your dealer.

- No other programs should be running on the PC during an exposure.

7.2 Hygienic protection

Hygienic protection

Please use Sirona hygienic protective sleeves for hygienic protection.

⚠ CAUTION

Use only the XIOS hygienic protective sleeves offered by Sirona, especially in connection with the XIOS sensor holders.

⚠ CAUTION

Hygienic protective sleeves and sensor holder tabs are single use devices. Do not use hygienic protective sleeves more than once!

- Prior to each application on a new patient, the sensor must be covered with a new hygienic protective sleeve.
- Do not bend the sensor cable when slipping the hygienic protective sleeve over it!
- Please use the hygienic protective sleeve which correctly matches the sensor.

Hygienic protective sleeve

- XIOS Hygienic protective sleeve for sensor size 1
  300 pcs, Order No.: 62 01 839
- XIOS Hygienic protective sleeve for sensor size 2
  300 pcs, Order No.: 62 01 847

NOTICE

Make sure that the cable connecting the sensor is run out of the patient's mouth in such a way that the patient cannot bite it.

NOTICE

Make sure that the cable connecting the sensor to the USB module is run out of the patient's mouth in such a way that the patient cannot bite it.

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7.2.1 Sliding the hygienic protective sleeve over the sensor

Handling



1. Please select a hygienic protective sleeve with a size that matches the sensor.
2. Slide the sensor into the hygienic protective sleeve.

NOTICE

Size of the hygienic protective sleeve

The hygienic protective sleeve is slightly undersized, so that it surrounds the sensor tightly and prevents the sensor from slipping out of place.

3. Position the sensor holder tab on the hygienic protective sleeve.

NOTICE

The exact position depends on the sensor holder tab used and the X-ray exposure area. The following sections contain specific information on how to position different sensor holder tabs.

Handling information for the parallel technique

If the supplied XIOS sensor holder tab set is used, the hygienic protection sleeve must be placed between the sensor and the holder. The sensor holder tab must not be glued onto the unprotected sensor.

NOTICE

Never slide the hygienic protective sleeve over the sensor with glued on sensor holder!

7.2.2 Removing the hygienic protective sleeve from the sensor

NOTICE

Leave the sensor holder tab attached to the sensor and slide the sensor out of the hygienic protective sleeve using your thumb.

NOTICE

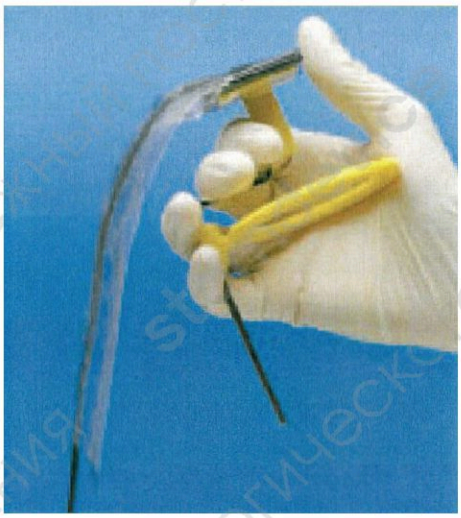
Please do not pull on the sensor cable while pushing the sensor out of the hygienic protective sleeve!

NOTICE

Always handle the cable with care when removing the hygienic protective sleeve.

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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.



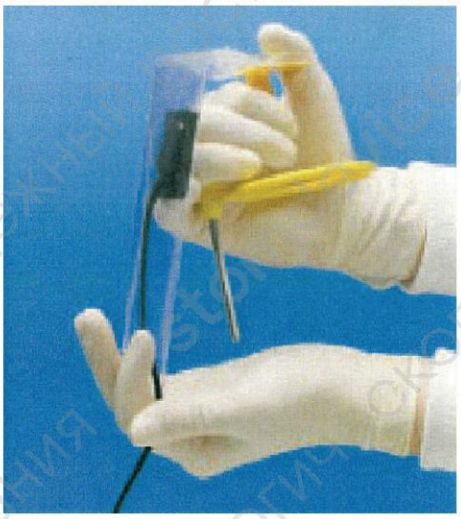
2. Carefully push the sensor out of the part of the hygienic protective sleeve that is glued to the sensor holder tab with your thumb.



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

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

7.3 Parallel technique with radiation limiter!

For enhanced dose reduction, we recommend using the radiation limiter and the XIOS holder system for the parallel technique.

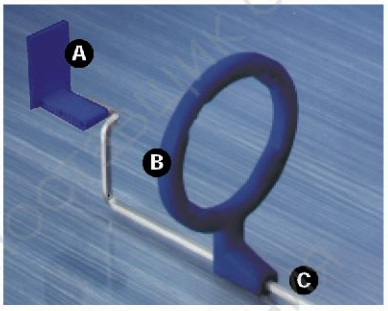
7.3.1 Anterior tooth exposure

Explanation

A special "anterior" sensor holder tab is available for anterior tooth exposures.

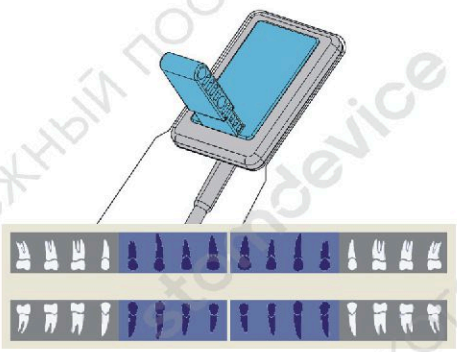
- This sensor holder tab and the matching localizer ring are color-coded **blue**.
- The (triple-offset) guide rod and the blue localizer ring for **anterior tooth exposures** must be used.
- The following illustrations show how to attach the sensor holder tab to the hygienic protective sleeve with sensor.

Preparation



1. Plug together the triple-offset guide rod **(C)** and the blue localizer ring **(B)** of the XIOS holder system for **anterior tooth exposures**.
2. Select the blue sensor holder tab for periapical exposures **(A)** and plug it onto the guide rod **(C)**.
3. Slide the sensor into the hygienic protective sleeve, When doing so, follow the instructions for sensors. [→ 30]

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4. Adhere the sensor holder tab in the middle of the active area of the sensor to the hygienic protective sleeve as shown in the illustration. The active area of the sensor is identified by dots on the sensor.

X-ray image



1. Position the sensor in the patient's mouth.
2. Place the X-ray tube assembly in the correct position. Change the position of the sensor holder if necessary.
3. Release an X-ray exposure.
4. Discard the sensor holder tab and the hygienic protective sleeve following the patient examination.
5. The guide rod and localizer ring must be cleaned and sterilized.

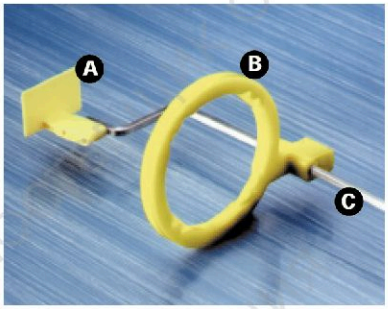
7.3.2 Posterior tooth exposures

Explanation

The "posterior" type sensor holder tab is available for periapical posterior tooth exposures.

- This sensor holder tab and the matching localizer ring are color-coded **yellow**.
- The (double-offset) guide rod and the yellow localizer ring for posterior tooth exposures must be used.
- The following illustrations show how to attach the sensor holder tab to the hygienic protective sleeve with sensor.

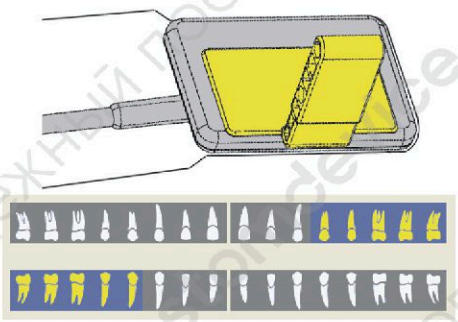
Preparation



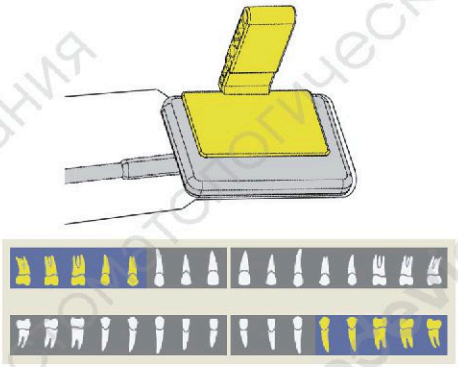
1. Plug together the double-offset guide rod **(C)** and the yellow localizer ring **(B)** of the XIOS holder system for **posterior tooth exposures**.
2. Select the yellow sensor holder tab for periapical posterior tooth exposures **(A)** and plug it onto the guide rod **(C)**.
3. Slide the sensor into the hygienic protective sleeve, When doing so, follow the instructions for sensors. [→ 30]

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4. **For the left upper jaw and right lower jaw:** Position the sensor holder tab in the middle of the active area of the sensor as shown in the illustration. The active area of the sensor is identified by dots on the sensor. The edge of the sensor holder tab must be flush with the edge of the sensor.



5. **For the right upper jaw and left lower jaw:** Position the sensor holder tab in the middle of the active area of the sensor as shown in the illustration. The active area of the sensor is identified by dots on the sensor. The edge of the sensor holder tab must be flush with the edge of the sensor.

X-ray image



1. Position the sensor in the patient's mouth.
2. Place the X-ray tube assembly in the correct position. Change the position of the sensor holder if necessary.
3. Release an X-ray exposure.
4. Discard the sensor holder tab and the hygienic protective sleeve following the patient examination.
5. The guide rod and localizer ring must be sterilized.

7.3.3 Bite wing exposures

Explanation

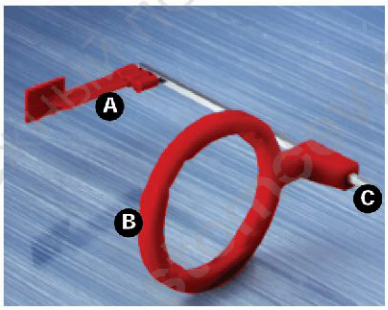
The "bite tab" type sensor holder tab is available for bite wing exposures.

- This sensor holder tab and the matching localizer ring are color-coded **red**.
- The straight guide rod and red localizer ring for bite wing exposures must be used.
- The following illustrations show how to attach the sensor holder tab to the hygienic protective sleeve with sensor.

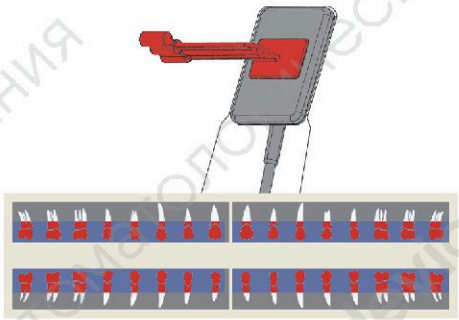
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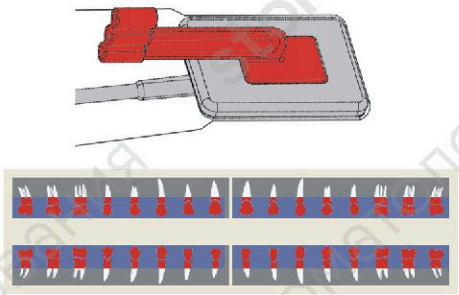
Preparation



1. Plug together the straight guide rod **(C)** and the red localizer ring (**B**) of the XIOS holder system for **bite wing exposures**.
2. Select the (bite tab type) red sensor holder tab **(A)** for bite wing exposures and plug it onto the guide rod **(C)**.
3. Slide the sensor into the hygienic protective sleeve, When doing so, follow the instructions for sensors. [→ 30]

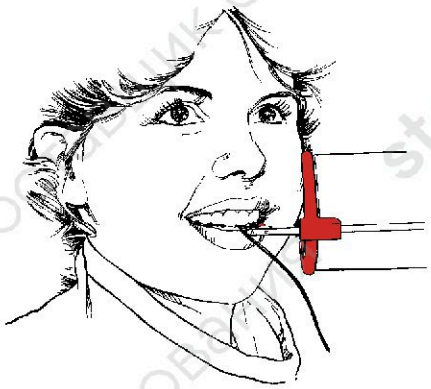


4. **For vertical bite wing exposures:** Position the sensor holder tab vertically on the hygienic protective sleeve in the middle of the active area of the sensor as shown in the illustration. The active area of the sensor is identified by dots on the sensor.



5. **For horizontal bite wing exposures:** Position the sensor holder tab horizontally on the hygienic protective sleeve in the middle of the active area of the sensor as shown in the illustration. The active area of the sensor is identified by dots on the sensor.

X-ray image



1. Position the sensor in the patient's mouth.
2. Place the X-ray tube assembly in the correct position. Change the position of the sensor holder if necessary.
3. Release an X-ray exposure.
4. Discard the sensor holder tab and the hygienic protective sleeve following the patient examination.
5. The guide rod and localizer ring must be sterilized.

7.3.4 Endodontics

Explanation

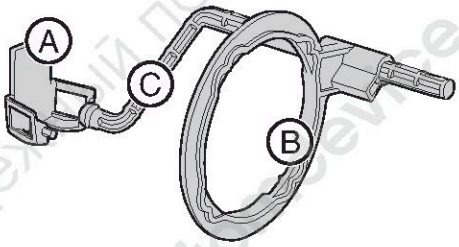
The "endo" type sensor holder tab is available for endodontics.

- This sensor holder tab, the matching guide rod and the matching localizer ring are color-coded **gray**.

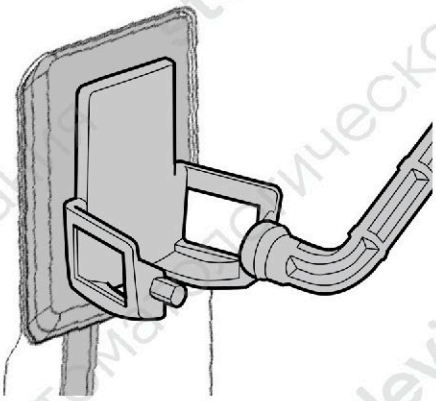
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Preparation



1. Plug together the gray guide rod made of plastic **(C)** and the gray localizer ring **(B)** of the XIOS holder system for endodontic exposures.
2. Select the gray sensor holder tab **(A)** for endodontic exposures and plug it onto the guide rod **(C)**.
3. Slide the sensor into the hygienic protective sleeve, When doing so, follow the instructions for sensors. [→ 30]
4. Adhere the sensor holder tab in the middle of the active area of the sensor to the hygienic protective sleeve as shown in the illustration. The active area of the sensor is identified by dots on the sensor.



X-ray image

NOTICE

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

1. Position the sensor in the patient's mouth.
2. Place the X-ray tube assembly in the correct position. Change the position of the sensor holder if necessary.
3. Release an X-ray exposure.
4. Discard the sensor holder tab and the hygienic protective sleeve after completing the root treatment.
5. The guide rod and localizer ring must be disinfected.

7.4 Half-angle technique without radiation limiter

Depending on the size of the tooth or position of the area to be exposed, place the X-ray sensor in the patient's mouth vertically or horizontally.

The patient may be asked to immobilize the sensor by holding it himself.

7.4.1 Endodontic Exposures

Explanation

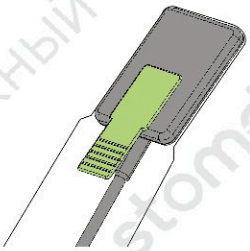
A special universal sensor holder tab is available for exposures with the half-angle technique.

- This universal sensor holder tab is color-coded **green**.
- The following illustrations show how to attach the sensor holder tab to the hygienic protective sleeve with sensor.

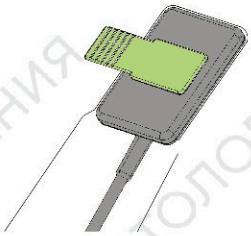
Preparation

1. Slide the sensor into the hygienic protective sleeve, following the instructions for sensors. [→ 30]

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2. Select the green universal sensor holder tab and remove the protective foil from the adhesive surface.
3. **Anterior tooth exposures:** To take anterior tooth exposures, position the sensor holder tab on the edge of the sensor near the cable.



4. **Posterior tooth exposures:** To take posterior tooth exposures, position the sensor holder tab in the middle of the active area of the sensor. The active area of the sensor is identified by dots on the sensor.

X-ray image

1. Position the sensor in the patient's mouth.
2. Place the X-ray tube assembly in the correct position. Change the position of the sensor holder if necessary.
3. Release an X-ray exposure.
4. Discard the universal sensor holder tab and the hygienic protective sleeve following the patient examination.

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8 Image acquisition

8.1 Messages

NOTICE

Risk of crash during image acquisition

During image acquisition, programs running in the background (e.g. media player, print manager, backup software, etc.) can cause SIDEXIS XG to crash.

➢ Before image acquisition, close all programs that are not required for the operation of SIDEXIS XG. In cases of doubt, consult your system administrator.

8.2 Preparation

The USB module and sensor have been installed as described in the chapter on "Installation" and connected to the PC.

8.3 Readying the unit for a scan





✓ The SIDEXIS XG program has been started.

1. Start by registering a patient in SIDEXIS XG.

2. To take a single exposure, click the intraoral exposure button.
   ↳ If several intraoral sensors/systems exist, then a component selection dialog box is displayed. Select the appropriate X-ray system/component here.

↳ Exposure readiness is enabled automatically.

Display of exposure readiness

- The exposure readiness dialog box opens on the SIDEXIS XG user interface.
  The green display in the exposure readiness dialog box starts flashing. Depending on the capacity of the connected PC, this may take 10 seconds or longer.
  The message *"Waiting for exposure ..."* is displayed in the exposure readiness dialog box.

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- The green signal LED (**A**) lights up on the USB module.
- The orange readiness LED (**B**) flashes.

8.4 Positioning the sensor

1. Use the holder to position the sensor in the patient's mouth.
2. Bring the intraoral X-ray unit into position.

You will find more information pertaining to handling the sensor in the chapter "Use of the X-ray sensor [→ 28]".

8.5 Releasing the exposure

Operation notes

Sensor and USB cables

- Do not fold or bend any cables.
- Do not pinch any cables (e.g. in drawers).
- Do not roll over cables (e.g. with a chair).
- Do not allow patients to bite the sensor cables.
- Do not pull on the cable. When unplugging cables from sockets, always pull the plug only.

Sensor

- Do not allow patients to bite the sensor.
- Do not drop the sensor.

Sensor holder

- The sensor holders are single use devices.
- **Only for the same patient:** The sensor holder can be removed and reattached repeatedly during a series of exposures, even if it already has come into contact with saliva.

Exposure

1. Before taking an exposure, check to make sure that the orange readiness LED (**B**) of the USB module and the green indicator in the

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exposure readiness dialog box of the SIDEXIS XG user interface are flashing.

NOTICE

An audible alarm is emitted by the PC 5 seconds before the exposure readiness period expires.

2. Take an X-ray exposure (Observe chapter on "Exposure times").
3. Remove the hygienic protective sleeve as described in the section "Removing the hygienic protective sleeve from the sensor" [→ 30].
4. Following the X-ray exposure, carefully remove the sensor to prevent it from falling down. E.g. place the sensor in the wall holder for safekeeping.
5. Disinfect the sensor if necessary.
6. Clean and sterilize the guide rod and localizer ring.
7. Continue with image processing.

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9 Exposure times

Explanation

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 beam focus and sensor,
- Morphology of patient,
- Object (i.e. tooth), which is to be X-rayed.

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

The X-ray dose influences the image quality that can be achieved by an X-ray system. Based on fundamental laws of physics, with digital X-ray sensors - as with film - an insufficient dose generally means higher image noise, which usually leads to poorer detail discrimination.

On the other hand, a too-high dose can cause the sensor to be overexposed. This is noticeable by a decreasing detail discrimination, specifically in darker areas.

Brightness and contrast can always be optimally adjusted through the XIOS image preprocessing function, independent of dose.

XIOS 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.

NOTICE

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.

NOTICE

Image degradations resulting from an insufficient dose

Image degradations resulting from an insufficient dose can be partially compensated through image postprocessing.

NOTICE

Image degradations caused by overexposure of the sensor cannot be compensated!

Exposure times for size 1 and size 2 XIOS X-ray sensors

Short exposure times are adequate for the highly sensitive size 1 and size 2 XIOS X-ray sensors.

The exposure parameters specified for X-ray sensors in the documentation for the various Sirona intraoral X-ray systems therefore do not apply to size 1 and size 2 XIOS X-ray sensors.

Recommended exposure times for Sirona devices are described below. Exposure times of 0.06 - 0.12 s correspond to dose values between approx. 300 and 600 µGy at the sensor when measured without an object and with a focus-sensor-distance of 23 cm. Corresponding values apply

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to devices from other manufacturers and to AC tube units. However, for optimal image quality DC tube units should be used.

NOTICE

Please observe the corresponding specifications of the X-ray device manufacturer.

NOTICE

Better image quality

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

9.1 HELIODENT DS

General

HELIODENT DS has its own exposure times for operation with digital X-ray sensors.

The preset exposure times are not valid for XIOS^{Plus} sensors.

To switch from conventional to digital acquisition, briefly press the **D** button.

- The word "DIGITAL" lights up on the membrane keyboard to indicate the switch-over.
- The reduced exposure time is indicated.

➢ In this case please use the radiation limiter for digital acquisition.

For a detailed description please refer to the Operating Instructions of the HELIODENT DS.

9.1.1 HELIODENT DS Serial Nos. 15864 and higher (wall model) and 4416 and higher (ceiling model)

NOTICE

Prior to an exposure, check the following:

- Is digital exposure selected (illuminated display "DIGITAL")?

- Is the correct exposure time for the exposure region displayed?

Possible exposure times

0.01	0.02	0.03	0.04	0.05	0.06	0.08	0.10	0.12	0.16	0.20	0.25	0.32	0.40	0.50	0.64	0.80	1.00	1.25	1.60	2.00	2.50	3.20

Recommended exposure times – with 8" SSD cone and XIOS size 1 / size 2 X-ray sensors

An excellent image quality is achieved with XIOS sensors when using a radiation time of 0.08 to 0.10 s (at 60 kV, 7 mA).

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- The positioning of the sensors using the parallel technique (with XIOS sensor holders) ensures an optimal positioning of the sensors in the beam path of the cone.
- It is the responsibility of each individual dentist to determine the required dose for each patient in order to achieve image quality suitable to make a diagnosis. Sirona can only make recommendations.

When the desired patient symbol is set to the tooth symbol, the recommended exposure times are assigned automatically.

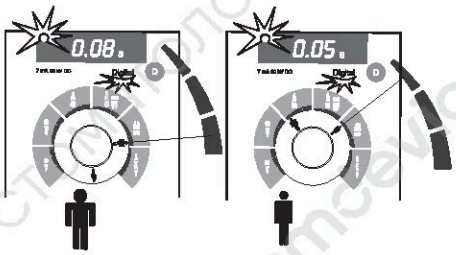
Each tooth symbol is subdivided into three different exposure times.

For digital X-ray exposures, make sure to set the longest exposure time setting within a tooth symbol for X-rays of adults, and the shortest exposure time setting for X-rays of children.

Only then does the corresponding value appear on the digital display.

Adjacent example: Maxillary molar

Valid for software version 17 and higher (number appears briefly after the unit is switched on).



Classification of recommended exposure times by tooth region:

8"	C D E	F G H
A	0,08 s – 0,10 s	0,08 – 0,12 s
B	0,06 s – 0,08 s	0,06 – 0,08 s

- **A** = adults
- **B** = children
- **C** = Mandibular anterior tooth
- **D** = Mandibular canine tooth
- **E** = Maxillary anterior tooth
- **F** = Maxillary molars
- **G** = Maxillary canine tooth / Mandibular molars
- **H** = occlusal exposure

If a 12" SSD cone is used together with a size 1 / size 2 XIOS X-ray sensor, the above exposure times are doubled!

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9.1.2 HELIODENT DS up to Serial No. 15863 (wall model) and 4415 (ceiling model)

NOTICE

Prior to an exposure, check the following:

- Is digital exposure selected (illuminated display "DIGITAL")?
- Is the correct exposure time for the exposure region displayed?

Possible exposure times

0.01	0.02	0.03	0.04	0.05	0.06	0.08	0.10	0.12	0.16	0.20	0.25	0.32	0.40	0.50	0.64	0.80	1.00	1.25	1.60	2.00	2.50	3.20

Recommended exposure times – with 8" SSD cone and XIOS size 1 / size 2 X-ray sensors

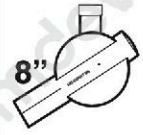
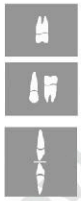
An excellent image quality is achieved with XIOS sensors when using a radiation time of 0.08 to 0.10 s (at 60 kV, 7 mA).

- The positioning of the sensors using the parallel technique (with XIOS sensor holders) ensures an optimal positioning of the sensors in the beam path of the cone.
- It is the responsibility of each individual dentist to determine the required dose for each patient in order to achieve image quality suitable to make a diagnosis. Sirona can only make recommendations.

⚠ WARNING

The orientation according to tooth symbols on the user interface HELIODENT DS previously used for setting the exposure time is no longer valid for these sensors!

Classification of recommended exposure times by tooth region:

	 C D E	 F G H
A	0,08 s – 0,10 s	0,08 – 0,12 s
B	0,06 s – 0,08 s	0,06 – 0,08 s

- A = adults
- B = children
- C = Mandibular anterior tooth
- D = Mandibular canine tooth
- E = Maxillary anterior tooth
- F = Maxillary molars

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- G = Maxillary canine tooth / Mandibular molars
- H = occlusal exposure

If a 12" SSD cone is used together with a size 1 / size 2 XIOS X-ray sensor, the above exposure times are doubled!

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10 Care of outer surface

10.1 Care and cleaning agents

NOTICE

Approved care and cleaning agents

Use only care and cleaning agents which have been approved by Sirona!

A continuously updated list of approved agents can be downloaded from the Internet at the address *"www.sirona.com"*. In the navigation bar, go to the menu items *"SERVICE"* I *"Care and cleaning"* and then open the document *"Care and cleaning agents"*.

If you do not have any access to the Internet, please contact your dental depot to order the list.

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10.2 Cleaning

USB module

Remove dirt, grime and disinfectant residue regularly using mild, commercially available cleaning agents.

NOTICE

Risk of short circuit

Do not allow liquids to run into the plug connections!

NOTICE

Immediately wipe off medications that come into contact with the surface.

PC and monitor

When cleaning the PC and the monitor, please follow the operating instructions supplied for these components.

10.3 Disinfecting

General

The following components can **only** be disinfected by wiping them off:

- USB module
- USB cable
- Size 1 and size 2 XIOS X-ray sensors



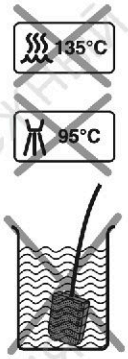
NOTICE

Never spray with disinfectants or cleaning agents!

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Sensors



The following should be observed regarding XIOS sensors and their connecting leads:

- Sensors must **not** be thermally disinfected!
- Sensors must **not** be immersed in disinfectant solutions!
- The sensors must **not** be disinfected or sterilized with radiation!

10.4 Sterilizing

General

NOTICE

Risk of destruction of the XIOS sensors

The XIOS sensors are **not** sterilizable!

NOTICE

Risk of damage

Please follow the instructions given below carefully. Otherwise, your components, the autoclaves or any other objects you have placed in the autoclaves may be damaged.

The following components can be sterilized:

- Rods and rings of the XIOS holder system

The manufacturer's instructions have to be observed for other systems.

NOTICE

Durability of plastic parts

Plastic parts have a limited durability and therefore should be replaced regularly. The durability of plastic parts is shortened by every sterilizing procedure.

NOTICE

Risk of melting and distortion of plastic parts

- During sterilization plastic parts must be in a sterilization pouch which is separate from metal parts!

- During sterilization the temperature in the autoclave must not exceed 132°C (270°F)!

Interval

Used rods and rings must be cleaned and sterilized after every patient treatment.

Preparation

1. Separate the rods and rings.
2. Remove any residues with hot soapy water or mild dishwashing liquid.

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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 autoclave, ensuring sufficient distance to the walls of the autoclave and the heating element.

Sterilization

NOTICE

- **Do not** use glutaraldehyde with a phenol base!

- **Do not** use cleaners specialized for specific applications or ultrasonic cleaners!

- **Do not use chemical sterilizers** or **hot air sterilizers**!

- **Do not** perform cold sterilization!

➢ Operate the autoclave according to the manufacturer's instructions. (the conditions for sterilization are specified below).

Conditions for sterilization

Sterilized contents packed loosely

Sterilizer temperature/pressure, length of cycle:

- Steam sterilizer 121 °C/103.4 kPa (250°F/15 psi) 20 minutes.

or

- Steam sterilizer 132 °C /206.8 kPa (270°F/30 psi) 8 minutes.

Sterilized contents packed tightly

Sterilizer temperature/pressure, length of cycle:

- Steam sterilizer 121 °C/103.4 kPa (250°F/15 psi) 20 minutes.

or

- Steam sterilizer 132 °C /206.8 kPa (270°F/30 psi) 10 minutes.

10.5 Care and cleaning agents

NOTICE

Approved care and cleaning agents

Use only care and cleaning agents which have been approved by Sirona!

A continuously updated list of approved agents can be downloaded from the Internet at the address *"www.sirona.com"*. In the navigation bar, go to the menu items *"SERVICE"* I *"Care and cleaning"* and then open the document *"Care and cleaning agents"*.

If you do not have any access to the Internet, please contact your dental depot to order the list.

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the menu items *"SERVICE"* I *"Care and cleaning"* and then open the document *"Care and cleaning agents"*.

If you do not have any access to the Internet, please contact your dental depot to order the list.

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11 Inspection and maintenance

11.1 Regular inspection and maintenance

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

- The system owner must make sure that no changes are made to the additional second protective ground wire connection.
- The system owner must also make sure that all components (cables, sensors and housing parts) are in undamaged condition.

NOTICE

All parts of the device are maintenance-free. In case of malfunctioning, please always contact your specialized dealer.

NOTICE

The USB module must not be opened or repaired by the user.

11.2 Monthly check performed by the system owner or authorized persons

Every month the operator must:

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

11.3 Annual check performed by the system owner or authorized persons

Image quality check

The image quality should be assessed by the system owner at regular intervals, at least once a year.

If digital image receptors are used, an increasing number of image postprocessing operations performed with the brightness or contrast control in the image processing software (e.g. SIDEXIS) is employed 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.

Observe any possible additional country-specific requirements.

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12 Electromagnetic compatibility

NOTICE

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

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

12.1 Accessories

Designation of the interface cables	Order No.
PC as peripheral device	
USB hub	
USB cable, 3m	61 77 401

- The UNIT may be operated only with accessories and spare parts approved by Sirona. Unapproved accessories and spare parts may lead to an increased emission of or a reduced immunity to interference.
- The UNIT should not be operated immediately adjacent to other devices. If this proves to be unavoidable, the UNIT should be monitored to ensure that it is used properly.

12.2 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 – guidance
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**	Complies	

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12.3 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 – guidance**
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 wood, concrete, or ceramic tile. If floors are 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 ± 2 kV common mode voltage	± 1 kV differential mode ± 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 5sec. (>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 5sec. (>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.
Remarks: 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:

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Interference immunity tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF interference **IEC 61000-4-6**	3 V_{eff} 150 kHz to 80 MHz[1]	3 V_{eff}	$d = [1.2] \sqrt{P}$
Radiated RF interference **IEC 61000-4-3**	3 V/m 80 MHz to 800 MHz[1] 3 V/m 800 MHz to 2.5 GHz[1]	3 V_{eff} 3 V_{eff}	$d = [1.2] \sqrt{P}$ at 80 MHz to 800 MHz $d = [2.3] \sqrt{P}$ at 800 MHz to 2.5 GHz where P is the nominal transmitter output in watts (W) specified by the transmitter manufacturer and d is the recommended working clearance 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. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. An investigation of the location is recommended to determine the electromagnetic environment resulting from stationary HF 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 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 150kHz to 80MHz, field strengths should be less than 3V/m.

12.4 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 duly observing the minimum distances between portable and/or mobile RF communication devices (transmitters) and the **UNIT**. These values may vary according to the output power of the relevant communication device as specified below.

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Rated maximum output power of transmitter [W]	Working clearance according to transmission frequency [m]		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = [1.2] \sqrt{P}$	$d = [1.2] \sqrt{P}$	$d = [2,3] \sqrt{P}$
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

For transmitters whose maximum nominal output is not specified in the above table, the recommended working clearance d in meters (m) can be determined using the equation in the corresponding column, where P is the maximum nominal output of the transmitter in watts (W) specified by the transmitter manufacturer.

Remark 1

An additional factor of 10/3 is applied when calculating the recommended working clearance between transmitters in the 80 MHz to 2.3 GHz frequency range in order to reduce the probability that a mobile/portable communication device unintentionally brought into the patient area could lead to interference.

Remark 2

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

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13 Configuration

Explanation

It is possible to automatically optimize the image quality of an X-ray image after capture with the XIOS sensor using a configuration dialog.

Call

➢ Follow the path *"start"|"programs"|"SIDEXIS"|"SIDEXIS Manager"* and start the application *"XIOS Configuration"*.

↳ The application *"XIOS Configuration"* opens.

Structure

- *"Automatic Image Optimization"* check box
  The *"Automatic Image Optimization"* check box activates the *"Contrast"* area.
- *"Contrast"* area
  The modifications made in this area will be executed for each X-ray image when the Automatic Image Optimization check box is activated.
  Selection fields *"Filter 1"*, *"Filter 2"*, *"Filter 3"*: Filter operations can be selected here, which will be processed in the following order: *"Filter 1"*, then *"Filter 2"*, then *"Filter 3"*.
  Selection field *"Brightness"*: The brightness can be corrected here.
  Selection field *"Contrast"*: The contrast can be corrected here.
- *"16 bit"* check box
  When the *"16 bit"* check box is activated, the standard gray scale reduction is deactivated (8 bit gray levels).
  The *"16 bit"* setting prevents a loss of information caused by a reduction of the gray levels.
  In this case, the amount of data doubles.

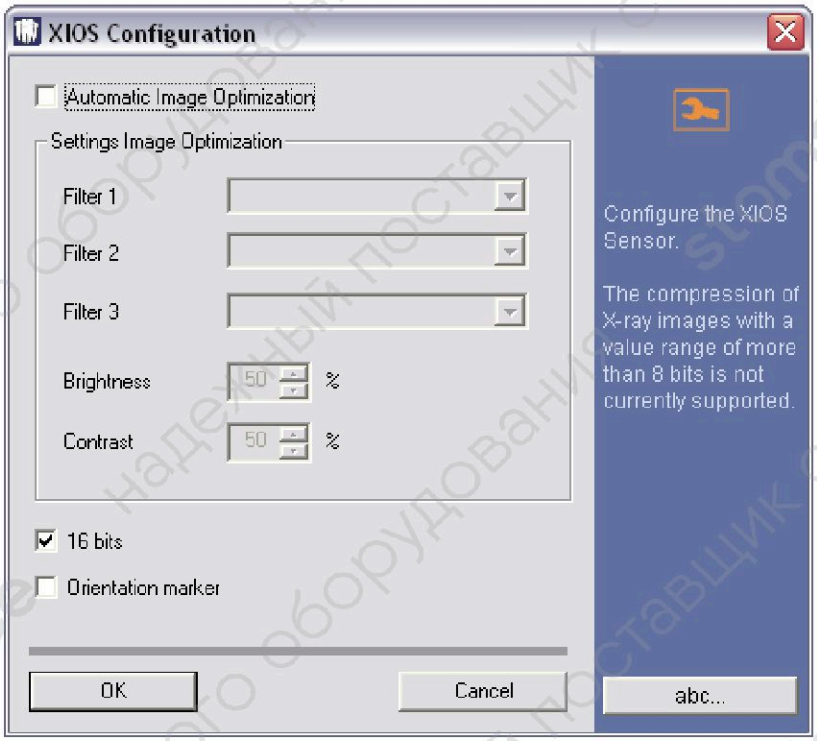
IMPORTANT
The compression of X-ray images with a value range of more than 8 bits is not currently supported.

- *"Orientation marker"* check box
  The activation of the *"Orientation marker"* check box causes the position of the XIOS sensor during the exposure to be retained; this is achieved with the displayed sensor size (**1** = sensor size 1; **2** = sensor size 2).
  The sensor size is displayed on the XIOS sensor at the point at which the name SIRONA is located.
  For example, a mirror-inverted **1** or **2** shows that the image was mirror-inverted.

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Example screen



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