stomdevice

SOPIX SERIES

User's manual

IMAGING ACTEON

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Contents

1 FOREWORD 2

2 DIGITAL X-RAY SYSTEM INTRODUCTION 3

3 PRECAUTIONS FOR USE 5

4 STANDARDS AND REGULATIONS 8

5 SYSTEM CONFIGURATION 14

6 INSTALLATION AND CONNECTION 16

7 USE 18

8 MAINTENANCE 20

9 AFTER-SALES SERVICE 23

10 TECHNICAL FEATURES 25

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1 FOREWORD

Thank you for placing trust in us by purchasing a SOPIX series system.

The SOPIX series comprises the SOPIX, SOPIX², SOPIX inside and SOPIX² inside systems. This user's manual applies to each of the systems in the SOPIX series.

To optimise the use of this device, we recommend you read the owner's manual thoroughly before using a SOPIX series system and carefully follow the instructions contained in this manual.

Please carefully consider the messages "CAUTION", "WARNING", and "NOTE" when using the system.

⚠ WARNING: the term WARNING describes potential incidents likely to jeopardize safety.

⚠ CAUTION: the term CAUTION refers to incidents that may interfere with smooth running of the imaging system and cause minor injuries.

NOTE : the term NOTE highlights particular points in order to aid system maintenance or clarify important information.

⚠ CAUTION: Federal laws restrict these devices to sale by or on the order of a dentist.

NOTE : Some models described in this manual may not be available for sale in United States.Please consult Sopro's representative for availability

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2

DIGITAL X-RAY SYSTEM INTRODUCTION

2.1. FUNCTIONS AND PERFORMANCE

The SOPIX series digital X-ray imaging systems are intended to be used by a dental practitioner. The sensor (located in the patient's mouth just like a silver film) captures the X-rays produced by the generator. Then it transmits this data to the computer to display the X-ray image on the screen.

All the images captured with the SOPIX series system can be recalled onto the screen with the Sopro Imaging software provided with the system. This software manages the display, processing and storage of images taken with the SOPIX series system.

A.C.E™ (Automatic Control Exposure) technology, patented by SOPRO, provides the system with outstanding features. In real time it analyses the quantity of energy received by the sensor, which fixes the image acquisition once it has received the energy needed to produce a good-quality image. As a result, every image is protected against overexposure.

Integration of the SOPIX inside and SOPIX² inside systems into the X-Mind unity X-ray generator from the company De Götzen, which is a member of the ACTEON group, provides a communication that is unique in the world. Once the sensor has received the energy necessary to obtain a good-quality image, it sends the information to the generator which cuts X-ray emission. The dose received by the patient is thus adapted to his/her dental morphology. Since the A.C.E technology affects exposure time, when used in combination with X-Mind Unity X-Ray generator, the SOPIX Inside and SOPIX2 Inside A.C.E feature is an automatic exposure control technology.

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2.2. PARTS LIST

The SOPIX or SOPIX² dental digital X-ray system is composed of the following elements:

- A sensor, size 1, linked to its controller via a cable of 3.70 meters total length

or

- A sensor, size 2, linked to its controller via a cable of 3.70 meters total length
- A sensor holder.

The SOPIX inside or SOPIX² inside dental digital X-ray system is composed of the following elements:

- A sensor, size 1, linked to its controller via a cable of 0.70 meter in length.
- A sensor, size 2, linked to its controller via a cable of 0.70 meter in length.
- A sensor holder ready-positioned on the controller.
- An installation manual.
- A 5 meter USB active repeater cable.

All the digital X-ray systems in the SOPIX series combine the following elements:

- A batch of 10 sensor sleeves.
- A CD-ROM of SOPRO Imaging software.
- Multilingual user's manual incorporated into the Sopro-Imaging software CD-ROM.
- A quick startup guide.
- A poster presenting sensor precautions for use.
- Optional: the positioning kit.

The SOPIX series systems are packaged in a custom carton. This carton should be kept for future possible transportation. For more details about these products, please refer to our catalogue or contact our commercial service.

NOTE :

The SOPIX series systems and their accessories have been designed to maximize performance and safety. The use of different origin accessories may reduce the performance and safety of these devices. Only use SOPRO accessories and authorized SOPRO after-sales services.

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3 PRECAUTIONS FOR USE

3.1. SAFETY INSTRUCTIONS

⚠ WARNING:

- Comply with the operating and storage requirements to avoid any risk of electric shock or degradation of the SOPIX series system.
- Never insert any metallic object into the device, in order to avoid any risk of electric shock, fire, short-circuit or hazardous discharge.
- Do not put the device in a humid environment or where it could be sprayed with water, in order to avoid any risk of degradation of the SOPIX series system or any risk of electric shock.
- Only use the connecting cable(s) supplied with the SOPIX series system in order to avoid any risk of electric shock or degradation of the system.

⚠ CAUTION:

- Do not open the system and do not try to take it apart or modify it, in order to avoid any risk of malfunctioning of the SOPIX series system.
- Always connect the device to a USB port to avoid any risk of malfunctioning of the SOPIX series system. For more information, please refer to section 3.5 of this manual.

⚠ WARNING:

Sopix Series Sensors require x-rays: Before using this x-ray system please refer to the regulation in force in your area concerning paediatric patients, pregnant women and anyone with health issues that contraindicate the use of x-rays. Investigate and make sure of this condition before start the exposure.

⚠ WARNING:

Modification of these systems, without the permission of the manufacturer, is prohibited.

⚠ WARNING:

If the system is modified an appropriate control and test should be performed to ensure that the system can still be used safely.

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3.2. SYSTEM OPERATING ENVIRONMENT

Refer to section 10 “Technical features”.

3.3. TRANSPORT AND/OR STORAGE ENVIRONMENT OF THE SYSTEM

Refer to section 10 “Technical features”.

3.4. PRECAUTIONS FOR THE SENSOR(S)

It is imperative to take some precautions for use of the sensors, particularly:

⚠ CAUTION:
- YOU MUST handle the sensor with great care.
- YOU MUST use a positioning kit to correctly place the sensor.
- YOU MUST use a disinfectant wipe to clean the sensor.
- YOU MUST put the sensor on its support.
- DO NOT ask the patient to bite the sensor or the connecting cable.
- DO NOT immerse the sensor.
- DO NOT open the sensor or controller in case of failure.
- DO NOT use protections other than the SOPRO sensor sleeves.

⚠ WARNING:
- YOU MUST use a SOPRO sensor sleeve for each patient.
- DO NOT put the sensor in an autoclave.
- DO NOT drop the sensor.
- DO NOT hold the sensor with clamp forceps.
- DO NOT hold the sensor by the connecting cable.
- DO NOT roll over or walk on the connecting cable.
- DO NOT use abrasive product to clean the sensor.

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3.5. PRECAUTIONS FOR THE USB PORT

Most current motherboards are equipped with two USB channels. Each channel has two USB ports to which various peripherals can be connected.

⚠ CAUTION:
It is advisable to dedicate a High Speed USB channel to the digital X-ray system. This will ensure that the performance and the transmission speed of the SOPIX series system data will not be affected by the fact that another peripheral is on the same channel.

3.6. ELECTROMAGNETIC INTERFERENCE

Electromagnetic compatibility (CEM) is the ability of electronic device elements to correctly interact in an electronic environment. Although the SOPIX series systems were designed with due regard to this compatibility and comply with the electromagnetic interference thresholds established by the regulatory agency, there is no guarantee about the interference likely to occur on a particular installation.

If a SOPIX series system generates interference with radio-communication services (which can be determined by switching it off and on), the user is recommended to try to correct this phenomenon by taking some or all of the following measures:
- Change the direction of the receiving antenna.
- Reposition the product in relation to the receiver.
- Distance the computer from the receiver.

The SOPIX series digital X-ray systems were designed and tested to be used in a domestic environment, class B Group 1, according to CISPR11 standard.

3.7. ELECTROSTATIC INTERFERENCE

A strong electrostatic discharge may logically disconnect a SOPIX series system from the computer's USB (Universal Serial Bus) port. In most cases, the SOPIX series system recovers by itself. Thereafter, it is wise to:
- Set up the sensor sleeve before putting the SOPIX series system in readiness for image acquisition,
- Dissipate your static charge by touching, for example, a metallic part of the dental chair before taking an X-ray image.

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4 STANDARDS AND REGULATIONS

4.1. COMPLIANCE WITH STANDARDS AND REGULATIONS

Compliance with European Community directives

The SOPIX series system design, manufacturing and distribution comply with the requirements of the European Medical Devices Directive 93/42/EEC.

SOPRO certifies that this device underwent control tests and was declared as complying with the restrictions imposed by the safety standards for medical electrical equipment (IEC 60601-1) and electromagnetic compatibility (IEC 60601-1-2).

Medical device vigilance

Like any medical device, SOPIX series systems are subject to medical device vigilance provisions; any serious malfunction should then be the subject of a report to the competent authorities and to the manufacturer as soon as possible and as precisely as possible.

Scrapping the system

SOPIX series systems bear the recycling symbol according to the European directive 2002/96/EC concerning waste electrical and electronic equipment (WEEE).
By correctly disposing of this device, you will avoid damaging the environment and human health.

The symbol  appearing on the device or on the accompanying documentation indicates that this product cannot under any circumstances be treated as household waste. Therefore, it should be given to a waste collection center that handles electrical and electronic equipment recycling. Standards in force in the country of installation relating to waste disposal must be observed. For more details about the treatment, recovery and recycling of this device, please contact your dental device distributor (or failing that, the ACTEON group site) regarding the recommended procedure.

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⚠ WARNING:
To avoid any risk of environmental contamination likely to cause mild or serious injuries, be sure to dispose of the device and its accessories as special waste.

Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emissions		
The SOPIX series systems are intended for use in the electromagnetic environment specified below. The customer or the user of the SOPIX series systems should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	The SOPIX series systems use 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 CISPR 11	Class B	The SOPIX series systems are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic current emissions EN 61000-3-2	Not applicable	
Voltage fluctuations / Flicker EN 61000-3-3	Applicable	

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Guidance and manufacturer's declaration –electromagnetic immunity			
The SOPIX series systems are intended for use in the electromagnetic environment specified below. The customer or the user of the SOPIX series systems should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment Guide
Electrostatic discharges EN 61000-4-2	± 6 kV when in contact ± 8 kV in the air	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Fast transient bursts EN 61000-4-4	± 2 kV for the feed cables ± 1 kV for the input/output cables	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage shocks EN 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	± 1 kV N.A.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations EN 61000-4-11	<5 % U_T (>95 % dip in UT) for 10 ms 40 % U_T (60 % dip in UT) for 100 ms 70 % U_T (30 % dip in UT) for 500 ms <5 % U_T (>95 % dip in UT) for 5 sec	< 5% Ut 10 ms < 40% Ut 100 ms < 70% Ut 500 ms < 5% Ut 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of a SOPIX series system requires continued operation during power mains interruptions, it is recommended that the SOPIX series systems be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field 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 : UT is the a.c. mains voltage prior to application of the test level.			

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Guidance and manufacturer's declaration –electromagnetic immunity			
The SOPIX series systems are intended for use in the electromagnetic environment specified below. The customer or the user of the SOPIX series systems should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment Guide
			Portable and mobile RF communications equipment should be used no closer to any part of the SOPIX series systems, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	d = 1.16/P
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	d = 1.16/P 80 MHz to 800 MHz d = 2.33/P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency band applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SOPIX series systems are used exceeds the applicable RF compliance level above, the SOPIX series systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SOPIX series systems.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communication equipment and the SOPIX series systems

The SOPIX series systems are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SOPIX series systems can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SOPIX series systems as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter - m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	d = 1.6 /P	d = 1.6 /P	d = 2.33 /P
0.001	0.116	0.116	0.233
0.1	0.366	0.366	0.736
1	0.16	1.16	2.33
10	3.66	3.66	7.36
100	11.6	11.6	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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4.2. KEY TO STANDARDISED SYMBOLS

The symbols appearing on the connection housings identify the SOPIX series systems according to the international standards IEC 60601-1 and IEC 60417.


Sensor sleeve for single use.


"Type BF applied part".


Follow instructions for use.

Continuous voltage.


Disposal of electrical and electronic equipment marketed after 13 August 2005. This symbol indicates that the product cannot be treated with domestic waste.


For medical devices, this symbol is accompanied by the year of manufacture (expressed in four digits).


For medical devices, this symbol is accompanied by the name and address of the manufacturer.

CE 0459 Product compliance according to the European Medical Devices Directive 93/42/EEC.

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5 SYSTEM CONFIGURATION

5.1. COMPUTER SYSTEM REQUIREMENTS

To use one of the SOPIX series systems, you must make sure the computer and its peripherals do not have any limitation of use that might affect personal safety. It should also meet the following requirements:

Windows® configuration:

	Minimum Configuration	Recommended Configuration
Operating system	Windows® XP Pro SP3	Windows® 7 Pro SP1
Processor	Intel® Pentium IV - 1.3 GHz	Intel® Core 2
Memory	512 MB	2 GB or more
Hard disk	250 GB	320 GB or more
USB ports	2 USB2.0 Hi-Speed ports	4 USB2.0 Hi-Speed ports
Video board	Graphic board 32 MB of unshared video RAM compatible with DirectX 9	Chipset Nvidia or ATI / 512 MB RAM unshared video RAM compatible with DirectX 9 or higher.
USB Chipset	Intel or NEC® / RENESAS®	Intel or NEC® / RENESAS®
Screen resolution	1024 x 768	1280 x 1024 or more

MAC® configuration:

	Minimum Configuration	Recommended Configuration
Computer	MAC® Book Pro 13.3" or iMac® 21.5"	iMac® 27"
Operating system	MAC® OS X 10.6 Snow Leopard	MAC® OS X 10.7 Lion
Processor	Intel® Core 2	Intel® Core i7
Memory	2 GB	4 GB

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5.2. IMAGING SOFTWARE

The SOPIX series systems are provided with the Sopro Imaging dental imaging software, running in Windows® and MAC®. It is versatile software that captures, processes, and files the X-ray images taken with the SOPIX series systems, but also allows network sharing of your data.

Sopro Imaging can also interface with third party software (dental practice management software, imaging software). For more information, please contact your distributor.

5.3. COMPATIBILITY WITH X-RAY GENERATORS

The SOPIX and SOPIX² digital X-ray systems are potentially compatible with all intraoral X-ray generators. Nevertheless, we recommend X-Mind generators from De Götzen, a member of the ACTEON group, which are perfectly adapted to the SOPIX and SOPIX² systems and provide very good system performance.

The digital imaging systems SOPIX inside and SOPIX² inside were designed to operate in combination with the X-Mind unity generator from De Götzen to create unique communication that reduces the level of X-ray emission.

Since the A.C.E technology affects exposure time, when used in combination with X-Mind Unity X-Ray generator, the SOPIX Inside and SOPIX2 Inside A.C.E feature is an automatic exposure control technology.The suggested technique factors and dosimetry information pediatric population are described in X Mind unity operator's manual Chapter 5 and Chapter 6. To obtain the default exposure times, please select SOPIX2 Inside/Child table. It is the operator's responsibility to protect the patient against unnecessary or excessive radiation doses.

For more information on this topic please consult : http://pedrad.org/associations/5364/ig/Procedures/DigitalRadiography/EducationalMaterials.aspx

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6 INSTALLATION AND CONNECTION

6.1. INSTALLATION OF SOPIX INSIDE AND SOPIX² INSIDE TO THE ARM OF THE X-RAY GENERATOR

Refer to the installation manual for SOPIX inside and SOPIX² inside provided with the system.

⚠ WARNING: Installation must be performed by a specialized, SOPRO-authorized technician.

6.2. INSTALLATION OF SOPRO IMAGING SOFTWARE

Refer to the Sopro Imaging installation manual to be found on the Sopro Imaging software CD-ROM in the document directory.

6.3. SOPIX SERIES SYSTEM INSTALLATION

Before installing the SOPIX series digital X-ray system, make sure the computer is connected to a correctly earthed socket.

Now, go through the following steps:

⚠ CAUTION: Insert the Sopro Imaging software CM-ROM into the CD drive in order to install the drivers.

- Select the device driver by checking the box “SOPIX/SOPIX2”.
- Click on “Install selected items”.
- After clicking on “Install selected items”, the “Minimum requirements” window appears.
- When verification is finished, click on “Ok”.

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• Follow the successive steps displayed on the screen.

• Connect the SOPIX series system USB connector to the computer.

⚠ CAUTION:

• Never connect the USB cable to the port found on the computer front plate.

• In fact, the connectors found on the computer front plate are much more sensitive to the various forms of USB signal interference and this may cause a malfunction of the digital X-ray system.

• For electrical safety reasons, the computer to which the imaging system is to be connected, as well as the peripherals, must comply with standard IEC 60950-1 (EN 60950-1). Make sure their manuals indicate that they do comply with this standard and that they provide a cleaning and/or disinfecting procedure.

• The elements connected to SOPIX series systems should not be placed within the patient's environment, in compliance with standard IEC 60601-1-1 (EN 60601-1-1). The minimum horizontal distance between the patient and these elements is 1.5 meters. The minimum vertical distance between the patient and these elements is 2.5 meters.

• No mobile stand with multiple plugs, no extension cord (other than that supplied by SOPRO) should be connected to the system. Check the electrical installation compliance with the standards in force in the country where the system is located.

6.4 SETTING UP SOPRO IMAGING SOFTWARE WITH A SOPRO SERIES SYSTEM

Refer to the Sopro Imaging user's manual to be found on the Sopro Imaging software CD-ROM in the document directory.

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7 USE

The SOPIX series systems are intended to be used by a dental practitioner. Their use does not require any special training. Consult the instructions in this manual.

7.1. ACQUISITION OF AN X-RAY IMAGE

First, switch on the PC on which the SOPIX series system is installed and launch the imaging software (Sopro Imaging, for example).

- Set your generator and the timer.
- Slip the sensor into a sensor sleeve

⚠ WARNING:
Always verify device integrity before using it, no breaks in plastic parts, no cut wires : risk of electric shock.
Before each examination, it is mandatory to apply to the collimator cone (Beam Limiting Device) a disposable protection sheath designed to cover the end part of the X-ray unit, which is more susceptible of being directly contaminated during the X-ray exposure: risk of cross-contamination

NOTE :
For further information, please refer to section 7.2 "Using sensor sleeves".

- Place the sensor in the patient's mouth parallel to the long axis of the tooth with the active face against the tooth.

⚠ WARNING:
If using a positioning kit, refer to the instructions provided with this kit. In order to prevent any risk of cross-contamination, always observe the necessary precautions and hygiene measures described in these instructions.

- Move the generator closer to the patient's head. Make sure the generator tube is perpendicular to the sensor positioning.
- Activate the timer trigger.

Once the exposure is finished, the imaging software downloads the x-ray image onto the screen.

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If using SOPIX inside or SOPIX² inside, the imaging software downloads the data from the X-Mind unity X-ray generator (settings, programmed and real exposure time, dose delivered to the area of irradiated tissues (DAP), dose saving for the patient, etc.) thanks to the ACE technology combined with the X-Mind unity.

! CAUTION:
If the image file is damaged, do not use it for diagnosis.

7.2. USING SENSOR SLEEVES

In order to ensure maximum hygienic safety for the patient, it is imperative to cover the SOPIX series sensor with a disposable sensor sleeve.

⚠ WARNING:
- Wear gloves to place the sensor sleeves,
- Change the sensor sleeve for each new patient,
- Preferably use the sensor sleeves especially designed for the SOPIX series systems,
- Keep the sensor sleeves in a dry and clean place,
- Dispose of the used sensor sleeves with other biologically and potentially hazardous infected waste,
- NEVER USE FINGER COTS.

It is advisable to be well-prepared and stock up with plenty of disposable sensor sleeves because a SOPIX series system can no longer be used once you have run out of these consumables.

NOTE :
If the sensor sleeve is torn when examining a patient or if the SOPIX series sensor has been contaminated when withdrawing the sensor sleeve, it is essential to fully disinfect the SOPIX series sensor and the first 40cm of cable. In order to do this, please refer to the table in the "sensor maintenance" section.

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8 MAINTENANCE

The SOPIX series digital X-ray systems do not need any maintenance if they are used according to the manufacturer's directions for use and cleaning instructions. Only Sopro's Qualified technician can proceed to service.

NOTE :

Quality control: European legislation in force in certain European countries -notably Germany -which requires a check (once per month) of the quality of the sensor(s) by means of a test card specially designed for the purpose. Even when use in another country that does not required such control, SOPRO recommends that such control should be made regularly (once per month) to insure the product is still able to be use for diagnosis. This control is to be done by a dental practicioner.
If you use SOPRO Imaging Software please refer to Calibration chapter of Sopro Imaging Manual. It will allow you to maintain records of the controls. If you use an other imaging software consult software instructions:

- *With a test card specially designed for the purpose, proceed to an image of this pattern under X-Ray in specified conditions (for example DC 70Kv 8 mA)*

- *Compare the images from month to month and control the following criteria*
  - *Modification of uniformity on a specific area or modification of contrast over 15 %from the original image: please contact your local dealer*
  - *Resolution: resolution with less than 6.5 line pair per mm can't be used for diagnosis : please contact your local dealer.*

- *Based on these criteria, state if the sensor quality's is still ok for dental use. If the criteria are not met , do not use your device anymore and contact your local dealer.*

Before first using the equipment, it is imperative to follow the complete disinfecting procedure.

Any SOPIX series system returned from servicing or maintenance should be completely disinfected before being used.

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⚠ CAUTION:

Do not use products containing:

- Ammoniac
- Trichloroethylene
- Dichloroethylene
- Ammonium hydrochlorid
- Chlorinated and aromatic hydrocarbon
- Ethylene dichloride
- Methylene chloride
- Ketones

Use of these chemicals may subject plastic parts to risk of deterioration.

⚠ CAUTION:

Do not directly spray disinfectant products onto SOPIX series sensors.

⚠ WARNING:

In order to prevent any risk of cross-contamination, always observe the necessary precautions and hygiene measures while handling SOPIX series systems and sensor sleeves.

8.1. CONTROLLER MAINTENANCE

DESCRIPTION	RECOMMENDATIONS	USE INSTRUCTIONS AND PRECAUTIONS	
		✓	x
Surface disinfection	Surface cleaning and disinfectant wipes e.g. CAVIWIPES - KERR company.	✓ Take the wipe, remove excess moisture, and then wipe the equipment until visible cleanliness is obtained. ✓ Allow to air dry. ✓ Carefully close the packaging box.	× Do not rinse. × Do not scrub. × Do not immerse in a disinfectant liquid.
	Surface disinfectant spray of Septol™ type Spray Surface without Aldehyde - Pierre Rolland.	✓ Spray at 40 cm from the surface and allow to dry.	

8.2. SENSOR MAINTENANCE

DESCRIPTION	RECOMMENDATIONS	USE INSTRUCTIONS AND PRECAUTIONS	
		✓	x
Decontamination and disinfection of the sensor and first 40 cm of cable.	Surface cleaning and disinfectant wipes e.g. CAVIWIPES - KERR company.	✓ Take the wipe, remove excess moisture, and then wipe the equipment until visible cleanliness is obtained. ✓ Allow to air dry. ✓ Carefully close the packaging box.	× Do not rinse. × Do not scrub. × Do not immerse in a disinfectant liquid. × Do not directly spray disinfectant product onto SOPIX series sensors.
	Surface disinfectant spray of Septol™ type Spray Surface without Aldehyde - Pierre Rolland.	✓ Spray the disinfectant product onto a clean cloth before cleaning the sensor.	

⚠ CAUTION:
It is imperative to comply with the sensor precautions for use. Please refer to section 3 of this manual “Precautions for use”.

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AFTER-SALES SERVICE

9.1. LIMITED LIABILITY

The SOPIX series was designed to ensure the acquisition of dental X-ray images, their transfer in the form of computer data, as well as their storage. Nevertheless, SOPRO Company shall not be liable for inappropriate use of this equipment or for any loss of stored data in the computer system due to a problem of use or any possible technical problem.

9.2. WARRANTIES

SOPRO guarantees its products to be free from material and manufacturing defects for a period of one (1) year from the date of purchase. This warranty does not apply to misused, modified, untended, or accidentally damaged products, or products subject to abnormal use and handling conditions. The distributors, other than ACTEON Group's subsidiaries, are not authorized to apply an extended warranty period on behalf of SOPRO.

The entire liability of SOPRO is limited, at its discretion, to replacing or repairing the defective product free of charge, if it has been sent to SOPRO After-Sales Service. This applies for the warranty period.

Outside France, recourse to the warranty is only possible if the product was bought at a point of sale by an authorized SOPRO dealer in the country where it will be used.

THIS WARRANTY APPLIES ONLY TO THIS UNIQUE REMEDY. IT REPLACES ANY OTHER WARRANTY, FOR EXAMPLE, A WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, WHETHER EXPRESS OR IMPLIED. SOPRO SHALL NOT BE LIABLE FOR ANY PARTICULAR DAMAGE, INDIRECT, ACCIDENTAL OR CONSEQUENTIAL NOR FOR ANY DETERIORATION OR DATA LOSS, ON A CONTRACTUAL, NON-CONTRACTUAL OR OTHER BASIS.

The liability exclusion or limitation for direct or indirect damages does not apply under the regulatory or legal rules in force in some countries and the present exclusion may not apply to a purchaser in those countries.

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9.3. TROUBLESHOOTING

PROBLEMS	CAUSES	SOLUTIONS
After the timer has been activated, no image appears on the screen.	1. The sensor is incorrectly positioned in relation to the generator cone. 2. Exposure time is too short. 3. Failure of the generator. 4. Wire connection problem. 5. USB port.	1. Use a KERR type sensor positioning kit recommended by SOPRO. 2. Slightly increase the exposure time. 3. Check for proper generator operation. 4. Check the sensor is correctly connected to the computer. 5. Avoid using a port on the front plate.
The SOPIX control window has a red spot.	Wire connection problem.	1. Check the sensor is correctly connected to the computer. 2. The USB port may be put in standby by Windows.
Some white areas appear on the image.	The sensor is incorrectly positioned in relation to the generator cone.	Use a KERR type sensor positioning kit recommended by SOPRO.
The image is blurry, stretched or scratched.	1. The sensor is incorrectly positioned. 2. The patient moved when the image was taken. 3. The generator head was not stabilized when the timer was activated.	1. Use a KERR type sensor positioning kit recommended by SOPRO. 2. The patient should be still when the image is taken. 3. Stabilize the generator head.

In case of a problem not mentioned above, please contact your dealer who will undertake to uninstall and return the SOPIX series system to the SOPRO after-sales department.

NOTE :
No maintenance should be performed by a third party.

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10

TECHNICAL FEATURES

SENSOR - SIZE 1
External dimensions: 38.9 x 24.9 x 5.3 mm
Active area dimensions: 20 x 30 mm (600 mm^2)
Pixel number: 1.5 million (1000 x 1500)
Cable length: 70 cm
Liquid penetration: IP67 (temporal immersion)

SOPIX AND SOPIX INSIDE SYSTEMS
Technology: CMOS + fiber-optic + scintillator*
Pixel size: 20 x 20 µm
Theoretical resolution: 25 pl / mm
Real resolution: >12 pl / mm
TWAIN-compatible: Yes

USB CONTROLLER SOPIX / SOPIX2
Power supply: Non-power-fed via USB port / 5V
Consumption: 400 mA
Dimensions: 27.5 x 98 x 13 mm
Total weight: 118 g
Liquid penetration: IPX0 (protection index)
USB cable length: 3 m

SENSOR - SIZE 2
External dimensions: 30.4 x 42 x 5.3 mm
Active area dimensions: 26 x 34 mm (884 mm^2)
Pixel number: 2.21 million (1300 x 1700)
Cable length: 70 cm
Liquid penetration: IP67 (temporal immersion)

SOPIX2 AND SOPIX2 INSIDE SYSTEMS
Technology: CMOS + fiber-optic + scintillator*
Pixel size: 20 x 20 µm
Theoretical resolution: 25 pl / mm
Real resolution: >18 pl / mm
TWAIN-compatible: Yes

USB CONTROLLER SOPIX INSIDE / SOPIX2 INSIDE
Power supply: Non-power-fed via USB port / 5V
Consumption: 400 mA
Dimensions: 40 x 150 x 40 mm
Total weight: 180 g
Liquid penetration: IPX0 (protection index)
USB cable length: 5 m

** Scintillator: GADOX for SOPIX & SOPIX INSIDE, CSI for SOPIX² & SOPIX² INSIDE.*

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System operation environment
Temperature: from + 10 to + 40°C
Humidity rate: from 20 to 60% RH
Atmospheric pressure: no noticeable influence of the environmental conditions

System transport and/or storage environment
Storage temperature: from -20 to +45°C *
Humidity rate: from 10 to 90% RH
Atmospheric pressure: 700 hPa to 1060 hPa

- Not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.
- Complies with the European Medical Devices Directive 93/42/EEC.
- Complies with the standard IEC60601-1 Ed3, ES60601-1 and CSA - C22.2 No. 60601-1 : 08.

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IMAGING
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