PSPIX

User Manual

IMAGING ACTEON

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1 FOREWORD

Congratulations and thank you for buying ACTEON's PSPIX system.
In order to obtain the best results, please read the information presented in this user manual carefully.

Always be aware of those messages marked as "WARNING", "CAUTION" and "NOTE" when using the PSPIX.

⚠ **WARNING:** WARNING identifies potential incidents that can occur through the use of the PSPIX system.

CAUTION: CAUTION refers to any incident likely to either impact the correct operation of the imaging system or cause injury.

NOTE: NOTE emphasizes specific points of importance for system maintenance or information clarification.

NOTE :

Correct use and handling of the device is outlined within the user manual. The user is entirely responsible for any damage that may result from improper use.

2

PRESENTATION OF THE PSPIX SYSTEM

2.1. DESCRIPTION

NOTE:

These instructions concern a system that comprises of two medical devices: the PSPIX system and radioluminescent imaging plates. We also present the accessories associated with these two medical devices.

The PSPIX system is a laser X-ray device designed to digitize, display and erase imaging plates (IPs) - also known as phosphor plates.

The PSPIX system operates with a computer (PC or Mac) running dental imaging software. It can be directly connected to a computer or the network with an Ethernet cable. The PSPIX system can be configured to operate with a single computer for a single user or several computers in a multi-user configuration. The multi-user configuration allows the PSPIX system to be connected to up to ten computers, each workstation using the PSPIX system successively.

The dental X-ray image is obtained by exposing the IP to X-rays, this is achieved by placing the IP's behind the dental area of the patient to be X-rayed. The IP is then inserted into the PSPIX system for reading. The information from the IP is displayed simultaneously as an X-ray image on both the PSPIX screen and the connected computer through the PSPIX acquisition module.. This image is then interpreted by the practioner/dentist.

The PSPIX system has been designed to offer optimal quality and workflow. The available features, simplifies use by making it possible to interact with the PSPIX system..

Through its reduced size and its futuristic design, the PSPIX system will fit perfectly into any dental practice.

CAUTION:

Federal Laws restrict these devices to the sale or on order to a dentist.

2.2 SYSTEM COMPONENTS

The PSPIX system includes the following items.

- the IP reader, known as the PSPIX
- Two Size-1 IPs
- Two Size-2 IPs
- One start-up kit of 100 hygiene bags and protective covers for each size of the IP's supplied.
This protection is in the form of a protective cover in a hygiene bag.
- A box of 10 samples of SOPROWIPE IP cleaning wipes.
- A microfiber cloth.
- 8 SOPROTABS samples, which are soft pads to support an IP in the mouth.
- A storage box for IPs
- A stylus for the PSPIX screen
- An Ethernet Cable
- An external 100 – 240 V~50/60 Hz FRIWO FW7362M/12 adapter
- A Quick Start
- A CD-ROM to install the PSPIX acquisition module

Optional:
- Size-0 and Size-3 IPs
- Box of hygiene bags and protective covers for Size-0 and Size-3 IPs
- A Size-4 starter kit with two Size-3 IPs, a plastic support and hygiene bags.
- Autoclavable and removable parts: insert for IP and receptacle for IP.

CAUTION:

Risk of contamination and/or malfunction of the PSPIX system. The PSPIX system and its accessories have been designed to optimize the safety and performance of the product. Use of accessories other than those originally supplied can result in a risk to the patient, the user or the equipment. Do not use IPs, protective covers, or hygiene bags supplied by other manufacturers.

NOTE:

The PSPIX system has been delivered in a cardboard package to ensure maximum protection of the equipment. This package should be kept for any subsequent shipping.

2.3 PRINCIPLE OF OPERATION

The PSPIX system is only intended for the optical reading and processing of IP images. The PSPIX system converts the image data stored on the IP into a digital image. This image is then transfered by an acquisition module and displayed on the screen by dental imaging software, and is finally viewed and interpreted by the practitioner.

Stage 1: Acquiring a X-ray image

• The IP is slid into a single-use cover integrated in a hygiene bag, which is also single-use.

• The protected IP is now placed in the patient's mouth behind the part of the mouth to be X-rayed.

• After exposure, the protected IP is removed from the patient's mouth and then disinfected with a disinfectant cloth. The user can then remove his/her gloves and clean his/her hands.

• The cardboard protective cover along with the IP contained inside are taken out of the plastic hygiene bag by the user.

Stage 2: Reading the image data

• Once the PSPIX system is ready to use, the IP (with it's protective cover still attached) must be correctly inserted into the IP slot (1) of the PSPIX system.

• The IP is then detected by the PSPIX system and is automatically logged by the system to be read.

• The protective cover remains in place in the IP slot (1). Once empty, it can be removed and discarded.

• The IP then arrives in the PSPIX system reading module where the images are read with the aid of a laser. The IP's are then collected, processed and transferred to the connected computer via an acquisition module. An animation indicates the progress of the IP reading.

• After several seconds the digital image will appear simultaneously on the Touch screen of the PSPIX (2) and on the computer screen through the dental imaging software.

Stage 3: Deleting the image data

• After reading, the IP passes through the delete module, where the image data is deleted.

• It then falls into the IP receptacle (3) of the PSPIX system and can be directly used for a new X-ray image.

• The PSPIX system is now ready to read the next IP.

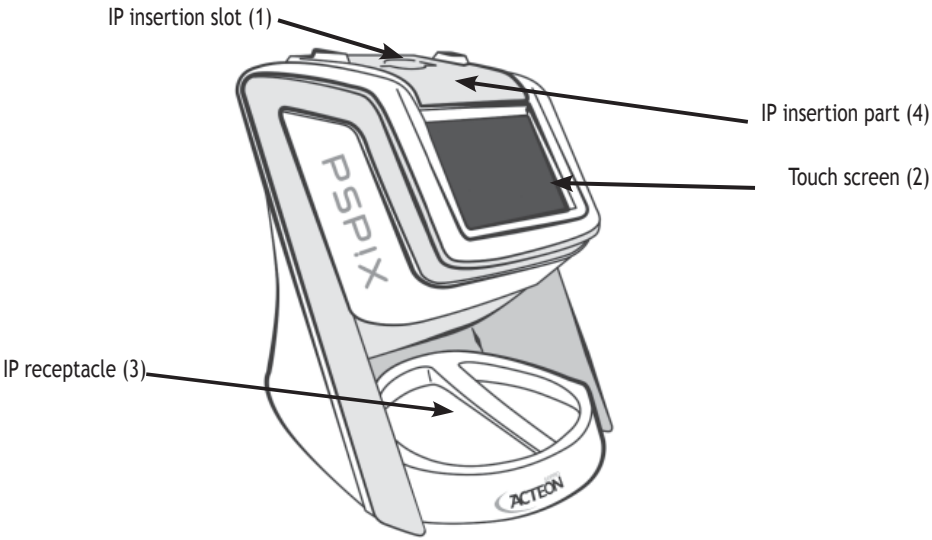
Stage 4: Additional X-rays

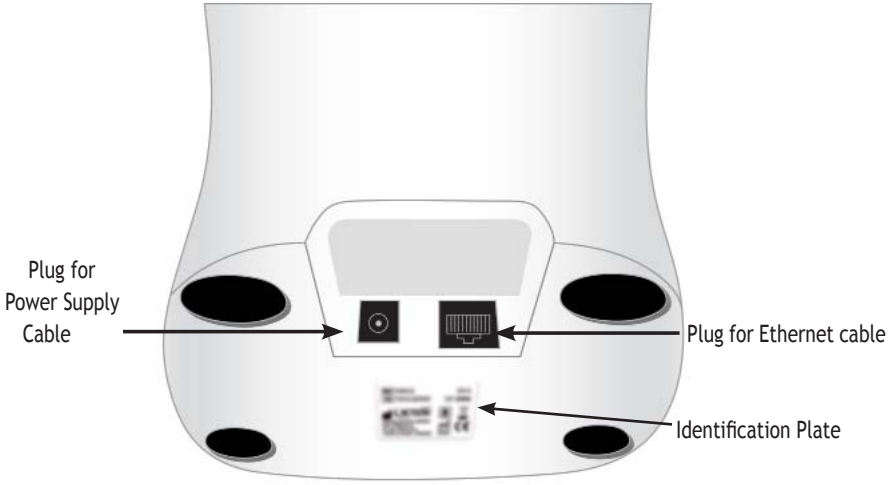
• If the IPs are not reused immediately they must be stored in the storage box, kept away from exposure to ambient light.

The IPs must not be exposed to sunlight, UV rays or X-rays outside their period of acquisition.

When used correctly the IPs are reusable hundreds or even thousands of times. Before every new use it is important to check that the IP is not scratched or damaged. Never use IPs that are damaged, creased, modified and/or discolored.

2.4 MAIN COMPONENTS




Plug for
Power Supply
Cable
Plug for Ethernet cable
Identification Plate

Back

3

SAFETY INFORMATION

3.1. GENERAL SAFETY INFORMATION

⚠ **WARNING:**

This medical device is designed to be used on patients (persons) that are fit to have a dental X-ray.

- The devise is intended to be used in an aseptic environment within a dental practice, dental clinic or hospital examination room by a qualified dentist in order to avoid any risk of contamination and/or malfunction of the PSPIX system.

- The PSPIX system must not be used in the presence of flammable anesthetics, pure oxygen or nitrous oxide to avoid any risk of explosion.

- The PSPIX system is a category 1 laser product. Once the top is lifted the PSPIX system becomes a category 3B laser product. Ensure you do not expose your eyes to the laser beam, to avoid risk of damage. .

Any commands, adjustments or interventions other than those specified within this manual can possibly result in exposure to dangerous laser radiation and can cause damage to the eyes.

- Only specialist, trained technicians approved by ACTEON are authorized to install the equipment and carry out maintenance and/or repairs in order to avoid any risk of electrocution and/or malfunction of the PSPIX system. The PSPIX system does not comprise of any components that are repairable by the user.

- The PSPIX system and its accessories particularly the IP's, the protective covers and the hygiene bags, have been designed and developed to guarantee maximum safety and performance. The use of accessories other than those originally supplied can cause risk to the patient, the user or the equipment. Do not use IPs, protective covers, or hygiene bags supplied by other manufacturers, in order to avoid any risk of contamination or malfunction of the PSPIX.

- The PSPIX system and its accessories must not be modified, transformed or refurbished, in order to avoid any risk contamination and/or malfunction of the PSPIX system.

- Do not swallow the IPs! Risk of poisoning
- Always observe the necessary health precautions when handling the IP, the covers and hygiene bags, in order to avoid any risk of cross-contamination

- Always comply with anti-contamination and sterilization measures when using accessories such as positioning holders, the generator and IPs. It is essential to follow the user instructions supplied by the manufacturer in order to avoid any risk of cross-contamination.

- Do not drop the PSPIX system. After dropping the device do not reconnect the PSPIX system, but send it to your approved distributor or to the SOPRO Service Department in order to avoid any damage to eyes and/or any malfunction of the PSPIX system.

- The PSPIX system meets standard IEC 60601-1. Only peripherals that meet standard IEC 60950-1 may be connected to the PSPIX system in order to avoid any malfunction of the PSPIX system.

CAUTION:

- To ensure safe use and correct operation of the PSPIX system, it is essential to use the power supply provided with the PSPIX system. The power supply provided with the PSPIX system must only be replaced with the same model: FRIWO FW7362M/12 100 – 240 V~ 50/60 Hz 700 mA, in order to avoid any risk of electrocution and/or malfunction of the appliance.

- Use of the PSPIX system may, due to its EMC characteristics, affect or cause a malfunction of other appliances in the vicinity.

- The use of other devices may interfere with the PSPIX system, due to their EMC characteristics. This can may cause a PSPIX system malfunction.

- The reading of IPs and the transfer of the image from the PSPIX system to a computer may be sensitive to electromagnetic disturbance, this can also cause a disturbance to the computer network. A stable Ethernet network must be maintained at the dental practice or clinic, in order to avoid any malfunction of the PSPIX system.

- Do not move or bang the PSPIX system when it is processing the image, in order to avoid any risk of the system malfunction.

WARNING :

You will find other safety information in all the chapters of this user manual. Please read this entire user manual.

3.2. OPERATING SYSTEM ENVIRONMENT

Please refer to chapter 5 “System Configuration”.

3.3. ENVIRONMENTAL CONDITIONS FOR STORING AND/OR TRANSPORTING THE PSPIX SYSTEM.

Please refer to chapter 11 “Technical Specifications”.

3.4. PRECAUTIONS TO BE TAKEN WITH THE ETHERNET CONNECTION

For Ethernet port connections, use the CAT5 (RJ45) cable provided. It can be directly connected to a computer or a local area network. This must be standardized according to the standards EN60950 or IEC60950 or UL 60950.

4

REGULATORY STATEMENT

4.1. COMPLIANCE WITH STANDARDS AND REGULATIONS

The PSPIX system has been designed and manufactured by SOPRO, a company which is certified with the ISO13485 Quality Control System Standard. It complies with the essential requirements of European Directive 93/42/EEC concerning medical devices. It therefore particularly complies with the IEC standards on electrical safety and Electromagnetic Compatibility (EMC).

4.2. ELECTROMAGNETIC INTERFACES AND ELECTROSTATIC DISCHARGES

Electromagnetic compatibility (EMC) covers the ability of the components of electronic appliances to correctly interact in an electronic environment. Although the PSPIX system has been designed with this compatibility and respects the thresholds of electromagnetic interferences put in place by the regulatory body, no guarantee is given regarding the interferences likely to be produced at a given facility. If the PSPIX system generates interference with radio communication services (which can be checked by switching it on and then switching it off again) we advise that you avoid this by taking all or some of the following steps:

- Change the position of the receiving antenna
- Reposition the PSPIX system in relation to the receiver.
- Keep the computer at a good distance from the receiver.

The PSPIX system is designed and tested to be used in a domestic class B and group 1 environment in compliance with standard CISPR11.

! CAUTION:

The internal components of the PSPIX system may be sensitive to electrostatic discharges once the IP insertion part has been removed. Do not insert any metallic object or any source likely to cause an electrostatic discharge into the device. This can cause a PSPIX system malfunction.

4.3. MONITORING SYSTEMS FOR MEDICAL DEVICES

As with any medical device, the PSPIX system is equipped with monitoring systems for medical devices. Any serious malfunction must be reported both to the competent authorities and to the manufacturer as soon as and with as much detail as possible.

4.4. END OF LIFESPAN

The PSPIX system is recyclable in accordance with European Directive 2002/96/EC on the disposal of electric and electronic waste (DEEE or WEEE).
By correctly disposing of the PSPIX system, you help to avoid deterioration of both the environment and human health.

The symbol affixed to the device and displayed on its accompanying documents means that the PSPIX system must not, under any circumstances whatsoever, be treated as household waste. It must therefore be sent to a waste collection center capable of recycling electric and electronic equipment. Please comply with current rules concerning waste disposal in the country of installation. For any further information on the processing, collection and recycling of the machine, please do not hesitate to contact your dental equipment distributor (or the website of the ACTEON group (www.acteongroup.com) to obtain information on what action to take.

4.5. ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions		
The PSPIX system is intended for use in the electromagnetic environment specified below. The customer or the user of the PSPIX system should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - Guidance**
RF emissions CISPR 11	Group 1	The PSPIX system 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 CISPR 11	Class B	The PSPIX system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic current emissions EN 61000-3-2	Class A	
Voltage fluctuations / Flicker EN 61000-3-3	Compliant	

Guidance and manufacturer's declaration - electromagnetic immunity			
The PSPIX system is intended for use in the electromagnetic environment specified below. The customer or the user of the PSPIX system 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 in contact ± 8 kV in the air	± 6 kV in contact ± 8 kV in the air	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 supply cables ± 1 kV for input/ output cables	± 2 kV for supply cables ± 1 kV for input/ output cables	Mains power quality should be that of a typical commercial or hospital environment.
Voltage shocks EN 61000-4-5	± 1 kV in differential mode	± 1 kV in differential mode	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 % UT - (> 95 % in immersion at UT over 0.5 cycles) • 40 % UT (> 60 % in immersion at UT over 5 cycles) • 70 % UT > 30 % in immersion at UT over 25 cycles) • < 5% UT (> 95 % in immersion at UT over 5 cycles)	• < 5% UT (> 95 % in immersion at UT over 0.5 cycles) • 40% UT (> 60% in immersion at UT over 5 cycles) • 70 % UT (> 30% in immersion at UT over 25 cycles) • < 5% UT (> 95 % in immersion at UT over 5 cycles)	Mains power quality should be that of a typical commercial or hospital environment. If the user of a PSPIX system requires continued operation during power mains interruptions, it is recommended that the PSPIX system 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.

Guidance and manufacturer's declaration – electromagnetic immunity

The PSPIX system is intended for use in the electromagnetic environment specified below. The customer or the user of the PSPIX system 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 outside of recommended distance from any part of the PSPIX system, including cables. 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 Vms 150 kHz to 80 MHz	3V	d = 1.16√P d = 1.16√P 80 MHz to 800 MHz
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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 system is used exceeds the applicable RF compliance level above, the PSPIX system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PSPIX system.
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 PSPIX system

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

Nominal Maximal Output of the device in W	Separation distance in meters (m) detIPined by transmitter frequency		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	d = 1.2 √P	d = 1.2 √P	d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

4.6 SYMBOLS

The symbols displayed in this manual, on the labels below the PSPIX system and on its packaging comply with international standards.

Warning!

Laser beam

High voltage

Alternating current

Ethernet

Complies with the essential requirements of European Directive 93/42/EEC concerning medical devices.

Disposal of commercial electric and electronic equipment after 13 August 2005. This symbol denotes that this product cannot be disposed with along with household waste.

Unearthed class II power supply. The power supply plug is used to disconnect the device from the electricity network.

Sensitive to electrostatic discharges

Autoclable at 134 °C

Autoclable at 132 °C

ThIPo-disinfectable

Do not reuse

Serial Number

Manufacture date

Manufacturer

Upper temperature limit

Temperature limit

Keep out of direct sunlight

Upper humidity limit

Humidity limit

Refer to the User Manual

Catalog reference

5

CONFIGURATION OF THE PSPIX SYSTEM

5.1 REQUIRED COMPUTER CONFIGURATION

To use the PSPIX system you must ensure that the computer and its peripherals have no limits on their use for the safety of persons.

⚠ **WARNING:**

Only peripherals compliant with standard IEC 60950-1 can be connected to the PSPIX system Risk of PSPIX system malfunction.

The computer must 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 i3 of higher
Memory	512 MB	2 Gb or more
Hard disk	250 Gb	500 Gb or more
Video card	32 MB individual RAM Video Card. DirectX9 compatible	CHIPSET NVIDIA® graphics card or dedicated ATI® / 512 MB RAM individual video card. Compatible with DirectX 9 or later.
Ethernet Card	100 Mb/s to 1 Gb/s	1 Gb/s
Screen resolution	1024 x 768	1280 x 1024 or more

CAUTION:

Risk of PSPIX system malfunction. For Ethernet port connections, use the CAT5 (RJ45) cable provided. It can be directly connected to a computer or a local area network. This must be standardized according to standards EN60950, IEC60950 or UL 60950.

Mac® Configuration:

	MINIMUM CONFIGURATION	RECOMMENDED CONFIGURATION
Computer	MAC® Book Pro 13.3” or iMac® 21.5”	iMac® 27”
Operating system	MAC® OS X 10.9	MAC® OS X 10.9
Processor	Intel® Core 2	Intel® Core i7
Memory	2 Gb	4 Gb
Ethernet Card	1 Gb/s	1 Gb/s

! CAUTION:

Risk of PSPIX system malfunction. For Ethernet port connections, use the CAT5 (RJ45) cable provided. It can be directly connected to a computer or a local area network. This must be standardized according to standards EN60950, IEC60950 or UL 60950.

5.2 COMPATIBILITY WITH X-RAY GENERATORS

The PSPIX system is compatible with all intra-oral X-ray generators currently on the market. We nevertheless recommend the use of ACTEON generators, which are perfectly adapted to the PSPIX systems.

6

INSTALLATION AND SETTINGS

6.1 INSTALLATION OF THE PSPIX SYSTEM

⚠ **WARNING:**

Risk of electrocution and/or malfunction of the PSPIX system. *Only specialist, trained technicians approved by SOPRO are authorized to install and commission the PSPIX system.*

- Position the PSPIX system as tabletop equipment in the dental clinic.

⚠ **WARNING:**

Risk of short circuit due to condensation. Only install the PSPIX system in a secure, dry and correctly ventilated location. The ambient temperature must be not less than +10 °C and not more than +40 °C.

⚠ **WARNING:**

Risk of explosion. The PSPIX system is not intended for use in environments where there is a risk of explosion or where the atmosphere is combustible. Areas subject to explosion may be created where flammable products such as anesthetics, oxygen, cleaners and surface disinfectants are used.

CAUTION:

Risk of PSPIX system malfunction.
- Never leave the PSPIX system in direct sunlight or near to a bright light source. This allows for optimal viewing of the information displayed on the PSPIX system's touch screen .
- Risk of PSPIX system malfunction. Avoid the presence/ interference of radiation sources (magnetic fields for example) in the room where the equipment is installed.
- Risk of PSPIX system malfunction. The PSPIX system must be positioned on a flat and stable surface to avoid any risk of vibration that may harm the image quality.
- Risk of PSPIX system malfunction. The PSPIX system must not be stacked on or placed in contact with other items of equipment.

- Connect the PSPIX system to the electrical mains.

⚠ WARNING:

Risk of electrocution and/or malfunction of the PSPIX system.
- The PSPIX system must only be connected to a compliant wall plug.
- Before connecting the PSPIX system, check that the mains voltage and frequency indicated on the power supply correspond to those of mains supply.
- Before switching on, ensure that the neither PSPIX system nor the power supply cable are damaged. Damaged cables and connectors must be replaced immediately.
- Never touch the patient and non-protected connectors on the PSPIX system at the same time.
- Place the PSPIX system so that you can easily access the electrical socket to disconnect it.
- Where you are using multiple adapters, the requirements of IEC 60601-1 must be observed. Do not place the multiple adapters on the ground. Other systems must not be connected to the same multiple adapter.

The PSPIX system allows up to ten computers to be connected.
- Connect the PSPIX system with the supplied Cat5 Ethernet Cable:
• either directly to a computer, when only one workstation is being connected
• or to the existing network when either one or more computers are being connected.
- Ensure that the computer connected to the PSPIX system is connected to a correctly earthed and switched-on mains socket.

! CAUTION:

Risk of electrocution. The computer connected to the PSPIX system must not be used near the patient, in compliance with IEC standard 60601-1. The minimum horizontal distance between the patient and the computer must be 1.5 m. The minimum vertical distance between the patient and the computer must be 2.5 m.

- Once the PSPIX system is connected to the computer or network, install the PSPIX acquisition module on the computer. This is on the CD-ROM supplied with the system.

-Insert the CD-ROM supplied with the PSPIX system into the computer drive to install the acquisition module.

NOTE:

The SOPRO IMAGING software is also available on the CD-ROM supplied with the PSPIX system . The PSPIX acquisition module is directly integrated into this software. If you wish to use SOPRO IMAGING, please install it and follow the instructions displayed on the screen up until the end of the procedure.

If not please refer to the user manual for the imaging software being used.

-Follow the instructions displayed on the screen up until the end of the procedure.
- Repeat this installation process for all computers you wish to connect the PSPIX system to.

6.2 CONFIGURATION OF THE PSPIX SYSTEM

Configuring the PSPIX system is done by the system's Touch screen and via the computer connected to the PSPIX system, in the PSPIX acquisition module.

Setup up the PSPIX system via the touch screen

-During the first start-up of the PSPIX system, you must select the language you wish to use. Scroll through the languages until you find the desired language. Click OK to confirm.

- You will then be taken to the home screen, which displays the "PSPIX" logo and the time.

NOTE:

The time is set automatically. It uses the system time of the computer connected to the PSPIX system.

NOTE:

If the red computer icon *appears in the top right-hand corner of the touch screen , this means that the PSPIX is not connected to the computer or the network.*

- Please ensure that the Ethernet cable is correctly connected to the network plug.

-OR Click on the "Setup" icon to access the Configuration of the IP address in the "Configuration" / "Ethernet" menu .

-Next click on the "Setup" icon. You can now directly access screen brightness Setup and the Configuration and Delete menus.

NOTE:

At any time, click on the "Home" icon *if you wish to return to the Home screen.*

- To alter the brightness Setup, slide the cursor to the left or right to obtain the required backlighting.

- Then click on the "Configuration" icon .

In the Configuration menu, you can access the "Languages" , " Ethernet" , and "Time" menus . Click on the icon corresponding to the configuration you require.

- In the “Languages” menu, scroll through the languages until you find the desired language. Click OK to confirm.

NOTE:

By default, the PSPIX network /IP adress configuration is automatic (DHCP ON). If you wish to manually allocate an IP address, click on the “Ethernet” icon .

- In the “Ethernet” menu, click on the “DHCP Auto ON” icon, if you wish to manually allocate an IP address to the PSPIX. This will switch this option off.
- Next click on the “Configure Fixed IP” button.
- The active number appears in orange color. Delete by pressing the button, then type in the desired fixed IP address using the numerical keypad. Confirm by pressing the OK button.
- Once all the fields are complete, confirm by pressing the OK button, or cancel by pressing the red cross. You will automatically return to the “Configuration” menu.

- In the “Time” menu, you can set:

• “Eco mode” time: the time limit after which the light on the PSPIX system screen automatically dims due to inactivity in order to save energy. By default it is set at 5 minutes. You can set it for time periods between 0 minutes and 60 minutes
• Set up the “Preview” time: the time for which the Preview of the image remains displayed on the screen after reading an IP. By default it is set at 5 sec. You can set it for time periods between 0 minutes and 20 seconds.

- To do this, delete the digit by pressing the button, then type in the desired time period with the numeric keypad. Confirm by pressing the OK button.
- Once all the fields are complete, confirm by pressing the OK button, or cancel by pressing the red cross. You will automatically return to the “Configuration” menu.

Configuration of the PSPIX in the acquisition module via the computer.

Please refer to the CD-ROM user manual supplied with the PSPIX system in the “Document” section.

7 USE

⚠ **WARNING:**

The PSPIX system is designed to be used by a qualified dentist. Its use does not require any specific training. Please refer to the instructions in this manual.

7.1 PREPARATION OF THE PSPIX SYSTEM, THE IP AND THE CONSUMABLES.

1. Switch on the computer that is connected to the PSPIX system.

2. On your computer, please open your dental imaging software and then either create a new patient file or open an existing patient file. Open the PSPIX acquisition module.

✍ **NOTE:**

If you use the SOPRO IMAGING software, the PSPIX acquisition module will open automatically when the patient file is opened.

⚠ **WARNING:**

Risk of confusing X-rays. X-rays are always listed one after the other in the patient file open in the dental imagery software. In order to avoid confusion with X-rays belonging to other patients, only those attributed to the open patient file must be inserted in the PSPIX system.

✍ **NOTE:**

If you are using the PSPIX system for the first time it is recommended that you check and/or modify the configuration options (for example, the required reading resolution). If you are using the SOPRO IMAGING software, please refer to the CD-ROM user manual supplied with the PSPIX system, located in the "Document" section.

3. If the PSPIX system is not connected to the electrical mains, switch it on by connecting to the power supply network. The PSPIX initially launches an installation sequence, and then is ready to use.

✍ **NOTE:**

If the PSPIX system is in standby mode, the opening ofacquisition module automatically takes it out of this standby mode. You can also touch the Touch screen to bring it out of its standby mode.

4. Obtain the required size of IP from the storage box.

⚠ WARNING:

Risks of image degradation. Check visually that the IP is not deteriorated.

NOTE:

Natural X-rays and/or the rays diffused by X-rays may pre-expose the IP prior to their normal use.

⚠ WARNING:

Risks of image degradation. If it is the first time that the IP is being used, if it has not been used over the course of the last 24 hours or if it has been stored in a dark room, you MUST erase it to avoid any potential misting due to ambient radiation. For more information, please refer to paragraph 7.4 "Erasing an IP".

⚠ WARNING:

Cross-contamination Risk. Ensure that you always observe the necessary hygiene precautions when handling the IP, the covers and hygiene bags to avoid any risk of cross-contamination.

5. Slide the IP into the protective cover in the hygiene bag. The black side of the IP, marked with the ACTEON logo must correspond to the white side of the protective cover marked with the ACTEON logo. More importantly, the blue side of the IP must correspond to the black side of the hygiene bag.

NOTE:

The letter "P" is printed on the active side of our IPs and it is therefore visible on the X-ray image. It serves as a reference point for the dentist when he/she is placing the IP in the patient's mouth, and facilitates orientation of the X-ray image during diagnosis.
Note that the "P" point is marked on the protective cover. The two reference points must be superimposed over each other when the IP is placed in the protective cover.

⚠ WARNING:

The hygiene bag protects the IP from direct contact with saliva both during and after acquisition of an X-ray, as this could lead to a risk of contamination and toxicity for the patient. The hygiene bags also protect the IP from light both during and after acquisition of a X-ray image. Like the IP, they are available in different sizes. Select the appropriate size.

⚠ **WARNING:**

The protective covers prevent physical and mechanical damage to IP, protect the IP from light during and after acquisition of the X-ray image to avoid erasing image data, and avoid cross-contamination between patients. Like the IP, they are available in different sizes. Select the appropriate size.

6. Peel back the paper and then close the hygiene bag by passing the thumb and forefinger across the whole adhesive strip to ensure complete sealing.

⚠ **WARNING:**

The hygiene bag and the protective cover are single-use items and must not be re-used.
The re-use of a single-use medical item exposes you to iatrogenic infection risks from pathogenic organisms through this medium, and to accidents related to materiovigilence.

7.2 ACQUIRING A X-ray IMAGE

⚠ **WARNING:**

Contamination Risk. Disinfect the hygiene bag before placing it in the patient's mouth, using a disinfectant wipe or by spraying disinfectant on a lint-free cloth.

⚠ **WARNING:**

Contamination Risk. Wear protective gloves when positioning the hygiene bag in the patient's mouth.

1. Place the closed hygiene bag containing the IP in the patient's mouth, parallel to the longitudinal axis of the tooth. The back of the hygiene bag (black side) must be toward the X-ray source.

NOTE:

If you are using a positioning holder, please refer to the instructions supplied with this device. The use of a positioning holder is recommended to guarantee a specific position for the IP in relation to the tooth, and to obtain standardized images that are both reproducible and without distortion. Please refer to the instructions supplied with this device to ensure that it is decontaminated and sterilized prior to use.

⚠ **WARNING:**

Risk of poisoning and/or skin lesions. If you use positioning holders, please only use rings that do no damage the hygiene bag or the protective cover of the IP. Please avoid positioning holders with sharp edges.

2. Select an exposure value on the X-ray generator.

3. Move the generator towards the patient's mouth. Ensure that the axis of the generator cone is perpendicular to the position of the IP.

4. Operate the trigger on the timer to expose the dental zone and the IP to X-rays, ensuring that you comply with all safety procedures.

5. After acquisition, remove the hygiene bag containing the IP from the patient's mouth.

⚠ **WARNING:**

Contamination Risk. Wear protective gloves when removing the hygiene bag from the patient's mouth.

! **CAUTION:**

Contamination Risk. Clean and disinfect the hygiene bag before opening it.

6. Clean and disinfect the hygiene bag using a disinfectant wipe or by spraying disinfectant on a lint-free cloth. Then remove the protective gloves. Disinfect and clean your hands.

⚠ **WARNING:**

Risk of PSPIX system malfunction.
Before handling the IP, it is important to remove any powder residue (from protective gloves) from your hands. This can damage the PSPIX and have consequences for the X-ray image.

7. Open the hygiene bag by tearing off the adhesive strip.

8. Remove the protective cover containing the IP from the hygiene bag.

9. Keep the IP in the protective cover until it is introduced into the PSPIX system, taking care not to touch it or expose it to ambient light.

⚠ **WARNING:**

Risks of image degradation. Image data on a IP will be erased by light. Keep the exposed IPs in their protective covers until they are inserted into the PSPIX system.

7.3 READING THE IP

Single User Configuration:

Please ensure that the PSPIX system is ready.

NOTE:

If the PSPIX system is operating in multi-user configuration, refer to the following paragraph: "multi-user configuration".

1. If the PSPIX acquisition module is not open, the Touch screen displays the single-user home page, which displays the "PSPIX" logo and the time. To read an IP, check that your dental imaging software is open at the correct patient file, and that the PSPIX acquisition module is also open.

2. If the connection is correct, the animation on the Touch screen asks you to insert the IP in the PSPIX system. The patient's name and dentist's name are displayed on the screen.

Place the protective cover containing the IP in the insertion slot of the PSPIX system.
- vertically
- with the side containing the ACTEON logo facing towards you.
- with the open side of the protective cover facing towards the insertion slot.

The protective cover partially opens and the IP is automatically detected then enters the PSPIX system. The protective cover remains in the insertion slot.

CAUTION:

Risk of PSPIX system malfunction. Only insert IPs into the PSPIX system. Do not insert any metal object, protective cover or liquid into the IP insertion slot.

NOTE:

If the IP does not enter the PSPIX system this means that the IP has an alignment problem and it was not correctly placed in the insertion slot (an animation on the Touch screen will ask you to correctly place it). Therefore, correctly place the IP in the insertion slot.

3. Only remove the protective cover when it is empty.

4. An animation and a percentage will appear on the screen, showing the progress of the IP reading.

5. After several seconds, the digital image will appear simultaneously on the computer and PSPIX screen

allowing you to quickly check the image and the computer screen. The Pre-view display time on the Touch screen is configurable from the “Setup”/”Configuration”/”Time” menu.

6. After reading, the IP passes through the delete module, where the image data is deleted. It then falls into the IP receptacle of the PSPIX system and can be reused for a new X-ray image.

NOTE:

If an image cannot be transferred onto the computer due to a network error, computer failure or software bug, the last image read is saved in the PSPIX system. A warning window appears on the Touch screen of the PSPIX and no other IP can be inserted for reading.

You are offered three options:

- Attempt to re-establish the Ethernet connection with the computer to automatically transfer the image. To do this ensure that the Ethernet cable is correctly connected OR ensure that the PSPIX acquisition module is correctly open.
If the Ethernet connection is reconnected then a new window confirming the reconnection will be displayed during the image transfer time.

- Delete the X-ray image from the memory by clicking on the “Trash” icon . Confirm the deletion by pressing the OK button.

-Collect the image from the PSPIX acquisition module of another computer connected to the PSPIX system (in the case of a multi-user configuration). Take care to open the correct patient file in the imaging software, then access the “Setup” menu, then the “Image” tab in the PSPIX acquisition module. Finally click on the “Retrieve the Last Scanned Image” button.

7. Retrieve the IP from the IP receptacle. The PSPIX system is now ready to read the next IP (the animation on the screen asks you to insert a new IP).

NOTE:

Avoid sliding the IP when retrieving it from the IP receptacle in the PSPIX system. Lift out the IP by holding it along its edges.

CAUTION:

Risk of PSPIX system malfunction. Do not put an IP back in the insertion slot of the PSPIX system until the previous IP has fallen into the IP receptacle.

Multi-User Configuration

NOTE:

The PSPIX system may be connected and used by one computer (single-user configuration) or by several computers (multi-user configuration). The multi-user configuration allows you to share the PSPIX with a maximum of ten computers. Each workstation uses the PSPIX system successively. The PSPIX system therefore has the same function: send an image to a given computer via the acquisition module.

NOTE:

It is possible to reserve the PSPIX system:
-via the PSPIX touch screen
-OR via the PSPIX acquisition module from the workstation.

• Reservation from the PSPIX screen:

1. To reserve the PSPIX system from the touch screen , directly click on the number that corresponds to your workstation. This is located on the multi user home page.

NOTE:

Workstations in blue represent computers that are connected and in operation. Workstations in white represent disconnected computers. Workstations in grey represent unassigned workstation numbers.

NOTE:

In order for the station number to appear in blue on the Touch screen the dental imaging software must be open on the patient file and the acquisition module must be switched on.

NOTE:

Once the PSPIX system is reserved, the workstation number, the patient and practitioner names are displayed on the PSPIX system's touch screen .
A countdown on the screen shows the time remaining to insert the IP in the PSPIX system. At the end of this time, the PSPIX system will automatically free itself up and return to the multi-user home page.

NOTE:

When the PSPIX system is reserved for a given workstation number, a notification will appear in the acquisition module of the other users. It is impossible for them to reserve the PSPIX system during this period.

2. Then follow **steps 2 to 7 for the single user configuration** described above for reading the IP.

3. To manually free up the PSPIX system click on the “Home” icon in the bottom right-hand corner of the PSPIX screen. You will return to the home page.

NOTE:

If an image cannot be transferred onto the computer due to a network error, computer failure or software bug, the last image read is saved in the PSPIX system. A caution window appears on the Touch screen of the PSPIX and no other IP can be inserted for reading.

You are offered three options:

- Attempt to re-establish the Ethernet connection with the computer to automatically transfer the image. To do this ensure that the Ethernet cable is correctly connected OR ensure that the PSPIX acquisition module is correctly open.
If the Ethernet connection is reconnected then a new window confirming the reconnection will be displayed during the image transfer time.

- Delete the X-ray image from the memory by clicking on the “Trash” icon . Confirm the deletion by pressing the OK button.

-Collect the image from the PSPIX acquisition module of another computer connected to the PSPIX system (in the case of a multi-user configuration). Take care to open the correct patient file in the imaging software, then access the “Setup” menu, then the “Image” tab in the PSPIX acquisition module. Finally click on the “Retrieve the Last Scanned Image” button.

CAUTION:

Risk of PSPIX system malfunction. Do not put the IP back into the insertion slot of the PSPIX system until the previous IP has fallen into the IP receptacle.

• Reservation from the work station:

1. To reserve the PSPIX system from your work station click on the “unlock” icon on the PSPIX acquisition module. The icon then changes to “locked” .

NOTE:

Once the PSPIX system is reserved, the work station number, the patient and practitioner names are displayed on the PSPIX system’s touch screen .

A countdown on the screen shows the time remaining to insert the IP in the PSPIX system. At the end of this time, the PSPIX system will automatically free itself up and return to the multi-user home page. This

reservation time for each work station is configurable from the PSPIX acquisition module in the “Setup” menu from the “Configuration” tab.

NOTE:

When the PSPIX system is reserved for a given workstation number, a notification will appear in the acquisition module of the other users. It is impossible for any other workstation to reserve the PSPIX system during this period.

2. Then follow steps 2 to 7 for the single user configuration described above for reading the IP.

3. To manually free up the PSPIX system click on the “Home” icon in the bottom right-hand corner of the PSPIX screen, OR click on the “locked” icon on your acquisition module. You will return to the PSPIX multi-user home page.

NOTE:

If an image cannot be transferred onto the computer due to a network error, computer failure or software bug, the last image read is saved in the PSPIX system. A caution window appears on the Touch screen of the PSPIX when no other IP can be inserted for reading.

You are offered three options:

- Attempt to re-establish the Ethernet connection with the computer to automatically transfer the image. To do this ensure that the Ethernet cable is correctly connected OR ensure that the PSPIX acquisition module is correctly open.
If the Ethernet connection is reconnected then a new window confirming the reconnection will be displayed during the image transfer time.

- Delete the X-ray image from the memory by clicking on the “Trash” icon .
Confirm the deletion by pressing the OK button.

-Collect the image from the PSPIX acquisition module of another computer connected to the PSPIX system (in the case of a multi-user configuration). Take care to open the correct patient file in the imaging software, then access the “Setup” menu, then the “Image” tab in the PSPIX acquisition module. Finally click on the “Retrieve the Last Scanned Image” button.

CAUTION:

Risk of PSPIX system malfunction. Do not put an IP back in the insertion slot of the PSPIX system until the previous IP has fallen into the IP receptacle.

7.4 ERASING AN IP

After being read, the IP is automatically erased before falling into the IP receptacle of the PSPIX system.

However, it is necessary to erase an IP if it is the first time it is used, if it has been stored for more than 24 hours, if it has been stored in a dark room or if the image data has not been deleted following a PSPIX system malfunction. The “Erase” menu allows you to quickly and simply erase IPs.

NOTE:

During the erasure, no image is sent to the dental imaging software.

1. Click on the “Setup” icon on the PSPIX system’s touch screen .

2. Next, click on the “Erase” icon .

3. An animation will appear on the screen asking you to insert the IP to be erased.

Place the protective cover containing the IP in the PSPIX system’s insertion slot.
- vertically
- with the side containing the ACTEON logo facing towards you.

IP is automatically detected then enters the PSPIX system.

CAUTION:

Risk of PSPIX system malfunction. Only insert IPs into the PSPIX system. Do not insert any metal object, protective cover or liquid into the IP insertion slot.

NOTE:

If the IP does not enter the PSPIX system this means that the IP has an alignment problem and it is not correctly placed in the insertion slot (an animation on the Touch screen will ask you to correctly align it). Therefore, correctly place the IP in the insertion slot.

4. An animation will appear on the screen showing the progress of the IP erasure.

5. Once the IP has been erased, it is automatically ejected into the IP receptacle, ready for a new operation. Remove the IP, taking care to handle it by its edges.

6. The PSPIX system is now ready to erase the next IP (the animation on the screen asks you to insert a new IP for erasure).

NOTE:

The "Erasing" mode takes longer than reading an IP. This ensures that the IPs are correctly erased, even when they have been stored in darkness for an extended period.

NOTE:

To return to the home page, click on the "Home" icon . If you do not, this will happen automatically after a few seconds.

7.5 ECO MODE AND STANDBY MODE

Eco mode

Following several minutes of inactivity, the backlight on the PSPIX Touch screen will dim to save energy. The "Eco mode" is configurable from the PSPIX Touch screen in the "Setup"/"Configuration"/"Time" menu. By default, it is set at 5 minutes. You can set it for time periods between 0 minutes and 60 minutes

NOTE:

All of the animations and buttons displayed on the Touch screen remain visible when it is in "Eco mode".

The PSPIX system automatically leaves "Eco mode" when the user changes the status of the PSPIX system. This includes when he/she places an IP in the insertion slot, touches the screen or reserves the PSPIX system from the acquisition module from his/her workstation.

Standby

A few minutes after closing the PSPIX acquisition module, the Touch screen of the PSPIX system will completely switch off to reduce its power consumption. This standby time is configurable from the PSPIX acquisition module from the "Setup" menu in the "Configuration" tab. By default it is set at 15 minutes. You can set it for time periods between 0 minutes and 60 minutes

The PSPIX system automatically exits standby mode when the user restarts his/her imaging software, opens a patient file and launches the PSPIX acquisition module.

You can also touch the Touch screen to bring it out of its standby mode.

7.6 SWITCHING OFF THE PSPIX SYSTEM

1. Disconnect the PSPIX system's power supply to turn the unit off completely.

NOTE:

If the PSPIX system contains an image that has not been transferred from its memory at the time it is switched off, this X-ray image will be lost.

NOTE:

Place the PSPIX system so that you can easily access the electrical socket to disconnect it.

8

IMAGING PLATE (IP)

8.1 GENERAL INFORMATION CONCERNING IPS

⚠ **WARNING:**

Risk of poisoning. IPs are not intended to come into direct contact with the patient mouth. Always place them in a hygiene bag prior to positioning them in the patient's mouth. If the patient swallows all or part of the IP, immediately remove it from the patient's mouth. The patient must seek specialist medical assistance specialist as soon as possible. If a patient bites and damages the hygiene bag, thoroughly rinse out his/her mouth.

• An IP is a flexible intra-oral X-ray image receptor. It is made up of a layer of small photo-stimulable phosphorus particles uniformly coated onto a polyester support film and shielded with a top coat protective layer.

Phosphorus

We do not use phosphorus or phosphorous-based materials for our IPs. We use phosphorescent particles. These phosphorescent particles are sealed between the upper protective layer and the polyester support film. When used normally, these particles cannot become detached from the other parts of the IP.

The phosphorescent particles in the IP are excited by X-rays and store this energy in the form of a latent image. When the IP is scanned by the PSPIX system, this latent image is stimulated by a laser, activated and then converted into a digital image. The IP is then exposed to light so it can be erased and immediately reused.

• The IP has 2 sides:

- The blue side of the IP is the side that "records" the X-ray image. This is the ACTIVE side.
The letter "P" is printed on the active side of the IPs and it is therefore visible on the X-ray image. It serves as a reference point for the dentist when he/she is placing the IP in the patient's mouth, and facilitates orientation of the X-ray image during diagnosis.
Note that the same reference point is marked on the protective cover. The two reference points must be superimposed over each other when the IP is placed in the protective cover.

- The black side is the inactive side. It is marked with the ACTEON logo, the size and the IP serial number.

8.2 USE OF IPS

CAUTION:

Risk of PSPIX system malfunction. Use the PSPIX system in combination with the IPs supplied by the ACTEON group.

CAUTION:

Risks of image degradation. You must handle and use IPs carefully in order to guarantee an optimal image quality and maximize lifespan. You must also ensure that you transport and store them in the box supplied with the PSPIX system.

• The IPs are reusable. Exposure to X-rays does not age the IPs, as they are resistant to hundreds, or even thousands of exposures. Their lifespan depends on the precautions taken during their handling and use. Please observe the information given below to maximize lifespan.

The blue side of the IP is the active side. Protect the active side of the IP:
- from scratching, wear and tear due to friction or mechanical deterioration.
- fingerprints, stains, dirt, dust particles etc...

CAUTION:

Risks of image degradation
• Handle an IP with the same care as you would handle a photographic film, a CD or a DVD.
• Only handle IPs by their edges.
• Never use tweezers, pliers or other mechanical implements to take and/or handle IPs.
• Do not touch the active surface of the IP with fingers or nails.
• Do not leave fingerprints, stains, dirt or dust on the active side of the IP.
• Protect the active side of the IP from scratches and any other form of scratching due to friction or mechanical degradation.
• Avoid unnecessarily folding the IP.
• Do not exert pressure on the IP with any object that is likely to leave a mark or print on the active side.
• Do not clean them in an autoclave
• Potential scratches, stains, soiling, fingerprints or dust on the active side of the IP may affect the image quality and inhibit its interpretation.

WARNING:

Risk of poisoning The IP must not come into contact with the patient's saliva or any type of body fluid. Use a hygiene bag to protect the IP.

CAUTION:

Risks of image degradation. Information "stored" on an IP after X-ray exposure is sensitive to light. Consequently it must be protected from sunlight and daylight by a protective cover and a hygiene bag until it has been read.

• *For the best image quality it is advised to immediately read the IP after exposure to X-rays.*

• *During X-rays exposure always use protective covers and hygiene bags in order to ensure optimal protection of IPs to:*
- eliminate cross-contamination risks.
- preserve the image quality.
- maximize the IP's lifespan.

⚠ **WARNING:**

Contamination Risk. The hygiene bags and protective covers consumables are single use. The reusing of single use items can expose patients to a contamination risk.

8.3 REPLACING IPS

An IP must be replaced in the following cases:

• Signs of deterioration/wear on the active side.
• Visible scratches on the image.
• Stains or clearly visible marks that do not disappear after cleaning.
• Active surface worn or damaged by another vectors
•Any of the aforementioned marks that do not disappear after cleaning according to the instruction set out in this manual.
• Damaged protective film on the active side.
• IP torn or significantly bent out of shape.

! **CAUTION:**

Risks of image degradation. Never use IPs that are damaged, creased, modified and/or discolored.

8.4 GENERAL INFORMATION - FOR STORAGE AND ERASURE OF THE IP

• IPs are sensitive to ambient light. If an IP is exposed to ambient light and it is used to acquire an X-ray image, a shadow may appear on the image and the quality of the image can be degraded.

• When not being used, IPs must be stored in a storage box supplied with the PSPIX, unwrapped and unexposed to ambient light to avoid a shadow appearing on the IP image.

• IPs can be stored in their protective cover and hygiene bag for short periods of time. However, if they are stored under such conditions for more than 24 hours, you must erase the IPs before acquiring a X-ray image. To do this, click on the “Erase” menu on the PSPIX touch screen . For further information, refer to chapter 7.4.

• Storing IPs in their box protects them from dust and any risk of splashes in the dental practice.

• To avoid potential scratches, never leave IPs flat on a surface, particularly on their active side.

• Never store IPs under hot or humid conditions.
Keep them at temperature of less than 33 °C and less than 80 % relative humidity.

• Never expose IPs to X-rays if this is not for the purposes of a X-ray acquisition.

• Never expose IPs to ultraviolet light.

• Use IPs with the appropriate size of protective covers.

• Use IPs with the appropriate size of hygiene bag.

9 MAINTENANCE

The PSPIX system requires no maintenance if it is used in compliance with the operating and cleaning instructions provided in this manual.

Before using the PSPIX system for the first time, it is essential to follow the disinfection procedure.
Any PSPIX system undergoing alteration or maintenance must be subjected to the full disinfection procedure prior to any use.

CAUTION:

Risk of deterioration of the PSPIX system and its accessories.
Only disinfection and cleaning approved by ACTEON may be used. Other cleaning and disinfectant products could damage the PSPIX system and its accessories.

CAUTION:

Risks of image degradation. You must handle and use IPs carefully in order to guarantee an optimal image quality and maximize lifespan. You must also ensure that you store them in the box supplied with the PSPIX system.

9.1 MAINTENANCE OF THE PSPIX SYSTEM

CAUTION:

Risk of PSPIX system deterioration and malfunction. When cleaning or disinfecting the PSPIX system, stop the system by disconnecting it from the mains first.

NOTE:

Wear gloves and other protective clothing when disinfecting the PSPIX system.

DESIGNATION	RECOMMENDATIONS	METHOD AND PRECAUTIONS	
		DO	DO NOT
Cleaning the PSPIX system and removable parts (IP insertion part and receptacle)	Remove the removable parts from the PSPIX system (IP insertion part and receptacle). -To clean the PSPIX system and its removable parts, use a non-abrasive cloth dipped in: -cold or tepid water, -soapy water -a light detergent -butyl alcohol, -ethanol (ethyl alcohol) from 70 - 96 %. -Use a compressed air system to clean the black part underneath the IP insert.	After cleaning, wipe the PSPIX system with a non-abrasive cloth dipped in cold water.	-Never use solvents or abrasive cleaning products to clean the PSPIX system. -Do not spray the cleaning solution directly onto the PSPIX system. -Do not place cleaning solution in the PSPIX system's insertion slot. -Never use a wet cloth on the black part of the IP's insertion part.

Disinfecting the PSPIX system	Remove the removable parts from the PSPIX system (IP insertion part and receptacle) and disinfect them separately. -Disinfect the PSPIX body with a cloth dipped in a disinfectant solution.	All surfaces must be dry before using the PSPIX system.	-Never use disinfectants that contain abrasive or corrosive substances, or that contain solvents. -Never spray the disinfectant directly onto the PSPIX system. -Do not introduce disinfectant in the PSPIX system's insertion slot. Never use a wet cloth on the black part under the IP's insertion slot.
Disinfection of removable parts (IP insertion part and receptacle)	Remove the removable parts from the PSPIX system (IP insertion part and receptacle) To disinfect the removable parts, use -a cloth dipped in a disinfectant solution. -or washer disinfector. The following logo on the back of the removable parts indicates that they are thIPo-disinfectable. Program your washer disinfector so that the thermal disinfection takes place at 93 °C for five minutes.	-Ensure that the parts are completely dry and are at ambient temperature before putting them back into the PSPIX system and using them.	-Never use disinfectants that contain abrasive or corrosive substances, or that contain solvents. -When using a washer disinfector, do not exceed a period of five minutes when thermal disinfection takes place at 93 °C.

OPTIONAL: Autoclave disinfection of removable parts (IP insertion part and receptacle)	-Ensure that the removable parts supplied with your PSPIX system are autoclave-proof, as they are sold as options. Turn them over and check that the following logos are present: 134 C 132 C -Clean and disinfect the removable parts according to the procedures set out above. -Condition the removable parts and place them in the autoclave. - For pre-vacuum steam sterilizer the following parameters have been validated: 132°C (270°F) for 4 minutes, 20 minutes dry time. -For Gravity-displacement steam sterilizer the following parmeters have been validated: 121° C (250°F) 30 minutes, 30 minutes dry times.	-Ensure that the parts are completely dry and are at ambient temperature before putting them back into the PSPIX system and using them.	-Never autoclave items above 134 °C.

NOTE:

The disinfection techniques used both for the PSPIX system and the dental practice must comply with all national and local legislation in force.

CAUTION:

Risk of deterioration of the PSPIX system. No liquid must enter into the equipment. The PSPIX system must therefore never be sprayed with any disinfectant or cleaning solution.

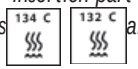
⚠ **WARNING:**

Risk of explosion. Never use vaporized disinfectants. The vapor could catch fire and cause an accident.

CAUTION:

Risk of deterioration of the PSPIX system. Disinfection of the removable parts in the thermal washer disinfector may cause wear of these parts. It is therefore advisable to replace these parts every 100 thermal washer disinfection cycles, on average.

CAUTION:

Risk of deterioration of the PSPIX system. Autoclable and removable parts (IP insertion part for IP and receptacle for IP)are sold as OPTIONS. Turn them over and check that the logos 

are present on the back of the parts before placing them in an autoclave.

CAUTION:

Risk of deterioration of the PSPIX system. Sterilization of removable parts may cause wear of these parts. It is therefore advisable to replace these parts before they get major wear.

NOTE:

The autoclave procedure described in this chapter is a recommended procedure. It is not a substitute for official recommendations and directives.

NOTE:

Product decontamination, methods and tools used, remain the sole responsibility of those people in charge.

9.2 IP MAINTENANCE

DESIGNATION	RECOMMENDATIONS	METHOD AND PRECAUTIONS	
		DO	DO NOT
Cleaning IPs	1.1 Use the soft, lint-free and dry microfiber cloth supplied with the PSPIX system. 1.2 Begin by cleaning with a vertical and then horizontal movement, and then finally with a circular motion. 2.1 Use the SOPROWIPE single-use cleaning wipes. 2.2 Begin by cleaning with a vertical and then horizontal movement, and then finally with a circular motion. 2.3 Wipe the IP with the soft, lint-free and dry microfiber cloth. 2.4 Ensure that the IP is completely dry before using it again.	CLEANING SOLUTIONS SUITABLE FOR IPs: -SOPROWIPE single-use cleaning wipes.	TO CLEAN, DO NOT USE: -Single-use cleaning cloths containing more than 55 % ethanol. -cleaning fluids containing phenol, isopropyl (= propanol 2, isopropanol and isopropyl alcohol) -acetone-based solvents, etc.. -autoclave -disinfectant baths -abrasive cleaners

! CAUTION:

Risk of deterioration of the IPs. Do not clean IPs in an autoclave. Disinfection by immersion destroys them.

! CAUTION:

Risk of deterioration of the IPs. An unsuitable cleaning solution is liable to damage, delaminate or destroy the IP of the PSPIX system. Only use cleaning wipes that are tested and approved by ACTEON, the SOPROWIPES.

CAUTION:

Risk of image degradation and deterioration of the IPs. The use of a cleaning wipe may leave residues on the active side. This can lead to marks on images if the IP is not wiped after cleaning. Ensure that you wipe the IP properly and only use it after you are sure that it is completely dry.

NOTE:

Avoid excessively wiping the markings on the inactive side of the IP. These markings (such as the ACTEON logo, IP size and serial number) are resistant to cleaning , but excessive and repeated wiping with cleaning wipes can partially erase them.

NOTE:

Product decontamination, methods, and tools used, remain the sole responsibility of those people in charge.

9.3 MAINTENANCE OF THE IP STORAGE BOX

DESIGNATION	RECOMMENDATIONS	METHOD AND PRECAUTIONS	
		DO	DO NOT
Cleaning the IP storage box	To clean the storage box, use a non-abrasive cloth, dipped in: -cold or tepid water, -soapy water - a light detergent -butyl alcohol, -ethanol (ethyl alcohol) from 70 - 96 %.	Let it to dry before using it again.	Never use solvents or abrasive cleaning products to clean the PSPIX system.
Disinfecting the IP storage box	Disinfect the storage box with a cloth dipped in a disinfectant solution.	Let it to dry before using it again.	Never use solvents or abrasive cleaning products to clean the PSPIX system.
Autoclave the base (lower part) of the IP storage box.	Clean and disinfect the base according to the procedures set out above. -Condition the base and place it in the autoclave. -The base can be sterilized at 134 °C, on Prion cycle. -Dry the base using the autoclave drying cycle OR by opening the autoclave door and allowing them to dry in the air.	Let the base cool to ambient temperature before placing the IP inside.	Never autoclave the base above 134 °C.

! CAUTION:

Deterioration Risk for the base of the IP storage box. Sterilization of the base of the box with autoclave can cause wear. It is therefore advisable to replace the storage box every 50 sterilization cycles, on average.

NOTE:

The autoclave procedure described in this chapter is a recommended procedure. It is not a substitute for official recommendations and directives.

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AFTER SALES SERVICE

10.1 RESTRICTIVE LIABILITY CLAUSE

The PSPIX system is designed to acquire dental X-ray images and convert them into digital form. However, SOPRO does not accept any liability in the case of abusive use of this material, or in case of loss of data.

10.2 WARRANTY

SOPRO guarantees the absence of material defects and workmanship errors in its products for a period of two years following purchase. This warranty does not apply where products have been incorrectly used, modified, involuntarily or accidentally damaged or subjected to abnormal conditions of use and storage. Distributors other than subsidiaries of the ACTEON Group are not authorized to apply an extended warranty on behalf of SOPRO.

The entire liability of SOPRO is limited, at their convenience, to the replacement or repair (free of charge) of the defective product, if it has been sent to SOPRO's After Sales Department. This is valid for the entire warranty period.

Outside France, the warranty is only valid if the product has been purchased from an approved point of sale in the country where it is used.

THIS WARRANTY IS THE SOLE AND UNIQUE MEANS OF RECOURSE. IT SHALL REPLACE ANY OTHER WARRANTY (FOR EXAMPLE A WARRANTY FOR ADAPTATION FOR A SPECIFIC PURPOSE), WHETHER THIS IS EXPLICIT OR IMPLIED. SOPRO SHALL NOT BE LIABLE IN ANY WAY WHATSOEVER IN CASE OF PARTICULAR DAMAGE OF ANY KIND, (WHETHER INDIRECT, ACCIDENTAL OR CONSECUTIVE) OR FOR ANY DETERIORATION OR LOSS OF DATA UNDER THE TYPES OF CONTRACTUAL, NON-CONTRACTUAL OR OTHER CLAUSES.

The exclusion or limitation of liability in the case of direct or indirect damages does not apply to regulations or legislation in force in certain countries, and this exclusion cannot apply to a buyer present in these countries.

10.3 IN CASE OF PROBLEMS WITH THE PSPIX SYSTEM.

If there is a problem with the PSPIX system, an error window or warning window will appear on the PSPIX Touch screen to warn the user.

If the problem is blocking its operation, an error code will appear on the PSPIX system touch screen . Make a note of this error code and contact your approved reseller or SOPRO Customer Services.

If the problem is not blocking its use, a caution code will appear on the screen. Make a note of this warning code and follow the on-screen instructions. There are two possibilities:
-Contact your approved reseller or SOPRO Customer Services.
-OR Refer to the warnings table below.
One press on the OK button will allow you to continue using the PSPIX system.

Warnings table:

WARNING CODE	CAUSE	SOLUTION
Warning 202 to 206	Defective Ethernet Communications	-Ensure that the PSPIX system's Ethernet cables and the computer are properly connected to a network port. -Ensure that the computer is switched on, the imaging software is open and that both the patient file and the PSPIX acquisition module are open. - Check you network Ethernet Setup. To do this, please contact your network administrator. -Contact your approved reseller or SOPRO Customer Services.
Warning 207	Network outage, computer failure or a problem with the imaging software during the IP reading.	The image could not be transferred to the computer and remains in the PSPIX system memory. You are offered three options: -Attempt to reestablish the Ethernet connection with the computer to automatically transfer the image. To do this ensure that the Ethernet cable is correctly connected OR ensure that the PSPIX acquisition module is correctly open. If the Ethernet connection is reconnected then a new window confirming the reconnection will be displayed during the image transfer. -OR Delete the X-ray image from the memory by clicking on the "Trash" icon . Confirm the deletion by pressing the OK button. -OR Collect the image from the PSPIX acquisition module from another computer connected to the PSPIX system (in the case of a multi-user configuration). Take care to open the correct patient file in the imaging software, then access the "Setup" menu, then the "Image" tab in the PSPIX acquisition module. Finally click on the "Retrieve the Last Scanned Image" button.
Warning 601	Ambient temperature too low	-Check and increase the temperature in the room where the PSPIX system is located.
Warning 602	Ambient temperature too high	-Check and lower the temperature in the room where the PSPIX system is located.

⚠ **WARNING:**

Risk of electrocution and/or malfunction of the PSPIX system. No outside contractor shall be authroised / recommended to carry out the maintenance.

11

TECHNICAL SPECIFICATIONS

PSPIX² System

• Dimensions: H 205 mm x D 194 mm x W 154 mm (Height x Depth x Width)
• Weight: 2.6 kg
• Operating voltage: 12 V ⎓
• Operating current: less than 2.5 A
• Bit depth: 14 gray scale bits
• Theoretical resolution: greater than or equal to 20 lp/mm in high resolution.
• Actual resolution: greater than or equal to 20 lp/mm in high resolution.
• Ambient operating temperature: +10 °C to +40 °C, 30 to 85 % relative humidity, 700 to 1060 hPa.
• Ambient conditions for storage/transport: -10 °C to +45 °C, 20 to 85 % relative humidity, 700 to1060 hPa.
• Interface cable: for Ethernet port connections, use a CAT5 LAN cable. The Computer/Ethernet switch that the PSPIX system is connected to must be appropriately approved (e.g. per EN 60950, IEC60950, UL 60950).
• Continuous operation
• Not protected against running water (IPXO)
• Class 1 Equipment
• External power supply: 100 – 240 V ~ 50/60 Hz 700 mA FRIWO FW7362M/12
• Class 1 laser product according to EN 60825-1:2007
Complies with the essential requirements of European Directive 93/42/EEC concerning medical devices.
• Compliant with IEC 60601-1.
• Not suitable for use in the presence of flammables such as anesthetic, oxygen or nitrous oxide.

Imaging Plate (IP)

The normal lifespan of an IP is several hundred, or even thousands of cycles, that the IP is handled with care and the manufacturer instructions are observed.

Size 0 Dimensions: 22 x 35 mm
Size 1 Dimensions: 24 x 40 mm
Size 2 Dimensions: 31 x 41 mm
Size 3 Dimensions: 27 x 54 mm
Size 4 Dimensions: 52 x 54 mm
This consists of two size-3 IPs placed side-by-side in a appropriate plastic support. The size 4 image is subsequently reconstructed by the computer.

USE

• From +18 °C to +45 °C, at least 80 % relative humidity (without condensation).

STORAGE

• Unwrapped, unexposed to ambient (not direct) light in the storage box supplied. The box must be kept closed to avoid dust and/ or liquid splashing on the IPs.

• Less than +33 °C / 80 % relative humidity (without condensation), protected against X-rays and UV light.

MATERIAL

• photo-stimulable phosphorus applied uniformly on a plastic medium. Protected by an upper layer on the active surface and sealed around the edges.

DISPOSAL

• IPs are industrial waste that must be disposed of in compliance with current national and local laws concerning the disposal of said material.

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CE

SOPRO • A company of ACTEON Group
ZAC Athélia IV • Avenue des Genévriers • 13705 LA CIOTAT cedex • France
Tel +33 (0) 442 980 101 • Fax +33 (0) 442 717 690
E-mail: info@sopro.acteongroup.com • www.acteongroup.com