INSTRUCTIONS FOR USE

PSPIX2 SCANNER
IMAGING PLATES
& ACCESSORIES

CONTENTS

1 FOREWORD

Thank you for your confidence and for buying this medical device. It is essential that you familiarize yourself with the contents of these Instructions for Use. It will help you get the best out of your equipment and its accessories and ensure that all necessary safeguards are in place. We have tried to make these Instructions for Use as straightforward as possible to help with installation and use of the medical device and accessories.

NOTE UDI-DI: Custom products have a different UDI from the one shown on the cover of this manual. You will find it on the product label and labels on the packaging. In this user manual, SOPRO does not use any text, brand names, pictures, figurative signs or other items liable to mislead the user or patient over the purpose, safety and performance of the device.

The Instructions for Use are an integral part of the medical device. The document must be made available to the user. Proper use and correct handling of the device entail following these instructions. You are responsible for any damage that may result from improper use.

The PSPIX2 system includes: the PSPIX2 SCANNER, the IMAGING PLATES (IP) and the PROTECTIVE BAGS and COVERS. These instructions for use apply to each of the PSPIX2 system.

Medical Device Picture	Device Name	Basic UDI-DI
	PSPIX2	801337602782D0001CP
 PROTECTIVE COVER	PROTECTIVE BAGS & COVERS *(Sizes 0, 1, 2 and 3)*	801337602782P0001GT
 PROTECTIVE BAG		801337602782P0001GT
 PROTECTIVE BAG & COVER		801337602782P0001GT
 PHOSPHOR IMAGING PLATE (IP)	IMAGING PLATES (IP) *(Sizes 0, 1, 2 and 3)*	801337602782D0002CR

1.1 ASSOCIATED DOCUMENTATION

These Instructions for Use must be used in association with the following documents:

- Acteon Imaging Suite User Manual (AIS)
- Quick Start “GUIDE” (011777 / 011639)
- Quick Start “CLEANING PLATES” (011706)
- Quick Start “REPLACING PSPIX2” (011811)

The Quick Start document is a simplified summary designed to help you get started but cannot replace these Instructions for Use. The only official instructions are these Instructions for Use and the regulatory documents accompanying the medical device and accessories.

1.2 ELECTRONIC DOCUMENTATION

The Instructions for Use are provided in electronic format on the website. If you cannot access the website, please try again later. To obtain a free copy of the documentation in printed form within 7 days, please submit a request by filling in the request form on our website, by phone or in writing.
The electronic user instructions are available in PDF format (Portable Document Format). You will need to have PDF reader software installed to read the electronic version of the user instructions. It is important for you to read and understand the content of the user instructions relating to the use of your device and its accessories prior to using the device.

WARNING: DO NOT USE YOUR DEVICE WITHOUT FIRST FAMILIARIZING YOURSELF WITH THE INSTRUCTIONS FOR USE.
The device’s Instructions for Use can be consulted at the following address: www.acteongroup.com

As soon as you receive the device, it is important that you print and download all documents or sections of documents that you may need to consult in the event of an emergency, if you are unable to connect to the Internet or if your electronic display device (computer, tablet, etc.) stops working. We recommend that you visit the website regularly to view and download the latest version of your device’s Instructions for Use. Keep the documents on hand for consultation when necessary.
All printed and electronic documentation relating to the medical device and its accessories must be retained for the devices’ entire service life.
Please retain all original documentation relating to the medical device and its accessories for reference at a later date.
When loaning out or selling the device, the documentation must be provided with it.

2 SAFETY INSTRUCTIONS

2.1 CONTRAINDICATIONS

None known.

2.2 WARNINGS

2.2.1 PSPIX2 SCANNER

- The PSPIX2 is a re-usable device supplied non-sterile. PSPIX2 is not sterilizable (no autoclave or other sterilization process). Only optional removable parts (IP insertion guide and receptacle) are autoclavable.
- Always verify device's integrity before using it; no breaks in plastic parts, no cut wires: risk of electric shock.
- The PSPIX2 must only be connected to a compliant wall plug.
- Before connecting the PSPIX2, check that the mains voltage and frequency indicated on the power supply correspond to those of the mains supply.
- Before switching "ON", ensure that neither PSPIX2 nor the power supply cable are damaged.
  Damaged cables and connectors must be replaced immediately.
- Place the PSPIX2 that you can easily access the electrical socket to disconnect it.
- The PSPIX2 is a category 1 laser product. Once the top is lifted, the PSPIX2 becomes a category 3B laser product: avoid all exposure to the laser beam to avoid any risk of ocular damage.
- Do not use the device if it is damaged.
- Do not use the medical device if any of the peripherals are damaged.
- Do not place heavy objects on top of the PSPIX2.
- Do not insert metal objects into the device to avoid any risk of electric shock, fire, short-circuit or hazardous emissions. Only insert IP into the PSPIX2.
- Do not expose the device to splashed water or store in damp areas.
- Never place the device near a heat source or in a location where it is exposed to vibration and/or shock.
- Not suitable for use in the presence of a flammable anaesthetic mixture with air and oxygen or nitrous oxide.
- The PSPIX2 and its accessories must not be subjected to any modification, transformation, or refurbishment, to avoid any risk contamination and/or malfunction of the PSPIX2.
- Do not submit the device to excessive dust exposure.
- Do not apply excessive force on the device.
- Do not open the PSPIX2 and do not try to disassemble or modify it to avoid any risk of malfunction of the PSPIX2. Only specialist, trained technicians approved by ACTEON are authorized to install and commission the equipment and carry out maintenance and/or repairs, to avoid any risk of electrocution and or malfunction of the PSPIX2.
  The PSPIX2 does not comprise any components that are repairable by the user.
- Do not drop the PSPIX2. If dropping the device, do not reconnect it. Send the PSPIX2 to your approved distributor or to the SOPRO Service Department to avoid any damage to eyes and/or any malfunction of the device.
- Never leave the PSPIX2 in direct sunlight or near to a bright light source. This allows for optimal viewing of the information displayed on the PSPIX2 's touch screen.
- Never touch the patient and non-protected connectors on the PSPIX2 at the same time.
- Where you are using multiple adapters, the requirements of IEC 60601-1 must be observed. Do not place the multiple adapters on the ground. Others must not be connected to the same multiple adapters.
- Do not pull on the cable to disconnect the medical device.

2.2.2 IMAGING PLATES

The IP are reusable. Exposure to X-rays does not age the IP. They are resistant to hundreds of exposures. Their lifetime depends on the precautions taken during their handling and use.

- Potential scratches, stains, soiling, fingerprints, or dust on the active side of the IP may affect the image quality and inhibit its interpretation.
- Never use tweezers, pliers, or other mechanical implements to take and/or handle IP.
- To avoid potential scratches, never leave IP flat on a surface, particularly on their active side.
- 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.
- Do not swallow the IP! Risk of poisoning.
- Do not let the imaging plate stand under direct rays.
- Do not exert pressure on the IP with any object to avoid leave a mark or print on the active side.
- Avoid unnecessarily folding the IP.
- Do not scratch the imaging plate with your nails.

- Never expose IP to X-rays if this is not for the purposes of an X-ray acquisition.
- Never expose IP to ultraviolet light.
- Never use IP that are damaged, creased, modified and/or discoloured.
- Do not clean IP in an autoclave. Disinfection by immersion destroys them.
- The IP must not come in contact with the patient's saliva or any type of body fluid.
  Use a hygiene bag to protect the IP.
- Do not put an IP back in the insertion slot of the PSPIX2 until the previous IP has fallen into the IP receptacle.
- The reading of IP and the transfer of the image from the PSPIX2 to a computer may be sensitive to electromagnetic disturbance and to disturbance on the computer network. A stable Ethernet network must be maintained at the dental practice or clinic, to avoid any malfunction of the PSPIX2.

2.2.3 PROTECTIVE BAGS & COVERS

- Protective bags & covers are single-use devices, non-sterile, non-sterilizable and must be discarded after each use. Dispose of the used protective bags & covers with other infected, biologically, and potentially dangerous waste.
- It is recommended that you plan and wear disposable protective bags & covers because, when these consumables are used up, the PSPIX2 should no longer be used.
- Clean and disinfect the hygiene bag before opening it.
- Change the protective bag & protective cover for each new patient.
- Never use a finger cot.

2.3 PRECAUTIONS

2.3.1 PSPIX2 SCANNER

- You are recommended to set up the device on a stable surface to prevent any risk of falling.
- Prior to each use, make sure the device does not have any rough surfaces, sharp edges or protuberances which could lead to safety problems.
- Use only the accessories supplied with the device or recommended as options by SOPRO.
- The devices that connect to video or USB outputs should comply with the IEC 62368-1 standard.
- Before the first use of the PSPIX2 scanner, it is imperative to follow the complete disinfection procedure.
- PSPIX2 should be installed in a clean, dry, and well-ventilated place.
- The PSPIX2 must be positioned on a flat and stable surface to avoid any risk of vibration that may harm the image quality.

2.3.2 IMAGING PLATES

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

- You must handle and use IP carefully to guarantee an optimal image quality and maximize lifetime. You must also ensure that you transport and store them in the box supplied with the PSPIX2.
- You must wear protective gloves when placing and removing the protective cover into the patient's mouth.
- You must handle the IP with great care, by its edges.
- If you use positioning holders, please use only use rings that do not damage the protective bag or the protective cover of the IP. Please avoid positioning holders with sharp edges.
- Check that the protective bag and protective cover are not damaged.
- Use IP with the appropriate size of protective covers.
- Use IP with the appropriate size of protective bag.
- Protect the active side of the IP from scratches and any other form of scratching due to friction or mechanical degradation.
- Image information stored in the IP is sensitive to light after exposure. Use a protective cover to avoid deletion of the X-ray image.

2.4 ELECTROMAGNETIC INTERFERENCES AND ELECTROSTATIC DISCHARGE

Although this product meets standards relating to EMC, it is possible under very specific circumstances that it may cause interference to other devices, or that it may itself be affected by other devices or an unfavourable electromagnetic environment. To avoid such situations, you are recommended:

- To ensure the electrical supply network is of good quality (particularly that all devices and trolleys are earthed);
- To keep the device away from sources of electromagnetic interference (e.g., compressor, motor, transformer, HF generator etc.).

2.5 USE OF ACCESSORIES PROVIDED BY ANOTHER MANUFACTURER

The medical devices were designed and developed to guarantee maximum safety and performance. The use of accessories from other sources could put you and your patients at risk and could damage your medical device.
Even if the manufacturer or dealer of your accessory claims full compatibility with SOPRO devices, it is advisable to exercise caution with regard to the origin and safety of the product offered. Look out for warning signs such as a lack of information, information in a foreign language, very attractive prices, suspect appearance, mediocre quality, or premature wear.
In the event of doubt, contact an approved dealer or the SOPRO after-sales service team.

2.6 UNDESIRABLE SIDE EFFECTS

There is no known undesirable side effect associated with the PSPIX2.

2.7 DEVICE MOVING

The PSPIX2 scanner may be moved using a trolley. Do not move the PSPIX2 scanner while a procedure is under way.

2.8 DEVICE ASSEMBLY AND DISASSEMBLY

The PSPIX2 scanner must only be opened by a competent technician approved by the manufacturer.

3 REQUIRED INFORMATION

NOTE: The following note is only applicable for the United States of America.
United States Federal Law restricts the use of this medical device within its territory to health professionals who are qualified, fit, and certified, or to those under their control.
CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a dentist.

3.1 CONTENTS

The PSPIX2 system consists of the following elements:

- 1 ACTEON phosphorus plate reader, called PSPIX2 SCANNER
- 1 Cleaning plate for imaging plates
- 2 Imaging Plates – Size 1
- 2 Imaging Plates – Size 2
- 1 Bags & Covers Start-Up Kit
  (composed of 100 pieces of protective bags & covers – Size 1 + 100 pieces of protective bags & covers – Size 2)
- 1 Microfiber cloth
- 1 Storage box for the imaging plates
- 1 Stylus for the PSPIX2 touch screen
- 1 Ethernet cable
- 1 external Power supply
- 1 Quick Start
- 1 Installation CD-ROM for the PSPIX2 acquisition module

Optional:

- *Imaging Plates – Size 0*
- *Imaging Plates – Size 3*
- *Box of single-use protectors for Size 0 and Size 3 imaging plates in the form of cardboard envelopes previously integrated into protective covers*
- *Starter Kit – Size 4 (composed of 1 support – Size 4, 2 Imaging Plates – Size 3 and 1 protective bag – Size 4)*
- *Autoclavable removable parts (insert for imaging plate and receptacle for plates)*

The devices have been delivered to you in cardboard packaging to be retained for use if transporting the device.
NOTE: Any other consumable or accessory not sold by SOPRO will have its own manual. Please refer to it before using the product. Keep the packaging in case you need to transport the equipment later.

3.2 DESCRIPTION

The PSPIX2 system provides a radiographic image whose information comes from phosphor plates, via an acquisition module present in the plate reader (scanner). This image will then be interpreted by the dentist, in the dental office, indeed the PSPIX2 system is an aid in diagnosis.

The PSPIX2 System is composed of:

- ✓ Digital imaging plate Scanner PSPIX2 (plate reader)
- ✓ Imaging plates (*available in various sizes*)
- ✓ Protective bags & covers which is a set of protective cover and protective bag (*available in various sizes*) into which is inserted the imaging plate (*available in various sizes*)
- ✓ Protective cover in which is inserted the imagine plate (*available in various sizes*)
- ✓ Protective bag in which is inserted the imaging plate & the protective cover (*available in various sizes*)

3.3 INDICATION

No indication is claimed for the PSPIX2 System.

3.4 INTENDED PURPOSE

3.4.1 PSPIX2 SCANNER

The PSPIX2 scanner is a dental laser X-ray device intended to digitize the SOPRO's phosphor imaging plate (IP), display the image and erase the plate to re-use it.

3.4.2 IMAGING PLATE

The phosphor imaging plate is an intra-oral flexible intended to receipt radiographs obtained with an X-ray generator.

3.4.3 PROTECTIVE BAG

The protective bag is intended to protect the SOPRO's imaging plate 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 protective bag is also intended to protect the imaging plate from light both during and after acquisition of an X-ray image.

3.4.4 PROTECTIVE COVER

The protective cover is intended to:

- ✓ prevent physical and mechanical damage to SOPRO's imaging plate;
- ✓ protect the imaging plate from light during and after acquisition of an X-ray image to avoid erasing image data;
- ✓ avoiding cross contamination between patients.

Any use outside of these areas constitutes improper use of the product and the user will therefore be considered responsible for such use. The manufacturer does not accept any liability in this case.

3.5 PERFORMANCES

The performances for PSPIX2 system are:

- ✓ Better differentiation of the dental tissue;
- ✓ More reliable diagnosis thanks to the FIBER2PIXEL technology allowing to an extreme precision of the image;
- ✓ Various sizes available depending on patient morphology and clinical applications;
- ✓ Large colour touchscreen provides intuitive indications for quick and easy use;
- ✓ Thinner and more flexible, the PSPIX2 imaging plates are easy to use and provide outstanding patient comfort;
- ✓ PSPIX2 offers unique autoclavable parts to eliminate risk of infection;
- ✓ Hygiene bags and covers ensure high degree of protection against cross-contamination.

3.6 BENEFIT

PSPIX2 scanner, imaging plates, protective bag and cover are intended to acquire and record an intra-oral dental radiographic image after x-ray radiography for diagnosis purpose related to teeth diseases.
Even if these devices could be used as preventive action for diagnosis purpose, these devices achieve their intended use without having a direct therapeutic or diagnostic function themselves.
Thereby, no clinical performance is claimed for PSPIX2 scanner, imaging plates and protective bags & covers associated, neither direct clinical benefit.

3.7 PRINCIPLE OF OPERATION

3.7.1 PSPIX2 SYSTEM

The key functional components of the PSPIX2 system are:

1. The digital imaging plate scanner PSPIX2 (plate reader)
2. The phosphor imaging plate (IP) for digital dental x-ray system
3. The protective cover in which is inserted the imagine plate
4. The protective bag
5. The protective bag & cover

PSPIX2 SCANNER

PHOSPHOR IMAGING PLATE (IP)

PROTECTIVE COVER

PROTECTIVE BAG

PROTECTIVE BAG & COVER

The PSPIX2 system works with a computer (PC or MAC) equipped with dental imaging software. It can be connected directly to a computer or to the network via an Ethernet cable.

The PSPIX2 system can be configured to work with a single computer, in a single-user configuration, or with multiple computers, in a multi-user configuration.

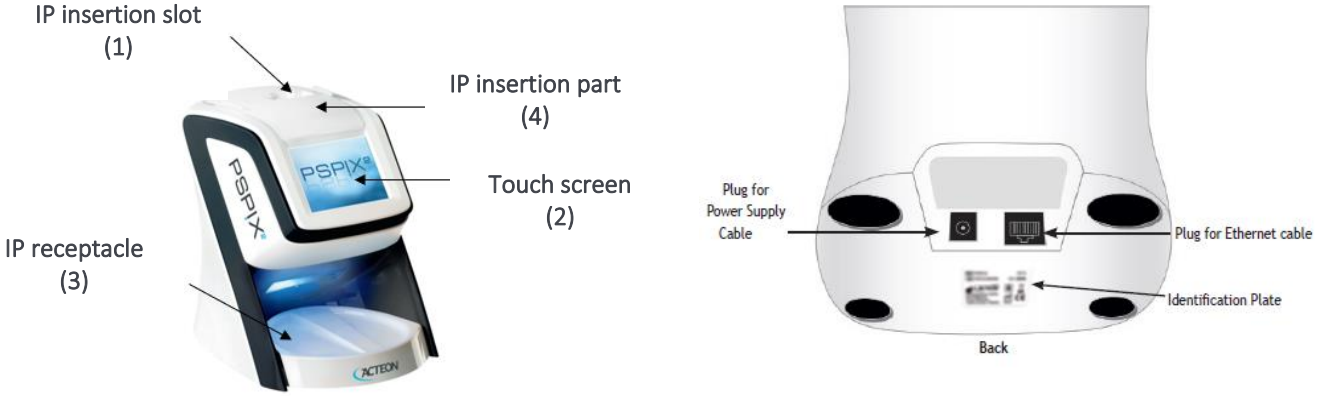
The multi-user configuration allows the PSPIX2 system to be connected to one or up to ten computers, with each workstation taking turns using the PSPIX2 system.

The dental X-ray image is obtained out by exposing the imaging plates to X-rays, protected by the cover and the protective bag, after placing it behind the dental area of the patient to be X-rayed.

This imaging plate is then inserted into the PSPIX2 scanner for reading.

The information from the imaging plate is displayed simultaneously as a X-ray image on the PSPIX2 screen and on the connected computer through the PSPIX2 acquisition module. This image is then interpreted by the dentist.

MAIN COMPONENTS:



3.7.2 IMAGING PLATES

An imaging plate (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 topcoat protective layer.

PHOSPHORUS:
We do not use phosphorus or phosphorous-based materials for our IP.
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 PSPIX2, 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 lighter (*blueish*) side of the IP is the ACTIVE side which stores the X-ray image; it is the sensitive side. The letter "P" is printed on the active side of the IP 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.

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

NOTE: 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.

WARNING: IP 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.

3.8 USER POPULATION RECOMMENDATIONS

3.8.1 USER POPULATION

The PSPIX2 system is intended for use by:

- ✓ A qualified and graduated dentist who performs the medical examination and handles the associated medical devices and accessories;
- ✓ A qualified and certified dental hygienist/ assistant who handles the device and its accessories under the dentist's responsibility, cleans the devices and returns them to SOPRO in case of a defective device, and recycles the devices;
- ✓ A qualified and certified maintenance personnel of SOPRO or a designated person, who repairs the equipment.

The user must not be prone to any of the following:

- ☞ Visual impairments: Any vision problems must be corrected by glasses or contact lenses / Colour perception is mandatory;
- ☞ Infirmity of the upper limbs which could prevent manual manipulation of a hand-held device.

The user must wear gloves.
The device is suitable for use in a professional healthcare facility environment.
The device is not intended for self-treatment.

The device can be used by any adult practitioner of any weight, age, height, gender and nationality.

3.8.2 SPECIFIC USER TRAINING

No specific training other than initial professional training is required to use this medical device.
The practitioner is responsible for performing clinical treatments and for dangers that may arise due to a lack of skill and/or training.

3.8.3 DEVICES IN CONTACT WITH THE USER

- PSPIX2 scanner, imaging plates and protective bags & covers are in indirect contact with the user because he/she wears gloves).
- PSPIX2 scanner does not come in contact with the patient.
- IP do not come in direct contact with the patient's mouth because they are covered with the disposable protective cover.
- The protective bag is in direct contact with the patient's mouth. It is biocompatible according to ISO 10993-1.

3.9 PATIENT POPULATION RECOMMENDATIONS

3.9.1 PATIENT POPULATION

This medical device is designed to be used with the following patient populations:

- Children
- Adolescents
- Adults
- Elderly persons

This medical device can be used irrespectively of the patient's details such as weight, age, height, gender, and nationality.

3.9.2 PATIENT POPULATION RESTRICTION

The user is the only person who can decide whether to treat his/her patients.
Dental practitioners should refer to local legislation regarding children (including infants), pregnant women, and all persons with health conditions which contraindicate the use of x-rays. Analyse the situation before starting an examination.

3.9.3 APPLIED PART(S)

No applied part within the meaning of international standard IEC 60601-1.

3.10 BASIC SAFETY AND ESSENTIAL PERFORMANCE

3.10.1 NORMAL CONDITIONS OF USE

The normal conditions of use the PSPIX2 system are the following:

- Storage
- Installation
- Use
- Maintenance
- Disposal

3.10.2 ESSENTIAL PERFORMANCE

Within the meaning of the applicable electromedical device safety standard, the manufacturer has determined that the medical devices do not support essential performance.

3.11 LIFETIME

- PSPIX2 scanner lifetime is 7 years.
- Imaging plates lifetime is at least 200 uses.
- Protective bag and protective cover are single-use devices.

4 DEVICE INSTALLATION

No special training is required to install the device.

4.1 CONNECTING PSPIX2 SYSTEM TO A COMPUTER

4.1.1 REQUIRED COMPUTER CONFIGURATION

To use the PSPIX2 System, it is necessary to make sure that the computer and its peripherals do not present any limitation of use which could concern the safety of people.
Only peripherals that comply with the IEC 62368-1 standard may be connected to the PSPIX2 system.
The computer must meet the following requirements:

Windows® configuration:

	Minimum Configuration	Recommended Configuration
Operating system	Windows® 10 Pro 64 bits	Windows® 10 Pro 64 bits
Processor	Intel® Core i3	Intel® Core i5 or more
Memory	4 GB	8 GB or more
Hard disk	250 GB	500 GB or more
USB ports	4 USB2.0 Hi-Speed ports	4 USB2.0 Hi-Speed ports
Video board	Graphic board 1 GB of unshared video RAM – Memory compatible with DirectX 9	Graphics card with NVIDIA® CHIPSET or ATI® dedicated video card / 2 GB unshared video RAM – Memory compatible with DirectX 9 compatible or more
Ethernet card	100 MB/s	1 GB/s
Screen resolution	1024 x 768	1 280 x 1 024 or more

MAC® configuration:

	Minimum Configuration	Recommended Configuration
Computer	MacBook® Pro 13.3'' or iMac® 21.5''	iMac® 27''
Operating system	MacOS® X 10.15 (Catalina)	MacOS® X 11 (Big Sur)
Processor	Intel® Core i5	Intel® Core i7
Memory	4 GB	8 GB
Ethernet card	1 GB/s	1 GB/s

The device has been tested in the environments specified above.
The manufacturer cannot be held responsible for any malfunction of the device if it is used in an environment not claimed in this paragraph.
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 62368-1.

CAUTION: For Ethernet port connections, use the CAT6 (RJ45) cable provided. It can be directly connected to a computer or a local area network.

4.1.2 IMAGING SOFTWARE INSTALLATION AND CONFIGURATION

The PSPIX2 System is provided either:

- With the Acteon Imaging Suite (AIS) dental imaging software, running in Windows® and MAC®: it is versatile software that captures, processes, and files the X-ray images taken with the PSPIX2 System, but also allows network sharing of your data. Acteon Imaging Suite (AIS) can also interface with third party software (dental practice management software, imaging software);
- With the SOPRO Imaging (SI) dental imaging software, running in Windows® and MAC®: it is versatile software that captures, processes, and files the X-ray images taken with the PSPIX2 System, but also allows network sharing of your data. Acteon Imaging Suite (AIS) can also interface with third party software (dental practice management software, imaging software).

For more informations, please contact your distributor.

4.1.3 COMPATIBILITY WITH X-RAY GENERATORS

The PSPIX2 System is potentially compatible with all intraoral X-ray generators. Nevertheless, we recommend X-Mind generators from DE GÖTZEN S.R.L, a company of the ACTEON group, which are perfectly adapted to the PSPIX2 System.

4.2 INSTALLATION OF THE SOFTWARE

Refer to the Acteon Imaging Suite (AIS) or SOPRO Imaging (SI) installation manual found on the respective CD/DVD-ROM.

4.3 INSTALLATION OF THE PSPIX2 SYSTEM

Position the PSPIX2 scanner as tabletop equipment in the dental clinic.
Connect the PSPIX2 to the electrical mains.

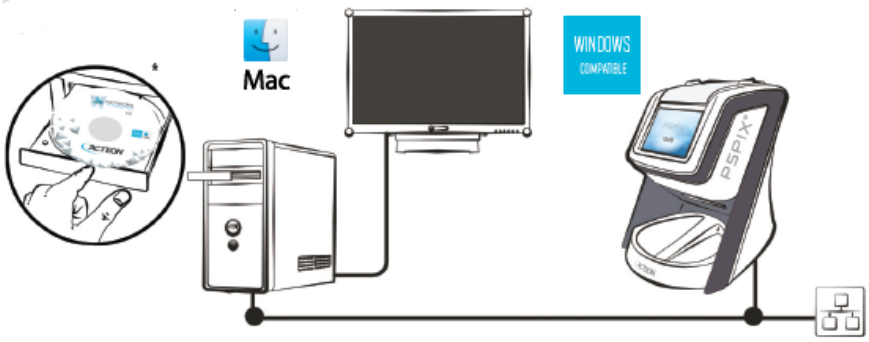
The PSPIX2 scanner can be connected from one to ten computers.

1. Connect the PSPIX2 scanner with the supplied CAT6 Ethernet Cable:
   - Either directly to a computer, when only one workstation is being connected;
   - Or, to the existing network when either one, or more computer(s) is (are) being connected.

2. Ensure that the computer connected to the PSPIX2 scanner is connected to a correctly earthed and switched on mains socket.

WARNING: The computer connected to the PSPIX2 scanner 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 meter. The minimum vertical distance between the patient and the computer must be 2.5 meters.

Once the PSPIX2 scanner is connected to the computer or network, install the PSPIX2 acquisition module on the computer. This is on the CD-ROM supplied with the system.
Insert the CD-ROM supplied with the PSPIX2 system into the computer drive to install the acquisition module.
Refer to the Acteon Imaging Suite (AIS) or SOPRO Imaging (SI) installation manual located on the respective CD/DVD-ROM, in the "*Documents*" section.



Note: The Acteon Imaging Suite (AIS) software is also available on the CD-ROM supplied with the PSPIX2 system.

The PSPIX2 acquisition module is directly integrated into this software. If you wish to use Acteon Imaging Suite (AIS), 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 PSPIX2 scanner to.

4.4 SETTING UP IMAGING SOFTWARE WITH THE PSPIX2 SCANNER

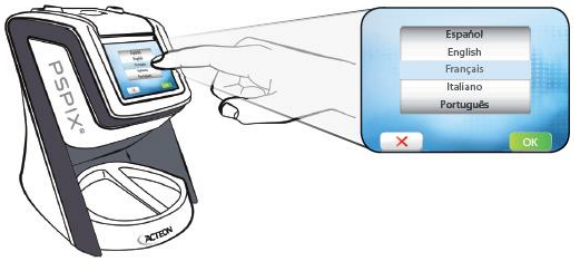
Refer to the Acteon Imaging Suite (AIS) or SOPRO Imaging (SI) installation manual found on the respective CD/DVD-ROM in the "*Documents*" section.

4.5 CONFIGURATION OF THE PSPIX2 SCANNER

Configuring the PSPIX2 is done by the system's Touch screen and via the computer connected to the PSPIX2, in the PSPIX2 acquisition module.

4.5.1 SET UP THE PSPIX2 SCANNER VIA THE TOUCH SCREEN

During the 1st start-up of the PSPIX2 , 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 "PSPIX2" logo and the time.

Note: The time is set automatically; it uses the system time of the computer connected to the PSPIX2.

Note: If the red computer icon  appears in the top right-hand corner of the touch screen, this means that the PSPIX2 is not connected to the computer or the network.

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

☞ If not, click on the “**Setups**”  icon to access the Configuration of the IP address in the “**Configuration**” 

«**Ethernet** » menu  .

Next, click on the “**Setups**”  , icon “**Parameters**”.

You can now directly access screen brightness Setups 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 Setups, 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 PSPIX2 network /IP address 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 PSPIX2. This will switch this option OFF.
Next click on the “Configure Fixed IP” button.

The active number appears in orange colour. 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 after which the PSPIX2 display light is automatically switched off in case of inactivity to save energy.By default, it is set at 5 minutes. You can set it for time periods between 0 and 60 minutes.

“**Pre-view**” Time: The time for which the pre-view 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 and 20 seconds.

To do this, delete the digit by pressing the  button. Then type in the desired time periods 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.

4.5.2 CONFIGURATION OF THE PSPIX2 IN THE ACQUISITION MODULE VIA THE COMPUTER

Please refer to the CD-ROM user manual supplied with the PSPIX2 in the “*Documents*” section.

5 USE OF THE DEVICE

The PSPIX2 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.

5.1 USE OF THE PSPIX2

1. Before first using the PSPIX2, it is imperative to follow the complete disinfecting procedure.
2. Switch on the computer that is connected to the PSPIX2.
3. 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 PSPIX2 acquisition module.

   NOTES:
   - If you use the Acteon Imaging Suite (AIS) software or the SOPRO Imaging (SI) software, the PSPIX2 acquisition module will open automatically when the patient file is opened.

   - If you are using the PSPIX2 for the first time it is recommended that you check and/or modify the configuration options (such as, for example, the required reading resolution). If you are using the Acteon Imaging Suite (AIS) software, please refer to the CD-ROM user manual supplied with the PSPIX2, located in the "*Documents*" section.

   WARNING: 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 PSPIX2.

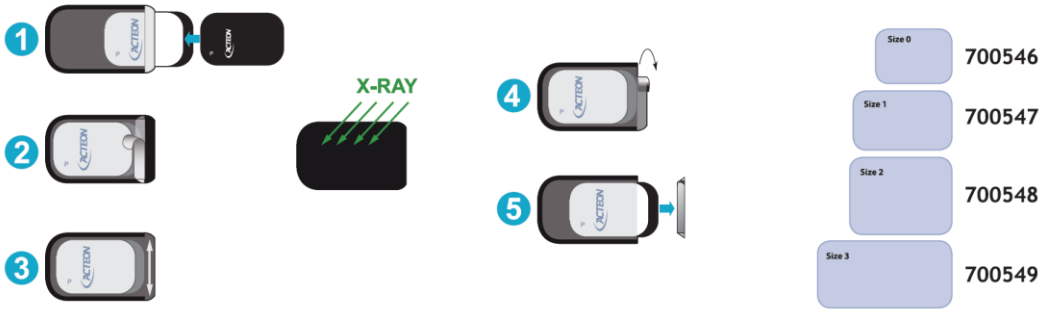
4. If the PSPIX2 is not connected to the electrical mains, switch it on by connecting to the power supply network.
   The PSPIX2 initially launches an installation sequence, and then is ready to use.
   Note: If the PSPIX2 is in standby mode, the opening of acquisition module automatically takes it out of this standby mode.
   You can also touch the Touch screen to bring it out of its standby mode.

5.2 USE OF IP, PROTECTIVE COVER AND PROTECTIVE BAG

CAUTION: ACTEON imaging plates are exclusively designed and manufactured for PSPIX2. Those are the only ones that can be used with the PSPIX2. The use of alternative IP, regardless of brand, is strictly forbidden.

1. Obtain the required size of IP, protective bag and protective cover from the storage box.
   WARNING: Check visually that the IP is not deteriorated.
   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.

2. Slide the IP in the protective cover into the protective bag.
   WARNING: 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.
   NOTE: Natural X-rays and/or the rays diffused by X-rays may pre-expose the IP prior to their normal use.



5.3 PREPARATION OF THE PSPIX2, THE IP, THE PROTECTIVE COVER AND THE PROTECTIVE BAG

1. Switch on the computer that is connected to the PSPIX2.
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 PSPIX2 acquisition module.
3. If the PSPIX2 is not connected to the electrical mains, switch it on by connecting to the power supply network. The PSPIX2 initially launches an installation sequence, and then is ready to use.
4. Obtain the required size of IP from the storage box.
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.
6. Peel back the paper and then close the hygiene bag by passing the thumb and forefinger across the whole of the adhesive strip to ensure complete sealing.

NOTES:

- If you use the Acteon Imaging Suite (AIS) software, the PSPIX2 acquisition module will open automatically when the patient file is opened.

- If you are using the PSPIX2 for the first time it is recommended that you check and/or modify the configuration options (such as, for example, the required reading resolution). If you are using the Acteon Imaging Suite (AIS) software, please refer to the CD-ROM user manual supplied with the PSPIX2, located in the "Document" section.

- If the PSPIX2 is in standby mode, the opening of acquisition module automatically takes it out of this standby mode. You can also touch the Touch screen to bring it out of its standby mode.

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

- The letter "P" is printed on the active side of our IP 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: X-rays are always listed one after the other in the patient file open in the dental imagery software. To avoid confusion with X-rays belonging to other patients, only those attributed to the open patient file must be inserted in the PSPIX2.

- Check visually that the IP is not deteriorated.

- 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 **5.6** "Erasing an IP".

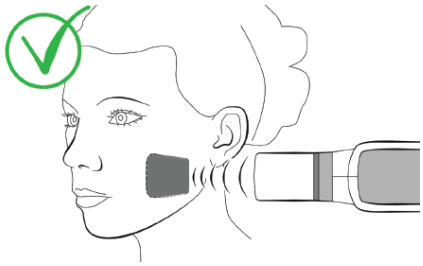
- Ensure that you always observe the necessary hygiene precautions when handling the IP, the covers and hygiene bags to avoid any risk of cross-contamination.

- 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 an X-ray image. As the IP, they are available in different sizes. Select the appropriate size.

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

5.4 ACQUISITION OF AN X-RAY IMAGE

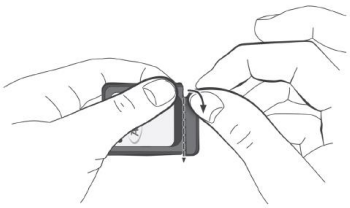
1. Place the closed hygiene bag containing the IP in the patient's mouth, parallel to the longitudinal axis of the tooth. The back of the hygiene bag (black side) must be toward the X-ray source.
   NOTE: If you are using a positioning holder, please refer to the instructions supplied with this device. 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 use only use rings that do not 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 protective bag containing the IP from the patient's mouth.
6. Clean and disinfect the protective bag using a disinfectant wipe or by spraying disinfectant on a lint-free cloth:

7. Remove the protective gloves. Disinfect and clean your hands.
8. Open the protective bag by tearing off the adhesive strip:



9. Remove the protective cover containing the IP from the protective bag:

10. Keep the IP in the protective cover until it is introduced into the PSPIX2, taking care not to touch it or expose it to ambient light.

WARNING: Risk of image degradation: Image data on an IP will be erased by light. Keep the exposed IP in their protective covers if they are not inserted in the PSPIX2.

5.5 READING THE IP

The PSPIX2 may be connected and used by one computer (single-user configuration) or by several computers (multi-user configuration).

5.5.1 SINGLE-USER CONFIGURATION

Please ensure that the PSPIX2 is ready.
Note: If the PSPIX2 is operating in multi-user configuration, refer to the following paragraph: “multi-user configuration”.

1. If the PSPIX2 acquisition module is not open, the Touch screen displays the single-user home page, which displays the “PSPIX2” logo and the time. To read an IP, check that your dental imaging software is open at the correct patient file, and that the PSPIX2 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 PSPIX2. 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 PSPIX2:
   - ✓ 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, the IP is automatically detected and enters the PSPIX2.
   The protective cover remains in the insertion slot.

   Note: If the IP does not enter the PSPIX2 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 PSPIX2 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 “Setups”/” 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 PSPIX2 and can be directly used for a new X-ray image.

CAUTION : Avoid sliding the IP when retrieving it from the IP receptacle in the PSPIX2. Lift out the IP by holding it along its edges.

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 PSPIX2. A warning window appears on the Touch screen of the PSPIX2, 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 PSPIX2 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 PSPIX2 acquisition module of another computer connected to the PSPIX2 (in the case of a multi-user configuration). Take care to open the correct patient file in the imaging software, then access the "**Setups**" menu, then the "**Image**" tab in the PSPIX2 acquisition module. Finally click on the "Retrieve the Last Scanned Image" button.

7. Retrieve the IP from the IP receptacle. The PSPIX2 is now ready to read the next IP (the animation on the screen asks you to insert a new IP).

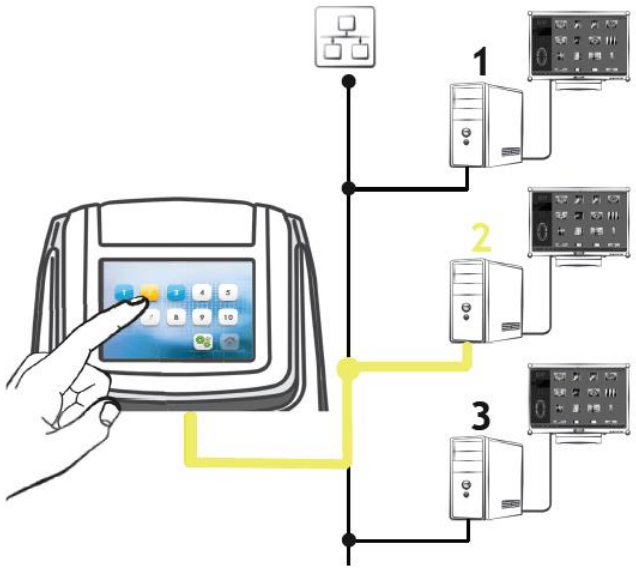
5.5.2 MULTI-USER CONFIGURATION

The multi-user configuration allows you to share the PSPIX2 with a maximum of ten computers. Each workstation uses the PSPIX2 successively. The PSPIX2 therefore has the same function: send an image to a given computer via the acquisition module.

It is possible to reserve the PSPIX2 via the PSPIX2 touch screen or via the PSPIX2 acquisition module from the workstation.

5.5.2.1 RESERVATION FROM THE PSPIX2 SCREEN

1. To reserve the PSPIX2 from the touch screen, directly click on the number that corresponds to your workstation. This is located on the multi-user home page.



NOTES:

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

- Once the PSPIX2 is reserved, the workstation number, the patient and practitioner names are displayed on the PSPIX2's touch screen .
  A countdown on the screen shows the time remaining to insert the IP in the PSPIX2. At the end of this time, the PSPIX2 will automatically free itself up and return to the multi-user home page.

- When the PSPIX2 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 PSPIX2 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 PSPIX2 click on the "**Home**" icon  in the bottom right-hand corner of the PSPIX2 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 PSPIX2. A warning window appears on the Touch screen of the PSPIX2, 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 PSPIX2 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 PSPIX2 acquisition module of another computer connected to the PSPIX2 (in the case of a multi-user configuration). Take care to open the correct patient file in the imaging software, then access the "**Setups**" menu, then the "**Image**" tab in the PSPIX2 acquisition module. Finally click on the "Retrieve the last scanned image" button.

5.5.2.2 RESERVATION FROM THE WORKSTATION

1. To reserve the PSPIX2 from the workstation, click on the "*Unlock*" icon  on the PSPIX2 acquisition module.

   The icon then changes to "*Locked*"  .

   NOTES:
   - Once the PSPIX2 is reserved, the workstation number, the patient and practitioner names are displayed on the PSPIX2 's touch screen.

   - When the PSPIX2 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 PSPIX2 during this period.
     A countdown on the screen shows the time remaining to insert the IP in the PSPIX2. At the end of this time, the PSPIX2 will automatically free itself up and return to the multi-user home page. This reservation time for each workstation is configurable from the PSPIX2 acquisition module in the "**Setups**" menu from the "**Configuration**" tab.

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

3. To manually free up the PSPIX2 click on the "**Home**" icon  in the bottom right-hand corner of the PSPIX2 screen or click on the "*Locked*" icon  on your acquisition module. You will return to the PSPIX2 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 PSPIX2. A warning window appears on the Touch screen of the PSPIX2, 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 PSPIX2 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 PSPIX2 acquisition module of another computer connected to the PSPIX2 (in the case of a multi-user configuration). Take care to open the correct patient file in the imaging software, then access the "**Setups**" menu, then the "**Image**" tab in the PSPIX2 acquisition module.
Finally click on the "Retrieve the last scanned image" button.

CAUTION: Do not put an IP back in the insertion slot of the PSPIX2 until the previous IP has fallen into the IP receptacle.

5.6 ERASING AN IMAGING PLATE

After being read, the IP is automatically erased before falling into the IP receptacle of the PSPIX2.
However, it is necessary to erase an IP if it is the first time it is used, or if it has been stored for more than 24 hours, or if it has been stored in a dark room or if the image data has not been deleted following a PSPIX2 malfunction.

To do this, the "**Erase**"  menu allows you to erase IP quickly and simply.

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

1. Click on the "**Setups**" icon  on the PSPIX2'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 PSPIX2's insertion slot:
   - ✓ vertically;
   - ✓ with the side containing the ACTEON logo facing towards the user.

   IP is automatically detected then enters the PSPIX2.

   Note: If the IP does not enter the PSPIX2 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, place the IP correctly 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 PSPIX2 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 IP are correctly erased, even when they have been stored in darkness for an extended period.

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

5.7 ECO MODE AND STANDBY MODE

5.7.1 ECO MODE

Following several minutes of inactivity, the backlight on the PSPIX2 Touch screen will dim to save energy. The "**Eco mode**" is configurable from the PSPIX2 Touch screen in the "**Setups**" -> "**Configuration**" -> "**Time**" menu.
By default, it is set at 5 minutes. You can set it for time periods between 0 and 60 minutes.

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

The PSPIX2 automatically exits "**Eco mode**" when the user changes the status of the PSPIX2. This includes when he/she places an IP in the insertion slot, touches the screen or reserves the PSPIX2 from the acquisition module from his/her workstation.

5.7.2 STANDBY MODE

Few minutes after closing the PSPIX2 acquisition module, the Touch screen of the PSPIX2 will completely switch OFF to reduce its power consumption. This standby time is configurable from the PSPIX2 acquisition module from the "**Setups**" menu in the "**Configuration**" tab. By default, it is set at 15 minutes. You can set it for time periods between 0 and 60 minutes.

The PSPIX2 automatically exits "**Standby mode**" when the user restarts his/her imaging software, opens a patient file and launches the PSPIX2 acquisition module. You can also touch the Touch screen to bring it out of its standby mode.

5.8 SWITCHING OFF THE PSPIX2

Disconnect the PSPIX2 power supply to turn the unit off completely.

NOTES:

- If the PSPIX2 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.

- Place the PSPIX2 so that you can easily access the electrical socket to disconnect it.

IMPORTANT: An erroneous image should not be used to establish a diagnosis.

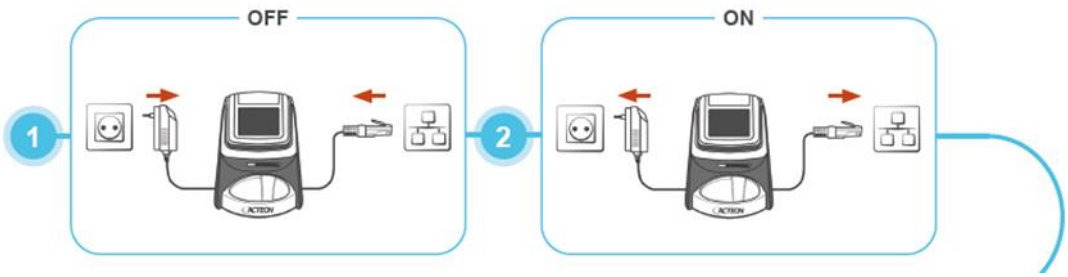
5.9 REPLACING IMAGING PLATES

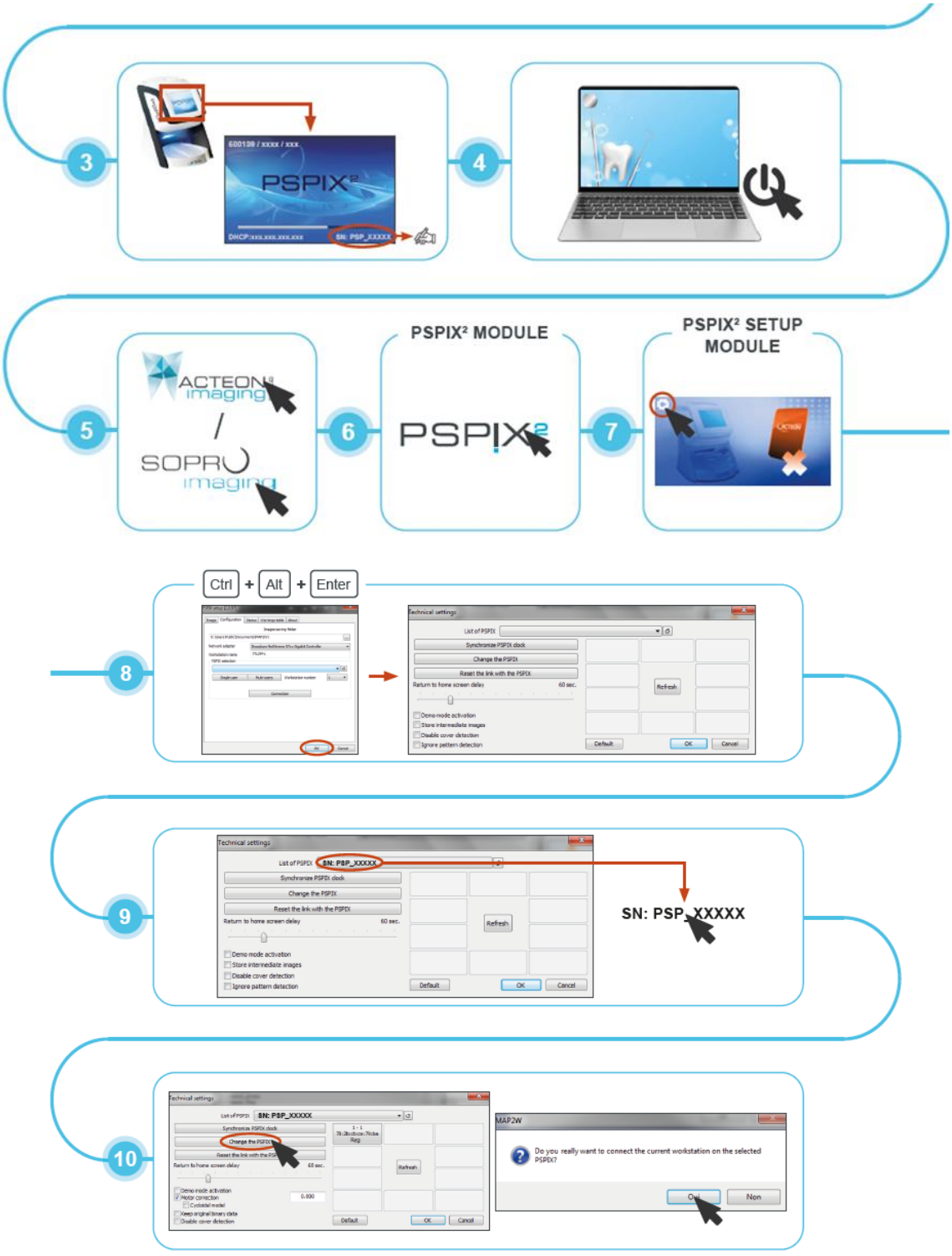
An IP must be replaced in the following cases:

- 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 instructions set out in this Instructions for Use;
- Damaged protective film on the active side;
- IP torn or significantly bent out of shape.

5.10 REPLACING THE PSPIX2

Follow the instructions below when changing the PSPIX2:




3
PSPIX²
4
5
ACTEON imaging
/
SOPRO imaging
6
PSPIX² MODULE
PSPIX²
7
PSPIX² SETUP MODULE
8
Ctrl + Alt + Enter
9
SN: PSP_XXXXX
10
Do you really want to connect the current workstation on the selected PSPIX?

6 CLEANING, DISINFECTION AND STERILIZATION

In accordance with EN ISO 17664, this section provides users with instructions for cleaning, disinfection, and sterilization of SOPRO reusable medical devices. All cleaning, disinfection and sterilization instructions provided by SOPRO for the company's medical devices and accessories have been validated. This section is applicable only to devices manufactured by SOPRO.
In countries where the reprocessing requirements are more stringent than those detailed in these Instructions for Use, the user must always comply with national guidelines, laws, and regulations.
Always follow the recommendations of the manufacturers of the products and equipment used.

Cleaning is defined as the removal of visible soil (e.g., organic and inorganic material). Cleaning reduces the initial population of microorganisms, preventing blood proteins and other contaminants from drying on the devices, facilitating subsequent processing steps and protecting personnel who handle medical devices, in addition to preventing contamination of the environment. Disinfection reduces the number of pathogenic microorganisms, except bacterial spores. The sterilization process is used to render product free of viable microorganisms with a Sterility Assurance Level (SAL) of 10^{-6}.

6.1 DEVICES AND PROCESS TO APPLY

Before using the PSPIX2 scanner for the first time, it is essential to follow the disinfection procedure.
Any PSPIX2 scanner undergoing alteration or maintenance must be subjected to the full disinfection procedure prior to any use.

The PSPIX2 body (without removable part) is a reusable device non sterilizable, it must be disinfected before the first use.

The removable parts provided in with the PSPIX2 scanner (IP insertion part and receptacle) are reusable devices; they must be cleaned and disinfected. These parts cannot be sterilized.
The optional removable parts (IP insert part and receptacle) are reusable devices: they must be first cleaned, disinfected, and finally sterilized by autoclave before use.

The imaging plates are reusable devices not sterilizable. IP must be cleaned with the SOPROWIPE single-use cleaning wipe. The IP storage box must be cleaned using a non-abrasive cloth.

NOTE: The disinfection techniques used both for the PSPIX2 and the dental practice must comply with all national and local legislation in force.

6.2 PSPIX2 SCANNER: PROCESS TO APPLY

6.2.1 CLEANING

1. Remove the removable parts from the PSPIX2 scanner (IP insertion part and receptacle).
2. To clean the PSPIX2 scanner and its removable parts, wipe them using a non-abrasive cloth dipped in one of the following solutions: cold or tepid water, soapy water, a light detergent, Butyl alcohol, Ethanol (Ethyl alcohol) from 70-96%.
3. Use a compressed air to clean the back part underneath the IP insert.
4. After cleaning, wipe the PSPIX2 with a nonabrasive cloth dipped in cold water.

WARNINGS:

- Never use solvents or abrasive cleaning products to clean the PSPIX2 scanner.
- Do not spray the cleaning solution directly onto the PSPIX2 scanner.
- Do not place cleaning solution in the PSIX2 scanner.
- Never use a wet cloth used on the black part on the IP's insertion part.

6.2.2 DISINFECTION

6.2.2.1 DISINFECTION OF THE PSPIX2 SCANNER WITHOUT OPTIONAL REMOVABLE PARTS (IP INSERTION PART AND RECEPTACLE)

1. Remove the removable parts from the PSPIX2 (IP insertion part and receptacle) and disinfect them separately.
2. Disinfect the PSPIX2 body with a cloth dipped in a disinfectant solution.

WARNINGS:

- Never use disinfectants that contain abrasive or corrosive substances, or that contain solvents.

- Never spray disinfectant directly onto the PSPIX2 scanner.
- Do not introduce disinfectant in the PSPIX2 ’s insertion slot.
- Never use a wet cloth on the black part under the IP’s insertion slot.
- All surfaces must be dry before using the PSPIX2 scanner.

6.2.2.2 DISINFECTION OF THE *OPTIONAL* REMOVABLE PARTS (IP INSERTION PART AND RECEPTACLE)

1. Remove the removable parts from the PSPIX2 (IP insertion part and receptacle).
2. To disinfect the removable parts, you can 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 désinfectables. Program your washer disinfector so that the thermal disinfection takes place at 93 °C for five minutes.

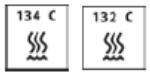
WARNINGS:
- Never use disinfectants that contain abrasive or corrosive substances or that contain solvents.
- Never spray the disinfectant directly onto the PSPIX2 scanner.
- When using a washer disinfector, do not exceed a holding time of 5 minutes during thermal disinfection at 93 °C.
- All surfaces must be dry before using the PSPIX2 scanner.

CAUTION:
- Risk of damage to the PSPIX2: No liquids may enter the device.
- Risk of damage to the PSPIX2: Disinfection of attachments with a thermal washer disinfector can lead to wear and tear of the attachments. It is therefore advisable to replace these parts every 100 disinfection cycles per thermal washer-disinfector, on average.

6.2.3 STERILIZATION

6.2.3.1 STERILIZATION OF THE *OPTIONAL* REMOVABLE PARTS (IP INSERTION PART AND RECEPTACLE)

1. Ensure that the removable parts supplied with your PSPIX2 are autoclave-proof, as they are sold as options. Turn them over and check that the following logos are present:



2. Clean and disinfect the removable parts according to the procedures set out above.
3. 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 parameters have been validated: 121° C (250°F) 30 minutes, 30 minutes dry time.

Note: The autoclave procedure described in this chapter is a recommended procedure. It is not a substitute for official recommendations and directives. Product decontamination, methods and tools used, remain the sole responsibility of those people in charge.

WARNINGS:
- Never autoclave items above 134°C.
- Ensure that the parts are completely dry and are at ambient temperature before putting them back into the PSPIX2 and using them.

CAUTION:
- Risk of deterioration of the PSPIX2: Autoclavable 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.
- Risk of deterioration of the PSPIX2: Sterilization of removable parts may cause wear of these parts. It is therefore advisable to replace these parts before they get major wear.

6.3 IMAGING PLATES: PROCESS TO APPLY

6.3.1 CLEANING

1. Use the soft, lint-free and dry microfiber cloth supplied with the PSPIX2.
2. Begin by cleaning with a vertical, then horizontal movement and finally with a circular motion.
3. Use the SOPROWIPE single-use cleaning wipes.
4. Begin by cleaning with a vertical, then horizontal movement and finally with a circular motion.
5. Wipe the IP with the soft, lint free and dry microfiber cloth.
6. Ensure that the IP is completely dry before using it again.

WARNING: 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 IP; Do not clean IP in an autoclave. Disinfection by immersion destroys them.
- Risk of deterioration of the IP; An unsuitable cleaning solution is liable to damage, delaminate or destroy the IP of the PSPIX2. Only use cleaning wipes that are tested and approved by ACTEON, the SOPROWIPES.
- Risk of image degradation and deterioration of the IP; 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 and only use it after you are sure that it is completely dry.

NOTES:

- 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.

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

6.4 IP STORAGE BOX: PROCESS TO APPLY

6.4.1 CLEANING

To clean the storage box, use a nonabrasive cloth, dipped in one of the following solutions:

- 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.

CAUTION: Never use solvents or abrasive cleaning products to clean the PSPIX2.

6.4.2 DISINFECTION

Disinfect the storage box with a cloth dipped in a disinfectant solution.
Let it to dry before using it again.

CAUTION: Never use solvents or abrasive cleaning products to clean the PSPIX2.

6.4.3 STERILIZATION

Autoclave the base (lower part) of the IP storage box:

1. Clean and disinfect the base according to the procedures set out above.
2. Condition the base and place it in the autoclave.

3. The base can be sterilized at 134°C / 18 minutes, on Prion cycle.
4. Dry the base using the autoclave drying cycle or by opening the autoclave door and allowing them to dry in the air.
5. Let the base cool to ambient temperature before placing the IP inside.

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

WARNING: Never autoclave the base above 134 °C.

CAUTION: Risk of deterioration 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.

7 MAINTENANCE AND AFTER-SALES SERVICE

7.1 MAINTENANCE

The PSPIX2 does not need any maintenance if they are used according to the Manufacturer's directions for use and cleaning instructions.
Before first using the equipment, it is imperative to follow the complete disinfecting procedure.
Any device returned from servicing or maintenance should be completely disinfected before being used.

WARNING: Any incorrect use of the device is not covered by the guarantee.
If a problem persists and the device needs to be returned to the after-sales department, make sure it is sent in its original packaging. Please return all components of the device (the power supply cable, and the control unit). Make sure to include an explanation of the problem you have encountered with your shipping form.

7.2 AFTER-SALES SERVICE

WARRANTIES: SOPRO guarantees its products to be free from material and manufacturing defects for a period of two (2) years from the date of purchase. This warranty does not apply to misused, modified, untended, or accidentally damaged products nor to 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 to discretionary replacement or repair of the defective product free of charge if it has been sent to SOPRO After-Sales Service. This applies to the warranty period only.
Outside of France, access 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 RECOURSE. IT REPLACES ANY OTHER WARRANTY, FOR EXAMPLE, A WARRANTY OF ADEQUACY TO A PARTICULAR AIM, EXPLICIT OR IMPLICIT. SOPRO SHALL NOT BE LIABLE FOR ANY PARTICULAR DAMAGE, INDIRECT, ACCIDENTAL OR CONSEQUENTIAL NOR FOR ANY DETERIORATION OR DATA LOSS, ON A CONTRACTUAL, NONCONTRACTUAL 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.

WARNING: The equipment must be disinfected prior to return for repairs. When returning the equipment, check its condition and note down any anomalies on the shipping form as necessary. Confirm those anomalies to the carrier by recorded letter within 48 hours. If equipment shipped by us suffers damage during transport, the total cost of repairs will be billed to the carrier if exceptions have been communicated within the deadline, otherwise such charges will be billed to the addressee.

7.3 TROUBLE SHOOTING

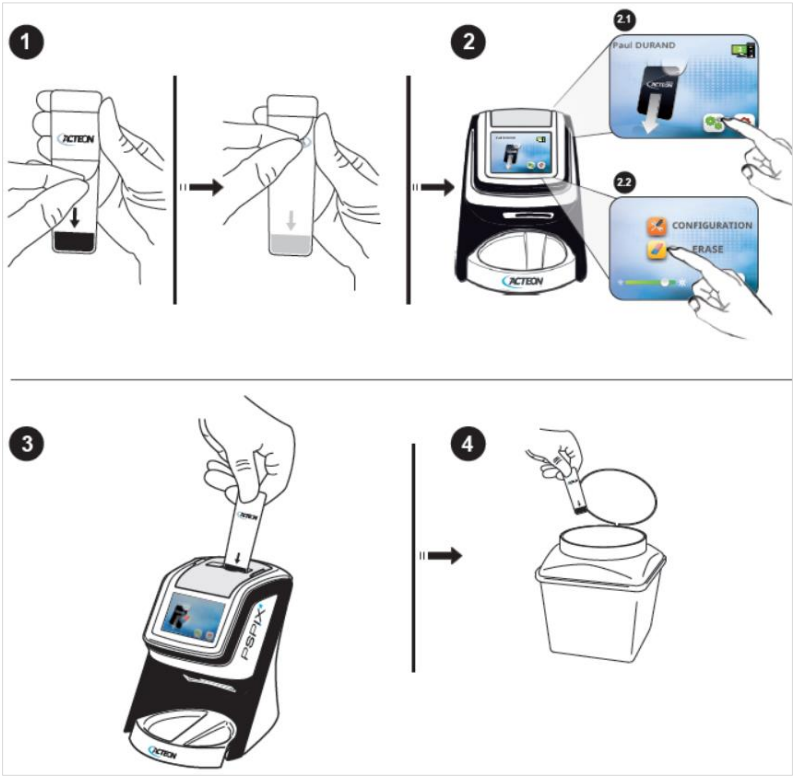
Problems	Causes	Solutions
Warnings 202 to 206	Defective Ethernet communication	- Ensure that the PSPIX2 's Ethernet cable and the computer are properly connected to a network port. - Ensure that the computer is switched on, the imaging software in launched and that both the patient file and the PSPIX2 acquisition module are open. - Check you network Ethernet Setups. 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 PSPIX2 memory. 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 PSPIX2 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.

Problems	Causes	Solutions
		☞ or Collect the image from the PSPIX2 acquisition module from another computer connected to the PSPIX2 (in the case of a multi-user configuration). Take care to open the correct patient file, in the imaging software, then access the "**Setups**" menu, then the "**Image**" tab in the PSPIX2 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 PSPIX2 is located.
Warning 602	Ambient temperature too high	Check and lower the temperature in the room where the PSPIX2 is located.

For any other problems, contact your nearest after-sales service department.

7.4 CLEANING PLATES USE

To remove dust particles which could lead to PSPIX2 dysfunction, please follow the instructions described below:



WARNING: The cleaning plate could be used up to 5 times.

8 ELECTROMAGNETIC COMPATIBILITY

All the informations below are based on the requirements of standards to which the manufacturers of electrical medical devices must adhere (as stated in standard IEC 60601-1-2).
The medical device complies with the electromagnetic compatibility standards in force.
However, you must make sure that any electromagnetic interference does not create an additional risk, such as radio-frequency transmitters or other electronic devices.
This chapter contains the information required for you to install and use your medical device in optimum conditions in terms of electromagnetic compatibility.
Different medical device leads must be kept separate from each other.
Sometimes mobile telecommunication devices such as mobile phones can interfere with the medical device. The recommended separation distances in this chapter must therefore be strictly observed.

WARNING: The use of accessories, transducers, and cables other than those specified or sold by SOPRO as replacement parts, may have consequently an increase of emission or decreased immunity of the medical device and result in inadequate operation.

8.1 CABLE LENGTH

Cables and accessories	Maximum length
Supply cable, Ethernet cable	< 3 m

8.2 APPLICABLE TESTS

Test type	In compliance with	Applicable (A)/ Not applicable (N/A)
Conducted disturbances (conducted emissions)	CISPR 11	*N/A*
Electromagnetic radiation disturbance (radiated emissions)	CISPR 11	A
Harmonic current emissions	IEC 61000-3-2	*N/A*
Voltage changes, voltage fluctuations and flickers emissions	IEC 61000-3-3	*N/A*
Electrostatic discharge immunity	IEC 61000-4-2	A
Radiated RF electromagnetic field immunity	IEC 61000-4-3	A
Immunity to proximity fields from RF wireless communications equipment	IEC 61000-4-3	A
Electrical fast transient/burst immunity – A.C Mains	IEC 61000-4-4	A
Electrical fast transient/burst immunity – I/O SIP/SOP PORTS	IEC 61000-4-4	A
Surge immunity	IEC 61000-4-5	*N/A*
Immunity to conducted disturbances, induced by RF fields (Immunity to conducted RF disturbances) – A.C Mains	IEC 61000-4-6	A
Immunity to conducted disturbances, induced by RF fields (Immunity to conducted RF disturbances) – SIP/SOP PORTS	IEC 61000-4-6	A
Power frequency magnetic field immunity	IEC 61000-4-8	A
Voltage dips immunity	IEC 61000-4-11	*N/A*
Voltage short interruptions and voltage variations immunity	IEC 61000-4-11	*N/A*
Proximity magnetic fields	IEC 61000-4-39	*N/A*

8.3 RECOMMENDED SEPARATION DISTANCES

The medical device is designed to be used in an electromagnetic environment in which interferences caused by RF radiation are controlled.
The user or installer of the medical device can help prevent any electromagnetic interference by applying a minimum distance, according to the maximum power of the radio-frequency transmission equipment.

WARNINGS:

- You should avoid using this device alongside other devices or stacked with them, since that could cause incorrect operation. If such use is necessary, you should carefully observe this device and other equipments to check that they are operating normally.

- Portable RF communications devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the medical device, including specified cables by the manufacturer. Otherwise, the performance of these devices could be impaired.

8.4 ELECTROMAGNETIC EMISSIONS

The medical device is designed for use in the electromagnetic environment described in the table below. The user and/or installer must therefore ensure that the medical device is used in the environment described below.

Emission test	Conformity	Electromagnetic environment – comments
Conducted disturbances (conducted emissions) *CISPR 11*	Group 1	The medical device uses RF energy for its internal functioning.
Electromagnetic radiation disturbance (Radiated emissions) *CISPR 11*	Class B	Professional healthcare facility environment and home healthcare environment.
Harmonic current emissions *IEC 61000-3-2*	*N/A*	
Voltage changes, voltage fluctuations and flicker emissions *IEC 61000-3-3*	*N/A*	

The medical device is intended for use in a professional healthcare environment (hospital, clinic) and in a home healthcare environment (dental office in a residential area).
The user and installer should therefore ensure that the medical device is used in the environment described below.

For the professional healthcare environment, the medical device should not be used in the vicinity of electrosurgery equipment or in the vicinity of an electromagnetically shielded room for magnetic resonance imaging (MRI) equipment where the intensity of electromagnetic disturbances is high.

8.5 MAGNETIC AND ELECTROMAGNETIC IMMUNITY

The medical device is designed for use in the magnetic and electromagnetic environment described in the table below.
The user and/or installer must ensure conformity of the electromagnetic environment.

Immunity test	Test level applied	Test level (IEC 60601-1-2)	Electromagnetic environment / comments
Electrostatic discharge immunity *IEC 61000-4-2*	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air		Environment of a professional health care facility and in domestic premises or connected to the public electricity network.
Radiated RF electromagnetic field immunity *IEC 61000-4-3*	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz		Professional healthcare facility environment.
Immunity to proximity fields from RF wireless communications equipment *IEC 61000-4-3*	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz		Environment of a professional health care facility and in domestic premises or connected to the public electricity network.

Immunity test	Test level applied	Test level (IEC 60601-1-2)	Electromagnetic environment / comments
Electrical fast transient/burst immunity – A.C. Mains *IEC 61000-4-4*	± 2 kV 100 kHz repetition frequency ± 2 kV for SIP/SOP ports		Environment of a professional health care facility and in domestic premises or connected to the public electricity network.
Surge immunity *IEC 61000-4-5*	*N/A*	± 0.5 and 1 kV differential mode ± 0.5, 1 and 2 kV common mode	*N/A*
Immunity to conducted disturbances induced by RF fields (Conducted RF disturbance immunity) – A.C. Mains and SIP/SOP PORTS *IEC 61000-4-6*	3 V 0.15 at 80 MHz 6 V in ISM band and band ranging from 0.15 to 80 MHZ amateur radio band included. 80 % AM with 1 kHz		Environment of a professional health care facility and in domestic premises or connected to the public electricity network.
Power frequency magnetic field immunity *IEC 61000-4-8*	30 A/m		Environment of a professional health care facility and in domestic premises or connected to the public electricity network.
Voltage dips immunity *IEC 61000-4-11*	*N/A*	0% UT For 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT For 1 cycle 70% UT For 25 cycles at 50 Hz For 30 cycles at 60 Hz Single phase at 0°	*N/A*
Voltage short interruptions and voltage variations immunity *IEC 61000-4-11*	*N/A*	0% UT For 250 cycles at 50 Hz For 300 cycles at 60 Hz	*N/A*
Proximity magnetic fields *IEC 61000-4-39*	*N/A*		*N/A*
Transient electrical conduction along supply lines *ISO 7637-2 :2011*	*N/A*		*N/A*

9 TECHNICAL DESCRIPTION

9.1 ENVIRONMENTAL CONDITIONS

9.1.1 PSPIX2 SCANNER

Transport temperature	-20 °C / +45 °C
Storage temperature	+10 °C / +40 °C
Operating temperature	+10 °C / +40 °C
Operating relative humidity	30% to 85 %
Relative humidity for transport and storage	10% to 90%
Transport, storage and operating atmospheric pressure	700 hPa to 1060 hPa
Electrical classification (IEC 60601-1)	Class II
Applied part	*N/A*
Photobiological risk group (IEC 62471)	Group 1
This medical device complies with the following international standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, ISO 14971, ISO 15223-1, IEC 62304, IEC 62366-1	

9.1.2 IMAGING PLATES

Transport temperature	Below 33°C
Storage temperature	Below 33°C
Operating temperature	+10°C / +40°C
Operating relative humidity	80% RH or less without dew condensation
Relative humidity for transport and storage	80% RH or less without dew condensation
Transport, storage and operating atmospheric pressure	700 hPa to 1060 hPa
Electrical classification (IEC 60601-1)	*N/A*
Applied part	*N/A*
Photobiological risk group (IEC 62471)	*N/A*
This medical device complies with the following international standards: ISO 14971, ISO 15223-1, IEC 62304, IEC 62366-1	

9.2 TECHNICAL CHARACTERITICS

9.2.1 PSPIX2 SCANNER

Dimensions (*Height x Depth x Width*)	205 x 194 x 154 mm
Weight	2.6 kg
Operating voltage	12 V
Operating current	Less than 2.5 A
Bit depth	14 bits Unit grey scale 16 bits Image grey scale
Theoretical resolution	Greater than or equal to 20 lp/mm in high resolution
Liquid penetration	IPX0 (IP Protection) – Not protected against water chutes.

9.2.2 IMAGING PLATES

Size 0	22 x 35 mm
Size 1	24 x 40 mm
Size 2	31 x 41 mm
Size 3	27 x 54 mm
Size 4 *Size 4 consists of two Size 3 IP placed side-by-side in an appropriate plastic support.*	52 x 54 mm
Material	Photo-stimulable phosphorus components

10 DISPOSAL AND RECYCLING

This device bears a recycling symbol. By correctly disposing of this device, you will help prevent any harm to the environment and to human health.

The symbol  present on the device or in the accompanying documentation shows that this product cannot under any circumstances be processed as domestic waste. It must therefore be disposed of at a waste centre designated for the recycling of electrical and electronic equipment.

Protective bags and protective covers are single-use disposal devices.

For disposal, please comply with current rules concerning waste disposal in the country of installation.
To obtain further detailed information about the processing, salvage, and recycling of this device, please contact your nearest retailer who will tell you how to proceed.

11 REGULATORY INFORMATIONS

11.1 APPLICABLE STANDARDS AND REGULATIONS

The medical devices comply with the requirement on medical devices.
They were designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.
The information in these Instructions for Use is based on the requirements of standards to which the manufacturers of medical devices must adhere (as stated in standard IEC 62366-1).

11.2 MEDICAL DEVICE CLASSIFICATION

- PSPIX2 scanner and protective bags & covers are Class I medical devices (CE) according to the European regulation on medical devices.
- Imaging plates are Class II medical devices (CE0459) according to the European regulation on medical devices.

11.3 VIGILANCE

Any serious incident concerning the medical device or its accessories, except for the expected secondary effects must be reported to the relevant competent authorities and to the manufacturer as soon as possible. Generally, the notification period should consider the seriousness of the incident. Consult local applicable regulations.
Manufacturer's contact details: please see the last page of the Instructions for Use.

11.4 MANUFACTURER'S RESPONSIBILITY

Failure to comply with the recommendations provided by the manufacturer in this document and those supplied subsequently in written, electronic, or whatever other form will render the warranty null and void. The manufacturer shall be released from any liability, including for direct or indirect injuries to persons or damage to property and the environment. Furthermore, the managers of the facility, customers or collaborators shall be held liable for any damage and/or accidents and/or deterioration of patients' or operators' health or of the surrounding environment.

12 SYMBOLS

	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates the medical device manufacturer.
	Indicates the date when the medical device was manufactured.
	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Indicates a medical device that has not been subjected to a sterilization process.
	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the Instructions for Use for additional information.
	Indicates the temperature limits to which the medical device can be safely exposed.
	Indicates the range of humidity to which the medical device can be safely exposed.
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Indicates a medical device that is intended for one single-use only.
	Indicates a medical device that is intended for five uses only.
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action to avoid undesirable consequences.
	Indicates on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.
	Follow Instructions for Use.
	Indicates a carrier that contains Unique Device Identifier information.
	Indicates on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.
	On medical equipment. To identify a type of BF applied part complying with IEC 60601-1. B: Body / F: Floating applied part
	Indicates the product (put on the market after 13/08/2005) cannot under any circumstances be processed as domestic waste. It must therefore be disposed of at a waste centre designated for the recycling of electrical and electronic equipment.
	Indicates the item is a medical device.
	To indicate correct upright position of the transport package.
	Indicates a medical device that can be broken or damaged if not handled carefully.
	Indicates a medical device that needs to be protected from moisture.

CE 0459

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