



Digital X-ray Phosphor Plate System

REF PS500UM Rev 3
211870 ver 1



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Manufactured for:

Gendex Dental Systems
1910 North Penn Road
Hatfield, Pa 19440.

Manufacturer:

PaloDEX Group Oy
Nahkelantie 160,
FI-04300 Tuusula, Finland
Tel. +358 10 270 2000
Fax +358 9 851 4048



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1. The GXPS-500™

1.1 Introduction

This manual describes how to use the **GXPS-500** digital X-ray phosphor plate unit (the unit) which is part of the digital X-ray photostimulable phosphor plate system (the system). The complete system comprises the following:

- the **GXPS-500** phosphor plate unit (the unit).
- Gendex Photostimulable Phosphor Plates (PSPs), protective covers, hygiene bags and other related imaging plate accessories.
- a PC (not supplied) in which suitable dental imaging software has been installed.
- the local area network (LAN) cable will be required if the system is to be used in a network.

The **GXPS-500** unit uses a laser to automatically scan and read reusable Gendex Photostimulable Phosphor Plate sizes 0, 1, 2, and 3. After reading the images they can be examined on the PC using dental imaging software.

The unit can either be connection directly to the PC or to network via the LAN cable.

The unit can be set up to work with a single PC, the **single user** configuration, or with several PCs, the **Multi-Room Connection** (multiple user) configuration.

With the Multi-Room Connection configuration up to eight PCs can be used, one at a time, with the unit.

NOTES:

Only personnel trained and authorized by the manufacturer of the unit are allowed to install and configure the unit.

Only use the photostimulable phosphor plates, protective covers and hygiene bags supplied by the manufacturer of the unit.

Please read the section **6. Warnings and precautions** before using the unit.

1.2 System installation

Positioning the unit

Do not position the unit in direct sunlight or near bright light. Sunlight or bright light must not be allowed to shine directly on the unit door into which the PSPs are inserted.

Position the unit on a stable flat surface so that vibrations will not degrade the image quality. The unit can also be attached to a wall, under or on a shelf with the optional mounting kit.

The unit must not be positioned so that it is touching other equipment. It must not be placed on top of or under other equipment.

The unit can be positioned within the environment in which the patient is examined and treated (patient environment).

Positioning the PC(s)

The PC(s) connected to the unit should not be used in the patient environment.

The minimum horizontal distance between the patient and the PC(s) is 4.5 ft (1.5 m).

The minimum vertical distance between the patient and the PC(s) is 6.5 ft (2.5 m).

Other devices

DO NOT connect any other devices to the unit or the PC(s) connected to the unit that are:

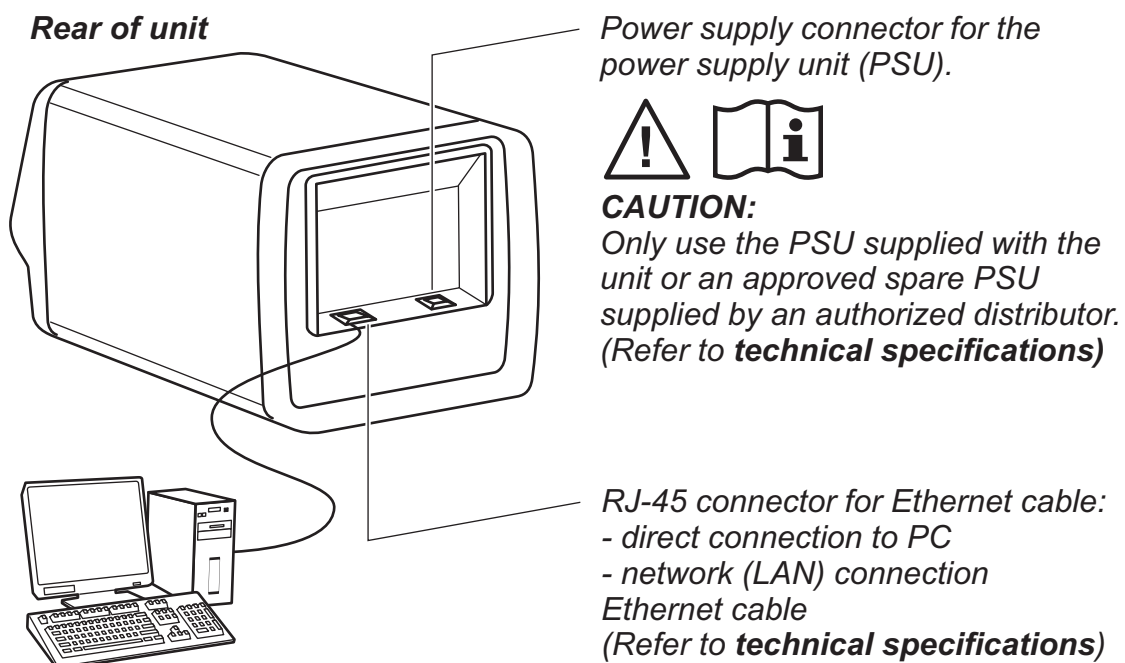
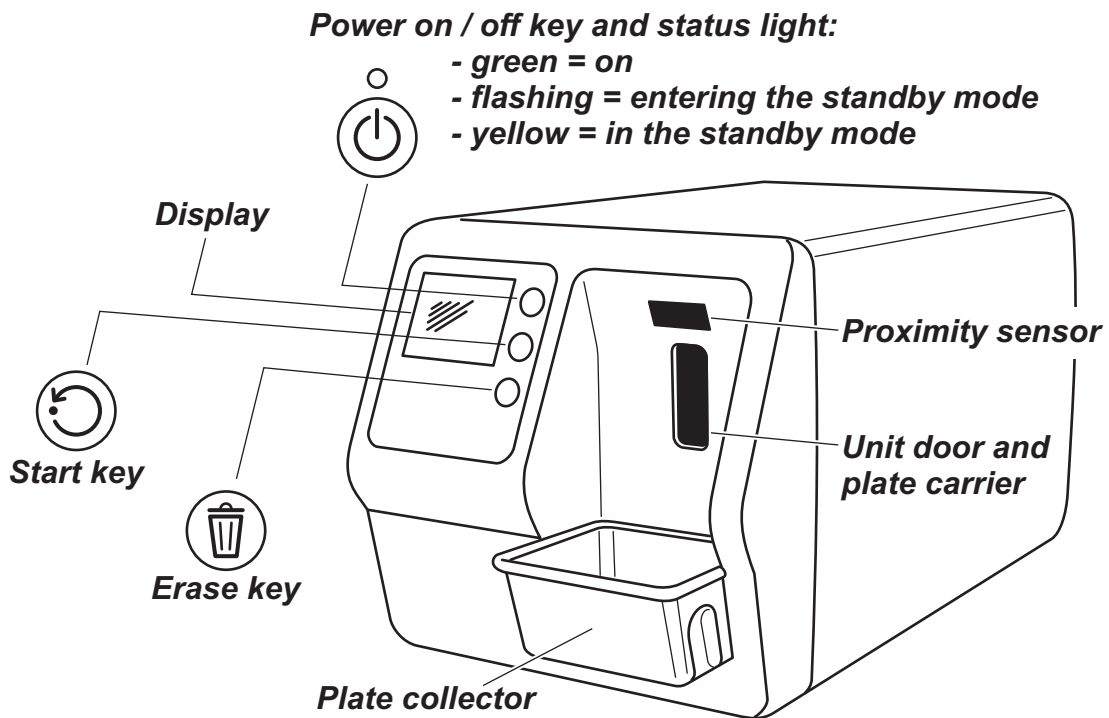
- not part of the supplied system
- not supplied by the manufacturer of the unit
- not recommended by the manufacturer of the unit.

1.3 Setup properties

There are numerous setup properties in the GxPicture Software Driver that allow you to set the operation of the unit and the image quality to your requirements. Refer to the documentation supplied with the **GxPicture Software Driver** for more information.

2. Intraoral phosphor plate unit

2.1 Main parts and controls



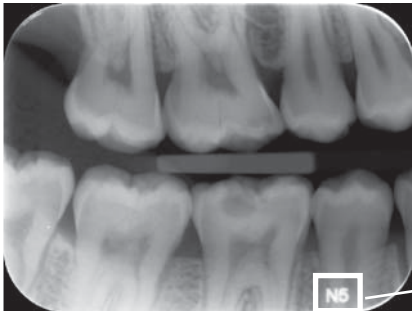
PC (not included) with digital imaging software that conforms to the MDD

2.2 Accessories

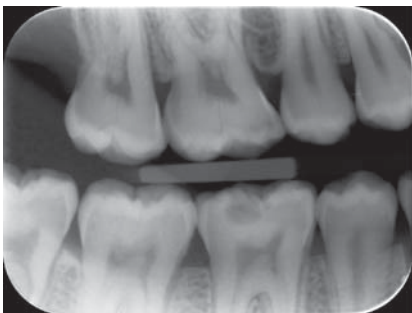
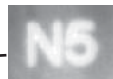
For additional information about the accessories listed below contact your authorized dealer. Not all accessories are available for all units.



Photostimulable Phosphor Plates (PSPs). Equivalent to film sizes 0, 1, 2 and 3.



IDOT version. An identification code (IDOT) is printed on the PSP and will appear on the intraoral image. The IDOT identification mark allows the PSP used for an exposure to be easily identified and removed if it damaged.



Standard (STD) version. The standard version has no identification mark.

Protective covers. For PSPs 0, 1, 2 and 3.

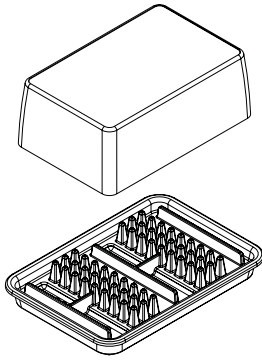


Hygiene bags. For PSPs 0, 1, 2 and 3.

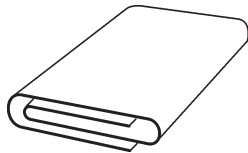
CAUTION:

For optimum performance only use PSPs, protective covers and hygiene bags supplied by the manufacturer of the unit or the manufacturer's authorized distributors.

The manufacturer will not be held responsible for problems caused by using accessories from other manufacturers.

**PSP storage box**

For storing PSPs safely and conveniently

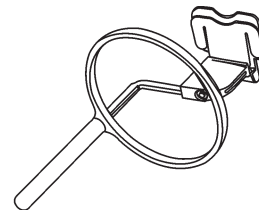
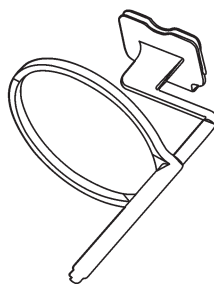
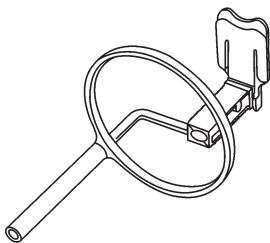
**Microfiber cloth**

For cleaning PSPs

PSP holders (optional)

For bitewing, periapical and endodontic exposures (optional, not included)

See section **Photostimulable phosphor plate holders** for more information.



2.3 Display symbols and what they mean

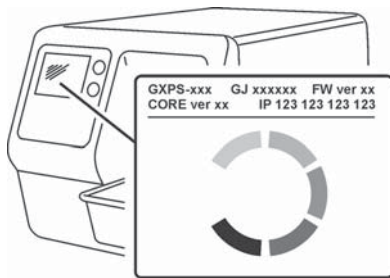
During use symbols and animations will appear on the unit display. These:

- indicate the status of the unit
- help you to operate the unit correctly
- show user mistakes and corrective actions
- display error codes
- display a preview image

The main symbols are:

Startup

During startup the unit serial number, PSP address and other information will appear on the unit display.



Multi-Room Connection wait

Multi-Room Connection configuration. The unit is not reserved by any PC in the system.

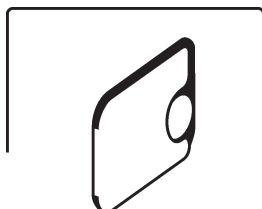


Multi-Room Connection reservation

Multi-Room Connection configuration. The unit has been reserved by a PC (e.g. PC number 2).

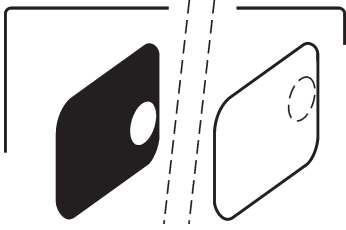


Unit door

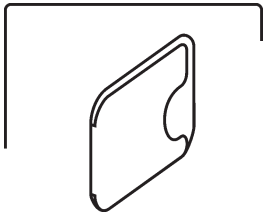


Protective cover and imaging plate

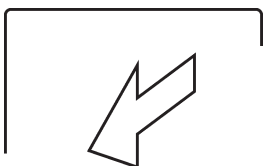
Yellow: remove protective cover



Imaging plate
 Yellow: wrong way round, rotate



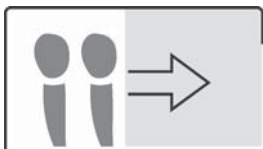
Protective cover



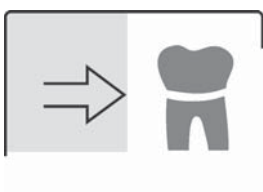
Remove / disconnect



Insert / connect



Busy
 Blue - unit scanning
 Red - unit erasing



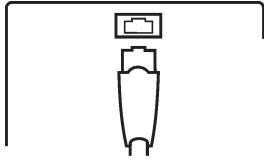
Unit in erasing mode



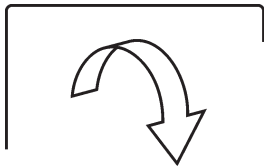
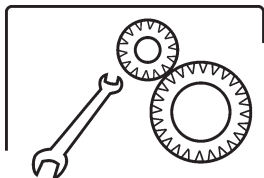
Check
 Something wrong or take alternative action.

**GxPicture Interface**

GxPicture is not connected to the unit.

**Unit connection**

Not connected or connection not working.

**Rotate****Error state and error number****Check documentation supplied with the unit****Unit in service mode**

(Service technicians only)

2.4 Using the system

For optimum performance only use PSPs, protective covers and hygiene bags designed for this unit and supplied by authorized distributors.

The manufacturer of this unit will not be held responsible for any problems caused by using accessories from other manufacturers.

Proper handling, cleaning and storage of the PSPs ensures the best image quality and maximum service life of the PSPs. Refer to section **4. Handling and care of photostimulable phosphor plates.**

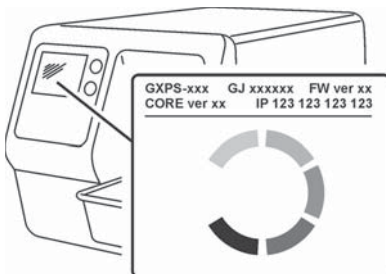
Preparing the system

1. **PC:** Switch on the PC connected to the unit.
2. **PC:** Open the dental imaging software and a new or existing patient file where you wish to store the intraoral images.

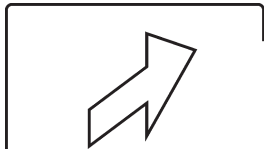
NOTE:

If you are using the system for the first time you may wish to check and / or change the setup options. Refer to the documentation supplied with the **GxPicture Software Driver** for more information.

3. Press the **on/off** key to switch the unit on.



The startup animation will appear on the display and the unit will carry out self test during which the PSP carrier will slide out of the unit door.



When the status light turns green and ready animation, indicating PSP insertion, appears on the unit display, the unit is ready to use (in the ready state).

NOTE:

If the ready animation does not appear, check the system setup described in the installation instructions.

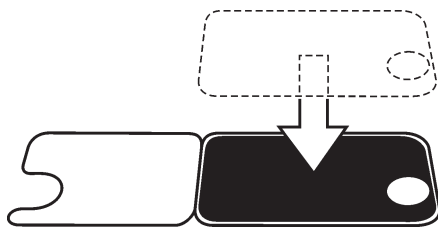
Preparing a PSP for exposure

IMPORTANT NOTE

If the PSP is being used for the very first time or if it has not been used within the last 24 hours, it must be erased before use to remove any fogging caused by background radiation. See section, **PSP erasing mode (Initial erasing of the PSPs)**.

CAUTION:

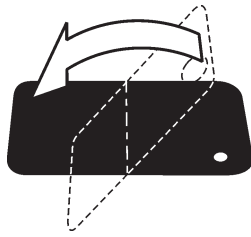
When handling PSPs, protective covers and hygiene bags take all appropriate measures and precautions to prevent cross contamination.



1. Place the PSP you wish to use onto a protective cover. The **light blue** side (sensitive) of the PSP must face and be placed on the half of the protective cover that is the same shape as the PSP.

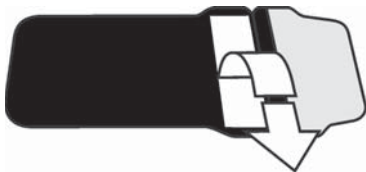
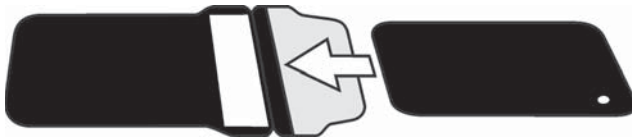


2. Fold the half of the protective cover with the semicircular cutout over onto the PSP. The metal disk on the back (black side) of the PSP must appear in the semicircular cut out.



3. Turn the protective cover and PSP over so that the black side of the protective cover is uppermost. This makes it easier to slide the protective cover and PSP into the hygiene bag.

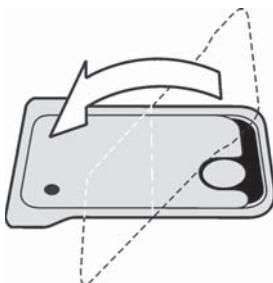
4. Slide the protective cover and PSP into the hygiene bag as far as they will go. Make sure that the black side of the protective cover is on the same side as the black side of the hygiene bag.



5. Peel off the cover paper from the sealing tape and then fold the flap, along the pre-formed line, over and onto the sealing tape.



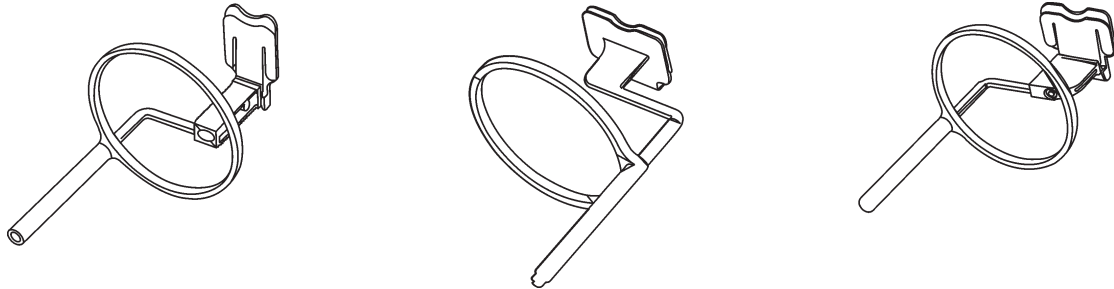
6. Press and slide your thumb along the tape to ensure that the flap is properly sealed.



7. Turn the sealed hygiene bag over and check that the PSP and protective cover are in the correct position. You must be able to see the light side of the protective cover and the metal disk on the PSP.

Photostimulable phosphor plate holders

It is recommended that photostimulable phosphor plate holders be used to ensure accurate PSP positioning and consistently good images quality.



Using photostimulable phosphor plate holders improves image quality because:

- the PSP is positioned correctly in relation to the tooth
- there is no positioning guesswork
- the PSP is not bent and thus distortion is eliminated
- the PSP cannot move in relation to the X-ray unit
- images are standardized and reproduceable
- there is no overlapping nor cone cut off
- PSP wear and tear is minimized
- image quality can be maintained irrespective of who takes the image
- time is saved and profitability increased

Problems caused by manually positioning the PSP include:

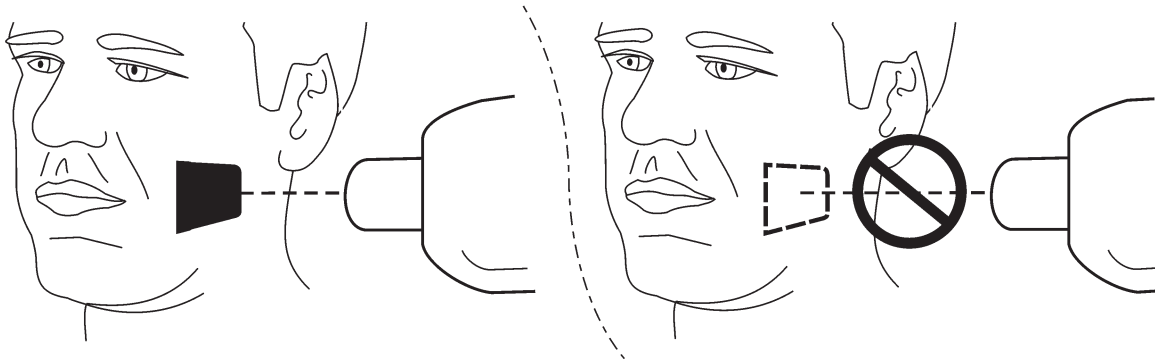
- incorrect vertical alignment
- distortion
- cone cut off
- poor projection standardization
- inferior image quality

For more information on photostimulable phosphor holders and systems, contact your dealer.

Taking an exposure

1. Place the PSP, in its sealed hygiene bag, into the appropriate imaging plate holder and then insert it into the patient's mouth in the position for the image you wish to take.

Note that the back of the sealed hygiene bag, the black side, must face the X-ray source.



2. Select exposure values appropriate for the exposure you are taking.

The system will produce excellent images even if the exposure values differ considerably from the optimum values. In most cases the same exposure values can be used for virtually all imaging purposes.

For normal everyday use select the **Adult Bite-wing** exposure time from the following table. If required the exposure time can be increased for very large patients and reduced for children.

The optimum exposure values also depends on the performance of the X-ray unit being used and may vary by ± 1 step from the values in the following table.

If the exposure time is too short, images will be noisy. Such images may still be usable for some diagnostic purposes.

If the exposure time is too long, images will be too dark or will show patient movement. These images will not be good enough for accurate diagnostic examination.

The exposure values table below should only be used as a guide.

Recommended exposure values (s) for DC x-ray units*

	60 kV, 7 mA				70 kV, 7 mA			
	short cone		long cone		short cone		long cone	
	Adult	Child	Adult	Child	Adult	Child	Adult	Child
Bitewing	0.25	0.16	0.50	0.32	0.12	0.08	0.25	0.16
Maxillary incisor	0.20	0.12	0.40	0.25	0.10	0.06	0.20	0.12
Maxillary cuspid	0.20	0.12	0.40	0.25	0.10	0.06	0.20	0.12
Maxillary molar	0.30	0.20	0.63	0.40	0.16	0.10	0.33	0.20
Mandibular incisor	0.20	0.12	0.40	0.25	0.10	0.06	0.20	0.12
Mandibular cuspid	0.25	0.16	0.50	0.32	0.12	0.08	0.25	0.16
Mandibular molar	0.25	0.16	0.50	0.32	0.12	0.08	0.25	0.16

*For AC x-ray units increase the exposure times by about 30%



3. **Protect yourself from radiation** and take the exposure.

4. Remove the sealed hygiene bag from the patient's mouth after the exposure.

CAUTION:

If there is a risk of cross contamination, wash, disinfect and dry the hygiene bag before opening it.

Reading an imaging plate

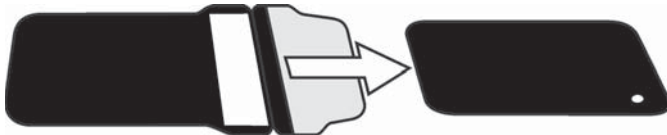
NOTE:

Start image capture from the dental imaging software you are using.

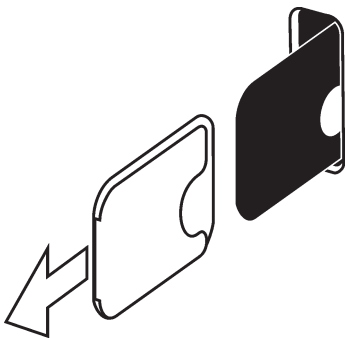


1. Pull the flap to open the hygiene bag.

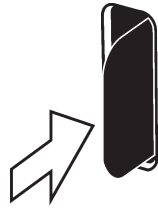
2. Keep the PSP in the protective cover so that you do not touch the PSP or allow it to be exposed to ambient light, and then slide the protective cover and PSP out of the hygiene bag.



3. Hold the protective cover and PSP so that the white side of the protective cover is on the right. The metal disk on the PSP will also be on the right. Insert the protective cover and PSP into the unit door. A magnet will hold the PSP in the correct position.



4. Slide the protective cover off of the PSP, and leave the PSP in position half way in the unit door.



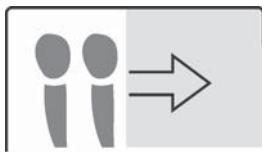
As soon as the protective cover is removed the unit detects that the PSP is in the unit door and will switch from the standby state to the ready state (ready to use) and automatically slide the PSP into the unit.

CAUTION:

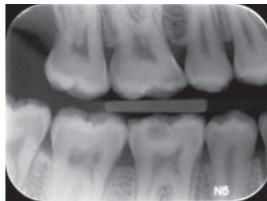
If the PSP does not slide into the unit after the protective cover has been removed, the PSP is misaligned or has been placed in the unit the wrong way round. Reposition the PSP and insert it into the unit again.



If after repositioning the PSP it still does not slide into the unit press the **Start** key to manually switch the unit from the standby to the ready state and the PSP will then slide into the unit when the protective cover is removed.

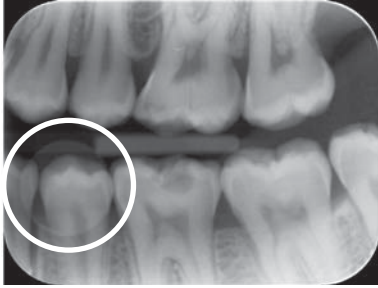


The busy animation will appear on the display which indicates that the PSP is being read.



After few seconds a preview image will appear on the unit display

PC: A read-out progress window will appear on the PC display. After a few seconds the image will appear in the dental imaging software. The image can now be saved. Refer to the documentation supplied with the dental imaging software you are using.

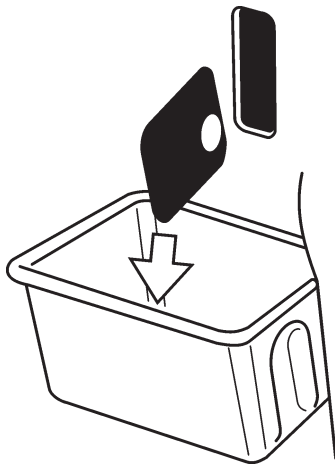
**CAUTION:**

If the metal disk on the rear of the PSP can be seen on the digital image, it indicates that the PSP was exposed from the wrong side.

CAUTION - RETRIEVING IMAGES

If the image is not transferred to the PC because of a network, PC or software failure, the image can be retrieved from the unit's memory as long as the unit is **NOT** switched off.

Refer to the documentation supplied with the **GxPicture Software Driver** for more information.



5. After the PSP has been read it will be automatically erased and then ejected from the unit into the plate collector.

After the PSP has been ejected the ready animation will reappear on the display. The unit is now ready to read the next PSP.

**Removing PSPs from the plate collector**

When removing PSPs from the plate collector hold them by their edges. Alternatively, pull the plate collector out of the unit and tip the PSPs out onto a flat clean surface. If they are not to be reused immediately or within a short period of time, store them in their storage box.

Standby mode

If no PSP is inserted into the unit within a certain period of time, the unit will beep several times and the status light will start to flash. When it turns yellow the unit is in the standby mode.



The unit will automatically exit the standby mode as soon as a new PSP is inserted into the unit or when the **Start** key is pressed.

After four hours the unit will exit the standby mode and automatically shut down.

Retrieve last image

If the last image read is not transferred to the PC because of a network, communication, PC or software failure, the last image read can be retrieved.

IMPORTANT NOTE

The LAST read image can only be retrieved if the unit is left on. **If the unit is switched off the image will be lost.**

For more information on how to retrieve the last scanned image refer to the documentation supplied with the **GxPicture Software Driver**.

Shutting down the unit



1. Press and hold power on / off key until the indicator light goes off.

NOTE:

If there is an untransferred image in the unit memory the unit cannot be shut down. The image must be transferred first. Refer to the documentation supplied with the **GxPicture Software Driver** for more information.

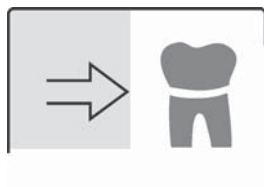
PSP erasing mode (Initial erasing of the PSPs)

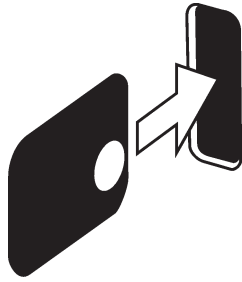
If a PSP is being used for the very first time or has not been used for 24 hours and has not been exposed to ambient light the erasing procedure must be carried out before the PSP is used. The erasing procedure removes any fogging due to background radiation.

The dedicated erasing mode erases the PSP but does not send the image (blank) to the dental imaging software.



1. Press the **Erase** key and the erase mode animation will appear on the unit display. The unit is now in the erase mode.





2. Hold the PSP by its edges (or use a protective cover) and position it so that the side with the metal disk (the back) is on the right. Insert the PSP into the unit door (remove the protective cover if used). A magnet will hold the PSP in position and then automatically slide it into the unit.

NOTE:

It may take longer to erase PSPs using the erasing mode than the normal read and erase mode. This is to ensure that PSPs that have not been used recently are erased properly.

3. After the PSP has been erased it will be ejected from the unit. The PSP can now be used to take an exposure.



4. To exit the erasing mode, either wait 15 seconds for the unit to automatically exit the mode, or press the **Erase** key. The erase animation will disappear.

Errors



- If there is a problem with the unit the error state symbol and an error number will appear on the unit display.

Restart the unit. The error should clear. If not contact your authorized distributor for assistance.

- **PC:** If the message:

Degraded image quality

appears on the image after a PSP has been read it indicates that the image may not be within the factory-set quality limits. If the image is good enough for diagnostic purposes no action is necessary. If the message appears frequently, contact your authorized distributor for assistance.

3. Handling and care of photostimulable phosphor plates

The correct use, handling, cleaning and storage of photostimulable phosphor plates guarantees the best image quality and maximum service life of the photostimulable phosphor plates.

3.1 General

- X-ray exposures DO NOT cause PSPs to age.
- The light-coloured side of the PSP is the side which “stores” the x-ray image. It is the SENSITIVE side!
- Image information “stored” on a PSP after an exposure is sensitive to light.

3.2 Handling

- Handle PSPs in the same way as you would handle CDs or DVDs.
- Hold PSPs by their edges using your finger tips.
- Protect the sensitive side of the PSP from:
 - scratches, wear and mechanical damage
 - stains, dirt, dust and fingerprints

NOTE:

Stains/fingerprints on the sensitive side can degrade the diagnostic value of the image
Dust/wear on the sensitive side can appear as white/grey spots on the image!

- Unprotected PSPs must not come in contact with the patient, the patient's saliva or any other bodily fluids.
Always use hygiene bags and protective covers with PSPs when taking exposures to:
 - eliminate cross contamination
 - maintain image quality
 - maximize PSP service life.

3.3 Cleaning

If PSPs are handled and stored correctly cleaning should not be necessary or can be kept to an absolute minimum.

Clean the PSP if there you see any visible marks or stains (which are not obvious scratches) on the image or if there is a reason to believe that the PSP is contaminated.

- Use the microfibre cloth supplied.
- First very gently wipe the PSP in a backwards forwards movement in both the widthwise and lengthwise directions and then finish with a circular wiping movement.
- For stubborn marks and stains that cannot be removed using the microfibre cloth, use 70...96% ethanol (70...96 EtOH / 30...4 DI WATER) or ethanol anhydride. Wipe the PSP as described above and then wipe dry.

NEVER USE abrasive chemicals or materials to clean PSPs.

Unsuitable cleaning solutions/methods may damage or destroy the PSPs or leave residues on the sensitive surface that may appear on the images.

3.4 Storage

- Unpacked, exposed to ambient light in the dedicated storage box
- Below 33°C / 80% RH and shielded from X-rays and ultraviolet radiation.
- If a PSP is stored for over 24 hours in a hygiene bag or in a location that is shielded from ambient light, the PSP must be erased, to remove any potential fogging, before being used to take an exposure.

3.5 Replacement

Replace a PSP if:

- the image shows marks, spots or dots, which still appear on images even after the PSP has been properly cleaned.
- the PSP is mechanically damaged (scratched) or badly bent.

3.5 Disposal

PSPs must be disposed of in accordance with all local, national and international regulations regarding the disposal of non-environmentally friendly or hazardous materials.

Phosphor substance, under the top coat, on the sensitive side of PSPs must not be swallowed.

4. Unit care and maintenance

WARNING

Switch the unit off and disconnect it from the main power supply before cleaning or disinfecting the unit.

Do not allow liquids to enter the unit.

4.1 Cleaning the unit

Use a non abrasive cloth moistened with either:

- cool or lukewarm water,
- soapy water,
- mild detergent,
- butylalcohol,
- or ethanol (ethyl alcohol) 70 - 96%

to clean the unit. After cleaning wipe the unit with a non abrasive cloth moistened with water.

Never use solvents or abrasive cleaners to clean the unit. Never use unfamiliar or untested cleaning agents. If you are not sure what the cleaning agent contains, DO NOT use it.

If you use a spray cleaning agent DO NOT spray it directly into the unit door.

4.2 Disinfecting unit

CAUTION

Wear gloves and other protective clothing when disinfecting the unit.

Wipe the unit with a cloth dampened with a suitable disinfectant solution such as ethanol 96%. Never use abrasive, corrosive or solvent disinfectants. All surfaces must be dried before the unit is used.

WARNING

Do not use any disinfecting sprays as the vapor could ignite and cause injury.

Disinfecting techniques for both the unit and the room where the unit is used must comply with all local and national regulations and laws concerning such equipment and its location.

4.3 Maintenance tasks

To ensure that the unit operates reliably throughout its service life and to maintain the warranty, the following maintenance procedures should be carried out:

- User maintenance tasks
- Preventative maintenance

User maintenance tasks

The user should regularly check and/or continuously monitor the following:

- i. Make sure that **ONLY** original Gendex Photo-stimulable Phosphor Plates, protective covers and hygiene bags are used. The manufacturer of the unit will not be held responsible for problems caused by using accessories from other manufacturers.
- ii. Visually check the condition of the IPs to ensure that they are not damaged in any way. Refer to section **4. Handling and care of imaging plates** for complete information on how to handle, clean and store IPs.
- iii. Make sure that the unit functions correctly in the same way as described in this manual.
- iv. If the unit starts to operate differently than described in this manual or starts to make abnormal noises, stop using the unit and call service.
- v. Make sure that all visible labels on the unit are intact and legible.
- vi. Take regular reference images to ensure that there are no visual changes in image quality. Use a test phantom (available from your distributor) and repeatable X-ray exposure techniques when taking the reference images. If you notice a change in image quality call service.

Preventative maintenance

Preventative maintenance is designed to ensure that the unit will operate reliably and with minimum service downtime during the service life of the unit.

Preventative maintenance has two levels:

Level 1 maintenance must be carried out every year or after 25,000 scans, whichever comes first.

Level 2 maintenance must be carried out every two years or after 50,000 scans, whichever comes first.

All preventative maintenance MUST be carried out by an approved service technician.

CAUTION:

Unauthorized maintenance may cause the unit to function incorrectly and cause degradation of image quality.

WARNING:

Removing unit covers and maintaining the unit without adequate training and expertise is dangerous.

There is high voltage and a laser inside the unit.

Maintenance must be carried out by approved service personnel only.

Refer to the service manual for full information on how to carry out the preventative maintenance tasks.

Preventative maintenance task	Frequency
Clean the unit and check all the accessories. Make sure that ONLY original INSTRUMENTARIUM DENTAL™ imaging plates, protective covers and hygiene bags are used. The manufacturer of the unit will not be held responsible for problems caused by using accessories from other manufacturers.	Level 1 maintenance. Yearly or after 25,000 scans (whichever comes first).
Check and calibrate the plate detector sensor.	
Check and calibrate the plate eject mechanism.	
Check and calibrate the mirror system.	
Check the firmware version.	
Take test images.	
Check the image viewing conditions and ambient lighting.	

Clean, adjust and if necessary replace the belts.	Level 2 maintenance. Every two years or after 50,000 scans (whichever comes first).
Clean and lubricate the plate carrier and guide rails.	
Check mechanical movements.	
Replace the erasing lamp.	

4.4 Repair

If the unit is damaged or malfunctions in any way it must only be repaired by service personnel authorized by the manufacturer of the unit.

4.5 Disposal

At the end of the useful working life of the unit and/or its accessories make sure that you follow national and local regulations regarding the disposal of the unit, its accessories, parts and materials. The unit includes some or all of the following parts that are made of or include materials that are non-environmentally friendly or hazardous:

- electronic circuit boards
- electronic components

5. Symbols that may appear on or in the unit



Name and address of the manufacturer



Date of manufacture



DANGEROUS VOLTAGE



LASER RADIATION



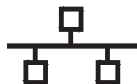
ATTENTION, Consult accompanying documents



Consult instructions for use



Direct current



Ethernet connector RJ45 straight cable



CE (0537) Symbol MDD 93/42/EEC
This unit is marked according to the Medical Device Directive 93/42/EEC (if the unit contains the CE mark)



ETL symbol



This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

6. Warnings and precautions

THE UNIT IS A CLASS 1 LASER PRODUCT

Note! When covers are removed the unit is a class 3B laser product – avoid exposure to the laser beam.

CAUTION - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure

- When handling photostimulable phosphor plates, protective covers and hygiene bags always take the appropriate hygiene measures and precautions to prevent cross contamination.
- The photostimulable phosphor plates are harmful if swallowed.
- Do not move or knock the unit when it is reading a photostimulable phosphor plate.
- This unit must only be used to read photostimulable phosphor plates supplied by the manufacturer and must not be used for any other purpose. NEVER use photostimulable phosphor plates, protective or hygiene bags from other manufacturers.
- This unit, or its accessories, must not be modified, altered or remanufactured in any way.
- Only the manufacturer's authorized service personnel are authorized to carry out maintenance and repair of the unit. There are no user serviceable parts inside the unit.
- Infection control procedures must be observed when using accessories, such as film holders, x-ray tube guides and imaging plates. When using accessories always follow the manufacturer's instructions on how to use the accessory and prevent cross contamination from one patient to another.
- This unit can interfere with other devices due to its EMC characteristics.
- Other devices can interfere with this unit due to their EMC characteristics.
- This unit complies with IEC 60601-1 standard. Accessory equipment connected to this device must be in compliance with the related nationally harmonized IEC standards.

- Unit not suitable for use in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- For ethernet connections, use an unshielded CAT6 LAN cable, so that multiple chassis must not be connected! The PC / Ethernet switch to which unit is connected to, should be approved appropriately (e.g. EN 60950, IEC 60950, UL 60950). After installation check that the IEC 60601-1 leakage current levels are not exceeded.
- In order to maintain safe and correct functioning of the unit, only the power supply unit (PSU) delivered with the unit or distributed by authorized dealers. Please refer to the unit technical specifications for a list of the PSUs.
- If this device will be used with 3rd party imaging application software not supplied by the manufacturer, the 3rd party imaging application software must comply with all local laws on patient information software. This includes, for example, the Medical Device Directive 93/42/EEC and/or FDA if applicable.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information.

Appendix A. Technical Specifications

A1. Unit

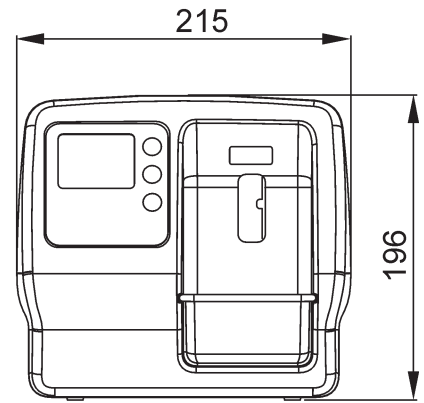
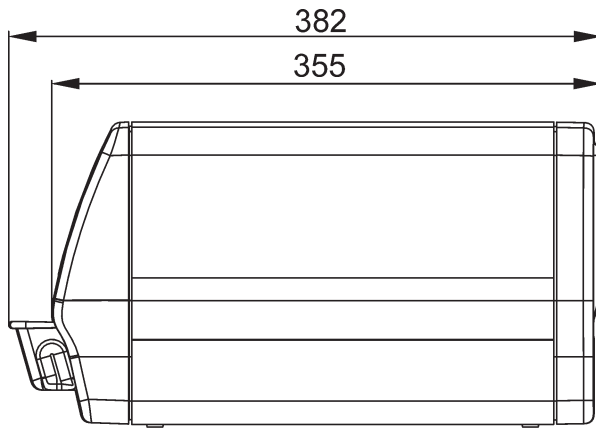
Intraoral laser scanning unit	
GXPS-500 Classification IEC60601-1	- Class 1 or 2 equipment depending on the classification of the PSU. No applied part. - Continuous operation - IPX0 (enclosed equipment without protection against ingress of liquids)
Laser Safety Classification	CLASS 1 LASER PRODUCT EN 60825-1 :2007
Dimensions (H x W x D)	196 mm x 215 mm x 382mm (7.7in x 8.5in x 15.0in)
Weight	9.8 – 10.3 kg (21.6 – 22.7 lb)
Power supply unit (PSU)	POWERBOX EMX 805121
Operating voltage	24 VDC (PSU: 100 – 240 VAC, 50/60 Hz)
Operating current	Less than 1.5 A
Pixel size, selectable	35 µm (Super), 64 µm (High)
Bit depth	14 bits grayscale
Clinical resolution	10 lp/mm
Spatial resolution	14.3 lp/mm
Interface cable	For Ethernet connections, use an unshielded CAT6 LAN cable, so that multiple chassis must not be connected! The PC / Ethernet switch to which unit is connected to should be approved appropriately (e.g. EN 60950, IEC 60950, UL 60950).
Operating environment	+10°C - +40°C, 30 – 90 RH%, 700 – 1060 mbar
Storage / transportation environment	-10°C – +50°C, 0 – 90 RH%, 500 – 1080 mbar

A2. Photostimulable Phosphor Plates and hygiene bags

Photostimulable phosphor plates (PSP)				
Size	Size 0	Size 1	Size 2	Size 3
Dimensions (mm)	22 x 31	24 x 40	31 x 41	27 x 54
Image size (pixels), 35 µm	628 x 885	685 x 1143	886 x 1171	771 x 1542
Image size (KB), 35 µm	1085	1529	2026	2322
Image size (pixels), 64 µm	484 x 344	625 x 375	641 x 484	844 x 422
Image size (KB), 64 µm	325	458	606	695
Storage environment	Photostimulable phosphor plates must be stored in their protective box below 33°C. The box must be kept closed to remain dust free.			
Material	Photo-stimulable phosphorous material uniformly coated on a support plastic material. Shielded with a top coat layer on the active surface and encapsulated with lacquer around edges. Imaging plates do not include phosphor.			
Disposal	Imaging plates are industrial waste and must be disposed of in accordance with local and national regulations concerning the disposal of such material. Never use damaged imaging plates.			


Hygiene bags	
Material	Food-grade polyethylene - Latex free
Packaging	Supplied in boxes
Disposal	Observe relevant national requirements.

A3. Main dimensions



Guidance and manufacturer's declaration – electromagnetic emissions		
The GXPS-500 is intended for use in the electromagnetic environment specified below. The customer or the user of the GXPS-500 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The GXPS-500 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 GXPS-500 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 emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The GXPS-500 is intended for use in the electromagnetic environment specified below. The customer or the user of the GXPS-500 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients/bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If use of the GXPS-500 requires continued operation during power mains interruptions, it is recommended that the GXPS-500 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 field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer’s declaration – electromagnetic immunity			
The GXPS-500 is intended for use in the electromagnetic environment specified below. The customer or the user of the GXPS-500 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the GXPS-500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$ <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^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 predicated 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 GXPS-500 is used exceeds the applicable RF compliance level above, the ICR-1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the GXPS-500.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the GXPS-500.			
The GXPS-500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GXPS-500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GXPS-500 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.			

Appendix B. Installation and setup

Installation and setup must only be carried out by service personnel trained and approved by the manufacturer of the unit.

B1. System installation

B1.1 Positioning the unit

Do not position the unit in direct sunlight or near bright light. Sunlight or bright light must not be allowed to shine directly on the unit door into which the PSPs are inserted.

Position the unit on a stable flat surface so that vibrations will not degrade the image quality. The unit can also be attached to a wall, under or on a shelf with the optional mounting kit.

The unit must not be positioned so that it is touching other equipment. It must not be placed on top of or under other equipment.

The unit can be positioned within the environment in which the patient is examined and treated (patient environment).

B1.2 Positioning the PC(s) (not supplied)

The PC(s) connected to the unit should not be used in the patient environment.

The minimum horizontal distance between the patient and the PC(s) is 4.5 ft (1.5 m).

The minimum vertical distance between the patient and the PC(s) is 6.5 ft (2.5 m).

B1.3 Other devices

DO NOT connect any other devices to the unit or the PC(s) connected to the unit that are:

- not part of the supplied system
- not supplied by the manufacturer of the unit
- not recommended by the manufacturer of the unit.

B2. Connecting the unit to a PC / LAN and configuring the unit

For information on how to connect the unit to a PC or LAN, refer to the documentation supplied with the **GxPicture Software Driver** for more information.

B3. Troubleshooting

PROBLEM

The unit does not come on. The unit's power on / off status light and display are off.

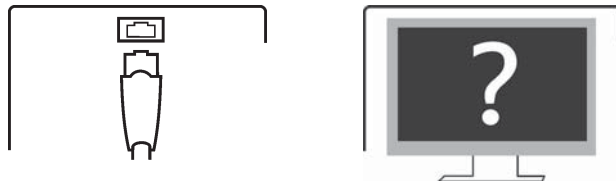
CAUSE / SOLUTION

The main power supply to the unit is off or the unit is not switched on.

- i. If the LED on the PSU is not on it is not receiving power from the mains. Switch the mains power on.
- ii. If the LED on the PSU is on switch the unit on.
- iii. If status light and display still do not come on check the unit's membrane control panel and cabling. Replace if faulty.

PROBLEM

Animation displaying either **Unit connection** or **GxPicture Interface** appear on the unit display and the unit will not work.



CAUSE / SOLUTION

- Defective RJ45 cable. Replace.

PROBLEM

The IP-connection between the unit and the PC does not work.

CAUSE / SOLUTION

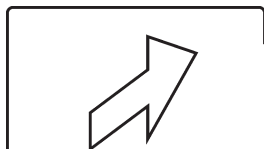
- i. Check that the **Direct** connection method was configured correctly. If all the settings are correct but the connection still does not work, use the **IP** connection method.
- ii. The unit has been configured to work with one PC only and does not recognize any other PCs. Reconfigure the system for multiple users.

PROBLEM

The unit is connected to the PC but cannot scan images.

CAUSE / SOLUTION

- i. Reserve the unit and check that it is configured for multiple users. If not, reconfigure the system.
- ii. If the **GxPicture Interface** animation appears it indicates that a patient has not been selected for the scanned image(s). Select a patient.
- iii. If the **Insert** animation appears on the unit display while inserting the PSP but the unit does not insert the PSP into the unit nor start scanning, the reflective sensor in the unit door is faulty (refer to the service manual).



PROBLEM

Local area network / subnet configuration problem

CAUSE / SOLUTION

- i. If the **GxPicture Interface** animation appears and cable(s) / router(s) are known to be okay ask your network administrator for assistance.

- ii. Conflict / mismatch IP-addresses and / or subnet mask of the unit / PC.
Use command <ipconfig> from the command prompt (**Start >> Run >> cmd** in Windows) to get information about the active network settings.
Change either the IP address of the PC or the unit so that they are both in the same subnet.
If the problem persists ask your network administrator for assistance.

- iii. Network connection not functioning or not stable due to LAN signal quality problems.
Install a network switch between the unit and PC or network socket.

PROBLEM

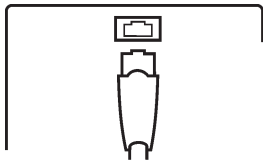
Ethernet link not active.

The Ethernet connection consists of correctly installed cabling and any switches and/or hubs used, basically the complete Ethernet link

If the link is active it does not necessarily mean that the unit is physically connected to PC. It only means that the unit is physically connected to something that is Ethernet compatible (hub, switch, another PC etc.)

CAUSE / SOLUTION

First remove and then reconnect the Ethernet cable between the unit and PC to see if this solves the problem.



- i. Physical connection is okay (link active), but the **GxPicture Interface** animation appears on the unit display. The unit is not configured correctly. Reconfigure.
- ii. Cabling not correct (link not active), and the **Unit connection** animation appears on the unit display. The unit is not physically connected to the PC. Connect the unit to the PC.
- iii. The PC's Ethernet connector(s) is faulty. There is usually a green link LED near the PC's Ethernet connector(s) on the NIC. If the LED is not on replace the NIC.

PROBLEM

The unit display is not active but the power on / off status light is on, green or yellow.

CAUSE / SOLUTION

- Green LED - defective display or its cabling.
Replace
- Yellow LED - unit is in standby (energy save) mode.

