

**LOGOS**  
IMAGING



# **Pixium Imaging System**

**Operator's Manual**

# Introducing the Pixium Portable System

Congratulations on your purchase of the Pixium Portable system. The Pixium Portable is a mobile radiography system that converts static radiographic images into clean digital images. This user guide will help you start using your Pixium Portable system for basic operations quickly and safely.

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## Regulatory Compliance and Safety

The Pixium Portable System complies to the following regulations and standards.

RoHS 2002/95/EC

ISO 14971

IEC 60601-1 3rd Ed : Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 3rd Ed : Medical electrical equipment - Part 1-2: Electromagnetic compatibility

IEC 60601-1-3 2nd Ed : Medical electrical equipment - Part 1-3: Radiation protection in diagnostic X-ray equipment

USA UL 60601-1 "Medical electrical equipment. Part 1 : General requirements for safety"; 1st edition, dated April 25, 2003

Canada CAN/CSA-C22.2 No. 601-1-M90 "Medical electrical equipments for safety", November 1990

Europe EN 60601-1 "Medical electrical equipment"

### **Bio-compatibility**

The Pixium Portable is compliant with the following standards related to bio-compatibility (in the frame of general medical regulations and standards).

NF EN ISO 10993-1, evaluation and trials

NF EN ISO 10993-5, cytotoxicity

NF EN ISO 10993-10

NF EN ISO 10993-11, systematic toxicity.

FDA Blue book memorandum #95-1, required biocompatibility training and toxicology profiles for evaluation of medical devices.

FDA CFR 21 part 58, good laboratory practices for non-clinical laboratory studies.

## Symbols

Be familiar with the following symbols that appear on this document so you can safely use the Pixium Portable.



This WARNING sign means that there is certain danger.



This PROHIBITION sign means that you must not...



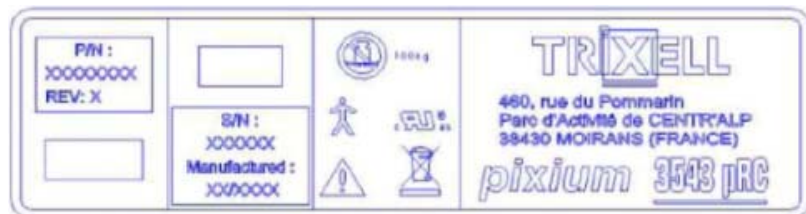
This MANDATORY ACTION sign means that you must...



This sign means that you should follow instructions given in the mentioned document.

## Labels

### Main Label



### Symbols



Attention, consult accompanying document



Recycling label

LED



Do not apply more than 100Kgs on detector



Applied equipment



Detector Status



WiFi Status (not Applicable)



Battery Status (Not Applicable)

## Environmental Information

This equipment has required the extraction and use of natural resources for its production. It may contain hazardous substances for health and environment. In order to avoid the dissemination of those substances in the environment and to diminish the pressure on natural resources, we encourage you to use the appropriate take-back systems. Those systems will reuse or recycle most of the materials of your end-of-life equipment in a sound way.

If you need more information on the collection, reuse and recycling systems, please contact your local or regional waste administrator. You can also contact your reseller for more information on the environmental performance of our products.

# Cautions

## Installation and Maintenance

Read the safety and operating instructions before operating the device.

Retain safety and operating instructions for future reference.

Adhere to all warnings on the device and in the operating instructions manual. Follow all instructions for operation and use.



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Only qualified personnel shall carry out the installation, the adjustment and the maintenance of the Pixium Portable.

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## Hazardous Substances



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Logos Imaging can ensure the recycling of the Pixium Portable. The product must be returned to Logos Imaging when such recycling is needed.

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The Pixium Portable includes materials that are potentially hazardous for human health in case of contact. These materials are:

Thallium-doped Cesium Iodide scintillator material (Thallium qty 1.4 g)

Lead protection plates (weight 0.32 kg)



In case of dismantling of the Pixium Portable, the local regulations regarding the hazardous substances must be followed and precautions must be taken to prevent damage to the health of people and to the environment.

## Operation

Observe the following cautions when operating the Pixium Portable.



The Pixium Portable is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.



The Pixium Portable does not offer protection against ingress of water. Never expose it to rain or moisture. Never use it near water - e.g. near a bathtub, washbasin, swimming pool, kitchen sink, laundry tub, or in a wet basement.



Two shock sensors are incorporated in the detector and visible when the back cover is opened. Those shock sensors are display a red color if the detector was subjected to a shock corresponding to a 70 cm drop height or higher. Logos Imaging does not guarantee the performance of the detector in any case if one of those sensors is red.

## LED

The LED output power is compliant to IEC 60825 Class-1 limitations, and emits continuous visible LED light at 650nm.

## Electromagnetic Compatibility (IEC 60601-1-2 Standard)

The installation and servicing of the Pixium Portable shall be carried out according to EMC information provided in this document.



The use of radiofrequency transmitters such as portable and mobile RF communication equipments close to the system can affect the operation of the Pixium Portable.



The use of cables and accessories other than those specified and/or delivered can involve an increased emission or decreased immunity of the Pixium Portable.

## General

In case of collision of the Pixium Portable with a tough surface or in case of rough shock, a visual inspection is required in order to detect any mechanical deformation. In such case, the use of detector must be considered as hazardous and the detector must be send back to after sale service for repairing.

The image quality is specified for a tilt of 45° max with respect to the X-ray beam axis.

Movement of the detector during the X-ray exposure that can cause blurred image

The Pixium Portable is designed to handle up to 150 kg uniformly spread over the top face or 100 kg concentrated on a small surface (40 mm).

The Pixium Portable is designed to cope with falls up to 75 cm without any damage. In case of fall above this height, the use of detector must be considered as hazardous and the detector must be send back to after sale service for repairing.

# System Contents

## Standard Items

1. Portable detector
2. Detector interface box
3. System interface box
4. Interface box stands (2 each)
5. Interface power supplies (2 each)
6. Wireless X-ray firing device for Golden sources
7. Logos Imaging software
8. Detector cable
9. System cable
10. Carrying case

## Optional Items

1. Golden Engineering XR200 or XRS-3
2. Notebook computer
3. Detector stand

# Pixium Portable Detector

## Detector Description

The Pixium Portable detector consists of a metal housing with a carbon fiber composite window for X-ray input, and internal lead shielding to protect the electronics against X-rays (not intended for user protection against X-rays). It also integrates a handle within the housing for easy manipulation, LED indicator for internal status, and connector for a dedicated cable.

## Identification

The identification labels on the back side of the detector housing provide information for :

- Part number with revision code (P/N)
- Serial number (S/N)
- Manufacturing date (DC)
- Warnings and cautions

## Input Window

The X-ray input window (upper side of the Pixium Portable detector) is made of a carbon fiber composite substrate to protect the sensitive layer and active array of the detector. This input window can withstand a maximum weight of 100 kg over a circle of 4 cm diameter, and 150 kg uniformly distributed over the complete surface.



FRAGILE : Do not push on the upper face of the detector.

**Cable Connection** A connector is accessible on the right side of the detector housing (close to the handle), in order to connect the detector cable from the Panel interface box.

**Cooling the Detector** The detector is equipped with a temperature sensor used to measure the FE electronics temperature. There is no particular requirement for the detector cooling, provided natural airflow is allowed on the back face of the detector housing.

**NOTE:** If the detector overheats, the Temperature Limit icon in the Logos Imaging Application will turn Red.

## Working with the Pixium Portable

This section provides the information you need in order to operate the Pixium Portable system.

The connection areas are accessible from the outside of the detector and the outside of the interface boxes (removing any covers voids the warranty).

During setup, ensure that no sharp corners or edges can damage the cabling.

**CAUTION!**

- Do not connect unspecified electrical devices to the system.
- Use only grounded electrical connections

**System Interface Box Connections**



**Panel Interface Box Connections**



## Unpacking the System

1. Remove the detector from the carrying case.
2. Lift the detector tray from the carrying case.
3. Remove the two interface boxes from the carrying case ensuring that the wireless radio is connected to the Radio connector on each interface box.
4. Attach the interface boxes to the interface stands.
5. Remove the computer from the carrying case.
6. Remove the detector cable, system cable, and wireless X-ray device from the cable bag.

## Charging the Interface Box Batteries

1. Connect the power supply to the Charger port on the interface box.
2. Connect the power supply to a power source.
3. Switch the interface switch to the OFF position.

Note: The interface battery does not charge when the interface power switch is in the ON position.

## Connecting the Detector (Wireless Mode)

4. Connect the system cable to an Ethernet port on the computer.
5. Connect the other end of the system cable to the Laptop port on the Station interface box.
6. Connect the detector cable to the Panel port on the Panel interface box.
7. Connect the other end of the detector cable to the Pixium detector.
8. Connect the wireless X-ray device to the 5 pin LEMO connector on the Golden Engineering X-ray machine.
9. Turn power on to the computer.
10. Switch power on to the Station interface box.
11. Switch power on to the Panel interface box.
12. Wait 20 seconds for the Pixium detector's LED to turn green.

## The LED Indicator Lights

The lights on the front right of the Pixium Portable detector indicate the current status of the system.



LED Color	Status
	Detector is ready to acquire an image
OFF	Image acquisition is in process or there is no power to the detector
	Detector is not ready to acquire an image.

## Acquiring an Image



### Starting Logos Software from the Desktop

1. Find the **Logos.exe** shortcut on the desktop.
2. Double click the shortcut to start the application.
3. The application starts and displays the workspace.

### Set the Pixium as the Default Scanner

1. On the File menu, click Preferences.
2. Select the Pixium from the Default Scanner drop down list.
3. Click OK.
4. The Logos Image button in the Project Manager window will use the default device for image acquisition.

### Adding and Image

1. Select the appropriate project database from the Project File Location drop-down list on the right side of the top menu bar or select All Project Locations.
2. In the Project Manager pane, create a Project, or select the name of the project you want to open from the Project Manager drop-down list.
3. Switch power on to the X-ray machine.
4. Click Logos Image.
5. The Pixium dialog will appear and show a status message indicating that the device is connecting. When the Pixium is connected, the X-ray icon will become active .
6. Select the appropriate X-ray machine from the drop down-menu.
7. Set the number of pulses to fire by typing the correct number in the pulses field.
8. Click the X-ray icon  to fire the X-ray.
9. Upon completion of the X-ray exposure, the Pixium will transfer the image to the Logos software, and a preview window will appear.
10. The image can then be imported to the Project database for further editing or deleted.

### Editing Images

Refer to the Logos Imaging Software Application Manual for image editing information.

# Cleaning the Pixium Portable System

## Cleaning Procedure

The detector housing can be cleaned using a sweet towel, with respect to ESD safety conditions. Note that the detector is not watertight.

The detector remains functional under limited exposure to the liquids defined in the table below.

**Limited exposure means limited to the exposure level defined within the standard of water tightness guaranteed for the concerned part.**

## Liquid Exposure Guidelines

Active substance class	Cleaning agent	Concentration
	Water	
Aldehyde	Lysofomin 3000	3 vol%
Quaternary compounds	Biguanid Fläche	4 vol%
Guanidine derivates	Bacillocid spezial	6 vol%
Peroxide compounds	Dismozon pur	4 weight%
Pyridine derivates	Spray active	undiluted
Chlorine derivates	Clorina	1 weight%
Alcohol	Ethyl alcohol	undiluted
Benzine	Benzine	undiluted
Household dishwashing liquid	Grün und Mild	10 vol%
	Isopropanol	100%
	Ethanol	70%
	Chlorehexidine 0,5% in 70% Ethanol	0.5%
	Haemosol in 1 liter water	1%
	Chlorine : 250ppm in 1 liter water	250 ppm
	Artificial sweat (5% KCL, pH=3)	5%
	Natriumchloride 0,9% (NaCL)	0.9%
	Coffee with milk and sugar	
	Iodine 1% in 70% ethanol	1%
	Hexabrix 320	

# Technical Specifications

## Physical Dimensions

Length	402.0 mm
Width	488.4 mm
Thickness	25.1 mm
Weight	4.4 kg
Active Matrix	432.0 mm x 345.6 mm

## Transport and Storage

The transport and storage environmental conditions (detector packed in its original packing) are:

Temperature range:	-10 °C to + 55 °C
Relative humidity:	5 % R.H. to 95 % R.H
Pressure:	500 mbar to 1100 mbar
Bumps:	10 g max @ half-sine / 16 ms / 1000 times / 6 directions (unpacked detector) 25 g max @ half-sine / 6 ms / 1000 times / 6 directions (packed detector)
Vibrations:	2 g max @ 10-150 Hz, displacement 0.30 mm peak-peak / 3 axis / 10 sweeps / 1min/oct. (unpacked detector) 10 g max @ 10-150 Hz, displacement 1.4 mm peak-peak / 3 axis / 10 sweeps / 1min/oct. (packed detector)
Drop:	55 cm height (packed detector)

## Operation

The operation environmental conditions are:

Temperature range for full performance:	+ 18 °C to + 30 °C
Temperature range for functional performance:	+ 10 °C to + 35 °C (functional means only “no image link loss” / performance is not guaranteed)
Relative humidity:	20 % R.H. to 75 % R.H.
Pressure:	700 mbar to 1100 mbar

Vibrations:	0.3 g max @ 10-200 Hz / 3 axis / 2 sweeps / 1min/oct. (image quality not guaranteed)
Drop:	70 cm height

## Guidance and Manufacturer's Declaration - EMC

The Pixium Portable is intended for use in the electromagnetic environment specified below. The customer or the user of the Pixium Portable should assure that it is used in such an environment.



The Pixium Portable should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Pixium Portable should be observed to verify normal operation in the configuration in which it will be used.

### Emissions Test

Emissions test declarations for the Pixium Portable (detector only) are specified in Table 8.

**TABLE 8: Emissions Test**


Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The Pixium Portable detector 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 A	The Pixium Portable detector is suitable for use in all establishments, with the following exceptions:
Harmonic emissions IEC 61000-3-2	Not Applicable	<ul style="list-style-type: none"> <li>▪ Domestic,</li> <li>▪ Establishments directly connected to a public low-voltage power supply network that supplies buildings used for domestic purposes.</li> </ul>
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

## Immunity Test

**TABLE 9: Immunity Test**

<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment Guidance</b>
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 transient/burst 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	Power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	The Pixium Portable is powered by a 18 V DC source.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% <i>UT</i> (>95% dip in <i>UT</i> ) for 0.5 cycle 40% <i>UT</i> (60% dip in <i>UT</i> ) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i> ) for 25 cycles <5% <i>UT</i> (>95% dip in <i>UT</i> ) for 5 sec.	<5% <i>UT</i> (>95% dip in <i>UT</i> ) for 0.5 cycle 40% <i>UT</i> (60% dip in <i>UT</i> ) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i> ) for 25 cycles <5% <i>UT</i> (>95% dip in <i>UT</i> ) for 5 sec.	The Pixium Portable is powered by a 18 V DC source.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	N/A	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

**TABLE 9: Immunity Test (Continued)**

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Pixium Portable, including cables, than the recommended separation distance calculated from the - equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.17 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.33 \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

- Note:**
- At 80 MHz and 800 MHz, the higher frequency range applies
  - Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m
  - Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pixium Portable is used exceeds the applicable RF compliance level above, the

performance of the Pixium Portable should be observed to verify normal operation. If abnormal performance is observed, corrective measures may be necessary, such as re-orienting or relocating the Pixium Portable.

## Recommended Separation Distances

With the help of your service representative, you can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pixium Portable as recommended in Table 10, according to the maximum output power of the communications equipment.

**TABLE 10:** Recommended Separation Distances: Separation distance (in meters) according to frequency of transmitter.

Rated Maximum Output Power of Transmitter (in watts)	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.4
100	11.7	11.7	23.3

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

**NOTE:** 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.

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