THALES
Microwave & Imaging Sub-Systems
460 rue du Pommarin
38430 Moirans - France
Tel: +33 4 76 57 52 80

PIXIUM DYNAMIC X-RAY FLAT PANEL DETECTORS

END USER MANUAL

CE 0123

OPEN

Table Of Contents

1. DOCUMENT HISTORY

Revision	Status	Date	Modification
-	Approved	September 2022	Creation
A	Approved	July 2023	Update for MDR submission
B	Approved	August 2023	• Add PIXIUM SURGICAL 2121S-AU2 F • *"**Symbols**"*, add AC voltage, CHP/REP, TX/RX and minor test modification about serial number
C	Approved	April 2024	• "***Environment Operating, Storage And Handling Conditions***", correct min temperature to 35°C for non guaranteed image quality specification • *"**Environment Operating, Storage And Handling Conditions**"*, add 0°C-10°C range for 3030S and 3030S-AU for non guaranteed image quality specification. • *"**Regular Maintenance**"*, add information. • *"**Dark Calibration**"*, add alert notices. • *"**Environment Operating, Storage And Handling Conditions**"*, add humidity (non condensing) information for FL4, F5B and F5 • *"**Product Scope**"*, header correction of compatibility matrix to improve readability • *"**Medical Devices Applications**"*, *"**Indications**"*, useless information removed
D	Approved	October 2024	• Add PIXIUM SURGICAL 2121S-HDi • Add PIXIUM SURGICAL 3131S-HDi

2. SYMBOLS

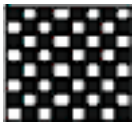
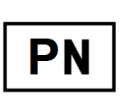
- Read the safety and operating instructions before operating the device.
- Retain safety and operating instructions for future reference.
- Adhere to all warnings on the device and in the operating instructions manual.
- Follow all instructions for operation and use

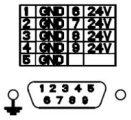
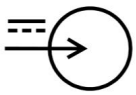
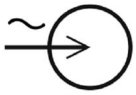
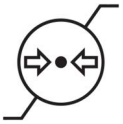
2.1. End User Manual Symbols Definition

	**Caution** Caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Dangerous voltage
	**General mandatory action** Risk to people not following the mandatory action specified by the supplementary sign
	**General prohibition** Risk to people specified by the supplementary sign
	**Reference** Indicates the need for the user to consult the i*nstructions for use*
	**Note** Read carefully this note. Important information is given.
	CE marking of conformity.
	**Electrostatic sensitive device** To indicate packages containing electrostatic sensitive devices, or to identify a device or a connector that has not been tested for immunity to electrostatic discharge. Procedure is required to prevent any damage.
	Protective Earth (Ground).

	Earth (Ground).

2.2. Labels And Packaging Symbol Definition

	Indicates the item is a *medical device*
	Indicates the *medical device manufacturer*
	Serial Number symbol followed by the serial number of the product (8 alpha-numeric digits and barcode 128)
	Indicates a carrier that contains unique device identifier information
	Data Matrix code (UDI)
	Indicates the date when the medical device was manufactured in France.
	Indicates the date when the device was manufactured. The date code in the format YYYY-MM-DD • YYYY = Year - 4 digits • MM = Month - 2 digits • DD = Day - 2 digits
	Part number. To identify the manufacturer's part number of the detector.
	Indicates the manufacturer’s catalogue number so that the medical device can be identified
	UL Recognized Component Mark for Canada and the USA
	CE marking of conformity provided by TÜV SÜD notified body

	WEEE Conformity symbol (recycling)
	9-pin D-Sub connector for power supply.
	Rated power input (DC), followed by powering information (DC xx V, x A).
	Rated power input (AC), followed by powering informationowering information (AC 100/240 V 2/1 A 60/50 Hz).
	Protective Earth (Ground).
	Earth (Ground).
	Indicates the range of atmospheric pressure 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 temperature limits to which the medical device can be safely exposed.
	Model Number, indicates the product family followed by the product family
	**Caution** Caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Refer to instruction manual/booklet to signify that the instruction manual/booklet must be read

	includes "Pb" to inform that detector include lead
	No activated mobile phone to prohibit activated mobile phones
Rx Only	Indicates that equipment shall be used by professional.
	Indicates the representative name and address in Switzerland
	Indicates there is optical link
	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.
	Indicates the number of pieces in the package.
	Indicates that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.
	Indicates that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.
	Indicates the actual dimensions.
	Indicates the weight.
	Indicates the weight of an object that may be lifted or is being lifted.

	Indicates correct upright position of the transport package.
	Indicates that the device must not be used if the package holding the device is damaged, for example on packaging of medical devices.
	Indicates a general warning. When used a supplementary sign give further information about the hazard.
	Indicates packages containing moisture sensitive devices, or to identify a device or a connector that has not been tested for immunity to moisture.
	To indicate that the contents of the transport package are fragile and the package shall be handled with care.
	To indicate that the transport package shall be kept away from rain and in dry conditions.

3. GLOSSARY

Name	Definition
PixDyn	Name of the standard Thales Message-based Protocol (MP) suitable for all the surgical dynamic Pixium flat panel detectors proposed by Thales. This Message-based Protocol provides functionalities to the OEM system such as detector control, image acquisition, calibration of the system, image pre-processing and service information.
PixDyn Lite	Refers to a PixDyn version installed directly in the Host PC.
Dynamic SW FL	Name of the standard Thales software suitable for Pixium 4343 FL3 flat panel detector proposed by Thales. This software provides functionalities to the OEM system such as detector control, image acquisition, calibration of the system, image pre-processing and service information.
Dynamic SW RF	Name of the standard Thales software suitable for Pixium 4343 F4 flat panel detector proposed by Thales. This software provides functionalities to the OEM system such as detector control, image acquisition, calibration of the system, image pre-processing and service information.
Pixium	Patented generic name for all Thales flat panel digital detectors (manufactured by Trixell)
Pixium 2121S-HDi	Refers to the 21 x 21 cm X-ray flat panel detector alone with an IGZO plate with a 109 µm pixel size.
PIXIUM SURGICAL 2121S-HDi	Refers to a medical device including a Pixium 2121S-HDi detector and PixDyn software.
PIXIUM SURGICAL 2121S-HDi (P1)	Refers to a medical device including a Pixium 2121S-HDi detector and PixDyn software running under Windows.
Pixium 2121S-A	Refers to the 21 x 21 cm X-ray flat panel detector alone with an a-Si plate with a 154 µm pixel size.
PIXIUM 2121S-A	Refers to a medical device including a Pixium 2121S-A detector and PixDyn software.
PIXIUM SURGICAL 2121S Option A	Refers to a medical device including a Pixium 2121S-A detector and PixDyn software.
PIXIUM SURGICAL 2121S Option A (PU ALPHA)	Refers to the package including PixDyn running on a PROCESSING UNIT ALPHA and a Pixium 2121S-A.
PIXIUM SURGICAL 2121S Option A (PIXDYN LITE)	Refers to the package including PixDyn running on a Host PC and a Pixium 2121S-A
Pixium 2121S-AU	Refers to the 21 x 21 cm X-ray flat panel detector alone with option A (a-Si plate) with a 200 µm pixel size.
PIXIUM 2121S-AU	Refers to a medical device including a Pixium 2121S-AU detector and PixDyn software.
PIXIUM SURGICAL 2121S Option AU	Refers to a medical device including a Pixium 2121S-AU detector and PixDyn software.

Name	Definition
PIXIUM SURGICAL 2121S Option AU (PIXDYN LITE)	Refers to the package including PixDyn running on a Host PC and a Pixium 2121S-AU.
PIXIUM SURGICAL 2121S Option AU (PU ALPHA)	Refers to the package including PixDyn running on a PROCESSING UNIT ALPHA and a Pixium 2121S-AU.
Pixium 2121S-AU2	Refers to the 21 x 21 cm X-ray flat panel detector alone an a-Si plate with a 200 µm pixel size.
PIXIUM SURGICAL 2121S-AU2 F	Refers to a medical device including a Pixium 2121S-AU2 detector manufactured in France and PixDyn software.
PIXIUM SURGICAL 2121S-AU2 F (P1)	Refers to a medical device including a Pixium 2121S-AU2 detector manufactured in France and PixDyn software running under Windows.
PIXIUM SURGICAL 2121S-AU2 F (P2)	Refers to a medical device including a Pixium 2121S-AU2 detector manufactured in France and PixDyn software running under Ubuntu.
PIXIUM SURGICAL 2121S-AU2 F (PIXDYN LITE)	Refers to the package including PixDyn running on a Host PC and a Pixium 2121S-AU2.
Pixium 3030S-A	Refers to the 30 x 30 cm X-ray flat panel detector alone with an a-Si plate 154 µm pixel size.
PIXIUM 3030S-A	Refers to a medical device including a Pixium 3030S-A detector and PixDyn software.
PIXIUM SURGICAL 3030S Option A	Refers to a medical device including a Pixium 3030S-A detector and PixDyn software.
PIXIUM SURGICAL 3030S Option A (PU ALPHA)	Refers to the package including PixDyn running on a PROCESSING UNIT ALPHA and a Pixium 3030S-A.
PIXIUM SURGICAL 3030S Option A (PIXDYN LITE)	Refers to the package including PixDyn running on a Host PC and a Pixium 3030S-A
Pixium 3030S-AU	Refers to the 30 x 30 cm X-ray flat panel detector alone with option A (a-Si plate) with a 200 µm pixel size.
PIXIUM 3030S-AU	Refers to a medical device including a Pixium 3030S-AU detector and PixDyn software.
PIXIUM SURGICAL 3030S Option AU	Refers to a medical device including a Pixium 3030S-AU detector and PixDyn software.
PIXIUM SURGICAL 3030S Option AU (PIXDYN LITE)	Refers to the package including PixDyn running on a Host PC and a Pixium 3030S-AU.
PIXIUM SURGICAL 3030S Option AU (PU ALPHA)	Refers to the package including PixDyn running on a PROCESSING UNIT ALPHA and a Pixium 3030S-AU.
Pixium 3131S-HDi	Refers to the 31 x 31 cm X-ray flat panel detector alone with an IGZO plate with a 109 µm pixel size.
PIXIUM SURGICAL 3131S-HDi	Refers to a medical device including a Pixium 3131S-HDi detector and PixDyn software.
PIXIUM SURGICAL 3131S-HDi (P1)	Refers to a medical device including a Pixium 3131S-HDi detector and PixDyn software running under Windows.

Name	Definition
Pixium 4343 FL3	Refers to the 43 x 43 cm X-ray flat panel detector alone with an a-Si plate with a 148 µm pixel size.
PIXIUM 4343 FL3	Refers to the medical device including Dynamic SW FL running on a PROCESSING UNIT RF 4343 FL and a Pixium 4343 FL3
PIXIUM RF 4343 FL3	Refers to the medical device including Dynamic SW FL running on a PROCESSING UNIT RF 4343 FL and a Pixium 4343 FL3.
Pixium 4343 FL4	Refers to the 43 x 43 cm X-ray flat panel detector alone
PIXIUM 4343 FL4	Refers to a medical device including a Pixium 4343 FL4 detector and PixDyn software.
PIXIUM RF 4343 FL4	Refers to a medical device including a Pixium 4343 FL4 detector and PixDyn software.
PIXIUM RF 4343 FL4 (PU ALPHA)	Refers to the package including PixDyn running on a PROCESSING UNIT ALPHA and a Pixium 4343 FL4
PIXIUM RF 4343 FL4 (PIXDYN LITE)	Refers to the package including PixDyn running on a Host PC and a Pixium 4343 FL4
Pixium 4343 F4	Refers to the 43 x 43 cm X-ray flat panel detector alone with an a-Si plate with a 148 µm pixel size.
PIXIUM 4343 F4	Refers to the medical device including Dynamic SW RF running on a PROCESSING UNIT RF 4343 and a Pixium 4343 F4
PIXIUM RF 4343 F4	Refers to the medical device including Dynamic SW RF running on a PROCESSING UNIT RF 4343 and a Pixium 4343 F4
Pixium 4343 F5	Refers to the 43 x 43 cm X-ray flat panel detector alone
PIXIUM 4343 F5	Refers to a medical device including a Pixium 4343 F5 detector and PixDyn software.
PIXIUM RF 4343 F5	Refers to a medical device including a Pixium 4343 F5 detector and PixDyn software.
PIXIUM RF 4343 F5 (PIXDYN LITE)	Refers to the package including PixDyn running on a Host PC and a Pixium 4343 F5
Pixium 4343 F5 B	Refers to the 43 x 43 cm X-ray flat panel detector alone
PIXIUM 4343 F5 B	Refers to a medical device including a Pixium 4343 F5 B detector and PixDyn software.
PIXIUM RF 4343 F5 B	Refers to a medical device including a Pixium 4343 F5 B detector and PixDyn software.
Pixium 3040F	Refers to the 30 x 40 cm X-ray flat panel detector alone with option A (a-Si plate) with a 154 µm pixel size.
PIXIUM 3040F	Refers to a medical device including a Pixium 3040F detector and PixDyn software.
PIXIUM DYNAMIC 3040 Option F	Refers to a medical device including a Pixium 3040F detector and PixDyn software.

Name	Definition
PIXIUM DYNAMIC 3040 Option F (PIXDYN LITE)	Refers to the package including PixDyn running on a Host PC and a CONVERTER 5G and a Pixium 3040F
Pixium 2630	Refers to the 26 x 30 cm X-ray flat panel detector alone with an a-Si plate with a 184 µm pixel size for CBCT applications.
PIXIUM 2630	Refers to a medical device including a Pixium 2630 detector, a CONVERTER 2630 and PixDyn software
PIXIUM 2630 CB	Refers to a medical device including a Pixium 2630 detector, a CONVERTER 2630 and PixDyn software.
CONVERTER 2630	Refers to the converter of optical signal to gigabyte Ethernet signal placed between the Pixium 2630 and the Host PC.
CONVERTER 5G	Refers to the converter of optical signal to gigabyte Ethernet signal placed between a detector (if applicable) and the Host PC
PROCESSING UNIT ALPHA	Refers to a processing box with embedded PixDyn software. The PROCESSING UNIT ALPHA is responsible for the real time pre-processing.
PROCESSING UNIT RF 4343	Refers to a processing box with embedded Dynamic SW RF or software. The PROCESSING UNIT RF 4343 is responsible for the real time pre-processing correction of acquired image.
PROCESSING UNIT RF 4343 D	Refers to a processing box with embedded Dynamic SW RF or software. The PROCESSING UNIT RF 4343 D is responsible for the real time pre-processing correction of acquired image.
PROCESSING UNIT RF 4343 FL	Refers to a processing box with embedded Dynamic SW FL or software. The PROCESSING UNIT RF 4343 FL is responsible for the real time pre-processing correction of acquired image.
PROCESSING UNIT RF 4343 FL D	Refers to a processing box with embedded Dynamic SW FL or software. The PROCESSING UNIT RF 4343 FL D is responsible for the real time pre-processing correction of acquired image.

4. DEVICE INFORMATION

⚠	In case of collision of the detector with a tough surface or in case of rough shock, a visual inspection is required 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 repair.

⚠	In case of earthquake, the Product must be inspected before being reused.

4.1. Product Scope

4.1.1. Medical Devices

The present manual applies to the following **Medical Devices**:

- PIXIUM SURGICAL 2121S family:
  - PIXIUM SURGICAL 2121S Option A
  - PIXIUM SURGICAL 2121S Option AU
  - PIXIUM SURGICAL 2121S-AU2
  - PIXIUM SURGICAL 2121S-AU2 F
  - PIXIUM SURGICAL 2121S-HDi
- PIXIUM SURGICAL 3030S family
  - PIXIUM SURGICAL 3030S Option A
  - PIXIUM SURGICAL 3030S Option AU
- PIXIUM SURGICAL 3131S family:
  - PIXIUM SURGICAL 3131S-HDi
- PIXIUM DYNAMIC 3040 family
  - PIXIUM DYNAMIC 3040 Option F
- PIXIUM RF 4343 FL family
  - PIXIUM RF 4343 FL3
  - PIXIUM RF 4343 FL4
- PIXIUM RF 4343 family
  - PIXIUM RF 4343 F4
  - PIXIUM RF 4343 F5
  - PIXIUM RF 4343 F5 B
- PIXIUM 2630 family:
  - PIXIUM 2630 CB

4.1.2. Dynamic Flat Panel Detectors

The present User Manual applies to the following **Dynamic Flat Panel Detectors**:

- PIXIUM SURGICAL 2121S family:
  - Pixium 2121S-A
  - Pixium 2121S-AU
  - Pixium 2121S-AU2

  - Pixium 2121S-HDi

- PIXIUM SURGICAL 3030S family:
  - Pixium 3030S-A
  - Pixium 3030S-AU
- PIXIUM SURGICAL 3131S family:
  - Pixium 3131S-HDi
- PIXIUM DYNAMIC 3040 family:
  - Pixium 3040F
- PIXIUM RF 4343 FL family:
  - Pixium 4343 FL3
  - Pixium 4343 FL4
- PIXIUM RF 4343 family:
  - Pixium 4343 F4
  - Pixium 4343 F5
  - Pixium 4343 F5 B
- PIXIUM CBCT 2630 family:
  - Pixium 2630

4.1.3. Accessories

The present User Manual applies to the following **Processing Units:**

- PROCESSING UNIT ALPHA
- PROCESSING UNIT ALPHA-I
- PROCESSING UNIT RF 4343
- PROCESSING UNIT RF 4343 D
- PROCESSING UNIT RF 4343 FL
- PROCESSING UNIT RF 4343 FL D

The present User Manual applies to the following **Converters:**

- CONVERTER 5G
- CONVERTER 2630

4.1.4. Compatibility Matrix

Detectors	Accessories							
	PROCESSING UNIT ALPHA	PROCESSING UNIT ALPHA-I	CONVERTER 5G	CONVERTER 2630	PROCESSING UNIT RF 4343	PROCESSING UNIT RF 4343 D	PROCESSING UNIT RF 4343 FL	PROCESSING UNIT RF 4343 FL D
Pixium 2121S-A	X	X						
Pixium 2121S-AU	X							
Pixium 2121S-AU2								
Pixium 2121S-HDi								
Pixium 3030S-A	X	X						
Pixium 3030S-AU	X							
Pixium 3131S-HDi								
Pixium 3040F			X					
Pixium 4343 F4					X	X		
Pixium 4343 F5								
Pixium 4343 F5 B								
Pixium 4343 FL3							X	X
Pixium 4343 FL4	X							
Pixium 2630				X				

Detectors	Software		
	PixDyn on Host PC	Dynamic SW RF	Dynamic SW FL
Pixium 2121S-A	X		
Pixium 2121S-AU	X		
Pixium 2121S-AU2	X		
Pixium 2121S-HDi	X		
Pixium 3030S-A	X		

Detectors	Software		
Pixium 3030S-AU	X		
Pixium 3131S-HDi	X		
Pixium 3040F	X		
Pixium 4343 F4		X	
Pixium 4343 F5	X		
Pixium 4343 F5 B	X		
Pixium 4343 FL3			X
Pixium 4343 FL4	X		
Pixium 2630	X		

Conditions of compatibility of PIXIUM DYNAMIC detectors / accessories with others components of radiologic system are communicated directly to OEM or retrofitters. It is their responsibility to respect these conditions during integration.

4.2. Medical Devices Applications

	Pixium Dynamic Detectors are intended for general radiographic and/or fluoroscopic imaging of the whole body.

4.2.1. Medical Devices using PixDyn on Host PC

The PIXIUM 2121S-A,PIXIUM 2121S-AU,PIXIUM SURGICAL 2121S-AU2 F,PIXIUM SURGICAL 2121S-HDi,PIXIUM 3030S-A,PIXIUM 3030S-AU,PIXIUM SURGICAL 3131S-HDi,PIXIUM 3040F,PIXIUM 4343 FL4,PIXIUM 4343 F5,PIXIUM 4343 F5 B,PIXIUM 2630 flat panel detectors detect and convert the dynamic X-ray images into digital images that will be processed by the PixDyn software running on a Host PC.

4.2.2. Medical Devices using PixDyn on PROCESSING UNIT ALPHA

The PIXIUM 2121S-A, PIXIUM 2121S-AU, PIXIUM 3030S-A, PIXIUM 3030S-AU, PIXIUM 4343 FL4 flat panel detectors detect and convert the dynamic X-ray images into digital images that will be processed by the PixDyn software running on a PROCESSING UNIT ALPHA or PROCESSING UNIT ALPHA-I. Those systems are intended to be used in diagnostic or interventional product.

4.2.3. Medical Devices using PROCESSING UNIT RF 4343 or PROCESSING UNIT RF4343 FL

The PIXIUM 4343 F4 using Dynamic SW RF

The PIXIUM 4343 FL3 using Dynamic SW FL

4.3. Product Legal Manufacturer and Manufacturing Site

THALES AVS FRANCE SAS
75-77 Avenue Marcel Dassault
33700 MERIGNAC FRANCE

Manufactured by THALES AVS FRANCE SAS
460 rue du Pommarin 38430 MOIRANS FRANCE

4.4. Intended User

	Pixium Detectors are intended to be integrated by technical employees of Original Equipment Manufacturer having an expertise in the integration of flat panel detector. The OEM integrator can be located worldwide and has a working level of English. Thales does not distribute the detectors to the end-users but only to OEMs (or retro-fitters) who are responsible of the product integration into the complete system. The clinical end-users are intended to be qualified/trained doctors or technicians

4.5. Use Environments

PXIUM DYNAMIC detectors are intended to be used in various clinical environments at a hospital, such as Interventional radiology suite (IR suite) but are not limited to:

- surgery
- vascular
- orthopaedic
- neurology
- oncology
- ...

These rooms are equipped with controlled air-conditioning, normal room lighting or even additional lights such as OR-lights for additional illumination during surgeries.

Since the PIXIUM DYNAMIC detectors are sold to OEM in order to be implemented into radiology systems, there is another use environment: OEM laboratory. These laboratories are used for testing, verifying and validating imaging systems.

4.6. Operating Principle

The converter is a small electronic sub-assembly. It is necessary with some detectors because it can ensure interface with detector optical input/output, converts it into a Gig-E signal and an electrical command line for X-ray synchronization.

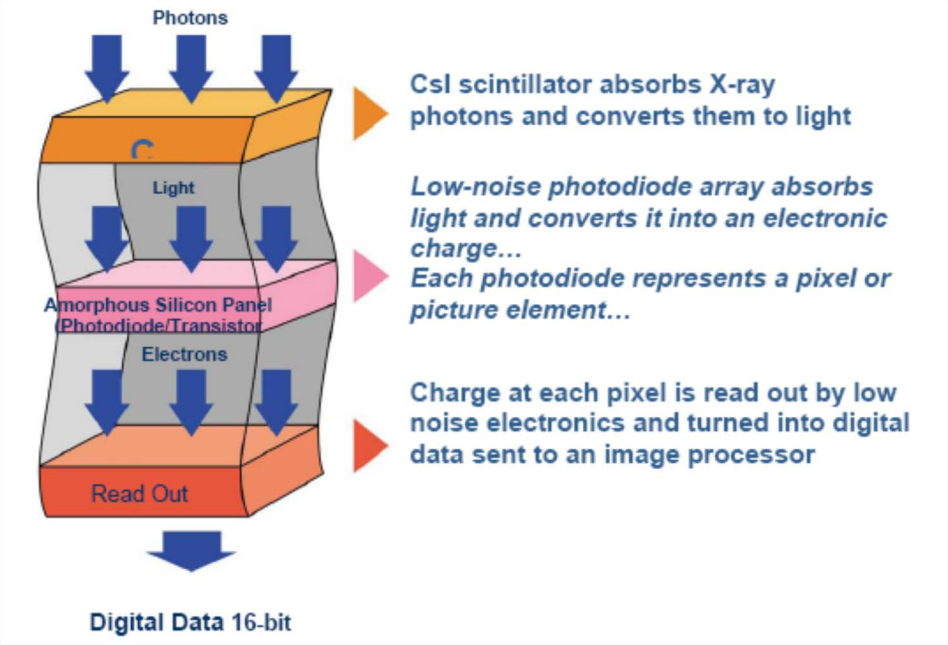
The Processing Uni is a mini-PC ensuring image processing (from raw image to clean image) at video rate and providing Ethernet link.

X-ray Flat Panel Detectors (FPD) are intended to convert a low-intensity X-ray image into a digital image.

As presented in the figure below, the intended purpose of the device is accomplished through the function of each of the following components, corresponding to a typical architecture for the various references of the range of products PIXIUM DYNAMIC:

- **CsI scintillator** which absorbs X-ray photons and converts them into visible light.
- **Low-noise photodiode** active matrix absorbs light and converts it into electronic charges.
- **Low-noise electronics** readout the charge at each pixel and turn it into digital data sent to an image processor (OEM system).

- **The software** main element is a library that aims to manage the calibration and to acquire raw images coming from the detector, process them and deliver them to the host system computer as clean images. It delivers pre-processing functionalities to Original Equipment Manufacturer.



4.7. Intended Purpose (For EU Countries Only) / Indication For Use (USA only)

ⓘ	PIXIUM DYNAMIC Detectors are a part of the imaging chain of an overall radiology system and are intended to generate high quality digital image flow.

4.8. Indications

ⓘ	Pixium Dynamic Detectors are intended for general radiographic and/or fluoroscopic imaging of the whole body.

4.9. Intended Patient Population

ⓘ	There is no limitation on patient target group nor patient selection criteria.

4.10.Contraindications

	There are no contraindications associated with PIXIUM DYNAMIC products

4.11.Limitations

	There is no limitation.

4.12.Adverse effects / Undesirable side-effects

	Potential side effects are the results of multiple irradiations for the same patient due to damaged image quality due to detector malfunctioning.

4.13.PIXIUM DYNAMIC Detector Main Characteristics

4.13.1. PIXIUM SURGICAL 2121S-HDi

Parameter	Value	Unit
Plate	IGZO TFT + photodiode plate	-
Scintillator	CsI	-
Pixel pitch	109	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Ethernet cable	-
Total transmitted image width	1920	pixels
Total transmitted image height	1920	pixels
Maximum frame rate (full image, 1x1)	30	fps
Maximum frame rate (full image, 2x2)	60	fps
DQE RQA5 0 lp/mm 2µGy	80	%
X-Ray generator voltage range	40 to 125	kV

The main features of the **detector** are:

- Cold start feature (1 minute)
- Offset stability validity up to 10 minutes
- Fluoroscopy and radiography images capability

- Passive cooling device
- High speed image transfer using Ethernet link
- Low noise modes
- NEO algorithm for noise reduction
- Sensitivity boost modes

4.13.2. PIXIUM SURGICAL 2121S Option A

Parameter	Value	Unit
Plate	Single a-Si TFT + photodiode plate	-
Scintillator	CsI	-
Pixel pitch	154	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Ethernet cable	-
Total transmitted image width	1344	pixels
Total transmitted image height	1344	pixels
Maximum frame rate (full image, 1x1)	25	fps
Maximum frame rate (full image, 2x2)	30	fps
DQE RQA5 0 lp/mm 2 µGy	77	%
X-Ray generator voltage range	40 to 150	kV

The main features of the **detector** are:

- Cold start feature (1 minute)
- Offset stability validity up to 10 minutes
- Fluoroscopy and radiography images capability
- Passive cooling device
- High speed image transfer using Ethernet link

4.13.3. PIXIUM SURGICAL 2121S Option AU

Parameter	Value	Unit
Plate	Single a-Si TFT + photodiode plate	-
Scintillator	CsI	-
Pixel pitch	200	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Ethernet cable	-
Total transmitted image width	1024	pixels

Parameter	Value	Unit
Total transmitted image height	1024	pixels
Maximum frame rate (full image, 1x1)	30	fps
Maximum frame rate (full image, 2x2)	30	fps
DQE RQA5 0 lp/mm 1 µGy	75	%
X-Ray generator voltage range	40 to 125	kV

The main features of the **detector** are:

- Cold start feature
- Offset stability validity up to 10 minutes
- Fluoroscopy and radiography images capability
- Passive cooling device
- High speed image transfer using Ethernet link

4.13.4. PIXIUM SURGICAL 2121S-AU2 F

Parameter	Value	Unit
Plate	Single a-Si TFT + photodiode plate	-
Scintillator	CsI	-
Pixel pitch	200	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Ethernet cable	-
Total transmitted image width	1024	pixels
Total transmitted image height	1024	pixels
Maximum frame rate (full image, 1x1)	40	fps
Maximum frame rate (full image, 2x2)	80	fps
DQE RQA5 0 lp/mm 1 µGy	77	%
X-Ray generator voltage range	40 to 125	kV

The main features of the **detector** are:

- Cold start feature
- Offset stability validity up to 10 minutes
- Fluoroscopy and radiography images capability
- Passive cooling device
- High speed image transfer using Ethernet link
- Low noise modes
- Sensitivity boost modes

	For a PIXIUM SURGICAL 2121S-AU2, the cold start duration is maximum 1 minute.This time corresponds to the time to have a stabilized offset (correction valid during 10 minutes).

4.13.5. PIXIUM SURGICAL 3030S Option A

Parameter	Value	Unit
Plate	Single a-Si TFT + photodiode plate	-
Scintillator	CsI	-
Pixel pitch	154	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Ethernet cable	-
Total transmitted image width	1956	pixels
Total transmitted image height	1956	pixels
Maximum frame rate (full image, 1x1)	12	fps
Maximum frame rate (full image, 2x2)	30	fps
DQE RQA5 0 lp/mm 2 µGy	77	%
X-Ray generator voltage range	40 to 150	kV

The main features of the **detector** are:

- Cold start feature (1 minute)
- Offset stability validity up to 10 minutes
- Fluoroscopy and radiography images capability
- Passive cooling device
- High speed image transfer using Ethernet link

4.13.6. PIXIUM SURGICAL 3030S Option AU

Parameter	Value	Unit
Plate	Single a-Si TFT + photodiode plate	-
Scintillator	CsI	-
Pixel pitch	200	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Ethernet cable	-
Total transmitted image width	1534	pixels
Total transmitted image height	1534	pixels

Parameter	Value	Unit
Maximum frame rate (full image, 1x1)	20	fps
Maximum frame rate (full image, 2x2)	20	fps
DQE RQA5 0 lp/mm 1 µGy	77	%
X-Ray generator voltage range	40 to 125	kV

The main features of the **detector** are:

- Cold start feature
- Offset stability validity up to 10 minutes
- Fluoroscopy and radiography images capability
- Passive cooling device
- High speed image transfer using Ethernet link

4.13.7. PIXIUM SURGICAL 3131S-HDi

Parameter	Value	Unit
Plate	IGZO TFT + photodiode plate	-
Scintillator	CsI	-
Pixel pitch	109	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Ethernet cable	-
Total transmitted image width	2848	pixels
Total transmitted image height	2848	pixels
Maximum frame rate (full image, 1x1)	30	fps
Maximum frame rate (full image, 2x2)	70	fps
DQE RQA5 0 lp/mm 2µGy	80	%
X-Ray generator voltage range	40 to 125	kV

The main features of the **detector** are:

- Cold start feature (1 minute)
- Offset stability validity up to 10 minutes
- Fluoroscopy and radiography images capability
- Passive cooling device
- High speed image transfer using Ethernet link
- Low noise modes
- NEO algorithm for noise reduction
- Sensitivity boost modes

4.13.8. PIXIUM DYNAMIC 3040 Option F

Parameter	Value	Unit
Plate	Single a-Si TFT + photodiode plate	-
Scintillator	CsI	-
Pixel pitch	154	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Multi-Gigabit Ethernet with Converter	-
Total transmitted image width	2586	pixels
Total transmitted image height	1904	pixels
Maximum frame rate (full image, 1x1)	30	fps
Maximum frame rate (full image, 2x2)	60	fps
DQE RQA5 0 lp/mm 2 µGy	77	%
X-Ray generator voltage range	40 to 150	kV

The main features of the **detector** are:

- Cold start feature (5 minutes)
- Offset stability validity up to 15 minutes
- Fluoroscopy and radiography images capability
- Passive cooling device
- High speed image transfer using Multi-Gigabit Ethernet link (with Converter)

4.13.9. PIXIUM RF 4343 F4

Parameter	Value	Unit
Plate	Single a-Si TFT + photodiode plate	-
Scintillator	CsI	
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Optical link	

Thales KEYWORDS	ITEM	Unit	min	max
Image geometry characteristics	**Image geometry characteristics**			
matrix_size_h_pixel	Total # of pixels Horizontal	pixels	2880	
matrix_size_v_pixel	Total # of pixels Vertical	pixels	2881	
pitch_um	Pixel size	µm	148	

Thales KEYWORDS	ITEM	Unit	min	max
image_shielded_top_pixel_OV_1x1	Lost lines on top (Buffer zone width). It corresponds to physical lines. Thus to image lines in OV binning 1x1	pixels		3
image_shielded_bottom_pixel_OV_1x1	Lost lines on bottom (Buffer zone width). It corresponds to physical lines. Thus to image lines in OV binning 1x1	pixels		3
image_shielded_top_pixel_OV_grouped	Lost lines on top (Buffer zone width). It corresponds to image lines in OV grouped (2x2 or 2x3 or 3x3) modes	pixels		2
image_shielded_bottom_pixel_OV_grouped	Lost lines on bottom (Buffer zone width). It corresponds to image lines in OV grouped (2x2 or 2x3 or 3x3) modes	pixels		2
Image_shielded_left_OV_1x1_pixel	Lost columns on left (Buffer zone width). It corresponds to image lines in OV grouped	pixels		20
Image_shielded_right_OV_1x1_pixel	Lost columns on right (Buffer zone width). It corresponds to image lines in OV grouped	pixels		20

- Cold start feature (210 minutes)
- Offset stability validity up to 30 minutes

4.13.10. PIXIUM RF 4343 F5

Parameter	Value	Unit
Plate	Single a-Si TFT + photodiode plate	-
Scintillator	CsI	-
Pixel pitch	148	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Ethernet cable	-
Total transmitted image width	2880	pixels
Total transmitted image height	2880	pixels
DQE RQA5 0 lp/mm 2 µGy	73	%
X-Ray generator voltage range	40 to 150	kV

The main features of the **detector** are:

- Cold start feature (60 minutes)
- Offset stability validity up to 15 minutes
- Fluoroscopy and radiography images capability

- Passive cooling device
- High speed image transfer using Multi-Gigabit Ethernet link

4.13.11. PIXIUM RF 4343 F5 B

Parameter	Value	Unit
Plate	Single a-Si TFT + photodiode plate	-
Scintillator	CsI	-
Pixel pitch	148	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Ethernet cable	-
Total transmitted image width	2880	pixels
Total transmitted image height	2880	pixels
DQE RQA5 0 lp/mm 2 µGy	73	%
X-Ray generator voltage range	40 to 150	kV

The main features of the **detector** are:

- Cold start feature (60 minutes)
- Offset stability validity up to 15 minutes
- Fluoroscopy and radiography images capability
- Passive cooling device
- High speed image transfer using Multi-Gigabit Ethernet link

4.13.12. PIXIUM RF 4343 FL3

Parameter	Value	Unit
Plate	Single a-Si TFT + photodiode plate	-
Scintillator	CsI	
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Optical link	

Thales KEYWORDS	ITEM	Unit	min	max
Image geometry characteristics	**Image geometry characteristics**			
matrix_size_h_pixel	Total # of pixels Horizontal	pixels	2880	
matrix_size_v_pixel	Total # of pixels Vertical	pixels	2880	
pitch_um	Pixel size	µm	148	

Thales KEYWORDS	ITEM	Unit	min	max
image_shielded_top_pixel_OV_1x1	Lost lines on top (Buffer zone width). It corresponds to physical lines. Thus to image lines in OV binning 1x1	pixels		3
image_shielded_bottom_pixel_OV_1x1	Lost lines on bottom (Buffer zone width). It corresponds to physical lines. Thus to image lines in OV binning 1x1	pixels		3
image_shielded_top_pixel_OV_grouped	Lost lines on top (Buffer zone width). It corresponds to image lines in OV grouped (2x2 or 3x3) modes	pixels		2
image_shielded_bottom_pixel_OV_grouped	Lost lines on bottom (Buffer zone width). It corresponds to image lines in OV grouped (2x2 or 3x3) modes	pixels		2
Image_shielded_left_OV_1x1_pixel	Lost columns on left (Buffer zone width). It corresponds to image lines in OV grouped	pixels		20
Image_shielded_right_OV_1x1_pixel	Lost columns on right (Buffer zone width). It corresponds to image lines in OV grouped	pixels		20
Image_shielded_left_OV_2x2_pixel	Lost columns on left (Buffer zone width). It corresponds to image lines in OV grouped (2x2)	pixels		10
Image_shielded_right_OV_2x2_pixel	Lost columns on right (Buffer zone width). It corresponds to image lines in OV grouped (2x2)	pixels		10
Image_shielded_left_OV_3x3_pixel	Lost columns on left (Buffer zone width). It corresponds to image lines in OV grouped (3x3)	pixels		7
Image_shielded_right_OV_3x3_pixel	Lost columns on right (Buffer zone width). It corresponds to image lines in OV grouped (3x3)	pixels		7
image_shielded_Z_1x1_2x2_3x3_left	Lost columns on left (Buffer zone width). It corresponds to image lines in zoom grouped	pixels		0
image_shielded_Z_1x1_2x2_3x3_right	Lost columns on right (Buffer zone width). It corresponds to image lines in zoom grouped	pixels		0
image_shielded_Z_1x1_2x2_3x3_top	Lost columns on top (Buffer zone width). It corresponds to image lines in zoom grouped	pixels		1
image_shielded_Z_1x1_2x2_3x3_bottom	Lost columns on bottom (Buffer zone width). It corresponds to image lines in zoom grouped	pixels		1

- Cold start feature (270 minutes)
- Offset stability validity up to 15 minutes

4.13.13. PIXIUM RF 4343 FL4

Parameter	Value	Unit
Plate	Single a-Si TFT + photodiode plate	-
Scintillator	CsI	-
Pixel pitch	148	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	Ethernet cable	-
Total transmitted image width	2880	pixels
Total transmitted image height	2880	pixels
DQE RQA5 0 lp/mm 2 µGy	74	%
X-Ray generator voltage range	40 to 150	kV

The main features of the **detector** are:

- Cold start feature (60 minutes)
- Offset stability validity up to 15 minutes
- Fluoroscopy and radiography images capability
- Passive cooling device
- High speed image transfer using Ethernet link

4.13.14. PIXIUM 2630 CB

Parameter	Value	Unit
Plate	A-Si: H plate with Photodiode	-
Scintillator	CsI	-
Pixel pitch	184	µm
Quantization depth	16	bits
Power supply input	24 ±10%	V_{DC}
Communication / image transfer	1 single optical Aurora protocol	-
Maximum transmitted lines	1440	pixels
Maximum transmitted columns	1560	pixels
Active Area size	264.96 x 287.04	mm^2

4.14.Reliability

	The X-ray spectrum used to evaluate the functional integrated dose performance is 120 kV tube setting with 2.5 mm Aluminum filtration, 2.4 Gy/h, and no object on the detector surface. This cumulated dose delivered in a short period of time (few days) regarding the whole detector lifetime (10 years) can be seen as a worst-case scenario. The specified loss of sensitivity is measured 40 days after the exposure.

4.14.1. PIXIUM SURGICAL 2121S-HDi

The dose reliability specification of the **PIXIUM SURGICAL 2121S-HDi** is:

Reliability Performances	Unit	Min	Typ	Max
Functional integrated dose	Gy			700
Functional lifetime with and without packaging	Years	10		

	The detectors sensitivity loss after applying 1200 Gy shall not exceed 12 % maximum. The detectors sensitivity loss after applying 700 Gy shall not exceed 10 % maximum. The detectors sensitivity loss after applying 100 Gy shall not exceed 5 % maximum.

4.14.2. PIXIUM SURGICAL 2121S Option A

The dose reliability specification of the **PIXIUM SURGICAL 2121S Option A** is:

Reliability Performances	Unit	Min	Typ	Max
Functional integrated dose	Gy			700
Functional lifetime with and without packaging	Years	10		

	The detectors sensitivity loss after applying 100 Gy shall not exceed 5%. The detector sensitivity decrease after applying 700 Gy shall not exceed 35%.

4.14.3. PIXIUM SURGICAL 2121S Option AU

The dose reliability specification of the **PIXIUM SURGICAL 2121S Option AU** is:

Reliability Performances	Unit	Min	Typ	Max
Functional integrated dose	Gy			700
Functional lifetime with and without packaging	Years	10		

	The detectors sensitivity loss after applying 100 Gy shall not exceed 15%. The detectors sensitivity decrease after applying 700 Gy shall not exceed 35%.

4.14.4. PIXIUM SURGICAL 2121S-AU2 F

The dose reliability specification of the **PIXIUM SURGICAL 2121S-AU2 F** is:

Reliability Performances	Unit	Min	Typ	Max
Functional integrated dose	Gy			700
Functional lifetime with and without packaging	Years	10		

The detectors sensitivity loss after applying 100 Gy shall not exceed 15%. The detectors sensitivity decrease after applying 700 Gy shall not exceed 35%.

4.14.5. PIXIUM SURGICAL 3030S Option A

The dose reliability specification of the **PIXIUM SURGICAL 3030S Option A** is:

Reliability Performances	Unit	Min	Typ	Max
Functional integrated dose	Gy			700
Functional lifetime with and without packaging	Years	10		

The detectors sensitivity loss after applying 100 Gy shall not exceed 5%. The detector sensitivity decrease after applying 700 Gy shall not exceed 35%.

4.14.6. PIXIUM SURGICAL 3030S Option AU

The dose reliability specification of the **PIXIUM SURGICAL 3030S Option AU** is:

Reliability Performances	Unit	Min	Typ	Max
Functional integrated dose	Gy			1000
Functional lifetime with and without packaging	Years	10		

The detectors sensitivity loss after applying 100 Gy shall not exceed 15%. The detectors sensitivity decrease after applying 700 Gy shall not exceed 35%.

4.14.7. PIXIUM SURGICAL 3131S-HDi

The dose reliability specification of the **PIXIUM SURGICAL 3131S-HDi** is:

Reliability Performances	Unit	Min	Typ	Max
Functional integrated dose	Gy			700

Reliability Performances	Unit	Min	Typ	Max
Functional lifetime with and without packaging	Years	10		

	The detectors sensitivity loss after applying 1200 Gy shall not exceed 12 % maximum. The detectors sensitivity loss after applying 700 Gy shall not exceed 10 % maximum. The detectors sensitivity loss after applying 100 Gy shall not exceed 5 % maximum.

4.14.8. PIXIUM DYNAMIC 3040 Option F

The dose reliability specification of the **PIXIUM DYNAMIC 3040 Option F** are:

Reliability Performances	Unit	Min	Typ	Max
Functional integrated dose	Gy			500
Functional lifetime with and without packaging	Years	10		

The reliability specification of the **CONVERTER 5G** is:

Reliability Performances	Unit	Min	Typ	Max
Functional lifetime with and without packaging	Years	10		

4.14.9. PIXIUM RF 4343 F4

The dose reliability specification of the **PIXIUM RF 4343 F4** are:

Thales KEYWORDS	ITEM	Unit	min	max
Service and reliability	**Service and reliability**			
pm_func_integrated_dose_Gy	Allowable Integrated dose over lifetime	Gy	100	
pm_func_lifetime_y	Lifetime	year	10	

4.14.10. PIXIUM RF 4343 F5

The dose reliability specification of the **PIXIUM RF 4343 F5** is:

Reliability Performances	Unit	Min	Typ	Max
Functional integrated dose	Gy			100
Functional lifetime with and without packaging	Years	10		

4.14.11. PIXIUM RF 4343 F5 B

The dose reliability specification of the **PIXIUM RF 4343 F5 B** is:

Reliability Performances	Unit	Min	Typ	Max
Functional integrated dose	Gy			100

Reliability Performances	Unit	Min	Typ	Max
Functional lifetime with and without packaging	Years	10		

4.14.12. PIXIUM RF 4343 FL3

The dose reliability specification of the **PIXIUM RF 4343 FL3** are:

Thales KEYWORDS	ITEM	Unit	min	max
Service and reliability	**Service and reliability**			
pm_func_integrated_dose_Gy	Allowable Integrated dose over lifetime	Gy	100	
pm_func_lifetime_y	Lifetime	year	10	

4.14.13. PIXIUM RF 4343 FL4

The dose reliability specification of the **PIXIUM RF 4343 FL4** is:

Reliability Performances	Unit	Min	Typ	Max
Functional integrated dose	Gy			100
Functional lifetime with and without packaging	Years	10		

4.14.14. PIXIUM 2630 CB

The dose reliability parameters of the **PIXIUM 2630 CB** are:

Service and reliability	Unit	Min	Typ	Max
pm_func_integrated_dose_Gy	Gy	400		
stability_drift_long_term_lsb_10min(g4)	years	10		

The reliability specification of the **CONVERTER 2630** is:

Reliability Performances	Unit	Min	Typ	Max
Functional lifetime with and without packaging	Years	10		

4.14.15. PROCESSING UNIT ALPHA

The reliability specification of the **PROCESSING UNIT ALPHA** is:

Reliability Performances	Unit	Min	Typ	Max
Functional lifetime with and without packaging	Years	10		

4.15.Essential Performance

	In case of system failure, it shall be recoverable (automatically or by reset) and an emergency fluoroscopy shall be available again in a short time, desirable value 1 minute or less.

5. SAFETY AND PRECAUTIONS

5.1. General Precautions

The end users must be aware about several risks linked to the use of the detector. The following information must be clearly indicated in the radiology system User Manual:

	In case of collision of the detector with a tough surface or in case of rough shock, a visual inspection is required 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 repair.
	During maintenance of the detector, a visual inspection is required 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 repair.
	During maintenance and installation of the detector in the system, it must be handled with care. In case of falling down on someone's foot, the detector can cause injury to the person.
	In case of earthquake, the Product must be inspected before being reused.
	Only qualified and authorized service engineers must carry out product installation, adjustment and maintenance described in this document. Qualified in this context means that the engineers have been trained accordingly or have acquired the necessary experience in practice. Authorized means that the engineers have been authorized by the operator of the system to perform maintenance work.
	The detector is sensitive to moisture. While not used, it must be stored with protection against humidity. If this condition is not observed, the detector may be damaged or destroyed.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Product, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

	Do not push on the carbon fiber window of the detector, it may damage the detector.
	To avoid the risk of electric shock, this equipment must be connected to a protective earth
	No modification of the product is allowed. Warranty is void on a modified product.
	Do not allow liquids to get into contact with the product.
	Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established. This information must to be shared with the patient.
	Cybersecurity is under OEM/integrator and Thales responsibility.

5.2. Applied Parts

	The detector must be over housed by protective covers in the radiological equipment. There is no direct contact between the patient and the detector.
	The PROCESSING UNIT ALPHA is not an applied part, which implies that the PROCESSING UNIT ALPHA should be over housed in the final system.

5.3. Degree Of Safety (Flammable Anesthetic Mixture)

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

5.4. Continuous Operation

This product is designed to run in continuous operation.

5.5. Disposal

	In case of disposal, the end user must contact the integrator to ensure safe dismantling

The product contains the following toxic substances:

- Thallium-doped Cesium Iodide scintillator material
- Lead protection plates

	The exposition to toxic substances can occur only during the dismantling of the product.

	In case of dismantling the product, the local regulations regarding the hazardous substances must be followed and precautions must be taken to prevent damage to the personnel's health and to the environment.

	THALES expects his customers to take care of the recycling of the detector within the framework of the System recycling procedure.

5.6. X-Ray Management

The emission of the ionizing radiation is controlled by the equipment manufacturer.

The detector is not designed to control the emitted X-ray dose.

	In case of crash of any part of the system (workstation, PU, converter or detector), the whole system must be restarted to restore the communication.

	When using message protocol, it is under imaging solution manufacturer responsibility to implement a «watch dog like» process to monitor the state of communication and to stop the emission of X-rays in case of communication lost in order to prevent unnecessary exposure of the patient.
	It is the System manufacturer responsibility to control the actual emission of X-Radiation.
	The integrator is responsible to implement safety procedure to stop X-ray emission of the generator in case of the crash of the host system.
	In case of loss of communication with the detector, an alarm is sent to the system. It is OEM (Original Equipment Manufacturer) responsibility to manage the x-ray exposure.
	The X-ray signal has to be transmitted only during X-ray enable signal is in active state. Otherwise, some degradation of images may occur.

6. MAINTENANCE

	Power On Self Test (POST) are performed at each startup of the system. In case of failure of, at least, one test the communication with the detector cannot be initiated. It is necessary to contact OEM/integrator.

	Calibration needed for image quality is performed as defined by the OEM or integrator under Thales recommendations.

	It is recommended that the integrator checks the detector's sensitivity periodically (every year). Thales does not ensure good performance when the sensitivity of the detector is too low.

6.1. Dark Calibration

	The dark calibration **cannot** be launched if an image acquisition is ongoing.

	The offset correction is not disabled if the offset calibration table is not valid.

	It is recommended to do the calibration for the offset reference at the **lower frame rate & maximum X-ray windows** to improve the defect detection.

6.1.1. PIXIUM SURGICAL 2121S-HDi

	Before performing a good dark calibration, the detector shall be powered on for at least 1 minute.

	The default and recommended life time duration for the dark reference calibration table for a PIXIUM SURGICAL 2121S-HDi is **10 minutes**.

6.1.2. PIXIUM SURGICAL 2121S Option A

	Before performing a good dark calibration, the detector shall be powered on for at least 1 minute.

	The default and recommended life time duration for the dark reference calibration table for a PIXIUM SURGICAL 2121S Option A is **10 minutes**.

6.1.3. PIXIUM SURGICAL 2121S Option AU

	Before performing a good dark calibration, the detector shall be powered on for at least 1 minute.

	The default and recommended life time duration for the dark reference calibration table for a PIXIUM SURGICAL 2121S Option AU is **10 minutes**.

6.1.4. PIXIUM SURGICAL 2121S-AU2 F

	Before performing a good dark calibration, the detector shall be powered on for at least 1 minute.

	The default and recommended life time duration for the dark reference calibration table for a PIXIUM SURGICAL 2121S-AU2 F is **10 minutes**.

6.1.5. PIXIUM SURGICAL 3030S Option A

	Before performing a good dark calibration, the detector shall be powered on for at least 1 minute.

	The default and recommended life time duration for the dark reference calibration table for a PIXIUM SURGICAL 3030S Option A is **10 minutes**.

6.1.6. PIXIUM SURGICAL 3030S Option AU

	Before performing a good dark calibration, the detector shall be powered on for at least 1 minute.

	The default and recommended life time duration for the dark reference calibration table for a PIXIUM SURGICAL 3030S Option AU is **10 minutes**.

6.1.7. PIXIUM SURGICAL 3131S-HDi

	Before performing a good dark calibration, the detector shall be powered on for at least 1 minute.

	The default and recommended life time duration for the dark reference calibration table for a PIXIUM SURGICAL 3131S-HDi is **10 minutes**.

6.1.8. PIXIUM DYNAMIC 3040 Option F

	Before performing a good dark calibration, the PIXIUM DYNAMIC 3040 Option F detector shall be powered on for at least **5 minutes**.

	The default and recommended life time duration for the dark reference calibration table for a PIXIUM DYNAMIC 3040 Option F is **15 minutes**.

6.1.9. PIXIUM RF 4343 F4

	The detector has to be powered on for at least 210 minutes before starting the calibration process in order to achieve good temperature stabilization and a full quality image

	The periodicity of this calibration has to be determined by the integrator according to environmental conditions and time constraints. Thales recommended period is 30 minutes for offset calibration

6.1.10. PIXIUM RF 4343 F5

	Before performing a good dark calibration, the PIXIUM RF 4343 F5 detector shall be powered on for at least **60 min** for an offset valid during 15 min.

	The default and recommended life time duration for the dark reference calibration table for a PIXIUM RF 4343 F5 is **15 minutes**.

6.1.11. PIXIUM RF 4343 F5 B

	Before performing a good dark calibration, the PIXIUM RF 4343 F5 B detector shall be powered on for at least **60 min** for an offset valid during 15 min.

	The default and recommended life time duration for the dark reference calibration table for a PIXIUM RF 4343 F5 B is **15 minutes**.

6.1.12. PIXIUM RF 4343 FL3

	The detector has to be powered on for at least 270 minutes before starting the calibration process in order to achieve good temperature stabilization and a full quality image

	The periodicity of this calibration has to be determined by the integrator according to environmental conditions and time constraints. Thales recommended period is **15 minutes** for offset calibration

6.1.13. PIXIUM RF 4343 FL4

	Before performing a good dark calibration, the PIXIUM RF 4343 FL4 detector shall be powered on for at least **30 minutes** for an offset valid during 5 min or **60 minutes** for an offset valid during 15 min.

	The default and recommended life time duration for the dark reference calibration table for a PIXIUM RF 4343 FL4 is **15 minutes**.

6.1.14. PIXIUM 2630 CB

	The cold start time is maximum **1 minute**. This time corresponds to the time to have a stabilized offset.

6.2. X-Ray Calibration

X-ray Calibration will generate:

- Linear gain reference calibration table
- Defect map reference calibration table

	The X-Ray calibration **cannot** be launched if an image acquisition is ongoing.

	After the calibration, the user shall check the image quality to make sure that the calibration was successful.

	There should be no object (except RQA5 aluminum filter) in the field during the X-ray calibration.

	There should be no detector motion during the X-ray calibration.

6.2.1. PIXIUM SURGICAL 2121S-HDi

	Before performing a good X-Ray Calibration, the detector shall be powered on for at least **15 minutes**

	The default and recommended life time duration for the gain/defect reference calibration table is 1 year.

6.2.2. PIXIUM SURGICAL 2121S Option A

	Before performing a good X-Ray Calibration, the detector shall be powered on for at least **15 minutes**

	The default and recommended life time duration for the gain/defect reference calibration table is 1 year.

6.2.3. PIXIUM SURGICAL 2121S Option AU

	Before performing a good X-Ray Calibration, the detector shall be powered on for at least **15 minutes**

	The default and recommended life time duration for the gain/defect reference calibration table is 1 year.

6.2.4. PIXIUM SURGICAL 2121S-AU2 F

	Before performing a good X-Ray Calibration, the detector shall be powered on for at least **15 minutes**

	The default and recommended life time duration for the gain/defect reference calibration table is 1 year.

6.2.5. PIXIUM SURGICAL 3030S Option A

	Before performing a good X-Ray Calibration, the detector shall be powered on for at least **15 minutes**

	The default and recommended life time duration for the gain/defect reference calibration table is 1 year.

6.2.6. PIXIUM SURGICAL 3030S Option AU

	Before performing a good X-Ray Calibration, the detector shall be powered on for at least **15 minutes**

	The default and recommended life time duration for the gain/defect reference calibration table is 1 year.

6.2.7. PIXIUM SURGICAL 3131S-HDi

	Before performing a good X-Ray Calibration, the detector shall be powered on for at least **15 minutes**

	The default and recommended life time duration for the gain/defect reference calibration table is 1 year.

6.2.8. PIXIUM DYNAMIC 3040 Option F

	Before performing a good X-Ray Calibration, the detector shall be powered on for at least **100 minutes.**

	The default and recommended life time duration for the gain/defect reference calibration table is 1 year.

6.2.9. PIXIUM RF 4343 F4

	The detector has to be powered on for at least 210 minutes before starting the calibration process in order to achieve good temperature stabilization and a full quality image

	Thales recommended period is 13 months for linear gain calibration. The periodicity of this calibration has to be determined by the customer according to environmental conditions, conditions of use and time constraints.

6.2.10. PIXIUM RF 4343 F5

	Before performing a good X-Ray Calibration, the detector shall be powered on for at least **1 hour**

	The default and recommended life time duration for the gain/defect reference calibration table is 13 months

6.2.11. PIXIUM RF 4343 F5 B

	Before performing a good X-Ray Calibration, the detector shall be powered on for at least **1 hour**

	The default and recommended life time duration for the gain/defect reference calibration table is 13 months

6.2.12. PIXIUM RF 4343 FL3

	The detector has to be powered on for at least 270 minutes before starting the calibration process in order to achieve good temperature stabilization and a full quality image

	Thales recommended period is 13 months for linear gain calibration. The periodicity of this calibration has to be determined by the customer according to environmental conditions, conditions of use and time constraints.

6.2.13. PIXIUM RF 4343 FL4

	Before performing a good X-Ray Calibration, the detector shall be powered on for at least **1 hour**

	The default and recommended life time duration for the gain/defect reference calibration table is 13 months

6.2.14. PIXIUM 2630 CB

	Before performing a good image calibration (x-ray calibration), the system shall be powered on for at least **10 minutes**.

6.3. Regular Maintenance

Recurrent maintenance activity includes the required tests according to IEC 62353.

It must be performed at least every 24 months.

List of activity to be performed on the detector, accessories and parts in this order:Visual check:

- Safety related marking, labels and manuals are legible and complete;
- Mechanical parts are intact;
- There is no damage or contamination;
- Documentation is available and reflects the current revision and/or configuration of the detector.

Electrical safety check (according to IEC 62353 recommendations) :

- Measure of protective earth resistance;
- Measure of device leakage current;

Performance check:

- Detector turns on in less than 1 minute.

Qualified and authorized service engineer who performed the recurrent maintenance activity is responsible to report and archive test results.

In case of deviation, please contact OEM after sale service.

7. ENVIRONMENT OPERATING, STORAGE AND HANDLING CONDITIONS

	The user shall ensure that detector is never submitted to condensation.

	The temperature ranges stands for the room temperature.

7.1. PIXIUM SURGICAL 2121S-HDi Operating Conditions

The following table gives information about environmental operating conditions for the **PIXIUM SURGICAL 2121S-HDi**:

Parameter	Min	Max	Comment
Operational temperature – **Full performance** (°C)	10	35	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	35	40	
Humidity range (%HR) in standard operating mode	5	93	
Humidity range (%HR) in cold start situation	5	80	
Humidity ratio (g of water/g of dry air)		0.039	
Operating vibrations unpacked (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Operating bumps (g)		25	½ sine, 8 ms, 1000 times, 6 directions
Operating bumps (g)		30	½ sine, 8 ms, 20 times, 6 directions
Atmospheric pressure (mbar)	700	1100	

The following table gives information about environmental operating conditions for the detector: During operation, the detector is submitted to vibrations that can cause local artifacts. A visual inspection is carried out as a first step and the following measurement is done additionally.

Measure	Min	Max	Test conditions
“aoi_difference” artefact: the difference between AOIs of the considered dark offset corrected images.		30 grey levels	Binning 1x1, gain 0 at 10 fps. Maximum vibration specifications to be applied to check specified limited performances • 0.6 g • 10 Hz - 200 Hz • 3 axis • 5 sweeps • 1 minute/octave

7.2. PIXIUM SURGICAL 2121S-HDi Storage and Transport Conditions

The packed detector is tested according to ISTA 3A 2018 standard with the following parameters:

- Package type: standard
- Sequences to be tested: 1->6
- Humidity specification: hot humidity

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Unpacked
Storage and transport vibrations (g) - Unpacked		2	Measurement done according to the standard IEC 60068-2-6 • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Storage and transport pressure conditions (mbar)	500	1100	The detector mounted on the C-arm can be stored and transported under this pressure condition

7.3. PIXIUM SURGICAL 2121S Option A Operating Conditions

The following table gives information about environmental operating conditions for the **PIXIUM SURGICAL 2121S Option A**:

Parameter	Min	Max	Comment
Operational temperature – **Full performance** (°C)	10	35	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	35	40	

Parameter	Min	Max	Comment
Humidity range (%HR) in standard operating mode	5	90	
Operating vibrations unpacked (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Operating bumps (g)		25	½ sine, 8 ms, 1000 times, 6 directions
Operating bumps (g)		30	½ sine, 8 ms, 20 times, 6 directions
Atmospheric pressure (mbar)	700	1100	

The following table gives information about environmental operating conditions for the detector: During operation, the detector is submitted to vibrations that can cause local artifacts. A visual inspection is carried out as a first step and the following measurement is done additionally.

Measure	Min	Max	Test conditions
“aoi_difference” artefact: the difference between AOIs of the considered dark offset corrected images.		30 grey levels	Binning 1x1, gain 0 at 10 fps. Maximum vibration specifications to be applied to check specified limited performances • 0.6 g • 10 Hz - 200 Hz • 3 axis • 5 sweeps • 1 minute/octave

7.4. PIXIUM SURGICAL 2121S Option A Storage and Transport Conditions

The packed detector is tested according to ISTA 3A 2018 standard with the following parameters:

- Package type: standard
- Sequences to be tested: 1->6
- Humidity specification: hot humidity

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Unpacked

Parameter	Min	Max	Comment
Storage and transport vibrations (g) - Unpacked		2	Measurement done according to the standard IEC 60068-2-6 • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Storage and transport pressure conditions (mbar)	550	1100	Within Thales packaging

7.5. PIXIUM SURGICAL 2121S Option AU Operating Conditions

The following table gives information about environmental operating conditions for the **PIXIUM SURGICAL 2121S Option AU**:

Parameter	Min	Max	Comment
Operational temperature – **Full performance** (°C)	10	35	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	35	40	
Humidity range (%HR) in standard operating mode	5	90	
Humidity range (%HR) in cold start situation	5	80	
Humidity ratio (g of water/g of dry air)		0.039	
Operating vibrations unpacked (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Operating bumps (g)		25	½ sine, 8 ms, 1000 times, 6 directions
Operating bumps (g)		30	½ sine, 8 ms, 20 times, 6 directions
Atmospheric pressure (mbar)	700	1100	

The following table gives information about environmental operating conditions for the detector: During operation, the detector is submitted to vibrations that can cause local artifacts. A visual inspection is carried out as a first step and the following measurement is done additionally.

Measure	Min	Max	Test conditions
“aoi_difference” artefact: the difference between AOIs of the considered dark offset corrected images.		20 grey levels	Binning 1x1, gain 0 at 10 fps. Maximum vibration specifications to be applied to check specified limited performances • 0.3 g • 10 Hz - 200 Hz • 3 axis • 5 sweeps • 1 minute/octave

7.6. PIXIUM SURGICAL 2121S Option AU Storage and Transport Conditions

The packed detector is tested according to ISTA 3A 2018 standard with the following parameters:

- Package type: standard
- Sequences to be tested: 1->6
- Humidity specification: hot humidity

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Unpacked
Storage and transport vibrations (g) - Unpacked		2	Measurement done according to the standard IEC 60068-2-6 • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Storage and transport pressure conditions (mbar)	550	1100	Within Thales packaging

7.7. PIXIUM SURGICAL 2121S-AU2 F Operating Conditions

The following table gives information about environmental operating conditions for the **PIXIUM SURGICAL 2121S-AU2 F**:

Parameter	Min	Max	Comment
Operational temperature – **Full performance** (°C)	10	35	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	35	40	
Humidity range (%HR) in standard operating mode	5	90	

Parameter	Min	Max	Comment
Humidity range (%HR) in cold start situation	5	80	
Humidity ratio (g of water/g of dry air)		0.039	
Operating vibrations unpacked (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Operating bumps (g)		25	½ sine, 8 ms, 1000 times, 6 directions
Operating bumps (g)		30	½ sine, 8 ms, 20 times, 6 directions
Atmospheric pressure (mbar)	700	1100	

Measure	Min	Max	Test conditions
“aoi_difference” artefact: the difference between AOIs of the considered dark offset corrected images.		20 grey levels	Binning 1x1, gain 0 at 10 fps. Maximum vibration specifications to be applied to check specified limited performances • 0.3 g • 10 Hz - 200 Hz • 3 axis • 5 sweeps • 1 minute/octave

7.8. PIXIUM SURGICAL 2121S-AU2 F Storage and Transport Conditions

The packed detector is tested according to ISTA 3A 2018 standard with the following parameters:

- Package type: standard
- Sequences to be tested: 1->6
- Humidity specification: hot humidity

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Unpacked

Parameter	Min	Max	Comment
Storage and transport vibrations (g) - Unpacked		2	Measurement done according to the standard IEC 60068-2-6 • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Storage and transport pressure conditions (mbar)	550	1100	Within Thales packaging

7.9. PIXIUM SURGICAL 3030S Option A Operating Conditions

The following table gives information about environmental operating conditions for the **PIXIUM SURGICAL 3030S Option A**:

Parameter	Min	Max	Comment
Operational temperature – **Full performance** (°C)	10	35	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	0	10	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	35	40	
Humidity range (%HR) in standard operating mode	5	90	
Operating vibrations unpacked (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Operating bumps (g)		25	½ sine, 8 ms, 1000 times, 6 directions
Operating bumps (g)		30	½ sine, 8 ms, 20 times, 6 directions
Atmospheric pressure (mbar)	700	1100	

The following table gives information about environmental operating conditions for the detector: During operation, the detector is submitted to vibrations that can cause local artifacts. A visual inspection is carried out as a first step and the following measurement is done additionally.

Measure	Min	Max	Test conditions
“aoi_difference” artefact: the difference between AOIs of the considered dark offset corrected images.		30 grey levels	Binning 1x1, gain 0 at 10 fps. Maximum vibration specifications to be applied to check specified limited performances • 0.6 g • 10 Hz - 200 Hz • 3 axis • 5 sweeps • 1 minute/octave

7.10.PIXIUM SURGICAL 3030S Option A Storage and Transport Conditions

The packed detector is tested according to ISTA 3A 2018 standard with the following parameters:

- Package type: standard
- Sequences to be tested: 1->6
- Humidity specification: hot humidity

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Unpacked
Storage and transport vibrations (g) - Unpacked		2	Measurement done according to the standard IEC 60068-2-6 • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Storage and transport pressure conditions (mbar)	550	1100	Within Thales packaging

7.11.PIXIUM SURGICAL 3030S Option AU Operating Conditions

The following table gives information about environmental operating conditions for the **PIXIUM SURGICAL 3030S Option AU**:

Parameter	Min	Max	Comment
Operational temperature – **Full performance** (°C)	10	35	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	0	10	

Parameter	Min	Max	Comment
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	35	40	
Humidity range (%HR) in standard operating mode	5	90	
Humidity range (%HR) in cold start situation	5	80	
Humidity ratio (g of water/g of dry air)		0.039	
Operating vibrations unpacked (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Operating bumps (g)		25	½ sine, 8 ms, 1000 times, 6 directions
Operating bumps (g)		30	½ sine, 8 ms, 20 times, 6 directions
Atmospheric pressure (mbar)	700	1100	

The following table gives information about environmental operating conditions for the detector: During operation, the detector is submitted to vibrations that can cause local artifacts. A visual inspection is carried out as a first step and the following measurement is done additionally.

Measure	Min	Max	Test conditions
“aoi_difference” artefact: the difference between AOIs of the considered dark offset corrected images.		30 grey levels	Binning 1x1, gain 0 at 10 fps. Maximum vibration specifications to be applied to check specified limited performances • 0.3 g • 10 Hz - 200 Hz • 3 axis • 5 sweeps • 1 minute/octave

7.12.PIXIUM SURGICAL 3030S Option AU Storage and Transport Conditions

The packed detector is tested according to ISTA 3A 2018 standard with the following parameters:

- Package type: standard
- Sequences to be tested: 1->6
- Humidity specification: hot humidity

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Within Thales packaging

Parameter	Min	Max	Comment
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Unpacked
Storage and transport vibrations (g) - Unpacked		2	Measurement done according to the standard IEC 60068-2-6 • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Storage and transport pressure conditions (mbar)	550	1100	Within Thales packaging

7.13.PIXIUM SURGICAL 3131S-HDi Operating Conditions

The following table gives information about environmental operating conditions for the **PIXIUM SURGICAL 3131S-HDi**:

Parameter	Min	Max	Comment
Operational temperature – **Full performance** (°C)	10	35	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	35	40	
Humidity range (%HR) in standard operating mode	5	93	
Humidity range (%HR) in cold start situation	5	80	
Humidity ratio (g of water/g of dry air)		0.039	
Operating vibrations unpacked (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Operating bumps (g)		25	½ sine, 8 ms, 1000 times, 6 directions
Operating bumps (g)		30	½ sine, 8 ms, 20 times, 6 directions
Atmospheric pressure (mbar)	700	1100	

The following table gives information about environmental operating conditions for the detector: During operation, the detector is submitted to vibrations that can cause local artifacts. A visual inspection is carried out as a first step and the following measurement is done additionally.

Measure	Min	Max	Test conditions
“aoi_difference” artefact: the difference between AOIs of the considered dark offset corrected images.		30 grey levels	Binning 1x1, gain 0 at 10 fps. Maximum vibration specifications to be applied to check specified limited performances • 0.6 g • 10 Hz - 200 Hz • 3 axis • 5 sweeps • 1 minute/octave

7.14.PIXIUM SURGICAL 3131S-HDi Storage and Transport Conditions

The packed detector is tested according to ISTA 3A 2018 standard with the following parameters:

- Package type: standard
- Sequences to be tested: 1->6
- Humidity specification: hot humidity

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Unpacked
Storage and transport vibrations (g) - Unpacked		2	Measurement done according to the standard IEC 60068-2-6 • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Storage and transport pressure conditions (mbar)	500	1100	The detector mounted on the C-arm can be stored and transported under this pressure condition

7.15.PIXIUM DYNAMIC 3040 Option F Operating Conditions

The following table gives information about environmental operating conditions for the **PIXIUM DYNAMIC 3040 Option F**

Parameter	Min	Max	Comment
Operational temperature – **Full performance** (°C)	10	35	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	35	40	
Humidity range (%HR) in standard operating mode	5	90	

Parameter	Min	Max	Comment
Humidity range (%HR) in cold start situation	5	75	
Operating vibrations unpacked (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Operating bumps (g)		10	½ sine, 16 ms, 1000 times, 6 directions
Operating bumps (g)		20	½ sine, 8ms, 20 times, 6 directions
Atmospheric pressure (mbar)	700	1100	

The following table gives information about environmental operating conditions for the detector: During operation, the detector is submitted to vibrations that can cause local artifacts. A visual inspection is carried out as a first step and the following measurement is done additionally.

Measure	Min	Max	Test conditions
“aoi_difference” artefact: the difference between AOIs of the considered dark offset corrected images.		30 grey levels	Binning 1x1, gain 0 at 10 fps. Maximum vibration specifications to be applied to check specified limited performances • 0.6 g • 10 Hz - 200 Hz • 3 axis • 5 sweeps • 1 minute/octave

7.16.PIXIUM DYNAMIC 3040 Option F Storage and Transport Conditions

The packed detector is tested according to ISTA 3B 2017 standard with the following parameters:

- Package type: Palletized
- Sequences to be tested: 1->13
- Humidity specification: hot humidity

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Unpacked

Parameter	Min	Max	Comment
Storage and transport vibrations (g) - Unpacked		2	Measurement done according to the standard IEC 60068-2-6 • 10-200 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Storage and transport shocks (g) – Unpacked		10	½ sine, 16 ms, 1000 times, 6 directions
Storage and transport pressure conditions (mbar)	550	1100	Within Thales packaging

7.17.PIXIUM RF 4343 F4 Operating conditions

The following characteristics are valid if active cooling is implemented and operated.

Item	Unit	Min	Max
Temperature with specified performance (96 with cycles)	°C	15	35
Distance to the ambient temperature of calibration for full performances	°C	-6	6
Temperature variation allowing limited performances (offset stability)	°C / minute		+/-0.5
Operation humidity at 40°C without condensing (16h)	%RH	20	75
Operation pressure	mbar	700	1100
Operation vibrations: 10 – 200 Hz / 3 axis / 5 sweeps / 1 oct/ min.	g		0.3

Acclimatization time before to open detector package is 7h30.

7.18.PIXIUM RF 4343 F4 Storage And Transport Conditions

When not specifically mentioned, the storage & transport conditions are applicable on the detector packed with appropriate packing (humidity sealed).

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	55	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Both packed and unpacked
Storage & transport cyclic damp heat (%RH)		95	

Parameter	Min	Max	Comment
Storage and transport vibrations (g) - Unpacked		2	• 10-58 Hz • Displacement 0.15 mm • 58-150 Hz • 3 axis • 5 sweeps • 1 minute/octave
Storage and transport bumps (g) – Unpacked		10	½ sine, 16ms, 1000 times, 6 directions
Storage and transport pressure conditions (mbar)	500	1060	Within Thales packaging

7.19.PIXIUM RF 4343 F5 Operating Conditions

The following table gives information about environmental operating conditions for the **PIXIUM RF 4343 F5**:

Parameter	Min	Max	Comment
Operational temperature – **Full performance** (°C)	10	35	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	35	40	
Operational temperature variation rate		0.1°C/minute	
Humidity range (%HR)	20	75	
Humidity (non condensing) (%HR)		93	
Operating vibrations unpacked (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-150 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Operating bumps (g)		10	½ sine, 16 ms, 1000 times, 6 directions
Atmospheric pressure (mbar)	700	1060	

The following table gives information about environmental operating conditions for the detector: During operation, the detector is submitted to vibrations that can cause local artifacts. A visual inspection is carried out as a first step and the following measurement is done additionally.

Measure	Min	Max	Test conditions
“aoi_difference” artefact: the difference between AOIs of the considered dark offset corrected images.		30 grey levels	Binning 1x1, gain 0 at 10 fps. Maximum vibration specifications to be applied to check specified limited performances • 0.3 g • 10 Hz - 200 Hz • 3 axis • 5 sweeps • 1 minute/octave

7.20.PIXIUM RF 4343 F5 Storage and Transport Conditions

The packed detector is tested according to ISTA 3B 2017 standard with the following parameters:

- Package type: Palletized
- Sequences to be tested: 1->13
- Humidity specification: hot humidity

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	55	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Packed
Storage and transport humidity range (%HR)	9	90	Unpacked
Storage and transport shocks (g) – Unpacked		10	½ sine, 16 ms, 1000 times, 6 directions
Storage and transport pressure conditions (mbar)	500	1060	Within Thales packaging

7.21.PIXIUM RF 4343 F5 B Operating Conditions

The following table gives information about environmental operating conditions for the **PIXIUM RF 4343 F5 B**:

Parameter	Min	Max	Comment
Operational temperature – **Full performance** (°C)	10	35	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	35	40	
Operational temperature variation rate		0.1°C/minute	
Humidity range (%HR)	20	75	
Humidity (non condensing) (%HR)		93	

Parameter	Min	Max	Comment
Operating vibrations unpacked (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-150 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Operating bumps (g)		10	½ sine, 16 ms, 1000 times, 6 directions
Atmospheric pressure (mbar)	700	1060	

The following table gives information about environmental operating conditions for the detector: During operation, the detector is submitted to vibrations that can cause local artifacts. A visual inspection is carried out as a first step and the following measurement is done additionally.

Measure	Min	Max	Test conditions
“aoi_difference” artefact: the difference between AOIs of the considered dark offset corrected images.		30 grey levels	Binning 1x1, gain 0 at 10 fps. Maximum vibration specifications to be applied to check specified limited performances • 0.3 g • 10 Hz - 200 Hz • 3 axis • 5 sweeps • 1 minute/octave

7.22.PIXIUM RF 4343 F5 B Storage and Transport Conditions

The packed detector is tested according to ISTA 3B 2017 standard with the following parameters:

- Package type: Palletized
- Sequences to be tested: 1->13
- Humidity specification: hot humidity

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	55	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Packed
Storage and transport humidity range (%HR)	9	90	Unpacked
Storage and transport shocks (g) – Unpacked		10	½ sine, 16 ms, 1000 times, 6 directions
Storage and transport pressure conditions (mbar)	500	1060	Within Thales packaging

7.23.PIXIUM RF 4343 FL3 Operating Conditions

The following characteristics are valid if active cooling is implemented and operated.

Item	Unit	Min	Max
Temperature with specified performance (96 with cycles)	°C	15	35
Distance to the ambient temperature of calibration for full performances	°C	-6	6
Operation humidity at 40°C without condensing (16h)	%RH	20	75
Operation pressure	mbar	700	1060
Operation vibrations: 10 – 200 Hz / 3 axis / 5 sweeps / 1 oct/ min.	g		0.3

Environmental operating conditions for the PIXIUM RF 4343 FL3 detector

7.24.PIXIUM RF 4343 FL3 Storage And Transport Conditions

When not specifically mentioned, the storage & transport conditions are applicable on the detector packed with appropriate packing (humidity sealed).

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	55	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Both packed and unpacked
Storage & transport cyclic damp heat (%RH)		95	
Storage and transport vibrations (g) - Unpacked		2	• 10-58 Hz • Displacement 0.15 mm • 58-150 Hz • 3 axis • 5 sweeps • 1 minute/octave
Storage and transport bumps (g) – Unpacked		10	½ sine, 16ms, 1000 times, 6 directions
Storage and transport pressure conditions (mbar)	500	1060	Within Thales packaging

7.25.PIXIUM RF 4343 FL4 Operating Conditions

The following table gives information about environmental operating conditions for the **PIXIUM RF 4343 FL4**:

Parameter	Min	Max	Comment
Operational temperature – **Full performance** (°C)	10	35	
Operational temperature – **Functional / Warning** (°C) -> IQ performances are not guaranteed	35	40	
Operational temperature variation rate		0.1°C/minute	
Humidity range (%HR)	20	75	
Humidity (non condensing) (%HR)		93	
Operating vibrations unpacked (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-150 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Operating bumps (g)		10	½ sine, 16 ms, 1000 times, 6 directions
Atmospheric pressure (mbar)	700	1060	

The following table gives information about environmental operating conditions for the detector: During operation, the detector is submitted to vibrations that can cause local artifacts. A visual inspection is carried out as a first step and the following measurement is done additionally.

Measure	Min	Max	Test conditions
“aoi_difference” artefact: the difference between AOIs of the considered dark offset corrected images.		30 grey levels	Binning 1x1, gain 0 at 10 fps. Maximum vibration specifications to be applied to check specified limited performances • 0.3 g • 10 Hz - 200 Hz • 3 axis • 5 sweeps • 1 minute/octave

7.26.PIXIUM RF 4343 FL4 Storage and Transport Conditions

The packed detector is tested according to ISTA 3A 2018 standard with the following parameters:

- Package type: standard
- Sequences to be tested: 1->6
- Humidity specification: hot humidity

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	55	Within Thales packaging
Temperature slope (°C/min)	-1	1	
Storage and transport humidity range (%HR)	5	95	Unpacked
Storage and transport shocks (g) – Unpacked		10	½ sine, 16 ms, 1000 times, 6 directions
Storage and transport pressure conditions (mbar)	500	1060	Within Thales packaging

7.27.PIXIUM 2630 CB Operating conditions

The following table gives information about environmental operation conditions of the detector:

Parameter	Min	Max	Comment
Operating Temperature (Functional) (°C)	10	40	
Operating Temperature (Full Performance) (°C)	15	35	
Humidity (%)	5	90	No loss in image quality
Atmospheric Pressure (mbar)	700	1060	
Operating Vibration (g)		2	IEC 60068-2-6-test Fc: • 10 - 200 Hz • displacement = 0.15mm max • 3 axis • 5 sweeps • 1 oct / min

7.28.PIXIUM 2630 CB Storage and Transport Conditions

The following table gives information about the environmental storage and transport conditions for the detector.

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Following IEC 60068-2-1 Cold storage (72h test) IEC 60068-2-2 Dry heat storage (72h test) IEC 60068-2-30 Damp heat, cyclic (6x24h test) Without special packaging
Relative Humidity (%HR)	5	90	Unpacked case
	5	95	Packed case
Storage and transport pressure conditions (mbar)	550	1100	Following IEC 60068-2-13 test using a 16 hours test.

7.29.PROCESSING UNIT ALPHA Operating Conditions

The following table gives information about environmental operating conditions for the PROCESSING UNIT ALPHA:

Parameter	Min	Max	Comment
Operational temperature – Full performance (°C)	10	50	Test done without condensing
Humidity range (%HR)	20	75	Test done at 40°C without condensing
Operating vibrations (mm)		0.15	10-58 Hz – displacement max peak to peak Measurement to check specified limited performance is done according to the following conditions: • 3 axis • 4 cycles per direction
Operating vibrations (g)		1	58 - 150 Hz Measurement to check specified limited performance is done according to the following conditions: • 3 axis • 4 cycles per direction
Atmospheric pressure (mbar)	700	1060	

7.30.PROCESSING UNIT ALPHA Storage and Transport Conditions

The following table gives information about the environmental storage and transport conditions for the PROCESSING UNIT ALPHA:

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Within Thales packaging
Storage and transport humidity range (%HR)	5	95	Packed in Thales packaging.Non condensing.
Storage and transport pressure conditions (mbar)	550	1060	Packed in Thales packaging.
Storage and transport bumps (g) – Unpacked		10	½ sine, 16 ms, 1000 times, 3 axis
Drop test for PROCESSING UNIT ALPHA packaging			Compliant with ISTA 3A option 2.
Storage & transport vibrations conditions for PROCESSING UNIT ALPHA packaging			Compliant with ISTA 3A block 7.
Storage & transport bumps conditions for PROCESSING UNIT ALPHA packaging			Compliant with ISTA 3A block 3.

7.31.PROCESSING UNIT RF 4343 Operating Conditions

The following characteristics are valid if active cooling is implemented and operated.

Parameter	Unit	Min	Max
Temperature with specified performance (96h with cycles)	°C	10	40
Temperature variation allowing limited performances (offset stability)	°C/minute		+/-0.5
Operation humidity at 40 °C without condensing (16h)	%RH	20	75
Operation pressure	mbar	700	1060

Environmental operating conditions for PROCESSING UNIT RF 4343

7.32.PROCESSING UNIT RF 4343 Storage And Transport Conditions

When not specifically mentioned, the storage and transport conditions are applicable on the detector packed with appropriate packing (humidity sealed).

Item	Unit	Min	Max
Storage and transport temperature (tested 72h at min & 72h at max)	°C	-20	70
Storage and transport temperature variation	°C/minute		+/-1
Storage and transport humidity at 40 °C without condensing (96 hours)	%RH	5	95
Storage and transport pressure	mbar	500	1060

7.33.PROCESSING UNIT RF 4343 FL Operating Conditions

The following characteristics are valid if active cooling is implemented and operated.

Parameter	Unit	Min	Max
Temperature with specified performance (96h with cycles)	°C	10	40
Temperature variation allowing limited performances (offset stability)	°C/minute		+/-0.5
Operation humidity at 40 °C without condensing (16h)	%RH	20	75
Operation pressure	mbar	700	1060

Environmental operating conditions for PROCESSING UNIT RF 4343 FL

7.34.PROCESSING UNIT RF 4343 FL Storage And Transport Conditions

When not specifically mentioned, the storage and transport conditions are applicable on the detector packed with appropriate packing (humidity sealed).

Item	Unit	Min	Max
Storage and transport temperature (tested 72h at min & 72h at max)	°C	-20	70
Storage and transport temperature variation	°C/minute		+/-1
Storage and transport humidity at 40 °C without condensing (96 hours)	%RH	5	95
Storage and transport pressure	mbar	500	1060

7.35.CONVERTER 2630 Operating conditions

The following table gives information about environmental operation conditions of the converter.

Parameter	Min	Max	Comment
Operational temperature - (°C) -	0	45	
Humidity range (%HR)	5	95	
Operating vibrations (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-150 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Atmospheric pressure (mbar)	700	1060	

7.36.CONVERTER 2630 Storage and Transport Conditions

The following table gives information about the environmental storage and transport conditions for the converter.

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Following IEC 60068-2-1 Cold storage (72h test) IEC 60068-2-2 Dry heat storage (72h test) IEC 60068-2-30 Damp heat, cyclic (6x24h test) Without special packaging
Relative Humidity (%HR)	5	95	Both packed and unpacked
Storage and transport pressure conditions (mbar)	550	1060	

7.37.CONVERTER 5G Operating Conditions

The following table gives information about environmental operating conditions for the Converter:

Parameter	Min	Max	Comment
Operational temperature - (°C) -	0	45	
Humidity range (%HR)	5	95	
Operating vibrations (g)		2	Measurement to check specified limited performance is done according to the following conditions. • 10-150 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave
Atmospheric pressure (mbar)	700	1060	

7.38.CONVERTER 5G Storage And Transport Conditions

The following table gives information about the environmental storage and transport conditions for the Converter:

Parameter	Min	Max	Comment
Storage and transport temperature (°C)	-25	70	Within Thales packaging
Storage and transport humidity range (%HR)	5	95	Both packed and unpacked
Storage and transport pressure conditions (mbar)	550	1060	
Storage and transport shocks (g) – Unpacked		25	½ sine, 6 ms, 1000 times, 3 directions
Storage and transport shocks (g) – Packed		30	½ sine, 6 ms, 1000 times, 3 directions
Storage and transport vibrations (g) - Unpacked		2	Measurement done according to the standard IEC 60068-2-6 • 10-150 Hz • Displacement 0.15 mm max • 3 axis • 5 sweeps • 1 minute/octave

8. END-USER TECHNICAL SUPPORT

This manual can be sent in paper format on request within 7 calendar days.

All Countries
x-rayimaging.support@thalesgroup.com
Tel: +33 4 76 57 52 80

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