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# PIXIUM DYNAMIC X-RAY FLAT PANEL DETECTORS

## END USER MANUAL

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OPEN

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## 1. DOCUMENT HISTORY

| Revision | Status   | Date           | Modification                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----------|----------|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| -        | Approved | September 2022 | Creation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| A        | Approved | July 2023      | Update for MDR submission                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| B        | Approved | August 2023    | <ul style="list-style-type: none"><li>• Add PIXIUM SURGICAL 2121S-AU2 F</li><li>• “<b>Symbols</b>”, add AC voltage, CHP/REP, TX/RX and minor test modification about serial number</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| C        | Approved | April 2024     | <ul style="list-style-type: none"><li>• “<b>Environment Operating, Storage And Handling Conditions</b>”, correct min temperature to 35°C for non guaranteed image quality specification</li><li>• “<b>Environment Operating, Storage And Handling Conditions</b>”, add 0°C-10°C range for 3030S and 3030S-AU for non guaranteed image quality specification.</li><li>• “<b>Regular Maintenance</b>”, add information.</li><li>• “<b>Dark Calibration</b>”, add alert notices.</li><li>• “<b>Environment Operating, Storage And Handling Conditions</b>”, add humidity (non condensing) information for FL4, F5B and F5</li><li>• “<b>Product Scope</b>”, header correction of compatibility matrix to improve readability</li><li>• “<b>Medical Devices Applications</b>”, “<b>Indications</b>”, useless information removed</li></ul> |
| D        | Approved | October 2024   | <ul style="list-style-type: none"><li>• Add PIXIUM SURGICAL 2121S-HDi</li><li>• Add PIXIUM SURGICAL 3131S-HDi</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| E        | Approved | April 2025     | <ul style="list-style-type: none"><li>• “<b>Glossary</b>”, Update.</li><li>• “<b>Adverse effects / Undesirable side-effects</b>”, Add an Application note quality image and multiple irradiation.</li><li>• “<b>X-Ray Management</b>”, add application note in case of crash system.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| F        | Approved | October 2025   | <ul style="list-style-type: none"><li>• “<b>Symbols</b>”, Updated User Manual Symbols</li><li>• “<b>Glossary</b>”, correction</li><li>• “<b>Reliability</b>”, correction</li><li>• “<b>Glossary</b>”, correction</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

## 2. SYMBOLS

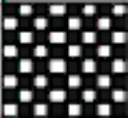
- Read the safety and operating instructions before operating the device.
- Retain safety and operating instructions for future reference.
- Adhere to all warnings on the device and in the operating instructions manual.
- Follow all instructions for operation and use

### 2.1. End User Manual Symbols Definition

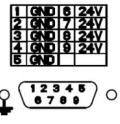
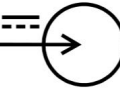
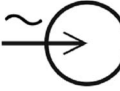
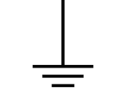
|                                                                                     |                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | <b>Caution</b><br>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                                                                                                                                                                                                                                               |
|   | <b>General mandatory action</b><br>Risk to people not following the mandatory action specified by the supplementary sign                                                                                                                                        |
|  | <b>General prohibition</b><br>Risk to people specified by the supplementary sign                                                                                                                                                                                |
|  | <b>Reference</b><br>Indicates the need for the user to consult the <i>instructions for use</i>                                                                                                                                                                  |
|  | <b>Note</b><br>Read carefully this note. Important information is given.                                                                                                                                                                                        |
|  | CE marking of conformity.                                                                                                                                                                                                                                       |
|  | <b>Electrostatic sensitive device</b><br>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).                                                                                                                                                                                                                                      |

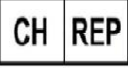
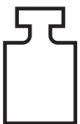
|                                                                                   |                 |
|-----------------------------------------------------------------------------------|-----------------|
|  | Earth (Ground). |
|-----------------------------------------------------------------------------------|-----------------|

## 2.2. Labels And Packaging Symbol Definition

|                                                                                     |                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Indicates the item is a <i>medical device</i>                                                                                                                                                                                             |
|    | Indicates the <i>medical device manufacturer</i>                                                                                                                                                                                          |
|    | 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 that the medical device was manufactured in France                                                                                                                                                                              |
|  | Indicates the date when the device was manufactured.<br>The date code in the format YYYY-MM-DD <ul style="list-style-type: none"> <li>• YYYY = Year - 4 digits</li> <li>• MM = Month - 2 digits</li> <li>• DD = Day - 2 digits</li> </ul> |
|  | 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                                                                                                                                                             |
|  | <b>Caution</b><br>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                                                                                                                                   |
| <b>Rx Only</b>                                                                      | Indicates that equipment shall be used by professional.                                                                                                                                         |
|    | Indicates the representative name and address in Switzerland                                                                                                                                    |
|    | Indicates there is an 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 a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information. |
|    | Indicates 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.                                     |
|   | Indicates a medical device that can be broken or damaged if not handled carefully.                                                                                                      |
|  | Indicates a medical device that needs to be protected from moisture.                                                                                                                    |

### 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 the package 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 SURGICAL 2121S Option A         | Refers to a medical device including a Pixium 2121S-A detector and PixDyn software.                                                                                                                                                                                                                                                        |
| PIXIUM SURGICAL 2121S-AP (PIXDYN LITE) | Refers to the package including a Pixium 2121S-A detector and PixDyn software running under Windows.                                                                                                                                                                                                                                       |
| 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 SURGICAL 2121S Option AU        | Refers to a medical device including a Pixium 2121S-AU detector and PixDyn software.                                                                                                                                                                                                                                                       |
| PIXIUM SURGICAL 2121S-AU (PIXDYN LITE) | Refers to the package including a Pixium 2121S-AU detector and PixDyn software running under Windows.                                                                                                                                                                                                                                      |
| PIXIUM SURGICAL 2121S-AU (P2)          | Refers to the package including a Pixium 2121S-AU detector and PixDyn software running under Ubuntu.                                                                                                                                                                                                                                       |
| PIXIUM SURGICAL 2121S-AU-H             | Refers to the package including PixDyn running on a PROCESSING UNIT ALPHA and a Pixium 2121S-AU.                                                                                                                                                                                                                                           |

| Name                                   | Definition                                                                                                          |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| 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 the package including a Pixium 2121S-AU2 detector and PixDyn software running under Windows.              |
| PIXIUM SURGICAL 2121S-AU2 F (P2)       | Refers to the package including a Pixium 2121S-AU2 detector and PixDyn software running under Ubuntu.               |
| 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 SURGICAL 3030S Option A         | Refers to a medical device including a Pixium 3030S-A detector and PixDyn software.                                 |
| PIXIUM SURGICAL 3030S-A                | Refers to the package including PixDyn running on a PROCESSING UNIT ALPHA and a Pixium 3030S-A.                     |
| PIXIUM SURGICAL 3030S-AP (PIXDYN LITE) | Refers to the package including a Pixium 3030S-A detector and PixDyn software running under Windows.                |
| 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 SURGICAL 3030S Option AU        | Refers to a medical device including a Pixium 3030S-AU detector and PixDyn software.                                |
| PIXIUM SURGICAL 3030S-AU (PIXDYN LITE) | Refers to the package including a Pixium 3030S-AU detector and PixDyn software running under Windows.               |
| PIXIUM SURGICAL 3030S-AU-H             | 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 the package including a Pixium 3131S-HDi detector and PixDyn software running under Windows.              |
| 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 RF 4343 FL4                     | Refers to a medical device including a Pixium 4343 FL4 detector and PixDyn software.                                |
| PIXIUM RF 4343 FL (MODEL 4)            | Refers to the package including PixDyn running on a PROCESSING UNIT ALPHA and a Pixium 4343 FL4                     |

| Name                          | Definition                                                                                                                                                                      |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PIXIUM RF 4343 FL-P (MODEL 4) | Refers to the package including a Pixium 4343 FL4 detector and PixDyn software running under Windows.                                                                           |
| 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 RF 4343 F5             | Refers to a medical device including a Pixium 4343 F5 detector and PixDyn software.                                                                                             |
| PIXIUM RF 4343 F5 (P1)        | Refers to the package including a Pixium 4343 F5 detector and PixDyn software running under Windows.                                                                            |
| Pixium 4343 F5 B              | Refers to the 43 x 43 cm X-ray flat panel detector alone                                                                                                                        |
| PIXIUM RF 4343 F5 B (P1)      | Refers to the package including a Pixium 4343 F5 B detector and PixDyn software running under Ubuntu.                                                                           |
| 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 DYNAMIC 3040 option F  | Refers to a medical device including a Pixium 3040F detector and PixDyn software.                                                                                               |
| PIXIUM DYNAMIC 3040F-AP       | CONVERTER 5G with a Pixium 3040F detector and PixDyn software                                                                                                                   |
| 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. |

| Name                         | Definition                                                                                                                                                                         |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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

|                                                                                   |                                                                                                                                                                                                                                                                                                          |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>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.</p> |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                   |                                                                                  |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
|  | <p>In case of earthquake, the Product must be inspected before being reused.</p> |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|

### 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                 |               |               |

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| 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

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>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.</p> <p>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.</p> <p>The clinical end-users are intended to be qualified/trained doctors or technicians</p> |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

4.5. Use Environments

PIXIUM 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.

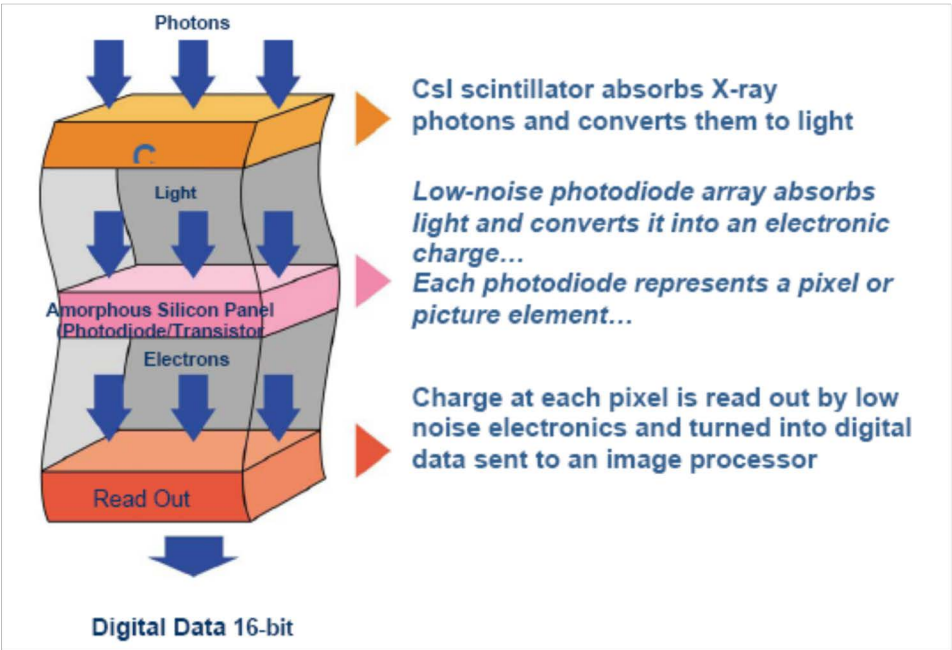
X-ray Flat Panel Detectors (FPD) are intended to convert a low-intensity X-ray image into a digital image.

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

|                                                                                   |                                                                                                                                                                                                                         |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | When the image quality is damaged due to detector malfunctioning, it can lead to the repetition of the irradiations. In case of multiple irradiations on a same patient, some potential side effects may appear on him. |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 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 <sub>DC</sub> |
| 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

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- 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 <sub>DC</sub> |
| 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 <sub>DC</sub> |
| Communication / image transfer | Ethernet cable                     | -               |
| Total transmitted image width  | 1024                               | pixels          |

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| 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 $\mu$ Gy          | 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                                | $\mu$ m         |
| Quantization depth                   | 16                                 | bits            |
| Power supply input                   | 24 $\pm$ 10%                       | V <sub>DC</sub> |
| 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 $\mu$ Gy          | 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 <sub>DC</sub> |
| 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 <sub>DC</sub> |
| Communication / image transfer | Ethernet cable                     | -               |
| Total transmitted image width  | 1534                               | pixels          |
| Total transmitted image height | 1534                               | pixels          |

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| 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 $\mu$ Gy          | 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                         | $\mu$ m         |
| Quantization depth                   | 16                          | bits            |
| Power supply input                   | 24 $\pm$ 10%                | V <sub>DC</sub> |
| 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 2 $\mu$ Gy          | 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 <sub>DC</sub> |
| 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 <sub>DC</sub> |
| Communication / image transfer | Optical link                       |                 |

| Thales KEYWORDS                              | ITEM                                         | Unit   | min  | max |
|----------------------------------------------|----------------------------------------------|--------|------|-----|
| <b><u>Image geometry characteristics</u></b> | <b><u>Image geometry characteristics</u></b> |        |      |     |
| 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  |     |

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| 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 <sub>DC</sub> |
| 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 <sub>DC</sub> |
| 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 <sub>DC</sub> |
| Communication / image transfer | Optical link                       |                 |

| Thales KEYWORDS                       | ITEM                                  | Unit   | min  | max |
|---------------------------------------|---------------------------------------|--------|------|-----|
| <u>Image geometry characteristics</u> | <u>Image geometry characteristics</u> |        |      |     |
| 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  |     |

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| 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 <sub>DC</sub> |
| 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 <sub>DC</sub> |
| 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 <sup>2</sup> |

## 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 5%. The detector 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    |     |     | 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%.

#### 4.14.7. 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  |     |     |

|                                                                                   |                                                                                                                                                                                                                                                                                  |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>The detectors sensitivity loss after applying 1200 Gy shall not exceed 12 % maximum.</p> <p>The detectors sensitivity loss after applying 700 Gy shall not exceed 10 % maximum.</p> <p>The detectors sensitivity loss after applying 100 Gy shall not exceed 5 % maximum.</p> |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### 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 |
|--------------------------------|-----------------------------------------|------|-----|-----|
| <u>Service and reliability</u> | <u>Service and reliability</u>          |      |     |     |
| 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 |

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| 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 |
|--------------------------------|-----------------------------------------|------|-----|-----|
| <u>Service and reliability</u> | <u>Service and reliability</u>          |      |     |     |
| 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.<br>Qualified in this context means that the engineers have been trained accordingly or have acquired the necessary experience in practice.<br>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 a multiplane configuration, the AOC must not be used while X-ray are emitted on another plane. |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|

|                                                                                     |                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | <p>In case of crash of any part of the system (workstation, PU, converter or detector), PixDyn must restart automatically and it is recommended to restart the complete system.</p>                                                                                                                  |
|    | <p>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.</p> |
|    | <p>It is the System manufacturer responsibility to control the actual emission of X-Radiation.</p>                                                                                                                                                                                                   |
|    | <p>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.</p>                                                                                                                                                  |
|  | <p>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.</p>                                                                                                                  |
|  | <p>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.</p>                                                                                                                                                   |



## 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 <b>10 minutes</b> . |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|

## 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 <b>10 minutes</b> . |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|

## 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 <b>10 minutes</b> . |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|

## 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 <b>10 minutes</b> . |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|

## 6.1.6. PIXIUM SURGICAL 3030S Option AU

|                                                                                   |                                                                                                                                                            |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>Before performing a good dark calibration, the detector shall be powered on for at least 1 minute.</p>                                                  |
|  | <p>The default and recommended life time duration for the dark reference calibration table for a PIXIUM SURGICAL 3030S Option AU is <b>10 minutes</b>.</p> |

## 6.1.7. PIXIUM SURGICAL 3131S-HDi

|                                                                                    |                                                                                                                                                      |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | <p>Before performing a good dark calibration, the detector shall be powered on for at least 1 minute.</p>                                            |
|  | <p>The default and recommended life time duration for the dark reference calibration table for a PIXIUM SURGICAL 3131S-HDi is <b>10 minutes</b>.</p> |

## 6.1.8. PIXIUM DYNAMIC 3040 option F

|                                                                                     |                                                                                                                                                         |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>Before performing a good dark calibration, the PIXIUM DYNAMIC 3040 option F detector shall be powered on for at least <b>5 minutes</b>.</p>          |
|  | <p>The default and recommended life time duration for the dark reference calibration table for a PIXIUM DYNAMIC 3040 option F is <b>15 minutes</b>.</p> |

## 6.1.9. PIXIUM RF 4343 F4

|                                                                                     |                                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>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</p>                        |
|  | <p>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</p> |

## 6.1.10. PIXIUM RF 4343 F5

|                                                                                   |                                                                                                                                                                    |
|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>Before performing a good dark calibration, the PIXIUM RF 4343 F5 detector shall be powered on for at least <b>60 min</b> for an offset valid during 15 min.</p> |
|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                   |                                                                                                                                              |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>The default and recommended life time duration for the dark reference calibration table for a PIXIUM RF 4343 F5 is <b>15 minutes</b>.</p> |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|

## 6.1.11. PIXIUM RF 4343 F5 B

|                                                                                   |                                                                                                                                                                      |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>Before performing a good dark calibration, the PIXIUM RF 4343 F5 B detector shall be powered on for at least <b>60 min</b> for an offset valid during 15 min.</p> |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                    |                                                                                                                                                |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>The default and recommended life time duration for the dark reference calibration table for a PIXIUM RF 4343 F5 B is <b>15 minutes</b>.</p> |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|

## 6.1.12. PIXIUM RF 4343 FL3

|                                                                                     |                                                                                                                                                                                       |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>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</p> |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                     |                                                                                                                                                                                                                     |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>The periodicity of this calibration has to be determined by the integrator according to environmental conditions and time constraints. Thales recommended period is <b>15 minutes</b> for offset calibration</p> |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 6.1.13. PIXIUM RF 4343 FL4

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

|                                                                                     |                                                                                                                                               |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>The default and recommended life time duration for the dark reference calibration table for a PIXIUM RF 4343 FL4 is <b>15 minutes</b>.</p> |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|

#### 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 <b>15 minutes</b> |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|

|                                                                                   |                                                                                                           |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
|  | 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 <b>15 minutes</b> |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|

|                                                                                    |                                                                                                           |
|------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
|  | 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 <b>15 minutes</b> |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|

|                                                                                     |                                                                                                           |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
|  | 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 <b>15 minutes</b> |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|

|                                                                                     |                                                                                                           |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
|  | 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 <b>15 minutes</b> |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|

|                                                                                   |                                                                                                           |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
|  | 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 <b>15 minutes</b> |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|

|                                                                                    |                                                                                                           |
|------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
|  | 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 <b>100 minutes.</b> |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|

|                                                                                     |                                                                                                           |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
|  | 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 <b>1 hour</b> |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|

|                                                                                   |                                                                                                             |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
|  | 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 <b>1 hour</b> |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|

|                                                                                    |                                                                                                             |
|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
|  | 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 <b>1 hour</b> |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|

|                                                                                     |                                                                                                             |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
|  | 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 – <b>Full performance</b> (°C)                                           | 10  | 35    |                                                                                                                                                                                                                                                                      |
| Operational temperature – <b>Functional / Warning</b> (°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. <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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.<br>Maximum vibration specifications to be applied to check specified limited performances <ul style="list-style-type: none"> <li>• 0.6 g</li> <li>• 10 Hz - 200 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |

## 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 <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| Humidity ratio (g of water/g of dry air)         |     | 0.039 |                                                                                                                                                                                                                             |
| 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 – <b>Full performance</b> (°C)                                           | 10  | 35  |         |
| Operational temperature – <b>Functional / Warning</b> (°C) -> IQ performances are not guaranteed | 35  | 40  |         |

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| 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. <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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.<br>Maximum vibration specifications to be applied to check specified limited performances <ul style="list-style-type: none"> <li>• 0.6 g</li> <li>• 10 Hz - 200 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |

## 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 <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| Storage and transport pressure conditions (mbar) | 550 | 1100 | Unpacked                                                                                                                                                                                                                    |

## 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 – <b>Full performance</b> (°C)                                           | 10  | 35    |                                                                                                                                                                                                                                                                      |
| Operational temperature – <b>Functional / Warning</b> (°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. <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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.<br>Maximum vibration specifications to be applied to check specified limited performances <ul style="list-style-type: none"> <li>• 0.3 g</li> <li>• 10 Hz - 200 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |

## 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 <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| Storage and transport pressure conditions (mbar) | 550 | 1100 | Unpacked                                                                                                                                                                                                                    |

## 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 – <b>Full performance</b> (°C)                                           | 10  | 35  |         |
| Operational temperature – <b>Functional / Warning</b> (°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. <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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.<br>Maximum vibration specifications to be applied to check specified limited performances <ul style="list-style-type: none"> <li>• 0.3 g</li> <li>• 10 Hz - 200 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |

## 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 <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| Storage and transport pressure conditions (mbar) | 550 | 1100 | Unpacked                                                                                                                                                                                                                    |

## 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 – <b>Full performance</b> (°C)                                           | 10  | 35   |                                                                                                                                                                                                                                                                      |
| Operational temperature – <b>Functional / Warning</b> (°C) -> IQ performances are not guaranteed | 0   | 10   |                                                                                                                                                                                                                                                                      |
| Operational temperature – <b>Functional / Warning</b> (°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. <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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.<br>Maximum vibration specifications to be applied to check specified limited performances <ul style="list-style-type: none"> <li>• 0.6 g</li> <li>• 10 Hz - 200 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |

## 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 <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| Storage and transport pressure conditions (mbar) | 550 | 1100 | Unpacked                                                                                                                                                                                                                    |

## 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 – <b>Full performance</b> (°C)                                           | 10  | 35  |         |
| Operational temperature – <b>Functional / Warning</b> (°C) -> IQ performances are not guaranteed | 0   | 10  |         |

| Parameter                                                                                        | Min | Max   | Comment                                                                                                                                                                                                                                                              |
|--------------------------------------------------------------------------------------------------|-----|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Operational temperature – <b>Functional / Warning</b> (°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. <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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.<br>Maximum vibration specifications to be applied to check specified limited performances <ul style="list-style-type: none"> <li>• 0.3 g</li> <li>• 10 Hz - 200 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |

## 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 |

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| 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 <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| Storage and transport pressure conditions (mbar) | 550 | 1100 | Unpacked                                                                                                                                                                                                                    |

### 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 – <b>Full performance</b> (°C)                                           | 10  | 35    |                                                                                                                                                                                                                                                                      |
| Operational temperature – <b>Functional / Warning</b> (°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. <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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.<br>Maximum vibration specifications to be applied to check specified limited performances <ul style="list-style-type: none"> <li>• 0.6 g</li> <li>• 10 Hz - 200 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |

## 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 <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| Humidity ratio (g of water/g of dry air)         |     | 0.039 |                                                                                                                                                                                                                             |
| 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 – <b>Full performance</b> (°C)                                           | 10  | 35  |         |
| Operational temperature – <b>Functional / Warning</b> (°C) -> IQ performances are not guaranteed | 35  | 40  |         |

| Parameter                                       | Min | Max  | Comment                                                                                                                                                                                                                                                              |
|-------------------------------------------------|-----|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Humidity range (%HR) in standard operating mode | 5   | 90   |                                                                                                                                                                                                                                                                      |
| 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. <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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.<br>Maximum vibration specifications to be applied to check specified limited performances <ul style="list-style-type: none"> <li>• 0.6 g</li> <li>• 10 Hz - 200 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |

## 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 <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| Storage and transport shocks (g) – Unpacked      |     | 10   | ½ sine, 16 ms, 1000 times, 6 directions                                                                                                                                                                                     |
| Storage and transport pressure conditions (mbar) | 550 | 1100 | Unpacked                                                                                                                                                                                                                    |

Vibration tests shall be performed in accordance with the following applicable standards:

- IEC 60068-2-6, Edition 7.0 (2007-12 : Environmental testing – Part 2-6: Tests – Test Fc: Vibration (sinusoidal)
- IEC 60721-3-2, Edition 2.0 (1997-03) :Classification of environmental conditions – Part 3-2: Classification of groups of environmental parameters and their severities – Transportation

Test parameters in the packed configuration (sinusoidal acceleration):

- Number of axes: 3
- Amplitude of deflection (5 to 9 Hz): 3.5 mm
- Acceleration amplitude (9 to 200 Hz): 10 m/s<sup>2</sup>
- Acceleration amplitude (200 to 500 Hz): 15 m/s<sup>2</sup>

## 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:<br>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   |                                                                                                                                                                                    |
| Storage and transport vibrations (g) - Unpacked  |     | 2    | <ul style="list-style-type: none"> <li>• 10-58 Hz</li> <li>• Displacement 0.15 mm</li> <li>• 58-150 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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 – <b>Full performance</b> (°C)                                           | 10  | 35           |                                                                                                                                                                                                                                                                      |
| Operational temperature – <b>Functional / Warning</b> (°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. <ul style="list-style-type: none"> <li>• 10-150 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| Operating bumps (g)                                                                              |     | 10           | ½ sine, 16 ms, 1000 times, 6 directions                                                                                                                                                                                                                              |

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| Parameter                   | Min | Max  | Comment |
|-----------------------------|-----|------|---------|
| 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.<br>Maximum vibration specifications to be applied to check specified limited performances <ul style="list-style-type: none"> <li>• 0.3 g</li> <li>• 10 Hz - 200 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |

## 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 – <b>Full performance</b> (°C)                                           | 10  | 35  |         |
| Operational temperature – <b>Functional / Warning</b> (°C) -> IQ performances are not guaranteed | 35  | 40  |         |



| Parameter                              | Min | Max          | Comment                                                                                                                                                                                                                                                              |
|----------------------------------------|-----|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. <ul style="list-style-type: none"> <li>• 10-150 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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.<br>Maximum vibration specifications to be applied to check specified limited performances <ul style="list-style-type: none"> <li>• 0.3 g</li> <li>• 10 Hz - 200 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |

## 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                |

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| Parameter                                        | Min | Max  | Comment                                 |
|--------------------------------------------------|-----|------|-----------------------------------------|
| 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:<br>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    | <ul style="list-style-type: none"> <li>• 10-58 Hz</li> <li>• Displacement 0.15 mm</li> <li>• 58-150 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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 – <b>Full performance</b> (°C)                                           | 10  | 35           |                                                                                                                                                                                                                                                                      |
| Operational temperature – <b>Functional / Warning</b> (°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. <ul style="list-style-type: none"> <li>• 10-150 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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.<br>Maximum vibration specifications to be applied to check specified limited performances <ul style="list-style-type: none"> <li>• 0.3 g</li> <li>• 10 Hz - 200 Hz</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |

## 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)       | 9   | 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: <ul style="list-style-type: none"> <li>• 10 - 200 Hz</li> <li>• displacement = 0.15mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 oct / min</li> </ul> |

## 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)<br>IEC 60068-2-2 Dry heat storage (72h test)<br>IEC 60068-2-30 Damp heat, cyclic (6x24h test)<br>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<br>Measurement to check specified limited performance is done according to the following conditions: <ul style="list-style-type: none"> <li>• 3 axis</li> <li>• 4 cycles per direction</li> </ul> |
| Operating vibrations (g)                        |     | 1    | 58 - 150 Hz<br>Measurement to check specified limited performance is done according to the following conditions: <ul style="list-style-type: none"> <li>• 3 axis</li> <li>• 4 cycles per direction</li> </ul>                              |
| 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. <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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)<br>IEC 60068-2-2 Dry heat storage (72h test)<br>IEC 60068-2-30 Damp heat, cyclic (6x24h test)<br>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:

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| 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. <ul style="list-style-type: none"> <li>• 10-200 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |
| 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 <ul style="list-style-type: none"> <li>• 10-150 Hz</li> <li>• Displacement 0.15 mm max</li> <li>• 3 axis</li> <li>• 5 sweeps</li> <li>• 1 minute/octave</li> </ul> |



## 8. END-USER TECHNICAL SUPPORT

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

| All Countries                                                                                  |
|------------------------------------------------------------------------------------------------|
| <a href="mailto:x-rayimaging.support@thalesgroup.com">x-rayimaging.support@thalesgroup.com</a> |
| Tel: +33 4 76 57 52 80                                                                         |

End of document

