THALES

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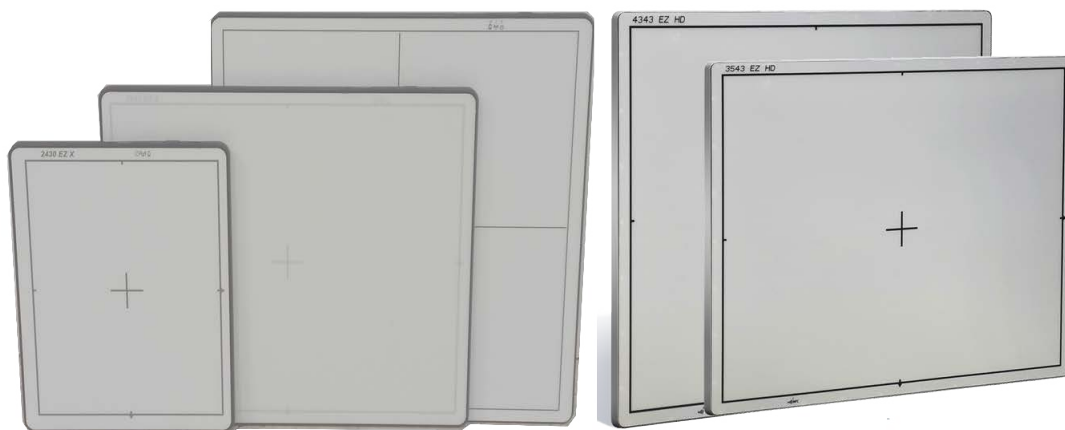Tel: +33 4 76 57 52 80

PIXIUM STATIC X-RAY FLAT PANEL DETECTORS

END USER MANUAL

CE 0123

OPEN

83270259-SER-MIS-EN-002

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1. DOCUMENT HISTORY

Revision	Status	Date	Modification
-	Approved	January 2024	Creation.
A	Approved	May 2024	• *"Performance"*, DQE values for 6 µGy added, values for 2 µGy removed • *"Using the NFC Tag"*, added Adding detailed information of Pixium EZ X on: • *"Symbols"*, • *"Glossary"*, • *"Product Scope"*, • *"Cybersecurity"*, • *"Product Legal Manufacturer and Manufacturing Site"*, • *"Main Physical Characteristics"*, • *"General Precautions"*, • *"Shocks"*, • *"Pacemaker"*, • *"Performance"*, • *"Accessories Important Safety Instructions"*, • *"FCC Rules (U.S.A.)"*, • *"Supplier's Declaration of Conformity Pixium EZ X"*, • *"IC (Canada)"*, • *"RED directive (Europe)"*, • *"Pixium 2430 EZ X"*, • *"Pixium 3543 EZ X"*, • *"Pixium 4343 EZ X"*, • *"LED Location"*, • *"Meaning of the Symbols"*, • *"Status LED"*, • *"Wi-Fi LED"*, • *"Pixium EZ X Display Interface"*, • *"Using the NFC Tag"*, • *"Battery LED"*, • *"Pixium EZ X Series"*, • *"Turn ON, turn OFF"*, • *"Hot-swap functionality (Pixium 3543 EZ X and Pixium 4343 EZ X only)"*, • *"Maintenance And Cleaning"*, • *"Operating Conditions"*, • *"Storage And Handling"*,
B	Approved	March 2025	Adding Pixium EZ X series J on: • *"Glossary"*, • *"Product Scope"*, • *"Supplier's Declaration of Conformity Pixium EZ X"*,

2. DISCLAIMER

The following document is written in English.

(!)	Thales writes at least its User Manual in one of the official languages of the EU, according to the Annex II - Technical Documentation, of the MDR 2017/745/EU.The necessary translation of the documents intended for the end-users in the official language of the country the product is sold, as well as their availability, is in charge of the OEM or integrators, which can request to Thales a translation, if necessary.

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3. 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

3.1. End User Symbols Definition

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

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Symbol	Signification
	Earth (Ground).
	Warning: Flammable material
	Warning: Explosive material
	Warning: Toxic material
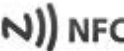
3.2. Products Symbols definition

Pixium EZ X

Symbol	Signification
	Status LED indicator
	Wi-Fi LED indicator
	Battery LED indicator

Symbol	Signification
	Area of the NFC interface
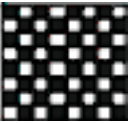
Pixium EZ HD
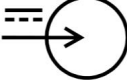
Symbol	Signification
	Area of the NFC interface

3.3. Labels And Packaging Symbols Definition

Symbol	Signification
MD	Indicates the item is a *medical device*
	Indicates the *medical device manufacturer*
SN	Serial Number symbol followed by the serial number of the product (8 alpha-numeric digits and barcode 128)
UDI	Indicates a carrier that contains unique device identifier information
	Data Matrix code (UDI)
FR	Indicates the date when the medical device was manufactured in France.
	Indicates the date when the device was manufactured. The date code in the format YYYY-MM-DD • YYYY = Year - 4 digits • MM = Month - 2 digits • DD = Day - 2 digits
PN	Part number. To identify the manufacturer's part number of the detector.
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified
CE 0123	CE marking of conformity provided by TÜV SÜD notified body
	Applied part (For PIXIUM PORTABLE items only)

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Symbol	Signification
	WEEE Conformity symbol (recycling)
	Radio Frequency Radiation Symbol Indicates equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
IP56	Ingress protection dust protected and against Water jets (For PIXIUM PORTABLE items only)
IP67	Ingress protection dust-tight and against immersion, up to 1 meter depth (For PIXIUM PORTABLE items only)
100kg	Not placing any objects over 100 kg on the surface (For PIXIUM PORTABLE items only)
Rx Only	Prescription only - device restricted to use by a qualified/trained doctor or technican
FC contains FCC ID : VPQ-WNFB265AXIBT FCC ID : VPQ-EZ3NFC IC ID : 7392A-NFB265AXIBT IC ID : 7392A-EZ3NFC	Radio certification of the Wi-Fi module and NFC controller: - USA: FCC Identifier (FCC ID)
FC contains FCC ID : TK4WLE900VX IC : 7849A-WLE900VX FCC ID : OWROM5578-PN7150S	Radio certification of the Wi-Fi module and NFC controller: - USA: FCC Identifier (FCC ID)
	Rated power input (DC), followed by powering information (DC xx V, x A).
	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
	Refer to instruction manual/booklet to signify that the instruction manual/booklet must be read

Symbol	Signification
	No activated mobile phone to prohibit activated mobile phones
Pb	includes "Pb" to inform that detector include lead
Rx Only	Indicates that equipment shall be used by professional.
TX RX	Indicates there is optical link
	Indicates on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.
	Indicates the number of pieces in the package.
	Indicates that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.
	Indicates that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.
	Indicates the actual dimensions.
	Indicates the weight.
	Indicates the weight of an object that may be lifted or is being lifted.

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Symbol	Signification
↑↑	Indicates correct upright position of the transport package.
(do not use if damaged symbol)	Indicates that the device must not be used if the package holding the device is damaged, for example on packaging of medical devices.
⚠	Indicates a general warning. When used a supplementary sign give further information about the hazard.
(moisture sensitive symbol)	Indicates packages containing moisture sensitive devices, or to identify a device or a connector that has not been tested for immunity to moisture.
(fragile glass symbol)	To indicate that the contents of the transport package are fragile and the package shall be handled with care.
(umbrella symbol)	To indicate that the transport package shall be kept away from rain and in dry conditions.
(no pacemaker symbol)	No access for people with active implanted cardiac devices.
(magnetic field warning)	Warning magnetic field.

4. GLOSSARY

The present End User Manual applies to following Static Flat Panel Detectors:

Name	Definition
Pixium	Patented generic name for all Thales flat panel digital detectors.
PixRad	Name of the generic Thales Application Programming Interface suitable for all the static Pixium flat panel detectors proposed by Thales. This API provides functionalities to the OEM system such as control of the detectors, images aquisition, calibration of the system, image pre-processing and service information.
Pixium EZ X	Refers to all detectors Pixium 2430 EZ X, Pixium 3543 EZ X and Pixium 4343 EZ X.
Pixium 2430 EZ X	Refers to any 24 x 30 cm X-ray flat panel detector alone with an a-Si plate
Pixium 3543 EZ X	Refers to any 35 x 43 cm X-ray flat panel detector alone with an a-Si plate.
Pixium 4343 EZ X	Refers to any 43 x 43 cm X-ray flat panel detector alone with an a-Si plate.
PIXIUM PORTABLE 2430 EZ-C X	Refers to the package including a Pixium 2430 EZ X detector and PixRad API.
PIXIUM PORTABLE 3543 EZ-C X	Refers to the package including a Pixium 3543 EZ X detector and PixRad API.
PIXIUM PORTABLE 4343 EZ-C X	Refers to the package including a Pixium 4343 EZ X detector and PixRad API.
PIXIUM PORTABLE 3543 EZ-C X D	Refers to the package including a Pixium 3543 EZ X detector and PixRad API.
PIXIUM PORTABLE 4343 EZ-C X D	Refers to the package including a Pixium 4343 EZ X detector and PixRad API.
PIXIUM PORTABLE 2430 EZ-C X J	Refers to the package including a Pixium 2430 EZ X detector and PixRad API.
PIXIUM PORTABLE 3543 EZ-C X J	Refers to the package including a Pixium 3543 EZ X detector and PixRad API.
PIXIUM PORTABLE 4343 EZ-C X J	Refers to the package including a Pixium 4343 EZ X detector and PixRad API.
Pixium EZ HD	Refers to all detectors Pixium 3543 EZ-C HD and Pixium 4343 EZ-C HD.
Pixium 3543 EZ-C HD	Refers to any 35 x 43 cm X-ray flat panel detector alone with an a-Si plate (option CMEDB).
Pixium 4343 EZ-C HD	Refers to any 43 x 43 cm X-ray flat panel detector alone with an a-Si plate (option CAEH).
PIXIUM PORTABLE 3543 EZ-C HD	Refers to the package including a Pixium 3543 EZ-C HD (option CAEH) detector and PixRad API.

Name	Definition
PIXIUM PORTABLE 4343 EZ-C HD	Refers to the package including a Pixium 4343 EZ-C HD (option CAEH) detector and PixRad API.

The present User Manual applies to following components

Name	Definition
BATTERY EZ HD	The BATTERY EZ HD is designed to power the Thales flat panel detectors Pixium EZ HD.
CHARGER EZ HD	The CHARGER EZ HD is intended to recharge the BATTERY EZ HD used to power the Thales flat panel detectors Pixium EZ HD. The CHARGER EZ HD is designed to recharge one unit of BATTERY EZ HD.
CABLE EZ HD 1M	The CABLE EZ HD 1M is designed to provide the power to the Thales flat panel detectors Pixium EZ HD, as well as to insure the data transfer between the host computer and the detector.
BATTERY NPT EZ X	The BATTERY NPT EZ X is designed to power the Thales flat panel detectors Pixium EZ X.
BATTERY CHARGER EZX	The BATTERY CHARGER EZX is intended to recharge the BATTERY NPT EZ X used to power the Thales flat panel detectors Pixium EZ X. The BATTERY CHARGER EZX is designed to recharge up to three units of BATTERY NPT EZ X.

5. DEVICE INFORMATION

5.1. Product Scope

5.1.1. Medical Devices

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

- Pixium 2430 EZ X:
  - PIXIUM PORTABLE 2430 EZ-C X
  - PIXIUM PORTABLE 2430 EZ-C X J
- Pixium 3543 EZ X:
  - PIXIUM PORTABLE 3543 EZ-C X
  - PIXIUM PORTABLE 3543 EZ-C X D
  - PIXIUM PORTABLE 3543 EZ-C X J

- Pixium 4343 EZ X:
  - PIXIUM PORTABLE 4343 EZ-C X
  - PIXIUM PORTABLE 4343 EZ-C X D
  - PIXIUM PORTABLE 4343 EZ-C X J

- Pixium EZ HD:
  - PIXIUM PORTABLE 3543 EZ-C HD
  - PIXIUM PORTABLE 4343 EZ-C HD

5.1.2. Accessories

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

- BATTERY EZ HD
- BATTERY NPT EZ X

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

- CABLE EZ HD 1M

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

- CHARGER 2 EZ
- CHARGER EZ HD
- BATTERY CHARGER EZX

5.1.3. Compatibility Matrix

Detectors			
	BATTERY NPT EZ X	BATTERY CHARGER EZX	CABLE PIXIUM EZ

Detectors			
PIXIUM PORTABLE 2430 EZ-C X	X	X	X
PIXIUM PORTABLE 3543 EZ-C X	X	X	X
PIXIUM PORTABLE 4343 EZ-C X	X	X	X
PIXIUM PORTABLE 3543 EZ-C X D	X	X	X
PIXIUM PORTABLE 4343 EZ-C X D	X	X	X
PIXIUM PORTABLE 2430 EZ-C X J	X	X	X
PIXIUM PORTABLE 3543 EZ-C X J	X	X	X
PIXIUM PORTABLE 4343 EZ-C X J	X	X	X

Detectors			
	BATTERY EZ HD	CHARGER EZ HD	CABLE EZ HD 1M
PIXIUM PORTABLE 3543 EZ-C HD	X	X	X
PIXIUM PORTABLE 4343 EZ-C HD	X	X	X

Detectors	Software
	PixRad on Host PC
PIXIUM PORTABLE 2430 EZ-C X	X
PIXIUM PORTABLE 2430 EZ-C X J	X
PIXIUM PORTABLE 3543 EZ-C X	X
PIXIUM PORTABLE 3543 EZ-C X D	X
PIXIUM PORTABLE 3543 EZ-C X J	X
PIXIUM PORTABLE 4343 EZ-C X	X
PIXIUM PORTABLE 4343 EZ-C X D	X
PIXIUM PORTABLE 4343 EZ-C X J	X
PIXIUM PORTABLE 3543 EZ-C HD	X
PIXIUM PORTABLE 4343 EZ-C HD	X

Conditions of compatibility of PIXIUM STATIC 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.

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5.2. Medical Devices Applications

The Thales PIXIUM STATIC PRODUCTS is a device that converts static radiological images into digital clean images.

The Thales PIXIUM STATIC PRODUCTS includes:

- an X-ray flat panel detector which allows acquiring raw X-ray images;
- an image pre-processing software called PixRad that converts the detector raw images in clean images ready to be used by the OEM system for further processing.

Thales RAD products are active medical devices. They are designed to convert low intensity X-ray images into a digital images for medical diagnosis or therapeutic interventional radiology. They can also be used in more universal medical applications, as a part of imaging chain of an overall radiology system.

The Thales X-Ray flat panel is meant to be integrated into a full x-ray imaging equipment by an OEM

5.3. IT networks characteristics

ⓘ	For a given host, its Ethernet interface must have only one defined IP address.

5.3.1. PC HOST characteristics

The PixRad software is compatible with the following operating systems:

- Windows 7 and Windows 10 / 32 bits
- Windows 7 and Windows 10 / 64 bits

5.4. IT Security

All IT security measures, including protection against unauthorized access, necessary to run the software as intended shall be taken. Please refer to Good practices for the security of healthcare services recommended by ENISA.

5.5. Cybersecurity

In the integration and operation of the X-ray flat panel detectors and Pixrad solution, cybersecurity is a collaborative effort that involves the legal manufacturer, the integrator and the end user.The manufacturer is responsible for ensuring that Pixrad and the panel's hardware and software are designed with robust security features and that any known vulnerability that would jeopardize the cybersecurity of the solution is addressed prior to shipment.The integrator plays a critical role in securely installing and configuring the panel within its system network and within the customer's network, adhering to industry best practices to prevent unauthorized access.Finally, the end user must commit to maintain the security of the solution by implementing strong access controls, regularly updating password when applicable, and monitoring the system for any unusual activity.Together, these parties work in unison to uphold the integrity and confidentiality of sensitive data processed by the solution composed of Pixrad and the X-Ray flat panel detector.

5.6. 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

5.7. Intended User

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

According to the impact that system components and integration may have on the product, performances are under integrator responsibility, especially to prevent image to freeze in case of inadequate PC workload and which could lead to a wrong patient diagnostic or treatment.

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

Pixium Static Detectors are a part of imaging chain of an overall radiology system and are intended to generate high quality digital image.

5.9. Indications

Pixium Static Detectors allow Imaging of the skull, chest, shoulders, spine, abdomen, and extremities. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

5.10. Intended Patient Population

There is not limitation on patient target group nor patient selection criteria.

5.11. Contraindications

Fluoroscopy, angiography and mammography are excluded

5.12. Limitations

There is no limitation.

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5.13. Adverse effects / Undesirable side-effects

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

5.14. Acclimatization Time

The most important unpacking and handling instructions are attached to and visible on the outer packaging, within the *Storage and Handling instructions* document. More general instructions and cautions are given in the present document.

A special care shall be taken in unpacking the Pixium in order to avoid water condensation due to an abrupt temperature and humidity transition.

📖ⓘ	Refer to the *Storage and Handling instructions* document for more information about the storage, handling, packing and unpacking of the Pixium.

🚫	Do not turn on the Pixium if condensation is formed on it.

5.14.1. Pixium Portable detector

Do not open the inner protective bag before a sufficient acclimatization time of 1 hour. During the acclimatization time, it is recommended to remove the Pixium from the cardboard box. However do not under any condition open the sealed protective bag during this time.

5.15. Main Physical Characteristics

5.15.1. PIXIUM PORTABLE EZ-C X Series

The Pixium EZ X is a new generation of portable detector featuring:

- Cassette size 16 mm thickness
- Wireless communication
- Exchangeable batteries
- Embedded memory
- X-ray auto-detection

Parameter	Value			Unit
	Pixium 4343 EZ X	Pixium 3543 EZ X	Pixium 2430 EZ X	
Detector technology	Flexible amorphous silicon array			-
Plate	Single a-Si TFT + photodiode plate			-
Total image width	4320	3520	2336	pixel
Total image height	4316	4316	2880	pixel

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Parameter	Value			Unit
	Pixium 4343 EZ X	Pixium 3543 EZ X	Pixium 2430 EZ X	
pixel pitch	99			µm
Typical overall dimensions	460.5 x 460.5 x 16.0	384.5 x 460.5 x 16.0	268.5 x 328.5 x 16.0	mm
Quantization depth	16			bit
Power supply input	12 +/-10%			V DC
Communication / image transfer	Wi-Fi (IEEE802.11a, b, g, n, ac, ax 2x2 MIMO) or Ethernet cable			-

5.15.2.   PIXIUM PORTABLE EZ-C HD Series

The PIXIUM PORTABLE EZ-C HD is a new generation of portable detector featuring:

- Cassette size 15 mm thickness
- Wireless communication
- Exchangeable batteries
- X-ray auto-detection

Parameter	Value		Unit
	PIXIUM 4343EZ HD	PIXIUM 3543EZ HD	
Plate	Single aSi TFT + photodiode plate		-
Scintillator	CsI		-
Total image width	4302	3534	pixel
Total image height	4302	4302	pixel
Pixel pitch	100	100	µm
Typical overall dimensions	460 x 460 x 15	383 x 460 x 15	mm
Quantization depth	16		bit
Power supply input	24 +/-10%		V DC
Communication / image transfer	Wi-Fi (compliant with 802.11ac standard) or Ethernet cable		-

6. SAFETY AND PRECAUTIONS

6.1. General Precautions

⚠	In case of earthquake, the Product must be inspected before being reused.
⚠	Power supply inversion or out of range may harm the detector. Be sure to correctly connect and clamp the power supply cable.
⚠	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.

6.1.1. PIXIUM PORTABLE all series

❗	Only qualified and authorized service engineers must carry out product installation, adjustment and maintenance described in this document.Qualified in this context means that the engineers have been trained accordingly or have acquired the necessary experience in practice.Authorized means that the engineers have been authorized by the operator of the system to perform maintenance work.
❗	Usage of the PIXIUM detectors is strictly reserved to qualified staff.
❗	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 returned to Thales for analysis and / or repair.
⚠	Power supply inversion or out of range may harm the detector. Be sure to correctly connect and clamp the power supply cable.
❗	Avoid to place the detector too close to life supporting devices.

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🚫	Do not push on the upper face of the Pixium more than specified in the dedicated detector *specification*. Do not expose the Pixium to rain or near water. Do not open the Pixium. Warranty is void if opened. There shall be no heating source close to the Pixium in normal use. No modification of the Pixium is allowed.
⚠️	For the X-Ray flat panel portable detector, before taking any X-ray image, the operator must be sure to use the right detector (attached with the right radiological system). A good practice consists in placing colored label on panel and radiological system.
❗	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.
⚠️	Potential side effects are the results of multiple irradiations for the same patient due to damaged image quality due to detector malfunctioning.
⚠️	With storage enabled, if internal memory is full (meaning there is not enough storage left for acquisition in 1x1 mode), status LED turns solid orange (i.e. not blinking).
ℹ️	Storage function is not available on Pixium EZ HD.

6.2. Shocks

6.2.1. PIXIUM PORTABLE EZ-C X Series

The Pixium EZ X includes a shock sensor feature that detects the occurrence of a shock, stores the date of the occurrence and transmits on request the latest shock events to the system.

The shock sensor feature includes a lithium battery, which is not the removable battery of the detector, and can record shocks while the detector is not powered. The range and charging time of this internal battery are as follows:

• The range of the shock monitoring without external power is 6 months
• The charging duration from empty state to full range is **20 h**

The shocks are detected thanks to electrical shock sensors which turn on when the acceleration exceeds their threshold. The data from the shock sensors is used as an input for standard warranty application. There are two shock sensors for each of the following thresholds:

• Threshold 1 (shock level 1): gives indication of significant shocks due to incautious use. An excessive repeatability of shocks of level 1 may void the standard warranty.

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- Threshold 2 (shock level 2): means that the detector has not been used in conformity with the operating conditions described in the present document. As soon as the threshold 2 has been triggered, the standard warranty is void.

The shock sensor feature records one time-stamped event each time at least one internal shock sensor has turned on.

The shock sensor feature stores the latest 7500 shocks in a FIFO non-volatile memory.

Thanks to PixRad functions, the OEM integrator is informed on new events and can read the event list.

The status of the shock sensor is readable when the battery is removed.
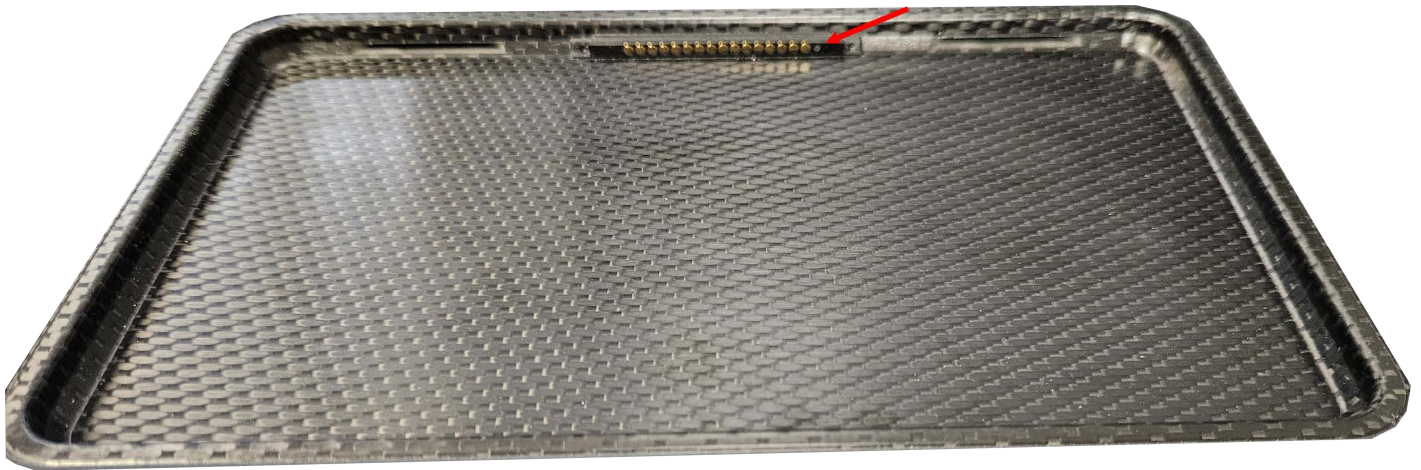
6.2.2. PIXIUM PORTABLE EZ-C HD Series

The Pixium EZ HD includes a shock sensor feature that detects the occurrence of a shock, stores the date of the occurrence and transmits on request the latest shock events to the system.

The shock sensor feature can record shocks while the detector is not powered:

- The range of the shock monitoring without external[1] power is 3 months

The shocks are detected thanks to electrical shock sensors which turn on when the acceleration exceeds their threshold. The data from the shock sensors is used as an input for standard warranty application. There are two shock sensors for each of the following thresholds:

- Threshold 1 (shock level 1): gives indication of significant shocks due to incautious use. An excessive repeatability of shocks of level 1 may void the standard warranty.
- Threshold 2 (shock level 2): means that the detector has not been used in conformity with the operating conditions described in the present document. As soon as the threshold 2 has been triggered, the standard warranty is void.

The shock sensor feature records one time-stamped event each time at least one internal shock sensor has turned on.

The shock sensor feature stores the latest 50 shocks in a FIFO non-volatile memory.

Thanks to PixRad functions, the OEM integrator is informed on new events and can read the event list.

6.3. Radio Frequency Protection

⚠	The detector should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the operability of the detector must be tested in the modified configuration.

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1. With ≤ 25% of internal battery charge remaining.

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⚠	The means of communication (mobile phone, walkie talkie, DECT phone...) should be located outside the patient environment.

6.4. Electro magnetic Compatibility (EMC) Compliance

⚠	The use of radio-frequency transmitters such as portable and mobile Radio Frequency communication equipments close to the system can affect the operation of the X-Ray Flat-Panel detector.

⚠	The X-Ray Flat-Panel detector should not be used next to or stacked with other equipment. If this is unavoidable, the detector should be observed to verify correct operation in the configuration in which it will be used.

⚠	Use ESD protection and precautions while unpacking the X-Ray Flat-Panel detector from its protective bag and installing it in its operational place.

6.5. Applied Parts

6.5.1. PIXIUM PORTABLE all SERIES

❗	The detector has applied parts: it may be in direct contact with the patient.

6.6. Biocompatibility

6.6.1. PIXIUM PORTABLE all SERIES

❗	The detector is designed to be safe in case of short-term contact with damaged skin (less than 1 hour). Nevertheless, if such case occurs, the detector will be preferably wrapped with sterile plastic bag.

6.7. Sterile

❗	The detector is delivered non sterile.

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6.8. Pacemaker

Warning for humans wearing a pacemaker.

6.8.1. PIXIUM PORTABLE EZ-C X Series

- **Wi-Fi**

	The design of the detectors is safe for humans wearing a pacemaker (assuming the pacemaker is conform to EN 45502-2-1) when a minimum distance between the detector and the pacemaker is respected: • 41 cm

- **Detector Magnets**

	If no Wi-Fi is used, respect a minimum distance of 5 cm between the pacemaker and any of the 6 magnets contained in the detector (2 magnets on the connector (detector side), 2 magnets on the backup cable interface (optional), and 2 magnets in the battery locker).

- **Backup Cable Magnets**

	Respect a minimum distance of 5 cm between the pacemaker and the magnetic connector of the backup cable.

- **NFC**

	The detector generates weak electromagnetic fields (NFC) resulting in potential interference with pacemakers. Based on current knowledge these fields would not seem to pose a significant health problem for the vast majority of pacemaker wearers. Still, for patients / hospital staff with pacemakers some simple precautions might be considered to be sure that no interaction problems occur. • Take care to maximize NFC distance to where the pacemaker is implanted. • The detector has possibility to disable NFC via Software if required If any unusual symptoms are observed on pacemaker level, detector shall be removed from direct patient surrounding.

6.8.2. PIXIUM PORTABLE EZ-C HD SERIES

- **Wi-Fi**

	The design of the detectors is safe for humans wearing a pacemaker (assuming the pacemaker is conform to EN 45502-2-1) when a minimum distance between the detector and the pacemaker is respected: • 41 cm

- **Detector Magnets**

	If no Wi-Fi is used, respect a minimum distance of 5 cm between the pacemaker and any of the 4 magnets contained in the detector (2 magnets on the connector (detector side), 2 magnets on the backup cable interface (optional))

- **Backup Cable Magnets**

	Respect a minimum distance of 5 cm between the pacemaker and the magnetic connector of the backup cable.

- **NFC**

	The detector generates weak electromagnetic fields (NFC) resulting in potential interference with pacemakers. Based on current knowledge these fields would not seem to pose a significant health problem for the vast majority of pacemaker wearers. Still, for patients / hospital staff with pacemakers some simple precautions might be considered to be sure that no interaction problems occur. • Take care to maximize NFC distance to where the pacemaker is implanted. • The detector has possibility to disable NFC via Software if required If any unusual symptoms are observed on pacemaker level, detector shall be removed from direct patient surrounding.

6.9. 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.

6.10. Disposal

6.10.1. Pixium

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

The product contains the two following toxic substances:

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

	In case of dismantling the detector, 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.

	This symbol indicates that this detector should NOT be treated as household waste, according to the WEEE directive (2012/19/EU) and your national law.

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	This product should be handed over to a designated collection point or to an authorized collection site for recycling waste electrical and electronic equipment (EEE). Improper handling for this type of waste could have a possible negative impact on the environment and human health due to potentially hazardous substances that are generally associated with EEE. By insuring that this detector is disposed correctly, you will contribute to the effective usage of natural resources. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, waste authority, approved WEEE scheme or your household waste disposal service.

	You can also contact us for more information on the environmental performances of our detectors.

	Thales can ensure the recycling of the detector. Please, contact your local Thales representative for such service.

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

	In case where a collision causes the detector (CsI) panel to break, there is a risk that Thallium-doped CsI particles are released in the environment. In such situation, it is recommended to follow the instructions given hereafter: • place a dust mask on the face of the operator • wear plastic gloves • collect dropped particles and place them with the detector into a sealed package, clean all surfaces that can be in contact with particles. The used dusters will be placed in the same sealed package • clearly identify the package with following sentence "WARNING: DAMAGED DETECTOR" • send back the package containing the damaged detector to Thales which will take the appropriate actions to properly recycle the detector

6.10.2. Batteries

	This marking shown on the battery or its literature, indicates that it should NOT be disposed with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

	Place only discharged batteries in a battery collection container. Use electrical tape or other approved covering over the battery connection points to prevent short circuits.

	Worn-out batteries must be recycled or disposed of properly according to local regulations. Lithium-Ion batteries are subject to disposal and recycling regulations that vary by country and region. Always check and follow your applicable regulations before disposing of any battery.

	End users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial wastes for disposal.

6.10.3. Charger

	The charger meet the requirements of the Waste Electronic & Electrical Equipment Directive(2002/96/EC & 2003/108/EC).

6.10.4. Cables

	The cables meet the requirements of the Waste Electronic & Electrical Equipment Directive(2002/96/EC & 2003/108/EC).

6.11. X-Ray Management

	The detector does not include built-in X-Ray shielding, except some thin and narrow lead plates for electronic components protection. Protection of operator and patient against transmitted X-Ray shall be considered by the end user (either with protective clothing or other suitable means).

	Do not shoot X-rays when a dysfunction of the detector is noticed, either by the LED indicators or at system level.

	In case of loss of communication with the detector, the system sends an alarm to the integrator system. It is integrator responsibility to manage the x-ray exposure.

6.12.Performance

6.12.1. PIXIUM PORTABLE EZ-C X Series

Thales KEYWORD	ITEM	Unit	Typ	min	Max
PTS_cumulate.d_dose	Allowable Integrated dose over lifetime	Gy	-	100	-
PTS_func_lifetime	Detector life time (except battery)	year	10	-	-

ITEM	Unit	Typ	min	Max
X-ray kVp range	kVp	-	40	150
MTF @ 0.5 LP/mm	%	86	80	-
MTF @ 1.0 LP/mm	%	68	61	-
MTF @ 1.5 LP/mm	%	53	46	-
MTF @ 2.0 LP/mm	%	41	34	-
MTF @ 2.5 LP/mm	%	32	25	-
MTF @ 3.0 LP/mm	%	24	18	-
MTF @ 3.5 LP/mm	%	18	13	-
MTF @ 4.0 LP/mm	%	12	6	-
MTF @ 4.5 LP/mm	%	7	2	-
DQE @ 0.0 LP/mm (6µGy)	%	73		-
DQE @ 1.0 LP/mm (6µGy)	%	54		-
DQE @ 2.0 LP/mm (6µGy)	%	47		-
DQE @ 3.0 LP/mm (6µGy)	%	42		-
DQE @ 4.0 LP/mm (6µGy)	%	33		-
DQE @ 5.0 LP/mm (6µGy)	%	17		-

6.12.2. PIXIUM PORTABLE EZ-C HD Series

Thales KEYWORD	ITEM	Unit	Typ	min	Max
cumulate.d_dose	Allowable Integrated dose over lifetime	Gy	-	100	-
func_lifetime	Detector life time	year	10	-	-

ITEM	Unit	Typ	min	Max
X-ray kVp range	kVp	-	40	150

ITEM	Unit	Typ	min	Max
MTF @ 0.5 lp/mm	%	82	79	-
MTF @ 1 lp/mm	%	62	56	-
MTF @ 1.5 lp/mm	%	46	40	-
MTF @ 2 lp/mm	%	33	27	-
MTF @ 2.5 lp/mm	%	24	18	-
MTF @ 3 lp/mm	%	17	13	-
MTF @ 3.5 lp/mm	%	12	8	-
MTF @ 4 lp/mm	%	8	6	-
MTF @ 4.5 lp/mm	%	6	4	-
DQE @ 0 lp/mm (6 µGy)	%	70	60	-
DQE @ 0.5 lp/mm (6 µGy)	%	59	51	-
DQE @ 1 lp/mm (6 µGy)	%	52	44	-
DQE @ 1.5 lp/mm (6 µGy)	%	47	41	-
DQE @ 2 lp/mm (6 µGy)	%	44	38	-
DQE @ 2.5 lp/mm (6 µGy)	%	41	32	-
DQE @ 3 lp/mm (6 µGy)	%	38	29	-
DQE @ 3.5 lp/mm (6 µGy)	%	33	23	-
DQE @ 4 lp/mm (6 µGy)	%	28	18	-
DQE @ 4.5 lp/mm (6 µGy)	%	21	11	-
DQE @ Nyquist (6 µGy)	%	13	7	-

6.13.Accessories Important Safety Instructions

Failure to observe these precautions could result in a hazardous situation which, if not avoided, could result in death or serious injury.

6.13.1. BATTERY NPT EZ X SERIES

- Do not expose the BATTERY NPT EZ Xto heat or fire. Avoid storage in direct sunlight.
- Do not short-circuit the BATTERY NPT EZ X.
- Do not store the BATTERY NPT EZ Xhaphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects.

	In case of prolonged discharge or if the last use date of the battery is unknown DO NOT connect the battery to the battery charger.

	• Immediately discontinue use of the BATTERY NPT EZ X if, while using, charging, or storing the battery, the battery emits an unusual smell, feels hot, changes color, changes shape, or appears abnormal in any other way. Contact your sales location or Thales technical support if any of these problems are observed • Seek medical advice immediately if the content of the BATTERY NPT EZ X has been swallowed. • In the event of a BATTERY NPT EZ X leaking, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.

	In case of smoke or any kind of smell emanated from the BATTERY NPT EZ X, immediately isolate the BATTERY NPT EZ X in a ventilated area.

	• Use only the BATTERY NPT EZ X in the application for which it was intended. • When possible, remove the BATTERY NPT EZ X from the equipment when not in use. • Retain the original product literature for future reference. • After extended periods of storage, it may be necessary to charge and discharge the BATTERY NPT EZ X several times to obtain maximum performance. • Keep the BATTERY EZ out of the reach of children. • Always purchase the correct battery for the equipment. • Before use, visually check the BATTERY NPT EZ X for any physical damage. If damage is found, the BATTERY NPT EZ X must not be used. • Keep the BATTERY NPT EZ X lean and dry. • Wipe the BATTERY NPT EZ X terminals with a clean dry cloth if they become dirty. • The BATTERY NPT EZ X needs to be charged before use. Always use the dedicated battery charger and refer to the manufacturer's instructions or equipment manual for proper charging instructions.

	• Do not dismantle, open or shared the BATTERY NPT EZ X. • Do not remove the BATTERY NPT EZ X from its original packaging until required for use. • Do not subject the BATTERY NPT EZ X to mechanical shock. • Do not use any charger other than that specifically provided for use with the equipment. • Do not use any cell or battery which is not designed for use with the equipment. • Do not leave the BATTERY NPT EZ X on prolonged charge when not in use. • Dispose of properly.

6.13.2.   BATTERY EZ-C HD SERIES

	• Do not expose the BATTERY EZ HD to heat or fire. Avoid storage in direct sunlight. • Do not short-circuit the BATTERY EZ HD. • Do not store the BATTERY EZ HD haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects.

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⚠️	In case of prolonged discharge or if the last use date of the battery is unknown DO NOT connect the battery to the battery charger.

☠️	• Immediately discontinue use of the BATTERY EZ HD if, while using, charging, or storing the battery, the battery emits an unusual smell, feels hot, changes color, changes shape, or appears abnormal in any other way. Contact your sales location or Thales technical support if any of these problems are observed • Seek medical advice immediately if the content of the BATTERY EZ HD has been swallowed. • In the event of a BATTERY EZ HD leaking, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.

❗	In case of smoke or any kind of smell emanated from the BATTERY EZ HD, immediately isolate the BATTERY EZ HD in a ventilated area.

❗	• Use only the BATTERY EZ HD in the application for which it was intended. • When possible, remove the BATTERY EZ HD from the equipment when not in use. • Retain the original product literature for future reference. • After extended periods of storage, it may be necessary to charge and discharge the BATTERY EZ HD several times to obtain maximum performance. • Keep the BATTERY EZ HD out of the reach of children. • Always purchase the correct battery for the equipment. • Before use, visually check the BATTERY EZ HD for any physical damage. If damage is found, the BATTERY EZ HD must not be used. • Keep the BATTERY EZ HD lean and dry. • Wipe the BATTERY EZ HD terminals with a clean dry cloth if they become dirty. • The BATTERY EZ HD needs to be charged before use. Always use the dedicated battery charger and refer to the manufacturer's instructions or equipment manual for proper charging instructions.

🚫	• Do not dismantle, open or shared the BATTERY EZ HD. • Do not remove the BATTERY EZ HD from its original packaging until required for use. • Do not subject the BATTERY EZ HD to mechanical shock. • Do not use any charger other than that specifically provided for use with the equipment. • Do not use any cell or battery which is not designed for use with the equipment. • Do not leave the BATTERY EZ HD on prolonged charge when not in use. • Dispose of properly.

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6.13.3. CHARGER EZ-C X SERIES

!	• Refer to BATTERY CHARGER EZX safety instructions before use. • Before use, visibly check the BATTERY CHARGER EZX and BATTERY NPT EZ X for any physical damage. If damage is found, the BATTERY CHARGER EZX and BATTERY NPT EZ X must not be used. • Keep the BATTERY CHARGER EZX out of the reach of an operator with an altered condition, physical or mental. • Prevent metallic objects from coming into contact with the metal part of the DC plug of the BATTERY CHARGER EZX. If it happens, a short circuit may occur and the unit may be damaged. • The BATTERY CHARGER EZX is an ordinary accessory, not intended for use in the patient environment. • Place the BATTERY CHARGER EZX indoors on a hard flat heat resistant surface, in a well-ventilated area. • Remove BATTERY NPT EZ X when the charger is not in use. • Safeguard from moisture, respect operation and storage temperature limits. • Dry the BATTERY CHARGER EZX and store protected from impacts and humidity. • Always keep metallic contacts clean. • Keep the BATTERY NPT EZ X out of the reach of children. • Keep the BATTERY NPT EZ X clean and dry. • Retain the original product literature for future reference. • When possible, remove the BATTERY NPT EZ X from the equipment when not in use.

🚫	• Do not attempt to recharge none-rechargeable battery packs. • Do not use any BATTERY NPT EZ X other than that specifically provided for use with the charger. • Do not dismantle or open. There are no user serviceable components of safety elements inside. • Do not use any battery other than that specifically provided for use with the charger. • Do not place the BATTERY CHARGER EZX in locations that are extremely hot or cold, dusty or dirty or very humid. • Do not apply mechanical shock or drop the BATTERY CHARGER EZX. • Do not bend the power cord forcibly or place a heavy object on it. This will damage the cord and may cause fire or electrical shock. • Do not operate the BATTERY CHARGER EZX with a damaged cord or if the charger has been dropped or damaged. • Do not cover the BATTERY CHARGER EZX. • Dispose of properly.

6.13.4. CHARGER EZ-C HD SERIES

ⓘ	• Refer to BATTERY EZ HD safety instructions before use. • Before use, visibly check the CHARGER EZ HD and BATTERY EZ HD for any physical damage. If damage is found, the CHARGER EZ HD and BATTERY EZ HD must not be used. • Keep the CHARGER EZ HD out of the reach of an operator with an altered condition, physical or mental. • Prevent metallic objects from coming into contact with the metal part of the DC plug of the CHARGER EZ HD. If it happens, a short circuit may occur and the unit may be damaged. • The CHARGER EZ HD is an ordinary accessory, not intended for use in the patient environment. • Place the CHARGER EZ HD indoors on a hard flat heat resistant surface, in a well-ventilated area. • Remove BATTERY EZ HD when the charger is not in use. • Safeguard from moisture, respect operation and storage temperature limits. • Dry the CHARGER EZ HD and store protected from impacts and humidity. • Always keep metallic contacts clean. • Keep the CHARGER EZ HD out of the reach of children. • Keep the CHARGER EZ HD clean and dry. • Retain the original product literature for future reference. • When possible, remove the BATTERY EZ HD from the equipment when not in use.

🚫	• Do not attempt to recharge none-rechargeable battery packs. • Do not use any BATTERY EZ HD other than that specifically provided for use with the charger. • Do not dismantle or open. There are no user serviceable components of safety elements inside. • Do not use any battery other than that specifically provided for use with the charger. • Do not place the CHARGER EZ HD in locations that are extremely hot or cold, dusty or dirty or very humid. • Do not apply mechanical shock or drop the CHARGER EZ HD. • Do not bend the power cord forcibly or place a heavy object on it. This will damage the cord and may cause fire or electrical shock. • Do not operate the CHARGER EZ HD with a damaged cord or if the charger has been dropped or damaged. • Do not cover the CHARGER EZ HD. • Dispose of properly.

6.13.5. CABLES

🚫❤	The cable includes a connector with magnets. All persons with pacemakers have to stay away of the cable.

⚠	Respect a minimum distance of 5 cm between the pacemaker and the magnetic connector of the backup cable.

6.14.FCC Rules (U.S.A.)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1)   This device may not cause harmful interference, and
2)   this device must accept any interference received, including interference that may cause undesired operation.

	This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.These limits are designed to provide reasonable protection against harmful interference in a residential installation.This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction, may cause harmful interference to radio communications.However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct interference by one or more of the following measures: • Reorient or relocate the receiving antenna. • Increase the separation between the equipment and receiver. • Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. • Consult the dealer or an experienced radio/TV technician for help.

FCC CAUTION: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Operations in the 5.15-5.25GHz band are restricted to indoor usage only.

Radiation Exposure Statement:

	This device complies with FCC RF radiation exposure limits set forth for general population.This device must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

The product comply with the FCC portable RF exposure limit set forth for an uncontrolled environment and are safe for intended operation as described in this manual. The further RF exposure reduction can be achieved if the product can be kept as far as possible from the user body or set the device to lower output power if such function is available.

This device is intended only for OEM integrators under the following conditions:

1)   The antenna must be installed such that 20 cm is maintained between the antenna and users, and
2)   The transmitter module may not be co-located with any other transmitter or antenna.
3)   Module approval valid only when the module is installed in the tested host or compatible series of host

As long as 3 conditions above are met, further transmitter test will not be required. However, the OEM integrator is still responsible for testing their end-product for any additional compliance requirements required with this module installed.

IMPORTANT NOTE: In the event that these conditions cannot be met (for example certain laptop configurations or co-location with another transmitter), then the FCC authorization is no longer considered valid and the FCC ID cannot be used on the final product. In these circumstances, the OEM integrator will be responsible for re-evaluating the end-product (including the transmitter) and obtaining a separate FCC authorization.

	The user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

6.14.1. Supplier's Declaration of Conformity Pixium EZ HD

THALES
Building a future we can all trust

Supplier's Declaration of Conformity

47 CFR § 2.1077 Compliance Information

Unique Identifier:

PIXIUM PORTABLE 3543 EZ-C HD [1]

Responsible Party – U.S. Contact Information

- Manufacturer:

THALES AVS FRANCE SAS

75-77 Avenue Marcel Dassault

33700 MERIGNAC FRANCE

FRN: **0033311036**

- US representative:

THALES COMPONENTS CORPORATION

7415 Emerald Dunes Drive, Suite 2000

Orlando, FL 32822

USA

Contact: pfarmer@tccus.com

Compliance information for the modular components used in this device :

Component	Manufacturer	Product reference	FCC ID
Wi-Fi module	Compex	WLE900VX	**TK4WLE900VX**
NFC (SRD) module	NXP	PN7150	**OWROM5578-PN7150S**

FCC Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) This device may not cause harmful interference, and
2) This device must accept any interference received, including interference that may cause undesired operation.

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1. or PIXIUM PORTABLE 4343 EZ-C HD

6.14.2. Supplier's Declaration of Conformity Pixium EZ X

Supplier's Declaration of Conformity

47 CFR § 2.1077 Compliance Information

Unique Identifier:

PIXIUM PORTABLE 3543 EZ-C X [1]

Responsible Party – U.S. Contact Information

- Manufacturer:

THALES AVS FRANCE SAS

75-77 Avenue Marcel Dassault

33700 MERIGNAC FRANCE

FRN: **0033311036**

- US representative:

THALES COMPONENTS CORPORATION

7415 Emerald Dunes Drive, Suite 2000

Orlando, FL 32822

USA

Contact: pfarmer@tccus.com

Compliance information for the modular components used in this device:

Component	Manufacturer	Product reference	FCC ID
Wi-Fi module	SPARKLAN COMMUNICATIONS INC.	WNFB-265AXI	**VPQ-WNFB265AXIBT**
NFC (SRD) module	NXP	PN7150	**VPQ-EZ3NFC**

FCC Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) This device may not cause harmful interference, and
2) This device must accept any interference received, including interference that may cause undesired operation.

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1. or PIXIUM PORTABLE 2430 EZ-C X, PIXIUM PORTABLE 4343 EZ-C X, PIXIUM PORTABLE 3543 EZ-C X D, PIXIUM PORTABLE 4343 EZ-C X D, PIXIUM PORTABLE 2430 EZ-C X J, PIXIUM PORTABLE 3543 EZ-C X J, PIXIUM PORTABLE 4343 EZ-C X J.

OPEN

6.15.IC (Canada)

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1) This device may not cause cause interference, and
2) this device must accept any interference received, including interference that may cause undesired operation.

Radiation Exposure Statement:

⚠	This device complies with Canada portable RF radiation exposure limits set forth for general population.This device must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

This device complies with ISED radiation exposure limits set forth for general population. This device must be installed to provide a separation distance of at least 20cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

This device is intended only for OEM integrators under the following conditions: (For module device use)

1) The antenna must be installed such that 20 cm is maintained between the antenna and users, and
2) The transmitter module may not be co-located with any other transmitter or antenna.
3) Module approval valid only when the module is installed in the tested host or compatible series of host

As long as 3 conditions above are met, further transmitter test will not be required. However, the OEM integrator is still responsible for testing their end-product for any additional compliance requirements required with this module installed

ⓘ	**IMPORTANT NOTE:** In the event that these conditions cannot be met (for example certain laptop configurations or co-location with another transmitter), then the Canada authorization is no longer considered valid and the IC ID cannot be used on the final product. In these circumstances, the OEM integrator will be responsible for re-evaluating the end-product (including the transmitter) and obtaining a separate Canada authorization.

⚠	The user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

6.15.1. Pixium EZ X

Component	Manufacturer	Product reference	IC
Wi-Fi module	SPARKLAN COMMUNICATIONS INC.	WNFB-265AXI	**7392A-NFB265AXIBT**
NFC (SRD) module	NXP	PN7150	**739A-EZ3NFC**

6.15.2. Pixium EZ HD

Component	Manufacturer	Product reference	IC
Wi-Fi module	Compex	WLE900VX	**7849A-WLE900VX**

6.16.RED directive (Europe)

The Pixium EZ HD, Pixium EZ X is certified to be used in the following European countries:

Country (country code according to ISO 3166)					
Andorra (AD)	Austria (AT)	Belgium (BE)	Bosnia and Herzegovina (BA)	Bulgaria (BG)	Croatia (HR)
Cyprus (CY)	Czech Republic (CZ)	Denmark (DK)	Estonia (EE)	Finland (FI)	France (FR)
Germany (DE)	Greece (GR)	Hungary (HU)	Iceland (IS)	Ireland (IE)	Italy (IT)
Latvia (LV)	Liechtenstein (LI)	Lithuania (LT)	Luxembourg (LU)	Macedonia, former Yugoslav Republic of (MK)	Malta (MT)
Monaco (MC)	Montenegro (ME)	Netherlands (NL)	Norway (NO)	Poland (PL)	Portugal (PT)
Romania (RO)	San Marino (SM)	Serbia (RS)	Slovakia (SK)	Slovenia (SI)	Spain (ES)
Sweden (SE)	Switzerland (CH)	United Kingdom (GB)	Vatican city state (VA)	-	-

For all of these countries, the 5.15-5.35 GHz band is restricted to indoor use.

Regulatory Statement: Operation of this device is subjected to the following National regulations and may be prohibited to use if certain restriction should be applied.

Bulgarian: С настоящото Thales декларира, че Pixium EZ HD, Pixium EZ X е в съответствие със съществените изисквания и други съответни разпоредби на Директива 2014/53/ЕС.

Czech: Společnost Thales tímto prohlašuje, že zařízení Pixium EZ HD, Pixium EZ X je v souladu se základními požadavky a dalšími příslušnými ustanoveními směrnice 2014/53/EU.

Danish: Undertegnede Thales erklærer herved, at følgende udstyr Pixium EZ HD, Pixium EZ X overholder de væsentlige krav og øvrige relevante krav i direktiv 2014/53/UE

Dutch: Hierbij verklaart Thales dat het toestel Pixium EZ HD, Pixium EZ X in overeenstemming is met de essentiële eisen en de andere relevante bepalingen van richtlijn 2014/53/UE.

English: Hereby, Thales, declares that the Pixium EZ HD, Pixium EZ X is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/UE.

Estonian: Thales kinnitab käesolevaga, et Pixium EZ HD, Pixium EZ X vastab direktiivi 2014/53/EL olulistele nõuetele ja muudele asjakohastele sätetele.

Finnish: Thales vakuuttaa täten että Pixium EZ HD, Pixium EZ X tyyppinen laite on direktiivin 2014/53/UE oleellisten vaatimusten ja sitä koskevien direktiivin muiden ehtojen mukainen.

French: Par la présente, Thales déclare que le Pixium EZ HD, Pixium EZ X est conformes aux exigences essentielles et aux autres dispositions de la directive 2014/53/UE qui lui sont applicables.

German: Hiermit erklärt Thales, dass sich Pixium EZ HD, Pixium EZ X in Übereinstimmung mit den grundlegenden Anforderungen und den anderen relevanten Vorschriften der Richtlinie 2014/53/UE befindet". (BMWi).Hiermit erklärt Thales die Übereinstimmung des Gerätes Pixium EZ HD, Pixium EZ X mit den grundlegenden Anforderungen und den anderen relevanten Festlegungen der Richtlinie 2014/53/UE. (Wien).

Greek: ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ Thales ΔΗΛΩΝΕΙ ΟΤΙ Pixium EZ HD, Pixium EZ X ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 2014/53/UE.

Hungarian: Ezennel a Thales kijelenti, hogy a Pixium EZ HD, Pixium EZ X megfelel a 2014/53/UE irányelv alapvető követelményeinek és egyéb vonatkozó rendelkezéseinek.

Italian: Con la presente Thales dichiara che questo Pixium EZ HD, Pixium EZ X è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti stabilite dalla direttiva 2014/53/UE.

Latvian: Ar šo Thales deklarē, ka Pixium EZ HD, Pixium EZ X atbilst Direktīvas 2014/53/ES būtiskajām prasībām un citiem ar to saistītajiem noteikumiem.

Lithuanian: Šiuo dokumentu „Thales" patvirtina, kad „ " ir „Pixium EZ HD" atitinka pagrindinius direktyvos 2014/53/ES reikalavimus bei kitas susijusias nuostatas.

Polish: Niniejszym Thales oświadcza, że Pixium EZ HD, Pixium EZ X jest zgodne z zasadniczymi wymaganiami i innymi odpowiednimi przepisami dyrektywy 2014/53/UE.

Portuguese: Thales declara que este Pixium EZ HD, Pixium EZ X está conforme com os requisitos essenciais e outras disposições da Directiva 2014/53/UE.

Romanian: Prin prezentul document, Thales declară că Pixium EZ HD, Pixium EZ X este în conformitate cu cerințele esențiale și cu alte dispoziții relevante ale Directivei 2014/53/UE.

Slovak: Spoločnosť Thales týmto vyhlasuje, že Pixium EZ HD, Pixium EZ X je v súlade so základnými požiadavkami a ďalšími príslušnými ustanoveniami smernice 2014/53/EÚ.

Slovenian: S tem pri družbi Thales izjavljamo, da je Pixium EZ HD, Pixium EZ X v skladu z osnovnimi zahtevami in drugimi pomembnimi določili Direktive 2014/53/EU.

Spanish: Por medio de la presente Thales declara que los Pixium EZ HD, Pixium EZ X cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 2014/53/UE.

Swedish: Härmed intygar Thales att denna Pixium EZ HD, Pixium EZ X står I överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 2014/53/UE.

6.16.1.   Wi-Fi Label on Pixium EZ HD Packaging

The following label is located on the detector packaging.

European countries:

AD	AT	BE	BA	BG	HR	CY	CZ
DK	EE	FI	FR	DE	GR	HU	IS
IE	IT	LV	LI	LT	LU	MT	MC
ME	NL	NO	PL	PT	RO	SM	RS
SK	SI	ES	SE	CH	MK	GB	VA

Figure: Wi-Fi label on packaging

OPEN

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For all of these countries, the 5.15-5.35 GHz band is restricted to indoor use.

7. WI-FI INTERFACE

7.1. Pixium 2430 EZ X

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7.2. Pixium 3543 EZ X

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7.3. Pixium 4343 EZ X

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7.4. PIXIUM 3543 EZ-C HD

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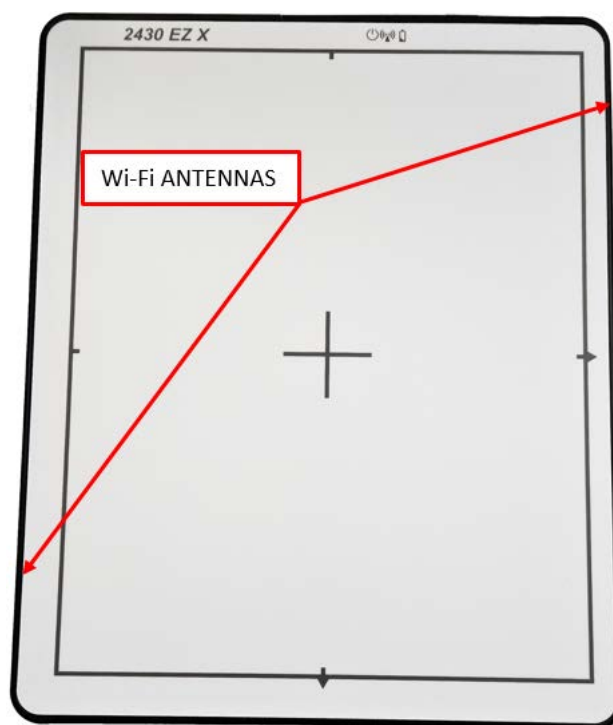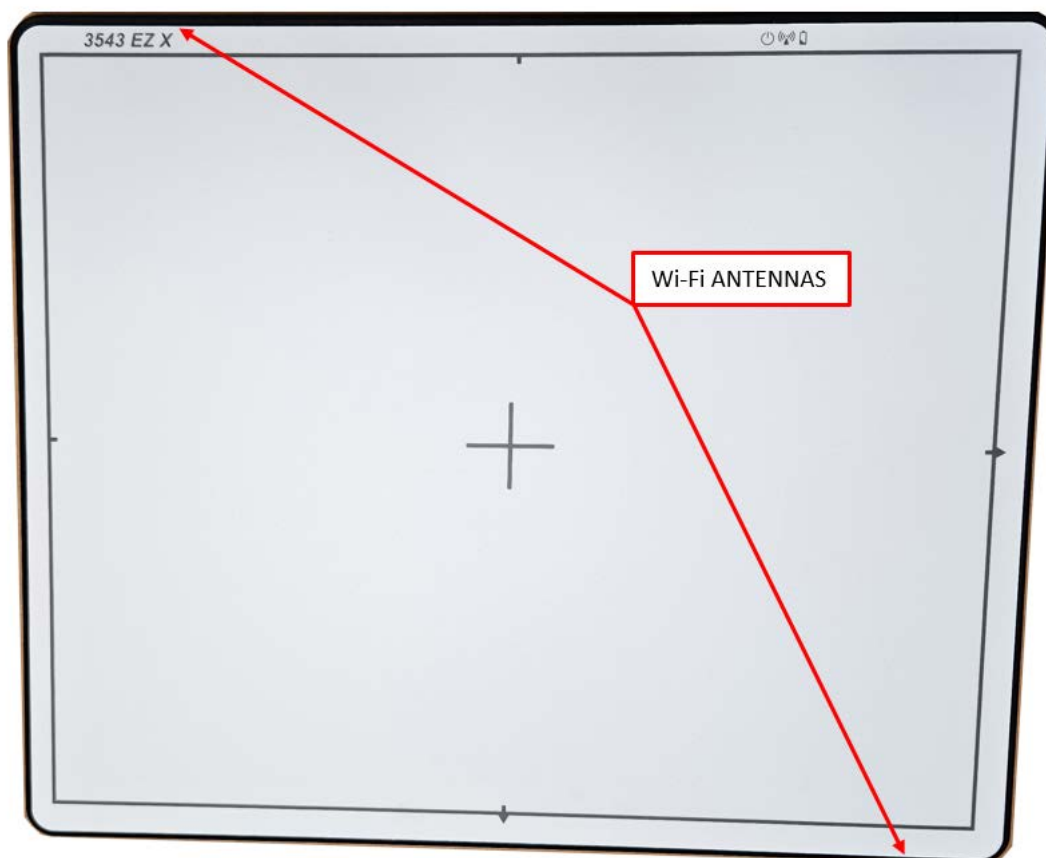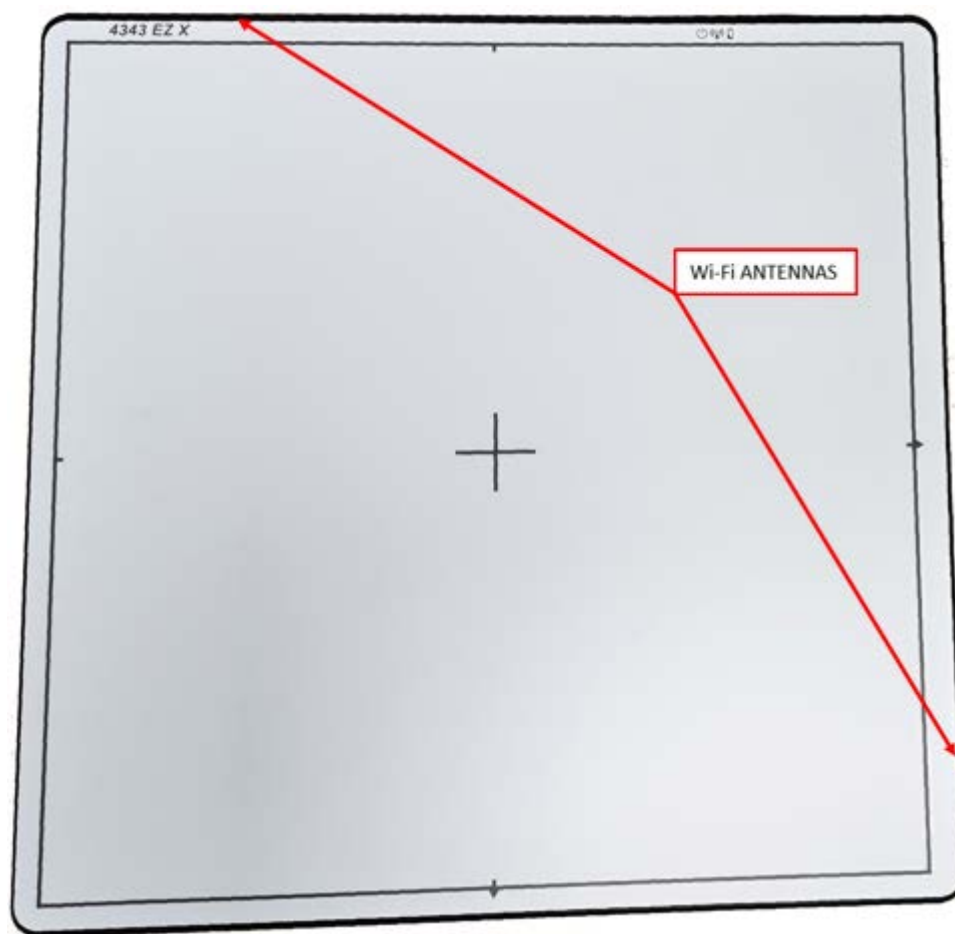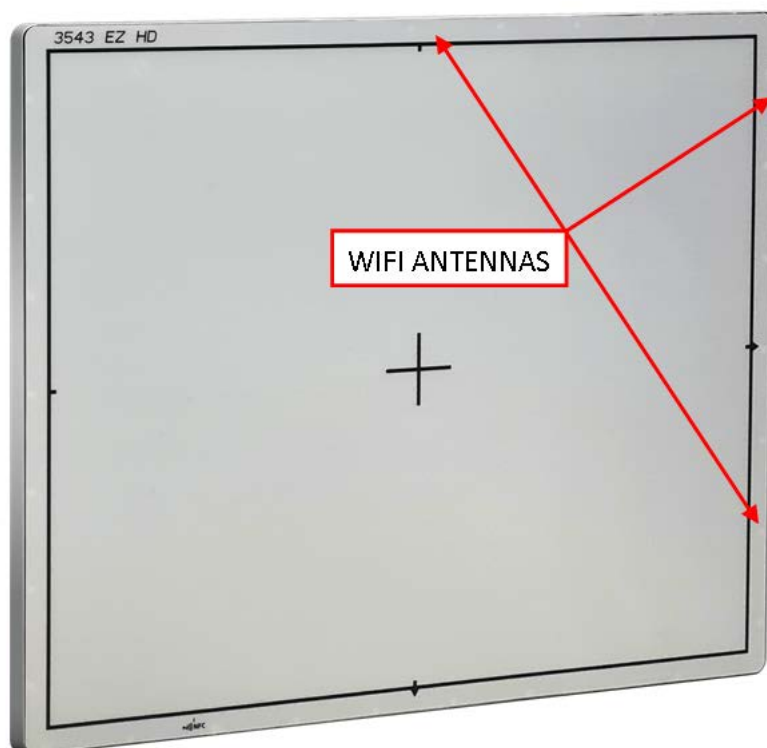
7.5. PIXIUM 4343 EZ-C HD

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8. LED INDICATORS

8.1. LED Location

8.1.1. PIXIUM EZ-C X Series

8.1.2. PIXIUM EZ-C HD Series

8.2. LED Meaning - Pixium EZ X Series

8.2.1. Meaning of the Symbols

Symbol	Meaning
●	Continuous light
○	LED off
☀	Blinking slow
☀	Blinking fast

8.2.2.   Status LED

Symbol:

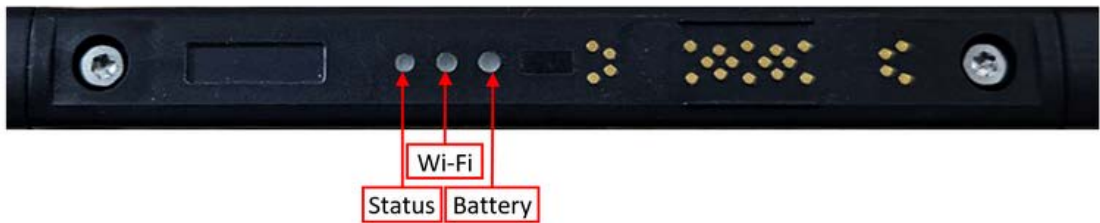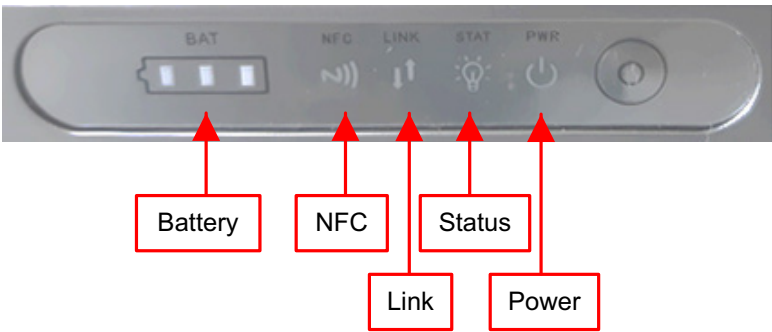| LED state	Color	Meaning
● (green)	green	The detector is connected or it has been connected since it is ON or since it has been reset
● (orange)	orange	The detector has never been connected since it is ON or since it has been reset or DOWNLOAD state
◄●► (green, blinking)	green	LISTEN state, low consumption
○ (off)	off	OFF state
◄●► (orange, blinking)	orange	During switch ON or error state
☀ (orange, fast blinking)	orange	Switching OFF (going to OFF state) when requested by software or by time-out

🚫 Status LED sequence during acquisition sequence:
- OFF during image integration (X-ray window) and image readout.
- Orange continuous until the image is successfully transferred or stored.
- Remains orange, in case of image storage, if the memory is full and don't allow acquiring the required image.

Status LED during network configuration:
- All 3 LED blink orange fast after receiving the order for changing the network configuration.
- If the reconfiguration is accepted, the 3 LEDs flash green 3 times (during around 1.5 s).
- If the reconfiguration is not accepted, the 3 LEDs flash red 3 times (during around 1.5 s).

🚫 When the detector is auto trigger mode and in listen state, do not wake it up by sending the *Start_Acquisition* command. After the detector has woken up, wait 2 seconds before starting an acquisition.

8.2.3. Wi-Fi LED

Symbol:

The following behavior is applicable to OPERATING, LISTEN, DOWNLOAD and ERROR states:

LED state	Color	Meaning
🟢	green	Wi-Fi available (detector connected to an Access Point)
⚪	off	Wi-Fi disabled by software or detector is turned off or booting
🟠	orange	Wi-Fi not ready (detector not connected to an Access Point)

In OFF state, the Wi-Fi LED is OFF.

During boot, the Wi-Fi LED is OFF.

8.2.4. Battery LED

Symbol:

The following behavior is applicable to OPERATING, LISTEN, DOWNLOAD and ERROR states:

LED state	Color	Meaning
🟢	green	Battery charge level between 100% and 10%
🟠	orange	Battery charge level between 10% and 5%
☀	orange	Battery capacity below 5%

LED state	Color	Meaning
◯	off	No battery
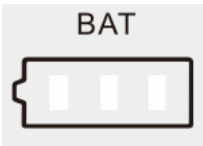
In OFF state, the battery LED is OFF.

During boot, the battery LED is OFF.

8.3. LED Meaning - Pixium EZ HD Series

Symbol:
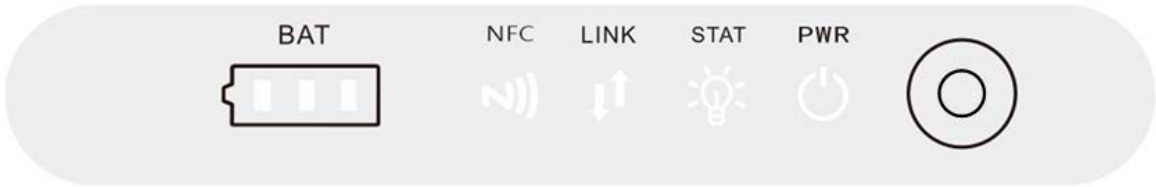
The following behavior is applicable to OPERATING, LISTEN, DOWNLOAD and ERROR states:

Symbol	Meaning
BAT	**BAT** • Is lit when the Pixium EZ HD is powered on or connected to a DC power supply. • Is flashing when battery is not full. • Keeps green when battery is full.
NFC	**NFC** • IDLE: Keeps green when the NFC is idle.In this state, the Pixium EZ HD is ready to read a NFC tag. READING: Blinking (frequency: 2 Hz) when the Pixium EZ HD is reading a NFC tag. • READING OK: If the setting is PASS, the NFC LED blinks green slowly during 3 seconds (frequency: 0.5 Hz). Then, the Pixium EZ HD goes into Idle state and the NFC tag can be removed. • READING FAIL: If the setting is FAIL, the NFC LED blinks green quickly during 3 seconds (frequency: 4 Hz). Then, the Pixium EZ HD goes into Idle state and the NFC tag can be removed.
LINK	**LINK** • Keeps green when the Pixium EZ HD is connected. • Is flashing in other case.

Symbol	Meaning
STAT	**STAT** • Keeps green when the Pixium EZ HD is in Idle state. • Is flashing during acquisition.
PWR	**PWR** • Lit up when the Pixium EZ HD is powered on.

The following behavior is applicable during battery CHARGE

Charge	
Symbol	**Meaning**
BAT	The remaining power is in the range of (0% - 25%), led 1 flashes, led 2 and led 3 are off.
BAT	The remaining power is in the range of (25% - 50%), led 1 is always on, led 2 flashes, and led 3 is off.
BAT	The remaining power is in the range of (50% - 87.5%), led 1 and led 2 are always on, led 3 flashes.
BAT	The remaining power is in the range of (87.5% - 100%), led 1, led 2 and led 3 are always on.

The following behavior is applicable during battery DISCHARGE

Discharge	
Symbol	**Meaning**
BAT	The remaining power is in the range of (0% - 25%), led 1, led 2 and led 3 are off.

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Discharge	
Symbol	**Meaning**
BAT	The remaining power is in the range of (25% - 50%), led 1 is always on, and led 2 and led 3 are off.
BAT	The remaining power is in the range of (50% - 87.5%), led 1 and led 2 are always on, and led 3 is off.
BAT	The remaining power is in the range of (87.5% - 100%), led 1, led 2 and led 3 are always on.

9. PIXIUM EZ X DISPLAY INTERFACE
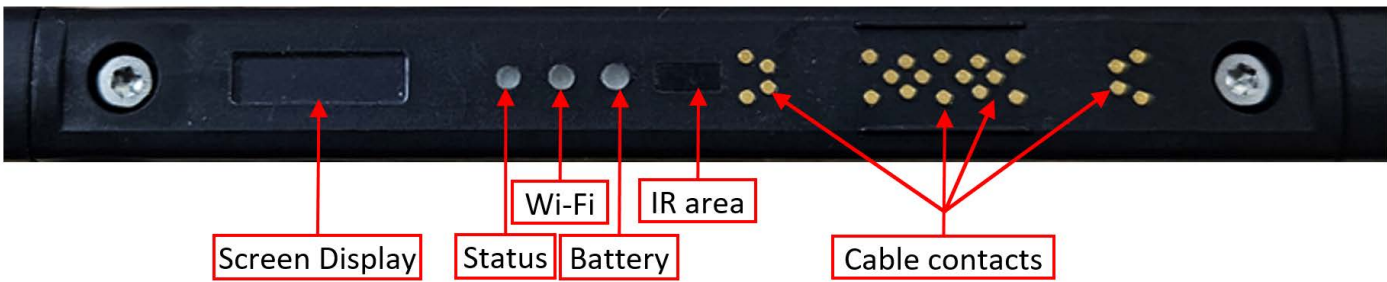
9.1. LCD display interface

The Pixium EZ X features a LCD display of 120x28 pixels with black and white color.

This section describes the different messages available and meaning of symbols on the display interfaceregarding the different use cases.

The display shows:

- A battery icon giving a visual indication of the remaining battery level and if the battery is being charged
- The connection mode, a computer icon indicating that the detector is connected to a host.
- The number acquisitions that can be performed with the detector (taking into account the remaining storage capacity on the two right digits).

To protect the battery from excessive discharge, the display is normally off. To switch on the detector for a fewseconds, lightly shake the detector.

Symbol	Meaning
	Battery charge level
	Connected to a host

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Symbol	Meaning
70	Digits indicating remaining storage capacity

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10. NEAR FIELD COMMUNICATION

10.1.Using the NFC Tag

For changing the IP address, the NFC tag should be applied on the NFC area, on the back side of the Pixium EZ X .

The main functionality of NFC interface is to change the following parameters:

- SSID
- password
- IP address

Step	Action
1	While the Pixium EZ X is in operation state, present a NFC tag in front of the NFC interface of the Pixium EZ X.The distance between the NFC tag and the Pixium EZ X must be less than 1 cm.

Step	Action
2	 As soon as the Pixium EZ X emits a long bip, the NFC tag can be removed.
3	 Then, the 3 LEDs blink orange fastly during about 3 seconds:
4a	 If the Pixium EZ X setting is PASS, the 3 LEDs blink green slowly 3 times:
4b	 If the Pixium EZ X setting is FAIL, the 3 LEDs blink red slowly 3 times: Try again and, if needed, verify that programmation of the NFC tag comply with the protocol.

10.2. Using the NFC Tag

For changing the IP address, the NFC tag should be applied on the NFC area, on the back side of the Pixium EZ HD, near the led indicator area.

Step	Symbol	Action
1 IDLE	NFC	 IDLE: Keeps green when the NFC is idle.In this state, the Pixium EZ HD is ready to read a NFC tag. While the Pixium EZ HD is in operation state, present a NFC tag in front of the NFC interface of the Pixium EZ HD. The distance between the NFC tag and the Pixium EZ HD must be less than 1 cm.
2 READING	NFC	READING: Blinking (frequency: 2 Hz) when the Pixium EZ HD is reading a NFC tag.

Step	Symbol	Action
3a READING OK		 READING OK: If the setting is PASS, the NFC LED blinks green slowly during 3 seconds (frequency: 0.5 Hz). Then, the Pixium EZ HD goes into Idle state and the NFC tag can be removed.
3b READING FAIL:		READING FAIL: If the setting is FAIL, the NFC LED blinks green quickly during 3 seconds (frequency: 4 Hz). Then, the Pixium EZ HD goes into Idle state and the NFC tag can be removed. Try again and, if needed, verify that programming of the NFC tag comply with the protocol detailed in the previous chapter.

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11. BATTERY

11.1. Pixium EZ X Series
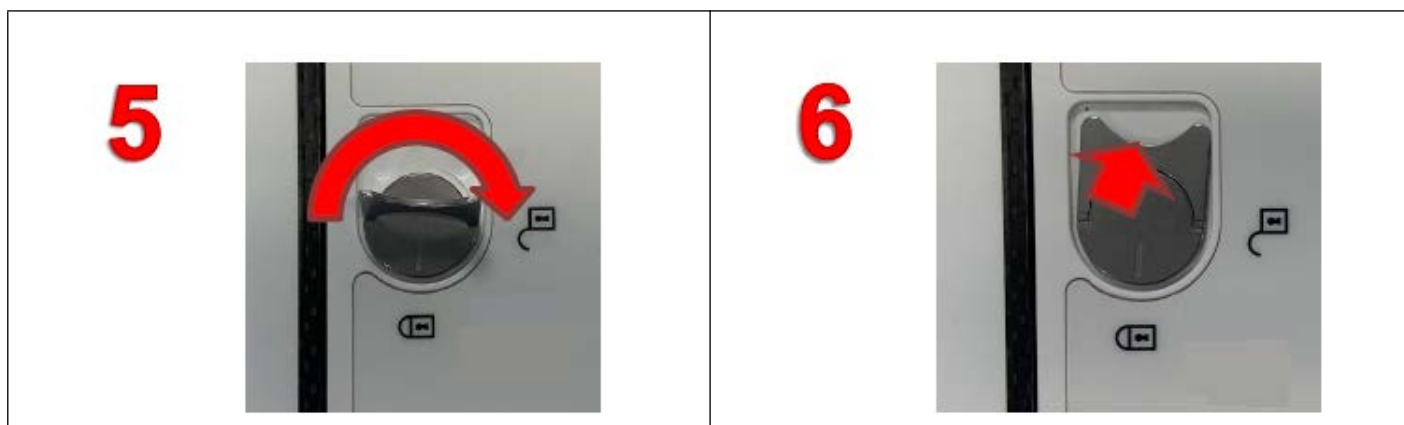
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11.2.PIXIUM EZ HD Series
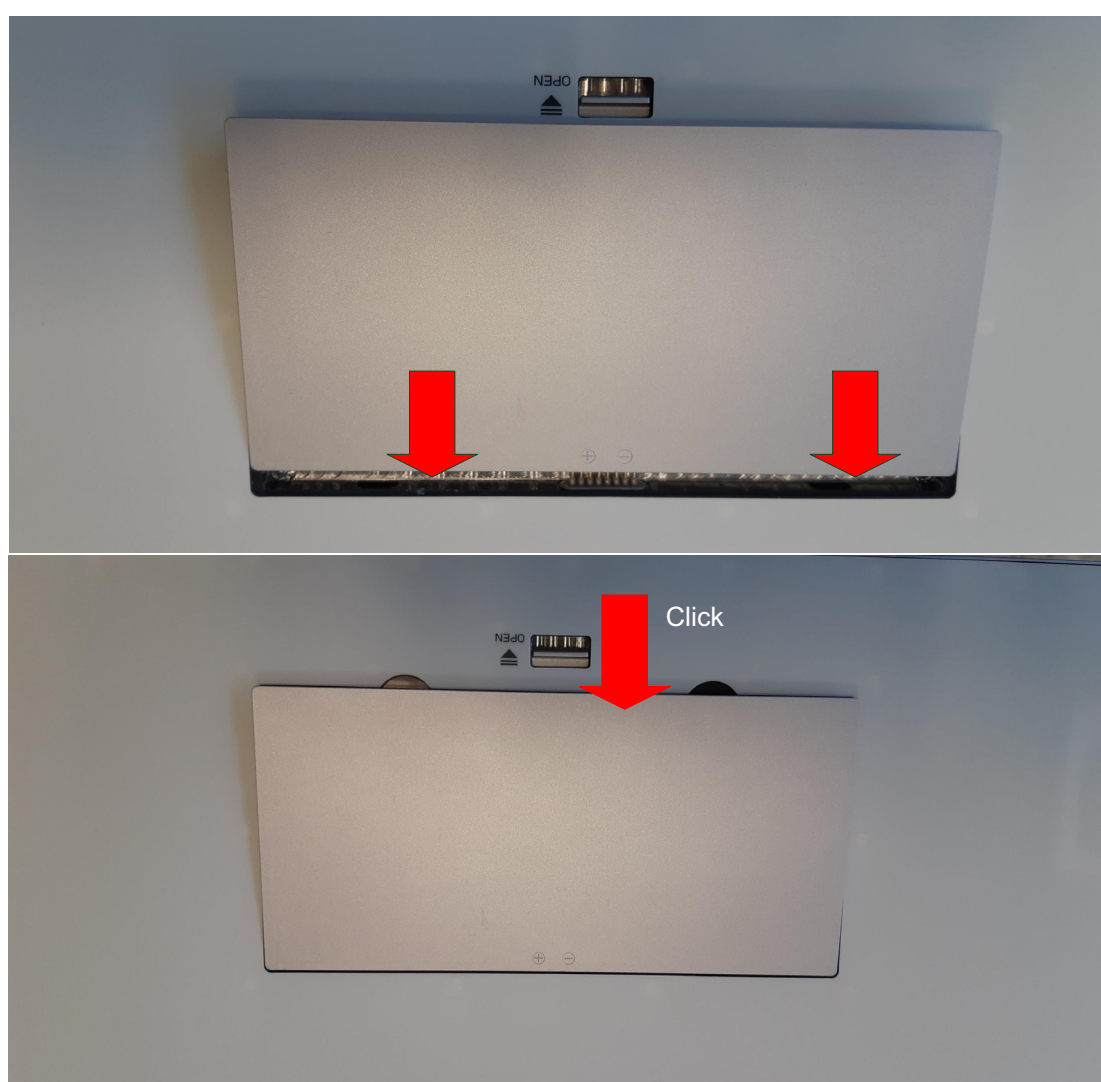
12. TURN ON, TURN OFF

12.1. PIXIUM EZX Series

ℹ️	To turn on the detector, insert a charged battery or connect a backup cable (if available).To turn off the detector, use a dedicated system command (see system user manual) or remove the battery.In the last case and except for Pixium 2430 EZ X, the hot-swap functionality will maintain the detector ON during at least 30 seconds before starting the switch off procedure.

The figure shows the electrical interface area of the Pixium EZ X.
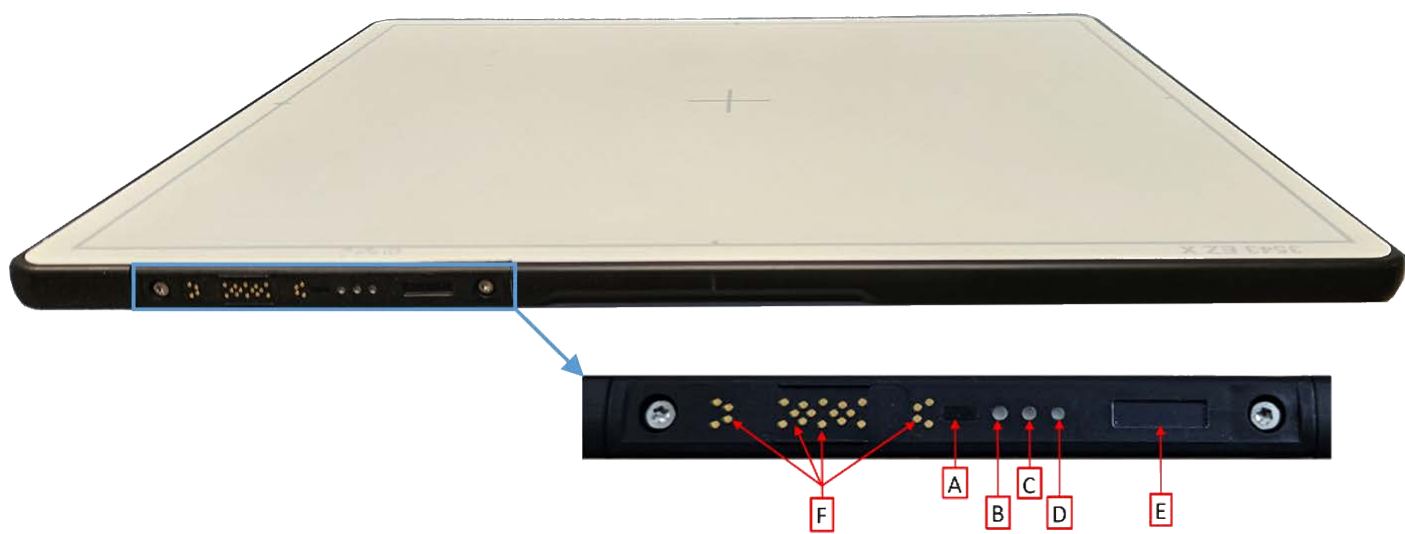
Label	Description
A	IR interface
B	Battery LED
C	Wi-Fi LED
D	Status LED
E	Screen Display
F	Back up cable interface

12.2. PIXIUM EZ-C HD Series

ℹ️	To turn off the detector, use a dedicated system command (if available) or use the button available on the main connector during at least 3 seconds.

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The figure shows the electrical interface area of the PIXIUM EZ HD.
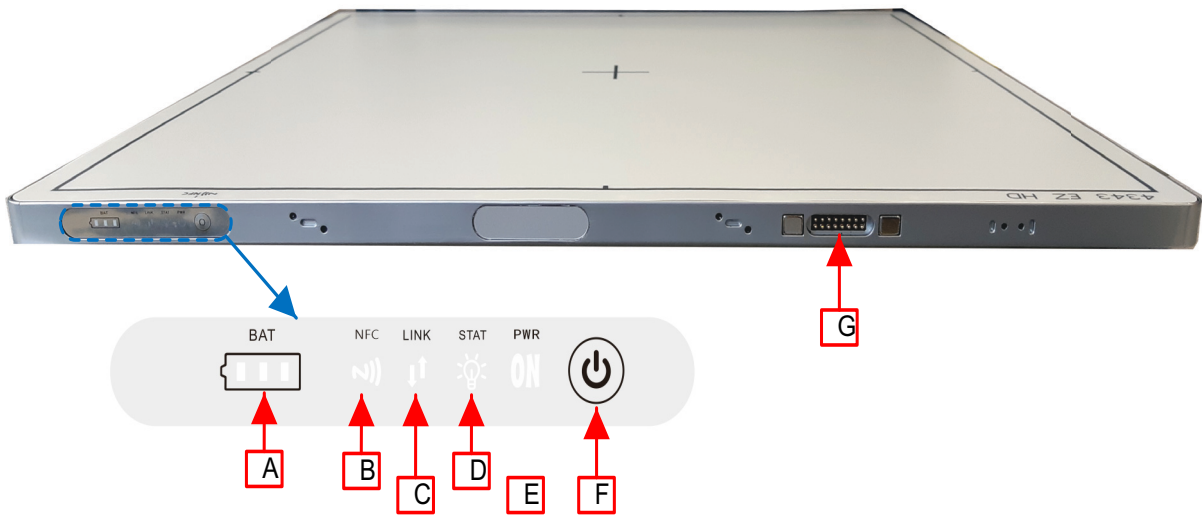
Figure: Electrical interface area on the PIXIUM EZ-C HD

Label	Description
A	BAT - Battery LED
B	NFC - NFC LED
C	LINK - Connection
D	STAT - Status
E	PWR - Power
F	Push button
G	Back up cable interface

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13. HOT-SWAP FUNCTIONALITY (PIXIUM 3543 EZ X AND PIXIUM 4343 EZ X ONLY)

Pixium 3543 EZ X and Pixium 4343 EZ X include the hot-swap functionality that allows to maintain the detector on during the battery exchange operation.

ⓘ	The battery exchange operation must be complete in less than 30 seconds, otherwise the detector will start a switch off procedure.

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14. MAINTENANCE AND CLEANING

In order to ensure the safety and normal use of the equipment, please be sure to check the equipment before use. In the process of inspection, if any problem is found but cannot be solved, please contact sales representative or product distributor.

(i)	These cases can occur on detectors whose "power on" function is activated when the cable is plugged in.The following symptom can be observed when the cable is plugged in, no battery LED lights up.To recover the detector, turned off it by pressing the power button.Leave the detector on charge for at least 45 minutes.Once the battery LEDs begin to flash, the detector can be turned on and used while charging.

14.1.Daily Inspection

Before using this product, the following checks need to be performed:

Item	Operation
CABLE EZ HD 1M	Make sure there is no crack or short circuit on the power supply.
	Make sure that the detector cable is not broken or damaged.
	Ensure that the power supply cord is reliably connected to the AC input and output socket.
	The cable must be firmly connected with the detector without any looseness.
Pixium EZ HD	Make sure that no screws are loose or broken.
	Make sure that there is no dust at the connecting pins.
	Make sure there is no crack or short circuit at the connecting pins.
	Make sure that the Pixium EZ HD can be turned on normally after the power is turned on.

14.2.Monthly and yearly inspection

Item	Frequency	Execution operation
Artifact	Monthly / yearly	After calibration, check the exposure image.
Calibration	Half a year / when the exposure condition has changed	When the number of bad spots or lines of detector increases, or the core components (such as X-ray generator, collimator, etc.) are replaced.
BATTERY EZ HD	Monthly	Ensure the battery can be charged and discharged normally.

14.3.PIXIUM PORTABLE EZ-C HD

When there are stains on the surface of the PIXIUM EZ HD, such as blood, etc., it needs to be treated. When cleaning a PIXIUM EZ HD, first the power must be turned off and then it must be cleaned with a non-corrosive cleaner.

1) Turn off the product before cleaning.
2) Using detergent carefully, it avoids damage to the skin and eyes.
3) Cleaning should be done in a ventilated place and gloves should be worn at all times.
4) Don't use sharp cleaning products.
5) The cleaner should not penetrate into the inside of the PIXIUM EZ HD.

6) Don't use wipes repeatedly.
7) Don't spray the cleaner directly on the PIXIUM EZ HD.
8) Don't let the interface get wet.
9) Flat panel detectors should not be soaked in detergent.
10) Don't wipe too frequently, it may cause damage.
11) After the PIXIUM EZ HD is cleaned, it is dried in time.

Note that the detector has a degree of protection against ingress of water of IP 56 according to IEC 60529.

14.4. PIXIUM all SERIES

The detector housing can be cleaned using a smooth towel, with respect to ESD safety conditions.

Cleaning: wipe the product with a dry, soft, lint-free cloth.

Disinfection: wipe the product with a soft, lint-free cloth slightly moistened in ethylene alcohol or isopropyl alcohol.

Avoid moisture and particles that could contaminate the product connector.

The sterilization, disinfecting, and cleaning conditions are defined by the System manufacturer in the context of the System use.

⚠️	When the detector is going to be cleaned; remove the cables, battery pack from the battery compartment, and wait until the detector powers off. Never use diluent, benzine, acetone, or other flammable cleaning agents.

14.5. Cleaning Agent Pixium EZ X

The Pixium EZ X housing can be cleaned using a smooth towel, with respect to ESD safety conditions.The sterilization, disinfecting, and cleaning conditions are defined by the System manufacturer in the context ofthe System use.

ℹ️	Note that the detector has a degree of protection against ingress of water of IP 67 according to IEC 60529.

The following table contains cleaning agents with the associated active substances.

Line	Cleaning Agent
	The detector should be free of any cosmetic and mechanical degradation under exposure to the liquids defined in the following table.Exposure is tested through contact of 500 h with the liquid.
#1	Metrex Caviwipes
#2	Schuelke Perform
#3	Bode Mikrobac tissues
#4	Ecolab Incidin plus
#5	Anios Surfa'safe
#6	PDI Sani-Cloth Active
#7	PDI Sani-Cloth Plus
#8	Virox / Diversey AccelTB

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Line	Cleaning Agent
#9	Isopropyl alcohol
#10	Ethanol 70 %
#101	Clorox - Dispatch towels with bleach
#102	Clorox - Hydrogen peroxide
#104	Freshening Industries - Hospicare 70
#105	Freshening Industries - Hospicare Multi-Surface 60R
#106	PDI - Sani-Cloth Prime
#107	Tristel - Duo-wipes + ULT

In addition to this list, the external film is known to be free of any cosmetic degradation when exposed to thefollowing liquids:

- #F01 Metrex Caviwipes XL
- #F02 Schuelke Mikrozid sensitive wipes
- #F03 Schuelke Terralin protect
- #F04 Schuelke Mikrozid AF wipes
- #F05 Schuelke Mikrozid PAA wipes
- #F06 Bode Bacillol 30 Tissues
- #F07 Bode Dismozon plus
- #F08 Bode Bacillol AF
- #F09 Bode Mikrobac forte
- #F10 Ecolab Incidin pro
- #F11 Ecolab Incidin active#F20 PDI Sani-Cloth Bleach#F21 Clorox Bleach germicidal wipes#F22 Diversey - sealed air Accel Five TB Wipes
- #F12 Anios Surfanios premium
- #F13 Dr Schumacher Biguanid Flache
- #F14 Dr Schumacher Cleanisept (wipes 7.5% from liquid)
- #F15 Lysoform Lysoformin 3000
- #F16 Lysoform Clorina
- #F17 BBraun Meliseptol Rapid
- #F18 PDI Sani-Cloth AF3
- #F19 PDI Sani-Cloth Super

The battery is considered as a part of the Front End, thus same list of liquids applies.

14.6. Cleaning Agent Pixium EZ HD

The following table contains cleaning agents with the associated active substances.

Line ID	Cleaning Agent
1	Super sani cloth wipes (62% Isopropyl alcohol (IPA) and 0.5% Dual Quaternary Ammonium Compounds (Quats))

The detector housing can be cleaned using a smooth towel, with respect to ESD safety conditions.Cleaning: wipe the product with a dry, soft, lint-free cloth.Disinfection: wipe the product with a soft, lint-free cloth slightly moistened in ethylene

alcohol or isopropyl alcohol.Avoid moisture and particles that could contaminate the product connector.The sterilization, disinfecting, and cleaning conditions are defined by the System manufacturer in the context of the System use.

14.7.Dark Calibration

ℹ️	In case of RAD Dual mode, the dark calibration allows acquiring the offset reference for the preview image correction. This operation has to be performed only if the image acquisition requires a preview image.

ℹ️	In case of RAD Single mode, the dark calibration allows acquiring the offset reference for the preview and full X-ray image correction.

❗	The dark references cannot be shared between a **rad** mode and a **rad.autotrigger** mode using the same detector mode. Therefore, the dark calibration for **rad** and **rad.autotrigger** operating modes must be done separately.

ℹ️	The PIXIUM EZ-C HD includes an automatic dark calibration. No manual dark calibration is needed

14.8.X-RAY Calibration

For a given Detector Mode, the PixRad API needs at least one Gain Reference and one Defect Map.

These two reference files are created during the X-ray Calibration process and saved in the Reference directory.

An ID number identifies the gain and defect map reference files.

The Gain Reference takes into account either the response of the detector and the uniformity of the X-ray flow. Therefore, for a given Detector Mode, it could be necessary to have several Gain References to cover different X-ray configurations (different SID, grid and no grid, X-ray source orientation …).

Only one Defect Map per Detector Mode is requested as it depends only on the detector performance.

❗	The center of the detector active area must be aligned with the center of the X-ray beam during the X-ray calibration. This procedure is not described in the present document.

❗	Take care that no object is present in the X-ray beam between the source and the detector (no object, collimator well opened…) during calibration.

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| ❗ | The detector must remain stable during the calibration. |

| ⚠ | An optimal image quality is ensured only if the temperature gap between calibration and images shots is within the distance to calibration temperature values defined in the **technical specification**. |

| ❗ | The detector must be calibrated after its installation and at least every 12 months.
After each calibration, the image quality must be verified at system level before operational use. |

| ❗ | Before launching the calibration, verify that the parameter **level.sensitivity** in the **DetectorXXXX.ini** file is preset with the sensitivity of the detector currently used or PixRad will use the value got from the detector. |

14.9. 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;
- Measure of patient leakage current.

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15. OPERATING CONDITIONS

15.1. PIXIUM PORTABLE EZ X Series Operation Conditions

	Typ	Min	Max
Temperature	+25 °C	+10 °C	+40 °C
Humidity (for a temperature of 40°C) (for a temperature of 35°C)	-	20% RH	80% RH 90% RH
Pressure	1000 mbar	700 mbar	1100 mbar
Weight (allowed weight uniformly distributed over the complete surface)	-	300 kg	-
Weight (allowed weight uniformly distributed over the surface of a 4 cm diameter disc)	-	100 kg	-
Vibrations	-	-	1 g

> ⓘ When the ambient temperature is in the range 35°C…40°C, please note that applied part of Pixium EZ X may reach 43°C.

15.2. PIXIUM PORTABLE EZ-C HD Series Operating Conditions

	Typ	Min	Max
Temperature	+25 °C	+0 °C	+40 °C
Humidity (for a temperature of 40°C)	-	10% RH	75% RH
Pressure	-	500 mbar	1500 mbar
Weight (allowed weight uniformly distributed over the complete surface)	-	-	300 kg
Weight (allowed weight uniformly distributed over the surface of a 4 cm diameter disc)	-	-	150 kg
Vibrations (The detector shall recover from vibration of at least 2,5 g during 20 minutes, in any directions without any loss in image quality)	-	-	2,5 g

16. STORAGE AND HANDLING

16.1. PIXIUM PORTABLE EZ X Series Environmental Storage and Transport

Unless special mention, the storage and transport environmental conditions only apply for the detector or anyseparate parts in the original package provided by THALES and battery not connected.

	Typ	min	Max
Temperature range	-	- 10 °C	+55 °C
Temperature variation	-	-1 °C/min	+1°C/min
Humidity (non-condensing)	-	5% RH	95% RH
Pressure (air pressure)	-	500 mbar	1100 mbar
Shocks in original package (according to IEC 60068-2-27 Test Ea)	-	-	25 g
Shocks unpacked (according to IEC 60068-2-27 Test Ea)	-	-	10 g
Vibrations in original package (sinusoidal vibration according to IEC 60068-2-6 Test Fc)	-	-	10 g
Vibrations unpacked (sinusoidal vibration according to IEC 60068-2-6 Test Fc)	-	-	2 g
Drop test (applies to packed parts)	-	-	120 cm

16.2. PIXIUM PORTABLE EZ-C HD Series Environmental Storage and Transport

	Typ	min	Max
Temperature range	-	-20 °C	+55 °C
Temperature variation	-	-1 °C/min	+1°C/min
Humidity (non-condensing)	-	10% RH	75% RH
Pressure (air pressure)	-	500 mbar	1500 mbar
Shocks in original package (according to IEC 60068-2-27 Test Ea)	-	-	25 g
Shocks unpacked (according to IEC 60068-2-27 Test Ea)	-	-	10 g
Vibrations in original package (sinusoidal vibration according to IEC 60068-2-6 Test Fc)	-	-	10 g
Vibrations unpacked (sinusoidal vibration according to IEC 60068-2-6 Test Fc)	-	-	2,5 g
Drop test (All the packed parts of the detector are guaranteed to resist to a drop test of the following height)	-	70 cm	-

17. END-USER TECHNICAL SUPPORT

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

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

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