pixium EZ3
Integration Manual and General Cautions

DOCUMENT HISTORY

Version	DOORS Baseline	Date	Author	Description	DM
- draft 1	NA	November 10th, 2021	O. Chastel	Initial version	-
- draft 2	NA	October 10th, 2022	O. Chastel	Update information for display Update labelling	-
- draft 3	NA	November 30th, 2022	O. Chastel	Update RF statements for Canada Update cleaning agents list Add information for IEC 61000-2-54 Add information for IEC 60601-1-2 Add information related to Canadian deviation Add information related to IEC 62366-1	-
- draft 4	NA	December 1st, 2022	O. Chastel	Add comments from internal reviewers	-
-	NA	December 14th, 2022	O. Chastel	Official release	323258
A draft 1	NA	December 19th, 2022	O. Chastel	Update for FCC and Canadian RF declaration	-
A draft 2	NA	January 11th, 2023	O. Chastel	Insert chapter 4.2 about cybersecurity	-
A draft 3	NA	October 13th, 2023	O. Chastel	Add mandatory information for Chinese users Update RED certificate number	330604
A draft 4	NA	October 13th, 2023	O. Chastel	Update §11.9.2 and §11.9.3 with infomration from LCIE for USA and Canada RF certificates	330604

CONTENTS

LIST OF TABLES

LIST OF FIGURES

1. PRESENTATION

1.1. INTRODUCTION

This manual describes the installation and operation of a **pixium EZ3** digital X-ray detector. It also provides information for service and safety operation. It is intended for use by a System integrator. Please read this manual carefully before performing any installation or use of a **pixium EZ3** detector.

This manual is intended to help integrators in the installation of a **pixium EZ3** detector and its first operation. The figures and data given in this manual shall be considered as indicative and are not contractual. Consult TRIXELL for additional information.

1.2. GENERAL DESCRIPTION

pixium EZ3 detector is a part of a digital image acquisition chain in an overall Radiological System. It features a portable equipment designed for mobile applications or for retrofit of a CR system.

pixium EZ3 detector complies with ISO 4090 standard for the external dimensions.

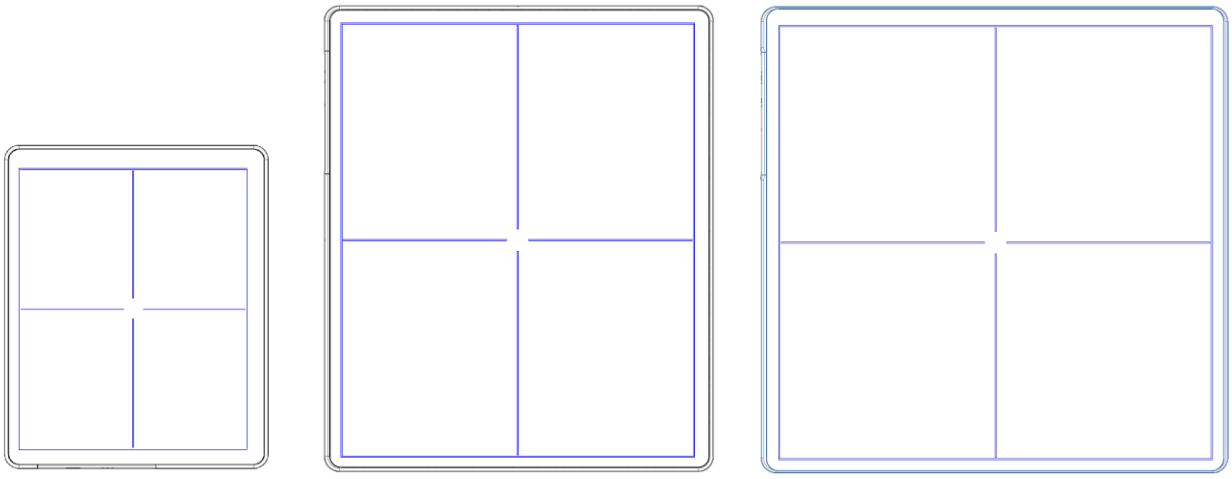
The detector is designed to be used for both domestic and professional healthcare facility environment.

1.3. DETECTOR

The detector consists of a complete carbon fibre housing. They integrate:

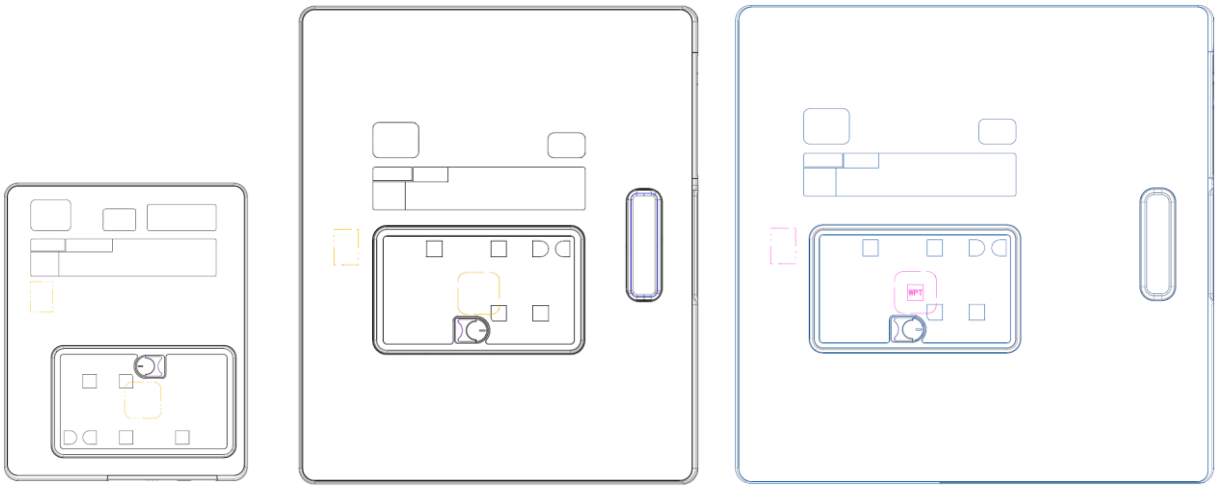
- LEDs indicators for internal status,
- NFC module for pairing with host system,
- Optionally, LCD display,
- Connector for a dedicated cable,
- A removable battery,
- Identification, warning labels and RF certificate ID (refer to appendix A for label drawings).

It does not include internal lead shielding against X-rays.



pixium 2430 EZ3 | pixium 3543 EZ3 | pixium 4343 EZ3

Figure 1: Top view (sensitive side)



pixium 2430 EZ3 pixium 3543 EZ3 pixium 4343 EZ3

Figure 2: Bottom view (battery side)

Please note that the overfilm (color and printing) could be customized by customers on request.

1.4. DELIVERY

The standard **pixium EZ3** delivery includes:

- the detector,
- one backup cable(Cable EZ3),
- one battery (Battery EZ X),
- one battery charger (Charger EZ X),
- accompanying documentation.

Note that each customer may have a specific configuration for delivery.

The standard **pixium EZ3** delivery does not include in particular:

- an external power supply (part of the customer System),

an Ethernet insulator,

1.5. IDENTIFICATION

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

- type (**pixium EZ3**)
- part number (P/N)
- revision code (Rev.)
- serial number (S/N)
- manufacturing date
- connections (power supply inputs / communication links)
- various warnings and cautions

See appendix A for label models.

1.6. STANDARDS

The **pixium EZ3** is:

- a class I product according to IEC 60601-1 standard

- a software product class B according to IEC 62304 standard
- a class B product according to EN 55011 standard
- a class IIa medical devices according to the 2017/745/EEC regulation

The **pixium EZ3** is labeled as follow:

- UL : Combined UL/CSA certification (C-UL) label
- CSA : Combined UL/CSA certification (C-UL) label

System integrator is in charge of CE labeling for the overall equipment. However, TRIXELL provides a compliance certificate for essential requirements relative to 2017/745/EEC regulation.

Note: For full list of applicable standards please refer to standard compliance [SCC]

1.7. REFERENCE DOCUMENTS

Bookmark	Document title	Reference	CTD
[EUM]	End User Manual	63121447	108
[PTS]	Product Technical Specification	63098146	306
[PSS]	Product Standard Specification	63102442	306
[MIS]	Mechnical Interface Specification	63098150	306
[EIS]	Electrical Interface Specification	63098148	306
[UCS]	Use Case Specification	63106094	306
[AID]	Application Interface Definition	63098149	108
[HARMS]	Hazard and Risk Management Summary	63098151	530
[SHARMS]	Software Hazard and Risk Management Summary	63098152	530
[SH]	Generic Storage and Handling	62756802	108
[OUT_DRW]	Outline drawing	2430: 63110349 3543: 63101437 4343: 63103095	041
[DISM_DRW]	Dismantling drawing	63127633	066
[SCC]	Standard Compliance Certificate	2430: 63137754 3543: 63121448 4343: 63127667	600
[BATT_USR]	Battery EZ X user manual	63127737	108
[CHG_USR]	Charger EZ X user manual	63127736	108
[P3543_STR]	Unpacking instructions	62756802	108

Table 1: Reference documents

Note: Be sure to use the latest revision of these documents

1.8. DEFINITION, ACRONYMS, ABREVIATION

The following table presents the acronyms that may be used in this document:

Acronyms	Definition
CCK	Complementary Code Keying
ADC	Analog to Digital Converter
CE	Conformité Européenne (meaning European Conformity)
CFR	Code of Federal Regulations
COA	Condition Of Acceptability
CPT	Contact Power Transfer
CSA	Canadian Standards Association
DC	Direct Current
EIRP	Equivalent Isotropically Radiated Power
EMC	Electro Magnetic Compatibility
ESD	Electro-Static Discharge
FCC	Federal Communications Commission
FDA	Foods and Drugs Administration
FE	Front-End
IEC	International Electro-technical Committee
IEEE	Institute of Electrical and Electronics Engineers
ISO	International Standard Organization
ISM	Industrial, Scientific and Medical
LED	Light Emitting Diode
OFDM	Orthogonal Frequency-Division Multiplexing
RF	Radio Frequency
SIRN	Software Integration Release Note
TBD	To Be Defined
TDLP	Trixell Detector Link Protocol
WPT	Wireless Power Transfer

Table 2: Acronyms

2. INSTALLATION

2.1. INSTALLATION REQUIREMENTS

Components needed for installation and operation are the following:

- One **pixium EZ3** detector
- One Charger EZ X (including its external power supply)
- One Battery EZ X
- One external single DC power supply (+12V) (not provided)
- One access point (not provided)

During installation, ensure that neither a sharp corner nor edge can damage the cabling.

Mechanical fixation of cables and connectors must be provided in order to prevent unnecessary wear out of the cables.

2.2. INSTALLATION PROCEDURE

Please follow the below instructions before switching on the detector:

- Remove detector from its original packaging. Refer to [P3543_STR] for unpacking instructions.
- In case a power supply is available, compliant with [EIS] requirement, power connector of the Cable EZ3 shall be plugged to this power supply.
- If a charged battery is available, it can be plugged into the detector on its backside, instead to use the cable for power.
- Battery EZ X delivered in its original packaging can be plugged directly into the detector.
- Ethernet connector of the Cable EZ3 shall be plugged to network interface provided by the system and the power connector shall be connected to external power supply provided by the system
- Then the magnetic connector of the cable can be plugged to the detector. There are two possible orientations to plug this cable: both orientations can be used for proper operation.
- System shall be compatible with following default values of the detector for network compatibility:
  - host IP address: 192.168.1.5
- If this is not the case, user shall use the infra-red link or NFC to set correct network configuration to the detector.
- Configure the access point with the correct country code (please refer to user manual of access point)
- First operation shall be done either by cable or infra-red. Wi-Fi settings (Wi-Fi SSID, Wi-Fi password) shall be performed through System interface during this first operation.

2.2.1. MECHANICAL INSTALLATION

Accessible parts: Charger EZ X is considered as non-accessible part. As consequence, it must not be placed in patient environment.

Applied parts: Sensitive side of **pixium EZ3** is considered as an applied part.

pixium EZ3 is compatible with ISO 4090 cassette holder size

Constraints*:* **pixium EZ3** is qualified to be exposed to variations of accelerations refer to Appendix B environmental conditions section. The detector can't be used with non-natural variations of pressure.

Tightness*:* pixium EZ3 has a degree of protection against ingress of water of IP 67 according to IEC 60529.

2.2.2. CONNECTICS

2.2.2.1. Connector unit

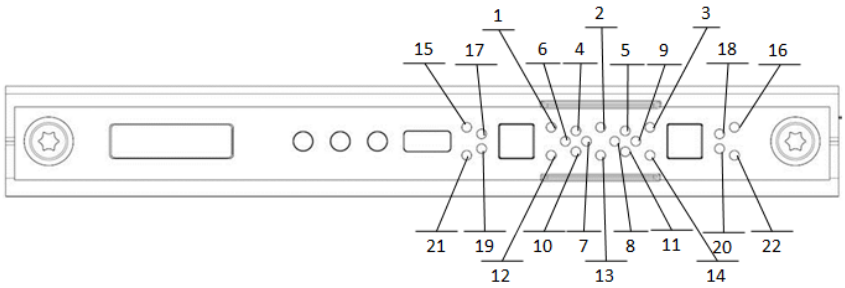


Figure 3: Backup cable connector

Pin number	Signal
1	GND_SHIELD
2	GND_SHIELD
3	GND_SHIELD
4	TXRXP_B
5	TXRXM_A
6	P12V
7	GND
8	GND
9	P12V
10	TXRXM_B
11	TXRXP_A
12	GND_SHIELD
13	GND_SHIELD
14	GND_SHIELD
15	GND_SHIELD
16	GND_SHIELD
17	TXRXP_C
18	TXRXM_D
19	TXRXM_C
20	TXRXP_D
21	GND_SHIELD
22	GND_SHIELD

Table 3: Connector pin-out for connector unit

2.2.2.2. Cable EZ3: Power supply

Backup cable contains a double insulated connector on system side for power supply (connector reference given in [EIS] document):

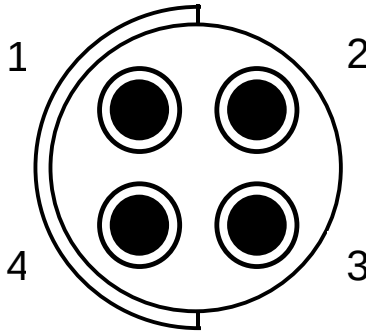


Figure 4: Power supply connector

Pin number	Signal
1	P12V
2	-
3	GND
4	-

Table 4: Power supply connector pin-out

- CAUTION -

Power supply polarity inversion or out of range power supply (including a missing power supply) may harm the detector.

Be sure to correctly connect and clamp the power supply cable and the connector.

Check the power supply polarity before switching on. There is no hazard resulting from switching on and off the power supply.

2.2.2.3. Cable EZ3: TDLP link

Cable EZ3 contains a RJ45 connector on system side:

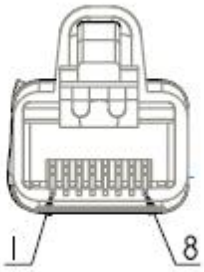


Figure 5: RJ45 connector

Pin number	Signal
1	TXRXP_A
2	TXRXM_A
3	TXRXP_B
4	TXRXP_C
5	TXRXM_C
6	TXRXM_B
7	TXRXP_D
8	TXRXM_D

Table 5: RJ45 connector pin-out

2.2.2.4. Cable EZ3: Detector connector

A connector is accessible on the left side of the detector housing, in order to connect a cable from the System. The purpose is to recharge the battery when discharged and to allow going on with image acquisition.

The attachment of the cable to the detector can be done in two orientations (rotation of 180° is allowed without impact on the connection).

When the cable is attached on System side and connected to the detector, the Wi-Fi operation is disabled and data transfer is managed through this cable (Ethernet link). The cable can be “hot-plugged”, meaning it can be plugged and unplugged at any time without special precaution.

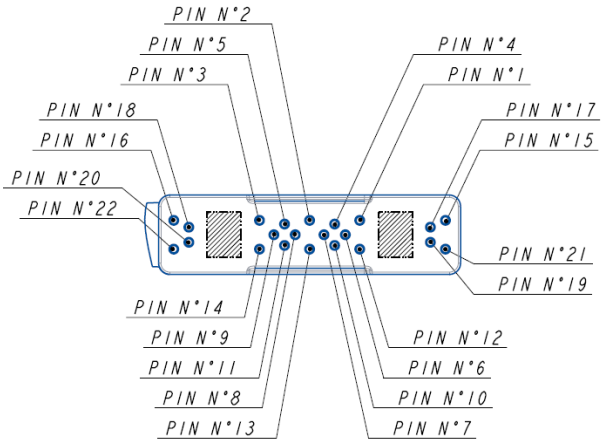


Figure 6: Backup cable connector

Pin number	Signal
1	GND_SHIELD
2	GND_SHIELD
3	GND_SHIELD
4	TXRXP_B
5	TXRXM_A
6	P12V
7	GND
8	GND
9	P12V
10	TXRXM_B
11	TXRXP_A
12	GND_SHIELD
13	GND_SHIELD
14	GND_SHIELD
15	GND_SHIELD
16	GND_SHIELD
17	TXRXP_C
18	TXRXM_D
19	TXRXM_C
20	TXRXP_D
21	GND_SHIELD
22	GND_SHIELD

Table 6: Connector pin-out for backup cable

Note that Cable EZ is compatible with pixium EZ3. Nevertheless, the data rate will be reduced to 100Mb/s.

2.2.2.5. Battery EZ X: CPT connector

The connection to the pixium EZ3 through the battery's CPT are as follow:

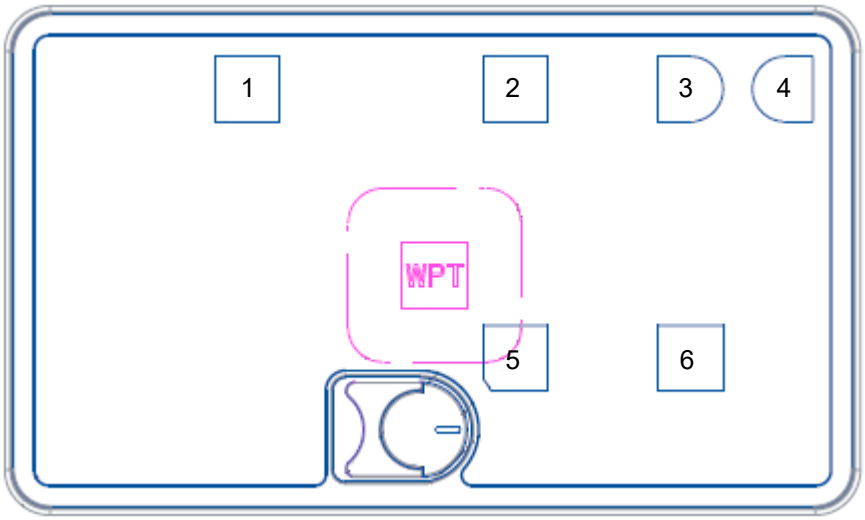


Figure 7: Battery EZ X connection

Pin number	Signal
1	GND
2	P12V
3	P12V
4	GND
5	GND
6	GND

Table 7: Connection pin-out for Battery EZ X

2.2.3. INSULATION DIAGRAM

2.2.3.1. Protective earth

pixium EZ3 and Charger EZ X do not contain any PE.

Safe design: The system-earthing diagram must be in accordance with document [EIS] (galvanic separation of electrical circuits) and recalled hereafter.

- CAUTION -

Connector and cable shields must not be used as protective earth connection.

There is no protective insulation between the electronics inside the detector and the housing.

2.2.3.2. Insulation diagram

System integration: System Design must be in accordance with insulation design of detector given hereafter.

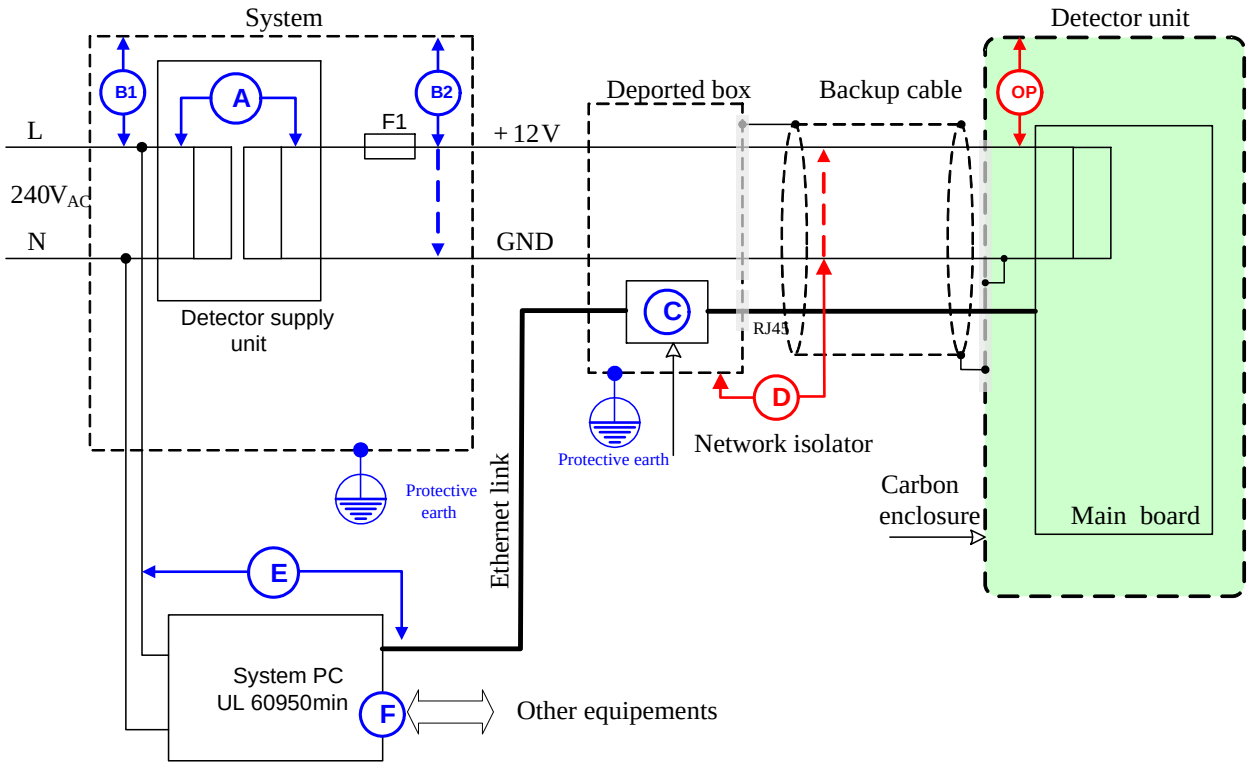


Figure 8: Insulation diagram for pixium EZ3 with Cable EZ3

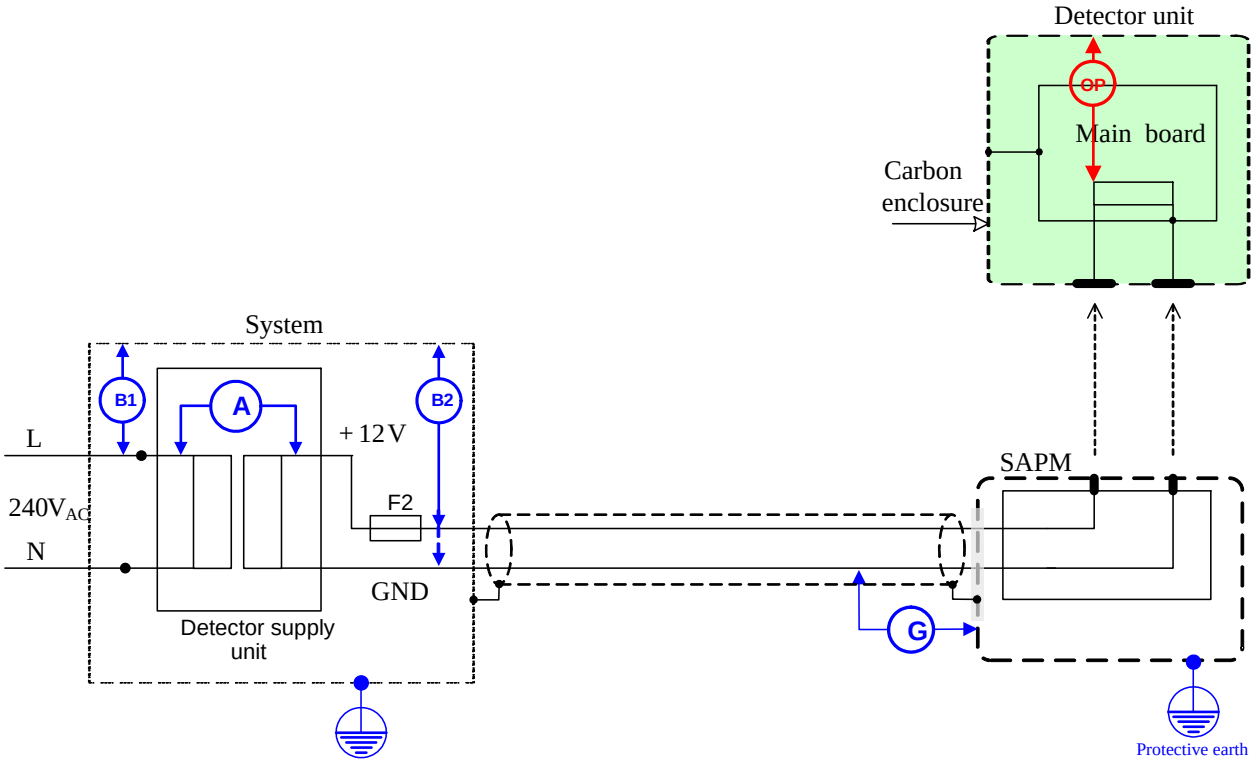


Figure 9: Insulation diagram for pixium EZ3 with CPT

Location	Protection	Reference voltage	Creepage distance	Air clearance	Test voltage
A	**2 MOPP**	**240 V_{AC}**	**8 mm** (table 12)	**5 mm** (table 12)	**4000 V_{AC}** (table 6)
B1	**1 MOPP**	**240 V_{AC}**	**4 mm** (table 12)	**2.5 mm** (table 12)	**1500 V_{AC}** (table 6)
B2	**2 MOPP**	**12 V_{DC}**	**3.4 mm** (table 12)	**1.6 mm** (table 12)	**1000 V_{AC}** (table 6)
C	**1 MOPP**	**240 V_{AC}**	**4 mm** (table 12)	**2.5 mm** (table 12)	**1500 V_{AC}** (table 6)
	2 MOPP	**15 V_{DC}**	**3.4 mm** (table 12)	**1.6 mm** (table 12)	**1000 V_{AC}** (table 6)
D	**2 MOPP**	**12 V_{DC}**	**3.4 mm** (table 12)	**1.6 mm** (table 12)	**1000 V_{AC}** (table 6)
E	**2 MOOP**	**240 V_{AC}**	**5 mm** (table 16 + note)	**4.56 mm** (table 8, 9 and 13)	**3000 V_{AC}** (table 6)
	1 MOPP	**240 V_{AC}**	**4 mm** (table 12)	**2.5 mm** (table 12)	**1500 V_{AC}** (table 6)
F	See note 6	See note 6	See note 6	See note 6	See note 6
OP	NA	**12 V_{DC}**	**Operational**	**Operational**	NA

Table 8: Insulation safety distances

Insulation diagram hypothesis:
The distances given in the insulation table here before are defined according to following hypothesis:
- Pollution degree is 2
- Material group is III b
- Maximum altitude is 3000 meters

Notes:
1. On this diagram, appear constraints on host system (written in blue). Constraints written in red are applied to pixium detectors and their accessories. **Any other insulation diagram compliant with IEC 60601-1 requirements and taking into account the detector insulation (red) can be acceptable.**
2. F1 prevents pixium detectors against excessive temperatures in SFC and must be calculated in order to limit power supply to 15 Watts max (or maximum 900 Joules during 1 minute). **Any other equivalent means of protection can be acceptable.**
3. Inside the pixium detectors, housing is connected to the GND of the power supplies.
4. **C** insulation is a network isolator (i.e. EN-30 from EMO Systems or any other equivalent device). It is only required if detector could be in the patient environment while backup cable connected
5. System PC must be IEC 62368-1 certified. It must be placed outside of patient environment.
6. **F** insulation is only required if system PC is connected to equipment that can apply more than 15 V_{DC} in Single Fault Condition.
7. In case of use above 2000m, the PC must be certified accordingly.

To fulfill the **A** insulation, the power supply unit must be IEC60601-1 certified.

2.2.4. X-RAY GENERATOR CONNECTION

X-Ray source: The emission of the ionizing radiation is controlled by the system manufacturer.

pixium EZ3 is not approved to control the emitted X-ray dose. If the **pixium EZ3** is used as a "sub-assembly" in an X-ray dose loop, the corresponding risk management has to be done at the radiological system level.

- CAUTION -

X-ray Enable signal only indicates to the System that the detector is ready to receive X-rays. It's the System responsibility to control the actual emission of X-rays.

System accompanying documents must indicate:

- Procedure for X-ray alignment measurement
- Prohibition to order any radiation when a dysfunction is noticed by the operator, whatever this dysfunction

2.2.5. COOLING

pixium EZ3 detector has a passive cooling concept.

Thermal interface resistance is defined in §10.4.

2.2.6. MAXIMUM ALLOWED WEIGHT ON THE DETECTOR

The X-ray input window (upper side of the detector) is made of a carbon fibre composite substrate, to protect the sensitive layer and active array of the detector.

This input window can withstand maximum weight without any image artefact:

PUID	Description	Product	Min	Value	Max	Unit
[PTS-REQ-1680] PTS_perf_weight	The detector shall remain at full performance for:	3543EZ3, 4343EZ3, 2430EZ3				
	• A mechanical weight uniformly distributed over the complete surface of:	3543EZ3, 4343EZ3, 2430EZ3	150			kg
	• A mechanical weight uniformly distributed over the surface of a 4 cm diameter disc of:	3543EZ3, 4343EZ3, 2430EZ3	100			kg

This input window can withstand maximum weight without any irreversible degradation:

PUID	Description	Product	Min	Value	Max	Unit
[PTS-REQ-1670] PTS_func_weight	The detector shall remain functional for:	3543EZ3, 4343EZ3, 2430EZ3				
	• A mechanical weight uniformly distributed over the complete surface of:	3543EZ3, 4343EZ3, 2430EZ3	300			kg
	• A mechanical weight uniformly distributed over the surface of a 4 cm diameter disc of:	3543EZ3, 4343EZ3, 2430EZ3	100			kg

2.2.7. DETECTOR SETTINGS

Initial detector settings are performed at the factory. Please refer to System Integrator installation procedure for eventual image quality optimization.

2.2.7.1. Communication link settings

For Wifi configuration and Ethernet configuration, please refer to §2.2

2.2.7.2. Other settings

Not applicable

2.2.8. ADDITONAL ACCESSORIES

Spare battery is available upon request. Refer to Battery EZ X documentation for additional information.

Spare backup cable is available upon request.

No anti-scattered grid is delivered with the detector.

In some mode of operation, an automatic exposure control device can be used. This device is not part of the detector; it must be supplied and installed by the System integrator.

2.2.9. PROTECTION AGAINST MECHANICAL DAMAGE IN BUCKY TRAY

pixium EZ3 is compatible with ISO 4090 film cassette standard. In order to avoid damage of the plastic detector cover in standard bucky trays, TRIXELL recommends to protect with thin tape (like kapton) any sharp metallic parts in the bucky tray such as fixation clamps or insertion rails.

3. FIRST OPERATION

3.1. SWITCH ON

There is no switch to be activated to start operating the detector, provided the battery is connected and charged, or an external power (cable, CPT or WPT) is used.

While switched on (during boot sequence), status LED (refer to §3.3.1) is blinking slow in orange colour.

For regular operation, wake-up of the detector depends on the System configuration.

3.2. SWITCH OFF

3.2.1. SYSTEM CONTROL

Operation can be stopped by software command: refer to System information.

During such sequence, status LED (refer to §3.3.1) is blinking fast in orange colour.

3.3. DETECTOR INDICATORS

LED's and indicators are provided for operation maintenance on the detector side (close to the connector), to give basic information on the detector behaviour. The different LED and indicator behaviours are described hereafter:

In the following, the meaning of symbols is:

Symbol	Meaning
	Continuous light
	LED off
	Blinking slow
	Blinking fast

Table 9: Symbols

3.3.1. DETECTOR STATUS LED

Symbol:

LED color / status	Meaning
	OPERATING state and ONLINE
	OFFLINE
	LISTEN state
	OFF state
	ERROR state
	DOWNLOAD state
	Buffer full (not enough space for one acquisition in 1x1 mode) in case storage is enabled
	Switch on Start of boot (after wake-up) :

LED color / status	Meaning
	When the detector has finished boot sequence, it arrives in error or operating state (see above)
 then  red flash light on the 3 LEDs then OFF	Switch off (going to OFF state) when requested by message or by time-out

Table 10: Detector status

Image sequence: Switch-off Status LED during Image “chrono” is running, that means from “request image frame” or X-ray detected to end of panel read-out.

The status LED remains then orange until the key image is securely transmitted or stored, that means until the event “detector ready to do an image again”. If buffer is full (no enough space for the required acquisition in case of storage enabled), the status LED remains orange.

As consequence, user shall check at LED status (green light) before removal of the battery.

After reception of an SNC (network reconfiguration requested):

- All the 3 LEDs orange blinking fast at least 2 s
- If reconfiguration is accepted, the 3 LEDs flash green 3 times (around 1.5s in total)
- If reconfiguration is not accepted, the 3 LEDs flash red 3 times (around 1.5s in total)

Reconfiguration cannot start before the 2 first seconds

If SNC parameters are identical to previous one, we handle it like an accepted reconfiguration

3.3.2. WIFI LED

Symbol:

LED color / status	Meaning
	Wi-Fi available (detector connected to an Access Point)
	Wi-Fi not used (Wi-Fi switched off by software)
	Wi-Fi not ready (detector not connected to an Access Point)

Table 11: Wifi status

In Listen, Download, Error states, same behaviour as in Operating state.

In OFF state, wifi LED is OFF.

During boot, wifi LED is OFF.

3.3.3. BATTERY LED

Symbol:

LED color / status	Meaning
	Battery capacity between 100% and Low_level_trigger_2
	Battery capacity between Low_level_trigger_2 and Low_level_trigger_1
	Battery capacity below Low_level_trigger_1
	No battery

Table 12: Battery status

The battery LED follows the previous rules independently of the cable voltage.

In Listen, Download, Error states, same behaviour as in Operating state.

In OFF state, battery LED is OFF.

During boot, battery LED is OFF.

3.3.4. DISPLAY

pixium EZ3 equipped with full connector unit owns a LCD display on the edge of the detector used for provide information to the end user:

Figure 10: Display

Symbol:

Indicators	Meaning
	Gives a visual indication of the remaining battery level and if the battery is being charged.
	When lighted, indicates that the detector is connected to a host,
	Indicates the number acquisitions that can be performed with the detector (taking into account the remaining storage capacity and battery capacity) on two digits.

Table 13: Display symbols

3.4. SOFTWARE FEATURES

The detector can send to the System, upon request, messages containing the hardware and software revision numbers, and the detector's serial number and date code.

The detector has built-in self-test features to provide the System with information for malfunction diagnostic.

The detector can generate, upon request issued by the System, error or warning messages in case of communication or internal electronics malfunctions (such as internal voltage drifts or breakdowns).

It is the System's responsibility to decide what to do in case of such an error or warning.

The detector has a built-in set of test patterns that can be used to check the operation of the detector's electronics (analog test patterns) and of the image data transmission (digital test patterns): refer to mode table.

If the detector has to reboot due to an internal error, it is able to come up to a normal operating mode by itself.

3.5. OPERATION MODES

For information about available operationnal modes please refer to mode table in [PTS].

3.5.1. TABLE MODE DEFINITION

The table mode is given in a separate document called SIRN provided to system integrator with each software version. Please refer to the SIRN before integrating a new software.

- CAUTION -

Modes that are not described in the SIRN are TRIXELL reserved.

3.5.2. SPATIAL RELATIONSHIP

The relationship between the physical detectors and the corresopnding images issued from an acquisition are as follow:

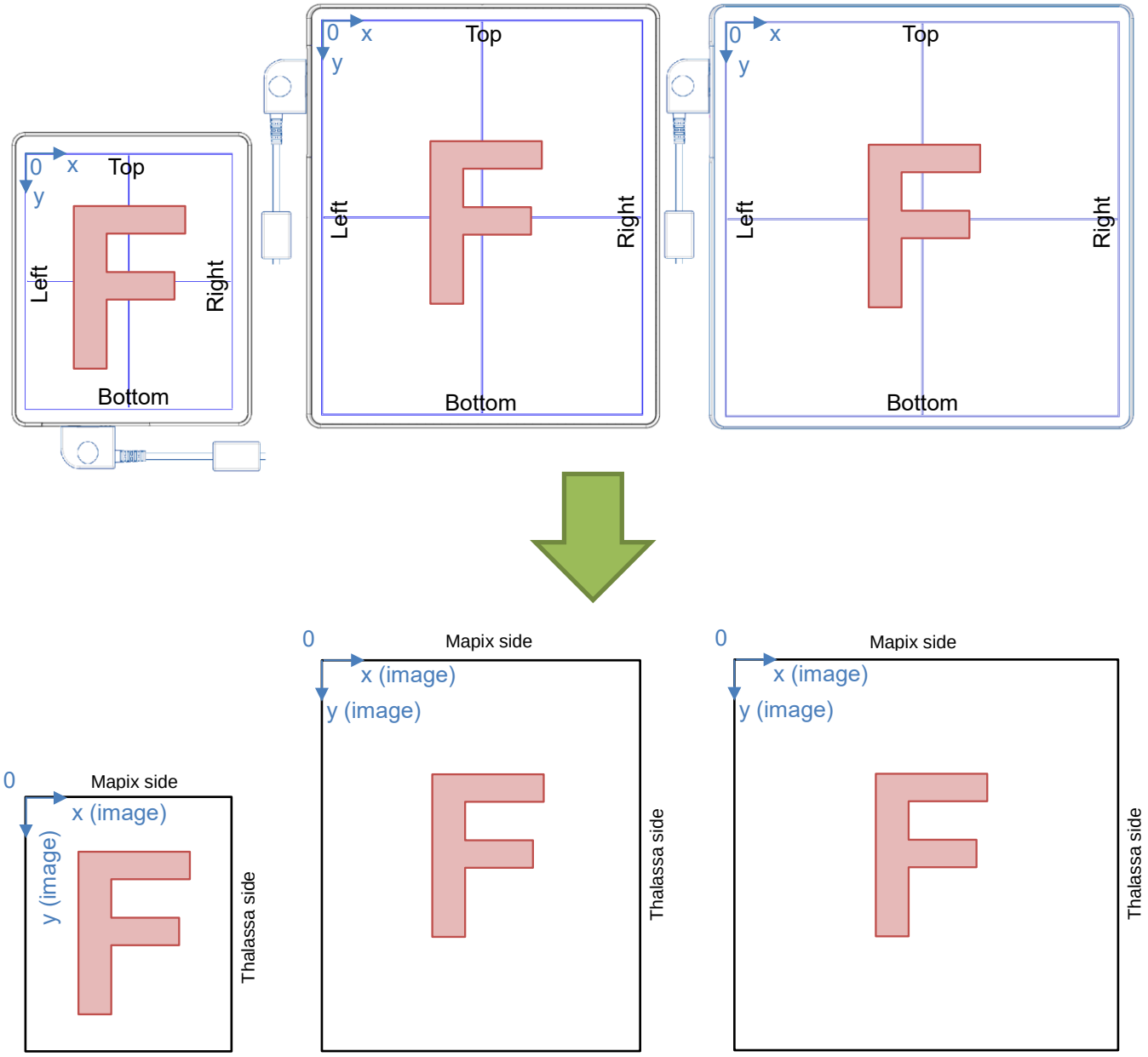


Figure 11: Spatial relationship

4. CAUTIONS AND RECOMMENDATIONS

4.1. SAFETY MEASURES FOR THE SYSTEM INTEGRATOR

- CAUTION -

If pixium EZ3 is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

Medical diagnostic radiology: The final destination of **pixium EZ3** is the medical diagnostic radiology. They must be carried out in presence of a qualified medical personal. The possible clinical parameters are under the control of the system manufacturer.

Applied parts: pixium EZ3 has applied parts (there is direct contact between the patient and the detector, except when it is mounted in a bucky table or a wall-stand Radiological System.

Biocompatibility: The sensitive side of **pixium EZ3** is designed to be safe in case of short-term contact with damaged skin (less than 24 hours). Nevertheless, if such case occurs, the FE will be preferably wrapped with sterile plastic bag.

pixium EZ3 is not a device delivered in a sterile state.

- CAUTION -

Charger EZ X is an ordinary accessory which is not intended to be used in patient environment.

The COA below (included for information) shows a list of safety measures that shall be taken by the system integrator. This list comes from Hazard Analysis and Risk Management Summary [HARMS] and Software Analysis and Risk Management Summary [SHARMS] archived in accordance with ISO 14971 standard.

4.1.1. CONDITIONS OF ACCEPTABILITY FROM HARMS

[COA_HARMS_0002]: The system integrator is aware that pixium EZ3 is not intended to control the generated X-ray dose.

[COA_HARMS_0003]: The system must manage the risk of loss or degradation of imaging caused by the detector to an acceptable level.

[COA_HARMS_0004]: The system integrator is aware the detector is equipped wit Thallium doped CsI. System integrator shall provide adapted measures to deal with Thalium in accident cases or at detector's end of life.

[COA_HARMS_0005]: In case of use of the detector attached to a system, system integrator shall provide clear information to the end user on the attachement to right system. Any other solution reducing risk of crossover can be used.

[COA_HARMS_0008]: When the auto-trigger function is used, TRIXELL recommends the physician to set the X-ray generator insuring a correct level of X-ray on the detector allowing the trig of an image (see [PTS] for detail). Otherwise, if the level received by the detector is too low, there is a risk to not trig the image.

[COA_HARMS_0017]: The network setting (hospital and/or systems) must be done by qualified people. The end-user should not be allowed to modify the setting.

[COA_HARMS_0023]: The system integrator will make sure the information provided in the EUM is available at end user level.

For Canadian end-users, the accompanying documents shall be also translated in French.

If requested, a training program for end-users shall be established by the integrator including information provided in document [EUM].

4.1.2. CONDITIONS OF ACCEPTABILITY FROM SHARMS

[COA_RMS_0190]: The system integrator shall address the risk "Software compatibility between detector and system".

[COA_RMS_0200]: The system must manage the risk of loss or degradation of imaging caused by the detector to an acceptable level.

[COA_RMS_0220]: The detector shall only be used during medical examination, except if a specific use case is agreed between TRIXELL and a system integrator.

[COA_RMS_0230]: To system integrator: To prevent overheat, TRIXELL recommends to the system integrator to manage internal temperature in order to prevent overheat, by reading temperature through software or by a validated mean.

[COA_RMS_0240]: System integrator shall monitor temperature to detect malfunction degrading image quality.

[COA_RMS_0340]: System integrator shall activate at least IR or NFC systematically inside UCF and verify systematically that previously IR or NFC device is perfectly working.

[COA_RMS_0370]: Simultaneous access to memory by software interface and secured file transfer protocol (SFTP) shall be forbidden by system integrator interface in case of multi user.

[COA_RMS_0380]: System integrator shall be aware that in autonomous mode images can be triggered accidently without X-rays, leading to unexpected additional images. Therefore system integrator shall have special focus on the synchronization of acquired images in auto-trigger mode and patient information (for instance by analyzing the image counter provided by the detector).

[COA_RMS_0400]: WiFi environment is complex and actual WiFi performances depend on local environment and installation. The System Integrator is responsible for the WiFi level of service.

[COA_RMS_0420]: System integrator shall manage in its own hazard analysis how to minimize the risk linked to "having several images with artifact after a day tour".

[COA_RMS_0460]: The system integrator is responsible for battery management and powering the detector. The system ensures that the detector is always powered during image cycle from the request image acquisition to end of image storage or transmission, otherwise current image is lost.

[COA_RMS_0570]: The system integrator is responsible for imaging network (as support asset enabling communication) In terms of quality of service (See definition). In addition, , when used in wifi-direct legacy mode, the system integrator shall change the SSID of the detector once up a year to prevent the connection of old devices from connecting to the detector. The system integrator is responsible for the setting of the country code.

[COA_RMS_0590]: The system integrator is responsible for managing the detector and system certificates (content, data, expiration date) and embedded clocks for the communication process with the detector.

[COA_RMS_0600]: The system integrator shall strictly follow the instruction given in the information files when a new software version has been released.

[COA_RMS_0610]: The system integrator is responsible for managing the health check at detector startup. He must check the detector health using the BIST features.

[COA_RMS_0620]: The system integrator must check that Hotswap is Available before doing any action with the battery (i.e.: changing the battery)

4.2. CYBERSECURITY

Pixium detector was developed taking into account Cyber Security constraints. The methodology for Trixell risk analysis is based on EBIOS and is compliant to ISO27K5.

Note: Pixium EZ 3 detectors exists in two different SW versions:

- Legacy version based on SIS
- A secured version based on DDS

For legacy constraints, not all risk mitigations have been implemented in the SIS version.

System integrator and end customer shall put special care to limit non-authorized access to the detector. In particular, the detector should be stored in a restricted area in order to avoid stealing or unauthorized access to the detector.

Users shall take special care on WiFi password management:

- It is recommended to change the default WiFi password before first installation and on a frequent basis (at least every 90 days)
- A strong complexity/entropy should be put in place (at least 12 characters, at least one number and at least one none alpha numeric character)
- System should keep at least the last 3 passwords in memory. User should use different password.

It is recommended to have a second spare battery available in order to avoid impact regarding image acquisition, and transfer.

4.3. EMPERATURE

The Battery EZ X includes a thermal protection that shuts down the battery power in case of very high temperature causing the Front End unusable. Two situations can occur:

- Software protection: the battery pack will be usable as soon as the temperature drops below a specified limit,
- Hardware protection: the battery pack must be exchanged.

For more information about overheating protection please refer to [PTS] and [SIS] documents.

4.4. EMC COMPLIANCE

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information.

Radio frequency (RF) communications: Portable and mobile RF communications equipment can affect medical electrical equipment.

- CAUTION -

The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity of the equipment.

- CAUTION -

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.

- CAUTION -

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

For more information about electromagnetic compatibility, please refer to appendix D .

4.4.1. CABLES AND CONNECTORS

The system integrator must take care with the kind of cables used to connect the pixium to the system :

TRIXELL recommends using a shielded power supply cable. The shielding must be properly connected to the dedicated connector metallic body in order to insure a good electrical connection. The EMC conformity of the detector was checked with 360° shielded cables.

4.5. LASER CONTENT

Invisible laser diode used for data transmission (IrDA module) is classified as LASER CLASS 1.

Max power out is the lesser of Class 1 safety limits (FDA CFR21 §I part 1040 and EN 60825-1) or receiver power max.

- CAUTION -

Avoid direct eye exposure to beam.

4.6. WARM-UP TIME FROM A COLD START

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-0270] PTS_cold_start_time_dual	-	As the detector normal use is to be switched-off regularly, or to go frequently into high-autonomy state, detector is designed to achieve full image performance quickly after being in Operation state. This implies that the cold start time to ensure full image performance is equal to <PTS_wake_up_time> when detector comes from Off state. (ref to <PTS_listen_to_full_IQ_delay> for detector coming from Listen state).	-	-	40	s
[PTS-REQ-0280] PTS_cold_start_time_single	-	In single mode, the cold start time (time to reach full image performance) is:	-	-	2	h

4.7. HUMIDITY

Operating humidity:

The operating humidity is valid within the operating temperature range. However customer shall ensure that detector is never submitted to condensation.

Customer shall take care that NO CONDENSATION occurs on the detector surface.

Storage humidity:

If detector is shipped mounted on the System to final customer: it is the responsibility of customer to ensure that detector is never exposed to condensation.

See Appendix B for environmental conditions.

4.8. MAINTENANCE

No other preventive maintenance action is required except the calibration needed for image quality, whose periodicity is defined by the System program.

The battery can be replaced due to limited lifetime. In case of malfunction, the detector will be returned as it is to the manufacturer for repair. However, possible software release can be realized using the control link: contact TRIXELL customer service for instructions.

For maintenance please refer to system integrator maintenance manual.

4.9. SOFTWARE USE INFORMATIONS

When detector is powered on, the system must check the result of the **pixium EZ3** internal self-tests.

During operation, TRIXELL recommends the system to check:

- the header of every image sent by the detector,
- if possible, the internal temperature,
- the level of battery when powered by Battery EZ X,
- the WiFi link quality before requesting an image during free-cassette mode,
- the status of the anti-scatter grid (presence and type) thanks to dedicated command.

5. TROUBLESHOOTING

5.1. POWER SUPPLY RANGE

During boot-up sequence, if the power supply fails out of the specified range, the detector might turn to a “Not available” status and will not go to normal operation (no image generated).

When connected to an external power (cable, CPT or WPT) , if power supply output is too low or too high, the detector will not boot-up at all. Check your power supply to restart operation.

5.2. OTHER FAILURE

A “Not Available” status can also be issued by self-test functions, in case of internal failure on the electronic board (firmware error, memory failure...).

After verifying that power supply range and internal temperature are correct, and if the detector is still issuing a “Not Available” status, please contact Trixell field service.

If detector is not operational after reboot, Trixell recommends to retrieve error buffer through software command to get more information about last error. To do this, a communication link with system is mandatory (backup cable or wireless). See [AID] for detail.

6. CLEANING AND DISINFECTIONS INSTRUCTIONS

The detector housing can be cleaned using a sweet towel, with respect to ESD safety conditions. Note that the detector has a degree of protection against ingress of water of IP 67 according to IEC 60529.

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

PUID	Description
[PTS-REQ-1800] PTS_cleanable_liquids	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
	#9 Isopropyl alcohol
	#10 Ethanol 70 %

Table 14: Cleaning agent list

In addition to this list, the external film is known to be free of any cosmetic degradation when exposed to the following 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
- #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
- #F20 PDI Sani-Cloth Bleach
- #F21 Clorox Bleach germicidal wipes
- #F22 Diversey - sealed air Accel Five TB Wipes

Battery EZ X is considered as a part of the Front End, so same list of liquids applies.

7. ECO-DESIGN

7.1. CLEANING

Any material used to clean, sterilize, and disinfect a **pixium EZ3**, such as towelettes and dust clothes, must be processed using dedicated waste recycling procedures.

7.2. RECYCLING/REFURBISHMENT

Refer to pixium detector End Of Life datasheet (available on demand) for information about detector recycling and refurbishment.

7.2.1. BATTERY

The end user must be clearly informed that battery packs Battery EZ X used in **pixium EZ3** contain hazardous substances for the environment and must take all preventive actions to manage the battery end of life (recycling plan).

7.2.2. FRONT END, BACKUP CABLE AND BATTERY CHARGER

TRIXELL is in charge of the recycling of **pixium EZ3** and their accessories (Cable EZ3 and Charger EZ X). TRIXELL's customers are in charge of managing the way to collect these products (end of their life or out of order) and ship them to TRIXELL for recycling.

Information:

- **pixium EZ3** contains Thallium-doped Cesium Iodide scintillator material (Thallium qty < 2 g)
- **pixium EZ3** contains one or more lead plates of several sizes

TRIXELL expects its customers to take care of the recycling of the **pixium EZ3** within the framework of the System recycling procedure.

7.3. REACH INFORMATION (FOR EUROPE ONLY)

Information on declarable substances are given in BOMcheck website (http://bomcheck.net/) accessible by our direct customers.

8. MANUFACTURER

pixium EZ3 is manufactured by:

TRIXELL
460, rue du Pommarin
38430 Moirans FRANCE
Phone : (+33)-4-76-57-41-00
Fax :(+33)-4-76-57-40-48

Contact your local representative for additional information.

9. APPENDIX A: PIXIUM DETECTOR IDENTIFICATION LABELS

9.1. DEFINITION OF SYMBOLS

Symbol	Signification
	Caution, consult accompanying documents
	Consult accompanying documents
	Direct current
	RF equipment
	Applied part
	Maximum allowed weight
	Degree of protection provided by enclosure
	Detector status
	Battery charge status
	Recycling label
	Manufacturer

Symbol	Signification
	Date of manufacture
SN	Serial number
REF	Catalog number

Table 15: Labels

9.2. LABELS

9.2.1. LABELS NON CE MARKED BY TRIXELL

The labels presented below are not contractual and done for information

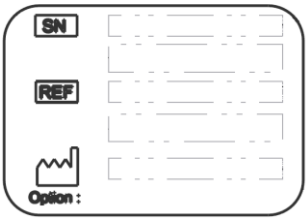


Figure 12: Identification label

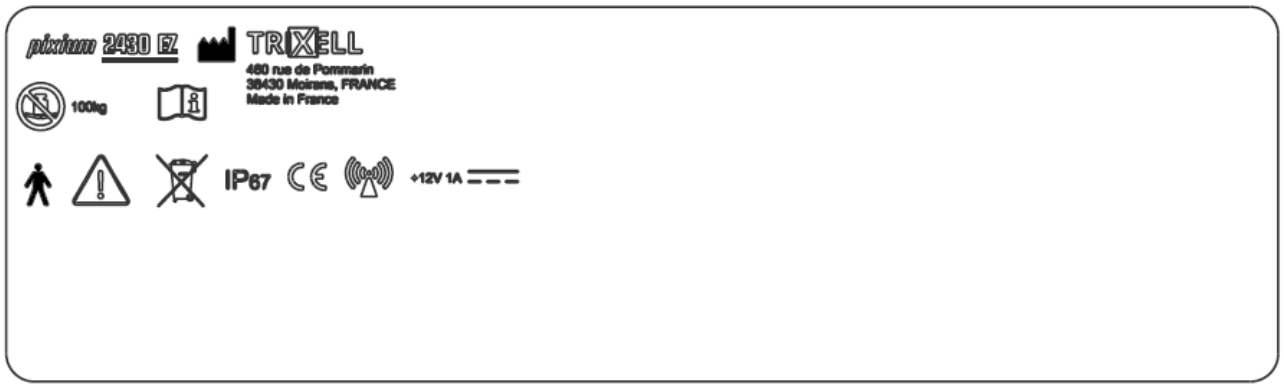


Figure 13: pixium 2430 EZ3 main label

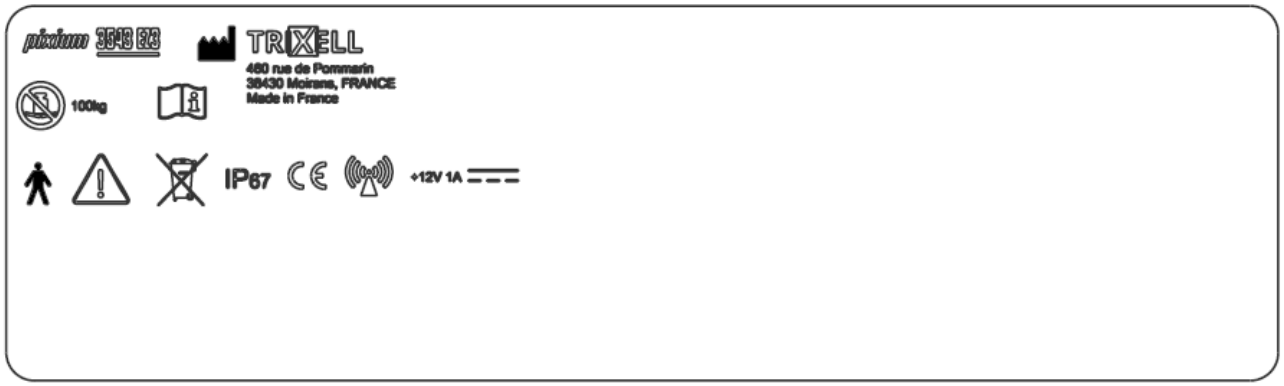


Figure 14: pixium 3543 EZ3 main label

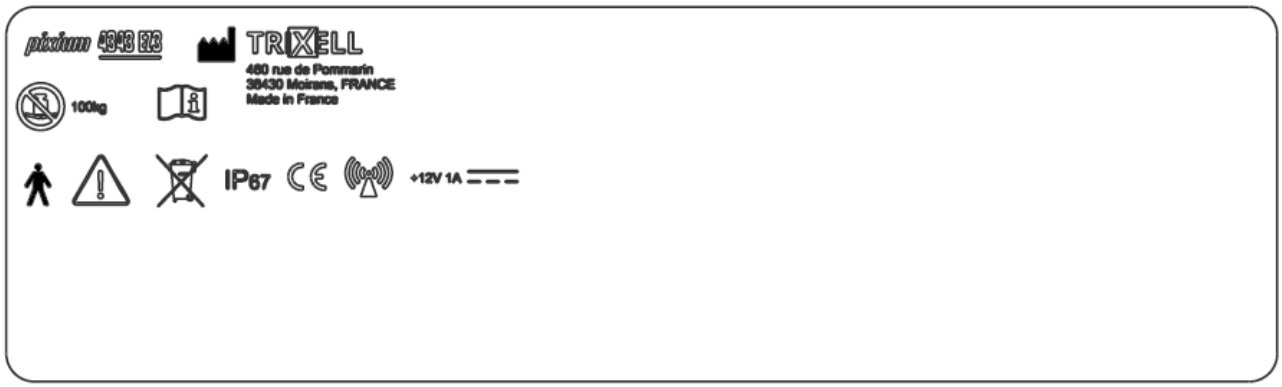


Figure 15: pixium 4343 EZ3 main label

Note that empty zone is reserved for RF certificate ID

10. APPENDIX B: PIXIUM DETECTOR SUMMARY SHEET

10.1. IMAGE GEOMETRY

Transmitted image size:

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-0740] PTS_transmitted_img_h	2430	Width:	-	-	2336	pel
	3543	Width:	-	-	3520	pel
	4343	Width:	-	-	4320	pel
[PTS-REQ-0750] PTS_transmitted_img_v	2430	Height:	-	-	2880	pel
	3543	Height:	-	-	4316	pel
	4343	Height:	-	-	4316	pel

Pitch size:

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-0760] PTS_pitch	-	Pitch:	-	98.75	-	µm

10.2. ELECTRO-OPTICAL PERFORMANCES

X-ray tube peak range:

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-1130] PTS_x_ray_range_kvp	-	The X-ray tube peak voltage range is:	40	-	150	kVp

Angle between the X-ray central propagation axis and the normal axis of the entrance plane:

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-1110] PTS_x_ray_angle	-	The angle between the X-ray central propagation axis and the normal axis of the front-end entrance plane - taken at the center point of the matrix - should remain within the following range:	-45	0	45	°

10.3. ELECTRICAL INTERFACE

Main ADC characteristics:

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-0810] PTS_quantization_depth	-	The quantization depth of the digitized image data signals is equal to (independently of possible modes):	-	16	-	bits

Input voltage on connector unit / CPT contacts:

Specification	Product	Description	Min	Value	Max	Unit
[EIS-REQ-0510] EIS_pwr_input_voltage_V	-	DC input power supply voltage shall be in the following range:	10.8	12	13.2	V

Input current on connector unit:

Specification	Product	Description	Min	Value	Max	Unit
[EIS-REQ-0040] EIS_pwr_input_current_A	-	Typical and maximum sustained current in mode 1, gain 4, image readout.	-	0.5	1	A
[EIS-REQ-0070] EIS_pwr_input_inrush_A	-	Maximum peak current (at power ON or during image acquisition) shall be lower than:	-	-	3.5	A

10.4. MECHANICAL INTERFACE

Information provided in Outline Drawing [OUT_DRW]

Specification	Product	Description	Min	Value	Max	Unit
[MIS-REQ-0250] MIS_thermal interface_resistance	-	The maximum thermal resistance (Rh) shall be:	-	-	0.7	°C/W

10.5. ENVIRONMENTAL CONDITIONS

10.5.1. TEMPERATURE

Storage temperature range:

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-1220] PTS_storage_packed_temperature	-	Ambient air temperature variation that can be withstood by the detector during storage & transport without any damage. Provision shall be taken to avoid any condensing inside the detector.	-10	-	55	°C

Functional and operational (IQ) temperature range:

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-1570] PTS_temperature_operational	-	The operational temperature range: is the ambient temperature range where the detector performances, reliability and image quality are guaranteed within the specifications. All the components shall respect their temperature specification in order to insure the reliability performance of the product. The accessible parts temperature limitations shall be respected.	10	25	35	°C
[PTS-REQ-1600] PTS_temperature_functional	-	The functional temperature range: is the ambient temperature range where the detector functionality is guaranteed but not the full image quality. All the components shall respect their temperature specification.	35	-	40	°C

10.5.2. AIR PRESSURE

Air pressure range on packed detector:

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-1260] PTS_storage_packed_pressure	-	The detector can be stored and transported under following pressure conditions:	500	-	1100	mbar

Air pressure range for opertional performances (IQ):

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-1640] PTS_pressure_range_operational	-	The functional and performance operating conditions for air pressure are:	700	1000	1100	mbar
[PTS-REQ-1650] PTS_dist_calib_pressure	-	The reference restrictions for distance to calibration conditions for air pressure are:	-50	-	+50	mbar

10.5.3. HUMIDITY

Humidity range when pixium detector is packed:

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-1240] PTS_storage_packed_humidity	-	The packed detector can be stored and transported without any damage in the following humidity range: (Provision shall be taken to avoid any condensing inside the detector.)	5	-	95	%HR

Operational and functional humidity range:

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-1620] PTS_humidity_range_operational	-	The functional and performance operating conditions for relative humidity (non condensing) for a temperature up to 40°C are:	20	-	80	%HR
[PTS-REQ-1620] PTS_humidity_range_operational	-	The functional and performance operating conditions for relative humidity (non condensing) for a temperature up to 35°C are:	20	-	90	%HR

10.5.4. VIBRATIONS AND SHOCKS

Vibrations and shock on unpacked detector:

Specification	Product	Description	Min	Value	Max	Unit
[PTS-REQ-1280] PTS_storage_unpacked_shocks	-	In the **unpacked** case, the parameters of the test are:	-	-	10	g
[PTS-REQ-1320] PTS_storage_unpacked_vibrations	-	In the **unpacked** case, the parameters of the test are:	-	2	-	g

11. APPENDIX D: STANDARDS

It is important to refer to the relevant checklist to analyze the answer made by TRIXELL to the various clauses of the standards.

11.1. IEC 60601-1 ED 3.2 / ANSI AAMI 60601-1 / CAN/CSA C22.2 N°60601-1 STANDARDS

The detector is compliant with following standards. However, some items are considered as not applicable to this detector and are listed hereafter for clarification purpose.

The compliance of the system requires checking some clauses at system level. These clauses are noted: "Compliance ensured by system manufacturer if compliance is demanded at system level".

Clause	Title	Compliance ensured by
4 to 17, except points below	-	TRIXELL
4.3	Essential performances	TRIXELL
4.6	Parts that contact the patient	System manufacturer: used of sterile plastic bag recommended by TRIXELL.
7.4.1	Main switch clearly identified	System manufacturer, if compliance is demanded at system level (no main switch on **pixium EZ3**)
7.8.1	Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	System manufacturer, if compliance is demanded at system level.
7.8.2	Color red used only for push-button by which a function is interrupted in case of emergency	System manufacturer, if compliance is demanded at system level.
7.9.3.2	Replacement of fuses, POWER SUPPLY CORDS and other part	System manufacturer, shall limit the output power of the power supply to 15W maximum.
8.5	Separation of parts	System manufacturer, if compliance is demanded at system level.
8.8	Dielectric strength / Insulation	System manufacturer: schematic insulation diagram recommended by TRIXELL (see §2.2.3).
8.11.2	Power cord mains plug is "Hospital Grade" type / MULTIPLE SOCKET-OUTLETS	System manufacturer, if compliance is demanded at system level.

Clause	Title	Compliance ensured by
9.4.2.2	Equipment does not overbalance during normal use when tilted through an angle of 10° / Instability excluding transport	TRIXELL
15.3.5	Rough handling test	System manufacturer, if compliance is demanded at system level.
16	ME systems	System manufacturer, if compliance is demanded at system level.

Table 16: IEC 60601-1 guideline

ATRICLE 14.13 : TRIXELL SHALL instruct the RESPONSIBLE ORGANIZATION that:

- Connection of the PEMS to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties;
- Subsequent changes to the NETWORK/DATA COUPLING could introduce new RISKS and require additional analysis;
- Changes to the NETWORK/DATA COUPLING include:
  - changes in NETWORK/DATA COUPLING configuration;
  - connection of additional items to the NETWORK/DATA COUPLING;
  - disconnecting items from the NETWORK/DATA COUPLING;
  - update of equipment connected to the NETWORK/DATA COUPLING;
  - upgrade of equipment connected to the NETWORK/DATA COUPLING.

11.2. IEC 60601-1-2 STANDARD

pixium EZ3 is conform with IEC 60601-1-2 edition 4.1 standards.

11.2.1. PERFORMANCES

The essential performances of the **pixium EZ3** with regard to EMC are:

- Software robustness
- Robustness of the communication link with system
- No image lost
- No artifact on the image which can be misinterpreted

If essential performances are not reached due to electromagnetic disturbances, it might occur:

- Image lost
- Poor image quality

11.2.2. ELECTROMAGNETIC EMISSIONS

pixium EZ3 is intended to be used in both domestic and professional healthcare facility environment (see IEC 60601-1-11 for definition). The customer or the user of the **pixium EZ3** should assure that it is used in the corresponding electromagnetic environment specified below.

Emission test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	**pixium EZ3** uses RF energy for data transmission. Therefore, its RF emissions can cause interferences in nearby electronic equipment.
RF emissions CISPR 11	Class B	**pixium EZ3** is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	**pixium EZ3** is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	**pixium EZ3** is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Table 17: EMC emissions guideline

11.2.3. ELECTROMAGNETIC IMMUNITY

pixium EZ3 is intended to be used in both domestic and professional healthcare facility environment (see IEC 60601-1-11 for definition). The customer or the user of the **pixium EZ3** should assure that it is used in the corresponding electromagnetic environment specified below.

Immunity test	IEC 60601-1-2 ed 4.1 test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30 %.
Radiated RF IEC 61000-4-3 (continue)	10 V/m 80 MHz to 2.7 GHz modulation 80%AM / 1kHz _____	10 V/m 80 MHz to 2.7 GHz modulation 80%AM / 1kHz with reduced specification: Correlated line noise <40%un _____	Interference may occur in the vicinity of equipment marked with the following symbol:  All RF communication devices (mobile phone, walkie talkie, phone DECT ...) should be located outside the patient environment (1,5m).

Immunity test	IEC 60601-1-2 ed 4.1 test level	Compliance level	Electromagnetic environment - Guidance
	Spot frequencies in accordance with IEC 60601-1-2 table 9	Spot frequencies in accordance with IEC 60601-1-2 table 9 with reduced specification: Correlated line noise <40%un	Recommended separation distance: $d = \frac{6}{E} \times \sqrt{P}$ * d is the distance between the EUT and the generator of disturbances in m * E is the immunity test level in V/m * P is the maximum radiated power in W
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical domestic or hospital environment.
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	N/A : See risk assessment TRI6_15_0586	Mains power quality should be that of a typical domestic or hospital environment.
Conducted RF IEC 61000-4-6	3 V_{RMS} 150 kHz to 80 MHz modulation 80%AM / 1kHz ——————— Additional ISM frequencies in accordance with IEC 60601-1-2 table 6 note j) and table 8 note i).	3 V_{RMS} 150 kHz to 80 MHz modulation 80%AM / 1kHz ——————— Additional ISM frequencies in accordance with IEC 60601-1-2 table 6 note j) and table 8 note i).	Frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic or hospital environment. Interference may occur in the vicinity of equipment marked with the following symbol: 
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m at 50 Hz and 60 Hz	30 A/m @ 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic or hospital environment.

Immunity test	IEC 60601-1-2 ed 4.1 test level	Compliance level	Electromagnetic environment - Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5% U_T (> 95 % dip in U_T) for 5 sec NOTE: U_T is the a.c. mains voltage prior to application of the test level	Not applicable because only DC voltage. Additionally, the detector automatically switches to battery when DC voltage disappears.	Mains power quality should that of a typical domestic or hospital environment. If the user of pixium detector requires continued operation during power mains interruptions, it is recommended that pixium detector be powered from an uninterruptible power supply or battery.
Proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz IEC 61000-4-39	8 A/m @ 30 kHz: Carrier wave 65 A/m @ 134.2 kHz: Pulse modulation 2;1kHz 7,5 A/m @ 13,56 MHz: Pulse modulation 50 Hz	8 A/m @ 30 kHz: Carrier wave 65 A/m @ 134.2 kHz : Pulse modulation 2;1kHz 7,5 A/m @ 13,56 MHz : Pulse modulation 50 Hz	Recommended separation distance to get full image quality is 130 cm

Table 18: EMC immunity guideline

NOTE 1: These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 2: It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.

NOTE 3: Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radiobroadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If abnormal performance is observed, additional measures may be necessary, such as relocating pixium EZ3 or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: 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 pixium EZ3, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”

The pixium 2430 EZ3, pixium 3543 EZ3, pixium 4343 EZ3 were tested according to the recommendations of IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

11.3. IEC 60601-1-3 STANDARD

Clause	Title	Compliance ensured by
4	General requirements	System manufacturer, if compliance is demanded at system level.
5	ME equipment identification, marking and documents	System manufacturer, if compliance is demanded at system level.
5.1	Marking on the outside of the equipment or parts of equipment	-
5.1.1	General	TRIXELL
5.1.2	Marking requirements in subclauses	System manufacturer, if compliance is demanded at system level.
5.2	Accompanying documents	-
5.2.1	References in subclauses	System manufacturer, if compliance is demanded at system level.
5.2.2	Dosimetric calibration	System manufacturer, if compliance is demanded at system level.
5.2.3	General requirements for the reference of subassemblies and accessories	TRIXELL
5.2.4	Instructions for use	System manufacturer, if compliance is demanded at system level.
6	Radiation management	System manufacturer, if compliance is demanded at system level.
7	Radiation quality	System manufacturer, if compliance is demanded at system level.
8	Limitation of the extent of the X-Ray beam and relationship between X-Ray Field and image reception area	System manufacturer, if compliance is demanded at system level.
9	Focal spot to skin distance	System manufacturer, if compliance is demanded at system level.
10	Attenuation of the X-ray beam between the patient and the X-Ray image receptor	Not applicable
11	Protection against stray radiation	Detector does not contains any part of the primary protective shielding: Protection against stray radiation

Clause	Title	Compliance ensured by
		must be ensured by appropriate means defined by system manufacturer.
12	Protection against stray radiation	Not applicable
13	Protection against stray radiation	System manufacturer, if compliance is demanded at system level.

Table 19: IEC 60601-1-3 guideline

11.4. IEC 60601-2-54 STANDARD

Clause	Title	Compliance ensured by
203.10	X-ray equipment specified for radiography	Aluminium attenuation equivalent for X-ray entrance window of pixium EZ3 is 225 µm. This corresponds to "*Total of all layers composing the front panel of cassette holder*" of the standard and must be lower than 1.2 mm.

Table 20: IEC 60601-2-54 guideline

11.5. IEC 60825-1 STANDARD

Laser classification: pixium EZ3 is classified as Class I equipment, and includes:

Clause	Title	Compliance ensured by
4	a Class I laser product with invisible LED radiation (IrDA link)	System manufacturer, if compliance is demanded at system level.

Table 21: IEC 60825-1 guideline

11.6. ISO 10993 STANDARD

pixium EZ3 complies with ISO 10993-1. The sensitive side is suitable to be in contact with skin, mucosal membrane and breached or compromised surface for a limited period (< 24 hours).

11.7. 2017/745/EEC REGULATION

Annex	Title	Compliance ensured by
Annex I	General safety and performance requirements	TRIXELL
Annex XV	Clinical investigations	Compliance with the essential requirements is not based on the clinical data. The clinical investigations are applicable at the complete medical device, and are under responsibility of the system manufacturer.

Table 22: 217/745/EEC regulation guideline

11.8. FDA CFR21 §I - PART 1020

Clause	Title	Compliance ensured by
1020	Performance standards for ionizing radiation emitting products	
1020.10	Television receivers	Not applicable
1020.20	Cold-cathode gas discharge	Not applicable
1020.30	Diagnostic X-ray systems and their major components	
	a) Applicability	TRIXELL
	b) Definitions	TRIXELL
	c) Manufacturer's responsibility	System manufacturer, if compliance is demanded at system level.
	d) Assembler's responsibility	System manufacturer, if compliance is demanded at system level.
	e) Identification of X-ray components	System manufacturer, if compliance is demanded at system level.
	f) [Reserved]	-
	g) Information to be provided to assemblers	This document
	h) Information to be provided to users	Defined by system manufacturer
	i) [Reserved]	-
	j) Warning label	System manufacturer, if compliance is demanded at system level.
	k) Leakage radiation from the diagnostic source assembly	System manufacturer, if compliance is demanded at system level.
	l) Radiation from components other than the diagnostic source assembly	Not applicable
	m) Beam quality	System manufacturer, if compliance is demanded at system level.
	n) Aluminum equivalent of material between patient and image receptor	Not applicable

Clause	Title	Compliance ensured by
	o) Battery charge indicator	TRIXELL
	p) [Reserved]	-
	q) Modification of certified diagnostic X-ray components and systems	System manufacturer, if compliance is demanded at system level.
1020.31	Radiographic equipment	System manufacturer, if compliance is demanded at system level.
1020.32	Fluoroscopic equipment	Not applicable
1020.33	Computed tomography (CT) equipment	Not applicable
1020.40	Cabinet X-ray system	Not applicable

Table 23: FDA guideline

11.9. RF CERTIFICATES

It is the responsibility to system integrator and/or hospital maintenance staff to properly configure the embedded WiFi module with respect to the country where **pixium EZ3** detector is installed.

Note that the WiFi functionalities can only be used in the countries listed hereafter. For other countries, **pixium EZ3** family detectors must be used in wired configuration and the WiFi modules switched off.

11.9.1. RED DIRECTIVE (EUROPE)

CE

pixium EZ3 is certified to be used in the following European countries:

Country (country code according to ISO 3166)					
Andorra (AD)	Austria (AT)	Bosnia and Herzegovina (BA)	Belgium (BE)	Bulgaria (BG)	Croatia (HR)
Cyprus (CY)	Czech Republic (CZ)	Denmark (DK)	Estonia (EE)	France (FR)	Finland (FI)
Germany (DE)	Greece (GR)	Hungary (HU)	Iceland (IS)	Ireland (IE)	Italy (IT)
Latvia (LV)	Liechtenstein (LI)	Lithuania (LT)	Luxembourg (LU)	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)	The former Yugoslav Republic of Macedonia (MK)	Vatican city state (VA)	-	-	-

Table 24: European countries

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.

English:

Hereby, *TRIXELL*, declares that the **pixium EZ3** is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/UE.

Finnish:

TRIXELL vakuuttaa täten että **pixium EZ3** tyyppinen laite on direktiivin 2014/53/UE oleellisten vaatimusten ja sitä koskevien direktiivin muiden ehtojen mukainen.

Dutch:

Hierbij verklaart *TRIXELL* dat het toestel **pixium EZ3** in overeenstemming is met de essentiële eisen en de andere relevante bepalingen van richtlijn 2014/53/UE.

Bij deze verklaart *TRIXELL* dat deze **pixium EZ3** voldoet aan de essentiële eisen en aan de overige relevante bepalingen van Richtlijn 2014/53/UE.

French:

Par la présente, *TRIXELL* déclare que le **pixium EZ3** est conformes aux exigences essentielles et aux autres dispositions de la directive 2014/53/UE qui lui sont applicables.

Swedish:

Härmed intygar *TRIXELL* att denna **pixium EZ3** står I överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 2014/53/UE.

Danish:

Undertegnede *TRIXELL* erklærer herved, at følgende udstyr **pixium EZ3** overholder de væsentlige krav og øvrige relevante krav i direktiv 2014/53/UE

German:

Hiermit erklärt *TRIXELL*, dass sich **pixium EZ3** in Übereinstimmung mit den grundlegenden Anforderungen und den anderen relevanten Vorschriften der Richtlinie 2014/53/UE befindet". (BMWi).

Hiermit erklärt *TRIXELL* die Übereinstimmung des Gerätes **pixium EZ3** mit den grundlegenden Anforderungen und den anderen relevanten Festlegungen der Richtlinie 2014/53/UE. (Wien).

Greek:

ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ *TRIXELL* ΔΗΛΩΝΕΙ ΟΤΙ **pixium EZ3** ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 2014/53/UE.

Italian:

Con la presente *TRIXELL* dichiara che questo **pixium EZ3** è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti stabilite dalla direttiva 2014/53/UE.

Spanish:

Por medio de la presente *TRIXELL* declara que los **pixium EZ3** cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 2014/53/UE.

Portuguese:

TRIXELL declara que este **pixium EZ3** está conforme com os requisitos essenciais e outras disposições da Directiva 2014/53/UE.

EU type examination certificate: RED_771

11.9.2. 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 instructions, 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 the interference by one 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.

Radiation Exposure Statement:

This transmitter 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 transmitter must only be used with Taoglas' antennas reference FXP831.07.0100C.

FCC ID: VPQ-EZ3NFC
contains FCC ID : VPQ-WNFB265AXIBT

11.9.3. IC (CANADA)

ACCORDING TO MAIL HARDY: Le manuel de l'utilisateur final doit inclure la déclaration de conformité à la FCC Part 15 / ISED RSS GEN relative à l'émetteur comme indiqué dans ce manuel.

Le fabricant de l'appareil est responsable de la conformité de l'appareil, du module qui y est intégré ainsi que de toute autres exigences relatives au système telles mentionnées dans la section Part 15 B, ICES 003.

Il est fortement recommandé au fabricant de l'appareil dans lequel est intégré le module, de confirmer la conformité de l'émetteur avec la FCC/ISED lorsque le module est installé dans l'appareil. A cet effet une étiquette libellée "Contient FCC ID: VPQ-WNFB265AXIBT", "Contient IC : 7392A-NFB265AXIBT" devra être apposée de manière visible sur l'extérieur de l'appareil hôte.

Les instructions limitant les conditions d'utilisation par des professionnels doivent également être mentionnées par extension et en référence au manuel d'instruction du fabricant du système hôte.

Si le produit final implique des conditions de transmissions simultanées ou différentes conditions de fonctionnement pour un module unique, alors le fabricant du système hôte devra consulter le fabricant du module pour l'installation dans le produit final.

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 interference, and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Radiation Exposure Statement:

This device complies with ISED radiation exposure limits set forth for general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

Déclaration d'exposition aux radiations:

Le présent appareil est conforme aux niveaux limites d'exigences d'exposition RF aux personnes définies par ISDE. L'appareil ne doit pas être installé à proximité ou être utilisé en conjonction avec une autre antenne ou un autre émetteur.

- CAUTION -

The device for operation in the band 5150–5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems.

- AVERTISSEMENT -

Le dispositif fonctionnant dans la bande 5150-5250 MHz est réservé uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux.

IC: 7392A-EZ3NFC
contains IC: 7392A-NFB265AXIBT

11.9.4. HONG-KONG

There is no specific RF certificate for **pixium EZ3** since it is already certified for Europe and United States

11.9.5. CMIIT (CHINA)

1. 符合“微功率短距离无线电发射设备目录和技术要求”的具体条款和使用场景，采用的天线类型和性能，控制、调整及开关等使用方法；
2. 不得擅自改变使用场景或使用条件、扩大发射频率范围、加大发射功率（包括额外加装射频功率放大器），不得擅自更改发射天线；
3. 不得对其他合法的无线电台（站）产生有害干扰，也不得提出免受有害干扰保护；
4. 应当承受辐射射频能量的工业、科学及医疗（ISM）应用设备的干扰或其他合法的无线电台（站）干扰；
5. 如对其他合法的无线电台（站）产生有害干扰时，应立即停止使用，并采取措施消除干扰后方可继续使用；
6. 在航空器内和依据法律法规、国家有关规定、标准划设的射电天文台、气象雷达站、卫星地球站（含测控、测距、接收、导航站）等军民用无线电台（站）、机场等的电磁环境保护区域内使用微功率设备，应当遵守电磁环境保护及相关行业主管部门的规定；
7. 禁止在以机场跑道中心点为圆心、半径5000米的区域内使用各类模型遥控器；
8. 微功率设备随整机工作，整机正常工作时运行温度为10℃至40℃，供电电压为12V。

CMIIT ID : TBD

11.9.6. OTHER COUNTRIES

For countries not listed here before, the system integrator must disable the RF functionalities (see appropriate command in document [SIS]). In such configuration, **pixium EZ3** is compliant with CISPR11 class B limits and can be considered as non-radio product.

In such countries, the end-users must not be allowed to activate the RF functionalities by their own.

12. APPENDIX E: RF COMMUNICATION

Since **pixium EZ3** can be used without any cable, it exchanges data (as commands, synchronization images…) thanks to radio frequency modules which are able to operate in the ranges 2.412GHz…2.484GHz, 5.180GHz…5.320GHz, 5.500GHz…5.700GHz and 5.725GHz…5.825GHz.

The availability of some specific channels and/or operational frequency bands are country dependent and are firmware programmed at the factory to match the intended destination. The firmware setting is not accessible by the end-user.

pixium EZ3 also contains a NFC module operating in 13.553 MHz ...13.657 MHz band.

12.1. RF FEATURES

- Operate at ISM frequency bands (2.4GHz and 5GHz)
- IEEE standards compatible: IEEE 802.11a, IEEE 802.11b, IEEE 802.11g, IEEE 802.11n; IEEE 802.11ac and IEEE 802.11ax
- WPA2-PSK/AES coding supported

12.2. RF SPECIFICATIONS

Functional specifications:

Standard	IEEE 802.11ax/ac/a/b/g/n (2T2R)
Operating frequency	2.400 GHz ~ 2.4835 GHz (2.4GHz ISM Band) 5.150 GHz ~5.850GHz (5GHz UNII Band)
Modulation techniques	802.11b: DSSS (DBPSK, DQPSK, CCK) 802.11g: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11n: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11a: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11ac: OFDM (BPSK, QPSK, 16-QAM, 64-QAM, 256-QAM) 802.11ax: OFDMA (BPSK, QPSK, 16-QAM, 64-QAM, 256-QAM, 1024-QAM)
Data Rate	802.11b: 11Mbps 802.11a/g: 54Mbps 802.11n: MCS0~15 802.11ac: MCS0~9 802.11ax: HE0~11
Network architecture	Infrastructure and Ad hoc modes
Transmission	MIMO 2x2

Table 25: RF specifications

12.3. EIRP

Measured EIRP (according to EN 300 328 v2.2.2 and EN 301 893 v2.1.1) are provided in [EUM].

END OF DOCUMENT