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	<b>63138470</b>	<b>108</b>	<b>-d2</b>	SIF-F-003 RevI

# **pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk Integration Manual and General Cautions**

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## DOCUMENT HISTORY

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Version	DOORS baseline	Date	Authorr	Description	DM
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## 1 GENERAL

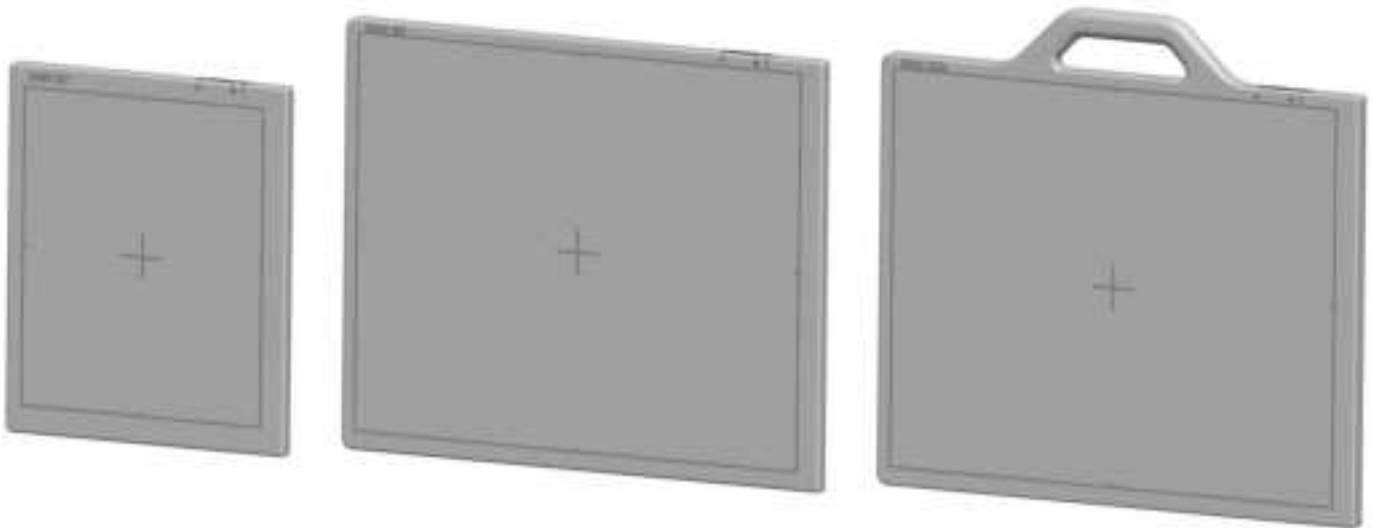
The pixium 3543 EZk (except option G###[BH]), pixium 3543 EZkh, pixium 2430 EZk (except option G###[BH]) are a part of a digital image acquisition chain in an overall Radiological System. It features a portable equipment designed for mobile applications or for retrofit of a CR system.

pixium 3543 EZk option G###[BH] and pixium 2430 EZk option G###[BH] are designed to be used in Non Destructive Test applications.

pixium 3543 EZk and pixium 2430 EZk comply with ISO 4090 standard for the external dimensions.

pixium 3543 EZkh is thicker and includes a handle for handiness improvements.

The detector consists of a complete carbon fibre housing. It integrates LEDs indicators for internal status, and connector for a dedicated cable. The backside (with respect to the active sensitive array) includes a removable battery.



Pixium 2430 EZk

Pixium 3543 EZk

Pixium 3543 EZkh

### Remarks:

- Detector pictures are for illustration purpose only.
- Two types of batteries are available (Battery EZ and Battery 2EZ). In the following, we use Battery applying for available batteries. Please refer to dedicated battery user manual for complementary information [BATT\_USR].
- Two charger devices are available (Charger EZ and Charger 2EZ). In the following, we use Charger Device applying for available chargers. Please refer to dedicated charger user manual for complementary information [CHRG\_USR].

## 1.1 GLOSSARY

The following glossary only concerns specific terms used by TRIXELL:

CPT:	Contact Power Transfer (for Px3543EZkh only)
DHCP:	Dynamic Host Configuration Protocol
EUM:	End User Manual
EUT:	equipment under tests
FE:	Front End
FTR:	Frame Transmission Request
IR:	Infra-Red
ISM:	Industry, Science, Medical
PE:	Protective Earth
RIA:	Request Image Acquisition
RIF:	Request Image Frame

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SFTP: Secured File Transfer Protocol  
SIS: Software Interface Specification  
UCF: User Configuration File

Option: X mean only one character (X in this example)  
# means any character from A to Z  
[AB] means one character of the list into the brackets (A or B in this example)

## 2 CAUTIONS AND SAFETY INFORMATION

### 2.1 SAFETY MEASURES FOR THE SYSTEM INTEGRATOR

#### - CAUTION -

**If pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.**

#### - CAUTION -

**Charger EZ 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.

#### 2.1.1 Conditions Of Acceptability from HARMS

COA ID	Mitigation measures for system integrator
[COA_HARMS_0002]	The system integrator is aware that pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk are 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]	<u>Px3543EZk with option C only</u> : The system integrator is aware the detector is equipped with Thallium doped CsI. System integrator shall provide adapted measures to deal with Thallium 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 attachment 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.

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COA ID	Mitigation measures for system integrator
[COA_HARMS_0023]	The system integrator will make sure the information provided in the [EUM] is available at end user level.

### 2.1.2 Conditions Of Acceptability from SHARMS

COA ID	Mitigation measures for the system integrator
[COA_SHARMS_0001]	In his own hazard analysis, system integrator shall address the risk « Detector not operational after reboot ».
[COA_SHARMS_0002]	In his own hazard analysis, system integrator shall address the risk « Software compatibility between detector and system».
[COA_SHARMS_0005]	For any communication, the final status is given either by the return or by a timeout given by SIS. Therefore, the system integrator shall be able to detect a communication failure. TRIXELL recommends to the system integrator to implement a timeout management.
[COA_SHARMS_0006]	The detector shall only be used in public privilege during intervention/radiology. Except if a specific use case is agreed between TRIXELL and a system integrator, specified in use case specification [UCS_pdt].
[COA_SHARMS_0010]	To system integrator: To prevent overhear, TRIXELL recommends to the system integrator to manage internal temperature in order to prevent overhear, by internal info (temperature) SIS command or by a validated mean.
[COA_SHARMS_0011]	Here the point is how to ensure that the system really monitor the temperature to guarantee the image quality? To System Integrator: To monitor temperature, TRIXELL provides two means : - II command info temperature - Internal temperature inside header
[COA_SHARMS_0018]	The system integrator is responsible for image management (Patient ID, picture ID, posture) TRIXELL provides a dedicated function to identify each stored image.
[COA_SHARMS_0019]	System integrator is responsible for adequate IP management on imaging network.
[COA_SHARMS_0020]	In case of frame transmission request (FTR) timeout, the system shall first retry a FTR, before issuing a reboot. The best practice is, first, to plug the cable and then retry a FTR.
[COA_SHARMS_0021]	System integrator is responsible for adequate network quality management on imaging network.
[COA_SHARMS_0022]	As reasonable usage, the system integrator shall not modify the battery level.
[COA_SHARMS_0023]	As reasonable usage, the system integrator shall implement a timeout between RIA and RIF to prevent the "meanwhile battery discharge".
[COA_SHARMS_0024]	The system integrator is responsible for network security.
[COA_SHARMS_0026]	TRIXELL recommends to System integrator to pay attention to battery handling i.e. switch off the detector before removing the battery or else the cable must be previously plugged.
[COA_SHARMS_0027]	TRIXELL recommends to activate IR systematically inside UCF and verify systematically that previously IR devices are perfectly working.
[COA_SHARMS_0028]	TRIXELL recommends the System integrator to handle inside its own HARMS the DHCP piracy risk.

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COA ID	Mitigation measures for the system integrator
[COA_SHARMS_0029]	When image storage is activated, in order to avoid embedded-image confusion, TRIXELL recommends forbidding any user to change the image name. The storage memory space shall be a reference space (not a workspace). TRIXELL provides a dedicated function to identify each stored image.
[COA_SHARMS_0031]	Simultaneous access to memory (by SIS and SFTP) shall be forbidden by system integrator interface in case of multi user
[COA_SHARMS_0032]	System integrator shall be aware that in autonomous mode images can be triggered accidentally 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_SHARMS_0034]	System integrator is responsible for RFC 5735 application, else the detector will not be operational inside a network.
[COA_SHARMS_0036]	Wi-Fi is extremely complex to master. During the system integration tests inside hospital facilities, TRIXELL recommends to add and customize some WiFi tests in the integration test plan updated following local practices.
[COA_SHARMS_0041]	TRIXELL recommends system integrator to manage the identification of patient for each image taken in autonomous mode.
[COA_SHARMS_0043]	Trixell recommends to system integrator to manage in its own hazard analysis how to minimize the risk linked to "having several images with artifact after a day tour".

## 2.2 MEDICAL

**Medical diagnostic radiology:** The final destination of pixium 3543 EZk, pixium 3543 EZkh and pixium 2430 EZk are 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 3543 EZk, pixium 3543 EZkh and pixium 2430 EZk have applied parts (there is direct contact between the patient and the detector, except when they are mounted in a bucky table or a wall-stand Radiological System..

**Biocompatibility:** pixium 3543 EZk, pixium 3543 EZkh and pixium 2430 EZk are designed to be safe in case of short-term contact with damaged skin (less than 24 hours). Nevertheless, in case of damaged skin, it is recommended to preferably wrap the detector with a sterile plastic bag".

pixium 3543 EZk, pixium 3543 EZkh and pixium 2430 EZk are not devices delivered in a sterile state.

## 2.3 X-RADIATION

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

pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk are not designed to control the emitted X-ray dose.

### - CAUTION -

**Whatever possibility is used, the X-ray window information only indicates to the System that the detector is ready to receive X-radiation. It is the System manufacturer responsibility to control the actual emission of X-Radiation.**

**System accompanying documents** must indicate:

- Procedure for X-ray alignment measurement (system maintenance manual)

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- Prohibition to order any radiation when a dysfunction is noticed by the operator, whatever this dysfunction (system user manual)

Tolerance, selection and bending of the system must be in accordance with detector field limitation requirements.

## 2.4 INSULATION DIAGRAM

pixium 3543 EZk, pixium 3543 EZkh, pixium 2430 EZk and ChargerEZ do not contain any PE.

**Safe design:** The system-earthing diagram must be in accordance with pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk Electrical Interface Specification (galvanic separation of electrical circuits). Any other appropriate system-earthing diagram taking into account internal insulation of pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk is acceptable. See [EIS]

## 2.5 ELECTRO-MAGNETIC COMPATIBILITY (EMC)

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

**Radio frequency (RF) communications:** Portable and mobile RF communications equipment can affect medical electrical equipment. Because detector contains RF device, system manufacturer must take care of interferences caused by the pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk.

Please refer to §2.6 RF COMMUNICATION

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

**AVERTISSEMENT :** *L'utilisation d'accessoires, de transducteurs et de câbles autres que ceux spécifiés peuvent parasiter ou dégrader la protection de l'équipement.*

**WARNING:** 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.

**AVERTISSEMENT :** *Le détecteur ne doit pas être utilisé posé ou adjacent à un autre équipement. Dans le cas contraire, son fonctionnement doit être contrôlé dans la configuration d'utilisation.*

### 2.5.1 CABLES AND CONNECTORS

The system integrator must take care of the kind of cables used to connect the backup cable of pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk to the system:

- When the powered 2-meter cable is used, power supply cable must be shielded. The shielding must be properly connected to the connector metallic body in order to insure a good electrical connection between earth and cable shielding.
- The Ethernet cable must be FTP or STP type, category 5 or above (5E or 6).

The connection to the pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk shall be ensured by Cable EZ (powered 2-meter, straight 2-meter or 7-meter) only. No other cable is allowed.

## 2.6 RF COMMUNICATION

Since pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk can be used without any cable, it exchanges data (as commands, synchronization images...) thanks to a radio frequency module which is 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.



**- CAUTION -**

**Avoid to place pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk too close to life-supporting devices (see §2.6.2).**

### 2.6.1 RF features

- Operate at ISM frequency bands (2.4GHz and 5GHz) with 260Mbps data rate
- IEEE standards compatible: IEEE 802.11a, IEEE 802.11b, IEEE 802.11g and IEEE 802.11n.
- WPA2-PSK/AES coding supported

### 2.6.2 RF specifications

Functional specifications:

Standard	IEEE 802.11a, IEEE 802.11b; IEEE 802.11g; IEEE 802.11n
Theoretical data rate	802.11a: 54 Mbps (OFDM) 802.11b: 11 Mbps (CCK) 802.11g: 54 Mbps (OFDM) 802.11n: 65 Mbps (OFDM) 802.11n: 260 Mbps (OFDM)
Modulation techniques	OFDM/CCK
Network architecture	Infrastructure mode

**Measured EIRP (according to ETSI EN 300 328 v 2.2.2 and ETSI EN 301 893 v2.1.1):**

Frequency band	EIRP
2.4 GHz	Lower than 12.28 dBm
5.18 ~ 5.24 GHz	Lower than 10.73 dBm
5.26 ~ 5.32 GHz	Lower than 10.85 dBm
5.50 ~ 5.70 GHz	Lower than 11.06 dBm

## 2.7 POWER SUPPLY

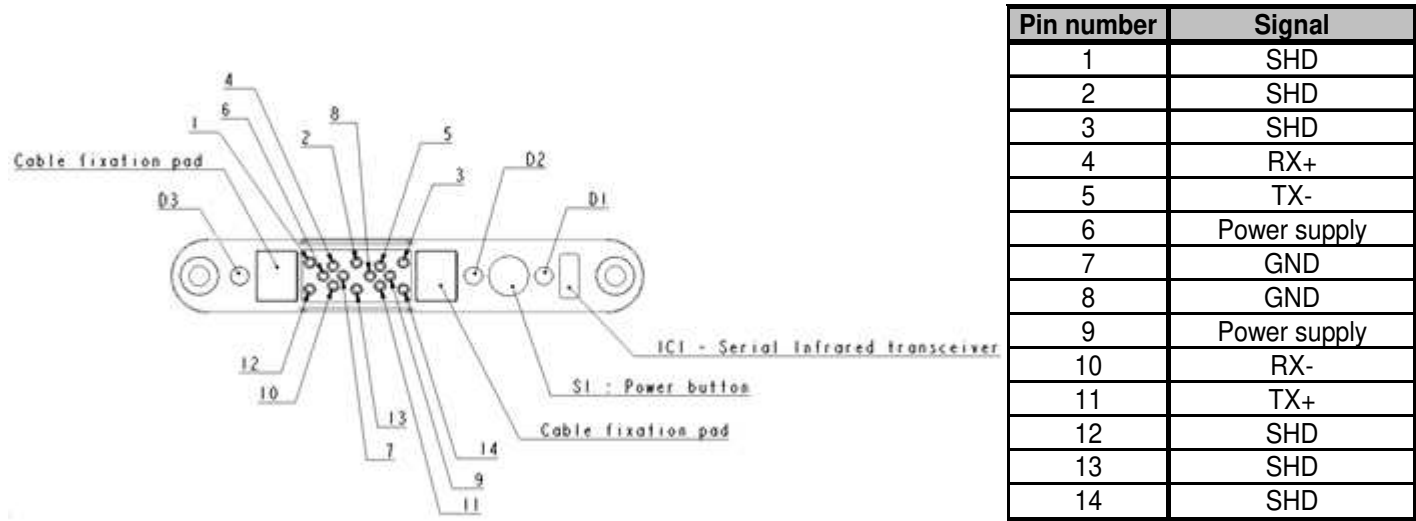
**Power supply when used with powered 2-meter cable or through CPT plate:** The power supply of pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk is not carried out by MAINS, but by Safety Extra Low Voltage source.

The ChargerEZ is powered by its own power supply unit provided by TRIXELL.

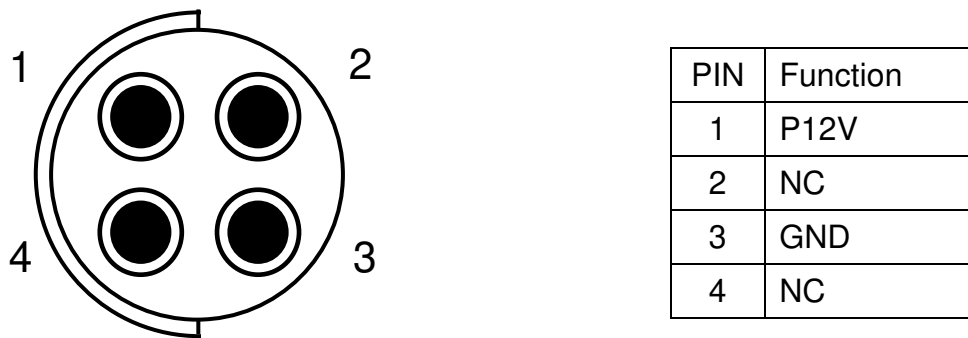
**- CAUTION -**

**Power supply polarity inversion or out of range power supply (including a missing power supply) may harm the detector and ChargerEZ. Be sure to correctly connect and clamp the power supply cable and the connector.**

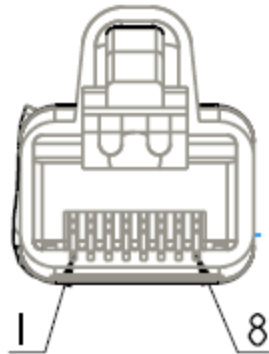
**Front End connector pin-out:** The pin-out of pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk is given here below:



**Cable power supply connector pin-out for powered 2-meter cable only:**

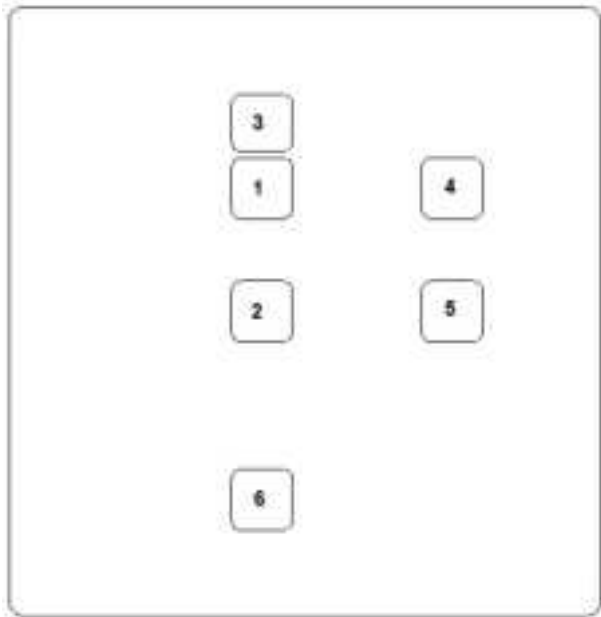


**Cable Ethernet connector pin-out:**



PIN	Function
1	TX +
2	TX -
3	RX +
4	no signal
5	no signal
6	RX -
7	no signal
8	no signal

**CPT plate pin-out for Px3543EZhk only:**



Pin #	Voltage	Description
1, 2	12V	12V power input.
3, 4, 5, 6	GND	12V power supply GND.

**ChargerEZ power supply connector pin-out:** The battery charger is directly powered by MAIN with standard plug regarding the country where the system is installed and should be provided by the system integrator.

## 2.8 MECHANICAL INSTALLATION

**Accessible parts:** ChargerEZ is considered as non-accessible part because it must not be placed in patient environment.

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**Applied parts:** Front side of pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk are considered as applied parts. Other sides are considered as accessible parts.

**Constraints:** pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk are qualified to be subjected to variations of accelerations defined in User Manual - environmental conditions section. The detector cannot be used with non-natural variations of pressure.

**Water tightness:** pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk alone are protected against ingress of water with a degree of protection of IP 67 according to IEC 60529 standard, whereas they are protected with their battery against ingress of water with a degree of protection of IP 43 according to IEC 60529 standard.

ChargerEZ is protected against ingress of water with a degree of protection of IP 40 according to IEC 60529 standard.

## 2.9 OPERATION

When detector is powered on, the system must check the result of the pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk 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 during free-cassette mode,
- 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.

## 2.10 OVERHEATING PROTECTION

The battery pack 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.

## 2.11 MAINTENANCE

System maintenance manual must indicate:

- Inspections during preventive maintenance,
- Periodic calibration of pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk,
- Periodic control of detector performance (image quality) (acceptance and constancy testing).

## 2.12 OTHERS

**Toxic substances:** pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk contain Thallium-doped Cesium Iodide scintillator material, and lead protection plates. TRIXELL ensures the recycling of the detector, so it must be returned to TRIXELL when recycling is needed.

**Hazard Analysis:** TRIXELL provides to its customers a specific Hazard Analysis / Risk Management Summary reference (62415347\_530) and a specific Software Hazard Analysis / Risk Management Summary reference (62733117\_530) linked to the use of the pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk and ChargerEZ. Nevertheless, TRIXELL recommends to work out a Hazard Analysis accounting the integration of the detector in the system, and to carry out the qualification tests corresponding.

**Backup cable:** The 2 meter cable is not designed to be mechanically abused. As consequence, the system integrator shall take care of the location of system connector in order to limit the risk to push (roll) a trolley over the cable, or walk over the cable;

### 3 STANDARDS

The detector is compliant with following standards. However, some items are considered as not applicable to pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk 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".*

#### 3.1 IEC60601-1 / UL60601-1 / CAN/CSA C22.2 STANDARDS

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
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.
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.

ARTICLE 14.13 : TRIXELL SHALL instruct the RESPONSIBLE ORGANIZATION that:

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- 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.

## 3.2 IEC/EN 60601-1-2 STANDARD

### - CAUTION -

**To be compliance with IEC / EN 60601-1-2 standard, pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk are delivered with additional ferrite (ref. 742 711 42 or ref. 742 711 11 from Würth Elektronik for powered 2-meter and straight 2-meter cables or ref. 742 711 31 from Würth Elektronik for 7-meter cable) that must be placed on the backup cable at maximum 10 cm from Front End connector.**

**Please note that conformity with IEC / EN 60601-1-2 cannot be guaranteed if the ferrite is not properly installed.**

### 3.2.1 Performance

The expected performances of pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk with regard to EMC are:

- Software robustness
- Robustness of the communication link with the system
- No image lost
- Artifacts on the image can occur but without any risk of wrong diagnostic.

### 3.2.2 Electromagnetic emissions

With respect to IEC 60601-1-2, pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk are intended to be used in both domestic and professional healthcare facility environment (see IEC 60601-1-11 for definition). The customer or the user should assure that they are used in such environment.

Test	Test and Compliance Level	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	pixium detector uses RF energy for data transmission. Therefore, its RF emissions can cause interferences in nearby electronic equipment.
RF emissions CISPR 11	Class B	pixium detector 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	System manufacturer, if compliance is demanded at system level.	pixium detector 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	System manufacturer, if compliance is demanded at system level.	pixium detector 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.

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### 3.2.3 Electromagnetic immunity

With respect to IEC 60601-1-2, pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk are designed to be used in domestic and professional healthcare environment. The customer or the user should assure that it is used in such environment.



#### **- CAUTION -**

**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 detector, including cables specified by the manufacturer. Otherwise, degradation of the performance of the pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk could result.**

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Test	Test and Compliance Level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD): IEC 61000-4-2	± 8 kV contact ± 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	10 V/m  80 MHz to 2.7 GHz modulation 80%AM / 1kHz  Spot frequencies in accordance with IEC 60601-1-2 table 9	Interference may occur in the vicinity of equipment marked with the following symbol:   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 (only ethernet cable)	Mains power quality should be that of a typical commercial or hospital environment.
Surge: IEC 61000-4-5	± 0,5 kV  ± 1 kV, ± 2 kV : Not applicable, see risk assesment TRI 6_15_0586	Mains power quality should be that of a typical commercial or hospital environment.
Conducted disturbances, induced by RF fields immunity: IEC 61000-4-6	3 V <sub>RMS</sub>  150 kHz to 80 MHz modulation 80%AM / 1kHz  6 V <sub>RMS</sub> , additional ISM and radio-amateur 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 commercial or hospital environment. Interference may occur in the vicinity of equipment marked with the following symbol:   Px3543EZhk only accepts 1V <sub>RMS</sub> of disturbance when powered through CPT plate
Power frequency (50/60 Hz) magnetic field: IEC 61000-4-8	30 A/m @ 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines: IEC 61000-4-11	< 5 % U <sub>T</sub> (> 95 % dip in U <sub>T</sub> ) for 0.5 cycle 40 % U <sub>T</sub> (60 % dip in U <sub>T</sub> ) for 5 cycles 70 % U <sub>T</sub> (30 % dip in U <sub>T</sub> ) for 25 cycles < 5% U <sub>T</sub> (> 95 % dip in U <sub>T</sub> ) for 5 sec  System manufacturer, if compliance is demanded at system level  NOTE: U <sub>T</sub> is the a.c. mains voltage prior to application of the test level	Mains power quality should that of a typical commercial 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.

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 is 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 the detector or using a shielded location with a higher RF shielding effectiveness and filter attenuation

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### 3.3 IEC60601-1-3 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 ME EQUIPMENT or ME EQUIPMENT parts	-
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 RESIDUAL RADIATION	Detector does not contains any part of the primary protective shielding: Protection against stray radiation must be ensured by appropriate means defined by system manufacturer.
12	Protection against LEAKAGE RADIATION	Not applicable
13	Protection against STRAY RADIATION	System manufacturer, if compliance is demanded at system level.

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### 3.4 IEC 60825-1 STANDARD

**Laser classification:** pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk do not include any laser product.

### 3.5 RF CERTIFICATES

It is the responsibility to system integrator and/or hospital maintenance staff to properly configure the embedded WiFi modules with respect to the country where pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk is installed.

Note that the WiFi functionalities can only be used in the countries listed hereafter. For other countries, pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk must be used in wired configuration and the WiFi modules switched off.

#### 3.5.1 RED directive (Europe)



pixium 3543 EZk, pixium 3543 EZkh, pixium 2430 EZk are certified to be used in the following European countries:

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)	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)	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.

#### English:

Hereby, **TRIXELL**, declares that the *pixium 2430 EZk*, *pixium 3543 EZk* and *pixium 3543 EZhk* is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

#### Finnish:

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TRIXELL vakuuttaa täten että *pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk* tyypinen laite on direktiivin 2014/53/EU oleellisten vaatimusten ja sitä koskevien direktiivin muiden ehtojen mukainen.

Dutch:

Hierbij verklaart *TRIXELL* dat het toestel *pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk* in overeenstemming is met de essentiële eisen en de andere relevante bepalingen van richtlijn 2014/53/EU.

Bij deze verklaart *TRIXELL* dat deze *pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk* voldoet aan de essentiële eisen en aan de overige relevante bepalingen van Richtlijn 2014/53/EU.

French:

Par la présente, *TRIXELL* déclare que le *pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk* est conforme aux exigences essentielles et aux autres dispositions de la directive 2014/53/EU qui lui sont applicables.

Swedish:

Härmed intygar *TRIXELL* att denna *pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk* står i överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 2014/53/EU.

Danish:

Undertegnede *TRIXELL* erklærer herved, at følgende udstyr *pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk* overholder de væsentlige krav og øvrige relevante krav i direktiv 2014/53/EU.

German:

Hiermit erklärt *TRIXELL*, dass sich *pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk* in Übereinstimmung mit den grundlegenden Anforderungen und den anderen relevanten Vorschriften der Richtlinie 2014/53/EU befindet". (BMW).

Hiermit erklärt *TRIXELL* die Übereinstimmung des Gerätes *pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk* mit den grundlegenden Anforderungen und den anderen relevanten Festlegungen der Richtlinie 2014/53/EU (Wien).

Greek:

ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ *TRIXELL* ΔΗΛΩΝΕΙ ΟΤΙ *pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk* ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 2014/53/EU.

Italian:

Con la presente *TRIXELL* dichiara che questo *pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk* è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti stabilite dalla direttiva 2014/53/EU.

Spanish:

Por medio de la presente *TRIXELL* declara que los *pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk* cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 2014/53/EU.

Portuguese:

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TRIXELL declara que este *pixium 2430 EZk*, *pixium 3543 EZk* and *pixium 3543 EZhk* está conforme com os requisitos essenciais e outras disposições da Directiva 2014/53/EU.

### 3.5.2 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.

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

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

- The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.
- The device has been tested and in compliance with SAR limits. This equipment should be installed and operated with a minimum distance of 5mm between the radiator and a human body.
- The device may not be co-located with any other transmitter

OEM's final product shall state that it "Contains FCC ID: XO2-SPB228D" on an external label and in the user manual.

### 3.5.3 IC (Canada)

This device complies with RSS-210 of the Industry Canada 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.

#### **Radiation Exposure Statement:**

The product comply with the Canada 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.

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

- 1) The transmitter module may not be co-located with any other transmitter or antenna.
- 2) Module approval valid only when the module is installed in the tested host or compatible series of host

As long as 2 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.

IC: 8713A-SPB228D

**3.5.4 Australia and New Zealand**

A specific logo is affixed on the labeling.



**3.5.5 WPC WING (India)**

RF certificate references are:

ETA certificate No.: **NER-ETA/200**

ETA certificate No.: **NER-ETA/199**

*For information:*

*TRIXELL has already applied for ETA, which mean Equipment Type Approval. And this ETA certificate is indeed for the Wireless approval from WPC only. This does not mean the customers / importers can use this document for importation.*

*The customers / importers still need to apply an import license to get the product pass the custom. Import License must state the quantity of import and applied by Dealer Possession License in India. Each importation must apply for this license.*

**3.5.6 Hong Kong**

There is no specific RF certificate for pixium 3543 EZk, pixium 3543 EZkh, pixium 2430 EZk detectors since they are already certified for Europe and United States.

**3.5.7 CMIIT (China)**

pixium 3543 EZk detector :

Certificate no: **CMIIT ID: 2013AJ7169**

pixium 3543 EZkh detector :

Certificate no: **CMIIT ID: 2013AJ7138**

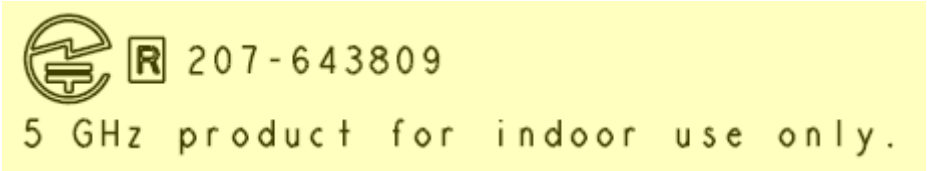
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pixium 2430 EZk detector :

Certificate no: **CMIIT ID: 2013AJ7137**

### 3.5.8 MIC (Japan)

No mandatory text required for Japan. Only label apposed on devices containing ID are required. Note that 5GHz band is not allowed to be used outdoor.



### 3.5.9 Channels vs. countries table

The following table summarizes which channels can be used in each certified country. The ISO 3166 country code is used.

Before reading this table, please refer to the important note at the beginning of the chapter '§3.5 RF CERTIFICATES'

Channels		1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	12, 13	36, 40, 44, 48	34, 38, 42, 46	52, 56, 60, 64	100, 104, 108, 112, 116, 120, 124, 128, 132, 136, 140	149, 153, 157, 161, 165
<b>Europe</b>								
Andorra	ad	•	•	•		• indoors	•	
Armenia	am	•	•	•		• indoors	•	
Austria	at	•	•	•		• indoors	•	
Azerbaijan	az	•	•	•		• indoors	•	
Belgium	be	•	•	•		• indoors	•	
Bosnia and Herzegovina	ba	•	•	•		• indoors	•	
Bulgaria	bg	•	•	•		• indoors	•	
Croatia	hr	•	•	•		• indoors	•	
Cyprus	cy	•	•	•		• indoors	•	
Czech Republic	cz	•	•	•		• indoors	•	
Denmark	dk	•	•	•		• indoors	•	
Estonia	ee	•	•	•		• indoors	•	
Finland	fi	•	•	•		• indoors	•	
France	fr	•	•	•		• indoors	•	
Germany	de	•	•	•		• indoors	•	
Greece	gr	•	•	•		• indoors	•	
Hungary	hu	•	•	•		• indoors	•	
Iceland	is	•	•	•		• indoors	•	
Ireland	ie	•	•	•		• indoors	•	
Italy	it	•	•	•		• indoors	•	
Latvia	lv	•	•	•		• indoors	•	
Liechtenstein	li	•	•	•		• indoors	•	
Lithuania	lt	•	•	•		• indoors	•	
Luxembourg	lu	•	•	•		• indoors	•	
Malta	mt	•	•	•		• indoors	•	
Monaco	mc	•	•	•		• indoors	•	
Montenegro	me	•	•	•		• indoors	•	
Netherlands	nl	•	•	•		• indoors	•	
Norway	no	•	•	•		• indoors	•	
Poland	pl	•	•	•		• indoors	•	
Portugal	pt	•	•	•		• indoors	•	
Romania	ro	•	•	•		• indoors	•	
Russia	ru	•	•	•		•	•	
San Marino	sm	•	•	•		• indoors	•	
Serbia	rs	•	•	•		• indoors	•	
Slovakia	sk	•	•	•		• indoors	•	

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Channels		1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	12, 13	36, 40, 44, 48	34, 38, 42, 46	52, 56, 60, 64	100, 104, 108, 112, 116, 120, 124, 128, 132, 136, 140	149, 153, 157, 161, 165
Slovenia	si	•	•	•		• indoors	•	
Spain	es	•	•	•		• indoors	•	
Sweden	se	•	•	•		• indoors	•	
Switzerland	ch	•	•	•		• indoors	•	
The former Yugoslav Republic of Macedonia	mk	•	•	•		• indoors	•	
United Kingdom	gb	•	•	•		• indoors	•	
Vatican city state	va	•	•	•		• indoors	•	
<b>America</b>								
Canada	ca	•		•		•	•	•
United States	us	•		•		•	• except 120, 124, 128	•
<b>Asia</b>								
China	cn	•	•	•	• except 34	•		•
Hong Kong	hk	•	•	•		•	•	•
<b>Oceania</b>								
<b>Africa</b>								

**- IMPORTANT REMARK -**

**In the here-above table, Cells in orange indicate channels which shall no longer be used because of local regulations. However, in case of after sale service exchange, these channels are still open for the replacement Pixium detector only if they were allowed at initial Pixium detector delivery.**

**For after sale service reasons, once opened, channels are still technically supported. Thus, it is the responsibility of system integrator to only use channels in coherence with this table for new Pixium detector deliveries.**

### 3.5.10 Other countries

For countries not listed here before, the system integrator must disable the RF functionalities (see appropriate command in SIS document). In such configuration, pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk are 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.

## 3.6 ISO 10993 STANDARD

pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk comply with ISO 10993-1. They are suitable to be in contact with skin, mucosal membrane and breached or compromised surface for a limited period (< 24 hours).

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### 3.7 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 assembler	This document
	h) Information to be provided to users	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 to pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk
	m) Beam quality	System manufacturer, if compliance is demanded at system level
	n) Aluminum equivalent of material between patient and image receptor	Not applicable
	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 systems	Not applicable

#### TRIXELL PROPRIETARY INFORMATION

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<b>TRIXELL</b>	FID / Référence SAP	CTD / Type document	Version	<b>26 / 26</b>
	<b>63138470</b>	<b>108</b>	<b>-d2</b>	SIF-F-003 RevI

## 4 DISPOSAL

### 4.1 BATTERY

The end user must be clearly informed that battery packs used in pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk contain hazardous substances for the environment and must take all preventive actions to manage the battery end of life (recycling plan).

### 4.2 FRONT END, BACKUP CABLE, BATTERY AND BATTERY CHARGER

TRIXELL is in charge of the recycling of pixium 2430 EZk, pixium 3543 EZk and pixium 3543 EZhk and their accessories (cable, battery pack and ChargerEZ).

TRIXELL's customers are in charge of managing the way to collect these products (at the end of their life) and either ship them to TRIXELL for recycling or recyle them by themselves.

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