

<b>TRIXELL</b>	FID / Document identification	CTD / Type	VS / Release	<b>1 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

**PIXIUM 3543 pR**  
**General caution and standard prescriptions**  
**applying to system integration**

This manual describes all caution and safety information for PIXIUM 3543 pR system integration. It also provides information to satisfy standards agreements of detector integrated into a system. It is intended for use by a system designer. Please read this manual carefully before performing, designing or qualifying a system installation.

***Document history***


<u>Version</u>	<u>Date</u>	<u>Author</u>	<u>Modification</u>
-	16/01/2008	O.CHASTEL	Création
Adraft1	24/01/08	O.CHASTEL	Add requirements from R&TTE. Add remark on water tightness. Update WiFi Indonesia and Taiwan logo
B			
C			

**CONFIDENTIEL TRIXELL**

*Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.*

**TRIXELL PROPRIETARY INFORMATION**

*Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.*

	FID / Document identification	CTD / Type	VS / Release	2 / 32
	61676632	108	Ad1	

## Table of contents


<b>1</b>	<b>GENERAL</b> .....	<b>3</b>
<b>2</b>	<b>CAUTION AND SAFETY INFORMATIONS</b> .....	<b>3</b>
2.1	MEDICAL.....	3
2.2	X-RADIATION.....	3
2.3	PROTECTIVE EARTH (PE) .....	4
2.4	ELECTRO MAGNETIC COMPATIBILITY (EMC) .....	8
2.4.1	<i>Cables and connectors</i> .....	8
2.5	RF COMMUNICATION.....	9
2.5.1	<i>RF features</i> .....	9
2.5.2	<i>RF specifications</i> .....	9
2.6	POWER SUPPLY .....	11
2.7	SAPM INSTALLATION .....	12
2.8	MECHANICAL INSTALLATION .....	12
2.9	OPERATION .....	14
2.10	OVERHEATING PROTECTION .....	14
2.11	MAINTENANCE .....	14
2.12	OTHERS .....	14
2.13	END USER INFORMATION.....	15
<b>3</b>	<b>STANDARDS</b> .....	<b>17</b>
3.1	IEC60601-1 / UL60601-1 / CAN/CSA C22.2 STANDARDS.....	17
3.2	IEC/EN 60601-1-2 STANDARD .....	18
3.2.1	<i>Performance</i> .....	18
3.2.2	<i>Electromagnetic emissions</i> .....	18
3.2.3	<i>Electromagnetic immunity</i> .....	19
3.3	IEC60601-1-3 STANDARD.....	21
3.4	IEC 60825-1 STANDARD.....	22
3.5	93-42-EEC STANDARD.....	22
3.6	R&TTE DIRECTIVE .....	22
3.7	FCC RULES .....	25
3.8	CANADA (IC) .....	27
3.9	NCC (TAIWAN).....	28
3.10	MIC (KOREA) .....	29
3.11	RUSSIA FAC (DOC) .....	29
3.12	ANATEL (BRAZIL) .....	29
3.13	MII-SRMC (CHINA) .....	30
3.14	DGPT (INDONESIA) .....	30
3.15	ISO 10993 STANDARD .....	30
3.16	FDA: CFR21 §I – PART 1020 .....	30
<b>4</b>	<b>DISPOSAL</b> .....	<b>32</b>
4.1	BATTERY.....	32
4.2	FRONT END, DOCKING STATION, BACKUP CABLE AND SAPM.....	32
4.3	GRID FRAME .....	32

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

	FID / Document identification	CTD / Type	VS / Release	3 / 32
	61676632	108	Ad1	

## 1 GENERAL

The PIXIUM 3543 pR is part of a digital image acquisition chain in an overall Radiological System. It includes a portable equipment (Front-End) designed for mobile applications.

The PIXIUM 3543 pR detector package is split into two devices: the “Detector Front-End” (PIXIUM FE 3543 pR or “FE” herewith) and the “Docking Station” (PIXIUM DS 3543 pR or “DS” herewith). The customer interface and the customer power supply are connected to the Docking Station. The communication between FE and DS (both for data and control) are managed through a WiFi link, or using an optional electric cable.

The PIXIUM FE 3543 pR is hand-held equipment.

## 2 CAUTION AND SAFETY INFORMATIONS

### 2.1 MEDICAL

**Medical diagnostic radiology:** The final destination of the PIXIUM 3543 pR is the medical diagnostic radiology. This one 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 pR Front-End 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 PIXIUM FE 3543 pR is design to be safe in case of short-term contact with damaged skin (less than 1 hour). Nevertheless, if such case occurs, the FE will be preferably wrapped with sterile plastic bag.

The detector is not a device delivered in a sterile state.

### 2.2 X-RADIATION

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

The PIXIUM 3543 pR is not designed to control the emitted X-ray dose.

#### CONFIDENTIEL TRIXELL

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

#### TRIXELL PROPRIETARY INFORMATION

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

<b>TRIXELL</b>	FID / Document identification	CTD / Type	VS / Release	<b>4 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

**!!! CAUTION !!!**

**Whatever possibility is used, the X-ray Enable signal 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.**

**!!! ATTENTION !!!**

*Quel que soit le mode d'utilisation, le signal X-Ray Enable indique seulement au système que le détecteur est prêt à recevoir le rayonnement X. Il est de la responsabilité du constructeur du système de contrôler l'émission de rayonnement X.*

**System accompanying documents** must indicate:

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

### 2.3 PROTECTIVE EARTH (PE)

PIXIUM 3543 pR participates in the earthing diagram of the Medical System. The detector is provided with a protective earth terminal (specified bolt) located on the DS and on SAPM devices. The FE does not contain any PE.

**Safe design:** The system-earthing diagram must be in accordance with PIXIUM 3543 pR Electrical Interface Specification (galvanic separation of electrical circuits).

**!!! CAUTION !!!**

**Connector and cable shields must not be used as protective earth connection. The specified bolt must not be used for any other purpose than protective earth connection. Removing this connection must need a service tool.**

**!!! ATTENTION !!!**

*Les connecteurs et les blindages des câbles ne doivent pas être utilisés pour la mise à la terre du détecteur. Le goujon spécifique doit être utilisé exclusivement pour la mise à la terre du détecteur. Le démontage de cette connexion doit nécessiter un outil.*

**System integration:** System Design must be in accordance with insulation design of detector given hereafter. Note that customers using their own battery-charging module (SAPM not

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

<b>TRIXELL</b>	FID / Document identification	CTD / Type	VS / Release	<b>5 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

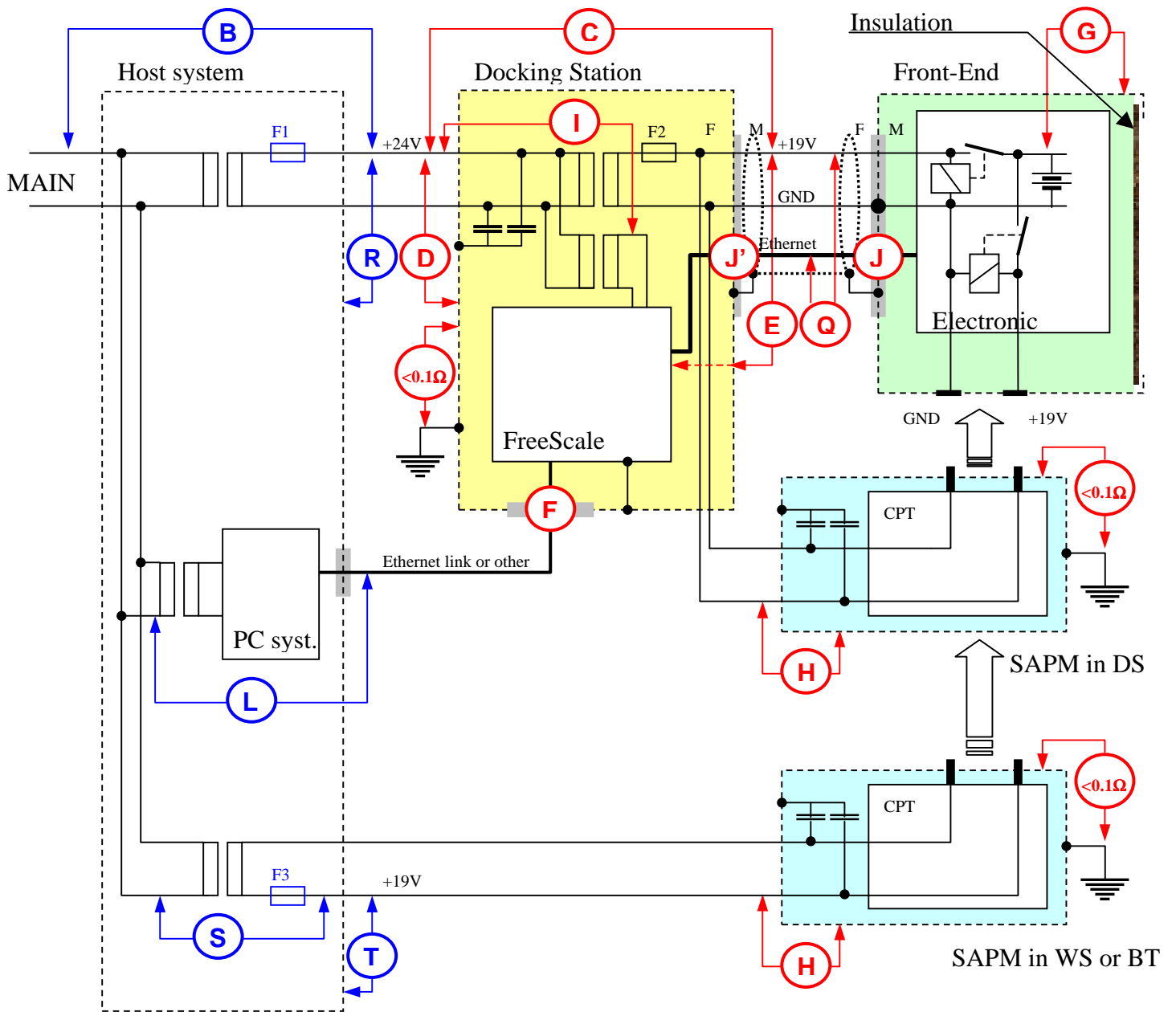
designed by TRIXELL), insulation diagram can slightly differ than this one accordingly to their requirements. Nevertheless, they remain responsible for the complete earthing diagram. The system manufacturer must take care of deported box or extension cable to stay compliant with this insulation diagram.

**CONFIDENTIEL TRIXELL**

*Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.*

**TRIXELL PROPRIETARY INFORMATION**

*Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.*



**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

Location	Dielectric strength (UL 20.1 only)	Insulation type	Reference voltage	Air clearance	Creepage distance	Test voltage	Comments
<b>B</b>	A-e	DI	230 V <sub>AC</sub>	5 mm	8 mm	4000V	Parasitic capacitance and leakage impedance between MAIN and 24V must guarantee a maximum leakage current of 10 μA <sub>DC</sub> and 100 μA <sub>AC</sub>
<b>C</b>	A-b	BI	24V <sub>DC</sub> +19V <sub>DC</sub>	1.2 mm	2.3 mm	500V	Leakage impedance between primary and secondary must guarantee a maximum leakage current of 10 μA <sub>DC</sub>
<b>D</b>	A-a <sub>1</sub>	BI	24 V <sub>DC</sub>	1 mm	2 mm	500V	
<b>E</b>	A-e	DI	19 V <sub>DC</sub>	2 mm	4 mm	500V	DI is also required between +19V and +5V layout on DS board
<b>F</b>	-	OP	-	-	-	NA	
<b>G</b>	-	OP	-	-	-	NA	
<b>H</b>	A-e	DI	19 V <sub>DC</sub>	2 mm	4 mm	500V	
<b>I</b>	A-b	BI	24V <sub>DC</sub> +5V <sub>DC</sub>	1 mm	2 mm	500V	Leakage impedance between primary and secondary must guarantee a maximum leakage current of 10 μA <sub>DC</sub>
<b>J</b>	-	OP	-	-	-	NA	
<b>J'</b>	A-c	DI	2.5 V <sub>DC</sub>	1.6 mm	3.4 mm	500V	
<b>L</b>	A-e	DI	230 V <sub>AC</sub>	5 mm	8 mm	4000V	
<b>Q</b>	A-c	DI	19 V <sub>DC</sub>	2 mm	4 mm	500V	
<b>R</b>	A-a <sub>1</sub>	BI	24 V <sub>DC</sub>	1 mm	2 mm	500V	
<b>S</b>	A-e	DI	230 V <sub>AC</sub>	5 mm	8 mm	4000V	
<b>T</b>	A-e	DI	19 V <sub>DC</sub>	2 mm	4 mm	500V	WARNING : T is Double Insulation

**Notes:**

1. On this diagram, only appear constraints on host system (written in blue)
2. F1 prevents DS against excessive temperatures in SFC.
3. F2 prevents FE and SAPM against excessive temperatures in SFC.
4. F3 prevents SAPM against excessive temperatures in SFC.
5. DS and SAPM are double isolated (either BI + earth or DI).

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

	FID / Document identification	CTD / Type	VS / Release	8 / 32
	61676632	108	Ad1	

6. SAPM's power supply is not isolated

F1: UL Fast fuse of 4A rated current, blowing or tripping after maximum 50s for 250% of rated current, BUT withstanding 250% of rated current during at least 0,5s.

F3: UL Fast fuse of 3A (TBC) rated current, blowing or tripping after maximum 50s for 250% of rated current, BUT withstanding 250% of rated current during at least 0,5s.

## 2.4 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 accompanying documents.

**Radio frequency (RF) communications:** Portable and mobile RF communications equipment can affect medical electrical equipment. Because both of the FE and the DS contain RF devices, system manufacturer must take care of interferences caused by the PIXIUM 3543 pR.

**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.*

### 2.4.1 Cables and connectors

The system integrator must take care of the kind of cables used to connect the Pixium DS 3543 pR to the system:

- Power supply cable must be shielded. The shielding must be properly connected to the DB15 connector metallic body in order to insure a good electrical connection between cable shielding and Pixium DS 3543 pR housing.
- The Ethernet cable must be FTP or STP type, category 5 or above (5E or 6).


#### CONFIDENTIEL TRIXELL

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

#### TRIXELL PROPRIETARY INFORMATION

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.



	FID / Document identification	CTD / Type	VS / Release	9 / 32
	61676632	108	Ad1	

## 2.5 RF COMMUNICATION

Since the FE 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 2.412 GHz...2.484 GHz; 5.150 GHz...5.250 GHz or 5.470 GHz...5.825 GHz.

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 the PIXIUM FE 3543 pR or the PIXIUM DS 3543 pR too close to life-supporting devices (see IEC60601-1-2 version 2001)**

### **!!! ATTENTION !!!**

***Eviter de placer le PIXIUM FE 3543 pR ou la PIXIUM DS 3543 pR trop près d'appareils de maintien de la(voir IEC60601-1-2 version 2001).***

### 2.5.1 RF features

- Operate at ISM frequency bands (2.4GHz and 5GHz) with 54Mbps data rate
- IEEE standards compatible : IEEE 802.11a, IEEE 802.11b and IEEE 802.11g
- WPA2 coding supported

### 2.5.2 RF specifications

#### Functional specifications

Standard	IEEE 802.11a; IEEE 802.11b; IEEE 802.11g
Data rate	802.11a: 9, 12, 18, 24, 36, 48, 54 Mbps 802.11b: 11, 5.5, 2, 1 Mbps;

#### **CONFIDENTIEL TRIXELL**

*Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.*

#### **TRIXELL PROPRIETARY INFORMATION**

*Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.*


	802.11g: 11, 5.5, 2, 1 (DSSS/CCK); 6, 9, 12, 18, 24, 36, 48, 54 Mbps (OFDM)	
Radio technology	802.11g: DSSS/CCK, OFDM	
Modulation techniques	OFDM/CCK	
Network architecture	Infrastructure mode (PIXIUM DS 3543 pR as Access Point)	
Operating channels	802.11a: 4: (channels 34-46) – N. America 4: (channels 34-46) – Japan 15: (channels 36-48 / 100-140) – Europe ETSI 5: (channels 149-165) – Taiwan 9: (channels 36-48 / 149-165) – Australia 5: (channels 149-165) – China 4: (channels 36-48) – Korea 15: (channels 36-48 / 100-140) – Russia 9: (channels 36-48 / 149-165) – Mexico  15: (channels 36-48 / 100-140) – Brazil	802.11b and 802.11g: 11: (channels 1-11) – N. America 14: (channels 1-14) – Japan 13: (channels 1-13) – Europe ETSI  11: (channels 1-11) – Taiwan 13: (channels 1-13) – Australia  13: (channels 1-13) – China 13: (channels 1-13) – Korea 13: (channels 1-13) – Russia  11: (channels 1-11) – Mexico  13: (channels 1-13) – Indonesia 13: (channels 1-13) – Brazil
Frequency range	802.11a: 5.150 ~ 5.250 GHz – N. America 5.150 ~ 5.250 GHz – Japan 5.150 ~ 5.250 GHz / 5.470 ~ 5.725 GHz – Europe ETSI 5.725 ~ 5.825 GHz – Taiwan 5.150 ~ 5.250 GHz / 5.725 ~ 5.825 GHz – Australia 5.725 ~ 5.825 GHz – China 5.150 ~ 5.250 GHz – Korea 5.150 ~ 5.250 GHz / 5.470 ~ 5.725 GHz – Russia 5.150 ~ 5.250 GHz / 5.725 ~ 5.825 GHz – Mexico  5.150 ~ 5.250 GHz / 5.470 ~ 5.725 GHz – Brazil	802.11b and 802.11g: 2.412 ~ 2.462 GHz – N. America 2.412 ~ 2.484 GHz – Japan 2.412 ~ 2.472 GHz – Europe ETSI  2.412 ~ 2.462 GHz – Taiwan 2.412 ~ 2.472 GHz – Australia  2.412 ~ 2.472 GHz – China 2.412 ~ 2.472 GHz – Korea 2.412 ~ 2.472 GHz – Russia  2.412 ~ 2.462 GHz – Mexico  2.412 ~ 2.472 GHz – Indonesia 2.412 ~ 2.472 GHz – Brazil
Transmit output power	802.11a: <ul style="list-style-type: none"> <li>+17.5 dBm @ 6, 9, 12, 18, 24Mbps</li> </ul>	802.11b: <ul style="list-style-type: none"> <li>+17 dBm @ 1, 2, 5.5, 11Mbps</li> </ul>

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

	FID / Document identification	CTD / Type	VS / Release	11 / 32
	61676632	108	Ad1	

	<ul style="list-style-type: none"> <li>+16 dBm @ 36Mbps</li> <li>+14.5 dBm @ 48Mbps</li> <li>+13 dBm @ 54Mbps</li> </ul>	802.11g: <ul style="list-style-type: none"> <li>+16.5 dBm @ 6, 9, 12, 18, 24Mbps</li> <li>+16 dBm @ 36Mbps</li> <li>+14.5 dBm @ 48Mbps</li> <li>+13.5 dBm @ 54Mbps</li> </ul>
Receiver sensitivity	802.11a: <ul style="list-style-type: none"> <li>-87 dBm @ 6Mbps</li> <li>-67 dBm @ 54Mbps</li> </ul>	802.11b: <ul style="list-style-type: none"> <li>-94 dBm @ 1Mbps</li> <li>-87 dBm @ 11Mbps</li> </ul> 802.11g: <ul style="list-style-type: none"> <li>-87 dBm @ 6Mbps</li> <li>-70 dBm @ 54Mbps</li> </ul>
Antenna type	PIXIUM DS 3543 pR: <ul style="list-style-type: none"> <li>Type: Patch antenna</li> <li>Number : 2</li> </ul>	PIXIUM FE 3543 pR <ul style="list-style-type: none"> <li>Type: 3D antenna</li> <li>Number: 2</li> </ul>
Security	WPA2 (can be disabled on request)	

## 2.6 POWER SUPPLY

**Power supply:** The power supply of the PIXIUM 3543 pR is not carried out by MAINS, but by Safety Extra Low Voltage source. The detector power supply must be used to power the detector only.

### !!! 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.**

### !!! ATTENTION !!!


*Une inversion de polarité ou une alimentation hors gamme peut endommager le détecteur. Vérifier le raccordement et la fixation des connecteurs.*

#### CONFIDENTIEL TRIXELL

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

#### TRIXELL PROPRIETARY INFORMATION

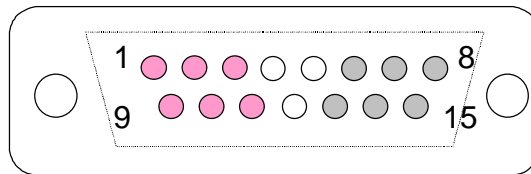
Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

	FID / Document identification	CTD / Type	VS / Release	12 / 32
	61676632	108	Ad1	

**System integration:** Power supply voltage must be checked continuously by the system.

**Power supply connector pin-out:** The power supply connector is located on the PIXIUM DS 3543 pR and the pin-out is given herebelow:

Pin #	Voltage	Description
1, 2, 3, 9, 10, 11	0 V	24V power supply GND. Isolated from other PixBox local GND, and from the connector shield.
6, 7, 8, 13, 14, 15	24 V	24V power output. The total current shall not exceed 4A.
4, 5, 12	NC	Reserved, do not connect.



The Docking Station power cable must be shielded for EMC purposes. The shield must be 360° connected on the Docking Station connector. The shield must be connected to mechanical ground on the Docking Station side. The connector type must be DB15 male connector.

## 2.7 SAPM INSTALLATION

In order to secure the tray opening of the SAPM, two switches are demanded to control the SAPM module. For more information about electrical connection, please refer to SAPM module user manual.

## 2.8 MECHANICAL INSTALLATION

**Accessible parts:** PIXIUM FE 5343 pR and PIXIUM DS 5343 pR devices (and the PIXIUM SAPM 5343 pR if used by the system manufacturer) are considered as accessible part. They do not need to be wrapped.

### CONFIDENTIEL TRIXELL

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

### TRIXELL PROPRIETARY INFORMATION

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

	FID / Document identification	CTD / Type	VS / Release	13 / 32
	61676632	108	Ad1	

**Constraints:** The detector is qualified to be subjected to variations of accelerations defined in User Manual - environmental conditions section. The detector can't be used with non-natural variations of pressure.

**Tightness:** The detector is an ordinary equipment without protection against ingress of water. Nevertheless, the PIXIUM FE 3543pR is specified IPX1 regarding the functionality and image performance. However, any liquid flowing on the FE can be stuck behind the rim and TRIXELL take no responsibility for any biological contamination risk.

**Battery charging-module:** A special care must be taken with the battery charging-module. The system manufacturer must guarantee that no voltage appears on the pins when the FE is not properly installed or the tray opened.

**CONFIDENTIEL TRIXELL**

*Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.*

**TRIXELL PROPRIETARY INFORMATION**

*Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.*

	FID / Document identification	CTD / Type	VS / Release	14 / 32
	61676632	108	Ad1	

## 2.9 OPERATION

**When detector is powered**, the system must check the result of the Pixium 3543 pR internal self-tests.

**During operation**, Trixell recommends the system to check continuously:

- the header of every image sent by the detector,
- all internal voltages of the detector.
- if possible, the internal temperature

## 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:

- Inspection of the detector after a collision implying the detector,
- Inspections during preventive maintenance,
- At least annual calibration of Detector front-end,
- Periodic control of detector performance (image quality) (acceptance and constancy testing).

## 2.12 OTHERS

**Toxic substances:** PIXIUM 3543 pR contains 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 reference 61658545\_530 (and the Risk Management Summary reference 61658546\_530 associated) linked to the use of the PIXIUM 3543 pR. Nevertheless, TRIXELL recommends to work out an Hazard Analysis accounting the integration of the detector in the system, and to carry out the qualification tests corresponding.

### CONFIDENTIEL TRIXELL

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

### TRIXELL PROPRIETARY INFORMATION

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

	FID / Document identification	CTD / Type	VS / Release	<b>15 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

## 2.13 END USER INFORMATION

The end users must be aware about several risks linked to the use of the PIXIUM 3543 pR. The following information must be clearly indicated in the radiology system's User Manual:

- In case of collision of the FE with a tough surface or in case of rough shock, a visual inspection is required in order to detect any mechanical deformation. In such case, the use of detector must be considered as hazardous and the detector must be send back to after sale service for repair.
- The design of the PIXIUM 3543 pR is safe for patients wearing a pacemaker (according to IEC45502-2-1) and for life supporting device (according to IEC 60601-1-2 edition 2 and above). Nevertheless, we expressly recommend the end users to connect the backup cable and switch off the wireless function before using the PIXIUM 3543 pR.
- Because the FE is an handled-equipment, the end user must pay attention to avoid any unwanted movement of the FE during the X-ray exposure that can cause blurred image.
- The image quality is specified for a tilt of 45° max with respect to the X-ray beam axis.
- Before taking any X-ray image, the end user must be sure to use the right FE (attached with the right DS). A good practice consists into placing coloured labels on FE and DS.
- The end user must take care (for himself and for the patient) of avoiding to stumble on the cable when the BUC is used. When not used, the BUC must be stored in the DS.
- The FE must be handled with care. In case of falling down on the foot of someone, the FE can cause injuries to the person.
- The FE is designed to cope with mass up to 150 kg uniformly spread all over the top face or 100 kg concentrated on a small surface (Ø 40 mm). A risk of patient's injuries (mechanical or electrical shock) or bad image quality can happen for heavier loads.
- The FE is designed to cope with falls up to 75 cm without any damage. In case of fall above this height, the maintenance staff must check the internal shock sensor located into the battery compartment. If turned to red, the use of detector must be considered as hazardous and the detector must be send back to after sale service for repairing.
- The end user must be aware that the FE does not include any X-ray barrier protection. He must not stay behind the FE without individual protection during the X-ray pulses.
- TRIXELL recommends wrapping the FE with single use plastic bag in order to prevent infection by virus or bacteria. If not possible, TRIXELL recommends to disinfect the FE after each patient.
- TRIXELL recommends avoiding to used female DB15 connector and DB9 Phenix in the neighborhood of the DS
- Since Pixium 3543 pR is running under Linux Operation System, the risk to be infected by a virus is not negligible. A special care must be taken by integrator in order to avoid any risk of virus infection.

**CONFIDENTIEL TRIXELL**

*Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.*

**TRIXELL PROPRIETARY INFORMATION**

*Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.*

<b>TRIXELL</b>	FID / Document identification	CTD / Type	VS / Release	<b>16 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

- In case of earthquake, Pixium DS 3543 pR and Pixium FE 3543 pR must be inspected before being reused.
- If the DS is switched off and the FE is in the DS, the SAPM pins may be blocked outside: the FE should be removed before switching off!

**CONFIDENTIEL TRIXELL**

*Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.*

**TRIXELL PROPRIETARY INFORMATION**

*Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.*



	FID / Document identification	CTD / Type	VS / Release	17 / 32
	61676632	108	Ad1	

### 3 STANDARDS

The detector is compliant with following standards. However, some items are considered as not applicable to PIXIUM 3543 pR, 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
3 to 59, except points below		TRIXELL
6.3a	Mains switch clearly identified	System manufacturer, if compliance is demanded at system level.
6.5a	Protective earth conductor has green/yellow insulation	System manufacturer, if compliance is demanded at system level.
6.7a	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.
6.7b	Color red used only for push-button by witch a function is interrupted in case of emergency	System manufacturer, if compliance is demanded at system level.
6.8.3b	Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	System manufacturer: mains supply external circuit request 4 A fuse or polyswitch.
20	Dielectric strength	System manufacturer: schematic insulation diagram recommended by TRIXELL in general caution (this document, see §2.3).
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	System manufacturer: equipment is component fixed into system.
57.2	Power cord mains plug is “Hospital Grade” type	System manufacturer, if compliance is demanded at system level.

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

	FID / Document identification	CTD / Type	VS / Release	18 / 32
	61676632	108	Ad1	

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

#### 3.2.1 Performance

The essential performances of the PIXIUM 3543 pR detector with regard to EMC are:

- Software robustness
- Robustness of the communication link with the system
- No image lost
- Artifacts on the image (correlated noise level).

#### 3.2.2 Electromagnetic emissions

With respect to IEC 60601-1-2, the PIXIUM 3543 pR is intended for use in the electromagnetic environment specified below. The customer or the user of the PIXIUM 3543 pR should assure that it is used in such environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The PIXIUM 3543 pR uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PIXIUM 3543 pR is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	System manufacturer, if compliance is demanded at system level.	
Voltage fluctuations / flicker emissions IEC 61000-3-3		

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.


**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

<b>TRIXELL</b>	FID / Document identification	CTD / Type	VS / Release	<b>19 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

### 3.2.3 Electromagnetic immunity

With respect to IEC 60601-1-2, the PIXIUM 3543 pR is intended for use in the electromagnetic environment specified below. The customer or the user of the PIXIUM 3543 pR should assure that it is used in such environment.

<u>Immunity test</u>	<u>IEC 60601 test level</u>	<u>Compliance level</u>	<u>Electromagnetic environment - guidance</u>
ElectroStatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact Not applicable	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	3 V/m 80 MHz to 2.5 GHz  80 MHz to 1 GHz	3 V/m 80 MHz to 2.5 GHz 80 MHz to 1 GHz	TRIXELL Interference may occur in the vicinity of equipment marked with the following symbol:  
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 commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode  ± 2 kV common mode	± 1 kV differential mode  ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V <sub>RMS</sub> 150 kHz to 80 MHz	3 V <sub>RMS</sub> 150 kHz to 80 MHz	TRIXELL


**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

<b>TRIXELL</b>	FID / Document identification	CTD / Type	VS / Release	<b>20 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

<u>Immunity test</u>	<u>IEC 60601 test level</u>	<u>Compliance level</u>	<u>Electromagnetic environment - guidance</u>
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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 % $U_T$ (> 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	System manufacturer, if compliance is demanded at system level.	Mains power quality should that of a typical commercial or hospital environment.  If the user of the PIXIUM 3543 pR requires continued operation during power mains interruptions, it is recommended that the PIXIUM 3543 pR be powered from an uninterruptible power supply or battery.
NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level			
GSM modulation ENV 50204	3 V/m 900 MHz modulated @ 200 Hz (square signal)	3 V/m 900 MHz modulated @ 200 Hz (square signal)	TRIXELL Interference may occur in the vicinity of equipment marked with the following symbol:  

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

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

	FID / Document identification	CTD / Type	VS / Release	21 / 32
	61676632	108	Ad1	

performance is observed, additional measures may be necessary, such as relocating PIXIUM 3543 pR or using a shielded location with a higher RF shielding effectiveness and filter attenuation

### 3.3 IEC60601-1-3 STANDARD

Clause	Title	Compliance ensured by
SECTION I – GENERAL		-
4.	General prescriptions relating to tests	System manufacturer, if compliance is demanded at system level.
6.	Identification, marking and documentation	System manufacturer, if compliance is demanded at system level.
6.1	Marking on the outside of the equipment or parts of equipment	-
6.1.201	Prescription of marking in the paragraphs	System manufacturer, if compliance is demanded at system level.
6.1.202	General prescriptions	TRIXELL
6.8	Accompanying documents	-
6.8.201	References in the paragraphs	System manufacturer, if compliance is demanded at system level.
6.8.202	General requirements	TRIXELL
SECTION V		-
29.201	Radiation quality	System manufacturer, if compliance is demanded at system level.
29.202	Limitation and indication of the X-Ray beam area	System manufacturer, if compliance is demanded at system level.
29.203	Relation between X-Ray field and the image reception area	System manufacturer, if compliance is demanded at system level.
29.204	Leakage radiation	Not applicable.
29.205	Outdistance between radiation source and skin	System manufacturer, if compliance is demanded at system level.

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

<b>TRIXELL</b>	FID / Document identification	CTD / Type	VS / Release	<b>22 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

Clause	Title	Compliance ensured by
29.206	Attenuation of the X-ray beam	Not applicable.
29.207	Primary protective shielding	A lead protective shielding in the FE only protects the electronic components against excessive X-ray beam. As consequence, it's the responsibility of the system manufacturer to check the compliance with this clause.
29.208	Protection against stray radiation	System manufacturer, if compliance is demanded at system level.

### 3.4 IEC 60825-1 STANDARD

**Laser classification:** PIXIUM 3543 pR is classified Class I equipment, and includes a Class I laser product with invisible LED radiation in the DS.

### 3.5 93-42-EEC STANDARD

Clause	Title	Compliance ensure by
1 to 13	-	TRIXELL
Annexe X	General provisions and 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

### 3.6 R&TTE DIRECTIVE



**The Pxium 3543 pR is certified to be used in the following European countries:**

<p><b>CONFIDENTIEL TRIXELL</b></p> <p>Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.</p> <p><b>TRIXELL PROPRIETARY INFORMATION</b></p> <p>Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.</p>
---

Albania (AL)	Andorra (AD)	Austria (AT)	Azerbaijan (AZ)	Belarus (BY)	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)	Moldova (MD)	Monaco (MC)	Netherlands (NL)	Norway (NO)	Poland (PL)	Portugal (PT)
Roumania (RO)	Russian Federation (RU)	San Marino (SM)	Serbia and Montenegro (CS)	Slovakia(SK)	Slovenia (SI)	Spain (ES)	Sweden (SE)
Switzerland (CH)	The former Yugoslav Republic of Macedonia (MK)	Turkey (TR)	Ukraine (UA)	United Kingdom (GB)	Vatican (VA)		

**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 these *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* are in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

**Finnish:**

*TRIXELL* vakuuttaa täten että *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* tyyppinen laite on direktiivin 1999/5/EY oleellisten vaatimusten ja sitä koskevien direktiivin muiden ehtojen mukainen.

**Dutch:****CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

	FID / Document identification	CTD / Type	VS / Release	24 / 32
	61676632	108	Ad1	

Hierbij verklaart *TRIXELL* dat het toestel *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* in overeenstemming is met de essentiële eisen en de andere relevante bepalingen van richtlijn 1999/5/EG

Bij deze verklaart *TRIXELL* dat deze *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* voldoet aan de essentiële eisen en aan de overige relevante bepalingen van Richtlijn 1999/5/EC.

French:

Par la présente *TRIXELL* déclare que les appareils *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* sont conformes aux exigences essentielles et aux autres dispositions pertinentes de la directive 1999/5/CE

Par la présente, *TRIXELL* déclare que ces *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* sont conformes aux exigences essentielles et aux autres dispositions de la directive 1999/5/CE qui lui sont applicables

Outdoor use limited to 10mW e.i.r.p. within the band 2454 – 2483.5 MHz. Derogation in French overseas departments of Guyane and La Reunion: outdoor use not allowed in band 2400 - 2420 MHz.

Swedish:

Härmed intygar *TRIXELL* att denna *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* står i överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 1999/5/EG.

Danish:

Undertegnede *TRIXELL* erklærer herved, at følgende udstyr *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* overholder de væsentlige krav og øvrige relevante krav i direktiv 1999/5/EF

German:

Hiermit erkläre *TRIXELL*, dass sich *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* in Übereinstimmung mit den grundlegenden Anforderungen und den anderen relevanten Vorschriften der Richtlinie 1999/5/EG befindet". (BMW)

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.



<b>TRIXELL</b>	FID / Document identification	CTD / Type	VS / Release	<b>25 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

Hiermit erklärt *TRIXELL* die Übereinstimmung des Gerätes *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* mit den grundlegenden Anforderungen und den anderen relevanten Festlegungen der Richtlinie 1999/5/EG. (Wien)

Greek:

ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ *TRIXELL* ΔΗΛΩΝΕΙ ΟΤΙ *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 1999/5/ΕΚ

Italian:

Con la presente *TRIXELL* dichiara che questo *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti stabilite dalla direttiva 1999/5/CE.

Spanish:

Por medio de la presente *TRIXELL* declara que los *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 1999/5/CE

Portuguese:

*TRIXELL* declara que este *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* está conforme com os requisitos essenciais e outras disposições da Directiva 1999/5/CE.

**3.7 FCC RULES**

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.
- (2) This device must accept any interference received, including interference that may cause undesired operation.

**Federal Communications Commission (FCC) Requirements, Part 15:**

<p><b>CONFIDENTIEL TRIXELL</b></p> <p>Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.</p> <p><b>TRIXELL PROPRIETARY INFORMATION</b></p> <p>Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.</p>
---

	FID / Document identification	CTD / Type	VS / Release	26 / 32
	61676632	108	Ad1	

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 or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

**Regulatory Information/Disclaimers:**

Installation and use of this Wireless LAN device must be in strict accordance with the instructions included in the user documentation provided with the product. Any changes or modifications (including the antennas) made to this device that are not expressly approved by the manufacturer may void the user’s authority to operate the equipment. The manufacturer is not responsible for any radio or television interference caused by unauthorized modification of this device, or the substitution of the connecting cables and equipment other than manufacturer specified. It is the responsibility of the user to correct any interference caused by such unauthorized modification, substitution or attachment. Manufacturer and its authorized resellers or distributors will assume no liability for any damage or violation of government regulations arising from failing to comply with these guidelines.

**IMPORTANT NOTE:**

FCC Radiation Exposure Statement:

The *PIXIUM DS 3543 pR* equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

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

The *PIXIUM FE 3543 pR* equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying

<p><b>CONFIDENTIEL TRIXELL</b></p> <p><i>Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.</i></p> <p><b>TRIXELL PROPRIETARY INFORMATION</b></p> <p><i>Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.</i></p>
---

	FID / Document identification	CTD / Type	VS / Release	27 / 32
	61676632	108	Ad1	

RF exposure compliance. To maintain compliance with FCC RF exposure compliance requirements, please follow operation instruction as documented in this manual.

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

**Caution:**

1. For operation within 5.15 ~ 5.25GHz frequency range, it is restricted to indoor environment.
2. 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.

**3.8 CANADA (IC)**

Industry Canada statement

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.

**IMPORTANT NOTE:**

IC Radiation Exposure Statement:

The *PIXIUM FE 3543 pR* equipment complies with IC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

The *PIXIUM FE 3543 pR* equipment complies with IC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. To maintain compliance with IC RF exposure compliance requirements, please follow operation instruction as documented in this manual.

**Caution:**

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

High power radars are allocated as primary users (meaning they have priority) of 5250-5350 MHz and 5650-5850 MHz and these radars could cause interference and/or damage to LE-LAN devices.

<p><b>CONFIDENTIEL TRIXELL</b></p> <p><i>Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.</i></p> <p><b>TRIXELL PROPRIETARY INFORMATION</b></p> <p><i>Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.</i></p>
---

<b>TRIXELL</b>	FID / Document identification	CTD / Type	VS / Release	<b>28 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

### 3.9 NCC (TAIWAN)

## 注意！

依據 低功率電波輻射性電機管理辦法

第十二條 經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

第十四條 低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。前項合法通信，指依電信規定作業之無線電信。低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

#### **CONFIDENTIEL TRIXELL**

*Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.*

#### **TRIXELL PROPRIETARY INFORMATION**

*Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.*

<b>TRIXELL</b>	FID / Document identification	CTD / Type	VS / Release	<b>29 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

### 3.10 MIC (KOREA)

당해 무선설비는 운용 중 전파혼신 가능성이 있음  
당해 무선설비는 전파혼신 가능성이 있으므로  
인명안전과 관련된 서비스는 할수 없음

*PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* contain Korea MIC approved wireless mini-PCI module, with MIC ID: TXL-CM10



인증번호: **TXL-CM10**

### 3.11 RUSSIA FAC (DOC)

Подтверждение соответствия Мининформсвязи России:

Декларация соответствия № Д-ТП-xxxx от dd.mm.yyyy года, действительна до dd.mm.yyyy года, зарегистрирована в Федеральном агенстве связи dd.mm.yyyy года

### 3.12 ANATEL (BRAZIL)

Este equipamento *PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* opera em caráter secundário, isto é, não tem direito a proteção contra interferência prejudicial, mesmo de estações do mesmo tipo, e não causar interferência a sistema operando em caráter primário.

*PIXIUM FE 3543 pR / PIXIUM DS 3543 pR* contain Brazil ANATEL approved wireless mini-PCI module.

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

<b>TRIXELL</b>	FID / Document identification	CTD / Type	VS / Release	<b>30 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	



HHHH - AA - FFFF



(01) 0789 RRRRRR PPP D

### 3.13 MII-SRMC (CHINA)

PIXIUM FE 3543 pR / PIXIUM DS 3543 pR contain China MII-SRMC approved wireless mini-PCI module, with MII ID: [CM10](#)

### 3.14 DGPT (INDONESIA)

PIXIUM FE 3543 pR / PIXIUM DS 3543 pR contain DGPT approved wireless mini-PCI module.

**06137/POSTEL/2008  
2510**

### 3.15 ISO 10993 STANDARD

TBD

### 3.16 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.

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

Clause	Title	Compliance ensured by
	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	TRIXELL
	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 3543 pR.
	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	Not applicable.
	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

**CONFIDENTIEL TRIXELL**

Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.

**TRIXELL PROPRIETARY INFORMATION**

Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.

	FID / Document identification	CTD / Type	VS / Release	<b>32 / 32</b>
	<b>61676632</b>	<b>108</b>	<b>Ad1</b>	

## 4 DISPOSAL

### 4.1 BATTERY

The end user must be clearly informed that batteries (Pixium BT 3543 pR) used in the Pixium FE 3543 pR 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, DOCKING STATION, BACKUP CABLE AND SAPM

Trixiell is in charge of the recycling of the Front End (Pixium FE 3543 pR), the Docking Station (Pxium DS 3543 pR), the Backup cable (Pixium BC 3543 pR) and the SAPM module (Pixium SM 3543 pR). Trixiell's customers are in charge of managing the way to collect these products (at the end of their life) and ship them to Trixiell for recycling.

### 4.3 GRID FRAME

Since the grid frame provided by Trixiell does not contain the most polluting part (which is the anti-scattering grid), it is under the responsibility of Trixiell's customers to manage the recycling of this part.

**END OF DOCUMENT**

**CONFIDENTIEL TRIXELL**

*Copyright © 2008 TRIXELL. Tous droits réservés. Ce document et l'information qu'il contient sont la propriété exclusive de TRIXELL. Ils ne peuvent être reproduits ou divulgués sous quelque forme que ce soit sans l'accord préalable écrit de TRIXELL.*

**TRIXELL PROPRIETARY INFORMATION**

*Copyright © 2008 by TRIXELL. All rights reserved. This document and the information contained therein are TRIXELL's exclusive property. Any copy and/or disclosure thereof in any form whatsoever are subject to TRIXELL's prior written consent.*