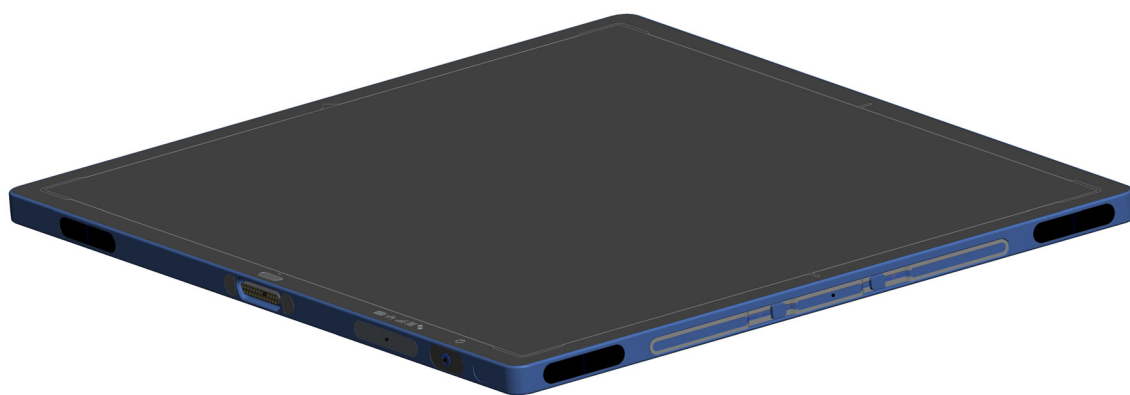


XRpad2 4336 Digital X-ray Detector System User Manual



Before using the X-ray detector, be sure to read this manual thoroughly along with any other manuals for the software and other system components. Keep this manual where it is easily accessible.

Before You Begin

- To avoid personal injury or product damage, read the manual and all accompanying information carefully before installing and using the X-ray detector.
- The X-ray detector is intended for use by trained and qualified professional personnel who are knowledgeable with the use of X-ray detectors, X-ray systems, and electrical equipment.
- The user is responsible for using and maintaining the detector according to prescribed installation, usage, maintenance, handling, and storage specifications. To keep the detector and its accessories in a safe and proper condition, only trained and qualified professional person(s) shall be in charge of maintenance.
- X-ray imaging, image processing, image acquisition, and data storage must be performed in accordance with the applicable laws. The user is also responsible for compliance to laws pertaining to the privacy of image data.
- In no event is X-ray detector manufacturer liable for direct, indirect, or consequential injury, damage, or loss of equipment operation time or image data arising from the use of the X-ray detector, its components, and/or accessories.





Protection Against Ionizing Radiation

- Exposure of any part of the human body to X-radiation may be harmful to health. Whenever X-ray equipment or radioactive sources are in use, appropriate safety precautions and measures shall be instituted, and all regulatory requirements must be met. It is the responsibility of the X-ray system installer, operator, and user to comply with applicable requirements.
- The X-ray detector is intended to be installed, maintained, and used by qualified professional personnel who are trained and qualified in the installation, maintenance, and use of X-ray equipment.
- The X-ray detector does not contain a primary barrier for X-rays or Gamma rays. The X-ray system installer or X-ray system manufacturer must provide the necessary protection based on the X-ray system's intended use.
- For portable applications, the X-ray system installer or X-ray system manufacturer must provide the necessary training for operators to protect themselves, patients, and surrounding persons.






For Your Safety

To avoid personal injury or product damage, read this manual and all accompanying information carefully before handling, installing, or using the X-ray detector. Follow all instructions, warnings, and cautions in this manual and all warnings and cautions printed on the warning label. Ignoring instructions, warnings, or cautions in the handling, installing, or using of the detector may result in personal injury, death, or product damage. Keep this manual for future reference.






Meaning of Alerts and Notes

 DANGER	This indicates a potentially hazardous situation which, if ignored, <u>will</u> result in severe personal injury, death, or substantial product damage.
 WARNING	This indicates a potentially hazardous situation which, if ignored, <u>may</u> result in severe personal injury, death, or substantial product damage.
 Caution	This indicates a potential hazardous situation which, if ignored, <u>may</u> result in minor or moderate personal injury or damage to the product.
 Note	This emphasizes or supplements important information about the main text.







Installation and Environment of Use

 WARNING	<p>Do not operate the X-ray detector in or around flammable gases, gas mixtures, liquids, chemicals, or other substances. Ignoring this warning may result in explosion, fire, or electric shock, which may result in severe personal injury, death, or substantial product damage.</p>
 Caution	<p>Do not operate the X-ray detector in a location with the following conditions.</p> <ul style="list-style-type: none"> • Close to fluid or places where fluid is used • Close to heat sources, such as a heater • High temperature environment • High humidity environment • High condensation environment • Extreme cold environment • Dusty environment • Salty or sulphurous environment • Near a vibrating environment <p>Ignoring this caution may result in personal injury or damage to the product.</p>
 WARNING	<p>Do not connect the X-ray detector to any component or accessory other than the manufacturer's specified components and accessories. Ignoring this warning may result in explosion, fire, or electric shock, which may result in severe personal injury, death, or substantial product damage.</p>
 WARNING	<p>Do not modify or alter the X-ray detector, its components, or accessories. Ignoring this warning may result in explosion, fire, or electric shock, which may result in severe personal injury, death, or substantial product damage.</p>
 WARNING	<p>The detector is not designed to control X-ray dose. The system integrator is responsible for controlling the X-ray radiation.</p>










Interface and Power Unit and Cables




 WARNING	<p>Be sure to turn OFF the power of the X-ray detector, including turning off the power supply or removing the battery (if applicable) before servicing, maintaining, connecting, or disconnecting the cables or accessories.</p> <p>Do not touch the power supply, Lithium Battery Pack, X-ray detector, cable, connector, or any other electrical component or equipment with wet hands. Ignoring this warning may cause electrical shock, which may result in severe personal injury, death, or substantial product damage.</p>
 WARNING	<p>Disconnect the cables by pulling on the connector and not the cable itself. Ignoring this warning may cause electrical shock, which may result in severe personal injury, death, or substantial product damage.</p>
 WARNING	<p>Do not modify the cables or subject the cable to external stress or damage. Avoid placing anything heavy, including the detector, on the cable, stepping on the cable, pulling the cable, or subjecting the cable to excessive bending or bundling. Ignoring this warning may cause cable failure resulting in electrical shock, which may result in severe personal injury, death, or substantial product damage.</p>
 WARNING	<p>Do not turn ON the power supply or X-ray detector when condensation is on the X-ray detector or any of its components or accessories. Ignoring this warning may cause electrical shock, which may result in severe personal injury, death, or substantial product damage.</p>
 WARNING	<p>To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.</p>

Handling







 WARNING	<p>Never disassemble, modify, or alter the X-ray detector, its components, Lithium Battery Pack battery, battery charger, or accessories. Ignoring this warning may cause electrical shock and/or unknown hazards, which may result in severe personal injury, death, or substantial product damage.</p>
 WARNING	<p>Do not touch the interface and power unit or cable and the patient at the same time. Do not let the patient touch the interface and power unit or cable. Ignoring this warning may cause electrical shock and/or unknown hazards, which may result in severe personal injury, death, or substantial product damage.</p>
 Caution	<p>Place the X-ray detector horizontally on a flat, stable surface. If the X-ray detector is placed vertically or in any tilted position, the X-ray detector must be securely placed in the Bucky tray or securely fastened to the X-ray detector enclosure or support structure. Ignoring this caution may result in personal injury or damage to the product.</p>
 Caution	<p>Do not exceed the maximum uniform load weight of 150 kg distributed across the surface of the X-ray detector.</p>
 Caution	<p>Do not exceed the maximum load weight of 100 kg distributed on an area of 40 mm in a diameter of the X-ray detector surface.</p>
 Caution	<p>Do not drop the X-ray detector. If the X-ray detector is dropped, remove the X-ray detector from service, and immediately ask your establishment's safety representative to verify or re-validate the proper function of the X-ray detector prior to resuming use of the detector. Further use under abnormal conditions may result in severe personal injury, death, or substantial product damage.</p>

Battery





 WARNING	Do not use the XRpad2 LBP (battery) if the casing is broken or if it emits an unusual odor, smoke, or excessive heat, or if it leaks any substance. Avoid contact with any substance seeping from the battery pack. If any fluid touches your skin or eyes, wash the affected area with clean, running water and immediately seek medical attention.
 WARNING	The cells within the battery contain toxic substances. Do not attempt to open the battery. Do not insert any object into the battery pack or use any device to pry at the battery pack casing. Attempting to open the battery casing will damage the casing, which could cause the battery to release toxic and harmful substances causing injuries such as electric shock or burns, or cause a fire, and will render the pack unusable.
 WARNING	Observe and follow all safety information in this manual and on the warning label found on the battery. Ignoring a warning may result in personal injury or damage to the product.
 WARNING	Use only charging devices approved by device manufacturer, and never attempt to bypass or override their charging protection circuits.
 WARNING	Keep out of reach of children.
 WARNING	Remove the battery if the X-ray detector is not likely to be used for some time.
 WARNING	Do not submerge the battery in water or other liquid.
 WARNING	Do not charge the battery near flammable materials.
 WARNING	Do not connect the battery to an electrical outlet directly, or to any other electrical source not described in the manual.

 WARNING	Do not drop or hit the battery against hard objects since this may cause damage to the battery and risk release of the battery toxic and harmful substances, causing injuries such as electric shock or burns or causing a fire, and will render the battery unusable.
 WARNING	Do not use the battery charger in the patient environment.
 Caution	There is a risk of explosion, personal injury, or damage to product if the battery is replaced by non-OEM approved components.



WLAN

 WARNING	Do not obstruct the detector antenna. If it is obstructed by metal, wood, or a human body, the wireless communication can be slowed down or disconnected.
 WARNING	Follow the laws and regulations for each country, and select the regional code accordingly.
 WARNING	Do not use the detector in aircraft because there is a potential affect to aviation systems.
 Caution	Use WLAN access point devices to get the best communication performance.
 Caution	The electromagnetic emission of the detector may influence implantable medical devices like pacemakers. Check the information for these devices.
 WARNING	Do not modify or alter the detector as this can violate the certification of the Radio Law.

Automatic Exposure Detection (AED) Mode

 WARNING	<p>The AED mode requires a sufficient X-ray dose rate to the detector surface. The required dose rate can vary between X-Ray tube, generator, and X-ray voltage. The system integrator must evaluate the AED operation with the complete X-ray setup in order to secure a proper image acquisition in AED mode.</p>
 WARNING	<p>The external sync mode is the default acquisition mode, and the detector needs to switch into the AED mode to use the Auto Exposure detection. It is important that a settling time for the AED is implemented by the system integrator. If the settling time is too short, the image can show artifacts.</p>
 WARNING	<p>The AED on-time is limited and must be turned off directly after acquiring the image. Staying longer in AED mode will reduce the battery duty cycle and heat up the detector.</p>
 WARNING	<p>Do not apply any, handling, loading, mechanical shock, or electronic noise to the detector while it is in AED mode. These actions can start an unwanted acquisition (false trigger). If a false trigger is applied to the detector, the detector will not be able to react on a real X-ray exposure until it has acquired the false trigger image.</p>

If a Problem Occurs

 WARNING	<p>If any abnormal condition, such as smoke, fumes, or strange sounds, is evident, turn off the X-ray detector, turn off and unplug the power supply from the AC outlet, and immediately ask your establishment's safety representative to contact your dealer, distributor, or device manufacturer.</p> <p>Further use under abnormal conditions may result in severe personal injury, death, or substantial product damage.</p>
 WARNING	<p>When liquid has been spilled into or on any part of the X-ray detector or power supply (if applicable), or when the X-ray detector, its component, or accessory is dropped, unplug the power supply from the AC outlet, and immediately ask your establishment's safety representative to contact your dealer, distributor, or device manufacturer.</p> <p>Further use under abnormal conditions may result in severe personal injury, death, or substantial product damage.</p>

Maintenance and Inspection





 WARNING	<p>Turn off the power of the X-ray detector when the inspections indicated in this manual are going to be performed. Ignoring this warning may result in electric shock, which may result in severe personal injury, death, or substantial product damage.</p>
 WARNING	<p>When the X-ray detector system is going to be cleaned, turn off the X-ray detector and remove the battery. If the X-ray detector is connected to a power supply, turn off the power switch and/or unplug the power supply cable from the AC outlet. If the X-ray detector is battery powered, remove the battery. Never use thinner, benzine, acetone, or other flammable cleaning agents. Ignoring this warning may result in explosion, fire, or electric shock, which may result in severe personal injury, death, or substantial product damage.</p>
 WARNING	<p>The X-ray detector must be repaired by X-ray detector manufacturer-authorized personnel only. Ignoring this warning may result in explosion, fire, electric shock, or unknown hazards, which may result in severe personal injury, death, or substantial product damage.</p>
 Caution	<p>Follow the manufacturer's recommendations for inspecting the X-ray detector before use.</p>

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1.0 Scope

This document describes design elements and respective interfaces for the XRpad2 4336 detector. Applicable mechanical, electronic, and software interfaces are addressed. PerkinElmer digital X-ray Flat Panel Detectors and their accessories are components designed to be integrated into products by X-ray system manufacturers. Manufacturers are responsible for qualifying, validating, and certifying their products for their intended uses and meeting all applicable regulatory requirements.

Final application and intended use is based on the completed X-ray system design. It is the responsibility of the X-ray system manufacturer to confirm the efficacy and compliance of the X-ray system for its intended use, inclusive of the detector. The Digital Radiography Software referred to in this manual is medical imaging software for radiography, which is typically supplied by the X-ray system manufacturer or third-party provider and is not part of the XRpad2 4336 detector.

2.0 Usage

The XRpad2 4336 detector is a component of a digital imaging system used for generating radiographic images of human anatomy for diagnostic X-ray procedures, wherever conventional Screen-Film (SF), Digital Radiography (DR), or Computed Radiography (CR) systems may be used.

3.0 Audience

This document is for users of the X-ray detector and for X-ray system manufacturers and X-ray system installers who are responsible for installing the X-ray detector into an X-ray system.

4.0 Abbreviations

Table 1 includes a list of abbreviations used in this manual and a description of each abbreviation.

Table 1 Abbreviations

Abbreviation	Description
AED	Automatic Exposure Detection
AP	Access Point
CR	Computed Radiography
DFS	Dynamic Frequency Selection
DR	Digital Radiography
ESS	Extended Service Set
FoV	Field of View
fps	Frames per second
GigE	Gigabit Ethernet
I/F	Interface
IP	Internet Protocol
IPU	Interface and Power Unit
LAN	Local Area Network
LBC	Lithium Battery Charger
LBP	Lithium Battery Pack
LED	Light Emitting Diode
MDD	Medical Device Directive
OEM	Original Equipment Manufacturer
REF	Radiated Electromagnetic Field
Rx	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
SELV	Separated or Safety Extra-Low Voltage
SF	Screen Film
WAP	Wireless Access Point
WEEE	Waste Electrical and Electronic Equipment
Wi-Fi	Wireless Fidelity
WLAN	Wireless Local Area Network

5.0 References

Table 2 includes a list of documents referred to in this manual. For access to the following references, contact your establishment's representative or your dealer, distributor, or device manufacturer.

Table 2 **References**

	Document Name	Document #
1	<i>XRpad LBC Charger for Rechargeable Lithium-Ion Battery Pack</i>	48773
2	<i>XRpad LBP Rechargeable Lithium-Ion Battery Pack</i>	48772
3	<i>XRpad2 4336 Digital X-ray Detector System Reference Manual</i>	69652
4	<i>Digital Radiography Software Manual</i>	Supplied by X-ray system manufacturer or third-party provider
5	Digital Radiography Software	Supplied by X-ray system manufacturer or third-party provider
6	<i>Access Point Manual</i>	Supplied by the Access Point Manufacturer or third-party provider

6.0 Definition of Symbols

Table 3 includes a list of symbols and a description of each symbol.

Table 3 **Symbols**










Symbol	Description
	This Way Up.
	Handle with Care.
	Keep Dry.
	Reusable.
	Disposal (WEEE). Follow all local and regional disposal requirements.
	Refer to instruction manual/booklet.
	Manufacturer's name and address.
	Date of Manufacture, YYYY-MM, YYYY=Year, MM=Month.
	REF = Reference Number. PerkinElmer Catalog Number, Part Number, or Material Number.

Table 3 Symbols (Continued)






















Symbol	Description
	Serial Number.
~	AC Input.
≡	D.C. Voltage.
	Temperature Limitation.
	Relative Humidity Limitation.
	Potential Equalization.
	Functional Earth Connection.
	Protection Class I.
	Protection Class II.
	Non-Ionizing Radiation.
	Battery charge condition. <ul style="list-style-type: none"> • Battery Charged (> 75%). • Battery $\frac{3}{4}$ ($\leq 75\%$). • Battery Half ($\leq 50\%$). • Battery Low ($\leq 25\%$). • Battery Empty ($\leq 10\%$). • No Battery.
	Wireless Connectivity/No Wireless Connectivity.
	LAN Connection/Missing LAN Connection.
	Access Point
	Trigger Connection.
	Push Button.
	Power Switch.
	Do not crush.
	Do not expose to fire.

Table 3 Symbols (Continued)

Symbol	Description
	Keep away from children.
	Maximum Load.
	UL Recognized component mark for US and Canada.
	European Conformity markings for the product.

7.0 Standards and Regulations

The X-ray detector is designed to be compliant with the standards and/or regulations detailed in [Table 4](#). The manufacturer's certifications to standards and regulations are valid only if the original accessories (as listed in [Table 8](#)) are used according to prescribed instructions. Product certification and warranty are rendered void if any modification or alteration to the product is made, or any instruction, warning, or caution is not followed.

Table 4 Standards and Regulations

Standards and Regulations	Description
ANSI/AAMI Std ES60601-1:2005	Medical electrical equipment Part 1: General Requirements for Basic Safety and Essential Performance
EN IEC 60601-1:2006/ AC:2010	General Requirements for Basic Safety for Medical Electrical Equipment
EN IEC 60601-1-2:2007	Medical Electrical Equipment, Part 1-2: General Requirements for Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility
CAN CSA C22.2 No 60601-1 08	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
FCC Part 15 subpart B/E	Radio Frequency Exposure
ETSI EN 301 893 V.1.7.1 (2012)	Broadband Radio Access Networks (BRAN); 5 GHz high performance RLAN
ETSI EN 301 489-1 V1.9.2 (2011)	Electromagnetic Compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
ETSI EN 301 489-17 V2.2.1 (2012)	Electromagnetic Compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for 2.4 GHz wideband transmission systems and 5 GHz high performance RLAN equipment"
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

Table 4 Standards and Regulations (Continued)

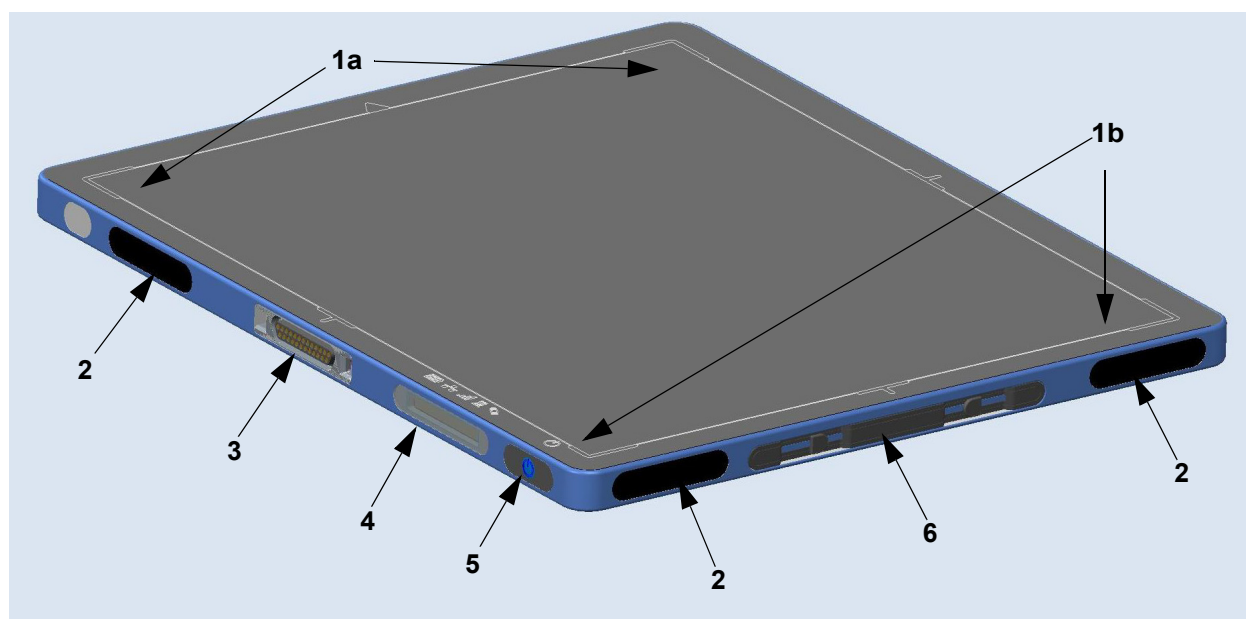
Standards and Regulations	Description
EN ISO 10993-10-2010-2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 4090:2004	Photography – Medical Radiographic Cassettes/Screens/Films and Hard-Copy Imaging Films – Dimensions and Specifications
EN 60529:1991 + A1:2000	Degrees of Protection Provided by Enclosures (IP-code)

8.0 Description of the X-ray Detector

8.1 Overview of the X-ray Detector













The XRpad2 4336 is a wireless, light weight, cassette-sized flat panel detector for digital radiography. It fits into a conventional table or wall-stand Bucky, just like a film-screen cassette.

[Figure 1](#) shows the front view of the X-ray detector, and [Table 5](#) includes a brief description of each feature.

**Figure 1 X-ray Detector (Front View)****Table 5 Overview of the X-ray Detector**

1	Active Area with Markers: 1a) Top and 1b) Bottom Side of the Image
2	Antenna. Make sure that they are not obstructed
3	Power and communication tethered connector

Table 5 Overview of the X-ray Detector (Continued)

4	Display	
	Battery charge condition	
	<ul style="list-style-type: none"> Battery Charged (> 75%) Battery $\frac{3}{4}$ ($\leq 75\%$) Battery Half ($\leq 50\%$) Battery Low ($\leq 25\%$) Battery Empty ($\leq 10\%$) No Battery 	     
	Wireless Connectivity/No Wireless Connectivity	 / 
	Access Point	
5	LAN Connection/No LAN Connection	
	 / 	
	Push Button with a LED  (blue light)	
	Short press and LED OFF	Power ON and LED flashes
	Short press and LED ON or flashes	Switch On of the display
	Long Press (4s) and LED ON or flashes	Power OFF
	LED Status (blue light)	
	LED OFF	Detector is not powered
	LED flashing (first instance)	Detector is initializing
	LED flashing (second instance)	Detector is Ready
	LED ON	Detector is not connected to the software
6	Battery Insert	

8.2 Environmental Considerations



WARNING

Storage or use of the X-ray detector and power supply in environmental conditions outside the specification may cause fire, electrical shock, and unknown hazards, which may result in severe personal injury, death, or substantial product damage or reduced product lifetime.

Table 6 includes a list of environmental considerations for the transport, storage, and operation of the X-ray detector.

Table 6 Environmental Considerations

Environment	Transportation/Storage ^a	Operation
Ambient Temperature ^b (30d/365d)	-10°C to 55°C/0°C to 55°C	10°C to 35°C
Relative Humidity	5% to 90%	10% to 85%
Atmospheric Pressure	520 hPa to 1070 hPa	690 hPa to 1070 hPa
Vibration ^c (EN60068-2-64)	5 m ² /s ³ (10 Hz to 100 Hz) 1 m ² /s ³ (100 Hz to 2000 Hz)	0.5 m ² /s ³ (10 Hz to 100 Hz) 0.1 m ² /s ³ (100 Hz to 2000 Hz)
Shock ^c (EN 60068-2-27)	25 g (duration 6 ms)	2 g (duration 6 ms)
Ingress protection rating	IPx4 rated (protection against splashing water)	

- a. In original transport container for 365 days.
- b. Temp. Gradient: max 4.5 K/hour.
- c. Image quality cannot be guaranteed during shock or vibrations.

8.3 X-ray Detector Specification

Table 7 includes the specification for the X-ray detector.

Table 7 X-ray Detector Specification

Sensor	
Panel	Single substrate amorphous silicon active TFT/diode array
Scintillator	Direct deposition CsI:TI
Pixel Matrix	3524 x 4288
Pixel Pitch	100 μ m
Electronics	
Amplifiers	Low noise ASICs with user selectable gains
ADC	16-bit
Image Transfer Time	Wired: 500 ms; Wireless: 3000 ms
On-board Memory	1 GB DDR3, 4 GB SDHC card
Mechanical	
Size	ISO 4090 for 35 cm x 43 cm (14" x 17") cassette size
Active Area	352.4mm x 428.8 mm
External Dimensions	384 mm (w) x 460 mm (l) x 15 mm (h)
Weight	3.1 kg
Housing	Aluminum frame with carbon-fiber entrance window
Communication	
Status Display	OLED display with Wi-Fi, LAN, battery, and sensor indicators
Wireless Data I/F	802.11n Wi-Fi standard @ 5 GHz Channel: WAP: 36-48, 149-165 Stationary: 36-48, 149-165 Stationary DFS: ^a 52-64, 100-116, 132-140
Wired Data I/F	GigE via optional power and communication tether
X-ray I/F	Integrated X-ray trigger control Automatic Exposure Detection
Image Performance	
Limiting Resolution	5 cy/mm
Typical MTF	70% (1 cy/mm), 40% (2 cy/mm), 15% (4 cy/mm) for RQA5
Typical DQE	75% (0 cy/mm), 60% (1 cy/mm), 40% (3 cy/mm) for RQA5

a. Country-dependent.

8.4 X-ray Detector Dimensions

Figure 2 shows the dimensions for the X-ray detector.

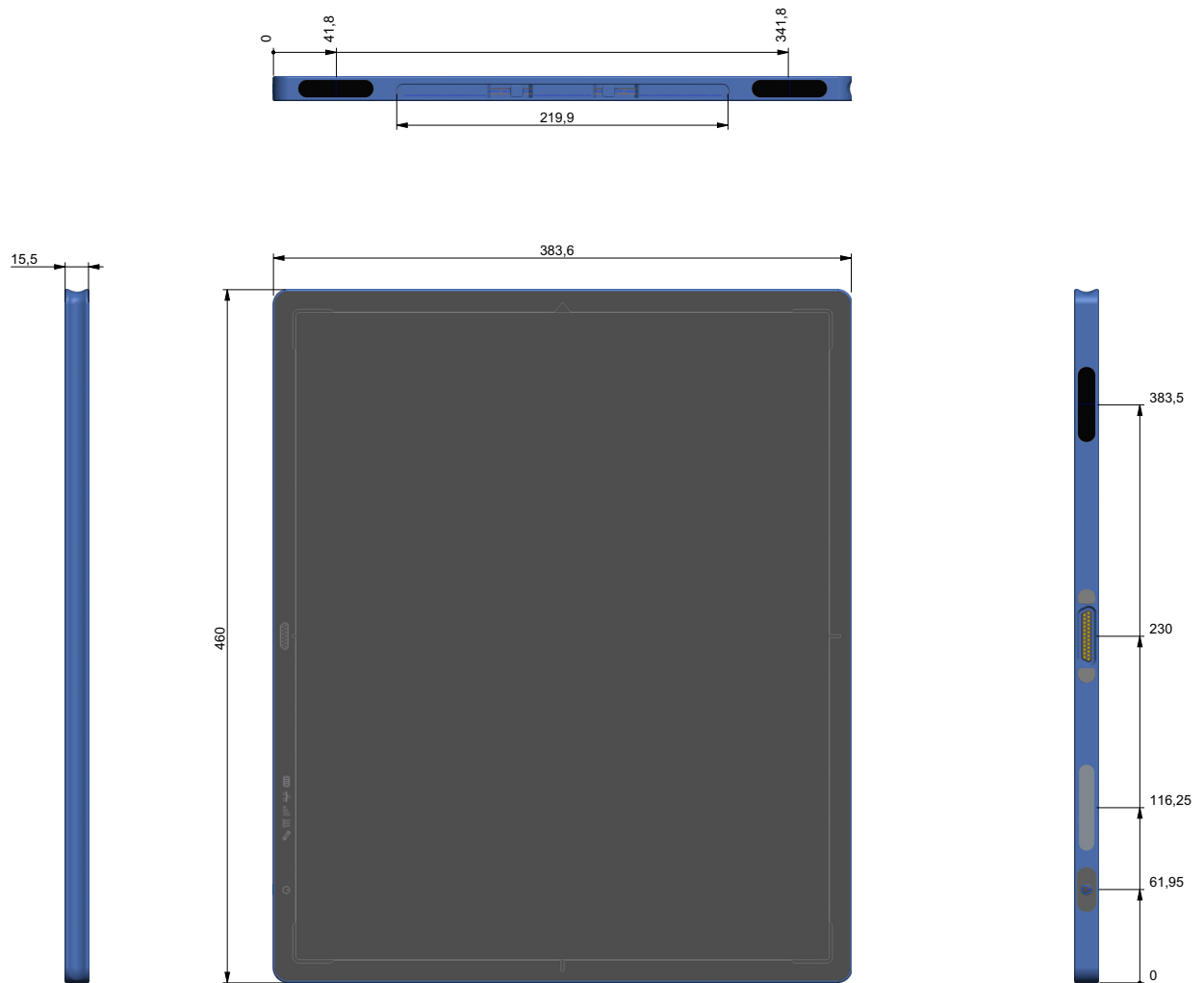


Figure 2 Dimensions for the X-ray Detector

8.5 X-ray Detector Accessories

The X-ray detector shall only be used with its approved OEM Lithium Battery Pack XRpad2 LBP, cables, and connectors. Product certification and warranty are rendered void if any modification or alteration to the product is made, or any instruction, warning, or caution is not followed. It is important that the X-ray detector is not directly connected to the clinical network. Connection of the X-ray detector directly with the clinical computer network may disturb the IT environment. The imaging workstation and the Wi-Fi access point must comply with IEC 60601-1 and/or IEC 60950-1, depending on the usage and application.

Table 8 includes a list of accessories for the X-ray detector.

Table 8 Accessories for the X-ray Detector

PerkinElmer Article No.	Description
95510949H-01	XRpad2 LBP (Lithium Battery Pack)
95510921H	XRpad LBC (Lithium Battery Charger)
95510928H	XRpad IPU-2 (Interface Power Unit)
95510970H	XRpad2 LPT Detector Cable
95510590H	XRpad2 Protective Insert
95510246H	AC Cable IEC 60320 C13 DE
95510249H	AC Cable IEC 60320 C13 US
95510256H	Trigger Cable 5 m/16.5 ft
95510257H	Trigger Cable 20 m/65.5 ft
95510621H	XRD GigE Interface Cable 7.6 m/25 ft
95510622H	XRD GigE Interface Cable 15.25 m/50 ft
95510623H	XRD GigE Interface Cable 30.5 m/100 ft

Do not use any non-medical equipment in the patient vicinity, as shown in [Figure 3](#).

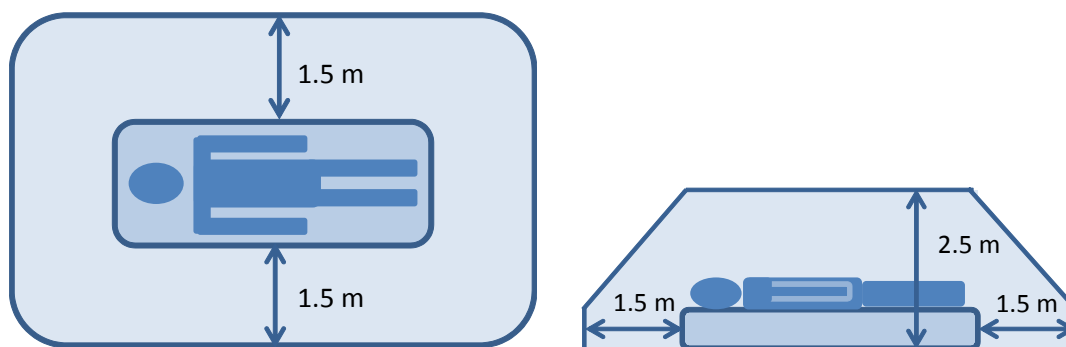




Figure 3 Patient Vicinity

 WARNING	Connection of the X-ray detector directly to the clinical computer network may disturb the IT environment.
 WARNING	Do not use any non-medical equipment, such as the Battery Charger or Wi-Fi access point, in the patient environment.

8.5.1 Rechargeable Lithium Battery Pack (XRpad2 LBP)

Figure 4 shows the XRpad2 LBP.

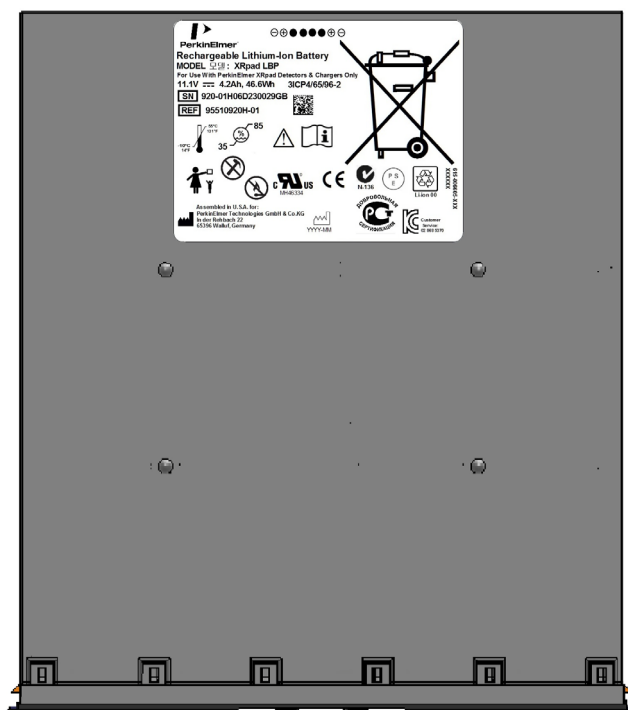


Figure 4 XRpad2 LBP



WARNING

Storage or use of the Lithium Battery Pack environmental conditions outside the specification may cause fire, electrical shock, and unknown hazards, which may result in severe personal injury, death, or substantial product damage or reduced product lifetime.

Table 9 includes the specification for the XRpad2 LBP.

Table 9 Specification of the XRpad2 LBP

General	
REF	95510949H-01
Voltage	11.1V
Amp-hours	4.2Ah
Capacity	46.6Wh
Charging Time	Within 3 hours
Environmental	
Relative Humidity	35% to ~85%
Operating (discharging)	-10°C to 55°C
Charging	0°C to 42°C
Transportation	-20°C to 45°C
Storage (up to 3 months)	15°C to 35°C
Ingress	
Ingress Protection Rating	IP54
Lifetime	
Charge-discharge Cycles	500 cycles on average under normal usage conditions. Battery should be discarded on or before five years from date of manufacture indicated on the battery label.

8.5.1.1 Charging the XRpad2 LBP

- A new rechargeable Lithium Battery Pack (XRpad2 LBP) comes in a discharged condition and must be charged using the dedicated lithium battery charger (XRpad LBC) before use. Refer to the XRpad LBC manual for more details.
- The XRpad LBC will charge the XRpad2 LBP to a usable condition within three hours depending on the initial state of charge. The X-ray a detector, when connected to the XRpad Interface and Power Unit (XRpad IPU-2), can also charge the XRpad2 LBP, but the charge rate is much slower.
- A charged battery will eventually lose its charge if unused. Upon initial use (or after a prolonged storage period), the battery may require three to four charge/discharge cycles before achieving maximum capacity.
- The actual battery run-time will depend on the power demands made by the X-ray detector.
- The XRpad2 LBP is keyed and can only be inserted into the XRpad LBC charger in one orientation.

- Check to ensure the XRpad2 LBP is clean, dry, and free of foreign contamination or debris. If cleaning is necessary, see [“Section 8.5.1.6, Cleaning the XRpad2 LBP” on page 17](#) for cleaning instructions.
- Ensure the XRpad LBC charger is powered on.
- Orient the XRpad2 LBP to match the orientation of the XRpad LBC Charger, and insert the XRpad2 LBP firmly into the XRpad LBC charger. Keep the XRpad LBP in the XRpad LBC charger until all the four charge status LEDs maintains a solid green, indicating a full charge. To remove, lift the battery out of the XRpad LBC charger.

**WARNING**

Do not drop or hit the XRpad2 LBP against hard objects as this may cause a risk of damage to the XRpad2 LBP, which may result in exposure to the corrosive cell contents, fire, or explosion.

8.5.1.2 Installing the XRpad2 LBP

When installing the XRpad2 LBP in the X-ray detector in place of the XRpad2 Protective Insert, or to change a used XRpad2 LBP, remove the XRpad Protective Insert or used XRpad2 LBP before installing the new XRpad2 LBP (see [“Section 8.5.1.3, Removing the XRpad2 LBP” on page 16](#)).

**WARNING**

There is risk of explosion, personal injury, or damage to the product if the Battery XRpad2 LBP is replaced by a non-OEM approved component.

To install the XRpad2 LBP:

- 1 Fully support the X-ray detector to prevent it from dropping or slipping.
- 2 Check to ensure the battery compartment of the X-ray detector is clean, dry, and free of foreign contamination or debris. If cleaning is necessary, see [“Section 8.5.1.6, Cleaning the XRpad2 LBP” on page 17](#) for cleaning instructions.
- 3 Check to ensure the XRpad2 LBP is clean, dry, and free of foreign contamination or debris. If cleaning is necessary, refer to [“Section 8.5.1.6, Cleaning the XRpad2 LBP” on page 17](#) for cleaning instructions.
- 4 The XRpad2 LBP is keyed and can only be inserted into the XRpad2 4336 detector in one orientation. Align the orientation of the XRpad2 LBP to match the orientation required on the X-ray detector.
- 5 Insert the charged XRpad2 LBP into the X-ray detector in the corresponding orientation, and gently press on the end cap until the latches secure the XRpad2 LBP inside the detector.

- 6 Push the **Power** button on the X-ray detector to power on.
- 7 Check the battery charge status on the X-ray detector. If the battery charge status shows sufficient battery charge is present, the X-ray detector is ready for use. If the battery charge status shows lower than desired battery charge level, replace the battery with a charged battery.

8.5.1.3 Removing the XRpad2 LBP



Caution

Dispose of a used XRpad2 LBP according to the instructions in ["Section 11.0, Disposing of the X-ray Detector" on page 35.](#)

To remove the XRpad2 LBP:

- 1 Fully support the X-ray detector and XRpad2 LBP before performing this task to prevent them from dropping or slipping.
- 2 Power off the X-ray detector by pressing the **Power** button on the X-ray detector.
- 3 Move the two sliding latches closer to the center to disengage the XRpad2 LBP from the X-ray detector (see [Figure 5](#)). Remove the XRpad2 LBP from the battery compartment of the X-ray detector using a slow and steady pulling motion, supporting both the X-ray detector and the XRpad2 LBP.
- 4 Store the XRpad2 LBP in a cool, dry, clean environment if not in use or when recharging the XRpad2 LBP for the next use.



Figure 5 Removing the XRpad2 LBP

8.5.1.4 Transportation and Storage

When transporting and storing the XRpad2 LBP:

- Follow all local, state, and federal/national regulations for handling, packaging, labeling, and transporting Lithium-Ion batteries.
- Before transporting the battery, inspect it to confirm that there is no damage or leakage from the battery.
- When possible, transport the battery in a discharged state.
- Transport the battery in approved packaging only. Retain the original packaging, inclusive of the Safety Data Sheet (SDS), for transporting the battery.
- Store the battery in a cool, dry, clean environment if not in use. Do not remove the battery from its original packaging until required for use.

- Store within approved temperatures: -20°C to 45°C for short periods (less than one month). Recommended storage conditions are 15°C to 35°C, 85% RH Max.
- Do not leave or store the battery in extremely hot or cold temperatures (for example, in direct sunlight, cars, or car trunks). The battery may overheat causing fire, or performance life will be shortened.
- Do not short-circuit the battery or store the battery without sufficient packaging in a location where it may short-circuited. This may cause a risk of fire, an explosion, or a severe burn hazard.

8.5.1.5 Maintaining the XRpad2 LBP

To maintain the XRpad2 LBP:

- Before inserting the XRpad2 LBP into the X-ray detector or XRpad LBC, inspect the XRpad2 LBP for signs of damage, defects, or abnormalities. Do not use damaged, defective, or abnormal conditioned XRpad2 LBP.
- Check to ensure the XRpad2 LBP is clean, dry, and free of foreign contamination or debris. If cleaning is necessary, see [“Section 8.5.1.6, Cleaning the XRpad2 LBP” on page 17](#) for cleaning instructions.
- The XRpad2 LBP has no repairable parts. Do not disassemble. No modification of this product is allowed.
- If the XRpad2 LBP emits an odor or generates heat or in any way appears abnormal during use, recharging, or storing, immediately remove it from the device or battery charger, and stop using the XRpad2 LBP.
- Using a damaged or defective XRpad2 LBP may reduce function time or cause the X-ray detector system to fail.
- If an XRpad2 LBP leaks, do not touch the leaking fluid. If the fluid touches your skin or eyes, wash the affected area with clean, running water and immediately seek medical attention.
- If the XRpad2 LBP has not been used or charged for an extended period of time (approximately 30 days), check the condition of the XRpad2 LBP, and recharge if necessary before using.

8.5.1.6 Cleaning the XRpad2 LBP

To clean the XRpad2 LBP:

- Avoid exposure of the XRpad2 LBP to liquids and solvents when possible.
- Do not allow liquids or solvents to contact the electrical contacts on the XRpad LBP.
- When necessary, clean the XRpad2 LBP using a lightly moistened cloth with 70% isopropyl alcohol or 3% hydrogen peroxide.
- Never use thinner, benzene, acetone, or any other corrosive or flammable cleaning agents.
- Ensure the XRpad2 LBP is completely clean and dry before storing inserting the XRpad2 LBP into the X-ray detector, or inserting the XRpad2 LBP into the XRpad LBC.

8.5.1.7 Disposing of the XRpad2 LBP

To dispose of the XRpad2 LBP:

- The XRpad2 LBP shall not be disposed with other waste at the end of its working life.
- Recycle or dispose the battery in accordance with local, state, and federal/national laws and environmental regulations.
- Do not place the battery in fire or incinerate.
- For transporting, follow the requirements in [“Section 8.5.1.4, Transportation and Storage”](#) on page 16.

8.5.2 XRpad IPU-2

The XRpad IPU-2 is an Interface and Power Unit. The XRpad IPU-2 combines the Power Supply Unit with additional communication and trigger interfaces. The tethered power and communication cable is connected to the X-ray detector. The communication data are split inside the XRpad IPU-2 into Gigabit Ethernet Interface, Detector Trigger Interface, Hand Switch and Generator Interface, and Detector Push Button Interface. The Gigabit Ethernet Interface of the XRpad IPU-2 is connected to the Imaging Workstation using a Cat 5e/6 cable. The maximum cable length is 31m. The AC cable must be connected to a properly grounded receptacle. The AC cable is removable and will be plugged to an IEC connector. The XRpad IPU-2 must be connected with a ground by the functional ground connector (Figure 6 [13]) or with the potential of the hospital by the potential equalization connector (Figure 6 [12]). The socket outlet shall be near the XRpad IPU-2 and shall be easily accessible. To isolate the equipment electrically from supply main on all poles simultaneously, the supply main switch (Figure 6 [1]) must be used.



WARNING

Connecting the XRpad IPU-2 LAN port directly to the clinical computer network may disturb the IT environment.

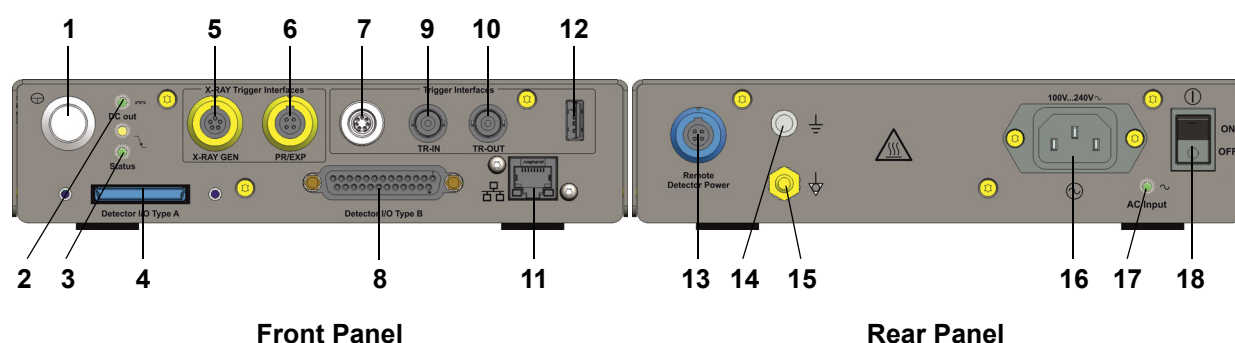


Figure 6 XRpad IPU-2

Table 10 includes an overview of the XRpad IPU-2.

Table 10 Overview of the XRpad IPU-2

1	XRpad Push Button (⊕)	
2	DC Output LED (Yellow) (==)	
	LED Yellow	DC Output OK, no output load
	LED Green	DC Output OK, output loaded
3	Status LED (Yellow) (↘)	
	LED Yellow	N/A
	LED Green	N/A
4	XRpad Interface and Power I/O (1)	
5	Trigger Out Signal to Generator	
6	Trigger In Signal from Hand Switch (Prep/Expose)	
7	Trigger In/Out I/F	
8	XRpad Interface and Power I/O	
9	TRIG IN Signal	
10	TRIG OUT Signal	
11	LAN Port to Imaging Workstation	
12	USB Connector	
13	Remote Detector Power	
14	Potential Equalization Connector	
15	Functional Ground Connector	
16	Power In	
17	AC Input LED (Green) (↘)	
18	XRpad IPU-2 Power Switch	

Table 11 includes the specification for the XRpad IPU-2.

Table 11 Specification of the XRpad IPU-2

Electrical Specification	
AC Input Voltage [16]	100 V ... 240 V
AC Frequency [16]	50 Hz/60 Hz
DC Output [8]	12.5 V/5 A, 15 V/1 A (voltage level is dependent of load)
Trigger In Signal from Hand Switch [6]	5 V ... 24 V/10 mA (SELV)
Trigger Out Signal to Generator [5]	Same level as Trigger In Signal
Trigger In Signal [7, 9]	3.3 V ... 5 V (SELV)
Trigger Out Signal [7, 10]	3.3 V
DC Output 5PF [7]	5 V/100 mA
Mechanical Specification	
Size	260 mm (L) × 205 mm (W) × 50 mm (H)
Temperature Ranges	
Operating	10°C to 35°C
Transportation/Storage	-10°C to 70°C
Relative Humidity	
Operating	10% to 90%
Transportation/Storage	0% to 90%
Ingress Protection Rating	
IP40 rated (protection against particles > 1 mm)	



WARNING

All external signals that are connected to the IPU-2 (especially PREP/ EXPOSE and Trigger signals) should be from a Separated or Safety Extra-Low Voltage (SELV) circuit. Ignoring this warning may result in electric shock, which may result in severe personal injury, death, or substantial product damage.

8.5.2.1 Cleaning the XRpad IPU-2

If the XRpad IPU-2 (Interface and Power Unit) surface is dirty or dusty, clean it with a cleaning cloth dampened with ethanol or a diluted neutral detergent. If you are using a disinfectant other than those specified, we recommend you consult a specialist for the procedure for disinfection. Turn off the XRpad IPU-2, and disconnect the AC power cable, detector power, and detector communication tethered cables before cleaning.



WARNING

When the Interface Power Unit is going to be cleaned, be sure to turn off the XRpad IPU-2 (Interface and Power Unit), and unplug all cables. Never use thinner, benzine, acetone, or other flammable cleaning agents. Ignoring this warning may result in explosion, fire, or electric shock, which may result in severe personal injury, death, or substantial product damage.





8.6 Minimum System Requirements

The following are the minimum requirements for the host computer that controls the X-ray detector.

- 1 Gigabit Ethernet Infrastructure and a free Gigabit Ethernet Port or Wi-Fi Infrastructure.
- 2 Intel compatible Multi Core Processor (> 2 GHz).
- 3 RAM > 4 GB.
- 4 Windows 7 (32-bit/64-bit).
- 5 If a Firewall is used, make sure that it allows a connection to the detector.
- 6 Access Point:
 - a WPA2 encryption support.
 - b 802.11n standard with 20 MHz channel bandwidth 36-48, 52-64, 100-116, 132-140, 149-165.
 - c MIMO 3x3.
 - d Complying with IEC 60601-1 or IEC 60950-1.

8.7 Operating the X-ray Detector

Before connecting the X-ray detector, ensure that the Digital Radiography Software is installed as described in its manual. If not, install the software first. The X-ray detector can be used in different configurations depending on the desired application. The following sections describe the different use cases.

 WARNING	Do not exceed the maximum uniform load weight of 150 kg distributed across the surface of the X-ray detector.
 WARNING	Do not exceed the maximum load weight of 100 kg distributed at one location in a 40mm diameter of the X-ray detector surface.
 Caution	Check the threshold of the auto trigger mode regularly.
 Caution	Do not acquire images and calibration files while handling the detector. This can disturb the image quality and result in the wrong diagnosis.

8.7.1 Wired X-ray Detector Connection

Figure 7 shows the wired connection of the X-ray detector in a clinical environment. In the wired application, the X-ray detector is connected to the XRpad IPU-2, which powers the X-ray detector and is responsible for the data transfer. The AC outlet should be installed near the XRpad IPU-2 and should be easily accessible.

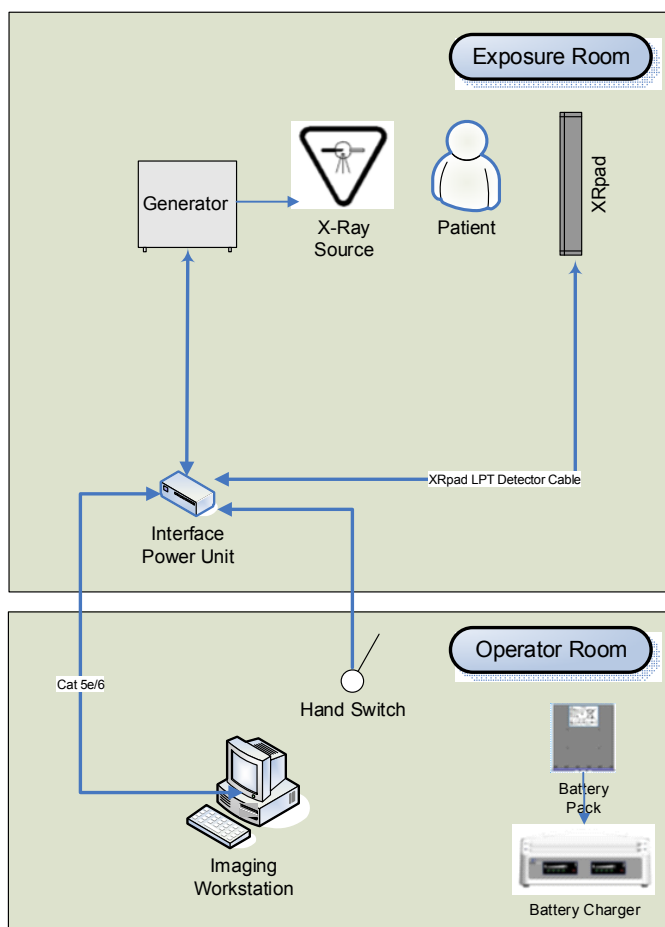


Figure 7 Wired Connection of the X-ray Detector

The XRpad IPU-2 may be mounted in an equipment enclosure if there is adequate ventilation within the equipment enclosure. The XRpad IPU-2 is connected to the Imaging Workstation using a Cat 5e/6 cable. Make sure that the XRpad IPU-2 is not connected directly with the clinical network. The Trigger I/F of the XRpad IPU-2 must be connected with the Generator and with the Hand switch if the detector is used in external trigger mode.

The XRpad IPU-2 communicates using a standard Gigabit Ethernet network Interface and comes equipped with an RJ45 interface port. Due to the overall network traffic, it is recommended that you use this interface in a direct (Point-to-Point) connection with the host computer in order to achieve optimal speed performance. The XRpad IPU-2 should be connected to the host computer by one of the PerkinElmer XRD GigE Interface Cables or a CAT5e/CAT6 (shielded twisted pair, stranded, or solid copper conductor) cable. The cable length can be up to 31 m.

8.7.2 Wireless X-ray Detector Connection

Figure 8 shows the wireless connection of the X-ray detector in a clinical environment. The X-ray detector is connected using WLAN over a Wi-Fi Access Point with the Imaging Workstation. The Wi-Fi Access Point may be wall or ceiling mounted to maximize wireless signal strength. Make sure that the router is not connected directly to the clinical network. The detector can also be connected directly to the Imaging Workstation using WLAN with the WAP mode of the detector (see Figure 9). Before imaging, make sure that the XRpad2 LBP charge is sufficient and the X-ray detector antenna is not obstructed.

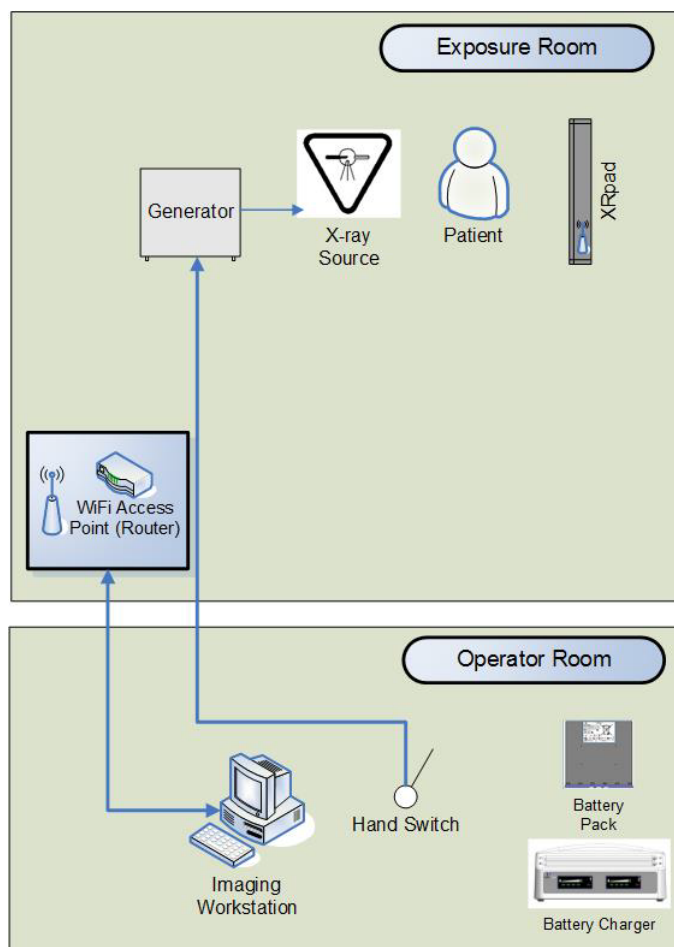


Figure 8 Wireless Connection of the X-ray Detector (Station/Client Mode)

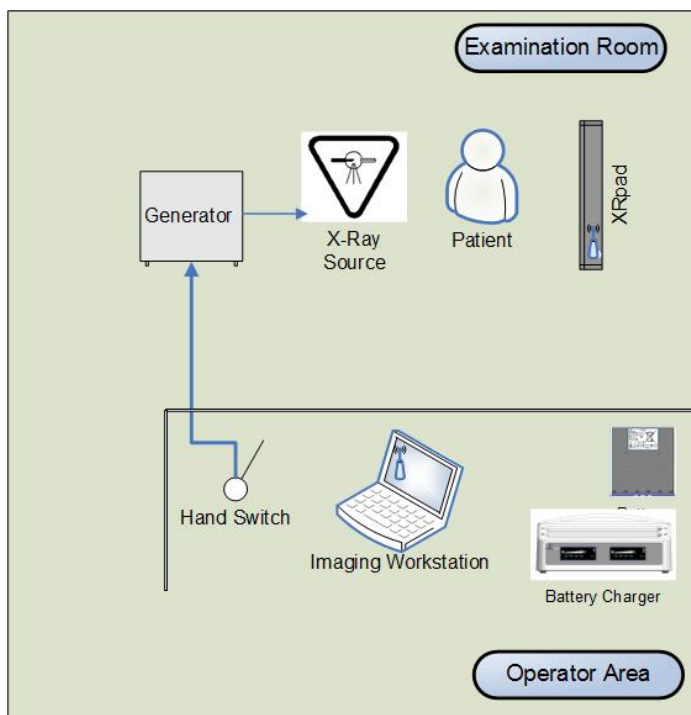




Figure 9 Wireless Connection of the X-ray Detector (WAP Mode)

8.7.3 Before Using the X-ray Detector

Sudden cooling or heating of the room will cause condensation. In this case, wait until condensation disappears before powering on the X-ray detector.

 WARNING	<p>If the X-ray detector system is used under conditions where condensation can occur, problems in image quality or malfunction of the detector system may occur. In addition, this may cause fire, electrical shock, and unknown hazards, which may result in severe personal injury, death, or substantial product damage.</p>
 Caution	<p>The X-ray detector should only be used with an inserted XRpad2 LBP or XRpad2 Protective Insert.</p>

8.7.4 Powering On the X-ray Detector

This section describes how to power on the X-ray detector. For more information, refer to the *Digital Radiography Software Manual*. Ensure that the IP setting on your network adapter is set to static IP and correlates to the X-ray detector. The default settings of the X-ray detector are 192.168.2.158 for the LAN connection and 192.168.22.1 for the WLAN connection with the submask 255.255.255.0. The X-ray detector must have an XRpad2 Protective Insert or an XRpad2 LBP inserted into battery compartment.

8.7.4.1 Wired Mode

To power on the X-ray detector in wired mode:

- 1 Plug in the power cord to the XRpad IPU-2, and switch the power on.

The AC Input LED turns on (green), and the DC Output LED turns on (yellow).

- 2 To power on the X-ray detector, press the X-ray detector **Power** push button on the XRpad IPU-2, or press the push button on the X-ray detector for one second.

The DC Output LED turns from yellow to green, and the detector push button LED turns ON for a few seconds.

During the initialization of the detector, the detector push button LED starts flashing. Once the X-ray detector is powered on, the X-ray detector display is on and shows the current status of the X-ray detector. The X-ray detector LED will turn from flashing to constant on. After the Radiography Imaging Software has initialized the detector, the X-ray detector LED starts flashing.

8.7.4.2 Wireless Mode

To power on the X-ray detector in wired mode:

- 1 When the detector is not connected to the XRpad IPU-2, check the status of the XRpad LBP to ensure the charge of the battery is more than 50%. If the status is low, exchange the XRpad2 LBP with a charged one, or use the wired operation mode.
- 2 Press the X-ray detector's push button for one second, and the X-ray detector will be powered on, which is shown by the detector's push button LED.

During the initialization of the detector, the detector push button LED starts flashing. Once the X-ray detector is powered on, the X-ray detector display is on and shows the current status of the X-ray detector including battery status. The X-ray detector LED will turn from flashing to constant on. After the Radiography Imaging Software has initialized the detector, the X-ray detector LED starts flashing.

8.7.5 Powering Off the X-ray Detector

The X-ray detector is powered off by holding down one of the following three push buttons for more than four seconds:

- X-ray detector (Figure 1 [5]) (wireless and wired mode).
- XRpad IPU-2 push button (Figure 6 [5]) (wired mode).
- Extended hand switch push button (wired mode)

8.7.6 General Workflow for Acquiring an Image

Figure 10 shows the procedure for acquiring a clinical image after starting the Radiography Imaging Software. Details of the Radiography Imaging Software and the X-ray generator are described in their corresponding operation manuals.

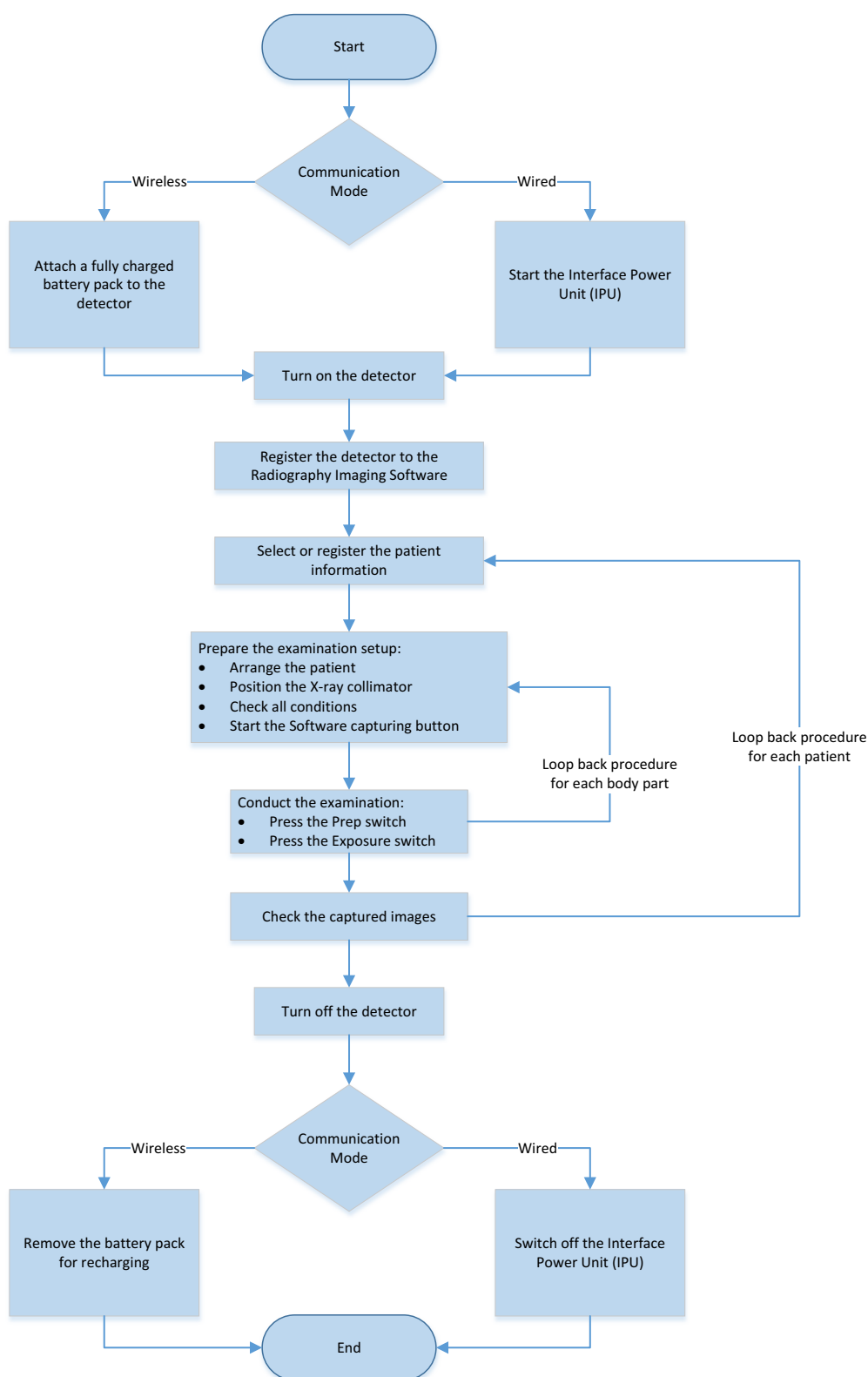




Figure 10 Workflow for Acquiring an Image

9.0 Inspection and Maintenance

 WARNING	The X-ray detector must be repaired by PerkinElmer authorized personnel only. Ignoring this warning may result in explosion, fire, electric shock, or unknown hazards, which may result in severe personal injury, death, or substantial product damage.
 Caution	Inspect the X-ray detector before use. In addition, carry out prescribed, regular inspections per the instructions in this manual.

It is important that the X-ray detector is used safely and as intended. Inspect the detector and its accessories before use. If any problem is found during the inspection, correct the problem, and take the measures indicated in this section. The X-ray detector and the Interface and Power Unit do not have any internal exchangeable parts. Only the accessories listed in [Table 8](#) can be changed after consulting your with establishment’s safety representative. If the problem cannot be corrected, contact your dealer, distributor, device manufacturer, or any PerkinElmer subsidiaries (regional service headquarters) listed on the last page of this document.

We recommend that records of the inspection be kept close to the detector. You can use copies of the checklist in this section, or you can make your own copies of the checklist.

9.1 Daily Inspection

Perform the following inspection daily. If there is any problem, immediately ask your establishment’s safety representative to contact your dealer, distributor, or device manufacturer.

9.1.1 Before Turning On the Power

Inspection		Result			Remedy
		Date /	Date /	Date /	
Cables	Check all cables, if applicable, (Power and communication tethered cord, DC-cable, Ethernet cable, Sync cable) to ensure that they are not damaged and the insulation is not damaged.	Good/Bad	Good/Bad	Good/Bad	Contact your dealer, distributor, or device manufacturer if there is a problem.
	Check all connector plugs and locks to ensure they are not loose.	Good/Bad	Good/Bad	Good/Bad	Fully insert the cables and lock them.

	Inspection	Result			Remedy
		Date /	Date /	Date /	
Detector	Check that the detector is not damaged.	Good/Bad	Good/Bad	Good/Bad	Contact your dealer, distributor, or device manufacturer if there is a problem.
	Check the manufacturing date of the Battery Pack to ensure that its age is not five years or older.	Good/Bad	Good/Bad	Good/Bad	Replace the Battery Pack with a new one and recycle the old one.
	Check that the Battery Pack (wireless mode) or the Protective Insert (wired mode) is in the battery compartment and the sliding latches are closed.	Good/Bad	Good/Bad	Good/Bad	Slide the Battery Pack or the Protective Insert into the battery compartment as described in “Section 8.5.1.3, Removing the XRpad2 LBP” on page 16.
	Check that the Battery Pack is not damaged.	Good/Bad	Good/Bad	Good/Bad	Replace the Battery Pack with a new one.
	Check that the detector is not loose and all screws are fixed.	Good/Bad	Good/Bad	Good/Bad	Contact your dealer, distributor, or device manufacturer if there is a problem.

9.1.2 After Turning On the Power

	Inspection	Result			Remedy
		Date /	Date /	Date /	
General	Check that the wireless connectivity or the AP symbol (📶) is shown in the display if wireless mode is used.	Good/Bad	Good/Bad	Good/Bad	Connect the X-ray detector and the Wi-Fi Access Point as described in the <i>Access Point Manual</i> .
	Check that the LAN connectivity symbol (🌐) is shown in the display if the wired mode is used.	Good/Bad	Good/Bad	Good/Bad	Connect the Gigabit Ethernet cable and the tethered power and communication cable properly.
	Check the battery charge condition (Battery Half or better (🔋)).	Good/Bad	Good/Bad	Good/Bad	Exchange the Battery Pack with a charged one.
	Check that the detector LED is ON.	Good/Bad	Good/Bad	Good/Bad	Set the Detector to Exposure Ready as described in the <i>Digital Radiography Software Manual</i> .
	Perform test exposure as described in the <i>Digital Radiography Software Manual</i> .	Good/Bad	Good/Bad	Good/Bad	If any error messages appear, follow the instructions in the <i>Digital Radiography Software Manual</i> . If there is a problem, contact your dealer, distributor, or device manufacturer.

9.1.3 After Turning Off the Power

	Inspection	Result			Remedy
		Date /	Date /	Date /	
General	Check that the X-ray detector is turned off normally and that all LEDs are OFF.	Good/Bad	Good/Bad	Good/Bad	See “Section 8.7.5, Powering Off the X-ray Detector” on page 27 for turning off the X-ray detector.
	Make sure that the X-ray detector is clean and disinfected.	Good/Bad	Good/Bad	Good/Bad	See “Section 9.5, Cleaning the X-ray Detector” on page 33 for cleaning the X-ray detector.

9.2 Monthly Inspection

Perform the following inspection at least once a month. If there is a problem, immediately ask your establishment's safety department to contact your dealer, distributor, or device manufacturer.

	Inspection	Result			Remedy
		Date /	Date /	Date /	
General	Execute the Dark Noise and X-ray Uniformity tests (refer to the <i>XRpad2 4336 Digital X-ray Detector System Reference Manual</i>).	Good/Bad	Good/Bad	Good/Bad	If there are changes in performance, acquire new calibration files as described in the <i>Digital Radiography Software Manual</i> . Contact your dealer, distributor, or device manufacturer if there is any problem.
	Make sure that the XRpad IPU-2 is clean from dirt or dust.	Good/Bad	Good/Bad	Good/Bad	Use the instructions in "Section 8.5.1.6, Cleaning the XRpad2 LBP" on page 17 for cleaning.
	Check the manufacturing date of all Battery Packs to ensure that their age is not five years or older.	Good/Bad	Good/Bad	Good/Bad	Replace the Battery Pack with a new one and recycle the old one.

9.3 Yearly Inspection

Perform the following inspection at least once a year. If there is any problem, immediately ask your establishment's safety department to contact your dealer, distributor, or device manufacturer.

	Inspection	Result			Remedy
		Date /	Date /	Date /	
General	Execute the Dark Noise, X-ray Uniformity, Bad Pixel, and Resolution tests (refer to the <i>XRpad2 4336 Digital X-ray Detector System Reference Manual</i>).	Good/Bad	Good/Bad	Good/Bad	If there are changes in performance, acquire new calibration files as described in the <i>Digital Radiography Software Manual</i> . Contact your dealer, distributor, or device manufacturer if there is any problem.

9.4 Calibrating the X-ray Detector

When exposure conditions have changed significantly (for example, new energy settings, new X-ray tube, and new distances), acquire new gain calibration files. Follow the instructions in the *Digital Radiography Software Manual* for acquiring new calibration files. Never acquire calibration files while handling or transporting the detector.



WARNING

Do not acquire images and calibration files while handling the detector. This can disturb the image quality and result in the wrong diagnosis.

9.5 Cleaning the X-ray Detector



WARNING

When the detector system is going to be cleaned, be sure to turn off X-ray detector and remove the battery. If the detector is connected to a power supply, turn off the power switch and/or unplug the power and communication tethered cable, if applicable. If the X-ray detector is battery powered, remove the battery. Never use thinner, benzene, acetone, or other flammable cleaning agents. Ignoring this warning may result in explosion, fire, or electric shock, which may result in severe personal injury, death, or substantial product damage.

To clean the X-ray detector:

- 1 Turn off the X-ray detector and the power and communication tethered cable, if applicable.
- 2 Insert the XRpad2 Protective Insert into the battery compartment before cleaning or disinfecting the detector.
- 3 If the detector surface is dirty, clean it with a cleaning cloth dampened with ethanol or a diluted neutral detergent.



Note

If you are using a disinfectant other than those specified, we recommend you consult a specialist for the procedure for disinfection.

Do not allow any fluid, detergent, or solution to get inside the battery compartment of the X-ray detector.

- 4 Remove any excess detergent or solution.
- 5 Wipe the X-ray detector surface with a clean cloth to completely dry the X-ray detector.
- 6 Allow the X-ray detector to completely air dry before turning on or storing the X-ray detector.

9.6 Error Messages and Troubleshooting

If any error messages appear, follow the instructions in the *Digital Radiography Software Manual*. If there is any problem that is not described in the manual, immediately ask your establishment's safety representative to contact your dealer, distributor, or device manufacturer. Further use may result in severe personal injury, death, or substantial product damage.



WARNING

If any abnormal condition, such as smoke, fumes, or strange sounds, is evident, turn off the X-ray detector, turn off and unplug the power supply from the AC outlet, and immediately ask your establishment's safety representative to contact your dealer, distributor, or device manufacturer.

Further use under abnormal conditions may result in severe personal injury, death, or substantial product damage.

10.0 After-Sales Service for PerkinElmer Products

Contact your sales person, distributor, or device manufacturer for after-sales service (including warranty) or any other information. If information is not available, contact one of the PerkinElmer subsidiaries (regional service headquarters) listed on the last page of this document.

Field service is limited to replacement of the detector or adding and replacing approved accessories by authorized personnel. The detector and its accessories are not intended to be repaired in the field.

For product returns, contact your distributor or device manufacturer for shipping and packaging instructions. Do not return products to PerkinElmer for repair or service without advance notification. Include all required papers in the shipment.

If the X-ray detector or accessories have been contaminated with potentially harmful substances or activated by high energy X-rays, gamma rays, or neutrons, they cannot be accepted without written evidence of decontamination.

To ship the XRpad2 LBP, follow the local and regional requirements for proper packaging and shipping of Lithium Batteries.

11.0 Disposing of the X-ray Detector

If the X-ray detector is activated by high energy X-rays, gamma rays, or neutrons follow the local radiation protection regulation.

Contact your supplier or distributor, and check the terms of conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

A label with a crossed-out wheeled bin symbol and a rectangular bar indicates that the product is covered by the Waste Electrical and Electronic Equipment (WEEE) Directive and is not to be disposed of as unsorted municipal waste. Any products marked with this symbol must be collected separately, according to the regulatory guidelines in your area.



The objectives of this program are to preserve, protect, and improve the quality of the environment, protect human health, and utilize natural resources prudently and rationally. Specific treatment of WEEE is indispensable in order to avoid the dispersion of pollutants into the recycled material or waste stream. Such treatment is the most effective means of protecting the customer's environment.

Requirements for waste collection, reuse, recycling, and recovery programs vary by regulatory authority at your location. Contact your local responsible body (for example, your hospital, clinic, establishment, or site manager) or authorized representative for information regarding applicable disposal regulations. Contact PerkinElmer at the following web site for information specific to PerkinElmer products.

Web Address:

<http://www.perkinelmer.com/pages/010/onesource/environmental-health-and-safety/environmental-directives-compliance.xhtml>

The PerkinElmer product may be attached as part of a component to other manufacturers' systems. These other manufacturers are directly responsible for the collection and processing of their own waste products under the terms of the WEEE Directive. Contact these producers directly before discarding any of their products. Consult the PerkinElmer web site (above) for producer names and web addresses.

12.0 Declarations

This section includes the manufacturers' declaration of standards and/or regulations for which the product complies.

12.1 Guidance and Manufacturer's Declaration

Table 12 Guidance and Manufacturer's Declaration of Electromagnetic Emissions

Guidance and Manufacturer's Declaration of Electromagnetic Emissions		
The X-ray detector is intended for use in the electromagnetic environment specified below. The installer, X-ray system manufacturer, or user of the X-ray detector is responsible for the usage condition of the detector to be within such environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF-emissions CISPR 11	Group 1	The X-ray detector 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. Should any interference (EMC) be detected with any other equipment, reposition the X-ray detector or the other equipment away from each other.
RF-emissions CISPR 11	Class B (wireless) Class A (wired)	The X-ray detector is suitable for use in industrial and clinical environments in the wired mode.
Harmonic emissions IEC 61000-3-2	Class B (wireless) Class A (wired)	In the wireless mode the X-ray detector is suitable for use in all environments within Class B.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	Should any interference (EMC) be detected with any other equipment, reposition the X-ray detector or the other equipment away from each other.


Table 13 Guidance and Manufacturer's Declaration of Electromagnetic Immunity

Guidance and Manufacturer's Declaration of Electromagnetic Immunity			
The X-ray detector is intended for use in the electromagnetic environment specified below. The installer, X-ray system manufacturer, or user of the X-ray detector is responsible for the usage condition of the detector to be within such environment.			
Immunity Test	IEC 60601 Test	Compliance	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	Contact: 6 kV Air: 8 kV	Contact: 6 kV Air: 8 kV	Floors should be made of wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients (Burst) IEC 61000-4-4	0.5 kV (AC) 1 kV (DC)	0.5 kV (AC) 1 kV (DC)	Mains power quality should be that of a typical commercial and/or hospital environment.
Transients-Surges IEC 61000-4-5	1 kV / 2 kV	1 kV / 2 kV	Mains power quality should be that of a typical commercial and/or hospital environment.
Power frequency 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 and/or hospital environment.
Voltage dips and short interruptions IEC 61000-4-11	-95%/10 ms -60%/100 ms -30%/500 ms >-95%/5000 ms	-95%/10 ms -60%/100 ms -30%/500 ms >-95%/5000 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the X-ray detector requires continued operation during power mains interruptions, we recommend that the X-ray detector be powered from an uninterruptible power supply or battery.

Table 14 Recommended Separation Distance between Portable and Mobile RF-Communication Equipment and the X-ray Detector

Recommended Separation Distance between Portable and Mobile RF-Communication Equipment and the X-ray Detector			
The X-ray detector is intended for use in the electromagnetic environment specified below. The installer, X-ray system manufacturer, or user of the X-ray detector should assure that it is used in such an environment.			
Rated Maximum Output Power of the Transmitter (W)	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For a transmitter rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output (power rating of the transmitter in watt [W]) according to the transmitter manufacture and d is the recommended separation distance in meter (m).			
Note: This guideline may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Table 15 Guidance and Manufacturer's Declaration of Electromagnetic Immunity (Portable Equipment)

Guidance and Manufacturer's Declaration of Electromagnetic Immunity			
The X-ray detector is intended for use in the electromagnetic environment specified below. The installer, X-ray system manufacturer, or user of the X-ray detector should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test	Compliance	Electromagnetic Environment – Guidance
Conducted radio-frequency fields (CEF) IEC 61000-4-6	3 V 150 kHz to 80 MHz	[V1] 3 V 150 kHz to 80 MHz	Portable and mobile RF-communication equipment should not be closer to any part of the X-ray detector including the data cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. $d = 1.2\sqrt{P}$, for 150 kHz to 80 MHz, $d = 1.2\sqrt{P}$, for 80 MHz to 800 MHz, $d = 2.3\sqrt{P}$, for 800 MHz to 2.5 GHz, where P is the maximum output of the transmitter in watt (W) according to the transmitter manufacturer and d is the recommended separation distance in meter (m). Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than 3 V/m. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated electromagnetic field (REF) IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E1] 3 V/m 80 MHz to 2.5 GHz	
<p>Note 1: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> <p>Note 2: It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.</p>			

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, 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 the measured field strength in the location in which the X-ray detector is used exceeds the applicable RF compliance level above, the X-ray detector should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the X-ray detector.

12.2 Declaration of Conformity for European Union (and EEA)

English	Hereby, PerkinElmer Inc. declares that this XRpad2 4336 is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.
Česky	PerkinElmer Inc. tímto prohlašuje, že tento XRpad2 4336 je ve shodě se základními požadavky a dalšími příslušnými ustanoveními směrnice 1999/5/ES.
Dansk	PerkinElmer Inc. erklærer herved, at denne XRpad2 4336 overholder de væsentlige krav samt øvrige relevante bestemmelser i direktiv 1999/5/EF.
Deutsch	Hiermit erklärt PerkinElmer Inc., dass der XRpad2 4336 den grundlegenden Anforderungen und anderen einschlägigen Bestimmungen der Richtlinie 1999/5/EG entspricht.
Eesti	Käesolevaga kinnitab PerkinElmer Inc. seadme XRpad2 4336 vastavust direktiivi 1999/5/EU põhinõuetele ja nimetatud direktiivist tulenevatele teistele asjakohastele sätetele.
Español	Por medio de la presente, PerkinElmer Inc. declara que el XRpad2 4336 cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 1999/5/CE.
Français	Par la présente, PerkinElmer Inc. déclare que ce XRpad2 4336 est en conformité avec les exigences essentielles et autres dispositions pertinentes de la directive 1999/5/CE.
Ελληνική	ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ Η PerkinElmer Inc. ΔΗΛΩΝΕΙ ΟΤΙ ΤΟ XRpad2 4336 ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 1999/5/EK.
Italiano	Con la presente, PerkinElmer Inc. dichiara che questo XRpad2 4336 è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti della direttiva 1999/5/CE.
Íslenska	Her með lýsir PerkinElmer Inc. yfir því að XRpad2 4336 er í samræmi við grunnkröfur og aðrar kröfur, sem gerðar eru í tilskipun 1999/5/EC.
Latviski	Ar šo PerkinElmer Inc. paziņo, ka XRpad2 4336 atbilst Direktīvas 1999/5/EK būtiskajām prasībām un citiem ar to saistītiem noteikumiem.
Lietuviu	PerkinElmer Inc. patvirtina, kad šis XRpad2 4336 atitinka Direktyvos 1999/5/EB esminius reikalavimus ir kitas nuostatas.
Malti	Hawnhekk, PerkinElmer Inc., jiddikjara li dan XRpad2 4336 jikkonforma mal-htigijiet essenzjali u ma provvedimenti oħrajn relevanti li hemm fid-Dirrettiva 1999/5/EC.
Magyar	Alulírott, PerkinElmer Inc. nyilatkozom, hogy az XRpad2 4336 megfelel a vonatkozó alapvető követelményeknek és az 1999/5/EK irányelv egyéb előírásainak.
Nederlands	Hierbij verklaart PerkinElmer Inc. dat het toestel XRpad2 4336 in overeenstemming is met de essentiële eisen en de andere relevante bepalingen van richtlijn 1999/5/EG.
Norsk	PerkinElmer Inc. erklærer herved at utstyret XRpad2 4336 er i samsvar med de grunnleggende krav og øvrige relevante krav i direktiv 1999/5/EF.

Polski	Niniejszym PerkinElmer Inc. oświadcza, że XRpad2 4336 jest zgodny z zasadniczymi wymogami oraz pozostałymi stosownymi postanowieniami Dyrektywy 1999/5/EC.
Português	PerkinElmer Inc. declara que este XRpad2 4336 está conforme com os requisitos essenciais e outras disposições da Directiva 1999/5/CE.
Suomi	PerkinElmer Inc. vakuuttaa taten etta XRpad2 4336 tyyppinen laite on direktiivin 1999/5/EY oleellisten vaatimusten ja sita koskevien direktiivin muiden ehtojen mukainen.
Slovensko	PerkinElmer Inc. izjavlja, da je ta XRpad2 4336 v skladu z bistvenimi zahtevami in ostalimi relevantnimi določili direktive 1999/5/ES.
Svenska	Härmed intygar PerkinElmer Inc. att denna XRpad2 4336 står i överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 1999/5/EG.

The XRpad2 4336 may be operated in the following countries:

AT	BE	BG	CH	CY	CZ	DE	DK	EE	ES	FI
FR	GB	GR	HU	IE	IT	IS	LI	LT	LU	LV
MT	NL	NO	RO	PL	PT	SE	SI	SK		

12.3 Federal Communication Commission Interference Statement (US)¹

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.



Caution

Any changes or modifications not expressly approved by PerkinElmer Medical Imaging could void the user's authority to operate the equipment.



Note

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his or her own expense.

The country code selection is for non-US models only and is not available to all US models. Per FCC regulation, all Wi-Fi products marketed in the US must be fixed to US operation channels only.

IMPORTANT





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

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


1. Section is only applicable to the US

12.4 Industry Canada Statement (English)²

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.

 Caution	The device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems
 WARNING	The maximum antenna gain permitted for devices in the bands 5250-5350 MHz and 5470-5725 MHz shall comply with the e.i.r.p. limit.
 WARNING	The maximum antenna gain permitted for devices in the band 5725-5825 MHz shall comply with the e.i.r.p. limits specified for point-to-point and non-point-to-point operation as appropriate.
 WARNING	Users should also be advised that high-power radars are allocated as primary users (for example, priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices.





The product complies 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.

 Note	This equipment does not exceed the Class A limits for radiated emissions as described in the Radio Interference Regulations of the Canadian Department of Communications.
---	---

2. Section is only applicable to Canada.

12.5 Industrie Canada – Déclaration (Français)³

Le présent dispositif est conforme à la norme RSS-210 d'Industrie Canada. L'exploitation est autorisée aux deux conditions suivantes : (1) ce dispositif ne doit pas causer d'interférences nuisibles, et (2) ce dispositif doit accepter toute interférence reçue, y compris les interférences susceptibles de causer un dysfonctionnement.

 Mise en garde	Le dispositif fonctionnant dans la bande 5 150-5 250 MHz est réservé exclusivement à une utilisation en intérieur afin de réduire les risques d'interférences nuisibles pour les systèmes mobiles par satellite utilisant les mêmes canaux.
 Mise en garde	Le gain maximal d'antenne permis pour les dispositifs utilisant les bandes 5 250-5 350 MHz et 5470-5 725 MHz doit se conformer à la limite de p.i.r.e.
 Mise en garde	Le gain maximal d'antenne permis (pour les dispositifs utilisant la bande 5 725-5 825 MHz) doit se conformer à la limite de p.i.r.e. spécifiée pour l'exploitation point à point et non point à point, selon le cas.
 Mise en garde	De plus, les utilisateurs devraient aussi être avisés que les utilisateurs de radars de haute puissance sont désignés utilisateurs principaux (c.-à-d., qu'ils ont la priorité) pour les bandes 5 250-5 350 MHz et 5 650-5 850 MHz et que ces radars pourraient causer du brouillage et/ou des dommages aux dispositifs LAN-EL.

Le produit est conforme aux limites d'exposition pour les appareils portables RF pour les Etats-Unis et le Canada établies pour un environnement non contrôlé. Le produit est sûr pour un fonctionnement tel que décrit dans ce manuel. La réduction aux expositions RF peut être augmentée si l'appareil peut être conservé aussi loin que possible du corps de l'utilisateur ou que le dispositif est réglé sur la puissance de sortie la plus faible si une telle fonction est disponible.


Remarque: Cet appareil numérique ne dépasse pas les limites de la classe A pour les émissions radio, telles que définies dans le Radio Interference Regulations du Département Canadien des Communications.

Cet équipement ne dépasse pas les limites de la classe A pour les émissions rayonnées, telles que définies dans le règlement sur le brouillage radioélectrique édicté par le ministère des Communications du Canada.

CAN ICES-3 (A)/NMB-3 (A)/CAN NMB-3(A)

3. Section is only applicable to Canada.

12.6 Korean

Type of Equipment	User's Guide
A 급 기기 (업무용 방송통신기자재)	이 기기는 업무용 (A 급) 전자파적합기기로서 판매자 또는 사용자는 이 점을 주의하시기 바라며 , 가정외의 지역에서 사용하는 것을 목적으로 합니다 .
 주의	해당 무선설비는 전파혼신 가능성이 있으므로 인명안전과 관련된 서비스는 할 수 없음 해당 무선 설비는 5150-5250MHz 대역에서 실내 에서만 사용할 수 있음 .

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