

XRpad2 4343 Digital X-ray Detector 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 all applicable laws. The user is also responsible for compliance to laws pertaining to the privacy of image data.
- In no event is Varex 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, ionizing, 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 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	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.
 WARNING	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.
 WARNING	<p>The AED mode requires a sufficient X-ray dose rate to the detector surface to trigger image acquisition. The required dose rate can vary at different use conditions. The system integrator must evaluate the AED operation with the complete X-ray setup in order to secure the proper image acquisition in AED mode.</p> <p>Depending on conditions, including but not limited to, environmental conditions, installation method, X-ray system setup, and subject to be imaged, the use of AED mode may result in false trigger or no trigger of X-ray image acquisition. The risk of false trigger or no trigger of X-ray image acquisition must be assessed for the specific intended use and application. For the most reliable image acquisition method, use of the external or software trigger mode to synchronize with the X-ray source is recommended.</p>
 WARNING	Do not connect the X-ray detector or the interface-and-power unit (IPU-2) 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.
 WARNING	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.
 WARNING	The X-ray detector shall only be used with its approved Varex accessories and replacement parts. 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 installed network. Connection of the X-ray detector directly with the installed computer network may disturb the IT environment. The imaging workstation and the Wi-Fi access point must comply with IEC 60601-1 or IEC 60950-1.

 WARNING	The detector is not designed to control X-ray dose. The system integrator is responsible for controlling the X-ray radiation.
 WARNING	Connection of the X-ray detector to the installed IT network that includes other equipment could result in previously unidentified risk to patients, operators or third parties. the responsible organization should identify, analyze, evaluate and control these risk. Subsequent changes to the IT-network could introduce also new risks and require additional analysis.
 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 • Environment where there is insufficient air circulation to enable the X-ray detector, and power supply to dissipate heat. <p>Ignoring this caution may result in personal injury or damage to the product.</p>
 Caution	When using the X-ray detector in Automatic Exposure Detection (AED) mode, the temperature may increase due to the heat generated by the X-ray detector electronics to support the AED mode. Follow the integration guide and instructions for the use of the X-ray detector in AED mode. Ignoring this caution may result in personal injury or damage to the product.
 Caution	Monitor the temperature of the X-ray detector and allow the detector to cool down when the temperature of the detector gets hot. Ignoring this caution may result in personal injury or damage to the product.
 Caution	An Image Quality Test or Customer Acceptance test should be performed before the detector is used for the first time with patients.










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, 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	Never disassemble, modify, or alter the X-ray detector, its components, Battery Pack, 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.
 WARNING	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.
 Caution	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.
 Caution	Do not exceed the maximum uniform load weight of 150 kg distributed across the surface of the X-ray detector.
 Caution	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.
 Caution	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.
 Caution	Do not expose the backside of the detector with X-rays. Always use the top side of the detector for examinations.

Battery





 WARNING	Do not use the battery pack 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 pack contain toxic substances. Do not attempt to open the battery packs. 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 pack casing will damage the casing, which could cause the LBP 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 pack. 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 pack if the X-ray detector is not likely to be used for some time.
 WARNING	Do not submerge the battery pack in water or other liquid.
 WARNING	Do not charge the battery pack near flammable materials.
 WARNING	Do not connect the battery pack 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 LBP 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 pack 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 pack 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.
 WARNING	Do not modify or alter the detector as this can violate the certification of the Radio Law.
 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.
 Caution	Use a Wi-Fi friendly environment and avoid Bluetooth devices, mobile phones, and other Wi-Fi devices close to the detector or router.

Automatic Exposure Detection (AED) Mode

 WARNING	<p>The AED mode requires a sufficient X-ray dose rate to the detector surface to trigger image acquisition. The required dose rate can vary at different use conditions. The system integrator must evaluate the AED operation with the complete X-ray setup in order to secure the proper image acquisition in AED mode.</p> <p>Depending on conditions, including but not limited to, environmental conditions, installation method, X-ray system setup, and subject to be imaged, the use of AED mode may result in false trigger or no trigger of X-ray image acquisition. The risk of false trigger or no trigger of X-ray image acquisition must be assessed for the specific intended use and application. For the most reliable image acquisition method, use of the external or software trigger mode to synchronize with the X-ray source is recommended.</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 should 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 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 pack. 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 4343 detector. The XRpad2 4343 X-ray detector series contain specific models for which the main difference is the scintillator. Applicable mechanical, electronic, and software interfaces are addressed. Varex 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 determined by the X-ray system manufacturer and is based on the completed X-ray system design. It is the responsibility of the X-ray system manufacturer to confirm the safety, 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 4343 detector.

2.0 Detector Options

The XRpad2 4343 X-ray detector series contain specific models for which the main difference is the scintillator. The detector types are listed below:

- XRpad2 4343 HWA
- XRpad2 4343 HWC
- XRpad2 4343 HWJ
- XRpad2 4343 HWK
- XRpad2 4343 HWN

3.0 This section intentionally left blank.

4.0 This section intentionally left blank.

5.0 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.

6.0 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

7.0 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 #
XRpad LBC Charger for Rechargeable Lithium-Ion Battery Pack	48773
XRpad LBP Rechargeable Lithium-Ion Battery Pack	48772
XRpad2 4343 Digital X-ray Detector Reference Manual	#####
Digital Radiography Software Manual	Supplied by X-ray system manufacturer or third-party provider
Digital Radiography Software	Supplied by X-ray system manufacturer or third-party provider
Access Point Manual	Supplied by the Access Point Manufacturer or third-party provider

8.0 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
	Refer to Instruction Manual
	Caution
	Manufacturer's name and address
	Date of Manufacture, YYYY-MM, where YYYY=Year, MM=Month OR Date of Manufacture, YYYY-MM-DD, where YYYY=Year, MM=Month, DD=Day
	REF = Reference Number Varex Catalog Number, Part Number, or Material Number
	Serial Number
	AC Input
	DC Voltage
	Temperature Limitation
	Relative Humidity Limitation
	Potential Equalization
	Functional Earth Connection
	Protection Class I

Table 3 Symbols (Continued)



























	Protection Class II
	Non-Ionizing Radiation
	Battery charge condition <ul style="list-style-type: none"> • Battery Charged ($> 80\%$) • Battery $\frac{3}{4}$ ($\leq 80\%$) • Battery Half ($\leq 60\%$) • Battery Low ($\leq 40\%$) • Battery Empty ($\leq 20\%$) • No Battery
	Shock Sensor
	Temperature Warning
	Wireless Connectivity/No Wireless Connectivity
	LAN Connection/Missing LAN Connection
	Access Point
	Trigger Connection
	Detector Push Button
	Detector Power Switch on IPU
	Do not crush
	Do not expose to fire
	Keep away from children
	Maximum Load
	Maximum Concentrated Load
	Applied Part
	Docking Connector
	AC Connector (XRpad IPU-2)
	AC Power Switch

Table 3 Symbols (Continued)

	UL Recognized component mark for US and Canada
	European Conformity marking for the product "0050" shows the notified body number for MDD
	Do not X-ray backside
	Environmental Friendly Use Period of 10 years
	Intertek ETL Classified Logo - United States 5005875
	Intertek ETL Classified Logo - Germany 5005874
IPx4	Ingress Protection rating

9.0 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 60601-1:2006/ A1:2013	General Requirements for Basic Safety for Medical Electrical Equipment
EN 60601-1-2:2015	Medical Electrical Equipment, Part 1-2: General Requirements for Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility
EN 60601 EN 60601-1-6:2010 IEC 6601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Usability
EN 62366 EN 62366:2008 IEC 62366:2007	Medical devices - Part 1: Application of usability engineering to medical devices
CAN CSA C22.2 No 60601-1 08 (Adopted IEC 60601-1:2005, third edition, 2005-12)	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 V2.1.1 (2017)	Broadband Radio Access Networks (BRAN); 5 GHz high performance RLAN
DRAFT ETSI EN 301 489-1 V2.2.0 (2017-03)	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering essential requirements Article 3.1(b) 2014/53/EU and Article 6 2014/30/EU
DRAFT ETSI EN 301 489-17 V3.2.0 (2017-03)	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonise standard covering essential requirements Article 3.1(b) 2014/53/EU.
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2010-2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Table 4 Standards and Regulations (Continued)

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)
EN 50566:2013/AC:2014	Product standard to demonstrate compliance of radio frequency fields from handheld and body-mounted wireless communication devices used by the general public (30 MHz - 6 GHz)
EN 62311: 2008	Product standard to demonstrate compliance of radio frequency fields from handheld and body-mounted wireless communication devices used by the general public (30 MHz - 6 GHz)
EN 62209-02:2012	Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Human models, instrumentation, and procedures - Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz)
EN 60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013	Information technology equipment - Safety - Part 1: General requirements; Low Voltage (LVD)

 Note	<p>Conforms to AAMI STD. ES60601-1 & IEC STD. 62366 & 60601-1-6</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>ETL CLASSIFIED</p>  <p>Intertek 5005875</p> </div> <div style="text-align: center;"> <p>ETL CLASSIFIED</p>  <p>Intertek 5005874</p> </div> </div> <p>Certified to CSA STDS. C22.2 #60601-1</p>
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10.0 Description of the X-ray Detector

10.1 Overview of the X-ray Detector

The XRpad2 4343 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.









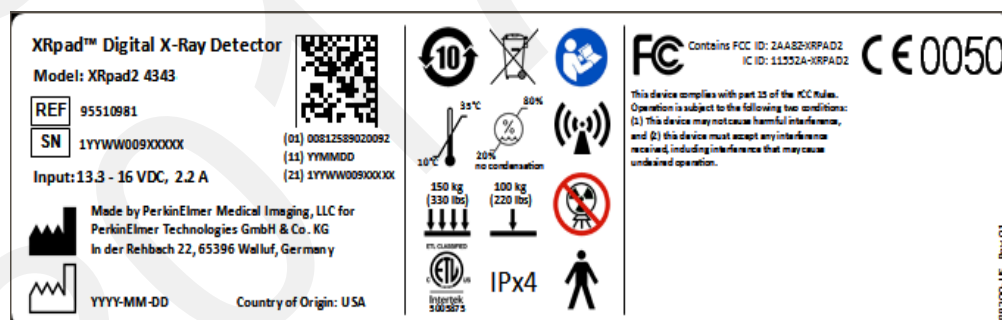
Figure 1 X-ray Detector (Front View)

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	
4	Display	
	Battery charge condition	
	• Battery Charged (> 80%)	
	• Battery ¾ (≤ 80%)	
	• Battery Half (≤ 60%)	
	• Battery Low (≤ 40%)	
	• Battery Empty (≤ 20%)	
	• No Battery	

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

	Shock Sensor	
	Temperature Warning	
	Wireless Connectivity/No Wireless Connectivity	
	Access Point	
	LAN Connection/No LAN Connection	
5	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 (4 s) 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	Varex Battery Pack
7	Detector ID sticker: In multiple detector application the colored Detector ID symbols can be used to identify the correct detector and to match it with the corresponding workstation.	

**Figure 2 Typical Detector Label**

10.2 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 (14 days)	-10°C to 55°C/0°C to 55°C	10°C to 35°C
Relative Humidity (14 days)	10% to 90%	20% to 80%
Atmospheric Pressure (14 days)	500 hPa to 1060 hPa	660 hPa to 1060 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.

10.3 X-ray Detector Specification

Table 7 displays the specifications for the X-ray detector. In addition, Figure 3, Figure 4, and Figure 5 below display the measured DQE (per the IEC 62220-1 Ed.1 standard at $\sim 8 \mu\text{Gy}$), MTF, and characteristic curves of the X-ray detector.

Table 7 X-ray Detector Specification

Sensor	
Panel	Single substrate amorphous silicon active TFT/diode array
Scintillator	Direct deposition CsI:Tl Gd ₂ O ₂ S:Tb (Gadox)
Pixel Matrix	4288 × 4288
Pixel Pitch	100 μm
Electronics	
Amplifiers	Low noise ASICs with user selectable gains
ADC	16-bit
Image Transfer Time	Wired: 1000 ms; Wireless: 5500 ms
On-board Memory	1 GB DDR3, 8 GB SDHC card
Mechanical	
Size	ISO 4090 for 43 cm × 43 cm (17" × 17") cassette size
Active Area	426 mm × 426 mm
External Dimensions	460 mm (w) × 460 mm (l) × 15.5 mm (h)
Weight	4.1 kg (9.03 lbs)
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, trigger and power via optional docking connector
X-ray I/F	Integrated X-ray trigger control Automatic Exposure Detection
Image Performance	
Limiting Resolution	5.0 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
Typical Radiographic Lag	1%

a. Country-dependent.

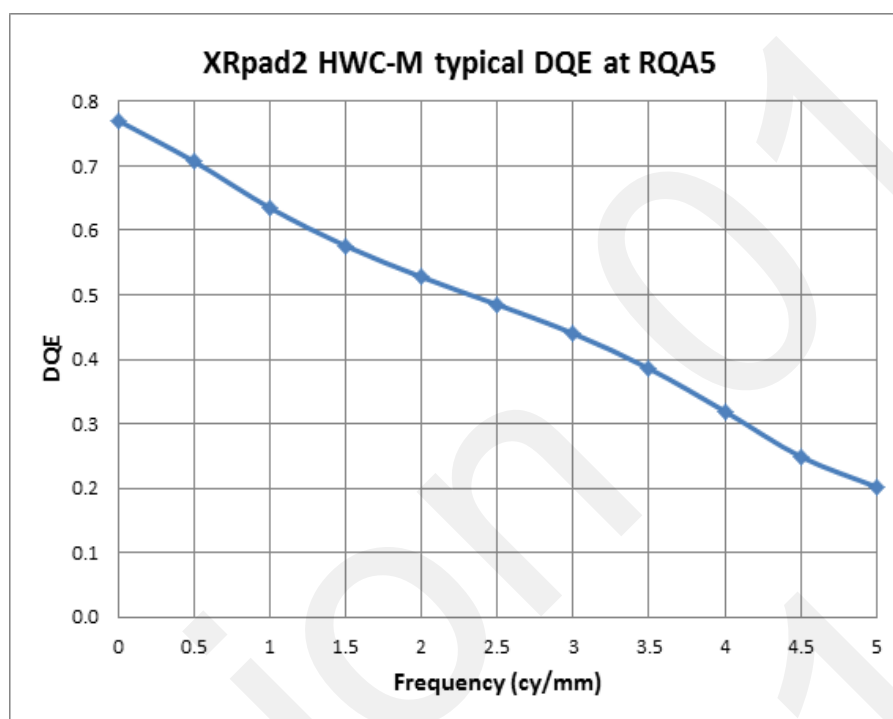


Figure 3 DQE vs Frequency

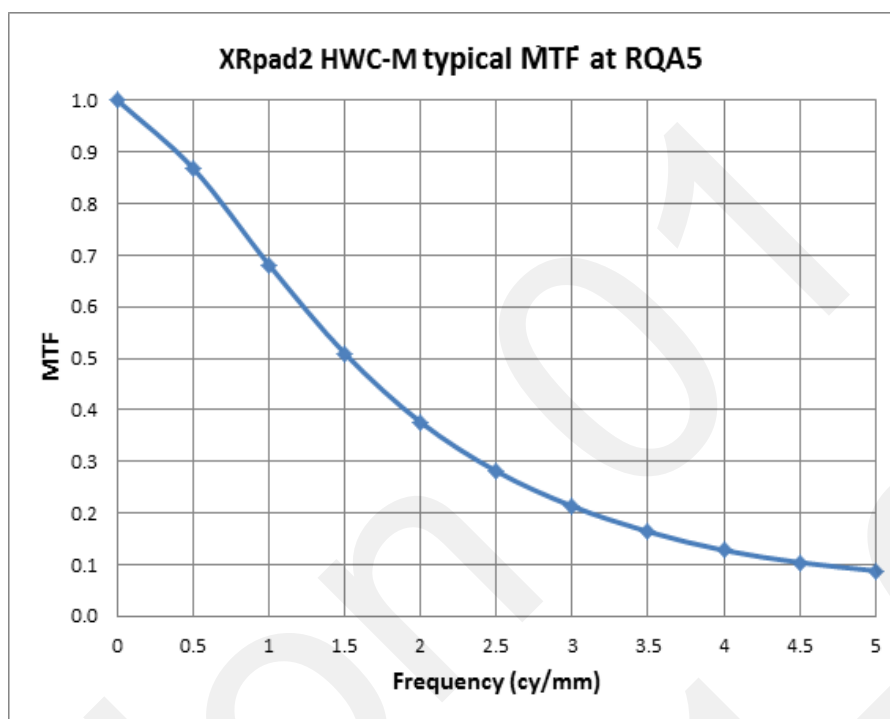


Figure 4 MTF vs Frequency

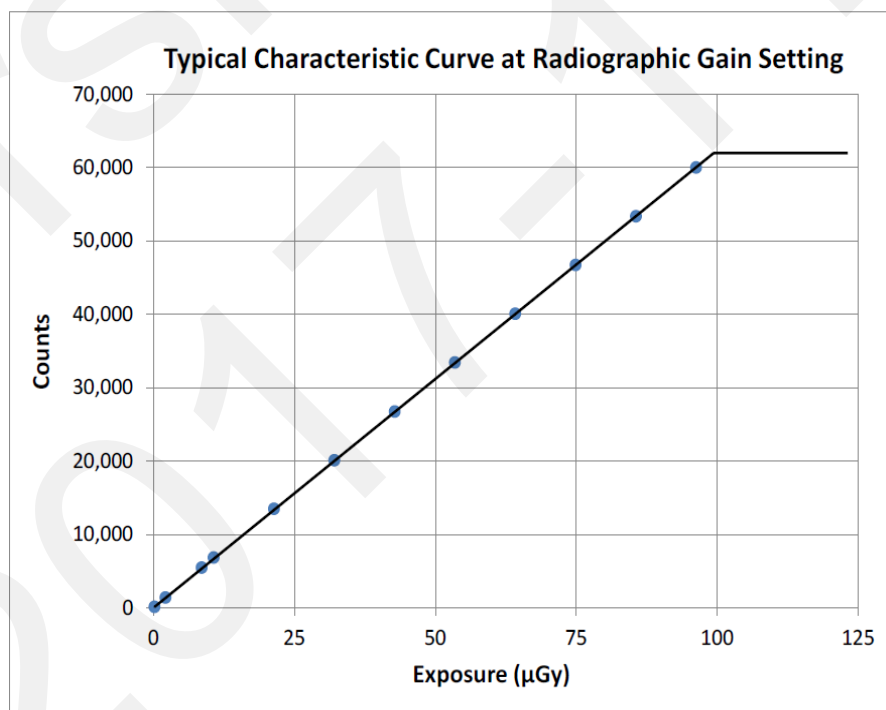


Figure 5 Plot of Characteristic Curve (Signal vs Exposure)

10.4 X-ray Detector Dimensions

Figure 6 shows the dimensions (in mm) for the X-ray detector.

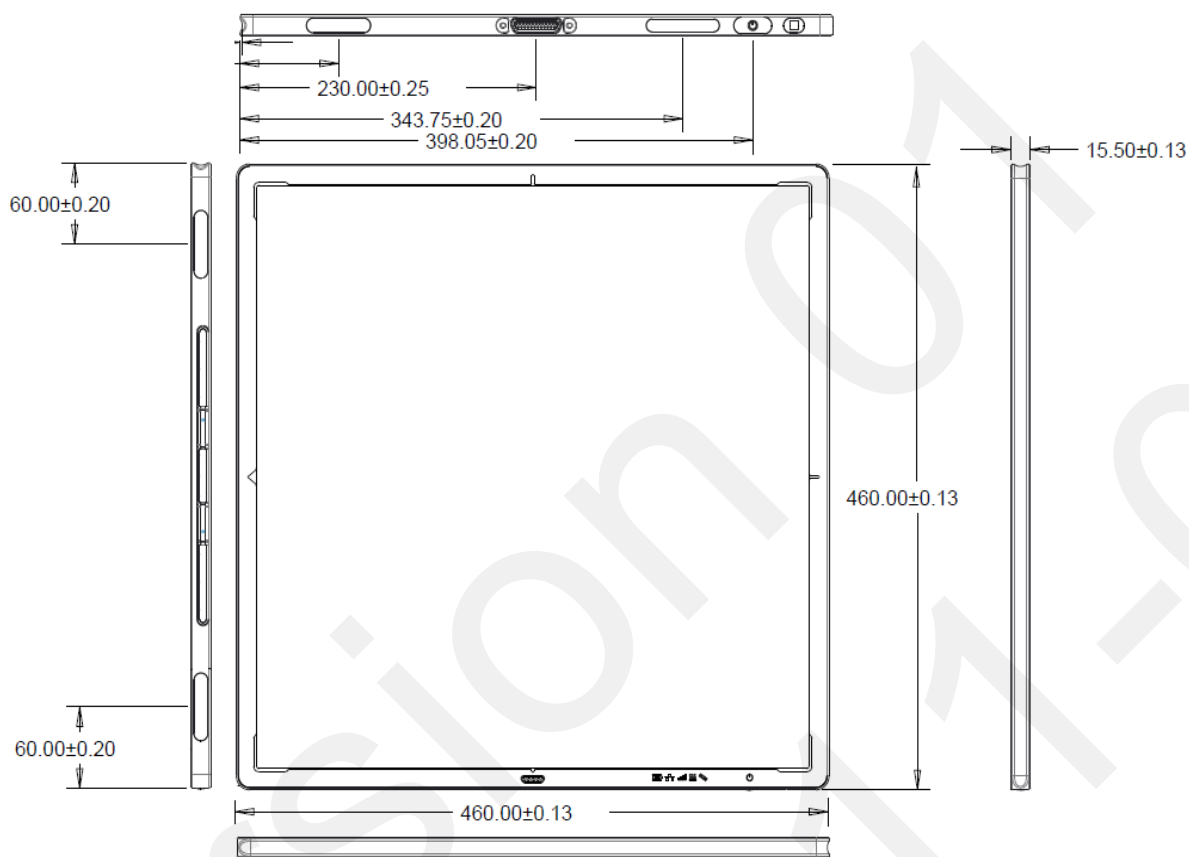


Figure 6 Dimensions for the X-ray Detector

10.5 X-ray Detector Accessories and Replacement Parts

The X-ray detector shall only be used with its approved Varex accessories and replacement parts. 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 installed network. Connection of the X-ray detector directly with the installed computer network may disturb the IT environment. The imaging workstation and the Wi-Fi access point must comply with IEC 60601-1 or IEC 60950-1.

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

Table 8 Accessories and Replacement Parts for the X-ray Detector

Varex Article No.	Description
95510949H-01	XRpad2 LBP (Lithium Battery Pack)
95510921H	XRpad LBC (Lithium Battery Charger)
95510928H	XRpad IPU-2 (Interface and Power Unit)
95510970H	XRpad LPT Detector Cable 33 ft/10 m
95510968H	XRpad2 LPT Detector Cable 16.5 ft/5 m
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 7](#).

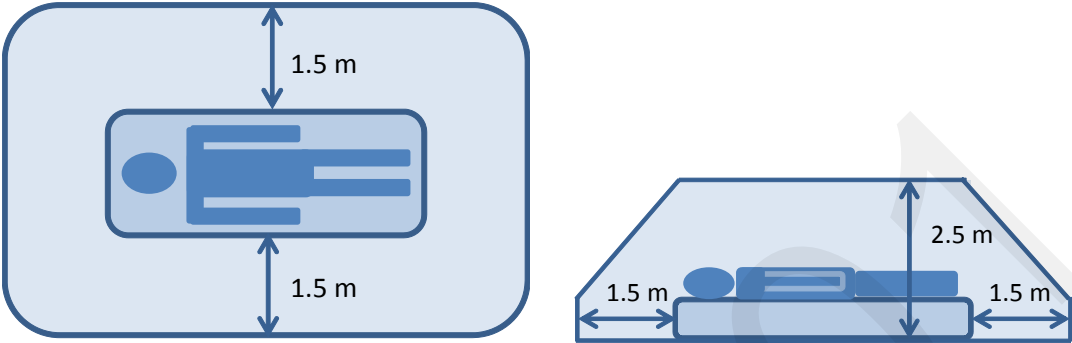




Figure 7 Patient Vicinity

	WARNING	Connection of the X-ray detector directly to the installed 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.

10.5.1 Rechargeable Battery Pack

Figure 8 shows the battery pack.



Figure 8 XRpad2 LBP



Note

Contents on the label of the battery are for reference only and may be different or subject to change.



WARNING

Storage or use of the 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 battery pack.

Table 9 Specification of the Battery Pack

General	
REF	95510949H-01
Voltage	11.1 V
Amp-hours	4.2 Ah
Capacity	46.6 Wh
Charging Time	≤ 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.

10.5.1.1 Charging the Battery Pack

- A new rechargeable battery pack comes in a discharged condition and must be charged using the dedicated battery charger before use. Refer to the battery charger manual for more details.
- The battery charger will charge the battery pack to a usable condition within three hours depending on the initial state of charge. The X-ray detector, when connected to the XRpad Interface and Power Unit (XRpad IPU-2), can also charge the battery pack, 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 battery pack is keyed and can only be inserted into the battery charger in one orientation.
- Check to ensure the battery pack is clean, dry, and free of foreign contamination or debris. If cleaning is necessary, see [“Section 10.5.1.6, Cleaning the Battery Pack” on page 22](#) for cleaning instructions.

- Ensure the battery charger is powered on.
- Orient the battery pack to match the orientation of the battery charger, and insert the battery pack firmly into the battery charger. Keep the XRpad2 LBP in the battery charger until all the four charge status LEDs maintains a solid green, indicating a full charge. To remove, lift the battery out of the battery charger.

**WARNING**

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

10.5.1.2 Installing the Battery Pack

When installing the battery pack in the X-ray detector in place of the XRpad2 Protective Insert, or to change a used battery pack, remove the used battery pack before installing the new battery pack (see [“Section 10.5.1.3, Removing the Battery Pack” on page 21](#)).

**WARNING**

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

To install the battery pack:

- 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 10.5.1.6, Cleaning the Battery Pack” on page 22](#) for cleaning instructions.
- 3 Check to ensure the battery pack is clean, dry, and free of foreign contamination or debris. If cleaning is necessary, refer to [“Section 10.5.1.6, Cleaning the Battery Pack” on page 22](#) for cleaning instructions.
- 4 The battery pack is keyed and can only be inserted into the X-ray detector in one orientation. Align the orientation of the battery pack to match the orientation required on the X-ray detector.
- 5 Insert the charged battery pack into the X-ray detector in the corresponding orientation, and gently press on the end cap until the latches secure the battery pack 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.

10.5.1.3 Removing the Battery Pack

	Caution	Dispose of a used battery pack according to the instructions in the “Section 13.0, Disposing of the X-ray Detector” on page 41.
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To remove the battery pack:

- 1 Fully support the X-ray detector and battery pack 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 battery pack from the X-ray detector (see [Figure 9](#)). Remove the battery pack from the battery compartment of the X-ray detector using a slow and steady pulling motion, supporting both the X-ray detector and the battery pack.
- 4 Store the battery pack in a cool, dry, clean environment if not in use or when recharging the battery pack for the next use.



Figure 9 Removing the Battery Pack

10.5.1.4 Transportation and Storage

When transporting and storing the battery pack:

- 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.

	Note	Transport the battery in approved packaging only. Retain the original packaging, inclusive of the Safety Data Sheet (SDS), for transporting the battery.
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- 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.

10.5.1.5 Maintaining the Battery Pack

To maintain the battery pack:

- Before inserting the battery pack into the X-ray detector or battery charger, inspect the battery pack for signs of damage, defects, or abnormalities. Do not use damaged, defective, or abnormal conditioned battery pack.
- Check to ensure the battery pack is clean, dry, and free of foreign contamination or debris. If cleaning is necessary, see [“Section 10.5.1.6, Cleaning the Battery Pack” on page 22](#) for cleaning instructions.
- The battery pack has no repairable parts. Do not disassemble. No modification of this product is allowed.
- If the battery pack 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 battery pack.
- Using a damaged or defective battery pack may reduce function time or cause the X-ray detector system to fail.
- If an battery pack 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 battery pack has not been used or charged for an extended period of time (approximately 30 days), check the condition of the battery pack, and recharge if necessary before using.

10.5.1.6 Cleaning the Battery Pack

To clean the battery pack:

- Avoid exposure of the battery pack to liquids and solvents when possible.
- Do not allow liquids or solvents to contact the electrical contacts on the battery pack.
- When necessary, clean the battery pack 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 battery pack is completely clean and dry before storing inserting the battery pack into the X-ray detector, or inserting the battery pack into the battery charger.

10.5.1.7 Disposing of the Battery Pack

To dispose of the battery pack:

- The battery pack 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 10.5.1.4, Transportation and Storage” on page 21.](#)

10.5.2 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 31 m. 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 10 [14]) or with the potential of the hospital by the potential equalization connector (Figure 10 [15]). 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 10 [18]) must be used.



WARNING

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

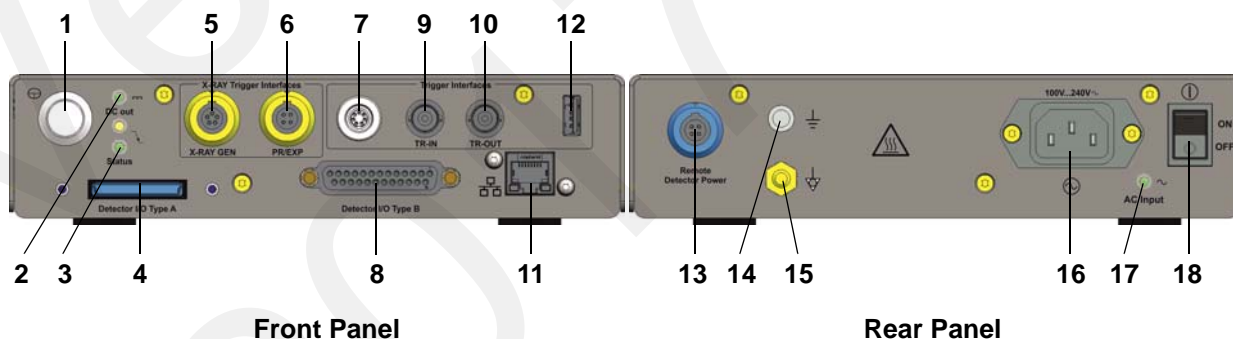


Figure 10 XRpad IPU-2

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




Table 10 Overview of the XRpad IPU-2

1	Detector Power Switch on IPU(⊕)	
2	DC Output LED (Yellow) (⏏)	
	LED Yellow	DC Output OK, no output load
	LED Green	DC Output OK, output loaded (Detector is powered on or Battery is loaded)
3	Status LED (Yellow) (⏏)	
	LED Yellow	USB trigger function enabled
	LED Green	Remote Detector Power via USB
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	Functional Ground Connector	
15	Potential Equalization Connector	
16	Power AC connector (⏏)	
17	AC Input LED (Green) (⏏)	
18	AC Power Switch ①	

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]	13.5 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]	5 V (SELV)
Trigger Out Signal [7, 10]	5 V
DC Output 5PF [7]	5 V/40 mA
Protection Class:	⊕
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 XRpad 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.
 WARNING	The detector must not be used in a situation where it controls the X-ray dose delivered to the patient.
 WARNING	The trigger signals from the detector must not be the sole activation means for X-ray delivery, and must be used in association with other control inputs: for example, a hand switch, safety interlocks, and a means of controlling the beam duration.

10.5.2.1 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 and Power Unit is going to be cleaned, be sure to turn off the XRpad IPU-2, and unplug all cables. 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.








10.6 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.

10.7 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 40 mm diameter of the X-ray detector surface.
 WARNING	<p>The AED mode requires a sufficient X-ray dose rate to the detector surface to trigger image acquisition. The required dose rate can vary at different use conditions.</p> <p>Depending on conditions, including but not limited to, environmental conditions, installation method, X-ray system setup, and subject to be imaged, the use of AED mode may result in false trigger or no trigger of X-ray image acquisition. The risk of false trigger or no trigger of X-ray image acquisition must be assessed for the specific intended use and application.</p>
 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.
 Caution	Monitor the temperature of the X-ray detector and allow the detector to cool down when the temperature of the detector gets hot or when the temperature warning appears. Ignoring this caution may result in personal injury or damage to the product.
 Note	The X-ray detector has two temperature limits. When the near thermal limit occurs, immediately finish the exam and then power down the detector to reduce the thermal load. When a maximum thermal limit occurs, the detector will power off automatically, as soon as the ongoing exam has been completed.

10.7.1 Wired X-ray Detector Connection

Figure 11 shows the wired connection of the X-ray detector in an installed 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.

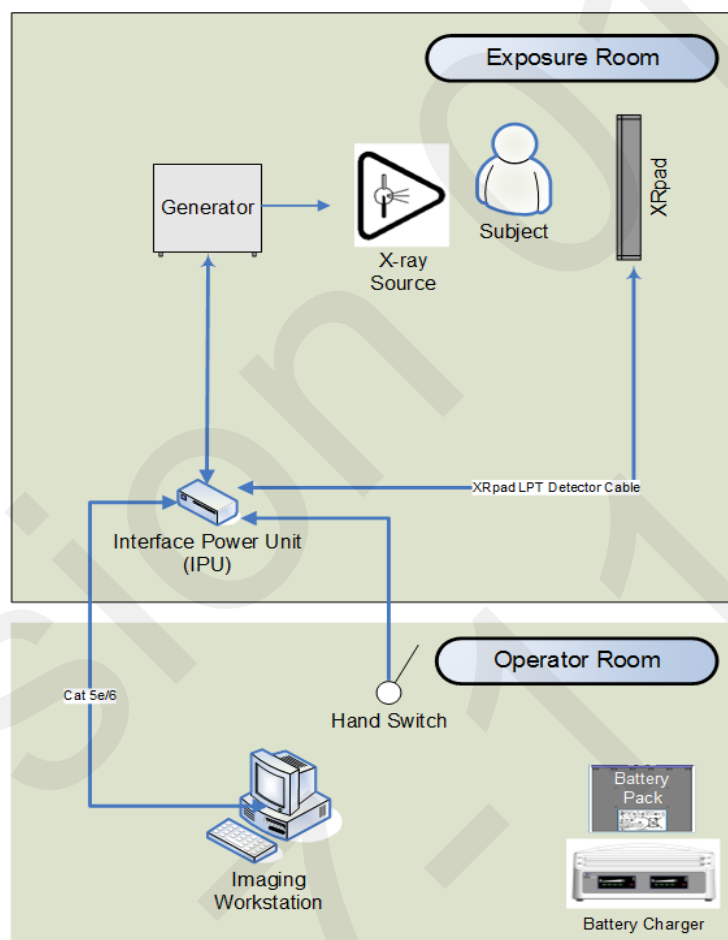


Figure 11 Wired Connection of the X-ray Detector

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 installed 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 Varex 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.

10.7.2 Wireless X-ray Detector Connection

Figure 12 shows the wireless connection of the X-ray detector in an installed 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 installed network. The detector can also be connected directly to the Imaging Workstation using WLAN with the WAP mode of the detector (see Figure 13). Before imaging, make sure that the battery pack charge is sufficient and the X-ray detector antenna is not obstructed.

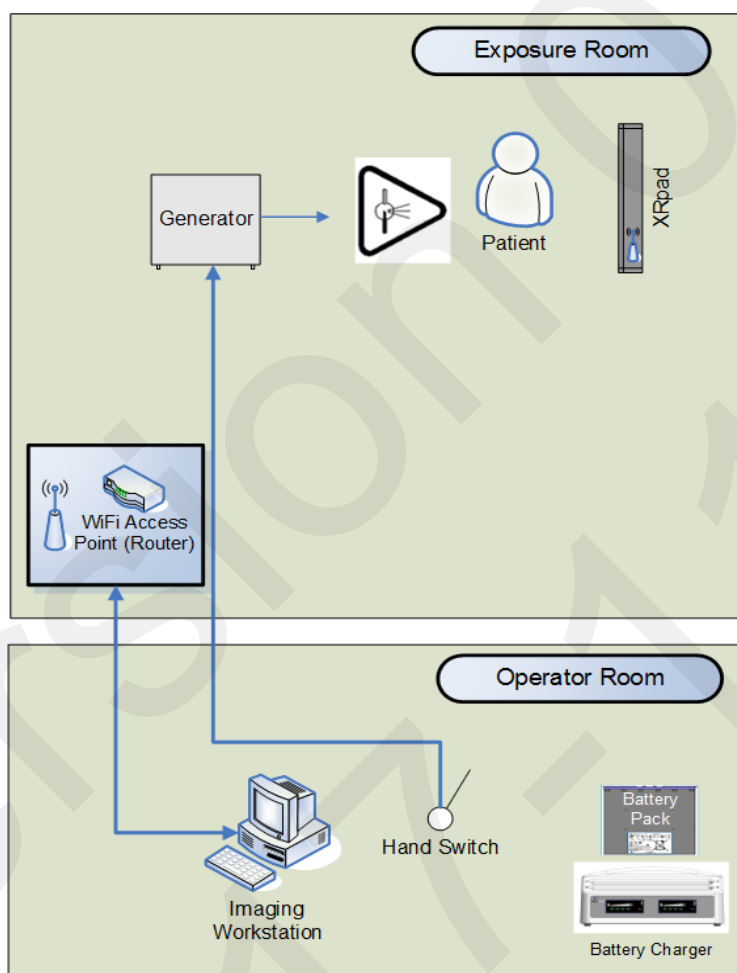


Figure 12 Wireless Connection of the X-ray Detector (Station/Client Mode)

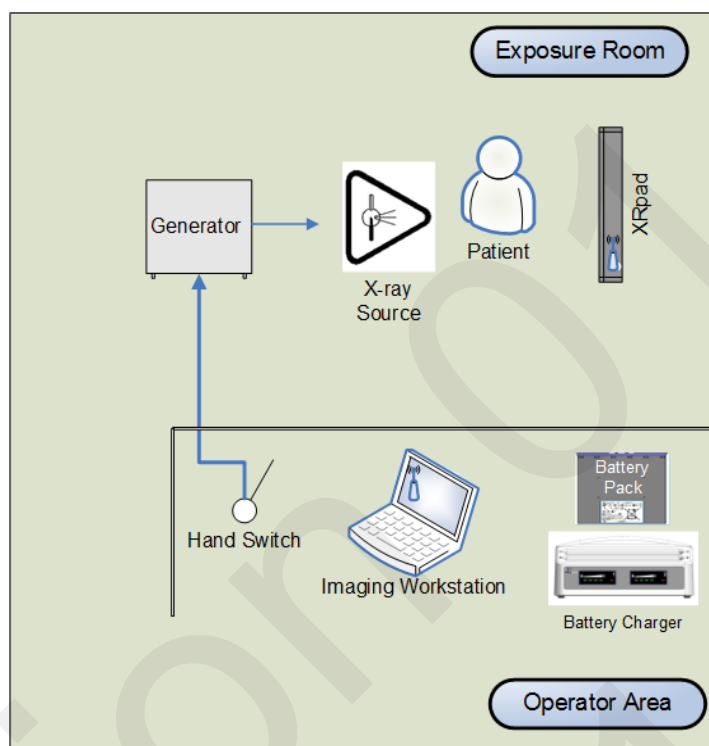




Figure 13 Wireless Connection of the X-ray Detector (WAP Mode)

10.7.3 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 battery pack or XRpad2 Protective Insert.</p>

10.7.4 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 a battery pack inserted into battery compartment.

10.7.4.1 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** switch 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.

10.7.4.2 Wireless Mode

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

- 1 When the detector is not connected to the XRpad IPU-2, check the status of the battery pack to ensure the charge of the battery is more than 50%. If the status is low, exchange the battery pack 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.





Caution

Use a Wi-Fi friendly environment and avoid Bluetooth devices, mobile phones, and other Wi-Fi devices close to the detector or router.

10.7.5 Powering Off the X-ray Detector

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

-  X-ray detector ([Figure 1 \[5\]](#)) (wireless and wired mode).
-  XRpad IPU-2 push button ([Figure 10 \[1\]](#)) (wired mode).
- Extended hand switch push button (wired mode)

10.7.6 Temperature Warning Limits

The XRpad2 4343 detector has two temperature limits that prompts the Digital Radiography Software and displays a temperature symbol on the detector display informing the user of the temperature.

- When the near thermal limit occurs (typically 41°C), immediately finish the exam and then power down the detector to reduce the thermal load.
- When the maximum thermal limit occurs (typically at 43°C), the detector will power off automatically, as soon as the ongoing exam has been completed.

10.7.7 General Workflow for Acquiring an Image

[Figure 14](#) shows the procedure for acquiring an 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.

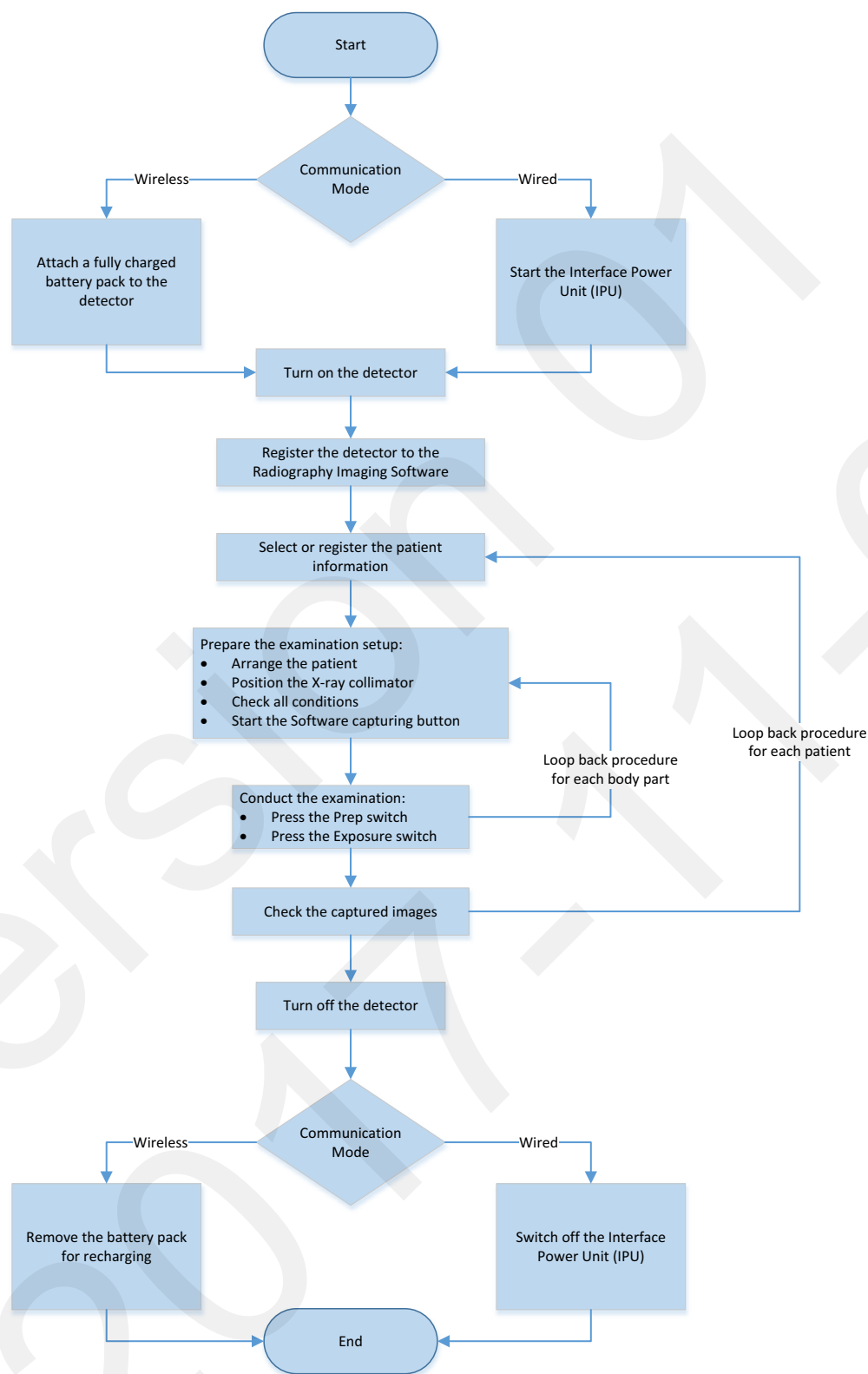




Figure 14 Workflow for Acquiring an Image

11.0 Inspection and Maintenance

 WARNING	The X-ray detector must be repaired by Varex 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 XRpad IPU-2 Interface and Power Unit do not have any internal exchangeable parts. Only the accessories listed in [Table 8](#) can be changed after consulting with your establishment's safety representative. If the problem cannot be corrected, contact your dealer, distributor, device manufacturer, or any Varex 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.

11.1 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.

11.1.1 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 10.5.1.3, Removing the Battery Pack” on page 21.
	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.

11.1.2 After Turning On the Power

General	Inspection	Result			Remedy
		Date /	Date /	Date /	
	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.

11.1.3 After Turning Off the Power

General	Inspection	Result			Remedy
		Date /	Date /	Date /	
	Check that the X-ray detector is turned off normally and that all LEDs are OFF.	Good/Bad	Good/Bad	Good/Bad	See “Section 10.7.5, Powering Off the X-ray Detector” on page 32 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 11.5, Cleaning and Disinfecting Instructions” on page 38 for cleaning the X-ray detector.

11.2 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 4343 Digital X-ray Detector 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 10.5.1.6, Cleaning the Battery Pack " on page 22 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.

11.3 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 4343 Digital X-ray Detector 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.

11.4 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.

11.5 Cleaning and Disinfecting Instructions



WARNING

When the detector system is going to be cleaned or disinfected, 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.

11.5.1 Material-Compatible Chemicals for Cleaning and Disinfecting

- 0.55% Sodium Hypochlorite Solution:
 - Commercial option: Clorox Healthcare Bleach Germicidal Wipes
 - Approximated as 1:10 dilution of common household bleach
- Alcohol-Quat solution containing the following active ingredient concentrations:
 - 0.25% n-Alkyl dimethyl ethylbenzyl ammonium chlorides
 - 0.25% n-Alkyl dimethyl benzyl ammonium chlorides
 - 55.00% Isopropyl Alcohol.
 - Commercial option: PDI SuperSani-Cloth Germicidal Disposable Wipes or Clinell Universal Wipes
- 1.4% Hydrogen Peroxide solution:
 - Commercial option: Clorox Healthcare Hydrogen Peroxide Wipes

All chemicals listed above as approved for use can be used for cleaning and disinfecting device surfaces. To achieve full cleaning and disinfecting results, perform the procedures in [Section 11.5.2](#) and [Section 11.5.3](#) for each cleaning product.

11.5.2 Cleaning the X-ray Detector

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 Locate and read the cleaning instructions specified on the product label. Follow the product instructions for cleaning.



Note

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

- 4 Dispense wipe from container.
- 5 Visually inspect the device. If soil is present, use a wipe to remove soil from the device surface. Use multiple wipes, as applicable, to remove all visible soil.
- 6 Take care to remove soil from seams, joints, and other difficult-to-reach areas.
- 7 Dispose of each wipe used for cleaning.
- 8 If visible residue from the cleaning product is evident after air drying, remove residue with a general isopropyl alcohol wipe, and let air dry.

11.5.3 Disinfecting the X-ray Detector

To disinfect 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 Locate and read the cleaning instructions specified on the product label. Follow the product instructions for cleaning.



Note

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

- 4 Wipe the entire surface of the target areas of the system until they are visibly wet with the chemical solution. Target areas include any surface that was cleaned and/or any other surfaces potentially contaminated during system use without visible soil.
- 5 Take care to wet seams, joints, and other difficult-to-reach areas.

- 6 Ensure that the surfaces remain visibly wet for the maximum necessary disinfection time specified on the product label.
 - a If a disinfection time is not specified on chemical label for the concentration used, ensure that the surfaces remain visibly wet for a minimum of 10 minutes.
 - b Use additional fresh wipes as needed to ensure continuous wet contact time during the specified disinfection period.
 - i Let air dry.
 - ii If visible residue is evident after air drying, remove residue with a general isopropyl alcohol wipe, and let air dry.
 - iii Do not reuse wipes. Discard wipes and gloves into clinical waste.

11.6 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.

12.0 After-Sales Service for Varex 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 Varex 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 Varex 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 battery pack, follow the local and regional requirements for proper packaging and shipping of Lithium Batteries.

13.0 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 Varex at the following web site for information specific to Varex products.

Web Address:

www.perkinelmer.com/weee

The Varex 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 Varex web site (above) for producer names and web addresses.

14.0 Declarations

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

14.1 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 installed 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.

14.2 Declaration of Conformity for European Union (and EEA)

English	Hereby, Varex Imaging declares that this XRpad2 4343 is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.
Česky	Varex Imaging tímto prohlašuje, že tento XRpad2 4343 je ve shodě se základními požadavky a dalšími příslušnými ustanoveními směrnice 2014/53/EU.
Dansk	Varex Imaging erklærer herved, at denne XRpad2 4343 overholder de væsentlige krav samt øvrige relevante bestemmelser i direktiv 2014/53/EU.
Deutsch	Hiermit erkläre Varex Imaging, dass der XRpad2 4343 den grundlegenden Anforderungen und anderen einschlägigen Bestimmungen der Richtlinie 2014/53/EU entspricht.
Eesti	Käesolevaga kinnitab Varex Imaging seadme XRpad2 4343 vastavust direktiivi 2014/53/EU põhinõuetele ja nimetatud direktiivist tulenevatele teistele asjakohastele sätetele.
Español	Por medio de la presente, Varex Imaging declara que el XRpad2 4343 cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 2014/53/EU.
Français	Par la présente, Varex Imaging déclare que ce XRpad2 4343 est en conformité avec les exigences essentielles et autres dispositions pertinentes de la directive 2014/53/EU.
Ελληνική	ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ Η Varex Imaging ΔΗΛΩΝΕΙ ΟΤΙ ΤΟ XRpad2 4343 ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 2014/53/EU.
Italiano	Con la presente, Varex Imaging dichiara che questo XRpad2 4343 è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti della direttiva 2014/53/EU.
Íslenska	Her með lýsir Varex Imaging yfir því að XRpad2 4343 er í samræmi við grunnkröfur og aðrar kröfur, sem gerðar eru í tilskipun 2014/53/EU.
Latviski	Ar šo Varex Imaging paziņo, ka XRpad2 4343 atbilst Direktīvas 2014/53/EU būtiskajām prasībām un citiem ar to saistītiem noteikumiem.
Lietuviu	Varex Imaging patvirtina, kad šis XRpad2 4343 atitinka Direktyvos 2014/53/EU esminius reikalavimus ir kitas nuostatas.
Malti	Hawnhekk, Varex Imaging, jiddikjara li dan XRpad2 4343 jikkonforma mal-htigijiet essenzjali u ma provvedimenti ohrajn relevanti li hemm fid-Dirrettiva 2014/53/EU.
Magyar	Alulírott, Varex Imaging nyilatkozom, hogy az XRpad2 4343 megfelel a vonatkozó alapvető követelményeknek és az 2014/53/EU irányelv egyéb előírásainak.
Nederlands	Hierbij verklaart Varex Imaging dat het toestel XRpad2 4343 in overeenstemming is met de essentiële eisen en de andere relevante bepalingen van richtlijn 2014/53/EU.
Norsk	Varex Imaging erklærer herved at utstyret XRpad2 4343 er i samsvar med de grunnleggende krav og øvrige relevante krav i direktiv 2014/53/EU.
Polski	Niniejszym Varex Imaging oświadczam, że XRpad2 4343 jest zgodny z zasadniczymi wymogami oraz pozostałymi stosownymi postanowieniami Dyrektywy 2014/53/EU.

Português	Varex Imaging declara que este XRpad2 4343 está conforme com os requisitos essenciais e outras disposições da Directiva 2014/53/EU.
Suomi	Varex Imaging vakuuttaa taten että XRpad2 4343 tyyppinen laite on direktiivin 2014/53/EU oleellisten vaatimusten ja sitä koskevien direktiivin muiden ehtojen mukainen.
Slovensko	Varex Imaging izjavlja, da je ta XRpad2 4343 v skladu z bistvenimi zahtevami in ostalimi relevantnimi določili direktive 2014/53/EU.
Svenska	Härmed intygar Varex Imaging att denna XRpad2 4343 står i överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 2014/53/EU.

General description of the radio equipment:

SW version: 1.0

- 23.00 dBm, 5.15~5.25GHz
- 22.50 dBm, 5.25~5.35GHz
- 23.00 dBm, 5.47~5.725GHz

The XRpad2 4343 may be operated in the following countries:

5150 ~ 5350 MHz is limited to indoor use in the following countries:

	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR
	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT
	RO	SI	SK	FI	SE	UK	LI	IS	NO	TR	CH
Note: The abbreviations for Member States shall be as follows: Belgium (BE), Bulgaria (BG), Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL), Spain (ES), France (FR), Croatia (HR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands (NL), Austria (AT), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE), United Kingdom (UK), Liechtenstein (LI), Iceland (IS), Norway (NO), Turkey (TR), Switzerland (CH).											

14.3 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 Varex 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 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

14.4 Industry Canada Statement (English)²

This device complies with Industry Canada’s license-exempt RSSs. 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
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	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.
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	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.

14.5 Industrie Canada – Déclaration (Français)³

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. 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.

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

3. Section is only applicable to Canada.

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