

4343W/4336W X-ray Detectors



Before using the X-ray Detectors, 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 papers carefully before operating the X-ray Detectors.
- The X-ray Detectors are intended for use by qualified professional personnel who are trained and knowledgeable in the use of X-ray Detectors, X-ray systems, and electrical equipment.
- Install the X-ray Detector horizontally on a flat, stable surface. It is required to use a bucky or a wall-mount for vertical or tilted positions. The X-ray Detector may cause an injury if it falls or is dropped.
- The User is responsible for using and maintaining the X-ray Detector according to prescribed installation, usage, maintenance, handling, and storage specifications. To keep the X-ray Detector and its accessories in safe and proper condition, only trained and qualified person(s) shall be in charge of maintenance.
- X-ray imaging, 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 the 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-ray 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 Detectors do 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 use of the X-ray 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 Detectors are 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. All parts of the X-ray Detectors are suitable for use within the patient environment. The proximity of the X-ray Detectors to the patient is dependent upon the application by the system integrator.
	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	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.
	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 is not designed to control X-ray dose. The system integrator is responsible for controlling the X-ray radiation.
	WARNING	The X-ray Detector is not intended to be used as a primary barrier to X-rays. The user is responsible for ensuring the safety of the operator, bystanders, and the subjects being radiographed.
	WARNING	The X-ray Detector is not suitable for use in the presence of or in combination with active implanted devices such as defibrillators and pacemakers. Doing so may prevent normal operation of these peripherals.
	WARNING	For portable applications, the operator and end-user must take precautions to protect themselves against dangerous X-ray exposure when using the X-ray Detector in the X-ray beam path.
	WARNING	Portable RF communications equipment should be used no closer than 30cm from the X-ray Detector or degradation of performance could result.
	Caution	The X-ray Detectors have an IP68 ingress protection rating. They are completely protected against ingress of dust and has protection against full water immersion for up to 60 minutes, at depths up to 1m.

	Caution	It is important that the X-ray Detector is not directly connected to the installed network. Connection of the X-ray Detector with the installed computer network may disturb the IT environment.
	Caution	Do not operate the X-ray Detector in a location with the following conditions: • 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 sulfurous environment • Near a vibrating environment • Environment where there is insufficient air circulation to enable the X-ray Detector and power supply to dissipate heat Ignoring this caution may result in personal injury or damage to the product.
	Caution	The X-ray Detector is an applied part (patient contact device) and the surface shall not exceed 42°C. Internal temperature sensor data is provided in the diagnostic data attached to each image. These temperature measurements are well correlated with the X-ray Detector external surface temperature. It is advisable to monitor this diagnostic data as an additional safety precaution, see document 03236 FP2032 - VSP Software Interface. Also, see Table 8 .
	Note	The X-ray Detector is intended to be installed, maintained, and used in a professional healthcare facility.
	Caution	Monitor the temperature of the X-ray Detector and allow the X-ray Detector to cool down when the temperature of the X-ray Detector gets hot. The device is not designed to supply heat to a patient. 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 X-ray Detector is used for the first time with patients.
	Caution	No part of the X-ray Detector is intended to be attached to the patient and/or contact the patient.

Service Cable (4343W) and Tether Cable (4336W)

	WARNING	Disconnect the Cable by pulling on the connector and not the cable itself. Ignoring this warning may cause substantial product damage.
	WARNING	Do not modify the Cable or subject the cable to external stress or damage. Avoid placing anything heavy, including the X-ray 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 substantial product damage.
	WARNING	The Service Cable (4343W) does not support image acquisition. It should only be used for the following: • to retrieve an orphaned image from the X-ray Detector, when a wireless connection is not available • for service
	Note	Varex Imaging tests every X-ray Detector, using the tether cable, for communication and link speed defects. Varex's supplier of the tether cable individually tests each cable before shipping.

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 use the Battery Latch as a handle. Ignoring this warning may cause damage to the Battery Latch or increase the likelihood that the X-ray Detector may be dropped causing 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 300 kg distributed across the surface of the X-ray Detector.
	Caution	Do not exceed the maximum load weight of 200 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 X-ray Detector. Further use under abnormal conditions may result in severe personal injury, death, or substantial product damage.
	Caution	In the event that the X-ray Detector is dropped, a new Gain Calibration must be performed.
	Caution	Do not expose the backside of the X-ray Detector with X-rays. Always use the top side of the X-ray Detector for examinations.

Battery, Inductive Charger, and X-ray Detector Power Supply

	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 battery pack 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	Be sure to remove the battery before servicing and maintaining. Do not touch the 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.
	WARNING	Do not insert the battery into the 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.
	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 from the X-ray Detector 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 battery pack 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.
	Caution	There is a risk of explosion, personal injury, or damage to product if the battery pack is replaced by non-OEM approved components.
	Caution	The Varex provided accessory power supply for tether mode (4336W) will not introduce noise. An aftermarket power supply may not be used with the X-ray Detector.

WLAN

	WARNING	Do not obstruct the X-ray Detector antenna. If it is obstructed by metal, wood, or a human body, the wireless communication can be slowed down or disconnected.
	WARNING	Do not route Ethernet cables near or with power cables, degradation of performance could result.
	WARNING	Follow the laws and regulations for each country and select the regional code accordingly.
	WARNING	Do not use the X-ray Detector in aircraft because there is a potential affect to aviation systems.
	WARNING	Do not modify or alter the X-ray Detector as this can violate the certification of the Radio Law.
	Caution	Use WLAN access point devices to get the best communication performance. Please contact your Varex representative for a list of approved wireless access points.
	Caution	The electromagnetic emission of the X-ray 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 X-ray Detector or router.

Network

	WARNING	Do not connect the X-ray Detector to the common IT network, but use a point-to-point connection or tethered connection with the host computer or dedicated WLAN access point. Ignoring this warning may cause unauthorized access to this device.
	WARNING	Ensure that only authorized users have access to the X-ray Detector and the WLAN access point. Unauthorized access may cause disruption to the normal operation of the X-ray Detector and access point.

vTrigger Mode (Automatic Exposure Detection)

	WARNING	The vTrigger mode requires a sufficient X-ray dose rate to the X-ray Detector surface to trigger image acquisition. The required dose rate can vary at different use conditions. The system integrator must evaluate the vTrigger operation with the complete X-ray setup in order to secure the proper image acquisition in vTrigger mode.
	WARNING	vTrigger starts exposure upon detecting X-rays. Before exposure, software must be switched to a configuration mode that has vTrigger enabled. Do not expose before the software indicates the X-ray Detector is prepared for acquisition.
	WARNING	When the X-ray Detector is armed, it will time-out if no exposure is initiated within ten minutes, resulting in the X-ray Detector entering Standby Mode.
	WARNING	Do not apply any, handling, loading, mechanical shock, or electronic noise to the X-ray Detector while it is in vTrigger mode.

If a Problem Occurs

	WARNING	If any abnormal condition, such as smoke, fumes, or strange sounds, is evident, remove the battery from the X-ray Detector, 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.
	WARNING	When liquid has been spilled into or on any part of the X-ray Detector or battery, or when the X-ray Detector, its component, or accessory is dropped, immediately clean the liquid, see Section 12.1.2, and operation may resume. Further use under abnormal conditions may result in severe personal injury, death, or substantial product damage.

Maintenance and Inspection

	WARNING	Turn off the power of the X-ray Detector, see Section 11.4, 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.
	WARNING	When the X-ray Detector system is going to be cleaned; remove the battery pack, cables, and wait until the X-ray Detector powers off. 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.
	WARNING	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.
	Caution	Follow the manufacturer's recommendations for inspecting the X-ray Detector before use.

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1.0 Scope

This document describes design elements and respective interfaces for the Varex Imaging Wireless X-ray Detectors 4343W-G5 and 4336W-G5. All applicable mechanical, electronic, and software interfaces are described.

2.0 Contraindication

There are no contraindication situations.

3.0 Intended Use

Varex Imaging Wireless X-ray Detectors and their accessories are components designed to be integrated into products by X-ray system manufacturers. Final application and intended use are 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 safety, efficacy and compliance of the X-ray system intended for use, inclusive of the X-ray Detector. The Digital Radiography Software referred to in this manual is intended to be used by system integrators to control and operate the X-ray Detector, as well as, for development, testing, and maintenance purposes only.

	Note	The X-ray Detector is designed to be integrated into a complete X-ray system by a qualified system integrator. The system integrator is responsible for obtaining FDA clearance for medical use.
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4.0 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.

5.0 Abbreviations

Table 1 Abbreviations

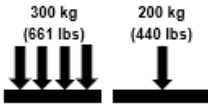
Abbreviations	Descriptions
AED	Automatic Exposure Detection (see vTrigger)
API	Application Program Interface
a-Si	Amorphous Silicon
CsI	Cesium Iodide
LED	Light Emitting Diode
OEM	Original Equipment Manufacturer
PREP	Prepare
REQ	Request
SDK	Software Developer Kit
ViVA	Varex Imaging and Viewing Application
VSP	Varex Smart Panel
vTrigger	Automatic Exposure Detection
WLAN	Wireless Local Area Network

6.0 Definition of Symbols

Table 2 Definition of Symbols

Symbol	Description
I	On (power connection)
○	Off (power disconnection)
	Handle with Care
==	Direct Current
	Authorized Representative in the European Community/European Union

Table 2 Definition of Symbols (Continued)

Symbol	Description
IP68	The X-ray Detectors have an IP68 ingress protection rating. It is completely protected against ingress of dust and has protection against full water immersion for up to 60 minutes, at depths up to 1m.
	Consult Instruction for Use
	Load Weight Restrictions
	Do Not Discard with Domestic Waste
CE XXXX	European Union Mark of Conformity to Applicable European Directives
	Manufacturer
	Non-ionizing radiation
	Type B Applied Part
	Underwriters Laboratory Safety Mark
	China RoHS environmentally friendly for 10 years

7.0 Standards and Regulations

The X-ray Detectors are designed to be compliant with the requirements detailed in [Table 3](#) below. All regulatory certificates are valid only if the original accessories are used. All regulatory certificates are rendered invalid if any modifications to the Product are made, or any portion thereof, without obtaining the prior written authorization of Varex Imaging.

Table 3 Standards and Regulations

Detector Standard	Description
UL 60601-1	Medical Electrical Equipment, Part 1: General Requirements for Safety 1st ed.
IEC 60601-1	Medical Electrical Equipment Part 1: General Requirements for Safety 2nd ed.
EN/IEC 60601-1	2006+A1:2013/ 2005+A1:2012 (ED. 3.1)
ANSI/AAMI ES60601-1 (2005)	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.
CSA-C22.2 No 60601-1 (2008)	Medical Electrical Equipment, Part 1 General Requirements for Basic Safety and Essential Performance.
CAN/CSA-C22.2 No 601.1-M90, 2005	Medical Electrical Equipment, Part 1 General Requirements for Safety.
EN/IEC 60601-1-2	Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility 4th ed.
93/42/EEC	European Union Medical Device Directive
2014/30/EC	European Union Electromagnetic Compatibility Directive
2014/53/EU	European Union Radio Equipment Directive
FCC Part 15 Subpart E	Telecommunication - Intentional Radiators and Unlicensed Devices
EN 301 893	Wide-band Transmission Systems: 5GHz
EN 301 489-1	Radio Equipment - Electromagnetic Compatibility
EN 301 489-17	Broadband Data Transmission Systems
4343W/4336W have the capability to be internally powered.	
MDD Class IIa	
A Declaration of Conformity has been filed for this product and available upon request by contacting Varex Imaging.	

8.0 Description of the X-ray Detectors

The X-ray Detectors are lightweight and wireless designed for medical and veterinary use. The X-ray Detector together with the Varex Smart Panel (software is designed for integration into an X-ray system. The VSP is the interface between the X-ray Detector and the Client PC; such as control, image acquisition and calibration.

The X-ray Detectors fit into standard bucky trays and the wireless communication enables easy migration between table and other physical applications.

The wireless access point is the interface between the X-ray Detector and the imaging system and may be mounted in an equipment enclosure, or it may also be wall or ceiling mounted to maximize wireless signal strength. A Service Cable is supplied with the 4343W to allow for set-up of the wireless interface and to retrieve images from the X-ray Detector in case of failed wireless transmission. A Tether Cable is provided with the 4336W to provide power and allows operation of the X-ray Detector through a wired interface.

During operation, the X-ray Detector is often draped or bagged to ensure cleanliness and sterilization. It is manipulated such that the X-ray Detector's input window is located near, but on the opposite side of the patient, from the X-ray source.

Figure 1 shows the configuration of the X-ray Detector in the context of the typical overall imaging system.

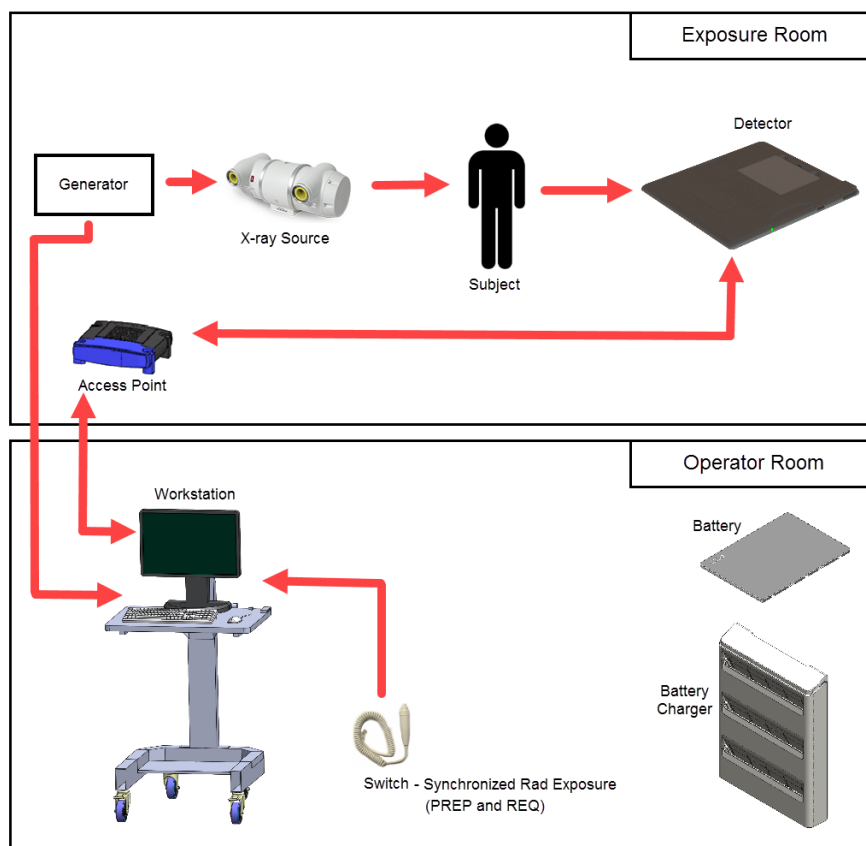


Figure 1 Typical Detector Configuration

	WARNING	For proper operation, X-ray Detector antennas and access point antennas should be unobstructed.
	WARNING	Access point should not be installed next to power supply or generator equipment. Please contact your Varex representative for a list of approved access points.



Figure 2 X-ray Detector as Access Point



Figure 3 X-ray Detector with Router



Figure 4 Service Cable Connection (4343W only)

	Note	The Service Cable functions as an interface between the X-ray Detector and the workstation by providing a 100Mbps Ethernet connection for set-up of the wireless interface and as a last resort for retrieval of images from the X-ray Detector in case of wireless transmission failure.
	Note	The Service Cable does not support image acquisition.
	Note	The Service Cable does not provide power to the X-ray Detector when tethered. Before servicing, ensure that a fully charged battery is inserted.

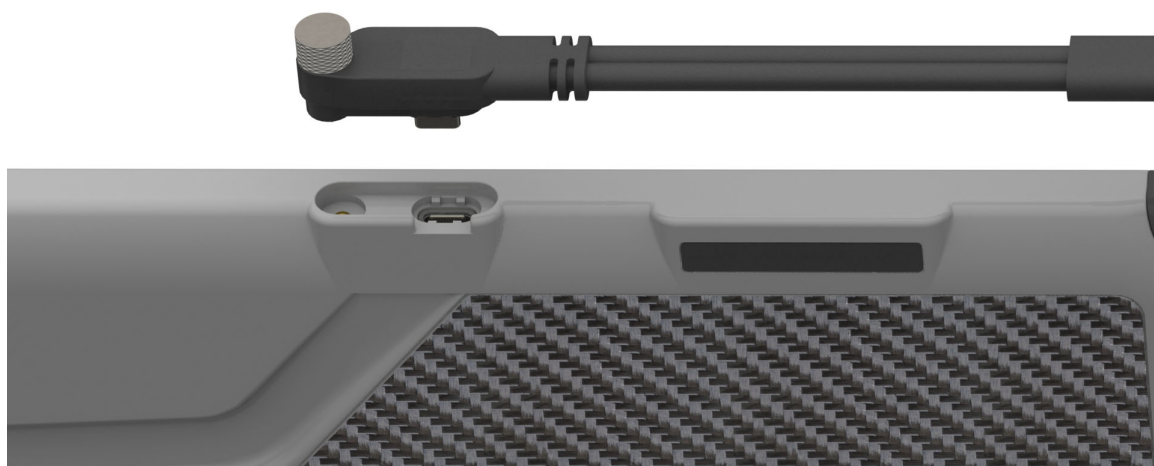


Figure 5 Tether Cable Connection 4336W

	Note	The Tether Cable functions as an interface between the X-ray Detector and the workstation by providing a 1 Gbp/s Ethernet connection for tether communication, set-up of the wireless interface, and as a last resort for retrieval of images from the X-ray Detector in case of wireless transmission failure.
	Note	The Tether Cable is verified for image acquisition.
	Note	The Tether Cable provides 19V to the X-ray Detector which allows it to run on tether power and charge the Battery.

8.1 Shipment Contents

Items received in each shipment:

- Wireless X-ray Detector
- X-ray Detector Test Results DVD (Files specific to the X-ray Detector in the shipment) - is there a DVD
- Software DVD - Is there a DVD
- VSP/ViVA System Software
- Wireless X-ray Detector Reference Manual (DVD) - is there a DVD?

8.2 Accessories

The X-ray Detector shall only be used with its approved Varex Imaging accessories and replacement parts. Product certification and warranty are void if any modifications to the product is made, or any instruction, warning, or caution is not followed.

Table 4 Optional Parts and Accessories

Description	Length
Inductive Charger	N/A
Inductive Charger Power Supply	5 ft/1.5m
Varex 1-bay Battery Charger	N/A
Varex 1-bay Battery Charger Power Supply, 65W, 19V	3.3 ft/1m
1-bay Battery Charger Mounting Plate	N/A
Varex 3-bay Battery Charger	N/A
Varex 3-bay Battery Charger Power Supply 19V, 85W	3.3 ft/1m
3-bay Battery Charger Mounting Plate	N/A
Varex Wireless Battery	N/A
Battery Overlay LED Display (Silver, Pd Silver, Black, Pure White, Var101 White)	N/A
Mains Hospital Grade 110V Cable	6.5 ft/2.0m
Mains European Cable	8.2 ft/2.5m
Mains Chinese Cable	8.2 ft/2.5m
Service Cable	6 ft.
Tether Cable	6.5 ft.
Power Supply	

	Note Accessory or optional equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e., IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anyone connecting additional or optional equipment to the signal inputs or signal outputs as part of a configuration for medical equipment is therefore responsible for compliance with the equipment standard IEC 60601-1. If in doubt, consult technical support personnel.
---	--

Upon receipt, inspect the shipment and its contents against the Delivery Note enclosed with the shipment for evidence of damage or missing components. Save all shipping containers in case a return is warranted. If there is any discrepancy, see [Section 13.1](#)

8.3 X-ray Detector Surfaces and Features

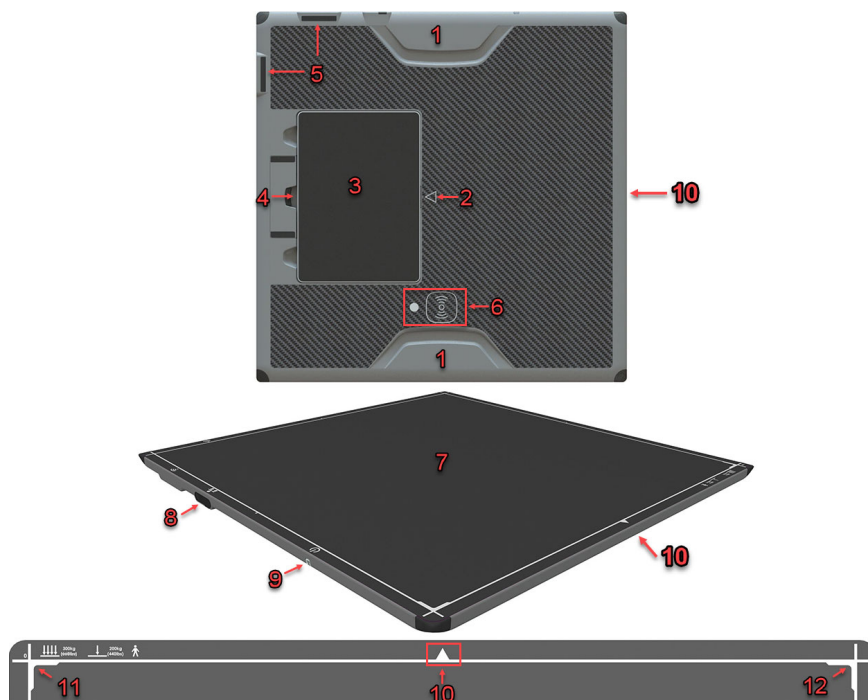


Figure 6 4343W X-ray Detector Surfaces and Features

Table 5 Description of Detector Surfaces and Features

Number	Description
1	Handles
2	Battery Alignment Marker
3	Battery and Battery Well
4	Replaceable Battery Latch
5	Antennas
6	Inductive Charging Receiver
7	Patient Contact Surface
8	Service Cable Connection
9	LED Status Indicator
10	Top of X-ray Detector, interior electronics location
11	Orientation Mark, also indicates glass array coordinates (X=0, Y=0)
12	Orientation Mark

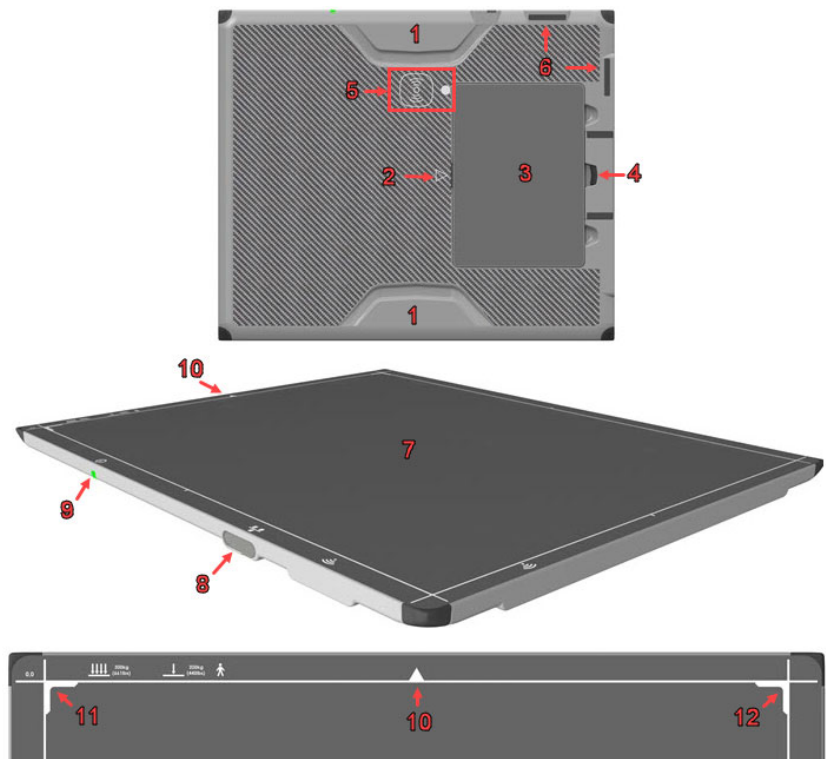


Figure 7 4336W X-ray Detector Surfaces and Features

Table 6 Description of Detector Surfaces and Features

Number	Description
1	Handles
2	Battery Alignment Marker
3	Battery and Battery Well
4	Replaceable Battery Latch
5	Inductive Charging Receiver
6	Antennas
7	Patient Contact Surface
8	Tether Cable Connection
9	LED Status Indicator
10	Top of X-ray Detector, interior electronics location
11	Orientation Mark, also indicates glass array coordinates (X=0, Y=0)
12	Orientation Mark

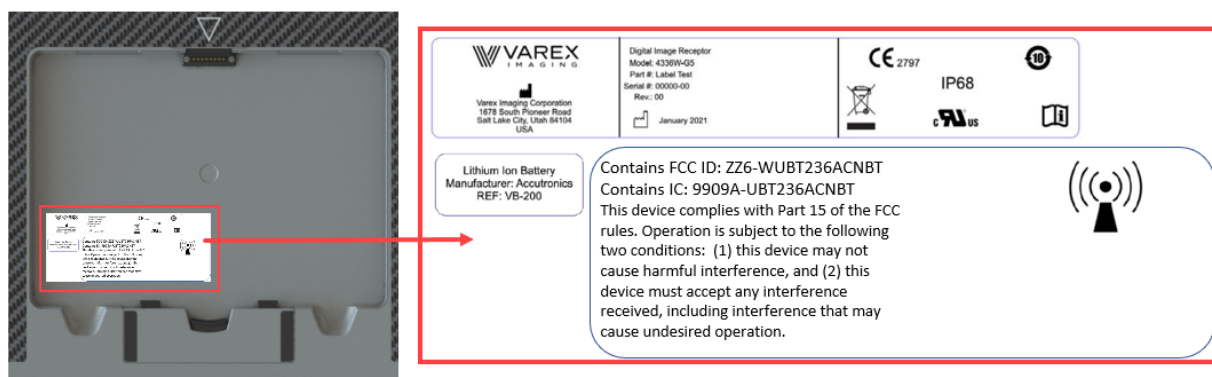


Figure 8 4336W X-ray Detector Labels and Location

8.4 X-ray Detector Dimensions

Measured in mm and [inches in brackets].

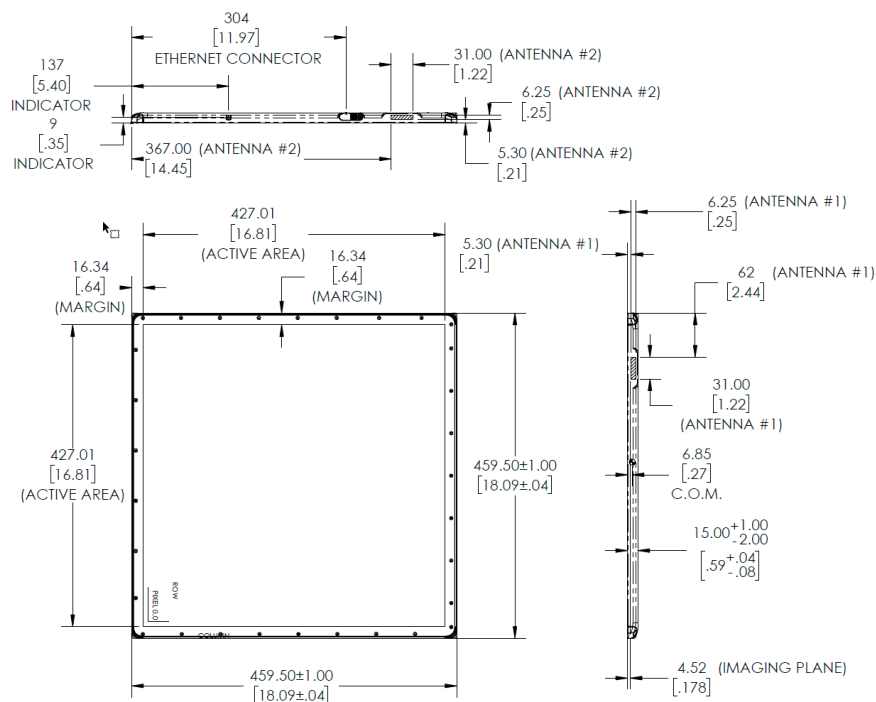


Figure 9 4343W X-ray Detector Dimensions in mm (and inches)

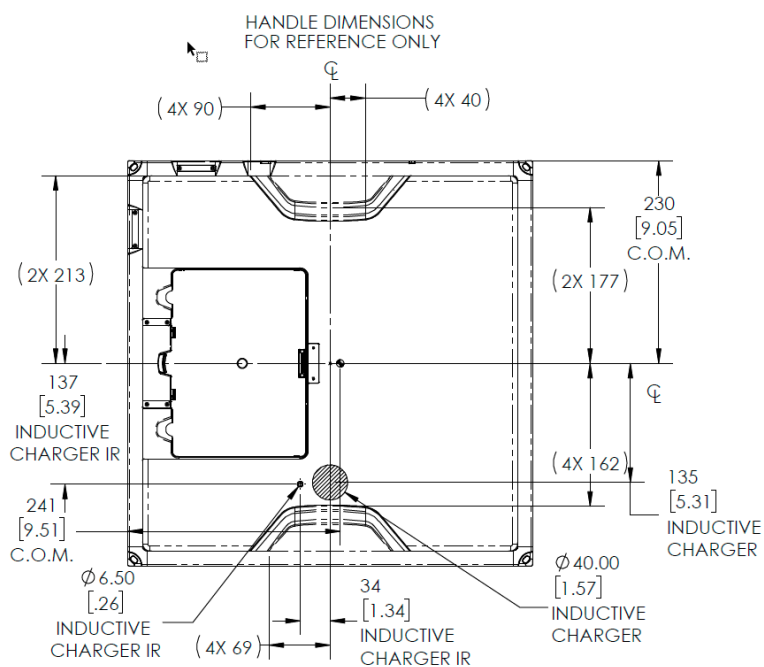


Figure 10 4343W X-ray Detector Dimensions in mm (and inches)

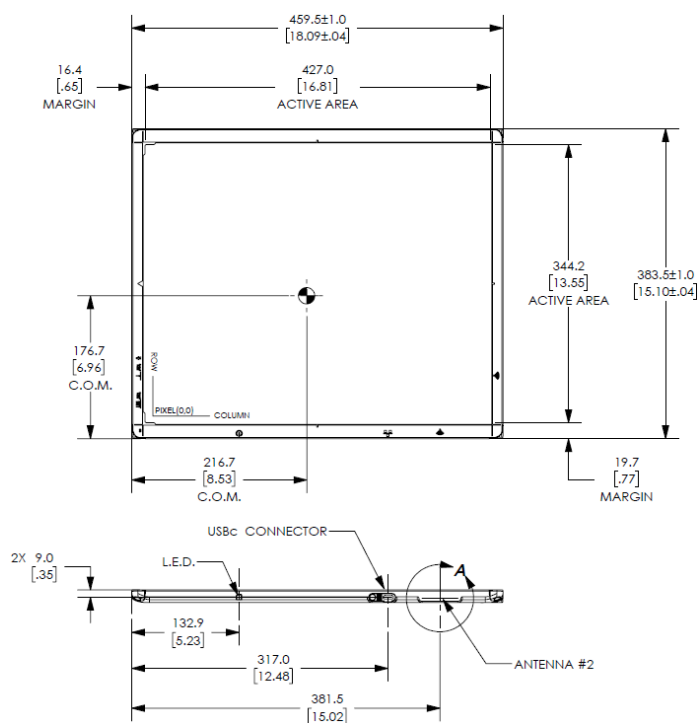


Figure 11 4336W X-ray Detector Dimensions in mm (and inches)

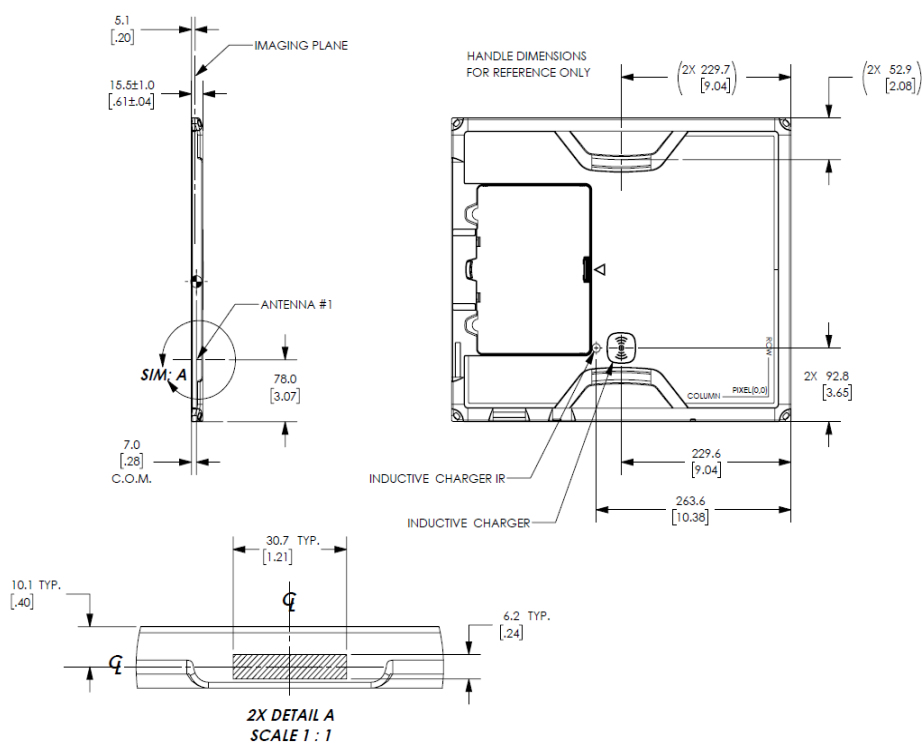


Figure 12 4336W X-ray Detector Dimensions in mm (and inches)

8.5 X-ray Detector Specifications

Table 7 X-ray Detector Specifications

Sensor	4343W	4336W
Detector	Amorphous Silicon active TFT/PIN diode Technology	Amorphous Silicon active TFT/PIN diode Technology
Scintillator	CsI Premium, CsI Standard, and DRZ+	CsI Premium, CsI Standard, and DRZ+
Pixel Matrix	3072 (v) x 3072 (h)	3072 (v) x 2476 (h)
Pixel Pitch	139 μm	139 μm
Active Area	3052 (v) x 3052 (h) DRZ+, 3032 (v) x 3032 (h) CsI	3052 (v) x 2456 (h) DRZ+, 3032 (v) x 2436 (h) CsI
Electronics		
Battery	Lithium-ion	Lithium-ion
Battery Charger	1 or 3 Bay, Inductive	1 or 3 Bay, Inductive
ADC	16-bit	16-bit
Mechanical		
Housing	Plastic with Carbon Fiber entrance window	Plastic with Carbon Fiber entrance window
Weight (without Battery)	DRZ+ 3.1 kg (6.83 lbs), CsI 3.3 kg (7.27 lbs)	DRZ+ 2.65 kg (5.84 lbs), CsI 2.85 kg (6.28 lbs)
Load Support	200 kg over diameter 40 mm at center, 300 kg entire surface	200 kg over diameter 40 mm at center, 300 kg entire surface
Surface Temperature	Rated to not exceed 42°C	Rated to not exceed 42°C
Wireless Communication		
Signal Strength	Requires > -70 dBm or no image will be acquired	Requires > -70 dBm or no image will be acquired
Standard	IEEE 802.11ac/a/n	IEEE 802.11ac/a/n
Interface	USB	USB
Security	• WEP • WPA • WPA2	• WEP • WPA • WPA2
Operating Voltage	DC 5V	DC 5V

Table 7 X-ray Detector Specifications (Continued)

Radio		
Antenna	2 x IPEX connector for 2T2R	2 x IPEX connector for 2T2R
Frequencies	• UNII - 1: 5150MHz - 5250MHz • UNII - 3: 5725MHz - 5850MHz Note: Subject to local regulations	• UNII - 1: 5150MHz - 5250MHz • UNII - 3: 5725MHz - 5850MHz Note: Subject to local regulations
Modulation	• 802.11a: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) • 802.11n: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) • 802.11ac: OFDM (BPSK, QPSK, 16-QAM, 64-QAM, 256-QAM)	• 802.11a: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) • 802.11n: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) • 802.11ac: OFDM (BPSK, QPSK, 16-QAM, 64-QAM, 256-QAM)
Transmit Power WIFI_Chain 0	• 802.11a: 14.5 ± 1dBm • 802.11n/ac 20_5180MHz~5240MHz: 13.5 ± 1dBm • 802.11n/ac 20_5745MHz~5825MHz: 13 ± 1dBm • 802.11n/ac 40_5190MHz: 11 ± 1dBm • 802.11n/ac 40_5230MHz: 13.5 ± 1dBm • 802.11n/ac 40_5755MHz~5795MHz: 13 ± 1dBm • 802.11ac 80: 10.5 ± 1dBm	• 802.11a: 14.5 ± 1dBm • 802.11n/ac 20_5180MHz~5240MHz: 13.5 ± 1dBm • 802.11n/ac 20_5745MHz~5825MHz: 13 ± 1dBm • 802.11n/ac 40_5190MHz: 11 ± 1dBm • 802.11n/ac 40_5230MHz: 13.5 ± 1dBm • 802.11n/ac 40_5755MHz~5795MHz: 13 ± 1dBm • 802.11ac 80: 10.5 ± 1dBm

Table 7 X-ray Detector Specifications (Continued)

Transmit Power WIFI_Chain 1	• 802.11n/ac 20_5180MHz~5240MHz: 13.5 ± 1dBm • 802.11n/ac 20_5745MHz~5825MHz: 13 ± 1dBm • 802.11n/ac 40_5190MHz: 11 ± 1dBm • 802.11n/ac 40_5230MHz: 13.5 ± 1dBm • 802.11n/ac 40_5755MHz~5795MHz: 13 ± 1dBm • 802.11ac 80: 10.5 ± 1dBm	• 802.11n/ac 20_5180MHz~5240MHz: 13.5 ± 1dBm • 802.11n/ac 20_5745MHz~5825MHz: 13 ± 1dBm • 802.11n/ac 40_5190MHz: 11 ± 1dBm • 802.11n/ac 40_5230MHz: 13.5 ± 1dBm • 802.11n/ac 40_5755MHz~5795MHz: 13 ± 1dBm • 802.11ac 80: 10.5 ± 1dBm
Receive Sensitivity	• 802.11a: ≤ -70dBm@54Mbps • 802.11n/5GHz (HT20): ≤ -60dBm@MCS7 • 802.11n/5GHz (HT40): ≤ -60dBm@MCS7 • 802.11ac (VHT80): ≤ -51dBm@MCS9	• 802.11a: ≤ -70dBm@54Mbps • 802.11n/5GHz (HT20): ≤ -60dBm@MCS7 • 802.11n/5GHz (HT40): ≤ -60dBm@MCS7 • 802.11ac (VHT80): ≤ -51dBm@MCS9

8.6 Environmental Conditions

Environments outside the specification reduce the lifetime and may irreparably damage the X-ray Detector.

Table 8 Environmental Conditions

Category	Limits
Storage & Transport Temperature (ambient)	-20° C to +55° C
Operating Temperature (ambient)	10° C to 40° C
Storage and Operating Humidity Range (non-condensing)	10% to 90%
Atmospheric Pressure Range	70kPa to 106kPa
Shock (any direction no power applied)	20G
Vibration Tolerance (25Hz, 30 min each Axis, without power)	2.5G
Ingress Protection	IP68
Detector Altitude	Operates at ≤ 3000m



Note

The X-ray Detector is intended to be installed, maintained, and used in a professional healthcare facility.

8.7 Temperature Sensors

Table 9 Temperature Sensor Readings

X-ray Detector	Temperature Sensor	Max and Min Reading
4343W	T1 Minimum	16° C
	T1 Maximum	46° C
	T2 Minimum	16° C
	T2 Maximum	46° C
4336W	T2 Minimum	19° C
	T2 Maximum	47° C

	Note	The T1 (4343W) and T2 temperature sensors are used to monitor the internal temperature of the glass. These are the only temperature sensors that need to be monitored by the OEM, see Table 9 .
	WARNING	If the maximum temperature is reached, the X-ray Detector must be turned off and allowed to cool. Ignoring this warning may result in substantial product damage.

8.8 Position Sensing

The X-ray Detector is equipped with two position sensors that communicate with software the X-ray Detector's exact position within a bucky setup. Refer to document **03236 FP-2032 - Varex Smart Panel Software Interface** for integration of Position Sensing.

8.9 Detector Sharing

The X-ray Detector is equipped with Detector Sharing capability. Detector Sharing allows the IP address, password, and SSID to be set via software command. The software command for Detector Sharing can be sent via wireless or the Service Cable. Refer to document **03236 FP-2032 - Varex Smart Panel Software Interface** for more information.

9.0 The Detector Configuration File

A configuration file will ship with the X-ray Detector. The file is loaded by Varex onto the X-ray Detector and will contain 1 or more modes. The configuration file is stored in the X-ray Detector's non-volatile memory.

The purpose of each mode is to configure the X-ray Detector to achieve optimal performance during specific imaging procedures. Each mode is a combination of settings, such as; cycle time, rad or vTrigger, and integration time. The integration time or window exposure time is set dynamically, see [Section 11.9](#). Refer to document **03236 FP-2032 - Varex Smart Panel Software Interface** for more information on how to dynamically change the integration time.

The X-ray Detector supports Radiographic and vTrigger modes of operation, see [Table 10](#) for a typical mode example. The sensitivity of the X-ray Detector is optimized to match the X-ray dose used in each mode.

Table 10 Operational Mode Example

Characteristic	4343W	4336W
Modes	Radiography or vTrigger	Radiography or vTrigger
Pixel Binning	1 x 1	1 x 1
Integration Time	1000ms default (350ms - 4000ms possible)	550ms default (350ms - 4000ms possible)
X-ray Window Time	0.35 to 4 seconds Dynamic Integration	0.35 to 4 seconds Dynamic Integration
Cycle Time (@1000ms)	≤ 4.7 seconds	≤ 4.1 seconds
Image Area	Full Field	Full Field
Frame Size	3072 x 3072	3072 x 2476

10.0 System Software

The X-ray Detector deploys the Varex Smart Panel (VSP) architecture. X-ray Detector software is composed of two parts:

- Detector Software necessary to capture, process, and correct X-ray images (embedded in the detector).
- The VSP SDK client libraries.

Because the main software is embedded within the X-ray Detector, the only software required on the workstation is a small set of DLLs that are copied from the DVD to the workstation.

Software interacting with the X-ray Detector make API calls to these SDK libraries to control the image acquisition process. These libraries manage connections to the X-ray Detector and the transfer of files from the X-ray Detector to the workstation.

10.1 Radiography Acquisition

Radiographic acquisition is controlled by software. Each acquisition results in multiple frames (exposed and post-offset). Exposure is initiated by sending the Prepare command followed by the Trigger API command. When the trigger command is sent, it starts integration. The integration time is defined in the customer configuration file and may be different for each mode. APIs can be used to obtain several of the configuration file mode settings.

When trigger is called, the software sends notifications indicating the begin and end of integration. These signals are used to interface with the X-ray generator. The *exposure on* notification indicates that integration has started and exposure can happen. The *exposure off* notification indicates that integration has stopped, and the exposure should end. X-ray exposure must happen between these two events.

As noted, each acquisition is based on at least two frames being read from the detector. The first readout is the exposed frame which is readout immediately after the integration window. The second readout is the post-offset frame(s). If corrections are turned on, corrections will be applied to the exposed frame and a single frame is transferred to the workstation as soon as possible. When the frame is transferred to the workstation, a *Transfer End* event is sent to the workstation indicating that the corrected frame has been delivered to the workstation (see 03236 FP-2032 - Varex Smart Panel Software Interface for more information on acquisition and use of APIs).

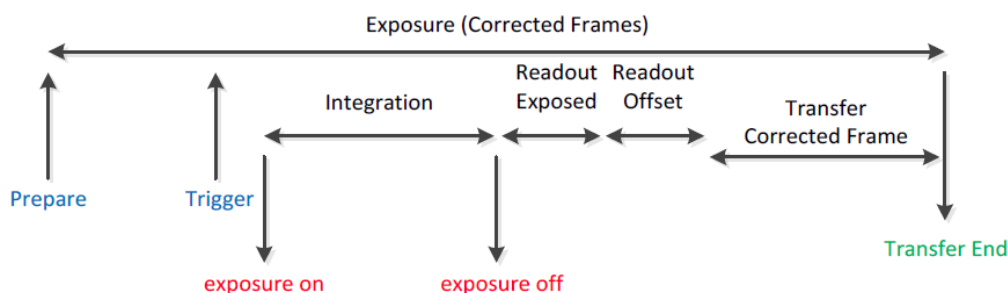


Figure 13 Exposure: Corrected Frames

If corrections are not turned on (i.e. raw frames), multiple frames will be delivered to the workstation (i.e. uncorrected exposed frame, and the post offset), see [Figure 14](#).

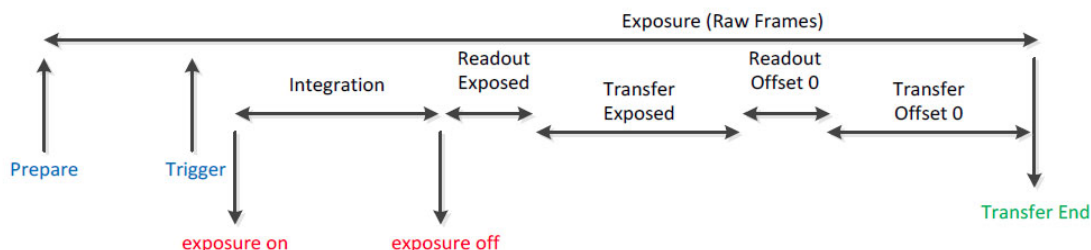


Figure 14 Exposure: Raw Frames

10.2 vTrigger Acquisition (AED)

The vTrigger acquisition is controlled by hardware. However, software is used to select a mode prior to arming the X-ray Detector. With the vTrigger mode selected, `vsp_acquisition_prepare()` is called, to arm the X-ray Detector in that mode. vTrigger modes are set up in the detector configuration file prior to use. These configuration file modes give the OEM the benefit of not requiring any hardware synchronization with the generator. A vTrigger acquisition mode utilizes the X-ray Detector's hardware to sense when X-rays are exposed to the X-ray Detector (i.e. Automatic Exposure Detection). Once X-rays have been detected, vTrigger automatically begins integration followed by image readout.

For modes that use vTrigger, only the Prepare command is used to arm the X-ray Detector, but the Trigger command is not needed since the X-ray Detector is in a vTrigger mode that uses automatic exposure detection. vTrigger modes will send the same notifications as those in the radiographic mode (e.g. *exposure on*, *exposure off*, *transfer end*, etc.)



Note

The minimum dose to initiate an exposure depends on system integrator requirements.

The sequences for integration and readout are the same as depicted in [Figure 13](#) and [Figure 14](#).

10.3 X-ray Generator Interface Signals

Normally a set of hardware signals are used to interface between the X-ray Detector and the X-ray generator and hand switch. For example, **PREP** and **REQ** are two hand switch signals that are typically used to indicate the user request for an X-ray exposure. Typically **PREP** (Prepare) indicates the user's input that X-ray exposure is imminent, while **REQ** (Request) indicates the user's input for immediate X-ray exposure. In response to the **REQ** signal, the X-ray Detector will indicate the proper time for the X-ray exposure with the **EXP_OK** (Exposure OK) signal.

To accomplish this task of passing hardware signals to-and-from the detector, VSP provides a software version of these signals in the API. For X-ray Detectors, the workstation software must provide the hardware interface to the X-ray generator and hand switch and relay those signals to the various API calls in the VSP Library. Upon receiving **PREP** signal, the workstation software should call the *Prepare* API function; upon receiving **REQ** signal, the workstation software should call the *Trigger* API function. When *exposure on* event is received, the workstation software should turn on the **EXP_OK** signal and when *exposure off* event is received, the workstation software shall turn off the **EXP_OK** signal.

	Note	For interfaces connection, synchronization and timing diagrams information please reference the Software Interface Specification 03236 FP2032_VarexSmartPanel_SoftwareInterfaceSpecification.pdf .
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10.4 SDK Installation

The VSP SDK requires that **libvsp.dll** and **libvsp-zf.dll** and Apple's **Bonjour** package be installed on the workstation.

Discovery of the VSP detector is simplified also by using **Zero-configuration (Zeroconf)** networking for detection of the detector by the operating system.

10.4.1 SDK Files

The installation of the SDK will copy several items to the workstation:

- The VSP COMM Libraries - **libvsp.dll** and **libvsp-zf.dll**
- SDK API Documentation
- Sample Code
- ViVa Test Application
- Third party libraries:
 - **Bonjour** (optional) - used by **Zeroconf**

Pre-compiled DLLs are provided for customers working with a Microsoft Windows operating system. Sample code (C#) will also be provided to illustrate the sequence of API calls needed to acquire X-ray images. This will include sample code for the standard set of APIs as well as usage of the consolidated API methods. For customers working in other operating environments, source code for the VSP DLL may be licensed for re-compilation.

It should be noted that corrections files are not stored on the workstation. Corrections and configuration files are stored on the X-ray Detector.

	Note	Refer to: 03236 FP2032_VarexSmartPanel_SoftwareInterfaceSpecification.pdf which provides API documentation for the software.
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10.4.2 Bonjour Installation Files

Bonjour is an optional installation and is required if you use the `List() / vsp_list()` API function and ViVA software. The following installations are provided:

- Bonjour.msi
- Bonjour64.msi

10.4.3 Sample Code

- vsp-example.cs – C# sample code project
- vsp-example.c – C/C++ sample code project

10.4.4 Utility Software

This file utility is used to transfer a configuration file to the X-ray Detector. This is a service function and should not be used by OEM customers. Additionally, transferring a new file to the X-ray Detector is typically only needed if modifications have been made to the configuration file.

- vsp-file.exe

11.0 X-ray Detector Operation

This section describes the operation of the X-ray Detector.

11.1 X-ray Detector Battery

This section describes installing and removing the Battery, Battery charge status, and Battery hot-swap.

	Note	New Batteries are shipped from Varex in shut-down mode. Before installing into the X-ray Detector, the Battery must be inserted into the 1 or 3-bay charger to remove it from shut-down mode.
	Note	For additional PDF information about the Varex Imaging Wireless Battery and Chargers, visit www.vareximaging.com .

11.1.1 Battery Installation

- 1 Insert Battery at a slight angle so that the side with contacts sits over the adjoining contacts in the battery compartment.

	Note	When inserting the battery the angle of the Battery should not be more than 20 degrees, inserting a battery at a larger angle could cause damage to the battery contact pins.
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- 2 Lay the Battery down, with the side opposite of the battery contacts slightly lifted.
- 3 Press down on the lifted side of battery, the Battery will snap into place in the Battery compartment.
- 4 The X-ray Detector is now ready for use.

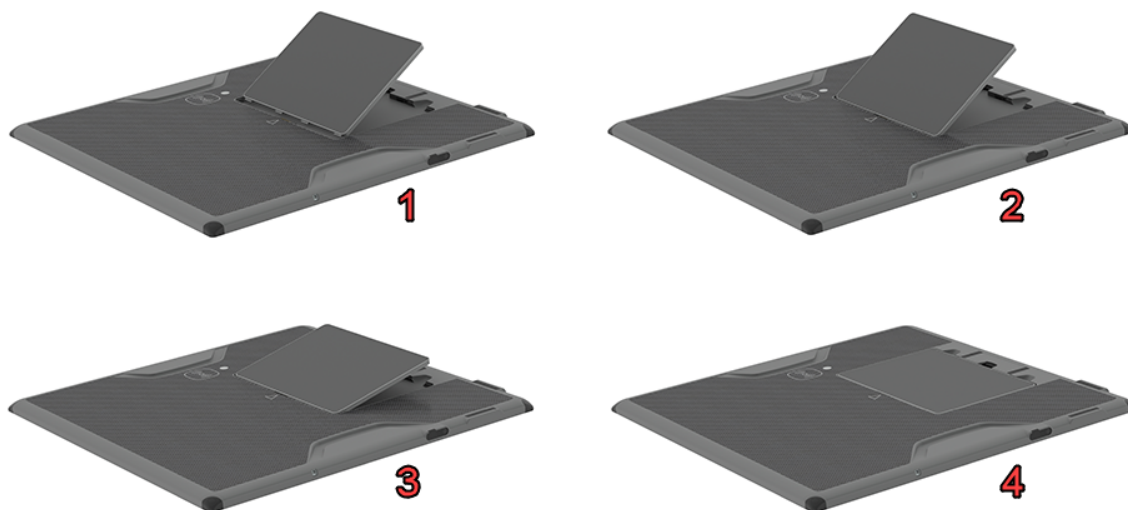


Figure 15 Representation of Battery Installation

11.1.2 Battery Removal

- 1 Press-in the Battery latch until an audible click is heard. The latch will stay in closed position.
- 2 Place a finger in opening on either side of the latch and lift the battery out.

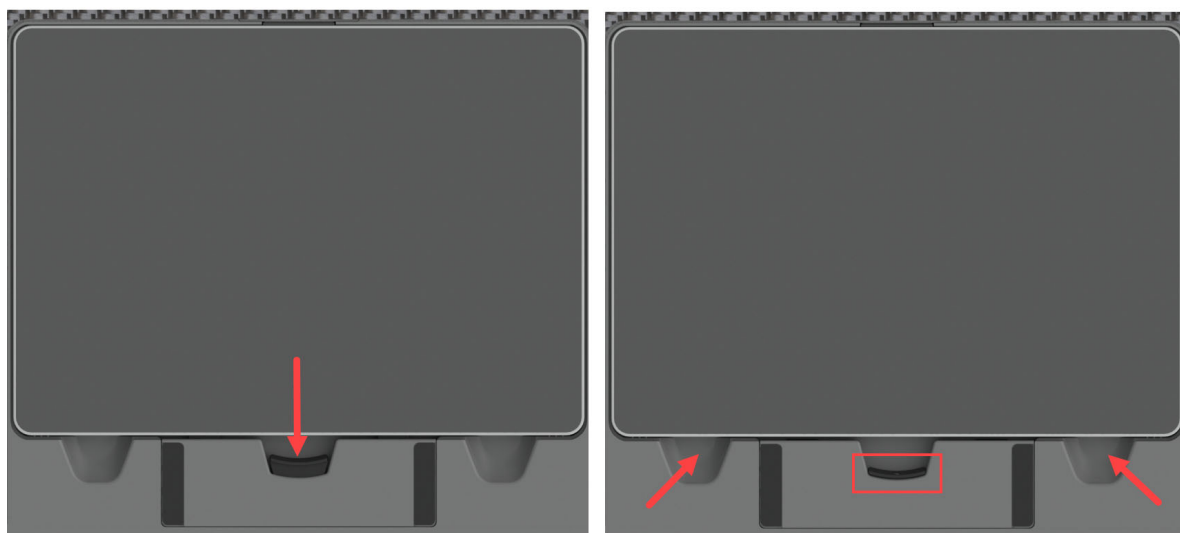


Figure 16 Unlatch Battery



Figure 17 Battery Removal



WARNING

Do not use the Battery Latch as a handle. Ignoring this warning may cause damage to the Battery Latch or increase the likelihood that the X-ray Detector may be dropped causing substantial product damage.

11.1.3 Battery Charge Level

The Battery charge level is found on the Battery. Press the indicator button on the Battery and charge level will illuminate. Each LED illuminated represents 25% charge.

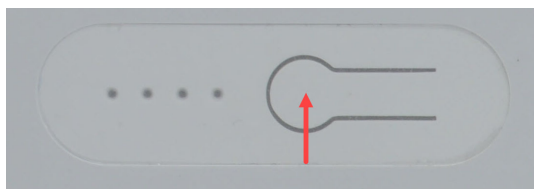


Figure 18 Battery Charge Level

11.1.4 Battery Hot-Swap

The X-ray Detectors are equipped with a Hot-Swappable Battery. When a discharged Battery is removed from the X-ray Detector, the User will have a set amount of time for the Battery Hot-Swap to occur.

Table 11 Battery Hot-Swap Operation Time

X-ray Detector	Operation Time
4343W	3 minutes
4336W	

	WARNING	If a fully charged battery is not re-inserted within the time window, the X-ray Detector will power-OFF.
	Note	Acquisition and calibration features are not available while Hot-Swapping a Battery.

11.2 Optional Varex Provided Inductive Battery Charger

The Battery may be charged using the Varex provided Inductive Battery Charger while the X-ray Detector is installed in the bucky tray.

	Note	During image acquisition or calibration, inductive battery charging will pause if Varex Inductive Battery Charger is used.
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11.2.1 Installing the Varex Provided Inductive Battery Charger

- 1 Install the Varex Inductive Battery Charger and Detector Support to the bucky tray.
- 2 Self-tapping screws with washers, machine screws with washers into PEM nuts (installed on the bucky tray), or 1mm (thickness) VHB Tape may be used to attach the Varex Inductive Battery Charger and Detector Support into the bucky tray. Use [Figure 19](#), [Figure 20](#), and [Figure 21](#) for mounting locations.
- 3 Route the USB-C Cable from the Varex Inductive Battery Charger to the Power Supply in a way that the opening and closing of the bucky tray does not cause damage to the cable. The USB-C Cable can be replaced if damaged.

	WARNING	Alignment between the Varex Inductive Battery Charger and the X-ray Detector should be exact. Poor alignment or foreign objects may cause overheating.
	Caution	The Varex Inductive Battery Charger and the X-ray Detector charging location should be flush when charging.
	Caution	The Varex Inductive Battery Charger and Detector Support may not fit all bucky trays. System Integrator should qualify bucky tray before installing.
	Caution	Screw heads must be sub-flush to avoid damage caused to the X-ray Detector when inserted into the bucky tray.



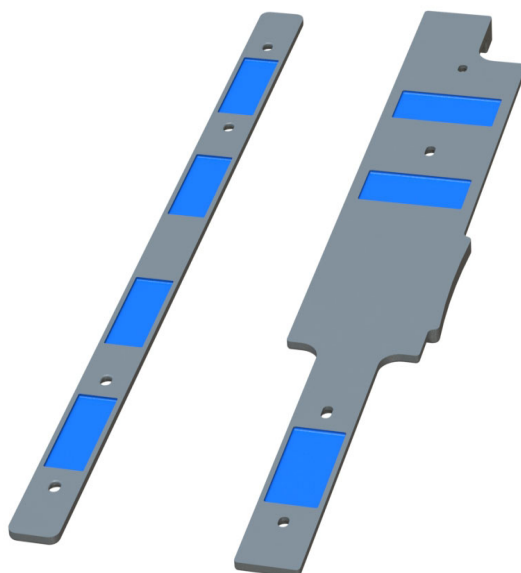


Figure 20 VHB Tape Placement Locations on Varex Inductive Battery Charger

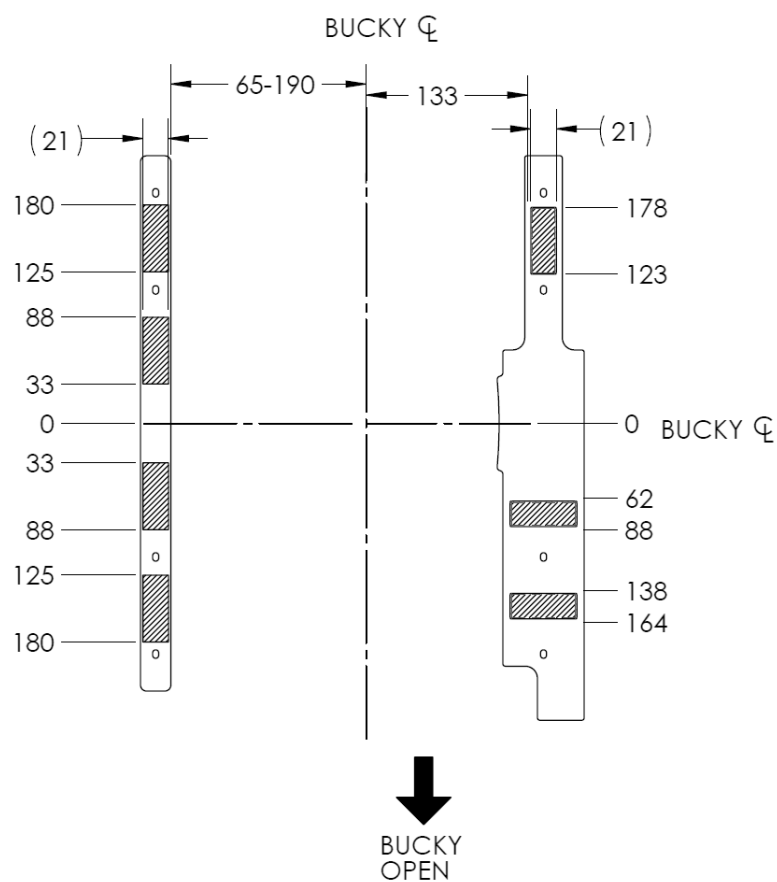


Figure 21 VHB Tape Placement Dimension on Varex Inductive Battery Charger

11.3 Using a Third-Party Inductive Battery Charger

Any third-party Inductive Battery Charger meeting the **Qi 1.2 standard at 15 watts** may be used for battery charging outside of the bucky tray. Refer to [Figure 22](#) for the location of the inductive charger receiver on the X-ray Detector for integrating a third-party Inductive Battery Charger.

	WARNING	Third-party Inductive Battery Chargers must not be used in the bucky tray. Ignoring this warning may result in image artifacts or damage to the X-ray Detector.
	Caution	Third-party Inductive Battery Chargers do not support image acquisition while using the charger.
	Note	To support image acquisition while using the charger, the Varex supplied Inductive Battery Charger must be used, see Section 11.2 .

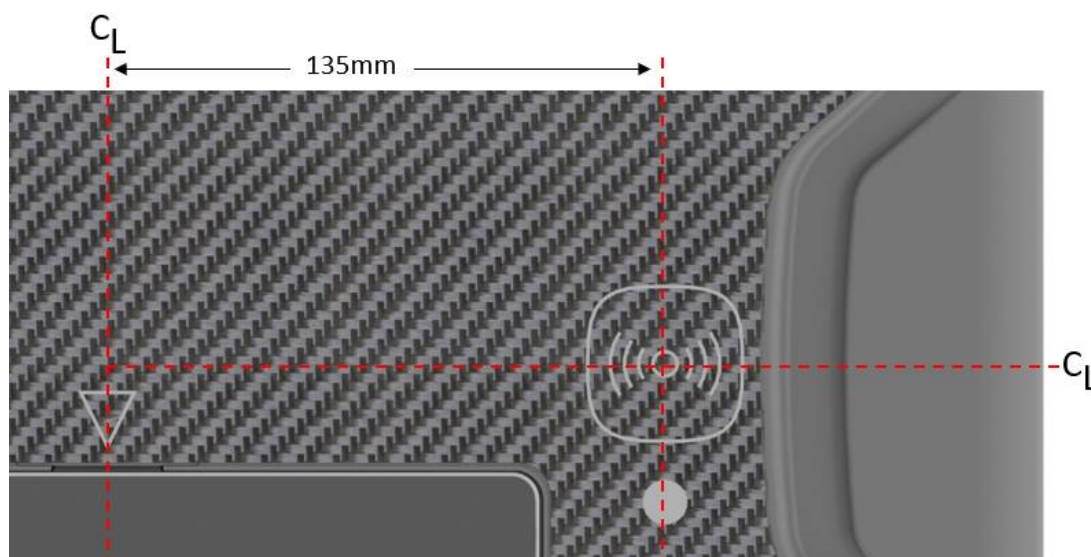


Figure 22 Third-party Inductive Battery Charger, 4343W, and 4336W X-ray Detector Alignment

11.4 Power-on and Power-off Sequence

To Power-on:

- 1 Insert the Battery into the 1 or 3-bay charger to remove from shut-down mode (only applies to Batteries that are new).
- 2 Place Battery into X-ray Detector making sure the Battery latches into place, see [Section 11.1.1](#) and [Section 11.1.2](#). The X-ray Detector will automatically **power-on** when battery is inserted.

	Note	When a Battery is inserted into the X-ray Detector, the LED Status Indicator will turn orange as it boots. After booting, it connects to the configured wireless router and is in Standby Mode, where the LED Status Indicator will blink twice (2) per second. If the X-ray Detector does not connect to the configured wireless router, it will blink slowly.
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To Power-off:

- 1 Remove the battery from the X-ray Detector.

	Note	Removal of the Battery does not automatically power-off the X-ray Detector. The X-ray Detector will stay powered-on for approximately 3 minutes or until discharged after battery removal.
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11.5 Reboot Sequence

The X-ray Detector may be rebooted if needed. To reboot:

- 1 Insert and remove the Battery **4 times within an 8 second window**, see [Figure 23](#).

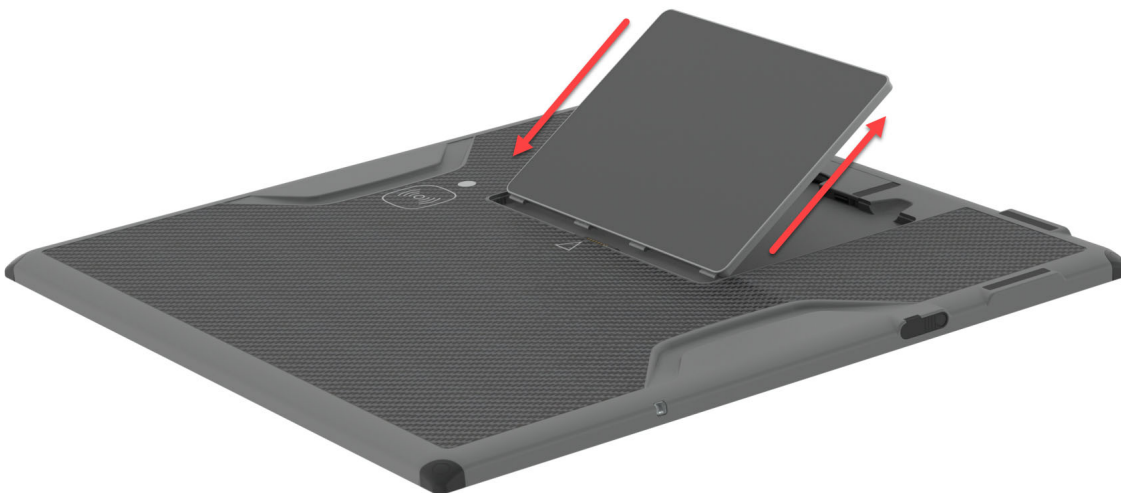


Figure 23 Reboot Sequence

11.6 LED Status Indicator Behavior



Figure 24 LED Status Indicator



Note

The blinking behavior occurs based on a 4Hz clock. Each digit for the blinking pattern represents 1/4s. **0** =LED OFF, **1** =LED ON, **X** = Previous State.

Table 12 LED Status Details **add details about LED behavior for Tether cable connected**

LED Behavior	Status
Orange Solid (111111)	Booting
Green Blinking (100000)	No connection to the detector, blinks every 1.5 seconds
Green Blinking (101010)	Connected to the detector, blinks twice (2) per second
Green Solid (111111)	Link Opened, detector controlled remotely, LED always on
Green Blinking (110011)	Connected to Service Cable (4343W) or Tether Cable (4336W), blinks once (1) per second
Yellow Solid (111111)	Detector Error
Purple Blinking (1xxxxx)	Battery Hot-Swap Active (battery exhausted or removed)
Blue Blinking (1xxxxx)	Battery is able to charge
No LED	Off

11.7 Linking to the X-ray Detector

- 1 Place a battery into the battery slot on the X-ray Detector and latch into place. The X-ray Detector LED will be solid **Orange**, then begin to blink **Green**. See [Table 12](#).
- 2 To link to the X-ray Detector, click the **ViVA icon** to launch the application.



Figure 25 The ViVA Icon

- 3 The X-ray Detector will link automatically in ViVA. When the X-ray Detector is linked, the **Mode Drop Down Menu** will become populated.

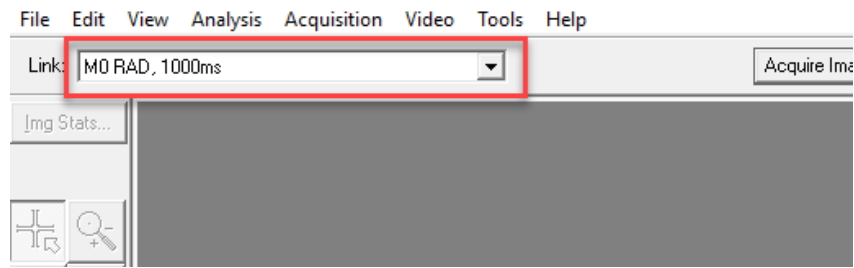


Figure 26 Detector Linked in ViVA

	Note	Automatically linking to the X-ray Detector in ViVA will require that Bonjour is installed.
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11.8 ViVA Configuration Settings

This section describes the ways to view or change calibration and system settings that are currently used in ViVA.

- 1 Choose the **desired imaging mode** from the Mode Drop Down Menu.

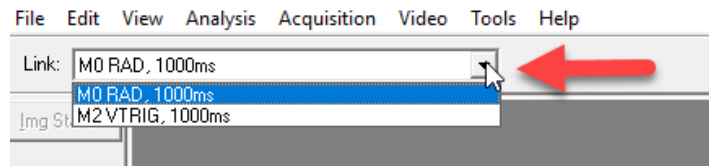


Figure 27 Mode Drop Down Menu

- 2 To enable or disable **Hardware Handshaking**, click **Acquisition** under the **Menu Bar** and select or de-select **Hardware Handshaking**. ViVA will remember your preferences for future launches. Hardware Handshaking is needed for gain calibration, see [Section 11.10.4](#).

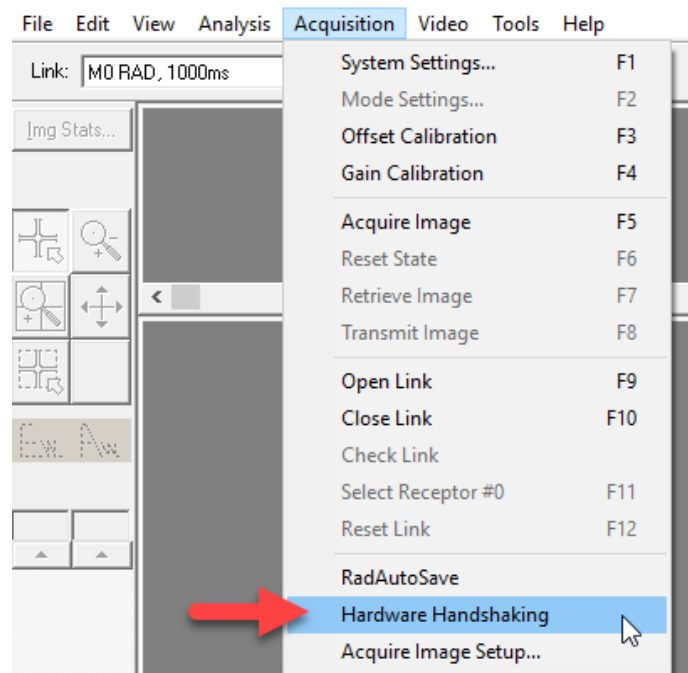


Figure 28 Hardware Handshaking Not Selected

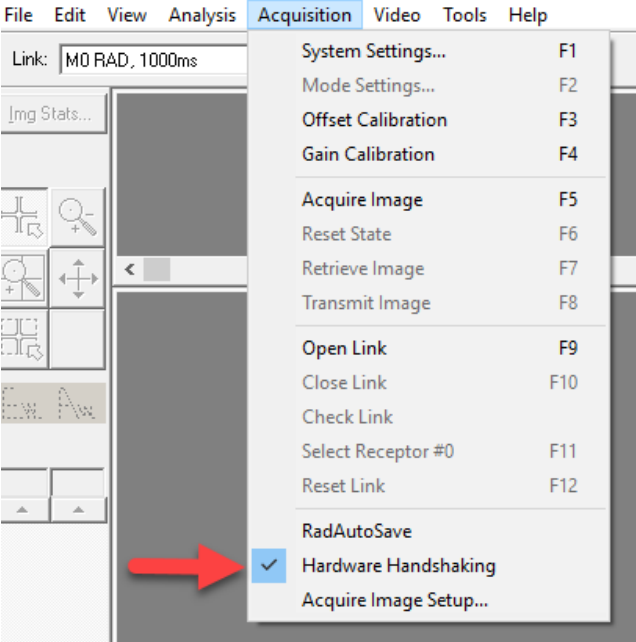


Figure 29 Hardware Handshaking Selected

- 3 To see **System Settings**, click **Acquisition** under the Menu Bar.
- 4 Click on **System Settings**. A **System Settings** window will appear. Image and calibration settings may be turned **On** or **Off** in this window.

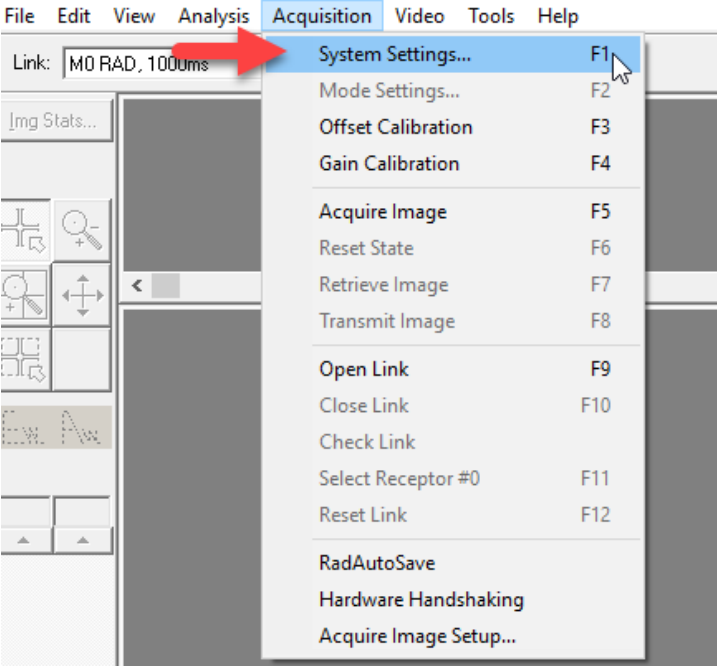


Figure 30 Open System Settings

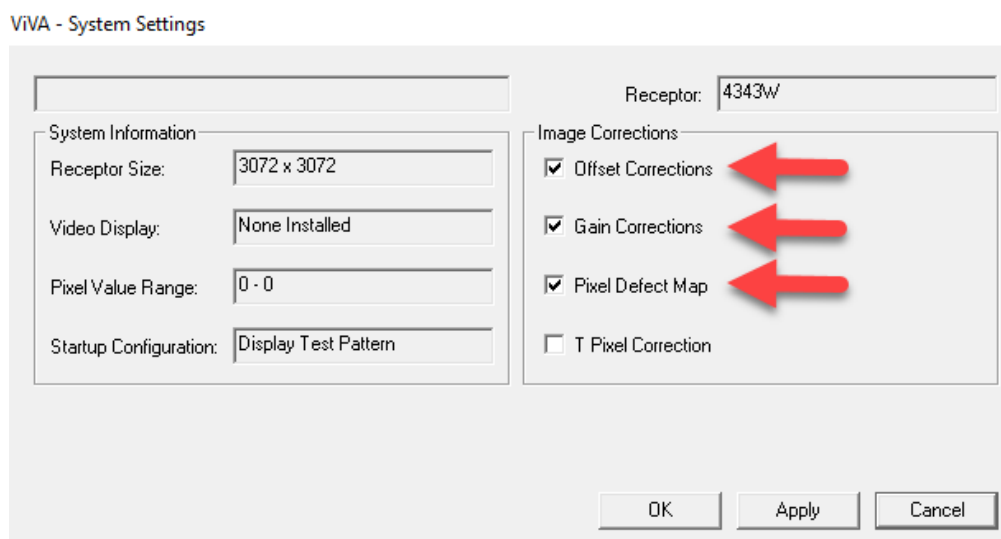


Figure 31 System Settings window

11.9 Dynamic Integration Settings

Dynamic Integration allows the User to change the exposure time settings within ViVA.

- 1 Click the desired mode from the **Mode Drop Down Menu**.

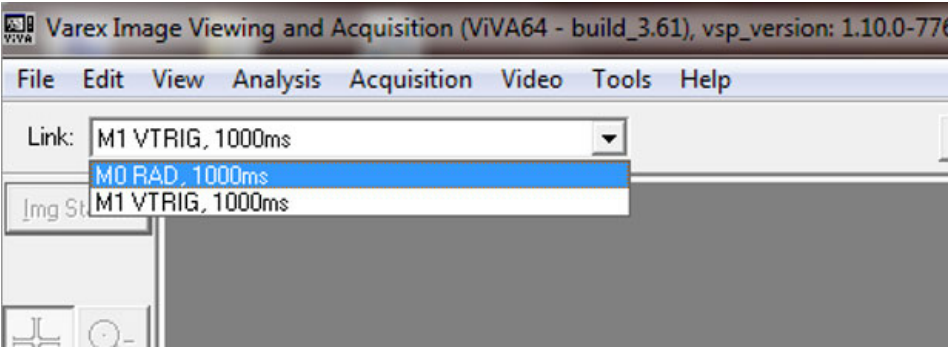


Figure 32 Select Mode

- 2 Click **Acquire Image Setup** from the menu bar under Acquisition.

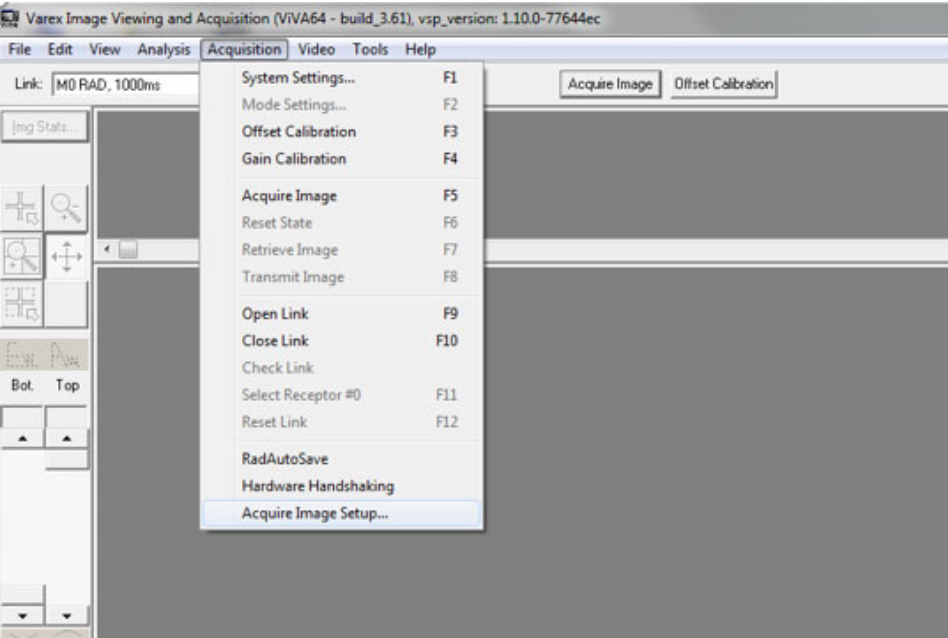


Figure 33 Acquire Image Setup

- 3 A message box will appear, click **OK** to proceed.

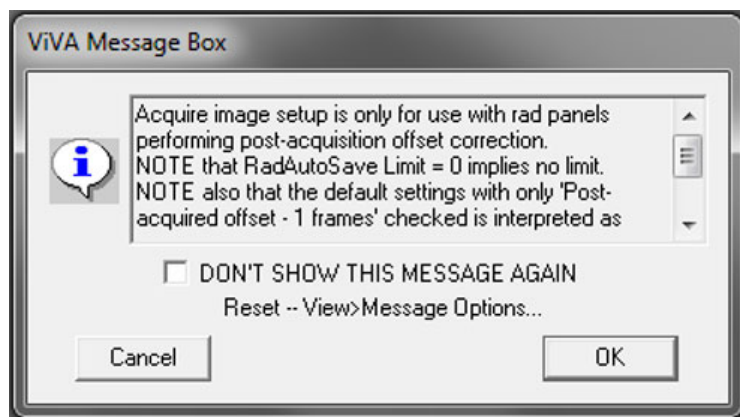


Figure 34 Message Box

- 4 Enter the **integration time** (exposure time) in the input box. Only values from 350 - 4000 ms will be accepted.

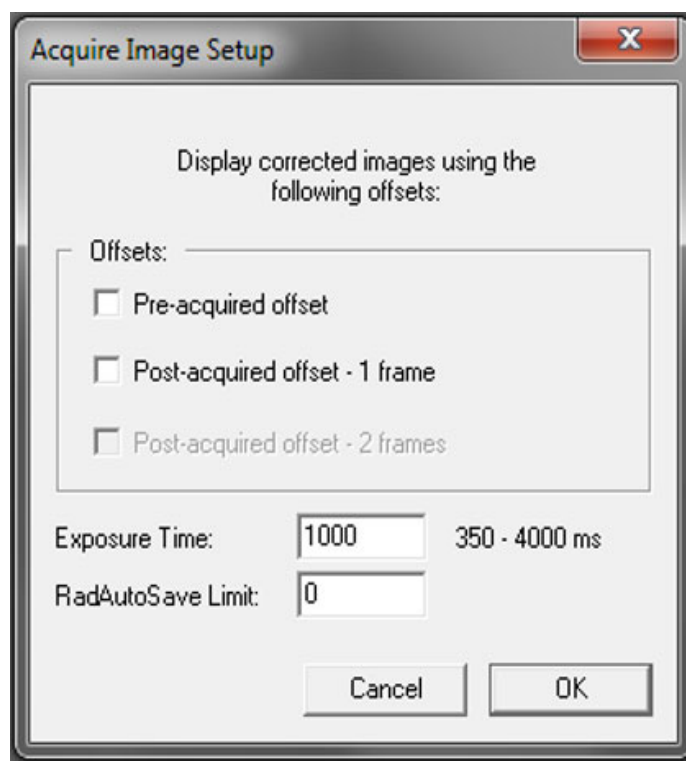


Figure 35 Enter Integration Time



Note

This selection will be maintained until a new integration time is entered, a different mode is selected, or the link has been closed.

11.10 X-ray Detector Calibration

X-ray Detector calibration files are stored inside the detector's non-volatile memory. There are three calibration files per mode: offset, gain, and defects. Calibration files are used for corrections during image acquisition.

	Note	After a calibration, ensure the new calibration files are used by closing and re-opening the link to the X-ray Detector.
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11.10.1 Offset Calibration

Offset calibration compensates for fixed pattern pixel intensity variations in the image associated with the dark current and electronic offsets. The Offset reference image is an average of a series of frames acquired without X-ray and referred to as dark fields. Prior to acquiring images, an offset calibration must be performed in each mode. The Offset calibration file created by this calibration is used by the corrections module to correct the preview image.

- Offset calibration must not be performed during X-ray.
- The X-ray to digital conversion factor does not change because of calibration.

11.10.2 Offset Calibration Steps

ViVA can be used to run the calibration process.

- 1 Choose the desired mode from the **Mode Drop Down Menu**.

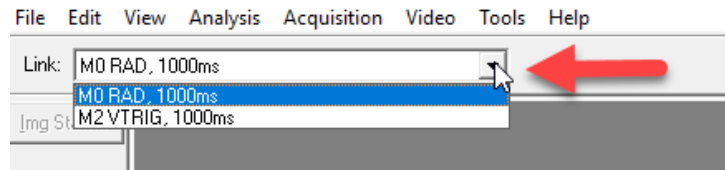


Figure 36 Mode Drop Down Menu

- 2 Click the **Offset Calibration Button** or click **Offset Calibration** from the menu bar under Acquisition.

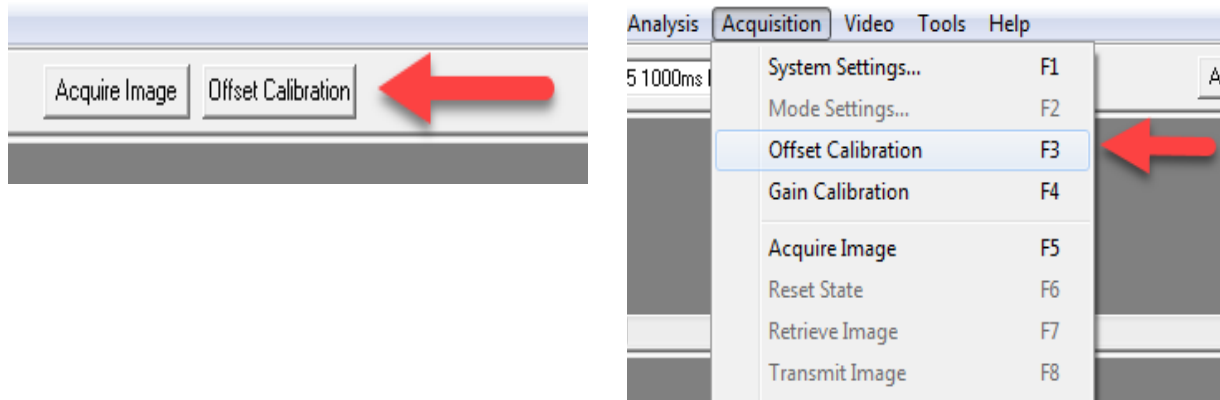


Figure 37 Initiate Offset Calibration

- 3 A **Calibration Setting** window appears.
- 4 Enter the **number of frames** desired and click **OK**.

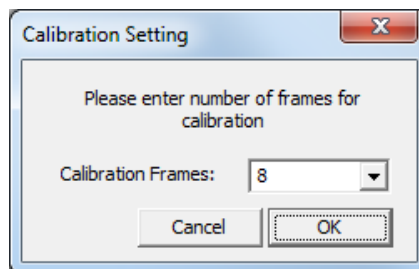


Figure 38 Calibration Setting window

- 5 An **Offset Calibration Progress** window appears.

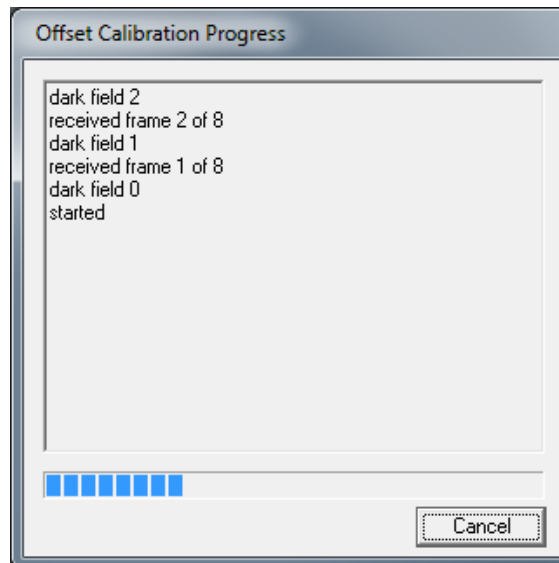


Figure 39 Offset Calibration Progress

- 6 Once all frames are acquired, the X-ray Detector is updated with the averaged offset calibration frame for the current mode. The updated message will show on the progress window and **calibration process is complete**.
- 7 Click **Close**.

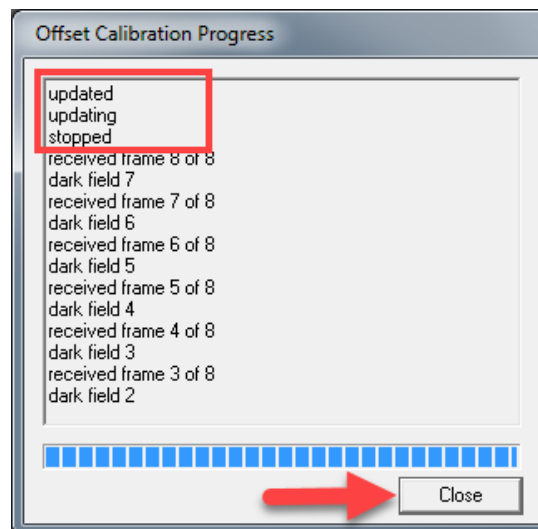


Figure 40 Finish Offset Calibration

11.10.3 Gain Calibration

To compensate for non-uniformities in the X-ray Detector, a gain reference image (flat field) is used by the Corrections module to correct all images. The flat field image must be captured by the VSP prior to acquiring images. The process of capturing the flat field image is known as gain calibration.

	Note	The gain calibration process will include automatically running an Offset calibration to ensure that the detector is properly calibrated.
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Gain calibration is based upon the linear response of the X-ray Detector to dose. Normalization is achieved by applying the flat field image acquired during the gain calibration to all images corrected by the VSP. Gain calibration should be performed in the range where the detector is linear.

Flat field images acquired near or exceeding the saturation point will cause normalization failures with all images acquired until a gain calibration with the correct dose is performed.

	Note	It is recommended that flat field images be acquired with a median count of approximately 11000 - 15000 .
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This range will ensure that gain calibration will meet both the upper and lower dose requirements under all modes of operation. Dose requirements are determined by the settings of the generator X-ray source.

To reduce the effects of noise, the average of each pixel in the flat field image is calculated by accumulating a number of frames into an internal memory buffer, then dividing the sum of each pixel by the number of frames acquired.

	Note	Gain calibration requires X-ray dose. Certain precautions must be taken by the human operator.
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The number of calibration frames used during Gain and Offset calibrations can be adjusted under the Mode Settings pull down menu.

	Note	We recommend accumulating 32 frames for gain calibration and 8 frames for offset calibration for optimal image quality.
	Note	Gain calibration should be performed at least once per year.

The actual number of calibration frames used is determined by the system integrator depending upon their specific performance requirements.

	Note ViVA provides the convenience of automatically running Offset Calibration as part of the gain calibration process. However, API driven gain calibrations do not automatically run Offset Calibration. OEM Applications should be sure to run Offset Calibration prior to gain calibration.
---	--

11.10.4 Gain Calibration Steps

The general procedure for gain calibration for all modes is described in [Table 13](#).

Table 13 Gain Calibration Sequence in ViVA- All Modes

Action	Results
Power On	Power On the detector by inserting a battery. Once the detector is powered on the detector is in low-power state. Wait 5 minutes prior to gain calibration.
Offset Calibration	Software performs a new Offset calibration referred to as dark field acquisition. Note: X-rays must not be used for this part of the calibration.
Gain Calibration	Multiple Gain frames taken. Software pauses at each frame so that the operator can apply X-ray exposure. Note: The exposure should ideally be at a level and technique representative of the typical exposure dose for the detector during procedures.
Repeat	The above procedure must be repeated for each of the stored imaging modes.

- 1 Choose the **desired imaging mode** from the Mode Drop Down Menu.

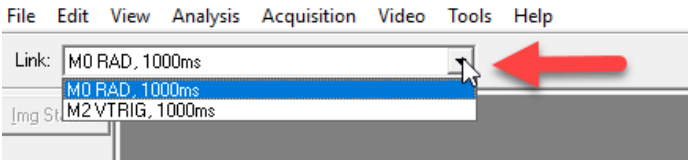


Figure 41 Mode Drop Down Menu

- 2 Under the Acquisition menu, click **Gain Calibration**. This invokes **hardware handshaking** for the dark field calibration.

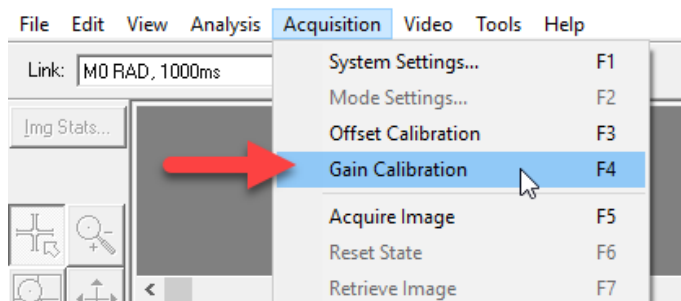


Figure 42 Initiate Gain Calibration



WARNING

In order to acquire an image with X-ray exposure in vTrigger mode, Hardware Handshaking must be enabled, see [Figure 29](#), or an image without exposure will be returned.

- 3 A **Gain Calibration Progress** window will appear. When prompted (waiting for X-ray), perform exposure.

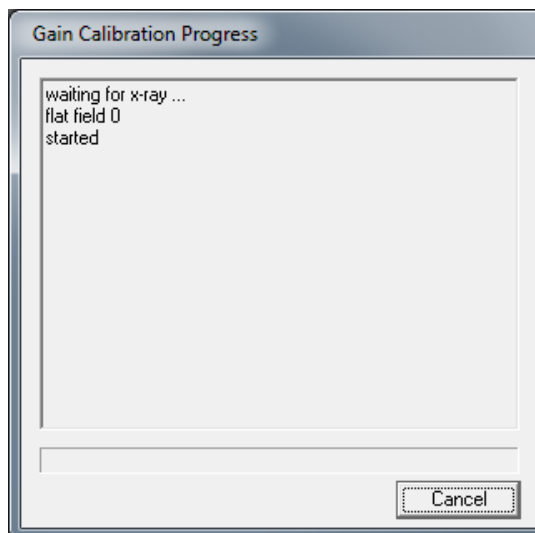


Figure 43 Gain Calibration Progress window

- 4 Once all X-ray frames have been accumulated, the calibration process will average the gain calibration image for the current mode.

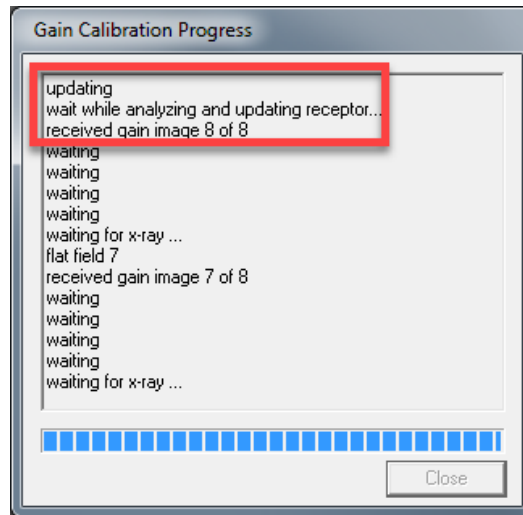


Figure 44 Gain Calibration Updating

- 5 When complete, an **updated** message and **successfully finished calibration** message will appear. The calibration process is complete. Click **Close**.

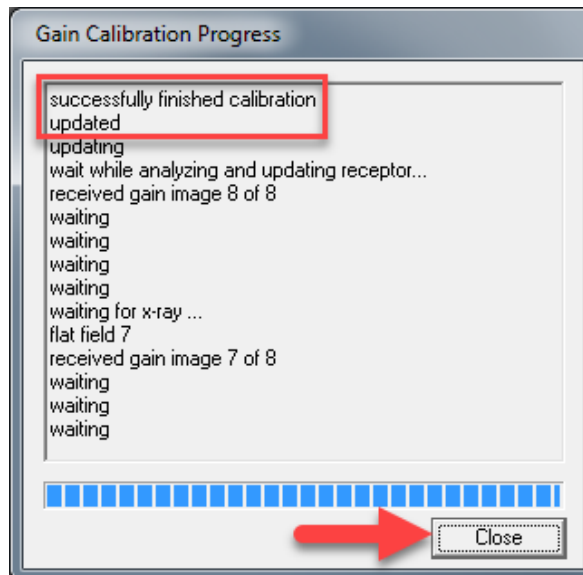


Figure 45 Gain Calibration Complete

	Note	Gain calibration should be performed at regular intervals: • At least, every twelve (12) months. • If the central beam of the X-ray source has been moved relative to the X-ray Detector. • If the X-ray tube is replaced. • If the X-ray Detector is dropped.
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11.11 Image Acquisition

Acquisition can be performed after Offset and gain calibration have been performed. This section describes how to acquire images.

Before performing acquisition, settings should be checked to ensure that the desired corrections are applied to acquired frames. Table 14 lists the types of corrections that can be applied.

Table 14 Types of Corrections that can be applied during Acquisition

Type	Images transferred to Workstation
Raw	Exposed Frame and Post-Offset Frame
Corrected	A single fully corrected frame
Offset Corrected	A single offset corrected frame, without gain and defect correction
Gain Corrected	A single gain corrected frame, without defect correction



Note

When acquiring Corrected, Offset Corrected, and Gain Corrected images; if preview is enabled and additional preview frame will be delivered to the workstation prior to any additional frames.

- 1 To set the Correction type, click on **Settings**, the **Acquisition Settings Menu** will appear.

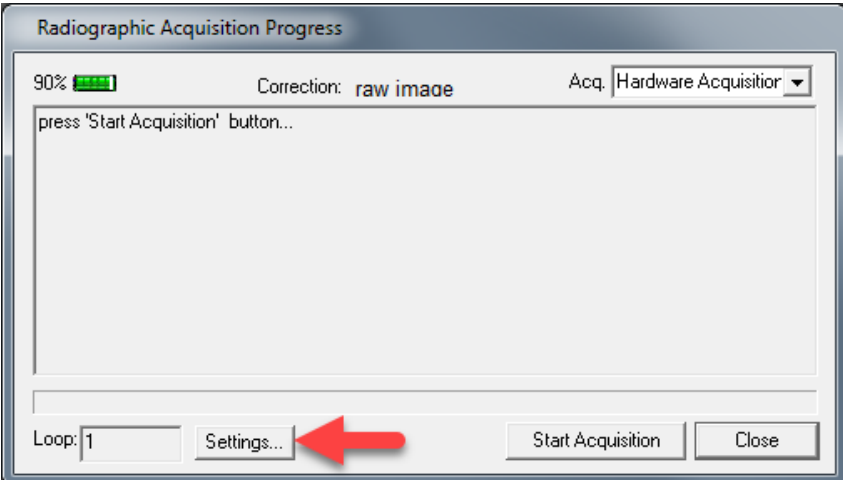


Figure 46 Radiographic Acquisition Settings

- 2 In the **Acquisition Settings** window; the type of **corrected image**, the number of **loop acquisitions (if desired)**, **Auto Save**, and **Debug Verbosity** may be selected. Click **OK**.

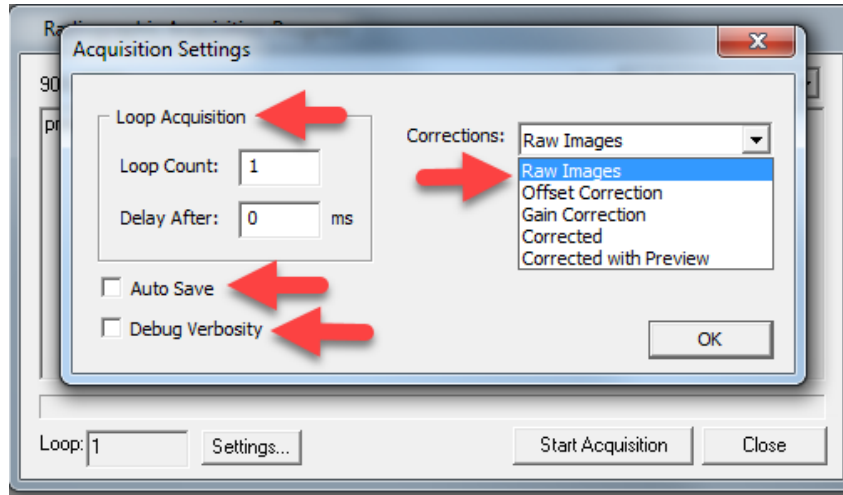


Figure 47 Radiographic Acquisition Settings window

11.11.1 Acquiring Radiography Images

Radiography provides single-shot, high-resolution images for diagnosis.

	Note	The OEM workstation should have the ability to employ the PREP and Expose_OK signals. See Section 10.3 or Section VSPADU-UTILITY in 03236 FP2032_VarexSmartPanel_SoftwareInterfaceSpecification.PDF for an example of controlling the X-ray Generator.
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- 1 Choose the **desired imaging mode** from the Mode Drop Down Menu.

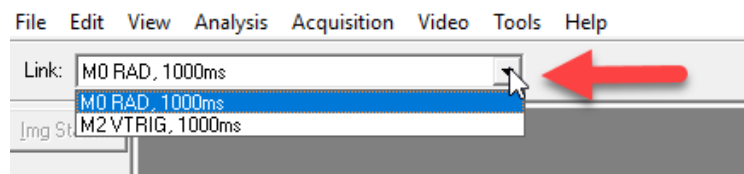


Figure 48 Mode Drop Down Menu

- 2 Make sure **Hardware Handshaking** is selected, see [Figure 29](#).

	Note	In order to acquire an image with X-ray exposure in vTrigger mode, Hardware Handshaking must be enabled, see Figure 29, or an image without exposure will be returned.
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- 3 Click **Acquire Image** button or click **Acquire Image** in the Acquisition menu under the Menu Bar to begin acquiring images.



Figure 49 Acquire Image Button

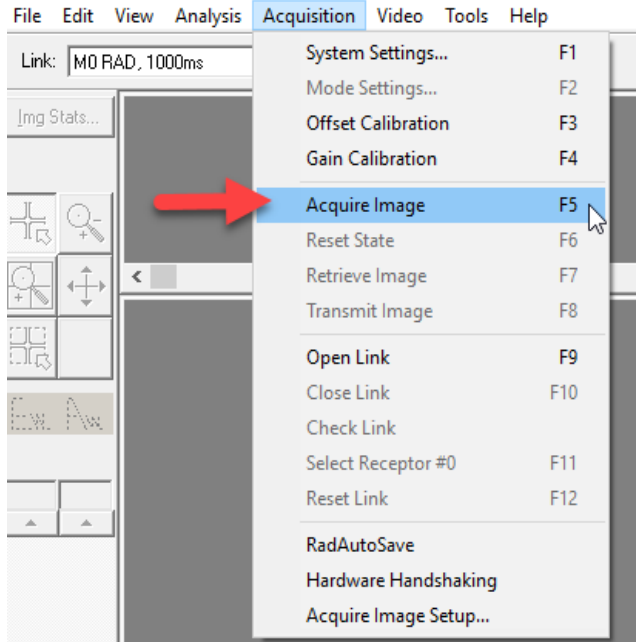


Figure 50 Acquire Image

- 4 An **Acquisition Progress** window will appear. Click **Start Acquisition** and initiate X-ray exposure.

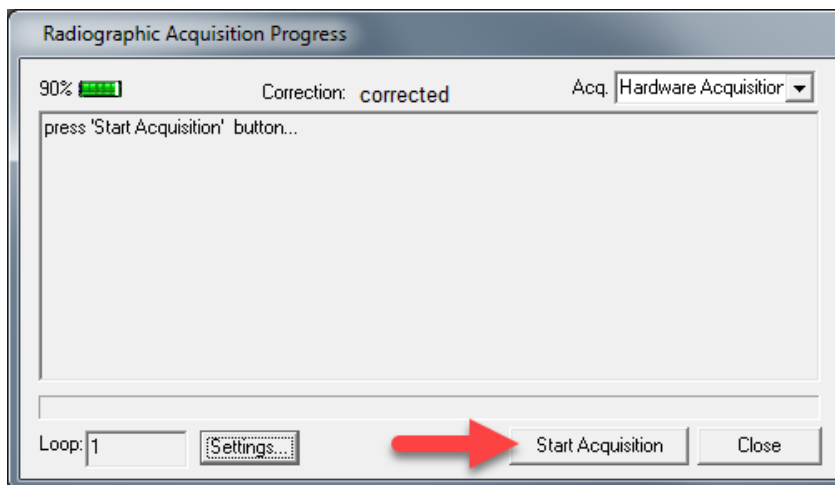


Figure 51 Start Acquisition

- 5 The **Radiographic Acquisition Progress** window will begin to show acquisition process with a blue status bar.

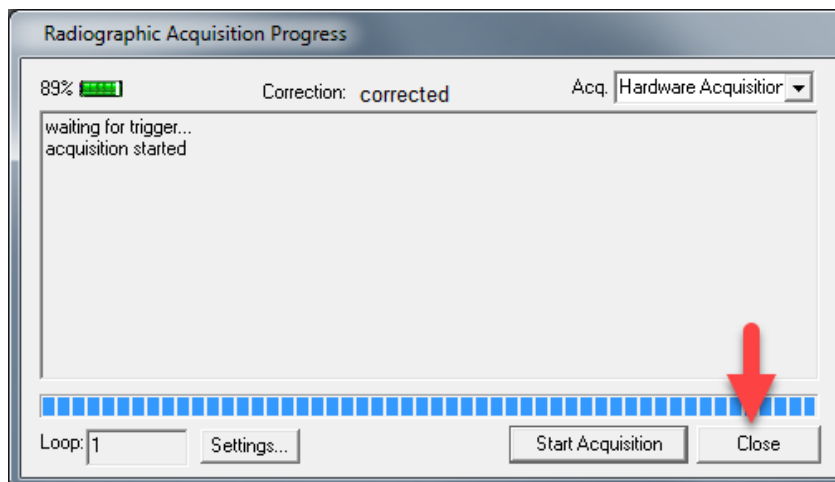


Figure 52 Image Acquisition Progress

- 6 The acquired image can be saved in the desired file format by clicking **File/Save As**.

11.11.2 Radiographic Acquisition Settings

In the **Radiographic Acquisition Progress** window the type of acquisition may be changed.

- 1 Click the **Acquisition Type Drop Down Menu** to switch between **Software** or **Hardware Acquisition** (vTrigger).

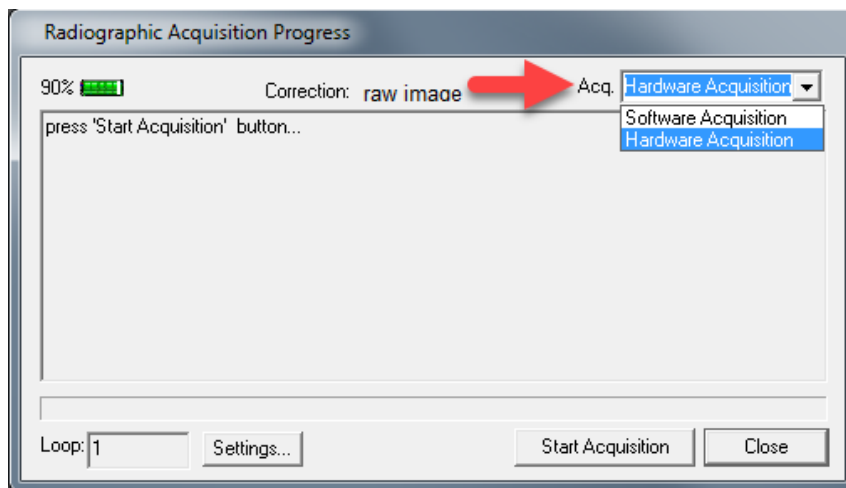


Figure 53 Acquisition Type Drop Down Menu

11.12 VSP Control Panel

Varex Smart Panels utilize a Control Panel to manage detector configuration settings. The Control Panel is accessed using a web browser (using the X-ray Detector's IP address). The Control Panel allows administrators to work with the following configuration settings:

- Detector settings
- WiFi settings
- Change Password
- Firmware Update
- View detector information
- View the Error Log
- Update Country Codes file
- Reset software to Factory Image

**Note**

Control Panel screens will vary slightly for the type of detector. WiFi related settings will only display for wireless detectors.

11.12.1 Access the VSP Control Panel

To access the Control Panel:

- 1 Open a **browser** and navigate to the IP Address of the X-ray Detector, example:
http://192.168.2.31
- 2 Authentication is required to make any modifications to the settings in Control Panel. The first time any of the links are clicked on the left side of the control panel, you will be prompted with a dialog box which allows you to log in.

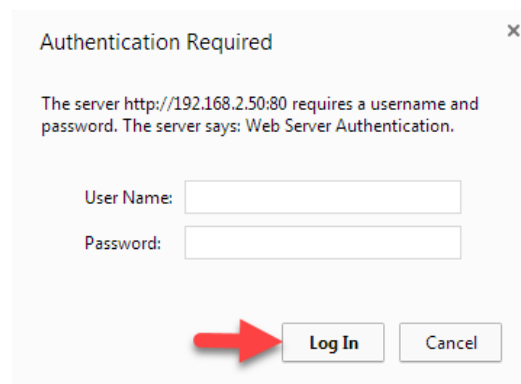


Figure 54 VSP Control Panel Access Authentication

	Note	The Authentication Required Dialog Box will look different in each browser, but require the same User Name and Password.
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- 3 Enter the default user and password:
- User Name: **admin**
 - Password: **password**
- 4 Click **Log In**.

	Note	Once the X-ray Detector is configured, the default password should be changed.
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- 5 The main VSP Control Panel screen displays links in the left pane. When a link is clicked the content will show in the right pane.

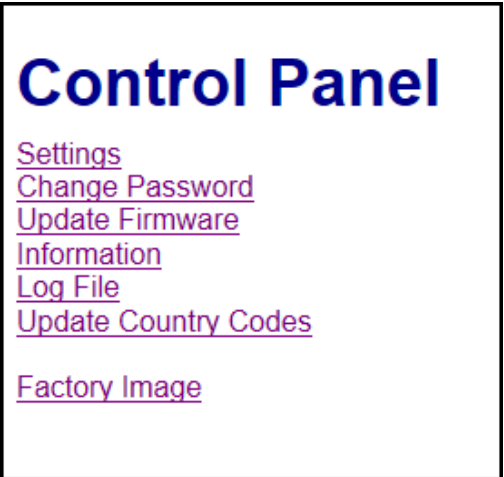


Figure 55 VSP Control Panel

11.12.2 Modify Settings

To modify the settings:

- 1 Click **Settings**.
- 2 The **Settings** content will load and any settings that are able to be modified.
- 3 After inputting desired settings, click **Update**. The X-ray Detector will reboot and the new settings will be updated on the X-ray Detector.

Control Panel

[Settings](#) [Change Password](#) [Update Firmware](#) [Information](#) [Log File](#) [Update Country Codes](#) [Factory Image](#)

Network Settings

IP Address ex. 192.168.2.31/24, Blank = use DHCP

Logging Settings

Logging Method ex. 192.168.2.101 = SYSLOG Server and Log File, Blank = Log File Only
Logging Level DEBUG should not be used in a clinical environment

Wireless Settings

Wireless Mode ☒ Station ☐ Access Point
Valid SSID and Pass Phrase characters are 0-9, A-Z, a-z, ! # % + , - . ? [] ^ _ }
Wireless SSID
Wireless Pass Phrase

Figure 56 Modify VSP Control Panel Settings

11.12.3 Change Password

To change the password after logging in:

- 1 Click **Change Password**.
- 2 Enter a new **Password**.
- 3 Once the new password is entered along with its matching confirmation, click **Change** to confirm the new password.
- 4 To clear the passwords entered in the forms, click **Reset**.

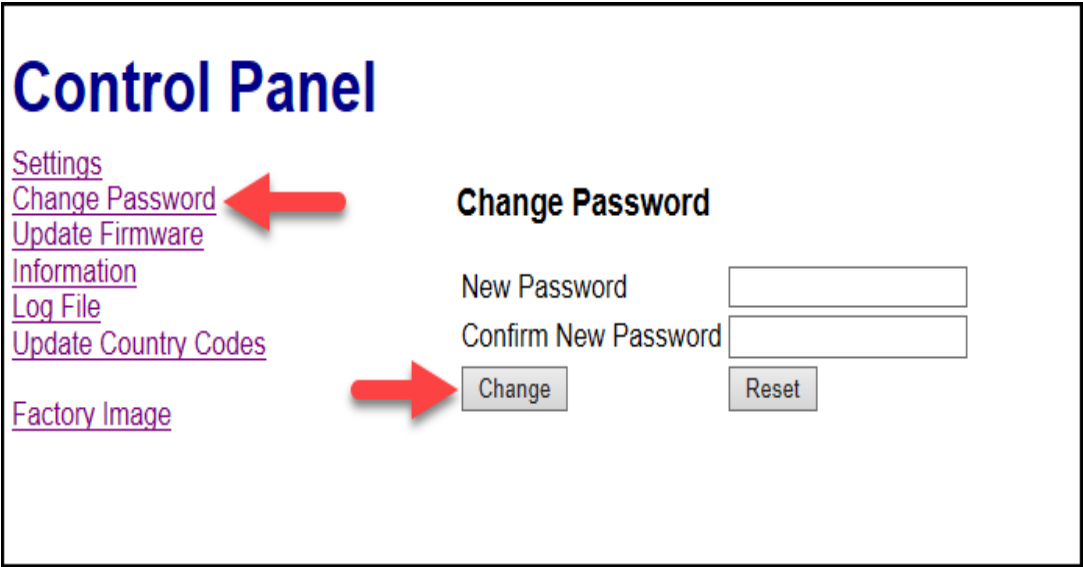


Figure 57 Change Password

	Note	Passwords must be at least 8 characters in length.
	WARNING	There is no back door available to the User or Varex for password recovery. If the password is mismanaged, it will result in the return of the X-ray Detector for service.

11.12.4 Firmware Update

To update the VSP Firmware:

- 1 Click **Update Firmware**. This option is used to update all X-ray Detector software (embedded software, firmware, etc).
- 2 Select the Varex provided firmware image by clicking **Browse**.
- 3 After selecting the desired firmware, click **Update Firmware** to send the image to the VSP and start the upgrade process.

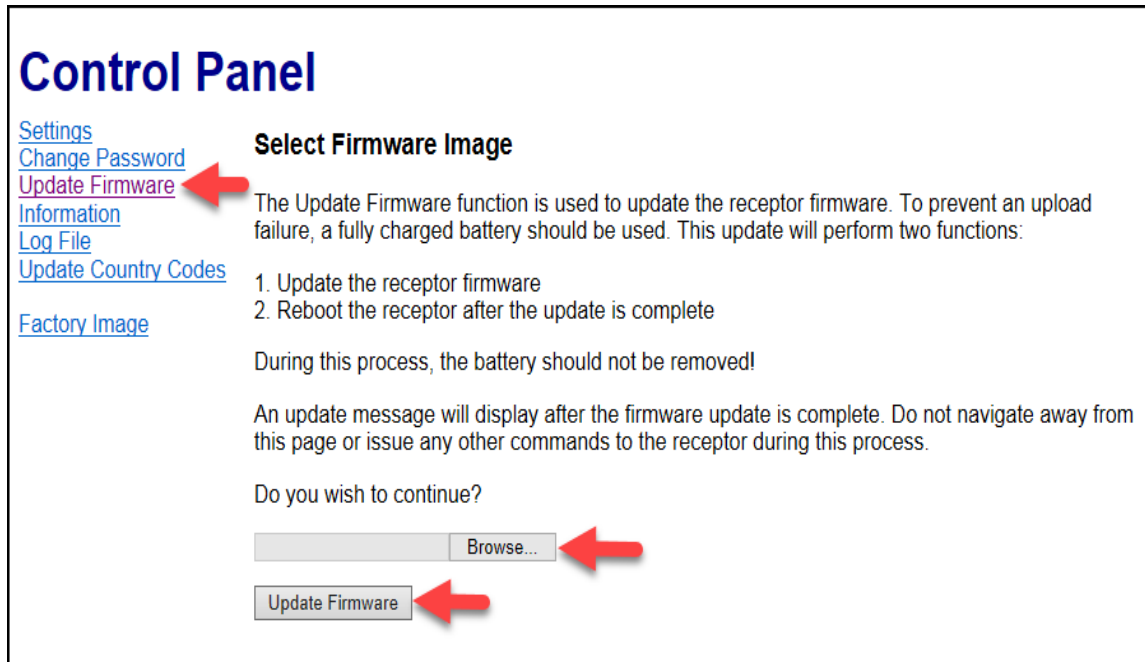


Figure 58 Updating the Firmware

- 4 During the update, another page will display showing the file upload was successful. At this point the X-ray Detector will apply the updated firmware.

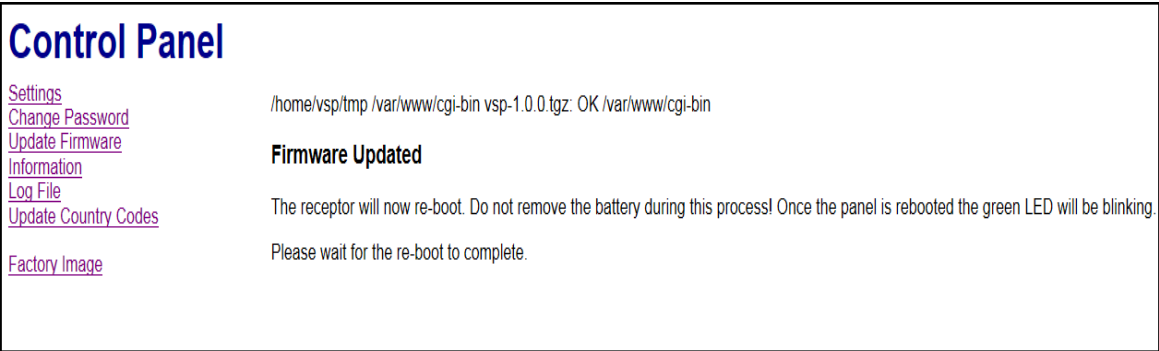


Figure 59 Firmware Updated

	WARNING	A fully charged battery should be used during firmware update. Do not remove the battery during firmware update.
	WARNING	Do not remove the Service Cable until the X-ray Detector's LED is blinking Green.

12.0 Maintenance

In principle, the X-ray Detector assembly is maintenance-free, however; it is important that all calibrations are regularly performed and used for image processing.

Although the a-Si X-ray Detectors are resistant to X-rays they can exhibit degradation over time when exposed to high X-ray dose environments. Sensitivity and uniformity may change depending on the weekly exposure duration and X-ray dose. Therefore, the pixel correction maps should be checked and updated regularly.

12.1 Cleaning and Disinfecting

The X-ray Detector is likely to become contaminated during use. The specific material most likely to become contaminated is the X-ray grade carbon fiber input window and housing.

	WARNING	When the X-ray Detector system is going to be cleaned or disinfected, be sure to remove the battery pack. Ignoring this warning may result in explosion, fire, or electrical shock, which may result in severe personal injury, death, or substantial product damage.
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12.1.1 Material Compatible Chemicals for Cleaning and Disinfecting

All chemicals listed below are approved for use can be used for cleaning and disinfecting X-ray Detector surfaces. To achieve full cleaning and disinfecting results, perform the procedures in [Section 12.1.2](#) and [Section 12.1.3](#) for each cleaning product.

A list of chemicals is presented below:

- CAVI-Wipes from Metrex
- Isopropyl Alcohol
 - 70% aqueous solution
- Mild Soap and Water
- Ethanol 70%
 - Chlorine Bleach, 3% aqueous solution
- Quaternary Ammonium Components
 - Steris Coverage Plus NPD
 - 1 part Coverage Plus NPD to 255 parts Water

12.1.2 Cleaning the X-ray Detector

To clean the X-ray Detector:

- 1 Remove the battery from the X-ray Detector.
- 2 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.
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- 3 Dispense wipe from container.
- 4 Visually inspect the device. If contamination is present, use a wipe to remove the contamination from the device surface. Use multiple wipes, as applicable, to remove the visible contamination.
- 5 Take care to remove contamination from seams, joints, and other difficult-to-reach areas.
- 6 Dispose of each wipe used for cleaning.
- 7 If visible residue from the cleaning product is evident after air-drying, remove the residue with a general Isopropyl Alcohol wipe, and let air-dry.

12.1.3 Disinfecting the X-ray Detector

To disinfect the X-ray Detector:

- 1 Remove the battery from the X-ray Detector.
- 2 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.
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- 3 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.
- 4 Take care to wet seams, joints, and other difficult-to-reach areas.
- 5 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 a 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.

- c Let air-dry.
- d If visible residue is evident after air-drying, remove the residue with a **general Isopropyl Alcohol wipe**, and let air dry.
- e Do not re-use wipes. Discard wipes and gloves into the correct waste container.

	WARNING	Do not use flowing liquid or immersion on the X-ray Detector, battery, battery compartment, or battery charger.
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12.2 Field Replaceable Parts

The X-ray Detector has been designed to allow for field replacement of parts that may wear out after repeated usage, avoiding the need to return the X-ray Detector to Varex for repair. Contact Varex customer support ([Section 13.1](#)), for procedure to replace the following items:

- Antenna Overlay
- Battery Contacts
- Battery Latch (w/Screw Overlay)
- Carbon Fiber Overlay
- Housing Overlay
- Service and Tether Cable Connection Cover
- Varex Inductive Charger

13.0 Troubleshooting

This section describes suggestions for troubleshooting.

Table 15 Problems and Solutions

Problem	Solution
Detector fails to link wirelessly	1. Ensure that the detector is associated to the access point, refer to Table 12 for LED indicator behavior. 2. Let power-off (Section 11.4) or reboot the detector (Section 11.5), re-insert the battery, and try to associate with the access point again. 3. If the detector will still not link, power cycle the access point. 4. If the detector will still not link, check the connections and the settings on the access point. Check SSID, IP Address, and password to ensure they match. 5. If problem persists, consult the manufacturer or field service technician for help.
Detector causes Electro-Magnetic Interference	1. Reorient or relocate the receiving device. 2. Increase the separation between the equipment. 3. Consult the manufacturer or field service technician for help.
Acquired image is Non-linear or the pixel are past the saturation point of dose	1. Let power-off (Section 11.4) or reboot the detector (Section 11.5), re-insert the battery, re-establish the link. 2. Ensure that the tube dose is set to the correct settings. 3. Acquire another image at the recommended median count as stated in Section 11.10.3. 4. If problem persists, consult the manufacturer or field service technician for help.
Acquired image is completely dark	1. Let power-off (Section 11.4) or reboot the detector (Section 11.5), re-insert the battery, re-establish the link and acquire another image. 2. Check synchronization between the X-ray Detector and the X-ray source. 3. If problem persists, consult the manufacturer or field service technician for help.

Table 15 Problems and Solutions (Continued)

Acquired image is noisy	1. Ensure that surrounding equipment is not interfering and re-position the detector further away from equipment. 2. Let power-off (Section 11.4) or reboot the detector (Section 11.5), re-insert the battery, re-establish the link and acquire another image. 3. Move the X-ray Detector from any device that may introduce noise. 4. If problem persists, consult the manufacturer or field service technician for help.
Acquired image shows a white or a black channel	1. Let power-off (Section 11.4) or reboot the detector (Section 11.5), re-insert the battery, re-establish the link. 2. Ensure that the tube dose is set to the correct settings. 3. Acquire another image at the recommended median count as stated in Section 11.10.3. 4. If problem persists, consult the manufacturer or field service technician for help.
Acquired images show defective pixels	1. Let power-off (Section 11.4) or reboot the detector (Section 11.5), re-insert the battery, re-establish the link. 2. Ensure that the tube dose is set to the correct settings. 3. Acquire another image at the recommended median count as stated in Section 11.10.3. 4. If the problem persists, add the defective pixels to the defect map and redo a gain calibration. 5. Acquire another image. 6. If problem persists, consult the manufacturer or field service technician for help.
Acquired image does not respond to exposure or the subject that is being X-rayed does not show up in the acquired images	1. Let power-off (Section 11.4) or reboot the detector (Section 11.5), re-insert the battery re-establish the link. 2. Ensure that the tube dose is set to the correct settings and that the detector is in the path of the X-ray beam. 3. Acquire another image at the recommended median count as stated in Section 11.10.3. 4. Ensure that the X-ray Detector is in the X-ray Beam path. 5. If problem persists, consult the manufacturer or field service technician for help.

Table 15 Problems and Solutions (Continued)

Acquired image shows vertical or horizontal lines	1. Let power-off (Section 11.4) or Reboot the detector (Section 11.5), re-insert the battery, re-establish the link. 2. Ensure that the tube dose is set to the correct settings. 3. Acquire another image at the recommended median count as stated in Section 11.10.3. 4. If the problem persists, add the defects to the defect map and redo a gain calibration. 5. Acquire another image. 6. Move the X-ray Detector away from any device that may introduce noise. 7. If problem persists, consult the manufacturer or field service technician for help.
Residual X-ray image from previous acquired image shows in current acquired image	Charge on the sensor pixels from an exposure beyond the saturation point of the pixels may cause a residual image. It can be erased by increasing time between exposures or taking multiple images until the artifact fades away.
Out of virtual memory	Close some of the windows that are currently open.
ViVA software freezes	Restart the computer and re-launch the ViVA software.
ViVA error message	1. Email the viva.log and vsp.log files (located where viva.exe is found) generated to: flatpanel.warranty@vareximaging.com. This log file is normally found at C:\users\{username}\AppData\Local\crashdumps\viva.log
Detector dropped	1. Power-off the detector (Section 11.4) and inspect for damage. 2. If the battery does not appear damaged, place into battery charger to see if battery charger reports an error. 3. Inspect the detector for any physical damage. 4. Insert a charged battery into the detector and see if it powers on. 5. Re-establish a link. 6. Acquire an image from the detector and inspect for regions of missing data. Note: If the detector has been dropped and is not returned to Varex, a new gain calibration must be performed.

13.1 After-sales Service for Varex Imaging Products

To speak with our Technical Support Personnel, please call (800) 432-4422, wait for the voice prompt, then press 0 to be connected to an operator.

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

We request that you obtain an RMA number for in-warranty and out-of-warranty returns of products.

Contact: flatpanel.warranty@vareximaging.com

For warranty and returns, please visit:

<https://www.vareximaging.com/flat-panel-service-report>.

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

	WARNING	X-ray Detectors containing CsI scintillators have the potential to become activated above regulatory limits for shipping if they have been exposed to high energies 8.5 MeV or higher. Varex cannot accept any activated X-ray Detectors that have been used in environments 8.5 MeV or higher that exceed the local regulatory limits.
	WARNING	If the X-ray Detector or accessories have been contaminated with potentially harmful substances, they cannot be accepted without written evidence of decontamination. See Section 12.1.2 and Section 12.1.3 for procedure of decontamination.

14.0 Disposing of the X-ray Detector and Battery

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. Follow the local radiation protection regulations.

The Varex Imaging 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.

	WARNING	Precautions should be taken to not open the X-ray Detector. Depending upon the type of scintillator used, opening the X-ray Detector may expose the user to potentially toxic materials.
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15.0 Safety - Electromagnetic Interference

This equipment generates, uses and can radiate radio frequency (RF) energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices or may be affected by other equipment in the vicinity. If this equipment does cause harmful interference to other devices or is affected by other equipment, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the measures listed in [Section 13.0](#).

This equipment uses wireless LAN (WLAN) radios for transferring images. The WLAN power levels and antenna configurations have been tested and certified compliant through specific absorption rate (SAR) limits set by FCC/IC Canada (Less than 1.6W/kg) with separations as small as 0 cm between the panel antennas and human tissue. While compliant, it is still recommended to reduce exposure when possible by:

- Positioning subject to be X-rayed away from the antennas (this also helps reduce image transfer time).
- Removing the X-ray Detector promptly when X-ray exposure is complete.

The X-ray Detector does meet the IEC 60601 Safety definition for essential performance. However, some degradation of the image acquired and displayed is acceptable (e.g. small amount of noise, pixelation, video artifact, etc.) if the degradation would not affect the diagnosis or treatment. Images acquired shall be normal when the immunity interference stops. May require User intervention to clear an error message or continue operation.

15.1 Electromagnetic Emissions

Table 16 Radiated/Conducted Emissions, Harmonics, Voltage, Fluctuations & Flicker

Emissions test	IEC 60601-1-2 test level	Compliance	Electromagnetic environment
RF conducted emissions EN55011/CISPR11	Group 1, Class A, 150 kHz – 30 MHz	N/A Battery power equipment not connected to mains	The detector uses RF energy for its internal function. Nearby electronic equipment may be affected.
RF radiated emissions EN55011/CISPR 11	Group 1, Class A, 30 MHz – 1 GHz	Group 1, Class A, 30 MHz – 1 GHz	The detector uses RF energy for its internal function. Nearby electronic equipment may be affected.
Harmonic emissions EN/IEC 61000-3-2	Class A	N/A Battery power equipment not connected to mains.	The detector is suitable for use in all establishments other than domestic and those directly connected to the low voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	N/A Battery power equipment not connected to mains	The detector is suitable for use in all establishments other than domestic and those directly connected to the low voltage power supply network that supplies buildings used for domestic purposes.

15.2 Electromagnetic Immunity

Table 17 ESD, Transient/Burst, Surge, Voltage Variation, Magnetic Fields

Immunity test	IEC 60601-1-2 test level	Compliance	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	± 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV AC Mains ±2 kV I/O Lines	N/A Battery power equipment not connected to mains	Mains power quality should be that of a typical professional healthcare environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line to Line ±0.5 kV, ±1 kV, ±2 kV Line to Ground	N/A Battery power equipment not connected to mains	Mains power quality should be that of a typical professional healthcare environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0% UT (100% dip in UT) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% UT (100% dip in UT) for 1 cycle at 0° 70% UT (30% dip in UT) for 25/30 cycles at 0° Voltage Interruptions: 0% UT (100% dip in UT) for 250/300 cycle	N/A Battery power equipment not connected to mains	Mains power quality should be that of a typical professional healthcare environment. If the user of the detector requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.

Table 17 ESD, Transient/Burst, Surge, Voltage Variation, Magnetic Fields (Continued)

Immunity test	IEC 60601-1-2 test level	Compliance	Electromagnetic environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Magnetic field should be that of a typical location in a typical professional healthcare environment.
IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6V/m (in ISM bands between 0.15MHz and 80MHz n) 80% AM (at 1kHz e)	N/A Battery power equipment not connected to mains	-
IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz	$E = \frac{6}{d} \sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m and E is the Immunity Test Level in V/m. If the X-ray Detector complies with Immunity Test Levels for this test, the 30cm minimum separation distance (in 5.2.1.1 f) may be replaced with minimum separation distances calculated from the higher Immunity Test Levels.

Table 18 Test Specs for Enclosure Port Immunity to RF Wireless Communications Equipment

Test Frequency	Band	Service	Modulation	Max Power	Distance	Immunity Test Level
385	380-390	TETRA 400	Pulse Modulation b) 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM c) +/- 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE BAND 13, 17	Pulse modulation b) 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 1800; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	Pulse modulation b) 18 Hz		0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28

Table 18 Test Specs for Enclosure Port Immunity to RF Wireless Communications Equipment

Test Frequency	Band	Service	Modulation	Max Power	Distance	Immunity Test Level
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
5240 5500 2785	5100-2800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
Note: If necessary to achieve the Immunity Test Level, the distance between the transmitting antenna and the X-ray Detector may be reduced to 1m test distance is permitted by IEC 61000-4-3. - For some services, only the uplink frequencies are included. - The carrier shall be modulated using a 50% duty cycle square wave signal. - As an alternative to FM modulation 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

	Note	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
	Note	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 reorienting or relocating the X-ray Detector.

15.3 Radio Frequency (RF) Compliance Information

This section describes RF Compliance information.

15.3.1 United States FCC Compliance

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. This device meets all the other requirements specified in Part 15E, Section 15.407 of the FCC Rules.

Transmission Band Frequencies: 5.2GHz and 5.8Ghz band ranges

	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 their own expense.
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FCC responsible: Varex Imaging Corporation, 1678 South Pioneer Road, Salt Lake City, Utah 84104, USA, Tel: + 801/972-5000, Website: www.vareximaging.com

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the body is 1.319 W/kg.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures noted below:

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

Radiation Exposure Statement:

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

The user may find the following booklet prepared by the Federal Communications Commission helpful: The Interference Handbook

This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402. Stock No. 004-000-00345-4.

	Note	Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.
	Note	In the 5150 to 5250 MHz frequency range this transmitter is restricted to indoor use only.

16.0 Regulatory

This section includes the manufacturers' declaration of standards and regulations for which the X-ray Detector complies with.

16.1 Industry Canada Notice

To prevent radio interference to the licensed service, this device is intended to be operated indoors and away from windows to provide maximum shielding. Equipment (or its transmitting antenna) that is installed outdoors is subject to licensing. The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada's web site: www.hc-sc.gc.ca/rpb

Cet appareil numérique de la classe A est conforme à la norme NMB-003 du Canada Avis de Conformité à la Réglementation d'Industrie Canada:

Pour empêcher toute interférence aux services faisant l'objet d'une licence, cet appareil doit être utilisé à l'intérieur seulement et devrait être placé loin des fenêtres afin de fournir un écran de blindage maximal. L'installateur du présent matériel radio doit s'assurer que l'antenne est située ou pointée de manière à ce que cette dernière n'émette pas de champs radioélectriques supérieurs aux limites spécifiées par Santé Canada pour le grand public; consulter le Code de sécurité 6, disponible sur le site Web de Santé Canada, à l'adresse suivante: www.hc-sc.gc.ca/rpb

This device complies with ISSED license-exempt RSS standard(s). Operation is subject to the following two conditions:

- this device may not cause interference
- this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'ISED applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

- l'appareil ne doit pas produire de brouillage
- l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

English

- 1 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;
- 2 The maximum antenna gain permitted for devices in the band 5725-5825 MHz shall comply with the EIRP limits specified for point-to-point and non point-to-point operation as appropriate.
- 3 The worst-case tilt angle(s) necessary to remain compliant with the e.i.r.p. elevation mask requirement set forth in Section 6.2.2(3) shall be clearly indicated.

Francés

- 1 Les dispositifs fonctionnant dans la bande 5150-5250 MHz sont réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux;
- 2 Le gain maximal d'antenne permis (pour les dispositifs utilisant la bande 5725-5825 MHz) doit se conformer à la limite de e.i.r.p. spécifiée pour l'exploitation point à point et non point à point, selon le cas.
- 3 Les pires angles d'inclinaison nécessaires pour rester conforme à l'exigence de la p.i.r.e. applicable au masque d'élévation, et énoncée à la section 6.2.2 3), doivent être clairement indiqués.

Radiation Exposure Statement:

These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the body is 1.319 W/kg.

Ces exigences établissent une limite SAR de 1,6 W / kg en moyenne sur un gramme de tissu. La valeur SAR la plus élevée déclarée selon cette norme lors de la certification du produit à utiliser lorsqu'il est correctement porté sur le corps est de 1.319 W / kg.

16.2 Declaration of Conformity for European Union

Table 19 Europe - Declaration of Conformity in Languages of European Community

Language	Statement
Česky [Czech] [cs]	Varex Imaging, Inc. tímto prohlašuje, že tento Radiolan je ve shodě se základními požadavky a dalšími příslušnými ustanoveními směrnice 1999/5/ES.
Dansk [Danish] [da]	Undertegnede Varex Imaging, Inc. erklærer herved, at følgende udstyr Radiolan overholder de væsentlige krav og øvrige relevante krav i direktiv 1999/5/EF.
Deutsch [German] [de]	Hiermit erklärt Varex Imaging, Inc., dass sich das Gerät Radiolan in Übereinstimmung mit den grundlegenden Anforderungen und den übrigen einschlägigen Bestimmungen der Richtlinie 1999/5/EG befindet.
Eesti [Estonian] [et]	Käesolevaga kinnitab Varex Imaging, Inc. seadme Radiolan vastavust direktiivi 1999/5/EÜ põhinõuetele ja nimetatud direktiivist tulenevatele teistele asjakohastele sätetele.
English [en]	Hereby, Varex Imaging, declares that this Radiolan is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.
Español [Spanish] [es]	Por medio de la presente Varex Imaging. declara que el Radiolan cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 1999/5/CE.
Ελληνική [Greek] [el]	ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ Varex Imaging. ΔΗΛΩΝΕΙ ΟΤΙ Radiolan ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 1999/5/EK.
Français [French] [fr]	Par la présente Varex Imaging déclare que l'appareil Radiolan est conforme aux exigences essentielles et aux autres dispositions pertinentes de la directive 1999/5/CE.
Italiano [Italian] [it]	Con la presente Varex Imaging dichiara che questo Radiolan è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti stabilite dalla direttiva 1999/5/CE.
Latviski [Latvian] [lv]	Ar šo Varex Imaging deklarē, ka Radiolan atbilst Direktīvas 1999/5/EK būtiskajām prasībām un citiem ar to saistītajiem noteikumiem.
Lietuvių [Lithuanian] [lt]	Šiuo Varex Imaging deklaruoja, kad šis Radiolan atitinka esminius reikalavimus ir kitas 1999/5/EB Direktyvos nuostatas.
Nederlands [Dutch] [nl]	Hierbij verklaart Varex Imaging dat het toestel Radiolan in overeenstemming is met de essentiële eisen en de andere relevante bepalingen van richtlijn 1999/5/EG.
Malti [Maltese] [mt]	Hawnhekk, Varex Imaging, jiddikjara li dan Radiolan jikkonforma mal-htigijiet essenzjali u ma provvedimenti oħrajn rilevanti li hemm fid-Dirrettiva 1999/5/EC.
Magyar [Hungarian] [hu]	Alulírott, Varex Imaging nyilatkozom, hogy a Radiolan megfelel a vonatkozó alapvető követelményeknek és az 1999/5/EC irányelv egyéb előírásainak.

Table 19 Europe - Declaration of Conformity in Languages of European Community (Continued)

Language	Statement
Polski [Polish] 	Niniejszym Varex Imaging oświadcza, że Radiolan jest zgodny z zasadniczymi wymogami oraz pozostałymi stosownymi postanowieniami Dyrektywy 1999/5/EC.
Português [Portuguese] 	Varex Imaging declara que este Radiolan está conforme com os requisitos essenciais e outras disposições da Directiva 1999/5/CE.
Slovensko [Slovenian] 	Varex Imaging izjavlja, da je ta Radiolan v skladu z bistvenimi zahtevami in ostalimi relevantnimi določili direktive 1999/5/ES.
Slovensky [Slovak]	Varex Imaging týmto vyhlasuje, že Radiolan spĺňa základné požiadavky a všetky príslušné ustanovenia Smernice 1999/5/ES.
Suomi [Finnish] 	Varex Imaging vakuuttaa täten että Radiolan tyyppinen laite on direktiivin 1999/5/EY oleellisten vaatimusten ja sitä koskevien direktiivin muiden ehtojen mukainen.
Svenska [Swedish] 	Härmed intygar Varex Imaging att denna Radiolan står i överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 1999/5/EG.

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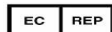
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